EOL ©, a 100% internet eCRF software package which is operational within weeks and compliant with industry guidelines for clinical research.

The biomedical research sector has already adopted electronic CRF; now simple, robust software validated under 21 CFR Part 11, with secure hosting is required.

EOL©, a comprehensive and affordable software package

EOL© is a multilingual AND <u>highly customizable</u> eCRF package for managing <u>interventional and observational studies</u>, which is suitable for academic research, manufacturers of medicines, medical devices, cosmetic products and food and CROs; for a small fee, EOL© allows you to conduct <u>single or multi-sites</u> studies autonomously and with up to several thousand patients.

EOL© is also used for registries, cohorts, and patients quality of life surveys.

EOL© includes several modules:
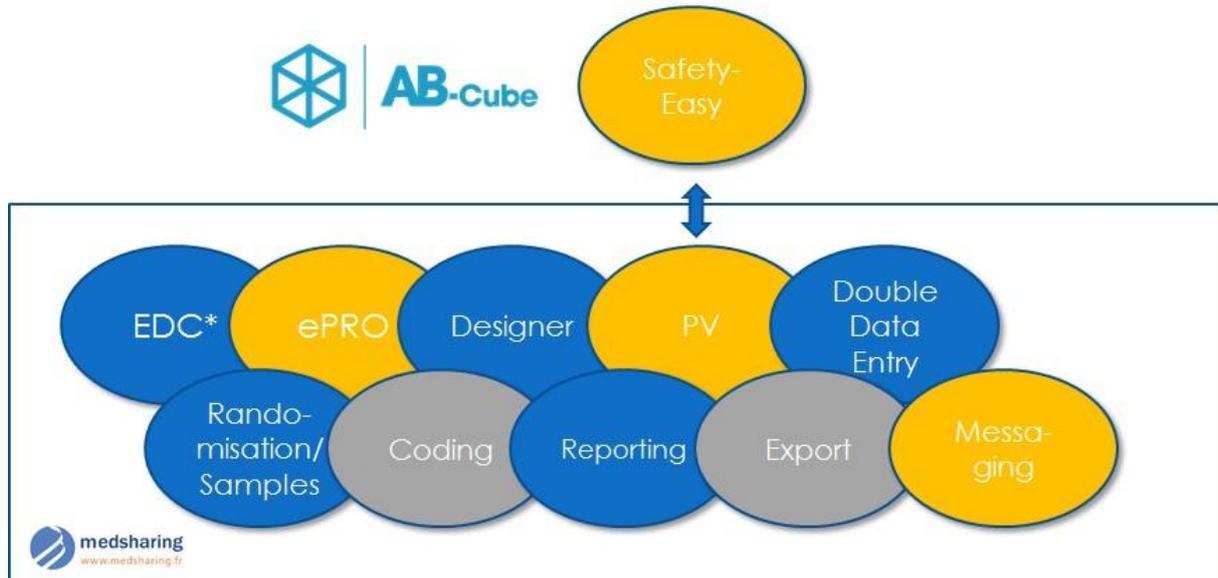
EOL© allows you to <u>design and configure the CRF and execute the randomisation and the samples allocation</u>. Clinical Research Assistants (CRAs), Clinical Study Technicians (CSTs) and investigators at sites can then <u>enter data online</u>. We can also design and configure studies for you with the involvement of your teams, with our iterative methodology.

We supply a <u>test and training environment</u> free-of-charge for each deployment.
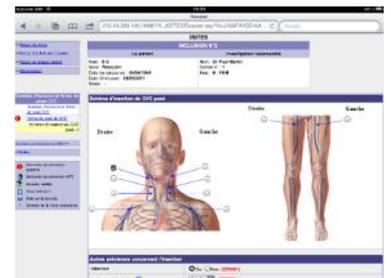
*EDC: Electronic Data Capture

Ready to go in two weeks - a responsive culture

Being a 100% internet software package, EOL© does not need to be installed on your machines. Consequently, deployment times are short (one or two weeks) and budgets are kept down.
The price is a fixed charge that includes common maintenance requests. We acknowledge your requests for changes within a day and resolve them in two days on average.

EOL© may be accessed from any device including tablets or smartphones. It is compatible with all available browsers.

Compliance with regulatory guidelines and secure hosting of medical data

Validated under 21 CFR Part 11, our software package is hosted in France by Claranet-Grita, a company approved by the Ministry of Health for medical data.
It is compliant with regulatory guidelines on matters such as the audit trail for data and electronic signatures.

IWRS and IVRS randomisation

Randomisation can be used as an autonomous module, or integrated in the eCRF. It can be performed via the web, phone, or an iPhone or iPad based on an algorithm or a list that you provide.

You can trial our 'Randomizer for Clinical Trial for iPad/iPhone' application free of charge. It can be downloaded from the App Store.

Standard analyses and data export

Analyses and inclusion tracking are available as standard in EOL©. Moreover, you can export data yourself for subsequent analysis in SAS, Excel or any other analysis software on the market.
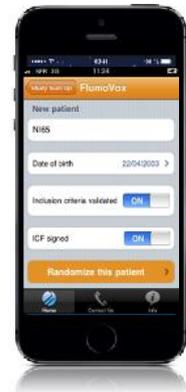
Interface with the main dictionaries on the market and with Safety-Easy Database

An interface with the market's main dictionaries is available (already set up for customers with MedDRA, Theriaque, Medic'AM dictionaries and the CTCAE dictionary for adverse events). We provide also an interface with Safety-Easy pharmacovigilance database from AB Cube (http://www.ab-cube.com/en/). Safety-Easy is used by over 100 organisations in Europe.

About Medsharing
Medsharing was set up in 2000. Based in France with a multidisciplinary team, it has developed expertise in 100% internet SaaS software. Medsharing has been ISO 9001:2008 certified for several years. Its EOL© software package was first developed in 2004 at the initiative of a hospital physician and has since been used in over 120 European interventional and observational studies. Some of our customer references and testimonials can be found at medsharing.fr.

Contact
Tel.: +33 (0)1 48 75 39 14
info@medsharing.fr
www.medsharing.fr

medsharing
partager pour réussir