SOP Number   01
SOP Title   eCRF Completion Guidelines SOP
Version   1.1

	NAME	TITLE	SIGNATURE	DATE
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Author v1.1	Eloïse Cook	Senior Clinical Trials Co-ordinator		18/12/2020

1. **PURPOSE**
   To describe the process for using the electronic Case Report Form (eCRF).

2. **DEFINITIONS**
   FALCON C-19 – Faciliating AcceLerated Clinical evalusation Of Novel diagnostics tests for COVID-19 (FALCON C-19)
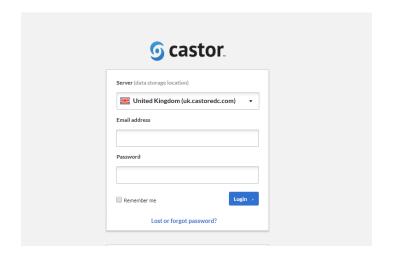   SOP – Standard Operating Procedure
   eCRF – Electronic Case Report Form
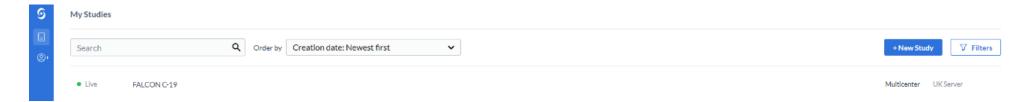   CRF – Case Report Form

3. **SPECIFIC PROCEDURES**
   1. **Creating an account:** To request an account, first ensure you have the relevant permissions on the Delegation Log. Then email FALCONstudy@mft.nhs.uk to request an account to be set up. Once the account has been set up, you should receive an email with a link to the database to finish setting up your account.

   2. **Logging in:** To log in to the Castor web portal, use the following URL: https://uk.castoredc.com/.
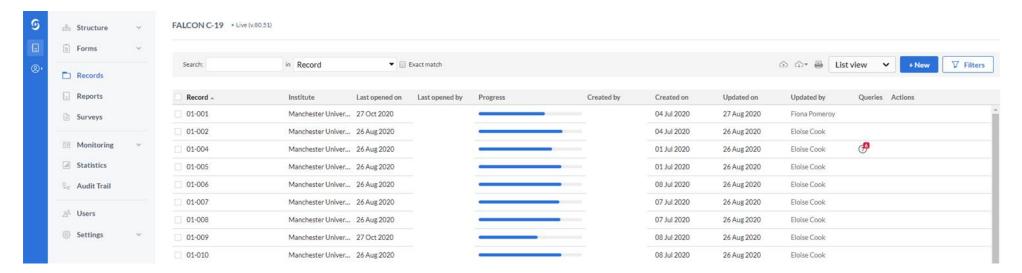
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Once you have logged in, you will start at the home page where it shows a list of studies you have access to.

3. Click on 'FALCON C-19' and this will take you to the homepage.
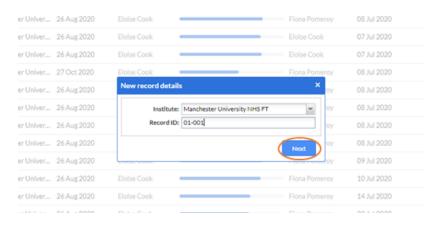
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4. **Creating a new record:** You can add a new participant record by clicking on the '+ New' icon in the top right.
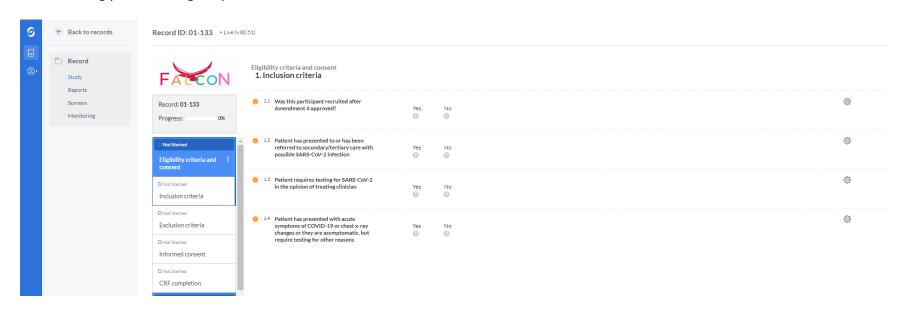

