



SECTION 5: DATA COLLECTION & ENTRY

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Data Collection

Data collection should be conducted using the Patient CRF Worksheet. Comprehensive instructions on how to collect each data point is found in the Patient CRF Instructions. The Patient CRF Worksheet is formatted to match how you will enter your data into REDCap. Each Patient CRF Worksheet organizes the data you will collect for each enrolled patient. The screen shot of the Patient CRF cover page, to the right, illustrates how the data is organized.

The [Patient CRF Worksheet and Instructions](#) can be downloaded from the website.

NOTE: The information found in the “Data Entry” section of this manual describes the electronic data capture system (REDCap) that you will use to enter the data you have collected. The procedures will also include instruction on how to navigate REDCap, general rules and data conventions (e.g. what format to use to enter dates), how the data you enter is checked for data discrepancies (i.e. queries) and how to organize your study documents.

Study ID #: _____

Patient CRF Worksheets

These Patient CRF Worksheets have been developed to assist your site in collecting data for the trial.

The following table can be used by the site to track the completion of data collection for the patient.

Complete (✓)	Form Name	Page
Baseline (These data are recorded on Day 1 only; Day 2 = ICU admission day)		
	Patient Information	
	Enrollment	
	Baseline SOFA Score	
	Nutrition Assessment	
	• Malnutrition	
	• Clinical Frailty Scale	
	• SARC-F	
	Nutrition Goals	
	• Determining Nutrition Goals	
	• Initiation of Nutrition Therapy	
Daily Data (These data are recorded daily until the first of ICU discharge, death or Day 28)		
	Daily Nutrition Data	
	Daily Enteral Nutrition (EN) Data	
	• Protein Supplements	
	• Non-Protein Modular Supplements	
	• EN Interruption	
	Daily Parenteral Nutrition (PN) Data	
	Daily Protein Data (Day 23-28)	
	(NOTE: these data are collected until the first of ICU discharge, death or Day 28)	
	Daily Nutritional Adequacy (Automatically calculated by REDCap)	
	• Energy	
	• Protein	
	Daily Vasopressors/Inotropes	
	Daily Renal Replacement Therapy	
Outcomes (These data are recorded at the first of ICU and hospital discharge and Day 90)		
	Vasopressors/Inotropes (Start and Stop Dates)	
	Mechanical Ventilation (Start and Stop Dates)	
	Renal Replacement Therapy (Start and Stop Dates)	
	Hospital Outcomes	
	• ICU Stay	
	• Hospital Discharge	
	• 90 Day Outcome	

Safeguarding Subject Privacy and Confidentiality

The site research team as well as the coordinating centre has the responsibility of safeguarding the privacy and confidentiality of the patients enrolled in the EFFORT study by safeguarding personally identifiable information (PII). You are responsible or ensuring local, provincial/state and national privacy regulations are followed.

Personally identifiable information (PII) - Is any data that could potentially identify a specific individual, when used alone or combined with other available information. Examples include, but are not limited to: name, initials, medical record/chart number, lab accession number, date of birth.

All participating sites must observe the following practices to safeguard the confidentiality of each research patient enrolled in the EFFORT study.

1. No patient record shall be removed from the participating site before it is de-identified. This includes any copies of patient records being faxed to the coordinating centre for data verification.

De-identification - Refers to the practice of obliterating PII from medical records and other study source documents to prevent an individual's identity from being connected with information.

2. All patient records sent to the coordinating centre, whether via fax, uploaded to REDCap or other method, will include the patient **study ID number ONLY**. This will be the number assigned to the patient at the time of randomization (via REDCap).

Data Entry

REDCap

REDCap™ is a web-based electronic data capture system that will be used as the EFFORT Trial electronic Case Report Forms (eCRFs). REDCap™ may be accessed directly at:

<https://ceru.hpcvl.queensu.ca/EDC/redcap/>.



You will be collecting data on each enrolled participant from the time of ICU admission until the Day 60 follow-up assessment. Refer to Table 2: Schedule of Events for the detailed timelines for the various types of data collection.

