GOOD MEDICINE
Health, Ethics and Innovation
a collaboration between Bioethics International and Scientific American

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Matters of Trust

Hippocrates, the Ancient Greek physician often called the father of medicine, might not have foreseen the privacy issues presented by Facebook patient groups, or the sharing of electronic health records. Nor would the transparency of data in clinical trials have been a concern to him or to the multitude of philosophical thinkers through the ages and across the world who have ruminated on the nature of medicine and the moral responsibilities of those who deliver it.

But these thinkers would have felt right at home at the intersection of medicine and ethics, a universal, timeless concept encompassing the “heart” of health and concerned not just with the well-being of the beneficiaries of care, but the context surrounding its transparency, discovery and equitable delivery.

With a pandemic commanding the attention of every stakeholder in the health-care ecosystem—patients, providers, scientists, policymakers, industry players, worried citizens in every country—the topic of health innovation and the ethical framework through which it must be viewed has taken on renewed urgency. How can government and industry deliver coronavirus vaccines fairly? Is the life-sciences industry committed to safety, transparency and patient-centric health care? The intersection of science and moral responsibility has never been more significant.

Exploring this critical intersection is the core mission of Good Medicine: Health, Ethics and Innovation, a debut media program and collaborative venture from the Scientific American Custom Media Group and Bioethics International. As medicine shifts from a focus on the doctor-patient relationship to more complex systems of care, and as therapeutic opportunities become more promising and dependent on technology, the innovators in medicine need to continually address the influence of the profit motive and the gap between the medical “haves and have-nots,” with the goal of building a health-care system that is as fair as possible.

We will explore the many challenges and issues of trust faced by the biopharma industry, and the ways in which collectively we can ensure that it serves the interests of patients everywhere. A key element of Bioethics International’s legacy work, the Good Pharma Scorecard, an index ranking the largest pharmaceutical and biotechnology companies and their products on ethical standards, is presented in a graphically rich format.

We are excited to bring you this timely and important project, in the hope that it ignites a broader discussion of the responsibility, transparency and trust in one of our planet’s most important endeavors, the pursuit of good health.

Sincerely,

Jeremy Abbate
Publisher, Scientific American
Fred Guterl
Project Editorial Director
Jennifer E. Miller, Ph.D.
Assistant Professor, Yale School of Medicine
Founder, Bioethics International
In deciding whether to undergo a certain treatment for cancer or another serious illness, a patient needs to know if it is indeed the safest and most effective option available.

A complicating factor in choosing the best option is the difference between the goals of the scientists who test and approve new drugs and the goals of a person seeking treatment. The goal of a randomized trial is to determine whether the benefits of the treatment outweigh its harms among patients who are similar to those who are enrolled in the trial. This is important information, to be sure, but the patient needs to know something more specific: Is the treatment safer and more effective for people like me—those with similar health characteristics?

A trial answers both questions only when a patient happens to be similar to the participants in the clinical trial. But that is often not the case. The volunteers in clinical trials tend to be whiter, younger, healthier and more likely male than real-world patients. For example, individuals aged 65 years or older account for about two thirds of new cancer diagnoses in the U.S., but less than one third of cancer clinical trial participants. One study found that patients age 75 years or older account for only 10 percent of trial participants but made up 30 percent of patients with cancer. Women make up fewer than 50 percent of participants in studies of cancer, HIV, heart disease and other conditions. A review of therapeutic cancer trials from 2003 to 2016 found that non-Latinx whites were far more likely to be enrolled than Black or Latinx patients. Across all clinical trials for cancer, Black and Latinx people are less well represented than they were 20 years ago.

There are several reasons for this lack of inclusion. Some scientific protocols explicitly exclude patients who are older, sicker, or who have functional impairments. For example, more than half of randomized trials for ischemic heart disease explicitly excluded elderly patients from enrollment, mainly because they tend to have serious chronic illnesses or are physically frail, which constitutes a de facto age restriction. A similar dynamic often results in the exclusion of Black patients, who face inequities in access to health care and insurance, chronic illnesses and racism that affects how they interact with the health system. In particular, inappropriate treatment of Black patients...
and research participants in the past has contributed to a lingering mistrust of the medical profession, which makes some individuals hesitant to sign up for a trial. The poor representation of real-world patients in trials dramatically limits the ability of doctors to distinguish which patients are likely to benefit from a given treatment. The example of bevacizumab, an antibody that inhibits the growth of blood vessels in tumors, is a case in point. In a randomized trial of 878 patients with advanced lung cancer, patients who received bevacizumab lived 12 months on average—about two months longer than patients in the comparison group. About one in four trial participants were age 70 years or older. By comparison, half of all patients diagnosed with lung cancer in the U.S. are older than 70 years. This age difference is troubling because an analysis of the 224 patients in the trial older than 70 years found that bevacizumab was not associated with increased survival—and the risk of toxicity was twice as high. Of course, 224 patients over the age of 70 is a small sample size, which makes it hard to say if these results are meaningful. This kind of uncertainty is commonplace for many drugs and many patient groups. Yet new treatments still diffuse into clinical practice: Despite this unfavorable benefit-to-risk ratio, up to 20 percent of older patients with lung cancer were receiving this treatment shortly after FDA approval, studies show.

One obvious way around this dilemma is to build upon our existing clinical trial infrastructure—that is, to keep enrolling patients using the same tools we’ve always used, largely focused in large academic medical centers—and simply strive to make the studies larger. This approach would be expensive and still might not offer a broad enough population coverage, and of course it would not solve the enrollment problem.

Technology presents us with a more realistic option: the use of electronic medical records to gather data about drug safety and efficacy in the real world, outside clinical trial infrastructure—on home and away fields—over the course of a long season. By the same token, gathering data about real-world test subjects—without even knowing it; they will take the drug before its risks and benefits are accurately determined in their age group. In this respect, this solution is not ideal, but it is better than the current system, where data is not systematically collected once a drug is approved—on home and away fields—over the course of a long season. By the same token, gathering data about drugs after they’ve reached clinical trials, after regulatory approval. By increasing our ability to harness and analyze data, digital technology has led to a growing appreciation among medical scientists for the role that real-world data can play in informing clinicians about the appropriateness of treatments for specific groups of patients.

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The importance of real-world data should be evident to fans of sports. Every spring, baseball teams start their training sessions brimming with optimism that this will be the year they make it to the World Series. A team with a roster full of stars might “look good on paper.” But we don’t really know which team is best until they actually compete against other teams—one on home and away fields—over the course of a long season. By the same token, gathering data about drugs after they’ve reached clinical practice and continuing to test them iteratively, comparing treatments against alternatives, in diverse patient populations, would help doctors better prescribe winners.

