EICON ECG

A comprehensive data management solution for Clinical Trials ECG data addressing the needs of the pharmaceutical industry, Clinical Research Organizations/Core Labs and regulatory agencies. Study Workflows for Clinical Trials ECGs. Data collection. Data QC and storage. Data Review. XML/ASCII Reconciliation. Export to FDA Data Warehouse. Export for AI analysis. And much more.

Key Features:

- Workflow:
  - Create/Manage Study
    - Assign Data Access Control
    - Assign Data Quality Control using templated QC specifications
  - Upload Data (**EICON FLOW** or **EICON COLLECT**)
    - Upload ASCII
    - Upload XML
  - Storage
    - Store source XML for eventual regulatory submission
    - Parse and store constituent data and metadata to support review, assessment and analysis of ECGs
  - Data Reconciliation
    - Verify consistency of ASCII (Case Report Form) and XML (aECG XML).
    - Verify correctness of calculations and derived values
    - Provide reconciliation feedback loop with third party data provider
  - Download/Export.
- ECG Data Review
  - Standard set of data review reports for ASCII and XML data
  - ECG Viewer – browser based ECG Viewer with measurements, findings and interpretations
  - Export to ECG Workstation
- Security: multi-level, as follows
  - Integrate with Single Signon. Alternatively, use standard User ID/Password.
  - Encryption of ECG data in transit and at rest
  - Role-based system access control using a user/role/transaction matrix
  - Study-level data access controls
- Configurability

  - Specification of QC templates for ASCII and XML data
  - Specification of Data Mapping templates to verify formats of all uploaded ECG data
  - Management of external Organizations, their Domains, Findings, etc
- Submission to FDA Warehouse
- Regulatory Compliance

Key Benefits:

- Early data Access for review and decision support
- Enable submission of ECG data to FDA Warehouse
- Reconcile all Core Lab data feeds and verify consistency between aECG XML data and CRF ASCII data, including derived measurements
- Facilitate AI analysis of the data using either EICON-based or third-party algorithms