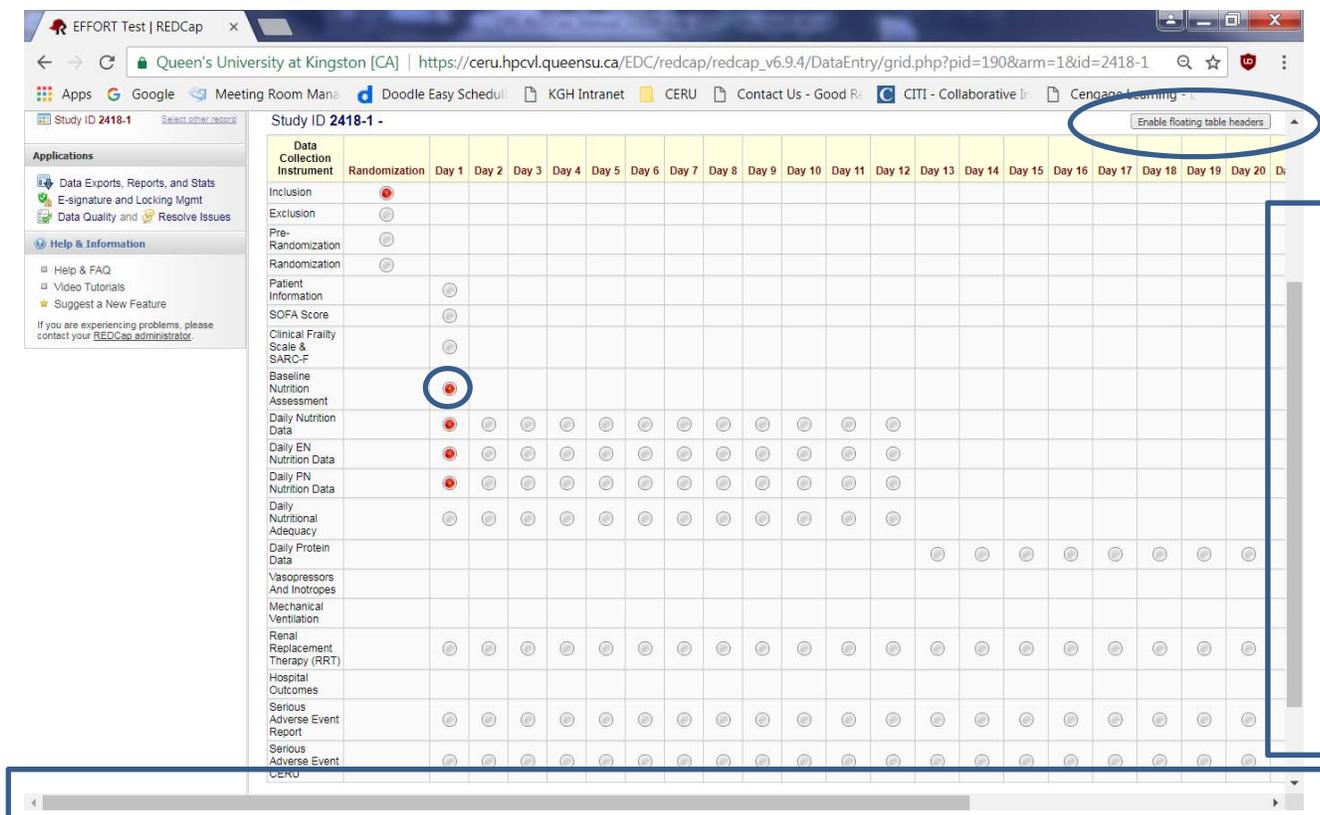
REDCap Navigation

After you have selected a participant, you will be brought to the Event Grid. The Event Grid gives you a snap shot of the data entry forms for the participants.

Each type of data entry form (i.e. Data Collection Instrument) is the table row labels; each column of the table is labelled with the study day.

Each dot in the table represents an individual data entry form that is required for a particular participant.

Each individual entry form can be accessed by clicking on the dot. As you can see below, the circled dot is the Baseline Nutrition Assessment form for study day 1.



Select the 'Enable Floating table headers' button circled, seen on the top right side of the event grid. This will allow the heading to follow as you scroll (i.e. similar to how you can 'freeze' cells in excel). Slide the horizontal navigation scroll bar outlined at the bottom to the right of the screen to reveal the rest of the Event Grid. You must select this button each time you return to the event grid.

You can navigate between forms on the same study day using the form links on the left side navigation menu by clicking on the desired data entry form.

