MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

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Multi-Regional Clinical Trials Center (MRCT Center) of Brigham and Women's Hospital and Harvard
2022 Annual Meeting

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& VIRTUAL MEETING

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Executive Summary

The MRCT Center's 2022 hybrid Annual Meeting convened a diverse group of stakeholders focusing on emerging issues facing global clinical trials. Attendees engaged in the following meeting topics: (1) Fireside chat with Ken Frazier, Retired Chairman and CEO of Merck, (2) Expanding the Footprint of Clinical Trials, (3) Establishing the Ethical and Regulatory Basis for Secondary Research Uses of Biospecimens, (4) Select MRCT Center Initiatives and Ongoing Work.

Fireside Chat with Dr. Kenneth Frazier (Retired Chairman and CEO of Merck)
Dr. Bierer asked Mr. Frazier to describe his career journey, and Mr. Frazier outlined how he joined Merck after 15 years at a law firm in Philadelphia where he represented several drug companies. During his time as CEO, Mr. Frazier declined to cut Merck's research and development (R&D) budget. That decision reinforced the corporate soul and culture of Merck as focusing on cutting-edge science and discovery of new therapeutic options for patients.

Dr. Bierer then asked about the role of social justice in pharma. Mr. Frazier concurred that there is a tension in clinical research between addressing social justice and understanding the biology of subpopulations. New medications cannot be tested in every subgroup for practical and sample size constraints; nevertheless, inclusion is important. He presented an analogy with the FIFA World Cup, a competition where many countries are not included, but each region of the world has a number of competitive slots so that we can reasonably conclude that we have a world champion in the end.

Dr. Bierer noted that every society has marginalized people and asked Mr. Frazier to consider diversity in the global context. Mr. Frazier responded that we need richer ethnicity data. For the first time in 15 years of annual check-ups, Mr. Frazier noted that there were questions on food and housing security and on mental health in his recent health screening. He mentioned that Merck has not been collecting SDOH data in its trials, but the company appreciates that social determinants are real issues. Mr. Frazier emphasized that a focus on inclusion must extend beyond healthcare. He described how the U.S. has non-inclusive prosperity and a gap in wage productivity, resulting in many people who work 40-hr/week jobs but who are unable to support a family. Mr. Frazier described the One Ten Initiative and how a group of companies came together after the 2020 George Floyd murder to form a coalition committed to hiring, over ten years, one million African Americans into positions in which they could earn a family-sustaining income, even though they don't possess a four-year degree.

To end the fireside chat, Dr. Bierer asked what a small organization like the MRCT Center can do to influence change. Mr. Frazier responded that we need to keep these kinds of conversations going and cannot ignore the suffering that affects fellow Americans and others globally –

whether related to clinical trials or other aspects of society. We need to do more to understand issues and to find solutions on a large scale. Mr. Frazier concluded by saying that the MRCT Center has helped make a more inclusive environment.

Panel 1 Discussion: Expanding the Footprint of Clinical Trials
This panel explored the vision, challenges, opportunities, and different approaches of large pharmacies, health technology companies, and others engaging in clinical trials.

Dr. Owen Garrick, Chief Medical Officer of Clinical Trials Services at CVS Health, explained that CVS Health started working in clinical research two years ago with the long-term goal of making clinical trials part of people's everyday life. Dr. Garrick emphasized key issues surrounding trust, awareness, and access that Diversity, Equity, and Inclusion (DEI) efforts and decentralization initiatives hope to mitigate.

Ms. Ramita Tandon, Chief Clinical Trials Officer at Walgreens, explained that Walgreens is looking to make it easier for patients to participate in clinical trials. Almost half of Walgreens' locations are described as being in socially vulnerable areas. Through partnerships, Walgreens has access to electronic medical records (EMRs) and real-world evidence (RWE) ecosystems to identify patients with more precision.

Dr. Pamela Tenaerts, Chief Scientific Officer at Medable Inc., stated that the goal at Medable is to bring clinical trials to anybody, anywhere, at any time. Medable has been doing significant work on digital technologies in clinical trials, looking at where and how to collect data through such technologies as phones and wearables.

Ms. Ann Meeker-O'Connell, Director of the Office of Clinical Policy at the FDA reiterated the importance of making trials simpler and more accessible and focused her comments on the need to improve diversity, equity, and inclusion. In April 2022, the FDA issued draft guidance for the submission of plans to enroll more patients from underrepresented racial groups into clinical trials.

During the **Discussion,** Dr. Bierer asked the panelists which social determinants of health (SDOH) variables they would advocate adding to data collection templates. Responses included race, digital access, language preference, transportation access, working hours, caregiver status, and a discussion about whether to collect income data. Dr. Bierer then asked about translations for clinical research. Panelists agreed on the importance of making translations available to participants but remarked that sponsors are the ultimate deciders on translation. One initiative makes investments in patient navigators who speak different languages.

Panel 2 Discussion: Establishing the Ethical and Regulatory Basis for Secondary Research Uses of Biospecimens

This panel explored challenges with secondary uses of biospecimens in research.

Rita Lawlor, Ph.D.: Centre for Applied Research on Cancer/ISBER, who works in cancer research at the University of Verona, explained that storing specimens in biobanks helps to create a central governance framework for their ethical and regulatory use. Many governing bodies have recently issued new regulations on the use of biospecimens and associated data for secondary research. In countries with particularly strict regulations, such as Italy where Prof. Lawlor is located, broad consent forms are no longer adequate; the donor or next-of-kin needs to be contacted for each specific use.

Zisis Kozlakidis, Ph.D., MBA: Head, Laboratory Services and Biobanking at IARC/WHO shared that using biospecimens for secondary research is a good investment that lowers the overall cost of research; however, there is a timeframe to collect and use the specimens efficiently. Dr. Kozlakidis coordinates one of the largest and most varied international biobanks in the world and noted that regulations governing the secondary use of specimens – and therefore biobanking activities – differ widely among countries.

Annette Schmid, Ph.D.: Sr. Director, Global Science Policy, Takeda, works in research and development, often in the rare disease space which requires working with patients worldwide, as a single country or region may have too few patients to conduct rigorous scientific research. Institutions in the same geographical region may have different policies with regard to reusing previously-collected samples and/or their associated data, and individuals within the same geographic region may have different preferences meaning that analysis must be done at the individual consent form. This leads to a lack of predictability in the research in addition to a significant administrative burden with direct time and cost implications and impact on the validity of the research for the broader population if samples from a particular region or subpopulation cannot be used.

During the **Discussion**, Mr. Peloquin asked about consent analysis when there is no clear indication for future use. Panelists explained that broad consent forms are no longer valid in an increasing number of countries because they do not address new regulatory requirements. They suggested creating a common terminology and a master consent form and using technology to improve this process, as a medium-term solution. Audience members raised questions that additional research could reveal disease-linked genes that study participants may or may not want to know. To resolve this problem, we may need a higher-level approach to increase public knowledge and engagement as well as international harmonization.

