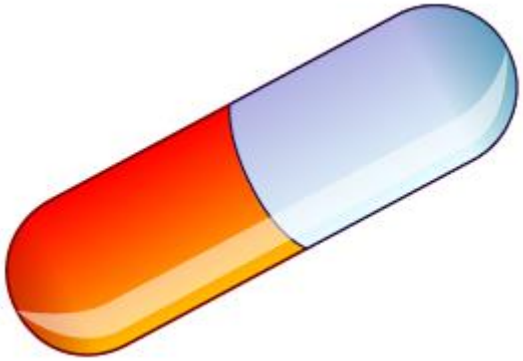
IMP-Track

User Manual

(Investigational Medicinal Product Tracker)



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1 Contents

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The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

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2 Introduction

The Investigational Medicinal Product (IMP) Tracker (herein referred to as 'IMP-Track') is designed to facilitate the tracking and accountability of IMP in clinical trials of investigational medicinal products (CTIMPs). IMP-Track enables drug packets to be tracked throughout their lifecycle, form the point of manufacture through to destruction. Via IMP-Track, users can distribute drug packets across multiple locations, allocate drug packets to trial participants based on their randomised allocations and account for their returns, loss or quarantine. Central admin users can control the access privileges of other users within a trial e.g. site research nurses or pharmacists, restricting access to functions relevant to their roles only.

IMP-Track has an Application Programming Interface (API) which allows external applications (such as in-house randomisation systems or study/trial software) to interact with IMP-Track via the web. Support is available to help set up authorised access to the API and to process responses. IMP-Track also has in-built randomisation functionality.

IMP-Track can accommodate drug packet allocation for two or more group parallel, factorial and cross-over trial designs with complex follow-up schedules. IMP-Track can be operated in masked or unmasked modes. Individual participant allocations can be unmasked if required, e.g. following a serious adverse reaction, by users with relevant privileges.

IMP-Track maintains a full audit trail which can be printed or exported.

This user manual is aimed at Centre Admin users at clinical trials units (CTU) or trial managers who are part of a research group. This manual is not designed to be disseminated to users outside of a CTU/research group. The CTU/research group are expected to generate separate trial-specific working instructions to inform participating sites and pharmacies how to use IMP-Track within the context of the trial it is being used in.

3 Internet browser requirements

The browser being used to run the IMP-Track web application must be up to date; capable of displaying HTML5/CSS3 and running JavaScript (e.g. up to date versions of browsers such as Internet Explorer, Edge, Chrome, Firefox, or Safari) and have a stable internet connection. Some browsers such as older Internet Explorer versions are unable to run the IMP-Track web application without issues. IMP-Track cannot be used offline.

4 Accessing IMP-Track

4.1 Activating the first user for a new trial

The first user on a new trial will be registered and approved by the Bristol Trials Centre. The user will be assigned the role ‘Admin_Centre’ (herein referred to as Centre Admin) and provided with all user permissions (see Table 1). The Centre Admin can review and approve, un-approve or delete prospective users requesting access to their trial. Centre Admins are responsible for managing the permissions of other users with access to their trial. When a prospective user registers for IMP-Track access, Centre Admin users will receive a notification email.

4.2 Registering for user access – all users except the first user on a new trial

Follow the instructions below to register for access to IMP-Track.

i. Open the IMP-Track web application via the link provided (CTUs should contact CTEU Bristol for links to individual trials).
ii. Click ‘Register’ (Figure 1).
iii. Complete all required fields on the registration form (Figure 2).
iv. Select the name of the trial for which access is required.
v. Click ‘Create User’.
vi. The CTU Centre Admin user will review the registration request and approve or un-approve access (see section 5 User Management).
vii. If registration is approved, follow the instructions in section 4.3 (Logging in) to access IMP-Track.

Figure 1 User registration

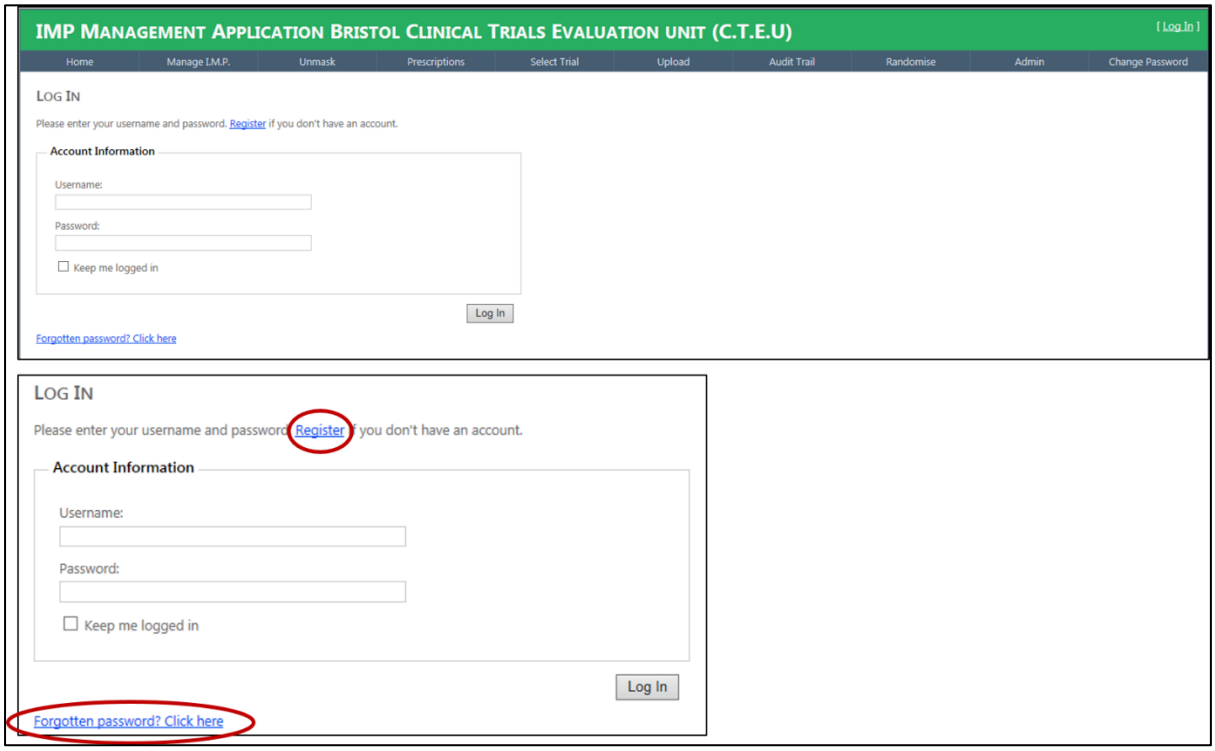
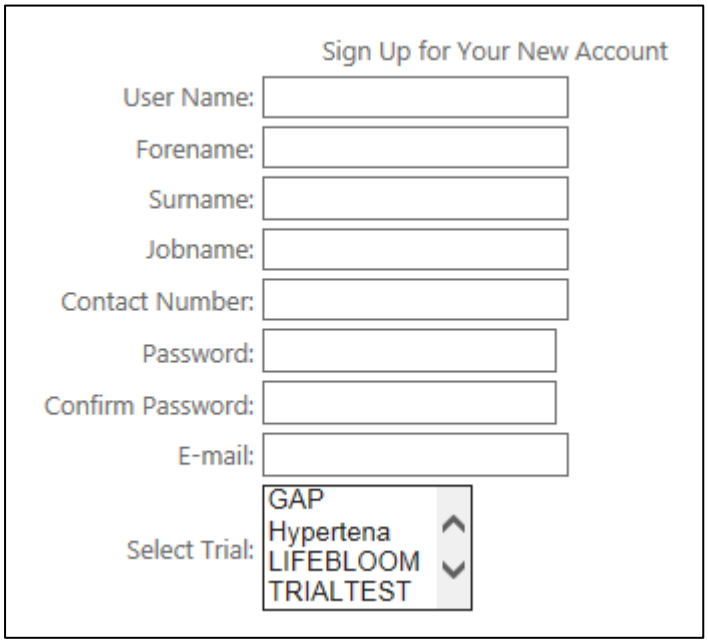


Figure 2 Registration form fields



4.3 Logging in

i. Open the IMP-Track web application via the link provided to the CTU by CTEU, Bristol.
ii. Enter your username and password in to their respective fields (Figure 1).
iii. Click ‘Log In’.

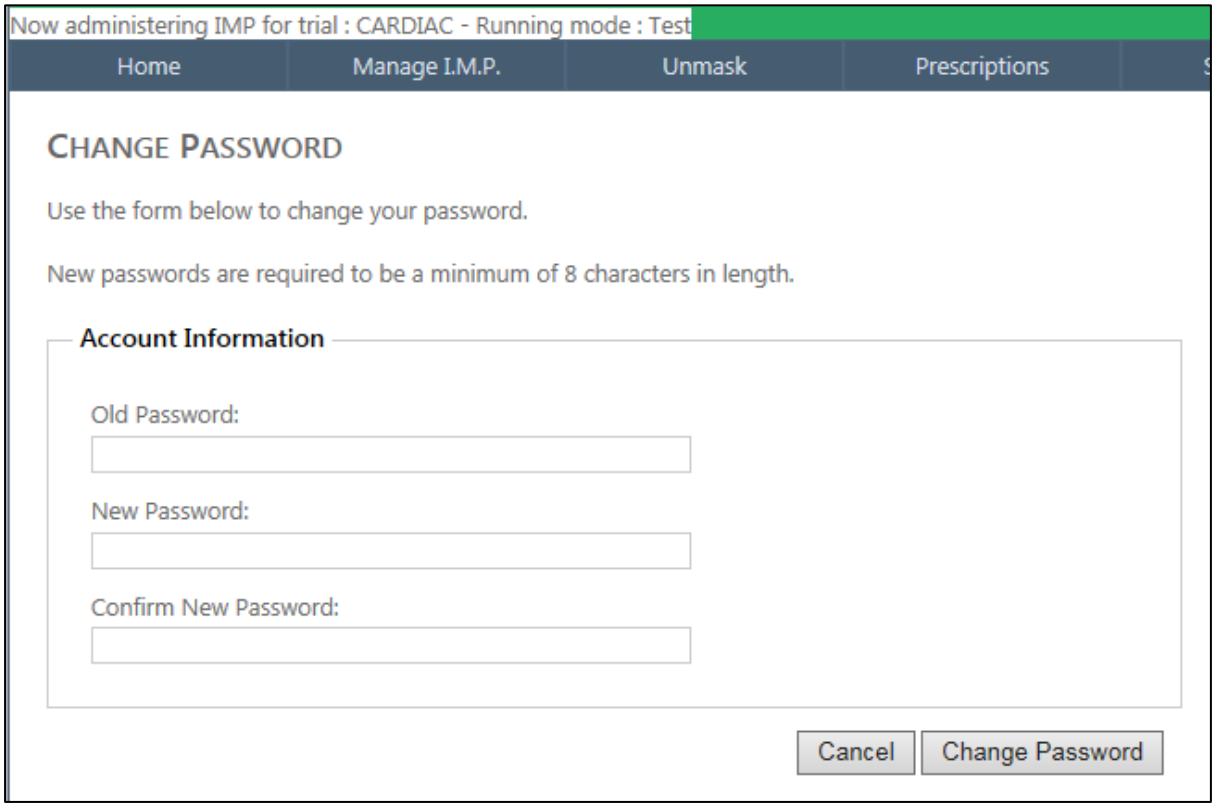
4.4 Changing passwords

Users can choose to change their password when logged in to IMP-Track following the instructions below.

Note. To reset a forgotten password, see section 4.5 Forgotten passwords.

i. Select the ‘Change Password’ tab.
ii. Enter the current password in to the ‘Old Password’ field (Figure 3).
iii. Enter the new password in to the ‘New Password’ field.
iv. Enter the new password again in to the ‘Confirm New Password’ field.
v. Click ‘Change Password’.
vi. The password will be updated to the new password.

Figure 3 Changing passwords



4.5 Forgotten passwords

If a user forgets their password, they can reset it following the instructions below.

i. Open the IMP-Track web application.

ii. Click the ‘Forgotten password? Click here’ link (Figure 1).

iii. Enter the account username or email address into the field ‘Username or Email’.

iv. Click ‘Send Link’.

v. An email will be sent to the email address registered to the user account.

vi. Click the link within the email or copy and paste it into an internet browser page.

Note. The link is only valid for 24 hours.

vii. Enter a new password into the field ‘New password’ (Figure 4).

viii. Enter the new password again into the field ‘Confirm new password’.

ix. Click ‘Confirm’.

x. The password will be updated to the new password and the user can log in via the Log in process (section 4.3).

Figure 4 Entering a new password

5 User management

Centre Admin users can review prospective user profiles, approve users, edit user permissions or inactivate or delete users.

5.1 Reviewing a users' profile

i. Select the 'Admin' tab.
ii. Select 'Users' from the menu options.
iii. All approved users and prospective users (i.e. users pending approval) will be displayed in a list.
iv. To view the profile page of a user, click on the user name hyperlink (Figure 5).
v. Within a user profile page (Figure 6), the Centre Admin can assign or remove roles (i.e. permissions), trial centres and access to a trial by checking or un-checking the relevant check-boxes.
vi. If changes are made to a users' profile, click 'Update' to save the form.
vii. Return to the list of users by repeating steps i and ii.

5.2 Approving prospective users

i. To approve a prospective user repeat Section 5.1, steps i - vii.
ii. Once returned to the list of users after reviewing the user profile, Click 'Approve' (Figure 7).
iii. The newly-approved user will receive a notification email to inform them that their registration was approved.

5.3 Inactivating, unlocking or deleting user accounts

i. Repeat Section 5.1, steps i and ii.
ii. To inactivate a user but retain their user profile, click 'Unapprove' (e.g. when a user has ceased working on a trial; Figure 7). This will keep a record of the user within the system, but the user will not be able to log in. The account can be reactivated later by clicking 'Approve'.
iii. If a user enters their password incorrectly five or more consecutive times they will be locked out of their account. To unlock their account, click 'Unlock'.
iv. Or, to delete a user from the system, click 'Delete' (Figure 7). The user profile will be permanently deleted from IMP-Track e.g. if an inappropriate prospective user registers for access.

Figure 5 Link to user profile

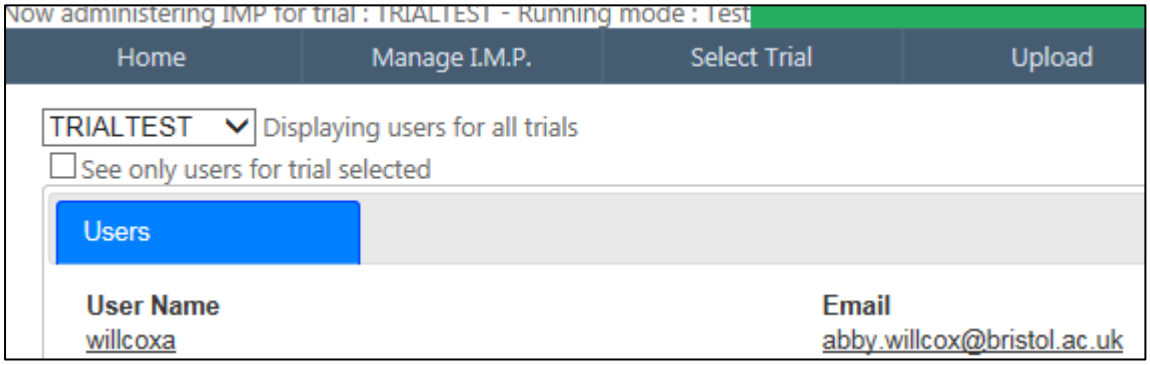


Figure 6 User profile page

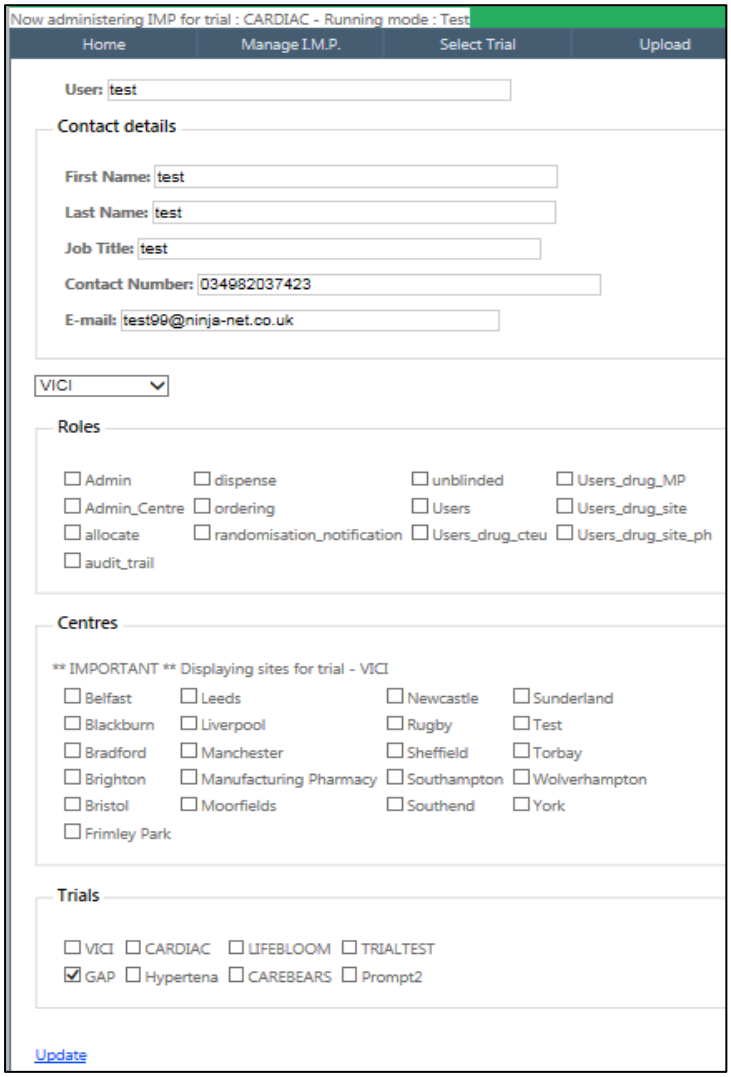
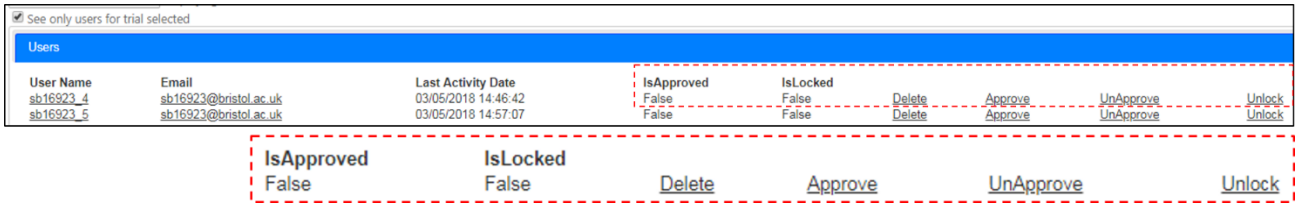


Figure 7 User list with approve/unapprove, delete and unlock options



6 Tabs and menu options

IMP-Track is organised in to tabs, some of which contain a further set of menu options within. Visibility of tabs is role-restricted per user e.g. only users with permissions to allocate or dispense IMP with be able to view the 'Prescriptions' tab. Table 1 demonstrates the available tabs, the menu options within them and the permissions (i.e. roles) which must be assigned to permit users to access them.

