Clinical Data Standards in the era of AI, ML & Digital Transformation

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Agenda

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- COVID-19 and the wave of Digital Transformation
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Motivation – Need of the hour

The need of the hour is to reach Patients Faster

- By reducing both the drug development timeline and the overall cost of Pharmaceutical Research and Development **we can reach Patients faster.**

- **COVID-19 has been a good example of just what can be achieved**. Vaccines were developed within a year, pre COVID, this was unheard of with vaccines typically taking many years to develop.

Role of Biometrics in enabling faster Drug Development

- For Biometrics Teams, this means that **we need to be quick and accurate in Data collection, processing and analysis**.

- In order to cut short, the timeline and improve efficiency, we need to **automate many steps involved in the Clinical Data Life Cycle** (planning phase, data collection, tabulation, statistical analysis, and exchange/sharing of data) and, **in order to automate, we must have consistent Metadata, Standards, and technology.**

COVID-19 and the wave of Digital Transformation

We can all agree that COVID-19 has acted as something of a catalyst, **encouraging increased Innovation, Technology adoption, and a willingness to embrace digital transformation.**

As a result, we are witnessing a "**new normal**" - including an **increased number of Virtual Trials being** successfully designed.

Virtual trials have helped Patient Recruitment, retention, real-time access to Data, and better Quality

Digital Data collection methodologies (mobile technology, Wearables, Electronic patient-reported outcomes (ePRO), Electronic Clinical Outcome Assessment (eCOA) etc.) *have been instrumental, acting as game changers to enable robust data capture in the era of Covid-19*

Why Data Standards?

A true measure of the data is the impact it has

As clinical research becomes more increasingly complex, the opportunity to bring clarity to the data is more important than ever.

Science comes to life through data

Data doesn't mean anything if you have to struggle to understand where it is located, how it is organized, or how to analyze it. One cannot harmonize anything or combine without standards.

Enables Sound Scientific review and Patient Centric Decisions

Standardization helps in Data Aggregation, Accessibility, Interoperability, Re-usability and traceability. Ultimately, standardization helps regulators to focus on their Scientific review and make Patient Centric Decisions.

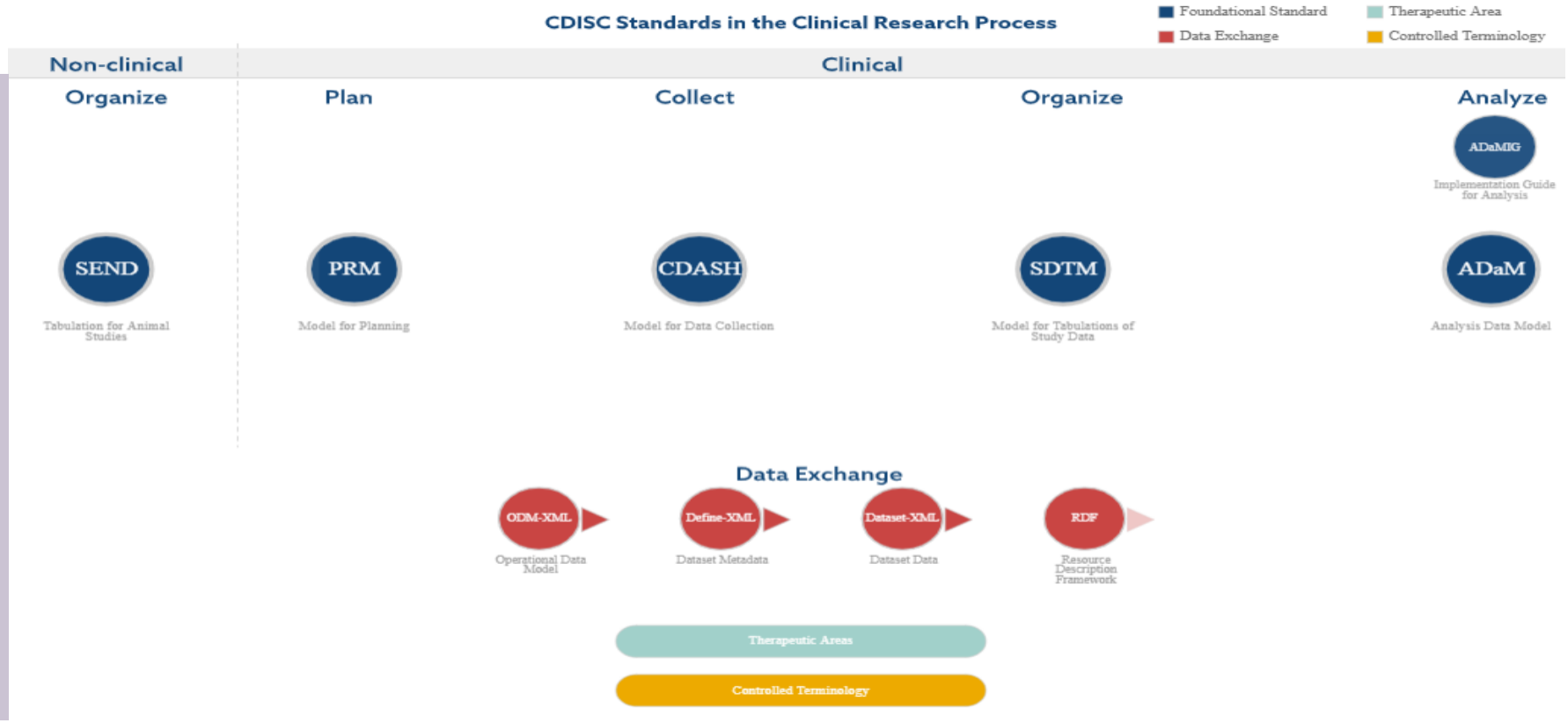
Enables Built in Quality starting much early in the process