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fifteen years ago, the claim was audacious: that the best way to assure the health of pregnant women was to make sure they were included in experimental research on drugs and vaccines. For years bioethicists and scientists had assumed the opposite—that exposing a fetus to a drug under study was ethically unacceptable. Oversight committees routinely required provisions that minimized the likelihood of pregnancy in almost all clinical studies. They insisted on pregnancy tests and contraception. A woman who became pregnant during a study had to be removed, and asked to discontinue use of the experimental drug. Such caution has had an unintended and harmful consequence: profound knowledge gaps around the safety and use of medications in pregnancy.

In recent years, however, researchers and policymakers have turned this ethical frame completely around. They have begun to recognize that ethics do not preclude research in pregnancy but rather require it. Organizations that offer guidance about the development and use of drugs are now offering strong statements in favor of including pregnant women and their interests in the biomedical research agenda. For instance, recent draft guidance from the Food and Drug Administration calls filling knowledge gaps about medications in pregnancy a “critical public health need.” A taskforce report to the Secretary of Health and Human Services offers recommendations to advance the base of research data. More than 25 professional organizations have come together to advocate health policy initiatives that advance pharmacologic trials in pregnant and lactating women. According to revised U.S. research regulations in effect January 2019, pregnant women are no longer designated as a vulnerable population.

After a long battle, the question now is not whether to do research with pregnant women, but how to, ethically and efficiently, make up for so much lost ground. Many challenges remain.

One challenge is determining when to include pregnant women in research and when to exclude them. The answers depend on many factors pertaining to a particular study. Some note that including a small number of women who are pregnant can add complexity and cost to a study and may not yield enough data to make useful conclusions specific to pregnancy. Other unresolved issues include what studies should be conducted exclusively with pregnant women, at which point in the drug development pipeline pregnancy-specific data should be generated, and, after drug approval, how long is it acceptable to wait to assess safety or dosing for women who are pregnant.

Incentives also need some attention. Despite the shift in ethical reasoning, many of those responsible for drug development may still have reason to exclude women. Pharmaceutical manufacturers may prefer not to use pregnancy-specific product labeling, which can make them liable for any drug-related harms to the
Questions of risk are vexing. Often they involve taboos, such as any consideration of trade-offs between maternal and fetal health.

the women or their offspring; without such labeling, the liable party is usually the prescribing doctor. Many researchers and oversight committees tend to focus narrowly on minimizing risk among study subjects (or protecting institutional interests) rather than considering the interests of the general population who will be administered the drugs.

Entrenched patterns of exclusion can persist even where a study drug is likely to be beneficial or even lifesaving. In the 2013–2016 Ebola epidemic pregnant women were excluded from all drug and vaccine trials against the disease, even though Ebola in pregnancy is a very grave danger (for both mother and baby). More recently, pregnant women have been widely excluded from COVID treatment trials—even in trials of drugs already widely used in pregnancy for other conditions. There have been appeals for inclusion in both cases, which is progress, but continued efforts will be needed to ensure that pregnant women are not again left behind.

Going forward, questions will arise about how to interpret and communicate data, especially about risk. Questions of risk and pregnancy are particularly vexing and difficult; often they involve taboos, such as any consideration of trade-offs between maternal and fetal health. For the most feared outcome—medication-associated birth defects—risks will take time to characterize. Definitive estimates may require thousands of exposures, raising questions about how to communicate early or uncertain results; how to reassure women or doctors that a drug is safe or safe enough; and how to appropriately honor the values and experience of the women for whom illness and pregnancy co-occur.

I am optimistic that change is within reach. Through the PHASES Project, a multi-year project funded by the National Institutes of Health, I have worked closely with an international group of experts from leading research and advocacy organizations on developing guidance toward ethically advancing research with pregnant women in the context of HIV and related infectious diseases. We have learned much from women at risk for, or living with, HIV. And we have found broad consensus on many strategies that foster inclusion. For instance, researchers should commit to including pregnant women in studies whenever possible; oversight committees should require justification whenever pregnancy is on the list of exclusion criteria; and pregnant women should be guaranteed fair access to trials or programs offering experimental life-saving interventions.

Many people now are deeply committed to redressing the evidence gaps and ensuring that the interests of pregnant women and their babies are represented fairly in the biomedical research agenda. Doing so is an ethical imperative; the pathway forward is becoming clear and beckoning more strongly than ever.

Annie Drapkin Lyerly, MD, MA, is a professor of social medicine and associate director of the Center for Bioethics at the University of North Carolina, Chapel Hill, and research professor in obstetrics and gynecology. She is the author of A Good Birth: Finding the Positive and Profound in Your Childbirth Experience.
The urgency of the coronavirus pandemic has led to enormous research efforts and some shortcuts.

BY MICHELLE MELLO AND DAVID MAGNUS

The COVID-19 pandemic has triggered the biggest mobilization of scientific effort in a generation. Scientists from fields as diverse as immunology and computer science quickly pivoted to studying drivers of the epidemic and potential countermeasures. More than 54,000 articles relating to the SARS-CoV-2 virus have been published in academic journals in the biomedical and life sciences to date.

This scientific surge is astounding and inspiring, but it has produced some ethical dilemmas. The urgency of the crisis has led to a proliferation of studies, some of which short-circuit the most rigorous scientific standards. Results often get disseminated to the public before they’ve been reviewed by experts, which can lead to a situation in which doctors, politicians and others advocate unproven cures.

BALANCING SPEED AND RIGOR

The gold standard for scientific learning is the randomized, controlled trial (RCT), in which a group of participants is randomly assigned to receive either the treatment being investigated or a comparison treatment, which might be a placebo. Randomly assigning participants to these two groups ensures that the groups are similar, reducing the possibility of bias.

Although SARS-CoV-2 vaccines are being tested using RCTs, nonrandomized studies have been common for COVID-19 therapies. Many have occurred within “expanded access programs,” through which the Food and Drug Administration allows patients to access therapies that have not yet received marketing approval. For instance, for convalescent plasma (blood plasma from disease survivors), evidence from case reports and animal studies was provocative enough to justify launching an RCT to test it for COVID-19. However, the federal government instead approved an expanded access program through which physicians administered plasma to nearly 70,000 patients without any control groups. Without randomization, researchers have not conclusively shown that improved outcomes are the result of taking plasma. Nevertheless, the FDA granted an emergency-use authorization for convalescent plasma in August. Another cautionary tale is hydroxychloroquine, the drug President Trump began touting in March. The FDA authorized it on the basis of observational studies and later had to
reverse itself when RCTs showed it to be ineffective and unsafe.

