Strength through Collaboration

Unlocking the potential for healthcare treatments is the aim of all clinical trials. One way could be to align research teams both nationally and internationally in order to influence and improve routine clinical care as speedily and safely as possible, and thereby enable a better quality of life for patients

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For many years, governing bodies in the UK were unable to accurately determine the level and contribution of clinical research. However, it now seems that a fresh approach to tackling this issue is yielding results and providing evidence of how collaboration is driving the clinical research agenda forward.

Over the past 10 years, medical research has seen the introduction of a number of new compliance and regulatory policies. Fundamentally, these have been based on ensuring the quality and delivery of clinical and medical research but, ultimately, they serve as the cornerstone for patients' safety and the protection of research participants from ethical issues.

Sharing Knowledge

Historically, however, there has been a mentality that research is conducted in 'siloes', which has hindered the progress for drug and healthcare innovation. The performance of a research environment cannot improve or be maintained via the dated spreadsheet and paper systems that are in place. This way, clinical trial data are either not shared, or shared in ways that do not support learning. Why? Because the data are generally collected in a variety of formats that will not allow them to 'talk'. This practice of 'siloed research' is a disease in itself, leading to redundancies, dead ends, the loss of valuable time and billions of dollars. Most tragically, when data do not talk, we lose our patients.

Commercial companies use disparate systems and inbound this technology into sites, which are left with multiple system logins and variations. Breakthroughs like the successful mapping of the human genome and treatments for HIV occurred when scientists, researchers and others within the research field collaborated. They shared what was working and, just as importantly, what was not. Having large numbers of dedicated people from different disciplines comparing data and understanding what they are saying simply brings us closer to finding the answers we need.

Right now, we could possibly have the cure for cancer, but the answers may be buried in report notebooks somewhere. Combining and comparing data can highlight that essential element we need to unlock cures. To do this, we must first format data to enable sharing, which can significantly shorten the time gap between clinical research results and better clinical care decisions. Collecting and sharing data means smarter research and new knowledge that could lead to life-saving therapies, instead of repeating previously made, dead-end mistakes.

Even though we live in the electronic age, the method of disseminating trial findings is still stuck in the moveable type groove such as publication in medical journals. In fact, the majority of studies are not published and, when they are, it is often 2-3 years after the findings were discovered. If you are developing a new drug treatment, then that is millions of dollars lost; and if you are a patient with a serious illness – or a mother, father, brother, sister, son or daughter of one – that is two years too long.

Medical Research in the UK

Information and knowledge around what clinical research is being carried out within Britain has now become more important due to a change in culture to embed it within the NHS constitution. This research is an important aspect in the standard delivery of care, as it has a better informed policy and identifies the strengths that exist in medical research – both nationally and internationally.

In 2006, the Department of Health set up the National Institute for Health Research (NIHR) to create a world-class research system within the NHS. One of its key aims was to gain a better understanding of what research is being conducted and how that is being funded. NIHR organisations work with all stakeholders – both academic and commercial – to leverage a vision of the UK as a leader in medical research. But with the need for information comes the need for an efficient information management system overseeing the research pathway, from concept of a hypothesis to the publication of the results.

The NIHR Clinical Research Networks (CRN) Coordinating Centre – which is primarily responsible for the provision of key performance metrics to the government and industry in order to inform the implementation of health research policies and increase research activity – recognised that in pockets of the country, or within specific disease topic networks, their performance was better. Principally, this was due to a different approach to collaboration, networking and management. In its appraisal, the NIHR noted that these areas had certain things in common and one was the use and analysis of high-quality information.

Through 2014, the NIHR restructured the clinical research landscape in England into 15 local CRNs (LCRNs). Its aim was to contractually oblige these new networks to invest in the necessary information systems. This was to ensure that the underlying stakeholders – the NHS, plus academic and commercial organisations – were provided with the necessary tools to give research sites the capability to understand their own portfolios by improving the quality and structure of data required by the NIHR, and that this then served as the baseline for information to flow into the NIHR's new central portfolio management system to be combined with other information. Research sponsors would then be linked with the sites conducting the actual work and this then leads to the removal of as much duplication from the process that was encountered in previous NIHR network structures.

