

CURRICULUM VITAE

DAVID CHARLES KLONOFF, M.D., FACP, FRCP (Edin), FELLOW AIMBE

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SUMMARY

David C. Klonoff, M.D. is an endocrinologist specializing in the development and use of diabetes technology. He is Medical Director of the Dorothy L. and James E. Frank Diabetes Research Institute of Mills-Peninsula Medical Center in San Mateo, California and a Clinical Professor of Medicine at UCSF. Dr. Klonoff received the American Diabetes Association's 2019 Outstanding Physician Clinician [Award](#). He received an FDA Director's Special Citation Award in 2010 for outstanding contributions related to diabetes technology. In 2012 Dr. Klonoff was elected as a Fellow of the American Institute of Medical and Biological Engineering (AIMBE) and cited as among the top 2% of the world's bioengineers for his engineering work in diabetes technology. He received the 2012 Gold Medal Oration and Distinguished Scientist Award from the Dr. Mohan's Diabetes Specialities Centre and Madras Diabetes Research Foundation of Chennai, India. Dr. Klonoff was invited to speak to the US Congressional Diabetes Caucus in 2017, participate in the White House Health and Cybersecurity Roundtable in 2015, and speak at the European Parliament in 2010. He is the Founding Editor-in-Chief of Journal of Diabetes Science and Technology. He has authored over 280 publications in PubMed journals including four of the first ten articles on diabetes device cybersecurity. His h-index is 50. Dr. Klonoff has been a Principal Investigator on over 120 clinical trials of diabetes drugs and devices. He was the lead investigator for the first randomized controlled multicenter trial of an outpatient artificial pancreas product by Medtronic, whose results were published in the New England Journal of Medicine. He chaired the scientific advisory board for the first FDA-cleared insulin patch pump and participated in developing the first FDA-cleared dedicated diabetes telemedicine system. Dr. Klonoff coined the term "diabetes technology" and founded the Diabetes Technology Meeting and the Hospital Diabetes Meeting. He is senior editor of the first book about diabetes digital health. Dr. Klonoff has chaired or served on 59 grant review panels including for NIH, CDC, NASA, NSF, US Army, NOAA, ADA, and JDRF; plus agencies in 11 foreign countries. He is Chair of the Scientific Advisory Board of the TexasA&M/UCLA/FIU/Rice PATHS-UP Engineering Research Center, He chaired the first and second CLSI POCT05 Performance Metrics for Continuous Interstitial Glucose Monitoring Panel, and the Continuous Glucose Monitors and Automated Insulin Dosing Systems in the Hospital Consensus Guideline Panel. Dr. Klonoff is a graduate of UC Berkeley, where he was elected to Phi Beta Kappa in his junior year, and UCSF Medical School, where he was elected to Alpha Omega Alpha in his junior year. His postgraduate training included two years at UCLA Hospital and three years at UCSF Hospitals. He is Chair of the IEEE 2621 Standards for Wireless Diabetes Device Security Assurance Committee and he chaired DTSec and DTMoSt, the world's 1st and 2nd consensus medical device cybersecurity standards. For this work Dr. Klonoff was featured in an article in [Wired Magazine](#).

PRESENT ACADEMIC AND PROFESSIONAL POSITION

2006-Present Editor-in-Chief, *Journal of Diabetes Science and Technology*
2000-Present Medical Director, Dorothy L. and James E. Frank Diabetes Research Institute,
Mills-Peninsula Medical Center, San Mateo, California
1995-Present Clinical Professor, Department of Medicine, U.C. San Francisco

EDUCATION

1972-1976 University of California at San Francisco: **M.D.**
1968-1972 University of California at Berkeley: **B.S.** in Genetics (with Highest Honors)

POSTGRADUATE TRAINING

- 1979 – 1981 Fellowship: Metabolic Research Unit, University of California at San Francisco
San Francisco, California, Endocrinology and Metabolism
- 1978 – 1979 Residency: University of California at San Francisco Hospitals and Clinics
San Francisco, California, Internal Medicine
- 1977 – 1978 Residency: UCLA Hospital, Los Angeles, California, Internal Medicine
- 1976 – 1977 Internship: UCLA Hospital, Los Angeles, California, Internal Medicine

BOARD CERTIFICATION

- 1981 Diplomate, American Board of Endocrinology and Metabolism
- 1980 Diplomate, American Board of Internal Medicine

MEDICAL LICENSURE

California #G35726 (1977)

HONORS/AWARDS

- 2019 American Diabetes Association's 2019 Outstanding Physician Clinician in Diabetes Award
- 2016– 2021 Cited in the Castle Connolly Medical Ltd. List of Top Doctors in the US
- 2015– 2016 Cited in San Francisco Magazine: Bay Area's Top Doctors (Endocrinology)
- 2014 Fellow, Royal College of Physicians (Edinburgh)
- 2013 Fellow, American Institute of Medical and Biological Engineering (AIMBE) and cited as one of the 1000 top bioengineers in the world, and as being one of the top 2% of the world's bioengineers.
- 2013 Cited in San Francisco Super Doctors, 2013 (Endocrinology)
- 2012 Cited in San Francisco Super Doctors, 2012 (Endocrinology)
San Francisco Chronicle Magazine. August 5, 2012
- 2012 20th Annual Gold Medal Oration and Distinguished Scientist Award from Dr. Mohan's Diabetes Specialties Centre and Madras Diabetes Research Foundation of Chennai, India
- 2011–2016 Cited in the Castle Connolly Medical Ltd. List of Top Doctors in the US as being in the top 1% of endocrinologists nationally
- 2010 FDA Director's Special Citation Award for outstanding contributions to the Center for Devices and Radiological Health related to diabetes technology
- 2006 Physician of the Month, Mills-Peninsula Health Services
- 2005 Health Hero Award of Mills-Peninsula Health Services
- 1994 Cited in "Outstanding Physician Specialists of the Bay Area" and rated Best Endocrinologist in San Mateo County by Bay Area Consumers' Checkbook
- 1991 Fellow, American College of Physicians
- 1981 American Diabetes Association, San Mateo County Chapter, Distinguished Service Citation
- 1980 – 1981 Dorothy Lang Frank Diabetes Fellowship
- 1975 **Alpha Omega Alpha** (Junior Year)
- 1972 UC San Francisco Regents Scholarship
- 1972 UC Berkeley Department of Genetics Citation
- 1971 **Phi Beta Kappa** (Junior Year)

PROFESSIONAL ACTIVITIESNATIONAL

- 2021– Present California State University – Chico: Cybersecurity for Executives Program Advisory Council, member
- 2020– Present Precision Medicine in Diabetes Initiative of the American Diabetes Association, Working Group on Monitoring, Chair
- 2020– Present CDC Inpatient Hypoglycemia Reporting Project via the National Healthcare Safety Network (NHSN) - Subject Matter Expert
- 2020 Endocrine Society ENDO 2020 Abstract Reviewer
- 2019– Present Scientific Advisory Board, Chair: Texas A&M/UCLA/FIU/Rice University Precise Advanced Technologies and Health Systems for Underserved Populations Engineering Research Center (PATHS-UP)
- 2019– Present Nebraska Applied Research Institute,(NARI) Bio-Cyber Initiative, Advisor
- 2019 FDA/MITRE CyberMed Safety Expert Analysis Board (CYMSAB), Planning and Tabletop Exercise Meeting, Participant
- 2019 American Diabetes Association, Reviewer of their report (jointly authored with the European Association for Study of Diabetes): “Diabetes Digital App Technology: Benefits, Challenges, and Recommendations. Consensus Report.”
- 2018 Diabetes Digital Dialogue Sponsored by MSD. The future of digital technology in the treatment of type 2 diabetes patients. Webinar transmitted live on World Diabetes Day to 6500 physicians
- 2018– Present Healthcare Sector Coordinating Council Joint Cyber Working Group Medical Device and Healthcare IT Joint Strategic Plan Task Group 1B, Member.
- 2018 American Diabetes Association, IBM Watson Health Sci-sessions Webcast Content, Clinical Reviewer
- 2018– 2019 Scientific Advisory Board, Member: Texas A&M/UCLA/FIU/Rice University Precise Advanced Technologies and Health Systems for Underserved Populations Engineering Research Center (PATHS-UP)
- 2018 ENDO 2018 (The Endocrine Society) Abstract Reviewer
- 2017– 2018 Endocrine Society, Task Force on Technology in Type 1 Diabetes
- 2017 United States Congress, Diabetes Caucus Briefing: Accuracy of Cleared Blood Glucose Monitor Systems
- 2017 Centers for Medicare and Medicaid Services Briefing: Accuracy of Cleared Blood Glucose Monitor Systems.
- 2017– Present IEEE Engineering in Medicine and Biology (EMB) Society Healthcare Device Security Assurance Working Group for medical device cybersecurity standard P2621, which will be co-managed by IEEE and UL, Chair
- 2017– 2018 DTMoSt (DTS Mobile Platform Controlling A Diabetes Device Security and Safety Standard, Steering Committee), Chair, with participation by FDA, DHS, FBI, NIST, NIH, NASA, USAF, US Army, US Navy, IEEE, and UL
- 2017– Present Clinical and Laboratory Standards Institute, Subcommittee of Performance Metrics for Continuous Interstitial Glucose Monitoring, POCT5, Chair
- 2017– Present Baylor College of Medicine Center for Space Medicine, Affiliate Member
- 2016– Present UCSF Medical Device Security Committee, Member
- 2015– 2017 JDRF T1D Outcomes Program - Advisory Committee, Member
- 2015 White House Health and Cybersecurity Roundtable, Member (Issues facing the healthcare sector and the challenges associated with bringing together large amounts of health information as envisioned in the Precision Medicine Initiative)
- 2015– 2017 CMS Alliance to Modernize Healthcare (CAMH) sponsored by Centers for Medicare & Medicaid Services (CMS) and operated by The MITRE Corporation, Advisor.
- 2015– 2017 American Association for Diabetes Educators, Technology Advisory Committee, Member

- 2015– 2017 DTSec (DTS Cybersecurity Standard for Connected Devices Steering Committee), Chair, with participation by FDA, DHS, NIST, NIH, NASA, USAF, Health Canada, ADA, JDRF, TES, and AADE.
- 2015– 2016 The Endocrine Society, Current Procedural Terminology (CPT) Advisor for Continuous Glucose Monitoring codes
- 2015– Present University of Connecticut Center for the Development and Application of Biosensor-Based e-Health Technologies, Proposal Reviewer
- 2015– 2017 American College of Cardiology Diabetes Collaborative Registry, Stakeholder Panel, Member
- 2014– Present UCSF Diabetes Center, Team Member
- 2014– 2018 DTS Surveillance Program for Cleared Blood Glucose Monitors, Chair (Participating organizations include ADA, JDRF, AADE, TES, CAP, and AACC)
- 2013 University of Arizona, Department of Surgery, Faculty Evaluator
- 2012– 2016 Certified Diabetes Technology Clinician (C.D.T.C.) certification program, Planning Committee, and Examination Committee, Chair
- 2012 International Diabetes Center Panel on Optimizing Glucose Reporting, Analysis, and Clinical Decision Making in Type 1 Diabetes: the Ambulatory Glucose Profile (AGP), Member
- 2012–2016 American Diabetes Association Scientific Sessions Abstract Reviewer
- 2011–2014 FDA/Diabetes Technology Society/ADA/Endocrine Society/AAMI Error Grid Panel for Clinical Accuracy of Blood Glucose Monitors, Chair
- 2011 FDA, Draft Guidance - The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for *Artificial Pancreas Device Systems*, Reviewer
- 2011 FDA, Draft Guidance - The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for *Low Glucose Suspend (LGS) Device Systems*, Reviewer
- 2011–2015 Clinical and Laboratory Standards Institute, Consensus Committee on Point-of-Care Testing, Member.
- 2010–2011 Association for the Advancement of Artificial Intelligence (AAAI) Computational Physiology Spring Symposium, Program Committee
- 2010–2012 JDRF Clinical Recommendations Panel on Closed Loop Systems, Member
- 2010–2011 Drug Information Association (DIA), Medical Device Task Force
- 2010–2011 Pulmonary Health Task Working Group of US Army Military Operational Medicine Research Program, Member
- 2010–2013 Oak Ridge National Laboratory, US Department of Energy, Oak Ridge, TN Medical Device Research Center, Advisor
- 2009– 2016 NASA Exploration Medical Capabilities Standing Review Panel, Member
- 2009–2010 University of Pittsburgh Diabetes Institute, Planning Committee
- 2009–2011 Diabetes Mellitus Interagency Coordinating Committee Subgroup on Resources and Infrastructure, Member
- 2009–2011 Diabetes Mellitus Interagency Coordinating Committee Subgroup on Bioengineering Technologies, Member
- 2007–2011 Endocrine Society Continuous Glucose Monitor Guideline Task Force, Chair
- 2007–2011 Clinical and Laboratory Standards Institute, Subcommittee of Methods Comparison of Glucose Methodologies, POCT6, Member
- 2007 –2009 Medical Officer, US Army Medical Research and Materiel Command (USAMRMC) Telemedicine and Advanced Technology Research Center (TATRC)
- 2006 –2008 Clinical and Laboratory Standards Institute, Subcommittee of Performance Metrics for Continuous Interstitial Glucose Monitoring, POCT5, Chair
- 2006 US Federal Trade Commission, Consultant
- 2004 New England Healthcare Institute, Cambridge, MA, Consultant
- 2004 NIH National Human Genome Research Institute, International Haplotype Map (“HapMap”) Project, Advisor
- 2004 A1C Review Panel for Systematic Glycemic Control
- 2003– 2017 National Space Biomedical Research Institute, Houston, TX, Board of

