About Accrual

Accrual is the total number of patients either currently enrolled or anticipated to be enrolled on the clinical study. Enrolled means a participant's, or their legally authorized representative's, agreement to participate in a clinical study following completion of the informed consent process. Potential participants who are screened for the purpose of determining eligibility for the study, but do not participate in the study, are not considered enrolled, unless otherwise specified by the protocol. For more information, refer to https://prsinfo.clinicaltrials.gov/definitions.html#IntEnrollment.

The CTRP Accrual application provides authorized members of the cancer research community with access to their clinical study registered in CTRP for the purpose of reporting accrual. It enables users to enter accrual based on the study category: *Complete* or *Abbreviated/Imported*. Only one type of accrual reporting is permitted per study. For information on these types, refer to CTRP Trial Categories, Study Sources or https://cancercenters.cancer.gov/GrantsFunding/eData#dt4.

The CTRP Accrual application, REST Services and Batch Upload allows users to report the following types of accrual data:

Study Type	Default Accrual Reporting Type
Complete Interventional	Subject
Complete Non-Interventional	Subject
Abbreviated/Imported Interventional	Summary
Abbreviated/Imported Non-Interventional	Summary

- Subject: Study subject level reporting of demographic data.
  - Subject accrual is expected to be reported for Complete studies, both Interventional and Non-Interventional, and is the default accrual reporting type.
- Partial Subject: Requires the reporting of Study Subject ID, Registration Date and Participating Site data only. The other accrual data elements are optional.
  - Partial Subject accrual was implemented for unique instances when full Subject/patient-level accrual reporting is not feasible.
  - The reporting of Partial Subject accrual on a Complete Interventional trial requires an approval request submitted to the CTRO (NCICTRO@mail.nih.gov).
  - Centers can change the default accrual reporting type on Complete Non-Interventional studies to Partial Subject within the Accrual application, as long as accrual has not been reported. If accrual has been reported, then the following actions are required:
    - Any previously reported accrual will need to be nullified prior to the change in accrual reporting type.
    - An approval request will need to be submitted to the CTRO (NCICTRO@mail.nih.gov) to change the accrual reporting type to Partial Subject.
- Summary: Total number (count) of study subjects accrued per site on a given study.
  - Summary accrual is expected to be reported for Abbreviated/Imported studies, and is the default accrual reporting type.
  - Centers can change the default accrual reporting type on Complete Non-Interventional studies to Summary within the Accrual application as long as accrual has not been reported. If accrual has been reported, then the following actions are required:
    - Any previously reported accrual will need to be nullified prior to the change in accrual reporting type.
    - An approval request will need to be submitted to the CTRO (NCICTRO@mail.nih.gov) to change the accrual reporting type to Summary.
  - The reporting of Summary accrual on a Complete Interventional trial requires an approval request submitted to the CTRO (NCICTRO@mail.nih.gov).
  - The reporting of Subject or Partial Subject accrual on an Abbreviated/Imported study requires an approval request submitted to the CTRO (NCICTRO@mail.nih.gov).

Refer to the following for required and optional accrual data elements: Accrual Data Elements with CTRP-Accepted Values for Complete Trials