REI SYSTEMS

CASE STUDY

Advancing FDA Inspection Operations Through End-to-End Digital Modernization

4131-001

Background

The U.S. Food and Drug Administration (FDA) protects public health by overseeing food, drugs, and medical products. Within the agency, the Office of Inspections and Investigations (OII) leads inspection, investigation, and compliance activities that support regulatory decision-making nationwide.

As mission demands and regulatory complexity have grown, the FDA has modernized inspection operations through digital technologies, evolving from paper-based processes to integrated platforms that improve consistency, communication, and efficiency. The introduction of eNSpect enabled structured data capture and centralized information management, and ongoing collaboration between the FDA and REI has further enhanced performance, mobility, and system integration in support of the agency's mission.

Challenge

The FDA's legacy inspection and assignment processes effectively supported regulatory operations for decades. As inspection volume, data complexity, and coordination needs grew, opportunities emerged to improve efficiency, usability, and access to information across workflows. Inspection records—including notes, photographs, videos, and supporting documentation—were managed across multiple systems, requiring additional effort to organize and reference materials. Structured data collection tools enabled comprehensive inspections but presented performance and usability challenges that increased reliance on post-inspection data entry. Firm responses to regulatory observations were also managed largely outside core systems, adding coordination and review steps.

Growing volumes of digital evidence exceeded earlier storage capabilities, while managing consumer complaints and inspection follow-up activities across multiple tools required additional reconciliation to maintain visibility and continuity. Investigators also relied on multiple systems to assemble safety and risk information before inspections. While these factors did not impede the FDA's mission, they increased administrative effort and highlighted opportunities to better align tools, workflows, and information management at enterprise scale.

The Solution

Building on challenges across assignment planning, inspection execution, data management, and coordination, the FDA and REI partnered on an end-to-end modernization effort to improve how work is managed throughout the inspection lifecycle. Rather than addressing individual issues separately, the initiative focused on enhancing efficiency, scalability, and operational continuity while minimizing disruption to field activities.

Close collaboration with FDA stakeholders and field users ensured that enhancements were introduced incrementally and aligned with real-world workflows. This approach enabled the platform to evolve alongside growing mission demands while establishing a scalable foundation for future operations.

MODERNIZING ASSIGNMENT MANAGEMENT (AMS)

As part of its partnership with the FDA, REI collaborated with stakeholders to modernize how inspection and investigation work is planned, created, and managed. This effort focused on strengthening interoperability, improving performance, and enabling consistent work creation across regulatory programs.

The result was the Assignment Management System (AMS) – a dedicated platform that centralizes assignment creation and tracking while supporting integration with related FDA systems. By separating work creation from inspection execution, AMS streamlined planning workflows and improved responsiveness for work planners, supervisors, and field staff.

AMS was designed to support broad reuse across program areas, enabling standardized yet flexible assignment management. It integrates with multiple FDA operational systems and continues to evolve alongside agency needs, reinforcing consistency while accommodating diverse regulatory activities.

Key design principles included usability, configurability, and data integrity. Dashboards, global search capabilities, and standardized templates help users quickly locate and manage assignments, while system validations and automated data sharing promote accuracy and reliability throughout the workflow.

Continuous collaboration is central to the AMS program. REI works closely with FDA program staff, work planners, supervisors, and system stakeholders to assess operational needs, validate enhancements, and refine functionality as mission demands evolve. This ongoing engagement supports steady improvement while ensuring that assignment-creation processes remain aligned with real-world planning and field coordination activities.

Prior to the introduction of AMS, inspection and investigation operations were created and managed through multiple platforms. Following the design and deployment of AMS as a dedicated assignment-management capability, operational volume has continued to grow. Over the most recent two-year period, more than 78,000 operations have been created and managed through AMS, reflecting its role as a centralized planning foundation supporting expanded inspection and investigation activity.

Together, these outcomes reinforce AMS's value as a scalable and resilient coordination layer—one that enables the FDA to accommodate increased operational demand while maintaining consistency, visibility, and oversight across programs.

FROM WORK CREATION TO WORK EXECUTION: ENSPECT

In parallel, REI has continued to enhance eNSpect, the application that supports field inspection and investigation execution. Modernization efforts focused on performance, usability, and the seamless application of FDA policy within inspection workflows.

Central to eNSpect is the Inspection Protocol, which guides investigators through program-specific requirements. By modernizing underlying technologies and refining application architecture, REI worked with FDA stakeholders to significantly improve responsiveness and real-time data entry capabilities. Investigators can now document observations as they occur, resulting in more complete and timely inspection records.

This evolution in inspection execution has occurred alongside a significant increase in data volume. Over the past 2 years, eNSpect has processed more than 453,000 documents, demonstrating improved capacity to manage the growing volumes of inspection evidence, firm records, and supporting materials.

