

PANDEMIC RESPONSE: RESILIENCE AND RECOVERY IN THE ERA OF COVID-19
COVID-19 Response at the Local and National Scale

JUNE 24 | 12PM - 3PM ET | bit.ly/panfabagenda

DAY 2 AGENDA

Speaker list [below](#)

12:00 PM	Welcome and Introduction
12:05 PM	Panel 1: COVID-19 Therapeutics: Repurposing drugs and developing vaccines Moderator: Mark Namchuk, <i>Harvard Medical School</i> Panelists -- Florence Bourgeois, <i>Harvard-MIT Center for Regulatory Science</i> -- Barbara Bierer, <i>Brigham and Women's Hospital</i> -- Don Ingber, <i>Wyss Institute</i> -- Joe Loscalzo, <i>Brigham and Women's Hospital</i> -- Jens Bitsch-Norhave, <i>Johnson & Johnson Innovation</i>
1:15 PM	<i>Break</i>
1:25 PM	Panel 2: Resiliency & Trust: Local, regional, and national response to PPE Shortages Moderator: Peter Sorger, <i>Harvard-MIT Center for Regulatory Science</i> Panelists -- Ben Linville-Engler, <i>MIT & Manufacturing Emergency Response Team</i> -- Deb Plana, <i>Harvard Medical School & PanFab</i> -- Shuhan He, <i>GetUsPPE.org & Mass General Hospital</i> -- Anindita Saha, <i>Food and Drug Administration</i>
2:35 PM	Closing remarks Peter Sorger, <i>Harvard-MIT Center for Regulatory Science</i>
2:45 PM	End of Day 2

DAY 2 SPEAKER BIOS



Mark Namchuk, PhD

Executive Director Therapeutics Translation, Harvard Medical School

Mark Namchuk PhD joined Harvard Medical School in January 2020 as the executive director of therapeutics translation. In this role, Namchuk works with HMS scientists to identify and harness basic insights into clinical therapies, creating an infrastructure that advances the School's scientific discoveries along a translational trajectory while training the next generation of therapeutics investigators. Namchuk joined HMS after a 24-year research and development career in the biotech industry, working in a number of areas, including drug discovery, translational science and pharmaceutical development. In 2015, he joined Alkermes as senior vice president of research and nonclinical and pharmaceutical development. Previously, Namchuk held a number of senior research positions at Vertex Pharmaceuticals over 17 years, including senior vice president of North American research and interim global head of research. Over more than two decades he has directed drug discovery efforts in numerous therapeutic areas, including infectious disease, oncology, neurodegenerative and psychiatric disorders, immune-mediated inflammatory disease, inflammatory bowel disease and orphan diseases, including cystic fibrosis.



Barbara E. Bierer, MD

Professor of Medicine, Harvard Medical School

Faculty Director, MRCT Center, Brigham and Women's Hospital

Barbara E. Bierer, M.D., a hematologist-oncologist, is Professor of Medicine at Harvard Medical School and the Brigham and Women's Hospital (BWH). Dr. Bierer co-founded and leads the Multi-Regional Clinical Trials Center of BWH and Harvard ([MRCT Center](#)), a collaborative effort to improve standards for the planning and conduct of international clinical trials. In this capacity, she works with regulators around the world, pharmaceutical companies, CROs, academia and patients/patient advocates to harmonize policies for and approaches to clinical trial regulation. In 2017, the MRCT Center launched the non-profit [Vivli](#), a global clinical research data sharing platform. She is also the Director of the Regulatory Foundations, Ethics, and Law program at the Harvard Catalyst, and Director of Regulatory Policy for [SMART IRB](#). She serves as Faculty in the Center for Bioethics, HMS and Affiliate Faculty in the Petrie-Flom Center for Health Law at HLS. From 2003 – 2014, Dr. Bierer served as Senior Vice-President, Research, BWH. During her tenure, Dr. Bierer founded and served as Executive Sponsor of the Brigham Research Institute and the Brigham Innovation Hub (iHub), a focus for entrepreneurship and innovation in healthcare. She has authored over 220 publications.



Donald Ingber, MD, PhD

Founding Director, Wyss Institute

Judah Folkman Professor of Vascular Biology, Harvard Medical School & Boston Children's Hospital

Donald E. Ingber, M.D., Ph.D. is the Founding Director of the Wyss Institute for Biologically Inspired Engineering at Harvard University, Judah Folkman Professor of Vascular Biology at Harvard Medical School and the Vascular Biology Program at Boston Children's Hospital, and Professor of Bioengineering at the Harvard John A. Paulson School of Engineering and Applied Sciences. He received his B.A., M.A., M.Phil., M.D. and Ph.D. from Yale University. Ingber is a pioneer in the field of biologically inspired engineering, and at the Wyss Institute, he currently leads a multifaceted effort to develop breakthrough bioinspired technologies to advance healthcare and to improve sustainability. His work has led to major advances in mechanobiology, tumor angiogenesis, tissue engineering, systems biology, nanobiotechnology and translational medicine. Ingber has authored more than 500 publications and over 135 issued or pending patents, founded 5 companies, and has been a guest speaker at more than 550 events internationally. He is a member of the National Academy of Medicine, National Academy of Inventors, American Institute for Medical and Biological Engineering, and the American Academy of Arts and Sciences.



