

ANIMATE

A phase II study of nivolumab monotherapy in patients with relapsed/refractory Hodgkin lymphoma, fit for autologous stem cell transplant, who fail to reach complete remission after first or second line salvage therapy

SAMPLE TRACKING WEBSITE MANUAL

For the online tracking of samples and scans for central analysis

Version 1.0 22.11.2018



Bristol-Myers Squibb

Cancer Research UK and
UCL Cancer Trials Centre



CANCER
RESEARCH
UK

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1. Introduction

The purpose of this sample and scan tracking website manual is to describe the process for the online tracking of samples and scans for central analysis in the ANIMATE trial.

Each blood sample, tissue block, PET-CT scan and contrast enhanced CT scan sent to central laboratories must be tracked online using the sample tracking website which can be found at <https://online.ctc.ucl.ac.uk/>.

In order to preserve the integrity of the patient samples, designated staff at each participating site are responsible for ensuring that research samples and scans are accurately recorded and sent for analysis on time in accordance with the instructions in this manual and the current approved version of the trial protocol. Designated staff should be appropriately trained and listed on the Site Staff Delegation Log as authorised by the Principal Investigator to carry out these tasks before any trial related activities and procedures can be performed by them.

It is important that site staff ensure that all research samples are transported to the specified laboratories within the time frames specified in the trial protocol and as set out in the Laboratory Manual and that samples are not shipped to arrive at the laboratories either on a weekend or Bank Holiday.

In addition to tracking online, please ensure that all samples sent to central laboratories are also recorded on the Biological Samples Shipping Log, filed in the Investigator Site File.

For more information on the analyses that will be performed on biological samples for the ANIMATE trial, please refer to section 10 of the protocol.

For more information about the collection and shipping of samples and scans for central analysis, please see the Laboratory Manual and PET-CT manual.

2. Registration for a tracking website account

UCL CTC must be provided with the details of at least one site staff member to be registered to use the tracking website before site activation, although it is highly recommended that as many members of the site research team as possible have access to allow for prompt tracking of samples and scans. UCL CTC will provide them with access to the tracking website when the site is activated.

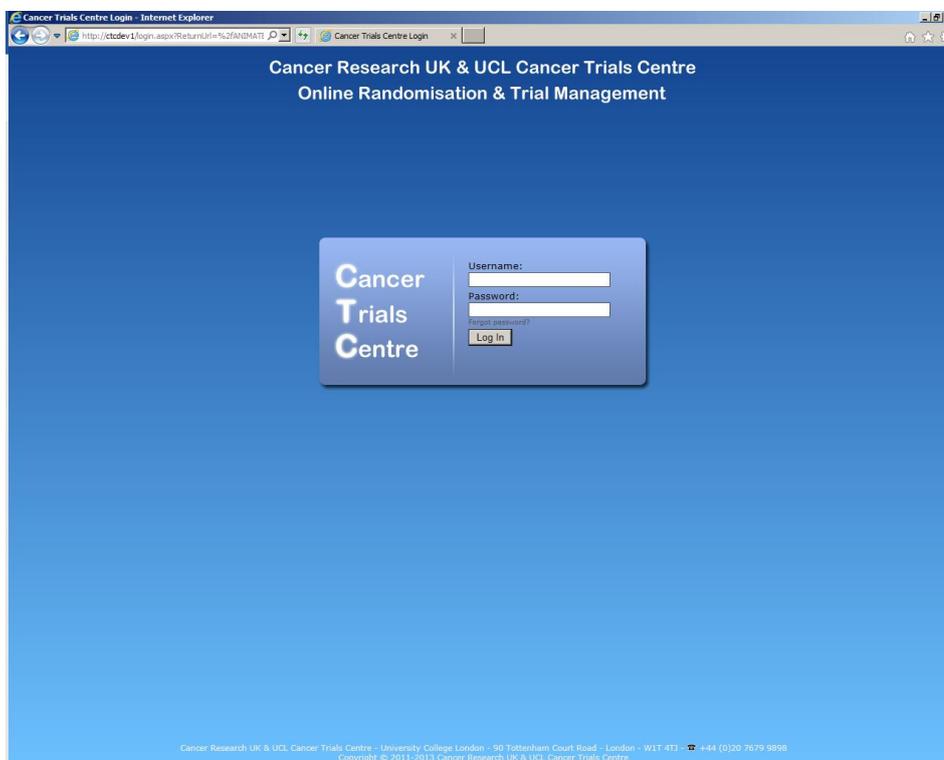
Likewise, central laboratories that will be receiving samples and scans during the treatment phase of the trial must provide UCL CTC with details of at least one member of laboratory staff to be registered to use the tracking website prior to activation of the first trial site.

Logins are unique to individual staff members and should not be shared. To request access for other staff members during the course of the trial, email the name(s) and email address(es) of the staff member(s) requiring access to the ANIMATE trial coordinator: (ctc.animate@ucl.ac.uk).

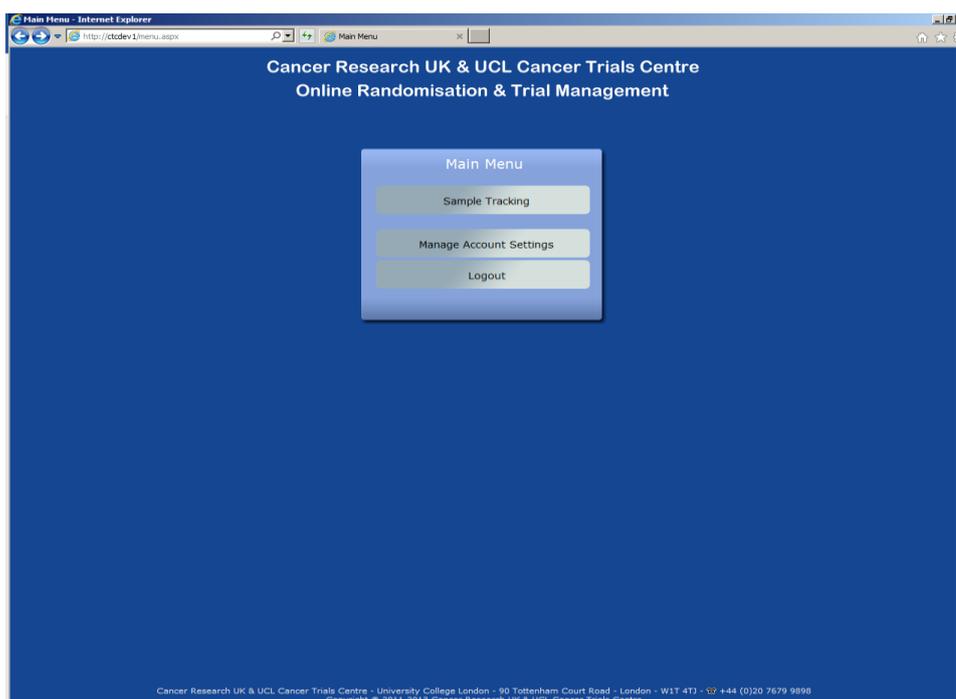
3. How to track a sample or scan online: Information for Sites