Scientific Counselors
 2003–2004 JDRFI of New York, NY, Technology Reimbursement Advisory Panel
 2003–2004 American Diabetes Association Scientific Sessions Planning Committee
 2003 UC San Diego, Department of Bioengineering, Faculty Evaluator
 2002–2007 US Army Technologies for Metabolic Monitoring Steering Committee
 2002–2010 American Diabetes Association Scientific Sessions Abstract Reviewer
 2001– Present Diabetes Technology Society, Founder and President
 2001 HealthTech of San Francisco, CA, Consultant on Sensors for Monitoring and Artificial Organs
 1999 Optical Society of America, Annual Meeting Committee
 1995–2000 Diabetes Coalition of California, established by the California Department of Health Services
 1994–2001 NIH Diabetes Prevention Trial - Type 1, Coordinator, Stanford University, Clinical Center, Northern San Mateo County Satellite Site

INTERNATIONAL

2020 International Diabetes Federation Congress 2022 Lisbon Planning Committee, Clinical, Therapeutic and Technology Research stream, Member
 2020–Present International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Working Group on Continuous Glucose Monitoring, Member
 2018 European Diabetes Forum, Member
 2017 International Diabetes Federation Meeting, Abstract Reviewer
 2016 Tokyo University of Agriculture and Technology, Graduate School of Engineering, Visiting Professor and Global Innovation Research Organization, Member
 2009–Present Scientific Council of the of the Polish Academy of Sciences Institute of Biocybernetics and Biomedical Engineering, Member
 2008–2009 International Working Group on Self Monitoring of Blood Glucose, established by the International Diabetes Federation, Member
 2008–2011 Coalition for Clinical Research, Self Monitoring of Blood Glucose, Chair
 2005–2006 Diabetes Technology Society International Panel for Establishment of Performance Standards for Continuous Glucose Monitors, Chair
 2004 European Society for Artificial Organs, Scientific Advisory Board, Member
 1993–1994 International Chronic Fatigue Syndrome Study Group, established by Centers for Disease Control and Prevention (CDC), Consultant

RESEARCH GRANT REVIEWER

National Institutes of Health (*NIH*),

- 1) RFA-DK-17-023 “Clinical, Behavioral and Physiological Research Testing Current and Novel Closed Loop Systems (R01), Member, 2018
- 2) Type 1 Diabetes Pathfinder Award (DP2), Member, 2016
- 3) Special Emphasis Panel on Artificial Pancreas, Small Business Innovation Research, Member, 2013
- 4) Special Emphasis Panel on Closed Loop Technologies, Member, 2013
- 5) Study Section on Small Business Innovation Research to Develop New Therapeutics and Monitoring Technologies for Type 1 Diabetes (T1D) Towards an Artificial Pancreas; Special Emphasis Panel, Member, 2012
- 6) Study Section on Diabetes, Metabolism, Nutrition and Obesity; Small Business Special Emphasis Panel (EMNR E10 B), Member, 2010
- 7) Grant Review Panel: The Cooperative Multicenter Research Network to Test Glucose Sensors in Children with Type 1 Diabetes, Member, 2001
- 8) Study Section on Biotechnology, Member, 1998

National Aeronautics & Space Administration (*NASA*)

- 9) Human Research Program Exploration Medical Capability Element Standing Review Panel, Member 2009 - 2016
- 10) NSBRI Technology Development Panel, **Chair**, 2007- 2013
- 11) International Clinical Research and Medical Technology Panel, **Chair**, 2004
- 12) Smart Medical Systems Panel, **Chair**, 2002 - 2007
- 13) Clinical Physiology Panel, Member, 2000
- 14) Study Section on Advanced Technology Development, Member, 1999
- 15) Office of Life and Microgravity Sciences and Applications, Mail Reviewer, 1998 and 2001

Centers for Disease Control and Prevention (CDC), Division of Laboratory Sciences

- 16) Special Emphasis Panel (SEP) RFA-DP-17-003: Natural Experiments of Policy and Built Environment Impact on Diabetes Risk, Member 2017
- 17) Study Section on Noninvasive Measurement of Micronutrients, **Chair**, 2000
- 18) Study Section on Detection and Monitoring of Diabetic Hypoglycemia, Member, 1999

Juvenile Diabetes Research Foundation (JDRF)

- 19) Strategic Research Agreement, Reviewer, 2016-2017
- 20) Industry Discovery and Development Partnerships Grant Reviewer, 2013
- 21) Panel on Glucose Control Training, Innovative & Strategic Research Agreement, Member, 2012
- 22) Panel on Glucose Control Training, Innovative & Strategic Research Agreement, Member, 2011
- 23) Panel on Glucose Control Training, Innovative & Strategic Research Agreement, Member, 2010
- 24) Study Section on Glucose Sensors, **Chair**, 2000
- 25) Study Section on Glucose Sensors, Member, 1999

US Army

- 26) Product Line Review, Diabetes and Chronic Disease: Filling the Gaps, 2010
- 27) Product Line Review, Biomonitoring Technologies, 2009
- 28) Product Line Review, Biomonitoring Technologies, 2008
- 29) TATRC Proposal Review Board: Grant Reviewer, 2008
- 30) Product Line Review, Chronic Diseases, 2007
- 31) SBIR Phase 1 of OSD04-DH02, Grant Review Panel, Member: Non-invasive Metabolic Monitoring, 2004
- 32) Technologies for Metabolic Monitoring, Grant Review Panel, 2002-2006
- 33) SBIR Phase 1 of OSD02-DH02, Grant Review Panel, Member: Non-invasive Transdermal Near Infrared Glucose Monitors, 2002

American Institute of Biological Sciences

- 34) Peer Reviewed Medical Research Program, Grant Reviewer, 2005

National Science Foundation (NSF)

- 35) Site visit team, Atlanta, for the Engineering Research Center at the Georgia Tech/Emory Center for Engineering Living Tissues, 2004

National Oceanic and Atmospheric Administration

- 36) Grant Review for the Saltonstall-Kennedy Competitive Research Program, 2017

American Diabetes Association

- 37) Grant Review Program, Reviewer, 2013
- 38) Grant Review Program, Reviewer, 2012

Yale University Diabetes Research Center

- 39) Diabetes Grant Program, Reviewer, 2016

University of Michigan, Michigan Diabetes Research and Training Center,
40) Pilot Feasibility Grant Program, Grant Reviewer, 2013
41) Pilot Feasibility Grant Program, Grant Reviewer, 2011
42) Pancreatic Islet Encapsulation Pilot Program, Grant Reviewer, 2002

Boston Area Diabetes Endocrinology Research Center
43) Pilot and Feasibility Grant program, Grant Reviewer, 2012

Kansas City Area Life Sciences Institute
44) Blue Cross and Blue Shield Outcomes Research, Grant Reviewer, 2018

Singapore
45) Science & Engineering Research Council of the Agency for Science,
Research & Technology, Grant Reviewer, 2004
46) Biomedical Research Council, A*STAR Industry Alignment Fund – Prepositioning
Programme Health and Biomedical Sciences Domain, Grant Reviewer, 2018

Hong Kong Special Administrative Region Government
47) Innovation and Technology Commission, Grant Reviewer, 2005

Belgium Industrial Research Fund, K.U. Leuven
48) Technology Transfer Program, Grant Reviewer, 2010

Canadian Mitacs Accelerate Research Program
49) Graduate Research Internship Program, Grant Reviewer, 2014
50) Accelerate Research Program, Grant Reviewer, 2019

Norwegian Academy of Science and Letters
51) Centre of Advanced Study, Grant Reviewer, 2015

University of Nantes, France, Health and Engineering Excellence Trajectory (NExT)
52) Interdisciplinary Research Projects, Grant Reviewer, 2018

Diabetes UK
53) Intermediate Clinical Fellowship Grant Reviewer, 2016
54) Grant Reviewer, 2017

Israeli Ministry of Science and Technology
55) Grant Reviewer, 2018
56) Grant Reviewer, 2021

Kuwait Institute of Science and Research
57) Grant Reviewer, 2018

The National Health Care Institute (Zorginstituut Nederland) and the Netherlands Organisation for
Health Research and Development (ZonMw)
58) Grant Reviewer, 2021

University of Bern, Multidisciplinary Center for Infectious Diseases (MCID), Switzerland
59) Grant Reviewer, 2021

PREVIOUS JOURNAL

1999 – 2006 Diabetes Technology & Therapeutics, Founding Editor-in-Chief

TEACHING ACTIVITIES

- 2002 – Present Attending Physician, Diabetes Clinic, UCSF; also 1981 – 1995. (Responsible for teaching students, house officers, and fellows about management of diabetes)
- 2015 Preceptor Metabolism & Nutrition, First Year Medical Students, UCSF
- 1998 – 1999 Preceptor for Nurse Practitioner Program, School of Nursing, UCSF
- 1994 Preceptor, Medicine 160.04, UCSF
- 1988 – 1990 Section Leader, Physiology 101, UCSF
- 1980 – 1982 Physical Diagnosis for Dentists, School of Dentistry, UCSF

MENTORING

- 2000– Present *Three college students who have been mentored at the MPMC Diabetes Research Institute have gone onto Medical School (UCSD), Dental School (Temple), and Osteopathy School (NYIT).
- 2000 – Present *Seven college students who have been mentored at Diabetes Technology Society have gone on to Medical School (UCLA, Washington University of St. Louis, LSU, Loma Linda, and Case Western), Osteopathy School (Alabama College of Osteopathy), and Dental School (University of the Pacific). One other student has been accepted to USC Medical School for 2022.
- 2011- 2012 *A post-doctoral fellow, David Kerr, M.D., who was mentored at the MPMC Diabetes Research Institute went on to become Director of Diabetes Research and Innovation at the Sansum Diabetes Research Institute in Santa Barbara.
- 2000 – Present *Two diabetes research nurses who were mentored at the MPMC Diabetes Research Institute have gone on to receive a CDE.
- 2000 – Present * Two-four letters of recommendation per year have successfully supported job promotions of national faculty members in diabetes research (not at UCSF); one letter of support each year has successfully supported receipt of permanent resident status for USCIS; a letter has successfully supported selection of a recipient of the ADA Physician-Clinician Award; and a letter has successfully supported selection of a recipient of the AIMBE Pierre Galletti Award (the top award of that organization).

PREVIOUS PROFESSIONAL POSITIONS AT UCSF

- 1999 – 2000 Director, Diabetes Symposium Series, UCSF (Planned agenda and selected speakers)
- 1996 – 1998 Co-Director, Diabetes Symposium Series, UCSF (Planned agenda and selected speakers)
- 1993 – 1995 Assistant Director, Diabetes Clinic, UCSF (In charge of Clinic - no Director present)
- 1992 – 1993 Acting Assistant Director, Diabetes Clinic, UCSF (In charge of Clinic - no Director present)
- 1990 – 1995 Associate Clinical Professor, Department of Medicine, UCSF
- 1986 – 1990 Assistant Clinical Professor, Department of Medicine, UCSF
- 1981 – 1986 Clinical Instructor, Department of Medicine, UCSF
- 1981 Associate, Department of Medicine, UCSF
- 1980 – 1982 Consultant, School of Dentistry, UCSF
- 1979 – 1981 Consultant, Comprehensive Medical Clinic "A",
Department of General Internal Medicine, UCSF

PROFESSIONAL SOCIETIES

- 2007 – Present Endocrine Society
- 2003 – Present European Association for the Study of Diabetes
- 2001 – Present Diabetes Technology Society, President
- 1981 – Present American Diabetes Association
- 1981 – Present San Mateo County Medical Society
- 1981 – Present UCSF Faculty/Alumni Association
- 1974 – 1975 Associated Students UCSF School of Medicine, Student Body President

HOSPITAL STAFF PRIVILEGES

2017 – Present Mills-Peninsula Medical Center – Burlingame and San Mateo, California
 1996 – 2017 Mills-Peninsula Health Services – Burlingame and San Mateo, California
 1981 – Present UCSF Hospitals & Clinics - San Francisco, California
 1981 – 1996 Peninsula Hospital - Burlingame, California
 1981 – 1996 Mills Memorial Hospital - San Mateo, California
 2002 – 2008 San Mateo County General Hospital
 1981 – 2007 Seton Medical Center - Daly City, California

SCIENTIFIC MEETINGS ORGANIZED, INTERNATIONAL

Diabetes Technology Society

Virtual International COVID-19 and Diabetes Summit, 2020 (Pending)

European Society of Artificial Organs Congress, Warsaw, **Poland**

How to prevent hypoglycemia, Co-Chair, 2016

Polish Academy of Sciences, International Centre of Biocybernetics,

Seminar on Telecare of Diabetes, Warsaw, **Poland**, Co-Chair, 2009

Polish Academy of Sciences, International Centre of Biocybernetics,

69th Seminar on: Technical, biological and bio-technical approaches of the diabetes treatment.

