

## Simplify and strengthen your End-to-End labeling process with **Labeling Assessment Express™**

Regulators are changing the way they look at labeling. Their focus has expanded beyond the traditional pharmacovigilance scope. Regulators now expect the industry to deliver accurate and timely labeling information and risk minimization activities, all the way to patients and healthcare professionals.

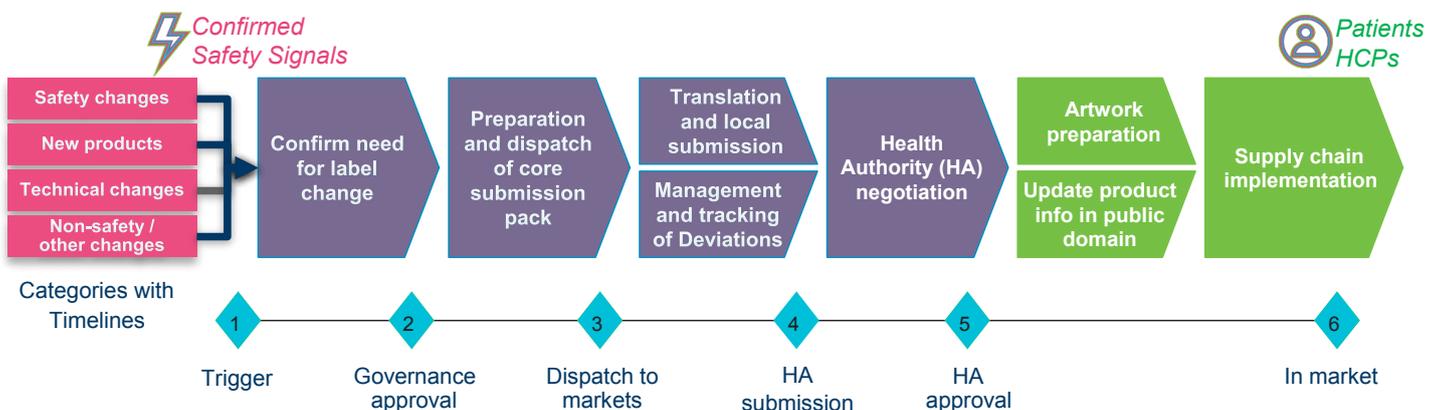
Labeling is one of the most complex, cross-functional processes within the pharmaceutical industry. Unsurprisingly, it is also one of the most common areas for critical inspection findings. An effective, robust and yet streamlined End-to-End (E2E) labeling process is essential to safeguard patient safety, ensure compliance with global regulations and protect the company's reputation through the avoidance of fines and unwanted media attention.

### How can you ensure your labeling process will put the patient first and stand up to regulatory scrutiny, whilst avoiding a long drawn out process improvement initiative?

Typical labeling process improvement initiatives can be time consuming and costly. **Labeling Assessment Express™** is a highly cost-effective diagnostic approach which provides a rapid analysis of the health of an E2E labeling system, in as little as a week.

Navitas Life Sciences has developed **Labeling Assessment Express™** using its extensive experience and insight, gained through a long history of E2E labeling improvement projects and its industry leading best practice forum, **labelnet**.

