CAPTURE - Biological samples database for A-Star project

The CAPTURE (ChArting PaTient outcomes Using an online Resource) application is the online database to capture patient and sample data for the UK-Irish A-STAR register. Patient records are stored in a secure environment used by many research sites throughout the UK. This User Manual gives the instructions on how to use it.

To begin….

You must first complete the training exercises given on the final page before we can give you access to the CAPTURE database to log your own samples.

➢ **To pass your training, you will be required to follow 2 training exercises using the guidance below to practice.** Rather than setting up multiple test patients, just use the dummy Case Report Form (CRF) which is shared with you to set up your patient, using your own first name as the first name and last name, then make up any other details not on the CRF. Remember that anyone accessing CAPTURE will be able to view the information entered on the training site, so don't use any real patient information.

➢ **When you feel comfortable entering data on CAPTURE,** email the CAPTURE team (capture@gstt.nhs.uk) **and** Prakash Patel, the A-STAR Study Manager (prakash.patel@gstt.nhs.uk) to inform them that you have completed the training. They will verify your dummy CRF entry and provide any feedback.

➢ **Once any feedback has been addressed,** or if there are no notes to share your access will then be changed from the training site to the live site for your centre(s), according to the access you have been granted.

The next steps….

If you are an external user, that is to say accessing CAPTURE online outside of Guy's & St Thomas' NHS Foundation Trust, ensure you have successfully set up your token (mobilePASS phone app or PC application), before you try to access CAPTURE as otherwise it will not work. For more information on this, please contact the CAPTURE team @ capture@gstt.nhs.uk .

- Log into CAPTURE database:
    o Enter username in the format: External\username e.g. External\TUser
    o Enter password: set a password you will remember.
      PLEASE NOTE: We cannot keep a record of your password. Please keep this stored somewhere safe.
    o Enter your one time passcode (OTP) using the SafeNet application on your smart phone/PC.
      PLEASE NOTE: We cannot keep a record of your 6 digit SafeNet Pin number. Please keep this stored somewhere safe.
    o There is limited functionality on Internet Explorer, which may affect your user experience. We suggest that where possible, you should instead use Firefox or Google Chrome. When using either browser, you may need to move past an error message about security by clicking on 'advanced' and 'proceed anyway' or similar, which is safe.
    o **PLEASE NOTE: when saving CAPTURE in your favourites folder,** be sure to only save the address itself https://capture.gstt.nhs.uk (anything after this is a redirection relating to a specific session, and may result in an error message blocking your access).
    o **This is it, you can start recording your samples on the database!**

Contents

1. PATIENTS TAB

a. To search for an existing patient

Use the search fields to look for your patient. Select ASTAR study from the 'study' drop down menu and then enter the 'study ID' in that field, or alternatively you can use the date of birth. If you added a patient but did not complete the 'add to study' task, you will need to use date of birth to find them.

b. To add a new patient

STEP 1: ADD PATIENT TO CAPTURE

Go to the '**PATIENTS**' tab in the top right hand corner of the screen.

You can check first if your patient already exists on CAPTURE by entering their details into 'search patients'. If you have any concerns about duplication of patients, please contact the Coordinating Centre for advice.


Otherwise, click on the '**ADD PATIENT**' button.

Note – for training purposes *please use your first name as your first name and last name, and make up the other information. Do not use real information as this will be visible to all other training users across sites.*

- o Complete the data fields on this page – note that mandatory fields are marked with "*" but we would also like you to add participants' hospital number.
- o 'Other name' should be used for any aliases or maiden names, but middle names should be added alongside the first name.
- o Ensure you have chosen the correct radio button for NHS number (England & Wales) or CHI (Scotland), before you add that information.
- o There is no need to add country of origin, which is a field used by other studies.
- o Please note the rules for data entry, e.g. no spaces between digits in telephone numbers.
- o Enter contact details here if the patient has consented to recall (for real patients see Informed Consent Form - ISF).
- o Click on the 'SAVE' button to generate and move on to the 'patient profile' page

Need to edit patient details? Click 'edit' button in the top-right hand corner, amend and click 'save'.

