TransCelerate BIOPHARMA INC.

Adoption Story from a Biopharmaceutical Organization

Case Study: The Digital Schedule of Activities (DSOA) – Using Digital Data Flow for Portfolio Acceleration

2024

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Overview

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To begin the digital transformation of clinical trials, this biopharmaceutical organization developed a shared vision

Information-centric Protocols

Capture information at inception

Eliminate the white space

This biopharmaceutical organizations' future state vision included moving from document-centric thinking for an information-centric paradigm, where information is captured at the moment of inception. With this shared definition of what done would look like, the organization would be able to reduce delay within trial operations, such as when contracting with central labs, or when programming with EDC systems. Furthermore, downstream functions that traditionally relied upon an approved protocol before initiation would realize the benefit of getting an earlier start on their work to automate their activities. This digital transformation would allow the organization to do more trials in fixed amount of time.

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Future State Vision

Digital End to End
from Protocol Authoring to Clinical Study Report Generation

Information-centric Protocols

FROM

Existing authoring processes build upon the traditional document paradigm to which most professionals are accustomed. Document authoring is people-friendly but not good for digital information capture & downstream use.

TO

Protocol authoring transforms into an information generation activity. Resulting data can be mined for new insights, inform new study designs, and propagated downstream with high accuracy.

Capture Information at Inception

FROM

Existing business processes wait for protocol approval as a pre-requisite for translating protocol content into downstream action.

TO

Protocol content is captured digitally at inception, enabling downstream jump-start of trial initialization and setup activities in parallel with authoring. Overall productivity increases even with possible downstream rework resulting from protocol changes prior to Approval.

Eliminate the White Space

FROM

Existing business processes execute sequentially as they **wait for upstream people & systems to complete tasks** and inform the next stage that it's OK to take it from there.

TO

Digital-driven automation **eliminates process wait-time and facilitates process parallelization.** Trial planning, startup, execution, analysis and submission takes less overall time. The Portfolio achieves greater velocity and throughput.

How do we start the Transformation?

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Use Case Description

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This biopharmaceutical organization chose to begin the digital data flow journey with one use case – a Digital Schedule of Activities (DSOA)

The organization chose to begin their transformation with a Digital Schedule of Activities (DSOA) for 3 reasons:

1. It is a more focused and manageable scope
2. Use case allowed the organization to make incremental changes to business processes while saving most significant changes, such as protocol authoring, for last
3. Use case provided highest return on investment while reducing white space in clinical operations, letting business automate downstream activities with the same bandwidth

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Start with a Digital Schedule of Activities (DSOA)

Why Start With SOA?

"Build a little, test a little, learn a LOT"
-- Adm. Wayne Meyer

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Start with a Digital Schedule of Activities (DSOA)

Incremental Process Impact

Current State: Authoring activities unaffected
Target State: Non-SOA authoring activities unaffected

Why Start With SOA?

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Biggest Whitespace Impact

Drives greatest number of downstream consumer automation opportunities

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How Do We Get There?

Proof of Concept

- Extract SOA from Approved Protocol Docs.
- Refine Extraction Logic
- Experiment with consumers for consumption
- Organizational Change Management!

Pilot

- Pre-populate draft SOA appendix
- Extract SOA during Protocol Authoring
- Harden Extraction Logic
- Initial Automated downstream consumption
- Organizational Change Management!

Scale

- Capture SOA information digitally at inception
- Expand and harden downstream consumption
- Organizational Change Management!

