

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 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 one of the 1000 top bioengineers in the world, as well 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 at 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 270 publications. Dr. Klonoff has been a Principal Investigator on 110 clinical trials of diabetes drugs and devices, and has been lead investigator on multicenter trials for Novo, Sanofi, Medtronic, Biorad, and Diasome. He was the lead investigator for the first randomized controlled multicenter trial of an outpatient artificial pancreas product, and published the results 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, the Digital Diabetes Congress, and the Medical Device Security and Privacy Meeting. Dr. Klonoff has chaired or served on grant review panels for NIH, CDC, NASA, NSF, US Army, NOAA, ADA, JDRF, Yale University, University of Michigan, and Diabetes UK. He is a member of the Scientific Advisory Board of the Texas A&M/UCLA/FIU/Rice PATHS-UP Engineering Research Center and an affiliate member of the Baylor University Center for Space Medicine. 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 was a member of the NIH Diabetes Interagency Coordinating Committee, whose ten-year research plan was released in 2011. 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: <https://www.wired.com/2015/11/the-doctor-on-a-quest-to-save-our-medical-devices-from-hackers/>

PRESENT ACADEMIC AND PROFESSIONAL POSITION2006-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

EDUCATION1972-1976 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

- 2017 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

- 2018– Present Scientific Advisory Board: 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 P2721, which will be co-managed by IEEE and UL, Chair
- 2017– Present 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– Present CMS Alliance to Modernize Healthcare (CAMH) sponsored by Centers for Medicare & Medicaid Services (CMS) and operated by The MITRE Corporation, Advisor.
- 2015– Present 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

- 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 International Center of Biocybernetics of the Polish Academy of Sciences, 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) Type 1 Diabetes Pathfinder Award (DP2), Member, 2016
- 2) Special Emphasis Panel on Artificial Pancreas, Small Business Innovation Research, Member, 2013
- 3) Special Emphasis Panel on Closed Loop Technologies, Member, 2013
- 4) 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
- 5) Study Section on Diabetes, Metabolism, Nutrition and Obesity; Small Business Special Emphasis Panel (EMNR E10 B), Member, 2010
- 6) Grant Review Panel: The Cooperative Multicenter Research Network to Test Glucose Sensors in Children with Type 1 Diabetes, Member, 2001
- 7) Study Section on Biotechnology, Member, 1998

National Aeronautics & Space Administration (NASA)

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

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

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

Juvenile Diabetes Research Foundation (JDRF)

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

US Army

- 25) Product Line Review, Diabetes and Chronic Disease: Filling the Gaps, 2010
- 26) Product Line Review, Biomonitoring Technologies, 2009
- 27) Product Line Review, Biomonitoring Technologies, 2008
- 28) TATRC Proposal Review Board: Grant Reviewer, 2008

- 29) Product Line Review, Chronic Diseases, 2007
- 30) SBIR Phase 1 of OSD04-DH02, Grant Review Panel, Member:
Non-invasive Metabolic Monitoring, 2004
- 31) Technologies for Metabolic Monitoring, Grant Review Panel, 2002-2006
- 32) SBIR Phase 1 of OSD02-DH02, Grant Review Panel, Member:
Non-invasive Transdermal Near Infrared Glucose Monitors, 2002

American Institute of Biological Sciences

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

National Science Foundation (NSF)

- 34) 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

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

American Diabetes Association

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

Yale University Diabetes Research Center

- 38) Diabetes Grant Program, Reviewer, 2016

University of Michigan, Michigan Diabetes Research and Training Center,

- 39) Pilot Feasibility Grant Program, Grant Reviewer, 2013
- 40) Pilot Feasibility Grant Program, Grant Reviewer, 2011
- 41) Pancreatic Islet Encapsulation Pilot Program, Grant Reviewer, 2002

Boston Area Diabetes Endocrinology Research Center

- 42) Pilot and Feasibility Grant program, Grant Reviewer, 2012

Kansas City Area Life Sciences Institute

- 43) Blue Cross and Blue Shield Outcomes Research, Grant Reviewer, 2018

Singapore Science & Engineering Research Council of the Agency for Science,

- 44) Research & Technology, Grant Reviewer, 2004

Hong Kong Special Administrative Region Government

- 45) Innovation and Technology Commission, Grant Reviewer, 2005

Belgium Industrial Research Fund, K.U. Leuven

- 46) Technology Transfer Program, Grant Reviewer, 2010

Canadian Mitacs Accelerate Research Program

- 47) Graduate Research Internship Program, Grant Reviewer, 2014

Norwegian Academy of Science and Letters

- 48) Centre of Advanced Study, Grant Reviewer, 2015

Diabetes UK

- 49) Intermediate Clinical Fellowship Grant Reviewer, 2016
- 50) Grant Reviewer, 2017

JOURNALS

2016 – Present Journal of Precision Medicine – Editorial Board
 2007 – Present Diabetes, Metabolism and Heart (German) – Editorial Board
 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 osteopath school (NYU).
 2000 – Present *Four college students who have been mentored at Diabetes Technology Society have gone on to Medical School (UCLA and UMass), Osteopathy School (Alabama College of Osteopathy), and Dental School (University of the Pacific).
 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 and one has received a CDTC certification.
 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

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 2016, Co-Organizer

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)

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

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)

Diabetes Technology Society/FDA: Insulin Pump Safety Meeting, San Mateo, California 2009 (Chair)
 Insulin Pump Safety Meeting, Bethesda, Maryland. 2008. (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 / CDC / NSBRI / UC Berkeley Department of Bioengineering / Georgia
 Tech/Emory Center for the Engineering of Living Tissues / Technologies for Metabolic Monitoring
 Joint Program (Chair)

Eighteenth Diabetes Technology Meeting, Bethesda, 2018 (pending)

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, 2015

Workshop 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, 2014

Workshop 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, 2013

Workshop 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, 2012

Workshop 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, 2011

Workshop 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, 2010

Workshop 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, 2009
 Workshop 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, 2008
 Workshop 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, 2007
 Workshop 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, 2006
 Workshop 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 Mgmt 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

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

Second Digital Diabetes Congress, San Francisco, California, 2018 (pending)
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**
- 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

