

Advancing Transparency, Patient-centricity, and Trustworthiness in Pharma: Metrics and Trends from the **Good Pharma Scorecard**

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PHUSE, Austin Texas, March 24, 2026

Yale SCHOOL OF MEDICINE



-
- An index that rates + ranks pharmaceutical companies on their bioethics performance, annually.



Pharma's ethics shortcomings in literature + media

Bioethical Inquiry (2015) 12:101–106
DOI 10.1007/s11673-014-9596-2

ORIGINAL RESEARCH

Nonconsensual Clinical Trials: A Foreseeable Risk of Offshoring Under Global Corporatism

Bethany Spielman

Received: 1 December 2013 / Accepted: 17 November 2014 / Published online: 29 January 2015
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Abstract This paper explores the connection of offshoring and outsourcing to nonconsensual global pharmaceutical trials in low-income countries. After discussing reasons why the topic of nonconsensual offshored clinical trials may be overlooked in bioethics literature, I suggest that when pharmaceutical corporations offshore clinical trials today, nonconsensual experiments are often foreseeable and not simply the result of aberrant ethical conduct by a few individuals. Offshoring of clinical trials is structured so that experiments can be presented as health care in a unique form of outsourcing from the host country to pharmaceutical corporations. Bioethicists' assessments of the risks and potential benefits of offshore corporate pharmaceutical trials should therefore systematically include not only the hoped for benefits and the risks of the experimental drug but also the risk that subjects will not have consented, as well as the broader international consequences of nonconsensual experimentation.

global health issues, including pharmaceutical research. This paper explores how offshoring of experiments to low-income countries by pharmaceutical corporations and outsourcing of health care to pharmaceutical corporations by low-income host country government officials are connected to a lack of subjects' consent to participate in those experiments.¹ It then suggests that, under certain circumstances, a broader view be taken of the risks of experiments to include the foreseeable risk of nonconsensual experiments.

The significance of the risk of a lack of consent was recently evident when, in response to more than 200 different nonconsensual experiments, an Indian judge threatened in 2013 to stop all foreign clinical trials (experiments) in India because, he said, "[u]ncontrolled clinical trials are causing havoc to human life" (NDTV All India Agency France Press 2013: 45). The risk also has materialized recently in a Chinese firm's Artequick

Sacklers Gave Millions to Institution That Advises on Opioid Policy

Even as the nation's drug crisis mounted, the National Academies of Sciences, Engineering and Medicine came to accept funds from some members of the Sackler family including those involved with Purdue Pharma.

Pharma Giants Block Access to Vaccine Doses for Research

Pfizer and Moderna are preventing scientists from using their current vaccine doses for research. The U.S. should act now to restore competition.

BY ZACHARIA KAFUKO JULY 3, 2023

195 shares



Kafuko-Covid vaccine development 070323.jpg

BENOIT DOPPAGE/BELGA/SIPA USA

The New York Times

Vaccine Makers Keep Safety Details Quiet, Alarming Scientists

Researchers say drug companies need to be more open about how vaccine trials are run to reassure Americans who are skeptical about getting a coronavirus vaccine.

Give this article



Pascal Soriot, chief executive of the drug company AstraZeneca, in Washington in February. Erin Schaff/The New York Times

Biogen finalizes \$900M deal to settle whistleblower's long-running MS kickback suit

By Angus Liu • Sep 27, 2022 09:56am

Biogen kickbacks multiple sclerosis settlement

How Big Pharma rips you off on drugs

Yrthur Caplan and Zachary Caplan, Special to CNN
Updated 9:12 AM EDT, Thu April 25, 2013



FDA and NIH let clinical trial sponsors keep results secret and break the law

Science investigation of ClinicalTrials.gov reveals that federal promises to enforce trial transparency have fizzled

13 JAN 2020 • BY CHARLES FILLER



4 important – and overlooked – questions



Prevalence



Remedies



What good practices can
and should look like



Efficacy of policy +
regulations

Good Pharma Scorecard (GPS)

Index that rates + ranks pharmaceutical companies on their bioethics performance, annually. Designed to:

1. Set + communicate ethics goals
2. Evaluate and track progress on goals
3. Recognize good practices
4. Catalyze better behaviors

Rankings

View Good Pharma Scorecard rankings by			
Company	awarded in	with	
	2023	Diversity	
Company	Diversity Score		
#1 United Therapeutics			
#2 Puma			
#2 Sanofi			
#2 Takeda			
#5 Amgen			
#5 Bristol-Myers Squibb			



LMIC Access to Medicines



Patient Centricity

5 Scorecards

Is pharma paying
attention?





[Bioethics International Good Pharma Scorecard](#)

Sanofi was also awarded a "Gold Badge", the highest rating possible, from Bioethics International within their Good Pharma Scorecard, which ranks companies on ethics and social responsibility performance criteria, focusing on issues that are critical to patients and public health.

Sanofi

- CSR Report (2023)
- Impact Report (2022)

BMS ESG, Health Equity & Access Reports

	Introduction	Health Equity & Access to Healthcare	Scientific Innovation	Our People	Inclusion & Diversity	Environmental Responsibility	Ethics, Integrity, Quality & Governance	Looking Ahead	Appendix
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2022 Environmental, Social and Governance Report



Introduction

Health Equity & Access to Healthcare

Scientific Innovation

Inclusion & Diversity and Clinical Trial Efficacy

BMS recognizes the urgent need to narrow the gaps in care among underserved communities, both to achieve our health equity goals and to support our mission to develop medicines that improve lives.

It is crucial to have inclusion and diversity in clinical trials to reduce biases that result in healthcare disparities and promote health equity.

To ensure our patient population is reflective of the real world and aligned with the disease epidemiology we study, we constantly track our performance. In the U.S., we already have trial sites in highly diverse geographic regions and work with study team partners to design clinical trials that build on our efforts to be more inclusive. The scope of our inclusion and diversity efforts

A Clinical Study Report (CSR) is developed for all interventional studies and provides a summary of the safety and efficacy or the data collected and analyzed for the individual clinical trial.

In addition to a CSR, patient lay summaries are created to communicate results of the study to participants in the clinical trial.

BMS has demonstrated its commitment to pediatrics by establishing the Pediatrics Center of Excellence with the objectives of:

- Serving as the cornerstone for internal pediatric capabilities and external pediatric activity and providing inclusive cross-functional, cross-TA guidance on pediatric strategy
- Advancing pediatric drug development by maximizing efficiencies, championing innovation and ensuring pediatric considerations are embedded early and throughout the overall drug development process

is expanding with extensive ongoing assessments of the need to evolve our focus beyond the U.S. and to ensure that patients who are neurodiverse, LGBTQ+, sexual and gender diverse or who experience physical mobility challenges are also included in clinical trials.

Clinical Trials and Health Equity

Clinical trials are an essential stage of pharmaceutical research, generating data that helps us evaluate the efficacy and safety of new medicines and treatment options—and ensuring they meet regulations and health authority standards. We leveraged learnings from conducting clinical trials during the COVID-19 pandemic, and we are now more widely adopting remote clinical trial tools of third parties.

Selecting representative locations to host a clinical trial is an essential part of achieving diversity in clinical trials.

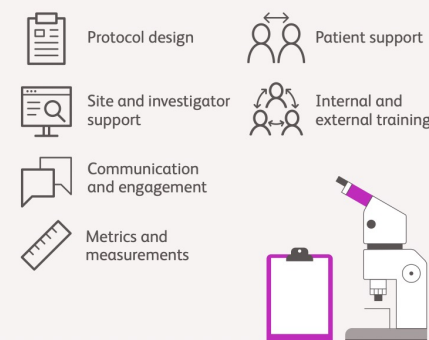
In less than two years, we met our goal by locating 58% of our clinical trial sites in highly diverse regions of the U.S.—surpassing our initial goal of 25% three years earlier than expected.

- Providing forward-looking development and regulatory guidance based on the evolving pediatric landscape, in concert with adult drug development
- Helping development program teams more efficiently fulfill requirements and maximize opportunity for pediatric and adult development, including exclusivity extensions and other business opportunities
- Becoming a leader in the wider pediatric community, representing the BMS corporate mission and embedding pediatrics into the discovery, development and delivery of medicines to help all patients prevail over serious diseases

Additionally, BMS maintains a detailed Clinical Trial Risk Management approach, which supports clinical trial execution through definition and implementation of a strategy that will identify, assess, control, review and communicate risks to minimize the potential impact on participant rights/wellbeing and clinical trial data integrity. We also have a risk assessment and categorization tool, which stipulates patient populations as a risk category for consideration and emphasizes the criticality of protecting the vulnerable population by deploying various risk mitigation strategies.

Relocating trials makes it easier for everyone to participate in the development of therapies and should improve the efficacy of therapies for all patients, including underserved communities.

BMS follows six formal workstreams to promote diversity in clinical trials:



Our efforts to improve clinical trial diversity were recognized in 2022 with a **Gold Badge Rating** on the Bioethics International Scorecard.



A Letter from Our Leaders	➤
Our Investments	➤
Research & Development	
Partnering with Patients	
Clinical Data Transparency	
Sales & Marketing	
Our Relative Investment	
Value	➤
Pricing & Patient Access	➤
Resources for Patients	➤
References	➤

"We're honored to be recognized in the top spot for the **Good Pharma Scorecard** for the second year in a row. At Johnson & Johnson, we believe sharing clinical trial data honors the patients who participated in the trial, and contributes to improving patient care."

— Joanne Waldstreicher, M.D.,
Chief Medical Officer of Johnson & Johnson

Clinical Data Transparency

The patients and health care professionals who rely on our medicines place their trust in our clinical research and development.

We believe making clinical trial data available advances science and benefits public health in important ways: it promotes the understanding of disease, expands the knowledge needed to develop new treatments, and generates new insights and more complete evidence that lead to better health care decisions for patients. Like others in our industry, we disclose information about our clinical trials on clinicaltrials.gov, the largest U.S. public registry, and we seek to publish the results of company-sponsored trials and health economic studies in peer-reviewed medical journals.

We have also pioneered new initiatives to further enhance clinical trial data transparency. In a first-of-its-kind agreement with the Yale University School of Medicine, we share pharmaceutical, device, and consumer product clinical trial data through the Yale Open Data Access (YODA) Project; its mission is to advocate for the responsible sharing of clinical [research](#) data, open science, and research transparency.

The YODA Project serves as an independent review panel, evaluating researchers' requests for access to participant-level trial data and research reports, which provide extensive details about the methods and results

of a clinical trial. Researchers can use these clinical trial data in their own scientific or medical research to increase medical knowledge and improve public health. Launched in 2014 to share pharmaceutical clinical trial data, the YODA Project expanded to include Johnson & Johnson medical devices and consumer clinical trial data in 2016 and 2017 respectively.

