SCHERING
making medicine work

CDISC SDTM and Controlled Terminology
A pharmaceutical industry perspective

Dr. Andreas Gromen

TMF e.V. CDISC Workshop
Berlin, July 01, 2005

Contents

Part I

Global Data Dictionary (SCHERING Standard)

Part II

Study Data Tabulation Model (CDISC)

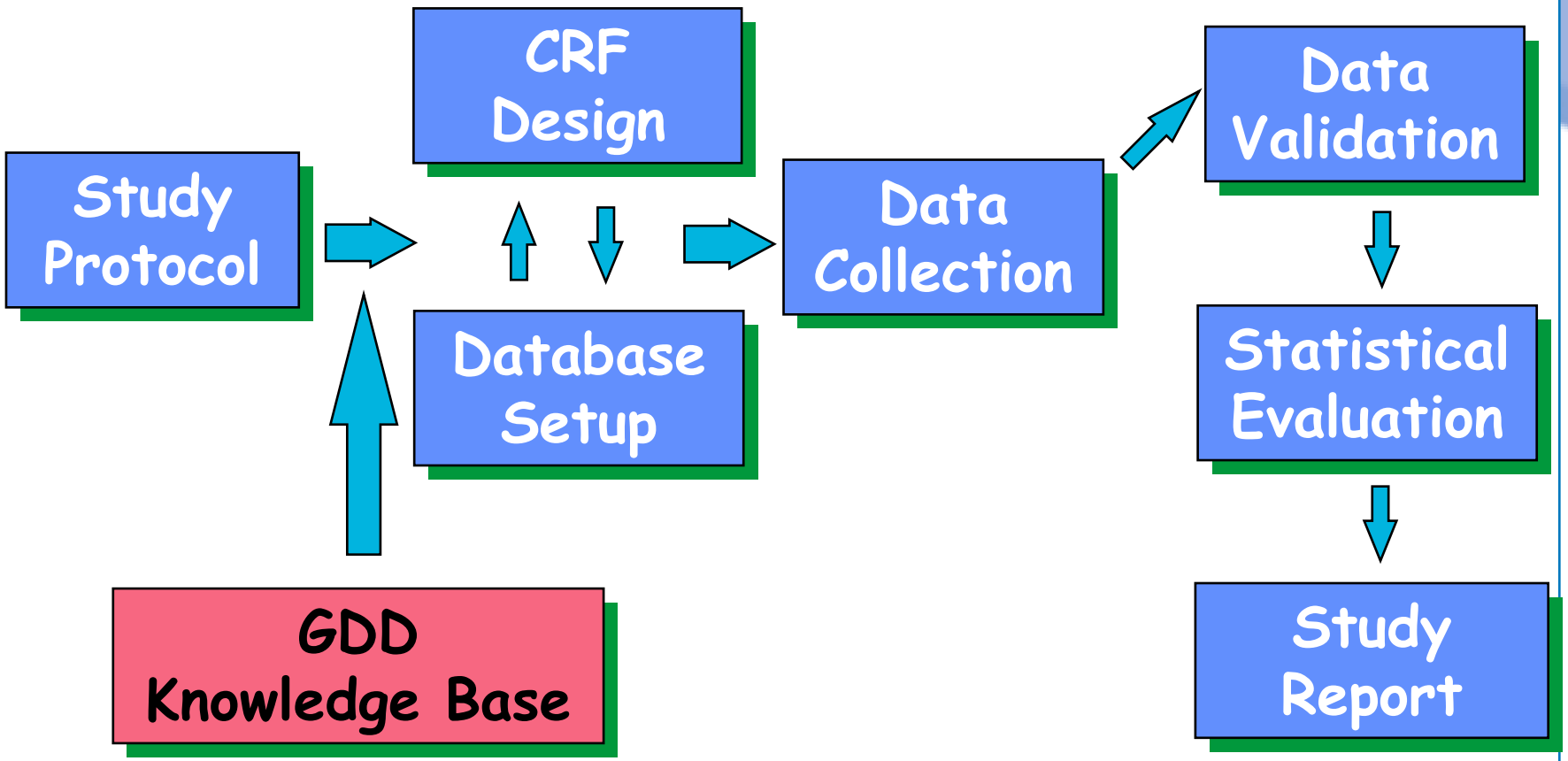
Part III

Controlled Terminology (CDISC)

