

Thursday, November 10, 2016

Workshop A: Implanted Sensors

Panel 1: Long – Term Implantable Glucose Sensors

- 08:00 **Moderators**
Kong Chen, PhD, MSCI
National Institutes of Health,
Bethesda, Maryland
David Kerr, MBChB, DM, FRCPE
William Sansum Diabetes Center
Santa Barbara, California
- 08:05 **Update of Clinical Experience with a Long Term Fully – Implanted CGM System**
Joseph Lucisano, PhD
Glysens Incorporated, San Diego, California
- 08:15 **Tissue – Integrating Sensors**
Natalie Wisniewski, PhD
Profusa, San Francisco, California
- 08:25 **Results from U.S PRECISE II Pivotal Trial of a 90-Day Fully Implanted Glucose Sensor**
Mark Christiansen, MD
Diablo Clinical Research, Walnut Creek, California
- 08:35 **Long – Term Implantable Optical Continuous Glucose Monitoring System**
Jeffrey Joseph, DO
Thomas Jefferson University, Philadelphia, Pennsylvania
- 08:45 **GlucoWizzard, a Minimally Invasive, CGM Device**
Michail Kastellorizios, PhD
Biorasis, Storrs Mansfield, Connecticut
- 08:55 **An Implanted Osmotic Glucose Sensor**
Andreas Pfützner, MD, PhD
Pfützner Science & Health Institute
Frankfurt, Germany
- 09:05 **What do Clinicians want an Implantable CGM**
Jessica Castle, MD
Oregon Health Services University, Portland, Oregon
- 09:15 **Q & A**
- 09:35 **Break**

Panel 2: Market Opportunities, Financial Issues and Exit Strategy

- 09:55 **Moderators**
Jeffrey Joseph, D.O
Thomas Jefferson University
Philadelphia, Pennsylvania
Matthew Maryniak, MBA
Fenix Group International, LLC
Wyomissing, Pennsylvania
- 10:00 **Market Opportunities and Customer Preference Data for a Fully Implanted Long – Term CGM Solution**
William Markle, MBA
Glysens Incorporated, San Diego, California
- 10:10 **Tiny Sensor, Great Big World**
Ben Hwang, PhD
Profusa, San Francisco, California
- 10:20 **Next Generation Technology for New Market Challenges**
Tim Goodnow, PhD
Senseonics, Germantown, Maryland

- 10:30 **The Value Proposition of Implants**
Paul Strasma, MBA
Capillary Biomedical, Irvine, California
- 10:40 **Utilizing Start – Up Accelerators to Advance CGM Devices: Lessons Learned from Mass Challenge**
Fotios Papadimitrakopoulos, PhD
Biorasis, Storrs Mansfield, Connecticut
- 10:50 **Value Creation through Science or Distribution?**
Rune Frisvold, MBA
Lifecare, Bergen Area, Norway
- 11:00 **What do corporate investors want in an implantable CGM**
Matthew Maryniak, MBA
Fenix Group International, LLC, Philadelphia, Pennsylvania
- 11:10 **Q & A**
- 11:30 **End of workshop/Lunch**

Thursday, November 10, 2016

Workshop B: Biomarkers For Diabetes

Panel 1: Update on Established Biomarkers

- 08:00 **Moderators**
George Cembrowski, PhD
Alberta Health Services
Edmonton, Alberta, Canada
- 08:05 **eA1C**
Boris Kovatchev, PhD
University of Virginia, Charlottesville, Virginia
- 08:20 **Blood Ketones – Measurement, Interpretation and Clinical Utility**
Andrew Drexler, MD
University of California, Los Angeles
- 08:35 **A1C – Update on Measuring, Interpreting and Including POC tests**
Michelle Magee, MD
MedStar Diabetes and Research Institutes, Washington, DC
- 08:50 **Metrics to Measure CGM**
Pratik Choudhary, MD, MBBD, MRCP
King's College London, London, United Kingdom
- 09:05 **Q & A**
- 09:35 **Break**

Panel 2: Emerging biomarkers

- 09:55 **Moderators**
Gerold Grodsky, PhD
University of California
San Francisco, California
- 10:00 **The Need for a New Definition of Hypoglycemia**
Brian Frier
Edinburgh, Scotland
- 10:15 **Noninvasive Glucose Measurement**