In 2017, the YODA Project received 23 requests for data from researchers and physicians at institutions and academic centers in the U.S. and around the world, all of which were approved. Additionally, two papers were published this past year as a result of data we shared.²⁰ For more information about the YODA Project and to request access to data from Janssen's clinical trials, please visit yoda.yale.edu.

Our leadership in clinical data transparency has been recognized by external organizations like Bioethics International. For the second consecutive year, Johnson & Johnson achieved the highest overall clinical trial transparency score — 100 percent — from Bioethics International in its second **Good Pharma Scorecard** (GPS), an annual index that ranks large pharmaceutical companies and new drugs on their clinical trial transparency.²¹ The 2017 GPS report evaluated clinical trial registration, results reporting, clinical study report synopsis sharing, and journal article publication rates for new drugs approved by the FDA in 2014 that were sponsored by large drug companies.²²

Janssen Global Trial Finder

In addition to advancing science, sharing information about clinical trials helps patients identify clinical studies that may be appropriate for them. We developed the Janssen Global Trial Finder to help people find information on Janssen clinical trials around the world. The interface makes it easy to search for Janssen clinical trials that are accepting new participants. People interested in enrolling in a clinical study can use the Janssen Global Trial Finder, available at globaltrialfinder.janssen.com/about-clinical-trials, to search for Janssen clinical trials by medical condition and geographic location.

BY THE NUMBERS: 2017 YODA RESULTS²⁰

23 requests for data 100% requests approved 2 papers were published using YODA data



A Letter from Our Leaders	➤
Our Investments	➤
Value	➤
Pricing & Patient Access	➤
Resources for Patients	➤

Johnson & Johnson

2017 Health for Humanity Report 114

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Sustainability Approach
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Innovation
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required. We seek to publish the results of company-sponsored trials in patients and health economic studies in peer-reviewed medical journals.

We believe that by sharing our clinical trial data we advance the science that is the foundation of medicine and honor the patients who participate in clinical trials who want to make a difference for themselves and other patients in the future. Through groundbreaking partnerships, including our participation in the Yale Open Data Access (YODA) Project, we are sharing pharmaceutical, device and consumer product clinical trial data with researchers and physicians around the world. In 2017, Johnson & Johnson's Consumer business segment became the first consumer company to make clinical trial data available to researchers through the YODA Project. We felt it was important for the millions of consumers who use our products every day to know we are committed to rigorous scientific assessments supporting the safety and efficacy of all our healthcare products, including consumer products.

Access to Investigational Medicines For patients with serious or life-threatening health conditions, experimental treatments may offer a way forward when all existing options have been exhausted and clinical trials are not an option. Our Company is involved in R&D of life-saving medicines, and it is our responsibility to help people who urgently need new treatment options in a way that doesn't put the individual or the larger patient community at risk of unnecessary harm.

Access can take many forms, and most patients obtain access to investigational medicines through participation in clinical trials. For late-stage medicines in development for life-threatening conditions, we generally create a formal Expanded Access Program (EAP) that provides a protocol-driven path to gain access for patients, similar to those who participated in the clinical trial. For

provide access through compassionate use, or single-patient requests. To help provide a fair, ethical evaluation of compassionate use requests, the Janssen Pharmaceutical Companies of Johnson & Johnson employ the Compassionate Use Advisory Committee (CompUAC) globally. Developed in collaboration with New York University Langone Health, CompUAC facilitates the review of compassionate use requests by an independent, external body of internationally recognized medical experts, bioethicists and patient representatives. After a successful pilot that began in 2015, CompUAC was expanded to include additional investigational medicines in development at Janssen.

In 2017, Johnson & Johnson was awarded an Ethical Leadership Award by the Fellowship at Aschrichtz for the Study of Professional Ethics. This award was given in recognition of our leadership in both the areas of compassionate use for our work on CompUAC, as well as our approach to sharing our clinical trial data through the YODA Project.

Last year, Janssen was one of several industry collaborators supporting the launch of the Regeneron-Udall Foundation's Expanded Access (EA) Navigator, the first-of-its-kind website that provides patients, caregivers and physicians with critical information about EA. The EA Navigator represents a unique private-public partnership among advocacy, government and industry communities to create a resource that addresses the critical need to understand options when commercially available treatments have been exhausted and clinical trials are not an option.

Our Commitment to Animal Welfare At Johnson & Johnson, we work tirelessly to impact the trajectory of human health. From the beginning, our focus has been on bringing life-

Bioethics International Good Pharma Scorecard

In December 2017, Johnson & Johnson earned the highest overall score of 100% for clinical trial transparency in Bioethics International's second publication of its Good Pharma Scorecard. Bioethics International is a not-for-profit organization dedicated to raising the bar on ethics, transparency, and patient-centricity in pharma. The annual index ranks the top 20 largest pharmaceutical companies and new medicines on their clinical trial transparency, and is published in BMJ Open (formerly British Medical Journal).

66 We're honored to be recognized in the top spot for the Scorecard for the second year in a row. At Johnson & Johnson, we believe sharing clinical trial data honors the patients who participated in the trial, and contributes to improving patient care. The Good Pharma Scorecard transparency standards match our own standards, and we recognize the work Bioethics International is doing to shine a light on transparency in the industry. **79**

Joanne Waldstreicher, M.D.
Chief Medical Officer
Johnson & Johnson

Johnson & Johnson can deliver these innovative products and technologies because of our rigorous research. Where this research involves animals, we employ every method available to safeguard their welfare. This includes ethical review committees, personnel training, and ensuring that all Johnson &

J&J / Janssen Reports

Sharing patient-level data and documents with researchers

Data are a powerful force driving healthcare forward and can be used to pose new questions, uncover new findings, and validate breakthrough hypotheses. Celgene shares patient-level data and documents with researchers who provide a robust, scientifically sound request that includes an analysis and publication plan. Access to Celgene data can be requested using our researcher portal, which is located at <https://celgeneclinicaldatasharing.com/>.



Providing summaries to study participants

Communicating trial results engages sponsors and investigative sites and helps to fulfill the ethical obligation of researchers to inform study volunteers about what was learned from their participation in a trial. Since 2017, Celgene has provided lay summaries of

CELGENE CLINICAL TRIALS BY THE NUMBERS

201

clinical trials currently being sponsored by Celgene

35

unique compounds being examined in clinical trials

16,897

patients enrolled in our clinical trials

CELGENE RANKED IN TOP 5 FOR CLINICAL TRIAL TRANSPARENCY

Bioethics International has ranked Celgene among the top five companies for clinical trial transparency on its **Good Pharma Scorecard**. We're proud to receive this recognition and believe that responsible clinical trial data sharing can help continually enhance the impact our medicines have in changing the course of diseases and providing new treatment options for patients.



Additional details about Celgene's Clinical Trial Data Sharing Policy and program can be accessed at <https://celgeneclinicaldatasharing.com/>.



Bold Science, Promise for Patients

2018 Corporate Responsibility Report



Notice of 2022 Annual Meeting of Stockholders

To the stockholders of our company:

You are cordially invited to attend the 2022 Annual Meeting of Stockholders to be held on May 6, 2022, where we will be voting on the below matters. You will be able to attend the Annual Meeting via live webcast by visiting www.virtualshareholdermeeting.com/ABBV2022.

Items of business

- To elect four directors to hold office until the 2025 Annual Meeting or until their successors are elected.
- To ratify the appointment of Ernst & Young LLP as AbbVie's independent registered public accounting firm for 2022.
- To vote on an advisory basis on the approval of executive compensation.
- To vote on a management proposal to eliminate supermajority voting.
- To consider any other matters that may properly come before the meeting, including four stockholder proposals, if presented during the meeting.

Your vote is important.
Please vote promptly using one of the methods mentioned below:



Internet
Visit www.proxyvote.com to vote online.



Mail
Sign and return your proxy card in the enclosed envelope if you received a printed version of the proxy card.



Telephone
Call toll-free 1-800-690-6903 in the U.S. and Canada.



The Annual Meeting of Stockholders of AbbVie Inc. (the "Annual Meeting") will be held on Friday, May 6, 2022 at 9:00 a.m. Eastern Time. The Annual Meeting will be a virtual meeting of stockholders.



DATE AND TIME:
Friday, May 6, 2022
9:00 a.m. CT



WHERE:
Via live webcast online at
www.virtualshareholdermeeting.com/ABBV2022.

Thank you for your continued support of and interest in the company.

By Order of the Board of Directors

Laura J. Schumaker
Secretary
March 21, 2022



Adjusted research and development spend is a non-GAAP measure, which is reconciled in Appendix B.

10 **abbvie** | 2022 Proxy Statement

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External Recognition as a Top Company

Our work hasn't gone unnoticed. We've been honored to receive some of the most prestigious ratings and recognitions in our industry. And we've received more than 40 Top Employer and Top Employer rankings globally. For more information, visit <https://news.abbvie.com/media-resources/fact-sheets/abbvie-ratings-and-recognition-fact-sheet.htm>

Workplace & Diversity	Environmental, Social and Governance	Citizenship	
✓ DiversityInc "Top 50 Companies for Diversity" – Top 15	✓ Dow Jones Sustainability World Index	✓ Civic 50	✓ F
✓ FORTUNE "100 Best Companies to Work For" – Included for four consecutive years	✓ Dow Jones Sustainability North America Index	✓ 3BL Media "100 Best Corporate Citizens"	✓ F
✓ Great Place to Work "World's Best Workplaces" – Included for five consecutive years	✓ Ecovadis Corporate Social Responsibility Assessment Gold Medal	✓ PEOPLE Companies that Care	✓ F
✓ Human Rights Campaign Corporate Equality Index – Scored 100% for six consecutive years	✓ FTSE4GoodIndex	✓ Bioethics International Good Pharma Scorecard for clinical trial transparency – Tied for first	✓ F
✓ Seramont "100 Best Companies for Working Mothers" – Top 15 for four consecutive years	✓ S&P 500 ESG Index		
	✓ AbbVie ranked on the 2021 Purpose Power Index		

Abbvie SEC filings (2022)



LMIC Access to medicines



Patient Centricity

5 Scorecards

SPECIAL ARTICLE

Compliance with Results Reporting at ClinicalTrials.gov

Monique L. Anderson, M.D., Karen Chiswell, Ph.D., Eric D. Peterson, M.D., M.P.H., Asba Tasneem, Ph.D., James Topping, M.S., and Robert M. Califf, M.D.

