

Data Entry Notes



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1. Adding a new record

To add a new participant to the eCRF, click the “+ New” button at the top of the records table.

The screenshot shows the STAR-COVID19 TEST interface. At the top right, a box labeled "Add a new record" has an arrow pointing to the "+ New" button in the top navigation bar. Below the navigation bar is a table of records. A modal window titled "New record details" is open, showing a dropdown menu for "Institute" set to "Tayside" and a text input field for "Record ID" containing "01004". A "Next" button is at the bottom of the modal. Two callout boxes provide instructions: one points to the "Institute" dropdown with the text "Institute will be automatically populated with your site", and another points to the "Record ID" field with the text "Enter STAR-COVID19 participant ID as provided by TRuST in the following format:" followed by a color-coded example: "Participant ID" in blue, "01004" in red, and "Site ID" in red.

Record	Institute	Last open...	Last open...	Progress	Created by	Created on	Updated on	Updated by	Qu...	Actions
<input type="checkbox"/>	01003	TCTU	15 Oct 20...	Eva Lahns...	<div style="width: 100%;"></div>	Eva Lahnst...	30 Sep 2020	15 Oct 2020	Eva Lahnst...	
<input type="checkbox"/>	01002	TCTU	15 Oct 20...	Andrew M...	<div style="width: 50%;"></div>	Marcus Ac...	07 Oct 2020	15 Oct 2020	Andrew Mc...	

After successfully creating a subject, you will see a view similar to the one below. This is the default data entry page for a new record.

The screenshot shows the data entry page for Record ID: 01004. On the left is a sidebar with navigation options: Record, Study, Reports, Surveys, and Monitoring. The main content area features the STAR-COVID-19 logo and a progress bar for "Record: 01004" at 0%. Below the progress bar is a list of sections: "Not Started", "Baseline" (selected), "Informed Consent", "Not Started", and "Demographics". The "Baseline" section is titled "1. Informed Consent" and contains two items: "1.1 Date of Consent" with a date input field and "1.2 Consent provided by" with a dropdown menu.

2. Data Entry Process

Phases

The main trial visits of STAR-COVID19 are represented by PHASES in Castor. Each phase can be found in the blue phase list, as shown below.

NOTE: The blue phase list also contains the Completion of Trial/Early Withdrawal form. Whilst this is not a trial visit, it is a mandatory form which should be completed for every participant entered onto the eCRF.

Record ID: 01004



Record: 01004

Progress: 0%

- Not Started
Baseline
- Completed
In Hospital: Daily Data Collection
- Not Started
Day 3
- Not Started
Day 5
- Not Started
Day 8
- Not Started
Day 11
- Not Started
Day 15
- Not Started
Day 29
- Completed
Completion of Trial/Early Withdrawal

Phase list containing STAR-COVID19 trial visits and the completion of trial/early withdrawal form

Steps

Each phase in Castor is made up of STEPS. Steps represent the different sections of a trial visit and contain the various fields required for data entry. The different steps contained within a trial phase can be accessed by clicking on the appropriate blue phase. Below is an example of the steps contained within the Screening phase.

The screenshot displays the 'Steps' for a 'Baseline' phase in the Castor system. The interface includes a sidebar with navigation options (Record, Study, Reports, Surveys, Monitoring), a main content area with a list of steps, and a 'Next' button. Annotations with arrows point to the 'Baseline' step, the list of steps, and the 'Next' button.

Record ID: 01004

STAR TEST COVID-19

Record: 01004
Progress: 0%

Baseline
1. Informed Consent

- 1.1 Date of Consent
- 1.2 Consent provided by

Not Started
Baseline
Not Started
Informed Consent
Not Started
Demographics
Not Started
Hospital Admission
Not Started
Focused Medical History
Not Started
Signs and Symptoms on Admission
Completed
Clinical Assessments
Not Started
Clinical Status and NEWS
Completed
Samples
Not Started
CURB65 score

Previous Next

Click on the appropriate phase

All steps contained within the phase appear below. Click on the appropriate step to access the study fields

Click the "Next" or "Previous" button to navigate between the steps in order

Reports

Whilst the overarching structure of the STAR-COVID19 is made up of phases and steps, the system also contains a number of REPORTS. Reports are used to capture data that is recorded across various trial visits. For example, reports are used to record AEs, concomitant medications, vital signs and bloods. Reports can also be used to record unscheduled events like the unscheduled assessment in the event of an AE or the discontinuation of trial medication form.

The majority of the reports featured on the STAR-COVID19 eCRF have been embedded into the trial phases and steps. This means that you will be able to easily add reports as you complete the trial visit for a participant.

Below is an example of how to complete a VITAL SIGNS report for a trial visit.

Click on the appropriate step “Clinical Assessments” and then “Add measurement” button. The page will automatically redirect to the newly created vital signs report, as shown below.

