Vivli

CENTER FOR GLOBAL CLINICAL RESEARCH DATA

IN CONJUNCTION WITH

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

INNOVATIONS IN DATA SHARING

2024 Vivli Annual Meeting
Co-hosted with MRCT Center of Brigham and Women's Hospital and Harvard

November 15th, 2024, 9am-2pm EST
Harvard Faculty Club, in-person and hybrid

8:30am - Registration and coffee
Welcome and Introductions
Keynote: Steffen Thirstrup, CMO, European Medicines Agency (EMA) "Looking to the future: The opportunities for data sharing and the European Health Data Space"
Panel Discussion: The Opportunities for data sharing and the European Health Data Space (EHDS) Following on from the keynote address, panelists will discuss the potential of the EHDS. Participants will have the opportunity to ask questions of the panel. Moderator: **Rebecca Li,** CEO and Co-founder, Vivli **David Leventhal,** Data Sharing & Disclosure Lead, Pfizer **David McAllister**, Professor of Clinical Epidemiology and Medical Informatics, University of Glasgow **Steffen Thirstrup**, CMO, EMA **Aneta Tyszkiewicz,** Director, Digital & Data, EFPIA

Coffee break

Panel Discussion: Use of Health Information Exchange (HIE) data for research: legal and ethical challenges

The panel will discuss challenges related to the use of HIEs and other U.S. data sharing frameworks for research purposes, including research recruitment, retrospective studies, and more. Participants will have the opportunity to ask questions of the panel.

Moderator: **Barbara Bierer**, Faculty Director, MRCT and Vivli co-founder

Jill De Graff, VP of Regulatory, b.well Connected Health
Irene Koch, Executive Vice President and Chief Legal Officer, Hospital for Special Surgery, New York City
David Peloquin, Partner, Ropes & Gray

Panel Discussion: Risks and Opportunities in AI and data sharing

Panelists will discuss AI's risks and opportunities for sharing and re-using data today and in the coming years. Participants will have the opportunity to ask questions of the panel.

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

Karla Childers, Head, Bioethics-based Science & Technology Policy, Johson & Johnson
Dawei Lin, Associate Director for Bioinformatics & Senior Advisor to the Director at DAIT, NIAID, NIH
Subha Madhavan, Vice President & Head of AI/ML, Quantitative & Digital Sciences, Research and Development, Pfizer and Vivli Board member
David Peloquin, Partner, Ropes & Gray

A Way Forward

Wrap-up and Close

Lunch

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Speaker Biographies

Barbara Bierer, M.D.

Faculty Directory of the Multi-Regional Clinical Trials Center and Vivli Co-Founder

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

Karla Childers, M.S.

Head, Bioethics-based Science and Technology Policy, Johnson & Johnson

Karla Childers joined Johnson & Johnson (J&J) in 2013 in the Office of the Chief Medical Officer where her primary responsibility has been leading and coordinating various bioethics-based, science and technology policy projects. Ms. Childers chairs the J&J Bioethics Committee and serves as a subject matter expert for internal and external science and technology policy work.

Ms. Childers began her career in industry 20 years ago as a chemist in Merck Research Labs (MRL). She then joined MRL's global project management organization and managed cross functional drug development teams in various therapeutic areas and stages of development.

She received her BA in Chemistry from Indiana University-Purdue University in Indianapolis and a MS in Jurisprudence (Health Law) from Seton Hall Law School. She is also a graduate of Columbia University with a MS in Bioethics.

Jill DeGraff, J.D.

Vice President of Regulatory, b-well Connected Health

Jill DeGraff is the VP of Regulatory at b.well Connected Health.

She has over 20 years of legal and regulatory experience. DeGraff has served as a trustee and board vice chair at Connected DMV, an advisor for DC's HIE Policy Board, and was a partner with the healthcare practice of Manatt, Phelps & Phillips. She founded Aperture Law Group, focused on furthering technological innovation in healthcare by assisting companies in meeting healthcare, privacy, and security requirements.

DeGraff holds a B.A. in History and Economics from Wellesley College, a J.D. from University of Virginia School of Law, and a graduate certificate in health policy from George Washington University's Milken School for Public Health.

Irene Koch, J.D.

Executive Vice President and Chief Legal Officer, Hospital for Special Surgery, New York City

Irene Koch has held her current post since April 2015. Before this, she was Executive Vice President and General Counsel for Healthix. She has also been Executive Director for Brooklyn Health Information Exchange, Deputy Counsel, Health Information Technology and Associate General Counsel for Maimonides Medical Center, Associate Counsel for NYS Department of Health, and Associate Attorney with Willkie Farr & Gallagher LLP. She received her J.D. from Fordham University School of Law and her B.A. in Biology and Society from Cornell University.

David Leventhal, M.B.A.

