Proceedings
Multi-Regional Clinical Trials Center (MRCT Center) of Brigham and Women's Hospital and Harvard 2020 Annual Meeting

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VIRTUAL MEETING

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

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Executive Summary

The MRCT Center's 2020 Annual Meeting virtually convened a diverse group of stakeholders focusing on global clinical trials. The principal topics discussed were: (1) Equity and Diversity in the Age of COVID, (2) Emerging Issues in Global Pediatric Clinical Trials, (3) Diversity, Inclusion, and Equity in Clinical Research, (4) European Union General Data Protection Regulation (EU GDPR).

Keynote: Equity and Diversity in the Age of COVID

Dr. Michelle McMurry-Heath (Biotechnology Innovation Organization, BIO) offered feedback on the MRCT Center's *Achieving Diversity, Inclusion, and Equity in Clinical Research* guidance document, described BIO's commitment to clinical trial diversity, discussed encouraging diversity in the data for Pfizer and Moderna's phase III COVID-19 vaccine trials, and highlighted a new BIO campaign to address COVID-19 vaccine hesitancy. Dr. McMurry-Heath outlined the urgent need for diversity in clinical research, applauded the MRCT Center guidance document's broad definition of diversity, highlighted the usefulness of the logic models throughout the guidance, and noted that the MRCT Center document will play a significant role in the push to improve diversity in clinical research. The MRCT Center diversity document aligns with BIO's agenda to promote equality and access to science by promoting health equity, investing in the current and next generation of scientists, and expanding opportunities for women and underrepresented populations in biotechnology supply chains and companies. After reviewing the promising efforts to increase diversity in COVID-19 vaccine trials by Pfizer and Moderna and sharing BIO's new website on COVID-19 vaccine facts, Dr. McMurry-Heath emphasized that access to science is the distributive justice issue of our age.

Panel Discussion: Emerging Issues in Global Pediatric Clinical Trials

Lisa Koppelman (MRCT Center) gave an overview of the MRCT Center project Promoting Global Clinical Research in Children. Ms. Koppelman described the importance and necessity of the work as well as the project's objectives that are being addressed by a leadership team comprised of individuals with pediatric expertise in bioethics, industry, and regulatory bodies, backed by a workgroup comprised of 80+ dedicated individuals representing a range of expertise. Monthly thematically organized subgroup meetings discuss issues related to the following:

1) Decision making at level of the child and family which includes topics of assent, consent, and addressing discordant opinions,
2) Benefit-risk considerations in pediatric trials, specific to safety and efficacy; with a focus on decision making at the level of institutional review boards, ethics committees, health authorities, and
3) Challenges in implementation of global pediatric trials.

The project is mid-flight, and the plan for next year includes drafting a better model of regulatory cooperation and transparency in global pediatric research studies, developing an array of educational materials targeting youth to support the conduct of global pediatric research studies, and developing practical recommendations to guide meaningful patient engagement for this population.

Amy Ohmer (International Children's Advisory Network, iCAN) provided an introduction to iCAN that has several global in-person chapters as well as virtual chapters. iCAN has recently established a new young adult professional group for those who have graduated from their pediatric group and wish to continue to support and contribute to the mission of the organization.

Jennifer Preston (University of Liverpool, eYPAGnet) underscored the importance of balancing the risk and benefit of participation in research, especially with regard to the wider pediatric population, and emphasized that patients and their caregivers are the most informative voices. Ms. Preston described a few key items to consider: (1) invest time up front to bring patients and the life sciences together so that people representative of intended population for the research are able to give input and offer suggestions on how to overcome issues/barriers/burdens; (2) solicit views and opinions for study design and include such an assessment in the ethics application, and (3) develop a blueprint for patient engagement via open, transparent relationships with patients and families.

Jasmine "Jaz" Gray, University of North Carolina began her session with a spoken word performance that elucidated how stories and narratives are important in the healthcare and research journey of patients, especially pediatric patients. Ms. Gray explained that storytelling can allow an individual to clarify sense-making, change, assertion of control, decision making, as well as reveal values, reasons, conflicts, and fears. Ultimately, stories help build community via collective narratives that illustrate a communal history.

Panel Discussion: Diversity, Inclusion, and Equity in Clinical Research

Barbara Bierer (MRCT Center) gave an overview of the work done to date and the imperative of diverse representation in research and development, most recently revealed in the context of the COVID-19 pandemic. She explained how the MRCT Center Guidance Document is mapped onto the participant trial journey as well as the process of drug or product development. Sections are specific to either different areas of opportunity, different phases of drug development, or different stakeholders involved. She then concluded with a few remarks about ongoing and future work of the MRCT Center in this focus area.

Richard Moscicki (PhRMA) gave an introduction to PhRMA's efforts on improving clinical trial diversity, beginning with a description of the new chapter of PhRMA's principles that addressed clinical trial diversity. Dr. Moscicki explained PhRMA's new initiatives, including the objective to

create and support a public/private partnership, a community of practice to ensure broad, sustained stakeholder inclusion.

Monica Webb Hooper **(National Institute on Minority Health and Health Disparities [*NIMHD], NIH)** described the continued focus of the NIH on diversity and inclusion. She focused on work to advance an understanding of Social Determinants of Health (SDoH), first defining SDoH and then reminding the audience that SDoH are not necessarily negative. She discussed the longstanding narrative around the lack of diversity in clinical trials, and how individuals are often deemed uninterested without addressing upstream factors for underrepresentation. Within the SDoH, Dr. Webb Hooper explained how trust/distrust is an important SDoH, and how the onus for improving trust, and then achieving diversity in clinical trials, should fall within the scope of research teams and clinicians.

Roberto Lewis-Fernández (Columbia University) emphasized the role of diversity as a marker for the differential risk of exposure to adversity. He gave examples on how contextual background mechanisms (such as SDoH) are important in understanding treatment response, especially heterogeneity of treatment effect (HTE), across communities. He also discussed allostatic load, which describes the physiological consequences on the body over time from exposure to chronic stress, and how this is important in understanding HTE. He noted the importance of understanding how to apply methods for studying and standardizing Diversity, Inclusion, and Equity and SDoH by working with communities and establishing trust with communities.

Project Update: EU General Data Protection Regulation

David Peloquin (Ropes & Gray) introduced the MRCT Center's work on the General Data Protections Regulation (GDPR), which started approximately seven years ago. Mr. Peloquin highlighted the contributions that the MRCT Center has made to this topic since the last Annual Meeting, including two published articles, a white paper, and participation in a conference on challenges of GDPR for cross-border data transfers.

Mr. Peloquin mentioned that Joseph (Joe) Liss, a legal fellow at the MRCT Center, recently analyzed in an internal memorandum the impact of the Court of Justice of the European Union (CJEU) *Schrems II* decision on research data transfers. The decision invalidated the EU-US Privacy Shield that facilitated cross-border data transfer, largely due to concerns stemming from surveillance activities conducted by U.S. governmental authorities. The *Schrems II* decision has resulted in private parties needing to make an assessment of the adequacy of data privacy legislation in countries to which personal data are transferred. As a result of this decision, US research entities have begun receiving letters from EU partners that ask the US entities about their relationships with US national security agencies. The MRCT Center is currently drafting an article that focuses on "demystifying" the *Schrems II* decision for the research community.

