Proceedings
Shaping the next 10 years in Data Sharing:
Building on the gains made and looking ahead
to the next 10 years in advancing human health

November 16th, 2023, 8:30am-4:00pm EST

Room 120, National Academy of Sciences,
2101 Constitution Ave. NW, Washington, DC 20418
& Virtual Meeting

Contents

Executive Summary

The conference titled "Shaping the next 10 years in Data Sharing: Building on the gains made and looking ahead to the next 10 years in advancing human health" held on November 16th, 2023, brought together leading experts to discuss the progress and future directions of sharing of clinical research data. The meeting was held both in person at the National Academy of Sciences in Washington, DC, and virtually.

Link to playlist of all recorded sessions

Keynote Addresses:

President of the National Academy of Medicine, Victor Dzau opened the event by stressing the importance of shared clinical research data and the emergence of AI in this field. He discussed the implementation of principles from the IOM 2015 report and the vision for the future amidst new challenges.

FDA Commissioner Robert Califf discussed the progress in data sharing since the IOM 2015 report and the improving quality of traditional trial data. He raised concerns about the influence of non-traditional data sources on healthcare decisions and the declining interest of clinicians in trials.

NIH Director Monica Bertagnolli emphasized the criticality of data sharing, the under-represented groups in data sharing, and the importance of collaboration. She mentioned NIH initiatives like the STRIDES initiative and the new policy requiring NIH-funded researchers to share their data.

Panel Discussions:

Panel 1 Moderated by Dr. Bernard Lo revisited the 2015 IOM report recommendations on data sharing and discussed the achievements and challenges ahead. The panelists reflected on the successes and the unanticipated issues in data sharing, with a focus on new technologies as well as the role of academia and the private sector.

Panel 2 Moderated by Dr. Murray Stewart showcased the tangible benefits of data sharing with five real-life case studies, demonstrating its impact on scientific knowledge and patient care.

Panel 3 Moderated by Dr. Barbara Bierer addressed the current academic culture, discussing the incentives for data sharing in academia and the need for a shift in the promotion and tenure processes to acknowledge data sharing contributions.

Panel 4 Moderated by Dr. Ida Sim explored key technologies influencing data sharing, focusing on machine learning and AI. The panel discussion centered on the need for responsible AI use and the potential of AI to democratize data accessibility while maintaining transparency and engender trust.

Panel 5 Moderated by Dr. Steven Kern debated regulations and policies to promote data sharing and reuse, reflecting on national policies and the roles of regulators, governments, and publishers.

Closing Remarks:

The conference concluded with a call to action for stronger collaboration among stakeholders to overcome barriers to data sharing. The importance of patient engagement and the development of infrastructure that supports the ethical and efficient sharing of data were emphasized.

Overall Impact:

The conference underscored the critical role of data sharing in advancing human health and the importance of aligning incentives, standardizing data sharing practices, and embracing new technologies like AI and ML responsibly. The need for a cultural shift in academia to support data sharing was highlighted, as was the importance of creating patient-centered data sharing models. There was consensus that while progress has been made, there is still a need for continued dialogue, collaboration, and innovation to fully realize the potential of data sharing in the next decade.

Welcoming Remarks
Victor J Dzau, M.D., President, National Academy of Medicine

Dr. Victor Dzau opened the meeting with remarks that the environment has changed since he was in this same room five years ago at the National Academies announcing the launch of Vivli. He reflected on the journey that led to the formation of Vivli and highlighted the significance of shared clinical research data in facilitating scientific and public health advances. Dr. Dzau highlighted a workshop held in 2012 on sharing clinical research data, which involved participants from various sectors. This workshop initiated a multi-year conversation that culminated in a report by the IOM (Institute of Medicine, now the National Academic of Medicine) in 2015, "[Sharing Clinical Trial Data: Maximizing Benefits and Minimizing Risk](#)." Dr. Dzau acknowledged that many of the authors of the report are part of this meeting today to continue the conversation. The recommendations from this report laid the foundation for the creation of Vivli as an independent and neutral platform. A key aim for Vivli was to create a bridge between existing data sharing platforms.

Dr. Dzau posed several questions to the audience, including whether the principles of the report have been successfully implemented and if the vision set out in the report had been achieved or whether there are now new challenges we must understand now overcome. He also acknowledged the evolving landscape, particularly the emergence of artificial intelligence (AI) and machine learning and emphasized the need for human design and oversight in utilizing these technologies. Dr. Dzau highlighted the importance of discussing AI in the context of data sharing and mentioned ongoing efforts to develop an AI code of conduct in health and medicine by the National Academy of

Medicine. He encouraged the audience to guide conversations on this topic and collaborate with government agencies such as the NIH and FDA to establish acceptable standards for data sharing. Dr. Dzau concluded by expressing his eagerness to hear from the audience and work together to expedite progress in the field.

Keynote addresses
Monica Bertagnolli, M.D., NIH Director
Link to recording

Dr. Bertagnolli, National Institutes of Health Director (NIH), on her fifth day as the NIH director, shared her delight to be speaking at this meeting to talk about the work of the NIH in sharing and use of data to overcome current global health challenges. She stated that it is critical to our ability to take care of people to share data across research efforts and mentioned that there are groups that are under-represented within data sharing, such as older adults, and those with rare diseases. She said that the benefits of new computational methods applied to highly complex and very diverse data collections will make it possible to provide more insights to help individual patients.

She emphasized the need for collaboration and building communities to ensure responsible data sharing becomes standard practice across all of biomedical research; ideally to achieve this all stakeholders' incentives must be aligned. Dr. Bertagnolli highlighted the success of initiatives such as the Childhood Cancer Data Initiative (CCDI) from NCI, which has brought together researchers, patients, and families to share data previously held in silos and improve outcomes for childhood cancer (all of which are rare diseases). In this case, the CCDI community rallied around use of the data that in turn drove incentives to bring data to the platform. She pointed out that the NIH now has more similar programs in-use and under development.

Looking back to the 2015 IOM consensus data sharing report, Dr. Bertagnolli celebrated how far clinical data sharing has come, and also the progress made in delivering better treatments. Along with new therapeutics, data generation has accelerated, and a new challenge for the NIH is storing that data for future sharing. She shared the headlines from the 2015 IOM data sharing report, including that it should serve public interest, foster sound regulatory decisions, opening the door for new research, and increasing knowledge. Dr. Bertagnolli emphasized that there is also a need to engender trust in science, and data sharing is one way to do that, and that success requires the right incentives, the right protections, interoperable data formats, shorter timelines to access data, an engaged and capable workforce and sustainable models for data collection, storage, and use.

Dr. Bertagnolli highlighted the White House's Cancer Moonshot launched in 2016 by then Vice President Biden as a successful initiative that made data sharing a key goal. Every project funded through the Cancer Moonshot has made the underlying data available as quickly as possible, and findings have been published in open access formats. The Moonshot invested in critical data sharing infrastructure such as the Cancer Research Data Commons that is broadly available to the research community. She also shared that the White House Office of Science and Technology Policy has issued guidelines to make federally-funded research freely available, from all agencies including NIH – this will be implemented by the end of 2025.

She reported that the NIH has several pilot initiatives underway to build platforms for research data of all types and the capabilities to meet the FAIR (Findable, Accessible, Interoperable, Reusable) standards; the pilot phase produced as one example the STRIDES initiative a public/private partnership to allow researchers access to cost-effective cloud services. In January 2023, the NIH made effective its policy to require that researchers receiving NIH funding have a plan for sharing their data in their new funding applications. She stated that NIH is grateful to all platforms such as Vivli because now they need a home for these data.

On the topic of engendering trust among patients to allow their data to be shared, Dr. Bertagnolli stated that it has to be done in a way that patients understand and accept, and which maintains their privacy and security. She touched on advancements in computational methods in machine learning, which can also be of concern to the patients.

In closing, Dr. Bertagnolli reiterated that it takes many teams working together to build an ecosystem that ensures responsible data sharing is standard practice, methods must evolve as new challenges and opportunities appear, and that this work will be a central feature of all NIH programs. She re-affirmed her commitment to making this work a central feature of all NIH programs and to use data sharing to realize the full potential of all NIH programs.

Robert Califf, M.D., FDA Commissioner
Link to recording

Commissioner Robert Califf discussed several key points regarding the progress and challenges related to the clinical research system. He highlighted the improvements in data sharing since 2015 when the IOM data sharing report was issued, particularly in terms of compliance improvements in posting of trials and results to ClinicalTrials.gov. Since industry sponsors know that trial results will be posted, initial arguments over contracts regarding publishing negative results have diminished. He also noted that the quality of trial data has improved as more researchers have gained access; sunshine on trial databases has a positive effect. Also previously, institutions often took the position that the institution did not have accountability for investigators' conduct but this has shifted to more support and oversight by research institutions in more recent years.

Dr. Califf stated that traditional randomized clinical trials are improving in terms of quality and transparency, but they are becoming a diminishing part of the decision-making ecosystem. He looked forward to Dr. Monica Bertagnolli's tenure as NIH Director (a keynote speaker in the afternoon session) and welcomed suggestions in the inter-agency possibilities and collaborations. One concern he voiced was that as traditional trial data quality was improving, other types of data and sources were now increasingly influencing healthcare decisions and informing health systems about patient care and decisions; these are performed outside traditional structures that are committed to transparency of methods and data. For example, data aggregators using anonymized data are providing analyses to inform health systems about policies and formularies. Another major concern is the difficulty that clinicians experience as they consider participating in trials due to increasing pressure from health systems and clinical practices on efficiency in practice. He

collectively challenged us to make trials more appealing to clinicians and patients to increase overall participation.

Dr. Califf lastly addressed issues related to governance, permissions and de-identification as the field moves deeper into the world of AI and machine learning. He acknowledged that there may be difficulties in determining the right policies in this evolving landscape. He discussed the potential of AI and machine learning to positively impact the clinical research system for instance by making it easier to clean data and share data across disparate standards and terminologies. These technologies may enable higher-quality simulations using larger datasets; however, he also cautioned against the potential negative consequences of algorithms driven by profit rather than patient care.

