



Checklist for selecting a registry solution

Registries are powerful tools for generating real-world evidence.

With registry data, device manufacturers can demonstrate the unique competitive advantages of their products in large patient populations and get a head start on long-range regulatory endeavors. This makes registries a major investment. Knowing what to consider when selecting a patient registry software therefore means weighing a host of factors – usability, technical capabilities, security aspects, and usefulness for answering complex research questions.

To support the considerations that go into this process, the following checklist compiles the major technical and functional features that support not only successful start-up but also the prolonged viability of your patient registry.

Functions		Description
Data management and quality		
☐	Flexible database design	Design highly customizable eCRFs and ePROs for gathering treatment, demographic, and long-term outcome data.
☐	Medical image data management	Securely upload, transfer, and store medical images (X-ray, CT, ultrasound, etc.) in DICOM format with HIPAA- and GDPR-compliant automatic image de-identification.
☐	Unlimited database size	Expand your database to support scalability for large-scale, longitudinal data collection.

☐	Automated data structuring for retrospective analysis	Structure clinical data into an organized format fully automatically to support retrospective analysis and reduce the effort needed to understand study results
☐	Intuitive query management and resolution tool	Query for patient demographic information, missing data, and easily resolve open queries with sites via chat function.

Data analysis

☐	Advanced medical image analysis	Gain rich insights into device performance with the latest advancements in highly precise, validated, automated image analysis by a renowned Imaging Core Lab .
☐	Complete, consistent data for publications	Demonstrate the efficacy, safety, and validity of products derived from registry insights to larger scientific audiences.
☐	Network of radiologists	Evaluate qualitative indicators of device performance with access to expert radiologists and KOLs.
☐	Robust reporting	Answer complex research questions with robust reports, including customizable display of data completeness, radiographic parameter values, and registry milestones.

Technical features	Description
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Interface

☐	Web-based interface	Enable data collection from diverse patient populations. Include sites of varying technical capacity with a readily available, reliable web-based interface.
☐	Multilingual questionnaires and user interface	Reduce language barriers with multilingual questionnaires that enable capture of patient data with no variation in user experience.
☐	Automatic e-mail notifications	Send push notifications to sites and patients about upcoming questionnaires, images, and study progress.

☐	Site-level EHR extraction via FHIR HL7 v2, v3	For large-scale data collection: optional secure extraction of EHR data from healthcare providers' systems, providing a complete and accurate representation of a patient's medical history.
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Security

☐	Automatic image de-identification	Remove all protected health information from DICOM files with browser-based image de-identification to ensure compliance with HIPAA and GDPR requirements.
☐	Role-based access	Implement restricted access to patient data and imaging data based on the user's role and responsibilities.
☐	Audit trail	Log all actions, changes, data entries, and approvals in an immutable, internal audit trail, including user, data, and time stamps.
☐	Data protection	Ensure maximum data protection with encrypted data storage that meets all international information security standards and regulatory requirements (e.g., ISO 27001, ISO 13485, 21 CFR part 11, HIPAA, GDPR, GCP)

If you have any questions, please do not hesitate to contact us: sales@raylytic.com