The screenshot illustrates the process of adding a vital signs report. On the left, the 'Clinical Assessments' section is active, and the 'Add measurement' button is highlighted. An arrow points from this button to the 'Vital Signs - Baseline' report form on the right. The form includes a progress indicator, a list of vital signs to be recorded (Pulse, Blood Pressure systolic, Blood Pressure diastolic, Tympanic temperature, SpO2, and SpO2 measured on), and a 'Close report' button at the bottom.

Once data has been entered for this questionnaire, click on the “Close report” button. This will redirect you back to the trial phase/step from before. The recently added vital signs report now appears in the vital signs table.

The screenshot shows the 'Vital Signs' table after the report has been closed. The table contains one entry with the following data:

Created on	Pulse	Blood Pre...	Blood Pre...	Tympanic...	SpO2	SpO2 me...
2020-10-...	50	120	90	38	71	Air

Additional reports for positive SARS-CoV-2 tests

At each of the Day visits, within the step 'Clinical Status', there is a section which allows to add reports for any additional SARS-CoV-2 tests done. It is important to note that only positive test results need to be added to this report. All additional test results done during any of the phases will be visible in the reports table.

Visibility of individual reports

Any ConMeds or AEs reports added during the study will be visible at any of the Steps where the ConMeds and AEs reports are present. Each of the reports can be edited at any time by selecting the individual report from the table. For e.g. a ConMed/AE report added during Phase-Day 3 will be visible at all other phases Day 5, Day 8, Day 11, Day 15 and Day 29.

Similarly, the 'Date of Discharge' reports table is also set up to show all reports added during any phase.

However, this is not the case for Blood Results reports. There are separate reports for each of the individual Phases Baseline, Day 3 and Day 15. A Blood results report added during one phase will not be visible at any other phase.

Record: 01002
Progress: 40%

Day 15
31. AEs and ConMeds

Please add an AE and/or ConMeds report if the participant has experienced any AEs, or had any changes to ConMeds since last day of data collection.

31.1 Adverse Events

Created on	Descripti...	Identifica...	Name of n...	Method o...	If 'Other', ...	Onset date	
2020-10-...	Test	NO				20-09-20...	⚙️
2020-10-...	Pancreas ...	NO				09-10-20...	⚙️
2020-10-...	Bleeding f...					01-02-20...	⚙️
2020-10-...	Test	YES					⚙️

All AE reports added are visible.

Record: 01002
Progress: 40%

Baseline
8. Samples

8.2 Blood samples

Created on	Date of bl...	Was U&E...	Sodium	Potassium	Creatinine	Urea	
2020-10-...	01-08-20...	YES	120	5	7	7.1	⚙️

Only one Blood results report is visible.

AE reports - Identification of new infections

In STAR-COVID19 study, if a participant is presented with a new infection at any given timepoint while in hospital, it should be recorded in an AE report. The AE report has fields to record the 'Name of new infection' and the 'Method of Diagnosis'.

How to add “Unscheduled Reports” and “Discontinuation of Trial Medication Forms”

Whilst the majority of the reports featured on the STAR-COVID19 eCRF can be added via the main trial phases, there are two report types which cannot be added via this method. These are the UNSCHEDULED ASSESSMENT IN THE EVENT OF AN AE report and the DISCONTINUATION OF TRIAL MEDICATION report.

As these reports can happen at any point in the trial they have been set-up as unscheduled reports on the STAR-COVID19 eCRF. These reports can be created via the REPORTS tab within the participant record.

The screenshot shows the 'All reports' section for Record ID: 01004. The interface includes a sidebar with 'Reports' highlighted, a progress bar for Record: 01004, and a table of reports. A callout box points to the 'Reports' tab, and another points to the 'Add a report' button.

Status	Report	Name	Type	Created on	Created by	Assigned to
●	Vital Signs - Baseline	Vital Signs - Baseline - 16-...	Repeated measure	2020-10-16 12:47:32	Eva Lahnsteiner	Baseline

Click on report tab within the record view to view all of the participant's reports

Click on the “Add a report” button to generate a new report

After the clicking the “Add a report” button, the following message window will appear. In this example, a discontinuation of trial medication form is required for this participant.

