

EICON (REACH) COLLECT

EICON COLLECT simplifies the collection, storage, and management of clinical trials data from external partners/ third parties. **EICON COLLECT** is a specific configuration of the **EICON REACH** product (see full description, below).

EICON REACH is designed to generically facilitate 'Edge Computing'. It uses a hub-andspoke architecture, with a Cloud-based HUB at the center and a set of distributed Clinical Access Nodes (CANs) at the edge.

A set of capabilities ("assets") that comprehensively address the business case – in this case, data collection – are provided on the HUB, and are distributed from the HUB for execution on the remote target locations (CANs). Control of the CANs remains within the HUB while execution of the data collection function is performed on the remote CAN.

Key Features:

- Simplify. At the Core Lab/CRO, a folder is designated into which the Core Lab/CRO will copy data that are ready for upload to the Sponsor. The CAN includes a Folder Watcher that senses the data in the folder and sends it in realtime to the HUB.
- Central control. All data collection is fully configured and managed in the EICON HUB.
- Flexibility. Each CAN is configured individually to address the specific topology of the third party whose data are to be collected using that particular CAN.
- Each CAN is deployed adjacent to the data source
- > Once the CAN has been deployed, it can operate independently of the HUB
- Data flow from the data source to the CAN to the HUB
- Storage. The EICON COLLECT HUB can be configured to store the uploaded data using one of the following additional options:
 - Data can be automatically stored into existing back-end systems using system APIs, where they exist. (Out of the box integrations are included for EICON RADIOLOGY and EICON ECG).
 - A simple storage solution is available for data for which no storage/ management solution is currently available. (This will typically be implemented as part of a solution that includes EICON SEARCH, so that stored data can be indexed, searched, found, and reviewed.)
- Notes on Technology:
 - All components of this solution are containerized (Docker)

IBIS

- Comprehensive Security
- Data upload is fully automated
- Full control over communication model configurable to allow requests to originate only from HUB or only from CAN
- Regulatory Compliance

Key Features (additional options):

- Data QC. Quality specifications can be configured on the HUB and executed on the CAN. If a file fails a QC check, it is not uploaded, and the CRO/Core Lab is notified of the failure.
- EICON SEARCH can be integrated with EICON COLLECT and used to index all data collected into a common OpenSearch metadata repository for search and review.

Key Benefits:

- Model for the future. A single, uniform architecture enables the Sponsor to remove all complexity from the third-party data upload operation.
- Consistency across data types and data sources. A single, centrally controlled solution for all data upload operations.
- The separation of management from execution and the high level of configurability makes this an extremely scalable solution that can easily be adapted for enterprise-level data integrations with external partners.

UNDERLYING TECHNOLOGY

EICON REACH is an implementation of 'Edge Computing'. It uses a hub-and-spoke architecture, with a Cloud-based control Module (HUB) at the center and a set of distributed Clinical Access Nodes (CANs) at the edge. **EICON REACH** provides Cloud-based control over remote environments with minimal intrusion and maximum flexibility. All workflows, configurations, rules, business and technical processes are maintained in the HUB in a single, consistent, extensible set of "assets". Control and execution of these assets on remote CANs is fully managed from the Cloud-based HUB.

Design Goals for EICON REACH: Maximize versatility, configurability and extensibility; minimize complexity for the user; simplify deployment; assure strong security and scalability.

Overview / Key Components: EICON REACH consists of three major components:

- 1. A library of assets for configurations, workflows, rules, dataflows, business/technical processes, etc., which are created, stored and managed in the Cloud
- 2. A containerized Cloud-based Control Module (HUB), and
- 3. Any number of Clinical Access Node (CAN) containers, i.e., remote clients.

A secure API is used for all communication between HUB and CAN.

The HUB has access to all assets in the central store and is used to configure CANs, download CANs to target environments, associate assets with CANs, and manage the execution of assets on CANs.



EICON REACH Control Module (HUB)

EICON REACH Clinical Access Node (CAN)

Here is the architecture for a single CAN. There will typically be more than one, possibly many, CANs associated with each Control Module/HUB.



Additional Notes

- The Remote Communications/Access Node (CAN) is designed to be minimally "smart". Its purpose is to receive and execute instructions from the HUB. This enables us to model and manage the remote CAN's behavior without changing anything on the CAN itself.
- For the current set of EICON REACH-based solutions, all configurations, workflows, transformations, rules, etc. are set up by IBIS. In the future, there may be some exceptional situations that require a particular customer-specific capability on the CAN that is not configurable on the Cloud environment. This will need to be included as part of the CAN Docker image.
- CAN-based activity, logs and audit trail are communicated back to the HUB from the CAN, stored in a repository and presented to the user on the system UI.
- A CAN's access to the local file system is controlled in the docker-compose configuration.