

ORGANIZATIONAL SELF ASSESSMENT

Instructions for Use

Purpose of the assessment

The purpose of the assessment is to evaluate a company's readiness to adopt Digital Data Flow (DDF). This assessment is intended for a company's internal use.

Audience for the assessment

This assessment is recommended for leaders in departments responsible for protocol authoring, study startup, clinical data standards, and the development or support of technologies enabling the activities of these departments within an organization.

Pework to using the assessment

Before using the assessment, consider watching the [DDF Overview](#) video. The video will give you helpful background information about the DDF vision and solution.

Use of the assessment

The assessment may be used to arrive at an aligned point of view on a company's readiness for DDF. This may involve one or more leaders in the organization informally discussing or formally documenting answers to the questions. The ***Audience for the assessment*** section above contains recommendations for leaders who might be involved in such discussions.

Companies might choose to use the assessment to generate internal discussion and consider actions to facilitate their DDF journey.

Once leaders have answers from the assessment, they may use the **Considerations for your organization** column to plan next steps to advance DDF readiness or adoption.

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Topic	Considerations for your organization
<p>My company or department routinely re-uses study protocol and study design information across studies and programs.</p> <p>Answer on a 3-point scale ranging from (1=Strongly disagree, 2=Neutral, 3=Strongly agree)</p>	<p>Developing an internal business case for Digital Data Flow in your organization might be easier if a culture and mindset of content reuse, and automation of reuse, is already valued highly with demonstrated examples of return on investment.</p> <p>Confirm the benefits of content reuse by watching the DDF Overview and by familiarizing yourself with TransCelerate's Clinical Content & Reuse initiative by watching the TransCelerate eTemplates Overview.</p>
<p>My company currently uses a document-based approach to authoring study protocols.</p> <p>Answer yes or no.</p> <p>If yes - Does your company use protocol templates such as the TransCelerate Common Protocol Template or eCPT?</p>	<p>Use of common templates for document-based authoring is an important step toward streamlining and harmonizing content and promoting valuable reuse across the organization. This enables a stronger baseline for adopting a digital data flow approach.</p> <p>Furthermore, technology-enabled templates, such as the eCPT, can promote more automated reuse of content across documents and downstream processes, such as clinical trial registry population.</p> <p>The Digital Data Flow initiative further automates and streamlines reuse by breaking the document paradigm, using a new data model standard to structure and organize protocol information in a digitized format.</p> <p>Your organization might consider comparing the new data model standard for DDF (Unified Study Definitions Model) to your existing protocol templates, related content libraries, or both. Such a comparison may result in a gap analysis to determine the scale of difference between the current organizational approach and the industry-standard approach developed under DDF by CDISC.</p>

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<p>My company either currently uses, or plans to introduce, a more digital or data-based approach to authoring study protocols. Examples of this approach include structured content authoring tools, eProtocol/digital authoring, and study builder tools.</p> <p>Answer on a 3-point scale ranging from (1=Strongly disagree, 2=Neutral, 3=Strongly agree)</p>	<p>If the score is 2 or less - Confirm the benefits of introducing a more digital or data-based approach to authoring study protocols by watching the DDF Overview video.</p> <p>You will gain insight into the cost of process inefficiency, quality issues, and time delays related to manual interpretation, data entry, and downstream systems configuration using protocol documents rather than structured protocol data. A digital or data-based approach also enables greater advanced analytics across protocol datasets. This becomes difficult when protocol information is locked in a document format.</p> <p>You might consider discussing with your leadership peers the benefits of the DDF opportunity and the barriers in the organization to adopting a digital data flow approach. This can help you identify the challenges and potential approaches to overcome them</p> <p>If the score is 3 - Identify the templates, software solutions, or both that your organization currently uses to author protocols or to produce protocol / study definition data in a structured format (for example, study builders or structured content authoring tools).</p> <p>Identify the software solutions your organization currently uses that make use of protocol / study definition data (for example, EDC/CDMS, CTMS, and others). This represents a list of software that may be in-scope for your company's transition to a DDF approach, enabling a more end-to-end, dynamic flow of study definitions (protocol data) throughout processes and systems involved in study start-up and execution, minimizing or eliminating manual data entry.</p>