The FDA Commissioner ended by praising the success of NIH policies aimed at increasing diversity in clinical trials, pointed out that this positive experience should give us confidence that new policies on data sharing at the NIH should succeed.

Overall, Dr. Califf emphasized the need for ongoing focus on reforming the clinical research system, particularly in the post-market phase, given the opportunity for federal, industry and academic collaboration in this phase.

Panel 1: The 2015 IOM Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk Recommendations and Challenges Ahead

Jeffrey M. Drazen, The New England Journal of Medicine; Bernard Lo, University of California San Francisco; Arti K. Rai, Duke Law; Ida Sim, University of California San Francisco; Joanne Waldstreicher, Becton Dickinson and Structure Therapeutics
Link to recording

Moderator: Bernard Lo, M.D., Professor of Medicine Emeritus, University of California San Francisco and President Emeritus, The Greenwall Foundation

Jeffrey M. Drazen, M.D. NEJM Group Editor, The New England Journal of Medicine
Arti K. Rai, Elvin R. Latty Professor of Law, Duke Law
Ida Sim, M.D., Ph.D., Professor of Medicine and Computational Precision Health, University of California San Francisco; Vivli co-founder
Joanne Waldstreicher, M.D., Independent Director, Becton Dickinson and Structure Therapeutics; Former Chief Medical Officer, Johnson & Johnson (retired); Faculty Affiliate, Division of Medical Ethics, New York University School of Medicine

This panel focused on looking back at what has been achieved in data sharing and looking to the future, the remaining challenges and what more needs to be done.

Dr. Lo introduced the panel, all members of the committee that wrote the 2015 Institute of Medicine (IOM) report on Clinical Trial Data Sharing. He began with an overview of the recommendations

from that report: data sharing should become the norm, and analyzable individual participant data that supports the published findings should be shared, along with supporting documentation. Deidentified individual participant data could thus be used for new discoveries. There should be multiple data sharing platforms with a variety of access models, adequate financial support for data sharing, and fair allocation of costs between data providers and data users. Additionally, disincentives to data sharing should be reduced and risks of patient identification should be minimized, and best practices in data sharing should be identified and improved.

Dr. Lo asked each panelist to state what they thought was the most meaningful recommendation of the report and what needs to be further done to fulfil that recommendation.

Professor Rai started by stating that all the recommendations were significant, but she would focus on how the promise and peril of data sharing is accentuated by rise of AI. The report talked about the benefits of accessing large amounts of data, but at that point the full extent of possibilities using AI had not been anticipated. AI can be used to optimize clinical trials and comparative effectiveness studies, to decipher new indications, and to enhance subgroup analyses. Professor Rai saw the use of ML as a key technological development that offered the promise of both greater benefits and greater risk., Professor Rai spoke about the use of soft law to incentivize data use agreements to address such issues as privacy, security, confidential information, scope of data and ownership of the outcomes of secondary work. She encouraged private sponsors to work together on approaches for protection of commercially confidential information (CCI). She would also like to see companies sharing more data on abandoned and failed drugs in order to advance collective knowledge. She praised the work the NIH is doing to mandate more data sharing and hoped that the FDA and the European Medicines Agency (EMA) would do more in terms of hard (mandatory) law.

Dr. Drazen pointed out that since the IOM report, many of the fears about data sharing have not come to pass. For example, there have been very few secondary analyses using the data to recreate the original analyses and dispute the published findings. A second fear was that secondary researchers would access datasets and publish additional analyses before the original investigators had a chance to fully analyze and publish all they had planned. This has not been a widespread problem. Dr. Drazen said that it's great to see large fractions of trials from Pharma companies shared clinical trials data, driving forward clinical practice. Although he suspects the number is low, he would like to know what proportion of data requests are denied by sponsors because of concerns about data misuse. Dr. Drazen said that the bad news about data sharing is that academics are not contributing data as often as they should; he hoped that this would change with the new NIH policy. Academics generally don't have the resources, know-how, or desire to share data in a suitable format, an issue that needs to be addressed.

Dr. Sim said a major success is several data sharing platforms, which the NIH Generalized Repository Ecosystem Initiative (GREI) has shown are working together. She then asked how data are shared, and whether "the juice is worth the squeeze". For individual academic investigators, the practicalities of sharing their data are daunting. She asked what academic institutions are doing to support their researchers, and whether data sharing should be an institutional responsibility. Dr. Sim said data sharing should cover not just randomized clinical trials, but also other types of human participants research, including qualitative and social science studies. Dr. Sim said that de-

identification of data is an issue because it is a spectrum rather than an either-or dichotomy. Legal, policy and technical experts need to develop policy recommendations to support investigators sharing data effectively, which requires sharing not only data but also supporting information to allow others to understand and use the data. Artificial intelligence (AI) and ML could go some way to democratizing the data re-use through the FAIR principles (findable, accessible, interoperable, reusable). Another aspect of data sharing that needs to be discussed is real-world evidence generation.

Dr. Waldstreicher said that, in her view, the most meaningful part of the IOM report for pharma was that sharing clinical trial data was now the default position. Large pharma companies have put significant resources behind data sharing. She felt that the report also set out important guardrails for innovation within the ecosystem, such as ensuring that data sharing was only required after regulatory approval to give the FDA and EMA a quiet period to review the submissions and potentially carry out additional analyses. Another important guardrail was that sponsors are required to share data from phase II, III and IV clinical studies, but not phase I/healthy volunteer studies; sharing data from all phase I studies would be a significant burden with so many small studies in healthy volunteers that likely had less overall value for science and clinical care. Data sharing, including by academic investigators, should focus on ensuring sharing data from trials with clinical impact. From a pharma perspective, the benefits of data sharing are trust, transparency and honoring the participants contributing to the broader world of science beyond product development. She felt that, together, requiring publication of study results and data sharing had raised the quality of trials and publications. Pre-approval trials are scrutinized by health authorities, but now that data from post-approval studies are published and can also be shared and scrutinized has led to more attention and rigor. Some companies have also reported that external data sharing, policies and procedures for internal data sharing have also been tightened, thereby strengthening the commitments made to participants. To address Dr. Drazen's question, Dr. Waldstreicher said that in her experience with the YODA/J&J effort, data sharing requests are seldom refused. If they are not shared, it might be, for example, because the requestor did not specify a research question that could be addressed by the data, or the product may not be approved yet. Something to think about for academic data sharing efforts is whether there should always be a scientific review of data requests to ensure that the data will be used for a valid, pre-defined purpose and has a solid data analysis plan, as the reviews by the YODA team led to changes in a approximately a third of requests for J&J data.

Dr. Lo invited the panel members to provide a closing thought.

Dr. Sim charged the group with thinking about real-world evidence – what evidence are we looking for and what are we hoping it will do for us? Should research always be hypothesis-driven, or is this too constraining in the ML world and closing the door to valuable science?

Dr. Drazen emphasized that we need to enroll patients in clinical trials across the spectrum of the disease and not just those who can afford to buy the medicine, and that those data should be shared widely. Patients enrolling in trials should be told how they are contributing to the broader scientific endeavor.

Professor Rai reiterated the need for soft law in data sharing. She questioned whether hard law was needed in the pre-approval space, although it is needed for AI.

Dr. Waldstreicher ended with a reminder that the spirit of the report was to maximize benefits and minimize risk. Because the data sharing landscape has changed since 2015, another look is needed to set out new opportunities and guardrails, and especially to protect the privacy of participants given the new advances in data science.

Dr. Lo thanked the panelists and closed the session.

Summary of breakout session on visioncasting

Dr. Lo and Dr. Rai facilitated and summarized the visioncasting breakout session. The main themes included the need for standardization and the reasons why standardization is so hard to achieve. Every trial group uses its own variation of data standards, although industry tends to use CDISC/STDM standards. Smaller companies and academia would benefit from templates and examples of data standards to follow. The group also discussed education and the role of data management professionals. There was a discussion about meta-analysis and how this skill is not as valued in the U.S. as elsewhere, such as in the U.K.. The group called for educating early-career researchers about meta-analysis and its value. The group also discussed open-source software and privacy.

Panel 2: The Value of Data Sharing Realized

Ricardo Jorge de Oliveira Ferreira, Nursing School of Lisbon; Murray Stewart, Vivli Board member; Richard Liwski, Critical Path; Rebecca Li, Vivli; Sarah Nevitt, University of York; Ronald Summers, NIH Clinical Center
Link to video

Moderator: Murray Stewart, M.D., Chief Medical Officer, Rhythm Pharmaceuticals, Inc., Vivli Board member

Ricardo Jorge de Oliveira Ferreira, Ph.D., Auxiliary Researcher at the Nursing Research, Innovation and Development Centre of Lisbon (CIDNUR), Nursing School of Lisbon (ESEL)
Richard Liwski, Chief Technology Officer and Director, Critical Path Institute's Data Collaboration Center
Rebecca Li, Ph.D., CEO and co-founder, Vivli
Sarah Nevitt, Ph.D., Senior Research Fellow, Centre for Reviews and Dissemination, University of York
Ronald Summers, M.D., Ph.D., Senior Investigator, Imaging Biomarkers and Computer-Aided Diagnosis Laboratory, NIH Clinical Center

This panel focused on real-life case studies that demonstrate the culmination of efforts to share data and its impact on science. The case studies focused not only on how those data sharing efforts added to scientific knowledge, but also how the sharing of data helped improve the lives of patients.

Dr. Murray Stewart introduced the panel and reflected on his experiences with sharing data at GSK and how when we start seeing changes in clinical decision making, that shows the value of data sharing.

A [video](#) was shown of Ricardo Jorge de Oliveira Ferreira, an Auxiliary Researcher at the Nursing Research, Innovation and Development Centre of Lisbon (CIDNUR), Nursing School of Lisbon (ESEL), discussing his research that reviewed the scoring criteria for whether a patient with rheumatoid arthritis is in remission. His research analyzed 6,000 patients and found that based upon one question about the burden of the disease, 19% failed to achieve remission, even though there were no differences in terms of radiographic damage, progression, or bone erosions. This led to Dr. Ferreira and his research team proposing an updated dual target model to replace the current target strategy. This has led to further research to determine the feasibility and effectiveness of this new model of care.

