

The Future of the Digitized Data Flow (TT07)

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OUTLINE

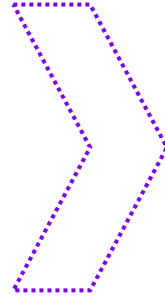
- ❑ **Motivation and Overview**
- ❑ **Enabling the Digital Data Flow: Design, Define, and Build**
- ❑ **Examples from Industry**
- ❑ **Conclusion**



DIGITAL DATA FLOW

Motivation

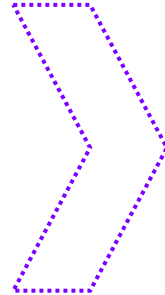
Clinical trial protocols are growing more complex



Average increase of 70 % in the number of total procedures conducted in Phase III protocols over a 10-year period

Getz, K., & Campo, R. (2017). Trial watch: Trends in clinical trial design complexity. *Nature Reviews Drug Discovery*, 307.

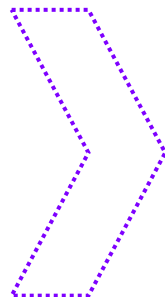
Translating a protocol to the systems and processes required to implement it is time consuming and thought-intensive



68.3 days on average to build and release a study database

Tufts – Veeva 2017 eClinical Landscape Study

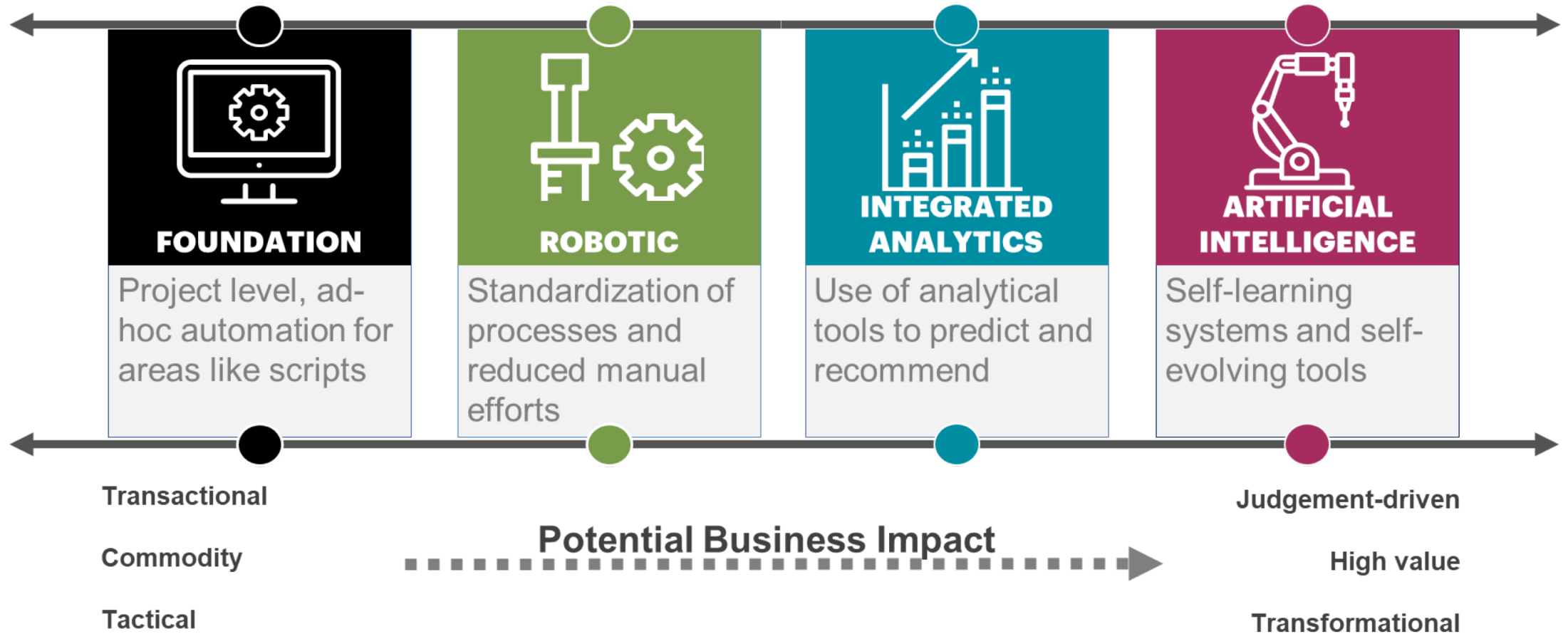
New technologies create opportunity



Automation tools, machine-learning, and graph databases allow us to **re-think what is possible**