Florence Bourgeois, MD, MPH

*Associate Professor of Pediatrics, Harvard Medical School
Co-Director, Harvard-MIT Center for Regulatory Science*

Dr. Bourgeois, MD, MPH is Associate Professor of Pediatrics at Harvard Medical School and Co-Director of the Harvard-MIT Center for Regulatory Science. At Boston Children's Hospital, she directs the Initiative in Pediatric Therapeutics and Regulatory Science. Dr. Bourgeois' research is focused on the regulation and use of medications in children and the evaluation of gaps in pediatric drug evidence at the point of care. She has led studies investigating the development of drugs and devices in pediatric populations, the quality of pre-market pediatric safety and efficacy assessments, and the development of standardized metrics to assess the impact of FDA's regulatory programs on pediatric product information. She is the recipient of an Innovation in Regulatory Science Award from the Burroughs Wellcome Fund to evaluate the epidemiology of off-label drug and biologic use in children and improve provider access to benefit-risk information on FDA-regulated products. Most recently, Dr. Bourgeois served as an Expert Visitor to the European Medicines Agency to analyze the EU's pediatric drug legislation.



Jens Bitsch-Norhave, PhD, MBA

Vice President of Transactions, Johnson & Johnson Innovation

He joins Johnson & Johnson Innovation from Johnson & Johnson Global Public Health, where he served as head of business development and licensing. Jens joined Johnson & Johnson in 2005 as part of the Janssen Business Development team and has successfully led and completed numerous transactions for both R&D, commercial and public health opportunities. He has significant expertise in creating innovative deal structures and re-thinking business models for sustainable value creation. Prior to joining Johnson & Johnson, Jens held various positions in R&D and business development in both biotech and pharma companies. Jens holds a MSc in Biochemistry, a PhD in Neuropharmacology, and an MBA in Innovation Management.



Joseph Loscalzo, MD, PhD

*Hersey Professor of the Theory and Practice of Medicine, Harvard Medical School
Soma Weiss MD Distinguished Chair in Medicine; Chairman, Department of
Medicine; Physician-in-Chief, Brigham and Women's Hospital*

Dr. Loscalzo is the Hersey Professor of the Theory and Practice of Medicine at Harvard Medical School, and Chairman of the Department of Medicine and Physician-in-Chief at Brigham and Women's Hospital. He is a summa cum laude graduate of the University of Pennsylvania, where he also obtained his M.D. and Ph.D. in biochemistry in 1978. He trained in internal medicine and cardiology at Brigham and Women's Hospital, after which he was appointed to the hospital staff and Harvard Medical School faculty. In 1994 Dr. Loscalzo moved to Boston University, first as Chief of Cardiology, and, in February of 1997, Chair of Medicine. In July, 2005, he returned to the Harvard faculty in his current role. He has authored over 1,000 articles, 50 books, and 32 patents for his work in the field of vascular biology. He has received many awards including election to the National Academy of Medicine, the American Academy of Arts and Sciences, and the Académie Royale de Médecine de Belgique. He is a past member of the Advisory Council of the National Heart, Lung, and Blood Institute, and on the Council of Councils of the National Institutes of Health, as well as having served on several NIH study sections and the AHA Research Committee. He is the recipient of a MERIT Award from the National Institutes of Health, the Research Achievement Award from the American Heart Association, the Outstanding Investigator Prize from the International Society for Heart Research, the William Silen Lifetime Achievement Award in Mentoring from Harvard Medical School, and the International Pericle d'Oro Prize. He is an Editor-at-Large for the New England Journal of Medicine, was Editor-in-Chief of Circulation for twelve years; and is currently a senior editor of Harrison's Principles of Internal Medicine.



