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Study Design Optimization with DDF assets

Presented by
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Meet the Speakers

Bazgha Qutab

Title: Principal

Organization: ZS Associates

Bazgha is a global leader within our Digital Transformation and R&D Excellence space based in Europe. She has over 18 years' experience in strategic advisory, clinical development, real world data analytics, data management, and technology transformation within R&D and Commercial in Life Sciences.

Siddharth Shah

Title: Associate Principal

Organization: ZS Associates

Siddharth has 19 years of technology led business transformation experience advising life sciences companies in the various areas within R&D (Study design, Investigator Platform, clinical trial management, regulatory intelligence and safety automation), commercialization and manufacturing.

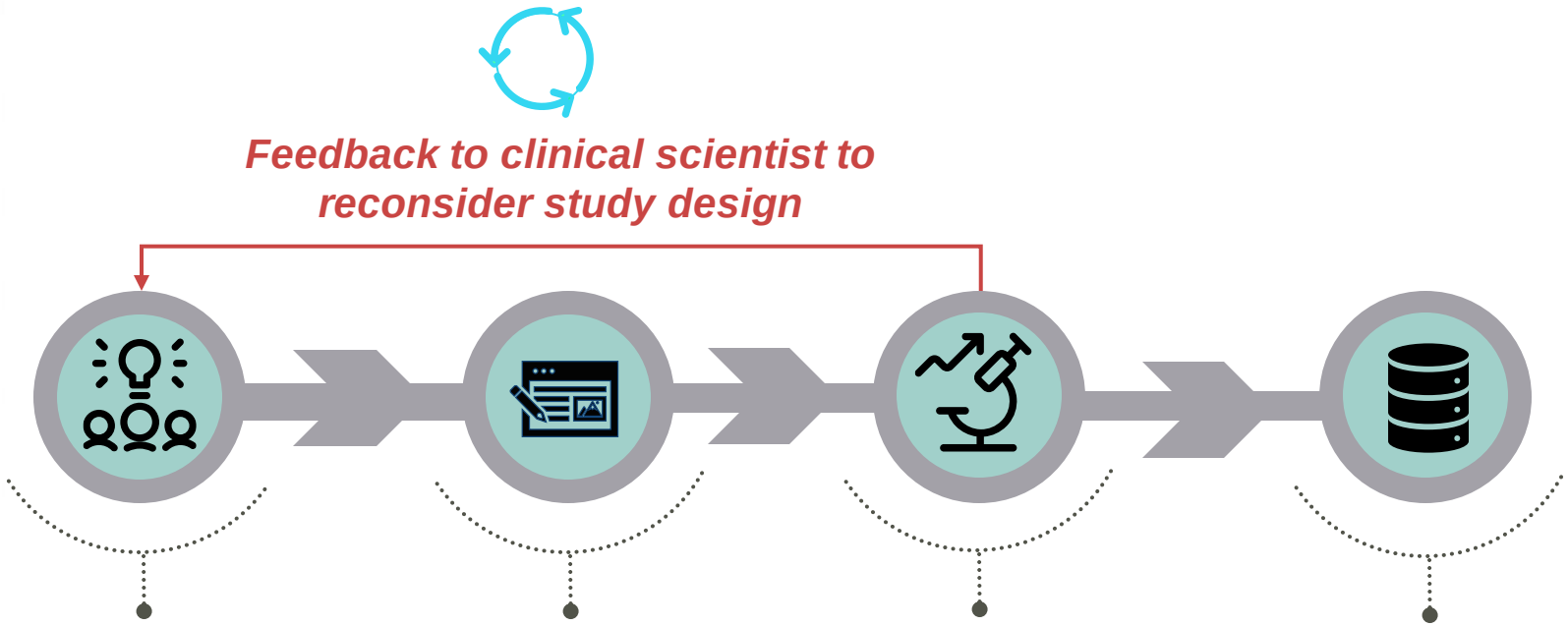
Disclaimer and Disclosures

- *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 CDISC.*

- *The author(s) have no real or apparent conflicts of interest to report.*

Industry Challenge and Solution(s)

Traditionally, optimization is an after thought in study design process, often leading to lower operational and enrollment delays