Local Portfolio Management System

This approach has led to 80% of clinical trials in the UK being managed through one system only, which has three core elements:

- The software
- The collaborative environment for sharing of ideas and best practice
- The principle of entering the right data once

With the development of clinical studies underpinning the personalised and stratified medicine programmes, a standardised local portfolio management system (LPMS) will mean an individual site can ensure and more proactively deliver recruitment and possibly additional research information that is not captured by the electronic patient record.

Figure 1: Communications highway

> **This collaboration of users drives efficiencies through the clinical trials process by the sharing of best practice and skills, and is strengthened through the 'communications highway' that this standardisation creates**

In the UK, LCRNs have been formed to make sure that this delivery can be described, measured and reported against the NIHR performance metrics and high-level objectives that they are expected to monitor with their underlying stakeholders. Ultimately, there is a need to make certain that sites are able to effectively manage information flows internally to allow them to actively monitor the clinical and management processes of research; doing this in real time means that we can adapt the portfolio and map new trials to disease areas locally, regionally and nationally. This will drive growth and access to patients for high-quality research.

The need to implement the LPMS systems of choice (SoC) framework was based around a move away from just administration and performance measurements, to a new approach that drove continued service improvement and the facilitation of research at sites. The NIHR's commitment to ensure that funding was made available to LCRNs resulted in all regions having a solution within their geography, where previously only some may have invested.

Not only did the new LPMS SoC deliver the technical solution but, more importantly, a community of users was created, which grew in strength to a position today where over 80% of the UK's clinical research trials are hosted through one clinical trial management system solution, managing over 81,000 trials with over 36,000 users for over 2.5 million patients. This collaboration of users drives efficiencies through the clinical trials process by the sharing of best practice and skills, and is strengthened through the 'communications highway' that this standardisation creates. Today, different stakeholders – such as clinical departments at sites, finance departments, sponsors and funders – can, through subscription, access the details of the clinical trial through one system and communicate with all of its members.

This was, therefore, an investment into moving the NHS research agenda into a new phase by ensuring that information is central to the development and growth of research activity. Previously, this had been missing and highlighted by the discrepancy in the data provided historically, where the information had been disjoined or lagged in time behind the events within the research path. For sponsors and funders, this meant that the relationship with the sites performing their studies could be strengthened, accurate and real time activity monitoring enabled and correct remuneration for all parties put in place.

Through the principal of entering the right data once, they are improved and become more real time. This strategy is central to the needs of the industry and the granularity required by the government.

LPMS SoC removed a bottleneck in the current information flow, thereby ensuring that the activity occurring at the site is visible in real time – leading to a shift of focus to one of facilitating and building networks of supporting structures and collaboration.

Collaborative Partnerships

Pharmaceutical companies traditionally 'inbound' technology into sites to manage their specific trials, but now the capability exists to subscribe to the embedded system in place to monitor specific clinical studies in the UK. This drive for standardisation and building collaborative user communities is not unique to Britain, and has now been expanded to deliver trial research efficiencies throughout the Canadian Cancer Clinical Trials Network and provincially through Alberta, Canada. Further partnerships are emerging and evolving in the rest of the country, Asia and Europe.

It is not just a standard system that drives this collaborative strength, but the underpinning terminology. The Clinical Data Interchange Standards Consortium (CDISC), a nonprofit organisation, is leading on this to develop data standards to streamline clinical research and enable connections to healthcare, ultimately impacting patient treatment.

About the author

James Batchelor is Director of the Clinical Informatics Research Unit at the University of Southampton, UK, and is a professorial fellow of clinical informatics and healthcare innovation. About 15 years ago, he developed EDGE, a local portfolio management system that is now adopted across 80% of the NHS. James is also a Committee member and advisor to the Republic of Ireland e-Health Programme, as well as being involved in the development of clinical research standards with the University of Cologne, Germany, and within the CDISC. He has worked in this area of research for over 15 years and is well known within the research community, both in the UK and overseas, for his practical solutions to clinical informatics.

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