Dr. Stewart asked Dr. Ferreira how easy it was to access and perform the analysis. Dr. Ferreira said that prior to Vivli he requested the data from four different sponsors. It was time-consuming and difficult to manage four separate requests. Once three of the sponsors migrated to Vivli and the fourth to YODA it was much easier. He then put in a separate new request directly to Vivli and that facilitated the process. He has been sharing the process with researchers in Europe, so they understand the improved process.

A [video](#) was shown of Sarah Nevitt, Senior Research Fellow, Centre for Reviews and Dissemination, University of York, discussing a network meta-analysis that she published in the Cochrane Library in 2022 using data from 39 clinical trials involving 15,000 participants with a new diagnosis of epilepsy. The meta-analysis looked at the effectiveness of 11 different medications currently used for two different epileptic seizure types. The results of this network meta-analysis have directly informed the update of UK guidelines, which were published in 2022. This research is already informing the treatment of patients newly diagnosed with epilepsy in the UK.

Dr. Stewart asked Dr. Nevitt why she and her team went to the effort of conducting a network meta-analysis versus using summary-level data. Dr. Nevitt shared they choose this approach so that people with epilepsy and their health care providers can have a more personalized discussion around which treatment may be suitable for them, based on their own clinical characteristics, and their own priorities.

Rick Liwski, Chief Technology Officer and Director, Critical Path Institute's Data Collaboration Center, spoke about a project creating a qualification of total kidney volume for polycystic kidney disease trials. The project provided evidence for a new prognostic biomarker for the FDA. The team spent most of their time on this project collecting the data, signing legal contracts, and then curating and standardizing the data. The outcome of this is that the FDA approved the biomarker as a surrogate endpoint. Since that time, the first drug to treat polycystic kidney disease has been approved and now there are many more drugs in the pipeline.

Dr. Stewart then asked Mr. Liwski about other projects Critical Path is working on and he shared that they are working on more than 20 different projects across 17 consortia. For example, they are working on a disease progression model for Alzheimer's using 41 studies.

Dr. Ronald Summers, Senior Investigator, Imaging Biomarkers and Computer-Aided Diagnosis Laboratory, NIH Clinical Center, spoke about a project his center performed in 2017 releasing a large data set of chest radiographs and using AI to improve chest radiograph interpretation. At that time, there were no standards and so the group manually inspected 100,000 chest radiographs for protected health information (PHI). The data set has been downloaded more than 60,000 times and currently has 3,700 citations. Other groups have followed suit to share their chest images which has led to more funding to enable this type of data sharing.

Dr. Stewart expressed his admiration for this work and asked what advice he would give to a researcher wanting to undertake this kind of research. Dr. Summers said that the biggest lesson was the importance of the accurate labeling of images. He said it was important to not just release the images but release accurate labels that were understood.

Rebecca Li, Vivli CEO, spoke about the case study of Vivli and she referred to a paper published 7 years ago, "Is the Juice worth the Squeeze?" in reference to data sharing and indicators of the impact of data sharing from that time period. The Vivli platform was created as a unified platform to make data discoverable and analyzable in one place. Today Vivli has more than 230 publications from proposals received to date. The number of publications have dramatically increased in the past few years as has Vivli's global reach but there remain gaps in certain regions. In addition, Vivli has coded the publications to look at seven outcome categories and more than half of the publications were found to inform patient care decisions. Other top outcomes included shaping clinical trial design and tools such as web-based decision calculators.

Dr. Stewart thanked the Vivli team for their hard work. He then asked about the gaps data re-use in Africa, Asia and South America. Dr. Li agreed these were significant gaps and that Vivli wished to collaborate with others in the data sharing ecosystem to close those gaps, particularly in Africa.

The panel then took questions from the audience. The first question was for Dr. Li about the % proposal approvals. Dr. Li said that Vivli has over 89% of the requests it received that have been approved. Those requests that are denied, the vast majority due to studies being requested out of scope as they do not meet the sponsor's criteria for sharing.

The next question asked whether there was a correlation between making data more openly available, and the data being used more or cited more often. The panelists responded that the fewer barriers that are imposed the more likely the data is to be accessed. The final question to the panel was about sharing more rare disease data. The panelists replied that there does seem to be a willingness to share rare disease data but that the big challenge is making sure the data is properly anonymized to protect patients' privacy which is a challenge for rare disease data. The panel noted that the challenge remains, but having platforms to share data was a big step forward to ensuring access to those data sets in future, long after the trial has been completed.

Dr. Stewart thanked the panelists for the discussion and closed the session.

Panel 3: Credit and incentivizing the academic culture.

Elliott Antman, Harvard Medical School; Barbara Bierer, MRCT Center, Brigham and Women's Hospital and Harvard Medical School; Daniel Ernest Ford, Johns Hopkins Institute for Clinical and Translational Research; Benjamin Pierson, Bill & Melinda Gates Foundation

Link to video

Moderator: Barbara E. Bierer, M.D., Faculty Director, MRCT Center, Brigham and Women's Hospital; Professor of Medicine, Harvard Medical School; Director Regulatory Foundations, Ethics and Law, Harvard CTSA; Vivli co-founder

Elliott Antman, M.D., Director, Harvard Postgraduate Program in Clinical/Translational Science, Professor of Medicine, Harvard Medical School
Daniel E. Ford, M.D., M.P.H., Director & Professor of Medicine, Senior Associate Dean for Clinical and Translational Research, Johns Hopkins Institute for Clinical and Translational Research
Benjamin Pierson, Deputy Director, Enterprise Data, Bill & Melinda Gates Foundation

This panel focused on data sharing in the academic setting and the question of whether investigators can be incentivized and/or supported to be more successful data contributors. The panel discussed funding sources and activities related to data sharing that require funding including data management planning, anonymization, secondary analysis, and publication. Reflections on the overall goals of data sharing, a need for data sharing standards, and the complexity of the academic promotion process were shared.

Elliott Antman started the conversation by acknowledging the leadership of Vivli in advancing data-sharing efforts. He referred to a 2019 report he co-authored on individual patient-level data sharing for continuous learning. The discussion focused on obstacles to data sharing, particularly the tension between primary data generators and secondary data users. He mentioned certain challenges including insufficient incentives for primary researchers to share, consent and privacy issues, operational expenses, and the lack of research standards for data sharing. Dr. Antman emphasized the need for an authoritative body to establish standards to encourage the widespread adoption of data-sharing principles. He also highlighted the importance of defining metrics for success, with the goal being the improvement of healthcare through the adoption of common metrics.

Dan Ford shared insights on data sharing from the perspective of the clinical investigator, particularly focusing on the challenges and priorities faced by young investigators. He emphasized the need for academic institutions to take responsibility for Clinicaltrials.gov reporting. Dr. Ford suggested that implementation of data sharing does not appear to be a top priority for young investigators, and the NIH's requirement for a data-sharing plan, therefore, has been essential. He proposed the establishment of national consent standards for data sharing in clinical trials to facilitate wider uptake. Dr. Ford also discussed the tension between data generators and users, highlighting the lack of a team-oriented approach in data-sharing proposals. He advocated for a

more collaborative model, suggesting that early engagement with data contributors could enhance the understanding and analysis of subgroups. He underscored the importance of focusing on subgroups for optimized study design. Additionally, he shared experiences from the COVID-19 pandemic, where efforts to encourage real-time data sharing faced resistance from principal investigators due to potential trial disruptions. Dr. Ford concluded by emphasizing the need for a shift in the academic and funding structures to enhance support for data-sharing initiatives.

Ben Pierson, representing the Bill & Melinda Gates Foundation, discussed the Foundation's mission and the unique value of data in achieving their goals which include eradicating diseases and reducing disparities in health outcomes, poverty, and education. He emphasized the importance of data for decision-making, broad-based evidence, and innovation.

He shared challenges faced in implementing the Foundation's 2015 open access policy, highlighting that less than 1% of funded research data was effectively shared. The discussion also delved into the role of data in responding to the COVID-19 pandemic and the need for speed in data sharing. He outlined the Foundation's efforts to improve data sharing by incorporating data management and sharing plans into grant agreements, ensuring specificity on metadata and the data repository. He emphasized the shift from a philanthropic funder perspective - from viewing data repositories like Vivli as separate data sharing infrastructure to treating them as services for research grantees to meet data sharing requirements. Moving forward, challenges include operationalizing consistent data sharing, addressing privacy concerns, navigating global privacy regimes, and ensuring equity in data sharing practices, particularly concerning data flow between high-income and low-and-middle-income countries. He suggested that there was a need for funders to collaborate and share best practices, emphasizing the importance of interoperability and standardization in data-sharing initiatives.

Barbara Bierer emphasized the importance of standardization in data sharing, suggesting that data dictionaries, protocols, and metadata should be shared as a best practice along with individual participant data (IPD). She addressed the consent issue, noting that in the Vivli model implementation, where data is provided via a managed process, privacy concerns are considerably less acute than in an open data model in which data can be downloaded. Dr. Bierer highlighted the distinction between the perspectives of data scientists and clinical investigators, with data scientists desiring freely available data, while clinician investigators tend to be more cautious about data sharing.

In the question-and-answer section of the panel, a participant expressed the need for standards in data sharing. They proposed creating standards for data sharing that facilitate reuse in a semantically coherent way. The participant suggested that statisticians could play an important role in initiating this effort, with a call to action for interdisciplinary collaboration, potentially involving recipient institutions of NIH's Clinical and Translational Science Awards (CTSAs). The panel agreed on the importance of semantic coherence and the engagement of statisticians, highlighting that statisticians on research teams may drive the implementation of those standards. The conversation touched on the need for teamwork and the importance of changing the academic culture to provide credit to collaborative efforts. The discussion also mentioned the potential for incentivizing data sharing beyond first-author publications. The conversation then shifted to address the challenges

and opportunities related to data management plans (DMPs) and the early inclusion of standardized data in repositories.

