Practical Approach to Implementing Digital Data Flow:

A Framework to Getting Started

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TransCelerate BIOPHARMA INC.

Please Note:

This document details common elements and examples of factors that organizations may encounter when evaluating whether to initiate a protocol digitalization transformation, particularly in connection with project proposal processes. Users must decide for themselves whether different processes and approaches for developing and presenting project proposals may work better in the unique circumstances existing within the user's organization.

Moreover, the decision to consider and to proceed with such a transformative project is solely the prerogative and responsibility of each individual company informed by its own strategies and assessments, following its own internal approval processes.

Examples given in this document are for illustrative purposes only and do not constitute a recommendation to adopt or approve a particular project, how to determine whether to approve a project, or how to secure approval.

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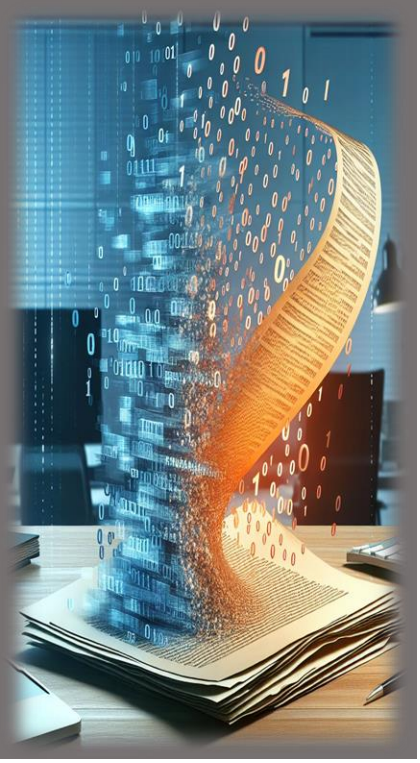

Genesis of TransCelerate Digital Data Flow (DDF)

In recent years, digital transformation has not significantly impacted the processes for designing clinical studies and authoring protocols. The focus has been on areas like electronic data capture, recruitment platform and informed consent. Given this, opportunities to enhance quality and efficiency in clinical operations are being lost.

14.6% projected global market growth rate from 2023 to 2030 for **Electronic Data Capture (EDC) systems**[1]
($1.25B Global Market Size, 2022)

12.6% projected global market growth rate from 2024 to 2030 for **eConsent**[2]
($432.2M Global Market Size, 2023)

16.4% projected global market growth rate from 2024 to 2034 for **ePRO, e-patient diaries, and eCOA**[3]
($3.6B US Market Size, 2024)

18.18% projected global market growth rate from 2025 to 2033 for **Tele-monitoring Services**[4]
($26.16B Global Market Size, 2024)

7.59% projected global market growth rate from 2025 to 2033 for **Patient Data Hub Solutions**[5]
($1.55B Global Market Size, 2024)

11% projected global market growth rate of from 2025 to 2033 for **Clinical Decision Support Systems**[6]
($1.55B Global Market Size, 2024)

The promise of the Unified Study Data Model (USDM)

The DDF initiative worked with Clinical Data Interchange Standards Consortium (CDISC), an industry standard-setting organization, to create a standard (USDM) to enable a digital workflow with protocol digitization that will help modernize and streamline information management processes across the clinical trial ecosystem.

By moving away from traditional document models, it facilitates standardized, machine-readable representations of study protocols, leading to improved clinical data flow and enhanced automation and AI efficiencies.

1. Quality Clinical Data Flows

Allows for the reuse of standardized protocol data between systems without the need for custom transformations.

2. Automation and AI

A digital format of the clinical protocol and essential data enhances automation opportunities across systems, boosting speed, quality, and consistency in processes.

Automated quality data flow may minimize manual tasks and enhance quality and compliance by decreasing manual transcription. This enables companies to allocate their workforce to more valuable activities like complex projects and study designs, improving efficiency.

In digital protocol, two methods have surfaced: protocol digitization and protocol digitalization.

Protocol Digitization

Converting an analog protocol to a digital format

Protocol Digitalization

A deeper transformation that harnesses digital technology to create and manage digital protocols from their inception

In this document, the term protocol digitalization refers to the concept of a digital protocol.

Support for the DDF initiative

The DDF initiative is the result of collaborative efforts with non-profit industry stakeholders, such as the CDISC, which focuses on data standards, and TransCelerate, which focuses on delivering pragmatic ways to accelerate clinical drug development.

[1] Grand View Research Electronic Data Capture Systems Market Size, Share & Trends Analysis Report
[2] Grand View Research eConsent In Healthcare Market Size, Share & Trends Analysis Report
[3] Fact.MR ePro, e-patient Diaries and eCOA Market Study
[4] Grand View Research Tele-monitoring Services Market Size, Share & Trends Analysis Report
[5] Grand View Research Patient Data Hub Solutions Market Size, Share & Trends Analysis Report
[6] Grand View Research Clinical Decision Support Systems Market Size, Share & Trends Analysis Report

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Digitalization of protocols

Various organizations are advancing protocol digitalization by introducing multiple standards. This list highlights some significant initiatives but is not comprehensive.

