

Accenture Life Sciences

Rethink Reshape Restructure...
for better patient outcomes

Octagon is now part of Accenture



Introduction to the CDISC Standards

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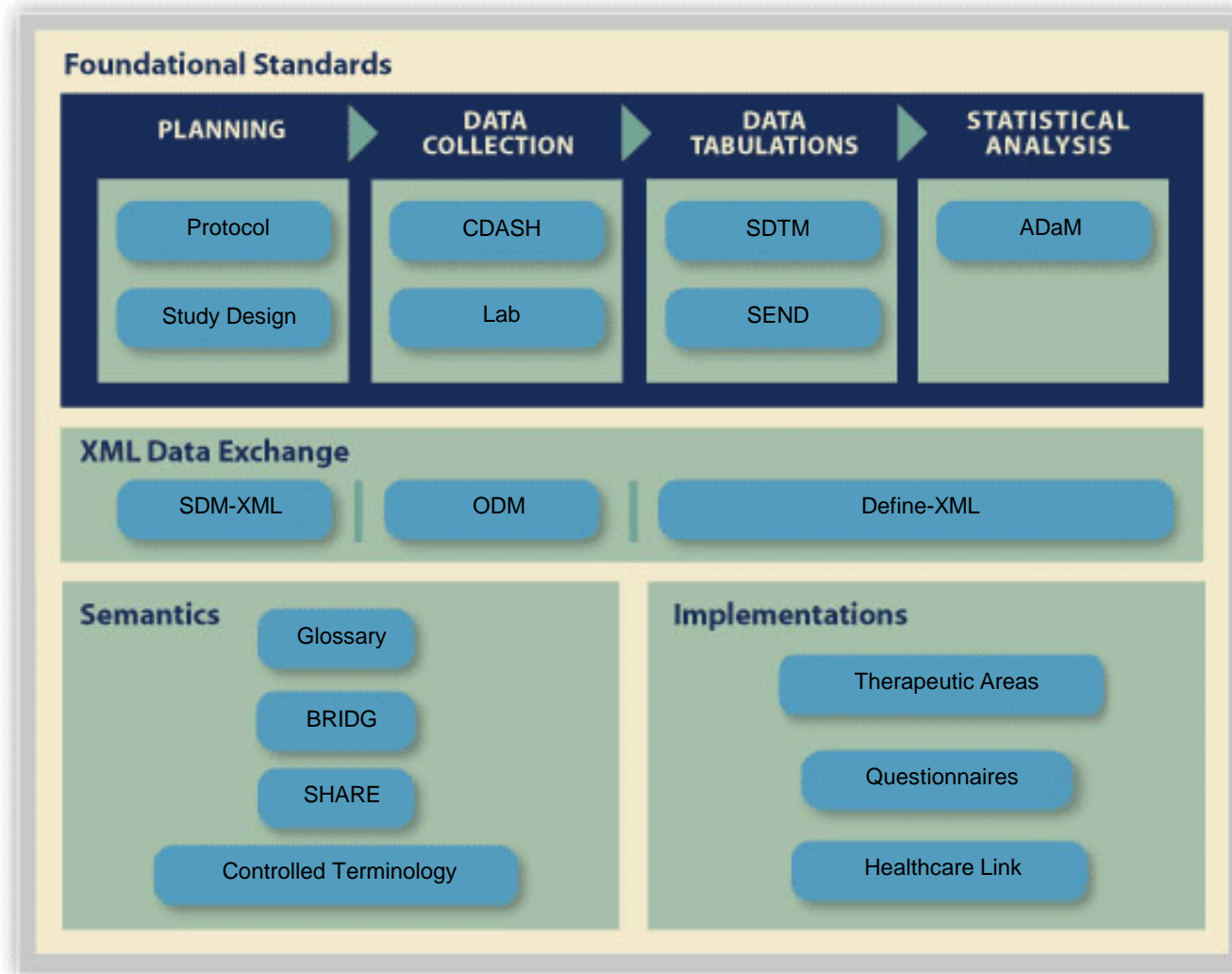
Introduction to the CDISC Standards

- Agenda
 - CDISC Overview
 - Foundational Standards
 - Data Content
 - Data Exchange
 - Semantics
 - Implementations
 - CDISC and Industry

CDISC Overview

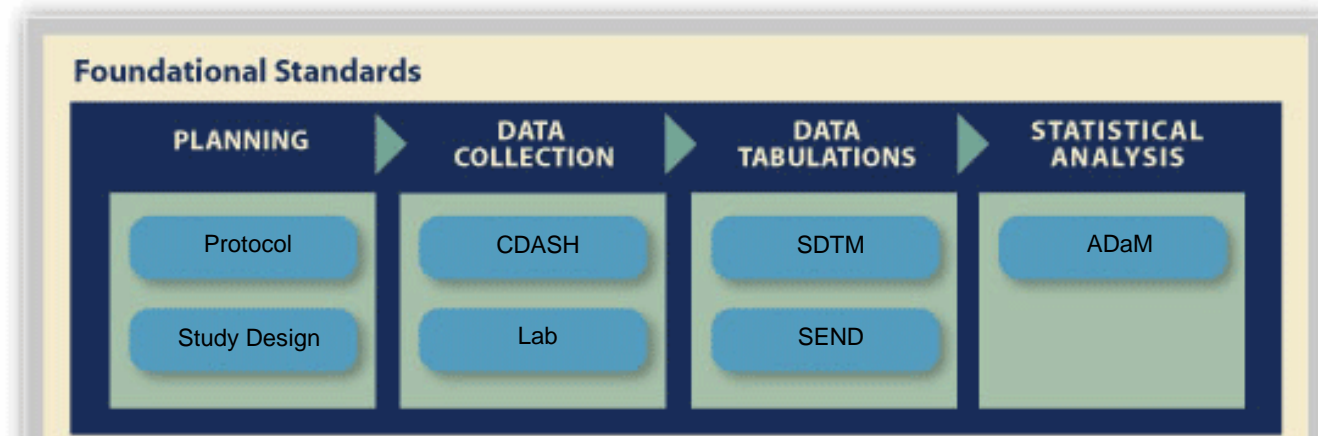
- Clinical Data Interchange Standards Consortium
- Global
- Platform-Independent and Vendor-Neutral
- Free and Open
- Work done mostly by Volunteers
- Goal is Efficiency
 - Developers
 - Reviewers

