Appian

Use Cases for Life Sciences: Clinical Operations

How can you harmonize clinical operations across multiple geographies and systems?

APPIAN CUSTOMER

- Large multi-national pharmaceutical company.
- >100,000 employees.
- Footprint across >100 countries.

CHALLENGES

- Largely paper-based processes.
- Lack of visibility due to many legacy clinical trial management systems operating in silos.
- Global risk of missing strict filing deadlines across many local, country-based regulations.

GOALS

- Converge all clinical operations from across multiple geographies and systems.
- Take advantage of a single platform.
- Accelerate time to submission...Accelerate time to market.

Sample Clinical Operations Apps

Form-1572

BUSINESS CASE

- Egregious examples of impropriety at some study sites create significant regulatory (FDA) risk.

APPROACH

- Automate key components of the clinical trial start up process.
- Increase transparency to ensure compliance.

RESULTS

- Reduced start-up cycle times by 60%.
- Reduced cycle time (end to end) by 32%.
- Increased regulatory compliance to >99%.

Global CRO Contracts Management

BUSINESS CASE

- Bottlenecks and lack of visibility cause contract processing (RFP development, RFP bidding, vendor selection, and contract execution) to take between three and six months.

APPROACH

- Streamline entire process from RFP creation to contract execution.
- Keep internal groups and external vendors up to date with current information.
- Drive better contracting decisions by creating a single, unified view of data and metrics.

RESULTS

- >50% reduction in cycle time from RFP development to contract execution.
- Reduced average cycle time to 60 days.

Clinical Study Start Up

BUSINESS CASE

- Address the many inefficiencies of Study Start-Up (SSU).
- Achieve complete visibility for better oversight and faster action.
- Access up-to-date analytics to identify trends and more proactively address them.

APPROACH

- Leverage process automation to minimize manual activities, eliminate duplicate entries, and reduce risk of errors.
- Automate import of study information from across multiple sources.
- Automate SSU task management to eliminate gaps from manual work processes.
- Standardize processes globally while allowing for local variations.
- Unify all data with Appian Records so a complete and current view of SSU elements is always accessible.

RESULTS

- Study Start-Up time reduced from a high of 6 months to a low of 2 weeks.
- Study times previously took 2-6 months; now they take 2-8 weeks.

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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

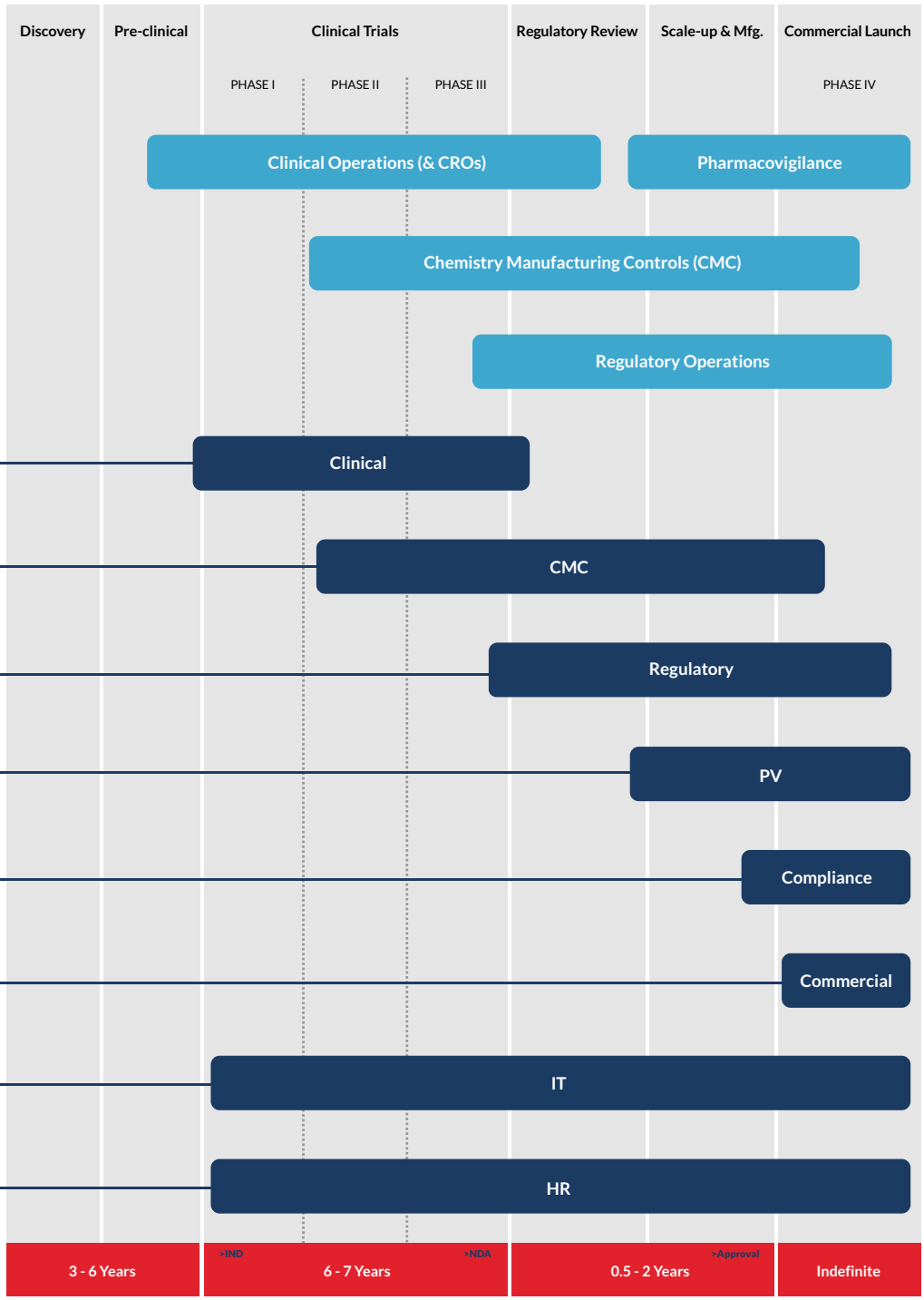
PV: Safety Information Management, Safety Signal Tracking

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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