To track a sample, follow these steps:

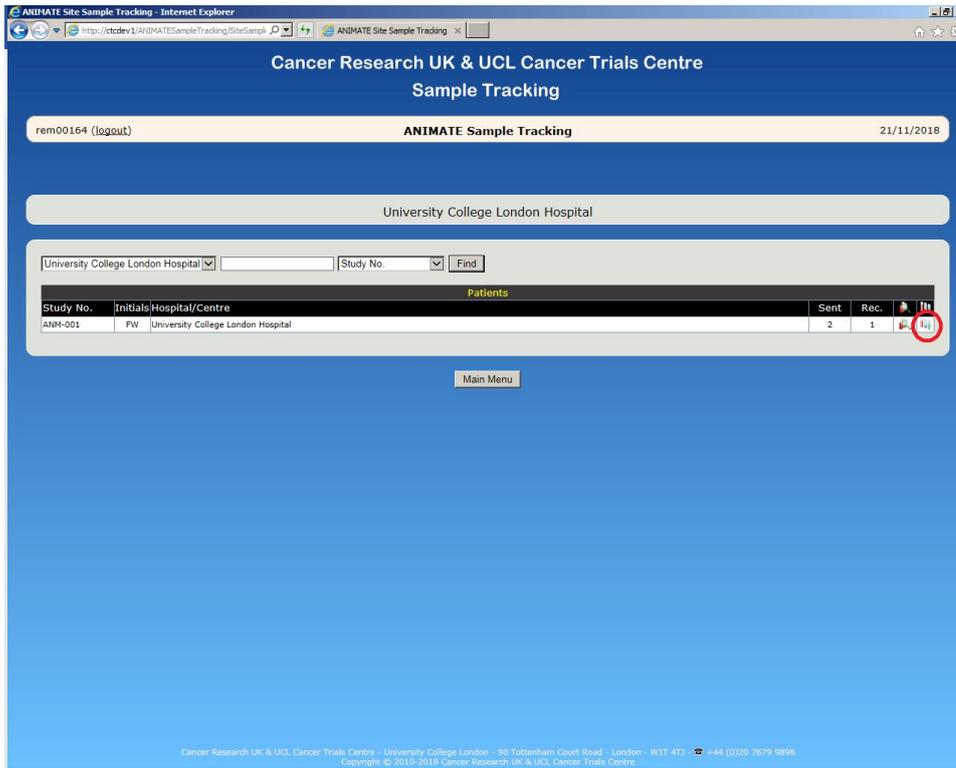
1. Log in to the website at <https://online.ctc.ucl.ac.uk/> by entering the user name and password you have been given.



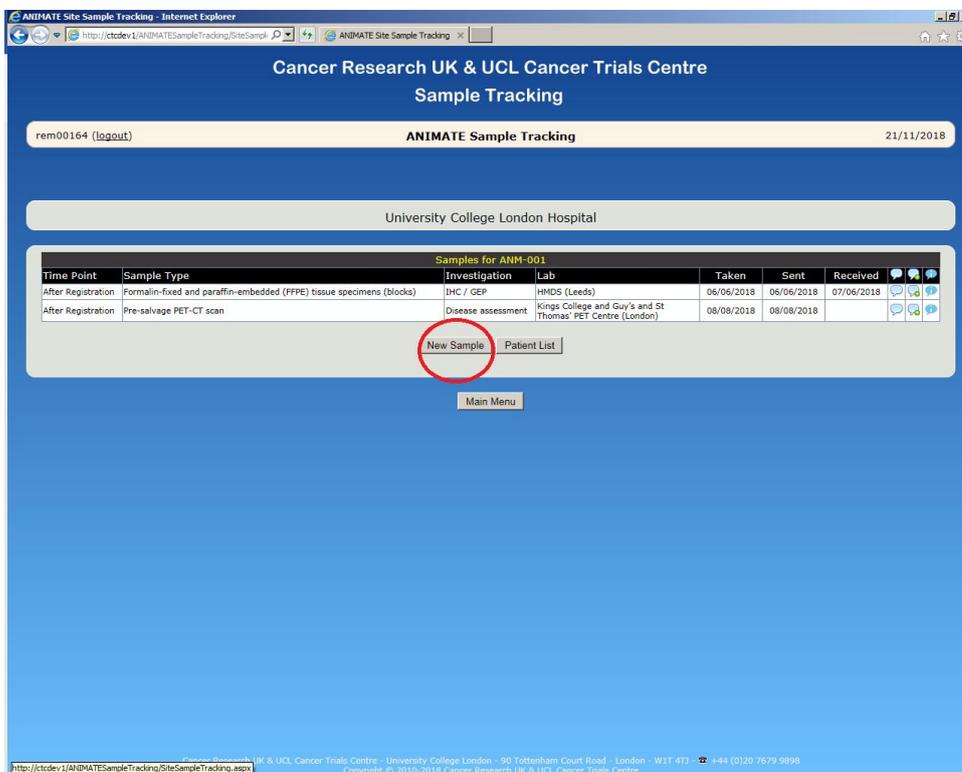
2. Click on “Sample Tracking” and then “ANIMATE”. This will bring up the list of patients at your site. New patients will be added to the website by UCL CTC when they are registered into the trial.