Recent development and perspectives. Warsaw, **Poland**

Co-Chair and Co-Author of proceedings summary, 2003

SCIENTIFIC MEETINGS ORGANIZED, UNITED STATES

NIH/FDA/JDRF Artificial Pancreas Workshop, Bethesda, Maryland 2022, Co-Organizer (Planned)

NIH/FDA/JDRF Artificial Pancreas Workshop, Bethesda, Maryland 2016, Co-Organizer

NIH/FDA/JDRF Artificial Pancreas Workshop, Bethesda, Maryland 2013 (Planning Committee)

Diabetes Technology Society

Integration of Continuous Glucose Monitoring Data into the Electronic Health Record (iCoDE)
 (Project Manager) 2022 (Planned)

Green Diabetes Summit, Virtual, 2021. (Chair)

Continuous Ketone Monitoring Meeting 2021. (Chair) Virtual

Virtual International COVID-19 and Diabetes Summit, 2020 (Chair)

Continuous Glucose Monitor/Closed Loop Systems in the Hospital: Consensus Guideline Panel.
 Virtual 2020 (Chair)

YSI 2300 Replacement Meeting. Herndon, Virginia. 2019 (Chair)

FDA Precertification Program for Software as a Medical Device. Herndon, Virginia. 2018 (Chair)

DTS Surveillance Program for Cleared Blood Glucose Monitors – Payers Meeting, Bethesda,
 Maryland, 2014 (Chair)

Verifying the Performance of Blood Glucose Monitors Following FDA Clearance, Bethesda,
 Maryland, 2013 (Chair)

DTS Performance of Blood Glucose Monitors Following FDA Approval, Arlington, Virginia, 2013 (Chair)

AAMI / FDA Infusion Device Summit, Silver Spring, Maryland, 2010
Insulin Pump Safety and Security (Planning Committee)

NIH Workshop on Virtual Reality for Diabetes and Obesity, Bethesda, Maryland. 2010.
(Planning Committee)

CDC Sticking With Safety Meeting, Atlanta, Georgia, 2010
(Planning Committee)

US Army Military Operational Medicine Research Program / Department of Defense,
Pulmonary Health Working Group. Frederick, Maryland. 2010. (Chair)

Diabetes Translational Research Meeting for the US Air Force, Bethesda, Maryland. 2009. (Chair)

Personalized Medicine for Diabetes for the US Air Force, San Francisco, California. 2009. (Chair)

US Army Military Operational Medicine Research Program / Department of Defense
Personal Physiological Monitoring and Predictive Modeling for the Warfighter Workshop.
Frederick, Maryland. 2009. (Co-Chair)

US Army TATRC / Department of Defense
Diabetes Coordination Meeting. Fort Detrick, Frederick, Maryland. 2008. (Co-Chair)

Diabetes Technology Society/FDA: Insulin Pump Safety Meeting, San Mateo, California 2009 (Chair)
Insulin Pump Safety Meeting, Bethesda, Maryland. 2008. (Chair)

Diabetes Technology Society

Twenty Second Diabetes Technology Meeting, 2022 (pending)

Twenty First Diabetes Technology Meeting, Virtual, 2021

Workshop on: *New technologies for glucose monitoring*

Workshop on: *Connected Health*

Twentieth Diabetes Technology Meeting, Virtual, 2020

Workshop on: *Novel Software*

Workshop on: *Glucose Monitoring*

Nineteenth Diabetes Technology Meeting, Bethesda, 2019

Workshop on: *Continuous Glucose Monitoring*

Workshop on: *Diabetic Complications: Success and Failure*

Workshop on: *Digital Health*

Workshop on: *Blood Glucose Monitoring: What is its Future?*

Eighteenth Diabetes Technology Meeting, Bethesda, 2018

Workshop on: *Adherence to Treatment*

Workshop on: *Diabetes Technology in the Hospital*

Workshop on: *The Future of Self Monitoring of Blood Glucose*

Workshop on: *Novel Hardware*

Seventeenth Diabetes Technology Meeting, Bethesda, 2017

Workshop on: *Reimbursement for Technology*

Workshop on: *Advances in Insulin Delivery*

Workshop on: *Social Media for Diabetes: Communications and Advertising*

Workshop on: *Developments in Glucose Monitoring*

Sixteenth Diabetes Technology Meeting, Bethesda, 2016

Workshop on: *Implanted Sensors*

Workshop on: *Biomarkers for Disease*

Workshop on: *Coding, Coverage, Reimbursement, and Competitive Bidding*

Workshop on: *Metrics for Diabetes*

Fifteenth Diabetes Technology Meeting, Bethesda, 2015Workshop on: *Investing in Diabetes Technology*Workshop on: *New Treatment Paradigms*Workshop on: *Glucose Measurement Errors and Insulin Dosing Errors*Workshop on: *A Reassessment of Markers of Glycemia***Fourteenth Diabetes Technology Meeting**, Bethesda, 2014Workshop on: *Reimbursement for Diabetes Technology*Workshop on: *Technology for Detection and Prevention of Hypoglycemia*Workshop on: *Regulatory Science; New Performance Guidances & the New Surveillance Error Grid*Workshop on: *Improving Adherence to Diabetes Technology Devices***Thirteenth Diabetes Technology Meeting**, San Francisco, 2013Workshop on: *Diabetes Technology – Save Lives and saves Money*Workshop on: *Blood Glucose Monitors and Continuous Glucose Monitors*Workshop on: *Standards for BG Monitors and Counterfeit BG Strips*Workshop on: *Pens, Pumps, and Other Insulin Delivery Technologies***Twelfth Diabetes Technology Meeting**, Bethesda, 2012Workshop on: *Overcoming Barriers to Adoption of Diabetes Technology*Workshop on: *The Sensor-Tissue Interface*Workshop on: *Bolus Calculators*Workshop on: *Glycemic Variability***Eleventh Diabetes Technology Meeting**, San Francisco, 2011Workshop on: *Investment Opportunities in Diabetes Technology*Workshop on: *Physiology of Interstitial Fluid Related to Implanted Sensors*Workshop on: *New Developments in Blood Glucose Monitoring*Workshop on: *Hospital Technology***Tenth Diabetes Technology Meeting**, Bethesda, 2010Workshop on: *The New Bundled World: Monitoring Diabetes Following Hospital Discharge*Workshop on: *Continuous Glucose Monitoring*Workshop on: *New Ideas in Blood Glucose Monitoring*Workshop on: *Safety and Security Issues for Insulin Pump Therapy***Ninth Diabetes Technology Meeting**, San Francisco, 2009Workshop on: *Investment Opportunities in Diabetes Technology*Workshop on: *Laboratory and Clinical Aspects of Hemoglobin A1c*Workshop on: *SMBG: Data Management and Decision Support*Workshop on: *Future Drugs for Diabetes***Eighth Diabetes Technology Meeting**, Bethesda, 2008Workshop on: *Intellectual Property in Diabetes*Workshop on: *Noninvasive Glucose Monitoring*Workshop on: *Data Management for SMBG*Workshop on: *Measuring the Effects of Diet and Exercise***Seventh Diabetes Technology Meeting**, San Francisco, 2007Workshop on: *Investment Opportunities in Diabetes Technology*Workshop on: *Noninvasive Glucose Monitoring*Workshop on: *Glycemic Variability*Workshop on: *Hospital Management of Diabetes***Sixth Diabetes Technology Meeting**, Atlanta, 2006Workshop on: *Reimbursement Strategies for Diabetes Technologies*Workshop on: *Physiology of Interstitial Fluid*Workshop on: *Databases and Diabetes***Fifth Diabetes Technology Meeting**, San Francisco, 2005*International Workshop for Establishment of Performance Standards for Continuous Glucose Monitors*Workshop on: *Business and Diabetes*Workshop on: *Technology for Weight Management in T2DM and Obesity***Fourth Diabetes Technology Meeting**, Philadelphia, 2004

Workshop on: *Reimbursement Strategies for Diabetes Technologies*

Workshop on: *Defining Accuracy in Blood Glucose Monitors*

Workshop on: *Treatment of Diabetes and Its Complications*

Third Diabetes Technology Meeting, San Francisco, 2003

Workshop on: *Connectivity Standards Utilizing Computers for Analyzing Data from Blood Glucose Monitors and Insulin Delivery Systems*

Workshop on: *Use of Technology for Clinical Practice*

Second Diabetes Technology Meeting, Atlanta, 2002

Workshop on: *New Therapy for Diabetes*

Workshop on: *Calibration of Continuous Glucose Sensors*

Diabetes Technology Society

Thirteenth Clinical Diabetes Technology Meeting, Houston, Texas, 2017

Twelfth Clinical Diabetes Technology Meeting, San Diego, California 2016

Eleventh Clinical Diabetes Technology Meeting, Orlando, Florida, 2015

Tenth Clinical Diabetes Technology Meeting, Los Angeles, California, 2014

Ninth Clinical Diabetes Technology Meeting, Atlanta, Georgia 2013

Eighth Clinical Diabetes Technology Meeting, Los Angeles, California 2012

Seventh Clinical Diabetes Technology Meeting, Philadelphia, Pennsylvania 2011

Sixth Clinical Diabetes Technology Meeting, San Antonio, Texas 2010

Fifth Clinical Diabetes Technology Meeting, Long Beach, California 2009

Fourth Clinical Diabetes Technology Meeting, Orlando, Florida 2008

Third Clinical Diabetes Technology Meeting, San Diego, California 2007

Second Clinical Diabetes Technology Meeting, Boston, Massachusetts 2006

First Clinical Diabetes Technology Meeting, San Francisco California, 2005

Second European Clinical Diabetes Technology Meeting, Copenhagen, Denmark, 2014

First European Clinical Diabetes Technology Meeting, Frankfurt, Germany, 2013

Eighth Hospital Diabetes Meeting, Virtual 2022 (pending)

Seventh Hospital Diabetes Meeting, Virtual 2020

Sixth International Hospital Diabetes Meeting, Atlanta, Georgia 2017

Fifth International Hospital Diabetes Meeting, San Francisco, California 2015

Fourth International Hospital Diabetes Meeting, Arlington, Virginia, 2014

Third International Hospital Diabetes Meeting, Cambridge, Massachusetts, 2012

Second International Hospital Diabetes Meeting, Barcelona, Spain, 2011

First International Hospital Diabetes Meeting, San Diego, 2010

2nd MEDSec Meeting: The Medical Internet of Things, San Jose, California, 2017

1st MEDSec Meeting: The Medical Internet of Things, San Jose, California 2016

Third Digital Diabetes Congress, San Francisco, California, 2019

Second Digital Diabetes Congress, San Francisco, California, 2018

First Digital Diabetes Congress, San Francisco, California 2017

ADA/UCSF/Mills-Peninsula Health Services: **The Sixteenth Northern California Diabetes Symposium**, San Francisco, 2002

Mills-Peninsula / CDC / NASA / Juvenile Diabetes Research Foundation International / UC Berkeley Department of Bioengineering: **The First Diabetes Technology Meeting**, San Francisco, California, 2001

Juvenile Diabetes Research Foundation International / NASA: *The Bioartificial Pancreas*, Arlington, Virginia, 2001

MODERATOR AT MEETINGS, INTERNATIONAL

- 2017 ATTD 10th International Conference on Advanced Technologies & Treatments for Diabetes
Paris, **France**. *Cybersecurity of Medical Devices (Diabetes and Artificial Pancreas)*
- 2016 ATTD 9th International Conference on Advanced Technologies & Treatments for Diabetes
Milan, **Italy**. *Is It Time to Move to Time in Range as the Main Glycemic Control Measure?*
- 2015 International Diabetes Federation / World Diabetes Congress. Vancouver, **Canada**
Computational Approaches to Diabetes
- 2015 ATTD 8th International Conference on Advanced Technologies & Treatments for Diabetes
Paris, **France**. *Regulation of Diabetes Devices*
- 2014 European Association for the Study of Diabetes, 50th Annual Meeting. Vienna, **Austria**
Symposium on *Use of the InsuPad™ for rapid Insulin Delivery*
- 2013 European Association for the Study of Diabetes, 49th Annual Meeting. Barcelona, **Spain**
Symposium on *InsuPad™ - Improvement of Insulin Therapy – a new Option*.
- 2013 ATTD 6th International Conference on Advanced Technologies & Treatments for Diabetes
Paris, **France**. *Continuous Glucose Monitoring*.
- 2008 International Diabetes Federation (IDF) Global SMBG Workshop, Amsterdam, **Holland**
Self Monitoring of Blood Glucose in Diabetes: Appraisal of Available Data and
Defining Perspectives. *Other Trial Data*
- 2004 European Association for the Study of Diabetes (EASD), 40th Annual Meeting.
Munich, **Germany**. *Alternate Routes of Insulin Delivery Poster Session Discussion Leader*

MODERATOR AT MEETINGS, UNITED STATES

American Diabetes Association

- 2016 American Diabetes Association, 76rd Scientific Sessions, New Orleans
Guided Audio Poster Tour. *Glucose Sensing Helps*
- 2013 American Diabetes Association, 73rd Scientific Sessions, Chicago
Guided Audio Poster Tour
Blood Glucose Monitoring
- 2004 American Diabetes Association, 64th Scientific Sessions, Orlando
Pharmacologic Treatment of Type 2 Diabetes
Controversies in Glucose Monitoring
- 2003 American Diabetes Association, 63rd Scientific Sessions, New Orleans
Pulmonary Delivery of Insulin
GI complications of diabetes

