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CYSTIC FIBROSIS REGISTRY OF IRELAND
DATA COLLECTION
CFRI DATA COLLECTION – GENERAL DATA ENTRY
STANDARD OPERATING PROCEDURE

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Dr. B. Linnane – Prof. N.G. McElvaney – Prof. P. McNally – Prof. B. Plant – Mr. P. Watt

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1. Purpose and scope of document

This document relates to **CFRI general data entry processes**. This document aims to outline the processes and associated definitions on general data entry at CFRI. This document does not deal with how to use the CFRI Tracker2 database for data entry, nor does it deal with the practical details regarding accessing medical charts within each of the data collection sites. These processes are detailed within the wider pack of data collection standard operating procedures (referenced in Section 9).

General data entry at CFRI refers to the process of using relevant information available in patient charts and e-health records and entering this information into the CFRI Tracker2 database on an encounter basis. CFRI fully migrated to Tracker2 in 2022. Key updates to this system have allowed CFRI to ensure that data input is as accurate and accessible as possible for users, as well as for data input and output.

CFRI collect data from patient medical charts and e-health records (where applicable) in CF centres across Ireland. We collect data on an encounter basis, meaning that the data comes from the patient encounters with their multi-disciplinary CF teams (MDTs) and consultants at centres across the country.

Within this SOP we deal with the processes around the following:

i. The centres CFRI collect data from
ii. Indicative data collection timelines
iii. Ensuring data quality at CFRI
iv. The process of data collection

2. Policies and regulations

(A) External policies and regulations

- This standard operating procedure has been developed in the context of the General Data Protection Regulation (EU), or GDPR, 2016 and the Data Protection Act (DPA) (2018). The collection of data at CFRI should be compliant with these legal requirements for data protection and security. CFRI run regular refresher sessions on GDPR/DPA. However, should users require any further information on these regulations, please contact your line manager or point-of-contact.
- Data entry and analysis also needs to be compliant with the data collection requirements and timelines of ECFSPR (European Cystic Fibrosis Society Patient Registry).

(B) Internal policies and regulations

- Data entry needs to be compliant with individual centre ethical submissions which are amended (if required) on an annual basis.
- Data entry needs to be compliant with the CFRI annual timelines for data entry as outlined in Section 6.

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3. Responsibilities

The primary audience for this document are the CFRI (S)CRAs and data collectors. Individual responsibilities are outlined in Table 1.

Role	Responsibilities
SCRA (Senior Clinical Research Associate)	Data entry, enrolling patients, patient transfer, querying data, dealing with queries, training CRAs, key point of contact for data entry across centres, ensuring data quality
CRAs (Clinical Research Associates)/ data collectors	Data entry, dealing with queries, raising data entry discrepencies/uncertainties, liasing with MDTs/consultants, arranging data collection at centres, ensuring data quality
Research team @ CFRI	Querying data, user permission control on CFRI Tracker2, data quality
MDTs (multi-disciplinary teams)/consultants	Overseeing consenting process and sign-off, providing access to charts and required patient information
Head of Operations	Review of relevant SOPs/data entry documentation, overseeing training of CRAs, overseeing data collection progress, data quality
Data Protection Officer (DPO)	Maintaining data incident log, GDPR/DPA training, overseeing data security, reporting relevant data incidents to the Data Protection Commissioner.

Table 1 CFRI data entry responsibilities

4. Definitions & abbreviations

	Term/abbreviation	Definition
General data entry	SOP	Standard operating procedure
	CFRI Tracker2	The CFRI database where patient information is input according to a pre-defined variable list.
	Data collection/entry	The process by which data is taken from medical charts/e-health records and added to the CFRI Tracker2 database.
	Data	Pieces of information input into CFRI Tracker2 relating to CFRI data collection variables
	CFRI variable	The information we seek to collect from consented CFRI patients (see the CFRI Data Dictionary).
Data quality	Data quality	The extent to which the data we collection is accurate, complete, timely, consistent, and valid for the purposes it serves.
	Data completeness	The comprehensiveness of our dataset. By identifying which information is required and which is optional, the registry can ensure it always captures te minimum required data to perform analyses and tasks required of CFRI.
	Data timeliness	Data is available when it is needed i.e., the data is available at the times when we require it. The intended use of the data often indicates what is deemed timely.
	Data validity	A measure of whether the data meets expected ranges or definitions.
	Data accuracy	The extent to which data repesents or measures what it is intended to measure.