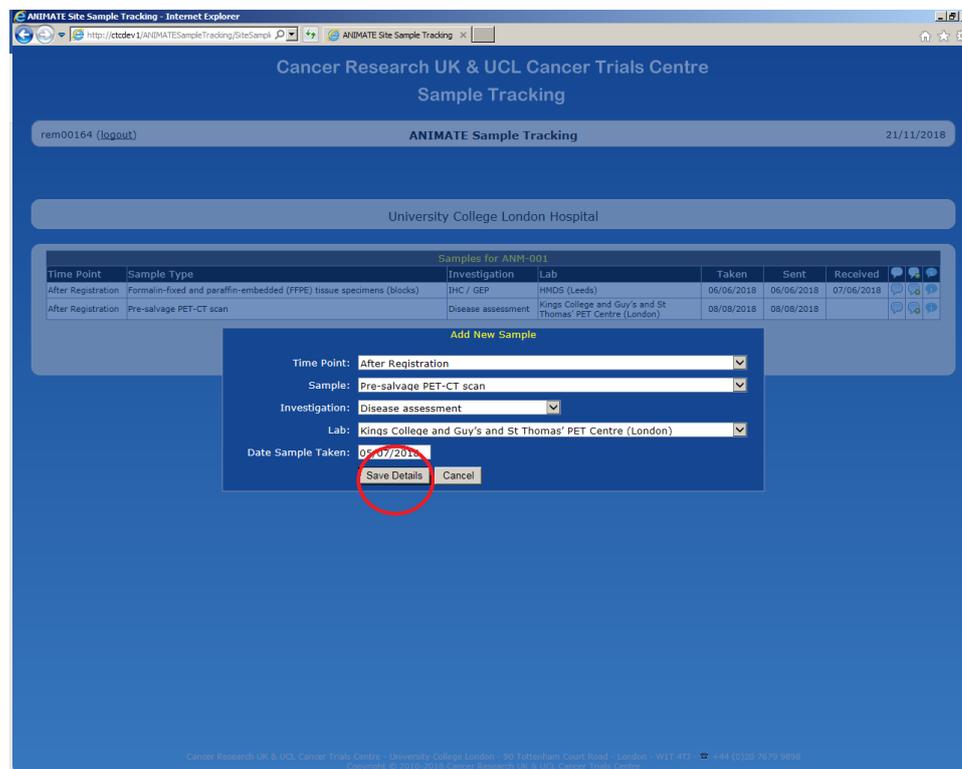
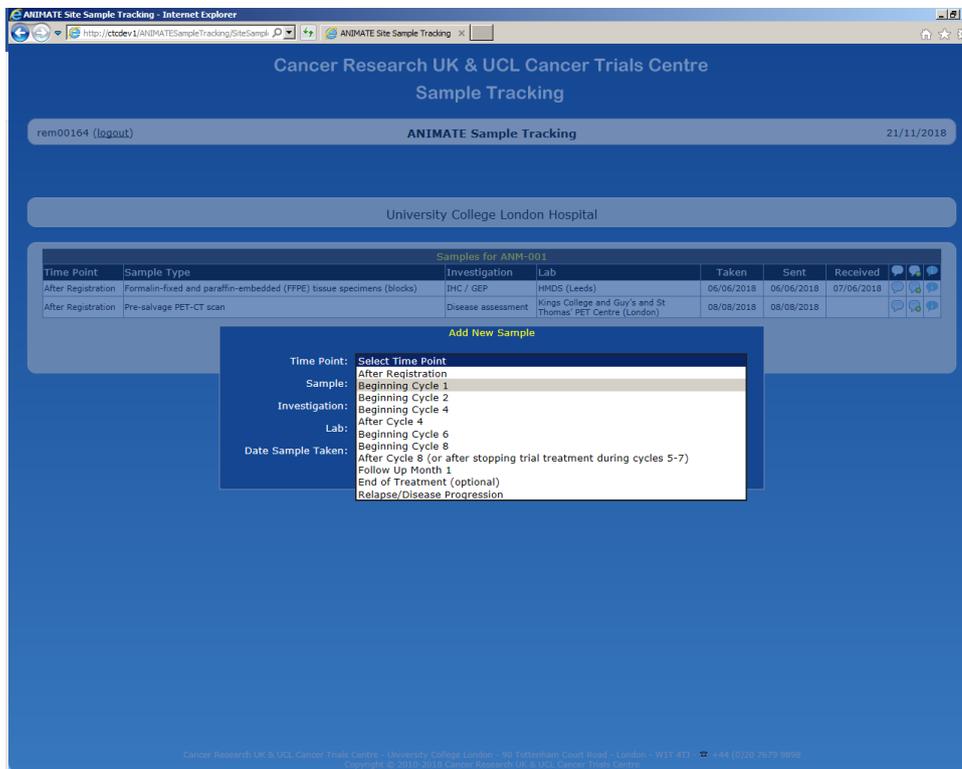
- To bring up the list of samples and scans for each patient click on the icon on the far right (represented by 3 test tubes).



