Data Entry Notes

Document control

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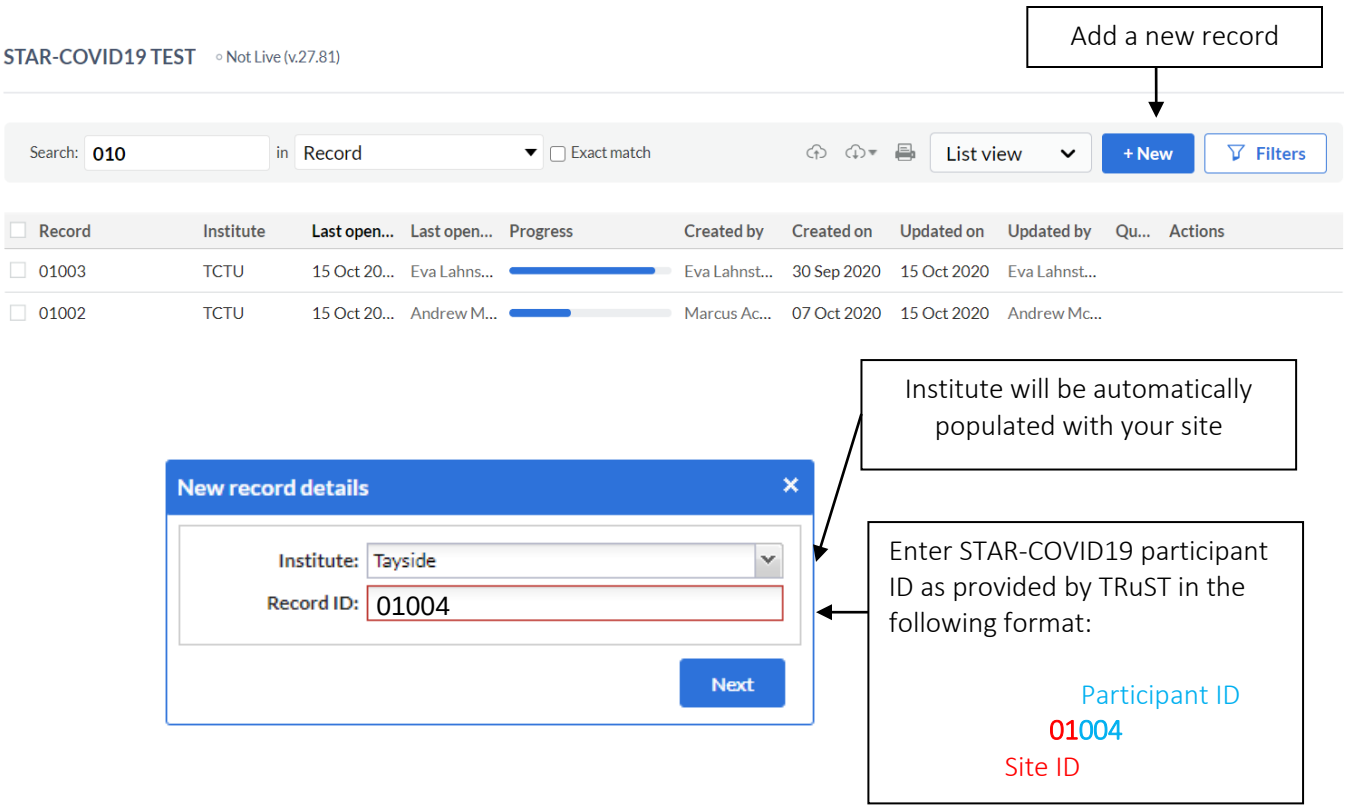
Version Control

Version	Edited by (include role)	Effective Date	Comments
0.1	Eva Lahnsteiner, Data Manager	16/10/2020	First draft
0.2	Hasithi Umagiliya Bandara, Database Manager	20/10/2020	draft
V1	Hasithi Umagiliya Bandara, Database Manager	02/11/2020	Final version

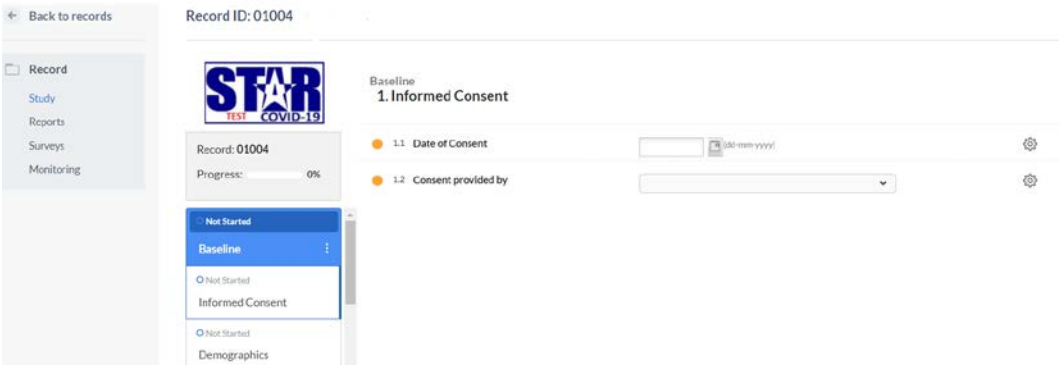
Contents

1. Adding a new record

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



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.

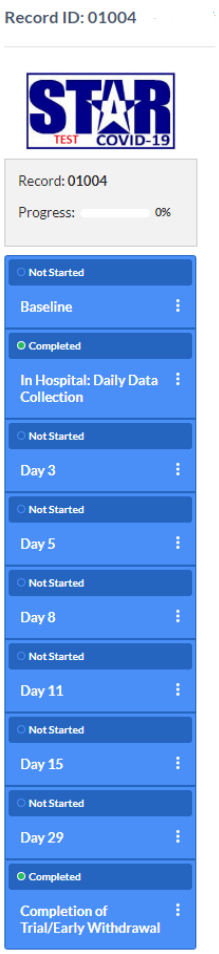


2. Data Entry Process

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.

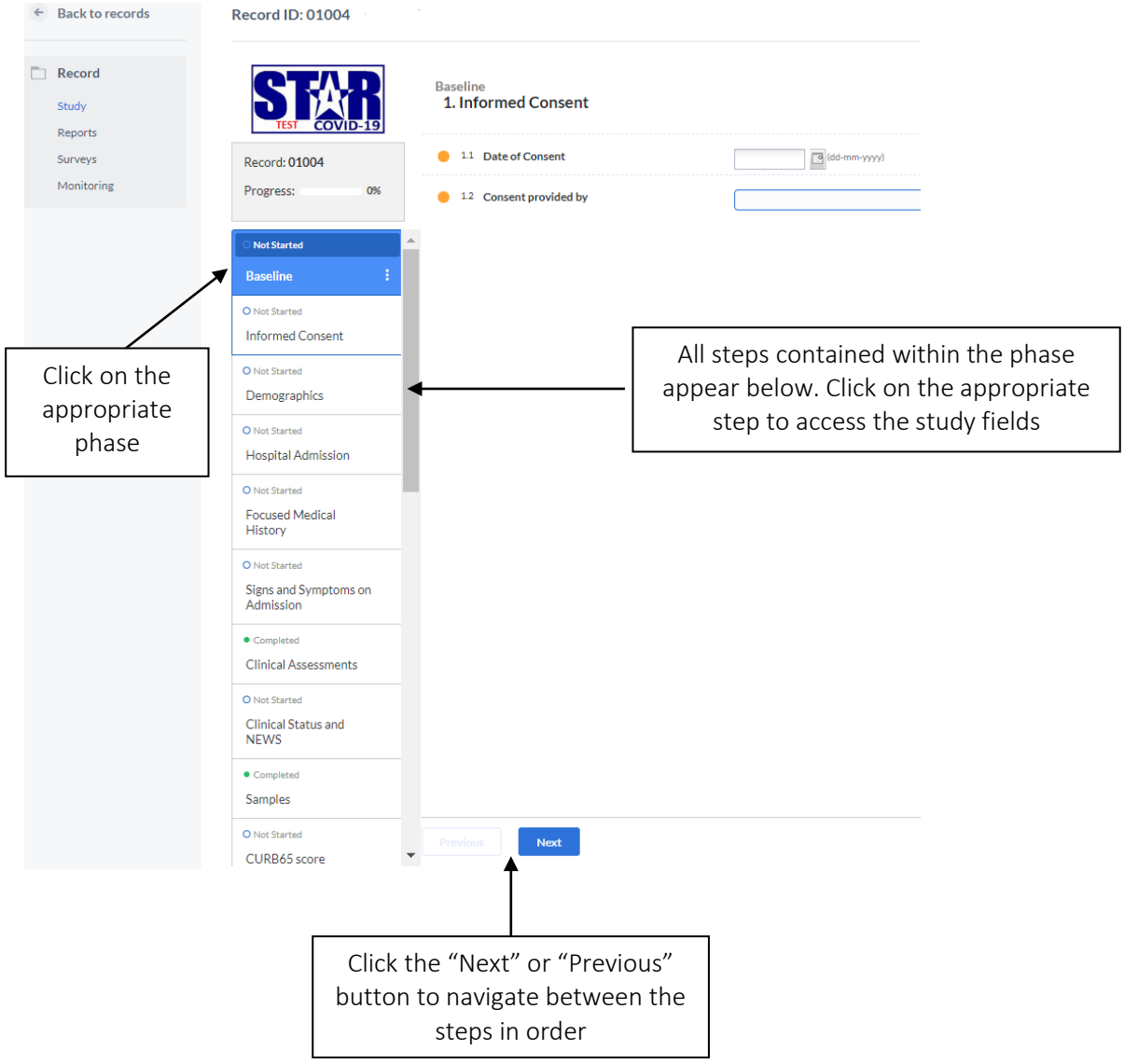
NOTE: The blue phase list also contains the Completion of Trial/Early Withdrawal form. Whilst this is not a trial visit, it is a mandatory form which should be completed for every participant entered onto the eCRF.