DIGITAL DATA FLOW

Fit for Purpose Automation



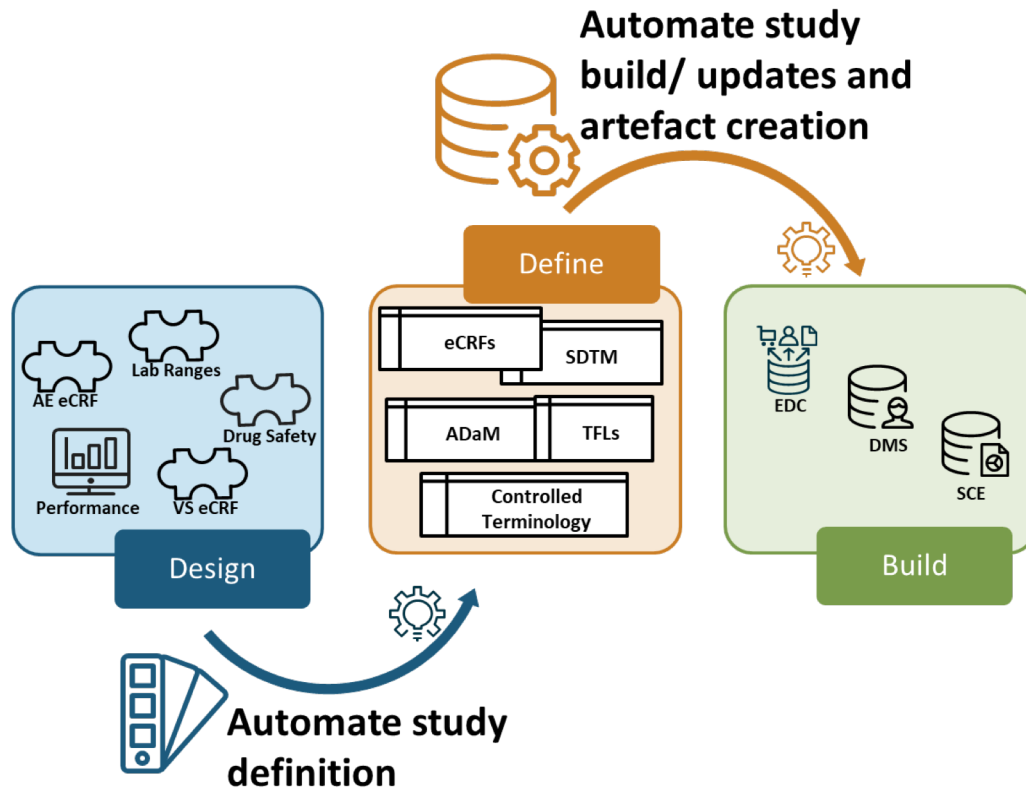
DIGITAL DATA FLOW

Translate Design to Action

The dream: **Streamline the clinical data flow from collection to aggregation to reporting**

The outcomes:

- ▶ Improved efficiency by automating the definition and build of databases, collection tools, and study artefacts
- ▶ Near real-time access to aggregated data and analyses to improve decision-making during study conduct



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Design: Gaps and Enablers

Design

Key Protocol and Analysis Elements

Schedule of Activities



Objectives / Endpoints

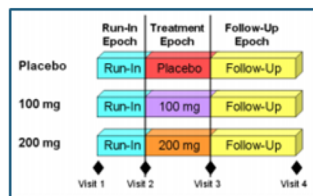


Analysis Plan



Trial Design Content

Trial Design



Inclusion / Exclusion Criteria



Gaps

1. Structured, machine-readable protocol and analysis elements
2. Semantic relationships between protocol elements, analysis elements, and standards
3. Linked standards to promote re-use of existing standards and identification of new content that requires development