At the end of each form, you will be asked to specify the form status. This legend is to be used to assist you in remembering what data is incomplete, unverified or complete. The status is indicated on the Event Grid Field using the following convention.

Legend for status icons:

- Incomplete
- Incomplete (no data saved) ?
- Unverified
- Complete

Incomplete (red dot)	No data has been entered on a form. Blanks forms will automatically be set to incomplete.
Unverified (yellow dot)	Data entry is partially completed on a form. The RC wants to double check data already entered on a form. Partially completed forms will automatically be set to unverified.
Complete (green dot)	Data entry is complete on a form. Further changes to the data are not anticipated. Only forms manually set to complete will have this status.
Locked (lock symbol)	Locked status will appear on all forms after all finalization checks are completed. Data on locked forms cannot be changed.

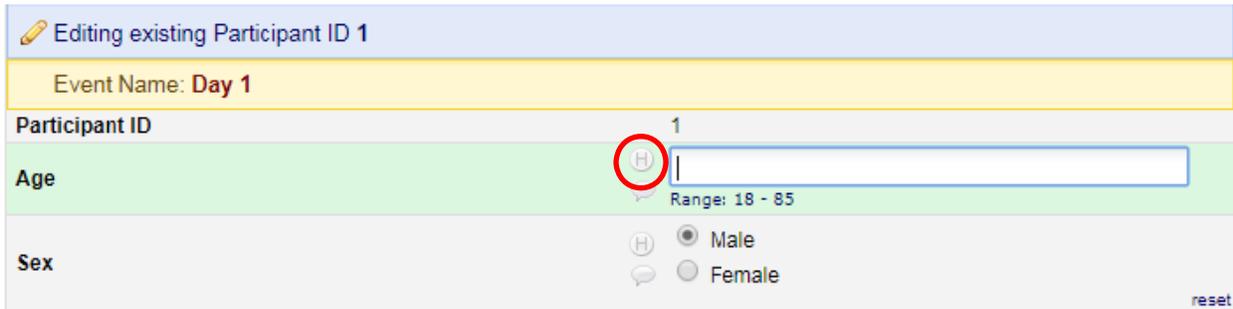
There may be up to 4 options at the end of each form to save your progress.

The following example is for: **Daily Nutrition – Study Day 1**

NOTE: Always remember to “Save” before you navigate away from a form. Navigating from a form without saving will result in loss of data.

Data Entry History

REDCap™ has an option for users to see the data entry history for each data field. By clicking on the  just left of the field (see below).



Editing existing Participant ID 1

Event Name: Day 1

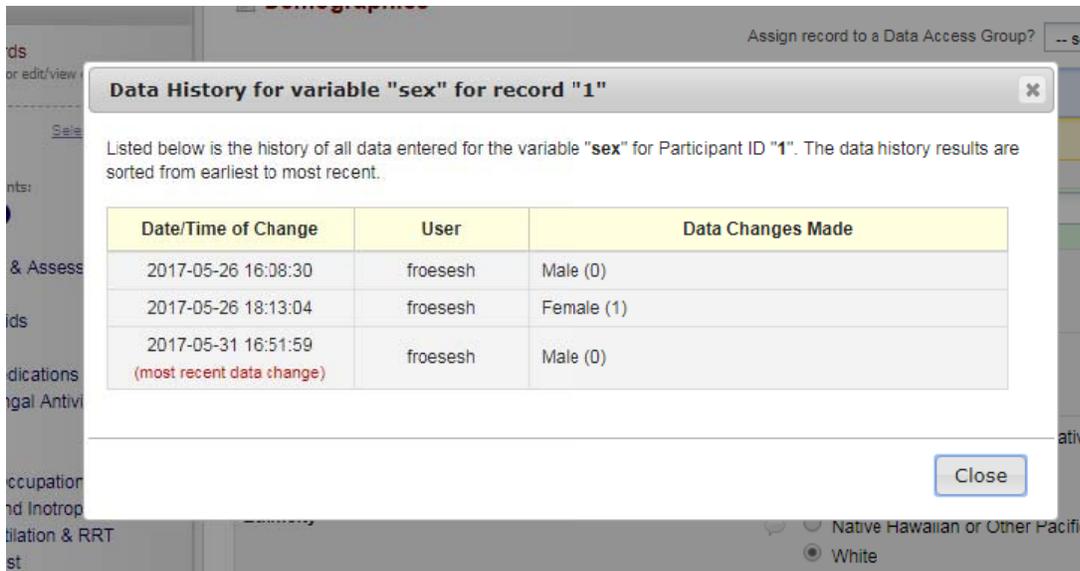
Participant ID 1

Age  Range: 18 - 85

Sex Male Female

reset

A window will pop up listing the data entry history for that field showing the date and time, the date was entered, the user who entered the data and the data entered at that time.



