

Use Cases for Life Sciences: Fair Market Value and External Stakeholder Engagement Management

COMPANY PROFILE

- A leading multinational biotechnology company
- More than 5,000 employees serving customers in almost 100 countries
- Focus on discovering, developing, manufacturing and delivering medicines and other treatment options

CHALLENGES

The current economic climate has meant that businesses need an even stronger corporate culture to monitor compliance and fight the risks of fraud, bribery and corruption. Keeping compliance and monitoring programs up to date with the latest changes is a significant challenge. In early 2013, final rules were issued regarding the US Physician Payments Sunshine Act. They require annual reports on certain payments or transfers of value to Health Care Professionals (HCP) and other recipients and Key Opinion Leaders (KOL). In addition, companies are required to have a standardized basis for calculating compensation for services, and proving that the services were delivered: Fair market value - to establish a clear basis for the compensation, as well as increasing consistency of compensation. In addition, Proof of Service to ensure that adequate documentation is produced by an approval process substantiating the business case and estimated costs before a contract is entered into, and documentation to prove that the services were actually performed or expenses incurred prior to payment.

The organization struggled with gaining full transparency and control over its external stakeholder engagement. The new legal obligations and the tedious manual processes that went along with them made compliance difficult to maintain. The organization had several segregated systems with no ability to integrate data into a single interface. This segregation also made multi-national implementation challenging and standardization of certain processes impossible.

SOLUTION GOALS

The organization needed an automated system to handle complex rules and processes. They also sought an engagement-based tracker that would identify stakeholders for them. They wanted to integrate data from seven separate systems into a unified interface that could be accessed in at least eight different languages. In addition, the organization needed an application that ensured global compliance and standardization of payments to key opinion leaders speaking on their behalf around the world, plus a way to curtail budget overruns and more importantly control the spend with each KOL and HCP to comply with regulatory documentation proof of service requirements and adherence to complying with fair market value standards.

The organization chose Appian, The Digital Transformation Platform™, to create a workflow management system that enables a uniform process for engaging with external stakeholders.

RESULTS

With Appian, the organization was able to achieve its goals:

- Automated processes to gain approvals and review outliers
- Business rules to ensure guidelines are in place for compliance with rules and regulations across the globe
- Ability to select, validate, tier, and establish fair market value (FMV) for engagement with stakeholders
- Ability to manage content requirements surrounding stakeholder engagement
- Interfaces in 8 different languages to support multi-national implementation and compliance across many jurisdictions
- Increased speed of delivery
- Ability to identify and report potential stakeholders



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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

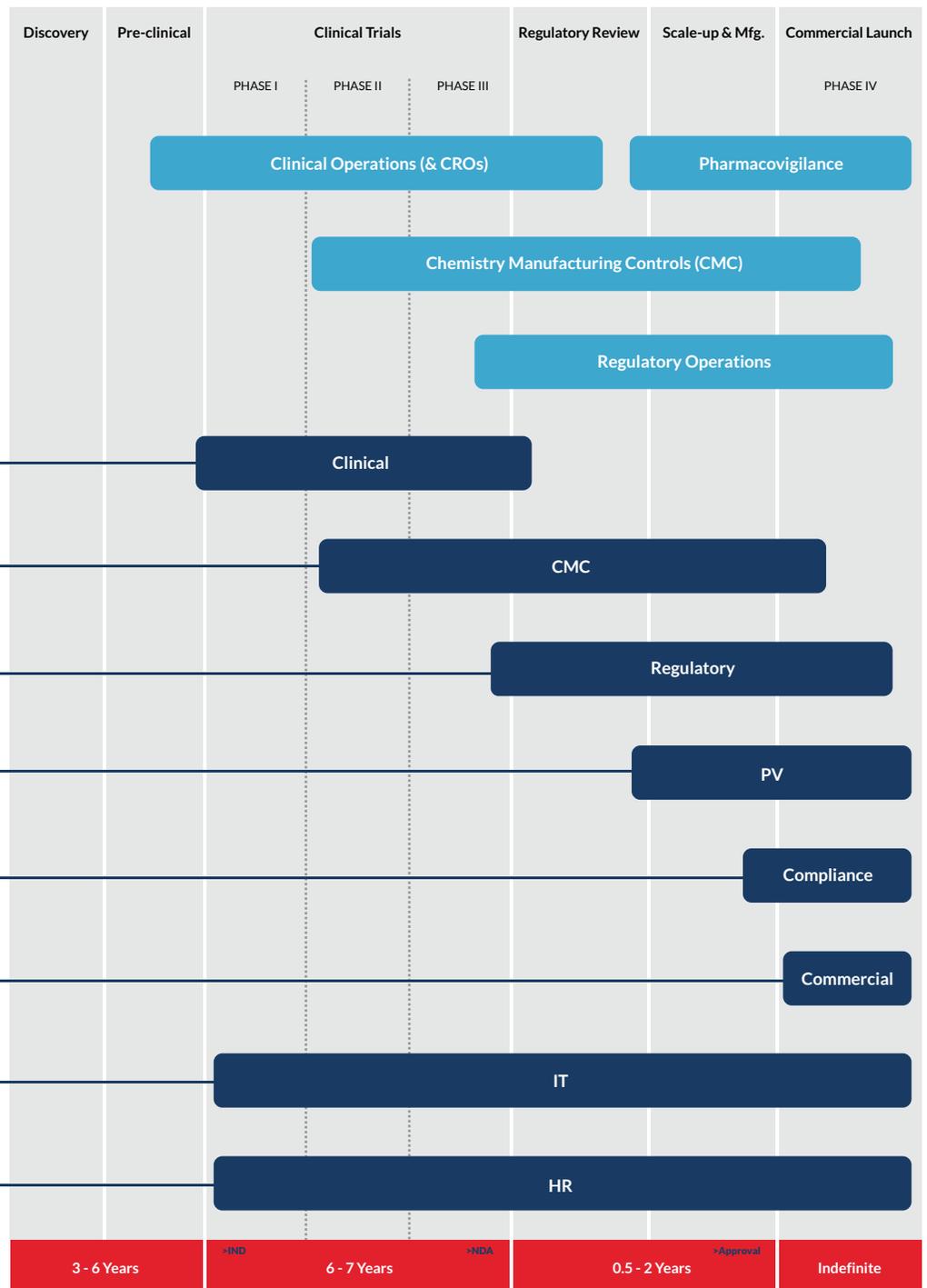
PV: Safety Information Management, Safety Signal Tracking

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



Appian

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