Information Request Modernization Demonstration Project

Prepared for
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)

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Final Report

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1.0 EXECUTIVE SUMMARY

The Information Request (IR) Modernization Demonstration Project is a joint regulator/industry initiative in fulfillment of the PDUFA VII commitments to advance cloud-based capabilities, incorporating industry feedback into the development process. This report presents the outcomes of that demonstration, providing evidence that cloud-based technologies can meaningfully transform critical regulatory workflows. The project focused on transforming a paper- and email-based IR process through the introduction of structured data, centralized communication, and improved transparency, directly addressing challenges that impact FDA's public health mission.

At its core, the demonstration delivered a proof-of-concept (POC) built on three design paradigms: unique identifiers for granular tracking, structured data transmission that integrates with existing FDA cloud-based systems, and standardized responses enabling automated linking. These capabilities address fragmented communication, manual tracking, and inconsistent processes across review divisions.

A defining feature of this project was direct collaboration with industry stakeholders throughout design, development, and testing. Rather than developing the solution in isolation, FDA engaged industry participants in hands-on sessions to execute real-world workflows and provide actionable feedback. This ensured that the solution reflects both regulatory requirements and sponsor operational realities.

The outcome of this POC shows measurable improvements in operational efficiency. IR delivery times decreased from up to 3 business days to near real-time, automated response linking eliminated manual matching bottlenecks, and centralized communication hubs replaced fragmented email threads and document searches.

This approach aligns with PDUFA VII commitments by advancing cloud-based capabilities while incorporating industry feedback into the development process. The result is a validated, scalable, and user-centered model for modernizing regulatory interactions.

2.0 BACKGROUND AND CONTEXT

2.1 Current State Challenges

The current IR process has evolved in a decentralized manner, resulting in variability across offices in workflows, tools, and communication methods. This fragmentation introduces inefficiencies for both FDA reviewers and industry sponsors. For the purposes of this analysis, the FDA examined the IR process in three main sections: FDA sending the IR to the Sponsor, the sponsor reviewing the IR and responding to it, and the FDA receiving the response and reviewing its content.

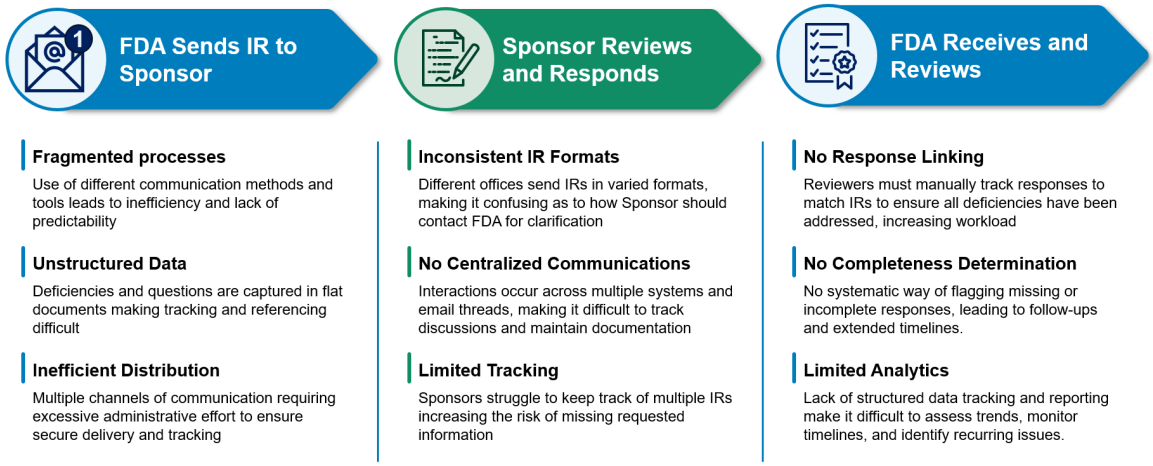

Figure 1. Current State Pain Points Discovered During Analysis

Our current state analysis revealed systemic inefficiencies:

