Access and Attitude to Clinical Trial Technology: The Global Investigator Perspective

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Introduction: A Technology Revolution for Sites

The pharmaceutical industry has been criticized for being outdated, old-fashioned, and for relying on traditional paper-based methods, which are often cited as significant contributors to the ever-growing costs and timeframes of clinical development. Adopting new technology is crucial if the pharmaceutical industry is to make measurable improvements in speeding study start-up, streamlining clinical trial data transmission, and overhauling how studies are monitored.

While industry has historically been slow to adopt new technology, great strides have recently been made. With the support of collaborative initiatives such as TransCelerate BioPharma, and regulatory authorities' willingness to consider new approaches to clinical trial operation, technology is now being introduced into clinical trials at a rapid rate. With sponsors, regulatory authorities, CROs, and technology companies all working together to improve the efficiency of clinical trial operations, the outstanding question becomes whether sites, globally, are prepared to implement the growing alphabet soup of clinical trial technologies: EDC, ePRO, eTMF, and many more.

This article explores this knowledge gap by summarizing results from a global investigator survey regarding what access investigators currently have to technology, their attitudes toward these new advances, broadly and more specifically related to EMR, one of the emerging tools that sponsors are evaluating for integration into clinical trial operations.

Methods: Global Investigator Survey

To better understand clinical trial investigators' access to and attitude towards technology, DrugDev surveyed 572 clinical trial investigators from eleven countries (Argentina, Australia, Brazil, Egypt, France, Germany, India, South Africa, Thailand, the UK, and the US) in its global network. An invitation to participate in the 27-question online survey was emailed to approximately 10,800 randomly selected investigators. Respondents answered a series of questions related to their access to current clinical trial technology, and their attitudes towards the development of clinical trial technology and its capacity to decrease administrative burden. The survey was open from February 17th to April 14th, 2015.

Results: Sample Characteristics

The target sample for this group was 100 completed responses from the US, and 50 completed responses from all other countries. The US received a higher weighting due to the fact that it represents approximately 30% of studies globally. Emails were sent to achieve each country's desired sample size; no further emails were distributed after these targets were met, but all completed surveys were evaluated, even if the country-level target was surpassed.

Survey targets were achieved or exceeded in eight of the eleven surveyed countries: Argentina, Australia, Brazil, France, India, South Africa, the UK, and the US. Because Germany failed to meet the target sample size by only one respondent, we also included Germany in the final sample. Egypt and Thailand were excluded from the analysis because investigator participation was far below the country-level target (eight completed responses from Egypt and 11 from Thailand).

In total, the global analysis included 572 investigators across nine countries. The survey completion rate (excluding Egypt and Thailand) was 5.3%, ranging from 3% in Germany to 14% in South Africa.

Table 1: Sample Characteristics

Variable	Responses	Response Rate
Country-level survey completion rates:*		
• Argentina	50	4.1%
• Australia	53	5.1%
• Brazil	57	10.3%
• France	57	3.8%
• Germany	49	3.2%
• India	53	3.6%
• South Africa	66	14.3%
• United Kingdom	56	4.6%
• United States	131	7.1%
Variable	**Responses (N=572)**	**% of Total Responses**
Experience:		
• 0 to 1 studies	20	3.5%
• 2 to 4 studies	110	19.2%
• 5-10 studies	128	22.4%
• >10 studies	314	54.9%
Therapy areas (with >15 mentions):		
• Metabolic/Endocrine	88	15.4%
• Cardiovascular	74	12.9%
• Oncology	74	12.9%
• Neuroscience	42	7.3%
• Respiratory	39	6.8%
• Pediatrics	30	5.2%
• Psychiatry	28	4.9%
• Infectious Disease	25	4.4%
• Critical Care	23	4.0%
• Musculoskeletal	22	3.8%
• Dermatology	21	3.7%
• Autolmmunology	19	3.3%
• Pain	19	3.3%
• Nephrology	16	2.8%
• Women's Health	16	2.8%
Average therapeutic areas per investigator	2.6	-

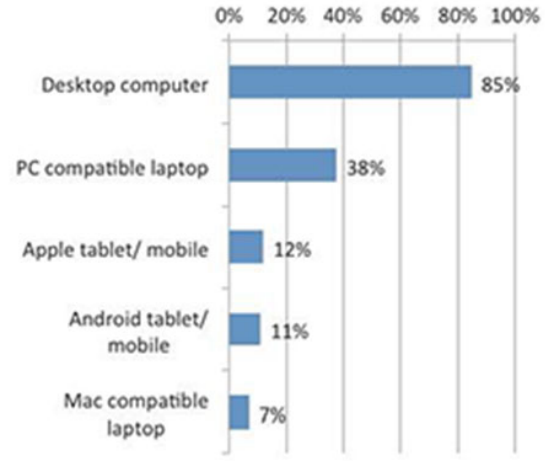
*Calculated based on: responses received/total emails sent to investigators in that country