Conducting nonrandomized studies not only generates lower-quality evidence but can also divert patients, funding, and researchers’ time that might otherwise have been directed to RCTs. Every effort should be made to implement RCTs during disease outbreaks. Getting them going quickly requires planning beforehand. When the next strain of coronavirus appears, for example, which therapeutic approaches should we test and what should the RCT design be?

**SHARING RESULTS QUICKLY**

Is it advisable, given the urgency of learning during pandemics, to publicize study findings before they undergo peer review? During a crisis, sharing results quickly can save lives or motivate other scientists to pursue additional work or abandon dead ends, but it can also cause rapid dissemination of low-quality studies with potentially flawed conclusions.

Traditionally, study reports aren’t made public until they have been submitted to a scholarly journal, which asks experts to critique them. Journal editors then either reject the paper or require the authors to respond to questions and address reviewers’ criticisms. There may be several rounds of back and forth until the editors are satisfied that the report is ready for public consumption. This process can take months.

Even before COVID-19, science was shifting toward earlier sharing of reports. In 2019, Cold Spring Harbor Laboratory, Yale University, and BMJ, a scientific journal company, created two online platforms, medRxiv and bioRxiv, where researchers in the health and biological sciences could post “preprints” of their papers. Because journals often require authors to keep papers confidential until they’re published—a strong disincentive to share results early—the platform founders got leading journals to allow pre-publication dissemination. MedRxiv and bioRxiv now host nearly 9,000 papers related to SARS-CoV-2. These early releases have played an important role in informing pandemic responses.

Scientists understand the limitations of non-peer-reviewed reports—however, others may not. Thanks to social media, preprints are being circulated quickly, widely, and with little reflection on their merits. Yet a study of COVID-19 preprints later published in journals found that more than a quarter underwent changes to the abstracts that affected the study’s conclusions.

Before physicians start changing their clinical care based on preprints, these papers should undergo at least some review by experts. The open-access journal RR:C19, launched in July, is a promising vehicle. An initiative of the MIT Press and the University of California Berkeley, it produces expert reviews of important preprints on COVID-19 in a few days. But it can only reach a fraction of the many preprints being published. Researchers have called for more scientists to volunteer for and mobilize rapid-review services.

**SHARING RESULTS QUICKLY**

Even in a global pandemic, researchers can face a shortage of patients at research hospitals who are willing and eligible to enroll in clinical trials. When research teams are jockeying to recruit sick patients, who should get priority?

The explosion of human studies during epidemics raises the prospect that lower-quality studies could crowd out higher-quality research, or that all trials will encounter under-enrollment. Unfortunately, our system of human research oversight is not designed to prioritize among studies. We need a fair, transparent process in which a multi-disciplinary committee of experts that includes representation from disease-affected communities decides whether a given trial is worth doing at a given site, what resources it will consume, what the cost to other research studies or clinical care will be, whether there’s duplication with other studies, and whether it contributes to diversity in the overall portfolio of research being pursued. Such committees should be organized at universities, the federal government and the World Health Organization as part of pandemic preparedness efforts.

Among the emerging lessons of COVID-19 is that getting the most out of a scientific surge requires planning. Creating structures to ensure wise allocation decisions and reasonable quality control during emergencies will pay dividends.

**Michele Mello, JD, PhD, is a professor of medicine and law and David Magnus, PhD, is a professor of medicine and biomedical ethics at Stanford University.**
In 2018, a whistleblower employee of the Wellcome Sanger Institute filed a complaint against its parent organization, Genome Research Limited, accusing the institute of seeking to commercialize DNA samples from Indigenous tribes in Africa in violation of ethics and of legal agreements with African institutions. Officials from Sanger and life-sciences firm Thermo Fisher had talked about developing a research tool based on the DNA samples, according to emails obtained by The Times, a London-based newspaper.

The project ended shortly after the talks came to light, and Sanger's partner, Stellenbosch University in South Africa, demanded that Sanger return the DNA samples. Sanger, which declined an interview request, has said that independent investigators found no breach of contract or infringement on intellectual-property rights. But the episode brought into sharp relief the fears of African researchers.
about the industry’s recent interest in the genomic data of African people.

In recent years, scientists have come to realize that studying the genomes mainly of people of European descent omits a broad range of genetic variation that could be useful in precision medicine. African genomes have already helped researchers understand who may be at heightened risk for developing kidney disease, why some people have an adverse reaction to the use of codeine, and who may be most vulnerable to certain infectious diseases. So far, however, European genomes account for 80 percent of the genetic data that’s been studied.

Genomics researchers in academia and the drug industry have recently accelerated efforts to develop large sets of genomic data from Africans—libraries of tens of thousands of genomes—along with patient medical records. Analyzing large data sets is important for developing new diagnostics and therapies that would allow physicians to tailor treatments to individual patients and provide for early interventions for people at risk of developing certain diseases.

Medical researchers agree on the value of the science. But African researchers are concerned about how research participants are recruited and who controls the research agenda. These fears are shaped by the history of colonial powers profiting from the labor and natural resources of the continent, as well as the Sanger episode.

“I’m concerned the genomes of Africans are going to be used and exploited for good stuff, but then they will have nothing back,” says Christian T. Happi, director of the African Center of Excellence for Genomics of Infectious Diseases in Nigeria [see sidebar on page 14].

MISSING CONSENT

The concern is not abstract. Western firms have recently engaged in ethically questionable practices. For instance, thousands of blood samples from infected patients during an Ebola outbreak in West Africa were sent without patients’ consent to researchers outside Africa, leaving researchers in the affected countries unable to study them, according to the investigative journalist Emmanuel Freuden-thal, who first reported on the issue for Le Monde and The Telegraph. The samples would be critical for the development of treatments. Thousands of the samples were sent to Public Health England, the U.K.’s health agency, which had operated labs in Sierra Leone during the outbreak. But it is unclear who has had access to the samples. (Americans, too, worry about who has access to their medical data and how that data is used—anecdotal evidence suggest that the DNA samples from COVID-19 tests are owned by the testing companies.)

African scientists also point to “helicopter” researchers, who make trips to Africa to collect genetic material and return home to use it as they wish, sometimes publishing without crediting scientists in Africa who may have gathered the materials. The work does not necessarily seek to answer scientific questions of relevance to people in Africa, such as the role genetics plays in malaria, tuberculosis, sleeping sickness and other diseases.

