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Transcelerate DDF – SDR-RI MVS Streamlining Protocol to Study Design

Jennifer Duff, General Manager, Clinical Development Solutions
Mark Laney, Clinical Development Sales Engineering & Product Partnership Lead

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Meet the Speakers

Jennifer Duff

Title: General Manager, Clinical Development Solutions

Organization: Merative

Jennifer has over 24 years of experience in the Life Sciences industry with specialization in enabling and scaling industry-leading services and technology solutions for pharma, med device and biotech clients. In her role as General Manager, Clinical Development Solutions, she is responsible for harnessing the power of their unified clinical data management and data acquisition technology along with the skills of the consulting & services team members to solve complex challenges for their customers in the Life Sciences industry. Merative solutions empower their customers to take control in every stage and their solution is designed to help accelerate trial outcomes with confidence, to help put you at the center of health.

Mark Laney

Title: Clinical Development Sales Engineering & Product Partnership Lead

Organization: Merative

Mark has over 20 years of experience with software in the Life Sciences industry focused on delivering the right solutions for customers. As the Sales Engineering and Product Partnerships Leader for Merative Clinical Development, he is tasked with solving customer challenges using the breadth of functionality and flexibility of Merative's unified clinical data management solution while facilitating partnerships with complimentary industry leading vendors to offer customers a robust technology solution for their clinical needs. Prior to joining Merative, Mark held roles in training, implementations, client success, and technical sales as part of the Merge Healthcare eClinical team that launched and scaled the platform now known as Clinical Development.

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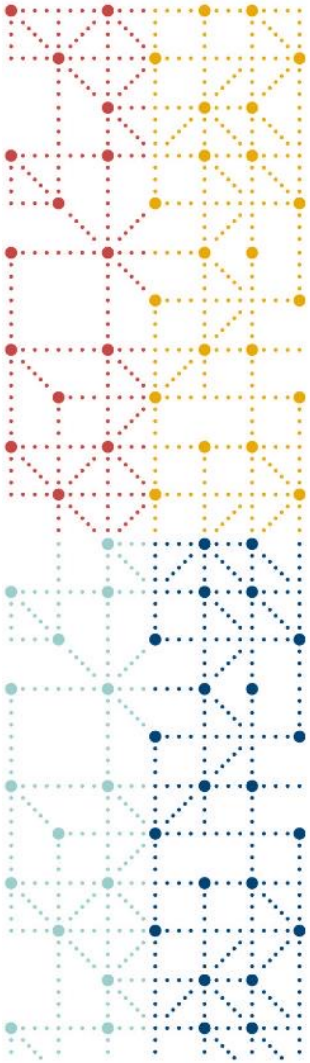
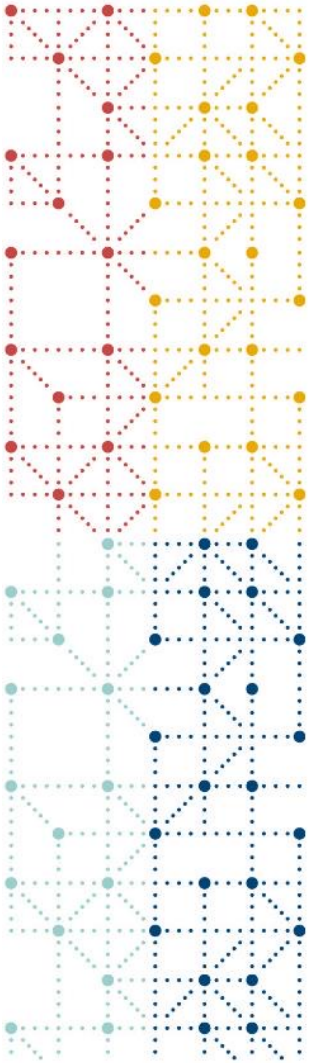


Agenda

1. Defining the Transcelerate DDF – SDR RI MVS project
2. Our experience
3. Benefits and future potential



Transcelerate DDF – SDR-RI MVS

Digital Data Flow (DDF)

Study Definitions Repository (SDR)

Reference Implementation (RI)

Minimum Viable Solution (MVS)

Transcelerate Digital Data Flow Initiative

What is the DDF Initiative?