Digital Data Flow (DDF) initiative

Click for more info

Digital Data Flow initiative aims to modernize clinical trials through a digital workflow, facilitating automated creation of study assets and configuration of study systems for trial execution.

Organizations & Collaborations

- *Initiative & Reference Implementation Owner*
- *USDM Standards Owner*
- *Collaborating with Sponsor Companies; Life-sciences Technology Solution Vendors*

Initiative Solutions

- CDISC Unified Study Definitions Model (USDM) Reference Architecture establishes standards for storage and transmission of clinical protocol data.
- TCB Study Definitions Repository Reference Implementation (SDR RI) codebase serves as an example of a functional clinical protocol data repository, built on the most recent version of USDM RA.

Development of ICH harmonized guideline for clinical protocols, Clinical Electronic Structured Harmonised Protocol (CeSHarP) M11 initiative

Click for more info

ICH M11 guideline on Clinical Electronic Structured Harmonized Protocol aims to standardize the organization and content of clinical protocols.

Organizations & Collaborations

- *Initiative & M11 Guidance Owner; Partnering with FDA & EMA on development*
- *Developing Controlled Terminology Standards For ICH M11 Technical Specification + USDM*

Initiative Solutions

- ICH M11 CeSHarP template document offers detailed organization and standardization for clinical protocols, outlining both required and optional content.
- ICH M11 CeSHarP technical specification offers guidelines for the interoperable electronic exchange of protocol content.
  Note: It is in alignment with USDM.

Utilizing the Digital Protocol (UDP) initiative

Click for more info

A joint initiative by Vulcan, CDISC, and TransCelerate, using ICH M11 to create an Information Model, Terminology, and a FHIR Implementation Guide.

Organizations & Collaborations

- *Initiative & FHIR Messaging Owner*
- *Collaborating on UDP*
- *Collaborating on UDP*
- *Sponsor Company Collaboration via Vulcan and TCB Membership*

Initiative Solutions

- FHIR messages created for electronic exchange of ICH M11 protocols.

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A tipping point is approaching

The DDF initiative began in 2019, Since then, progress has been made in maturing CDISC's data standards and promoting adoption of these standards in the industry.

As DDF, ICH M11, and other standardization efforts converge, the pharmaceutical sector is nearing a critical juncture. Regulatory bodies are increasingly focused on protocol digitalization, indicating future requirements for interoperability in clinical trial data.

With the release of CDISC USDM Version 4 and the expected finalization of ICH M11 guidance in 2025, pharmaceutical companies can best prepare for the forthcoming transformational changes to the ecosystems by actively establish an implementation pathway for protocol digitalization, alongside technology providers.

History of Key Milestones With Protocol Digitization

Q1 2019
DDF Initiative Launch

*Concept Creation for **Study Builder** & **Study Design Repository***

APR 2020
Hackathon

JUNE 2020
Focus shift ***from*** study builder ***to*** standards development, open-source & study repository

*Design Innovation for **Unified Study Definitions Model** (study definition standards) and **Study Definitions Repository***

SEP 2021
Press Release Regarding Implementation Approach for DDF

*Development & Build of **SDR Reference Implementation** Based on the **USDM***

MAY 2022
Launch of a V1 working Minimal Viable Product (MVP) of the SDR

SEP 2022
Connectathon

OCT 2022
ICH M11 Step 2b Draft Protocol Template & Technical Specifications

JUNE 2023
USDM V2 & SDR RI V2 Launched

APR 2024
USDM V3 & SDR RI V3 Launched

MAR 2025
ICH M11 Updated Step 2b Draft Technical Specifications

APR 2025
USDM V4 & SDR RI V4 Launched

TBD 2025
ICH M11 Final Protocol Template & Technical Specifications

Key Terms & Definitions

- **Unified Study Definitions Model (USDM)**
  CDISC Study Protocol Standards and Reference Architecture that includes a class diagram, application programming interfaces, and controlled terminology
- **Study Definitions Repository (SDR) Reference Implementation (RI)**
  A model implementation of a repository that uses the USDM to facilitate data exchange

Focus of this document

This document does not advocate for specific implementation solutions or technologies. Instead, it seeks to assist companies in positioning themselves to take advantage of efficiencies from digital protocol standards and to meet future regulatory demands. Leverage this paper to help your organization realize a future vision for protocol digitalization.

Change is challenging! Enabling digital protocols across the industry is unprecedented and will keep evolving.

By working together, the industry can collectively influence its future.

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One size does not fit all

Making changes often demands considerable time and effort. There isn't a single correct method for implementing changes, as numerous factors will influence the process.

Company size

(startups vs. established firms)

Organization type

(biotech, pharmaceutical company, technology solution vendor)

Organizational style

(siloed, decentralized, hierarchical, flat)

Process landscape

(flexible vs. formal governing SOPs)

Technology ecosystems

(many legacy systems vs. Limited solutions)

Company culture

(open to rapid innovation vs. specific structure for approving changes)

It's impossible to outline every scenario, but you can use this general framework in connection with efforts to gain approval for implementing a process or technology solution.

Initiating protocol digitalization implementation

Developing and advocating for a proposed project vs. executing on a technology implementation project

Proposing a project and ushering it through the approval process differs from executing on a technology implementation project. Each phase has unique objectives, activities, and outcomes. Most company internal processes will have a distinction between the two approaches.

