Appian

Use Cases for Life Sciences: Certificate of Free Sale

COMPANY PROFILE

- Large government health agency in Europe

- Top regulatory authority for pharmaceuticals and medical devices

- Over 1,200 employees across multiple site locations

- Responsible for ensuring the safety of medicines and medical devices internationally

CHALLENGES

Certificates of Free Sale (CFS) are required by governments in a growing number of countries to ensure that export products are meeting all state and federal laws and regulations. The organization provides these certificates to products, allowing manufacturers and authorized representatives to export them to other countries.

The organization's CFS process struggled with handling an overwhelming amount of device and manufacturer data. They had difficulty tracking orders and couldn't provide a clear interface for users.

SOLUTION GOALS

The organization wanted to be able to better track CFS orders. They needed a more efficient and accurate system to manage device and manufacturer data. They sought an application platform that provided a clearer interface for users that could help streamline and standardize the CFS process, ensuring a faster and more intuitive execution.

RESULTS

The organization chose Appian to improve the CFS process. Built on Appian's platform, the solution:

- Offers the tools to keep track of CFS orders, managing devices, products and more

- Previews CFS certificates and schedules before purchase and allows for online payments

- Provides the ability to add devices and products for CFS and upload CE (Conformité Européene) Marking certificates

- Helps organize manufacturers and devices and tracks orders in real-time

- Provides standardization for the use of device terms

Discovery	Pre-clinical	Clinical Trials			Regulatory Review	Scale-up & Mfg.	Commercial Launch
		PHASE I	PHASE II	PHASE III			PHASE IV

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Existing Applications

Clinical Operations (& CROs)

Pharmacovigilance

Chemistry Manufacturing Controls (CMC)

Regulatory Operations

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

Clinical

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

CMC

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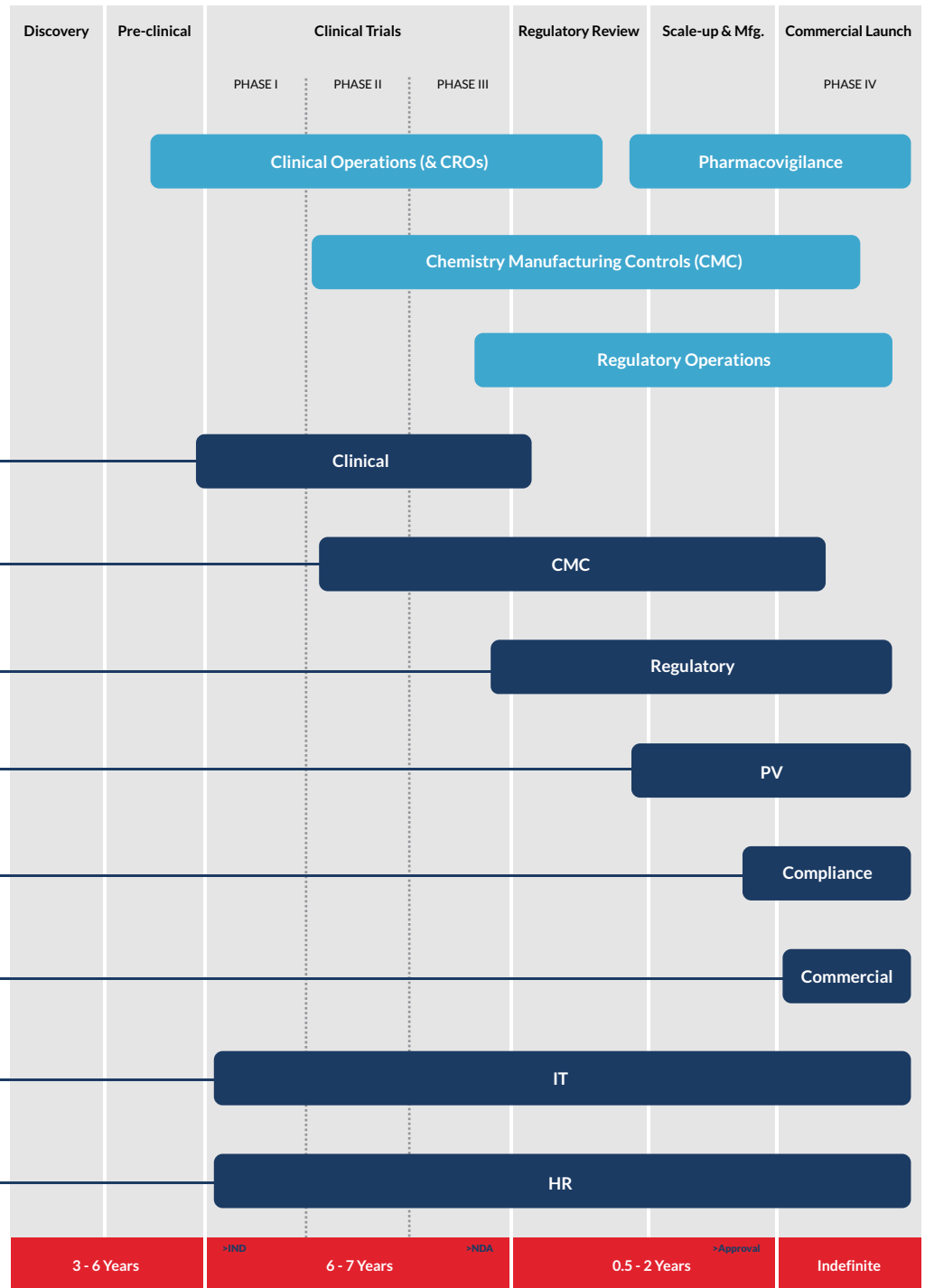
Regulatory

PV: Safety Information Management, Safety Signal Tracking

PV

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

Compliance

COMMERCIAL: Sales Force Automation, Contracts

Commercial

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

IT

HR: On Boarding, Recruiting

HR

3 - 6 Years	>IND 6 - 7 Years >NDA	0.5 - 2 Years >Approval	Indefinite

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.

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