ABSTRACT

BACKGROUND

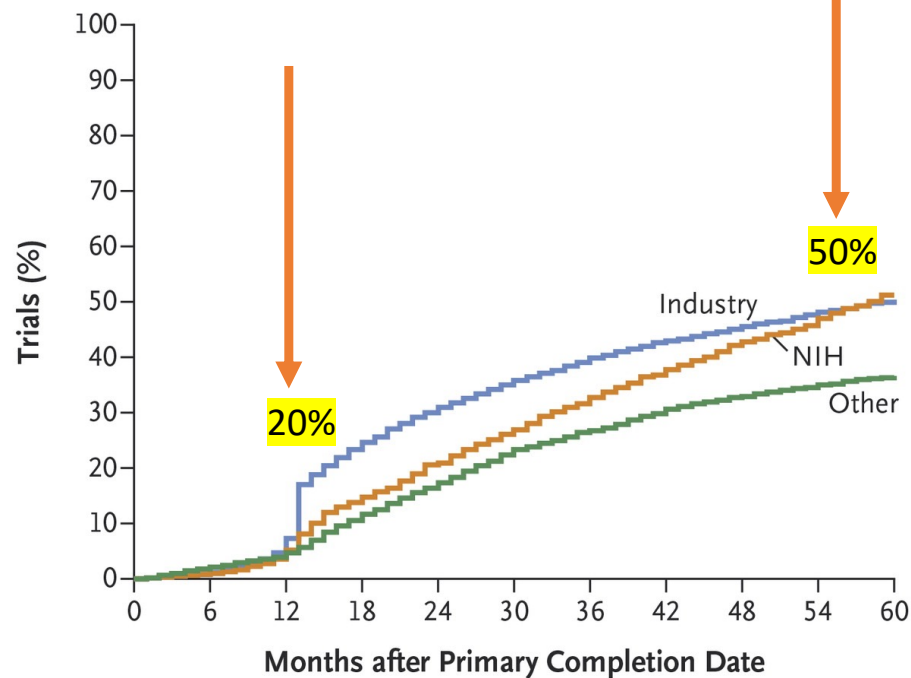
The Food and Drug Administration Amendments Act (FDAAA) mandates timely reporting of results of applicable clinical trials to ClinicalTrials.gov. We characterized the proportion of applicable clinical trials with publicly available results and determined independent factors associated with the reporting of results.

METHODS

Using an algorithm based on input from the National Library of Medicine, we identified trials that were likely to be subject to FDAAA provisions (highly likely applicable clinical trials, or HLACTs) from 2008 through 2013. We determined the proportion of HLACTs that reported results within the 12-month interval mandated by the FDAAA or at any time during the 5-year study period. We used regression models to examine characteristics associated with reporting at 12 months and throughout the 5-year study period.

RESULTS

From all the trials at ClinicalTrials.gov, we identified 13,327 HLACTs that were terminated or completed from January 1, 2008, through August 31, 2012. Of these trials, 77.4% were classified as drug trials. A total of 36.9% of the trials were phase 2 studies, and 23.4% were phase 3 studies; 65.6% were funded by industry. Only 13.4% of trials reported summary results within 12 months after trial completion, whereas 38.3% reported results at any time up to September 27, 2013. Timely reporting was independently associated with factors such as FDA oversight, a later trial phase, and industry funding. A sample review suggested that 45% of industry-funded trials were not required to report results, as compared with 6% of trials funded by the National Institutes of Health (NIH) and 9% of trials that were funded by other government or academic institutions.



No. of Trials	0 Mo	<12 Mo	<24 Mo	<36 Mo	<48 Mo	<60 Mo
Industry	8728	8321	5132	3408	2127	914
NIH	1895	1828	1323	925	544	212
Other	2691	2585	1872	1208	717	320

Why transparency in research is important



Quality medical
evidence and
patient care



Innovation



Honoring &
protecting
research
participants

GPS. Transparency Measures

Sample: Trials supporting FDA approval of novel drugs + biologics

- “All trials”
- “Trials in patients”
- “FDAAA applicable trials”



Registration



Results reporting



Publication



Legal compliance



Data sharing



How are we scoring on
transparency metrics today?

Median overall transparency scores of **large companies**, 2012 - 2017 approvals

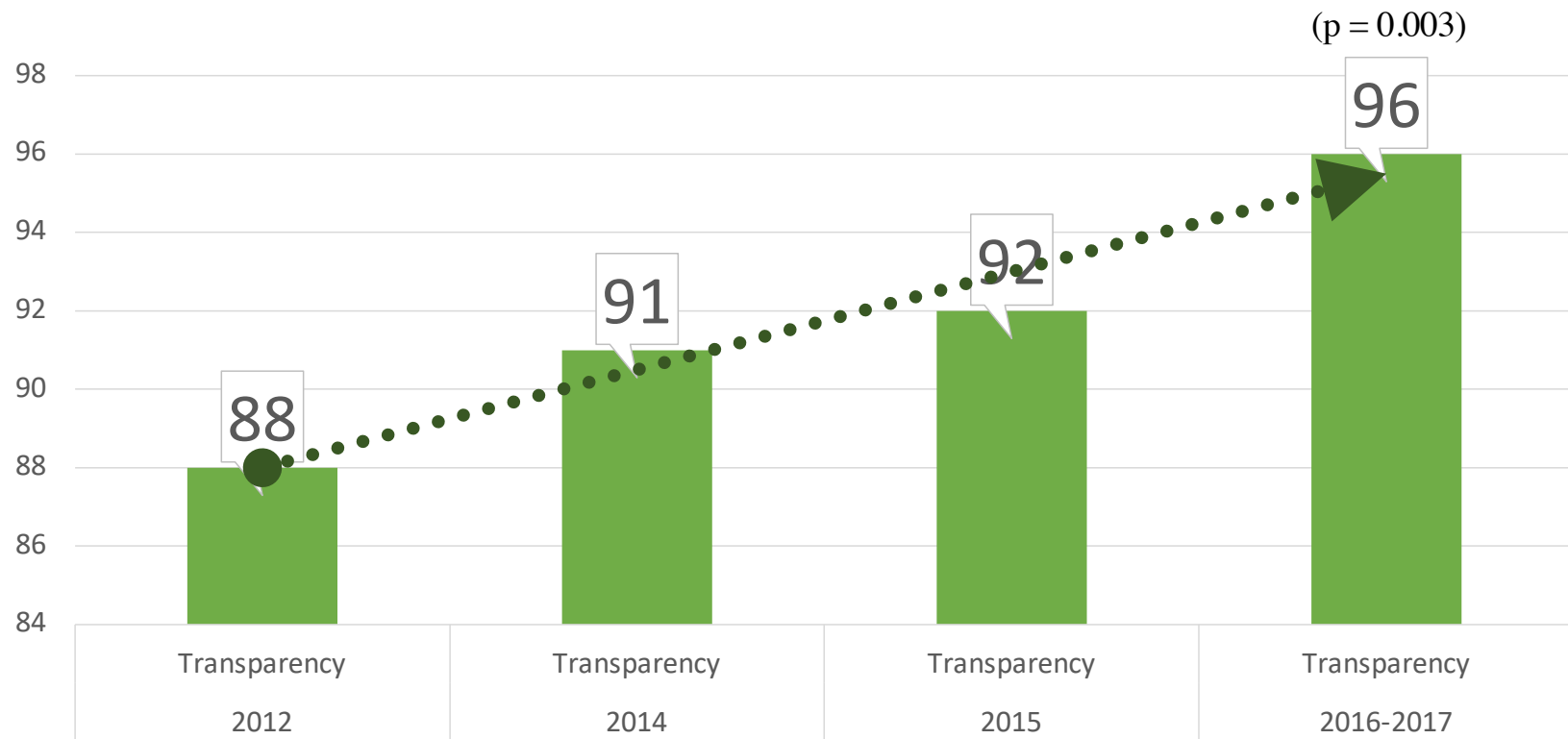
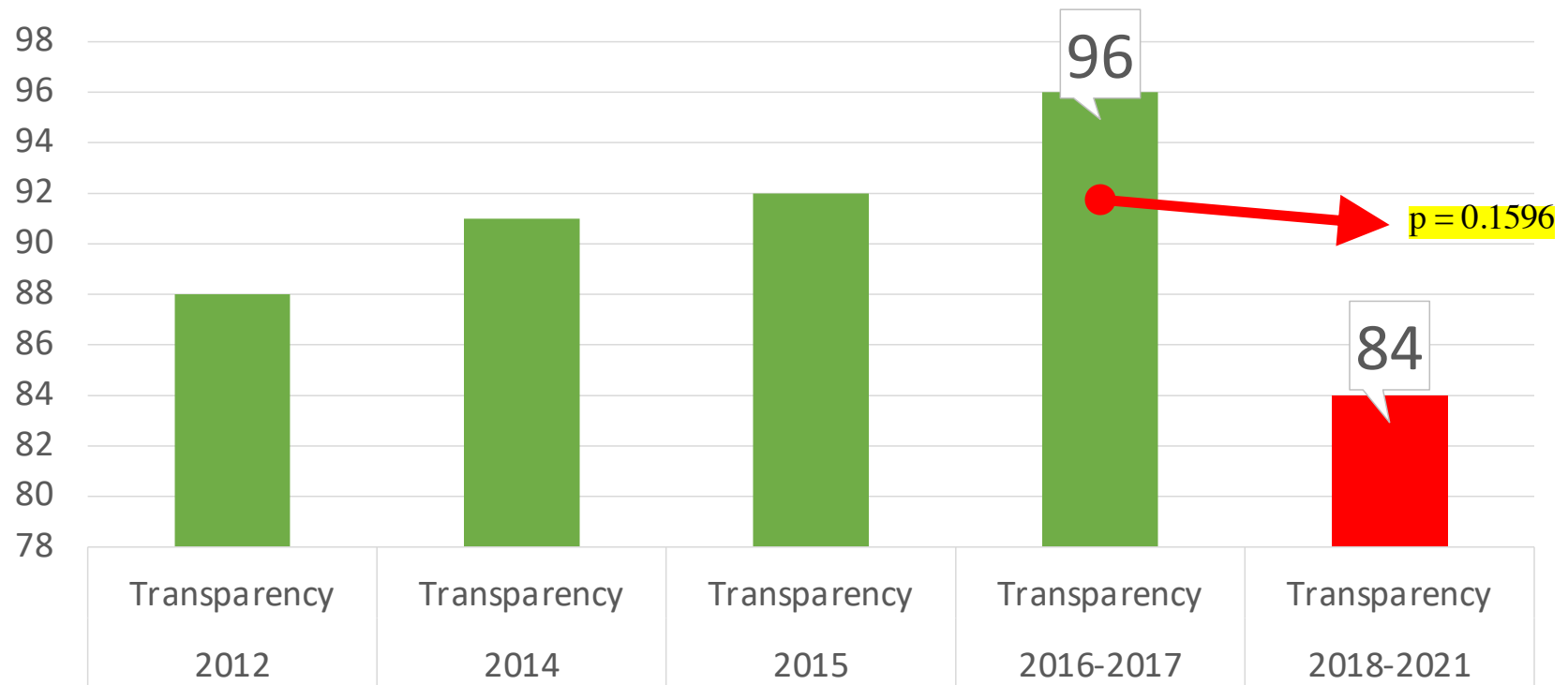
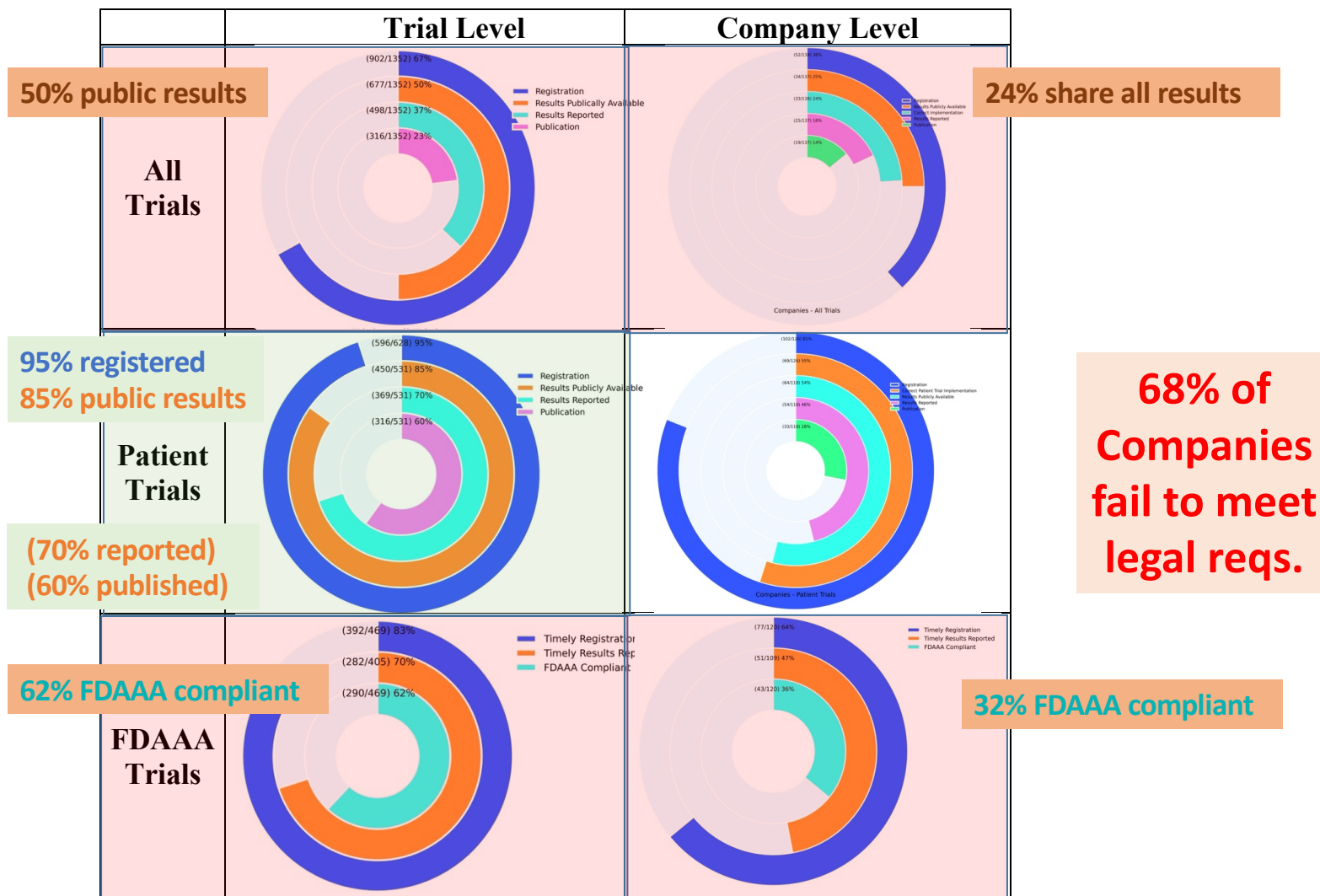