"The Digital Data Flow (DDF) initiative aims to modernize clinical trials by enabling a digital workflow to allow for automated creation of study assets and configuration of study systems to support clinical trial execution. This initiative will establish a foundation for a future state of automated and dynamic readiness that can transform the drug development process."

What is the SDR Project?

"The initial objective of DDF is to automate and expedite the study start-up process by revolutionizing how data flows."

What is the RI Phase?

"Transcelerate will develop an open-source, vendor agnostic, SDR reference implementation (SDR RI). The SDR reference implementation will enable the format of information from a digitized protocol and other sources to be standardized and thus allow the information to be passed to systems that are used for study execution and data collection, and reused throughout the clinical development lifecycle."

Source: Direct Data Flow Overview, Transcelerate Biopharma Inc.

The role of CDISC in DDF

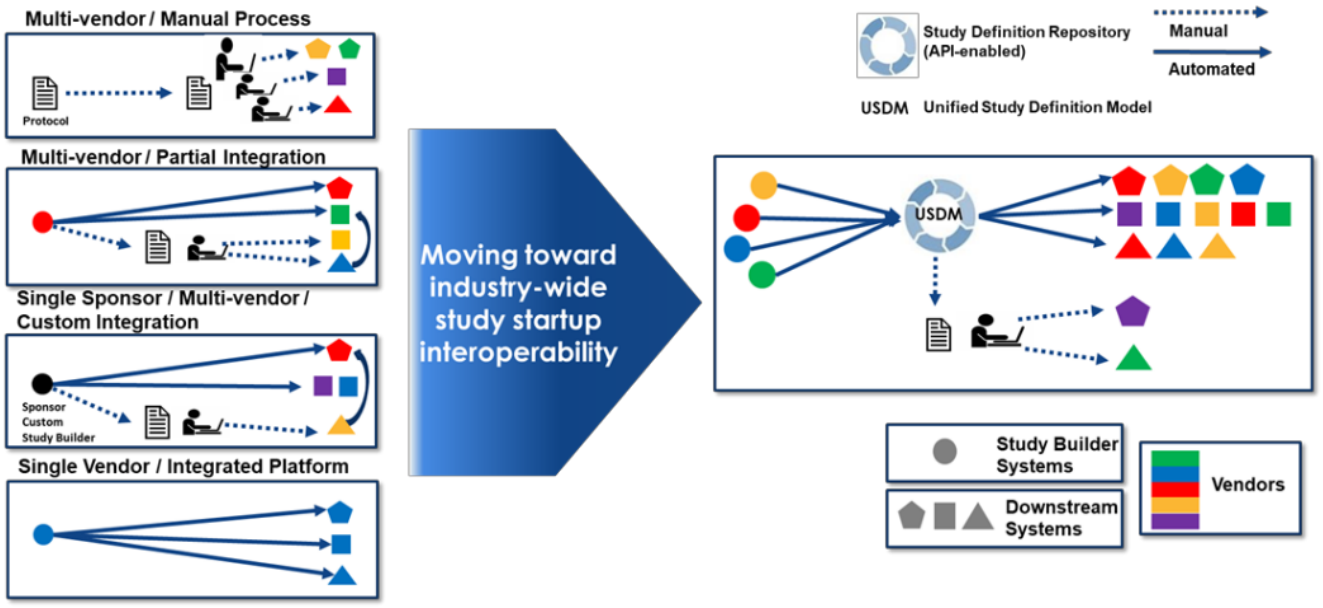
"To create a consistent, comprehensive, and structured representation of a study definition as described in text in clinical trial protocols, **CDISC data standards will need to be augmented and a new standard defined.** To this end, the USDM will be created, and study definitions in the SDR will conform to this data standard."