Welcome and Introduction

Sarah White, MRCT Center

MRCT Center Executive Director, Sarah White, welcomed everyone to the MRCT Center Annual Meeting, and remarked that she would have been flanked by MRCT Center Faculty Director, Dr. Barbara Bierer, and MRCT Center Faculty Co-Director, Mark Barnes, JD, were this an in-person meeting.

Ms. White briefly reviewed the vision of the MRCT Center which is to improve the integrity, safety, and rigor of global clinical trials, and its mission to engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions. The MRCT Center employs one of several approaches to work with stakeholders to craft solutions: Workforce for large, multi-part issues; Task Force for short term, defined issues; Programmatic Initiative for regularly scheduled roundtable meetings focusing on one issue; and Global Regulatory Engagement for consultation by senior team with governments and in-country stakeholders.

Ms. White briefly introduced the MRCT Center team, which has mostly worked remotely during this year. She also introduced to the MRCT Center Senior Advisors and MRCT Center External Advisory Board and Executive Committee and Steering Committee. Then Ms. White framed the agenda of today's Annual Meeting.

Lastly, Ms. White highlighted several ongoing MRCT Center projects that were not further discussed during the Annual Meeting:

- The MRCT Center continued its work in **Health Literacy** in 2020 piloting a **process to develop consensus on a plain language clinical research glossary**.
- Early in the pandemic the MRCT Center developed, in collaboration with Harvard Catalyst, a series of **COVID-19 patient facing resources**, meant to help the public decide whether to join a COVID-19 related study.
- The MRCT Center transitioned its **Bioethics Collaborative (BC)** **and** **Research, Development, and Regulatory Roundtable (R3)** to a series of virtual meetings this year.
- Over the past year, the **core team of our Proactive Safety Surveillance** project has drafted a conceptual framework, intended to complement current surveillance methods, to envision the future of drug safety.
- The MRCT Center launched a free, self-paced introductory 10-module online course titled **Interpretation and Application of ICH E6(R2).** As of the beginning of November 2020, more than **1100 individuals from over 70 countries** have engaged in this training.
- The MRCT Center is participating in the **RADx-Underserved Populations** project. This project is focused on implementation strategies specifically designed to enhance testing of

COVID-19 in underserved, under-represented and/or vulnerable populations. The MRCT Center will help create a **community-based Ethics and Equity Board**.

- In order to improve its resources for the research community, the MRCT Center team is reviewing and refining its work in the Return of Individual Results. To date, the MRCT Center team has conducted a **landscape analysis and has convened a small taskforce** that will begin meeting in January 2021.
- The Joint Taskforce for Clinical Trial Competency (JTF) released **version 3.1 of the JTF framework** that included competencies related to clinical project management. The MRCT Center has worked with collaborators to **translate the framework**; the framework is now posted in Spanish and Japanese and is expected to be posted in French, Portuguese, and Italian next year.

Keynote: Equity and Diversity in the Age of COVID

Dr. Michelle McMurry-Heath, Biotechnology Innovation Organization (BIO)

Dr. Michelle McMurry-Heath outlined her four goals for the keynote session: 1) offer feedback on the MRCT Center's *Achieving Diversity, Inclusion, and Equity in Clinical Research* guidance document, 2) describe BIO's commitment to clinical trial diversity, 3) discuss Pfizer and Moderna's encouraging recruitment of diversity for their respective phase III COVID-19 vaccine trials, and 4) highlight a new BIO campaign to address COVID-19 vaccine hesitancy.

Dr. McMurry-Heath applauded the MRCT Center's broad definition of diversity and use of logic models throughout the diversity document, noting how the COVID-19 pandemic has vindicated this broad definition by exposing how infected individuals' health outcomes vary dramatically along dimensions such as race, gender, age, co-morbidities, nutritional intake, and others. Past efforts to increase diversity in clinical research have led to improvements in gender diversity but have not led to improvements in the representation of Black and Latinx communities in research. The MRCT Center diversity guidance provides an actionable roadmap for involving these populations and others in clinical research and will be a significant push to succeed where past initiatives have fallen short. Before moving on to the second aim of her presentation, Dr. McMurry-Heath highlighted the strength and importance of the MRCT Center Black Lives Matter statement.

BIO is advancing a three-pronged approach to promote equality: 1) promote health equity, 2) invest in the current and next generation of scientists, and 3) expand opportunity for women and other underrepresented populations. One specific strategy that BIO is using to promote diversity in clinical trials, and thus promote health equity, is partnering with contract research organizations to set and meet enrollment goals for diverse populations, an effort with which the MRCT Center will collaborate. Strategies in the BIO equality agenda also include promoting access to COVID-19 vaccines and therapies by lowering or eliminating costs to the patient, establishing best practices for training underrepresented populations in STEM, and increasing

the use of businesses owned by women and underrepresented populations in biotechnology supply chains.

Pfizer and Moderna have taken different routes to achieving diversity in their respective COVID-19 vaccine trials, but both companies have returned promising results. Forty-two percent of the participants in Pfizer's trial were from diverse backgrounds, and the company enrolled 43,000 people from six different countries to meet their diversity goals. Pfizer also lowered the age requirement for their clinical trials to twelve, an important step towards developing safe vaccines for children.

Moderna's CEO explicitly stated that diversity was more important than speed while testing their COVID-19 vaccine in clinical trials. The company remained committed to this statement, holding trial enrollment open until their goals for representation from underrepresented populations were met. Moderna enrolled Latinx patients above their population share in the United States, and Black patients were enrolled at a rate that estimates based on historical data would suggest. Moderna produced a graphic that quantifies the representation of different demographics in their COVID-19 vaccine research, allowing individuals to "see themselves in the data." This graphic may help individuals overcome their vaccine hesitancy.

BIO will soon be releasing a website on COVID-19 vaccine facts to help individuals overcome vaccine hesitancy. The website is organized in a question-and-answer format and uses plain language and clear graphics throughout. The website is also accessible in Spanish. BIO understands the factors driving vaccine hesitancy, and the clinical research and healthcare communities need to answer questions patiently.

Dr. McMurry-Heath concluded by emphasizing that access to science is the distributive justice question of this era. Growing up in Oakland, Dr. McMurry-Heath saw vulnerable populations suffering from a lack of clean water, clean air, healthcare, and nutritious food—all issues that science can address. Now at BIO, Dr. McMurry-Heath recognizes how we can combat inequality through drug development and research. Together, we can "bend the arc towards justice." Dr. McMurry-Heath exemplified BIO's dedication to this collaborative approach by ending the keynote presentation with several questions for attendees: How can BIO support others working towards this goal? What materials can we disseminate to our stakeholders? How can we deepen partnerships to incite change?

