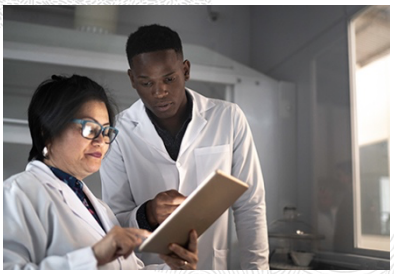
ORACLE

Activate

Driving site activation



Accelerating site startup can jump-start a clinical trial, but with the hours and weeks spent manually tracking tasks and documents and without visibility into where the bottlenecks lie, how can you make that happen?

Improve operational performance

Study teams are under intense pressure to speed clinical trials and restrain costs, but inefficiencies tied to complicated protocols, globalization, and paper-based methods have stalled these efforts. Oracle Health Sciences Activate Cloud Service (Activate) improves operational efficiencies with real-time monitoring of items on the critical path to ensure key milestones are met.
With Activate, you can:

- Leverage more than 70 standardized country workflows for quick site activation
- Track any activity, document, submission, or ad-hoc documents
- Drive optimization with role-based assignments and dependency triggers
- Enhance planning with predictive capabilities that guide team members in milestone planning activities
- Utilize multi-plan comparison and visualization tools to scenario plan optimal study setup

Streamline document management

The "old way" of using email, spreadsheets, and e-rooms to track documents and activities associated with activating study sites does not work for today's clinical trials. Study teams need real-time access to documents and automated, compliant workflows.
Activate lets you:

- Know you're working with the right file with document lineage
- Select documents for IP release reviews or submission packages
- Proactively request new documents prior to expiry with alerts

"Activate's robust, industry-proven library of country-specific workflows and management-based approach to site activation is central to our efforts to build out our infrastructure of 'best of breed' applications in our eClinical suite. Using a workflow-based approach to study startup, critical indicators of quality can be assessed on an ongoing basis so that corrective actions, if needed, can be made earlier."

MIKE TOWNLEY
CIO, CLINIPACE

Activate streamlines and automates study startup, cutting cycle time by over 30 percent.

Easily access actionable data

When a clinical trial does not unfold as planned, it may be heading for rescue. The key to avoiding study rescue is proper identification of red flags signaling a study may be veering off course.

Activate provides:

- Real-time study progress reporting that provides transparency and highlights opportunities ripe for optimization
- Critical path tracking reports that show which activities delay key milestones
- Alerts that notify study team members when pre-requisite work is completed

Drive collaboration and deliver compliance

Sponsors often have multiple studies running concurrently with multiple CROs, complicating oversight. Having open and transparent communications across all your trial partners is critical, but this is difficult when you're tied to slow, manual processes. Foster open communication and trust with Activate by:

- Providing a centralized view of all assigned study team members
- Exchanging documents, notes, and completed activities
- Monitoring partners' status with audit trail reporting
- Ensuring compliance with organizational SOPs and country-specific regulations

Automated Workflow

Intelligent workflows drive study teams to complete and track specific documents and tasks required for any site, country, or study based on regulatory requirements and standard operating procedures.

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