- 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

- 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 (pending)
- 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**
- 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)

- 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

- 2018 78th Scientific Sessions, Orlando, Florida (pending)
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

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 (pending)
- 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

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

American Association for Clinical Chemistry

- 2014 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)** (pending)
Fall Congress: Cybersecurity for Diabetes Devices, Arlington, Virginia (keynote)

Great Plains Pediatric Endocrine Symposium

- 2017 Continuous Glucose Monitoring, Kansas City, Missouri (pending)

Precision Medicine Meeting

- 2016 Panel on New Technologies, San Diego, California

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
- IEEE Conference on Body Sensor Networks Meeting**
- 2016 *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)
- 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 (pending)
- University of California at Berkeley,**
- 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

Georgia Institute of Technology, Atlanta, Georgia

- 2011 Bioengineering Seminar: *The Artificial Pancreas*
 2002 Bioengineering Seminar: *New Technology for Glucose Monitoring and Sensing*

- 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.

BIBLIOGRAPHYPublications – 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; 2:537-9.
- 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.

- 39) **Klonoff D.C.**: Microdialysis of interstitial fluid for continuous glucose measurement. *Diabetes Technology & Therapeutics*. 2003; 5:539-543.
- 40) **Klonoff D.C.**: The importance of portable blood lactate monitoring. *Diabetes Technology & Therapeutics* 2003; 5:929-31.
- 41) Wojcicki, JM, **Klonoff DC**: Introduction to Seminar on Technical, Biological, and Bio-technical Approaches of the Diabetes Treatment. *Diabetes Technology & Therapeutics*. 2003; 5:863-865.
- 42) **Klonoff D.C.**: The need for separate performance standards for glucose monitors during hypoglycemia, normoglycemia, and hyperglycemia. (Invited editorial) *Diabetes Care*. 2004; 27:834-6.
- 43) Simmons M, Gillett D, Catanzaro B, Jacobs B, **Klonoff D.C.**, Sage B: A Closed Loop Drug Infusion System. *Diabetes Technology & Therapeutics*. 2004; 6:607-620.
- 44) **Klonoff D.C.**: Continuous Glucose Monitoring: Roadmap to 21st Century Diabetes Therapy. *Diabetes Care*. 2005; 28:1231-1239.
- 45) **Klonoff D.C.**: New technology for glucose monitoring. *On the Cutting Edge*. American Dietetic Association. 2005
- 46) **Klonoff D.C.**: Pharmacologic Treatment of Type 2 Diabetes Mellitus: Introduction. *Am J Med*. 2005; 118 (Suppl 1): 1-3.
- 47) **Klonoff D.C.**: Pyruvate therapy for severe hypoglycemia. *Diabetes Technology & Therapeutics*. 2005; 7: 583-586.
- 48) Crowe D, **Klonoff D.C.**: Time synching or time sinking? *Diabetes Technology & Therapeutics*. 2005; 7: 663-664.
- 49) **Klonoff D.C.**: A review of continuous glucose monitoring technology. *Diabetes Technology & Therapeutics*. 2005; 7:770-775.
- 50) **Klonoff D.C.**: Continuous Glucose Monitoring Technology Delivers Detailed Diabetes Data. *Point of Care*. 2006; 5:105-111.
- 51) **Klonoff D.C.**, Bergenstal RM, Cole TG, Ammirati EB, Blatt JM, Irvin BR, Stivers CR, Clark AL: Clinical Evaluation of a Rapid A1C Test (A1cNow®) for Home-Use. *Point of Care*. 2006; 5:116-120.
- 52) **Klonoff D.C.**, Friedl K, Grodsky G, Heinemann L: J Diabetes Sci Technol and the diabetes technology community. *J Diabetes Sci Technol*. 2007; 1:1-2.
- 53) Nichols JH, **Klonoff, D.C.**: The need for performance standards for continuous glucose monitors. *J Diabetes Sci Technol*. 2007; 1:92-95.
- 54) **Klonoff D.C.**: The Artificial Pancreas: How Sweet Engineering Will Solve Bitter Problems. *J Diabetes Sci Technol*. 2007; 1:72-81.
- 55) Buse JB, **Klonoff D.C.**, Nielsen LL, Guan X, Bowlus CL, Holcombe JH, Maggs DG, Wintle, ME: Metabolic Effects of Two Years of Exenatide Treatment on Diabetes, Obesity, and Hepatic Biomarkers in Patients with Type 2 Diabetes: An Interim Analysis of Data from the Open-Label, Uncontrolled Extension of Three Double-Blind, Placebo-Controlled Trials. *Clin Ther* 2007; 29:139-153.