Discussion

Annual Meeting attendees asked Dr. McMurry-Heath to reflect on how she saw the COVID-19 pandemic changing future clinical trials. Responses to the pandemic have shown that clinical trials can occur outside academic medical centers and need not involve multiple burdensome trips to the research site. Further, the FDA can be more flexible and adaptable, working with manufacturers early in the research process to consider adaptive designs, encourage flexible trial eligibility criteria, and encourage the use of Bayesian statistics to analyze subpopulation

responses to therapies and vaccines. The clinical research enterprise will likely see an increase in the use of adaptive trial designs, real-world evidence, and monitoring techniques that can capture real-time safety and efficacy data. In order to maintain the changes in regulatory flexibility and clinical trial diversity that have been spurred by the pandemic, stakeholders should be fearless about calling for investments in the talent and recruitment of individuals dedicated to these causes at the FDA, within their companies, and elsewhere. Additionally, the various stakeholders in the clinical research enterprise need to communicate and collaborate in their efforts to improve representation in clinical trials.

Dr. McMurry-Heath also reflected on how to lower pharmaceutical prices and make therapies more accessible. BIO has advocated for very low, if not completely eliminated, out-of-pocket costs for patients. Many vulnerable communities suffer from diseases that do not have effective pharmacological interventions, such as obesity and Alzheimer's disease, and Dr. McMurry-Heath sees a need for economic policies to incentivize the generation of these breakthroughs. Finally, Dr. McMurry-Heath and BIO are thinking creatively about how to develop payment plans for curative therapies. For example, should payers be allowed to pay overtime? Should there be a money-back guarantee if the therapy fails? As Mark Barnes, Faculty Co-Director of the MRCT Center and Partner at Ropes & Gray LLP, noted, how to incentivize innovation while keeping prices manageable is the question of our age.

Panel Discussion: Emerging Issues in Global Pediatric Clinical Trials: Perspectives on patient/family/caregiver engagement

Lisa Koppelman, MRCT Center

Lisa Koppelman introduced the panel session with an overview of the MRCT Center project Promoting Global Clinical Research in Children. The scope of the work was developed through initial conversations held with individual experts in the field of pediatric research. The outcome was consensus for a harmonized approach to the conduct of pediatric clinical trials. Ms. Koppelman further described the importance and necessity of the work:

- Pediatric populations deserve access to safe and effective treatments, and the historical protectionist stance often renders children under-represented in research.
- "Pediatric" population is an umbrella term that encompasses a varied group with differing needs and requires further delineation.
- From a regulatory standpoint, many countries have their own governing principles and interpretation of those principles is actualized differently across the globe, hence the need for harmonization. Some countries have regulations that prohibit children from participating in research, and for others, the operational and implementation challenges appear insurmountable.

- As a response to this, the MRCT Center established a leadership team and workgroup to convene and discussing the pressing issues in pediatric involvement in clinical research.

The MRCT Center pediatric project has a leadership team comprised of individuals with pediatric expertise in bioethics, industry, and the regulatory realm. Leadership is backed by a workgroup comprised of 80+ dedicated individuals representing a range of expertise. The workgroup has co-developed a list of preliminary objectives intended to help provide solutions to address the challenges in pediatric clinical trials, including plans to:

- Conduct a global legal landscape analysis of pediatric research governance (gaps and inconsistencies);
- Understand and leverage existing and ongoing initiatives;
- Identify challenges in decision-making and how to engage patients, families and their caregivers in a meaningful way; and
- Understand the benefit-risk considerations for those deciding whether to participate in research.

To meet the project's objectives, the work is structured as following:

- Weekly leadership meetings
- Monthly workgroup meeting, inclusive of all members
- Three monthly subgroup meetings covering:
    1. Decision making at level of the child and family which includes topics of assent, consent, and addressing discordant opinions
    2. Benefit-risk considerations in pediatric trials, specific to safety and efficacy; with a focus on decision making at the level of institutional review boards, ethics committees, health authorities
    3. Challenges in implementation of global pediatric trials

Ms. Koppelman concluded by noting that the project is mid-flight and the plan for next year includes:

1) Draft a better model of regulatory cooperation and transparency in global pediatric research studies;
2) Develop an array of educational materials targeting youth to support the conduct of global pediatric research studies;
3) Describe what meaningful patient engagement means to this population – beyond "checking the box" to say patients were included—what are the best practices of who, how, when and why patient engagement is necessary in pediatric research?

Gianna McMillan, Bioethics Institute at Loyola Marymount University

Ms. Koppelman introduced Dr. Gianna McMillan, Faculty and Program Administrator at the Bioethics Institute at Loyola Marymount University, to moderate the panel discussion. Dr. McMillan is an educator with extensive experience as a patient and patient advocacy and co-

leads a subgroup within the pediatric project. Dr. McMillan graciously accepted her introduction and continued by introducing the following panelists:

Amy Ohmer, International Children's Advisory Network (iCAN), Inc.

Amy Ohmer provided an introduction to iCAN and noted that there are several global in-person chapters, each with different needs and different characteristics, including the prevalence of represented diagnoses. Ms. Ohmer highlighted the availability of iCAN's virtual chapters to ensure equity of access. She described how iCAN initiated a new- young-adult professional groups for those who have graduated from their pediatric group and want to continue to support and contribute to the mission of the organization. iCAN has an international summit scheduled for July 2021, hopefully in person, in Lyon, France. Ms. Ohmer encouraged everyone in attendance to learn more about the organizations work at www.icanresearch.org.

Jennifer Preston, University of Liverpool; European Young Persons Advisory Groups (eYPAGnet)

Jennifer Preston opened by noting the importance of balancing the 'ask' of clinical research participants with the burden of disease, and to consider how that may vary by disease and diagnosis. Ms. Preston underscored the importance of balancing the risk and benefit of participation in research, especially with regard to the wider pediatric population, and emphasized that patients and their caregivers are the most informative voices for patient, community, and caregiver engagement.

Ms. Preston then described how studies reviewed by the European Young Persons Advisory Groups (eYPAGnet) have different risk-benefit profiles, the presentation of each being influential and important to reviewers. A few of the key items to consider include:

- Invest time initially to bring patients and life sciences together so that people representative of the intended population are able to give input and offer suggestions as to how to overcome issues/barriers/burdens.
- Solicit views and opinions for study design and include such an assessment in the ethics application.
- Develop a blueprint for patient engagement via open, transparent relationships with patients and families.

Jasmine "Jaz" Gray, University of North Carolina

Jazmine ("Jaz") Gray began her session with a spoken word performance that elucidated how stories are important in the healthcare and research journey of patients, especially pediatric patients. She described why patients need stories and advised on how researchers can achieve greater engagement through stories.

Ms. Gray summarized some key words that describe the potential impact storytelling has on patient engagement and research relationships. Storytelling can allow an individual to clarify sense-making, change, control, and decision making, and can also reveal values, reasons,

conflicts, and fears. Ultimately, stories help build community via collective narratives that illustrate a communal history.

