Boehringer Ingelheim

PhUSE Single Day Event 2009
Brussels 2009-04-02

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Implementing CDISC at Boehringer Ingelheim

CDISC – Impact

Boehringer Ingelheim

2004 – 07 – 21

B.C.

Before CDISC

According to CDISC

Agenda

- **Motivation and Target**
- **Approach: Design Example**
- **Results: Enhancing SDTM**

Motivation

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- Issue:
  analyses on pooled databases (PDB) are increasing

- Need:
  all clinical data of a project/substance available in one standardized structure for all clinical data

- Task:
  investigate the CDISC data standards
  for usability for analysis & reporting

Motivation

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1) need for efficient pooled databases (PDB)

2) need to submit data in CDISC standard

Implementing CDISC at BI

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Target

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design and implementation of a

CLINICAL DATA MODEL

based on CDISC principles

Target

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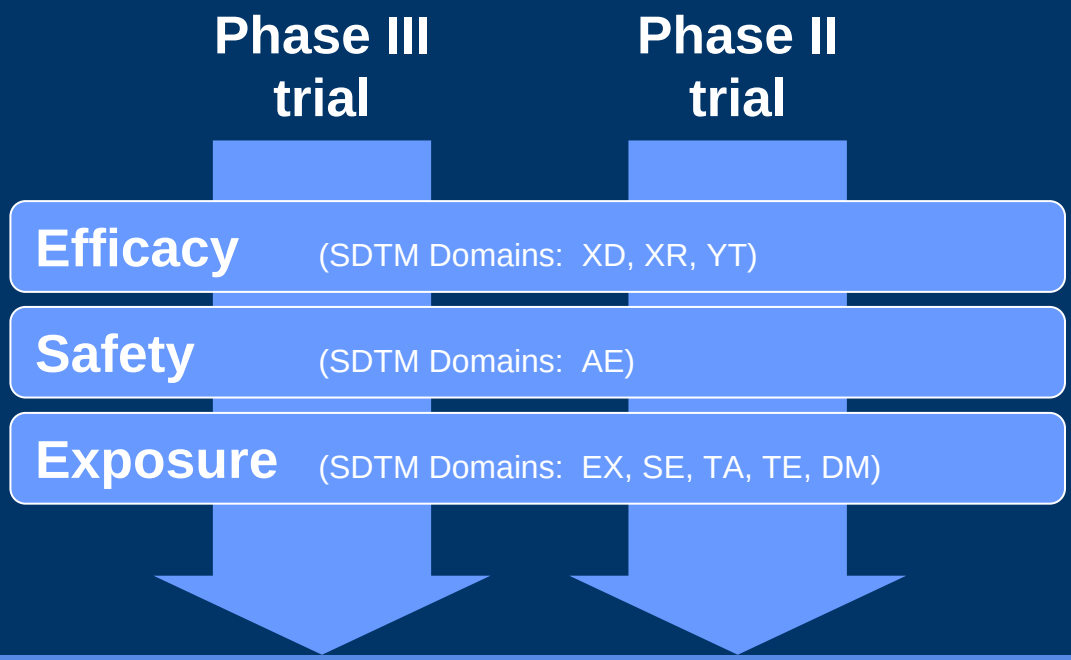
CLINICAL DATA MODEL

- corporate wide
  across trials, projects, substances
- integral part of the in-house clinical data business process
- operational for single trials and pooled databases (PDB)
  - data quality check
  - Analysis Data Set (ADaM / ADS) creation
  - ad hoc analysis
- CDISC principles of SDTM, ADaM, ODM, CT

Agenda

- Motivation and Target
- **Approach: Design Example**
- Results: Enhancing SDTM

Design Example - Objective



XD – Diagnostic Assessments
XR – Central Assessments
YT – Bleeding Events
AE – Adverse Events
EX – Exposure
SE – Subject Elements
TA – Trial Arms
DM – Demographics