In the breakout session moderated by Dr. Bierer, the challenge of academic credit for data sharing and ideas on how to incentivize data generators in academia were discussed. The primary focus was on the academic culture that emphasizes traditional metrics such as first and last authorship in publications, metrics that are not suitable for evaluating contributions to data sharing. The conversation explored the difficulties in finding alternative pathways to assess academic scholarship and included concerns about the interpretation of primary data generators by secondary data users.

Various proposed solutions were discussed, such as crediting datasets with DOIs to track their impact and value over time. The discussion recognized the mismatch between the current academic credit practices and the changing landscape of data sharing, pointing out the need both to address the contribution of less well-resourced individuals, groups, and countries and to reconsider the ownership of data collected. The overall message acknowledged the complexity of the issue and the recognition that more in-depth consideration is needed.

Panel 4: Key Technologies that will Influence Data Sharing (Machine learning, AI)

Joshua C. Mandel, Microsoft; Philip Payne, Institute for Informatics, Data Science and Biostatistics (I2DB), Washington University School of Medicine in St. Louis; Jane Perlmutter, Gemini Group Consultancy; Ida Sim, University of California San Francisco
Link to video

Moderator: Ida Sim, M.D., Ph.D., Professor of Medicine and Computational Precision Health, University of California San Francisco; Vivli co-founder (moderator)

Joshua C. Mandel, M.D., Chief Architect for Healthcare, Microsoft
Philip Payne, Ph.D., FACMI, FAMIA, FAIMBE, FIAHSI, Director, Institute for Informatics, Data Science and Biostatistics (I2DB); Chief Data Scientist and Associate Dean of Health Information & Data Science; Washington University School of Medicine in St. Louis
Jane Perlmutter, M.B.A., Ph.D., President and Founder, Gemini Group Consultancy

This panel focused on the implications and opportunities of generative artificial intelligence (AI) in the realm of data sharing, particularly pertaining to clinical research data. Ida Sim, the panel moderator, framed the conversation around the distinctive nature of generative AI compared to traditional machine learning (ML). While ML often generates predictions or numeric outcomes, generative AI processes textual data (most of the internet content) to produce coherent text, such as sentences, stories, or descriptions. The focus for the panelist presentations and wider discussion

was on potential impacts on data sharing, encompassing data generation, study design, integration, quality assurance, query extraction, and broader user accessibility.

The first panel presenter, Philip Payne, highlighted how generative AI could democratize data access by creating abstraction layers. It could help those without technical expertise to access and interpret complex datasets, potentially leading to easier code generation. However, he cautioned that this might obscure critical details, affecting reproducibility and rigor in data analysis.

Panelist, Josh Mandel, emphasized the importance of transparency in utilizing generative AI for broader audiences, including the general public and research participants. He highlighted the role of AI in making the processes on data-sharing platforms more visible and comprehensible, albeit with the need for caution to avoid errors and inaccuracies.

Panelist Jane Perlmutter, spoke from a patient advocate perspective, and emphasized the significance of generating plain language summaries for public understanding and accessibility. Generative AI might also be useful for improving patient facing information material, including Informed Consent documents. She also stressed the potential of utilizing shared clinical trial data not only for drug development but also for treatment optimization. This can include optimizing doses, schedules and/or sequences as well as , identifying differences across patient populations.

The panel's presentations were followed by a roundtable discussion and then a Q&A session involving the in-person and virtual audiences. The discussion primarily revolved around the responsible use of AI, particularly in healthcare contexts. The panelists and audience participants discussed the need for guardrails to balance the exciting possibilities of AI with potential risks and maintain trust in AI-driven systems. Participants raised real-world examples focused on data sharing, generative AI in writing plain language summaries, and the challenges and solutions regarding the application of AI in various healthcare scenarios.

Dr. Perlmutter expressed the importance of ensuring that humans review AI-generated plain language summaries and patient facing material. She also advocated for improved patient engagement in clinical trials and the need for optimized communication between data scientists and clinicians to maximize the benefits of AI in clinical trials.

Dr. Mandel discussed the implementation of responsible AI principles at Microsoft, emphasizing the importance of industry consensus in deploying AI tools in healthcare settings. He also stressed the need for rigorous testing, including randomized controlled trials, to evaluate the broader outcomes of AI model deployments.

Dr. Payne emphasized four critical questions for evaluating AI-driven interventions in healthcare: right data, right task, evidence standards, and real-world deployment. He underscored the importance of ensuring the feasibility and impact of AI interventions in clinical workflows.

The audience participants offered perspectives on the challenges of implementing AI in pharmaceutical development, the significance of storytelling to overcome barriers in adopting AI, and the use of AI in writing informed consent documents. They also explored the need for transparency in AI models, including the importance of disclosing training data and prompts used in generating AI outputs.

Overall, the conversation in this panel, and in the accompanying breakout session, emphasized the importance of establishing guardrails for AI in healthcare. Transparency, thoughtful governance, ethical considerations, continuous evaluation, and improvement of AI models were identified as critical factors in ensuring trust and reliability in their application within the healthcare domain. The need for collaboration and establishment of common standards among various stakeholders, including patients, researchers, and industry experts, emerged as a key element in leveraging AI's potential while developing systematic approaches to assess and address risks.

Panel 5: Regulations and policies to promote data sharing and re-use

Steven Kern, Global Health Labs; Michael Lauer, NIH Office of the Director; Deven McGraw, Invitae; Sharon Terry, Genetic Alliance
Link to video

Moderator: Steven Kern, Ph.D., Executive Director, Global Health Labs

Michael Lauer, M.D., Deputy Director for Extramural Research, NIH Office of the Director
Deven McGraw, J.D., M.P.H, LLM, Lead, Data Stewardship and Data Sharing, Invitae
Sharon Terry, M.A., Chief Executive Officer, Genetic Alliance

Given recent shifts in national policies to promote data re-use as well as efforts by publishers to promote data reuse, this panel focused on what more can be done by regulators, national governments, publishers and other key actors to advance data sharing and subsequent re-use. Dr. Steven Kern introduced the panel and asked them to share their perspective on what they bring to the conversation.

Michael Lauer shared that the NIH recently implemented a policy that requires grant applicants and recipients to submit data sharing plans and follow them.

Deven McGraw shared that in her role as lead of data stewardship and data sharing at a genetic testing company, she is involved in broader data sharing issues beyond clinical trial data. Ms. McGraw also shared the observation that there are existing federal measures that compel data sharing in various contexts but questioned whether similar, more forceful steps are needed specifically for clinical trial data sharing.

Sharon Terry had a personal interest in data sharing as her children were diagnosed with a rare genetic disorder in 1994, and since 1996 she has been involved in establishing data sharing platforms. She emphasized the importance of aligning policies with people's needs and expectations, drawing from her experience of building such initiatives from the ground up.

Dr. Kern then asked the panel to reflect on the types of policies and infrastructure needed to enhance data sharing, framing this as both the structures and incentives to move the field forward.

Dr. Lauer reflected on the evolving nature of policies, guidance, and procedures related to data sharing and how incentives can encourage researchers to publish their work as well as their datasets. He also shared that there is work being done to promote data standards as well as data sharing, and how certain metrics such as one used by his colleague called the 'S' or Sharing Index could be used as an incentive for promotion and tenure discussions.

Dr. Kern reflected that it should be more valuable to a researcher professionally to see their data re-used and new insights identified than to have their original paper cited, so ideally there needs to be a shift in the perceived value of data sharing.

Dr. Kern posed a question about whether the panel could see a day when grants would be refused because the data sharing plans were not robust. Dr. Lauer shared that the NIH is proactively addressing this potential for conflict by instructing staff to evaluate data sharing plans with an emphasis on viable plans for sharing. The NIH is pulling in experts to support the review of data management plans, particularly complex ones.

Ms. Terry spoke on policies that would help individuals become more involved in promoting and moving towards the sharing policy, starting with the acknowledgment of the challenge to do so within the current healthcare system. Ms. Terry advocated for the need for a more patient-centered and responsive approach, building on patient-focused drug development and real-world evidence as examples that are moving in the right direction.

Ms. McGraw acknowledged the progress made since the original IOM report on data sharing but stated that there is an opportunity to change the culture around data sharing with greater haste with incentives, but not relying solely on punitive measures. Ms. McGraw spoke about the pain points that entities who are already embracing data sharing are facing such as funding, risk minimization and accountability, and how attention to these issues could remove barriers. She also spoke about how changes this significant in the culture will take time and may require concessions to the current state to encourage more substantive data sharing without resorting to unsuccessful forceful measures that may undermine long term success.

Dr. Kern reflected on his own experience working at the Gates Foundation running a data challenge where researchers were given tools and access to data to come up with interesting questions and some groups were funded to do further research. Given the right incentives and tools to be able to continue their research, a subset of researchers continued the research even without funding.

Dr. Kern posed the question of what can be learned from other fields that experience similar challenges.
Ms. Terry also suggested learning from business model shifts in industries like ride sharing and music sharing. The fears of the shifts within those industries were not realized, but the business models changed. There is an opportunity to experiment and provide "safe harbor" pilots that mandate more data sharing. Dr. Kern and Dr. Lauer connected this to the similarity of one of the pilots, N3C experience, from the NIH during the COVID pandemic to encourage CTSAs to share data.

Ms. McGraw discussed that the US Congress in the '21st Century Cures Act' passed information blocking rules, which penalize healthcare entities for not sharing electronic health information for lawful purposes. Enforcement has just begun, and it remains to be seen if the law will be effective or face legal challenges. While the law is focused on clinical decisions, payment decisions, and patient access, Ms. McGraw suggested it could potentially be extended to include research as a priority use case in the future.

Dr. Kern reflected on the challenge of data sharing that many feel responsible, but there is no one entity that actually is responsible for aggregating or harmonizing data, and this might create an opportunity within the biomedicine/data sharing space. The cost for data sharing and how to manage a business model to support this harmonized approach remains complicated and unclear. For some of the larger funders to provide extra funding to enable researchers to share their data would be helpful and needs to be mandated up front. Dr. Lauer shared that at the NIH, they consider costs for data curation, management and sharing as costs that can be directly charged to the grant and that at this time, they are doing informal analysis to better understand the cost of data sharing to help research teams make an appropriate request in their applications.

