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VACCINE CLINICAL TRIALS AND DATA INFRASTRUCTURE

Ana Santos Rutschman*

I. INTRODUCTION

We find ourselves at a momentous turn in the history of vaccines. The COVID-19 pandemic triggered a quasi-global vaccine race that not only compressed vaccine research and development timelines, but also paved the way for the administration of a new type of vaccine technology—mRNA vaccines, which work in substantially different ways from the vaccines in use before the pandemic.[1]

While the process of bringing emerging COVID-19 vaccines to market has taken place in an unusually short timeframe,[2] it was largely predicated on the same scientific and regulatory processes that govern the development, approval and deployment of other new vaccines. For decades, these processes have encompassed several phases of vaccine testing—first without and subsequently with the involvement of human subjects[3]—followed by an analysis of the emerging data.[4]

This Article reflects on the evolution and status quo of the ways in which these data are gathered and disseminated within the context of the development of new vaccines. It treats information stemming from clinical trials as the initial building blocks of our vaccine data infrastructure, and surveys problems related to data collection and disclosure that have long been pervasive in the vaccine research and development ecosystem.

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[1] *See, e.g.*, *Understanding and Explaining mRNA COVID-19 Vaccines,* CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 24, 2020), https://www.cdc.gov/vaccines/covid-19/hcp/mrna-vaccine-basics.html [https://perma.cc/53X7-HCTD] (describing the new type of vaccine technology that emerged during the COVID-19 pandemic).

[2] *See, e.g.*, Will Brothers, *A Timeline of COVID-19 Vaccine Development*, BIOSPACE (Dec. 3, 2020), https://www.biospace.com/article/a-timeline-of-covid-19-vaccine-development/ [https://perma.cc/HSG6-UJ32] (providing an overview of the compressed timeline for the development of COVID-19 vaccine candidates).

[3] *See generally* CARL H. COLEMAN, JERRY A. MENIKOFF, JESSE A. GOLDNER & NANCY NEVELOFF DUBLER, THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS (2005) (providing a brief history of the use of human subjects in vaccine research and development).

[4] *See generally* HARRY M. MARKS, THE PROGRESS OF EXPERIMENT: SCIENCE AND THERAPEUTIC REFORM IN THE UNITED STATES, 1900–1990 (1997) (providing a historical overview of clinical trials in the United States throughout the twentieth century).

Part II of this Article situates the discussion of vaccine clinical trial data within historical boundaries. Section II.A travels back in time to the polio vaccine trials of the 1950s in the United States, which were one of the main catalysts of the adoption of the clinical trial structure now in place throughout the world. Section II.B then charts the formalization of the modern vaccine clinical trial model through legislation adopted between the polio and the COVID-19 vaccine races.

Even though this formalization has resulted in a seemingly robust legal framework, there remain multiple problems that affect both the ways in which vaccine clinical trial data are actually generated and then utilized. Using examples from both past vaccine clinical trials and the COVID-19 vaccine race, Section III.A focuses on data collection issues, with an emphasis on the under-representation of minority populations in vaccine clinical trials. Section III.B then considers how imperfectly generated data meet further roadblocks in the form of delayed reporting or lack of reporting of clinical trial results, as well as restrictions to data sharing often attributable to agency interpretations of trade secrecy provisions that have long been disputed by several legal scholars.[5]

These problems affect both the transparency and accountability of vaccine innovation processes and pose significant hurdles to subsequent research and development. They can also impair public trust in vaccine innovation processes at a time in which vaccine misinformation is quickly eroding overall levels of trust in vaccination as a public health tool.[6] Part IV concludes this Article by pointing towards emerging ways to enrich the existing vaccine clinical trial data infrastructure. Specifically, it provides a short case study on the COVID-19 data sharing policy implemented in the European Union by its counterpart to the U.S. Food and Drug Administration, the European Medicines Agency. This ad hoc policy quickly expanded the disclosure of information about emerging COVID-19 drugs and vaccines in response to mounting pressure for more transparency about the drug and vaccine approval process. As such, it may be used as a blueprint by regulators elsewhere, as well as by proponents of a more robust system for the disclosure and sharing of clinical trial data.

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[5] *See infra* notes 183–85 and accompanying text.

[6] *See* Alexandre de Figueiredo, Clarissa Simas, Emilie Karafillakis, Pauline Paterson & Heidi J. Larson, *Mapping Global Trends in Vaccine Confidence and Investigating Barriers to Vaccine Uptake: A Large-Scale Retrospective Temporal Modelling Study*, 396 LANCET 898, 907 (2020), https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31558-0/fulltext [https://perma.cc/WS9Z-YZAV].

II. VACCINE CLINICAL TRIALS AND DATA INFRASTRUCTURE: A HISTORICAL PERSPECTIVE

A. The Polio Vaccine and the Origins of Modern Clinical Trials

April 26, 1954. Franklin Sherman Elementary School in McLean, Virginia.

This date and place marked the beginning of the field trials[7] for the polio vaccine candidate developed by Jonas Salk.[8] This was a momentous occasion in the history of vaccinology. Called the largest experiment in public health to date, these trials encapsulated the evolution of vaccine research, development and testing.[9]

Poliomyelitis—a compound word bringing together the Greek for gray (*polios*) and marrow (*myelos*) with the Latin suffix used to denote inflammation (*itis*)[10]—is a highly contagious infectious disease transmitted by the poliovirus.[11] While 90% of people who contract the disease experience mild symptoms like fatigue or fever, or no symptoms at all, the virus causes paralysis in the remaining 10% of the patient population.[12] Affecting most commonly the legs,[13] paralysis is permanent in most cases, and 5% to 10% of paralyzed patients die.[14] The disease primarily affects children under the age of five,[15] and before a vaccine was developed—and the

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[7] Vaccine field trials are tests typically conducted in multiple sites across one or several countries in order to assess the performance of an experimental pharmaceutical or biopharmaceutical product. *See* W. Charles Cockburn, *Field Trials in the Evaluation of Vaccines*, 47 AM. J. PUB. HEALTH 819, 824 (1957).

[8] *See* DAVID M. OSHINSKY, POLIO: AN AMERICAN STORY 3–6 (2005) (recounting Salk's development of a killed-virus vaccine and supervision of the Salk Vaccine Trials of 1954).

[9] Paul Meier, *The Biggest Public Health Experiment Ever: The 1954 Field Trial of the Salk Poliomyelitis Vaccine*, *in* STATISTICS: A GUIDE TO THE UNKNOWN (Judith M. Tanur et al. eds., 1972), https://www.medicine.mcgill.ca/epidemiology/hanley/c622/salk trial.pdf [https://perma.cc/35YA-LXL5].

[10] OSHINSKY, *supra* note 8, at 9.

[11] *Poliomyelitis (Polio): Overview*, WORLD HEALTH ORG., https://www.who.int/health-topics/poliomyelitis#tab=tab_1 [https://perma.cc/Y2TH-5WBF] (last visited Jan. 28, 2021).

[12] *Poliomyelitis (Polio): Symptoms*, WORLD HEALTH ORG., https://www.who.int/health-topics/poliomyelitis#tab=tab_2 [https://perma.cc/M4RT-MYWK] (last visited Jan. 28, 2021).

[13] *See, e.g.*, Amy Berish, *FDR and Polio*, FRANKLIN D. ROOSEVELT PRESIDENTIAL LIBR. & MUSEUM, https://www.fdrlibrary.org/polio [https://perma.cc/R8UY-E9PT] (last visited Jan. 28, 2021) (describing President Roosevelt's lower limb paralysis after contracting polio at the relatively late age of thirty-nine).

[14] *Poliomyelitis (Polio): Symptoms*, *supra* note 12.

[15] *Poliomyelitis: Key Facts,* WORLD HEALTH ORG. (July 22, 2019), https://www.who.int/news-room/fact-sheets/detail/poliomyelitis [https://perma.cc/YHU3-5MWT].

disease incidence reduced by 99%[16]—polio outbreaks struck fear, especially among parents of young children.[17]

The 1950s brought about a series of scientific breakthroughs that eventually resulted in two foundational vaccines becoming available in the United States and then abroad.[18] Building on recent work on the poliovirus,[19] the research teams of Hilary Koprowski, Albert Sabin, and Jonas Salk developed different types of polio vaccine candidates.[20] Salk's vaccine using a killed virus was the first one to be licensed,[21] following the largest human trials for any medical product up to that point in history.[22]

The 1954–55 trials of the Salk vaccine were sponsored by the National Foundation for Infantile Paralysis,[23] now known as March of Dimes,[24] and are

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[16] *See Does Polio Still Exist? Is It Curable?*, WORLD HEALTH ORG. (Jan. 20, 2020), https://www.who.int/news-room/q-a-detail/does-polio-still-exist-is-it-curable [https://perma.cc/W87Q-26A5]. *See generally* THOMAS ABRAHAM, POLIO: THE ODYSSEY OF ERADICATION (2018). *But see* Anna N. Chard, S. Deblina Datta, Graham Tallis, Cara C. Burns, Steven G.F. Wassilak, John F. Vertefeuille & Michel Zaffran, *Progress Toward Polio Eradication — Worldwide, January 2018–March 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 784, 784–89 (2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6925a4.htm [https://perma.cc/2SZV-WJNN] (documenting increases in polio outbreaks and disruption in surveillance and immunization activities due to the COVID-19 pandemic).

[17] *See* Volker Janssen, *When Polio Triggered Fear and Panic Among Parents in the 1950s*, HISTORY (Apr. 2, 2020), https://www.history.com/news/polio-fear-post-wwii-era [https://perma.cc/R54E-CM33]; *Polio Elimination in the United States*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 25, 2019), https://www.cdc.gov/polio/what-is-polio/polio-us.html [https://perma.cc/9RDH-2CEZ]; *cf.* PHILIP ROTH, NEMESIS (2010) (presenting a fictional portrayal of widespread parental fear during polio outbreaks in summertime).

[18] *See generally* OSHINSKY, *supra* note 8 (describing the polio vaccine race).

[19] *See generally* Hans J. Eggers, *Milestones in Early Poliomyelitis Research (1840 to 1949)*, 73 J. VIROLogy 4533 (1999), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC112492/ [https://perma.cc/UL32-SZRK] (providing an overview of the research that enabled the development of polio vaccines in the 1950s); John F. Enders, Thomas H. Weller & Frederick C. Robbins, *Cultivation of the Lansing Strain of Poliomyelitis Virus in Cultures of Various Human Embryonic Tissues*, 109 SCIENCE 85 (1949), https://science.sciencemag.org/content/109/2822/85 [https://perma.cc/X2AZ-NQSL] (reporting the successful in vitro propagation of the poliovirus).

[20] OSHINSKY, *supra* note 8.

[21] *See Science and the Regulation of Biological Products*, U.S. FOOD & DRUG ADMIN. (Mar. 28, 2018), https://www.fda.gov/about-fda/histories-product-regulation/science-and-regulation-biological-products [https://perma.cc/BH8R-AZJ7].

[22] *See* Meier, *supra* note 9; *see also* Marcia Meldrum, *"A Calculated Risk": The Salk Polio Vaccine Field Trials of 1954*, 317 BRITISH MED. J. 1233, 1233 (1998), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1114166/ [https://perma.cc/RG6A-4U4L].

[23] Meldrum, *supra* note 22.

[24] *Who We Are*, MARCH OF DIMES, https://www.marchofdimes.org/mission/who-we-are.aspx [https://perma.cc/4C5E-R96A] (last visited Feb. 8, 2021).

generally regarded as marking the beginning of modern clinical trials.[25] The trials focused on young children (first through third grade),[26] and used a dual protocol, with both placebo[27] and observed controls in place.[28] During the polio vaccine trials, 623,972 children participated in the placebo-controlled trial, in which some received the vaccine candidate while others received a placebo.[29] At the same time placebo-controlled trials were taking place, an even larger trial of the Salk vaccine unfolded, in which over a million other children received the vaccine and no placebo was administered.[30]

The results of these combined trials were announced in 1955, showing that the Salk vaccine was 80% to 90% effective in generating protective immunity to polio.[31] Broad administration of the Salk vaccine—and subsequently of other types of polio vaccines[32]—led to a drastic reduction in the number of polio cases in the United States and around the world.[33] In 1979, polio was officially eliminated in the United States.[34] No cases have originated domestically since then, and the instances in which travelers have brought the virus to the United States have been few and far between, the last one occurring in 1993.[35]

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[25] *See, e.g.*, Arnold S. Monto, *Francis Field Trial of Inactivated Poliomyelitis Vaccine: Background and Lessons for Today*, 21 EPIDEMIOLOGICAL REVS. 7, 7 (1999) (listing the characteristics of the 1954–55 polio vaccine trials that place them "squarely at the start of the modern era" of clinical trials).