Table. Sample characteristics, 2018-2021 approvals

	No. (%)
Products, total*	208
Drugs	155 (75)
Biologics	53 (25)
Sponsors, total	136
<i>Industry</i>	135 (99)
Large sponsors	16 (12)
Non-large sponsors	119 (88)
<i>Headquarters, United States (US)</i>	81 (60)
Broad indications⁺	
Oncology and Hematology	72 (35)
Infectious disease	21 (10)
Neurology	18 (9)
Metabolic / Genetic Disorders	12 (6)
Dermatology	8 (4)
Rheumatology / Immunology	6 (3)
Pain Management / Anesthesiology	5 (2)
Other	65 (31)
Trials, total [analyzed]	1,414 [1,352]
Trials in patients	628 (44)
FDAAA applicable	469 (33)
Trial participants, total	333,842

Median overall transparency scores of large companies, 2012 - 2021 approvals

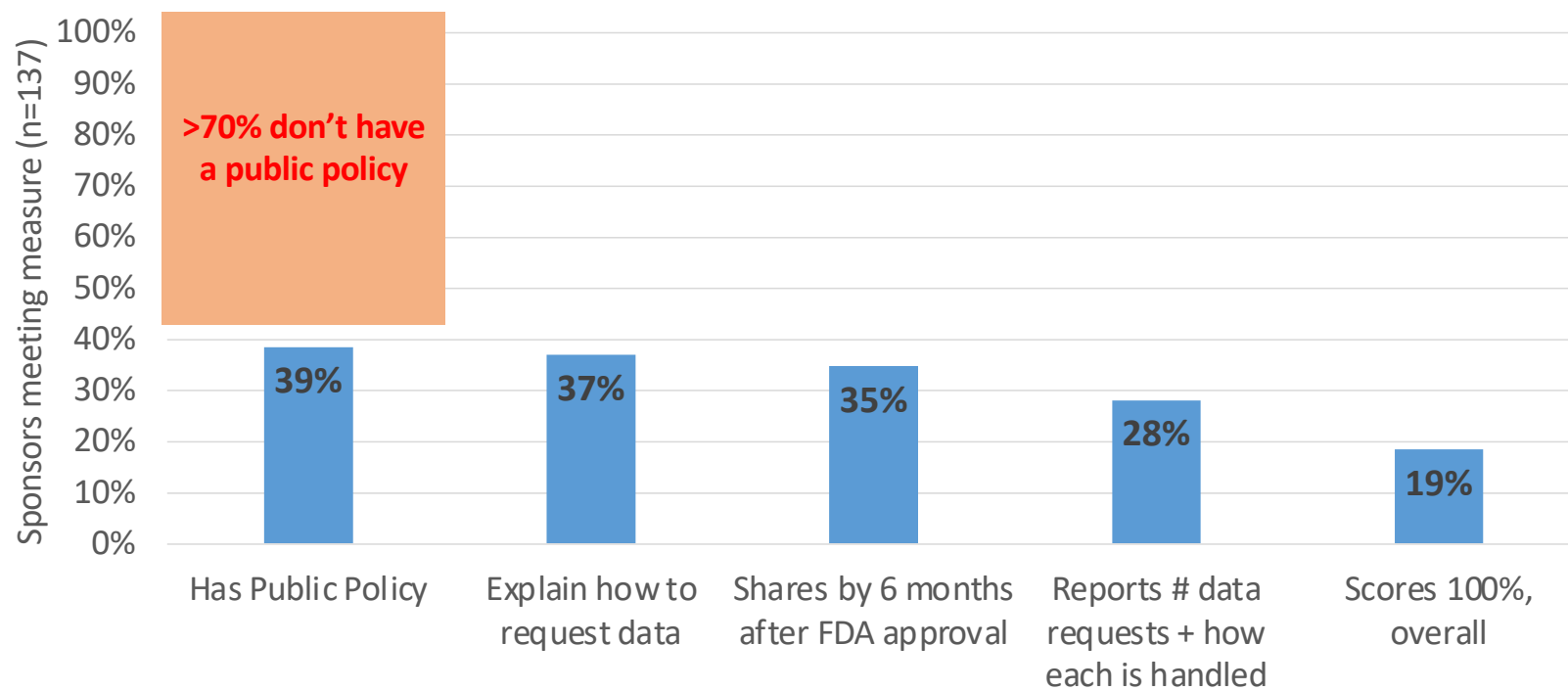




Association of **company size** w/ median clinical trial transparency measure scores

Measures	Sponsor size		
	Large Median (IQR)	Non-large Median (IQR)	P-value
Public availability, all trials	62 (43-70)	61 (38-100)	0.64
Public availability, patient trials	87 (80-100)	100 (71-100)	0.82
FDAAA compliance	77 (55-9)	67 (33-100)	0.61
Data sharing score	98 (97-100)	20 (18-71)	<0.0001
Overall company score	84 (80-94)	61 (40-73)	<0.0001

Data Sharing Measures





LMIC Access to medicines



Patient Centricity

5 Scorecards

Diversity in clinical research: public health and social justice imperatives

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ABSTRACT

It is well established that demographic representation in clinical research is important for understanding the safety and effectiveness of novel therapeutics and vaccines in diverse patient populations. In recent years, the National Institutes of Health and Food and Drug Administration have issued guidelines and recommendations for the inclusion of women, older adults, and racial and ethnic minorities in research. However, these guidelines fail to provide an adequate explanation of why racial and ethnic representation in clinical research is important. This article aims to both provide the missing arguments for why adequate representation of racial and ethnic minorities in clinical research is essential and to articulate a number of recommendations for improving diversity going forward. Appropriate racial and ethnic representation and fair inclusion help (1) increase the generalisability of clinical trial results, (2) equitably distribute any benefits of clinical research and (3) enable trust in the research enterprise.

Although black, Latinx and Indigenous patients have been disproportionately affected by the COVID-19 pandemic, evidence suggests racial and ethnic minorities may be under-represented in COVID-19 clinical trials.^{1–3} In fact, in the USA, racial and ethnic minorities are under-represented in clinical trials for most therapeutics and vaccines.^{4–8} Clinical trial participants are more often male and tend to be whiter, younger and healthier than real-world patients, raising concerns about the safety and effectiveness of novel therapeutics and vaccines for under-represented populations.⁹

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) have made strides to improve demographic representation in research since at least the 1980s. The NIH Revitalization Act of 1993, for example, directed the NIH to establish guidelines for the inclusion of women and racial and ethnic minorities in clinical research.⁹ Additionally, the statute required NIH-sponsored clinical research to address the inclusion of historically under-represented demographic groups in proposed research and in phase 3 clinical trials. Recently, the FDA published detailed guidance for research sponsors, as part of the FDA Reauthorization Act of 2017 mandate, on how to better enrol diverse study participants.¹⁰ The guidance makes recommendations, such as broadening protocol eligibility criteria and avoiding unnecessary exclusion criteria in research, to better understand the safety and efficacy of novel therapeutics in a diverse patient population.

