inVita intelligence

INRstar®: Instructions for Use

Contents

1. Symbols

Within the Instructions for use, device labelling and the Software you may encounter the following symbols, shown here with their meaning:

Manufacturer
Indicates the medical device manufacturer, as defined in EU Directives 93/42/EEC and 98/79/EC.

Authorized representative in the European Community

Catalogue Number
Indicates the manufacturer's catalogue number so that the medical device can be identified.

CE Mark
By affixing the CE marking to a product, a manufacturer declares that the product meets all the legal requirements for CE marking.

Caution
Indicates the need for the user to consult the instructions for use.

In vitro diagnostic medical device

Caution
Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot be presented on the medical device itself.

2. Abbreviations

- AC Anticoagulation
- ALT Alanine aminotransaminase
- APTT Activated partial thromboplastin time
- BCSH British Committee for Standards in Haematology
- CDSS Clinical Decision-Support Software
- CSV Comma Separated Values
- DDD Digital Dosing Diary
- DOAC Direct Oral Anticoagulation
- DOB Date of Birth
- EPL External Patient Look-up
- EQC External Quality Control
- EULA End User License Agreement
- GP General Practitioner
- Hb Haemoglobin
- HCA Health Care Assistant
- HCP Health Care Professional
- IFU Instructions for Use
- INR International Normalised Ratio
- IQC Internal Quality Control
- LMWH Low Molecular Weight Heparin
- NPSA National Patient Safety Agency
- NSAID Non-steroidal anti-inflammatory drug
- PDF Portable Document Format
- POCT Point of Care Testing
- TTR Time in Therapeutic Range

3. Overview of inVita Intelligence Limited INRstar®

INRstar® *(hereinafter to referred to as INRstar)* is a web-based clinical decision-support software (CDSS) which provides clinical decision-support to clinicians who are prescribing oral anticoagulation (AC) for patients with a variety of physical conditions. The system uses standard, published algorithms to suggest a new warfarin dose and the date of the next International Normalised Ratio (INR) blood test in response to a clinician inputting a new INR result for an individual patient taking long-term AC medication.

The algorithms provided by INRstar include:

- The Coventry Maintenance dosing algorithm
- The Hillingdon Maintenance dosing algorithm
- Induction Fast Fennerty-Gedge
- Induction Slow Oates
- Induction Slow Tait
- A Manual dosing option, which allows a clinician to induct or maintain a patient using warfarin without requiring a dosing suggestion from the system.

INRstar is designed to facilitate management of patients by a clinician. This provides recording and monitoring functions, review periods, appropriate warnings, reports, audits, and reminders, using validated dosing algorithms which provide appropriate dose suggestions, where necessary.

The system also supports the management of direct oral anticoagulant (DOAC) medication, giving the clinician a broader choice of AC management possibilities and the ability to track and manage reviews.

Software System: The application is hosted on secure servers within Europe. INRstar runs within a dedicated Windows client which is downloaded from the INRstar server and then resides on the user's machine.

All data transmitted between the INRstar servers and individual user data is encrypted to industry standards. Comprehensive internal and external security testing has been undertaken to ensure that the system cannot be exploited maliciously. The system complies with ISO/IEC 27001 standards.

4. Introduction

4.1. Intended Use

INRstar is a software program intended for use by Health Care Professionals to support their management of patients taking anticoagulant medication.

4.2. Important Information

Read this inVita Intelligence '**Instructions for Use'** (IFU) carefully and completely before using INRstar for the first time.

The INRstar Instructions for Use provide the information required to operate INRstar.

For questions not answered in the INRstar Instructions for Use, please contact Technical Support at enquiries@invitaintelligence.com.

Please note: Instructions are combined with example screenshots. Some screens may look different in the Software depending on the version being used or regional differences.

4.3. Contraindications

The software is intended to offer decision-support to clinicians trained and experienced in the management of AC in patients over the age of 18 years and is not intended for use in patients below this age. INRstar is a CDSS, and users should be trained and competent in AC management before use.

4.4. Warnings and Precautions

Only use the inVita Intelligence INRstar for its intended purpose and in accordance with the Instructions for Use, Warnings and Precautions. Users should be aware of the residual risks identified below, and detailed in Appendix D – Clinical Risk Assessment, and should follow the recommended guidance.

4.4.1. Instructions for Use

The IFU does not constitute a local AC protocol; organisations using INRstar should have a formal AC policy and procedures. Formal training on the use of the system should be completed prior to use of the software in a clinical setting with patients.

4.4.2. Inappropriate selection of a maintenance dosing algorithm.

Selection of the appropriate dosing method is an area of risk and should only be undertaken by trained users with clinical knowledge and understanding of the significance of and differences between warfarin induction and maintenance dosing methods.

4.4.3. Inappropriate selection of an induction dosing algorithm.

Selection of dosing method should only be undertaken by trained users with clinical knowledge and understanding of the significance of and differences between warfarin induction and maintenance dosing methods.

4.4.4. Inappropriate change of induction to maintenance dosing algorithm.

Selection and changing of dosing algorithms are a high-risk activity. Selection of dosing method should only be undertaken by trained users with clinical knowledge and understanding of the significance of and differences between warfarin induction and maintenance dosing methods.

4.4.5. Inappropriate change of dosing or review period settings.

The organisation clinical lead should be a clinician with an in-depth understanding of anticoagulation treatment. Organisation clinical lead status can only be granted by the organisation administrator and should not be granted to a user without sufficient training, experience, and knowledge of the practice of oral anticoagulation treatment.

4.4.6. Accurate entry of the new INR result is critical.

Users should confirm that the result they have entered is correct when the confirmation dialogue is displayed.

Interfaces with the POCT coagulometers which directly import the result should be used, where available, to minimise the risk of transcription errors when entering new INR results.

4.4.7. Incorrect existing warfarin dose is a major area of risk.

All dosing algorithms rely on the fact that the patient's current dose of warfarin is correctly recorded so that the new suggested dose is accurate. All users should be aware of the importance of confirming with the patient that the currently recorded warfarin dose is still correct before a new dose is calculated.

4.4.8. Accurate entry of the manual INR and dose data is critical.

Users should positively confirm that the result they have entered is correct when the confirmation dialogue is displayed.

4.4.9. Overriding of suggested doses is a safety critical area.

Users should positively confirm that the new data they have entered is correct and appropriate in the context of the patient's current clinical situation. Dose overrides are disabled during the induction protocol.

4.4.10. Overriding of suggested review periods is a safety critical area.

Users should positively confirm that the new data they have entered is correct and appropriate in the context of the patient's current clinical situation.

4.4.11. Warfarin induction is a safety critical activity.

It should only be carried out by users with clinical knowledge and experience in anticoagulation management. The user must be prepared to dose the patient manually if the INR falls outside the parameters of the induction protocol.

5. Getting Started

The **'Getting Started with INRstar'** guide is an outline of how to operate INRstar.

INRstar is a market-leading, evidence-based software for safe and effective AC management. This CDSS provides complete AC support for the induction, dosing, review and connected self-care of patients on both traditional AC and DOACs.

The clinically assessed roles and permissions available in INRstar supports care-teams in the delegation of tasks and in limiting clinical decisions to appropriate staff.

INRstar is designed to be flexible and responsive to the requirements of the service provider, allowing users to manage and review patients on DOACs, Vit K antagonists and Low Molecular Weight Heparin (LMWH).

The examples used within this document are only for the purpose of illustrating the functionality of INRstar and do not convey any clinical guidance.

5.1. Minimum Specification for Installing INRstar

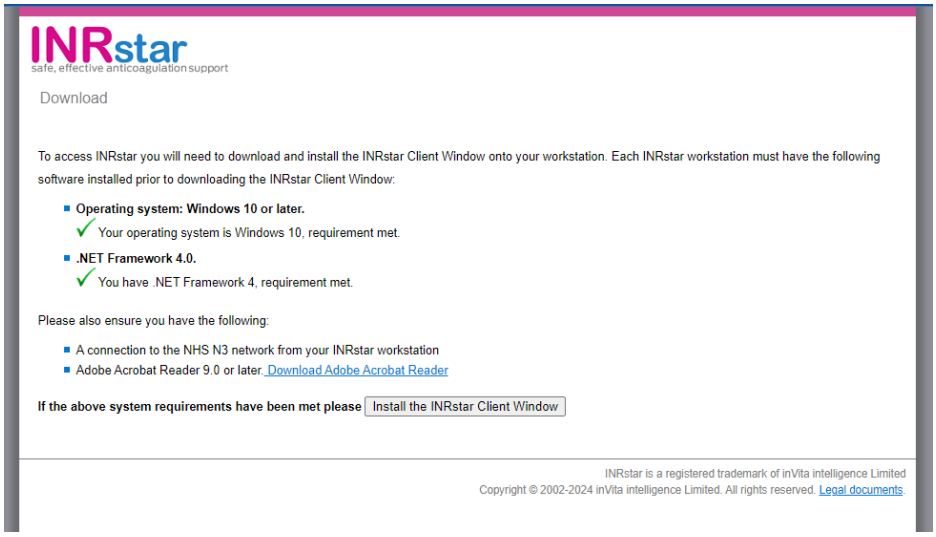
To access INRstar you will need to download and install the INRstar client window onto your workstation. Each INRstar workstation must have the following software installed prior to downloading the INRstar client window:

- Operating system: Windows 10 or later.
- .NET Framework 4.0 or later
- Adobe Acrobat Reader 9.0.

6. Installing INRstar

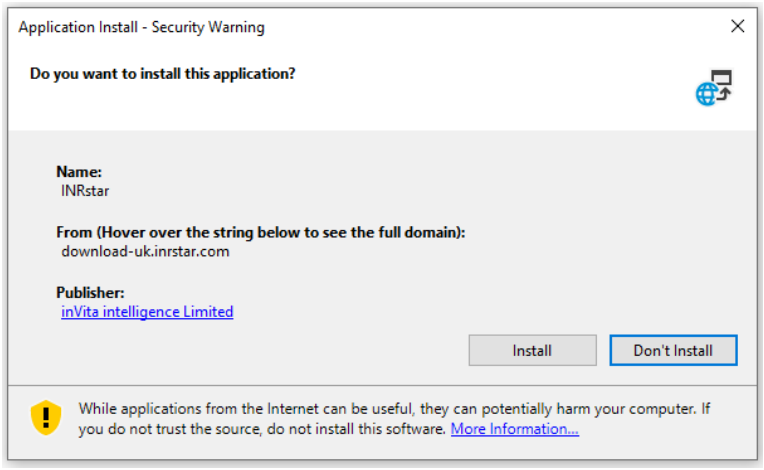
INRstar can be installed on the desktop of every user that requires access to the software. If you use more than one workstation you will need to install it on each computer.

1. Go to https://download-uk.inrstar.com/ to download INRstar to your workstation. (For Ireland go to https://download-ie.inrstar.com). The web page will verify (where possible) whether the minimum software requirements have been met on the computer and provide help with downloading the software



Note: If there are two green ticks INRstar can be installed. If you have one or more red crosses you will need to install the relevant Microsoft download. We recommend that an IT Technician from your IT department or practice, with administrator rights, logs onto the computer to perform the necessary downloads.

2. Click on the **'Install the INRstar Client Window'** button once you have two green ticks (found at the bottom of the page).
3. An **'Application Install'** box will appear. Click **'Install'**.



The INRstar application will then install. This may take a few minutes, after which INRstar will open and be ready to use.

Please note: Once a site license is purchased there is no limit on the number of workstations on which you can install the software.

6.1. INRstar Updates

To improve user experience, expand INRstar features and apply bug fixes, we regularly release updates.

Often, updates can be deployed with minimal disruption to users, but others require a new version of the software to be installed. The software update usually takes 30-60 seconds to install and should be completed at the earliest opportunity to ensure the version in use is clinically safe and compliant with regulations such as GDPR.

Once a new version has been deployed, users will be prompted to install the next time they open INRstar; **the update should be accepted and installed at this point.**

The software can be used with the same login details and settings immediately.

If the update **is not accepted and installed**, the existing version will need to be uninstalled and replaced with the latest version (see Appendix E – Update Installation Troubleshooting for assistance).

7. Location Management

Before a practice or organisation can start using INRstar, all the INRstar users will need to have a user account created and be assigned the correct level of permissions.

These tasks can be completed by the INRstar **'Location Administrator(s)'** for your practice or organisation. If you are a **view only location**, i.e. a practice or prison that has registered patients who are tested at another INRstar location, location management tasks are carried out by the '**View Only Administrator(s)**' for your practice or organisation.

Note: It is the organisation's responsibility to ensure their protocols specify which clinical roles can undertake the appropriate treatment activities. The designation of roles to users should comply with local protocols.

All clinical users of INRstar who are involved with patient treatment should regularly attend updates in AC and use of CDSS.

The following sections demonstrate how the tasks below can be completed:

- Creating User Accounts
- Setting or Editing User Permissions
- Resetting User Passwords
- Permission Levels
- Disabling a User Account

7.1. Creating User Accounts

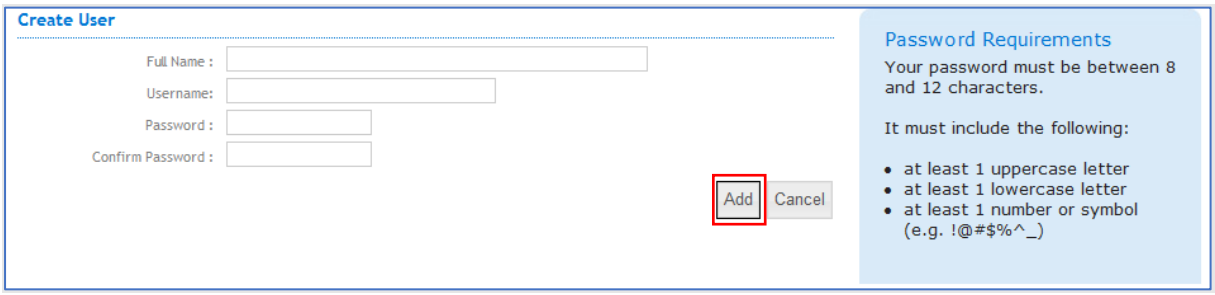
User accounts can be created only by a user with location administrator or location clinical lead permissions.

1. Open and log into INRstar.
2. Navigate to the blue **'Options'** tab.
3. Select the **'Location Management'** tab.
4. Select the **'Users'** tab.

   Note: This area of INRstar allows administrators to add a new user, manage existing users and reset passwords.

   You are now able to see a drop-down box; this contains a list of all users currently registered on the system. If you have not yet added any users, this drop-down will only contain your username.

5. To create a user, click the **'Add User'** button on the right-hand side.



6. Enter the following user details:
   - **Full Name:** Enter the individual's full name including their title.
   - **Username:** Must be unique. It is recommended to maintain the same format for every user, for example **'firstname.surname'**. If the username already exists add a number at the end, e.g. **'john.smith1'**. Usernames are case sensitive.
   - **Password:** Create a default password for the user; password requirements are displayed on the right-hand side of the screen. When the user logs into INRstar for the first time they will be required to change their password.
   - **Confirm password:** Confirm the password.
7. To save the new user's details, click the **'Add'** button.

Note: Each user will be set to read-only as a default until permission levels are set for each user you create. Make a note of the username and password to inform the user.

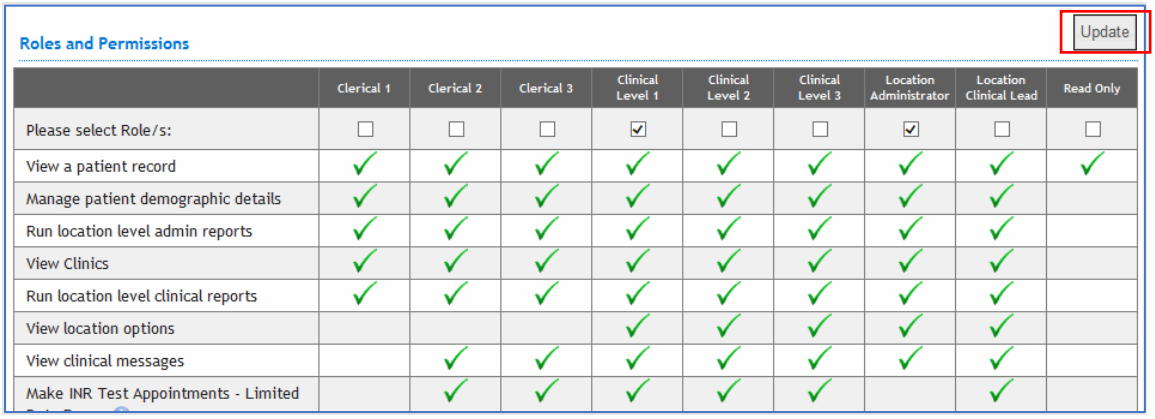
7.2. Setting or Editing User Permissions

Once the user has been added, the designated permissions level needs to be set within INRstar. You will need an account with **'Location Administrator'** or '**Location Clinical Lead**' permissions (or '**View Only Administrator'** if at a view only location) to perform this task.

Note: Due to the potentially serious clinical consequences of an incorrect warfarin dose it is important that you limit INRstar access only to staff who are familiar with the management of AC therapy and who have been trained in its correct use. This is to ensure and maximise the safety of patients managed in the system.

1. Open and log into INRstar.
2. Navigate to the **'Options'** tab.
3. Select the '**Location management'** tab and then the **'Users'** tab.
4. Select the user from the drop-down box.

5. Click the '**Manage User**' button and then the '**Roles & Permissions**' tab.



6. Select the level of permission required by placing a tick above the relevant role title, untick '**Read Only**' and then click '**Update**'.

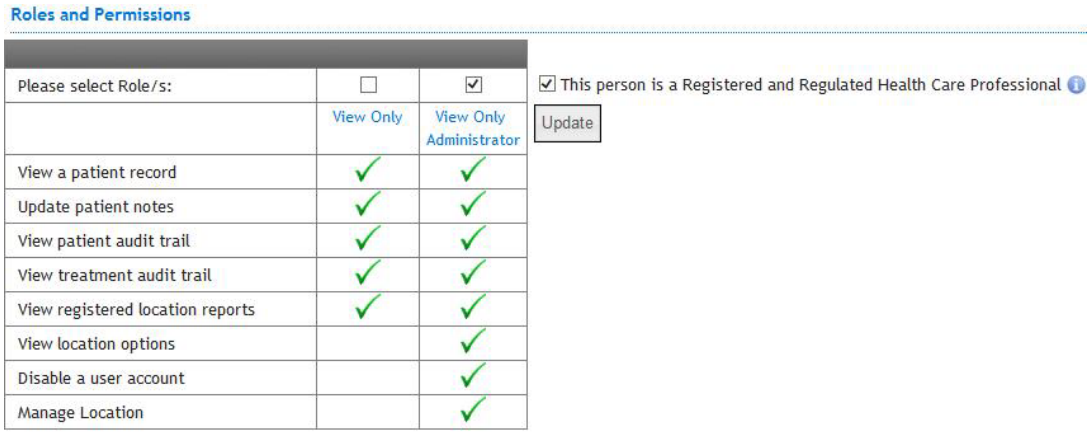
   More than one box can be ticked. It is recommended to have more than one **'Location Administrator'** in case of absence.

The **'Administrative Lead**'(s) should consult the **'Clinical Lead'** when setting permission levels to ensure that each team member has the correct access level that matches their clinical knowledge and competency. In addition it is recommended that roles and permissions should be clearly defined in the local AC protocol.

7.2.1. View Only Locations

1. Follow steps 1 – 5 as above.

   A '**View Only Administrator**' will see a reduced set of view only role options:



2. Select the level of permission required by placing a tick above the relevant Role title.
3. Tick the **'This person is a Registered and Regulated Health Care Professional'** box if the user is a registered and regulated healthcare professional in order for them to use the External Patient Lookup feature.
4. Click '**Update**'.

More than one box can be ticked. We advise that you set another user as a **View Only Administrator** in order to reset passwords or change permission levels if needed in your absence.

7.3. Resetting User Passwords

You will need to have an account with **'Location Administrator'** permissions.

1. Open and log into INRstar.
2. Navigate to the **'Options'** tab.
3. Select the **'Location Management'** tab and then the **'users'** tab.
4. Select the user from the drop-down box.

5. Click the **'Manage User'** button.
6. Click the button **'Reset Password'**.

Inform the user of the password generated. The user will have to enter this temporary password when they next login and will then be asked to change their password.

7.4. Permission Levels

Only the '**Location Administrator**' and the '**Location Clinical Lead**' have control over user accounts and can assign levels of permissions.

Clerical 1 - Admin Assistant, Receptionist

This level is a non-treatment level. Patient records can be viewed, and location level admin reports run. Demographic details can be completed.

Clerical 2 - Clerical Administrator

This level is a non-treatment level. Patient records can be viewed, dosing diaries can be printed, treatment comments and patient notes can be edited, location level administrative and clinical reports run. Demographic details can be completed. Clinics can be viewed, and appointments booked/moved within a limited date range; **'Next Test Date'**(s) can also be changed within a limited date range.

Clerical 3 - Senior Clerical Administrator

This level is a non-treatment level. Patient records can be viewed, dosing diaries can be printed, treatment comments and patient notes can be edited, location level administrative and clinical reports run. Demographic details can be completed. Clinics can be viewed, and appointments booked/moved within a limited date range, **'Next Test Date'**(s) can also be changed. **'Treatment Plan'** demographics can be created, and **'Historical Treatments'** can be added.

Note: The clinical treatment plan must first be created by a level 2 or 3 clinician.

Clinical Level 1 – Health Care Assistant (HCA) / Phlebotomist

A **'Clinical Level 1'** user typically could be an HCA or phlebotomist who has regular contact with the patients, they are able to edit demographic details, update patient notes and enter a new INR test result. We recommend that Clinical Level 1 users have undertaken training in anticoagulation at a level appropriate for this role. An understanding of the implications of an abnormal reading would be required.

If the local protocol allows stable patients with no changes to their treatments can be managed at this level.

Clinical Level 2 - Registered Nurse

A **'Clinical Level 2'** nurse, typically a practice or general nurse would have all the permissions of **'Clinical Level 1'.** In addition, they can deactivate and reactivate patients, make changes to patient clinical details and complete out-of-range treatments if accepting the recommendations of INRstar CDSS.

Clinical Level 3 – General Practitioner (GP), Lead Clinical Nurse

A **'Clinical Level 3'** permission typically assigned to a doctor, nurse prescriber or pharmacist. This is a higher permissions level that allows dose changes to be made to a patient's suggested treatment. A user with this level of authority would be able to authorise referrals from users with a lower level of permission and make changes to suggested doses, target INR and next review date. The clinician can also manually dose patients and document their prescribing decisions in the software and in the patient treatment plan. INRstar recommends the level 3 user has undertaken specific anticoagulation training and is therefore an experienced practitioner.

Location Administrator - Practice or Service Manager

This is usually the practice or service manager. This role allows Testing Location reports to be run, patient treatment records can be viewed but not amended. Location Administrators can also create user accounts, reset user passwords and disable/enable accounts.

Location Clinical Lead - Lead GP or Haematologist

A location **'Clinical Lead'** takes ultimate responsibility for all users of INRstar. The location **'Clinical Lead'** ensures all users are adequately trained in the use of INRstar and have a good understanding of AC. This level allows further accounts to be created and disabled. It allows a complete view of the audit trail of all changes made to records by users. This level can also add bespoke diagnosis if not in the standard list.

7.5. Disabling a User Account

It is good practice to disable a user account which no longer uses the system, e.g. if the user no longer works in the service or requires access.

You will need to have **'Location Administrator'** permission.

1. Open and log into INRstar.
2. Navigate to the **'Options'** tab.
3. Select the **'Location Management'** tab and then the **'Users'** tab.
4. Select the user from the drop-down box.

5. Click the '**Manage User**' button.
6. Click the button '**Disable Account**'.

The user will still appear in the user list, for auditing purposes, but will display **'(disabled)'** after the username.

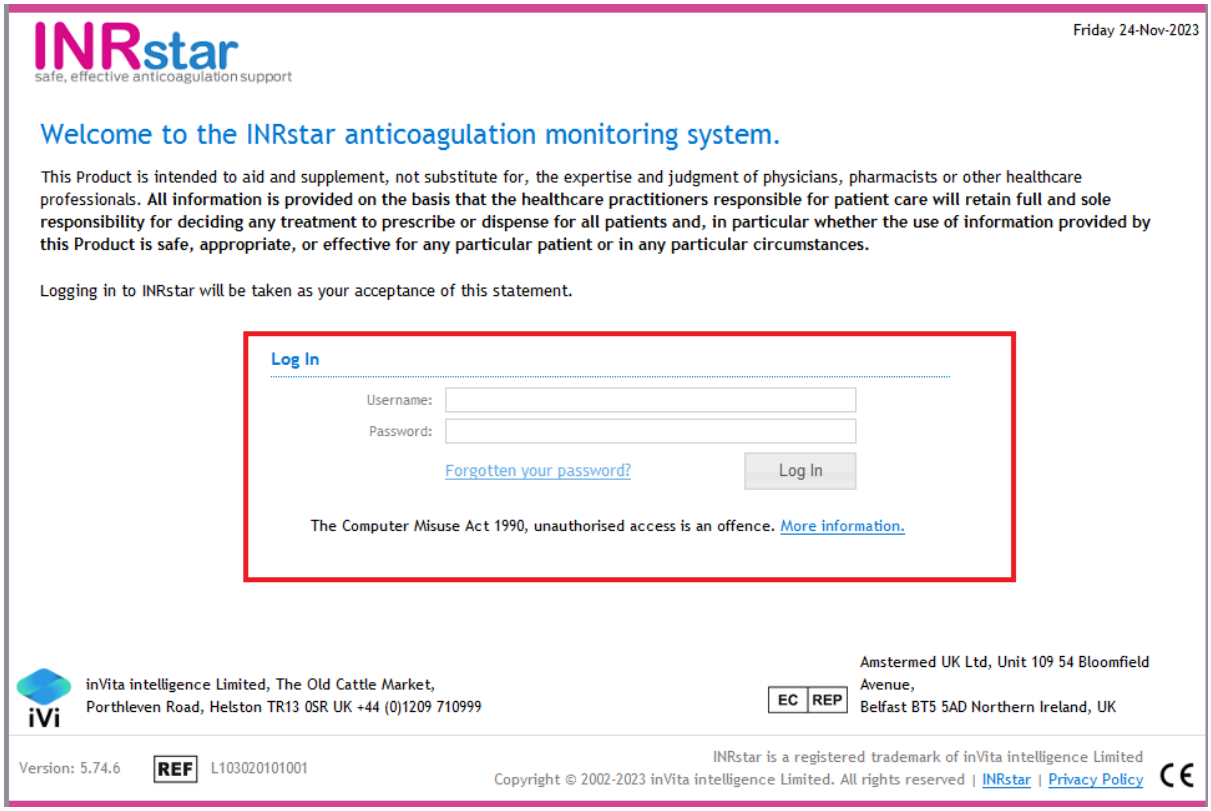
8. Logging into INRstar

To log into INRstar CDSS your service will need a license and to install the desktop client (see sections 5 and 6 for client installation instructions).

Before a practice or organisation can start using INRstar, all INRstar users will need to have a user account created and be assigned the correct permissions level. This is usually done by the system administrator (see section 7.1 for instructions).

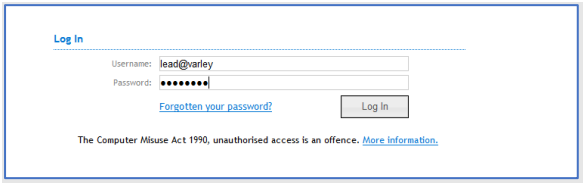
8.1. Login Page

Click on the desktop client to open the system to the login page.



Note: The acceptance statement on which provision of INRstar is predicated may be found in the header section of the screen. By continuing to use the system you confirm your acceptance of this.

Now enter your **'Username'** and **'Password'** provided by your system administrator for the service; press Enter, or click the '**Log In**' button displayed.

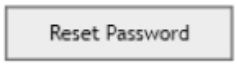


On your first log in the Licence Agreement is displayed. Once you have read and agreed the statement, you will be prompted to change your password and then asked to enter an email address. Your '**Profile**' section is displayed next, where your email address and other details can be edited (See Profile, section 9.2).

The next time you log in you will be taken to the **'Home**' page.

8.2. Forgotten Your Password?

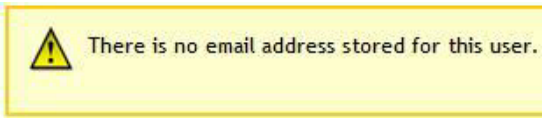
To reset a forgotten password:

1. Open INRstar.
2. Click Forgotten your password?
3. Enter your INRstar username.
4. Click 

.
5. Check your inbox for an email titled **"INRstar Password Reset Request"** and take note of the **Temporary Password.**
6. Enter the temporary password into INRstar and click 

.
7. Type your new password in both fields and click **Update Password.**

Note: If you see the following message:

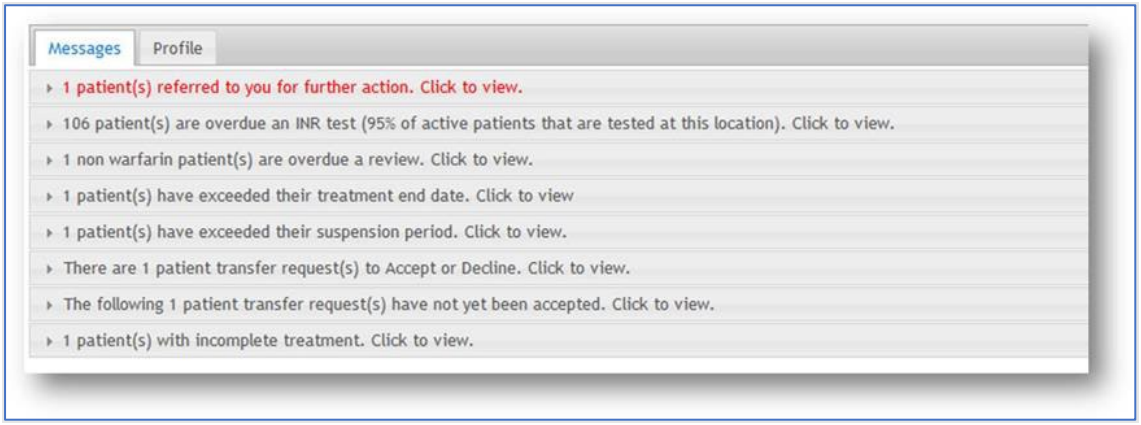


You will have to either contact your Location Administrator or call 01209 710999 to reset your password. Next time you log in you should enter your email address details into your user **Profile** (see section 9.2.3 'Manage Your Email Address').

9. Home Page

The **'Home'** page is the first page you reach when you next log into INRstar. Here you can select messages, patient records, run report lists, view/edit your profile tab.

9.1. Messages



System-wide messages are always displayed in yellow at the top of the screen.

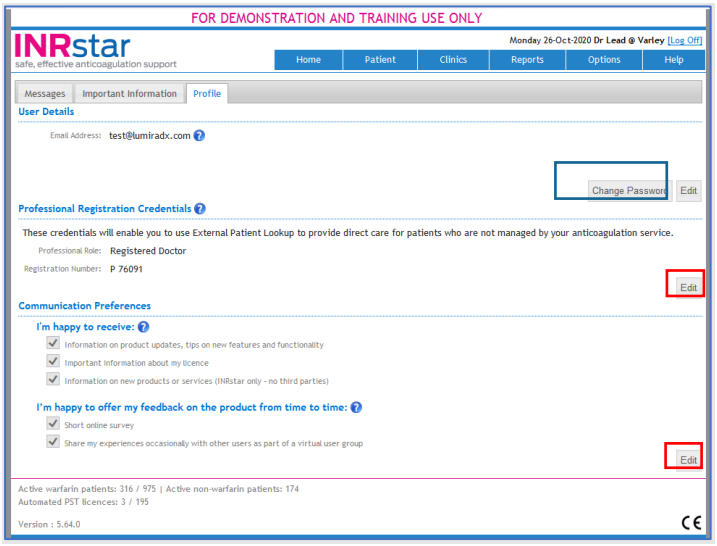
Other messages provide a report of patients who may require user intervention.

If you are a Clinical Level 1, Clinical Level 2, Clinical Level 3 or Location Clinical Lead user and wish to view a report, click the report header and it will open and display the names of the patients. To view a patient's record, click their name.

For more information on the various Home Page report types, see Appendix A - Home Page Messages.

Note: If you remain logged in on the Home Page then you will need to click '**Refresh Messages**' button in order for new messages to appear.

9.2. Profile

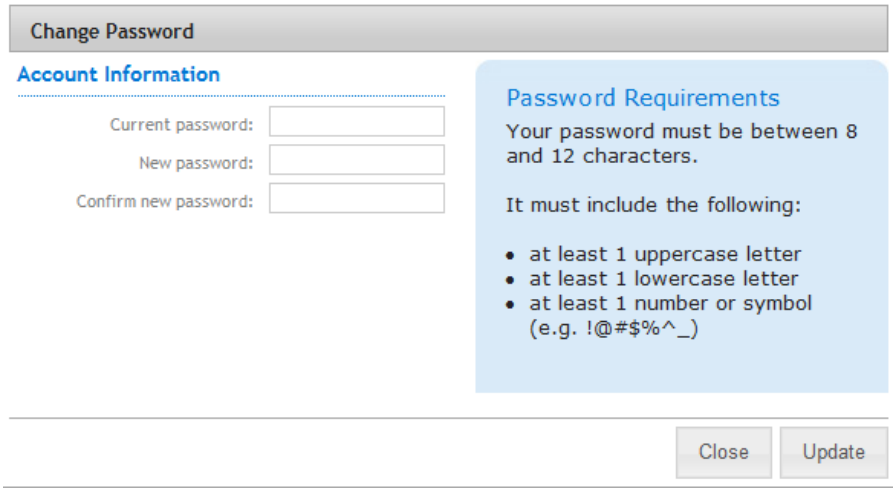


Use this screen to:

- Change your password.
- Record your email address to enable you to reset your own password.
- Record your professional role and registration number if applicable.
- Select your preferences for communications from INRstar/providing feedback.
- Add and save INPS Vision user credentials where appropriate.

9.2.1. Change your Password

Open the Profile tab and click the Change Password button.



To change the password, complete the following:

- **'Current password'**: type the existing password into this field.
- **'New password'**: type the chosen new password into this field.

- **'Confirm new password**': repeat the chosen new password here.

Passwords must conform to the **Password Requirements**.

Once these three fields have been filled out correctly, click the Update button to save the changes. Alternatively, click Close to remove the Change Password dialogue without applying the change.

9.2.2. Add Your Professional Registration Credentials

Open the Profile tab; under Professional Registration Credentials click Edit.

Select your professional role from the drop down list:

Click Update.

9.2.3. Manage Your Email Address

Open the Profile tab and click Edit under '**User Details'**.

Now fill in the following fields:

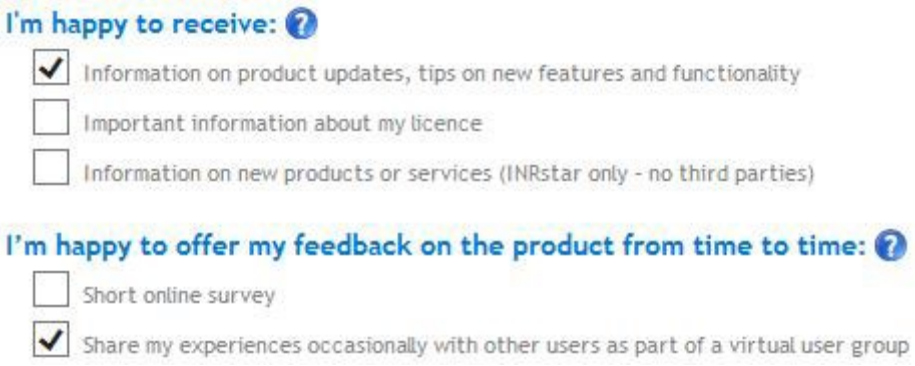
When both fields are complete, click Update to save your changes.

We will not share your email address with any third parties.

9.2.4. Record Your Communication Preferences

Open the Profile tab and click Edit underneath '**Communication Preferences'.**

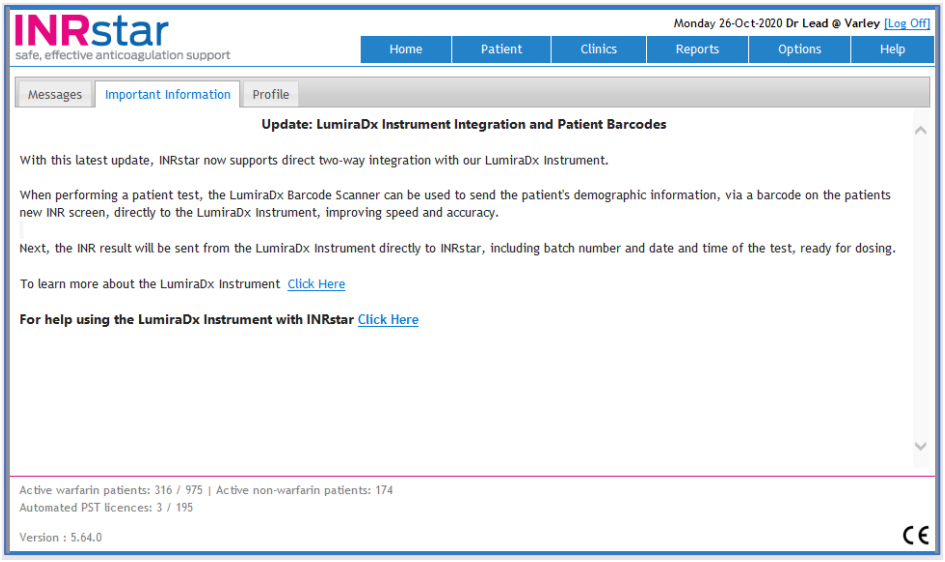
Tick or untick the boxes to the left of the options to select your preferences:



Click Update when your selections are complete.

9.3. Important Information

Updates and changes to the software are communicated on the '**Important information'** page.

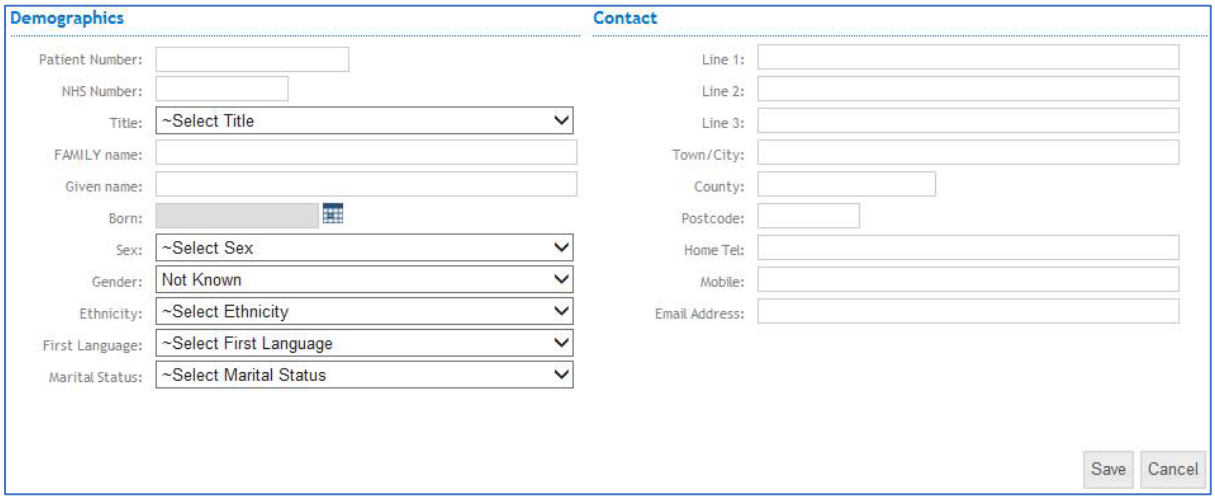


10. Patient Tab

10.1. Adding a Patient

Before treating a patient in INRstar you will need to add the patient record to INRstar. The demographic details ensure that the user can identify the correct patient without the risk of entering clinical data into the wrong record.

1. Click on **'Patient'** tab, then '**Add Patient**'.
2. This will expand the Demographics tab and patient details can be added in the open text fields.



   The patient demographic details can be imported automatically from the external clinical system (see Appendix C - External Clinical Systems) if the interface has been set up.

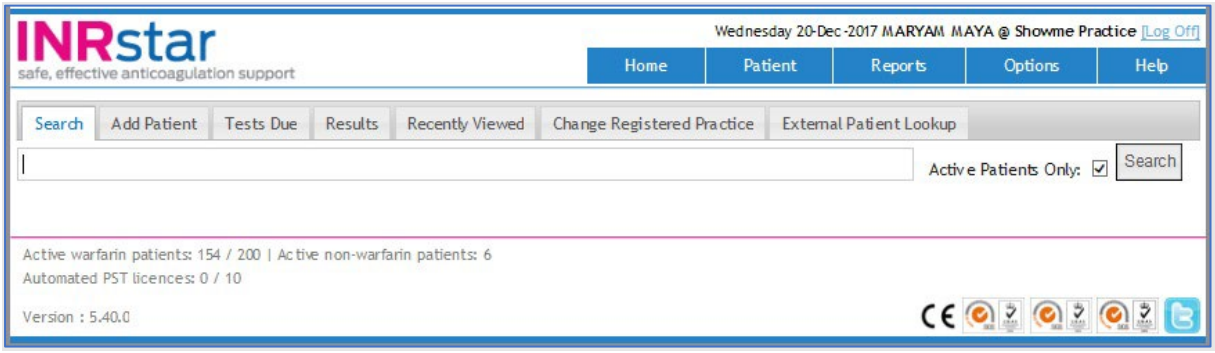
3. When complete, click '**Save**'. As soon as the demographics have been completed you will then be able to add the patient treatment plan.

The new patient record will appear in the home screen messages under 'patients either have no diagnosis or no treatment plan'. Click here to access the record and start a new treatment plan.

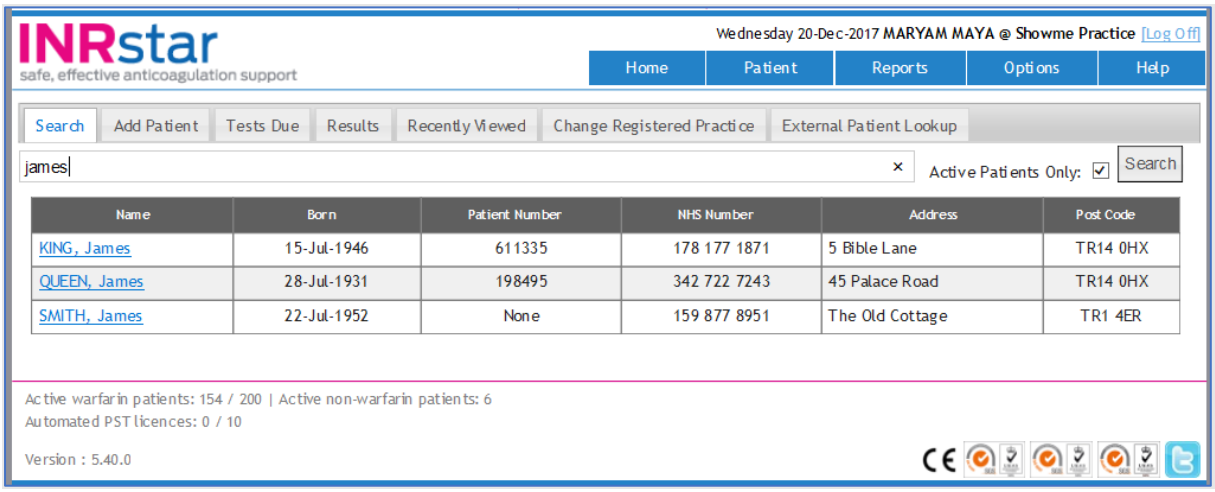
10.2. Selecting a Patient

To select a patient, either:

1. Select the **'Patient'** tab.
2. Enter the first few letters of the patient's first name/surname/clinical number /identification and click on the **'Search'** button.

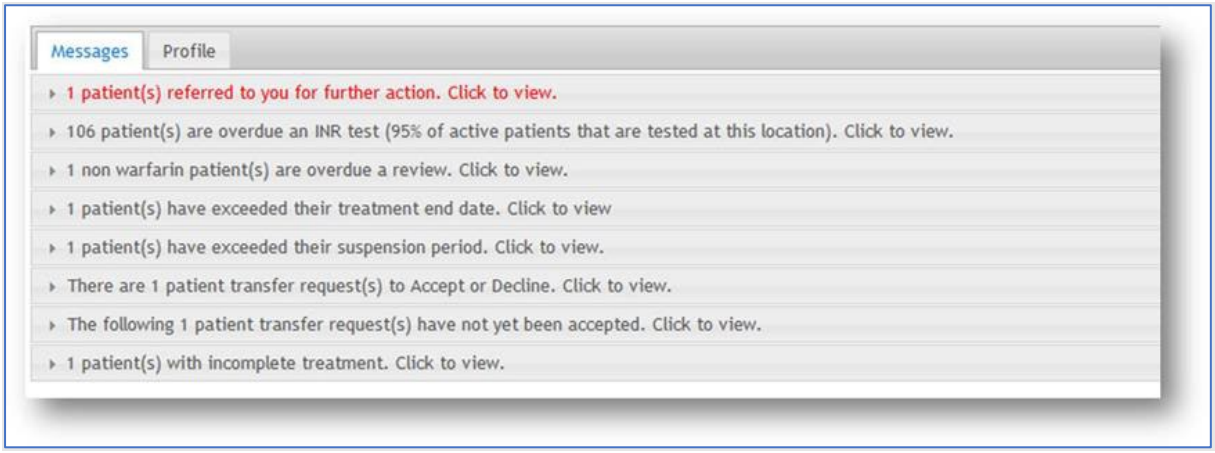


3. Identify the patient from the list.

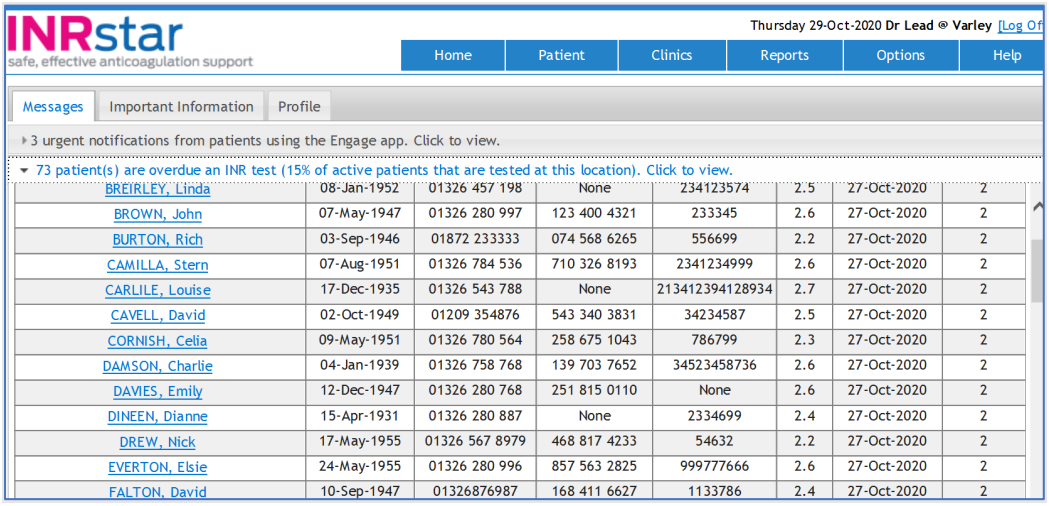


OR

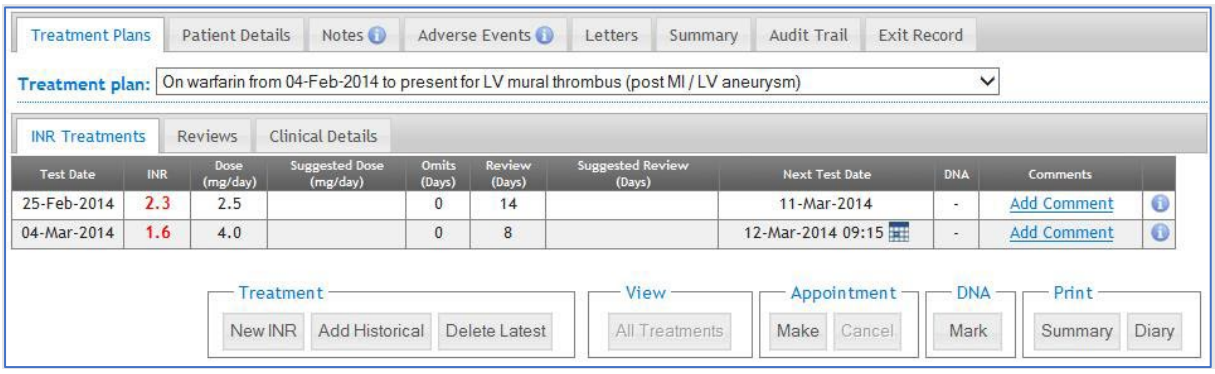
1. Select the **'Overdue Patient**' list on the **'Home'** page.



2. Click on the patient name.



This will open the patient record in the **'Treatment Plans'** tab (unless there is a patient note – see 10.3).



10.3. Patient Notes

The '**Notes'** section of the patient record includes qualifying remarks relating to patient care which are entered manually by the clinician, plus any items entered automatically (for example when records are deactivated).

Where there is a patient note, this is displayed first when the patient record is opened. If the note is still relevant, proceed to the treatment tab.

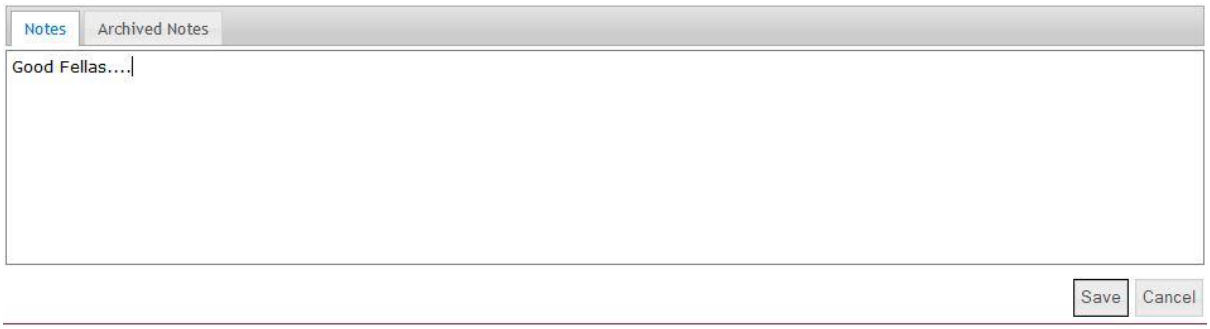
Note: a patient note that is no longer relevant should be archived (see 'Archive Patient Notes', below)

10.3.1. Add a Patient Note

To add a note, find the relevant patient, open their record and click 

.

Click the '**Add Note**' button.



Now enter your freehand note – the space will expand to accommodate a lengthy note but it is recommended you keep the number of characters to a minimum!

Click the '**Save**' button to confirm.

The note will now be added and displayed on the '**Notes'** screen. To show a patient has a note, the information icon will be shown on the **'Notes'** tab.

It is not possible to delete notes once added, but those no longer relevant should be archived.

10.3.2. Archive Patient Notes

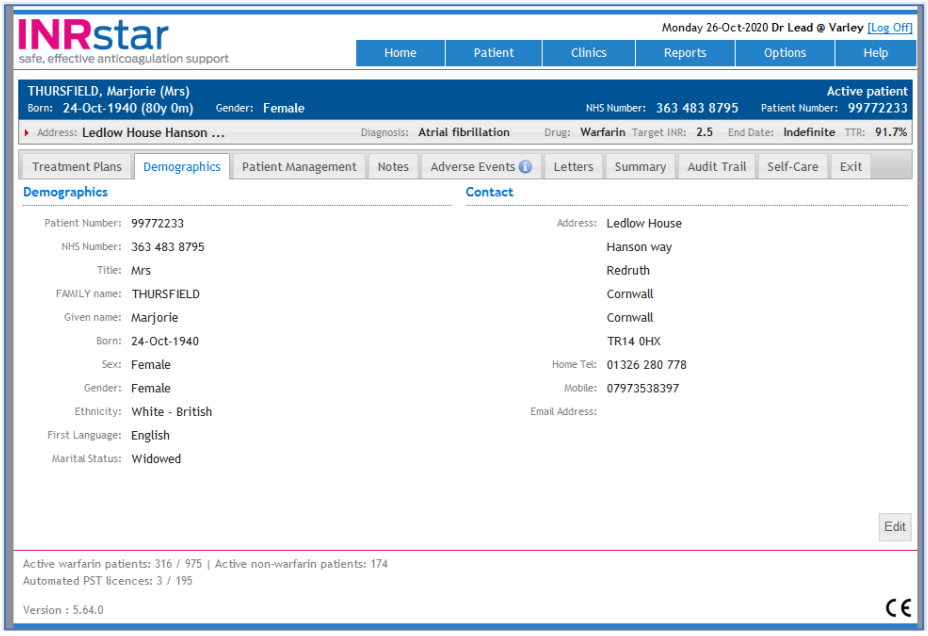
To archive patient notes, open the patient's '**Notes**' tab, tick the '**Archive**' checkbox adjacent to the note(s) to be archived and then click the **'Archive Notes(s)'** button.

Once a patient's note has been marked as archived it will no longer appear in the list of notes for that patient. To view an archived note, open the '**Archived Notes**' tab:

Please Note: Once a patient's note has been archived it cannot be restored.

10.4. View Patient Demographic Details

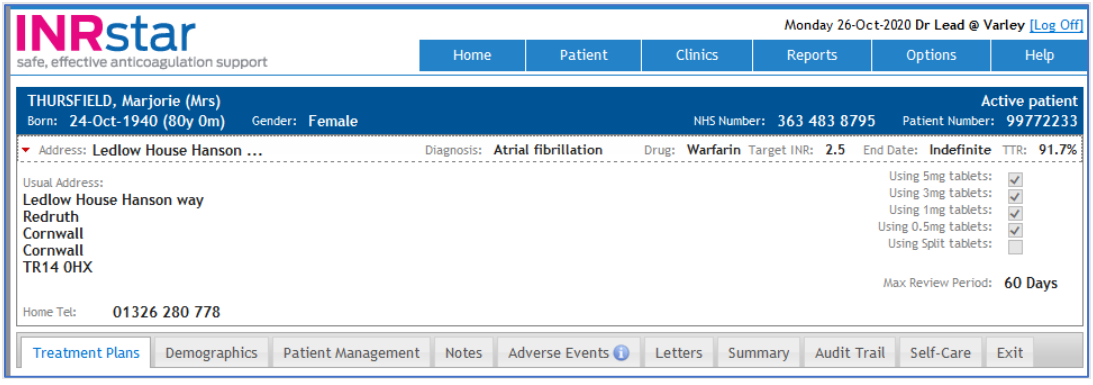
Patient demographic details can be viewed in the patient **'Demographics'** screen.



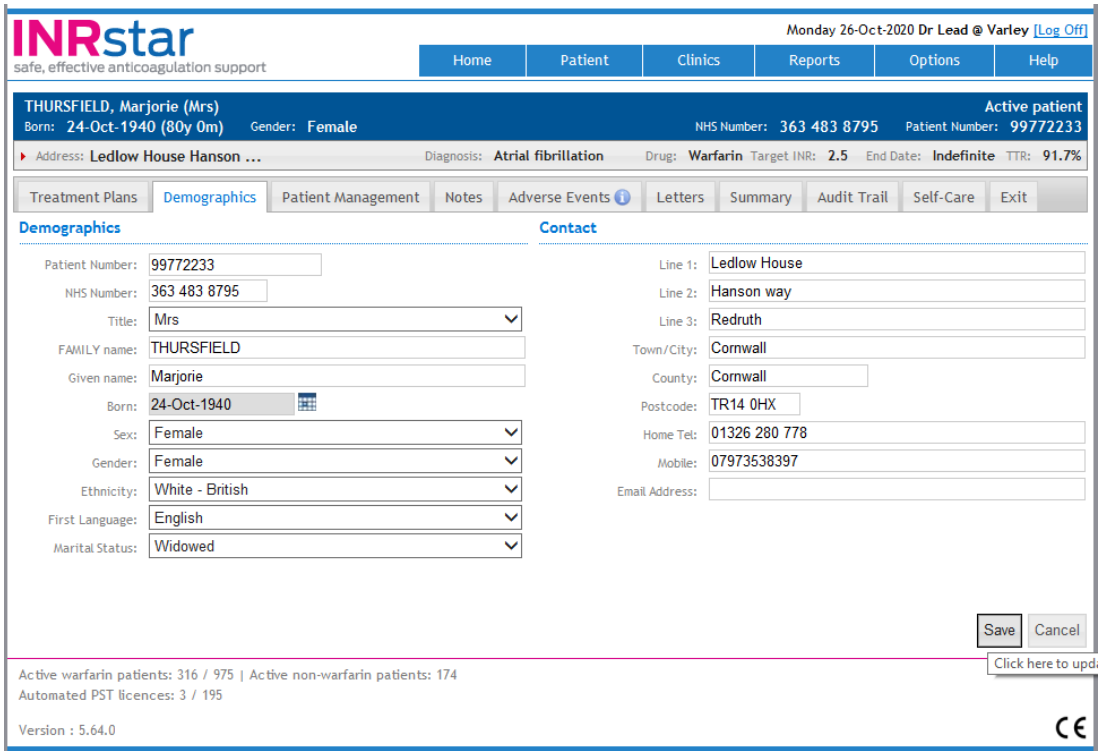
10.5. Editing Patient Details

If the demographic details of a patient have changed, it is important to amend the record in INRstar.

The patient's demographic details can be viewed by expanding the patient banner by clicking on the red arrow (as below) or by clicking on the **'Demographic Data'** tab in the patient record.



- To change any of these details click the **'Edit'** button in the patient demographics tab.
- To save any changes click the **'Save'** button, or the **'Cancel'** button to discard any changes.



10.6. Duplicate Patient Records

Duplicate patient: Adding or editing a patient record.

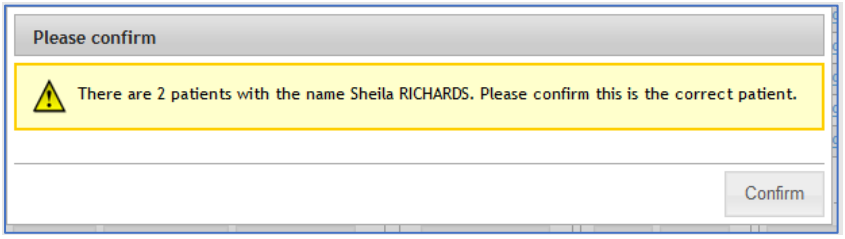
Often a location requests transfer of a record from a previous location when a patient newly registers with them, and meanwhile create a new record. When the transferred record then arrives onto their message screen, awaiting acceptance or decline, they will be unable to use either record until they decide which record to keep and which to mark as a duplicate.

Below are the scenarios where such entry will be prevented.

1. If all the following information entered for a new patient matches an existing one.
    - Family Name
    - First Initial of Given Name
    - Date of Birth
    - Gender

    Note: the existing patient may be active or inactive.
2. When trying to add/edit a patient who has the same patient number as another patient at your location.

Note: If this happens, you will see the following message:



If you receive a duplicate error message, you already have a treatment plan for a patient with the same details. The number should be verified as two patients cannot have the same system identification details.

The treatment plan may have been deactivated and you will need to reactivate the patient record.

For assistance, contact INRstar support: enquiries@invitaintelligence.com

Note: See also patient status (section 11.1).

11. Individual Patient Management

This section outlines patient records and their administration on INRstar including:

- Patient status details – active, deactivated, suspending or unsuspending.
- Care team details.
- Patient group – records transport, home visit or complex.
- Transferring Testing Location or changing Registered Practice.

11.1. The Patient Record

11.1.1. Patient Status

Patient status is displayed as **'Active'**, **'Deactivated'** or **'Suspended'.**

The status of a patient's treatment can be managed and recorded as active, de-activated or suspended within INRstar.

Active: An active patient is currently undergoing AC treatment. When treating a patient their treatment plan status should remain **'Active'**. When activated a patient will show on all reports.

Deactivated: A deactivated patient is not currently undergoing AC treatment. When a patient's treatment plan has ended, they should be deactivated. The patient will now not appear on your active patient list, or in any reports run that relate to the period after their deactivation date.

11.1.2. Suspending a Patient

The patient record should only be deactivated if they have permanently left your care or have stopped all AC treatment.

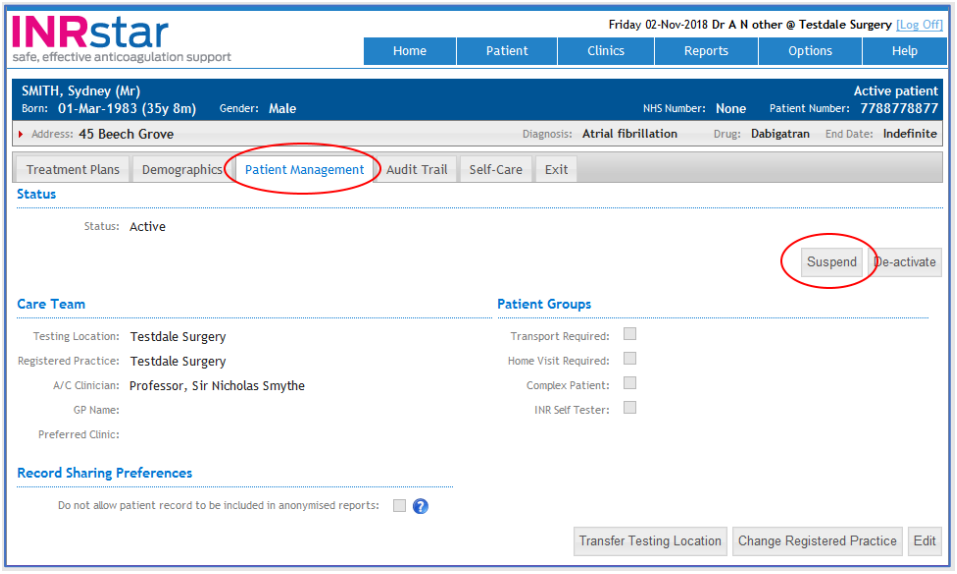
If a patient is going to be away from his or her usual Testing Location for a length of time, you may wish to temporarily suspend the patient at your location for up to 6 months. This might be appropriate if the patient is going on holiday or is being admitted to hospital for treatment or respite care.

Note: the suspended patient record can still be accessed elsewhere using External Patient Lookup to add a treatment (see section 12.2).

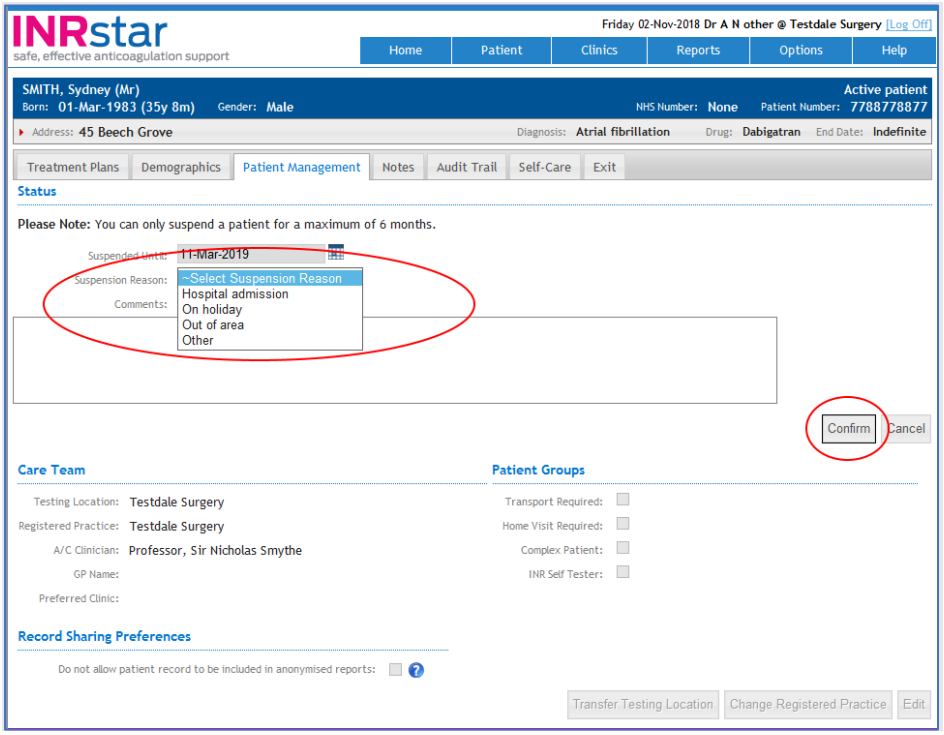
You will need to set an end date and record a reason for the suspension period. During the suspension period the patient will not appear in overdue INR test reminder messages or reports.

To suspend a patient:

1. Click on the **'Patient Management'** tab in the patient record.
2. Click on the **'Suspend**' button in the **'Status'** section.

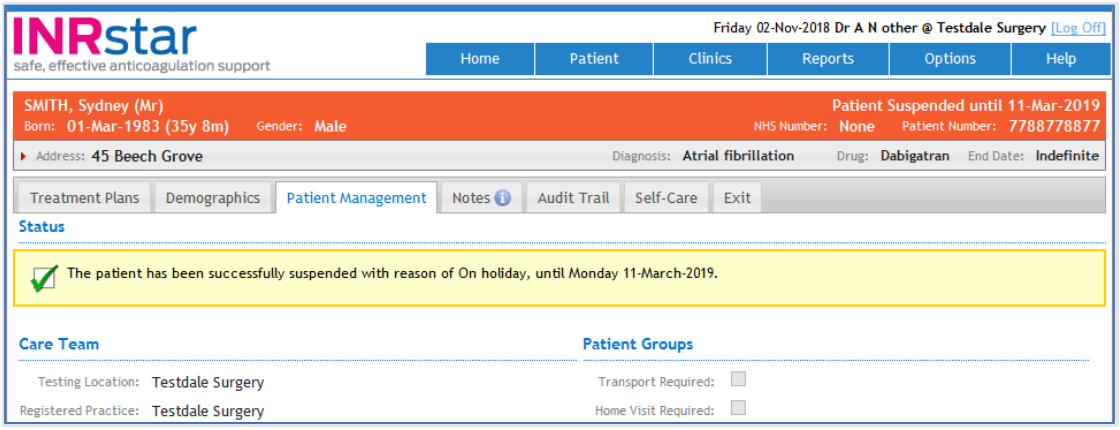


3. Enter a suspension end date.
4. Select a reason for the suspension from the drop-down menu.



5. Enter any relevant comments as needed.
6. Click on the '**Confirm**' button.

The background colour of the patient demographic banner will change to orange during the suspension period and a message will be displayed if the patient record is opened. A comment will automatically be entered in the patient notes giving details of the suspension period. Free text comments can be added to supplement the information on the record.

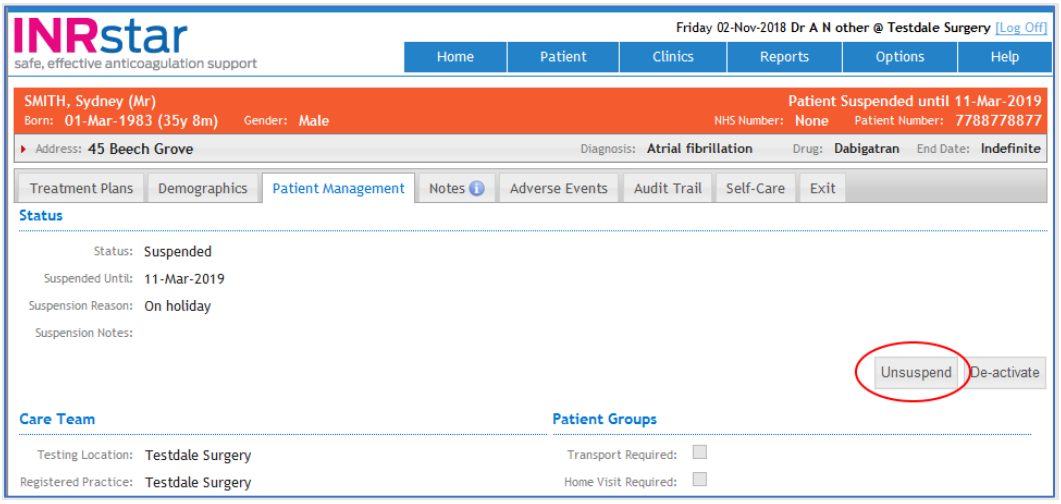


11.1.3. Un-suspend a Patient

A suspended patient can be un-suspended at any time during the suspension period. When a patient's suspension end date has been reached a message will be displayed on the home page.

To un-suspend a patient:

1. Click on the **'Patient Management'** tab in the patient record.
2. Click on the **'Unsuspend'** button in the **'Status'** section.



3. Check that the current treatment details recorded in INRstar are still correct.

If the patient has had INR tests or dose changes elsewhere during the suspension period, you will need to add this information to the patient record as historical treatments.

Failure to add a missing historic test result could lead to inappropriate future dosing suggestions.

11.1.4.

11.1.5. Deactivate a Patient Record

The patient record should only be de-activated if they have permanently left your care or have stopped all AC treatment.

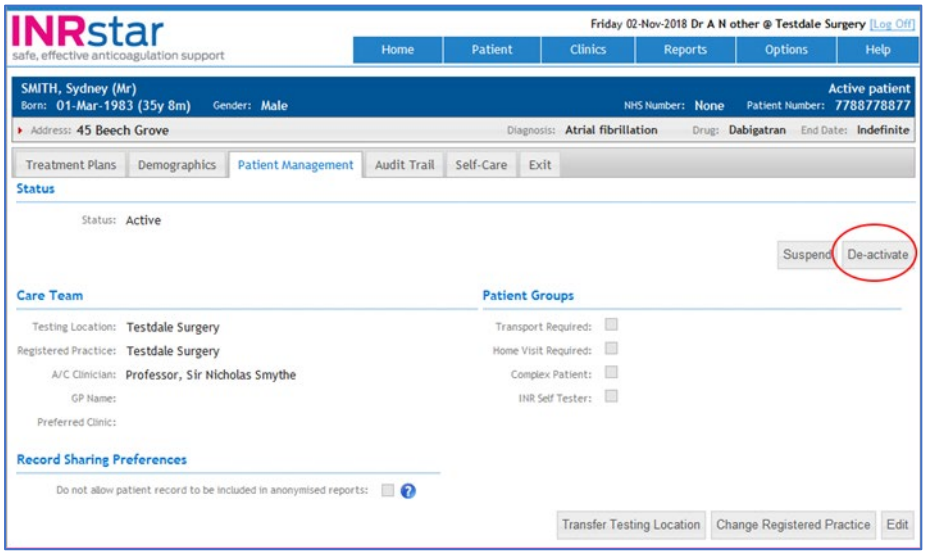
This function removes patients from the active list – patient details are retained but reinstating them will require a new treatment plan.

This activity is restricted to **'Clinical Level 3'** users.

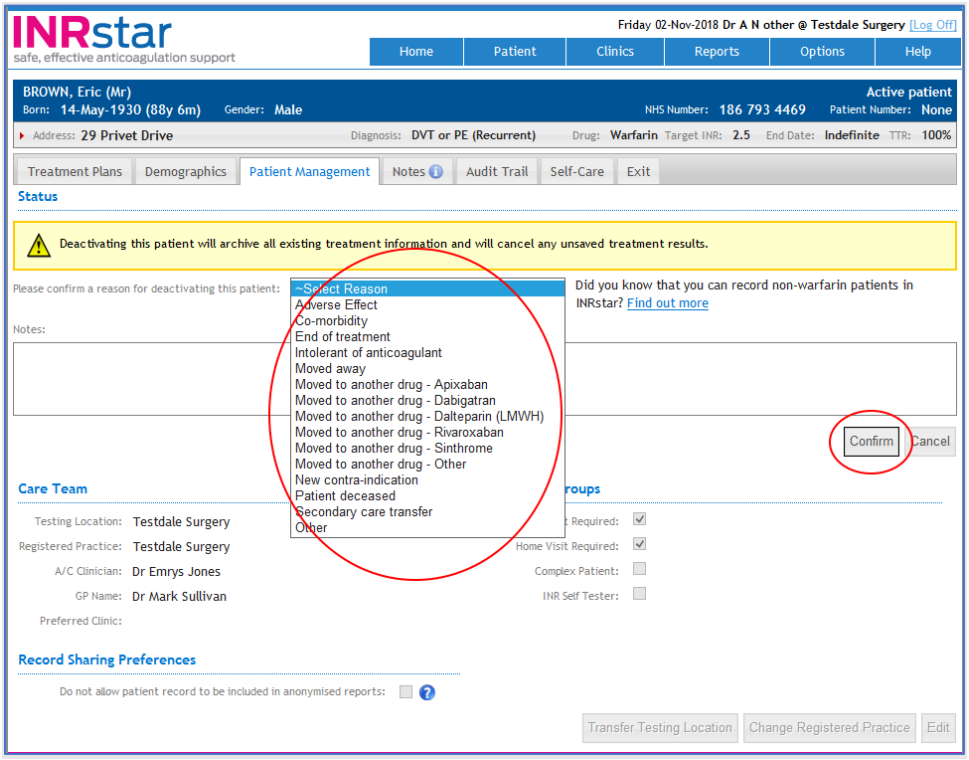
Note: Do not deactivate a patient if the record is likely to be transferred to another INRstar location, suspending for an appropriate time to await a transfer request could be considered.

To de-activate a patient:

1. Click on the **'Patient Management'** tab in the patient record.

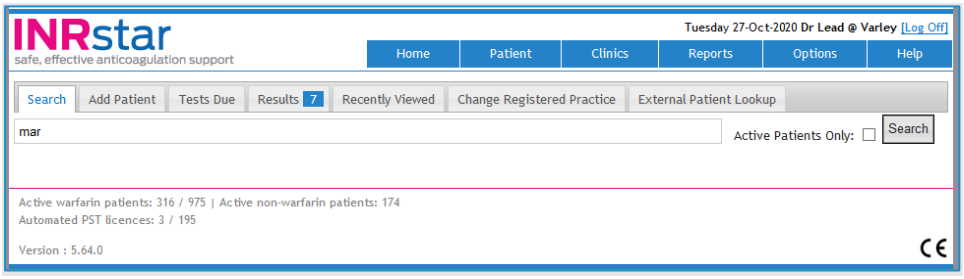


2. Click on the **'De-activate'** button in the **'Status'** section.
3. Choose the reason why you are de-activating the patient from the drop-down list then confirm the deactivation.



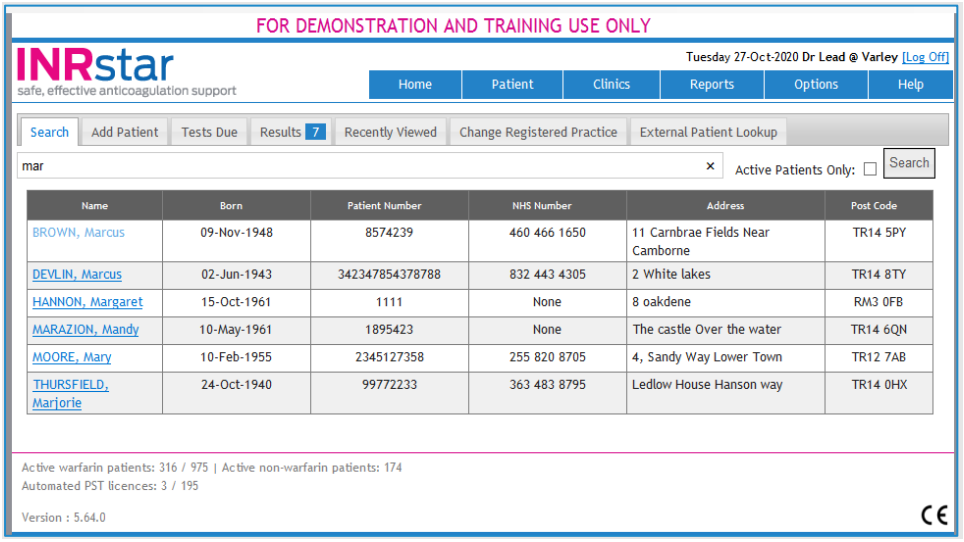
11.1.6. Reactivate a Patient Record

1. Open '**Search**' in the '**Patient**' tab.

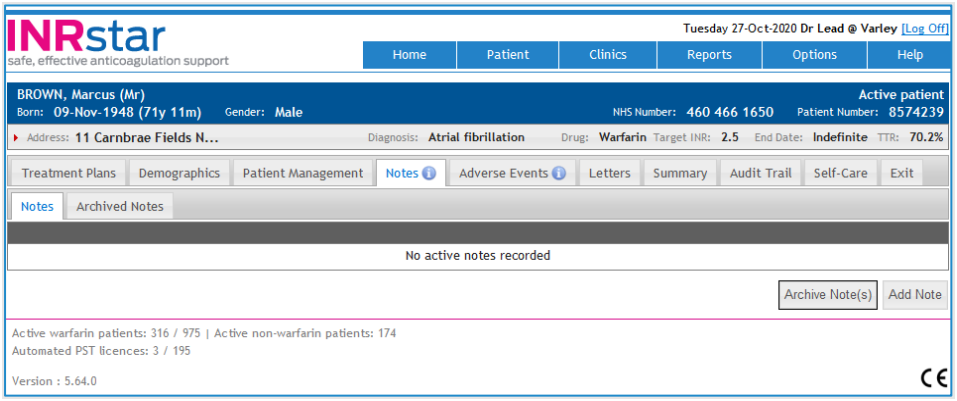


2. Un-tick the **'Active Patient Only'** box and search for the patient.

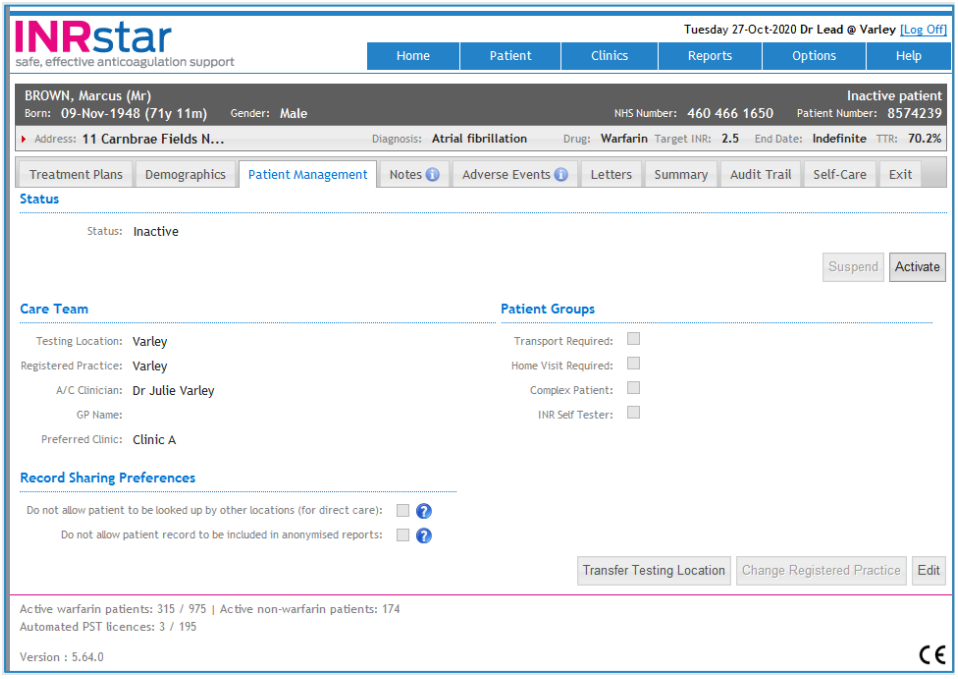
3. Use the criteria to identify the patient.