[26] Meldrum, *supra* note 22.

[27] Placebos are inert substances that do not produce a therapeutic effect. *See generally* Usha Gupta & Menka Verma, *Placebo in Clinical Trials*, 4 PERSPS. CLINICAL RSCH. 49 (2013) (describing the use of placebo in clinical trials); Annette Rid, Abha Saxena, Abdhullah H. Baqui, Anant Bhan, Julie Bines, Marie-Charlotte Bouesseau, Arthur Caplan, James Colgrove, Ames Dhai, Rita Gomez-Diaz, Shane K. Green, Gagandeep Kang, Rosanna Lagos, Patricia Loh, Alex John London, Kim Mulholland, Pieter Neels, Punee Pitisuttithum, Samba Cor Sarr, Michael Selgelid, Mark Sheehan & Peter G. Smith, *Placebo Use in Vaccine Trials: Recommendations of a WHO Expert Panel*, 32 VACCINE 4708 (2014) (addressing the specificities associated with the use of placebo in vaccine clinical trials).

[28] Meldrum, *supra* note 22.

[29] *Id.*

[30] *Id.*

[31] *Id.*

[32] *See generally* Lee Hampton, *Albert Sabin and the Coalition to Eliminate Polio from the Americas*, 99 AM. J. PUB. HEALTH 34 (2009) (discussing the oral polio vaccine and mass vaccinations); Anda Baicus, *History of Polio Vaccination*, 1 WORLD J. VIROLOGY 108 (2012) (addressing the eradication of poliomyelitis and the three poliovirus serotypes).

[33] *See supra* note 16 and accompanying text; *see also* Philip D. Minor, *Polio Vaccines and the Cessation of Vaccination*, 2 EXPERT REV. VACCINES 99 (2003) (discussing the eradication of polio and the difficulties associated with the entire cessation of vaccination); Ananda S. Bandyopadhyay, Julie Garon, Katherine Seib & Walter A. Orenstein, *Polio Vaccination: Past, Present and Future*, 10 FUTURE MICROBIOLOGY 791 (2015) (analyzing the eradication of the wild polio virus).

[34] *Polio Elimination in the United States*, *supra* note 17.

[35] *Id.*

In addition to generating the data necessary to support the licensure of the vaccine,[36] the 1954–55 polio vaccine trials also established the standard now in place for clinical trials involving all types of pharmaceutical products: randomized controlled trials.[37] But while the polio trials in the United States provided the blueprint for what would become the global clinical trial standard, it took a major public health incident in the early 1960s for clinical trials to become mandatory for new drugs and vaccines entering the market.[38]

The sedative drug thalidomide, which was administered in several countries outside the United States in the late 1950s to pregnant women for several conditions, caused extensive birth defects in children.[39] Working as a medical officer at the FDA, Dr. Frances Kelsey reviewed and rejected the application to market thalidomide in the United States due to insufficiencies in the information provided by the sponsor.[40] While Dr. Kelsey's intervention averted what would otherwise have almost certainly been an enormous public health crisis, the problems associated with the review of thalidomide by regulatory agencies across the world called attention to the lacking legal framework governing the approval of new drugs and vaccines.[41]

Prior to the 1938 Federal Food, Drug and Cosmetic Act (FDCA), there were no statutory requirements that drug sponsors submit data demonstrating the safety and efficacy of the products they intended to bring to market.[42] The FDCA established

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[36] *See, e.g.*, Rebekah H. Griesenauer & Michael S. Kinch, *An Overview of FDA-Approved Vaccines & Their Innovators*, 16 EXPERT REV. VACCINES 1253 (2017) (discussing the development of immunotherapies); *see also Science and the Regulation of Biological Products*, *supra* note 21.

[37] Monto, *supra* note 25, at 7, 13; *see also* COLEMAN ET AL., *supra* note 3; ROBERT J. LEVINE, ETHICS AND REGULATION OF CLINICAL RESEARCH (2d ed. 1988) (collectively providing an overview of the regulation of clinical research leading to, and including, clinical trials).

[38] *See, e.g.*, Lewis A. Grossman, *AIDS Activists, FDA Regulation, and the Amendment of America's Drug Constitution*, 42 AM. J.L. & MED. 687, 695 (2016); Joshua M. Sharfstein, *Crises and Population Health*, 96 MILBANK Q. 223 (2018); Sharon B. Jacobs, *Crises, Congress, and Cognitive Biases: A Critical Examination of Food and Drug Legislation in the United States*, 64 FOOD & DRUG L.J. 599, 608–12 (2009) (collectively describing how the 1961 thalidomide crisis directly led to the passage of the 1962 Drug Amendments in the United States).

[39] *See generally* Jack Botting, *The History of Thalidomide*, 15 DRUG NEWS & PERSPS. 604 (2002) (analyzing the effects of thalidomide, particularly in connection with birth defects).

[40] *Frances Oldham Kelsey: Medical Reviewer Famous for Averting a Public Health Tragedy*, U.S. FOOD & DRUG ADMIN. (Feb. 1, 2018), https://www.fda.gov/about-fda/virtual-exhibits-fda-history/frances-oldham-kelsey-medical-reviewer-famous-averting-public-health-tragedy [https://perma.cc/PBD7-FQMH].

[41] Jacobs, *supra* note 38, at 609.

[42] *See* SUZANNE WHITE JUNOD, FDA AND CLINICAL DRUG TRIALS: A SHORT HISTORY 1, 5–7 (2016), https://www.fda.gov/media/110437/download [https://perma.cc/G4LZ-9S4Q].

the principle that safety data must be submitted to the FDA before a new drug or vaccine comes to market by requiring that sponsors conduct "adequate tests by all methods reasonably applicable to show whether or not the drug is safe."[43] In 1962, in direct response to the thalidomide crisis, Congress passed the Kefauver-Harris Amendments to the FDCA, which introduced the requirement that sponsors of new drugs and vaccines demonstrate that their product is "efficacious" before coming to market.[44] Sponsors were thus required to produce "substantial evidence" of the effectiveness of a drug or vaccine by presenting data generated through "adequate and well-controlled studies."[45]

While the new law made clinical trials a pre-requisite of market entrance, it did not define the concepts of "adequate" or "well-controlled" studies, nor did FDA guidance provide much more information to sponsors immediately after the Kefauver-Harris Amendments were enacted.[46] The legal framework that would make clinical trials the *sine qua non* of drug and vaccine approval was nonetheless in place, and it was incrementally strengthened through legislative and regulatory interventions in the following decades.[47]

The clinical trial paradigm applied on a large scale during the 1954–55 polio vaccine trials and codified in 1962 in the United States quickly became part of the regulatory frameworks in other countries.[48] Randomized controlled trials became

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[43] *Id.* at 5.

[44] *Id.* at 8–12 (noting other measures introduced to strengthen the role of the FDA in drug review); *see also Kefauver-Harris Amendments Revolutionized Drug Development*, U.S. FOOD & DRUG ADMIN. (Sept. 10, 2012), https://www.fda.gov/consumers/consumer-updates/kefauver-harris-amendments-revolutionized-drug-development [https://perma.cc/LGH5-WFTJ].

[45] *See* JUNOD, *supra* note 42, at 11–12.

[46] *Id.* at 12.

[47] *Id.*; Hearing Regulations and Regulations Describing Scientific Content of Adequate and Well-Controlled Clinical Investigations, 35 Fed. Reg. 7250 (May 8, 1970); Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296; Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823; *Clinical Trials Guidance Documents*, U.S. FOOD & DRUG ADMIN. (Jan. 21, 2020), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-trials-guidance-documents [https://perma.cc/G8MU-VJU6].

[48] *See, e.g.*, Ulrike Lindner & Stuart S. Blume, *Vaccine Innovation and Adoption: Polio Vaccines in the UK, the Netherlands and West Germany, 1955–1965*, 50 MED. HIST. 425 (2006), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1592614/ [https://perma.cc/Y4KA-SG7K]; Gail A. Van Norman, *Drugs and Devices: Comparison of European and U.S. Approval Processes*, 1 JACC: BASIC TO TRANSLATIONAL SCI. 399 (2016), https://www.sciencedirect.com/science/article/pii/S2452302X16300638 [https://perma.cc/C283-2ZC5] (noting similar substantive drug review procedures and standards in the United States and countries in the European Union in spite of organizational differences between the FDA and the European Medicines Agency).

known as the "gold standard" in drug and vaccine effectiveness research and have remained a core component of the scientific and drug review processes ever since.[49]

B. From Polio to COVID-19 and the Emergence of New Vaccine Technology

March 16, 2020. Kaiser Permanente Washington Research Institute in Seattle.

This date and place marked the beginning of the clinical trials for the first COVID-19 vaccine candidate.[50] Less than nine months later, the FDA authorized the emergency use of the first COVID-19 vaccines ever developed.[51]

Several parallels have been drawn between the COVID-19 and the polio vaccine races, even though more than six decades separate these events.[52] In both cases, an infectious pathogen not fully understood by the scientific community triggered a major public health crisis, spread fear among the populations most vulnerable to the disease and their families, and prompted a vaccine race amidst multiple competitors in different countries, resulting in the development, manufacturing and distribution of groundbreaking vaccines within extremely compressed timelines.[53]

By the time the COVID-19 trials began, however, the legal framework regulating clinical trials had evolved considerably, both to reflect evolving scientific notions and to strengthen the protection of clinical trial volunteers.

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[49] LEVINE, *supra* note 37 and accompanying text; *see also* Elliott M. Antman & Barbara E. Bierer, *Standards for Clinical Research: Keeping Pace with the Technology of the Future*, 133 CIRCULATION 823, 823 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4778966/ [https://perma.cc/WM9N-3KCY].

[50] *First COVID-19 Vaccine Trial at Kaiser Permanente Washington*, KAISERPERMANENTE.ORG (Mar. 16, 2020), https://about.kaiserpermanente.org/our-story/health-research/news/first-covid-19-vaccine-trial-at-kaiser-permanente-washington [https://perma.cc/QY2C-FLRM].

[51] U.S. FOOD & DRUG ADMIN., EMERGENCY USE AUTHORIZATION OF MEDICAL PRODUCTS AND RELATED AUTHORITIES: GUIDANCE FOR INDUSTRY AND OTHER STAKEHOLDERS (2017), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities [https://perma.cc/X653-TFDY]; *cf.* 21 U.S.C. § 360bbb-3 (2017) (statutory authority for emergency use authorization).

[52] *See, e.g.*, David Oshinsky, *What the Polio Vaccine Can Teach Us About the Covid-19 Vaccine*, CNN (Nov. 17, 2020, 11:47 AM ET), https://www.cnn.com/2020/11/17/opinions/covid-polio-vaccine-parallels-oshinsky/index.html [https://perma.cc/GJR6-VD9G]; Arthur Allen, *Trust, Fear and Solidarity Will Determine the Success of a COVID Vaccine*, KAISER HEALTH NEWS (Aug. 17, 2020), https://khn.org/news/trust-fear-and-solidarity-will-determine-the-success-of-a-covid-vaccine/ [https://perma.cc/7SYS-5TXE].

[53] *Compare* Ewen Callaway, *The Race for Coronavirus Vaccines: A Graphical Guide*, NATURE (Apr. 28, 2020), https://www.nature.com/articles/d41586-020-01221-y [https://perma.cc/8H5S-FJJY] (chronicling the early stages of the COVID-19 vaccine race), *with* Gilbert King, *Salk, Sabin and the Race Against Polio*, SMITHSONIAN MAG. (Apr. 3, 2012), https://www.smithsonianmag.com/history/salk-sabin-and-the-race-against-polio-169813703/ [https://perma.cc/A7LA-DPDV] (chronicling the polio vaccine race).

While the polio vaccine trials are still hailed by many commentators as a great achievement in medical research,[54] they were also conducted partly in ways that would constitute a violation of modern ethical principles governing biomedical research, such as the testing of the vaccine on institutionalized physically and intellectually disabled children during the early stages of research.[55]

There were cases of even more extensive ethical violations in medical research even as clinical trials became progressively more regulated, both in the context of vaccine research and in other areas. The most well-known example is the Tuskegee Study, a forty-year federally-funded medical research program (1932–72) conducted with the purpose of observing the evolution of untreated syphilis in black male populations, during the course of which several egregious ethical violations were repeatedly committed.[56] These violations included deceptive statements about the purpose of the study made by researchers to economically disadvantaged volunteers,[57] as well as the intentional deprivation of available treatments to syphilis patients, which produced detrimental effects to both the health of the individuals involved in the study and that of their families and communities.[58] The repercussions of the Tuskegee Study are felt to this day, with lower levels of trust in medical research registered among minority communities being partially connected to the memory and impact of Tuskegee.[59] A study published in 2018—forty-six years after the end of Tuskegee—found that, in addition to giving rise to medical mistrust issues, the Tuskegee Study "correlated with increases in . . . mortality and decreases in both outpatient and inpatient physician interactions for older black men."[60]

In the case of vaccine-related research, one of the most prominent examples is the so-called "experiment" at Willowbrook State School in Staten Island.[61]

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[54] *See* Meier, *supra* note 9 and accompanying text.

