

10.3 Entities and Elements

Entities and elements in OpenClinica use the same names as their counterparts in ODM. For example, the ODM definitions for study event and Study Event Definition are valid for the entities of the same name in OpenClinica (see Section 2.6, Entities and Elements, of the ODM specification):

- A *study event* is a reusable package of forms usually corresponding to a study data-collection event.
- A *Study Event Definition* describes a particular type of study event (mostly by listing the types of forms it can contain).
- The clinical data of a study will typically have many actual study events corresponding to each StudyEventDef,

Where the usage of these entity names in OpenClinica diverges from the ODM definition, it will be noted in this document.



Approved for publication by Cal Collins. Signed on 2014-04-02 2:56PM

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