Challenges and opportunities in medical device clinical trials in Europe

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In mid-2021, a survey was launched to evaluate where European medical device manufacturers and pharmaceutical companies see the greatest challenges in clinical trials and which trends they envision in this area in coming years. The top challenges included lack of personnel, time investments, complexity of the study protocol, the identification of suitable subjects, and data analysis and publication. Although most participants had not yet conducted decentralized trials, more than two-thirds said they planned to use them in the coming years.

Clinical trials are essential for medical progress. However, in light of the pandemic, most clinical trial sites (other than those related to COVID-19) have experienced delays in their timelines and sometimes a complete halt of operations, which has affected clinical research outcomes. In a new survey, Clmedo Health and Cureaditis wanted to find out which other challenges companies in the European Union (EU) are facing, particularly across different study phases as well as before and after market approval. Another goal was to assess the state of technology trends, such as decentralized clinical trials (DCTs), which gained a lot of traction in the face of COVID-19.
Survey participants and methodology

A total of 60 participants from Europe joined the survey in the summer of 2021 (Figure 1). Sixty-five percent of participants worked for medical device manufacturers, and 22% were from pharmaceutical or biotech companies. The remainder worked for in vitro diagnostics or other companies. To maintain a representative picture, nonmanufacturers were asked to answer the questions on behalf of their clients. With regard to company size, 69% of participants worked for an organization with 500 or fewer employees, and 31% worked for companies with more than 500 employees.

We were also interested in what type of studies these companies conducted, that is, premarket, postmarket, or both. Eleven percent said they conducted only premarket studies, 13% said only postmarket studies, and the remaining 76% said they carried out both pre- and postmarket studies.

Climedo Health’s online survey tool was used to gather and evaluate the survey responses.

Results

Planning phase

We started out by focusing on the planning phase of clinical trials. This phase typically includes the study design and protocol, feasibility analysis, the ethics vote, user acceptance tests and the start-up phase.

Figure 1. Survey participants
**Time needed of the planning phase**
For premarket studies, 26% of participants said they needed 3 to 6 months for planning, 41% said they needed 7 to 12 months, and 32% said they needed 13 to 24 months. In the postmarket phase, the planning phase seemed to be slightly shorter on average – 36% said their planning phase took 3 to 6 months, 43% said 7 to 12 months, and just 21% said 13 to 24 months.

**Greatest challenges in the planning phase**
Next, we focused on the main difficulties in the planning phase, again distinguishing between pre- and postmarket studies. The top three challenges in the premarket planning phase were “Lack of personnel” (cited by 56%), “Identifying suitable sites” (56%), and the “Time investments” required (46%; Figure 2).

For the postmarket planning phase, we saw a similar result, but in a slightly different order: 62% named “Time investments” as their main challenge, while 56% said “Lack of personnel,” and 46% cited “Identifying suitable sites.”

Other challenges named in both pre- and postmarket studies were “High costs or lack of budget,” “Creating study documents,” and “Approval by authorities.” So clearly, even this first phase can be costly and time-consuming for companies, regardless of whether their product has been taken to market or not.

Finally, we asked companies to rate how challenging they found this phase overall. On a scale of 1-5, they rated it 3.2, suggesting it was moderately challenging.

**Overcoming challenges in the planning phase**
When asked what they believed was needed to overcome these issues, respondents named “More personnel” (41%), and “More digital processes” and “More practical

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**Figure 2. Challenges in the planning phase**

**What are your greatest challenges in this phase?**

Source: Challenges and Opportunities in Clinical Studies 2021
experience” (both 37%), for the premarket phase. For postmarket studies, they also emphasized “More personnel” (52%), “More digital processes” (48%), and “Support by authorities” (36%).

**Digitalization in the planning phase**
Next, we wanted to see which areas have the most potential for digital transformation in the planning phase on a scale of 1-5. Here, respondents rated “Feasibility analysis” in first place, followed by “Communication with authorities,” “Patient recruitment,” “Identifying suitable study sites,” and “Study design.”

Another goal was to assess which technologies companies can envision using in their planning phase in the next 1 to 2 years. The top three technologies named were “Smart form development” (cited by 63%), “Planning tools (such as medical workflows and patient journeys)” (56%), and a “Protocol optimizer,” which was cited by just under half (48%). Other potential digital solutions named were “Recruitment forecast” (41%), a “Study guide for planning phases” (37%), “Site performance monitoring” (37%), and “Interoperability” (26%).

**Implementation phase**
The implementation phase involves patient recruitment, first-patient-in, patient screenings, rounds, home data collection, monitoring, and last-patient out. It is usually the longest and most complex phase.