STEP 2: ADD PATIENT TO STUDY

Click 'ADD PATIENT TO STUDY' button:
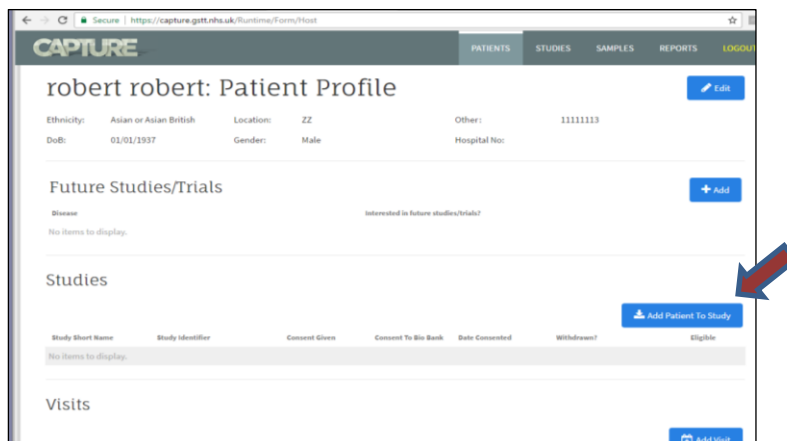
1. Select study from drop down menu (the options will depend on which studies you work on).
2. Complete consent details (including whether they have consented to (i) provision of samples for genetic analyses, (ii) to remaining DNA being added to the biobank (iii) and recall), getting this information from the CRF or Informed Consent Form – ***note: it is <u>essential</u> this reflects the consent given***)
3. Enter the Study ID (this may be auto generated in your live website if you prefer)
4. Select the option 'Consent to DNA analyses' or 'Consent to storage and use in future studies for DNA samples', depending on the patient's consent.
5. Click 'NEXT'
6. Enter eligibility details
7. Click 'SAVE'

STEP 3: ADD VISIT

1. Click 'ADD VISIT' button
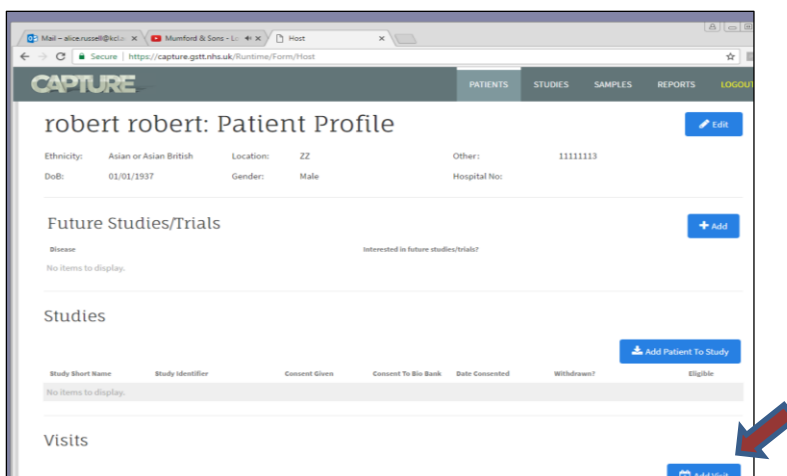
2. Add the date of visit
3. Select study from drop down menu
4. Select visit type from drop down menu – *note* that if it is the first visit you are adding for this patient, it will always be called a baseline even if you are actually collecting the blood at a follow-up. Do not worry if it is not the A*STAR baseline for this patient, just ensure that the visit date is correct and this can be matched up later.
5. Click 'NEXT'

c. To add a sample

▪ Select the relevant sample types you have collected and check the number of tubes/volume of collection are correct. Do not record information that you are not sure of, or that is not expected.

