goBalto™

activate

the smarter, faster way to start your clinical trial on the web

case study

case study

Purpose-built tools shorten study startup time

Using purpose-built tools to track and manage document exchanges and other study startup tasks results in reduced activation times

A full service clinical research organization (CRO) provides high-quality Phase I - IV clinical trial support to the world's pharmaceutical, biotechnology, and medical device companies. With staff worldwide and experience in a variety of therapeutic specialities, the CRO starts over 20 studies annually.

Too much tracking — too little time

The CRO's study startup process begins with site identification and concludes when sites are activated. They exchange budgets, contracts, and regulatory documents with sites using a variety of methods including fax, mail, and email. To track startup progress, CRO staff enter the dates that tasks were initiated and completed into a CTMS.

type

contract research organization with employees in multiple countries

Each week CRO staff compile data into reports so that management can track and evaluate startup progress. Key questions that management tries to answer with the data include:

- Which documents have sites completed?
- How are sites progressing towards activation?
- Where are the bottlenecks?

the challenge

managing study startup is manual and time-consuming

Using spreadsheet report data, their benchmarks for startup times show it takes 106 days to complete the following tasks:

- Identify sites
- Execute confidentiality agreement
- Determine site feasibility
- Conduct pre-study and site initiation visits
- Negotiate budget and contract
- Collect regulatory documents
- Receive IRB/EC approval

the benefits

- exchange documents in a compliant, secure manner
- eliminate spreadsheets and manual tracking
- know startup progress at a glance and in real-time
- shorten activation time

The goal is to increase operational efficiencies and cut costs, using a purpose-built, real-time, workflow management and study startup tool that streamlines and automates tasks.

Activate use during a 3-month pilot study

A pilot study was conducted to determine if using a purpose-built study startup tool to exchange study documents and track other tasks speeds site activation. They hypothesized that using a startup tool could reduce startup time by 17%.

The company used go**Balto**'s Activate, a web-based study startup tool that automates key startup tasks from site identification through activation and facilitates secure document exchanges over the web. 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 sensitive study data.

The staff then used Activate to send email study invitations and track site acceptance. Sites who accepted the invitation received a free account to access the Activate portal.

Instead of exchanging documents by email or other methods, they posted the documents into Activate for each site to download at the appropriate time. By posting documents to Activate's library, they were able to automate many document tasks and reduce staff involvement.

Activate is an alerts-based workflow system that notifies sponsors and sites when to post or review documents or perform other tasks. It also sends real-time or daily digest notifications by email so that CRO and site staff can always know that tasks are due.

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.

Activation time shortened

At the conclusion of the study, the CRO exported task completion times from Activate and compared those times to the average task times experienced when performing tasks using legacy methods (email, fax, etc). **Table A** shows the time it took (in days) for each site to complete tasks compared to the average legacy method.

TABLE A: Time to complete startup tasks (in days)

	Feasibility	PSV	Reg docs	IRB/EC
legacy method	10.0	14.0	28.0	31.0
with Activate	9.5	5.9	19.6	29.1
time saved	0.5	8.1	8.4	1.9

The results show a significant time savings compared to legacy methods (see **Tables B-F** in the appendix for the percentage savings for each workflow step). Overall, the average time savings was 22% (exceeding the hypothesized 17% savings) and a reduction in total time of 8.4 days.

Conclusion

Purpose-built systems for study startup shorten overall site activation times, resulting in quicker time-to-market. For every day that a blockbuster drug isn't on the market, approximately 1 million dollars in revenue is lost along with potentially thousands of lives.

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™, launched in June 2011, is the first purpose-built Software-as-a-Service clinical research tool that enables clinical trial sponsors to collaborate with multiple partners directly from the web in a transparent and regulatory-compliant manner.

Appendix: Task completion times

These tables show task completion times for specific steps in the startup workflow.

TABLE B: Feasibility

Target estimate:	10 days
Min. time:	2.3 days
Max. time:	13 days
Avg. time:	9.5 days
Avg. percentage savings:	5%

TABLE C: Budgets

Target estimate:	28 days
Min. time:	4.7 days
Max. time:	34.7 days
Avg. time:	17.3 days
Avg. percentage savings:	38%

TABLE D: Contracts

Target estimate:	28 days
Min. time:	10.8 days
Max. time:	27.6 days
Avg time:	14.5 days
Avg percentage savings:	48%

TABLE E: Reg docs

Target estimate:	28 days
Avg time:	19.6 days
Avg percentage savings:	30%

TABLE F: Feasibility, budget, and contract steps

Target estimate:	38 days
Min. time:	15.1 days
Max. time:	43.7 days
Avg time:	29.5 days
Avg percentage savings:	22%