Digitalization and Data Standardization in Clinical Trials

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Meet the Speaker

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Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of KSCD (Korean Society for Clinical Development) or Novotech.*

- *I have no financial relationship or conflict of interest related to this presentation*

Agenda

01 The Evolution of Clinical Trials

02 Key Benefits of Clinical Trial Digitalization

03 MCTC (Modernizing Clinical Trial Conduct) and the Key Roles of CDISC

04 The New Normal in Clinical Trial Operations

05 Challenges and Calls to Action

The Evolution of Clinical Trials

"Patient-Centric Clinical Trials"

"Data-Driven Clinical Trials"

"AI-Powered Technology"

The Evolution of Clinical Trials

What we have seen over the past decades:

01 Clinical trials has transformed from paper-based to digital data capture, enhancing efficiency and accuracy.

02 Today, electronic systems enable real-time data collection and integration across devices.

03 In the future, connected digital data flow will seamlessly link diverse systems, enabling continuous monitoring and advanced analytics for more patient-centric trials.

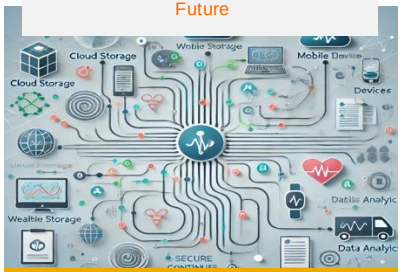
Past

Paper-based

eCRF, ePRO, eCOA, eConsent, CTMS, eTMF, mobile devices

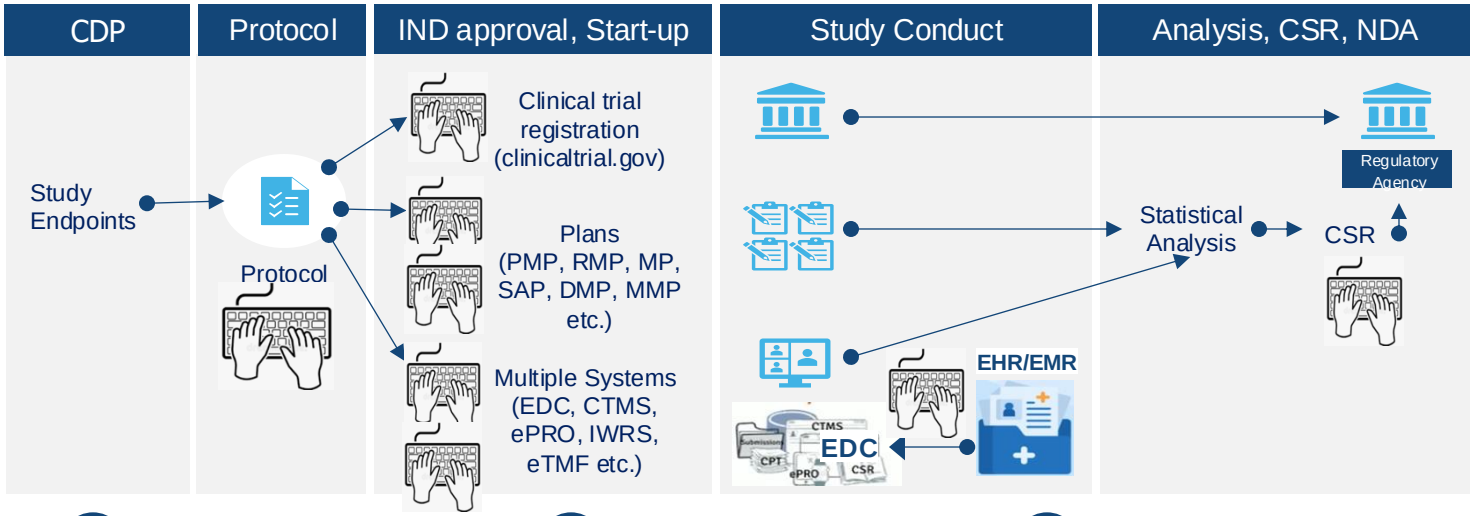
Electronic Data Capture

Future



Fully Connected Digital Systems (Digital Data Flow)

Clinical Trial Information/Data Flow



01 "Can we automate data entry to prevent duplication and ensure data integrity across systems?"

02 "Are systems integrated for seamless, real-time data sharing?"

