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Study Design Optimization with DDF assets

Presented by
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Siddharth Shah, Associate Principal, ZS Associates

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.*



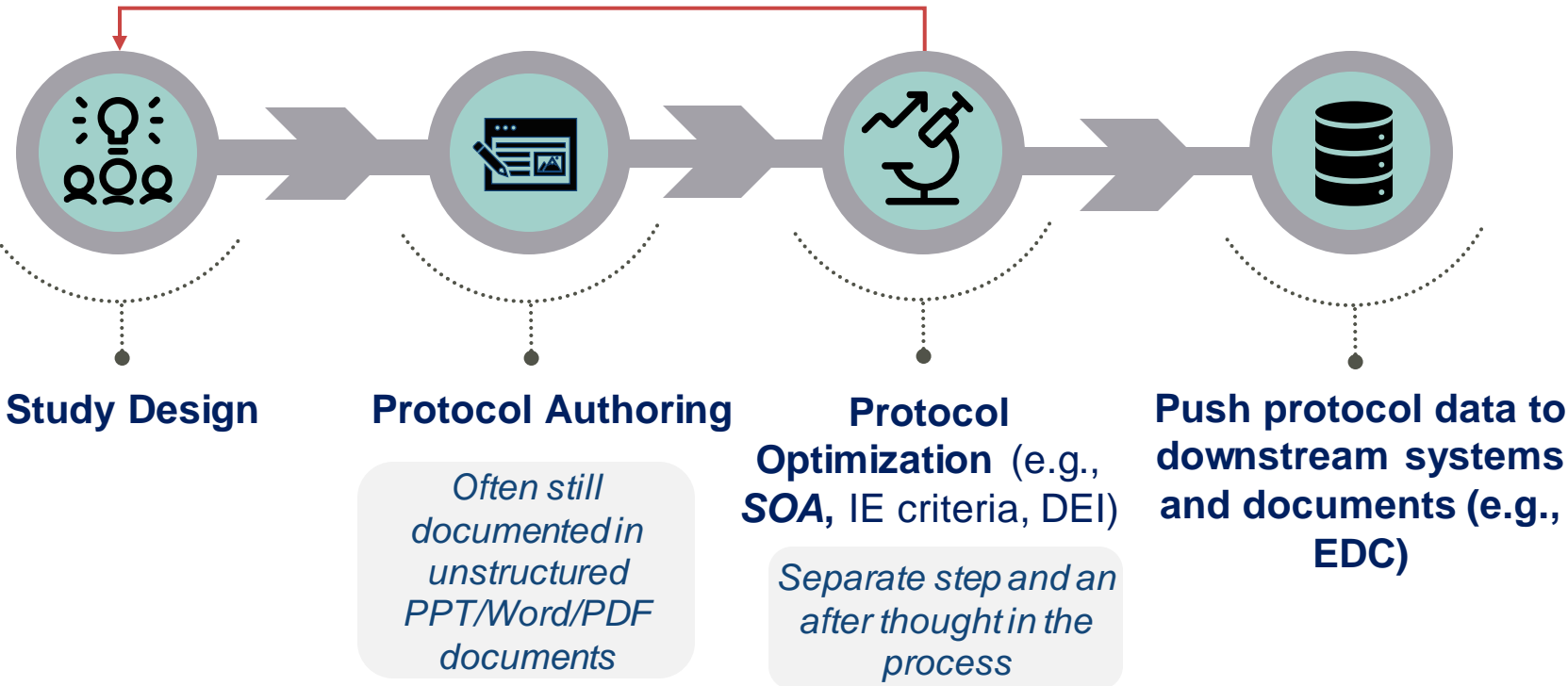
Industry Challenge and Solution(s)