- 56) **Klonoff D.C.:** Subcutaneous Continuous Glucose Monitoring in Severe Burn Patients. *Critical Care Med.* 2007 35:1445.
- 57) **Klonoff D.C.:** Technology to treat hyperglycemia in trauma patients. *J Diabetes Sci Technol.* 2007; 1:151-152.
- 58) **Klonoff D.C.:** Dirlotapide, an FDA approved first-in-class obesity drug for dogs - will humans be next? *J Diabetes Sci Technol.* 2007 1:314-316.
- 59) **Klonoff D.C.:** Replacements for Trans Fats -Will there be an Oil Shortage? *J Diabetes Sci Technol.* 2007; 1:415-422.
- 60) **Klonoff D.C.:** Bariatric surgery for obese adolescents. *J Diabetes Sci Technol.* 2007; 1:451-453.
- 61) **Klonoff D.C.:** The new FDA CDRH Engineering and Physics Laboratory and methods for testing software that controls infusion pumps. *J Diabetes Sci Technol.* 2007; 1:608-611.
- 62) **Klonoff D.C.:** The benefits of implanted glucose sensors. *J Diabetes Sci Technol.* 2007; 1:797-800.
- 63) **Klonoff D.C.:** Buse JB, Nielsen LL, Guan X, Bowlus C, Holcombe JH, Wintle ME, Maggs DG. Effects of At Least Three Years of Exenatide Treatment on Diabetes, Obesity, Cardiovascular Risk Factors, and Hepatic Biomarkers in Patients with Type 2 Diabetes: Current Medical Research Opinion, 2008; 24:275-286.
- 64) **Klonoff D.C.:** Business and economics of diabetes. *J Diabetes Sci Technol.* 2008; 2:1-3.
- 65) **Klonoff D.C.:** The “Catalyst to Better Diabetes Care Act of 2007”. *J Diabetes Sci Technol.* 2008; 2:175-177.
- 66) **Klonoff D.C.:** Personalized medicine for diabetes. *J Diabetes Sci Technol.* 2008; 2:335-341.
- 67) **Klonoff D.C.:** New Evidence Demonstrates That Self-Monitoring of Blood Glucose Does Not Improve Outcomes in Type 2 Diabetes—When This Practice Is Not Applied Properly. *J Diabetes Sci Technol.* 2008; 2:342 -348.
- 68) **Klonoff D.C.:** Spending for diabetes drugs in the US is increasing. *J Diabetes Sci Technol.* 2008; 2:543-545.
- 69) **Klonoff D.C.:** Designing an artificial pancreas to be compatible with other medical devices. *J Diabetes Sci Technol.* 2008; 2:741-745.
- 70) **Klonoff D.C., Greenway F:** Obesity drugs in the pipeline. *J Diabetes Sci Technol.* 2008. 2:913-918.
- 71) Rosenstock J., Bergenstal R, DeFronzo RA, Hirsch IB, **Klonoff, D.C.**, Boss A, Kramer D, Petrucci R, Yu W, Levy B: Efficacy and safety of Technosphere inhaled insulin compared with Technosphere powder placebo in insulin-naïve Type 2 diabetes suboptimally controlled with oral agents. *Diabetes Care.* 2008; 31:2177-2182.
- 72) **Klonoff D.C.:** United Kingdom Prospective Diabetes Study follow-up studies establish a legacy effect of therapy for hyperglycemia but not hypertension. *J Diabetes Sci Technol.* 2008; 2:922-924.

- 73) **Klonoff D.C.**, Bergenstal R, Blonde L, Boren SA, Church T, Gaffaney J, Jovanovic L, Kendall D, Kollman C, Kovatchev B, Leippert C, Owens D, Polonsky WH, Reach G, Renard E, Riddell M, Rubin RR, Schnell O, Siminiro LM, Vigersky RA, Wilson DM, Wollitzer AO: Consensus Report of the Coalition for Clinical Research—Self-Monitoring of Blood Glucose. *J Diabetes Sci Technol.* 2008; 2:1030-1053.
- 74) **Klonoff D.C.**: The increasing incidence of diabetes in the 21st century. *J Diabetes Sci Technol.* 2009; 3:1-2.
- 75) Fleming GA, **Klonoff D.C.**: GAD Therapy for recent-onset Type 1 Diabetes: Are We at the End or the Beginning of Finding a Cure? *J Diabetes Sci Technol.* 2009; 3:215 - 218.
- 76) **Klonoff D.C.**: Continuous glucose monitoring study does not demonstrate benefit in children and adolescents. *J Pediatr.* 2009; 154:463-4.
- 77) **Klonoff D.C.**, Reyes JR: Insulin pump safety meeting: summary report. *J Diabetes Sci Technol.* 2009; 3:396 - 402.
- 78) **Klonoff D.C.**: The sweetened beverage tax to combat the obesity epidemic as well as related absenteeism and presenteeism. *J Diabetes Sci Technol.* 2009; 3:408-410.
- 79) **Klonoff D.C.**: Using telemedicine to improve outcomes. *J Diabetes Sci Technol.* 2009; 3:624-628.
- 80) **Klonoff D.C.**: The missing element of telemedicine for diabetes: decision support software. *J Diabetes Sci Technol.* 2009; 3:996-1001.
- 81) **Klonoff D.C.**, Cobelli C, Kovatchev B, Zisser HC: Progress in development of an artificial pancreas. *J Diabetes Sci Technol.* 2009; 3:1002-1004.
- 82) Raskin P, Lewin A, Reinhardt R, Lyness W; Repaglinide/Metformin Fixed-Dose Combination Study Group including **Klonoff D.C.**: Twice-daily dosing of a repaglinide/metformin fixed-dose combination tablet provides glycaemic control comparable to rosiglitazone/metformin tablet. *Diabetes Obes Metab.* 2009;11:865-873.
- 83) Buse JB, Rosenstock J, Sesti G, Schmidt WE, Montanya E, Brett JH, Zychma M, Blonde L; LEAD-6 Study Group including **Klonoff D.C.**: Liraglutide once a day versus exenatide twice a day for type 2 diabetes: a 26-week randomised, parallel-group, multinational, open-label trial (LEAD-6). *Lancet.* 2009 Jul 4; 374(9683):39-47.
- 84) Raskin P, Lewin A, Reinhardt R, Lyness W; Repaglinide/Metformin Fixed-Dose Combination Study Group including **Klonoff D.C.**: Twice-daily and three-times-daily dosing of a repaglinide/metformin fixed-dose combination tablet provide similar glycaemic control. *Diabetes Obes Metab.* 2009;11:947-952.
- 85) **Klonoff D.C.**: The beneficial effects of a Paleolithic diet on type 2 diabetes and other risk factors for cardiovascular disease. *J Diabetes Sci Technol.* 2009; 3:1229-1232.
- 86) **Klonoff D.C.**: The need for a glycemia modeling comparison workshop to facilitate development of an artificial pancreas. *J Diabetes Sci Technol.* 2010; 4: 1-3.
- 87) **Klonoff D.C.**: Regulatory controversies surround blood glucose monitoring devices. *J Diabetes Sci Technol.* 2010; 4: 231-235.
- 88) Zhang Y, Jones PL, **Klonoff D.C.**: Second insulin pump safety meeting: summary report. *J Diabetes Sci Technol.* 2010; 4: 488-493.

