

Thursday, October 22, 2015

## Workshop A: Business Opportunities in Diabetes Technology

### Panel 1: Investing in Diabetes Technology

- 08:00 **Moderators**  
James Scott, JD  
Applied Policy, Alexandria, Virginia  
Paul Radensky, MD, JD  
McDermott Will & Emery LLP, Washington, DC
- 08:05 **21<sup>st</sup> Century Technology and Early 20<sup>th</sup> Century Reimbursement**  
Bruce Quinn, MD, PhD  
FaegreBD Consulting, Washington, DC
- 08:20 **What a Venture Capitalist Looks For?**  
John Ryan, MBA  
ONSET Ventures, Menlo Park, California
- 08:35 **Investment Opportunities**  
Karen Drexler  
Hygieia, Los Altos, California
- 08:50 **What a Large Corporate Partner Looks For?**  
James Petisce, PhD  
BD Diabetes Care, Andover, Massachusetts
- 09:05 **Q & A**
- 09:30 **Break**

### Panel 2: Reimbursement

- 09:55 **Moderators**  
Bruce Quinn, MD, PhD  
FaegreBD Consulting, Washington, DC  
John Ryan, MBA  
ONSET Ventures, Menlo Park, California
- 10:00 **Competitive Bidding for Insulin Pumps: Medicare's National Expansion of Flawed Payment Rates**  
James Scott, JD  
Applied Policy, Alexandria, Virginia
- 10:15 **Healthcare Insurance Reimbursement for Continuous Glucose Monitoring: Getting it Right!**  
Mary Ann Hodorowicz, RD, LDN, MBA, CDE, Certified Endocrinology Coder  
Mary Ann Hodorowicz Consulting, LLC, Palos Heights, Illinois
- 10:30 **Reimbursement Update**  
Paul Radensky, MD, JD  
McDermott Will & Emery LLP, Washington, DC
- 10:45 **Coding, Coverage, and Reimbursement for CGM**  
Meredith Dyer  
The Endocrine Society, Washington, DC
- 11:00 **Q & A**
- 11:25 **End of workshop/Lunch**

Thursday, October 22, 2015

## Workshop B: New Treatment Paradigms

### Panel 1: Do It Yourself

- 08:00 **Moderators**  
Alicia Warnock, MD  
Walter Reed National Military Medical Center,  
Bethesda, Maryland
- Yogish Kudva, MD  
Mayo Clinic, Rochester, Minnesota
- 08:05 **Patient-Powered: How Technology is Changing the “Patient” Paradigm**  
Patricia Salber, MD, MBA  
Health Tech Hatch & The Doctor Weighs In, Larkspur, California
- 08:20 **Regulatory Aspects**  
Courtney Lias, PhD  
U.S. Food and Drug Administration, Silver Spring, Maryland
- 08:35 **N-of-1 Studies for Novel Technology**  
Richard Kravitz, MD, MSPH  
University California Davis, Sacramento, California
- 08:50 **Patient Perspective on DIY Artificial Pancreas**  
Bryan Mazlish  
Bigfoot Biomedical, Inc., Milpitas, California
- 09:05 **Q & A**
- 09:30 **Break**

### Panel 2: Big Data and Precision Medicine for Diabetes

- 09:55 **Moderators**  
Guillermo Arreaza-Rubin, MD  
National Institute of Diabetes, Digestive,  
and Kidney Diseases | NIH, Bethesda, Maryland
- 10:00 **Mobile Technologies to Collect Data for Precision Medicine for Diabetes**  
William Riley, PhD  
National Institutes of Health, Bethesda, Maryland
- 10:15 **Diabetes Care Desperately Needs Precision Medicine**  
Rodney Hayward, MD  
University of Michigan, Ann Arbor, Michigan
- 10:30 **Diabetes Data Analytics using Electronic Health Records and Patient Social Media**  
Hsinchun Chen, PhD  
University of Arizona, Tucson, Arizona
- 10:45 **Precision Medicine Driven by Big Data, Genomics and Personalized Digital Health Tracking: Overpromised Hype or Impending New Era for Health, Wellness and Preventive Medicine?**  
Robert Cuddihy, MD  
Janssen Pharmaceuticals, Raritan, New Jersey
- 11:00 **Q & A**
- 11:25 **End of workshop/Lunch**