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



Feedback to clinical scientist to reconsider study design

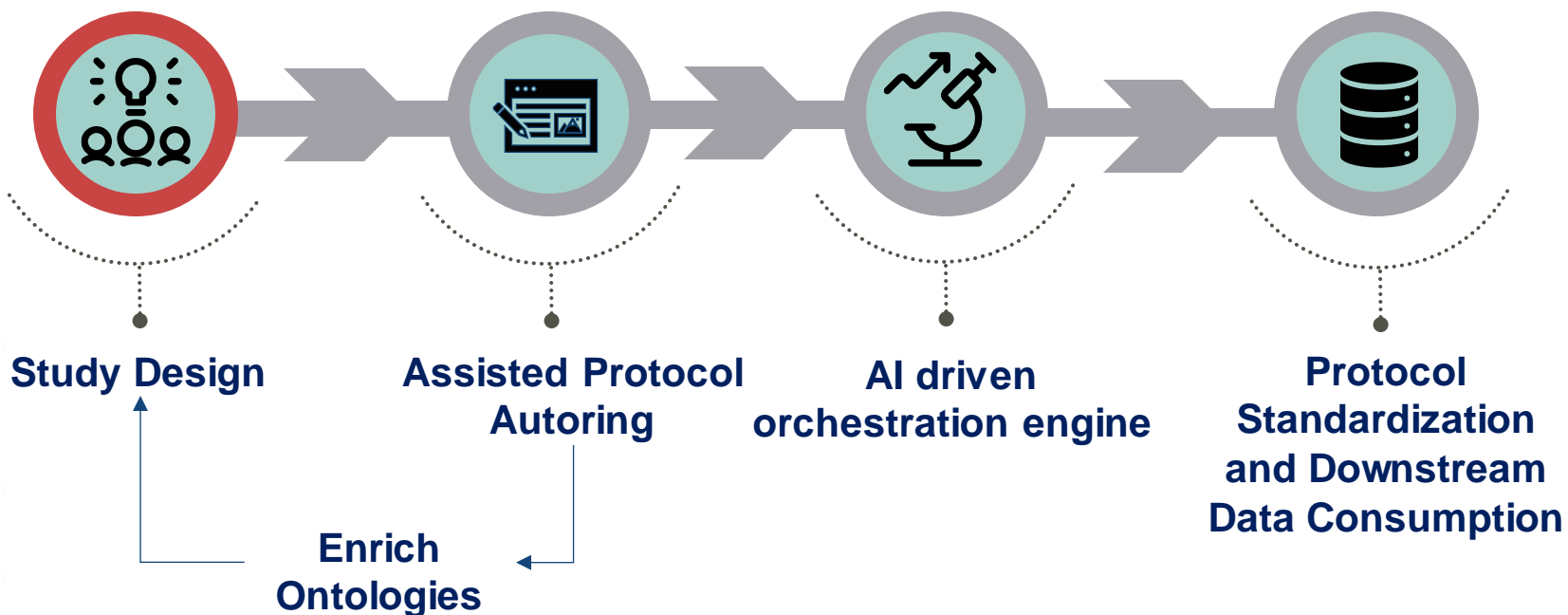


The current process leads to inefficiencies

- 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

Protocol optimization



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.



Case Study - SOA Optimization using digitization and optimization solutions

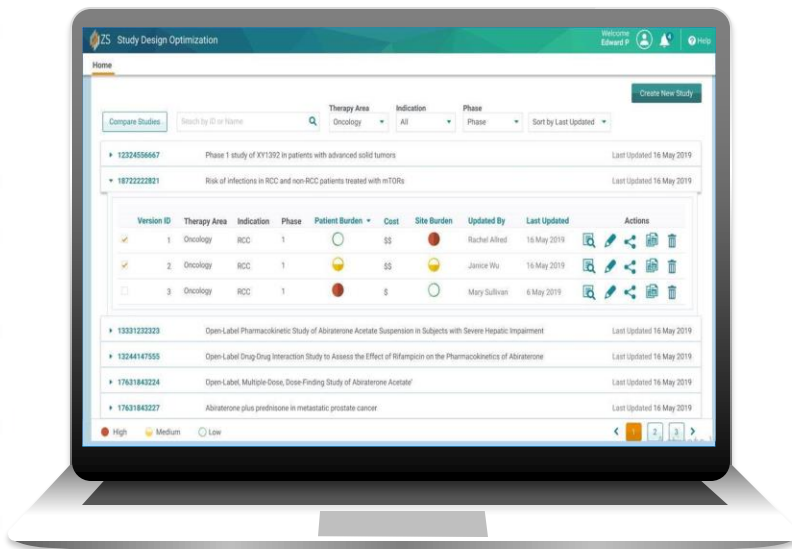
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ZS' approach was selected as one of the unique solutions during TransCelerate DDF Connect-a-thon