- 89) **Klonoff D.C.**: FDA is now preparing to establish tighter performance standards for blood glucose monitors. *J Diabetes Sci Technol.* 2010; 4: 499-504.
- 90) **Klonoff D.C.**: Fibroblast growth factor: will this hormone be the Hemoglobin A1c for managing phosphorus balance in chronic kidney disease? *J Diabetes Sci Technol.* 2010; 4: 770-772.
- 91) **Klonoff D.C.**, Perz JF: Assisted Monitoring of Blood Glucose: Special Safety Needs for a New Paradigm. *J Diabetes Sci Technol.* 2010; 4: 1027-1031. (Also posted on CDC website and the Pennsylvania Department of Public Welfare website) (*)
- 92) **Klonoff D.C.**: Incretin Therapy for Type 2 Diabetes Mellitus. *Adv Ther.* 2010; 27:881-894.
- 93) **Klonoff D.C.**: Hospital diabetes – why quality of care matters to both patients and hospitals. *J Diabetes Sci Technol.* 2011; 5: 1-4.
- 94) **Klonoff D.C.**: Smart Sensors for Maintaining Physiologic Homeostasis. *J Diabetes Sci Technol.* 2011; 5: 470-475.
- 95) **Klonoff D.C.**: Intensive Insulin Therapy in Critically Ill Hospitalized Patients: Making it Safe and Effective. *J Diabetes Sci Technol.* 2011. 5: 755-767.
- 96) **Klonoff D.C.**, Zimlik C, Stevens A, Beaton P, Pinkos A: Innovations in Technology for the Treatment of Diabetes: Clinical Development of the Artificial Pancreas (an Autonomous System). *J Diabetes Sci Technol.* 2011; 5: 804-826.
- 97) **Klonoff D.C.**, Buckingham B, Christiansen JS, Montori VM, Tamborlane WV, Vigersky RA, Wolpert W. Continuous Glucose Monitoring: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2011; 96: 2968-2979.
- 98) **Klonoff D.C.** Improving the safety of blood glucose monitoring. *J Diabetes Sci Technol;* 2011; 5: 1307-1311. (*)
- 99) Brazg RL, Bailey TS, Garg S, Buckingham BA, Slover RH, **Klonoff D.C.**, Nguyen X, Shin J, Welsh JB, Lee SW. The ASPIRE Study: Design and Methods of an In-Clinic Crossover Trial on the Safety and Efficacy of Automatic Insulin Suspension in Exercise-Induced Hypoglycemia: A First Pilot Randomized Study. *J Diabetes Sci Technol.* 2011; 5: 1466-1471.
- 100) **Klonoff D.C.**, Blonde L, Cembrowski G, Chacra AR, Charpentier G, Colagiuri S, Dailey G, Gabbay R, Heinemann L, Kerr D, Nicolucci A, Polonsky W, Schnell O, Vigersky R, Yale J-F. Consensus Report: The Current Role of Self-Monitoring of Blood Glucose in Non-Insulin Treated Type 2 Diabetes. *J Diabetes Sci Technol.* 2011; 5: 1529-1548.
- 101) Paul N, Kohno T, **Klonoff D.C.**: A review of the security of insulin pump infusion systems. *J Diabetes Sci Technol.* 2011; 5: 1557-1562.
- 102) **Klonoff D.C.**: The impact of ISO 22870 on the quality and competence of continuous glucose monitoring in the hospital setting. *Point of Care: The Journal of Near-Patient Testing & Technology.* 2011; 10:179-181.
- 103) **Klonoff D.C.**: The need for clinical accuracy guidelines for blood glucose monitors. *J Diabetes Sci Technol.* 2012; 6: 1-4.

- 104) Garg S, Brazg RL, Bailey TS, Buckingham BA, MD, Slover RH, **Klonoff DC**, Shin J, Welsh JB, Kaufman FR.: Reduction of exercise-induced hypoglycemia by automatic insulin pump suspension: The ASPIRE study. *Diabetes Technol Ther.* 2012; 14:205-9.
- 105) **Klonoff D.C.**: Improved outcomes from diabetes monitoring occur with better adherence, therapy adjustments, patient education, and telemedicine support. *J Diabetes Sci Technol.* 2012; 6: 486-490.
- 106) **Klonoff D.C.**: The current status of bolus calculator decision support software. *J Diabetes Sci Technol.* 2012; 6: 990-994.
- 107) **Klonoff D.C.**: Fluorescence glucose sensing: a technology with a bright future. *J Diabetes Sci Technol.* 2012; 6: 1242-1250.
- 108) Bergenstal RM, Ahmann AJ, Bailey T, Beck RW, Bissen J, Buckingham B, Deeb L, Dolin RH, Garg SK, Goland R, Hirsch IB, **Klonoff D.C.**, Kruger DF, Matfin G, Mazze RS, Olson BA, Parkin C, Peters A, Powers MA, Rodriguez H, Southerland P, Strock ES, Tamborlane W, Wesley DM. Recommendations for standardizing glucose reporting and analysis to optimize clinical decision making in diabetes: the Ambulatory Glucose Profile (AGP). *Diabetes Technol Ther.* 2013; 15:198-211.
- 109) **Klonoff D.C.**: Twelve modern digital technologies that are transforming decision making for diabetes and all areas of health care. *J Diabetes Sci Technol.* 2013; 7:291-295.
- 110) Bergenstal RM, Ahmann AJ, Bailey T, Beck RW, Bissen J, Buckingham B, Deeb L, Dolin RH, Garg SK, Goland R, Hirsch IB, **Klonoff D.C.**, Kruger DF, Matfin G, Mazze RS, Olson BA, Parkin C, Peters A, Powers MA, Rodriguez H, Southerland P, Strock ES, Tamborlane W, Wesley DM. Expert Panel: Optimizing Glucose Reporting, Analysis and Clinical Decision Making in Type 1 Diabetes: The Ambulatory Glucose Profile (AGP), March 28-29, 2012, Tampa, Florida: Recommendations for Standardizing Glucose Reporting and Analysis to Optimize Clinical Decision Making in Diabetes: The Ambulatory Glucose Profile. *J Diabetes Sci Technol.* 2013; 7: 562-578.
- 111) Pfützner A, Bailey T, Campos C, Kahn D, Ambers E, Niemeyer M, Guerrero G, **Klonoff D**, Nayberg I. Accuracy and preference assessment of prefilled insulin pen versus vial and syringe with diabetes patients, caregivers, and healthcare professionals. *Curr Med Res Opin.* 2013; 29:475-481.
- 112) Heinemann, L, **Klonoff D.C.**: Blood Glucose Meter Market: This World is Undergoing Drastic Changes. *J Diabetes Sci Technol.* 2013; 7: 584-586.
- 113) **Klonoff D.C.** The current status of mHealth for Diabetes: will it be the next big thing? *J Diabetes Sci Technol.* 2013; 7: 749-758.
- 114) Bergenstal, RM, **Klonoff D.C.**, Garg SK, Bode BW, Meredith M, Slover RH, Ahmann AJ, Welsh, JB, Lee SW, Kaufman FR. for the ASPIRE In-Home Study Group. Threshold-based insulin-pump interruption for reduction of hypoglycemia. *N Engl J Med.* 2013 Jul 18; 369(3):224-32.
- 115) Draznin B, Gilden J, Golden SH, Inzucchi SE; PRIDE investigators, Baldwin D, Bode BW, Boord JB, Braithwaite SS, Cagliero E, Dungan KM, Falciglia M, Figaro MK, Hirsch IB, **Klonoff D.**, Korytkowski MT, Kosiborod M, Lien LF, Magee MF, Masharani U, Maynard G, McDonnell ME, Moghissi ES, Rasouli N, Rubin DJ, Rushakoff RJ, Sadhu AR, Schwartz S, Seley JJ, Umpierrez GE, Vigersky RA, Low CC, Wexler DJ. Pathways to quality inpatient management of hyperglycemia and diabetes: a call to action. *Diabetes Care.* 2013 Jul;36(7):1807-14.