**Time needed of the implementation phase**
For the premarket phase, 11% of participants said they needed 1 to 6 months, 33% said they needed 7 to 12 months, 39% said they needed 13 to 24 months, and less than one fifth (17%) said 25 months to 48 months. None of the participating companies needed more than 2 years.

In the postmarket phase, 17% needed 1 to 6 months, exactly a third needed 7 to 12 months, and 17% needed 13 to 24 months, 25 to 48 months, and more than 48 months, respectively. This would suggest implementation phases of postmarket studies can take longer than for premarket studies.

**Greatest challenges in the implementation phase**
In terms of challenges for premarket studies during this major phase, companies said study protocols were too complex (69%) and also cited “Identifying suitable study subjects” (56%) and “High costs” (50%). Two factors that were particularly challenging in the planning phase, but seemed a little less problematic during study implementation, were “Lack of personnel,” “High time investments” (both just over 40%). Finally, 38% of respondents named “Frequent protocol adjustments” for premarket studies in the implementation phase.

When asked about postmarket studies, companies named “Identifying suitable study subjects” in first place (62%), the fact that the study protocol was too complex (56%), and “High costs” (46%), which was again, quite similar to the premarket
phase. In fourth place, they mentioned the high data protection requirements and high time investments, as well as the lack of a monitoring tool (all just above 40%).

Regarding the difficulty of this phase, respondents rated it a 3.4 on a scale of 1 to 5 on average, so slightly more challenging than the planning phase. The implementation was also seen as the most challenging of all three phases.

**Overcoming challenges in the implementation phase**

To overcome these issues, participants named “Motivated study centers and patients,” “More digital support,” and “More personnel” for both pre- and postmarket studies in the same order for the implementation phase.

**Digitalization in the implementation phase**

For this phase, too, we looked at the areas companies believed could be digitalized. In first place, they named “Data capture,” which plays a major role in clinical research. This was followed by “Communication with patients” — much of which is now happening remotely because of the pandemic. Next were “Monitoring,” “Patient compliance, motivation, and retention,” and “Patient recruitment” (Figure 3). These findings reflect claims in a Pharmafile article, which explains that patient recruitment and retention are particularly difficult for pharmaceutical studies.

We also explored which technologies companies could imagine using in the implementation phase in the near future. In first place, three-quarters cited “Integrating data from the electronic patient record,” followed by “Data interfaces for a centralized data exchange” (65%), and “Automated data validation and cleansing” (65%). Next came “Automated patient suitability assessment” and “Telehealth solutions” (60% each).

**Figure 3. Which areas of the implementation phase could be digitalized?**

On a scale of 1-5, how high do you rate the digitalization potential for the following areas of the implementation phase?

- Data capture
- Communication with patients
- Monitoring
- Patient compliance, retention and motivation
- Patient recruitment

*Multiple answers possible

The greatest potential for digitalization in the implementation phase is seen in data capture.

Source: Challenges and Opportunities in Clinical Studies 2021
A study by McKinsey\textsuperscript{3} supports the uptake of telehealth. Early in the COVID-19 pandemic, usage surged as both patients and healthcare providers looked for new ways to access and deliver healthcare service while maintaining social distancing measures. Telehealth growth peaked in April 2020 and has since stabilized.

Other technologies named in the survey were “Smart form development,” “Automated notifications and edit checks,” and “AI for pattern recognition.”

**Close-out phase**
Finally, the close-out phase involves queries, data management, database freeze, data export, the statistical analysis, as well as the final report and publication.

**Time needed of the close-out phase**
Unsurprisingly, the close-out phase was relatively short compared with the previous two phases. In premarket studies, 60% of respondents said they needed 1 to 6 months, 27% said 7 to 12 months and the remaining 13% said 13 to 24 months. For postmarket studies, 67% said 1 to 6 months, 11% said 7 to 12 months, and 22% said 13 to 24 months.

**Greatest challenges in the close-out phase**
Despite its short duration, the close-out phase is not without its challenges. The top three areas causing difficulties in premarket studies were “Data analysis” and “Aggregating and publishing results” (both around 60%), as well as the “High costs” involved (40%).

For postmarket studies, respondents named “Aggregating and publishing results” (78%), “Time investments,” and “Data analysis” (both 56%). This would suggest that the close-out phase is more time-consuming and aggregating results from it are more complex in postmarket studies than premarket studies.

In terms of the overall perceived difficulty of this phase, the close-out phase was rated 2.8 on a scale of 1 to 5, so less challenging than both of the previous phases analyzed.