The dialog box 'Add a report to record 01004' contains the following fields:

- Report: Discontinuation of Trial Medication
- Custom name: Discontinuation of Trial Medication - 16-10-2020 13:04:30
- Attach to: Phase 6, Day 11

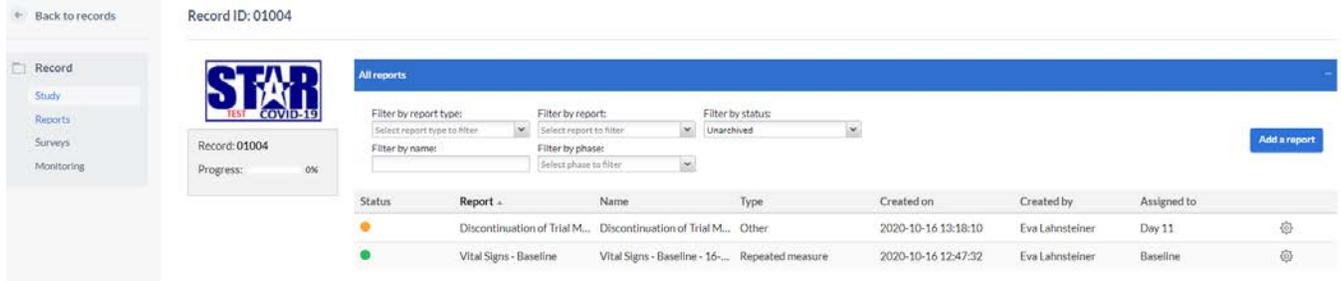
Buttons: Create, Create and add another, Cancel

Report is the type of report you want to create (Discontinuation of Trial Medication or Unscheduled Assessment in the event of an AE)

The Custom name will generate automatically and shows date and time the report was created. This can be changed if required.

Attach to: Please select the Phase when you found out about the discontinuation of trial medication.

Press “Create” and enter the data in the report form. When you close the report again, the reports overview will show an entry for the new report.

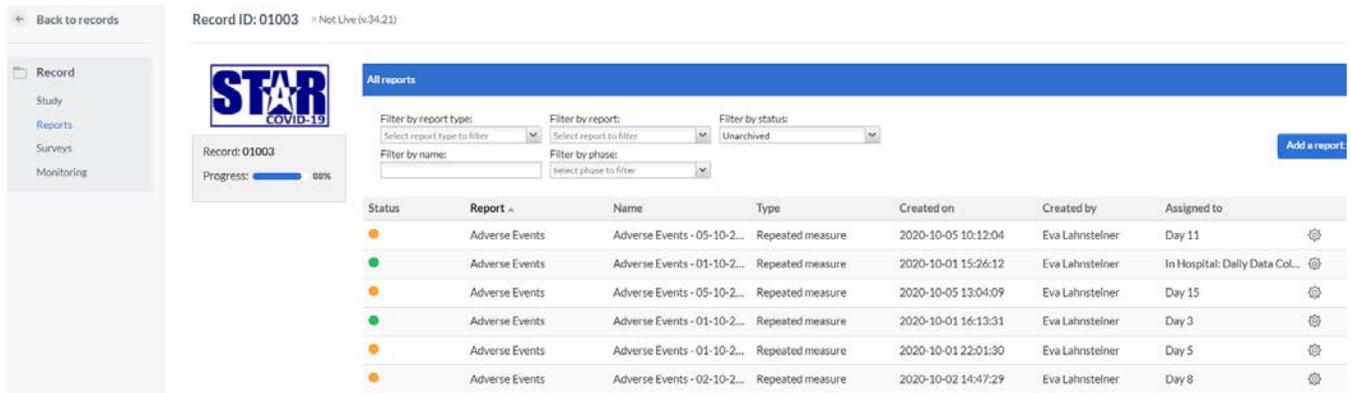


To return to the study schedule, click on “Study” in the left hand menu.

NOTE: Please only use this method for creating the **Discontinuation of Trial Medication report** or **Unscheduled Assessment in the event of an AE report**. If you are unsure about creating these or any other reports in the eCRF, please contact Hasi from the Data Management at STAR-COVID-DM@dundee.ac.uk.

How to remove reports entered in error

Navigate to the Report section (left hand menu) for the participant and you should see all the reports in the list on the right.



Click on the cogwheel for the report you want to delete



Click on “archive report” in the menu

NOTE: By archiving a report, the data will not be deleted completely and we can restore reports in the future if required.

After you've archived a report it will disappear from the table, but if you want to see all archived reports, just change the "filter by status" dropdown on the top of the page from "unarchived" to "archived".

All reports

Filter by report type: Filter by report: Filter by status:
 Filter by name: Filter by phase:
 Unarchived
 Archived

Status	Report	Name	Type	Created on
●	Adverse Events	Adverse Events - 08-...	Repeated measure	2020-09-08 1

*** Research Blood samples for Sample Sites Only**

In STAR-COVID19 study, the sites that obtain Research Bloods from participants will be referred to as 'Sample Sites' on Castor. This will mainly be Tayside only. The research bloods will be collected for neutrophil tests, NRF2 pathway tests and the measurement of Interleukins and TNF-alpha tests.