- 116) **Klonoff, D.C.** Bergenstal RM, Garg SK, Bode BW, Meredith M, Slover RH, Ahmann AJ, Welsh, JB, Lee SW, Kaufman FR for the ASPIRE In-Home Study Group. ASPIRE In-Home: Rationale, Design, and Methods of a Study to Evaluate the Safety and Efficacy of Automatic Insulin Suspension for Nocturnal Hypoglycemia. *J Diabetes Sci Technol.* 2013; 7:1005-1010.
- 117) Rodbard HW, Cariou B, Zinman B, Handelsman Y, Philis-Tsimikas A, Skjøth TV, Rana A, Mathieu C; BEGIN Once Long trial investigators including **Klonoff, D.** Comparison of insulin degludec with insulin glargine in insulin-naïve subjects with Type 2 diabetes: a 2-year randomized, treat-to-target trial. *Diabetic Med.* 2013; 30:1298-1304.
- 118) **Klonoff D.C.**, Reyes JS. Do currently available blood glucose monitors meet regulatory standards? 1-day public meeting in Arlington, Virginia. *J Diabetes Sci Technol.* 2013; 7:1071-1083.
- 119) Chaudhry T, **Klonoff D.C.** SMBG Out of Control: The Need for Educating Patients About Control Solution. *Diabetes Educ.* 2013 Sep-Oct; 39(5):689-95.
- 120) Sosenko JM, Skyler JS, Palmer JP, Krischer JP, Yu L, Mahon J, Beam CA, Boulware DC, Rafkin L, Schatz D, Eisenbarth G; Type 1 Diabetes TrialNet Study Group; Diabetes Prevention Trial-Type 1 Study Group including **Klonoff D.** The prediction of type 1 diabetes by multiple autoantibody levels and their incorporation into an autoantibody risk score in relatives of type 1 diabetic patients. *Diabetes Care.* 2013; 36:2615-2620.
- 121) Sosenko JM, Skyler JS, Beam CA, Krischer JP, Greenbaum CJ, Mahon J, Rafkin LE, Matheson D, Herold KC, Palmer JP; Type 1 Diabetes TrialNet and Diabetes Prevention Trial-Type 1 Study Groups including **Klonoff D.** Acceleration of the loss of the first-phase insulin response during the progression to type 1 diabetes in diabetes prevention trial-type 1 participants. *Diabetes.* 2013;62:4179-4183.
- 122) Heinemann L, **Klonoff D.C.** Freedom of speech and science: can companies force us to withdraw data they don't like? *J Diabetes Sci Technol.* 2013 Sep 1;7(5):1100-1.
- 123) Pfützner A, **Klonoff D.C.**, Pardo S, Parkes JL. Technical aspects of the Parkes error grid. *J Diabetes Sci Technol.* 2013 Sep 1;7(5):1275-1281.
- 124) **Klonoff D**, Nayberg I, Rabbone I, Landgraf W, Domenger C, Danne T. JuniorSTAR® half-unit insulin pen in young people with type 1 diabetes – user perspectives. *Eur Endocrinol.* 2013;9(2):82–5.
- 125) Rodbard HW, Cariou B, Zinman B, Handelsman Y, Philis-Tsimikas A, Skjøth TV, Rana A, Mathieu C; BEGIN Once Long trial investigators including **Klonoff D.C.** Comparison of insulin degludec with insulin glargine in insulin-naïve subjects with Type 2 diabetes: a 2-year randomized, treat-to-target trial. *Diabet Med.* 2013 Nov;30(11):1298-304.
- 126) Garg SK, Brazg RL, Bailey TS, Buckingham BA, Slover RH, **Klonoff D.C.**, Shin J, Welsh JB, Kaufman FR. Hypoglycemia begets hypoglycemia: The order effect in the ASPIRE in-clinic study. *Diabetes Technol Ther.* 2014;16:125-130.
- 127) **Klonoff D.C.** New Wearable Computers Move Ahead: Google Glass and Smart Wigs. *J Diabetes Sci Technol.* 2014; 8: 3-5.
- 128) **Klonoff D.C.** ADAG Study Group Data Links A1C Levels with Empirically Measured Blood Glucose Values - New Treatment Guidelines Will Now be Needed. *J Diabetes Sci Technol.* 2014 Apr 30;8(3):439-443.

