Overcoming Challenges in Disposition Data Collection: Enable Flexibility and Design Thinking into data collector design


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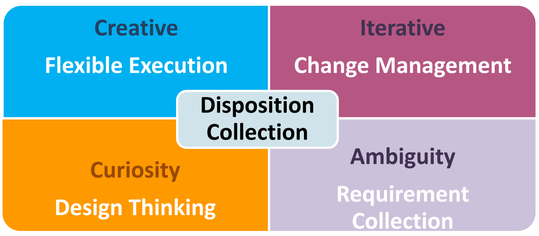
Abstract

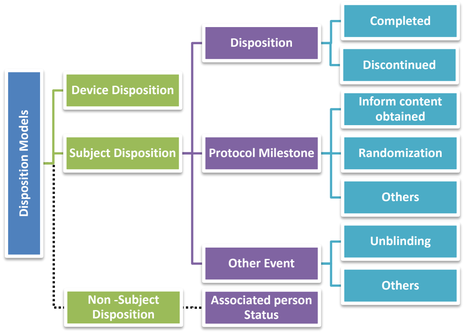
Disposition data collection in clinical trials presents challenges such as the need to meet the variable submission requirements, pandemic-related disruptions, and adherence to protocol requirements. It is important to explore the flexibility and design thinking in CDASH and SDTM for overcoming challenges in disposition data collection.

The DS domain and related models will be introduced. Several cases will show how to inject flexibility into data collection design. Robust design thinking enables to explore the ways in which CDASH and SDTM can be customized to fit the specific needs of each trial.



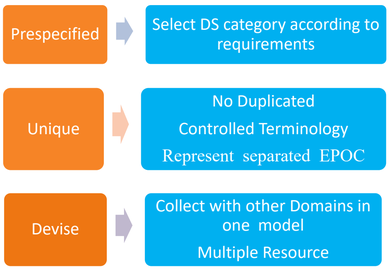
Disposition and Related Date Models

Disposition in a clinical trial refers to the outcome or status of a participant. It includes the reasons for early termination of participation, completion status, and any follow-up visits required. Disposition information is crucial for data analysis and interpretation, as it provides insights into the efficacy and safety of the investigational treatment.

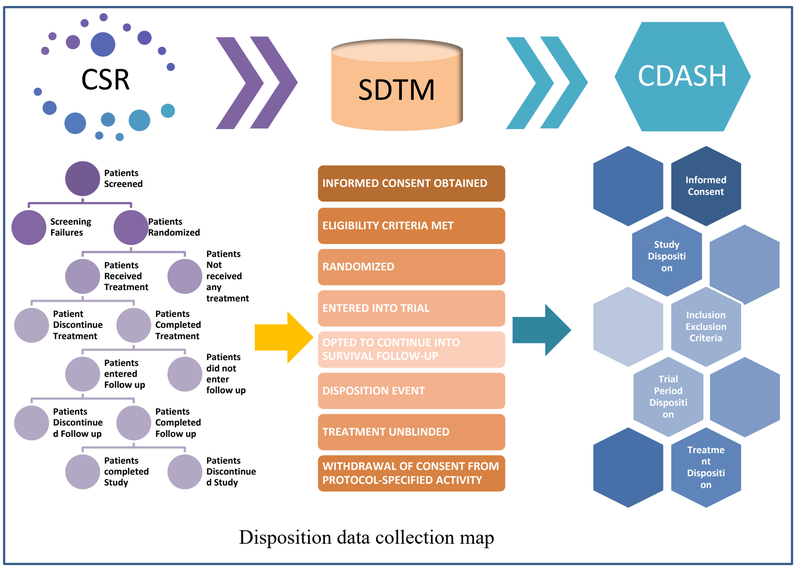


Case Sharing - Disposition Data Collection Map For Oncology Studies

Clinical trials for oncology drug involve complex design and gather comprehensive disposition data from trial participants which is crucial for accurate analysis and decision-making. We summarized the disposition data collection map using design thinking, Form data collected in CSR to SDTM Disposition variables then to CDASH data collection models, a clear identification of Disposition data and endpoint is made



Disposition data collection Design Principe



Disposition data collection map

Case Sharing - Additional disposition collection during the COVID-19 Public Health Emergency

Since the start of the COVID-19 pandemic in 2020, FDA has issued more than 80 COVID-19-related guidance. For all trials that are impacted by the COVID-19 public health emergency, a listing of all participants affected by the COVID-19 related study disruption by unique trial participant number identifier and by investigational site, and a description of how the individual's participation was altered.