4. Select the patient to be activated.
5. Open the treatment plan and select the **'Patient Management'** tab.

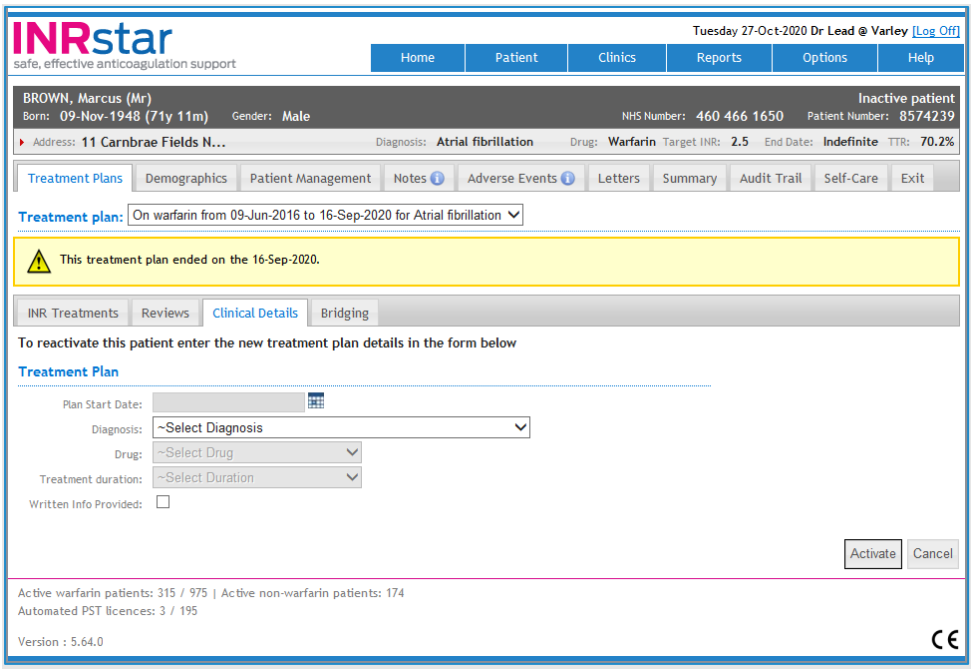


6. Select the **'Activate'** button.



7. Enter new treatment plan details and click **'Activate'**.

You have now set up a new treatment plan and re-activated the patient record in INRstar.



11.1.7. Patient Management Section

Care Team

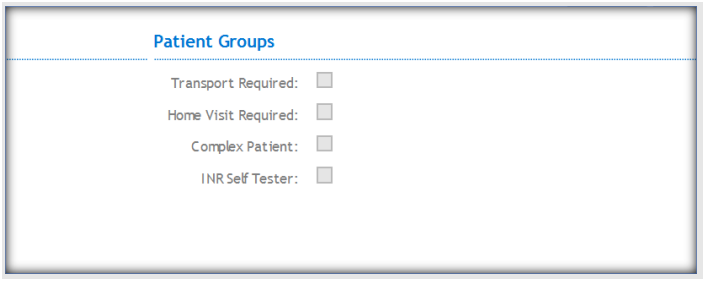
In this section within INRstar the Testing Location and Registered Practice are detailed. An AC clinician can be assigned to the patient, GP name recorded, and a preferred clinical location documented.

Notes:

- To be assigned to the patient, the AC Clinician must first have been added to the database by a Location Administrator or the Location Clinical Lead. This is done via the '**Options**' / '**A/C Clinicians**' tab.
- Similarly, referred clinics must first have been added to the database by a Location Administrator or the Location Clinical Lead. This is done via the '**Options**' tab / '**Location Management**' section / '**Clinical Locations**' tab.

Patient Groups

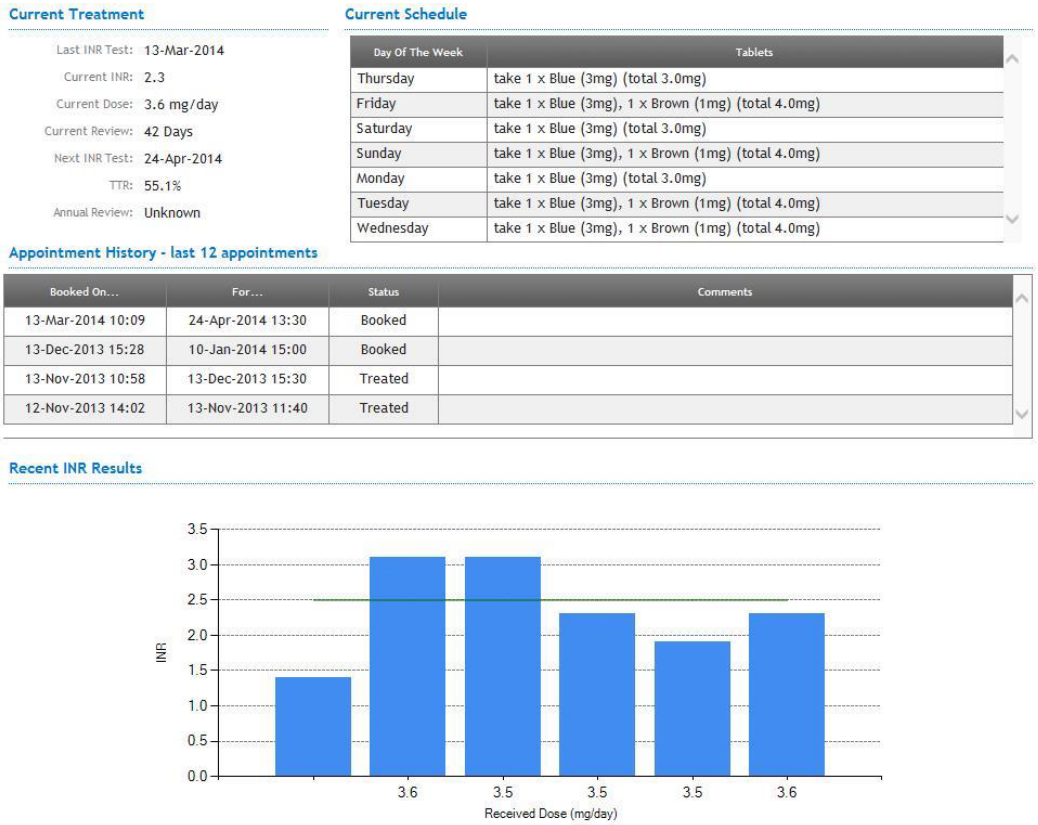
Patients can be assigned to specific groups: e.g. if they require transport, home visits, or are a designated complex patient or self tester.



If marked as '**Home Visit Required**' or an '**INR Self Tester**' these can be searched for in the '**Tests Due**' tab of the '**Patient**' section; test types are also collated in a '**Reports**' section report.

11.1.8. Patient Summary

Click the Summary tab to display a summary of various aspects of the patient's management.



In the top left hand corner are various details of the patient's current INR treatment:

- **Last INR Test:** The date the INR test was taken.
- **Current INR:** The patient's current INR taken from the last INR test.
- **Current Dose:** The patient's dose from the last INR test.
- **Current Review:** The number of review days from the last INR test.
- **TTR:** Time in Therapeutic Range – the % of time the patient is spending within range of their Target INR +/- 0.5.

In the top right hand corner is a copy of the patient's current dosing schedule.

At the bottom of the screen is a bar chart showing how the patient's INR varies with consecutive doses of warfarin.

Note: None of these fields can be edited in this screen. The information is for display purposes only.

11.1.9. Other Tabs in Patient Record

- **'Demographics'** – displays the patient's demographics which are populated from the hospital system. The demographics include the patient's email address, telephone, and fax numbers.
- **'Notes'** - notes can be added or archived here; they will be displayed on the patient's current treatment plan until archived. While there are active notes these display on first opening of the patient record to highlight their importance; therefore should only remain if still relevant to current treatment. For more information see section 10.3.
- **'Audit trail'** – all activities performed on patient in INRstar, accurately recorded to the second.
- **'Adverse Events'** (see section 11.2).
- **'Self-Care'** (see section 18 - Managing Patients in INRstar Engage).

11.2. Adverse Events

The **'Adverse Events'** page allows you to record and view any adverse events connected with a patient's AC therapy.

When a patient has a recorded adverse event an information icon will appear on the **'Adverse Events'** tab.

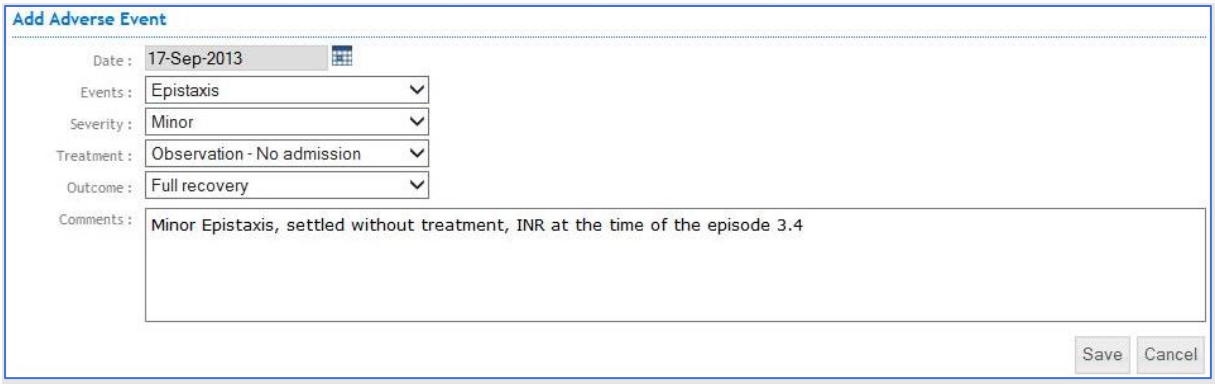
11.2.1. View Adverse Events

Note: If any adverse events have been recorded for a patient, an information icon will appear next to the **'Adverse Events'** tab on the patient's treatment record screen.

- Click on '**Adverse Events**'.

The **'Adverse Events'** page will be displayed.

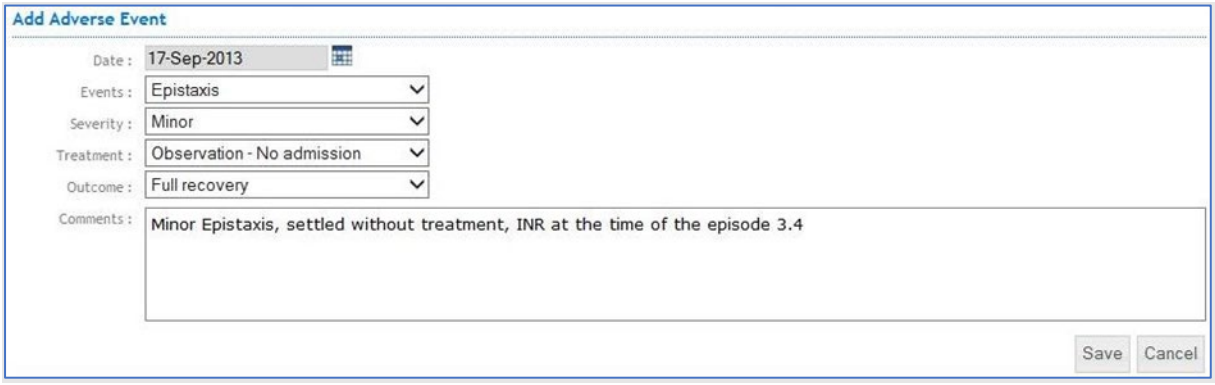
The date and nature of any recorded adverse events will be listed in chronological order. Clicking on an adverse event will expand the event to show the full details.



Click on the event date again, to hide the data.

11.2.2. Add New Adverse Event

1. Click on '**Adverse Events**' the patient's record screen.
2. The **'Adverse Events'** page will be displayed.
3. Click the **'Add Event'** button to display the **'Add Adverse Event'** screen.
4. To proceed fill out all the fields in the **'Add Adverse Events'** screen.
5. Click on the **'Date'** calendar icon to select the date of the adverse event.



6. Select the event type from the drop-down list of **'Events'**.
7. Select the event severity from the drop-down list of **'Severity'**.
8. Select the event treatment from the drop-down list of **'Treatments'**.
9. Select the event outcome from the drop-down list of **'Outcome'**.
10. Add some explanatory '**Comments**' about the adverse events to document details.
11. Click the '**Save**' button to save the adverse event to the patient record, or click '**Cancel**' to remove the details.

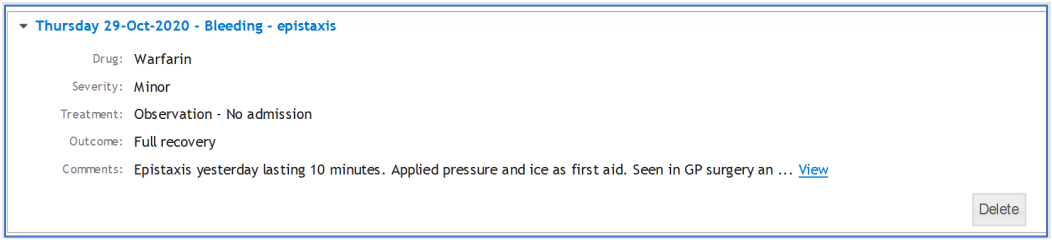
A confirmatory message will be displayed when the adverse event has been saved successfully to the patient's record.

11.2.3. Delete Adverse Event

If you add an adverse event to a patient's record in error, it can be deleted.

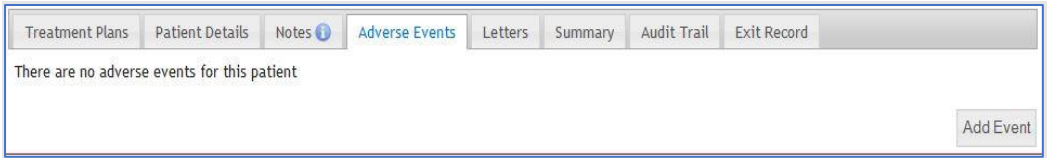
1. Click on **'Adverse Events'** in the patient record screen. 

2. Click the event you wish to delete. The event will expand to display the details.



3. Click on the **'Delete'** button.
4. Click **'Confirm'** on the message if you wish to continue.

The adverse event details will be removed from the patient record.



Note: Details of any recorded adverse events will also be shown in the individual patient review page.

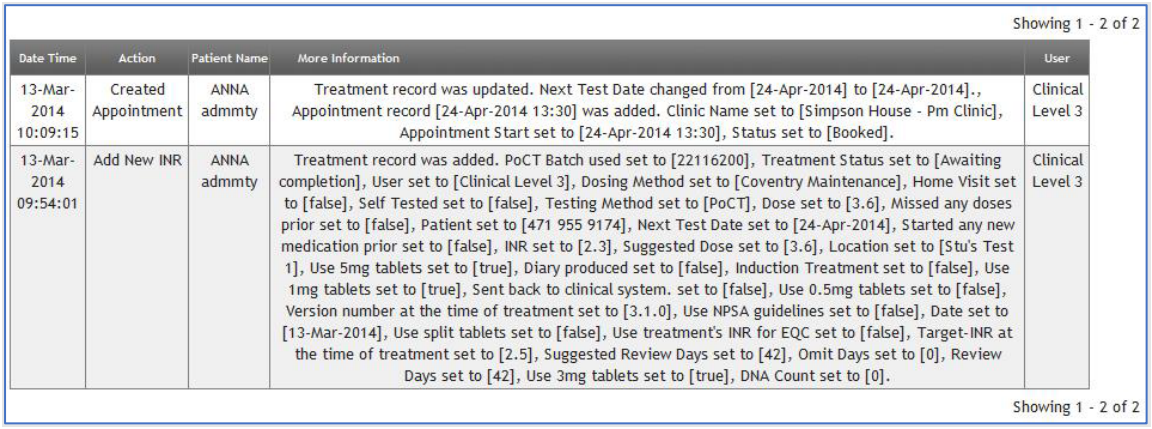
11.3. Patient Audit Trail

The patient audit trail contains details of all activities performed for the selected patient in chronological order. It may be helpful to view the audit trail to understand the sequence of events in the patient's INR treatment.

To view the patient audit trail:

- Click on '**Audit Trail**' on the relevant patient's record screen.

Each entry is listed with the name of the logged-on user responsible for the entry.

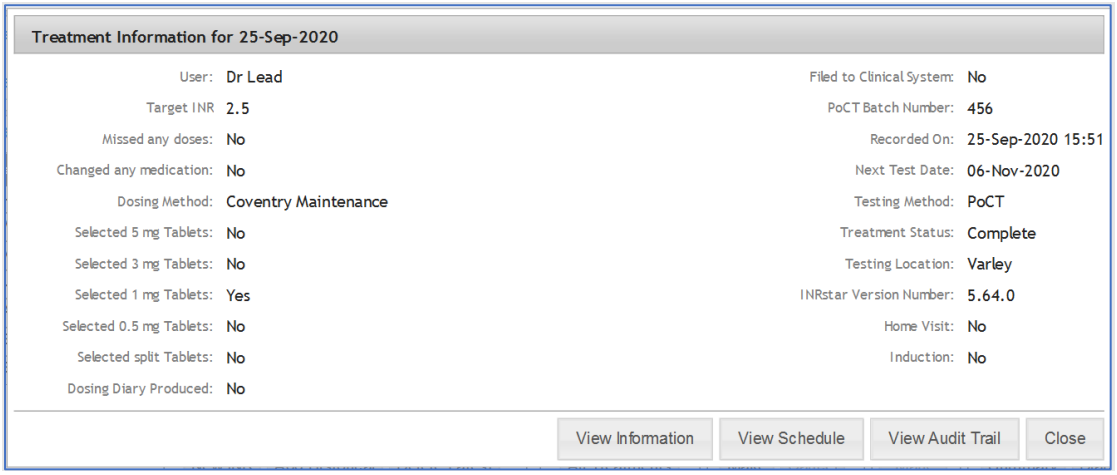


The audit trail can be navigated by clicking the links at the bottom of the screen.

Note: The patient audit trail records actions at the patient level. For further details of an individual treatment inspect the INR treatment audit trail.

11.3.1. Treatment Information Audit

The INR **'Treatment Information'** displays all selected INR treatments information.

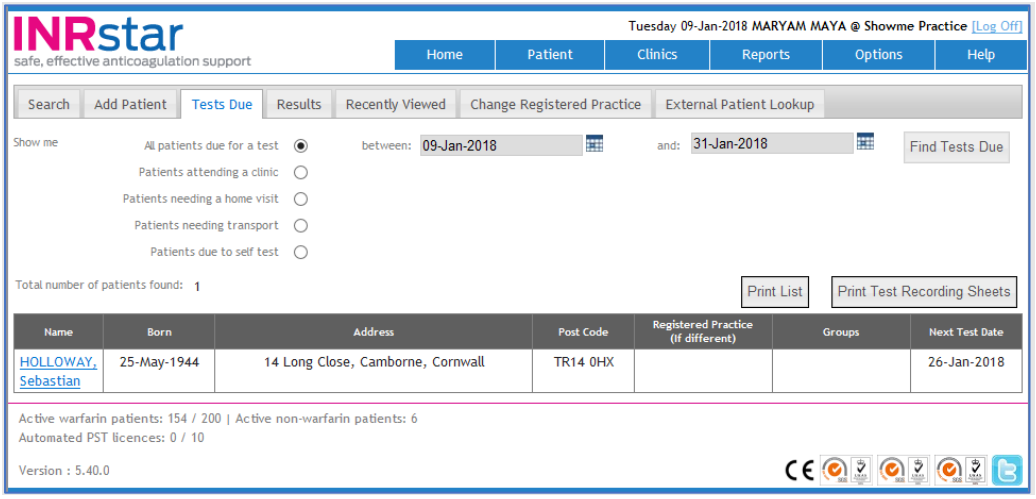


11.3.2. INR Treatment Audit Trail

The INR **'Treatment Audit Trail'** displays the audit trail for the selected treatment.

12. Tests Due and Home Visits

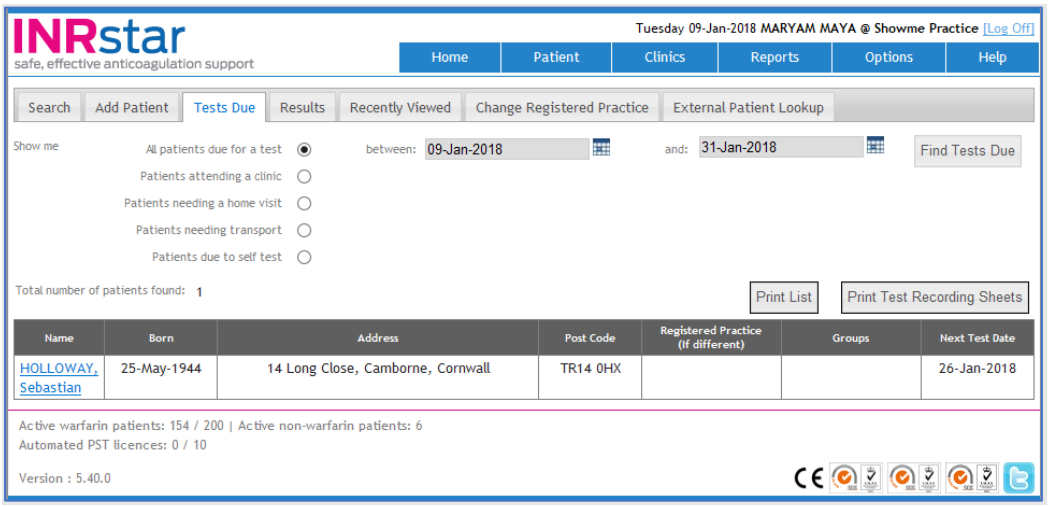
The **'Tests Due'** page shows a list of patients who are due to be tested within the date range specified. This date range will default to today.

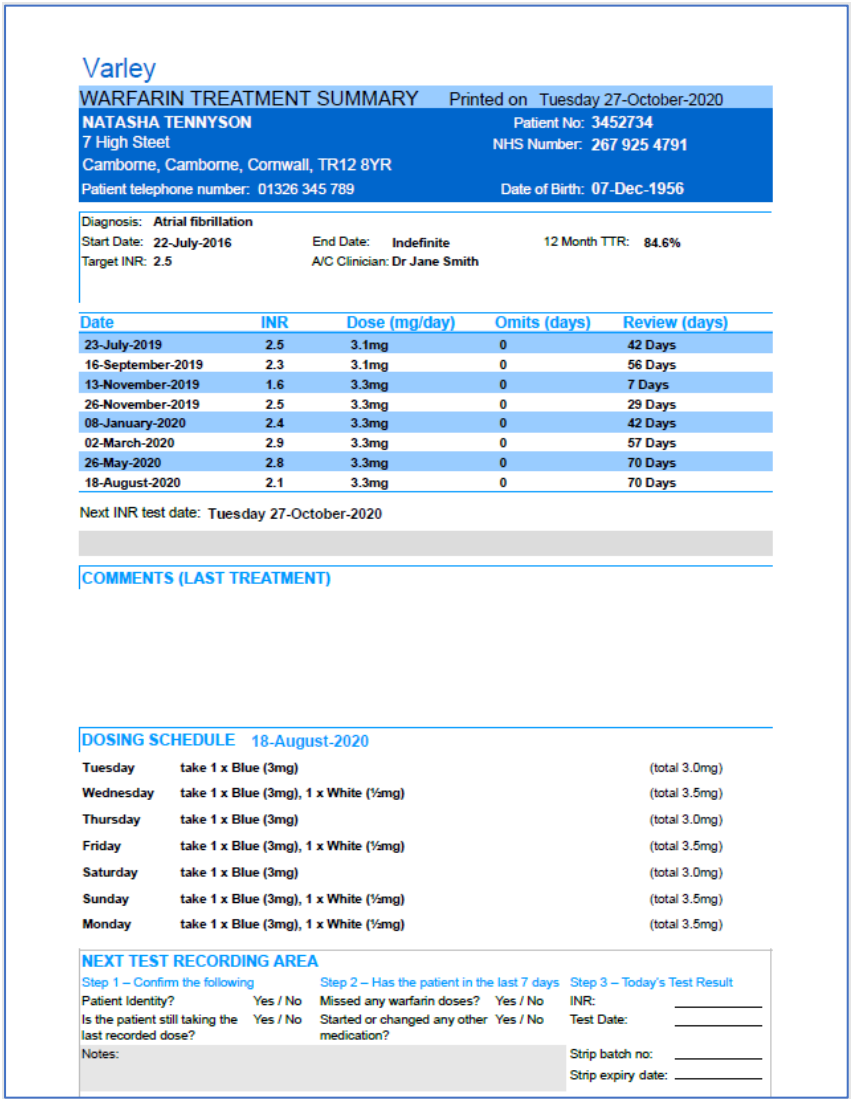


The default list will show all patients due to be tested, including those due to be seen at the clinic, patients due a home visit, and patients sending their INR result electronically.

The list of patients can be filtered by these options, and by those requiring organised transport to the clinic.

For patients who are unable to attend a clinic, a set of **'Test Recording Sheets'** can be produced for the visiting clinician.





Varley

WARFARIN TREATMENT SUMMARY Printed on Tuesday 27-October-2020

NATASHA TENNYSON
7 High Steet
Camborne, Camborne, Cornwall, TR12 8YR
Patient telephone number: 01326 345 789

Patient No: 3452734
NHS Number: 267 925 4791
Date of Birth: 07-Dec-1956

Diagnosis: Atrial fibrillation
Start Date: 22-July-2016
Target INR: 2.5
End Date: Indefinite
A/C Clinician: Dr Jane Smith
12 Month TTR: 84.6%

Date	INR	Dose (mg/day)	Omits (days)	Review (days)
23-July-2019	2.5	3.1mg	0	42 Days
16-September-2019	2.3	3.1mg	0	56 Days
13-November-2019	1.6	3.3mg	0	7 Days
26-November-2019	2.5	3.3mg	0	29 Days
08-January-2020	2.4	3.3mg	0	42 Days
02-March-2020	2.9	3.3mg	0	57 Days
26-May-2020	2.8	3.3mg	0	70 Days
18-August-2020	2.1	3.3mg	0	70 Days

Next INR test date: Tuesday 27-October-2020

COMMENTS (LAST TREATMENT)

DOSING SCHEDULE 18-August-2020

Tuesday	take 1 x Blue (3mg)	(total 3.0mg)
Wednesday	take 1 x Blue (3mg), 1 x White (½mg)	(total 3.5mg)
Thursday	take 1 x Blue (3mg)	(total 3.0mg)
Friday	take 1 x Blue (3mg), 1 x White (½mg)	(total 3.5mg)
Saturday	take 1 x Blue (3mg)	(total 3.0mg)
Sunday	take 1 x Blue (3mg), 1 x White (½mg)	(total 3.5mg)
Monday	take 1 x Blue (3mg), 1 x White (½mg)	(total 3.5mg)

NEXT TEST RECORDING AREA

Step 1 – Confirm the following
Patient Identity? Yes / No
Is the patient still taking the last recorded dose? Yes / No

Step 2 – Has the patient in the last 7 days
Missed any warfarin doses? Yes / No
Started or changed any other medication? Yes / No

Step 3 – Today's Test Result
INR: _____
Test Date: _____

Notes:

Strip batch no: _____
Strip expiry date: _____

12.1. External Test Results

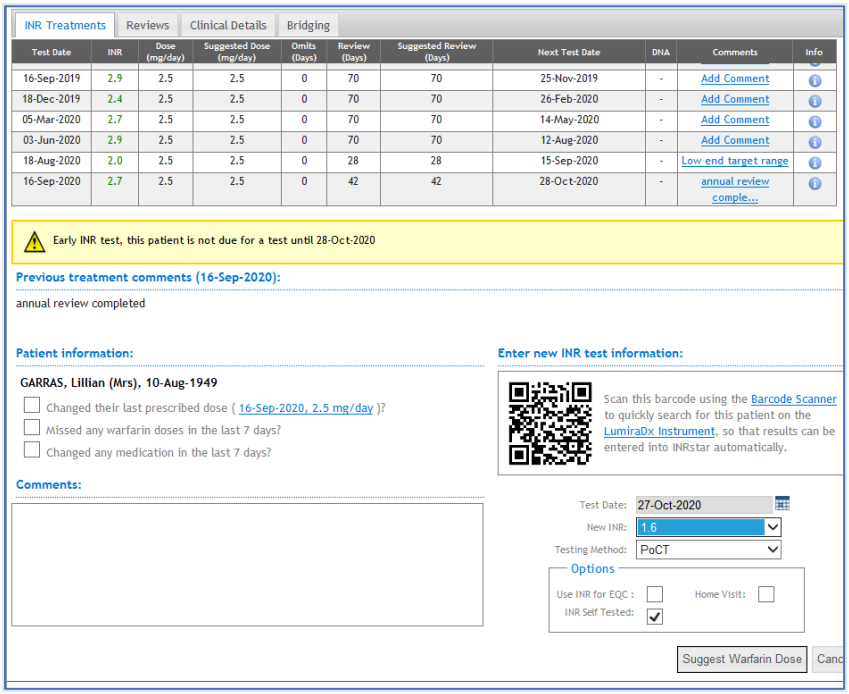
The '**Test Results'** screen enables integration of the integrated hospital laboratory systems with INRstar.

The interface files INR readings from the Instrument and hospital laboratory system directly back to the INRstar software within the clinic. There is no need to manually enter the patient INR result into INRstar, this saves time and reduces the risk of manual entry error.

12.1.1. Processing Test Results

1. Click on the **'Patient'** tab.
2. Click the **'Results'** tab.
3. Click the **'INR'** tab.
4. If the result matches a patient in INRstar you can click the **'Dose Patient'** button.

5. Complete the details in the **'New INR'** page for the patient to complete the treatment using the prepopulated result.



12.1.2. Patient Demographic Discrepancy

If the result does not match a patient in INRstar, click **'Find Patient'**.

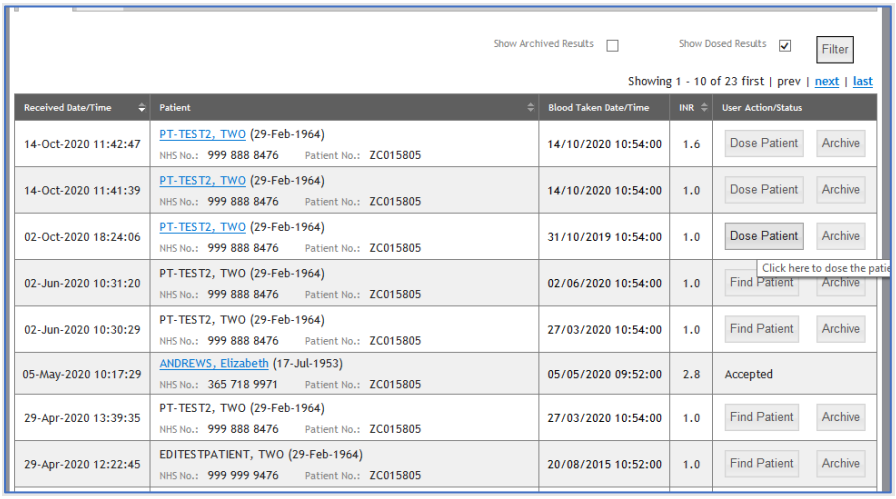
Search for the patient's name and select if the correct patient is found.

If the patient is not in INRstar, but you still want to treat them, click '**Add New Patient**'.

The demographic details from the laboratory results will be prepopulated with the patient's NHS number, Name and Date-of-birth (DOB). Complete the relevant details and add a treatment plan for the patient.

The patient will now be available for dosing, following processing of the test results.

- To view all dosed results, click on the **'Show Dosed Results'** filter.

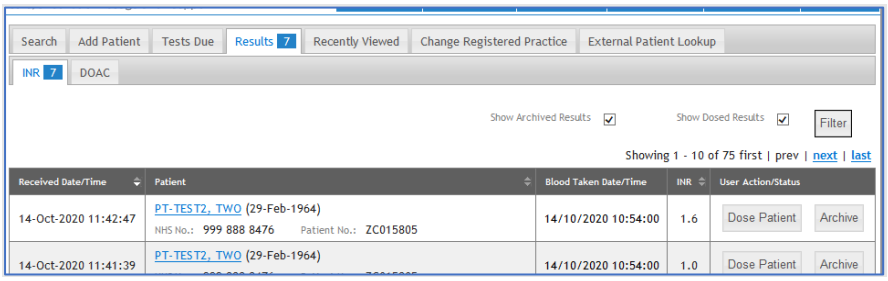


12.1.3. Archiving Unwanted Test Result

If a test result cannot be actioned due to an incorrect format or is not required, it can be archived to remove it from the new test result page.

1. Select **'Archive'**.
2. Enter the reason and Click **'OK'**.

To view all archived results, click on the **'Show Archived Results'** filter.



12.1.4. Test Results Sorting

Click the sort icon in the column headers to refresh the list of results and include any newly received results.

The sort feature is available in the following:

- The **'Received Date and Time'** column.
- The **'Patient'** column.
- The **'INR'** column.

The data can be sorted either ascending or descending.

Results that are out of range are displayed with a message next to them.

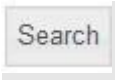
Results that are a duplicate are also displayed with matching text on the column next to archive.

12.2. External Patient Look-up (EPL)

INRstar's External Patient Lookup feature allows you to access the record of and provide direct care for a patient who is not managed by your anticoagulation service.

1. Click 

.
2. Click 

.
    - **Please Note** - If you have not added in your Professional Registration Credentials, in your '**Profile**' section on the home page, you will need to complete the information via a pop up box in order to continue using the functionality.
3. Select your '**Reason for using EPL'** now and add any comments.
4. Now fill one of the two sections under '**Mandatory Search Criteria'** and any '**Optional Search Criteria'**.
5. Click 

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6. A patient's name, date of Birth, NHS number, address, postcode, and Testing Location will then appear below if the correct search criteria was entered in correctly. Select the correct patient by clicking on their name.
7. You will now have accessed the patients record that you required.

Once the record is open the user will then be permitted to view and/or treat the patient. **Users will not be allowed to edit the patient's treatment plan or change any demographic details.**

12.3. Transferring Testing Location or Change Registered Practice

This is usually performed following a request by the patient's new Testing Location.

Testing Location: This is the site or service that tests, doses and manages the patient. It is possible to change the Testing Location if for example a patient is moving out of the area and will be treated elsewhere. The treatment location has full visibility of the patient's record, including treatment history, can edit demographics, add treatments and adverse events. Only the Testing Location can edit the patient's treatment plan or add a new treatment plan.

Registered Practice: This is the registered GP practice of the patient. This will be the same as the Testing Location if the patient is treated by their registered GP. If the

patient has their anticoagulation monitored elsewhere, a warning is shown on the patient's record. The Registered Practice has full visibility of the patient's record, including treatment history, can edit demographics, add treatments and adverse events. If the Registered Practice is not also the Testing Location, they cannot edit the patient's treatment plan or add a new treatment plan.

Note: A warning is shown next to any treatment that was performed elsewhere.

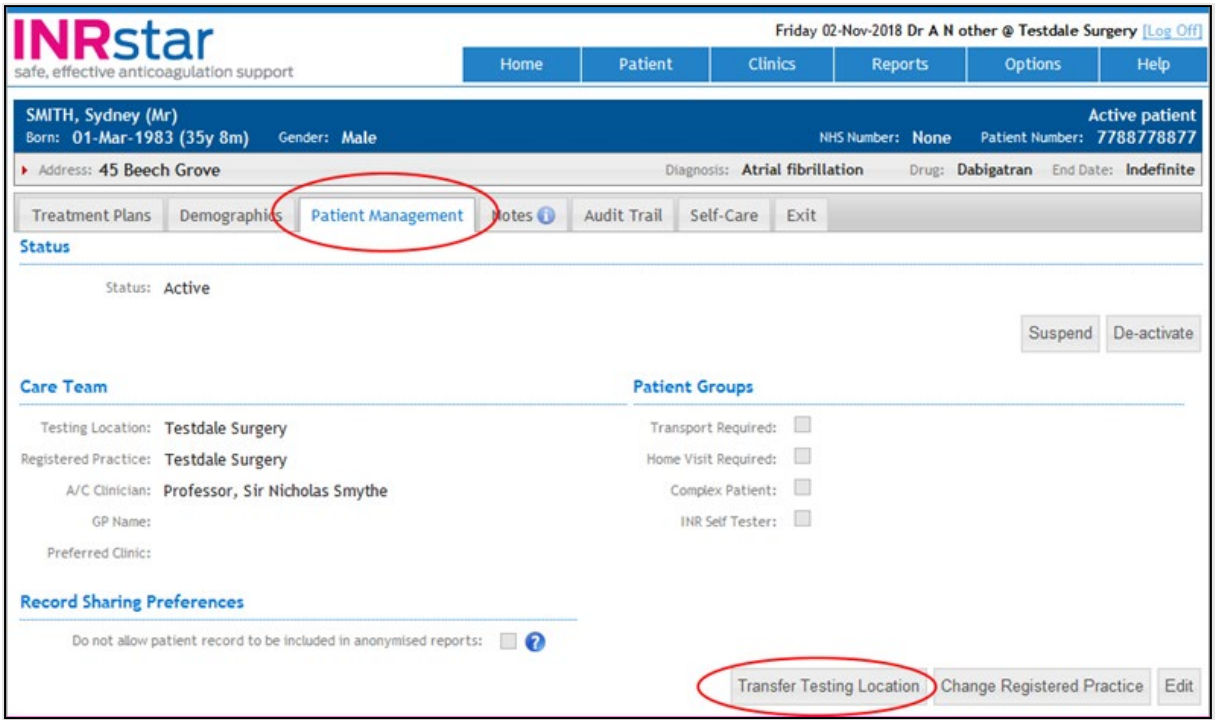
You can transfer a patient to any INRstar Testing Location held within the database.

Note: If the patient is also changing their registered GP, you will need to change the patient's 'Registered Practice' first, i.e. before transferring the Testing Location. This is because once the Testing Location has been transferred (pending acceptance) the Registered Practice cannot be changed, except by the new Testing Location once accepted.

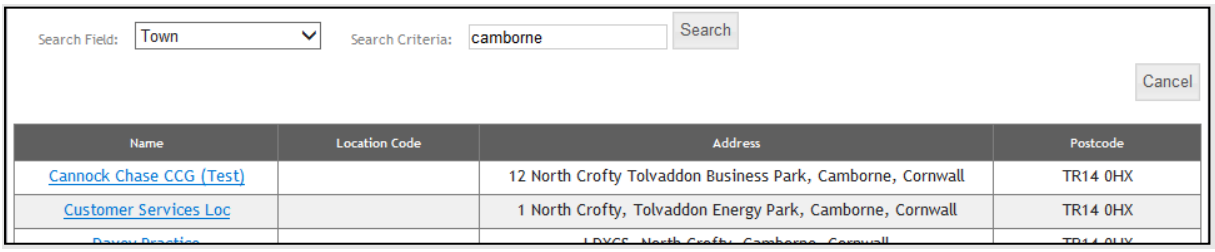
To transfer a patient's Testing Location:

1. Click on the **'Patient Management'** tab in the patient record.
2. Click on the **'Transfer Testing Location'** button.
3. You will now need to search for the patient's new Testing Location:

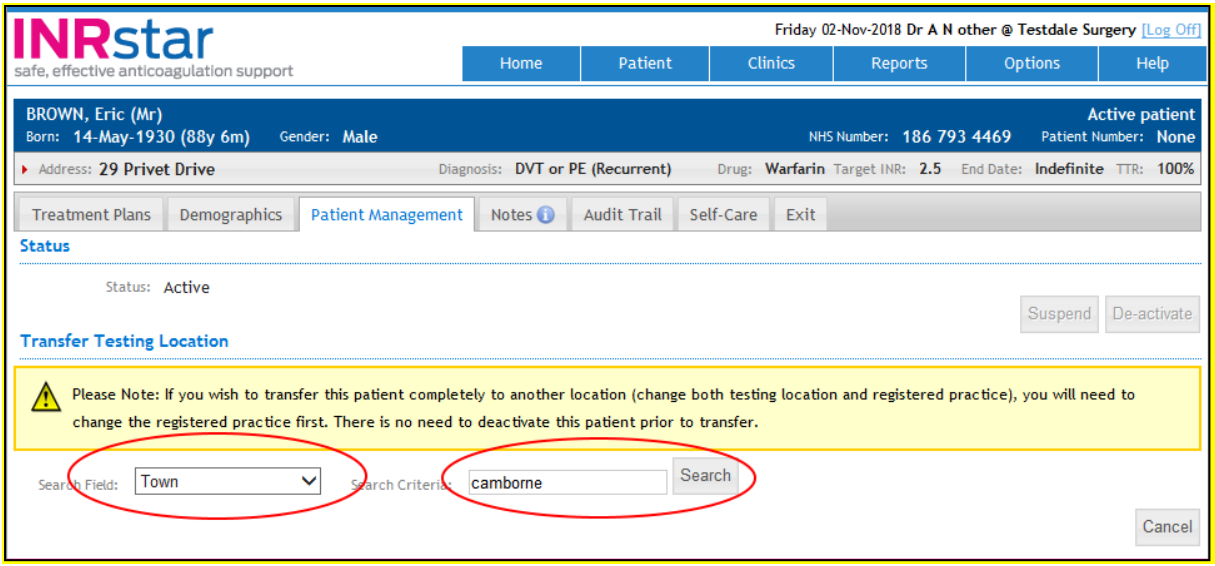
   First select the search criterion required from the drop-down menu (e.g. name, postcode, etc.) Then enter the first few letters of the search criterion you have chosen.

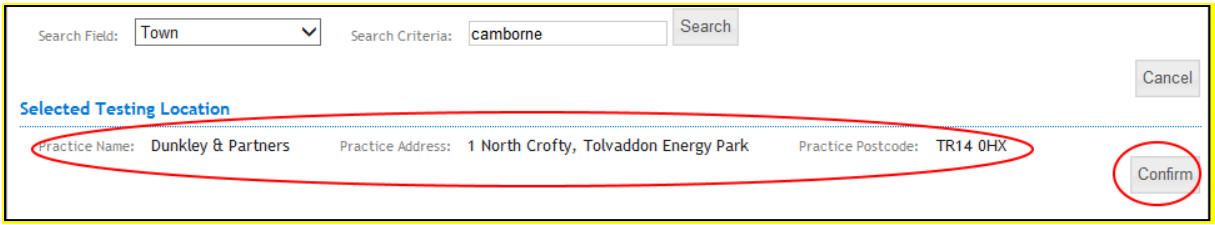


4. Click on the **'Search'** button.
5. Select the relevant Testing Location from the list of locations displayed.

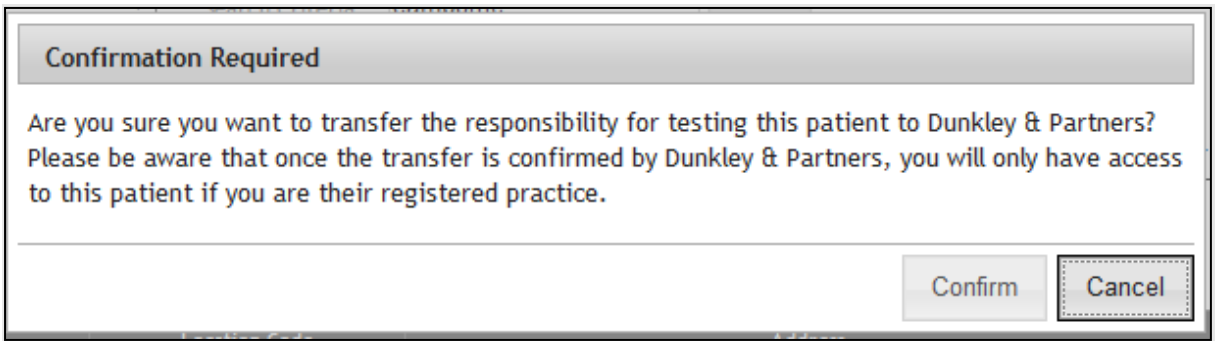


6. Check that the correct location is displayed in the '**Selected Testing Location**' section.





7. Click on the **'Confirm'** button.



8. Click **'Confirm'** to confirm that you wish to transfer the patient to the new location.

A transfer request message will now be sent to the new Testing Location – this will appear on the home page of all clinical level users at the new location.

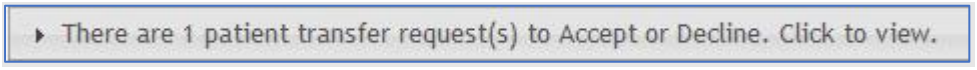
The new location can accept or decline the transfer request, but:

- The new location can examine the patient's record before deciding whether to accept or decline the transfer.
- New treatments can be added by either the Testing Location or the registered location, both before and after the transfer is accepted.
- Once the transfer of Testing Location is completed only the Testing Location can edit and create new treatment plans.
- A message will be displayed on the patient record with the status of the transfer request.
- If the transfer request is declined, the patient's record will remain at your location and an explanatory message will appear on your home page.

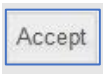
Note: You cannot transfer a patient enrolled to INRstar Engage. You would have to first un-enrol them from INRstar Engage and then transfer the patient.

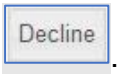
12.3.1. Transfer Request Acceptance

If your location has been transferred a patient record, you will see the following message on the **Home** screen.



Expand this message to see details of the patient details.

Here you can select either 

or 

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If you click the '**Accept'** button the patient record has been transferred.

Once accepted, check that the patient record demographics are up to date, e.g. address and telephone number may now need to be changed.

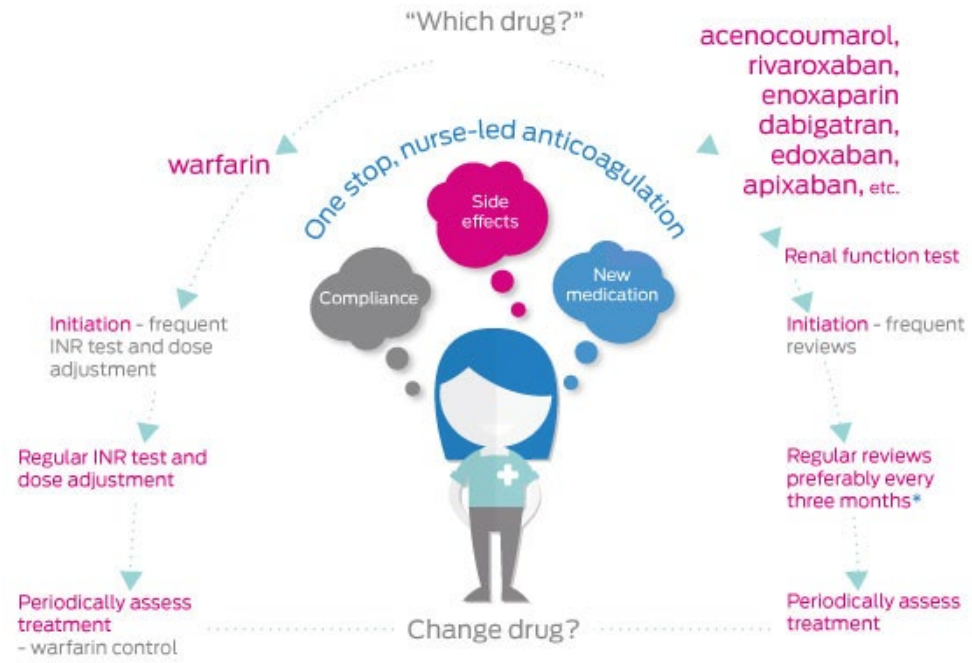
13. Managing Non-warfarin Patients in INRstar

Patients on non-warfarin anticoagulants can be managed within INRstar.

Although patients taking DOACs no longer need regular INR tests, the national experts still recommend regular clinical review and many anticoagulation services are now adapting their clinics to cater for those patients taking the newer agents. Non-warfarin Vitamin K antagonists such as acenocoumarol require regular INR tests.

Which non-warfarin drugs are currently supported on INRstar?

Currently supported drugs are apixaban, dabigatran, rivaroxaban, edoxaban, acenocoumarol, enoxaparin (Low Molecular Weight Heparin (LMWH)) and dalteparin (LMWH).



Recording these reviews in INRstar ensures that those patients are not lost to follow up, and all your anticoagulation patients can be reported on as a whole.

Please note:

- Treatment plans are only able to be set up for drugs licenced to the authorised diagnosis. Non-warfarin treatment plans are not currently able to be set up for custom diagnoses.
- Patients overdue a review will appear in a list on the home page.
- Patient reviews are filed back to the clinical system (currently only for EMIS Web & TPP SystmOne).

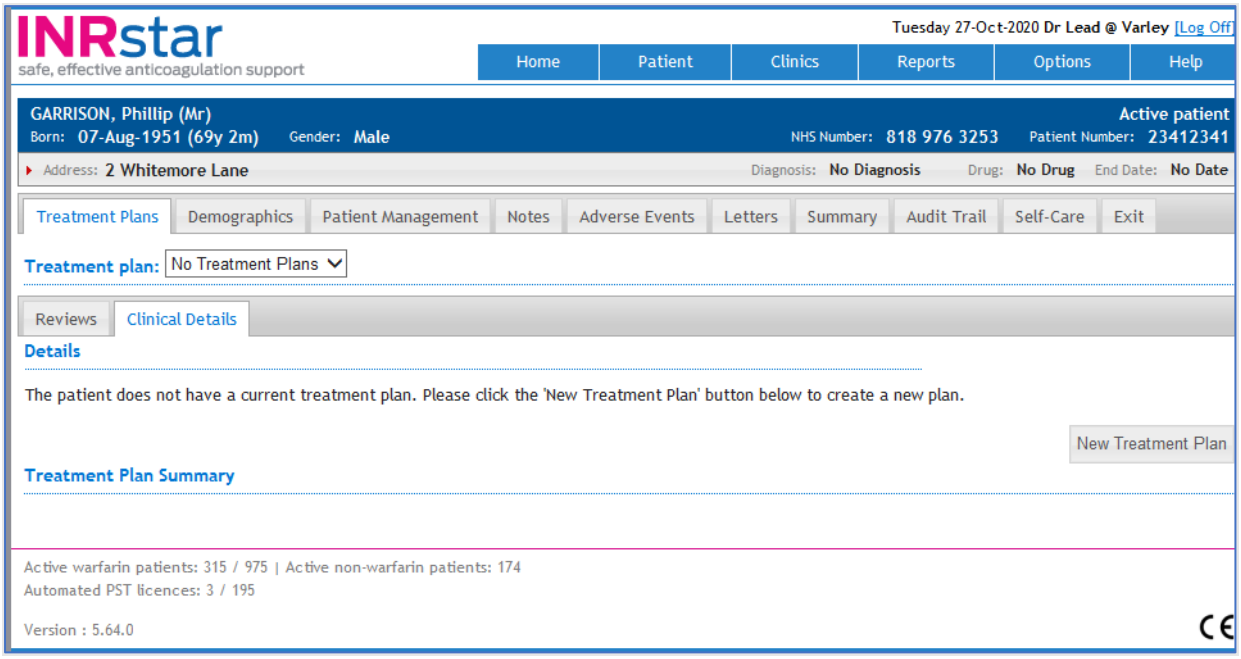
14. Adding a Treatment Plan – Warfarin

To manage treatments or reviews of a patient in INRstar each patient must have a treatment plan. The treatment plan defines the diagnosis, prescribed drug and length of treatment and collates all treatments and reviews together for that anticoagulation therapy.

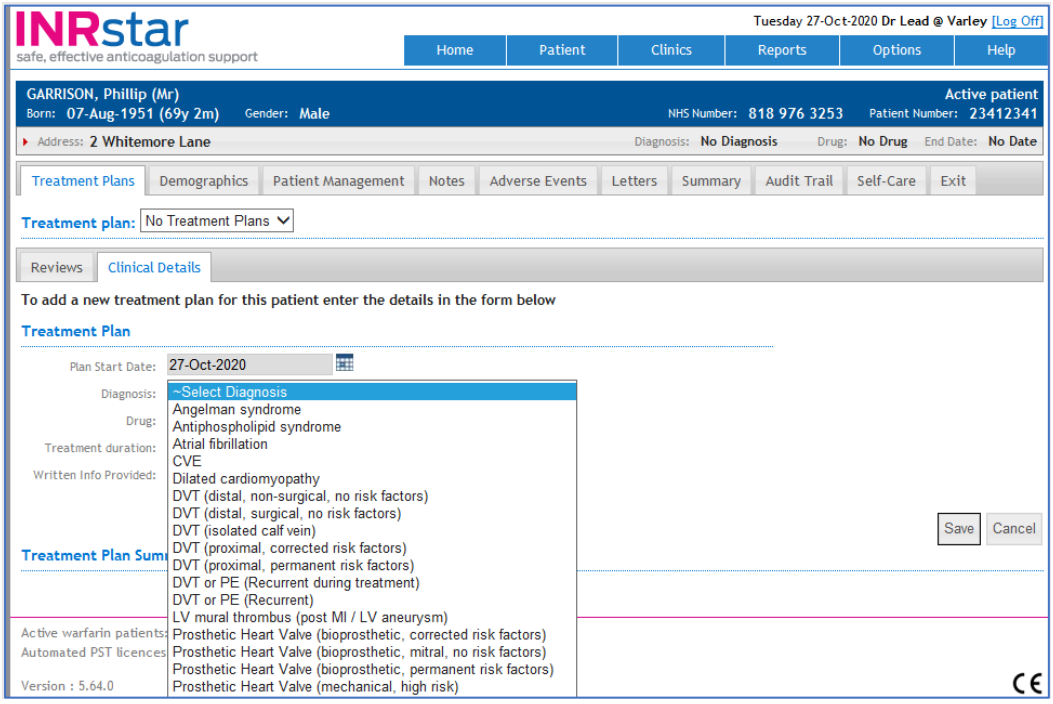
Warfarin treatment plans should not be used for any other AC drug than warfarin.

Entering clinical information:

1. Select the **'Clinical Details'** tab on the patient record.
2. Click on the **'New Treatment Plan'** button.



3. Enter the date that the patient started their current period of AC treatment.
4. Select the relevant diagnosis from the drop-down menu.

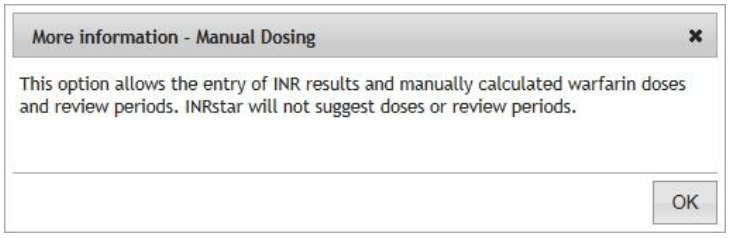


5. Select the AC drug to be used.
6. Select the appropriate duration of treatment.

   Note: Treatment duration will be automatically completed if the British Committee for Standards in Haematology (BCSH) evidence-based guideline recommendation exists. These can be clinically overridden on individual patients using the drop-down list if appropriate.
7. Select the **'Target INR'**.
8. Select the dosing algorithm to be used (See on-line FAQ for algorithm flow charts):

   - Induction – Slow Oates or Slow Tait
   - Fast Induction – Fennerty-Gedge
   - Maintenance – Coventry or Hillingdon
   - Manual dosing

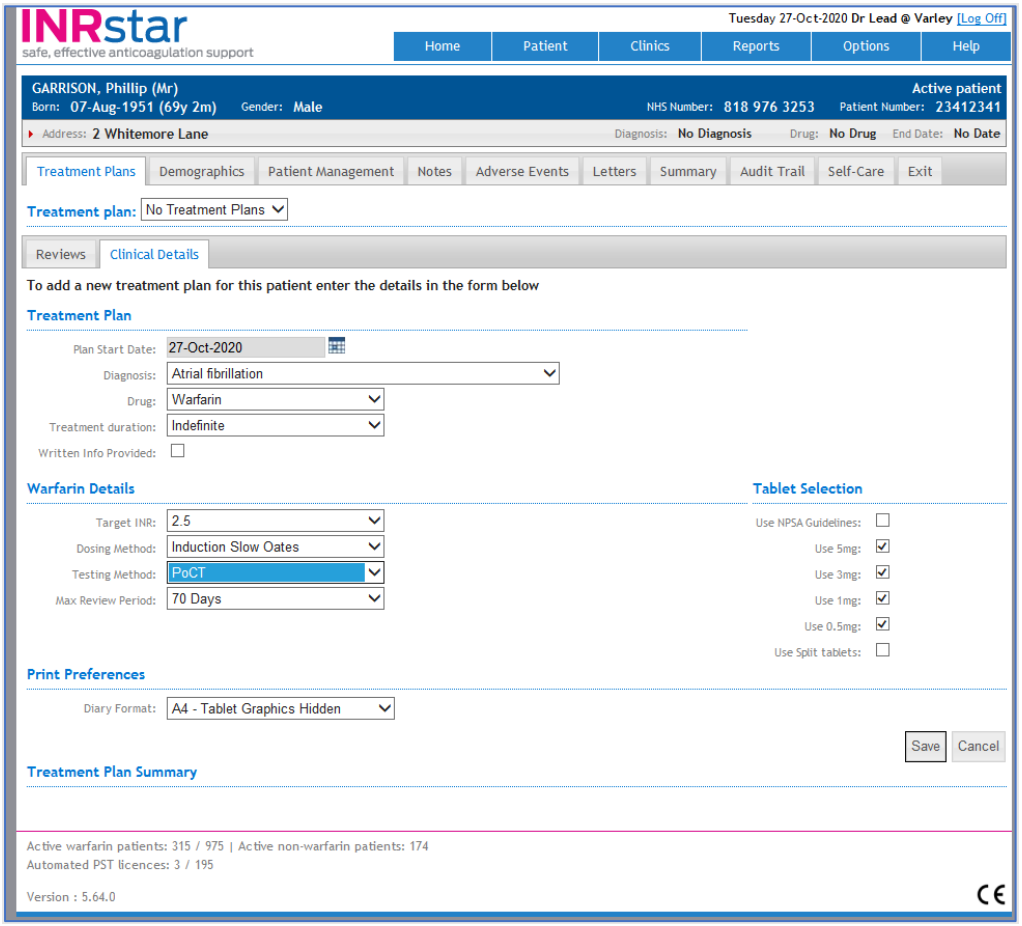
   Note: when Manual dosing is selected a warning is displayed reminding the user of the significance of the Manual dosing option:



   Click '**OK**' to acknowledge the message.

When the patient record is next displayed a warning message appears, beneath the patient detail at the top of the screen, reminding the user that the dosing method is set to Manual dosing.

9. Select the INR '**Testing Method**' to be used.
10. Point of Care Testing (PoCT) or Laboratory.
11. Select the maximum interval period between INR tests for the patient.
12. Select the format of the printed diary.

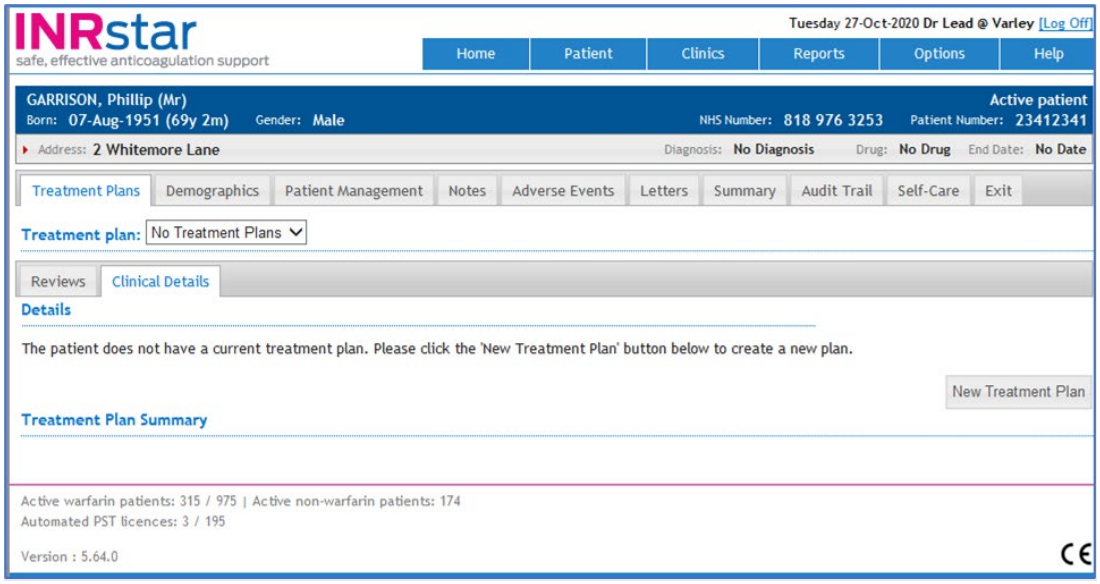


13. Click **'Save'** This will take you to the patient treatment screen where a historic or new INR can be recorded.

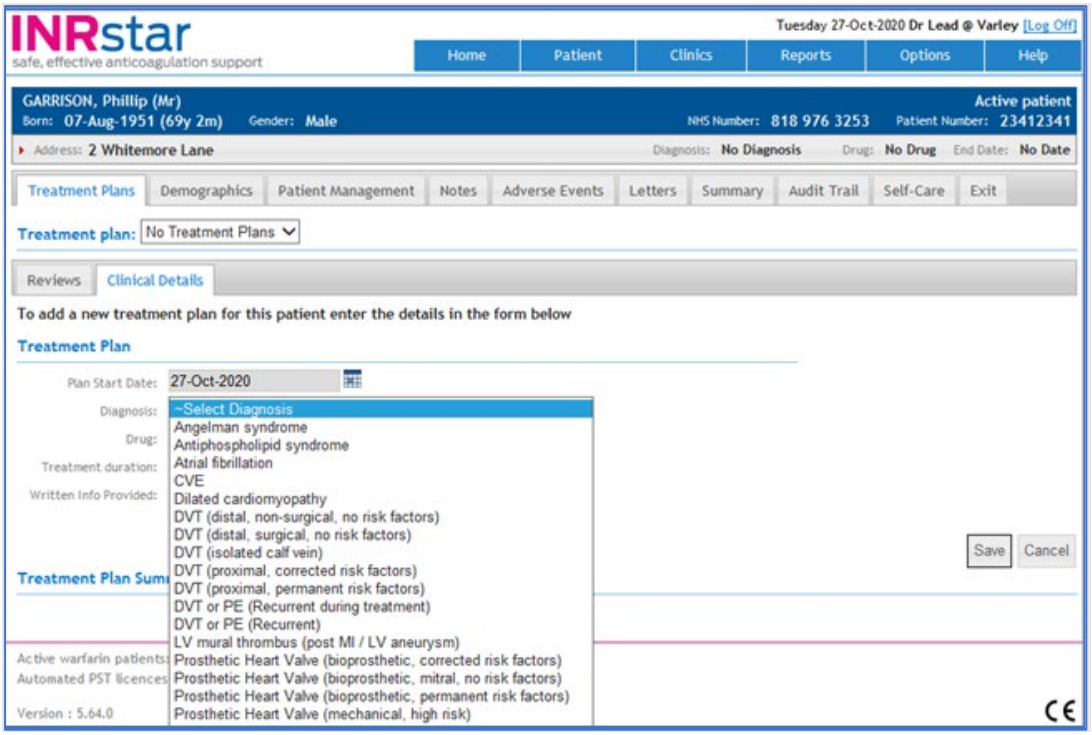
15. Adding a Treatment Plan – DOAC or LMWH

Entering clinical information:

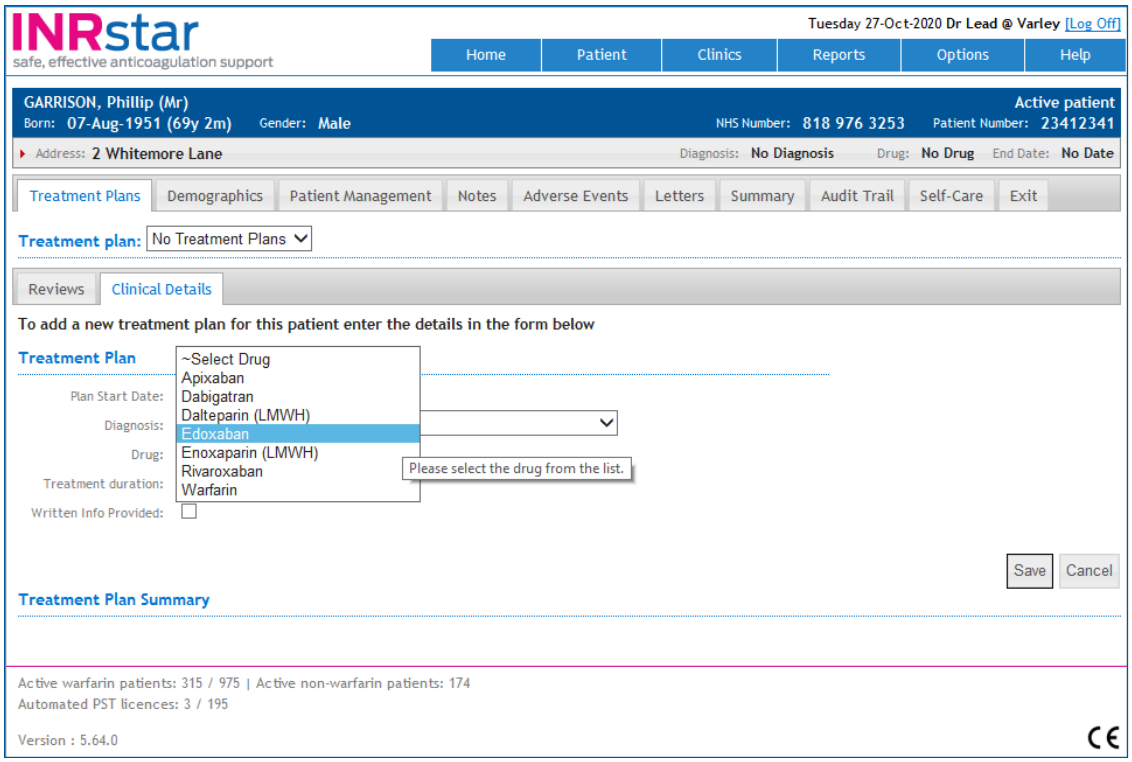
1. Select the **'Clinical Details'** tab on the patient record.
2. Click on the **'New Treatment Plan'** button.



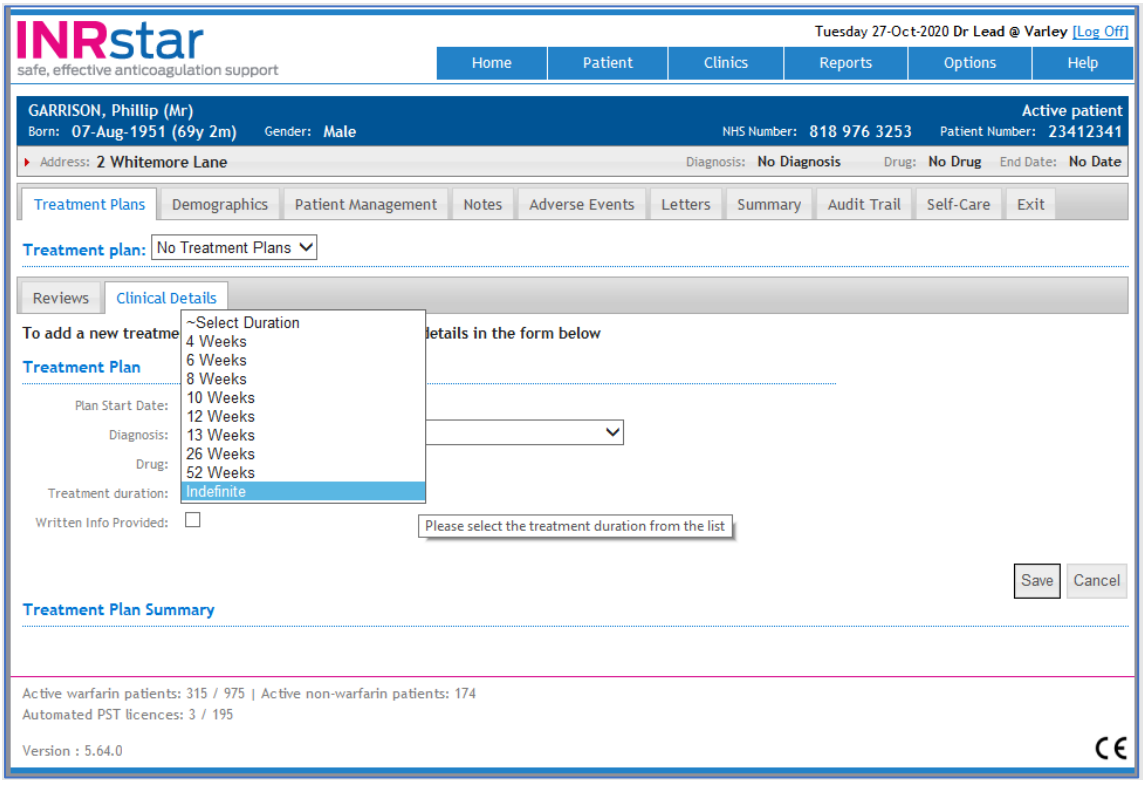
3. Enter the '**Plan Start Date**' for the patient's AC treatment plan.
4. Select the relevant diagnosis from the '**Diagnosis**' drop-down list.



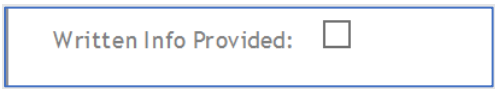
5. Select the AC drug from the '**Drug**' drop-down list.



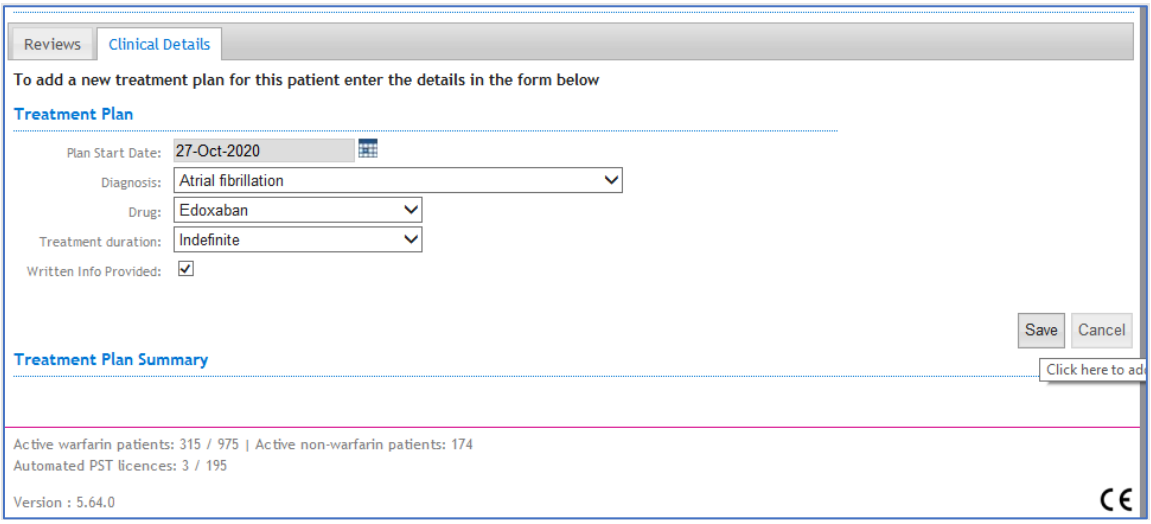
6. Select the '**Treatment Duration**' from the drop-down list.



7. Tick the box to confirm '**Written Information**' has been provided to the patient.



8. Click '**Save**' to confirm the DOAC or LMWH treatment plan.



Your treatment plan is now complete, and you will be taken to the review section.

If not ready to review just yet, scroll to the bottom of the review page to cancel. The patient record will then be in the home screen messages list of **'Non-Warfarin Patient(s) overdue reviews'**, where it is also possible to change the review date on a review. This is useful to know when adding several patients at once who are on a DOAC for example.

16. Patient Treatments

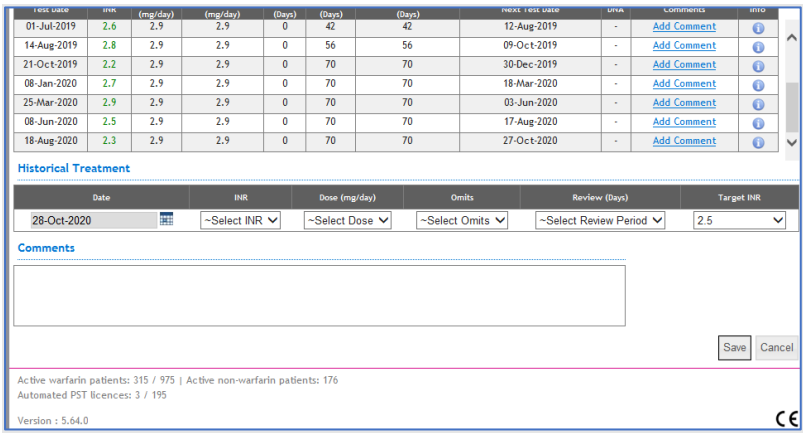
This section outlines the clinical use of INRstar for a patient when the treatment plan has been previously entered for patients treated on warfarin.

16.1. Recording a Historical Treatment

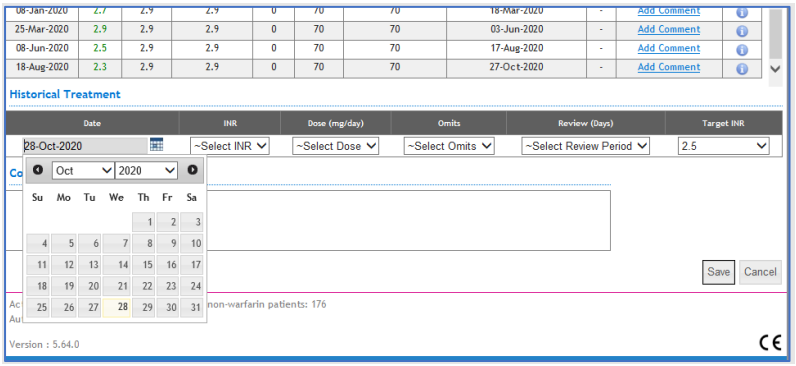
There are several situations where a user will need to record a treatment episode which has occurred in the past.

For example:

- Recording treatments performed before the patient was added to INRstar and their treatment plan was first created.
- Recording treatments performed while the patient was on holiday or in hospital.
- Recording the actual dose being taken, if the patient is no longer taking the dose that is currently recorded in their INRstar record screen.



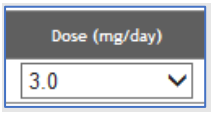
1. Click on the **'Add Historical'** INR button.
2. The add '**Historical Treatment'** screen will be displayed.
3. Proceed to fill out the **'Historical Treatment'** data entry and drop-downs.
4. Click on the '**Date'** calendar icon and select the date of the historical INR test.



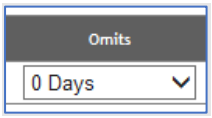
5. Select the '**INR'** result from the drop-down list by clicking the down arrow.

Note: if there is no new INR taken since the last recorded INR, the last recorded INR would be used here.

6. Select the average daily warfarin dose in milligrams/day from the drop-down list by clicking the down arrow. You need to calculate the dose by dividing the total weekly warfarin dose by seven to arrive at the average daily dose, to the nearest 0.1mg.