- 129) Chiang JL, Kirkman MS, Laffel LM, Peters AL; Type 1 Diabetes Sourcebook Authors including **Klonoff D.C.** Type 1 diabetes through the life span: a position statement of the American Diabetes Association. *Diabetes Care*. 2014 Jul;37(7):2034-54.
- 130) Landau Z, **Klonoff D.**, Nayberg I, Feldman D, Levit SB, Lender D, Mosenzon O, Raz I, Wainstein J. Improved pharmacokinetic and pharmacodynamic profile of insulin analogs using InsuPatch, a local heating device. *Diabetes Metab Res Rev*. 2014 Mar 10.
- 131) **Klonoff, D.C.**, Lias C, Vigersky R, Clarke W, Parkes JL, Sacks DB, Kirkman MS, Kovatchev B, The Error Grid Panel. The Surveillance Error Grid. *J Diabetes Sci Technol*; 2014. 8: 658-672.
- 132) Kovatchev, B, Wakeman C, Breton M, Kost G, Louie R, **Klonoff D.C.** Computing the Surveillance Error-Grid Analysis: Procedure and Examples. *J Diabetes Sci Technol*. 2014; 8: 673-684.
- 133) **Klonoff D.C.**, Reyes JS. Hospital diabetes meeting: Arlington, Virginia, May 13, 2014. *J Diabetes Sci Technol*. 2014 Sep;8(5):1048-51.
- 134) **Klonoff D.C.** SMBG Accuracy in the Hospital Setting. *Diabetes Spectrum*. 2014. 27:174-179.
- 135) **Klonoff D.C.**, Emerging Technologies in Rapid-Acting Prandial Insulin Practical Diabetol. 2014 Sept/Oct: 13-18.
- 136) Matuleviciene V, Joseph JI, Andelin M, Hirsch IB, Attvall S, Pivodic A, Dahlqvist S, **Klonoff D.**, Haraldsson B, Lind M. A Clinical Trial of the Accuracy and Treatment Experience of the Dexcom G4 Sensor (Dexcom G4 System) and Enlite Sensor (Guardian REAL-Time System) Tested Simultaneously in Ambulatory Patients with Type 1 Diabetes. *Diabetes Technol Ther*. 2014; 16: 759-767.
- 137) **Klonoff D.C.**, Vigersky RA, Nichols JH, Rice MJ. Timely Hospital Glucose Measurement: Here Today, Gone Tomorrow? *Mayo Clin Proceedings*. 2014; 89:1331-1335.
- 138) **Klonoff D.C.** Afrezza inhaled insulin – the fastest acting FDA-approved insulin on the market has favorable properties. *J Diab Sci Technol*. 2014; 8:1071-1073.
- 139) Efficacy and safety of a fixed-ratio combination of insulin degludec and liraglutide (IDegLira) compared with its components given alone: results of a phase 3, open-label, randomised, 26-week, treat-to-target trial in insulin-naïve patients with type 2 diabetes. Gough SC, Bode B, Woo V, Rodbard HW, Linjawi S, Poulsen P, Damgaard LH, Buse JB; NN9068-3697 (DUAL-I) trial investigators including **Klonoff D.** *Lancet Diabetes Endocrinol*. 2014; 2:885-893.
- 140) **Klonoff D.C.** Precision medicine for diabetes management. *J Diab Sci Technol*. 2015; 9:3-7.
- 141) Pfützner A, Raz I, Bitton G, **Klonoff D.**, Nagar R, Hermanns N, Haak T. Improved Insulin Absorption by Means of Standardized Injection Site Modulation Results in a Safer and More Efficient Prandial Insulin Treatment: A Review of the Existing Clinical Data. *J Diabetes Sci Technol*. 2015; 9:116-22.
- 142) Cembrowski G, Lyon M, **Klonoff D.C.** Glucose data mining study inconclusive. *Canada J Diabetes*. 2015 May 28. pii: S1499-2671(15)00383-4.

- 143) **Klonoff D.**, Nayberg I, Rabbone I, Domenger C, Stauder U, Oualali H, Danne T. Functional Evaluation of the Reusable JuniorSTAR® Half-Unit Insulin Pen. *J Diabetes Sci Technol*. 2015 Jan 28. pii: 1932296815569246. [Epub ahead of print].
- 144) **Klonoff D.C.** Trends in FDA Regulation of Software to Control insulin Dosing. *J Diab Sci Technol*. 2015;9(3):503-6.
- 145) **Klonoff D.C.** Cybersecurity for connected diabetes devices. *J Diab Sci Technol*. 2015; 9(5): 1143-1147. (**)
- 146) **Klonoff D.**, Nayberg I, Erbstein F, Cali A, Brulle-Wohlhueter C, Haak T. Usability of the Gla-300 Injection Device Compared With Three Other Commercialized Disposable Insulin Pens: Results of an Interview-Based Survey. *J Diabetes Sci Technol*. 2015 Jul;9(4):936-8. doi: 10.1177/1932296815586219. Epub 2015 May 22.
- 147) Weiss R, Garg SK, Bergenstal RM, **Klonoff DC**, Bode BW, Bailey TS, Thrasher J, Schwartz F, Welsh JB, Kaufman FR; ASPIRE In-Home Study Group. Predictors of Hypoglycemia in the ASPIRE In-Home Study and Effects of Automatic Suspension of Insulin Delivery. *J Diabetes Sci Technol*. 2015 May 18. pii: 1932296815586014. [Epub ahead of print]
- 148) **Klonoff D.C.**, Prahalad P. Performance of Cleared Blood Glucose Monitors. *J Diabetes Sci Technol*. 2015;9:895-910. doi: 10.1177/1932296815584797. Epub 2015 Jun 8.
- 149) Sosenko JM, Skyler JS, Beam CA, Boulware D, Mahon JL, Krischer JP, Greenbaum CJ, Rafkin LE, Matheson D, Herold KC, Palmer JP; Type 1 Diabetes TrialNet and Diabetes Prevention Trial–Type 1 Study Groups including **Klonoff D.** The development and utility of a novel scale that quantifies the glycemic progression toward type 1 diabetes over 6 months. *Diabetes Care*. 2015;38: 940-942.
- 150) **Klonoff D.**, Nayberg I, Thonius M, See F, Abdel-Tawab M, Erbstein, F, Haak T. Accuracy and injection force of the Gla-300 injection device compared with other commercialized disposable insulin pens. *J Diab Sci Technol*. 2015 Aug 26. pii: 1932296815601441. [Epub ahead of print]
- 151) Armstrong DG, Kleidermacher DN, **Klonoff D.C.**, Slepian MJ. Cybersecurity Regulation of Wireless Devices for Performance and Assurance in the Age of “Medjacking”. *J Diabetes Sci Technol*. 2015 Aug 27;10(2):435-438. (**)
- 152) Pfützner A, Sachsenheimer D, Grenningloh M, Heschel M, Walther-Johannesen L, Gharabli R. **Klonoff D.** Using Insulin Infusion Sets in CSII for Longer Than the Recommended Usage Time Leads to a High Risk for Adverse Events: Results From a Prospective Randomized Crossover Study. *J Diabetes Sci Technol*. 2015 Sept 3; 9(6): 1292-1298.
- 153) **Klonoff D.C.**, Draznin B, Drincic A, Dungan K, Gianchandani R, Inzucchi SE, Nichols JH, Rice MJ, Seley JS. PRIDE Statement on the Need for a Moratorium on the CMS Plan to Cite Hospitals for Performing Point-of-Care Capillary Blood Glucose Monitoring on Critically Ill Patients. *J Clin End Metab. J Clin Endocrinol Metab*. 2015 Oct;100(10):3607-12. doi: 10.1210/jc.2015-2435. Epub 2015 Sep 23. PMID: 26398626
- 154) **Klonoff D.C.** What Do Your Fingernails say about you? Can they indicate that you have diabetes? *J Diab Sci Technol*. 2015. *J Diabetes Sci Technol*. 2015 Oct 30;9(6):1167-9. doi: 10.1177/1932296815608980.

