Polaris
a QuintilesIMS company

Investigator Initiated Studies Management

Manage the ongoing process of investigator initiated studies and internal research

Polaris delivers full process automation from concept submission to final report.

Our Investigator Initiated Studies (IIS) platform provides configurable forms and flexible workflows to automate all steps in the research process. Polaris' solution supports all countries, currencies and languages and complies with global research and data privacy requirements.

- **Global best-in class compliant processes**
  Delivers a consistent and integrated process for submission, review, decision and ongoing management of research studies, while also following global compliance research requirements and guidelines.

- **Lifecycle management of multi-year and multi-site studies**
  Provides global visibility into studies and their status with ongoing study update submission to track progress, enrollment and payments.

- **Business analytics, intelligence and reporting**
  Allows transparency of funding across the global organization. Operational, financial, strategic and compliance reporting is available to provide extensive process and spend reporting capabilities, with the ability to pivot on country, therapeutic area, product and other data points of interest.

Our IIS system provides a scalable, global platform for the funding and tracking of internal and external research:

- Online registration of all investigators and submission for all types of research requests
- Electronic review and approval of requests including validation of required questions and documentation
- Centralized online repository for research agreements and expiration tracking
- Detailed budget definition with Fair Market Value
- Capture of Study Startup information such as IND Status, IRB Approval, Pharmacy License and additional site information
- Ongoing study management to track timeline, enrollment and to confirm when a milestone is satisfied
- Submission of the Final Study Report, IRB Closure Notice and draft publication for review prior to final payment release

End-to-end process automation

From registration to the final report, our time-tested technology benefits your organization by providing an efficient, transparent and compliant process:

Registration and request submission

- Capture key organization and investigator information including financial/affiliation disclosures, license information, medical specialty and degrees
- Require documentation that confirms the Requestor's identity such as tax documents and investigator CVs
- Select various research types such as Interventional, Observational and Preclinical, Concept or Full Protocol
- Enter general study information, protocol design elements, detailed budget and supporting documentation

Approvals and ongoing study management

- Automated additional information requests allow the applicant to edit fields requiring an update
- Configurable approval groups based on geography, therapeutic area and product
- Store critical documentation for compliant research execution
- Regular reminder emails are sent to the investigator to ensure timely submission of update reports
- Milestone payment tracking and forecasting in addition to drug shipment tracking for distribution of product

Trial conclusion and reconciliations

- Auto generated notifications to submit final study deliverables
- Electronic routing and review by key stakeholders of final study deliverables
- Final payment withheld until all required study deliverables are confirmed complete

Data analytics and transparency reporting

- Business-user-friendly ad-hoc reporting and chart generation
- Strategic reports to illustrate number of studies submitted, approved, and ongoing in various geographies and for the different therapeutic areas, products and indications
- Financial reports to forecast milestone payments by month or quarter
- Operational reports to illustrate performance bottlenecks and process gaps
- Compliance reports to show key indicators and track expiration of key research documents to help identify potential compliance issues

Technology and Software Solutions • Insightful Guidance • Confident Compliance

About Polaris

Polaris, a QuintilesIMS company, is the world's leading software and consulting firm, providing innovative, quality end-to-end solutions to Life Sciences companies.

Uniquely focused solely on the Life Sciences industry, Polaris delivers best-in-class solutions for today's toughest compliance challenges. The firm's services range from comprehensive technology and software solutions to expert consulting, strategy and planning, as well as end-to-end managed services and data analytics. Since 2001, the world's most recognized pharmaceutical, biotech and medical device companies have relied on Polaris as their trusted Life Sciences compliance solutions partner.

Learn more about all of Polaris solutions:

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