[55] *Polio Brochure 1*, HISTORY OF VACCINES, https://www.historyofvaccines.org/content/salk-begins-early-polio-vaccine-tests-0 [https://perma.cc/3JXK-W44W] (last visited Jan. 28, 2021). For further discussion of ethical aspects of the Salk vaccine development and testing, see generally Howard Markel, *April 12, 1955—Tommy Francis and the Salk Vaccine*, 352 N. ENG. J. MEDICINE 1408 (2005).

[56] *See generally* Ruqaiijah Yearby, *Exploitation in Medical Research: The Enduring Legacy of the Tuskegee Syphilis Study*, 67 CASE W. RSRV. L. REV. 1171 (2017).

[57] *Id.* at 1172.

[58] *Id.* at 1172–73.

[59] *Id.*; *see also* Allan M. Brandt, *Racism and Research: The Case of the Tuskegee Syphilis Study*, 8 HASTINGS CTR. REP. 21, 27 (1978) ("The degree of deception and damages have been seriously underestimated."). *See generally* HARRIET A. WASHINGTON, MEDICAL APARTHEID: THE DARK HISTORY OF MEDICAL EXPERIMENTATION ON BLACK AMERICANS FROM COLONIAL TIMES TO THE PRESENT (2008) (detailing the history of the exploitation of Black American populations in medical research before and after Tuskegee).

[60] Marcella Alsan & Marianne Wanamaker, *Tuskegee and the Health of Black Men*, 133 Q.J. ECON 407, 407 (2018).

[61] *See generally* Stephen Goldby, *Experiments at the Willowbrook State School*, 297 LANCET 749 (1971). *But see* Saul Krugman, *The Willowbrook Hepatitis Studies Revisited: Ethical Aspects*, 8 REVS. INFECTIOUS DISEASE 157 (1986) (offering a defense of the study design by the lead researcher in the Willowbrook study).

Researchers interested in understanding more about hepatitis C with the eventual goal of developing a vaccine conducted a non-therapeutic study for roughly fifteen years (1955/56–71)[62] on developmentally disabled children by deliberately infecting them with the virus and monitoring their progress.[63]

A *Forbes* journalist interviewed the mother of one of these children over fifty years after the Willowbrook study began, and aptly characterized some of the ways in which parental consent was obtained as a "Faustian bargain":

> In order to get [her severely autistic daughter] a spot at the overcrowded facility, however, she had to make a Faustian bargain—consenting to allow her daughter to be part of a quest to find a vaccine for hepatitis. "I had no choice," McCourt says, "I had tried so many different places and so many arrangements, and they didn't work out, so I went along with it."[64]

In response to systemic ethical failures long observed in medical research, and in particular as a direct response to the publicization of the Tuskegee Study, a code of conduct known as the Belmont Report was published in the United States in 1979,

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[62] There are disparities in the reporting of the starting date for the Willowbrook study. *Compare Willowbrook Hepatitis Experiments* in EXPLORING BIOETHICS 1, 1 (2009), https://science.education.nih.gov/supplements/webversions/bioethics/guide/pdf/master_5-4.pdf [https://perma.cc/Z32F-XN7W] (providing a 1955 starting date), *with* James M. DuBois, *Hepatitis Studies at the Willowbrook State School for Children with Mental Retardation*, *in* ETHICS IN MENTAL HEALTH RESEARCH (2008), https://sites.google.com/a/narrativebioethics.com/emhr/contact/hepatitis-studies-at-the-willowbrook-state-school-for-children-with-mental-retardation [https://perma.cc/KK4D-2NKA] (providing a 1956 starting date).

[63] Trials in which healthy participants are infected with a pathogen are also known as challenge studies. *See, e.g.*, Annette Rid & Meta Roestenberg, *Judging the Social Value of Controlled Human Infection Studies*, 34 BIOETHICS 749, 750 (2020). The topic of challenge studies has also been discussed in the context of the COVID-19 vaccine race. *See, e.g.*, Jeffrey P. Kahn, Leslie Meltzer Henry, Anna C. Mastroianni, Wilbur H. Chen & Ruth Macklin, *For Now, It's Unethical to Use Human Challenge Studies for SARS-CoV-2 Vaccine Development*, 117 PNAS 28538 (2020), https://www.pnas.org/content/117/46/28538 [https://perma.cc/9KRP-3WTG] (arguing against the use of challenge studies in the COVID-19 vaccine race); Seán O'Neill McPartlin, Josh Morrison, Abie Rohrig & Charles Weijer, *Covid-19 Vaccines: Should We Allow Human Challenge Studies to Infect Healthy Volunteers with SARS-CoV-2*, 371 BRIT. MED. J. 4258 (2020) (exploring arguments both in favor and against challenge studies for COVID-19 vaccines).

[64] Leah Rosenbaum, *The Hideous Truths of Testing Vaccines on Humans*, FORBES, https://www.forbes.com/sites/leahrosenbaum/2020/06/12/willowbrook-scandal-hepatitis-experiments-hideous-truths-of-testing-vaccines-on-humans/?sh=10e391a4279c [https://perma.cc/LZK5-N4KH] (last visited Jan. 28, 2021); *see also* COLEMAN ET AL., *supra* note 3, at 40 (describing further the Willowbrook study).

providing a set of ethical principles and guidelines designed to protect participants in clinical research.[65]

The subsequent decades brought about significant changes in the legal protections offered to participants in biomedical research. Some of these changes were directly aimed at protecting volunteers participating in clinical trials, as is the case of laws regulating informed consent, while others protected volunteers indirectly by focusing on the collection of data during trials and ensuing permissible uses.

In 1981, the principles enshrined in the Belmont Report became the foundation of the legal framework governing federal protection of human subjects involved in clinical research, primarily through the regulation of informed consent.[66] In 1991, they were codified in the Common Rule,[67] which was revised in 2018.[68]

In an attempt to correct asymmetries in data collection, particularly with regard to the representation of women and racial and ethnic minorities, the NIH Revitalization Act of 1993 was introduced to mandate appropriate inclusion of minority volunteers in research funded by the National Institutes of Health.[69] As noted in Section III.A in the context of COVID-19 vaccine trials, problems of under-representation of racial and ethnic minorities persist in spite of these legislative efforts.

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[65] THE NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RSCH., U.S. DEP'T OF HEALTH, EDUC. & WELFARE, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979) (establishing the ethical principles of respect for persons, beneficence and justice, and requiring three elements in connection with informed consent: information, comprehension and voluntariness); *see also* Eli Y. Adashi, LeRoy B. Walers & Jerry A. Menikoff, *The Belmont Report at 40: Reckoning with Time*, 108 AM. J. PUB. HEALTH 1345 (2018) (surveying the application of the Belmont Report and emerging issues not contemplated by the drafters of the Report).

[66] 45 C.F.R. § 46.116 (2019).

[67] *See* 45 C.F.R. § 46 (1992) and 21 C.F.R. § 50 (1992) (collectively laying out the regulatory regime for the protection of human subjects in clinical trials, the former in the context of federally funded research and the latter in the context of clinical trials overseen by the FDA).

[68] *Revised Common Rule*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html [https://perma.cc/4J2H-K8QG] (last visited Jan. 28, 2021); *see also* Jerry Menikoff, Julie Kaneshiro & Ivor Pritchard, *The Common Rule, Updated*, 376 NEW ENG. J. MEDICINE 613 (2017); Valerie Gutmann Koch & Kelly Todd, *Research Revolution or Status Quo?: The New Common Rule and Research Arising from Direct-to-Consumer Genetic Testing*, 56 HOUS. L. REV. 81 (2018).

[69] National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43, 107 Stat. 22. *But see* Stacie E. Geller, Abigail R. Koch, Pamela Roesch, Amarette Filut, Emily Hallgren & Molly Carnes, *The More Things Change, the More They Stay the Same: A Study to Evaluate Compliance with Inclusion and Assessment of Women and Minorities in Randomized Controlled Trials*, 93 ACAD. MED. 630, 630 (2018) (finding that "NIH policies have not resulted in significant increases in reporting results by sex, race, or ethnicity").

As also described in Section III.B, another strand of longstanding problems affects the collection and dissemination of clinical trial data. On the one hand, not all clinical trials are registered, a phenomenon that poses significant hurdles to research transparency and accountability, as well as to access to existing data for purposes of follow-on innovation.[70] On the other hand, even in the case of registered trials with published results, current industry practices result in the availability of severely incomplete data, which similarly impairs transparency, accountability and subsequent research.[71]

The Declaration of Helsinki, originally adopted in 1964 and last amended in 2018, established that clinical trials must be registered in publicly available databases,[72] and imposed a duty of dissemination of clinical trial results on medical researchers.[73] The United States codified clinical trial reporting requirements consistent with the Declaration of Helsinki,[74] and in 1997 the Food and Drug Administration Modernization Act (FDAMA) required the registration of clinical trials for serious or life-threatening diseases and conditions.[75] Three years later, the National Institutes of Health launched a national registry of clinical trials, Clinicaltrials.gov, hosted by the U.S. National Library of Medicine.[76] Registration requirements for clinical trials were scaled up in 2007 by the Food and Drug Administration Amendments Act (FDAAA),[77] which required the government to expand the federal clinical trial data bank.[78]

However, as further detailed in Part III, registration of clinical trials remains far from uniform.[79] There has been very little institutional support within the Department of Health and Human Services (HHS) for the enforcement of the trial registration and data reporting requirements set by FDAMA and FDAAA. In 2016,

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[70] *See infra* Section III.B.

[71] *Id.*

[72] WORLD MED. ASS'N, DECLARATION OF HELSINKI: ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS ¶ 35 (2018), https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ [https://perma.cc/GPQ4-7BQR] [hereinafter DECLARATION OF HELSINKI].

[73] *Id.* at ¶ 36.

[74] *See* 42 C.F.R. pt. 11 (2020); Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110–85, § 801, 121 Stat. 823, 904.

[75] Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 113, 111 Stat. 2296, 2310; *see also Regulations: Good Clinical Practice and Clinical Trials*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/regulations-good-clinical-practice-and-clinical-trials [https://perma.cc/KS9C-YMGA] (last visited Jan. 28, 2021).

[76] CLINICALTRIALS.GOV, https://clinicaltrials.gov [https://perma.cc/JJ75-AH83] (last visited Jan. 29, 2021).

[77] Food and Drug Administration Amendments Act § 801.

[78] 42 U.S.C. § 282(j)(2)(A)(i) (2018).

[79] *See infra* Section III.B.

six years after the statutory deadline,[80] the Department of Health and Human Services issued a final rule implementing the data reporting requirements set forth in FDAAA.[81] The rule, which became effective in January of the following year, exempted clinical trials[82] completed before January 18, 2017, from data reporting requirements in cases in which the sponsored product had not been approved by the FDA at the date of completion of the trial.[83] In 2020, the District Court for the Southern District of New York found that the FDAAA unambiguously required sponsors to submit data and HHS to include it in ClinicalTrials.gov irrespective of trial completion date or product approval, thus striking down the reporting exemption.[84]

Contemporary vaccine clinical trials thus take place against a legal and normative background that is vastly different from the ones in which the polio vaccine trials were conducted—albeit one in which profound shortcomings persist at the participant-representation, registration, data reporting and data sharing levels, as illustrated by the vaccine-specific examples provided in the following Part.[85]

Recently, the introduction of new and disruptive vaccine technology has ratcheted up the challenges posed to the clinical trial ecosystem and the data infrastructure it generates. After over a decade of study, the COVID-19 vaccine race provided the final catalyst for late-stage development of a novel type of vaccine: Messenger RNA (mRNA) vaccines.[86] mRNA is a type of genetic material that contains instructions for the human body to create certain types of proteins.[87] In the case of mRNA vaccines, scientists use a synthetic version of mRNA to direct the human body to produce some of the same proteins that the virus normally produces, without actually ever introducing viral matter into the body.[88] In response to the

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[80] *See* 42 U.S.C. § 282(j)(3)(D)(i) (2018); s*ee also* Complaint at 11, Seife v. U.S. Dep't of Health & Hum. Servs., 440 F. Supp. 3d 254 (S.D.N.Y. 2020) (No. 18-cv-11462), https://law.yale.edu/sites/default/files/area/center/crit/document/01_complaint.pdf [https://perma.cc/4WQL-MFPH].