Diabetes Technology Society

- 2018 2nd Digital Diabetes Congress, San Francisco, California
Cybersecurity
- 2017 1st Digital Diabetes Congress, San Francisco, California
Cybersecurity and Privacy
- 2017 2nd MEDSec Meeting: Regulatory Aspects of Cybersecurity, San Jose, California
Regulatory Aspects of Cybersecurity

- 2016 1st MEDSec Meeting: The Medical Internet of Things, San Jose, California
Policy, Standards, and Privacy
- 2017 17th Diabetes Technology Meeting, Bethesda, Maryland
The Diabetes Technology Society Surveillance of Cleared Blood Glucose Monitor Systems Project
- 2016 16th Diabetes Technology Meeting, Bethesda, Maryland
Regulatory Topics in Diabetes Technology
- 2015 15th Diabetes Technology Meeting, Bethesda, Maryland
Cybersecurity for Connected Diabetes Devices
- 2014 14th Diabetes Technology Meeting, Bethesda, Maryland
Performance of Cleared Blood Glucose Monitors; What is Needed?
- 2014 FDA Public Workshop – Regulatory Science Considerations for Software Used in Diabetes Management, Silver Spring, Maryland. *Insulin Bolus Calculators*
- 2013 IEEE Conference on Body Sensor Networks Meeting, Cambridge, Massachusetts, *Sensors*
- 2016 NIH/FDA Fourth Artificial Pancreas Workshop, Bethesda, Maryland:
Testing and Adoption of Current and Emerging Technologies
Interoperability, Data Management, and Cybersecurity
- 2013 NIH/FDA/JDRF Artificial Pancreas Workshop, Bethesda, Maryland.
Learning Algorithms with More Inputs and Fault Detection
- 2012 FDA Workshop on Clinical Study Design and Performance of Hospital Glucose Sensors.
Silver Spring, Maryland
What accuracy is needed to ensure a safe and effective device?
- 2010 FDA/NIH Workshop: Innovations in Technology for the Treatment of Diabetes:
Clinical Development of the Artificial Pancreas (an Autonomous System).
Gaithersburg, Maryland
Clinical Expectations for Artificial Pancreas Device Systems
- 2010 CDC: Sticking With Safety Meeting, Atlanta, Georgia
Industry Panel
- 2008 FDA / NIH / JDRF Workshop: Towards an Artificial Pancreas, Bethesda, Maryland
Beyond Insulin-dependent Diabetes Mellitus
- 2018 Biosensors 2018. 28th Anniversary, World Congress on Biosensors, Miami, Florida
Signal transduction technology (including magneto, piezo, optical and direct electrochemical techniques)
- 1998 Non/Minimally Invasive Measurement of Physiological Analytes Technology Workshop organized by the National Aeronautics and Space Administration (NASA) and the Juvenile Diabetes Foundation (JDF), Arlington, Virginia:
Session on Minimally Invasive Sensing

RECENT PRESENTATIONS, INTERNATIONAL

- 2018 Singapore-Stanford Biodesign, Thought leader Series. **Singapore**
Diabetes Sandbox: Interface between Medical Technology and Digital Health (Panelist)
Singapore Ministry of Health Office of Healthcare Transformation **Singapore**
How Digital Health Can Increase Adherence to Treatments
- 2016 Tokyo University of Agriculture and Technology, Tokyo, **Japan**.

Overcoming barriers to the artificial pancreas

- 2016 Tokyo University, Tokyo, **Japan**.
Overcoming barriers to the artificial pancreas
- 2016 Kyoto Medical Center, Kyoto, **Japan**.
Overcoming barriers to the artificial pancreas
- 2015 World Diabetes Congress of the International Diabetes Federation, Vancouver, **Canada**.
New insulins and insulin-delivery technologies for closed-loop systems.

European Association for the Study of Diabetes

- 2018 54th Annual Meeting, Berlin, **Germany**
Use of digital health to increase adherence to treatments
Optimising ultra-fast insulins in pumps
Satellite Session, *Innovation within insulin management of type 1 diabetes*
- 2005 41st Annual Meeting, Athens, **Greece**
Satellite Session, *Overview of the Technology and Research on Continuous Glucose Monitors*
- 2004 40th Annual Meeting, Munich, **Germany**
New Technologies for Glucose Sensing and Insulin Delivery
Satellite Session, *Continuous Glucose Monitoring*
- 2002 38th Annual Meeting, Budapest, **Hungary**
Satellite Session, *“Continuous Glucose Monitoring: Clinical Usefulness of the Microdialysis Technique and Other Glucose Sensors” Closed Loop Systems – How Long is the Road?*

Advanced Technologies & Treatments for Diabetes

- 2020 13th International Conference. Madrid, **Spain**
Digitalizing Diabetes Care: Cybersecurity
Real World evidence
- 2018 11th International Conference. Vienna, **Austria**
Trends in Digital Health for Diabetes
Efficacy and safety of continuous subcutaneous insulin infusion of Faster Aspart compared with Insulin Aspart in type 1 diabetes
- 2017 10th International Conference. Paris, **France**.
Cybersecurity of medical devices (Diabetes and Artificial Pancreas)
- 2016 9th International Conference. Milan, **Italy**.
Ease of use of the new insulin glargine 300 U/ml pen injector in insulin-naïve people with type 2 diabetes.
- 2015 8th International Conference. Paris, **France**.
Regulation of diabetes technology in the US
Short, medium, and long term markers of glycemia
- 2014 7th International Conference. Vienna, **Austria**.
Simplifying life with diabetes: Data as servant and not master

Diabetes Technology Society

- 2014 2nd Annual European Clinical Diabetes Technology Meeting, Copenhagen, **Denmark**.
Blood glucose monitoring: technology and clinical need
- 2013 1st Annual European Clinical Diabetes Technology Meeting, Frankfurt, **Germany**.
Performance of marketed blood glucose monitors following clearance
- 2013 Visiting Lecturer Series, *Update on Diabetes Technology, 2013*
Diabetes Medical Center, Tel Aviv, **Israel**.

- 2012 Indo-US International Symposium on Pancreas Focusing on the Exocrine and Endocrine Aspects. DMDSC and MDRF Gold Medal Oration, Chennai, **India**.
Advances in Glucose Monitoring and Insulin Delivery
- 2011 Second International Hospital Diabetes Meeting, Barcelona, **Spain**.
Safe Assisted Monitoring of Blood Glucose Practices in the Hospital
- 2010 European Union, Life Sciences Circle, European Parliament, Brussels, **Belgium**
Self Monitoring of Blood Glucose Empowers Patients with Diabetes to Achieve Improved Blood Glucose Levels
- 2009 Telecare of Diabetes, Polish Academy of Sciences, Warsaw, **Poland**
Trends in Diabetes Telemedicine
- 2008 Biocentrum Ochota Consortium, Polish Academy of Sciences, Warsaw, **Poland**
Diabetes Science and Technology
- 2008 International Working Group SMBG, Amsterdam, **Holland**
Critical Assessment of Available Evidence on SMBG Utilization
- 2008 International Working Group SMBG, Rome, **Italy**
Activities of the Coalition for Clinical Research SMBG
- 2007 Jagiellonian University, Clinical Chemistry Rounds, Krakow, **Poland**
New Bioengineered Devices for Diabetes
- 2014 Institute of Biocybernetics and Biomedical Engineering, Special Lecture, Warsaw, **Poland**
The Artificial Pancreas
- 2007 Institute of Biocybernetics and Biomedical Engineering, Special Lecture, Warsaw, **Poland**
New Bioengineered Devices for Diabetes
- 2006 World Congress on Medical Physics and Biomedical Engineering, Seoul, **Korea**
The Artificial Pancreas: a Cure for Diabetes?
- 2005 University of Cambridge Addenbrooke Hospital, Department of Pediatrics Seminar, Cambridge, **England**, *New Technologies for Insulin Delivery*
- 2004 European Society for Artificial Organs, Warsaw, **Poland**, *The Artificial Pancreas*
- 2003 Polish Academy of Sciences
69th Seminar of the International Centre of Biocybernetics, Warsaw, **Poland**,
Future Perspectives for Bio and Techno Support of the Diabetes Treatment

RECENT PRESENTATIONS, UNITED STATES

- US Food & Drug Administration (FDA)**
- 2016 NIH/FDA Fourth Artificial Pancreas Workshop, Bethesda, Maryland: Testing and Adoption of Current and Emerging Technologies
Cybersecurity Considerations for an Integrated System
- 2013 NIH/FDA Workshop on Innovation Towards an Artificial Pancreas, Bethesda, Maryland
mHealth
- 2012 FDA Workshop on Clinical Study Design and Performance of Hospital Glucose Sensors. Silver Spring, Maryland
Performance expectations for hospital glucose sensors

- 2010 FDA/NIH Workshop: Innovations in Technology for the Treatment of Diabetes: Clinical Development of the Artificial Pancreas (an Autonomous System). Gaithersburg, Maryland
Low Glucose Suspend Systems
The Artificial Pancreas
- 2010 FDA/CDRH Public Workshop: Identifying Unmet Public Health Needs and Facilitating Innovation in Medical Device Development, Gaithersburg, Maryland:
Standards & Interoperability for Better Diabetes Technology
- 2010 FDA/CDRH Public Meeting: Blood Glucose Meters, Gaithersburg, Maryland:
Panel discussion on accuracy and presentation on *Where do we go from here?*
- 2009 Office of In Vitro Devices (OIVD) Special Seminar, Silver Spring, Maryland:
Diabetes Technology
- 2008 Towards an Artificial Pancreas Workshop, Bethesda, Maryland
Compatibility of an Artificial Pancreas with Other Devices
- 2007 Artificial Pancreas Working Group, Rockville, Maryland, *The Artificial Pancreas*
- 2005 11th FDA Science Forum, Washington, D.C.
Novel technologies for delivering insulin and other peptide drugs
- 2003 Workshop on Innovative Systems for Delivery of Drugs and Biologics: Scientific, Clinical, and Regulatory Challenges, Bethesda, Maryland
Novel technologies for treatment of diabetes: metabolic monitoring, the artificial pancreas, and alternate routes for administering insulin
- 2003 Office of Science and Technology (OST) Special Seminar, Rockville, Maryland:
New technologies for managing diabetes
- 2002 Center for Devices and Radiological Health (CDRH),
Office of Device Evaluation (ODE) Special Seminar, Rockville, Maryland:
Advances in diabetes technology
- FDA, Department of Homeland Security, Department of Health and Human Services, and the National Healthcare Information Sharing and Analysis Center**
- 2016 2nd Public Workshop on Collaborative Approaches for Medical Device and Healthcare Cybersecurity. Silver Spring, Maryland. 2016
DTSec (Diabetes Technology Society Cybersecurity Standard for Connected Devices)
- US Army Telemedicine and Advanced Technology Research Center**
- 2008 TATRC / Department of Defense Diabetes Coordination Meeting.
Diabetes Technology Research, Frederick, Maryland
- 2007 Developing an Interdisciplinary Institute for Emerging Health Technologies.
(Keynote) *Treatment of Diabetes in 2030*. Honolulu, Hawaii
- 2007 Nanotechnology Solutions for Long-term Implantable Devices, Houston, Texas
The Need for Implantable Glucose Sensors
- 2007 Partnering to Enable Technology: From Basic Research to Deployment / 15th Annual Medicine Meets Virtual Reality, Long Beach, California
(Keynote) *Technology to Treat Hyperglycemia in Trauma Patients*
- US Army Research Institute of Environmental Medicine**
- 2009 Seminar on Military Nutrition. Natick, Massachusetts
New Technologies for Metabolic Monitoring
- US Army Technologies for Metabolic Monitoring Program**
- 2004 Current Progress and Future Directions, Philadelphia, Pennsylvania: *Military and industrial activities: The diabetes need for metabolic monitoring: technologies that are currently available and what the future might hold*
- 2002 The Future of Metabolic Monitoring of Glucose: Identifying Complementary Measurable Parameters, Arlington, Virginia, *The diabetes need for metabolic monitoring: technologies that are currently available and what the future might hold*

Committee on Military Nutrition Research (CMNR),

- 2003 Food and Nutrition Board, Institute of Medicine, Workshop on Metabolic Monitoring for Military Field Applications, Brooks Air Force Base, San Antonio, Texas
Technologies for Measuring Glucose and Lactate

Centers for Disease Control and Prevention (CDC)

- 2020 Division of Healthcare Quality Promotion (Virtual)
Tracking inpatient medication-related hypoglycemia event rates using the National Healthcare Safety Network (NHSN) (pending)
National Diabetes Laboratory, Seminar, Atlanta, Georgia:
- 2005 *Continuous Glucose Monitoring*
2004 *New technologies for measuring glucose and delivering insulin*
2001 *Bioartificial pancreas*
1999 *Noninvasive and minimally invasive blood glucose monitoring*
1999 *Inhaled insulin*

