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
ever amount 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 envelope 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.

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.

For more information, visit www.appian.com