Global Data Dictionary (GDD)

- Contains all database objects for all studies throughout the SCHERING Group
- A graphical library provides all CRF modules
- Centrally-maintained, networked system
- Central knowledge base

Information Flow in Clinical Studies

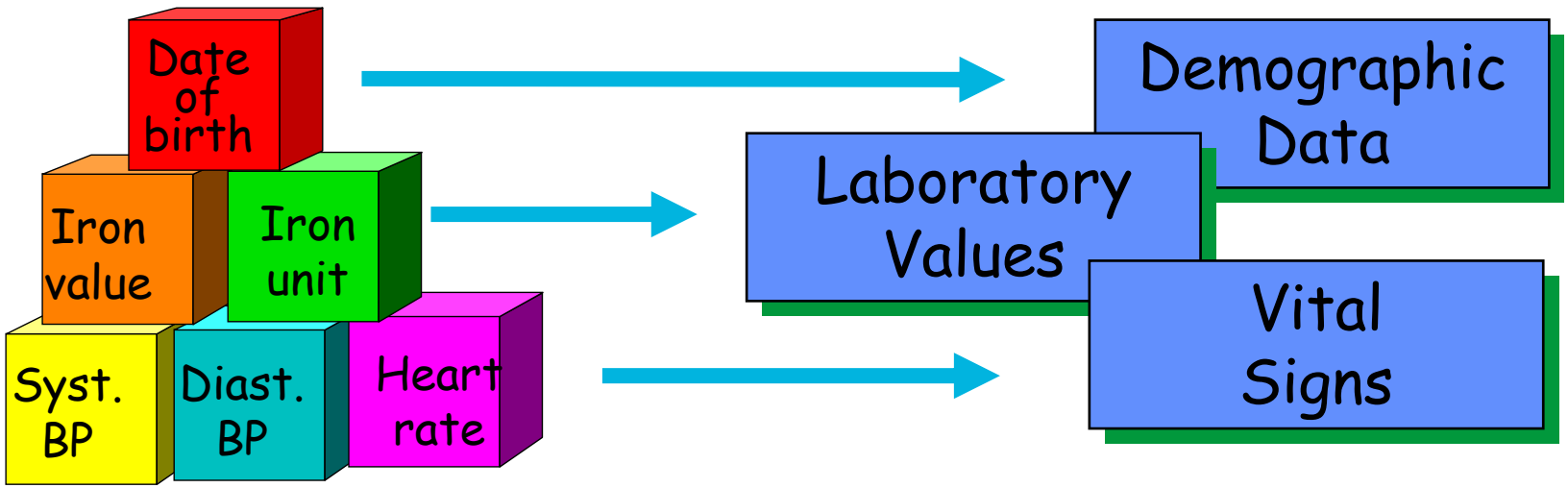


GDD Content

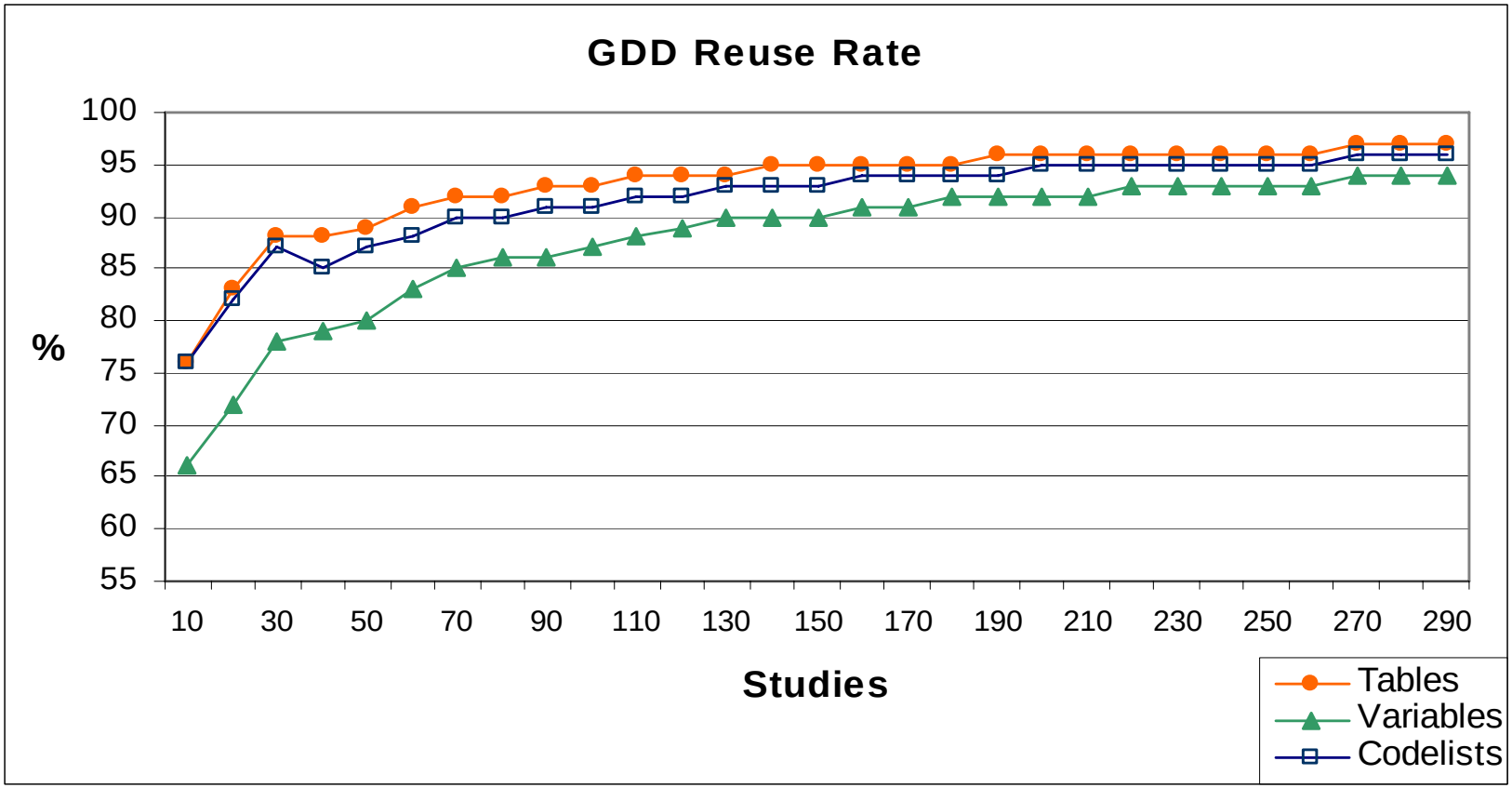
All information related to

specific questions on the CRF (= variables)

specific group of questions on the CRF (= tables)



GDD Object Reusage Rate



Enhancement of Project Performance

- Easy data pooling and exchange
- Ensuring quality
- Simplification of information flow
- Acceleration on the critical path
- Saving resources