CDISC Foundational Standards*



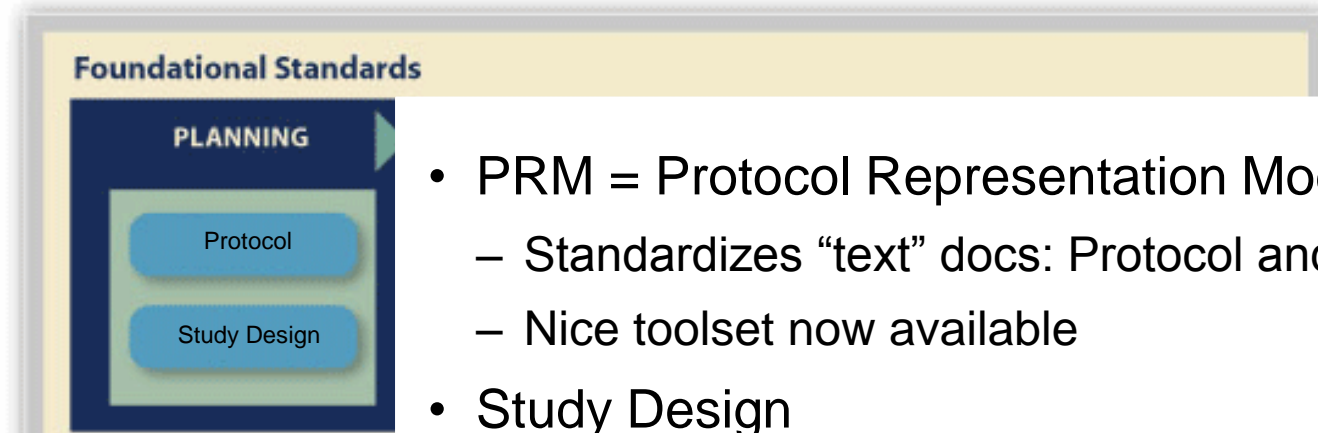
* From the CDISC website: www.cdisc.org

Data Content Standards



- Not all are in heavy use/adoption in industry
 - Data Flow: Plan -> Collect -> Tabulate -> Analyze

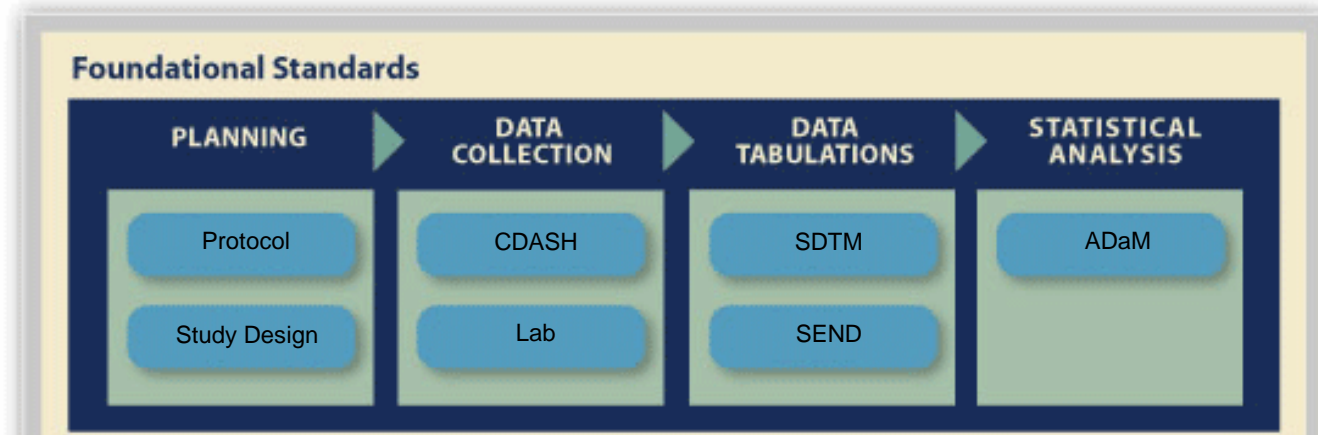
Data Content Standards: Planning



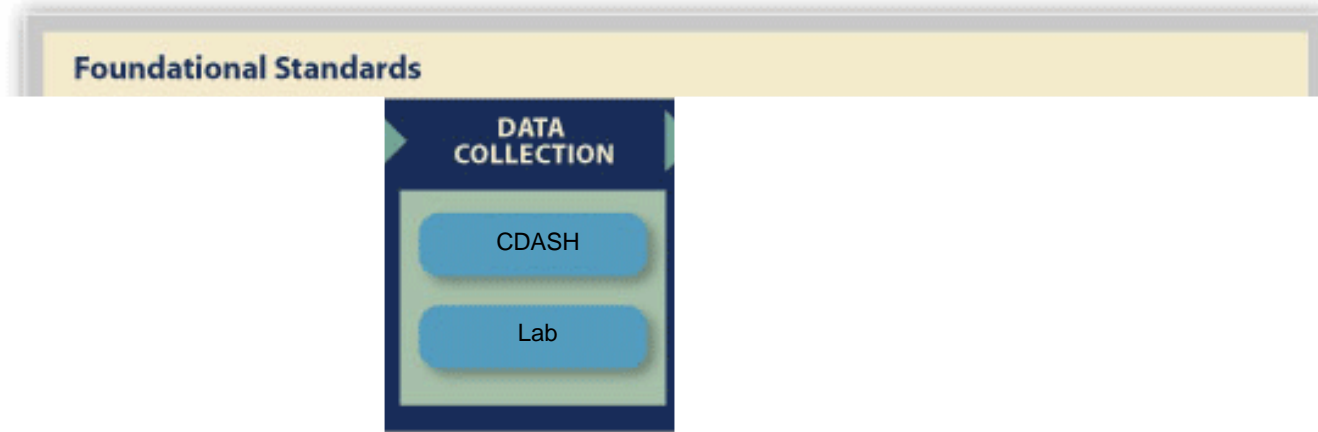
- PRM = Protocol Representation Model
 - Standardizes “text” docs: Protocol and SAP
 - Nice toolset now available
- Study Design
 - Uses XML technology