TransCelerate Connect-a-thon Theme

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

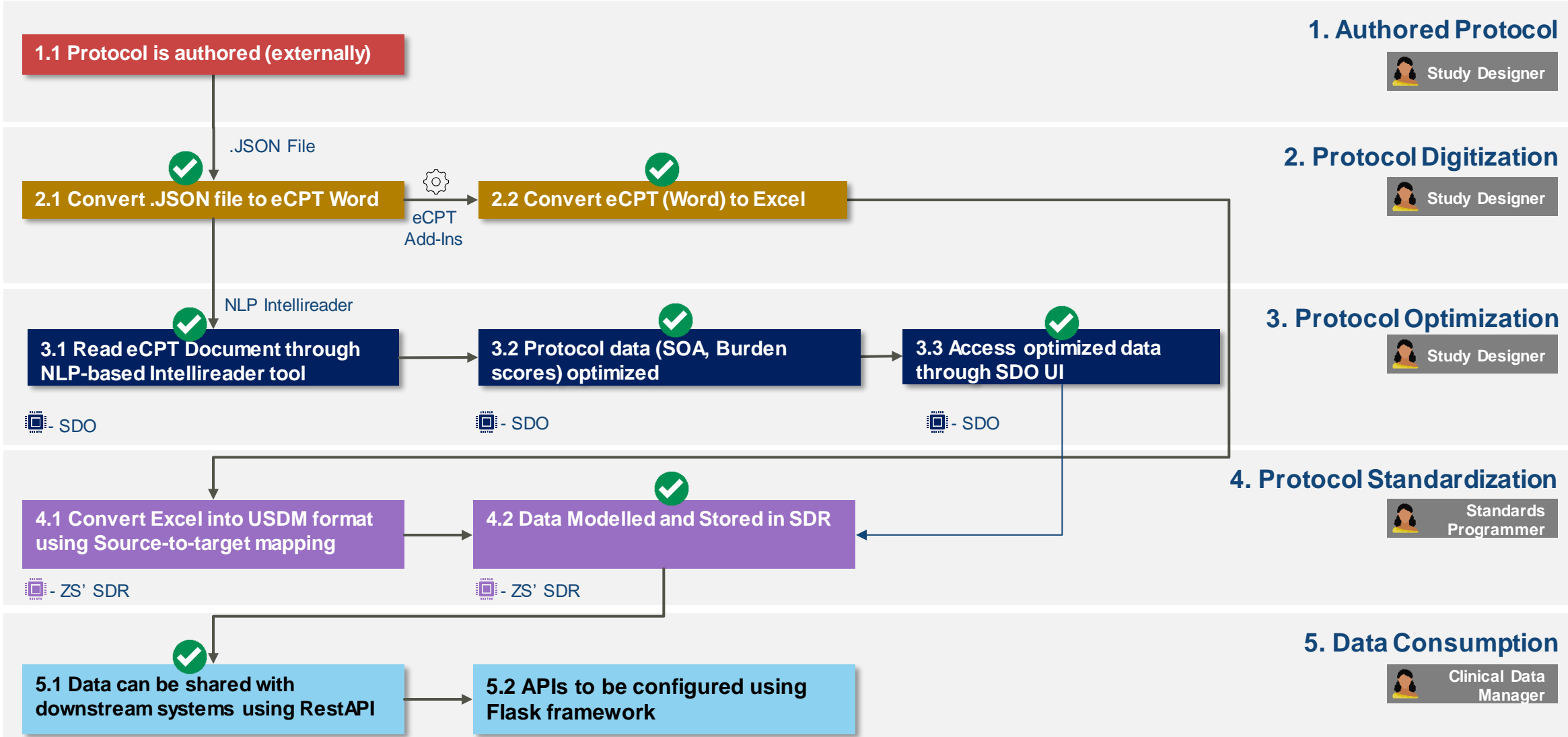
Our Approach



- 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

✔ Leveraging ZS study design optimizer





Protocol Digitization – Steps 2.1, 2.2

2.1 Source file ingestion in .JSON format

The screenshot shows a GitHub repository for 'transcelerate/ddf-home'. The file 'ddf-home / documents / DDF - Connectathon - Sample Data JSON (BMS).json' is selected. The commit history shows a commit by 'luke-thompson-pac' with the message 'Rename BMS.json to DDF - Connectathon - Sample Data JSON (BMS).json'. The file content is displayed as JSON:

```
1 {
2   "studyTitle": "BMS Test Study",
3   "studyVersion": "1",
4   "studyType": {
5     "code": "C98388",
6     "codeSystem": "http://www.cdisc.org",
7     "codeSystemVersion": "2022-03-25",
8     "decode": "Interventional Study"
9   },
10  "studyPhase": {
11    "code": "C49686",
12    "codeSystem": "http://www.cdisc.org",
13    "codeSystemVersion": "2022-03-25"
```