“The mistrust has built over the years,” says Ambroise Wonkam, associate professor and senior spe-

“The principle should be that Africans should not just be used as subjects for study. African scientists have to be part of it, and it has to be something that is for the collective benefit.” —GORDON AWANDARE

BIG VALUE

Although scientists are still in the early stages of exploring the genetic richness of the African genome, its value seems to become more apparent with each passing study. Sarah Tishkoff, founding director of the Penn Center for Global Genomics and Health Equity at the University of Pennsylvania, recently analyzed the genomes of 180 people from 12 different ethnic groups in Africa. They found 5.7 million mutations of genes that were not contained in exist-
ing genetic databases, many of which are expected to be found to alter the way a gene functions.

Life-sciences companies have flocked to Africa in a race to collect data. 54Gene, founded in 2019, established a subsidiary in Lagos, Nigeria. Sequencing giant Illumina has collaborated, since 2016, with the H3Africa Consortium to develop and provide arrays for the study of African genomes. Roche Diagnostics is investing $42.1 million to expand its facility in Cape Town, South Africa; it expects to add 300 jobs over three years. And the genomics company Global Gene Corp in 2018 announced a collaboration with the University of Namibia and the Namibian Ministry of Higher Education, Training and Innovation for a national genomics initiative that includes plans to build a Center of Excellence in Genomics in Namibia.

A single patient’s genetic data is worth as much as $1,700, estimates global consulting firm EY; the figure, from a 2019 report, is based on an analysis of deals made by consumer genetics companies. When a patient’s medical history and genomic data are combined, the value climbs to $5,000. The U.K.’s government funded health-care system, the National Health Service, generates nearly $6.2 billion a year through its marriage of whole-genome sequences to medical records, according to EY.

“When we speak about African genomes, we speak about something that has considerable value,” says University of Cape Town’s Jantina de Vries.

**ETHICAL PATH**

Recent efforts to establish ethical norms for drug companies in dealing with study participants have made some progress. The San Code of Research Ethics may be the first ethics code created by an Indigenous population in Africa. It requires community approvals for research projects, calls for researchers working with the San people of Southern Africa to adhere to values of fairness, respect, care, and honesty. The San drafted the code after a 2010 study in *Nature*, in which researchers failed to consult their leaders about obtaining informed consent.

The paper was a turning point for the San, who had long complained that they’d gotten no benefits from all the attention they received. Genomics researchers used offensive terms like “bushman,” photographed breastfeeding women and children without consent, ignored social customs and failed to meet their promises to provide feedback that could be useful for public health.

To address the complaint of African scientists that they are often not treated as equal partners by their non-African peers, the U.S. National Institutes of Health and Wellcome Trust provided $176 million in funding for ten years to establish the Human Heredity and Health in Africa Consortium, known as H3Africa. The African Academy of Sciences joined in 2016 and has provided an additional $12 million in funding.

H3Africa’s mission is to build research capacity, scientific skills, and leadership for genomic research to benefit the health and economy. “The idea for H3Africa was to root the projects that would be supported in Africa—that is, the principal investigators have to be African, the work needs to occur in Africa, and it would be serving the individuals of the continent,” says Neil Hanchard, assistant professor of molecular and human genetics at Baylor College of Medicine in Houston, who has conducted genomic studies with African colleagues.

The group has grown to include 94 sites in 30 African countries and recruited more than 67,000 research participants for 51 projects. It funds research led by African scientists and has developed infrastructure to sequence, analyze, and store data and samples. It also provides mentoring and training for African scientists and develops ethical guidelines for conducting genomic research.

“One of the things we lack in Africa is enough skills,” says Michèle Ramsay, professor in the division of human genetics at the National Health Laboratory Service at the University of the Witwatersrand in Johannesburg. “That critical mass is still
small, and we need to grow it so that more people can do incredible science. H3Africa has allowed us to do big science in Africa.”

Ramsay believes the creation of infrastructure and opportunities can help reverse a brain drain that has scattered African talent around the world. The consortium has supported the bioinformatics network H3ABioNet, which has nodes in 16 African countries; the African Center of Excellence for Genomics of Infectious Diseases in Nigeria; and the U.K.-based Malaria Genomic Epidemiology Network, which has a presence in 23 African nations. “For decades, if you wanted to be part of big science projects, you literally had to leave the continent,” says Ramsay. Now, “you don’t necessarily have to go to Europe or America.

H3Africa has taken steps to ensure African scientists lead research and get credit for their work. For one, it only funds projects led by African researchers. Its policy provides them the opportunity to publish before other researchers capitalize on their work. H3Africa researchers are required to make genomic data available to other researchers after submitting data to a repository, but they are granted up to 23 months to do so, compared to six months for most NIH-funded research.

While H3Africa has accomplished much, it can’t match the big money that multinational pharmaceutical companies bring to bear. But it doesn’t necessarily have to. Its goal is not only to attract commercial investment but also to maintain control over the research agenda.

Some outside investors seem to be heeding local concerns. Adjuvant Capital, a venture capital firm whose limited partners include the Bill & Melinda Gates Foundation, the Global Health Fund, and Novartis, led a $15-million venture round in April for

Ninety-nine percent of the revolutionary history of humans is contained in the genomes of African people. In the search for medicines and vaccines and to fulfill the potential of precision medicine to tailor treatments to individuals, Africa holds the key.

The value of this data is not lost on pharmaceutical companies and their investors. In 2018 Goldman Sachs forecast a $5-trillion global market for genomic medicine.

It’s good that the world is beginning to appreciate the genetic richness of Africa. But researchers on the continent are becoming increasingly concerned about exploitation. If history is anything to go by, the quest to mine Africa’s data will produce a few winners and many losers.

The companies and funding agencies often cast their motives in humanitarian terms: their work will help alleviate the genomic data inequity gap. They make promises that the benefits of genomic research will accrue to the Africans who participate and to their com-
54Gene, which is building a curated genomic data set from African populations. The company launched the African Center for Translational Genomics, an initiative that brings together top researchers in Nigeria to collaborate on high-impact studies for publication.

HEALTH BENEFITS
Ensuring that Africans share in health gains that result from genomics research is a more difficult problem than developing research infrastructure. If new diagnostics and therapies from genomics remain unaffordable to Africans, new discoveries won’t benefit them.