- **Fragmented processes and lack of structured tracking:** Inconsistent communication methods and tools across offices create inefficiencies and unpredictable sponsor experiences, while siloing knowledge that could otherwise inform agency-wide improvements.
- **Manual effort and inability to link communications:** RPMs cannot automatically identify which IR items are being addressed in responses, requiring manual review and cross-referencing that delays the review process and creates opportunities for incomplete records.
- **Limited transparency and decentralized communication channels:** IRs are communicated to Industry through email as the predominant channel, with fax or mail used on rare occasions. This lack of a standardized submission pathway creates inconsistent sponsor experiences and challenges in maintaining organized records. Industry lacks structured visibility (e.g., dashboard) into the status of FDA's review of IR responses – including whether a response has been received, is

under review, or requires additional information – while communication delays impact timelines.

The IR process was selected as an ideal demonstration project because these widespread challenges presented a compelling opportunity to showcase how cloud technology could transform critical regulatory activities.

2.2 Project Objectives

The project was designed to establish a structured and scalable approach to IR management. Through comprehensive analysis, IR challenges were concluded to be a data problem. Without proper data structure and unique identification, communications could not be effectively tracked, linked, or managed.

To address these challenges, the project established the following measurable objectives:

- **Enable item-level traceability**: Assign unique identifiers to each IR letter and individual IR item, ensuring that 100% of sponsor responses can be systematically linked back to their originating requests, eliminating manual cross-referencing.
- **Consolidate communication into a centralized platform:** Replace fragmented multi-channel communication – including email, fax, and mail – with a single secure portal equipped with streamlined account registration, reducing communication-related delays with secure email certificates and creating a complete, auditable record of all IR interactions.
- **Improve visibility into IR status for both FDA and industry**: Provide real-time tracking and status updates accessible to both FDA reviewers and industry sponsors, reducing response ambiguity and enabling proactive management of outstanding items.

These objectives support a broader vision of a modernized IR process that enhances efficiency, reduces ambiguity, and improves collaboration.

2.3 Alignment with PDUFA VII Commitments

The demonstration aligns with PDUFA VII commitments to advance cloud-based technologies[1] while establishing a foundation for broader FDA modernization:

[1] The demonstration projects are outlined in Section IV.A-6 of the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027

- **Cloud-Hosted Services:** Demonstrates cloud-based technologies through secure shared environments using OneNexus and CDER NextGen Portal platforms.
- **Near Real-Time Collaboration:** Enables applicant-regulator interactions through immediate notifications, direct communication workflows, and automated response tracking, transforming one-way correspondence into dynamic exchanges.
- **Modular Architecture:** Creates flexible technical capabilities that can be leveraged for multiple regulatory purposes beyond IR, prompting convergence through common cloud-hosted components.

The use of structured data, portal-based interaction, and industry engagement reflects the agency's emphasis on modern, collaborative regulatory capabilities.

2.4 Industry Co-Development and Engagement Model

A central component of this demonstration was the active involvement of industry stakeholders throughout the project lifecycle. The effort was structured as a co-development initiative rather than a traditional demonstration. FDA conducted three initial sessions with industry participants to confirm and prioritize current pain points, jointly develop requirements, and demonstrate the POC.

Session I	Session II	Session III
Date: March 4th, 2025	**Date: March 11th, 2025**	**Date: May 6th, 2025**
Time: 11AM – 1PM EST	**Time:** 11AM – 1PM EST	**Time:** 11AM – 1PM EST
Location: Virtual	**Location:** Virtual	**Location:** Virtual
Purpose of Session:	**Purpose of Session:**	**Purpose of Session:**
❑ Kickoff and Introduction	❑ Identify Pain Points	❑ Demo Proof of Concept
❑ Review Current IR challenges	❑ Prioritize Pain Points	❑ Collect Feedback
❑ Review Pre-Meeting Questions	❑ Draft Requirements	❑ Discuss Next Steps

Figure 2. Industry Engagement Sessions and Agendas

Feedback loops were iterative, with insights from each session informing refinements to functionality and workflow design. This human-centered approach ensured that the solution is both technically robust and operationally effective, increasing the likelihood of successful adoption.

