CBCAN

CBC Accelerator Network

Chicago Biomedical Consortium

presents

CBC Accelerator Network:

Early Stage Regulatory Guidance on the Pathway to an IND

Thursday, April 19, 2018
4:00 - 6:30 PM

Prentice Women's Hospital
Pavilion Conference Center
3rd Floor, Room L South
250 East Superior Street
Chicago, Illinois 60611

CBC

The CBC gratefully acknowledges support from the Searle Funds at The Chicago Community Trust

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Part I	PROGRAM	3rd Floor, Room L South

4:00 PM **PARTICIPANTS' SELF-INTRODUCTION**
Each person introduces themselves and their institution/affiliation.

4:10 PM **INTRODUCTORY REMARKS**
Introduction of the panel.

Jim Audia, CBC Executive Director and **Nancy Tyrrell,** CBC Associate Director for Translational Activities

4:15 PM **PANEL DISCUSSION:**
Early Stage Regulatory Guidance on the Pathway to an IND

Moderators: **Jim Audia** and **Nancy Tyrrell**

PANELISTS:

Diane Barnes-Glait, MS
Director, Global Regulatory Affairs
Astellas Pharma

Kenneth G. Miller, PhD
New Business Development, Regulatory, Quality, Patient Safety
AbbVie

Teresa Raich, PhD, MBA
Senior Director, Regulatory Affairs
Abbott Diagnostics

Michael J. Schlosser, PhD, DABT
President
MSR Pharma Services, Inc.

5:25 PM **CONCLUDING REMARKS**

Jim Audia and **Nancy Tyrrell**

Part II	NETWORKING	3rd Floor, Harris Family Atrium

5:30 PM **NETWORKING RECEPTION**

6:30 PM **ADJOURN**

DIANE BARNES-GLAIT, MS

Director, Global Regulatory Affairs, Astellas Pharma

Diane has a 30-year career in the pharmaceutical industry. She earned her bachelor's degree at Northwestern University and her MS in Pharmacology at Loyola University. She started her career at Abbott Laboratories in basic research in a discovery laboratory. She then transitioned into pharmaceutical development working in Research Quality Assurance and Clinical Operations. After that, Diane participated in translational and development research in Pharmacogenomics and was past Chair of the Industry Pharmacogenomics Working Group. She then moved into regulatory affairs and had functioned as a global regulatory lead on numerous development projects in therapeutic areas such as oncology, neurology, psychiatry, cardio-renal and endocrinology. She is currently the Global Regulatory Lead for neurology and psychiatry products at Astellas in Northbrook, IL.

KENNETH G. MILLER, PHD

New Business Development, Regulatory, Quality, Patient Safety, AbbVie

Ken holds BS and PhD degrees in Analytical and Physical Chemistry and has held senior positions in multiple drug development functions including manufacturing, toxicology, chemistry, and regulatory affairs since 1990. His experience includes filing over 40 INDs and launching 14 new drugs including Bivigam, Orbactiv, Cangrelor, Cleviprex, Angiomax, Illaris, Sutent, Chantix, Camptosar, Zyrtex, Geodon, Trovan, Aricept, Cardura, Caduet, and Cardura XL. Ken has worked for General Motors, BASF, Pfizer, Novartis, The Medicines Company, Abbott Laboratories, and most recently, AbbVie Inc.

TERESA RAICH, PHD, MBA

Senior Director, Regulatory Affairs, Abbott Diagnostics

Terry joined Abbott Diagnostics in 2014, bringing over 20 years of experience leading strategic initiatives and global projects as well as developing, managing, and launching multiple *in vitro* diagnostic products in the medical device industry. She is currently responsible for managing and executing the global regulatory strategy for the Immunoassay and Clinical Chemistry product life cycle franchise. Prior to Abbott, she was VP of Global Clinical, Regulatory and Scientific Affairs for Nanosphere, Inc.; Director of Assay Product Development at HandyLab/BD Diagnostics and Director of Medical & Scientific Affairs at Roche Diagnostics. Terry received her PhD in Microbiology from Colorado State University and her BS in Veterinary Sciences from West Virginia University. She completed an AAM/CPEP-approved Postdoctoral Training Fellowship in Medical and Public Health Laboratory Microbiology at Baylor College of Medicine. She received a MBA from Indiana Wesleyan University.

MICHAEL J. SCHLOSSER, PHD, DABT

President, MSR Pharma Services, Inc.

Mike has over 25 years of pharma/biotech industry experience. Through MSR Pharma Services, he advises pharmaceutical companies, venture capitalists, and academia in drug discovery and development, issue management, and strategic planning. Mike founded Midwest BioResearch (MBR) in 2003, a drug disposition and toxicology service laboratory, which he successfully sold to WIL Research (now Charles River Laboratory) where he served as VP of analytical, metabolism and *in vitro* toxicology. Prior to starting MBR, Mike was head of nonclinical safety at the Pharmacia/Pfizer Skokie facility, and was responsible for supporting discovery, development, and registration of novel drugs. Mike has contributed to 15 drug registrations and numerous INDs for both small and large molecules. He has a PhD in toxicology/pharmacology from the University of Mississippi, performed a postdoctoral fellowship in Biochemistry and Molecular Biology at Thomas Jefferson University, and is a Diplomate of the American Board of Toxicology.

CBC MISSION

The mission of the Chicago Biomedical Consortium (CBC) is to stimulate collaboration among scientists at Northwestern University, The University of Chicago, the University of Illinois at Chicago and others to accelerate discovery that will transform biomedical research and improve the health of humankind. The CBC will:

- Stimulate research and education that bridge institutional boundaries,
- Enable collaborative and interdisciplinary research that is beyond the range of a single institution,
- Mentor and develop a strong cadre of biomedical leaders, researchers, and entrepreneurs in Chicago,
- Enhance and promote the development of the biomedical ecosystem in Chicago,
- Facilitate development of therapeutics that will, over the long term, improve the health of citizens of Chicago and beyond.

CBC LEADERSHIP

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