Thursday, October 22, 2015

## Workshop C: Glucose Measurement Errors and Insulin Dosing Errors

### Panel 1: Metrics of BGM & CGM Accuracy

12:25 **Moderators**

George Cembrowski, MD, PhD  
Alberta Health Services,  
Edmonton, Alberta, Canada

Joan Lee Parkes, PhD  
Joan Lee Parkes Consulting Inc., Bristol, Indiana

12:30 **Accuracy and Precision of Blood Glucose Meters and Continuous Glucose Monitors (CGM)**

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

12:45 **Does MARD Convey the Real Measurement Performance of a CGM Device?**

Luigi Del Re, PhD  
Johannes Kepler University Linz, Linz, Austria

13:00 **Metrics of BGM & CGM Accuracy and Their Limitations**

Rolf Hinzmann, MD, PhD  
Roche Diagnostics GmbH, Mannheim, Germany

13:15 **Metrics of Accuracy**

Marc Breton, PhD  
University of Virginia, Charlottesville, Virginia

13:30 **Q & A**

13:55 **Break**

### Panel 2: How to Avoid Insulin Dosing Errors

14:20 **Moderator**

Patricia Beaston, MD, PhD  
U.S. Food and Drug Administration, Silver Spring, Maryland

14:25 **Reference Systems to Improve the Accuracy of Testing in Diabetes Management**

Hubert Vesper, PhD  
Centers for Disease Control and Prevention, Atlanta, Georgia

14:40 **Variability of Insulin Absorption**

Tim Heise, MD  
Profil GmbH, Neuss, Germany

14:55 **Dark Side of Insulin Therapy: Insulin Dosing Errors and Unexpected Insulin Absorption**

Eda Cengiz, MD, MHS  
Yale School of Medicine, New Haven, Connecticut

15:10 **Substances that Interfere with BG Testing**

Barry Ginsberg, MD, PhD  
Diabetes Technology Consultants, Wyckoff, New Jersey

15:25 **Q & A**

15:50 **End of workshop**

16:00–18:30 **Poster session and inauguration of the 2015 Diabetes Technology Meeting**

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

Thursday, October 22, 2015

## Workshop D: A Reassessment of Markers of Glycemia

### Panel 1: New Developments in Hemoglobin A1C

- 12:25 **Moderator**  
David Sacks, MD  
National Institutes of Health, Bethesda, Maryland
- 12:30 **Modeling HbA1c to Explore Relationship of HbA1c and the Blood Glucose Concentration**  
Piotr Ładyżyński, PhD, DSc  
Biocybernetic Institute, Polish Academy of Sciences, Warsaw, Poland
- 12:45 **Estimated A1C**  
Boris Kovatchev, PhD  
University of Virginia, Charlottesville, Virginia
- 13:00 **Mismatches Between HbA1c and Blood Glucose - Mechanisms**  
Robert Cohen, MD  
University of Cincinnati, Cincinnati, Ohio
- 13:15 **What is the Value of Home A1C Testing?**  
James Anderson Jr., MD, FFPM, FACE  
PTS Diagnostics, Indianapolis, Indiana
- 13:30 **Q & A**
- 13:55 **Break**

