

why ease of use is so important in real world studies

Getting real world data means dragging a wide net. The picture is only complete if it includes as many people as possible, both doctors and patients.

The doctors are, of course, very busy. On top of this they don't all take part in clinical trials and haven't learnt to use clinical trials software.

They do, however, all use the internet for shopping, banking and other real-life activities.

From the doctor's point of view, there's no reason why the chore of entering data should be any more difficult than booking a holiday, and they don't need training to do that.

If your edc system is easy, you cut training costs and your doctors are happy. You cut down on data queries and you have less chasing-up to do because data entry, although still a chore, is not a frustration.

And you can go further. Your edc system isn't just an edc system - it's a web site. You can share study information with doctors, build a community and get them involved.

It doesn't need to be difficult.
It's real life data we want - why turn your study into a trial?

cisiv

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online from start to finish

design

design, document and review in a shared online environment

prototype

get prototypes on demand to see how your edc will work

collect

capture data easily through an intuitive edc system

communicate

engage investigators through an online web portal

manage

control your study through a full-featured management portal, supported by our experienced service team

real life is not a trial

baseline plus: web technology for real-world studies

cisiv
edc for real life

baseline designer



baseline designer is a shared online environment for study design and definition. It produces documentation and eCRF prototypes and allows review and sign-off online, reducing cost, saving time and increasing efficiency.

baseline plus



baseline plus edc has a unique workflow which captures high quality data easily and efficiently. Edit checks control data quality at the point of entry and subsequent queries are managed online with a full audit trail. You can set up local country variations quickly and cost-effectively and it has a module for paper data entry for studies where you need to use paper CRFs.

baseline portal



baseline portal embeds the eCRF in a study web site for the investigators. It can provide access to publications, reports, newsletters and other communications as well as FAQs and live study status charts.

baseline manager



baseline manager provides comprehensive study management through role-based access to features which include automated quality control, study status reports, registration, email and SMS reminders, query management and monitoring tools.

international features



baseline plus is used in large scale international studies and has a range of features to make these studies run efficiently.

Built-in support for local protocol variations and local language translation allows you to tailor the eCRF to the requirements of specific countries. A hierarchical user account structure provides separation between the international and local study management, so that everyone gets access to the most relevant reports, data and study management tools. The communication portal merges international information with local information, ensuring that investigators see an entirely relevant set of news, publications and messages.

about cisiv

cisiv has worked closely with leading pharmaceutical companies for over 10 years developing collaborative web software for use in post-approval activities.

baseline plus was developed to meet the need to capture essential real world data in an international setting. Its aim was to keep data quality levels high through data entry rules and automated queries whilst keeping data entry easy and intuitive, essential in large, long-term non-interventional studies with low levels of monitoring.

In our latest releases we're better still. **baseline plus** maximises the opportunities provided by the internet to engage investigators in the study, improving retention and data flow. It has been used in projects across the world since 2003.

“ **baseline plus** provides you with a flexible, cost effective, quick to implement and very easy to use edc system for non-expert users. ”

what is baseline plus?

baseline plus is a suite of innovative web-based tools specifically developed for the design, data capture and management of non-interventional studies.

It has been designed to capture real world patient data quickly, accurately and easily whilst providing real-time study management information to study managers and sponsors.

baseline plus simplifies data entry with an intuitive workflow which makes completing an eCRF as easy as shopping online. Its powerful rules engine, combined with a data entry sequence designed for non-interventional studies, produces high quality data with reduced queries, allowing you to extract meaningful interim data sets from early in the study. It has a comprehensive range of study management tools providing complete control of study status, queries and monitoring.

baseline plus provides you with a flexible, cost-effective, quick to implement and very easy to use EDC system for non-expert users.

at a glance

- edc designed specifically for non-interventional studies
- very low training overheads
- high investigator acceptance
- high quality data, low numbers of queries
- scalable from one site to thousands of sites
- rapid study setup
- on-demand access to data
- international support for local languages and protocols

examples of studies

baseline plus is used in studies run in over 20 countries with thousands of investigators delivering data for both reimbursement and safety data required as a condition of license.

Studies are built by our development team and supported by our service team, all of whom have extensive product and study experience and are committed to delivering you a highly responsive and flexible service.

	international			local
countries	19	21	9	1
sites	1,570	3,000	200	20
patients	10,000	20,000	830	180
purpose	HTA	safety	HTA	HTA