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.



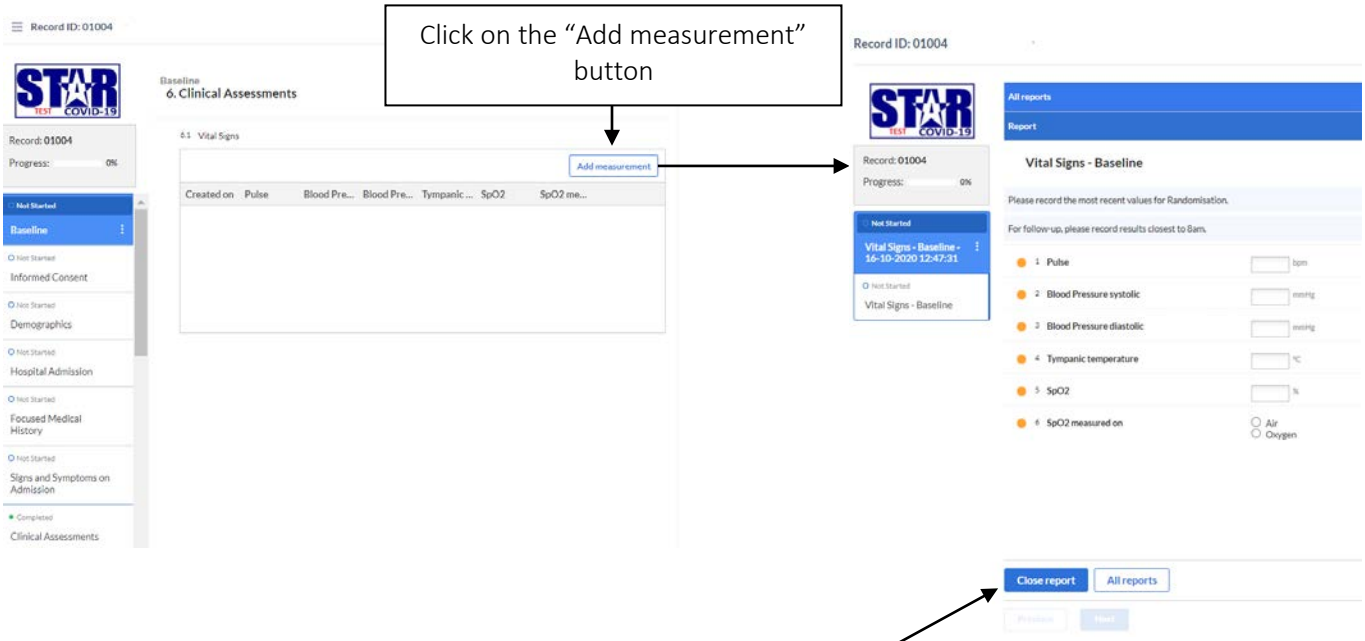
Reports

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.

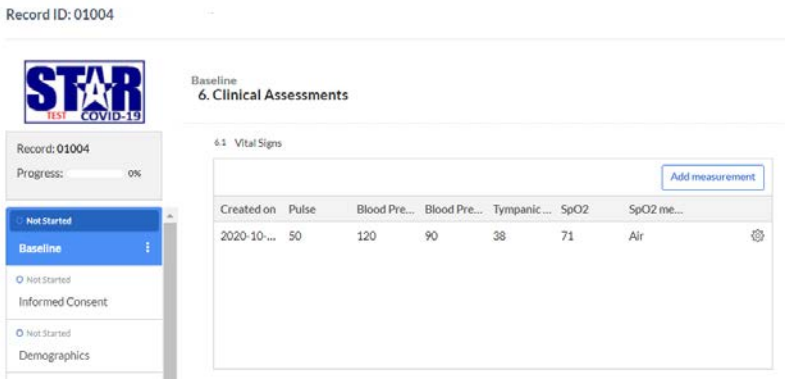
The majority of the reports featured on the STAR-COVID19 eCRF have been embedded into the trial phases and steps. This means that you will be able to easily add reports as you complete the trial visit for a participant.

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.



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.

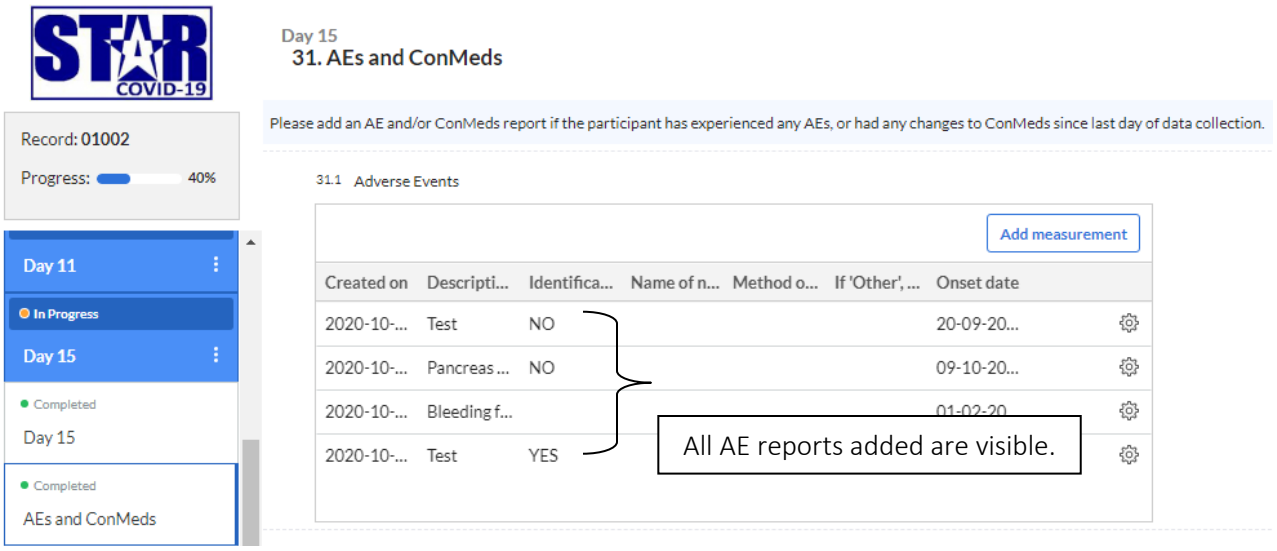


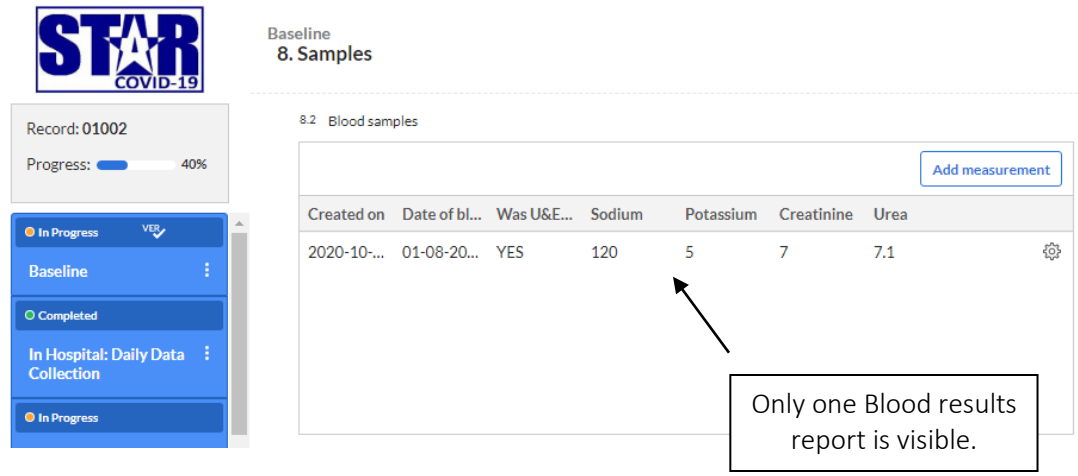
Additional reports for positive SARS-CoV-2 tests

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.





