The Gut Microbiome as a Paradigm for the Opportunities and Challenges of Human Subject Research

Sept. 26–27, 2018

Organized by the Digestive Disease Research Centers
Hosted by the Perelman School of Medicine at the University of Pennsylvania
Supported by the National Institute of Diabetes and Digestive and Kidney Diseases at the National Institutes of Health and the American Gastroenterological Association

PROGRAM AGENDA

DAY 1

8–8:15 a.m.	Introductions
8:15–9 a.m.	Keynote: Eric Alm, MIT

Session 1: Paradigm for the Translation of Research from the Bench to the Bedside

9–9:20 a.m.	The Value of Animal Model Systems in Demonstrating Proof-of-Concept in the Functionality of the Gut Microbiome R. Balfour Sartor, MD
9:20–9:40 a.m.	The Gut Virome from Bench to Bedside Scott Handley, PhD
9:40–10 a.m.	What Type of Human Interventions in the Gut Microbiome Can be Performed in Human Subjects/Patients? Gary D. Wu, MD, AGAF
10–10:30 a.m.	Panel Discussion
10:30–10:45 a.m.	Break

Session 2: Paradigm for Translation from Clinical Research to the Bench

10:45–11:05 a.m.	Cross-Sectional Human Gut Microbiome Studies for Hypothesis Generation Bernd G. Schnabl, MD, AGAF
11:05–11:25 a.m.	The Value of Prospective Longitudinal Human Cohort Studies on Gut Microbiome: What Have We Learned and What are the Limitations? Cynthia L. Sears, MD

11:25–11:45 a.m.	The Bedside-to-Bench Paradigm of Human Gut Microbiome Research Eugene B. Chang, MD, AGAF
11:45 a.m.–12:15 p.m.	Panel Discussion
12:15–1:45 p.m.	Break

Session 3: High-Throughput Platforms for Hypothesis-Generating Research

1:45–2:05 p.m.	Microbes, Metabolites and Mucosal Systems Ramnik J. Xavier, MD, PhD, AGAF
2:05–2:25 p.m.	Metabolomics in Gut Microbiome Research Andrew D. Patterson, PhD
2:25–2:45 p.m.	New Techniques: Proteomics Janet K. Jansson, PhD
2:45–3:15 p.m.	Panel Discussion
3:15–3:30 p.m.	Break

Session 4: Integration of Datasets Through Computational and Biostatistical Tools

3:30–3:50 p.m.	EHR as a Data Collection Tool Peter D. R. Higgins, MD, PhD, MSc
3:50–4:10 p.m.	Quantifying the Human Response to the Gut Microbiome Ashwin Ananthakrishnan, MD, MPH
4:10–4:30 p.m.	Data Integration, Systems Biology, and Precision Medicine Georg Gerber, MD, PhD, MPH
4:30–5 p.m.	Panel Discussion

DAY 2

Session 5: Human Subjects Research

8–8:20 a.m.	Design Considerations in Human Intervention Studies James D. Lewis, MD, MSCE, AGAF
8:20–8:40 a.m.	A Primer on Human Subjects Research Loren Laine, MD, AGAF
8:40–9 a.m.	From Serendipity to Improvement of Human Health: the Development of FcRn-based Therapeutic Agents Richard S. Blumberg, MD, AGAF
9–9:30 a.m.	Panel Discussion

9:30–9:45 a.m.	Break

Session 6: How to Organize and Support Team Research in Humans

9:45–10:05 a.m.	Building a Team and the Role of Clinicians Scott B. Snapper, MD, PhD
10:05–10:25 a.m.	Identifying and Utilizing Resources Available Through the NIH Clinical and Translational Science Awards Garret A. FitzGerald, MD
10:25–10:45 a.m.	Partnerships with NIH, Foundations and Industry Scott Plevy, MD
10:45–11:15 a.m.	Panel Discussion
11:15 a.m.–12 p.m.	Wrap Up Discussion

Learning Objectives

1. Understand how basic research can be translated to the bedside, and how clinical research can be leveraged for further basic biological discovery.
2. Describe the technological platforms and "big datasets" that can be used to generate hypotheses for new research.
3. Explain the considerations in design, oversight, and execution of human subjects research related to the gut microbiome.

Organizing Committee:

- Gary D. Wu, MD, AGAF, Chair
- Jorge A. Bezerra, MD, AGAF
- Nicholas O. Davidson, MD, DSc, AGAF
- Mark Donowitz, MD, AGAF
- Hashem B. El-Serag, MD, MPH
- Wayne I. Lencer, MD, AGAF
- Jacquelyn J. Maher, MD
- Richard M. Peek, Jr., MD, AGAF
- Robert S. Sandler, MD, MPH, AGAF
- Allan W. Wolkoff, MD, AGAF
- Ramnik J. Xavier, MD, PhD, AGAF