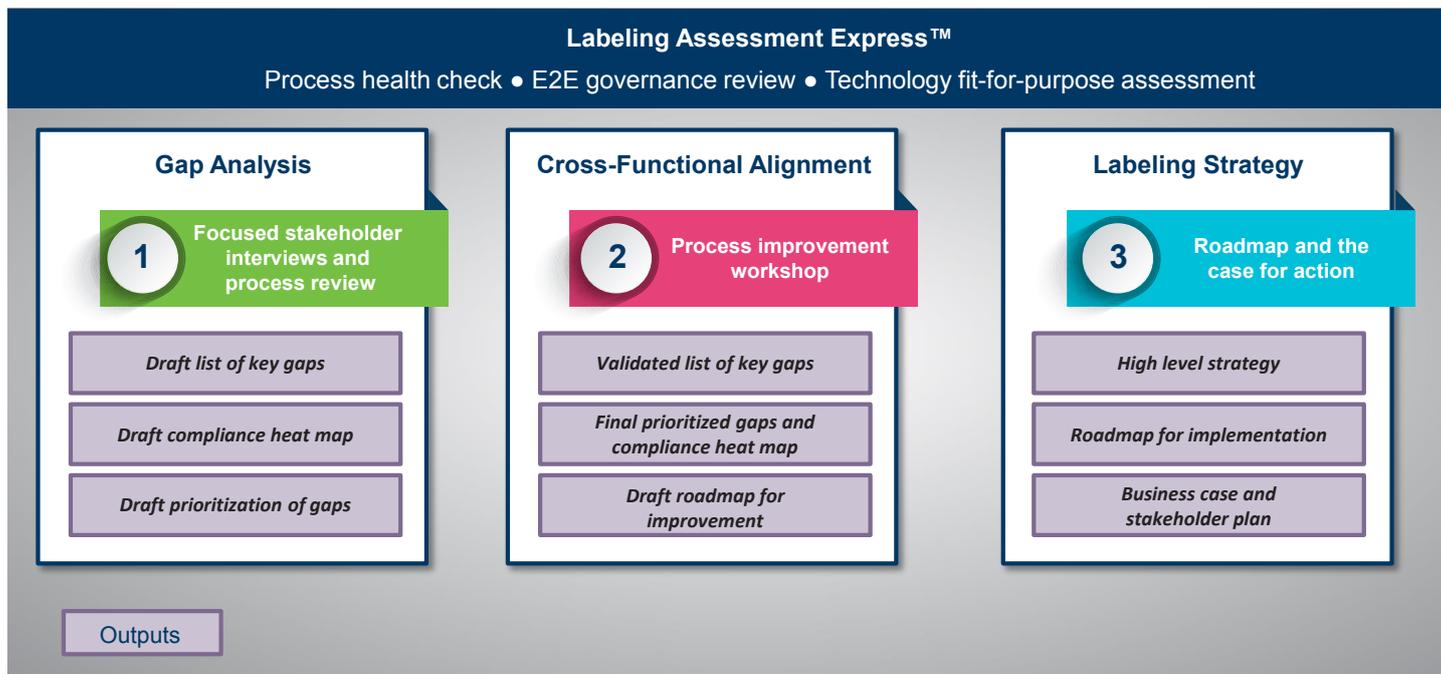
### At the heart of Labeling Network Express™ is the Navitas labeling model for success:



### The model for success builds on three key principles:

- Processes must be joined up, from signal to patient, from headquarters to affiliates, and from function to function
- Governance and technology must provide E2E oversight, data continuity and tracking across all functions involved in labeling (e.g. Development, Pharmacovigilance, Regulatory Affairs, Medical Affairs, Artwork, Supply Chain and Quality)
- Metrics and measures must be in place to monitor quality and compliance of all critical steps in the process

## Labeling Assessment Express™ is conducted in three simple steps



The multi-dimensional read-out provides valuable insights on key E2E health indicators:

- Process completeness and robustness
- Governance
- Organizational structure
- Capabilities and capacity
- Data management
- Technologies
- Inspection readiness



Step 1

A gap analysis is conducted that includes a process health check, an E2E governance review and a technology fit-for-purpose assessment versus industry good practice. The gap analysis results in a 'compliance heatmap' and an initial list of prioritized issues for focus.



Step 2

Step 2 builds on the outputs of step 1 by creating a single point of view on the current state of the labeling process. This is achieved by a cross-functional process improvement workshop. The output is a prioritized list of improvement opportunities that is agreed by all key functions and stakeholders, along with the elements of the future strategy and roadmap for improvement.



Step 3

In the final step Navitas Life Sciences leverages its labeling expertise to work with key stakeholders from the business to refine the strategy and roadmap, and to develop a business case for change.

**The result:** a clear picture of your company's E2E labeling process and a clear plan of the improvements required to meet the expectations of regulators and more importantly the needs of patients.



A TAKE Solutions Enterprise

### About Navitas Life Sciences

Navitas Life Sciences brings together the proven strengths of its legacy brands Navitas, Ecron Acunova and Intelent to serve as a strategic partner to global Life Sciences companies. Navitas Life Sciences leverages its industry insights and domain expertise to develop and implement consulting, technology and functional services across the spectrum of Clinical, Regulatory and Safety, to innovative and create value to address the needs of the industry uniquely.

### For more information

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