Project proposal process

Essential steps for starting a project include

- performing due diligence to verify the proposal's feasibility
- presenting a strong business case to decision-makers, and
- obtaining a decision for moving forward and for required resources

Note: This may involve a temporary team applying project management best practices for efficient planning and execution.

Obtaining a decision for an implementation project is critical for establishing a strong foundation, aligning expectations, and ensuring the project is justified, well-resourced, and effectively managed.

Project Decision Point

Executing on a technology implementation project

Once a decision has been made to move forward and logistics of the project work has been determined, teams can begin work.

The focus of implementation is on

- executing a detailed plan to meet project goals, and
- achieving the project's objectives within the defined constraints (such as, technology implementation).

Since these projects typically follow a standard development methodology, executing an approved project is relatively straight-forward.

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“Making it happen”

This document outlines approaches for putting together a compelling case for a digitalization implementation pathway.

Various factors to be considered include how a company internally operates, such as resource allocation, data collection and analysis scope, stakeholder alignment, risk identification and mitigation, and assessing and quantifying return on investment.

Key takeaways and lessons learned

Before exploring the specifics, reflect on these insights from companies that have started this journey.

You have support. Numerous resources exist to assist a company throughout this process.

Be receptive to different methods of implementation.

This is a journey. To build momentum, adopt an agile method that focuses on small, celebratory successes for the team.

Cross-functional **leadership backing and sponsorship** is crucial for success.

General assumptions

These assumptions are based on insights from companies that have started this journey.

It takes a sponsor	*It takes a leader*	*It takes a village*	*It takes change management*
A sponsor is required to make decisions regarding resource distribution and funding for work activities. *They also collaborate with stakeholders to advocate for the project, further decision-making and to ensure it aligns with other priorities.*	*The process requires someone to lead it, whether that's a senior leader, a dedicated colleague, or a small team.* *Project management should support the process and guide the team through its stages and steps.*	*Resources need to carry out different steps and activities at each stage of a proposed solution's implementation.* *Depending on the project's scope, it might be feasible to reduce the number of resources involved, provided they possess the necessary expertise.*	*In many cases, the intricate process of clinical development affects various stakeholders, particularly in biopharmaceutical firms.* *Change management aspects are integrated into each stage and step.*

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Leveraging current protocol digitalization solutions

This document assumes readers have a basic understanding of previously published solutions and standards outlined on page 3.

Given the technical content, it helps to involve a data scientist, technologist, or data architect for review.

Comprehending these standards and their possible applications to the existing ecosystem is an important part of the underlying research and analysis.

Introduction to the framework

When suggesting a project for digitalizing protocols in a company, differences arise from unique company factors, potential use cases for leveraging protocol data standards, and the requirement for efficient interoperability. Here is an example of typical variations among different types of companies:

	Large pharma	Small biotech	Technology solution vendor
Organization structure	Complex, including organizational silos and multiple hierarchical layers	Flat, focused teams, fluid roles	Focused teams supporting specific products
Process landscape	Multiple protocol development templates and structured review processes	Flexible or non-existent	Structured to support rapid product development with quality
Technology landscape	Multiple, discrete, minimally-integrated legacy systems	Minimal current technology, no integration	Not applicable
Innovation culture	Open to change; interested in more integration and efficiency	Open to innovation and evaluating existing technology	Innovation focused to support competitive product development

Because of the variability, the guideline for "making it happen" consists of general processes and includes four main stages:

1. Identify | **2. Discover** | **3. Plan** | **4. Deliver**

Considering all stages of this framework will allow for the best possible outcome and greatest chances of success.

- Execution of each phase differs by company.
- Each phase outlines proposed actions for the best results.
- While not every step needs to be fulfilled, completing as many as possible increases the chances of a successful proposal.

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Framework for developing a strong proposal for technology implementation project

The diagram illustrates the four stages important to building a compelling proposal for an implementation project.

1. Identify	A. Establish a key objective supported by at least one internal sponsor	B. Conduct a current state assessment	C. Determine a future state vision
2. Discover	A. Conduct gap analysis	B. Develop options for bridging gap	C. Identify a solution for endorsement
3. Plan	A. Identify the audience for the proposal	B. Develop the proposal	C. Review the proposal
4. Deliver	A. Confirm decision-making stakeholders	B. Present the proposal	C. Revise and re-represent the proposal, as needed

Each stage has several steps. Keep in mind that due to each company's specific circumstances, steps may occur simultaneously, be rearranged, or omitted entirely.

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STAGE 1
Identify

The goal of this stage is to determine a company's strategic direction for protocol digitalization, considering its present status, future aspirations, and unique factors.

A Establish a key objective supported by at least one internal sponsor.

Concept explanation

Digitalizing protocols can have different meanings for different companies. Due to the unique situations within each company, each company should look to define a specific approach for their needs.

Therefore, a clear project starting point is essential. Establishing a top-level objective with support from a decision-making sponsor offers direction for initial efforts.

Given the work's complexity, having at least one sponsor endorse the groundwork validates the effort and motivates the team.

Finding a decision-making sponsor may involve conversations with direct managers and colleagues within the organization.