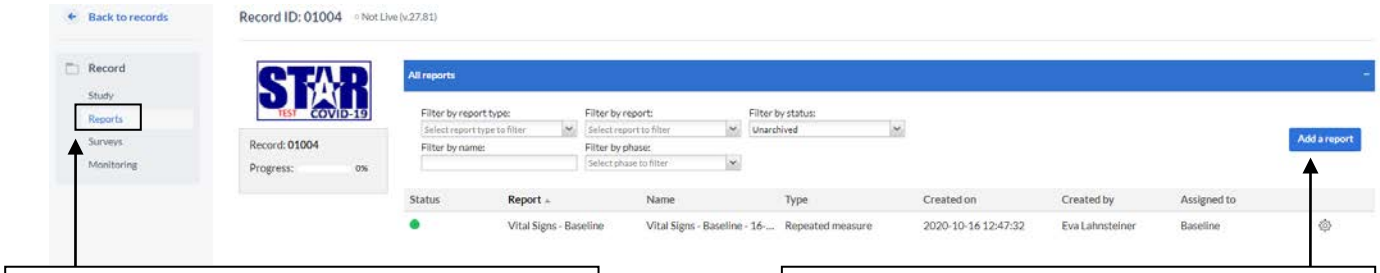
AE reports - Identification of new infections

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.

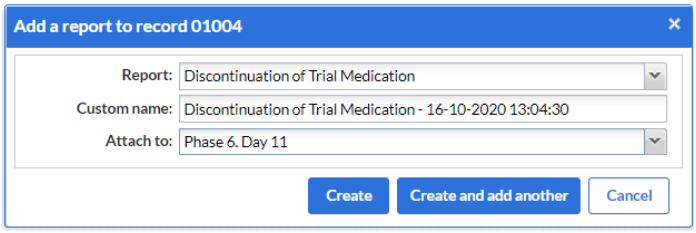
As these reports can happen at any point in the trial they have been set-up as unscheduled reports on the STAR-COVID19 eCRF. These reports can be created via the REPORTS tab within the participant record.



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.

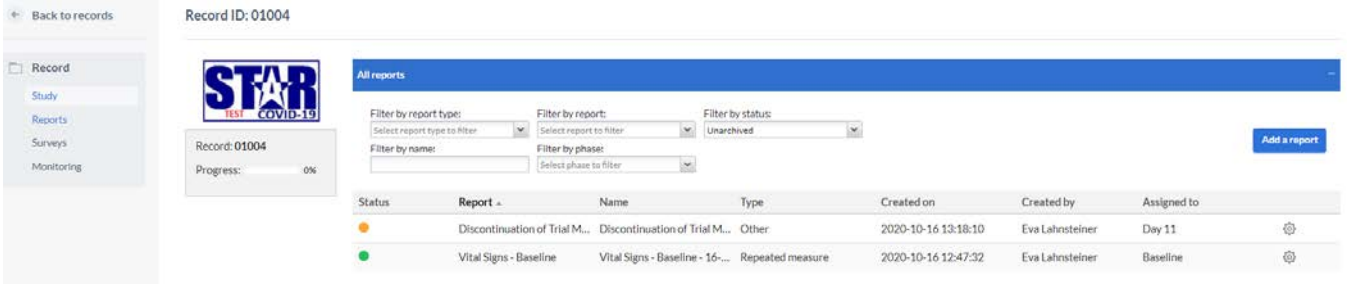


Report is the type of report you want to create (Discontinuation of Trial Medication or Unscheduled Assessment in the event of an AE)

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.

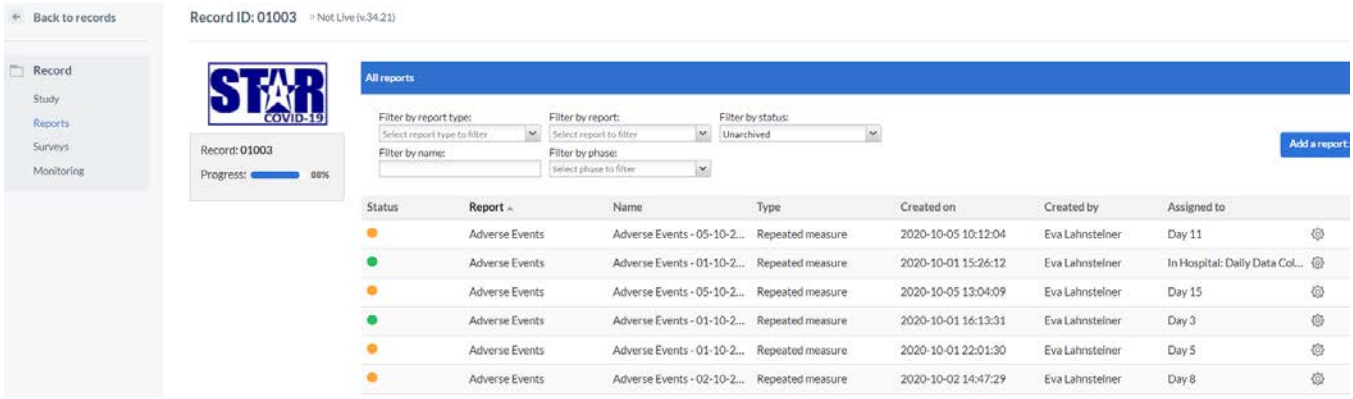


To return to the study schedule, click on “Study” in the left hand menu.

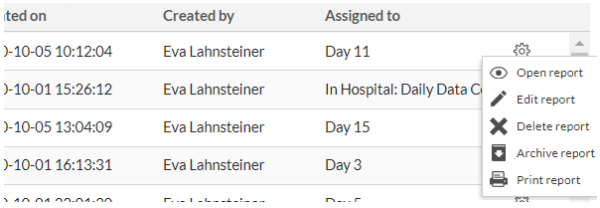
NOTE: Please only use this method for creating the **Discontinuation of Trial Medication report** or **Unscheduled Assessment in the event of an AE report**. If you are unsure about creating these or any other reports in the eCRF, please contact Hasi from the Data Management at STAR-COVID-DM@dundee.ac.uk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

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.

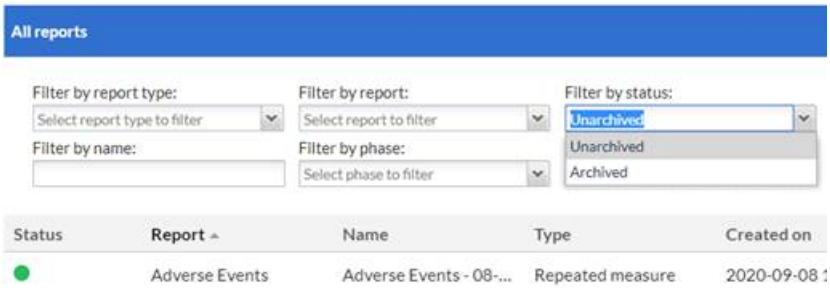


Click on the cogwheel for the report you want to delete



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".



* 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.

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.

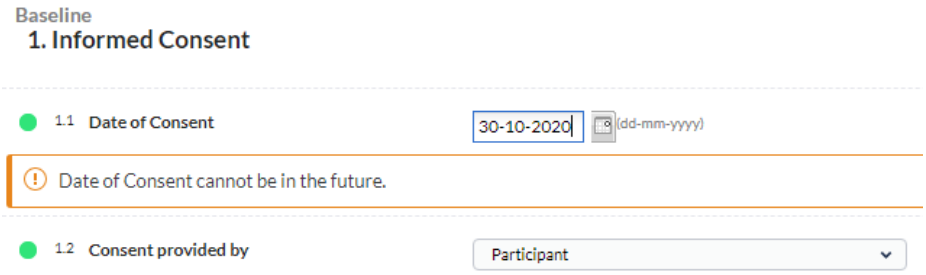
While the participant is in hospital, required data should always be available and can be retrospectively filled in.

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.

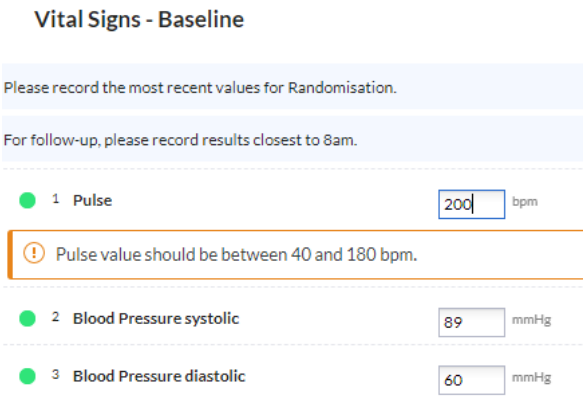
Simple validation error messages



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.

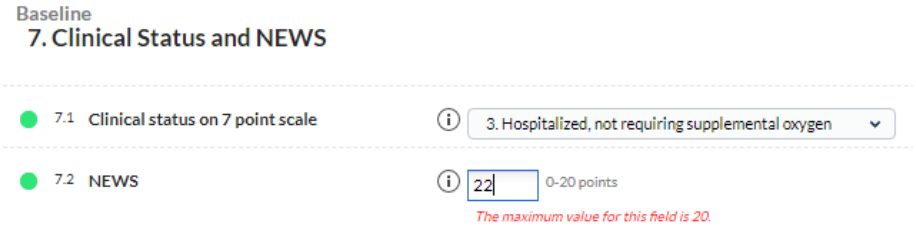
Please note, even when a discrepancy has been raised/closed to address the issue, the warning will stay visible.

