

1. OnCore CTMS Data Maintenance

Timely updates to trial data in OnCore are required for ensuring compliance with the Scientific Review Committee (SRC) Low Accrual Monitoring and avoiding erroneous notifications, probations, and closures. The following data fields are entered into the [OnCore Clinical Trial Management System \(CTMS\)](#) for all trials subject to SRC review.

- Protocol (Total) Target Accrual Goal
- Recruiting Center (RC) Total Accrual Goal
- Accrual Duration
- Recruiting Center Actual Accrual to Date
- Participant Statuses
- Current trial status and any temporary closure (Suspended status) and re-opened dates
 - **NOTE:** *Closed to Accrual is a permanent closure status and should not be used if the trial may re-open. Suspended is the correct status to use for temporary closures.*

IMPORTANT: The above must be updated within 1 business day of change or protocol modification

- Recruiting Center (RC) Annual Accrual Goal
 - **NOTE:** *This field is set by the SRC based on the accrual track and goal fields listed above. It cannot be changed by the PI or study team.*
- Accrual Track (conventional or alternative)
 - **NOTE:** *This is set by the SRC and cannot be changed without submission to SRC full review.*
- Earliest/original date Opened to Accrual

For more information on updating fields and statuses, please visit the [OnCore CTMS Documents and Video Site](#) or contact the CTMS Program Office at CTMS@fredhutch.org.

2. Accrual Expectations

The SRC is required to ensure that trials subject to their review accrue participants according to the guidelines in the [Low Accrual Policy](#). Trials that are Open to Accrual or Suspended and do not meet the expected enrollment per this policy will be reviewed and may be closed to further accrual. The annual accrual requirement is the value in the RC Annual Accrual field in OnCore and only Consortium participants with On Study dates are recognized as accruals.

Table 1 Minimum Annual Accrual Requirements for Trials

Accrual Track	Annual Accrual Requirements
Conventional	At least 50% of target accrual rate*
Alternative	At least 1
Exempt	0

* Annual accrual that does not meet or exceed the value in the RC Annual Accrual Goal field will require review.

In addition to the requirements in [Table 1](#), trials will be triggered for immediate closure if they do not meet the criteria outlined in [Table 2](#).

Table 2 Accrual Criteria for Trials Triggering Closure

Additional Criteria	Expected Accrual
Expected accrual 12 months after activation <i>Exempt: Alternative and Exempt Accrual Track trials</i>	At least 1
Expected annual accrual after two prior probations <i>Exempt: Exempt Accrual Track trials</i>	At least the minimum annual accrual requirement (Table 1)
Expected accrual at end of anticipated trial duration <i>Exempt: Alternative and Exempt Accrual Track trials</i>	At least 50% of target total accrual goal

Closures may be appealed once. Please see [Section 5, Closure and Appeals](#) and the [Low Accrual Policy](#) for requirements.

The assigned accrual track can be located in [OnCore](#). Navigate to the PC Console > Reviews > SRC.

3. Monitoring Schedule

Every year, after the trial has completed its annual monitoring period, it will be monitored for accrual progress. This schedule is tied to the original Open to Accrual status date in OnCore. Monitoring takes place after each open to accrual anniversary. For example, if a trial was first opened with an Open to Accrual date of 3/11/2020, the annual monitoring period will be from 3/11 to 3/10 every year. Participants with On Study dates that fall within this monitoring period will count towards that period's accrual.

In some cases, a trial may receive a review outside of this cycle, called a midcycle review. Midcycle reviews occur after the trial receives an SRC outcome of 6-month probation. The trial will be monitored six months after their open to accrual anniversary, *not* six months after the 6-month probation result letter date. If the trial receives a 12-month probation outcome during the midcycle review, the trial will return to its annual, open to accrual anniversary monitoring schedule described above. Midcycle reviews can also occur as part of a remediation effort, if it is found that a trial has skipped its scheduled monitoring date.

Prior to monitoring, the PI and study team will receive an emailed warning if their trial is at risk of closure or low accrual and the projected date of SRC review. At this time, it is important to review the Duration and RC Total Accrual Goal fields in the OnCore PC Console to ensure they are accurate and ensure your Protocol Status and Subject Accrual is up to date. OnCore updates and corrections must be made *prior to* the projected date of review in this warning.

At the time of monitoring, all trials will receive an OnCore notification alerting the PI, Research Group Director, and study team of this review outcome. If the outcome is approval, no response to the SRC is required. If the outcome is that a low accrual review is required, see [Section 4, Low Accrual Review](#). If the outcome is closure, see [Section 5, Closure and Appeals](#).