Table 1 User roles and associated functions

Tabs	Menu	Functions \ Roles	Admin_Centre	Allocate	API	Audit_trail	Dispense	Ordering	randomisation_notifcation	Randomise	unblinded	unmask
Home	Home	Home page	1	1	1	1	1	1	1	1	1	1
Manage IMP	Orders/Returns	Place order	0	0	0	0	0	1	0	0	0	0
Manage IMP	Orders/Returns	Cancel order/dispatch/receipt	0	0	0	0	0	1	0	0	0	0
Manage IMP	Orders/Returns	Change status of drug packet - all	0	0	0	0	0	1	0	0	0	0
Manage IMP	Orders/Returns	Change status of drug packet - restricted *2*3	1	0	0	0	0	1	0	0	0	0
Manage IMP	Orders/Returns	Move individual drug packets	0	0	0	0	0	1	0	0	0	0
Manage IMP	Log Dispatch	Log dispatch of order	0	0	0	0	0	1	0	0	0	0
Manage IMP	Log Receipt	Log receipt of order	0	0	0	0	0	1	0	0	0	0
Manage IMP	Check Stock	Check stock levels	0	0	0	0	0	1	0	0	0	0
Unmask	Unmask	Unmask allocations	0	0	0	0	0	0	0	0	0	1
Prescriptions	Dispense drugs	Allocate drug packets	0	1	0	0	0	0	0	0	0	0
Prescriptions	Dispense drugs	Confirm dispensing	0	0	0	0	1	0	0	0	0	0
Prescriptions	Dispense drugs	Cancel allocation	0	0	0	0	1	0	0	0	0	0
Prescriptions	Prescription history	View history of prescriptions per study ID	0	1	0	0	1	0	0	0	0	0
Upload	Upload	Uploading trial data	1	0	0	0	0	0	0	0	0	0
Audit trail	Audit trail	Audit trail of drug packets	0	0	0	1	0	0	0	0	0	0
Randomise	Randomise	Randomise participants	0	0	0	0	0	0	0	1	0	0
Randomise	Add/Edit study ID	Add/Edit unrandomised study ID	0	0	0	0	0	0	0	1	0	0
Admin	Trial Admin	Define parameters after uploading data	1	0	0	0	0	0	0	0	0	0
Admin	Users	Approve/unapprove/delete/permissions	1	0	0	0	0	0	0	0	0	0
Admin	Notifications	Add notifications	1	0	0	0	0	0	0	0	0	0
Admin	Notifications	Edit notifications	1	0	0	0	0	0	0	0	0	0
Admin	Themes	Change Themes	1	0	0	0	0	0	0	0	0	0
Change Password	Change Password	Change own password	1	1	1	1	1	1	1	1	1	1
Other functions not associated with a tab/menu option												
N/A	N/A	Receive randomisation notification	0	0	0	0	0	0	1	0	0	0
All forms with drug description displayed	All forms with drug description displayed	Able to see unmasked drug description	0	0	0	0	0	0	0	0	1	0
Application programming interface	Application programming interface	Application programming interface *4	0	0	1	0	0	0	0	0	0	0

0 (red) = role does not permit access to associated function; 1 (green) = role permits access to associated function.

*2 Users require both Admin_Centre AND Ordering roles to enable restricted drug packet status change function.

*3 Restricted drug packet status changes permits the user to make any change to the status of a drug packet.

*4 Assistance required from CTEU Bristol.

7 Application programming interface (API)

Support for the API will be provided by CTEU Bristol Trials Centre liaising with the customer CTU's IT department. The API is secured and will need some technical knowledge to authenticate and get external access to IMP-Track.
An example of how the API might be used is where randomisation has been done using an external randomisation system. A message can be sent via the web API to IMP-Track to both create the study ID in IMP-Track and assign it to the correct treatment arm in order that the correct drug packets can be allocated to it.

8 Trial metadata

For each trial, metadata files must be uploaded to IMP-Track before further set-up can be completed. The data required are 1) list of trial sites 2) drug packet data (i.e. list of individual drug packet IDs and what drug they correspond to) 3) minimum drug packet stock levels per trial site and 4) a treatment allocation list (only applicable if using IMP-Track's in-built randomisation function).

8.1 Metadata file format

Metadata files must comply with a specific format. Support will be provided to help generate the files in a compatible format while matching the trial set up data. The file must be comma separated (CSV).
An example CSV file of the trial site upload data displayed in Excel can be seen in Figure 8. A full definition of fields and accepted data types can be accessed via the link on the Upload page (Tab: Upload).
IMP-Track requires certain metadata to be uploaded, as indicated by the upload options available (Figure 9). Additional metadata requirements can be directed to CTEU Bristol Trials Centre for consideration on a per trial basis. Support to implement additional requirements can be provided by CTEU Bristol Trials Centre.
When configuring drug packet metadata files, it is important that the drug packets IDs are assigned in non-consecutive order and in a format which prevents a participants allocation from being guessed.

Figure 8 Example trial metadata CSV file

unique_id	description	ODS_Code_3	OCD_Code_5	ODS_Description_3	ODS_Description_5	local_centre_id	trial_site	username
1	Southampton					1	1	CTU_2_ADMIN
2	Belfast					4	1	CTU_2_ADMIN
3	Blackburn					5	1	CTU_2_ADMIN
4	Bristol					6	1	CTU_2_ADMIN
5	Brighton					7	1	CTU_2_ADMIN
6	Manufacturing Pharmacy					8	0	CTU_2_ADMIN
7	Test					10	1	CTU_2_ADMIN
8	Rugby					12	1	CTU_2_ADMIN
9	Frimley Park					13	1	CTU_2_ADMIN
10	Bradford					14	1	CTU_2_ADMIN
11	Liverpool					15	1	CTU_2_ADMIN
12	Moorfields					16	1	CTU_2_ADMIN
13	Manchester					17	1	CTU_2_ADMIN
14	Newcastle					18	1	CTU_2_ADMIN
15	Sheffield					19	1	CTU_2_ADMIN
16	Southend					20	1	CTU_2_ADMIN
17	Sunderland					21	1	CTU_2_ADMIN
18	Torbay					22	1	CTU_2_ADMIN
19	Wolverhampton					23	1	CTU_2_ADMIN
20	Leeds					24	1	CTU_2_ADMIN
21	York					25	1	CTU_2_ADMIN
22	BristolPharmacy					26	0	CTU_2_ADMIN
23	ImperialPharmacy					27	0	CTU_2_ADMIN
24	Imperial					28	1	CTU_2_ADMIN

8.2 Uploading metadata files

i. Select the ‘Upload’ tab.

ii. Select one of the data file options (Figure 9; Figure 10).

iii. Click ‘Browse’ to search for the corresponding data file.

iv. Click ‘Open’ to select the file.

v. Click ‘Upload’.

vi. After uploading trial site data or minimum stock level data, the data will be displayed in a table for review (no actions are required). *Note. Drug packet data cannot be displayed in a table due to the high volume of data. Allocation data is only required when the in-built randomisation function is used.*

vii. Click ‘Confirm’.

viii. Repeat steps i – v for each metadata file.

ix. Proceed to section 9 to set up the parameters of the trial within IMP-Track.

Note. Selecting ‘Upload drug packet data’ will open up additional options to enable either 1) extra drug packets to be added to existing ones or 2) replacement of existing drug packet data. Take care to select the correct option so as not to delete existing drug packet data in error.

Figure 9 Metadata file upload options

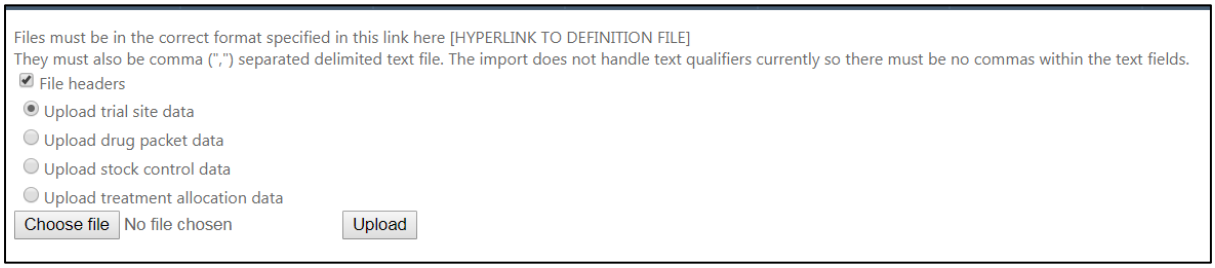
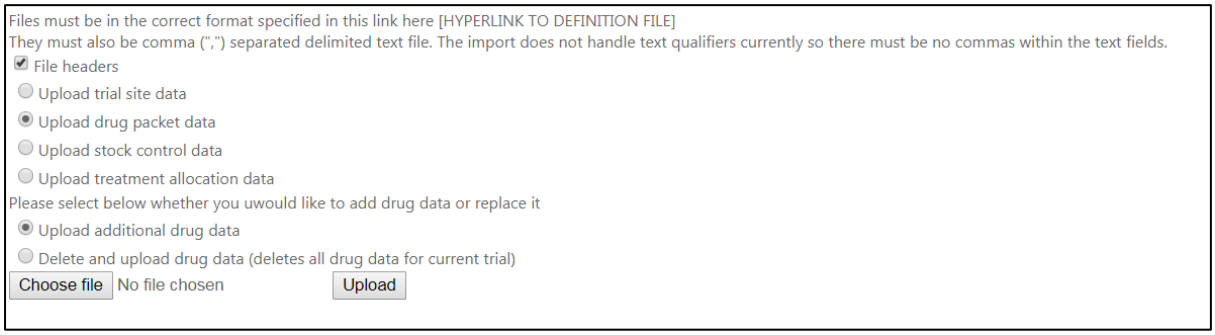


Figure 10 Expanded metadata file options; additional or replacement data



9 Defining trial parameters

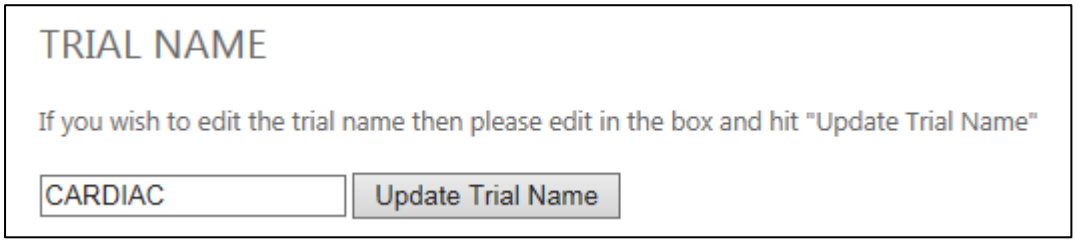
Once a new trial has been added to the database and the metadata files have been uploaded, the parameters of the trial can be defined within IMP-Track, including sites, treatment arms and treatment schedules. This section must be completed carefully and tested thoroughly before release of the database as errors in set-up could have a serious impact on downstream processes.

Note. Before this section can be completed the metadata files must be uploaded as described in section 8. Variables used to define the parameters must match the variable names specified in the uploaded metadata, e.g. drug_id. Variables which are predetermined by the metadata are highlighted by an (‡) symbol.

Follow the instructions below to define the trial parameters.

i. Select the 'Admin' tab.
ii. Select 'Trial Admin' from the menu options.
iii. If required, the trial name can be changed by following the instructions in the top right-hand side of the screen (Figure 11).

Figure 11 Editing a trial name



9.1 Adding trial sites

i. Select a site from the ‘Trial site description’ drop-down list (Figure 12). The drop-down list is populated with the sites uploaded in the metadata file.

ii. Select whether the site is active <Yes/No> from the ‘Active’ drop-down list.

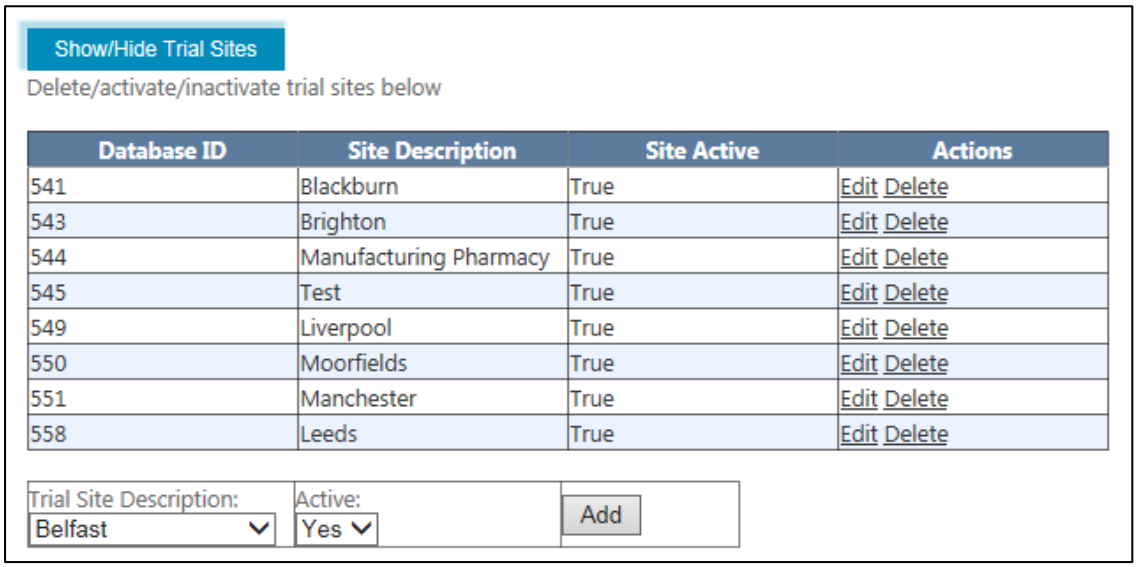
iii. Click ‘Add’.

iv. As sites are added they populate a table. The table can be hidden from view by clicking ‘Show/Hide Trial Sites’.

v. Optional: the status of the sites (i.e. active Yes or No) can be edited using the ‘Edit’ links in the ‘Actions’ column of the table.

vi. Optional: sites can be deleted from the table using the ‘Delete’ link in the ‘Actions’ column of the table. Sites can be added as they are activated.

Figure 12 Adding trial sites



9.2 Adding treatment arms

i. Enter a treatment arm description in the 'treatment_arm_description' field (Figure 13).

Note. A treatment arm description can be anything that describes the group/arm. For consistency it is advisable to use the nomenclature as defined in the protocol, e.g. Group A, Group B; Aspirin, Vitamin B12. An example for a cross-over trial would be 'Aspirin then Vitamin B12', 'Vitamin B12 then Aspirin'.

ii. Enter the treatment arm number *(‡)* in the 'treatment_arm_number' field. IMP-Track will prevent addition of duplicate treatment arm numbers.

iii. Click the 'Add' button.

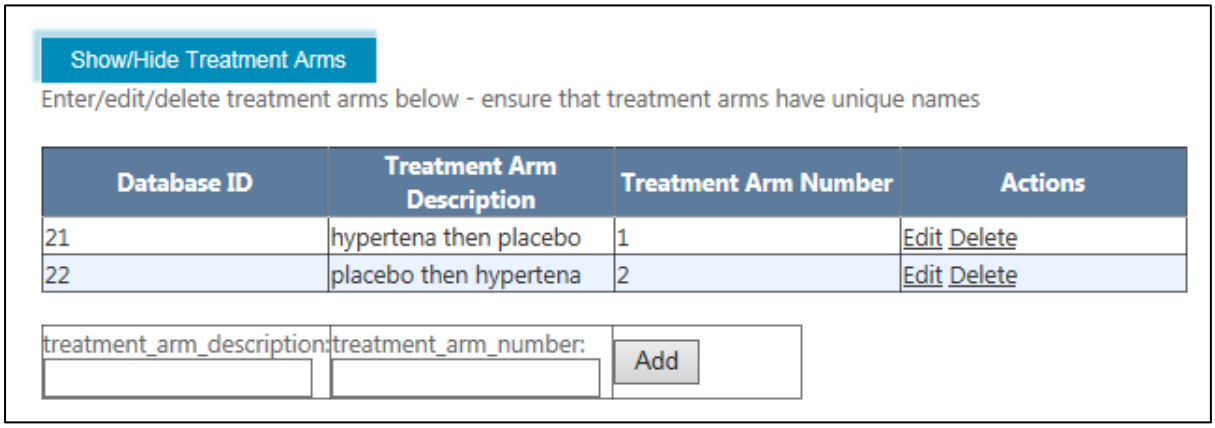
iv. Repeat steps i – iii for each treatment arm.

v. A table of treatment arms will populate above the drop-down list bar.

vi. Treatment arms can be edited or deleted from the table using the 'edit/delete' links in the 'Actions' column of the table.

Note. For trials with multiple drugs per treatment arm e.g. cross-over or factorial trials there should be one row input per treatment arm, not per drug. See Figure 13 *for an example of treatment arms input for a 2-arm cross-over trial.*

Figure 13 Adding treatment arms



9.3 Assigning masked and unmasked drug descriptions

i. Input the drug ID *(≠ drug_id)* in to the 'drug ID' field (Figure 14).

ii. Enter a description of the corresponding drug in to the 'drug_unmasked_description' field which will be visible to users with unmasked permissions e.g. aspirin, vitamin B12.

Note. The unmasked drug description should be unique for each drug ID.

iii. Enter a masked description of the drug in the 'drug_masked_description' field which will be visible to masked users e.g drug packet.

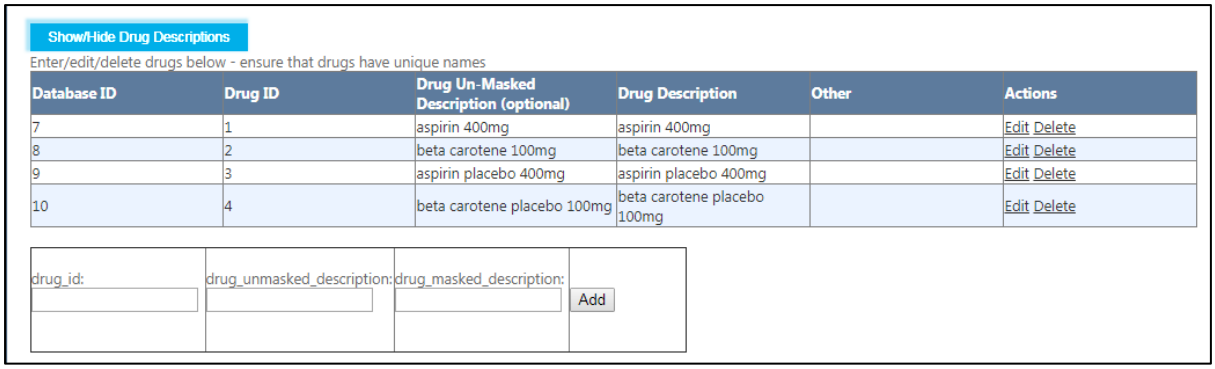
Note. *The masked drug description should be the same for each drug ID, e.g. drug / bottle / packet so as masked users cannot identify the drugs being allocated.*

iv. Click the 'Add' button.

v. Repeat steps i-v for each individual drug administered in the trial.

vii. A table of masked and unmasked drug descriptions will populate above the drop-down list bar.

Figure 14 Masked and unmasked drug descriptions



9.4 Assigning drugs to treatment arms

i. Select a treatment arm description from the ‘treatment_arm_description’ drop-down menu.
ii. Select one drug description from the ‘drug_description’ drop-down list which will be allocated to participants within the selected treatment arm.
iii. Click the ‘Add’ button.
iv. Repeat steps i-iii for all possible treatment arm/drug description combinations (see Table 2 and Figure 15, Figure 16, Figure 17, Figure 18 and Figure 19 for examples by trial design).