It is important to note that one blood sample will be used for all of these tests, therefore on Castor, for example if one question is answered 'Yes', then please answer 'Yes' to all questions too. On Castor, these questions will only be made visible to the Tayside site during Baseline, Day 8 and Day 15 phases.

Baseline
15. Sample Sites Only

●	15.1 <i>Sample Sites Only - Research blood sample taken for Neutrophil test?</i>	<input type="text" value="YES"/>	
●	15.2 <i>Sample Sites Only - Research blood sample taken for Nrf2 pathway?</i>	<input type="text" value="YES"/>	
●	15.3 <i>Sample Sites Only - Measurement of interleukin-6, interleukin-1 beta and TNF-alpha in blood</i>	<input type="text" value="YES"/>	

How to record Concomitant Medications

Please add a new ConMeds Report for each drug of interest. Any changes to a drug should be updated in the correct ConMeds Report.

The system is set up in a way for you to see all existing ConMeds reports in the repeating measurements table at every required time point.

Record date of discharge

The system allows to record the Date of Discharge as a Report. Date of Discharge information is visible in a table view at each required data collection form to ensure the same information does not have to be entered repeatedly.

If a participant is in and out of hospital, multiple discharge dates can be recorded as separate reports.

Study schedule

Castor calculates days of data collection (In Hospital: Daily Data Collection Form) and pre-populates scheduled data collection dates in data entry screens (Day 3, 5, 8, 11,15,29). The calculations are based on Date of First Dose as Day 1.

While the participant is in hospital, required data should always be available and can be retrospectively filled in.

If the participant has been discharged and the visits are performed via telephone call, there might be instances where the participant couldn't be contacted on the scheduled day. In those circumstances, please record the when the participant was phone in the appropriate date field (Date of Telephone Call/Date of Data Collection).

Error messages on Castor

After entering data into a field, Castor performs validation checks to ensure that the data is correct. If there is something wrong with the data that has been entered, an error will appear underneath the affected field. Below are some examples of the validation error messages you may encounter whilst entering data into the system.

Simple validation error messages

Baseline

1. Informed Consent

● 1.1 Date of Consent (dd-mm-yyyy)

❗ Date of Consent cannot be in the future.

● 1.2 Consent provided by

These types of error messages can be easily rectified by changing the data in the field to an expected outcome. If the data is correct but an error message stills shows below the field, please see the 4.Raising discrepancies section for how to add a query to the field.

Please note, even when a discrepancy has been raised/closed to address the issue, the warning will stay visible.

Range error messages

Vital Signs - Baseline

Please record the most recent values for Randomisation.

For follow-up, please record results closest to 8am.

● 1 Pulse bpm

❗ Pulse value should be between 40 and 180 bpm.

● 2 Blood Pressure systolic mmHg

● 3 Blood Pressure diastolic mmHg

These types of error messages can be rectified by entering a value within the expected range. If the data is correct but an error message stills shows below the field, please see the 4.Raising discrepancies section for how to add a query to the field.

Please note, even when a discrepancy has been raised/closed to address the issue, the warning will stay visible.

Baseline
7. Clinical Status and NEWS

7.1 Clinical status on 7 point scale	3. Hospitalized, not requiring supplemental oxygen
7.2 NEWS	22 0-20 points

The maximum value for this field is 20.

There are also some out of range error messages which appear in RED text directly below the affected field. These types of error messages can be rectified by entering a value within the expected range. If the data is correct but an error message stills shows below the field, please see section 4.Raising discrepancies for how to add a query to the field.

NOTE: With these types of error messages the data is NOT saved in the field – only values within the accepted range can be saved here. Navigating away from the associated step results in the data being automatically deleted.

Date logic error messages

Adverse Event

3 Onset date	20-09-2020
4 Is Onset date in the correct format?	YES
5 Date reported to Investigator	19-09-2020 (dd-mm-yyyy)
6 Is Date reported before Onset date?	YES

! Date reported cannot be before the date of onset.

Castor also checks whether the logic of dates entered into the system is correct. In this example, the date reported to the investigator is BEFORE the onset date of the adverse event. This type of error message will only disappear if the entered dates match the logic. If the entered dates are correct and a warning shows up, please raise a query on the field.

Cross phase/step checks error messages

Baseline
14. Randomisation

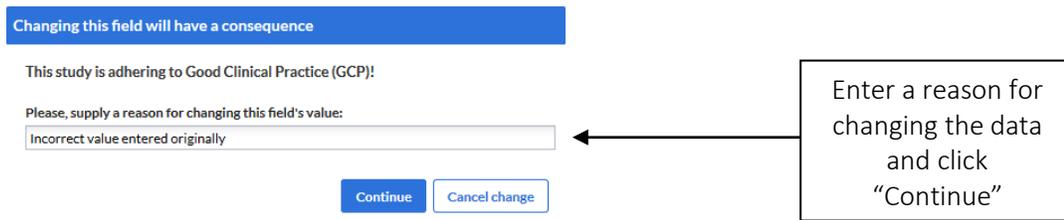
14.1 Has the participant been randomised?	YES
14.1.1 Date of Randomisation	06-08-2020 (dd-mm-yyyy)
14.1.2 Is Date of Randomisation valid?	NO - RANDO GT 4 DAYS AFTER ADM

! Date of Randomisation must happen within 96 hours hospital admission.

