



STANDARD OPERATING PROCEDURE	FALCON C-19
	SOP Number: 01
	eCRF Completion Guidelines SOP

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SOP Title eCRF Completion Guidelines SOP
Version 1.1

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1. PURPOSE

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

2. DEFINITIONS

FALCON C-19 – Facilitating Accelerated Clinical evaluation 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

- 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.
- 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.

My Studies

Search Order by Creation date: Newest first + New Study Filters

Live FALCON C-19 Multicenter UK Server

3. Click on 'FALCON C-19' and this will take you to the homepage.

FALCON C-19 • Live (v80.51)

Search: in Record Exact match List view + New Filters

Record	Institute	Last opened on	Last opened by	Progress	Created by	Created on	Updated on	Updated by	Queries	Actions
<input type="checkbox"/> 01-001	Manchester Univer...	27 Oct 2020		<div></div>		04 Jul 2020	27 Aug 2020	Fiona Pomeroy		
<input type="checkbox"/> 01-002	Manchester Univer...	26 Aug 2020		<div></div>		04 Jul 2020	26 Aug 2020	Eloise Cook		
<input type="checkbox"/> 01-004	Manchester Univer...	26 Aug 2020		<div></div>		01 Jul 2020	26 Aug 2020	Eloise Cook	8	
<input type="checkbox"/> 01-005	Manchester Univer...	26 Aug 2020		<div></div>		01 Jul 2020	26 Aug 2020	Eloise Cook		
<input type="checkbox"/> 01-006	Manchester Univer...	26 Aug 2020		<div></div>		08 Jul 2020	26 Aug 2020	Eloise Cook		
<input type="checkbox"/> 01-007	Manchester Univer...	26 Aug 2020		<div></div>		07 Jul 2020	26 Aug 2020	Eloise Cook		
<input type="checkbox"/> 01-008	Manchester Univer...	26 Aug 2020		<div></div>		07 Jul 2020	26 Aug 2020	Eloise Cook		
<input type="checkbox"/> 01-009	Manchester Univer...	27 Oct 2020		<div></div>		08 Jul 2020	26 Aug 2020	Eloise Cook		
<input type="checkbox"/> 01-010	Manchester Univer...	26 Aug 2020		<div></div>		08 Jul 2020	26 Aug 2020	Eloise Cook		

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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.

The screenshot shows the FALCON C-19 eCRF interface. On the left is a sidebar with navigation options: Structure, Forms, Records, Reports, Surveys, Monitoring, Statistics, Audit Trail, Users, and Settings. The main area displays a table of records. The table has columns: Record, Institute, Last opened on, Last opened by, Progress, Created by, Created on, Updated on, Updated by, Queries, and Actions. The 'Record' column contains IDs like 01-001, 01-002, etc. The 'Institute' column shows 'Manchester Univer...'. The 'Last opened on' column shows dates like 27 Oct 2020. The 'Progress' column shows a blue progress bar. The 'Created by' column shows names like Fiona Pomeroy, Eloise Cook. The 'Created on' column shows dates like 04 Jul 2020. The 'Updated on' column shows dates like 27 Aug 2020. The 'Updated by' column shows names like Eloise Cook. The 'Queries' column shows a red '6' icon. The 'Actions' column is empty. In the top right corner, there is a '+ New' button highlighted with an orange circle.

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.

The screenshot shows a 'New record details' pop-up box. It has a title bar with a close button (X). Inside the box, there is a dropdown menu for 'Institute' with 'Manchester University NHS FT' selected. Below it is a text input field for 'Record ID' with '01-001' entered. At the bottom right of the box is a 'Next' button highlighted with an orange circle. The background shows a blurred view of the records table from the previous screenshot.

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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.

Record ID: 01-133 Live (v.80.51)

Back to records

Record
Study
Reports
Surveys
Monitoring

Not Started

Eligibility criteria and consent

Inclusion criteria

Exclusion criteria

Informed consent

CRF completion

1. Inclusion criteria

11 Was this participant recruited after Amendment 4 approved?
Yes
No

12 Patient has presented to or has been referred to secondary/tertiary care with possible SARS-CoV-2 infection
Yes
No

13 Patient requires testing for SARS-CoV-2 in the opinion of treating clinician
Yes
No

14 Patient has presented with acute symptoms of COVID-19 or chest x-ray changes or they are asymptomatic, but require testing for other reasons
Yes
No

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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.