After clicking on the '+ New' icon, a pop-up box will appear allowing you to enter the study ID number in 'Record ID'. Select your site from the drop down list and type in the participant's study ID. The participant's ID should consist of your site number, a hyphen (-) and then the participant's unique identifier (001, 002, 003, etc). A list of site numbers can be found in Appendix A. Click next.
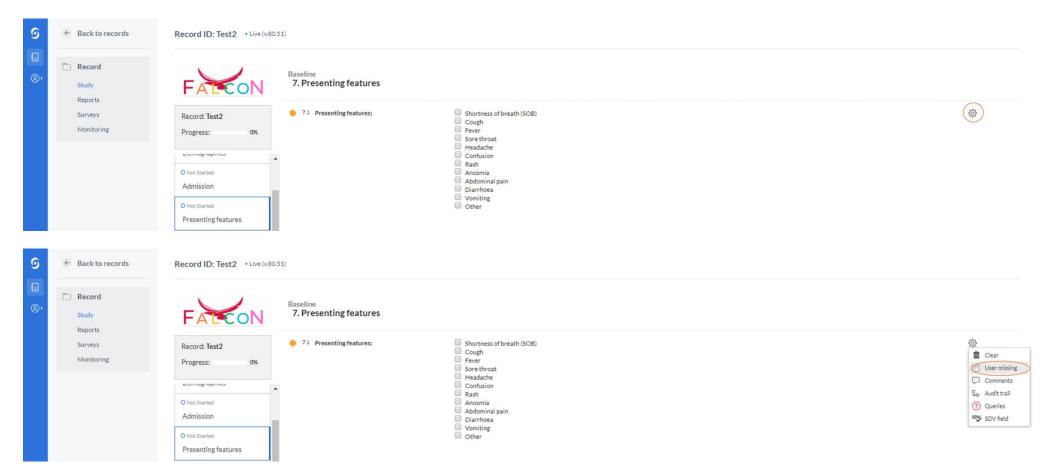
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This will bring you to the Eligibility criteria section of the eCRF, with all the other sections listed down the left hand side.

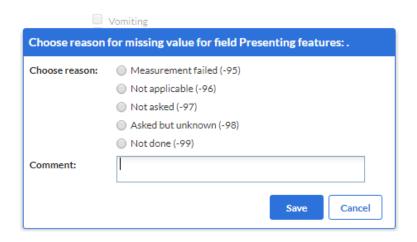Facilitating AcceLerated Clinical evaluation Of Novel diagnostic tests for COVID-19 (FALCON C-19)
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5. **Reporting data as missing/not applicable:** If data are marked as missing or not recorded in the Case Report Form (CRF), click on the cog icon next to the field and select 'User missing' from the menu.
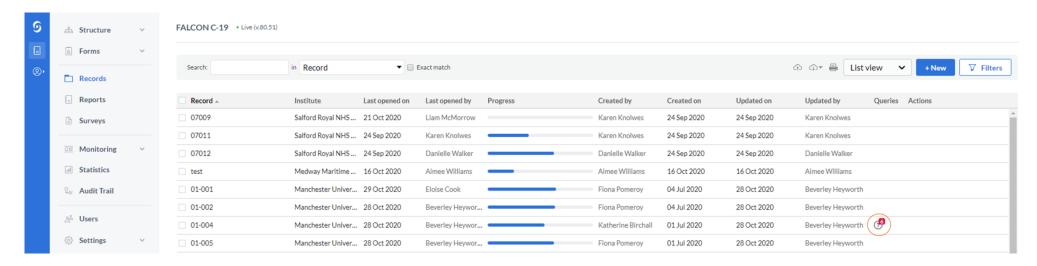
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After clicking on 'User missing', a pop-up box will appear where you can select a reason for the missing data and add any relevant comments. Then click 'Save'.

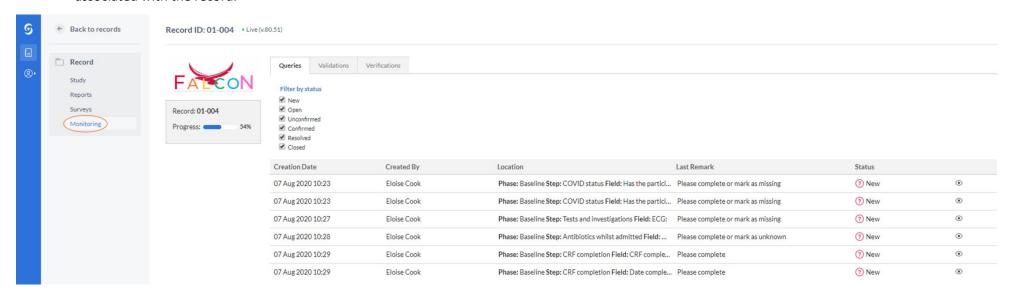6. **Resolving a query:** When a query has been raised and is open, a question mark will appear in the queries column on the participant record with a red number showing the number of open queries for that participant.

