



## Client Case Study

# End-to-End (E2E) Labeling for an international, independent, research-based pharmaceutical company



### 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.

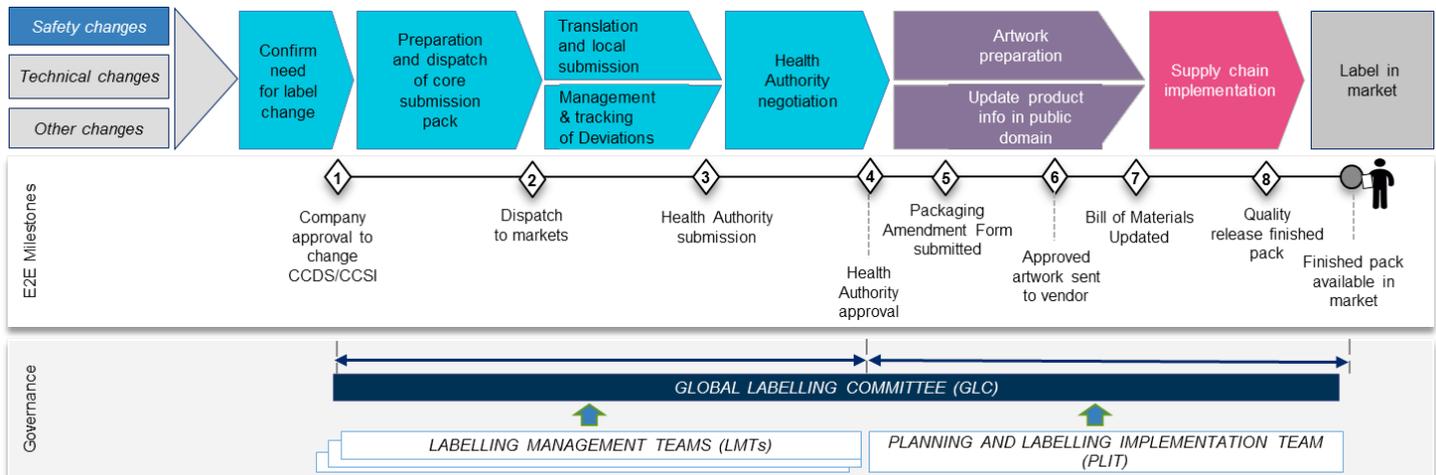
### Approach and Deliverables

To achieve E2E visibility, TAKE Solutions 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.



### TAKE Solutions 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

#### About TAKE Solutions

TAKE Solutions delivers domain-intensive services in Life Sciences. In the fast-growing Life Sciences space, TAKE offers clients a unique combination of full-service Clinical, Regulatory and Safety services backed by unique technology expertise. Our range of services span from clinical trials to regulatory submissions to post-marketing safety, all backed by insights derived through proprietary industry networks forums. With a team of leading Life Sciences experts, best-in-class systems and processes, and bespoke, industry-specific technology and analytics, TAKE delivers successful outcomes for clients. Our global roster of clients includes large and small innovator biopharmaceutical companies as well as generics manufacturers. With operations spread across North America, Europe, Asia, and South America, TAKE is a Public Company, listed in India on the Bombay Stock Exchange and the National Stock Exchange. Led by a team of industry stalwarts and domain experts, TAKE has been growing steadily with FY18 revenues touching INR 15,872 Mn, (USD 246 Mn).



#### For more information

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