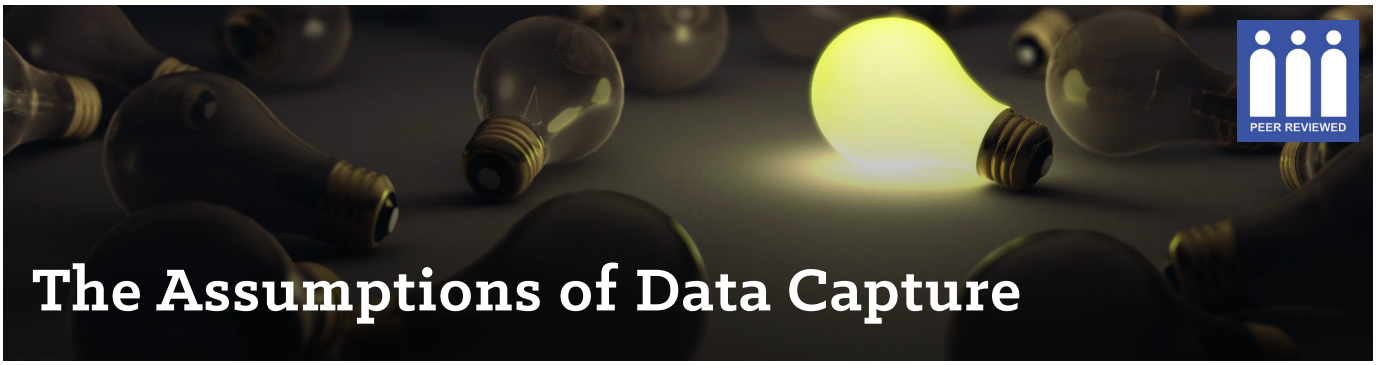


The Assumptions of Data Capture

Within the field of clinical research, there has been, for many years, a move away from the use of paper as a form of data capture, in favour of electronic data capture, particularly within industry. The advent of the use of electronic case record forms (eCRFs) is nothing new from that perspective: what remains a challenge is the use of electronic data capture (EDC) at site. This article will, I hope, with some broad generalisation, raise awareness of the issues from the sites' perspective.

A research nurse or person responsible for the recording of data relating to patients enrolled onto a study will inevitably be undertaking a number of clinical trials for different sponsors. They will, therefore, be using a number of different EDC products, each using a different platform and with different user credentials. In this article, by detailing their experiences and use of these platforms, I hope to highlight anecdotal issues and challenges that demonstrate the frustrations which we have discussed at various sites for a number of years.

Historically, this started with the phenomenon of the industry study laptop and broadband line; it became the critical point of data entry for some clinical trials. Despite the availability of computers within the clinical setting, the sponsors perpetuated the delivery of individual laptops, and sometimes associated broadband lines, for each study. These laptops eventually became a burden to the site with the responsibility to catalogue and store large numbers of these devices, many of which remain uncollected ever since.

The History of the Web Browser

On the whole, the world is using the latest technology across a number of different devices and operating systems; however, monitoring undertaken by the University of Southampton Clinical Informatics Research Unit, across software used in 80% of the NHS, has identified that there is still a large amount of variation on the number of different types and versions of web browsers used, particularly Internet Explorer 7 and 8, which are still prominent at 60% of NHS sites. Recently, a number of technology demonstrations from EDC suppliers presented the functional benefits of their application to industry customers that will optimally operate in IE11 or the latest versions of other browsers; ironically, there is a lack of information to both industry and the EDC supplier to inform them that, although this application works well in rendering the forms as an application in their own offices, the view of the application from the site version of the browser presents a number of issues in rendering the forms, which can result in considerable difficulty for the end-user operating it.