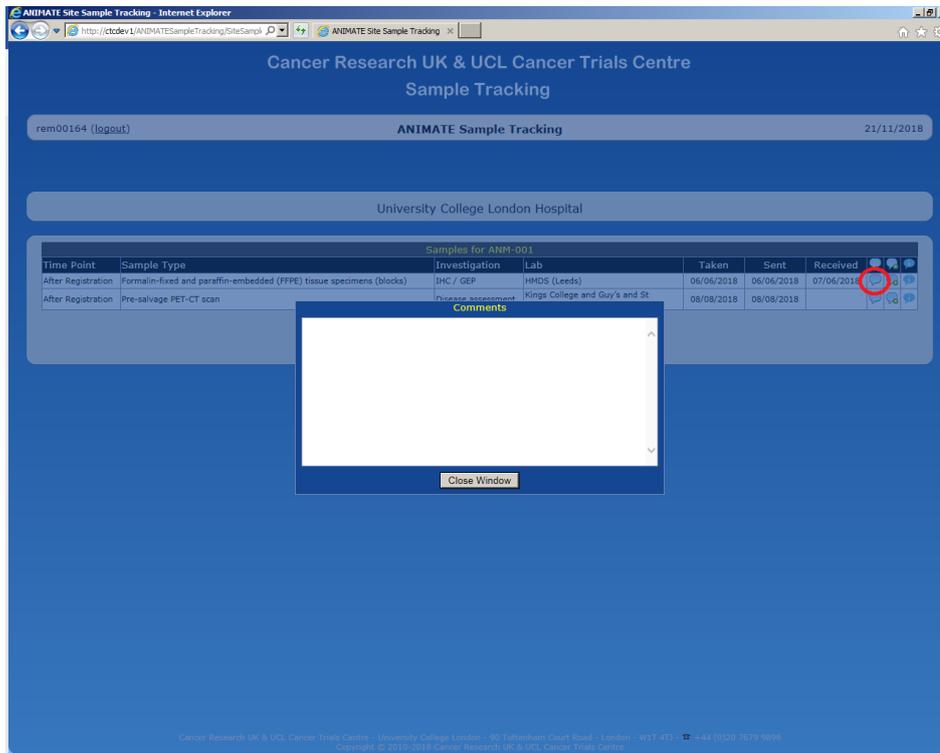
- Click on the “New Sample” button to begin tracking a sample or scan.



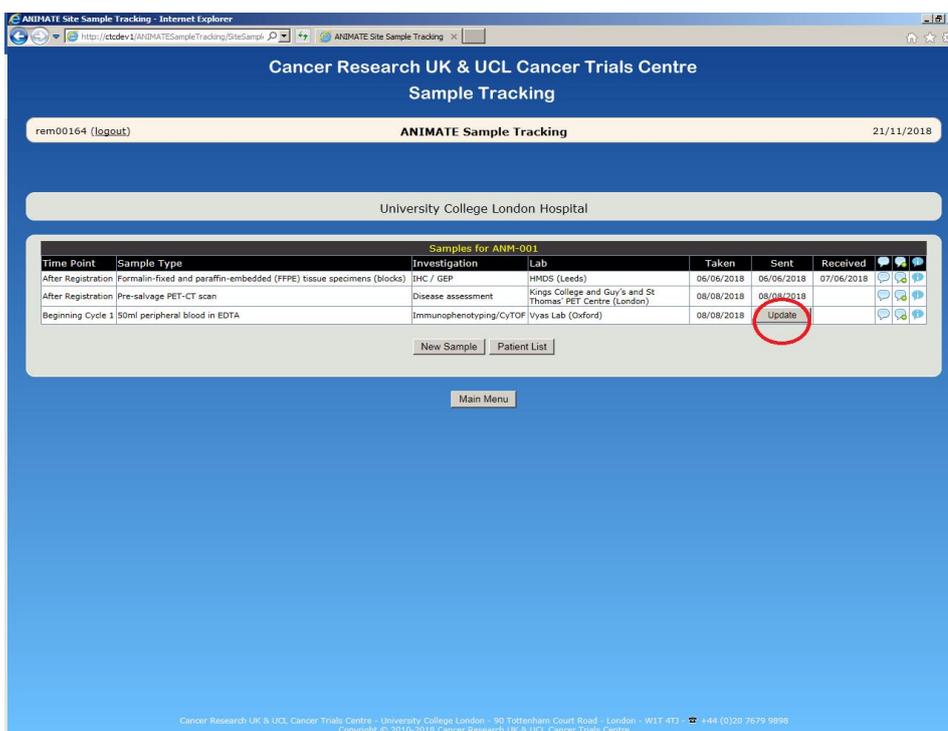
- Using the drop-down menus, enter the time point, sample or scan type (FFPE blocks, 50ml peripheral blood in EDTA, 5ml peripheral blood in serum gel tube, PET-CT scan or contrast-enhanced CT scan), investigation, the laboratory where it is being sent and the date sample or scan was taken. After completing all fields, click the “Save Details” button. For further information on when these samples should be taken and where they should be sent, please see section 10 of the trial protocol, Laboratory Manual and PET-CT Manual.

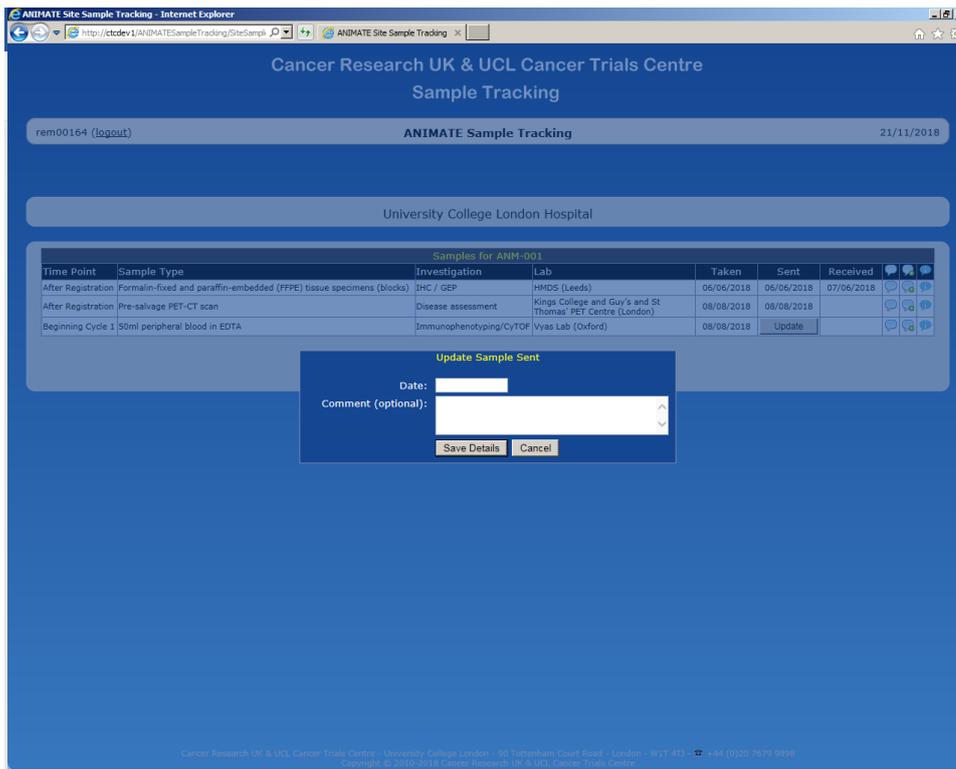


- After a new sample or scan has been added, the speech bubbles on the right can be used to view and add comments that can be seen by the central laboratory. Please use this if you wish to inform the lab of anything regarding the sample or scan you are shipping.

