Appian

Use Cases for Life Sciences:
Transforming the Regulatory Process

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
This regulatory organization suffered from inefficient processes and dated software solutions. Siloed systems, with no communication or integration abilities between them, meant they were struggling with data and account management. Yet they were hesitant to change their systems, anticipating high costs and the threat of extensive implementation times.

Demand for digital transformation increased with new data standards that intensified the need for an agile technology approach. Changes in global and national policies and regulations solidified the organization's decision to move forward with a digital solution.
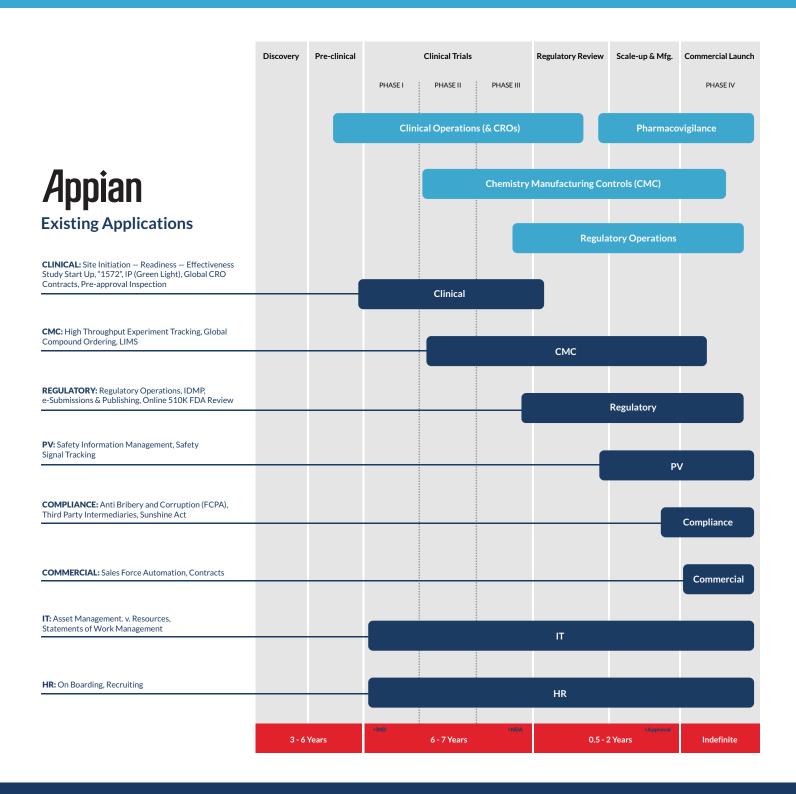
SOLUTION GOALS
The organization needed an improved experience for both their external and internal users. They wanted to reduce costs and complexity, while improving flexibility and productivity. This would be achieved through establishing automated processes for device registration, adverse incidents, clinical investigation, and regulatory advice. A streamlined system for registering, reviewing, and checking products to ensure regulation compliance was essential.

They chose a flexible solution that would enable them to meet all agency goals while also highlighting opportunities for future innovation and simplification. They chose Appian, The Digital Transformation Platform™.

RESULTS
- Improved document and casework management with Appian Records

- Implemented integrations with other software solutions within the organization

- Achieved a unified interface with customer-centric design and format

- Automated adverse incident adjudication and reporting

- Simplified device registration and clinical investigation processes

- Enhanced request tracking and monitoring abilities

- Increased productivity and streamlined processes

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.

For more information, visit www.appian.com