Select MRCT Center initiatives and ongoing work

International Capacity Building Efforts: The MRCT Center has recently provided training on Data Monitoring Committees in the Philippines, continued to host on-demand ICH GCP E6(R2) online modules and trained lecturers in biotech programs in Indonesia on principles of clinical research ethics. Partnering with the Bill and Melinda Gates Foundation and the African Vaccines Regulatory Forum (AVAREF), the MRCT Center designed and delivered the course *Training for Ethics Review of Clinical Research* to ethics committee chairs and members across the African continent. Beginning in 2023, the MRCT Center will initiate a 3-year grant funded by the WHO and Bill and Melinda Gates Foundation to build on this work. In addition, the MRCT Center, which is an ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) training associate, will be developing a series of introductory and in-depth training modules for ICH guidance documents E6, E8, and E17 beginning in 2023.

Accessibility by Design: inclusion of people with disabilities in clinical research: The Accessibility by Design project emerged from the Diversity, Equity, and Inclusion (DEI) program to consider all populations who have been historically marginalized and underserved, including people with disabilities (PWDs). PWDs are underrepresented in clinical trials. The MRCT Center assessed current guidelines surrounding supported decision-making in clinical research and examined inclusion and exclusion criteria in clinical trial protocols to identify language that facilitates and prohibits PWD inclusion. Currently, the MRCT Center team is completing a toolkit that encourages sponsors, researchers, and sites to design trials to be accessible from the outset.

Global Clinical Research in Children: The MRCT Center has learned through many multi-stakeholder discussions that the focus on community and patient engagement has not taken hold in the pediatric space, and the input of young people and those who care for them is not routinely solicited or included in the clinical research life cycle. As an offshoot of the overall project, the MRCT Center is hosting a 5-part webinar series funded in part by the FDA, entitled *Advancing International Pediatric Clinical Research.* In addition, the MRCT Center has developed an array of materials to aid both young people considering involvement in the product development process and investigators who wish to include young people's input in the clinical research/product development lifecycle.

Welcoming Remarks

Sarah White & Barbara Bierer, MRCT Center; David Peloquin & Julie Jones, Ropes & Gray

Sarah White, MRCT Center Executive Director, welcomed in-person and remote participants and introduced MRCT Center's mission. Dr. Barbara Bierer, MRCT Center Faculty Director, introduced the agenda of the meeting. David Peloquin, Partner at Ropes & Gray and MRCT Center Senior Advisor, also welcomed meeting participants, noting that unfortunately Mark Barnes, MRCT Center Faculty Co-Director, was unexpectedly unable to participate in this meeting.

Julie Jones, Chair of Ropes & Gray, welcomed the participants and emphasized the commitment and support of Ropes and Gray for the work of the MRCT Center. Mark Barnes, partner at Ropes & Gray, co-founded the MRCT Center with Barbara Bierer over a decade ago and continues to serve as co-faculty director. Many Ropes & Gray staff have been involved with the MRCT Center and have contributed work such as analyzing global data laws and how they affect cross-border research, evaluating laws that govern continued access to investigational products and benchmarking laws and regulations related to pediatric access to clinical trials. Ms. Jones noted that the work of the MRCT Center– improving the quality of clinical trials around the world, including in emerging countries – fits with Ropes & Gray's commitment to social justice, and the MRCT Center is a very important pro bono client. Ms. Jones made special mention of Katharine Wang, Partner at the Shanghai Ropes & Gray office, who has taken part and contributed to the MRCT Center's work over the last decade.

Fireside Chat

Kenneth C. Frazier, Merck, in conversation with Dr. Barbara Bierer

After welcoming Ken Frazier (Retired Chairman and CEO of Merck) to the MRCT Center's Annual Meeting, Dr. Bierer asked Mr. Frazier to describe his career journey to the assembled group. In response, he outlined how he joined Merck after 15 years at a law firm in Philadelphia, where he devoted significant pro bono time to social justice issues. At the same time, he represented several drug companies. Unexpectedly, one day he was contacted by the CEO of Merck and asked to join the company. Ken was drawn to the company's strong ethos around scientific excellence and ethics, as demonstrated in the well-known George Merck quote: "We try never to forget that medicine is for the people. It is not for the profits."

During Ken's time as CEO, even when Wall Street expected a cut in the R&D budget and investment in non-pharma assets, Ken declined to cut Merck's research and development

budget. That decision reinforced the corporate soul and culture of Merck as focused on cutting-edge science and discovery of new therapeutic options for patients. The subsequent R&D investment was worthwhile: in addition to a number of innovative products, a transformative oncology drug (Keytruda) was discovered. These advances rested on the foundation of productive relationships with scientific colleagues and rigorous clinical trials. These decisions can be difficult, but they help develop and strengthen the culture of an organization.

At this point in the conversation, Dr. Bierer highlighted another noteworthy moment in Ken's career, significant for the courage he displayed, when he chose to resign from President Donald Trump's Manufacturing Council following the President's minimalist response to the 2017 actions of white supremacists in Charlottesville, Virginia.

Dr. Bierer then asked about the role of social justice in pharma. She described the challenge of achieving statistical significance, or even meaningful insights, for the many different subpopulations in clinical trials. While diverse inclusion will increase confidence, the response of a subgroup—or the group overall—may decrease with the increase in heterogeneity. There is an apparent tension between biology and social justice.

Ken responded that while pharmaceutical companies must return on the investment of shareholders, Merck is populated with people who have values that are critical to them as employees and that are aligned with the company's mission. Ken concurred that there is a tension between social justice and biology – and biology is complex. New medications cannot be tested in every subgroup for practical and sample size constraints; nevertheless, inclusion is important. He presented an analogy with the FIFA World Cup. Many countries, including China, are not included in the 2022 World Cup but each region of the world has a number of competitive slots: We can therefore reasonably conclude that we have a world champion in the end. Ken explained that a similar approach can be taken for inclusion in research.

Dr. Bierer noted that every society has marginalized people and asked Ken to consider diversity in the global context, such as in low- and middle-income countries, and for under- and un-insured populations. He responded that we need richer ethnicity data -- humanity is far more diverse than current categorizations of race/ethnicity reflect. He agreed with Dr. Bierer that we should work with the Centers for Medicare and Medicaid Services (CMS) to ensure that people who do not have sufficient health insurance are offered research participation opportunities; CMS should be invited to the table to discuss the design of a fair and rational system of clinical trials.

The conversation then focused on social determinants of health (SDOH). For the first time in 15 years of annual check-ups, Ken noted that there were questions on food and housing security and on mental health in his recent health screening. He mentioned that Merck has not been collecting SDOH data in its trials, but the company appreciates that social determinants are real issues. Based on the knowledge that lower economic regions had higher morbidity and

mortality from COVID, Merck is now partnering with the Association of Clinical Research Professionals (ACRP) to train new CRPs from minority communities.