Avner Gal, MBA, MSCEE, MSc
Integrity Applications, Ashkelon, Israel

- 10:30 **C – Peptide and Proinsulin**
Andreas Pfitzner, MD, PhD
Pfitzner Science & Health Institute, Frankfurt, Germany
- 10:45 **Innovations in Novel Electrochemical Sensors, Methods and Analytes**
Jeff LaBelle, PhD
Arizona State University, Tempe, Arizona
- 11:00 **Q & A**
- 11:30 **End of workshop/Lunch**

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Workshop C: Coding, Coverage, Reimbursement & Competitive Bidding

Panel 1: Coding and Coverage

- 12:30 **Moderators**
Barry Ginsberg, MD, PhD
Diabetes Technology Consultants
Wyckoff, New Jersey
- 12:35 **An Overview of Coding & Coverage for Diabetes Products**
Bruce Taylor
Roche Diagnostics Diabetes Care, Indianapolis, Indiana
- 12:50 **How Reimbursement Coding & Coverage Affects Patient Choices**
Jerry Gomez
ArkrayUSA, El Paso, Texas
- 13:05 **Impact of Healthcare Reform on Reimbursement for New Technologies**
Patricia Telgener, RN, MDA
Emerson Consultants, Inc. Excelsior, Minnesota
- 13:20 **A New CPT Code for CGM Colon a Golden Opportunity or a Black Hole?**
Erika Miller, JD
Cavarocchi · Ruscio · Dennis Associates, LLC, Washington, D.C
- 13:35 **Q & A**
- 14:05 **Break**

Panel 2: Reimbursement and the Competitive Bidding Process by CMS

- 14:25 **Moderators**
Eric Zimmerman, MD
McDermott Will & Emery LLP
Washington, D.C
- Jane Chiang, MD
American Diabetes Association
Washington, D.C
- 14:30 **An Overview of the Competitive Bidding Process**
Tim Trysla
Alston & Bird, Washington, D.C
- 14:45 **The Danger of Competitive Bidding**
Gary Puckerin
National Minority Quality Forum, Washington, D.C
- 15:00 **The Anticipated Impacts of Competitive Bidding on Diabetes Health Outcomes**

David Marrero, PhD
Indiana University School of Medicine, Indianapolis, Indiana

15:15 **How Trends in Federal Health Policy Will Affect Diabetes?**

Tom Milam
TrueLifeCare, Nashville, Tennessee

15:30 **Q & A**

16:00 ***End of workshop***

16:00–18:30 **Poster session and inauguration of the 2016 Diabetes Technology Meeting**

18:30–20:00 **Posters remain on display for viewing**

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Workshop D: Metrics for Diabetes

Panel 1: Metrics for Describing Performance of a Monitor

12:30 **Moderators**

Vince Crabtree, PhD
Juvenile Diabetes Research Foundation
New York, New York

Courtney Lias, PhD
Food and Drug Administration
Washington, D. C

12:35 **The Relationship Between BGM and CGM**

David Simmons, MD
Ascensia, Tarrytown, NY

12:50 **Best Metrics of Glycemia Measured by a BGM**

David Rodbard, MD
Biomedical Informatics Consultants LLC, Potomac, Maryland

13:05 **Correct, Complete and Still Comprehensible – How to Best Describe Accuracy of Blood Glucose Meters?**

Rolf Hinzmann, MD, PhD
Roche, Mannheim, Germany

13:20 **Borrowing from Big Data Technologies to Drive CGM Metrics Ubiquity**

Annika Jimenez, BA, MIA
Dexcom, San Diego, California

13:35 **Q & A**

14:05 ***Break***

Panel 2: New Metrics for Control

14:25 **Moderators**

Guido Freckmann, MD
Institute for Diabetes Technology GmbH
Ulm, Germany

14:30 **The New Glucose Pentagon: Applying Novel Composite Metrics to Assess the Results of Glycemic Control in CGM-Based Studies**

Robert Vigersky, MD
Medtronic Diabetes, Washington, D.C

14:45 **Composite Metrics for Clinical Trials**

Alexander Fleming, MD
Kinexum, Harpers Ferry, West Virginia

- 15:00 **Is Calibration Necessary for CGMs**
Andrea Fachinetti, MS, PhD
University of Padova, Padova, Italy
- 15:15 **Long – Term Metrics**
Marc Breton, PhD
University of Virginia, Charlottesville, Virginia
- 15:30 **Q & A**
- 16:00 **End of workshop**
- 16:00–18:30 **Poster session and inauguration of the 2016 Diabetes Technology Meeting**
- 18:30–20:00 **Posters remain on display for viewing**