### Panel 2: Novel Markers

- 14:20 **Moderators**  
David Sacks, MD  
National Institutes of Health,  
Bethesda, Maryland
- Alicia Warnock, MD  
Walter Reed National Military Medical Center,  
Bethesda, Maryland
- 14:25 **A Multi-Dimensional Combined Endpoint for Understanding Glycemic Control**  
Robert Vigersky, MD  
Medtronic Diabetes, Washington, DC
- 14:40 **Detection of Hypoglycemia using EEG**  
Lykke Blaabjerg, MSc, PhD  
Hypo-Safe A/S, Kongens Lyngby, Denmark
- 14:55 **Combining Data Obtained by Heart Rate Variability and Continuous Glucose Monitoring Enables Prediction and Improves Detection of Hypoglycemic Events**  
Jesper Fleischer, PhD  
Aarhus University Hospital and Aarhus University, Aarhus, Denmark
- 15:10 **Service Dogs for Detecting Hypoglycemia**  
Jaclyn Shepard, PsyD  
University of Virginia Health System, Charlottesville, Virginia
- 15:25 **Q & A**
- 15:50 **End of workshop**
- 16:00–18:30 **Poster session and inauguration of the 2015 Diabetes Technology Meeting**
- 18:30–20:00 **Posters remain on display for viewing**

# Friday, October 23, 2015

07:00 *Continental Breakfast*

## Session 1: Welcome & Keynote Presentation

08:00 **Welcome/Opening Remarks**

David Klonoff, MD, FACP, FRCP (Edin), Fellow AIMBE  
Mills-Peninsula Health Services, San Mateo, California  
University of California, San Francisco, San Francisco, California

08:05 **Keynote Speech: Cybersecurity**

Daniel Prieto  
The White House, Washington, DC

## Session 2: DTSec (DTS Cybersecurity Standard for Connected Diabetes Devices project)

08:25 **Moderator**

David Klonoff, MD, FACP, FRCP (Edin), Fellow AIMBE  
Mills-Peninsula Health Services, San Mateo, California  
University of California, San Francisco, San Francisco, California

08:30 **Identifying and Addressing Potential Cybersecurity Legal Liability Risks for the Diabetes Device Community**

Bryan Cunningham  
Cunningham Levy LLP, Los Angeles, California

08:45 **Panel Discussion**

Seth Carmody, PhD  
Food and Drug Administration, Silver Spring, Maryland

Bryan Cunningham  
Cunningham Levy LLP, Los Angeles, California

Barry Ginsberg, MD, PhD  
Diabetes Technology Consultants, Wyckoff, New Jersey

David Kleidermacher  
BlackBerry Limited, Santa Barbara, California

Jeffery Reynolds, PhD  
Bayer Diabetes Care, Tarrytown, New York

Margie Zuk  
The MITRE Corporation, Boston, Massachusetts

09:45 **Q & A**

10:10 **End of session/Break**

## **Session 3: How Good Does CGM Need to be for a Primary Indication to Replace SMBG?**

10:35 **Moderators**

Courtney Lias, PhD

U.S. Food and Drug Administration, Silver Spring, Maryland

Andrea Facchinetti, PhD

University of Padova, Padova, Italy

10:45 **Diabetes Technology Society Leadership Award**

10:50 **Regulatory Considerations for Non-Adjunctive CGM Indications**

Alain Silk, PhD

U.S. Food and Drug Administration, Silver Spring, Maryland

11:05 **CGM Technology: Is It Ready to Replace Traditional Blood Glucose Monitoring?**

Grazia Aleppo, MD, FACE, FACP

Northwestern University, Chicago, Illinois

11:20 **How Good Does CGM Need to be for a Primary Indication to Replace SMBG?**

Marc Breton, PhD

University of Virginia, Charlottesville, Virginia

11:35 **Non-Adjunctive Use of CGM: Future Directions**

Jessica Castle, MD

Oregon Health and Science University, Portland, Oregon

11:50 **Q & A**

12:10 – 13:10 ***End of session/Lunch***

Friday, October 23, 2015

## Scientific Sessions

### Scientific 4: Best Approach to Type 1 Diabetes: Biological or Bioengineered?

- 13:10 **Moderators**  
Gerold Grodsky, PhD  
University of California San Francisco, San Francisco, California  
  