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General data entry terms	CFRI ID	A unique numerical code allocated to patients once enrolled on the CFRI Tracker2 database
	Enrollment data	The information about the patient required to enrol them on the CFRI Tracker2 base and generate a CFRI ID e.g., date enrolled, name, DOB (date of birth), sex, and consent details.
	Core data	Any information relating to core patients details e.g., patient status (alive/dead/lost to follow-up), death details (if relevant), lost to follow up details, Individual Health Indentifier number (if available), demographic details, reconsent information, care details (primary hospital/shared care/associated MRNs), diagnostic information, and transplant status.
	Encounter	An event in which a CF patient receives a medical review/assessment by a CF consultant or other CF team members, either in-person (face-to-face) or virtually (online or by phone). CF patients can access diagnostic, consultation, certain procedures or treatment and/or advice with CF medical staff.
	Encounter data	Any information collected related to the above definition of an encounter. The encounter form is to record all information relating to CF events with a CF patient. Encounters with non-CF related physicians (or other healthcare providers) should not be recorded.
	LFU	Lost to follow up: a patient registered with a particular centre has not had an encounter in a long time. Reasons for lost to follow-up can be known such an emigration, poor attendance, but can also be logged as 'missing'. If there have been no encounters in 2 years, check with centre – get MDT/nurse confirmation about the patient The definition of LFU differs slightly for ECFS whereby a patient is LFU if they are not seen in year of follow-up. This is calculated by our research team.
	Encounter types	
	(1)Routine review (examples below)	Refers to any scheduled appointment/medical review occurs either in OPD or CF day-unit (or treatment room); It normally is well planned as decided by CF medical staff.
	(1.1) Acute care visit	An encounter in which a patient needs to be treated by hospitalization or home IV due to experiencing a clinically significant increase in pulmonary symptoms. Patient admitted at routine review appointment.
	(1.2) Study visit	An encounter directly related to the patient's participation in a trial or some other research study.
	(2)Drop-in visit (examples below)	Refers to a patient's visit without a pre-scheduled appointment with CF medical staff; it is an unplanned visit.
	(2.1) Acute care visit	An encounter in which a patient needs to be treated by hospitalization or home IV due to experiencing a clinically significant increase in pulmonary symptoms. Patient admission unplanned/emergency.
	(3)Annual review	An annual assessment encounter is a detailed assessment of every aspect of the patient's condition and therapies to assess changes over the past year, identifies where treatments can be improved

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		and produces a management program for the following year. The process is divided into two parts: 1. The first part is the **Assessment Day** which involves a series of investigations and the clinical assessment of the patients' status by the CF team. 2. The final part of the process occurs 4-6 weeks later with the **Annual Review Appointment**. At this appointment, the CF Consultant discusses the various test results with the patient/careers. A personal care plan is agreed, and the patient/careers receive a written summary of the annual review results, discussions and management plan. Please note the Annual Review Appointment in some hospitals only happens within the CF team meeting without a patient's involvement. Please note that even if labs/tests etc. are done on different day, you can specify test dates within the annual review encounter itself, even if different from annual review encounter date. Also note that some centres do not do annual assessments. However, if there are labs/microbiology data there, capture the data within the relevant encounter.
	(4)Virtual encounter	Any encounter that takes place online or via telephone in place of what would otherwise have been an in-person encounter. To take the example of physiotherapy. If the patient sees a physiotherapist online or via phone and the physiotherapist reviews the patients and captures data in their chart, this would count as a virtual phsyio encounter. If however, the patient attends an online group class for phsyio or yoga, then this would not be recorded as an encounter, as the patient was likely not reviewed as a result.
	(5)Other encounter	Encounters that occur are not listed above such as routine port-a cath flush, changing dressing, drug trial follow-up etc.

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5. Data collection locations & frequency

We collect data from several sites across Ireland. Due to varying numbers of patients at each sites, data is collected with varying frequency. The sites from which we collect data and the frquency with which data is collected are summarised in Table 2.

