

A Brief History of the COVID-19 Pandemic and Current Efforts to Combat It

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ABSTRACT

The coronavirus disease 2019 (COVID-19) pandemic has necessitated that medical writers adapt their work practices quickly to assist with the preparation of documentation related to COVID-19 research and clinical trials, as well as to assess the impact of the pandemic on other clinical trials. Complexities and challenges medical writers have faced include the growing scientific knowledge of the virus, the burgeoning global footprint of the pandemic, and the evolving regulatory landscape on both COVID-19 and non-COVID-19 clinical trials.

INTRODUCTION

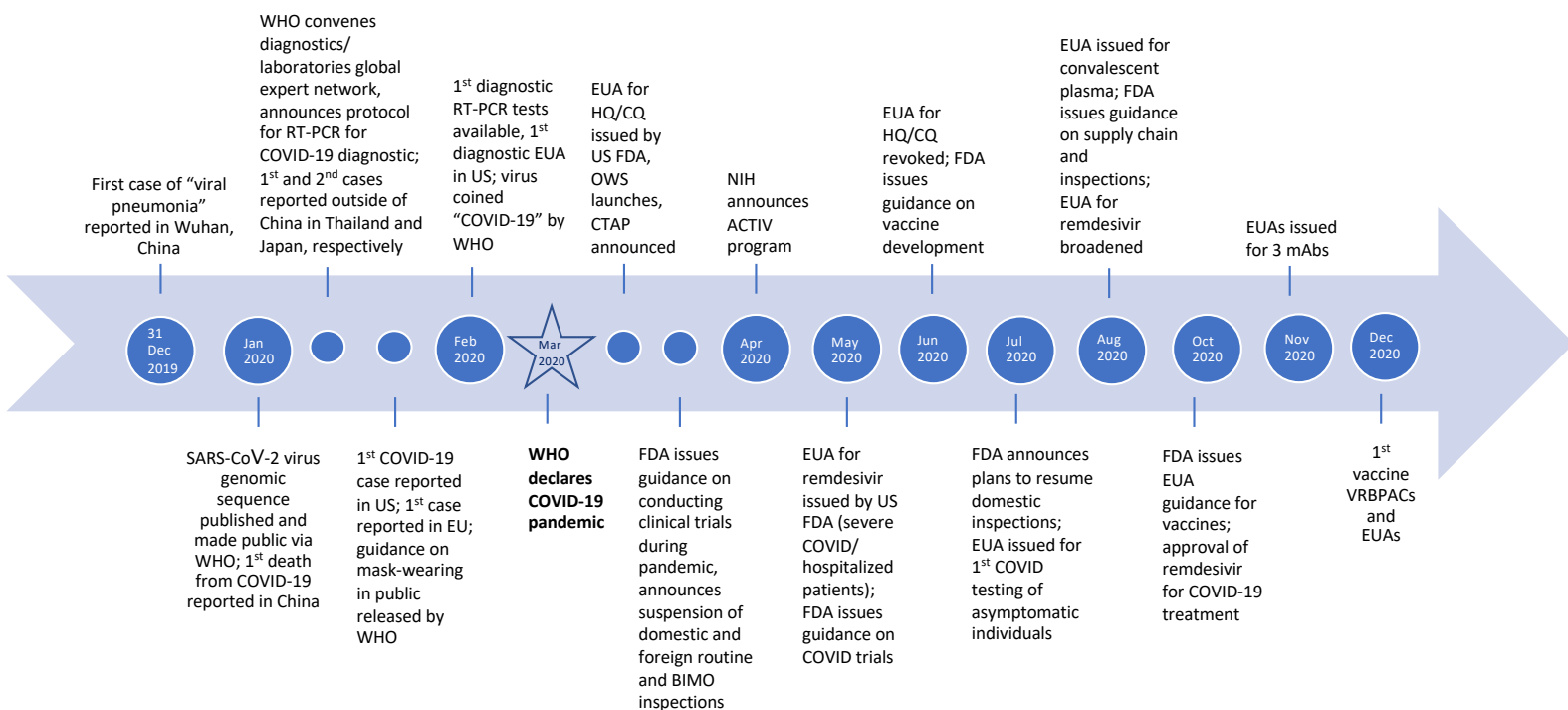
When cases of a novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), surfaced in the Hubei province of China in December 2019, leading to the outbreak of a complex respiratory illness (later coined coronavirus disease 2019 [COVID-19]), the world watched to see what would happen next. Many were cautiously optimistic that the virus would remain endemic to the region of the outbreak, as Middle East respiratory syndrome (MERS) had in 2012,¹ or, at worst, that it could be contained as the severe acute respiratory syndrome (SARS) epidemic had been in 2003.² The challenge of trying to contain the novel coronavirus was complicated by a lack of clarity on exactly how it was transmitted³; it was not until January 19, 2020, that the World Health Organization (WHO) announced that there was evidence of human-to-human transmission of the virus.⁴

