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Use Cases for Life Sciences: Regulatory Intelligence Database (RID)

COMPANY PROFILE

- A global Contract Research Organization (CRO) in a highly competitive industry
- More than 50,000 employees working in over 100 countries worldwide handling some of the most complex clinical drug trials
- Providing cutting edge technologies to the Pharmaceutical industry intended to improve the quality of health outcomes through channeled insights

CHALLENGES

The organization struggled with ensuring compliance and quality control over regulatory information across ever-changing global requirements. In addition to being able to maintain the required level of control, they had difficulty producing audit trails for their processes. Additionally, local and regional interpretations and assessments of regulatory requirements were collected locally and not in a global centralized repository, so that capturing and memorializing this critical knowledge proved challenging.

Their dispersed subject matter expertise needed to be better coordinated, but they lacked a means to organize and consolidate their scattered data sources and disparate procedures.

SOLUTION GOALS

The organization sought a solution that could bring together and organize regulatory intelligence and requirements data from their operational Regulatory Intelligence Units (RIU's). This included being able to sort and add a taxonomy for information on product lifecycle, safety, regulatory affairs, and medical affairs.

They additionally wanted to give end users the ability to customize how data would be viewed, validated, and updated within the RID system, without the need to bring in a software developer and systems integrator each time.

RESULTS

With the Appian platform, the company was able to digitally transform their processes to:

- Allow all end-users to have access to all content, while managing content ownership and edit capabilities based on user role and permissions
- Create multiple flexible change request processes and consolidate data into unified procedures
- Establish the flexibility to generate reports on any data within the system
- Provide a single, secure place for personnel to see the status of all Regulatory Intelligence activities
- Create a system for managing key regulatory form templates, latest regulations and documents by location
- Produce reports to assure that procedures such as validation approvals, process checklists, and fully reportable audit trails are being followed

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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

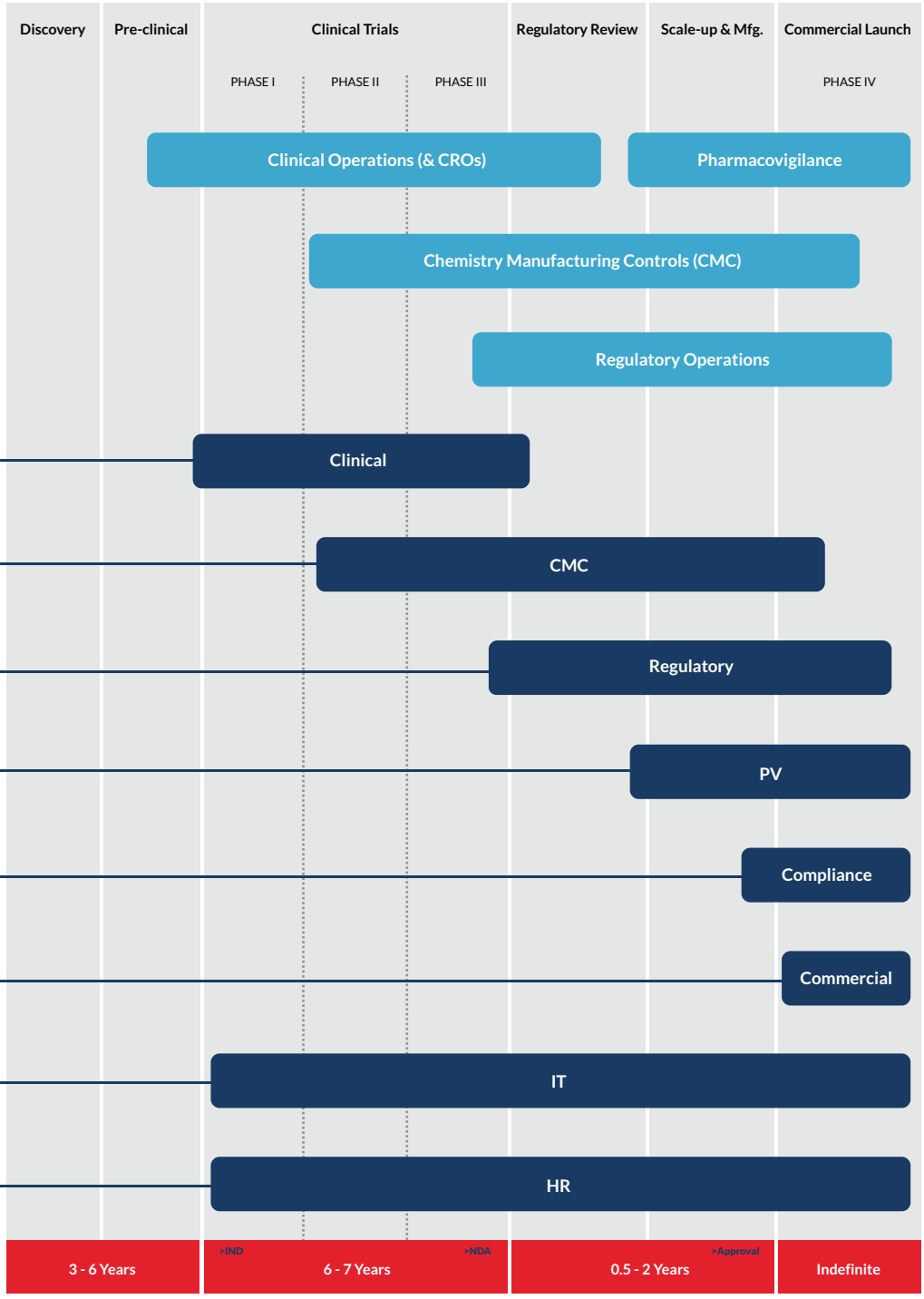
PV: Safety Information Management, Safety Signal Tracking

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



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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.

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