While helpful, these efforts, like many, fail to answer a fundamental question: why is racial and ethnic representation in clinical research important? Given that demographic representation in research advances understandings of safety, efficacy and effectiveness for novel therapeutics in the population expected to use them, demographic representation is important if there is reason to believe that there will be a differential response to a therapeutic by sex, age, race or ethnicity. It is well established that there can be differential responses to therapeutics between women and men and between older and younger adults due to differences in pharmacokinetics/pharmacodynamics and drug toxicity by sex and age.^{11–13} Yet, in failing to explain why race, a social construct, is grouped with sex and age, biological attributes, we worry that guidance to improve representation of racial and ethnic minorities in clinical research may unintentionally endorse a biological basis for race and ethnicity. Here, we provide the missing arguments for why racial and ethnic representation in clinical research is essential. We then articulate a number of recommendations for improving the enrolment of racial and ethnic minorities in clinical research going forward.

ARGUMENTS

Clinical characteristics and responses to novel therapeutics can differ by race and ethnicity. However, the underlying causes of any differences are driven by social determinants and structural racism, not inherent genetic differences.¹⁴ Racial and ethnic minorities are, for example, over-represented in poverty due to structural inequities, which results in disparities in access to quality education, healthy foods, a clean and safe environment, income and wealth, among other factors that contribute to a healthy life.^{15–16} This manifests in a disproportionate rate of comorbid conditions and concomitant medication use, both of which can alter the safety profile of a therapeutic.^{17–18} Therefore, failing to adequately include patients identifying as racial and ethnic minorities in research, can potentially limit understandings around the benefits, risks and harms of novel therapeutics for excluded and under-represented patients groups.

While race is not a biological construct, it is worth noting that evolutionary history or ancestry may be biologic constructs of value. However, ancestry is not a proxy for race and should not be used as such. Genetics research has illuminated how humans cannot be divided into biologically distinct categories and that there is more variation within racial groups than between racial groups.^{19–20} Although there may be some genetic

Representation in clinical trial enrollment includes 3 key goals:

Generalizability

Fair opportunity

Trust

(Varma, Jones, Oladele, Miller, J Med Ethics, 2023)

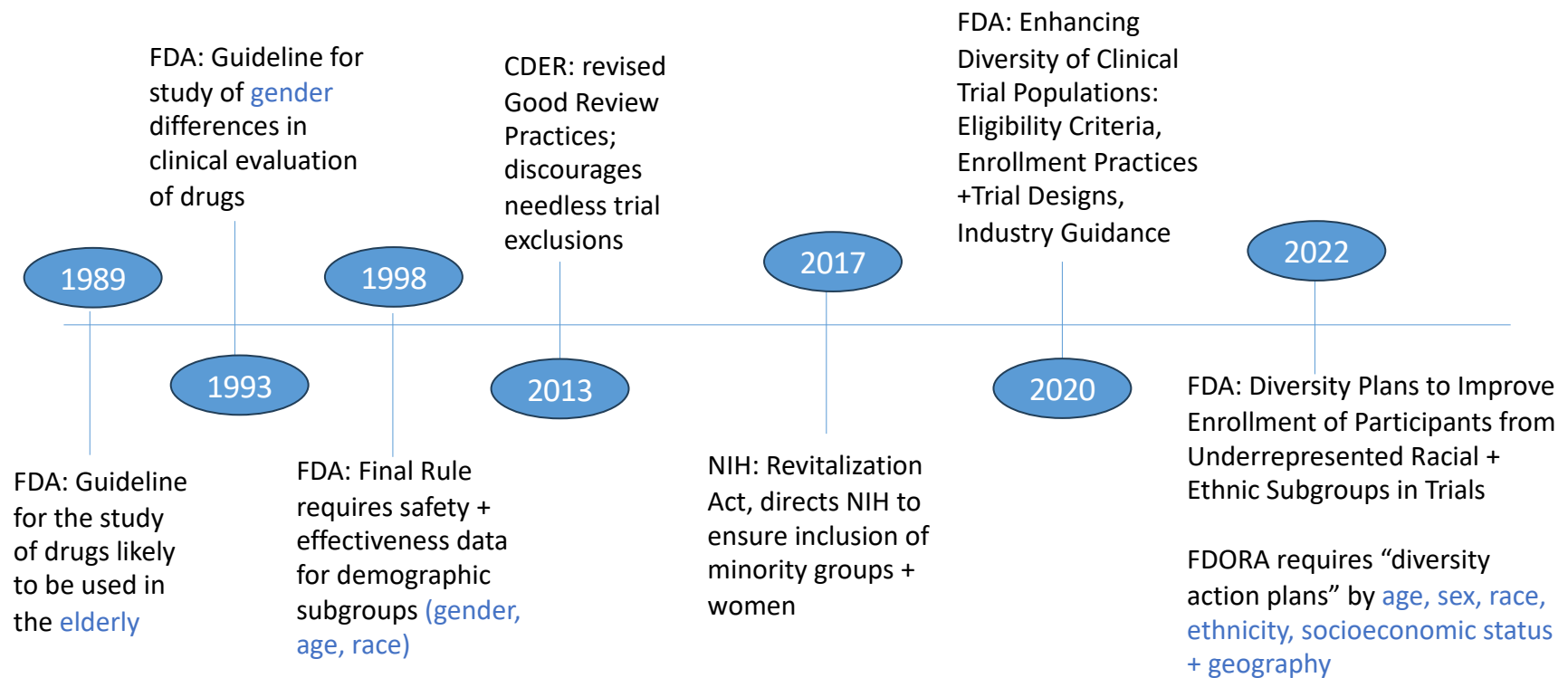


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Policy efforts to enhance representation span decades



Metrics Development Process

Step 1:
Literature Review



Step 2:
Guideline Review



Step 3:
Multi-Stakeholder
Engagement



- Consultations
- Focus Groups
- Interviews

Step 4:
Bright Spot
Analysis



GPS Measures. Using the condition-based approach

Component	Parameter	Outcome measure
Transparency (n=7)	Sex	Sex of participants reported
	Age	% Older adult participants reported (>64)
	Race	% Alaskan Native /American Indian participants reported
		% Asian participants reported
		% Black participants reported
		% Native Hawaiian / Pacific Islander participants reported
Representation (n=5)	Ethnicity	% Latino participants reported
	Sex	PPR for female participants ⁺
	Age	PPR for older adults (>64) ⁺
	Race	PPR for Black participants ⁺
		PPR for Asian participants ⁺
	Ethnicity	PPR for Latino participants ⁺

Transparency: Whether trials publicly report participant sex, age, and racial and ethnic identity

Representation: Whether trial participant demographics represent 80-120% of the US patient population for studied conditions

Fair inclusion: A composite measure of transparency + representation scores

Pilot

- **Objective** To develop a measure for adequate diversity and fair inclusion of women, older adults (65 years and older), and racially and ethnically minoritized patients in pivotal trials and use it to score, rate/rank the performance of trials, therapeutics and sponsor
- **Design** Retrospective cross sectional study.
- **Population** Sponsors of novel oncology therapeutics approved by the US FDA in 2012 - 2017.

Varma, Mello, Ross, Gross, Miller, *BMJ Medicine*, 2023

► Additional supplemental material is published online only. To view, please visit the journal online (<http://dx.doi.org/10.1136/bmjmed-2022-000395>).

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Metrics, baseline scores, and a tool to improve sponsor performance on clinical trial diversity: retrospective cross sectional study

Tanvee Varma ¹, Michelle Mello,^{2,3,4} Joseph S Ross,^{5,6,7} Cary Gross,^{7,8,9} Jennifer Miller ^{5,10,11,12}

ABSTRACT

OBJECTIVE To develop a measure for fair inclusion in pivotal trials by assessing transparency and representation of enrolled women, older adults (aged 65 years and older), and racially and ethnically minoritized patients.

DESIGN Retrospective cross sectional study.

POPULATION Sponsors of novel oncology therapeutics that were approved by the US Food and Drug Administration over 1 January 2012 to 31 December 2017.

DATA SOURCES Trial data from Drugs@FDA, ClinicalTrials.gov, and corresponding publications; cancer incidence demographics from US Cancer Statistics and the American Cancer Society.

MAIN OUTCOME MEASURES Transparency measures assess whether trials publicly report participant sex, age, and racial and ethnic identity. Representation measures assess whether trial participant demographics represent more than 80% of the US patient population for studied conditions,

calculated by dividing the percentage of study participants in each demographic subgroup by the percentage of the US cancer population with the studied condition per group. Composite fair inclusion measures assess average transparency and representation scores, overall and for each demographic group. Results are reported at the trial, product, and sponsor levels.

RESULTS Between 1 January 2012 and 31 December 2017, the FDA approved 59 novel cancer therapeutics, submitted by 25 sponsors (all industry companies) on the basis of 64 pivotal trials. All 25 sponsors (100%) reported participant sex, 10 (40%) reported age, and six (24%) reported race and ethnicity. Although 14 (56%) sponsors had adequate representation of women in trials, only six (24%) adequately represented older adults, and four (16%) adequately represented racially and ethnically minoritized patients (black, Asian, Hispanic or Latinx). On overall fair inclusion, one sponsor scored 100% and the median sponsor score was 81% (interquartile range 75–87%). More than half of sponsors (13 (56%) of 25) fairly included women, 20% (n=5) fairly included older adults, and 4% (n=1) fairly included racially and ethnically minoritized patients in trials. 80% of product had pivotal trials that fairly included women, 24% fairly included older adults, and 5% fairly included racially and ethnically minoritized patients.

CONCLUSIONS This novel approach evaluates trials, products, and sponsors on their fair inclusion of demographic groups in research. For oncology trials, substantial room was noted for improved inclusion of older adults and patients who identify as black or Latinx and transparency around the number of participants identifying as Native Hawaiian, Pacific Islander, American Indian, and Alaska Native. These measures can be used by sponsors, ethics committees, among others, to set and evaluate trial diversity goals to help spur progress toward greater research equity in the US.

Introduction

Demographic representation in clinical research is important for equitably assessing the safety and efficacy of novel therapeutics in the patients who will use them. However, women, older adults, and some racial and ethnic groups are often under-represented in research, particularly in cancer trials.^{1–4} This under-representation can challenge clinicians,

WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Women, older adults, and racially and ethnically minoritized patients are often under-represented in clinical research even though adequate representation is important for equitably assessing the safety and efficacy of novel therapeutics in the patients who ultimately use them.
- ⇒ Despite policy efforts to improve diversity, poor inclusion in trials persists, suggesting additional strategies are needed.
- ⇒ Development of accountability measures and publicly rating and ranking sponsors might be an effective reform strategy for improving diversity and fair inclusion in research.