Potential Enablers



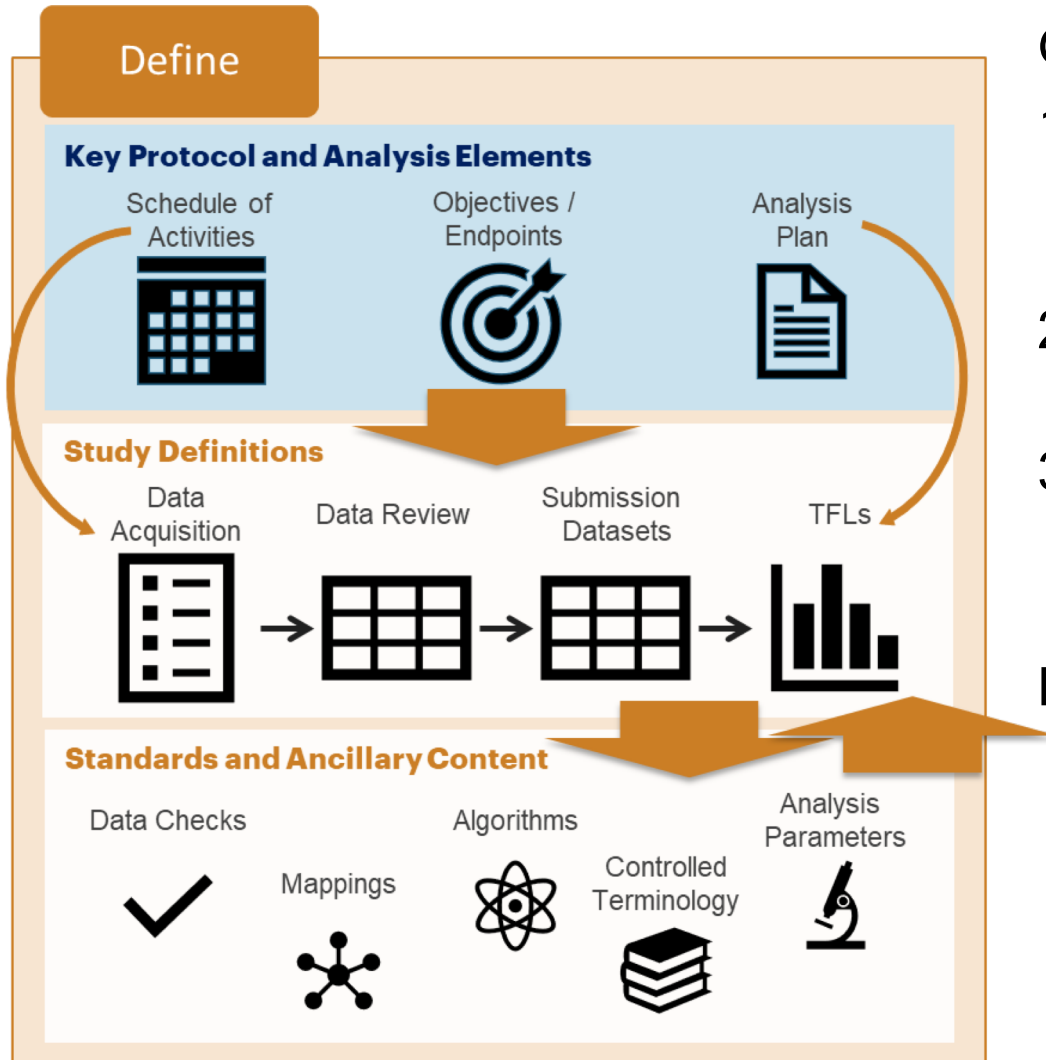
- Authoring capability for a structured protocol representation



- Natural language processing to digitize design and protocol libraries

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Define: Gaps and Enablers



Gaps

1. Automated tools for the study definition process using machine-readable protocol elements linked to standards
2. Linked standards across the data lifecycle to reduce manual mapping activities
3. Human focus on confirmation and development of new standards or bespoke, study specific content

