Clinical Research Support Office

CRSO Minimum Footprint Guidance to Study Teams

If you have questions about this document please contact us at CRSOstudyassist@uky.edu

This document only addresses clinical trials reported to EPIC that follow the CRSO scope of work

What studies need to be managed in OnCore?

All NIH-defined clinical trials conducted at UK must be entered into OnCore.

Note: This document is not a technical guidance to replace the OnCore targeted trainings and other SOPs issued by the CRSO/CTMS team. If you have questions about data entry components in OnCore, or other technical questions, please contact the CTMS support team at CTMS.support@uky.edu.

How are studies entered into OnCore? See below more detailed explanation

1. Summary Level – Accrual numbers entered quarterly, or accrual numbers entered one by one with limited demographic information
2. Milestone Subject Entry - Individual subjects and subject milestones/statuses are captured
3. Full subject management – milestone entry plus calendar visit check-ins

What studies need Coverage Analysis and billing review?

- All NIH-defined clinical trials entered into OnCore will need a Coverage Analysis (CA) and billing review
- All clinical research will need billing review if they meet the UKHC billing criteria – if the study would normally require a plan code for health care related services
- After the CA review, studies will be determined as qualifying or non-qualifying (to understand the difference please check the Final FAQs or contact us at CRSOstudyassist@uky.edu)
- All clinical research studies that contain UKHC billable items and services will go through a simplified billing process that does not require extensive data entry for subject management

Note: Studies at Markey Cancer Center that are fully observational or Non-NIH defined follow a separate process.

What studies need to be included in EPIC?

- Any Clinical research regardless if they meet the NIH definition of a clinical trial, which includes a prospective component with billable items**. Billable items** include any item/service:
    - provided by any healthcare professional (physician, nurse, technician and others) who may or may not be part of the study team, but will be rendering medical care (diagnostics, assessments, treatment, etc.) to patients as part of the study;

  - provided at a UKHC facility regardless of payer – this includes items such as labs or imaging services provided at UKHC and paid for by research funds
- Any study that requires **tracking of patients in** the electronic medical record (EPIC) – including registration process for study participants
- Any study that requires **Medicare Coverage Analysis – Check the CA FAQs or contact us at CRSOstudyassist@uky.edu if you are not sure**

How is it entered into OnCore

1. Summary Accrual Only (SAO)- This is an option for studies that do not meet the criteria for inclusion in EPIC. This includes studies that:
   - Are purely observational or data collection, with no services performed at UKHC facilities or by personnel for which the study has to compensate UKHC (i.e. studies that involve no billable items)
   - Meet the NIH-definition of a clinical trial, regardless of sponsor, but lacks the prospective component of billable items performed at UKHC or by a UKHC professional for which the study must pay to UKHC

   If your study meets the criteria for summary accrual, staff from the CRSO will contact you during the initial stages after your request is submitted.

2. Milestones - Limited subject data entry for flagging EPIC chart through RPE interface.
   Some studies meet the criteria for limited subject data entry in OnCore. These studies are NIH or federally funded and may or may not be qualifying for Medicare coverage. Some other studies funded by Cooperative Groups may apply the same exception. These studies will have calendars in some fashion (i.e., financial calendars for Non-Qualifying) but the teams will not be required to enter detailed visits in OnCore.
   Some Medicare qualifying studies with complex billing components, although funded by NIH or federally sources, may benefit from detailed subject visit data entry. The CRSO team will recommend this to you when processing your calendar and coverage analysis.

Note: Oncology studies at Markey Cancer Center may continue the detailed visit data entry regardless of funding.

Milestones subject entry – timeframe of 24 Hrs. for data entry: These studies will have a complete calendar and a coverage analysis; however, the subject data entry is limited to these milestones:

- **Consented:** Entered **within 24 hours** after subject signs consent
- **Eligible:** Date when PI determines the subject is eligible for enrollment into the study
- **On Study:** Subject is considered accrued when On Study date is entered in OnCore. Subjects may be moved to the On Study status once they have been formally registered/randomized or are otherwise considered evaluable per the protocol. This step typically occurs following verification of eligibility. For studies that do not include a "treatment", subjects will not be moved to the On or Off Treatment statuses. Instead, those subjects will remain On Study during the study participation/intervention period and then will move to an On Follow-up or Off Study status as appropriate.
- **On Treatment:** Subject is considered On Treatment when associated with a Treatment Arm and an On Treatment date is entered within the subject console.
- **Off Treatment:** An Off Treatment Date is entered for the subject. This date should reflect either the day after the last dose of therapy for subjects that complete treatment per protocol, or the

day that the decision is made to discontinue therapy. All subjects should be immediately moved into follow-up status or off study depending on the study.

- **On Follow-up:** An On Follow Up date is entered for the subject. All subjects in long term follow-up should be in this status. Typically, the On Follow-up date is the date after the subject's Off Treatment date.
- **Off Study:** An Off Study date is entered for the subject. This status is used when it is determined that no further interaction with the subject is required. You should confirm how long each subject is to be followed per protocol and their consent. If they are followed indefinitely, this date is only entered upon death (will populate automatically if you enter an expiration date), the subject withdraws from further follow-up, or the study is closed at the IRB (you will have to manually enter this date for all subjects).

3. Full Subject Management: To include milestone entry (as described above) PLUS individual subject calendar visit check-in
   - This level of build is required for All Industry sponsored studies and for studies, regardless of funding source, that have detailed budgets where payments are visit and/or procedure based
   - Each study visit, as defined in the protocol, will be marked Occurred/NA/Missed as appropriate for each subject's journey through the protocol timeline
   - Individual procedures performed at each visit will be listed and marked, as appropriate, with dates of service

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Some questions that may assist with understanding what studies are reported to EPIC:

- Are you enrolling/registering patients at any UKHC facility?
- Will this study require monitor visits for medical record review?
- Does the study contain billable items, services, or procedures? Billable items includes any services that maybe covered by the study but provided by UKHC (i.e. labs or blood draw)
- Is this study planning to use any UKHC facilities?
- Does the study include professional services billed through KMSF?