## REVISION HISTORY

<table>
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<tr>
<th>Version Number</th>
<th>Revision Date</th>
<th>Description of Change</th>
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<tbody>
<tr>
<td>1.0</td>
<td>September, 2013</td>
<td>Initial Document</td>
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1 Background

Establishing common study data standards will provide new opportunities to transform a vast and continually increasing amount of clinical study data into useful information to speed the delivery of new therapies to patients. Standardized data elements, terminologies, and data structures enable automation of important analyses of clinical study data to support more efficient and effective regulatory decision-making. In 2011, in response to an urgent need to further standardize study data terminologies and concepts for efficacy analysis, FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) compiled a prioritized list of disease and therapeutic areas (TAs) for which additional data standardization was needed, and made the list available on the FDA website. Several factors were considered in the identification and prioritization of these areas: (1) number and type of active investigational new drug applications (INDs), (2) existing standardization projects underway, and (3) industry input on drug development pipeline activity.

Section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), signed by the President on July 9, 2012, requires new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), and INDs to be submitted in electronic format specified by FDA in guidance, beginning no earlier than 24 months after the guidance is finalized. Using this new authority, FDA published draft guidance at the end of 2012 specifying that submissions to applications must be in standardized electronic Common Technical Document (eCTD) format. FDA plans to issue guidance that study data contained in such submissions must be in a standardized format that FDA can process, review, and archive. Under Section XII of the Prescription Drug User Fee Act V (PDUFA V) performance goals (reauthorized by FDASIA), FDA agreed to develop a project plan for developing distinct therapeutic area terminology standards using a public process that allows for stakeholder input through open standards development organizations.

In November 2012, the FDA requested public input relevant to study data standards by (1) convening a public meeting on November 5th entitled “Regulatory New Drug Review: Solutions for Study Data Exchange Standards,” to receive input from stakeholders on the advantages and disadvantages of current and emerging alternatives for the exchange of regulated study data, and (2) issuing a notice in the Federal Register (FR) informing the public of FDA’s intent to prioritize and develop study data standards for identified TAs, and requesting public comment on the TA roadmap as well as recommendations on how the effort could be accomplished most efficiently. The outcome of the November 5th meeting and comments received from the FR request for information informed the development of this project plan.


In December 2012, CDER made its Data Standards Strategy available on the FDA website. This document focuses on the ongoing commitment to develop, implement and maintain needed standards through a comprehensive data standards program. The strategy provides the operational framework and organizational structure within which this project plan will be implemented and maintained. Its companion document, the Data Standards Strategy – Action Plan, was published in March 2013. This plan provides a report on the status of the center’s portfolio of projects and activities with respect to the program objectives. It will report progress quarterly on the active projects identified within, and managed through, this project plan. This includes projects that are directly relevant to the effort and in which FDA participates, but are led by external parties (e.g., grants to develop standards for specific therapeutic areas).

2 TA Standards Initiative Overview

This TA standards development initiative focuses primarily on requirements for the efficacy review and evaluation of new medical products. FDA recognizes, however, that the value of clinical terminology standards extends well beyond the regulatory new drug review process, and that they are essential to the consistent delivery of quality health care. As such, FDA is embracing several core operating principles in the execution of this initiative:

- Ensure engagement and input of key authoritative clinical and medical professional societies in TA projects
- Adopt or adapt existing standards where possible
- Harmonize with nationally recognized healthcare standards and controlled terminologies wherever possible
- Use a well-defined data standards governance function
- Scope projects to develop standards incrementally such that benefits can be realized within a relatively short time, with additional value added iteratively.

This project plan will be the primary document for guiding all major aspects of this multi-year initiative. Updated annually and made available for public comment, the plan will provide the overall management framework for addressing and accomplishing the PDUFA V objectives to develop/adopt clinical terminology standards for therapeutic areas. This plan is not intended to provide a detailed timeline for the execution of this initiative. The Data Standards Strategy-Action Plan, published in March 2013, will be updated quarterly to provide updated information on the development, review, testing and implementation of each specific therapeutic area standard.