Industry participants also engaged in a hands-on demonstration that simulated real-world regulatory workflows, including submission, IR receipt, clarification exchanges, and response submission. This allowed FDA to observe user behavior, identify friction points, and gather feedback grounded in actual system interaction.

3.0 SOLUTION OVERVIEW

The modernized IR solution introduces structured IR item creation, centralized communication through a secure portal, near real-time collaboration capabilities, and enhanced transparency into IR status and tracking.

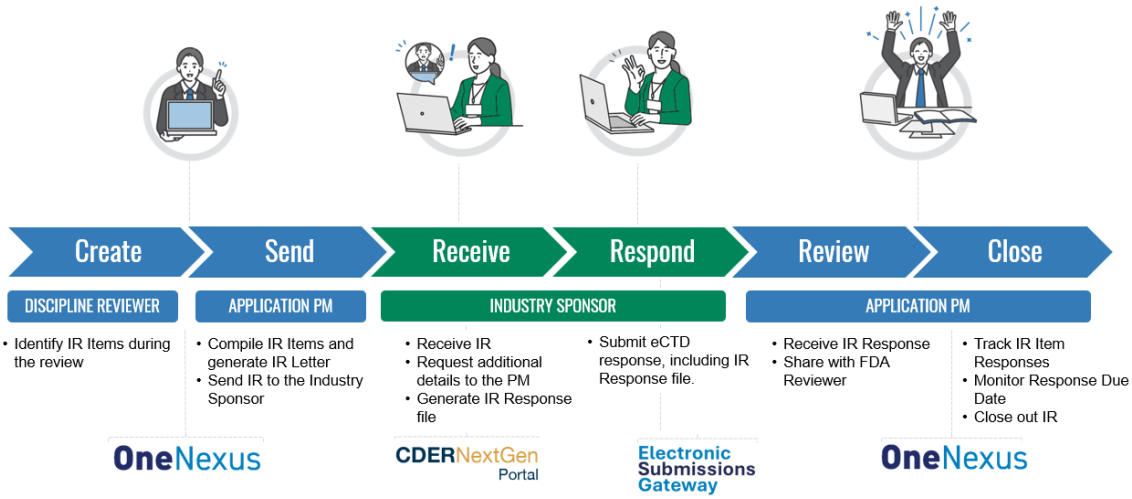

Figure 3. High Level Modernized IR Process

3.1 Approach

The modernization approach was grounded in a comprehensive information inventory that captured required processes, users, roles, data, systems, policies, and procedures across FDA. This foundational work was combined with staff interviews and structured industry engagement sessions to develop a wholistic understanding of existing IR workflows and establish a shared knowledge base.

This analysis served four strategic purposes: to create a foundational understanding of how IRs are managed across FDA; to build organizational awareness of the need for change; to establish consensus around a harmonized, future-state IR implementation; and to identify best practices currently utilized across the IR lifecycle.

3.2 Proof-of-Concept Design

Rather than introducing entirely new systems, the initiative leveraged existing FDA technology investments to rapidly prototype and validate a modern solution. The design is intentionally scalable so it can be utilized across CDER and CBER and is intended to serve as a foundation for broader FDA-wide adoption, supporting ongoing harmonization and consolidation efforts across the agency.

Key Enablers

- **ESG NextGen:** Submission gateway for structured data exchange
- **Harmonized Data Model (HDM):** Standardized data architecture

- **OneNexus:** Workflow and data integration
- **CDER NextGen Portal:** Industry-facing communication platform

Design Paradigm
The solution was built on three core design paradigms that address fundamental data and communication challenges:

- **Unique Identifiers:** Each IR letter and individual IR item receives a distinct identifier linked to the originating application and submission. This hierarchical system enables granular tracking and systematic linking of IR responses to originating requests.
- **Structured Data Transmission:** The enhanced data model integrates with existing FDA application and submission data structures, enabling automatic association of IRs with specific applications, submission types, review disciplines, and regulatory milestones.
- **Standardized Responses:** Industry sponsors generate structured IR Response XML files that clearly indicate which specific IR items are being addressed, enabling automated linking and eliminating manual matching processes.

These design paradigms create a flexible, scalable framework that leverages existing FDA technology investments and enables efficient implementation with minimal disruption.