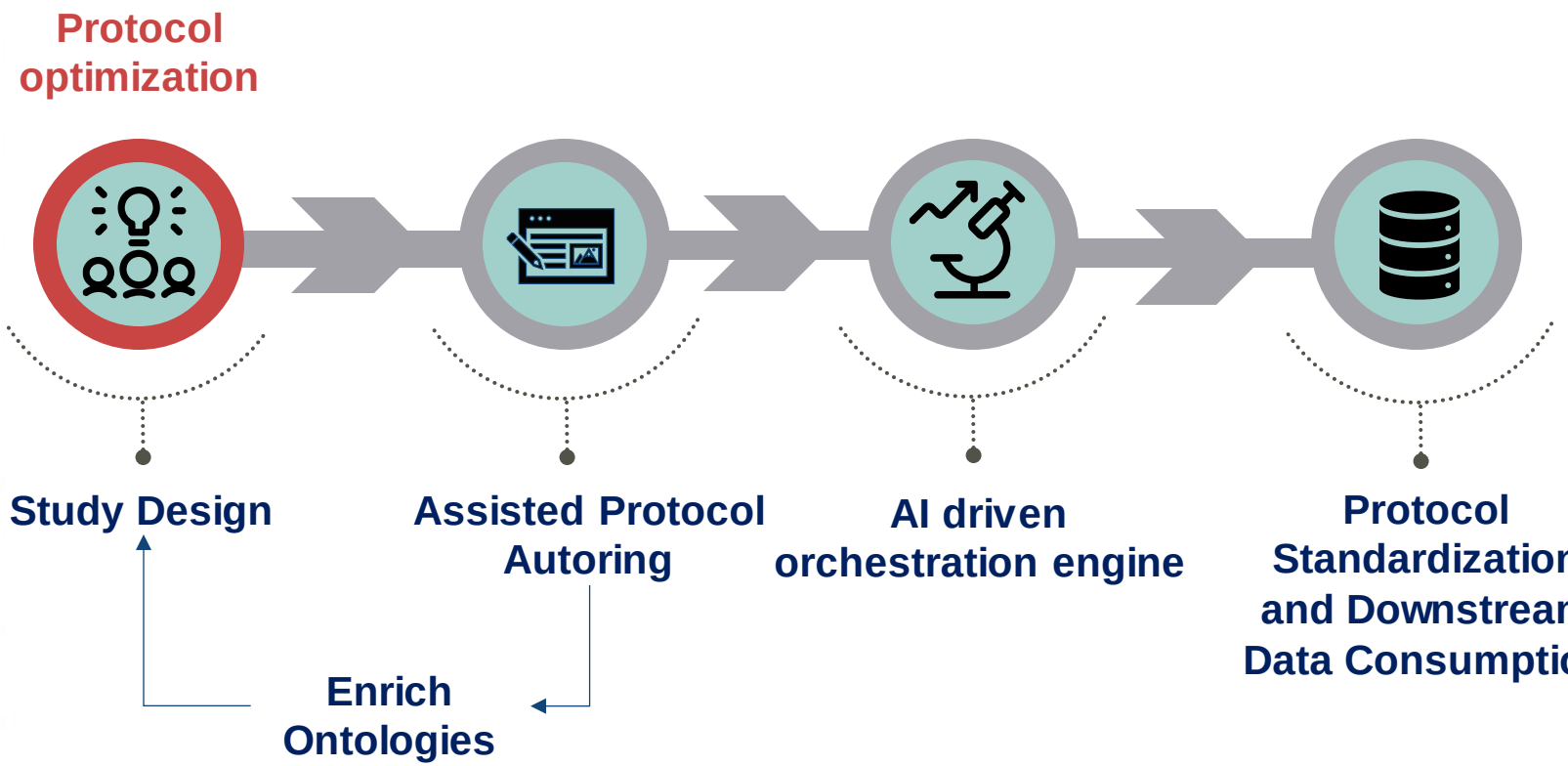
Often still documented in unstructured PPT/Word/PDF documents

Separate step and an after thought in the process

The current process leads to inefficiencies

- **Protocols being developed on word documents**
- **40% of clinical trials have amended protocols**
- **There is an average 4 months delay to FPFV**
- **30% of US patients leave an appointment due to excessive wait time**
- **Studies with tight timelines skip the optimization step**

Optimize during the study design itself, enabled by *digitization*, improves outcomes



Impact

- **Optimized study design** by clinical scientist will generate relevant and reliable clinical data
- **Improved participant experience and engagement**
- **Minimized protocol amendments will save time and reduce costs**

DDF enables protocol digitization and increases robustness of optimization process improving user experience