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<p>My company has a structured content repository or metadata repository that includes study design information, study protocol information, or both.</p> <p>Answer on a 3-point scale ranging from (1=Strongly disagree, 2=Neutral, 3=Strongly agree)</p>	<p>If the score is 2 or less - Existing use of a structured content or metadata repository within your organization can facilitate faster adoption of Digital Data Flow.</p> <p>Your company might wish to compare existing repository(ies) to the DDF Study Definitions Repository Reference Implementation and supporting standards (Unified Study Definitions Model, Controlled Terminology).</p>
<p>My company would benefit from digitizing information found in our protocols/study design information.</p> <p>What elements of a business case for digitized protocol / study design information would be most compelling to your company?</p> <ol style="list-style-type: none"> 1. Advanced analytics to improve study design 2. Automated workflow 3. Minimizing/Anticipating future amendments 4. Productivity/Cost savings 5. All the above 6. Others 	<p>Confirm the benefits of digitizing information found in protocols/study design information by watching the DDF Overview video.</p> <p>You will gain insight into the cost of process inefficiency, quality issues, and time delays related to data entry and systems configuration during study start-up.</p> <p>Use the key messages from this video to communicate with other members in your organization and consider roles in your organization that may need to participate in this initiative.</p> <p>Consider building a business case to adopt the DDF solution by quantifying the cost of process inefficiency, quality issues, or time delays related to data entry or systems configuration during study start-up.</p> <p>Identify net-new value your organization may receive from a digital data flow approach, such as support for more advanced analytics or predictive insights into study operations.</p> <p>Link these business case elements to existing tools or assets, such as your metadata repository. Doing so can accelerate your organization's adoption of DDF. Identify any ongoing initiatives that may synergize with DDF. Identify any leaders who sponsor or oversee such initiatives who should know about DDF. Assess whether current initiative roadmaps already align to DDF.</p>

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<p>My company either currently has, or has plans to start, an initiative or initiatives related to digital transformation, automation in study start-up, or both.</p> <p>Answer on a 3-point scale ranging from (1=Strongly disagree, 2=Neutral, 3=Strongly agree)</p>	<p>Identify which ongoing initiatives should be aware of DDF. Assess whether current initiative roadmaps already align to the principles or available solutions for DDF.</p> <p>Leaders who sponsor or oversee these internal initiatives may be appropriate partners or advocates for adopting the DDF solution.</p>
<p>My company is actively trying to create a digitally connected workflow across clinical operations platforms.</p> <p>Answer on a 3-point scale ranging from (1=Strongly disagree, 2=Neutral, 3=Strongly agree)</p>	<p>Identify any leaders who sponsor or oversee ongoing initiatives who should know about DDF. Assess whether current initiative roadmaps already align to the principles or available solutions for DDF.</p> <p>Leaders who sponsor or oversee these internal initiatives may be appropriate partners or advocates for adopting the DDF solution.</p> <p>Speak to leaders about the additional benefits of adopting industry standards created by CDISC out of the DDF initiative instead of organization- or vendor-specific standards.</p> <p>You can amplify connected workflow at an organizational level using industry-accepted standards and compatible solutions. Doing so enables connectivity across organizational boundaries, such as CROs or other research partners. It also enables a more flexible, plug-and-play approach for individual clinical programs, without relying on a single platform requiring customized integrations that are costly to build and maintain.</p>