Range error messages



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.

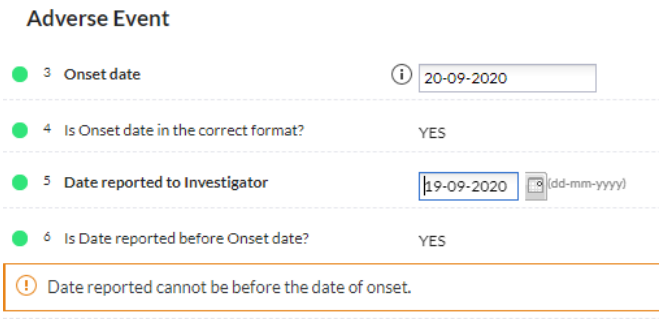
Please note, even when a discrepancy has been raised/closed to address the issue, the warning will stay visible.



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.

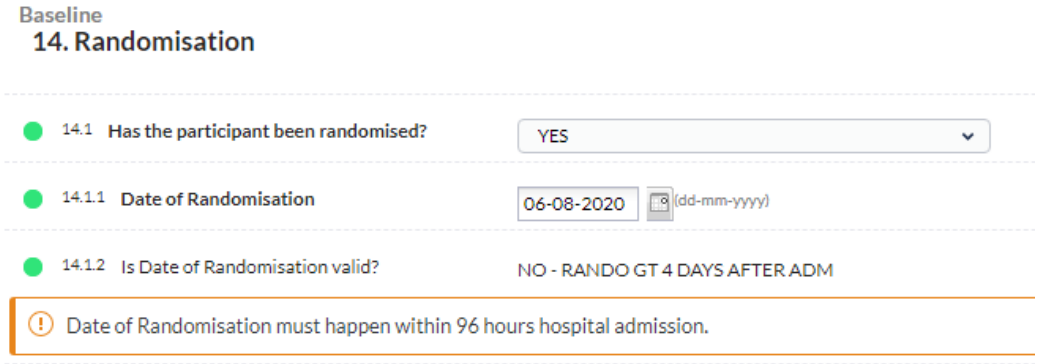
NOTE: With these types of error messages the data is NOT saved in the field – only values within the accepted range can be saved here. Navigating away from the associated step results in the data being automatically deleted.

Date logic error messages



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.

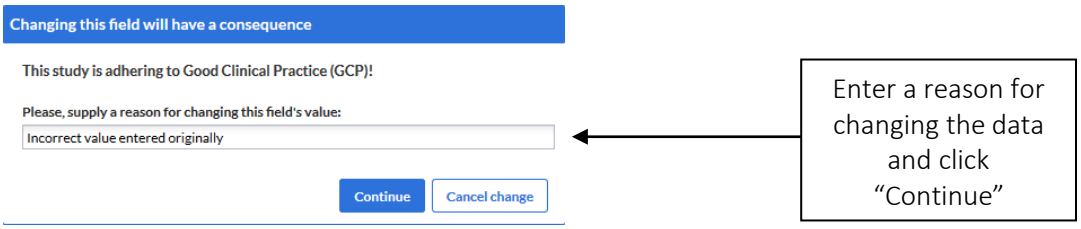
Cross phase/step checks error messages



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.

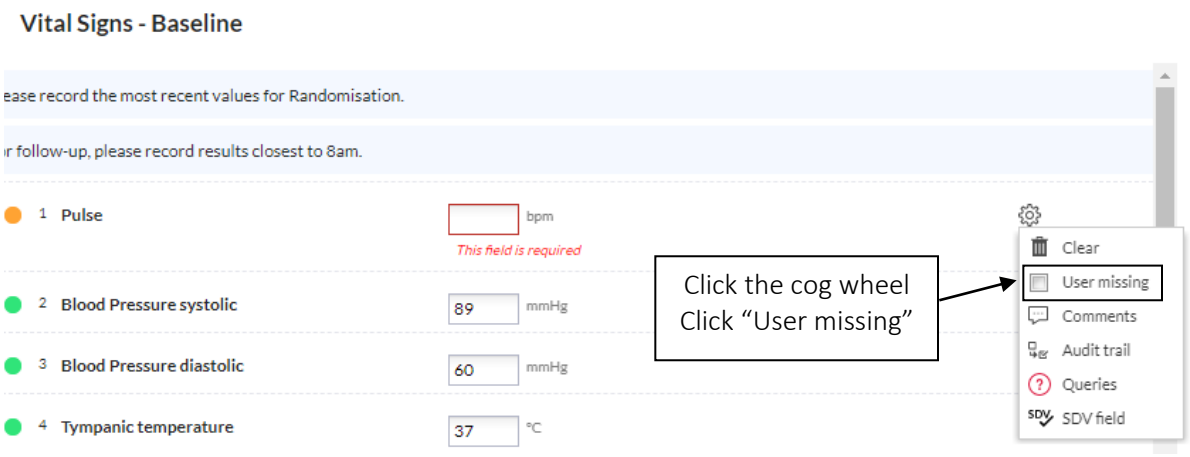


3. Raising discrepancies

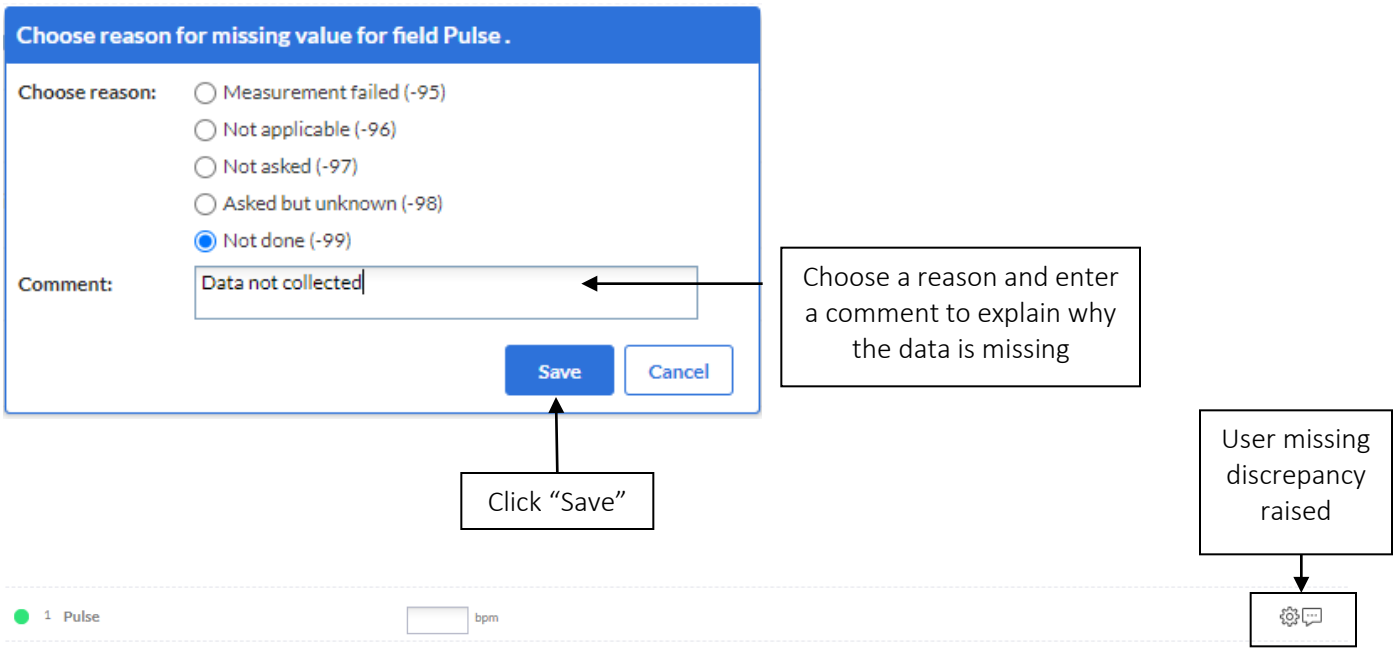
Whilst you may be able to rectify most error messages at the point of data entry, there may be occasions where the data that is being entered is correct, even though an error message has been generated. If this occurs, a discrepancy note should be raised on the affected field, to highlight the issue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

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

Missing data



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".