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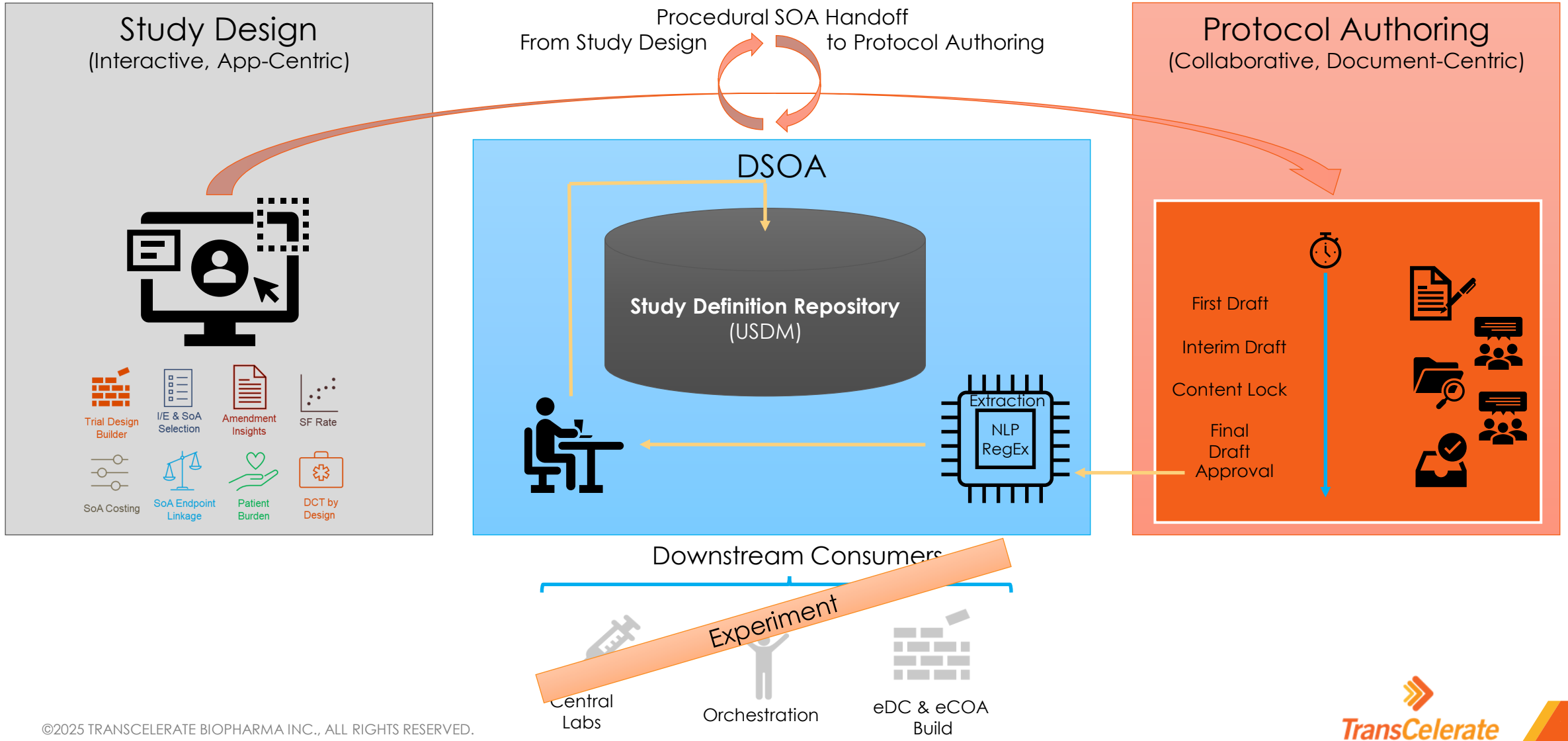
DSOA Current State (Proof of Concept)



