CDISC ADaM Datasets - from SDTM to submission

CDISC Experience Exchange and ADaM Workshop
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Summary

- Background
- ADaM datasets
- Process
- Conclusions

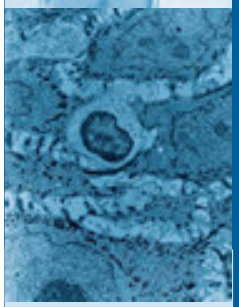
Project Background

- Therapeutic area – dermatology – psoriasis
- Baseline, Efficacy, Safety data
- Categorical & continuous efficacy data
- Imputed values for missing data

Project

- 16 phase 1, 2 and 3 studies
  - Baseline and safety – 16 studies
  - Efficacy – 7 studies
- 4500 patients
- Majority of studies already reported from non-ADaM datasets
- Some ongoing studies still to be reported
- Data Management provided SDTM datasets



ADaM Dataset Planning

ADaM guidelines

Previous ADaMs

New Thinking

Practical Use

ADaM Specification

ADaM Specification Example

ADSL: SUBJECT LEVEL ANALYSIS DATASET [ADSL.xpt]
1 record / USUBJID

Variable name	Label	Type	Format (codes)	Origin	Role	Comments
STUDYID	Study Identifier	Ch		DM.STUDYID	Identifier	
USUBJID	Unique Subject Identifier	Ch		DM.USUBJID	Identifier	
RAND	Randomised Population Flag	Ch	Y or N	Derived from SUPPQUAL.QVAL (where QNAM=RAND)	Selection	
SAFETY	Safety Population Flag	Ch	Y or N	Derived from SUPPQUAL.QVAL (where QNAM=SAFETY)	Selection	Study XXX flag is for Induction Phase
TRTSTDT	Start Date of Treatment	Dt		Derived from EX.EXSTDTC	Timing	Converted to SAS date
AGEGRP	Age Group	Ch	≤35 36-50 51-64 ≥65	Derived from DM.AGE	Results Qualifier, Analysis	

ADaM Datasets

- Approx. 100 study ADaM datasets
- Datasets relevant to each study

ADSL **Disposition** **4 Efficacy**

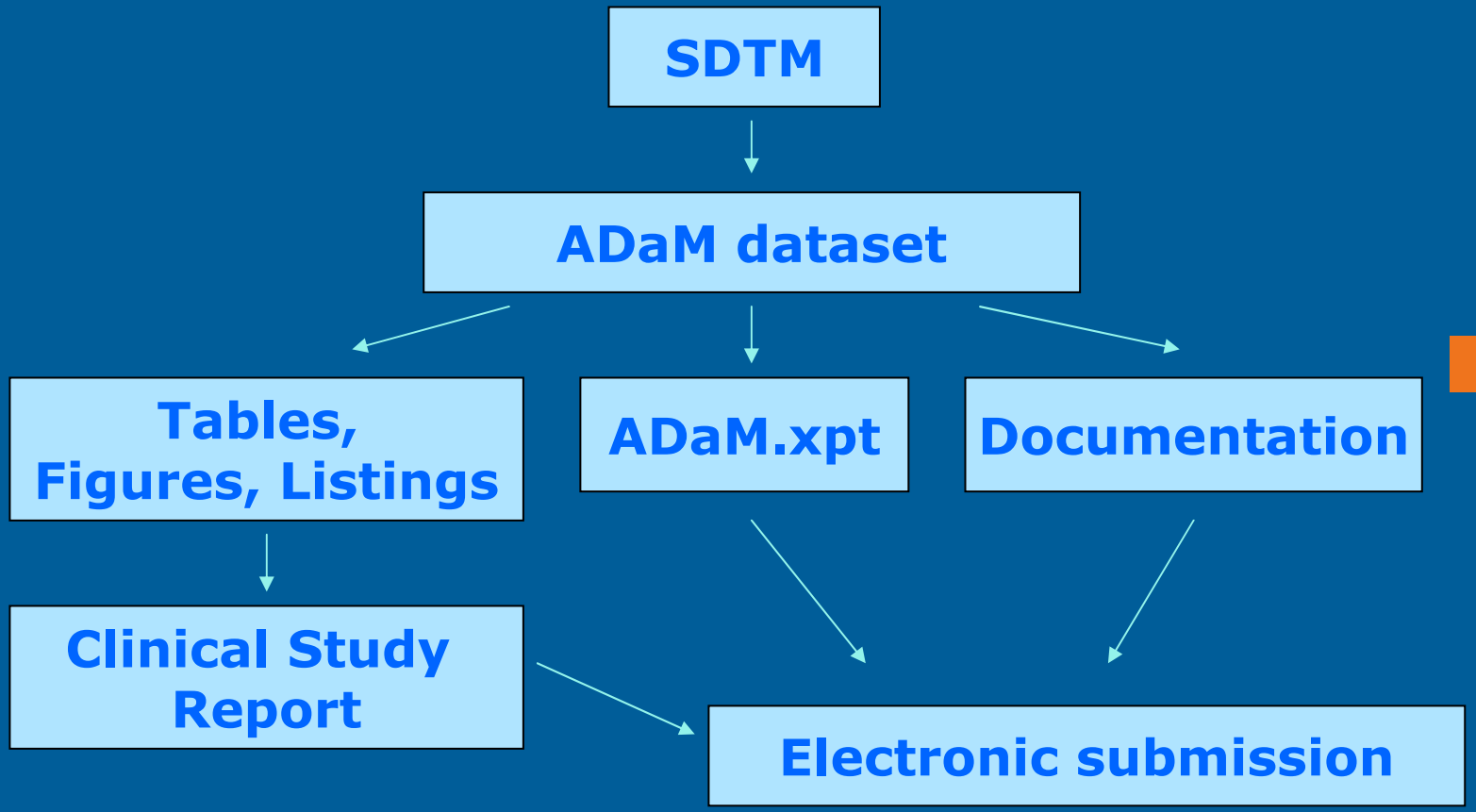
3 Adverse Event **Labs** **Vital Signs**