Here, groundwork refers to the necessary arrangements and agreements to initiate preparatory work. This may involve

- consulting colleagues on their willingness to participate
- coordinating with managers regarding resource availability, and
- promoting the idea across different functional areas as necessary.

Note: It may be beneficial to suggest a temporary project team to facilitate these efforts.

Considerations

You can begin the work without a sponsor, but by the end of this phase, securing a sponsor is essential for accountability.

Typically, a resource investment to carry out the work necessitates some form of approval.

The overall goal doesn't require extensive details.

The next steps in this phase will assist in transforming this goal into a vision for the future.

Consider leveraging DDF use cases to help formulate an initial high-level objective.

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Examples

In sponsor companies, any work outside of regular duties typically requires some form of authorization to ensure resources are directed to the right priorities.

For an individual contributor to start a project on protocol digitalization, at least one internal decision-making sponsor's support is usually necessary.

This sponsor may differ by company and most likely will need to collaborate with their peers since protocol digitalization affects multiple functions, as well as technology and processes.

Example characteristics of a decision-making sponsor

A person who

- is a personnel manager with direct reports
- is responsible for a budget
- is a leader of a functional area, and
- leads or oversees transformation projects.

Here are some examples of common sponsor company role personas and potential sponsor decision-makers to engage with to get started on protocol digitalization.

Clinical science

Potential initiator	Potential decision-making sponsor
Clinical Scientist	Therapeutic Area Head Clinical Strategic Lead
Medical Scientist	
Medical Monitor	

Information technology

Potential initiator	Potential decision-making sponsor
Software Architect	R&D Digital Lead
Infrastructure Architect	
Business Analyst	

Study design / Protocol authoring

Potential initiator	Potential decision-making sponsor
Medical Writer	Head of Medical Writing
Biostatistician	
Study Designer	

Data management

Potential initiator	Potential decision-making sponsor
Clinical Data Manager	Data Standards Head; Global Data Management Head
Biostatistician	
Standards Programmer	

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B Conduct a current state assessment

Concept explanation

Conduct a current state assessment to accurately grasp an organization's existing processes and operations.

Without this assessment, teams may make decisions that are either uninformed or misaligned with corporate strategy.

Understanding the current state aids in planning future changes and aligning with enterprise goals, identifying improvement areas, guiding decision-making, and preparing for change management.

Process mapping: Validate current workflows, procedures, and decision-making processes across various departments or functions.

Resource evaluation: Evaluate the accessibility, utilization, and effectiveness of human resources, technology systems and integration, and other assets.

Performance metrics: Evaluate key performance indicators (KPIs) to assess current performance levels.

Organization structures: Get familiar with the existing hierarchy, roles, responsibilities, decision-makers on key topics, and those accountable for various areas within the organization.

Stakeholder engagement: Collect input from key individuals to identify pain points and challenges while understanding needs of all end users involved in processes and systems.

Business operations framework: Recognize business factors such as approval processes, budgets, and regulatory requirements that may affect decision-making.

Organizational culture: Evaluate the company's willingness to change and be aware of any ongoing initiatives that could affect future activities.

Considerations

The overarching goal defines the extent of a current state assessment.

The assessment can be customized based on the concepts being examined.

Involve relevant stakeholders, such as data standards experts, system users, process owners, clinicians, medical writers, technology specialists, and system owners.

Engage them for process mapping, technology ecosystem review, and content evaluation.

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C Determine a future state vision

Concept explanation

Using the current assessment results, create a vision for digitalizing protocols in your company, outlining specific goals and objectives.

Such visions differ between companies, reflecting their unique priorities.

Typically, a future state vision encompasses a longer timeframe of 3 to 10 years to develop, implement, and assess processes and systems through KPIs and continuous improvements.

A future state vision is essential as it outlines a company's desired future, guiding decisions and aligning efforts toward a common goal across the company.

It fosters direction, team unity, informed decision-making, and strategic planning while allowing for change management to enhance the chances of success.

Considerations

The future vision may build on the overarching goal from *Stage 1: Identify*.

A current state assessment can reveal additional insights to enhance and clarify the final objective.

The list of internal sponsors and decision-makers may change as the direction becomes clearer.

Having the appropriate sponsors and decision-makers will lead to optimal results during this process.

Use DDF use cases to shape a vision for the future.

Examples

Scenario 1

A sponsor company currently had a Meta-Data Repository (MDR) that has reached its "end-of-life," indicating a potential need for replacement.

Evaluating the current state and envisioning future use presented several options for enhancing a new MDR to include additional capabilities, such as alignment with the USDM.

Scenario 2

A sponsor company had senior technology leaders already interested in protocol digitization.

With the launch of USDM V1, these leaders decided to develop a proof-of-concept (POC) to use USDM for digital protocol data.

By assessing the current use of protocol data and envisioning a future state, the company concentrated on the Schedule of Activities (SoA) for the POC.

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STAGE 2
Discover

The goal of this stage is to gather information to (a) facilitate informed decision-making and (b) create plans based on factual data.

It emphasizes identifying gaps between the current and desired future state, brainstorming potential solutions, and choosing a proposal strategy.

Depending on the results from *'Stage 1 – Identify,'* teams may need to perform various tasks like gap analysis, technology assessments, and stakeholder mapping to understand the current situation and envision the future.