American Diabetes Association

- 2021 81st Scientific Sessions, virtual
Session on Automation and Expanded Use of Technology in the Inpatient Setting
Inpatient Use of Continuous Glucose Monitoring to Prevent Hypoglycemia
- 2018 78th Scientific Sessions, Orlando, Florida
Session on Online and Mobile Support - Wading Through the Noise.
Building Cybersecurity into Connected Diabetes Devices
- 2016 76th Scientific Sessions, New Orleans, Louisiana.
Management of Hyperglycemia in the Hospitalized Patient (State-of-the-Art Lecture):
The Future of Technology in the Management of Inpatient Diabetes.
The PRIDE Group:
Continuous Glucose Monitoring in the Hospital
- 2014 74th Scientific Sessions, San Francisco, California, Joint Session with AACC on Blood Glucose Monitoring: 21st Century Issues. *The New Error Grid: Rationale, Development, and Clinical Value*
- 2014 74th Scientific Sessions, San Francisco, California. Symposium on Closed-Loop Insulin Delivery—One Step at a Time, *Do We Need More Rapid Acting Insulins?*
- 2013 73rd Scientific Sessions, Chicago, Illinois, Poster Tour Leader, *Glucose Monitoring*
- 2011 71st Scientific Sessions, San Diego, California, Session on Technology in Clinical Practice: Help or Hindrance. *Insulin Pumps and Continuous Glucose Monitors*
- 2005 65th Scientific Sessions, San Diego, California, Symposium on Molecular Medicine
The Artificial Pancreas
- 2002 62nd Scientific Sessions, San Francisco, California, Session on Glucose Monitoring and Sensing, *New Technology for Glucose Monitoring and Sensing*
- 2001 61st Scientific Sessions, Philadelphia, Pennsylvania, Session on Glucose Monitoring:
The future of noninvasive glucose monitoring
- 2001 Regional Postgraduate Course, Los Angeles, California: *Glucose sensors*

Diabetes Technology Society

- 2017 13th Clinical Diabetes Technology Meeting, Houston, Texas
Blood Glucose Monitoring Technology
- 2016 12th Clinical Diabetes Technology Meeting, San Diego, Florida
Blood Glucose Monitoring Technology
- 2015 11th Clinical Diabetes Technology Meeting, Orlando, Florida
Blood Glucose Monitoring Technology
- 2015 11th Clinical Diabetes Technology Meeting, Orlando, Florida
Continuous Glucose Monitoring Technology
- 2014 14th Diabetes Technology Meeting, Bethesda, Maryland
The New Surveillance Error Grid
- 2013 13th Diabetes Technology Meeting, San Francisco, California

- The New Error Grid*
- 2013 9th Clinical Diabetes Technology Meeting, Atlanta, Georgia
Blood Glucose Monitoring: Past, Present, and Future
- 2011 12th Diabetes Technology Meeting, Bethesda, Maryland
Assisted Monitoring of Blood Glucose
- 2012 3rd International Hospital Diabetes Meeting, Cambridge, Massachusetts
Assisted Monitoring of Blood Glucose
- 2011 2nd International Hospital Diabetes Meeting, Barcelona, Spain
Assisted Monitoring of Blood Glucose
- 2011 11th Diabetes Technology Meeting, San Francisco, California
The Role of SMBG in Non-Insulin Treated Type 2 Diabetes
- 2010 6th Clinical Diabetes Technology Meeting, San Antonio, Texas
Is Self Monitoring of Blood Glucose Clinically Useful?
- 2009 5th Clinical Diabetes Technology Meeting, Long Beach, California
The Coalition for Clinical Research-SMBG
- 2008 8th Diabetes Technology Meeting, Bethesda, Maryland
The Coalition for Clinical Research-SMBG
- 2006 2nd Clinical Diabetes Technology Meeting, Boston, Massachusetts
Benefits and Limitations of Intermittent BG, A1C, and Ketone Testing
- 2005 1st Clinical Diabetes Technology Meeting, San Francisco, California
Continuous Glucose Monitoring

Endocrine Society

- 2017 Endo 2017. *Meet the Professor: Sensors and Pumps*, Orlando, Florida
- 2013 Endo 2013. *Novel Sensor Technologies*, San Francisco, California
- 2012 Endo 2012. *Continuous Glucose Monitoring*; Houston, Texas
- 2010 Endo 2010. Forum: Application of Technology to Improve Diabetes Care -
Navigating the Labyrinth: Update on SMBG; San Diego, California

Controlled Release Society

- 2021 *Insulin Pumps* Virtual

American Association of Clinical Endocrinologists

- 2016 *The Power of continuous glucose monitoring*, Atlanta, Georgia
Georgia regional AACE Meeting
- 2014 Consensus Conference on Glucose Monitoring, Washington, DC
The DTS Surveillance Program for Cleared Blood Glucose Monitors

American Association of Diabetes Educators

- 2018 *How secure are diabetes devices?* Baltimore, Maryland
- 2017 *The Importance of Accuracy*, Indianapolis, Indiana
- 2016 *Diabetes Technologies and Devices: from Accuracy to Cybersecurity*,
San Diego, California
- 2013 *Glucose Monitoring*, Philadelphia, Pennsylvania
- 2012 *Publication Partnership: Meet the Editors*, Indianapolis, Indiana

- 2020 **Vumedi**. COVID-19 and Inpatient Diabetes Therapy. Virtual

- 2018 **Biosensors 2018**. 28th Anniversary, World Congress on Biosensors
Continuous Monitoring of Glucose for Diabetes. Miami, Florida, (Plenary)

Professional Liability Underwriting Society

- CyberLiability Symposium*,
IoT 2050: Smart Cities & Automated Medicine, Chicago, Illinois

- 2014 **American Association for Clinical Chemistry**

- Joint Session with American Diabetes Association on Blood Glucose Monitoring: 21st Century Issues. *The New Error Grid: Rationale, Development, and Clinical Value*. Chicago, Illinois.
- 2017 **Medical Device Innovation, Safety and Security Consortium (MDISS)**
Fall Congress: Cybersecurity for Diabetes Devices, Arlington, Virginia (keynote)
- 2017 **Great Plains Pediatric Endocrine Symposium**, Kansas City, Missouri
Continuous Glucose Monitoring
The Most Important Data for Best Use of Continuous Glucose Monitoring
- 2016 **Precision Medicine Meeting**
Panel on New Technologies, San Diego, California
- 2012 **DFCon 2012 Global Diabetic Foot Conference**
Missing Links: Crossing the Great Rift with Next Generation Home Monitoring (Lessons from the Diabetes Technology Society), Hollywood, California
- 2012 **Arizona State University**, Tempe Arizona
Bioengineering seminar, *Technology for Glucose Monitoring and Insulin Delivery*
- 2011 **Commercializing Companion Diagnostics Conference**
Role of Companion Diagnostics in Diabetes Drug Development, Millbrae, California
- 2016 **IEEE Conference on Body Sensor Networks Meeting**
Wearable sensors as game changers in chronic disease management: achieving physiological homeostasis in diabetes
Body Sensors Network, 2016, San Francisco, California
- 2013 *Continuous glucose sensors, mHealth*
Body Sensors Network, 2013 Cambridge, Massachusetts
- 2011 **American Association for Artificial Intelligence**
Smart Sensors for Maintaining Homeostasis (Keynote Address), Palo Alto, California
- 2009 **University of Pittsburgh**
Working Toward a National Model for Diabetes, Pittsburgh, Pennsylvania
- 2009 **Printed Electronics USA 2009**
Diabetes Applications for Printed Electronics, San Jose, California
- 2005 **The Children's Diabetes Foundation at Denver / University of Colorado**
Practical Ways to Achieve Targets in Diabetes Care, Keystone, Colorado
Hypoglycemia and alternate site testing
Glucose sensors in achieving target A1C
- 2003 **American Society of Clinical Pathology**
Teleconference #2894: *Emerging assays in diabetes*. Headquarters: Chicago, Illinois
- 2018 **Professional Liability Underwriting Society Cyber Symposium**
The Internet of Things, Chicago, Illinois (pending)
- 2018 **INTEGRIS Baptist Medical Center**, Security Committee, Oklahoma City, Oklahoma
Medical Device Cybersecurity
- 2003 **Walter Reed Army Medical Center / USUHS**, Washington, DC

Endocrinology Grand Rounds, *New technologies for managing diabetes*

University of California

2018 Systemwide IT Summit. Cybersecurity of Medical Devices. Santa Cruz, California

University of California at Berkeley,

2018 Aging Research & Technology Summit: *Diabetes Technology*.

2016 Electrical Engineering Seminar: *Wearable and Implantable Sensors for Diabetes*
Bioengineering 24: "Aspects of Bioengineering"

2007 *Bioengineering Research Opportunities in Diabetes*

2004 *Bioengineering Research Opportunities in Diabetes*

Bioengineering 24: "Biocomputing, Bio-Informatics, and Genomics"

2001 *Bioengineering Research Opportunities in Diabetes*

*Received highest evaluation of all course faculty

UC San Francisco

2017 IT Conference, *Cybersecurity and Standards for Connected Diabetes Devices*

2016 National Cyber Security Awareness Month: *Cybersecurity for Connected Medical Devices*

2014 Postgraduate Course on Endocrinology, San Francisco, California

Artificial Pancreas

2013 Endocrinology Rounds, *Advances in Glucose Monitoring and Insulin Delivery*

2013 Library Rounds, *Publishing Insider Hints & Tips*

2003 Endocrinology Grand Rounds, *New Technologies for managing Diabetes*

Stanford University,

2017 Information Technology Department, Stanford Health. *The Need for Common Hospital
Device Cybersecurity Requirements*

2016 SystemX Seminar, *Engineered Technologies to Monitor and Treat Diabetes*

2016 Electrical Engineering Journal Club, *Wearable and Implantable Sensors for Diabetes*

UC San Diego,

2003 Endocrinology Grand Rounds, *New Technologies for Managing Diabetes*

2001 Department of Bioengineering, Glucose Monitoring and Control Meeting,
Hazards of Hypoglycemia

2002 **Harvard Medical School / Joslin Diabetes Center,** Boston, Massachusetts

Longwood Area Diabetes/Metabolism Clinical Conference,

New Technologies for Measuring Blood Glucose

Weill Cornell Medical School

2021 Endocrinology Grand Rounds

Cybersecurity of Diabetes Devices

2021 **Medical College of Wisconsin**

Milwaukee Citywide Case Conference, *Cybersecurity of Diabetes Devices,* Virtual

Georgia Institute of Technology, Atlanta, Georgia

2011 Bioengineering Seminar: *The Artificial Pancreas*

2002 Bioengineering Seminar: *New Technology for Glucose Monitoring and Sensing*

2018 **Santa Clara University,** Innovations in Healthcare Conference,

Health Information Technology, Panelist, Santa Clara, California

2001 **Juvenile Diabetes Research Foundation International / NASA:** The Bioartificial

Pancreas, Arlington, Virginia: *Overview of the Bioartificial Pancreas*

2001 **American Society of Transplant Surgeons and the American Society of Transplantation** Transplant 2001, The Second Annual Joint Transplant Meeting of the, Chicago, Illinois: Session on Bioartificial Organs: *Bioartificial pancreas*

2015 **Palo Alto Medical Foundation**, San Carlos California
Special Seminar for the Korean Hospital Association:
Innovations in Telemedicine Care for Diabetes

Additional presentations at UCSF, Stanford, UC Davis, UCLA, Northwestern, Tulane, LSU, Albert Einstein, UMD New Jersey, and Emory medical schools, at NIH, the FDA, and the MIT Department of Chemical Engineering prior to 2000.

PATENTS

Sterling B, Hartstein P, Li K, Agostino M, **Klonoff D**, Gaffney R, Zheng P, Gable J, Witte K, Smith H, Sheill J, Munrow M, Hall WD, Goldberger D, Fennell MJ, Cortella JM, Braig JR, Rule, P. (Patent Application 20030090649). Reagent-less whole-blood glucose meter. Filed January 21, 2002.

Rule P, Braig J, Hartstein P, Smith H, **Klonoff D**. (Patent Application 20030175806). Method and apparatus for improving the accuracy of alternative site analyte concentration measurements. Filed November 21, 2002.

BIBLIOGRAPHY

Book Editor

Draznin B, Edelman S, Hirsch I, **Klonoff D**. *Diabetes Technology: Science and Practice*. American Diabetes Association. 2019.

Klonoff D.C., Kerr D, Mulvaney S. *Diabetes Digital Health*. Elsevier. 2020

Klonoff D.C., Kerr D, Weitzman E. *Diabetes Digital Health and Telehealth*. Elsevier
(In preparation)

Publications – Journals

- 1) Mohsenifar Z., **Klonoff D.**, Cassan S.: Propionobacterium acnes pneumonia in a patient with lymphoma. *Infection*. 1979; 7:146-148.
- 2) **Klonoff D.C.**: Macroamylasemia and other immunoglobulin-complexed enzyme disorders. *West. J. Med*. 1980; 133:392-407.
- 3) **Klonoff D.C.**, Karam JH: Diabetes mellitus and risk of skeletal fracture. *N. Engl. J. Med*. 1981; 304:115.
- 4) Kahn DG, Garfinkle JM, **Klonoff D.C.**, Pembroke LJ, Morrow DJ: Cryptosporidial and cytomegaloviral hepatitis and cholecystitis. *Arch. Pathol. Lab. Med*. 1987; 111:879-881.
- 5) **Klonoff D.C.**: Association of hyperinsulinemia with chlorpropamide toxicity. *Am. J. Med*. 1988; 84:33-37.
- 6) **Klonoff D.C.**, Andrews BT, Obana WG: Stroke associated with cocaine use. *Arch. Neurol*. 1989; 45:989-993.
- 7) **Klonoff D.C.**, Kahn DG, Rosenzweig W, Wilson CB: Hyperprolactinemia in a patient with a pituitary and an ovarian dermoid tumor: Case report. *Neurosurgery*. 1990; 26:335-339.