[81] 42 C.F.R. pt. 11 (2020).

[82] The rule applies to "primary completion" of clinical trials. *See* 42 C.F.R. § 11.42(b) (2020) (stating that "clinical trial results . . . must be submitted for any applicable clinical trial with a primary completion date on or after January 18, 2017"); 42 C.F.R. § 11.10(a) (2020) ("Completion date means . . . the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated.").

[83] 42 C.F.R. § 11.42(b) (2020) (exempting trials completed before January 18, 2017).

[84] *Seife*, 440 F. Supp. 3d at 279.

[85] *See infra* Section III.A (surveying participant-representation issues) and Section III.B (surveying registration, data reporting, and data sharing issues).

[86] *See, e.g.*, *Understanding and Explaining mRNA COVID-19 Vaccines*, *supra* note 1.

[87] *Messenger RNA (mRNA)*, NAT'L HUM. GENOME RSCH. INST., https://www.genome.gov/genetics-glossary/messenger-rna [https://perma.cc/RT34-3H3L] (last visited Jan. 29, 2021).

[88] *See generally* Jennifer Abbasi, *COVID-19 and mRNA Vaccines—First Large Test for a New Approach*, 324 JAMA 1125 (Sept. 3, 2020), https://jamanetwork.com/journals/jama/

presence of these proteins, the immune system triggers a protective response.[89] By contrast, vaccines available before the pandemic had to rely on small amounts of viral matter as a way to trigger the same type of response.[90]

The COVID-19 mRNA vaccine candidates were developed in a matter of months—faster than COVID-19 vaccines based on older technology could be—followed by a short period of clinical trials, thus calling for testing a medical technology never before used in humans.[91] Regulators across the world needed to evaluate data generated under extreme circumstances and decide whether to authorize the emergency use of vaccines before enough data was gathered for sponsors to request a full approval of their vaccine candidates.[92] As a trade-off for making critical public health tools available quickly to large segments of the population, these regulators—including the FDA—eventually granted emergency use authorizations to the leading COVID-19 vaccine candidates by relying on data inherently far more limited than the data normally supplied in support of applications to market new vaccines.[93]

This Article has so far provided contextual information on the emergence of the contemporary vaccine clinical trial model, noting longstanding issues in the ways vaccine-related knowledge is produced in clinical trials and resulting data are disclosed. These longstanding issues are now combined with challenges to regulatory review of new vaccines when vaccine data are generated on a timeline severely compressed by a public health crisis. Part III now focuses on systemic issues affecting the production and disclosure of vaccine clinical trial data.

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fullarticle/2770485 [https://perma.cc/B8UL-FUE6]; Carlo Iavarone, Derek T. O'Hagan, Dong Yu, Nicolas F. Delahaye & Jeffrey B. Ulmer, *Mechanism of Action of mRNA-Based Vaccines*, 16 EXPERT REV. VACCINES 871 (2017); *see also The Science and Fundamentals of mRNA Technology*, MODERNA.COM, https://www.modernatx.com/mrna-technology/science-and-fundamentals-mrna-technology [https://perma.cc/SMH2-UUD8] (last visited Jan. 28, 2021) (including a description of mRNA vaccine technology provided by one of the sponsors of an mRNA COVID-19 vaccine authorized in the United States in late 2020).

[89] *See Understanding and Explaining mRNA COVID-19 Vaccines*, *supra* note 1.

[90] *Id.*

[91] *See* Brothers, *supra* note 2.

[92] *See EMA Recommends First COVID-19 Vaccine for Authorisation in the EU,* EUR. MEDS. AGENCY (Dec. 21, 2020), https://www.ema.europa.eu/en/news/ema-recommends-first-covid-19-vaccine-authorisation-eu [https://perma.cc/7C6Z-XCP2]; *Statement on the U.S. Authorization of the Moderna COVID-19 Vaccine,* HEALTH CAN. (Dec. 18, 2020), https://www.canada.ca/en/health-canada/news/2020/12/statement-on-the-us-authorization-of-the-moderna-covid-19-vaccine.html [https://perma.cc/98Z2-ME2B]; *FDA Takes Key Action in Fight Against COVID-19 by Issuing Emergency Use Authorization for First COVID-19 Vaccine*, U.S. FOOD & DRUG ADMIN. (Dec. 11, 2020), https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19 [https://perma.cc/FK7J-XLKD] [hereinafter FDA *Takes Key Action*].

[93] *See FDA Takes Key Action*, *supra* note 92.

III. VACCINE CLINICAL TRIAL DATA AS BUILDING BLOCKS

Data generated during vaccine clinical trials are the bedrock of the scientific and regulatory processes that bring new vaccines to market.[94] Yet, the ways in which those data are produced have long resulted in a data infrastructure marked by gaps in foundational knowledge related to the development and testing of new vaccines. This, in turn, has an impact on the intrinsic completeness, accuracy and transparency of vaccine data collection—and by extension on instrumental uses of those data, such as the use of clinical trial data to support the approval (or denial) of a new vaccine—as well as on public perceptions of how vaccines are developed, tested and made available to populations at large. Section III.A examines these problems from the perspective of data collection, while Section III.B turns to issues arising in the data-sharing context.

A. Data Collection: Limitations of the Current Vaccine Clinical Trial Data Infrastructure

One of the most salient holes in the vaccine data infrastructure stems from the under-representation of certain segments of the population in vaccine clinical trials—most notably, minority populations.[95] Even though legislation has been enacted to address participant-representation problems in clinical trials in general,[96] minorities have long been underrepresented in clinical trials, both in the United

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[94] *See, e.g.*, Cynthia M. Ho, *Avoiding the TRIPS Trap: A Path to Domestic Disclosure of Clinical Drug Data Consistent with International Norms*, CORNELL INT'L L.J. (forthcoming 2021) (manuscript at 15–18) (on file with author) (linking the availability of clinical trial data to transparency); Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach*, 13 MARQ. INTELL. PROP. L. REV. 1, 51, 54–58 (2009) (making the case that treating clinical trial data as a public good would result in long-term follow-on innovation).

[95] There are additional categories of populations under-represented in vaccine clinical trials. Consider the case of pediatric populations during the COVID-19 pandemic: clinical trials for coronavirus vaccines did not enroll children until late 2020. *See, e.g.*, Jeffrey I. Campbell, Karen E. Ocwieja & Mari M. Nakamura, *A Call for Pediatric COVID-19 Clinical Trials*, 146 PEDIATRICS 1 (2020), https://pediatrics.aappublications.org/content/146/2/e20201081 [https://perma.cc/D8XX-K2EB]; Denise Grady, *Moderna Plans to Begin Testing Its Coronavirus Vaccine in Children*, N.Y. TIMES (Dec. 18, 2020), https://www.nytimes.com/2020/12/02/health/Covid-Moderna-vaccine-children.html [https://perma.cc/S7NL-G3YU].

[96] *See supra* note 69 and accompanying text.

States[97] and elsewhere.[98] For example, researchers have found both problems of minority under-representation in clinical trial design and a lack of uniformity across trial sites in the collection and reporting of data on race and ethnicity.[99] The landscape in vaccine clinical trials also reflects this systemic problem. For instance, an online registry made available early in the pandemic by the COVID-19 Prevention Network to enable individuals to express interest in participating in COVID-19 vaccine clinical trials had enlisted around 350,000 people by late August 2020, of which around only 10% were Black or Hispanic.[100]

The conduct of COVID-19 clinical trials further illustrates systemic problems affecting the participation of racial and ethnic minorities. Consider the cases of the Pfizer/BioNTech vaccine candidate, which in December 2020 became the first

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[97] *See* Paula A. Rochon, Azad Mashari, Ariel Cohen, Anjali Misra, Dara Laxer, David L. Streiner, Jocalyn P. Clark, Julie M. Dergal & Jennifer Gold, *The Inclusion of Minority Groups in Clinical Trials: Problems of Under Representation and Under Reporting of Data*, 11 ACOUNTABILITY IN RSCH: POLICIES & QUALITY ASSURANCE 215, 216 (2004); Barbara A. Noah, *The Participation of Underrepresented Minorities in Clinical Research*, 29 AM. J.L. & MED. 221, 224 (2003); Jill A. Fisher & Corey A. Kalbaugh, *Challenging Assumptions About Minority Participation in US Clinical Research*, 101 AM. J. PUB. HEALTH 2217, 2217 (2011); Ali Salman, Claire Nguyen, Yi-Hui Lee & Tawna Cooksey-James, *A Review of Barriers to Minorities' Participation in Cancer Clinical Trials: Implications for Future Cancer Research*, 18 J. IMMIGRANT MINORITY HEALTH 447, 448 (2016); Andrea L. Gilmore-Bykovskyi, Yuanyuan Jin, Carey Gleason, Susan Flowers-Benton, Laura M. Block, Peggye Dilworth-Anderson, Lise L. Barnes, Manish N. Shah & Megan Zuelsdorff, *Recruitment and Retention of Underrepresented Populations in Alzheimer's Disease Research: A Systematic Review*, 5 ALZHEIMER'S & DEMENTIA: TRANSLATIONAL RSCH. & CLINICAL INTERVENTIONS 751, 752 (2019); Bassel Nazha, Manoj Mishra, Rebecca Pentz & Taofeek K. Owonikoko, *Enrollment of Racial Minorities in Clinical Trials: Old Problem Assumes New Urgency in the Age of Immunotherapy*, 39 AM. SOC'Y CLINICAL ONCOLOGY EDUC. BOOK 3, 3 (2019).

[98] *See, e.g.*, Mahvash Hussain-Gambles, Karl Atkin & Brenda Leese, *Why Ethnic Minority Groups Are Under-Represented in Clinical Trials: A Review of the Literature*, 12 HEALTH & SOC. CARE CMTY. 382, 382 (2004) (discussing minority under-representation in the United Kingdom).

[99] *See generally* Hala T. Borno, Sylvia Zhang & Scarlett Gomez, *COVID-19 Disparities: An Urgent Call for Race Reporting and Representation in Clinical Research*, 19 CONTEMP. CLINICAL TRIALS COMMC'NS. 1 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7391979/ [https://perma.cc/XB93-FSVW] (surveying clinical trials focusing on products other than vaccines).

[100] Carolyn Y. Johnson, *Large U.S. Covid-19 Vaccine Trials Are Halfway Enrolled, But Lag on Participant Diversity*, WASH. POST (Aug. 27, 2020, 1:25 PM MDT), https://www.washingtonpost.com/health/2020/08/27/large-us-covid-19-vaccine-trials-are-halfway-enrolled-lag-participant-diversity/ [https://perma.cc/ZT63-T9UF].

vaccine authorized by the FDA for emergency use,[101] and of the Moderna vaccine candidate, which was the first to enter clinical trials.[102]

Phase 3 of the clinical trial that produced the data used to support the emergency use authorization granted to Pfizer/BioNTech was initially designed with a target of 30,000 patients and later expanded.[103] On December 14, 2020, Pfizer reported a total enrollment of 44,863 volunteers in 150 sites across six countries, including the United States.[104] By then, 43,004 volunteers (95.9% of the trial population) had received the second shot.[105] At that point, demographic data from the United States indicated that 13% of volunteers were Latinx, 10% were Black, 6% were Asian and 1.3% were Native American.[106] Although Pfizer's announcement did not specify this information at the time, these numbers imply that 69.7% of the volunteers in the Pfizer/BioNTech vaccine trial in the United States did not belong to racial or ethnic minorities, for an overall diversity rate of 30.3%.[107]

Moderna's vaccine clinical trial, which took place across sites in over twenty U.S. states,[108] drew from a somewhat smaller volunteer pool (30,000 participants) and displayed a slightly higher diversity rate. Just over a month before submitting its emergency use authorization application to the FDA, Moderna released a report on phase 3 trials for its vaccine candidate, which at that point had met its enrollment

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[101] Letter from Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to Elisa Harkins, Regulatory Lead, Pfizer, Inc. (Dec. 23, 2020), https://www.fda.gov/media/144412/download [https://perma.cc/TR86-3F55].

[102] *First US Clinical Trial of Covid-19 Vaccine Candidate Begins*, CLINICAL TRIALS ARENA (Mar. 17, 2020), https://www.clinicaltrialsarena.com/news/first-us-covid-19-vaccine-trial-moderna/ [https://perma.cc/W9WQ-TFKU]; *see also* Press Release, Moderna, Moderna Announces First Participant Dosed in NIH-Led Phase 1 Study of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus (Mar. 16, 2020), https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-first-participant-dosed-nih-led-phase-1-study [https://perma.cc/3ED4-6Q9G].