▪ **PLEASE NOTE: Once you create a sample in CAPTURE by selecting a sample and submitting this information, it cannot be amended. Please double check that the data you submit on this page is correct, <u>before</u> pressing 'save and continue'. If you make a mistake, email [capture@gstt.nhs.uk.](mailto:capture@gstt.nhs.uk)**

▪ Your samples will then appear in the sample summary page. If they do not, click on the menu on the left hand side and go back into 'sample summary', before you try to add samples again.

1. Select the sample collection on the left side of the screen (Blood, Saliva) and complete the different fields and then press 'Submit & continue'.

The 'Final Check' window opens. If the data entered is correct, please select 'Yes' (or 'No' to edit) and 'Enter'

2. Click on 'Sample Summary' to see the samples you've just entered and then press 'Continue'.

3. 'Add Additional Sample' should only be used to record any additional samples which have been requested e.g. in the case of any issue with the quality of the first sample.

Since you cannot amend samples after step 1, should you make any errors you will need to speak with capture@gstt.nhs.uk *(0207 188 7188 x56073)*

All samples MUST be labelled with the following fields as a minimum:

1. A-STAR Study ID number
2. The date sample was collected
3. Participant initials

And then if you have been able to add the samples on CAPTURE before freezing them, please also label each tube with:

4. **The Sample ID number generated by CAPTURE** e.g. XX123456.1 (see first column of the sample summary, as in the above example) – always get this from CAPTURE and never guess what it will be as it may change from the expected sequence.

In order that our records are correct we need your sample ID on the tube and/or paperwork to match CAPTURE so if you're not able to add it to the sample, please ensure it is added to the sample slip (also called the sample request form).

→ **PLEASE NOTE: the sample ID is linked to the sequence of samples added to CAPTURE**, NOT to the study ID. If they match, it is just because you have entered the patients in the same order that samples were taken, so please take care that you are using the correct ID.

IF SENDING SAMPLES AT ROOM TEMPERATURE IN ROYAL MAIL BOXES – skip to 'completing a visit' and then jump to 'creating a batch of samples'

IF FREEZING SAMPLES LOCALLY, THEN SHIPPING ON DRY ICE – follow the next steps to first store your sample(s), before completing your visit

d. To store a sample

Note - You can do so in different ways; in the study visit itself (shown here), or by searching for your sample in the samples tab (described in the **SAMPLES TAB** section below). During the study visit works best for individual sample processing. The samples tab allows you to bulk process/store if you have lots of samples from the same clinic.

Within the study visit:

1. **In sample summary** and double click on the sample line (anywhere <u>except</u> on the blue arrows)
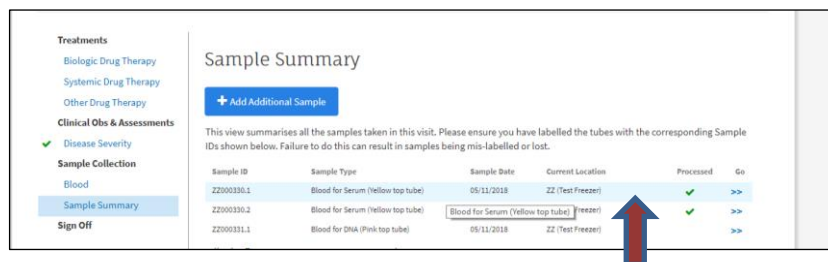
2. **In the Store Sample tab**: record where the samples have been stored (choose your freezer from the location 1 – tell the CAPTURE team what to add for your site if it doesn't appear) and the date and time stored. Note you do NOT need to complete location 2 or the project fields.
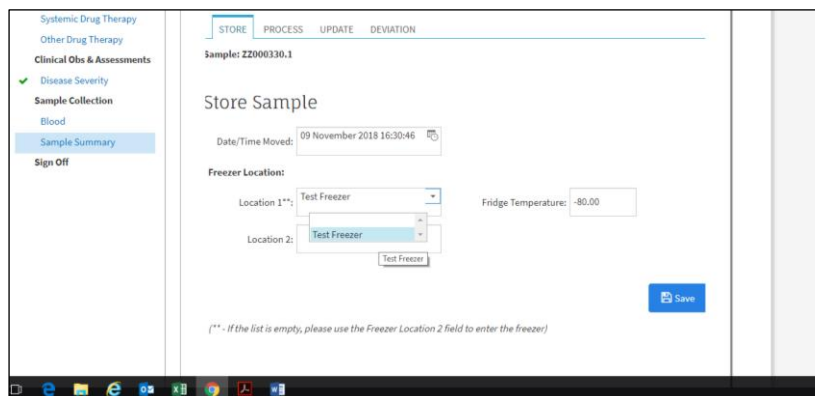
Repeat steps 1 & 2 for your second tube to ensure they both show as stored

