phuse·share
connect·share·advance

Single Day Event

Standardization and Implementation in Clinical Trial Data for Drug Development

Baoqing Li,
Johnson & Johnson Innovative Medicine

phuse.global

Disclaimer

This presentation is for informational purposes only and does not represent professional guidance or advice. Any views and opinions expressed during this presentation are those of the presenters and do not necessarily reflect the views or policies of Johnson & Johnson.

Agenda

- Overview of clinical data standards
- End to End standards in clinical trial
- Standardization Processes
- Challenges
- Opportunities (automation, AL/ML)
- Conclusion

Clinical Data Standards

What is a standard:

- Reusable and stable
- Governance
- Benefits: efficiency, consistency, quality, data sharing, etc.
- Global standards, TA/DA standards

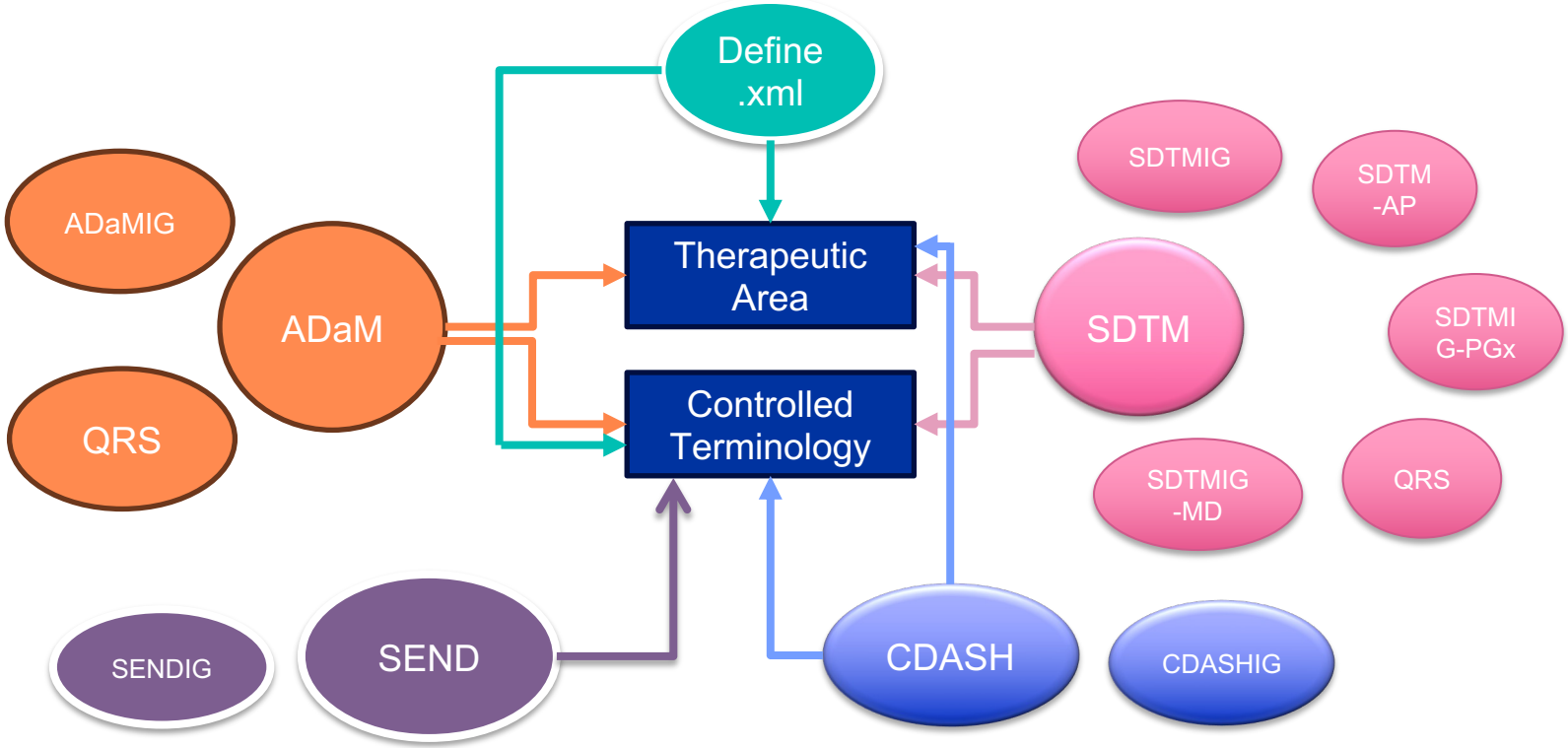
Clinical Data Standards

- Clinical standards
  - Data collection (CRF, DTA, COA), SAP, ADaM, DLP, etc.
  - Dictionaries, CDISC, eSource- HL7 FHIR, etc.
- Regulatory submission
  - Define.xml
  - BIMO
- Tools
  - Pinnacle 21E
  - ADaM metadata, dataset convention