- 155) **Klonoff D.C.**, Lias C, Beck S, Parkes JL, Kovatchev B, Vigersky RA, Arreaza-Rubin G, Burk R, Kowalski A, Little R, Nichols J, Petersen M, Rawlings K, Sacks D, Sampson E, Scott S, Seley J, Slingerland R, Vesper HW. Development of the DTS Blood Glucose Monitor System Surveillance Protocol. *J Diabetes Sci Technol. J Diabetes Sci Technol* 2016. May 3; 10(3):697-707.
- 156) **Klonoff D.C.** Telemedicine for diabetes: current and future trends. *J Diabetes Sci Technol.* 2016; 10 (1):3-5.
- 157) Andelin M. Kropff J. Matuleviciene V. Joseph JL. Attvall S. Theodorsson E. Hirsch IB. Imberg H. Dahlqvist S. **Klonoff D.** Haraldsson B. DeVries JH. Lind M. Assessing the accuracy of continuous glucose monitoring (CGM) calibrated with capillary values using capillary or venous glucose levels as a reference. *J Diabetes Sci Technol.* 2016 Jan 24. pii: 1932296815626724. [Epub ahead of print].
- 158) **Klonoff D.C.** Telemedicine for diabetes: economic aspects. *J Diabetes Sci Technol.* March 2016 10: 251-253.
- 159) **Klonoff D.C.**, Kleidermacher DN. Now is the time for a cybersecurity standard for connected diabetes devices. *J Diabetes Sci Technol.* 2016 May; 10 (3): 623-626.
- 160) Carter AW, Heinemann L, **Klonoff D.C.** Quality Control of Insulins and Biosimilar Insulins: What do We Know? *J Diabetes Sci Technol.* 2016 Jul; 10(4):811-5.
- 161) Kameya M, Tsugawa W, Yamada-Tajima M, Sakaguchi-Mikami A, Ferri S, **Klonoff D**, Sode K. Novel Enzymatic Sensing System for Glycated Albumin Requiring No Proteolytic Digestion Process Employing Fructosamine 6-Kinase. *Biotechnol J.* 2016 Jun; 11(6):797-804.
- 162) Wallia A, Umpierrez GE, Nasraway SA, **Klonoff D.C.**; PRIDE Investigators. Round Table Discussion on Inpatient Use of Continuous Glucose Monitoring at the International Hospital Diabetes Meeting. *J Diabetes Sci Technol.* 2016 Jun 10. pii: 1932296816656380.
- 163) **Klonoff, D.C.**, Kerr, D. Digital Diabetes Communication: There's an app for that! *J Diabetes Science Technol.* 2016 Aug 22;10(5):1003-5. doi: 10.1177/1932296816660210.
- 164) Demircik F, **Klonoff D.**, Musholt P, Ramljak S, Pfützner, A. Successful performance of laboratory investigations with blood glucose meters employing a dynamic electrochemistry-based correction algorithm is dependent on careful sample handling. *Diabetes Technol Ther.* 2016 Oct; 18(10):650-656. .
- 165) Wallia A, Umpierrez GE, Nasraway SA, **Klonoff D.C.**; PRIDE Investigator. Round Table Discussion on Inpatient Use of Continuous Glucose Monitoring at the International Hospital Diabetes Meeting. *J Diabetes Sci Technol.* 2016, Aug 22;10(5):1174-81.
- 166) Pohlmeier H, Berard L, Brulle-Wohlhueter C, Wu J, Dahmen R, Nowotny I, **Klonoff D.** Ease of Use of the Insulin Glargine 300 U/mL Pen Injector in Insulin-Naïve People with Type 2 Diabetes. *J Diabetes Science Technol.* 2017 Mar;11(2):263-269. doi: 10.1177/1932296816668877. Epub 2016 Sep 25.
- 167) Drincic A, Prahalad P, Greenwood D, **Klonoff D.C.** Evidence - Based Mobile Medical Applications in Diabetes. *Med Clin N America.* 2016 Dec;45(4):943-965.
- 168) **Klonoff D.**, Nayberg I, Stauder U, Oualali H, Domenger C. Half-unit insulin pens – disease management in patients with diabetes. *J Diabetes Science Technol.* 2016. Nov 27. pii: 1932296816679180. [Epub ahead of print].