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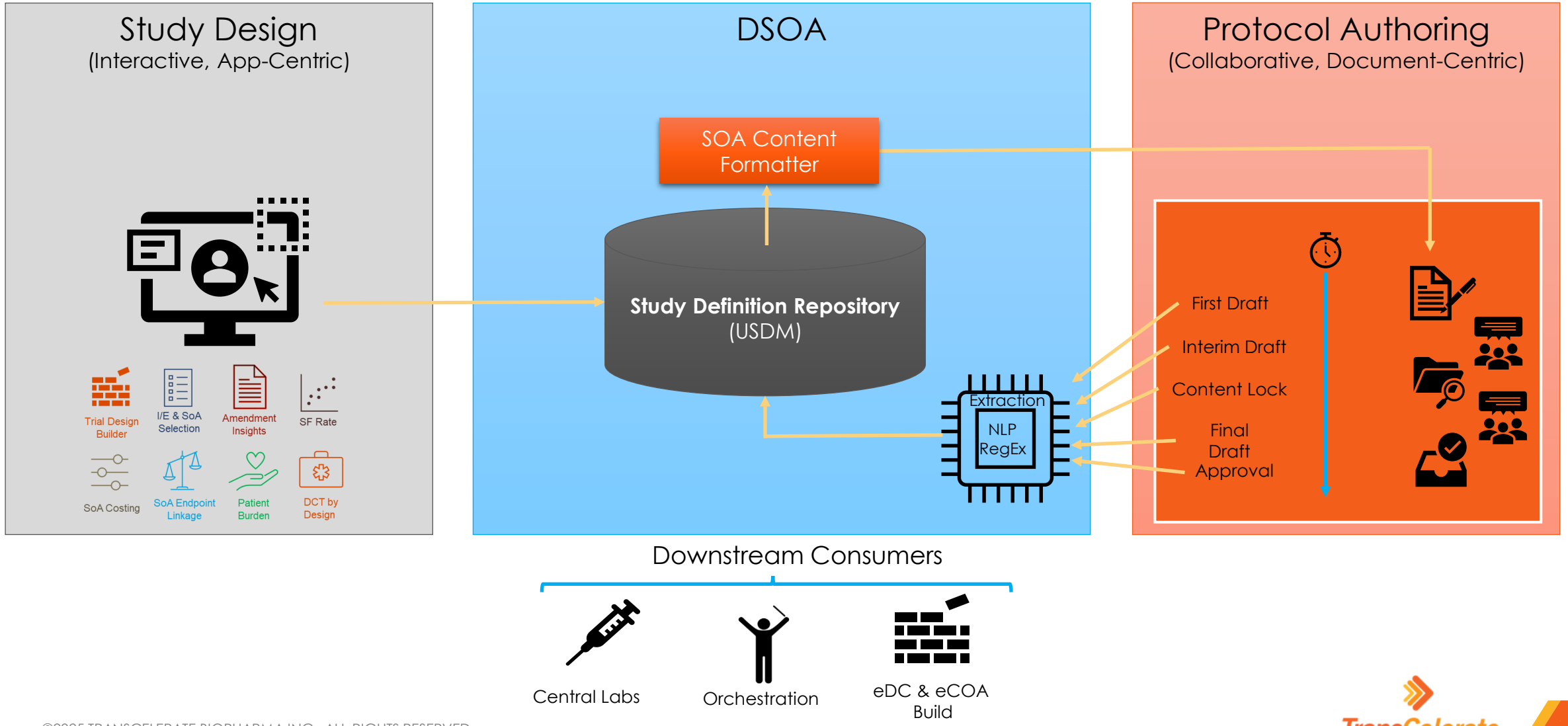
DSOA Interim State (Pilot – in development)



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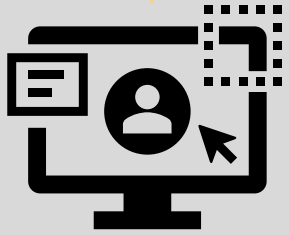
DSOA Target State (Scale)

Study Design
(Interactive, App-Centric)

DSOA

Protocol Authoring
(Collaborative, Document-Centric)

SOA Builder
Interactive SOA planning, design & authoring application



Trial Design Builder
I/E & SoA Selection
Amendment Insights
SF Rate
SoA Costing
SoA Endpoint Linkage
Patient Burden
DCT by Design

Study Definition Repository
(USDM)

Downstream Consumers

Central Labs
Orchestration
Budgeting
Trial Materials
eDC & eCOA Build
Monitoring
Pharmaceutical Dispensing

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Challenges & Considerations

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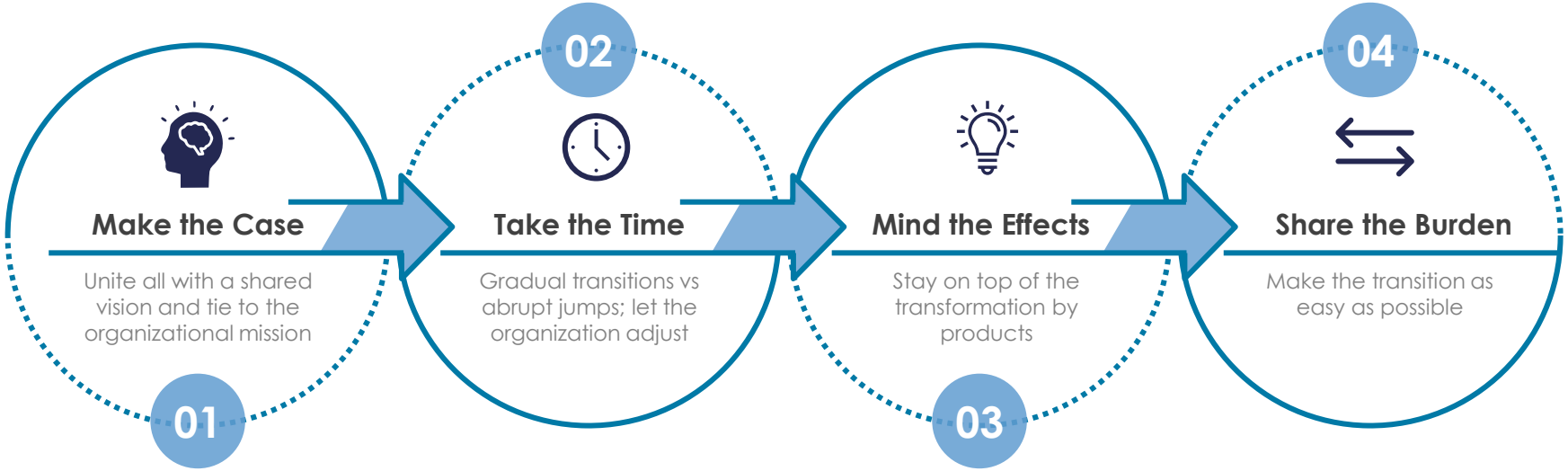
Organizational Change Management (OCM) Considerations