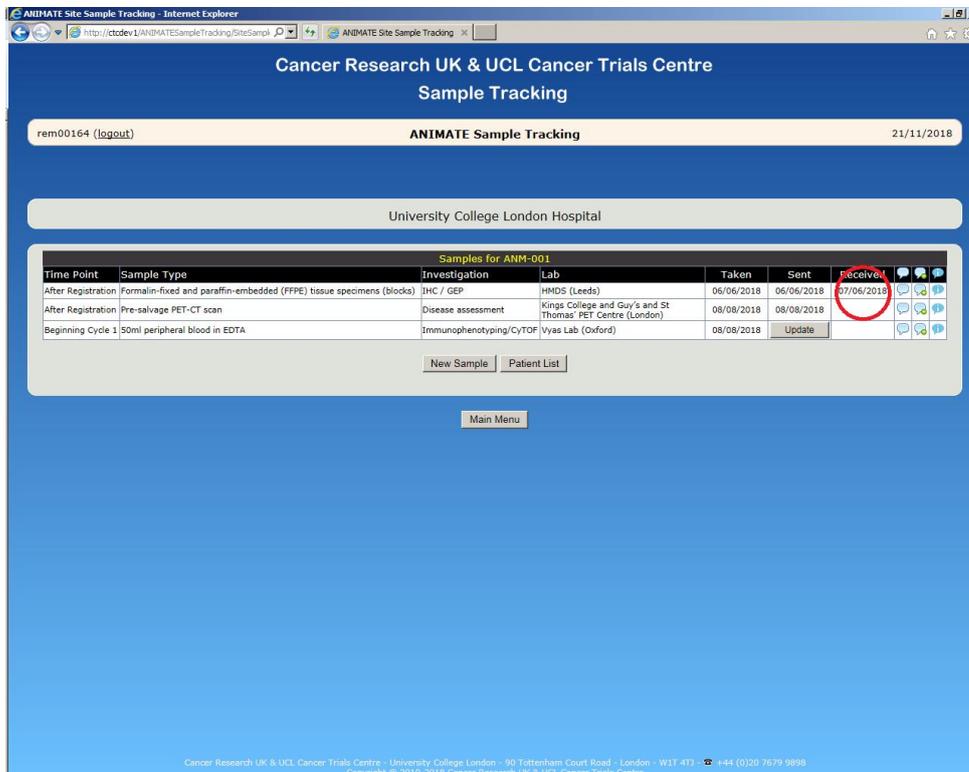


- To add the date a sample or scan was sent, click on the "Update" button for the relevant sample or scan. Enter the date in a dd/mm/yyyy format then click "Save Details". To ensure our records are complete, you need to add the date the sample was taken or the date the scan was performed and the date it was sent, even if these are the same day.





- UCL CTC and the central laboratory will then be notified that a sample or scan has been sent. On receipt, the central laboratory will track the sample or scan, and the "Received" column will be updated and be viewable by site staff.



If any errors are made when tracking a sample or scan, such as entering the wrong date, please contact the ANIMATE trial coordinator (ctc.animate@ucl.ac.uk) as soon as possible and ask for the incorrect data to be amended.

N.B. The information icon or “I” button on the far right of the table can be clicked on as prompt for the shipping and storage information required for that sample.

The screenshot shows the ANIMATE Sample Tracking interface. At the top, it says "Cancer Research UK & UCL Cancer Trials Centre Sample Tracking". Below that, there's a user login area with "rem00164 (logout)" and "ANIMATE Sample Tracking" and a date "21/11/2018". The location is "University College London Hospital".

The main content is a table titled "Samples for ANM-001". The table has columns: Time Point, Sample Type, Investigation, Lab, Taken, Sent, Received, and an information icon. The data rows are:

Time Point	Sample Type	Investigation	Lab	Taken	Sent	Received	Info
After Registration	Formalin-fixed and paraffin-embedded (FFPE) tissue specimens (blocks)	BHC / GEP	HMDS (Leeds)	06/06/2018	06/06/2018	07/06/2018	[Info]
After Registration	Pre-salvage PET-CT scan	Disease assessment	Kings College and Guy's and St Thomas' PET Centre (London)	08/08/2018	08/08/2018		[Info]
Beginning Cycle 1	50ml peripheral blood in EDTA	Immunophenotyping/CYTOf	Vyass Lab (Oxford)	08/08/2018	Update		[Info]

A pop-up window titled "Shipping/Storage Information" is displayed over the table. It contains the following text:

Storage Temperature: **Ambient Temperature**
 Shipment: **Ambient Temperature**
 To Arrive At Lab Within: **Within 3 days prior to start of cycle 1**

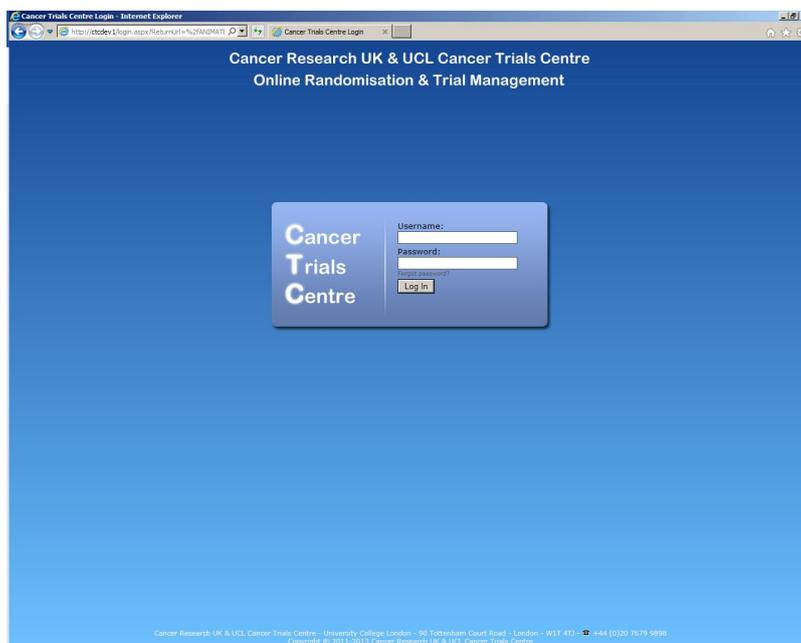
There is a "Close Window" button at the bottom of the pop-up.