A Conduct a gap analysis

Concept explanation

Digitalization projects often involve assessing technology components.

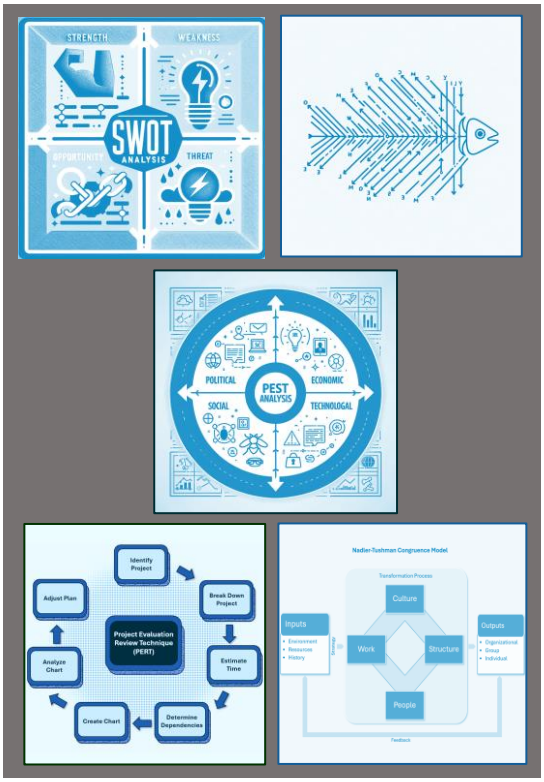
Various tools and models aid in technology assessments, such as SWOT analysis, Fishbone diagrams, PEST analysis, PERT charts, Nadler-Tushman Congruence Model and more.

Effective gap analysis involves planning, gathering information, engaging stakeholders, and iterating on discussions.

It helps in decision-making by assessing the differences between the current state and future goals, identifying opportunities for change.

The gap analysis may necessitate input from different stakeholders and subject matter experts, depending on its scope.

Additionally, the size and complexity of the organization might require dedicated resources for this step.



Considerations

Engage the appropriate stakeholders in gap analysis discussions.

This may include data standards experts, current users, process owners, clinicians, medical writers involved in protocol design, technology specialists, and existing system owners.

This will necessitate facilitators skilled in conducting a gap analysis.

If necessary, consider using external resources.

Holding a workshop could be a viable way to effectively engage different stakeholders.

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B Develop options for bridging the gap

Concept explanation

In a gap analysis, teams explore various strategies to close the gaps between the current and future states.

Each option can vary in impact regarding cost, complexity, resources, end users, processes, communication, and timing.

Clearly outlining these alternatives, especially in comparison, aids in informed decision-making for the organization's advancement.

This step can align with the gap analysis phase.

Assessing potential solutions aids in forming a proposal by pinpointing the most feasible and efficient option, aiding risk management, and fostering stakeholder support.

Considerations

Involve relevant **stakeholders** when exploring possible options.

These stakeholders may consist of data standards specialists, system end users, process owners, protocol creators, technology professionals, and system owners.

Facilitators experienced in conducting a gap analysis will be helpful.

Consider using external resources if required or useful.

Hosting a **workshop** could be a practical way to engage effectively with different stakeholders.

To ready yourself for change management, **monitor** how the change affects different roles, responsibilities, tasks, and activities.

Examples

Scenario

A sponsor company is looking into developing a study designer and an information library for studies.

The project team assessed the current state and considered a custom study designer. A gap analysis revealed several key points:

- *Variations between a paper document and its digital counterpart*
- *Capabilities that a digital document management system might offer*

These insights aided stakeholders in grasping the possible functionality, benefits, and costs tied to their vision.

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C Identify a solution for endorsement

Concept explanation

After performing a gap analysis and exploring ways to bridge the gap, teams should recommend the best solution for approval, particularly if multiple options exist.

Depending on the situation's complexity, the team and stakeholders might need to achieve an initial consensus.

This step is distinct from a formal decision to initiate an implementation project, which may require additional effort from the team.

A more focused implementation plan with a limited scope might be more attractive to senior leadership because of its clarity, ease of approval, manageable risks, efficient resource use, scalability, and potential for quick successes.

Considerations

In organizations with intricate structures and various decision-makers, achieving agreement on a suggested solution is crucial for several reasons:

Promotes stakeholder alignment through a mutual understanding and dedication to defined project objectives.

This alignment helps avoid conflicts and misunderstandings during execution.

Tackling issues early on **promotes a smoother approval process and minimizes delays during implementation**.

This approach can conserve time and resources, enabling the project to progress more effectively.

Encourages ownership and backing from stakeholders.

This enhances the chances of project endorsement and proposal approval, leading to more successful implementation.

Fosters trust and credibility within the organization.

Open and inclusive decision-making reflects values of collaboration and respect, contributing to a positive work environment and facilitating change management after implementation.

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STAGE 3
Plan

The aim at this stage is to create a solid plan for proposal to decision-makers for implementation. This could include steps such as identifying the audience for a proposal presentation and drafting the proposal itself.

A Identify the proposal audience

Concept explanation

A proposal serves as a decision-making tool that gathers essential information for key stakeholders to evaluate a proposal.