- Most companies are not using these standards
 - Considered “Leading Edge”
 - Huge efficiencies when part of end-to-end solution

Data Content Standards

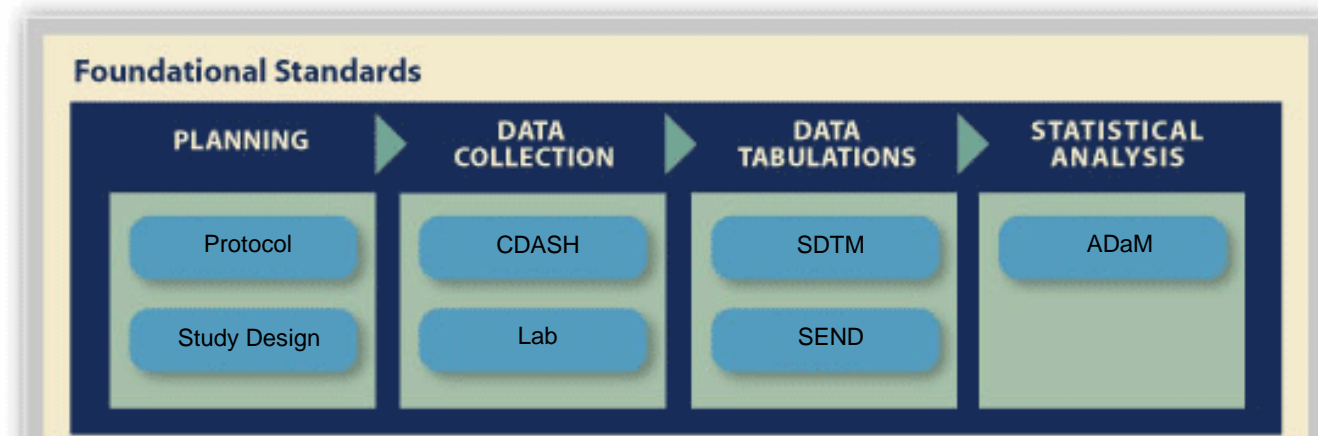


Data Content Standards: Collection

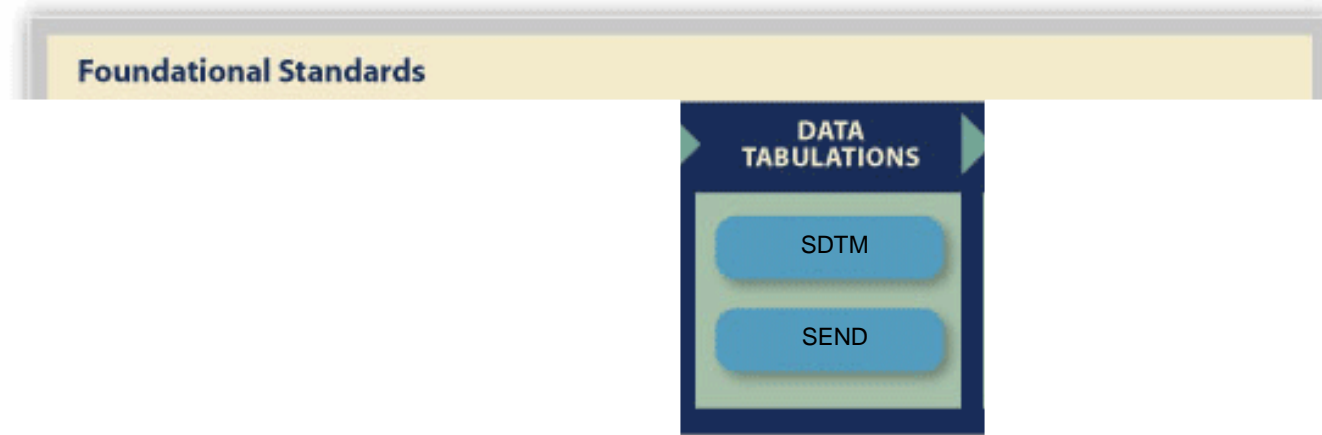


- CDASH = Clinical Data Acquisition Standards Harmonization
 - Developed after SDTM was in production
 - Is a pre-cursor to SDTM
 - Designed to be easily exported to SDTM
 - Use is increasing
- Lab = Laboratory Data Model
 - Used to deliver results from (central) lab to client

Data Content Standards

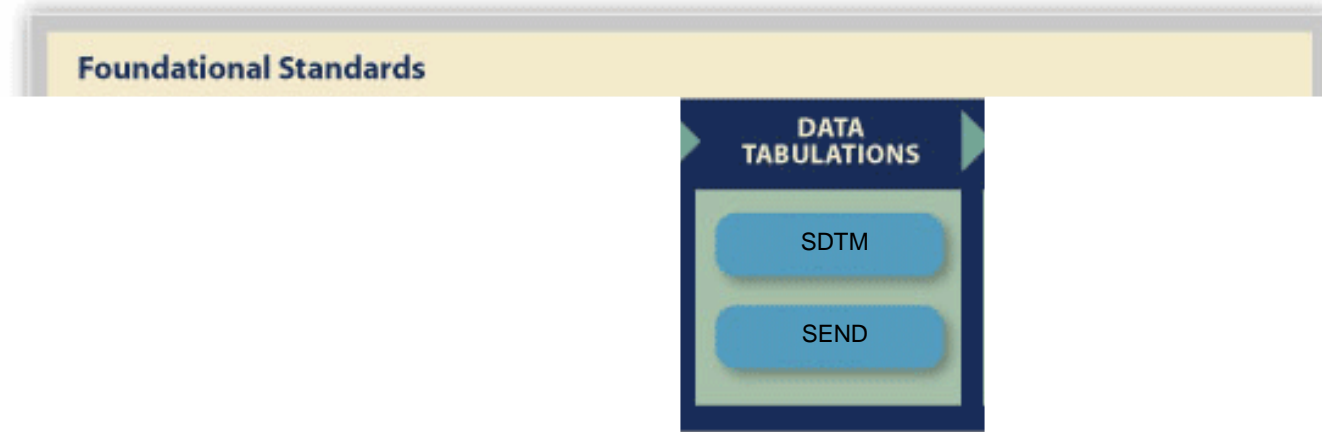


Data Content Standards: Tabulation (1)



