



goBalto™

Starting a clinical trial? You probably track site and country activation tasks and documents using a clunky spreadsheet, expensive 3rd-party application, or cumbersome internal solution. Why do we continue to settle for confusing and overpriced tools? **Not anymore.**

“smart” workflows and automation

Activate, goBalto’s flagship product, provides workflows that guide study teams to



complete and track specific documents and tasks required for any site, country, or study based on your SOPs or internal processes. With over 60 standardized country workflows to choose from, we’ll get your study up and running fast. Configure Activate to track any activity, document, submission, even ad-hoc documents that you receive unexpectedly. Activate also has workflows that track protocol amendments and quality reviews and with our recent release, the ability to track expiring documents.

streamlined document management

- **Study library:** Share study documents from a centralized library with study countries and sites. Activities that depend on study documents, such as translations and reg packs, are automatically triggered to enable task automation, study-wide or within specific countries.
- **Document lineage:** For any document that’s derived from a study-level document, you can see the lineage and know you’re working with the right file. If your organization stores files on a shared drive, just enter the URL or path.
- **Submission and IP release (green light) packages:** Select any study, country, or site document to include in an IP release review or submission package, then track status. Activate also provides an audit trail of each packages.
- **Expiring document management:** Use Activate to manage expiring documents. Just enter the date a document is expected to expire and Activate tracks them so you can proactively request new documents from sites. Your organization chooses when the notification occurs; 30, 60, 120, or any number of days before expiration.

collaborate with sites and partners

The entire study team sees the baseline, planned, and actual dates for key milestones on Activate’s study country and site level timelines. Change a date in a way that impacts other milestones, and Activate lets you know.

Exchange documents and notes, complete activities, and monitor status. Sites who don’t want the burden of managing another login can use Activate LITE to complete activities. Now everyone sees the status of documents and packages, what’s due, and what’s been communicated.

co-exists with your existing systems

Import study, country, and site information from your investigator database into Activate, and at closeout, export all documents, metrics, dates, and study communications to your CTMS or eTMF.

reports and metrics provide actionable data to accelerate startup

Activate records when each task starts and completes. No need to compile status reports — everyone sees real-time study progress on their Activate dashboard. Critical path tracking reports show which activities prevent key milestones from being met so that you can quickly resolve bottlenecks.



Analyze, our reporting module, is a best-in-class tool that enables you to interact with your data, run ad-hoc reports, and create visualizations across multiple trials as part of your clinical study startup monitoring strategy.



Use Analyze to share Activate data with your study team and external partners. Anyone you grant access can subscribe to regular report updates and view them in Analyze or in an email.

Smart, customizable processes

Workflows can be customized to reflect your SOPs.

- Create workflows that support your document review and approval process
- Re-use workflows for other studies
- Perform an activity only when all pre-requisites are met (Dependencies)
- Assign team members to manage tasks and activities
- Specify and track documents and sites for each submission or IP release review package
- Record notes about sites, documents, and submissions then save them as part of a site or country record

Actionable reports and metrics

The entire study team sees study status on their Activate dashboard, in real-time across sites.

- Gain new metrics and insights into your study team's performance by tracking tasks and completion times for each activity
- Sponsors can benchmark CRO(s) performance via visually rich dashboards
- Quickly determine status and milestones with visual timelines, at risk indicators, charts, and graphs
- View study country and site timelines for baseline, projected, and actual dates of key global milestones
- Use country manager and sponsor reports to view global milestone status and drill down into the details
- Print reports or export to a spreadsheet
- View entire, consolidated startup history, accessible by the entire study team
- See at a glance which activities haven't started, are in-progress, or are activated
- See all activities in one convenient place
- See which team members are assigned to a site or country
- Create custom reports and visualizations
- Subscribe to reports by email

Streamlined document management

Documents can be shared and tracked across teams.

- Share study documents with some or all study countries and automate downstream activities
- Store documents in an easily accessible study repository for convenient anytime, anywhere access
- Specify a document location for access to external file systems
- See documents required for each country and site
- Manage protocol amendments
- See source of derived documents (document lineage)
- Track expiring documents (enter expire dates and manage from a listing)



Alerts

Alerts help organize the work and let you know when it's time to take action.

- Full audit trails and traceability.
- Single sign-on for secure, controlled access management

Safety and compliance

System requirements

Activate is hosted in the cloud and runs on multiple Internet browsers: Internet Explorer 9+, Firefox, Safari, and Chrome.

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