Friday, November 11, 2016

07:00 **Continental Breakfast**

Session 1: Patient – Generated Health Data for the Precision Medicine Initiative

- 08:00 **Moderators**
Judy Fradkin, MD
National Institutes of Health,
Bethesda, Maryland
Karl Friedl
University of California
San Francisco, California
- 08:10 **The Connected Patient**
Howard Zisser, MD
University of California, Santa Barbara
- 08:25 **Health Data Analytics Applied to Diabetes**
Shahram Ebadollahi, PhD
IBM Watson Health, New York, New York
- 08:40 **A Open Source Platform Enabling an Ecosystem of Diabetes Apps and Research**
Howard Look
Tidepool, Palo Alto, California
- 08:55 **Leveraging Patient Generated Data and Decision Support to Deliver Personalized Recommendations**
Rick Altinger
Glooko, Palo Alto, California
- 09:10 **Q & A**
- 09:25 **Break**

Session 2: Regulatory Initiatives in Diabetes Technology

- 09:45 **Moderators**
David Klonoff, MD, FACP, FRCP(Edin), Fellow AIMBE
Mills – Peninsula Health Services
San Mateo, California
- 09:50 **Diabetes Technology Society Leadership Award**
- 09:55 **DTSec**
David Kleidermacher
BlackBerry Limited, Santa Barbara, California
- 10:10 **Medical Device Cybersecurity: An FDA Perspective**
Suzanne Schwartz, MD, MBA

FDA, Washington, D.C

- 10:25 **The DTS – BGMs Surveillance Program: Results of the First Series of 18 BGMs Marketed in the USA**
Joan Lee Parkes
Consulting, Inc., Bristol
- 10:40 **News from FDA on Glucose Monitoring Regulation**
Courtney Lias, PhD
FDA, Washington, D.C
- 10:55 **JAMA Privacy of Diabetes Apps**
Sarah Blenner, JD, MPH
UCLA Fielding School of Public Health, Los Angeles, California
- 11:10 **What's New with HIPAA**
Iliana Peters, JD, LLM
U.S Department of Health and Human Services, Washington, D.C
- 11:25 **Q & A**
- 11:55 **End of session/Lunch**

Friday, November 11, 2016

Session 3: Use of Mobile Apps to Increase Adherence

- 12:50 **Moderators**
Bakul Patel, MBA
Food and Drug Administration
Washington, D.C
Riccardo Bellizzi
University of Pavia, Italy
Pavia, Italy
- 12:55 **A Clinical Perspective**
TBD
- 13:10 **A Psychological Perspective**
Shelagh Mulvaney, PhD
Vanderbilt University Medical Center
- 13:25 **A European Perspective**
Pratik Choudhary, MD, MbbD, MRCP
King's College London, London, United Kingdom
- 13:40 **Q & A**
- 13:55 **End of session/Break**

Session 4: Artificial Pancreas – Recent Innovations in Algorithms

- 14:15 **Moderators**
Jeffrey Joseph, D. O
Thomas Jefferson University
Philadelphia, Pennsylvania
Marc Torjman, PhD
Cooper University Hospital - UMDNJ
Camden, New Jersey
- 14:20 **Artificial Pancreas Award**
- 14:25 **Model Predictive Control for AP: Cost Function Design to Improve Safety & Performance**
Ravi Gondahalekar, PhD
Harvard, Cambridge, Massachusetts
- 14:35 **Combining Two Schools of Thoughts in One Algorithms**
Moshe Phillip, MD
Schneider Children's Med. Ctr. of Israel

- 14:45 **Individually Adaptive Algorithm for Artificial Pancreas: In Silico & One- Month Outpatient Free-Living Conditions**
 Claudio Cobelli, PhD
 University of Padova, Padova, Italy
- 14:55 **inControl: a Closed Loop Control System for Type 1 Diabetes**
 Patrick Keith-Hynes, PhD
 University of Virginia – Centers for Diabetes Technology, Charlottesville, Virginia
- 15:05 **Multi – Module Multivariable Artificial Pancreas Control Systems**
 Ali Cinar, PhD
 ITT, Chicago, Illinois
- 15:15 **Integration of an Adaptive Bolus Calculator in an Artificial Pancreas**
 Nick Oliver, BSc, MBBS, MRCP
 Imperial College, United Kingdom, United Kingdom
- 15:25 **Translation of Hybrid Closed – Loop Technology into Better Care for T1D**
 William Tamborlane, PhD
 Yale School Medicine, New Haven, Connecticut
- 15:35 **Q&A**
- 16:00 **End of Session**
- 16:00–18:30 **Poster Session Night Two**
- 18:30–20:00 **Posters remain on display for viewing**