Type of centre	Centre name	Frequency of data collection
HSE-designated CF specialist centres	Beaumont Hospital	Ongoing
	St Vincents University Hospital	Ongoing
	CHI National Children's Hospital Tallaght	Ongoing
	CHI Our Lady's Children's Hospital Crumlin	Ongoing
	CHI Temple Street Children's University Hospital	Ongoing
	University Hospital Galway	Ongoing
	Cork University Hospital (adults & paediatrics)	Ongoing
	University Hospital Limerick (adults & paediatrics)	Ongoing
CF Clinics	Cavan General Hospital	Twice/year
	Mayo University Hospital	Twice/year
	Our Lady of Lourdes Hospital Drogheda	Twice/year
	Sligo University Hospital	Twice/year
	University Hospital Waterford	Twice/year
Irish National Lung Transplant Programme	Mater Misericordiae University Hospital Dublin	Ongoing

Table 2 Data collection locations & frequency

6. Annual data collection timelines

The information in Table 3 describes the key indicative deadlines and timepoints throughout the year relevant to data collection/entry. It is important that data collection activity sticks to the below timelines to ensure we can meet deadlines associated with submissions to ECFS and other sponsors.

Data collection task	Timelines	Indicative annual deadline(s)
Data collection continued from previous calendar year	January - March	31st March
Data collection for current calendar year	April - December	n/a
Quarterly data collection check-ins	Quarterly	n/a
Patient census / patient survey (in advance of Killarney meeting)	January	31st January
Data cleaning	April	30th April

Table 3 Annual CFRI data collection timelines

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7. Ensuring data quality

In the following sub-sections, there are guidelines on ensuring data quality throughout the processes detailed in Section 8.

(A) Data accuracy

i. Consult the CFRI data dictionary to ensure that you are recording the relevant data in the correct format.
ii. CFRI Tracker2 has built in functionality (RAG error messages) to alert the user when data is in the incorrect format or is outside of normal ranges of particular values.

(B) Data completeness

i. Ensure that all available and relevant data in the chart is input into CFRI Tracker2
ii. If information in charts is unclear or obviously missing, consult relevant MDTs
iii. The CFRI Tracker2 will indicate which variables are required/mandatory to enter for particular forms and sections (see CFRI Tracker2 User Guide).
iv. If any required/mandatory data in unavailable, you will be unable to save the form you are working on.

(C) Data timeliness

i. CRAs/data collectors should ensure they check patient charts regularly.
ii. It is a requirement in CFRI Tracker2 to input the date individual charts were last reviewed, even when no new encounter data has been input. This will allow CFRI to calculate how up-to-date we are overall in terms of data collection. This is important all through the year in order to assess our progress towards key deadlines as well as to shift capacity in the case of staff illness/time off/turnover.
iii. Table 2 indicates how often visits should be made to each centre – some of the peripheral centres require less frequent visits due to low patient numbers.
iv. In most cases, (S)CRAs should ensure all patient charts are reviewed once a quarter.
v. The Head of Operations/SCRA will ensure each centre gets a quarterly check-in point to feedback on any challenges/progress.

(D) Data consistency

i. The SCRA/Head of Operations ensures new users are adequately trained in data collection using relevant CFRI SOPs and training documents
ii. The Head of Research/Head of Operations/SCRA should ensure any changes or discrepencies in the way data is collected/recorded are communicatied to all staff/contracted data collectors
iii. Should (S)CRAs come across any discrepencies/challenges in the consistency of data collection, these issues should be raised with the Head of Operations/Head of Research/SCRA to ensure any uncertainties are discussed, resolved and communicated across the team as well as recorded in the relevant SOPs.

(E) Data validity

i. The SCRA ensures new users are adequately trained in data collection using relevant CFRI SOPs and training documents
ii. The CRAs ensure that they are familiar with and consult the CFRI data dictionary to ensure they are entering data in accordance with intended data definitions and ranges.

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8. Process

N.B. Please refer to the CFRI site-specific data collection SOP, the CFRI Tracker2 user SOP, and the CFRI data dictionary alongside this standard operating procedure.

