End-users and patients have the first and last say

CONTRACT RESEARCH OPIS promotes patient-centred thinking with a portfolio of user-centred solutions to optimize clinical trial management.

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Designing products or developing services in a framework of processes where needs, wants and even limitations of end-users take the centre stage is not a new concept. It is called User-centred design (UCD) or User-driven development (UDD) and can be characterised as a multi-stage problem solving process that not only requires designers to analyse and foresee how users are likely to use a product, but also to test the validity of their assumptions with regard to user behaviour in real world tests.

The chief difference from other product or service design philosophies is that user-centred design tries to optimise the product or service around how users can, want, or need to use the product, rather than forcing the users to change their behaviour to accommodate the product. Smartphone producers are doing it, airlines are doing it, and even delivery services are doing it. Healthcare and pharma companies are no exception and it is evident that voices of their end-users, i.e. patients, are no longer ignored. A whirlwind is sweeping through the industry and more than ever, patients are at the forefront of future thinking.

Patient-centred thinking

The pharmaceutical industry is ready to embrace the possibility of connecting all clinical stakeholders to benefit patients. The process is facilitated by

OPIS
A personal touch.

renewed Principal Investigator awareness and by initiatives of patient associations and nursing agencies – this is fundamental for homecare services especially in orphan drug and paediatric indications where every patient counts. Connecting all these players can be accomplished through a user-friendly digital platform.

Furthermore, clinical study protocols are ideally built and based on pa-

The OPIS suite of clinical trial solutions supports patient-centred thinking with user-centred design.

tient input. The biometry and medical writing departments draft study material that is as patient and user-friendly as possible and for the first time, OPIS has recently collected informed consent form signatures electronically in a clinical trial.

So, to no surprise, it is technology driving this transformation. Electronic Medical Records or digital versions of patient charts are facilitating data tracking and record-keeping. It is a known fact that user-driven development is steering patient education. The creation of on-line patient communities and social media platforms to spread information about disease and therapeutic possibilities also helps to promote clinical trial awareness.

For medical research, gathering patient insights has the potential to assist outcome-driven innovation and create breakthrough products and services. It is only a matter of time until patient involvement in drug development processes becomes standard practice.

EDC and trial design with an end-user approach

At OPIS, user-centred design is a philosophy and the company is continuously striving to optimise its services around what their end-users want and need. As an e-Clinical service provider, OPIS is committed to providing Sponsors with EDC solutions that have the potential to enhance patient-centred drug development. Applied to clinical trials, the OPIS platform is designed with web-based patient data collection tools for ePRO (electronic patient reported outcomes) that measure symptoms, mental state or the effects of a disease and eCOA (electronic clinical outcome assessments) that are used to determine whether a drug provides a treatment benefit.

As a next step, OPIS is implementing wearables with digital applications to enhance patient experience in clinical trials.

COMPASS – compassionate use programmes

Medical professionals use the term "compassionate use" or "extended access" to refer to the treatment of a seriously ill patient using a new, unapproved drug when no other marketed treatments are available. Upon a medical practitioner's request, a Pharma company will enroll a patient in a compassionate use programme and provide the medication free of charge for the entire pre-market authorisation period. Ensuring patient safety is a priority, OPIS has just released an in-house developed e-product to manage workflow and processes related to compassionate use programmes very effectively.

Fully compliant with global, EU and local requirements, the independent, web-based, modular platform is accessible to password protected and profile specific users. Highly customisable and extremely user-friendly, the system allows for guided compilation of all documents and a validated audit trail tracks all processes. Other features include centralised document management with easy document upload, online reporting and a customisable report builder.

e-Clinical environment today

The e-Clinical environment today is all about EDC that provides patient-centred, data-driven, technological solutions that ensure on time and on budget execution of projects.

Providing sponsors with high-tech, user-centred solutions for clinical trials is what OPIS does best. ■

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Figure: OPIS