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

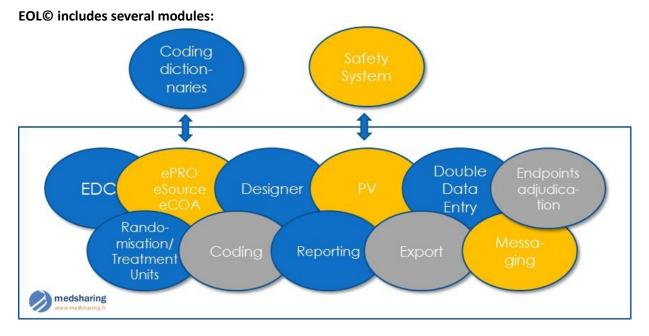
The biomedical research sector has already adopted electronic CRF; now simple, robust software validated under 21 CFR Part 11, with secure hosting is required.

## EOLC, a comprehensive and affordable software package

EOL© is a multilingual and <u>highly customizable</u> solution for managing <u>interventional and observational studies</u>; for a small fee, EOL© allows you to conduct <u>single or multi-sites</u> studies autonomously and with up to several thousand patients. You can have an unlimited number of site users.

You configure the CRF once, and EOL© can generate automatically an eCRF, an <u>eSource</u>, an <u>eCOA</u>, or a <u>Patient's Diary</u>. Hence it is well suited for <u>registries</u>, <u>cohorts</u>, <u>and patient's quality of life surveys</u>. It adapts to any screen type and size, see picture on the right. eCRF amendments can be done on the fly, without the need for an IT expert.

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Information		
Study name		Barotox
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Number of subject		90
Riccishe		4
Randomization follow up		
Privet serviced		6
A+Euro/Vax		8
B - Caralie		
Numberleh		45
	Fondomization list	•)
	Randomize a new patient	•
	2	



EOL© allows you to <u>design and configure the CRF and execute the randomisation and</u> <u>the treatment units 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

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## Ready to go in two weeks - a responsive culture

Being a 100% internet software package, EOL<sup>©</sup> does not need to be installed on your machines. Consequently, <u>deployment times are short</u> (one or two weeks) and budgets are kept down.

The <u>price is a fixed charge</u> 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 <u>tablets or smartphones</u>. It is compatible with <u>all available</u> <u>browsers</u>. The user experience can be improved by using scales or <u>interactive images</u> (see image supra).

#### Compliance with regulatory guidelines and secure hosting of medical data

Validated under 21 CFR Part 11, our software package is hosted in France by OVH, a company approved by the Ministry of Health for <u>medical data</u>.

It is compliant with regulatory guidelines on matters such as the <u>audit trail</u> for data and <u>electronic signatures</u>.

## **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. It can include <u>treatment unit management</u>.

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, Interpanel reports and data export

Analyses and inclusion tracking are available as standard in EOL©, allowing for Clinical Trial Management and Monitoring. Moreover, you can export data yourself for subsequent analysis in SAS, Excel or any other analysis software on the market. Interpanel reports are possible.

#### Interface with the main dictionaries on the market

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).

#### **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 <u>ISO 9001:2015</u> 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 160 European interventional and observational studies. Some of our customer references and testimonials can be found at medsharing.fr.

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