This article provides a brief overview of the COVID-19 pandemic time course, the regulatory actions taken to allow for unprecedented rapid development of diagnostic and therapeutic products in the United States for COVID-19, and the impact of the pandemic on medical writers in the biotech and pharmaceutical industry.

Arrival of COVID-19 in the United States and Initial Impact on Biotech and Pharmaceutical Companies

A recent retrospective analysis of SARS-CoV-2-reactive antibodies in archived blood donation samples, spanning 9 states from the East to West coasts, indicates that COVID-19 may have been widely introduced into the United States as early as mid-December 2019.⁵ Despite the first cases of COVID-19 being observed in the United States and Europe on January 19 and 24, 2020, respectively (Figure),^{4,6} operations for biotech and pharmaceutical companies in the United States continued as normal into February. On February 26 and 27, a large conference was hosted by a biotech company in Boston, Massachusetts, which was later deemed a “superspreader” event,⁷ with approximately 100 diagnosed cases after the event ultimately being associated by genomic analysis with up to 330,000 subsequent cases. Following this event, biotech and pharmaceutical companies across the United States, particularly those in states experiencing a surge in cases, began enacting business continuity plans per local and state guidelines, including sheltering in place to the extent possible. Meanwhile, a shortage of personal protective equipment led many companies to donate their current laboratory supplies to local health care centers in surge states in early spring.⁸ For those employees who did have to go on site at their companies to perform experiments, a lack of COVID-19 testing supplies contributed to uncertainty for how to continue critical research while minimizing the risk for virus spread.

With guidelines on safe business operation being issued at the state level, it was not immediately clear how planned research and development (R&D) activities would be impacted or for how long. To address local social distancing requirements, some companies had to prioritize laboratory research for COVID-19 and for certain conditions with unmet need.⁹ It was also not immediately clear to what extent biotech and pharmaceutical companies, and the venture capital firms that finance their R&D activities, would invest in developing treat-



Abbreviations: ACTIV, Accelerating COVID-19 Therapeutic Interventions and Vaccines; BIMO, Biomedical Research Monitoring; COVID-19, novel coronavirus 2019; CQ, chloroquine; CTAP, Coronavirus Treatment Acceleration Program; EU, European Union; EUA, Emergency Use Authorization; FDA, Food and Drug Administration; HQ, hydroxychloroquine; mAb, monoclonal antibody; NIH, National Institutes of Health; OWS, Operation Warp Speed; RT, reverse transcription polymerase chain reaction; SARS-CoV-2, virus that causes coronavirus 2019 disease; US, United States; VRBPAC, Vaccines and Related Biological Products Advisory Committee; WHO, World Health Organization.

Figure. Timeline of key events associated with the COVID-19 pandemic. Sources: WHO,^{3,4,10} GenBank,¹¹ FDA.^{15,18-22,24,33,47-49}

ments for a novel virus that might not persist in the long term, based on evolving information on SARS-CoV-2 as well as prior SARS/MERS experience. These factors represented an initial threat to an industry that is largely dependent upon the continuous advancement of research.

Declaration of a Pandemic, the US Food and Drug Administration Response, and the Shift to Real-Time Drug Development

Pursuant to a rise in the number, severity, and location of cases, a pandemic was formally declared on March 11, 2020, by WHO.¹⁰ The Director of WHO urged countries worldwide to change the course of the pandemic and to “First, prepare and be ready. Second, detect, protect and treat. Third, reduce transmission. Fourth, innovate and learn.”

