Joshua C. Rubin, JD, MBA, MPH, MPP is the Program Officer for Learning Health System Initiatives at the University of Michigan Medical School Department of Learning Health Sciences. He also serves as Executive Director of the Joseph H. Kanter Family Foundation, the only philanthropic foundation founded by a patient whose overarching mission is to realize a patient empowering Learning Health System vision. Previously, Rubin served as Senior Policy Fellow at eHealth Initiative and as Senior Consultant at IBM Global Business Services. He serves as the founding President and CEO of the Learning Health Community, a multi-stakeholder grassroots movement dedicated to realizing the Learning Health System vision on a national (and ultimately global) scale.

Rebecca Daniels Kush, Ph.D. is Chief Scientific Officer, Elligo Health Research and a founding director of the Learning Health Community. Dr. Kush has ~40 years of experience in the area of clinical research and related technology, including positions with the U.S. National Institutes of Health, academia, a global CRO and pharmaceutical companies in the U.S. and Japan. She earned her PhD in Physiology and Pharmacology from the University of California San Diego (UCSD) School of Medicine and a BS in Biology and Chemistry from the University of New Mexico. Dr. Kush is Founder and President Emeritus of CDISC, which she led for 20 years. She has served on boards for HITSP, DIA, CDISC, NCI and HL7, served on the HIT Standards Committee for 5 years and is now on advisory boards for Saama, ACRES and Litmus Health.

Kaci Sykora is a graduate student at the University of San Diego in Health Care Informatics. Her graduation date is May 2021. She holds a BA in Psychology from Louisiana Tech University. Kaci serves as the Learning Health Community administrative assistant. She is also a consultant for Sense Corp's clean data initiative. Previously, Kaci served as the executive assistant for the founder and president emeritus of CDISC, Dr. Rebecca D. Kush. In 2017 Kaci served as the board secretary for Horse Empowered Learning Programs (H.E.L.P.). H.E.L.P. aids clients with physical and mental disabilities with the use of equine facilitated learning (EFL) and equine facilitated psychotherapy (EFP).

Rakesh Maniar is a TransCelerate eSource Workstream Co-Lead and SCDM eSource Implementation Initiative Co-Chair/Co-founder. At Novartis, area of responsibilities includes technology optimization, enable adoption of new technologies & provide value added services for efficient clinical trial execution. He supports initiatives in Digitization space such as eSource, ePRO, Novel Settings. Previously, He was the Global Head of Clinical Database Delivery in the Clinical Data Management at Novartis. He has been in the industry for 25 years and holds MS in Biomedical Engineering.

Lisbeth has been a GCP/PhV inspector at the Danish Medicines Agency since 2006. Prior to that, experience with regulatory affairs and as a clinical trial assessor. She also has experience from a research and hospital perspective from working with clinical pharmacology at a University Hospital in Denmark and experience as ab auditor in the medicinal industry.

Lisbeth has for the last 15+ years performed numerous national and international GCP and GVP inspections, on behalf of the Danish Medicines Agency and the European Medicines Agency in various settings such as sponsor sites, CRO/vendor sites and investigator sites.

Lisbeth is part of the GCP Inspectors Working Group and of the e-sub group currently drafting the upcoming guidance on expectations for electronic systems and data in clinical trials.

Mary Ann Slack has 30+ years of experience in both the public and private sectors developing informatics strategy and implementing solutions to business problems. She joined the FDA in 2003, where she currently serves as Director of FDA's CDER Office of Strategic Programs, charged with leading many of the Center's strategic initiatives such as decision support, data standards, program analysis, informatics, and governance. Ms. Slack has led numerous large, complex initiatives with broad stakeholder impact, including establishing CDER's data standards program and leading a team of experts in defining FDA's operational implementation of the FDA-EU mutual recognition agreement. She serves FDA's expert on multiple boards and committees focused on technology, standards, and governance.

Jesper Kjær joined as Director of the Data Analytics Centre in the Danish Medicines Agency on 1 April 2020. He holds a MSc in Bioinformatics and BSc (Hons) Computer Science. Jesper brings long experience of data handing, analyses and data visualization having worked in the academic environment and pharmaceutical industry. He has been leading development IT systems for the World Health Organization and University Hospital of Copenhagen and has also led the development of risk-based monitoring IT in Novo Nordisk. Headed up activities in EU Framework Programs (EuroSIDA, EuroCoord, CHAIN etc.), TransCelerate Biopharma eSource and IMI2 PharmaLedger (blockchain) and is on operations committee for the HL7 Project Vulcan.