Adoption of *digitization* and *optimization* solutions, combined with change management is key to success

Digitization Solutions

Quick Win

Implement TransCelerate's Digital Data Flow (DDF) solutions (e.g., eCPT, SDR):

- Open-source solutions
- Vendor-agnostic
- Limited budget required

Optimization Solutions

Implement study design optimization leveraging ZS' SDO solution:

- Aids in protocol digitization
- SOA optimization using burden scores
- Protocol Data Standardization

Communication and Change Management

- Clear strategy for adoption of new way of working
- Tailored to key stakeholder groups

Sponsors with no/limited budget can start their digitization journey today by leveraging TransCelerate's open-source solutions and ZS SDO tool.

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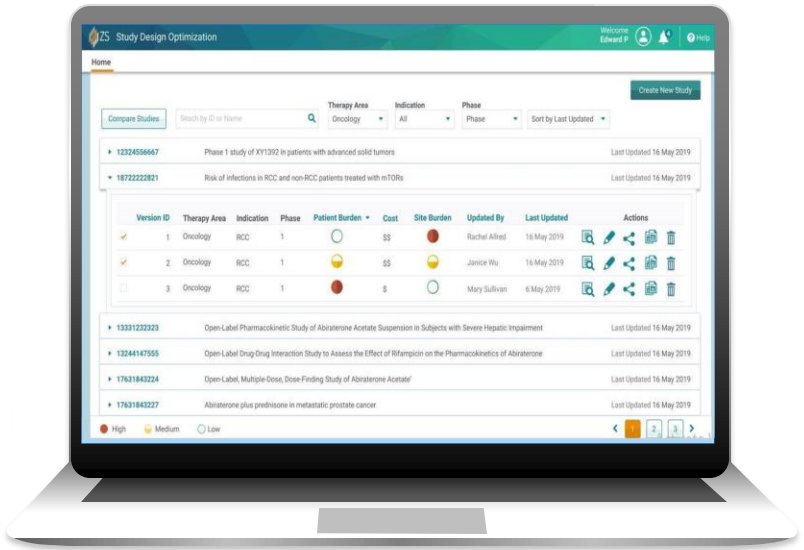
Case Study - SOA Optimization using digitization and optimization solutions

ZS' approach was selected as one of the unique solutions during TransCelerate DDF Connect-a-thon

TransCelerate Connect-a-thon Theme

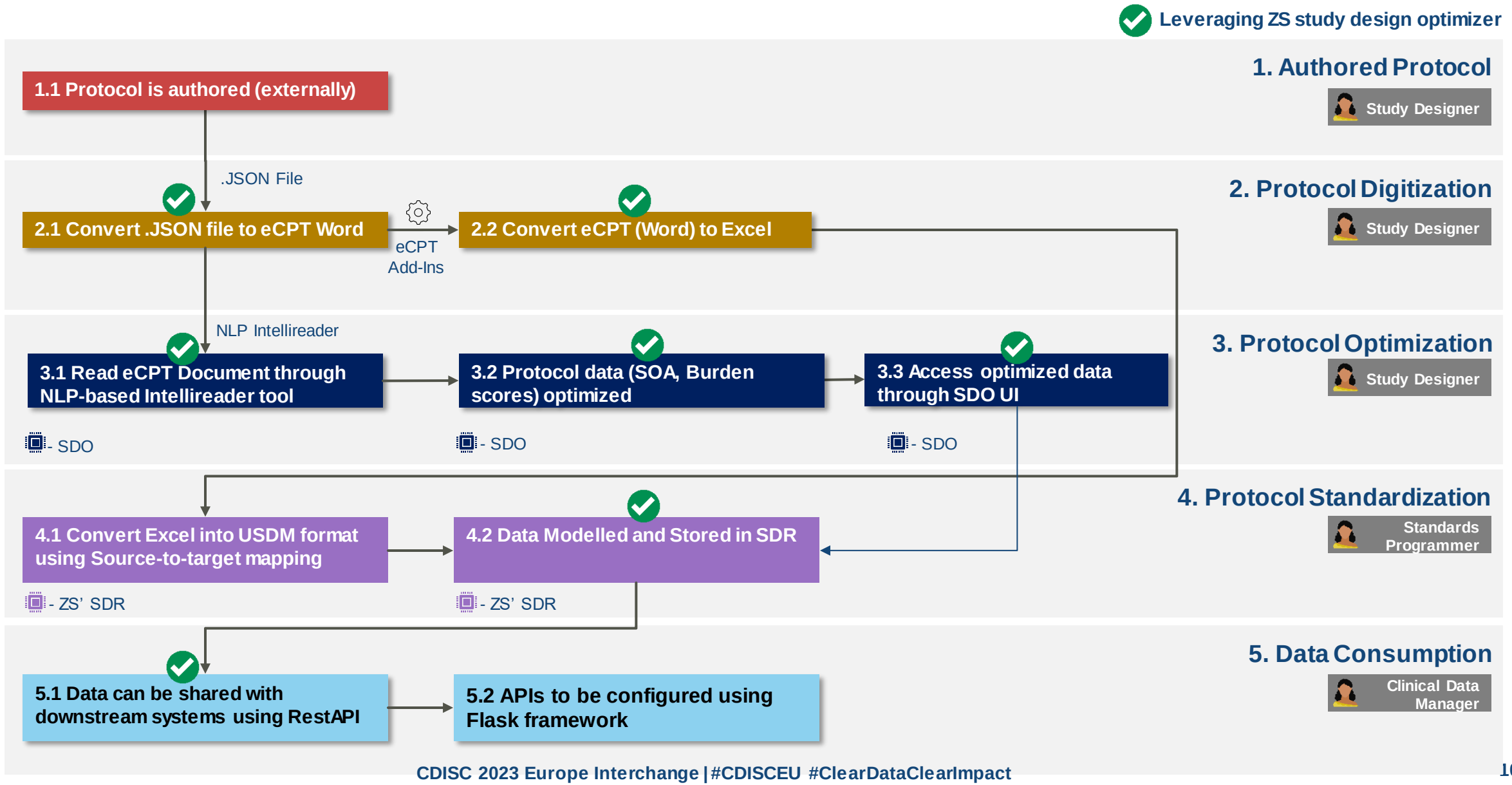
Demonstrate the robustness of USDM for digitization and standardization of protocol data for downstream consumption