e. Completing a visit

Once you've completed all data fields, you need to mark your visit as complete.

Ensure you've made any relevant comments in the Visit Comments section (e.g. to note missing data, or discrepancies between dates of clinical assessments and/or samples). Keep notes as succinct as possible and do not use 'enter' to distinguish between notes, but rather a full-stop. This makes it easier for the users of the data to read when getting a report from CAPTURE.

Once you have entered <u>all</u> data (including about samples storage), click on the 'Complete visit' section and click the 'Submit' button to submit this visit as complete. If you're not ready to do this, so long as you've saved as you go, you can return to add any missing information and then complete the visit at a later stage.

f. To make changes or add information after you have left the visit

If you have clicked on 'Complete visit' then you can still change information [except relating to samples collected which cannot be changed after they have been added except by the CAPTURE team]

g. To update the sample storage information

You will need to double click on the double blue arrows to open it, as shown below, and then go to the 'sample summary' menu on the left hand side to add the information following the steps above

h. To add a new/amend an existing visit comment or visit date

Instead of clicking on these arrows you should double click elsewhere on the visit line to bring up the 'Edit visit' dialogue box

You can also use this option to update the visit date if required
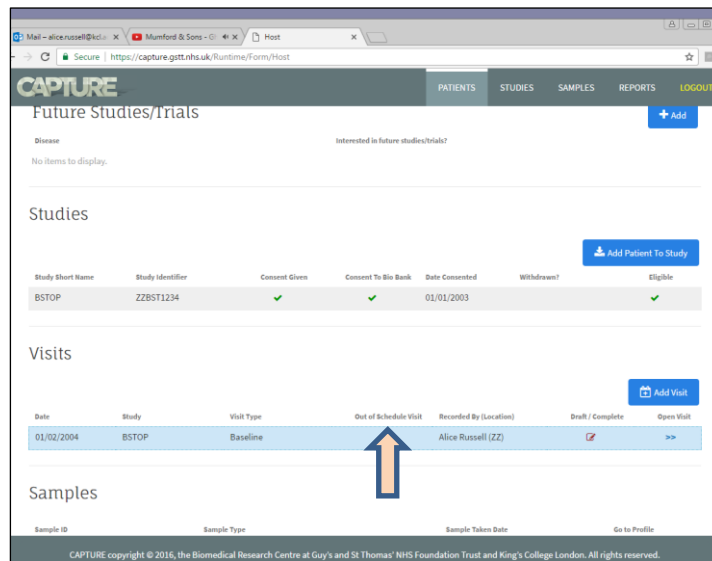
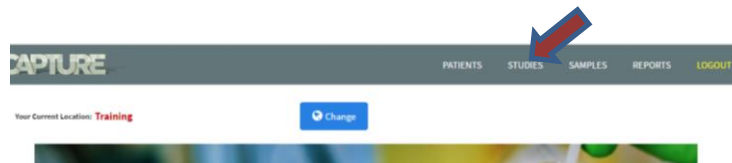Note that once you've added or changed a visit note, the visit will again need to be signed off as complete. Double click on the double blue arrows to open it and repeat the steps above to complete the visit.