As more became known publicly about the clinical course of the virus, many global biotech and pharmaceutical companies sprang into action to see if existing technology or assets could contribute to a cure or a treatment for COVID-19 or its sequelae. These companies included those already developing vaccines, those developing therapeutics who entered vaccine development *de novo*, those repurposing existing antiviral

and other drugs, and those developing new drugs. Several companies partnered with other biotech companies or academic institutions to optimize efficiency. The sequence of the virus was first made public in early January 2020,^{4,11} and by late January, the US Food and Drug Administration (FDA) announced that it was “actively leveraging the vast breadth of the FDA’s expertise” and had “begun employing the full range of our public health authorities to facilitate the development and availability of investigational medical products to help address this urgent public health situation.”¹² On January 31, 2020, the US Department of Health and Human Services declared that COVID-19 constituted a US public health emergency and that an Emergency Use Authorization (EUA) was needed to mitigate the threat of COVID-19. This action enabled the FDA, in consultation with the National Institutes of Health and Centers for Disease Control and Prevention (CDC), to authorize the emergency use of unapproved medical products (Table 1).^{13,14}

With so many companies advancing new COVID-19 pipeline assets, many of the biotech and pharmaceutical employees who were initially impacted by the halt of other clinical trials eventually were reassigned to COVID-19–related work.⁹

Table 1. Global and United States COVID-19 Preventive and Therapeutic Initiatives

Initiative Owner(s)	Initiative	Purpose
Various governments, scientists, businesses, civil societies, philanthropists, and global health organizations	The ACT Accelerator	Global collaboration to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines. ^{38,39,a}
WHO + global experts	R&D Blueprint	A global strategy and preparedness plan to fast-track the availability of effective tests, vaccines, and medicines that can be used to save lives and avert large-scale crises. Global Research Roadmap released in March 2020. ^{40,41}
WHO	Solidarity II international clinical trial ^{25,b} COVID-19 technical guidance: The Unity Studies: Early Investigation Protocols	Global collaboration led by WHO that promotes the implementation of serological surveys of SARS-CoV-2. Promotes standardized epidemiological, molecular, and serological methods to facilitate international comparisons so that both countries and the global community can collectively address knowledge gaps and inform an evidence-based COVID-19 response. ⁴²
US DHHS	OWS	Partnership among components of the DHHS, including the CDC, NIH, BARDA, and DoD with private firms and other federal agencies. Coordinates existing DHHS-wide efforts, including the NIH's ACTIV partnership, NIH's RADx initiative, and work by BARDA. Vaccine candidates from 3 companies are part of this initiative. ⁴³
FNIH	ACTIV	Public-private partnership to speed COVID-19 vaccine and treatment options. ⁴⁴
US DHHS, NIH	COVPN	Merged 4 existing NIAID-funded clinical trials networks: the HIV Vaccine Trials Network, HIV Prevention Trials Network, Infectious Diseases Clinical Research Consortium, and AIDS Clinical Trials Group. ⁴⁵
US DHHS, FDA	CTAP	Special emergency program for possible COVID-19 therapies. ⁴⁶ Provides FDA subject matter expertise for ACTIV initiatives, including for clinical trial design/conduct and regulatory standards.

ACT, Access to COVID-19 Tools; ACTIV, Accelerating COVID-19 Therapeutic Interventions and Vaccines; AIDS, acquired immunodeficiency syndrome; BARDA, Biomedical Advanced Research and Development Authority; COVPN, COVID-19 Prevention Trials Network; CTAP, Coronavirus Treatment Acceleration Program; DHHS, Department of Health and Human Services; DoD, Department of Defense; FNIH, Foundation of the National Institutes of Health; HIV, human immunodeficiency virus; NIAID, National Institute of Allergy and Infectious Diseases; NIH, National Institutes of Health; OWS, Operation Warp Speed; RADx, Rapid Acceleration of Diagnostics.

^a COVAX is the vaccines pillar of the ACT Accelerator. More information on the nonvaccine pillars of the ACT Accelerator is available at <https://www.who.int/initiatives/act-accelerator>. On December 31, 2020, the first vaccine received emergency use validation from WHO.³⁹

^b The results of the Solidarity I adaptive treatment trial became available October 15, 2020, and concluded that the 4 treatments studied (remdesivir, hydroxychloroquine, lopinavir/ritonavir, and interferon) had little or no effect compared with standard of care on overall mortality, initiation of ventilation, and duration of hospital stay in hospitalized patients. Additional agents to be evaluated per WHO.