Our Approach



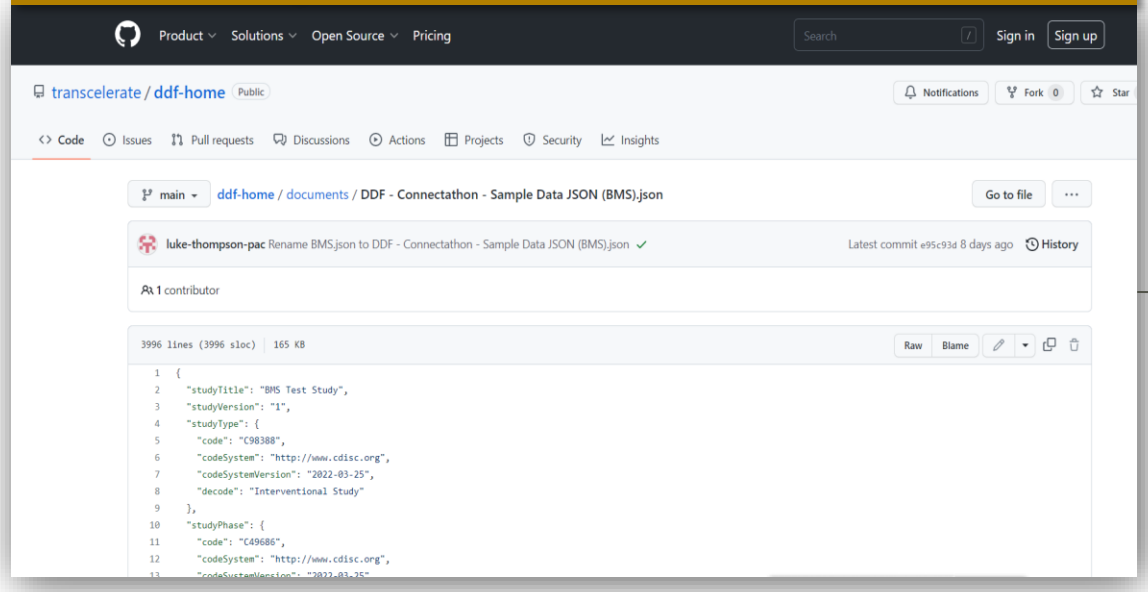
1. Leverage TransCelerate' s eCPT to digitize the protocol
2. Quantify protocol burden score and compare against quantified industry standard burden
3. Store optimized data leveraging SDR (USDM v1.0 data model)
4. Create more attractive, recruitable and operationally sound study designs for future

