

PP05 - SDTM Hackathon - To find a metadata driven software system that will allow BMS to automatically generate mapped SDTM datasets

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Background

As we **evolve** at BMS **transitioning** our programming from an outsourced model to an in-house solution, to allow us to deliver early and effective data-driven decisions for drug development, there was a need for us to prepare and deliver our SDTM datasets as effectively as possible utilizing metadata driven tools and the experienced team within BMS.

Our Goal

To find a metadata driven software system that will allow BMS to automatically generate mapped SDTM datasets needed for submission and analysis from BMS collection standards. This hackathon will use our standard metadata in the form of excel mapping specs along with the annotated CRF and electronic external data as input. The system should also allow our team of SDTM mapping experts to easily verify completeness and correctness of the mapped data with minimal manual input.

Our Approach

- To run an Internal and an external vendor hackathon
- Externally three providers were selected:
 - Each would have the same metadata and anonymized raw data
 - Deep dive sessions post-delivery with procurement and IT
- Final decision on provider based on hackathon outputs, deep dive sessions and RFP responses
- The concept of **adjacent possible** where the pattern of small steps of making an advance is the dominant framework for Innovation

The Adjacent Possible



The Adjacent Possible is "the next possible thing"

Every time the world changes in some fundamental way, every time a new technology is invented, every time our behaviours change, a series of new adjacent technologies and opportunities becomes possible

Internal Hackathon strategy

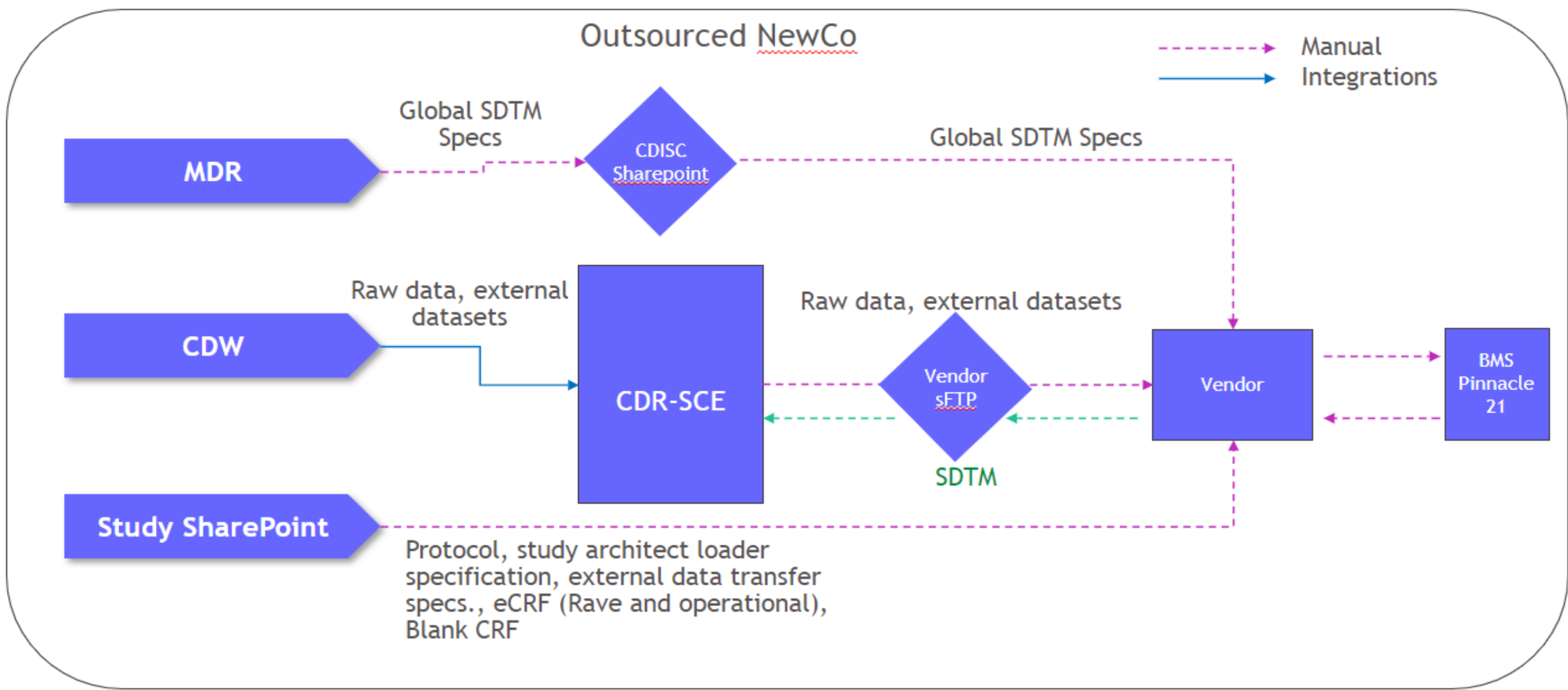
- Understand the voice of the customer - the everyday challenges they face and the need for the system
- Create an in-house team that contains a diverse group where each member brings different strength and skills
- Break down the objective into smaller goals and modules
- Develop generalized functions which can be applied within this project but are re-usable in other use-cases
- Hence focus on the R in F.A.I.R