4.0 INDUSTRY ENGAGEMENT AND DEMONSTRATION

The demonstration project consisted of hands-on sessions with industry participants. Each session simulated end-to-end regulatory workflows, including submission of test applications, issuance of IRs, near real-time communication, and structured response submission.

Participants successfully completed all workflow steps, validating both technical functionality and usability. IRs were delivered in near real time, clarification exchanges occurred within the portal, and structured responses were submitted and linked back to IR items.

5.0 OUTCOMES AND KEY FINDINGS

5.1 Validation Results and Industry Feedback

The demonstration project validated that structured IR workflows significantly improve clarity and reduce ambiguity. In a follow-up survey, participants unanimously characterized the solution as extremely useful or very useful, with the vast majority confirming the demonstration aligned with their expectations. All

participants rated their engagement as highly engaged and their overall collaboration experience as positive or very positive.

Requirements gathering was universally recognized as effective or very effective, with all participants confirming the FDA team successfully captured their organization's pain points. Core system features received strong validation, with participants unanimously selecting centralized communications and visual status confirmation as most beneficial, while the majority identified structured IR items and two-way communications as valuable. Most participants indicated readiness for adoption immediately or with minor preparation, suggesting favorable conditions for implementation.

5.2 Demonstrated Benefits and Efficiency Gains

The modernized system delivers measurable operational improvements:

- **Reduced IR Delivery Times:** IR delivery decreased from up to 3 business days to near real-time interactions, enabling sponsors to begin preparing responses immediately and maintain review momentum.
- **Eliminated Manual Matching:** Automated response linking eliminates bottlenecks for RPMs, freeing their time for higher-value activities and reducing the risk of mismatched or overlooked responses.
- **Streamlined Reviewer Workflow:** Centralized communication hubs replace fragmented approaches requiring cross-referencing of email threads and documents with automated logging and organization, significantly improving workflow speed and efficiency.
- **Enhanced Collaboration:** The secure shared environment provides single, accessible records of all communications, enabling efficient coordination across review disciplines. Participants highlighted the value of real-time exchanges in reducing delays and improving communication quality.

Additionally, the solution was shaped through direct collaboration with industry participants, ensuring alignment with real-world workflows and increased confidence in scalability and adoption. The successful integration of structured response files into existing submission processes demonstrates the potential for automation, analytics, and enhanced reporting capabilities. This co-creation model provides a blueprint for future initiatives, demonstrating how technology and stakeholder engagement can deliver impactful, user-centered solutions.

6.0 NEXT STEPS

FDA is using the outcomes of this demonstration project to inform its IT modernization efforts currently underway. Future efforts will focus on refining functionality based on industry feedback, expanding support to additional submission types, and integrating with existing FDA systems.

Continued collaboration with industry stakeholders will remain a priority to ensure the solution evolves in alignment with user needs and regulatory requirements.

7.0 CONCLUSION

The IR Modernization Demonstration Project represents a meaningful step forward in transforming regulatory communication between FDA and industry. By combining structured data, centralized communication, and a collaborative development approach, the project establishes a strong foundation for scalable modernization across FDA's regulatory review process.

The path from legacy IR processes to the modernized system represents more than a technological upgrade; it represents a fundamental shift in how FDA and industry collaborate during drug review. By replacing fragmented, manual workflows with centralized, automated capabilities, the modernized system has demonstrated the potential to accelerate the review process and reduces delays that can hinder the approval of life-saving treatments.

The strong validation results from both FDA staff and industry sponsors demonstrate readiness for adoption. The three core design paradigms- unique identifiers, structured data transmission, and standardized responses - ensure the solution can be implemented using existing tools, while establishing a foundation for broader modernization initiatives across the regulatory review process.

The co-creation model used in this effort offers a replicable blueprint for future initiatives, demonstrating how technology and meaningful stakeholder engagement can work together to deliver impactful, user-centered solutions. As FDA continues its IT modernization efforts, the efficiency gains, enhanced collaboration, and data-driven insights enabled by this system will strengthen the agency's ability to fulfill its public health mission and bring safe and effective drugs to patients who need them.