Our approach offers a one stop solution for protocol digitization and optimization, benefitting multiple personas



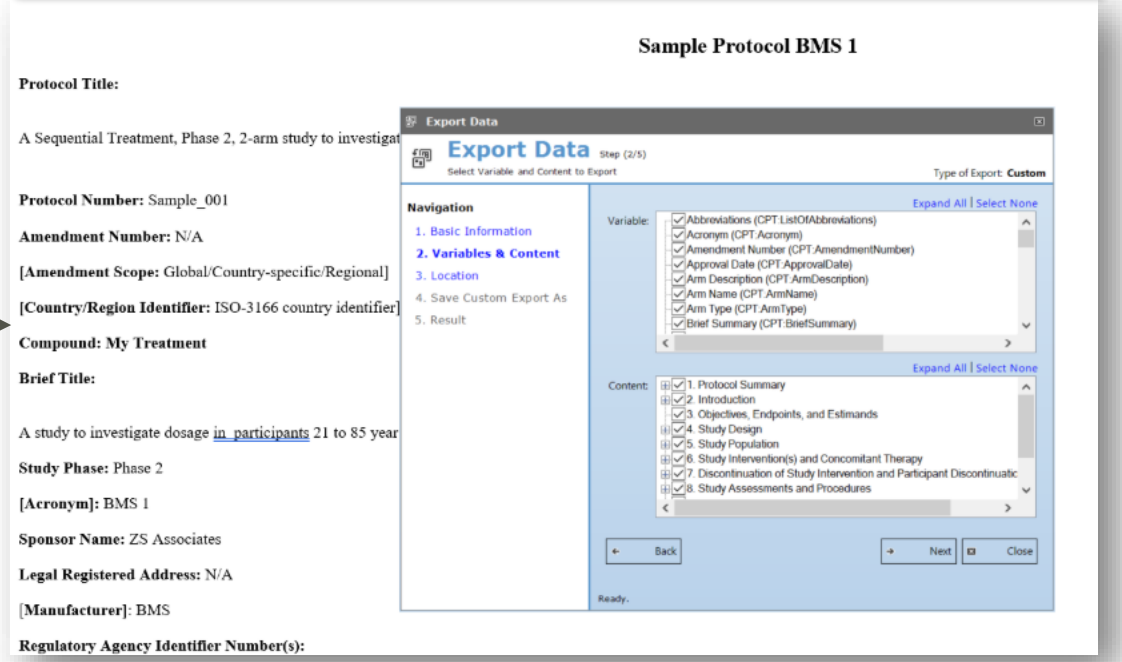
Protocol Digitization – *Steps 2.1, 2.2*