As the author experienced, and based on personal communication of the author with industry colleagues, medical writers set to work alongside researchers on manuscripts for COVID-19 research, many times resulting in unprecedented rapid review and release of results in journals ahead of peer review to allow for real-time dissemination. Regulatory medical writers collaborated with cross-functional colleagues on investigational new drug (IND) application and EUA documentation to enable clinical evaluation of diagnostic, therapeutic, and preventive products; others participated in conversations with contract research organizations (CRO) and sites, balancing

operational feasibility and cost while implementing evolving regulatory guidance, to determine if certain non-COVID-19 trials would be able to continue during the pandemic.

Although medical writers have connected with colleagues remotely via various electronic media for a long time, many recently have had to cope with a new shift in their workload and priorities. In addition, medical writers have had to change how and how often they communicate during the writing process to meet the demand of real-time drug development, oftentimes working in coauthoring environments or live meetings rather than iteratively.

Diagnostics and Medical Equipment for COVID-19 Under EUA

In early February 2020, the first EUA for a reverse transcription polymerase chain reaction COVID-19 diagnostic was issued for use at CDC laboratories.¹⁵ Emergency use authorizations were also subsequently issued for equipment needed to protect health care workers and treat patients with COVID-19 as well as for additional diagnostics at non-CDC laboratories that would reduce the time to and accuracy of results, including home testing kits most recently.^{13,16}

The issuance of FDA guidance on diagnostic testing in May 2020¹⁶ enabled the subsequent availability of additional testing options (for example, rapid antigen testing).

Upon availability of such testing options, medical writers began incorporating COVID-19 testing strategies into study protocols and amendments, with built-in flexibility in language to allow for regional differences in testing availability or adoption of CDC recommendations—a critical step toward the restart of early-phase trials, which often have an in-residence component at the Phase 1 unit.

Preventive and Therapeutic Products, Including Vaccines, for COVID-19 Under EUA

The writing of clinical trial protocols for COVID-19 studies began in the context of the burgeoning geographic footprint of the pandemic, with health care centers in some regions too overwhelmed by critically ill patients to contribute to research while simultaneously in dire need of experimental treatments, leading to an added layer of volatility in an already dynamic process. Accordingly, regulatory advice on the conduct of such studies developed over time. Medical writers worked in concert with their cross-functional partners, regulators, and other stakeholders to overcome these challenges and produce protocols for evaluation of a novel virus and to interpret and convey the results of those studies in record time.

The first EUA for a COVID-19 therapeutic was granted in March 2020 for antimalarial agents hydroxychloroquine and chloroquine (Table 2).¹³ The FDA issued several guidance documents in May 2020 toward expediting development of COVID-19 products,¹⁷ including information on the process for initiating discussions with the FDA (pre-IND)¹⁸ and study design recommendations, including patient selection, end-points, and analyses.^{19,20} Guidelines on vaccine development were issued the following month and updated in October and most recently in February of 2021 to outline the vaccine EUA process.^{21,22} Subsequent EUAs were granted for 9 additional products, including an antiviral in May, convalescent plasma in August, monoclonal antibody regimens in November, and the first vaccines in December 2020 (Table 2).^{13,23} Monitoring of previously issued EUAs continues and, in some cases, has

led to the withdrawal of the EUA, such as that which occurred for hydroxychloroquine and chloroquine upon analysis of conflicting data (including results from a randomized, controlled trial) that brought into question the benefit-risk profile of this regimen for treatment of COVID-19.^{13,24,25} The EUA issued for antiviral remdesivir in May led to approval of the drug as the first treatment for COVID-19 under the Coronavirus Treatment Acceleration Program (see Table 1) in October 2020.