The following are the 5-year goals of this initiative:

- Make significant progress in developing and implementing TA standards

• Implement binding guidance with a consistent and predictable approach
• Establish a consistent process that supports continued TA development
• Define a forward-looking model and timeline for study data standards to ensure sustainability and flexibility over time
• Make inroads in establishing interoperability with healthcare data standards

3 Scope and Objectives

The scope of this initiative includes the development and implementation of TA standards to support the regulatory review process for drugs and biologics.

FDA’s objectives for this initiative are as follows:

• Establish and implement FDA’s requirements

Data needed to support efficacy analyses (including primary, secondary, and exploratory outcome measures) remain largely nonstandardized. FDA must understand and document its requirements for efficacy data for the different TAs. These requirements will inform Standards Development Organizations (SDOs) and other stakeholders in project scoping and standards development, including evaluation of existing data standards, models, and terminologies that may meet the need.

• Use an open and transparent process

With one of the primary objectives of this plan being the development or identification of standard clinical terminologies, effective collaboration with SDOs is a core activity. Collaboration with stakeholder organizations with domain knowledge and common interests is essential.

FDA will take actions to engage stakeholders in standards development through SDOs and solicit public input on FDA-generated material through FR notices and other mediums. The Communications Plan further describes information sharing efforts.

• Express TA requirements in sustainable standards

Through this initiative, FDA is currently using Clinical Data Interchange Standards Consortium (CDISC) standards. However, development projects should adopt/adapt existing data elements and terminologies that are fit for their purposes. Where new concepts are developed, FDA will seek to harmonize with healthcare standards where possible.

Although these standards are sufficient in their current form, a continuous effort is called for to identify the best future direction to ensure that standards and terminologies are sustainable without undue burden to stakeholders.

• Implement in guidance

As noted above, FDA plans to issue guidance that study data contained in submissions must be in a standardized format that FDA can process, review, and archive. The final guidance (after public comment) will specify the electronic study data standards, formats, and terminologies that the FDA can process, review, and archive. In addition, the guidance will provide the Agency’s current recommendations on the best means for implementing standardized study data.
4 Implementation Approach

This section describes the standards activities and projects, both in progress and planned, that have been established to meet the objectives of the initiative. The combination of activities and projects, along with the identification and acknowledgment of the risks outlined in Appendix A, will result in the successful implementation of this initiative.

4.1 Consistent, Collaborative Process

Figure 1. Collaborative Therapeutic Area Standard Development Process

Figure 1 describes the process framework in which FDA performs development, testing, implementation, and guidance development for standards usage. The process will include mechanisms to engage stakeholders in key activities. This process lends itself to the inclusion of new stakeholders and/or SDOs as circumstances dictate.
4.2 Requirements Definition and Approach

As shown in Figure 2, the first stage of the standards development process is to define business needs and to determine the approach, for instance, through alternatives analysis or identification of an existing standard that may already meet the defined requirements.

FDA has initiated several efforts to capture reviewer requirements with respect to efficacy evaluation in distinct TAs. Combined, these efforts will result in a data model representing elements and concepts used in new drug and biologic reviews. The data model will be flexible to accommodate new and updated concepts as knowledge is acquired.

- TA Requirements Modeling

FDA is presently engaged in a project to collect and model TA-specific CDER/CBER review requirements in a fashion that is both useful for the standards development process, and understandable for FDA reviewers. An initial assessment indicates that this approach is producing useful results with minimal impact in terms of reviewers’ time. The project will continue with groups of 5-
10 TAs at a time and in a scope designed to achieve results within 4-6 months, with a goal of modeling core requirements of each of the identified TAs over the course of the next several years. The results will be provided as input to standards development projects as FDA requirements.

Each new TA standard will augment the standardized clinical data elements, concepts, and terminologies necessary for any study across disease domains (e.g., those presently captured in CDISC Standard Data Tabulation Model (SDTM) domains). TAS development will also influence the scope, definition, and representation of these data elements. Although some are used routinely by FDA reviewers, others are used on an as-needed basis. We will develop a "core" FDA study data model consisting of those data elements, concepts, and terminologies frequently used in the FDA review process, to help support the evolution and maintenance of the standard from the FDA review perspective. We expect that as additional TA standards are developed, they will generate fewer new elements and concepts as previously defined concepts are reused.