2.1 Source file ingestion in .JSON format



Manual Extraction

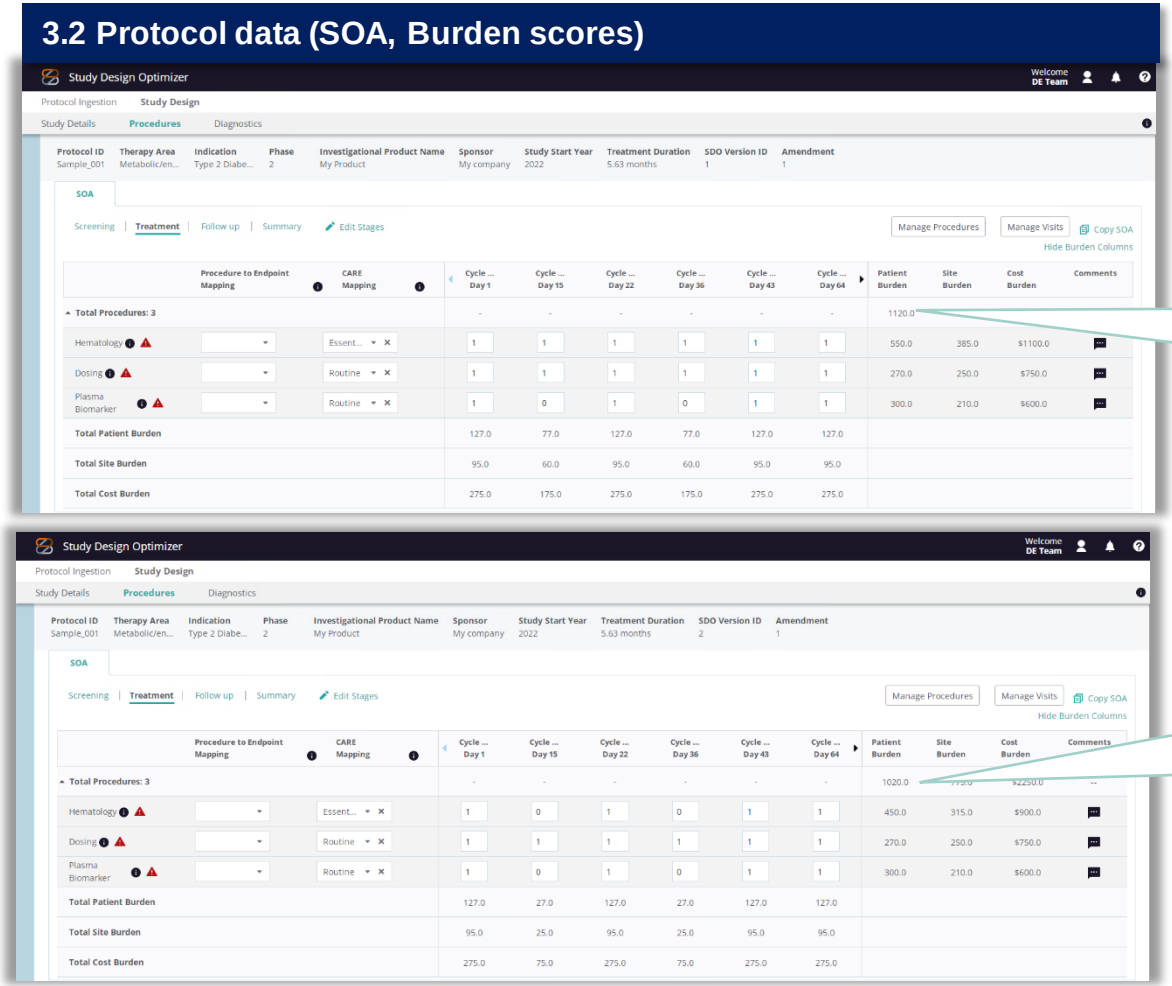
2.2 Convert protocol to Excel using eCPT MS Word Add-Ins



