QA Data

Overview of guidelines governing data-management

- ICH
- GCP
- FDA
- GCDMP
- CDISC

ICH

International Conference on Harmonisation

- Q-Quality
- S-Safety
- E-Efficacy
- M-Multidisciplinary

Q-QUALITY

- Stability studies, defining relevant thresholds for impurities testing and a more flexible approach to pharmaceutical quality based on Good Manufacturing Practice (GMP) risk management.

S-SAFETY

- **Safety Guidelines to uncover potential risks like carcinogenicity, genotoxicity and reprotoxicity. A recent breakthrough has been a non-clinical testing strategy for assessing the QT interval prolongation liability: the single most important cause of drug withdrawals in recent years.**

E-EFFICACY

- Design, conduct, safety and reporting of clinical trials. It also covers novel types of medicines derived from biotechnological processes and the use of pharmacogenetics/genomics techniques to produce better targeted medicines.

M-MULTIDISCIPLINARY

- Those are the cross-cutting topics which do not fit uniquely into one of the Quality, Safety and Efficacy categories. It includes the ICH medical terminology (MedDRA), the Common Technical Document (CTD) and the development of Electronic Standards for the Transfer of Regulatory Information (ESTRI).

GCP

- Good Clinical Practice – Topic E6 of ICH

FDA

- CRF Part 11
- Additional guidance documents

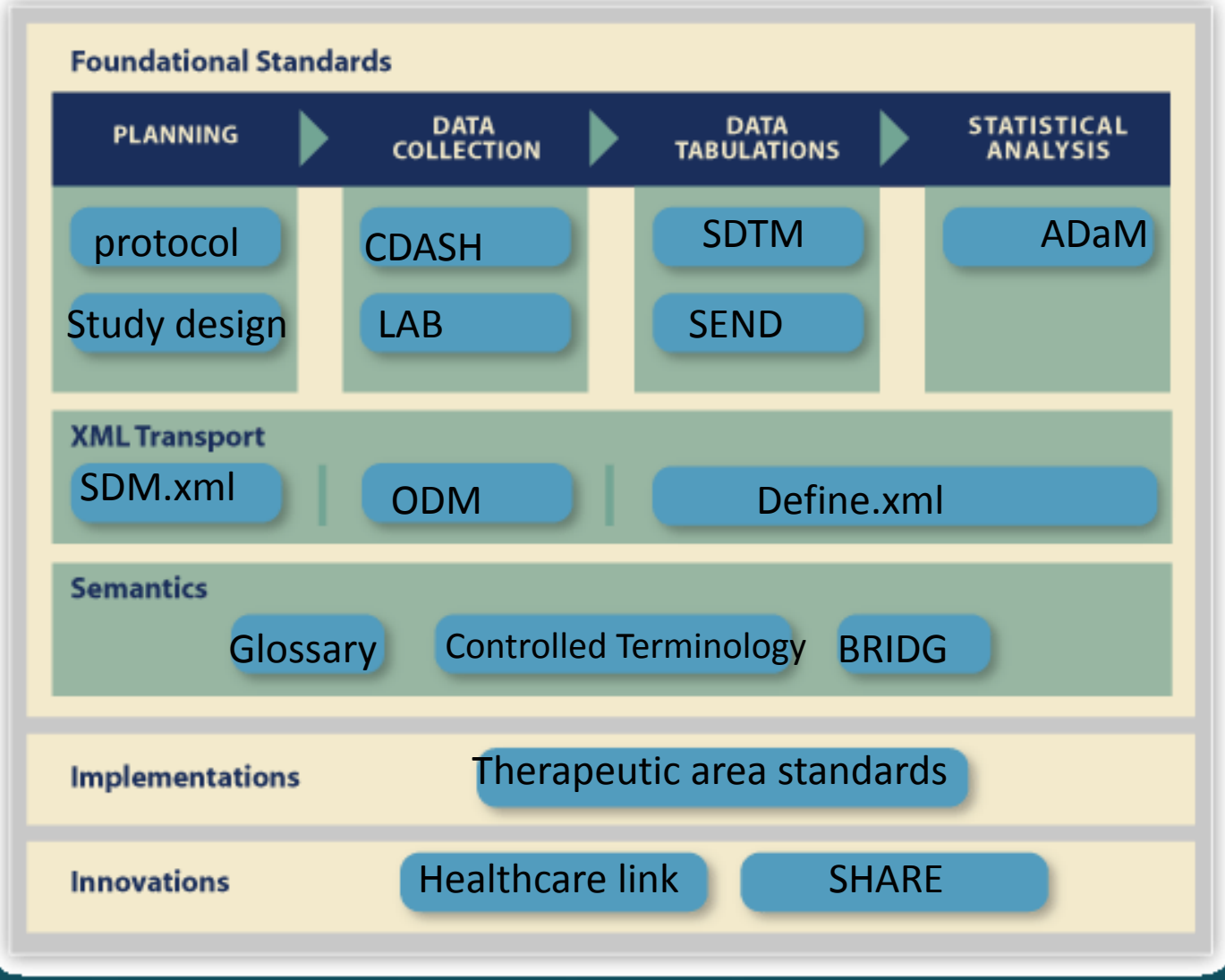
GCDMP

- Good Clinical Data Management Practices

CDISC

- Clinical Data Interchange Standards Consortium

CDISC


Foundational Standards
PLANNING
DATA COLLECTION
DATA TABULATIONS
STATISTICAL ANALYSIS
protocol
Study design
CDASH
LAB
SDTM
SEND
ADaM
XML Transport
SDM.xml
ODM
Define.xml
Semantics
Glossary
Controlled Terminology
BRIDG
Implementations
Therapeutic area standards
Innovations
Healthcare link
SHARE