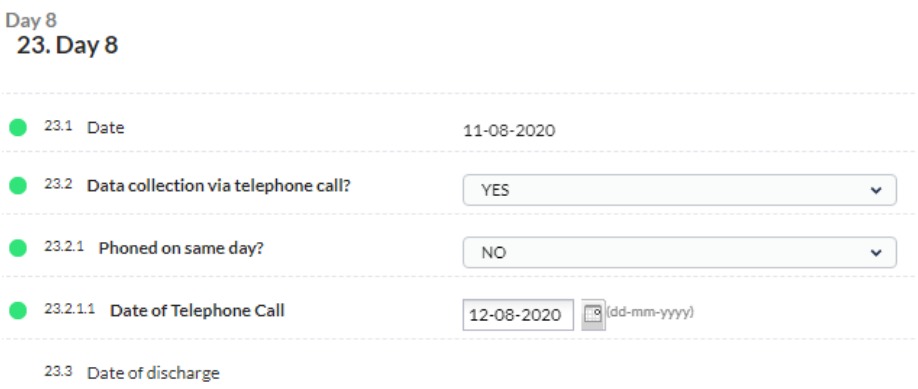
Once the discrepancy has been raised, the affected field will be “greyed out” and a missing discrepancy raised on the field.

*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.

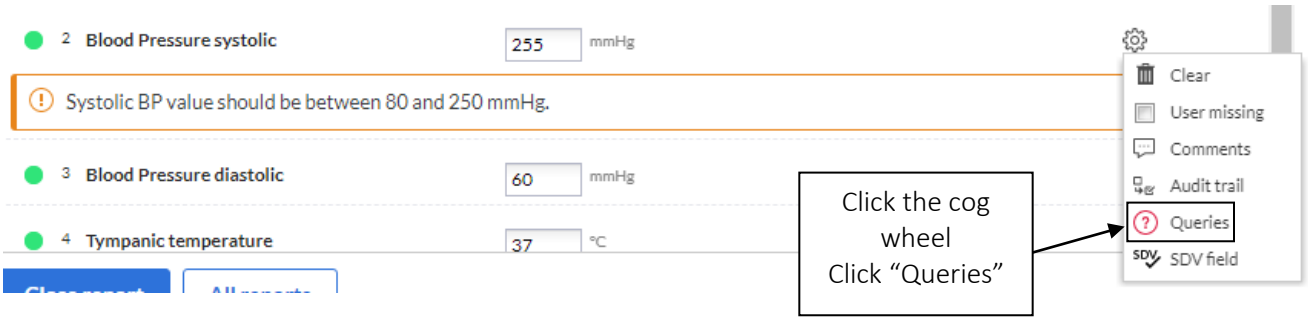
In the event that a telephone call cannot be performed on the scheduled date, for example because the designated day falls on a weekend or the patient is unable to be reached, every effort should be made to perform the telephone call soon afterwards and collect the study data retrospectively. The eCRF 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.



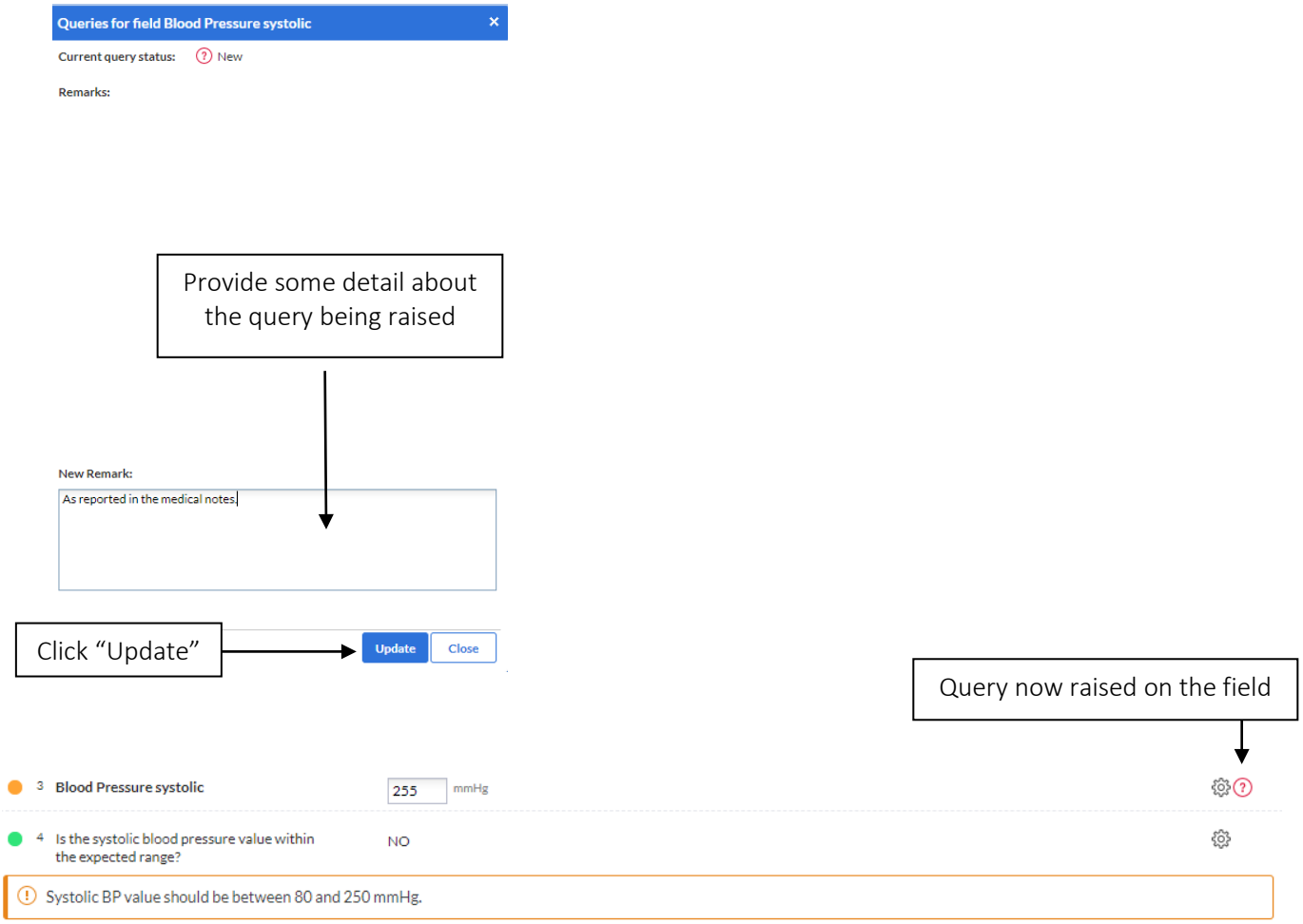
However, there may be some circumstances where the telephone call cannot be performed and if this occurs, the visit will be considered as missing and should be reported to the STAR-COVID19 trial team.

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.



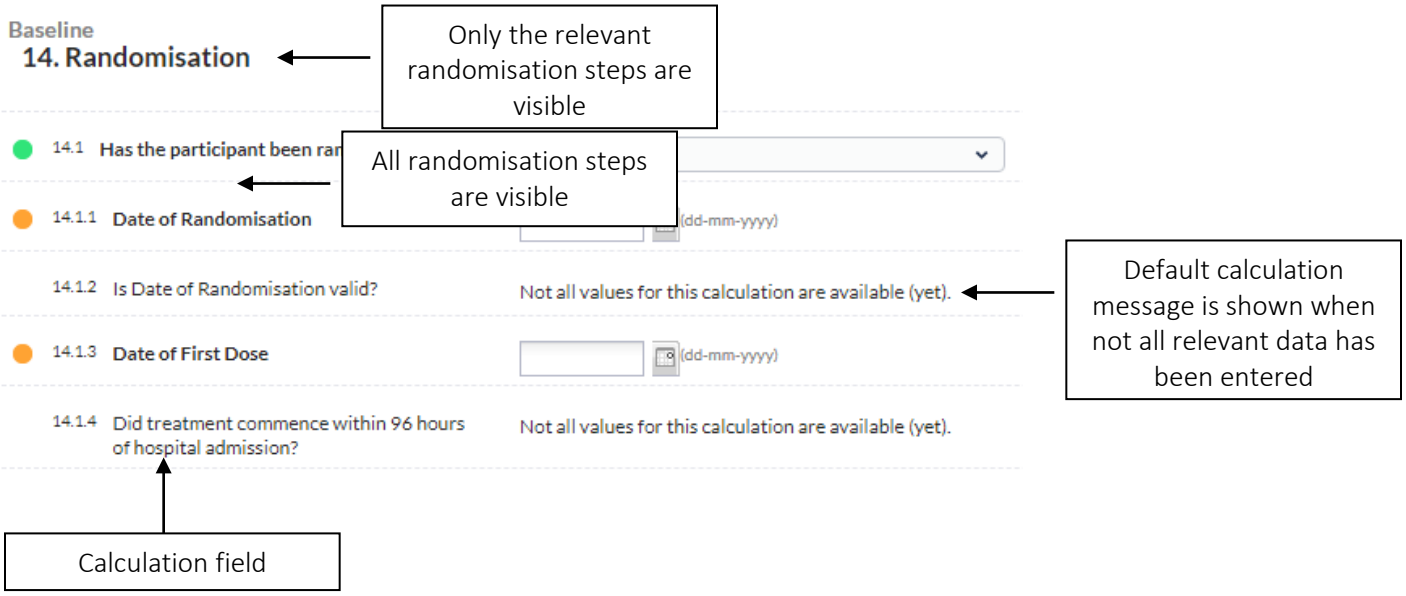
NOTE: The data that is entered remains saved in the field, even if it does not conform to the field range. It is also normal for the error message to remain visible after the query has been raised on the field.