Mitra Rocca joined Food and Drug Administration (FDA) in 2009 as the Senior Medical Informatician responsible for developing the health information architecture of the Sentinel System. She serves as the lead for the FDA CDER Health Information Technology (health IT) board focusing on the use of Real World Data (RWD) to enhance regulatory decision making. She serves as the FDA CDER lead to Health Level Seven (HL7), responsible for the review of HL7 draft standards. In addition, she serves as the CDER liaison to the Office of the National Coordinator for Health Information Technology (ONC).

Prior to joining FDA, Mitra served as the Associate Director, Healthcare Informatics at Novartis Pharmaceuticals Corporation focusing on the re-use of the Electronic Health Record (EHR) for clinical research.

Mitra has served as the co-chair of Health Level Seven (HL7) Clinical Interoperability Council (CIC). She holds her advanced degree in Medical Informatics from the University of Heidelberg in Germany.

Michael A. Ibara, Pharm.D. is the V.P. of Data Science at Elligo Health Research, with over 20 years experience in clinical research and development. He is former Head of Digital Healthcare for CDISC, and former Head of Business Development Coordination and Innovation and Head of Pharmacovigilance Innovation at Pfizer, where he worked for 15 years in various positions. He designed and led the ASTER project, which was the first time adverse events were retrieved directly from an EHR and delivered to FDA. His previous work includes an FDA project to harmonize common data models, the development of a real-world drug and device safety approach via the iSPY2+ OneSource project, and the application of practical ontologies to address fundamental issues in eSource, interoperability and the Learning Healthcare System. He has authored regulatory and policy recommendations for FDA on use of real world evidence, and he has a book chapter on informatics in pharmacovigilance and the impact and implications of machine learning, NLP and very large data sets. He has a Pharm.D. degree from the University of Michigan and Fellowship in Drug Research and Development with Burroughs Wellcome, Inc. and the University of North Carolina.

Denise Warzel, BBA, MSc, is a science program analyst at the National Cancer Institute. She leads the design and development of the Cancer Data Standards Registry and Repository (caDSR) where semantically annotated definitions of common data elements, models, and case report forms are created, maintained, and redistributed and is now focusing on expanding its services to address a broader spectrum standards, harmonization and transformation requirements to support the NCI Cancer Research Data Commons. She also serves as Convenor for ISO/JTC1/SC32/WG2 Data Management and Interchange, Metadata Standards. Her interests are in leveraging machine readable descriptions of data for organizational understanding and usage throughout the data lifecyle. Prior to joining NCI, Denise worked for the International Business Machines where she her involvement in data mining led her to NCI to help build infrastructure to enable using cancer data in similar ways.

Peter Van Reusel is a data standards expert with a passion for implementing practical solutions that work. He started his career in a large pharma company as a database analyst and has been working with data standards all his career.
In 2008, he started the Business & Decision Life Sciences CRO, specialized in CDISC Conversions and Biometric Services. He assumed the role of Chief Operating Officer, responsible for group operations, QA and IT.

Peter is a certified CDISC CDASH and SDTM trainer, delivering courses across Europe and he is the past chair of the CDISC E3C committee.
Since June 2018, Peter is the Chief Standards Officer for CDISC where he is responsible for the development and execution of the CDISC Data Standards strategy.

Ida Sim,MD, PhD is a professor of medicine at the University of California, San Francisco, where she co-directs Informatics and Research Innovation at UCSF's Clinical and Translational Sciences Institute, and is Director of Digital Health for the Division of General Internal Medicine. Dr. Sim's research focuses on open integrated architectures of mobile technologies for clinical research and primary care. She is a global leader in the policy and technology of large-scale sharing of clinical trials and mobile health data. In 2011, she co-founded Open mHealth, a non-profit organization that is breaking down barriers to mobile health app and data integration through an open software architecture. In 2017, she co-founded Vivli, a global data sharing platform for finding, requesting, and analyzing participant-level clinical trials data. Her digital health projects include integrating patient-reported outcomes into primary care, management of hypertension and depression in primary care, N-of-1 studies on wellbeing and chronic pain management, analytic platforms for real-time mobile data provenance and analysis, and cloud infrastructure for patient-generated data.

Dr. Sim has served on multiple advisory committees on health information infrastructure for clinical care and research, including committees of the National Research Council and National Academy of Medicine. 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. Dr. Sim is a practicing primary care physician with an ethnically and socioeconomically diverse panel of patients.