Ken emphasized that a focus on inclusion must extend beyond healthcare. He described how the U.S. has non-inclusive prosperity and a gap in wage productivity, resulting in many people who work 40-hr/week jobs but who are unable to support a family. Capitalism has winners and losers, Ken observed, but we must ask ourselves how much inequality is moral. And how can we create a society that is just? We simply cannot separate healthcare disparities from income disparities, he noted.

Ken then described the One Ten Initiative and how a group of companies came together after the 2020 George Floyd murder to form a coalition committed to hiring, over ten years, one million African Americans into positions with a family-sustaining income, even though they don't possess a four-year degree. The intent is to move away from credential-based hiring to skill-based hiring: talent is more evenly distributed than educational opportunity.

To end the fireside chat, Dr. Bierer asked what a "small but mighty" organization like the MRCT Center can do to influence change. Ken responded that we need to keep these kinds of conversations going. We cannot look the other way and ignore the suffering that affects fellow Americans and others globally – whether we are talking about clinical trials or other aspects of society, there is enormous progress to make. We need to do more to understand issues and to find solutions on a large scale. Ken concluded by saying that the MRCT Center has helped make a more inclusive environment through policy and by shaping clinical trials; by maintaining high standards for biological sciences, clinical trial conduct, and expanding access; and by training more people to conduct clinical research around the world.

With appreciation from the attendees and the MRCT Center, Dr. Bierer thanked Mr. Frazier for his valuable insights.

Panel 1: Expanding the Footprint of Clinical Trials: A discussion of current/future innovative practices

Owen Garrick, CVS Health; Ramita Tandon, Walgreens Health; Pamela Tenaerts, Medable; Ann Meeker-O'Donnell, FDA

With the growth and acceptance of decentralized clinical trials and attention to diverse representation in research, large pharmacies, health technology companies, and others are

engaging in clinical trials, enabling access to marginalized communities. This panel explored this vision, its challenges and opportunities, and different approaches to achieving the goals. Dr. Barbara Bierer introduced the panel and commented that we have seen growth in the commitment of organizations like Walgreens, CVS Health, and Medable to this innovative vision.

Dr. Owen Garrick, Chief Medical Officer of Clinical Trials Services at CVS Health, started the panelist conversation by stating that CVS Health started working in clinical research two years ago with recruitment for COVID-19 vaccine trials and the long-term goal of making clinical trials part of people's everyday life. CVS has been converting Minute Clinic locations to dedicated research sites working on participant recruitment. CVS Health now has 80 clinical research sites. In their model for site selection, 40% of the determinative metric is based on racial and economic diversity in the areas around their 1,200 CVS locations. Dr. Garrick emphasized key issues surrounding trust, awareness, and access that DEI efforts and decentralization initiatives hope to mitigate. To this point, CVS is working to ensure that the staff at their clinical research sites reflects the community demographically. CVS has also launched a partnership with Medable to allow patients to participate in clinical trials the whatever way they wish, including in community-based and home-based settings.

Ms. Ramita Tandon, Chief Clinical Trials Officer at Walgreens, concurred with Dr. Garrick. Walgreens is also looking to make it easier for patients to participate in clinical trials. Their vision is for clinical trials to become a care option, facilitating the integration into the company's overall healthcare strategy. Walgreens has a broad reach, serving nearly 10 million people daily in the United States across its nearly 9,000 stores. Almost half of these locations are described as being in socially vulnerable areas. Through partnerships, they now have access to millions of electronic medical records (EMRs). They are also looking to leverage the real-world evidence (RWE) ecosystems that they have created to go beyond overburdened provider ecosystems, identify patients with more precision, and streamline data collection so that information that exists in the EMR is not collected in a duplicative manner. Walgreens is bringing different pieces together to understand the patient journey more holistically.

Dr. Pamela Tenaerts, Chief Scientific Officer at Medable Inc., agreed that clinical trials should be more patient-centric and not collect data that already exist. She stated that the goal at Medable is to bring clinical trials to anybody, anywhere, at any time. Medable has been doing significant work on digital technologies in clinical trials, looking at where and how to collect data through such technologies as phones and wearables. They are thinking conscientiously about the responsible adoption of new clinical trial technology and e-consents and considering how to measure whether the new technologies are beneficial for different stakeholders. Medable is also considering what documents and technologies are helpful to sites and principal investigators (PIs) for oversight and planning, as stakeholders are subsumed by paperwork and burdened by orientation to new technologies.

Ms. Ann Meeker-O'Connell, Director of the Office of Clinical Policy at the FDA, reiterated the importance of making trials simpler and more accessible. She remarked that unnecessary complexity is a burden, and the clinical research community needs to distinguish between what is essential to and what may be deemed as supernumerary. She also focused her comments on the need to improve diversity, equity, and inclusion. In April 2022, the FDA issued draft guidance for the submission of plans to enroll more patients from underrepresented racial groups into clinical trials. To better enroll underrepresented populations, Ms. Meeker-O'Connell advocated for extending trials into new and under-resourced settings beyond academic medical centers, streamlining trial design, better understanding community concerns and challenges, engaging community-based physicians, drawing across the available tools, and clearly and effectively communicating about human research. She noted that many strategies have been developed to increase the enrollment of diverse populations, but more work is needed on how to best use those strategies together to drive change.

Discussion

Dr. Bierer asked the panelists which social determinants of health (SDOH) variables they would advocate adding to data collection templates. Ms. Meeker O'Connell responded that while the FDA guidance focuses on racial diversity, the FDA recommends that sponsors look at populations more broadly. Dr. Tenaerts said Medable, as a technology company, is concerned with digital access and digital literacy, while Dr. Garrick said that language preference, internet access, transportation access, working hours, and whether the person is a caregiver are key determinants of participation in clinical trials. There was some debate on whether the collection of income data and analysis of results by income level may have negative externalities. Ms. Tandon stated that Walgreens has found the use of income data helps to determine the best locations to situate clinical research sites serving underrepresented communities.

Dr. Bierer then pivoted to a question about views on translation in the technological space for clinical research. Dr. Tenaerts agreed that making translations available to patients and caregivers is very important and mentioned that it is a complicated process. For example, while many phones offer the option to toggle between languages, study instruments are designed in a single base language (usually English) for the design of electronic clinical outcomes assessments (eCOA) systems and need to be translated into other languages from there as needed for a study. Translations for eCOAs also need license holder review. Dr. Garrick remarked that CVS is not the ultimate decider on translation. Sponsors are, and they often have not thought about translation early in the planning stages and then do not agree to it. Ms. Tandon communicated that Walgreens has similar experiences and that one of their initiatives is to make investments in patient navigators that speak other languages. Ms. Meeker-O'Connell remarked that the FDA has draft guidance for informed consent forms and that translation of the entire consent form is important because it serves as a resource for patients throughout the trial. The panelists all agreed that consent is not a form, it is a process, and that while the

technical translation of the consent is important, clear communication of the concepts, in a straightforward, health-literate, and culturally-sensitive manner, is paramount.

