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COVID-19 and the impact on the clinical trial space

The effect of COVID-19 on clinical trials, the industry response, and the return to full operations

WHITEPAPER

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Executive summary

Clinical trials for therapeutic areas outside of COVID-19 are experiencing disruptions and delays as social distancing measures and travel restrictions are implemented across the world. Many sectors of the industry are also shifting R&D priorities towards finding new vaccines and treatments for COVID-19 at the expense of other indications. However, the biopharmaceutical industry is compelled to maintain its momentum in R&D in order to bring safe and effective therapies to market while protecting investments already made by companies. Telemedicine, virtual trials, and electronic data management are experiencing accelerated adoption as companies try to protect patients, investigators, and healthcare providers while maintaining R&D continuity. In addition, efforts to diversify clinical research across different geographies and demographics can create resiliency in clinical development programs by spreading the risk of disruption to areas experiencing limited impact from the pandemic. This also results in clinical data that is more representative of the real world. With these improvements in R&D efficiency in response to the pandemic, regulatory agencies will need to revisit traditional clinical-regulatory models in order to bring safe and effective drugs to market faster. This creates an opportunity for biopharma to turn mitigating responses to COVID-19 into a platform for accelerated growth post-pandemic.

Effect of COVID-19 on clinical trials

As social distancing measures are implemented across the world and pharmaceutical companies shift R&D efforts towards finding vaccines and treatments for COVID-19, clinical trials for therapeutic areas outside of coronavirus are increasingly becoming stalled.

Since social and travel restrictions were implemented in North America and the EU, public announcements of clinical trial suspensions and delays have increasingly become a daily occurrence due to concerns of coronavirus spread. Ongoing trials have been impacted by temporary closures, suspensions, or outright terminations, while some planned trials have been postponed, delayed, or cancelled. Eli Lilly[1] was among the earliest big-pharma companies to announce the suspension of a large proportion of its clinical trials, and since then, a growing number of companies throughout the industry have made similar pronouncements. An analysis of Informa Pharma Intelligence's Trialtrove and Pharmaprojects data reveals that of the approximately 14,900 ongoing industry trials across the globe, over 500 trials have been affected, with North America and Europe making up the largest proportion of affected trial sites. However, given the rapidly changing dynamic of the pandemic and its bearing on trial operations, this likely underestimates the full impact on the ongoing clinical trial space, with the number of affected trials expected to grow as trial dropouts

and further postponements are announced. In addition, many sponsors have made only general statements regarding the status of their clinical development programs without reference to specific trials or studies, further complicating the ability to accurately estimate the number of trials impacted by COVID-19.