Dr. Bertagnolli is the Richard E. Wilson Professor of Surgery in the Field of Surgical Oncology at Harvard Medical School, and a member of the Gastrointestinal Cancer and Sarcoma Disease Centers at Dana-Farber/Brigham & Women's Cancer Center. Dr. Bertagnolli has had numerous leadership roles in multi-institutional cancer clinical research consortia, and currently serves as the Group Chair of the Alliance for Clinical Trials in Oncology, a nation-wide NCI-funded clinical trials group. She is also the Chief Executive Officer of Alliance Foundation Trials, LLC, a not-for-profit corporation that conducts international cancer clinical trials. In addition, Dr. Bertagnolli is a past President and Chair of the Board of Directors of the American Society of Clinical Oncology, a 45,000 member international organization serving the needs of physicians and other clinicians who care for patients with cancer. She remains a senior advisor to CancerLinQ, ASCO's program to deliver real world data insights that improve clinical care for cancer patients.

Amy Elizabeth Cramer draws on her experience as a cardiac critical care nurse, clinical research coordinator, certified healthcare quality professional and clinical research informaticist. Amy has worked in a community hospital, an independent academic medical center, and world class academic medical institution. She is currently a Director on the Global Product Development Strategic Partnerships team for Pfizer, Inc. Amy is Co-Chair for the HL7 FHIR Accelerator dedicated to Translational and Clinical Research, Vulcan. And Vice-Co-Chair for the Society for Clinical Data Management eSource Consortium. Amy's focus throughout her career has been determining improvements that provide better patient centric care, whether that be developing a visualization for a complex hypoglycemia protocol, developing a transplant quality program or optimizing the use of the electronic health record for clinical research. Amy's current focus is on clinical trials solutions, which includes eSource; specifically, the secondary use of EHR data for clinical research. She is a previous Co-Chair of HL7 Clinical Interoperability Council. She is a TransCelerate member and reviewer for many professional journals. Amy received a Master's in Management of Clinical Informatics from Duke University School of Medicine.

Jonathan has a scientific education including BSc Natural Sciences, University of Cambridge, U.K. and BSc Pharmacology, University of Bath, U.K.

Over the past 20+ years he has worked within the biopharmaceutical industry in the U.K., Switzerland, and U.S. in a range of disciplines including pre-clinical pharmacological research (Ciba-Geigy), clinical data management (Parexel), statistical programming & analysis (Pfizer, Novartis), applications development (Pfizer, Roche), and process analysis, data standards & governance (Roche).

In his current role at Roche as Global Head, Data Standards & Governance within Product Development he has been leading a team accountable for the cross-functional governance and adoption of Roche's CDISC-aligned global data standards across all Roche sponsored early & late phase clinical trials.

Charles Friedman is the Josiah Macy Jr. Professor of Medical Education and Chair of the Department of Learning Health Sciences at the University of Michigan Medical School. In recent years, he has focused his academic interests and activities on the concept of Learning Health Systems, and the socio-technical infrastructure required to sustain them. He is editor-in-chief of the open-access journal *Learning Health Systems*.

Prior to coming to Michigan, Friedman held executive positions at the Office of the National Coordinator for Health IT (ONC) in the U.S. Department of Health and Human Services. Immediately prior to his work in the government, Dr. Friedman was Associate Vice Chancellor for Biomedical Informatics, and Founding Director of the Center for Biomedical Informatics at the University of Pittsburgh.

Francisco Ros holds a PhD from the Massachusetts Institute of Technology (Electrical Engineering and Computer Science) and an Advanced Management Program degree (PADE) from IESE Business School.

Dr. Ros is President of First-Tech Engineering. He has been member of the Board of Directors of Qualcomm (2010-20), Chairman of Asurion Spain, Ad-Honorem Professor at the Engineering University of Madrid, and (2004-10) Spain's Secretary of State (Viceminister) for Telecommunications and the Information Society.

He has also been co-founder and CEO of Alúa-BroadBand Optical Access, President and CEO of Unisource (a JV among KPN, Telia, Swisscom and Telefonica), and Managing Director of Telefonica.

In addition, he has been member of the Board of AT&T Micro-electronics, WorldPartners and Infonet in the U.S., Mannesmann Arcor in Germany, Siris in France, Entel in Peru, CANTV in Venezuela, CTC in Chile and Entel, TS1 and Inteco in Spain.