African nations continue to struggle with a lack of modern health-care facilities, a shortage of medical professionals, and low levels of government spending on health. In Sierra Leone there are only 22 physicians for every million people. In the Democratic Republic of Congo, less than a quarter of the population has access to clean water and proper sanitation facilities and 20 percent of children in Nigeria die before the age of five.

Ensuring research data and findings are shared will help to identify medication risks tied to genetic variations and help make better diagnostics available. The World Economic Forum’s Leapfrogging with Precision Medicine project is working to help low-to-medium resource put policy frameworks in place for this new medicine but acknowledges there is a mismatch between costs and available resources that limit access.

The dearth of resources makes it all the more critical that Africans share in the benefits of the genome revolution. Says University of Cape Town’s de Vries: “We need to think about the innovation chain, about where value is rewarded, and how we do these things in a way that is more just.”

Daniel S. Levine is a freelance journalist.

Researchers on the continent are becoming increasingly concerned about exploitation.

Communities. Groups like the World Economic Forum have been working with governments and others on ways to regulate this activity.

We are skeptical. What’s been missing is a broad societal debate about the ethical use of African genomic data by private companies, most of them funded from abroad.

Africans need a plan to prevent exploitation. That is a major goal of H3Africa, the non-profit research consortium. We have worked for several years to develop an ethical infrastructure for genomic research in Africa, including proposals for agreements about how profits generated from owning, trading or using African genomic data should be redistributed to benefit African individuals and their societies. Many of the companies and organizations are trying to circumvent these efforts.

The first step is for African academics involved in genomics research, including those in the African diaspora, to forge a blueprint for rules and regulations. Most important is to establish benefit-sharing arrangements with companies that collect African data. These could be crafted along the lines of the United Nations’ Nagoya Protocol, which provides guidance on benefit-sharing agreements for people using a country’s biodiversity but does not pertain to human samples and data. Guidance on licensing agreements should be in place before companies can collect or use African genomic data. These should include provisions to ensure that any products or therapeutics developed on the basis of African genomic data will be made available to African patients at a reasonable cost.

We need to develop creative ways of ensuring that African people benefit directly from the use of their data. One bold idea is to ensure that individuals can market or sell their genomic data. With strict guidelines, vetting procedures and public information about the value of one’s genome, such arrangements could perhaps be done ethically.

Efforts to collect African DNA and use it for research should include investment in African nations, so that they can develop their own industrial and research capacity. These investment efforts must lead to sustained social benefit for the countries involved.

Public trust is a key component in supporting the genomic revolution. Our task is to ensure that profit is used to create the world we want to see, not the world as it is.

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Million-Dollar Drugs
Allowing manufacturers in the U.S. to set prices creates problems for patients and is unsustainable for health-care payors.

BY LEAH Z. RAND AND AARON S. KESSELHEIM | ILLUSTRATION BY DAVIDE BONAZZI

The U.S. spends more on drugs than any other country, in absolute terms and per capita. Early prices of some brand-name drugs have reached shocking heights—some have topped $1 million for a course of treatment—and price increases tend to rise faster than the rate of inflation.

High drug prices create ethical dilemmas—especially in a pandemic, when the nation’s vast inequities in health care have taken on a new urgency. The fate of millions of Americans now rides on new treatments for COVID-19 and the prospect of effective vaccines. The more they cost, the harder it is for people to have access to them. High prices also require patients, insurers, and governments to make challenging choices in how to spend limited health-care resources. Determining when a price is appropriate for a new brand-name drug involves three fundamental questions: is the drug worth it, is it affordable, and is the price fair? Let’s take them one at a time.

The first principle of drug pricing is that a price should align with the value a drug provides—the benefit to patients and to health-care systems. Many countries determine whether a drug is worth its price by subjecting it to a process of evaluation to see whether the benefits are proportional. Such health-technology assessments in Germany, for instance, have helped reduce prices.

The U.S. does things differently. Many Americans tend to assume that markets will lead to prices that reflect willingness-to-pay, or the value of a good to someone. But drugs are different from most consumer goods. New drugs are invariably protected by numerous patents, which give the manufacturers market exclusivity. They have few constraints on how high they can set prices. Drugs are prescribed by doctors (meaning consumers often don’t lead the decision making) and, for the majority of U.S. patients, are paid for by insurance companies.

In many cases, such uncertainties make it difficult to evaluate the benefits of a drug. For example, the evidence on remdesivir, which is being used to treat patients with severe COVID-19, suggests that the drug reduces the time to clinical recovery by five days without a significant effect on mortality. However, Gilead, the manufacturer, set the price at $3,120 per course of treatment, which is less costly than five days of hospitalization. But it is not clear that the drug actually reduces hospitalization periods. In fact, some patients with COVID-19 reportedly are staying in the hospital longer to complete their courses of this intravenously administered drug.

A similar uncertainty has arisen in gene therapies such as onasemnogene abeparvovec-xioi (Zolgensma) for spinal muscular atrophy, which is listed at $2.1 million per patient, and voretigene neparvovec-rzyl (Luxturna) for a form of inherited blindness, which is listed at $850,000 per patient. Short-term trials of the drugs suggest that they offer important benefits to patients with the conditions they treat, which is what led to their approval. But there is no evidence yet that the effects will be long-lasting.

So far U.S. payors generally cover these prices for gene therapy because they are indicated for rare diseases. But as more gene therapies are discovered for other conditions, the burden on health-care resources will quickly become unsustainable. Gene therapies priced like onasemnogene abeparvovec-xioi for just 1 percent of Americans would cost $3 trillion—as much as all current spending on health...
care. While there may be conditions for which gene therapy offsets other medical spending, there is disagreement over how much of the resulting economic benefit manufacturers or society should be able to absorb, particularly in cases when taxpayer funding was a key driver of the discovery of the treatment. In such cases, drug prices should better align with their value, and if prices nevertheless remain high, they could be made dependent on the success of the treatment, with payments stretched out over time, rather than in a single up-front payment, and designed to end if the treatments stop working.

The second question is whether a drug or therapy is sustainable. Even when a drug is highly effective and offers good value for its price, it may still be unaffordable to the health-care system. This was the case with antiviral treatments for hepatitis C virus infections. Sofosbuvir (Sovaldi) was considered cost-effective even at its launch price of $84,000 per course of treatment because it offered a high cure rate. Because hepatitis C is so prevalent in the U.S., such a price would overwhelm payors like Medicaid that cannot afford to treat all of its patients without neglecting other medical needs. Money spent on sofosbuvir is money that is not available for other health-care needs or budget priorities. This issue may also arise when a COVID-19 vaccine is approved, because successful management of the virus will require widespread administration of it. Should COVID-19 vaccine manufacturers be able to set their own prices? Or should the federal government insist on a reasonable pricing structure as a condition for receiving billions of dollars in grants for vaccine development and testing? So far it has avoided the issue in deliberations over vaccines.

