Upwardly Mobile

It is estimated that there will be more mobile devices than people on earth by 2015, so the empowering influence of this technology is inevitably hitting clinical R&D. *ICT* asks some key stakeholders for their views

The potential of using mobile technology, or mHealth, in clinical trials is quickly being realised as the industry explores ways of leveraging the familiar and personal nature of mobile phones to help find and retain patients to participate in studies.

Along with the opportunity to ensure patient retention and compliance, the integration of mobile devices in trial designs holds great promise for aligning site and patient needs with faster study execution and reduced expense.

Here, ICT *puts some of the industry's most pressing questions on mHealth in clinical R&D to a number of key figures in the industry who are speaking at the upcoming MCT-Congress in March 2015.*

Johann Proeve, Global Strategy and Development Advisor, Global Data Sciences and Analytics at Bayer HealthCare

What role can mobile technology play in the empowerment of patients in clinical research?

When taking a closer look at the mobile technology available today for patients in clinical trials, there are many different options. On the one hand, there is the simple way of using mobile phones to send messages about glucometer results or adverse events directly to the treating physician or investigator. This permits a quick reaction in order to improve the patient status.

Also, the patient themselves can use mobile technology to keep track of their health situation by recording their experiences via a questionnaire or a diary in a timely fashion, rather than two weeks later at the next doctor's visit. Such an approach reduces the recall bias and substantially improves data quality.

Furthermore, patients can use small, constantly wearable devices, such as Fitbits or Withings to record their heart rate, their activity level, the calories they burn, their length and quality of sleep, or even the oxygen saturation in the blood. These data are usually transferred directly to smartphone applications and can also be made available to an investigator on an ongoing basis.

All of the above mean that patients can now contribute data in real-time and more directly influence the outcome of clinical studies. However, the industry still requires further analysis of whether more patient-generated data truly means better and more useful data for the outcome of trials and the development of new drugs.

Dr Urs-Vito Albrecht, Deputy Director of the Medical Informatics Department at Hannover Medical School

What areas in clinical trials is mobile currently impacting?

We are currently in the early stages of implementing smart devices like smartphones and tablet-PCs in trials, and it will take additional time to determine how to best make safe and efficient use of this technology. These aspects are crucial for the success of the trial.

Ideally, mobile technologies can support the study participants, as well as study personnel – thereby allowing for synergisms that can potentially lead to improvements in patient safety, trial management, and the acquisition of reliable and relevant data.

Aside from providing a way for recruitment, mobile trial apps can play a role in studies where a large audience needs to be reached and the protocol permits unsupervised data entry by the participants. Examples include apps accompanying clinical trials that allow participants to easily enter updates about their current status or provide feedback. Reminders can be sent about trial visits or when to take medication, while disease management features can be provided that let patients become more involved and improve adherence to the study's regimen.

For clinicians, mobile technology can simplify the access to study information at the point of care. However, ensuring privacy, data security and usability is a must in order to make such apps a success.

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Craig Lipset, Head of Clinical Innovation at Pfizer

What are the real benefits of using mobile technology in clinical research for pharmaceutical sponsors?

Mobile is more than a trend – it is estimated that by the end of 2014, the number of mobile-connected devices will exceed the number of people on earth. It is increasingly the platform-of-choice for consumers and patients to engage with information, and innovators in the field are creating new and engaging apps and tools on a daily basis.

There are many opportunities for sponsors of clinical research to pursue to realise impact and value:

- Patient recruitment – approaches may include mobile-friendly websites, recruitment apps, and the use of QR codes on recruitment material
- Patient education and electronic informed consent – using tablets to improve education to complement the informed consent process with video and other media
- Patient retention and compliance – from SMS messages to apps to ensure information is always accessible, including investigational drug management, upcoming visit calendars, etc
- Impact for patient-reported outcomes (PROs) – including the potential efficiencies for patients and sponsors accepting PROs on a patient's own mobile device, also known as 'bring your own device' (BYOD)
- New opportunities for data capture – leveraging clinical-grade sensors and wearable devices for continuous and streaming data for deep phenotyping
- Improving trial convenience – drawing on the tools from telemedicine and secure use of video to allow access to a remote investigator
- Study team resources – tools including electronic binders, screeners, calculators and other information being made more accessible for investigators and coordinators
- Monitoring and field resources – providing increasingly sophisticated resources to improve monitoring time in the field, from efficiency tools to educational tools
- Supply chain – including robust and secure tracking of the supply chain through new bar-coding approaches

Some of these areas improve upon existing processes, while others create entirely new and unprecedented sources of data and information. The latter brings the potential for fresh development pathways – incorporating digital diagnostics which may define patient populations or complement therapy to improve outcomes, This will require change for all stakeholders, including sponsors, regulators, payers, providers and patients.