Data Sharing and Disclosure Lead, Pfizer

David Leventhal is the Data Sharing & Disclosure Lead at Pfizer. He oversees the implementation of Pfizer's Clinical Trial Data Sharing and Disclosure Polices and serves as a single point of leadership for enterprise-wide sharing of sponsored clinical trial data. In addition, he and his team are responsible for fulfilling Pfizer's commitment to transparency by publicly disclosing accurate and timely study information and results, thereby providing access to information for patients, healthcare providers, and the scientific community. He has been with Pfizer for 29 years, and in that time has served in a variety of R&D and innovation functions including program management, business portfolio management, and Clinical Trial Operations.

David holds a Board of Director's seat at Healthix, a not-for-profit health information exchange regulated and funded by the New York State Department of Health. Healthix is the largest public health information exchange (HIE) in the United States, stewarding the data of over 20 million individuals.

David received his bachelor's degree from Hofstra University and his master's degree in Business Administration from Rensselaer Polytechnic Institute.

Rebecca Li, Ph.D.

CEO and Co-Founder, Vivli

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

Dawei Lin, M.S., Ph.D.

Associate Director for Bioinformatics & Senior Advisor to the Director at DAIT, NIAID, NIH

Dr. Dawei Lin is the Associate Director for Bioinformatics and Senior Advisor to the Director at the Division of Allergy, Immunology, and Transplantation (DAIT), NIAID, NIH. He leads data science strategy development and implementation, providing expertise for clinical networks and major research programs funded by the division. Dr. Lin directs the ImmPort program, a longstanding immunology and clinical data repository with over 20 years of history.

At NIH, he plays a key role in shaping biomedical data policies, supporting data repositories, and advancing initiatives in data sharing/reuse, AI, and emerging computational resources.

Internationally, Dr. Lin co-chairs the Research Data Alliance/World Data System Certification of Digital Repository Interest Group and serves on the CoreTrustSeal board, contributing to standards for certifying

trustworthy data repositories. He also leads efforts to develop and promote the TRUST Principles for digital repositories.

Before joining NIH, Dr. Lin established the Bioinformatics Core at the UC Davis Genome Center and was instrumental in modernizing the Protein Data Bank (PDB) at Brookhaven National Laboratory. He holds a Ph.D. in Physical Chemistry from Peking University, China.

Subha Madhaven, Ph.D.

Vice President & Head of AI/ML, Quantitative & Digital Sciences, Research and Development, Pfizer

Subha is a dynamic and results-driven leader with a strong track record of excellence in organizations that operate at the nexus of science, technology and business. She has initiated and successfully directed several productive clinical research and development programs at the Georgetown Lombardi Comprehensive Cancer Center, MedStar hospital network, FDA, NIH and BioPharma industry. She was co-leader of the FDA's Center for Excellence in Regulatory Science and worked with the Oncology and Vaccine teams. She was an advisory member to the Biden Foundation's Cancer Moonshot Program and advised on pre-competitive data sharing initiatives across Pharma, Health Tech companies and research organizations to drive innovation. She has been recognized for her work through several awards including the Service to America award in the Science and Environment category (2005), Research Acceleration Award by AACR and Pancreatic Cancer Action Network (2015), and Women in Tech Global award (2021). She is currently the Head of Clinical AI/ML & Digital Sciences at Pfizer worldwide R&D where she leads a team focused on advancing precision therapies across multiple treatment areas including Anti-Infectives, Oncology, Immunology & Inflammation among others.

David McAllister, Ph.D.

Professor of Clinical Epidemiology and Medical Informatics, University of Glasgow

David graduated in 2002 and worked in hospital medicine until 2010 including a period of doctoral research, funded via a personal fellowship with Chest, Heart and Stroke Scotland, at the University of Edinburgh with a spell in Columbia University.

In 2011, David transitioned to public health medicine, publishing influential work in cardiovascular, respiratory, and diabetes epidemiology. In 2016 he was awarded a Wellcome Intermediate Clinical Fellowship, as well as the Wellcome-Beit Prize, and moved to the University of Glasgow to study treatment effectiveness in people with multimorbidity (multiple chronic diseases).

During the COVID-19 pandemic David was seconded to Public Health Scotland, where he used his expertise in routine data epidemiology to study COVID-19, focusing specifically on healthcare workers, teachers and care home residents. David continues to serve as an Honorary Consultant in Public Health Medicine, providing methodological and public health advice, and sitting as a health technology assessment committee member for NICE.

He is interested in using novel statistical and epidemiological methods and the secondary analysis of clinical trial and routine healthcare data to improve healthcare decision making for people with multimorbidity and clinical frailty.

David Peloquin, J.D.

