



Department of Health and Human Services



Food & Drug Administration (FDA)

Center for Tobacco Products (CTP)

Request for Information

Comprehensive Data Management & Streamlining Solution for Business-Critical Data

(Data Stream)

Tobacco Product-Centric Data Modeling and AI Capabilities

1 Introduction

1.1 Background

To protect the public health of the U.S. population and create a healthier future, the Family Smoking Prevention and Tobacco Control Act ([Tobacco Control Act](#)), signed into law on June 22, 2009, gives FDA authority to regulate the manufacture, distribution, and marketing of tobacco products. The FDA Center for Tobacco Products (CTP) is responsible for regulating tobacco products and reviewing product marketing applications submitted by industry. A single marketing application submission to CTP may include information on one or many tobacco products. Review of a single tobacco product may require finding and assessing information from one or many submissions including original and amendment submissions.

Review of marketing applications requires understanding the health risks of each individual tobacco product. The health risks of tobacco products are not solely dependent on the measurable toxicity of tobacco products, but also on the way the products are used and on factors that promote or limit use. CTP's current data environment is primarily organized around individual submissions rather than products. Multiple submissions related to the same product, including resubmissions and incremental changes in amendments, are not consistently or easily linked, and tobacco products do not always have stable identifiers across systems or submissions. This limits the ability to view products longitudinally, understand product evolution over time, and efficiently support reviewer and analyst workflows.

CTP is seeking a product-centric approach that can improve reviewer navigation and reduce manual effort required to locate, interpret, and compare information across submission events.

1.2 Objective

The objective of this contract is to deliver evidence-based findings and one or more prototype capabilities that enable product-centric navigation and selective structuring of submission content to support reviewer workflows. Success will be demonstrated through:

1. A verified understanding of CTP's submission-related data sources and constraints
2. A CTP-specific product definition and lifecycle framework grounded in empirical evidence
3. Feasibility analysis for associating product representations across submissions when identifiers are missing or unstable
4. AI-enabled metadata tagging, prototypes, documentation, and integration-readiness artifacts suitable for FDA evaluation and for existing and new system incorporations.

1.3 Purpose

This Performance Work Statement (PWS) defines the requirements for contractor support to the Food and Drug Administration (FDA), Center for Tobacco Products (CTP) in developing a product-centric data approach that improves visibility, consistency, and efficiency across tobacco product submissions and reviews. A foundational and enabling element of this effort is to inventory, assess, and understand CTP's existing submission-related data assets, including what data exists, where it resides, how it is structured, and how it is currently used, in order to establish a factual baseline for all subsequent analysis.

2 SCOPE

The scope is to identify and determine whether, and under what conditions, AI-assisted approaches could support more end-to-end product-centric submission and product lifecycle. The scope is limited to discovery, data modeling, definition, feasibility analysis, and proof-of-concept activities necessary to inform future planning and investment decisions.

At a minimum, the Contractor shall address the following scope elements:

1. **Data Inventory and Assessment**
An inventory and characterization of relevant structured and unstructured data assets, including submissions, reference data, and derived datasets, sufficient to support product-centric analysis.
2. **Current State Understanding**
An assessment of the feasibility of producing a product-centric view across identified data assets, including identification of gaps, limitations, and constraints.
3. **Product Lifecycle Definition**
Documentation of current data structures, relationships, and constraints that affect the ability to represent products longitudinally across submissions and systems.
4. **Product-centric Data Model**
A conceptual and logical representation of a product-centric data model, including key entities, attributes, and relationships relevant to regulatory review and analysis.
5. **Metadata Tagging Structure**
Establishing a metadata tagging structure for unstructured submissions and identifying candidate use cases for AI-assisted processing, such as classification of document types or sections and identification of product changes across submissions.
6. **AI-enabled Prototypes**
Demonstration artifacts and supporting evidence sufficient to illustrate feasibility, maturity considerations, and decision tradeoffs associated with proposed approaches.
7. **Findings and Roadmap Development**
Documented findings and options, including recommendations, assumptions, and considerations necessary to support FDA decision-making regarding next steps.