Saturday, November 12, 2016

07:00 *Continental Breakfast*

Session 5: New Drugs

- 08:00 **Moderators**
 Alicia Warnock, LCDR, MC, USN
 Walter Reed National Military Medical Center
 Bethesda, Maryland
- 08:05 **Student Presentation**
- 08:25 **New Drugs: Glucagon**
 Jessica Castle, MD
 Oregon Health and Science University, Portland, Oregon
- 08:45 **Optimizing Basal Insulin**
 David Kerr, MD, FRCP
 William Sansum Diabetes Center, Santa Barbara, CA
- 09:05 **Novel Rapid Acting Insulins**
 Tim Heise, MD
 Profil GmbH, Neuss, Germany
- 09:25 **Biosimilar Insulin**
 Lutz Heinemann, PhD
 Science & Co, Dusseldorf, Germany
- 09:45 **Q & A**
- 10:00 **Break**

Session 6: New Insulins and Delivery Systems

- 10:20 **Moderators**
Deborah Greenwood, CNS, CDE, BC-ADM
Sutter Health
Sacramento, California
Dorian Liepmann, PhD
University of California, Berkeley
Berkeley, California
- 10:25 **Infusion Set Advances**
Lutz Heinemann, PhD
Science & Co, Dusseldorf, Germany
- 10:45 **Patch Pumps**
John Pickup, MD, PhD
King's College London, London, United Kingdom
- 11:05 **Apps for Insulin Dosing Software**
Signe Schmidt, MD, PhD
Hvidovre Hospital, Hvidovre, Denmark
- 11:25 **OpenAPs**
Rachel Sandlain, Bel Air, MD
- 11:45 **Q & A**
- 12:00 *End of session/Lunch*

Session 7: New Developments in Needle Sensor CGMs

- 13:00 **Moderators**
Andrea Bell – Vlasov, PhD
Food and Drug Administration
Silver Spring, Maryland
Jeffrey Sutton, MD, PhD
National Space Biomedical Research
Houston, Texas
- 13:05 **New Data on Flash Glucose Monitoring**
Scott Harper, BS
Abbott Diabetes Care, Alameda, California
- 13:20 **Accuracy of a Novel CGM System Employing Direct Electron Transfer Technology**
Shinjiro Sekimoto, MS
Arkray Inc., Kyoto, Japan

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- 13:35 **Pushing the Boundaries in CGM Performance**
Peter Simpson, M.Eng
Dexcom, San Diego, California
- 13:50 **New Developments in Sensor Technology**
Brian Kannard, BS
Medtronic MiniMed, Northridge, California
- 14:05 **New Data on the Accu–Chek Insight CGM System**
Gunther Schmelzeisen – Redeker, PhD
Roche Diabetes Care GmbH, Mannheim, Germany
- 14:20 **Q & A**
- 14:35 **Break**

Session 8: Social Media

- 14:55 **Moderators**

Leslie Landree, PhD
Food and Drug Administration
Silver Spring, Maryland

John Pickup, MD, PhD
King's College London School of Medicine
London, United Kingdom

15:00 **Harnessing Social Media for Diabetes Research**

Joyce Lee, MD, MPH
University of Michigan, Ann Arbor, Michigan

15:20 **How Social Media Affects Adoption and Use of Technology**

Amy Tenderich, MA
DiabetesMine, San Francisco, California

15:40 **The Diabetes Village – People with Diabetes Need to be Heard**

David Kerr, MD, FRCP
Sansum Clinic, Santa Barbara, California

16:00 **Q & A**

16:20 ***End of session/Break***

Session 9: Live Demonstrations

16:30 **Moderators**

John Pickup, MD, PhD
King's College London School of Medicine
London, United Kingdom

16:35 **Quell & Quell Apps**

16:50 **Meeting Summary**

17:00 ***Adjourn Meeting***