

dotforms™ - paperbased EDC

Shortcomings of EDC

The industry has been discussing the introduction of EDC into trial workflow for 15 years. Despite this, most trials carried out worldwide are still paper-based. This conservatism has to do with the shortcomings of EDC: high investment thresholds for online data entry hardware and software, high investigator learning curve, and not least the fact that EDC trials have proven to create an environment that inhibits intimate interviewing of the patient. It is difficult to communicate when there is a screen between the investigator and the patient. Thus, the central tool for EDC is also the central impediment to broad acceptance.

Of course, we do not deny certain benefits of EDC such as online plausibility checks. But we also see the long time frame needed for the preparation and design of databases, the necessary investment in hard- and software, technical problems and last but not least a certain aversion of investigators to act as data capture personnel.

PharmaForms introduces a perfect synthesis of the benefits of both, paper and electronic means. We have called it dotforms™.

Paper-based EDC

The industry makes claims for easy, quick, cheap and digital trials. We make good on these claims with dotforms™. This is a new technology approach to clinical trials with all the benefits of electronic data capture, but without the notorious shortcomings of screen and keyboard solutions.

Dotforms™ use pen and paper as the interface for your trial documentation, just as your investigators are accustomed to. But now your documentation is digital and electronically transferable, processable and archivable. We make paper become an input device.

How it works: Replace ordinary paper with dotforms™ and ordinary ballpoint pens with digital pens, and you're online. That's all there is to it! Our digital pen reads while writing, stores data and connects to an transmitting device when ticking the send box. A minute later the data management is able to have a look on the completed CRF page and can start data processing.

The Paper

The Swedish Anoto Group developed the functionality that makes dotforms™ a digital interface. Dotforms™ have two components: pen and paper.

Starting with paper: The layout looks like a regular preprinted CRF with checkboxes, spreadsheets, scales and commentary fields.

In the background there is a nearly-invisible dot pattern with a resolution of 0.3 square mm. This dot pattern gives the pen orientation and helps to identify the page. Due to a very specific coding procedure, there is a space of different dot patterns available, that covers the surface of Europe and Asia totally.

PharmaForms is the first certified print provider in Germany that is allowed to print this sophisticated pattern.

The Pen

A digital pen interacts with the IR-reflective dot pattern to read what you write or draw as digital vector graphics, and store them in its memory. Whenever you check a send-box at the bottom of the page, the pen sends the information to the PharmaForms' webserver via a connected USB cradle or Bluetooth-enabled mobile phone. There, we identify the corresponding page with the help of the dot pattern and make the information your investigator entered onto the dotforms™- CRF readable.

Seconds after you initiate synchronisation by checking the send-box on the paper form, you receive the completed form as an email attachment to the addresses you give us. Ask us for detailed information about the technology and its benefits.

Dotforms™ Services

Using dotforms™, your trial results will be available instantaneously and globally on the computers of your choice based on PharmaForms' dotforms™ services.

PharmaForms makes the pen strokes visible and provide you with the scanned pages. We detect manipulation on handwritten data and highlight later corrections made by patient or investigator due to a timestamp feature. Even the investigator's signature can be checked.

And that's not all. Because of the vector-based (and thus digital) format of your notes, Handwriting Recognition (HWR) software can identify your information reliably and translate it into computer data for straight entry into your database for statistical processing and preparation for your findings.

Dotforms™ significantly accelerate data circulation and data processing.

Dotforms™ Benefits

Dotforms™ give you all the advantages of barcode-based archiving and tracking systems, namely: Traceability, archivability, simultaneous monitoring, simultaneous and location independent processing, preparation of your data for e-CTD.

But dotforms™ also go far beyond this rather traditional semi-digital system:

- Significant reduction of handling costs

- Significant time savings

- Utmost transmission security

- Automatic data entry into database

- Complete automation of data transfer

- Avoidance of multipart NCR-pages

- Instantaneous distribution of electronic pages

- EDC at no-network-locations via mobile (e.g. patient diaries)

- And finally: happy trial investigators!

Getting Started

Dotforms™ will enhance the effectiveness of your data and document flow, and ultimately save money. Calculate the costs and compare them to the benefits, using a realistic time frame, and see for yourself. Let us know if you need help. We would love to open new vistas on the opportunities and benefits of implementing dotforms™ into your existing workflow.

PharmaForms provides you with digital pens and paper and, of course, with dotforms™ services.

Please ask for more details at dotforms@pharmaforms.com !