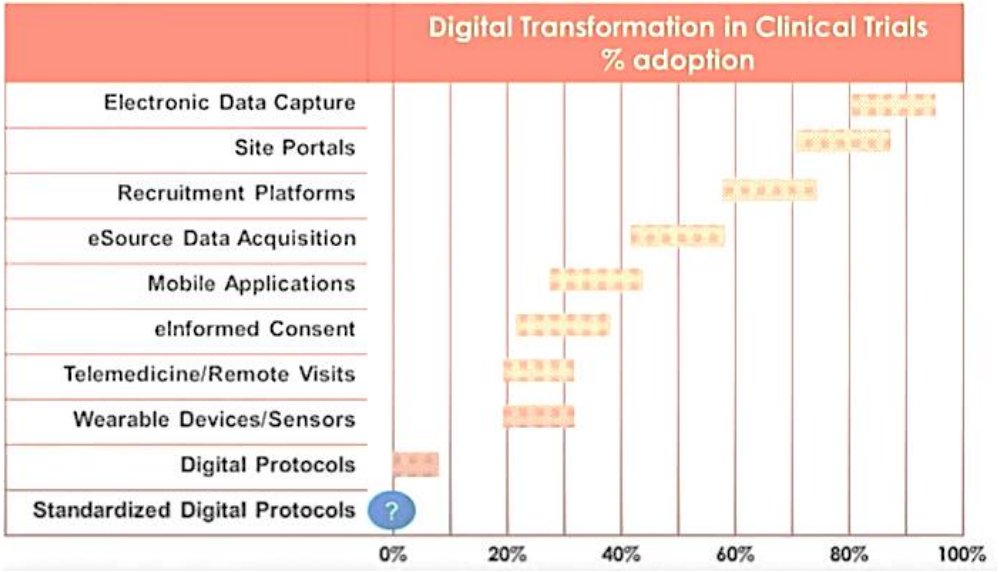
03 "Can we analyze and repurpose accumulated data for future study design and efficiency?"

Adoption Rate of Digital Tools in Clinical Trials

01 An overview of the adoption levels of various digital tools in clinical trials, as part of the digital transformation.

02 High adoption rates are seen in electronic data capture, mobile applications, and telemedicine, while digital protocols have lower adoption rates.

03 The adoption rate of digital tools might be lower in Korea



Ref: TransCelerate Dec13, 2023 - Modernizing Clinical Trials Using Digitized Protocol Information https://www.youtube.com/watch?v=nX86V8TJISw

Digitalizing Clinical Trials: Breaking the Paradigm

Embracing interoperability and AI-driven analytics to enhance patient-centricity and regulatory compliance.

Digitized Protocol	✓ Structured ✓ Machine readable ✓ Standard terminology
Electronic Data Collection & Management	✓ EMR, EHR, ✓ eCRF, ePRO, eCOA, Wearable devices ✓ eConsent, RTSM ✓ CTMS, eTMF
Patient-centric, and Remote Data Access and Analysis	✓ Remote and Centralized monitoring ✓ Real-time Data review and analysis ✓ Patient-centric, Decentralized Trials
Data Integration, Automated Data Flow	✓ Integration of Electronic Health Records (EHRs) ✓ Exchange of data across systems (Interoperability) ✓ Write once, Read many times ✓ Fully automated data flow between systems