As of January 2021, a search on the US National Library of Medicine's Clinicaltrials.gov (search terms of COVID-19 and SARS-CoV-2, with a recruitment status of not yet recruiting, recruiting, enrolling by invitation, active, or not recruiting) returns results for over 3,500 COVID-19 clinical trials that are ongoing or in start-up.²⁶

Clinical Trials During the COVID-19 Pandemic

Between approximately March and May 2020, thousands of clinical trials (or around 80% of non-COVID-19 trials) reported a disruption,²⁷⁻³⁰ with the majority of these being early-phase trials that had not yet started enrolling patients.^{27,29} The most affected therapeutic areas included those enrolling participants with advanced or life-threatening conditions such as cardiovascular disease or oncology—indeed, the very patients who are most at risk for COVID-19³¹—who often have few other treatment options; the typical intravenous administration route of oncologic treatments, which require patients to go to the clinical site for infusions, has led to additional logistical hurdles.^{29,32} Disruptions were reported as delay or suspension in enrollment, delay in study start-up activities or initiation of certain sites, delay in dosing, termination of enrollment at specific sites, early trial termination, and delay in trial completion or availability of data.^{26,29} In many cases, clinical trials that were nearly or already fully enrolled in patient populations with life-threatening conditions continued with modifications to address the uncertainties and challenges of conducting clinical trials in an already burdened health care system.²⁹

In March 2020, the FDA issued guidance on the conduct of clinical trials during the COVID-19 pandemic, with the goal of ensuring “the safety of trial participants, maintaining compliance with good clinical practice and minimizing risks to trial integrity.”³³ The guidance has been updated on a regular basis and covers key topics, such as:

- Electronic and other remote informed consent options
- Alternative formats for visits (eg, phone contact, virtual visit, alternative locations, local laboratory or imaging centers, home nursing)
- Alternative formats for clinical outcome assessments (ie, patient-reported outcomes, clinician-reported outcomes, and observer-reported outcomes), including protection of data privacy

Table 2. COVID-19 Therapeutics and Biological Products Approved Under EUA

Date of First EUA Issuance (Reissuance, if Applicable)	Approved Product Under EUA	Therapy Type	Authorized Use
March 29, 2021	Janssen COVID-19 vaccine	Recombinant, replication-incompetent human Ad26 vectored vaccine encoding a stabilized variant of the SARS-CoV-2 S protein	For the prevention of COVID-19 for individuals ≥ 18 years old
December 18, 2020 (Reissued February 25, 2021)	Moderna COVID-19 vaccine	mRNA vaccine	For the prevention of COVID-19 for individuals ≥ 18 years old
December 11, 2020 (Reissued February 25, 2021)	Pfizer-BioNTech COVID-19 vaccine	mRNA vaccine	For the prevention of COVID-19 for individuals ≥ 16 years old
February 09, 2021 (Reissued February 25, 2021)	Bamlanivimab and etesevimab	Antibodies	For the treatment of mild-to-moderate COVID-19 in adult and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are ≥ 12 years old, weigh at least 40 kg, and are at high risk for progressing to severe COVID-19 and/or hospitalization
November 21, 2020 (Reissued February 25, 2021)	Casirivimab and imdevimab	Antibodies	For the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (≥ 12 years old weighing ≥ 40 kg) with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progressing to severe COVID-19 and/or hospitalization
November 19, 2020	Baricitinib in combination with remdesivir	Antibody + antiviral	For emergency use by health care providers for the treatment of suspected or laboratory-confirmed COVID-19 in hospitalized adults and pediatric patients ≥ 2 years of age requiring supplemental oxygen, invasive mechanical ventilation, or ECMO
August 23, 2020 (Reissued March 09, 2021)	COVID-19 convalescent plasma	Convalescent plasma	For the treatment of hospitalized patients with COVID-19
August 13, 2020	Sodium chloride and sodium citrate renal replacement and regional solution for anticoagulation of the extracorporeal circuit	Replacement solution for CRRT	To be used as a replacement solution only in adult patients treated with CRRT, and for whom regional citrate anticoagulation is appropriate, in a critical care setting
May 8, 2020	Propofol 2%	Sedative	To maintain sedation via continuous infusion in patients >16 years old with suspected or confirmed COVID-19 who require mechanical ventilation in an ICU setting
May 1, 2020 (Reissued October 22, 2020) ^a	Remdesivir for certain hospitalized patients with COVID-19	Antiviral	For emergency use by licensed health care providers for the treatment of suspected or laboratory-confirmed COVID-19 in hospitalized pediatric patients weighing 3.5 kg to <40 kg or hospitalized pediatric patients <12 years old weighing at least 3.5 kg
April 30, 2020	Potassium-free and 2, 3, and 4 mmol/L potassium solution for hemodialysis/hemofiltration	Replacement solution for CRRT	To provide CRRT to treat patients in an acute care environment during the COVID-19 pandemic

Source: FDA 2021.¹³

Ad26, adenovirus serotype 26; CRRT, continuous renal replacement therapy; ECMO, extracorporeal membrane oxygenation; ICU, intensive care unit; mRNA, messenger RNA.