2. STUDIES TAB

You can use this tab to view all of your patients within a study. Choose 'A-STAR' when on the live site to see all of your patients at your own centre(s). If you click on a patient, it will take you to their patient profile page.

3. SAMPLES TAB

You can use this tab to view all of your samples collected which are stored at your site(s). From here you can store multiple samples at once, and send your samples virtually to other centres.

a. To store multiple samples together

Note that you will only need to record storage information if freezing samples and sending in bulk

1. You will need to use the **'store samples'** menu on the left-hand side. You can store different sample types together this time, as long as they are being stored in the same location at the same time.
2. Use the search fields to narrow down your search (see box on next page)

> *Tip: if you are adding the information retrospectively* and have more samples than you wish to process together appearing in your list, you can use the following to narrow down your search:
>
> **Date** – all samples after this date that have not yet been marked as 'stored' will be visible
>
> **Study ID** – all samples for one patient that have not yet been marked as 'stored' will be visible
>
> **Show max of 'X'** – change this to the number of samples you need after a certain date, e.g. if you needed the first 2 samples collected after the 9th of November, you could change the default 100 to '2' which would give me my first 2 samples. For the first 4, you could change it to 4, etc.

3. **Check that the list which appears are the samples you have processed at the same time**. If they are not you should NOT proceed as it is important this information is accurate**.**

4. **If happy,** click on **'process these samples'** to apply the same information to all samples at once in the 'store' tab of the box which appears. Select your freezer from Location 1 (please request that this be added by capture@gstt.nhs.uk if not already available), and ignore the fields Location 2 and Project.

b. To make a batch of samples to ship

1. Click on the 'BATCHES' tab on the left hand column.
2. Click the 'CREATE NEW BATCH' button.
3. Name your batch or use the default name provided.
4. Select the samples you wish to add to the batch of samples to send in one transfer by entering in the search criteria (e.g. collection type and/or date) and clicking the 'SEARCH' button.
5. To move samples in and out of the batch:

   - **To add all of your search results to the batch**: click the 'ADD ALL SAMPLES LISTED ABOVE TO BATCH' button.
   - **To add one or individual samples from your search results to the batch**: double click on the sample you want in the batch to move it to the right hand side (your batch list).
   - **To remove one or individual samples from your batch:** double click on the sample you want to remove to move it back into the samples search results.

6. When you think you're happy with the contents of your batch, click the 'SAVE BATCH' button. The list must all be about to be sent together in the same box

## c. To make a manifest of the samples in your batch (dry ice only)

This can be used to cross check against the samples you hold as you pack/prepare samples:

1. Go to the 'reports' tab
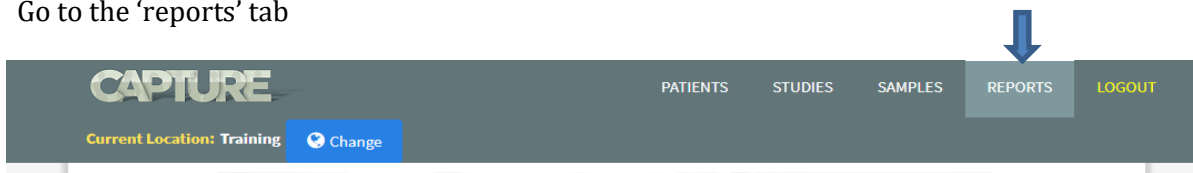
2. Choose the report related to batch contents. If you do not see it or can't access it, please contact capture@gstt.nhs.uk or call 0207 188 7188 x56073.