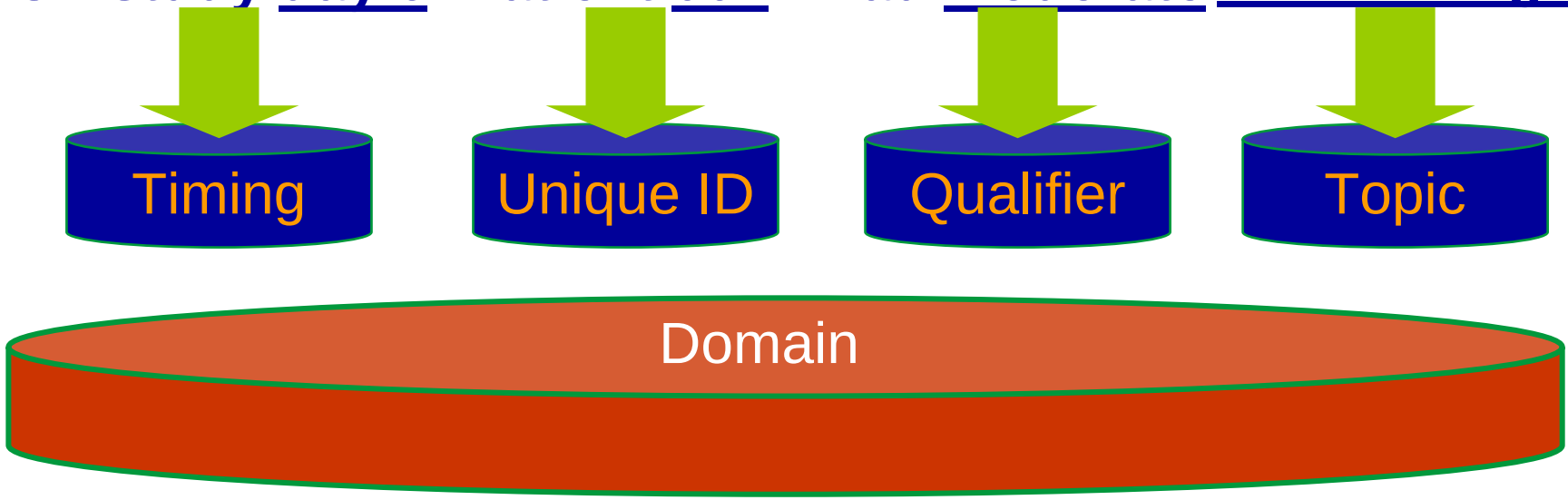
Part II
Study Data Tabulation Model (SDTM)