[103] *See* Matthew Herper, *Pfizer and BioNTech Announce Plan to Expand Covid-19 Vaccine Trial*, STAT (Sept. 12, 2020), https://www.statnews.com/2020/09/12/pfizer-and-biontech-announce-plan-to-expand-covid-19-vaccine-trial/ [https://perma.cc/RJ9S-XXLF].

[104] *Pfizer-BioNTech COVID-19 Vaccine Trial Overview*, PFIZER.COM, https://www.pfizer.com/science/coronavirus/vaccine [https://perma.cc/V383-PYAS] [hereinafter *Pfizer Trial Overview*].

[105] *Id.*; Press Release, Pfizer & BioNTech, Pfizer and BioNTech Announce Publication of Results from Landmark Phase 3 Trial of BNT162B2 Covid-19 Vaccine Candidate in the New England Journal of Medicine (Dec. 10, 2020), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-publication-results-landmark [https://perma.cc/ND3E-2SDY] [hereinafter Pfizer & BioNTech Press Release].

[106] Pfizer & BioNTech Press Release, *supra* note 105.

[107] *See id.* (listing U.S.-specific diversity rates for participants in the Pfizer/BioNTech clinical trial).

[108] MODERNA, MODERNA COVE STUDY 6 (2020) https://www.modernatx.com/sites/default/files/content_documents/2020-COVE-Study-Enrollment-Completion-10.22.20.pdf [https://perma.cc/XES6-ZBJL] (reporting data current through October 21, 2020).

goal of 30,000 volunteers in several sites across the United States.[109] By October 21, 2020, a total of 25,654 participants had received the second dose of the vaccine.[110] Demographic data showed that 20% of volunteers were Latinx, 10% were Black or African American, 4% were Asian, 63% were White, and all other races and ethnicities accounted for 3% of the trial population.[111] These numbers put the diversity rate almost 7 points above Pfizer/BioNTech's, at approximately 37%.

Yet neither Moderna nor Pfizer/BioNTech's goals for diversity enrollment are satisfactory according to experts.[112] In August 2020, Moderna used social media to promote its "diversity & inclusion" plan for COVID-19 trials, noting that their vaccine candidate was being tested in "nearly 100 sites with representative demography."[113] Shortly thereafter, however, the company had to slow down the enrollment process because it was not able to recruit enough participants from racial and ethnic minorities.[114] Facing similar problems, Pfizer expanded its target enrollment from 30,000 to 44,000 volunteers.[115] Pfizer's press release specifically noted that the expansion was driven by the goal to "increase trial population diversity."[116] In the context of this specific trial, diversity efforts were also focused on including younger populations in order to garner data on volunteers as young as age 16, as well as populations with certain conditions, such as chronic HIV and hepatitis C.[117]

The examples of Pfizer/BioNTech and Moderna within the context of the COVID-19 vaccine race are especially relevant given the fact that their vaccine candidates were the first to enter the United States market, but these companies are by no means the only ones facing diversity problems in vaccine clinical trials. A representative for Velocity Clinical Research, an organization involved in COVID-19 vaccine trials in multiple locations across the United States,[118] reported similar enrollment problems. The Velocity Clinical Research representative described

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[109] *Moderna's Fully Enrolled Phase 3 COVE Study of mRNA-1273*, MODERNA.COM, https://www.modernatx.com/cove-study [https://perma.cc/2Z8B-P66B] (last visited Jan. 29, 2021) [hereinafter *Moderna's Phase 3 COVE Study*].

[110] *Id.*

[111] MODERNA, *supra* note 108, at 2.

[112] *See infra* note 126 and accompanying text.

[113] @moderna_tx, TWITTER (Aug. 21, 2020, 4:51 PM MDT), https://twitter.com/moderna_tx/status/1296942996592746498 [https://perma.cc/7PJW-G2QA].

[114] Eric Boodman, *Among People of Color Asked to Join Covid-19 Vaccine Trials, Worries About Inequities Run Deep*, STAT (Sept. 25, 2020), https://www.statnews.com/2020/09/25/among-people-of-color-asked-to-join-covid-19-vaccine-trials-worries-about-inequities-run-deep/ [https://perma.cc/8DWQ-AV7W].

[115] *Id.*

[116] Press Release, Pfizer & BioNTech, Pfizer and BioNTech Propose Expansion of Pivotal COVID-19 Vaccine Trial (Sept. 12, 2020), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-propose-expansion-pivotal-covid-19 [https://perma.cc/52MY-ZGLS].

[117] *Id.*

[118] *See, e.g.*, VELOCITY CLINICAL RSCH., https://velocityclinical.com [https://perma.cc/V7N9-93KG].

instructions to slow down volunteer recruitment in a way that tersely illustrates the magnitude of the problem: "Some of our sites, bluntly, are situated in a largely white population [*sic*]. We have had sites in those places that were told, 'You need to stop now and only recruit from minorities.'"[119]

Moderna's data on the progression of clinical trial enrollment follows a similar recruitment pattern:

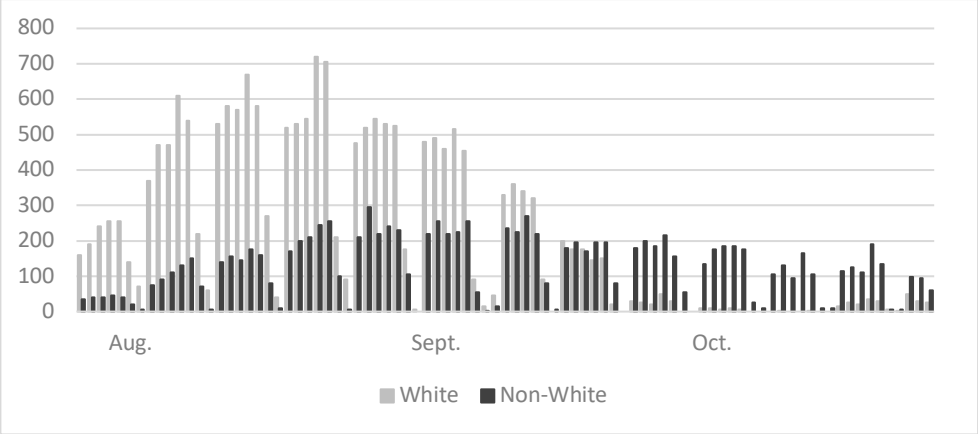

Figure 1: Moderna COVID-19 vaccine clinical trials enrollment, July 27, 2020 through October 21, 2020

The graph shows that during the first half of the enrollment period, White participants were being recruited at rates more than double those of non-White participants.[120] And perhaps even more telling, once diversity issues were flagged and the company began slowing down recruitment, it did not increase diversity by increasing recruitment rates among non-White populations, but rather by maintaining rates of non-White recruitment while drastically reducing the recruitment rate of White participants and eventually bringing it close to a halt.[121]

Nevertheless, this strategy can scarcely be said to have worked. Consider the case of enrollment of Black or African American volunteers for the Moderna vaccine trial. In August, when concerns about diversity in COVID-19 vaccine clinical trials began being voiced more forcefully,[122] the Moderna trial had enrolled only 7% Black or African American volunteers.[123] By mid-September that number had gone up to 13%.[124] Yet, as noted above, once enrollment was completed, the overall percentage of Black participants had dropped to 10%.[125] This number—as well as the overall

[119] Boodman, *supra* note 114.
[120] *Id.*
[121] *Id.*
[122] *See, e.g.*, Johnson, *supra* note 100; *see also* Cohen, *infra* note 126.
[123] Boodman, *supra* note 114.
[124] *Id.*
[125] *See Moderna's Phase 3 COVE Study*, *supra* note 109 (providing data on 25,654 out of 30,000 trial participants, which represents 85.5% of total enrollment).

diversity numbers in COVID-19 vaccine clinical trials—are far from the ones cited by public health experts as needed to accomplish the intertwined goals of accurately reflecting the racial and ethnic make-up of the United States and generating more granular data for purposes of regulatory review and vaccine trust-building.[126]

The specific demographic burden of COVID-19 makes substantial minority representation in vaccine clinical trials especially important. Dr. Anthony Fauci—the director of the National Institute of Allergy and Infectious Diseases—has noted that, given the disproportionately higher toll of COVID-19 on minorities, clinical trials for COVID-19 vaccines should enroll a significantly larger percentage of minority volunteers than other types of trials.[127] Dr. Fauci suggested that, in the specific case of COVID-19 vaccines, minority enrollment should be twice as high as the percentage of minorities in the United States population.[128] Relying on the most recent U.S. Census Bureau data, Dr. Fauci's recommendation translates into a goal of 66.4% minority enrollment in COVID-19 vaccine clinical trials.[129] While it is important that the representation goals articulated by Dr. Fauci are far higher than the standards typically used in vaccine clinical trials—and are in no way required by the FDA in assessing vaccine clinical trial data—the point remains that minority representation remains low as a feature of clinical trials in general, and vaccine clinical trials in particular. Dr. Fauci's approach is also not an isolated one. Other members of the scientific community agree that, given both the historical under-representation of minority populations in clinical trials and the burden of COVID-19 on minorities, it is necessary to oversample minority populations in vaccine trials.[130]

The problem of under-representation is exacerbated by inadequate reporting by research sponsors about research design for subgroup analysis. The Government Accountability Office, a non-partisan agency of the United States government,[131] issued a report in November 2020 finding that, albeit successful in generating data on vaccine candidates in record time, the COVID-19 vaccine clinical trials lacked transparency.[132] In particular, the report noted that the sponsors of the clinical trials provided little information on the collection and analysis of safety and efficacy data for population subgroups, including racial and ethnic minorities:

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[126] *See, e.g.*, Elizabeth Cohen, *Despite Effort, Enrollment of Minorities for Coronavirus Vaccine Trial Is Lagging*, CNN (Aug. 22, 2020, 8:52 AM ET), https://www.cnn.com/2020/08/22/health/coronavirus-moderna-minorities-lag/index.html [https://perma.cc/C9R5-7K98].

[127] *Id.*

[128] *Id.*

[129] *Id.*

[130] Johnson, *supra* note 100.

[131] U.S. GOV'T ACCOUNTABILITY OFF., https://www.gao.gov/about/ [https://perma.cc/RR9H-J5EL] (last visited Jan. 29, 2021).

[132] U.S. GOV'T ACCOUNTABILITY OFF., GAO-21-207, FEDERAL EFFORTS ACCELERATE VACCINE AND THERAPEUTIC DEVELOPMENT, BUT MORE TRANSPARENCY NEEDED ON EMERGENCY USE AUTHORIZATIONS 5 *passim* (2020), https://www.gao.gov/assets/gao-21-207.pdf [https://perma.cc/9ZL5-DD9R] [hereinafter GAO REPORT].

> [COVID-19 vaccine] clinical trial protocols provide limited details on how the vaccine developers will analyze their safety and efficacy data, specifically for population subgroups (e.g., the elderly, people with comorbidities, or racial/ethnic groups) or sample sizes needed for such subgroup analyses. Unless vaccine developers collect sufficient data for a subgroup analysis, it may not be possible to identify the potential for different safety or efficacy results for one or more subgroups, even if vaccine candidates are found safe and effective in the aggregate for the general population.[133]

This chronic under-representation of minority populations in vaccine clinical trials, compounded by a lack of transparency in data collection and subgroup data reporting, feeds into larger vaccine trust problems, explored in Section II.B. These trust problems contribute to vaccine hesitancy, leading individuals indicated for a vaccine to forego vaccination, sometimes even in cases in which the vaccine can be administered at no direct cost to the patient.[134] But addressing the trust problem requires overcoming other types of systemic disparities in racial and ethnic representation that pervade the vaccine development and distribution ecosystem.

Minorities' mistrust of medical research and the ways in which clinical trials have been conducted goes far beyond the domain of COVID-19 vaccines. For example, a study following the administration of H1N1 vaccines in Los Angeles County at free vaccination clinics during the 2009 swine flu pandemic found "[w]ide racial/ethnic disparities in vaccination rates," especially among Black populations.[135] Outside the context of pandemic vaccines, data gleaned over the years from seasonal flu vaccination provide a useful glimpse into disparities in vaccine distribution and access.[136] Vaccination rates among adult populations have historically been lower among Black, Hispanic, and American Indian or Alaska

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[133] *Id.* at 17.

[134] *See, e.g.*, Rueben C. Warren, Lachlan Forrow, David Augustin Hodge & Robert D. Truog, *Trustworthiness Before Trust—Covid-19 Vaccine Trials and the Black Community*, 383 NEW ENG. J. MEDICINE e121(1) (2020); William Wan, *Coronavirus Vaccines Face Trust Gap in Black and Latino Communities, Study Finds*, WASH. POST (Nov. 23, 2020, 5:55 PM MST), https://www.washingtonpost.com/health/2020/11/23/covid-vaccine-hesitancy/ [https://perma.cc/EEG5-V25H].