Drug Acc. **Exposure**

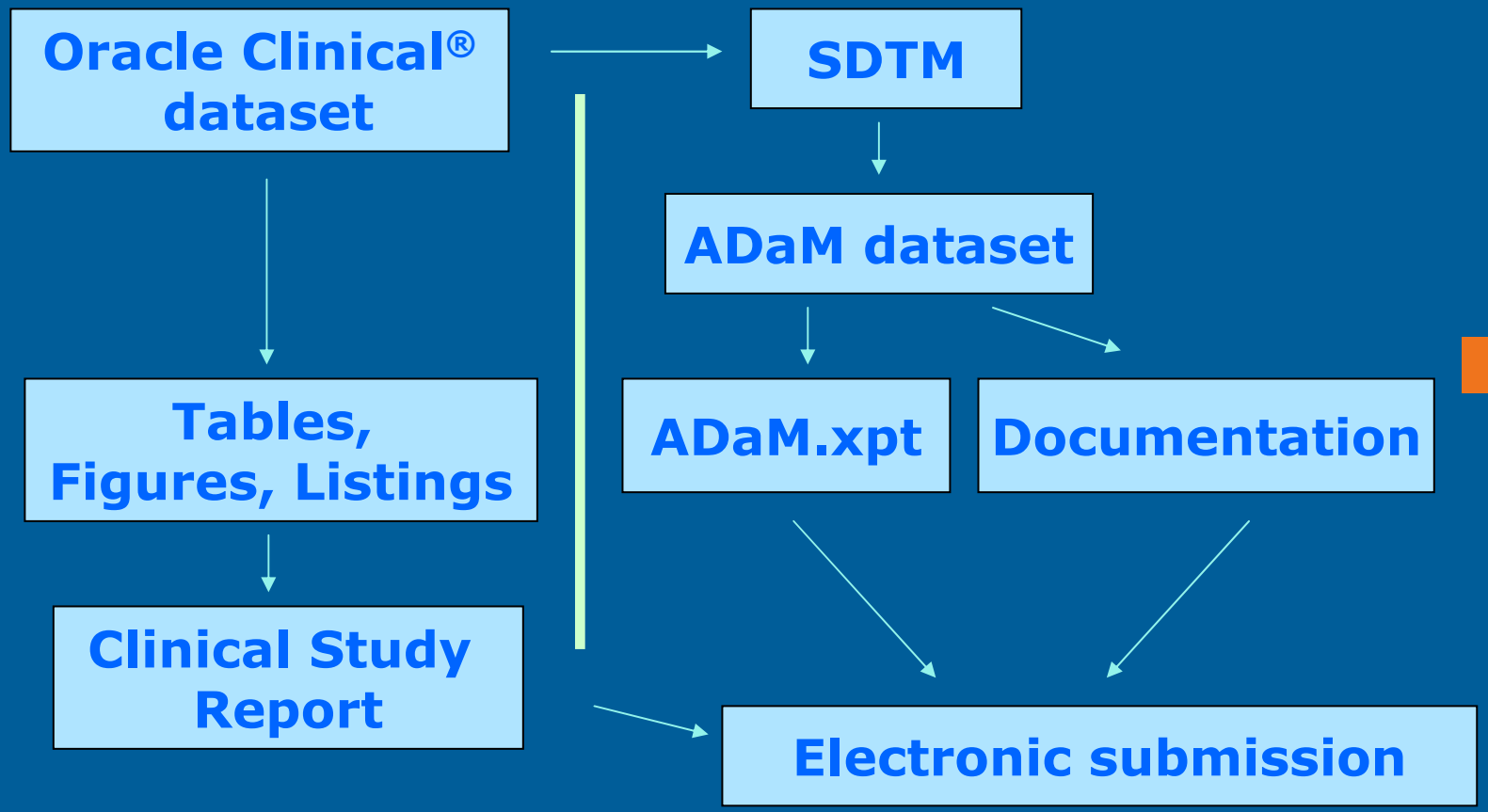
Considerations

- Order of variables
- Flags
- Missing values
- Dependencies between datasets
- >1 record per patient
- One or many datasets
  - Efficacy/adverse events
- ‘Analysis ready’ / ‘One proc away’

Process – Ongoing Studies



Process – Conversion



Pooled ADaM Datasets

- 13 pooled ADaM datasets
- Data from each relevant study

ADSL **Disposition** **Efficacy**

Adverse Event **Labs**

Drug Acc. **Exposure**

Pooled Data

ADaM – study 1

ADaM – study 2

ADaM – study 3

ADaM – study n

Pooled ADaM

ADaM – S1
ADaM – S2
ADaM – S3
.
.
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ADaM - Sn

Added Variables

Tables/Analysis

Documentation

Clinical Summaries

Electronic submission

Development

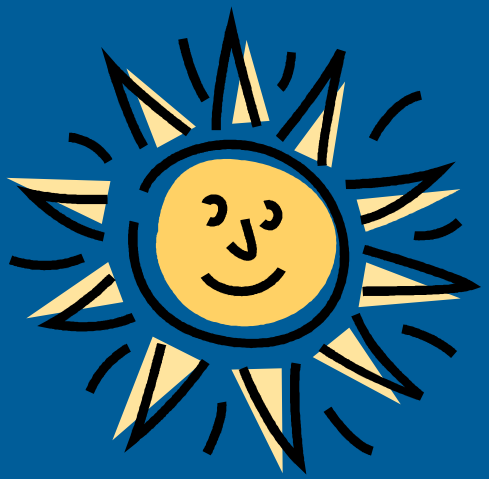
- Great to have new version of ADaM guidelines
  - More specific
  - Hopefully easier to implement
- Creating Global Library for Metadata instead of specifications
  - Use across projects
- Standard
  - Programs/macros
  - Process
  - Training

  to support new process

Challenges

- SDTM/ADaM format new
  - Learning curve
    - Concept
    - Terminology
    - Documentation
  - Variation in interpretation
- Need to use ADaM format?
  - Additional work
- Studies already reported
  - Additional work/QC

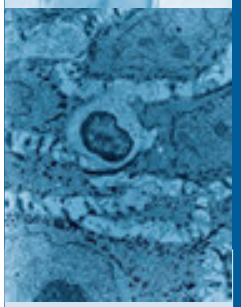