3 Tasks and Requirements

3.1 Task 1: Data Inventory and Baseline Assessment, Current State Characterization (Submission-Centric Environment)

3.1.1 Requirements

The Contractor shall conduct a comprehensive assessment of CTP's current submission data landscape, including the following:

1. The Contractor shall identify and document FDA-identified submission-related data sources.

2. The Contractor shall characterize each source at a level sufficient to support downstream feasibility assessments, including:
 - Content types (structured; semi-structured; unstructured)
 - Availability of metadata that supports traceability
 - Observed constraints that affect product-centric analysis (e.g., variability in submission packaging or organization).
3. The Contractor shall identify and document the presence of structured data capture artifacts and form-derived information that materially support product-centric analysis (e.g., registration/listing forms; ingredient listing forms; PMTA, SE forms) and shall characterize how master file references (e.g., TPMFs) are represented in available sources.
4. The Contractor shall document observable relationships and touchpoints between sources to the extent supported by evidence (e.g., how submission artifacts or product representations appear across sources).
5. The Contractor shall identify material gaps or constraints that may limit feasibility demonstrations and communicate them to the COR.
6. The Contractor shall describe current-state organization and limitations of submission-related data as observed from available sources and FDA input.
7. The Contractor shall identify key factors that drive manual effort to locate, interpret, and compare submission information across time.
8. The Contractor shall describe observed barriers to longitudinal, product-centric visibility (e.g., inconsistent structures; unstable identifiers; dispersed artifacts), based on evidence available.

3.1.2 Deliverables

1. Data Inventory and Baseline Assessment Summary
2. Limitations Analysis Report
 - Gaps in product-level visibility
 - Manual effort required for cross-submission analysis
 - Constraints on longitudinal product tracking
 - Potential data quality and consistency issues
3. Current State Characterization

3.2 Task 2: Product Definition, Product Lifecycle Framework and Cross-Submission Linking

3.2.1 Requirements

Building on the findings from Task 1, the Contractor shall analyze existing data structures and develop recommendations to enable clearer linkage of multiple submissions to a single product over time; use CTP-specific product definitions and to define the relationship between tobacco

products and submissions; identify data elements necessary for product linking across submissions; and identify business rules necessary for product linking across submissions.

1. The Contractor shall define a CTP-specific “product” concept for purposes of product-centric analysis and reviewer navigation, using evidence from available sources and FDA input.
2. The Contractor shall identify and document candidate attributes used to describe or distinguish a product as represented across available sources.
3. The Contractor shall identify submission-context attributes (e.g., submitting entity; establishment context; or other available organizational context) that may be relevant to interpreting or distinguishing product representations across submissions.
4. The Contractor shall document which attributes appear consistently available and which are unreliable or inconsistent, based on observed evidence.
5. The Contractor shall create a product lifecycle framework that document:
 - Methodology for identifying unique products across multiple submissions
 - Approach for linking related submissions to common products
 - Strategy for tracking product changes over time
6. The Contractor shall provide conceptual and logical data models using identified tooling that includes but not limited to:
 - Product entities and attributes
 - Relationships between products, submissions, party, reviews, and other key entities or domains
 - Cardinality and business rules
 - Alignment with regulatory review needs
7. The Contractor shall Conduct workshops with CTP business stakeholders to review and validate the framework

3.2.2 Deliverables

1. Product Definition and Attribute Framework
2. Product Lifecycle Framework Document
3. Conceptual Data Model
4. Logical Data Model
5. Workshop summary reports

3.3 Task 3: Prototypes to Assist Reviewer Workflow

3.3.1 Requirements

1. Leveraging the product-centric framework and data models established in Task 1 and Task 2, the Contractor shall create one or more prototype capability(ies) that assist reviewer workflow by enabling product-centric navigation and/or structuring of selected information from submission content.

2. The Contractor shall ensure prototype outputs can be traced back to the original source documents so the Government can evaluate them.
3. The Contractor shall create a metadata tagging structure for unstructured submissions that works with AI-assisted processing and identify and document potential use cases.
4. The Contractor shall ensure prototype outputs and specifications are ready to use without requiring changes to Government workflow platforms under this contract.
5. The Contractor shall evaluate the prototype tools and document:
 - What each prototype does
 - Key limitations and conditions that significantly affect how well it works
 - Factors observed in the sample data that affect results

3.3.2 Deliverables

1. Metadata Tagging Structure
2. Prototype Capability Package(s), including:
 - Prototype outputs
 - Traceability examples
 - Interface and/or output specification (as applicable)
 - Demonstration materials suitable for Government evaluation
3. Prototype Evaluation Results Summary

3.4 Task 4: Proof of Concept (PoC) Demonstration and Integration Readiness Artifacts (Optional)

3.4.1 Requirements

1. The Contractor shall demonstrate prototype capability(ies) using a Government-approved sample and provide artifacts sufficient for Government evaluation and downstream incorporation planning.
2. The Contractor shall provide integration readiness artifacts to support downstream incorporation by a Government-identified workflow implementation team, subject to Government environment constraints, including:
 - a) Interface and/or output specifications;
 - b) Input/output definitions;
 - c) Dependency notes;
 - d) Reproducibility notes sufficient for a Government team to recreate the demonstration behavior within the Government-approved environment.
3. The Contractor shall document what the Proof of Concept (PoC) does and does not demonstrate, including constraints and prerequisites observed.