**Overcoming challenges in the close-out phase**
Companies were also asked what they thought was needed to deal with these challenges. For premarket studies, they named “More digital processes” (53%), “More personnel” (47%), and “Consultation services” (40%). Postmarket studies in the close-out phase, could benefit from “More digital processes” (56%), “More personnel” (56%), and “More practical experience” (44%), according to the respondents.

**Digitalization in the close-out phase**
Which areas do participants believe could still undergo digital transformation in this final study phase? According to survey results, “Data management,” “Data export,” and “Statistical analysis” are the top three areas, followed by “Database freeze,” “Final report,” and “Publication” of the results (Figure 4, p. 7).
When asked about which technologies companies could imagine using in the near future, they named “Digital tools for analysis” (74%), “Digital, legally compliant archiving of study data” (68%), and “Optimization analysis for further studies” (58%). Additional tools named were a guide for “Reimbursement” (just under half), “AI for pattern recognition” (37%), and a guide for the close-out phase (just under a third).

**A look at the future**

The final part of the survey was about future trends in clinical trials. Here, we asked respondents about the most defining trends they foresee for the future of clinical trials. By far the biggest trend, cited by 89%, was “Minimal on-site monitoring through eCRF integration.” This plays a major role in DCTs, in which patients no longer, or rarely, need to travel to a physical site but can be monitored remotely through telehealth solutions. DCTs were named in second place by 58% of respondents, and those will be more closely covered in the next section. In third place, companies cited “High use of wearables” (47%; **Figure 5**, p. 8).

Data capture from wearables is a huge trend which is also supported by a Gartner study:4 It showed that worldwide end-user spending on wearable devices for healthcare purposes will total US$81.5 billion in 2021, an 18% increase from US$69 billion in 2020.

In all, 42% of participants also named as a defining trend “Patient centricity,” which can be greatly enhanced through DCTs. In traditional clinical trials, everything revolves around a physical study center or clinic, because patients need to travel to it to join a study. In DCTs, the patient is placed at the heart of study, since all data
capture is made as convenient as possible for them through telehealth solutions or digital surveys that can be completed on a mobile device at home, for example. Another two trends were “Adaptive trial design” (37%) and “AI as decision support” (32%).

**Decentralized clinical trials as the way of the future**

Next, we took a deep dive into the area of DCTs. The majority of our respondents (just under 80%) had not yet had any experience with DCTs, while around one-fifth had (Figure 6).

This would suggest that Europe is falling behind other geographical areas, such as the US, when it comes to this trial format. In a global survey by Informa Connect, 70% of respondents said they had been involved in, or worked on, trials that have implemented at least some decentralized element in the last 2 years.

In this survey, however, two-thirds of those who had not yet worked with DCT models said they planned to conduct DCTs within the next 3 years. In terms of the benefits of DCTs, those few who had already worked with them reported “Cost savings,” “Faster study completion,” “Facilitated patient recruitment,” and “Improved patient retention.” These advantages clearly speak to the potential of DCTs.

**Simplifying the clinical trial process**

The final question addressed the aspects which need to change in order to simplify the clinical study process for companies. In first place, respondents named “More openness towards digital technologies” (74%), which would make sense if we want
to use DCTs, telehealth, and real-world data capture through wearables. In second place, they cited “Better communication with study centers” (68%), and in third place, “Clearer communication of legal requirements by the state” (58%). Two final areas mentioned were “Less bureaucracy with authorities” and “Placing patients more at the center,” with the latter playing a major part in DCTs which favor enhancing patient centricity.

**Conclusion**

Clinical trials clearly bear many challenges of medtech and pharmaceutical companies alike across all three study phases, both for pre- and postmarket studies. But regardless of the phase or study type, our data consistently show that embracing digital technologies is perceived as one of the key solutions for overcoming these difficulties.⁶

One interesting point we noticed during the analysis was that pharmaceutical companies seemed to be slightly better positioned compared with medtech companies: When comparing their responses, not only did we find that they consider all three study phases a little less challenging overall – they also saw more potential in almost all digitalization areas than medtech companies did.

In an increasingly digitalized world, everything suggests that our healthcare industry is not sustainable without decentralized research solutions. COVID-19 and the resulting accelerated digital transformation across many industries have only reinforced this trend. Companies that continue to rely on traditional clinical trials run the risk of lagging behind competing firms using DCTs who will likely be in a better position to bring their medical innovations to market faster and continue to conduct high-quality studies and potentially discover new indications following...
market approval. While DCTs require a great deal planning, investment and change processes from companies, the long-term benefits will far outweigh the initial costs and allow companies to accelerate their clinical trials and involve larger and more diverse patient populations – both during the pandemic and beyond.

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References
All references with URLs accessed 27 September 2021.