- Fundamentals
- General Classes
- Variable Roles

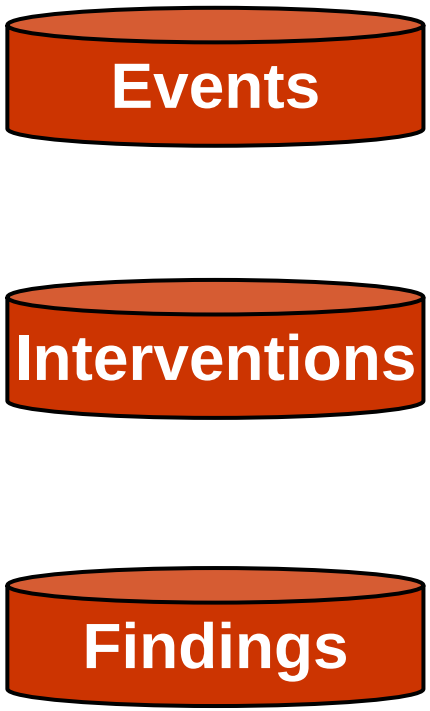
SDTM - Fundamentals

Adverse Event Observation

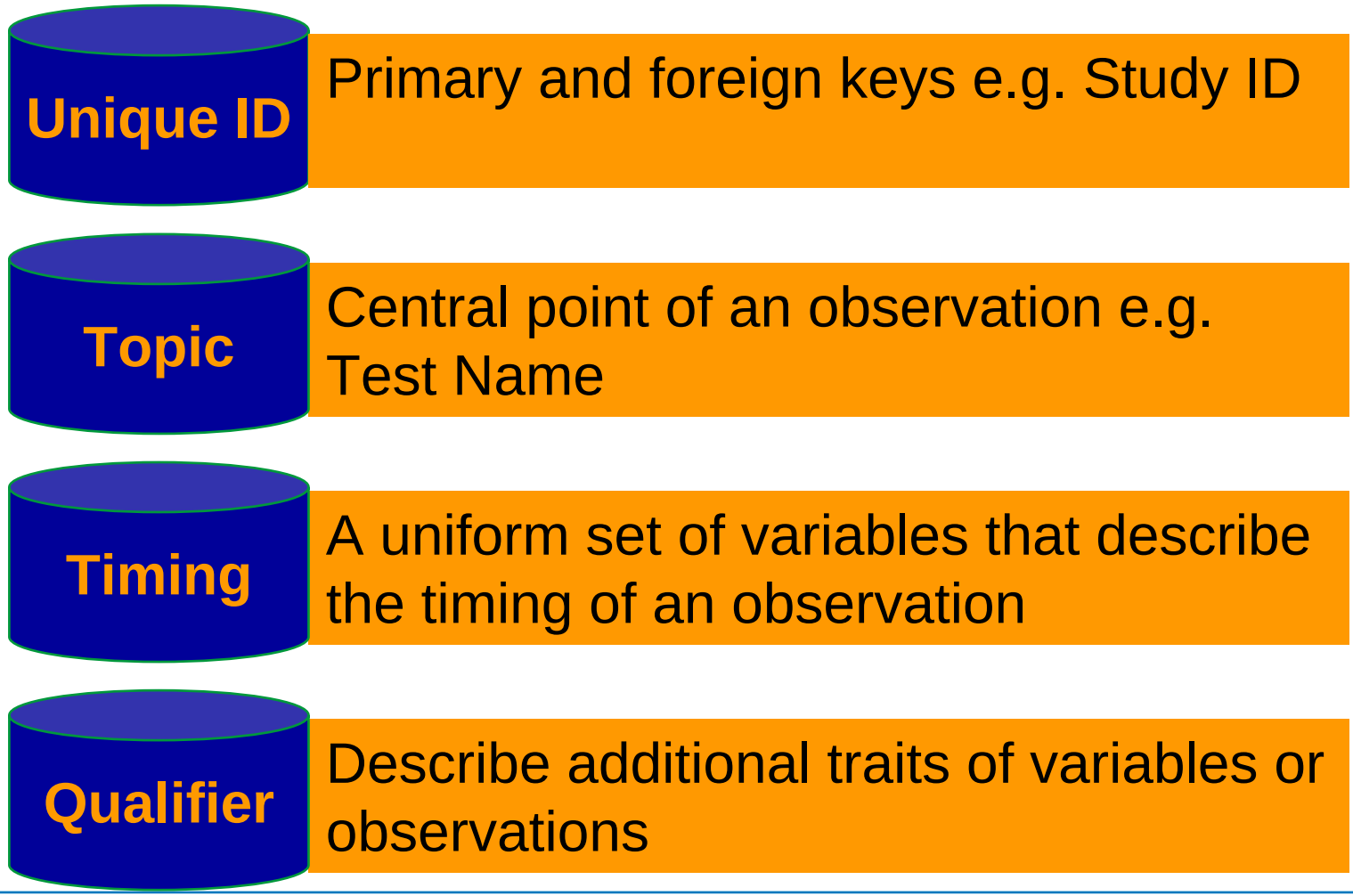
On study day 6 Patient 007 had moderate abdominalgia



SDTM - General Classes



SDTM - Variable Roles



Part III
Controlled Terminology (CT)

- Purpose
- Terminology Team

CT - Purpose

- CDISC Submission Data Tabulation Model needs Controlled Terminology for completion
- Controlled Terminology is also needed to achieve CDISC's main goal

Ensure consistent data acquisition/ transfer to avoid incompatible data

CT - Purpose: Example (I)