Ms. Gray concluded by summarizing how researchers can use storytelling to impact engagement and honor children by committing purposeful time and consistent effort toward modeling two story sharing objectives:

1) Listening for <each person's> story = active listening = act of compassion
2) Telling through <their own> story = using framing techniques to describe a situation = relatedness and understanding

Discussion

The conversation started with the topic of including pediatric patients and their parents/caregivers in focus groups since medicine and technology affects children in vastly different ways than adults. The day-to-day perspective of children is important – perhaps the study has noble goals, but a child or adolescent may care more about socializing or participating in a school event. Researchers who recognize this will help studies be designed in more achievable ways.

The group then discussed how the pediatric perspective may change during the course of the study, and that it is important to accommodate for that in study design – for instance, limiting appointments during school time and considering the substitution of home visits. It was also noted that throughout the study additional sensitive issues may come up – such as recruitment issues or dissemination of findings.

The panel discussed strategies for the research community to create authentic patient engagement opportunities:

- Start with asking yourself about your own motivations and be sure not to underestimate the importance of community knowledge.
- Patients are not just there "to be fixed." They give wisdom and knowledge – self-check your own perspectives.
- Use empathy – how can I match my goals to the goals of children?
- Overcome the fear of asking a child to share their perspective. It is important to hear from children. We will often learn something we never knew or considered before.
- Invest time to build relationships and get to know young people – what are they like when they are not thinking about their illness or condition? What is important to them?
- ASK! And offer a seat at the table – otherwise there will never be the conversation.

Panel Discussion: Diversity, Inclusion, and Equity in Clinical Research

Barbara Bierer, MRCT Center

Dr. Barbara Bierer, Faculty Director of the MRCT Center, began the session with an overview of the work done so far and the imperative of diverse representation in research and development in the context of COVID-19. Dr. Bierer gave background on why this is important for in terms of biology, equity, fairness, and trust.

Dr. Bierer provided some history on the MRCT Center workgroup that has been leading this work and contributing in different ways, resulting in the *Achieving Diversity, Inclusion, and Equity in Clinical Research* guidance and toolkit. Dr. Bierer gave an overview of the guidance, explained how the Guidance Document is mapped onto the participant trial journey and the drug development program, and addresses accountability. It is intended to be a solution-rich document.

Dr. Bierer summarized current and upcoming MRCT Center initiatives: a roundtable(s) to address and coordinate what we can do at various levels going forward; targeted projects for special populations to foster inclusion; roles of IRB in providing oversight; accountability and participation of CROs in collaboration with BIO; and moving towards progress in statistical analysis for subgroup identification and heterogeneity of treatment effect.

Dr. Bierer concluded with an ask for each of us in this system to think about what we can commit to moving forward. She emphasized a need to agree upon transparent metrics, to sit in uncomfortable conversations, and to commit to real change day after day.

Richard Moscicki, Pharmaceutical Research and Manufacturers of America (PhRMA)

Dr. Rich Moscicki, Executive VP for Science and Regulatory Advocacy and CMO at PhRMA, gave an introduction to PhRMA's efforts on improving clinical trial diversity, beginning with a description of the new chapter of PhRMA's principles that addressed clinical trial diversity, setting the stage for an overarching equity effort. These efforts and solutions must be ongoing and sustained.

Dr. Moscicki elaborated on who PhRMA sees as important advisory board members in industry, including civil rights groups, patient advocacy groups, faith-based organizations, and more. He then explained PhRMA's new initiatives further, including the objective to create and support a public/private partnership, a community of practice to ensure broad, sustained stakeholder inclusion. Lastly, Dr. Moscicki invited attendees to go to PhRMA.org/equity for more information.

Monica Webb Hooper, National Institute on Minority Health and Health Disparities (NIMHD)/ National Institutes of Health (NIH)

Dr. Monica Webb Hooper, Deputy Director of the National Institute on Minority Health and Health Disparities (NIMHD) at the National Institutes of Health (NIH), began with explaining the background of the NIMHD. She described the continued focus of NIH on diversity and inclusion. She focused on work to advance an understanding of Social Determinants of Health (SDoH), first defining SDoH and then reminding the audience that SDoH are not necessarily negative. SDoH determinants impact the odds of good health, and the goal is for everyone to have positive and protective SDoH in their lives.

Dr. Webb Hooper discussed the longstanding problem of the lack of diversity in clinical trials, and how prospective participants are often considered uninterested in research without addressing upstream factors for underrepresentation. She gave recommendations for increasing racial/ethnic minority representation in clinical trials, while recognizing that many reasons are not within the purview or control of the individual.

Dr. Webb Hooper explained how trust/distrust is an important SDoH, and how the onus for improving trust, and thus achieving diversity in clinical trials, should fall within the scope of research teams and clinicians. She described how increasing trust is complex, and therefore requires expertise from multisector stakeholders including community members, as they can be good messengers and provide appropriate helpful insight.

Dr. Webb Hooper then gave a brief overview on the assessment of SDoH, focusing on the special collection within the PhenX toolkit led by NIMHD, an effort to standardize the collection, use, and harmonization of SDoH data.

Roberto Lewis-Fernández, Columbia University

Dr. Roberto Lewis-Fernández, Professor of Clinical Psychiatry at Columbia, Director of NY State Center of Excellence for Cultural Competence and Hispanic Treatment Program, and Co-Director of the Anxiety Disorder Clinic at New York State Psychiatric Institute, provided remarks as the final member of the panel. He emphasized the role of diversity as a marker for the differential risk of exposure to adversity.

Dr. Roberto Lewis-Fernández explained how differential exposure to adversity becomes differential human biology, resulting in the necessity of including an evaluation of social factors in all clinical research, including biologic and interventional clinical trials. He gave examples of the importance of contextual background (including SDoH) in understanding treatment response, especially heterogeneity of treatment effect, across communities. For instance, negative SDoH such as air pollution and inadequate housing can lead to higher rates of asthma and higher mortality from COVID-19. If researchers do not account for differences in SDoH

(e.g., air pollution, crowded, multi-generational housing conditions), we will not understand why the results of an intervention are different during the trial and after marketing.

Dr. Lewis-Fernández also discussed allostatic load, which describes the physiological consequences on the body over time from chronic exposure to stress, and how this is important in understanding the heterogeneity of treatment effect. He illustrated this with an example from NHANES: This national survey found higher allostatic load among Blacks than whites. The highest load was sustained by poor Black women, and the second highest was sustained by non-poor Black women. NHANES illustrated that being Black, independent of poverty, is associated with poor health secondary to the impact of persistent racism and discrimination. These contextual data are important in understanding the heterogeneity of treatment effect.

Dr. Lewis-Fernández emphasized that these examples illustrate the ways we can understand differential exposure to risk leading to mediators—and modifiers—of clinical and biologic effects, and that this understanding can help target treatments for all, especially those most affected. He concluded by discussing methods for studying and standardizing Diversity, Inclusion, and Equity, and SDoH measures. He noted the importance of understanding how to apply these measures by working with communities and establishing trust with communities.