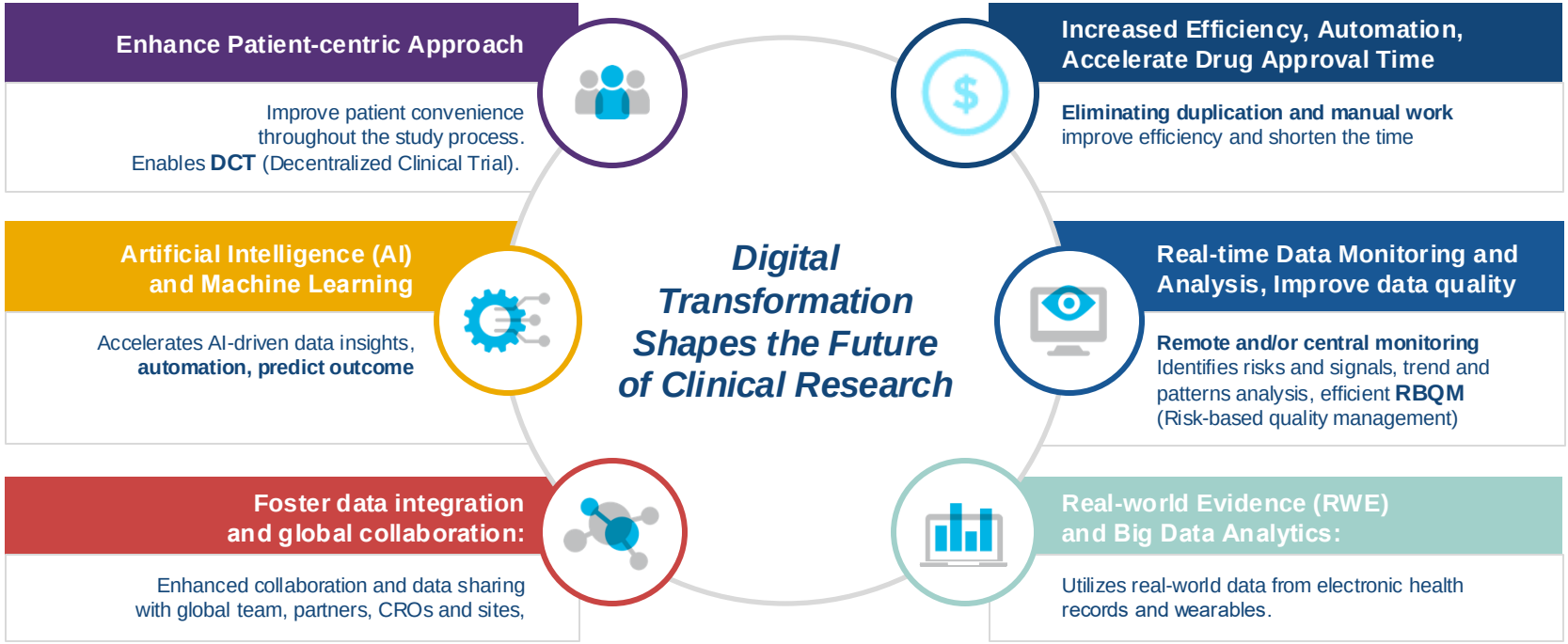
Automation

Integration

Efficiency Quality

AI and Machine Learning

Key Benefits of Clinical Trial Digitalization



KEY ISSUES

Despite the use of various electronic tools for data collection in clinical trials, many organizations struggle to realize the full benefits of digitalization due to several ***key issues****:*

Inconsistent Data Standards
Variations in data formats and standards across tools

Lack of Interoperability
Challenge to integrate data across platforms

1. **Fragmented Data Sources**
   Data comes from diverse sources without standardization
2. **Limited Real-Time Data Access**
   Real-time data monitoring and access remain limited in many trials
3. **Resistance to Change and Skills Gap**
   Adopting a digital approach requires changes in workflows and upskilling of staff
4. **Data Security and Compliance Concerns**
   Robust data governance required for data privacy and security
5. **Regional Differences**
   Regional differences in digital tool adoption and standards compliance

Collaboration Toward Modernizing Clinical Trial Conduct (MCTC)

A collaborative effort by government and industry organizations to advance the modernization of clinical trial conduct (MCTC) through digitalization.

Health Authority

DTRA (Decentralized Trials & Research Alliance)

DDF (Digital Data Flow): CDISC Standards support DDF

CPT (Common Protocol Template)

CDASH: Data Acquisition Standards

SDTM: Standards for Data submission

ODM: Data Exchange and Archiving

USDM: Unified Study Definitions Model for Study Definition Repository and Interoperability

HL7/FHIR: for Electronic Health Records (EHRs) Interoperability

ICH, CTTI

GCP Renovation: Modernization of ICH E8 and renovation of ICH E6, ICH M11 Protocol Template

Sites, CRO/Tech, Academy

Collaboration with sites, technology & data provider, academic research, patient advocacy community

CDISC Standards Support Digitalization and Standardization

CDISC (The Clinical Data Interchange Standards Consortium) is a global nonprofit organization that develops standards to streamline clinical research and enhance data quality.

CDISC standards provide a cohesive framework to enhance data interoperability, streamline clinical trial processes, and accelerate the adoption of digital tools in clinical research.

Foundation	Data Exchange	Terminology	Digital Data Flow	Trial Master File	In development
CDASH SDTM ADAM	ODM Define-XML Dataset-XML	Controlled Terminology	USDM	TMF Reference model Exchange mechanism	Digital health technologies

Key Roles of CDISC in Standardization and Interoperability

Importance of Data Standardization :
CDISC standards ensure consistent, high-quality data collection, enabling easier data sharing, collaboration, and regulatory submissions across global stakeholders.

Importance of Interoperability :
Interoperability is crucial in digitalization as it enables seamless data flow between systems, enhancing efficiency, data quality, and collaborative research.