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<p>My company has undertaken efforts to quantify the cost of process inefficiency, quality issues, or time delays related to data entry or systems configuration during study start-up</p> <p>Answer on a 3-point scale ranging from (1=Strongly disagree, 2=Neutral, 3=Strongly agree)</p>	<p>Consider building a business case to adopt the DDF solution by quantifying the cost of process inefficiency, quality issues, or time delays related to data entry or systems configuration during study start-up.</p> <p>Identify net-new value your organization may get from a digital data flow approach, such as support for more advanced analytics or predictive insights into study operations.</p> <p>Link these business case elements to existing tools or assets, such as your metadata repository. Doing so can accelerate your organization's adoption of DDF. Identify any ongoing initiatives that may synergize with DDF. Identify any leaders who sponsor or oversee such initiatives who should know about DDF. Assess whether current initiative roadmaps already align to DDF.</p>
<p>My company values investment in technology solutions capable of supporting interoperability standards.</p> <p>Answer on a 3-point scale ranging from (1=Strongly disagree, 2=Neutral, 3=Strongly agree)</p>	<p>Consider a discussion with your IT and business technology leaders to validate the benefits of interoperability across the clinical systems landscape, both to your organization and to industry at large.</p> <p>Identify whether a more specific technology business case for DDF may be warranted to quantify the cost of ownership associated with existing product suites or platforms used.</p> <p>Identify whether increased use of DDF-compatible solutions may reduce the need for costly systems integrations, bespoke integrations for individual programs, or an approach that limits product or technology choices.</p>

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<p>My company favors a flexible, plug-and-play approach to the systems landscape more than an “all-in,” single-platform approach.</p> <p>Answer on a 3-point scale ranging from (1=Strongly disagree, 2=Neutral, 3=Strongly agree)</p>	<p>Consider a discussion with your IT and business technology leaders to validate the benefits of a more flexible, plug-and-play approach to the systems landscape.</p> <p>Identify whether a more specific technology business case for DDF may be warranted to quantify the cost of ownership associated with existing product suites or platforms used.</p> <p>Identify whether increased use of DDF-compatible solutions may reduce the need for costly systems integrations, bespoke integrations for individual programs, or reliance on a single-vendor approach.</p>
<p>My company values open-source software and open-source projects.</p> <p>Answer on a 3-point scale ranging from (1=Strongly disagree, 2=Neutral, 3=Strongly agree)</p>	<p>DDF solutions are released to the public under a permissive open-source license (Apache 2.0). Permissive licenses allow users to download, transform, or improve the licensed code, and to incorporate that code in larger applications, including proprietary software. Permissive licenses do not require the modified code or applications to be made available under the same terms.</p> <p>The DDF initiative selected this license to encourage adoption of the open-source solutions by technology vendors of clinical systems, sponsor companies, CROs, and others in the community.</p> <p>If your company has existing policies, ways of working, or expertise in open-source software, engaging knowledgeable colleagues in your organization may help to promote awareness of DDF and teach the benefits of DDF's open-source solution.</p> <p>Encourage appropriate IT colleagues and others to visit the DDF GitHub repositories. There they can explore the available open-source code and supporting technical documentation for the DDF solution: [Link to GitHub]</p>

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<p>Leaders in my company are aware of the Digital Data Flow initiative.</p> <p>Answer on a 3-point scale ranging from (1=Strongly disagree, 2=Neutral, 3=Strongly agree)</p>	<p>If the score is 2 or less -</p> <p>Consider sponsoring several Town Hall events focused on DDF, undertaking a DDF roadshow across various business units or functions, promoting awareness of available DDF assets through internal channels or newsletters, or a combination of these.</p>
<p>Leaders in my company are willing to explore DDF or make use of it in the future.</p> <p>Answer on a 3-point scale ranging from (1=Strongly disagree, 2=Neutral, 3=Strongly agree)</p>	<p>If the score is 2 or less -</p> <p>Consider having a leadership discussion with cross-functional leaders and other peers to teach them about DDF and promote a common understanding of the benefits and change associated with DDF.</p>
<p>Where do you see the biggest challenges in exploring or adopting Digital Data Flow at your company?</p> <p>Answer in a free text field.</p>	<p>Encourage leaders in your company to explore DDF by hosting group discussions on the benefits, potential barriers or underlying reasons for aversion to change, and possible roadmap to DDF transformation.</p> <p>Consider a discussion on which roles are most likely to be impacted by DDF. You might follow this discussion with a more in-depth stakeholder change analysis.</p>