Appian

Use Cases for Life Sciences: Medical Device Registration

COMPANY PROFILE

- Large government health agency in Europe
- Top regulatory authority for pharmaceuticals and medical devices
- Over 1,200 employees with multiple site locations
- Responsible for ensuring the safety of medicines and medical devices internationally

CHALLENGES

The agency is responsible for managing medical device registrations, a legal requirement for all manufacturers and authorized representatives of these devices. This is especially critical with the new Medical Device Directive (MDD), which is replacing the well established Medical Device Regulations (MDR). The immense influx of data was overwhelming as they were challenged with correctly identifying and sorting devices according to new regulation nomenclature. Both their internal agency employees, as well as the public and regulated entities, struggled with disjointed and unclear processes.

SOLUTION GOALS

The agency needed a platform that could enable a streamlined automated process and help them unify their medical device registration data. The process would need to provide a single, unified interface, to provide clarity for users. The agency also wanted to offer their external users the ability to easily submit new device company registrations, apply for new device and product registrations, and better manage existing registrations in a more integrated way. Perhaps most importantly, the agency needed to create a flexible yet secure access environment for all users.

RESULTS

The agency chose Appian's digital transformation platform to meet their business needs. Their solution, built on Appian:

- Provides a single online account that customers can self-manage
- Allows staff to access and provide information to customers more efficiently
- Offers a more comprehensive and user-friendly interface
- Implements global medical device nomenclature to correctly identify devices for new medical devices regulation
- Presents a simpler, more streamlined service for external and internal users, reducing admin overhead and error rates in the process

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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

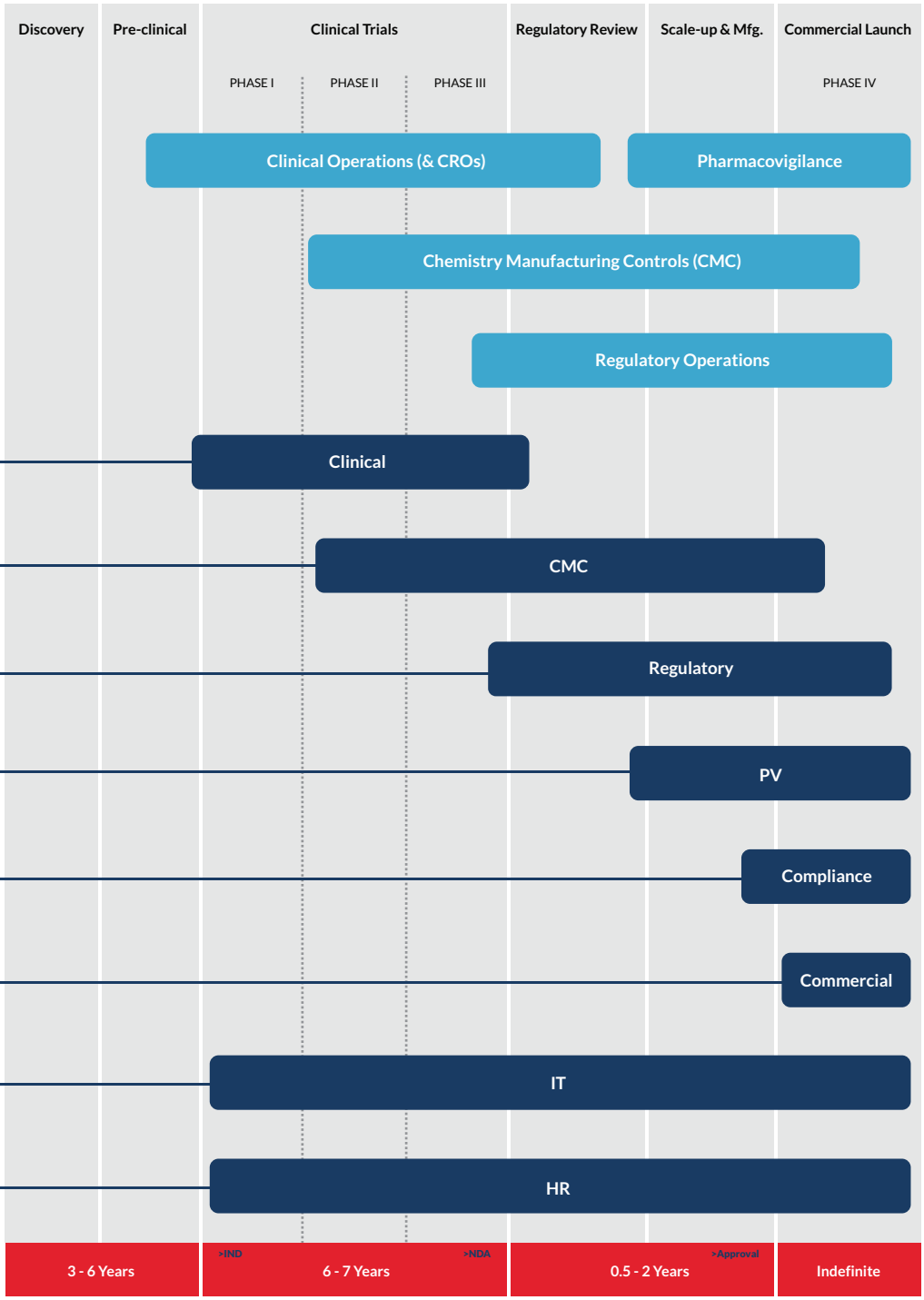
PV: Safety Information Management, Safety Signal Tracking

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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