John Pickup, MD, PhD  
King's College London, London, United Kingdom
- 13:15 **Biological Approach**  
Matthias Hebrok, PhD  
University of California San Francisco, San Francisco, California
- 13:30 **Bioengineered Approach**  
Roman Hovorka, PhD  
University of Cambridge, Cambridge, United Kingdom
- 13:45 **Panel Discussion**  
Speakers and Moderators
- 14:05 **Q & A**
- 14:30 **Break**

## Clinical Sessions

### Clinical 4: Debate: Is There a Role for Blinded CGM in Addition to Real Time CGM?

- 13:10 **Moderator**  
Stuart Weinzimer, MD  
Yale University School of Medicine, New Haven, Connecticut
- 13:15 **Overview of CGM**  
Stuart Weinzimer, MD  
Yale University School of Medicine, New Haven, Connecticut
- 13:35 **No**  
Steve Edelman, MD  
University of California San Diego, San Diego, California
- 13:55 **Yes**  
Ian Blumer, MD, FRCPC  
University of Toronto, Ontario, Canada
- 14:15 **Rebuttals**
- 14:25 **Q & A**
- 14:40 **Break**

Friday, October 23, 2015

## Scientific Sessions

### Scientific 5: Artificial Pancreas: What is Needed?

- 14:55 **Moderators**  
Jeffrey Joseph, DO  
Thomas Jefferson University  
Philadelphia, Pennsylvania
- Geoff Chase, PhD  
University of Canterbury  
Christchurch, New Zealand
- 15:00 **Artificial Pancreas Award**
- 15:05 **Need for Better Algorithms**  
Claudio Cobelli, PhD  
University of Padova, Padova, Italy
- 15:20 **Artificial Pancreas: Need for Better CGMS**  
Garry Steil, PhD  
Harvard Medical School, Cambridge,  
Massachusetts
- 15:35 **Artificial Pancreas: Need for Glucagon**  
Ahmad Haidar, PhD  
McGill University, Montreal, Quebec, Canada
- 15:50 **Need for Commercializing Actual Products**  
Moshe Phillip, MD  
Schneider Children's Medical Center of Israel, Tel-  
Aviv, Israel
- 16:05 **The Challenges of Using Model-Based Control for  
the Artificial Pancreas**  
Eyal Dassau, PhD  
Harvard University, Cambridge, Massachusetts
- 16:20 **Q & A**
- 16:45 **Adjourn**
- 16:45–19:15 **Poster session**
- 19:15–20:45 **Posters remain on display for viewing**

## Clinical Sessions

### Clinical 5: Developments in Insulin Pump Therapy

- 15:05 **Moderator**  
Eda Cengiz, MD, MHS  
Yale School of Medicine, New Haven, Connecticut
- 15:10 **How to Use Insulin Pumps**  
John Pickup, MD, PhD  
King's College London, London, United Kingdom
- 15:35 **A Practical Approach to Insulin Pump Therapy in  
Type 2 Diabetes**  
Juan Pablo Frias, MD, FACE  
National Research Institute, Los Angeles,  
California
- 16:05 **Which Treatment Will Dominate: New Insulin or  
Insulin Pumps?**  
Stuart Weinzimer, MD  
Yale University School of Medicine, New Haven,  
Connecticut
- 16:30 **Q & A**
- 16:40 **Adjourn**
- 16:45–19:15 **Poster session**
- 19:15–20:45 **Posters remain on display for viewing**