Discussion

The first question fielded by the panel was: How does genetic ancestry play into biologic change due to social determinants that have impacts over time? Dr. Lewis- Fernández responded by explaining that ancestry and genetics are some of the risk factors that people bring which also can be a source of resilience and strength. It is important to separate genetics from rough, unsophisticated racial categories used across the world to separate groups. He explained that we need to go beyond these racial categories to study genetic data and compare genetic data to the social determinants, which are unevenly distributed throughout society.

Dr. Bierer went on to posit a fundamental question on how to balance the collection of detailed SDoH parameters with practicality in clinical research, as we do not know which SDoH are most impactful, just that the constellation increases morbidity and mortality in certain diseases. A robust collection of SDoH data takes time and resources and may be difficult to defend in a time-pressured interaction. She asked whether there were good “top level” indicators that would then command further detail if appropriate.

Dr. Webb Hooper added that the NIH wants to encourage the standardization of measures, and recommends multilevel measures at both individual and structural levels. Dr. Bierer discussed the opportunity for funder-mandated collection and harmonization of these types of data, and the possibility to move towards progress more rapidly.

Project Update: European Union (EU) General Data Protection Regulation (GDPR)

David Peloquin, Ropes & Gray LLP

Mr. David Peloquin, Senior Adviser at the MRCT Center and Partner at Ropes & Gray LLP, introduced Annual Meeting attendees to the MRCT Center's work on the EU GDPR. Approximately seven years ago, the MRCT Center became one of the first organizations to highlight the implications that the then-draft GDPR may have for clinical research. The 2019 MRCT Center Annual Meeting featured a presentation on the key moments in the MRCT Center's instrumental and long-running GDPR project. These moments include:

- **November 2013:** Publication of article in Bloomberg BNA discussing challenges that draft GDPR poses to secondary use of clinical trials data
- **August 2014:** Publication of article in Bloomberg BNA discussing interaction of draft GDPR and EMA Policy 0070 on clinical trials data transparency
- **February 2016:** Publication of article in Bloomberg BNA discussing potential impact of final GDPR text on scientific research and secondary uses of data
- **2017-2018:** Publication of several articles on the basis for processing personal data under GDPR, the extraterritorial effect of GDPR, and consent under GDPR
- **December 2018:** MRCT Center co-sponsored a two-day conference with EMA on the impact of GDPR on research
- **November 2019:** MRCT Center co-sponsored a full-day seminar that took place on November 19, 2019 at the Mission of Switzerland to the European Union in Brussels, Belgium

The MRCT Center has continued work on the GDPR since the last Annual Meeting. Key activities include:

- **March 2020:** Article published in European Journal of Human Genetics (a Nature journal) on challenges of GDPR to secondary uses of data
    - the European Medicines Agency cited the article in its 2020 Discussion Paper for Medicines, Developers, Data Providers, Research-Performing and Research-Supporting Infrastructures on The General Data Protection Regulation: Secondary Use of Data for Medicines and Public Health Purposes
- **April 2020:** Submitted updated version of November 2019 white paper in response to call for comments on GDPR from the European Commission
- **May 2020**: Participation in Intelligence in Science (ISC) Intelligence conference on challenges of GDPR for data transfers
- **October 2020:** Article published in Science Magazine entitled 'How to fix the GDPR's frustration of global biomedical research;' draft responses submitted to two letters

commenting on the article. The publishing of this article was timely given recent developments on the GDPR and the transatlantic transmission of data.

The MRCT Center has a longstanding collaboration with the National Institutes of Health (NIH) Fogarty International Center on issues related to GDPR, and both parties continue to work together on the challenges that the GDPR poses for the NIH as a funder of research and as a recipient of European research data.

Joseph Liss, a legal fellow at the MRCT Center, recently analyzed the impact of the Court of Justice of the European Union (CJEU) *Schrems II* decision on research data transfers. The decision invalidated the EU-U.S. Privacy Shield that facilitated cross-border data transfer. The elimination of the Privacy Shield was less impactful on clinical research than feared because non-profit research entities were never eligible for the Privacy Shield, and many for-profit research entities had been skeptical of the long-term viability of the Privacy Shield, and thus relied on other mechanisms for cross-border data transfer.

The *Schrems II* decision also addressed the use of standard contractual clauses approved by the European Commission to legitimize the transfer of personal data from EU entities to entities located in other countries. The court expressed the concern that even when parties sign these clauses, US security agencies might surveil data entering the US The court did not invalidate these standard contractual clauses, but instead instituted the requirement that each EU entity that transfers personal data to the US must conduct an independent assessment of the safeguards present in the transfer and US law. As the *Schrems II* decision puts the assessment burden on private parties, US research entities have begun receiving letters from E.U. partners that ask the US entities about their relationships with US security agencies. The European Data Protection Board (EDPB) offered helpful guidance on the matter in November 2020, but questions remain for the research community. Mr. Liss has been researching the following issues raised by *Schrems II* and the EDPB guidance, and the MRCT Center hopes to publish this research in a way that is understandable to the research community:

- Do U.S. national security laws affect research data transfers?
- To what extent do Certificates of Confidentiality shield research data from disclosure under U.S. national security laws?
- Under the EDPB's guidance on supplemental measures, which measures are most relevant in the research context?
- Strategies for assisting European institutions in conducting assessment of adequacy of data protection by U.S. entities

Closing Remarks

Mark Barnes and Barbara Bierer, MRCT Center

Dr. Barbara Bierer reviewed upcoming meetings, including the MRCT Center Annual Meeting 2021 and the 2021 meetings of the Bioethics Collaborative and the Research, Development &

Regulatory Roundtable (R3). Meetings will be held virtual at least through June 2021. Dr. Bierer also reviewed the dates of 2021 Executive and Steering Committee meetings. She thanked participants for their support and collaboration, and thanked speakers and the keynote speaker of today's meeting.

Mr. Mark Barnes thanked everyone for participating and for everything that stakeholders contributed during the year. He also expressed appreciation for the rich discussions during the meeting and closed by wishing everyone happy holidays.

Appendix 1: Meeting Participants

First Name:	Last Name:	Job Title:	Institution/Affiliation:
Elizabeth	Adamson	Manager	Novartis
Salomi	Aladia	Research Specialist	University of Iowa
Albert (AJ)	Allen	Senior Medical Fellow, Pediatric Capabilities	Lilly
Ashley	Atkins	Director Corporate Responsibility	Novartis
Maria	Aspostolaros	Sr. Director, SRA	PhRMA
Susan	Bartlett	none	none
Ginny	Beakes-Read	Executive Director GRR&D Policy	Amgen
David	Bobbitt	President and CEO	CDISC
David	Borasky	Vice President, IRB Compliance	WCG IRB
Jeff	Bornstein	Vice President, Head Clinical Science, GI	Takeda
Stuart	Buck	Vice President	The Laura and John Arnold Foundation
Elizabeth	Cahn*	Program Director	Cancer Connection, Inc. (Northampton, MA)
John	Cerulli	Associate	Reservoir Communications Group
Christine	Chang	Manager	Deloitte
Karla	Childers	Senior Director Strategic Projects	Johnson & Johnson
Luther	Clark	Deputy Chief Patient Officer	Merck & Co., Inc
Francis P.	Crawley	Executive Director	GCPA & SIDCER
Patrick	Cullinan	Sr Director of Regulatory Affairs	Bluebird Bio
Lumilla	Daniels		
Claire	Destrampe	Associate Specialist	iCAN Inc.
Deborah	Esparza-St Louis	Senior Research Administrator	Brigham and Women's Hospital
Karen	Feinberg	Founder/Principal Consultant	Feinberg Consulting
Nicole	Forman	Sr Risk Management Physician	Boehringer Ingelheim

