

## TOWARDS AN ARTIFICIAL PANCREAS: AN FDA-NIH-JDRF WORKSHOP

Lister Hill Auditorium, National Institutes of Health, Bethesda, MD  
July 21–22, 2008

### MONDAY JULY 21, 2008

#### **7:55 Welcome and Introductory Remarks**

[Arleen Pinkos](#), Chair, Interagency Artificial Pancreas Working Group

8:00 [Janet Woodcock](#), M.D., Deputy Director, U.S. Food and Drug Administration

8:15 [Griffin Rodgers](#), M.D., M.A.C.P., Director, National Institute of Diabetes and Digestive and Kidney Diseases

8:30 [Lawrence Soler](#), Vice President, Government Relations, Juvenile Diabetes Research Foundation

#### **8:45 State of the Art: Designs and Results from the Latest Closed Loop Studies**

*Moderator:* [William Tamborlane](#), M.D., Yale University, New Haven, Connecticut

8:45 Introduction and Overview of Session  
[William Tamborlane](#), M.D., Yale University, New Haven, Connecticut

9:00 Closed-Loop Studies in Children  
[Stuart Weinzimer](#), M.D., Yale University, New Haven, Connecticut

9:20 Closed-Loop Studies in Adults  
[Fouad Kandeel](#), M.D., Ph.D., City of Hope, Duarte, California

9:40 Closed-Loop Studies Using Insulin and Glucagon  
[Edward Damiano](#), Ph.D., Boston University, Boston, Massachusetts

9:55 Prevention of Hypoglycemia with Automated Pump Shutoff  
[Bruce Buckingham](#), M.D., Stanford University, Stanford, California

10:15 Roundtable Discussion

#### **10:30 Coffee Break**

#### **11:00 Defining Success and Failure: Appropriate Measures**

*Moderator:* [Boris Kovatchev](#), Ph.D., University of Virginia, Charlottesville, Virginia

11:00 Introduction/Overview of Topic  
[Boris Kovatchev](#), Ph.D., University of Virginia, Charlottesville, Virginia

11:15 Clinical and Statistical Outcome Metrics  
[Stuart Weinzimer](#), M.D., Yale University, New Haven, Connecticut

11:35 Measurement and Quantification of Hypoglycemia  
[Robert Sherwin](#), M.D., Yale University, New Haven, Connecticut

11:55 Trial Design  
[Steven Russell](#), M.D., Ph.D., Massachusetts General Hospital, Boston, Massachusetts

12:15 Roundtable Discussion

#### **12:45 Lunch**

#### **1:45 Algorithms: State of the Art and Future Directions**

*Moderator:* [Roman Hovorka](#), Ph.D., University of Cambridge, Cambridge, United Kingdom

- 1:45 Introductions and Overview of Topic  
Roman Hovorka, Ph.D., University of Cambridge, Cambridge, United Kingdom
- 2:00 Algorithmic Approaches  
[Francis Doyle](#), Ph.D., University of California, Santa Barbara, Santa Barbara, California
- 2:20 In Silico Models: Application Prior to Human Testing  
Boris Kovatchev, Ph.D., University of Virginia, Charlottesville, Virginia
- 2:40 Roundtable Discussion: How to Compare and Judge Efficacy of Algorithms

**3:00 Coffee Break**

**3:30 Engineering and Patient Considerations When Building a Closed-Loop System**  
*Moderator: [Kelly Close](#), M.B.A., Close Concerns, Inc., San Francisco, California*

- 3:30 Overview of Session  
Kelly Close, M.B.A., Close Concerns, Inc., San Francisco, California

**3:45 Behavioral Aspects of a Closed Loop**  
[Timothy Wysocki](#), Ph.D., Nemours Children's Clinic, Jacksonville, Florida

- 4:00 Roundtable Discussions Among Panelists

**Industry:**

Abbott Diabetes Care, Alameda, California—[Tim Goodnow](#), Ph.D.  
DexCom, Inc., San Diego, California—[Brad Matsubara](#), M.D.  
Insulet Corporation, Inc., Bedford, Massachusetts—[John Garibotto](#), M.B.A.  
Johnson & Johnson, LifeScan Division—[David Horwitz](#), M.D., Ph.D.  
Medtronic Minimed, Inc.—[John Mastrototaro](#), Ph.D.  
Roche Diagnostics GmbH, DT.—[Matthias Essenpreis](#), Ph.D.  
Smiths Medical MD, Inc.—[Rhall Pope](#), Ph.D.

**Researcher/Engineer/Parent of Child with Diabetes:**

Edward Damiano, Ph.D., Boston University, Boston, Massachusetts

**Adult with Diabetes:**

Lawrence Soler, J.D., Juvenile Diabetes Research Foundation

**Behavioral Scientist:**

Timothy Wysocki, Ph.D., Nemours Children's Clinic, Jacksonville, Florida

**6:00 End of Day One**

**TUESDAY JULY 22, 2008**

**8:00 From Automated Insulin Delivery to an Artificial Pancreas: How We Get There**  
*Moderator: [Aaron Kowalski](#), Ph.D., Juvenile Diabetes Research Foundation, New York, New York*

- 8:00 Introduction/Overview of Session  
Aaron Kowalski, Ph.D., Juvenile Diabetes Research Foundation, New York, New York
- 8:15 Evaluation of Counter-Regulatory Hormone Responses During Hypoglycemia: Results of DirecNet Studies  
[Nelly Mauras](#), M.D., Nemours Children's Clinic, Jacksonville, Florida
- 8:35 Implantable Closed Loop: Lessons Learned and Future Opportunities  
[Howard Zisser](#), M.D., Sansum Diabetes Research Institute, Santa Barbara, California
- 8:55 Closed Loop in Early Onset of Diabetes  
Bruce Buckingham, M.D., Stanford University, Stanford, California
- 9:15 Bio-Mechanical Approaches  
[Kenneth Brayman](#), M.D., Ph.D., University of Virginia, Charlottesville, Virginia

- 9:35 Roundtable Discussion
- 10:00 Coffee Break**
- 10:30 Beyond Insulin-Dependent Diabetes**  
*Moderator: [David Klonoff](#), M.D., University of California San Francisco, Mills-Peninsula Health Services, San Mateo, California*
- 10:30 Introduction and Overview of Topic  
David Klonoff, M.D., University of California San Francisco, Mills-Peninsula Health Services, San Mateo, California
- 10:45 Application of Physiological Models to Artificial Pancreas Research  
[Claudio Cobelli](#), Ph.D., University of Padova, Padova, Italy
- 11:05 Novel Tools to Measure Metabolites, In-Hospital Studies  
[Jeffrey Joseph](#), D.O., Jefferson Medical College of Thomas Jefferson University, Philadelphia, Pennsylvania
- 11:20 Closing In on Automated Insulin Delivery: Clinicip  
Roman Hovorka, Ph.D., University of Cambridge, Cambridge, United Kingdom
- 11:40 Biofouling  
[William Reichert](#), Ph.D., Duke University, Durham, North Carolina
- 12:00 Department of Defense Technologies for Metabolic Monitoring Program  
[Charles Wade](#), Ph.D., U.S. Army Institute of Surgical Research, University of Texas Health Science Center at San Antonio, San Antonio, Texas
- 12:20 Roundtable Discussion
- 12:45 End of Workshop**