Peter K Sorger, PhD

Otto Kraye Professor, Department of Systems Biology; Head of the Harvard Program in Therapeutic Science, Harvard Medical School

Peter Sorger PhD is the Otto Kraye Professor of Systems Biology at Harvard Medical School, Head of the Harvard Program in Therapeutic Sciences (HiTS) and Director of its Laboratory of Systems Pharmacology. He received his PhD from Trinity College, Cambridge University U.K., under Hugh Pelham and trained as a postdoctoral fellow at the University of California, San Francisco with Harold Varmus. Prior to coming to HMS Peter served as a Professor of Biology and Biological Engineering at MIT. He leads the Harvard Program in Therapeutic Sciences (HiTS), a university-wide effort to advance the basic and translational science used to develop new medicines, identify responsive patients and evaluate new drugs via precision clinical trials. Sorger's research focuses on the systems biology of signal transduction networks controlling cell proliferation and death, the dysregulation of these networks in cancer and inflammatory diseases and the mechanisms of action of therapeutic drugs targeting signaling proteins. His group uses mathematical and experimental approaches to understand and eventually predict the responses of cells and tumors to drugs applied individually and in combination.



Anindita Saha, BS

Director of Partnerships to Advance Innovation and Regulatory Science, FDA Center for Devices and Radiological Health

Anindita (Annie) Saha is the Director of Partnerships to Advance Innovation and Regulatory Science (PAIRS) in the FDA's Center for Devices and Radiological Health (CDRH), Office of Strategic Partnerships and Technology Innovation (OST). During the COVID-19 public health emergency, Ms. Saha has been a part of managing CDRH's response efforts to mitigate and prevent shortages for medical devices. She is leading a team of staff to develop communications to health care providers, patients, and industry on issues related to PPE and other devices. Ms. Saha is working with collaborators outside of FDA on how partnerships can facilitate and mitigate device shortages.

In her usual day job, PAIRS develops and manages CDRH's external collaborations and public-private partnerships including the Medical Device Innovation Consortium (MDIC) and the Network of Experts program, fellowship programs including the Medical Device Fellowship and AIMBE Scholars programs, and technology transfer and collaboration efforts for the Center. PAIRS directs and coordinates CDRH's Regulatory Science and Critical Path programs to facilitate research to promote the development and assessment of high quality, safe, and effective medical devices. Ms. Saha and PAIRS work closely with the Patient Science and Engagement team at CDRH on patient preference information and patient-reported outcomes to foster incorporation of the patient perspective in our decision making. Ms. Saha has a Bachelor of Science in Bioengineering and Minor in History from the University of Pittsburgh.



Ben Linville-Engler

Industry and Certificate Director, System Design and Management, MIT

[Ben Linville-Engler](#) is the Industry and Certificate Director for MIT System Design and Management ([SDM](#)) where he first joined as a Fellow in 2016. SDM is jointly offered by MIT School of Engineering and Sloan School of Management; focusing on solving large sociotechnical challenges by taking a systems thinking approach to multidisciplinary engineering, design, and strategic decision making for complex products and services throughout the entire lifecycle. In this role, he establishes strategic industry partnerships, identifies industry trends, and teaches medical device and project-based courses to help partner companies and students develop new technologies, products, and leaders. Prior to MIT, Ben worked for over a decade in medical device product, team, and origination development. This experience included serving in Vice President roles in technology and product development, as well as engineering at Applied Medical, a global, vertically-integrated, company that develops innovative products that improve patient outcomes.

As part of the Baker-Polito Administration's response to the Covid-19 pandemic, Ben was asked to join the Massachusetts Manufacturing Emergency Response Team ([MA M-ERT](#)) under the MassTech Collaborative. The mission of the MA M-ERT is to mobilize, organize, and operationalize critical path work streams necessary for Massachusetts manufacturers to pivot their operations to produce needed medical devices and supplies.



Deborah Plana

MD-PhD Candidate, Harvard Medical School

Deborah Plana is an MD-PhD student in the Harvard-MIT Health Sciences and Technology program. She is currently pursuing her PhD in the Harvard Systems Biology program, jointly supervised by Peter Sorger and Adam Palmer from UNC School of Medicine. She previously earned her undergraduate degree in Biological Engineering at MIT, working under the supervision of Douglas Lauffenburger. Her research focuses on using data-driven approaches to design combination treatments in oncology. She is a founding member of the Greater Boston Pandemic Fabrication Team (PanFab) and is coordinating its volunteer efforts.



Shuhan He, MD

*Co-Founder, [GetUsPPE.org](#),
Emergency Medicine Physician, Mass General Hospital
Associate Director of Digital Growth Strategy, the Strategic Alliance
Initiative, Center for Innovation in Digital HealthCare*

Shuhan He, MD is an Emergency Medicine Physician at Mass General Hospital, an affiliate of Harvard Medical School. He is also the Associate Director of Digital Growth Strategy at the Strategic Alliance Initiative, with the Center for Innovation in Digital HealthCare ([CIDH.mass-general.org](#)). He is the co-founder of [GetUsPPE](#) and works in technology transfer between healthcare and industry.