Identifying relevant reviewers and decision-makers is crucial, as it helps tailor the case to their specific needs, anticipate concerns, and create a meaningful connection.

Considerations

Stakeholder analysis tools can be used to pinpoint the target audience for the proposal.

The proposal might require review from additional stakeholders for feedback, depending on the decision-makers' level.

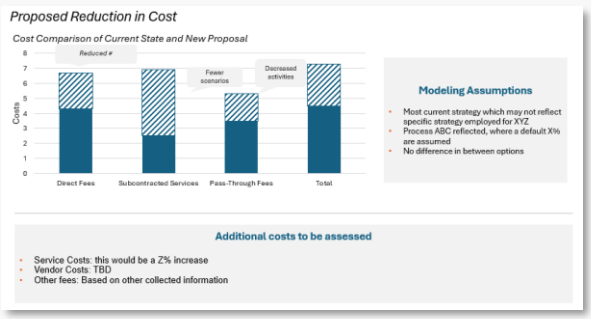
In certain complex scenarios, the team might need to deliver the proposal to various audiences at different levels, potentially necessitating multiple versions.

Examples

Scenario 1 – Emphasis on value

Senior executives usually prioritize value and return on investment, necessitating projections and analysis in their business case for justifying ROI.

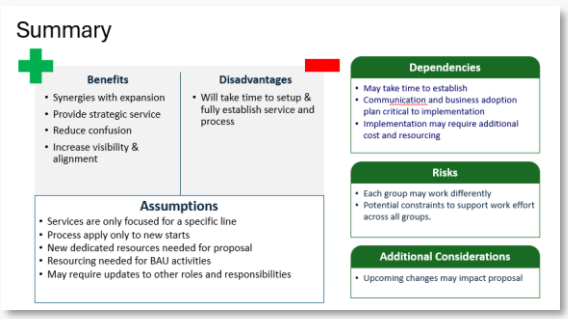
Example graphic:



Scenario 2 – Operations focus

Senior leaders overseeing teams that will utilize a new solution may concentrate on the associated risks and their mitigations.

Example graphic:



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B Develop the proposal

Concept explanation

A proposal justifies the initiating sponsor's recommendation, aligns it with strategic goals, details the effort and resources required, identifies risks and possible solutions, and establishes criteria to assess the success of the implemented solution.

A strong proposal should be convincing, thorough, and clear.

Since adopting technology often demands resources such as funds and staff, it should aid decision-making by outlining the return on investment and the benefits of the proposed solution.

Considerations

A strong proposal usually contains several essential elements, including potentially the following:

1. Executive summary

This section offers a summary of the proposal, outlining the issue or opportunity, the suggested solution, and the anticipated benefits.

It is helpful if this summary is succinct and engaging to attract the interest of decision-makers.

2. Problem statement

Clearly outlines the issue or opportunity the project intends to tackle, including evidence and data that highlight its importance.

This information can come from the results of *Stage 1: Identify* and *Stage 2: Discover*.

3. Analysis of options

Offers various alternatives to tackle the issue, outlining the advantages and disadvantages of each.

Includes the reasoning behind choosing the preferred solution, using information gathered from *Stage 2: Discover*.

4. Proposed solution

Presents a concise and thorough description of the proposed solution, highlighting its scope, objectives that align with strategic goals, and expected project deliverables.

This section can detail the methods and approaches to be employed, integrating insights and lessons from *Stage 2: Discover* where applicable.

5. Benefits and risks

Determines the anticipated benefits of the project, both in quantitative and qualitative terms.

Also, identifies potential risks and challenges, along with strategies for mitigation.

This information can be derived from the results of *Stage 2: Discover*.

6. Financial analysis

Includes a thorough financial analysis with cost estimates, funding needs, and expected return on investment.

This part can also feature a sensitivity analysis to evaluate how various scenarios affect financial results.

The financial analysis might be conducted separately after proposing a solution from *Stage 2: Discover*.

7. Implementation plan

Drafts a plan for executing the suggested solution, detailing the timeline, major milestones, and necessary resources.

Additionally, outlines the governance framework along with roles and responsibilities, referencing materials from *Stage 2: Discover*.

8. Performance metrics

Establishes the metrics and key performance indicators (KPIs) to evaluate the success of the solution's implementation.

This section can outline a strategy for tracking and reporting progress.

Choosing the right performance metrics might be a distinct task following the solution recommendation from *Stage 2: Discover*.

9. Stakeholder engagement

Outlines the strategy for interacting with key stakeholders during the project and post-implementation.

This can encompass a broad change management plan, featuring a stakeholder analysis and a communication strategy.

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C Review the proposal

Concept explanation

In our diverse and interconnected world, varying communication styles present notable challenges.

Everyone brings a unique perspective, background, and preferences to the table, which can lead to varied interpretations. This diversity in perception underscores the importance of a thorough review process.

Involving multiple stakeholders in the review before presenting to decision-makers can enhance the clarity and persuasiveness of the content.

Collaborative review enhances accuracy and quality, fosters consensus, aligns the proposal with strategic objectives, and supports informed decision-making.

This method also uncovers misunderstandings, improves the proposal's quality, and ensures effective communication with stakeholders.