The screenshots illustrate the process of reporting data as missing in the FALCON C-19 eCRF. The interface shows a sidebar with navigation options (Record, Study, Reports, Surveys, Monitoring) and a main content area for 'Record ID: Test2' (Live v.80.51). The 'Presenting features' section is highlighted, showing a list of symptoms with checkboxes. A cog icon is visible next to the 'Presenting features' field. In the bottom screenshot, the dropdown menu is open, showing options: Clear, User missing (highlighted), Comments, Audit trail, Queries, and SDV field.

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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'.

☐ Vomiting

Choose reason for missing value for field Presenting features: .

Choose reason:

☐ Measurement failed (-95)

☐ Not applicable (-96)

☐ Not asked (-97)

☐ Asked but unknown (-98)

☐ Not done (-99)

Comment:

- 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.

- Structure
- Forms
- Records
- Reports
- Surveys
- Monitoring
- Statistics
- Audit Trail
- Users
- Settings

FALCON C-19 • Live (v.80.51)

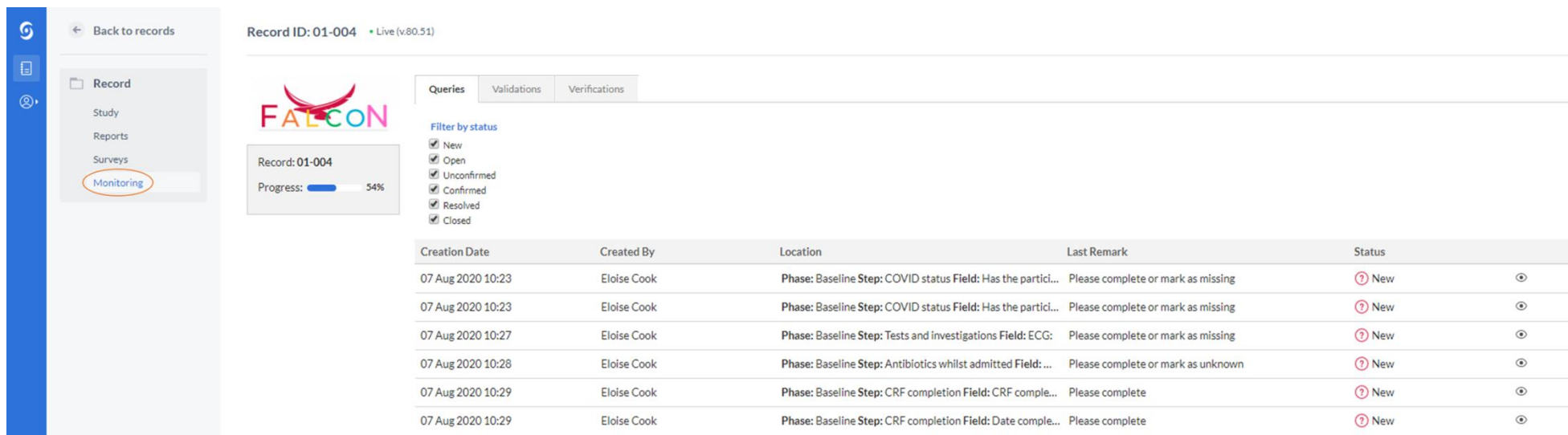
Search: in Record ☐ Exact match

List view + New Filters

<input type="checkbox"/> Record	Institute	Last opened on	Last opened by	Progress	Created by	Created on	Updated on	Updated by	Queries	Actions
<input type="checkbox"/> 07009	Salford Royal NHS...	21 Oct 2020	Liam McMorrow	<div></div>	Karen Knolwes	24 Sep 2020	24 Sep 2020	Karen Knolwes		
<input type="checkbox"/> 07011	Salford Royal NHS...	24 Sep 2020	Karen Knolwes	<div></div>	Karen Knolwes	24 Sep 2020	24 Sep 2020	Karen Knolwes		
<input type="checkbox"/> 07012	Salford Royal NHS...	24 Sep 2020	Danielle Walker	<div></div>	Danielle Walker	24 Sep 2020	24 Sep 2020	Danielle Walker		
<input type="checkbox"/> test	Medway Maritime...	16 Oct 2020	Aimee Williams	<div></div>	Aimee Williams	16 Oct 2020	16 Oct 2020	Aimee Williams		
<input type="checkbox"/> 01-001	Manchester Univer...	29 Oct 2020	Eloise Cook	<div></div>	Fiona Pomeroy	04 Jul 2020	28 Oct 2020	Beverley Heyworth		
<input type="checkbox"/> 01-002	Manchester Univer...	28 Oct 2020	Beverley Heywor...	<div></div>	Fiona Pomeroy	04 Jul 2020	28 Oct 2020	Beverley Heyworth		
<input type="checkbox"/> 01-004	Manchester Univer...	28 Oct 2020	Beverley Heywor...	<div></div>	Katherine Birchall	01 Jul 2020	28 Oct 2020	Beverley Heyworth		
<input type="checkbox"/> 01-005	Manchester Univer...	28 Oct 2020	Beverley Heywor...	<div></div>	Fiona Pomeroy	01 Jul 2020	28 Oct 2020	Beverley Heyworth		

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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.



Record ID: 01-004 • Live (v.80.51)

Record: 01-004
Progress: 54%