Table 2 Example treatment arm and drug combinations by trial design

	Parallel two group	
	Treatment Arm	**Drug description**
Treatment arm 1	Aspirin	Aspirin
Treatment arm 2	Vitamin B12	Vitamin B12
	Parallel two group with dose escalation	
	Treatment Arm	**Drug description**
Treatment arm 1	Aspirin	Aspirin 100 mg
	Aspirin	Aspirin 200 mg
Treatment arm 2	Vitamin B12	Vitamin B12 100 mg
	Vitamin B12	Vitamin B12 200 mg
	Parallel three group	
	Treatment Arm	**Drug description**
Treatment arm 1	Aspirin	Aspirin
Treatment arm 2	Vitamin B12	Vitamin B12
Treatment arm 3	Placebo	Placebo
	Factorial	
	Treatment Arm	**Drug description**
Treatment arm 1	Chemotherapy A + Aspirin	Chemotherapy A
	Chemotherapy A + Aspirin	Aspirin
Treatment arm 2	Chemotherapy A + Vitamin B12	Chemotherapy A
	Chemotherapy A + Vitamin B12	Vitamin B12
Treatment arm 3	Chemotherapy B + Aspirin	Chemotherapy B
	Chemotherapy B + Aspirin	Aspirin
Treatment arm 4	Chemotherapy B + Vitamin B12	Chemotherapy B
	Chemotherapy B + Vitamin B12	Vitamin B12
	Cross-over	
	Treatment Arm	**Drug description**
Treatment arm 1	Aspirin *then* Vitamin B12	Aspirin
	Aspirin *then* Vitamin B12	Vitamin B12
Treatment arm 2	Vitamin B12 *then* Aspirin	Aspirin
	Vitamin B12 *then* Aspirin	Vitamin B12

Figure 15 Setting up drug/treatment arm combinations; parallel two group trial

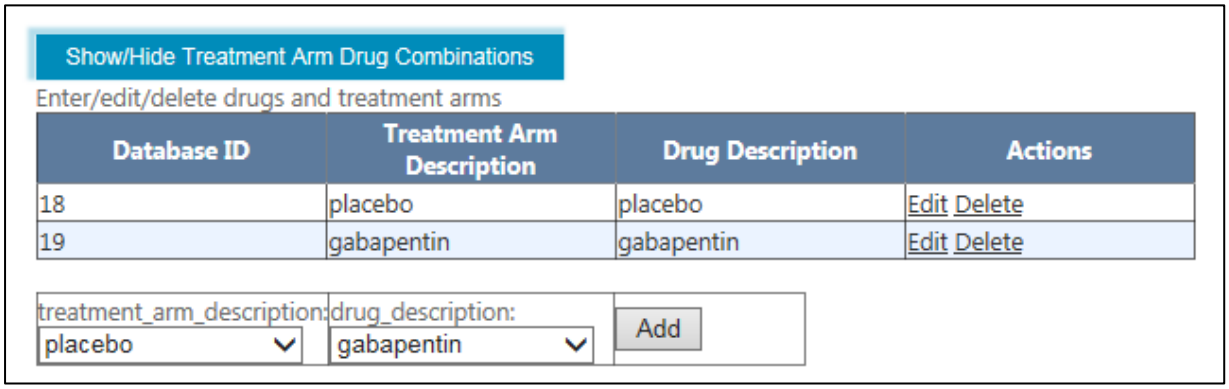


Figure 16 Setting up drug/treatment arm combinations; parallel two group trial with dose escalation

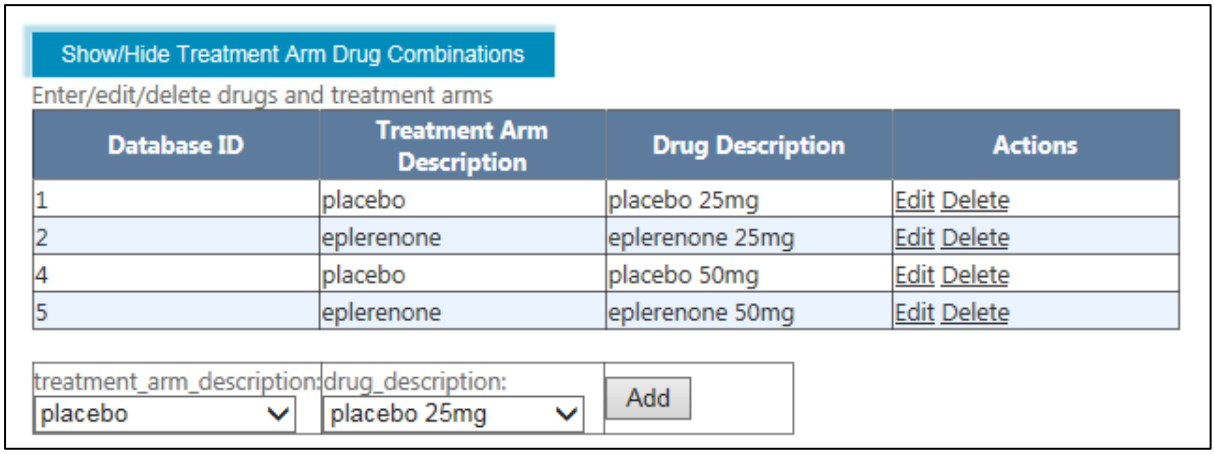


Figure 17 Setting up drug/treatment arm combinations; parallel three group trial

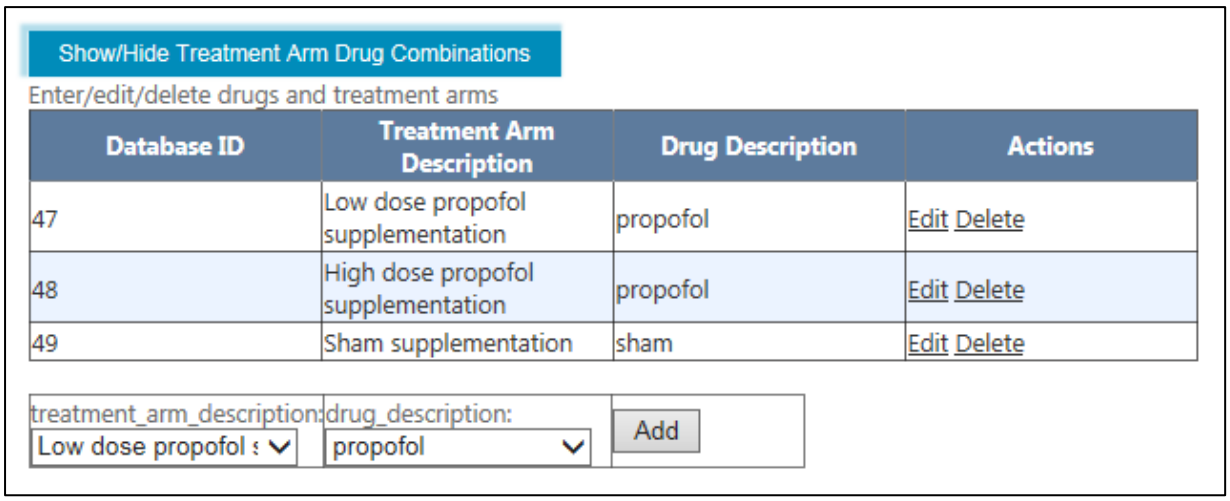


Figure 18 Setting up drug/treatment arm combinations; factorial trial

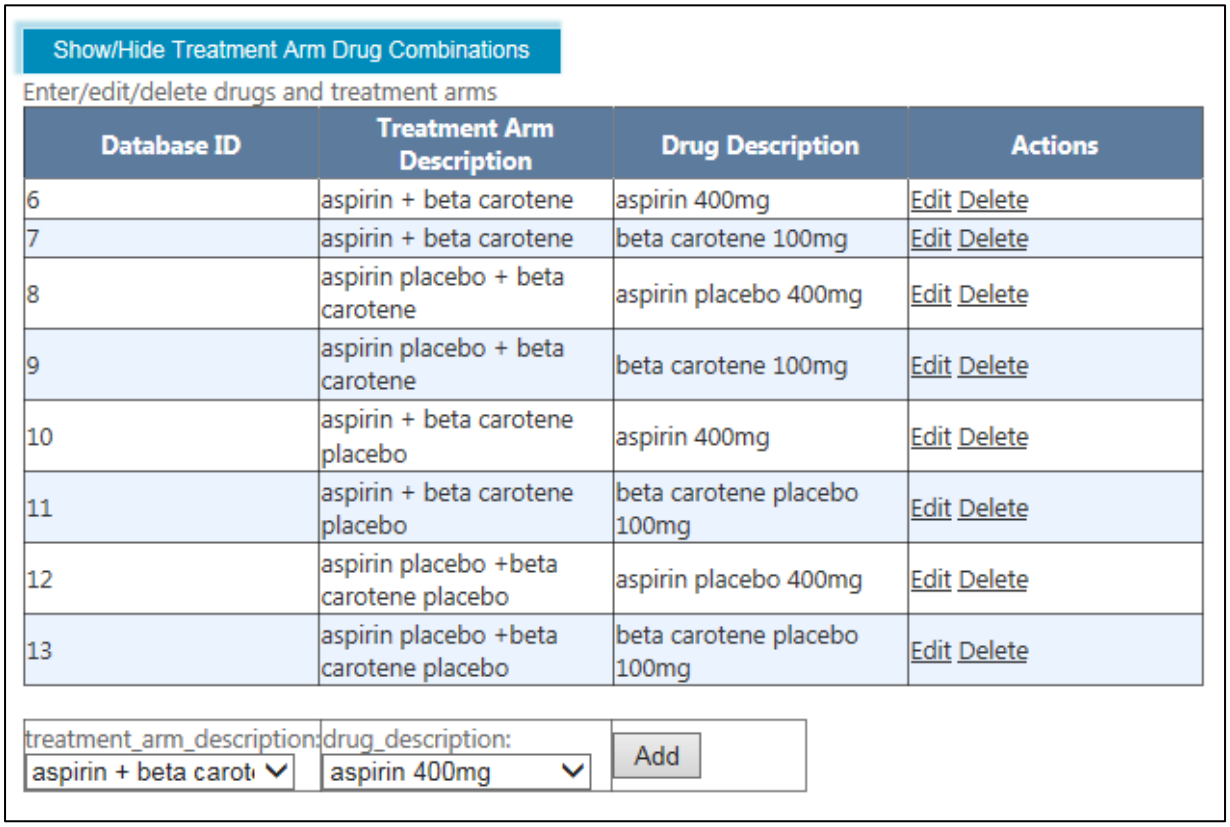
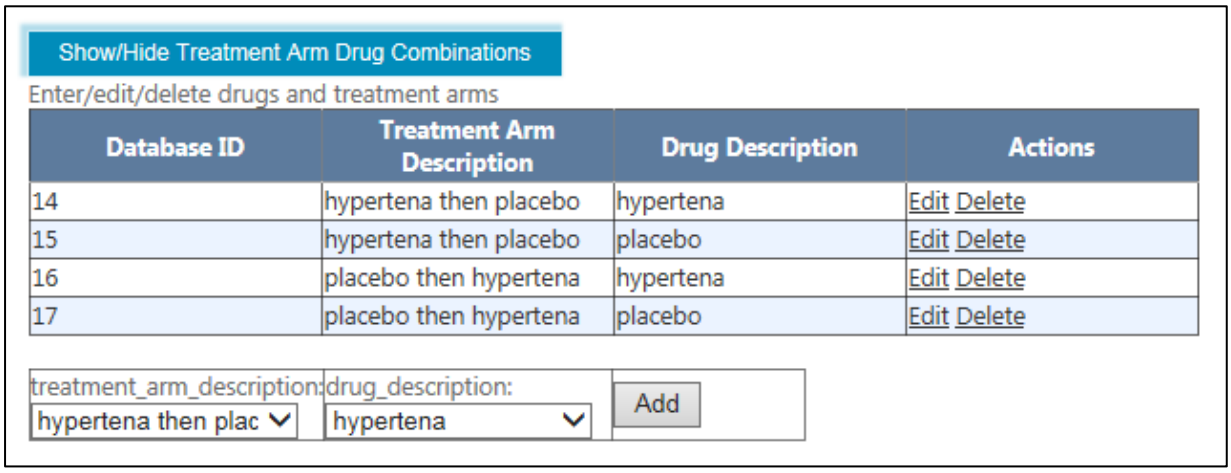


Figure 19 Setting up drug/treatment arm combinations; cross-over trial



9.5 Specifying treatment schedules

i. Input the visit number at which the first drug packet(s) will be allocated in to the 'Visit Number' field (Figure 20).

ii. Input the visit description, e.g. baseline / week 2, into the 'Visit Description' field.

Note. The visit description is not linked to uploaded trial data, but it is advisable to adhere to the visit description format detailed in the trial protocol for consistency.

iii. Select a drug that should be allocated at the specified visit number from the 'Drug' drop-down list.

iv. Select a treatment arm in which the above selected drug should be allocated from the 'Treatment Arm' list.

v. Select the quantity of drug packets that should be allocated at the specified visit number from the 'Volume Drug Packets' drop-down list.

vi. Click the 'Add' button.

vii. Repeat steps i-vi for all visit number/drug/treatment arm combinations.

viii. The data input will populate the table 'Treatment Drug Schedule' (Figure 21)

Note. Where more than one drug is to be allocated for a treatment arm at one time point e.g. in a factorial trial, separate entries must be input for each drug. See Table 3, Table 4, Table 5 *and* Table 6 *for examples covering a range of trial designs.*

Figure 20 Visit schedule data input bar

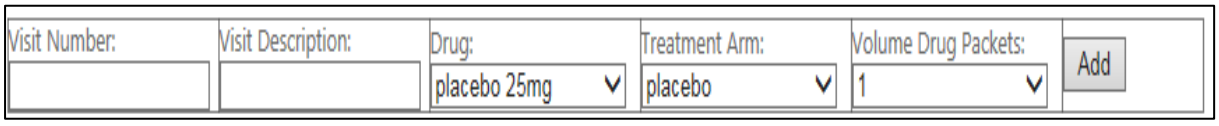


Figure 21 Specifying treatment schedule; example cross-over trial

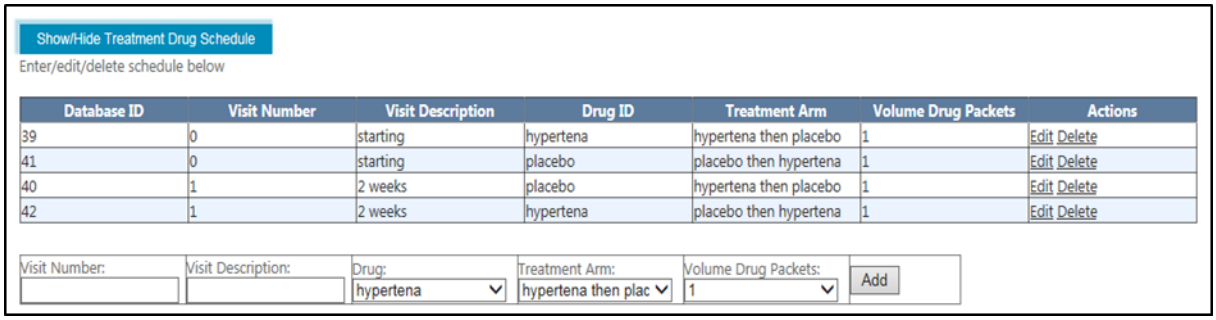


Table 3 Example visit schedule and drug packet volume: two group parallel trial

Visit number	Visit description	Drug	Treatment arm	Volume drug packets
0	**Baseline**	Vitamin B12	Vitamin B12	1
0	**Baseline**	Aspirin	Aspirin	1
1	**Week 2**	Vitamin B12	Vitamin B12	2
1	**Week 2**	Aspirin	Aspirin	2
2	**Week 6**	Vitamin B12	Vitamin B12	2
2	**Week 6**	Aspirin	Aspirin	2

Table 4 Example visit schedule and drug packet volume: two group parallel trial with dose escalation

Visit number	Visit description	Drug	Treatment arm	Volume drug packets
0	**Baseline**	Vitamin B12 50 mg	Vitamin B12	1
0	**Baseline**	Aspirin 100 mg	Aspirin	1
1	**Week 2**	Vitamin B12 100 mg	Vitamin B12	2
1	**Week 2**	Aspirin 200 mg	Aspirin	2
2	**Week 6**	Vitamin B12 100 mg	Vitamin B12	2
2	**Week 6**	Aspirin 200 mg	Aspirin	2

Table 5 Example visit schedule and drug packet volume: cross-over trial

Visit number	Visit description	Drug	Treatment arm	Volume drug packets
0	**Baseline**	Chemotherapy A	Chemotherapy *then* aspirin	1
0	**Baseline**	Aspirin	Aspirin *then* chemotherapy	1
1	**Week 4**	Aspirin	Chemotherapy *then* aspirin	1
2	**Week 4**	Chemotherapy A	Aspirin *then* chemotherapy	1

Table 6 Example visit schedule and drug packet volume: factorial trial

Visit number	Visit description	Drug	Treatment arm	Volume drug packets
0	**Baseline**	Chemotherapy A	Chemotherapy A + Vitamin B12	1
0	**Baseline**	Vitamin B12	Chemotherapy A + Vitamin B12	1
0	**Baseline**	Chemotherapy A	Chemotherapy A + Aspirin	1
0	**Baseline**	Aspirin	Chemotherapy A + Aspirin	1
0	**Baseline**	Chemotherapy B	Chemotherapy B + Vitamin B12	1
0	**Baseline**	Vitamin B12	Chemotherapy B + Vitamin B12	1
0	**Baseline**	Chemotherapy B	Chemotherapy B + Aspirin	1
0	**Baseline**	Aspirin	Chemotherapy B + Aspirin	1
1	**Week 2**	Chemotherapy A	Chemotherapy A + Vitamin B12	1
1	**Week 2**	Vitamin B12	Chemotherapy A + Vitamin B12	1
1	**Week 2**	Chemotherapy A	Chemotherapy A + Aspirin	1
1	**Week 2**	Aspirin	Chemotherapy A + Aspirin	1
1	**Week 2**	Chemotherapy B	Chemotherapy B + Vitamin B12	1
1	**Week 2**	Vitamin B12	Chemotherapy B + Vitamin B12	1
1	**Week 2**	Chemotherapy B	Chemotherapy B + Aspirin	1
1	**Week 2**	Aspirin	Chemotherapy B + Aspirin	1

10 Notifications

This section describes how to configure automated notification emails which are triggered by various transactions or events within IMP-Track. Notification emails can be set up to notify users of a) actions which have been completed (e.g. participant randomised, order placed) or b) actions which are required to be completed (e.g. to order more stock).

Notifications can be configured to distribute to individual users or to all users with specific roles or site permissions e.g. in the event of an order being placed, a notification can be distributed to the Centre Admin, the local site pharmacists and the manufacturing pharmacy/location the IMP is being sourced from. Local research nurses and pharmacists from other sites will not receive the notification. Similarly, if a participant is randomised at a site, a notification can be distributed to the Centre Admin and all users at the site where the participant was randomised but not to users at other sites or to the manufacturing pharmacy.

Notification email content is customisable; the subject line and main body of text can display any information the Centre Admin inputs and can automatically include a specific Drug Packet ID, Site and/or Study ID if required.