Castor also checks the validity of dates between different phases or steps within the eCRF. In this example, the Date of hospital admission was reported as "01/08/2020" and the Date of Randomisation was reported as "06/08/2020." For this trial, the participant should be randomised within 96 hours of hospital admission. This type of error message can be rectified by checking the dates and amending accordingly.

Reason for change error messages

If the data within a field is required to be updated, a reason must be given before the new data can be saved. Providing a reason for change allows for GCP (Good Clinical Practice) standards to be maintained on the eCRF.



The image shows a screenshot of a web-based form with a blue header bar that reads "Changing this field will have a consequence". Below the header, the text "This study is adhering to Good Clinical Practice (GCP)!" is displayed. A prompt asks the user to "Please, supply a reason for changing this field's value:". A text input field contains the text "Incorrect value entered originally". Below the input field are two buttons: "Continue" and "Cancel change". To the right of the form is a rectangular callout box with a black border containing the text "Enter a reason for changing the data and click 'Continue'". A black arrow points from the callout box to the text input field.

3. Raising discrepancies

Whilst you may be able to rectify most error messages at the point of data entry, there may be occasions where the data that is being entered is correct, even though an error message has been generated. If this occurs, a discrepancy note should be raised on the affected field, to highlight the issue to the Data Management team.

Below are some examples of when you may be required to raise discrepancies on the eCRF.

Missing data

Vital Signs - Baseline

Please record the most recent values for Randomisation.

For follow-up, please record results closest to 8am.

1 Pulse	<input type="text"/>	bpm
2 Blood Pressure systolic	89	mmHg
3 Blood Pressure diastolic	60	mmHg
4 Tympanic temperature	37	°C

This field is required

Click the cog wheel
Click "User missing"

- Clear
- User missing
- Comments
- Audit trail
- Queries
- SDV field

In this example, the pulse field is a mandatory field. However, data for this field was not collected at the visit. In order for this vital sign step to be marked as complete, this field needs to be marked as "user missing".

Choose reason for missing value for field Pulse .

Choose reason:

- Measurement failed (-95)
- Not applicable (-96)
- Not asked (-97)
- Asked but unknown (-98)
- Not done (-99)

Comment:

Click "Save"

Choose a reason and enter a comment to explain why the data is missing

User missing discrepancy raised

1 Pulse bpm

Once the discrepancy has been raised, the affected field will be “greyed out” and a missing discrepancy raised on the field.

*Please note that in the STAR-COVID19 study, at ‘Baseline’ phase, step ‘3.Hospital Admission’, if a participant was NOT tested for any other pneumonia pathogen, then the question ‘Causative pneumonia pathogen identified’ must be left blank and click on the cogwheel next to the field and mark as ‘User missing’ as described above. This is because pathogen testing is not required to be done if a participant had already tested positive for nCoV. However, if a participant had tested negative/inconclusive for nCoV, and a test was performed to identify any other causative pneumonia pathogen, then the question ‘Causative pneumonia pathogen identified’ must be answered.

Missing visits

Once a participant has been discharged, study visits are to be performed via a telephone call according to the study visit schedule.

In the event that a telephone call cannot be performed on the scheduled date, for example because the designated day falls on a weekend or the patient is unable to be reached, every effort should be made to perform the telephone call soon afterwards and collect the study data retrospectively. The eCRF has been designed to populate visit/call dates automatically, therefore no error messages will be generated on the system. If the telephone call was not performed on the designated day, then the date of when the telephone call took place can be recorded in the field ‘Date of Telephone Call’ as shown below.