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To view all queries for a participant record, go into the record and click on the 'Monitoring' tab in the left hand bar and this will bring up a list of queries associated with the record.

To view an open query, click on the eye symbol and this will open up the step that the query is associated with.

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To open and resolve a query, click on the red question mark.

This brings up a 'Queries' box, where you can answer the query in the 'New Remark' box and then choose 'Resolved' in the 'Change status to:' field. Then click on 'Update'.

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The tick will now turn orange, and when the query has been closed by the monitor, it will turn green.

4. APPENDIX A – List of Site ID Numbers

Site ID	Site Name
01	Manchester Royal Infirmary, Manchester University NHS FT
02	Oxford University NHS FT
03	St James' University Hospital, Leeds Teaching Hospital Trust
04	St George's, St George's University Hospitals NHS FT
05	Royal Victoria Infirmary, Newcastle-upon-Tyne NHS FT
06	Queen's Medical Centre, Nottingham University Hospitals NHS Trust
07	Salford Royal, Salford Royal NHS FT
08	Royal Berkshire Hospital, Royal Berkshire NHS FT
09	Southampton General Hospital, University Hospital Southampton NHS FT
10	Frimley Park Hospital, Frimley Health NHS FT
11	Wexham Park Hospital, Frimley Health NHS FT
12	Queen's Hospital (Romford), Barking, Havering and Redbridge University Hospitals NHS FT
13	Sandwell General Hospital, Sandwell & West Birmingham NHS Trust
14	City Hospital, Sandwell & West Birmingham NHS Trust
15	Airedale General Hospital, Airedale NHS FT
16	Royal Stoke University Hospital, University Hospitals of North Midlands NHS Trust
17	Royal Derby Hospital, University Hospitals of Derby and Burton NHS FT
18	Southmead Hospital, North Bristol NHS FT
19	Wonford Hospital, Royal Devon and Exeter NHS Foundation Trust
20	Northumbria Healthcare NHS Foundation Trust
21	Medway Maritime Hospital, Medway NHS FT
22	Charing Cross Hospital, Imperial College Healthcare NHS Trust
23	St Mary's Hospital, Imperial College Healthcare NHS Trust
24	Queen Elizabeth Hospital Birmingham, University Hospitals Birmingham NHS FT
25	Good Hope Hospital, University Hospitals Birmingham NHS FT
26	Heartlands Hospital, University Hospitals Birmingham NHS FT
27	Royal Oldham Hospital, Pennine Acute Hospitals NHS Trust
28	Sheffield Teaching Hospitals NHS FT
29	Milton Keynes University Hospital, Milton Keynes University Hospital NHS FT
30	Cardiff & Vale University Local Health Board
31	Swansea Bay University Health Board
32	Cwm Taf Morgannwg University Health Board
33	Betsi Cadwaladr University Health Board
34	Aneurin Bevan University Health Board
35	Royal Albert Edward Infirmary, Wrightington, Wigan and Leigh Teaching Hospitals NHS FT
36	Addenbrooke's Hospital, Cambridge University Hospitals NHS FT
37	Stoke Mandeville Hospital, Buckinghamshire Healthcare NHS Trust
38	Derriford Hospital, University Hospitals Plymouth NHS Trust
39	Warwick Hospital, South Warwickshire NHS FT
40	Southport and Formby DGHl, Southport and Ormskirk Hospital NHS Trust
41	Salisbury District Hospital, Salisbury NHS FT
42	Blackpool Victoria Hospital, Blackpool Teaching Hospitals NHS FT
43	Liverpool Women's Hospital, Liverpool Women's Hospital NHS FT
44	Kingston Hospital, Kingston Hospital NHS FT
45	Royal Infirmary of Edinburgh, NHS Lothian
46	St John's Hospital, NHS Lothian
47	Royal Alexandra Hospital, NHS Glasgow and Clyde
48	Queen Elizabeth Hospital, NHS Glasgow and Clyde

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49   Tameside General Hospital, Tameside and Glossop Integrated Care NHS FT
50   Queen Alexandra Hospital, Portsmouth Hospitals NHS Trust
51   King's College Hospital, King's College Hospital NHS FT
52   Musgrove Park Hospital, Somerset NHS FT
53   Torbay Hospital, Torbay and South Devon NHS FT
54   Cumberland Infirmary, North Cumbria Integrated Care NHS FT
55   William Harvey Hospital, East Kent University Hospitals NHS FT
56   Wythenshawe Hospital, Manchester University NHS FT

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