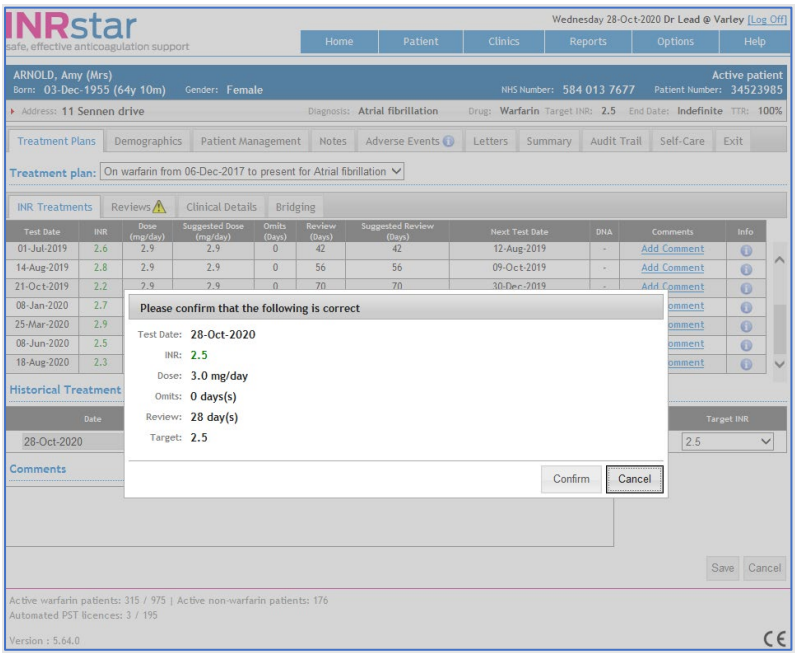
7. Select the appropriate omits (in days) from the **'Omits'** drop-down list.



- If the omits are unknown, please select **'Not Known'** from the list.

8. Select the review period in days from the drop-down list by clicking the down arrow.
9. The patient's current target INR will be displayed in the **'Target INR'** box. If the target INR was a different value at the time of the historical treatment you can select the correct value in the **'Target INR'** drop-down list by clicking the down arrow.

10. Type any comments relevant to the treatment in the comments box.
11. Click the '**Save**' button when you have finished entering the information, to save the historical INR treatment.
12. Check the information is correct when the confirmation dialogue is shown.

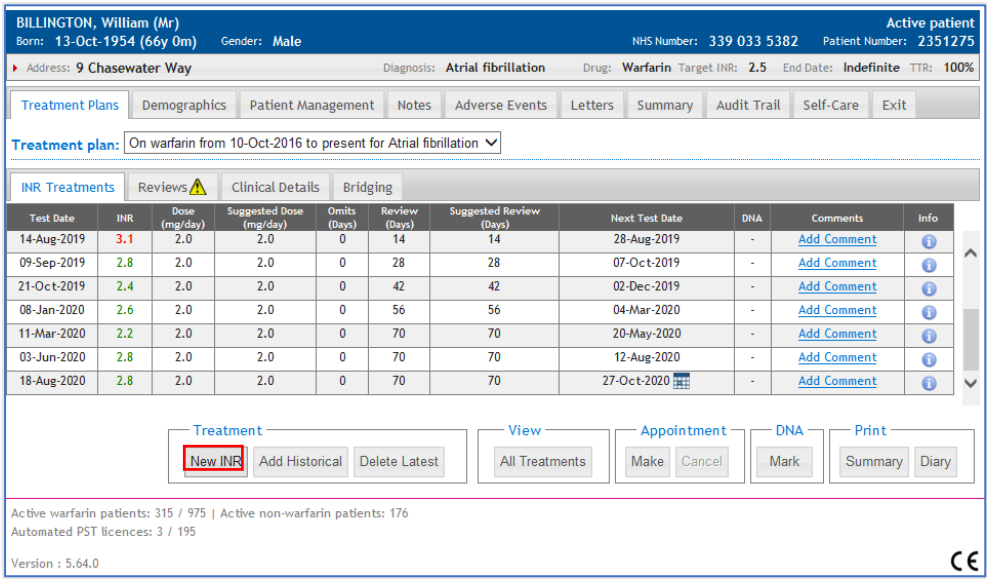


13. Click the **'Confirm'** button to continue if the information is correct or **'Cancel'** to edit the historical INR treatment.

The Historical treatment is now added to the treatment plan.

16.2. Add New INR Result

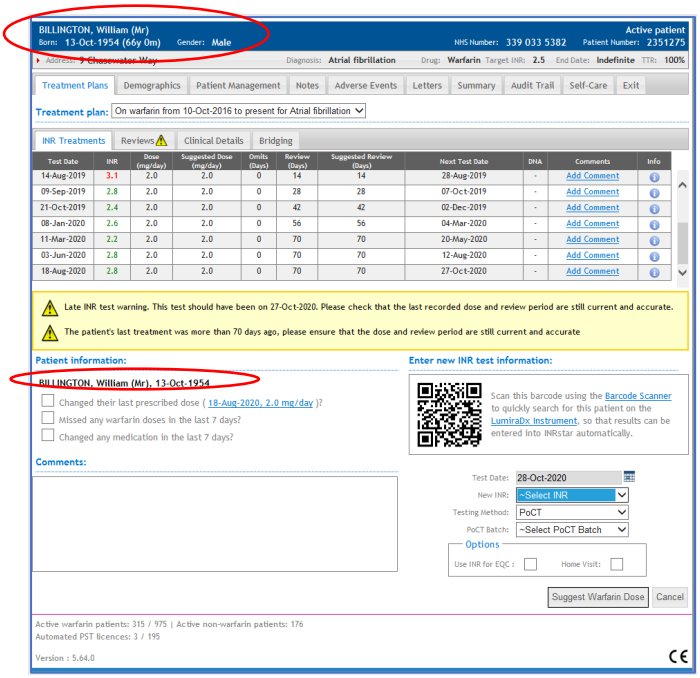
Click on the **'New INR'** button.



16.2.1 Confirm Patient Identity

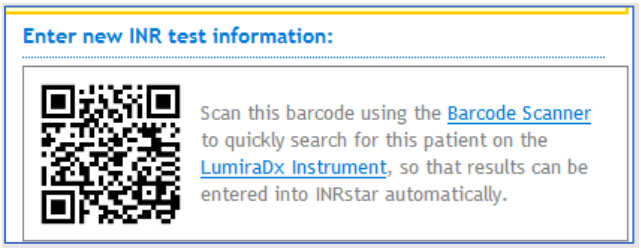
Patient information:

1. Confirm the patient identity and DOB.



2. Confirm the patient's current dose and tick the check box if the dose is changed. If the dose has changed, add the new dose to '**Add Historical'** record and the patient's treatment plan.
3. Tick the check box if the patient has any missed warfarin doses.
4. Tick the check box if the patient has had a change in any other medication.

   Note: Changes to medication may include clinically prescribed or over-the-counter medications.
5. Confirm date of INR test from the calendar icon.
6. Select and add the INR result from the pick list manually or scan the bar code if using the LumiraDx Instrument.



Scan this barcode using the Barcode Scanner to quickly search for this patient on the LumiraDx Instrument, so that results can be entered into INRstar automatically

INRstar supports direct two-way integration with the LumiraDx Instrument.

Note: When performing a patient test, the Barcode Scanner can be used to send the patient's demographic information, via a barcode on the patients new INR screen, directly to the LumiraDx Instrument. The INR result will be sent from the LumiraDx Instrument directly to INRstar, including batch number and date and time of the test, ready for dosing.

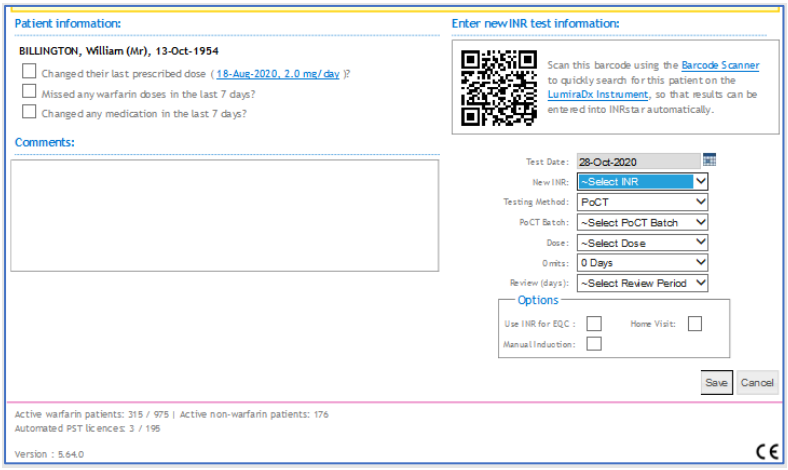
7. Confirm the testing method, '**PoCT'** or '**Lab'** if manually entering INR result.
8. Add or change the last prescribed dose under **'Adding INR'**.
9. Within the options box, mark if using the INR result for external quality control (**EQC**), or home visit.
10. Click on the **'Suggest Warfarin Dose'** button at the bottom right. Depending on the dosing method you might have to click on **'Save'** or **'Cancel'** (if you want to cancel) if the patient is being manually dosed.

After a click on the **'Save'** or **'Suggest Warfarin Dose'** button a confirmation pop-up is displayed. Confirm the data entered by clicking the **'Confirm'** button. Click **'Cancel'** if you want to make changes to the treatment.

16.3. Manual Dosing

If manual dosing is chosen in the **'Treatment Plan'** tab, when **'New INR'** is selected, the screen below is displayed. This is available for treating patients on warfarin.

Note: Manually entered INR treatments cannot be overridden or referred for dose authorisation. (Clinical Level 3 user permission required to manually dose).



1. Complete the date, '**new INR'**, '**Testing Method'** and '**Batch'** as previously.

   Note: If your PoCT Lot number has an expired date, a 'PoCT Batch Expired' warning is displayed. You may need to add your current PoCT Lot number to the list available for use within INRstar.

2. Select '**Dose'**, number of '**Omits'** (if appropriate) and next review date **'Review Days'.**

3. The manually entered treatment will be displayed with a suitable dosing schedule in the usual way, or you may have to select a dose if the required dose is not exactly available.
4. The dosing schedule can be re-ordered, or an alternative schedule can be selected if required.

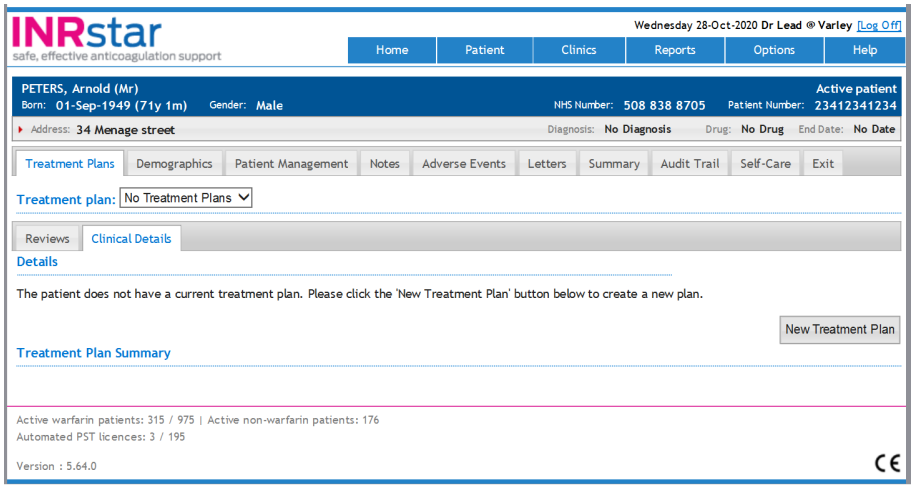
   Note: 'Skip or Boost' is not available for manual dosing and will display a warning message if you attempt to select it.
5. Click **'Save'** to save the INR treatment to the patient record to allow printing of a dosing diary and or patient summary sheet.

16.4. Oates Slow Induction

The Oates algorithm is intended for use with non-urgent induction of patients requiring an INR target of between 2.0 and 3.0. It cannot be used for urgent induction or for those patients who have a baseline INR > 1.3 or in those taking Amiodarone[1].

Warfarin Induction protocols have been designed to initiate warfarin treatment in patients who are not currently taking warfarin.

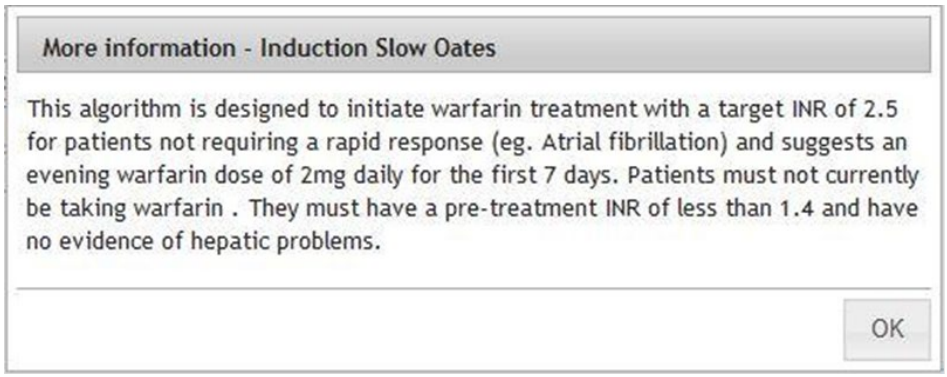
Before commencing ensure that 1mg tablets and/or 0.5mg tablets are selected. The patient's gender also needs to be added as on the 15th day of treatment the dosing is determined by INR and male/female gender.



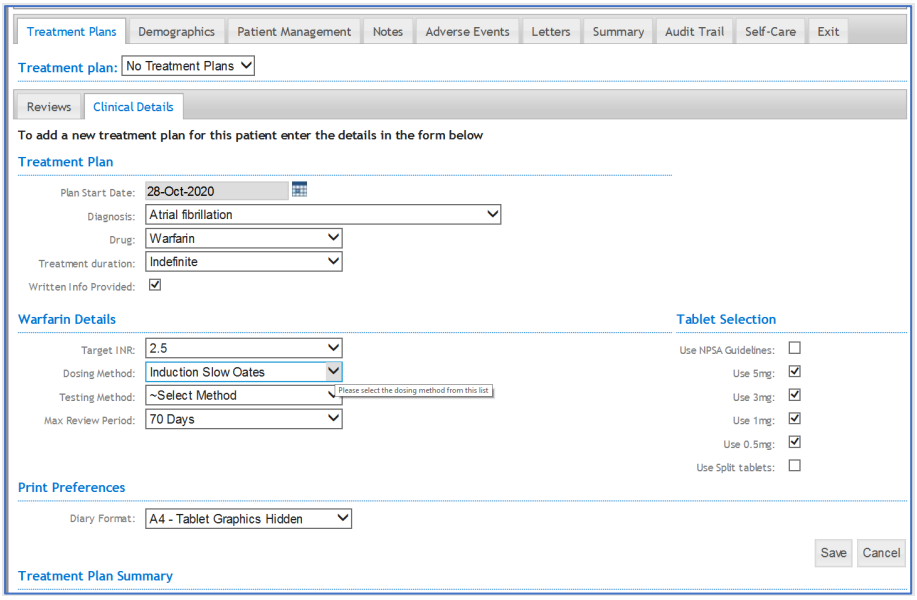
1. Select the clinical details tab in the patient record and click on '**New Treatment Plan'.**
2. Select the warfarin treatment start date from the calendar icon. For patients starting an Induction protocol this should be today's or yesterday's date.
3. Select the primary diagnosis for AC treatment from the diagnosis drop down list.

[1] *Reference: Br J Clin Pharmacology. 1998 Aug; 46(2):157-61*

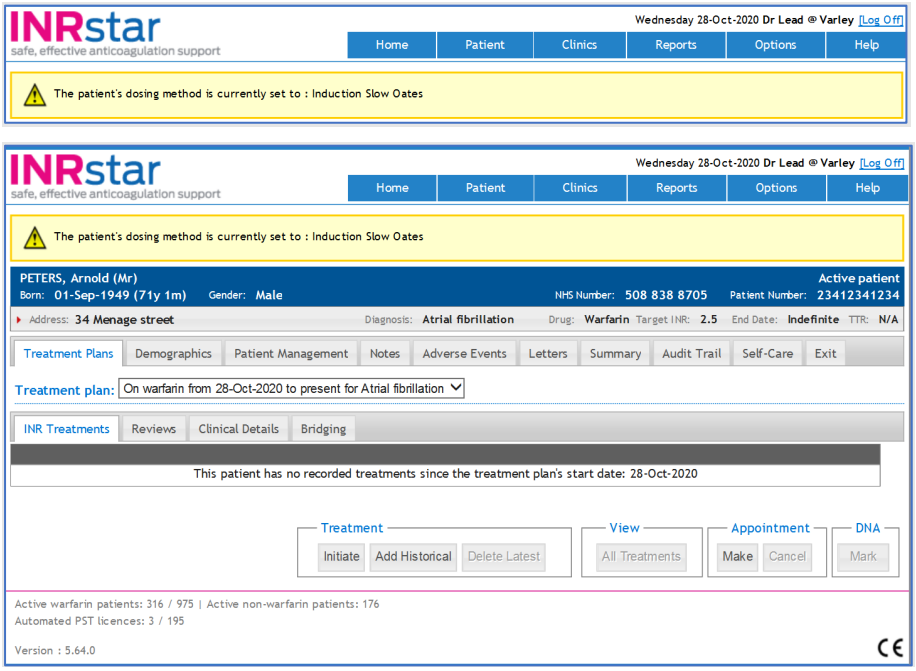
4. The recommended target INR and treatment duration will be populated automatically but can be edited by a user with Level 3 permission if required.
5. Then complete the patient warfarin details section:
   - '**Target INR**'.
   - Select the dosing method '**Induction Slow Oates'.** Confirm that this protocol is suitable for your patient when the confirmation dialogue is displayed.



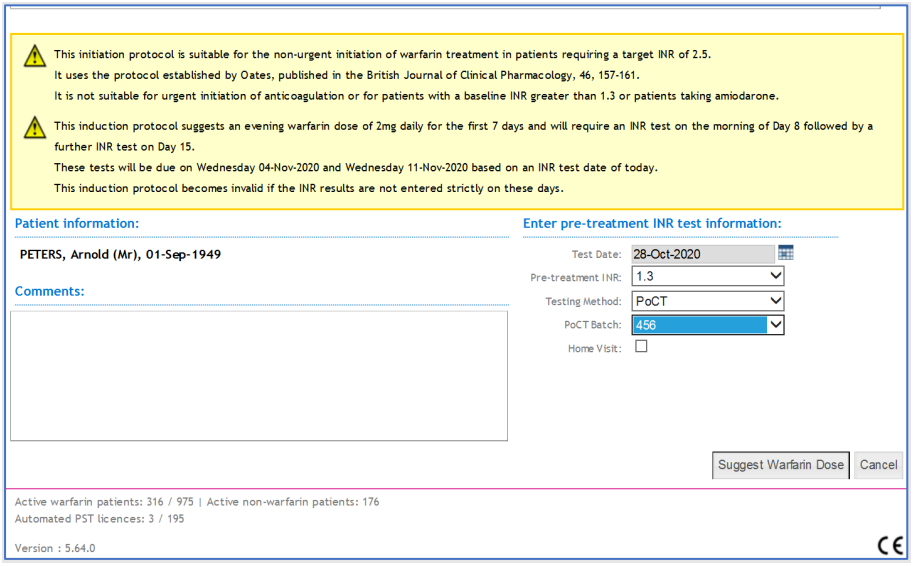
   - Select '**Testing Method**', 'PoCT' or 'Lab'.
   - Set the '**Maximum Review Period'** in between test (Max 70 days).
   - Confirm '**Written Information'** has been provided to the patient.
   - Select the warfarin tablet strengths appropriate for this patient from the **'Tablet Selection'**.
6. Select the '**Print Preferences'** for the diary format required.
7. Click the **'Save'** button to save the clinical details to the patient's record, or Click **'Cancel'** to exit without saving.



The patient is now set to **'Induction Slow Oates'**.

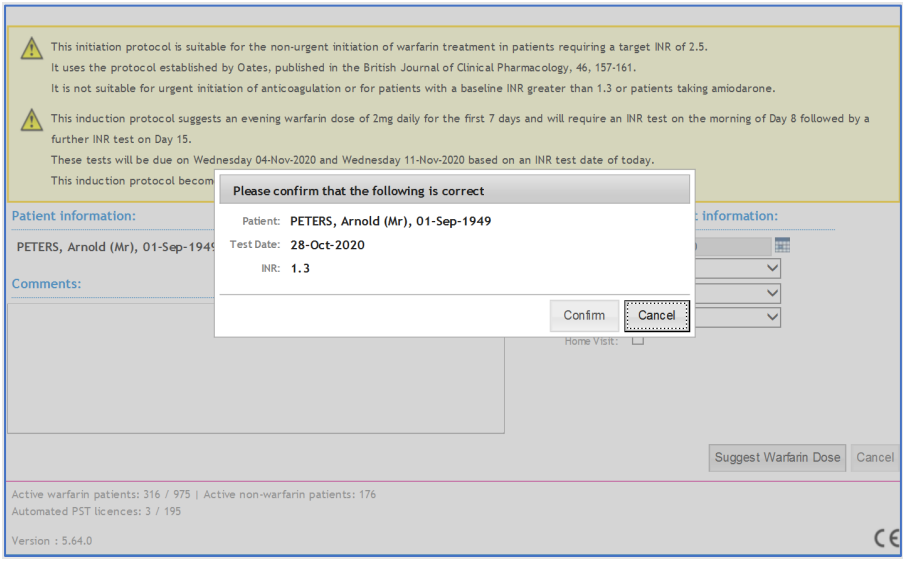


Click **'Initiate'** and the following screen will issue an outline message that provides an overview of the **'Induction Slow Oates'** and includes the dates the patient will require follow up tests.

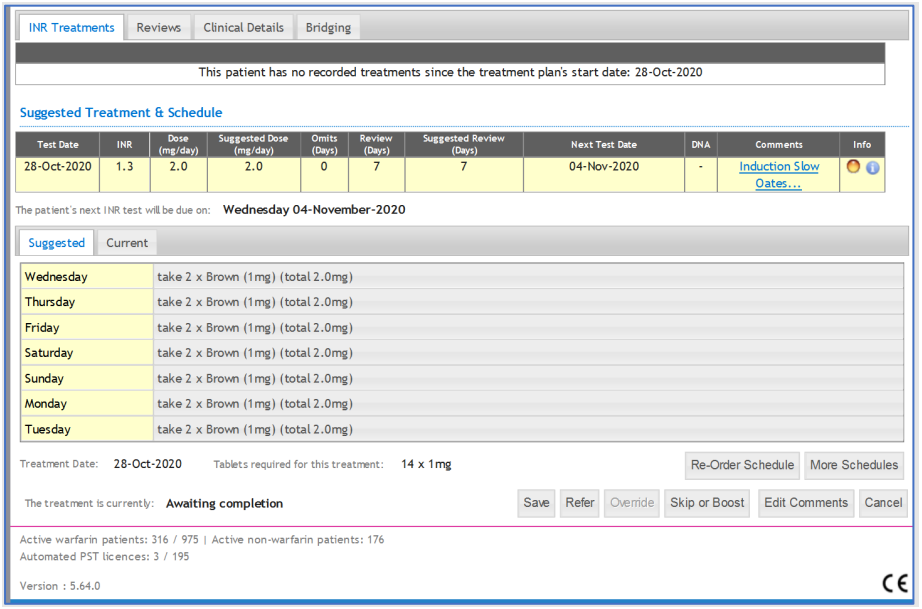


Note: At this stage it is essential to confirm with the patient that they will be able to attend for repeat INR tests on the next 7 days. The patient must be available to be tested on the dates detailed in the protocol. If the patient cannot be tested on the dates advised, the protocol is unsuitable and therefore the patient should be dosed manually.

- Click '**Suggest Warfarin Dose**'.
- Read and confirm the information entered is correct or **'Cancel'**.

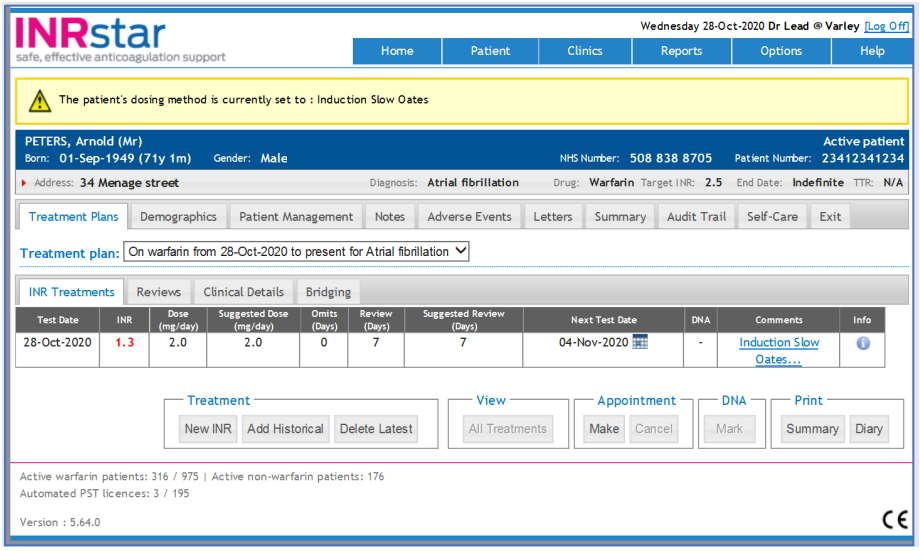


INRstar will suggest a 2mg dosing schedule for the next 7 days.



There are options to **'Save'**, **'Refer'** the record for approval or **'Cancel'**.

The dosing method is now set to: '**Induction Slow Oates'.**



On '**Day 8'** and '**Day 15'** the patient should be tested, and the INR result entered into INRstar. The '**Induction Slow Oates'** protocol will generate the recommended dose of warfarin and next review date.

When the patient has two INR results in target range with a minimum of 7 days in between results recorded, the treatment plan can be amended to a maintenance algorithm ('**Coventry'** or **'Hillingdon'**).

16.5. Tait Dosing Algorithm

The **Tait slow induction** is only available for patients being treated on warfarin.

Warfarin induction protocols have been designed to initiate warfarin treatment in patients who are not currently taking warfarin.

It cannot be used for:

- Urgent induction.
- Patients who have a baseline INR greater than or equal to 1.4.
- Patients taking Amiodarone[2].

The Tait slow induction protocol is used to initiate warfarin treatment in patients for whom a target INR of 2.5 (INR range 2.0-3.0) is appropriate and who do not need rapid induction of AC (e.g. patients with atrial fibrillation and non-urgent).

It is not suitable for patients who require higher target ranges or in whom rapid AC is needed (e.g. prosthetic valves or pulmonary emboli/deep vein thromboses, etc.).

Before starting this induction protocol, it is essential to ensure that:

[2] *Reference: Br J Haem. 1998; 101, 450-4*

- The patient is not currently taking an oral AC drug.
- The patient is not taking a drug with a potentially significant interaction with warfarin (especially antiplatelet agents, non-steroidal anti-inflammatory drugs or Amiodarone).
- They have no evidence of hepatic impairment.
- Their pre-treatment baseline INR is less than 1.4.
- The patient will be able to attend for INR testing on the required days (see below).

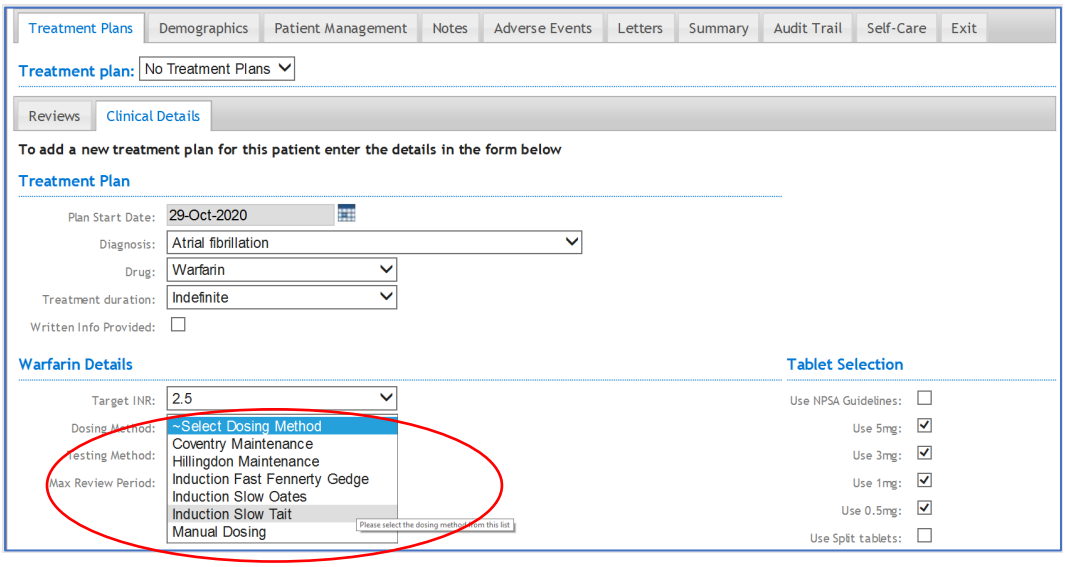
The Tait protocol suggests a warfarin dose of 5mg daily with an INR test on the fifth day. Further dosing suggestions will depend on the INR result on this day. A second INR result will be required on the eighth day of treatment and again suggestions will be made based on the INR result. On day 12 or 15 fine dose adjustments can be made and a clinical decision to select a suitable maintenance algorithm if appropriate.

It is essential that these INR tests are carried out on the required days (Day five, eight, 12 or 15); if not the protocol will be invalidated. In this situation the patient will need to be dosed manually until they are sufficiently stable to start on a maintenance dosing algorithm.

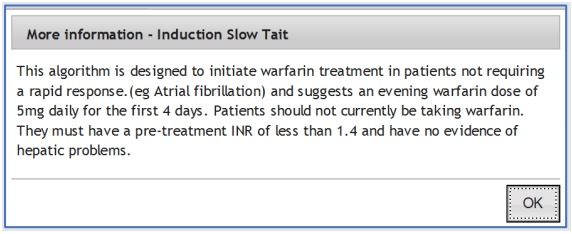
For patients who are being manually dosed on induction, see section 16.3.

Firstly, you will need to add the relevant clinical details to the treatment plan and set the dosing method to **'Induction Slow Tait'**.

1. Click on '**Treatment Plans**' and then '**Clinical Details**' and the patient's record screen to view the treatment details screen.
2. Select a warfarin start date from the calendar icon. For patients starting an induction protocol, this should be today's date.
3. Select a diagnosis from the '**Diagnosis**' drop-down list.
    - The recommended target INR and treatment duration will be added automatically.
    - Users with sufficient permission levels may edit the recommended values if needed.
4. Set the dosing method to induction by selecting **'Induction Slow Tait'** from the **'Dosing Method'** drop-down list.



5. Confirm that this protocol is suitable for your patient when the confirmation dialogue displayed.



6. Select the appropriate testing method from the '**Testing method**' drop-down list.
7. Select the warfarin tablet strength appropriate for this patient from the '**Tablet Selection**'.
8. Confirm that you have given the patient written information about AC treatment (e.g. 'Yellow Book') by clicking the **'Written Info Provided'** check box.
9. Click the **'Save'** button to save the clinical details to the patient's record, or click **'Cancel'** to exit without saving.

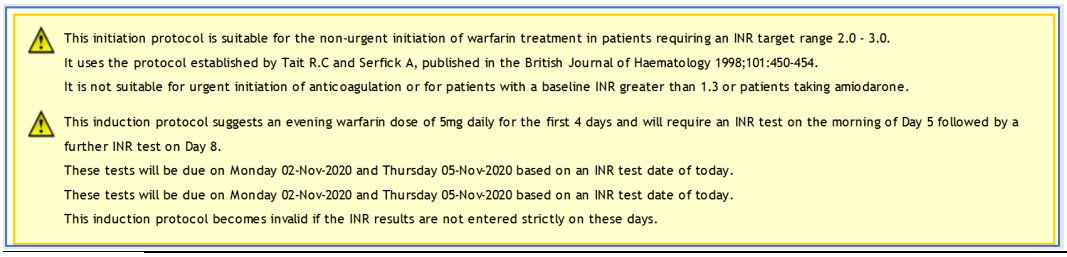
16.5.1. Stage 1 of the Tait Induction Protocol

The next step is to perform Stage 1 of the induction protocol:

1. Click on **'INR Treatments'** in the patient's clinical record screen.

   The induction protocol Stage 1 screen will be displayed.

2. Click the **'Initiate'** button.

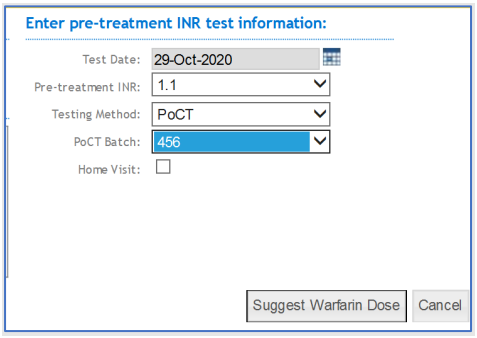


A reminder message about the appropriateness of using an induction protocol is displayed which includes the proposed dosing details and dates of INR tests shown.

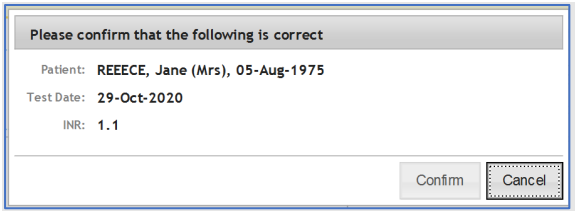
At this stage it is essential to confirm with the patient that they will be able to attend for repeat INR tests on the days shown. If not, the protocol will be invalidated.

If these days are not possible it might be necessary to delay the induction process to a different day so that the necessary INR review tests can be conducted to follow the protocol.

3. Confirm the patient identity.
4. Add the pre-treatment INR result by selecting it from the '**Pre-Treatment INR**' drop-down list.

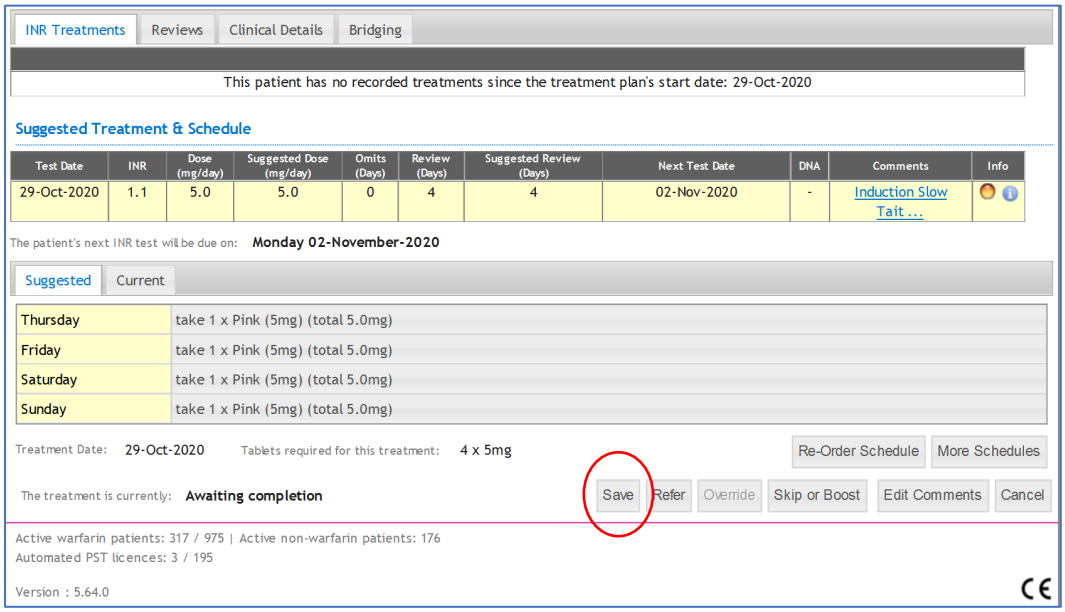


5. Click the '**Home Visit**' check box if the test was conducted on a home visit.
6. Click '**Suggest a Warfarin Dose**' to continue.
7. '**Confirm**' the pre-treatment INR when the confirmation dialogue is presented.



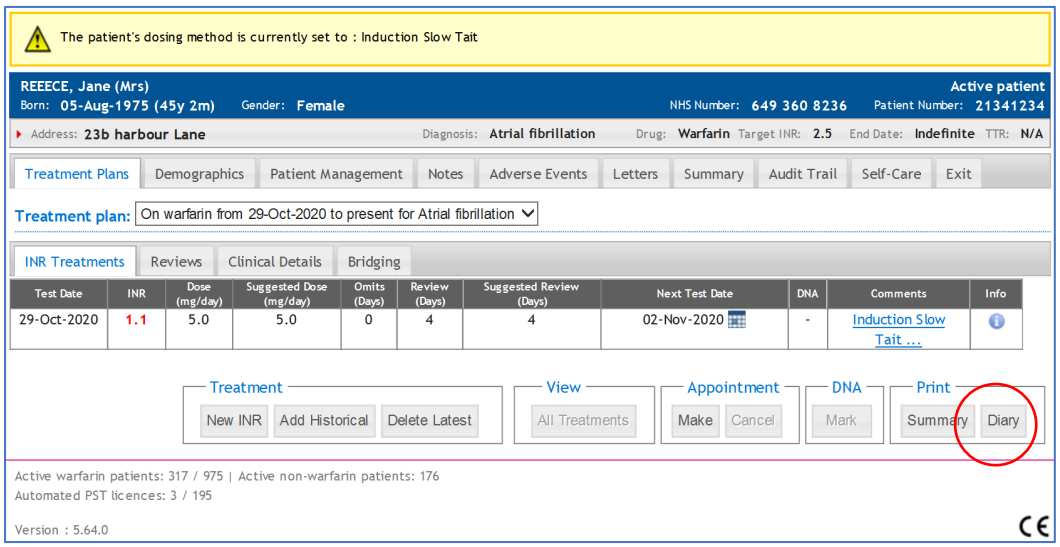
The dosing suggestion screen will be displayed. This will indicate the daily dose for the next four days and the date of the next INR test on day five.

Note: As this is an induction protocol it is not possible to override the dose or review period selection at this stage.



8. Click '**Save'** to save this treatment suggestion to the patient's record.
   - Or click '**Cancel'** to exit from this screen without saving the details to the record.

Note: Users with '**Clinical Level 2**' permissions will not be able to save an induction treatment. It must be referred to a '**Clinical Level 3**' user for authorisation.



The patient's INR treatment record screen is displayed, and by clicking on the **'Diary'** button the patient dosing diary can be printed or saved to be sent to the patient via fax or email.

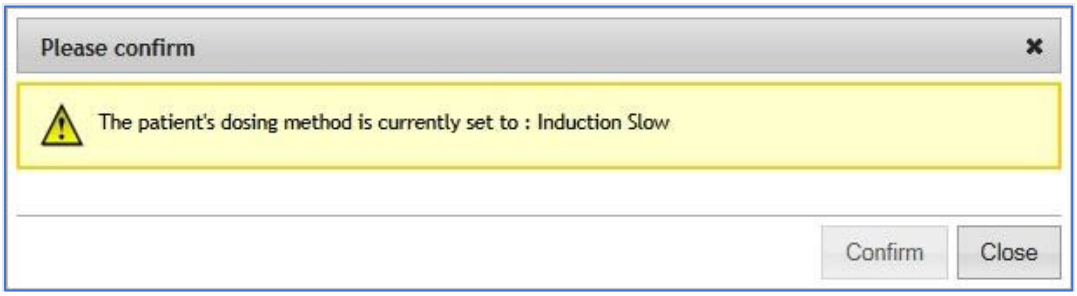
A comment will be added automatically to the INR treatment to indicate it is an induction treatment. By clicking on the hyperlink of the first few words of the comment, the full text can be viewed.

- Close the patient record by clicking **'Exit'**.

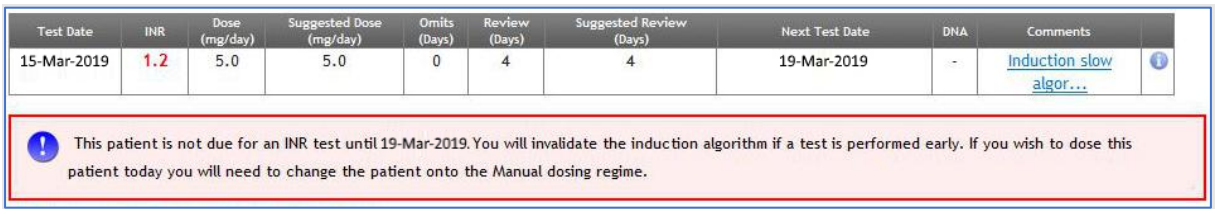
16.5.2. Stage 2 – Day Five

Stage 2 is entered when the patient attends for an INR test on **Day Five** of the protocol.

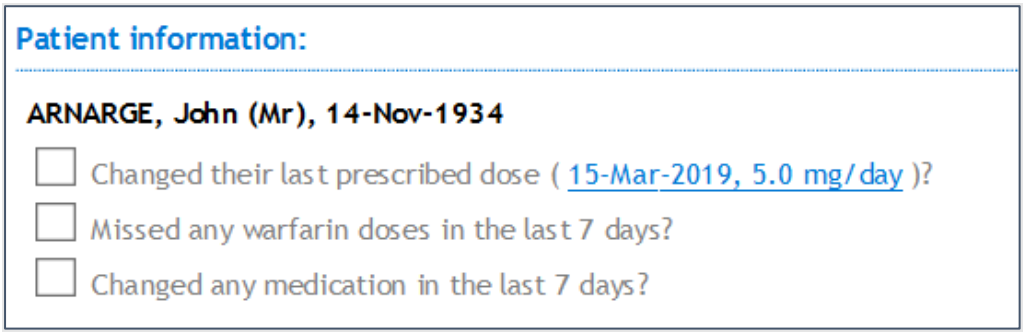
1. Select the patient from the patient search screen (see section 10.2).
2. A warning message will be displayed reminding the user that this patient is currently being treated using an induction protocol. Click **'Confirm'** to continue.



3. Click on '**Treatment Plan**' and then '**INR Treatment**' to display the treatment record.
4. Click '**New INR**'.
5. If the INR test date is not exactly as required by the protocol a warning message will be displayed.



The protocol is invalidated and INRstar will remove the patient from the induction process. The patient will then need to be **dosed manually** until sufficiently stable to be started on the appropriate **maintenance dosing algorithm.**



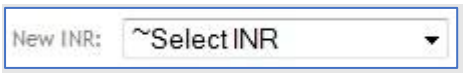
If the patient is tested on the correct day, confirm the data and INR result into the treatment schedule as required by the protocol.

6. Confirm the patient identity, that they are still taking the last warfarin dose recorded in the treatment record, and that the patient has not missed a warfarin dose in the

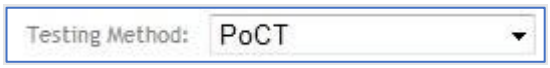
last seven days or started, stopped or changed any other medication since the last appointment.

Note: This could include prescribed or over-the-counter medication.

7. Select the **'New INR'** result from the drop-down list.



8. Select a **'Testing Method'** from the drop-down list if not laboratory or instrument.



Note: You will only need to do this if the patient's testing method for this test is different from the default method displayed in the box.

9. Select a **'POCT Batch'** from the drop-down list.

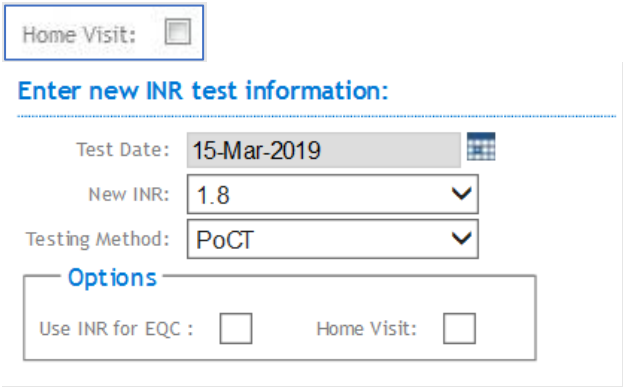
Note:

- You will only need to do this if the patient's testing method is POCT and your location has more than one POCT batch activated.
- If your PoCT Lot number has an expired date, a 'PoCT Batch Expired' warning is displayed. You may need to add your current PoCT Lot number to the list available for use within INRstar.

10. Click the **'Use INR for EQC'** check box if you wish to record this test in your EQC record log (see section 20.3).

Note: Normally an INR from a stable, in range patient is preferred for EQC testing that includes sending a parallel venous sample to the lab.

11. Click the **'Home Visit'** check box if the test was recorded on a home visit.



12. Click the **'Suggest Warfarin Dose'** button.

The new dosing suggestion screen will be displayed with the suggested new dose, review period and dosing schedule.

13. Click the **'Save'** button.

A comment will be added automatically to the treatment to indicate that it is an induction treatment. By clicking on the hyperlink of the first few words of the comment, the full text can be viewed.

- Print the patient dosing diary, or save it to be sent to the patient via fax or email, by clicking the '**Diary**' button.
- Close the patient record by clicking the '**Exit**' button.

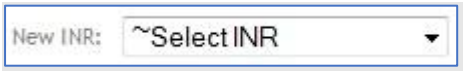
Note:

- If the new INR is outside the acceptable values specified in the induction protocol a message will be displayed and the patient removed from induction protocol. The patient will then need to be dosed manually until sufficiently stable to be started on an appropriate maintenance dosing algorithm.
- It is not possible to override a dose or review period suggestion during an induction protocol.
- Users with permission levels below **'Clinical Level 3'** will not be able to save an INR treatment during an induction protocol. The INR treatment must be referred for authorisation by a **'Clinical Level 3'** user.

16.5.3. Stage 3 - Tait Induction Protocol

This occurs when the patient attends for an INR test on day eight of the protocol.

1. Select the patient from the patient search screen (see section 10.2).
2. A warning message will be displayed reminding the user that this patient is currently being treated using an induction protocol. Click **'Confirm'** to continue.
3. Click on the '**INR Treatments**' tab in the '**Treatment Plans**' to display the INR treatment record.
4. Click on the '**New INR**' button.
5. Confirm patient identity, that the patient is still taking the dose as last recorded, has missed no warfarin doses, or changed other medication as in Stage 2 above.
6. Select the correct date of the INR test from the calendar icon. You can choose a date up to three days in the past, but the new INR cannot be before the previous treatment or on the same date.
7. Select the **'New INR'** result from the drop-down list.



8. Select a **'Testing Method'** from the drop-down list.

Note: You will only need to do this if the patient's testing method for this test is different from the default method displayed in the box.

9. Select a **'POCT Batch'** from the drop-down list.

   Note:

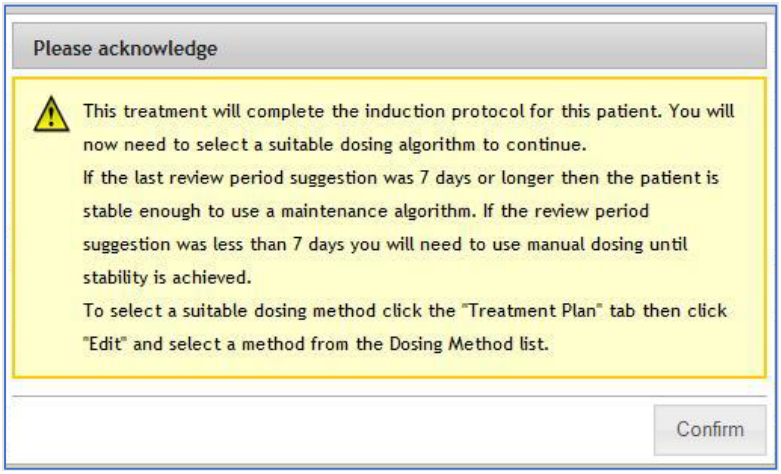
   - You will only need to do this if the patient's testing method is POCT and your location has more than one POCT batch activated.
   - If your PoCT Lot number has an expired date, a 'PoCT Batch Expired' warning is displayed. You may need to add your current PoCT Lot number to the list available for use within INRstar.

10. Click the '**Use INR for EQC**' check box if you wish to record this test in your EQC record log (see section 20.3).

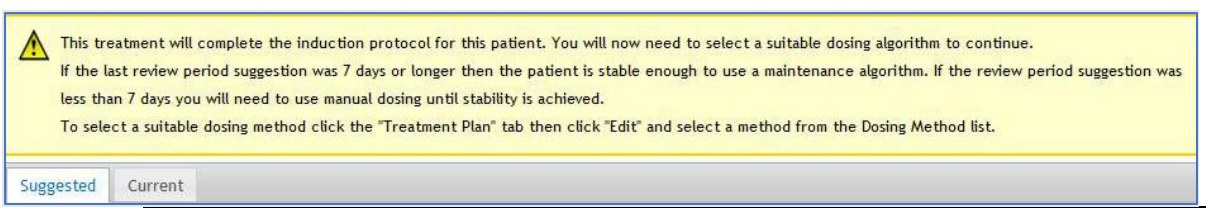
    Note: Normally an INR from a stable, in range patient is preferred for EQC testing that includes sending a parallel venous sample to the lab.

11. Complete any relevant text in the comments box.
12. Click the **'Suggest Warfarin Dose** 'button.

    At day 12/15 check INR and make fine dose adjustments as required. This will complete the induction process and the patient will automatically be removed from the induction protocol, which will be explained to you in a pop-up warning message, shown below. The patient will need to be transferred to a suitable maintenance algorithm before further dosing suggestions can be calculated (see section 16.7).



The new dosing suggestion screen will be displayed with the suggested new dose, review period and dosing schedule. The warning notice is displayed advising the user that the patient will now be removed from the Tait induction protocol and the message remains and can be viewed on the dosing suggestion screen.



Note:

- It is not possible to override a dose or review period suggestion during an induction protocol.

  A comment will be added automatically to the treatment to indicate that it is an induction treatment. By clicking on the hyperlink of the first few words of the comment, the full text can be viewed.

- Users with permission levels below **'Clinical Level 3'** will not be able to save a treatment during an induction protocol. The treatment must be referred for authorisation by a **'Clinical Level 3'** user.

- The patient will be removed from the induction protocol and their dosing algorithm will now be set to **'No Protocol'**; a message will be displayed. You will now need to select a suitable dosing algorithm to continue treating them, by editing the patient's clinical details.

13. Click the **'Save'** button.

- Print the patient dosing diary, or save it to be sent to the patient via fax or email, by clicking the **'Diary'** button.
- Close the patient record by clicking **'Exit'**.

16.6. Fast Induction - Fennerty-Gedge

The Fennerty-Gedge algorithm is supported by the British Committee for Standards in Haematology (BCSH) guideline 2011, which states that there is no evidence to support the use of a 10mg loading dose over a 5mg dose.

The initiation of warfarin is the prescription for a patient who has not previously received warfarin or has temporarily been taken off warfarin such that their INR is now less than 1.4. The aims of this protocol are:

- To ensure that evidence-based doses are prescribed for initiation of warfarin to ensure that a therapeutic INR is reached in a timely but safe manner.
- To satisfy the requirements of Patient Safety Alert 18 – actions that can make anticoagulant therapy safer.
- To reduce the occurrence of INRs greater than 6 which are associated with an increase in bleeding risk (and delayed discharge).

16.6.1. Prior to initiation of warfarin

- Confirm no contraindications to anticoagulation.
- Confirm patient is not on other oral anticoagulants, i.e. dabigatran, rivaroxaban, apixaban (note: if switching from one of these anticoagulants to warfarin, a period

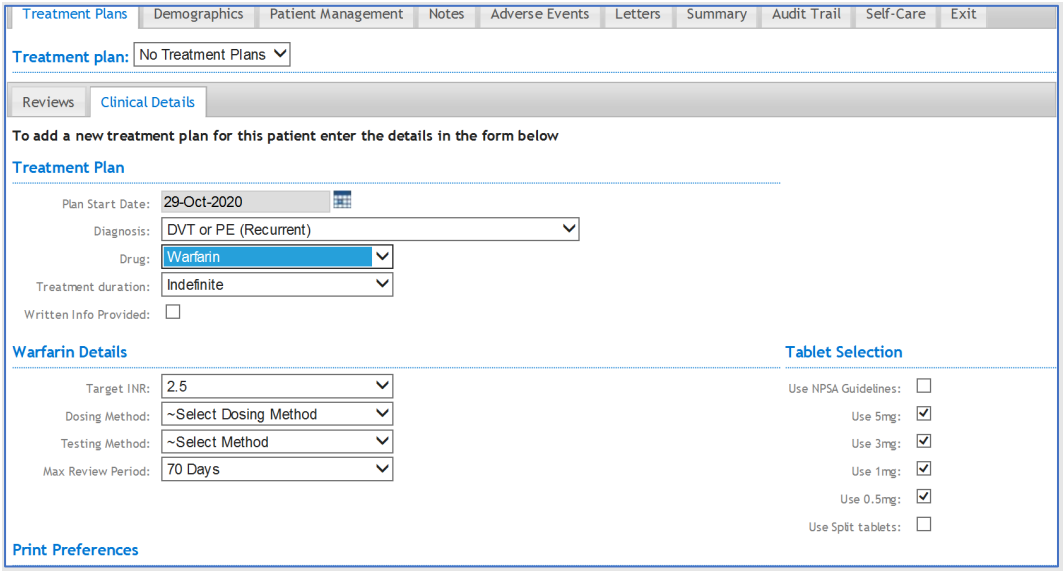
of overlap will be required – (see relevant drug's Summary of Product Characteristics for details).

- Consider discontinuation of anti-platelet drugs, i.e. Aspirin, Clopidogrel, Dipyridamole, Prasugrel, Ticagrelor.
- Further information on concurrent anticoagulation and anti-platelets can be found in BCSH guidelines.
- Consider discontinuation of drugs that may increase bleeding risk such as non-steroidal anti-inflammatory drugs (NSAIDs).
- Measure full blood count, liver function, INR and APTT.

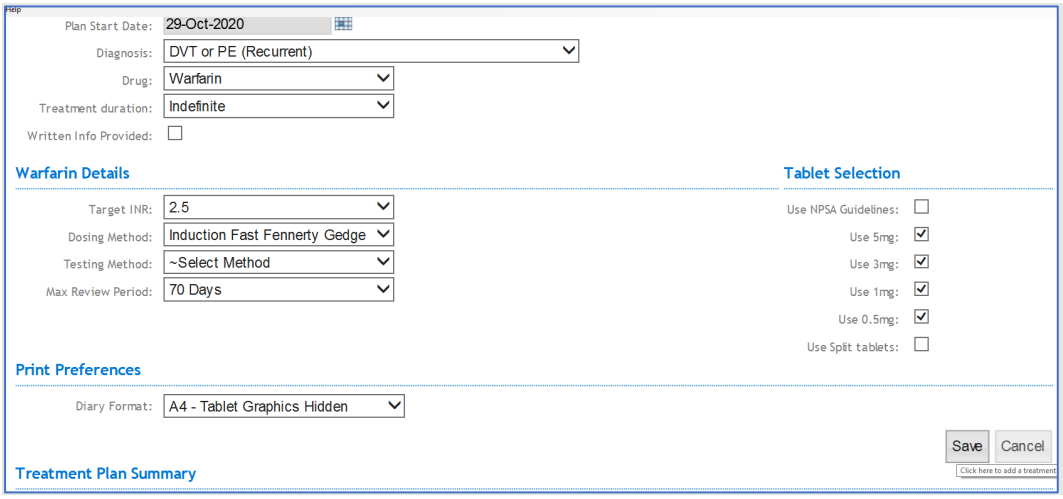
Note:

- Fast Induction cannot be selected if the patient is indicated as a 'Self Tester'.
- For patients who are being manually dosed on induction, please see section 16.3.
- The patient must be added to the demographic details in INRstar. See section 10.1.

1. Once the patient details are added, in the patient's record click on Treatment Plans and then on Clinical Details.
2. Complete the '**Treatment Plan'** section:
   - Select primary diagnosis for treatment.
   - Select drug – induction protocol only available for warfarin.
   - Treatment duration.
   - Confirm written information provided.

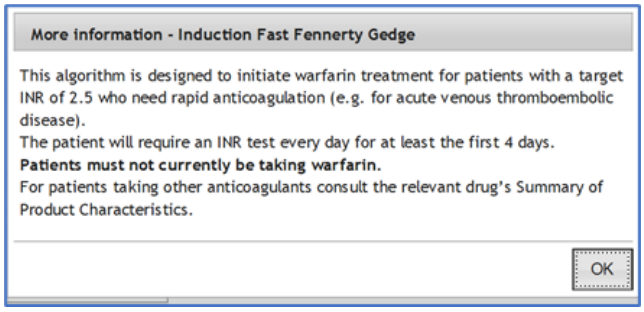


3. Complete the '**Warfarin Details**' section:



- Select the patient's '**Dosing Method**' of **'Fast Induction Fennerty-Gedge**'; select the '**Testing Method**' and '**Max Review Period**'.

- To acknowlege the confirmation message, click '**Ok'**:



4. Complete the **Tablet Selection -** Select the tablet strengths you want to treat the patient with.

   Please note: only 1mg and 3mg tablets can be selected for this Dosing Method.

5. Complete **Print Preferences –** Select the **'Diary format'** preference if different format to standard one for their Testing Location.

This can be a benefit if for example your default settings are set as label but you have a patient who are visually impaired, where it may be more appropriate for your patient's safety to set their printing preferences to A4 (see section 20.8 for more information).

16.6.2. Stage 1 - Induction Fast Fennerty-Gedge

The next step is to perform stage 1 of the Induction protocol:

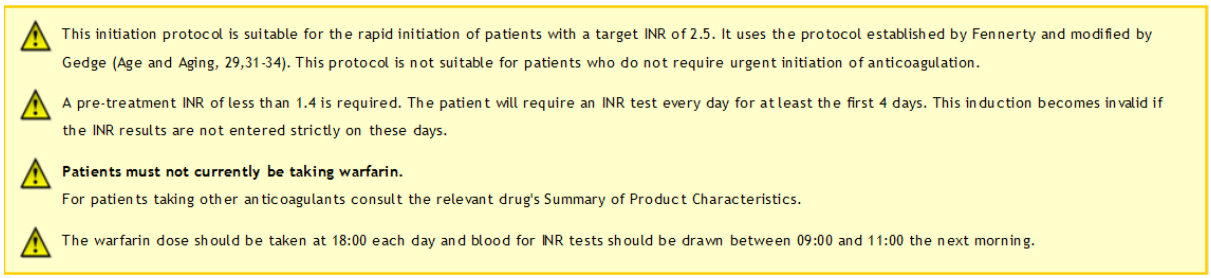
1. Click on 

on the patient's clinical record screen.

   The Induction protocol stage 1 screen will be displayed.

2. Click the 

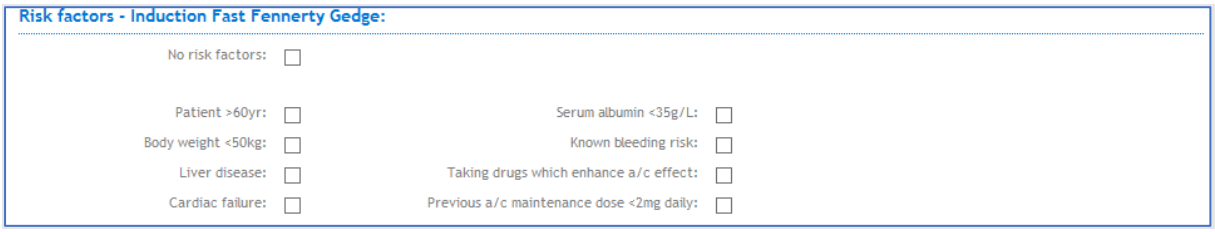
button.



3. A reminder message about the suitability of using an **'Induction'** is displayed, confirming dosing details and INR tests.

   At this stage it is essential to confirm with the patient that they will be able to attend for repeat INR tests on the next 3 days. If not, the protocol will be invalidated. If these days are not possible it might be necessary to delay the Induction process, so that the necessary review and INR tests can be performed, or alternatively consider manually dosing.

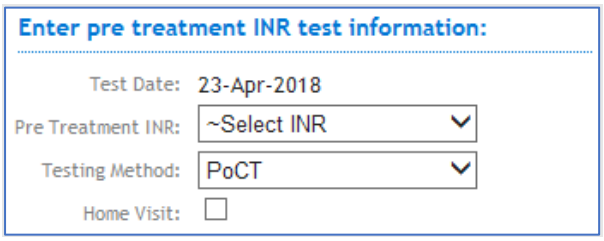
   The initial dose for the Fennerty-Gedge Protocol is decided depending upon various Risk Factors.



- If **NO** Risk Factors are present, the initial dose will be 10mg.
- If **ANY** of the Risk Factors are present, then the initial dose will be 5mg.

   Tick the appropriate checkboxes for the Risk Factors for the patient.

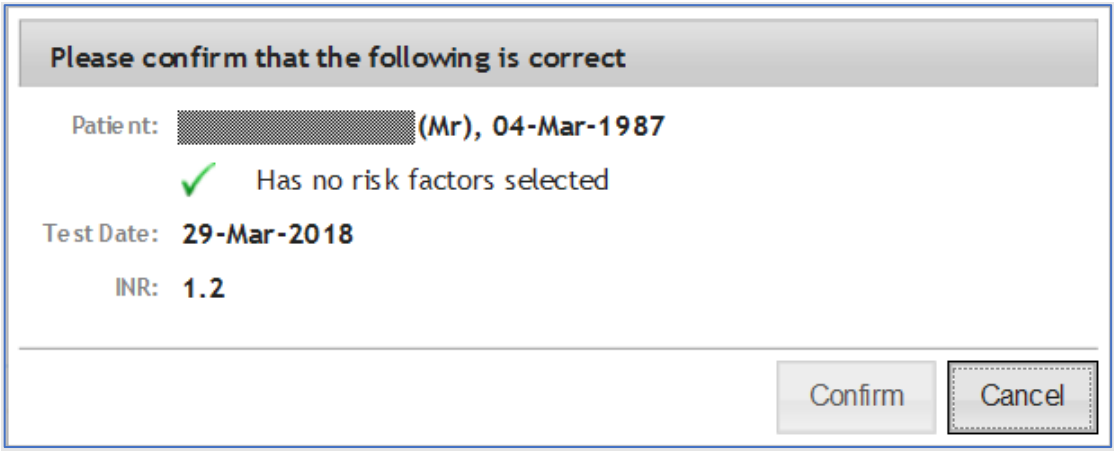
4. Add the pre-treatment INR result by selecting it from the '**Pre-Treatment INR'** drop-down list.



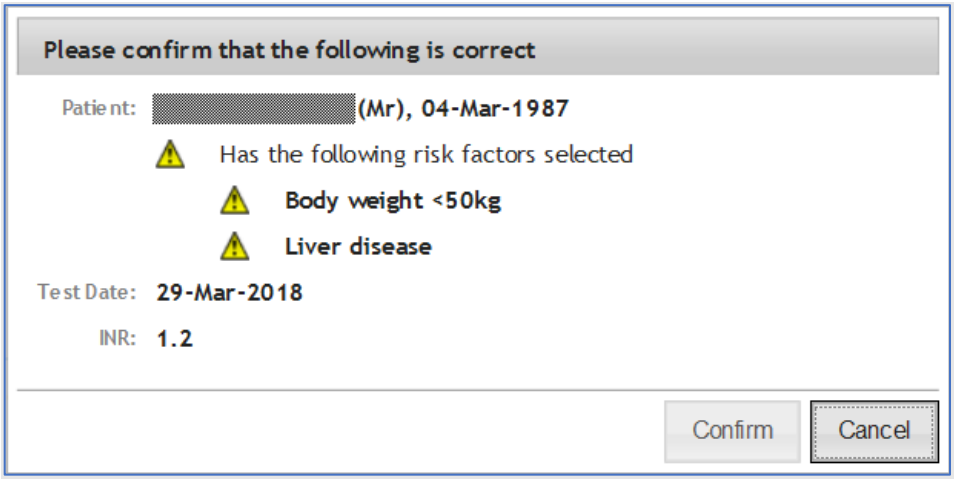
5. Click the **'Home Visit'** checkbox if the test was recorded on a home visit.
6. Click 

to continue.
7. Confirm the pre-treatment INR when the confirmation dialogue is displayed.

   No **'Risk Factors'** selected:

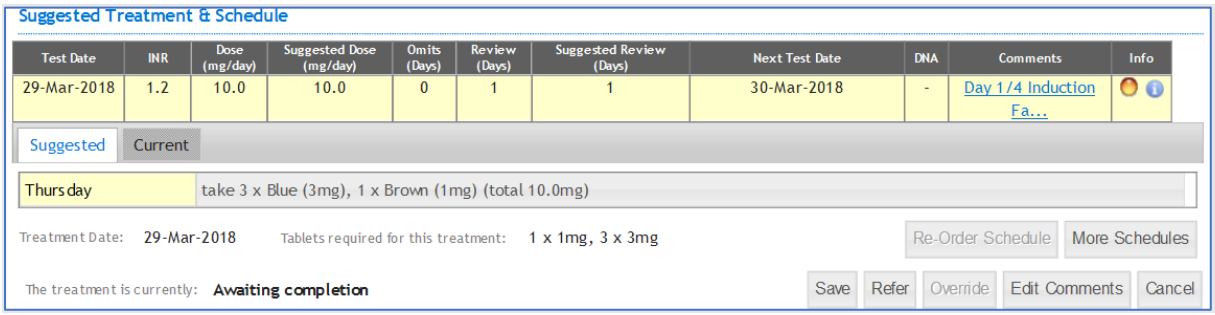


   With **'Risk Factors'** selected:



   The dosing suggestion screen will be displayed. This will indicate the daily dose for today and the next test date for tomorrow.

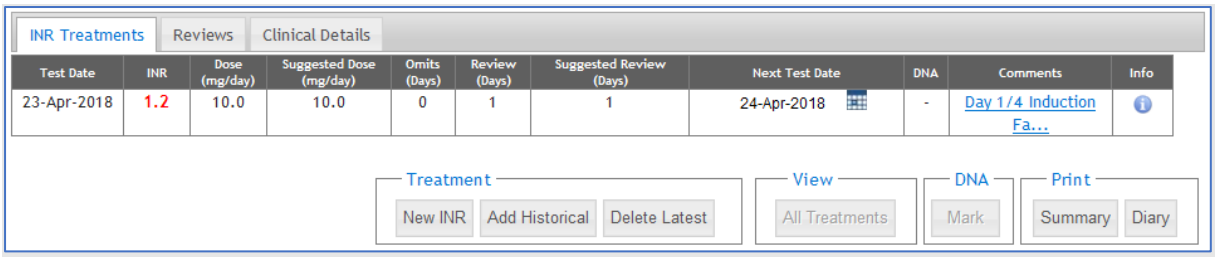
   As this is an Induction protocol it is not possible to override the dose or review period selection at this stage.



8. Click  to save this treatment suggestion to the patient's record.

- Or click  to exit from is screen without saving the details to the record.

Note: Users with Clinical Level 2 permissions will not be able to save an Induction treatment. It must be referred to a Clinical Level 3 user for authorisation.



When the patient's INR treatment record screen is displayed, by clicking on the **'Diary'** button the patient dosing diary can be printed or saved to be sent to the patient via fax or email.

A comment will be added automatically to the INR treatment to indicate that it is an Induction treatment. By clicking on the hyperlink in the comment box, the full text can be viewed.

- Close the patient record by clicking the **'Exit Record'** tab.

16.6.3. Stage 2 - Induction Fast Fennerty-Gedge

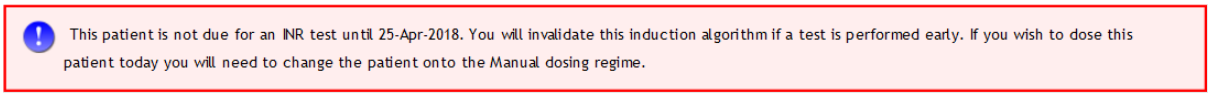
Stage 2 is initiated when the patient attends for an INR test on Day 2 of the protocol.

1. Select the patient from the patient search screen (see section 10.2).
2. A warning message will be displayed reminding the user that this patient is currently being treated using an Induction protocol. Click '**Confirm**' to continue.

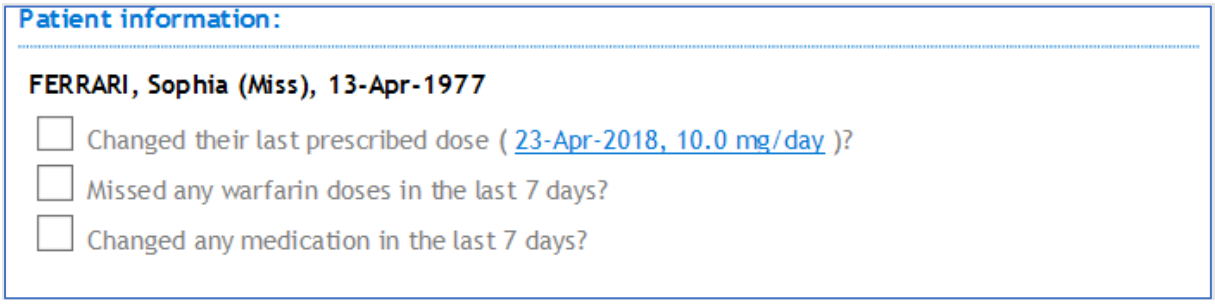
3. Click on  and then  to display the treatment record.

4. Click  .

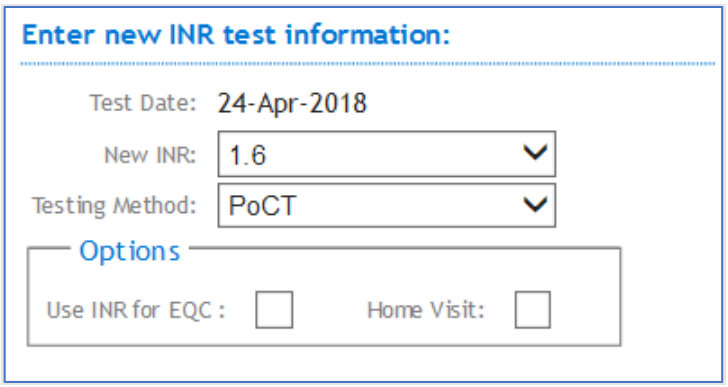
If the INR test date is not correct for Day 2 of the protocol a warning message will be displayed.



If an INR is added on the date set at stage one, the protocol becomes invalidated and INRstar will remove the patient from the Induction process. The patient will then need to be dosed manually until sufficiently stable to be started on an appropriate '**Maintenance Dosing'** algorithm.



5. Confirm that the patient is still taking the last warfarin dose which is recorded in the treatment record.
6. Tick the checkbox if the patient is taking a different dose.
7. Confirm that the patient has not missed a warfarin dose since the last clinic attendance. Tick the checkbox if any tablets were missed.
8. Confirm that the patient has not started, stopped, or changed any other medication since the last appointment. Tick the checkbox if they have missed tablets.



9. Select the new INR result from the dropdown list:

10. Select a testing method from the dropdown list:

Note: you will only need to do this if the patient's testing method for this test is different from the default method displayed in the box.

11. Select a PoCT batch from the dropdown list.

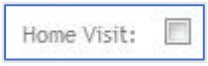
Note:

- You will only need to do this if the patient's testing method is PoCT and your location has more than one PoCT batch activated.
- If your PoCT Lot number has an expired date, a 'PoCT Batch Expired' warning is displayed. You may need to add your current PoCT Lot number to the list available for use within INRstar.

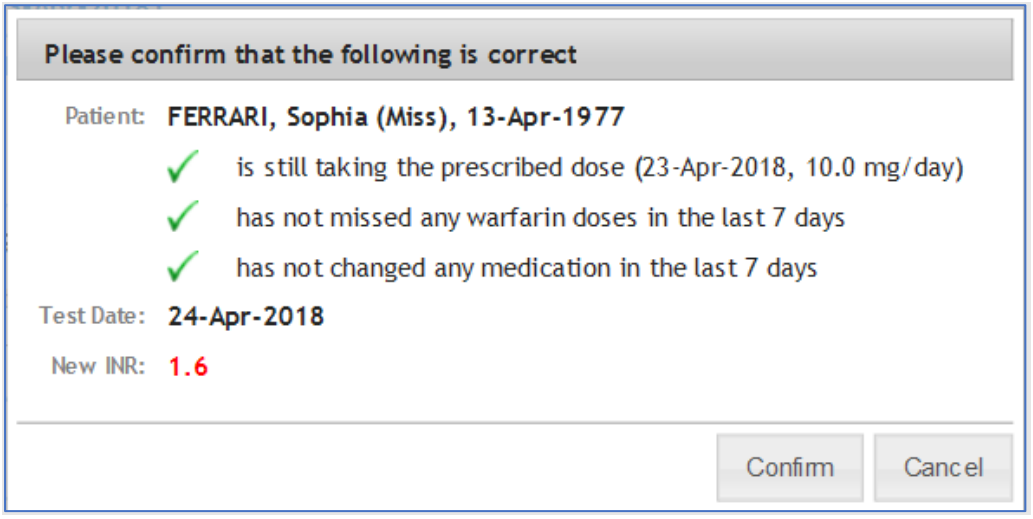
12. Click the **'Use INR for EQC'** checkbox if you wish to record this test in your External Quality Control (EQC) record log (see section 20.3 for adding an EQC result).

Note: Normally an INR from a stable, in range patient is preferred for EQC testing that includes sending a parallel venous sample to the lab.

13. Click the '**Home Visit'** checkbox if the test was recorded on a home visit.

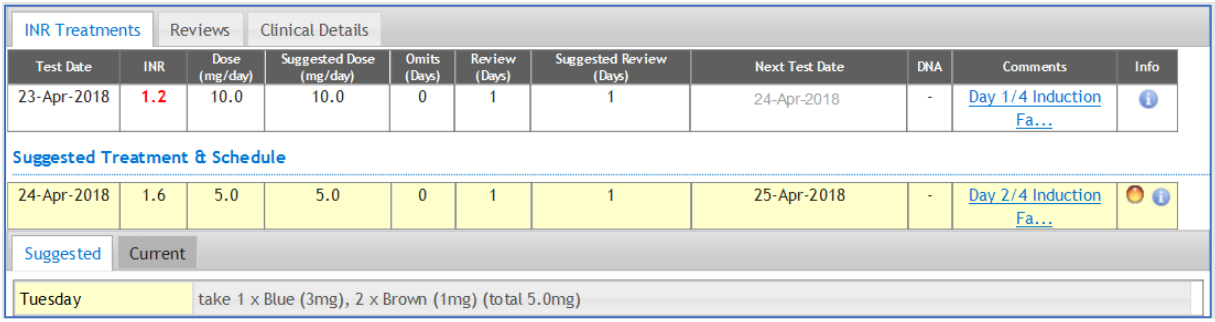


14. Click the '**Suggest Warfarin Dose'** button.



15. Review the values entered are correct in the notification and click the '**Confirm**' button or '**Cancel**'.

The new dosing suggestion screen will be displayed with the suggested new dose, review period and dosing schedule.



Note: It is not possible to override a dose or review period suggestion during an Induction protocol.

16. Click the **'Save'** button.

A comment will be added automatically to the treatment to indicate that it is an Induction treatment. By clicking on the hyperlink of the first few words of the comment, the full text can be viewed.

Note: Users with permission levels below Clinical Level 3 will note be able to save an INR treatment during an Induction protocol. The INR treatment must be referred for authorisation by a Clinical Level 3 user.

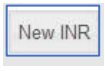
- Print the patient dosing diary, or save it to be sent to the patient via fax or email, by clicking the '**Diary**' button.
- Close the patient record by clicking the **'Exit Record**' tab.

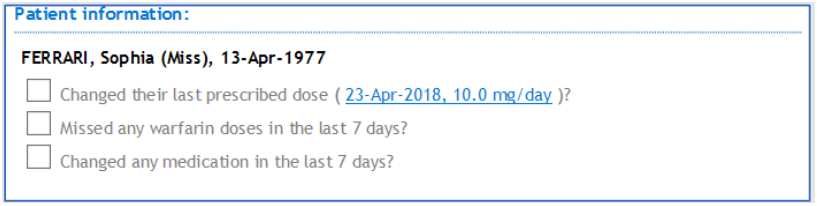
16.6.4. Stage 3 - Induction Fast Fennerty-Gedge

Stage 3 takes place when the patient attends for an INR test on Day 3 of the protocol.

1. Select the patient from the patient search screen, as before.
2. A warning message will be displayed reminding the user that this patient is currently being treated using an Induction protocol. Click **'Confirm'** to continue.

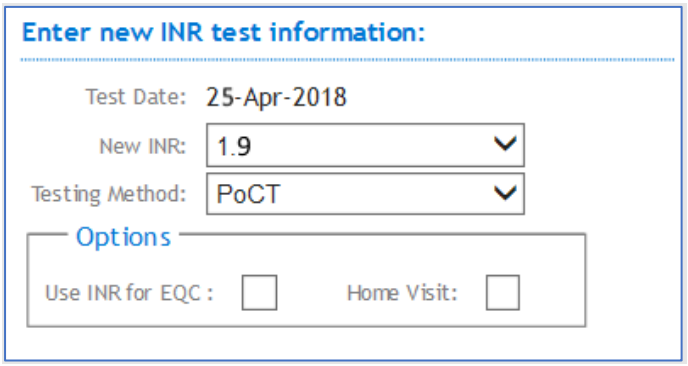
3. Click  and then  to display the treatment record.

4. Click  to display the patient treatment plan.



5. Confirm that the patient is still taking the last warfarin dose which is recorded in the treatment record. Tick the checkbox if the patient is taking a different dose.

6. Confirm that the patient has not missed a warfarin dose since the last clinic attendance. Tick the checkbox if any tablets were missed.
7. Confirm that the patient has not started, stopped, or changed any other medication since the last appointment. Tick the checkbox if they have.