"The USDM will consider existing standards … The new concept-based standards aim to link the different standards by providing additional semantics to enable **metadata-driven automation**."

Source: Direct Data Flow Overview, Transcelerate Biopharma Inc.

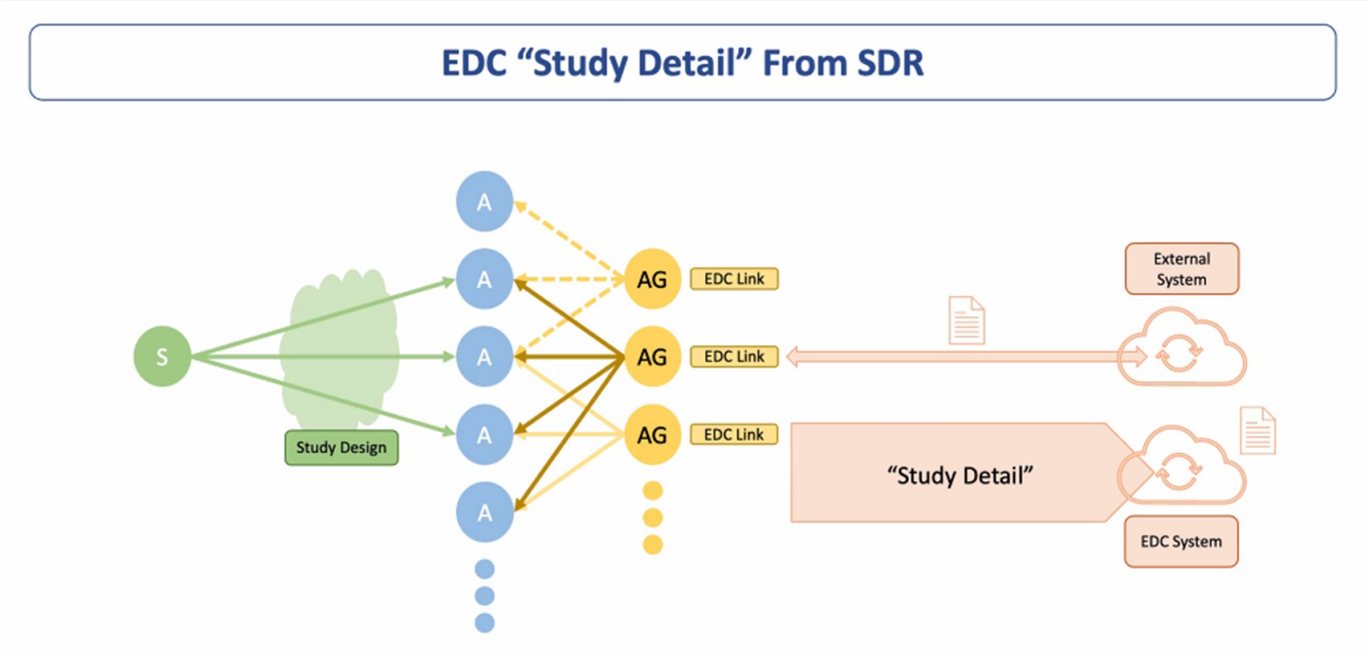
The DDF SDR-RI vision

How API-Enabled Definition Repository & Integration will work?



Source: Direct Data Flow Overview, Transcelerate Biopharma Inc.

Vision for Data Flow from SDR to downstream systems



Source: Architectural Review Session, Transcelerate Biopharma Inc.