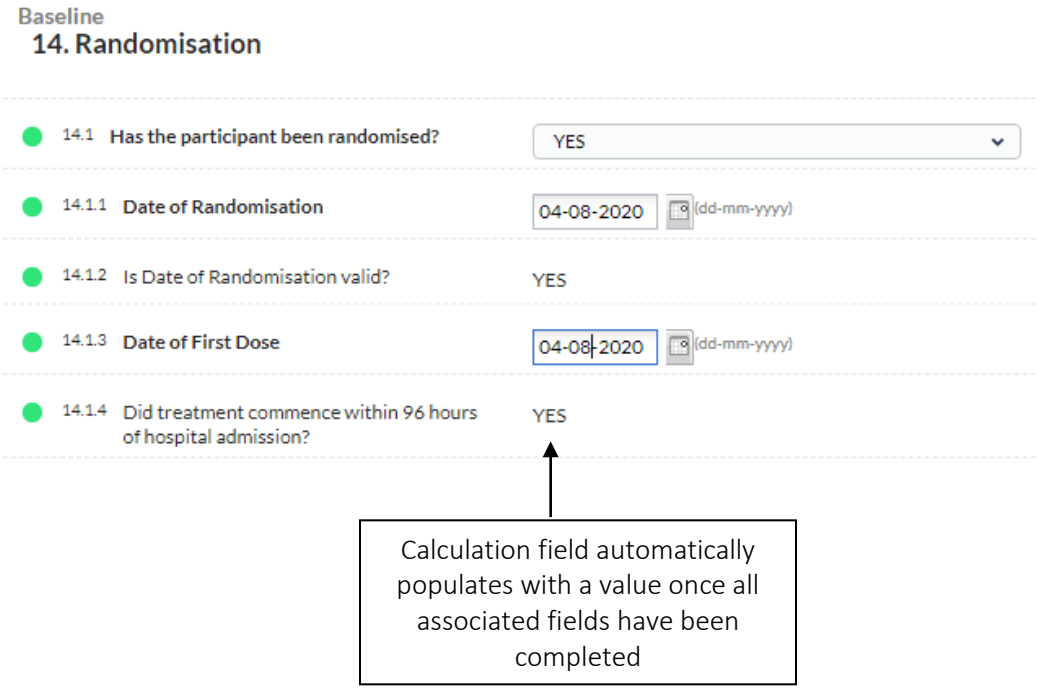
Additional information required to be recorded

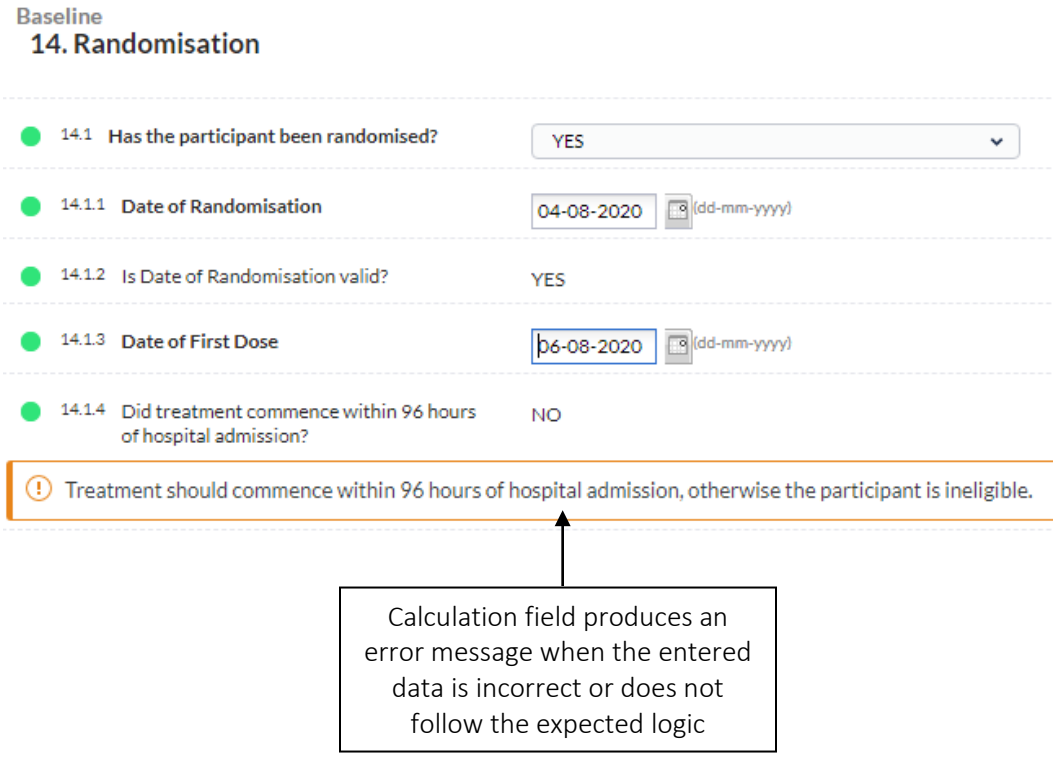
In the unlikely event that additional information (which cannot be captured by an existing field) is required to be recorded on the eCRF, a query should be raised on the field. This can be done by following the steps in the above example.

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.







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

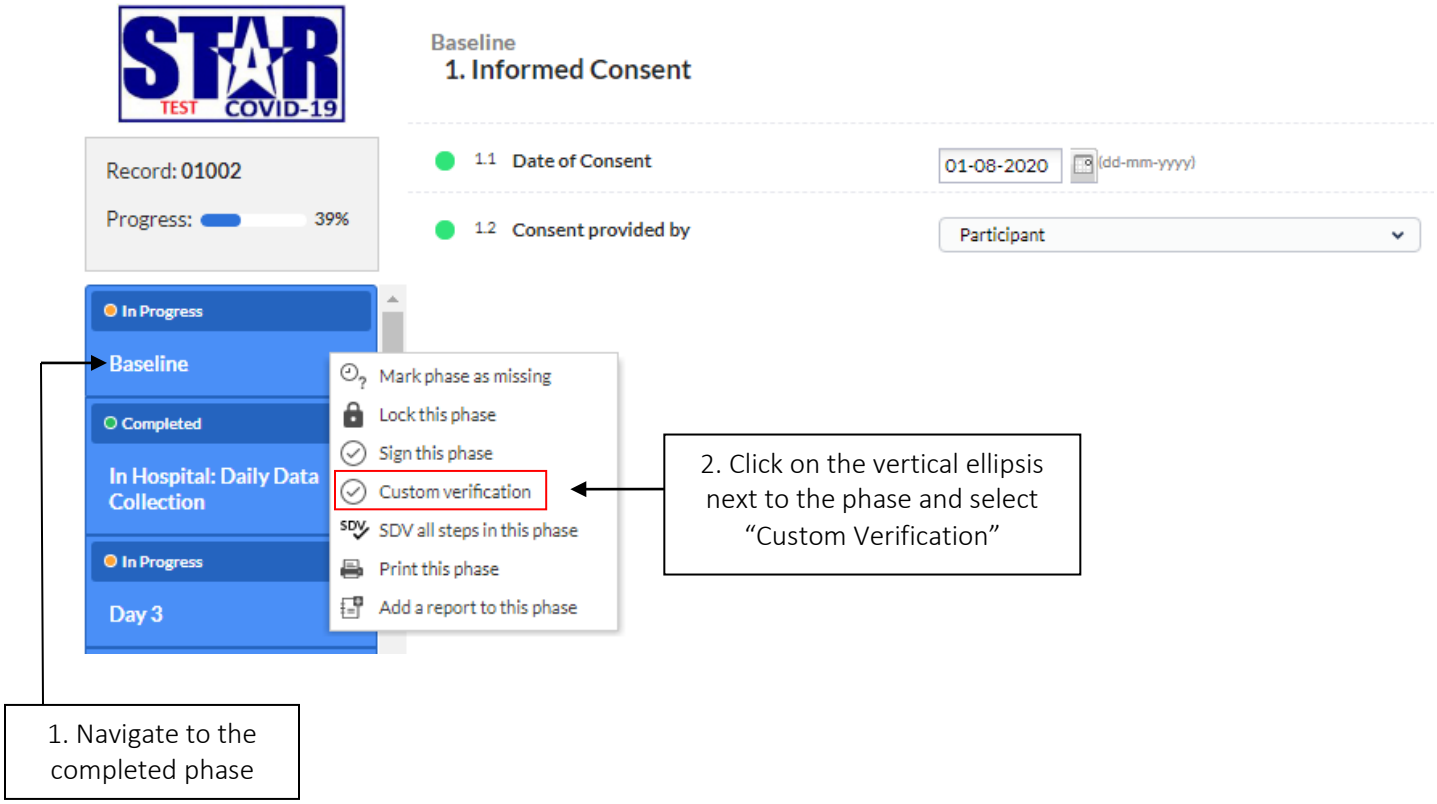
Once the appropriate data has been entered into each study phase, a visual verification of the data is required to confirm that the data entry process has been finalised. Visual verification consists of the data entry user checking that the entered data has been correctly transcribed between the medical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

