CLINICAL INVESTIGATION

EDITORIAL

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The importance of technology in global health trials

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Clinical trials bring new drugs and vaccines and drive improvements to manage healthcare issues such as safe childbirth and improving health-worker training. Communities in developing countries are under-represented in research and there is a need for better and more diverse clinical trials to address the highest impacting burdens on public health. There are many opportunities for new digital technologies to encourage and support clinical trials in resource-limited settings. These new digital tools bring mechanisms for making conduction of trials easier, for training staff and sharing skills or for bringing wider access to methods, data and resources. Here we describe some of these technologies and explain how they are making an impact.

"Digital technology provides two important mechanisms for improving clinical trials in developing countries. First, by bringing platforms for sharing experience, documents and methods in the form of online professional communities, and also as specific tools to resolve previously difficult tasks."

Clinical Trials have gained a reputation as being too cumbersome, expensive and difficult [1]. Furthermore, investigators (and would-be) investigators are finding the guidelines and regulations confusing and off-putting. These issues are faced by researchers globally [2], but have a greater impact in developing countries [3]. In these regions it would be beneficial to conduct more research into the highest causes of mortality, especially disease management trials to guide improvements in practice. Furthermore, there is a lack of trained research staff in these regions and it is therefore all the more difficult to overcome these challenges of trial design and conduct. There are several new technologies that are available that, if implemented more widely, could ease some of these challenges.

New technology

Below are some of the generic steps that need to be tackled in the conduct of any clinical trial. Here are examples of where application of new technology is making an impact.

■ Setting the question & building a team

Sharing methods and working in collaboration is becoming both necessary and advantageous in this era of reduced funding opportunities and increasingly expensive research costs. At the outset of developing a new trial it would be beneficial to gain opinions from others on the appropriateness of the question and how it is going to be tackled operationally in a protocol. Research networks are the ideal platform for gaining access to advice, contributions and views.

Recently, several of these methods have emerged specifically to enhance research in low-income settings and these online networks use new digital technology to play an important role. Online professional communities can be particularly beneficial in the critical stage of planning research and provide a forum in which to identify potential partnerships, learn of funding opportunities and to share ideas or seek advice [4–6]. These forums may be regional, disease specific or provide cross-cutting support.

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Protocol design tools

The success of a clinical trial is largely dependent on how well the trial was designed and the protocol written. This is not a simple task and comprises many elements, with some being statistical and some being operational. The Prathic group have developed a tool that guides researchers through the process of designing a protocol and this is available online at no charge [7,8]. It might be advantageous to see examples of other protocols that have tackled the same disease area, or used a similar approach. Many journals encourage researchers to provide the protocol as an online appendix, but few are available on a open-access basis. Reviewing other protocols would bring potential issues and challenges to the attention of the investigators that they may not have thought of.

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Clinical trial laboratories & sample tracking

Most clinical trials have a laboratory component and these are fundamental to a trial end point or enrolment. Clinical trial research groups need to ensure their laboratories meet international clinical trial standards and must have certain records and systems in place to achieve this, covering areas such as quality control, equipment calibration and staff training. These standards are not overly arduous and are readily achievable with some support and guidance. Connecting laboratory managers with each other and sharing their operating procedures and experience can really make an impact in achieving this [6,8]. Normal ranges are also very different in varied settings and populations, and it is therefore helpful that groups are sharing their validated normal ranges open access online [9]. Digital technology can also provide inexpensive mechanisms for research laboratories to label and track their samples with a barcode system. These are also extended to storing in freezers where a digital barcode system makes much better use of space and resources [10]. There is another important opportunity that digital sample logging can bring. Technology development allows procedures to be performed on tiny volumes of biological samples, therefore remaining blood or serum from a study can be stored and used at a later date for future research studies [101,11]. In the field of Global Health, where resources are scarce, this could be very impactful [101]. Whilst this of course requires clear consent by the participant donating the sample and full ethical approval for any subsequent trials, this is a very ethical approach because more benefit is gained from a single sample and from the original participant volunteering their sample to be used in research [11].

Having a digital log of samples (and how they were collected and stored) enables the creation of sample registries and the potential of sharing samples, technology and data [101]. For example, one research site might have a very valuable sample collection from a specific population or disease, but this site may not have the expertise or equipment to conduct certain assays or procedures that would really contribute to our understanding of that disease. Through sample registries, partnerships could be formed between sites with the samples and sites with the technology for cutting-edge research. These schemes need to carefully consider issues around research ethics, data protection, intellectual property, sample export and authorship to ensure that the partnership is fair. However, if these are properly managed then important research findings could be obtained without the need to enroll further participants. Such collaborations could speed up research in developing countries.

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Enrollment & retention

The success of clinical trials is largely dependent on the ability of the trial to retain the participants and complete the follow-up as described in the protocol. Participants dropping out of trials and not returning for follow-up visits are the most common reasons for trial failure and the inability to answer the questions they set. In developing country settings, following-up and retaining participants is a great challenge as research is often conducted in low-income rural or slum settings where addresses and telephone numbers are unreliable and not formal. Many groups running trials in these settings find that using hand-held global positioning satellite technology has been highly beneficial to this issue [12]. One approach is to send a field worker home with the participant after enrolment into the trial and then to mark the home with a grid reference and log its location on a hand-held device. This technology is becoming standard in epidemiology studies [13] and the maps created can then be used for identifying clinical trial participants within rural or urban communities.

Data capture & management

Electronic data capture is becoming the norm in clinical trials worldwide. Previously, lack of access to

computers and very slow internet connections resulted in limited uptake and use of electronic data capture forms in developing countries. In the past few years this has changed markedly, with the rapid uptake of handheld smart phones and vastly improved connection speeds. The cost of data management software had also been prohibitive, but widespread use of open-course software and groups who use it and share their experiences has also made a very positive impact [14].

Training & support

The lack of clinical trials in developing countries; especially local investigator-led research, is blamed on lack of trained researchers and research teams. Exploiting the benefits of digital technology could bring significant change to this situation. Many of the skills and practices in clinical trials are the same, irrespective of what disease is being studied. Global Health Trials has been set up to provide an environment where all levels of staff can share solutions to challenges they have faced and access skills training through e-learning [8].

Discussion

Digital technology provides two important mechanisms for improving clinical trials in developing countries. First, by bringing platforms for sharing experience, documents and methods in the form of online professional communities, and also as specific tools to resolve previously difficult tasks. To fully exploit the opportunities that digital technology offers we need to encourage the philosophy of sharing best practice with colleagues within these online groups and also invest in further new digital tools to address the remaining areas of difficulty for research teams.

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