(A) Accessing charts & CFRI Tracker2 system

1. Unless data collection is ongoing at a centre, arrange a suitable time to visit the centre with the respective contacts outlined in the CFRI site-specific data collection SOP
2. In advance of your visit, ensure that you have made any chart orders required and arrangements if you require office space at the centre.
3. If relevant, request access to any hospital computer systems (specifics @ CFRI site-specific data collection SOP) – you may need to do this in advance, or when you arrive at the centre.
4. Upon arrival at the centre, collect the pre-ordered/relevant available charts.
5. Log-on to CFRI Tracker2 (see CFRI Tracker2 user SOP for instructions on how to use CFRI Tracker2)

(B) New patients

1. If CF patients are new to the registry, the MDTs oversee the new patient consenting process. This is usually undertaken in-clinic. Please consult the CFRI consenting/reconsenting SOP for further information. MDTs have been provided with pre-paid envelopes to return signed consent forms to CFRI. If a centre require extra hard-copy materials, please contact the Head of Operations.
    a. CFRI consent forms should be sent directly back to Woodview House via pre-paid mail. In the instance, that you are given signed consent forms, please ensure they are securely mailed back to CFRI or are given to the Head of Operations as soon as possible.
    b. N.B. we currently only have ethical approval to consent CF-diagnosed patients to the registry. If you are unsure about a patient's diagnosis or it is unclear from the notes, please consult the SCRA or the MDT/consultant at the patient's hospital.
2. The Head of Operations will document the receipt of the new consent form and notify the SCRA.
3. The SCRA enrols the patient on the CFRI Tracker2 system (see CFRI Tracker2 user SOP for instructions).
4. Information requried to enrol the patient is detailed in the CFRI data dictionary and includes: enrollment date, name, DOB, sex, and consent information.
    a. A scanned version of the consent form should be uploaded via the 'attachments' tab on the patient side menu.
    b. After enrollment, the SCRA must set a patient label for the patient. The patient label is set by navigating to the 'set patient label' tab on the patient dashboard on CFRI Tracker2. The patient label should be set as **Firstname Lastname.**
5. Once enrolled, the patient is automatically assigned a CFRI ID, a unique numerical code used within CFRI to distinguish between individual patients.
6. Once the patient is enrolled on CFRI Tracker2, core data for the patient can be added. For instruction on how to add core data, please refer to section (D).
    a. N.B. once patient consent has been given, CFRI can retrospectively collect the patient's data, despite the date of consent. If it is a new patient who has a long history & many encounters over the years, we can make a sensible decision from which point we should collect data.

(C) Existing patients

1. For existing patients, the CRA should check the chart for any new encounters since the date the chart was last reviewed and the date of the last encounter. The date the chart was last reviewed should have been recorded in the CFRI Tracker2 system. This data field is found in the core data form.

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2. If there are any new encounters, these should be added to CFRI Tracker2. Please refer to section (E) for instruction on how to add encounter data.
3. Please note that for existing patients, core data can be updated at any time should additional information become available. For instruction on how to add core data, please refer to section (D).

(D) Adding core data

1. Once a patient has been consented to the registry (see CFRI consenting/reconsenting SOP) and has been enrolled onto CFRI Tracker2 by the SCRA, a CFRI ID will be automatically assigned for the patient.
2. The SCRA will inform CRAs when a patient has been enrolled and the CFRI ID is available.
3. Once a CFRI ID exists for the patient, the (S)CRA can add core data.
    a. N.B. alongside adding core data, the SCRA should upload a PDF version of the signed consent for to the patient's record on CFRI Tracker2. The upload link is accessed by the patient side-menu under 'attachments'.
    b. This file will be named in accordance with the rquired file labelling convention [HOSPITALNAME_ADULTPAEDS_CFRIID_MMYYYY].
    c. Tracker2 will require the file to given a label – replicate the file name.
    d. Users will be able to see that a file exists, but only users with service desk access will be able to view the file by entering a password.
4. All required core data must be entered and saved in CFRI Tracker2 before any encounter data can be added. Core data is defined above.
5. If some core data fields are not available in the patient chart, please consult the MDT(s) at the centre.
6. Once core data has been entered/updated, ensure that you save the entry so as no data is lost.
7. Only when required core data has been entered for a new patient, can the data collector add encounter information for the patient.

(E) Shared care/transferring patients

Patients can be shared with another centre (meaning data can be entered for that patient for both centres) or transferred completely (meaning data will only be able to be entered for a new centre going forward).