No actual patient data was used in the above images.

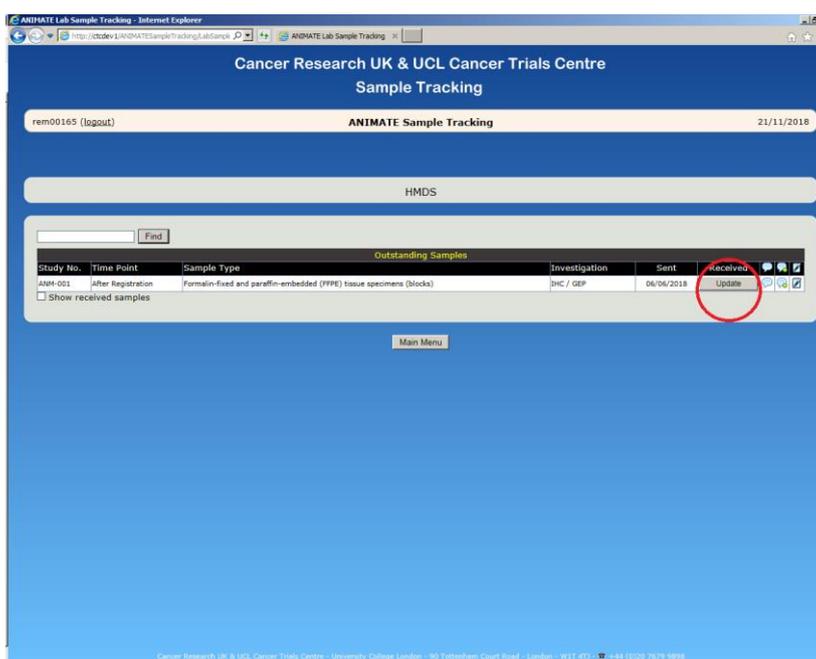
4. How to track a sample or scan online: Information for central laboratories

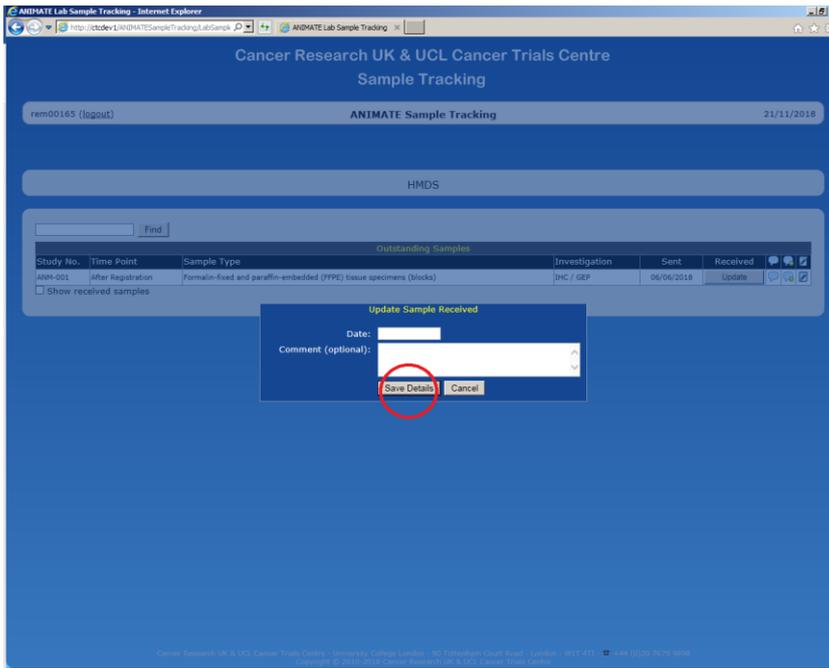
To track a sample or scan, follow these steps:

1. Log in to the website at <https://online.ctc.ucl.ac.uk/> by entering the user name and password you have been given.

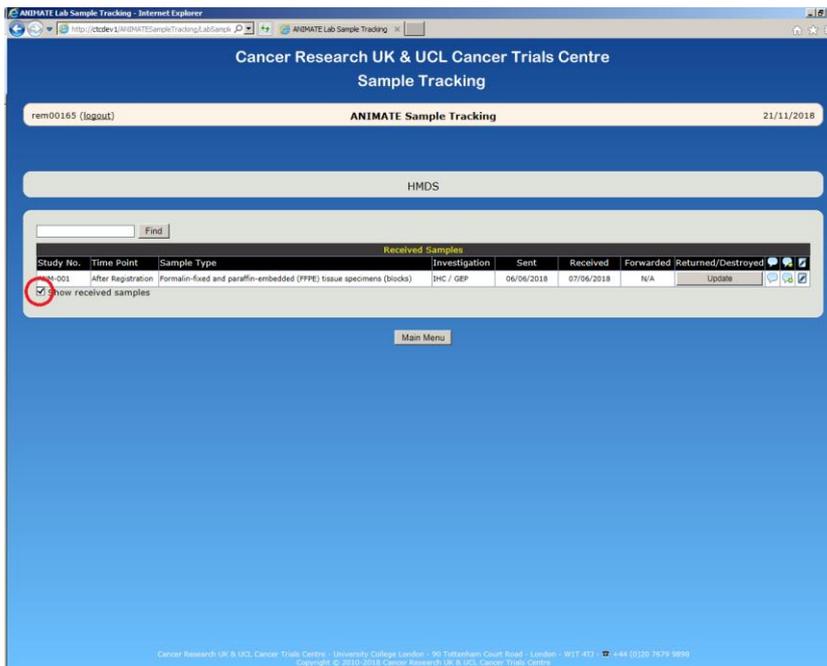


2. Click on "Sample Tracking" and then "ANIMATE". This will bring up the list of samples/scans that have been sent to your lab. To inform the site that a sample/scan was received, click on the "Update" button. Enter the date in a dd/mm/yyyy format then click "Save Details". Please do this punctually upon receipt.