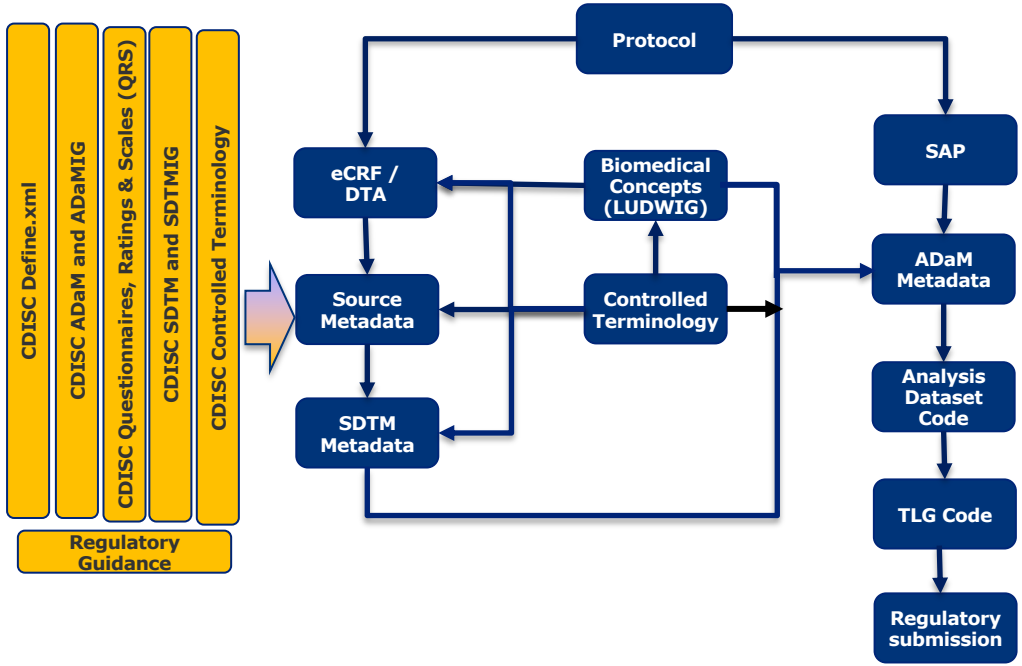
Standards Organizations

- Health Level 7 (HL7)
  - FHIR – Fast Healthcare Interoperability Resources
- CDISC (clinical trial data)

CDISC


Define
.xml
ADaMIG
ADaM
QRS
Therapeutic
Area
Controlled
Terminology
SDTMIG
SDTM
-AP
SDTM
SDTMI
G-PGx
SDTMIG
-MD
QRS
SENDIG
SEND
CDASH
CDASHIG

Integrated E2E Standards



- Controlled terminology and biomedical concepts are standards that are applied across the entire data flow, from collection to delivery and analysis
- Integrated standards create two efficiencies
  1. Metadata can be reused from one standard to the next.
  2. Traceability from analysis to delivery and collection. Analysis results in a display used in the clinical study report can be traced back to the point of collection (eCRF or eDT)

Standardization Processes

- Standards awareness and guidance
- Governance
- Development & adoption strategy
- Implementation

Industry Working Group

- PHUSE
  - Data Transparency
  - Data Visualization & Open Source Technology
  - Optimizing the Use of Data Standards
- CDISC
  - CDISC 360
  - Standards in development
- TransCelerate
  - eSource (EHR/EMR, devices & Apps, Non-CRFs, direct data capture)
  - Digital Data Flow

Standard Governance

Challenges

- Standards evolving
- Standard implementation
  - Resistance to change/competing priorities
  - Legacy studies
  - Company acquisition
- Data
  - Various data source
  - Data quality and consistency

Automation

- Automate and optimize the creation of submission-ready packages and facilitate their review and upload to reduce human-error
  - SDTM/ADaM package preparation and checking
- Autocode: ADaM metadata
- Robotic Process Automation (RPA)

AL/ML in Standardization

- Data cleaning and normalization
- Standardized terminology mapping
- Natural Language Processing (NLP) for CSR automation, SAR, narratives, etc.
- Quality control
- Clinical decision support

Conclusion

- Standards are NOT optional, it is a MUST.
- Involvement and participation in standard development

The Global Healthcare Data Science Community

Contact Channels

UK +44 1843 609600
office@phuse.global
phuse.global

Social Media

@phusetwitta
/phusebook
/phusetube
/company/phuse