- 8) **Klonoff D.C.**, Jurow AH: Acute water intoxication as a complication of urine drug testing in the workplace. *JAMA*. 1991; 265:84-85.
- 9) **Klonoff D.C.**, Jurow AH: Urine drug testing, water intoxication, and anticholinergic medication. *JAMA*. 1991; 265:2672.
- 10) Demeure MJ, **Klonoff D.C.**, Karam JH, Duh Q-Y., Clark OH: Insulinoma associated with multiple endocrine neoplasia Type 1: the need for a different approach. *Surgery*. 1991; 110:998-1005.
- 11) **Klonoff D.C.**: Chronic fatigue syndrome. *Clin. Infect. Dis*. 1992; 15:812-823.
- 12) **Klonoff D.C.**, Wiskocil RL: Inappropriate drug prescribing. *JAMA*. 1995; 273:456-457.
- 13) **Klonoff D.C.**, Barrett BJ, Nolte MS, Cohen RM, Wyderski, R.: Hypoglycemia following inadvertent and factitious sulfonylurea overdoses. *Diabetes Care*. 1995; 18:563-567.
- 14) **Klonoff D.C.**: The Diabetes Coalition of California. *Calif. J. Health-Syst. Pharm*. 1995; 7:4.
- 15) **Klonoff D.C.**: Neurally mediated hypotension and chronic fatigue syndrome. *JAMA*. 1996; 275:359-360.
- 16) **Klonoff D.C.**: Noninvasive blood glucose monitoring. *Diabetes Care*. 1997; 20:433-437.
- 17) **Klonoff D.C.**: In the pipeline: noninvasive blood glucose monitoring. *Clinical Diabetes*. 1998; 17:43-45.
- 18) **Klonoff D.C.**, Braig, J., Sterling, B., Kramer, C., Goldberger, D., Trebino, R.: Mid-infrared spectroscopy for noninvasive blood glucose monitoring. *IEEE Lasers and Electro-Optics Society Newsletter*. 1998; 12:13-14.
- 19) **Klonoff D.C.**: Welcome to Diabetes Technology & Therapeutics. *Diabetes Technology & Therapeutics*. 1999; 1:1-2.
- 20) Arnold MA, **Klonoff D.C.**: Noninvasive laser measurement of blood glucose - a bright idea or an optical illusion? *Diabetes Technology & Therapeutics*. 1999; 1:401-402.
- 21) **Klonoff D.C.**: New Products and New Technologies for Diabetes. *Diabetes Technology & Therapeutics*. 1999; 1:237-238.
- 22) **Klonoff D.C.**: Inhaled insulin. *Diabetes Technology & Therapeutics*. 1999; 1:307-313.
- 23) **Klonoff D.C.**: The promise of optical sensing strategies for glucose. *Diabetes Technology & Therapeutics*. 1999; 1:117-119.
- 24) **Klonoff D.C.**, Schwartz DM: An economic analysis of interventions for diabetes mellitus. *Diabetes Care*. 2000; 23:390-404.
- 25) **Klonoff D.C.**: Diabetes Technology & Therapeutics Enters the 21st Century. *Diabetes Technology & Therapeutics*. 2000; 2:1-2.
- 26) **Klonoff D.C.**: New home blood monitoring technology improves blood glucose control in diabetes. *Diabetes Technology & Therapeutics*. 2000; 2:181-183.

- 27) **Klonoff D.C.:** The use of a portable fructosamine monitor to screen for diabetes. *Diabetes Technology & Therapeutics*. 2000; 2:537-539.
- 28) **Klonoff D.C.:** The importance of continuous glucose monitoring in diabetes. *Diabetes Technology & Therapeutics*. 2000; 2:S1-S4.
- 29) **Klonoff D.C.:** New home blood monitoring technology improves blood control in diabetes. *Diabetes Technology & Therapeutics*. 2000; 2:181-184.
- 30) **Klonoff D.C.:** The need for hypoglycemia detection and prevention in type 1 diabetes. *Diabetes Technology & Therapeutics*. 2001; 3: 567-570.
- 31) **Klonoff D.C.:** The pen is mightier than the needle. *Diabetes Technology & Therapeutics*. 2001; 3:631-3.
- 32) **Klonoff D.C.:** *Diabetes Technology & Therapeutics* evolves, along with our knowledge about alternative site testing. *Diabetes Technology & Therapeutics*. 2002; 4:1-2.
- 33) **Klonoff D.C.:** Current, Emerging, and Future Trends in Metabolic Monitoring. *Diabetes Technology & Therapeutics*. 2002; 4:583-588.
- 34) **Klonoff D.C.:** European trends in diabetes technology – continuous glucose measurements and computerized information-processing tools. *Diabetes Technology & Therapeutics*. 2002; 4:763-764.
- 35) **Klonoff D.C.:** Diabetes and telemedicine – is the technology sound, effective, cost-effective, and practical? (Invited editorial) *Diabetes Care*. 2003; 26:1626-1628.
- 36) **Klonoff D.C.:** New technology for living well with type 1 diabetes: bioengineering advances in glucose measurement, the artificial pancreas, and insulin delivery. *Pediatric Endocrine Rev*. 2003; 1:94-100.
- 37) **Klonoff D.C.:** The link between diabetes, military metabolic monitoring, and NASA. *Diabetes Technology & Therapeutics*. 2003; 5:351-353.
- 38) **Klonoff D.C.:** A flaw in the use of sulfonylurea screening to diagnose sulfonylurea overdoses. *Diabetes Technology & Therapeutics*. 2003; 5:453-454.
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Publications – Abstracts

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- 3) Demeure M.J., **Klonoff D.C.**, Karam J.H., Duh Q.Y., and Clark O.H.: Insulinoma associated with multiple endocrine neoplasia Type 1. Abstract presented at the 12th Annual Meeting of the American Association of Endocrine Surgeons in San Jose, California, April 14 to 16, 1991.
- 4) **Klonoff D.C.**: Physical criteria and the case definition of the chronic fatigue syndrome. Meeting on the Research Case Definition of Chronic Fatigue Syndrome at the Division of Viral and Rickettsial Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention in Atlanta, Georgia, September 27, 1993.
- 5) **Klonoff D.C.**: Criteria for selecting chronic fatigue syndrome patients to participate in therapeutic trials. Abstract presented at the Workshop on Development of Outcome Measures for Therapeutic Trials in Chronic Fatigue Syndrome at the National Institutes of Health in Bethesda, Maryland, April 11, 1995.
- 6) **Klonoff D.C.**: Overview of current approaches to non-invasive and minimally invasive blood glucose monitoring. Abstract presented at the Non/Minimally Invasive Measurement of Physiological Analytes Technology Workshop organized by the National Aeronautics and Space Administration (NASA) and Juvenile Diabetes Foundation (JDF) in Arlington, Virginia, April 7 to 8, 1998.

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- 8) **Klonoff D.C.:** Noninvasive glucose monitoring: The solution to a thorny problem in diabetes management. Abstract presented at the Optical Society of America Annual Meeting and Exhibit in Santa Clara, California, September 26 to October 1, 1999.
- 9) Sterling B.B., Braig J.R., Kramer C.E. Zheng P., and **Klonoff D.C.:** Noninvasive glucose determination by conversion of thermal gradient data. Optical Society of America Annual Meeting and Exhibit in Santa Clara, California, September 26 to October 1, 1999.
- 10) **Klonoff D.C.:** Clinical Overview of Type 1 Diabetes: Defining the need for frequent monitoring and controlled insulin delivery. Abstract presented at The Artificial Pancreas Symposium: (Glucose Monitoring, Insulin Delivery, Feedback Control) of the Association for the Advancement of Medical Instrumentation 2000 Conference & Expo in San Jose, California, June 3 to June 7, 2000.
- 11) **Klonoff D.C.:** Hazards of Hypoglycemia. Abstract presented at the Glucose Monitoring and Control Meeting in La Jolla, California. February 16 to 18, 2001.
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- 13) Efficacy and Safety of inhaled insulin (Exubera®) compared to conventional subcutaneous insulin therapy in patients with type 1 diabetes: results of a 6-month randomized comparative trial. T Quattrin for the Exubera® Phase III Study Group. The Inhaled Insulin Phase III Study Group Investigators: Ahmann, A., Albu, J., Aronoff, S., Belanger, B., Black, J., Bohannon, N., Burge, M., Carey, D., Charles, M.A Clarke, W., Stephen Clement, Michael Davidson, Heather Dean, Ivy Fettes, Pavel Fort, David Gardner, Jeffrey Geohas, Priscilla Hollander, Irene Hramiak, Carol Joyce, Charles Kilo, **David Klonoff**, Lawrence Leiter, Janet McGill, Adi Mehta, Joseph Milbum Jr, Paul Moore, Teresa Quattrin, Susan Ratzan, Marc Rendell, Sid Rosenblatt, Julio Rosenstock, Stuart Ross, Richard Rowe, Sherwyn Schwartz, Allen Sussman, Robert Tanenberg, Kathryn Thrailkill, W Kenneth Ward, Stuart Weinzimer, Stuart Weiss and Neil White. Poster Presented at the American Association of Clinical Endocrinologists, 11th Annual Meeting and Clinical Congress, in Chicago, Illinois, May 1-May 5, 2002.
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- 15) Nayberg I., Ruano T, Mai T, and **Klonoff D.C.:** Prevalence of incorrectly calibrated blood glucose monitors in a suburban California population. Third Annual Diabetes Technology Meeting in San Francisco, California, November 6 to November 8, 2003.
- 16) **Klonoff D.**, Kaplan R., Miller S., John G., Simmons J., Davies J., Cresswell M.: Evaluation of In2iT, a new Point of Care analyzer for the rapid determination of A1c. Fourth Annual Diabetes Technology Meeting in Philadelphia, Pennsylvania, October 28 to October 30, 2004.
- 17) Nayberg, I., Ruano, T, and **Klonoff D.C.:** Patient Preferences in Blood Glucose Monitor Features. Fourth Annual Diabetes Technology Meeting in Philadelphia, Pennsylvania, October 28 to October 30, 2004.

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- 23) Paul N and **Klonoff D.C.**: Insulin Pump System Security and Privacy. In Proceedings of HealthSec '10, the 1st USENIX Workshop on Health Security and Privacy in Washington, DC, August 10, 2010.
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- 25) Bergenstal R, **Klonoff D.**, Bailey T, Vaughn DE, Muchmore DB. Human Hyaluronidase + Rapid Analog Insulin (RAI) Improves Postprandial Glycemic Control in Type 2 Diabetes (T2DM) Compared to Insulin Lispro Alone. Poster and poster tour presented at American Diabetes Association 72nd Scientific Sessions in Philadelphia, PA. June 8 to June 12, 2012.
- 26) Garg S, Slover R, Buckingham B, Brazg R, Bailey T, **Klonoff, D.**, Welsh B, Kaufman F, Shin J, Bristol S, Huang S, Mao M, Lee S. The Order Effect of the In-Clinic ASPIRE Study: Hypoglycemia Begets Hypoglycemia. American Diabetes Association 72nd Scientific Sessions in Philadelphia, PA. June 8 to June 12, 2012.
- 27) **Klonoff D.C.**, Nayberg I, David J, Landau Z, Feldman D, Shusterman A, Wainstein J, Lender D, Mosenzon O, Raz I. Accelerating Rapid Acting Insulin Analogs Pharmacokinetic Profile by Using CSII with the InsuPatch device. Poster and poster tour presented at the American Diabetes Association 72nd Scientific Sessions in Philadelphia, PA. June 8 to June 12, 2012. (Selected for Audio Tour by ADA and named as being among the top 4% of abstracts at the meeting by *Diabetes Conference Companion*)
- 28) Pfuetzner A, Bailey T, Campos C, Kahn D, Ambers E, Niemeyer M, Guerrero G, **Klonoff D.** Accuracy and Preference Assessment of FlexTouch vs. Vial & Syringe with Diabetes Patients and Health Care Professionals. American Diabetes Association 72nd Scientific Sessions in Philadelphia, PA. June 8 to June 12, 2012.