^aThe original EUA for remdesivir issued May 1, 2020, was for the treatment of suspected or laboratory-confirmed COVID-19 in adult and pediatric patients hospitalized with severe disease. The EUA was expanded to include adult and pediatric patients with COVID-19 irrespective of severity on August 28, 2020. Remdesivir was the first treatment to receive approval under Coronavirus Treatment Acceleration Program on October 22, 2020, for use in adults and pediatric patients with COVID-19 who are ≥ 12 years old and weigh ≥ 40 kg requiring hospitalization; the EUA was reissued to allow for continued access to a subset of hospitalized pediatric patients with suspected or laboratory-confirmed COVID-19 who weigh 3.5 kg to <40 kg or who are <12 years old and weigh at least 3.5 kg.

- Supply chain considerations, such as direct-to-patient shipping, administration by a home nurse, and disposal of the investigational product
- Remote site monitoring considerations, including prioritization of monitoring activities in the circumstance of clinical trial site closures, infectious disease control restrictions, or local travel constraints
- Serious adverse event (SAE) reporting, including reporting of cases of COVID-19 on non-COVID-19 clinical trials and cross-reporting of SAEs in the case of multiple INDs

A key takeaway of the guidance is to ensure collection of information on when and how any mitigations were implemented in a clinical trial to facilitate subsequent reporting on the impact of COVID-19 on the trial objectives.

In addition, the biotech and pharmaceutical industry has contributed to the discussion of clinical trial mitigations necessitated by COVID-19. TransCelerate Biopharma, a collection of member biotech and pharmaceutical companies working to standardize key clinical trial activities, released a number of COVID-19–related initiatives, including a data-sharing platform called DataCelerate for COVID-19 research, tools for risk-based monitoring and protocol deviation management, and a clinical study report template for outlining details on COVID-19–related clinical trial impact.^{34,35} With information changing regularly because of the dynamic nature of the pandemic and its regionally varied effects, and with ongoing updates from global health agencies, however, it is clear that any such tool will be a work in progress rather than a static guideline and that medical writers will need to stay informed on any updates over time.

It is unclear as of yet what impact these mitigations have had on the overall continuation of non-COVID-19 clinical trials during the pandemic. The success of the mitigations will need to be analyzed and reported on at an individual study level, depending on the company's assessment of what measures were needed at the time the pandemic affected the trial, with any publications based on the trial footnoted accordingly with this context. Based on regional variation on how the measures could be implemented, it is also possible that some mitigations will be successful in some regions but not others or that some mitigations were successful overall, whereas other planned mitigations were unsuccessful because of local circumstances. It is clear that properly contextualizing and reporting out the results of any such mitigations will be a time-consuming effort that requires complete source documentation and follow-up on details with CRO and site partners.

Looking Forward

For medical writers, the pandemic has provided both opportunities, such as the opportunity to work on the surge of COVID-

19–related clinical study protocols and manuscripts, and challenges, such as the interruption of some non-COVID-19 studies or research and the need to work with urgency to produce communication for various purposes.

As we pass the 1-year mark from when the first cases of COVID-19 were reported, with the recent approval of vaccines, some aspects of the medical writing profession and the industry in general may start to return to normal. Time will tell how biotech and pharmaceutical companies, which are reliant on raising capital for operational costs, will fare with the delay of important milestone reporting that helps raise those funds. Trials of preventive and therapeutic products for COVID-19 will continue, including those in nonhospitalized settings³⁶ and in different age groups and populations; sequelae of COVID-19 will also require treatment. Viral mutations and their implications on available treatments and vaccines will require monitoring,³⁷ and new waves of lockdowns may cause continued clinical trial enrollment and execution challenges as certain regions with increased case counts return to lockdown. It remains to be determined how some of the efficiencies gained during the pandemic will be applied as learning for future processes in a sustainable way.

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