Panel 2: Establishing the Ethical and Regulatory Basis for Secondary Research Uses of Biospecimens

Rita Lawlor, University of Verona; Zisis Kozlakidis, World Health Organization; Annette Schmid, Takeda

David Peloquin, JD: Partner at Ropes & Gray and Senior Advisor MRCT Center, stepped in as moderator for this panel discussion, as Mark Barnes, JD, LLM was unavailable. Mr. Peloquin invited each panelist to introduce themselves and to provide their opening thoughts on the secondary use of biospecimens.

Rita Lawlor, Ph.D.: Centre for Applied Research on Cancer/ISBER, works in cancer research at the University of Verona, where she also oversees the Applied Research on Cancer Network (ARC-Net) biobank. Prof. Lawlor explained that housing specimens in biobanks helps to create a central governance framework for their ethical and regulatory use. This centralized approach also allows better sample tracking which is an important ethical issue. This gives the research center the ability to provide information to the people who have donated biospecimens if they wish to know how their sample(s) have been used as well as associate more data to specimens as information becomes available from research studies, increasing their value and utility. This also permits the in-house biobank to select specific samples for secondary research based on molecular characteristics identified in previous studies. This secondary research is permissible due to a broad, ethics-committee-approved consent form signed by donors when they agree to participate in the biobank.

Many governing bodies have recently issued new regulations on the use of biospecimens and associated data for secondary research. In countries with particularly strict regulations, such as Italy where Prof. Lawlor is located, broad consent forms are no longer adequate; researchers wishing to use biospecimens from a biobank for secondary research must contact the donor – or their next-of-kin, if deceased – to obtain consent for each specific use. This places an enormous administrative burden on small research centers conducting secondary research and is a delicate issue when contacting next of kin. Prof. Lawlor discussed the concept of good stewardship in biobanking. Proper stewardship of biospecimens involves ensuring that samples are used in a way that respects the donor's intentions. Conservative interpretations of strict regulations often lead to samples not being used, which counters the intentions of the donors who contributed to the biobank to contribute to research and serve the greater good.

Secondary research is fundamental for scientific advancement, and a balance must be struck between adequate protection for participants and optimal use of samples and data.

Zisis Kozlakidis, Ph.D., MBA: Head, Laboratory Services and Biobanking at IARC/WHO has been working in biobanking for 20 years. In his experience, the more biospecimens and/or data are used for secondary research, the better the investment and the lower the overall cost of research. This is a common argument used by researchers advocating for secondary research. It is also important to realize there is a timeframe to collect and use the specimens efficiently, as technology develops and physical samples deplete and deteriorate over time. When a physical sample is no longer usable, there must be a framework for how to properly handle the data footprint that remains.

Dr. Kozlakidis coordinates one of the largest and most varied international biobanks in the world. The regulations governing the secondary use of specimens – and therefore biobanking activities – differ widely among countries. The regulatory landscape in low- and middle-income countries is especially fragmented, and regulations in some regions are contradictory. The uptake of international guidelines has been slow compared to other areas, likely, at least in part, because these guidelines do not account for local regulatory differences. Further work must be done to understand the slow uptake of harmonized international regulations and why secondary research using biospecimens continues to pose significant regulatory challenges.

Annette Schmid, Ph.D.: Sr. Director, Global Science Policy, Takeda, works on science policy relating to research and development with particular focus on policies relating to the science, preferences and needs of biomarker-defined patient populations, often in the rare disease space. This requires working with patients worldwide, as a single country or region may have too few patients to conduct rigorous scientific research. Thus, there is a need to understand the regulations and legislation in each of these regions to establish the appropriate use and reuse of previously-collected samples and/or their associated data. Compounding the issue, individuals within the same geographical region may also have very different preferences, needs and sensitivities so that an analysis must be done at the level of the individual consent form. In the current environment, this leads to a lack of predictability in the research conduct in addition to significant administrative burden with direct time and cost implications. Importantly, when specific samples from a particular region or subpopulation cannot be used, there can be significant impact on the validity of the research for the broader population.

Discussion

After the panelists shared their introductions and opening thoughts, Mr. Peloquin first mentioned how the three panelists discussed consent in different ways. Often, consent forms do not contemplate future data use, or the specimen is collected during standard of care where no consent form was needed. He asked the panelists to share how they think about consent analysis when there is no clear indication for future use.

Prof. Lawlor responded that when her biobank was created, they worked with ethics experts to create a broad consent form for the secondary use of biospecimens. These forms, however, are no longer valid in Italy and other EU countries. There are also times when researchers want to use samples from pathology archives – particularly rare samples – but know they cannot get a new, specific informed consent signed to proceed with secondary research. In the past, researchers would ask for permission from their Institutional Review Board (IRB), but now IRBs are unsure given the regulatory framework and this causes certain projects to be put on hiatus.

Dr. Kozlakidis stated that past consent forms had a common backbone, with additional specificity added as needed. He echoed Prof. Lawlor that prior broad consent forms are no longer valid in an increasing number of countries because they do not address new regulatory requirements. He believes that creating a common terminology for consent across countries would be beneficial.

Dr. Schmid explained that in industry, sponsors typically create a master or template consent form that is adjusted by a vendor/ CRO to the local requirements, as they differ significantly across regions. For Takeda, this template will typically allow participants to provide consent to a possible use of biospecimen for secondary research (outside the particular clinical trial). In the scenario where Takeda researchers are interested in identifying samples for secondary research this turns into a very time-consuming effort where the individual consent forms from each site need to be interrogated, creating a significant administrative burden. Takeda is working to use technology to improve this process by attaching metadata to each biospecimen that outlines what can and cannot be done with it. This is not available in the short term but is likely the way of the future. In addition, global regulatory harmonization would simplify the process and will be important for appropriate diverse and representative sample sets in the long run.

There was a comment from an audience member about their experience with this. Often, further research will be done using the specimens or data from a specific subset of trial participants. This can be difficult to address via standard consent forms. Additionally, some research may reveal disease-linked genetic markers with the potential to affect future generations' health and access to healthcare. For example, individuals with a known disease marker may have higher insurance premiums. These complex issues may not always be foreseeable at the outset of a study and may require genetic counseling or other interventions to be offered to participants. In response to this comment, Prof. Lawlor shared some unpublished results of a poll taken of audience members at a talk on biobanking that she delivered to the general public in Verona, Italy. The audience did not wish to be informed of findings that were indicators of risk or the potential to negatively impact their health, but the overwhelming majority wanted to be informed of findings that could impact their descendants. This raises the question of what younger generations would like to know. People were also hesitant about providing their samples to biotech and pharmaceutical companies due to concerns about companies profiting from them.