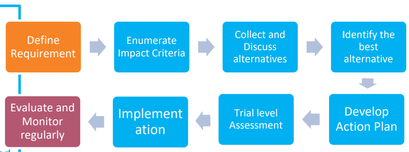
WHY-Need collect the COVID-19 related information

HOW-Create New CRF? Update existing CRF? Other source exEDC?

WHEN-Set up different target dates for different trials

WHAT-Components? Stakeholders? Possible implementation? Notes?..

1. Create eCRFs that contain Disposition information Only 1 new eCRF is included in appropriate trials
2. No other data collection impact for other eCRFs
3. No data will be re-entered

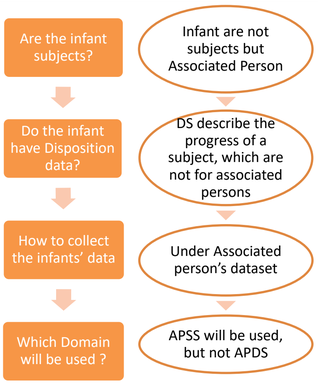


Agency: Revised or up version guidance and define a remain effective date

Sponsor: Retire temporary CRF and update existing CRFs appropriate for new trial

Case Sharing - Infant Status Data Collection in HIV Studies

In HIV Studies, when a subject becomes pregnant, she is permitted to continue treatment during the whole pregnancy phase. Infant safety data collection provides the ability to monitor growth of the infant as well as potential adverse effects that may be associated with prenatal drug exposure. In the infant follow up visits, if the infant complete the follow up visit, and the reason for uncompletion needs to collected



Associated Person

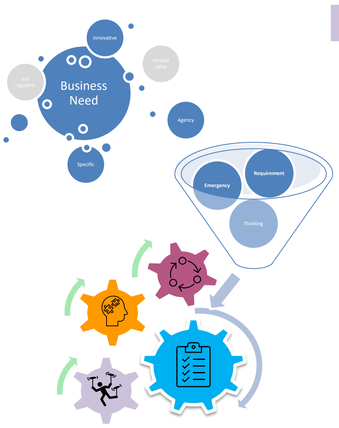
- ❑ Associated persons are not subjects in the trial
- ❑ The data are about the Associated Person, not the subject
- ❑ The associated person does not have a subject identifier (SUBJID).

Align with Industry Guidance, especially for the new guidance

Domains which describe the progress of a subject through a study are not relevant for associated persons

Flexible design for associated person, using dynamic visit

Summary for Disposition Design Thinking



Requirement Collection

- Agency or Industry requests to collect.
- *Protocol Specific data which will support analysis or monitoring, such as TAETORD will be used for the muti-dose vaccine.*

- Additional collection Requirements brought about by emergencies
- Standard updates brought by regular iterations

Design Thinking

- Characteristics of the disposition data
  - Unique
  - Prespecified
  - Time-sensitive
  - Integrity
- Compliance and Rationality
  - Data Protection
  - Clinically Appropriate
  - Analysis Needs
- Relevant deliverables
  - Data Validation Tool
  - Data Entry Guidance

Flexible Execution

- Align with Industry Guidance/Regulations
  - Include required variables in DS domain
  - Keep discontinuation reason unique and standard which may clarify the appropriate population
  - Provide a clear accounting of all patients who entered the study
- Provide additional element to support analysis which may identify a specific period within a trial
- Create reliable deliverables
- Flexibility for uncertain or complex situations

Change Management

- Regular Evaluation
- Change Requirement Collection
- Discussion for impact across different functional teams
- Select preferable change plan
- Change confirmation and document appropriately