

A Simple Challenge, a Daily Pain: Managing URLs and Passwords.

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What if?

You could place all your secure websites links and passwords in a single place, secure and accessible on the web from anywhere?

What’s the need?

The shift from paper-based operations to an electronic environment has brought some real practical challenges to the study coordinators. These challenges are usually not discussed in journals dedicated to clinical trials or to bio-IT. Besides the expected training, data entry and data management work that electronic data capture (EDC) system require, personnel also is required to comply with strict access control processes, which differ from system to system, sponsor to sponsor, and even, from study to study. This is true also for other systems that study personnel use, such as study portals, electronic medical records, and scheduling systems.

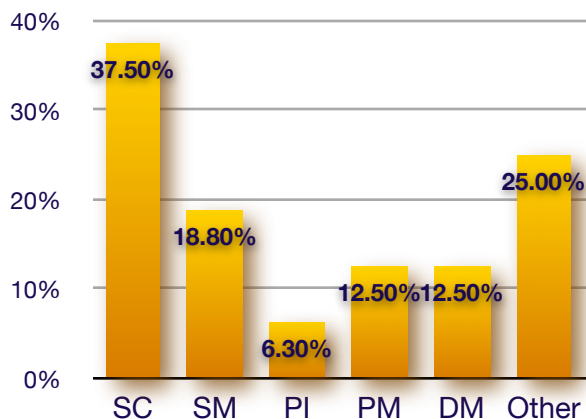
Experience shows that remembering all the addresses (URLs) and the corresponding credentials (usernames and passwords) is a real practical challenge for which few good solutions exist, if any. As a company dedicated to addressing real-life problems faced by research personnel, XeoTK endeavored to explore the issue further.

How Does Study Personnel Cope?

In a survey performed in October and November 2010, XeoTK asked various study personnel what their primary role was. Most participants (figure 1) were study coordinators (SC), site monitors (SM), project managers (PM), data managers (DM), and

investigators (PI), while 25% stated that they had “other” roles. This sample appears to represent well the various functions that are necessary to perform the necessary clinical research functions.

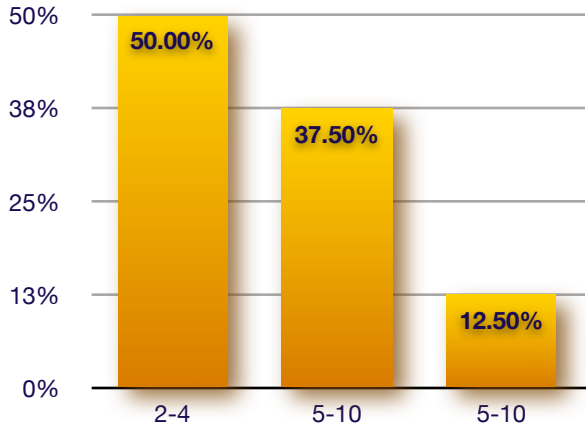
Fig 1: Participants



Scope of the Issue

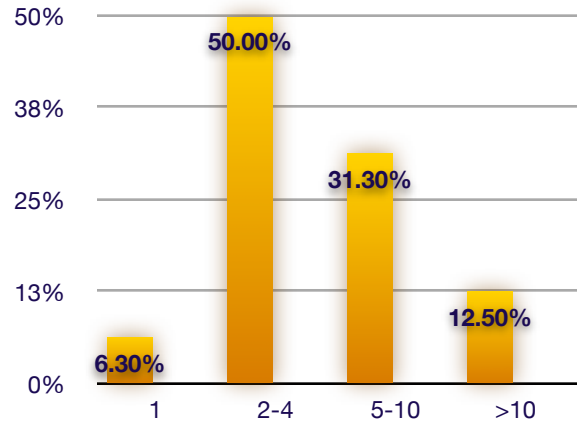
The issue really comes from the multiplication of secure web sites and of credentials that study personnel has to use on a daily basis. Indeed, managing the multiple web sites as a single study may require remains manageable to an extent even though accessing these many systems can be sometimes challenging. However, most study sites are involved in several studies at any given time (figure 2).

Fig 2: Number of Studies per Participant



According to XeoTK’s survey, eighty-seven percent of the respondents were involved in 2 to 10 studies. For each study, participants stated that they needed to access between 2 and 10 secure web sites (figure 3).