**Information Exchange Requirements**

The public’s responses to the November 2012 FR notice on TA prioritization, as well as discussions at the November 2012 public meeting on study data exchange, are being used to document a pathway for the replacement of SAS XPORT V5 files used for submission of study data content, with a more robust and flexible transport mechanism.

In order to develop an efficient and sustainable standard, FDA needs to ensure that the contents of clinical submissions closely reflect the regulatory review needs. Clearly defined review requirements will lay the foundation for the FDA use case for the clinical information exchange standard.

### 4.3 Standards Development

**Figure 3. SDO Development Process**
<table>
<thead>
<tr>
<th>TA Standard Project Stage</th>
<th>Status Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiation</td>
<td>The SDO, grantee, or other lead group working with the FDA and other Subject Matter Experts (SMEs) defines the project scope (e.g., what is needed for regulatory review decision making), develops a charter to define the project and ensure available resources, develops a plan, and conducts a kick-off of the project.</td>
</tr>
<tr>
<td>Development</td>
<td>The SDO, grantee, or other lead group conducts an iterative process of data element identification (e.g., elements needed to describe the study primary endpoint), definition, validation, and conducts a review with defined expert groups. FDA’s subject matter experts participate throughout the development phase. A key output is an implementation guide for the study data standard.</td>
</tr>
<tr>
<td>Internal Review</td>
<td>The Lead group conducts an internal review of internal teams or experts and begins the development of educational training materials. Once all internal comments are addressed, the standard package is prepared for external posting.</td>
</tr>
<tr>
<td>Public Review</td>
<td>The Lead group facilitates the TA data elements and associated artifacts to be released for a public review comment period. Comments are addressed per the Lead group’s process.</td>
</tr>
</tbody>
</table>

Figure 3 outlines the general standards development process. SDOs may have additional steps such as draft or provisional releases, multiple public reviews, etc. Currently, the Coalition for the Advancement of Standards and Therapies (CFAST), an initiative sponsored by CDISC and Critical Path (C-Path) Institute and supported by FDA and TransCelerate BioPharma, is underway to coordinate TA development work streams leading to the delivery of standard data elements, concepts and terminologies for each therapeutic area. Each TA standard must include SDTM representation and examples, a model of disease area clinical concepts, essential core data elements and identified terminologies, an Implementation Guide (with conformance requirements), Standard CDASH Case Report Forms (CRFs) (with SDTM annotations, when needed), and validation rules.

4.4 Testing and Implementation

![Figure 4. Testing and Implementation Processes](image)
<table>
<thead>
<tr>
<th>TA Standard Project Stage</th>
<th>Status Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testing</td>
<td>Depending on the TA, a project may be required to conduct testing for the TA standard to simulate regulatory review decision making. This testing will ensure that all identified factors (e.g., scale, impact, ability to meet regulatory review needs, fit within FDA infrastructure) are assessed and that all policy, regulatory, guidance, and technical specification needs are identified. Different approaches may be taken depending on the standard.</td>
</tr>
<tr>
<td>Adoption</td>
<td>If needed, changes to policy, guidance, and technical specification will be made to support implementation of a given data standard.</td>
</tr>
<tr>
<td>Implementation</td>
<td>The TA standard is implemented within the FDA environment. This phase includes all the steps to make this part of the regulatory review process.</td>
</tr>
<tr>
<td>Draft and Final Guidance</td>
<td>FDA will develop and issue draft guidance for public comment and then issue final guidance if the use of a new standard is required.</td>
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When a standard is released for public use by the SDO, it is not automatically supported by FDA. FDA will perform acceptance testing, as shown in Figure 4, to confirm its ability to receive, validate and use the standardized data for regulatory review.

