

Use Cases for Life Sciences: Labeling

COMPANY PROFILE

- A leading biotechnology company
- Over 20,000 employees in 100+ countries worldwide

CHALLENGES

The company struggled with poor visibility and tracking, as well as a significant manual effort to achieve compliant labeling. They needed to be able to globally distribute their products appropriately, and experienced inefficiencies when tracking for regulatory audits.

Tying together the process across local jurisdictions, by country, then region and finally at the corporate level was done by brute force and with the heroic efforts of a lot of individuals involved. There was no real-time visibility to the end to end labeling process, and there was a lack of consistent communication and transparency among the various functions, departments, and countries involved in the process.

Inconsistent branding and inefficient access to critical data was also plaguing their labeling process. Excessive costs were incurred when coping with these inefficiencies, so the company sought to digitally transform their labeling process.

SOLUTION GOALS

A system was needed to improve process efficiency and traceability for labeling. There was a clear need for process monitoring capabilities for distribution of data at the local, regional, and global levels. The desire was for a system that would afford all stakeholders and contributors to have a clear visibility to the overall process orchestration with automated workflows

that provide timely transparent views into work in process with situational awareness and clear flags and warnings of bottlenecks, barriers or opportunities for more efficient process drivers.

Every label printed needed to be inspected thoroughly, ensuring consistent and accurate information. The system to be implemented would need to meet industry standards for safety and liability, and comprise strict quality control processes.

RESULTS

The company chose Appian to assist with the digital transformation of their labeling process. With Appian's platform, they were able to:

- Update their internal and regulatory approved documentation
- Streamline their product creation method, both locally and globally
- Seamlessly integrate with other systems for product registrations, regulatory documents, safety signaling and tracking systems, product change management, supply chain, and central corporate data
- Achieve end-to-end visibility and auditability of their entire labeling process



Appian

Existing Applications

CLINICAL: Site Initiation – Readiness – Effectiveness Study Start Up, “1572”, IP (Green Light), Global CRO Contracts, Pre-approval Inspection

CMC: High Throughput Experiment Tracking, Global Compound Ordering, LIMS

REGULATORY: Regulatory Operations, IDMP, e-Submissions & Publishing, Online 510K FDA Review

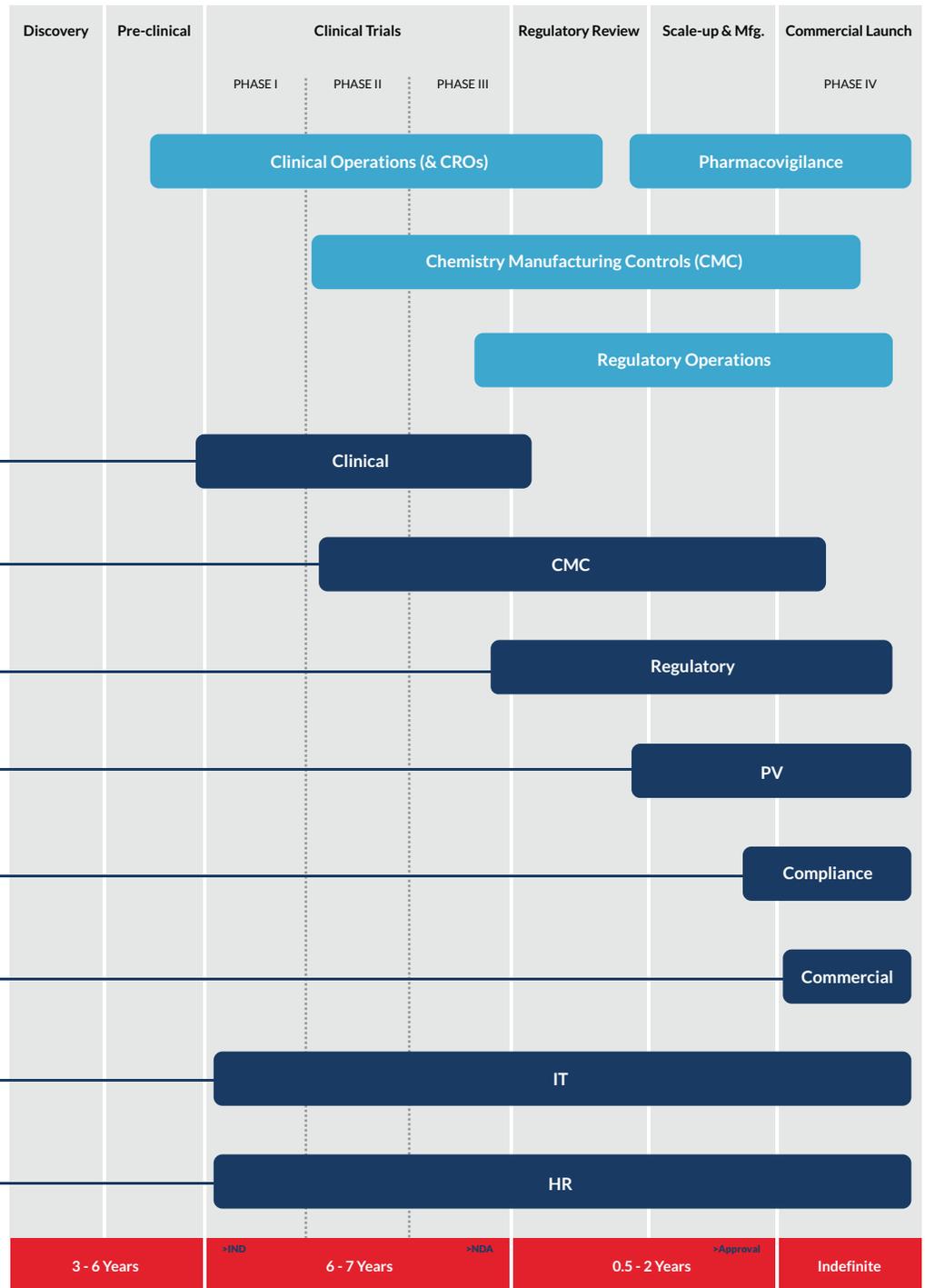
PV: Safety Information Management, Safety Signal Tracking

COMPLIANCE: Anti Bribery and Corruption (FCPA), Third Party Intermediaries, Sunshine Act

COMMERCIAL: Sales Force Automation, Contracts

IT: Asset Management v. Resources, Statements of Work Management

HR: On Boarding, Recruiting



Appian

Appian provides a leading low-code software development platform that enables organizations to rapidly develop powerful and unique applications. The applications created on Appian’s platform help companies drive digital transformation and competitive differentiation.

For more information, visit www.appian.com