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Use Cases for Life Sciences: Regulatory Start Up

Accelerate the clinical trial process and ensure compliance with a flexible and innovative platform

CUSTOMER PROFILE

- Leading international clinical trial and health data company
- 50,000+ employees
- Executes over 900 clinical trials a year globally
- Focus on improving clinical trial process and promoting innovation

CHALLENGE

The regulatory compliance and legal issues associated with clinical trials required a huge manual effort from employees. Variations in regulations across countries and sites provided added complexity to maintaining compliance. This made the planning and startup of clinical trials challenging and extensive, ultimately slowing down the entire process.

Once a trial had been initiated, keeping track of progress was a difficult task. Clinical trials were typically executed across multiple sites internationally, requiring tracking and monitoring across many regions simultaneously. Multiple systems were used for the purpose of managing these trials and much of the process was aided by the extensive use of spreadsheets for inserting and tracking manual updates on trial progress.

SOLUTION GOALS

The customer sought a Digital Transformation platform to streamline the clinical trial process. They needed automated and on-demand process tracking that offered continuous updates as well as the ability to tailor their processes to comply with varying international regulations. They also needed to implement efficient processes that would speed up their trial startup and execution time. They turned to Appian's enterprise-grade platform for help.

RESULTS

- Time to complete a clinical trial cut down 15%
- Customization to ensure compliance in every region
- Automated process tracking for all sites
- Improved customer service
- Enhanced employee experience
- Better oversight
- Reduced cost
- Enhanced quality
- Better Traceability and auditability
- Valuable metrics to support continuous process improvement

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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

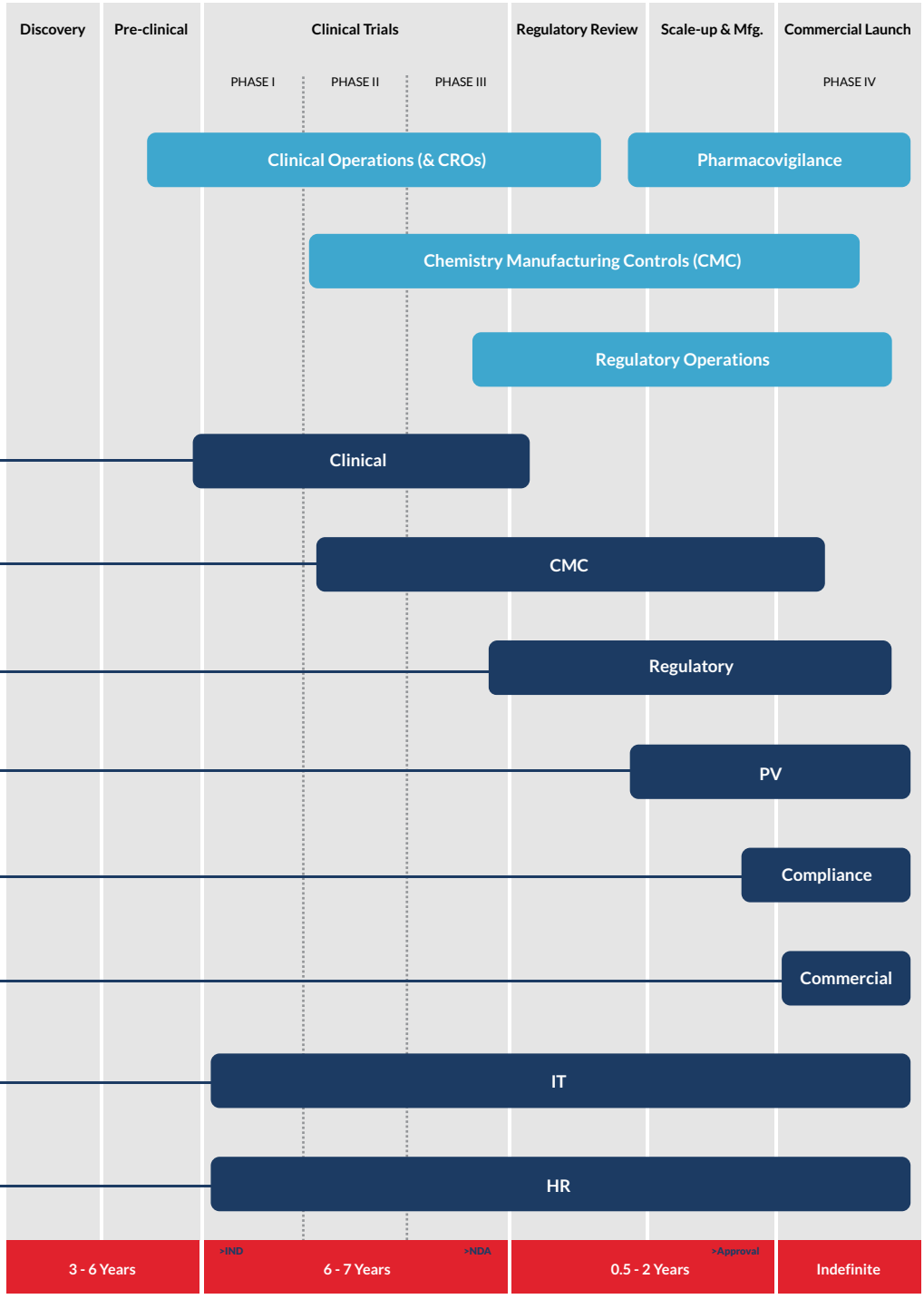
PV: Safety Information Management, Safety Signal Tracking

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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