FDA’s criteria for the acceptance of a therapeutic area standard include the following:

- Use of a public, transparent and collaborative process
- Conformity with FDA regulatory review requirements
- Harmonization with existing standards and/or data elements, wherever feasible
- Harmonization with nationally recognized healthcare standards and controlled terminologies wherever possible
- Timely preparation of conformance validation rules
- Ability to process, review, and archive received datasets

FDA will develop an acceptance testing process. This process will define testing approaches and appropriate measurement criteria to assess readiness. The testing approach is envisioned as collaborative FDA-industry effort to assess readiness to generate, transmit, receive, and use data in the standardized form.

This effort will include the following key components:

**Test datasets & process** – This component defines the steps, possible tools, and data to allow a review division and industry volunteers to agree on, generate, transmit, and receive a dataset in the new standard that is understandable and usable by the reviewers. This may involve a pilot period in which industry submits datasets (with real or placeholder data) that reviewers can evaluate using the tools they would be using for a normal review.
**Validation** – CDER’s Office of Computational Science (OCS) leads the CDER Data Fit project, an effort to develop content validation rules for study data, and consults with CBER on cross-cutting issues. The rules will be published in easily understood form to allow sponsors to check data in the same way as FDA. The development of the validation rules would be informed by the testing and would be a product of a successful acceptance process. This process will also inform the development of any required technical guidance.

**Training** – CDER/OCS provides and maintains online training tools in the use of study data standards. These tools will be evaluated and updated with each TAS released, as necessary, and reviewers will be provided with training to ensure that they can actively participate in testing and evaluation of the standard.

### 4.5 Continuous Process Improvement

Figure 5. Ongoing Process Improvement

In an ongoing effort to improve the Data Standards Process Framework, throughout the process we will collect feedback from stakeholders, document activities, identify changing requirements, and look for new and better ways of completing tasks. Periodically, we will review and evaluate what we have learned and adapt improved processes as needed to meet the TAS initiative goals.

### 4.6 Use of Grants and Cooperative Agreements

To facilitate progress on TA standards, FDA has established a small grants program to fund projects that develop disease/domain-specific TA standards. FDA is also evaluating cooperative agreements as another vehicle to facilitate development of TA standards. As with TAS development projects, the products of grants and cooperative research agreements are anticipated to be of limited scope (e.g., concerned with a subset of a TA or the most commonly used endpoints), with the possibility of adding to the project’s scope as needs and resources dictate. The results are expected within one year of award (unless extensions are granted), and will serve as the basis for the development of standards in particular areas. FDA has awarded a number of grants to external organizations for development of clinical data elements in areas such as Cardiovascular Imaging and Endpoints, Major Depressive Disorder, Virology, and Schizophrenia.
The grant process and announcement will be reviewed annually with respect to outcomes and expectations, and may be revised to leverage lessons learned. We will continue to engage interested investigators through these opportunities. In addition, FDA is evaluating other mechanisms to support concurrent TA-related development activities.

5 Future Direction (Sustainability)

Concurrent with advancing TA standards as described above, we are taking steps to ensure that standards remain viable over time. Although there is presently no industry-wide consensus on the best way to represent and maintain the data models, we recognize that a unified conceptual representation is required to accommodate the needs of multiple stakeholders. To that end, FDA is exploring options for harmonizing between different representations of clinical concepts to allow flexibility and efficient sustainability.

FDA will assess options based on a number of considerations critical to increasing the efficiency and effectiveness of the TA content development process, including:

- The need for a widely-accepted, open technology
- Ability to support evolving models that are implemented and shared by multiple stakeholders and systems, including maximized re-use and built-in business validation
- Availability of reliable tools and infrastructure promoting data discovery, re-use, pooling, and harmonization
- Potential to enable development of standards that can be harmonized, as needed
- Ability to achieve conceptual alignment through computable semantic interoperability, by reducing or eliminating the impact of differences in implementation technologies and transport protocols
- Having a significant base of current clinical research and life sciences standards and terminologies already captured and available for being referenced from TA models

FDA will be soliciting public participation in assessing the use of alternative technologies, via planned pilot studies, to arrive at an informed decision regarding the benefits of integrating them into the TA development process.