[135] Alonzo Plough, Benjamin Bristow, Jonathan Fielding, Stephanie Caldwell & Sinan Khan, *Pandemics and Health Equity: Lessons Learned from the H1N1 Response in Los Angeles County*, 17 J. PUB. HEALTH MGMT. & PRAC. 20 (2011).

[136] *See, e.g.*, Samantha Artiga, Josh Michaud, Jennifer Kates & Kendal Orgera, *Racial Disparities in Flu Vaccination: Implications for COVID-19 Vaccination Efforts*, KAISER FAMILY FOUND. (Sept. 15, 2020), https://www.kff.org/policy-watch/racial-disparities-flu-vaccination-implications-covid-19-vaccination-efforts/ [https://perma.cc/GWQ8-GRPG].

Native populations than among White populations.[137] The lower rates are attributable to multiple factors, including lower insurance rates and logistical hurdles.[138] However, trust deficits in the healthcare system and in medical research leading to the commercialization of new vaccines—and, more broadly, pharmaceutical products in general—remain a contributing factor in lower vaccine uptake among minority communities.[139]

Mistrust in the process leading to the commercialization of COVID-19 vaccines—both in the clinical trials and FDA review of clinical trial data, as explained in Section II.B—led to the announcement that entities were forming task forces or panels to perform ad hoc reviews of any COVID-19 vaccines authorized or approved by the FDA.[140] Notably, the entities do not play a role in drug regulation in the United States.

Responding to concerns about both minority under-representation and FDA review of COVID-19 vaccines, the National Medical Association (NMA) announced the creation of a task force composed of Black doctors to review COVID-19 vaccines and drugs.[141] The National Medical Association is a professional and scientific organization founded in 1895 to respond to problems posed by Jim Crow laws and other mechanisms of racial segregation leading to the disenfranchisement of Black Americans.[142] It began "representing African American physicians and health professionals in the United States" at a time in which membership in the American Medical Association was denied to non-White physicians,[143] and today it represents over 50,000 Black physicians.[144] In August 2020, the NMA approved a resolution to create a COVID-19 taskforce, which included doctors affiliated with federal public health institutions at the core of the response to COVID-19, like the Centers for Disease Control and Prevention (CDC). The task force also involved members from the vaccine advisory group responsible for federal vaccination

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[137] *See Influenza (Flu) General Population Vaccination Coverage*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/flu/fluvaxview/coverage-1920estimates.htm [https://perma.cc/L3MV-FJLG] (Jan. 29, 2021) (providing vaccination data on the most recent influenza season).

[138] Artiga et al., *supra* note 136.

[139] *Id.*; *see also* WASHINGTON, *supra* note 59.

[140] *See, e.g.*, Eric Boodman, *Not Trusting the FDA, Black Doctors' Group Creates Panel to Vet Covid-19 Vaccines*, STAT (Sept. 21, 2020), https://www.statnews.com/2020/09/21/black-doctors-group-creates-panel-to-vet-covid19-vaccines/ [https://perma.cc/C6VU-MQAS].

[141] *NMA Forms COVID-19 Task Force to Take the Politics Out of Vaccine Development*, NAT'L MED. ASS'N (Sept. 21, 2020), https://www.nmanet.org/news/527978/NMA-Forms-COVID-19-Task-Force-Take-the-Politics-Out-of-Vaccine-Development.htm [https://perma.cc/PZ5D-P6DX] [hereinafter *NMA Announcement*].

[142] *About Us*, NAT'L MED. ASS'N, https://www.nmanet.org/page/About_Us [https://perma.cc/6RHU-3QKW] (last visited Mar. 26, 2021); *History*, NAT'L MED. ASS'N, https://www.nmanet.org/page/History [https://perma.cc/JL5F-ADFG] (last visited Mar. 26, 2021).

[143] *History*, *supra* note 142.

[144] *Id.*

recommendations (the Advisory Committee on Immunization Practices, or ACIP), as well as representatives of medical professional organizations, such as the Infectious Disease Society of America and the Pediatric Infectious Disease Society.[145] The task force was charged with helping "address questions and concerns about efficacy, safety, and allocation of COVID-19 vaccines and therapeutics."[146] The NMA specifically framed the formation of the task force as prompted by concerns that diminishing "public trust in the FDA [ ] will adversely affect participation in clinical trials, especially in the African-American community."[147]

The NMA's taskforce was not the only instance in which players normally extraneous to the FDA's drug and vaccine review process announced interventions designed to act as a check on FDA review of COVID-19 clinical trial data. In late September 2020, citing politicization of the review of COVID-19 vaccine clinical trial data, the governor of New York announced that the state would independently review any COVID-19 vaccines approved by the FDA before allowing them to be distributed across the state.[148] In October 2020, the governor of California announced the formation of the California COVID-19 Scientific Safety Review Workgroup, formed by "California physician scientists" to "independently review the safety and efficacy of any vaccine that receives FDA approval for distribution."[149] And in October 2020, the states of Washington, Oregon and Nevada joined California's Review Workgroup.[150] Although the Review Workgroup eventually endorsed the COVID-19 vaccine sponsored by Pfizer/BioNTech to which the FDA granted the first vaccine emergency use authorization,[151] the formation of multiple state-level bodies charged with reviewing FDA vaccine authorizations speaks to the overall trust deficit in the United States in connection with vaccine

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[145] *NMA Announcement*, *supra* note 141.

[146] *Id.*

[147] *Id.*

[148] Michael Gold & Jesse McKinley, *New York Will Review Virus Vaccines, Citing Politicization of Process*, N.Y. TIMES (Dec. 3, 2020), https://www.nytimes.com/2020/09/24/nyregion/new-york-coronavirus-vaccine.html [https://perma.cc/7W2T-RG9D].

[149] *See Scientific Safety Review Workgroup*, CAL. DEP'T OF PUB. HEALTH (Jan. 21, 2021), https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Scientific-Safety-Review-Workgroup.aspx [https://perma.cc/3CGV-G2VY]; Press Release, Off. of Governor Gavin Newsom, Governor Newsom Names Scientific Safety Review Workgroup to Advise State on COVID-19 Vaccines (Oct. 19, 2020), https://www.gov.ca.gov/2020/10/19/governor-newsom-names-scientific-safety-review-workgroup-to-advise-state-on-covid-19-vaccines/ [https://perma.cc/3GM8-FKUH].

[150] Press Release, Off. of Governor Gavin Newsom, Western States Join California's Scientific Safety Review Workgroup to Ensure Safety of COVID-19 Vaccine (Oct. 27, 2020), https://www.gov.ca.gov/2020/10/27/western-states-join-californias-scientific-safety-review-workgroup-to-ensure-safety-of-covid-19-vaccine/ [https://perma.cc/GBZ5-8CYV].

[151] W. STATES SCI. SAFETY REV. WORKGROUP, SUMMARY OF FINDINGS (Dec. 12, 2020), https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/COVID-19/Scientific-Safety-Review-Workgroup-Recommendations-December-2020.pdf [https://perma.cc/K2C2-3VH2].

clinical trials—at least within the context of accelerated data production and regulatory review of vaccines as a major public health crisis unfolds.

It is possible, indeed probable, that some of the factors that contributed to distrust of emerging COVID-19 vaccines are specific to the ways in which the federal response to pandemic preparedness was perceived as defective by the general public and abundantly criticized by public health experts.[152] As such, some of the events that colored public perceptions of COVID-19 vaccines are likely to remain idiosyncratic to the current pandemic. Yet, vaccine trust deficits have long been partly rooted in public perceptions of how vaccine clinical trial data is generated and assessed. In addition to affecting the scientific and regulatory processes, longstanding holes in the vaccine data infrastructure resulting from the under-collection of information relative to minority populations pose challenges to vaccine trust. Absent more forceful corrective interventions, these trust issues that have long-characterized vaccine research and development will persist beyond the COVID-19 pandemic.

B. Data Sharing: Enabling Scrutiny and Subsequent Innovation

Even if imperfectly collected, data generated during vaccine clinical trials provide valuable clues not only to regulatory entities exercising their gatekeeping functions, but also to the scientific community and, ultimately, the public at large.[153] However, not all data collected during vaccine clinical trials can be scrutinized or used for subsequent research endeavors. On the one hand, there has long been evidence of significant under-reporting of data gathered during vaccine clinical trials.[154] On the other, data that is disclosed in a specific context may be treated as secret or proprietary vis-à-vis third parties. In the latter case, the most common scenario involves clinical trial data disclosed to a regulatory agency in connection with an application to market a new vaccine.[155] Together, these two types of restrictions erect significant hurdles to the free flow of data and scientific knowledge about newly developed vaccines.

As far as the reporting and publication of vaccine clinical trial data is concerned, law and practice have long been poorly aligned. As seen above, the Declaration of Helsinki established that medical researchers have a duty to make the results of studies involving human subjects publicly available.[156] Yet, studies have repeatedly found that the results of vaccine clinical trials are routinely published

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[152] *See, e.g.*, Drew Altman, *Understanding the US Failure on Coronavirus*, 370 BRIT. MED. J. 3417 (2020), https://www.bmj.com/content/370/bmj.m3417 [https://perma.cc/XXT5-EG45]; Eric C. Schneider, *Failing the Test —The Tragic Data Gap Undermining the U.S. Pandemic Response,* 383 NEW ENG. J. MEDICINE 299 (2020), https://www.nejm.org/doi/full/10.1056/nejmp2014836 [https://perma.cc/A5CX-R7TX].

[153] *See supra* note 94 and accompanying text.

[154] *See infra* notes 160–168 and accompanying text.

[155] *See infra* note 177 and accompanying text.

[156] DECLARATION OF HELSINKI, *supra* note 72.

after a considerable delay, and in many cases are not published at all.[157] These two phenomena have been documented when a pandemic compresses vaccine development and testing timelines, as well as outside the context of pandemics or other highly disruptive public health crises.[158]

The case of vaccine clinical trial data generated during the 2009 H1N1 swine flu pandemic is instructive. The H1N1 vaccines were developed on a timeline that was even more compressed than the timeline for the first COVID-19 vaccines: the strain of influenza that caused the 2009 pandemic was identified in April and the FDA approved four H1N1 vaccines in September of the same year.[159] Yet publication of clinical trial data lagged considerably. Of the 73 vaccine trials that took place between 2009 and 2010, only 21 had published data by June 2011, almost two years after FDA approval of the vaccines.[160] This represents less than one-third (29%) of the trial universe for vaccine candidates developed and tested in a situation of heightened public health need.[161] The results of most H1N1 vaccine clinical trials remained unpublished.[162]

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[157] *See* Lamberto Manzoli, Maria Elena Flacco, Maddalena D'Addario, Lorenzo Capasso, Corrado De Vito, Carolina Marzuillo, Paolo Villari & John P. A. Ioannidis, *Non-Publication and Delayed Publication of Randomized Trials on Vaccines: Survey*, 348 BRIT. MED. J. 3058 (2014), https://www.bmj.com/content/348/bmj.g3058 [https://perma.cc/JQX9-QXAQ] (reporting publication delays and lack of publication of clinical trial data for vaccines developed both during and outside the context of a pandemic); Christopher W. Jones & Timothy F. Platts-Mills, Editorial, *Delayed Publication of Vaccine Trials*, 348 BRIT. MED. J. 3259 (2014), (similarly addressing both contexts); John P. A. Ioannidis, Lamberto Manzoli, Corrado De Vito, Maddalena D'Addario & Paolo Villari, *Publication Delay of Randomized Trials on 2009 Influenza A (H1N1) Vaccination*, 6 PLOS ONE e28346 (2011), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0028346 [https://perma.cc/8JAD-FLHR] (presenting a case study focused solely on data from trials for H1N1 vaccines, which took place in response to the 2009 swine flu pandemic). Studies have also found that not all clinical trials are registered. *See, e.g.*, Scott M. Lassman, Olivia M. Shopshear, Ina Jazic, Jocelyn Ulrich & Jeffrey Francer, *Clinical Trial Transparency: A Reassessment of Industry Compliance with Clinical Trial Registration and Reporting Requirements in the United States*, 7 BRIT. MED. J. OPEN e015110 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5623439/ [https://perma.cc/337P-S8CJ]; Jennifer Miller, Joseph S. Ross, Marc Wilenzick & Michelle M. Mello, *Sharing of Clinical Trial Data and Results Reporting Practices Among Large Pharmaceutical Companies: Cross Sectional Descriptive Study and Pilot of a Tool to Improve Company Practices*, 366 BRIT. MED. J. l4127 (2019), https://www.bmj.com/content/366/bmj.l4217 [https://perma.cc/YGM6-V4GP].