Day 8

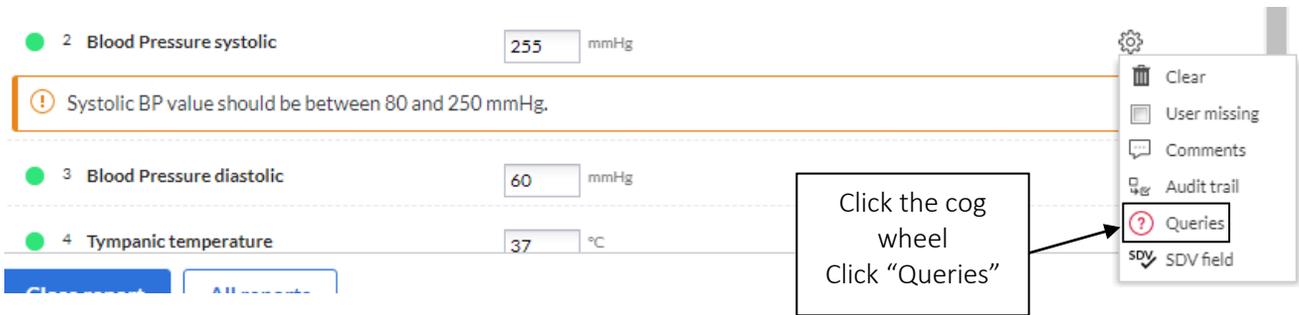
23. Day 8

23.1	Date	11-08-2020
23.2	Data collection via telephone call?	YES
23.2.1	Phoned on same day?	NO
23.2.1.1	Date of Telephone Call	12-08-2020 <small>(dd-mm-yyyy)</small>
23.3	Date of discharge	

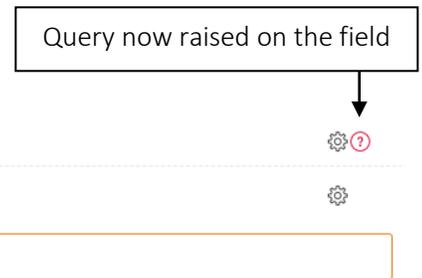
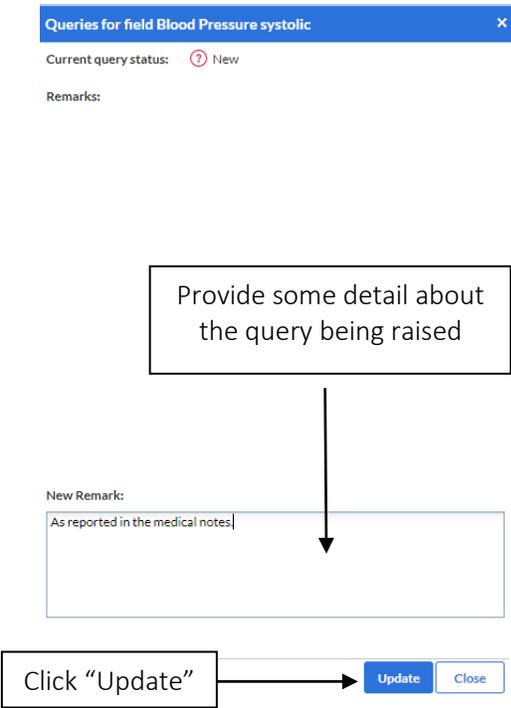
However, there may be some circumstances where the telephone call cannot be performed and if this occurs, the visit will be considered as missing and should be reported to the STAR-COVID19 trial team.

If you are unsure about when to contact participants for telephone calls and where data should be recorded on the eCRF, please contact the STAR-COVID19 trial team at STAR-CovidTM@dundee.ac.uk

Value outwith range



In this example, a value entered into a field is outwith the expected range. To allow for this step to be marked as complete, a query should be raised on the affected field.



NOTE: The data that is entered remains saved in the field, even if it does not conform to the field range. It is also normal for the error message to remain visible after the query has been raised on the field.

Additional information required to be recorded

In the unlikely event that additional information (which cannot be captured by an existing field) is required to be recorded on the eCRF, a query should be raised on the field. This can be done by following the steps in the above example.

4. Calculation fields

When entering data on the STAR-COVID19 eCRF, you may notice there are some fields which cannot be completed but are populated with a message. These fields are CALCULATION fields. Calculation fields are automatically populated once data has been added to another field (or fields) in the eCRF, and are used to generate error messages when something is not quite right with the data. Below are some examples of calculation fields in the STAR-COVID19 eCRF.

The screenshot displays a section of the eCRF titled "Baseline 14. Randomisation". It contains several data entry fields and calculation fields. Callouts explain the behavior of these fields:

- 14.1 Has the participant been randomised?**: A dropdown menu. Callout: "Only the relevant randomisation steps are visible".
- 14.1.1 Date of Randomisation**: A date input field. Callout: "All randomisation steps are visible".
- 14.1.2 Is Date of Randomisation valid?**: A calculation field displaying "Not all values for this calculation are available (yet)". Callout: "Default calculation message is shown when not all relevant data has been entered".
- 14.1.3 Date of First Dose**: A date input field.
- 14.1.4 Did treatment commence within 96 hours of hospital admission?**: A calculation field displaying "Not all values for this calculation are available (yet)". Callout: "Calculation field".