Danielle	Friend	Senior Director	Biotechnology Innovation Organization
Luke	Gelinas*	Chairperson	Advarra
Jennifer	Goldsmith	Director of Programs and Administration	Brigham and Women's Hospital
Bridget	Gonzales	Director, Training and Professional Development	ACRP
Polly	Goodman	Associate Director of Regulatory Affairs and Opera	Harvard Medical School
Janice	Gray	Agency Owner	State Farm Insurance Agency
Jasmine "Jaz"	Gray	Roy H. Park Doctoral Fellow	University of North Carolina at Chapel Hill
Eddie	Gray Jr	Retiree	FedEx Express
Margaret	Hamburg★	Former FDA Commissioner	None
Corrine	Hang	Business Manager	J Rich Capital, Inc.
Melissa	Heidelberg	Realization Project Manager	Roche
Nina	Hill★	President	Hill Scientific and Public Affairs, LLC
Patrick	Holmes	Senior Director, Innovation Policy Lead	Pfizer
Julie	Holtzople	Head Clinical Transparency and Data Sharing	AstraZeneca
Carlton	Hornung	University of Louisville	University of Louisville
Elisa	Hurley	Executive Director	PRIM&R
Yoichiro	Inagaki	VP, Clinical Development	Kowa Pharma Development Co.
Sheryl	Jacobs	Vice President	Amgen
Stephen	Keith	Medical Director	Syneos Health
Ariella	Kelman	Global Head of Bioethics	Genentech Inc.
Alison	Kiesler	Sr. Project Manager	Amgen
Aaron	Kirby	Director, Regulatory Affairs and Operations	Harvard Catalyst/SMART IRB
Tom	Koutsavlis	GVP, US Medical Affairs	Takeda
Katherine	Laessig	Vice President, Therapeutic Strategy	IQVIA
Vivian	Larsen	Associate Director - R&D Patient Engagement	Takeda

Kathy	Lenhard	CEO	PanAmerican Clinical Research LLC
Roberto	Lewis-Fernández	Professor of Clinical Psychiatry	Columbia University
Tiepu	Liu	Director	ClinChoice
Leanne	Madre	Director of Strategy	Clinical Trials Transformation Initiative
Tamara	Marshall	Physician	MNK
Priscilla	Mbimadong	Intern	Reservoir Communications Group
Sophia	McLeod	Director of Government Relations	Association of Clinical Research Organizations
Gianna	McMillan	Faculty and Program Administrator	Bioethics Institute at Loyola Marymount University
Michelle	McMurry-Heath	President & CEO	Biotechnology Innovation Organization (BIO)
Dave	Meyers	National Director Life Sciences	Microsoft
Jules	Mitchel	CEO	Target Health LLC
Sandra	Morris	VP Strategy Realization	Johnson & Johnson
Richard	Moscicki	Chief Medical Officer and Executive Vice President	PhRMA
Robert	Nelson	Senior Director, Pediatric Drug Development	Johnson & Johnson
P. Pearl	O'Rourke	Retired	Partners HealthCare
Amy	Ohmer	Director	International Children's Advisory Network, Inc.
Pandy	Opima	Assoc. Director Study Leader	AstraZeneca
Peter	Payne	VP, Head of the Digital Research Network	Optum
David	Peloquin*	Partner	Ropes & Gray, LLP
Shona	Pendse	Senior Medical Director	Kowa Pharma Development Co
Phoebe	Peng	Business Manager	JRICH CAPITAL
Claude	Petit	VP Biostatistics and Data Sciences	Boehringer Ingelheim
Jennifer	Preston	Senior Patient and Public Involvement Manager	University of Liverpool
Sandra	Prucka	Director of Genetic Counseling Clinical Services	Indiana University School of Medicine Dept. of Medical and Molecular Genetics

Chris	Reddick	Head of Health Equity	Takeda
James	Riddle	VP Research Services & Strategic Consulting	Advarra
Maria	Rocha	Assoc. Dir. Global Regulatory Affairs	Sunvion
Christopher	Romero	Medical Director, USA	Pan American Clinical Research LLC
Matthew	Rotelli	Senior Advisor, Bioethics	Eli Lilly and Company
Michele	Russell-Einhorn	Chief Compliance Officer and Institutional Official	Advarra
Wendy	Sanhai	Specialist Leader	Deloitte
Annette	Schmid	Sr. Director Global Science Policy	Takeda
Donna	Schwarz	Consultant	Schwarz Consultants
Jessica	Scott	Head of R&D Patient Engagement	Takeda
Moke	Sharma	Senior Vice President	Alexion
T. J.	Sharpe	Patient Engagement Program Manager	Medidata Solutions
Hairong	Shi	Statistician	FDA
Im Hee	Shin	Professor	Daegu Catholic Univ, Medical Center (DCUMC, School of Medicine) / Comprehensive and Integrative Institute (CIMI)
Evan	Sohn	Regulatory Affairs and Education Coordinator	Harvard Catalyst/HMS
Stephen	Sonstein*	Senior Advisor	MRCT Center
Michael	Steel	Senior Advisor, Chief Medical Office	Novartis Pharma AG
Walter	Straus	Associate Vice-President	Merck
David	Strauss*	Special Lecturer	Columbia University
Elyse	Summers	President and CEO	AAHRPP
Ara	Tahmassian★	Chief compliance officer	Harvard University
Camelia	Thompson	Senior Director, Science & Regulatory Affairs	Biotechnology Innovation Organization (BIO)
Isabel	Turi	Intern	RCG
Jennifer	Van Ekelenburg	Head Human Subject Research Gov & Disclosure	GSK

Monica	Webb Hooper	Deputy Director	National Institute on Minority Health and Health Disparities, NIH
Leanne	West	President	iCAN
Brad	Wilken	Deputy Director Product Development Operations	Bill and Melinda Gates Foundation
Elizabeth	Witte	Sr. Regulatory Affairs Operations Officer	Harvard Medical School
Hayat	Ahmed	Project Manager	MRCT Center
Carmen	Aldinger	Administrative and Training Manager	MRCT Center
Sylvia	Baedorf Kassis	Program Manager	MRCT Center
Mark	Barnes	Faculty Co-Director	MRCT Center
Barbara	Bierer	Faculty Director	MRCT Center
Jennifer	Ewing	Senior Communications Specialist	MRCT Center
Lisa	Koppelman	Program Manager	MRCT Center
Joseph	Liss	Legal Fellow	MRCT Center
Laura	Meloney	Program Manager	MRCT Center
Walker	Morrell	Project Manager	MRCT Center
Lisa	Murray	Project Manager	MRCT Center
Maya	Umoren	Administrative Assistant	MRCT Center
Sarah	White	Executive Director	MRCT Center
Deborah	Zarin	Director, Advancing Clinical Trials Enterprise	MRCT Center

