

ERS CESIL™ for Meaningful Re-Use of EHR data

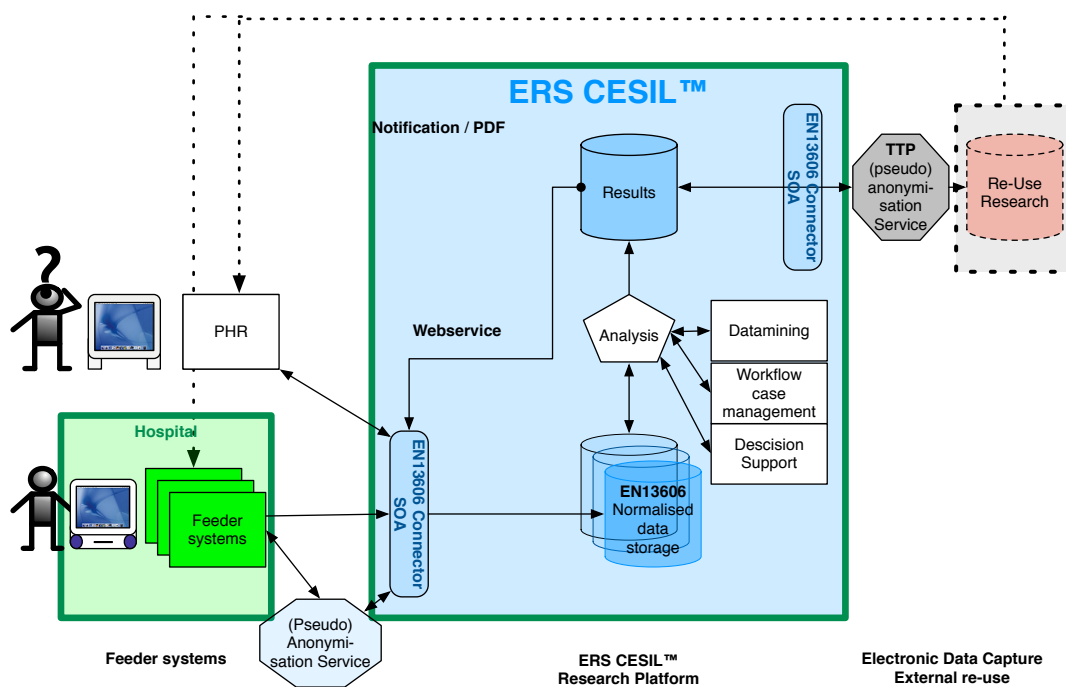
Hospital and regional health information systems must provide first of all the basic facilities for documentation of the provision of healthcare.

In addition this documented information can (and must) be re-used for clinical research, key performance indicators, obligatory reporting to disease registries but foremost to the support of collaborating healthcare providers. The data and information stored in the context of the care process is re-used in these other contexts.

Patients, healthcare providers and their organisations will reap benefits beyond financial incentives—such as reduction in errors, availability of records and data, reminders and alerts, clinical decision support, monitoring on the safety of drugs and e-prescribing/refill automation.

Meaningful use for EHR data is the term coined in the USA for all these expected and wished features of future e-Health systems.

ERS CESIL™ technology connects proprietary e-Health systems fast, flexibly and cost efficient.



ERS CESIL™ as technological solution

The ERS Cross Enterprise Semantic Interoperability Layer (CESIL™) is a CEN/ISO 13606 standards based middleware solution for persistence and communication. The CESIL™ acts as a fully scalable integration platform per enterprise and cross enterprise through federation, data warehouse and mediation system to third party solution.

It can be deployed for: data mining, clinical pathways, key performance indicator reporting, local, regional national or cross border patient summary (e.g. epSOS connector) and research.

ERS CESIL™ as research platform

The CESIL™ is in this brochure positioned as a Research Platform based on the CEN/ISO 13606 EHRcom standard.

This ERS CESIL™ platform sits between feeder systems in hospitals and systems for Electronic Data Capture (EDC) as deployed by the pharmaceutical industries for clinical research.

ERS CESIL™ collects data from feeder systems and transforms it into a normalized format. This normalized data is stored and can be transformed again into any format such as for instance the CDISC ODM format that the EDC-system can process further.

The CEN/ISO 13606 standard allows a very cost-effective way of collecting data from feeder systems and transformation in any format the recipient site needs and vice-versa.

In addition the ERS CESIL™ technology makes it possible to generate input and output screens in an extremely flexible way to support seamless integration with eCRF's and/or EDC-systems. The investigator can validate data used in the study collected from his feeder systems without re-typing and signing the data off for export to the EDC-platform.

The normalized data in the ERS CESIL™ research database (data warehouse) is available for other applications or services such as those for protocol feasibility and design testing, recruitment of patients, sites yield testing, clinical decision support, case management, (pseudo-)anonymisation services, remote monitoring, sending investigators alerts, etc.

Observe that an application or service that is conformant to this CEN/ISO 13606 standard is 'plug-and-play' connectable to the CESIL™. The CESIL™ Platform is a standards based neutral platform that makes it possible to create a research infrastructure at each site where competing vendors can write software for alike the Apple App-Store platform.

ERS CESIL™: Key characteristics

The ERS CESIL™ research platform has several key characteristics:

- ERS CESIL™ retrieves and transforms legacy data to and from the standardized format (CEN/ISO 13606).
- ERS CESIL™ stores and archives data in the research database in a normalized and configurable way to meet ethical, legal and regulatory requirements.
- ERS CESIL™ supports the creation of any screen form (CRF). Together with a connected Case Management service (EDC system) a complete study can be executed.
- ERS CESIL™ creates a platform with normalized data where other software services from other vendors can be used.
- ERS CESIL™ allows that study data can be monitored remotely.

ERS CESIL™: Added value for clinical research

Once installed the ERS CESIL™ research platform will have the following effects:

- Better protocol design because more information is known about study related patient data availability.
- Less protocol amendments because of better protocol design and planning.
- Better patient recruitment by querying existing data with inclusion and exclusion criteria resulting in improved hit rates in screening and a reduced attrition rate.
- Reduction of the re-typing of already digital available data.
- Better data quality since data from feeder systems are used directly (e.g. patient demographics, diagnosis, medication, lab results, etc.).
- Less queries for data cleansing, less typing errors, less site visits for source verification.
- Less premature study site closures with its effects on costs and extended study timelines.

ERS CESIL™: Business case for clinical results

Next to the reduction in study operational costs, the number of days needed to conclude a study will decrease, as the time between First Patient First Visit and Last Patient First Visit (recruitment phase) will be reduced. Also the time between Last Patient Last Visit and Database Closure can be reduced, due to less queries needed for data cleansing.

ERS CESIL™ allows for querying patient data by defining a set of rules in a simple-to-use editor. Such query functionality services can be used for i.e. study feasibility & protocol design, patient recruitment, high yield sites identification etc.

Services like these will increase study efficiency by reduction of study duration: improved patient recruitment with lower number of patients screened (improved hit rate) and patients better suited for the study protocol (reduced attrition rate).

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