

# CDASH from the Operational Data Modeling Team (ODM) and Controlled Terminology Perspective

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# Agenda

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- Introduction to CDASH-ODM team work
  - ODM basics
  - Terminology basics
- CDASH in ODM team's process & results
  - CDASH-ODM CRF/eCRF examples
- Lessons learned
- Conclusion



# Introduction to CDASH-ODM team work

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- Mandate: To use CDASH v1.0 to develop and Publish **Machine-Readable** Metadata (CDASH-ODM)
- Constraints:
  - CDASH v1.0
  - ODM (Operational Data Model)
  - CDISC Terminology



# ODM (Operational Data Model)

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## Operational Data Model (ODM)

- The XML-based content and format standard for the acquisition, exchange, reporting or submission, and archival of case report form (CRF)-based clinical research data.



# ODM (Operational Data Model)

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The CDISC ODM is designed to:

- Facilitates clinical data interchange and archive
- Meets regulatory requirements for electronic data handling
- Leverages existing standards (XML)
- Encourages uptake of new technologies
- Works with a wide variety of vendor specific systems



# ODM (Operational Data Model)

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- **Data** - Representations of facts, concepts, or instructions in a manner suitable for communication, interpretation, or processing by humans or by automated means.
- **Metadata** - Data about data
- **Metadata Elements** - The metadata of a study describing the types of study events, forms, item groups, and items that are allowed in the study.



Variable Name	Variable Label	Type	Examples
001001	Study Identifier	Char	Unique identifier for a study within the sponsor's portfolio
001002	Study Description	Char	Text description of the study for the sponsor which may be "CDASH"
001003	Study Subject Identifier	Char	Unique subject identifier within the sponsor
<b>Study Events</b>			
001004	Study Identifier for the Event	Char	Subject identifier used within the study as collected on CDASH
<b>Timing Variables</b>			
001005	Subject Reference Start Date/Time	Char	Reference Start Date/Time for the subject in ISO 8601 standard format (Locally equivalent to date base when subject has first exposure to study treatment)
001006	Subject Reference End Date/Time	Char	Reference End Date/Time for the subject in ISO 8601 standard format (Locally equivalent to date base when subject has last exposure to study treatment)

Study Data  
Tabulation Model  
Submission



CDASH Content  
Clinical Context



Terminology  
Codelists

```
<ODM>
  <Study>
    <Meta...
    </Meta...
  </Study>
</ODM>
```

CDASH - ODM  
Form

```
<GlobalVariables>
  <StudyName>CDASH Test Study
  <StudyDescription>Study to demo
  <ProtocolName>CDASH Example
</GlobalVariables>
<BasicDefinitions>
```

Operational  
Data Model  
Database Content  
and Structure



Presentation  
Extended ODM



Best Practice  
Modelling  
Structure

# CDISC Terminology

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The controlled standard vocabulary and code sets for the all CDISC models/standards

<http://www.cancer.gov/cancertopics/terminology/resources/cdisc>



# CDISC Terminology Guiding Principles

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- Adopt...Adapt...Develop Philosophy
- Evaluate and/or utilize existing terminology first
- Expand existing vocabularies where incomplete, working with vocabulary developer / owner
- Harmonize across CDISC Models and with pre-existing vocabulary initiatives



# CDISC Terminology Sample Codelist (SDTM & CDASH – VSPOS, EGPOS / HL7)

## Standard Terminology Codelist

*CDISC  
Controlled  
Terminology*

- Sitting
- Prone
- Standing
- Supine
- Fowlers
- Semi-Fowlers
- Trendelenburg
- Reverse Trendelenburg
- Right Lateral Decubitus
- Left Lateral Decubitus



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# CDASH-ODM team work started May '08

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- **Participating Companies**

- InterMune, Formedix, Quintiles, Shire, Schwartz Pharma, Outcome, AstraZeneca, eLilly, Metadata, ERT, XClinical, IPL, Octagon Solutions, CDISC, Cerner, Greenway, PRA Intl., GSK, Forrest Laboratories, Genzyme - ODM/Core

- **Initial Scope: CDASH DOMAINS**

- AE, Prior & Concomitant Meds, and Demography

- **Initial Deliverables: Feb/March 2009**

- Metadata tables
- Form representation (CRF)
- CRF with database annotation with CDASH alias
- Published ODM files



# CDASH-ODM project plan



- **Set 1**
  - Adverse events, Con Meds, Demographics, Common ID & Timing Variables
- **Set 2**
  - Vital Signs, Medical History, Substance Use, ECG & Lab
- **Set 3**
  - Subject Characteristics, Inc./Exc. Criteria, Disposition, Exposure, Protocol Deviations and Physical Exam



# Steps

- Started with CDASH variables for given domain/form
- Included “best practice” examples for CDASH and for ODM implementation
- Excluded many (but not all) “Optional” variables from example
- Built form... reviewed form... revised form (both eCRF and CRF)



# Examples

- The CRF and eCRF examples were published as HTML and converted to PDF for publication in the CDASH v1.1 User Guide.
- The ODM template was published as HTML (as well as in XML) and converted to PDF.
- The ODM and CRF examples were combined into one PDF file (PDF portfolio).







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# Team approach found and resolved:

- ODM ties metadata to data... CDASH/SDTM sometimes separates them
- ODM expects one datatype per variable... sometimes the datatype is dependent on the question asked, not the variable that's holding the data. The result might be text or numeric, but it would depend on the question
- We each have our own expertise... use your experts well!



# Team approach found and resolved:

- Consensus approach worked well but it took time.
- Assumptions needed to be made, depending on the domain and the variable. Examples were created that demonstrated different assumptions (ODM use of units as a metadata component of the result variable vs. separating the results and associated units into two different variables.)



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# Conclusion

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- ODM can be a very useful standard for implementing the CDASH data collection standard. It is powerful and captures all of the data and metadata in a way that meets regulatory needs.
- Understanding ODM and CDASH is helpful to get the full benefits of both standards and additional benefits from their integration.



# Thank You

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