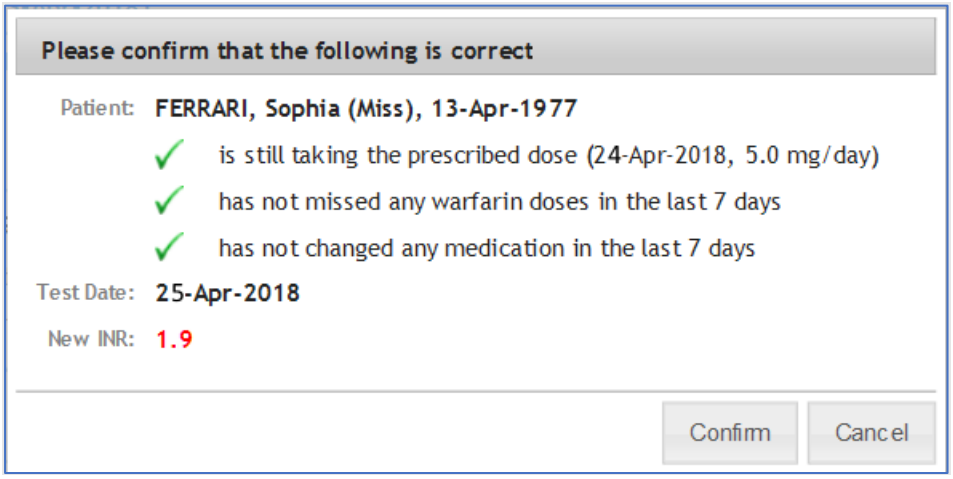


8. Repeat the process for stage one and two:
   - Select the '**New INR'** result from the dropdown list.
   - Select a '**Testing method'** from the dropdown list.

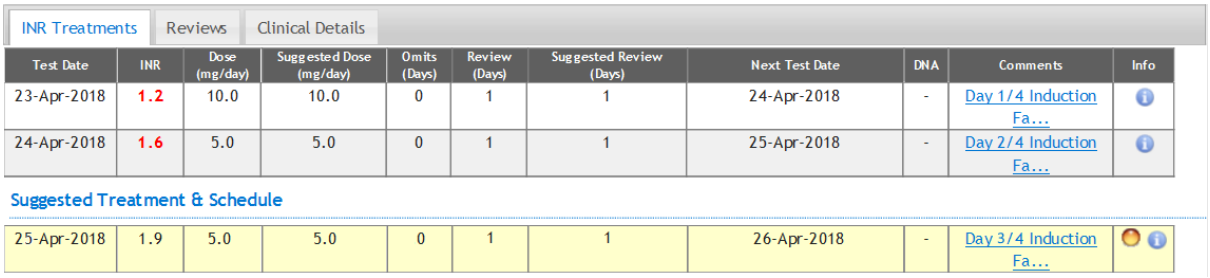
   Note: you will only need to do this if the patient's testing method for this test is different from the default method displayed in the box.
9. Select a PoCT batch from the dropdown list.

   Note:
   - You will only need to do this if the patient's testing method is PoCT and your location has more than one PoCT batch activated.
   - If your PoCT Lot number has an expired date, a 'PoCT Batch Expired' warning is displayed. You may need to add your current PoCT Lot number to the list available for use within INRstar.
10. Click the '**Use INR for EQC'** checkbox if you wish to record this test in your External Quality Control (EQC) record log (see section 20.3 for adding an EQC result).

    Note: Normally an INR from a stable, in range patient is preferred for EQC testing that includes sending a parallel venous sample to the lab.
11. Click the '**Home Visit'** checkbox if the test was recorded on a home visit.
12. Click the '**Suggest Warfarin Dose'** button.



The new dosing suggestion screen will be displayed with the suggested new dose, review period and dosing schedule.



Note: It is not possible to override a dose or review period suggestion during an Induction protocol.

13. Click the '**Save'** button.

A comment will be added automatically to the treatment to indicate that it is an Induction treatment. By clicking on the hyperlink of the first few words of the comment, the full text can be viewed.

Note: Users with permission levels below Clinical Level 3 will not be able to save an INR treatment during an Induction protocol. The INR treatment must be referred for authorisation by a Clinical Level 3 user.

- Print the patient dosing diary, or save it to be sent to the patient via fax or email, by clicking the '**Diary'** button.
- Close the patient record by clicking the '**Exit Record'** tab.

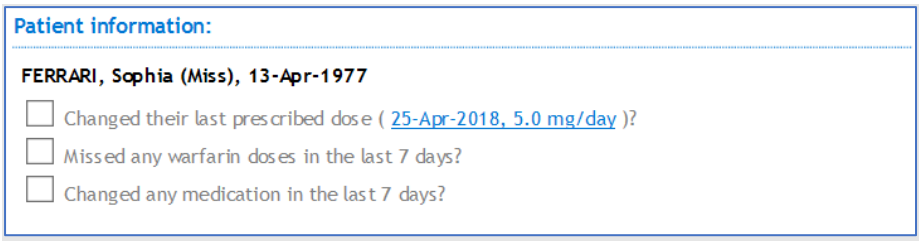
16.6.5. Stage 4 - Induction Fast Fennerty-Gedge

Stage 4 takes place when the patient attends for an INR test on Day 4 of the protocol.

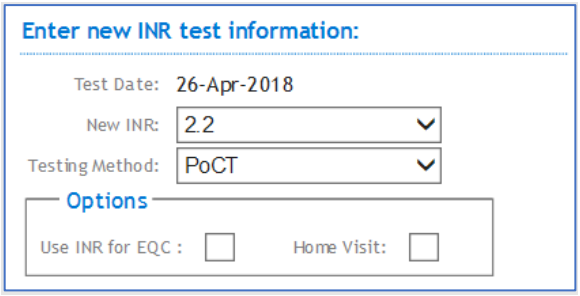
1. Select the patient from the patient search screen, as before.
2. A warning message will be displayed reminding the user that this patient is currently being treated using an Induction protocol. Click '**Confirm'** to continue.

3. Click on Treatment Plans and then INR Treatments to display the treatment record.

4. Click New INR.



5. Confirm that the patient is still taking the last warfarin dose which is recorded in the treatment record. Tick the checkbox if the patient is taking a different dose.
6. Confirm that the patient has not missed a warfarin dose since the last clinic attendance. Tick the checkbox if any tablets were missed.
7. Confirm that the patient has not started, stopped, or changed any other medication since the last appointment. Tick the checkbox if they have.

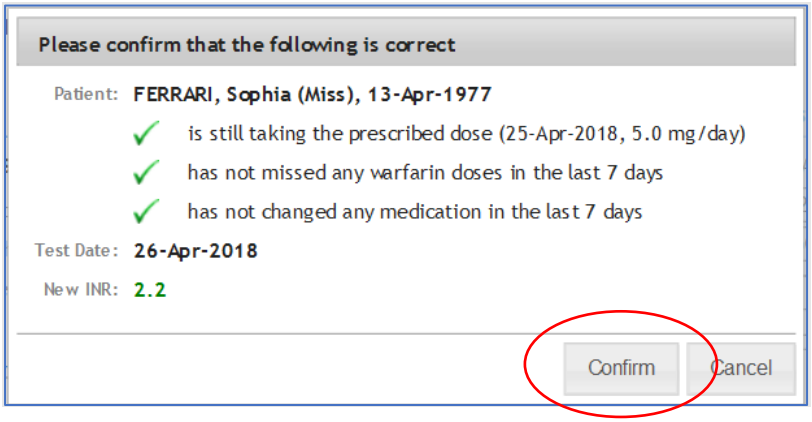


8. Repeat the process for stages one, two and three:
   - Select the **'New INR'** result from the dropdown list.
   - Select a '**Testing method'** from the dropdown list.

   Note: The user will only need to do this if the patient's testing method for this test is different from the default method displayed in the box.
9. Select a PoCT batch from the dropdown list.

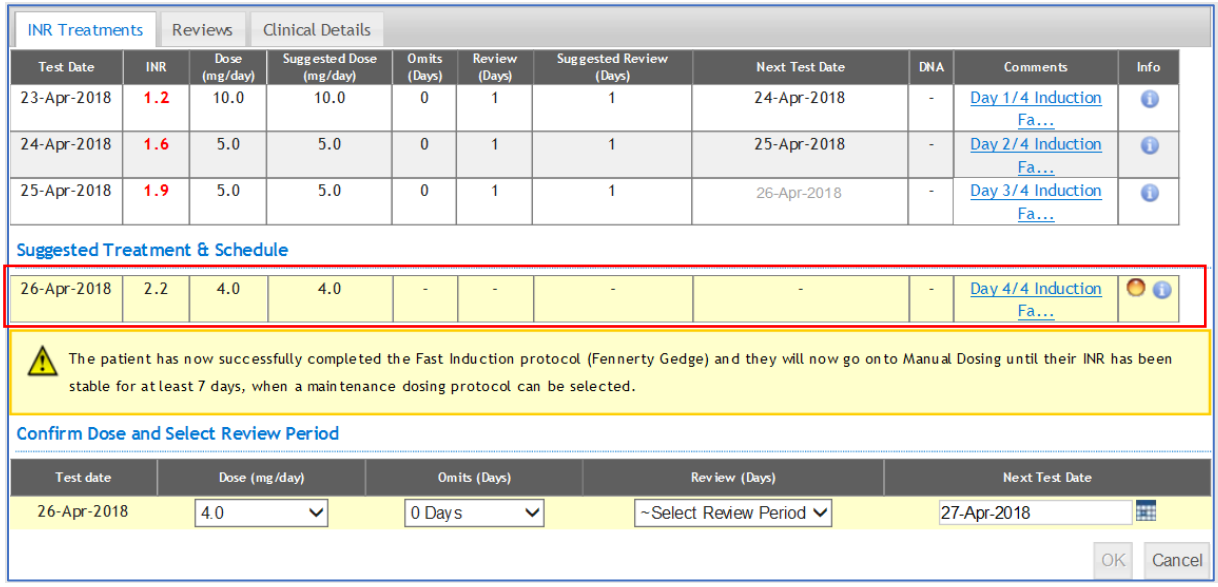
   Note:
   - The user only needs to do this if the patient's testing method is PoCT and your location has more than one PoCT batch activated.
   - If your PoCT Lot number has an expired date, a 'PoCT Batch Expired' warning is displayed. You may need to add your current PoCT Lot number to the list available for use within INRstar.

10. Click the **'Use INR**' for '**EQC**' checkbox if you wish to record this test in your External Quality Control (EQC) record log (see section 20.3 for adding an EQC result).
11. Click the **'Home Visit**' checkbox if the test was recorded on a home visit.
12. Click the **'Suggest Warfarin Dose**' button.
13. Review the values and information entered are correct.

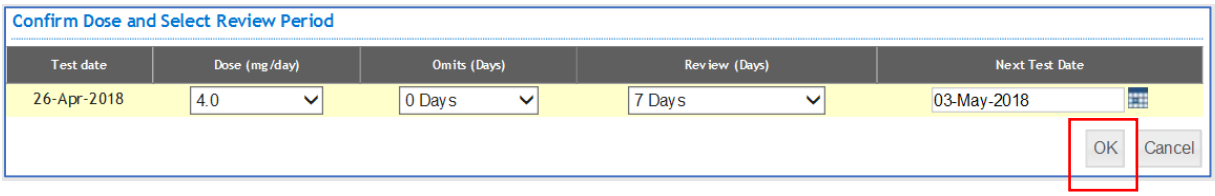


14. Click the **'Confirm'** button.

    The dosing suggestion screen will be displayed with the suggested new dose.



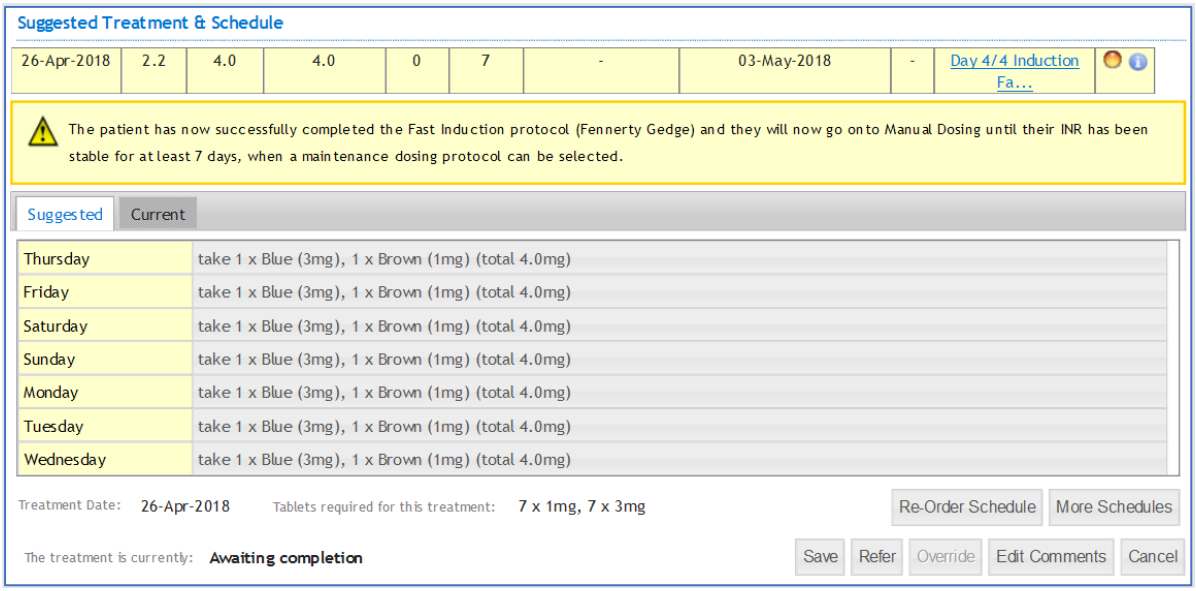
Note: You will now have to confirm the suggested dose and select a '**Review'** period.



15. Click the **OK** button.

A comment will be added automatically to the treatment to indicate that it is an Induction treatment. By clicking on the hyperlink of the first few words of the comment, the full text can be viewed.

The new schedule will be shown.



16. Click the **Save** button.

The patient has now been successfully initiated using the Fennerty-Gedge Fast Induction protocol.

Note: Users with permission levels below Clinical Level 3 will note be able to save an INR treatment during an Induction protocol. The INR treatment must be referred for authorisation by a Clinical Level 3 user.

- Print the patient dosing diary, or save it to be sent to the patient via fax or email, by clicking the **Diary** button.
- Close the patient record by clicking the **Exit Record** tab.

16.7. Coventry Maintenance

Only available for patients being treated on warfarin.

Coventry is the customer preferred dosing maintenance algorithm included in INRstar.

A maintenance dosing algorithm is used to suggest suitable warfarin doses and review periods for patients who are stable and fully established on warfarin treatment.

They are **not suitable** for initiating warfarin for patients who are starting oral AC, treating patients who are not yet sufficiently stable on treatment or treating those on non-warfarin anticoagulation drugs.

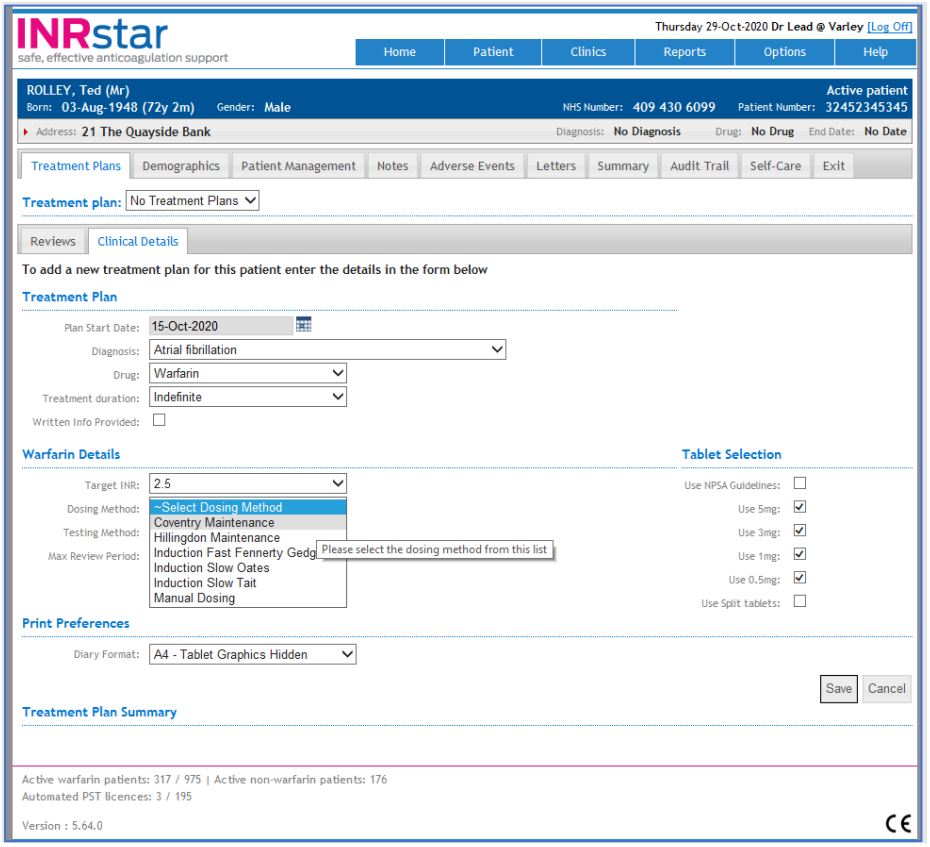
Patients should have had at least two in-range INR results with a seven-day review period between tests to be suitable for treating with a maintenance algorithm.

Patients who are starting warfarin should be dosed using an induction protocol or be dosed manually until sufficiently stable to be transferred to a maintenance algorithm for continued treatment.

Inappropriate use of a maintenance dosing algorithm could lead to significant over-dosing or under-dosing with warfarin, which could cause serious injury or fatality for the patient.

Firstly, in the patients record click on **'Treatment Plan'** and then on **'Clinical Details'**.

Here you will be able to view the **'Current Treatment Plan'** and underneath that, **'Warfarin Details'**.



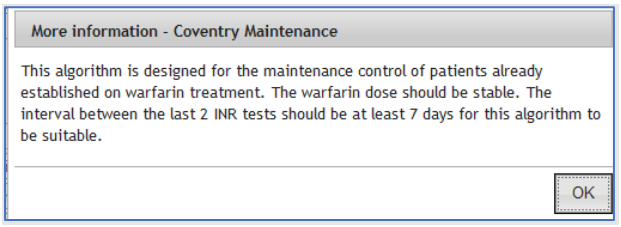
In '**Warfarin Details**' you can view the '**Dosing Method**'.

If you wish to change the '**Dosing Method**' click '**Edit Treatment Plan**' situated underneath the '**Warfarin Details**' section to the far bottom right.

The '**Warfarin Details**' can now be edited.

Simply select the maintenance dosing algorithm you wish to change from the '**Dosing Method**' drop down list and click '**Save**' where the '**Edit Treatment Plan**' button was before.

A confirmation message will appear with details of the dosing algorithm and for the user to acknowledge as suitable for use with the patient.



The patient treatment plan is now set to Coventry maintenance.

16.8. Hillingdon Maintenance

Developed at the Hillingdon Hospital, Middlesex, this algorithm was the first published warfarin dosing algorithm to be made available in the UK. Like the Coventry algorithm, which superseded it for routine use, it may only be used for warfarin dosing maintenance. It can be useful for the small minority of patients whose INR overreacts to even a small change in Dose[3].

- In the patient record click on Treatment Plans and then on Clinical Details.

You will be able to view the '**Current Treatment Plan'** and below the '**Warfarin Details'**.

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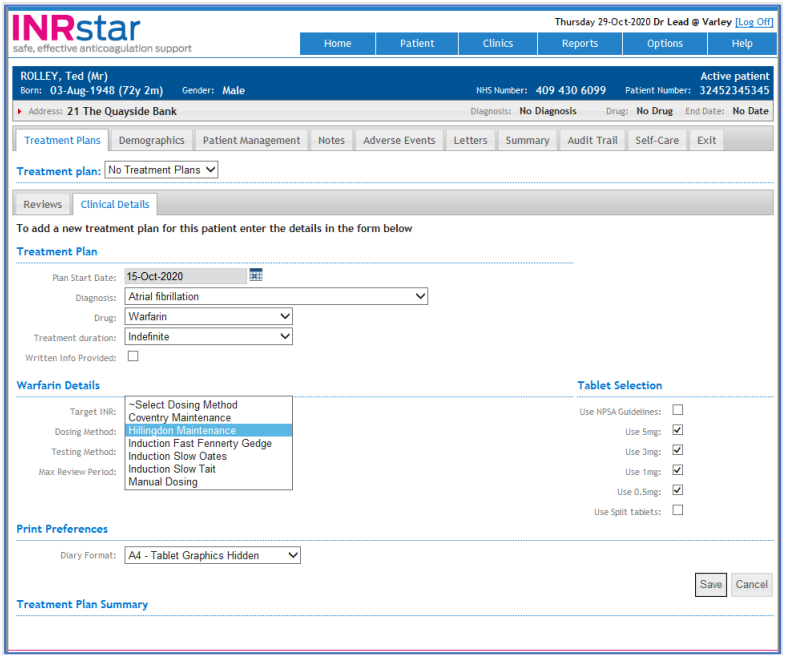
[3] *Reference: BMJ 1984; Vol 289: 422–424*



In the '**Warfarin Details'** you can view the '**Dosing Method'** and select **'Hillingdon Maintenance'** from the dropdown list.

To change the '**Dosing Method'** click the 

situated below the **'Warfarin Details'** section to the far bottom right.

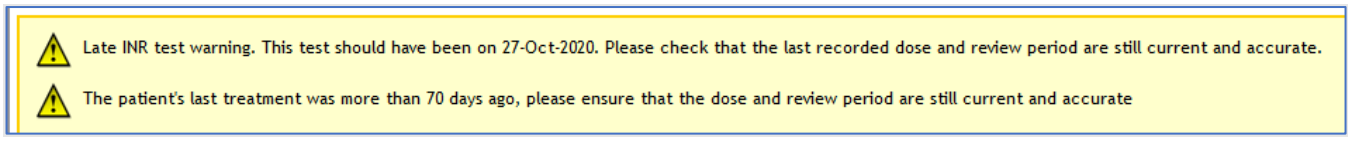
- Select the maintenance dosing algorithm you wish to change to from the **'Dosing Method'** drop down list and click 

.

16.9. Adding the INR Result for Maintenance and Induction

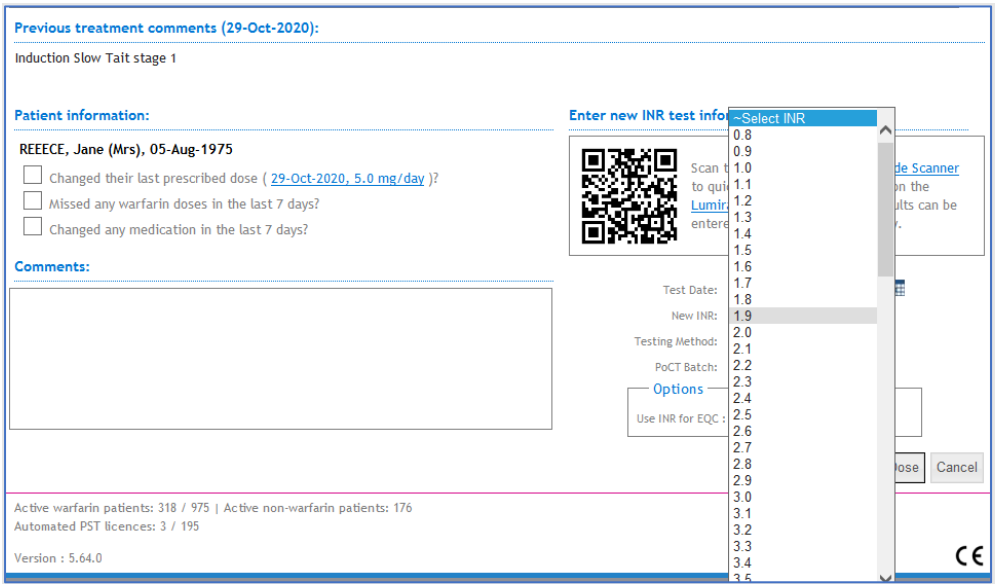
Select the **'New INR'** result from the drop-down menu.

Any relevant information or warning messages will be displayed below the INR treatment history area. In this example the patient has attended too early, or late for an INR test.

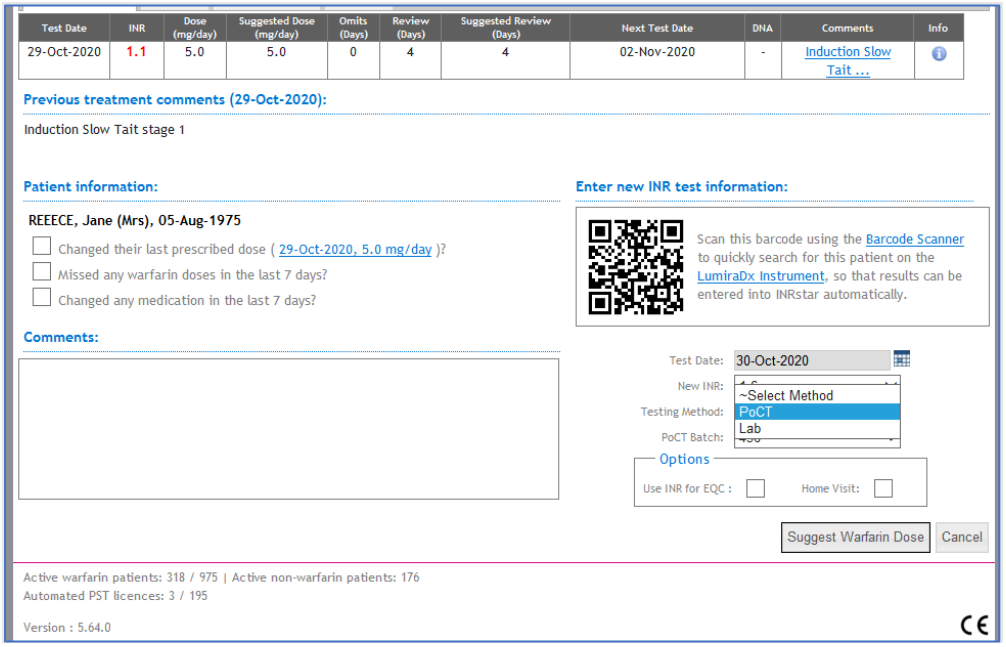


- If the previous INR treatment has a comment, that comment will be displayed just above the steps for a new INR.

Select the '**New INR**' from the drop-down:



Select the **'Testing Method'**: POCT or Lab (laboratory).

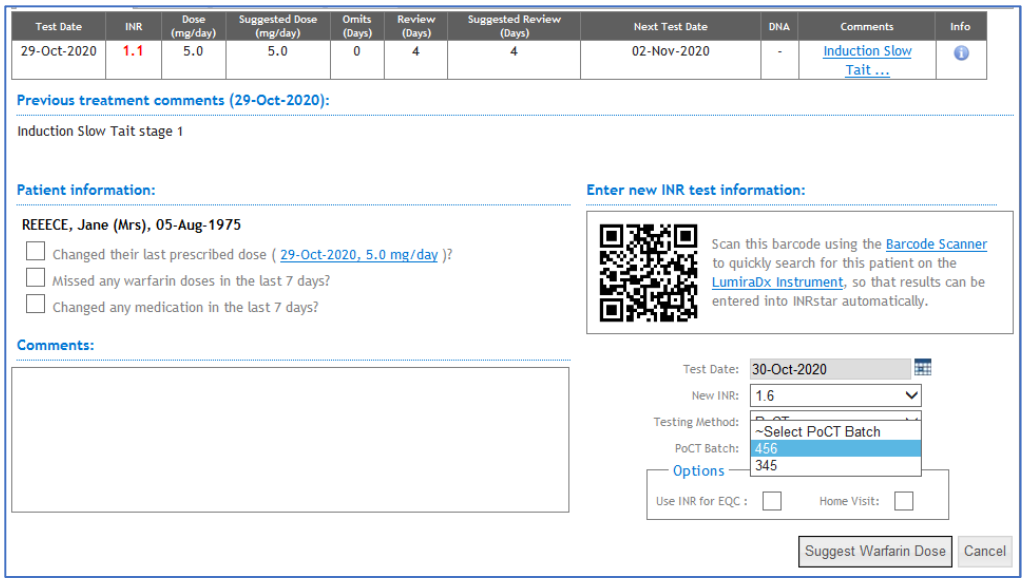


With PoCT the first data entry will prompt the user to select the correct strip batch number (if more than one batch is in use). Subsequent tests will default to the first chosen batch number until the next login; this can be changed if required.

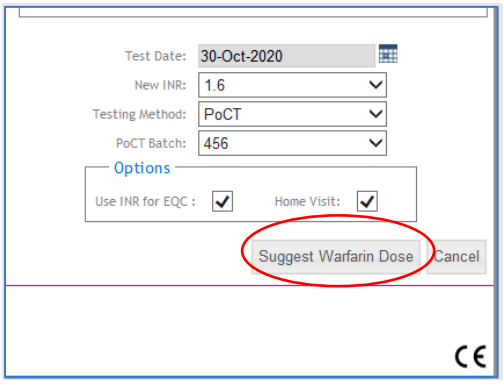
Note:

- If patient is recorded in patient management as a self-tester, along with their PoCT batch number, the batch will default to this. A repeat of the PoCT batch selection will then be required for the next patient.

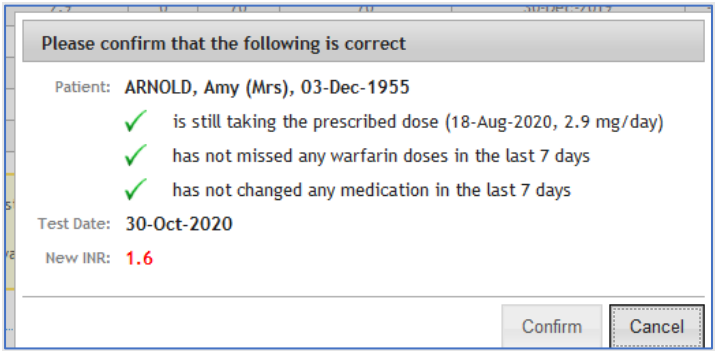
- If your PoCT Lot number has an expired date, a 'PoCT Batch Expired' warning is displayed. You may need to add your current PoCT Lot number to the list available for use within INRstar.



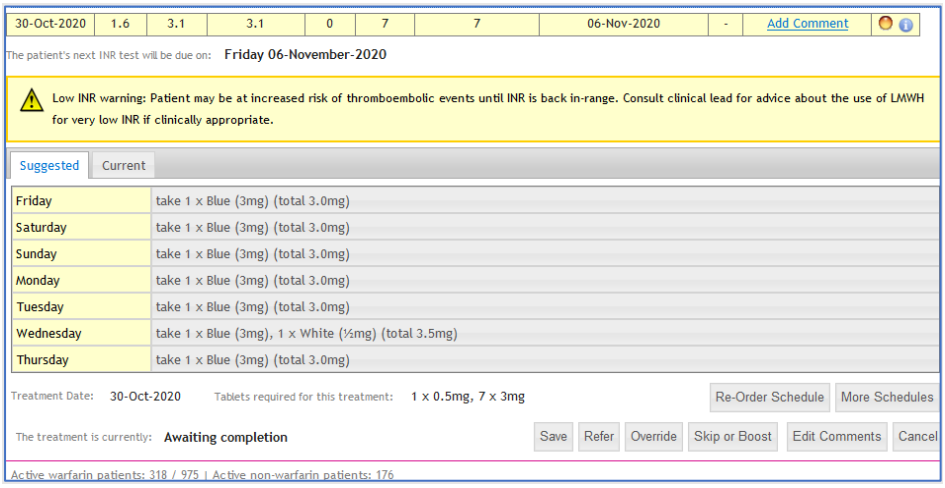
Optional recording of the following can be made here: home visit and use for EQC. If self-tester is recorded in the patient management section, an additional tick box is displayed here to identify the patient as a self-tester.



- Click on the **'Suggested Warfarin Dose'** button at the bottom right.
- Confirm that the data entered is correct in the overview screen.

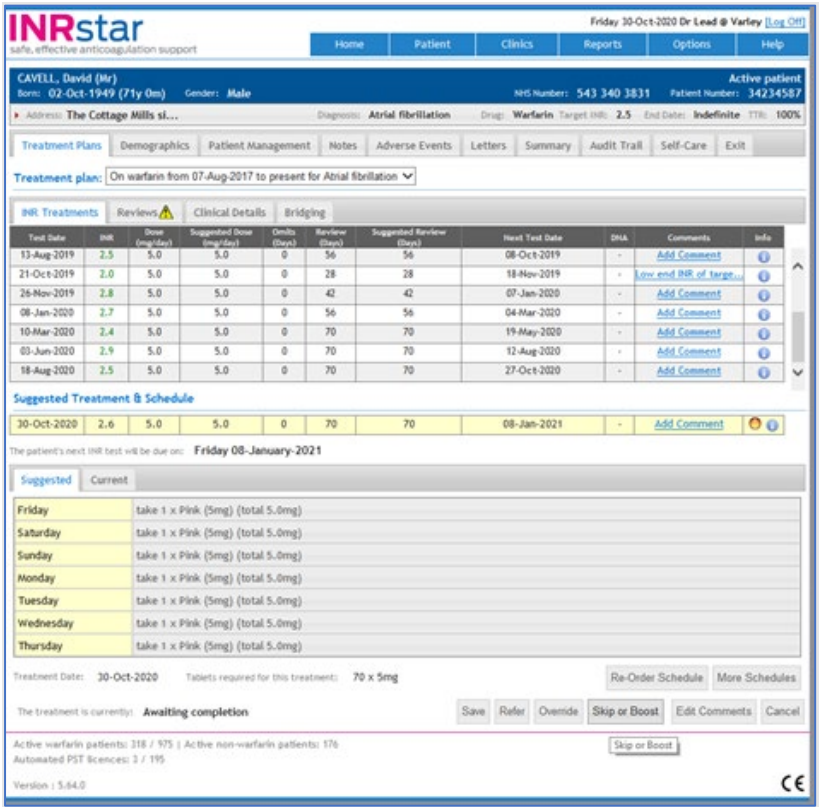


The new warfarin dosing suggestions will be displayed as suggested treatment and schedule.



16.10. Suggesting Treatment and Schedule

Review the new dosing suggestion.



- Click **‘Save’** if you want to accept the dosing suggestions. Save the treatment.
- Or click **‘Skip or Boost’** if required to amend the treatment schedule for up to three days. (Clinical Level 3 users only). See section 16.11.
- Or click **‘Refer’** if you need to refer this treatment to another user for authorisation (e.g. if a Clinical Level 1 or 2 user).
- Or click **‘Override’** if you wish to change the suggested dose or review period.

Note:

- If you are a **‘Clinical Level 1’** user, out-of-range INRs will need to be referred – see section 16.13 ‘Refer Treatment for Authorisation’.
- Only **‘Clinical Level 3’** and **‘Clinical Lead’** users are permitted to manage referral.

16.11. Skip or Boost Functionality

16.11.1. Overview

- You can perform a ‘**Skip or Boost’** on patients treated with warfarin and maintenance dosing method.
- You can ‘**Skip or Boost’** for up to 3 days.
- Original Schedules and review dates are not reset.

- Allows a temporary adjustment to your patient's dose which can be printed out.
- Recorded in INRstar maintaining a full and complete clinical audit trail.

16.11.2. Clinical Safety

The Skip or Boost feature cannot be used in the following situations:

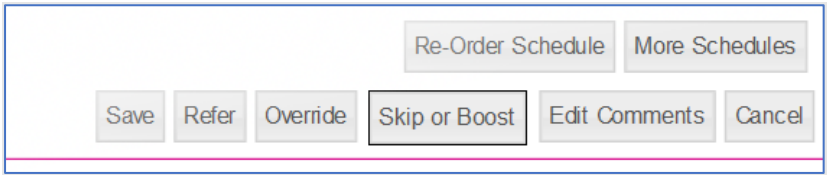
- The recommended selected schedule already includes 'Omit Days'.
- The recommended schedule is less than 7 days.
- Cannot be actioned by users with role permissions of less than Clinical Level 3.
- Cannot be used for patients on induction dosing algorithms.

16.11.3. 'Skip or Boost' is:

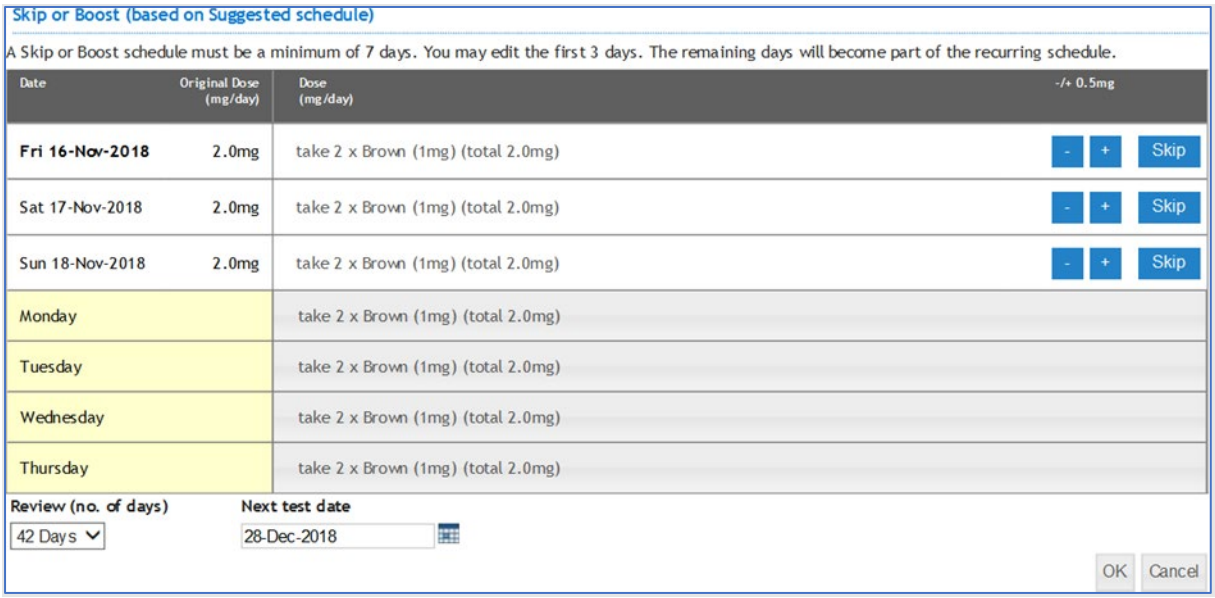
- Not enabled for patients using INRstar Engage or any clinical care programmes.
- Only available when adding a new treatment.

16.11.4. How to use Skip or Boost functionality

You can Skip or Boost by clicking on the **'Skip or Boost'** button.



The drug dosage to be taken for up to the first three days of the schedule can now be adjusted.

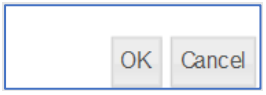


16.11.5. How to change the Dose

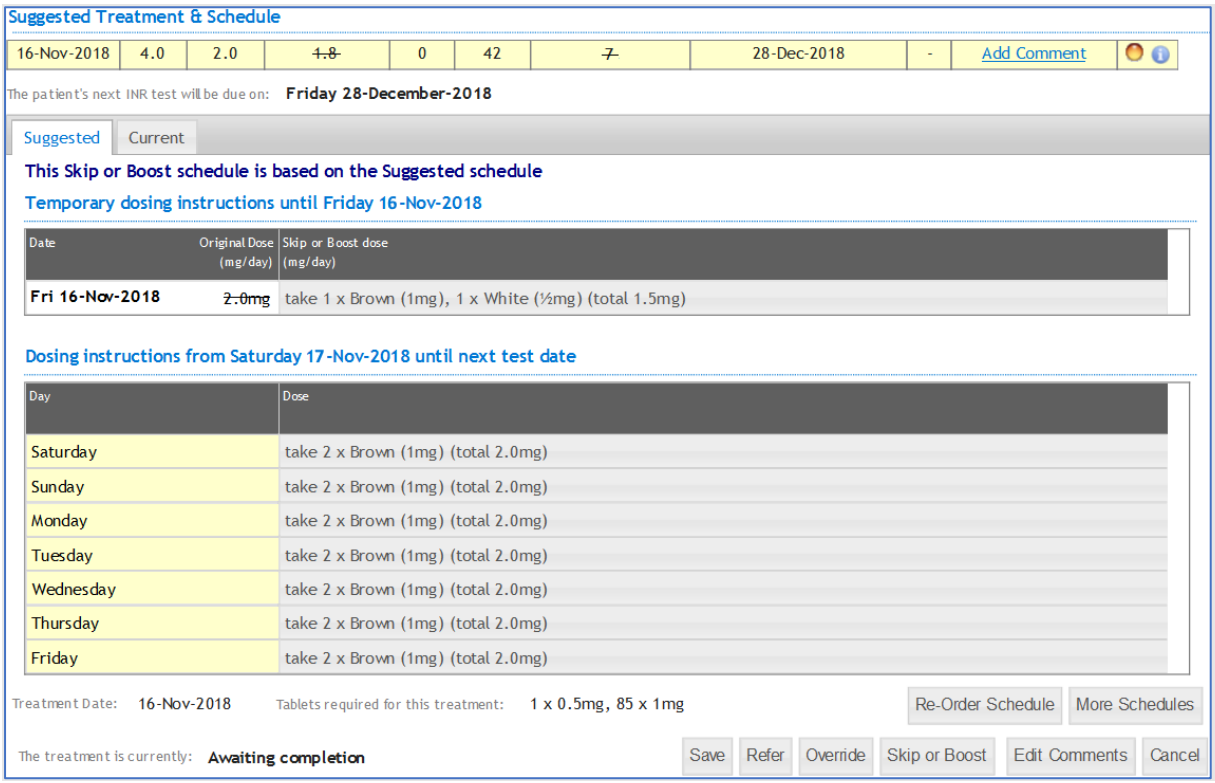
You can change the daily dose using the buttons alongside each of the three days:

- To '**reduce'** the dose to be taken on any day, use the negative buttons to step.
- To '**increase'** the dose, use the positive buttons to step up.
- To '**Skip'** completely for any day, either use the **'Skip'** button, or reduce the dose to zero using the negative button.
- To cancel any dose changes, use the **'Reset'** button:

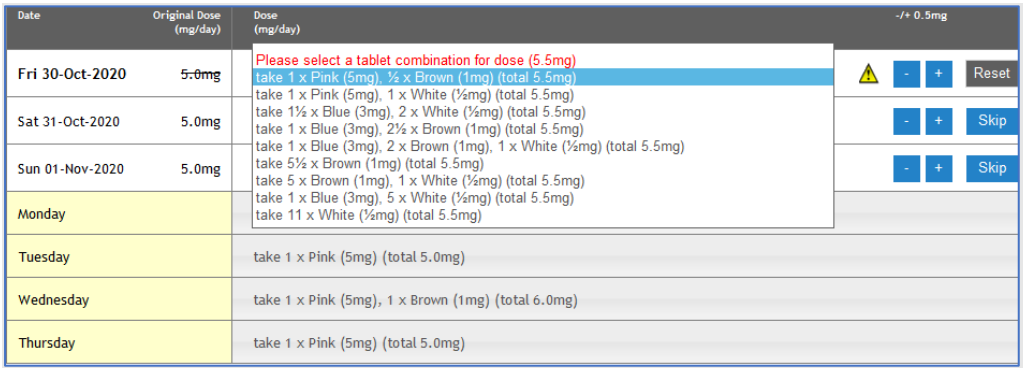
When all the necessary dose changes have been made, use the **'OK'** button to update the schedule.



You will now see the proposed schedule, with the '**Skip or Boost'** days followed by the regular schedule days.



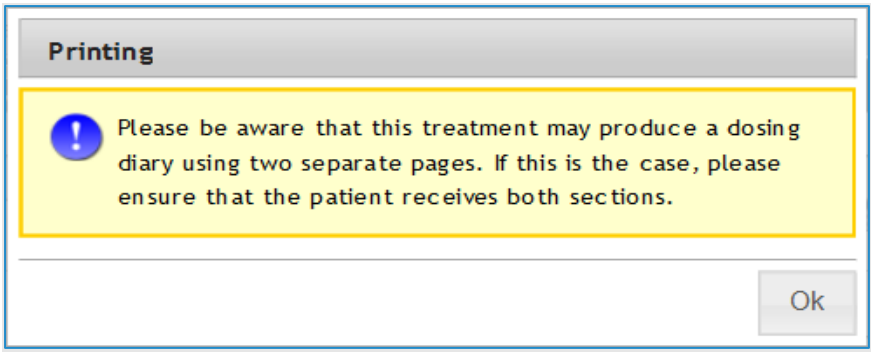
- Click the **'Save'** button and the treatment plan will then be available to print the schedule from the '**Diary**' or '**Summary**' buttons.



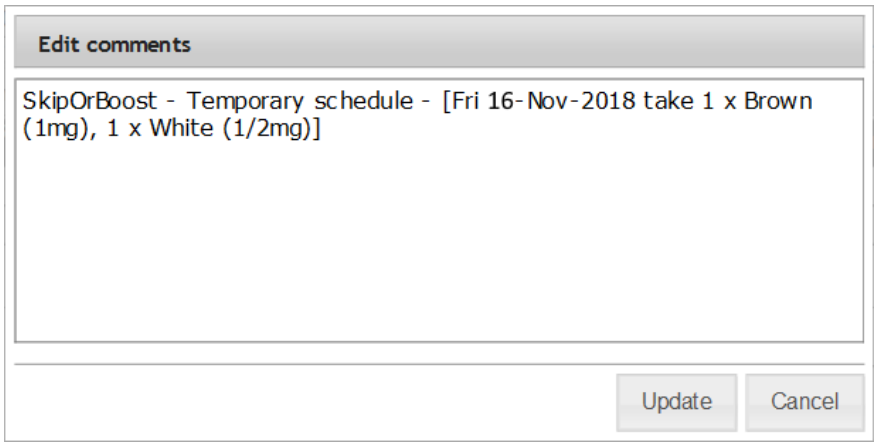
Note: When using **'Skip or Boost'** INRstar will offer the option of different tablet selections for the user to select from, if appropriate, in a drop-down list.

16.11.6. Saving and Printing

After saving the treatment note the warning about the possible number of pages for the diary.



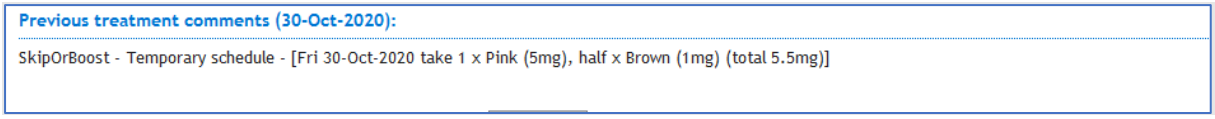
INRstar will add a comment to the treatment to indicate a **'Skip or Boost'** process was used and detail the temporary schedule and dose to be taken.



You may add any additional comments relevant to the patient treatment into the free text box when completing the patient record.

Comments added will be printed on the diary and summary outputs.

When the patient attends their next appointment, and a new INR is added 'Skip or Boost' and clinician comments are detailed on the open treatment plan.



16.12. Bridging

Bridging provides the ability for clinicians to create and manage a bridging record for warfarin only patients who require anticoagulation management whilst they undergo a medical procedure**.**

IMPORTANT: A bridging record is created completely separately and has no effect or impact on patients existing warfarin treatments. INRs recorded within the bridging record are **NOT** included in any TTR calculations.

16.12.1. Features and Benefits of Bridging

- Manage the patients dosing with warfarin and LMWH.
- Edit and update bridging records throughout the bridging period.
- Print schedules to give to the patient.
- View full audit trail in INRstar.

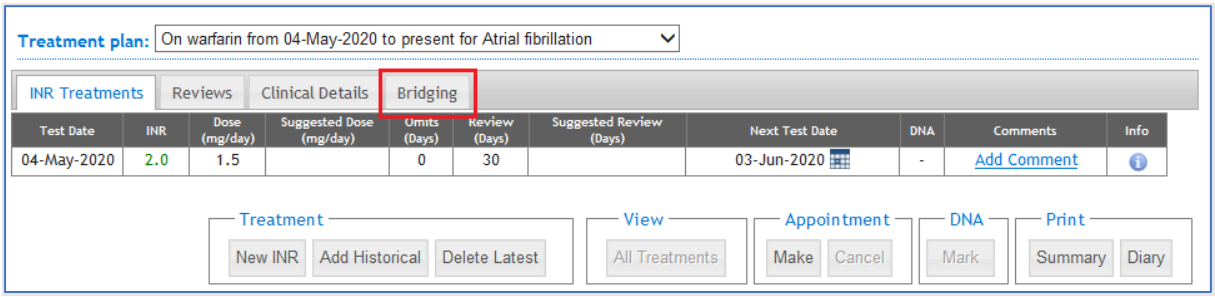
For more detailed descriptions of bridging's features and functions see the INRstar Help site https://help.inrstar.co.uk/

16.12.2. Clinical Safety

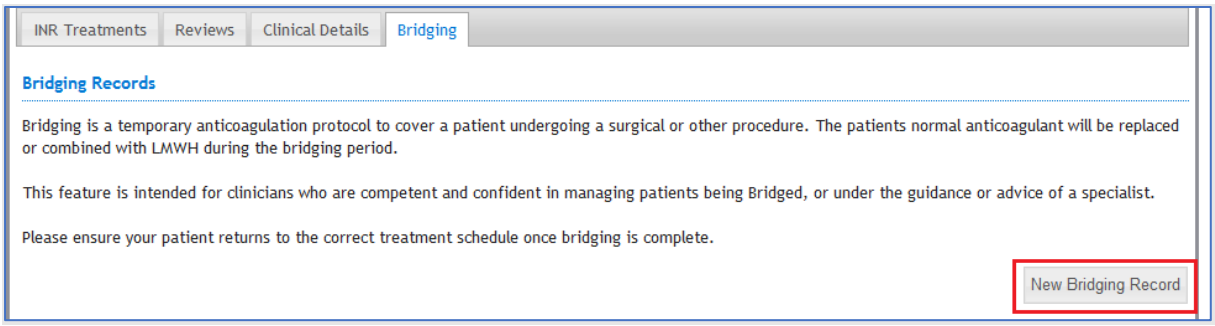
- Clinical Level 3 or Location Clinical Lead can create and manage bridging records.
- All other users can view bridging records.
- System alerts to remind clinicians of the importance of bringing patients back into therapeutic range following bridging.
- Change the patient's next test date on completion of bridging.
- **Not** enabled for patients using INRstar Engage or any of the care programmes.
- Only available for use with warfarin treatment plans.

16.12.3. Bridging Overview

1. Click on '**Bridging**' tab in the patient treatment plan.

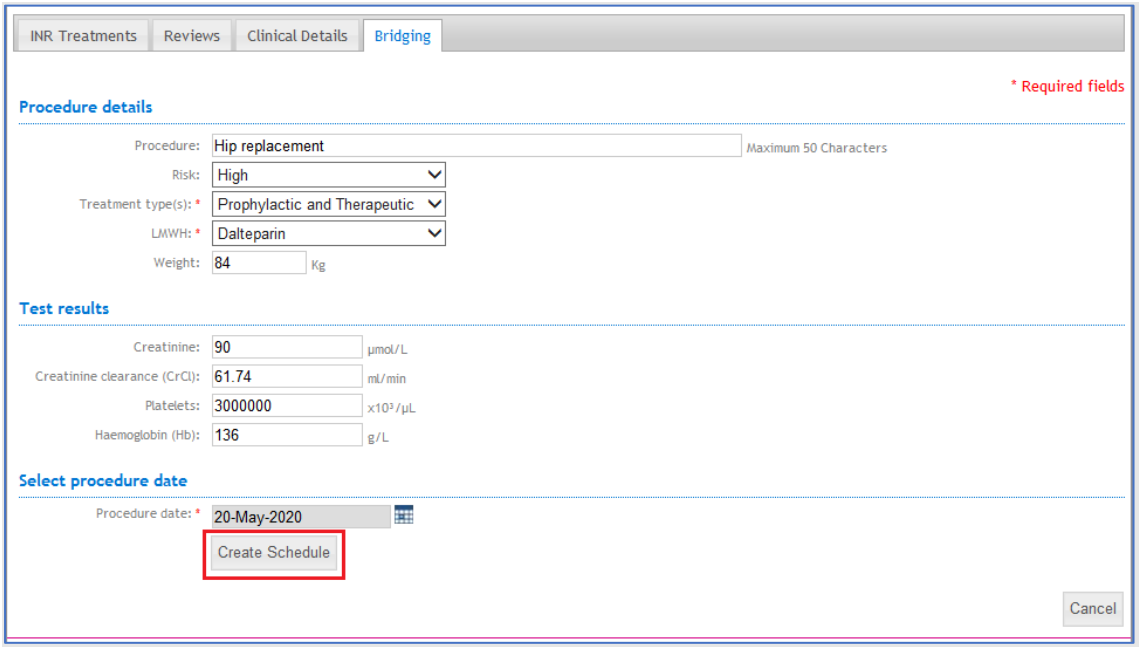


2. Click the '**New Bridging Record**' button:

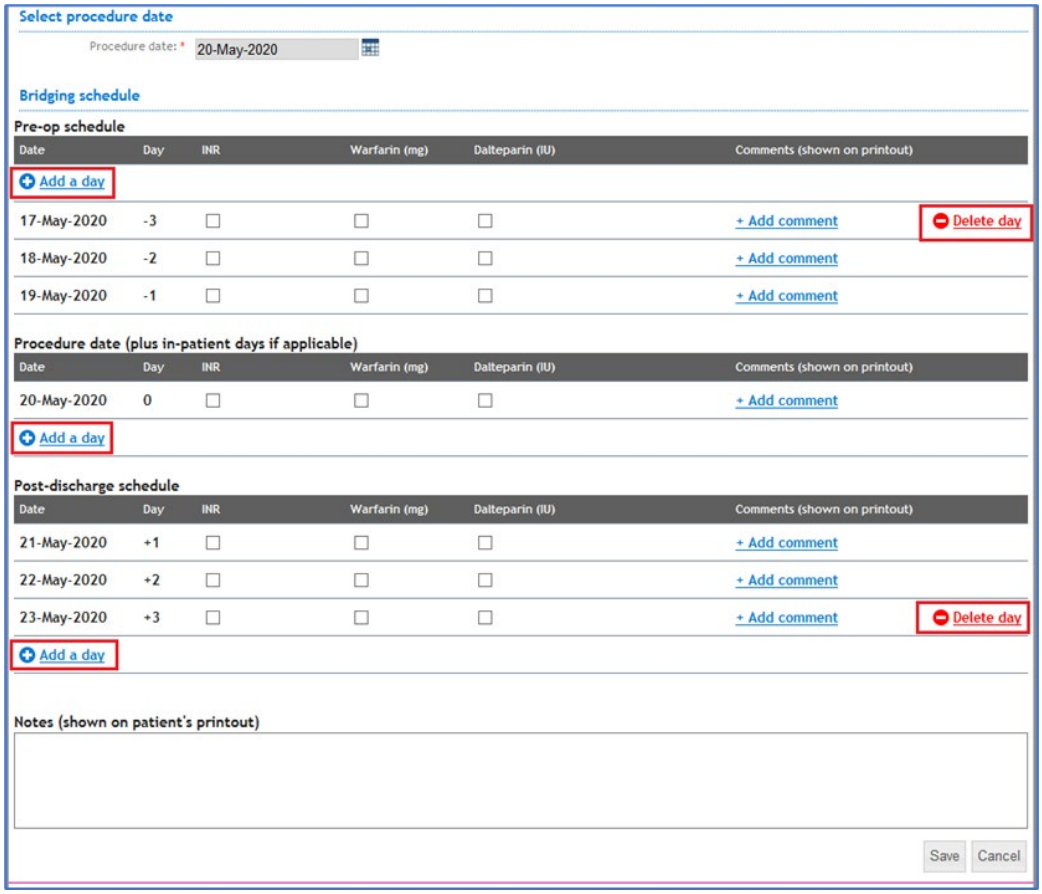


3. Complete the details as required in the pre-schedule section, select a procedure date, and click '**Create Schedule**' button.
4. The '**Risk**' drop down provides three options for you to select from, low, medium, and high. This is not a calculated field and is for you to decide, based on the procedure and patient.

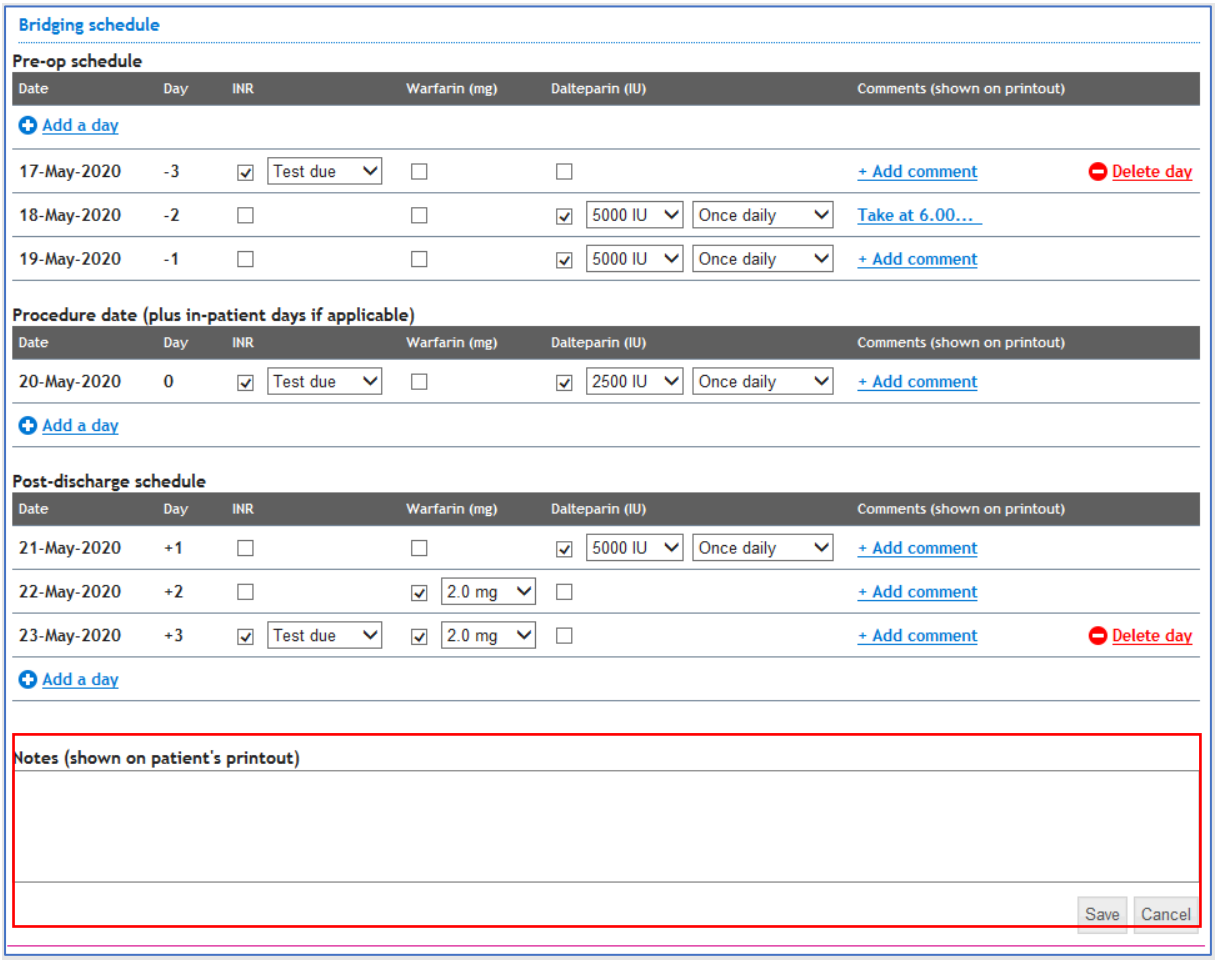
    - There is no creatinine clearance calculator on this screen; the value will need to be calculated manually.



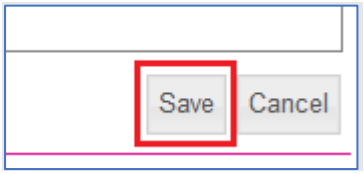
5. Define the number of days you require in each section of the schedule, by adding or deleting days.



6. Add INR test results, doses and any comments in the **'Notes'** field as required:



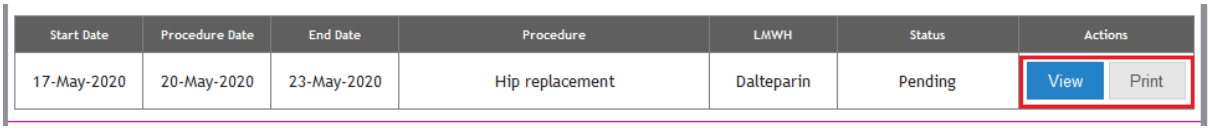
7. Click '**Save**':



8. Print the schedule.

Note: The schedule can only be printed if the status is '**Pending'** or '**Active**'.

9. The '**Bridging'** schedule can also be viewed if required.



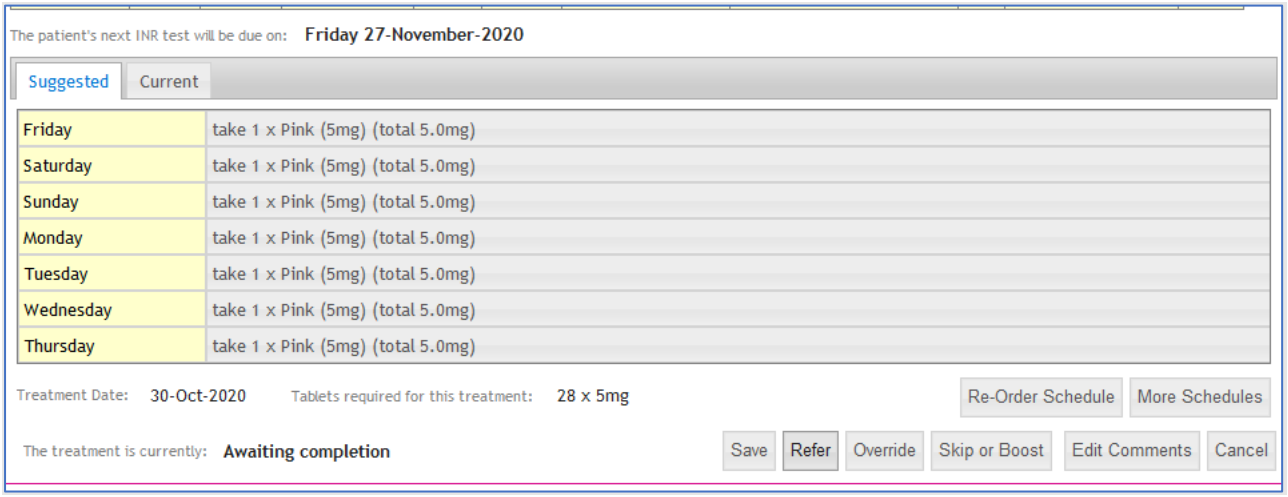
16.13. Refer Treatment for Authorisation

There may be times when a user needs to refer a patient's treatment to another member of staff with more clinical knowledge and experience and the appropriate clinical permission level in INRstar.

INRstar's referral functionality allows the user treating a patient to send an incomplete treatment to any member of staff with either '**Clinical Level 3'** or '**Clinical Lead'** permission levels within **INRstar**.

All users with these higher-level permissions (Level 3) will receive a message on their home page notifying that a patient has been referred for the treatment to be completed.

You can refer a treatment to another clinical user for advice or to authorise a dosing suggestion:



- Click on the  button, at bottom right of the new dosing suggestion screen.

The patient record will now close. A message will be sent to the home page of all users who have sufficient clinical permission levels to accept and process a referred treatment.

The status of this treatment will be changed from **'Awaiting completion'** to **'Referred, Awaiting Authorisation'** until the referral has been accepted and the treatment has been authorised by the referral clinician. The referred treatment is also visible to all on the messages screen, as a patient with an incomplete treatment.

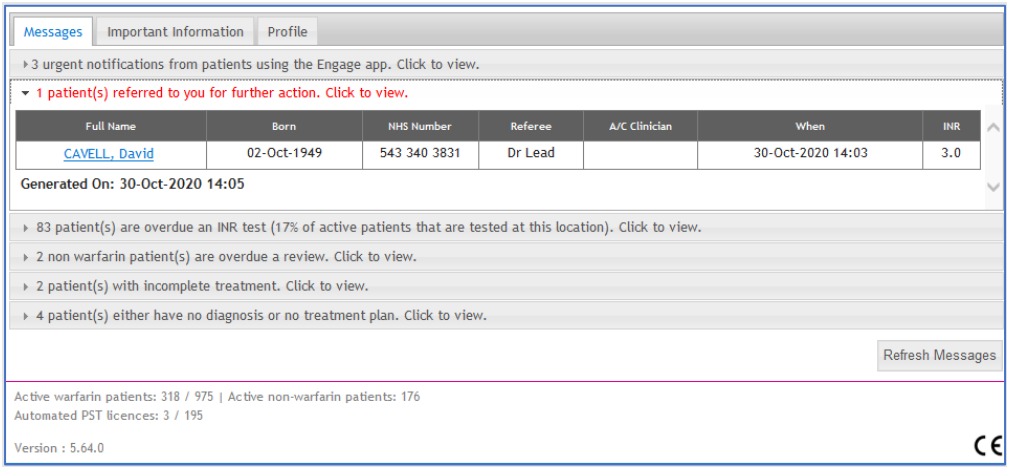
16.14. Accept a Referred Treatment

Note: Only **'Clinical Level 3'** and **'Clinical Lead'** users are permitted to manage, accept, and manage a referral.

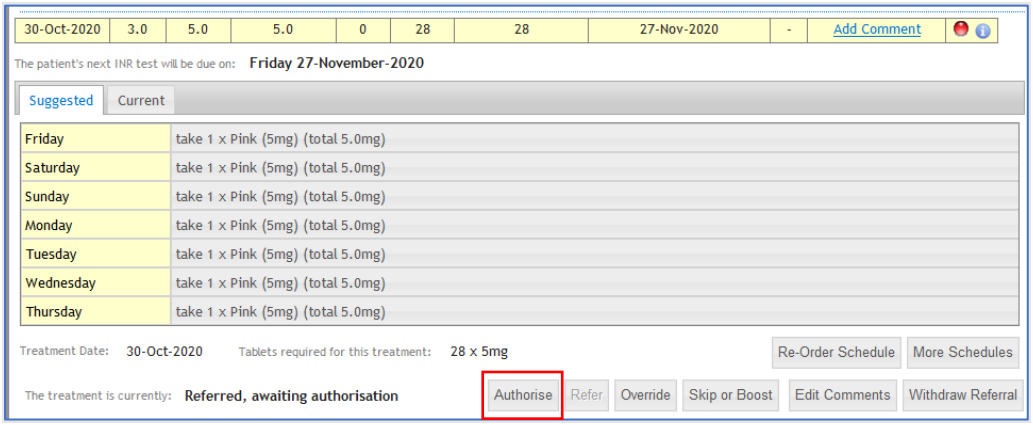
If you have the correct clinical permission level, you can accept referrals from other users. This allows a high-level clinical user to give advice on individual patients, override dosing suggestions and/or authorise the treatment. When a referral is made a message will be sent to the home page of all users who have clinical permission level to accept and process a referred treatment.

1. Click on the message to view a list of patients referred for dosing advice and authorisation.

2. Click on the name of a referred patient to view the patient record.

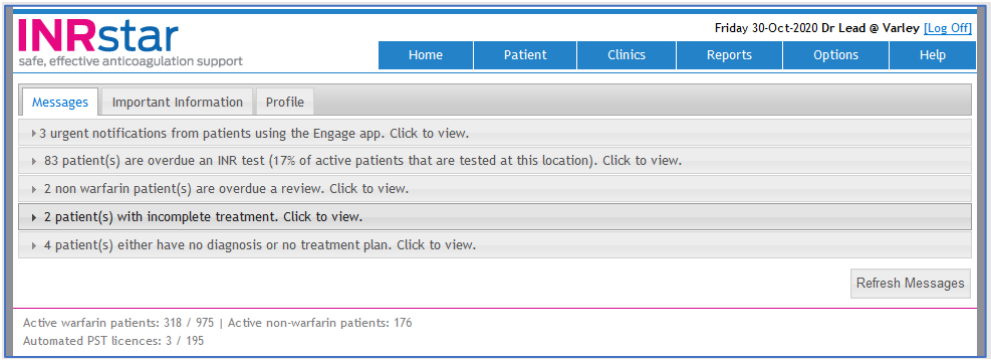


3. The treatment record will open with the suggested dosing schedule.



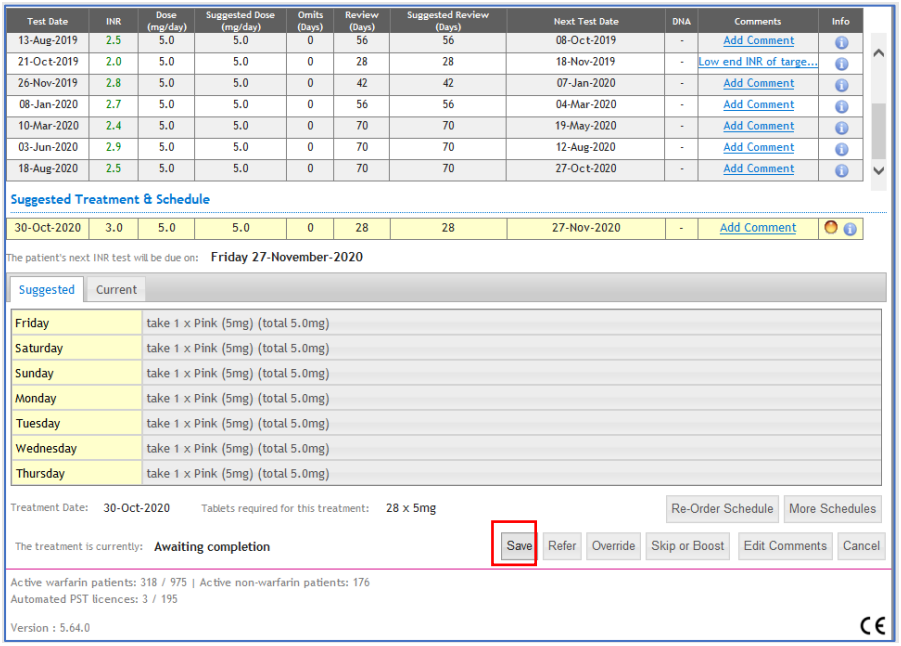
- Click **'Authorise'** to accept the suggestions and authorise the treatment.
- Click '**Override**' to override the dosing suggestions.
- Click '**Edit comments**' to add comments on the treatment.
- Click '**Withdraw Referral**' to cancel the referral of the treatment.

If the user clicks on the **'Authorise'** button, the patient record will close, and a message will be sent to the home page of all clinical users indicating that the treatment has been authorised and that it is now ready for completion. The message will apear as an incomplete treatment on the home screen.



The referring clinician can then open the patient record to complete the treatment by saving and printing the dosing diary, completing the treatment episode.

The status of this treatment currently will be set to '**Authorised, awaiting completion**' and not completed until the treatment has been saved:



When authorised the '**Save'** button will be available to Level 1 users to complete the treatment and dosing schedule.

16.15. Overriding Dosing Suggestions

Note: Only **'Clinical Level 3'** and **'Clinical Lead'** users are permitted to override dosing suggestions.

Amendments can be made to the warfarin dose, omission days, review period or the next test date.

Click on the **'Override'** button on the new '**Suggested Treatment and Schedule'** screen, then select your preferred dose, omission days, review period or next test date.

Click **'OK**' once you have completed your amendments to the suggested treatment.

16.16. Select Alternative Schedule

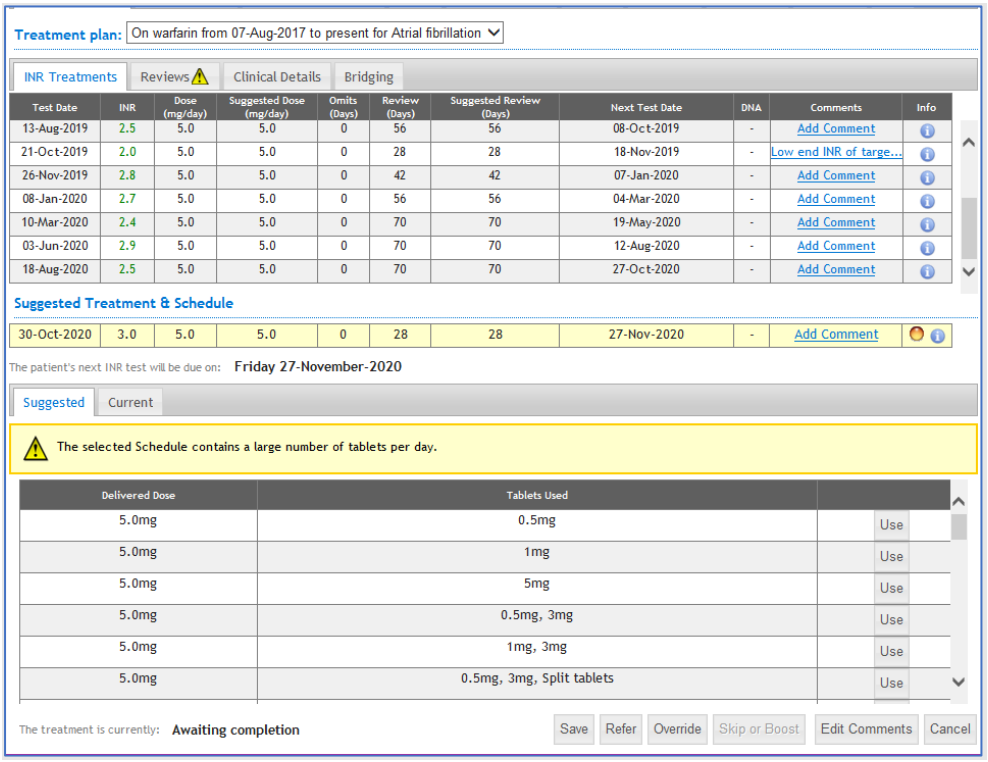
INRstar will always try to calculate a daily dosing schedule to provide the suggested daily dose of warfarin using the selection of tablet strengths which has been specified for the individual patient.

Occasionally you may wish to use a different dosing schedule from the one suggested.

This may be necessary if:

- The patient prefers to take certain doses on specific days of the week.
- Or INRstar cannot calculate a dosing schedule for a certain dose and review period combinations.

Click on the **'More Schedules'** button.



A selection of alternative schedules for the suggested dose will be displayed. This allows you to choose between alternative schedules, which provide slightly different doses.

Select your preferred schedule from the list and click the **'Use'** button.

Note:

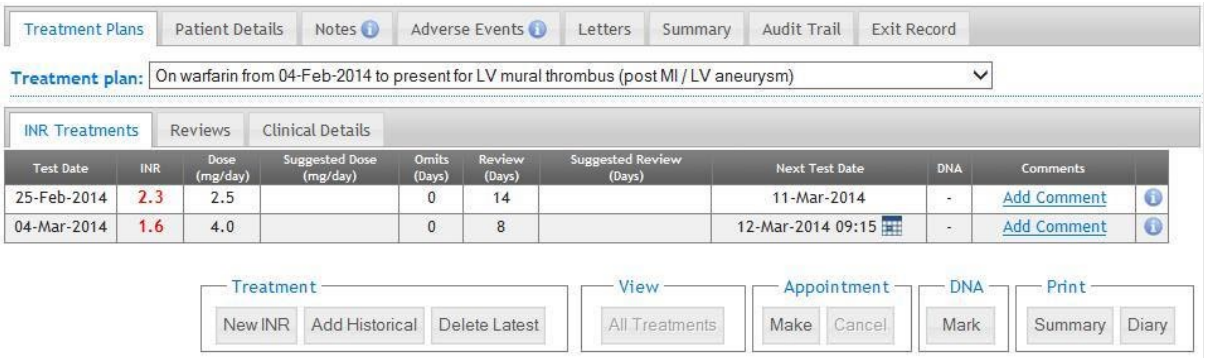
- Clinical Level 1 users can select schedules with same dose.
- Clinical Level 2 users can select schedules with dosing changes of up to 0.1mg a day.
- Clinical Level 3 and Clinical Lead users can select any alternative schedules.

16.17. Saved Treatment, Printing, Faxing or Emailing a Dosing Diary

- **INRstar** enables printing of the patient dosing diary either as a label or on an A4 sheet. This can be given as a schedule to a patient after their new dosing and review period suggestions have been saved in INRstar.
- **INRstar** enables users to decide on your default print preferences.
- **INRstar** also allows Printing Preferences to be set individually within each patient record**.**

Click **'Save'** to save the dosing suggestions to the patient record.

Click **'Diary'** to print a schedule to give to the patient.

