Appian

Study Start-Up Pressures Demand Transformative Technology

Pharmaceutical companies face intense financial pressures due to looming patent expirations on blockbuster drugs, weak drug pipelines, and heightened competition. This is forcing companies to explore alternative ways to achieve financial targets and better manage pipeline objectives. Improving operational efficiencies in clinical trials is one focus area which can shorten a new drug's time to market and reignite top-line growth.

Study Start-Up (SSU) is one of the most inefficient steps in the clinical trial process. Companies have invested heavily to shave weeks, days, and even hours from clinical trial timelines because of the potential financial impact. Yet, these efforts often hit a brick wall. Clear information and rapid, collaborative input is required to make appropriate decisions, but most pharmaceutical companies and clinical research organizations cannot get the necessary information and input in front of the right folks quick enough, putting them at undue risk. Why does this happen? Heavily siloed data, limited integrations, inconsistent standards across geographic boundaries and therapeutic categories, unreliable and highly variable processes, and complex, non-harmonized global regulations, among other reasons.

The net result is that SSU professionals are forced to work in inefficient and disjointed ways with lots of manual hand-offs and re-entry of data in places where automation should reign. For example, e-mail—exclusive by nature—is often the default collaboration tool, but rarely are all the right people included in a thread. Data required for regulatory reporting purposes is generally maintained in complicated spreadsheets, making it difficult to control versions and quickly produce SSU documents. These approaches bring with them increased risk of errors, lack of transparency and insight into the process, and limited analytic capabilities. Not surprisingly, SSU professionals usually waste hundreds of hours completing basic tasks with limited value added.

HOW SSU ORGANIZATIONS SHOULD FUNCTION

The very nature of SSU requires clear oversight, as well as fast action with a high degree of accuracy. Study impacts continually emerge with the potential of delays. Managers must have a complete understanding of the full volume of activity to quickly spot trends and raise alerts. People who can share relevant information must automatically be made aware of situations where they can contribute, whether or not others include them in communications. Issues that require reporting to the various regulatory bodies must be submitted in the format each regulator requires, which currently demands considerable manual effort.

The cost of not having great collaboration and timely information are multi-fold. Inefficiency of SSU staff—often highly trained professionals—is extremely costly. SSU information not handled appropriately, not reported in a timely manner, and not properly researched exposes the organization to regulatory impacts, as well as loss of precious time to market. Effective technology that can ensure proper

placement of information in the right hands at the proper time and facilitate maximum collaboration can make an enormous impact on getting a drug to market faster, putting critical treatments in the hands of caregivers for the sake of their patients.

THE APPIAN APPLICATION PLATFORM: THE NEW BACKBONE FOR STUDY START-UP

Appian is an application platform that allows organizations to create their own process- and data- based apps and integrate them with existing IT systems. Appian has roots in business process management (BPM) and has greatly expanded those concepts to include native mobile access, process-based collaboration, and unified records. Life sciences companies are using Appian technology to automate their unique processes and streamline everything from knowledge management in clinical research, to FCPA and Sunshine Act compliance, to clinical trials. The most advanced life sciences companies are using Appian as an interface to a variety of existing apps, as well as a platform for developing new apps that eliminate the gaps that cause manual work.

Here are some of the specific ways Appian has been used to transform SSU initiatives:

- **Real-Time access to study status details –** Minimize manual activities and duplicate entries while reducing risk of errors or inaccurate data through process automation. Automate the import of study information coming from multiple sources suitable for reporting purposes (Form 1572, Lab Documents, IRB Approval Letter, etc.).
- **Automate SSU task management –** Appian applications can be created to eliminate any "white spaces" between existing IT systems that SSU teams use. These white spaces result in manual work processes, which are difficult to track and impossible for managers to see clearly. Our complete audit trails and automatic software documentation protect the organization.
- **Increase SSU activity visibility –** With all work processes tracked and managed, providing a 360-degree view of all SSU activity requires just a simple report, which can be viewed from any mobile device just as easily as from a computer screen. This gives executives insight at any time to identify process inefficiencies and bottlenecks. Users can drill down through reports to see more detail and be better informed on the spot.
- **Standardize SSU processes with local variations –** Appian allows the organization to have one application that enforces efficient processes and SOPs across multiple geographies and therapeutic areas, while still allowing customization for unique local situations. Business rules are enforced and exceptions are documented.
- **Enhance collaboration –** Process steps can trigger push notifications to Appian's news feed, as well as individuals that require information on a SSU event. And, it all happens automatically based on role in an inclusive interface for communication and collaboration, without a need for email interaction. The same interface may be used to gather knowledge and take direct action, speeding up cycle times.
- **Unified records of any SSU element –** With Appian, information—for example, an SSU element like a compound, incident, or compelling event—is converged with a click from across systems to a single, drillable summary. With Appian, complete and current information is always immediately available when it is needed.

Appian is uniquely positioned to provide the technology solutions SSU organizations need to stay ahead of increasing demands and changing requirements to achieve shortened time to market.