Benefits



- Familiarity with CDISC
- Sceptics became converts
- Pooled data more straightforward
- Use of ADaMs now accepted as standard
  - Submission ready data

Conclusions

- CDISC ADaM format usable
- Accepted by FDA – now requesting them
- Quicker implementation -> less work in future
- ADaM is a different data format which can be used as well as any other – need to manage the change



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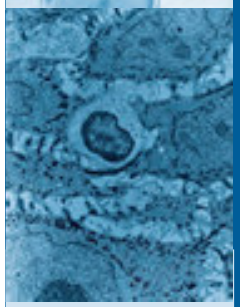
Questions

LEO

research based, people driven



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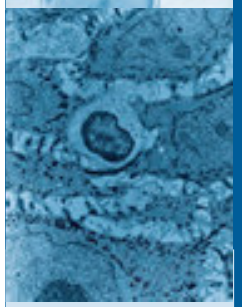

Facilitated Discussion

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research based, people driven

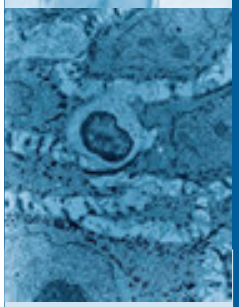
Individuals (5 minutes)

- Beginners
  - List main (suggest 3) items that you (your company) require to be able to start using ADaM.
- Users
  - List main (suggest 3) items that you (your company) require to be able to take use of ADaMs forward.

Table Discussion (10/15 mins)

- Pool/discuss items to create pooled list
- Identify the most common





Group Discussion (20/25 minutes)

- Take most common issues in turn from each table for discussion

FDA experience (15 mins)

- Any discussion with FDA
  - Prior to submission
  - After submission
- Requests
- Feedback