1. To access the option to share/transfer a patient, navigate to the sharing tab on the left-hand side of the patient dashboard
2. Shared care – click the share radio button. Select the centre the patient is to have shared care with.
3. Transferring – click the transfer radio button. Select the centre the patient is transferring to. Select an expiry date (the date from which data can no longer be entered for the old centre). Usually the expiry date is set to 1 year from the transfer date (to allow a time lag for data entry).

(F) Adding encounter data

1. Upon checking a patient's chart, add the date the chart was last reviewed in the **core data form**.
2. Record any details of individual encounters as they are defined above in the encounter form.
3. If the data collector is uncertain about whether to record something as an encounter, or what type of encounter to record, they can refer to the flowchart in appendix 1 to support them and the ecnounter definitions above. If it is still unclear, please contact the SCRA.
4. Details of how to record an encounter in CFRI Tracker2 can be found in the CFRI Tracker2 user SOP.
5. For any encounter, it is mandatory to record date of encounter, type of encounter, and which members of the MDT saw/reviewed the patient during the encounter as a minimum.
    a. If the above minimum information is unavailable, you will not be able to save the encounter in CFRI Tracker2.

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6. After entering the minimum required information, the data collector can proceed to adding information recorded during the encounter. Which information you record will vary from encounter to encounter, but you have the option of recording information on anthropometry, spirometry, complications, regular medications, microbiology, lab investigations, radiology, acute care, physiotherapy, and clinical trial data.
    a. The data in the following form sections will be carried over from previous encounters: anthropometry (adult height pre-populated for over 18s), complications, regular medications with continuing box checked (except for vitamins/minerals – name), acute care with continuing box checked, physiotherapy (oxygen therapy, non-invasive positive pressure ventilation therapy, exercise/activity), pregnancy[1], and clinical trial data. Please ensure you review this information each time you enter new encounter data to make sure it is up-to-date.
7. Once all relevant encounter data has been entered, you should click the 'save' button to ensure no date is lost.
8. You can edit existing encounters should additional information become available/recorded e.g. labs.

(G) Particulars regarding CFRI variable data entry

N.B. Alongside reading this SOP, please consult the CFRI Tracker2 variable list and CFRI data dictionary. These documents provide systematic descriptions of the variables for which data are collected at CFRI and how and in what format data should be entered for each variable. Below we consider some particulars relating to variables which can be difficult to record.

General data entry

i. 'Other' drop-downs/radio buttons
    a. Other – please only indicate 'other' in a drop-down menu if the data you have does not meet any of the other drop-down options
    b. 'If selected other, please specify' – if you have selected 'other' in a drop-down menu, the field may present an option to specify what you mean by 'other'. Please be as specific as possible.

Core data variables

i. Patients lost to follow-up (LFU) – it can often be difficult to decipher whether a patient can be classified as 'lost to follow up'. Our policy is outline in Section 4.
ii. Cause of death- there may be short delays in determining cause of death in which case the (S)CRA can add this information at a later time.
iii. Recording ethnicity – it is important to accurately record ethnicity. CFRI use ethnicity to accurately measure % predicted FEV1 using GLI equations (evidence-based and validated look-up tables). This is because results of % predicted FEV1 will vary across different ethnicities. To ensure the data and analyses produced by the registry are as accurate as possible, we need to accurately record this information. We use the recorded ethnicity to map to GLI standard ethnicity categories. The more accurate we can be, the more accurate the output.
    - Please ensure that before you record an ethnicity as 'other' that the ethnicity of the patient is not covered by one of the other drop-down options.
iv. Diagnosis reversal – if a patient has a diagnosis reversal, they should be removed from the registry as per the procedure in the CFRI release form and data deletion SOP.

[1] Check on "Please indicate if the patient is currently pregnant" if the next encounter is less than 40 weeks (280 days). Please indicate if the patient's pregnancy outcome is a live birth.

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v. Reversal of consent – if a consented CFRI patient decides that they no longer consent to participating in CFRI, we can remove them from the database. However, we do not delete data which has already been collected, we just do not collect anymore going forward. This procedure is outlined in the CFRI release form and data deletion SOP.