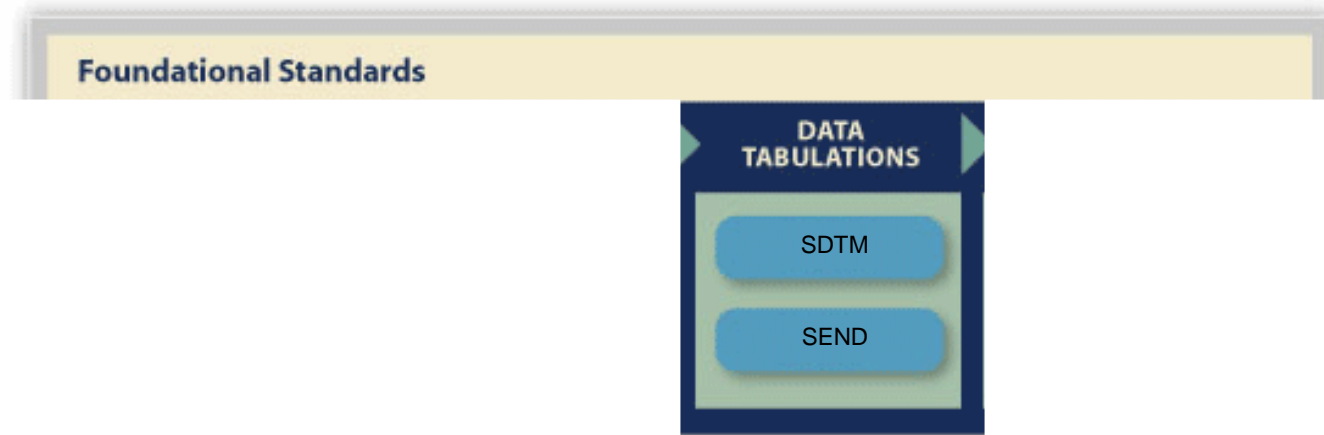
- SDTM = Study Data Tabulation Model
 - Most familiar/popular of all CDISC models
 - Designed for submitting study tabulation data
 - General observation classes
 - Events
 - Interventions
 - Findings

Data Content Standards: Tabulation (2)



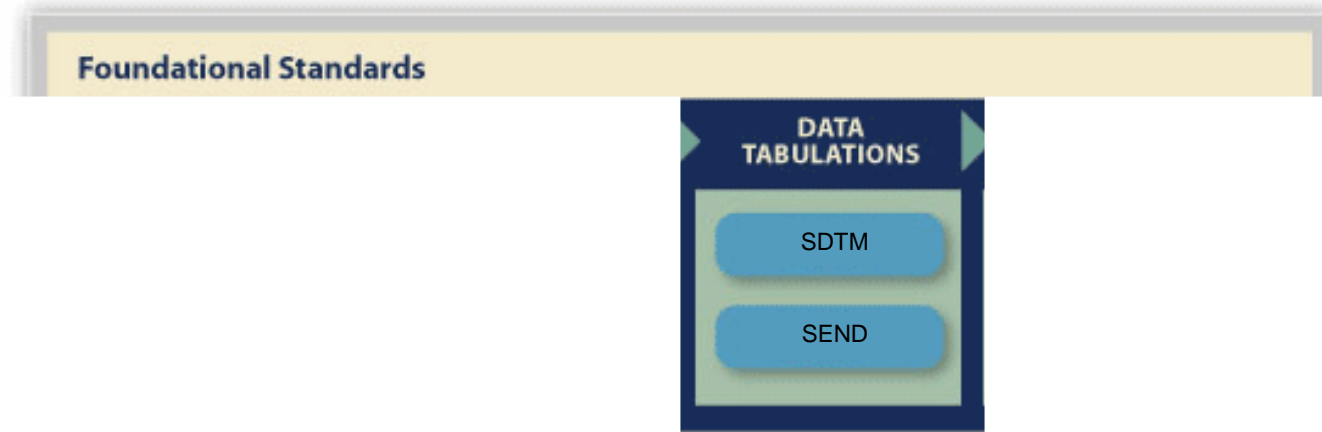
- SDTM = Study Data Tabulation Model
 - Other features include DM, Comments, FA, Trial Design, Relationships, Supplemental Qualifiers (SUPPQUAL)
 - 2 components:
 - SDTM document – high level
 - SDTMIG – lots of examples and applications

Data Content Standards: Tabulation (3)



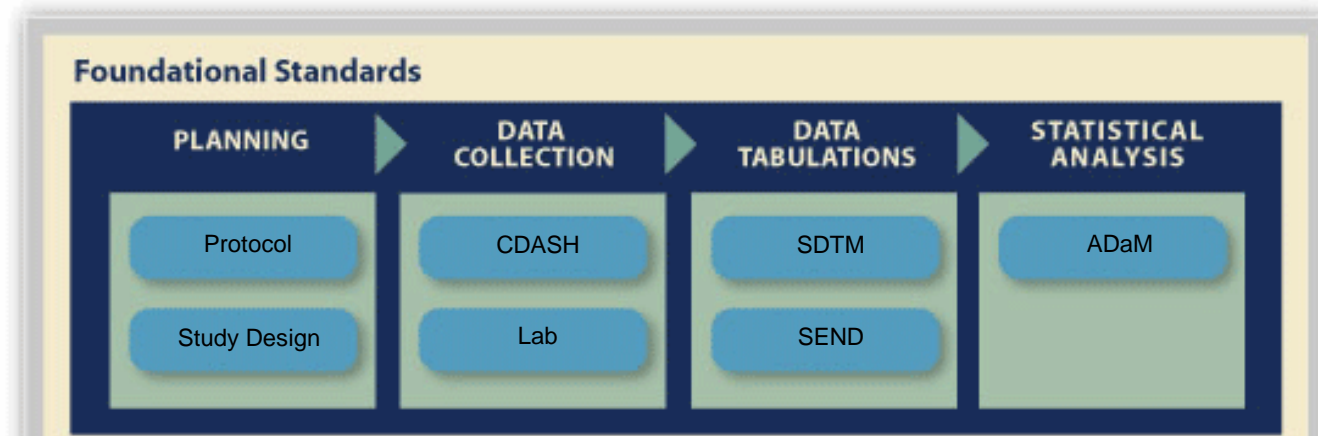
- SDTM doc is base for more than just SDTMIG
 - Standard Exchange of Non-Clinical IG
 - Medical Devices IG
 - Pharmacogenomics IG
 - Associated Persons IG