An attendee from a pharmaceutical company commented that selling data is indeed concerning, however, when data are shared, it is done so to improve future treatments and outcomes, not for profit. Much of what is put into the consent forms and protocols of industry-sponsored research is included at the request of academic institutions. They agreed with comments from earlier in the panel that a broad, IRB-approved consent form would be useful and suggested that it be paired with a standardized form allowing study participants to indicate what can and cannot be done with their data. They also noted that pharmaceutical research activities mimic that in academia, yet the public's trust in academic research is much higher. A better public understanding of biomedical research, what it involves, and the roles of the many players may help to facilitate greater comfort with secondary research and broad consent.

Prof. Lawlor reiterated that in their previous broad consent forms, they explained to participants that secondary research would only be done with approval from an ethics committee. She also echoed that many, if not all, of the bad practices pharmaceutical companies are accused of can be equally true of academic institutions and stated that the problem may lie in public lack of sufficient information and understanding that research carried out by biotech and pharmaceutical industries is essential to improve healthcare in the future.

Another audience member commented that the research community lives in an echo chamber. The concerns of the people in the room are not necessarily representative of the public's concerns; people in the greater world are worried about things like monetization. We are not adequately addressing the public's fears. Open communication with the public about the research process, how decisions are made, and the issues involved in research may open a broader conversation leading to innovative solutions. One specific area they mentioned that needs to be addressed is the over-reliance on consent. Consent to participate in a study is distinct from a data use contract, yet we are trying to address both with one document. While the intention to minimize the number of forms involved in research participation is good, failing to recognize such distinctions may backfire.

Dr. Schmid agreed that more dialogue with the public about how research is done is needed. This could help participants understand that research and innovation rely on collaboration and that secondary research is not a revenue-generating mechanism, but an essential part of the process.

Prof. Lawlor agreed that to solve this problem we need to take a higher-level approach and increase public knowledge and engagement. She mentioned the European Health Data Space as an initiative intended, among other things, to address the issues related to secondary research and the sharing and use of health data. She expressed concern however, that it may become overly reliant on current data protection regulations and thus continue to encumber secondary research . It may be time to abandon the highly conservative approaches to data use that have

hindered research thus far. Public input is undoubtedly critical to creating more effective solutions.

The session concluded with Dr. Kozlakidis reaffirming the earlier comments and reemphasizing the need for international harmonization – with considerations for local context – even though the task may be slow and difficult.

Select MRCT Center initiatives and ongoing work

Dr. Barbara Bierer and Ms. Sarah White provided an overview of several MRCT Center initiatives and ongoing work.

International Capacity Building Efforts

Dr. Barbara Bierer and Ms. Sarah White provided a brief overview of the MRCT Center's recent international capacity-building efforts. Ms. White shared the MRCT Center's history of focusing on capacity building trainings in areas including health literacy, Good Clinical Practice (GCP), Data Monitoring Committees (DMC), and Diversity, Equity & Inclusion (DEI). Before the COVID-19 pandemic, the MRCT Center conducted many in-person trainings but has since transitioned to virtual and on-demand trainings, including on **Equity by Design** and **Health Literacy for IRBs**.

The MRCT Center has recently provided trainings on Data Monitoring Boards in the Philippines, continued to host on-demand **ICH GCP E6(R2) online modules,** and trained lecturers in graduate and undergraduate biotech programs in Indonesia on principles of clinical research ethics. Additionally, partnering with the Bill and Melinda Gates Foundation and the African Vaccines Regulatory Forum (AVAREF), the MRCT Center designed and delivered the course *Training for Ethics Review of Clinical Research* to ethics committee chairs and members across the African continent. The overall goal is to strengthen the regulatory and ethical environment for clinical research throughout Africa. The course included 24 hours of virtual instruction which was delivered once in 2021 and again in 2022 using a combination of lecturers and case studies. Beginning in 2023, the MRCT Center will initiate a 3-year grant funded by the WHO and Bill and Melinda Gates Foundation to build on this successful initial work. The three focus areas of this work will be 1) converting the virtual trainings to enduring online training courses, 2) piloting utilizing a benchmarking tool for ethics committee review to provide targeted regional recommendations, and 3) analysis of existing processes and development of resources to increase the efficiency of trial timelines throughout Africa.

Finally, the MRCT Center, which is an ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) training associate, will be developing a series of introductory and in-depth training modules for ICH guidance documents E6, E8, and E17 beginning in 2023.

Accessibility by Design: inclusion of people with disabilities in clinical research

Dr. Bierer introduced Accessibility by Design, a project emerging from the Diversity, Equity, and Inclusion (DEI) program. DEI initiatives often prioritize racial and ethnic disparities, it is to consider all populations that have been historically marginalized and underserved, including people with disabilities (PWDs). PWDs are underrepresented in clinical trials.

Led by Willyanne DeCormier Plosky and supported by Juliette Pluviose-Philip, the MRCT Center continues to champion work related to inclusion of PWDs. The initial work with PWDs assessed current guidelines surrounding supported decision-making in clinical research. Additionally, the MRCT Center examined inclusion and exclusion criteria in clinical trial protocols to identify language that facilitates and prohibits PWD inclusion. The MRCT Center argued that inclusion or exclusion eligibility criteria should be explicit and justified. Both endeavors surrounding supported decision-making and inclusion/exclusion criteria have been published.

Taken together, accessibility benefits everyone. The MRCT Center is committed to continuing to address issues related to the accessibility and inclusion of PWDs. Currently, the MRCT Center team is completing a toolkit that encourages sponsors, researchers, and sites to design trials to be accessible from the outset, a resource that it aims to publish in Q2 of 2023.

Global Clinical Research in Children

Dr. Barbara Bierer provided updates to the ongoing project, *Promoting Global Clinical Research in Children.* Dr. Bierer began with a brief review of the impetus for the initiative, started 2+ years ago, and why this work remains important. In brief, children deserve access to safe and effective medicines; myriad ethical, regulatory and operational challenges remain that impede the smooth conduct of global pediatric clinical trials. Further, the MRCT Center has learned through multiple multi-stakeholder discussions that the focus on community and patient engagement has not taken hold in the pediatric space, and the input of young people and those who care for them are not routinely solicited or included in the clinical research life cycle.

Dr. Bierer described an offshoot of the overall project, a 5-part webinar series funded in part by the FDA, entitled *Advancing International Pediatric Clinical Research.* The webinars hosted by the MRCT Center to date have focused on: lessons learned from COVID-19 including the importance of starting pediatric vaccine trials early [October 2021]; elevating the voices of young people in clinical research, featuring and centering on work with young people [February 2022]; the nuances of assent and consent in the field with a focus on culture, context and respect [June 2022]; and examining existing models of pediatrics medicines development in an effort to achieve better global regulatory cooperation [November 2022].