*MRCT Center Senior Advisor ★MRCT Center External Advisory Board

Appendix 2: Meeting Agenda

MRCT Center 2020 Annual Meeting

Agenda

Thursday, December 3, 2020

Time	Topics/Speakers
10:00 AM – 10:05 AM	**Welcome and Introductions** • Sarah White (MRCT Center)
10:05 AM – 10:45 AM	***Keynote: Equity and Diversity in the Age of COVID*** **Dr. Michelle McMurry-Heath** **President & CEO** **Biotechnology Innovation Organization (BIO)** **Moderator:** Mark Barnes (MRCT Center; Ropes & Gray LLP) **Q & A**
10:45 AM – 11:45 AM	**Emerging Issues in Global Pediatric Clinical Trials: Perspectives on patient/family/caregiver engagement** **Moderator:** Gianna McMillan (Bioethics Institute at Loyola Marymount University) **Panel:** • Project overview – Lisa Koppelman (MRCT Center) • Amy Ohmer (International Children's Advisory Network, Inc.) • Jennifer Preston (University of Liverpool; eYPAGnet) • Jasmine "Jaz" Gray (University of North Carolina) **Q & A**
11:45 AM – 12:00 PM	**Break**
12:00 PM – 1:10 PM	**Diversity, Inclusion, and Equity in Clinical Research** **Moderator:** Sarah White (MRCT Center) **Panel:** • Current and future initiatives of the MRCT Center in DEI in Clinical Research:

	○ Barbara Bierer (MRCT Center) • Commitments to Diversity: Industry-wide commitments by PhRMA: ○ Richard Moscicki (PhRMA) • Social Determinants of Health: ○ Monica Webb Hooper (NIH) • Respondent: Roberto Lewis- Fernández (Columbia University) **Q & A**
1:10 PM – 1:25 PM	**European Union General Data Protection Regulation (GDPR)** **Moderator:** Mark Barnes (MRCT Center; Ropes & Gray LLP) • Recent updates ○ David Peloquin (Ropes & Gray)
1:25 PM – 1:30 PM	**Closing Remarks** • Mark Barnes and Barbara Bierer

Appendix 3: Speaker Biographies

Information and Biographies for MRCT Center Leadership and Staff are available on our website: https://mrctcenter.org/about-mrct/people/

Michelle McMurry-Heath assumed the leadership of the Biotechnology Innovation Organization (BIO) as President and CEO on June 1, 2020. A medical doctor and molecular immunologist by training, Dr. McMurry-Heath became just the third chief executive to steward the world's largest biotechnology advocacy group since BIO's founding in 1993.

BIO represents 1,000 life sciences companies and organizations from 30 countries. The organization's mission is to support companies that discover and deploy scientific breakthroughs that improve human heath, environmental stewardship, and sustainable agriculture.

The common thread in McMurry-Heath's work across academia, government and industry has been her focus on broadening access to scientific progress so more patients from diverse backgrounds can benefit from cutting-edge innovation. Driven by her own past family experiences navigating clinical trials and funding uncertainties within the rare disease community, McMurry-Heath calls "the distribution of scientific progress the social justice issue of our age."

She comes to BIO from Johnson & Johnson where she served as Global Head of Evidence Generation for Medical Device Companies and then Vice President of Global External Innovation and Global Leader for Regulatory Sciences. She was also instrumental in bringing J&J's incubator, JLabs, to Washington, DC. She led a global team of 900 with responsibilities in 150 countries around the globe.

Prior to her time at J&J, Dr. McMurry-Heath was also a key science policy leader in government. The Obama-Biden transition team tapped her to conduct a comprehensive analysis of the National Science Foundation's policies, programs and personnel. President Obama then named her associate science director of the FDA's Center for Devices and Radiological Health under Commissioner Peggy Hamburg. In that role, she championed clinical trial evolution, the use of real-world evidence in product evaluation, and an embrace of the patient's voice in health research so new medical products deliver outcomes that matter to them.

McMurry-Heath was the founding director of the Aspen Institute's Health, Biomedical Science, and Society Policy Program, where she promoted personalized medicine and bolstered international preparation for pandemic disease threats. She received her early training in science policy from the Robert Wood Johnson Foundation and later served as Senator Joe Lieberman's top legislative aide for science and health. In that role, she drafted legislation to protect the country from biological attacks.

McMurry-Heath received her MD/PhD from Duke's Medical Scientist Training Program, becoming the first African-American to graduate from the prestigious program. She spent 12 years working at the research bench before taking policy and leadership roles in government and industry.

McMurry-Heath lives in Washington, D.C. with her husband Sebastian Heath, a veterinarian, and their daughter, Isabella. To relax, she enjoys yoga, snorkeling and her daughter's sporting events.

Gianna (Gigi) McMillan, D. Bioethics, is Faculty and Program Administrator for the Bioethics Institute at Loyola Marymount University in Los Angeles, where she manages the graduate and undergraduate curriculum and teaches Research Ethics. She has extensive experience as a Subject/Patient Advocate on local and national IRBs, served on the Subpart A Subcommittee for the Secretary's Advisory Committee on Human Research Protection and is a member of the FDA's Pediatric Advisory Committee. Dr. McMillan is a Board Member for PRIM&R (Public Responsibility in Medicine & Research), has been on their faculty since 2004, and is the Director of Community Engagement for the academic journal, *Narrative Inquiry in Bioethics*. Her primary interests are consent issues in clinical research and the use of narrative as an educational tool in bioethics.

Amy Ohmer is the Director of the International Children's Advisory Network, Inc. (iCAN) and mother and caregiver of two daughters that were diagnosed with Type 1 Diabetes (T1D) at a very young age. After the first diagnosis in 2006, Amy has become the patient/caregiver voice in pediatrics; advocating for better treatment and care, while focusing on a cure for T1D. Amy specializes in creating collaboration through patient-centered care by focusing on the needs of patients/families as a consultant within research and medical communities.

Amy is a passionate advisor for the American Board of Medical Specialties (ABMS) Stakeholder Council, Patient/Parent Advisor Lead for research leading to better T1D outcomes through co-design within T1D Exchange, Patient Family Advisory Council (PFAC) for the University of Michigan, Patient/Family Lead for C.S. Mott Children's Pediatric Endocrinology, Advocate for American Diabetes Association, and member of the State of Michigan Diabetes Partners in Advocacy Coalition (DPAC).

With a BA from Michigan State University in Advertising, Communications Arts and Science, Amy brings a passion for engaging audiences by offering open patient/family communication by utilizing social networks, technology and marketing to strengthen the overall medical community.

