NAVITAS LIFE SCIENCES

A TAKE Solutions Enterprise

Client Case Study

End-to-End (E2E) Labeling

The Client

The client is an international, independent, research-based pharmaceutical company that develops, manufactures and markets pharmaceutical drugs to dermatologic and thrombotic patients in more than 100 countries globally.

The Project Objective

The End-to-End (E2E) Labeling project set out to provide the client with end-to-end visibility of the implementation of label changes and ensure these aligned to regulatory and organisational timelines.

Approach and Deliverables

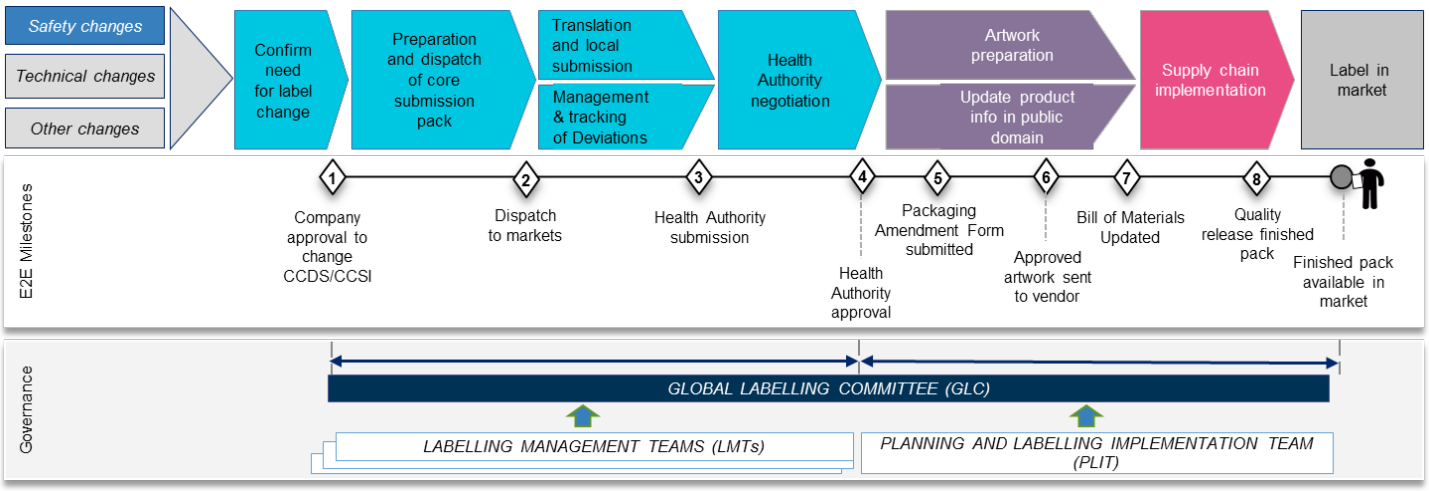
To achieve E2E visibility, Navitas Life Sciences worked with the client to ensure that there were effective linkages between all critical processes and systems spanning Pharmacovigilance, Regulatory, Quality and Supply Chain. In addition, a new governance structure was set up to oversee the E2E process and ensure adherence to the new cross-functional operating model.

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



By leveraging our change management expertise and including our clients' subject matter experts, who have deep institutional knowledge, prominently on project teams, improvements were implemented smoothly to ensure project benefits are realized beyond the end of our contractual engagement

Navitas Life Sciences helped the client achieve the following benefits

- Ensured compliance to regulations
- Improved cross-functional collaboration, processes and tools decreasing internal complexity and ensuring safety information reaches patients in a faster
- Smarter decision making enabling better planning and cost reduction
- Oversight and governance of the E2E process

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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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