High-priced medicines can also exacerbate health-care inequities. For a drug like sofosbuvir, limitations in Medicaid that were designed to control costs could end up widening the disparities between Medicaid patients and those with private insurance plans.

Taking budgets into account when negotiating a price is reasonable. The Institute for Clinical and Economic Research (ICER), an independent organization in the U.S. that assesses the value of some expensive drugs, considers a drug’s impact on budgets, which is important in setting policies that ensure access to them. More U.S. payors, including the Veterans Administration, New York’s Medicaid program, CVS, and some private insurers, have reportedly started collaborating with ICER to integrate its reports into their price negotiations.

The fate of millions rides on new treatments and vaccines for COVID-19.
be used by virtually the entire population, even low prices can have a significant budgetary impact.

The third key question is whether the price of a drug is fair. Manufacturers in the U.S. have argued that they should be able to recoup the cost of development and production and be compensated appropriately for risks in up-front investment. In recent years, however, public institutions have branched out from supporting basic and translational science to paying for later stages of drug development. About a quarter of new drugs approved by the FDA in the past decade had late-stage connections to publicly funded institutions. For example, one of the first CAR-T therapies approved to treat cancer, tisagenlecleucel (Kymriah), was developed in a collaboration of Novartis and the University of Pennsylvania, which received more than $200 million in taxpayer funds for the research. Given the substantial public investment, is the launch price of $475,000 fair? In the development of remdesivir for COVID-19, the federal government supported the key pivotal trial that showed its efficacy and its emergency-use authorization. Even though the government invested in the drug and took significant risks in its development, it played no significant role in setting its price.

Efforts have been underway in the U.S. to integrate these three key principles into systems of drug pricing. New York, Massachusetts, Maine and other states have adopted drug affordability boards to assess drug value and help state insurance programs better negotiate fair prices with manufacturers. While these are promising developments, action on the federal level will be needed to support the states and extend these principles to Medicare, which covers about one-third of U.S. prescription drug spending. President Trump promised such reforms during his 2016 campaign but dropped them after conferring with pharmaceutical-industry lobbyists, only to issue executive orders in July aimed at curbing high drug prices that have yet to take effect (and are designed to only have a limited impact if they do). The most advanced effort thus far has been the Elijah E. Cummings Lower Drug Costs Now Act, passed by the House of Representatives in late 2019, which would allow Medicare to negotiate prices for the most expensive brand-name drugs leveraging value determinations made in other comparable high-income countries around the world.

The U.S. practice of allowing manufacturers to set prices creates problems for patients and is unsustainable for health-care payors. Recent changes at the federal and state levels are a first step in better aligning benefits and costs.

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Each year scientists at hospitals and universities around the world start hundreds of thousands of clinical studies involving millions of patient volunteers and generating vast data about the effect of new treatments for myriad diseases.

The trouble with this system is that more than half of the studies are never published, and those that are are often incomplete, selectively reporting favorable outcomes and rarely reporting relevant safety findings. In recent years, researchers have come to recognize that encouraging the sharing of clinical research data presents an opportunity to advance medical science and improve the integrity of research.

As a result, the culture of science has begun to shift. Scientists strip their research data of names and other information that would identify specific patients and make it available to others. They can do it directly, when one scientist writes to another and asks for a copy of the data. Or they can do it indirectly, by depositing their data on a server from which others can download and use it.
Data sharing marks a significant departure from tradition. Scientists have often been reluctant to give away the fruits of their hard work. Many spend years planning and executing their studies, painstakingly collecting and curating the data for analysis, and then preparing a summary report to publish. However, the advantages of data sharing are becoming so apparent that this reticence is beginning to evaporate.

Sharing increases the amount of knowledge that scientists can draw from available data, without having to go through the expense and trouble of organizing new trials. For instance, scientists can re-analyze data from prior studies and use them to explore new questions concerning safety and efficacy or to draw new conclusions about specific subgroups of patients. Sometimes data from many different studies can be collected and combined for larger studies.

Sharing can improve the integrity of scientific research by encouraging multiple examinations and interpretations of any given research database. This could protect help against faulty analyses and contribute to the verification, refinement, or refutation of prior work. Furthermore, sharing helps researchers position clinical trial data as a public good, a resource for many to use and learn from.

Sharing can also make better use of limited scientific resources, minimizing duplication in data collection, which reduces research costs and lowers the burden on patient volunteers.

Patients who volunteer to participate in research studies seem to have few qualms about researchers sharing data. In a recent survey of 771 participants in trials in the U.S., 82 percent said they were likely to allow their data to be shared with scientists at for-profit companies and 93 percent felt the same about sharing with university scientists. Certainly, a significant number of patients worry about privacy—about a third expressed concern about data being used for marketing purposes and 30 percent worried about data being stolen. But in my experience, many patients also understand that one group of researchers may have different ideas, or approaches, than the original group of researchers, allowing them to learn new things from the same data, and prefer that their data can be used for research by as many scientists as possible.

Numerous data-sharing initiatives have been started in recent years. The U.S. National Institutes of Health now shares data from its largest studies, which include those examining treatments to control blood pressure, heart attack risk, and depression. The Centers for Disease Control and Prevention collects survey data from individuals throughout the U.S. each year with the express purpose of sharing it with the wider research community. Many large pharmaceutical companies similarly share clinical research data collected as part of studies to determine whether their products are safe and effective. For instance, multiple companies share clinical trial data through the ClinicalStudyDataRequest initiative for outside investigators to request and use the data for their own research, while Project Data Sphere is an open-access platform on which companies share clinical trial data from the placebo arms of their cancer clinical trials. The Good Pharma Scorecard [see page 22] recognizes companies who share data and encourage others to do the same.

In 2011, we developed a platform for responsible data sharing known as the Yale Open Data Access (YODA) Project. We have partnered with Johnson and Johnson and others to promote the sharing of clinical research data for investigators based in academia, government, or even at other companies. At present, researchers throughout the world have used data from more than 400 trials in more than 150 projects, many of which make use of multiple trials at a time. These studies have been used to inform clinical practice recommendations and World Health Organization guidance.