- 29) **Klonoff D.**, Bergenstal R, Bailey T, Vaughn DE, Muchmore DB. Human Hyaluronidase + Rapid Analog Insulin (RAI) Improves Postprandial Glycemic Control in Type 2 Diabetes (T2DM) Compared to Insulin Lispro Alone. Poster presented at European Association for the Study of Diabetes 48th Annual Meeting in Berlin, Germany. October 1 to October 5, 2012.
- 30) Choudhary T, **Klonoff, D.C.**: Control solution for blood glucose monitors. Twelfth Annual Diabetes Technology Meeting in Bethesda, Maryland, November 8 to November 10, 2012.
- 31) Ramljak S, **Klonoff D.C.**, Musholt PB, Ambers E, Forst T, Demircik F, Pfützner A. Handling is of Critical Importance for Successful Performance of Laboratory Investigations with Blood Glucose Meters Employing Dynamic Electrochemistry. American Diabetes Association 73rd Scientific Sessions in Chicago, IL. June 21 to June 25, 2013.
- 32) Bergenstal RM, **Klonoff D.C.**, Bode BW, Garg SK, Ahmann AJ, Slover RH, Meredith M, Kaufman FR. Reduction in Hypoglycemia and No Increase in A1C with Threshold-Based Sensor-Augmented Pump (SAP) Insulin Suspension: ASPIRE In-Home. American Diabetes Association 73rd Scientific Sessions in Chicago, IL. June 21 to June 25, 2013.
- 33) **Klonoff D.**, Nayberg I, Landgraf W, Dain M-P, Danne T. The JuniorSTAR Half-unit Pen is Easy to Use, Easy to Carry, Easy to Dial Back, and Suited to the Lifestyle of Young Patients with Type 1 Diabetes. 39th Annual Conference of the International Society for Pediatric and Adolescent Diabetes (ISPAD): Pediatric Diabetes in a Life – long Perspective in Gothenburg, Sweden. October 16 to 19, 2013.
- 34) **Klonoff D.C.**, Bailey TS, Brazg RL, Weinstock R, Bhargava A, Lee SW, Mao M, Shin J, and ASPIRE In-Home-Study Group. ASPIRE In-Home: a closer look at hypoglycemia. Diabetes Technology Meeting in San Francisco, California. October 31 to November 2, 2013.
- 35) **Klonoff D.**, Nayberg I, Domenger C, Dain M-P, Danne T. Functional testing of JuniorSTAR® half-unit pen for young people with Type 1 Diabetes (T1D). Diabetes Technology Meeting in San Francisco, California. October 31 to November 2, 2013.
- 36) Garg S, Bode BW, Bergenstal R, **Klonoff D.C.**, Mao M, Weiss R, Welsh JB, Aspire In-Home Study Group. Characteristics and Predictors of Nocturnal Hypoglycemia in the Run-In Phase of the ASPIRE In-Home Study. American Diabetes Association 74th Scientific Sessions in San Francisco, CA. June 13 to June 17, 2014.
- 37) **Klonoff D.C.**, Ahmann A, Garg S, Slover R, Bailey T, Bode B, Thrasher J, Brazg R, Schwartz F. Effects of automatic insulin pump interruption and bedtime glucose levels on nocturnal hypoglycaemic events in the ASPIRE In-Home Study. European Association for the Study of Diabetes 50th Annual Meeting in Vienna, Austria. September 15-19, 2014.
- 38) Weiss R, Bailey T, Schwartz F, Brazg R, Bergenstal R, Thrasher J, Weinstock R, Ahmann A, **Klonoff D.**, Slover R, Garg S, Welsh J, Mao M, ASPIRE In-Home Study Group. Effects of automatic insulin pump interruption on duration and weekly rate of nocturnal hypoglycaemic events in the APIRE In-Home Study. European Association for the Study of Diabetes 50th Annual Meeting in Vienna, Austria. September 15-19, 2014.
- 39) **Klonoff D.C.**, Nayberg I, Erbstein F, Cali AMG, Brulle-Wohlhueter C, Haak T. Results from an interview-based survey of the new Gla-300 SoloSTAR compared with three commercial disposable insulin pens. Diabetes Technology Meeting in Bethesda, Maryland. November 6-8, 2014.

- 40) Predictors of Nocturnal Hypoglycemia in Patients with Type 1 Diabetes: Effects of Automatic Threshold Suspend Feature Activation. Bailey TS, Thrasher J, Schwartz F, **Klonoff D.C.**, Weiss R, Mao M, ASPIRE In-Home Study Group. Diabetes Technology Meeting in Bethesda, Maryland. November 6-8, 2014.
- 41) **Klonoff D.**, Nayberg I, Rabbone I, Domenger C, Blancke S, Oualali H, Friedrichs A, Adler S, Danne T. Functional characterisation of four different half-unit reusable insulin pens. Advanced Technologies & Treatments for Diabetes 8th Annual Meeting in Paris, France, February 19-21, 2015.
- 42) **Klonoff D.**, Nayberg I, Erbstein F, Domenger C, Cali A, Brulle-Wohlhueter C, Haak T. Results from an interview-based survey of Gla-300m and SoloSTAR compared with three commercialized disposable insulin pens. Advanced Technologies & Treatments for Diabetes 8th Annual Meeting in Paris, France, February 19-21, 2015.
- 43) Pohlmeier H, **Klonoff D.C.**, Berard L, Brulle-Wohlhueter C, Wu J, Dahmen R, Nowotny I. Ease of use of the new insulin glargine 300 U/mL SoloSTAR® pen injector in insulin-naive people with type 2 diabetes. American Diabetes Association Meeting in Boston, Massachusetts, June 5-9, 2015.
- 44) Andelin M, Kropff J, Matuleviciene V, Joseph JJ, Attvall S, Theodorsson E, Hirsch IB, Imberg H, Dahlqvist S, **Klonoff D.**, Haraldsson B, DeVries H, Lind M. Assessing the accuracy of continuous glucose monitoring (CGM) calibrated with capillary values using capillary or venous glucose levels as a reference. European Association for the Study of Diabetes 50th Annual Meeting in Stockholm, Sweden. September 14-18, 2015.
- 45) Zuk M, Kleidermacher D, **Klonoff D.** Using common criteria evaluations to improve healthcare cybersecurity. International Common Criteria Conference 2015 in London, England, September 22-24, 2015.
- 46) Hashemi N, Valk T, **Klonoff D**, Houliand K, and Eskjaer NE. In-hospital Stabilisation of blood-sugar control using an Insulin Balanced Infusion System (Admetsys): Clinical results from FDA-approved clinical Studies in 43 Diabetes Patients. American Diabetes Association Meeting in New Orleans, Louisiana June 10-14, 2016.
- 47) **Klonoff D.** Novel Glucose-Sensing Technology and Hypoglycaemia in Type 1 Diabetes: A Multicentre, Non-Masked, Randomised Controlled Trial. PracticeUpdate website. Available at:<http://www.practiceupdate.com/content/novel-glucose-sensing-technology-and-hypoglycemia-in-type-1-diabetes/44424/65/8/1>. September 29, 2016.
- 48) **Klonoff D.** Accuracy of point-of-care glucose meters. PracticeUpdate website. Available at: <http://www.practiceupdate.com/content/accuracy-of-point-of-care-glucose-meters/45889/6/8/1#commentarea>. November 3, 2016.
- 49) Liang Y, Wanderer J, Nichols JH, **Klonoff D.C.**, Rice MJ. Blood gas analyzer glucose measurement accuracy. Diabetes Technology Meeting in Bethesda, Maryland. November 10-12, 2016.
- 50) Optimizing Basal-Bolus Therapy in T2D: A Randomized Controlled Trial Comparing Bolus Insulin Delivery Using an Insulin Patch vs an Insulin Pen. Bergenstal RM, Peyrot M, Dreon DM, Aroda V, Bailey TS, Brazg RL, Frias JP, Johnson ML, **Klonoff D.C.**, Kruger DF, Ramtoola S, Rosenstock J, Serusclat P, Weinstock RS, Naik RG, Shearer DM, Zraick V, Levy BL. American Diabetes Association Meeting in Orlando, Florida, June 22-26, 2018.
- 51) Billings LK, Altuntas Y, **Klonoff D.C.** Tentolouris N, Grøn R, Halladin N, Jódar E. Efficacy of IDegLira vs Basal-Bolus Therapy in Subjects with Type 2 Diabetes in DUAL

- VII by Baseline Characteristics. American Diabetes Association Meeting in Orlando, Florida, June 22-26, 2018.
- 52) Insulin Delivery Using an Insulin Patch vs an Insulin Pen. Bergenstal RM, Peyrot M, Dreon DM, Aroda V, Bailey TS, Brazg RL, Frias JP, Johnson ML, **Klonoff D.C.**, Kruger DF, Ramtoola S, Rosenstock J, Serusclat P, Weinstock RS, Naik RG, Shearer DM, Zraick V, Levy BL. European Association for the Study of Diabetes Meeting in Berlin, Germany, October 2-5, 2018.
 - 53) User- and Health Care Provider-Reported Outcomes for a Wearable Bolus Insulin Delivery Patch. Peyrot M, Bergenstal RM, Dreon DM, Aroda V, Bailey TS, Brazg RL, Frias JP, Johnson ML, **Klonoff D.C.**, Kruger DF, Ramtoola S, Rosenstock J, Serusclat P, Weinstock RS, Naik RG, Shearer DM, Zraick V, Levy BL. European Association for the Study of Diabetes Meeting in Berlin, Germany, October 2-5, 2018.
 - 54) Efficacy of IDegLira vs. basal-bolus therapy in subjects with type 2 diabetes in DUAL VII by baseline characteristics. Billings L, Altuntas Y, **Klonoff D.**, Tentolouris N, Bennett L, Grøn R, Halladin N, Jodar E. Academy of Managed Care Pharmacy Nexus 2018 in Orlando, Florida, October 22-25, 2018.
 - 55) Bergenstal RM, Hachmann-Nielsen E, Kaas A, Kvist K, **Klonoff D.C.** Glucose profile indicator – a simple combined measure of mean glucose, glycemic variability, and hypoglycemia for better evaluation of glycemia. Diabetes Technology Meeting in Bethesda, Maryland, November 8-10, 2018.
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 - 57) Philis-Tsimikas, **Klonoff D.**, Khunti K, Bajaj H, Leiter L, Tutkunkardas D, Troelsen LN, Bak BA, Heller S, Pieber T. Reduced risk of hypoglycaemia with degludec compared to glargine U300 in insulin-experienced patients with type 2 diabetes. European Association for the Study of Diabetes Meeting in Barcelona, Spain, September 16-20, 2019.
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 - 60) Goldenberg R, Aroda VR, Billings L, Donatsky AM, Frederiksen M, **Klonoff D.C.**, Rizi EP, Bergenstal B. Association Between Time in Range and A1C in Basal Insulin-Treated People with Type 2 Diabetes. American Diabetes Association’s Virtual 81st Scientific Session. June 25-29, 2021.
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CONTRACT AS PRINCIPLE SCIENTIFIC OFFICER

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RESEARCH GRANTS AS PRINCIPAL INVESTIGATOR

- 1) SmithKline Beecham Pharmaceuticals, *Protocols BRL 49653/024* and *BRL 49653/105*: Insulin sensitizing agent. 1996 – 1997.

- 2) Corning PACT: Comparative outcomes study, metformin versus conventional approach. 1996.
- 3) Bayer Corporation: Precose resolution of optimal titration to enhance current therapies. 1996.
- 4) Novartis: Valsartan, *Protocol CGP 48933*: (Value 405) plus extension study. 1996 - 1998.
- 5) OptiScan Biomedical Corporation, *Study ID #OBC 11-97-04*: Noninvasive glucose monitor – clinical prototype performance validation. 1997 – 1998.
- 6) Mercury Diagnostics, Incorporated, (Amira Medical), *Protocol #420 WIRB*: A clinical study of Mercury Diagnostics' blood glucose sampling device (“Mercury Sampler”). 1997 – 1998.
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- 9) Pfizer, *Protocol 106*; *Protocol 110*; *Protocol 111*: Inhaled insulin. (Extensions). 1998 – 2003
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- 11) Bio-Rad: Micromat II HbA1c test. 2000.
- 12) Provalis Diagnostics UK Ltd., *Protocol Gly B01 069-PDL*: Consumer field study – Evaluation of the “Home Use” performance of the Glycosal HbA1c test using diabetic patient participants. 2001.
- 13) Antares Pharma, *Protocol 1501*: Comparison of the Antares Medi-Jector Vision Insulin Jet Delivery System with needle-syringe injections on blood glucose control in patients with type 1 diabetes. 2001 –2002.
- 14) Restoragen, *Protocol BN02-C007*: A study comparing safety and efficacy of three doses of recombinant Glucagon-like peptide 1 (rGLP-1) to placebo given by continuous subcutaneous infusion in combination with metformin and sulfonylurea over 12 weeks in patients with type 2 diabetes mellitus. 2001- 2002.
- 15) Aerogen, Inc., *Protocol 6.0*: Inhaled insulin usability study. 2002.
- 16) Metrika, Inc., *Protocol 4*: Direct OTC Clinical Evaluation of A1c Now. 2002.
- 17) Amylin Pharmaceuticals, *Protocol 2993-112*: A phase 3 randomized, triple-blind parallel-group, long-term, placebo-controlled, multicenter study to examine the effect on glucose control (HbA1c) of AC2993 given two times a day in subjects with type 2 diabetes mellitus treated with metformin alone. 2002 – 2003.
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- 20) Amylin Pharmaceuticals, *Protocol 2993-116*: A Phase 2, randomized, triple-blind, placebo-controlled short-term, dose-response study to examine the effect on glucose control and safety and tolerability of AC2993 given two times a day in subjects with type 2 diabetes mellitus. 2002 - 2003.
- 21) Amylin Pharmaceuticals, *Protocol 2993-112E*: An open-label extension study of protocol 2993-112 to examine the longterm effect on glucose control (HbA1c) and safety and tolerability of AC2993 given two times a day to subjects treated with metformin alone. 2003 –2004.