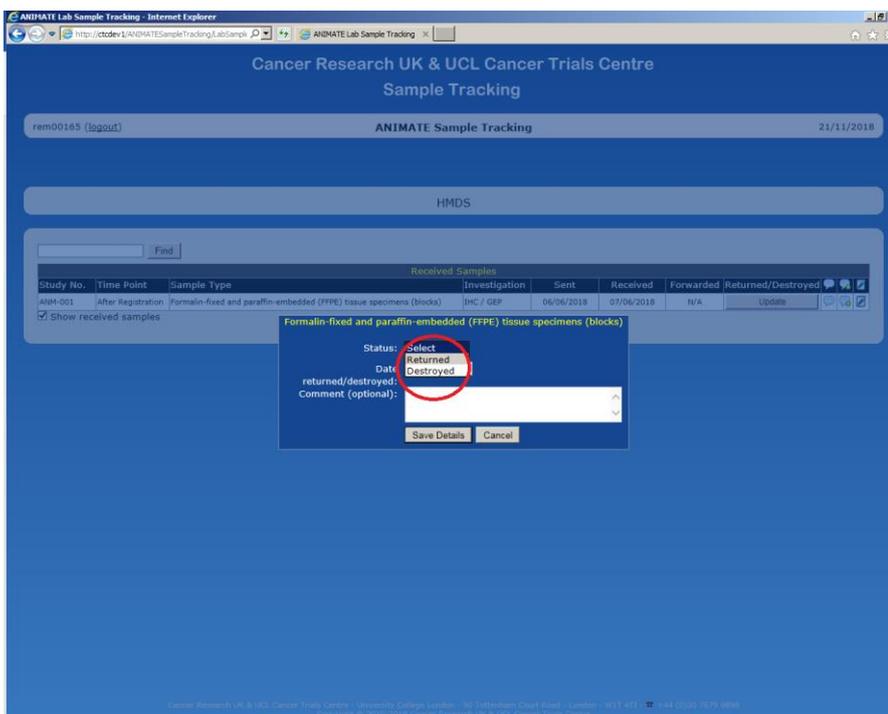
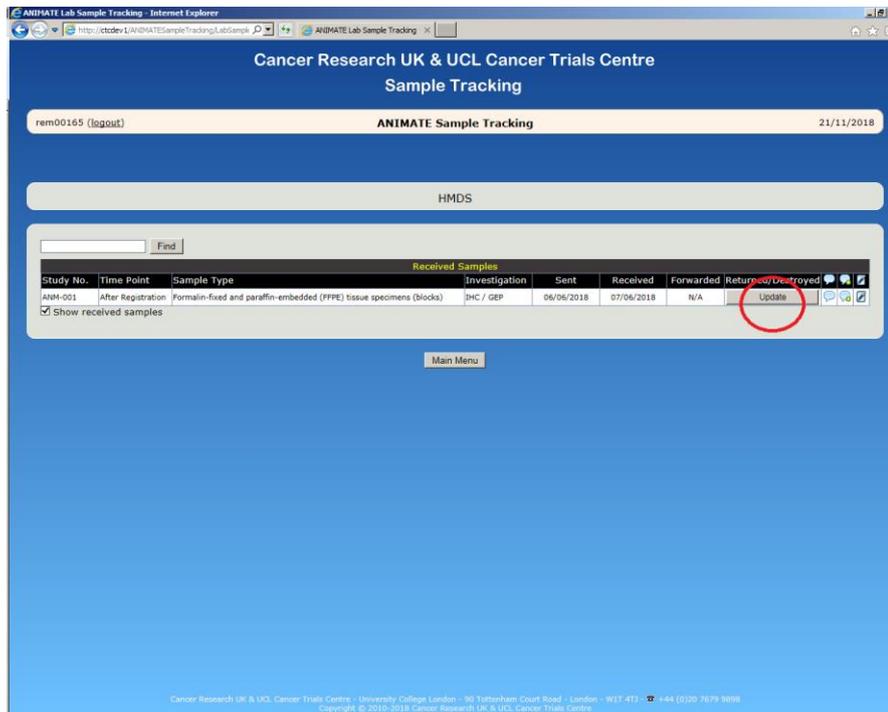




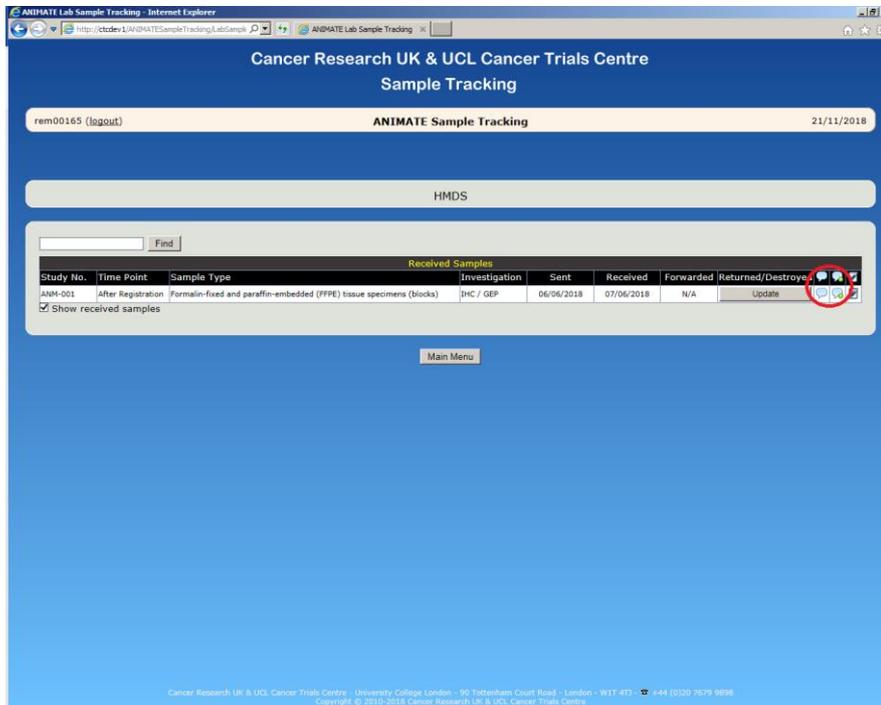
3. Samples/scans will disappear from the list once they have been acknowledged as received, click the “show received samples” box for a full list of everything received so far at your lab.