The YODA Project has enabled numerous studies that might not otherwise have been feasible, generating new knowledge and contributing to the clinical and scientific community and informing clinical practice. The same is no doubt true for the other data-sharing platforms. While these platforms took a great deal of time, effort, and resources to launch, this investment will pay off over the next decade as scientists draw new insights from clinical trial data. Before, only one group of investigators would use data from a trial. Now, one study can inform many investigators, each with their own point of view and their own goals for advancing science.

Joseph S. Ross, MD, MHS, is a professor of medicine and public health at the Yale School of Medicine.
More than a decade ago, I was alarmed by the high number of ethics scandals involving pharmaceutical companies documented in the media and the scholarly literature and hashed out in court cases and settlements. It was hard to know what to make of these reports. Were these ethics failures those of a few rogue companies or employees? Had the underlying issues been resolved? Or, did they constitute genuine widespread problems and risks for patients? I found myself wondering, are drug companies trustworthy, patient-centered, and socially responsible?

The general public certainly did not hold pharmaceutical companies in high regard, a condition that has only deteriorated since. The industry is perceived as the least socially responsible sector in health care. In some polls, drug companies rank just ahead of tobacco companies and behind Wall Street in perceived honesty, ethics and trustworthiness. Nine in 10 Americans think drug companies put profits before people; only 20 years ago, these firms were among the most esteemed and respected. (Frankly, large institutions in general are facing growing distrust, from regulators like the FDA to the media and political systems. Notwithstanding, the pharmaceutical sector is disproportionately distrusted.)

The Good Pharma Scorecard

To find out if drug companies are trustworthy, Bioethics International, along with researchers at Stanford and Yale, ranked them according to their ethics practices.

BY JENNIFER E. MILLER, PHD
Determined whether drug companies are trustworthy and fixing any ethics problems is an urgent public health matter. Access to medicines that are safe and effective is an important determinant of health. When you think about new medicines, you have to think about the pharmaceutical industry, which sponsors most of the clinical research for new medicines in the U.S. We cannot afford for such a major player in health care to be rife with problems or distrusted. When patients don't trust drug companies, they may be less likely to participate in clinical trials, take prescribed medicines and get vaccinated. For the sake of people's health, we have to get this right.

This was the start of a journey that ultimately led to the Good Pharma Scorecard (GPS), a ranking of pharmaceutical companies on how well they implement good ethical practices. The GPS helps bridge asymmetries of information about the ethical performance of the industry. It also recognizes best practices and catalyzes reform where needed.

Since my colleagues and I at Bioethics International, Yale School of Medicine and Stanford University put out the first GPS in 2015, it has had a measurable positive effect on drug companies' practices. Across all metrics, the industry has improved year after year, which suggests a steady improvement in ethical practices. Moreover, many large companies immediately improve practices, every year, upon receiving our recommendations on how to tighten their procedures, bringing them up to higher ethical standards. Many also use their GPS results in their annual reports, which itself creates an incentive to improve year over year. Health-care investors, especially those concerned with social responsibility, have begun to use the GPS in their Environmental-Social-Governance analyses. It has been hopeful to see many multi-national large companies changing nimbly and quickly, and tracking their progress year after year.

To date, BEI has assessed thousands of clinical trials that enrolled more than a million participants around the world. We used this data to publish GPS rankings in 2015 and 2017. In this issue we are presenting the results for 2019, the third round of data we gathered. But first, I want to explain how we arrived at the Scorecard as a vehicle for encouraging pharma to follow good ethical practices.

**Where to Start?**

The journey began by first mapping the chief ethics concerns about drug companies. Some companies were accused of hiding unfavorable data to make drugs appear safer and more efficacious. There were concerns, backed up by research, that doctors, formulary decision-makers, the Food and Drug Administration, patient groups, and medical educators were in the pocket of industry. Cases of companies bribing doctors with envelopes of cash were making the news. Experts accused drug companies of wasting money on marketing rather than researching and developing new drugs. Drugs were becoming increasingly unaffordable.

The next question was, should we tackle drug prices or marketing practices? I wanted to break off a piece of the problem that was not only important for public health but also ripe for reform.

We decided to tackle two issues: how well drug companies make the results of clinical trials available to the public and the medical profession (transparency), and how well they share the underlying data gathered during their trials (data sharing). In other words, whether companies are honest, truthful and transparent about the safety and efficacy of new medicines and vaccines. My colleagues and I reviewed medicines and vaccines approved by the FDA in 2012 for HIV, tuberculosis, breast cancer, rare diseases, pediatric meningitis and many other conditions.

We were not reassured by what we found. Only one in five drugs had public results for all the clinical trials supporting its FDA approval, when assessed a year after approval. For half of reviewed drugs on the market, the results of at least one phase 2 or 3 trial were unavailable to the public. (Phase 1 trials test a drug's safety, and phase 2 and 3 trials test its efficacy.) Overall, only a median of 65 percent of clinical trial results supporting FDA approval of each reviewed drug were publicly available a year after approval.

Improving transparency, we realized, was critical for science, patient care and public trust. Doctors need valid and objective clinical trial information to prescribe the right drug for the right patient at the right time. Patients, as partners in their own care, need it, too, to make informed treatment decisions. If trial results are hidden, the whole ethics of a trial...
come into question, and so does the quality of our medical evidence. (To be fair, this is a problem in research generally, not just industry-funded research.)

**Why We Chose a Scorecard**

Once we had decided to address transparency and data sharing, we needed to determine the best way to help improve industry practices. Passing new laws takes a long time; plus, we had already seen that laws were not being adequately monitored and enforced. Instead, we looked for a tool that could help us catalyze the change we felt was needed across the industry. We wanted to give drug companies an incentive to adopt better practices and help us track and communicate their progress over time.

I noticed that almost every industry has some type of accreditation, certification or rating, and that these programs are associated with improved quality and firm performance. We learned that health care was one of the first to adopt such programs. In 1910, Ernest Codman, a surgeon at Massachusetts General Hospital and a faculty member of Harvard Medical School, and his colleagues developed a set of hospital standards related to patient safety. When he conducted on-site inspections of 692 hospitals, he found that only 13 percent met the standards. This finding was so embarrassing to the health-care establishment that the list of failing hospitals was burned to keep the press from finding out.

Within five years, however, most hospitals were meeting or exceeding the standards—a prime illustration of the old saw, “what gets measured, gets done.” The potential to earn society’s trust, the threat to a company’s reputation, the knowledge that other organizations are performing better, opportunities to learn and refine beliefs about previously unobserved qualities—all these factors make rankings an effective way to prompt companies to change. Restaurant rankings, for instance, led to significant improvements in cleanliness and, in turn, a reduction in hospitalizations for foodborne illnesses. Consumers are also more likely to patronize an institution with the best social responsibility reputation, when quality, service and price are uniform.

