

Release v7.1 Collection of Pre-Treatment Adverse Events

March 24, 2021

Agenda



- Overview of the Pre-Treatment AE form
- Definition of a pre-treatment AE
- V7.1 ALS
- Persistent AEs
- Edit Checks

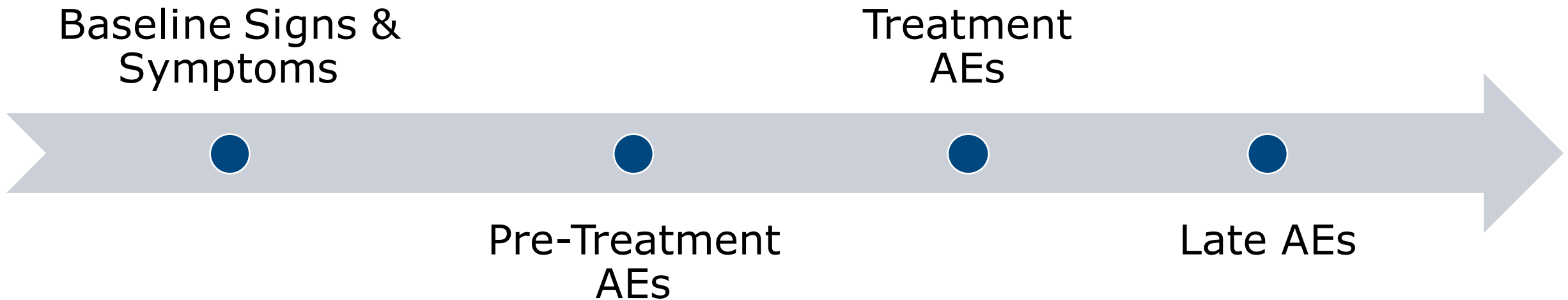
Overview

- › Pre-treatment Adverse Event (AE) form planned for inclusion in the next ALS release v7.1 (CTSUS_PAE)
- › The new AE form will be accompanied by an Expedited Reporting Evaluation form (CTSUS_PAER)
- › New studies will be built on the latest version of the ALS
- › Legacy studies will not be required to migrate to v7.1 ALS
- › If a legacy study wishes to use the pre-treatment AE form then the study must be migrated to ALS v7.1



Definition

- A pre-treatment AE is defined as any event starting after Informed Consent (IC) is signed and prior to the start of treatment.
- An event/condition with a start date prior to the study but continuing at the time the patient enters the trial will be considered baseline abnormalities or signs and symptoms.



Pre-Treatment AE form ALS

- › The CTSU_PAE form will look very similar to the Late AE form (CTSU_LAE) in terms of fields collected
- › Specifics of the CTSU_PAE fields are as follows:
 - TAC will be defaulted to a non-intervention value = TAC-0
 - Course/Cycle # = <Empty>
 - Course/Cycle Date = <Empty>
 - Study drug attribution = <NOT RELATED>



Persistent AEs: TBD

- › The Pre-treatment Adverse Event (AE) form will include the copy forward feature to capture AEs persisting into treatment (use for studies collecting start/end date).
- › More discussion is needed to develop reporting rules that can handle AEs that start while untreated and continue into treatment



Edit Checks

- › LPOs will be responsible for an edit check on AE start date to be certain the event begins on or after the IC was signed since the IC signature date is not included on a standard form that CTSU can access.
- › Nav package will roll the form out at the subject level upon patient initialization.

Note: The CTSU_PAE and CTSU_PAER forms will be included in their own folder named PRE-TREATMENT. Do not add these forms to a BASELINE folder that houses the baseline signs and symptoms form



Questions

