

Electronic Data Capture (EDC) for clinical trials, post marketing surveillance studies and patient registries

Electronic Data Capture (EDC) is the state of the art technology to improve the clinical development process and data management over all phases of the Life Cycle of a pharmaceutical product. EDC refers to data collection in an electronic form that can be delivered or uploaded in real time via Web-based transmission.

Business Case and Issues

Phase I – III clinical trials: One of the key objectives of Clinical Operations is to keep clinical development time as short as possible while maintaining or increasing data quality. Part of the solution is EDC, as a considerable amount of time during clinical development is spent on data cleaning. In clinical studies, well planned EDC allows for a reduction in queries while improving data quality, avoids double data entry and shortens study closure timelines.

Post Marketing Studies / Safety Surveillance Projects / Patient Registries: Phase IV studies to corroborate a marketing message or generate data for further claims are often part of the pharmaceutical product marketing strategy. These studies should reach a large target group while being at the same time easy from a logistics stand point and cost efficient. Pharmaceutical companies face a similar situation with Safety Surveillance Studies or Patient Registries, more and more requested by Health Authorities as part of the condition to get the product license.

Modern web-based EDC systems allow companies to implement such large-scale projects in a cost efficient manner, while addressing marketing and regulatory objectives.

Patient reported outcomes: Development of medication in certain therapeutic areas requires the reporting of data by patients. Studies show that paper and pencil reporting by patient is less than satisfactory as compliance (e.g. time point of data collection) is low. Health Authorities are therefore prefer, if not request, the use of EDC (e.g. electronic patient diaries) for patient reported outcomes.

Capabilities and Experiences of IBR AG

IBR AG has worked in the area of EDC since 1995. Projects carried out include:

- Planning and implementation of a worldwide Phase IV study with over 20'000 patients, on-line data access for physicians and an analysis tool for the evaluation of local data.
- Design and implementation of a post-approval safety surveillance study for a product prone to cause liver adverse events. EDC was used for this study requested by the Health Authorities.
- Transfer of large paper based patient registry to EDC to reduce the number of queries and operational costs consequently. One of the first large scale registries in Europe that used EDC technology.
- Setting up and deployment of phase IV study using patient diaries (PDAs) for patient reported outcomes

Services

You may expect from us:

- Planning and management of your project
- Evaluation of technology and vendor appropriate for your special needs
- Vendor and budget management
- Consulting in technical and regulatory aspects relevant to EDC
- Concept to assure validation of hardware and software
- Hands on day to day project support

Benefits of partnering with IBR AG

Working with IBR AG lets you take advantage of experience gained over years with a multitude of successful projects in the area of Electronic Data Capture. You will work with professionals with years of experience in the pharmaceutical industry and information technology, professionals who are well aware that EDC is not only a question of technology only, but above all a question of people and processes

Outlook

Electronic Data Capture for clinical studies, safety surveillance projects and patient reported outcomes, is only one, although important step, in the direction of modern trials management. Other e-applications of relevance include:

- Electronic Medical Records
- Electronic Source Documentation
- Protocol Development
- Patient Recruitment via the Internet
- Electronic Submission of Regulatory Documents