CDISC was designed to have built in Quality starting much early in the process. We need end-to-end data Standardization and integration strategy that considers all the dimensions of Clinical Data to achieve Quality & efficiency.

CDISC (Clinical Data Interchange Standards Consortium)

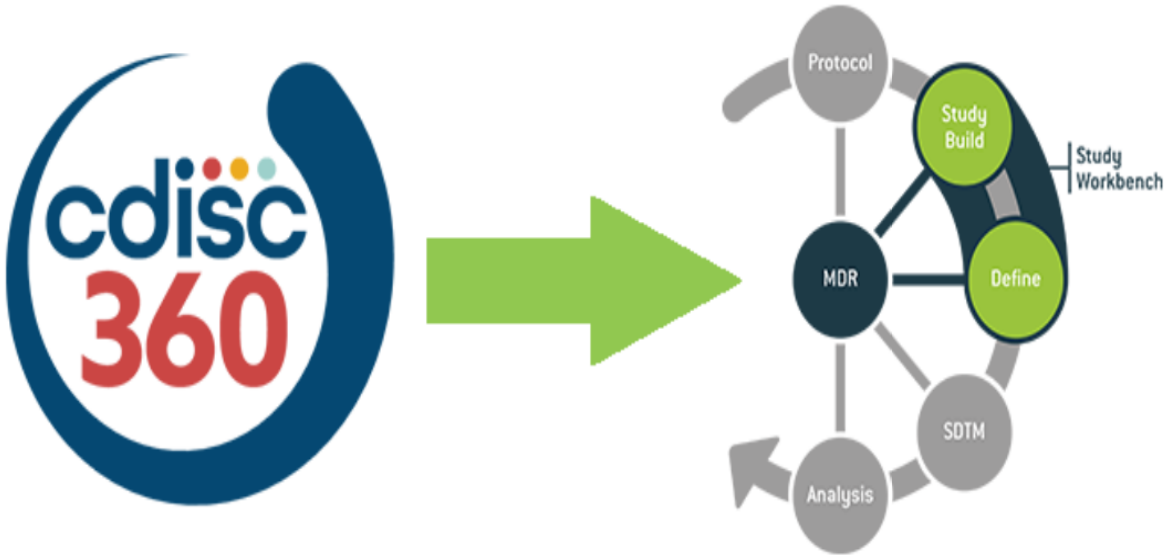
CDISC has played a significant role over the last two decades to achieve ***Data Quality*** ***(in order for us to trust the data to make credible and significant scientifically valid decisions****) and also gain efficiency across Clinical Trial Data Life Cycle processing.*

Originally focusing on common data domains in clinical trials (e.g. demographic information, adverse events, routine lab results, and subject status), ***CDISC has grown from PDFs to Machine readable standards****, and* ***from few safety domains to more Therapeutic Area specific standards*** *(a great example is COVID-19 guidelines).*



The Road ahead

- Since the formation of CDISC, one of the challenges faced was that **CDISC foundational standards were built in a two-dimensional model**, with and no significant CDISC support for the automation of foundational standards in the research enterprise.