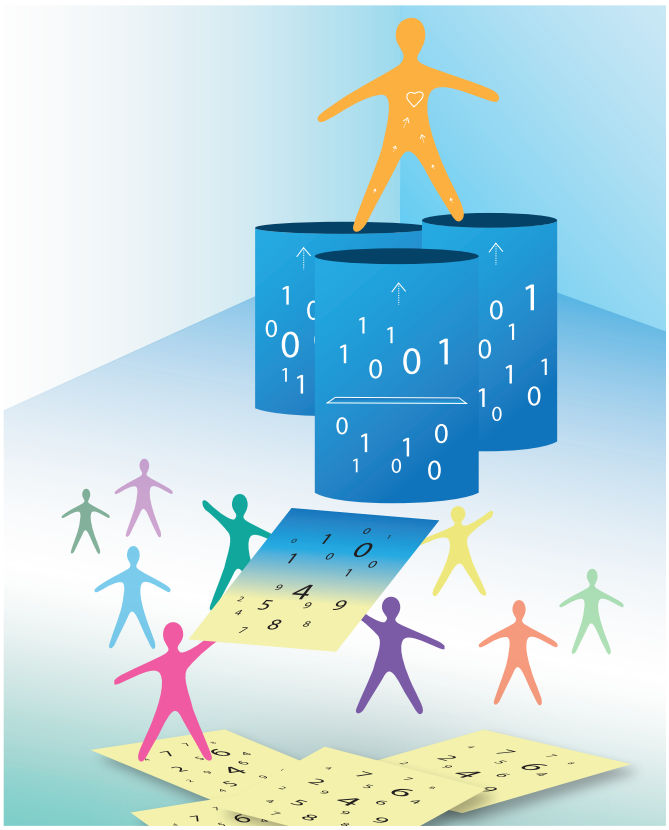
Optimised development of web-based solutions still needs to consider backwards compatibility with IE, or at least should be able to operate in Chrome with no requirements to install third-party controls or require Java plug-ins, as this will ultimately – rightly or wrongly – produce frustration at the site.

New Technology is Good, Right?

We are in a world of technology that is helping us wander around the planet with a phone in our hand, enabling us to take pictures, book tickets and turn the heating on and off at home. Generally, most industry sectors are embracing new technology, both in terms of software and hardware. So therefore, it appears obvious that there are technology solutions to help sites in the conduct of clinical trials. This seems to be true in the minds of contract research organisations who are keeping pace with technology and development.

There are several, seemingly obvious, technology solutions to aid the smooth running of clinical trials, ranging from infrastructure, small applications, add-ons and other opportunities which again, although well-meaning in a practical sense, are extremely difficult to implement into the actual site environment.

Common misperceptions of the capabilities of a site are quite often the reason for the downfall of a project, where we have heard again and again the cry of "surely you are joking", when this is explained.



Recently, I was asked about reviewing the option of remote data source verification by uploading a scanned copy of the clinical chart. For a start, the data protection and governance issues were going to be an issue with this approach but, from a technical perspective, there was the problematic fact that the sponsors presumed that we had multi-function devices that were capable of scanning and e-mailing a PDF or storing to a file location. In reality, this was going to make the whole process rather time-consuming: site staff would have to walk halfway across the site to find the one and only device with such a capability, before returning back to their desk to upload the PDF file into the sponsor's or CRO's system. This solution had not, it would appear, considered and examined the complex issues of taking a set of medical records apart in order to extract one page of data, copy and redact the sensitive information required, before scanning and then reconstructing the medical record.

I mentioned this to a member of the nursing staff who proposed that whoever dreamt up this concept might like to visit the hospital site to be given a demonstration of the proposed solution in practice – a demonstration given by, I conclude, a rather angry and exasperated individual.

The concept of clinical research data capture can be demonstrated using the following supermarket analogy: each shopper (funder/sponsor) has their own till system that the checkout staff (nurse/responsible person) are expected to use. In most quick, random polls of check-out staff responsible for clinical data capture at site, the average number of tills (unique eCRF solutions) is between seven and ten.

One session held to find out common complaints/problems about data capture, from the same staff, produced the following common complaints:

- CRF pages do not load correctly and the content can be hard to navigate, in hospital IT browser estate
- Systems' and clinical process logic do not align
- Too many login details for the same systems (single sign-in)
- Quality of life questionnaires for patients using iPads requires a lot of work with patients to help them use or complete the questionnaire, and patients forget their login details or pin numbers
- CROs are not collecting equipment after studies
- There is an increasing requirement for the scanning of documents.

Overall, there are exciting and obvious trends in adopting new technology and software. However, the question of whether the sites and patients are ready to implement and use this technology indicates that there are still some hurdles to jump before this technological approach can be fully adopted.

Technology companies, sponsors and contract research organisations need to consider that, in some respects, the end-user IS the site, but there is currently very little dialogue with these users and implementers of technology for data capture. Their input should be key in taking this forward.

I plead that the site staff supporting research data capture are openly engaged in conversations around data capture issues, and that they are willing to help industry understand these challenges: all you need to do is ask and involve them in the process of adopting new technology and solutions to make sure that the investment is worth it.

James Batchelor

Director of the Clinical Informatics Research Unit at the University of Southampton, UK, and Professorial Fellow of Clinical Informatics and Healthcare Innovation. Approximately 15 years ago Professor James Batchelor developed EDGE, a Local Portfolio Management System (LPMS) that is now adopted across 80% of the NHS. Its ultimate aim is to unify clinical research teams nationally and internationally in order to influence and improve routine clinical care, and thereby enable a better quality of life for patients. He 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. James 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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