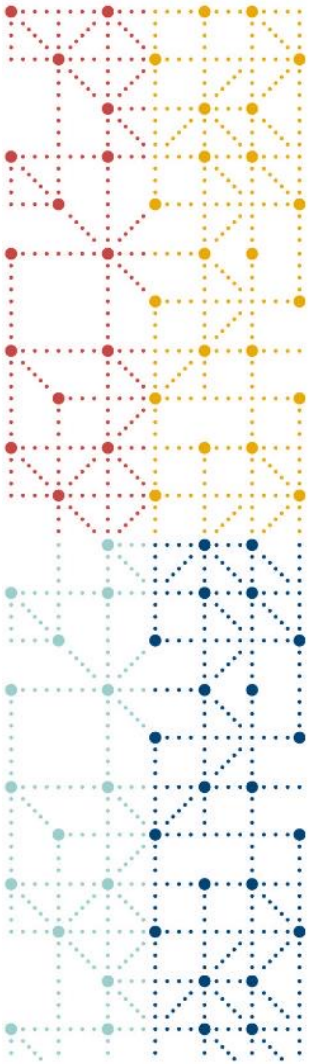
Our expectations coming into the MVS project

We got this! – by the end:

- We will demonstrate flow from design into Merative Clinical Development
- We will demonstrate measurable efficiency & speed
- We can leverage existing API capability within our system = low dev investment

The Future will be Bright

- Minimal study build times
  - Simplify processes
  - Remove silos
  - Remove manual work
  - Reduce transformation
- Significantly reduce need to create study-level requirements



Our Experience

Competitors working as colleagues

Collaboration:

- Ultimately, we all want the same thing
  - To make it easier to get treatments to patients
- Sharing lessons learned
  - Technical and Non-Technical
- Constructive and respectful disagreements
  - USDM v ODM

Feedback and Change:

- As a group, we aligned on changes
  - Regular meetings as a group
  - In-person workshop
- Feedback implemented / considered

Implementation:

- Building POCs
  - “Spare” time
  - Collaborating up/down stream
  - Demonstrations

The Process

Initiation:

- Project kick-off
- Team build up
- Credentials
- Regular meetings
- Development

Connection Showcase:

- Upstream
  - Study Design
- Downstream
  - EDC
- Collaboration

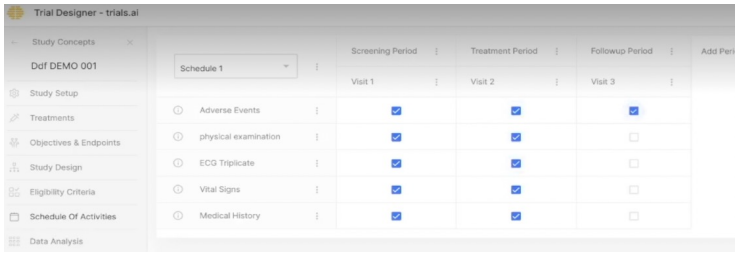
Connect-a-thon:

- Open to the industry
  - Data Interoperability
  - UI/UX
  - Analytics/Reporting
  - Supplemental Data and Additional Standards
  - Process Automation
  - SDR Host Migration
- Progress

Study Design to EDC in 4 Easy Steps

1. Build a study using Trials.ai

Trials.ai's unique interface allows scientists to use natural language to construct a structured USDM compliant protocol specification.

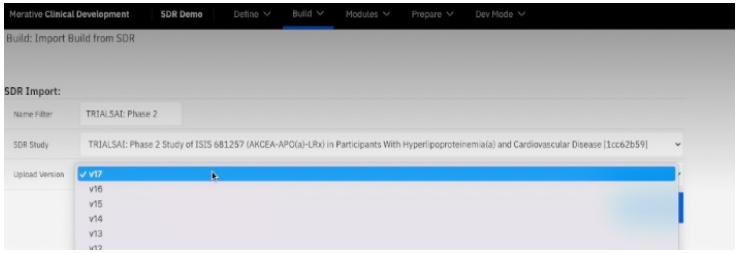


2. Trials.ai pushes to the SDR

Trials.ai utilizes the complete set of data elements defined by the USDM, connects to the SDR and pushes the study design specification for consumption.