Dr. Kenneth Gersing joined NCATS as the Director of Informatics in the Division of Clinical Innovation in January 2016. Dr. Gersing's focus is on the advancement of integrated health and research data, and the use of cutting-edge informatics technology to translate discovery data into improved patient outcomes, This includes: Electronic Medical Records, Data Mining, EMR's as Single Source for Clinical Trials, EMR as Resource for Continuous Quality Improvement, Predictive Modeling, Visualization of Data, Clinical Decision Support. As a physician and informatics expert, Dr. Gersing has 30 years' experience in clinical and research practice, and medical informatics.

Before joining NCATS, Dr. Gersing served as the Director of Clinical Information Services in the Department of Psychiatry and Behavioral Health at Duke University Medical Center. He earned his medical degree in 1993 at the University of Washington in Seattle and completed his psychiatric residency at Duke in 1997.

Dr. Volchenboum is an associate professor of pediatrics and the associate chief research informatics officer for the biological sciences division at the University of Chicago. He is the Dean of Masters Programs and directs a program in health sciences informatics for the division. His clinical specialty is pediatric hematology / oncology, caring for kids with cancer and diseases of the blood. In addition to his clinical practice, he directs the University of Chicago's Pediatric Cancer Data Commons, a research group dedicated to liberating and democratizing data for pediatric malignancies. Until 2019, Dr. Volchenboum directed the Center for Research Informatics, a 40-person group that supports biological research throughout the division. As director of this center, he oversaw high-performance computing, HIPAA-compliant storage and backup, application development to support clinical trials, development and maintenance of the clinical trials management system, the clinical research data warehouse, data analytics and visualization, and bioinformatics, including high-throughput genomic analyses and machine learning. He participates in and leads various data governance initiatives throughout the University and medical center. He is the director of the Informatics Core for the Clinical and Translational Science Award (CTSA). Since 2015, he has been the faculty director for the Masters in Biomedical Informatics at the Graham School at the University of Chicago.

Susan C. Winckler, RPh, Esq., is CEO of the Reagan-Udall Foundation for the Food and Drug Administration. The Foundation is the non-profit organization created by Congress to advance the mission of the FDA.

Prior to accepting the Foundation post, Winckler served as President of Leavitt Partners Solutions, a healthcare strategy firm founded by Gov. Michael O. Leavitt, former Secretary of the U.S. Department of Health and Human Services. She directly advised C-suite executives of a wide range of organizations on public policy and regulation, business strategy, investments, and other major business matters. A pharmacist and attorney by training, she was, earlier, CEO of the Food & Drug Law Institute, which provides class-leading legal and regulatory resources, analyses, updates, journals, and conferences.

As Chief of Staff for the U.S. Food and Drug Administration (2007-2009), Winckler managed the Commissioner's Office, served both Republican and Democratic commissioners as their senior-most staff adviser, analyzed complex policy challenges, and represented FDA with myriad government entities and external stakeholders. Her earlier career service included more than a decade at the American Pharmacists Association in a series of positions of increasing responsibility.

Mary F. Tobin, PhD, CSO of ACRES, a global non-profit. Dr. Tobin provides strategic planning and development to define and implement the organization's direction and initiatives, bringing formal systems thinking to areas such as bridging healthcare and research.

As Managing Principal of IMPACT, she provides research, analysis, and consultation to healthcare and research, focusing on significant organizational change barriers as well as assessing demographic, healthcare and cultural landscapes in conducting clinical trials internationally.

She has developed and conducted political competence and leadership programs as well as conflict interventions and change initiatives for corporate executives and managers in private sector, academia and US federal agencies such as HHS, FDA, Library of Congress, Agriculture, FEMA, OPM, DoE and DoD.

A certified mediator, Dr. Tobin has resolved conflict situations both for civil courts and in workplace environments.   She has developed university courses on cross cultural understanding and diversity issues and conducted ethnographic research in Russia, applying that knowledge to US business development activities.

Dr. Martin Kohn is a consultant working in health data analytics, health policy and healthcare management through his company MedPredixAI, LLC. He is an experienced physician, clinical informaticist, and health policy analyst. He was previously Chief Medical Scientist at Sentrian, which creates predictive analytic systems integrating home monitoring with longitudinal health data for patients with complex chronic diseases. Sentrian identified patients who are likely to need hospitalization days before they become seriously ill to provide time to intervene and avoid hospitalization. Prior to Sentrian, he was the Chief Medical Scientist for Care Delivery Systems in IBM Research developing analytic tools for healthcare, including the use of the Watson supercomputer.