3.4.2 Deliverables

1. Proof of Concept Demonstration Artifacts.
2. Integration Readiness Package.

3.5 Task 5: Findings for Future Planning

3.5.1 Requirements

1. The Contractor shall provide findings and options to help CTP plan future decisions about product-focused data approaches and how to expand them.
2. The Contractor shall identify key dependencies, risks, and limitations found during this work that could impact future phases and implementation.
3. The Contractor shall present findings and options in a way that clearly separates:
 - What was observed
 - What the analysis shows
 - What to consider for the future

3.5.2 Deliverables

1. Findings and Options Report
2. Executive Brief (briefing format), if requested by the COR

3.6 Task 5: Transition-In and Closeout

3.6.1 Requirements

1. Transition-In shall begin upon contract award. The contractor shall go through an onboarding process which includes background investigations to obtain FDA badges, FDA laptops, access to FDA's systems and network, and applicable government furnished information (GFI).
2. The Contractor shall provide a list of required software necessary to support this PWS to the COR.
3. The Contractor shall support closeout and knowledge transfer activities, including confirming delivery of final versions of all required documentation and integration readiness artifacts produced under this PWS.
4. Implementation Team Coordination: The Contractor shall coordinate transition and closeout activities with any Government-identified workflow implementation team to support continuity and downstream incorporation planning, subject to Government decisions and approvals.

As part of the closeout activities, the Contractor shall confirm (in writing) that:

1. FDA has received draft/in-progress and final versions of all task order documentation with an index table describing where each document is located (e.g., CONOPS, SOPs, requirements specifications, design specifications, configuration management plan, etc.), to include the native format of diagrams (e.g., Visio), even those embedded in documents, have been uploaded into the FDA's SharePoint project repository.
2. FDA has received all GFE and GFI, e.g., badges and laptops at the end of the transition period.
3. FDA has received all source code and database scripts and transferred knowledge to the Successor Contractor on how to compile from source.
4. The Contractor shall perform Data Uploads and Downloads as requested by FDA's COR/PM

3.7 Project Management

The Contractor shall provide program/project management support for the program to include:

3.7.1 Project Plan

The Contractor shall provide a project plan that includes contract oversight objectives, performance requirements of the PWS, methods for conducting quality assessments and evaluations of deliverables, major roles and responsibilities, program and project milestones and roadmaps, and contract risk and risk mitigation strategies.

3.7.2 Kickoff Meeting

The Contractor shall conduct a kickoff meeting within 10 business days of task order award to build clarity and consensus on contract execution activities. This meeting shall include a high-level plan and approach, contract milestones and deliverables, roles and responsibilities, staffing details, and an organizational chart to introduce the contractor team to the CTP COR and key stakeholders. The Contractor shall provide a COR-approved presentation with these items. The Contractor shall also provide the meeting minutes to the COR within three business days after the kickoff meeting and upload the minutes and presentation to the FDA's designated repository. Coordination with the CTP COR to determine the date, time, location, and attendees for the kickoff meeting is required.

3.7.3 Monthly Status Report

The Contractor shall provide monthly status reports to the COR/Project Managers (PMs). The Monthly Task Order Status Report shall include:

- Progress description for the task period, including the quantity and details of meetings attended and work accomplished
- Deliverable completion status by requirements
- Analysis of existing and potential issues, problems, and risks, including mitigation strategies and recommended resolutions by task area
- Projected work activities to be accomplished during the next period by task area
- An updated org chart that lists the task order team members, their roles, and management, noting key personnel with 'K' and subcontractors' personnel with an asterisk (*). Changes to the organizational structure shall be noted in the applicable Monthly Status Report (MSR).

3.7.4 Agile Roadmap

The Contractor shall provide an Agile Roadmap to the COR, reflecting the iterative implementation of the project, which includes the following information:

- High-level overview of the product(s)
- Articulation of the long-term strategy
- Estimated timelines for features/epics and milestones

The Contractor shall maintain and update the Agile Roadmap throughout the project's lifecycle. The roadmap shall be updated as part of increment planning.

3.7.5 Staffing Plan

The Contractor shall provide a staffing plan to ensure the allocation of personnel to complete the tasks outlined in the PWS. The Contractor shall submit a roster including names, positions, contact

information, and responsibilities of all staff (including subcontractors) working under this contract. Any revisions to the roster due to staffing changes shall be submitted to the COR per the direction of the COR or CO within the specified timeline. The staffing plan shall be adaptable and responsive to meet evolving demands within this order by ensuring that staff possess diverse skill sets enabling them to effectively work on all aspects of contract scope. The FDA will not provide funding for contractor training under this order. The Contractor is expected to already possess the skills and credentials necessary to effectively perform the work.