3. Use the top right hand corner 'parameters, batch:' to choose your batch from the drop down menu and then click on 'apply' in the bottom right corner.
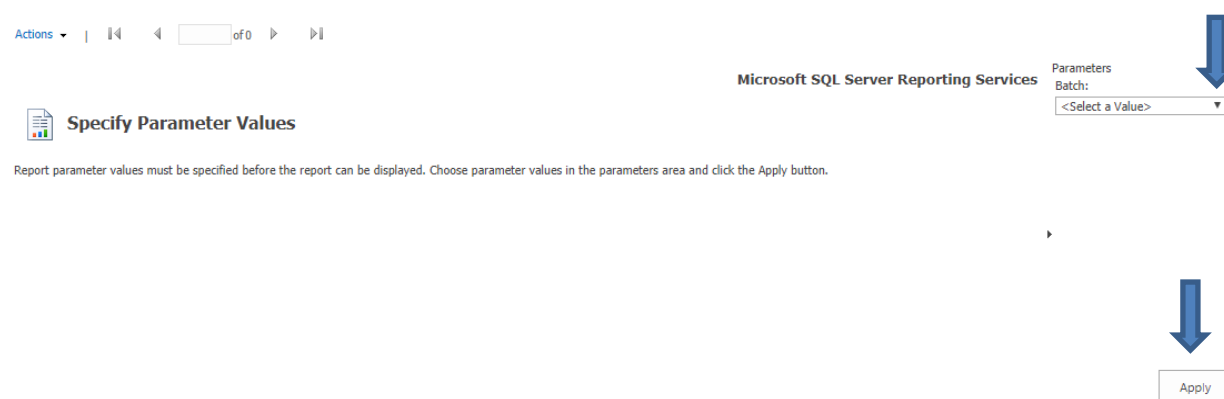

Your contents should appear in a table similar to shown here (with more samples!):

Batch List

Study ID	Sample ID	Sample Type	Sample Created Date	Batch Name
ZZBST5983	ZZ000101.2	Blood for DNA (Pink top tube)	02/08/2017	ZZ:Russell (02-08-2017)

4. To export, click on 'actions' in the top right corner and choose export and then either PDF or Excel file to generate a PDF or Excel report of the samples in your batch.
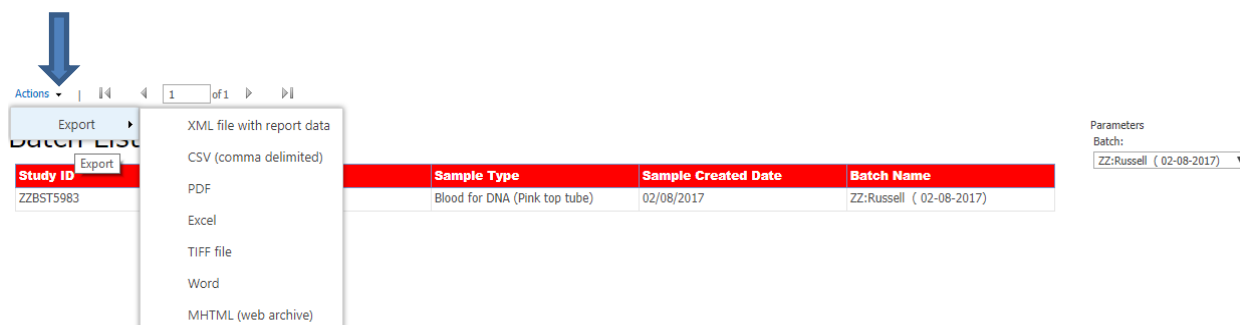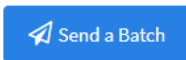