# Saturday, October 24, 2015

## Scientific Sessions

07:00 *Continental Breakfast*

### Scientific 6: Novel Insulins

- 08:00 **Moderator**  
Dorian Liepmann, PhD  
University of California Berkeley  
Berkeley, California
- 08:05 **Synthetic Glucose-Responsive Insulin**  
Matthew Webber, PhD  
Massachusetts Institute of Technology  
Cambridge, Massachusetts
- 08:20 **Dance 501, a New Novel Inhaled Insulin Delivery System**  
John Patton, PhD  
Dance Biopharm, San Francisco, California
- 08:35 **Biosimilar Insulin, Reflection or Mirage?**  
Alan Carter, PharmD  
MRIGlobal, Kansas City, Missouri
- 08:50 **Stability of Insulin and Global Warming**  
Andreas Pfützner, MD, PhD  
Pfützner Science & Health Institute  
Frankfurt, Germany
- 09:05 **Timing of Meal Insulin and Its Relation to Diabetes Outcomes**  
Karishma Datye, MD  
Monroe Carrell Jr. Children's Hospital at  
Vanderbilt, Nashville, Tennessee
- 09:20 **Q & A**
- 09:45 *End of session/Break*

## Clinical Sessions

07:00 *Continental Breakfast*

### Clinical 6: Nutrition & the Microbiome

- 08:00 **Moderator**  
Frank Greenway, MD  
Louisiana State University  
Baton Rouge, Louisiana
- 08:05 **The Diabetes Breakthrough for Successful Weight Loss**  
Osama Hamdy, MD, PhD  
Joslin Diabetes Center, Boston, Massachusetts
- 08:35 **Altering the Microbiome to Treat Diabetes**  
Frank Greenway, MD  
Louisiana State University  
Baton Rouge, Louisiana
- 09:05 **Meal Timing: Can It Protect Against Diabetes?**  
Amir Zarrinpar, MD, PhD  
University of California San Diego  
San Diego, California
- 09:35 **Q & A**
- 09:45 *End of session/Break*

**Saturday, October 24, 2015**

## **Scientific Sessions**

### **Scientific 7: Importance of Hypoglycemia as an Endpoint in Clinical Trials**

- 10:10 **Moderator**  
David Price, MD  
Dexcom, San Diego, California  
Rebecca Gottlieb, PhD  
Medtronic Diabetes, Northridge, California
- 10:15 **Diabetes Technology Society (DTS) Student Research Award**
- 10:20 **Presentation by DTS Student Research Award Winner**
- 10:35 **Panel Discussion**  
Timothy Dunn, PhD  
Abbott Diabetes Care, Alameda, California  
Alexander Fleming, MD  
Kinexum, Harpers Ferry, West Virginia  
Campbell Hutton, MSPH  
JDRF, New York, New York  
Boris Kovatchev, PhD  
University of Virginia, Charlottesville, Virginia  
John Pickup, MD, PhD  
King's College London, London, United Kingdom
- 11:45 **End of session/Lunch**

## **Clinical Sessions**

### **Clinical 7: The Social Media Phenomenon**

- 10:10 **Moderator**  
Patricia Salber, MD, MBA  
Health Tech Hatch & The Doctor Weighs In,  
Larkspur, California
- 10:15 **In Defense of Your Patients: How to Identify and Prevent Online Bullying (aka – Dia-Bullying)**  
Kevin McMahon, B.Sc.  
MediSelf Press, Sausalito, California
- 10:40 **The Reluctant Tweet(er)**  
Pratik Choudhary, MD, MbbD, MRCP  
King's College London, London, United Kingdom
- 11:05 **Social Media for Physicians**  
Patricia Salber, MD, MBA  
Health Tech Hatch & The Doctor Weighs In,  
Larkspur, California
- 11:30 **Q & A**
- 11:45 **End of session/Lunch**

Saturday, October 24, 2015

## Scientific Sessions

### Scientific 8: Mobile Apps

- 12:45 **Moderators**  
Richard Williams, MD  
National Aeronautics and Space Administration  
Washington, DC  
  
Judith Fradkin, MD  
National Institutes of Health, Bethesda, Maryland
- 12:50 **Mobile Apps in Diabetes: Quantity vs. Quality**  
Ellie Strock, ANP-BC, CDE  
Voluntis, Inc., Plymouth, Minnesota
- 13:05 **Linking CGM Data with an Electronic Health Record**  
Rajiv Kumar, MD  
Stanford University, Stanford, California
- 13:20 **Regulation of Mobile Apps**  
Bakul Patel, MBA, MSc  
U.S. Food and Drug Administration, Silver Spring, Maryland
- 13:35 **Q & A**
- 14:00 **End of session/Break**