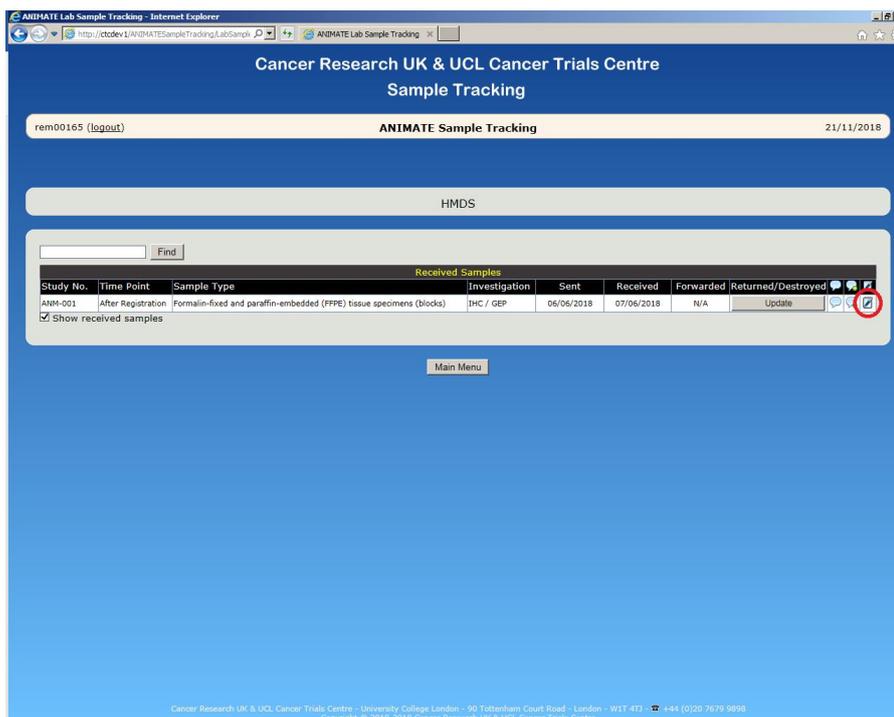
- Following analysis, you should update a site when a sample is returned or destroyed by opening a full list and clicking on the “Update” button for the relevant sample. Enter the date in a dd/mm/yyyy format then click “Save Details”. You can also add a comment in the box provided if you want to. The site and UCL CTC will then be informed if a sample was destroyed or returned. Sites will record if a tissue block is to be returned on the original Biological Sample Collection form, please consult this before any tissue blocks are destroyed. Blood samples are not to be returned and should be destroyed as per your local policy. No action is required from the PET Core Lab at this timepoint.

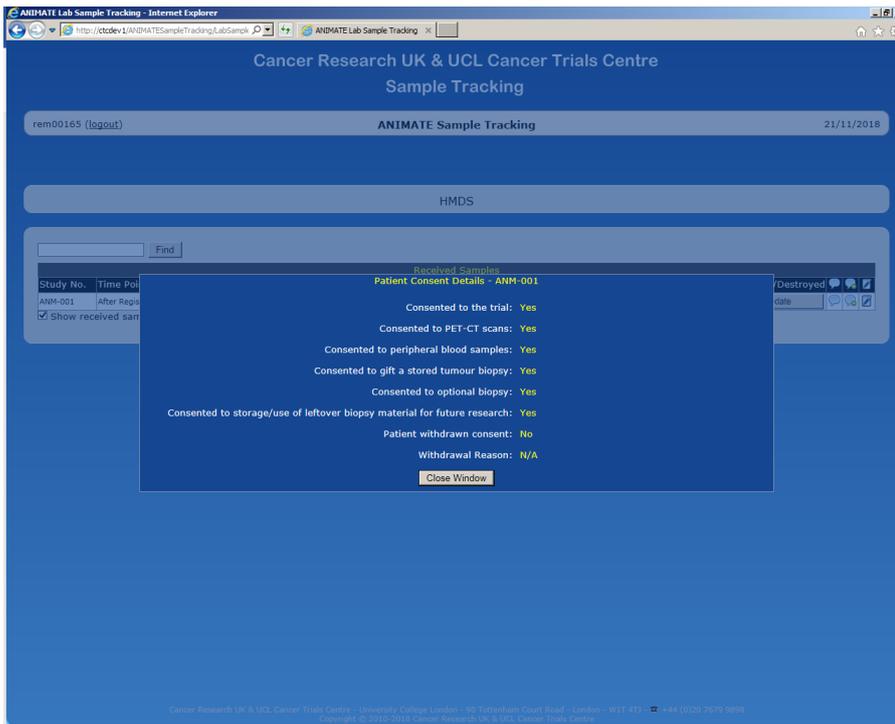


- The speech bubbles on the right can be used to view and add comments that can be seen by sites. Please check if any comments have been added by sites and use this if you wish to inform them of anything regarding the sample you are tracking or returning.



- The pen icon on the right can be used to view patient consent details. Please check to confirm that a patient has consented for optional sample collection and not withdrawn consent. If you believe that a sample should not have been sent to your lab, please inform the trial coordinator at UCL CTC (ctc.animate@ucl.ac.uk) immediately.





No actual patient data was used in the above images.

ANIMATE Sample Tracking Website Manual - Version History Log

Version number	Date	Summary of changes from previous version	Changes made by
1.0	22.11.2018	N/A	Oliver Schofield / Pip Patrick

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