10.1 Creating new notifications

i. Select the ‘Admin’ tab.
ii. Select the menu option ‘Add Notifications’.
iii. On the form select the ‘Add notification’ option (Figure 22).
iv. Enter a name of the notification (brief description e.g. order placed) in the ‘Enter New Notification_Name’ field.
v. Select a ‘Notification type’ from the drop-down list which corresponds to the purpose of the notification.
vi. Enter a subject line for the notification email in the ‘Email subject’ field.
vii. Optional: a drug packet ID, site and / or study ID can be automatically inserted in to the subject line, e.g. to notify users that a specific site has placed an order. Select ‘Drug packet ID’ ‘Site’ and/or ‘Study ID’ from the dropdown list adjacent to the ‘Email subject’ field and click ‘Add parameter to subject’.

Note. The ‘Study ID’ and ‘drug packet ID’ parameters are restricted to notification types where such content would be relevant e.g. Randomised Occurred.

viii. Enter the body of the notification email in the ‘Email content’ field. This information should clearly and concisely inform the recipient what action has been completed or what action is required of them and, if necessary, provide relevant contact details.

ix. Optional: a drug packet ID, site and / or study ID can be automatically inserted in to the body of the email. Select ‘Drug packet ID’ ‘Site’ and/or ‘Study ID’ from the dropdown list and click ‘Add parameter to content’.

x. Select the email address that the recipient(s) will see as the sender of the notification email from the ‘From Email’ drop-down list. This is so as the notification email ‘Sender’ will be recognisable to the recipient.

xi. Select the email address that replies should be sent to in the event the recipient of a notification email replies to it from the ‘Reply to Email’ drop-down list.

Sending notifications to select users, irrespective of site or user group

xii. The email addresses of all registered approved users will automatically pre-populate the ‘specific email addresses list’ (visible only in ‘Add emails directly’ mode; Figure 23).

xiii. To add an unregistered recipient email address to IMP-Track e.g. a generic pharmacy email address or principal investigator who will not use IMP-Track but needs to be notified of randomisations, enter the email address in the field next to the button ‘Add Email’ and click ‘Add Email’.

xiv. To add individual recipient email addresses to the notification, select the option ‘Add emails directly’.

xv. Hold the ‘Ctrl’ key on the computer keyboard and select all relevant email addresses from the ‘Specific email addresses’ list.

xvi. Click ‘Add/Edit Notification’.

Sending notifications to all users at a site or in a specific user group

xvii. To select all users from a specific site or user group as recipients, select the option ‘Add Emails via User Groups and Sites’ (Figure 24).

xviii. All sites will be pre-selected by default in the ‘Select sites’ list. To amend the list of recipient sites, click the ‘Ctrl’ key on the computer keyboard and un-select sites that should not receive the notification email.

xix. Select all relevant recipient user groups from the ‘Select roles’ list. Hold the ‘Ctrl’ key on the computer keyboard to select more than one role.

xx. Click ‘Add/Edit Notification’.

Note. If setting up notification emails to send to specific sites and user groups, it is mandatory to select at least one site.

Figure 22 Creating and editing notification emails

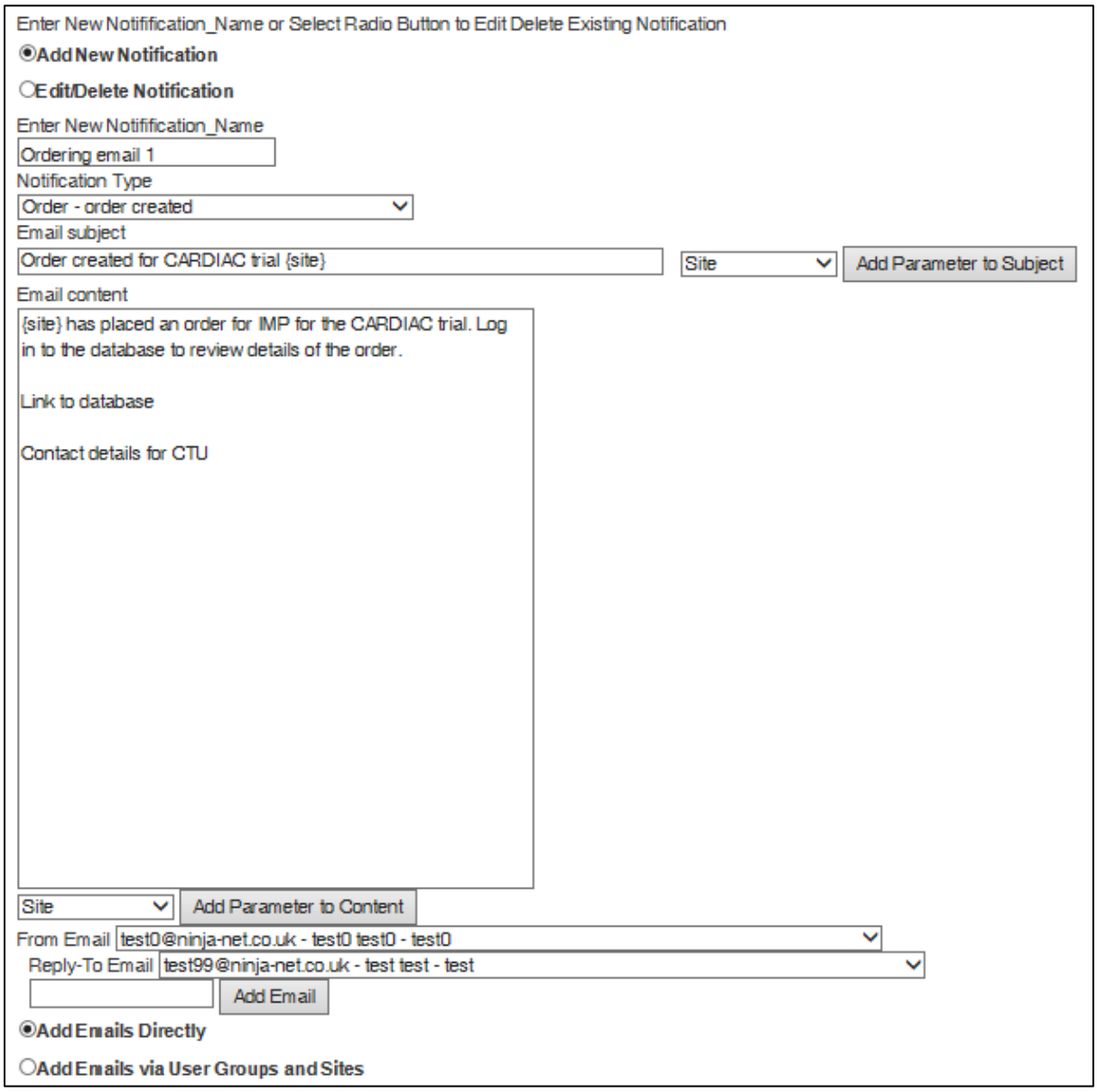


Figure 23 Selecting recipients by individual user email addresses

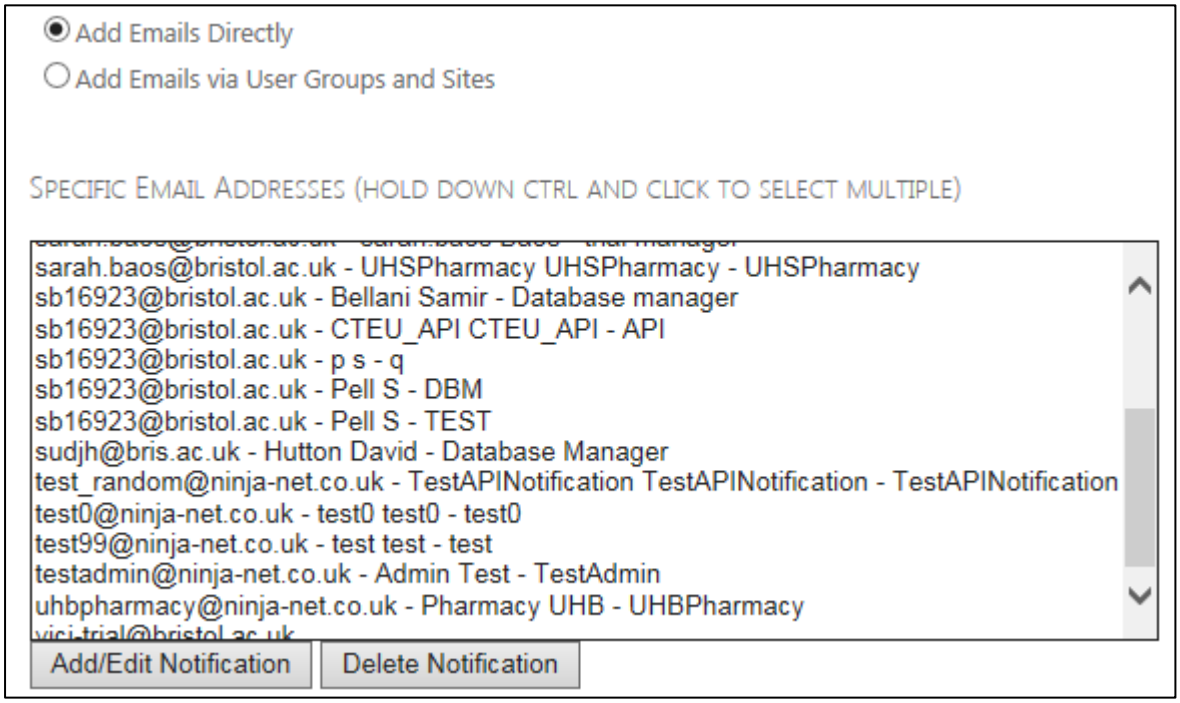
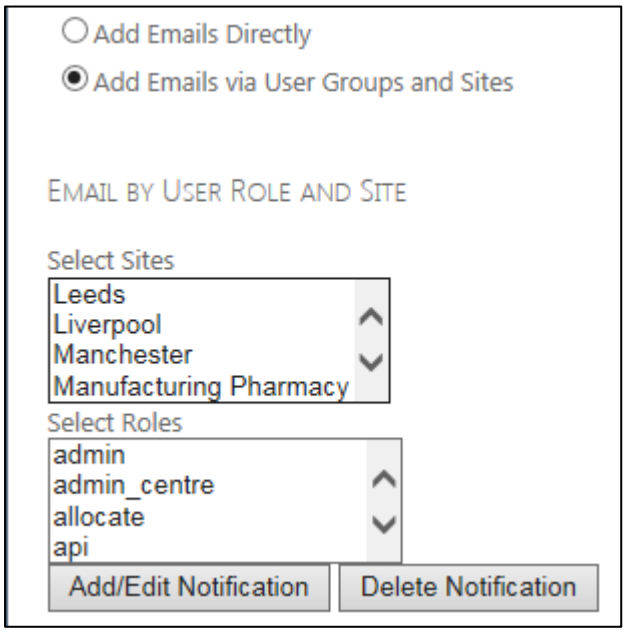


Figure 24 Selecting recipients by user group and/or sites



10.2 Editing and deleting notifications

To update or delete an existing notification follow the instructions below.

i. Select the ‘Admin’ tab.
ii. Select the menu option ‘Add Notifications’.
iii. Select the ‘Edit notification’ option.
iv. Select the notification to edit from the first drop-down list.
v. Make changes to the 'Email subject’ or ‘Email content’ as required.
vi. To edit recipients (individual or by user group/site), hold the ‘Ctrl’ key on the computer keyboard and select or unselect user email addresses or sites/user groups.
vii. Click ‘Add/Edit Notification’.
viii. *Or*, to delete a notification, repeat steps i – iv.
ix. Click ‘Delete Notification’.

11 Managing IMP stock

Ordering, dispatch and receipt of IMP stock, observing stock levels and accountability for individual drug packets can be managed centrally and by sites via the Manage IMP tab.

11.1 Placing an order: automatic drug packet selection

i. Select the 'Manage IMP' tab.
ii. Select the menu option 'Order/Returns'.
iii. Select 'Order' from the 'Transaction type' drop-down menu (Figure 25).
iv. Select the location the IMP is to be dispatched from using the 'Site From' drop-down menu (e.g. Manufacturing Pharmacy).
v. Select the location the IMP is to be dispatched to using the 'Site To' drop-down menu (e.g. a trial site).
vi. The quantity of each study drug type required by the recipient to bring stock levels up to target will automatically be calculated by IMP-Track.

*Note. The quantity of each drug type can be amended manually by clicking on the quantity drop-down list next to each drug type. Unmasked drug descriptions will only be visible to users with unmasked permissions (*Figure 25*), otherwise drugs will be presented cumulatively under their masked description (*Figure 26*).*

vii. Click 'Place Order'.
viii. A message will appear prompting the user to 'Confirm' or 'Cancel' the order.
ix. Click 'Confirm'.
x. A message will appear confirming the details of the order.
xi. Click 'Close'.

Figure 25 Placing an order; automatic drug packet selection, unmasked mode

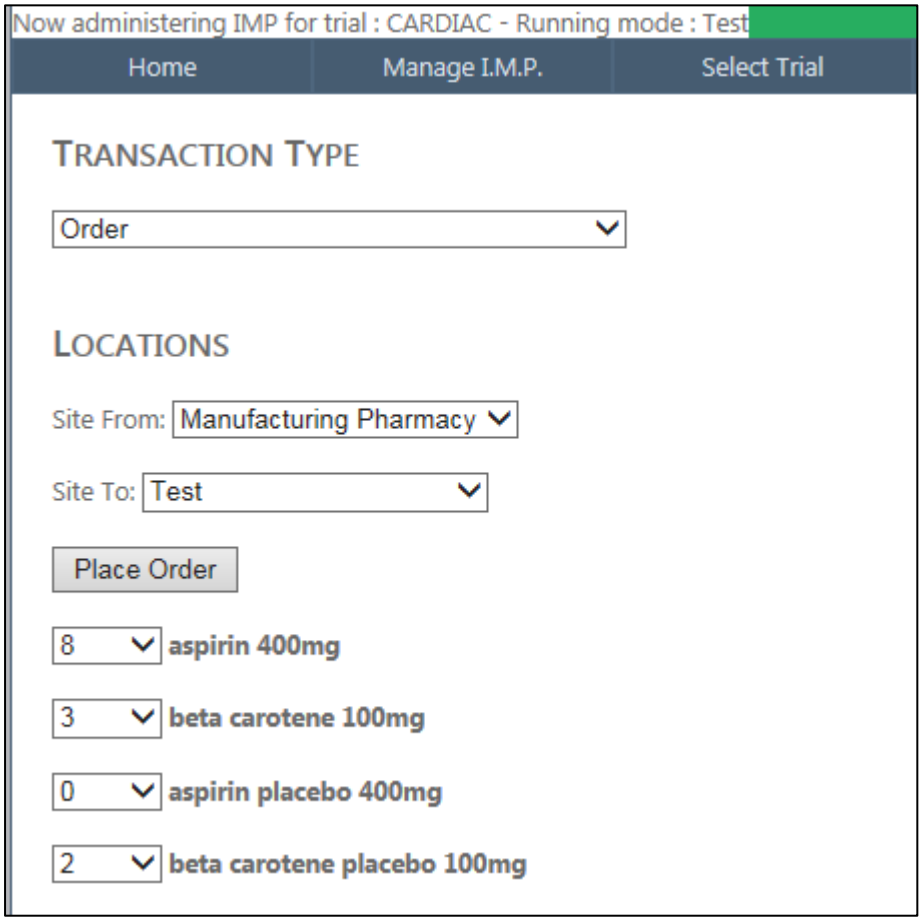
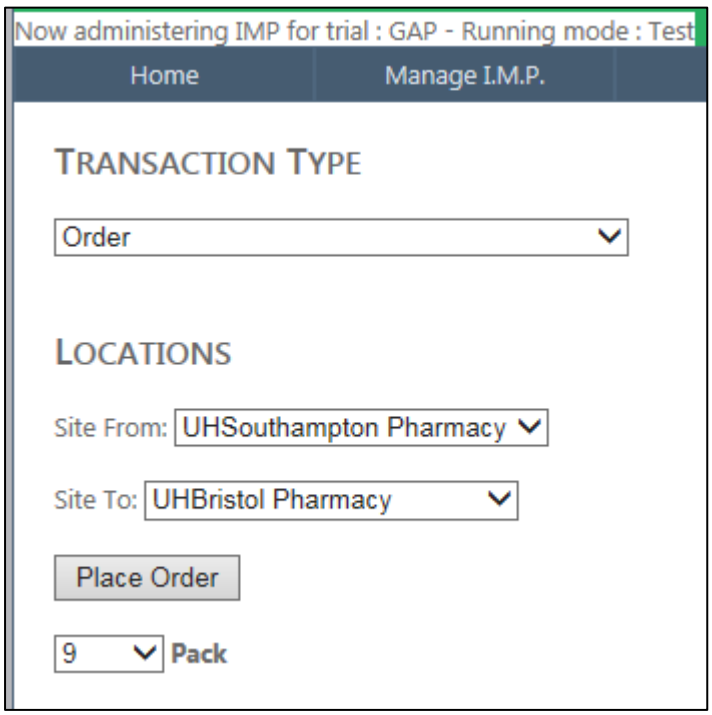


Figure 26 Placing an order; automatic drug packet selection, masked mode



11.2 Placing an order: selecting individual drug packets

It is possible to order specific drug packets for movement e.g. where drug packets of one allocation are to be returned to the manufacturing pharmacy to be re-distributed to a different site.

i. Select the 'Manage IMP' tab.
ii. Select the menu option 'Orders/Returns'.
iii. Select 'Select Individual Drug Packets for Movement' from the 'Transaction type' drop-down menu (Figure 27).
iv. Select the location the drug packets are to be dispatched from using the 'Site From' drop-down menu (e.g. the Manufacturing Pharmacy).

Note. If there are no drug packets located at the 'Site From', the message 'No drug packet data returned' will be displayed.

v. Select the location the drug packets are to be dispatched to using the 'Site To' drop-down menu.
vi. Select the individual drug packets that are to be moved by selecting the check boxes in the first column of the table of available IMP.
vii. To order the selected drug packets click 'Set ticked drug packets to be dispatched'.
viii. A confirmation message will appear asking the user to 'Proceed' or 'Cancel' the transaction.
ix. Click 'Proceed' and a message will appear stating 'Order confirmed – details stored on system'.
x. Click 'OK' to complete the order transaction.

11.3 Ordering individual drug packets filtered by batch or other variables

Drug packets can be filtered by batch number, other information or drug packet status before selecting individual drug packets to order, or the entire filtered list can be ordered without having to select individual drug packets e.g. all drug packets from batch XYZ103.

i. Complete steps i - v above (11.2).
ii. To filter by batch number, select the appropriate batch number from the 'Filter Batch' drop-down list (Figure 28).

iii. Click ‘Filter Batch’.

iv. Or, to filter by other information, select the appropriate option from the ‘Other Information’ drop-down list.

Note. An example of ‘Other information’ could be location or expiry date. It is input in the drug metadata file (variable VPG1) to the specification of the CTU on a trial-specific basis. CTEU Bristol Trials Centre can provide support with this feature when setting up IMP-Track for the trial.

v. Click ‘Filter on Other Information’.

vi. Or, to filter by drug packet status, select the appropriate status from the ‘Filter on Drug Packet Status’ drop-down list.

vii. Click ‘Filter on Drug Packet Status’.

viii. Select individual drug packets required for ordering from the filtered list.

ix. Click ‘Set ticked drug packets to be dispatched’.