WHAT THIS STUDY ADDS

- ⇒ This paper develops baseline quality measures for fair inclusion and diversity in clinical research that capture the transparency of participant demographics and representation of women, older adults, and racially and ethnically minoritized patients.
- ⇒ Applying the measures to score and rank novel oncology therapeutics FDA approved from 2012 through 2017, along with their sponsors and trials, we found that while a few sponsors have done well, most have substantial room for improvement on their inclusion of older adults and racially and ethnically minoritized patients, and to a lesser extent women.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE, OR POLICY

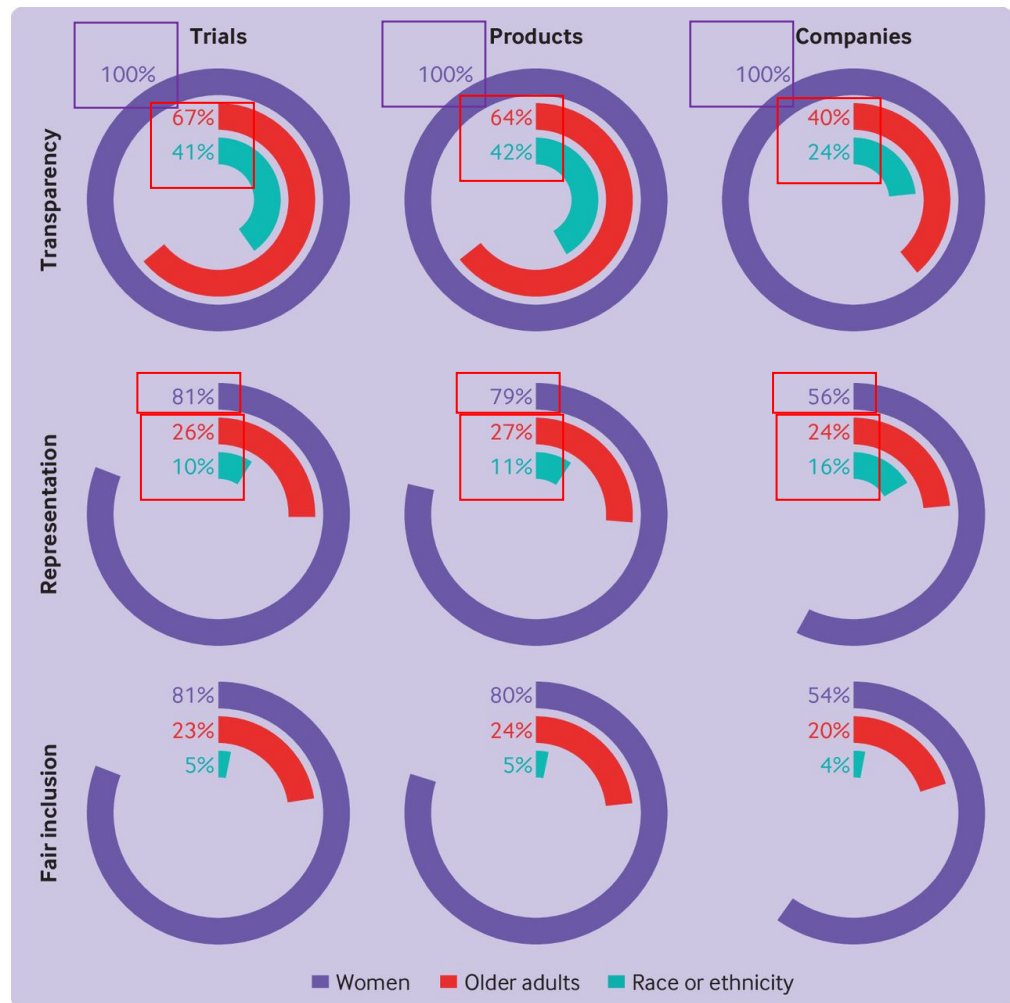
- ⇒ The fair inclusion score we developed and tested on oncology pivotal trials provides a useful, feasible method of assessing critical indices of equity in clinical trials.
- ⇒ The fair inclusion measure can be used to track and catalyze progress across the research ecosystem on clinical trial diversity, a key public health and social justice goal.



Sample
characteristics,
novel oncology
therapeutics FDA
approved 2012-17

Characteristic	Number (%)
Product Type	59
Drug	39 (66)
Biologic	20 (34)
Sponsors	25
Broad oncological indication	16
Leukemia	10 (17)
Lung cancer	6 (10)
Breast cancer	6 (10)
Multiple myeloma	6 (10)
Non-Hodgkin's lymphoma	6 (10)
Melanoma	5 (8)
Colorectal cancer	3 (5)
Ovarian cancer	3 (5)
Other*	13 (22)
Pivotal trials	64
Median, per product	1
Trial participants	29,959
Median, per trial (IQR)	326 (138-668)

- **Figure.** % of trials, products and companies receiving a 100% score on transparency, representation and fair inclusion measures for women, older adults, and racially and ethnically minoritized patients participating in pivotal trials for novel oncology therapeutics approved by the FDA during 2012-17.





	Transparency scores				Representation scores				Fair inclusion score
Company	Overall transparency	Sex	Older Adults	Race/ Ethnicity	Overall representation	Women	Older Adults	Race/ Ethnicity	
United Therapeutics	100	100	100	100	100	100	100	100	100
Puma	89	100	100	67	85	100	N/A	70	89
Sanofi	89	100	100	67	90	100	100	70	89
Takeda	94	100	83	100	89	100	90	76	89
Amgen	94	100	100	83	82	100	65	82	88
BMS	86	100	100	58	88	99	85	79	88
Eli Lilly	92	100	75	100	89	98	93	78	87
Merck KGaA	100	100	100	100	85	90	80	N/A	87
Otsuka	89	100	100	67	83	100	90	60	86
Pfizer	88	100	90	73	81	98	83	62	85
J&J	89	100	100	67	77	98	75	58	82
Gilead	92	100	75	100	72	80	60	77	81
Eisai	78	100	100	33	83	80	100	70	81
Novartis	88	100	92	72	70	100	48	63	80
Merck & Co	83	100	50	100	87	100	N/A	73	79
AstraZeneca	81	100	59	83	75	90	75	59	78
Clovis Oncology	72	100	50	67	98	100	N/A	95	77
Abbvie	69	100	75	33	100	100	100	100	76
Teva	72	100	50	67	95	90	N/A	100	76
GSK	87	100	83	78	65	100	75	20	75
Roche	76	100	82	45	74	98	67	57	73
Boehringer									
Ingelheim	61	100	50	33	100	100	N/A	100	72
Exelixis	67	100	100	0	80	60	100	N/A	60
Bayer	63	100	33	56	85	100	100	56	60
Spectrum	50	100	50	0	100	100	N/A	N/A	50

Representation of Women, Older Adults, and Racial and Ethnic Minoritized Patients in Pivotal Trials for US Food and Drug Administration Novel Oncology Therapeutic Approvals, 2012-2021: Bright Spot Trials and Trends Over Time

Jennifer E. Miller, MS, LIC, PhD^{1,2,3,4} ; William Pelletiers, MPH¹; Cary P. Gross, MD^{1,5}; Michelle Mello, MPhil, PhD, JD⁶ ; Reshma Ramachandran, MD, MPP, MHS¹ ; Jason L. Schwartz, PhD⁷; Sakinah Carter Suttiratana, PhD, MPH, MBA^{8,2} ; Tanvee Varma, MD⁹ ; and Joseph S. Ross, MD, MHS¹

DOI <https://doi.org/10.1200/OP-24-00563>

We identified

- **31** bright spot trials
- **19** were sponsored by a large company

We interviewed

- **13** participants
- **8** large companies (62%)

We found

- **14** factors associated w success

Characteristic	# (%)
Products, total	111
Drugs	78 (72.7)
Biologics	33 (27.3)
Sponsors	70*
Broad oncological indication	
Leukemia ⁺	17 (15.3)
Lung cancer	16 (14.4)
Breast cancer	11 (9.9)
Multiple myeloma	10 (9.0)
Non-Hodgkin's lymphoma	12 (10.8)
Melanoma	6 (5.4)
Colorectal cancer	3 (2.7)
Ovarian cancer	3 (2.7)
Other*	33 (29.7)
Pivotal trials, total (median per product)	121 (1)
Trial participants, total	39,846
Median, per trial (IQR)	187 (107-421)



Access to
Medicines:
LMICs
hosting trials
for FDA
approvals

Availability of novel drugs in the countries where they were tested for FDA approval

Original Investigation | Ethics

Evaluation of Drug Trials in High-, Middle-, and Low-Income Countries and Local Commercial Availability of Newly Approved Drugs

Jennifer E. Miller, PhD; Michelle M. Mello, JD, PhD, MPhil; Joshua D. Wallach, PhD, MS; Emily M. Gudbranson, BS; Blake Bohlig, PA-C; Joseph S. Ross, MD, MHS; Cary P. Gross, MD; Peter B. Bach, MD

Abstract

IMPORTANCE Clinical research supporting US Food and Drug Administration (FDA) drug approvals is largely conducted outside the US.

OBJECTIVE To characterize where drugs were tested for FDA approval and to determine how commonly and quickly these drugs received marketing approval in the countries where they were tested, both overall and by country income level and geographical region.

DESIGN, SETTING, AND PARTICIPANTS This cross-sectional analysis of trials supporting FDA approval of novel drugs in 2012 and 2014, sponsored by large drug companies, did not involve human participants. The settings were the countries hosting trials supporting US drug approval. Data sources included Drugs@FDA, ClinicalTrials.gov, PubMed, Google Scholar, EMBASE, and drug regulatory agency websites. Data analysis was completed March through September 2020.

MAIN OUTCOMES AND MEASURES The primary outcomes were the proportion of drugs approved for marketing in the countries where they were tested for FDA approval within 1, 2, 3, 4, and 5 years of FDA approval and the proportion of countries contributing participants to trials supporting FDA approvals receiving market access to the drugs they helped test within 1, 2, 3, 4, and 5 years of FDA approval.

RESULTS In 2012 and 2014, the FDA approved 34 novel drugs sponsored by large companies, on the basis of a total of 898 trials, 563 of which had location information available. Each drug was tested in a median (interquartile range [IQR]) of 25 (18-37) unique countries, including a median (IQR) of 20 (13-25) high-income countries, 6 (4-11) upper-middle-income countries, and 1 (0-2) low-middle-

Key Points

Question How commonly are drugs commercially available in the countries where they were tested?

Findings This cross-sectional study found that 5 years after their approval in the US, 15% of novel drugs (5 of 34 drugs) were approved in all countries where they were tested; among 70 countries contributing research participants, 7% (5 countries) received market access to the drugs they helped test within 1 year of US approval and 31% (22 countries) did so within 5 years. Approvals were faster in high-income countries, and access was lowest in African countries.

Meaning These findings suggest that substantial gaps exist between where drugs are tested and where they become available to patients, raising concerns about the equitable distribution of research benefits.