3.7.6 Quality Assurance Surveillance Plan (QASP)

The Quality Assurance Surveillance Plan (QASP) outlines the methods that the FDA will use to monitor and evaluate the performance of the contractor to ensure compliance with contract requirements and quality standards.

The contractor shall work with the COR to establish the QASP using the following template (Table 3):

Performance Standard	Acceptable Quality Level (AQL)	Method	Frequency

Table 1: QASP Template

The QASP template contains the following columns:

- **Performance Standard:** Description of the performance standard or goal
- **Acceptable Quality Level (AQL):** The acceptable threshold of performance, typically expressed as a percentage.
- **Method:** How performance will be measured (e.g., random sampling, 100% inspection)
- **Frequency:** How often the performance will be evaluated (e.g., daily, weekly, monthly, per the approved project schedule)

3.7.7 DRSI Repository Maintenance and Project Management Tools

The Contractor shall upload all documents and deliverables to a centralized SharePoint location provided by the COR or COR designee. The Contractor shall recommend an organized folder hierarchy in SharePoint to facilitate easy document retrieval. This proposed folder hierarchy must be approved by the COR or COR designee. Additionally, all uploaded documents must be tagged and annotated by adding comments for easy identification and searchability. Regular updates and maintenance of the SharePoint repository will be required immediately after any document is changed to ensure all information remains up to date. Furthermore, the Contractor shall provide training to relevant stakeholders on how to navigate the SharePoint site.

The Contractor shall use Jira, Microsoft Project, or other appropriate tools selected for the project to manage tasks, track progress, requirements, and issues. The selection and use of these tools must be approved by the COR. These tools will facilitate detailed task lists, deadline monitoring, responsibility assignments, and progress reporting, ensuring that project milestones are met, and potential risks are identified. CTP also encourages the use of modern collaboration tools including Microsoft Teams and techniques that support remote and cross-functional team interactions to enhance agility.

4 Deliverables

Deliverables are scalable relative to the risk, size and complexity of the project. The Contractor shall work with the FDA to determine the appropriate level of deliverables and milestones to ensure a successful outcome.

All deliverables and other Contract work products shall be solely owned by the FDA and shall not be labeled 'copyright', 'proprietary' or anything similar that might preempt the desired environment of fluid sharing and partnership. The Contractor shall provide to the FDA access to all work products including but not limited to: research, designs, code, constructs, databases, and documentation.

This section contains all the deliverables of this contract. The deliverables shall be provided in the following formats and miletones:

Section #	Activity/Deliverable	Format	Due Date
3.1.2	Data Inventory and Baseline Assessment Summary	Word/PowerPoint	Per the approved project schedule
	Limitations Analysis Report	Word/PowerPoint	Per the approved project schedule
	Current State Characterization	Word/PowerPoint	Per the approved project schedule
3.2.2	Product Definition and Attribute Framework.	Word/PowerPoint	Per the approved project schedule
	Product Lifecycle Framework Document	Word/PowerPoint	Per the approved project schedule
	Workshop summary reports	Word/PowerPoint	Per the approved project schedule
	Conceptual Data Model		Per the approved project schedule
	Logical Data Model		Per the approved project schedule
3.3.2	Metadata Tagging Structure		Per the approved project schedule
	Prototype Capability Package(s)		Per the approved project schedule
	Prototype Evaluation Results Summary	Word/PowerPoint	Per the approved project schedule
3.4.2	Proof of Concept Demonstration Artifacts		Per the approved project schedule
	Integration Readiness Package		Per the approved project schedule
3.5.2	Findings and Options Report	Word/PowerPoint	Per the approved project schedule
	Executive Brief (briefing format), if requested by the COR	Word/PowerPoint	Per the approved project schedule

Section #	Activity/Deliverable	Format	Due Date
3.7.1	Project Plan	Word	15 business days after award
3.7.2	Kickoff Meeting	PowerPoint	Within 10 days of the Award
3.7.3	Monthly Progress Reports	Word	By the 10th of each month for the previous month
3.7.4	Agile Roadmap	PowerPoint	30 business days after award
3.7.5	Staffing Plan	Word	15 business days after award
3.7.6	Quality Assurance Surveillance Plan (QASP)	Word	25 business days after award
3.6.1	Final Project Close-Out Report	Word	Draft: Within 3 weeks of the Order expiration date Final: By the Order expiration date

4.1 Contract Type

Firm Fixed-Price

4.2 Period of Performance

12 months