## Clinical Sessions

### Clinical 8: What's Next in Diabetic Limb Salvage and Prevention

- 12:45 **Moderator**  
Stephen Twigg, MBBS(Hons-1), PhD, FRACP  
University of Sydney, Sydney, Australia
- 12:50 **Gait Balls of Fire: Dosing Activity Like We Dose a Drug**  
Bijan Najafi, PhD  
University of Arizona, Tucson, Arizona
- 13:15 **New Treatments for Diabetic Foot Disease Using Technology**  
Stephen Twigg, MBBS(Hons-1), PhD, FRACP  
University of Sydney, Sydney, Australia
- 13:40 **How to Treat Pain Due to Diabetic Neuropathy: Facts and Controversies**  
Rodica Pop-Busui, MD, PhD  
University of Michigan, Ann Arbor, Michigan
- 14:05 **Q & A**
- 14:30 **End of session/Break**

# Saturday, October 24, 2015

## Scientific Sessions

### Scientific 9: New Developments in CGM

- 14:25 **Moderator**  
Stayce Beck, MD  
Food and Drug Administration, Silver Spring, Maryland
- 14:30 **CGM Systems**  
Rebecca Gottlieb, PhD  
Medtronic Diabetes, Northridge, California
- 14:42 **Dexcom G5® Mobile: CGM on Your Smartphone**  
Apurv Kamath, MS  
Dexcom, Inc., San Diego, California
- 14:54 **New Developments in Professional Sensor Glucose Monitoring**  
Scott Harper, BS  
Abbott Diabetes Care, Alameda, California
- 15:06 **Time Delay of CGM Sensors: Causes and Countermeasures**  
Guenther Schmelzeisen-Rekeker, PhD  
Roche Diabetes Care GmbH, Mannheim, Germany
- 15:18 **BREAK**
- 15:30 **Accuracy and Longevity of an Implantable Continuous Glucose Sensor in the Precise Study: A Prospective Multi-Center Pivotal Trial**  
Jort Kropff, MD  
Academic Medical Centre at the University of Amsterdam, Amsterdam, Netherlands
- 15:42 **A Novel CGM Sensing Technology**  
Shinjiro Sekimoto, MS  
Arkray Inc., Kyoto, Japan
- 15:54 **Application of a Second-Generation Long Term Implantable Continuous Glucose Monitoring System in Human Subjects**  
Joseph Lucisano, PhD  
GlySens Inc., San Diego, California
- 16:06 **Q & A**
- 16:35 **End Session**

## Clinical Sessions

### Clinical 9: SMBG & Bolus Calculators

- 14:55 **Moderator**  
Pratik Choudhary, MD, MbbD, MRCP  
King's College London, London, United Kingdom
- 15:00 **Benefits and Limitations of SMBG – The Implications and Assessment of Device Accuracy**  
Timothy Bailey, MD, FACE, CPI  
AMCR Institute, Escondido, California
- 15:25 **Benefits and Limitations of SMBG**  
Maurice J. O’Kane, MD  
Altnagelvin, Londonderry, Northern Ireland
- 15:50 **Getting the Most Out of Blood Glucose Monitors**  
Kathleen Dungan, MD, MPH  
The Ohio State University, Columbus, Ohio
- 16:15 **Q & A**
- 16:40 **Adjourn Meeting**

## Scientific & Clinical 10: Live Demonstrations

- 16:40 **Moderator**  
John Pickup, MD, PhD  
King's College London, London, United Kingdom
- 16:45 **The mySugr Ecosystem – Consistent All-Round Care Viamobile Tools, Education, Motivation and Coaching**  
Fredrik Dehong  
mySugr GmbH, Vienna, Austria
- 16:55 **Meeting Summary**
- 17:00 ***Adjourn Meeting***