Use Cases for Life Sciences: Investigator Sponsored Research

COMPANY PROFILE
• A publicly traded global biopharmaceutical company
• 11,000 plus employees worldwide
• Focus on developing innovative medicines for patients with life-threatening illnesses

CHALLENGES
This life sciences organization outgrew its current application as an off-the-shelf system for Investigator Sponsored Research. That system could no longer implement the full range of necessary processes, or accommodate their ongoing need to scale up capabilities. Their current capacity hindered their ability to move through processes quickly and thoroughly. In the absence of the right technology tools that provided the appropriate flexibility, stakeholders instead were forced to perform more manual workarounds.

The existing solution’s deficiencies included:
• Tracking and reporting challenges and lack of dashboards
• Lack of intuitive UI
• No single place to capture and review communications
• Lack of end-to-end integrations with other systems

RESULTS
While searching for a comprehensive solution, the organization evaluated over a dozen COTS and Platform vendors. They selected Appian for its ability to rapidly meet all of the desired requirements.

Using Appian, this group was able to deliver a flexible, scalable system that met their user requirements, including leveraging their active directory through single sign-on and multi-factor authentication for security and compliance. They also implemented mobile applications on both iOS and Android, natively, without additional development efforts while supporting flexibility for offsite work—especially important during the COVID-19 pandemic.

The Appian Platform built solution promotes collaboration across stakeholders including medical affairs, finance, and clinical operations, helping this organization to easily work and interact with investigators.

APPLICATION GOALS
The organization had a list of specific core capabilities necessary for application implementation and maintenance, with the ultimate goal of best serving stakeholders and ultimately their patients. With this same point of prioritizing patient needs, this process focused on accelerating product to market for their products. The desired core capabilities included:
• Web forms
• Enhanced user interface
• Dynamic workflow for task and user assignments
• Mobile enabled
• Ability to integrate with other systems’ infrastructure and to drive end-to-end visibility and transparency

GOAL FOR THIS APPLICATION INCLUDED:

<table>
<thead>
<tr>
<th>Goal</th>
<th>Description</th>
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<tbody>
<tr>
<td>Government compliance across the globe</td>
<td>Consistent process implementation globally</td>
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<tr>
<td>Functionality to support evolving business needs</td>
<td>Easy-to-use high functionality for evolving business</td>
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<tr>
<td>Easy to integrate with current systems</td>
<td>Cost effective implementation and maintenance</td>
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</table>
**Use Cases for Life Sciences: Investigator Sponsored Research**

<table>
<thead>
<tr>
<th>Discovery</th>
<th>Pre-Clinical</th>
<th>Clinical Trials</th>
<th>Regulatory Review</th>
<th>Scale-up &amp; Mfg.</th>
<th>Commercial Launch</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>PHASE I</td>
<td>PHASE II</td>
<td>PHASE III</td>
<td>PHASE IV</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clinical Operations (6 CROs)</td>
<td>Pharmacovigilance</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Chemistry Manufacturing Controls (CMC)</td>
<td>Regulatory Operations</td>
<td></td>
<td></td>
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<tr>
<td>3 - 6 Years</td>
<td>6 - 7 Years</td>
<td>18-24 Months</td>
<td>0.5 - 2 Years</td>
<td>Indefinite</td>
<td></td>
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**Clinical Operations**
- Site Initiation — Readiness — Effectiveness
- Study Start Up, “1572” IP (Green Light), Global CRO Contracts, Pre-approval Inspection

**Chemistry Manufacturing Controls (CMC)**
- High Throughput Experiment Tracking, Global Compound Ordering, LIMS

**Regulatory Operations**
- 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**

**HR**
- On Boarding, Recruiting

**Appian Existing Applications**

**Clinical**

**CMC**

**Regulatory**

**PV**

**Compliance**

**Commercial**

**IT**

**HR**

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**NINE OF THE WORLD’S TOP 10 LARGEST DRUG AND BIOTECH COMPANIES TRUST APPIAN**

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**Appian**

Appian provides a low-code automation platform that accelerates the creation of high-impact business applications. Many of the world’s largest organizations use Appian solutions to improve customer experience, achieve operational excellence, and simplify global risk management and compliance.

For more information, visit [www.appian.com](http://www.appian.com)

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