

ASSIST User Guide

Editing Cumulative (Actual) Inclusion counts

There are two ways to edit the existing Inclusion Enrollment Report (IER) data for Cumulative (Actual) counts:

1. You can update the cells online in the existing report in the web form.
2. You can upload participant-level data using the **Upload Participant Level Data Attachment** button. This is required for some applications (see **Notes**).

Notes:

- If you plan to upload the data, you **must** use the provided template by clicking the **Download Participant Level Data Template** button. This downloads a CSV file that can be updated with new totals.
- Individual-level participant data on sex/gender, race, ethnicity and age at enrollment are **required** in progress reports for competitive applications submitted for due dates on or after January 25, 2019 (See NIH Guide Notice [NOT-OD-18-116](#)).

To use the template:

- Download the spreadsheet template for entering participant-level data by clicking the **Download Participant Level Data Template** button below the Cumulative (Actual) table. Fill the template with data for the study.
 - The columns in the template **should not be altered**; altering the format or category titles will result in an error during the uploading process.
 - Data may be copied/transferred into the template from another source or entered directly into the template.
- Once the new totals have been entered into the template and the file has been saved, use the **Upload Participant Level Data Attachment** button to upload the file which will update the Cumulative (Actual) counts in the online web form.

5.1.3.9 Participant Level Data Collection

Participant Level Data rules (including Age):

1. Participant level data collection will include one or more entries with 5 fields: Race, Ethnicity, Gender, Age, and Age Unit. Data can be uploaded as a CSV file through ASSIST UI, or submitted as XML through S2S.
 - Race, Ethnicity, Sex/Gender must contain valid values per OMB standards (consistent with Grants.gov form). For S2S these should be enforced in the XML schema. - (DAT attached)
 - Race values are:
 - American Indian
 - Asian
 - Black
 - Hawaiian
 - More than one race
 - Unknown
 - White
2. Age must be a whole number between 0 and 9999 (four digits). Valid Age Units are Minutes, Hours, Days, Weeks, Months, Years, Ninety Plus, and Unknown. If the Age Units are any value other than Ninety Plus or Unknown, an Age number is required. If Ninety Plus or Unknown is specified as the Age Unit, the Age number must be blank.

5.2 Export and Upload Data to ClinicalTrials.gov

Once clinical trial data has been entered, ASSIST provides options to export the data and/or to upload it to the ClinicalTrials.gov site. Click a link below for further information and instructions.

- [Export Human Subjects Data to an XML File](#) to your local drive
- [Upload an XML File to ClinicalTrials.gov](#) from your local drive
- [Upload Human Subjects Data Directly to ClinicalTrials.gov](#) (without having to export an XML file)

5.2.1 Upload Human Subjects Data Directly to ClinicalTrials.gov

NIH applicants/awardees can upload study record data available in the Human Subjects System (HSS) directly to ClinicalTrials.gov, thereby avoiding the need to re-key those clinical study fields at that site.