test operability of CDISC SDTM

Design Example - Methodology

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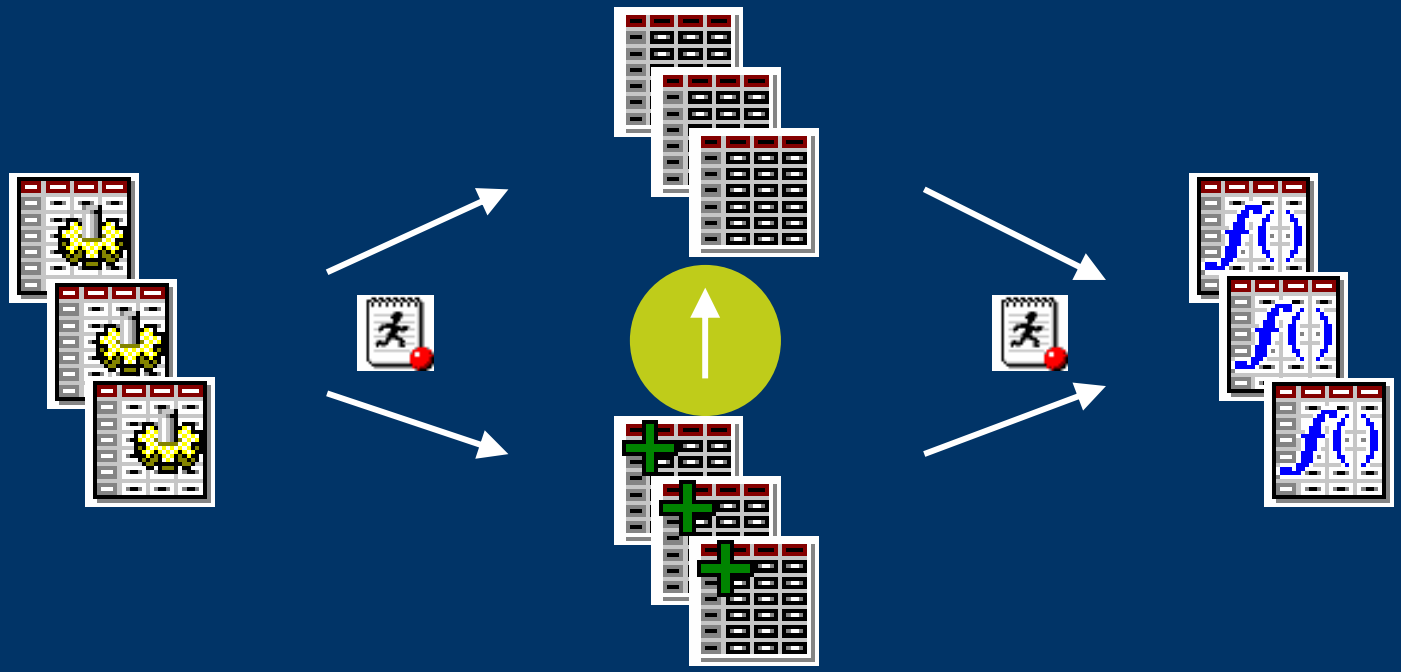
O*C views

SDTM / SDTM+

Analysis Data Sets



➔ detailed comparison SDTM vs. SDTM+

➔ analyse transformation SDTM+ to SDTM

Strive for the Goal

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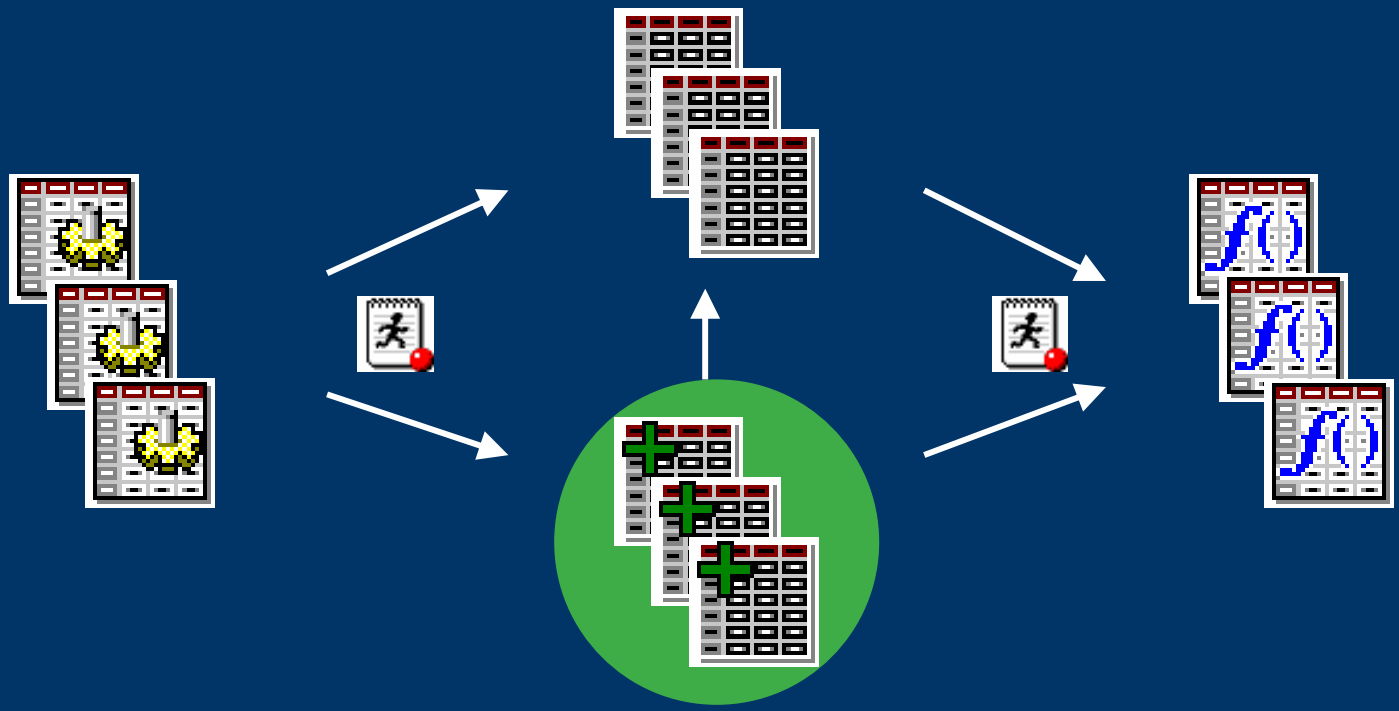
O*C views