[158] *See infra* note 168 and accompanying text.

[159] *See* Jones & Platts-Mills, *supra* note 157; Robert Roos, *FDA Approves Four Companies' H1N1 Vaccines*, CTR. FOR INFECTIOUS DISEASE RSCH. & POL'Y (Sept. 15, 2009), https://www.cidrap.umn.edu/news-perspective/2009/09/fda-approves-four-companies-h1n1-vaccines [https://perma.cc/BV39-VU3F].

[160] Ioannidis et al., *supra* note 157.

[161] *Id.*

[162] *Id.*

The same is true outside the context of pandemics.[163] A study conducted by Lamberto Manzoli and colleagues surveyed 384 randomized vaccine clinical trials enrolling over 404,758 participants.[164] In addition to surveying H1N1 vaccine clinical trials, this study included vaccines developed and tested outside pandemic contexts: human papillomavirus, meningococcal, pneumococcal, and rotavirus vaccines.[165] The study found that, on average, only half of vaccine clinical trials were published after a median of 26 months from completion of the trial.[166] Publication was defined as cases in which "one or more of the main outcomes appeared in a peer reviewed journal, either online or in print."[167] Almost two-thirds of the participant data in randomized vaccine clinical trials was not published in peer-reviewed literature.[168]

Delayed publication and lack of publication of vaccine clinical trial data produce detrimental effects that extend beyond the context of subsequent research.[169] As Kay Dickersin and Drummond Rennie noted in a 2003 study evaluating the implementation of the clinical trial registration requirements introduced by the 1997 Food and Drug Administration Modernization Act: "if the knowledge gained [through clinical trials] is never reported, the trust between patients and investigators and that between patients and research ethics review boards are both damaged."[170]

In addition to these problems, segments of the vaccine data infrastructure often remain inaccessible to many players in the vaccine innovation ecosystem—from researchers to follow-on innovators in biopharma to activists in the health space—for relatively long periods of time. These cases encompass situations in which data

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[163] Manzoli et al., *supra* note 157.

[164] *Id.*

[165] *Id.*

[166] *Id.*

[167] *Id.*

[168] *Id.* Some of the trials not published in peer-review publications shared results through the national registry of clinical trials, ClinicalTrials.gov. *See supra* note 76 and accompanying text. The combined percentage of vaccine clinical trials publishing in peer-review literature and ClinicalTrials.gov was 61%. *Id.* Studies in non-vaccine domains have similarly found that a significant percentage of clinical trials remains unpublished. *See, e.g.*, Joseph S. Ross, Tony Tse, Deborah A. Zarin, Hui Xu, Lei Zhou & Harlan M. Krumholz, *Publication of NIH Funded Trials Registered in ClinicalTrials.Gov: Cross Sectional Analysis*, 344 BRIT. MED. J. 7292 (2012), https://www.bmj.com/content/bmj/344/bmj.d7292.full.pdf [https://perma.cc/6MD8-HQKN] (finding that a third of registered NIH-funded trials are still unpublished after a median of fifty-one months following trial completion).

[169] *See, e.g.*, Trudo Lemmens & Candice Telfer, *Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency*, 38 AM. J.L. & MED. 63, 66 (2012), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1932436# [https://perma.cc/4RX3-VGQC] (making the case for greater clinical trial data registration and reporting from a human rights perspective).

[170] Kay Dickersin & Drummond Rennie, *Registering Clinical Trials*, 290 JAMA 516 (2003).

collected during vaccine clinical trials have been reported and submitted for independent review, but are not made available outside the regulatory context.[171]

Sponsors of drugs and vaccines are required to submit data to regulatory agencies across the world in standardized ways in the form of clinical study reports (CSR).[172] These reports tend to contain more data than what is disclosed through other channels, such as publication in peer-review literature.[173] However, not all the information contained in the clinical study reports submitted by drug and vaccine sponsors to regulatory entities is made publicly available.[174] As further detailed in Part IV, the European drug regulator has in recent years taken steps to promote the disclosure of both CSR data and information often not contained in clinical study reports, as is the case of individual patient data.[175]

In the United States, the FDA has long treated most of the data submitted by sponsors—including vaccine data—as proprietary or quasi-proprietary, either by virtue of existing legal frameworks regulating trade secrecy and other types of confidential information, or under the FDA's expansive approach to the concept of protected data.[176]

Data submitted to the FDA that qualifies as a trade secret cannot be disclosed by the agency.[177] The law defines a trade secret as "any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort."[178] Disclosure of data protected as a trade secret by

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[171] *See infra* notes 177–182 and accompanying text.

[172] U.S. FOOD & DRUG ADMIN., GUIDELINE FOR INDUSTRY: E3 STRUCTURE AND CONTENT OF CLINICAL STUDY REPORTS (July 1996), https://www.fda.gov/media/71271/download [https://perma.cc/R2AV-LFBZ] (providing context on FDA guidance on clinical study reports issued in accordance with the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use); *see also* Beate Wieseler, Michaela F. Kerekes, Volker Vervoelgyi, Natalie McGauran & Thomas Kaiser, *Impact of Document Type on Reporting Quality of Clinical Drug Trials: A Comparison of Registry Reports, Clinical Study Reports, and Journal Publications*, 344 BRIT. MED. J. 8141 (2012); Tom Jefferson, Peter Doshi, Isabelle Boutron, Su Golder, Carl Heneghan, Alex Hodkinson, Mark Jones, Carol Lefebvre & Lesley A. Stewart, *When to Include Clinical Study Reports and Regulatory Documents in Systematic Reviews*, 23 BRIT. MED. J. EVIDENCE BASED MED. 210 (2018).

[173] Ho, *supra* note 94, at 17.

[174] *See generally* Hilda Bastian, *What the Systematic Review of HPV Vaccine Clinical Study Reports Does, and Does Not, Reveal: Commentary on Jørgensen et al.*, 9 SYSTEMATIC REVS. 41 (2020) (exploring this problem in the context of vaccine clinical study reports).

[175] Ho, *supra* note 94, at 18; *see also* Anna L. Davis & James Dabney Miller, *The European Medicines Agency and Publication of Clinical Study Reports: A Challenge for the US FDA*, 317 JAMA 905 (2017).

[176] *But see* Peter Doshi, *FDA to Begin Releasing Clinical Study Reports in Pilot Programme*, 360 BRIT. MED. J. 294 (2018).

[177] 21 C.F.R. § 20.61(c) (2020).

[178] *Id.* § 20.61(a).

an officer or employee of the FDA is punishable by a fine and removal from office or employment, and may result in imprisonment for up to a year.[179]

The prohibition on disclosure extends to commercial and financial information deemed "privileged or confidential," which the law defines as "valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs."[180]

Clinical trial data has long been treated by the FDA as proprietary information, and specifically as a trade secret. The Food, Drug and Cosmetic Act (FDCA) in section 331(j) prevents the FDA from disclosing "any method or process" that qualifies as a trade secret.[181] In regulations issued in the 1970s, the Agency determined that "safety and effectiveness data for new drugs . . . fall within the trade secrets exemption and thus are not available for public disclosure[,]" a position it has maintained ever since.[182]

Several legal commentators, however, have disagreed with the FDA's interpretation of section 331(j) in the FDCA. Rebecca Eisenberg has made the case that "it is by no means obvious from the statutory language that 'any method or process which as a trade secret is entitled to protection' includes data from clinical trials."[183] Christine Galbraith has noted that some of the defining characteristics of clinical trials make them a poor fit for trade secrecy frameworks: "A fundamental tenet of trade secret law is that protection exists only as long as the information is kept confidential. The very nature of a clinical trial is quite public in many respects, making maintenance of complete secrecy fairly difficult."[184] And Arti Rai has argued that the passage of the Hatch-Waxman Act in 1984 further eroded the FDA's policy stance on clinical trial data by setting up a pathway for the approval of generic drugs that allows for FDA disclosure of data to follow-on innovators or the public in general, as long as the period of regulatory exclusivities attached to the reference drug has expired.[185]

In addition to the ongoing debate about the FDA's interpretation of the legal status of data submitted by drug and vaccine sponsors seeking market authorization, the mere existence of a filing of an investigational new drug application (IND) for a

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[179] 18 U.S.C. § 1905 (2018).

[180] 21 C.F.R. § 20.61(b)–(c) (2020).

[181] 21 U.S.C. § 331(j) (2020).

[182] 39 Fed. Reg. 44,602, 44,633 (Dec. 24, 1974); *see also* 42 Fed. Reg. 3,094 (Jan. 14, 1977).

[183] Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 380 n.129 (2007) (acknowledging also that "the longstanding administrative practice would make it difficult to adopt a narrower reading of the provision at this point").

[184] Christine D. Galbraith, *Dying to Know: A Demand for Genuine Public Access to Clinical Trial Results Data*, 78 MISS. L.J. 705, 753 (2009).

[185] Arti K. Rai, *Risk Regulation and Innovation: The Case of Rights-Encumbered Biomedical Data Silos*, 92 NOTRE DAME L. REV. 1641, 1656–57 (2017); s*ee also* 21 U.S.C. § 355(b) (2018).

biologic—the regulatory category vaccines belong to—cannot be disclosed or acknowledged by the FDA.[186] And even in the cases of information disclosed by sponsors as part of a submission to clinical trial registries, that information is not standardized, effectively allowing companies often to provide vague information.[187]

While the FDA announced some changes in connection with the authorization and approval of COVID-19 drugs and vaccines,[188] a report issued by the Government Accountability Office in November 2020 found that, at least in the case of COVID-19 therapeutic products, the FDA had not always been transparent in disclosing data supporting emergency authorizations for non-vaccine products "because the agency has not uniformly disclosed information from its scientific review of the safety and effectiveness data at the time of each authorization."[189] Similarly, some problems related to timely disclosure of information or data were reported in connection with COVID-19 vaccine clinical trials.[190] For example, Pfizer—the first vaccine sponsor to receive an emergency use authorization in the United States—was criticized for allegedly delaying the amended vaccine clinical trial protocol.[191] And another pharmaceutical company, AstraZeneca, was criticized for being too slow to share negative results from its COVID-19 vaccine candidate clinical trials.[192]

Recently, other jurisdictions have adopted measures designed to increase transparency and access to both clinical trial data and other types of information relative to new drugs and vaccines.[193] The next Part surveys an example of a data

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[186] 21 C.F.R. § 601.50(a) (2020); *see also id.* § 601.50(c) (carving out an exception for individuals who have experienced an adverse effect in connection with the administration of the biologic covered by an investigational new drug application).

[187] *See* Deborah A. Zarin, Nicholas C. Ide, Tony Tse, William R. Harlan, Joyce C. West & Donald A. B. Lindberg, *Issues in the Registration of Clinical Trials*, 297 JAMA 2112, 2116–17 (2007); s*ee also* Miller et al., *supra* note 157 (further describing transparency issues in the reporting of clinical trial data).

[188] *See, e.g.*, *COVID-19 Update: FDA's Ongoing Commitment to Transparency for COVID-19 EUAs*, U.S. FOOD & DRUG ADMIN. (Nov. 17, 2020), https://www.fda.gov/news-events/press-announcements/covid-19-update-fdas-ongoing-commitment-transparency-covid-19-euas [https://perma.cc/U7FK-6NGH].

[189] GAO REPORT, *supra* note 132, at 20.

[190] *See* Jennifer E. Miller, Joseph S. Ross & Michelle M. Mello, *Far More Transparency Is Needed for Covid-19 Vaccine Trials*, STAT (Nov. 5, 2020), https://www.statnews.com/2020/11/05/transparency-is-needed-for-covid-19-vaccine-trials/ [https://perma.cc/4WFW-V4F7].

[191] *Id.*

[192] *Id.*

[193] *See, e.g.*, Ho, *supra* note 94, at 5; *see also* EUR. MEDS. AGENCY, EUROPEAN MEDICINES AGENCY POLICY ON PUBLICATION OF CLINICAL DATA FOR MEDICINAL PRODUCTS FOR HUMAN USE (2019), https://www.ema.europa.eu/en/documents/other/european-medicines-agency-policy-publication-clinical-data-medicinal-products-human-use_en.pdf [https://perma.cc/2R84-SMDB]; HEALTH CANADA, PUBLIC RELEASE OF CLINICAL DATA*:* GUIDANCE DOCUMENT (2019), https://www.canada.ca/en/health-canada/services

policy adopted during the COVID-19 pandemic by one of these jurisdictions as a blueprint for implementing measures that mitigate some of the problems—albeit only on the data disclosure side—of the vaccine data infrastructure.

