goBalto ™

activate

the smarter, faster way to start

your clinical trial on the web

oncology study startup
cycle time

case study

![goBalto Activate logo]

Activate reduces cycle times

Removing guesswork from the study startup process and proactively using role-based handoffs to identify bottlenecks leads to greater efficiency and reduced cycle times

This case study covers a multinational pharmaceutical company. Focused solely on healthcare, its portfolio covers medicines, eye care products, generic pharmaceuticals, consumer health products, preventive vaccines, and diagnostic tools.

The mission

The pharma company's goals are to discover, develop, and successfully market innovate products that prevent and cure diseases, ease suffering, and enhance the quality of life. Their strategic priorities are innovation, growth, and productivity.

To achieve their corporate goals and strategic priorities, the customer implemented Activate to innovate, reduce cycle times, and increase efficiencies for a business unit within their Oncology division.

The scope

The customer started with 2 studies and 47 sites. After this successful pilot, they moved to full implementation for all of their U.S. studies, representing all sites and staff. The implementation was led by their regulatory document management team that is responsible for:

- Managing regulatory documents required for study startup and maintenance

- Distributing, collecting, and achieving approval of regulatory docs

- Facilitating IRB approval via central and/or local IRB

- Working with internal partners on the drug release and HA submission process

- Managing the electronic trial master file over the course of the study

type

an oncology division of a top 3, global healthcare organization operating in 140 countries

the challenges

- no automated task assignment
- heavy reliance on manual progress reports using spreadsheets
- no view of work in progress or real-time study startup status
- no mechanism for identifying bottlenecks
- stalled progress on corporate productivity goals

the benefits

- reduce study startup time
- know startup progress at a glance and in real-time
- enable tracking of high-level milestones for reporting
- enable process improvement

The company used go**Balto**'s Activate, a web-based study startup tool that automates key startup tasks from site identification through activation. Activate is hosted in the cloud, so it's deployed without involving IT staff to install, configure, or support the application. Each member of the startup team was issued a Activate account, then granted access to the study based on each member's role and need to access study data.

Instead of relying on to-do lists and spreadsheets to determine what tasks to complete, they used Activate's alerts-based workflows to gain better visibility into which activities were next, and the status of outstanding activities. Having status so readily available made it easier and faster to assemble progress reports. Bottlenecks at the site level were easier to identify and resolve.

Activate automatically records when tasks were started and completed. It also displays the real-time status to show each site's progress, negating the need to compile and distribute status reports to study staff and management.

These reports for all levels of oversight allow study team members and senior management to identify bottlenecks and lagging indicators. This enables teams to manage and account for document-level issues.

The results

After being live with Activate for just 8 months, the customer experienced an overall **32% reduction** in their study startup time (in weeks).

Activate is a single source of truth with seamless handoffs, individual real-time accountability, and configurable processes with full IT support

	Activate	customer's system	improvement
essential documents received from sites	17	30	43%
contracts and budget complete	3.5	4.2	17%
sites ready to receive IP	21	33	36%
Total	41.5	67.2	32%

Over the course of their implementation, the customer noted several other benefits to using Activate as their study startup solution.

- They gained real-time, transparent information with a single source of truth for all staff.

- Activate provided access to startup progress and data; since they did not own their existing system, they could not make necessary changes or updates.

- There were frequent system outages in their legacy system with no alerts for downtime; with Activate, there was no downtime.

- Role-based handoffs enabled them to identify bottlenecks.

- With Activate, there was greater granularity in reporting and tracking cycle times and study milestones.

- Tracking of high-level milestones allowed for reporting to study teams and senior management.

Conclusion

Activate improves study startup accuracy, reduces cycle times, and evolves behavior away from team and personal tracking spreadsheets. It provides easy to use and actionable progress reports, and improves communication. By allowing multiple functions to simultaneously work within a single platform, Activate lets every study member know what work needs to happen next, and accounts for the full SSU life cycle from FPP to SIV.

For more information

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About go**Balto**

go**Balto** develops web-based solutions that simplify how clinical trials are conducted in pharmaceutical, biotechnology, and medical device industries. Activate is the purpose-built Software as a Service clinical research platform that enables clinical trial sponsors to collaborate with multiple partners directly from the web, in a transparent and regulatory-compliant way.