Data History for variable "sex" for record "1"

Listed below is the history of all data entered for the variable "sex" for Participant ID "1". The data history results are sorted from earliest to most recent.

Date/Time of Change	User	Data Changes Made
2017-05-26 16:08:30	froesesh	Male (0)
2017-05-26 18:13:04	froesesh	Female (1)
2017-05-31 16:51:59 (most recent data change)	froesesh	Male (0)

Close

Data Conventions in REDCap™

- Dates should be entered using the YYYY – MM – DD format i.e. 2017 – 09 – 20. A date picker calendar is available to enter dates. Single ‘click’ on the  icon and you can choose the appropriate month and year from the drop down boxes. Then ‘click’ the appropriate day.
- Enter all times using the HH:MM 24-hour period format i.e. 22:37. The colon ‘:’ must be entered. Use leading zeros where applicable i.e. 01:28
 - Midnight should be entered as 00:00

- To enter data directly into any text field, **single click** anywhere in the box and type the information.
- Do NOT press enter after entering data into a field. This will cause the form to automatically save and bring you to a new screen that will allow you to return to the Event Grid.
- There should be NO blanks. If data is NOT available use the **'Not Available'** option. This includes:
 - Data that is unavailable because the test was not done. *Example: Total-Bilirubin was not done on a particular study day.*
 - Data that is not known. This assumes every effort has been made to find the data but it is missing from source documents. *Example: A particular data point was NOT entered in the medical chart. Or an ICU flow sheet has gone missing.*
- A Study Day begins and ends at midnight, regardless of when your ICU flow chart begins and ends. If your participant records are computerized and the default start time is not midnight, you should be able to set the start time to midnight for the purposes of your data collection. If you do not use the calendar clock (00:00 – 23:59) to enter your data into REDCap™, you may receive errors indicating you have too much or too little data; you will be unable to finalize such participants until these errors are resolved.

Data Flow

To help you determine the status of the patient data, we have designated different stages of data completion. Each stage marks the completion of a specific set of data. The diagram below summarizes the site responsibilities at these various stages.



Query System

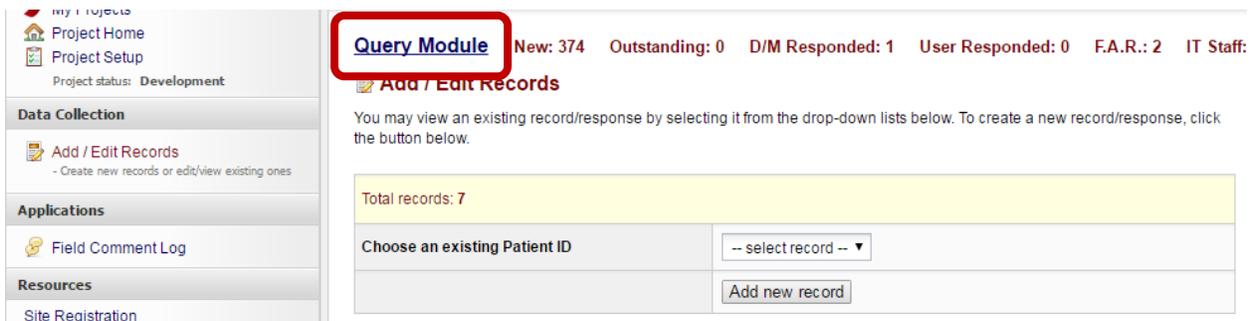
The Query System (or module) is the program that checks data entered into REDCap. Queries (or data checks) will be generated in the following circumstances:

- Blank data fields
- Blank forms
- Out of range values
- Data inconsistencies

How to Access the Query Module

Viewing ALL Queries

The Query Module can be viewed by clicking on “Query Module” at the top of the page. This will enable you to view all queries for all patients at your site.