Data Content Standards: Tabulation (4)



- Be sure to use right pairings of SDTM and IG
 - SDTMIG v3.1.2 goes with SDTM v1.2
 - SDTMIG v3.1.3 goes with SDTM v1.3
 - SENDIG v3.0 goes with either SDTM v1.2 or v1.3
 - SDTM v1.3 must be used for
 - Medical Devices IG
 - Pharmacogenomics IG
 - Associated Persons IG

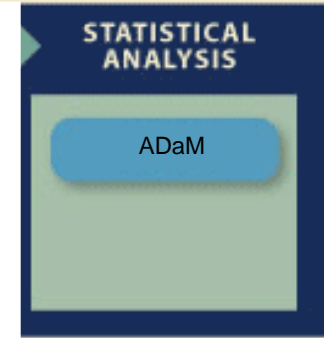
Data Content Standards



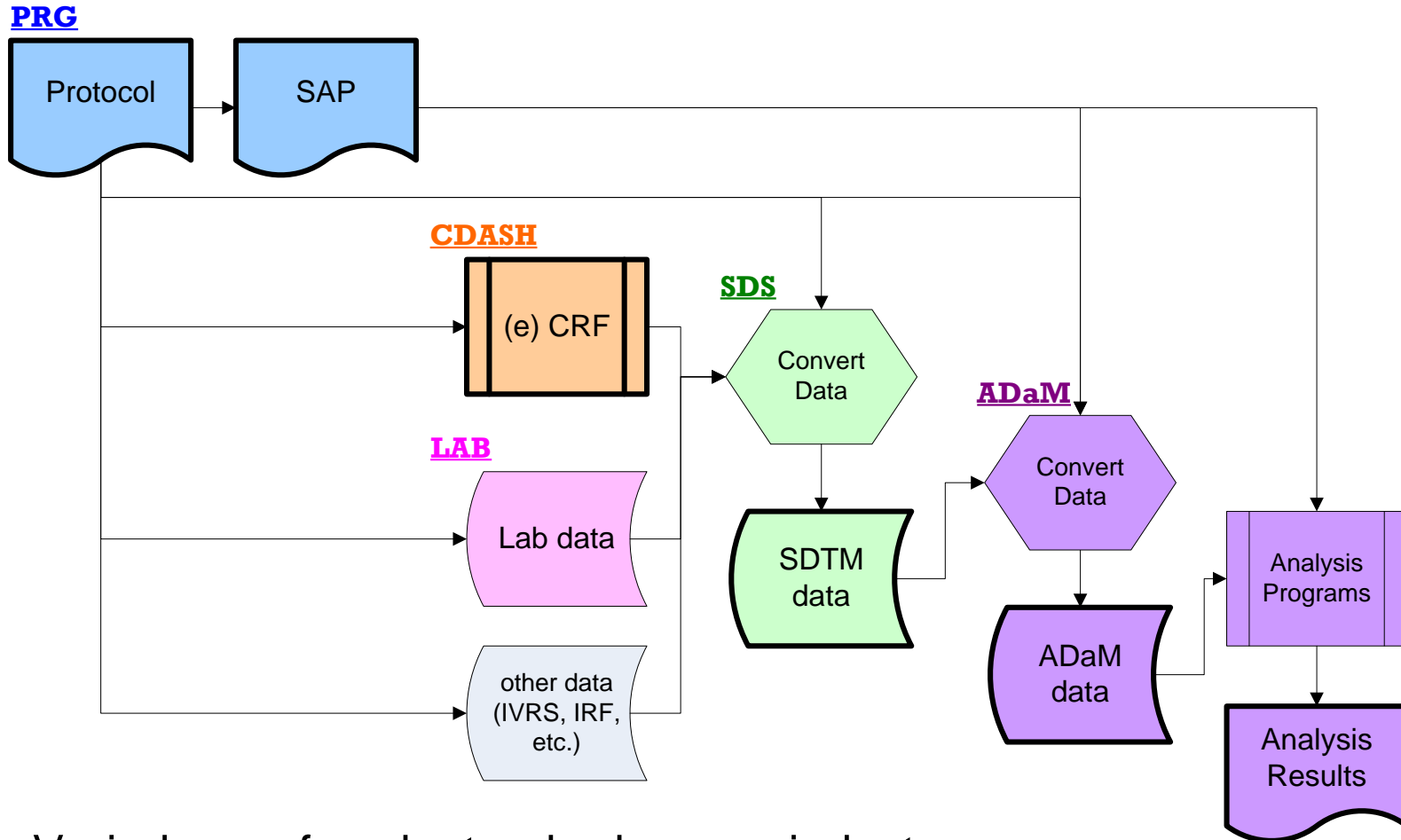
Data Content Standards: Analysis

Foundational Standards

- ADaM = Analysis Data Model
 - Reconfigures tabulation data for analysis
 - Goal is “analysis ready”
 - Three structures
 - ADSL (Subject Level)
 - BDS (Basic)
 - ADAE (Adverse Event)
 - Multiple documents on website
 - ADaM
 - ADaMIG
 - Appendices: Examples, TTE, ADAE