DDF Adoption = Technology + Standards + Integration + OCM

The Four OCM Challenges *(Peter Senge, The Fifth Discipline)*



*"We call this the era of **Never Normal**. This era is characterized by frequent shocks — both internal and external — and a constant need for crisis management."*

-- Gartner Predicts 2024: Strategic Portfolio Leaders Must Plan for the "Never Normal"

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OCM Considerations

Make the Case

DSOA → DDF → Digital from Protocol to CSR → Next

Take the Time

Get By-In for The Case; Seek regular stakeholder input; Understand & Discuss Impacts

Allow for Consumer Experimentation

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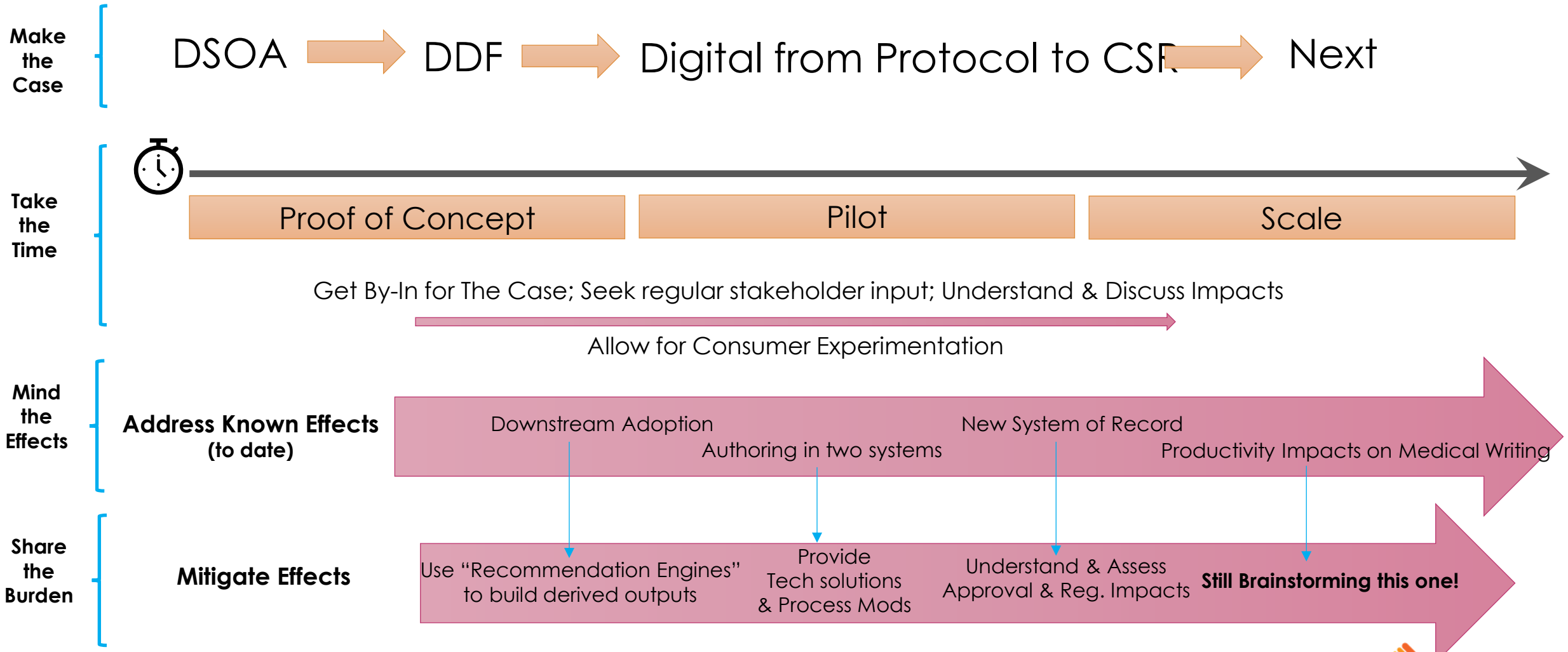
OCM Considerations



