NAVITAS LIFE SCIENCES

A TAKE Solutions Enterprise

Client Case Study

End-to-End (E2E) Labeling

The Client

The client is one of the world's largest biopharmaceutical companies that develops, manufactures and markets pharmaceutical drugs in more than 100 countries worldwide.

The Project Objective

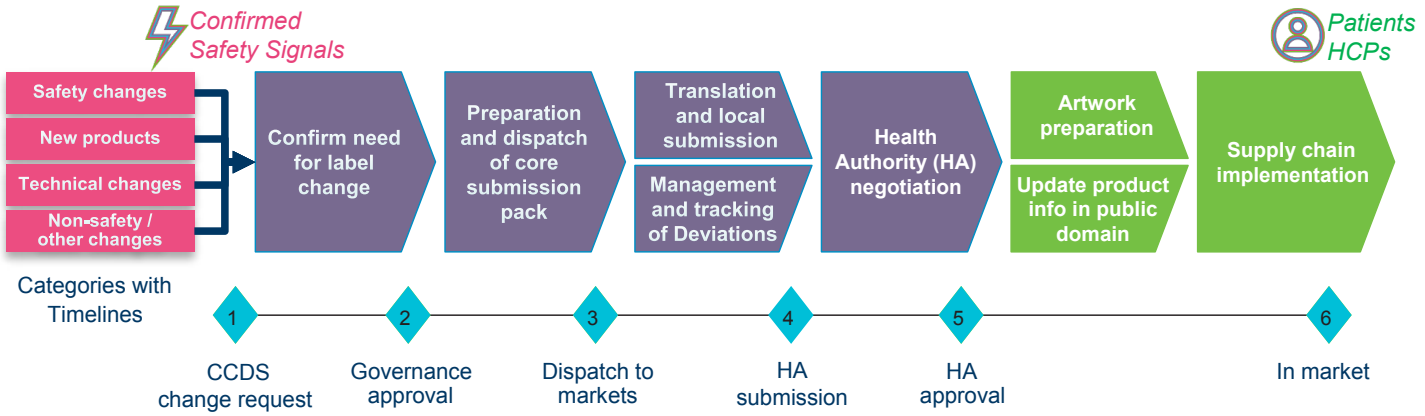
The overall objective of this project was to assess the current End-to-End Labeling processes, roles and responsibilities and technologies, compare these to industry best practices, and then design and implement a robust and systemically compliant 'To-Be' solution.

Approach and Deliverables

This End-to-End (E2E) Labeling project set out to provide the client with complete, global end-to-end visibility and traceability of the implementation and management of label changes and to ensure that these were aligned to regulatory and specified organisational timelines.

Key activities included:

- A detailed current state assessment to prioritize improvement opportunities utilizing data from all relevant stakeholders across the E2E process including Affiliates
- Alignment of Signal and Label categories to simplify as well as ensure the priorities continue through the E2E process
- Tracking points, timelines and KPIs were established for the different types of label changes based on their safety implications for submission and implementation
- A fit for purpose cross-functional governance structure was defined with active input from stakeholders to obtain buy-in and ensure implementation success
- Evaluated existing technology and provided options for establishing E2E tracking for further consideration
- Designed fit-for-purpose process refinements including a new timeline waiver process with clearly defined roles and responsibilities. All recommendations were supported by emerging best practices from our industry network labelnet
- Supported the implementation of process and governance improvements including reviewing controlled documents, incorporating revised responsibilities into role descriptions, and developing training plans and materials for roll-out across functional stakeholders



Some key Metrics from the engagement

Navitas Life Sciences ensured that we completed all key milestones on-time with a high quality outcome. This is a result of our focus on delivering outcomes while ensuring compliance.

- Developed a future state solution grounded in a thorough fact base
  - Involved more than 250 participants from 14 departments
- Identified more than 500 pain points throughout the assessment phase, to be addressed through the redesign
- Reduced the number of E2E process steps by more than 50%
- Reduced the number of governance bodies from 10 to 2, and reduced the membership by more than 50%
- Clarified all roles and responsibilities
- Implemented a tool allowing clarity and visibility for supply chain

General Principles - From Signal to Patient, not just HA submissions:

- Joined up processes i.e. End-to-End, Signal-to-Patient, HQ-to-Affiliates
- Effective cross-functional working and communications: PV, RA, Medical Affairs, Supply Chain, etc.
- Defined limelines for all process steps and milestones, together with metrics to monitor adherence

By leveraging our process and change management expertise, together with Navitas' and our client's subject matter experts, who have deep institutional knowledge, improvements were implemented smoothly to ensure that realized project benefits, were embedded and maintained far beyond the end of our contractual engagement.

Navitas Life Sciences helped the client achieve the following changes

- A redefined labeling department with clear roles and responsibilities
- Rationalized and simplified labeling governance bodies accompanied by the enhancement of a Quality Management System for labelling
- An integrated single process, applicable to medicinal products, combination products and biosimilars
- Clear Label content - new, user-friendly templates with consistent look and feel and patient-friendly label components
- New technology, enabling end-to-end capability through automated integration with other key label-related systems

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About Navitas Life Sciences

As a partner for the industry, Navitas Life Sciences leverages industry insights, consulting and technology capabilities to deliver full service clinical, regulatory and safety solutions and desired outcomes to clients. As the dedicated life sciences company of TAKE Solutions, Navitas harnesses the combined knowledge and experience of three legacy companies—Ecron Acunova, Navitas, and Intelent—to provide end-to-end services and solutions. Navitas helps clients address their most critical problems by bringing together the capabilities of a full-service CRO, a technology-led life sciences services provider across clinical, regulatory and safety, and a life sciences big data services and analytics provider. With a rich legacy of experience in life sciences, Navitas has worked with 9 of the top 10 pharma companies across the globe.

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