

**FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
DIABETES OUTCOME MEASURES BEYOND HEMOGLOBIN A1c WORKSHOP**

AUGUST 29, 2016

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

Patient Representative

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, d Q&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**