1. Characterize where drugs were tested for FDA approval
2. Did these drugs receive marketing approval in the countries where they were tested

Availability of novel drugs in the countries where they were tested for FDA approval

Original Investigation | Ethics

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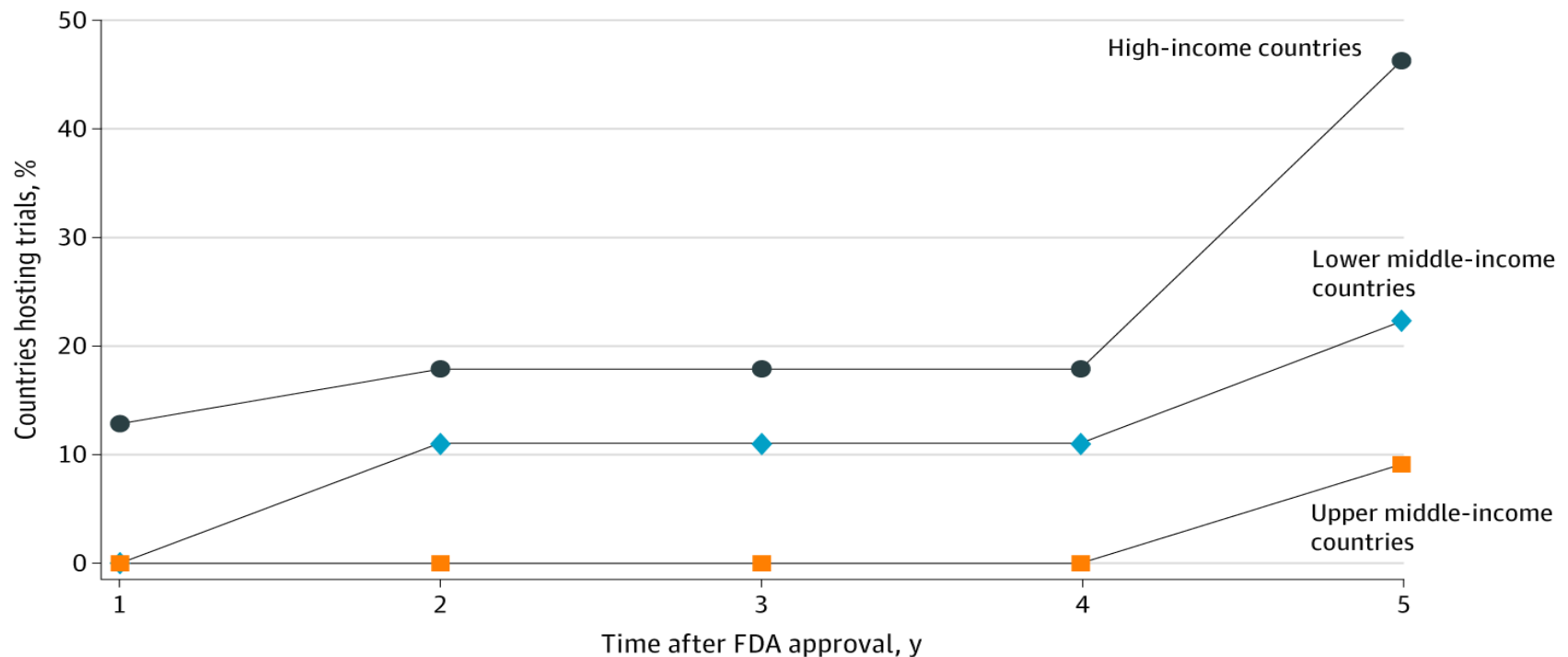
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Meaning These findings suggest that substantial gaps exist between where drugs are tested and where they become available to patients, raising concerns about the equitable distribution of research benefits.

Table. Characteristics of the Novel Drugs Sponsored by Large Companies and Approved by the US Food and Drug Administration in 2012 and 2014

Characteristic	Drugs, No. (%) (N = 34)
Approval year	
2012	15 (44)
2014	19 (56)
Treatment area	
Cancer and hematology	9 (26)
Infectious disease	10 (29)
Cardiovascular, diabetes, and hyperlipidemia	5 (15)
Autoimmune, musculoskeletal, and dermatology	3 (9)
Neurology and psychiatry	10 (29)
Other	6 (18)
Priority review, yes	17 (50)
Accelerated approval, yes	4 (12)
Orphan drug, yes	9 (26)
With public trial location data, yes	34 (100)
Trials with public location data (n = 898)	563 (63)

% of Countries Hosting Trials for FDA Drug Approvals Receiving Marketing Approval for Those Drugs Within 5 Years, by Income Level



- 70 countries contributing research participants: **7%** received market access to drugs w/in 1 year of FDA approval; **31%** w/in 5 years.

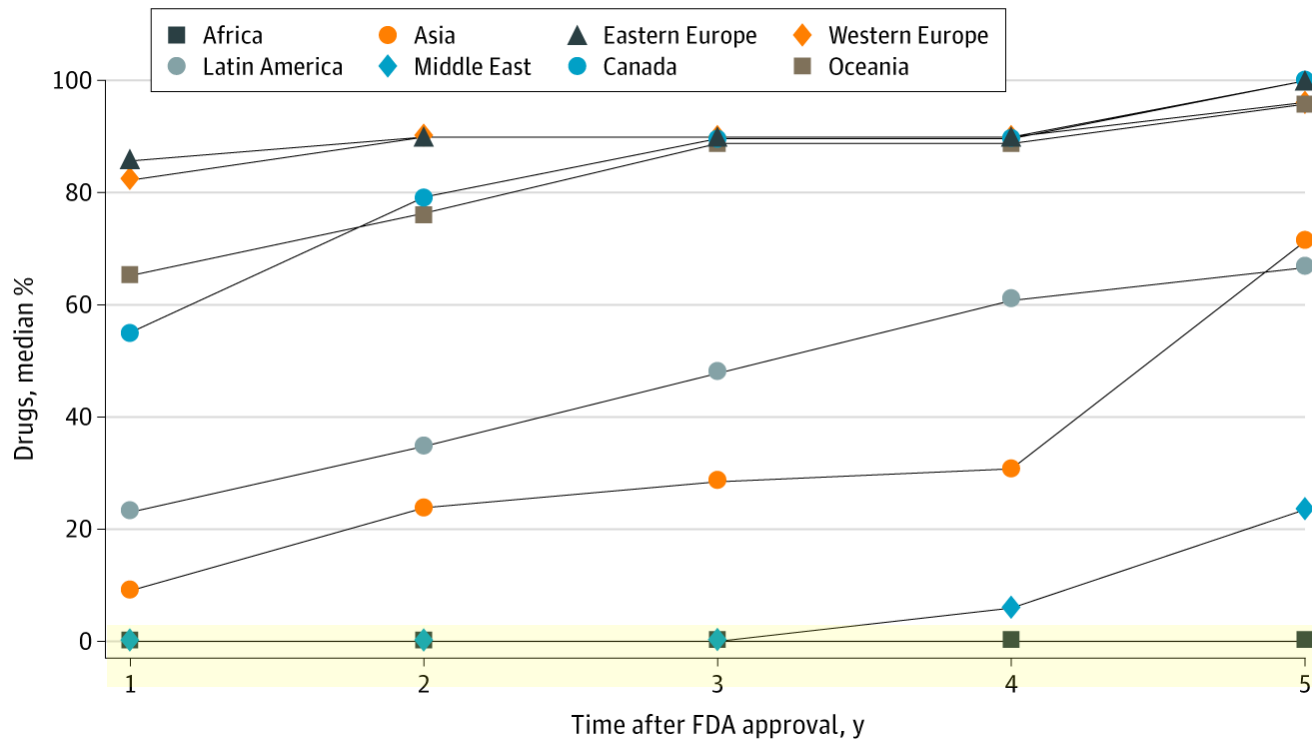


Figure. Percentage of Drugs Approved for Sale in the Countries Where They Were Tested for FDA Approval, by Geographical Regions

Original Investigation | Health Equity

Physical Accessibility of Medicines in Countries Hosting Trials for FDA Approvals

Chris J. Lee, BS¹; Cary P. Gross, MD^{2,3,4}; Jennifer E. Miller, PhD^{2,5}

> Author Affiliations | Article Information

RELATED ARTICLES
FIGURES
SUPPLEMENTAL CONTENT

Key Points

Question Are medicines physically accessible in the countries where they are tested for US Food and Drug Administration (FDA) approval, and has physical access improved over time?

Findings In this cross-sectional study of 172 medicines approved by the FDA from 2015 to 2018 and tested in 89 countries, 24% were physically accessible in all countries where they were tested 5 years after FDA approval. Countries in Western Europe had notably better access (82%) than countries in Africa (28%), with no improvements over time for low- and middle-income countries.

Meaning Most countries participating in trials for FDA approvals cannot physically access the medicines they test, particularly low- and middle-income countries, raising exploitation concerns, with no improvements over time.

Abstract

Importance Populations participating in clinical trials should benefit from resulting interventions, according to ethical guidance. Yet, exploratory studies show low- and middle-income countries (LMICs) participating in trials for US Food and Drug Administration (FDA) approvals lack timely access to the medicines they test, raising exploitation concerns.