Protocol Optimization (using ZAIDYN SDO UI) – *Step 3.2*

Original

Optimized

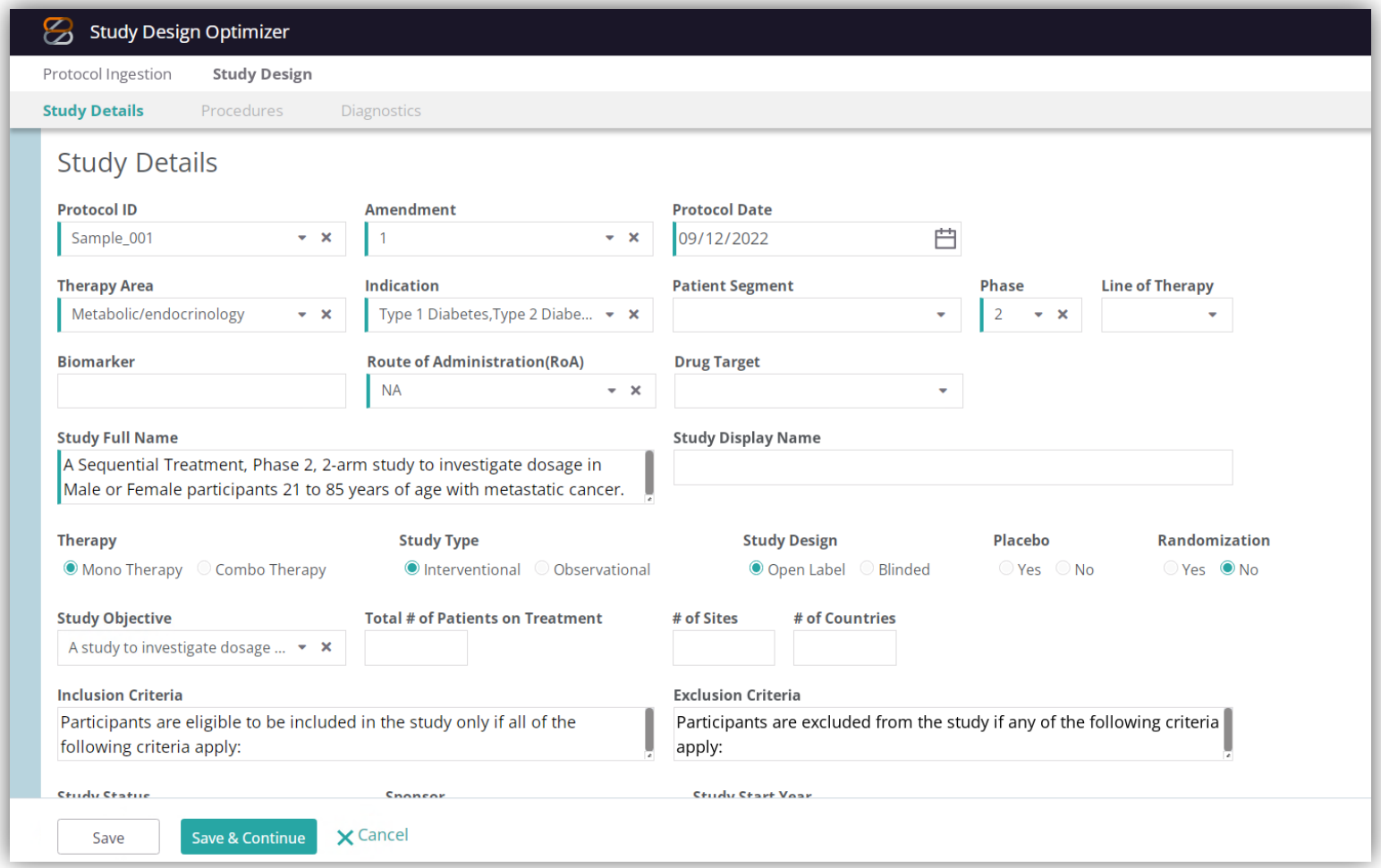


Source (draft) Protocol: High patient burden

Optimized SOA to reduce patient burden by reducing hematology frequency. This also results in lower site burden and cost burden

Protocol Optimization (using ZAIDYN SDO UI) – *Step 3.3*

3.3 Access optimized data through SDO UI



Progress made so far & next steps

Optimize SOA with ZS SDO tool

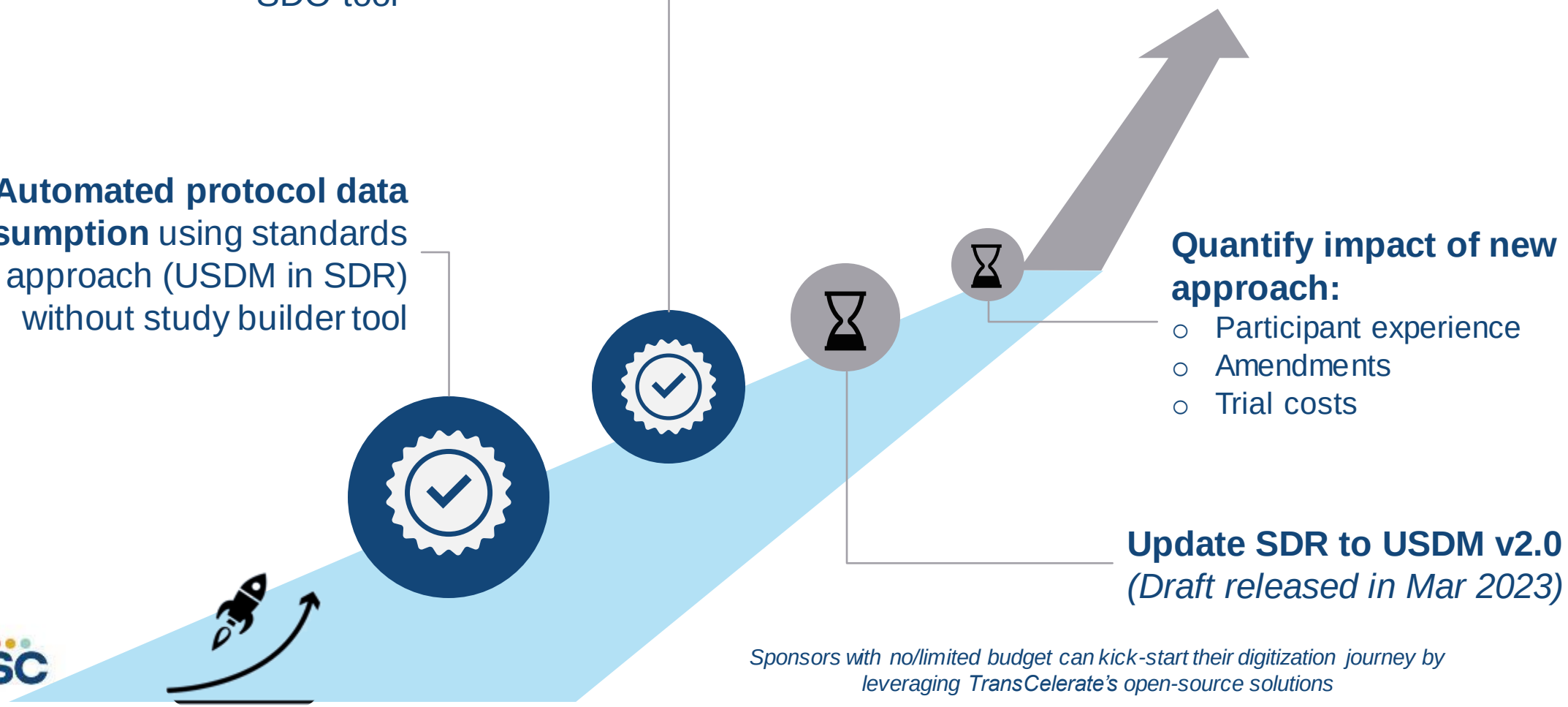
Automated protocol data consumption using standards approach (USDM in SDR) without study builder tool