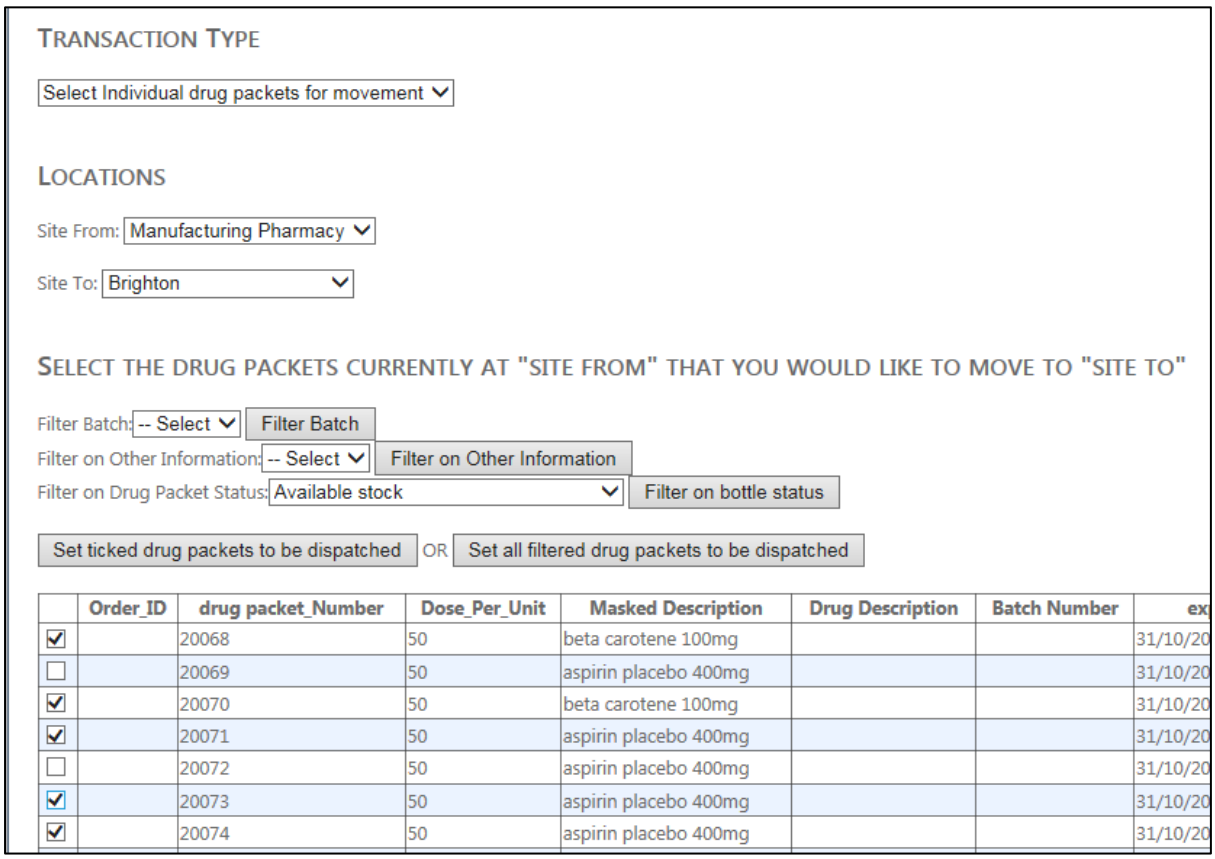
x. *Or*, to order all the filtered drug packets rather than selecting individual packets, click ‘Set all filtered drug packets to be dispatched’.

xi. A confirmation message will appear asking the user to ‘Proceed’ or ‘Cancel’ the transaction.

xii. Click ‘Proceed’ and a message will appear stating ‘Order confirmed – details stored on system’.

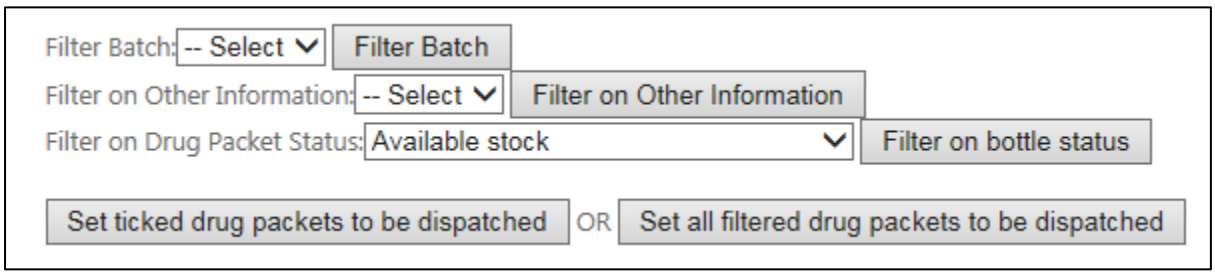
xiii. Click ‘OK’ to complete the order transaction.

Figure 27 Placing an order; selecting individual drug packets



	Order_ID	drug packet_Number	Dose_Per_Unit	Masked Description	Drug Description	Batch Number	ex
☑		20068	50	beta carotene 100mg			31/10/20
☐		20069	50	aspirin placebo 400mg			31/10/20
☑		20070	50	beta carotene 100mg			31/10/20
☑		20071	50	aspirin placebo 400mg			31/10/20
☐		20072	50	aspirin placebo 400mg			31/10/20
☑		20073	50	aspirin placebo 400mg			31/10/20
☑		20074	50	aspirin placebo 400mg			31/10/20

Figure 28 Placing an order; selecting individual drug packets filtered by batch or other criteria



11.4 Cancelling an order

Whole orders where individual drug packets have not yet undergone a status change since placing the order can be cancelled.

i. Select the ‘Manage IMP’ tab.
ii. Select the menu option ‘Orders/Returns’.
iii. Select ‘Cancel Order/Dispatch/Receipt’ from the ‘Transaction type’ drop-down menu (Figure 29).
iv. Select the relevant order from the ‘Orders available for status change’ drop-down menu.

v. Click ‘Display Order Contents’.

vi. Review the contents of the order to ensure it is appropriate to cancel it (Figure 30).

vii. Before cancelling an order, the order details can be printed or exported if required.

viii. Click ‘Cancel Order/Dispatch/Receipt’.

ix. A message will appear prompting the user to ‘Confirm’ or ‘Cancel’ the action.

x. Click ‘Confirm’.

xi. A message will display on the screen stating the order ID has been altered (Figure 31).

Figure 29 Cancelling an order

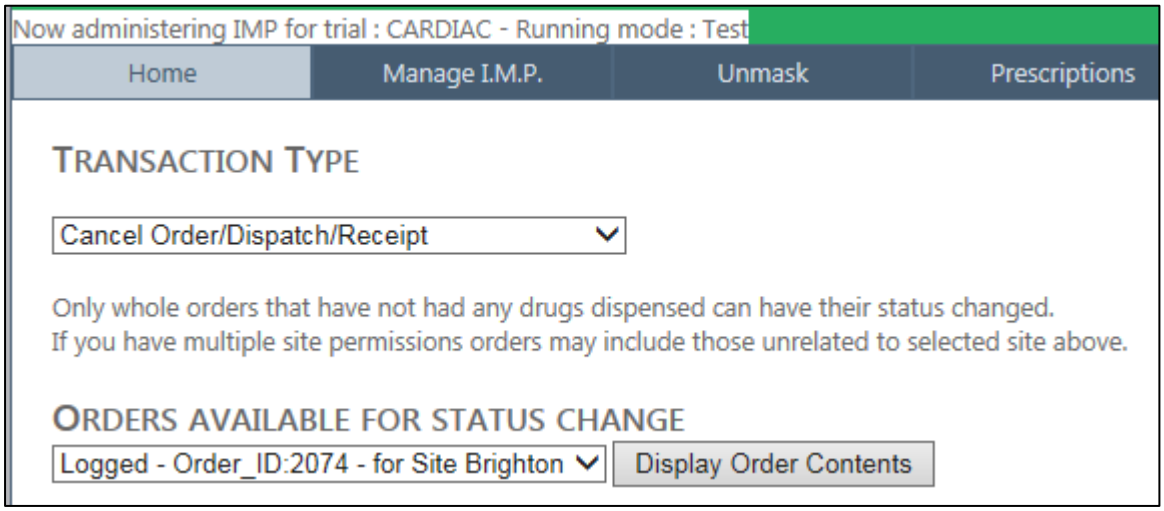
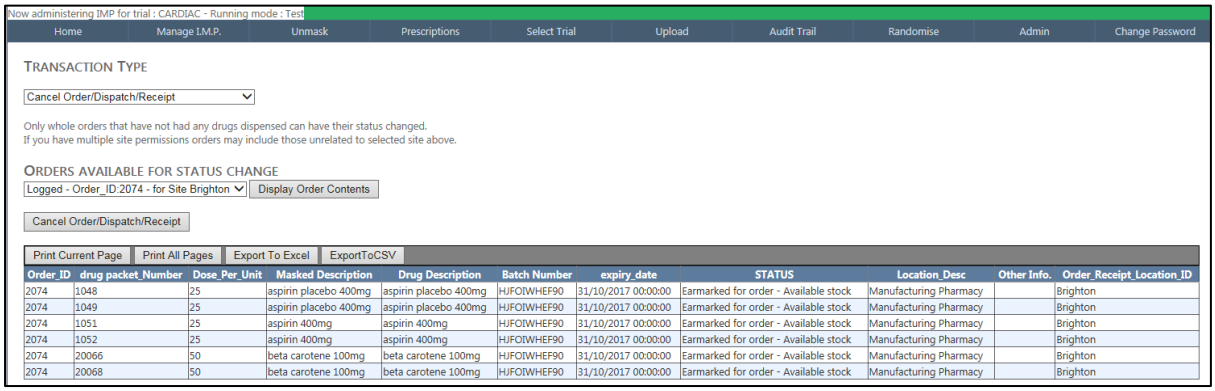


Figure 30 Reviewing an order prior to cancelling



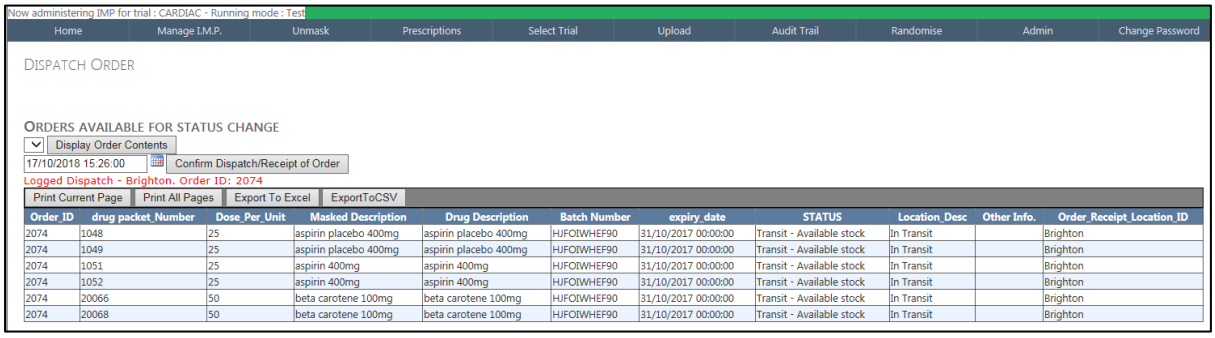
Order_ID	drug packet_Number	Dose_Per_Unit	Masked Description	Drug Description	Batch Number	expiry_date	STATUS	Location_Desc	Other Info.	Order_Receipt_Location_ID
2074	1048	25	aspirin placebo 400mg	aspirin placebo 400mg	HJFOIWHEF90	31/10/2017 00:00:00	Earmarked for order - Available stock	Manufacturing Pharmacy		Brighton
2074	1049	25	aspirin placebo 400mg	aspirin placebo 400mg	HJFOIWHEF90	31/10/2017 00:00:00	Earmarked for order - Available stock	Manufacturing Pharmacy		Brighton
2074	1051	25	aspirin 400mg	aspirin 400mg	HJFOIWHEF90	31/10/2017 00:00:00	Earmarked for order - Available stock	Manufacturing Pharmacy		Brighton
2074	1052	25	aspirin 400mg	aspirin 400mg	HJFOIWHEF90	31/10/2017 00:00:00	Earmarked for order - Available stock	Manufacturing Pharmacy		Brighton
2074	20066	50	beta carotene 100mg	beta carotene 100mg	HJFOIWHEF90	31/10/2017 00:00:00	Earmarked for order - Available stock	Manufacturing Pharmacy		Brighton
2074	20068	50	beta carotene 100mg	beta carotene 100mg	HJFOIWHEF90	31/10/2017 00:00:00	Earmarked for order - Available stock	Manufacturing Pharmacy		Brighton

Figure 31 Confirmation of order cancellation

11.5 Logging dispatch of an order

i. Select the ‘Manage IMP’ tab.
ii. Select the menu option ‘Log Dispatch’.
iii. Select the relevant order from the ‘Orders available for status change’ drop-down menu (Figure 32).
iv. Click ‘Display Order Contents’.
v. Record the time and date of order dispatch by clicking on the calendar icon.
vi. Click ‘Confirm Dispatch/Receipt of Order’.
vii. A message will appear prompting the user to ‘Confirm’ or ‘Cancel’ the action.
viii. Click ‘Confirm’
ix. A message will appear on the screen stating ‘Logged dispatch - <receiving location>. <Order ID XXXX>’.

Figure 32 Logging dispatch of an order



11.6 Logging receipt of an order

i. Select the ‘Manage IMP’ tab
ii. Select the menu option ‘Log Receipt’
iii. Select the relevant order from the ‘Orders available for status change’ drop-down menu
iv. Click ‘Display Order Contents’
v. Record the date and time of order receipt using the calendar icon
vi. Click ‘Confirm Dispatch/Receipt of Order’
vii. A message will appear prompting the user to ‘Confirm’ or ‘Cancel’ the action.
viii. Click ‘Confirm’
ix. A message will appear on the screen stating ‘Logged receipt - <receiving

location>. <Order ID XXXX>'.

Note. If all or part of an order is damaged upon receipt, the whole order must be logged as received. The status of individual affected drug packets can then be updated following the instructions in Section 17.1.

11.7 Cancelling dispatch or receipt of an order

i. Follow all steps from section 11.4, selecting the relevant order which has previously been logged as dispatched or received.

Note. This process will undo the last action applied to the order e.g. if the order has been logged as received, cancelling receipt will revert the order back to being dispatched (drug packet status 'In transit'). If the order was logged as dispatched, cancelling the dispatch will revert the drug packets back to being available at the original location i.e. their location before the order was placed.

11.8 Monitoring stock levels

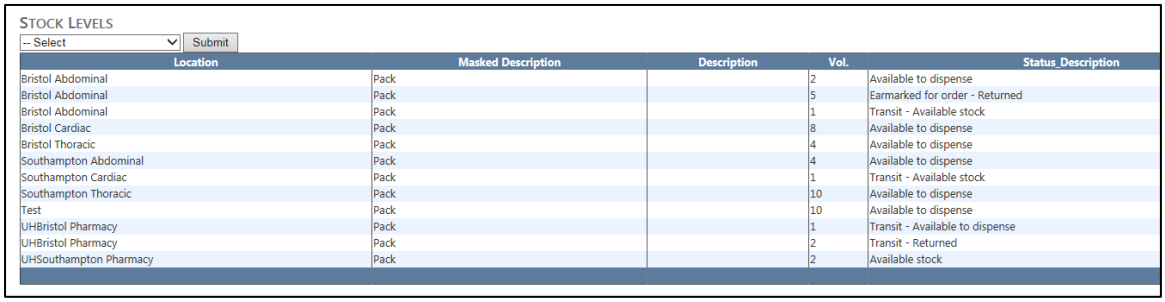
i. Select the 'Manage IMP' tab.
ii. Select the menu option 'Check Stock'.
iii. Cumulative available drug packets numbers per site will be displayed in a table (Figure 33) and in a histogram (Figure 34). Depending on user permissions, stock levels will be presented in a masked (cumulative stock levels) or unmasked (stock level per treatment arm) format.
iv. Hover the mouse over each histogram bar to see the number of available drug packets or the target number of drug packets required to meet minimum desired stock levels. Target stock levels are determined by the metadata.
v. To filter the cumulative stock table and histogram by site, select the relevant site from the drop-down menu at the top of the page.
vi. Click 'Submit'.

vii. When filtered by site, the histogram will display target and actual stock levels for the site selected only (Figure 35).

viii. A table of individual drug packets located at the site and their current status will be displayed below the histogram (Figure 36).

ix. The drug packet data table can be printed (options to print current page or print all pages of the table) or exported as an Excel or CSV file.

Figure 33 Monitoring drug packet stock levels; cumulative data table



STOCK LEVELS

-- Select | Submit

Location	Masked Description	Description	Vol.	Status_Description
Bristol Abdominal	Pack		2	Available to dispense
Bristol Abdominal	Pack		5	Earmarked for order - Returned
Bristol Abdominal	Pack		1	Transit - Available stock
Bristol Cardiac	Pack		8	Available to dispense
Bristol Thoracic	Pack		4	Available to dispense
Southampton Abdominal	Pack		4	Available to dispense
Southampton Cardiac	Pack		1	Transit - Available stock
Southampton Thoracic	Pack		10	Available to dispense
Test	Pack		10	Available to dispense
UHBristol Pharmacy	Pack		1	Transit - Available to dispense
UHBristol Pharmacy	Pack		2	Transit - Returned
UHSouthampton Pharmacy	Pack		2	Available stock

Figure 34 Monitoring drug packet stock levels; cumulative data histogram for all sites