These gains reflect not only enhanced system performance but also closer alignment between inspection tools and investigator workflows. By enabling more complete documentation within the application – and reducing reliance on manual or post hoc processes – eNSpect supports clearer inspection records while scaling to meet expanding operational demands.

eNSpect embeds regulatory guidance directly into application logic, aligning workflows with FDA policy and promoting consistency across inspections. Validation rules, standardized formats, and guided sequencing help ensure completeness while allowing investigators to focus on field activities.

Additional enhancements strengthened eNSpect's ability to manage inspection exhibits, firm interactions, and safety considerations. Expanded support for digital evidence enables comprehensive electronic records, while improved coordination with industry portals facilitates more efficient submission and review of corrective actions. Integrated safety alerts surface relevant risk information within inspection records, supporting investigator preparedness.

Ongoing updates have also improved consumer complaint synchronization, notifications, security controls, and protocol management. Throughout these efforts, REI has worked closely with OII, OIMT, OBISM, and field users to ensure technology advances reflect real-world operational needs.

Together, AMS and eNSpect now function as complementary components of a unified inspection platform, supporting assignment planning, execution, and reporting in a cohesive, collaborative environment.

The Results

The modernization of the FDA's inspection and assignment ecosystem has enabled the organization to absorb increased operational volume while improving efficiency, data quality, and user experience. By reducing manual effort, strengthening system integration, and aligning tools more closely with how inspections are planned and executed, the platform now supports a broader range of activities at a greater scale.

Across the inspection lifecycle, the FDA now manages a higher volume of assignments and inspection records than in prior periods, while maintaining consistency and regulatory rigor. These improvements allow staff to spend less time navigating systems and more time focusing on inspectional judgment, oversight activities, and timely response to public health risks.

Across the inspection lifecycle, the integrated platform reduces duplication, streamlines communication, and supports more effective use of available resources, contributing to improved inspection coverage and responsiveness.

Before vs. After Key Operational Impacts

Recall Response
Centralized assignment management and integrated system connections support more coordinated recall preparation and response.

Field Coordination
Automated status updates and shared workflows reduce reliance on manual communication and improve alignment among teams.

Inspection Documentation
Comprehensive digital exhibit support strengthens inspection records while reducing administrative overhead.

Investigator Safety
Integrated safety information improves awareness and preparedness during field activities.

Consistent Inspection Protocols
Standardized yet adaptable protocols promote uniform inspection execution nationwide.

These outcomes are reinforced by strong user adoption and positive feedback, reflecting improved usability, transparency, and effectiveness across roles. Collectively, these enhancements have enabled the inspection enterprise to support significant workload growth. Compared with the period before modernization efforts began, the integrated AMS and eNSpect platform now accommodates thousands of additional operations and tens of thousands more inspection records over comparable timeframes, without a corresponding increase in administrative burden. This expanded capacity directly supports broader oversight and more responsive regulatory operations.

Strategic Value

Introducing AMS and continuing to evolve eNSpect as part of an integrated platform has created lasting strategic value for the FDA. Together, these capabilities strengthen operational consistency, improve information flow, and support more timely regulatory decision-making.

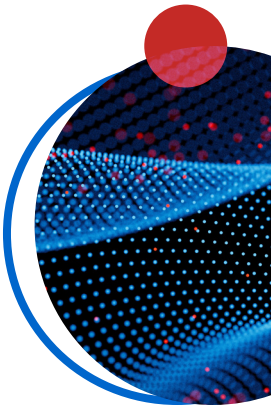
The end-to-end digital workflow connects planning, execution, and reporting across organizational boundaries, enabling improved visibility, coordination, and insight. Standardized processes reinforce regulatory consistency, while enhanced mechanisms for firm engagement support efficient and transparent compliance interactions.

Equally important, this effort demonstrates the value of a mission-driven, user-centered approach to modernization. Sustained collaboration among FDA offices and REI ensured alignment between policy, operations, and technology, resulting in a resilient platform that continues to evolve alongside the FDA's mission.

Forward Readiness and Future Evolution

Looking ahead, the AMS and eNSpect teams will continue their strong partnership with the FDA to advance modernization efforts and deliver new capabilities. These initiatives will support the evolving needs of investigators, supervisors, compliance officers, and leadership, while reinforcing the shared commitment to public health protection.

Conclusion



The modernization of FDA inspection operations, from assignment planning through field execution, illustrates how collaborative, user-focused technology investments can enhance government effectiveness. By strengthening and integrating core systems, the FDA and REI have established a scalable foundation that supports efficiency, consistency, and adaptability.

Together, AMS and eNSpect enable faster responses, higher quality inspection outcomes, and improved collaboration across the regulatory ecosystem. This partnership reflects a shared understanding of mission priorities and a commitment to continuous improvement, delivering value today while preparing for the challenges of tomorrow.

About REI

REI Systems delivers reliable and innovative technology solutions that empower federal, state, local, and nonprofit organizations to achieve their missions. For over 35 years, we've helped our customers solve complex challenges, make data-driven decisions, streamline processes, and improve citizen services. As a 100% employee-owned company, we are all directly invested in delivering excellence. With a fierce commitment to mission impact, we ensure measurable outcomes that align with our customers' strategic goals.
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