Dr. Bierer discussed an array of materials developed and available to aid both young people considering involvement in the product development process and investigators who wish to include young people's input in the clinical research/product development lifecycle. In response to a gap in available resources, a compendium of youth educational materials was developed for young people with an interest in becoming involved in some aspect of clinical research. A toolkit, in its final stages of external review, was developed to support investigators to engage youth in the planning of clinical trials. The toolkit was developed after participating on a panel at a national conference with a youth speaker and noting the logistical complications and operational issues unique to minor youths that were not considered. Finally, though not exhaustively, Dr. Bierer shared that the MRCT Center has a library of 5 brief videos produced with two collaborators, The International Children's Advisory Network (ICAN) and Dr. Gianna "Gigi" McMillan of Loyola Marymount University in Los Angeles, CA. These resources, available on the MRCT Center YouTube channel, feature young people from around the globe sharing their experiences in clinical research and their thoughts on what they wish adults who work with young people in research settings knew.

Closing Remarks

Sarah White, MRCT Center

Ms. White gave a recap of the Annual Meeting, which started with the fireside chat with Dr. Kenneth Frazier and both his memorable World Cup analogy and his encouragement to sustain the conversation. Panel 1, "Expanding the Footprint of Clinical Trials," included retail pharmacies that are engaging in clinical trials to build long-term commitment and trust in communities. Panelists mentioned how important it is to make clinical trials available to everyone. The FDA representative supported diverse participation in clinical trials as vitally important and making trials simpler. Panelists also talked about the critical nature of social determinants of health such as income and translations. In Panel 2, "Establishing the Ethical and Regulatory Basis for Secondary Research Uses of Biospecimens," panelists discussed how to consider societal needs in regard to using biospecimen and emphasized the critical role of secondary research. There is still a fragmented landscape and work to be done. Ms. White noted that she and Dr. Bierer had provided an overview of several ongoing projects and mentioned that updates on all ongoing MRCT Center projects can be found in the 2022 MRCT Center Impact Report and through our monthly newsletters and communications.

Discussion

One meeting participant mentioned the need to communicate with the public and to build relationships with scientists, "to get regular folks engaged in the issues." Another participant

elaborated on the need to be clear about what is clinical care and what is research since people experience a range of different medical experiences.

Appendix 1: Meeting Agenda

MRCT Center 2022 Annual

Meeting Agenda

Wednesday, December 14, 2022

Ropes & Gray, Prudential Tower, 49th floor,
800 Boylston Street, Boston, MA 02199

Time	Topics/Speakers
8:00 – 8:20 AM	**Breakfast & Registration**
8:20 – 8:45 AM	**Welcoming Remarks** *Dr. Barbara Bierer & Mark Barnes will provide opening remarks from the MRCT Center. Julie Jones will provide a welcome to Ropes & Gray.*
8:45 – 9:15 AM	**Fireside Chat**: • Kenneth C. Frazier Retired Chairman and CEO, Merck & Co., Inc. Chairman, Health Assurance Initiatives, General Catalyst **Q&A / Discussion** **Moderator**: Barbara Bierer, MD
9:15 – 10:15 AM	**Panel 1** **Expanding the Footprint of Clinical Trials:** A discussion of current/future innovative practices *With the growth and acceptance of decentralized clinical trials and attention to diverse representation in research, large pharmacies, health technology companies, and others are engaging in clinical trials, enabling access to marginalized communities. This panel will explore this bold vision, its challenges and opportunities, and different approaches to achieve the goals.* **Panelists:** • Ramita Tandon, Chief Clinical Trials Officer, Walgreens Health (virtual) • Pamela Tenaerts, MD MBA, Chief Scientific Officer, Medable, Inc.

	• Owen Garrick, MD, Chief Medical Officer, Clinical Trial Services, CVS Health (virtual) • Ann Meeker-O'Connell, MS, Director, Office of Clinical Policy, FDA (virtual) **Moderator**: Barbara Bierer, MD
10:15 – 10:30 AM	**Break**
10:30– 11:15 AM	**Panel 2:** **Establishing the Ethical and Regulatory Basis for Secondary Research Uses of Biospecimens** *Presentation and discussion related to establishing practical ethical standards for the collection, retention, and research uses of biospecimens.* **Panelists:** • Annette Schmid, PhD, Sr. Director, Global Science Policy, Takeda • Rita Lawlor PhD, Centre for Applied Research on Cancer / ISBER • Zisis Kozlakidis PhD, MBA, Head, Laboratory Services and Biobanking at IARC/WHO (virtual) **Moderator:** Mark Barnes, JD LLM
11:15 – 11:50 AM	**Select MRCT Center initiatives and ongoing work** • Accessibility by Design: *presentation of the MRCT Center's work for inclusion of people with disabilities in clinical research* • International Capacity Building Efforts: *overview of the MRCT Center's current efforts in global capacity building, training, and systems optimization* • Global Clinical Research in Children: *presentation of ongoing efforts to engage youth in research, and improve communication and harmonized data requirements of health technology assessment review* • Open discussion **Moderators:** Sarah White and Barbara Bierer
11:50 – 12:00 PM	**Closing Remarks** Mark Barnes and Sarah White
12:00 – 1:00 PM	**Lunch for all Attendees**

Appendix 2: Speaker Biographies

Kenneth C. Frazier
Retired Chairman and CEO, Merck & Co., Inc.
Chairman, Health Assurance Initiatives, General Catalyst

Kenneth C. Frazier is the former Chairman and CEO of Merck, following his retirement from more than 30 years with the company, including a decade-long tenure as CEO.

In his retirement from Merck, Ken has committed himself to organizations dedicated to leading social change and building greater equity for all people. He is the Co-Founder and Co-Chair of OneTen, a coalition of leading organizations committed to upskilling, hiring, and promoting one million Black Americans into family-sustaining jobs. In addition, he is Chairman, Health Assurance Initiatives, at the venture capital firm, General Catalyst, where he advises on investments and partnerships for companies that are well-positioned to help transform the healthcare industry through collaborative and responsible innovation.

Ken's contributions, especially in the legal, business, and humanitarian fields, have been widely recognized. Under his leadership, Merck delivered innovative life-saving medicines and vaccines as well as long-term and sustainable value to its multiple stakeholders. Ken substantially increased Merck's investment in research, including early research, while refocusing the organization on the launch and growth of key products that provide far-reaching benefits to society. He also led the formation of philanthropic and humanitarian initiatives that build on Merck's 130-year legacy.

Ken joined Merck in 1992 and held positions of increasing responsibility, including General Counsel, before becoming President and CEO in 2011. Prior to joining Merck, Ken was a Partner with the Philadelphia law firm of Drinker Biddle & Reath. He sits on the boards of Weill Cornell Medicine, Eikon Therapeutics, Kyra Paradigm, the National Constitution Center and Cornerstone Christian Academy in Philadelphia, PA. He also is a member of the American Academy of Arts and Sciences, the American Philosophical Society, the Council of the American Law Institute, the American Bar Association, and a Fellow of the College of Physicians of Philadelphia. Additionally, Ken is Co-Chair of the Legal Services Corporation's Leaders Council.