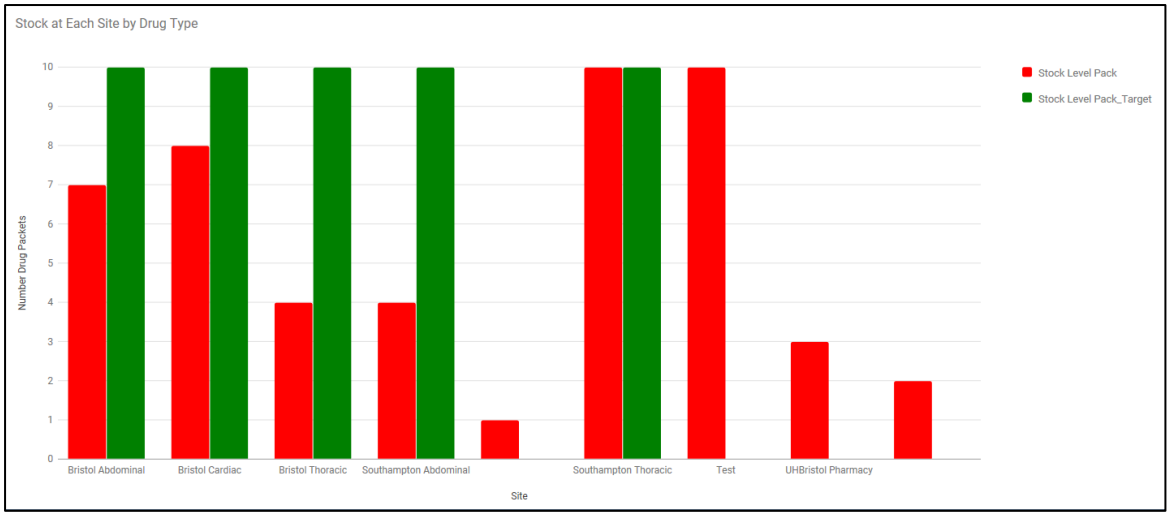


Figure 35 Monitoring drug packet stock levels filtered by site

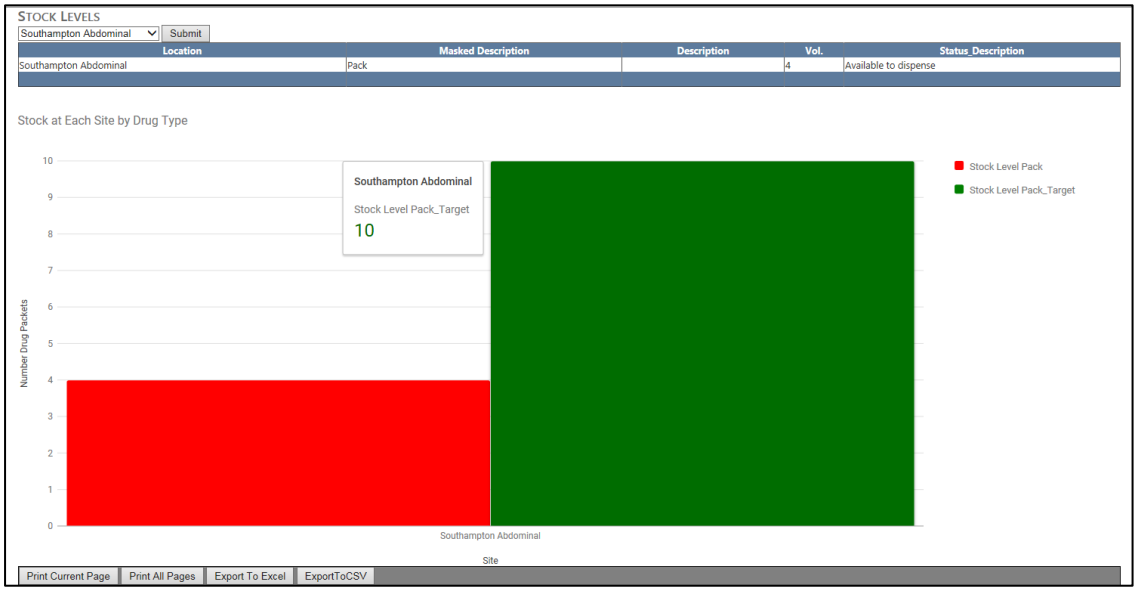


Figure 36 Table of individual drug packets located at a site

Site

Print Current Page | Print All Pages | Export To Excel | ExportToCSV

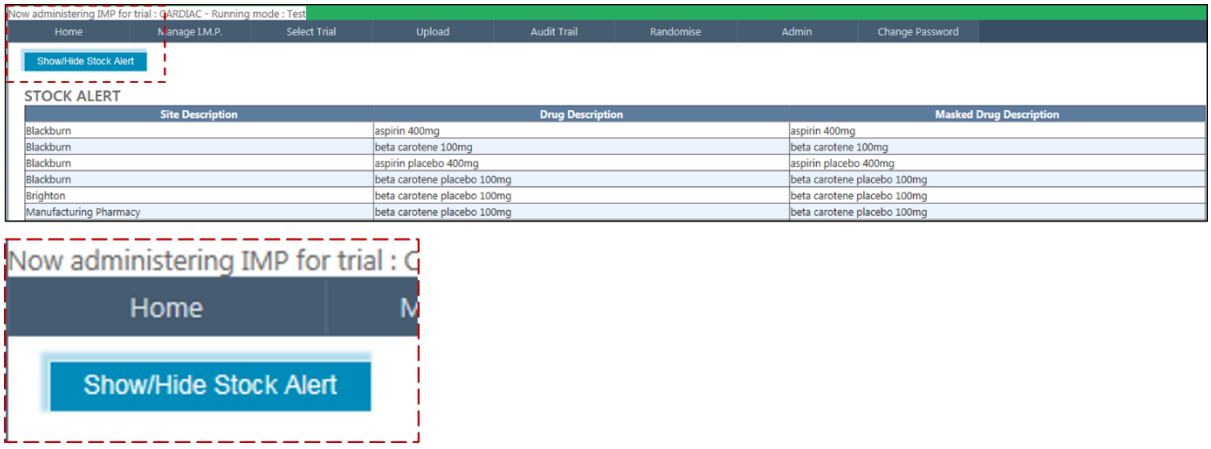
Order_ID	drug packet_Number	Dose_Per_Unit	Masked Description	Drug Description	Batch Number	expiry_date	STATUS	Location_Desc	Other Info.	Order_Receipt_Location_ID
2	30001		Pack	placebo		31/03/2020 00:00:00	Dispensed	Dispensed to patient - 4006 - Bristol Abdominal	Bristol Abdominal	
2085	30002		Pack	gabapentin		31/03/2020 00:00:00	Earmarked for order - Returned	Bristol Abdominal	Bristol Abdominal	
2	30004		Pack	placebo		31/03/2020 00:00:00	Dispensed	Dispensed to patient - 4004 - Bristol Abdominal	Bristol Abdominal	
2	30005		Pack	gabapentin		31/03/2020 00:00:00	Dispensed	Dispensed to patient - 4007 - Bristol Abdominal	Bristol Abdominal	
2	30006		Pack	placebo		31/03/2020 00:00:00	Earmarked for dispensing	Bristol Abdominal	Bristol Abdominal	
2	30007		Pack	gabapentin		31/03/2020 00:00:00	Dispensed	Dispensed to patient - 4005 - Bristol Abdominal	Bristol Abdominal	
	30008		Pack	placebo		31/03/2020 00:00:00	Dispensed	Dispensed to patient - 4001 -	Bristol Abdominal	

11.9 Stock alerts

If the actual stock level of a drug type falls below the desired stock level (≠), the database will display the information in a stock alert table. The stock alert table will be displayed by default at the top of each page of IMP-Track (Figure 37). The table can be hidden from view by clicking ‘Show/Hide Stock Alert’. The stock alert table is restricted by user site permissions. The table will contain a row per drug type per site.

Automated notification emails can be configured using the Add Notifications function (see section 10) to alert users that more stock should be ordered.

Figure 37 Stock alert table and Show/Hide function

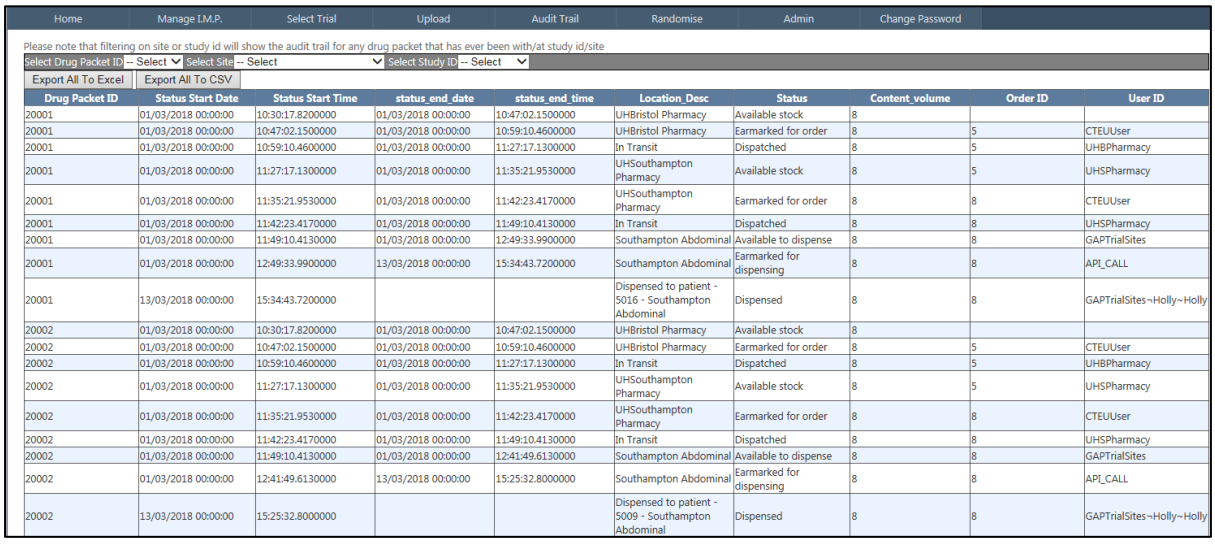


12 Audit trail

The audit trail for each drug packet can be viewed in a table under the ‘Audit Trail’ tab. One row of data is displayed for each movement/status change the drug packet has undergone. Data can be filtered by drug packet ID, site or study ID (only one filter can be applied at a time).

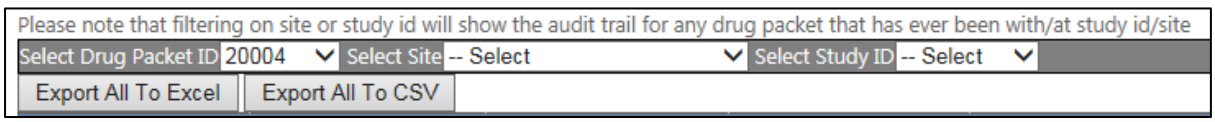
i. Select the ‘Audit Trail’ tab.
ii. The table will display all drug packet data (Figure 38).
iii. To filter by drug packet ID, select the drug packet from the ‘Select Drug Packet ID’ drop-down list (Figure 39).
iv. To filter by site, select the site from the ‘Select Site’ drop-down list.
v. To filter by study ID, select the study ID from the ‘Select Study ID’ drop-down list.
vi. The data can be exported as an Excel or CSV file.

Figure 38 Audit trail table



Drug Packet ID	Status Start Date	Status Start Time	status_end_date	status_end_time	Location_Desc	Status	Content_volume	Order ID	User ID
20001	01/03/2018 00:00:00	10:30:17.8200000	01/03/2018 00:00:00	10:47:02.1500000	UHBristol Pharmacy	Available stock	8		
20001	01/03/2018 00:00:00	10:47:02.1500000	01/03/2018 00:00:00	10:59:10.4600000	UHBristol Pharmacy	Earmarked for order	8	5	CTEUUser
20001	01/03/2018 00:00:00	10:59:10.4600000	01/03/2018 00:00:00	11:27:17.1300000	In Transit	Dispatched	8	5	UHBPharmacy
20001	01/03/2018 00:00:00	11:27:17.1300000	01/03/2018 00:00:00	11:35:21.9530000	UHSouthampton Pharmacy	Available stock	8	5	UHSPharmacy
20001	01/03/2018 00:00:00	11:35:21.9530000	01/03/2018 00:00:00	11:42:23.4170000	UHSouthampton Pharmacy	Earmarked for order	8	8	CTEUUser
20001	01/03/2018 00:00:00	11:42:23.4170000	01/03/2018 00:00:00	11:49:10.4130000	In Transit	Dispatched	8	8	UHSPharmacy
20001	01/03/2018 00:00:00	11:49:10.4130000	01/03/2018 00:00:00	12:49:33.9900000	Southampton Abdominal	Available to dispense	8	8	GAPTrialSites
20001	01/03/2018 00:00:00	12:49:33.9900000	13/03/2018 00:00:00	15:34:43.7200000	Southampton Abdominal	Earmarked for dispensing	8	8	API_CALL
20001	13/03/2018 00:00:00	15:34:43.7200000			Dispensed to patient - 5016 - Southampton Abdominal	Dispensed	8	8	GAPTrialSites¬Holly¬Holly
20002	01/03/2018 00:00:00	10:30:17.8200000	01/03/2018 00:00:00	10:47:02.1500000	UHBristol Pharmacy	Available stock	8		
20002	01/03/2018 00:00:00	10:47:02.1500000	01/03/2018 00:00:00	10:59:10.4600000	UHBristol Pharmacy	Earmarked for order	8	5	CTEUUser
20002	01/03/2018 00:00:00	10:59:10.4600000	01/03/2018 00:00:00	11:27:17.1300000	In Transit	Dispatched	8	5	UHBPharmacy
20002	01/03/2018 00:00:00	11:27:17.1300000	01/03/2018 00:00:00	11:35:21.9530000	UHSouthampton Pharmacy	Available stock	8	5	UHSPharmacy
20002	01/03/2018 00:00:00	11:35:21.9530000	01/03/2018 00:00:00	11:42:23.4170000	UHSouthampton Pharmacy	Earmarked for order	8	8	CTEUUser
20002	01/03/2018 00:00:00	11:42:23.4170000	01/03/2018 00:00:00	11:49:10.4130000	In Transit	Dispatched	8	8	UHSPharmacy
20002	01/03/2018 00:00:00	11:49:10.4130000	01/03/2018 00:00:00	12:41:49.6130000	Southampton Abdominal	Available to dispense	8	8	GAPTrialSites
20002	01/03/2018 00:00:00	12:41:49.6130000	13/03/2018 00:00:00	15:25:32.8000000	Southampton Abdominal	Earmarked for dispensing	8	8	API_CALL
20002	13/03/2018 00:00:00	15:25:32.8000000			Dispensed to patient - 5009 - Southampton Abdominal	Dispensed	8	8	GAPTrialSites¬Holly¬Holly

Figure 39 Filtering the audit trail table



13 Drug packet status definitions

Each drug packet will have a ‘status’ which reflects its current position in the drug packet pathway. See Table 7 for definitions of each drug packet status.

Table 7 Drug packet status definitions

Status	Definition
Available stock	Drug packet is available to order from the manufacturing pharmacy or other location.
Earmarked for order	Drug packet has been ordered but has not yet been dispatched from its location.
In transit	Drug packet has been ordered and dispatched to its destination.
Available to dispense	Drug packet previously in transit has been received at its destination and receipt has been logged.
Earmarked for dispensing	Drug packet has been allocated to a participant study ID but has not yet been dispensed from the site pharmacy.
Dispensed	Allocated drug packet has been dispensed to the participant.
Returned	Drug packet which has previously been dispensed to a participant has been returned to the site and logged as returned by the site pharmacy.
Destroyed	Drug packet has been destroyed.
Quarantined	Drug packet has been placed in to quarantine. Drug packets with this status cannot be allocated to a participant.
Damaged	Drug packet has been damaged. Drug packets with this status cannot be allocated to a participant.
Lost	Drug packet has been lost.
Expired	Drug packet has expired. Drug packets with this status cannot be allocated to a participant.

14 Adding study IDs and randomisation

IMP-Track can perform parallel, factorial and cross-over randomisation. It is also possible to randomise by strata. Before using the in-built randomisation system, the drug allocation metadata file must be uploaded (see section 8). See section 7 for guidance on setting up IMP-Track to interact with external randomisation systems or trial databases.

14.1 Adding a new study ID to IMP-Track

Before a participant can be randomised, the study ID must be added to IMP-Track and, if applicable, participants' must be assigned a strata.

i. Select the 'Randomisation' tab.
ii. Select 'Add/Edit Study_ID' from the menu options.
iii. Select the 'Add Study ID' option on the page (Figure 40).
iv. Select the site from the 'Site' drop-down list.
v. Enter the unique Study ID in to the 'Study _ID' field.
vi. Select a strata from the 'Study_ID_Strata' drop-down list.
vii. Click 'Add study ID'.
viii. A message will pop up asking the user if they want to proceed (Figure 41).
ix. Click 'OK'.
x. Once the process is complete a confirmation message will appear on the page.
xi. If the study ID has previously been added, a message will appear stating 'Cannot insert duplicate study ID into database table for this trial'.

Figure 40 Adding a new study ID to the system

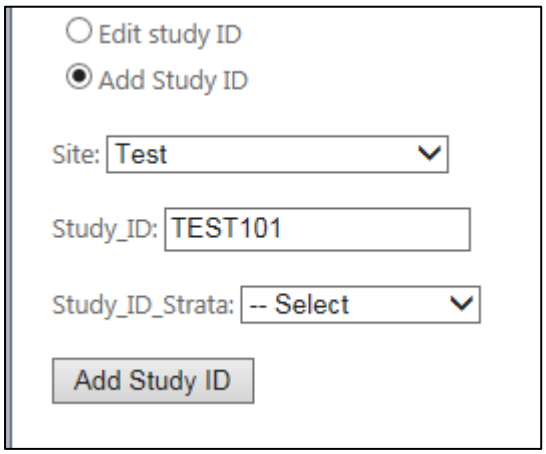
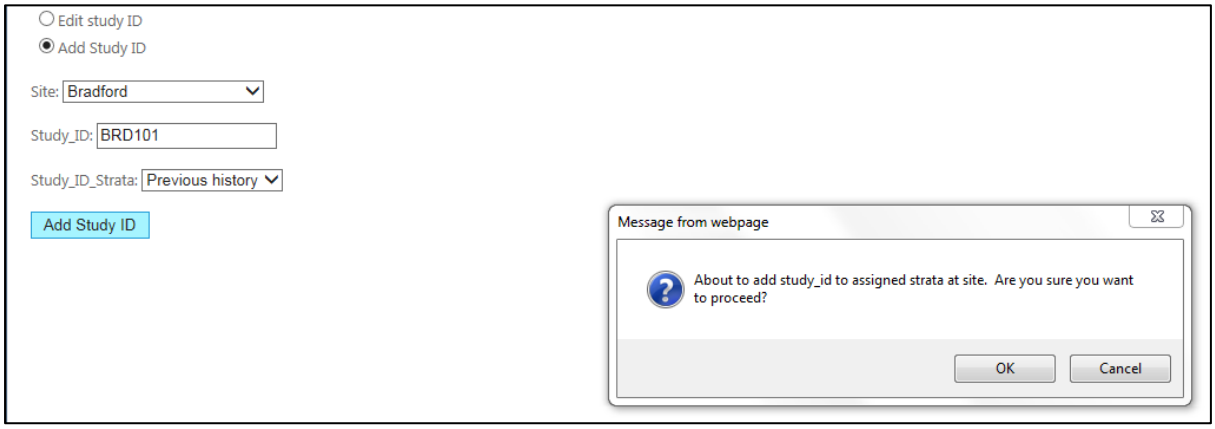


Figure 41 Confirming addition of a new study ID

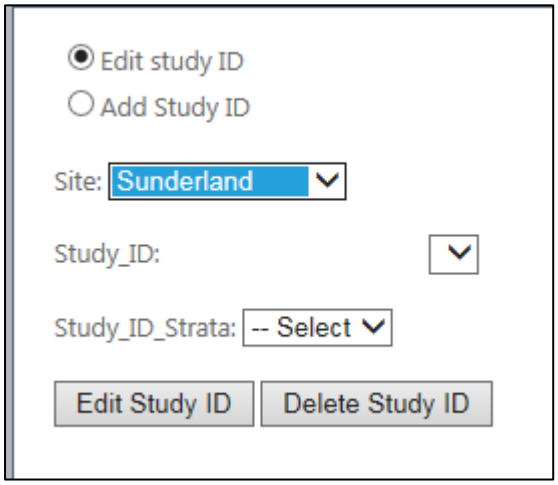


14.2 Editing or deleting an existing study ID

The only aspect of an existing study ID that can be edited is the strata, which can only be edited prior to randomisation. After randomisation a study ID cannot be edited.

i. Repeat section 14.1 steps i and ii.
ii. Select the 'Edit' Study ID' option (Figure 42).
iii. Select the site from the 'Site' drop-down list.
iv. Select the study ID that will be edited from the 'Study_ID' drop-down list.
v. Select the appropriate strata from the 'Study_ID_Strata' drop-down list.
vi. Click 'Edit Study ID'.
vii. Or, to delete a study ID click 'Delete Study ID'.
viii. A message will pop up asking to the user if they want to proceed.
ix. Click 'OK'.
x. Once the process is complete a confirmation message will appear on the page.