Query Module New: 374 Outstanding: 0 D/M Responded: 1 User Responded: 0 F.A.R.: 2 IT Staff: 0

Add / Edit Records

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, click the button below.

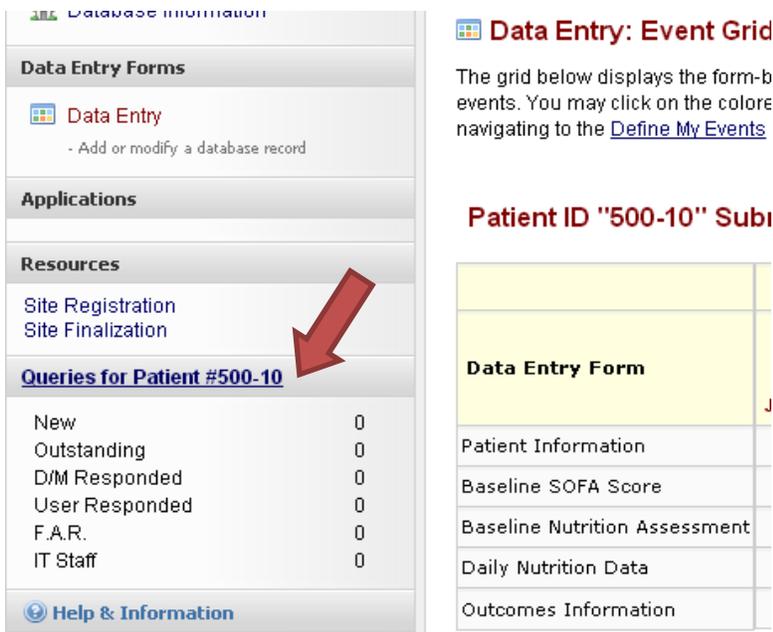
Total records: 7

Choose an existing Patient ID -- select record --

Add new record

Viewing Patient Specific Queries

Select an existing Patient ID in REDCap. In the left sidebar, click on “Queries for Patient ...” to view all of the queries for that particular patient.



Data Entry: Event Grid

The grid below displays the form-based events. You may click on the colored events. You may navigate to the [Define My Events](#)

Patient ID "500-10" Subj

Data Entry Form	
Patient Information	
Baseline SOFA Score	
Baseline Nutrition Assessment	
Daily Nutrition Data	
Outcomes Information	

Database Information

Data Entry Forms

Data Entry
- Add or modify a database record

Applications

Resources

Site Registration
Site Finalization

Queries for Patient #500-10

New	0
Outstanding	0
D/M Responded	0
User Responded	0
F.A.R.	0
IT Staff	0

Help & Information

Query Types

Queries are divided into two sections:

- Site Queries – Identified with a heading “Patient ID xxx-xx”
- Data Management
 - Pending Data Management (i.e. Coordinating Center) Queries
 - Resolved & Removed Queries

You are responsible for addressing all queries that appear in the Site Query section (example screen below).

Patient ID "2530-4"

Query #	Event	Form Name	Error Message	Query Status
590380	Day 1	Nutrition Assessment	Missing Other evidence of moderate to severe malnutrition (select all that apply).	New
590241	Day 1	Nutrition Assessment	Missing Is there other evidence of moderate to severe malnutrition not captured above?.	New
588687	Day 3	Daily Nutrition Data	Missing Did the patient have a hypoglycemic event? (< 3.5 mmol/L or < 63 mg/dL) on Day 3.	New
588376	Day 1	Nutrition Goals	Missing Was indirect calorimetry used to determine the goal calorie requirement? .	New
588371	Day 1	Daily Nutrition Data	Missing Phosphate Units Note: once you specify units here, these units will be assumed to be the same for all phosphate values for this patient. on Day 1.	New
588361	Day 1	Daily Nutrition Data	Missing Was any nutrition received orally/by mouth? on Day 1.	New
588349	Day 1	SOFA Score	Missing Lowest PaO2/FiO2 Ratio (also known as P/F ratio): .	New
587795	Day 1	Patient Information	Direct DM > Non-operative Condition System: Other neurologic disease (specify): stupor	D/M Responded

By referring to the far right column in the table, you will be able to quickly see the status of the query.