As a strong advocate for social justice and economic inclusion, Ken is the recipient of numerous awards and honors, including the Anti-Defamation League Courage Against Hate Award, the Botwinick Prize in Business Ethics from Columbia Business School, the Legend in Leadership Award from the Yale School of Management, the NAACP Legal Defense and Educational Fund National Equal Justice Award, and the National Minority Quality Forum's Lifetime Achievement Award.In 2018, Ken received the Harvard Law School Association Award, the highest honor given by the prestigious association, in recognition of his extraordinary service to the legal profession, Harvard Law School, and the public. In that same year, Ken was named one of the World's Greatest Leaders by *Fortune* magazine and was also named one of *TIME's* 100 Most Influential People; he again made that list in 2021. In 2019, he became the first recipient of the *Forbes* Lifetime Achievement Award for Healthcare. In 2021 his peers named Ken *Chief Executive* magazine's CEO of the Year. Most recently, he received the highly esteemed Fordham-Stein Prize from Fordham Law School, an honor bestowed for work embodying the highest standards of the legal profession.

Ken received his bachelor's degree from The Pennsylvania State University and holds a J.D. from Harvard Law School.

Barbara Bierer, MD, is the Faculty Director of the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center); Professor of Medicine, Harvard Medical School and Brigham and Women's Hospital, Boston; and a hematologist/oncologist. She is also the Director of the Regulatory Foundations, Ethics and Law Program of the Harvard Clinical and Translational Science Center and the Director of Regulatory Policy, SMART IRB. She is Faculty in the Center for Bioethics, Harvard Medical School, and Affiliate Faculty in the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School. 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 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, Dr. Bierer served or serves as Chair of the Secretary's Advisory Committee for Human Research Protections, Department of Health and Human Services (2008-2012); as a member of the National Academies of Sciences Committee on Science, Technology and the Law (2007-2016); on the Boards of Directors of Public Responsibility in Medicine and Research (PRIM&R; 2011-2020), Management Sciences for Health (MSH; 2013-2022), Vivli (2017-), Clinithink (2015-), and North Star Review Board (2020-). She chairs the Board of Trustees of the Edward P. Evans Foundation, a foundation supporting biomedical research. She has authored or co-authored over 260 publications.

Mark Barnes, JD, is the Faculty Co-Director of the MRCT Center. Mark's law practice and his teaching at Yale focus on health care law and finance, human and animal research, stem cell and genetic research, research grants and contracts, research misconduct, and international research. Mark formerly served at Harvard as the Senior Associate Provost and University Senior Research Officer and started and directed Harvard's HIV/AIDS treatment programs in Nigeria, Tanzania, and Botswana. Mark has held senior appointed positions in the New York City and State departments of health. In 2019, he was named the "Legal Innovator of the Year" by the *Financial Times,* and over the past two decades has served in various capacities on the HHS Secretary's Advisory Committee on Human Research Protections and its subcommittees.

David Peloquin, JD, practices law at Ropes & Gray LLP where he is a member of the firm's health care group. He focuses his practice on advising academic medical centers, life sciences companies, and information technology companies on issues related to human subjects research and data privacy. He frequently writes and speaks on topics related to each of these areas and is a regular presenter at conferences and webinars of the American Health Law Association, the Association for the Accreditation of Human Research Protection Programs, the International Association of Privacy Professionals, and central and institution-specific institutional review boards. Outside of his law practice, David served until recently as a

community member of the Institutional Review Board at Mass General Brigham in Boston. In recent years, David has spent considerable time advising clients on their response to the COVID-19 pandemic, including with respect to modifications to clinical research, implementation of telehealth technologies, and development and implementation of clinical diagnostic testing programs.

David has worked with MRCT Center since 2013. He has contributed to projects on data sharing, the return of research results to clinical trial subjects, and the impact of the European Union's General Data Protection Regulation (GDPR) on research. He has presented at the MRCT Center's Research, Regulatory, and Development Roundtable (R3) on topics including GDPR, secondary uses of health data for clinical trial recruitment purposes, legal and ethical issues that arise when a company or institution uses its own employees or students as research participants, and decentralized clinical trials.

David received his undergraduate degree from Carleton College, his law degree from the Yale Law School and clerked for Judge Diana E. Murphy of the United States Court of Appeals for the Eighth Circuit. Before attending law school, David worked as a project manager for Epic Systems, a manufacturer of electronic medical records.

Sarah White, MPH, MRCT Center Executive Director, is responsible for developing, defining, and implementing the overall strategy and vision for the Center as well as oversee all management aspects of the MRCT Center functions. Sarah has over 20 years of experience in human subjects' research including experience at both academic medical centers and industry.

Prior to joining the MRCT Center, Sarah was the Director of the Human Research Quality Improvement Program (QI Program) at Partners' Healthcare in Boston, Massachusetts. In this capacity, she was responsible for strategic planning and oversight of the QI Program activities across the human research communities at Partners Healthcare, including Massachusetts General Hospital and Brigham and Women's Hospital. In addition, Sarah oversaw FDA Sponsor-Investigator support and the centralized support of clinical trials registration and disclosure. Sarah is the co-chair of the national Clinical Trials Registration Taskforce, a large consortium of academic medical centers, hospitals and universities that identify best practices, develop tools, and serve as a communication forum associated with the requirements for clinical trials registration and results reporting that affect US academic health centers. Sarah received her undergraduate degree from Dartmouth College and her MPH from Boston University School of Public Health.

Ramita Tandon, As the Chief Clinical Trials Officer at Walgreens, Ramita Tandon is responsible for leading and driving growth for the Company's new clinical trials business. In her role, Ramita works across the healthcare and life sciences industries to enable next-generation clinical trials so that breakthrough treatments reach patients faster. Her team is focused on unlocking value and improving access, awareness and trust by efficiently matching diverse patient populations to sponsor-led trials, reducing trial operational complexities and patient burdens, as well as capitalizing on Walgreens deep patient insights and leveraging real-world data from owned and partner assets.

Ramita brings more than 25 years of leadership and operational experience across a portfolio of industry-leading businesses and services in real-world evidence and patient-centered

health outcomes. Prior to joining Walgreens, she served as the Chief Operating Officer at Trio Health, and prior to that she was the Executive Vice President, Commercialization and Outcomes at ICON.

As a transformational leader, Ramita is passionate in her belief that a best-in-class operating model employing insights and innovation can deliver gains in operations and forge stronger connections with all stakeholders, including biopharmaceutical companies, healthcare systems and payers. Ramita has recently been named to Drug Store News' Top Women in Health, Wellness & Beauty class of 2022 for Business Excellence, Fierce Healthcare's 2022 Women of Influence and listed in the 2018 PharmaVOICE 100.
Ramita is an internationally recognized speaker and author whose focus is on how to bridge the gap between commercial and clinical development. She is a graduate of the University of Michigan and the Boston University School of Public Health.