Unified digitization & optimization process in one interface leveraging Trials.ai

Quantify impact of new approach:

- Participant experience
- Amendments
- Trial costs

Update SDR to USDM v2.0
(Draft released in Mar 2023)



Sponsors with no/limited budget can kick-start their digitization journey by leveraging TransCelerate's open-source solutions

Case example: Understanding and solving for patient burden in protocol design for pharma co.

Background and Company Situation

One of the Top 10 pharma company wanted to:

- Objectively assess protocol burden
- Evaluate the implications
- Identify scenarios that optimize patient and site experience
- Understand impact of study design elements on trial performance

Solution

Ingest, synthesize and analyze their protocols* into ZS' SDO

Identify opportunities for optimization

Demonstrate speed, accuracy of analysis, and ease of approach

Assess correlation between burden and trial performance

Impact *(To date, as project is in progress)*

Facilitated cross-functional discussion between Clin. Science, Clin. Ops. and Digital Health for remedial action

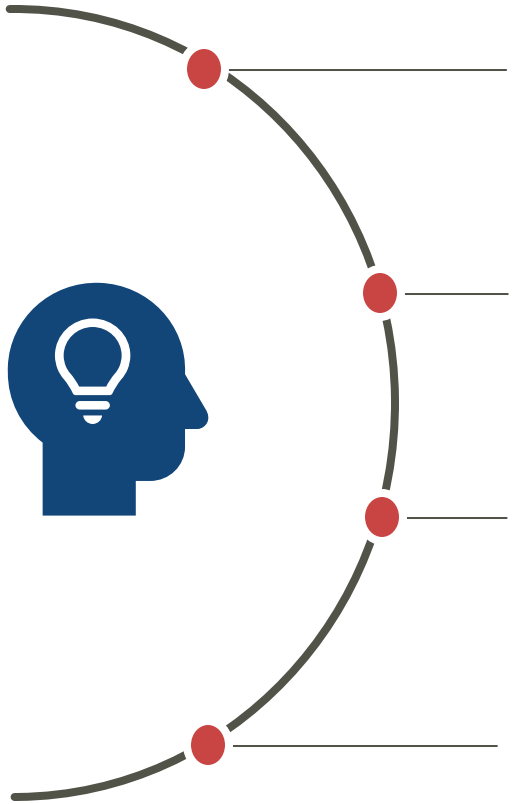
Identified low burden protocols for innovation pilots

Exploration into decentralized clinical trial modalities and PRO standardization

**Non-digitized, document-based protocols were used*

Summary

Successful study design optimization in a nutshell



Protocol optimization is currently an **after thought** in the protocol development process

DDF solutions create **a window of opportunity to optimize earlier** and in real time

ZS' SDO Platform can handle **automated protocol data consumption and optimize SOA**

A clear **change management strategy** is important for adoption of the new way of working

The industry future of real time study design optimization is starting now

Thank you