6 Progress Reporting

The Data Standards Strategy-Action Plan is the primary medium that FDA will use to present the startup and progress of projects within this initiative. The plan will be updated quarterly in alignment and concurrent with the PDUFA IT/Informatics Plan and will be posted on CDER’s Data Standards Program website. The Data Standards Strategy-Action Plan can be found at:


To avoid redundancy and inconsistency, FDA will maintain a table of TA development projects with primary collaborators when possible. This table will be regularly updated with status and primary lead organizations of the projects. The Data Standards Strategy-Action Plan will reference this table.
7 Guidance to Industry

The FDA intends to publish a draft guidance specifying the requirements for an electronic submission of standardized study data entitled “Providing Regulatory Submissions in Electronic Format-Standarized Study Data” (eStudy Data guidance). In accordance with section 745A(a) of the FD&C Act, following the issuance of the final eStudy Data guidance, study data contained in NDAs, ANDAs, BLAs, and INDs must be submitted electronically in a standardized format that FDA can process, review, and archive.

The eStudy Data guidance will incorporate by reference two other components: the Data Standards Catalog and the Study Data Technical Conformance Guide. The two components are described in sections 7.1 and 7.2.

7.1 Data Standards Catalog

The current Study Data Standards Catalog will be revised and renamed the Data Standards Catalog. For each data standard type (e.g., data exchange, terminology), it will provide a listing of supported standards, their uses, acceptance date, final guidance issue date (if applicable), date requirement begins (for submissions) and date support ends, as well as other pertinent information. Prospectively, following the public release of a new standard by an SDO (e.g., CDISC SDTM 3.1.x) and after FDA testing and implementation, FDA will issue an FR Notice of Availability on the new standard(s) and request comment on the new standard(s). At that time, the Data Standards Catalog will be updated indicating FDA’s support for the new standard(s). These updates may be made periodically; however, the effective date for all updated standards will correspond to a single date every year.

In addition to the requirement date information specified in the catalog, FDA will issue an annual FR Notice to raise awareness of the upcoming effective date. The notice will reference the information in the catalog.

7.2 Study Data Technical Conformance Guide

The Study Data Technical Conformance Guide will provide descriptions and recommendations on how to submit standardized study data in electronic submissions. It will be developed using existing technical guidance documents and other relevant documentation efforts. This technical conformance guide will augment, for purposes of clarity, study data standards Implementation Guides, as necessary, and address those regulatory requirements that may differ from the published standard (for instance, a regulatory requirement to use a different standard terminology for a specific data element).

Periodically, through an FR Notice of Availability, FDA will update, as needed, the Study Data Technical Conformance Guide and post new or revised technical guidance. This process will include draft guidance followed by final guidance after consideration of the comments received.

8 Governance

To meet this initiative’s objectives and those of other data standardization efforts ongoing in the Centers, a comprehensive FDA TAS operating structure (see Figure 7) has been established to provide
the leadership and management required. CDER’s Data Standards Program Board (DSPB)\(^5\) is comprised of representatives from each of CDER’s super offices, CBER, and the Center for Devices and Radiological Health (CDRH). The DSPB provides the leadership and oversight to guide FDA’s overall data standards strategy, and to ensure that its objectives are accomplished. The DSPB’s operating arm ensures appropriate outreach and engagement on data standards development activities with other stakeholders and advisory government agencies, including, but not limited to, the Office of the National Coordinator (ONC) and the National Institutes of Health (NIH).

The framework ensures that the FDA approaches critical initiative and program components consistently across all projects. The DSPB has oversight for these data standards operations.

**Figure 6. FDA TAS Initiative Operating Structure**

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9 Communications Management

The DSPB has established a Communications Plan\(^6\) that provides a framework to support the successful execution of the data standards program. The framework addresses information needs of internal and external stakeholders, and outlines the requirements of communication efforts to reach and inform each group, as well as to receive feedback. The plan is a key tool for promoting support, cooperation, participation, coordination, and transparency among all stakeholders involved in data standards. The stakeholders for this initiative are captured in the Communications Plan and this initiative will use that plan to inform its communication requirements.