SDTM

Clinical Data Model

Analysis Data Sets



Agenda

- Motivation and Target
- Approach: Design Example
- **Results: Enhancing SDTM**

Identified Plus +

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Topic	SDTM	SDTM +
NUM – CHAR	CHAR variables in general **Example:** --ORRES	have: - CHAR - NUM variables **Example:** --ORRES + "--ORRESN"
Code – Decode	only Decode (CHAR)	have: - Code (NUM) - Decode (CHAR) - associated SAS format
dates / times	all dates are CHAR (ISO8601)	have: - ISO8601 dates (CHAR) and - SAS dates (NUM)
date / time imputation	reported date / time (ISO8601)	have: - reported date / time - imputed date / time - imputation rule
Missing SDTM definitions	no definition for some BI-variables **Example:** TSORT - treatment sort order	t.b.d. - keep as plus variables, or - modify reporting tools

Identified Plus +

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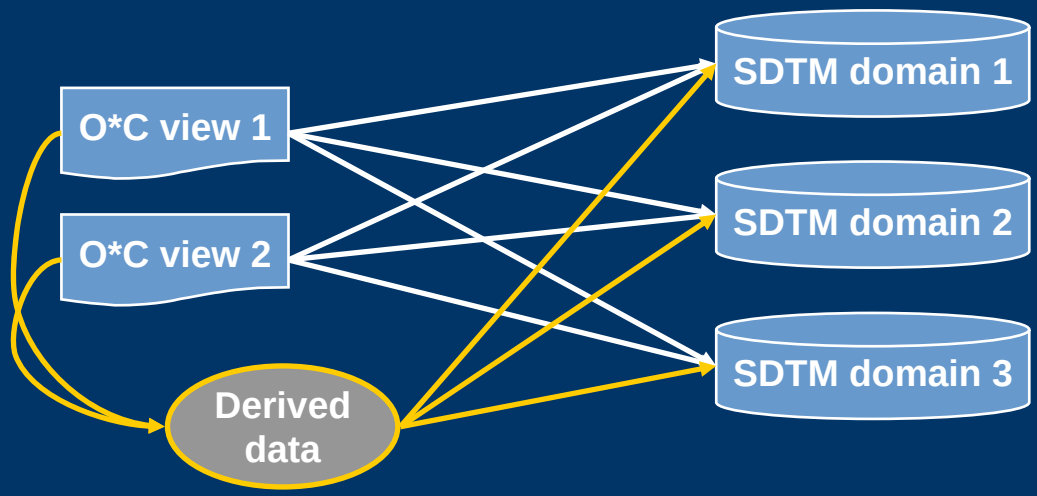
Topic	SDTM	SDTM +
No SUPPQUAL	- Parent Domain and - SUPPQUAL Domains	No SUPPQUAL, include in Parent domain Additional metadata (variable) required to flag qualifier information destined to SUPPQUAL
Tracking of same patient in multiple trials	no place for: - Previous Trial No. - Previous Patient No.	- Main + Follow-Up Trial No. - Main + Follow-Up Patient No. needed for - reporting and - to facilitate pooling
Key concept	STUDYID USUBJID DOMAIN --SEQ --GRPID --REFID --SPID only relate to SUPPQUAL, CO, RELREC	Keys to be defined based on clinical content to provide relationality across domains

Mapping: O*C ➔ SDTM



no 1:1 relationship CRF/O*C : SDTM domain

➔ carefully define mapping rules

Additional Results

- Variable renaming is exception - rule is complex transformations
- CDISC SDTM does not cover all analysis & reporting relevant data
  - → additional records e.g. IE
  - → additional domains e.g. efficacy

CT - Controlled Terminology

- consistency between variable and content
- pooling requirement
- CDISC CT does not provide sufficient cover yet