4. Low Accrual Review

If a trial has not met its expected enrollment per year (RC Annual Accrual Goal), a Low Accrual Notification will be released via emailed OnCore notification.

If the Accrual to Date in OnCore is not up to date, and you believe the trial met its expected enrollment per year (RC Annual Accrual Goal), ensure all data from [Section 1, OnCore CTMS Data Maintenance](#) is updated and provide a response in OnCore. Navigate to the Query Detail to reply that data was not updated on time and the trial may not be low accruing, then click "Respond." Accrual will be reevaluated and if the expected enrollment per year was met, no review is required. If the trial is still low accruing, a review is required.

IMPORTANT: Response to the Low Accrual Notification is required within 30 calendar days or the trial will be closed to accrual. Emailed and incomplete responses will not be accepted. PI Response must be submitted via OnCore Submission Console. No exceptions will be made.

The SRC requires the following:

1. Current trial protocol
 - a. The protocol should be added to the Documents section of the Low Accrual Review submission in the Submission Console **before** navigating to the Query Detail to respond.
2. [SRC Low Accrual PI Response Form](#)

IMPORTANT: If you believe the trial was incorrectly assigned to the Conventional Accrual Track at initial review, you can request an Accrual Track Determination review during the current Low Accrual Review. The request and justification must be clearly included in the PI response to the SRC.

The justification for being assigned the Alternative Accrual Track must include a statement of disease incidence (i.e., X/100,000). The trial must meet one or more of the following criteria:

- Disease incidence is equal to or less than 15/100,000.
- Disease is of uncommon clinical presentation (e.g., uncommon clinical subtypes of more common cancers).
- The trial involves narrow molecular subtypes.

Ensure the current protocol and [SRC Low Accrual PI Response Form](#) are uploaded to the Documents section of the Submission. The Query Detail will only allow one document to be uploaded; do not upload response documents there. Navigate to the Query Detail to reply that the required documents are added and click "Respond."

For assistance with uploading submission documents and replying to queries, please visit the [OnCore CTMS Documents and Video Site](#) or contact the CTMS Program Office at CTMS@fredhutch.org.

5. Closure & Appeals

If the SRC closes a trial to further accrual, this determination will be communicated via SRC Result Letter attached to an emailed OnCore notification.

The trial's initial closure may be appealed. Only one appeal will be accepted for each trial. Requests for expedited appeals will not be granted. Full committee review is required for all closure appeal reviews.

IMPORTANT: Closure appeals must be made within 30 calendar days. Only one closure appeal is allowed per trial and late requests will not be accepted. No exceptions.

Closure appeals must be made in the OnCore Submission Console using the Low Accrual Review submission.

Appeals require both the current protocol and the [SRC Low Accrual Closure Appeal Form](#) to be uploaded to the Documents section of the Submission. *For assistance with uploading submission documents, please visit the [OnCore CTMS Documents and Video Site](#) or contact the CTMS Program Office at CTMS@fredhutch.org.*

If the SRC finds the appeal appropriate, the trial will be reopened for accrual. This determination will be communicated via SRC Result Letter attached to an emailed OnCore notification. The CTMS office will update the OnCore status. Do not delete the Closed to Accrual status.

If the SRC does not find the appeal appropriate, the trial will remain closed to accrual with no further option to appeal. This determination will be communicated via SRC Result Letter attached to an emailed OnCore notification.

IMPORTANT: After a successful appeal, the CTMS office will update the trial status. Do not delete the Closed to Accrual status.

Please see the [Low Accrual Policy](#) for additional information on the closure process.

References

1. NCI/NIH: PAR-21-321 – Cancer Center Support Grants (CCSGs) for NCI-designated Cancer Centers
2. CC Plan: [Data and Safety Monitoring Plan of the Fred Hutch/UW/Seattle Children's Cancer Consortium](#)
3. CRS Policy: [CC.0003 SRC Low Accrual Policy](#)
4. CRS Template: [PRMS.0003 SRC Low Accrual PI Response Form](#)
5. CRS Template: [PRMS.0004 SRC Low Accrual Closure Appeal Form](#)
6. CRS Definitions Dictionary
7. [OnCore CTMS](#)
8. [OnCore CTMS Documents and Video Site](#)
9. [Cheng SK, Dietrich MS, Dilts DM. Predicting accrual achievement: monitoring accrual milestones of NCI-CTEP-sponsored clinical trials. Clin Cancer Res. 2011;17\(7\):1947-1955. doi:10.1158/1078-0432.CCR-10-1730](#)

Appendices

1. [Workflow to determine Accrual Track assignment](#)

Version Number	Current Effective Date	Original Effective Date
07	02/14/2025	07/01/2021

Appendix 1: Workflow to determine Accrual Track assignment

