RAYLYTIC
The AI healthtech company

# 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. |

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| ☐ | **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** |
| **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.** |

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| ☐ | **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.** |
| **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:**
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