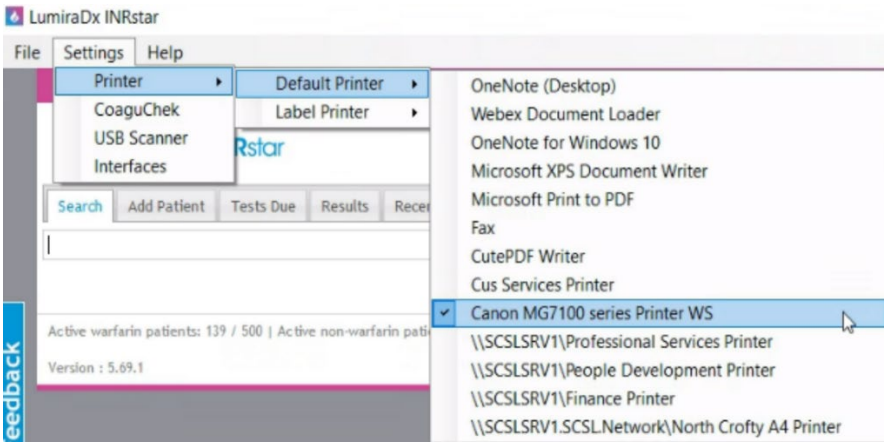


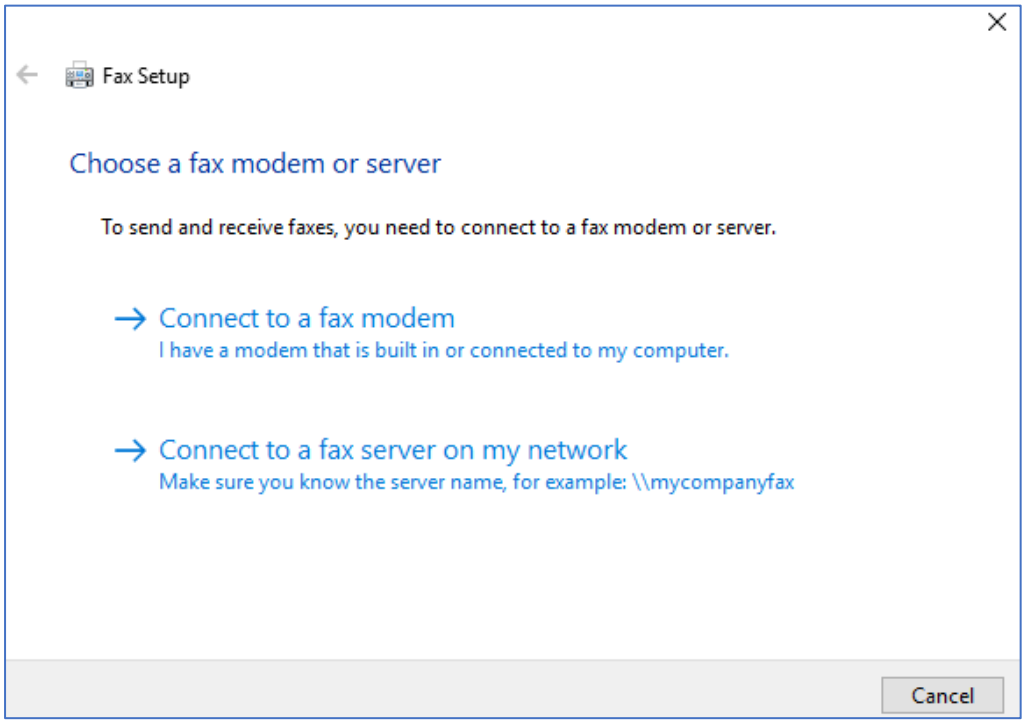
Or click **'Summary'** to print a new patient summary to file in the paper notes. This Doctor Summary Sheet summarises the patient's anticoagulation treatment. It contains sufficient information to allow Manual dosing of the patient if, for some reason, the computer system is unavailable.

The printed dosing diary can be produced with or without tablet graphics. This printed version can be faxed to patient if required.

The diary can also be saved as a portable document format (PDF) file, which can then be emailed/faxed to the patient.

If the user of INRstar has a modem attached to their computer, then the printer configuration in the menu can be set to fax.





If the patient has been enrolled in the **'Digital Dosing Diary'** self-care programme, then the diary does not need to be printed. The patient will be notified automatically by email of their new schedule, which they can view online or in the INRstar Engage smartphone app.

If the patient either does not acknowledge receipt of their dosing schedule within 3 hours or indicates they do not understand the schedule, the clinician is notified with a warning message on the home page of INRstar.

16.18. DNA (Did Not Attend)

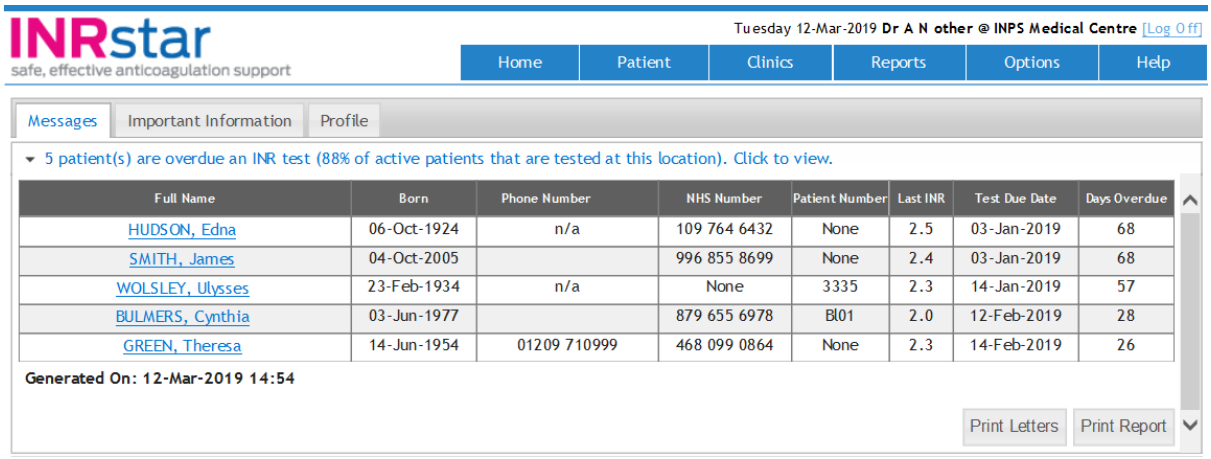
The DNA (did not attend) management functionality allows you to mark and record when patients do not keep their appointment for an INR test.

Marking tests using the DNA management functionality ensures that your patient records are kept up to date, and may assist you in managing local protocols for DNA management.

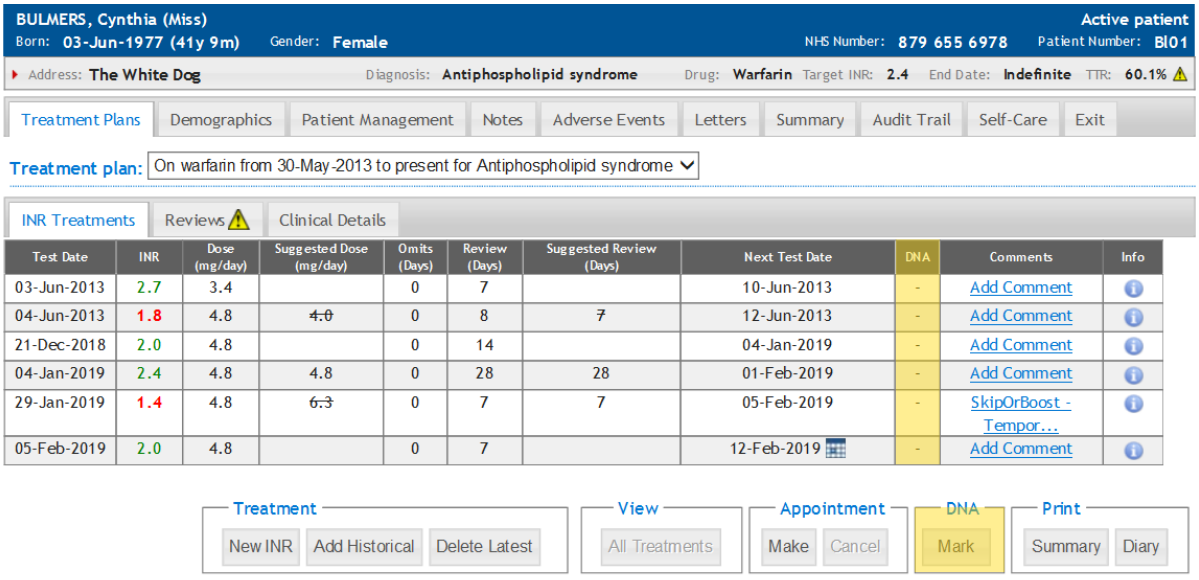
It is not essential for you to make use of the DNA management functionality, but in most scenarios users will appreciate the benefits it brings in terms of increased awareness of DNAs, clearer record keeping and improved patient safety.

16.18.1. Mark and Unmark DNA (Did Not Attend)

To find all patients who have Overdue INR test dates, open the **'Messages'** tab on the user's **'Home Page'**.



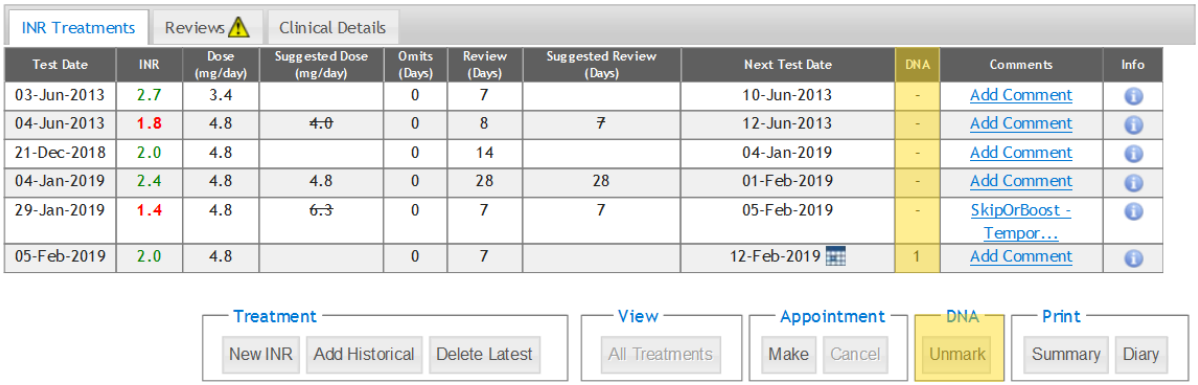
Expand the list and then select the patient concerned.



On the **'INR Treatments'** screen click on **'Mark'** to add a **'DNA'**.

Please Note:

- You can only add a 'Mark' to a missed next test date associated with the patient's latest treatment.
- You cannot mark 'DNA' on any test date that is in the future.



To undo these changes click on **'Unmark'** to remove a 'DNA'.

Please Note: you can only **'Unmark'** a marked missed next test date associated with the patient's latest marked treatment.

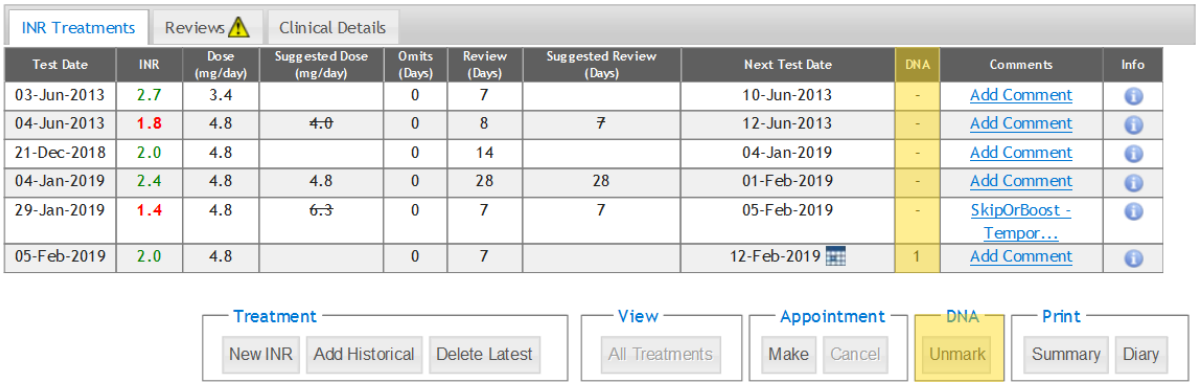
DNA Audit

In the **'Audit Trail'** tab the patient's status will now have **'DNA'** added.

16.18.2. Mark a Repeatedly Missed Next Test Date

If a next test date has been unattended on more than one occasion you can add multiple marks to the **'DNA'** column.

To do so click the **'Mark'** button in the **'Treatment Plans'** / **'INR Treatments'** tab.



Please Note: if the **'Next Test Date'** is not the most recent unattended test date the **'Mark'** button will show as **'Unmark'** and you won't be able to add an additional **'Mark'** to the **'DNA'** column.

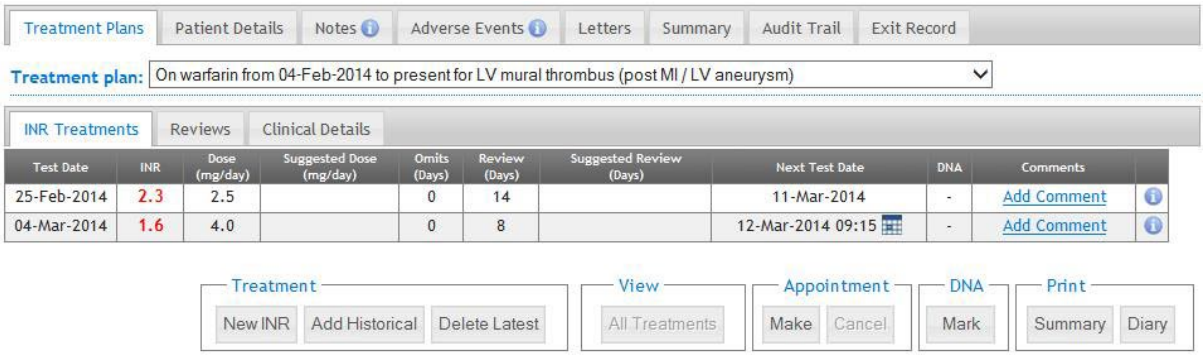
16.19. Deleting a Treatment

It may be necessary occasionally to delete a treatment that has already been saved to a patient's clinical record, for example where there has been an incorrectly entered date of INR test, INR result etc.

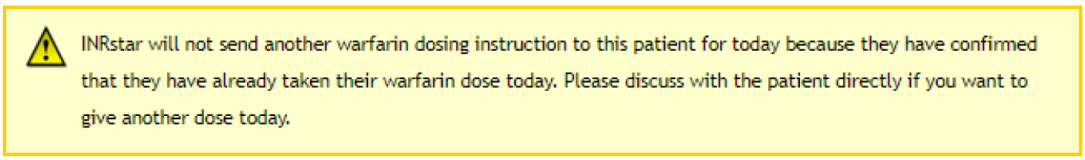
Note: Because of its potential clinical significance, deletion of a treatment is restricted to users with Clinical Level 3 permission levels and is limited to the last recorded treatment only.

16.19.1. To Delete a Treatment

1. Go to the patient's record where you would like to delete a treatment.
2. Click Treatment Plans and then INR Treatments to display the treatment history.

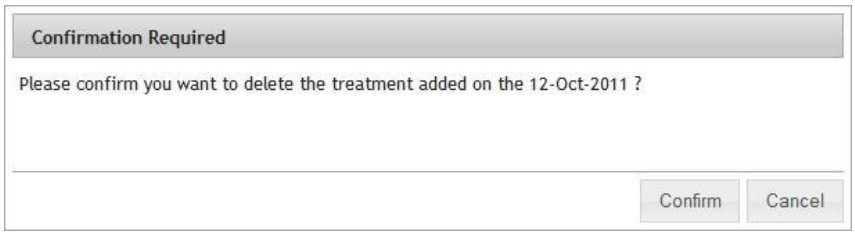


3. At the bottom of the page under **Treatment**, click Delete Latest.
4. If the patient is using the PST Care Programme and has already taken their Warfarin dose for today, a warning message will be shown:



   Click the '**Confirm**' button to continue.

5. Confirm the deletion by clicking the '**Confirm**' button on the confirmation dialogue. Click '**Cancel**' if you do not wish to delete the treatment.



The last recorded treatment will now be deleted and you will be returned to the patient's treatment record screen.

17. Clinical Reviews

National experts and guidance recommend that any patient managed on AC therapy should have an annual review to assess the risks and benefits of continued AC treatment in that patient.

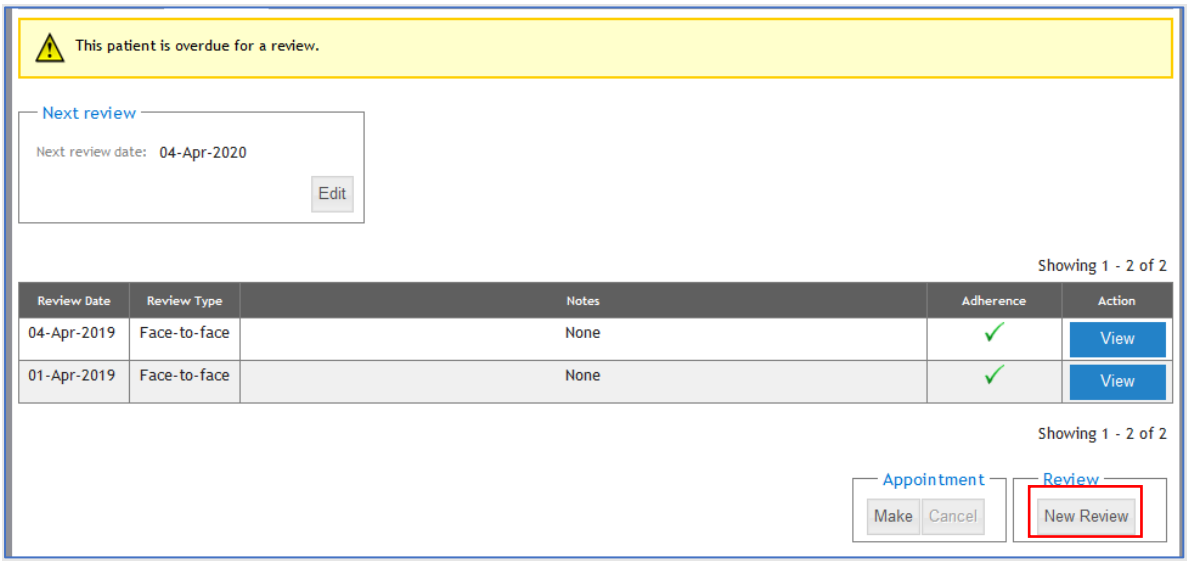
17.1. Adding a Review

Locate a patient needing a review via the patient search area, or by running the report 'Patients Overdue an Annual Warfarin Review' in the Reports section of INRstar (see section 21 Reports).

17.1.1.

1. Select the '**Treatment Plans**' tab on the patient record.
2. Select the '**Reviews**' tab. A yellow triangle with an exclamation mark indicates a review is due.

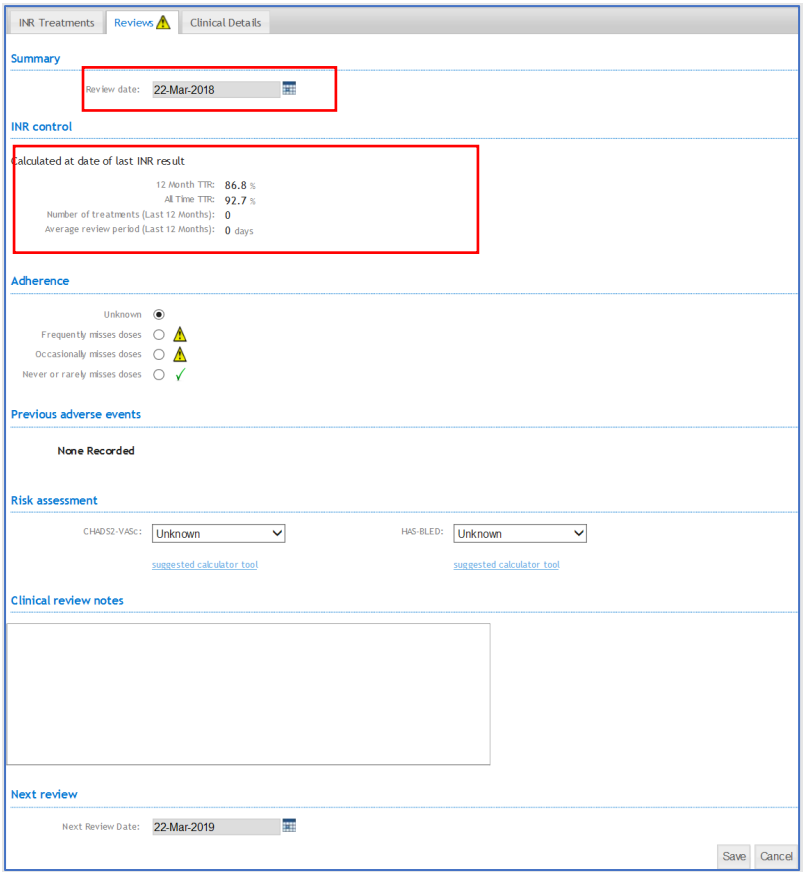
A summary of any existing reviews will be displayed if available.



3. Click on the **'New Review'** button.

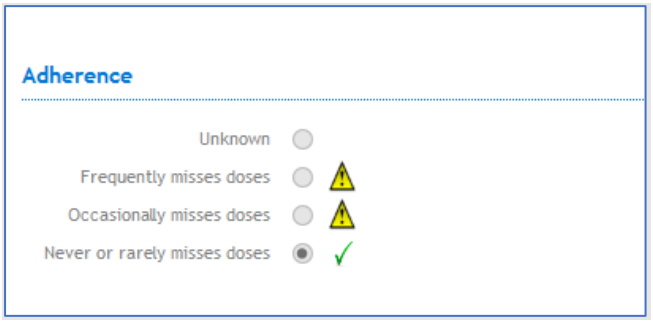
17.2. Adding a Warfarin Review

The warfarin clinical review entry screen will be displayed. Confirm that the correct review date is shown, or change it using the calendar icon.



On this screen you can review the display of AC control data as follows:

- Time in therapeutic range (TTR, 12 months and All Time).
- Number of tests.
- Average review period.
- Assessment of patient adherence and compliance.

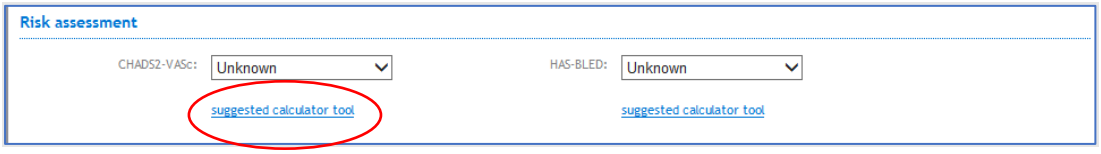


You can enter details of:

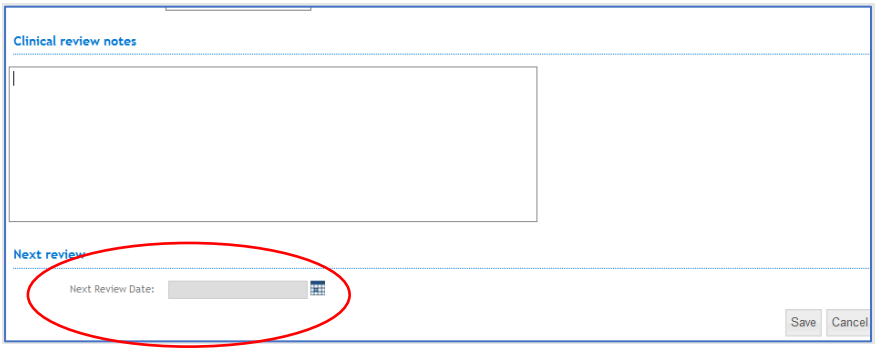
- '**Adherence**': your assessment of the patient's compliance with treatment.

- '**Risk Assessment**': document a CHADS2, CHADS2-VASc and HAS-BLED risk score if appropriate. These scores are used commonly to assess a patient's thromboembolic and bleeding risks to help identify them as potentially benefiting from AC treatment.

  Note: A link to a calculator tool is available:



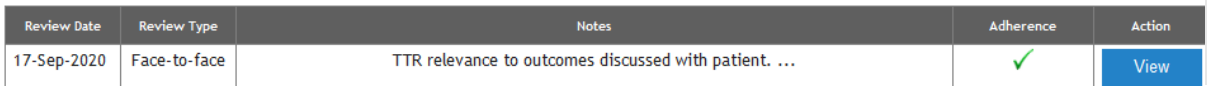
- Any relevant comments.
- A date for the next clinical review. Automatically defaults to the next annual review date, but can be changed using the calendar icon.



- Click **'Save'** when you have completed the review.

Note:

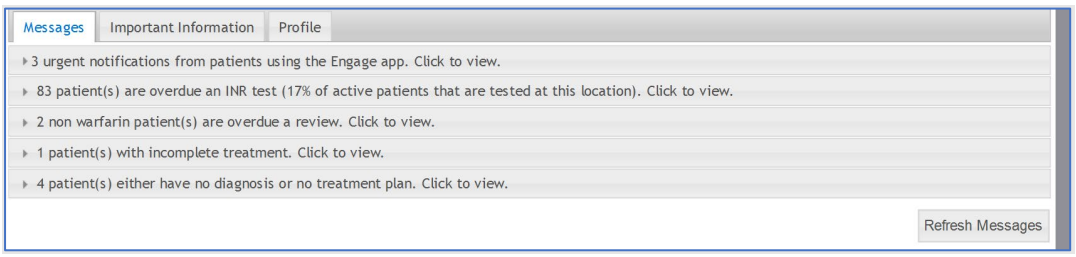
- The review can be re-opened, and the comments edited, after saving by clicking on '**View'.**
- The review cannot be deleted once saved.



17.3. Adding a DOAC or LMWH Therapy Review

To view a patient on DOAC or LMWH therapy either:

- Select the required patient in the **'Non-Warfarin Patient(s) overdue reviews'** section of the **'Messages'** tab.



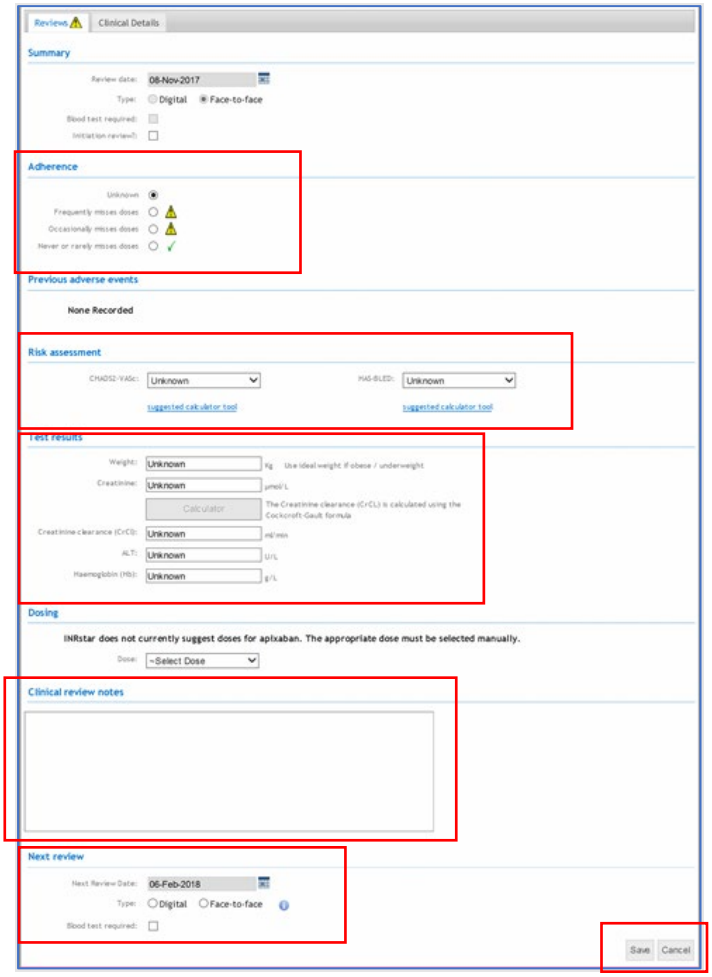
- Or search and select patient.

From the patient record:

- Select the **'Treatment Plans'** tab.
- Select the **'Reviews** tab.

A summary of any existing reviews will be displayed if available.

- Click the **'New Review'** button.
- The clinical '**Review'** screen will be displayed.



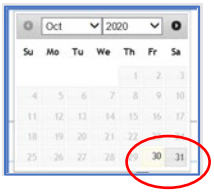
On this screen you can review the AC data.

You can enter the following details:

- Your assessment of the patient's compliance with their treatment.
- Assessed risk scores, e.g. CHADS2-VASc, etc, used commonly to assess a patient's thromboembolic and bleeding risks to help identify them as potentially benefiting from AC treatment.

- The specific measurements that help inform the future anticoagulant selection and dose: weight, creatinine, (creatinine clearance automatically calculated with the Cockcroft-Gault formula), ALT and Haemoglobin (HB).
- The dose selection for the chosen anticoagulant and a date for the next clinical review.
- Any relevant comments. Free text comments to be filed back to the clinical system.

Confirm treatment **'Review Date'** from the calendar icon.

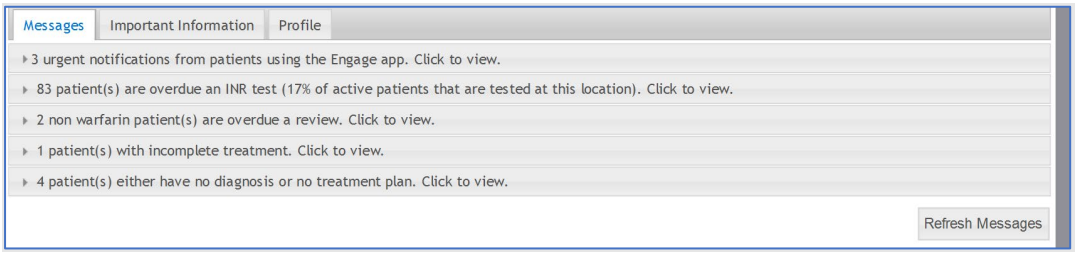


Click '**Save'** when you have completed the review, or '**Cancel'** if you do not want the document to be saved.

17.4. Adding an Acenocoumarol Review

To view a patient on Acenocoumarol therapy either:

- Select the required patient in the **'non-warfarin patient(s) overdue reviews'** section of the **'Messages'** tab.

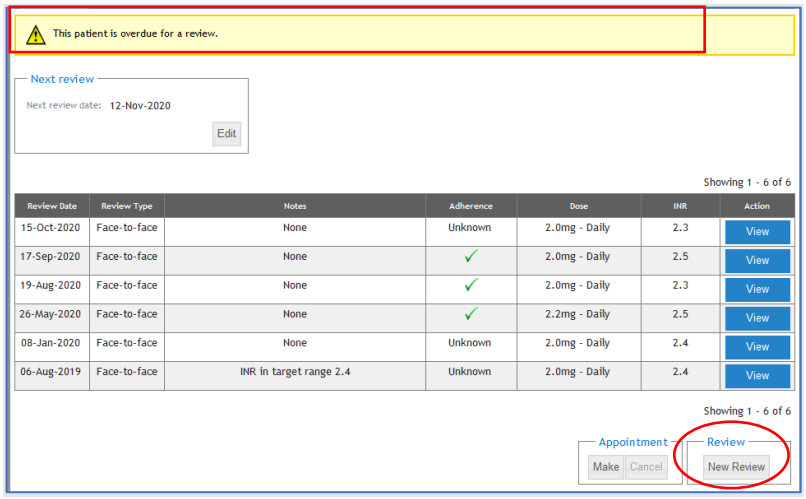


- Or search and select the patient.

From the patient record:

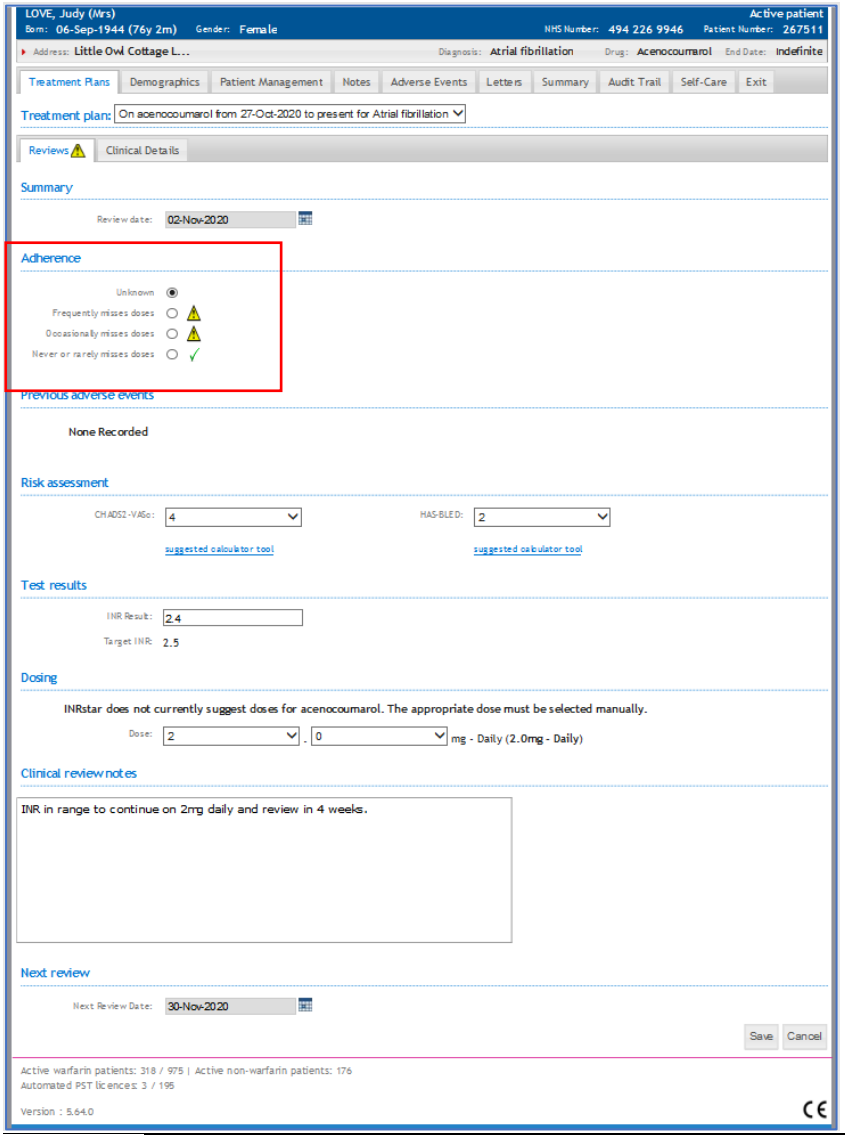
- Select the **'Treatment Plans'** tab.
- Select the **'Reviews** tab.

A summary of any existing reviews will be displayed if available.



- Click the **'New Review'** button.

The clinical '**Review**' screen will be displayed.



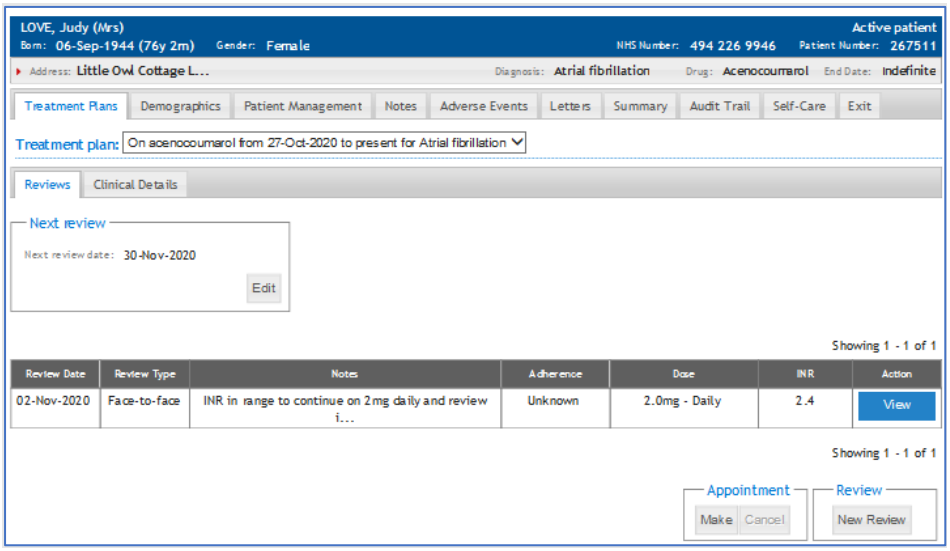
You can enter the following details:

- **'Adherence'** - An assessment of the patient's compliance with their treatment.
  - If this is an initiation you may need to tick the **'Unknown'** box.
  - Future reviews will allow you to record the patients level of compliance and adherence to the medication schedule.
- '**Risk assessment'** - An updated CHADS2, CHADS2-VASc and HAS-BLED risk score, used commonly to assess a patient's thromboembolic and bleeding risks to help identify them as potentially benefiting from AC treatment.
- '**Adverse Events**' - If previously recorded.
- '**Test results**' - INR result against target INR.
- '**Dosing**' - Select the required dose from the drop-down list.

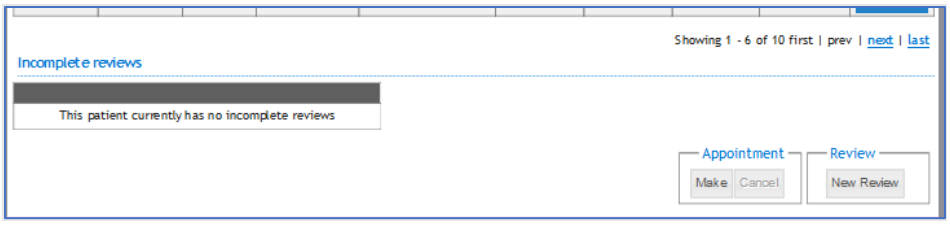
  Note: INRstar does not currently suggest doses for Acenocoumarol.

  The appropriate dose must be selected manually from the list available.
- '**Clinical review notes**' - Free text comments to be filed back to the clinical system.
- '**Next review date**' - Select a date for next planned review from the calendar.

Click **'Save',** or **'Cancel'** if you do not want the document to be saved.



The '**Review'** record is now complete. An overview of the Acenocoumarol review can be seen on the main screen and viewed at any time.

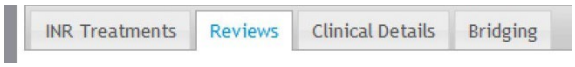


Where the location's database has been set up to use the Clinics functionality, an appointment can be made from this section by clicking on **'Make'** in the **'Appointment'** box.

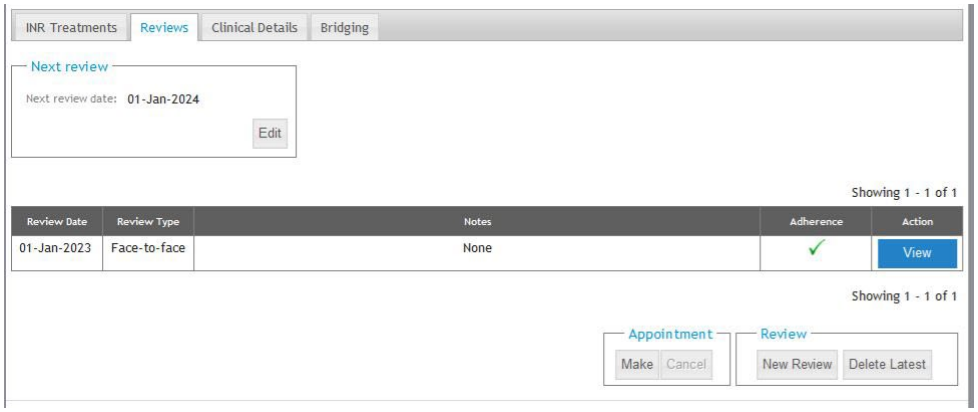
The date of the review can be edited in the **'Next Review'** box.

17.5. Deleting a Warfarin Review

In the patients record click on the Reviews tab



Any reviews that have been created are displayed within the Review Summary table.



Clicking the ***Delete Latest*** button you can delete the most recently completed review shown in the list, providing that you are one of the following users within INRstar.

- Clinical 1
- Clinical 2
- Clinical 3
- Location Clinical Lead

You will not be able to delete a review if;

- You are not one of the users listed above
- The patient status is Deactivated
- You are accessing the patient record via the External Patient Lookup feature
- The treatment plan has been completed

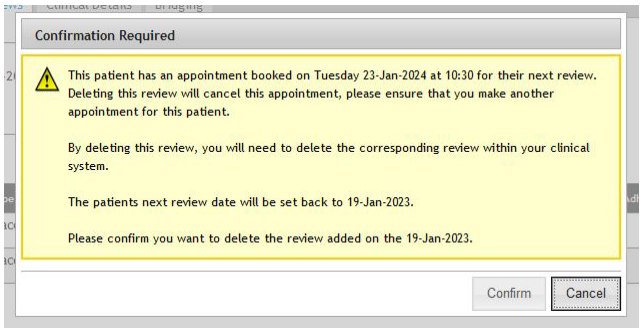
You can only delete one review at a time and that will always be the most recent one displayed. If the patient has multiple pages of reviews the Delete Latest button will only be enabled on the screen displaying the latest Review.

Deleted reviews are **NOT** filed back to any clinical system so any changes will need to be made manually, this will appear on a warning message to advise you.

If you use the INRstar clinics feature any associated appointment for the deleted review will also be deleted.

When a review is deleted the Next Review Date will change to that of the Date of the Review that you deleted. If this date is in the past it will appear on the Overdue Review notifications on the Home page.

Any of the above scenarios will display a warning message to you prior to you confirming the action. An example of how that will look is shown below, note this shows all messages where in some cases you many only see one or two.



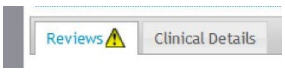
This process will be audited and will display as follows;

Date Time	Action	Patient Name	More Information	User
19-Jan-2023 11:07:38	Changed Next Review Date - Face-to-face.	Wonderful WARFARIN	Appointment record [19-Jan-2023] was added. Status set to [Booked], Date set to [19-Jan-2023], DNA set to [False]., NextDate record [Warfarin Review] was updated. Next Review Date changed from [23-Jan-2024] to [19-Jan-2023]., Appointment record [23-Jan-2024] was updated. Status changed from [Booked] to [Cancelled], Reason set to [Moved]., Consultation record was updated. Review Date changed from [19-Jan-2024] to [19-Jan-2023]., TreatmentPlan record [01-Jan-2023] was updated.	pauld@tpp
19-Jan-2023 11:07:38	Review dated 19-01-2023 deleted.	Wonderful WARFARIN		pauld@tpp
19-Jan-2023 11:06:32	Booked Review Appointment	Wonderful WARFARIN	ClinicToAppointment record [23-Jan-2024] was added. Clinic name set to [test clinic1], Start date set to [23-Jan-2024]., Appointment record [23-Jan-2024] was added. Status set to [Booked], Date set to [23-Jan-2024], DNA set to [False]., NextDate record [Warfarin Review] was updated. Next Review Date changed from [19-Jan-2024] to [23-Jan-2024]., Appointment record [19-Jan-2024] was updated. Status changed from [Booked] to [Cancelled], Reason set to [Moved].	pauld@tpp
19-Jan-2023 11:06:16	Fileback to the Clinical System	Wonderful WARFARIN		pauld@tpp

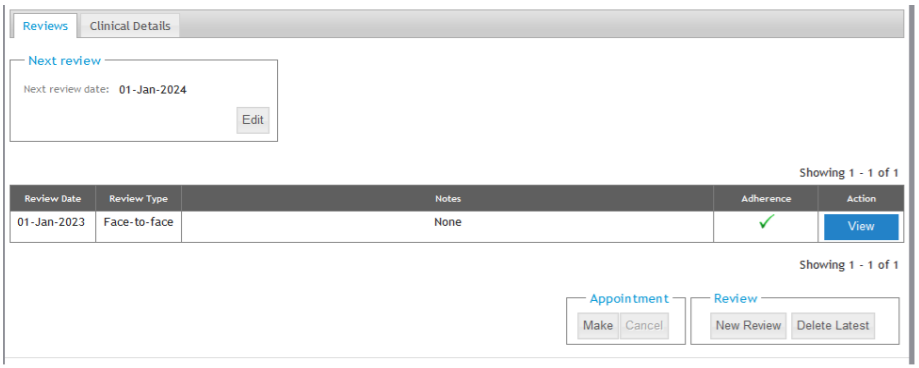
The above image shows, from the bottom up;

- the creation of a review and that it was filed back to the clinical system.
- the review was deleted
- the Next Review Date was changed to that of the review date of the one deleted.

17.6. Deleting a Non Warfarin Review

In the patients record click on 

Any reviews that have been created are displayed within the Review Summary table.



Clicking the ***Delete Latest*** button you can delete the most recently completed review shown in the list, providing that you are one of the following users within INRstar.

- Clinical 2
- Clinical 3
- Location Clinical Lead

You will not be able to delete a review if;

- You are not one of the users listed above
- The patient status is Deactivated
- Accessing the patient record via the External Patient Lookup feature
- If the treatment plan has been completed

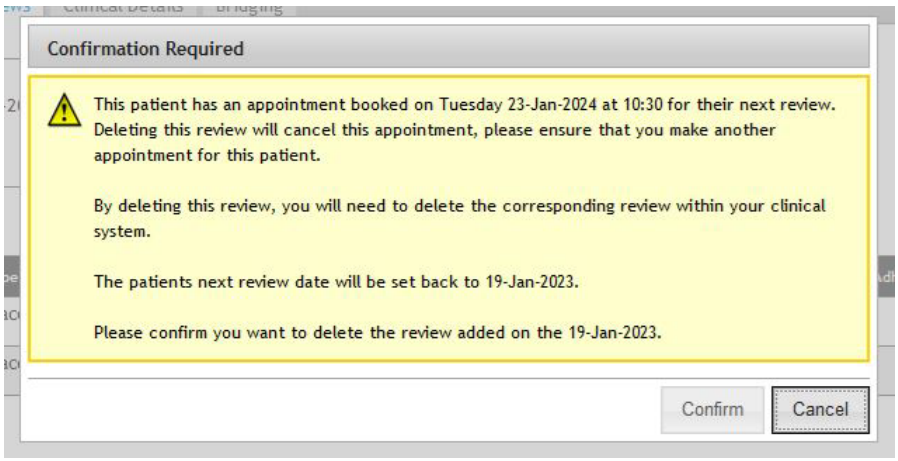
You can only delete one review at a time and that will always be the most recent one displayed. If the patient has multiple pages of reviews the Delete Latest button will only be enabled on the screen displaying the latest Review.

Deleted reviews are **NOT** filed back to any clinical system so any changes will need to be made manually, this will appear on a warning message to advise you.

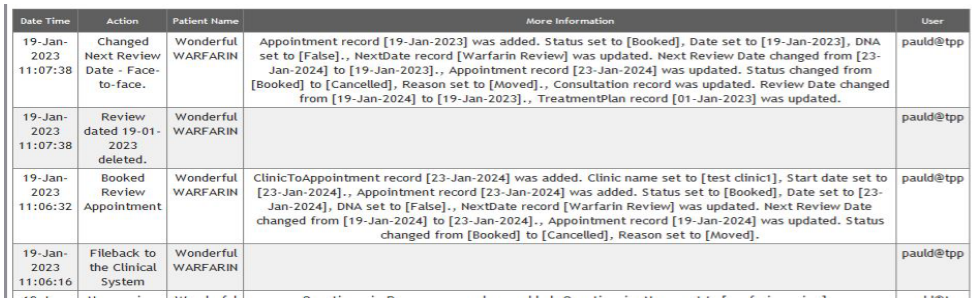
If you use the INRstar clinics feature any associated appointment for the deleted review will also be deleted.

When a review is deleted the Next Review Date will change to that of the Date of the Review that you deleted. If this date is in the past it will appear on the Overdue Review notifications on the Home page.

Any of the above scenarios will display a warning message to you prior to you confirming the action. An example of how that will look is shown below, note this shows all messages where in some cases you many only see one or two.



This process will be audited and will display as follows;



Date Time	Action	Patient Name	More Information	User
19-Jan-2023 11:07:38	Changed Next Review Date - Face-to-face.	Wonderful WARFARIN	Appointment record [19-Jan-2023] was added. Status set to [Booked], Date set to [19-Jan-2023], DNA set to [False]., NextDate record [Warfarin Review] was updated. Next Review Date changed from [23-Jan-2024] to [19-Jan-2023]., Appointment record [23-Jan-2024] was updated. Status changed from [Booked] to [Cancelled], Reason set to [Moved]., Consultation record was updated. Review Date changed from [19-Jan-2024] to [19-Jan-2023]., TreatmentPlan record [01-Jan-2023] was updated.	pauld@tpp
19-Jan-2023 11:07:38	Review dated 19-01-2023 deleted.	Wonderful WARFARIN		pauld@tpp
19-Jan-2023 11:06:32	Booked Review Appointment	Wonderful WARFARIN	ClinicToAppointment record [23-Jan-2024] was added. Clinic name set to [test clinic1], Start date set to [23-Jan-2024]., Appointment record [23-Jan-2024] was added. Status set to [Booked], Date set to [23-Jan-2024], DNA set to [False]., NextDate record [Warfarin Review] was updated. Next Review Date changed from [19-Jan-2024] to [23-Jan-2024]., Appointment record [19-Jan-2024] was updated. Status changed from [Booked] to [Cancelled], Reason set to [Moved].	pauld@tpp
19-Jan-2023 11:06:16	Fileback to the Clinical System	Wonderful WARFARIN		pauld@tpp

The above image shows, from the bottom up;

- the creation of a review and that it was filed back to the clinical system.
- the review was deleted
- the Next Review Date was changed to that of the review date of the one deleted.

18. Managing Patients in INRstar Engage

18.1. Digital Dosing Diary (DDD)

This gives your patients digital access to their current dosing schedule via the INRstar Engage app or website. As their latest treatment record is saved in INRstar, the new schedule is seamlessly transmitted to INRstar Engage and is instantly available to the patient.

INRstar Engage contains reminders of their daily dose and of their new INR test date.

The programme also provides comprehensive educational videos, available at any time, to help your patients learn more about warfarin and their anticoagulation therapy.

Topics include:

- Welcome to the Digital Dosing Diary
- Understanding your INR
- All about warfarin
- Diet and Alcohol
- Symptoms of bleeding
- Symptoms of clotting
- Taking other Medication

The **'Digital Dosing Diary'** is an electronic form of the traditional printed tablet schedule. This is the list of daily tablets they need to take for their AC and is known in INRstar as the **'Diary'**.

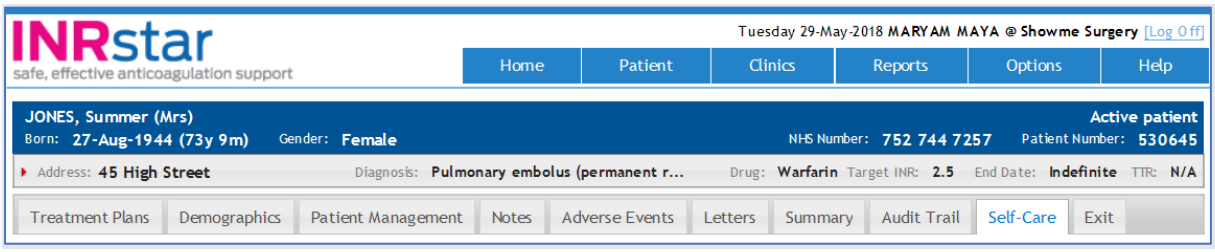
The INRstar Engage application, provided by inVita Intelligence, can be accessed using a smart phone, tablet device, laptop, or desktop computer. It consists of a series of simple instructions (known as 'tasks') for the patient to follow.

Through INRstar Engage and the seamless integration with INRstar, you will know if your patient has received and understands their schedule, so you can be confident your care team is providing the best possible support.

DDD is easy to set up, following simple steps to enrol your patient, so they can get started on learning more about their AC therapy.

18.2. Step 1 - Discuss Digital Dosing with a Patient

Select the correct patient record in INRstar and click on the **'Self-Care'** tab where you will find information about INRstar Engage and the '**DDD'**. Discuss **'DDD'** with your patients including how it can help them understand their AC therapy better whilst staying in touch with their care team.



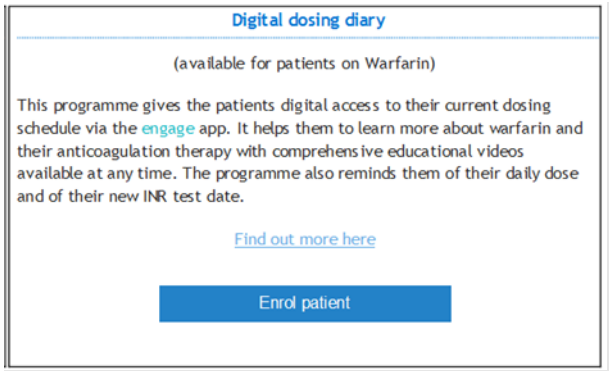
18.3. Step 2 - Confirm Patient's Details

You will need to ensure the patient has access to a smart phone, tablet device, laptop or desktop computer that is connected to their email account.

- Confirm the patient's demographics in INRstar contain either a home or mobile phone number and a valid email address.

18.4. Step 3 - Enrol Patient

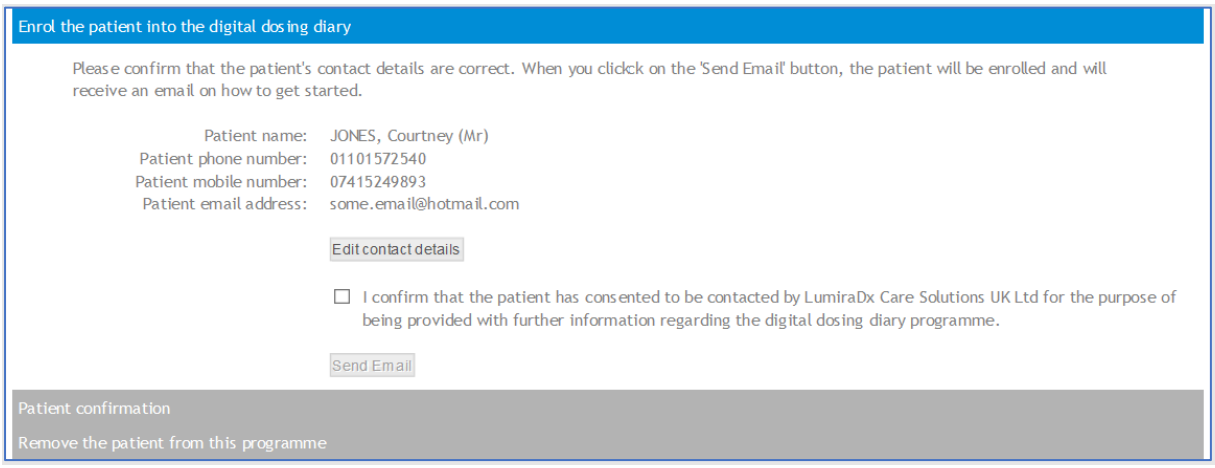
Enrol the patient in the appropriate digital programme, **'Digital Dosing Diary'**.



It is important to note that until the patient confirms they are ready to use the DDD, they will not receive their tablet schedule via INRstar Engage on their electronic device.

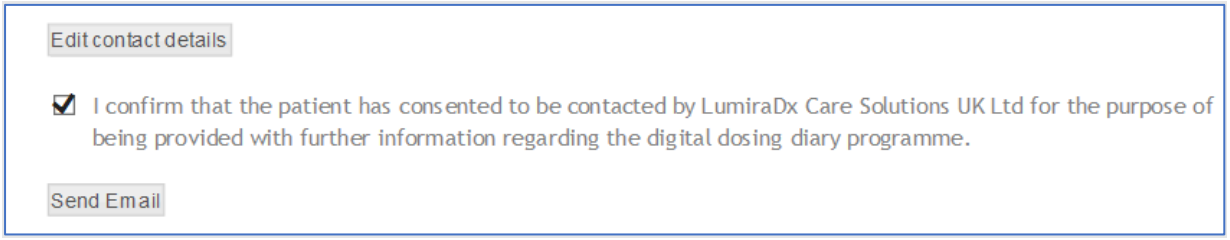
On the **'Self-Care'** page, click the **'Enrol Patient'** button in the **'Digital dosing diary'** area.

This will display the first stage of the process.



Check with the patient that the email address displayed is correct.

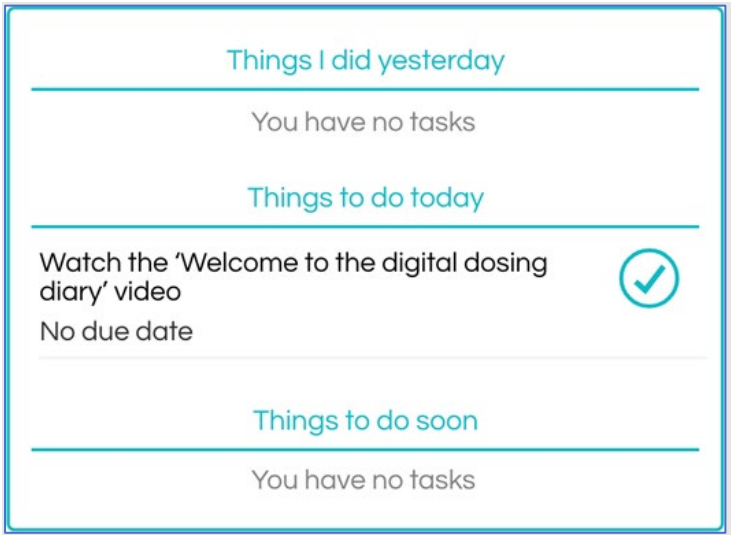
Tick the check box alongside the 'I confirm that patient has given consent to be contacted by inVita intelligence Limited for the purpose of being provided with further information regarding the digital dosing diary' text, then click on the **'Send email'** button.



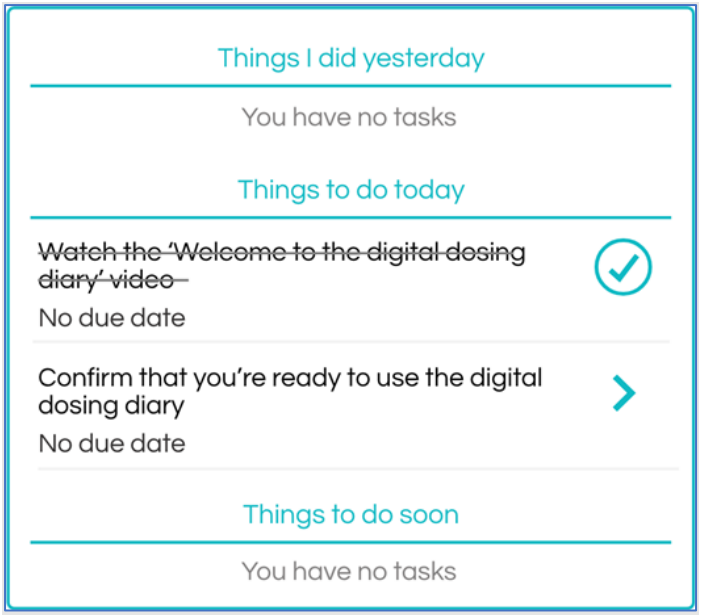
The patient will receive a welcome email, which will explain how to download, or access INRstar Engage and how to register.

When the patient has registered and logged in to INRstar Engage, they are asked to accept the EULA and privacy policy.

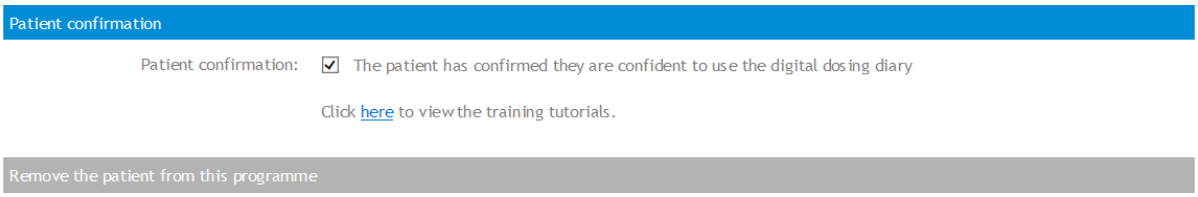
Once they are registered, they will be automatically sent a task to start their initial training.



All the training for the patient is contained within INRstar Engage. When they have completed their initial training, the patient can decide if they are ready to start using the selected the **'Digital Dosing Diary'** or **'Self Care'** programmes, by answering a task question.



When your patient has confirmed they are ready to use the Digital Dosing Dairy, they will be fully enrolled.



When you treat this patient in INRstar, you will see a message to indicate they are on the Digital Dosing Diary self-care programme. **Note:** If you do not see the message,

then your patient has not confirmed they are ready and will not receive their schedule electronically.

18.5. Manage Treatments Using Digital Dosing Diary

18.5.1. Pre-treatment Questions

When your patient arrives for their next appointment, ask the usual confirmation, clinical assessment questions and perform INR test.

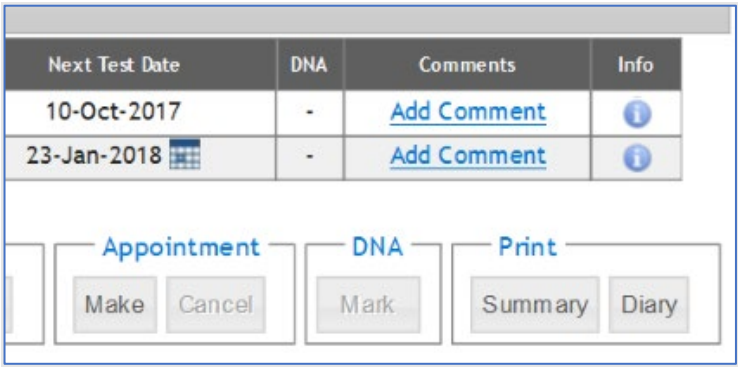
18.5.2. Create Treatment Record

If using the PoCT testing method, or when the INR test results are available from the lab, then create the INRstar treatment record.

As you save this record, INRstar will instantly send the new tablet dosing schedule to the INRstar Engage app.

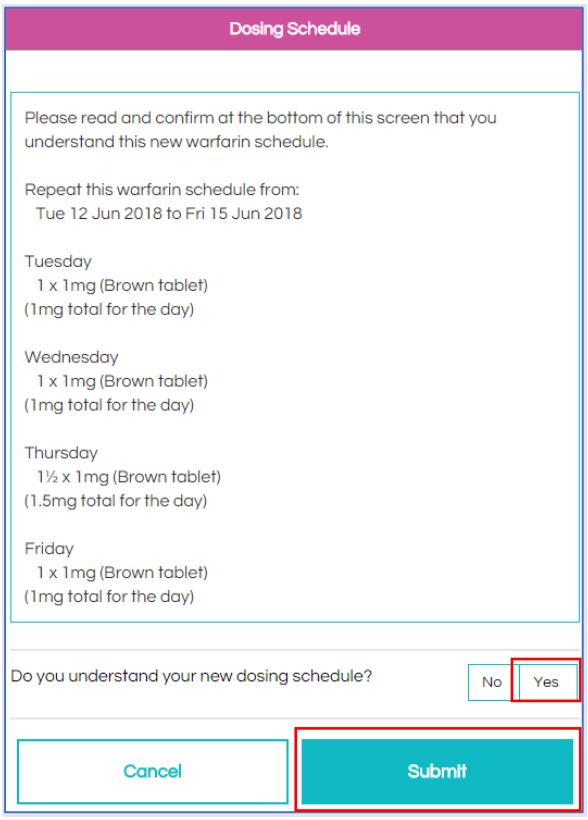
INRstar will also send the patient an email informing them they have a new schedule that they need to confirm.

You have no need to print the patient diary but may be required to print the patient summary sheet, for your own records.

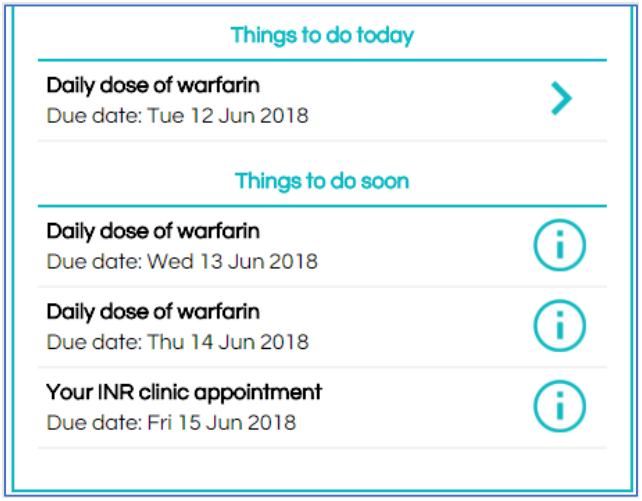


18.5.3. Patient Confirms Schedule

Your patient will then complete the task in INRstar Engage to indicate they understand the new schedule.

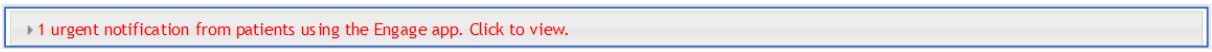


The patient will then be sent a set of daily tasks, stating which tablet or tablets they need to take each day. They will also get a task with their next test date.

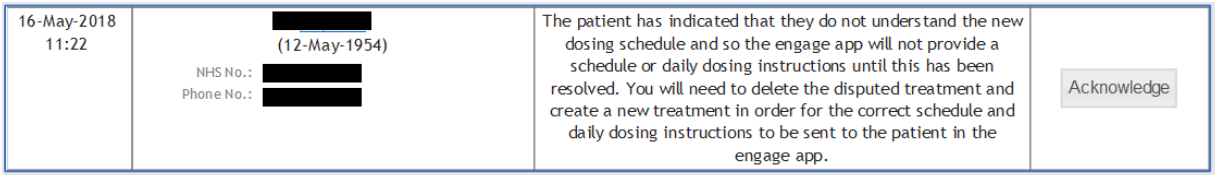


18.5.4. Patient does not 'Confirm Schedule' or does not 'Understand Schedule'

If the patient does not reply that they have received the schedule, or they indicate they have not understood it, INRstar will display a notification message on the home page that can be viewed by the clinician. The clinic would be notified after three hours if patients do not accept or refuse a new schedule, to alert clinicians of a need to action.

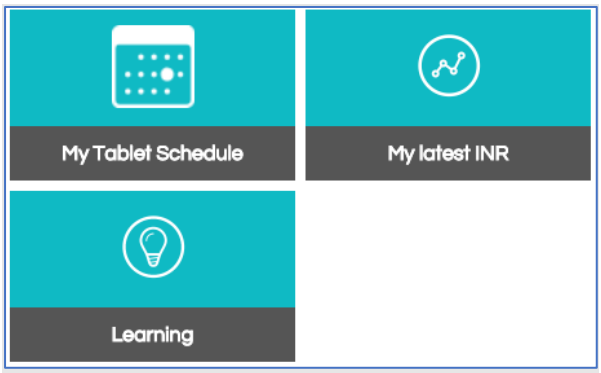


- Click on the message and open to view more information.

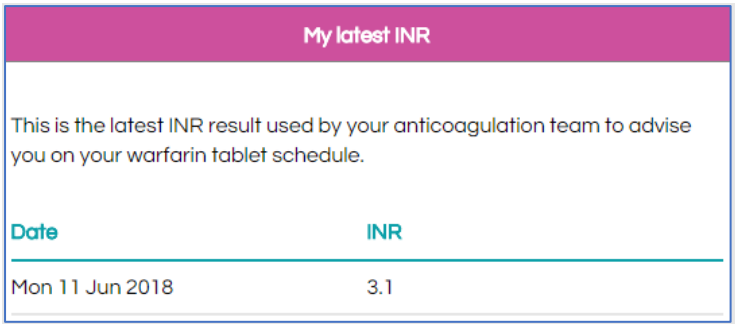


The message contains information that the clinician will need to acknowledge and then follow up with the patient directly.

The patient is also able to check what their last INR result was by using the option '**My latest INR'** in INRstar Engage.



- The last INR will be displayed:



18.6. Manage Patient on Warfarin Self Testing in INRstar Engage

Patients can learn how to self-test with step-by-step training and support through the clinically risk assessed INRstar Engage app. The clinician will need to confirm they are trained and competent, to enable the patient to self-test independently and send their INR result directly to INRstar via the app. The clinician will then review the results remotely and send the patient their new dosing schedule electronically through the INRstar Engage app.

INR stability is not a requirement for self-testing according to NICE[3], as patients with unstable INR may benefit from frequent testing. Additionally, patients with other

conditions requiring long-term vitamin K antagonist therapy may also be suitable for self-testing.

To use the INRstar Engage app your patient will need:

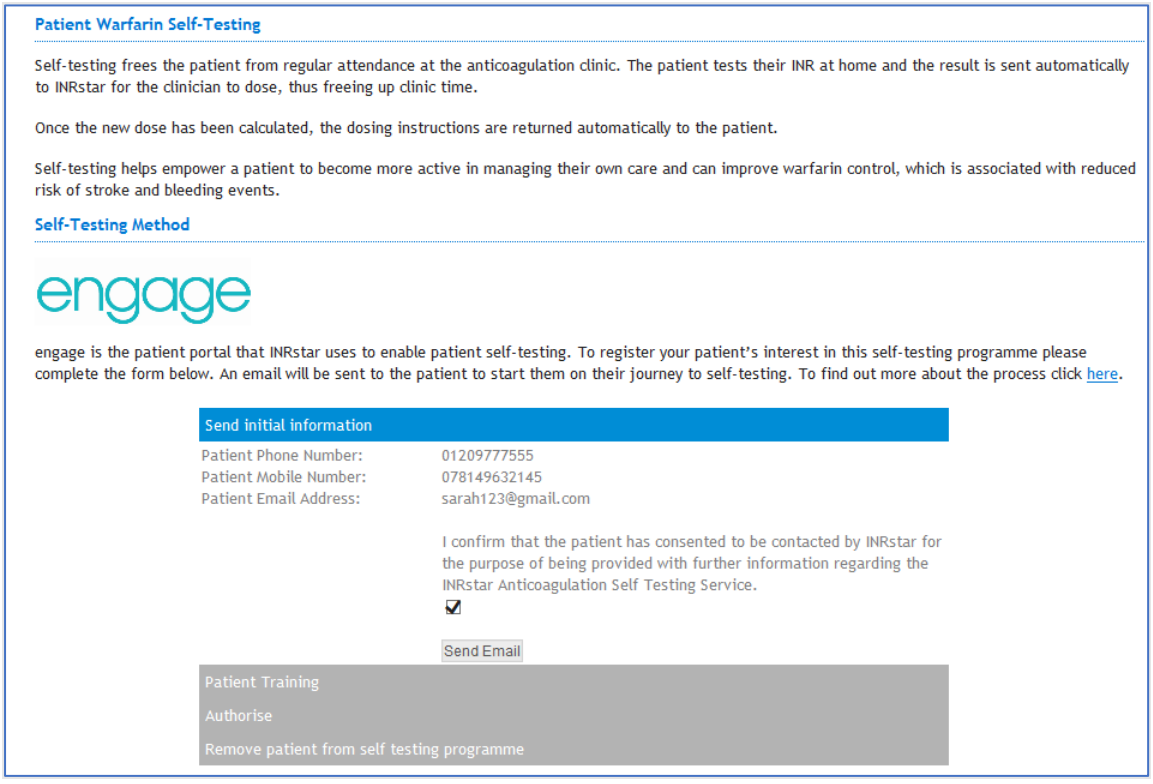
- A valid, unique email address and phone number.
- Access to the internet.
- A tablet, computer, or smartphone.

The self-testing programme is easy to set up, just follow the three steps and once your patient (or their carer) has demonstrated competence in performing their INR test and submitting it via the INRstar Engage app, they will be ready to self-test.

18.6.1. Self-Testing, Enrol Patient

Discuss the programme with the patient first and provide an overview; confirm the patient is willing to participate.

- Make sure your patient's record has a valid email address and phone number in INRstar.
- Once they have consented to be contacted by us and join the self-testing in INRstar Engage, tick the checkbox on the **'Self-Care'** tab and click '**Send Email**'.



An automatic email will then be generated to the patient with an online form to be submitted in order to proceed further. Once the online form has been received by

INRstar a welcome email will be sent to the patient with guidance on how to access the App and get started.

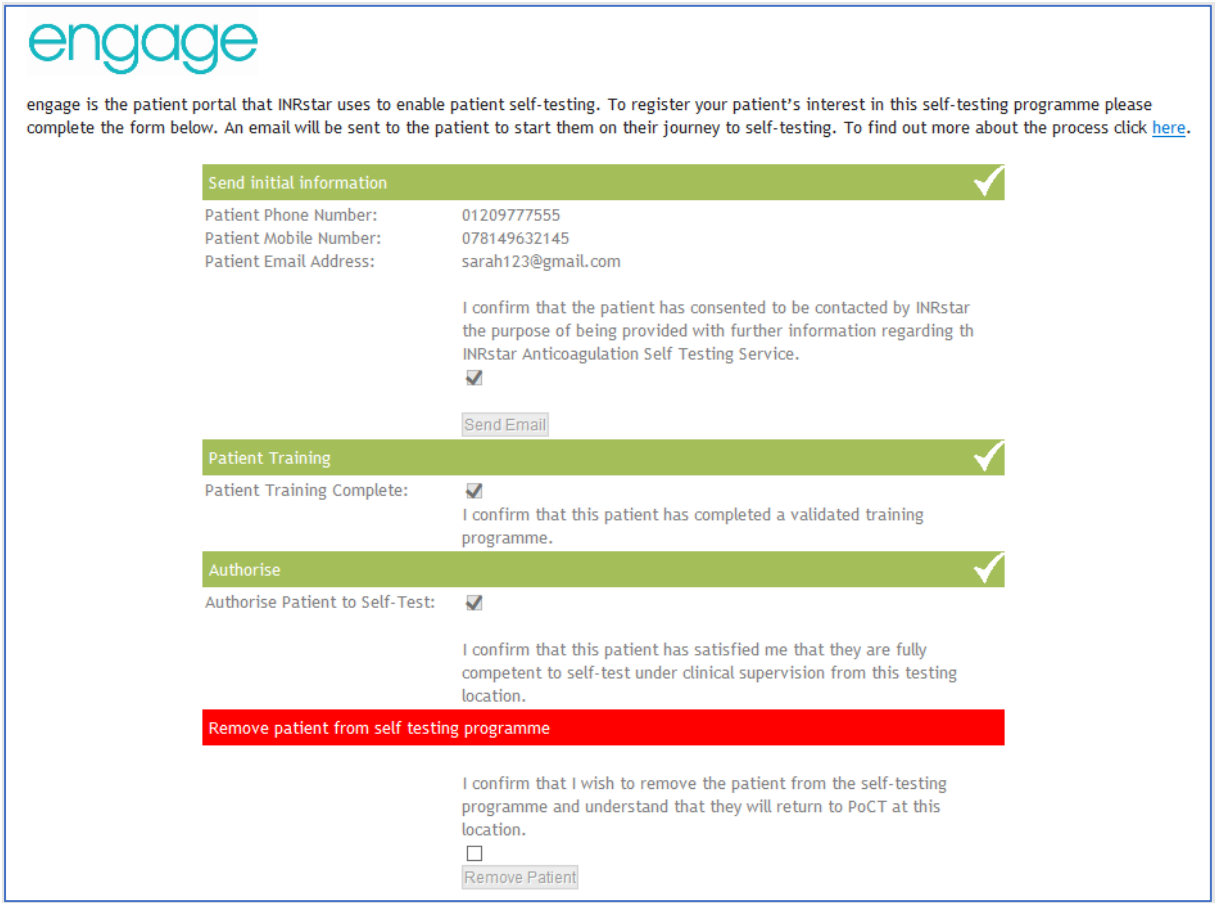
Before your next appointment, your patient will train on how to self-test via the INRstar Engage app.

On your next appointment ask your patient to:

- Show you in the INRstar Engage app that they have completed their training – There will be a tick on each of the training modules.
- Perform an INR test on their own INR meter.

If you are satisfied that your patient (or their carer) knows how to self-test, go to the '**Self-Care'** tab in **INRstar** and click that they have completed their training to authorise the patient to self-test.

Note: The final authorisation of a patient to allow self-testing must be done by an **INRstar** user with a Clinical Level 2 or higher access permission level.



Note: Whilst your patients are in training, the INRstar Engage app does not record their INR result and it does not send the result to your clinic. Once you authorise the patient to '**Self-test'**, their INR results will be recorded in the INRstar Engage app and sent to your clinic for you to dose your patient through INRstar.

18.6.2. Quality Checks

The clinician should check the patient's INR on your clinic's INR meter, which serves as the first quality check of your patient's INR meter.

It is important that your patients periodically bring their INR meter to the clinical team for quality control testing. Every six months is recommended.

18.6.3. Self-Testing Process

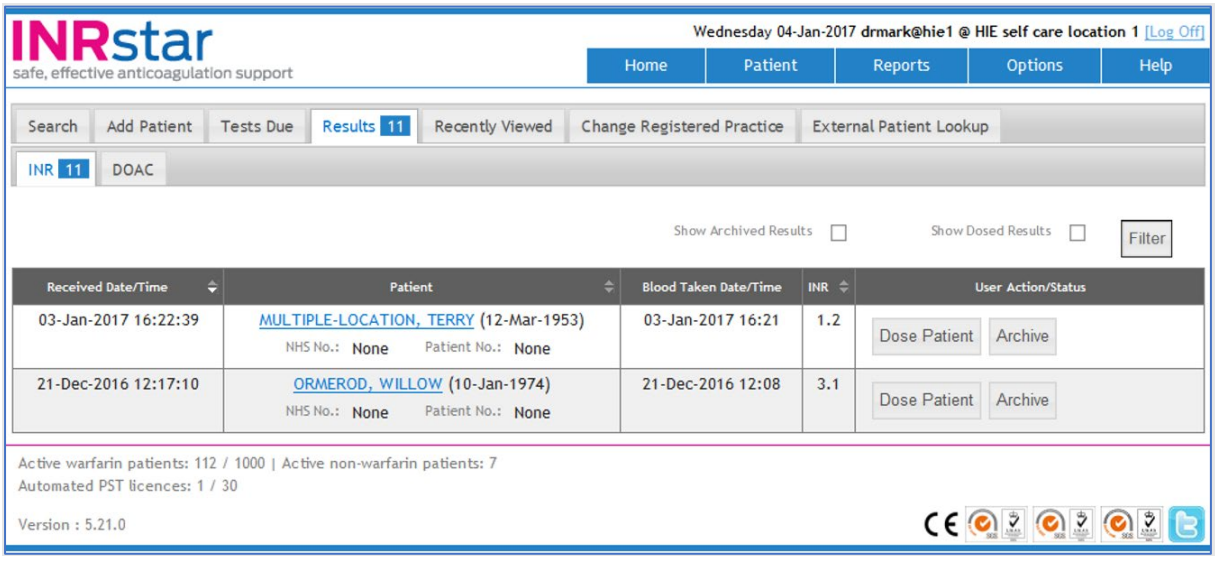
The patient is encouraged to take greater control of their health by using the INRstar Engage app to send you their INR results and receive their dosing schedule.