Fig 3: Web Sites per Study

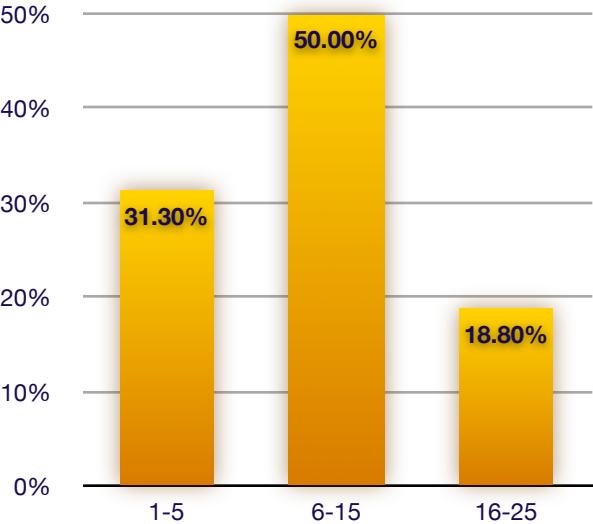


Compounding Factors

Considering that there is no coordination among the various sponsors and CROs who manage these web sites, it comes to no surprise that study personnel has to manage a multitude of usernames and passwords, besides having to remember the correct addresses (URLs) for the various portals and EDC/RDC systems. The result is obvious: study personnel, just to do their jobs, have to use a variety of web addresses and credentials, most often between 6 and 15, sometimes many more (figure 4). Some participants reported having to use well over 50 sets of credentials to access the various

systems that they are using on a very regular basis.

Fig 4: Passwords per Participant



Because studies from multiple sponsors and various institutions require using systems supported by many independent entities, no single place exists where access to these multiple systems and the corresponding credentials is made easy, safe and secure.

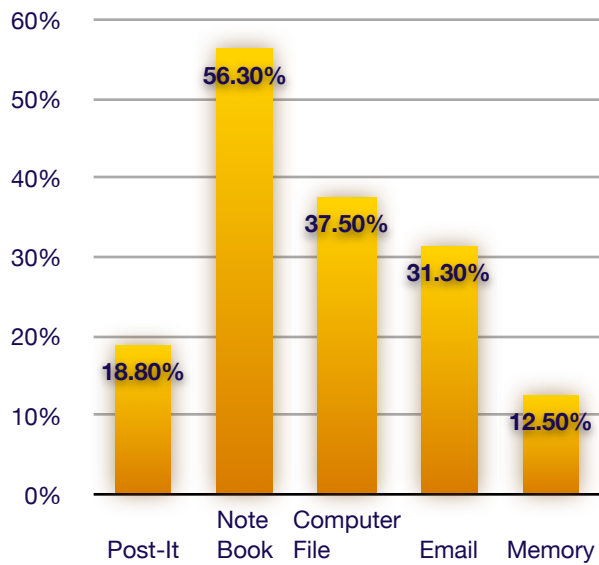
To put the matter in perspective, clinical research is now making extended use of information technology regardless of whether EDC/RDC is actually used. Most information and/or communications necessary to execute clinical trials such as study documents, IRB submissions, health records, lab data, reside on separate systems, each of them accessible on a different website and requiring secure login. Study meetings are increasingly virtual too. Since most study coordinators work simultaneously on different studies, the problem is compounded by the multiple sponsors and CROs, their specific study portals and preferred EDC/RDC systems, in addition to the systems put forth by IRBs, and core laboratories. The result: a study coordinator needs to remember on average 5-10 different credentials and web site addresses per study.

Managing Passwords

How do study coordinators usually manage remembering their secure login information?

Study personnel use multiple methods, often simultaneously, to keep track of their credentials. Post-It notes, note books, computer files, and emails are popular (figure 5). And when memory fails, the “retrieve my password” function is a surprisingly often used last resort option (12.5%).

Fig 5: Methods Used to Retrieve Credentials



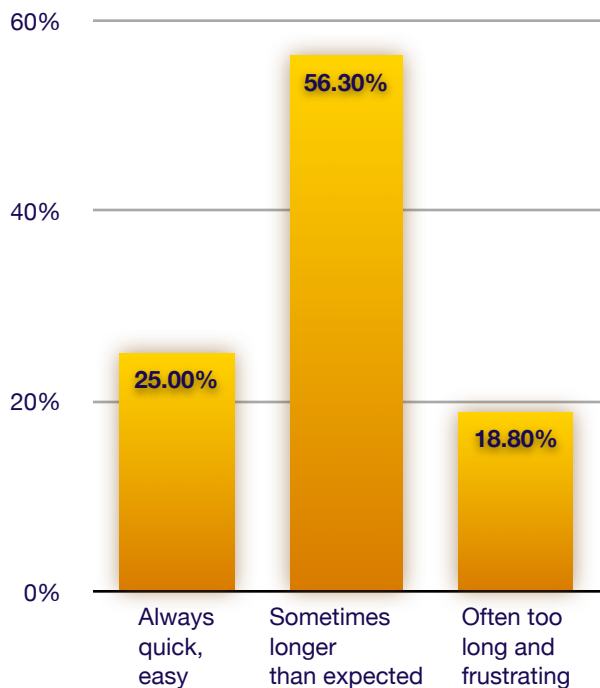
None of these methods is actually safe. Indeed, the credentials can be lost and found, seen or stolen with the associated risk of being then misused. Most importantly, even if not misused, lost credentials invalidate the associated electronic signatures that are critical to many systems used in clinical research, thus requiring generating new credentials, a time-consuming process.