Ms. McGraw highlighted the lack of cost awareness in proposals related to data sharing initiatives and emphasized the need for practical guidance on the expenses involved in data sharing. She suggested there was a need to provide examples and practical insights for different types of data sets and how they will be used. The IOM report discussed spreading the cost amongst all groups that benefit, including the public, so potential solutions may consider including a small tax on US insurance premiums or public money allocation, to support the creation of an ecosystem where data sharing is the norm, to ensure associated costs are adequately addressed. Ms. Terry reflected on the patient perspective and willingness to participate and share their data and noted that people are ready to share their data when it feels safe and particularly when the invitation to share data comes from within a community. Dr. Lauer echoed this sentiment from his own experience being a participant in a study in which he was able to define his own level of comfort with his data being shared.

The panel then took questions from the audience. The first question was a reflection on the challenge of balancing the regulations and incentives to share and potential for penalties. Ms. McGraw emphasized that laws do not necessarily create obstacles, but instead conservative interpretations that then prevent data sharing may create hurdles to sharing.

The second question came from an individual involved in a collaboration in rare disease trying to enhance clinical trials. They stated that there is a growing concern about sharing data because these data are valuable and could be monetized. They stated intellectual property concerns, (sharing without financial commitments). The panelists reflected on how information blocking rules can support moving past these proprietary interests. They expressed anticipation to see how the enforcement of hard law, such as the information blocking rules, will impact data sharing. They

discussed the complexity of intellectual property issues in quantitative research and the need for clarity in this regard.

The next question asked Dr. Lauer what the NIH would do if a researcher states in their grant application that their data sharing costs will be zero, and whether they allow changes to that line item. Dr. Lauer shared that the NIH has shared a guide to support the accounting and finance piece of data sharing as it is complex. Another participant emphasized that the financial model of grants within institutions needs to be changed to ensure funding for data sharing is available and is not based on individual projects.

Ms. Julie Wood summarized that virtual participants were suggesting a number of resources were already available to support data sharing: the data curation network, the DMP (data management plan) tool model, librarians, and data research services.

Dr. Kern thanked the panelists for the discussion and closed the session.

In the breakout session discussing this topic, the overall barrier discussed was the diversity of rules and standards and lack of uniformity in the standards and rules arena. Some implementation of uniform standards could provide structure that the community is seeking in order to minimize the "analysis paralysis" that can hinder data sharing. The group highlighted that one of the key solutions to data sharing challenges is developing a more patient-centric model that involves patients in data sharing discussions and keeps patients at the core of data sharing.

Discussion and Next steps

The vision session aimed at big-picture thinking and addressed the complexity of standardization, particularly the need to define what is meant by "standards" as there are variations among different groups, with industry being generally more comfortable with the idea of standards than academia. Discussants highlighted the utility of templates and examples over directive standards, especially for academia and smaller companies. The session also touched on the global appreciation of meta-analysis as a valuable skill. The discussion concluded with an acknowledgment of the need to work on these issues in a multistakeholder fashion over a period of time with the understanding that these could not be solved immediately.

The academic incentives session grappled with the issue of how to properly credit academic data contributors for data sharing, highlighting the challenge of evaluating academic scholarship and the long wait for researchers to see the value of their data through secondary use. Concerns were raised about the correct interpretation of "data" by secondary users and the potential for broad authorship, which complicates the credit system. The session also touched on the need to value contributions from less-resourced individuals and groups and the concept of data ownership, suggesting that data is owned by the individuals it pertains to, not the collectors. Solutions such as crediting datasets with DOIs for traceability and acknowledging the broader impact of data beyond

initial publication were considered, though no definitive solutions were reached. The discussion acknowledged the deep-rooted issues in the current academic credit system.

The AI session centered on the use of data in repositories for building AI models, particularly for patient care, and identified several red flags associated with such use, including closed-loop functioning, non-transparent (black box) AI, large language models, and biases in the underlying data. The discussion suggested that collaboration with primary data contributors might be necessary to address these concerns. However, there was debate on whether the concerns for AI models are unique or also applicable to statistical models. The group proposed establishing a systematic process to assess risks and develop community consensus on governance structures for AI's intersection with data sharing. References were made to existing AI efforts that could inform the governance principles for data repositories. The session concluded with the idea of an action item to develop overarching governance principles that individual data repositories could adapt and implement.

Closing Remarks

Dr. Lo and Dr. Li expressed gratitude to the audience for their participation and for discussing the advancements and challenges in data sharing since the 2015 IOM report. They acknowledge all speakers and participant's contribution to progress in the field. There are new challenges, including generative AI and data sharing as well as the promise of advocacy by the FDA Commissioner and incoming NIH Director working together jointly. Both speakers emphasized the significant progress made and the eagerness of leadership to engage with ideas from the community. Most importantly, there have been set goals, reflecting diverse advancements across the stakeholder ecosystem.

Appendix 1: Meeting Agenda

Shaping the next 10 years in Data Sharing:
Building on the gains made and looking ahead
to the next 10 years in advancing human health

November 16th, 2023, 8:30am-4:00pm EST
Room 120, National Academy of Sciences,
2101 Constitution Ave. NW, Washington, DC 20418

Hybrid Conference

8:30am - Registration and coffee
9:00am - Victor J Dzau, M.D., President, National Academy of Medicine**—Welcome**
Morning keynote **Robert Califf, M.D.** FDA Commissioner
The 2015 IOM <u>Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk</u> **Recommendations and Challenges ahead** Should we collectively set a new "north star" for the next 10 years? Moderator: **Bernard Lo, M.D.**, Professor of Medicine Emeritus, University of California San Francisco • **Jeffrey M. Drazen, M.D.** NEJM Group Editor, *The New England Journal of Medicine* • **Professor Arti K. Rai,** Elvin R. Latty Professor of Law, Duke Law • **Ida Sim M.D., Ph.D.,** Professor of Medicine and Computational Precision Health, University of California San Francisco; Vivli co-founder • **Joanne Waldstreicher, M.D.,** Independent Director, Becton Dickinson and Structure Therapeutics; Former Chief Medical Officer, Johnson & Johnson (retired); Faculty Affiliate, Division of Medical Ethics, New York University School of Medicine
The Value of Data Sharing Realized This session will focus on real-life case studies that show the fruition of efforts to share data and its impact on science. Moderator: **Murray Stewart, M.D.**, Chief Medical Officer, Rhythm Pharmaceuticals, Inc.

- **Ricardo Jorge de Oliveira Ferreira, Ph.D.,** Auxiliary Researcher at the Nursing Research, Innovation and Development Centre of Lisbon (CIDNUR), Nursing School of Lisbon (ESEL)
- **Richard Liwski,** Chief Technology Officer and Director, Critical Path Institute's Data Collaboration Center
- **Rebecca Li, Ph.D.,** CEO and co-founder, Vivli
- **Sarah Nevitt, Ph.D.,** Senior Research Fellow, Centre for Reviews and Dissemination, University of York
- **Ronald Summers, M.D., Ph.D.**, Senior Investigator, Imaging Biomarkers and Computer-Aided Diagnosis Laboratory, NIH Clinical Center

11:00am Coffee break

Credit and incentivizing the academic culture
With the recent policy announcements by the White House and the newly updated NIH Data Management and Sharing Policy, movements are afoot to prompt academic researchers to share. What more can be done to encourage academic researchers to share their data by leveraging incentives?

Moderator: **Barbara Bierer, M.D.**, Faculty Director, MRCT Center, Brigham and Women's Hospital; Professor of Medicine, Harvard Medical School; Director Regulatory Foundations, Ethics and Law, Harvard CTSA; Vivli co-founder

- **Elliott Antman, M.D.,** Director, Harvard Postgraduate Program in Clinical/Translational Science, Professor of Medicine, Harvard Medical School
- **Daniel Ernest Ford, M.D., M.P.H.,** Director & Professor of Medicine, Senior Associate Dean for Clinical and Translational Research, Johns Hopkins Institute for Clinical and Translational Research
- **Benjamin Pierson,** Deputy Director, Enterprise Data, Bill & Melinda Gates Foundation

11:45am Lunch keynote
Monica Bertagnolli, M.D., NIH Director

Key technologies that will influence data sharing (Machine learning, AI)
What role with key technologies such as Generative AI and other key technological advances play in data sharing? What are the key motivating factors and obstacles that will need to be addressed?

Moderator: **Ida Sim M.D., Ph.D.,** Professor of Medicine and Computational Precision Health, University of California San Francisco; Vivli co-founder

- **Joshua C. Mandel, M.D.,** Chief Architect for Healthcare, Microsoft
- **Philip Payne, Ph.D., FACMI, FAMIA, FAIMBE, FIAHSI,** Director, Institute for Informatics, Data Science and Biostatistics (I2DB); Chief Data Scientist and Associate Dean of Health Information & Data Science; Washington University School of Medicine in St. Louis
- **Jane Perlmutter, M.B.A., Ph.D.,** President and Founder, Gemini Group Consultancy

Regulations and policies to promote data sharing and re-use

Given recent shifts in national policies to promote data re-use as well as efforts by publishers to promote data reuse, what more can be done by regulators, national governments, publishers and other key actors to advance data sharing and subsequent re-use?

Moderator: **Steven Kern,** Executive Director, Global Health Labs

- **Steven Kern, Ph.D.,** Executive Director, Global Health Labs
- **Michael Lauer, M.D.,** Deputy Director for Extramural Research, NIH Office of the Director
- **Deven McGraw, J.D., M.P.H, LLM**, Lead, Data Stewardship and Data Sharing, Invitae

Sharon Terry, M.A., Chief Executive Officer, Genetic Alliance

2:15pm Coffee break

Shaping the inputs and direction for the next 10 years – All Participants

4 breakout sessions – led by moderators:
- Academic culture change
- Key technologies/AI
- Regulations and policies to promote data re-use
- Visioncasting

A way forward
Actions and next steps from breakout groups

Appendix 2: Speaker Biographies

Elliott Antman, M.D.