Encounter data variables

i. Type of encounter – when entering encounter data, the user will be prompted to define the type of encounter (via drop-down). The different types of encounter are defined in Section 4.

ii. Please note that for certain variables there are limits to the number of decimal places to can record. Please consult the CFRI data dictionary to confirm for variables such as height, weight, FEV1 % predicted (centre value), FVC, FVC % predicted (centre value), FEF25-75% (L/sec), FEF25-75% (centre value), LCI value.

iii. Carry over variables – certain variables will carry over from encounter to encounter. You can still update should new data be available in the patient's chart. If no new information is available, then the data fields will remain as they were previously input.
   a. The data in the following form sections will be carried over from previous encounters: anthropometry (adult height pre-populated for over 18s), complications, regular medications with continuing box checked (except for vitamins/minerals – name), acute care with continuing box checked, physiotherapy (oxygen therapy, non-invasive positive pressure ventilation therapy, exercise/activity), pregnancy[2], and clinical trial data.
   b. N.B. in a new encounter, if you unclick any of the continuing form sections, you will lose the carried over data. To retrieve any lost data, you will have to start entering data for the encounter again.

iv. CFTR modulators
   a. Often patients change from one modulator to another. In such cases, where a patient switches, ensure that the stop date is at least the day before the new start date. N.B. ECFS will reject data for modulators where the stop date for one modulator is the same as the start date of starting another.
   b. Pre-initialisation sweat test – collect pre-initialisation sweat test data for those patients starting on modulators. The data field for pre-initialisation sweat tests is located within the CFTRm section of the encounter form.
      i. Other sweat test data can be added under the lab investigations section of the encounter form.

v. Lab investigation results – some lab results are recorded in patient charts using '<' less than symbols or similar. In such cases, it is usually that the lab result is within range, or insignificant, or not abnormal/high. You can record the value given e.g. if it says <0.35, you can record 0.35. If you are unsure, get in touch with sbabu@cfri.ie for technical advice.

vi. Recording COVID-19 infections - to record positive covid tests, please use the microbiology section of the encounter form.
   a. Should there be a positive covid test noted on the patient's chart, please click that there was a culture positive result for pathogens.
   b. If you do not have the data of specimen collection, use the encounter date.

[2] Check on "Please indicate if the patient is currently pregnant" if the next encounter is less than 40 weeks (280 days). Please indicate if the patient's pregnancy outcome is a live birth.

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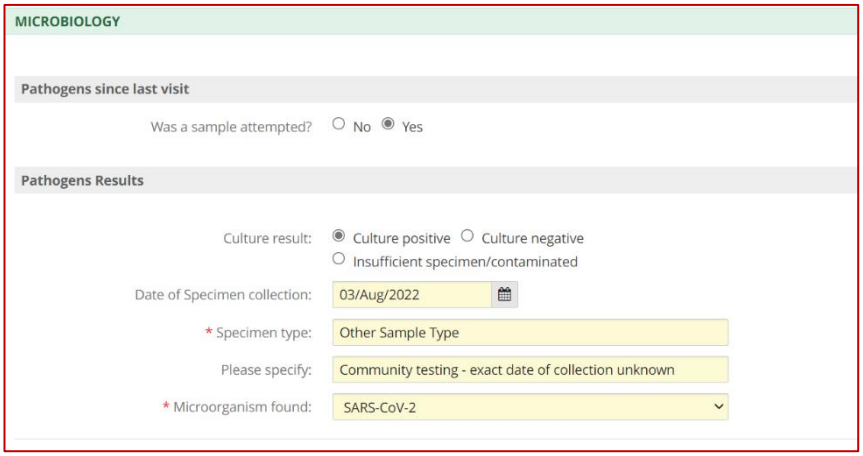
c. Log as 'Other Sample Type' in the drop down options and specify (as below) community testing & whether the date of collection was unknown.
d. Log SARS-CoV-2 as the microorganism.



Case studies

The following case studies illustrate complicated data entry situations you might come across and the resulting data entry solution. In many trickier situations, you may be required to use some personal judgement and discretion on what is the best course of action but of course, you can always consult with the SCRA/Head of Operations if you would like some advice.

