

# NEW ERA OF HOME CARE

**Widespread use of electronic health records and new forms of data transmission could link patient care, clinical research and public health, revolutionising the way clinical trials are conducted. Phin Foster meets Mats Sundgren of AstraZeneca to discuss how such progress could dramatically alter the drug development landscape.**



**T**hink of clinical trials and one likely pictures a private ward, white lab coats and captive patients. The advantages of such an approach are clear: readily available onsite expertise, guaranteed harmonisation, consistency of delivery and the ability to monitor developments around the clock. However, the traditional approach is also labour intensive, expensive, poses recruitment difficulties and more often than not fails to fully leverage the expertise or address the questions of medical practitioners and other stakeholders within the healthcare sector.

Some believe that this will not be the case for long. ‘The future of clinical trials is going to change dramatically,’ declares Dr Mats Sundgren. ‘We will see concepts far more focused on patient interaction, involving real-life studies enabled by an array of health information technologies. The implications are huge.’

## Dealing in data

As principal scientist within global clinical development at AstraZeneca R&D, Sundgren believes the impact of new and adapted technologies can potentially transform the manner in which some studies are conducted. He has dedicated the past five years of a 22-year career in pharmaceutical development to information management strategies, including extensive study into how electronic health records (EHR) and data transmission can enhance medical research. The influence of new technologies in this area could be revolutionary.

‘Take a Phase IIA study in the area of diabetes with a limited number of patients,’ he begins. ‘We can conduct real-life and real-time monitoring of the glucose levels transmitted through sensors attached to mobile phones, surveyed by

## Contributor profile



Dr Mats Sundgren is a principal scientist in global clinical development, AstraZeneca R&D, focusing on implementing strategies for bridging health information technology with clinical research. He is leading the European Federation of Pharmaceutical Association’s Electronic Health Records task force and represents AZ in the Innovative Medicine Initiative.

medical centres and studied by us. We can follow the patient and perform the clinical trial without any need for patients to be onsite. Not only does that have major cost-saving implications, it also allows for the collection of far richer materials and enhanced evaluation.’

It is not only the pharmaceutical companies that will stand to profit from these developments. Fundamental to the success of any such study will be the active participation of healthcare providers and an ability to produce, collate and share data in a far more focused, in-depth manner than has been traditionally possible, which has the potential to dramatically improve levels of frontline care. ‘Participants will be hooked onto their physicians and that whole system would leverage quality and improve the relationship between patient and healthcare provider,’ Sundgren believes.

‘Patients can also record additional information and greatly enhance the knowledge that their physician has of their case. There are a number of clinical trials that use qualitative instruments, IBS is a good example, and those types of studies offer a huge amount of potential for mutual wins. Patients must fill in questionnaires on a regular basis, but with this approach they could perform that task as and when they feel symptoms. That allows

such trials to be much more data intensive and gives practitioners a better hold on their patient's case.'

As well as diabetes and IBS, Sundgren lists an array of studies including IBD, hypertension, hyperlipidemia and cardiovascular disease, as areas well suited to such a shift in practice. Patients could carry out their own tests and the resulting information would become available in real time. 'It's quite possible to have standardised measuring devices installed in the home,' the genial Swede explains.

'Webcams, blood sample devices that digitalise results instantaneously and transmit them through a mobile device. Trust is a central concept here, but with these studies being conducted over a longer period of time a mindset will develop and, if we have the documentation in place demonstrating that those enrolled are fully capable of performing their own measurements, then I see no problem with validation of the results.'

### Secure transmission

Where a problem does arise is around the question of patient confidentiality and privacy laws governing the use of EHR and data transmission. Sundgren has invested a great deal of energy over the past few years in highlighting the significant benefits widespread use and reuse of EHR could have for patient healthcare, public health and clinical studies, but is realistic enough to appreciate that much must change before such innovations can become a reality.

'We need to develop a common platform that involves collaborating with healthcare institutions in a completely new way,' he says. 'We're all quite aware of the regulatory framework when it comes to security around electronic data capture and EHR. Overcoming this needs to be a joint-effort between regulatory, healthcare and industry bodies. It's not good enough that one pharmaceutical company goes it alone; there must be collaborative pilot projects that really demonstrate the value of having such a cost-effective and data-intensive research model, as well as the benefits of fully leveraging healthcare.'

Sundgren's experiences tell him that the appetite for such a seismic shift is out there, having presented his Real Time Interaction Patient Evaluation (RIPE) system at numerous conferences to a consistently positive response. Developed in collaboration with the IT University of Gothenburg University, RIPE is a computer platform designed for real-time capture of symptom profiles of patients that operates remotely and enables patients to submit their own results and communicate directly with their physician.

'It actually resides within the hospital,' Sundgren explains. 'There is a data security access transfer system in place that allows the pharmaceutical industry to log in and make use of the relevant information. It also increases the quality of the physician's work and creates added value that encourages patient participation. We're talking about a complete change from the distant, old way of doing things.'

### Cost and time savings

Having practitioners at the heart of this process, screening potential candidates for home study, would save a great deal of time and expenditure when it comes to patient recruitment, something Sundgren admits currently takes some six months to get a proper handle on. 'The clinic in question can use their EHR to screen for candidates that fit the inclusion criterion and then approach them for their consent to participate in a real life study,' he says. 'Through pseudo-anonymisation, participants' identities would not be revealed, but we would have access to the relevant data. We as an industry need to reshape our capabilities when it comes to the management of clinical information in order to fully realise this scenario and current disciplines are perhaps not best suited to making that happen, but the groundwork is being laid to make it a reality in the years to come.'

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Existing regulations might look like a stumbling block, but they can be overcome. 'If we demonstrate the scientific validity of data being produced and that all legal, ethical and confidentiality concerns are being addressed, that should be good enough,' Sundgren believes. 'It should not be a question of taking our lead from the regulators; apply these principles in the right way and I believe we will be able to move forward in the right direction.'

If this does happen as Sundgren foresees, he believes it could have a revolutionary effect on the manner in which new drug development is conducted, the reusing, transferring and capturing of data allowing for far faster and more successful validations of disease models.

'One of the problems we have is that it's hunky dory when going into pre-clinical research in regards to defining animal models and so on,' he explains, 'but when the pre-clinical models meet the clinical world it doesn't work out quite as expected. If we can work in a far more data-rich environment during the early stages of drug development, we'll be able to understand and validate our models in a positive way much earlier and potentially solve the attrition problem associated with new drug development.'

It is a lofty claim and for such a scenario to become a reality all key stakeholders must start moving forward together. Sundgren cites the Innovative Medicine Initiative as an example of the type of collaborative effort required to create such a paradigm shift and fully tap the mutual benefits of timely and secure access to patient data. 'It may look difficult but it can be done,' he declares. 'The technology already exists and, once everyone realises the potential here, the results could be extraordinary.' **WPF**