	# (%)
Products, total*	172
2015	45 (26)
2016	22 (13)
2017	46 (27)
2018	59 (34)
Sponsors, total	75
Large	18 (24)
Non-large	57 (76)
Broad indications ⁺	
Oncology and hematology	67 (39)
Infectious disease	24 (14)
Autoimmune, musculoskeletal, + dermatology	22 (13)
Neurology and psychiatry	18 (10)
Other**	41 (24)
FDA Approval pathway / review designation	
Priority review	80 (47)
Orphan drug status	81 (47)
Trials, total	885
Per drug, median [IQR]	4 [2-6]
Trial sites, total	2,563

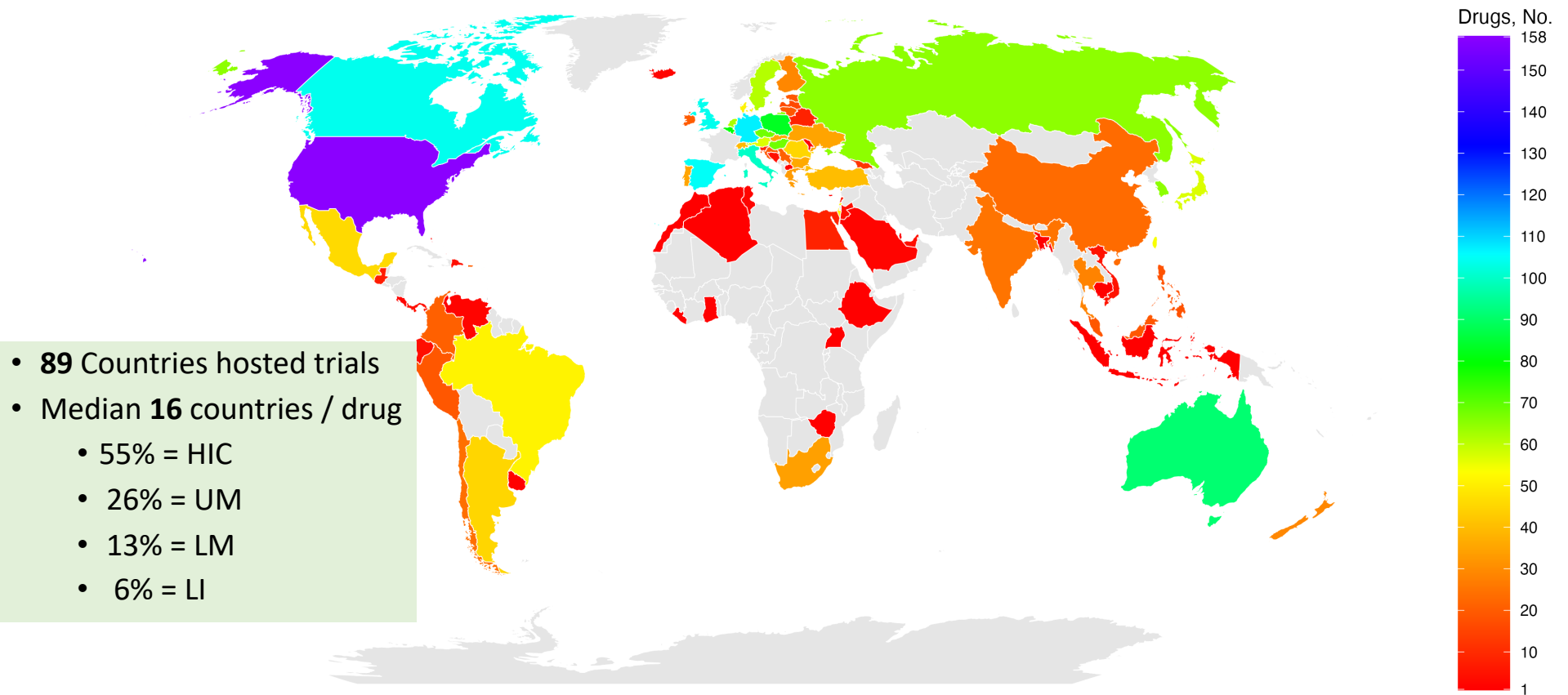
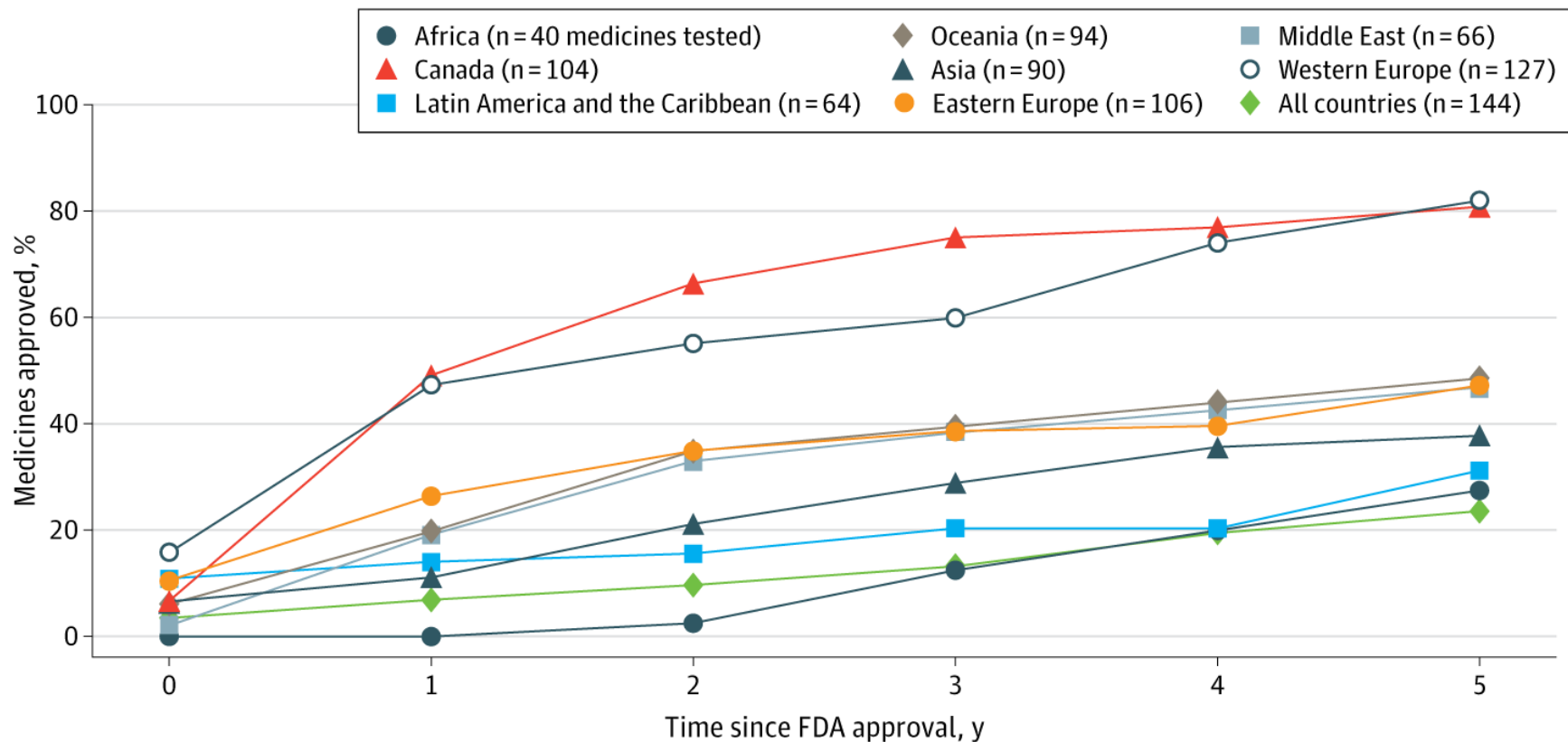


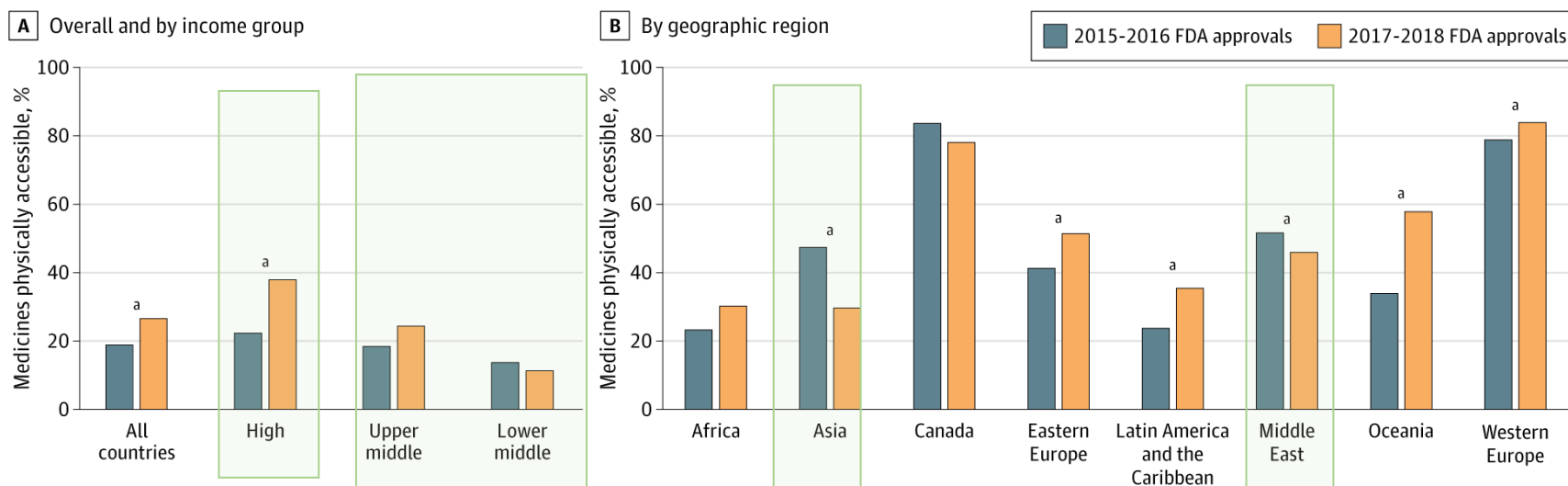
Figure: % of Drugs Authorized for Marketing (Accessible) in All Countries Where They Were Tested for FDA Approval, by Geographic Region





Is access improving?

- **Figure.** % of Medicines Accessible in All Countries Where Tested for FDA Approval, w/in 5 Years After FDA Approval



^a Results were considered statistically significant at $P < .05$.

Yale launches world partnership fund with inaugural projects to address urgent challenges

May 7, 2025 | Estimated read time: 4 minutes



YMAN

Yale Medicines Access Network

Yale and the World Partnership Fund 2025 awarded projects:

- Molly Brunson, Slavic Languages and Literatures — Central Asia Workshop
- Mariana Di Giacomo and Vanessa Rhue, Yale Peabody Museum — Institutional Knowledge Exchange: Elevating Practices in Collection Care of Fossils in the Americas
- Eva Garen, Yale School of the Environment — Forest Restoration Capacity Development in Rwanda
- Jeannette Ickovics and Daniel Carrion, Yale School of Public Health; Karen Seto, Yale School of the Environment; David Vlahov, Yale School of Nursing — Urban Pulse: Greening Schoolyards to Promote Urban Health and Climate Action
- Kaveh Khoshnood, Yale School of Public Health and Hani Mowafi, Yale School of Medicine — Building Research Capacity for Environmental Health in Armed Conflict Zones
- Jennifer Miller and Jeremy Schwartz, Yale School of Medicine — The Yale Medicines Access Network (YMAN)
- Zhao Ni, Yale School of Nursing — Enhancing an Educational and Research Collaboration in Indonesia
- Marc Schneeberger Pane, Yale School of Medicine — Beyond Isolation: A Network to Decipher Neural Mechanisms of Social Density Preferences, in Japan
- Andrey Zinchuk, Ilan Harpaz-Rotem, and Yevgeniy Mayr, Yale School of Medicine; Donna-Ann Thomas, Yale School of Nursing — Improving Pain Management and Mental Health Treatment in Conflict Territories: Ukraine



LMIC Access to medicines



Patient Centricity

5 Scorecards

Thank you!

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Yale SCHOOL OF MEDICINE