The following five-step cycle explains the self-testing process. The patient self-tests using their INR meter and sends their results to the INRstar Engage app.

In the INRstar Engage app the patient answers these four questions:

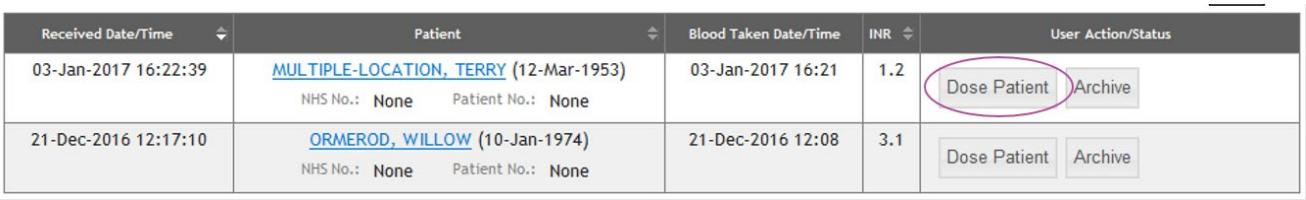
- What dose of warfarin did you take yesterday?
- Have you had any changes to your medications in the last 7 days?
- Have you had any bleeding symptoms in the last 7 days?
- Have you missed any warfarin dose in the last 7 days?

Once the patient has answered all four questions, the INRstar Engage app sends their INR result to the testing clinic. The treating clinician will be able to access their result on the '**Test Results**' tab in **INRstar**. There is a paging feature if there are more than 10 outstanding results.



Once you have received their INR result, you can review the information in the '**Test Results'** tab.

Click **'Dose Patient'** in the '**User/Action'** status column:

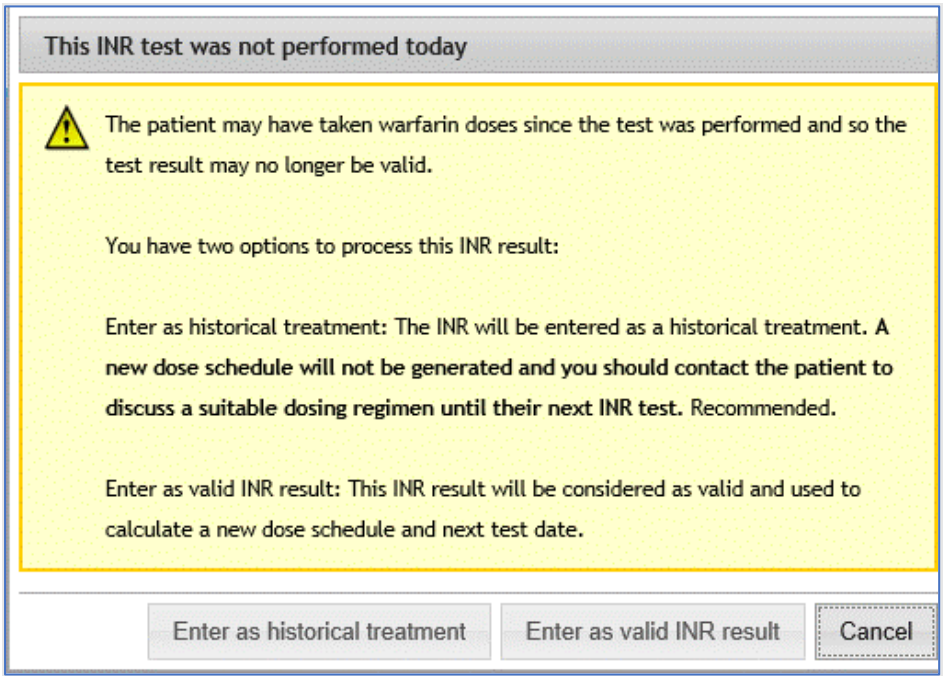


If the date of the INR result is today, the patient's records will automatically open on the '**New INR'** page. The rest of the process for dosing and completing a patient's treatment is the same as the one you follow for all patient treatments.

When 

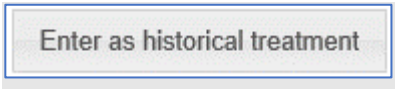
is clicked INRstar will automatically send the new schedule to your patient's INRstar Engage app.

If the date of the INR result is **up to 3 days prior to today**, you will be shown the following warning message.



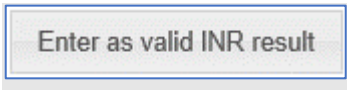
There are three options to select from:

- Enter the information as a historical treatment - (*recommended*).
- Enter the information as a valid INR result.
- Cancel the process.

- If you click the 

button, you will be taken to the '**Add Historical INR'** tab.

  Note: A new dose schedule will not be generated, and you should contact the patient to discuss a suitable dosing regimen until their next INR test.

- If you click the 

button, you will be taken to the '**New INR'** button. The remaining process for dosing and completing a patient's treatment is the same as the one you currently follow for patients.

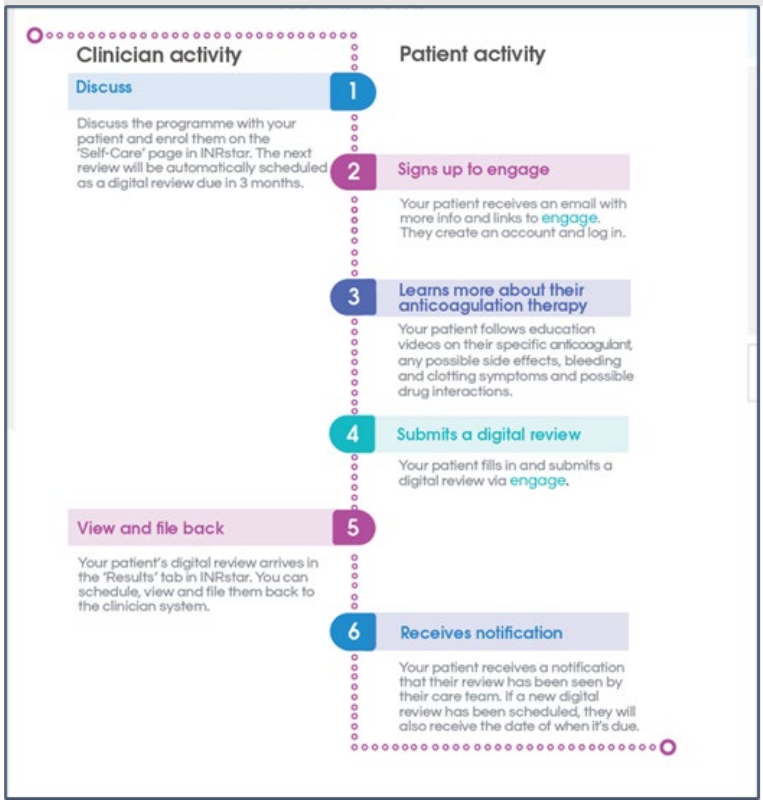
  When **'Save'** is clicked INRstar will automatically send the new schedule to your patient's INRstar Engage app.

Note: '**Skip or Boost**' is not enabled for patients using INRstar Engage.

18.7. DOAC Support Programme (DSP)

The programme helps patients to understand the benefits of their anticoagulation therapy and reinforces the importance of adherence. It also offers tailored educational videos about their anticoagulant and enables them to submit regular digital reviews helping service providers to follow NICE guidelines without significant impact on clinic time.

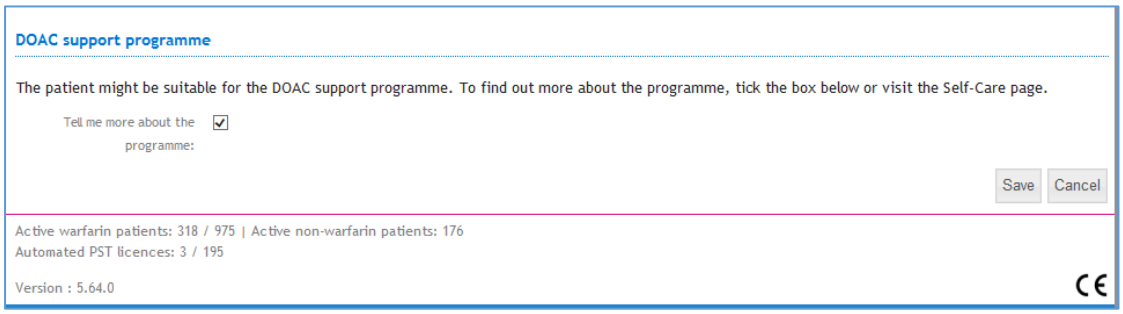
The flow chart below provides an overview of the DOAC review process in INRstar



18.7.1. Enrol Patient on a DOAC Support Programme

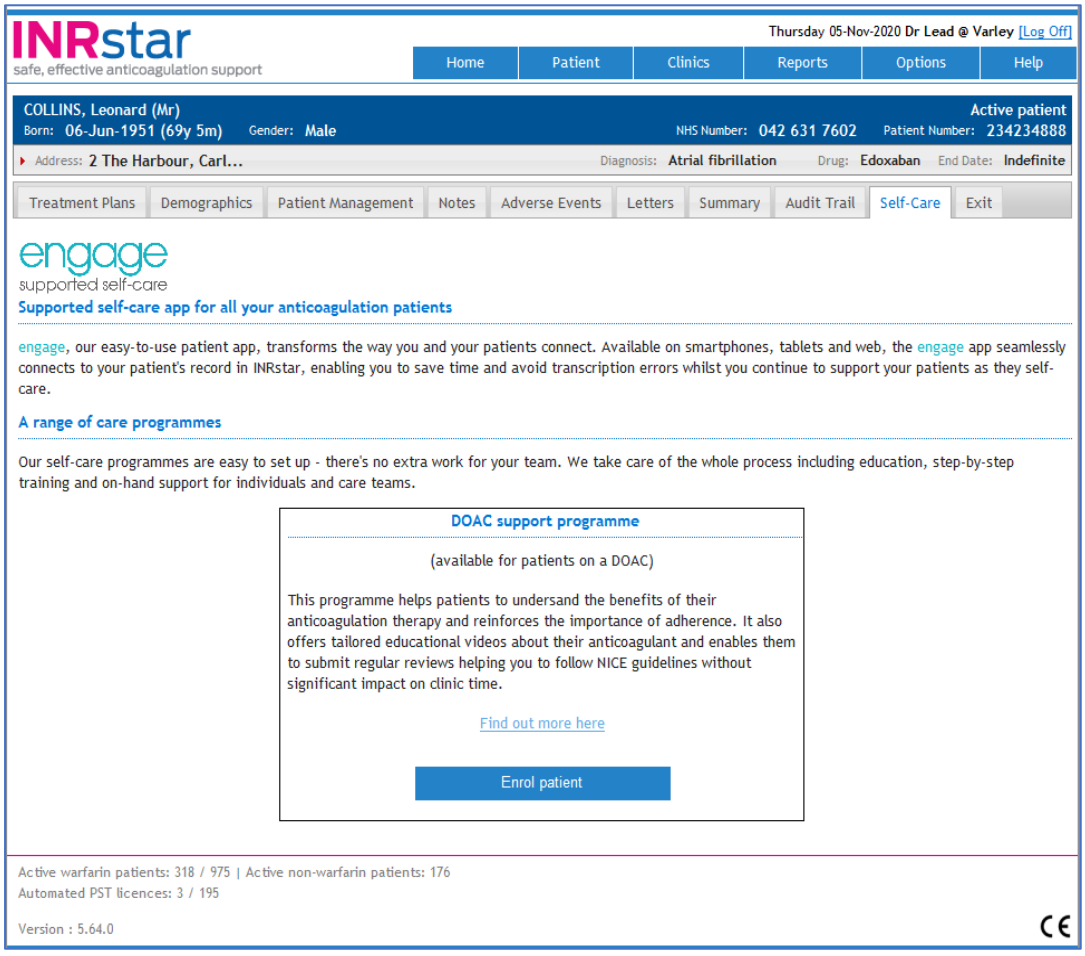
In the individual DOAC review, when the review is completed, the clinician could consider with the patient if the programme would be suitable.

Tick the box in '**DOAC support programme'** at the end of the review.



Note: the review must be saved.

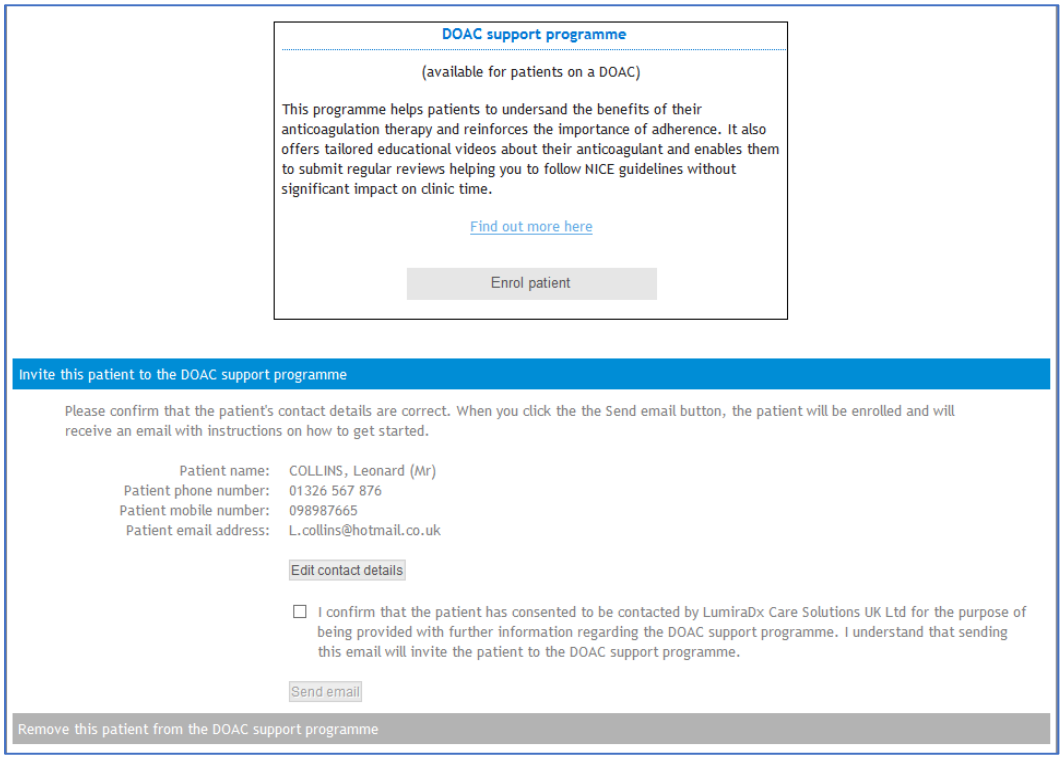
You will then be directed the '**Self-Care'** tab in the patient record:



Confirm the patient details:

- Name
- Phone numbers, mobile and landline
- Confirmed email address

Note: Click '**Edit details'** to make any changes.



Click to confirm that the patient has consented to be contacted by inVita intelligence Limited, for the purpose of being provided with further information regarding the DOAC support programme. Click '**Send email**'.

The patient will be emailed more information and links to enrol into the INRstar Engage app.

They will then be provided access to a series of videos to 'Learn more about anticoagulation therapy'. When the patient has followed the educational videos on their specific anticoagulant, possible side effects, bleeding, and clotting symptoms, and drug interactions they can confirm that they are ready to submit a review on a date decided by the managing clinician.

The patient receives a reminder that their DOAC digital review is due and completes the necessary information on their Phone app, iPad or computer.

The DOAC digital review details are received in the '**Results**' tab by the clinician managing the patient in INRstar and the information reviewed and filed back to the computer system in the normal way.

19. Clinics and Appointments

Where optionally enabled, the clinics and appointments feature allows you to view all your INR clinics and appointments.

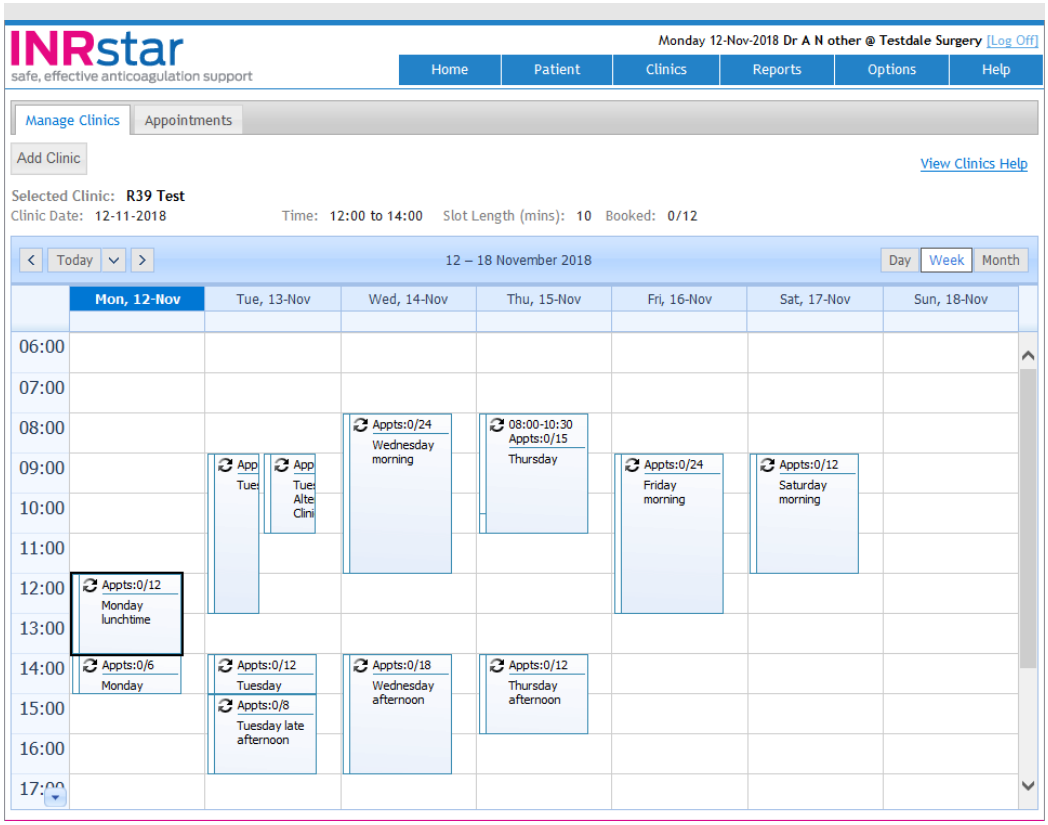
To book in and view appointments you must first set up your clinics. This will allow you to view all your INR clinics and appointments by month, week, or day. The day view provides a clear and easy layout for all the details to be displayed on the screen. This is particularly beneficial for services running multiple clinics at the same time.

19.1. Create a New Clinic

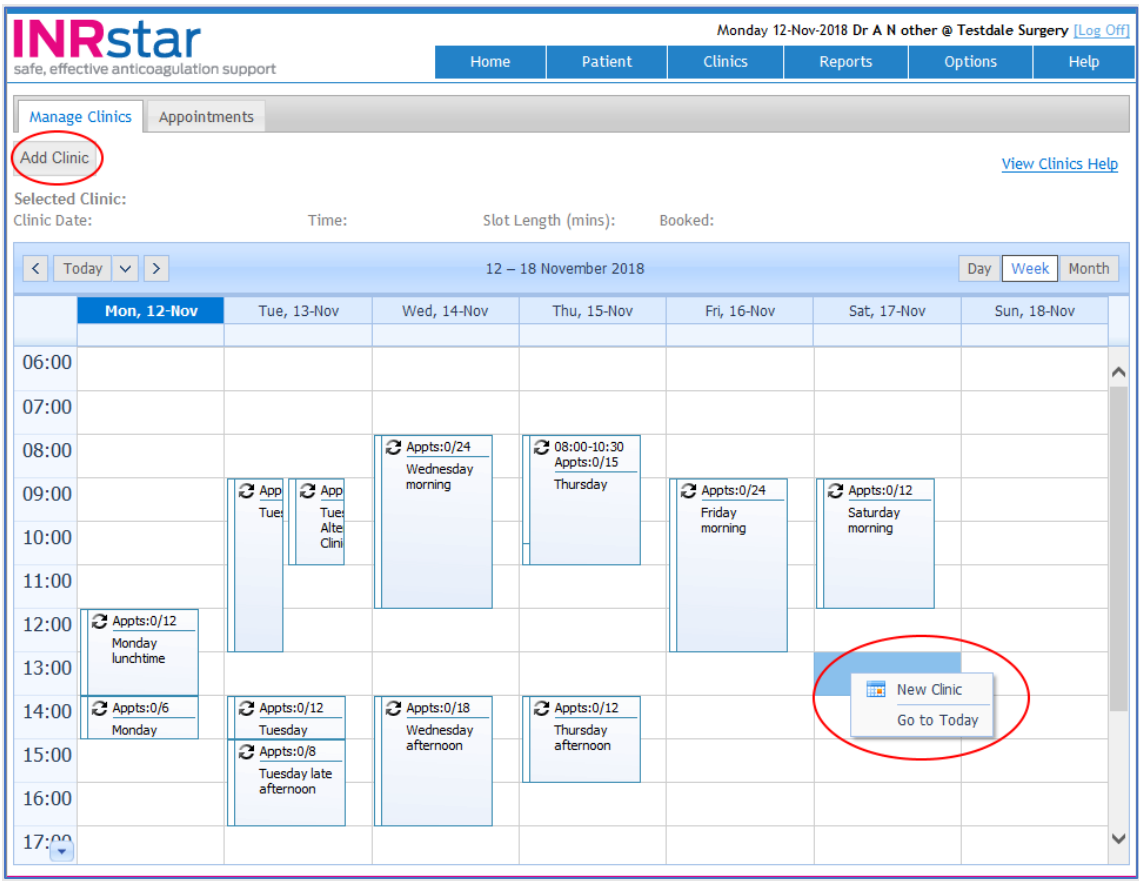
To create a new clinic, click on the **'Clinics'** tab on the INRstar blue navigation bar, then select the **'Manage Clinics'** tab.

A calendar will then be displayed, defaulting to the current week.

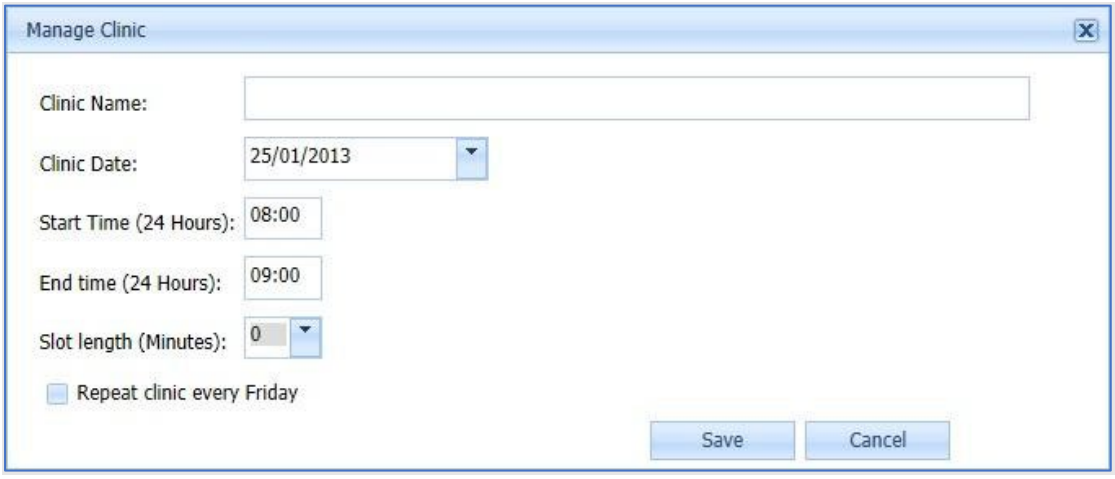
Clinics can be added on today's date and in the future. To select a date, you can either use the arrows located at the top left of the calendar to skip between weeks or click on the **'Month'** button located at the top right of the calendar to switch to month view.



To pick a time for the desired date, double click on the time slot and select **'New Clinic'** or click the **'Add Clinic'** button.



The **'Manage Clinic'** page will then be displayed. Enter a clinic name - we recommend that each clinic is given a different name - followed by a clinic date and start/end time.



Select an appointment length (slot length) for each patient appointment within this clinic, e.g. 10 minutes.

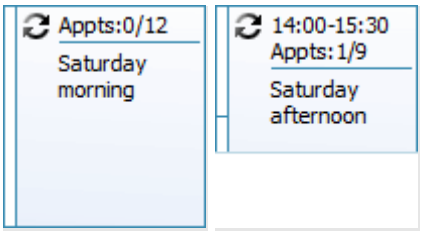
Appointment length can be a minimum of five minutes or maximum of 60 minutes. If your preferred appointment length is less than five minutes, e.g. two minutes, we recommend that two patients are added to a five-minute slot.

- For the clinic to repeat weekly for the selected day of the week click the check box named **'Repeat clinic every…'**.
- For the clinic to repeat every week with no end date, select the **'No end date'** option.
- For the clinic to repeat weekly until a certain date, e.g. 6 months in the future, choose the **'End by'** option and select a date.

When you have added all the required information click the **'Save'** button to save the clinic, or click the **'Cancel'** button to discard the changes.

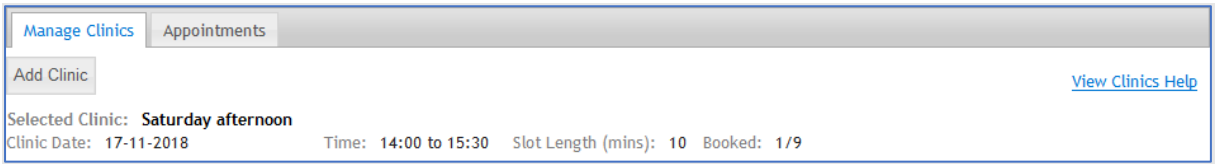
19.1.1. Clinic Details

Each clinic shows the clinic name, and the appointment slots booked out of the available appointment slots. If the clinic does not start or end on an exact hour, the clinic's run-time is also shown.



To view more information about the clinic, single click on the clinic and the following will be displayed at the top of the screen:

- '**Selected Clinic**' name.
- Selected '**Clinic Date**'.
- Selected clinic '**Time**' - 'from and to'.
- Selected clinic '**Slot Length**' in minutes.
- Number of appointments already '**Booked'** out in the selected clinic.

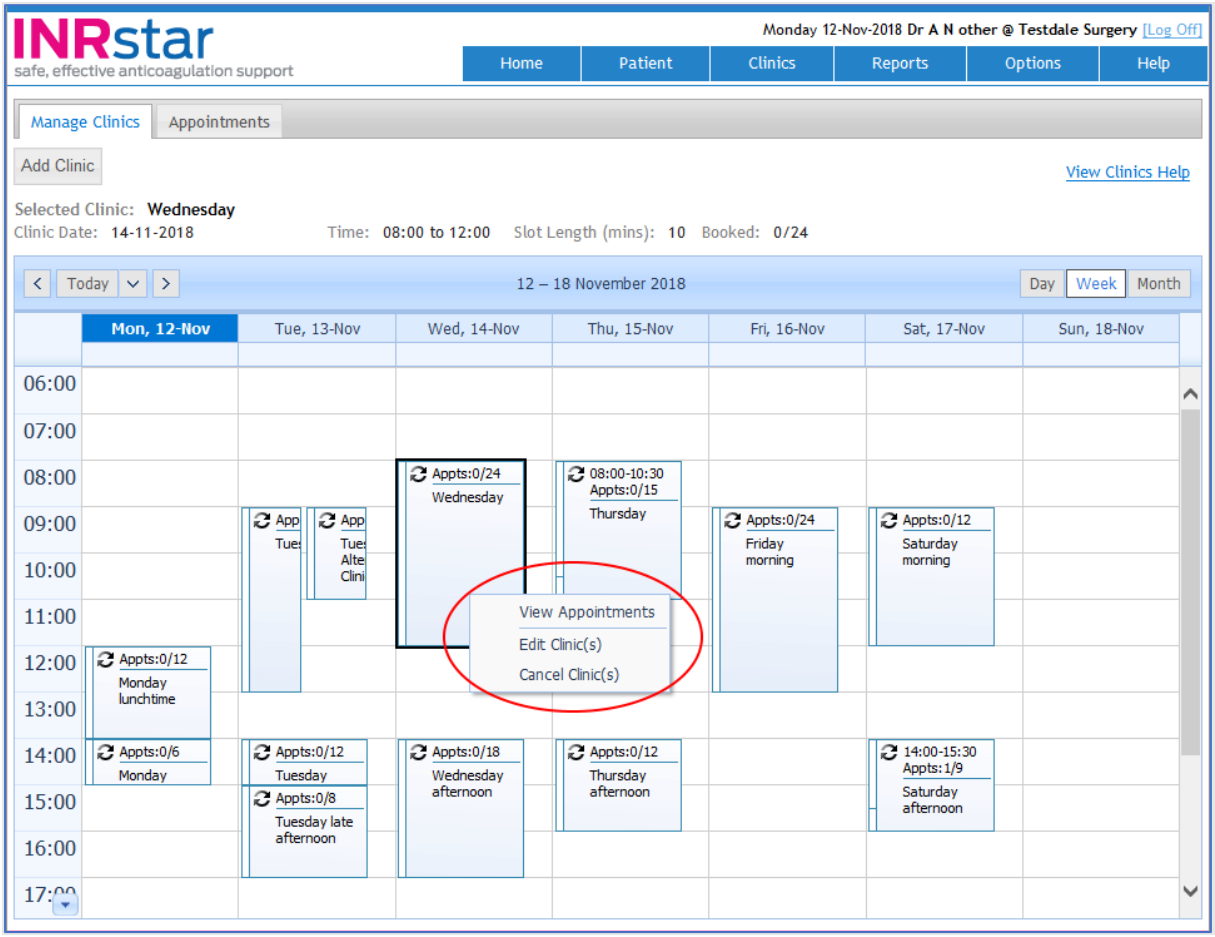


19.2. Edit a Clinic

To edit a clinic:

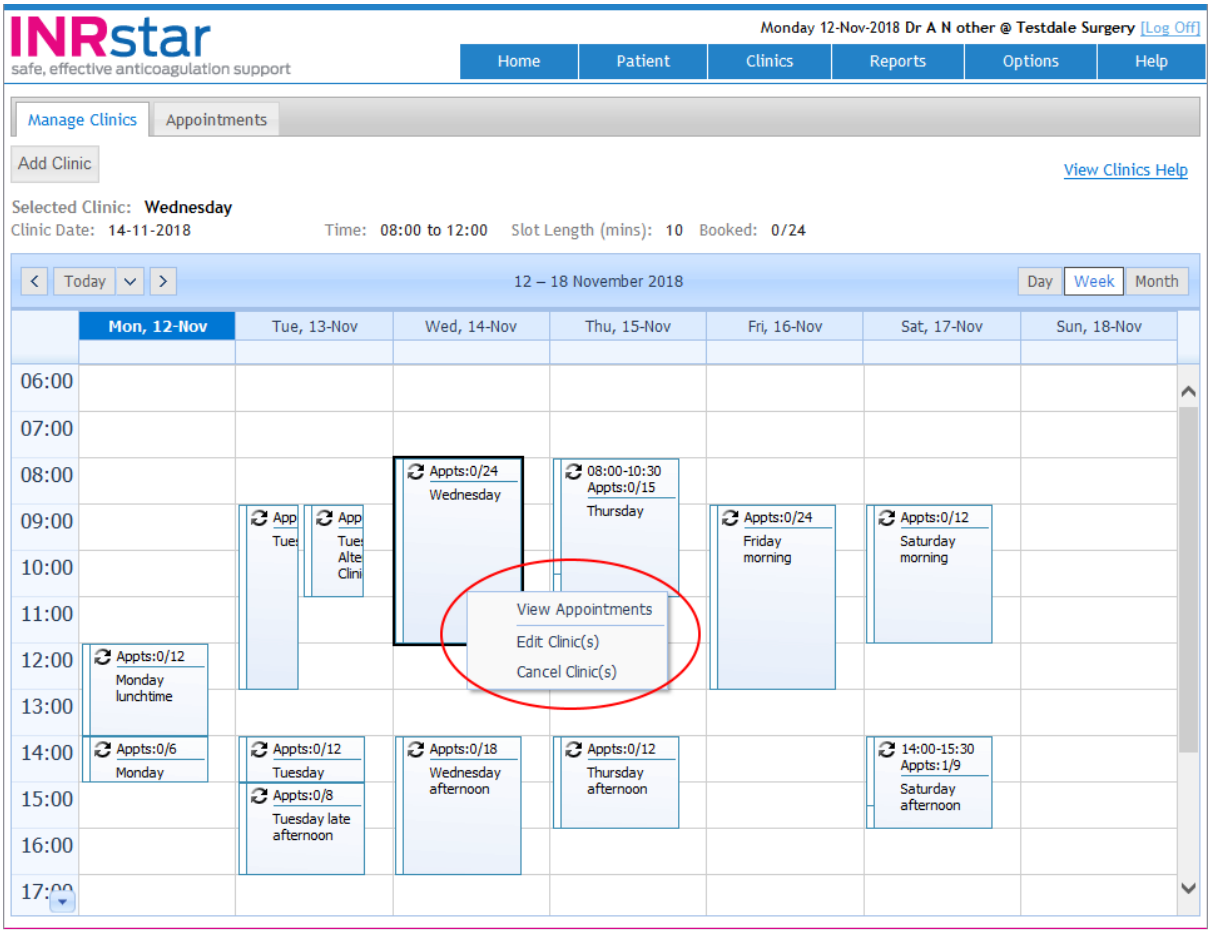
1. Click on the **'Clinics'** tab on the INRstar main navigation bar. If not selected by default, click on the **'Manage Clinics'** tab on the calendar.
2. Navigate to the date of the clinic you wish to edit.
3. Select the clinic by double clicking the clinic and then select the **'Edit Clinic(s)'** option.

Editing a clinic follows the same process as adding a clinic.



19.3. Cancel a Clinic

To cancel a clinic, double click on the required clinic and select the **'Cancel Clinic(s)'** option.



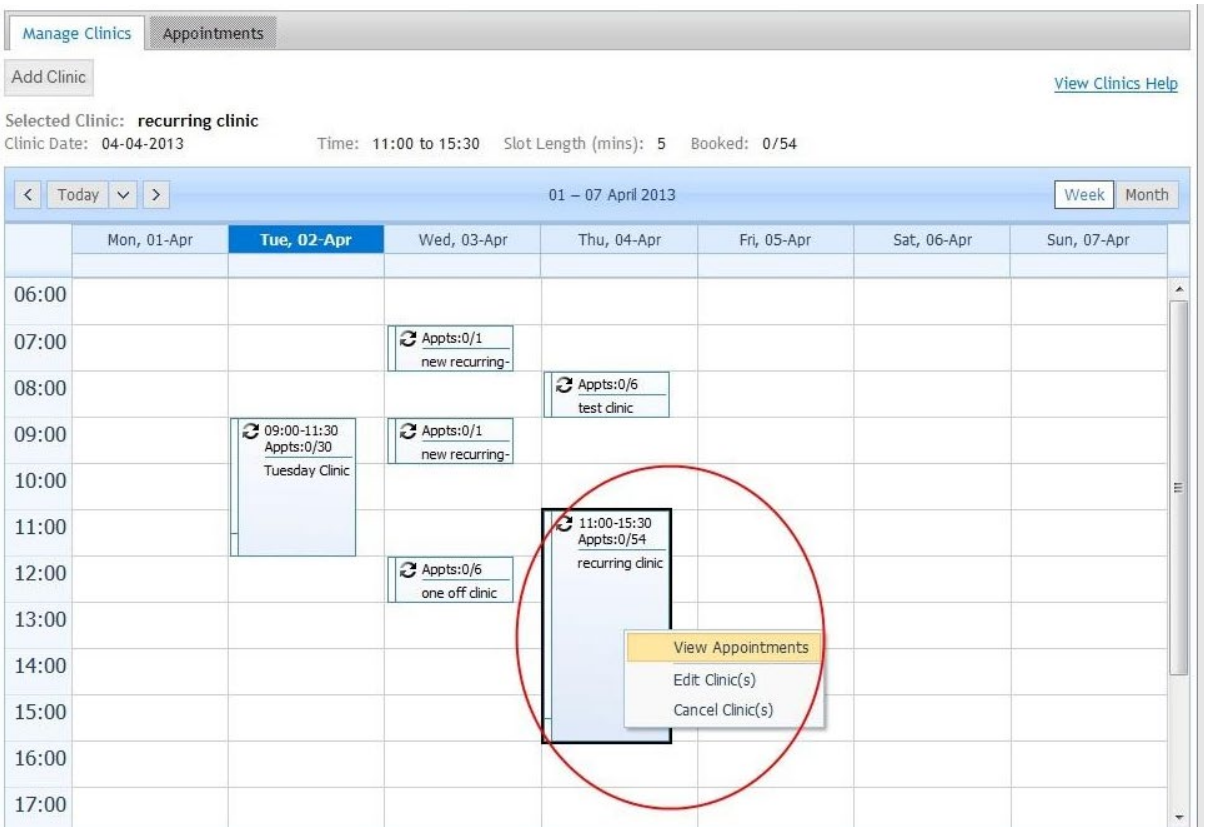
If the clinic is non-repeating, a popup is displayed where you can confirm cancellation of the clinic by clicking the **'Confirm'** button.

If you double clicked a repeating clinic, and there are no appointments in the series, you can cancel the specific clinic or cancel all clinics in the series.

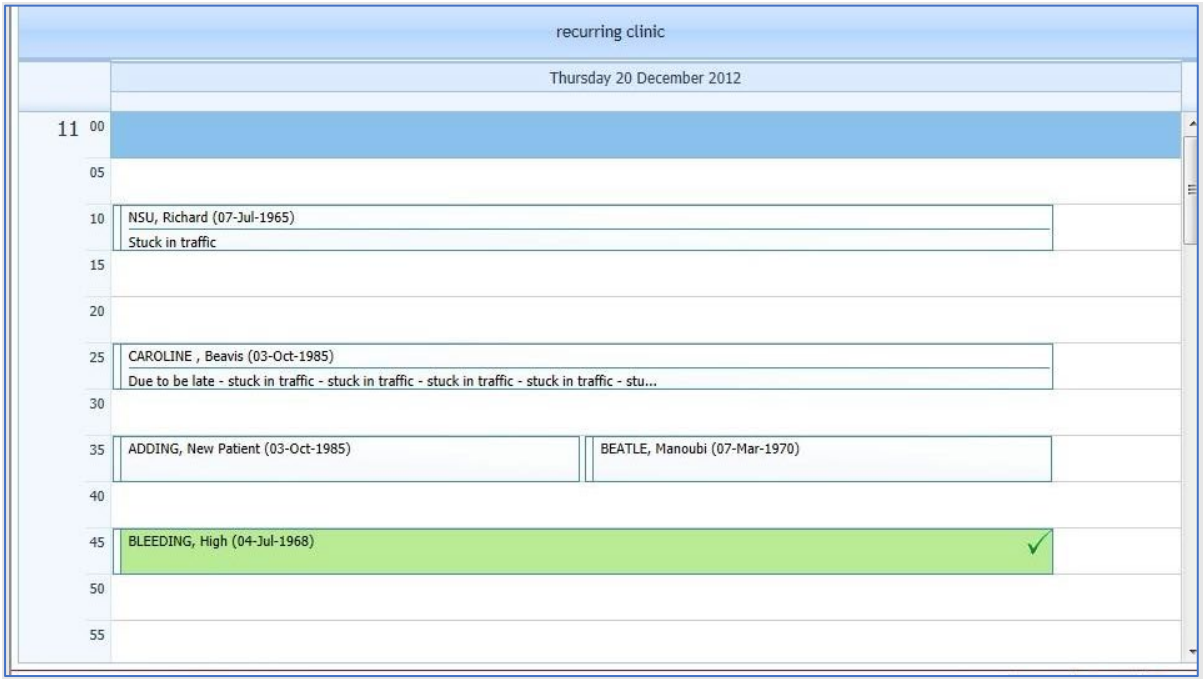
Note: To cancel a clinic with one or more occupied appointment slots, either cancel each appointment or set the clinic end date.

19.4. View Clinic Appointments

To view the names of patients booked in for clinic, double click on the required clinic and select the **'View Appointments'** option.



The **'Appointments'** list will then be displayed.



At the top of the page, the total number of appointments booked into the selected clinic is displayed.

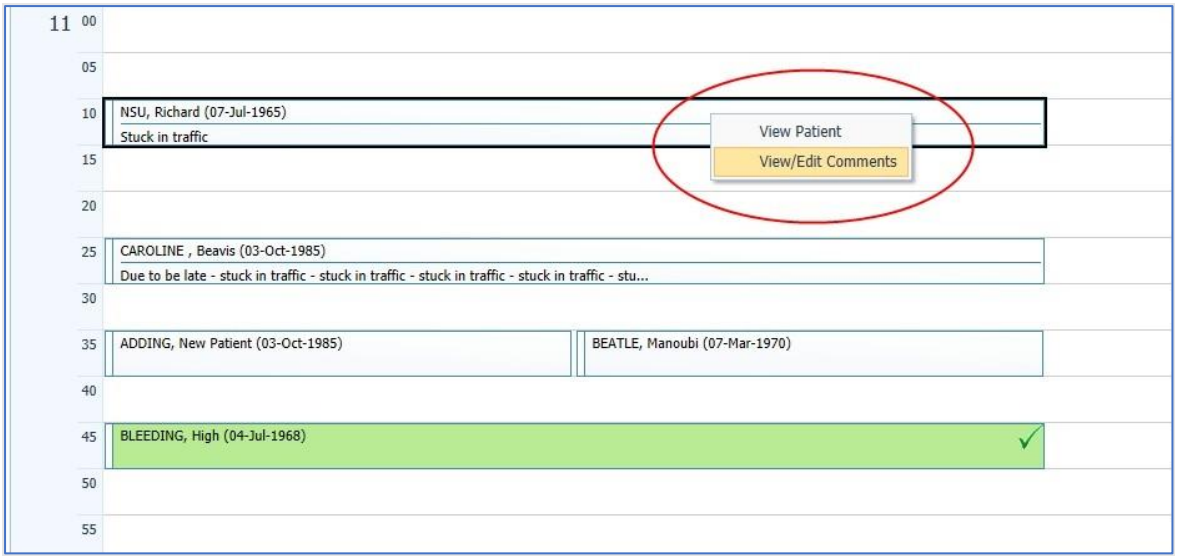
Each appointment shows the patient's name, DOB, and appointment comments, if any.

If a patient has turned up and had a treatment on the day of their appointment, the appointment background will be green and have a green tick, to show that it has been completed.

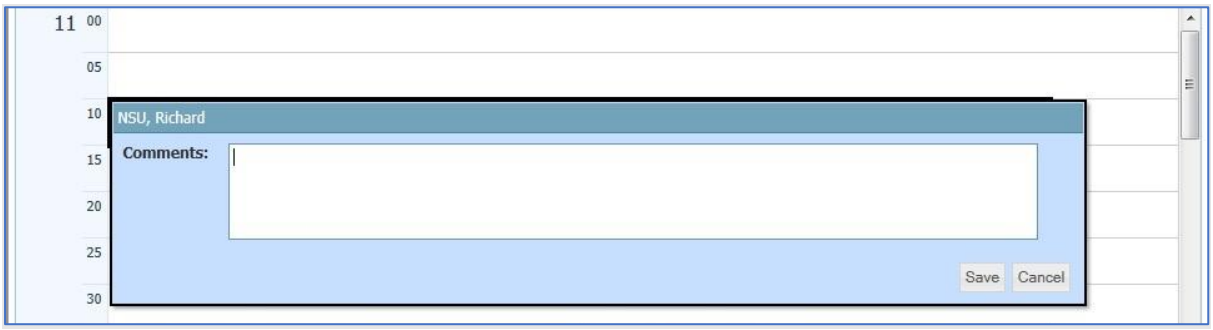
To navigate to a patient from the **'Appointments'** list, double click on an appointment and select the **'View Patient'** option.

19.5. View or Edit Appointment Comments

If you would like to add a comment to the appointment, double click the appointment and select **'View/Edit Comments'**.



- Type in the appointment comment and click the **'Save'** button.



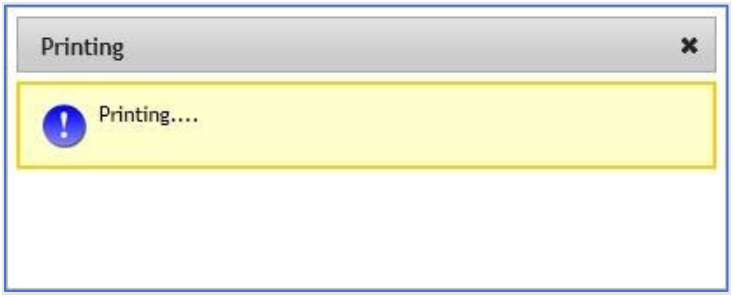
19.6. Print Appointments Lists

The **'Print Appointment List'** button produces a summary of the clinic, i.e. clinic name, date, start time, total booked appointments and total treated appointments, and a list of the patients with appointments within that clinic.

The status tells you whether this appointment was:

- **Booked** = Appointment booked but patient has not arrived for their appointment.
- **Treated** = Patient has been seen in the clinic and the appointment is complete.

To print a list of all appointments booked into a clinic you must first select a clinic by double clicking and selecting the **'View Appointments'** option. This will open the **'Appointments'** tab. Click on the **'Print Appointment List'** button in the top right corner to print a list of appointments in the selected clinic.

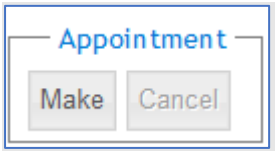


19.7. Make an Appointment

To create an appointment for a patient you must first select a patient.

Once you have selected a patient, click on the '**Treatment Plan'** tab.

Next click on either the **'Make'** button, located in the **'Appointment'** button group, or the calendar icon, located next to the patient's **'Next Test Date'**, in the same column.



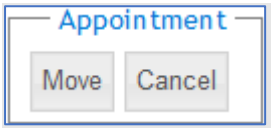
After the **'Make'** button or the calendar icon has been clicked a calendar is displayed showing the available clinics.

The calendar date defaults to the patient's **'Next Test Date'** set from their last treatment, with the date highlighted in a blue box. Today's date is also highlighted for your reference.

The patient's **'Next Test Date'** and **'Review'** period is displayed at the top of the screen.

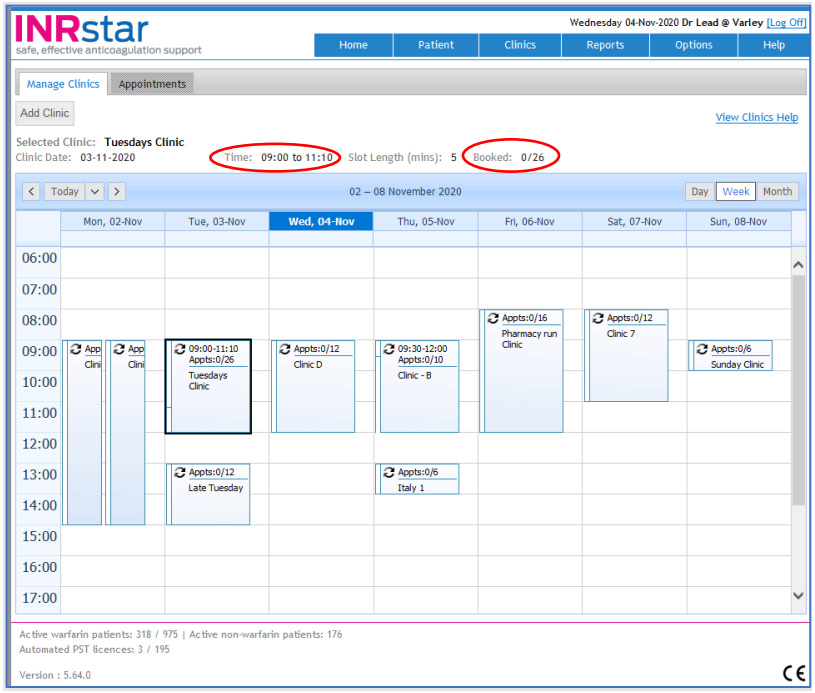
19.8. Cancel Appointments

- It is possible to change the '**Next Review Date**' and this will then cancel any associated clinic appointment.
- If the clinic appointment is moved, this will also change the associated **'Next Review Date'**.
- If the clinic appointment is cancelled, the '**Next Review Date'** will be retained.



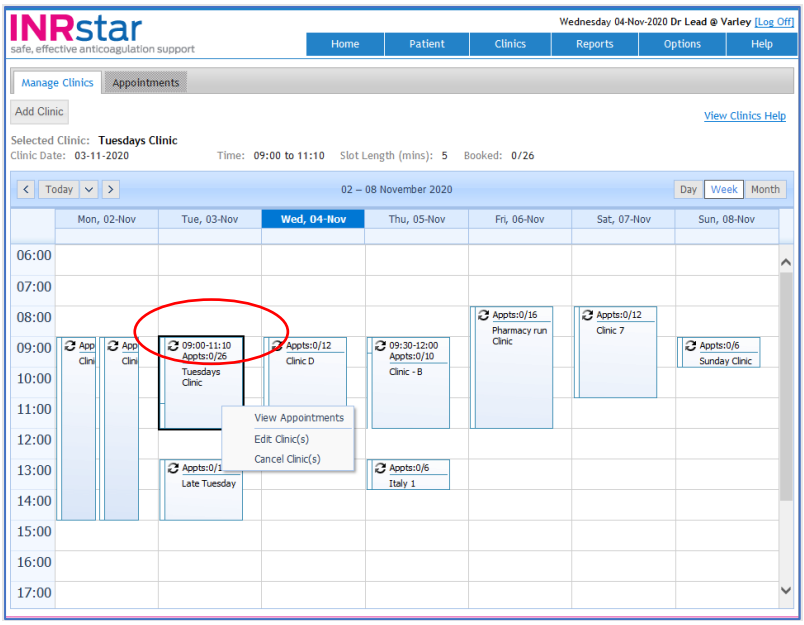
You can see more information about a clinic you have selected at the top of the screen:

- Selected clinic name.
- Number of appointments already booked into the selected clinic.

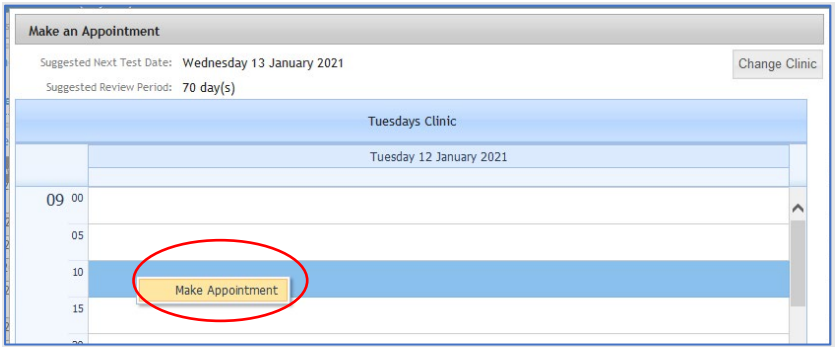


Important: If there is a clinic on the specified **'Next Test Date'** and the patient can make an appointment on this date, it is important that this clinic is selected for the patient's next appointment.

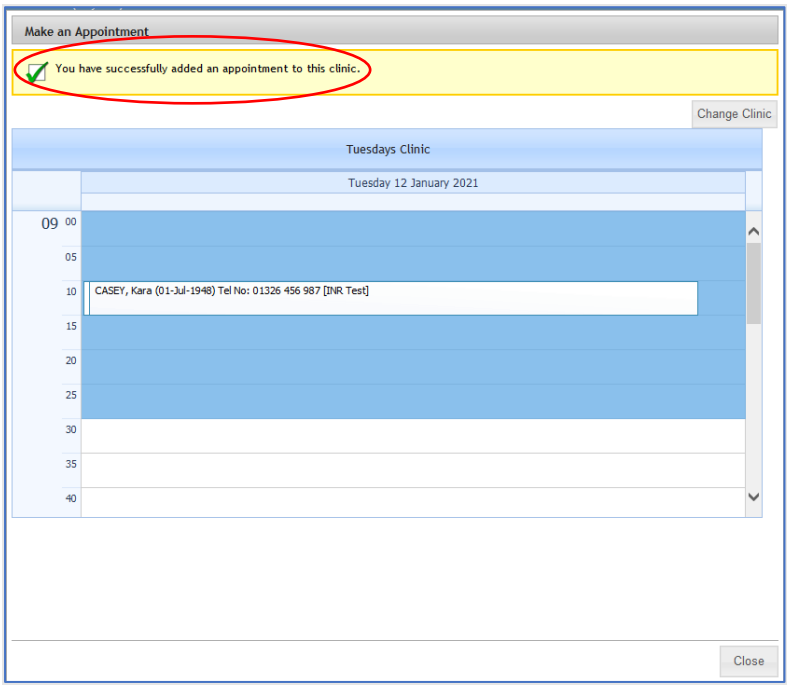
To add an appointment to a clinic, double click the required clinic and select the **'Select This Clinic'** option.



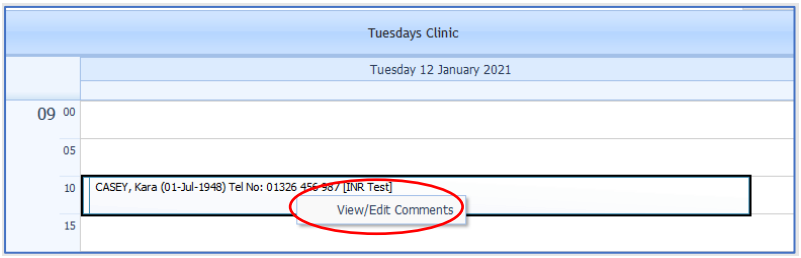
The **'Make an Appointment'** form will then be displayed, with the clinic divided into time slots. To make an appointment double click the applicable time slot and select the **'Make Appointment'** option. You can select multiple slots if you need to see the patient for a longer period: drag the mouse over the period you wish to move it to and right click for the option **'Move appointment'.**



After selecting the **'Make Appointment'** option you will see that the **'Make an Appointment'** form has been updated and an appointment for the selected patient has been added.



If you would like to add a comment to the appointment, double click the appointment and select **'View/Edit Comments'**.



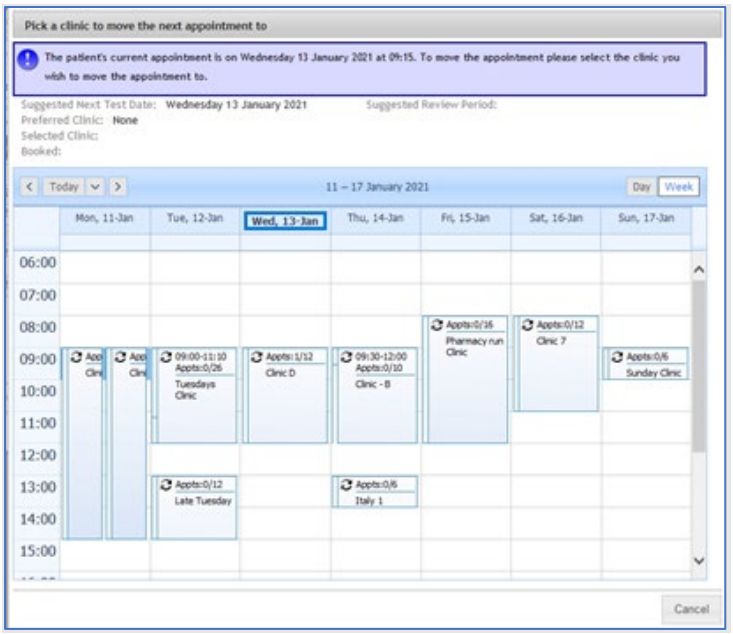
Type in the appointment comment and click the **'Save'** button.

19.9. Changes to Scheduled Appointments

To change a patient's appointment time or date the same process should be followed as making an appointment.

Once you have selected a patient, click on the **'Treatment Plan'** tab. Then click on either the **'Move'** button, located in the **'Appointment'** button group, or the calendar icon, located next to the patient's **'Next Test Date'** of their last treatment.

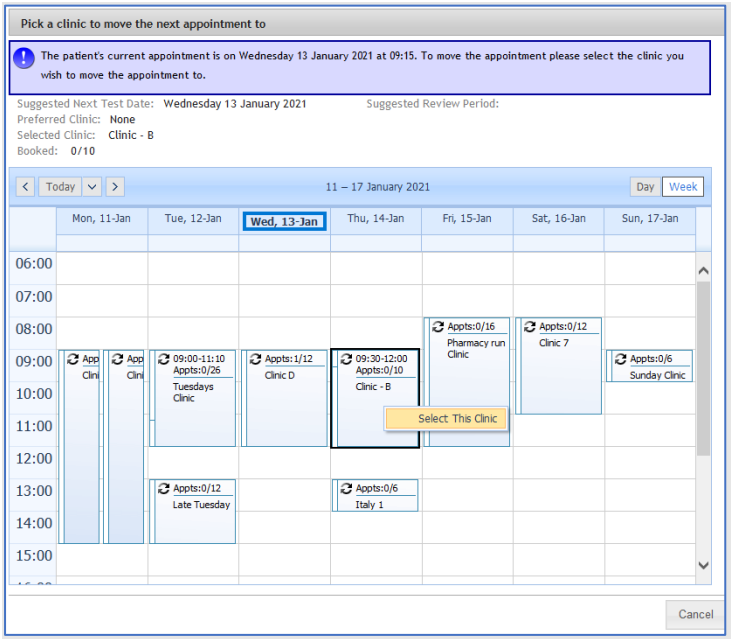
After the **'Move'** button or the calendar icon has been clicked a pop-up calendar displays available clinics. The calendar date defaults to the patient's next appointment date, with the date being highlighted in blue.



You can see more information about a clinic you have selected at the top of the screen:

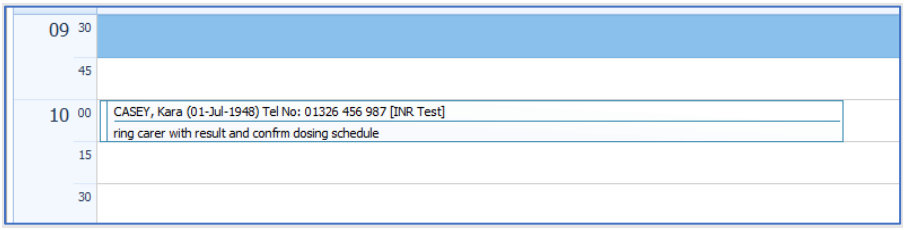
- Selected clinic name.
- Number of appointments already booked out in the selected clinic.

Double click or right click the clinic you wish to move the appointment to; select the **'Select This Clinic'** option.



The **'Move Appointment'** form will then be displayed. To move an appointment, double click or right click the applicable time slot and select the **'Move Appointment Here'** option.

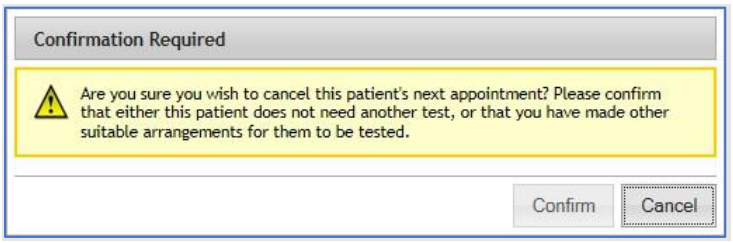
After selecting **'Move Appointment Here'** you will see that the **'Move Appointment'** form has been updated and an appointment for the selected patient has been moved to the clinic and time specified.



19.10. Cancel an Appointment

To cancel an appointment for a patient you must first select a patient. Next, click on the **'Treatment Plan'** tab and click the **'Cancel'** button located in the **'Appointment'** button group.

When the **'Cancel'** button is clicked a confirmation box is displayed to request you confirm cancellation of the patient's appointment. Click the **'Confirm'** button to cancel the appointment.



19.11. Create a Review Appointment

When a user is making the appointment in a clinic, they can select multiple time slots if appropriate.

If the user chooses a date for the review that is different to the **'Next Review Date'**, the associated **'Next Review Date'** will be changed to match. A **'Next Review Date'** appointment can only be selected from today to 13 months in the future.

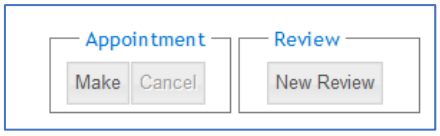
19.11.1. Move or Cancel a Review Appointment

Moving or cancelling an appointment makes it possible to change the **'Next Review Date'** and will cancel any associated clinic appointment.

If the clinic appointment is moved, this will also change the associated **'Next Review Date'**.

If the clinic appointment is cancelled, the **'Next Review Date'** will be retained.

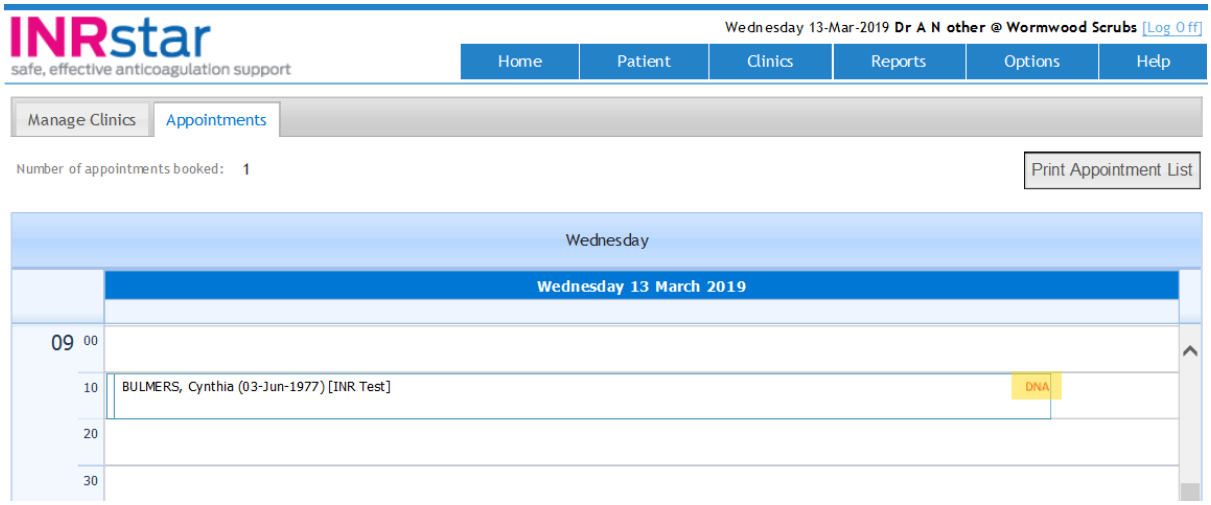
You will see this button on the reviews page:



Note: If a new Vitamin K Antagonist treatment plan is added with a start date over 12 months in the past, the **'Next Review Date'** will also be set in the past – the **'Next Review Date'** is automatically calculated as the treatment plan start date, plus 12 months.

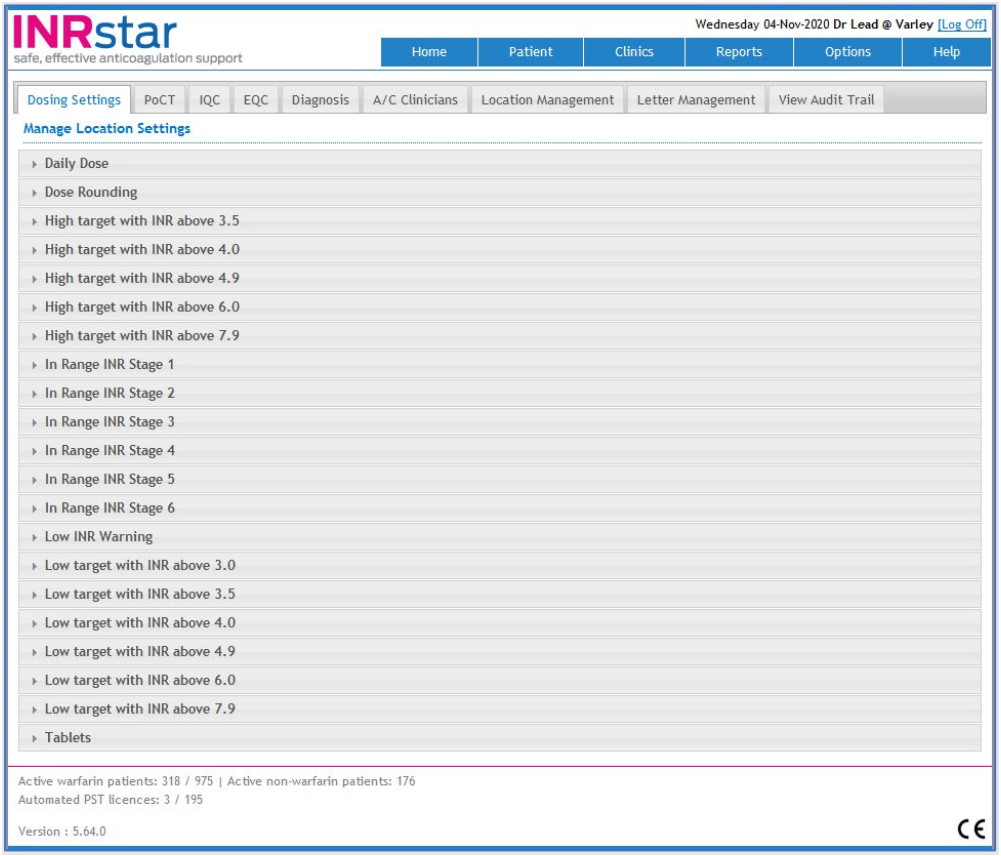
19.12. DNA (Did Not Attend) in Appointment

If you have marked a test date **'DNA'** for 'Did Not Attend' (see section 16.18 DNA (Did Not Attend)), 'DNA' will appear in the relevant Appointment Screen:



20. Options

The INRstar '**Options**' menu is divided into several sections separated by tabs. Click on these to open.



20.1. Dose Settings

These details are managed by the '**Organisation Clinical Lead**' and set the clinical rules for the dosing of patients using warfarin.

The '**Dosing Settings'** information can be viewed by any '**User'** but can only be changed by an '**Organisation Clinical Lead'** User. The values set within the '**Dosing Settings'** affect each location equally, so need to be agreed by the Clinical Lead(s) of the Practice or Organisation.

Note:

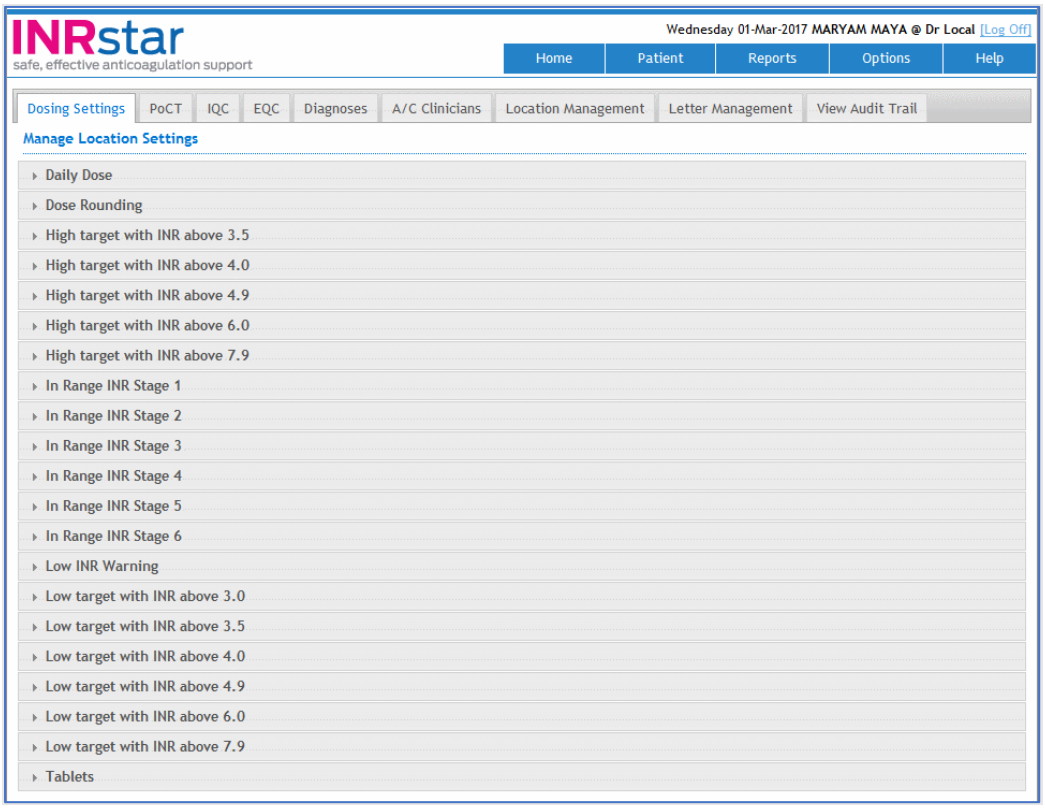
- **Changes to the default settings could have significant consequences to the dosing suggestions made by the software.**
- The '**Organisation Clinical Lead**' role should only be held by a Registered and Regulated Health Care professional with sufficient knowledge, training and experience in anticoagulation management to undertake these responsibilities.

1. In **'Dosing Settings'** and **'Manage Location Settings'** screen click on the settings title that you want to edit.

2. Click the **'Edit'** button.

Edit the setting by using the dropdown list or textbox.

3. Click the **'Save'** button to save your changes.



Daily Dose

- This option allows the setting of the maximum daily dose which INRstar will allow to be calculated and for which a schedule will be suggested.

Dose Rounding

- This option allows the setting of the optional threshold above which INRstar will round dose values to the nearest 0.5mg. See the section 'Dosing Issue (tablet strength) Rounding' for further information.

Low Target INRs

- INRstar defines a **Low Target** as any **Target INR** up to and including 2.9.

High Target INRs

- INRstar defines a **High Target** as any **Target INR** as 3 or above.

If a patient's INR value is over the patient's **Target INR** range (**Target INR** plus 0.5), the amount of difference between the **Target INR** and actual INR is graded into bands.

For each band, the dose calculation parameters and review period values can be adjusted from the default values.

Target INR above 3.5, 4.0, 5.0, 6.0, and 7.9 the following parameters can be changed:

- Omit days.
- Reduce percentage of current INR dose.
- Amend the recommended review period for the patient.

Note: A warning message to be displayed to the clinician, should the INR invoke these conditions.

In Range INR Stages

There are 6 **'In Range'** INR stages which can be adjusted to suggest the recommended **'Review Period'** for cumulative consecutive **'INR Range'** values.

The default review period values are 7 days, 14 days, 28 days, 42 days, 56 days, and 70 days.

These settings can be modified by the **'Organisation Clinical Lead'** to comply with local guidelines. The maximum review period can be increased to **84** days.

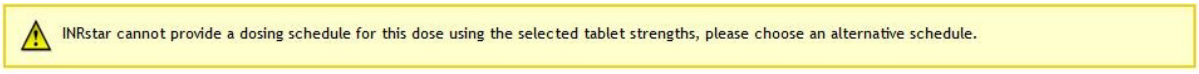
Note: The maximum review period of 70 days is recommended.

Tablets

- This option allows the default tablet settings to be set for all new patients.
- Changes to these values will not affect any existing patient's details.

20.1.1. Dosing Issue (tablet strength) Rounding

Sometimes it is mathematically impossible to create a dosing schedule for the suggested dose using the tablet strengths selected for the patient. For example a 0.5mg tablet is needed to create a suggested dose ending in 0.8 or 0.2, over a 7 day review period.



If this happens INRstar will give you the option to choose from a list of all available schedules. This includes using different tablets to obtain the exact dose, or using the tablets you have selected but a slightly alternative dose. The alternate doses are usually 0.1mg higher or lower per day. You will need to scroll down the schedules to view all suggestions.

Delivered Dose	Tablets Used	
2.8mg	0.5mg	Use
2.8mg	0.5mg, 1mg	Use
2.8mg	0.5mg, 3mg	Use
2.8mg	0.5mg, 1mg, 3mg	Use
2.7mg	1mg, 3mg	Use
2.7mg	3mg, 5mg	Use
2.7mg	0.5mg, 1mg	Use

To select a schedule, click the '**Use**' button on the right hand side of the screen. INRstar will then produce the dosing diary and the treatment can then be processed as normal.

Please note INRstar will never force you to use 0.5mg tablets, you always have the choice to select an alternative dose.

The **Dose Rounding** setting has the effect of rounding all daily doses at your practice to the nearest half-milligram.

In the above example, dose rounding is applied to all daily doses below 10mg.

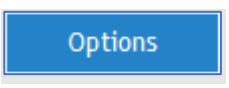
Refer also to 'Appendix B - NPSA Dosing Guidelines' for Q&As.

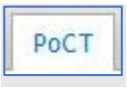
20.2. Point of Care Testing (PoCT)

This section allows the recording of the batches of test strip that are in use at the location.

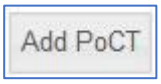
When starting a new batch of test strips, the user should add the batch number and expiry date in INRstar.

The PoCT batch number and expiry date of the testing kit consumables are documented in INRstar so users can track the use of INR testing consumables. This will allow the tracking of consumables against the testing of individual patients for Quality Assurance purposes.

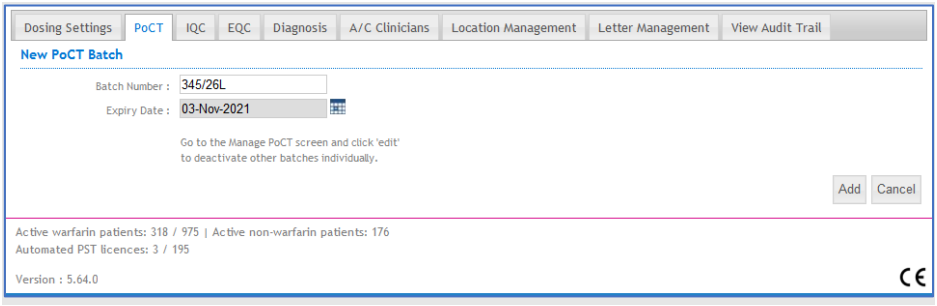
1. Click the 

button.
2. Click the 

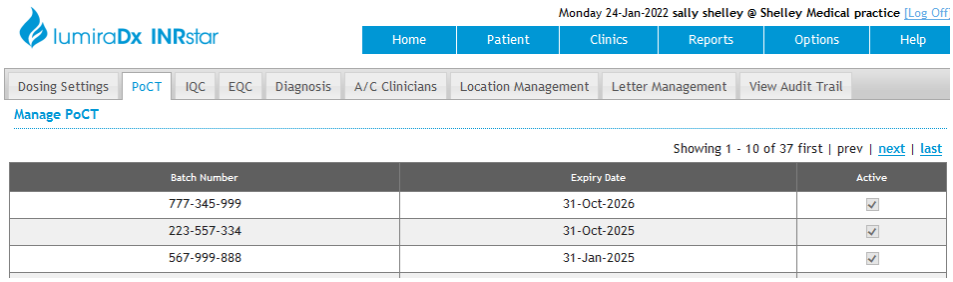
tab.

3. Click the button 

to add a new batch of test consumables. Add the Batch number - it is recommended to use two key identifiers where available, i.e. the Pot code chip number and lot number of the batch e.g. 444-6123456; set the expiry date using the calendar. Click '**Add**' or **'Cancel'.**

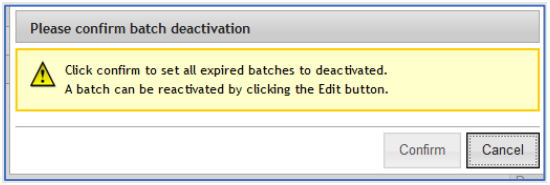


A list of recorded PoCT batches will be displayed:



The user has the option to deactivate expired batches:

- Click to remove the tick in the **'Active'** list box**.**



- Tick the checkboxes in the '**Active'** column next to the amend the PoCT batch details.

4. Click the 

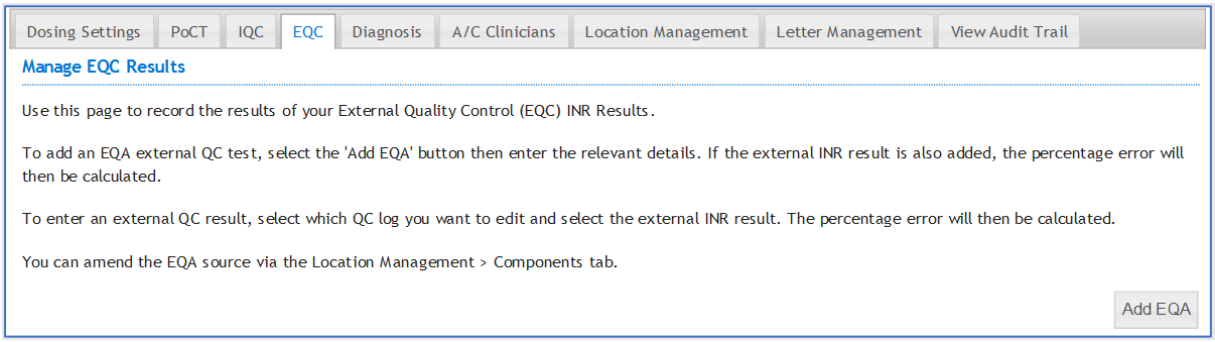
button.