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- 23) Amylin Pharmaceuticals, *Protocol 137-150E*: A multicenter, open-label, extension study of the long-term safety of pramlintide in subjects with type 1 diabetes mellitus completing protocol 137-150. 2003 – 2005.
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- 26) Eli Lilly & Company, *Protocol H80-MC-GWAA*: Effect of AC2993 (Synthetic Exendin-4) Compared with Insulin Glargine in Patients with Type 2 Diabetes Also Using Combination Therapy with Sulfonyleurea and Metformin. 2003 - 2004.
- 27) GenereX Biotechnology Corporation, *Protocol Gen-059-2003-Oralin-CGMS*: Comparison of Efficacy and Reproducibility of Oralin at Meal-times in Adult Subjects with Type-2 Diabetes maintained on Oral Agents for 3 days using the CGMS (Medtronic MiniMed Continuous Glucose Monitor. 2003 - 2005.
- 28) MannKind Corporation, *Protocol PDC-INS-0008*: Efficacy and Safety of Inhaled Technosphere®/Insulin compared to Technosphere®/Placebo in Patients with Type 2 Diabetes Mellitus following Diabetes Education. 2003 – 2005.
- 29) Eli Lilly & Company, *Protocol H80-MC-GWAN*: An Open-Label Study Examining the Long-Term Safety of Exenatide Given Twice Daily to Patients with Type 2 Diabetes Mellitus. 2004 – 2005.
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- 32) Provalis Diagnostics Limited, *Protocol H01006PD02P*: Consumer Field Study – Evaluation of the “Home-Use” Performance of the G5 HbA1c Home Test Using Diabetic Patient Participants. 2004.
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- 35) MannKind Corporation, *Protocol MKC-TI-010*: A three-year, safety and tolerability, open-label, follow on trial evaluating Technosphere®/Insulin in patients with type 2 diabetes mellitus. 2004 – 2008.

- 36) Novo Nordisk, *Protocol ANA-2190*: An open-label, multi center, clinical trial: External Continuous Subcutaneous infusion of insulin using Insulin Aspart (NovoLog®) in subjects with Type 1 and insulin requiring Type 2 diabetes. 2004 - 2005.
- 37) Sanofi-Aventis, *Protocol HMR1964A/3508*: Lantus® (insulin glargine) plus APIDRA™ (insulin glulisine) MDI versus Premix insulin treatment in subjects with diabetes mellitus (type 1 or type 2) evaluating differences in patient reported outcomes. A randomized, multicenter, cross over study. 2004 - 2007.
- 38) Eli Lilly & Company, *Protocol H7U-MC-IDAP*: Standard training versus intensive training for HIIP delivery system usage in insulin-naïve patients with Type 2 Diabetes Mellitus. 2004 – 2005.
- 39) Sankyo Pharma Development, *Protocol CS-011-203*: A randomized double-blind, double-dummy, placebo-controlled, 26 week dose-response study of Rivoglitazone HCl (CS-011) with active comparator (Pioglitazone HCl) in subjects with Type 2 Diabetes. 2004 – 2006.
- 40) Abbott Laboratories, *Protocol Noninvasive Glucose Monitor*: Abbott Laboratories Glucose Clamp Study. 2005.
- 41) Sanofi-Aventis, *Protocol HMR1964A/3503*: Apidra™ (insulin glulisine) administered premeal vs. postmeal in adult subjects with Type 2 Diabetes Mellitus receiving Lantus® (insulin glargine) as basal insulin: A multicenter, randomized, parallel, open-label clinical study. 2005 – 2007.
- 42) MannKind Corporation, *Protocol MKC-TI-030*: Pulmonary Outcomes within a 2-year period in subjects with diabetes mellitus treated with Technosphere®/Insulin or usual antidiabetic treatment and in subjects without abnormalities in glucose control. 2005 – 2007.
- 43) Keryx Biopharmaceuticals, *Protocol KRX-101-301*: The collaborative study group trial: The effect of Sulodexide in patients with type 2 diabetes and microalbuminuria. 2005 – 2007.
- 44) Novo Nordisk, *Protocol NN1998-2076*: Inhaled mealtime insulin with the AERx iDMS versus subcutaneously injected insulin aspart both in combination with insulin detemir in type 1 diabetes: a 104 week open label, multicenter, randomised, parallel trial (followed by a twelve-week re-randomised extension) to investigate safety and efficacy. 2006 – 2008.
- 45) Pfizer Inc., *Protocol A2171093*: A phase 3B, randomized, open-label, parallel group, multicenter trial assessing the efficacy of Exubera vs. lispro introduced into a Lantus based regimen in suboptimally controlled patients with type 2 diabetes mellitus. 2006 – 2008.
- 46) Takeda Pharmaceuticals, *Protocol 01-06-TL-322OPI-002*: A multicenter, double-blind study to determine the efficacy and safety of SYR-322 plus pioglitazone HCl (Actos), SYR-322 alone or pioglitazone HCl in subjects with type 2 diabetes. 2006 – 2008.
- 47) Novo Nordisk, *Protocol NN4440-1794*: Repaglinide and Metformin Combination Tablet (NN4440) in a TID Regimen Compared to a BID Regimen and BID Advamet in Subjects with Type 2 Diabetes: a Twenty-Six Week Open-Label, Multicenter, Randomized, Parallel Group Trial to Investigate Efficacy and Safety. 2006 - 2008.
- 48) Bidel, Inc., *Protocol VIAJECT-06J*: An Open Label, Multi-Center, Randomized, Parallel Group Study Comparing the Efficacy and Safety of Insulin VIAJECT and Regular Human Insulin in Patients with Type 1 Diabetes Mellitus. 2006 - 2010.
- 49) Bidel, Inc., *Protocol VIAJECT-08J*: An Open Label, Multi-Center, Randomized, Parallel Group Study Comparing the Efficacy and Safety of Insulin VIAJECT and Regular Human Insulin in Patients with Type 2 Diabetes Mellitus. 2007 - 2010.

- 50) Bidel, Inc., *Protocol VIAJECT-07J*: An Open Label, Multi-Center, Follow-on Study Examining the Long-Term Safety and Efficacy of Insulin VIAJECT™ in Subjects with Type 1 Diabetes Mellitus. 2007 - 2010.
- 51) C8 MediSensors, Inc., *Protocol C8MPHS-001*: Calibration Glucose Clamp Study for a Noninvasive Glucose Measuring Device. 2007 - 2009.
- 52) C8 MediSensors, Inc., *Protocol C8MPHS-002*: Validation Study for a Noninvasive Glucose Measuring Device. 2007 - 2010.
- 53) Novo Nordisk, Inc., *Protocol NN2211-1797*: Liraglutide Effect and Action in Diabetes – LEAD 6. Effect on glycaemic control of liraglutide or exenatide added to metformin, sulphonylurea or a combination of both in subjects with type 2 diabetes. A 26-week randomised, open-label, active comparator, 2-armed, parallel-group, multi-centre, multi-national trial with a 14 week non-randomised extension period. 2007 - 2009.
- 54) Medtronic MiniMed, *Protocol P26/GS042/A1*: An Evaluation of Six-Day subcutaneous Glucose Sensor Performance in Subjects with type 1 Diabetes Mellitus. 2007 – 2009.
- 55) GlaxoSmithKlein, *Protocol KG2110375*: A Once-Daily Dose-Ranging Study of GSK189075 Versus Placebo In The Treatment of Type 2 Diabetes Mellitus in Treatment-Naïve Subjects. 2007 - 2008.
- 56) DiObex, *Protocol Dio-502*: A Phase 2b, Randomized, Double-Blind, Parallel-Group, Study of Safety and Efficacy of 16 Weeks of Treatment with DIO-902 or DIO-902 Placebo in Addition to Metformin and Atorvastatin or Atorvastatin Placebo in Subjects with Type 2 Diabetes Mellitus. 2007 - 2008.
- 57) Merck, *Protocol 051*: A Phase 111, Multicenter, Randomized, Double-Blind Clinical Trial to Study the Safety and Efficacy of the Addition of Sitagliptin (MK-0431) to Patients with Type 2 Diabetes Mellitus Who have Inadequate Glycemic Control on Insulin Therapy (Alone or in Combination with Metformin). 2007 – 2008.
- 58) Bidel, *Protocol VIAJECT-09J*: An Open Label, Multi-Center, Follow-on Study Examining the Long-Term Safety and Efficacy of Insulin VIAject in subjects with Type 2 diabetes Mellitus. 2007 - 2010.
- 59) MannKind, *Protocol MKC-TI-126*: A 2-Month Safety Follow-up Trial of Subjects from MannKind Protocols MKC-TI-009, MKC-TI-102, MKC-TI-103 and MKC-TI-030. 2007 - 2010.
- 60) SymCare Personalized Health Solutions, inc. *Protocol 020202*. A Study to evaluate Human Factors and the Usability of a Diabetes Remote Management System. 2008.
- 61) MannKind, *Protocol MKC-TI-117*: A Phase 3, Multi-Center, Open-Label, Randomized, Clinical Trial Evaluating the Efficacy and Safety of Technosphere® Insulin Inhalation Powder in Combination with Lantus® Versus Humalog® in Combination with Lantus® in Subjects with Type 1 Diabetes Mellitus Over a 16-Week Treatment Period. 2008 – 2009.
- 62) sanofi-aventis, *Protocol EFC6019(GETGOAL-X)*: A randomized, open-label, active-controlled, 2-arm parallel-group, multicenter 24-week study followed by an extension assessing the efficacy and safety of AVE0010 versus exenatide on top of metformin in patients with type 2 diabetes not adequately controlled with metformin. 2008 – 2011.
- 63) sanofi-aventis, *Protocol AVE 0010 EFC6017*: A randomized, double-blind, placebo-controlled 2-arm parallel-group, 24-week main treatment period and an extension assessing the efficacy and

safety of AVE0010 on top of pioglitazone in patients with type 2 diabetes not adequately controlled with pioglitazone. 2008 – 2011.

- 64) Diasome, *Protocol DP 01-2007-03*: An 18-week randomized, double-blind, multicenter, comparator study of two doses of oral HDV-insulin and placebo with background metformin treatment in patients with type 2 diabetes mellitus. 2009– 2010.
- 65) CPEX Pharmaceuticals, Inc., *Protocol Nasulin-US-0100-CPEX011*. The effects of Nasulin vs. placebo on blood glucose control in patient volunteers with moderately controlled type 2 diabetes mellitus currently treated with basal insulin and oral antidiabetic medications, excluding secretagogues in a phase IIa, randomized parallel, double-blind, placebo-controlled, multicenter study. 2009– 2010.
- 66) IntelliDx, Inc. *IDx-2009-002*. Assessment of the Operational Performance of the OPTIMUS[®] Automated Ex Vivo Blood Analysis System - Glucose for the Measurement of Glucose in Whole Blood in Diabetic Volunteer Subjects. 2009.
- 67) C8 MediSensors, Inc. *Protocol C8MPHS-004*. Calibration testing of the HG-1 prototype noninvasive glucose monitor. 2009– 2011.
- 68) Novo Nordisk, Inc., *Protocol NN1250-3579*: A 52-week randomised, controlled, open label, multicentre, multinational treat-to-target trial comparing the efficacy and safety of SIBA and insulin glargine, both injected once daily in combination with oral anti-diabetic drugs (OAD), in subjects with type 2 diabetes mellitus currently treated with OAD(s) and qualifying for more intensified treatment. 2009 – 2011.
- 69) Novo Nordisk, Inc., *Protocol NN1250-3718*: BEGIN EASY PM. A trial comparing the efficacy and safety of NN1250 and insulin glargine in subjects with type 2 diabetes. A 26-week randomized, confirmatory, controlled, open-label, multicentre, multinational treat-to-target trial comparing the efficacy and safety of SIBA 200 U/ml three times weekly injected in the evening and insulin glargine once daily in a population of insulin naïve subjects with type 2 diabetes mellitus currently treated with OADs qualifying for intensified treatment. 2010 – 2011.
- 70) Eli Lilly & Company. *Protocol H9X-MC-GBDC*. The Impact of LY2189265 versus Metformin on Glycemic Control in Early Type 2 Diabetes Mellitus (AWARD-3: Assessment of Weekly Administration of LY2189265 in Diabetes). 2010 – 2011.
- 71) Kowa Co., Ltd. *Protocol SK-0403-2.01US*. Multicenter, Randomized, Parallel-Group, Double-Blind, Placebo and Active Controlled Phase 2 Dose Finding Study Comparing the Safety, Tolerance, and Efficacy of Various Doses of SK-0403 Versus Placebo and Sitagliptin 100 mg in Patients Not Well-Controlled on Metformin Therapy. 2010 – 2011.
- 72) Halozyme. *Protocol HALO-117-205*. A Phase II, Randomized, Double Blind, 2-Way Crossover Safety and Efficacy Study of Subcutaneously Injected Prandial Insulins: Lispro-PH20 or Aspart-PH20 Compared to Insulin Lispro (Humalog[®]) in Patients with Type 1 Diabetes. 2010 – 2011.
- 73) Halozyme. *Protocol HALO-117-206*. A Phase II, Randomized, Double Blind, 2-Way Crossover Safety and Efficacy Study of Subcutaneously Injected Prandial Insulins: Lispro-PH20 or Aspart-PH20 Compared to Insulin Lispro (Humalog[®]) in Patients with Type 2 Diabetes. 2010 – 2011.
- 74) InsuLine Medical. *Protocol G080106/A*. Protocol for Evaluation of the Effect of the InsuPatch Device on Insulin Pharmacokinetics in Clamp Studies. 2010 – 2011.
- 75) Amylin Pharmaceuticals, Inc. and Eli Lilly and Company. *Protocol BCB109*. EXenatide Study of Cardiovascular Event Lowering Trial (EXSCEL). A Randomized Placebo Controlled Trial to

Evaluate Cardiovascular Outcomes After Treatment with Exenatide Once Weekly in Patients with Type 2 Diabetes Mellitus. 2010 – 2012.

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Mellitus Patients Not Achieving Glycemic Targets on Basal Insulin With/Without Anti-Hyperglycemic Agents. 2015 – 2017.

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