IV. TOWARDS A RICHER VACCINE CLINICAL TRIAL DATA INFRASTRUCTURE

So far, this Article has highlighted some of the most salient and longstanding problems affecting the vaccine clinical trial data infrastructure. It has also surveyed some of the legislative efforts adopted from the mid-twentieth century onwards to improve the ways in which vaccine clinical trial data is both collected and shared. The shortcomings of current frameworks, however, indicate that further action continues to be necessary on these two fronts.

Many of the interventions required to address the systemic problems explored throughout this Article will necessarily have to occur on prolonged timelines, and require concerted efforts from different players in the vaccine development and deployment ecosystem. For example, addressing overall under-representation issues in vaccine clinical trials implies tackling intertwined yet fundamentally different problems. These problems include logistical hurdles ranging from transportation and childcare arrangements for trial participants to existing implicit biases against racial and ethnic minority patients held by a majority of healthcare providers,[194] just to name a few areas. Moreover, efforts to improve the representation of racial and ethnic minorities in vaccine clinical trials cannot be detached from efforts needed in connection with the under-representation of minorities in clinical trials involving other medical products.

But while improving vaccine clinical trial data collection and sharing remains a long-term, multi-prong proposition, there are some more immediate fixes available to regulators and policymakers that would enrich the vaccine clinical data infrastructure. As the COVID-19 pandemic exposed some of the holes in this infrastructure, it also provided the impetus for institutional players like the European

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/drug-health-product-review-approval/profile-public-release-clinical-information-guidance/document.html [https://perma.cc/LH38-XXE4].

[194] *See, e.g.*, William J. Hall, Mimi V. Chapman, Kent M. Lee, Yesenia M. Merino, Tainayah W. Thomas, B. Keith Payne, Eugenia Eng, Steven H. Day & Tamera Coyne-Beasley, *Implicit Racial/Ethnic Bias Among Health Care Professionals and Its Influence on Health Care Outcomes: A Systematic Review*, 105 AM. J. PUB. HEALTH e60, e60 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4638275/ [https://perma.cc/C3X2-8W2A] ("Most health care providers appear to have implicit bias in terms of positive attitudes toward Whites and negative attitudes toward people of color."). *See generally* Sheba George, Nelida Duran & Keith Norris, *A Systematic Review of Barriers and Facilitators to Minority Research Participation Among African Americans, Latinos, Asian Americans, and Pacific Islanders*, 104 AM. J. PUB. HEALTH (2014) e16, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3935672/ [https://perma.cc/T6N8-4E8P] (conducting a systematic review of forty-four published studies of barriers and facilitators to health research participation by minority populations).

Medicines Agency (EMA) and the FDA to respond to ongoing vaccine data-related problems, particularly with regard to the disclosure of clinical trial data.

Following years of criticism for lack of transparency of its clinical trial data sharing policy,[195] the EMA started publishing clinical trial data submitted by drug and vaccine sponsors in 2016 as part of an effort to render the regulatory review process more transparent.[196] The amount of information made publicly available by the Agency under this new policy vastly surpassed its previous practices, as well as the standard at the FDA.[197] For each drug or vaccine application, the new policy mandated the disclosure of the clinical overview of the product, the clinical summary, study reports associated with individual clinical studies, the study protocol, the sample case report form used to record information on an individual patient, and information on the statistical methods employed to evaluate the data collected during clinical trials.[198]

Nevertheless, the EMA suspended this new data disclosure policy in December 2018, shortly before relocating from London to Amsterdam in the wake of the Brexit vote.[199] While the Agency committed to reinstating the policy after the move was completed, it announced a delay in 2020 citing the onset of the COVID-19 pandemic as the cause.[200] As of January 2021 the policy remains suspended.[201] However,

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[195] *See, e.g.*, Tracy Hampton, *European Drug Agency Under Fire: Critics Charge that Trial Data Are Too Inaccessible*, 306 JAMA 593, 593 (2011).

[196] *See Clinical Data Publication*, EUR. MEDS. AGENCY, https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/clinical-data-publication [https://perma.cc/4YCX-K94W] (last visited Jan. 29, 2021) [hereinafter *Clinical Data Publication*]; *see also* EUR. MEDS. AGENCY, EXTERNAL GUIDANCE ON THE IMPLEMENTATION OF THE EUROPEAN MEDICINES AGENCY POLICY ON THE PUBLICATION OF CLINICAL DATA FOR MEDICINAL PRODUCTS FOR HUMAN USE (2018), https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/external-guidance-implementation-european-medicines-agency-policy-publication-clinical-data_en-3.pdf [https://perma.cc/7VC6-LMZF].

[197] *See* Davis & Miller, *supra* note 175.

[198] *Clinical Data Publication*, *supra* note 196; *see also* EUR. MEDS. AGENCY, COMMON TECHNICAL DOCUMENT FOR THE REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE: ORGANISATION OF COMMON TECHNICAL DOCUMENT (2004), https://www.ema.europa.eu/en/documents/scientific-guideline/ich-m-4-common-technical-document-registration-pharmaceuticals-human-use-organisation-ctd-step-5_en.pdf [https://perma.cc/L547-49WK] (describing the content of each one of these types of documents).

[199] *Clinical Data Publication*, *supra* note 196; *see also Relocation to Amsterdam*, EUR. MEDS. AGENCY, https://www.ema.europa.eu/en/about-us/history-ema/relocation-amsterdam [https://perma.cc/2Q3W-WSU6] (last visited Feb. 4, 2021); *see also* Zachary Brennan, *Brexit Impact: EMA Suspends Publication of Clinical Trial Data*, REGUL. FOCUS (Aug. 15, 2018), https://www.raps.org/news-and-articles/news-articles/2018/8/brexit-impact-ema-suspends-publication-of-clinica [https://perma.cc/7U26-LEY6] (reporting on the suspended publication process).

[200] *Clinical Data Publication*, *supra* note 196 (noting that, as of January 2021, the clinical trial data sharing policy "remains suspended due to ongoing business continuity linked to the COVID-19 pandemic").

[201] *Id.*

during the early stages of the COVID-19 pandemic there were repeated calls for the Agency to share more information about clinical trial data submitted in connection with applications for COVID-19 drugs and vaccines.[202] In response, in May 2020 the EMA announced the adoption of an ad hoc data policy for COVID-19 products, including vaccines.[203] The ad hoc policy restored not only the publication of clinical trial data for approved COVID-19 products, but also the expedited and increased disclosure of other types of information about experimental and approved COVID-19 products.[204] For example, the additional information now made available for COVID-19 products includes the expedited publication of product applications and assessment reports, as well as the disclosure of information that the EMA does not typically share under its standard policy, such as the publication of the full body of the risk management plan for a given product instead of the publication of only the summary of the plan.[205] In the specific case of vaccines, the EMA began publishing monthly safety updates for approved COVID-19 vaccines, something it does not do with other types of vaccines under the standard data policy.[206] Moreover, the Agency is also releasing additional safety information about vaccines on an ad hoc basis.[207]

The following chart summarizes some of the main changes between the standard policy and the COVID-19 ad hoc policy adopted by the EMA.

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[202] *See, e.g.*, Press Release, IQWiG, All Clinical Trial Data on Covid-19 Medicines and Vaccines Should Be Published on the Day of Marketing Authorisation! (May 14, 2020), https://www.iqwig.de/en/press/press-releases/all-clinical-trial-data-on-covid-19-medicines-and-vaccines-should-be-published-on-the-day-of-marketing-authorisation.13015.html [https://perma.cc/LH2F-4E8D] (providing the letter submitted to the EMA by the Institute for Quality and Efficiency in Healthcare, an independent drug and medical device review organization created in Germany in 2004). *See generally Legal Foundations of IQWiG*, IQWiG, https://www.iqwig.de/en/about-us/responsibilities-and-objectives-of-iqwig/legal-foundations-of-iqwig.2952.html [https://perma.cc/X5HW-UQ6Q] (last visited Jan. 29, 2021).

[203] *See* Letter from Guido Rasi, Executive Director, Eur. Meds. Agency, to Dr. Wieseler et al. (May 28, 2020), https://www.ema.europa.eu/en/documents/other/european-medicines-agency-response-iqwig-transparency-covid-19-related-activities_en.pdf [https://perma.cc/S577-N827].

[204] *Transparency: Exceptional Measures for COVID-19 Medicines*, EUR. MEDS. AGENCY, https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/transparency-exceptional-measures-covid-19-medicines [https://perma.cc/M3CK-RCUN] (last visited Jan. 29, 2021).

[205] *Id.*

[206] *Id.*

[207] *Id.*

	Standard Policy	Policy for COVID-19 Products
Scientific advice	No information is published	Publication of list of products that have received scientific advice or guidance
Marketing authorization applications	Active substance and therapeutic area disclosed on monthly list[208]	Announcement of application published within one day
Product information	Published in all E.U. languages with the product assessment report[209]	English version published within one day of favorable opinion from Committee for Medicinal Products for Human Use
Publication of European Public Assessment Report (EPAR)	Not published until at least two weeks after marketing authorization is issued	Published within three days of marketing authorization
Updates to EPAR	Updates published	Updates expedited for "major" changes
Risk Management Plan (RMP)	Summary of RMP published	Full body of RMP published
Clinical trial data	Publication suspended; set to resume after COVID-19 pandemic	Clinical trial data published after marketing authorization is issued. Additional trial data published if "major" changes occur
Application for extension of indication	Information not published	Announcement of application published within one day
Monthly safety updates for vaccines	Information not published	Published monthly for approved COVID-19 vaccines. Additional information provided on ad hoc basis

Figure 2: EMA's Standard Data Policy Versus COVID-19 Data Policy[210]

The quick adoption of the COVID-19 ad hoc data policy by the EMA shows how regulators can be more responsive to informational and transparency deficits in the vaccine data infrastructure—and to similar deficits affecting other types of medical products. This responsiveness is especially critical in the case of emerging vaccines. As seen in Part II.B, one of the most significant features of the COVID-19 vaccine race is that, unlike research and development focused on other COVID-19

[208] *Medicines Under Evaluation*, EUR. MEDS. AGENCY, https://www.ema.europa.eu/en/medicines/medicines-under-evaluation [https://perma.cc/C3ZN-9EPQ] (last visited Jan. 29, 2021) (providing the monthly list of medicines under evaluation by the EMA).

[209] *European Public Assessment Reports: Background and Context*, EUR. MEDS. AGENCY, https://www.ema.europa.eu/en/medicines/what-we-publish-when/european-public-assessment-reports-background-context [https://perma.cc/ZA75-LRAV] (last visited Jan. 29, 2021).

[210] Adapted from *id*.; *Transparency: Exceptional Measures for COVID-19 Medicines*, *supra* note 204.

medical products, it relies on a form of technology that, although studied for over a decade, is essentially new.[211] Cutting-edge science, follow-on improvements and perceptions of medical products resulting from these scientific processes are all predicated on a robust and transparent flow of information and data. Moving forward, the data policy adopted by the EMA for COVID-19 products can and should be regarded as a starting point towards the building of a richer and more transparent data infrastructure.

To be sure, the steps taken by the EMA to increase data disclosure during the pandemic happened on the heels of a policy suspension that greatly decreased the amount of information available about drugs, vaccines and other medical products outside the COVID-19 space.[212] Although this suspension is meant to be temporary, it also calls attention to the difficulties regulators face in broadening the disclosure of clinical trial data and other types of drug- and vaccine-related information. While the EMA's policy suspension appears to have been at least partly rooted in its adjustment to Brexit, there are hurdles that are more generalizable to drug regulators across the world. As Cynthia Ho has recently pointed out, efforts to increase data disclosure by national regulatory agencies often bring data-related debates into the realm of intellectual property negotiations, which in turn fall back on trade law channels to resolve international disputes, thus complicating the political economy of this area.[213]

Finally, it is important to note that the solution surveyed here addresses only one subset of problems in the vaccine data infrastructure. On their own, efforts to improve disclosure frameworks leave data generation, collection and publication problems untouched. This Article has highlighted a range of shortcomings in the vaccine data infrastructure related to the production of data about new vaccines, and concludes by pointing towards an existing example of the implementation of measures that address one of these shortcomings. Certainly, many other improvements are still necessary in the area of data disclosure alone, beginning with the adoption of more permanent data policies in Europe and, hopefully, beyond. Yet, amidst the pressures posed by the pandemic on the scientific and regulatory communities, the adoption of the COVID-19 data policy at the EMA shows a path forward.

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[211] *Infra* notes 86–90 and accompanying text.
[212] *See supra* note 199 and accompanying text.
[213] *See* Ho, *supra* note 94, at 2–3.