9. Reference documents

a. CFRI site-specific data collection SOP
b. CFRI data dictionary
c. CFRI Tracker2 user SOP
d. CFRI consenting/reconsenting SOP
e. CFRI release form and data deletion SOP

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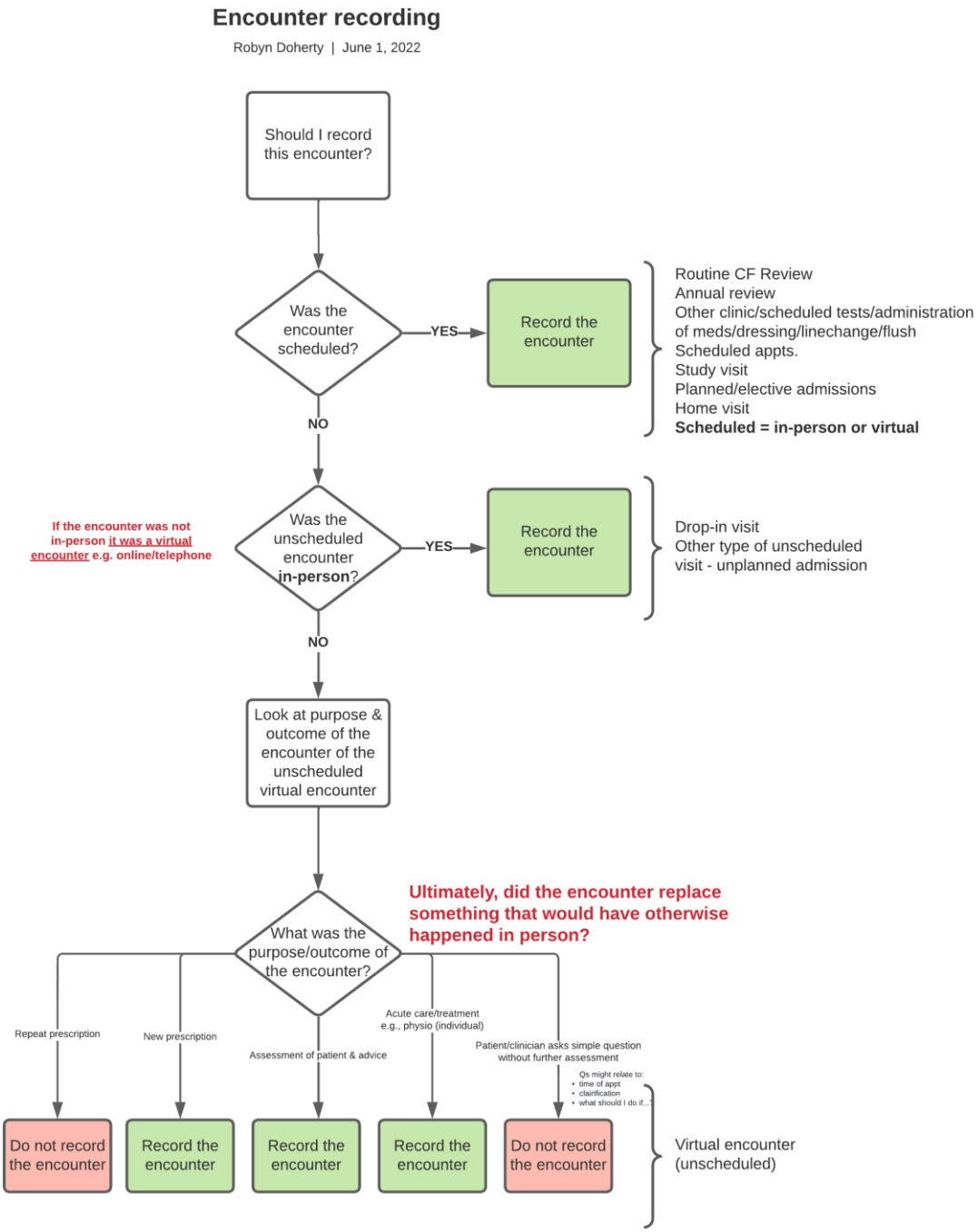
10. Appendices

Appendix 1 – encounter recording flow-chart



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11. Version history

Date	Version	Updates added
23/06/2022	V1.1	
07/07/2022	V1.2	
14/07/2022	V1.3	
14/09/2022	V1.4	Recording CFTRm pre-initialisation sweat test Recording COVID-19 infections Additional clarification on transferring patients Additional clarification on carry over variable functionality
23/11/2022	V1.5	Additional clarification on recording lab results using '<' symbols Additional clarification on recording encounter data retrospectively, despite date of consent

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