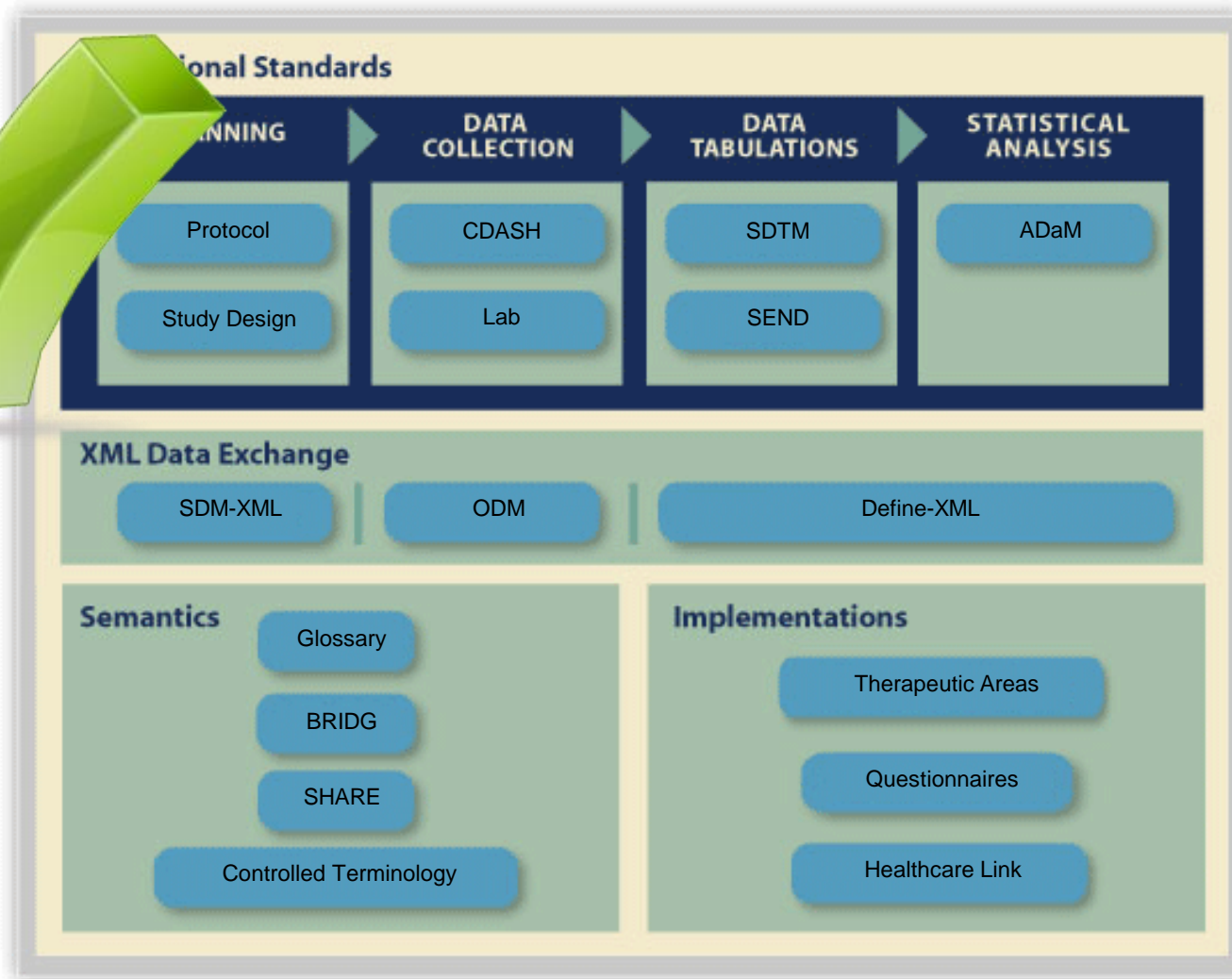


Data Content Standards: Typical Flow



- Varied use of each standard across industry

CDISC Foundational Standards



Exchange Standards

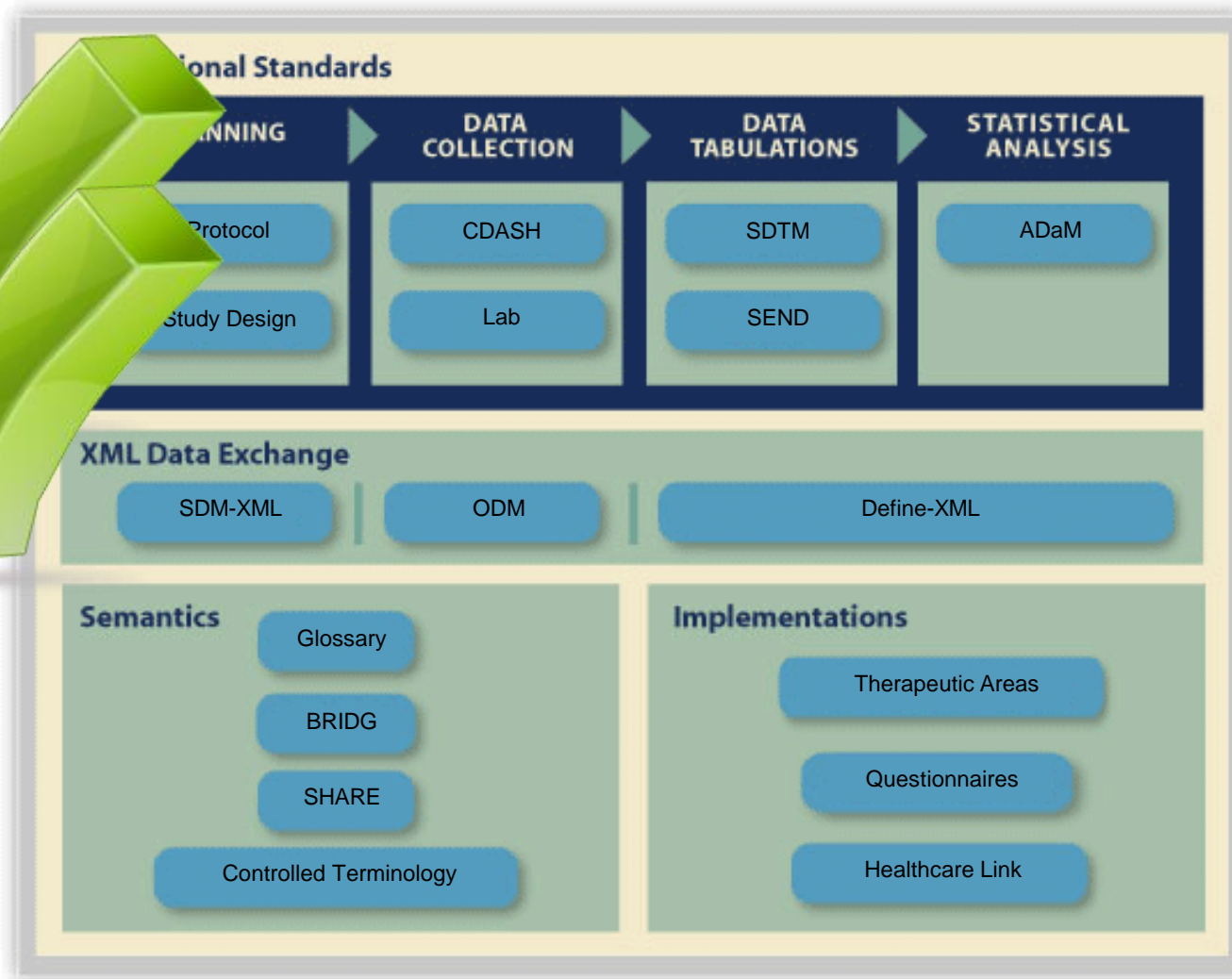


Exchange Standards



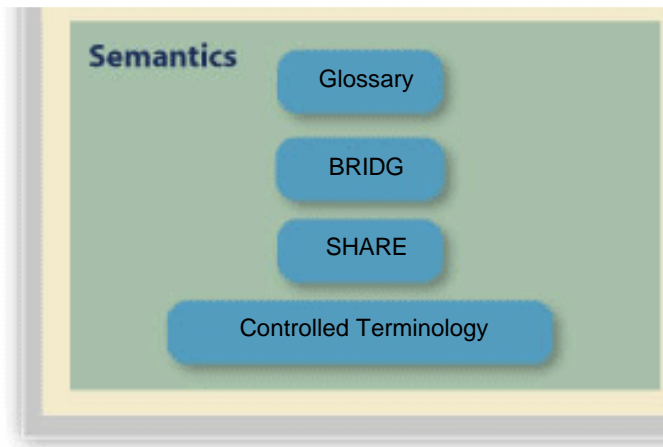
- XML (an Open International standard) used for all exchanges
- DEFINE.XML
 - CRT-DDS = Case Report Tabulation Data Definition Specification
 - Designed to describe and link Metadata
 - Dataset-level
 - Variable-level
 - Value-level **<- New in version 2.0**
 - References to other documents (Protocol, SAP, Data Guide)