Figure 1a: The impact of COVID-19 on clinical trials

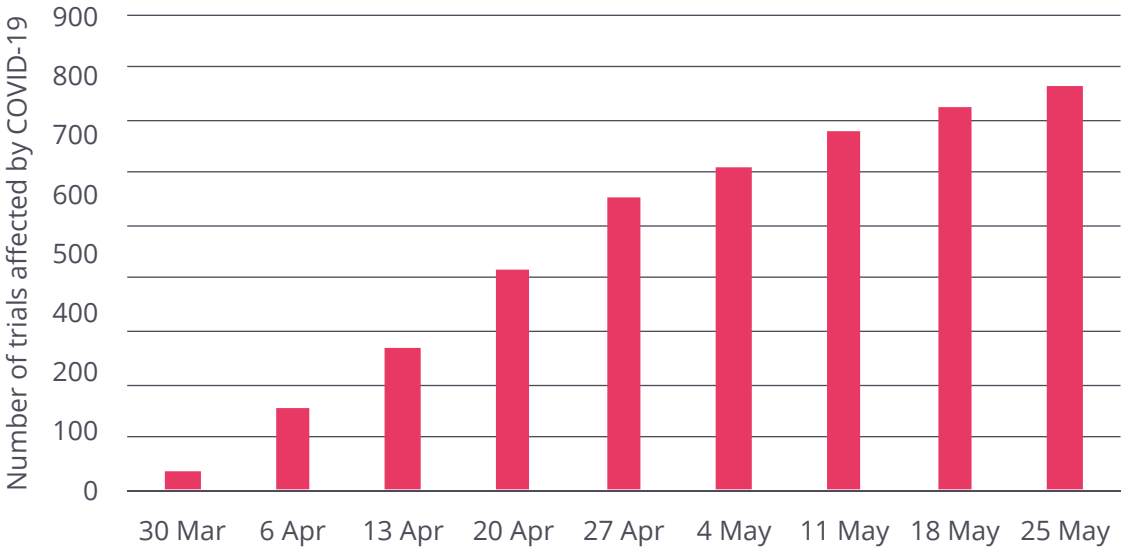
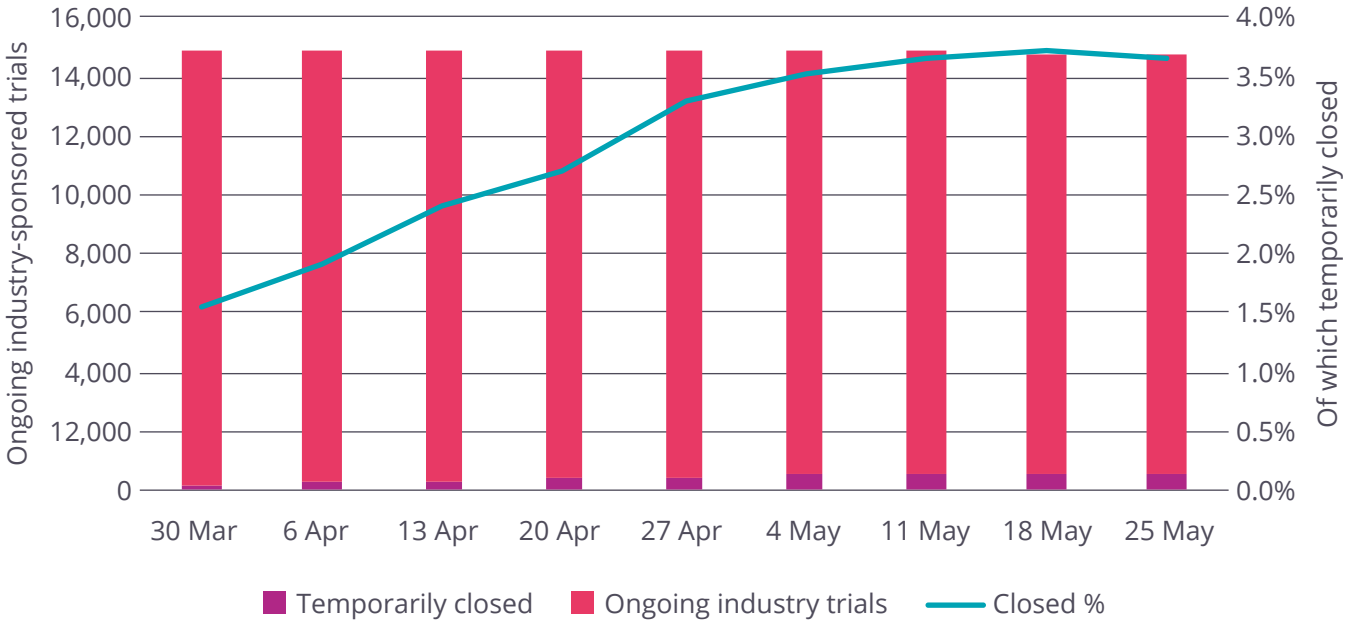


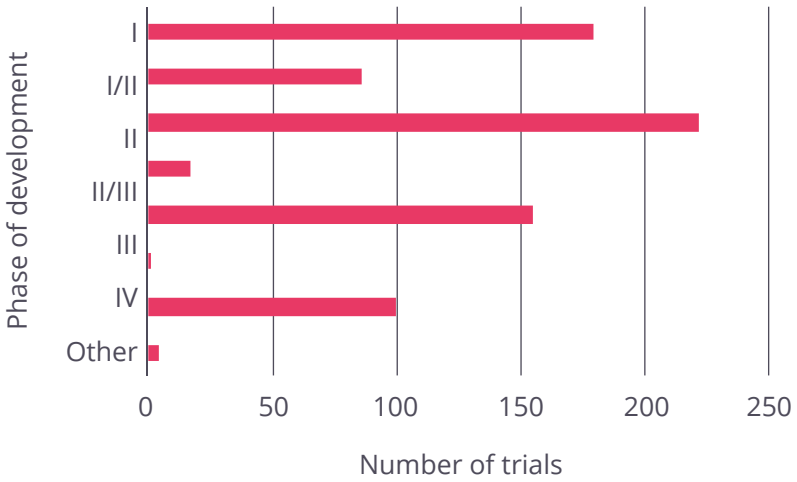
Figure 1b: The effect of COVID-19 on industry-sponsored trial status