Adverse event relatedness to study drug

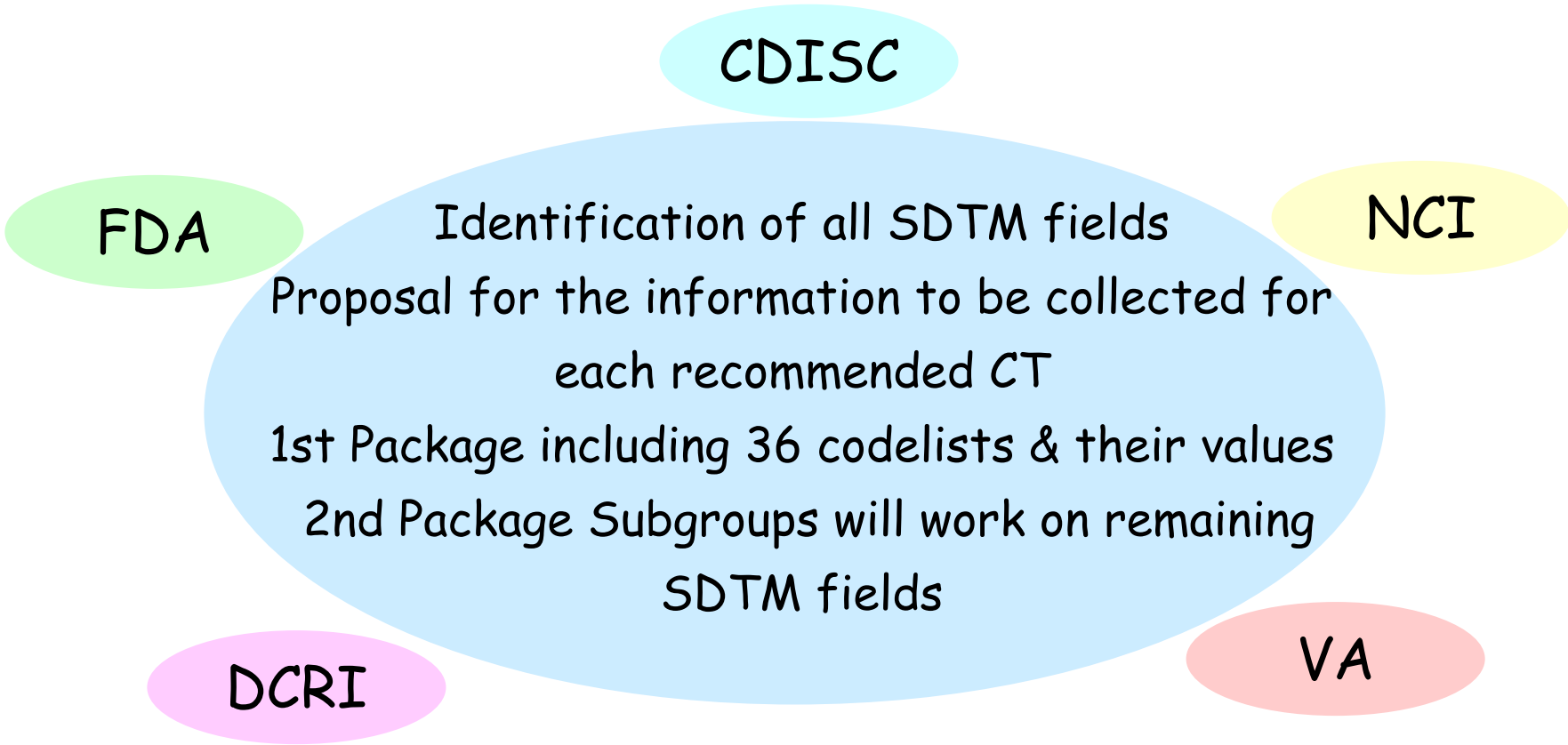
Company 1	Company 2	Company 3
no	Not Related	NO
unlikely	Doubtful	
possible	Possible	
definite	Very Likely	YES/UNKNOWN
probable	Probable	

CT - Purpose: Example(II)

Adverse event outcome

NCI	FDA	ICH
-fatal	-died	-fatal
	-improved	
-ongoing	-ongoing	-recovering/resolving
-resolved	-recovered	-recovered/resolved
-resolved with sequelae	-alive with sequelae	-recovered/resolved with sequelae
-unchanged	-persisting	-not recovered/not resolved
	-worsened	
		-unknown

Terminology Team - Status



Conclusion

Prospects:

- Improve the speed of regulatory approval
- Reduce the effort for a regulatory approval
- Reduce the costs and time of data transfer
- .....