→ define BI CT to comply with CDISC CT

→ consolidation of existing GLIB formats

Impact on …

Overall Risks and Benefits

- Risks
- Benefits

… Processes, Systems

- Clinical Data Flow
- Systems (O*C, LSH)
- External Data
- Legacy Data

… Resources, Commitment

- other BI Initiatives
- Effort and Cost
- Organisation

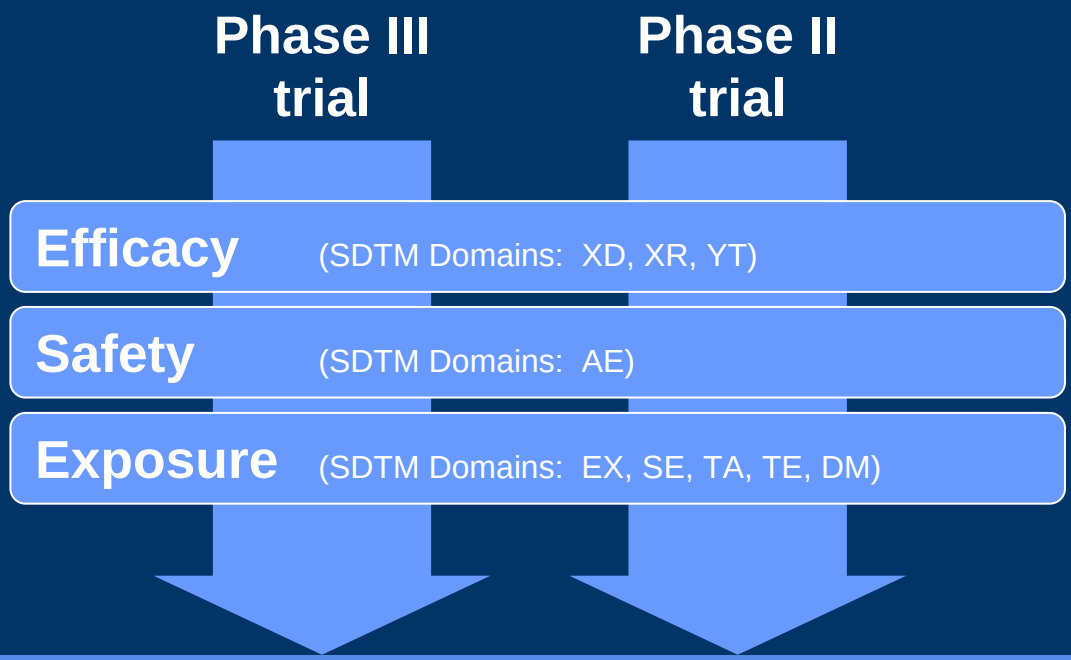
… Compliance

- Functions / Roles
- SOPs and Guidelines
- Training
- Validation

… Current Standards

- Current Standards
- Global Library
- Macros

Design Example - Objective



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test operability of CDISC SDTM

Operability of CDISC SDTM ?

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	SDTM_1	SDTM_2	SDTM_3	SDTM_4	PLUS_1	PLUS_2	PLUS_3	PLUS_4	PLUS_5	PLUS_6
1	SDTM	SDTM	SDTM	SDTM	+	+	+	+	+	+
2	SDTM	SDTM	SDTM	SDTM	+	+	+	+	+	+
3	SDTM	SDTM	SDTM	SDTM	+	+	+	+	+	+
4	SDTM	SDTM	SDTM	SDTM	+	+	+	+	+	+
5	SDTM	SDTM	SDTM	SDTM	+	+	+	+	+	+
6	+	+	+	+	+	+	+	+	+	+
7	+	+	+							
8	+	+	+							
9	+	+	+							
10	+	+	+							
11	+	+	+							
12	+	+	+							

	PLUS_11	PLUS_12	PLUS_13	PLUS_14	PLUS_15	PLUS_16	PLUS_17	PLUS_18
1	+	+	+	+	+	+	+	+
2	+	+	+	+	+	+	+	+
3	+	+	+	+	+	+	+	+
4	+	+	+	+	+	+	+	+
5	+	+	+	+	+	+	+	+
6	+	+	+	+	+	+	+	+
7	+	+	+	+	+	+	+	+
8	+	+	+	+	+	+	+	+
9	+	+	+	+	+	+	+	+
10	+	+	+	+	+	+	+	+
11	+	+	+	+	+	+	+	+
12	+	+	+	+	+	+	+	+
13	+	+	+	+	+	+	+	+
14	+	+	+	+	+	+	+	+
15	+	+	+	+	+	+	+	+

Benefit of Enhanced SDTM

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Clinical Data Model

- creation of pooled databases (PDB)
- facilitate analysis & reporting

The Goal

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O*C views

SDTM

Clinical Data Model

Analysis Data Sets