Director, Harvard Postgraduate Program in Clinical/Translational Science, Professor of Medicine, Harvard Medical School

Elliott Antman is faculty lead of Postgraduate Education in Clinical and Translational Science at Harvard Catalyst. He is a senior physician specializing in cardiovascular medicine at Brigham and Women's Hospital (BWH), as well as professor of medicine at Harvard Medical School (HMS). Antman's clinical interests include acute coronary syndromes, atrial fibrillation, and myocardial infarction. His research focuses on the clinical pharmacology of cardiovascular agents and evaluation in randomized control trials. He served as President of the American Heart Association in 2014-2015. He received his medical degree from Columbia University College of Physicians and Surgeons, completed an internal medicine residency at Columbia-Presbyterian Medical Center (now New York-Presbyterian Hospital), and a cardiology fellowship at Peter Bent Brigham Hospital.

Monica Bertagnolli, M.D.

Director of the National Institutes of Health (NIH)

Monica M. Bertagnolli, M.D., is the 17th director of the National Institutes of Health (NIH). She was nominated by President Joe Biden on May 15, 2023, confirmed by the U.S. Senate on November 7, 2023, and took office on November 9, 2023. She is the first surgeon and second woman to hold the position. As the NIH Director, Dr. Bertagnolli oversees the work of the largest funder of biomedical and behavioral research in the world. She previously served as the 16th director of the National Cancer Institute (NCI), the Richard E. Wilson Professor of Surgery in surgical oncology at Harvard Medical School, a surgeon at Brigham and Women's Hospital and a member of the Gastrointestinal Cancer Treatment and Sarcoma Centers at Dana-Farber Cancer Institute.

Throughout her career, Dr. Bertagnolli has been at the forefront of the field of clinical oncology. Her laboratory focused on advancing our understanding of the genetic drivers of gastrointestinal cancer development and the role of inflammation as a promoter of cancer growth. As a physician–scientist, she led translational science initiatives from 1994 to 2011 within the NCI-funded Cooperative Groups Program (now known as NCI's National Clinical Trials Network), and from 2011–2022 served as group chair of the Alliance for Clinical Trials in Oncology, a National Clinical Trials Network member organization. In addition, from 2007–2018, she served as the chief of the division of Surgical Oncology for the Dana-Farber Brigham Cancer Center.

Barbara Bierer, M.D.
Faculty Directory of the Multi-Regional Clinical Trials Center and Professor of Medicine, Harvard Medical School

Dr. Barbara Bierer is the faculty co-chair of the Multi-Regional Clinical Trials Center of Harvard and Brigham and Women's Hospital (MRCT Center), a Professor of Medicine, Harvard Medical School and Brigham and Women's Hospital, Boston and a hematologist/oncologist. She is the Director of the Regulatory Foundations, Ethics and the Law Program of the Harvard clinical and translational sciences center. Previously she served as senior vice president, research at the Brigham and Women's Hospital for 11 years, and was the institutional official for human subjects and animal research, for biosafety and for research integrity. She initiated the Brigham Research Institute and the Innovation Hub (iHub), a focus for entrepreneurship and innovation. In addition, she was the Founding Director of the Center for Faculty Development and Diversity at the BWH. In addition to her academic responsibilities, she serves on the Board of Directors of Public Responsibility in Medicine and Research (PRIM&R), dedicated to promoting the ethical conduct of biomedical and behavioral research; Management Sciences for Health (MSH), an international organization working in partnership globally to strengthen health care, local capability, and access; and the Edward P Evans Foundation, a foundation supporting biomedical research. Previously she has served as the chair of the Board of Directors of the Association for Accreditation of Human Research Protection Programs (AAHRPP) and as chair of the Secretary's Advisory Committee on Human Research Protections, HHS. She has authored or co-authored over 180 publications and is on the editorial boards of a number of journals including Current Protocols of Immunology. Dr. Bierer received a B.S. from Yale University and an M.D. from Harvard Medical School.

Robert Califf, M.D.
FDA Commissioner

Dr. Robert M. Califf was confirmed as the 25th Commissioner of Food and Drugs. He also served in 2016 as the 22nd Commissioner, and immediately prior to that as the FDA's Deputy Commissioner for Medical Products and Tobacco. He has spent a good portion of his career affiliated with Duke University, where he served as a professor of medicine and vice chancellor for clinical and translational research, director of the Duke Translational Medicine Institute, and was the founding director of the Duke Clinical Research Institute. He has had a long and distinguished career as a physician, researcher, and leader in the fields of science and medicine. He is a nationally recognized expert in cardiovascular medicine, health outcomes research, health care quality, and clinical research, and a leader in the growing field of translational research, which is key to ensuring that advances in science translate into medical care.

Jeffrey M. Drazen, M.D.
NEJM Group Editor, The New England Journal of Medicine

Born and raised in Clayton, Missouri, Dr. Drazen majored in applied physics at Tufts University and graduated from Harvard Medical School in 1972. He currently holds the positions of senior physician at the Brigham and Women's Hospital, Distinguished Parker B. Francis Professor of Medicine at Harvard Medical School, professor of physiology at the Harvard School of Public Health and adjunct professor of medicine at the Boston University School of Medicine. He is the recipient of honorary degrees from the University of Ferrara, the University of Athens, the University of Modena, and the University of Paris-Sud. From 2000 to 2019, Dr. Drazen was editor-in-chief of the *New England Journal of Medicine.* During his tenure, the *Journal* published major papers advancing the science of medicine, including the first descriptions of SARS, timely coverage of the Ebola and Zika virus epidemics, and advances in the treatment of cancer, heart disease and lung disease. It has been at the forefront of worldwide efforts to register all clinical trials and to share clinical trial data. He now serves as NEJM Group editor including the position as editor-in-chief of *NEJM Evidence*, a new medical journal from NEJM Group.

Victor J. Dzau, M.D.
NAM President

Victor Dzau is President of National Academy of Medicine (NAM), Vice Chair of the National Research Council, Chancellor Emeritus of Duke University, and past CEO of Duke Health System. Previously, he was Professor and Chairman of Medicine at both Harvard and Stanford Universities. Dr. Dzau is an internationally acclaimed leader and physician-scientist. His research laid the foundation for the class of lifesaving drugs known as ACE inhibitors, used globally to treat high blood pressure and heart failure. Dr. Dzau serves as inaugural president of NAM and led its transition from the Institute of Medicine (IOM). During Dzau's tenure, the NAM designed and led important initiatives including the Global Roadmap for Healthy Longevity, Vital Directions for Health and Health Care, Confronting the Opioid Crisis, and the Grand Challenge in Climate Change and Human Health. In 2015, the IOM – now the NAM – published a report entitled *Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk.* This study presented guiding principles and a practical framework for the responsible sharing of clinical trial data and concluded that a multi-stakeholder effort is needed to develop a culture, infrastructure, and policies that will foster responsible sharing—now and in the future.

Daniel Ford, M.D., M.P.H.
Director & Professor of Medicine, Senior Associate Dean for Clinical and Translational Research, John Hopkins Institute for Clinical and Translational Research

Daniel Ford, MD, MPH, is the David M Levine Professor of Medicine who came to Johns Hopkins in 1982 to complete the Osler Medicine residency. After completing a fellowship in Clinical Epidemiology at the National Institute for Mental Health and his Masters of Public Health at Johns Hopkins, he joined the faculty and developed his

approach to research as a member of the Welch Center for Prevention, Epidemiology and Clinical Research. He has joint appointments in Psychiatry, Epidemiology, Health Policy and Management and Nursing.

Dr. Ford's research has focused on understanding the relationships between depression and chronic medical conditions, particularly coronary artery disease, and how to improve care for patients with medical comorbidity. He was one of the first investigators to publish data documenting depression as a risk factor for myocardial infarction and stroke. In the spirit of translation, he has also sustained an interest in how to utilize Information Technology (IT) to improve care of patients with depression and tobacco abuse. Moving these interventions into the commercial world has been part of this process.

Ricardo Jorge de Oliveira Ferreira, Ph.D.
Auxiliary Researcher at the Nursing Research, Innovation and Development Centre of Lisbon (CIDNUR), Nursing School of Lisbon (ESEL)

Ricardo J. O. Ferreira is, since June 2022, Auxiliar Researcher at the Nursing Research, Innovation and Development Centre of Lisbon (CIDNUR), a differentiated unit of the School of Nursing in Lisbon (ESEL). He is also a researcher at the Rheumatology Department of the Centro Hospitalar e Universitário de Coimbra (CHUC) and at the Nursing Research Unit (NIE, CHUC), a clinical center of the Health Sciences Research Unit nursing (UICISA:E), hosted at the Nursing School of Coimbra (ESEnfC). He is the CEO of "QLV - Research Consulting", which provides higher quality and tailored education, consulting, and services to individuals and organizations. He was previously a Registered Nurse in the Vascular Surgery award (2003-2011) and at the Rheumatology Department (2011-2022) of the CHUC, in which he coordinated the nursing team of Outpatient Clinic (2020-2022), with two autonomous nursing consultations (for people with Fragility Fractures and People with Rheumatic conditions). Dr. Ferreira graduated from the Nursing School of Coimbra in 2003, and three years later obtained his master's degree in Health Sociopsychology from the Instituto Superior Miguel Torga, Coimbra.

Steven E. Kern, Ph.D.
Executive Director, Global Health Labs

Steven E. Kern, PhD, is Executive Director of Global Health Labs (www.ghlabs.org) whose mission is to develop innovative technologies to address unmet healthcare needs, especially in low and middle income countries. Global Health Labs helps to advance the strategic priorities of the Bill & Melinda Gates Foundation with technology innovations focused on diagnostics, reproductive, maternal and child health, and tools and equipment for primary care. It is created and funded by Gates Ventures, the private office of Bill Gates. Previously he served as for nearly 10 years as Deputy Director of Quantitative Sciences at the Bill and Melinda Gates Foundation. The Quantitative Sciences group is focused on data analysis to support program strategies for therapeutic projects that the foundation funds. This effort extends across all therapeutic areas in which the foundation is involved including maternal & child health, family planning, malaria, tuberculosis, neglected tropical diseases, HIV, and pandemic preparedness. He and

his team are strong advocates of making research data "always FAIR and sometimes OPEN" to improve the impact data can have towards the problem it was collected to address, and beyond. Prior to this, he was Global Head of Pharmacology Modeling at Novartis Pharma AG based in Basel Switzerland where he led a team focused on providing model-based drug development support to therapeutics across all stages of drug development. He joined Novartis in 2010 from the University of Utah in Salt Lake City, Utah where he was Associate Professor of Pharmaceutics, Anesthesiology, and Bioengineering, and served as co-investigator for their NIH funded Pediatric Pharmacology Research Unit. He has designed, conducted, and served as a principal investigator for clinical pharmacology studies that spanned the population from preterm infants to elderly adults.