Now when creating a new individual treatment, you can choose which PoCT batch that you are using for that treatment or will be prepopulated automatically if using the LumiraDx Instrument.

20.3. EQC Results

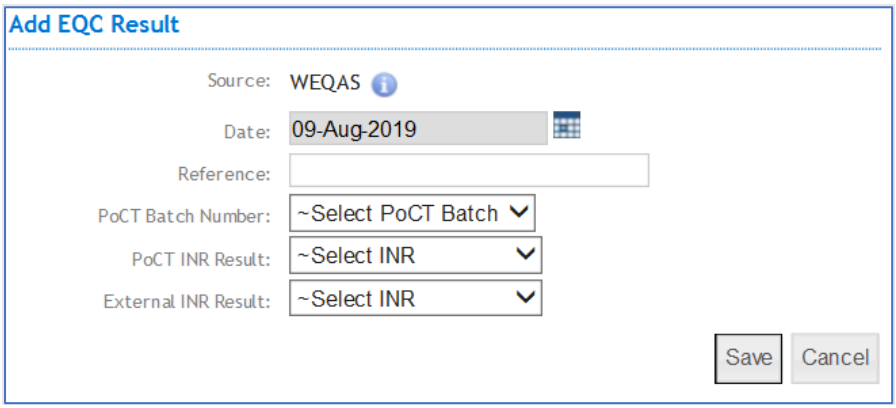
The **'EQC'** section in **'Options'** provides an area to record and document for audit purposes external quality control tests on the point of care testing device or individual patient parallel venous samples.

Note: The EQA SOURCE value is pre-set, according to your location's preferred EQA supplier in '**Options'**, '**Location management', 'Component', 'EQC'** source to amend and reflect the centre used.



In '**Manage EQC'** results:

- Click **'Add EQA'** to add details.



In **'Add EQC Result'** enter the details for the EQA result:

- **Date** of test: Date samples taken.
- **Reference**: Survey details e.g. 36\CUC XS: March 2020.
- **PoCT Batch Number**: Select from the drop down. **Note:** This could also be the Code Chip number found on the pot of strips. Two key identifiers are recommended i.e. the Pot code chip number and lot number of the batch e.g. 444-6123456.
- **PoCT INR Result**: e.g. 2.4 (test sample result).
- **External INR Result**: Instrument Median INR.

Note: You can enter in the **External INR Result** later.

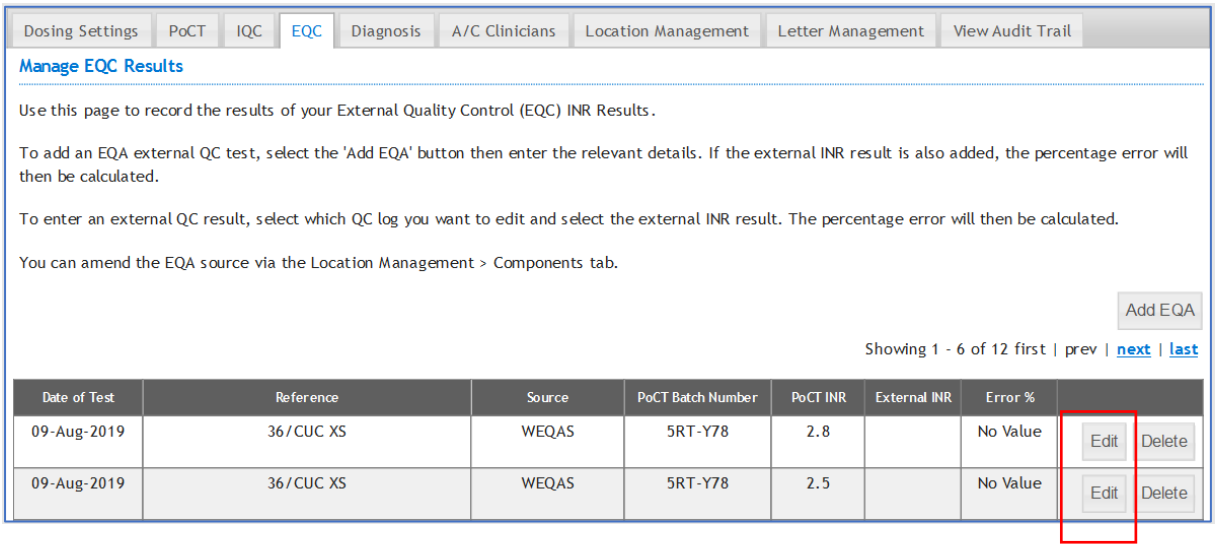
To complete the record, click '**Save**'.

Note:

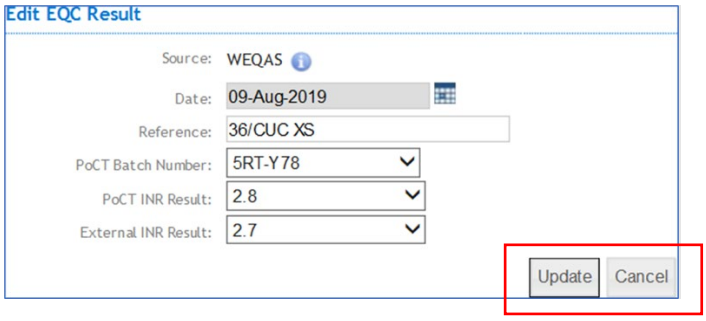
- There are always TWO sample test results to enter - please repeat this process again for the second sample.
- The percentage error for each test will not be calculated until the External INR Result is entered.

To enter the '**External INR Result'** later, simply click on 

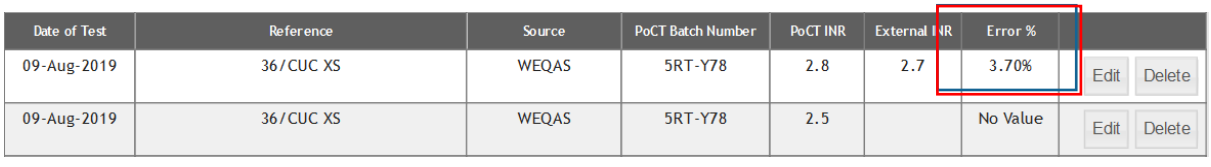
, find the test you want to add the result to and click '**Edit'**



- Add your result, then click **'Update'**:

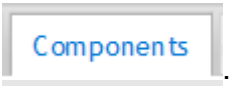


Your results can be viewed in the **'Manage EQA Result'** tab:

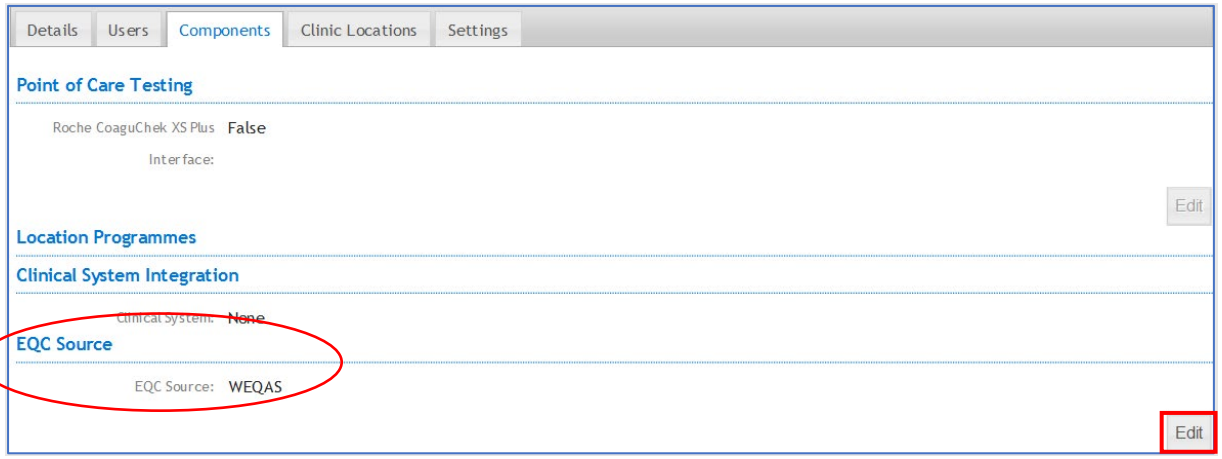


INRstar can record External Quality Assessment results from three independent organisations.

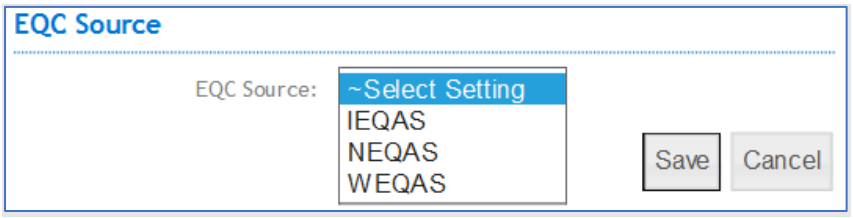
You can select which of these is your preferred supplier:

1. In '**Options**' click on '**Location Management'** and then 

.
2. In the **'Components'** tab select '**EQC source'** and '**Edit'** to reveal a drop down list of options.



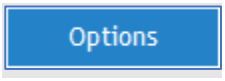
3. Select the **'EQC Source**':



4. Then click **'Save'** or **'Cancel'**.

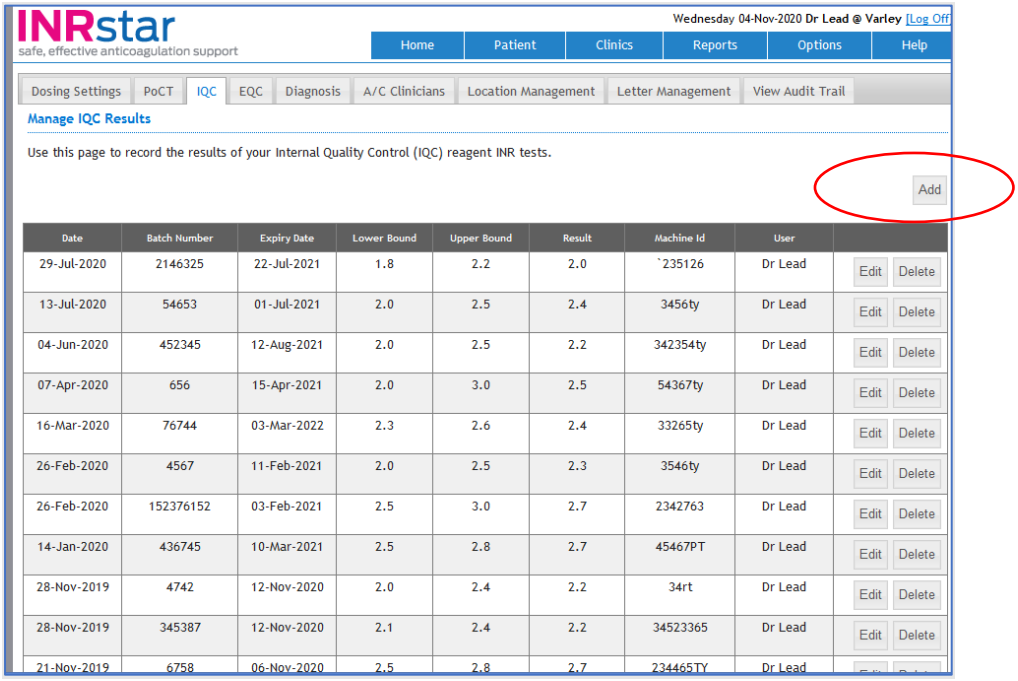
20.4. Internal Quality Control (IQC)

This section allows the INRstar user to document and record the IQC test details for audit purposes.

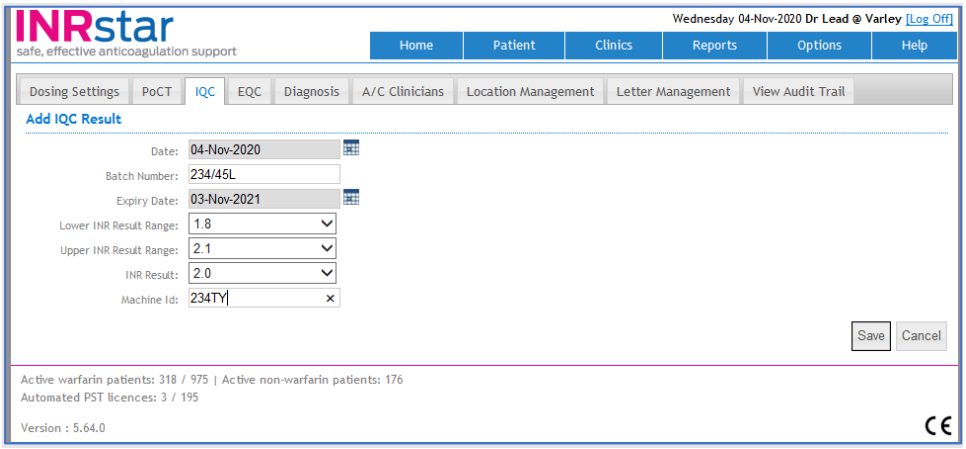
1. First click the 

button.
2. Then click the 

tab.
3. Click the **'Add'** button shown in the screen below:



4. Add the details of the IQC result and the following information:

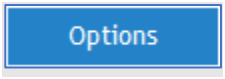


- The '**Date'** – the default date is today.
- The '**Batch number'** identification (Lot number) of the QC material you are testing.
- The '**Expiry Date**' of that Quality Control material.
- You will have entered the latest batch number, together with the expiry date in the '**PoCT'** tab in **'Options'**.
- The **'Lower INR Result Range'** of acceptable measured values – from the package insert.
- The '**Upper INR Result Range'** of acceptable measured values – from the package insert.

- The '**INR result'** you obtain from your test.
- The **'Machine ID'** - A local code (or serial number) to positively identify the test machine you used.

5. Once you have completed the data entry, click **'Save'**.

20.4.1. Edit an IQC result

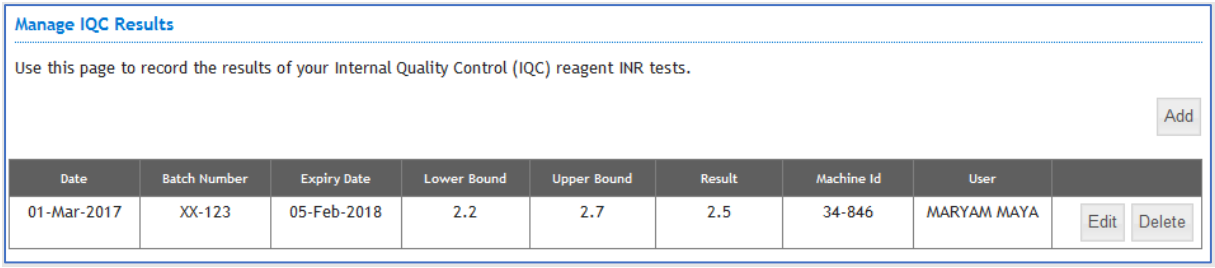
1. First click the 

button.

2. Then click the 

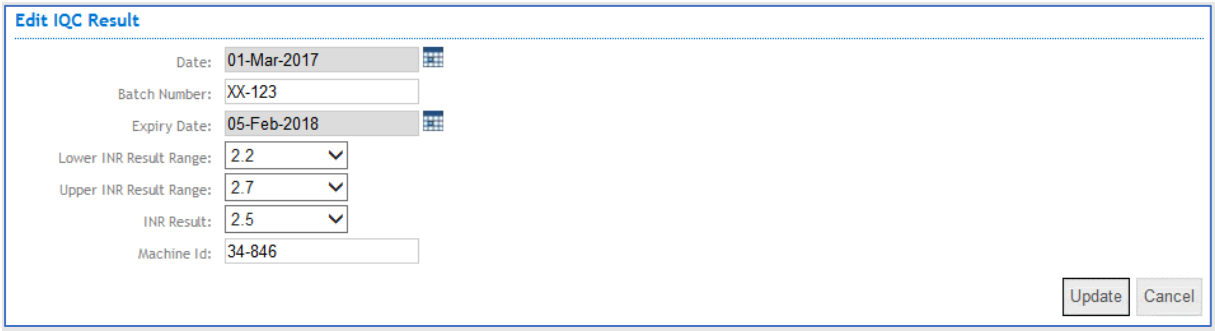
tab.

On **'Manage IQC Results'**, the IQC log will be displayed. Each row will show the date and result of the PoCT INR test, the batch number of the POCT reagent used for the test, the upper and lower bound result range, machine ID and name of the user.



3. Identify the correct IQC result and click the '**Edit**' button.

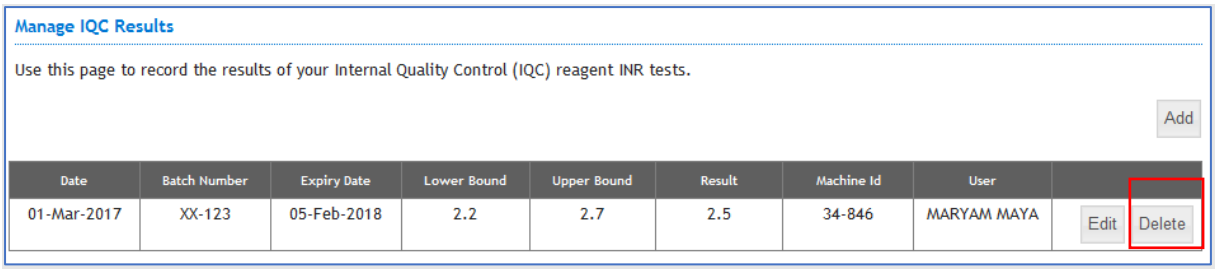
   This will open a window which allows any of the data to be altered:



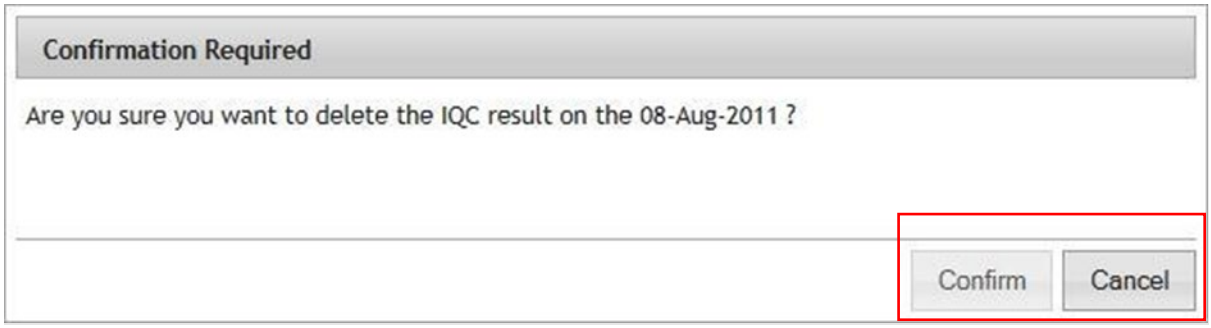
4. Click '**Update**' to record the amended IQC details to the database.

20.4.2. Delete an IQC result

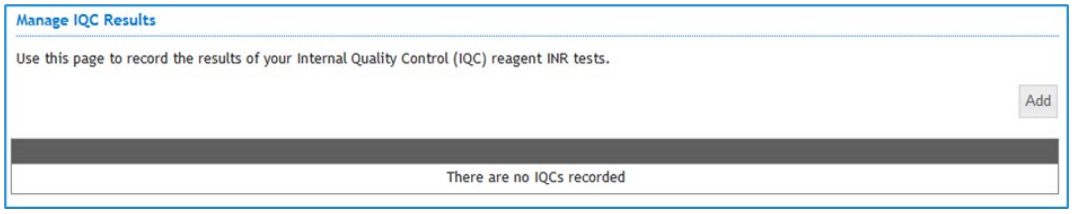
1. Navigate to the Options tab.
2. Select the IQC tab.



3. Click '**Delete**'.



4. A **'Confirmation Required'** message will appear to allow to user to '**Confirm**' or **'Cancel'** the data entry.



Once confirmed, the **IQC** record is removed.

20.5. Diagnosis

INRstar has a standard set of published Diagnoses which are suitable for treatment with anticoagulation drugs. INRstar supports the following anticoagulation drugs:

- Warfarin
- Acenacoumarol
- Apixaban
- Dabigatran
- Dalteparin (LMWH)
- Rivaroxaban
- Edoxaban
- Enoxaparin (LMWH)

Each warfarin diagnosis has a recommended ‘Target INR’ and 'Duration’ of treatment.

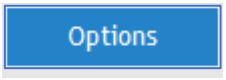
Unlisted diagnoses can be added to INRstar, but they will currently only be available for warfarin treatments plans.

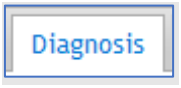
These details are managed by the organisation clinical lead. They define the standard diagnoses with their recommended treatment duration and target INR duration and target INR.

20.5.1. Adding a New diagnosis

Note: Do not add a new diagnosis if the only difference is the Target INR. Use the patient’s individual Treatment Plan to set the specific, non-standard Target INR.

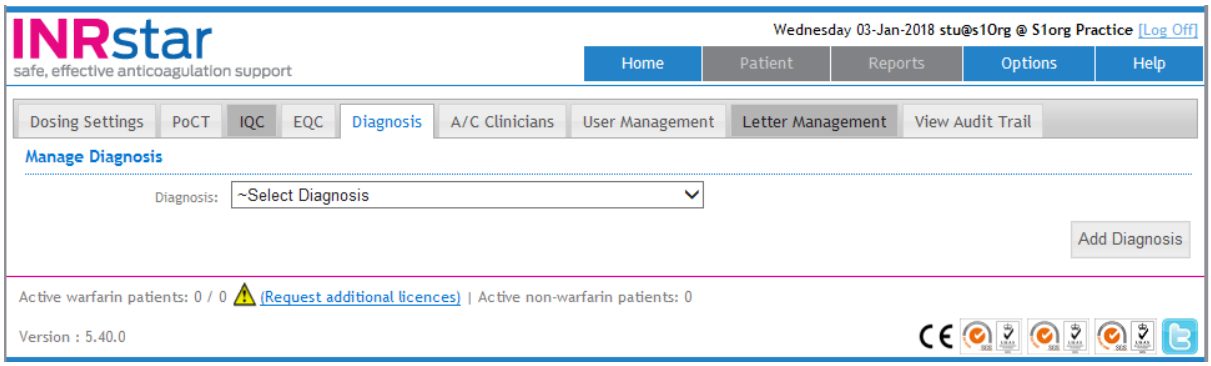
If you do need to add a new diagnosis, you must be logged into INRstar as the **Organisation Clinical Lead**. The available main menu options will be:

- Navigate to the 

tab.
- Select the 

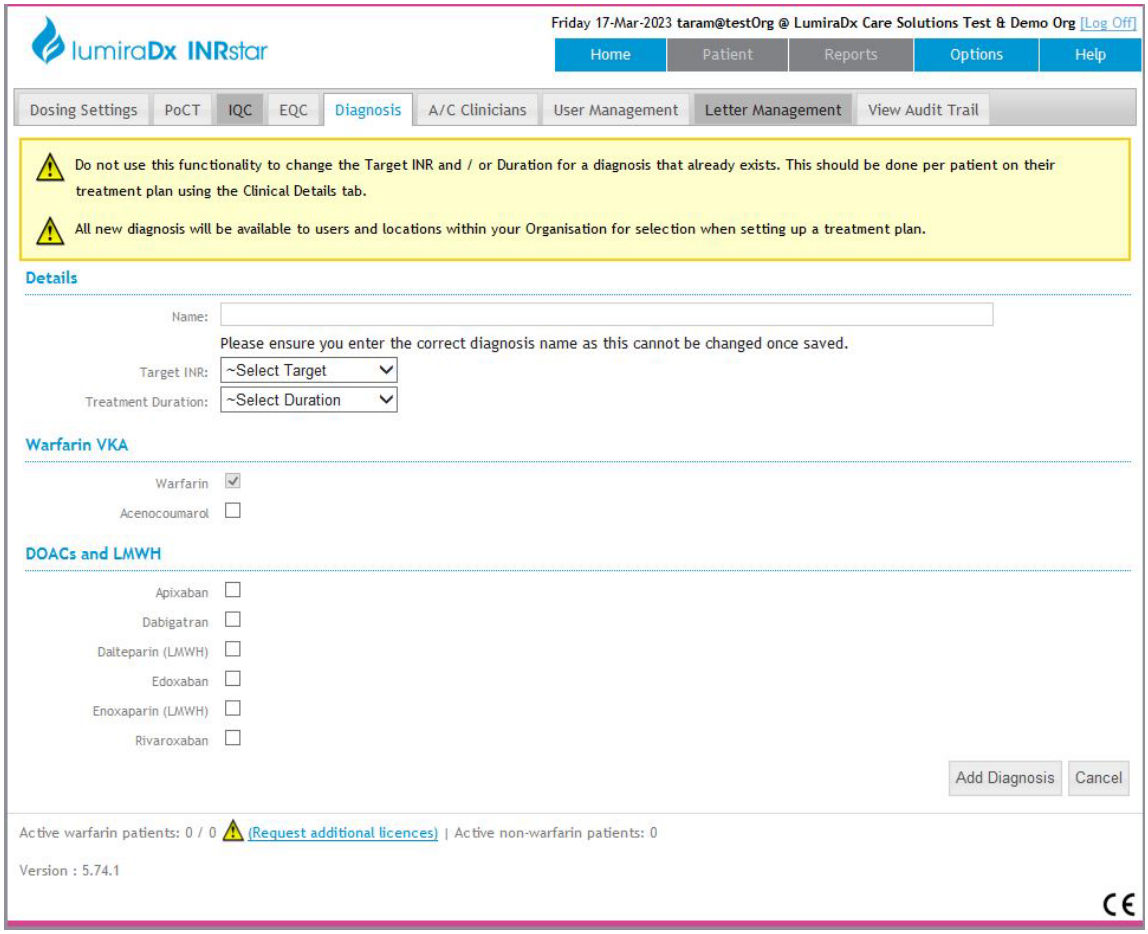
tab.

To add an unlisted diagnosis, click the **'Add Diagnosis'** button.



Enter the following fields:

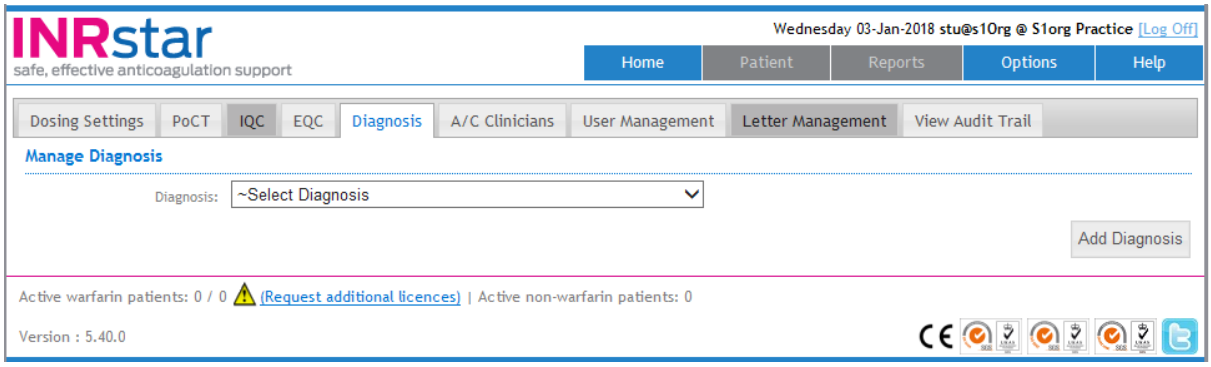
- Diagnosis' '**Name**'
- Diagnosis' '**Target INR**'
- Diagnosis' '**Treatment Duration**'
- Drug
    - Warfarin is always selected and this can't be removed
    - The user can add none, one or multiple drugs



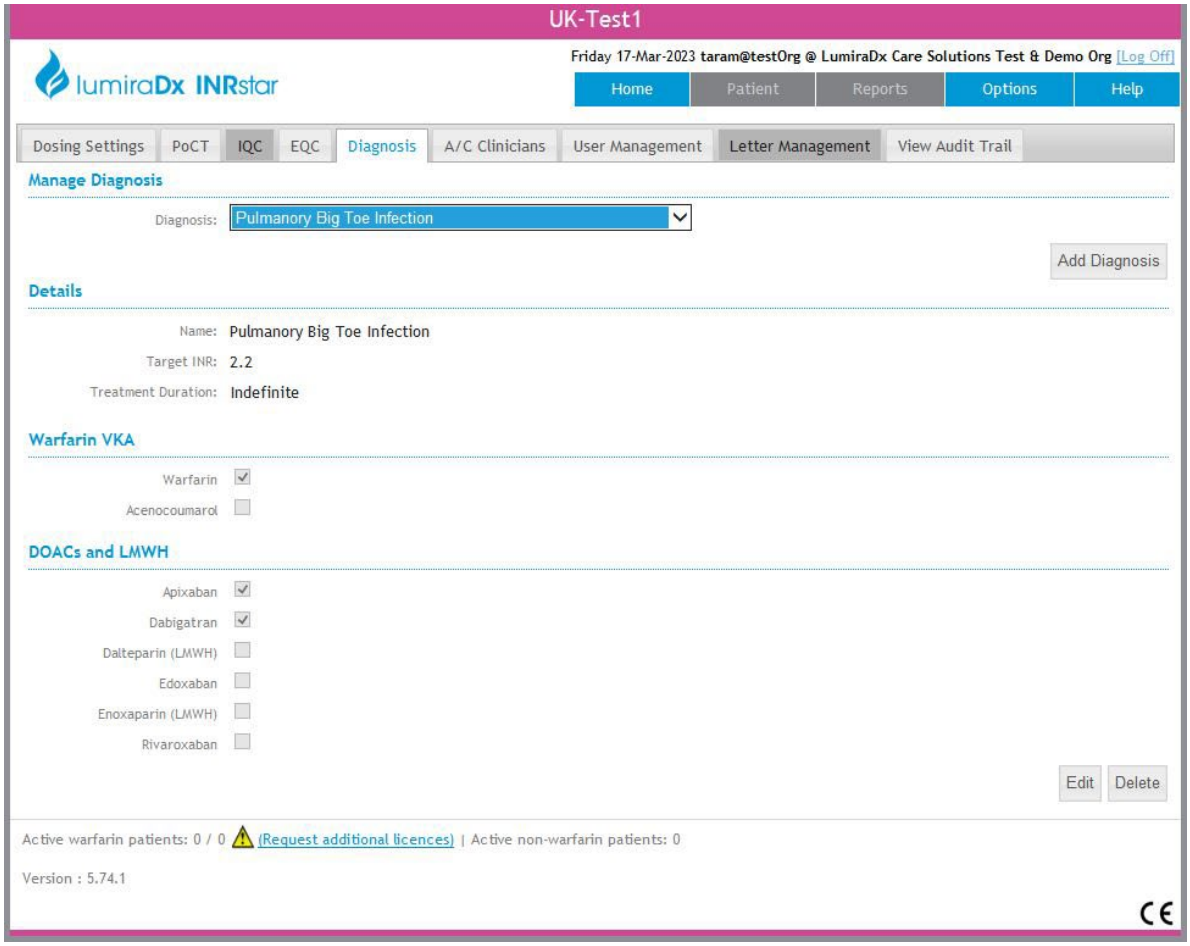
To save the new Diagnosis, click the **'Add Diagnosis'** button.

20.5.2. Edit an Existing Diagnosis

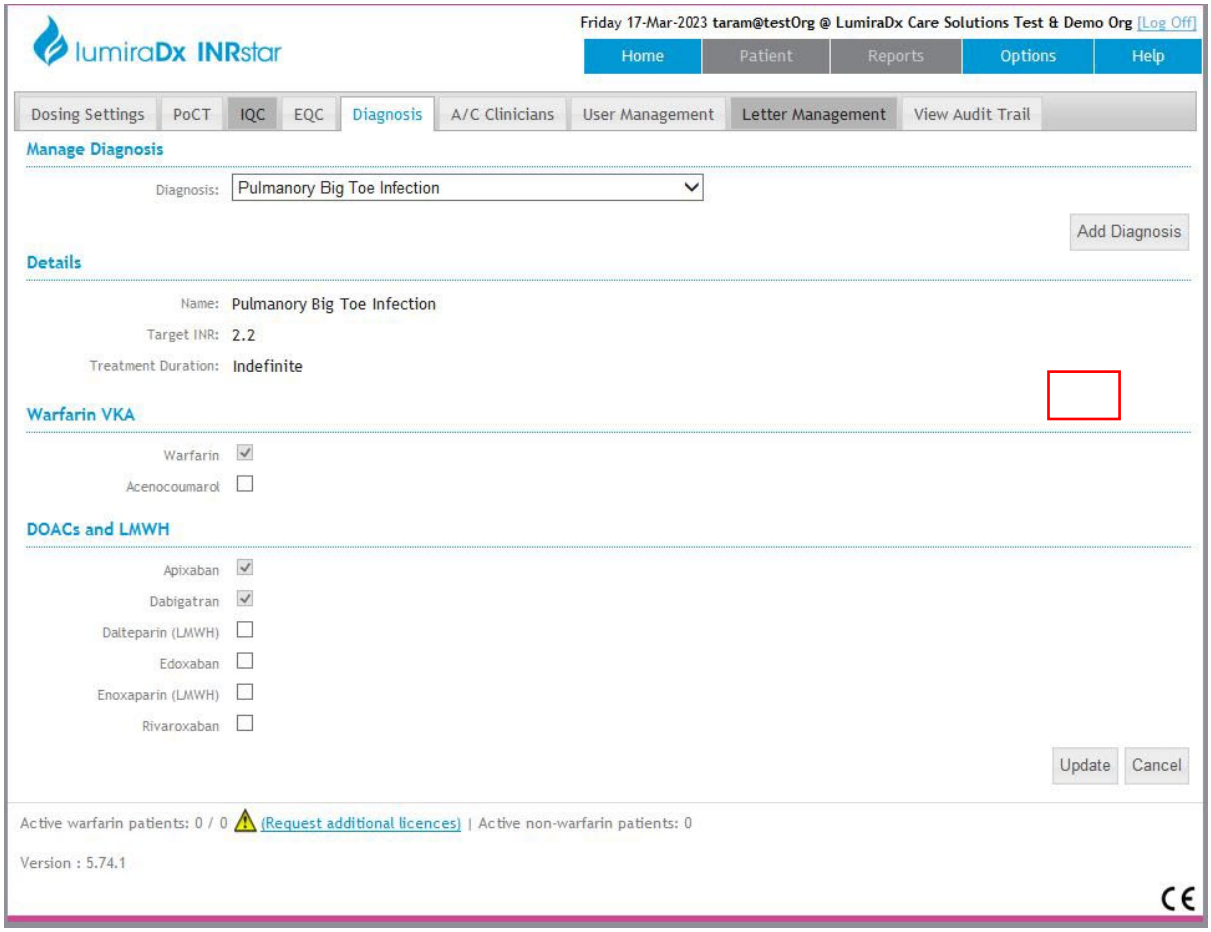
1. To edit an existing diagnosis, select the diagnosis from the dropdown list.



2. In the '**Details**' section, click the '**Edit**' button.



It is only possible to **add** a new drug to the diagnosis, it is no longer possible to edit Target INR or Treatment Duration or Diagnosis Name..

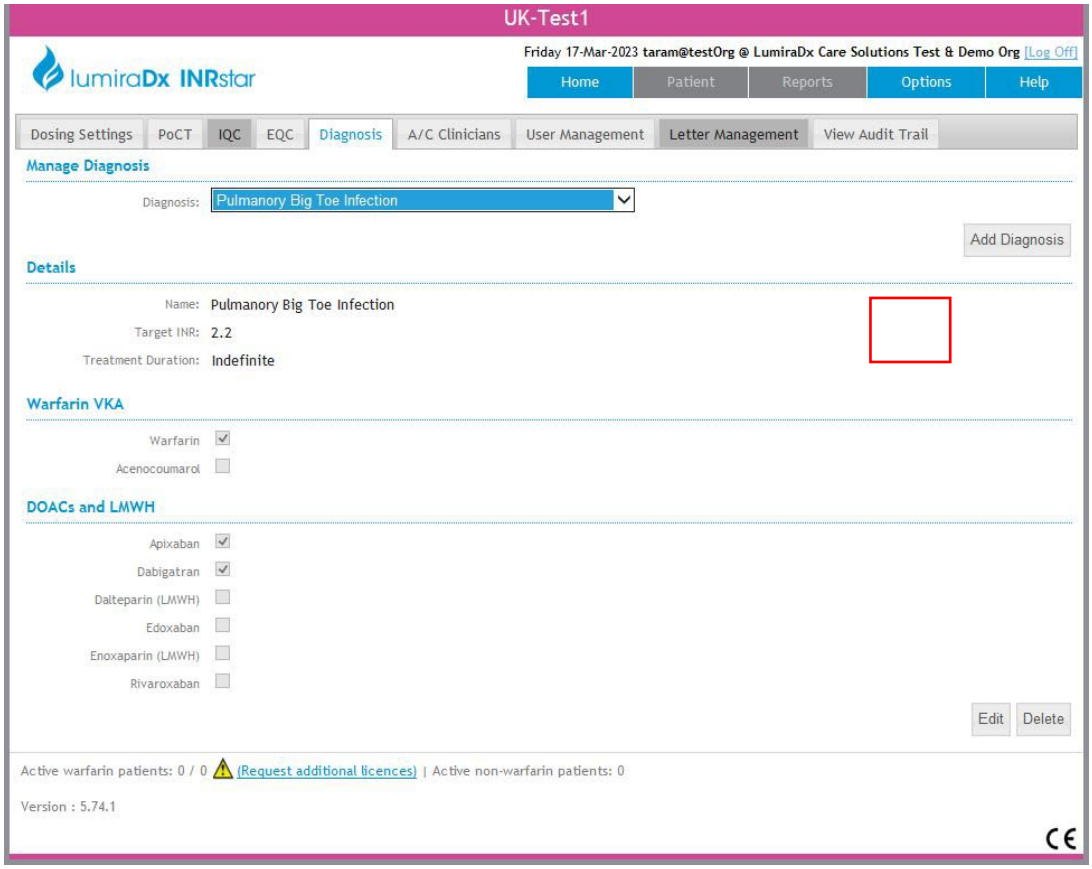


3. Then click the **'Update'** button.

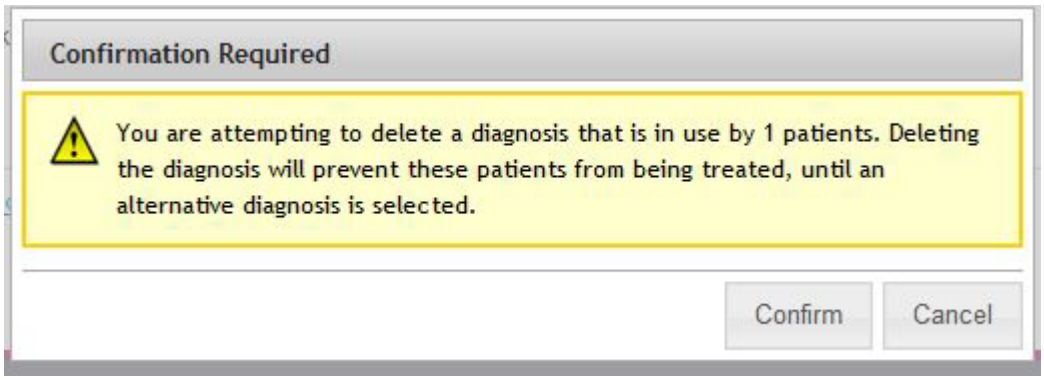
20.5.3. Delete a Custom Diagnosis

Only custom or edited standard diagnoses can be deleted. If an edited standard diagnosis is deleted, it will be replaced with the original standard diagnosis.

To delete a custom diagnosis, click the **'Delete'** button:



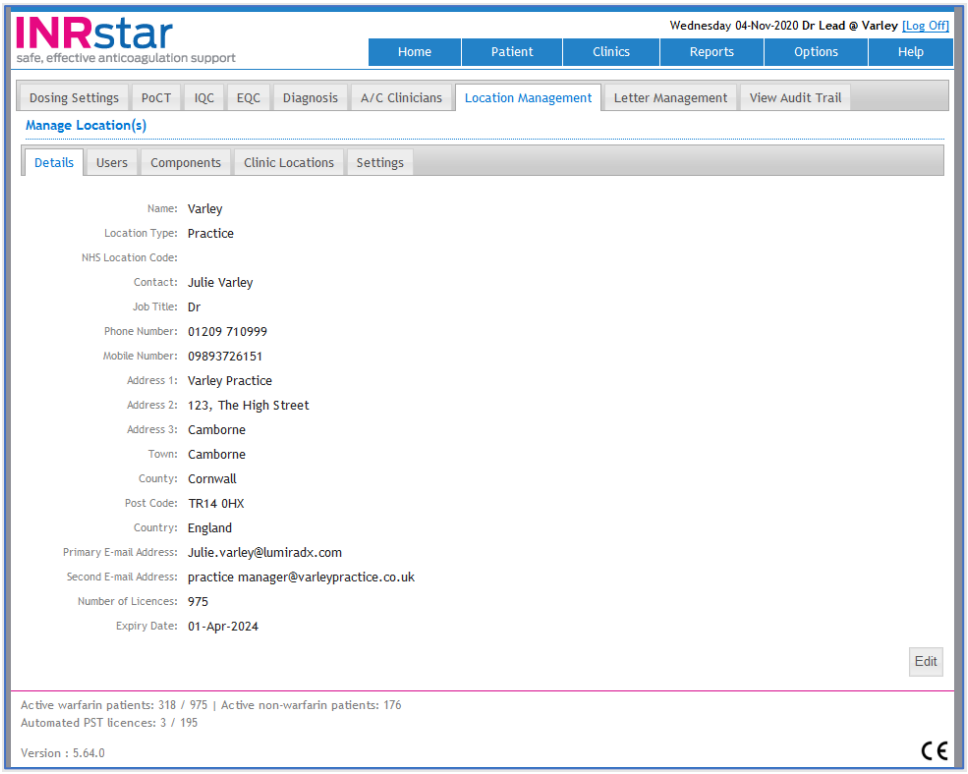
If there is an active patient within your Organisation with this diagnosis the following message is also displayed.



Click the **'Confirm'** button to confirm deleting the diagnosis, or click the **'Cancel'** button to cancel the deletion

20.6. Location Management

- **Details** – **Practice** or **Service** location details.
- **Users** – add users and allocate roles and permissions.
- **Components** – details of additional interfaces.
- **Clinic Locations** – add locations for selection as a patient's preferred clinic.
- **Settings:**
    - Allows selection of print preference: A4 graphics (colour) or A4 hidden (black and white).
    - Sets security logout time.



20.6.1. Log Out Time Configuration

For security reasons INRstar will log out a user if their session is inactive for longer than one hour by default.

Users with **Location Administrator** and **Location Clinical Lead** permission levels can change this setting for each location from 15 minutes to 3 hours:

1. Under '**Options**' / '**Location Management**', open the '**Settings**' tab.
2. Click '**Edit**', underneath '**Security Settings**'.
3. Select a time via the '**User Inactivity Timeout'** drop-down**:**

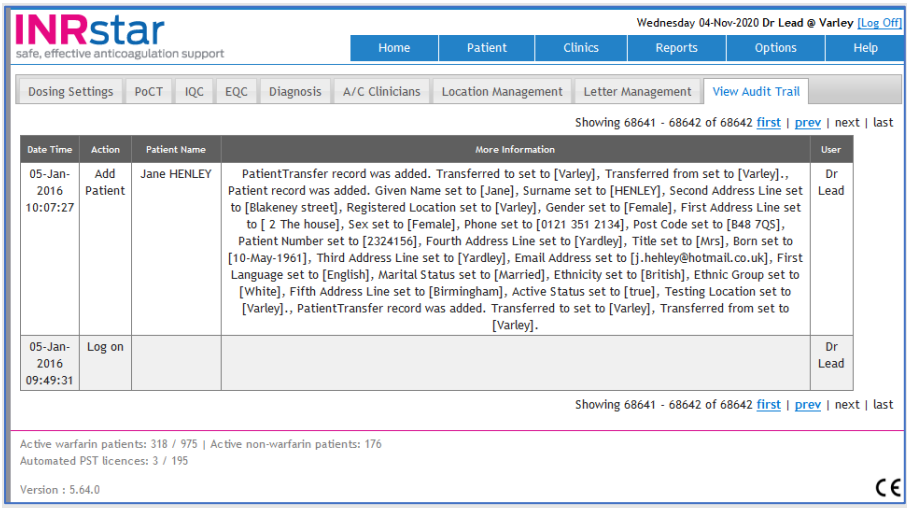
4. Click '**Save**' to apply your setting.

20.7. System Audit Trail

The audit trail details every action taken by users whilst managing or treating patients.

Location clinical lead and organisation clinical lead users can view an audit trail of actions performed on INRstar.

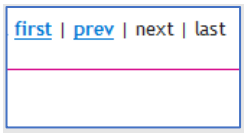
This is accessed from the **'View Audit Trail'** tab found in **'Options'**:



By default, INRstar will display a page containing all the user actions for this location.

This will include the date/time, action taken, patient's name, name of the user concerned and, if appropriate, the data added or amended.

Older entries can be accessed by means of links marked **'prev'** or **'first'**. Users can then navigate forward again with **'last'** or **'next'**.



20.8. Printing Settings

INRstar enables printing of the dosing diary either as a label or on an A4 sheet.

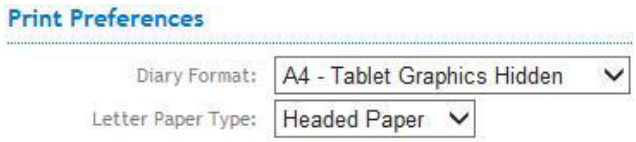
You will need to decide on your default print preferences. INRstar also allows Printing Preferences to be set individually within each patient record.

Please Note: The use of A4 diaries is recommended for patients with sight problems.

20.8.1. Edit Default Diary, Label and Letter Print Preferences

These are the default settings for all patients on INRstar. If you wish to edit an individual patient's settings to differ from the default, please see below.

1. Navigate to '**Options**', '**Location Management**', and then '**Settings**'.
2. Click the '**Edit**' button and choose from the dropdown list:

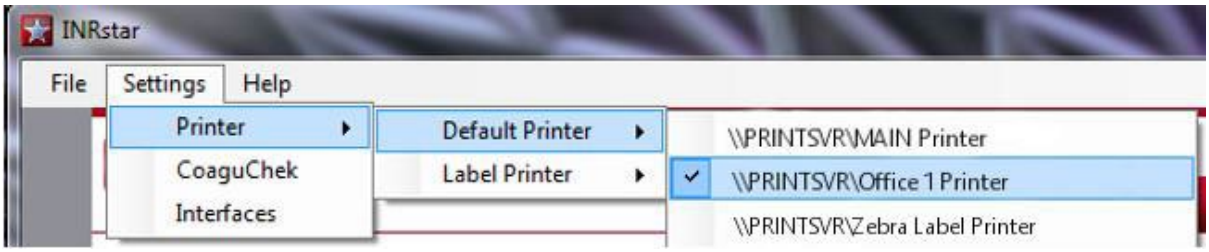


3. When you have selected your desired preferences, click '**Save**'.

Please Note: Displaying Tablet Graphics on a dosing diary is only designed for use with colour printers.

20.8.2. Set the Local Workstation Profiles

On the window in which INRstar is running, choose '**Settings**', '**Printer'**, '**Default Printer**' and then select the appropriate printer for the workstation:



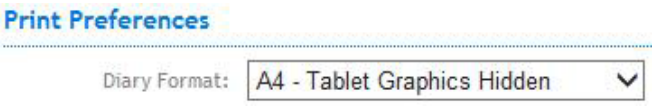
The Default printer will be used to print the practice activity, overdue and exceeded reports, overdue letters, Patient Dosing Diary and the Patient Summary document.

20.8.3. Change Individual Patient's Diary Print Preferences

You can set patients' print preferences to differ from the default on an individual basis in INRstar. For example you may wish to do this because you have one or more patients with sight problems that need A4 diaries, but where the default is set to label.

To change these print preferences for a patient:

1. Open the patient's record.
2. Click '**Treatment Plans**', then '**Clinical Details**'.
3. Click '**Edit Treatment Plan**'.
4. Under '**Print Preferences**', select the diary format you wish to give your patient from the drop-down list:

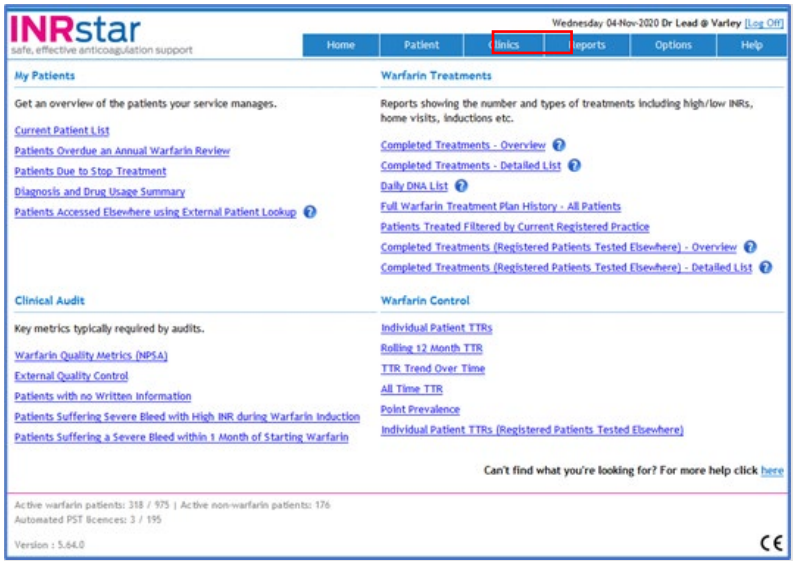


5. Click '**Save**' to complete these changes.

21. Reports

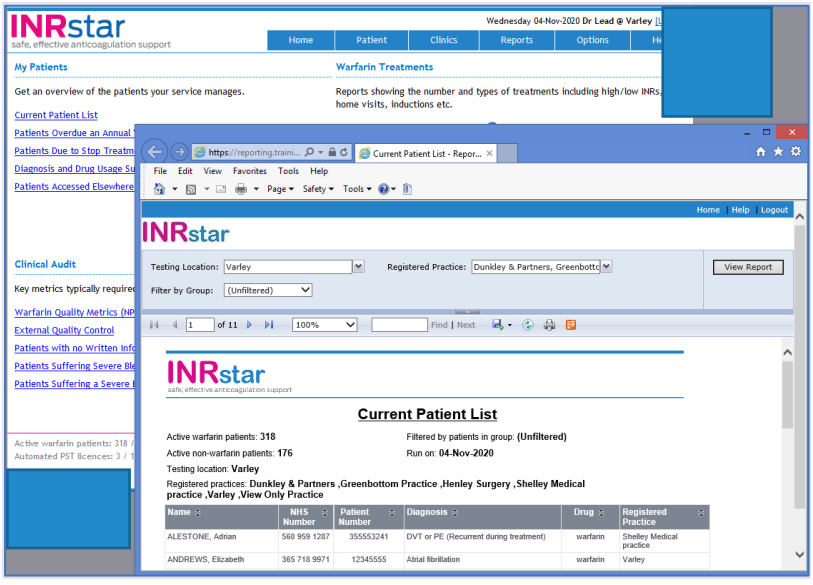
Select the **'Reports'** tab on the main menu to display the reports selection screen.

This screen includes several reports available for patients and treatments, divided into 4 section headers: '**My Patients'**, **'Warfarin Treatments'**, **'Clinical Audit' and 'Warfarin Control'**.

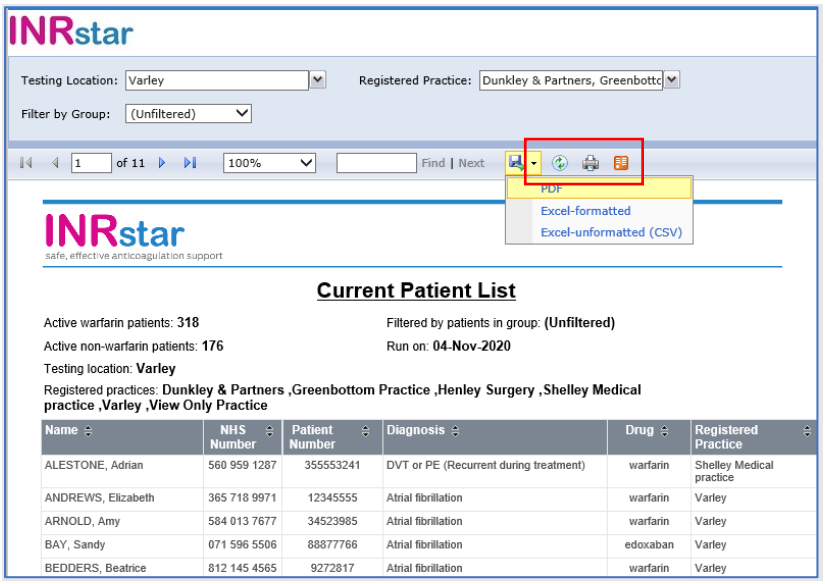


To view a report, click on its name.

If you would like more information, a brief description of the report can be found by hovering over the title.



Reports can be exported and saved in various formats: PDF, Excel-formatted or Excel-unformatted (CSV).



Click on the  icon to print the report documents.

22. Analytics

Analytics is an optional central analysis tool, separate to INRstar, allowing users to monitor AC services easily and efficiently with instant access to data across all your INRstar locations and providers.

22.1. Overview of INRstar Locations

INRstar analytics provides up-to-date information across all your INRstar locations.

INRstar analytics enables services to:

- Review and benchmark location TTR.
- Compare each location against high performance areas to share best practice (compare to country average).
- Make informed decisions on AC services across multiple locations.
- View the number of INRs within 0.5, 0.75 and 1.0 of the target range.
- Benchmark the number of adverse events and severity recorded at each location.
- Improve health outcomes at population level.

INRstar Analytics contains tool tips throughout the software. The information icon provides additional information for each section.

Supported web browsers are:

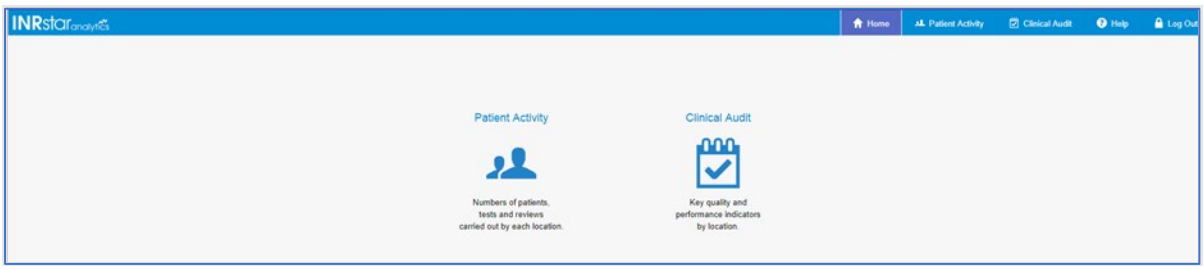
- Internet Explorer 10+
- Google Chrome

Login at: https://analytics-uk.caresolutions.lumiradx.com/

Use your username and password provided to sign into your designated site.

The **'Home'** screen will provide you with two options:

- '**Patient Activity**' – The number of patient tests and reviews at each location.
- '**Clinical Audit**' – Key quality and performance indicators by location.



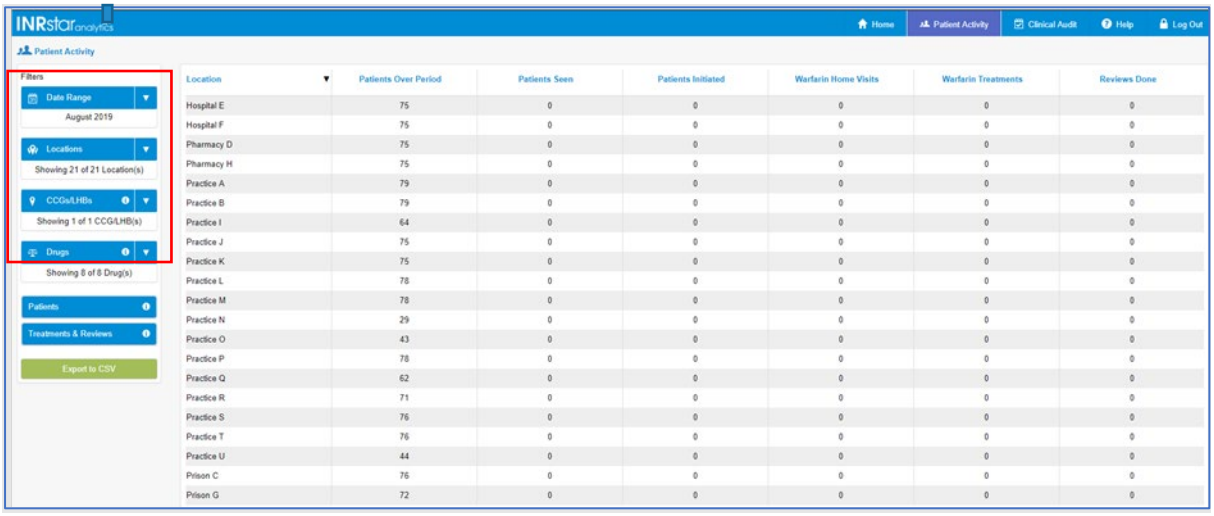
‘Patient Activity’ – Click on the ‘**Patient Activity’** symbol on the screen:

Or

The **‘Patient Activity’** section in the screen header bar:

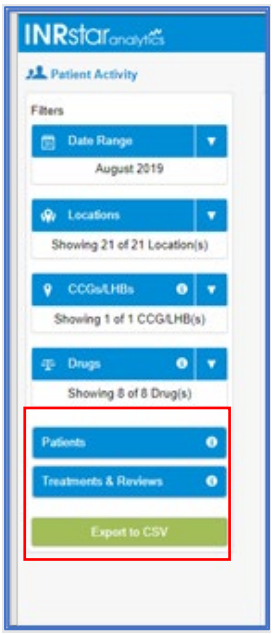
These take you to the **‘Patient Activity’** screen. Here, in the first column you will see a series of available data filters:

- Date Range
- Locations
- Organisations CCG/LHB (Health Authority)
- Drugs



In the same column you have a further two sections:

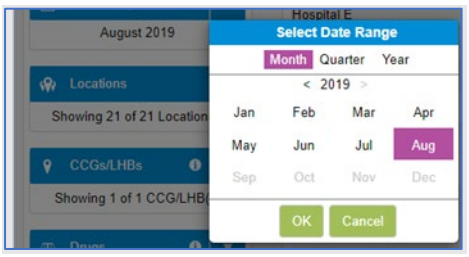
- Patients
- Treatments & Reviews



There is an option to export the data in the tool into Excel, as CSV files.

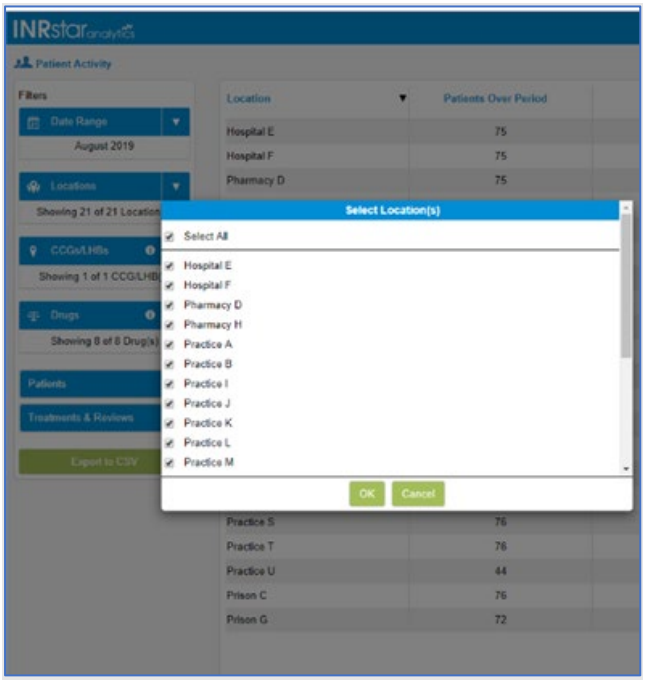
For each section that contains the symbol  you can hover over with a mouse and click to expand and reveal a detailed description of how the data is displayed.

22.1.1. Date Ranges



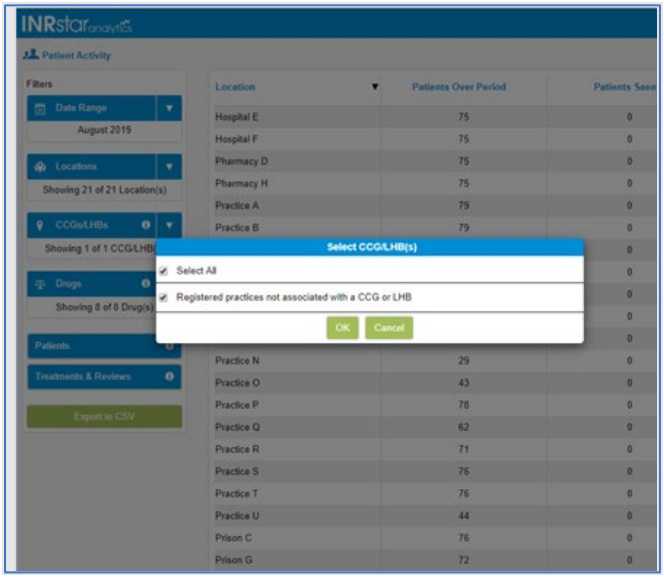
The date range filter can be set to month, quarter, or year. The filter will show the current or previous data in preceding years if available.

22.1.2. Locations



The system will detail all locations that have been set up for the organisation.

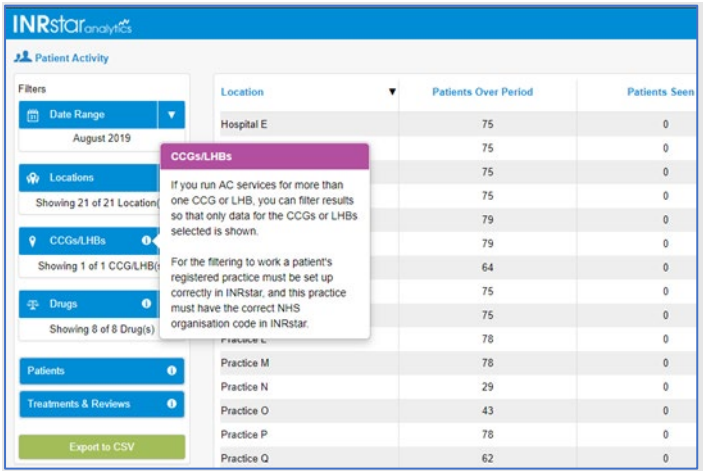
22.1.3. Organisations (PCN's, Local Health Boards, Federations)



The details of the organisation and locations assigned.

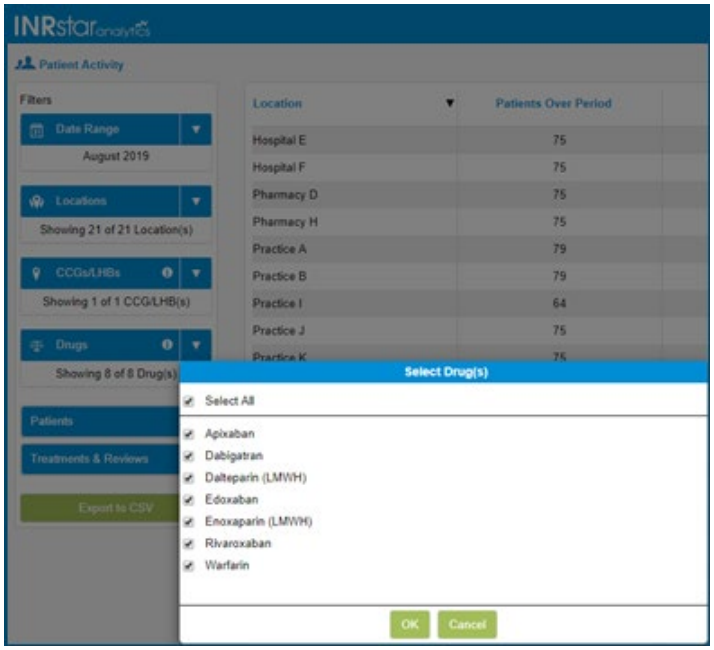
Note: Click on the search criteria box to include and present data on registered locations/practices not associated with the organisation.

The Icon when clicked reveals more information on how the data is presented for organisations.



22.1.4. Drugs

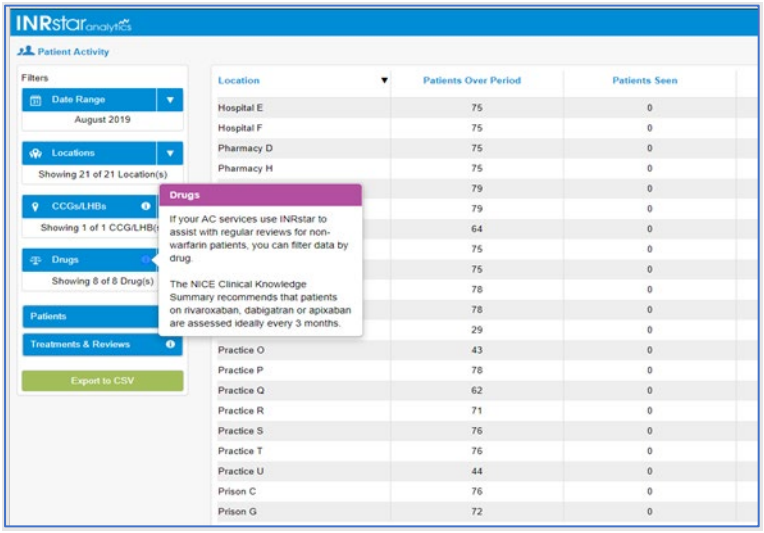
The **Drugs** list section (eight drugs) can be filtered to select individual, several, or all drugs.



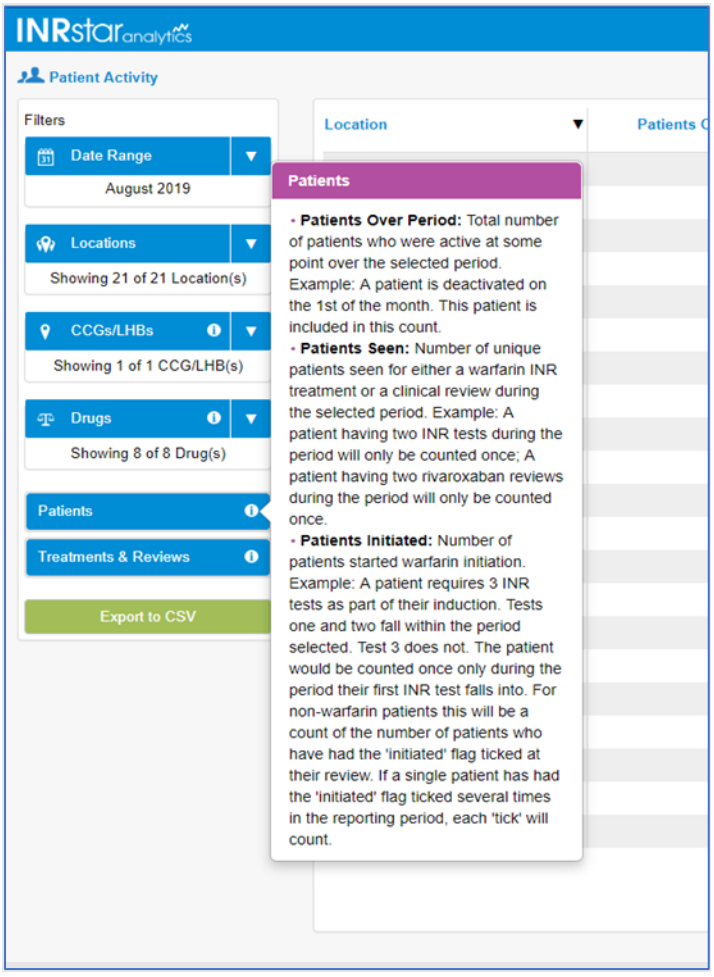
Click **'OK'** to confirm and run the search with data requirement or **'Cancel'** if not required.  reveals more information on how the data is presented.

22.1.5. Patients

The '**Patients'** section contains an information icon  that details how the data is presented in three formats, with a description for each report format.

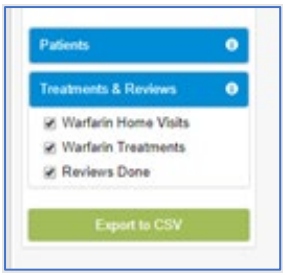


- Patients Over Period
- Patients Seen
- Patients Initiated

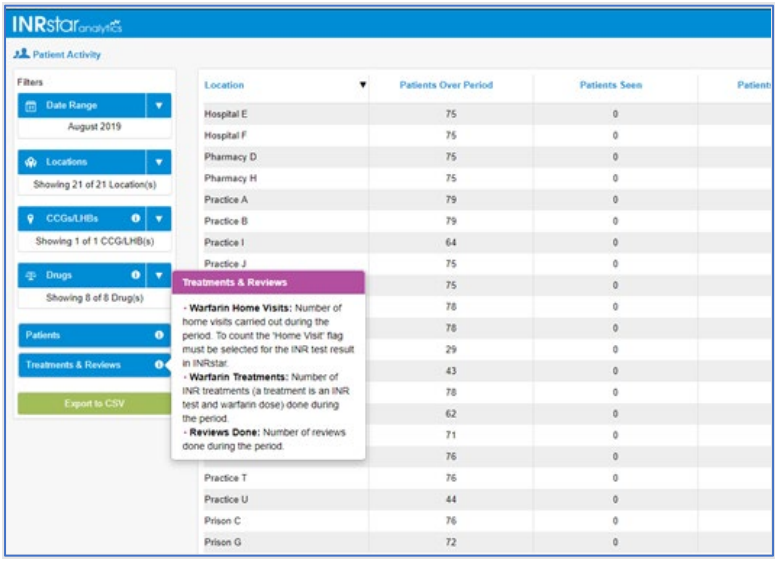


22.1.6. Treatments

The '**Treatments'** section contains an information icon  that details how the data is presented in three formats with a description:



- Warfarin Home Visits
- Warfarin Treatments
- Reviews Done



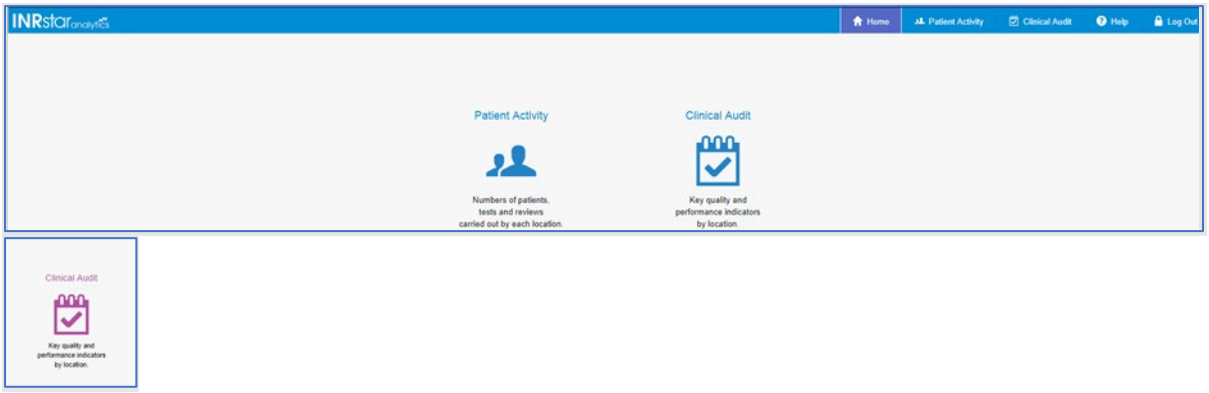
When each section has been selected the user can view data presented in charts on screen or, if required, export the data to a different format.

Use the 'scroll bar' at the edge of the display, by clicking and dragging with a mouse to view all rows and columns of the data.

Note: The export creates a CSV output which should be saved and then imported into appropriate software for analysis. The file should not be opened directly from the export function as some data could be misinterpreted due to the structure of the file.

22.2. Clinical Audit - Key Quality Indicators

Click on the **'Clinical Audit'** icon or the button header of the front screen to select and review the key quality indicators.

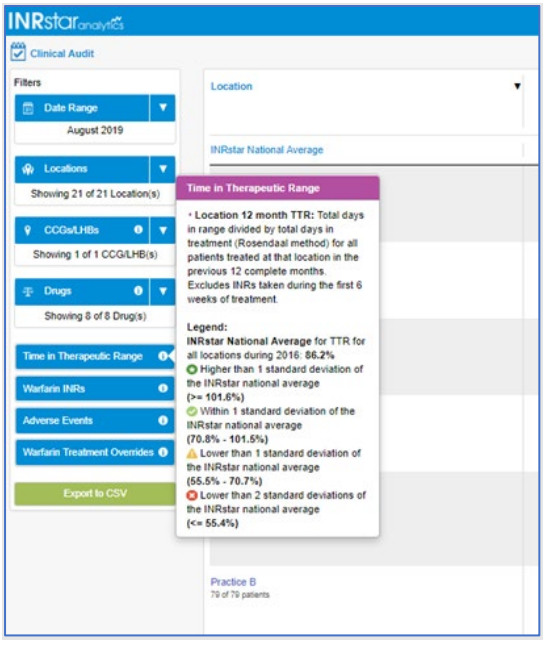


In the **'Clinical Audit'**, instructions for use remain the same as for **'Patient Activity'** for the following sections:

- Date range
- Locations
- Organisations/ASL details
- Drugs

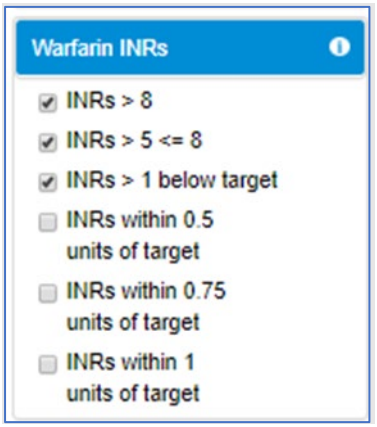
22.2.1. Time in Therapeutic Range (TTR)

Click on the TTR to search 12-month location TTR for each Testing Location. The information icon will display a description of the data provided and a **'Legend'** to identify the different categories of data for this section.

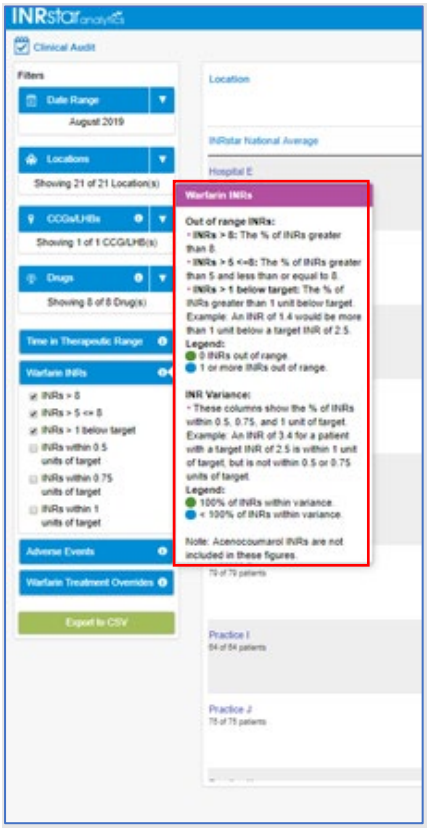


22.2.2. Quality Metrics for Warfarin INRs

The quality metrics for the **'Warfarin INRs'** section will provide the user options to select the data to be presented. Each section can be selected by a 'tick' in the list box, or the data can be segmented into individual data views.



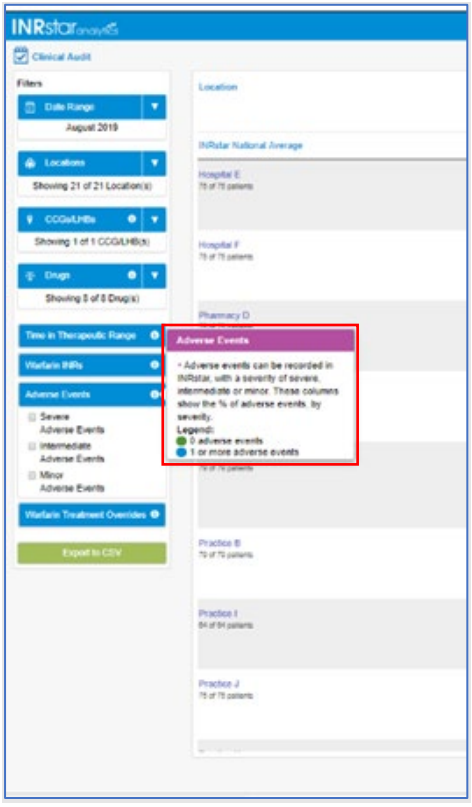
The information Icon  will display a description of the data provided and a **'Legend'** to identify the different categories of data for this section.