- ODM = Operational Data Model
 - Developed to transfer data between data standards or companies
 - Potential replacement for SAS® v5 transport files

CDISC Foundational Standards



Semantic Standards

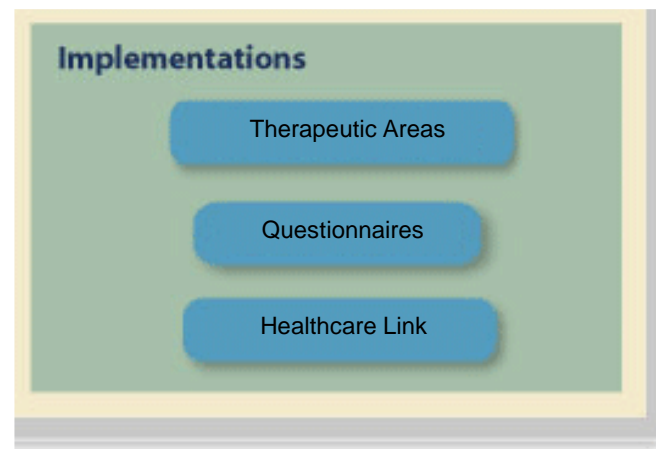
- Semantics provides additional meaning
- Glossary is a good resource for industry terms and acronyms
- BRIDG = Biomedical Research Integrated Domain Group
 - CDISC + HL7 + FDA + NCI
- SHARE = Shared Health And Clinical Research Electronic
 - Machine-readable version of standards
 - Focused on CDASH and SDTM initially