Reference: https://www.s-cubed-global.com/a3-suite-2/cdisc-360-project-a3-suite

- **One of the strategic goals for CDISC to address in the coming years** is to

"*Develop multidimensional standards in an open, transparent manner that allows community members to transition with as little disruption to their research as possible while unlocking greater benefits of standardization. Engage in concrete steps to achieve end-to-end standardization.*"

- Some of the **initiatives** in place to achieve this are:
  - **CDISC 360** (to demonstrate the feasibility of standards-based metadata-driven automation across the end-to-end clinical research data life cycle)
  - Evolve the expression of foundational conformance rules to an **electronic format to increase consistency** and instantiate multidimensional model artifacts in the CDISC Library.
  - Initiate a **process to build the model for machines first**, people second.
  - Commit to develop only **end-to-end TAUGs**

The Road ahead

- **Another key strategic goal of CDISC** is to expand and identify adjacent research areas that can benefit from data standardization. i.e. with the evolution of the model, selectively extend CDISC standards to support new data types and/or new technologies.
  - Expertise in **RWD/Real World Evidence (RWE)**
  - Consumer **wearables**
  - Medical devices
  - Device registry, likely via collaboration, that uniquely identifies devices and enables **automated mappings to CDISC standards**
  - CDISC-compliant registry toolkit that is built on the **CDISC Library API**
  - ‘Mapping registry’, which standardizes the conversion of **proprietary device data to CDISC standards**

CDISC and Microsoft are working together to plan the next generation CDISC Library

- *"The next generation CDISC Library will provide **machine-readable standards**, standardized mapping to other data standards, and serve as a tool for community curation of standards that support data becoming accessible across geographies and disciplines, **interoperable across systems and studies**, and reusable for research today and tomorrow."*

*"CDISC is excited to collaborate with Microsoft on this important next step, which will set the pace globally for clinical innovation regarding standardized data," **said David R. Bobbitt, President and CEO, CDISC.***

Reference: https://www.cdisc.org/news/cdisc-and-microsoft-hold-workshop-plan-next-generation-clinical-innovation-standardized-data

CDISC Partners with Gevity to Facilitate Use of **Electronic Health Record Data** in Clinical Research

- The **FHIR to CDISC project** will leverage Fast Healthcare Interoperability Resources (FHIR), HL7's standard for exchanging healthcare information electronically and CDISC's standards for data collection (CDASH) and data tabulation (SDTM) **to streamline the flow of data from EHRs to CDISC submission-ready datasets**. The mapping and Implementation Guide will be available via the CDISC Library API (source of CDISC standards metadata).

- "As EHRs and other real world data sources play an increasingly important role in clinical research and healthcare decision making, our FHIR to CDISC project is timelier than ever," said Rhonda Facile, Vice President, Development Opportunities.

"*Facilitating the development of quality tools to help unlock the benefits of standardization is an essential component of CDISC's Strategic Plan*," stated David R. Bobbitt, CDISC President and CEO.

Reference: https://www.cdisc.org/news/cdisc-partners-gevity-facilitate-use-electronic-health-record-data-clinical-research

The Road ahead

- RWD has the potential to provide answers to important questions. RWD may come from multiple sources including; **electronic health records (EHRs), medical claims and billing activities, product and disease registries, patient-generated data** (including in home-use settings) as well as data gathered from sources that can inform on health status, such as mobile devices.

- RWE is the clinical evidence regarding the usage and potential benefits, or risks of a medical product derived from the analysis of RWD. To fully understand the patient experience, one needs to access the **Extended RWD/RWE (broader sources of data)** in addition to EHR (Electronic health record).

We must figure out how to align previously existing data into standards and how to make sure impending data is collected in a standardized way in order to future proof. Standardization helps with the integration of RWD into the drug development processes and patient safety monitoring.

Key Takeaway

Evolving Standards

CDISC has grown from PDFs to Machine readable standards and from few safety domains to more Therapeutic Area specific standards

Leveraging RWD/RWE

Leveraging RWD CDISC, and other established and emerging standards (e.g., HL7-FHIR), have the potential to transform the healthcare industry

Machine readable standards

The next generation CDISC Library will provide machine-readable standards and support data becoming accessible across geographies and disciplines

Continued Innovation

We must think of developing innovations beyond our current boundaries.

References

1. PHUSE https://phuse.global/Education
2. CDISC
   - https://www.cdisc.org/
   - https://www.cdisc.org/sites/default/files/resource/CDISC_2019_2022_Strategic_Plan.pdf

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