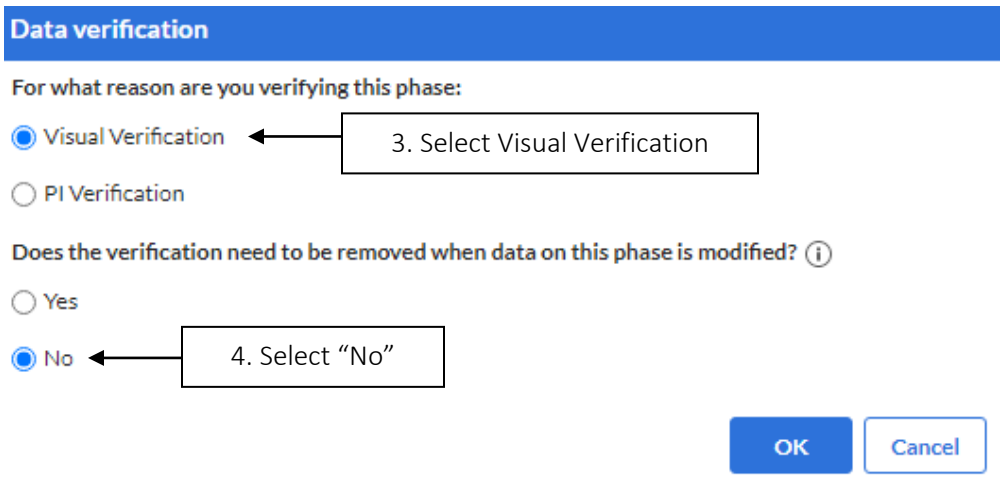
Visual Verification can be confirmed by VERIFYING phases and reports on the eCRF. For the STAR-COVID19 eCRF, every study phase (visit) is required to be verified. This verification should also include every report which has been generated within the associated phase. Unscheduled reports such as the Discontinuation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

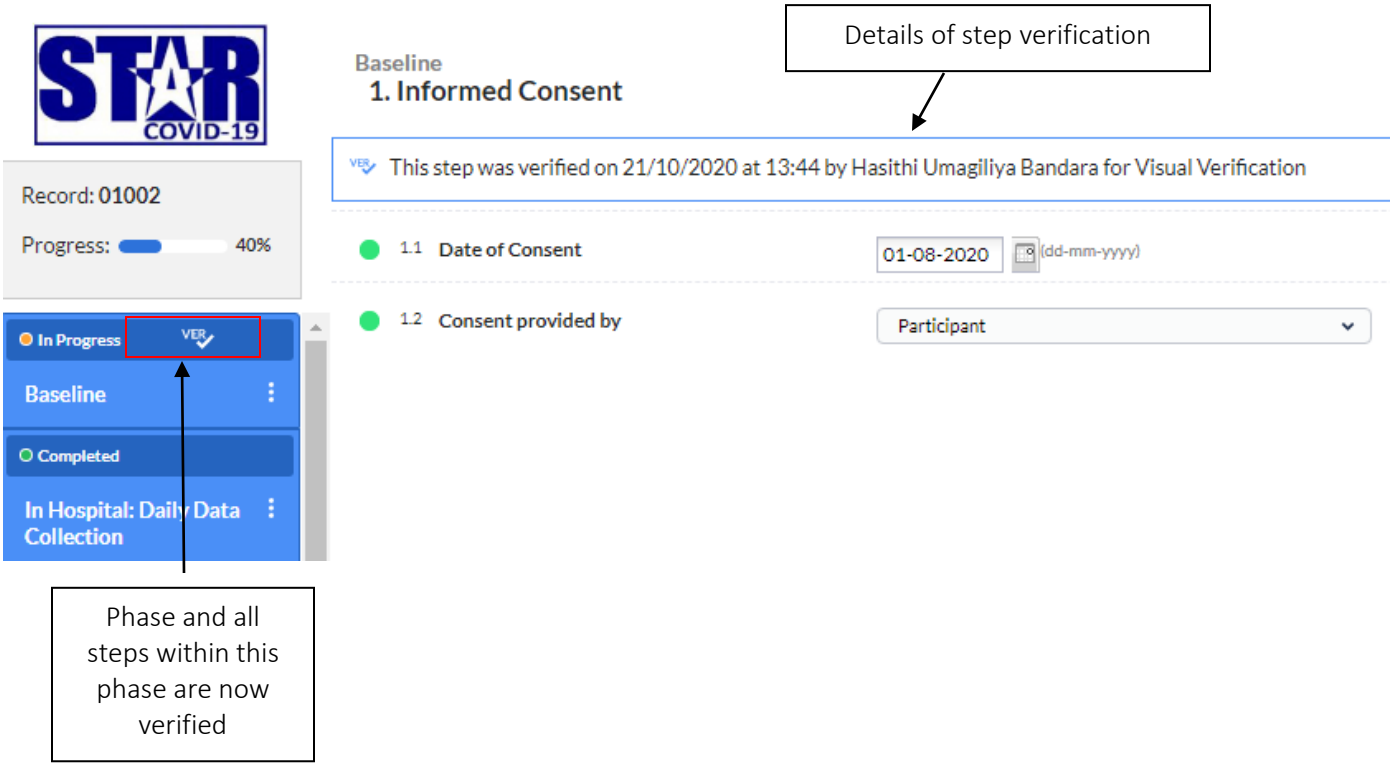
Below are some examples of how to verify phases and unscheduled reports on the eCRF.