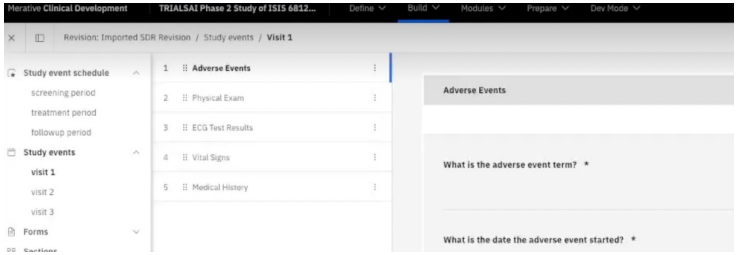
3. Merative connects to the SDR

Merative Clinical Development provides users the ability to connect to their SDR and select study definitions and versions.

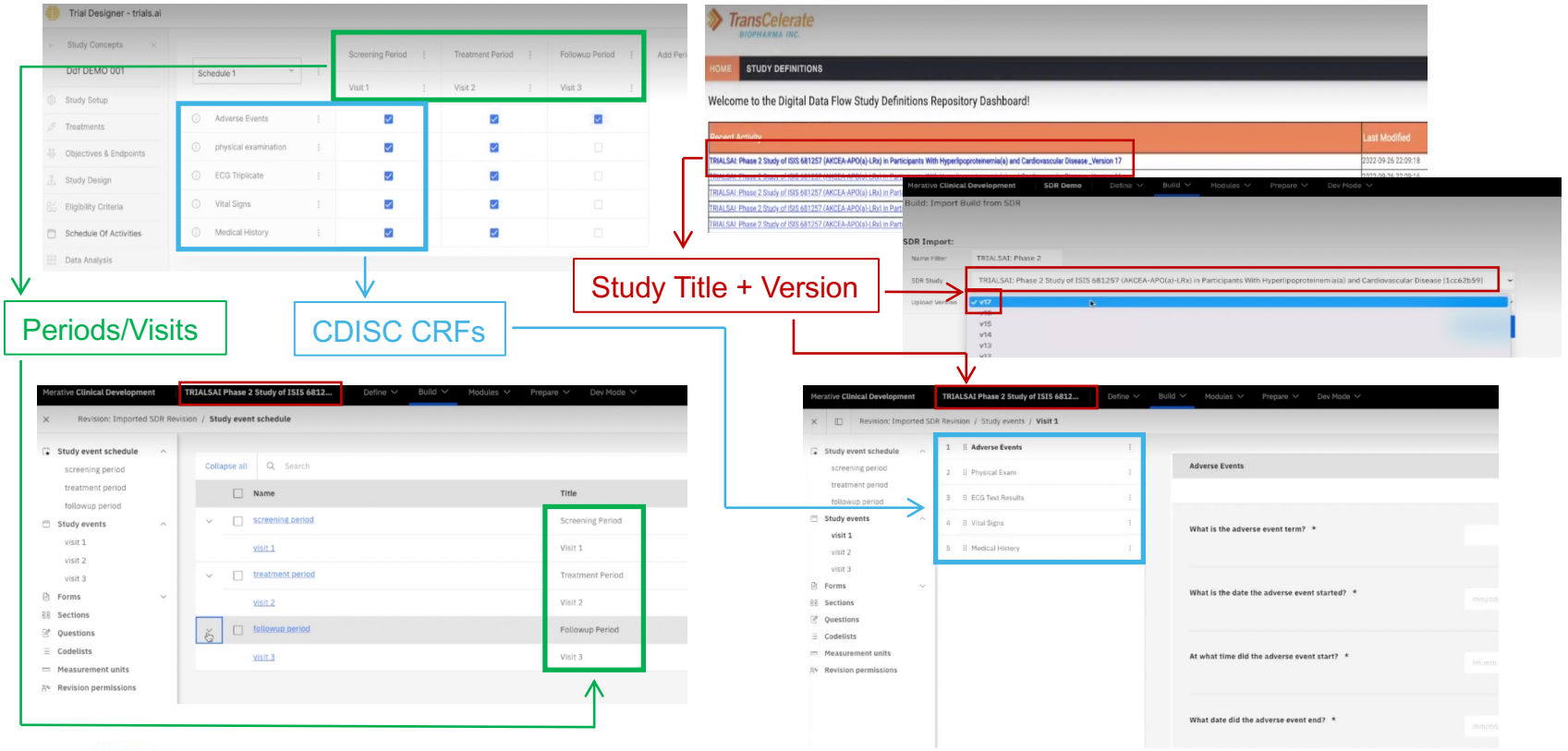


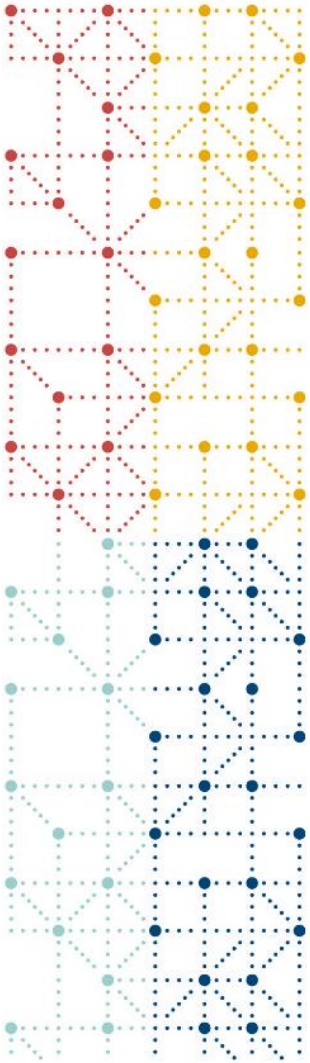
4. Merative builds the EDC

Merative Clinical Development imports study design from SDR and automatically builds EDC study design with full schedule of activities and associated eCRFs.



Mapping Trials.ai design to Merative EDC





Benefits and Future Potential

There will be tangible benefits

- ❑ SDR is the “great equalizer”
  - Not beholden to any one system
  - Study design/build skill sets less system-dependent
- ❑ Increased industry alignment – “single method” anyone?
- ❑ Build “once and done”