None of these methods is efficient either. To access a given web site, one needs to type in the correct address (URL), then the credentials, which have to be retrieved first. This leads to time wasted on processes that if streamlined, should be transparent (preferably) or at the least, very easy. The experience reported in our survey illustrates the point (figure 6).

Importantly, the experience of the users is reported on a perceptual basis, as opposed to absolute measures of time and motion. Thus, it is not clear from this survey whether “always quick and easy” corresponds to

computer industry standards that require screens to take less than 2 seconds to refresh from one to the next. Small gains in time to access may not mean much at first sight. However, as users have to switch from one system to the other, or login several times as sessions expired, the small gains may accumulate into significant time savings at the end of the day, as well as much decreased stress and frustration.

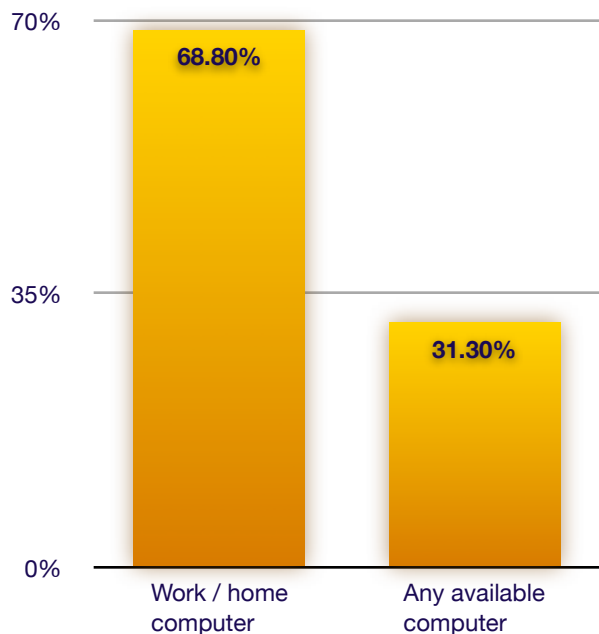
Fig 6: Speed of Access



Multiple Workstations

Another aspect that affects the efficiency of these methods is that, if they hosted on a computer (as files or applications), they are not portable. That means that about 1/3 of the respondents have to use alternative means (not computer-bound) of keeping track of their credentials as they use any computer that is available at work (figure 7), a trend that is expected to grow with the increasing use of information systems in medical practice, including the expanding use of electronic medical records. This is reflected in figure 7, which depicts what work stations our participants use to access the various web sites from.

Figure 7: Work Station Used



Managing Data Capture

As electronic signatures are particularly critical to EDC/RDC, the XeoTK survey more specifically inquired about the methods used by personnel involved in data entry to perform this task.

The results shown in figure 8 confirm that very often, any available computer is used.

They also show that, even though EDC/RDC aims at being paperless, worksheets are used by the majority of the participants concerned.

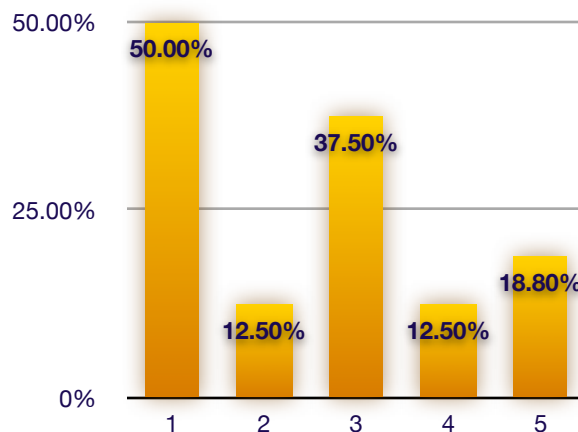
This figure also suggests that multiple methods may be used by the same personnel, probably depending on studies are set up, study requirements, and how user friendly systems are.

The key to the methods shown on the X-axis is as follows:

1. Capturing data on a worksheet, then entering using an assigned work computer
2. Capturing data on a worksheet, then entering using any computer

3. Direct data entry using an assigned work computer
4. Direct data entry using any computer
5. “Not applicable” corresponds to 18.8% of the participants who are not involved in any data entry activities.

Figure 8: Data Entry



In summary

Current methods used by study personnel to manage secure login information present a serious problem, because, by lacking security and efficiency, they essentially defeat the methods aimed at protecting the system used on clinical research, and the data that they host. However, we cannot blame study personnel for trying to address the problem with the means that are at hand. Current technologies allow for much better solutions that provide secure, mobile, fast and easy access to critically important web sites.

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