Michael Lauer, M.D.
Deputy Director for Extramural Research, NIH Office of the Director

Dr. Michael Lauer is the Deputy Director for Extramural Research at the National Institutes of Health (NIH), where he serves as the principal scientific leader and advisor to the Director of the NIH on all matters relating to the substance, quality, and effectiveness of the NIH extramural research program and administration. He received education and training at Rensselaer Polytechnic Institute, Albany Medical College, Harvard Medical School, Harvard School of Public Health, and the NHLBI's Framingham Heart Study. He spent 14 years at Cleveland Clinic as Professor of Medicine, Epidemiology, and Biostatistics. During his tenure at the Clinic, he led a federally funded internationally renowned clinical epidemiology program that applied big data from large-scale electronic health platforms to questions regarding the diagnosis and management of cardiovascular disease. From 2007 to 2015 he served as a Division Director at the National Heart, Lung, and Blood Institute (NHLBI), where promoted efforts to leverage big data infrastructure to enable high-efficiency population and clinical research and efforts to adopt a research funding culture that reflected data-driven policy. He has received numerous awards including the NIH Equal Employment Opportunity Award of the Year and the Arthur S. Flemming Award for Exceptional Federal Service in recognition of his efforts to grow a culture of learning and accountability.

Rebecca Li, Ph.D.
CEO and Co-Founder, Vivli

Rebecca Li, PhD, is the CEO of Vivli and on faculty at the Center for Bioethics at the Harvard Medical School. Previous to her current role she was the Executive Director of the MRCT Center of Brigham and Women's Hospital and Harvard for over 5 years and remains a Senior Advisor at the Center. She has over 25 years of experience spanning the entire drug development process with experience in Biotech, Pharma and CRO environments. She completed a Fellowship in 2013 in the Division of Medical Ethics at Harvard Medical School. She earned her PhD in Chemical and Biomolecular Engineering from Johns Hopkins University.

Richard Liwski

Chief Technology Officer and Director, Critical Path Institute's Data Collaboration Center

Richard Liwski is the Chief Technology Officer and Director of Critical Path Institute's Data Collaboration Center. He is responsible for aligning C-Path's Technology strategy with the organization's goals, for the architecture and development oversight of data sharing initiatives in support of C-Path programs and for the data curation, management and standardization activities to support all of the Data Collaboration Center projects. He also serves as C-Path's Chief Privacy Officer, responsible for the definition, implementation, training and monitoring of C-Path's policies for handling of clinical data. Richard joined C-Path in 2014. Prior to C-Path, he spent 26 years at IBM in development and management roles. His experience included assignments working with major US pharmaceutical companies and healthcare providers as the technical focal point for their data storage needs. Richard also serves on the Board of Directors of the Clinical Research Data Sharing Alliance (CRDSA) Mr. Liwski received his Bachelor of Science degree in electrical engineering from New Mexico State University.

Bernard Lo, M.D.

Professor of Medicine Emeritus, University of California San Francisco

Dr. Bernard Lo is Professor of Medicine Emeritus, Director Emeritus of the Program in Medical Ethics at UCSF. and President Emeritus of the Greenwall Foundation in New York.

A member of NAM, Dr. Lo chaired the 2009 report *Conflicts of Interest in in Medical Research, Education, and Practice.* He also chaired National Academies committees on *Sharing Clinical Trial Data* (2015), *Evidence-Based Clinical Practice Guidelines for Prescribing Opioids for Acute Pain* (2019) and co-chaired the committee *Ethical, Legal, and Regulatory Issues Associated with Neural Cell Transplantation, Chimeras and Organoids* (2021).

Dr. Lo serves on the Medical Advisory Panel of Blue Cross/Blue Shield and the Takeda Pharmaceuticals Ethics Advisory Committee. He co-chaired the Standards Working Group of the California Institute of Regenerative Medicine and served on the Board of Directors of Association for the Accreditation of Human Research Protection Programs (AAHRPP).

Dr. Lo is author of Resolving Ethical Dilemmas: A Guide for Clinicians (6th ed., 2019). He and colleagues have published over 250 peer-reviewed articles on ethical issues concerning decision-making near the end-of-life, stem cell research, oversight of human participants research, the doctor-patient relationship, and conflicts of interest. He continues a primary care medicine practice at UCSF on a volunteer basis.

Joshua Mandel, M.D.
Chief Architect for Healthcare, Microsoft; Lecturer on Biomedical Informatics, Harvard Medical School

Joshua C. Mandel, MD, is a physician and software developer working to fuel an ecosystem of health apps with access to clinical and research data. As Chief Architect for Microsoft Healthcare, Chief Architect for SMART Health IT, and Lecturer at the Harvard Medical School Department of Biomedical Informatics, Josh works closely with the standards development community to lay groundwork for frictionless data access, authorization, analytics, and app integration. Josh leads development of the SMART on FHIR specification (the basis for US Patient Access API capabilities that certified EHRs must support) and the SMART Health Cards specification (used by pharmacies, public health departments, and healthcare providers to issue verifiable records of vaccination status). Josh also launched the Clinical Decision Support Hooks project, supporting integration of external decision support services within the clinical workflow. During his service on the national Health IT Standards Committee, Josh showed a special interest in tools and interfaces that support software developers who are new to the health domain.

Deven McGraw, J.D., M.P.H, LLM
Lead, Data Stewardship and Data Sharing, Invitae

Deven McGraw is the lead for Data Stewardship and Data Sharing at Invitae, a clinical genetic medicine company. Previously, she co-founded and served as Chief Regulatory Officer for Ciitizen, a platform for patients to gather their health information, prior to its acquisition by Invitae. She was recently appointed by GAO to the Health Information Technology Advisory Committee. Widely recognized for her expertise in health privacy, she directed the Health Privacy Project at the Center for Democracy & Technology for six years, testifying before Congress on health privacy issues on multiple occasions and leading the privacy and security policy work for the HITECH Health IT Policy Committee. She is currently serving on the Data and Surveillance Workgroup of the CDC's Advisory Committee to the Director on CDC's Data Modernization Initiative and served on the Health Information Technology Advisory Committee's Adopted Standards Task Force. She has also served as the Chief Operating Officer of the National Partnership for Women and Families and, before joining federal government service, advised health industry clients on HIPAA compliance and data governance while a partner at Manatt, Phelps & Phillips, LLP. Deven graduated magna cum laude from Georgetown University Law Center and has a Masters of Public Health from Johns Hopkins University.

Sarah Nevitt, Ph.D.
Senior Research Fellow, Centre for Reviews and Dissemination, University of York

Sarah is a Senior Research Fellow in Evidence Synthesis and Health Technology Assessment at Centre of Reviews and Dissemination (CRD), University of York, United Kingdom. Sarah previously worked as a Senior Research Associate in the Department of Health Data Science, University of Liverpool, UK.

Sarah is a medical statistician with research interests in Health Technology Assessment, methods for evidence synthesis, secondary use of clinical trial data for evidence synthesis and application to clinical decision making and clinical guidelines. Her previous work has included conducting large network meta-analyses and individual participant data meta-analyses of epilepsy clinical trials.

Sarah has extensive experience of conducting and evaluating methodologically complex evidence syntheses as a statistical editor for Cochrane and delivering reports for National Institute for Health and Care Excellence (NICE)'s technology assessment review programme and guidelines programme in the UK.

Philip Payne, Ph.D., FACMI, FAMIA, FAIMBE, FIAHSI
Director, Institute for Informatics, Data Science and Biostatistics (I2DB); Chief Data Scientist and Associate Dean of Health Information & Data Science; Washington University School of Medicine in St. Louis

Dr. Payne is the Janet and Bernard Becker Professor and Director of the Institute for Informatics, Data Science and Biostatistics (I2DB) at Washington University in St. Louis. He also serves as the Associate Dean for Health Information and Data Science and Chief Data Scientist for the Washington University School of Medicine. He holds additional appointments as a Professor of General Medical Science in the School of Medicine and of Computer Science and Engineering in the McKelvey School of Engineering. Dr. Payne holds appointments on numerous national steering, scientific, editorial, and advisory committees, including efforts associated with the American Medical Informatics Association, AcademyHealth, the National Library of Medicine, the National Center for Advancing Clinical and Translational Science, and the National Academy of Medicine. Dr. Payne is the author of over 250 publications focusing on the intersection of biomedical informatics and the clinical and translational science domains. His research group currently focuses on: 1) computational approaches to the discovery of multi-scale phenotypes and the ensuing identification of precision diagnostic and therapeutic strategies; 2) interventional approaches to the use of EHRs and clinical decision support systems; and 3) the design and evaluation of open-science platforms that enable cooperative approaches to discovery science.