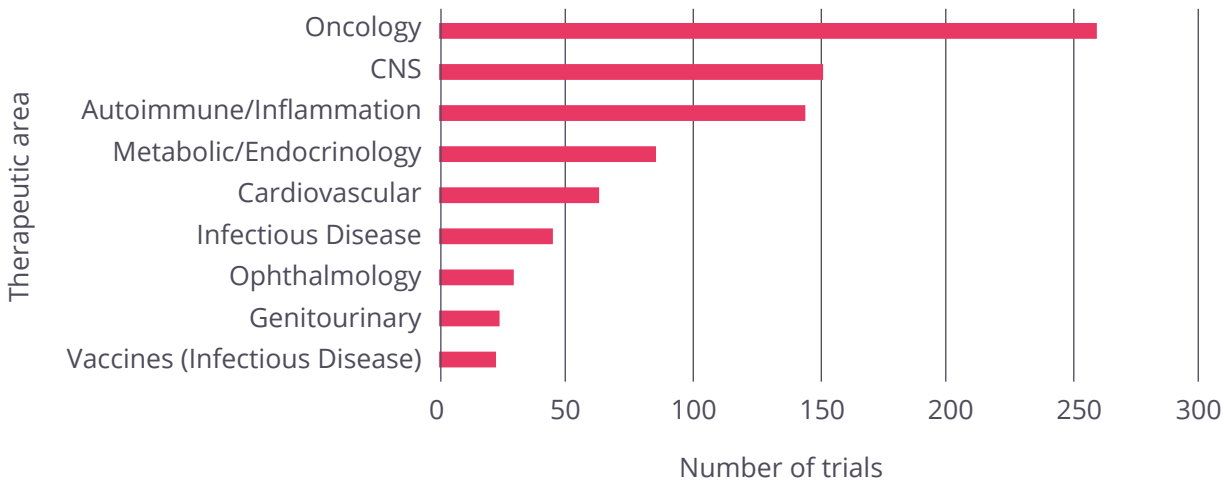


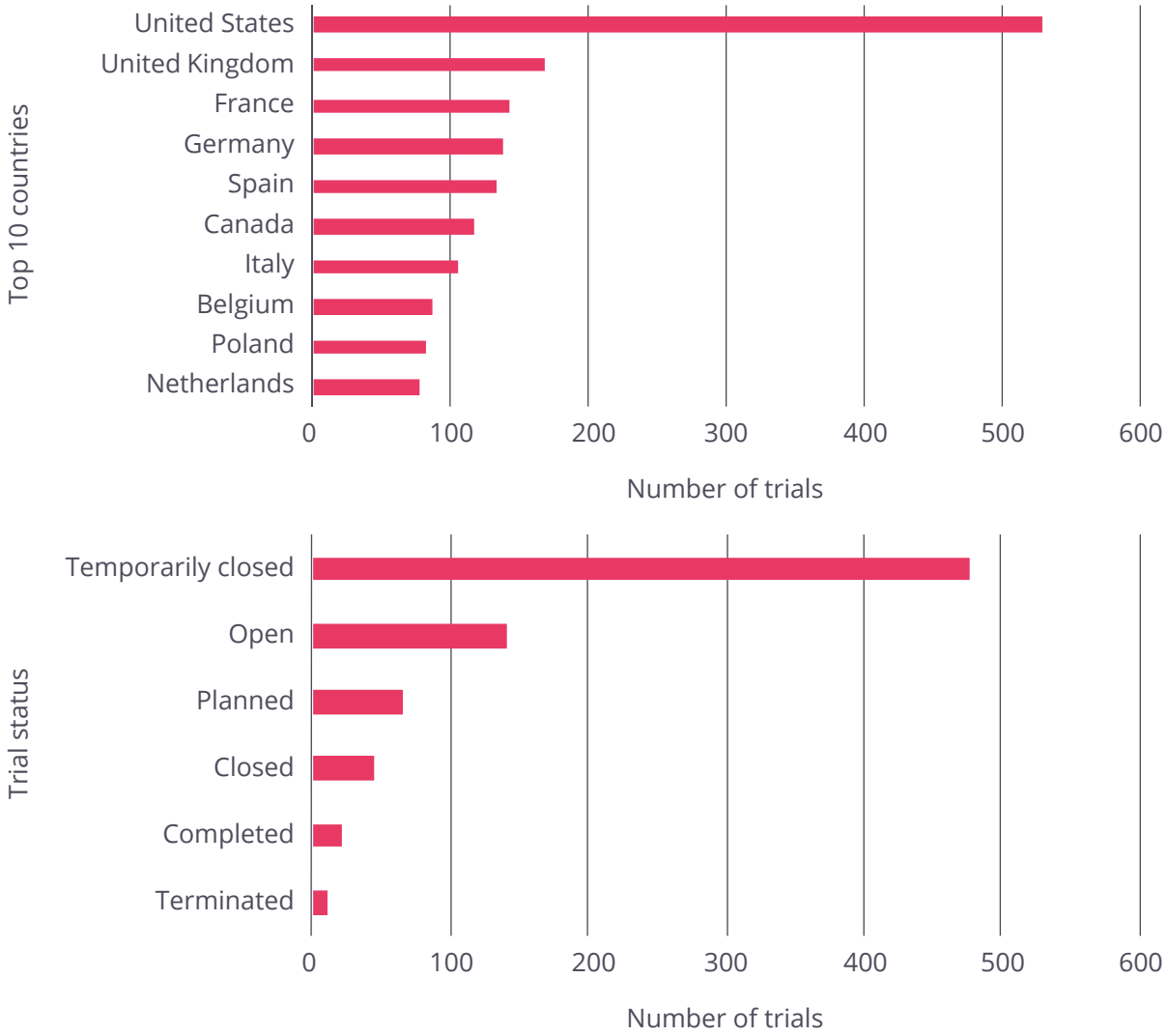
Source: Pharmaprojects® and Trialtrove®, May 2020

This impact is being felt most substantially in early-phase trials, which make up the greatest proportion of studies facing temporary suspensions, closures, or delays. Over two-thirds of COVID-19-affected industry-sponsored trials are in Phase I, Phase I/II, or Phase II development. Without early-phase data to support continued development in pivotal Phase III trials, drug filings for new therapies will be delayed, resulting in extensions to an already lengthy drug approval process. This will have significant downstream affects as clinical and commercial plans once considered critical before the pandemic are forcibly placed on hold. Therapeutic areas where patients are at greatest risk of complications from COVID-19 due to immuno-deficiencies and co-morbidities, such as oncology or autoimmune diseases, are feeling the impact the most, with these patients also now facing reduced access to potentially life-saving medicines. Nonetheless, all indications and phases of development are expected to be further impacted to some degree due to these challenges.

