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 21st Century Technology and Early 20th 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  Yogish Kudva, MD
Walter Reed National Military Medical Center,  Mayo Clinic, Rochester, Minnesota
Bethesda, Maryland

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**
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
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
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 Cantebury  
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**

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 Diabesity?
Amir Zarrinpar, MD, PhD
University of California San Diego
San Diego, California

09:35  Q & A

09:45  End of session/Break
### Scientific Sessions

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

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<th>Time</th>
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<td>10:10</td>
<td><strong>Moderator</strong></td>
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<td>David Price, MD</td>
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<td>Dexcom, San Diego, California</td>
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<td>Rebecca Gottlieb, PhD</td>
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<td>Medtronic Diabetes, Northridge, California</td>
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<td>10:15</td>
<td><strong>Diabetes Technology Society (DTS) Student Research Award</strong></td>
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<td>10:20</td>
<td><strong>Presentation by DTS Student Research Award Winner</strong></td>
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<td>10:35</td>
<td><strong>Panel Discussion</strong></td>
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<td>Timothy Dunn, PhD</td>
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<td>Abbott Diabetes Care, Alameda, California</td>
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<td>Alexander Fleming, MD</td>
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<td>Kinexum, Harpers Ferry, West Virginia</td>
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<td>Campbell Hutton, MSPH</td>
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<td>JDRF, New York, New York</td>
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<td>Boris Kovatchev, PhD</td>
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<td>University of Virginia, Charlottesville, Virginia</td>
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<td>John Pickup, MD</td>
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<td>King’s College London, London, United Kingdom</td>
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### Clinical Sessions

**Clinical 7: The Social Media Phenomenon**

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<td>Patricia Salber, MD</td>
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<td>Health Tech Hatch &amp; The Doctor Weighs In, Larkspur, California</td>
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<tr>
<td>10:15</td>
<td><strong>In Defense of Your Patients: How to Identify and Prevent Online Bullying (aka – Dia-Bullying)</strong></td>
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<td>Kevin McMahon, B.Sc.</td>
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<td>MediSelf Press, Sausalito, California</td>
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<td>10:40</td>
<td><strong>The Reluctant Tweet(er)</strong></td>
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<td>Pratik Choudhary, MD</td>
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<td>King’s College London, London, United Kingdom</td>
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<td>11:05</td>
<td><strong>Social Media for Physicians</strong></td>
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<td>Patricia Salber, MD</td>
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<td>Health Tech Hatch &amp; The Doctor Weighs In, Larkspur, California</td>
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<td>11:30</td>
<td><strong>Q &amp; A</strong></td>
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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
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<tr>
<th>Time</th>
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<th>Presenter/Institution</th>
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<tr>
<td>14:25</td>
<td><strong>Scientific Sessions</strong></td>
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<td></td>
<td>Scientific 9: New Developments in CGM</td>
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<td>14:25</td>
<td><strong>Moderator</strong> Stayce Beck, MD</td>
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<td></td>
<td>Food and Drug Administration, Silver Spring, Maryland</td>
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<td>14:30</td>
<td>CGM Systems</td>
<td>Rebecca Gottlieb, PhD</td>
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<td>Medtronic Diabetes, Northridge, California</td>
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<td>14:42</td>
<td><strong>Dexcom G5® Mobile: CGM on Your Smartphone</strong></td>
<td>Apurv Kamath, MS</td>
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<td>Dexcom, Inc., San Diego, California</td>
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<td>14:54</td>
<td><strong>New Developments in Professional Sensor Glucose Monitoring</strong></td>
<td>Scott Harper, BS</td>
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<td>Abbott Diabetes Care, Alameda, California</td>
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<td>15:06</td>
<td><strong>Time Delay of CGM Sensors: Causes and Countermeasures</strong></td>
<td>Guenther Schmelzeisen-Rekeker, PhD</td>
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<td>Roche Diabetes Care GmbH, Mannheim, Germany</td>
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<td>15:18</td>
<td><strong>BREAK</strong></td>
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<td>15:30</td>
<td><strong>Accuracy and Longevity of an Implantable Continuous Glucose Sensor in the Precise Study: A Prospective Multi-Center Pivotal Trial</strong></td>
<td>Jort Kropff, MD</td>
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<td>Academic Medical Centre at the University of Amsterdam, Amsterdam, Netherlands</td>
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<td>15:42</td>
<td><strong>A Novel CGM Sensing Technology</strong></td>
<td>Shinjiro Sekimoto, MS</td>
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<td>Arkray Inc., Kyoto, Japan</td>
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<td>15:54</td>
<td><strong>Application of a Second-Generation Long Term Implantable Continuous Glucose Monitoring System in Human Subjects</strong></td>
<td>Joseph Lucisano, PhD</td>
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<td>GlySens Inc., San Diego, California</td>
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<td>16:06</td>
<td><strong>Q &amp; A</strong></td>
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<td>14:55</td>
<td><strong>Clinical Sessions</strong></td>
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<td>Clinical 9: SMBG &amp; Bolus Calculators</td>
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<td>15:00</td>
<td><strong>Moderator</strong> Pratik Choudhary, MD, MbbD, MRCP</td>
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<td>King’s College London, London, United Kingdom</td>
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<td>15:25</td>
<td><strong>Benefits and Limitations of SMBG</strong></td>
<td>Maurice J. O’Kane, MD</td>
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<td>Altnagelvin, Londonderry, Northern Ireland</td>
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<td>15:50</td>
<td><strong>Getting the Most Out of Blood Glucose Monitors</strong></td>
<td>Kathleen Dungan, MD, MPH</td>
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<td>The Ohio State University, Columbus, Ohio</td>
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<td>16:15</td>
<td><strong>Q &amp; A</strong></td>
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<td>16:40</td>
<td><strong>Adjourn Meeting</strong></td>
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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 Debong
mySugr GmbH, Vienna, Austria

16:55  Meeting Summary

17:00  Adjourn Meeting