Baseline

14. Randomisation

● 14.1	Has the participant been randomised?	YES
● 14.1.1	Date of Randomisation	04-08-2020 (dd-mm-yyyy)
● 14.1.2	Is Date of Randomisation valid?	YES
● 14.1.3	Date of First Dose	04-08-2020 (dd-mm-yyyy)
● 14.1.4	Did treatment commence within 96 hours of hospital admission?	YES

Calculation field automatically populates with a value once all associated fields have been completed

Baseline

14. Randomisation

● 14.1	Has the participant been randomised?	YES
● 14.1.1	Date of Randomisation	04-08-2020 (dd-mm-yyyy)
● 14.1.2	Is Date of Randomisation valid?	YES
● 14.1.3	Date of First Dose	06-08-2020 (dd-mm-yyyy)
● 14.1.4	Did treatment commence within 96 hours of hospital admission?	NO

⚠ Treatment should commence within 96 hours of hospital admission, otherwise the participant is ineligible.

Calculation field produces an error message when the entered data is incorrect or does not follow the expected logic

NOTE: If a calculation field does not populate as expected or generates an error message incorrectly, please refresh the page in the first instance. If the problem persists, please contact Hasi in the TCTU Data Management Team (STAR-COVID19-DM@dundee.ac.uk).

CURB65 Score

In the phase 'Baseline', step 'CURB65 score', the values for Urea, Respiratory rate, Systolic and Diastolic Blood pressure and Age will be auto-populated from the data entered into the Baseline-Bloods and Baseline-Vital signs reports, respectively. Age will be populated from the Age entered in the step 'Demographics'.

Therefore, only the CURB65-Confusion score require to be selected from the drop-down menu. The 'Total CURB65 score' will then be calculated automatically.

5. Partial Dates

For date fields that do NOT have a calendar icon next to the field, it is possible to enter partial dates.

If the day or month of a date is unknown, please enter "NK" in the respective partial date field.

For example, the "Onset date" field in the AE log allows for the format "NK-MM-YYYY". For an unknown day in the month of June, the date "NK-06-2020" can be provided.

6. Visual Verification – Verifying Forms

Once the appropriate data has been entered into each study phase, a visual verification of the data is required to confirm that the data entry process has been finalised. Visual verification consists of the data entry user checking that the entered data has been correctly transcribed between the medical notes (and if appropriate, the worksheet) and the eCRF.

For the STAR-COVID19 trial, 100% of all data points are required to be visually verified. This is a requirement of the STAR-COVID19 data management plan and is in accordance with TASC SOP 053.

Visual Verification can be confirmed by VERIFYING phases and reports on the eCRF. For the STAR-COVID19 eCRF, every study phase (visit) is required to be verified. This verification should also include every report which has been generated within the associated phase. Unscheduled reports such as the Discontinuation of trial medication and the "Unscheduled assessment in the event of an AE" are also required to be verified.

Below are some examples of how to verify phases and unscheduled reports on the eCRF.

How to verify a Phase



Baseline 1. Informed Consent

Record: 01002

Progress: 39%

1.1 Date of Consent

01-08-2020

(dd-mm-yyyy)

1.2 Consent provided by

Participant

- In Progress
- Baseline**
- Completed
- In Hospital: Daily Data Collection
- In Progress
- Day 3

-  Mark phase as missing
-  Lock this phase
-  Sign this phase
- ✔ Custom verification
-  SDV all steps in this phase
-  Print this phase
-  Add a report to this phase

2. Click on the vertical ellipsis next to the phase and select "Custom Verification"

1. Navigate to the completed phase

NOTE: Visual verification should be completed once the data entry user is confident that the entered data is correct and as complete as possible.

Data verification

For what reason are you verifying this phase:

Visual Verification

3. Select Visual Verification

PI Verification

Does the verification need to be removed when data on this phase is modified? ⓘ

Yes

No

4. Select "No"

OK

Cancel



Record: 01002

Progress: 40%

- In Progress** VER ✓
- Baseline
- Completed
- In Hospital: Daily Data Collection

Phase and all steps within this phase are now verified

Details of step verification

Baseline
1. Informed Consent

VER This step was verified on 21/10/2020 at 13:44 by Hasithi Umagiliya Bandara for Visual Verification

1.1 Date of Consent

01-08-2020

1.2 Consent provided by

Participant

How to verify a Report

1. Navigate to the 'Reports' area in the participant record

2. Use this filter to select the appropriate report

3. Double click on the report

The screenshot shows the STAR COVID-19 interface. On the left, a sidebar menu has 'Reports' highlighted with a red box. An arrow points from this box to a callout box labeled '1. Navigate to the 'Reports' area in the participant record'. The main area shows a 'STAR COVID-19' logo, a record ID '99999', and a progress bar at 88%. Below this is a table titled 'All reports' with filters for report type, name, phase, and status. The 'Filter by report:' dropdown is set to 'Discontinuation of Trial Medication'. An arrow points from a callout box labeled '2. Use this filter to select the appropriate report' to this dropdown. The table has one row with a green status dot, 'Discontinuation...' in the Report and Name columns, 'Other' in the Type column, and '2020-09-29 15:3...' in the Created on column. An arrow points from a callout box labeled '3. Double click on the report' to this row. An 'Add a report' button is visible on the right.