How to verify a Phase

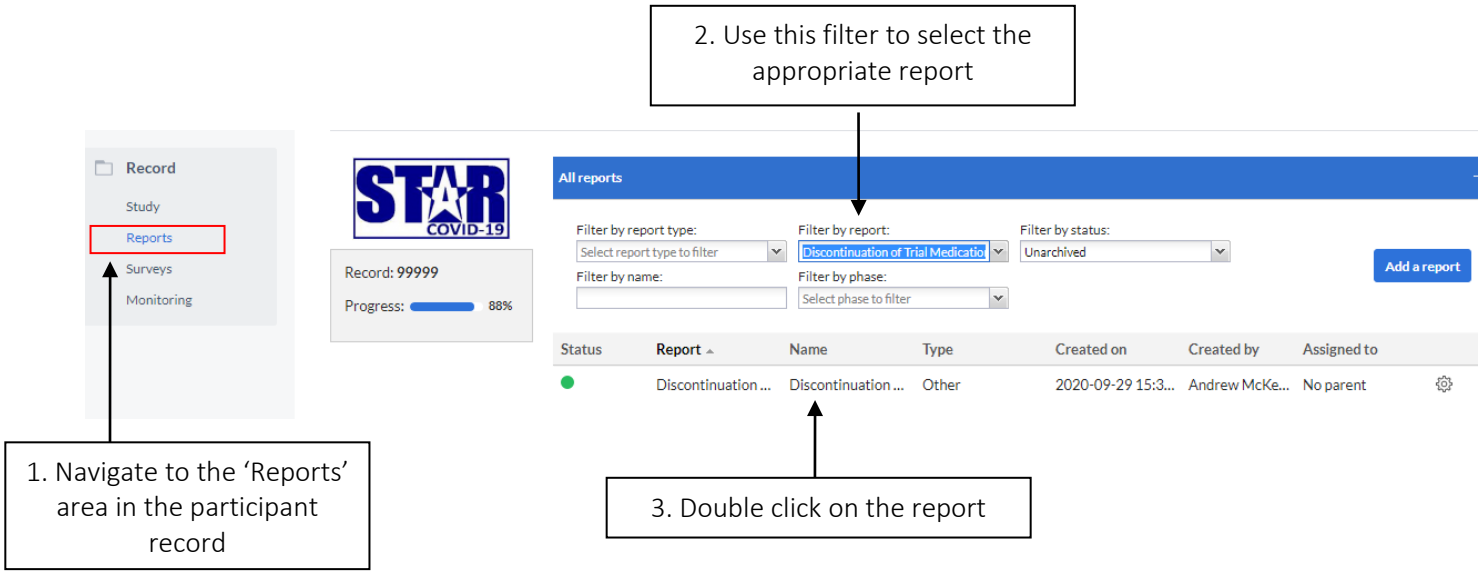


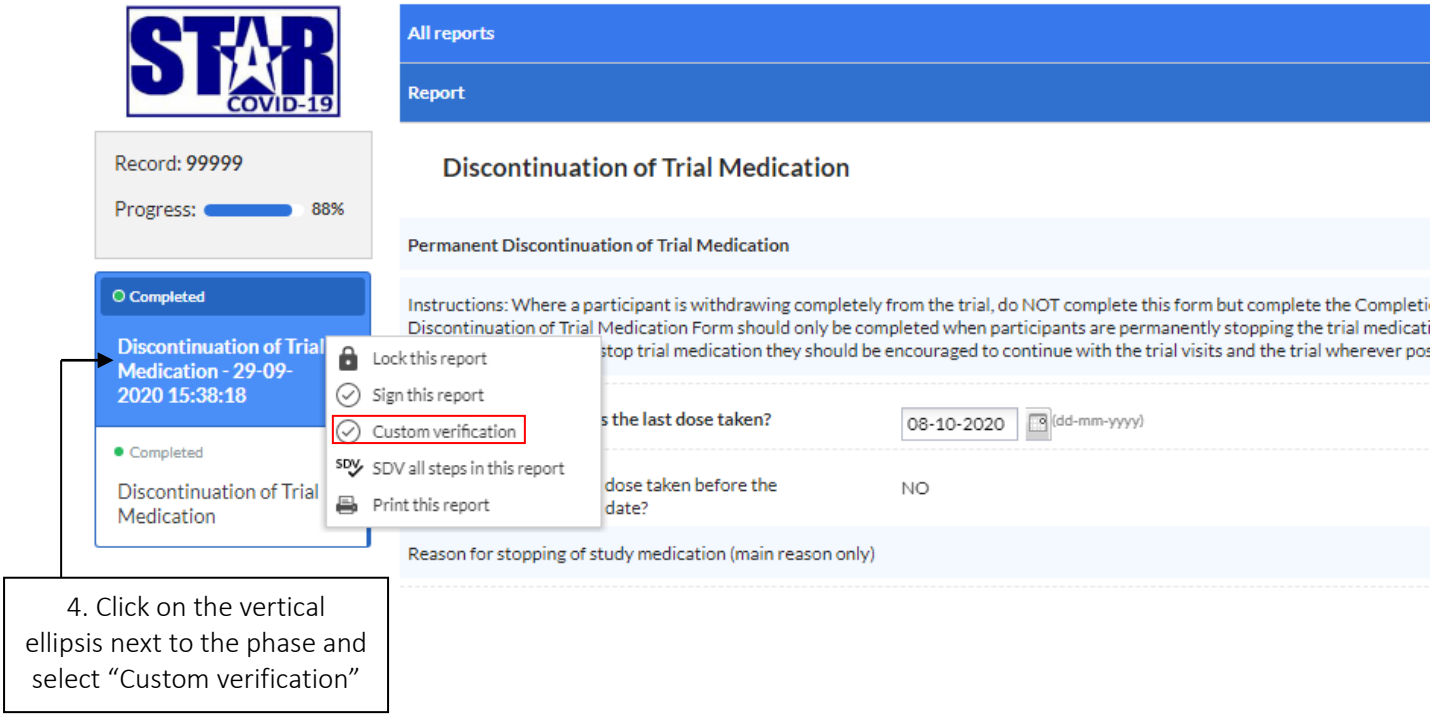
NOTE: Visual verification should be completed once the data entry user is confident that the entered data is correct and as complete as possible.

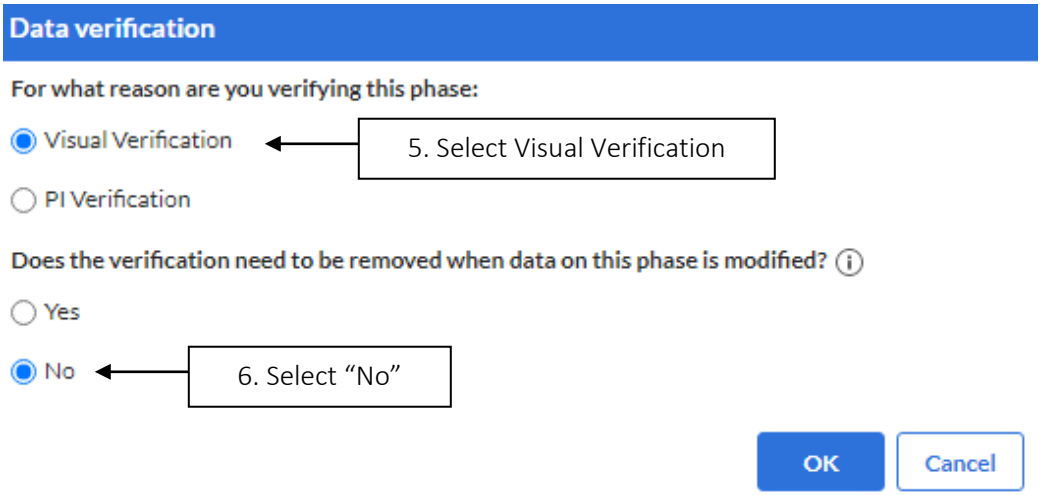



Details of step verification
Baseline
1. Informed Consent
This step was verified on 21/10/2020 at 13:44 by Hasithi Umagiliya Bandara for Visual Verification
1.1 Date of Consent
01-08-2020
(dd-mm-yyyy)
1.2 Consent provided by
Participant
Record: 01002
Progress: 40%
In Progress
Baseline
Completed
In Hospital: Daily Data Collection
Phase and all steps within this phase are now verified

How to verify a Report






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


STAR COVID-19
Record: 99999
Progress: 88%
Completed
Discontinuation of Trial Medication - 29-09-2020 15:38:18
Completed
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
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?
08-10-2020
(dd-mm-yyyy)
2 Is the date last dose taken before the
NO

7. PI Verification Signatures

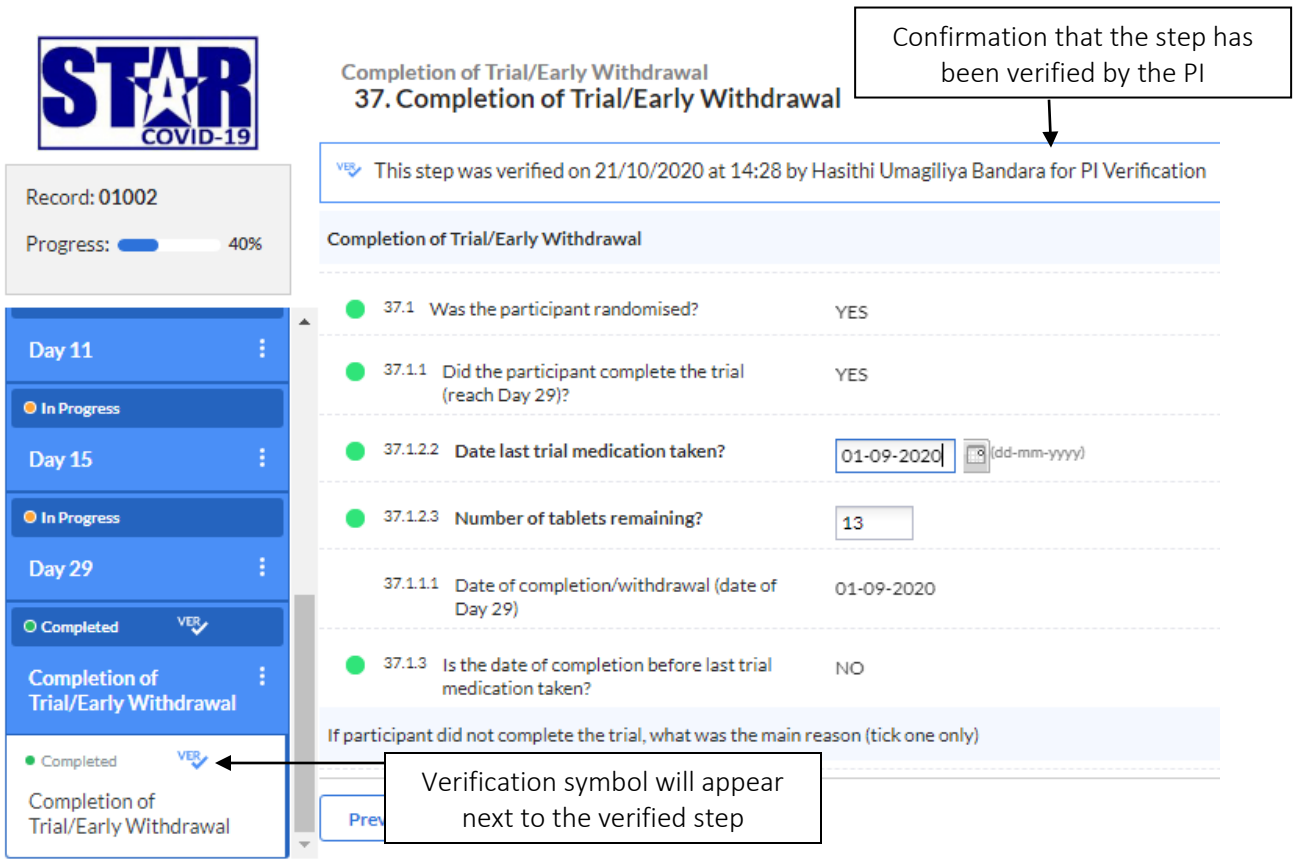
For STAR-COVID19, there are several steps of the eCRF which is required to be signed by the site Principal Investigator (PI). These include:

- 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:



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