The External Hackathon

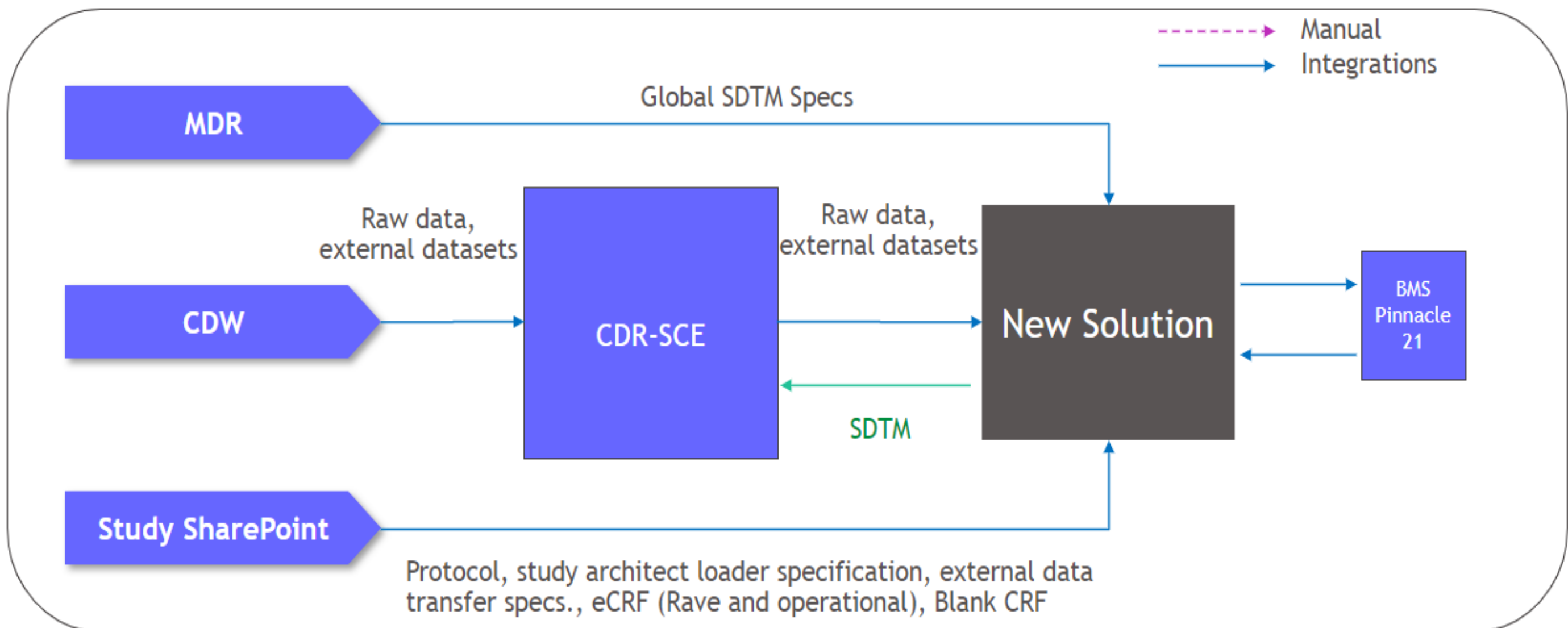
The challenge to our external vendors was that they had 5 weeks to present a scalable solution that demonstrated the capability to ingest clinical data, documentation and metadata provided by BMS, using our global and study level metadata to drive the SDTM transformation. The key deliverables of this Hackathon which they would be scored on were:

- Executable code
- Transformed SDTM data
- Study SDTM mapping specifications
- Define.xml
- Validation report
- Annotated CRFs

Current Outsourced SDTM Data Flow



Proposed Future State Data Flow



Outcomes

- Significant time reduction in SDTM transformation
- Early real-time access to SDTM data
- 50% cost savings per study
- Enable accelerated Standardization across BMS
- The chosen approach to be rolled out in 2023

"Accelerating clinical trial submissions and the approval life cycle by automating SDTM transformation capabilities will positively impact the biostatistical analysis and regulatory submission both in terms of time and quality. Furthermore, the speed and consistency we envisage with this solution will open up capabilities and uses of SDTM data beyond the traditional methods"