- **New** – means the query has recently been noted and you have not yet addressed it.
- **Outstanding** – means that a ‘new’ query has not been addressed for an extended period of time.
- **D/M Responded** – means that data management (i.e. the coordinating centre) has responded to the query and you must now review the response.

Responding to a Query

You have two options when responding to queries:

Option 1 – the query is the result of a data entry error or mistake and you need to correct the data.

Query #	Event	Form Name	Error Message	Query Status
4014		Outcomes Information	You indicated mechanical ventilation was discontinued in the ICU. If this is correct, Date/Time Mechanical Ventilation was discontinued (2012-07-19 12:00) cannot be after ICU Discharge (2012-07-01 15:00).	New
4015	Outcomes	Outcomes Information	ICU Discharge (2012-07-01 15:00) cannot be prior to ICU Admission (2012-07-02 14:50).	New
4016	Day 1	Daily Nutrition Data	It was indicated that the patient was in the ICU for 0 days, but data was entered on Day 4.	New

- a) In the query table click on the Form Name for the query you wish to address to be taken to that form.
- b) Enter the corrected data and save the form.

c) The next time the queries run that query will be removed. It will not be removed right away.

Option 2 – The data is correct and data management (i.e. the coordinating centre) would like you to provide confirmation and an explanation.

a) In the query table click on the Error Message for the query you wish to address.

Query #	Event	Form Name	Error Message	Query Status
4014	Outcomes	Outcomes Information	You indicated mechanical ventilation was discontinued in the ICU. If this is correct, Date/Time Mechanical Ventilation was discontinued (2012-07-19 12:00) cannot be after ICU Discharge (2012-07-01 15:00).	New

b) Select the appropriate response from the drop-down list and enter a comment, if required.

Date	Query #	Event / Form Name	Error Message	Related Data	Query Status	Response
2012-10-22 10:10	4014	Outcomes / Outcomes Information	You indicated mechanical ventilation was discontinued in the ICU. If this is correct, Date/Time Mechanical Ventilation was discontinued (2012-07-19 12:00) cannot be after ICU Discharge (2012-07-01 15:00).	View	New	

Response:	<input type="text"/> <ul style="list-style-type: none"> Data Has Been Corrected Data Correct As Entered Data Missing/Unknown Unable To Enter Corrected Data Alert Data Management Other
Comment:	<input type="text"/> 500 Characters Remaining

Response Option	Description	Resulting Query Status
Data Missing/Unknown	Data was missing from source or not done. A comment is required.	User Responded
Data Correct as Entered	Data is verified by source and is inputted correctly.	User Responded
Unable to Enter Corrected Data	Certain data points may get locked and you will not have access to change your data. A comment containing the correct data is required.	User Responded
Alert Data Management	Notify Data Management that there might be a problem with the check. A comment is required.	User Responded
Other	Situations that do not apply to the above response options, A comment is required.	User Responded

For those response options that require a comment, please provide a meaningful explanation. Data Management will review the comments and will query you further if:

- Not enough information is provided
- Information is contradictory to entered data
- Explanation is unclear

Submitting Data

Submitting the data lets the system know you are done and want to close the patient chart in REDCap.

1) When data entry is complete and all queries have been resolved click the ‘Submit’ button at the bottom of the grid.

Queries for Patient #10521001	
New	0
Outstanding	0
D/M Responded	0
User Responded	0
F.A.R.	0
IT Staff	0

All query types must equal ‘0’ in order to successfully ‘Submit’ the patient.

If you have not completed essential forms or still have queries left you will receive an error message.

Warning - There is 1 error preventing this patient's status from reaching Queries

You must address each of these errors before the patient's status will reach Queries.

Form	Error Message	Link to form
Hospitalization Overview	The Hospitalization Overview form must be completed.	Go to event

Clicking on ‘Go to event’ will take you directly to the form with the missing data.

2) The system will now check to see if you missed completing any forms. It will also check for any other complex data queries (logical sequence of events, etc).

Finalized Patient in REDCap

Once the patient is submitted, the outcomes information is entered and any queries have been resolved, the system will automatically finalize the patient. This will lock all of the patient’s data. The patient will be labeled as “Finalized”.

Please note that Data Management queries will also need to be resolved before the patient is finalized.

Remember that all patient charts should be finalized within 90 days of ICU admission.

Refer to the Query Training Module found in the EFFORT website [here](#).