10 Risk Management

Risk Management is an important component to the overall management of this initiative and its projects. The goal of risk management is to increase the likelihood of a project’s success by eliminating or mitigating those events that might adversely affect the project. For this project plan, risk is a measure of the ability to achieve the overall project objectives within the defined project requirements and constraints. This ability may be dependent on a number of factors, including funding, schedule, technical issues, and external events. Appendix A provides a list of risk categories, potential risks, impacts, and mitigation strategies. Each project under the initiative incurs these risks, and will employ mitigation strategies relevant to the specific project and circumstances.

To help ensure its success, the initiative to achieve therapeutic area standardization will proceed under the following assumptions:

- Stakeholders (e.g., CDISC, industry, government agencies) will commit adequate resources to define, model, and produce the required standards updates for each prioritized therapeutic area.
- The development of data standards for any TA is an incremental process and the specification may be a sub-set of data elements that support regulatory review requirements.
- Standardization projects for TAs will be scoped narrowly enough to be accomplished (e.g., scoping, modeling to SDTM Implementation Guide) within an estimated 8-12 month period.
- TAS projects will be coordinated to ensure awareness and consistent use of data elements across TAs to the widest extent possible.
- Stakeholders and existing or concurrent work will be clearly identified and included in TA standardization efforts. Stakeholders may include healthcare, research, quality improvement, performance measurement, and public health reporting. For example, clinical/medical professional societies could provide helpful input on clinical terminology data definitions.
- TA development projects will take into account availability and engagement of stakeholder organizations.

• Standards and related implementation guides will be reviewed and acceptance testing performed to verify that they meet scientific and regulatory requirements.

If any of these assumptions prove to be incorrect, or if any of the risks outlined in Appendix A are realized, FDA will implement a course adjustment that will facilitate continued progress towards meeting the initiative goals.
## Appendix A: Risks and Mitigations