5. Print it off and use it when you pack your samples to confirm all samples in the batch are included in the shipment
6. You may keep a copy of the ticked manifest in your site file and also send one with the samples for GSTT/KCL. If there are any discrepancies, we will update it and raise any queries with you upon receipt.
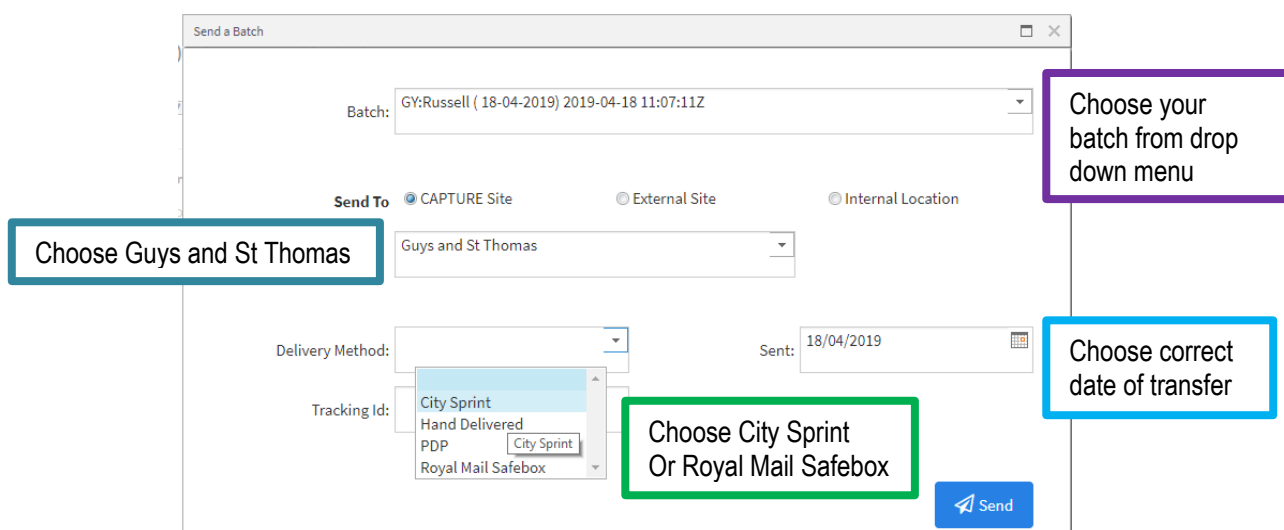
d. To send a shipment (batch of samples)

This is only the virtual transfer of samples and should only be completed in combination with an actual shipment.

1. **You will need to first have created a batch** – see this point above before continuing.
2. **If you are sending multiple samples on dry ice** - be sure to do the batch report check FIRST against the samples you have prepared to ship, before marking a batch as sent.
3. Click the **'OUTGOING BATCHES'** link on the left hand side menu (distinct from the 'batches' link).
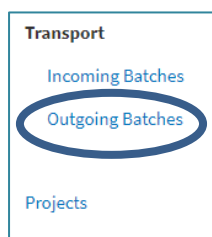
4. Click the **'SEND A BATCH'** button and complete the details in the box which appears:

5. Select the batch you wish to send.
6. Select the location you wish to send the batch to.
7. Select the method of transfer relevant for the sample type (e.g. City Sprint).
8. Click the 'SEND' button .

Once step 8 has been followed, your shipment has been virtually sent and the samples can be received electronically at GSTT/KCL. This is key as it means we have a record that those samples are no longer stored at your site.

4. CAPTURE training exercises

To complete before the logging of real patient data and samples.

Training exercise 1: Create a new dummy patient with the dummy CRF details provided, add this patient to A-STAR and create a visit using the dummy data and samples on the CRF. In this visit, say that 2 x 6ml tubes of blood for DNA were collected and record them as both stored in the sample summary before marking the visit as complete.

Training exercise 2: add a visit note to the follow-up to explain the bloods were taken on a different day to the visit (tip: see how to add/change a visit note p.9)

Once you have completed these exercises, please confirm this to the trial manager who will check your entry and switch you to the live site.