Figure 2: Cross-sectional view of COVID-19-affected trials







Source: Pharmaprojects® and Trialtrove®, May 2020

Regulatory bodies like the FDA and EMA have already begun releasing guidelines to help ensure data integrity as well as the safety of all trial participants, to include patients and trial personnel. FDA guidance for clinical trials impacted by the COVID-19 pandemic has stated that safety of trial participants is a key priority, adding that "sponsors should consider each circumstance, focusing on the potential impact on the safety of trial participants, and modify study conduct accordingly[2]." Additional considerations might include whether or not to continue use of the investigational product for patients already participating in the trial, continuing trial recruitment, and the need to change patient monitoring protocols during the trial. In order to maintain flexibility in a highly dynamic COVID-19 environment, the FDA guidance also outlines how to handle protocol deviations and amendments, allowing industry sponsors to consolidate implemented several protocol medications into a single protocol amendment. The MHRA and

EMA have similarly provided guidance on how to manage clinical trials during the pandemic, emphasizing the need for participant safety and flexibility. The MHRA[3], for example, notes that sponsors should conduct a risk assessment on the impact of COVID-19 on clinical trials across all phases, while the EMA[4] specifically advises temporary halts at some or all trial sites, though notes trial suspensions can in some cases compromise the overall well-being and best interest of patients, and measures should be taken to avoid such situations.

Despite guidance from regulatory bodies, companies looking to continue clinical trials or initiate new studies will have to take into account practical and ethical considerations in the face of the COVID-19 pandemic. Social distancing measures have made in-person treatment and evaluation difficult for trial participants, trial investigators, and healthcare providers. Trial participants may be unwilling or unable to travel for continued treatment and evaluation, resulting in non-compliance, protocol breaches, and patient dropouts. Furthermore, the lack of widespread COVID-19 testing in many study regions could result in infected patients participating in trials, compromising their safety and confounding clinical trial outcomes. These challenges will also impact enrollment in new trials and thus should be taken into consideration to ensure the safety and viability of all trials.

Industry will need to adapt in order to maintain momentum

Biopharma will need to rapidly adapt and evolve as an industry in order to maintain its momentum while at the same time alleviating the impact of COVID-19-related disruption. Guidance from regulatory agencies now allows for greater flexibility on the conduct of clinical trials, but biopharma companies ultimately have few options. Though health authorities outline how sponsors can maintain the momentum of ongoing studies, making procedural or protocol changes for ongoing studies can lead to additional clinical and commercial risk. The pandemic has thus necessitated a change in the way companies plan and conduct clinical trials, as well as the way in which regulatory bodies provide oversight, but continuity will be key in order to continue improving patient outcomes in indications outside of COVID-19 infection.

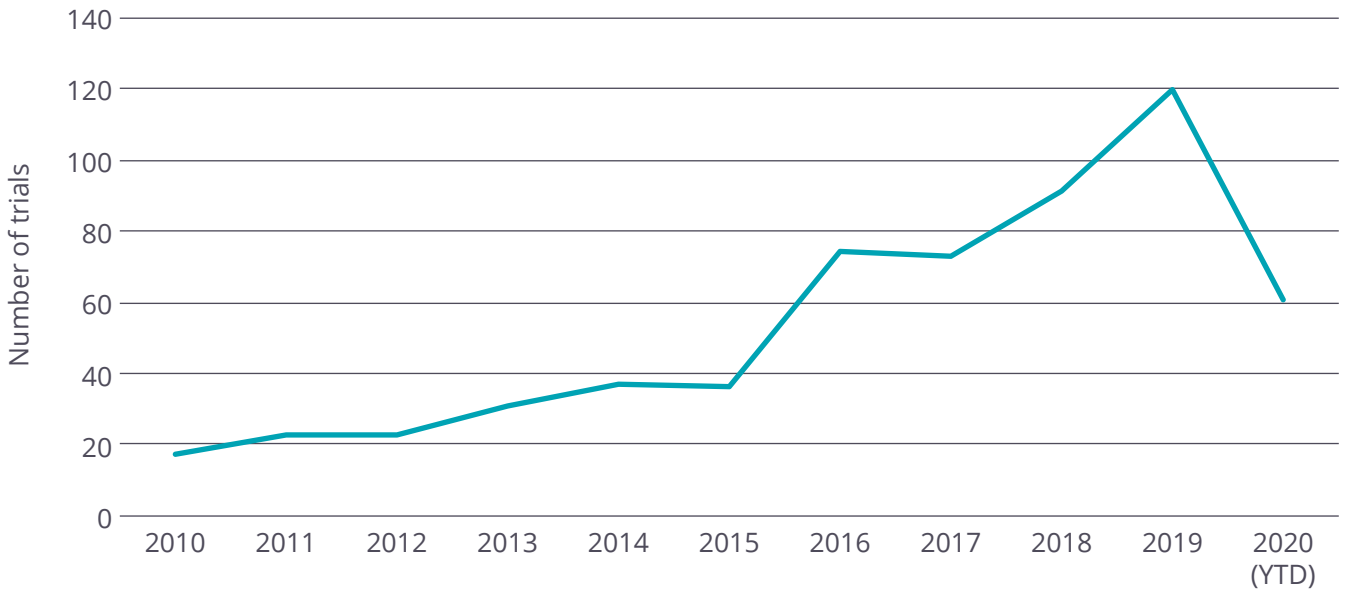
COVID-19 could accelerate the adoption of telemedicine and virtual trials