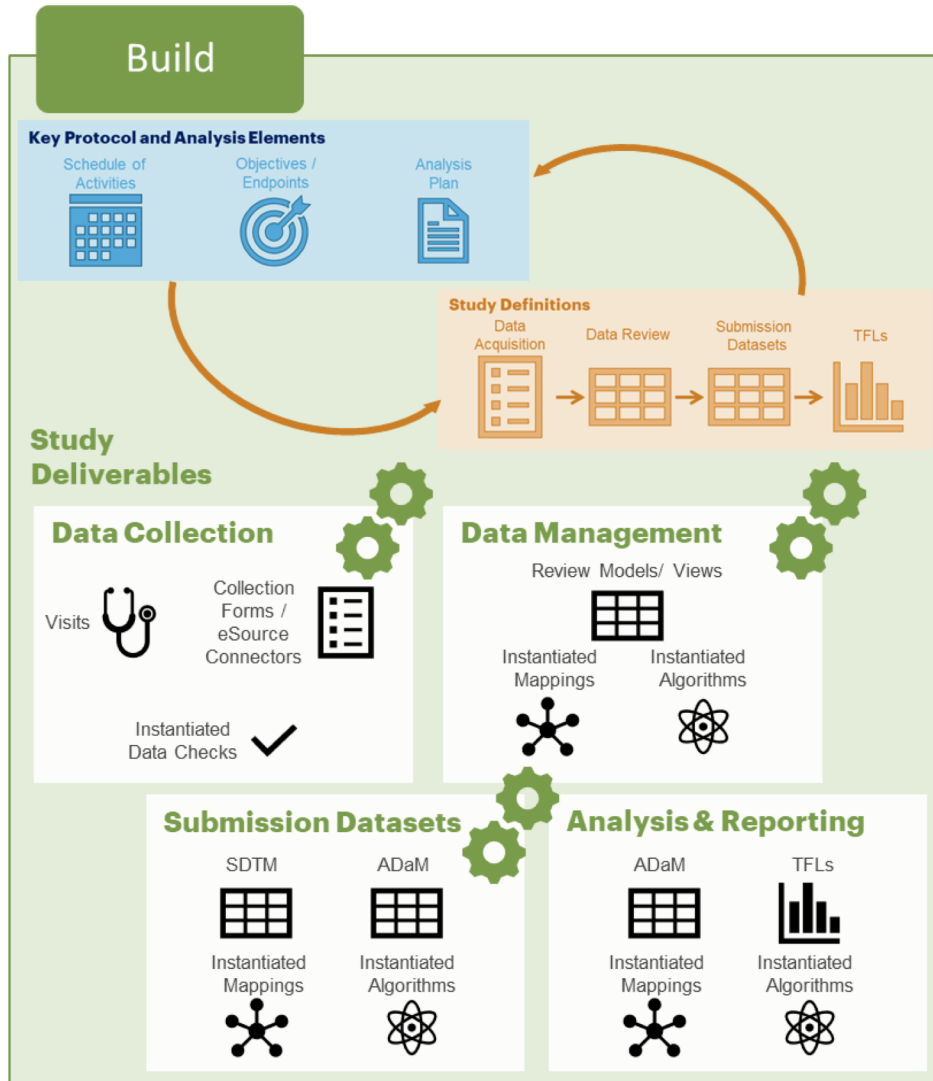
Potential Enablers



- Recommendation engine to automate standards selection and mappings
- Graph DB to manage semantic relationships between protocol elements, study definitions, and data standards

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Build: Gaps and Enablers



Gaps

1. Automated study build and data transformation via **metadata-driven transactions** in downstream systems
2. Traceability from operational artifacts to corresponding specifications and protocol elements

Potential Enablers



- Metadata-driven data transformation engine for standard data conversions
- Conformance reporting to ensure downstream systems are configured according to study specifications

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Examples: Structuring the Protocol

- TransCelerate's Technology Enabled Common Protocol Template (CPT) provides key protocol information in a semi-structured XML format for downstream consumption (Alsumidaie, 2017)
- Rho has developed a system that models trial design elements and supports automation of the SDTM Trial Design Domains (Abolafia & Dilorio, 2016)
- Roche developed a tool that provides a template-based approach to producing a schedule of assessments that promotes adoption and adherence to standards (Willson, 2013)
- Bayer reported the development of a Protocol Designer tool that links standards to Protocol Activities to enable automated standards setup for a study (Velurethu & Pangritz, 2015).

1. Alsumidaie, M. (2017, June 2017). TransCelerate Establishes Technology Common Protocol Template and Collaborates with the FDA / NIH. Retrieved from Applied Clinical Trials Online: <http://www.appliedclinicaltrialsonline.com/transcelerate-establishes-technology-common-protocol-template-and-collaborates-fdanih>
2. Abolafia, J., & Dilorio, F. (2016). Protocol Representation: The Forgotten CDISC Model. Retrieved from lexjansen: <https://www.lexjansen.com/phuse/2016/cd/CD01.pdf>
3. Willson, A.-L. (2013). Supporting End to End Standards in Study Set Up. Retrieved from lexjansen: <https://www.lexjansen.com/phuse/2013/pp/PP15.pdf>
4. Velurethu, A., & Pangritz, S. (2015). "Connect and Create" Connect Standards and Enable Protocol Authoring. Retrieved from lexjansen: <https://www.lexjansen.com/phuse/2015/dh/DH05.pdf>

DIGITAL DATA FLOW

Examples: Metadata Driven Transformations

Pilot demographics & timeline

- Proprietary global metadata and two data cuts of client source data (56 & 59 datasets respectively) were received by Accenture and transformed into **48** SDTM domains
- The entire effort, including Trial Design, took **31** business days

Pilot quality assessment

- In total there were 700 variables created across 48 SDTM domains
- 17 total findings in which:
 - 9 of the 17 were flagged as Accenture errors
 - 3 Major errors
 - 6 Minor errors
 - 8 were interpretation/global spec issues
- The overall quality metric was 98.9% ($1 - (\text{errors} / \text{variables})$)
- Accenture estimates that an additional 3 business days would be needed to address the findings noted as errors

Work Type Breakdown:

1. Global Spec Interpretation = 10%
2. Human-readable spec development = 15%
3. Machine-readable spec development = 40%
4. Code development = 5%
5. QC and Compliance Reviews = 15%
6. Client and Project Management = 10%
7. Client-specific team training = 5%

Thank You!

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