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Benefits

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Benefits realized from digital end to end

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Lessons Learned

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DDF Transformation Gets Complicated… FAST

Things to remember on the journey

Build a Roadmap – i.e., what *Done* looks like and how to get there

Secure & **Continuously Enforce Stakeholder Alignment**

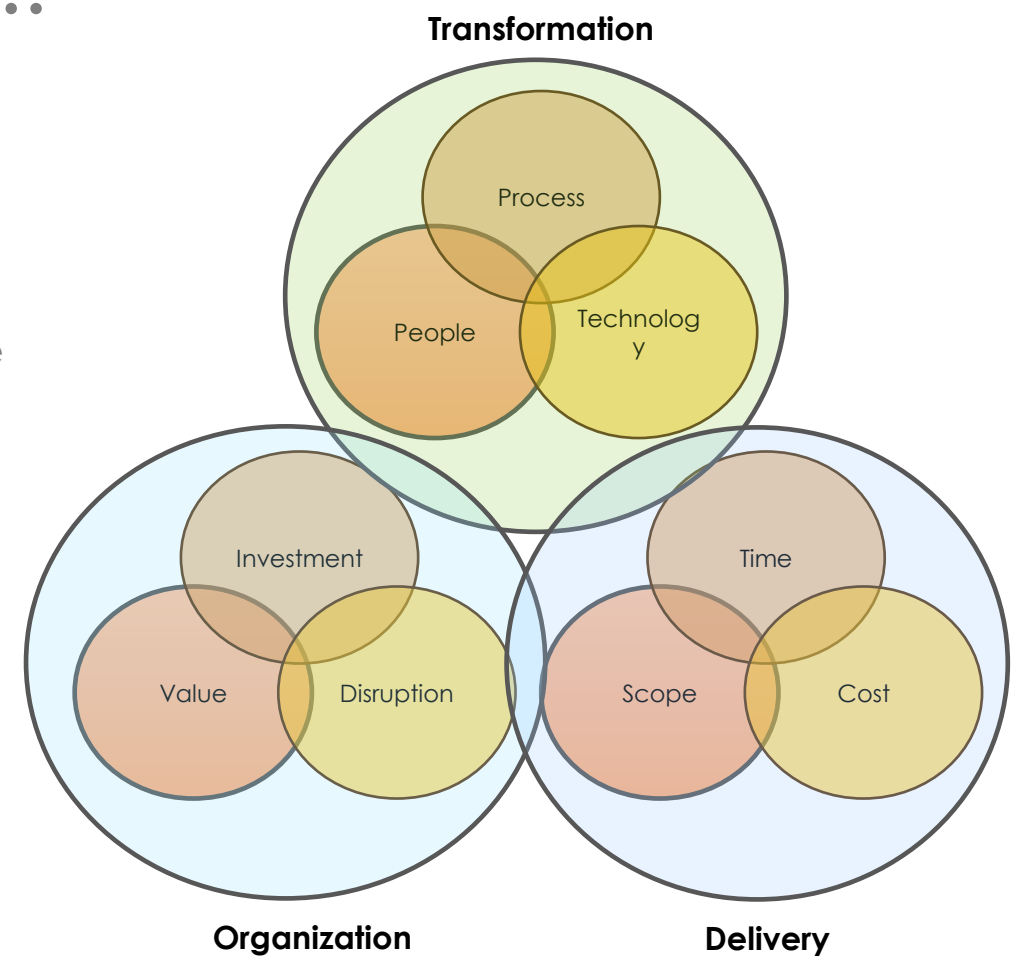
Iterate to *Done* with realistic & achievable instantiations

Learn and Adapt the roadmap as you go

Deliver incremental value to **Sustain Organizational Commitment**

Give people and the organization the **Time to Adjust**

Adoption is the Goal



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Thank you

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