With regulatory agencies and biopharma companies now looking for alternative ways of collecting safety and efficacy data in the face of the pandemic, digital technologies, telemedicine, and virtual trials are being recognized as potential solutions to mitigate risks and minimize trial disruptions.

In the FDA's guidance on clinical trial conduct during the COVID-19 pandemic, the agency suggested remote monitoring and virtual visits via telemedicine as options to in-person visits, though trial investigators, sponsors, and CROs will still need to assess whether these alternative methods are aligned with the study protocol and easily incorporated. The MHRA provided similar

suggestions in their guidance. Trialtrove captured less than 300 ongoing virtual trials evaluating drug safety and efficacy now incorporating telemedicine remote monitoring, with the vast majority of these trials taking place in the EU and North America. For the purpose of this analysis, virtual/decentralized trials are defined as those publicly disclosed as incorporating telemedicine, remote monitoring systems, wearable technologies, and/or mobile apps or devices, and may not occur in a traditional setting such as a clinical or hospital during all phases of treatment and evaluation. But while these data show that virtual trials are currently being used to only a limited extent, COVID-19 will in all likelihood accelerate their adoption on a larger, global scale.

Figure 3: Decentralized, virtual trial starts by year



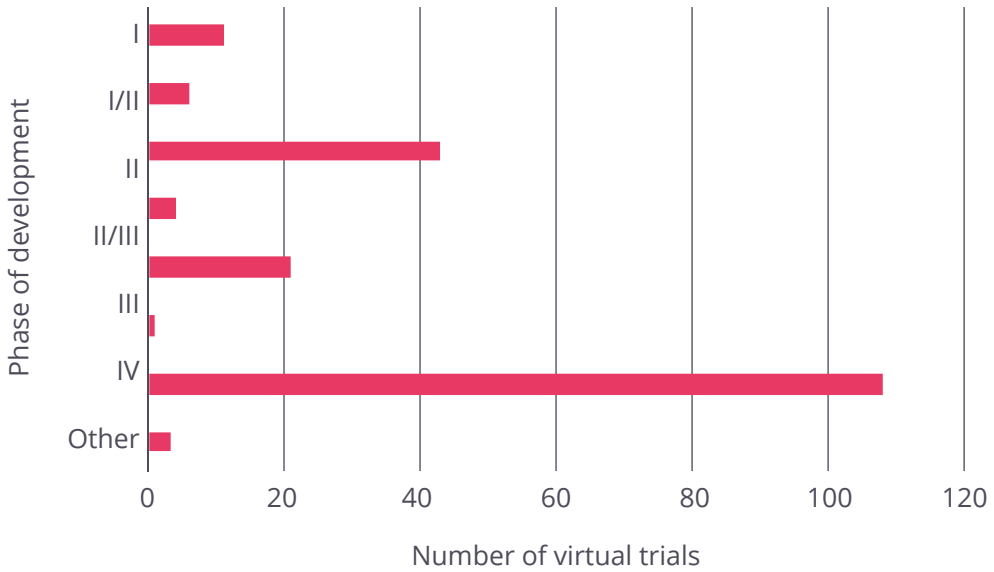
Source: Pharmaprojects® and Trialtrove®, May 2020