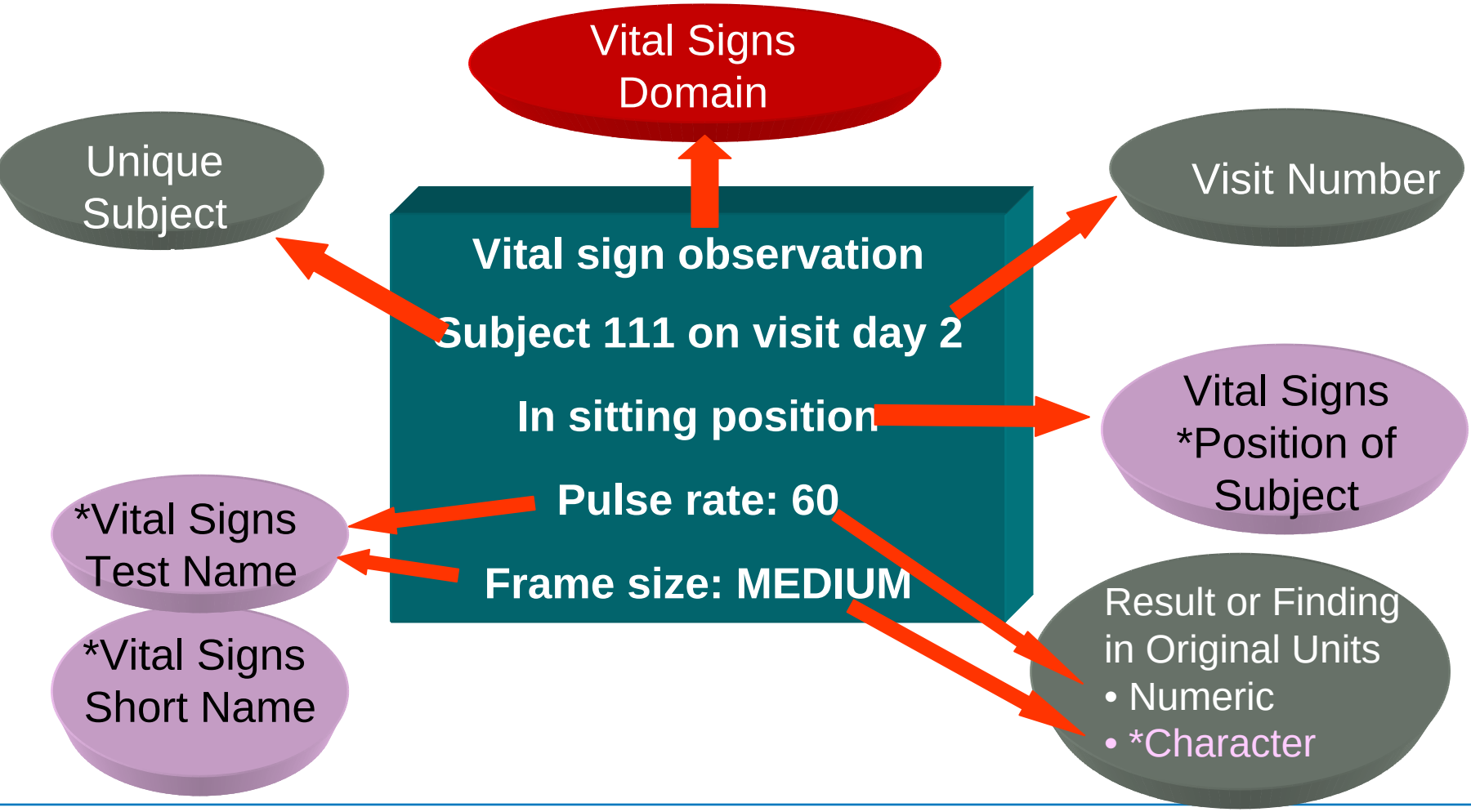
Impact:

- Applications: Data management/ Analysis/ Reporting
- Employees: Roles/ Responsibilities
- Standard Operating Procedures
- .....

Thank you!

Backup

SDTM & Controlled Terminology



SDTM & Controlled Terminology

Scenario I

SDTM qualifier variable & codelist

Example:

Positions of Subject

- **SUPINE**
- **STANDING**
- **SITTING**

Scenario II

SDTM topic variable & codelist

Example (VSTEST):

Vital Signs Test Names

- **Pulse Rate**
- **Frame Size**

Scenario III

Test name character result & codelist

Example:

Frame Sizes

- **SMALL**
- **MEDIUM**
- **LARGE**

Case Report Form

Example

CARDDG01C -/-/-/- -/-/-/-

Seq1 ?

● Cardiovascular diagnosis/procedure

Diagnosis/procedure (see codelist CDIAGF) **CARDCD – CDIAGF**	1 ☐ no 2 ☐ yes 997 ☐ unknown **CARDNY – NYF**
Date and time (24 hour clock) of procedure	**CDDIADT CDDIADT1 CDDIATM** **CDDIADT2 CDDIADTY** day month year hr min
Date of most recent procedure	day month year **CDRECDT CDRECDT1** **CDRECDT2 CDRECDTY**
Number of vessels	**VESSNO**
History of related diagnosis	1 ☐ no 2 ☐ yes **DIAGHIS – NYF**
Comments	**CARDDX**