Considerations

When seeking a review of a proposal, consider these best practices:

Make a specific request

When sending an email, ensure the subject line summarizes the request's intent. The email should briefly explain the review's purpose, clearly state what is needed from the reviewer, and include a due date.

Facilitate access to the proposal

Make sure reviewers can access the proposal if it's on a collaborative platform. Specify how they should give feedback, whether through comments or various editing methods. Activate automatic version control for the document.

Hold a review meeting if necessary

Be ready to organize a meeting to address questions and feedback, depending on the number of reviewers and the amount and nature of the comments received.

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STAGE 4
Deliver

The goal of this stage is to deliver and present the proposal to the company's relevant decision-makers and advocate for the proposal according to the company's internal operations, processes and culture.

A Confirm decision-making stakeholders

Concept explanation

In 'Stage 3: Plan', Step A advises teams to identify the audience for the proposal.

The initial stakeholder list may change during development and review, so it's important to verify the decision-makers before the presentation.

Reconfirmation aids in areas such as:

- preventing delays or misunderstandings, obtaining alignment, and getting support from involved parties, and
- facilitating future change management efforts for an implemented solution.

Considerations

Teams may need to recognize various levels of decision-makers for the relevant type of proposal, based on the organization's complexity.

Example

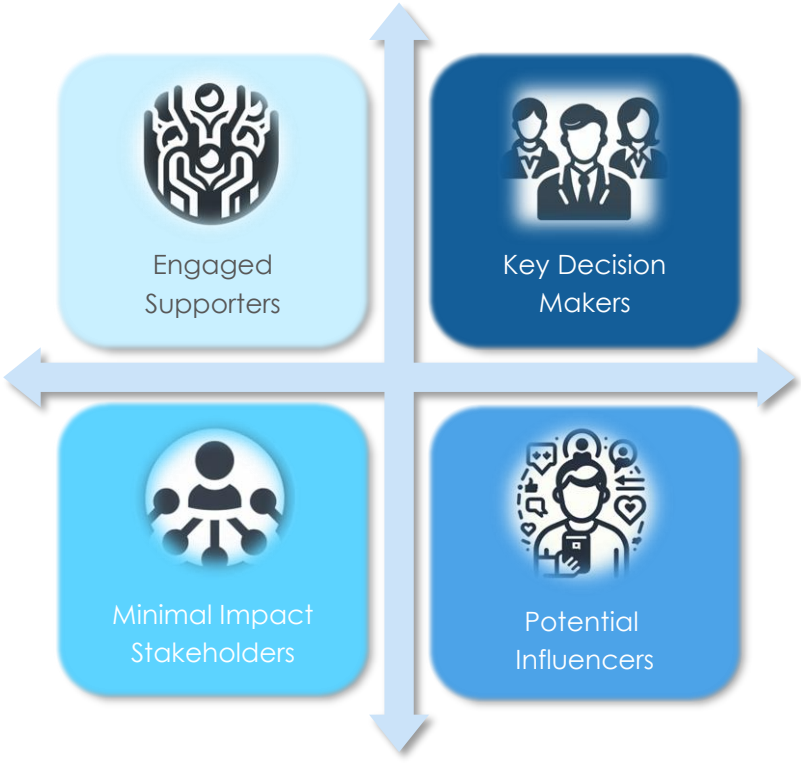
Factors for identifying and analyzing stakeholders:

Scenario

In an organization, key decision makers may come from different divisions.

For instance, while a technology department may manage the budget for tech solutions, a governance body of business users often makes the final decisions on budget allocation.

Other stakeholders may include end users of the solution or managers of systems that will integrate with it.



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B Present the proposal

Concept explanation

A meeting will probably be necessary to present the proposal. This meeting should allow for open discussion, including negotiations, questions, and clarification on future steps.

Stakeholder consensus

Gathering all parties and defining the objectives, scope, and anticipated results of the proposal fosters a common understanding and alignment among stakeholders.

Real-time clarification

Holding a meeting with a Q&A session facilitates immediate communication and addresses concerns right away.

This approach helps avoid misunderstandings and ensures that all participants understand the proposal clearly.

Collaborative decision-making

In the meeting, stakeholders can evaluate the advantages and disadvantages of the proposed project, exchange insights, and offer feedback. This teamwork facilitates informed decision-making and highlights potential risks and mitigation strategies not covered in the proposal.

Considerations

Reviewing a proposal for the first time in a meeting can be inefficient and lengthy, especially if it is complex and contains extensive content.

To enhance the effectiveness of the review, sending pre-read materials enables stakeholders to understand the case and prepare questions beforehand.

Various strategies can be used to achieve consensus, depending on the organization's culture and the solution's complexity.

Stakeholder Analysis

Following best practices, it's important to perform a stakeholder analysis early in *Stage 1: Identify* and *Stage 2: Discover*.

Recognizing each stakeholder's interests and concerns allows for a more targeted approach to address their specific issues.

Stakeholder Engagement

Engaging key stakeholders early fosters trust and ownership.

This strategy cultivates a common vision and promotes consensus, allowing stakeholders to advocate for the proposal and impact decision-making.