Marc Buyse, Founder of CluePoints

How can data quality be assessed when using mobile technology?

Using mobile technology to collect patient data provides huge potential benefits in terms of cost, speed and accuracy. Yet the quality of the data collected by this means must be checked more thoroughly than data coming from verifiable source documents. Centralised statistical monitoring (CSM) can be used to perform extensive analysis of the data – an approach that is especially well-suited to check data collected using mobile technology.

Remarkable findings of inadequate use of ePRO devices have been made in ongoing clinical trials analysed by this type of solution. In one study, the timing and sequence of entries for different patients revealed a case of fraud that would have been very hard to detect using traditional monitoring or simple data edit checks. The other benefit of using CSM is that the data coming from mobile technology are analysed in conjunction with all other clinical data, offering far more opportunities to spot issues than looking at these data in isolation.

Tim Davis, Chief Executive Officer at Exco InTouch

How is mobile technology helping to improve the accuracy and cost-efficiency of trials?

Mobile technology offers huge opportunities for clinical trials. The global growth of mobile ownership enables sponsors to implement BYOD strategies to engage patients and collect outcomes data from their personal mobile devices. This approach improves the accessibility, familiarity and usability of trial interaction and the investment associated with procurement, while logistics of specialised devices is significantly reduced, or even removed altogether.

The expectation we all have to communicate using mobile devices makes them the ideal platforms to keep in touch with patients and collect data from them – providing immediate access to outcomes data and the instant ability for investigators to be alerted of any non-compliance issues.

Maintaining contact through mobile devices enables content to be pushed out to patients, engaging them with the study and their treatment regimen. Using mobile technology also

A combination of barriers currently exists in the industry. First of all, clinical development has always been, and still is, a conservative sector. The pharma industry as a whole has been very successful in the last 50 years, and reluctance to change is higher than in other industries

allows sponsors to monitor compliance and intervene before patients are lost-to-follow-up.

The value of increased patient retention can have significant impact on trials in time and cost, so the use of in-app notifications, email and SMS messages to catch them before they disengage with a protocol is extremely effective.

Mobile technology is making it easier for patients to meet clinical trial obligations, and this results in fuller, more accurate datasets for analysis. Cost efficiencies can be measured both in terms of the savings achieved by improving trial processes and, more importantly, in reducing the time to first data entry and to database lock.

Valdo Arnera, General Manager Europe at PHT Corporation

What do you feel is currently the greatest barrier to the adoption of mobile technology in clinical research?

A combination of barriers currently exists in the industry. First of all, clinical development has always been, and still is, a conservative sector. The pharma industry as a whole has been very successful in the last 50 years, and reluctance to change is higher than in other industries.

The fear of regulatory authorities is the second factor, whether it is justified or not. A survey conducted 15 years ago asking what was the main concern for patients relating to the adoption of electronic diaries showed that the primary reason was the regulatory concern, even though at that time two EMA guidelines (for asthma and steroid contraceptives) recommended the use of electronic diaries. Since then, two guidance frameworks issued by the FDA have promoted the use of electronic data capture. But it is fair to say that there are still some unresolved challenges – for example, the difference in the screen size of patients using their own device to collect data in an unsupervised setting.

The third factor is clearly the cost, as the return on investment has not been always easy to demonstrate. However, pharma sponsors, having extensively assessed the cost comparison between paper and mobile technologies, have all come to the same conclusion that the latter is less expensive in the end.

Jeff Lee, Chief Executive Officer at mProve Health

In your opinion, what do the next five years holds for mHealth?

mHealth technologies look to transform how healthcare services are delivered and how patients manage their conditions. For this to happen, mHealth needs to extend beyond the early adopters and the 'quantified self-ers'. I believe this will happen as we see providers, employers and payers embracing mHealth technologies. For many of us, the motivation to change our health-related behaviour (diet, fitness, sleep) is extrinsic, relying on pressures from these outside parties.

In order for employers and payers to take up mHealth technologies, they need to be confident it will deliver meaningful benefits to healthcare outcomes. During the next five years, hundreds of longitudinal studies will begin to show whether/how mHealth programmes can make a positive impact.

In my view, segmenting an mHealth initiative, where patients are broken into sub-groups based on their psychological profile, will offer the best chance to drive positive behaviour change. Different people respond to different motivators. For instance, some patients respond to competition, while others prefer support from loved ones. The mHealth programmes that follow this segmentation will demonstrate the best outcomes and receive the most support from payers. Sensors will play a key role in this, as the data they provide allows the patient and the sponsor of the programme to better measure its adherence and results.

The last five years have represented significant growth of mHealth initiatives; I expect that the next five years will bring maturity and results to this field.

The above contributors will be part of the MCT-Congress 2015, an annual mHealth event taking place in Edinburgh on 24-25 March 2015. For further information, visit www.mct-congress.co.uk