As seen in Table 1, approximately 75% of respondents reported that they had conducted more than five studies in the past five years (22.4% had participated in five to ten studies, and 54.9% in more than ten). Most investigators reported experience in more than one therapy area (an average of 2.6 per investigator). 97.3% of respondents had done at least one industry-sponsored clinical trial in the last three years, and 37.6% had worked solely on industry-sponsored trials in the last three years.

Results: Access to Technology
80% of respondents reported that all of their staff had access to a computer for clinical data collection, ranging from a low of 66% in India to a high of 89% in Australia.

As seen in Figure 1, the primary type of device available at the site for clinical data collection was a desktop computer (85% of respondents), and the next most commonly available device was a PC-compatible laptop (38%). Tablet and mobile devices were much less commonly available (Apple table/mobile in 12%, and android tablet/mobile in 11%, of cases).

Figure 1: Primary Device Available For Data Collection

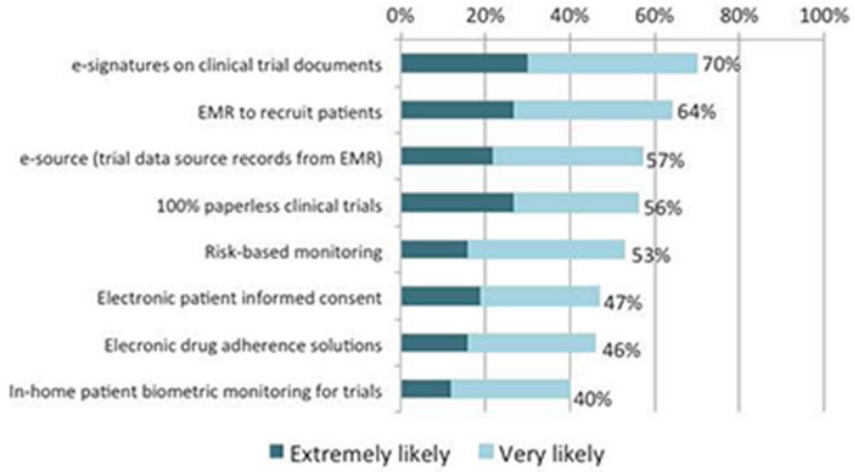


Question: Does your staff have access to devices to assist in the collection of clinical trial data (e.g. laptops, tablets, dedicated desktop computers)? What is the primary type of device available to your staff? Check all that apply. (n=572)

The survey also asked investigators whether their staff had access to wifi/internet at their site, and overall, this was the case for 92% of respondents (range: Germany 82%; US, Brazil and South Africa 97%). Wifi/internet access extended to the rooms where patient exams were conducted for 83% of sites (range: 59% India; 88% US).

Investigator Views on Future Clinical Trial Technologies
Respondents were asked to rate eight different clinical trial technologies/applications across two different scales: its likelihood of becoming the “gold standard” in the next three years, and the likelihood that it will reduce investigators’ administrative burden. 70% of investigators responded that it was extremely or very likely that clinical staff use of eSignatures on trial documents would be a gold standard in clinical trials within three years (see Figure 2). Use of EMR to recruit patients was rated as the second most likely “gold standard” technology within three years (64%).

Figure 2: Technology Extremely or Very Likely to Become a Gold Standard within Three Years



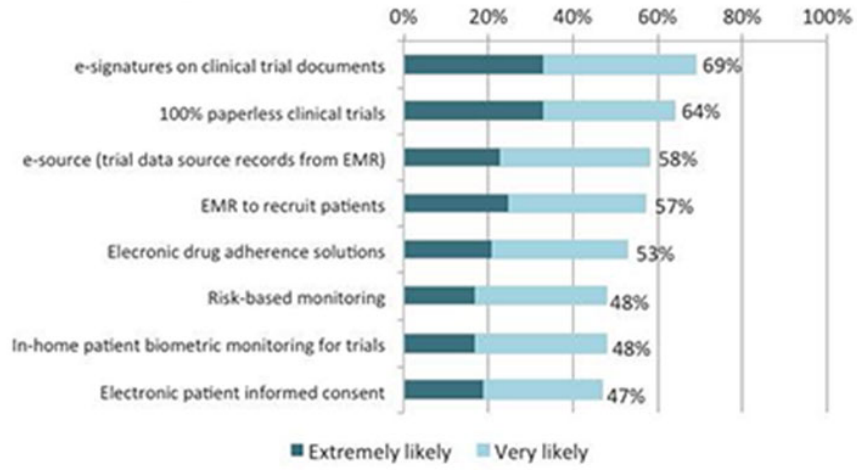
Question: In your opinion, how likely is it that the following advances in technology will become a gold standard for clinical trials in the next three years? (n=572)

