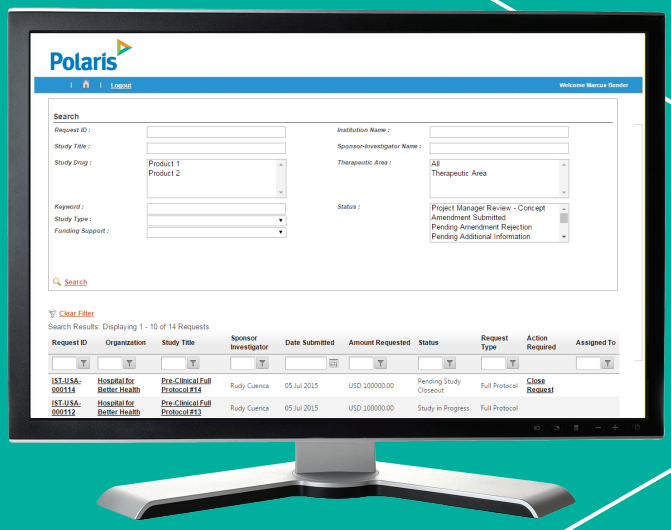
Polaris

Managing Investigator Initiated Studies & Trials

Polaris offers an online portal that manages the initial submission and ongoing process of investigator initiated studies and internal research. This portal supports both small and large volume research environments.

Our IIS platform provides flexible approval flows including configurable business rules and automation of key steps in a company's research process. Polaris' solution supports a global process, can be setup to support all major languages and currencies and is compliant with all global research study and data privacy requirements.



Polaris IIS Portal provides the following strategic advantages

- **Global best-in class - compliant processes**

  Provides consistent and efficient process for submission, review and ongoing management of research studies. Follows global compliance research requirements and guidelines.

- **Lifecycle management of large volume of multi-year and multi-country studies**

  Provides global visibility in studies and their progress, with timely submission of study updates to track on-time progress and enrollment. Tracks and manages requests for monetary funding and product.

- **Provies Business analytics, intelligence and reporting**

  Provides transparency of funding across the global organization. Includes transparency reporting requirements, and provides extensive reporting capabilities on process and spend.

Polaris' IIS System provides a scalable, global platform for the funding and tracking of research. The solution provides:

- Online registration of all Investigators and submissions of various research requests
- Electronic review and approval of request including validation of require documentation
- Online research agreements and expiration tracking
- Conctracting for all study types
- Fair Market Value FMV and budget definition
- Milestone progress tracking
- Online capture of study updates for milestones and enrollments including final reports
- Automated submission of study results to local authorities and transparency reporting

See reverse to learn more. ▶

Accountability. No Matter What.

End-to-End Process Automation

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

Registration and request submission

- Capture all investigator organization information and their qualifications, including financial/affiliation disclosures, license information, medical specialty, and degrees
- Create a global database of requested and approved studies, by investigator and/or internal applicant
- Facilitate concept to full protocol workflow including the capture of a detailed line-item budgets which can be used for FMV assessment
- Upload key documentation like organization tax documents and investigator CVs

Approvals, status updates, and milestones

- Additional information requests are automated only allowing the investigator/applicant to edit fields requiring an update
- Configurable approval groups based on geography, therapeutic area, and product
- Critical documentation is required and expiration date tracked for the research agreement, IND (if necessary), and various IRB/EC documents
- Regular reminder emails are sent to the investigator to ensure timely submission of update reports
- Milestone payment tracking and forecasting in addition to supply chain management for the distribution of product

Trial conclusion and reconciliations

- Auto generated notifications to submit final study deliverables
- Electronic routing and review by key stakeholders
- 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 and process bottlenecks
- Compliance reports to show key indicators and track expiration of key research documents

About Polaris

Polaris helps Pharmaceutical, Biotech and Medical Device Companies to be compliant with laws and regulations in and outside the US. We provide best in class solutions, that keep our clients competitive.

The world's most recognizable life sciences companies rely on us to achieve their goals, to add value to their bottom lines and to always know what's next. With proven global expertise in providing insightful consulting, strategic business process optimization and technology solutions, Polaris is the world's leader in innovative, end-to-end compliance services for life sciences companies. Only Polaris specializes exclusively in consulting and technology solutions for life sciences healthcare law compliance so we are uniquely positioned to assist our customers to increase efficiency, mitigate risk and improve patient safety.

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