Jane Perlmutter, M.B.A., Ph.D.
President and Founder, Gemini Group Consultancy

Jane Perlmutter is a long-term survivor of multiple cancers and an active advocate. While her advocacy is largely rooted in her own experiences, it is also informed by her formal training in cognitive psychology and experimental methods (Ph.D.), computer and information science (MS) and business (MBA), as well as her career experiences which included many years in academia, not-for-profit R&D, corporate senior management, and independent consulting. During her early advocacy Jane was a peer counselor and board member for Y-ME, as well as a grant reviewer for ACS, DOD and PCORI. More recently she focuses much of her advocacy on clinical trials, ensuring that the patient voice is considered in selection of research questions and that trial protocols are sensitive to patient issues. She is especially interested in innovative trial designs that can speed new treatments to patients who need them. Jane serves on the steering committees and is lead advocate on the I-SPY2 and TAPUR trials, two groundbreaking Master Protocol trials. She has been an advocate on NCI's Breast Steering Committee and CALGB's Breast and Health Outcomes Committees and is currently on NCI's Cancer Imaging Steering Committee and the Alliance for Clinical Trials in Oncology's DSMB and Cancer Control Executive Committee. Jane has also been involved in health advocacy beyond cancer and works with many government and not-for profit groups. She is past-chair of the Patient Centered Outcomes Research Institute's (PCORI) Patient Engagement Advisory Panel and a member of their Clinical Trials Advisory Committee. Jane is especially passionate about developing the next generation of advocates and fostering collaboration between advocates and researchers. She has developed and delivered training for many advocacy groups and been a long-term faculty member of the ASCO/AACR Methods in Clinical Research Workshop. In 2023 Jane was honored with AACR's 2023 Distinguished Public Service Award for Exceptional Leadership in Cancer Advocacy as well as ASCO's 2023 Patient Advocate Award.

Benjamin Pierson
Deputy Director, Enterprise Data, Bill & Melinda Gates Foundation

Ben is Deputy Director Enterprise Data at The Bill & Melinda Gates Foundation. He is responsible for maturing the Gates Foundation's ability to make data and evidence-driven strategies and investments. As part of this role he works across the organization to ensure that research investments yield reusable data and evidence to power better decisions. Prior to this role, Ben was a Senior Program Officer in the Foundation's Global Health Division. He led an initiative that enabled broad multi-disciplinary collaborations to generate precision health insights using subject-level data. He also led an investment portfolio focused on facilitating broader and faster data access. Ben's career has focused on social impact at scale, and specifically leveraging digital strategies to solve complex problems at the intersection of business, government, and non-profit sectors. He has held leadership roles in emergency response, economic development, global health, and finance. He has a BA from Cornell University and an MBA from the University of Washington.

Professor Arti K. Rai
Elvin R. Latty Professor of Law, Duke Law

Arti Rai, Elvin R. Latty Professor of Law and Faculty Director, The Center for Innovation Policy at Duke Law, is an internationally recognized expert in intellectual property (IP) law, innovation policy, administrative law, and health law. From March to December 2021, Rai served as Senior Advisor on innovation law and policy issues to the Department of Commerce's Office of General Counsel. She also regularly advises other federal and state agencies as well as Congress on these issues. She is a member of multiple distinguished councils, including the National Academies' Forum on Drug Discovery, Development, and Translation, the Polaris Advisory Council to the Government Accountability Office, and the American Law Institute. She has also served as a member of the National Advisory Council for Human Genome Research, as a public member of the Administrative Conference of the United States, and on numerous National Academies committees. Rai graduated from Harvard College, magna cum laude, with a degree in biochemistry and history (history and science), attended Harvard Medical School for the 1987-1988 academic year, and received her J.D., cum laude, from Harvard Law School in 1991.

Ida Sim, M.D., Ph.D.
Professor of Medicine and Computational Precision Health, University of California San Francisco; Vivli co-founder

Ida Sim, MD, PhD is Professor of Medicine at the University of California, San Francisco and co-directs Biomedical Informatics at UCSF's Clinical and Translational Sciences Institute. Dr. Sim earned her MD and her PhD in Medical Informatics from Stanford University, where her dissertation was on computational methods for data sharing of clinical trial results. She was trained in Primary Care Internal Medicine at the Massachusetts General Hospital and completed fellowships in General Medicine and Medical Informatics at Stanford. In 2005-6, Dr. Sim led the World Health Organization's International Clinical Trials Registry Platform which established the first global policy on clinical trial registration and defined the common 20-item Trial Registration Data Set. She has led multiple NIH and other grants on "trial bank publishing," ontology-based data sharing of human studies, and clinical trial visualization. Dr. Sim was a member of the 2015 Institute of Medicine committee on "Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk." She joined the MRCT Clinical Trials Data Sharing project in 2015 and is a co-founder of Vivli. In other work, Dr. Sim is a national leader in mobile health and co-founder of Open mHealth, a non-profit organization building open APIs and tools for integrating mobile health data. She has served on multiple national advisory committees on health information infrastructure for clinical care and research. She is a recipient of the United States Presidential Early Career Award for Scientists and Engineers (PECASE), a Fellow of the American College of Medical Informatics, and a member of the American Society for Clinical Investigation. She is a practicing clinician.

Michael Stebbins, Ph.D.
President Science Advisors. Vivli Board Chair

Michael Stebbins is the President of Science Advisors, a science and health consulting firm he founded in 2018 to provide science, technology, and public policy guidance to private companies, philanthropies, and non-profit organizations. He previously served as the Vice President of Science and Technology for the Laura and John Arnold Foundation where he was responsible for identifying and pursuing opportunities for philanthropic investment in Science and Technology. While at the Arnold Foundation he led initiatives that opened public access to data and publications created in the course of federally funded scientific research, and championed efforts in scientific reproducibility. His work at the Foundation addressed a broad set of critical issues including FDA policy on transparency, improving organ donation rates, leveraging the intellectual property sitting on shelves of universities and Federal agencies as well as opening access to scientific research publications and data. Dr. Stebbins served as the Assistant Director for Biotechnology in the Obama White House Office of Science and Technology Policy. At the White House, he developed eight Executive Orders and other directives addressing issues ranging from the antibiotic resistance crisis to restoring pollinator health. His work led to broad changes in practice across the Federal government regarding the purchasing of bio-based products, improving veterans' mental health, increasing access to federally funded scientific research publications and data, improving scientific reproducibility, evaluating and addressing the preferential purchasing of antibiotic free meats, reforming the regulatory system for biotechnology products, and improving the management of scientific collections. Dr. Stebbins previously served as a science advisor to the Obama Presidential Campaign and on the Obama White House Transition Team.

Murray Stewart, M.D.
Chief Medical Officer, Rhythm Pharmaceuticals, Inc.

Murray Stewart, M.D., is Chief Medical Officer at Rhythm Pharmaceuticals, Inc. Previously, he was Executive Vice President, Head of R&D, at Novelion Therapeutics Inc. From April 2014-September 2017, he was the Chief Medical Officer at GlaxoSmithKline. Dr. Stewart joined GSK in 2000 as Associate Director for Clinical Research & Development in the UK and since then has held a variety of positions in GSK he worked in Biopharm, was Therapy Area Head for the Cardiovascular and Metabolic therapy area. He has had extensive clinical development experience and worldwide regulatory interactions. Before joining the pharmaceutical industry, Dr. Stewart worked as a diabetes consultant and senior lecturer and was Consultant Physician/Honorary Senior Lecturer and Head of Clinical Services at the Diabetes Centre, Newcastle upon Tyne in the UK. His research was in lipid metabolism in type-2 diabetes, and he completed his medical training at Southampton Medical School in the UK and is a Fellow of the Royal College of Physicians.

Ronald Summers, M.D., Ph.D.
Senior Investigator, Imaging Biomarkers and Computer-Aided Diagnosis Laboratory, NIH Clinical Center

Dr. Ronald M. Summers is a pioneer in the use of artificial intelligence in radiology. His lab has made seminal contributions to the advancement of cancer diagnosis using radiology. Dr. Summers received the BA degree in physics and the MD and PhD degrees in Medicine/Anatomy and Cell Biology from the University of Pennsylvania. He directs the Imaging Biomarkers and Computer-Aided Diagnosis (CAD) Laboratory and is former and founding Chief of the NIH Clinical Image Processing Service. In 2000, he received the Presidential Early Career Award for Scientists and Engineers, presented by Dr. Neal Lane, President Clinton's science advisor. In 2012, he received the NIH Director's Award, presented by NIH Director Dr. Francis Collins. In 2017, he received the NIH Clinical Center Director's Award. He is a member of the editorial boards of the Journal of Medical Imaging, Radiology: Artificial Intelligence and Academic Radiology and a past member of the editorial board of Radiology. He is a program committee member of the Computer-aided Diagnosis section of the annual SPIE Medical Imaging conference and was co-chair of the entire conference in 2018 and 2019. He was Program Co-Chair of the 2018 IEEE ISBI symposium.

Sharon Terry, M.A.
Chief Executive Officer, Genetic Alliance

Sharon F. Terry is President and CEO of Genetic Alliance, an enterprise engaging individuals, families and communities to transform health. Genetic Alliance works to provide programs, products and tools for ordinary people to take charge of their health and to further biomedical research. As 'just a Mom' with a master's degree in Theology, she cofounded PXE International, a research advocacy organization for the genetic condition pseudoxanthoma elasticum (PXE), in response to the diagnosis of PXE in her two children in 1994. With others, she co-discovered the ABCC6 gene, patented it to ensure ethical stewardship in 2000, and assigned their rights to the foundation. She subsequently developed a diagnostic test and conducts clinical trials. She is the author of 150 peer-reviewed papers, of which 30 are clinical PXE studies. Her story is the topic of her TED Talk and TED Radio Hour. Terry is an Ashoka Fellow. She is an avid student and facilitator of Gestalt Awareness Practice, offering workshops and individual facilitation. Her daughter and son are why she started down this path. They and their wives and her granddaughter ground and enliven her.

Joanne Waldstreicher, M.D.

Independent Director, Becton Dickinson and Structure Therapeutics; Former Chief Medical Officer, Johnson & Johnson (retired); Faculty Affiliate, Division of Medical Ethics, New York University School of Medicine

Joanne Waldstreicher, MD, is a physician, scientist, independent board director, and advisor. She currently serves as a board director for Becton Dickinson and Structure Therapeutics and as an independent consultant. Until April 2023, Dr Waldstreicher served as the chief medical officer of Johnson & Johnson across pharmaceuticals, med tech, and consumer products, and prior to Johnson & Johnson, she led endocrinology and metabolism clinical research at Merck. She serves as an advisory board member of the Brooklyn College Cancer Center, an expert panelist for the Reagan Foundation for the US Food and Drug Administration, and a faculty affiliate of the Division of Medical Ethics, NYU School of Medicine. She graduated from Harvard Medical School and completed her internship and residency at Boston's Beth Israel Hospital and her endocrinology fellowship at Massachusetts General Hospital.