Jennifer (Jenny) Preston currently has a full-time position at the University of Liverpool, based at the Institute in the Park at Alder Hey Children's Hospital in Liverpool. Her role is to deliver a strategy for the involvement and engagement of children and young people and families in pediatrics health research. Current projects include coordinating and facilitates a National Group called GenerationR Alliance (www.generationr.org.uk), which is made up of Young Person's Advisory Groups across the UK, enabling 100s of young people to have a voice in research design and delivery both in the UK and across the globe. Jenny is also senior patient involvement lead on a six-year multidisciplinary public-private initiative conect4children (c4c), which is a large collaborative pediatric network that will facilitate the development of new drugs and other therapies for the entire pediatric population in Europe; co-founder of a European Young Person's Advisory Group Network (eYPAGnet) to empower young people and families across Europe to contribute to pediatric health research; patient involvement and engagement Executive Lead for the NIHR Children and Young People MedTech Co-operative (CYPMedTech) to advance medical technologies for children and young people.

Jenny has written and co-authored over 30 peer-reviewed articles about patient and public involvement including lead author of three book chapters.

Jenny has delivered numerous training sessions, workshops and conference presentations over the years for a variety of audiences including patients and families, health care professionals, and health researchers about the importance and impact of patient involvement in health research. She has just obtained a fellowship to undertake a PhD looking at the impact of young people's involvement in the design and delivery of pediatric research.

Jasmine (Jaz) Gray is a researcher, patient advocate, and transformational speaker from Memphis, TN. She speaks and leads workshops on a range of topics including the power of stories, healthy self-image, patient-centered care, health equity, and resilience. She has had over forty-six surgeries in thirty-two years for a rare condition called Arteriovenous Malformation. Her nonprofit Jaz's Jammies Inc. has donated over 6,000 pairs of new pajamas to sick and homeless children and created opportunities for over 2,000 donors and volunteers.

Jaz has been featured on affiliate networks for NBC, CBS, ABC, and Fox. She has worked for media publications including the *Nashville Tennessean* and the *Louisville Courier-Journal* and entertainment corporations including Cartoon Network, BET, and Paramount Pictures where she co-founded an ad-hoc committee to address health-related diversity.

In addition to a B.S. from Middle Tennessee State University and an M.A. from Syracuse University, she is currently pursuing a Ph.D. in Communication at the University of North Carolina at Chapel Hill where she is an instructor.

Richard (Rich) Moscicki, M.D. is the Executive Vice President for Science and Regulatory Advocacy and the Chief Medical Officer at Pharmaceutical Research and Manufacturers of America (PhRMA).

Dr. Moscicki (Mo-shis-ke) came to PhRMA in 2017 after serving as the Deputy Center Director for Science Operations for the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) since 2013. While at FDA, Dr. Moscicki brought executive direction of Center operations and leadership in overseeing the development, implementation, and direction of CDER's programs. Previous positions include serving as Chief Medical Officer at Genzyme Corporation from 1992 to 2011, where he was responsible for worldwide global regulatory and pharmacovigilance matters, as well as all aspects of clinical research and medical affairs for the company. He served as the senior vice president and head of Clinical Development at Sanofi-Genzyme from 2011-2013.

Dr. Moscicki received his medical degree from Northwestern University Medical School. He is board certified in internal medicine, diagnostic and laboratory immunology, and allergy and immunology. He completed his residency in internal medicine, followed by a fellowship at Massachusetts General Hospital (MGH) in clinical immunology and immunopathology. He remained on staff at MGH and on the faculty of Harvard Medical School from 1979 until 2013.

Dr. Monica Webb Hooper is Deputy Director of the National Institute on Minority Health and Health Disparities (NIMHD). She works closely with the Director, Dr. Pérez-Stable, and the leadership, to oversee all aspects of the institute and to support the implementation of the science visioning recommendations to improve minority health, reduce health disparities, and promote health equity.

Dr. Webb Hooper is an internationally recognized translational behavioral scientist and clinical health psychologist. She has dedicated her career to the scientific study of minority health and racial/ethnic disparities, focusing on chronic illness prevention and health behavior change. Her program of community engaged research focuses on understanding multilevel factors and biopsychosocial mechanisms underlying modifiable risk factors, such as tobacco use and stress processes, and the development of community responsive and culturally specific interventions. Her goal is to contribute to the body of scientific knowledge and disseminate findings into communities with high need.

Before joining NIMHD, Dr. Webb Hooper was a Professor of Oncology, Family Medicine & Community Health and Psychological Sciences at Case Western Reserve University. She was also Associate Director for Cancer Disparities Research and Director of the Office of Cancer Disparities Research in the Case Comprehensive Cancer Center. During her time as a professor, Dr. Webb Hooper was principal investigator of federal and foundation grants, totaling over $15 million. To date, she has published over 90 peer-reviewed articles and book chapters.

Dr. Webb Hooper completed her doctorate in clinical psychology from the University of South Florida, internship in medical psychology from the University of Florida Health Sciences Center, and her Bachelor of Science from the University of Miami.

Roberto Lewis-Fernández M.D. is a Professor of Clinical Psychiatry at Columbia University and the Director of the New York State Center of Excellence for Cultural Competence and the Hispanic Treatment Program, and the Co-Director of the Anxiety Disorder Clinic, at New York State Psychiatric Institute. His research focuses on developing culturally valid interventions and instruments to enhance patient engagement, reduce misdiagnosis, and help overcome disparities in the care of underserved cultural groups, especially Latinxs. He also studies the way culture affects individuals' experience of mental disorder and their help-seeking expectations, including how to explore this cultural variation during the psychiatric evaluation.

He led the development of the DSM-5 Cultural Formulation Interview, a standardized method for cultural assessment for use in mental health practice, and was the Principal Investigator of its international field trial. He is Chair of the Cultural Committee of the Group for the Advancement of Psychiatry, President of the World Association of Cultural Psychiatry, Immediate Past President of the Society for the Study of Psychiatry and Culture, and Past President of the American Society of Hispanic Psychiatry. He was a member of the NIMH National Advisory Mental Health Council and Chair of the Cross-Cultural Issues Subgroup of DSM-5. Currently, he is Co-Chair of the ICD-11 Working Group on Culture-Related Issues and a member of the Working Group on Somatic Distress and Dissociative Disorders. He is also Chair of the DSM Review Committee for Internalizing Disorders and Chair of the Cultural Issues Review Committee of DSM-5-TR. His awards include the 2014 Simón Bolívar Award and the 2018 Health Services Senior Scholar Research Award of the American Psychiatric Association, the 2014 Creative Scholarship Award of the Society for the Study of Psychiatry and Culture, and the 2015 Multicultural Excellence Award of the New York State Chapter of the National Alliance on Mental Illness.

Dr. Lewis-Fernández received a B.A. from Harvard College, an M.T.S. from Harvard Divinity School, and an M.D. from Yale Medical School.

David Peloquin is a Partner at Ropes & Gray and Senior Advisor of the MRCT Center.

David Peloquin 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 subject's 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 Lawyers 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 serves as a community member of the Institutional Review Board at Partners Healthcare in Boston. In recent months, 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.