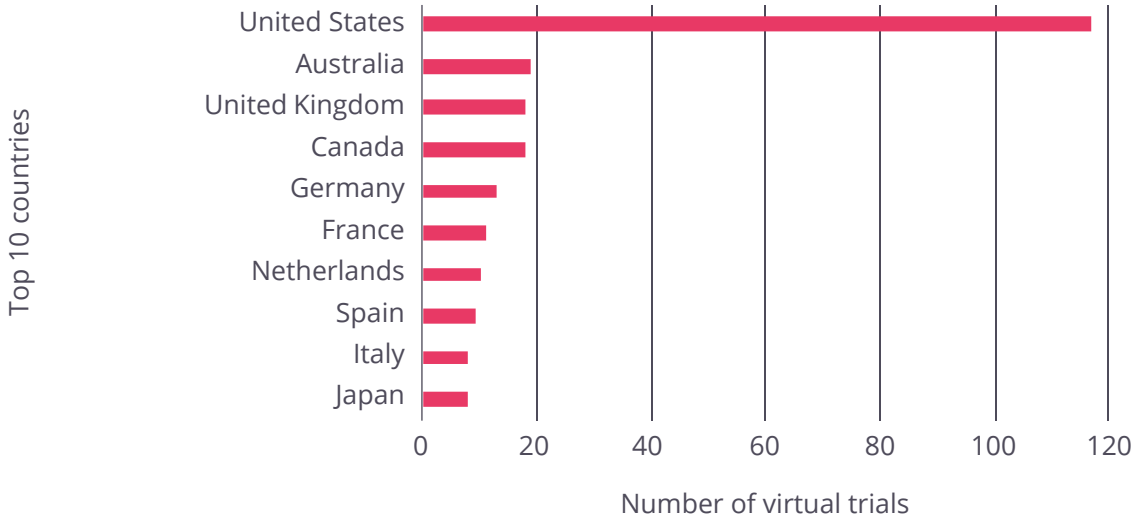
Since virtual trials integrate telemedicine, digital health technologies, and electronic remote monitoring systems to execute certain procedures within a clinical trial protocol, a significant proportion of the study can be conducted at decentralized locations remote from the study site. In most virtual trials, patients are located at home or other local treatment center, away from the trial investigators. Patients can be recruited digitally and can fill out an electronic informed consent form from the comfort of their homes. Investigational medicines are shipped directly to the patient's home or local treatment center, and digital health technologies, such as wearables or mobile apps, are used to capture safety and efficacy data. Regular televisits are also scheduled to evaluate patients and ensure assessments are conducted in accordance with the protocol.

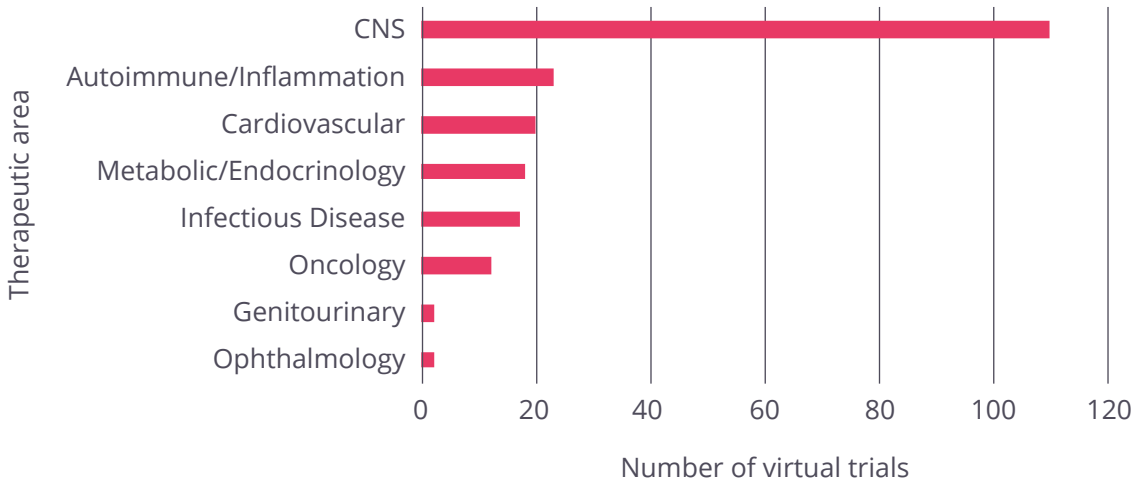
While many industry sponsors are scrambling to adapt in order to maintain momentum, several biopharma companies already began leveraging

the power of virtual trials and analytics prior to the COVID-19 pandemic. Companies that have already done so have a clear head start. In February 2020, Johnson and Johnson initiated the Heartline study, a virtual trial designed to see if a new iPhone app combined with an Apple Watch can help reduce the risk of stroke by detecting atrial fibrillation[5]. Since then, Janssen Pharmaceuticals and PRA also launched the first pivotal heart failure trial utilizing a decentralized, mobile design[6]. The CHIEF-HF trial uses PRA's mobile platform and wearable devices to capture real-world safety and efficacy data of canagliflozin in adults with heart failure, directly from patients. As the use of wearable technologies and remote monitoring systems captures the stream of real-time data from patients, new technology platforms such as AI and machine learning can be used to analyze data and provide predictive insights. Novartis's NerveLive platform, first announced in 2018, looks to utilize data analytics to blend traditional and virtual trial models, as well as interpret data more precisely and accurately in the hopes that it can lead to new medical and scientific breakthroughs[7, 8]. These decentralized trials from industry leaders, coupled with electronic data managements systems and advanced analytics, could thus provide a roadmap for biopharma companies looking to maintain continuity during the pandemic.