Key CDISC Models

CDASH (Clinical Data Acquisition Standards Harmonization):
Standardizes data collection fields across clinical trials.

SDTM (Study Data Tabulation Model):
Standardized format for clinical data submission.

ADaM (Analysis Data Model):
Facilitates data analysis through standardized datasets.

ODM (Operational Data Model):
Standardized exchange of clinical trial metadata and data across different systems, ensuring interoperability.

USDM (Unified Study Design Model):
Standardized structure for representing study designs, facilitating seamless data integration and reuse across trial phases and systems.

Digital Data Flow (DDF): Vision of the Future

01

A structured, standardized, and digitized protocol enables streamlined automation by allowing downstream systems to utilize its contents.

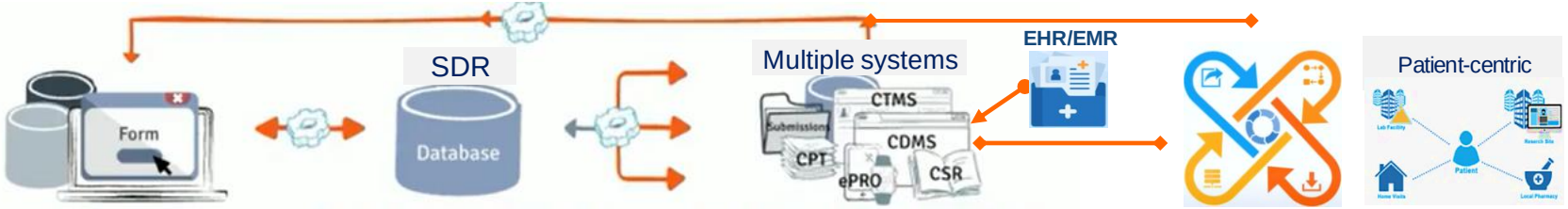
02

CDISC Standards and TransCelerate's DDF initiative will provide a common foundation for interoperability of data flow across the clinical trial ecosystem.

HL7/FHIR enables EHR data interoperability

03

Improve operational productivity, efficiency and quality by eliminating manual entry, duplication



Digitized Protocol

Standardized Data

Interoperable Systems

Study definition repository (SDR), Central source of protocol details supporting data integration across multiple systems (system interoperability)

How: **USDM** (Unified Study Definitions Module) Standards, Controlled Terminology

Operations systems & outputs, Automated flow of data.
Various systems, documents and outputs can obtain the Protocol contents consistently.

Automated transfer of EHR/EMR data into the EDC system, Automated data flow between systems

Efficiency & Advanced data analytics
No need of SDV,
Real-time data analysis during the study **(RBQM),** Advanced analytics such as AI and machine learning to improve study design.

Decentralized Clinical Trials (DCT)

The New Normal in Clinical Trial Management

Evolution of Clinical Trials Operation and Management - Enhanced Collaboration and Data Sharing, Increased needs for training and skills development as digitalization grows in the industry

Planning and Development

AI-driven predictive models will enhance protocol design. making trials more efficient and patient-centric.

Medical Writing

Automation tools will generate protocols, reports, regulatory documents faster

Clinical Operations

Allow remote site management and decentralized trials, Minimize SDV effort, Focus on SDR

Project Management

Digital tools streamline project management, better tracking of timelines and resources

Statistics

Automation will simplify statistical analyses, while advanced machine learning models will handle more complex data

Data Management Central Monitoring

Real-time data quality monitoring and predicted analytics (RBQM) enhance trial efficiency

Pharmacovigilance

Enhanced signal detection and more accurate safety monitoring

Implementation Challenges

Inconsistent Regulatory Standards:	Limited CDISC implementation in Korea
Data Standardization, Interoperability:	The lack of universal data standards hampers interoperability between systems. Initiatives like CDISC aim to address this, but widespread adoption remains a challenge.
Diversity of Legacy Systems:	Many clinical trial sites and sponsors still operate on legacy systems that are not compatible with modern digital tools. The challenge lies in upgrading these systems or migrating to new platforms without disrupting ongoing trials.
Site Readiness:	Not all clinical trial sites are equipped to handle the digital transformation. There is a wide variance in site readiness
Acceptance of Digitalization and Change Management	Cultural barrier, resistance to change, preferring traditional methods over digital innovations.
Data Security and Privacy	Ensuring compliance with data protection regulations while utilizing digital technologies is a key issue

Calls to Action – Collaborative Approach

01	02	03
Enhance global collaboration for digital integration	Promote CDISC standards for unified data.	Invest in training to bridge the digital skills gap.

Thank You!

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