

Workflow Status

The following table explains the accepted definition and use of workflow statuses for data elements and other administered items.

Status	Definition
Draft New	Status assigned to new Administered Items created during protocol review or in response to another request. Changes do not require versioning of items.
Draft Mod	Status assigned to new versions of existing Administered Items created to accommodate and represent requested changes.
Released	Status assigned to new or modified Data Elements, and their associated Administered Items, that have been reviewed and approved by the owning Context's review process (by committee or other decision-maker). Released Administered Items must be fully specified and compliant with the ISO 11179 model and associated naming guidelines and conventions. Changes to Released items require adherence to versioning rules.
Retired Archived	Status assigned to old versions of Administered Items that have been replaced with new versions. Retired Archived Data Elements should not be used on future trials and should not be sent through the owning Context's review process again.
Release d-non-compliant	Temporary status assigned to Released Data Elements that are not fully specified or compliant with the ISO 11179 standards and guidelines; these Data Elements will be specified and assigned the Released workflow status.