

Use Cases for Life Sciences: Regulatory Information Management

How can we be sure we are compliant with all regulations when there are so many to manage?

APPIAN CUSTOMER

- Large multi-national pharmaceutical company.
- Global presence across 150+ countries.
- Focus on regulatory compliance.

CHALLENGES

- Heavy reliance on manual processes, SharePoint, and Excel files.
- Current solutions in place do not provide comprehensive awareness of global portfolio.
- Internal audits uncover significant gaps in compliance.
- Silos of data across many systems creates a lack of visibility to the latest information.
- This lack of full awareness and visibility puts company at global risk.

GOALS

- Unify data from across many different systems and geographies.
- Ensure compliance across hundreds of global regulations to reduce global risk.
- Eliminate manual, mistake-prone SharePoint sites and Excel tracking sheets.
- Bring new drugs to market faster.

Sample App: Regulatory Submission Management Platform

BUSINESS CASE

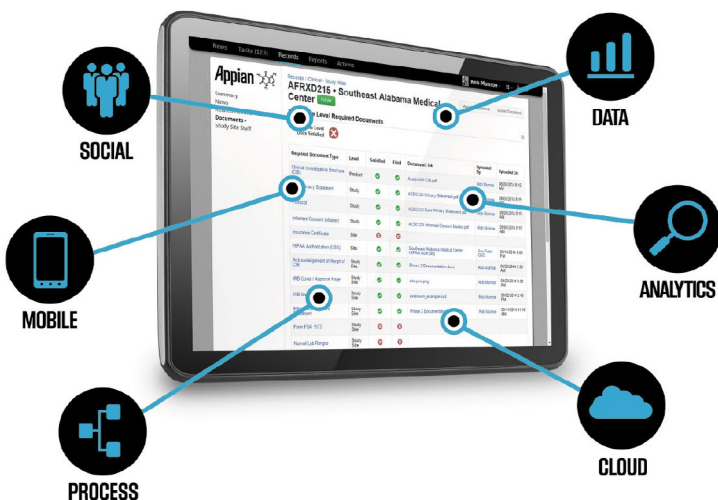
- Compliance regulations for >1000 products across 150+ countries.
- Challenge to balance quality and compliance with the need to take each new drug to market as quickly as possible.
- Information captured and stored in a multitude of silos across the global business.

APPROACH

- Simplify end-to-end business processes focused on planning, regulatory compliance, and productivity.
- Eliminate existing silos by creating a “single authoritative truth,” converging all data from across systems.
- Create a single, intuitive platform for use across multiple global departments.

RESULTS

- Reduced time to market for new drugs across regions and applications.
- Increased submission quality.
- Increased compliance to >99%.
- Decreased organizational complexity and processes.
- Significantly decreased system maintenance costs.



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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

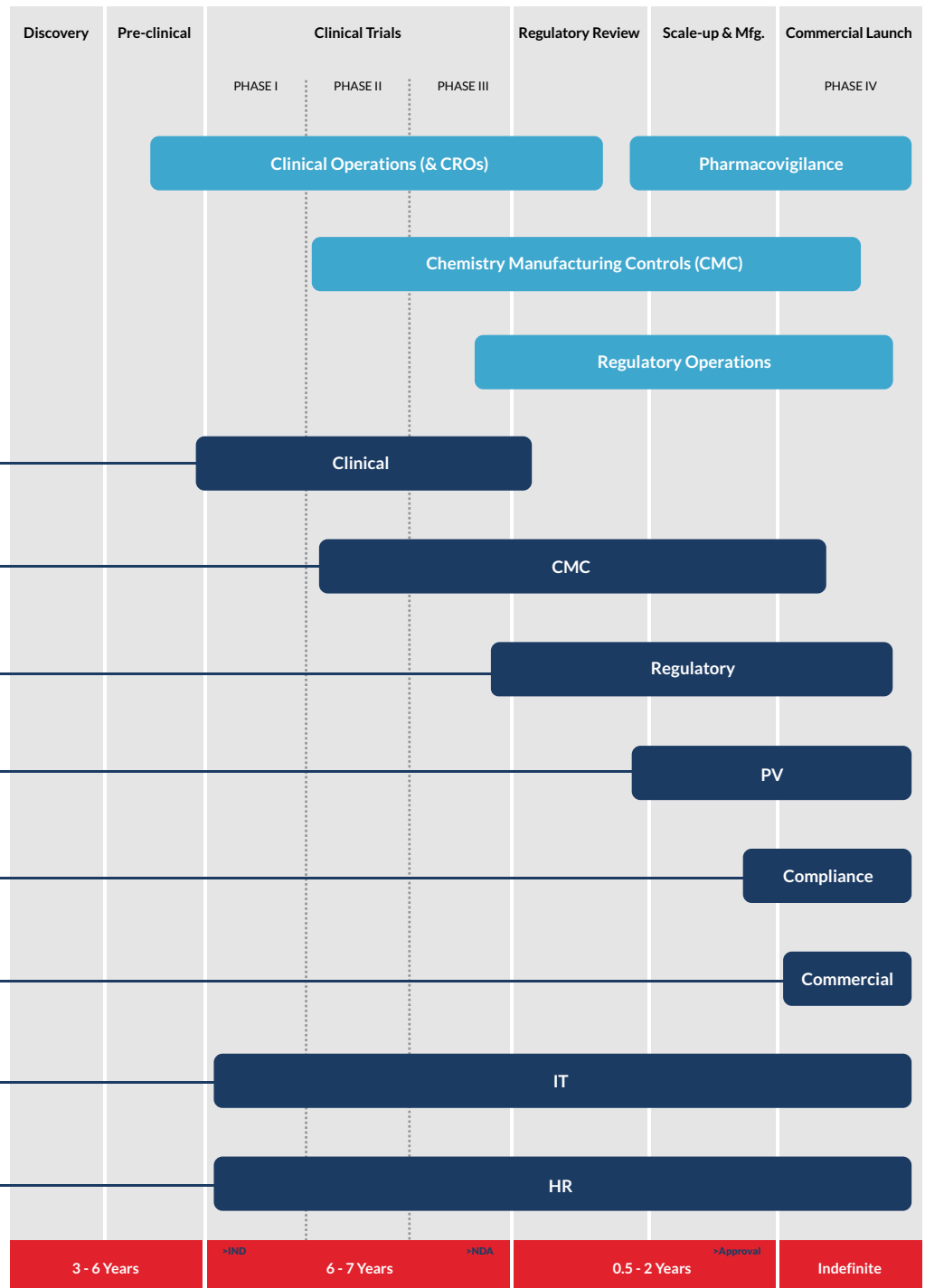
PV: Safety Information Management, Safety Signal Tracking

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 delivers an enterprise platform for digital transformation that speeds time to market and value to the patient. Powered by industry leading capabilities, Appian's approach radically accelerates the time it takes to build and deploy powerful, modern applications, on-premises or in

the cloud. The world's most innovative life sciences organizations use Appian to revolutionize their customer experiences, transform their operations, and master regulatory compliance.

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