Queries

Filter by status

- ☒ New
- ☒ Open
- ☒ Unconfirmed
- ☒ Confirmed
- ☒ Resolved
- ☒ Closed

Creation Date	Created By	Location	Last Remark	Status
07 Aug 2020 10:23	Eloise Cook	Phase: Baseline Step: COVID status Field: Has the partici...	Please complete or mark as missing	? New
07 Aug 2020 10:23	Eloise Cook	Phase: Baseline Step: COVID status Field: Has the partici...	Please complete or mark as missing	? New
07 Aug 2020 10:27	Eloise Cook	Phase: Baseline Step: Tests and investigations Field: ECG:	Please complete or mark as missing	? New
07 Aug 2020 10:28	Eloise Cook	Phase: Baseline Step: Antibiotics whilst admitted Field: ...	Please complete or mark as unknown	? New
07 Aug 2020 10:29	Eloise Cook	Phase: Baseline Step: CRF completion Field: CRF comple...	Please complete	? New
07 Aug 2020 10:29	Eloise Cook	Phase: Baseline Step: CRF completion Field: Date comple...	Please complete	? New

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

Creation Date	Created By	Location	Last Remark	Status	
07 Aug 2020 10:23	Eloise Cook	Phase: Baseline Step: COVID status Field: Has the partici...	Please complete or mark as missing	? New	
07 Aug 2020 10:23	Eloise Cook	Phase: Baseline Step: COVID status Field: Has the partici...	Please complete or mark as missing	? New	
07 Aug 2020 10:27	Eloise Cook	Phase: Baseline Step: Tests and investigations Field: ECG:	Please complete or mark as missing	? New	

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

Creation Date	Created By	Location	Last Remark	Status	
07 Aug 2020 10:23	Eloise Cook	Phase: Baseline Step: COVID status Field: Has the partici...	Please complete or mark as missing	? New	ⓘ
07 Aug 2020 10:23	Eloise Cook	Phase: Baseline Step: COVID status Field: Has the partici...	Please complete or mark as missing	? New	ⓘ

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’.

Queries for field Has the participant had any contact with a conf... X

Current query status: ? Open

Change status to:

Open

Remarks:

Please complete or m

Unconfirmed

Confirmed

Resolved

Closed

By: Eloise Cook

Date: 2020-08-07 10:23:42

New Remark:

Update

Close

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

4.2	Does the pain radiate to the right arm or shoulder?	<input type="radio"/> Yes <input type="radio"/> No	⚙️
4.3	Is the patient vomiting with the chest pain?	<input type="radio"/> Yes <input type="radio"/> No	⚙️ 
4.4	Is there a pattern of worsening angina?	<input type="radio"/> Yes <input type="radio"/> No	⚙️

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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, Warrington, 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 DGH, 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