In addition to eSignature and EMR for patient recruitment, over 50% of respondents rated three other technologies as extremely or very likely to become a gold standard in the next three years: 1) eSource (i.e., creating trial data source records electronically based on EMR/EHR data); 2) 100% electronic document storage (i.e., paperless clinical trials); and 3) risk-based monitoring.

Survey respondents were then presented with the same list and asked to rate the likelihood that each technology would decrease investigators' administrative burden.

As seen in Figure 3, nearly 70% of investigators rated clinical staff use of eSignatures on trial documentation as extremely or very likely to decrease administrative burden. 100% electronic document storage ranked second, with 64% rating this technology as extremely or very likely to decrease burden. Three other technologies were rated as extremely or very likely to decrease burden by over 50% of investigators: 1) eSource; 2) EMR to recruit patients; and 3) electronic drug adherence. It is interesting to note that risk-based monitoring was rated as extremely likely or very likely to decrease burden by less than 50% of investigators.

Figure 3: Technologies Extremely or Very Likely to Decrease Investigator Burden

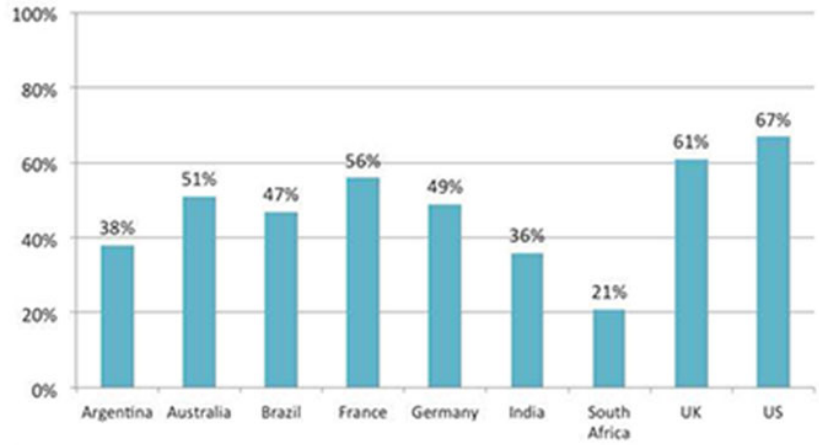


Question: In your opinion, which of the following has the greatest potential to decrease administrative burden for investigators? (n=572)

Electronic Medical Records

The percentage of investigators who use electronic medical records (EMR) at their site varied greatly between countries, from only 21% of respondents in South Africa to 67% in the US (see Figure 4). 53% of those using EMR were already using systems to collect clinical trial data.

Figure 4: Access to Electronic Medical Records by Country



Question: Do you use an electronic medical record (EMR) system at your site? (n=572)

The survey revealed a very fragmented picture of EMR systems in use. Of the 263 respondents providing a response regarding their EMR provider, only 93 (35%) selected one of 33 pre-set options. In total, nine commercially available EMRs had more than five mentions: Epic Systems, Cerner, Advanced Data Systems, MediStar, All Scripts, eMDs, eClinicalWorks, MV Systems, and GE Healthcare. With respect to the 170 (65%) of respondents who checked “other,” “in-house”

was the most frequently mentioned solution (n=24, 14%). 8% of respondents said that they used multiple systems at their site.

There was significant interest in using EMR to support a number of different clinical trial activities (assuming that the technology was available and provided to sites). Between 69% and 74% of respondents were extremely or very interested in using EMR in support of all of the clinical trial applications presented: to flag records of potential study candidates, identify potential subjects, identify patients already in a study, use as supporting documentation for CRFs, provide study feasibility information, and auto-populate CRFs.