As I mulled the merits of ratings and rankings, I started noticing them everywhere. My mother wouldn’t buy a loaf of bread unless it had the American Heart Association’s heart-check trademark on the packaging. My father was trying to obtain ISO certification for his company. Was Mom’s AHA-certified bread really healthier? Would Dad’s company truly improve its practices for the sake of certification? I reviewed 75 rating programs (including car safety ratings and fair trade food labels) to understand their promises and pitfalls. I also reviewed the scholarly literature for evidence of efficacy of these programs, or lack thereof, and best practices. There seemed to be enough evidence to support building a ranking system to measure and improve the ethical performance of pharmaceutical companies. The Susan G. Komen Foundation offered seed funding and Harvard University a fellowship grant to run a pilot test.

I enlisted a multi-stakeholder team of advisors through Bioethics International, a nonprofit I founded in 2005 to help improve ethics and make health care more patient-centric. We developed standards and a scoring system for evaluating each pharmaceutical company’s ethics, based on a rigorous process that included reviewing recommendations from expert bodies and multi-stakeholder consultation.

Because we wanted our ranking to have an immediate impact, we built in a 30-day amendment window to give companies an opportunity to raise their scores. By the end of the 30 days, if a company could demonstrate that it had improved its policies and practices, BEI would recalculate its score based on this new information and publish a pre and post score. A company would be included in a particular year’s ranking only if it had a novel drug approved that year. After successfully piloting the GPS with the Edmond J. Safra Center for Ethics at Harvard University, Arnold Ventures generously awarded us a large grant to scale the GPS from a pilot to an industry-wide annual global ranking system.

Most hospitals were meeting or exceeding standards, an illustration of the old saw, “what gets measured, gets done.”
“Our ongoing commitment to data transparency is centered on our patients and our focus to drive science forward.”
—Julia Galperin, global head and data-sharing officer, Roche

“Adopting a transparency policy that goes beyond global legal requirements is in line with our core values.”
—Merete Jørgensen, senior trial disclosure director, Novo Nordisk

Transparency
The GPS transparency rankings look at three tiers of standards. The baseline is whether a company is following current laws in reporting. (Being legally compliant is no small thing: too many companies fall short of this standard.) The middle tier asks if a company is disclosing the protocols and results of all the clinical trials conducted with patients to gain FDA approval of their drugs. The third tier asks if the company makes all data about the patients who participate in a trial available to researchers who request it (while observing patient privacy and consent).

In the latest GPS, only two companies scored 100 percent on all three measures: Roche and Novo Nordisk. Both companies disclosed the results for all of the trials conducted in patients that support FDA approval of their drugs. Further down the list, Allergan and Valeant Pharmaceuticals jumped up in the rankings compared to their performance in the 2017 rankings. (Valeant has been renamed Bausch Health.) Gilead Sciences and Johnson & Johnson (J&J) fell in the rankings from 2017. A company can fall in the rankings for many reasons. Sometimes its product will rely on older studies that date to a time when standards of transparency were less rigorous. Sometimes it will acquire a smaller company that hasn’t been adequately reporting trial results. Anecdotally, executives have shared privately that, as a result of the GPS evaluations, their companies now stipulate as a condition of an acquisition or merger that all transparency problems are fixed ahead of time.
Data Sharing

Drawing on recommendations from several expert bodies, including the Institute of Medicine (now known as the National Academy of Medicine), and consultations with patients, industry, academics, regulators and others, the data-sharing rankings evaluate whether companies provide others access to analysis-ready participant-level data sets and clinical study reports (CSR) for trials, within six months of FDA approval or 18 months of a trial’s completion. (CSRs contain a study’s protocol, case record, and statistical analysis plan, among other information.) We also evaluate whether companies transparently disclose how many data requests they receive and how each request is handled (i.e., granted or denied). In 2019, four companies achieved top scores in the GPS data-sharing ranking: J&J, Novartis, Novo Nordisk and Roche.

J&J was one of the first companies to commit to sharing patient-level data and helped develop a platform called the Yale University Open Data Access (YODA) Project. GlaxoSmithKline was also an early adopter, having helped create infrastructure to facilitate widespread data sharing among the industry (ClinicalStudyRequest.com); it was not included in the 2019 rankings because it didn’t have any new medicines approved that year but scored a 100 percent on data sharing in the 2015 rankings.

Roche, another consistent performer, has kept pace with evolving data-sharing standards, as has Novo Nordisk, which initially took a unique approach to data sharing: It shared data directly on its website, allowing researchers to download them without any intermediaries or other hoops.

Novartis did not initially get a top score. It was deficient in one respect: it had made a public commitment to share data after drug approval, but only if a trial’s results were published. Since results from many trials are never published, this could create a loophole of sorts and a gap in data. Novartis used the GPS 30-day amendment window to close this gap and commit to sharing data for approved medicines regardless of whether a paper is published on a clinical trial—joining its peers in committing to high ethical standards in research transparency.
Combined scores for all three Good Pharma rankings to date

Scores are based on companies’ transparency practices in developing drugs for market. Bioethics International has published three scorecards, but not all companies are included in each.

The Scorecard’s Impact

The pandemic has underscored the importance of data sharing in maintaining public trust in drug development and for public health. In the race to develop COVID-19 therapies and vaccines, drug companies have been inconsistent in their data-sharing practices, and regulators have been criticized for some of their decisions. This lack of transparency and the deterioration in public trust could make people reluctant to get vaccinated against coronavirus. Data sharing may help build public confidence in approved vaccines, as surveys show a majority of Americans would trust scientific research findings more if data were publicly shared. Given that there are no legal obligations to publish or share patient-level trial data with the public or health-care providers, we must rely on voluntary commitments by companies and other research sponsors. The GPS can help us track, improve and communicate progress on data sharing.

We believe we can continue to have a beneficial impact on the industry and patient care. We are working to expand the scope of the GPS into new areas and to new companies, to address issues that are important for patients, such as drug pricing and equity and inclusion in research, to name a few. The next rankings include, for the first time, companies of all sizes. The hope is that as ethical practices of pharma improve, as measured by this objective method, and progress is communicated to the public, the industry will earn back the respect of the people who depend on its products. People’s lives depend on it. For more information, please visit bioethicsinternational.org.