Manual
Extraction

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

The screenshot shows the 'Export Data' dialog box in eCPT MS Word Add-Ins. The dialog is titled 'Export Data' and is at 'Step 2/5'. The 'Type of Export' is set to 'Custom'. The 'Variable' list includes: Abbreviations (CPT ListOfAbbreviations), Acronym (CPT Acronym), Amendment Number (CPT AmendmentNumber), Approval Date (CPT ApprovalDate), Arm Description (CPT ArmDescription), Arm Name (CPT ArmName), Arm Type (CPT ArmType), and Brief Summary (CPT BriefSummary). The 'Content' list includes: 1. Protocol Summary, 2. Introduction, 3. Objectives, Endpoints, and Estimators, 4. Study Design, 5. Study Population, 6. Study Intervention(s) and Concomitant Therapy, 7. Discontinuation of Study Intervention and Participant Discontinuation, and 8. Study Assessments and Procedures. The 'Sample Protocol BMS 1' text is visible in the background:

Protocol Title:
A Sequential Treatment, Phase 2, 2-arm study to investigate

Protocol Number: Sample_001

Amendment Number: N/A

[Amendment Scope: Global/Country-specific/Regional]

[Country/Region Identifier: ISO-3166 country identifier]

Compound: My Treatment

Brief Title:
A study to investigate dosage in participants 21 to 85 year

Study Phase: Phase 2

[Acronym]: BMS 1

Sponsor Name: ZS Associates

Legal Registered Address: N/A

[Manufacturer]: BMS

Regulatory Agency Identifier Number(s):



Protocol Optimization (using ZAIDYN SDO UI) – Step 3.2

Original

3.2 Protocol data (SOA, Burden scores)

Study Design Optimizer

Protocol Ingestion | Study Design

Study Details | Procedures | Diagnostics

Protocol ID	Therapy Area	Indication	Phase	Investigational Product Name	Sponsor	Study Start Year	Treatment Duration	SDO Version ID	Amendment
Sample_001	Metabolic/en...	Type 2 Diabe...	2	My Product	My company	2022	5.63 months	1	1

SOA

Screening | **Treatment** | Follow up | Summary | Edit Stages

Manage Procedures | Manage Visits | Copy SOA | Hide Burden Columns

Procedure to Endpoint Mapping	CARE Mapping	Cycle ... Day 1	Cycle ... Day 15	Cycle ... Day 22	Cycle ... Day 36	Cycle ... Day 43	Cycle ... Day 64	Patient Burden	Site Burden	Cost Burden	Comments
Total Procedures: 3											
Hematology	Essent...	1	1	1	1	1	1	1120.0	550.0	385.0	\$1100.0
Dosing	Routine	1	1	1	1	1	1	270.0	250.0	\$750.0	
Plasma Biomarker	Routine	1	0	1	0	1	1	300.0	210.0	\$600.0	
Total Patient Burden		127.0	77.0	127.0	77.0	127.0	127.0				
Total Site Burden		95.0	60.0	95.0	60.0	95.0	95.0				
Total Cost Burden		275.0	175.0	275.0	175.0	275.0	275.0				

Source (draft) Protocol: High patient burden

Optimized

Study Design Optimizer

Protocol Ingestion | Study Design

Study Details | Procedures | Diagnostics

Protocol ID	Therapy Area	Indication	Phase	Investigational Product Name	Sponsor	Study Start Year	Treatment Duration	SDO Version ID	Amendment
Sample_001	Metabolic/en...	Type 2 Diabe...	2	My Product	My company	2022	5.63 months	2	1

SOA

Screening | **Treatment** | Follow up | Summary | Edit Stages

Manage Procedures | Manage Visits | Copy SOA | Hide Burden Columns

Procedure to Endpoint Mapping	CARE Mapping	Cycle ... Day 1	Cycle ... Day 15	Cycle ... Day 22	Cycle ... Day 36	Cycle ... Day 43	Cycle ... Day 64	Patient Burden	Site Burden	Cost Burden	Comments
Total Procedures: 3											
Hematology	Essent...	1	0	1	0	1	1	1020.0	450.0	315.0	\$900.0
Dosing	Routine	1	1	1	1	1	1	270.0	250.0	\$750.0	
Plasma Biomarker	Routine	1	0	1	0	1	1	300.0	210.0	\$600.0	
Total Patient Burden		127.0	27.0	127.0	27.0	127.0	127.0				
Total Site Burden		95.0	25.0	95.0	25.0	95.0	95.0				
Total Cost Burden		275.0	75.0	275.0	75.0	275.0	275.0				