Figure 4: Cross-sectional view of ongoing decentralized, virtual clinical trials







Source: Pharmaprojects® and Trialtrove®, May 2020

As with industry sponsors, CROs are adapting by leveraging remote monitoring, virtual visits, and other key aspects of home-cased care to sustain momentum and minimize disruption to the clinical trial space. Unified digital clinical trial platforms like Medidata seamlessly connect each step from initial trial design through data collection and analysis, allowing clinical trial operations to function continuously in the face of the pandemic[9]. Other CROs like Paraxel are utilizing a combination of real-world evidence studies, decentralized, and hybrid trial approaches where appropriate to maintain momentum in the clinical development process[10]. However, one of the keys to ensuring success during the shift to virtual trials is prioritizing and maintain consistent trial standards, which requires increased communication among industry sponsors, clinical CROs, and patients. Guidance from the Association of Contract Research Organizations

(ACRO) suggests that remote reviewing of patient visit data should be implemented through electronic data capture, focusing on patient safety and data quality[11]. In addition, the guidance recommends that clear strategies should be discussed between the sponsor and CROs on how data is to be monitored documented. Regardless of the steps that are taken, from the standpoint of CROs, the goal will be to maintain data integrity while still supporting clinical trial site and keeping patients safe.

Diversification of clinical research can help accelerate clinical research and improve its applicability to the real world

A key downstream advantage of decentralized, virtual trials is the ability to geographically diversify clinical trials. Combined with the diversification of traditional clinical trials and additional adoption of hybrid trial models, decentralized trials not only expand access to potentially life-saving medicines for patients not local to major clinical trial centers, but also facilitate optimal recruitment of eligible patients across a broader demographic and geographic spread. The result is a more inclusive, realistic study population, with greater applicability to the real world and improved resiliency to disruptions.

Clinical trial participation rates have not changed substantially in recent years despite the growing need for studies to test an ever-increasing number of new and promising therapies. However, data suggests that absence of available trials and patient ineligibility serve as the leading barriers to trial participation[12]. A 2019 meta-analysis published in the Journal of the National Cancer Institute revealed that for 55.6% of all cancer patients, no trial was available of the patient's cancer type and stage at a local treatment center. A further 21.5% of patients were simply not eligible for an available trial. In addition, 14.8% of patients were eligible for clinical trials, but did not enroll due to either not being asked or declining when they were asked, which can be attributed to variety of demographic and socioeconomic reasons[13, 14].

Combining virtual trials with a diversification of the traditional trials provides an opportunity for biopharma as an industry to not only address these barriers to clinical trial participation, but also maintain continuity during the COVID-19 pandemic while accelerating the pace of clinical research upon return to normalization. For many patients, a trial may not be available where the patient lives or is being treated and having to travel for participation can create a significant burden, particularly those of lower socioeconomic status where transportation, familial, or employment challenges may need to be overcome. As a result, recruitment may be limited to more developed metropolitan areas with major clinical trial and treatment centers. However, virtual trials can leverage digital technologies and apps to perform recruitment, schedule televisits, monitor patients remotely, and collect data, greatly expanding the geographic diversity of patients by bringing trials to rural and suburban areas away from major city centers, thereby supplementing traditional clinical trials. In indications, therapies, or treatment settings where fully virtual trials might not be appropriate or amenable, sponsors and CROs can also consider hybrid trial models. Hybrid clinical trials blend virtual trial approaches with traditional site-based aspects, offering many of the advantages of a decentralized approach with an intermediary

layer of flexibility and improved diversification. In addition, hybrid trials provide flexibility not only for sponsors but also patients by providing them options to travel for treatment and evaluation or staying local to their healthcare providers.

With this greater geographic diversity also comes greater stability and resiliency in the face of external factors such as the COVID-19 pandemic. Patients in areas less impacted by the pandemic thus become a key source of data as areas more heavily affected by the virus face greater disruption. This advantage extends beyond the country-specific level. Global studies utilizing geographically diverse clinical trials and/or decentralized, virtual trials similarly have the benefit of tapping countries that are less heavily affected by or are recovering from the COVID-19 pandemic. With biopharma companies increasingly seeking global approvals for drugs throughout their portfolio, data from diversified clinical trials also becomes more applicable to the real world.

The diversification of clinical research can only be optimally exploited by making clinical trials available to more patients through a re-assessment of inclusion and exclusion criteria, which continue to be a barrier to clinical trial participation. Although eligibility criteria serve to protect patients who might experience severe side effects and help minimize the impact of confounding factors on statistical analysis, some eligibility criteria have simply become commonly accepted for use with limited scientific or clinical rationale. One study published in the Journal of Thoracic Oncology revealed that the number of exclusion criteria in oncology trials has grown by over 60% over the past 30 years[15]. As a result, the NCI and FDA both release recommendations in 2018 and 2019, respectively, for broadening trial eligibility criteria[16, 17]. While the relaxation of trial criteria will likely necessitate larger sample sizes to assure statistical accuracy, this will also translate to greater clinical trial participation and accessibility, producing data that are ultimately more relevant to the broader patient population.