Figure 42 Editing an existing study ID



14.3 Randomising participants via the IMP-Track randomisation system

Before randomising a participant, the study ID must be added to IMP-Track by following the steps in section 14.1.

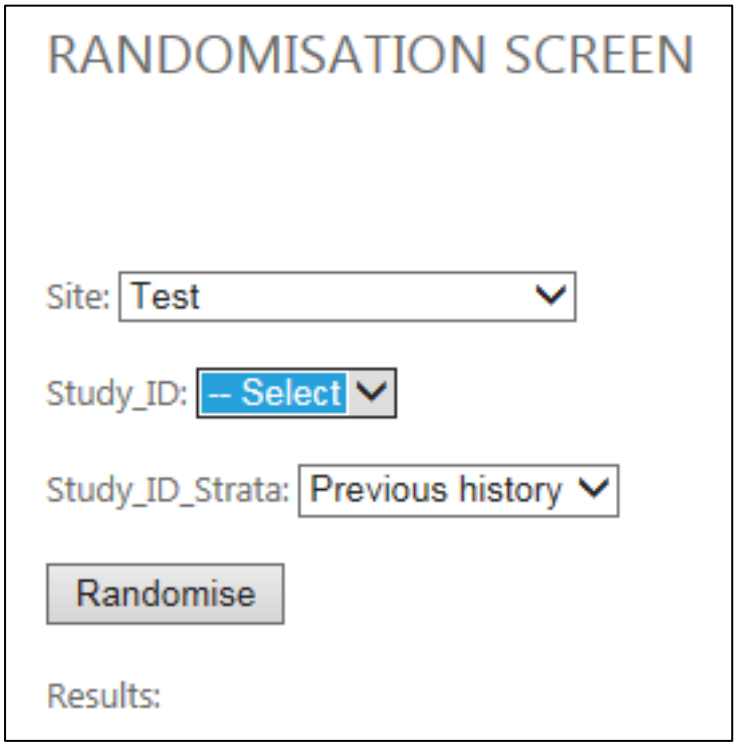
i. Select the 'Randomisation' tab.
ii. Select 'Randomise' from the menu options.
iii. Select the site from the 'Site' drop-down list (Figure 43).
iv. Select the study ID from the 'Study_ID' drop-down list
v. Select the strata from the 'Study_ID_Strata' drop-down list.

> Note. Only the strata which was assigned when adding the study ID will be available in the drop-down list. Randomisation cannot proceed without selecting the strata.

vi. Click 'Randomise'.
vii. A message will pop up asking to the user if they want to proceed.
viii. Click 'OK'.
ix. Once the randomisation has completed a message will appear on the page confirming the allocation (unmasked users) or confirming the randomisation occurred but the user is masked to the allocation (masked users).
x. Proceed to Section 15 (allocating and dispensing drug packets).

Note. The IMP database will prevent duplicate randomisation of the same participant. If the participant has already been randomised, the message generated at step ix will state that the participant has already been randomised.

Figure 43 Randomisation screen



15 Allocating and dispensing drug packets

15.1 Allocating drug packets

Follow the instructions below to allocate drug packets to participants.

i. Select the ‘Prescriptions’ tab.
ii. Select ‘Dispense Drugs’ from the menu options.
iii. Select the action ‘Allocate drug packets’ (Figure 44).
iv. Select the site from the ‘Select site’ drop-down menu.
v. Select the participant study ID from the ‘Select study ID’ drop-down menu.
vi. Click ‘Show available drug packets’.
vii. Check that the correct study timepoint has been automatically selected from the ‘Timepoint’ drop-down menu.
viii. Optional: if the automatically-selected timepoint is incorrect it can be amended manually by selecting the correct timepoint from the drop-down list.
ix. The allocated drug packets will be displayed in the field ‘Below drug packets available for patient - hit submit button to confirm prescription’.
x. Review the allocated drug packets to ensure the correct quantity have been allocated for the timepoint.
xi. Click ‘Submit’.
xii. A message will appear asking the user to ‘Confirm’ or ‘Cancel’ the allocation.
xiii. If drug packets have already been allocated on the same day, a warning message will appear to prevent multiple allocations. The user can opt to ‘Confirm’ or ‘Cancel’ the action.
xiv. Once drug packet allocation is complete a message will be displayed on the page confirming the drug packet IDs and study ID (Figure 45).

Figure 44 Allocating drug packets

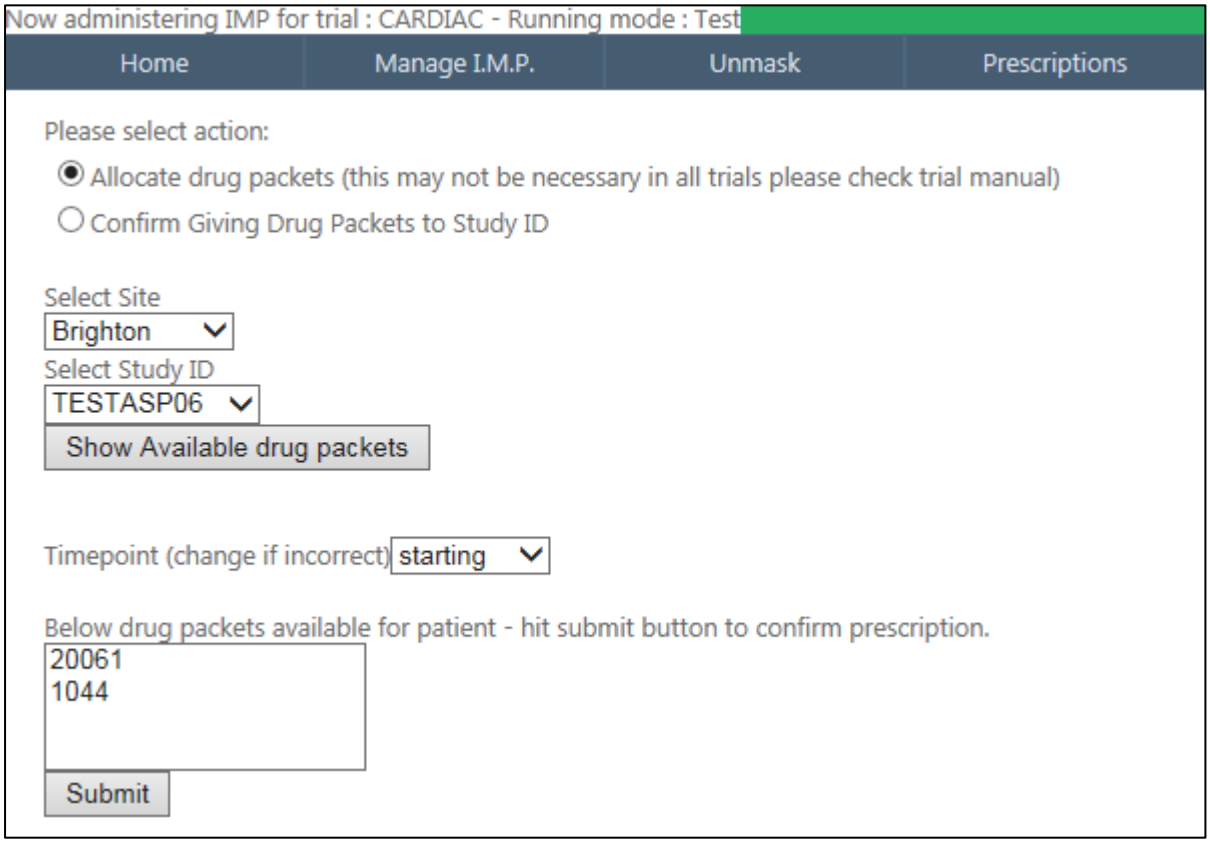
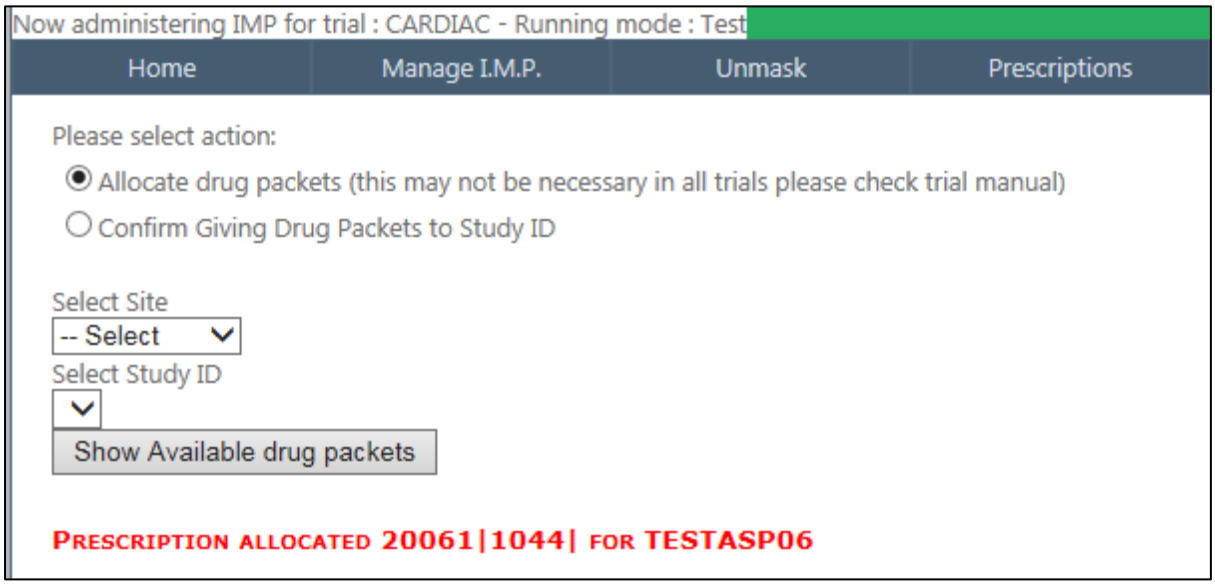


Figure 45 Confirmation of drug packets allocated to study ID



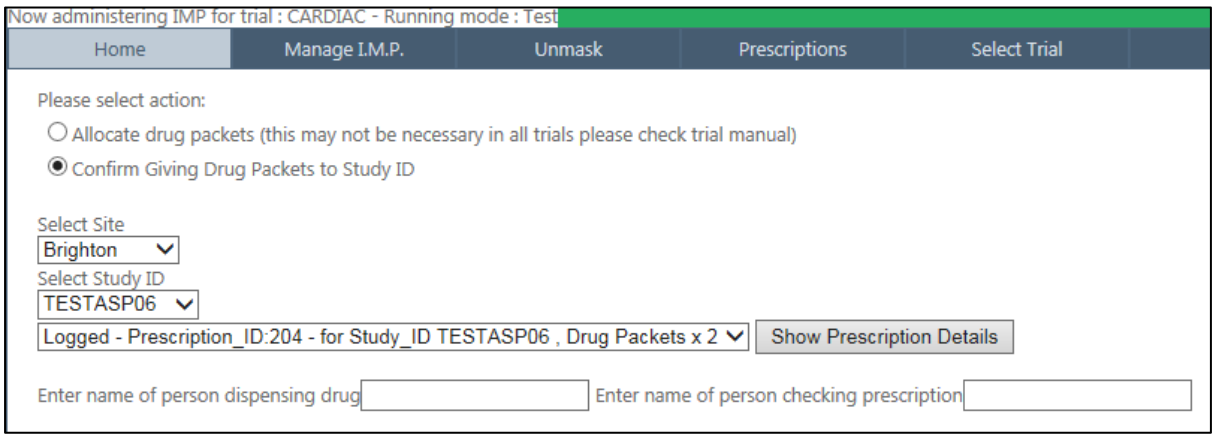
15.2 Dispensing drug packets

i. Select the ‘Prescriptions’ tab.
ii. Select ‘Dispense Drugs’ from the menu options.
iii. Select the action ‘Confirm Giving Drug Packets to Study ID’ (Figure 46).
iv. Select the site from the ‘Select site’ drop-down menu.
i. Select the participant study ID from the ‘Select study ID’ drop-down menu
ii. Select the correct prescription from the drop-down menu.

Note. There could be more than one prescription in the drop-down list if a previous prescription has not yet been confirmed as dispensed.

iii. Click ‘Show prescription details’.
iv. The details of the allocation/prescription including drug packet ID(s), masked and unmasked (unmasked users only) drug descriptions, batch number and status are displayed in a table for review before confirming dispensing.
v. The table can be printed or exported as an Excel or CSV file.
vi. Record the name of the person dispensing the drug and the name of the person checking the prescription in the respective free text fields.
vii. To confirm dispensing click ‘Confirm dispensing of drug packet(s) to patient’.
viii. A message will appear asking the user to ‘Confirm’ or ‘Cancel’ the dispensing action.
ix. Once the process is complete a confirmation message will appear on the page.

Figure 46 Confirming that allocated drug packets were dispensed



15.3 Cancelling (undoing) allocation of drug packets

If a drug packet allocation needs to be cancelled, e.g. if a participant is allocated drug packets more than once for the same timepoint, follow the instructions below.

> *Note. Cancelling allocations can only be performed if the drug packets have not been confirmed as dispensed as described Section 15.2.*

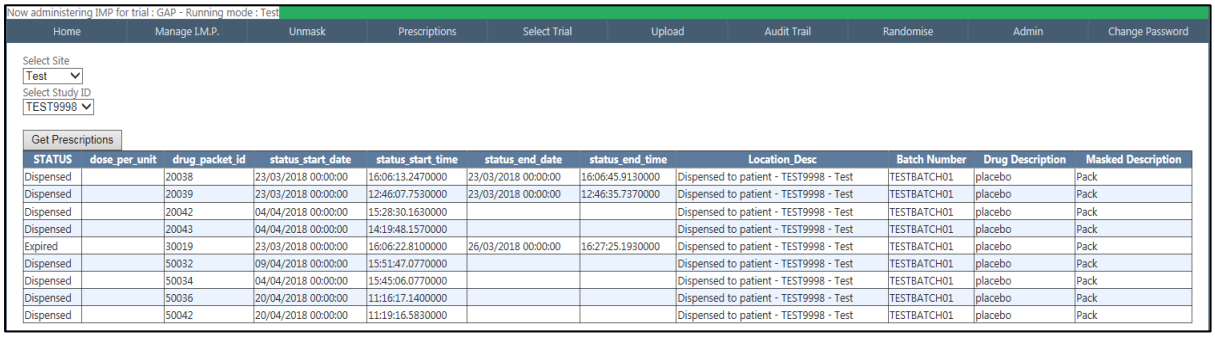
i. Repeat steps i – iv of section 15.2 (dispensing drug packets).
ii. To cancel the drug packet allocation, click 'Cancel prescription'.
iii. Once the process of cancelling the allocation is complete a confirmation message will appear on the page.

15.4 Prescription history

The history of drug packet allocations per participant can be viewed following the instructions below.

i. Select the 'Prescriptions' tab.
ii. Select 'Prescription history' from the menu options.
iii. Select the site from the 'Select site' drop-down list.
iv. Select the study ID from the 'Select study ID' drop-down list.
v. Click 'Get prescriptions'.
vi. All drug packets allocated to the study ID will be displayed in a table for review (Figure 47).

Figure 47 Viewing the prescription history



STATUS	dose_per_unit	drug_packet_id	status_start_date	status_start_time	status_end_date	status_end_time	Location_Desc	Batch Number	Drug Description	Masked Description
Dispensed		20038	23/03/2018 00:00:00	16:06:13.2470000	23/03/2018 00:00:00	16:06:45.9130000	Dispensed to patient - TEST9998 - Test	TESTBATCH01	placebo	Pack
Dispensed		20039	23/03/2018 00:00:00	12:46:07.7530000	23/03/2018 00:00:00	12:46:35.7370000	Dispensed to patient - TEST9998 - Test	TESTBATCH01	placebo	Pack
Dispensed		20042	04/04/2018 00:00:00	15:28:30.1630000			Dispensed to patient - TEST9998 - Test	TESTBATCH01	placebo	Pack
Dispensed		20043	04/04/2018 00:00:00	14:19:48.1570000			Dispensed to patient - TEST9998 - Test	TESTBATCH01	placebo	Pack
Expired		30019	23/03/2018 00:00:00	16:06:22.8100000	26/03/2018 00:00:00	16:27:25.1930000	Dispensed to patient - TEST9998 - Test	TESTBATCH01	placebo	Pack
Dispensed		50032	09/04/2018 00:00:00	15:51:47.0770000			Dispensed to patient - TEST9998 - Test	TESTBATCH01	placebo	Pack
Dispensed		50034	04/04/2018 00:00:00	15:45:06.0770000			Dispensed to patient - TEST9998 - Test	TESTBATCH01	placebo	Pack
Dispensed		50036	20/04/2018 00:00:00	11:16:17.1400000			Dispensed to patient - TEST9998 - Test	TESTBATCH01	placebo	Pack
Dispensed		50042	20/04/2018 00:00:00	11:19:16.5830000			Dispensed to patient - TEST9998 - Test	TESTBATCH01	placebo	Pack

16 Drug packet returns and destruction

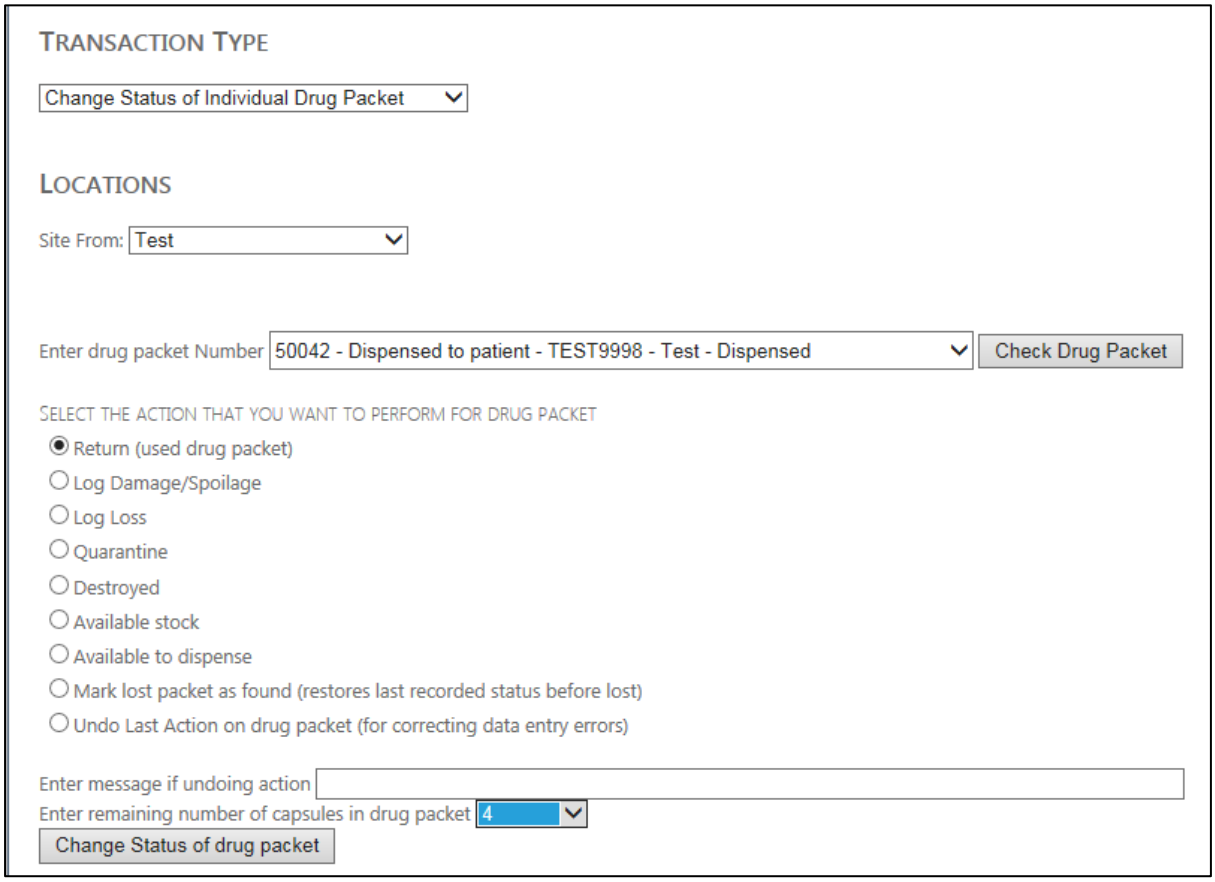
16.1 Recording returned drug packets

When a drug packet is returned to a site after being dispensed to a participant the drug packet can be logged as returned following the instructions below.