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

Study Design Optimizer

Protocol Ingestion **Study Design**

Study Details Procedures Diagnostics

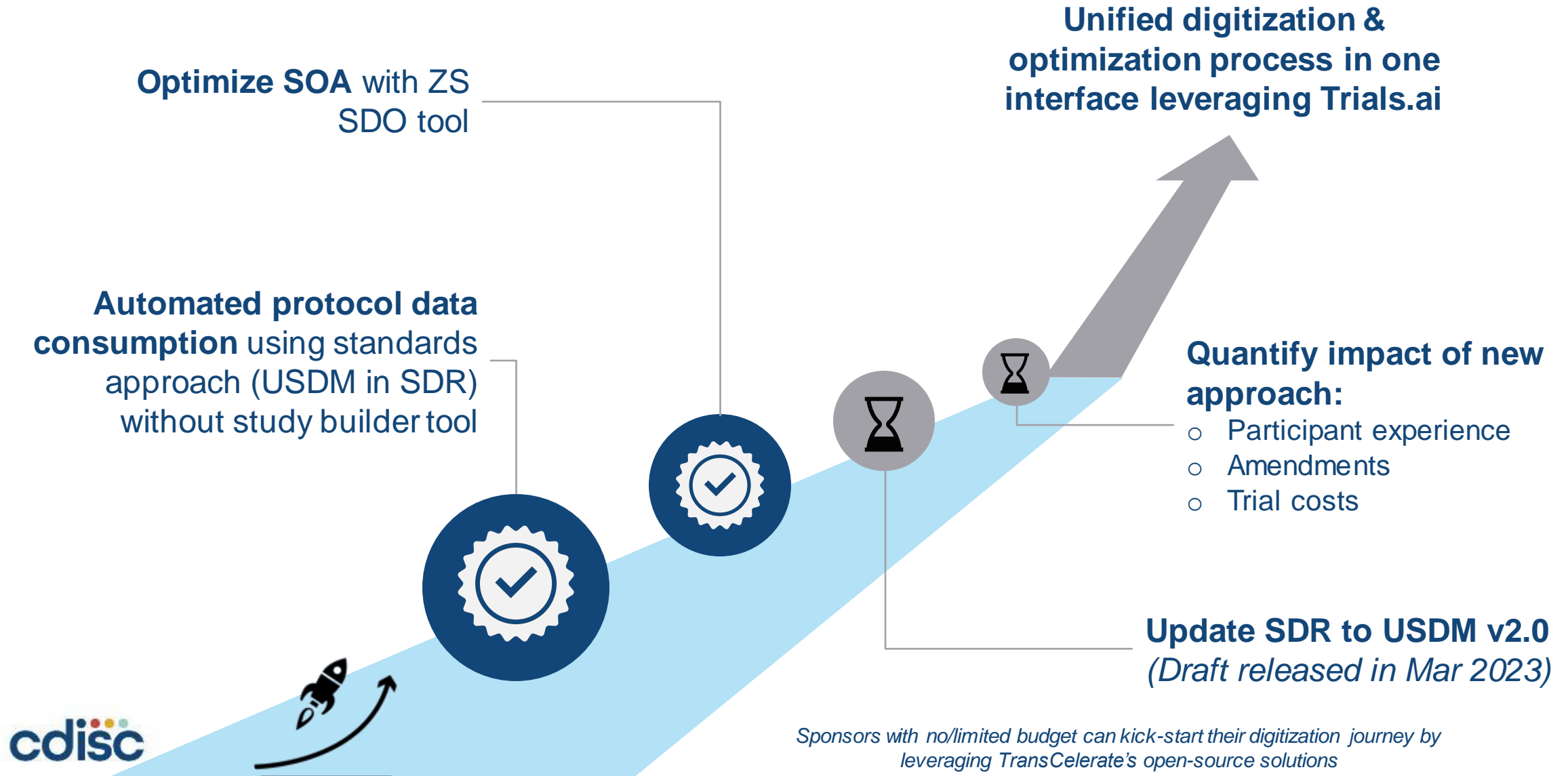
Study Details

Protocol ID Sample_001	Amendment 1	Protocol Date 09/12/2022		
Therapy Area Metabolic/endocrinology	Indication Type 1 Diabetes, Type 2 Diabe...	Patient Segment	Phase 2	Line of Therapy
Biomarker	Route of Administration(RoA) NA	Drug Target		
Study Full Name A Sequential Treatment, Phase 2, 2-arm study to investigate dosage in Male or Female participants 21 to 85 years of age with metastatic cancer.		Study Display Name		
Therapy <input checked="" type="radio"/> Mono Therapy <input type="radio"/> Combo Therapy	Study Type <input checked="" type="radio"/> Interventional <input type="radio"/> Observational	Study Design <input checked="" type="radio"/> Open Label <input type="radio"/> Blinded	Placebo <input type="radio"/> Yes <input type="radio"/> No	Randomization <input type="radio"/> Yes <input checked="" type="radio"/> No