The return to full clinical and commercial operations

Biopharma is hopeful of a recovery and return to normalization by the end of 2020

Although the COVID-19 pandemic has proven to be an obstacle for the biopharma industry, it is important that companies and organizations strike a balance between short-term mitigation and long-term planning for the return to full clinical and commercial operations.

While big pharma companies generally reported strong underlying demand and limited COVID-19 impacts in their Q1 earnings calls, the pandemic has undoubtedly led to delays, and key questions remain regarding what the timeline might be to get things back on track in R&D. Eli Lilly Chief Scientific Officer Dan Skovronsky had a highly optimistic outlook regarding clinical timelines during the company's Q1 earnings call, noting that clinical trial and enrolment timelines are often estimates rounded to the half year or calendar year, and a worst-case scenario would simply be a day-to-day delay[18]. As a result, Eli Lilly expects normalization to begin occurring in Q3/Q4 and has not changed its 2020 guidance. In contrast, leadership at Merck & Co announced an

anticipated $1.7bn hit to pharmaceutical sales for 2020, with the pandemic impact expected mainly in Q2[19]. The company expects reduced revenues to continue in Q3, but normalization in the fourth quarter. Nonetheless, Merck anticipates a growth of 1–5% for 2020, albeit this is reduced from the previous expectation of 5–8%.

CRO giants ICON and IQVIA echoed similar estimates regarding a return to normalization. IQVIA revealed during its Q1 earnings call that 80% of its clinical research sites are impacted due to travel restrictions and social distancing measures[20]. ICON CEO Steve Cutler similarly estimated that some two-thirds of its clinical trial sites are impacted[21]. However, both companies anticipate Q2 to be the hardest it in terms of revenue, followed by easing and recovery beginning in Q3 and continuing into Q4.

One key market that offers additional glimpses into pandemic recovery timelines is China. Merck based its normalization timeline estimates on its experience in China, where the COVID-19 impacted businesses earlier than North America and the EU but is now on the road to recovery. Although general drug demand fell sharply in China during the peak of the COVID-19 pandemic due to lockdowns, activity is expected to rebound significantly now that 99% of the country is now open with minor limitations[22]. ICON noted in its Q1 earnings call that conditions have been gradually improving in China since mid-March, with over 70% of the company's trial sites now reopened and monitoring activities recommencing. From a commercial standpoint, Lilly's revenue grew 30% in constant currency driven by 93% volume growth in Q1 while Merck reported 17% growth in Q1 China sales. While these specific cases should not be extrapolated to represent the industry as whole, they illustrate encouraging signs of a recovery and may provide some hopeful indicators for currently impacted markets in the future.

Post-pandemic R&D will experience significant shifts in how biopharma operates

There appears to be consensus within biopharma that even with a trajectory towards recovery and normalization in Q4 2020, post-pandemic R&D is going experience a 'new normal' with significant changes to how the industry operates from both clinical and commercial standpoints in the future.

With social distancing measures and travel restrictions in place across the US and EU in response to COVID-19, telehealth and decentralized, virtual trials are experiencing an increase in demand as the industry works to maintain momentum and improve the efficiency of clinical research. Telehealth and virtual trials offer the opportunity recruit patients, remotely monitor, collect data, and analyze results more quickly and efficiently across geographies and different patient demographics. But these improvements in R&D efficiency are also forcing sponsors, investigators, and regulatory agencies to revisit traditional clinical-regulatory models.

As digital technologies and geographic diversification improve efficiencies in clinical trial research, regulatory agencies should adapt to capitalize on these improvements to bring life-saving medicines to market more quickly. Despite advances over the past decade, the traditional clinical trial model still results in an average clinical development time of 10 years. This further results in enormous costs to often duplicate or

confirm previous data observed across Phase I, II, and III trials. In recent years, some indications such as oncology have seen an increased use of safety and preliminary efficacy data from Phase I/II trials leading to accelerated approvals. In other cases, Phase I/II 'bucket' studies incorporating several indications within a therapeutic area may serve as an initial starting point for several indication-specific Phase II studies. While this will likely require larger samples sizes for equivalent statistical power, development timelines can then be shorted by years if regulatory bodies provide more specific guidance on the requirements for accepting Phase II data as pivotal, resulting in additional cost savings. This can also be supplemented with real-world data, which serves as a more accurate representation of the true safety and efficacy of a drug compared with Phase III trials. The FDA, for example, is currently leveraging different sources of existing real-world data to quickly assess the potential of different treatment approaches to COVID-19, an approach that can extended to other indications[23]. With the adoption of technological innovation in clinical trials combined with regulatory changes to support bringing safe and effective therapies to market more quickly, biopharma has an opportunity to mitigate the effects of COVID-19 and emerge from the pandemic ready to accelerate future development.

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