4. Click on the vertical ellipsis next to the phase and select "Custom verification"

The screenshot shows the 'Discontinuation of Trial Medication' report form. The STAR COVID-19 logo is at the top left. Below it is the record ID '99999' and a progress bar at 88%. The report title is 'Discontinuation of Trial Medication - 29-09-2020 15:38:18'. A context menu is open over the 'Completed' phase, with 'Custom verification' selected and highlighted with a red box. An arrow points from a callout box labeled '4. Click on the vertical ellipsis next to the phase and select "Custom verification"' to this menu. The form includes a section for 'Permanent Discontinuation of Trial Medication' with instructions. Below this are fields for 'When was the last dose taken?' (08-10-2020) and 'Was a dose taken before the date?' (NO). A 'Reason for stopping of study medication (main reason only)' field is at the bottom.

Data verification

For what reason are you verifying this phase:

Visual Verification ← 5. Select Visual Verification

PI Verification

Does the verification need to be removed when data on this phase is modified? ⓘ

Yes

No ← 6. Select "No"

OK

Cancel



Record: 99999

Progress: 88%

Completed VER ✓

Discontinuation of Trial Medication - 29-09-2020 15:38:18

Completed VER ✓

Discontinuation of Trial Medication

Phase and all steps within this phase are now verified

All reports

Report

Details of step verification

Discontinuation of Trial Medication

VER ✓ This step was verified on 20/10/2020 at 13:47 by Hasithi Umagiliya Bandara for Visual Verification

Permanent Discontinuation of Trial Medication

Instructions: Where a participant is withdrawing completely from the trial, do NOT complete this form but complete Discontinuation of Trial Medication Form should only be completed when participants are permanently stopping the trial. When participants stop trial medication they should be encouraged to continue with the trial visits and the trial

1 What date was the last dose taken? (dd-mm-yyyy)

2 Is the date last dose taken before the randomisation date? NO

7. PI Verification Signatures

For STAR-COVID19, there are several steps of the eCRF which is required to be signed by the site Principal Investigator (PI). These include:

- Completion of Trial/Early Withdrawal step
- Each Adverse Event added to the eCRF

For the Completion of Trial/Early Withdrawal steps, it is the responsibility of the individual entering the data to notify the PI that the appropriate step is ready for signing. Each step should be verified by the PI at the earliest opportunity.

For adverse events, each PI will receive an automated email every time an adverse event is added to the eCRF. This will contain information about the study, the record ID, the name of the adverse event report (date and time stamp) and the user who added the adverse event report. The PI will then be required to log onto the system and verify the adverse event. This will be done for all adverse events added to the system.

Below is an example of a verified step on the STAR-COVID19 eCRF:

The screenshot displays the STAR-COVID19 eCRF interface. On the left, a sidebar shows a navigation menu with 'Day 11', 'Day 15', and 'Day 29' marked as 'In Progress', and 'Completion of Trial/Early Withdrawal' marked as 'Completed' with a 'VER' (verified) symbol. The main content area is titled 'Completion of Trial/Early Withdrawal 37. Completion of Trial/Early Withdrawal'. A blue banner at the top of this section states: 'This step was verified on 21/10/2020 at 14:28 by Hasithi Umagiliya Bandara for PI Verification'. Below this, a list of questions is shown:

Question ID	Question	Answer
37.1	Was the participant randomised?	YES
37.1.1	Did the participant complete the trial (reach Day 29)?	YES
37.1.2.2	Date last trial medication taken?	01-09-2020 (dd-mm-yyyy)
37.1.2.3	Number of tablets remaining?	13
37.1.1.1	Date of completion/withdrawal (date of Day 29)	01-09-2020
37.1.3	Is the date of completion before last trial medication taken?	NO

At the bottom of the list, there is a question: 'If participant did not complete the trial, what was the main reason (tick one only)'. A 'Prev' button is visible at the bottom left. A callout box points to the 'VER' symbol next to the 'Completion of Trial/Early Withdrawal' step in the sidebar, stating: 'Verification symbol will appear next to the verified step'. Another callout box points to the verification banner at the top, stating: 'Confirmation that the step has been verified by the PI'.

8. Contact

If you have any questions or experiencing any issues, please contact the TCTU Data Management Team at STAR-COVID19-DM@dundee.ac.uk.

9. Further Information

For further information, please see the Castor EDC Manual:
<https://helpdesk.castoredc.com/category/2-castor-edc-manual>