Partner, Ropes and Gray

David Peloquin is a partner in Ropes & Gray's health care group based in Boston who advises clients on a wide range of legal and regulatory issues in the area of clinical research, data privacy, provision of health care services, and related activities. David guides clients through complex regulatory questions arising under the Common Rule and FDA regulations, data privacy regulations (including HIPAA, U.S. state privacy laws, and GDPR), as well as state and federal fraud and abuse laws and health care licensing requirements. David is also a member of the firm's digital health practice and frequently advises clients on the use of digital technologies and artificial intelligence in research and clinical settings. David's clients include academic medical centers, universities, health systems, pharmaceutical and medical device manufacturers, information technology companies, and entities that invest in the healthcare sector. David is a graduate of the Yale Law School and Carleton College.

Ida Sim, M.D., Ph.D.

Professor of Medicine and Computational Precision Health, University of California San Francisco and Vivli Co-Founder

Ida Sim, MD, PhD is Professor of Medicine at the University of California, San Francisco. She is UCSF's inaugural Chief Research Informatics Officer and she co-directs the UCSF UC Berkeley Joint Program in Computational Precision Health. Dr. Sim earned her MD and her PhD in Medical Informatics from Stanford University, where her dissertation was on computational methods for data sharing of clinical trial results. She was trained in Primary Care Internal Medicine at the Massachusetts General Hospital, and completed fellowships in General Medicine and Medical Informatics at Stanford.

In 2005-6, Dr. Sim led the World Health Organization's International Clinical Trials Registry Platform which established the first global policy on clinical trial registration and defined the common 20-item Trial Registration Data Set. She has led multiple NIH and other grants on "trial bank publishing," ontology-based data sharing of human studies, and clinical trial visualization. Dr. Sim was a member of the 2015 Institute of Medicine committee on "Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk." She joined the MRCT Clinical Trials Data Sharing project in 2015 and is a co-founder of Vivli.

In other work, Dr. Sim is a national leader in mobile health and co-founder of the JupyterHealth project, an open software platform for secure personal health data ingestion and analytics. She has served on multiple national advisory committees on health information infrastructure for clinical care and research. She is a recipient of the United States Presidential Early Career Award for Scientists and Engineers (PECASE), a Fellow of the American College of Medical Informatics, and a member of the American Society for Clinical Investigation. She is a practicing clinician.

Steffen Thirstrup, M.D., Ph.D.

CMO, European Medicines Agency

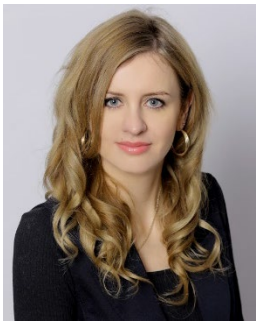
Steffen Thirstrup is a medical doctor and board-certified specialist in clinical pharmacology and therapeutics. He holds a PhD in pharmacology and has a long background in clinical internal medicine with special emphasis on adult respiratory medicine. Additionally, Dr. Thirstrup was appointed adjunct professor in pharmacotherapy at the Faculty of Health Sciences, University of Copenhagen, in 2012. From 2004-09 Steffen Thirstrup worked at Danish Medicines Agency first as the Danish member of CHMP at the European Medicines Agency (EMA) for five years including 10 months as joint CHMP- and CAT-member, followed by a short period as head of Danish Institute for Rational Pharmacotherapy dealing with HTA and best practice guidelines for primary care. In 2011 Prof. Thirstrup rejoined the licensing division at the Danish Medicines Agency acting as Head of Division for Medicines Assessment and Clinical Trials. During this period Prof Thirstrup co-chaired the European Commission's working group on market access for biosimilars medicinal products and acted as key scientific contact for the managing entity of the IMI beneficiaries for the PROTECT collaboration (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium).

In March 2013, Prof Thirstrup joined the pharmaceutical consultancy company NDA Group AB as a full-time medical advisor on NDA's regulatory advisory board. In April 2014 Prof Thirstrup was appointed as director for the Regulatory Advisory Board at NDA Regulatory Services Ltd.

Since June 2022 Prof Thirstrup has been the Chief Medical Officer at the European Medicines Agency, Amsterdam, The Netherlands.

Prof Thirstrup is author of more than 40 scientific papers, guidelines and text-book chapters as well as co-editor of 5th edition of Basal og Klinisk Farmakologi (Medical school pharmacology textbook in Danish).

Prof Thirstrup shares his life between Amsterdam and with his family in a small community (Værløse) just outside Copenhagen, Denmark



Aneta Tyszkiewicz, M.A.

Director, Digital & Data, European Federation of Pharmaceutical Industries

Aneta is Director Data and Digital at European Federation of Pharmaceutical Industries and Associations (EFPIA), representing the R&D-based pharmaceutical industry in Europe. She leads EFPIA's policy and advocacy activities in relation to data, RWE and new technologies. Her main goal is to support the digital transformation of European healthcare systems to enhance the discovery and development of innovative and trusted healthcare solutions that can bring tangible and meaningful benefits to patients. She has previously worked for the Council of European Dentists, International Diabetes Federation and a consulting agency.