Preliminary Meetings with Key Stakeholders

Prior to a key meeting, meet one-on-one with stakeholders to discuss key points and collect their feedback.

This extra effort aids in clarifying messages, addressing concerns, and fostering support before the official presentation.

Negotiation and Compromise

Stay receptive to feedback and ready to modify plans to consider various viewpoints.

At the meeting's conclusion, be ready to outline the next steps. Clear actions with a timeline can aid in advancing the proposal, especially if no decision is reached.

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C Revise and re-present the proposal (as needed)

Concept explanation

If no decision was reached in the proposal presentation, further meetings might be necessary.

These follow-up meetings may lead to changes in the original proposal, informed by discussions and results from the initial meeting.

More chances to present a proposal will strengthen it through further research and clarifications, while also ensuring that next steps are taken, progress is monitored, and additional clarifications are provided if necessary.

Considerations

Expect discussions about the proposed plan during this process and be receptive to changes. Some update and review cycles may extend over several months.

Example

Example of a proposal revision

As a proposal develops, it may receive diverse feedback on its content and format.

This example illustrates how a proposal can be improved through reviews and suggestions to create a more effective case.

Objectives	*Background*	*Background*	*Background example*	*Background example*
Proposal	*Proposal supportive data*	*Proposal supportive data*	*Request for approval*	

Updates made per feedback

Objectives	*Background*	*Supportive data for background added*	*Supportive data for background added*	*Background*
Background example	*Background example*	*Proposal*	*Proposal – more details added*	*Proposal supportive data (format modified)*
Proposal supportive data (format modified)	*Proposal supportive data (format modified)*	*Request for approval*	*Appendix*	*Implementation details*

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Summary of the four stages

Once approval for an implementation project is granted, the planning and execution phases commence.

Essential tasks include forming project teams, setting timelines, securing resources, executing the plan, and overseeing all activities to ensure successful implementation.

Implementation considerations

This document does not include specifics on implementation activities but identifies the following industry best practices.

Technology implementation operations best practices

- Use a suitable technology development method like agile, waterfall, scrum, or lean.
- Implement effective project management practices, including planning, resource allocation, risk assessment, stakeholder communication, and performance tracking.
- Perform detailed business analysis and gather requirements.
- Promote a solid technical design.
- Ensure careful coding and development.
- Implement a thorough quality assurance and testing plan.
- Create a change management strategy.

Technology assessment and vendor selection

- To effectively compare technologies, outline business requirements and categorize them as must-have, nice-to-have, immediate, or later. Evaluating each technology solution against this list can help achieve an objective analysis.
- The existing relationship with a vendor can impact selection but consideration should be given as to which vendor is the ideal choice for the specific solution.
- It's also advisable to identify multiple potential vendors and assess them to find the best fit.

Enterprise-level impacts and synergies

- This document describes a general process for developing a compelling proposal, but it is important to recognize that multiple proposals may receive consideration or approval within the organization, each targeting different objectives tied to protocol digitalization.
- By adopting consistent standards like CDISC USDM, various initiatives within a company can develop and eventually achieve end-to-end interoperability.

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Conclusion

Careful planning, preparation, and analysis in creating a robust proposal for a technology implementation project can facilitate decision making on getting started, especially with digital data flow due to interdependencies with interoperability and complexities with the level of detail.

Assembling a strong proposal that can withstand scrutiny and earn the backing of key stakeholders is a strong starting point for project implementation.

The importance of planning, preparation, and analysis cannot be underestimated, as they form the foundation for a well-justified, adequately resourced, and effectively managed implementation project.

By adopting a structured approach and utilizing industry best practices, organizations can start to tackle the challenges of protocol digitalization and work toward attaining successful results.

Pharmaceutical companies and tech vendors can proactively adopt technology solutions for protocol digitalization to help foster innovation in clinical research.

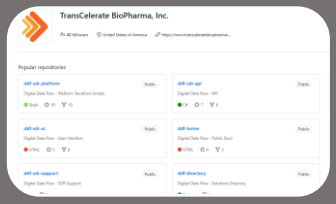
Use this document to create a robust proposal for your digital data flow project.

Stay Informed!

DDF Website

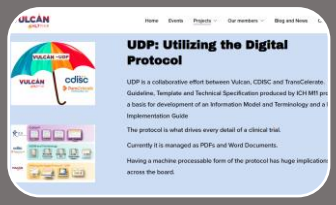
CDISC USDM

TransCelerate DDF Initiative



DDF GitHub Repos

ICH M11



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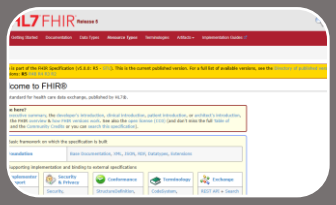

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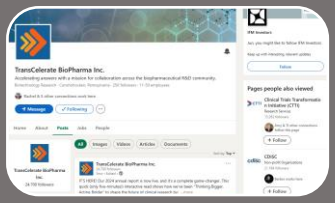

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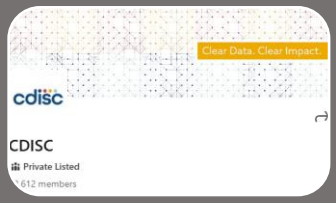

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