22.2.3. Adverse Events

The section details the **'Adverse Events'** recorded in INRstar, in three categories as follows:

- Severe
- Intermediate
- Minor



The information icon will display a description of the data provided and a **'Legend'** to identify the different categories of data for this section.

22.2.4. Warfarin Treatment Overrides

The **'Warfarin Treatment Overrides'** section shows the following data and can be selected by clicking the required box:

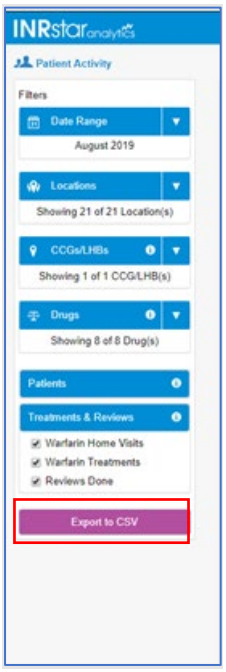
- Dose overrides
- Review (days) overrides

When each section has been selected the user can view collated data presented in charts on screen or, if required, look to export the data to a different format.

Use the 'scroll bars' at the edge of the display, by clicking and dragging with a mouse to view all rows and columns of the data.

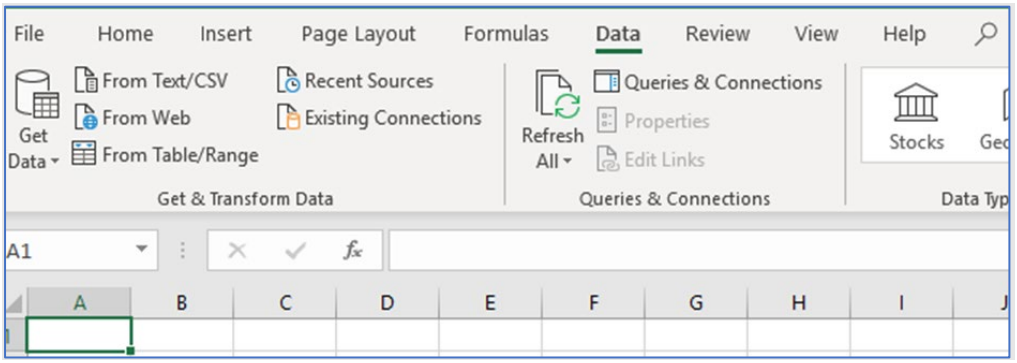
22.3. Export to CSV

The report tool can export the data to a CSV file by using the **'Export to CSV'** button at the bottom of the first column on the screen.



Note: The export creates a CSV output which should be saved and then imported into appropriate software for analysis. The file should not be opened directly from the export function as some data could be misinterpreted due to the structure of the file.

The data will be displayed correctly in Excel if the file is opened by Importing into Excel using the **'Get Data from Text/CSV'** option.



At the end of the Analytics session click on the **'Log Out'** icon on the task bar.

23. Legal Notices

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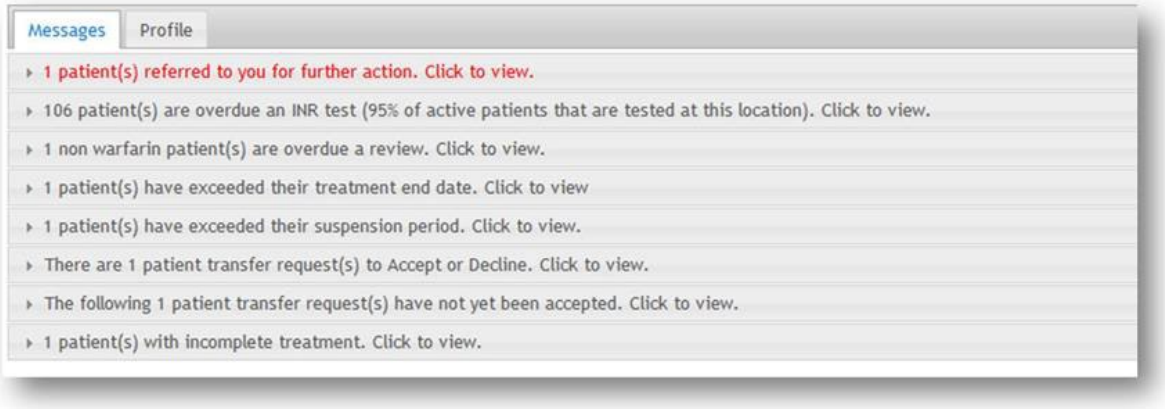
Appendix A - Home Page Messages

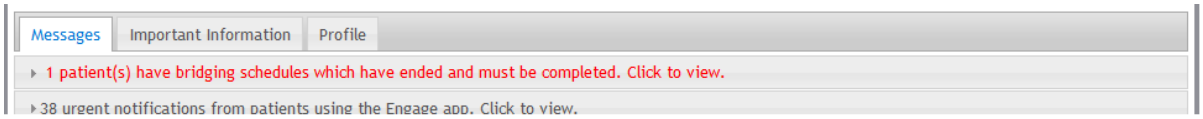
A selection of reports are displayed on the '**Messages'** tab of the user's **Home Page**.



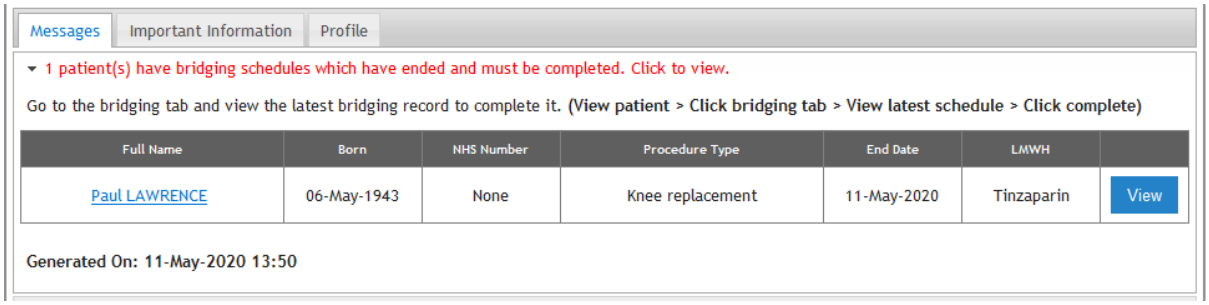
To view a report, click its title.

Patient(s) have bridging schedules which have ended and must be completed

This report is highlighted in red text to alert you to the importance of reviewing bridging records that have ended and that will need to be completed.

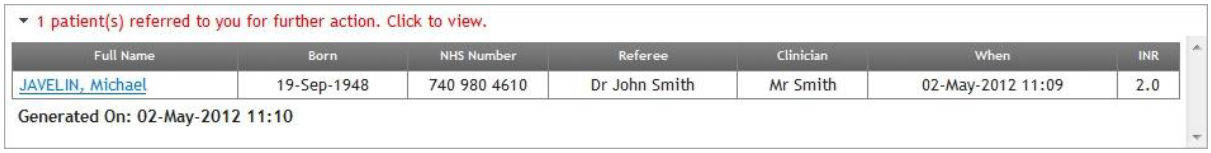


Open the notification and click the patient name or '**View**' button to access the patient's details and bridging records.



Patient(s) referred to you for further action

The report title shows the total number of active patients' INR treatments that have been referred by peers.


1 patient(s) referred to you for further action. Click to view.

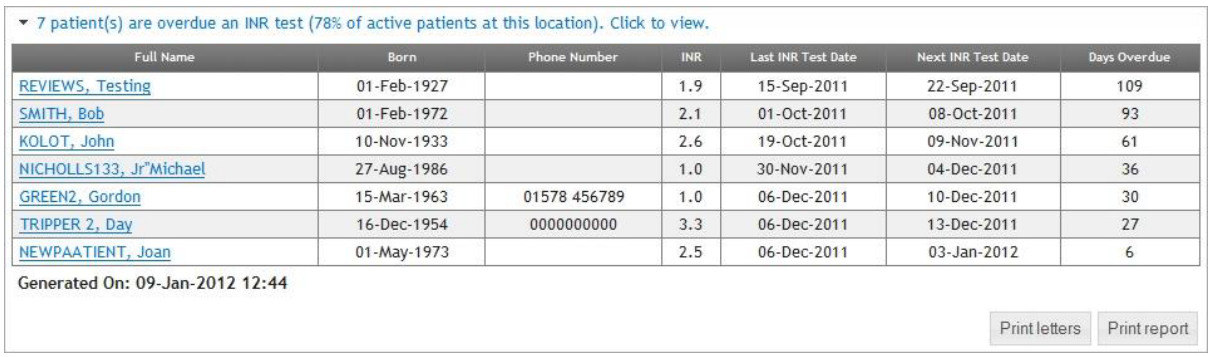
Full Name	Born	NHS Number	Referee	Clinician	When	INR
JAVELIN, Michael	19-Sep-1948	740 980 4610	Dr John Smith	Mr Smith	02-May-2012 11:09	2.0

Generated On: 02-May-2012 11:10

You can access the Treatment Plan of each patient directly from this list, by clicking the patient's name.

Patient(s) who are overdue an INR test

The report title shows the total number of active patients that are Overdue for their next INR blood test, along with the percentage, plus any patients who have recently finished their bridging schedule and the Next Test Date was moved by the clinician.


7 patient(s) are overdue an INR test (78% of active patients at this location). Click to view.

Full Name	Born	Phone Number	INR	Last INR Test Date	Next INR Test Date	Days Overdue
REVIEWS, Testing	01-Feb-1927		1.9	15-Sep-2011	22-Sep-2011	109
SMITH, Bob	01-Feb-1972		2.1	01-Oct-2011	08-Oct-2011	93
KOLOT, John	10-Nov-1933		2.6	19-Oct-2011	09-Nov-2011	61
NICHOLLS133, Jr"Michael	27-Aug-1986		1.0	30-Nov-2011	04-Dec-2011	36
GREEN2, Gordon	15-Mar-1963	01578 456789	1.0	06-Dec-2011	10-Dec-2011	30
TRIPPER 2, Day	16-Dec-1954	0000000000	3.3	06-Dec-2011	13-Dec-2011	27
NEWPAATIENT, Joan	01-May-1973		2.5	06-Dec-2011	03-Jan-2012	6

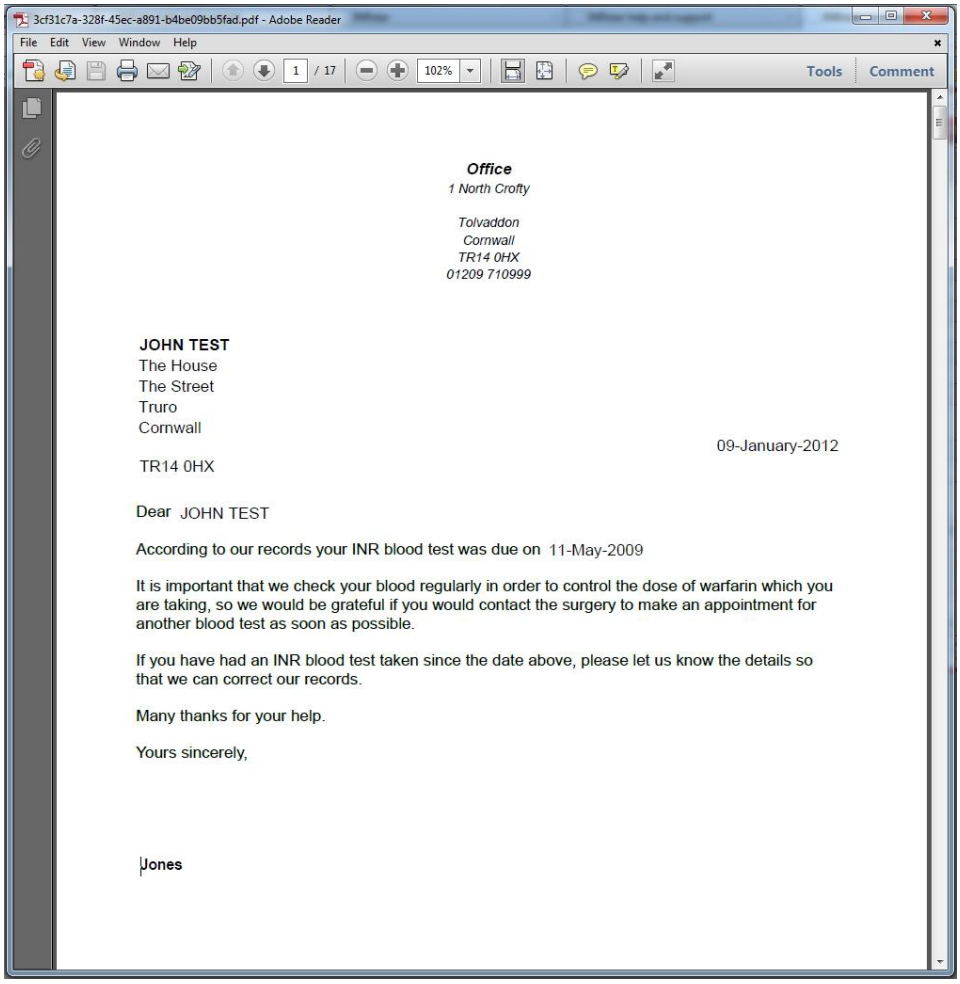
Generated On: 09-Jan-2012 12:44

Print letters Print report

You can access the treatment plan of each patient directly from this list, by clicking the patient's name.

To print out a letter for each overdue patient, click the **'Print letters'** button. This will open a .pdf document, and from here you can print all the letters or just a chosen few using the standard page selection.

Please Note: You need Adobe Acrobat to view and print this document.



To print the report of Overdue patients, click the **'Print report'** button.

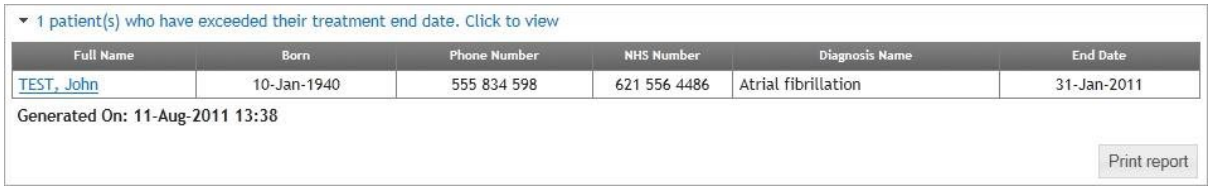
Non warfarin patient(s) are overdue a review

The report title shows the total number of non-warfarin patients overdue a review.

Click the patient(s) name and open the **'Treatment Plans'** and then **'Reviews'** tab to enter a new next Review Date.

Patient(s) that have exceeded their treatment end date

The report title shows the total number of active patients that are still being actively treated but have surpassed their treatment end date.



To print the report of Exceeded patients, click the **'Print report'** button.

You can access the treatment plan of each patient directly from this list, by clicking the patient's name.

Please Note: You need Adobe Acrobat to view and print this document.

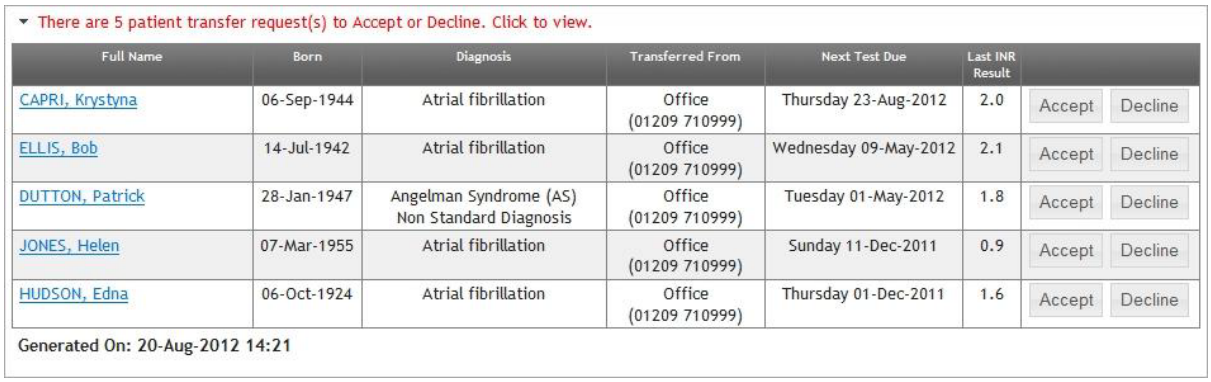
Patient(s) exceeded their suspension

The report title shows the total number of suspended patients that have surpassed their suspension end date.

The suspension feature allows a patient to be temporarily suspended from treatment, for a period of up to 6 months. This will allow a patient to remain 'Active', but to not appear on the overdue reports during their suspension period. The patient will not be automatically un-suspended, once the selected date has been passed.

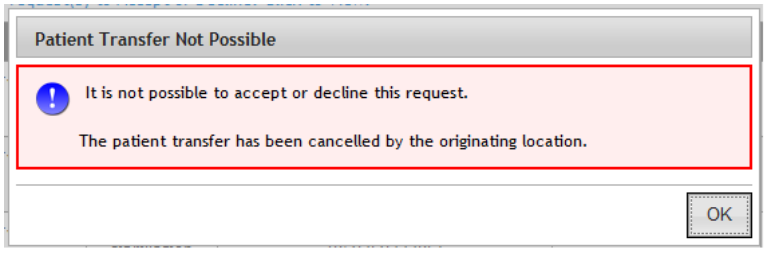
Patient transfer request(s) to Accept or Decline

The report title shows the total number of patients that have been transferred to your location that have not yet been accepted or declined.



To accept the patient transfer, which sets your location as the patient's Testing Location, therefore giving your location the responsibility of treating this patient, click the **'Accept'** button.

If the patient's transfer request has been cancelled by the originating location the following pop up message is displayed:

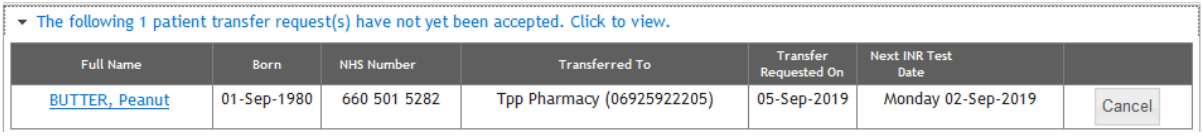


To decline the patient transfer, which sets the transferred from location to continue being responsible for the treating of this patient, click the **'Decline'** button.

You can access the patient's record directly from this list, by clicking the patient's name.

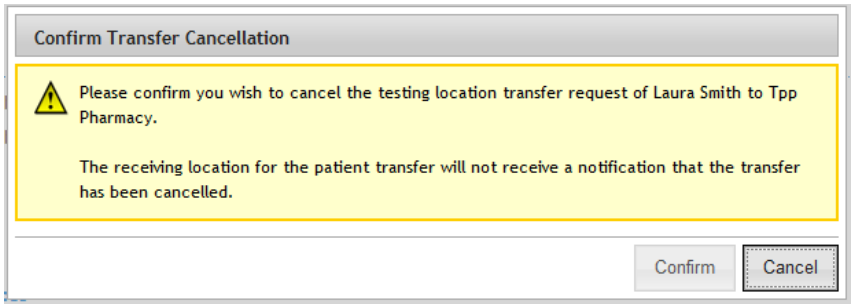
Patient transfer request(s) have not yet been accepted

The report title shows the total number of patients that you have requested a transfer to another Testing Location but have not yet been accepted.



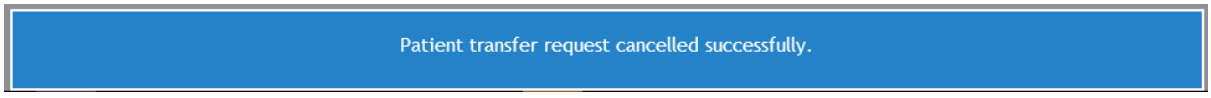
You can now cancel a request to transfer a patient's Testing Location from this report:

Click on the Cancel button. A pop up message box is displayed if the patient transfer request has not yet been accepted by the receiving location:

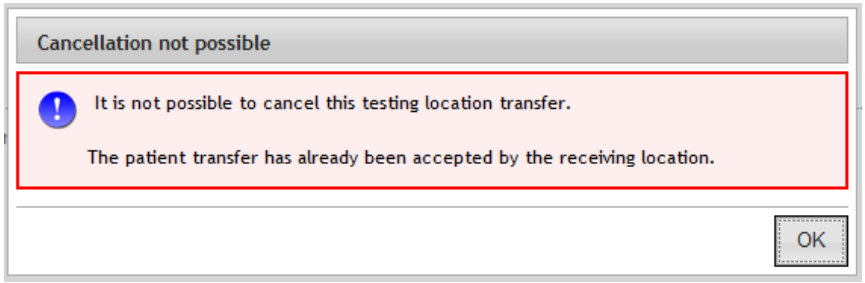


Click '**Confirm**' to keep the Patient record at your location, or '**Cancel**' to remove the message and the patient record will remain being transferred.

You will see the following confirmation at the bottom of your screen to advise when the request to cancel has been successfully completed:



If the receiving location has accepted the transfer request you will see the following message:



Patient transfer request(s) have been declined

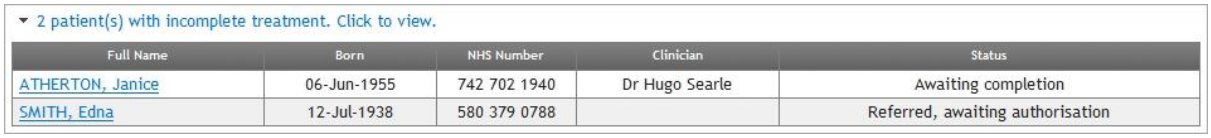
The report title shows the total number of patients for which you have a change of Testing Location but have been declined.

The patient transfer request being declined means that the patient is still under your location's responsibility to treat. You need to acknowledge the patient's declined transfer request before you can transfer this patient's Testing Location to another location.

You can access the patient's treatment plan directly from this list, by clicking the patient's name.

Patient(s) with incomplete INR treatment

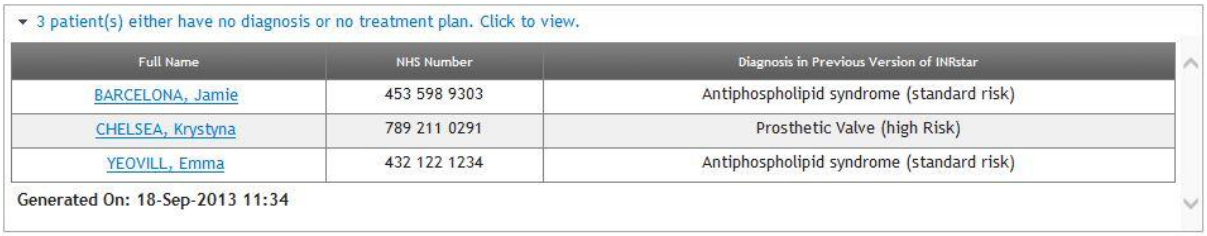
The report title shows the total number of active patients with an Incomplete INR treatment.



Access the treatment plan of each patient directly from this list, by clicking the patient's name.

Patient(s) either have no diagnosis or no treatment plan

The report title shows the total number of active patients that either have their diagnosis set to '**No Diagnosis**' or do not have a treatment plan.



You can access the treatment plan of each patient directly from this list, by clicking the patient's name.

Appendix B - NPSA Dosing Guidelines

Q. What are NPSA guidelines?

A. In 2007 the National Patient Safety Agency (NPSA) issued '**Patient Safety Alert 18'** which contained a set of recommendations aimed at increasing the safety of warfarin dosing.

In section 8 the guidelines state:

"Patient and carer groups have informed the NPSA that warfarin regimens with the following characteristics would promote safer use:

• use the least number of tablets each day;

• use constant daily dosing and not alternate day dosing;

• not require the use of half tablets – patients find it difficult to break tablets in half and instead, when necessary, would rather use 0.5mg tablets.

The NPSA recommends that NHS organisations should review their local practice to incorporate these characteristics. All strengths of warfarin tablets should be used to best meet the needs of individual patients. Not all patients will need all strengths of tablets.

It is recommended that oral anticoagulant doses should be expressed in mg and not as the number of tablets."

Read the full guidelines at Actions that can make anticoagulant therapy safer: Alert and other information (nationalarchives.gov.uk); select document titled 'Anticoagulation Compliance Checklist'.

Q. How does INRstar incorporate the NPSA dosing guidelines?

A. INRstar complies with the NPSA guidelines by adopting the following rules when calculating a suggested warfarin dose:

- All warfarin doses (greater than 3.0mg/day) are rounded to the nearest 0.5mg. This ensures that the dose of warfarin will be the same for each day of the week.
- All strengths of warfarin tablets (including 0.5mg) are made available for use in calculating dosing schedules.
- Split tablets are excluded from suggested dosing schedules.

Q. I don't like the guidelines. Can I turn them off?

A. Yes, you can switch the guidelines on or off at any time for individual patients. To disable the NPSA guidelines for an individual patient:

1. Click on the '**Clinical Details**' tab in the patient's treatment plan.

2. Click the '**Edit Treatment Plan**' button.
3. Uncheck the '**Use NPSA Guidelines**' box in the '**Tablet Selection**' section.
4. Select the warfarin tablet strengths you prefer for the patient.
5. Click '**Save**'.

Q. Can I prevent the NPSA guidelines from being the default dosing method for new patients?

A. Yes, the default dosing method for new patients can be configured by the organisation clinical lead to prevent NPSA dosing being applied as the default dosing method.

Q. How does INRstar round the warfarin doses?

A. If NPSA dosing is enabled, when a new INR result is added INRstar will calculate a new INR dose and then apply rounding to the dose as follows:

- For in-range INR results the existing warfarin dose will be rounded to the nearest 0.5mg.
- For a low INR result the new suggested dose will be rounded **up** to the nearest 0.5mg.
- For high INR result the new suggested dose will be rounded **down** to the nearest 0.5mg.

Note: Dose rounding will not be applied to doses less than 3.0mg/day.

Q. Why are low doses not rounded even if 'Use NPSA guideline' is selected?

A. For low doses (<3.0mg) rounding to the nearest 0.5mg could cause proportionately excessive dose changes which might lead to under or over anticoagulation. For this reason doses of <3.0 mg are not rounded even when NPSA dosing is enabled.

Q: Since migrating from an earlier version, INRstar is changing the doses of some patients with in-range INR results. Why is this?

A: Previous versions of INRstar did not apply rounding to doses when an in-range INR was entered. This did not fully meet the NPSA recommendation so this has been changed in the latest version. This will mean that, if you have recently migrated from an earlier version and you have NPSA dosing enabled, you will notice that some warfarin doses will round to the nearest 0.5mg even if the new NR is in-range.

Q: Since migrating from an earlier version, INRstar is reducing the review period to 28 days for some patients with in-range INR results. Why is this?

A: If INRstar changes the existing dose of a patient with an in-range INR result (by rounding it – as described above) it will also limit the associated review period to a maximum of 28 days. This is a safety precaution to prevent a patient having an excessively long review period following a change in the warfarin dose. This will

only apply to patients with previous review periods which are greater than 28 days – and will apply to this treatment only.

Q. We don't use 5mg strength warfarin tablets at our centre. Can I prevent these being used?

A. Yes, you can prevent the use of 5mg strength tablets whilst still using the NPSA dosing guidelines:

1. Click on the '**Clinical Details**' tab in the patient's treatment plan.
2. Click the '**Edit Treatment Plan**' button.
3. Uncheck the '**5mg tablet strength**' box in the '**Tablet Selection**' section.
4. Click '**Save**'.

Appendix C - External Clinical Systems

This section describes adding a new patient to INRstar from an external Clinical System where your location has the appropriate Clinical System interface licence.

Add a New Patient from TPP SystmOne

Please Note: You must have the patient you want to add into INRstar open in TPP SystmOne.

On the INRstar Navigation bar click the Patient button to display the patient Search screen.

Click the Add Patient tab to display the add patient screen.

When using INRstar, the first time you get a patient from TPP SystmOne or save a patient's new treatment into TPP SystmOne, a message box will appear in TPP SystmOne:

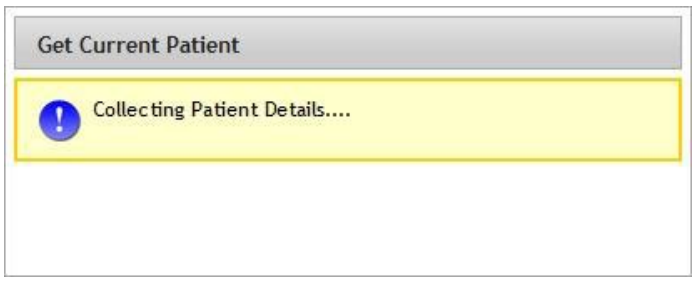
Click the **'Allow Connection'** button so that INRstar and TPP SystmOne can share data.

You will need to log out and then log back in again to TPP SystmOne to complete the interface settings.

A message box will appear, asking if you would like to get the current patient from TPP SystmOne:

Click the **'Yes'** button on the message box to get the patient details from TPP SystmOne.

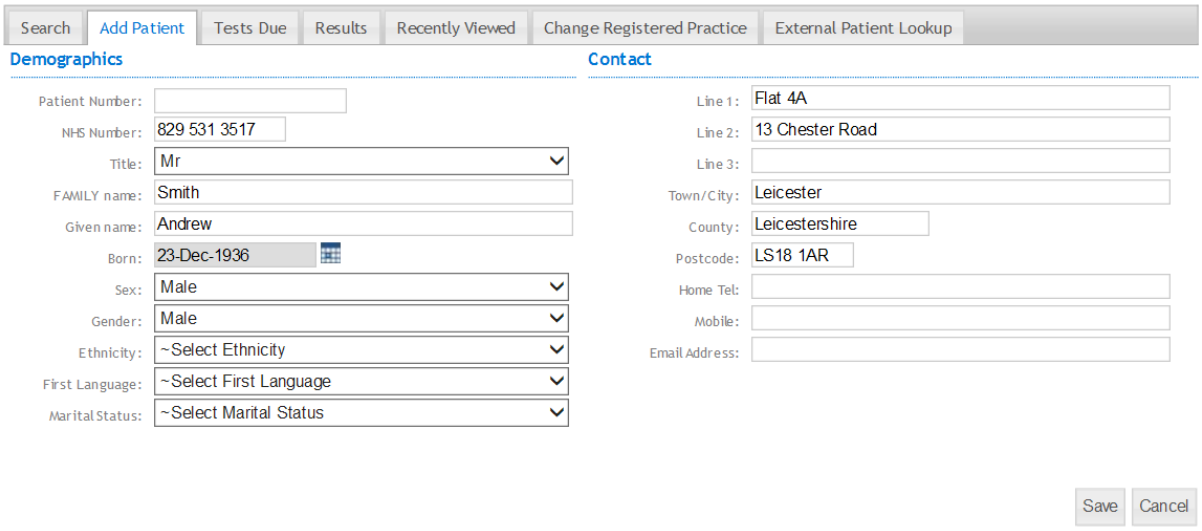
Step 1: INRstar will get the current patient's demographics from TPP SystmOne.



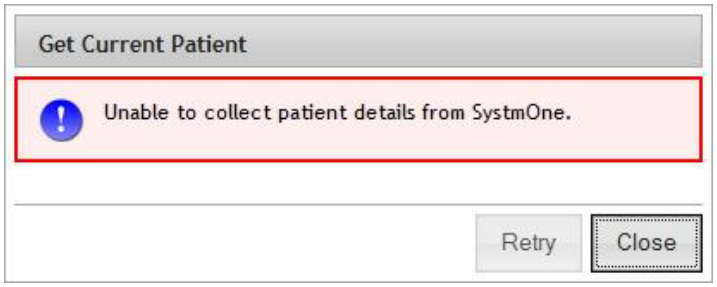
Step 2: The patient's details will populate the **'Add Patient'** form. Please check these are the expected patient's details.

Step 3: Please select the patient's Clinician in the **'Add Patient'** form.

Step 4: Click the **'Save'** button to save the patient into INRstar.



If a patient's record is not open in TPP SystmOne, or TPP SystmOne is not open, an error will appear:



If this happens, make sure TPP SystmOne is open, select the correct patient in TPP SystmOne and click the **'Retry'** button.

If you click the **'No'** button, the add patient's details screen will display to allow you to enter the patient's details in manually.

Add a New Patient from INPS Vision

When adding a new patient into INRstar you are able to automatically retrieve the patient's demographical information stored in INPS Vision.

Check INPS Vision is open and that you are logged in.

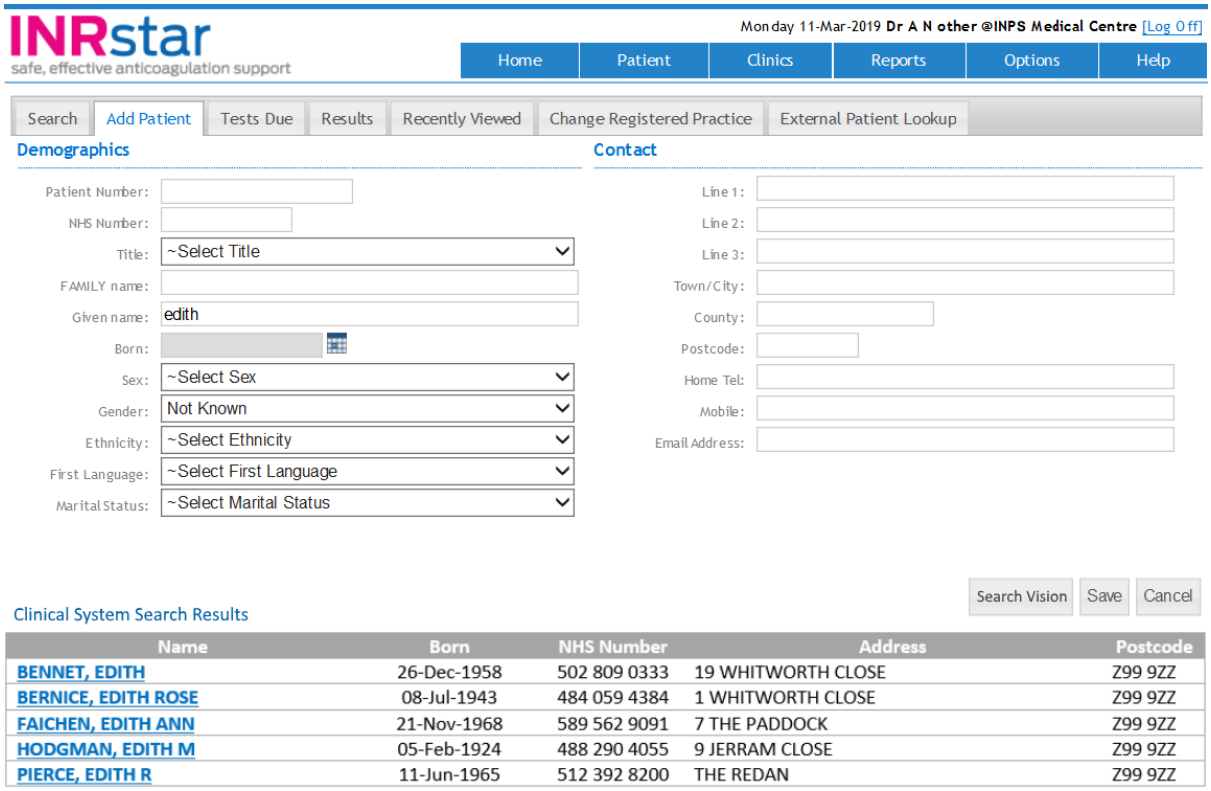
In INRstar navigate to the Patient page.

Click the Add Patient tab.

To search for a patient within INPS Vision, you need to enter either the patient's NHS number, Family Name, Given Name or Date of Birth or all four criteria.

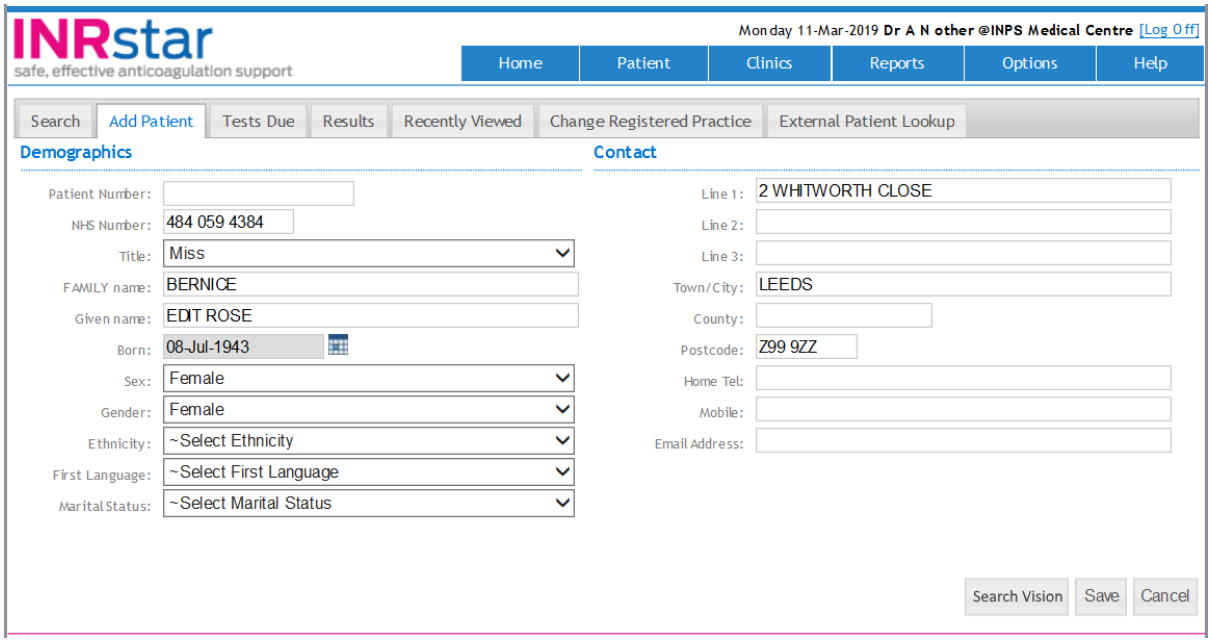
Click the **'Search Vision'** button.

The matching patients will be displayed below the form:



If your search criteria returns too many results the interface may time out. If this happens, enter more specific search criteria, for example a NHS number.

Choose a patient by clicking on the patient's name, this will fill in the **'Add Patient'** form with the selected patient's demographics that are stored in INPS Vision.



Check all the patient's details are correct and add any missing details and optional information, such as the patient's A/C Clinician.

To save the new patient, click the **'Save'** button.

To cancel, click the **'Cancel'** button.

Add a New Patient from EMIS Web, LV & PCS

The interface between INRstar and Clinical systems allow the user to:

- Extract a patient's demographic information from clinical system when adding a new patient record into INRstar.
- Save a patient's INR treatment under the corresponding patient record in the clinical system.

In order to use the clinical system interfaces within INRstar, you will need to contact the INRstar Sales team on 01209 710999 to purchase a clinical system licence. Without this licence on your account the clinical system integration options will not be available.

Once you have purchased your licence, you will need to enter your EMIS configuration settings into INRstar - you will only need to do this once. Use the guides below to see what information INRstar requires and where you will find that information in your EMIS system. See related content.

Please Note: You will need EMIS to be open.

Within INRstar you are able to add a new patient using the details stored in EMIS.

Step 1

Navigate to the Patient page using the navigation bar in the top right hand corner.

Then click the Add Patient tab.

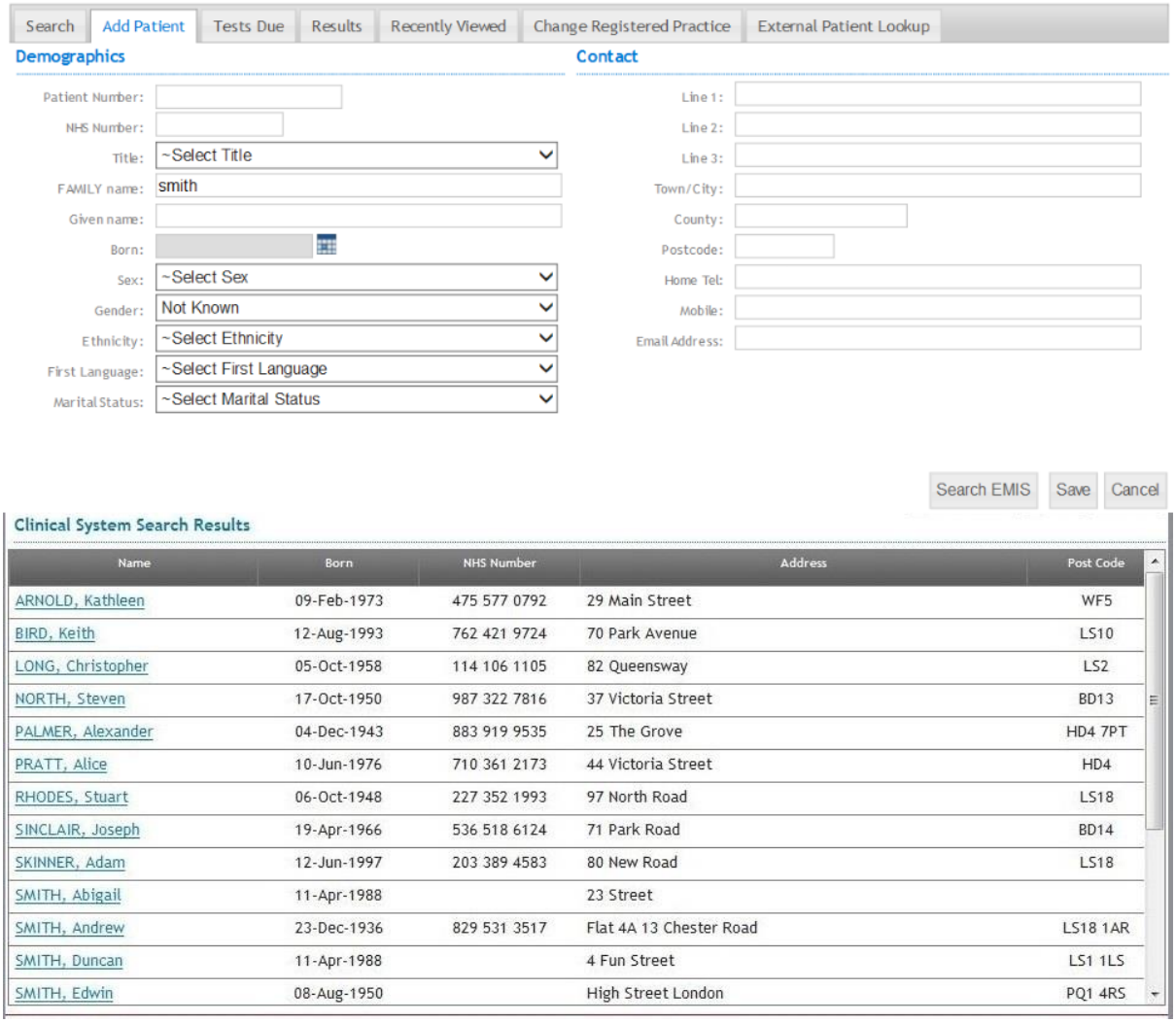
Step 2

To search for a patient within EMIS, you need to enter either the patient's NHS number, Family Name, Given Name or Date of Birth or all four.

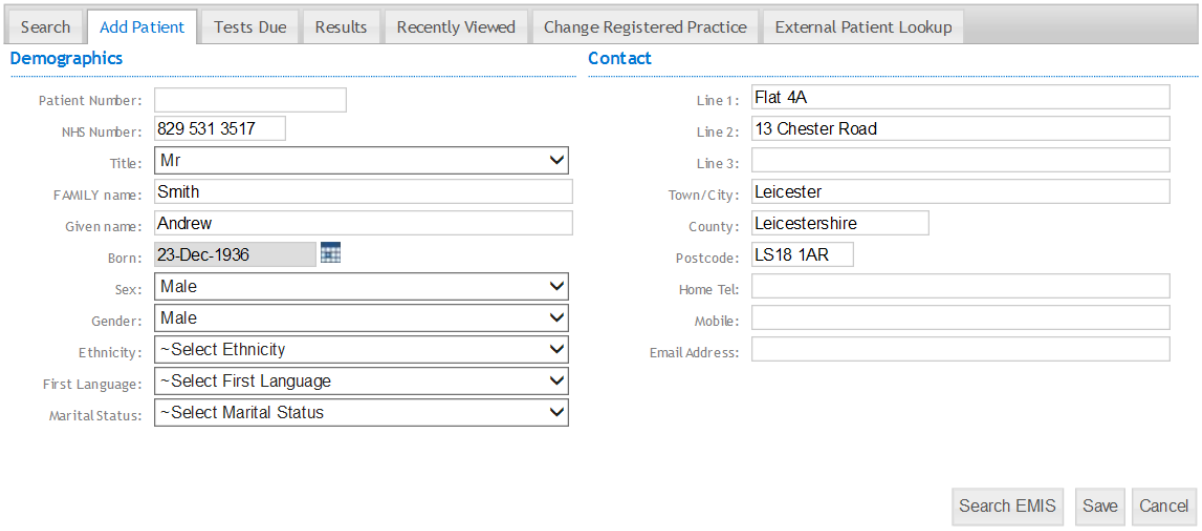
Click the **'Search EMIS'** button.

Step 3

The matching patients will be displayed below the form.



To choose a patient, select the patient's name, this will fill in the Add Patient form with the selected patient's details that are stored in EMIS.



Step 4

Please check all the patients' details are correct.

To save the new patient, click the **'Save'** button.

Appendix D – Clinical Risk Assessment

INRstar Anticoagulation Decision Support Software

Residual Risks **'As Far As Possible' ('AFAP')**

Background

Anticoagulation is an inherently risky process. It offers measurable benefits to patients in the reduction of the risk of thromboembolic events and in the treatment of established thrombotic episodes but, inevitably, it increases the risk of bleeding episodes. It is the aim of INRstar to reduce the risks and increase the benefits as far as possible.

To meet these aims INRstar undergoes a process of full Clinical Risk Assessment at all stages of its design, development and deployment. Standard approved risk assessment methods are used and risks quantified using an appropriate risk matrix (see Appendix 1 in this section).

Measures are implemented to reduce all identified clinical risks to an acceptable level but there are certain risks which it is not possible to fully mitigate. These residual risks are classified as AFAP risks ('As Far As Possible').

This section outlines the clinical risks assessed as AFAP within INRstar.

Users should be aware of these residual risks and should be particularly careful when performing actions which contain them.

Adding a patient

Risk

Inappropriate selection of a maintenance dosing algorithm.

Possible scenario

A user selects a maintenance dosing algorithm when adding a patient to the system. The patient has been initiated on warfarin elsewhere (e.g. in hospital) and is taking a loading dose. The patient attends the practice for review and is added to the system. The user selects a maintenance dosing algorithm when completing the clinical details screen. If a maintenance dosing algorithm is used before the patient is stably established on warfarin the dose suggestion will be inaccurate and could cause serious warfarin overdose. This could lead to significant bleeding, injury or death.

Pre-control risk D4 High

Controls

1. A warning message is displayed when a maintenance algorithm is selected as the dosing method. This explains the appropriate indications for the use of a maintenance algorithm.
2. The entry of a new INR is prevented if the last historical treatment entered has a review period of less than 7 days.
3. A dosing algorithm warning/confirmation message is displayed when a patient record is selected if there are fewer than 4 treatments in the record and the dosing method is a maintenance algorithm.
4. A dosing algorithm warning/confirmation message is displayed when a patient record is selected if warfarin start date is less than 28 days ago and the dosing method is a maintenance algorithm.
5. Addition or editing of Clinical details including selection of dosing method algorithms restricted to users with Clinical level 2 or 3 access permission.

Post Control Risk D2 Medium

Recommendation

Selection of the appropriate dosing method is an area of risk and should only be undertaken by trained users with clinical knowledge and understanding of the significance of and differences between warfarin induction and maintenance dosing methods.

Adding a patient

Risk

Inappropriate selection of an induction dosing algorithm.

Possible scenario

A user selects an induction dosing algorithm when adding a patient to the system. The patient has been taking warfarin for several months on a stable dose at a previous practice. The patient has now moved home and attends the new practice for review and is added to the system. The user selects a induction dosing algorithm when completing the clinical details screen. If an induction dosing algorithm is used when the patient is already established on warfarin the dose suggestion will be inaccurate and could cause serious warfarin overdose or under-dose. This could lead to significant bleeding, injury or death or risk of thromboembolic events.

Pre-control risk D4 High

Controls

1. A warning message is displayed when an induction algorithm is selected as the dosing method. This explains the appropriate indications for the use of a induction algorithm.
2. Warfarin induction is prevented if the last treatment entered has an INR result of >1.3.
3. An explanatory dialogue is displayed before the first induction treatment is produced.
4. A warning message is displayed when the patient screen is accessed whilst on induction protocol.
5. The warfarin induction screen has a different appearance from the usual maintenance treatment INR entry form.
6. Addition or editing of Clinical details including selection of dosing method algorithms restricted to users with Clinical level 2 or 3 access permission.
7. The saving and printing of induction treatments is restricted to users with clinical level 2 or 3 access permission.
8. Selection of induction algorithm is only enabled for new or re-activated patients.

Post Control Risk D2 Medium

Recommendation

Selection of dosing method should only be undertaken by trained users with clinical knowledge and understanding of the significance of and differences between warfarin induction and maintenance dosing methods.

Editing patient clinical details

Risk

Inappropriate change of induction to maintenance dosing algorithm.

Possible scenario

The patient has been initiated on warfarin and is taking a loading dose using the induction protocol. The user changes the dosing method from induction to a maintenance algorithm by editing the clinical details before the patient has been fully initiated onto a stable dose of warfarin. If a maintenance dosing algorithm is used before the patient is stably established on warfarin the dose suggestion will be inaccurate and could cause serious warfarin overdose. This could lead to significant bleeding, injury or death.

Pre-control risk D4 High

Controls

1. Confirmatory and explanatory dialogue displayed if user removes patient from induction algorithm.
2. A warning message is displayed when a maintenance algorithm is selected as the dosing method. This explains the appropriate indications for the use of a maintenance algorithm.
3. The entry of a new INR is prevented if the last historical treatment entered has a review period of less than 7 days.
4. A dosing algorithm warning/confirmation message is displayed when a patient record is selected if there are fewer than 4 treatments in the record and the dosing method is a maintenance algorithm.
5. A dosing algorithm warning/confirmation message is displayed when a patient record is selected if warfarin start date is less than 28 days ago and the dosing method is a maintenance algorithm.
6. Addition or editing of Clinical details including selection of dosing method algorithms restricted to users with Clinical level 2 or 3 access permission.

Post Control Risk D2 Medium

Recommendation

Selection and changing of dosing algorithms is a high risk activity. Selection of dosing method should only be undertaken by trained users with clinical knowledge and understanding of the significance of and differences between warfarin induction and maintenance dosing methods.

Editing organisation-level settings

Risk

Inappropriate change of dosing or review period settings.

Possible scenario

An untrained user changes the default dosing or review period settings at the organisation level. These settings will then be applied to all locations within the organisation.

For example: The percentage dose reduction suggested for INR results >5 is changed to 10%.

This setting will be applied to all locations and may result in an inappropriate dose reduction for patients with high INR results. This could lead to serious bleeding events, injury or death.

Pre-control risk D4 High

Controls

1. Editing of organisation-wide settings is restricted to the organisation clinical lead.
2. Organisation clinical lead status can only be granted by the organisation administrator.

Post Control Risk D2 Medium

Recommendation

The organisation clinical lead should be a clinician with an in-depth understanding of anticoagulation treatment. Organisation clinical lead status can only be granted by the organisation administrator and should not be granted to a user without sufficient training, experience and knowledge of the practice of oral anticoagulation treatment.

We recommend that only one named person holds organisation clinical lead status.

Performing a treatment

Risk

Incorrect selection of INR result when a new treatment is entered.

Possible scenario

A patient attends the clinic for an INR test. The result of the test is incorrectly entered as 1.2 instead of 2.2. The incorrect low INR will trigger a suggested dose increase. This would cause a significant overdose of warfarin which could lead to serious bleeding events, injury or death.

Pre-control risk D4 High

Controls

1. INR values selected from drop-down of valid figures.
2. New INR must be confirmed in a confirmatory dialogue before new warfarin dose is calculated.
3. No default INR value – result must be positively selected from list.
4. INR entry and dose calculation is restricted to users with clinical level access permissions.

Post Control Risk D2 Medium

Recommendation

Accurate entry of the new INR result is critical. Users should positively confirm that the result they have entered is correct when the confirmation dialogue is displayed. The confirmation dialogues should be regarded as a positive safety feature rather than a nuisance.

Interfaces with the POCT coagulometers which directly import the result should be used, where available, to minimise the risk of transcription errors when entering new INR results.

Performing a treatment

Risk

Incorrect existing warfarin dose.

Possible scenario

A patient attends the clinic for an INR test. The last recorded dose in INRstar is 4mg/day. The patient had been admitted to hospital since last attending the practice anticoagulation clinic and had been discharged home taking 2mg/day. Today's INR is in-range. The user enters today's INR but does not confirm that the patient is still taking the last recorded dose. The new dose suggestion is calculated based on the last recorded dose of 4mg/day.

This would cause a significant overdose of warfarin which could lead to serious bleeding events, injury or death.

Pre-control risk D4 High

Controls

1. The user must tick a confirmatory message box to confirm that the last recorded dose is still current and accurate before a new INR can be entered.
2. A new INR cannot be added if no previous dose is recorded.
3. If the date of the last recorded dose is longer ago than the patient's maximum review period (and might therefore be out of date) a warning message is displayed.
4. The last 6 doses are displayed chronologically on the new INR entry screen.
5. The existing treatment details are archived when an inactive patient is reactivated – a new existing dose must be recorded before a new INR can be entered.
6. INR entry and dose calculation is restricted to users with clinical level access permissions.

Post Control Risk D2 Medium

Recommendation

This is a major area of risk. All dosing algorithms rely on the fact that the patient's current dose of warfarin is correctly recorded so that the new suggested dose is accurate.

All users should be aware of the importance of confirming with the patient that the currently recorded warfarin dose is still current and correct before a new dose is calculated.

Performing a treatment

Risk

Incorrect date, INR, review details entered when recording a manual treatment.

Possible scenario

A patient attends the clinic for an INR test. The dosing method currently selected is Manual. This enables a clinician to enter an INR and a manually calculated dose and review period (without using INRstar's dose and review period suggestion algorithms). The manually calculated dose was entered incorrectly as 5mg instead of 0.5mg/day.

This would cause a significant overdose of warfarin which could lead to serious bleeding events, injury or death.

Pre-control risk D4 High

Controls

1. The user must confirm the new INR, dose and review period before saving the treatment.
2. Manual INR and dose entry is restricted to users with clinical level 3 access permissions.

Post Control Risk D2 Medium

Recommendation

Accurate entry of the manual INR and dose data is critical. Users should positively confirm that the result they have entered is correct when the confirmation dialogue is displayed. The confirmation dialogues should be regarded as a positive safety feature rather than a nuisance.

Performing a treatment

Risk

Inappropriate override of suggested warfarin dose.

Possible scenario

A patient attends the clinic for an INR test. The INR is below-range and the dose suggested is increased to 2mg/day. The user decides to override the suggested dose to 2.5mg/day but mistakenly enters a new dose of 5mg/day.

This would cause a significant overdose of warfarin which could lead to serious bleeding events, injury or death.

Pre-control risk D4 High

Controls

1. Dose overrides > 20% must be confirmed by user before saving the treatment.
2. Doses selected from pick list of valid doses. Limited to system-wide maximum dose.
3. Previous treatment history displayed on dose override screen to aid clinical decision making.
4. Full dose override enabled for clinical level 3 users only.
5. Minor dose override (+/- 0.1mg) enabled for clinical level 2 users only.
6. Save and Print of out-of-range treatments restricted to clinical level 2 or 3 level users.
7. Dose overrides are disabled during induction protocol - warning message displayed on attempted override.

Post Control Risk D2 Medium

Recommendation

Overriding of suggested doses is a safety critical area. Users should positively confirm that the new data they have entered is correct and appropriate in the context of the patient's current clinical situation. Confirmation dialogues should be regarded as a positive safety feature rather than a nuisance.

Dose overrides are disabled during the induction protocol.

Performing a treatment

Risk

Inappropriate override of suggested review period.

Possible scenario

A patient attends the clinic for an INR test. The INR is below-range and the dose suggested is increased. The suggested review period is 7 days. The patient is unable to attend on that date and the user decides to override the suggested review period to 6 weeks (42 days).

The increased warfarin dose might lead to overtreatment which would not be detected if the review period was extended inappropriately. This could lead to serious bleeding events, injury or death.

Pre-control risk D4 High

Controls

1. Previous treatment history displayed on review period override screen to aid clinical decision making.
2. Review period override selected from a list of valid days. Limited to patient's maximum review period.
3. Full review period override enabled for clinical level 3 users only.
4. Minor review period override (+/- 7 days) enabled for clinical level 2 users only.
5. Save and Print of out-of-range treatments restricted to clinical level 2 or 3 users.
6. Review period overrides are disabled during induction protocol - warning message displayed on attempted override.

Post Control Risk D2 Medium

Recommendation

Overriding of suggested review periods is a safety critical area. Users should positively confirm that the new data they have entered is correct and appropriate in the context of the patient's current clinical situation. Confirmation dialogues should be regarded as a positive safety feature rather than a nuisance.

Warfarin induction

Risk

INR result falls outside the limits for the induction protocol.

Possible scenario

A patient is being induced onto warfarin treatment using the Tait induction protocol. They attend the clinic as arranged on day 5 for an INR test. This is 6.0 and falls outside the limits of the induction protocol. Continuing with the induction protocol might lead to overtreatment which could lead to serious bleeding events, injury or death.

Pre-control risk D4 High

Controls

1. Patient is automatically removed from the induction protocol if the INR result >5. The user must then dose the patient manually until sufficiently stable to be dosed using a maintenance dosing algorithm.
2. Induction treatments can only be performed by users with clinical level access permissions.
3. Induction treatments can only be saved and printed by users with clinical level 3 access permission.
4. The protocol must be strictly adhered to. Doses and review periods cannot be overridden and INR tests must be done on the dates specified in the protocol.

Post Control Risk D2 Medium

Recommendation

Warfarin induction is a safety critical activity. It should only be carried out by users with clinical knowledge and experience in anticoagulation management. The user must be prepared to dose the patient manually if the INR falls outside the parameters of the induction protocol.

Appendix 1

Risk Assessment (NPSA Risk assessment of anticoagulation therapy 2006)

1. Consequences (C)

A	Negligible: little or no effect	This is an unexpected or unintended incident which required extra observations or minor treatment and caused minimal harm to one patient
B	Marginal: medium term harm	This is an unexpected or unintended incident which resulted in further treatment, cancelled treatment, transfer to another area, possibly critical care and which caused short term harm to one patient
C	Critical: causes severe harm	This is an unexpected or unintended incident which caused permanent or long term harm to one patient
D	Fatality	This is an unexpected or unintended incident which caused death for one patient
E	Catastrophic	This is an unexpected or unintended incident which caused death for two or more patients

2. **Likelihood (L)** Projected incidences of harm / year in UK

Class	Likelihood
1	Improbable
2	~2
3	~20
4	~200
5	~2,000
6	20,000

3. **Risk Matrix**

6	Medium	High	High	High	High
5	Medium	Medium	High	High	High
4	Low	Medium	Medium	High	High
3	Low	Medium	Medium	Medium	High
2	Low	Low	Low	Medium	High
1	Low	Low	Low	Low	Low
	A	**B**	**C**	**D**	**E**

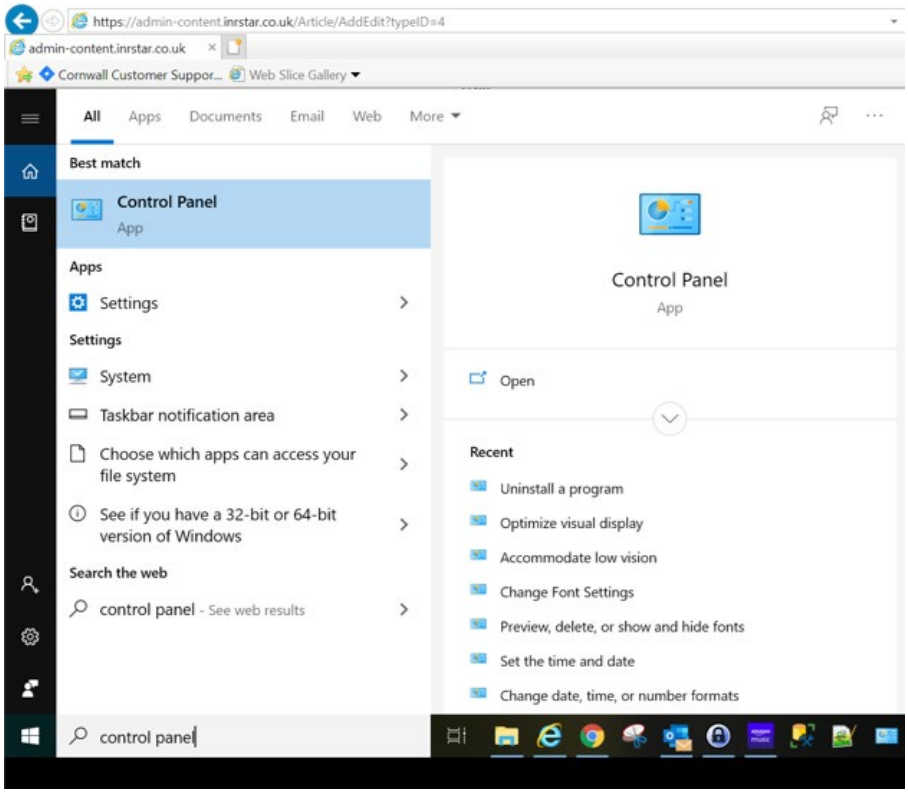
Appendix E – Update Installation Troubleshooting

If an INRstar update is not accepted and installed, the existing version will need to be uninstalled and replaced with the latest version.

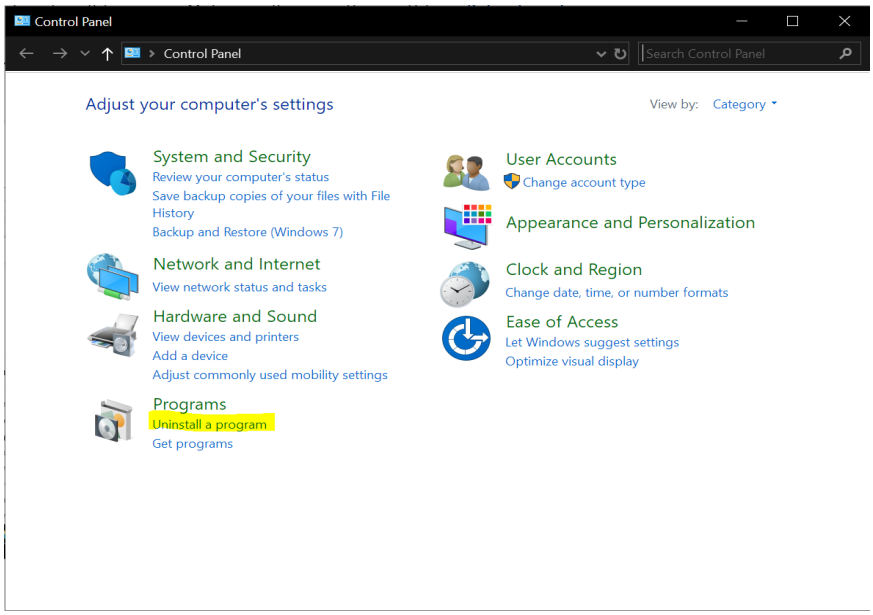
Support from your local IT personnel may be required to complete this process.

This section includes a step-by-step guide to uninstalling and reinstalling INRstar.

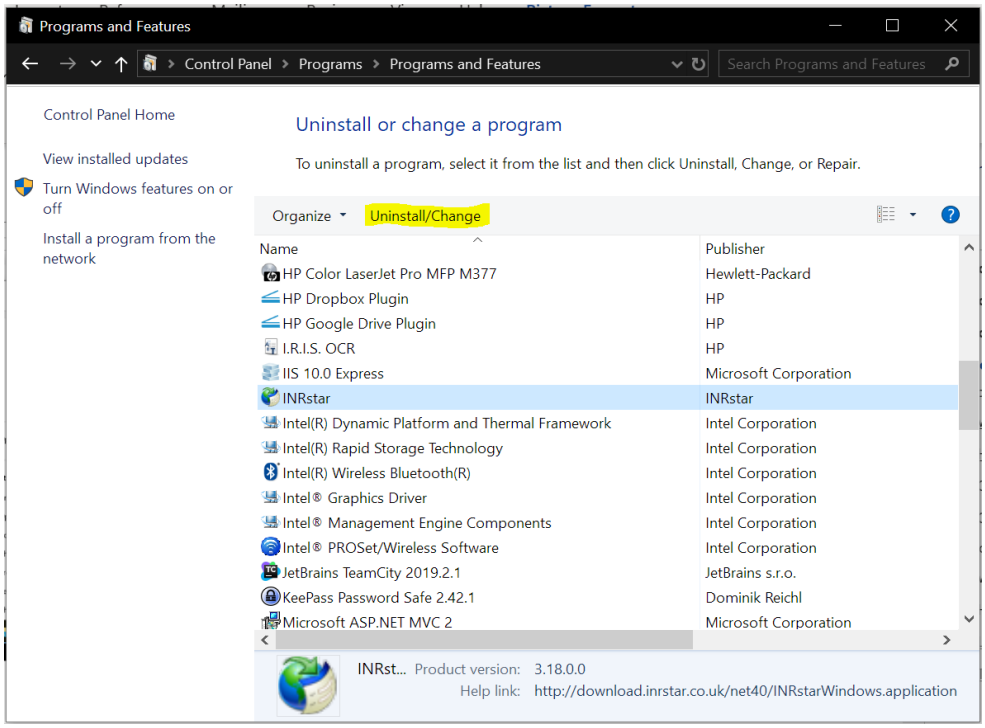
1. Click the **'Start'** icon in the bottom left corner of your screen, and type **Control Panel** into the search bar.



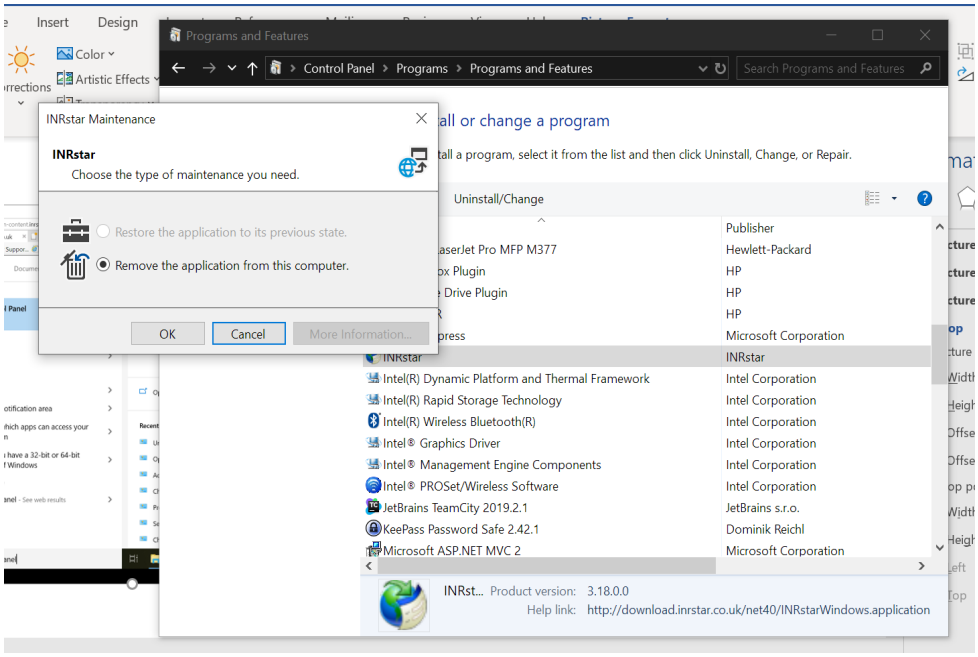
2. Open the **Control Panel**, navigate to **Programs**, then click **Uninstall a program.**



3. Scroll through list until you find **INRstar**. Click to highlight, then click **Uninstall.**

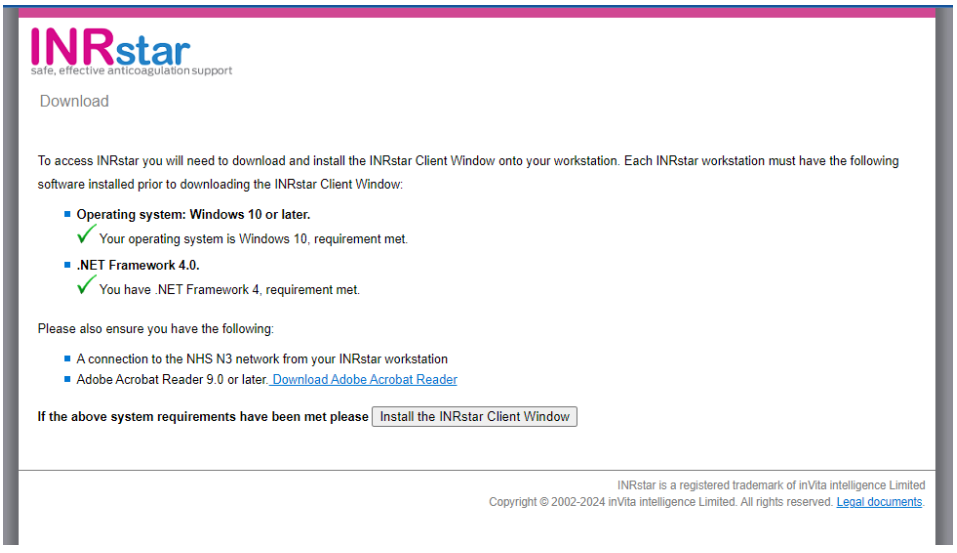


4. When the INRstar Maintenance box appears on your screen, click **Remove the application from this computer**, then **OK.**



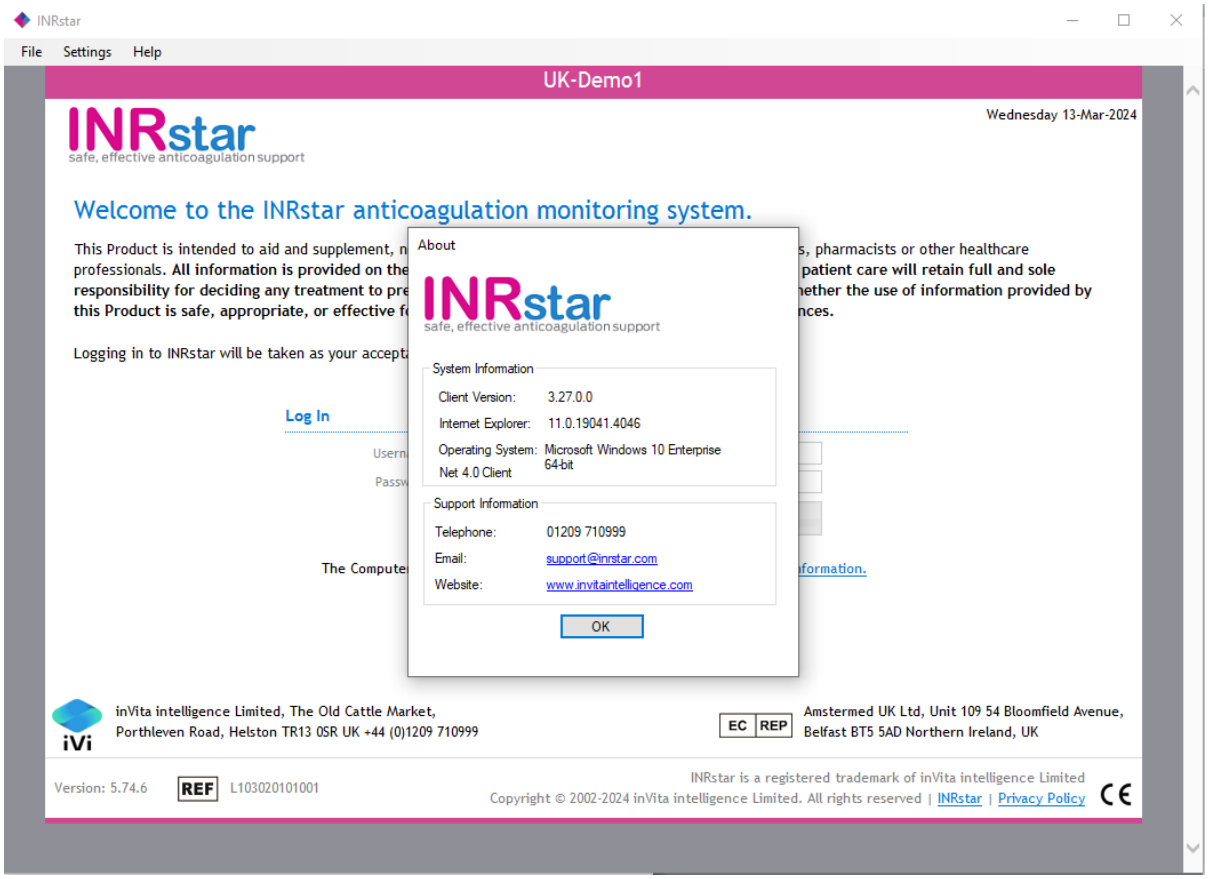
5. Once INRstar has uninstalled, open **Internet Explorer** and navigate to https://download-uk.inrstar.com/ (In Ireland go to https://download-ie.inrstar.com/). If Internet Explorer is not available, then use your default web browser and look for the downloaded file named 'INRstarWindows.application' in your download folder and double-click it to open.

6. Click **Install the INRstar Client Window** to begin the install process.

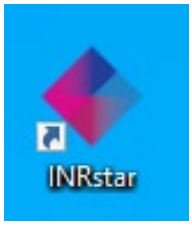


7. Once installed, the INRstar login page will open and you can access the software as normal.

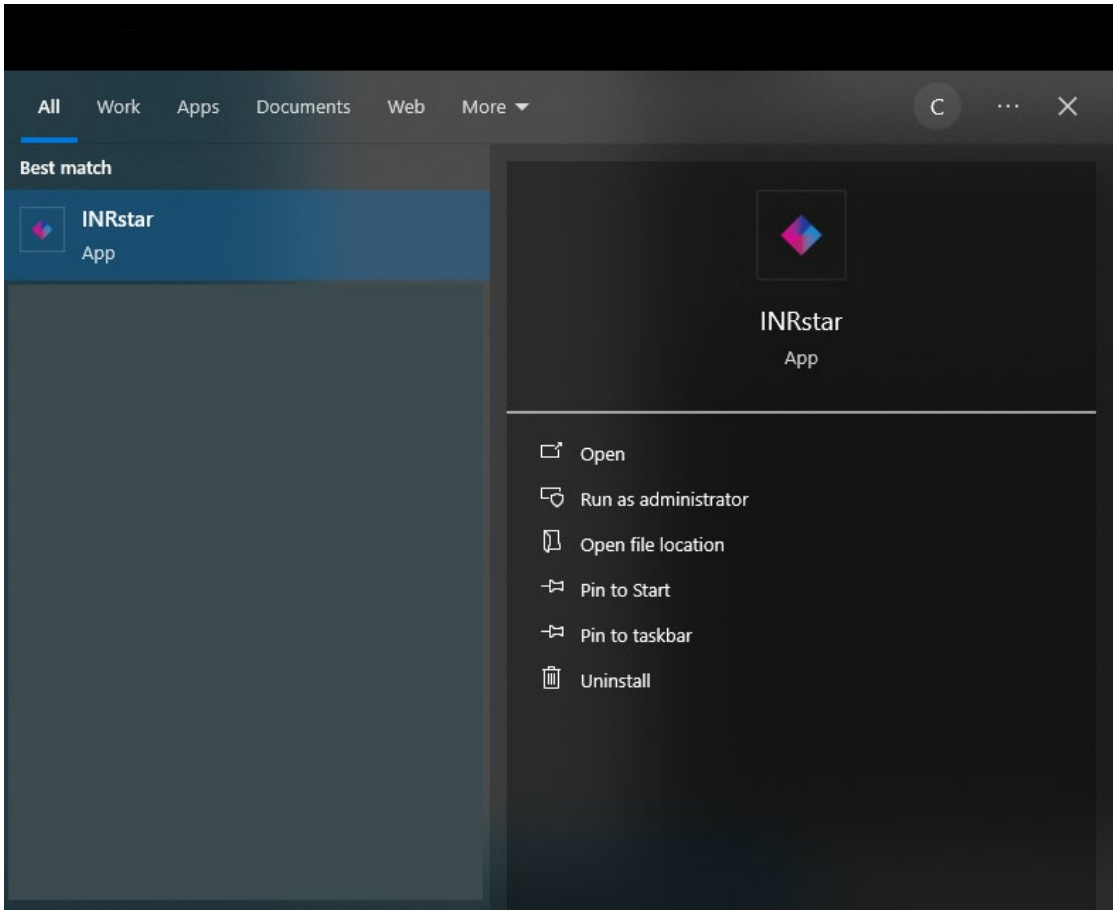
At this point, it is a good idea to confirm the INRstar version you have installed: click **Help** at the top of the INRstar window, followed by **About.**



If INRstar does not open automatically, look for a shortcut on your desktop like this:



or use the Windows search bar to find the "INRstar" application.



Revision History

Revision	Date	Details of Change
1	13th March 2024	First issue at inVita intelligence.
2	19th June 2024	Updated INRstar Windows Client installation instructions
3	1st July 2024	Additional updates to INRstar Windows Client installation
4	N\A	
5	9th April 2025	Updated the revision number to match the SharePoint version