- ❑ Stop shuffling the work around – imagine actually having *less* work?

Challenges to be overcome as DDF advances

What's the biggest challenge?

- ❖**Adoption**
- ❖**Adherence**

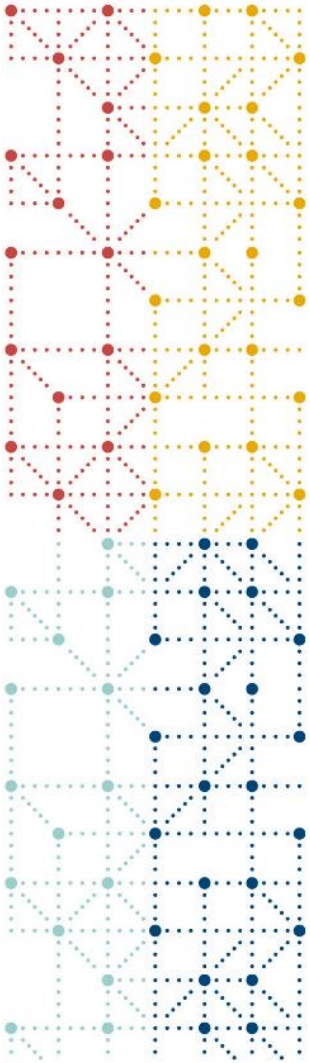
Other considerations:

- ***Troubleshooting complexity*** due to incorrect credentials or some issue at the SDR level (incoming from upstream system or from source)

- ***Change management*** – needs to be combo of tech & process

There are lots of exciting future opportunities

- ❑ Expand the concept and integrate with other parts of the process
  - Move beyond only Schedule of Events & CRF integration
  - Flow into: eConsent
    Stratification
    Randomization
- ❑ Bi-directional data flow



Thank You!

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