



Projection® Electronic Data Capture

EDC vs IDC (Intuitive Data Capture)

Projection® EDC is a full web based platform for capturing data. The interface is easy to use and friendly; it requires no installation (thin client) and can be use everywhere where an internet connection is available.

Projection® EDC is so easy to use that it requires a very short training. Data are organized as a paper CRF: a list of patients as a stack of CRFs, each patient CRF containing pages organized by visit.

Quality of data collected

Projection® EDC combines simplicity and quality. Data entry is structured by fields' formats (number, date, string, upper case, limited selection by list boxes or drop down menus.

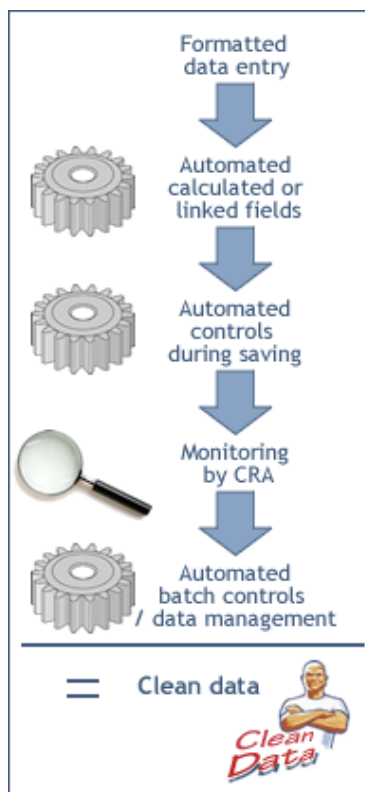
Data are controlled in real-time and tracked. Data can be controlled from zero to three times depending on targeted data quality:

- level 1: interactive and automated controls: usually non blocking warnings.
- level 2: monitoring, the CRAs can query the investigator and suggest an answer. Monitoring queries are accessible directly from the CRF and linked to the original data in or outside the context.
- level 3: batch controls (data management). Investigators can manage data management queries as monitoring queries.

Each field is associated with a "specify kind of missing value" selector which permit to select if data is :

- Not applicable,
- Not available,
- Unknown.

System controls empty fields and triggers a warning message if a field stays empty.



Integrated monitoring

Projection® EDC provides integrated monitoring functionalities:

- manual queries by CRAs,
- follow-up of status:
 - pages / data to control,
 - pages / data controlled with or without queries,
 - pages signed by the investigator,
- follow-up of answered queries: page / data to re-control after modification by the investigator,
- management of protocol deviations,
- management of SDV report,
- ...

Regulatory compliance

Projection® EDC is compliant with 21CFR Part 11 rules.

Data transmissions are encrypted through a SSL connection. All actions are monitored and logged (full audit trail).

Projection® EDC includes electronic signature.

All modules of Projection® System are validated.

Optional modules

Some modules can be implemented with Projection® EDC:

- IWRS module: give randomization capabilities,
- Drug management module: permit management of drug supply and logistic,
- eTMF module: manages sites documents,
- eLearning: permits clinicians training,
- ...

Arone's services

Arone can provides services around the eCRF:

- hosting
- training
- support
- CRF design
- data management

Technical requirements

Projection® EDC works as well on Windows or Mac OS computers. It runs on the most popular web browsers: Microsoft Internet Explorer, Mozilla Firefox, Apple Safari, Opera, Google Chrome...

Reporting capabilities, printing capabilities, alert capabilities

Projection® EDC includes standard or specific reports. Reports are accessible from menu or pushed by email. Some are triggered on specific events (new patient, randomization, Serious Adverse Event (SAE)...).

- Patients CRF can be printed or generated in PDF format.
- Data can be exported in CSV format.

Alerts can be triggered on specific events. Thus can be send by email, fax, SMS...

Alerts and E2B export ensure a best transmission of SAEs to authorities and the timeliness of reporting.

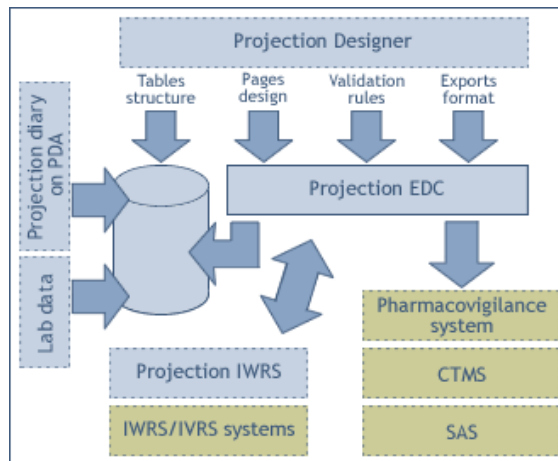
Security

Projection® EDC is fully secured. Users must be identified to connect to the system. Each user inherits the rights of his profile. Each user can have more or less rights on patients: read, write, ask queries... he can access more or less patients regarding his the site or the country of the patient.

Interface

Projection® EDC can be linked to external clinical trials systems like:

- Interactive Web Randomization Systems (IWRS) or Interactive Voice Randomization Systems (IVRS),
- pharmacovigilance systems (through E2B export),
- Clinical Trial Management Systems (CTMS),
- GED,
- ...



Multi-lingual interface

Projection® EDC core can be setup in English or French. Patient CRF can be shown by the clinician in his local language.

Data management

The Projection® system helps data manager. It provides in the same tool (the Projection® Designer):

- a CRF designer tool,
- a tool to program controls,
- a tool to setup export structure to SAS software.

It generates a report which can be included in the Data Handling Manual including the data structure with tables, panels, variables description and code lists.

The Projection® EDC can be connected to existents control programs (written in SAS for example) by queries loading.

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