Pamela Tenaerts, MD is Chief Scientific Officer at Medable, Inc. Dr. Tenaerts leads the scientific office at Medable to drive advancement of decentralized research methodologies with evidence-based best practices. Tenaerts is one of the leading advocates for innovation in clinical trials, with a unique personal background as a clinical trials investigator, hospital research administrator and academic in both the U.S. and Europe. Dr. Tenaerts joins Medable from Duke, where she led CTTI's efforts to develop and drive adoption of practices that increase the quality and efficiency of clinical trials, CTTI is a public-private partnership co-founded in 2007 by Duke and the U.S. Food and Drug Administration, comprised of more than 80 member organizations. With more than 30 years' experience in the conduct of clinical trials across a number of stakeholders, she practiced medicine in both the emergency department and private practice setting for several years before embarking on a career in research. She received her MD from Catholic University of Leuven, Belgium, and a MBA from the University of South Florida. She speaks five languages and has obtained Six Sigma Green Belt certifications.

Owen Garrick, MD, is Chief Medical Officer of CVS Health Clinical Trial Services. In this role, Dr. Garrick is responsible for the overall medical strategy across the portfolio, overseeing medical compliance, clinical insights, publications and clinical innovation. He will build out the medical affairs function across CTS. Dr. Garrick will continue to be the Executive Sponsor for the CTS-wide equity efforts, including diversity in clinical trials.

Dr. Garrick joined CVS Health as Vice President, Conduct Delivery for Clinical Trial Services, in April 2021. He helped build the nationwide, patient-centric clinical trial delivery model currently in expansion, as well as the Commitment on Diversity and Equity (CODE) in clinical trials initiative.

Prior to joining CVS Health, Owen was President of Bridge Clinical Research, where he had responsibility for the Clinical Trials, Research Analytics, Health Services Research and Healthcare Communications business units. Which at Bridge Clinical he helped launch multiple collaborative efforts in advancing precision medicine research and data science. His study "Does Diversity Matter for Health? Experimental Evidence from Oakland" won the 2021 Research Paper of the Year by the American Society of Health Economists.

Prior to joining Bridge Clinical, Dr. Garrick was Director of Strategy and Business Development at McKesson Corporation. Before joining McKesson, Dr. Garrick was Global Head of M&A Negotiations at Novartis Pharmaceuticals.

Dr. Garrick is a nationally recognized leader in the field of research and research ethics. He was confirmed and completed a term with the Department of Health and Human Services Advisory Council on Human Research Protections from 2012-2016. He has co-authored industry advisory documents around biospecimen data security and patient engagement in research and currently serves on the board of Professional Responsibility in Medicine & Research (PRIMR).

Dr. Garrick earned his MD from Yale School of Medicine and his MBA from Wharton School of Business. He holds an AB in Psychology from Princeton University.

Ann Meeker-O'Connell is the Director of FDA's Office of Clinical Policy (OCLiP) in the Office of the Commissioner. In this role, she leads an organization that is responsible for coordinating and leading the development of human subject protection and good clinical practice policy across the agency. Ms. Meeker-O'Connell has more than 20 years of experience in biomedical research and development in government, academic, and industry settings. This includes prior FDA service as the Acting Director of the Division of Good Clinical Practice Compliance within the Center for Drug Evaluation and Research, where she led efforts related to clinical trial modernization and clinical quality by design. She received an M.S. in Pharmacology and was an NIH Integrated Toxicology Fellow at Duke University.

Annette Schmid, PhD, is a Sr Director Global Science Policy at Takeda where she focusses on policies related to data, innovative scientific approaches in gene and cell therapies and appropriate representation of individuals from underrepresented and rare disease communities. She has 25+ years of experience as a scientist in academia and industry, co-founded the Science Policy Think Tank, has lead a number of industry fora, including PINTAD and GBITR and has been part of the QIBA steering committee and FNIH working groups with a particular interest in seeing appropriate innovation and industry consensus in clinical trial endpoints for novel treatments. Prior to her career in science, she worked for the German State Department mostly in cultural and legal affairs.

Rita Lawlor Ph.D, is associate professor of Laboratory Medicine Technical Sciences and a fellow of Information Privacy from IAPP (International Association of Privacy Professionals) at the University of Verona. Rita is originally a Computer Science graduate with a doctorate in translational biomedical sciences in Oncological Pathology. Rita Lawlor is co-founder of the ARC-Net applied cancer research centre where she coordinates research activities and runs the cancer biobank.

Rita is a member of the management committee of ICGC-ARGO, the international cancer genome consortium project to accelerate research in genomics oncology and is co-PI for the Italian associated project on Orphan tumors. She is a member of the steering committee of BC-NET (Biobank Cohort Network of Low Middle Income Countries) network of IARC (International Association for Research on Cancer). She is a former director of ISBER, International Society for Biological and Environmental Repositories (www.isber.org) and currently vice chair of ISBER Science Policy Community of Practice. She is past president of ESBB, the European, Middle Eastern and African Society for Biopreservation and Biobanking (www.esbb.org). She is currently on the board of the Italian Foundation for Pancreas diseases (FIMP).

Her current research interests are in molecular diagnostic markers and therapeutic targets and the role of cancer heterogeneity and molecular characterization of samples in the application of personalized medicine.

Zisis Kozlakidis, MD, is the Head of Laboratory Services and Biobanking at the International Agency for Research on Cancer, World Health Organization (IARC/WHO). He is responsible for one of the largest and most varied international collections of clinical samples in the world, focusing on gene–environment interactions and disease-based collections. This WHO infrastructure supports multinational efforts in making treatments possible and delivering those to resource-restricted settings. Dr. Kozlakidis has significant expertise in the field of biobanking and has served as President of ISBER, and as board member.

Dr. Kozlakidis is a virologist, with a PhD in microbiology from Imperial College London. He is an elected Fellow of the Linnean Society of London, the Royal Academy of Sciences, UK, and a Turnberg Fellow of the UK Academy of Medical Sciences. He serves EOSC as co-chair of the Taskforce on 'Upskilling countries'; and he also serves as editor-in-Chief for the peer-reviewed international scientific journal '*Innovations in Digital Health, Diagnostics and Biomarkers'.*

Dr Kozlakidis has contributed to seminal studies in the adoption of innovations into routine healthcare, and their associated financial impacts. He is scientific advisor to the PTEN Research Foundation, holds an MBA from the Business School, City University of London, and he is a co-founder of the City Healthcare Innovation Network, a conduit for providing and strengthening contacts between healthcare start-ups and financial institutions based in the financial district of London. He holds visiting faculty positions in China (Medical School, South Central University) and the UK (St. George's Medical School, University of London and Business School, City University of London).