AGENDA

9:00- 9:05 am- INTRODUCTION AND WELCOME
Francis Kalush, Ph.D.
Programs Health Coordinator, Professional Affairs and Stakeholders Engagement, CDER, FDA

9:05-9:15 am- FDA COMMISSIONER OPENING REMARKS
Robert Califf, MD.
Commissioner, FDA

9:15-9:25 am- CDER OPENING REMARKS
Robert Temple, MD.
Deputy Center Director for Clinical Science, CDER, FDA

REGULATORY PERSPECTIVE - Moderator: Francis Kalush, Ph.D.

9:25- 9:50- DIABETES DRUG APPROVAL PROCESS- REGULATORY PERSPECTIVE
Jean Marc Guettier, MD.
Director, Division Drug Metabolism and Endocrine Products, CDER, FDA

9:50-10:05 am- CLINICAL OUTCOME ASSESMENTS TO DEMONSTRATE TREATMENT BENEFIT FOR PATIENTS
Elektra Papadopoulos, MD. MPH.
Acting Director, Associate Clinical Outcome Assessment Staff, CDER, FDA

10:05-10:20 am- PATIENT INVOLVEMENT AT EMA IN THE ASSESSMENT FOR DIABETES DRUGS: PAST AND FUTURE.
Bart Vanderschueren, MD. Ph.D.
Scientific Advice Working Party, Committee for Medicinal Products for Human Use, EMA

10:20-10:30 am- HEALTH CANADA PERSPECTIVE ON THE USE OF PROs IN PATIENTS WITH DIABETES
Kader Kourad, MD. Ph.D.
Biologics and Genetic Therapies Directorate, Health Canada

10:30-11:00 am- ROUND TABLE DISCUSSION, Q&A
Online participants may use the Chat Box on Adobe Connect to ask questions.

11:00-11:15 am- BREAK

PATIENT/PATIENT ADVOCACY PERSPECTIVE - Moderator: Helene Clayton-Jeter, O.D.

11:15- 11:35 am- REVIEW OF QUALITY OF LIFE INSTRUMENTS IN DIABETES
David Marrero, Ph.D.
Immediate Past President of Healthcare and Education, American Diabetes Association

11:35am-11:50 am- FROM FARMER’S ALMANAC TO DOPPLER RADAR- A PATIENT-DRIVEN STUDY DESIGN FOR ESTABLISHING A NEW DIABETES OUTCOMES MEASURE CORRELATING GLYCEMIC VARIABILITY AND PATIENT-REPORTED OUTCOMES.
Anna McCollister-Slipp
11:50-12:10 pm - PATIENT OUTCOMES FOR DIABETES CARE - WHAT DOES SUCCESS LOOK LIKE?
Kelly Close and Richard Wood
Founder/Chair, diaTribe Foundation and CEO, dQ&A

12:10-12:20 - MEASURING OUTCOMES THAT MATTER TO PATIENTS, AN INTERNATIONAL VIEW
Simon Heller, MD.
International Hypoglycaemia Study Group

12:20-12:40 pm - T1D OUTCOMES PROGRAM AND PATIENT PREFERENCE STUDY IN T1D
Aaron Kowalski, Ph.D.
Chief Mission Officer and Vice President for Research, JDRF International

12:40-1:10 pm - ROUND TABLE DISCUSSION, Q&A
Online participants may use the Chat Box on Adobe Connect to ask questions.

1:10 pm-2:00 pm - BREAK

INDUSTRY EXPERIENCE ON OUTCOME MEASURES FOR DIABETES – Moderator: Rea Blakey

2:00-2:15 pm - PUTTING THE PATIENT AT THE CENTER OF DIABETES DRUG DEVELOPMENT: WHAT DO WE KNOW AND WHAT DO WE NEED TO KNOW
Alan Charles Moses, MD.
Global Chief Medical Officer, Senior Vice President, Novo Nordisk

2:15-2:30 pm - PATIENTS' PERCEPTIONS OF WEIGHT IN TYPE 2 DIABETES
Kristina S. Boye, Ph.D. MPH. MS. RPh.
Senior Research Advisor, Lilly Diabetes

2:30-2:45 pm - DIABETES OUTCOME MEASURES BEYOND HEMOGLOBIN A1c - THE SANOFI PERSPECTIVE
Rachele Berria, MD. Ph.D.
Vice President and Head Diabetes Medical Unit, Sanofi

2:45-3:00 pm - CHALLENGES AND OPPORTUNITIES FOR PATIENT REPORTED OUTCOME MEASUREMENTS IN DIABETES FOR INCLUSION IN LABELING
Shana Traina, Ph.D.
Director Global Market Access, Janssen

3:00-3:30 pm - ROUND TABLE DISCUSSION, Q&A
Online participants may use the Chat Box on Adobe Connect to ask questions.

3:30-4:15 pm - ROUND TABLE DISCUSSION: LESSONS LEARNED, WITH STAKEHOLDERS REPRESENTATIVES - Moderator: Francis Kalush, Ph.D
George Grunberger, MD. Immediate Past President, American Association of Clinical Endocrinologists
Jean Marc Guettier, MD. Director, Division Drug Metabolism and Endocrine Products, CDER, FDA
Elektra Papadopoulos, MD. Acting Associate Director, Clinical Outcome Assessment Staff, CDER, FDA
Anna McCollister-Slipp. Patient Representative
Kristina Boye, PhD. MPH. Senior Research Advisor, Lilly Diabetes
Bob Ratner, MD. CSMO, American Diabetes Association
Christel Aprigliano, VP. Diabetes Patient Advocacy Coalition

4:15 pm – 4:30 pm - CLOSING REMARKS