



Use Case 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, and increase consistency of compensation.

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 standardized payments to key opinion leaders speaking on their behalf around the world. They also needed a way to curtail budget overruns and remove control the spend with each KOL and HCP to comply with regulatory documentation proof of service requirements and adherence to fair market value standards.

The organization chose the Appian Low-Code 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:

- Segregate duties such that only those who need specific information can access it.
- Collect and aggregate committee votes as candidates move through the process.
- Digitize paper-based candidate documentation into electronic records.

Dynamic configuration of the file upload process to account for any potential changes addressed the long-term goal of future-proofing the application. With this forward-thinking planning, this institution and the Chief Academic Officer are looking forward to addressing additional, more high-profile projects with Appian.



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 and 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. vs. Resources,
Statements of Work Management

HR: Onboarding, Recruiting