Study Objective A study to investigate dosage ...	Total # of Patients on Treatment	# of Sites	# of Countries	
Inclusion Criteria Participants are eligible to be included in the study only if all of the following criteria apply:		Exclusion Criteria Participants are excluded from the study if any of the following criteria apply:		
Study Status	Sponsor	Study Start Year		

Save **Save & Continue** X Cancel



Progress made so far & next steps



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



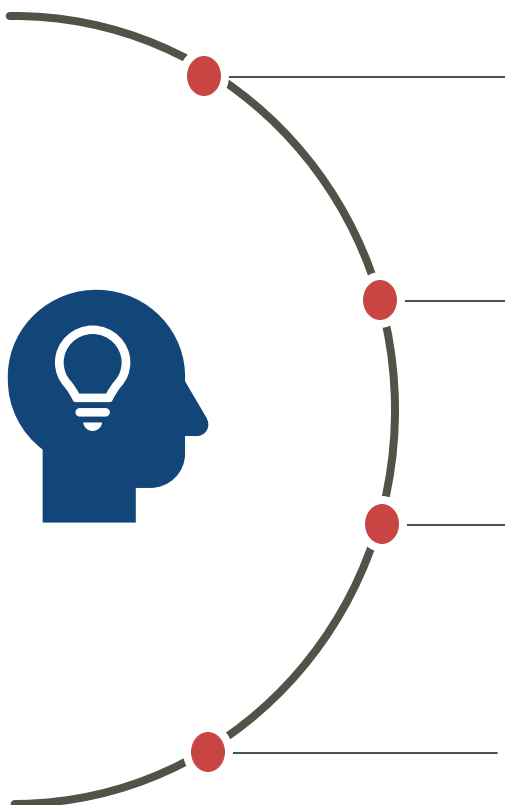
Exploration into decentralized clinical trial modalities and PRO standardization



Summary

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Successful study design optimization in a nutshell



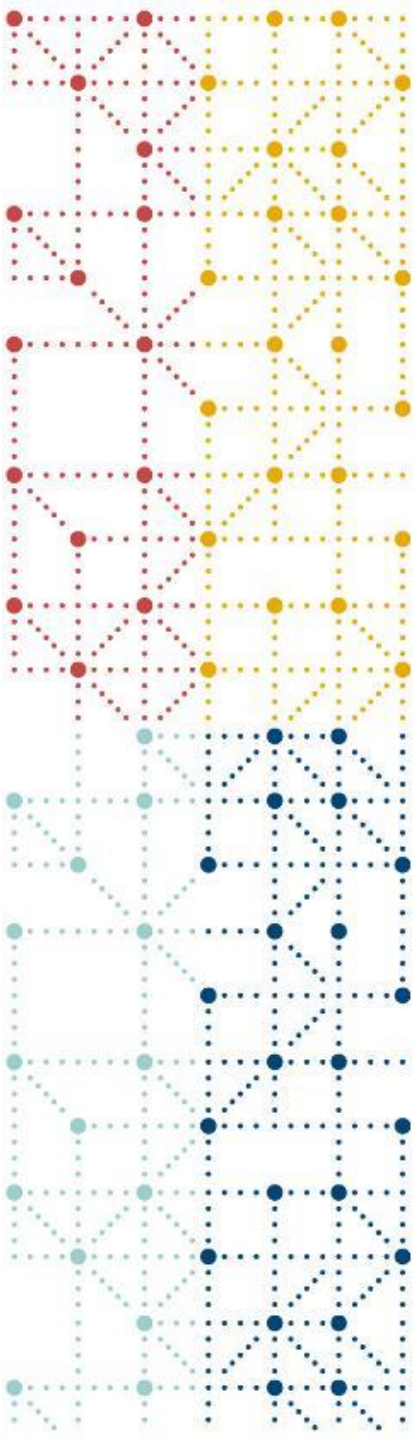
Protocol optimization is currently an **after thought** in the protocol development process

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

