Notes About Data Migration

Contents:

Data Source

Data in Oncore is populated from several sources:

SCC DB
- most protocol details,
- documents,
- PRMC/QASMC reviews,
- Pre-MyIRB, NCI CIRB, and Affiliate IRB Reviews
- Screening and Registration Data

MyIRB
- IRB review data (except NCI CIRB)
- IND/IDE data – 1 entry/FDA issued number
- RC Upper Accrual Goal (number approved to consent)

AllScripts
- populates the subject selection feature

The data in Oncore is only as good as the data in the source!

If your data didn't exist in SCC DB or MyIRB, it will not exist in Oncore.
If you used SCC DB or MyIRB fields other than as intended, your data may not appear correctly in Oncore.

General Items

Status
All statuses are set based on the most current date of the related item. If a status is incorrect, check the associated dates.

Truncation
Some text fields in SCC DB are larger than the corresponding field in OnCore. Therefore, especially long text entries may have been truncated to fit the field.

Unknown Dates
If Oncore required a date that did not exist in the SCC DB or MyIRB, we used a business rule to populate a date.
For example:
Unknown submission dates = 1/1/1900
Unknown review date = review action date
Unknown pt. consent date = date of pt. registration
Unknown pt. off tx. date = pt. off study date

Protocol Items

Accrual Duration
The accrual duration field in SCC DB is free text and could not be translated to the OnCore field. The actual accrual duration was calculated for studies closed to accrual. Studies currently enrolling participants should complete the field.

Data Monitoring
Institutional, Primary studies will indicate either the PI or the QASMC as the responsible party for data monitoring. Cooperative Group and Industry sponsored studies will indicate that the monitoring is performed by an External entity.

Disease Site = Multiple Sites
Studies with a NCI Disease Site of Multiple Sites in SCC DB will not have any disease sites listed in Oncore. When enrolling subjects to these studies the CRA will "view all" disease sites and select the most appropriate for the participant. The PRMC will update the Protocol NCI Disease site at the time of renewal based on the sites selected for the study enrollments.

Investigational Drug/Device
These fields populate based on data from MyIRB and are tied to the IND/IDE tab. When marked 'Yes', the corresponding IND ID or IDE ID field becomes required. Note that this data is specific to the protocol, not the drug or device. Multiple drugs listed in MyIRB under a single IND# will populate a single IND record in OnCore.

IRB Reviews
- OnCore is integrated with the MyIRB system. When a review approval is released by the IRB, the review will populate in OnCore. The MyIRB reviews will indicate 'Approval Released' and the released date. IRB reviews migrated from the SCC will indicate 'Approved' and the approved date.
- Mod/CR reviews completed prior to the integration will appear as Mod/CR. Those completed after the integration will populate as individual Mod and CR events released on the same date.
- NCI CIRB reviews and IRB reviews from other institutions will need to be entered directly into OnCore by a Regulatory Coordinator

Multi-site studies

Each institution affiliated with a study will appear on the Institutions tab. The affiliation may be from IRB review data, enrollment data, or both.
The consent date for participants enrolled at an affiliated institution will only populate if that institution has IRB review data (see consent details above).

Participating Sites
Because a patient may be consented at any site, all WUSTL Study Sites will be active. If a study has limited locations for conduct of the study, those will be noted on the Protocol Annotation Form.

Pediatrics
- Studies were designated as including children based on a Pediatric Managing Group in SCC DB. Pediatric studies conducted in other managing groups will need to be marked as such in Oncore.
- Accruals at St. Louis Children's Hospital and the Children's Specialty Care Center will appear on accrual reports under the WUSTL institution.

Protocol Statuses
Though logical, Protocol Statuses in Oncore are different than those in the SCC DB. A couple specific differences include:
New – this status was created for Oncore using the PRMC submission date, the IRB submission date (for non-PRMC studies), or the OnCore go-live date for studies not yet submitted.
PRMC Complete – this status does not exist in OnCore. Instead, there is a Closure event under the PRMC review history.

Staff
Staff in the SCC DB are recorded in 2 places: on the Study Team tab and on each enrollment record. OnCore is similar with Protocol Staff and Subject Staff. The difference is that the Oncore Protocol Staff includes all members of the Subject Staff. The enrollment Data Managers in SCC DB will appear on the OnCore Protocol Staff as CRC – Secondary. The Registering MDs and Treating MDs will appear as Sub-Investigators. On the Subject Staff, these roles will appear as Registering Coordinator, Registering Physician, and Treating Physician.

Participant Items

Allscripts Integration
Patient demographics are populated into OnCore nightly. If you need to register a patient that you cannot find in the subject selection dropdown, submit a Manual Patient Registration Form to the OnCore Support Team (OST).
Do not add patient demographics directly into the OnCore system.

Consent Details
Oncore ties participant enrollments to IRB reviews through the Consent version.
Consent version data was not available for migration therefore a Migrated Consent was created. The Migrated Consent version date is the Action Date of the IRB review current at the time of the enrollment.

Eligibility Status
Participants marked as Screen Fail, but also registered to the study in SCC DB will have an Eligibility Status of Eligible (O).

Patient number
In Oncore, patients may be identified by a Sequence number. The Sequence number is a concatenation of the Protocol Pt. No. and the Record ID from the SCC DB. Additionally, the 'e' on the number indicates that the numbers are from an enrollment record, whereas an 's' references a screening record.