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<thead>
<tr>
<th>Risk Category</th>
<th>Risk Description</th>
<th>Impact</th>
<th>Mitigation Strategy</th>
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</thead>
<tbody>
<tr>
<td>1 Scope</td>
<td>FDA’s requirements for a TAS have not been clearly articulated and vetted internally and/or externally.</td>
<td>The project start will be later than planned or the initiation stage of the project will be longer to accommodate requirements review and agreement across stakeholders.</td>
<td>The Table of Priority Therapeutic Area Standards document lists TAs where FDA has started requirements definition efforts. FDA requirements efforts include a vetting approach.</td>
</tr>
<tr>
<td>2 Resources</td>
<td>TAS projects may not have sufficient funding or staff to complete all planned deliverables.</td>
<td>FDA requirements may not be met, project timeline may be affected, and project objectives not fully accomplished</td>
<td>The lead group must assess resources to complete the project and then determine the best approach to address gaps (e.g., identify additional resources, or perhaps adjust scope).</td>
</tr>
<tr>
<td>3 Resources</td>
<td>External clinical/medical professional societies are not adequately engaged during the development and review of data elements for a therapeutic area.</td>
<td>The quality of the deliverables may be adversely impacted if key clinical/medical groups are not involved.</td>
<td>Projects should identify desired external stakeholders participants and include their engagement throughout development where appropriate. In addition, the standards will be released for public comment to ensure all groups have ample opportunity to provide comment.</td>
</tr>
<tr>
<td>4 Resources</td>
<td>FDA resources assigned to participate in the TAS development process are constrained, due to competing priorities. This would include:</td>
<td>PDUFA V goal to develop clinical terminology for therapeutic areas will be delayed.</td>
<td>FDA will work to use project plans to mitigate conflicts. Leadership support is gained in advance of commitment to projects. If conflicts arise, alternates could be identified or objectives adjusted.</td>
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<tr>
<th>Risk Category</th>
<th>Risk Description</th>
<th>Impact</th>
<th>Mitigation Strategy</th>
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</thead>
<tbody>
<tr>
<td>Resources</td>
<td>Personnel with the requisite skills to complete all project deliverables on time and with the highest quality may not be available.</td>
<td>This may adversely affect the schedule and quality of the deliverables</td>
<td>FDA and stakeholders need to acquire personnel with the required skills and prioritize projects to avoid competing for the same resources. Along with the determination of level of effort for the project, an assessment of skill availability for each resource is required before a commitment for a specific technical solution is made.</td>
</tr>
<tr>
<td>Resources</td>
<td>The implementation of the TA standards could be compromised due to their timing, number, and differences between them.</td>
<td>The objectives of the initiative will not be met.</td>
<td>FDA will use project plans to manage the schedule and scope. Using a well-defined implementation approach that includes requirements modeling using a core FDA study data model, and a standard development process, as TA standards are developed will lead to a successful implementation.</td>
</tr>
<tr>
<td>Process</td>
<td>Accountability for the TAS development process may not be clear across all stakeholders.</td>
<td>This may affect project plans or quality of deliverables.</td>
<td>The implementation approach section highlights stakeholder participation throughout the development process.</td>
</tr>
<tr>
<td>Process</td>
<td>A clear, consistent and transparent process for the development of clinical data elements has not been adequately presented</td>
<td>This may impact the quality of the deliverables and their broader acceptance across stakeholder groups.</td>
<td>Using a FR Notice process, this TAS initiative plan is being published for public comment. In addition, FDA will recommend external stakeholders inform their</td>
</tr>
<tr>
<td>Risk Category</td>
<td>Risk Description</td>
<td>Impact</td>
<td>Mitigation Strategy</td>
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<tr>
<td></td>
<td>for public comment.</td>
<td></td>
<td>stakeholder groups of this comment period.</td>
</tr>
<tr>
<td>9 Stakeholder Management</td>
<td>External stakeholder partnerships may not be able to sustain the development of TA projects due to financial constraints and/or insufficient staffing</td>
<td>Significant delays may occur in starting and completing TA projects, resulting in fewer TA standards and thus reduced benefit to stakeholders</td>
<td>FDA must have an alternative approach to TA data element definition as a contingency. See Implementation Section 4.0.</td>
</tr>
<tr>
<td>10 Stakeholder Management</td>
<td>FDA does not achieve harmonization with other government agencies engaged in therapeutic area development to meet project timeframes.</td>
<td>Schedules may be constrained by external organizations priorities. This may affect quality of the deliverables, efficiency, and cost if other agencies have data elements that can be leveraged.</td>
<td>FDA will agree at various stages that other key government agencies have provided input, as required.</td>
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### Appendix B: Acronym List

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>CBER</td>
<td>Center for Biologics Evaluation and Research</td>
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<td>CDER</td>
<td>Center for Drug Evaluation and Research</td>
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<tr>
<td>CDISC</td>
<td>Clinical Data Interchange Standards Consortium</td>
</tr>
<tr>
<td>CDRH</td>
<td>Center for Devices and Radiological Health</td>
</tr>
<tr>
<td>CFAST</td>
<td>Coalition for Accelerating Standards and Therapies</td>
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<td>C-Path</td>
<td>Critical Path Institute</td>
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<tr>
<td>CRFs</td>
<td>Case Report Forms</td>
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<td>Data Standards Program Board</td>
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<td>eCTD</td>
<td>Electronic Common Technical Document</td>
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<tr>
<td>FDASIA</td>
<td>FDA Safety and Innovation Act</td>
</tr>
<tr>
<td>FD&amp;C Act</td>
<td>Food, Drug, and Cosmetic Act</td>
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<td>FRN</td>
<td>Federal Register Notice</td>
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<td>IND</td>
<td>Investigational New Drug Application</td>
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<td>OCS</td>
<td>Office of Computational Sciences</td>
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<td>PDUFA</td>
<td>Prescription Drug User Fee Act</td>
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<td>SDO</td>
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<td>SDTM</td>
<td>Standard Data Tabulation Model</td>
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