Limitations

Although these survey results provide insight into the interest and ability to implement new clinical trial technological solutions at the site level, the study does have some limitations. First, the study was conducted among a sample of investigators who are members of the DrugDev Network and it is possible that the characteristics of the population could have influenced the results. For example, enrollment in DrugDev may self-select investigators who are more comfortable accessing and sharing information online. However, given that online and mobile communications are standard practice today (86% of clinicians now report use of smartphones in their professional activities), it is unlikely that this significantly impacted results.

While the response rate seen in this survey was similar to those reported for online surveys in other publications, another limitation of the study design is the potential for non-response bias. Despite the fact that the proportion of non-responders was high in this study, the results are not inconsistent with comments made by industry experts on the challenges posed to sites in the clinical research process (e.g., TransPerfect 2012 Investigator Survey).

An additional limitation is that investigators could only answer the questions put in front of them, and therefore were commenting on the technological solutions presented as options. To address this limitation, many survey questions included “other” options, allowing investigators to highlight choices we had not provided.

Discussion

Findings of this survey have implications for the global adoption of clinical trial technology by investigator sites. While 80% of investigators have access to a computer for clinical data collection, it is most often a desktop PC (85%) and may not be in every exam room. Access to a dedicated mobile device or tablet for clinical trial data collection at the investigator site was much lower (<15%). As a result, technology solutions involving a mobile device or tablet will likely require capital expense at the site level, provision of devices by the study sponsor, or the ability to use the solution on a staff member’s or patient's own device. And because only 83% of sites report having wifi in patient exam rooms (59% in India to 88% in the US), educating sites on how to train patients for home technology use will be important as more patient-centric technologies become available.

Investigators rated clinical staff use of electronic signatures on trial documents as most likely to both be a gold standard within the next three years (70% extremely or very likely) and to reduce investigator administrative burden (69% extremely or very likely). This result was consistent across levels of experience and across countries. While this survey did not make a distinction between electronic or digital signatures, advancing use of this technology should be a priority for industry and regulators.

A recent Eye For Pharma report on industry professionals’ views on data and technology in clinical trials in 2015 reported that 58% of companies were planning risk-based monitoring strategies in the next two years, with the main drivers being to reduce monitoring costs, to improve data quality, and to improve quality oversight. This was the top-rated clinical trial methodology planned for deployment by companies within the next two years.

Despite the strong industry view and dissemination of operational models for risk-based monitoring from individual companies and collaborations such as TransCelerate, it appears that there are still arguments to be made to over 50% of investigators of risk-based monitoring's value to sites. In our survey, only 53% of investigators globally rated risk-based monitoring as very or extremely likely to be gold standard within the next three years (39% in Germany to 62% in Argentina and India), and 48% said that RbM was very or extremely likely to reduce administrative burden (30% in Germany to 74% in Brazil).

Survey results showing variability in the use of Electronic Medical Records globally indicate that while EMR-based solutions may work in some countries (e.g., US 67% penetration, UK 61% penetration), it may not be possible in other countries (e.g., 21% South Africa, 36% in India, and 38% Argentina). This also looks like an area where standardization will be a considerable challenge, with significant fragmentation in the global EMR market, including a large cohort of sites that use an in-house system.

Nevertheless, there was considerable interest in the use of EMR to support clinical trials; indeed, 53% of those with an EMR system were already using the system to support clinical trial-related activities. Identifying technologies that can operate clinical trial applications across EMR providers, and/or encouraging EMR providers to rollout standard clinical trial applications within their own systems, appears to be valuable to both investigators and industry.

Conclusion

Technology and innovation are changing the landscape for clinical investigators and sites, and opportunities exist for sites to partner with sponsors and CROs to improve the implementation of technology which in turn can improve the patients' clinical trial experience.

According to analyses conducted by CenterWatch, Tufts, and others using FDA 1572 data, the investigator landscape has shifted in ways that challenge successful conduct of clinical trials (e.g., lower proportion of experienced sites, high turnover among new PIs, etc.). The resulting impact for sponsors is higher operational costs, especially related to site identification, qualification, and start-up. In addition, existing investigator sites are under significant pressure from increasingly complex protocols, more data points, an increase in inclusion/exclusion criteria leading to challenges in patient recruitment, stricter budgets, and contracts that include performance targets and penalties.

Technology can only serve as a solution to these problems if it is available globally and implemented correctly. Considering the type of devices accessible at the site, compared to technology available to consumers, will be important in ensuring that new solutions can be implemented consistently across a global study. In addition, training support for investigators and sites will be crucial in ensuring innovations in technology perform as intended and reduce, not increase, burden for investigators and patients, and also do not pose an additional challenge to site sustainability.