Note. A drug packet can only be logged as returned if the previous status was 'Dispensed to patient'.

i. Select the 'Manage IMP' tab.
i. Select 'Orders/Returns' from the menu options.
ii. Select 'Change status of individual drug packet' from the 'Transaction Type' drop-down menu (Figure 48).
iii. Select the site from the 'Site From' drop-down menu.
iv. Select the drug packet ID from the 'Enter Drug Packet Number' drop-down menu.
v. Select the option 'Return (used drug packet)' from the 'Select the action that you want to perform for drug packet' list.
vi. Enter the number of individual IMPs (e.g. capsules/pills) remaining in the drug packet from the 'Enter remaining number of capsules in drug packet' drop-down menu.
vii. Click 'Change status of drug packet'.
viii. A pop-up message will ask the user if they want to proceed with the transaction.
ix. Click 'OK' to proceed or 'Cancel' to stop the transaction.
x. If confirmed as OK to proceed, a message will pop up stating that the action is complete.
xi. Click 'Close'.
xii. Once the process is complete a confirmation message will appear on the page.

Figure 48 Logging return of used drug packets



16.2 Recording destruction of drug packets

To record that a drug packet has been destroyed follow the instructions below.

i. Select the 'Manage IMP' tab.
ii. Select 'Orders/Returns' from the menu options.
iii. Select 'Change status of individual drug packet' from the 'Transaction Type' drop-down menu.
iv. Select the site from the 'Site From' drop-down menu.
v. Select the individual drug packet ID from the 'Enter Drug Packet Number' drop-down menu.
vi. Select the action 'Destroyed' from the 'Select the action that you want to perform for drug packet' list.
vii. Click 'Change status of drug packet'.
viii. A pop-up message will ask the user if they want to proceed with the transaction.
ix. Click 'OK' to proceed or 'Cancel' to stop the transaction.

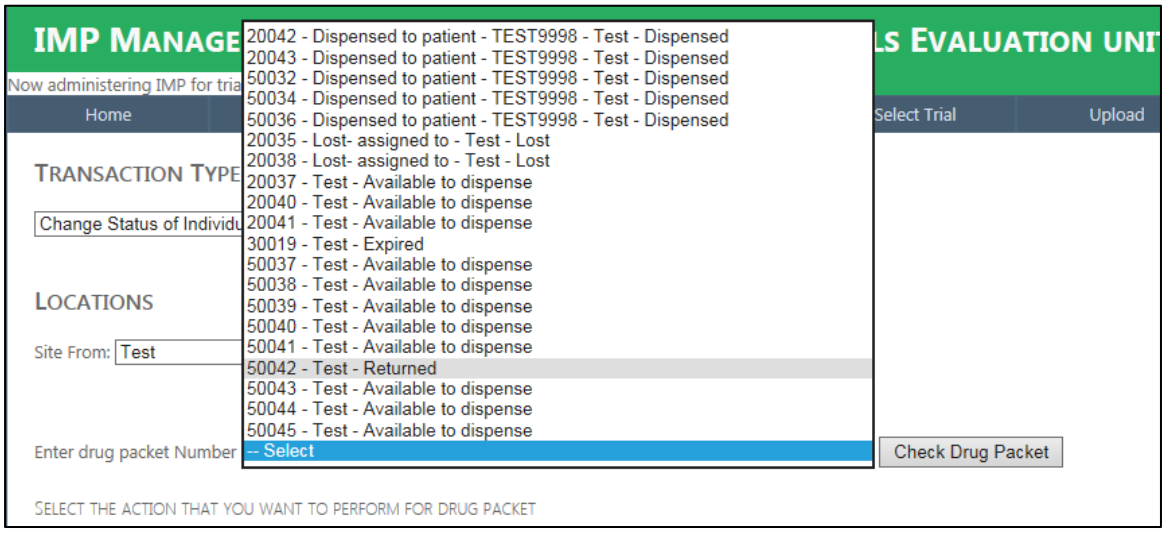
x. If confirmed as OK to proceed, a message will pop up stating that the action is complete.

xi. Click ‘Close’.

xii. Once the process is complete a confirmation message will appear on the page.

*Note. Once a status change has been actioned users can review the drug packet in the ‘Enter Drug Packet Number’ drop-down list to confirm the status change was applied (*Figure 49*), or refer to the ‘Audit Trail’ tab.*

Figure 49 Checking status of drug packets following a status change



17 Drug packet quarantine, damage and loss

17.1 Changing the status of quarantined, damaged or lost drug packets

The status of individual drug packets can be changed in the event of placing IMP in quarantine, recording drug packets as damaged or lost (e.g. through handling error or participants discarding used drug packets). To change the status of a drug packet follow the instructions below.

i. Select the 'Manage IMP' tab.
ii. Select 'Orders/Returns' from the menu options.
iii. Select 'Change status of individual drug packet' from the 'Transaction Type' drop-down menu.
iv. Select the site from the 'Site From' drop-down menu.
v. Select the individual drug packet ID from the 'Enter Drug Packet Number' drop-down menu.
vi. Select one of the following actions 'Quarantine', 'Log damage/spoilage' or 'Log Loss' from the 'Select the action that you want to perform for drug packet' list.
vii. Optional: if changing the status to 'damage/spoiled' or 'quarantined' the number of pills/capsules within the drug packet must be recorded in the 'Enter remaining number of capsules in drug packet' field. This step is not required when logging the loss of a drug packet.
viii. Click 'Change status of drug packet'.
ix. A pop-up message will ask the user if they want to proceed with the transaction.
x. Click 'OK' to proceed or 'Cancel' to stop the transaction.
xi. If confirmed as OK to proceed, a message will pop up stating that the action is complete.
xii. Click 'Close'.
xiii. Once the process is complete a confirmation message will appear on the page.

17.2 Undoing a drug packet status change

If a drug packet status is changed in error or if the status no longer applies (e.g. if a lost drug packet is returned or a quarantined drug packet is approved for use) the

previous action applied to the drug packet can be undone.

i. Repeat section 17.1 steps i – v.
ii. Select the action ‘Undo Last Action on drug packet’ from the ‘Select the action that you want to perform for drug packet’ list (Figure 50; see Table 1 for role restrictions).
iii. Record a reason for undoing the action in the ‘Enter message if undoing action’ free text field. The reason should concisely explain why the status is being changed.
iv. Click ‘Change status of drug packet’.
v. A pop-up message will ask the user if they want to proceed with the transaction.
vi. Click ‘Ok’ to proceed or ‘Cancel’ to stop the transaction.
vii. If confirmed as OK to proceed, a message will pop up stating that the action is complete.
viii. Click ‘Close’ (Figure 51).
ix. Once the process is completed a confirmation message will appear.

Figure 50 Undoing the last action applied to a drug packet

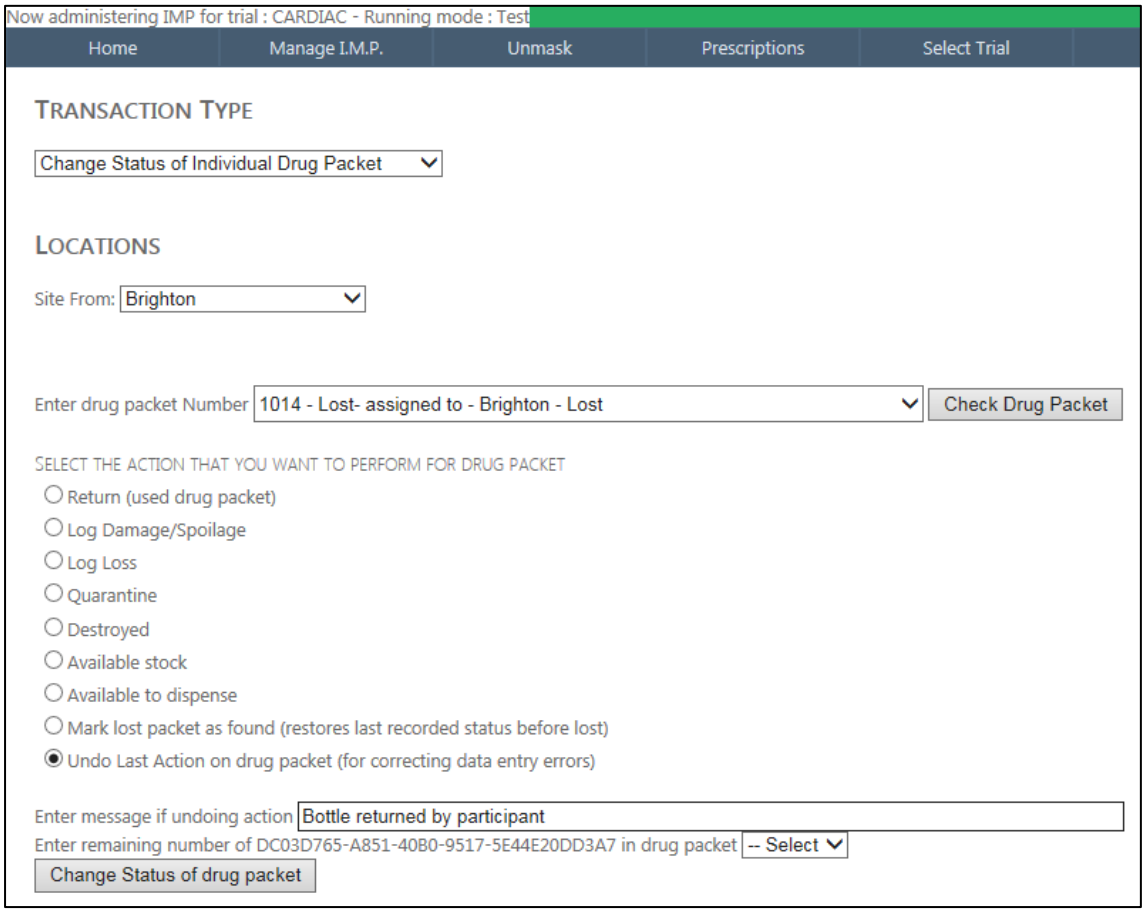
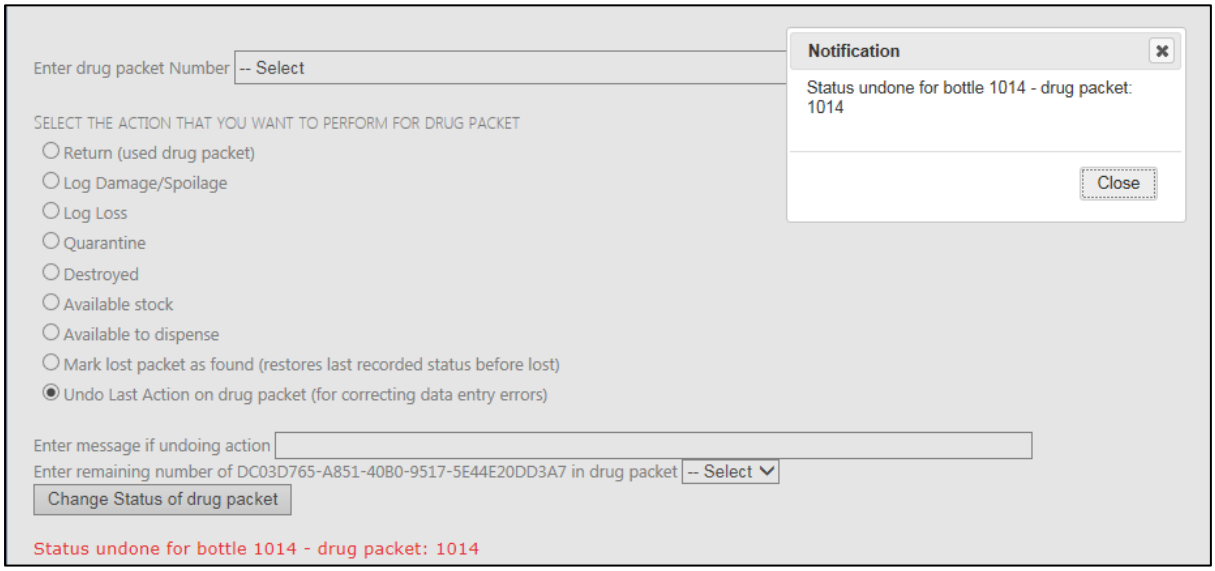


Figure 51 Confirmation of undoing a drug packet action



18 Unmasking

To find out which treatment arm a participant was allocated to, follow the instructions below.

Note. Users must be assigned the role 'Unmask' to perform this task.

i. Select the 'Unmask' tab.
ii. Select the site from the 'Select site' drop-down list (Figure 52).
iii. Select the study ID from the 'Select study ID' drop-down list.
iv. Record the name of the person who requested the unmasking (e.g. the treating clinician) in the 'Person Requesting Unmasking' free text field.
v. Record a reason for requesting the unmasking in the 'Reason for Unmasking' free text field.
vi. The user completing the unmasking form must record their name in the 'Person Completing Unmasking' free text field (Figure 53).
vii. Click 'Unmask'.
viii. The treatment arm will be displayed on the page (Figure 54).

Note. Unmasking information cannot be printed or exported from the IMP database so should be recorded as per trial-specific or local procedures.

Figure 52 Unmasking form

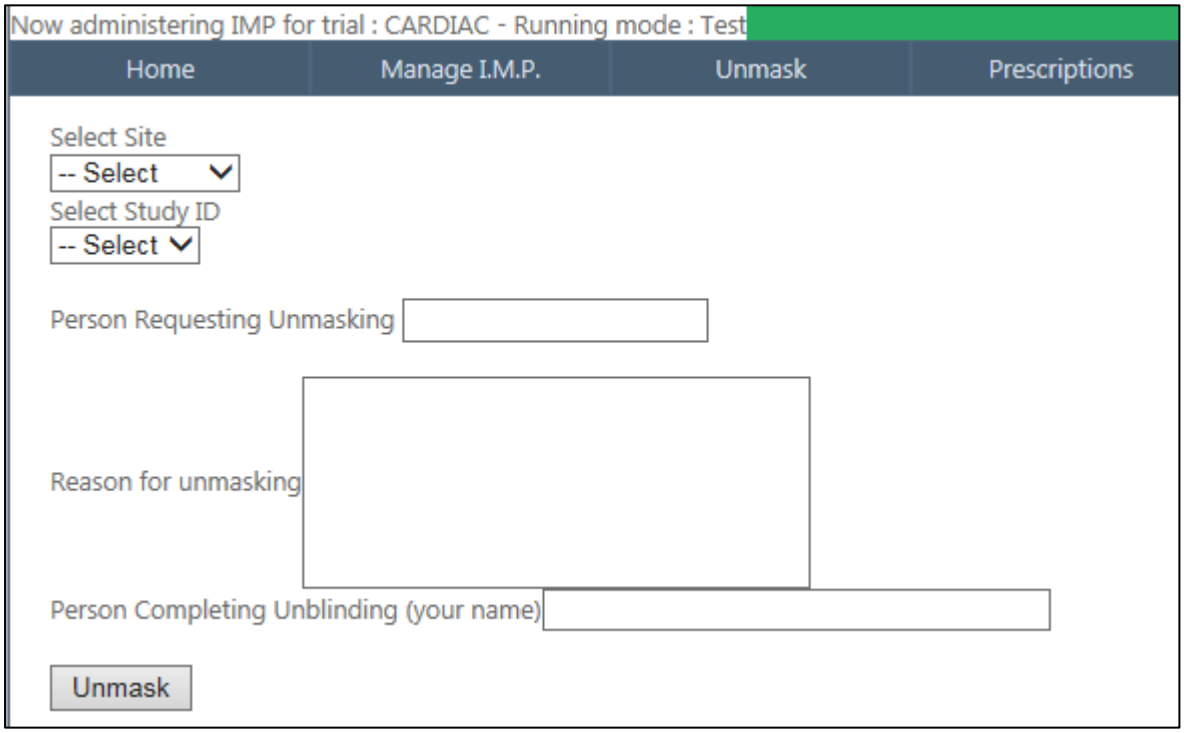


Figure 53 Example completed unmasking form

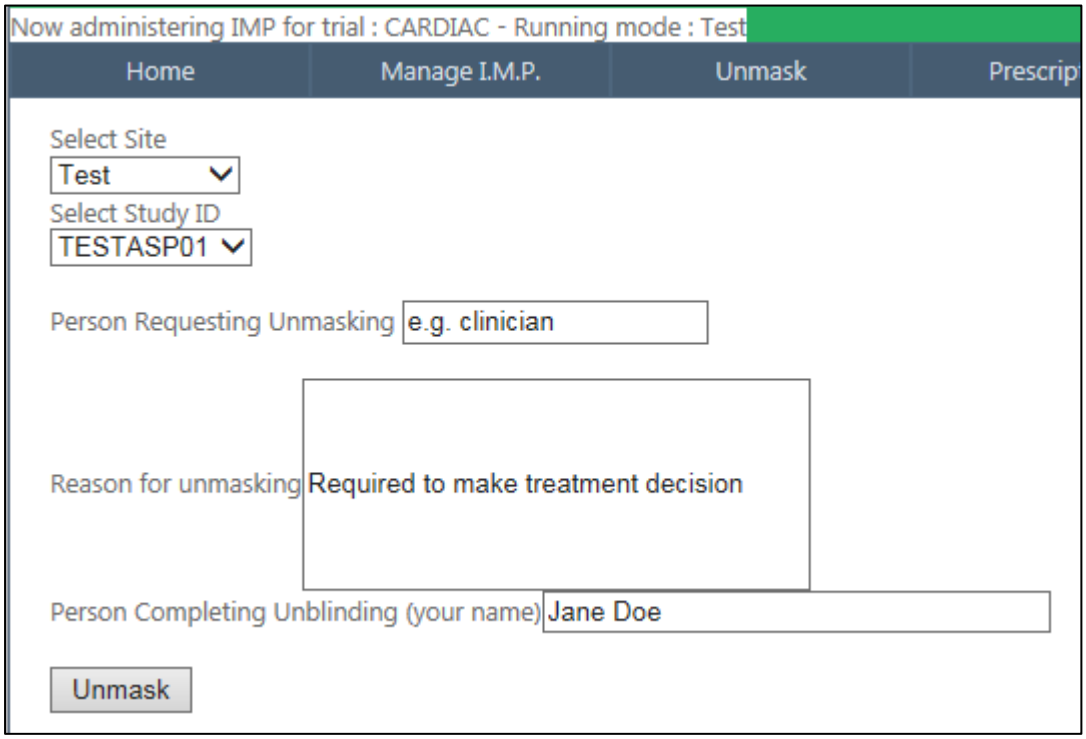


Figure 54 Unmasking form with allocation revealed