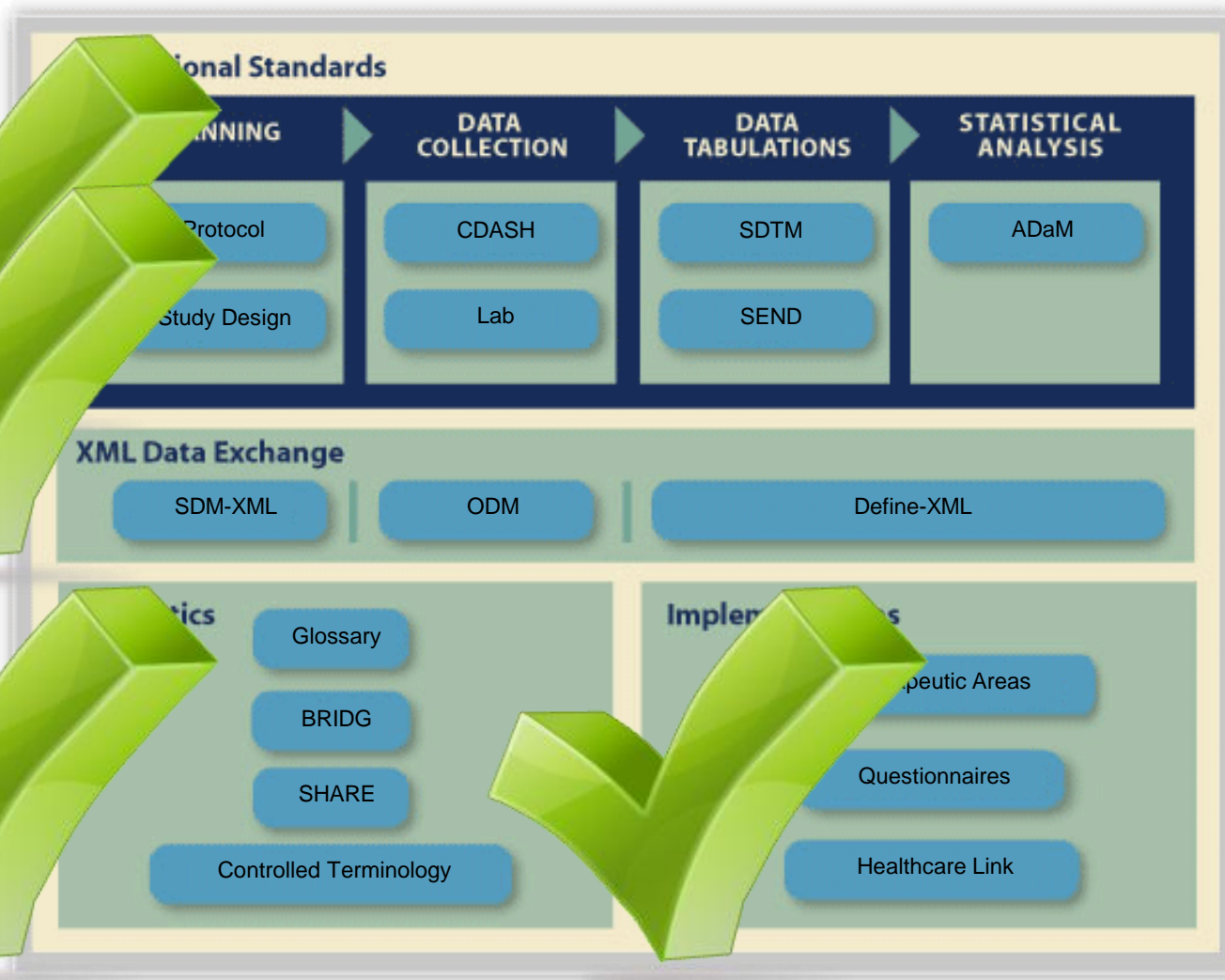
- Controlled Terminology
 - Maintained on NCI EVS website
 - SDTM, SEND, CDASH, ADaM
 - Updated quarterly
 - Download as .xls, .xml, .pdf, etc.
 - Can request/suggest new terms

Implementation Standards

- Therapeutic Area Standards
 - Designed to help make implementations consistent across indication
 - Huge focus of CDISC work, based on FDA priorities
 - Focused on SDTM and CDASH initially
- Questionnaires
 - Developing standards for common standard questionnaires
- Healthcare Link
 - Connects clinical trials to EHR
 - Major hurdle is patient confidentiality



CDISC Foundational Standards

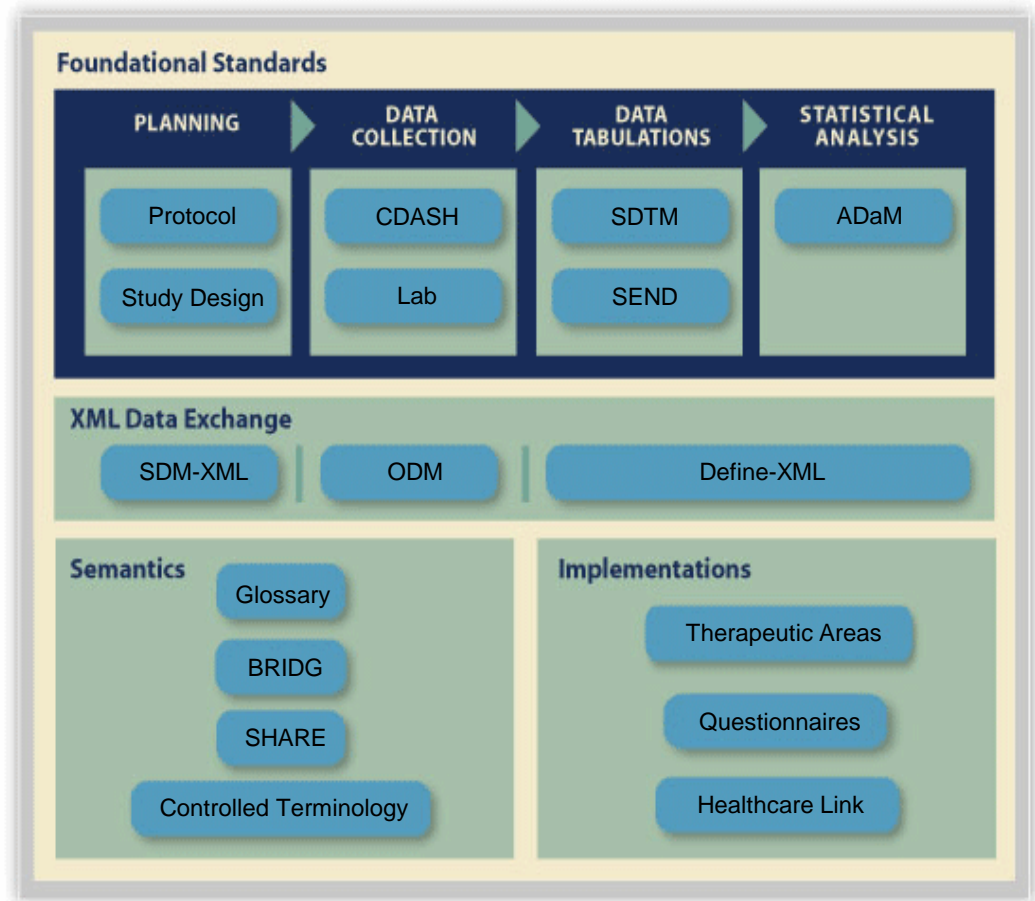


CDISC and Industry

- FDA
 - Driving force behind much of CDISC adoption
 - Standards allow
 - Reviewers to be more efficient on any individual filing
 - Data mining across large pool of submitted data
- Europe and Japan
 - Not currently requiring standard data, but are moving toward CDISC
- OpenCDISC
 - Compliance checker for SDTM and ADaM
 - NOT a product of CDISC, but created by outside consultants
 - Used at FDA

Questions?

- CDISC Overview
 - Foundational Standards
 - Data Exchange
 - Semantics
 - Implementations
- CDISC and Industry
- Website: www.cdisc.org



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(Full paper behind these slides available via PharmaSUG 2013)