- 169) Hatadaa M, Tsugawa W, Kamioa E, Loew N, **Klonoff D.C.**, Sode K. Development of a screen-printed carbon electrode based disposable enzyme sensor strip for the measurement of glycated albumin. *Biosensors Bioelectronics*. *Biosens Bioelectron*. 2017 Feb 15;88:167-173.
- 170) Sode K, Loew N, Ohnishia Y, Tsuruta H, Moric K, Kojimac K, Tsugawa W, LaBelle JT, **Klonoff D.C.**. Novel Fungal FAD Glucose Dehydrogenase derived from *Aspergillus niger* for Glucose Enzyme Sensor Strips. *Biosensors Bioelectronics*. 2017, Jan 15;87:305-311.
- 171) **Klonoff D.C.**, Fleming GA, Muchmore DB, Frier BM. Hypoglycemia evaluation and reporting in diabetes: importance for development of new therapies. *Diabetes Metab Res Rev*. 33(5); 2017. Online: 7 Mar 2017. DOI: 10.1002/dmrr.2883. [Epub ahead of print].
- 172) **Klonoff D.C.**, Nicholson, P. The Need for a Privacy Standard for Medical Devices that Transmit Protected Health Information Used in the Precision Medicine Initiative for Diabetes and Other Diseases. *J Diabetes Sci Technol*. 2017 Mar;11(2):220-223. doi: 10.1177/1932296816680006.
- 173) Pfützner A, **Klonoff D**, Heinemann L, Ejekjaer N, Pickup J. Euglycemic Ketosis in Patients with Type 2 Diabetes on SGLT2-Inhibitor Therapy – An Emerging Problem and Solutions Offered by Diabetes Technology. *Endocrine*. 2017. *Endocrine*. 2017 Apr;56(1):212-216. doi: 10.1007/s12020-017-1264-y. Epub 2017 Mar 17.
- 174) Ginsberg BH, **Klonoff D.C.**, Crabtree VP. Meeting Report: The Fourth Artificial Pancreas Workshop: Testing and Adoption of Current and Emerging Technologies. *J Diabetes Sci Technol*. 2017. 2017 Mar 1:1932296817699640. doi: 10.1177/1932296817699640. [Epub ahead of print]
- 175) **Klonoff D.C.**, Freckmann G, Heinemann L. Insulin Pump Occlusions – For Patients Who Have Been Around the (Infusion) Block. *J Diabetes Sci Technol*. 2017 May; 11(3): 451-454.
- 176) Wallia A, Umpierrez GE, Rushakoff RJ, **Klonoff D.C.**, Rubin DJ, Hill Golden S, Cook CB, Thompson B; DTS Continuous Glucose Monitoring in the Hospital Panel. Consensus Statement on Inpatient Use of Continuous Glucose Monitoring. *J Diabetes Sci Technol*. 2017 Sep;11(5):1036-1044.
- 177) Liang Y, Wanderer J, Nichols JH, **Klonoff D.C.**, Rice MJ. Blood gas analyzer glucose measurement accuracy. *Mayo Clin Proc*. 2017; Jul;92(7):1030-1041.
- 178) **Klonoff D.C.**, Kerr D, Kleidermacher D. Now is the time for a security and safety standard. *J Diabetes Sci Technol*. *J Diabetes Sci Technol*. 2017 Sep;11(5):870-873.
- 179) **Klonoff D.C.** Fog Computing and Edge Computing Architectures for Processing Data From Diabetes Devices Connected to the Medical Internet of Things. *J Diabetes Sci Technol*. 2017; 11(4):647-652.
- 180) **Klonoff D.C.**, Kerr D, Wong JC, Pavlovic, Koliwad, Hu J, Salber P, Aguilera A, Long W, Hamilton G, Chen K, Adi S. Digital Diabetes Congress 2017. *J Diabetes Sci Technol*. 2017 Aug 1:1932296817723037. doi: 10.1177/1932296817723037. Epub 2017 Aug 8.
- 181) **Klonoff D.C.**, Kerr D. A Simplified Approach Using Rate of Change Arrows to Adjust Insulin With Real-Time Continuous Glucose Monitoring. *J Diabetes Sci Technol*. 2017 Sep 1:1932296817723260. doi: 10.1177/1932296817723260. [Epub ahead of print].

- 182) Holman RR, Bethel MA, Mentz RJ, Thompson VP, Lokhnygina Y, Buse JB, Chan JC, Choi J, Gustavson SM, Iqbal N, Maggioni AP, Marso SP, Öhman P, Pagidipati NJ, Poulter N, Ramachandran A, Zinman B, Hernandez AF and the EXSCEL Study Group including **Klonoff D.** Effects of Once-Weekly Exenatide on Cardiovascular Outcomes in Type 2 Diabetes. *N Engl J Med.* 2017 Sep 28;377(13):1228-1239.
- 183) **Klonoff D.C.**, Drincic A, Ahn D. Continuous glucose monitoring: a review of the technology and clinical use of CGM. *Diabetes Res Clin Pract.* 2017 Nov;133:178-192. doi: 10.1016/j.diabres.2017.08.005. Epub 2017 Sep 1.
- 184) **Klonoff D.C.**, Kerr D. Overcoming barriers to adoption of digital health. *J Diabetes Sci Technol.* 2018 Jan; 12(1): 3-6.
- 185) Gao W, Brooks GA, **Klonoff D.C.** Wearable Physiological Systems and Technologies for Metabolic Monitoring. *J Appl Physiol* (1985). 2017 Sep 28:jap.00407.2017. doi: 10.1152/japphysiol.00407.2017. [Epub ahead of print]
- 186) Kerr D, Axelrod C, Hoppe C, **Klonoff D.C.** A utopian or dystopian future? *Diabetic Med.* 2018 *Diabet Med.* 2018 Jan 22. doi: 10.1111/dme.13586. [Epub ahead of print].
- 187) **Klonoff D.C.**, Kerr D. Smart insulin pens will improve insulin therapy. *J Diabetes Sci Technol* (in press).
- 188) King F, Ahn D, Hsiao V, Porco T, and **Klonoff D.C.** Performance of cleared blood glucose monitor systems (in preparation).
- 189) Okurita M, Suzukib N, Loew N, Yoshidad H, Tsugawa W, Morie K, Kojimae K, **Klonoff D.C.**, Sode K. Engineered fungus derived FAD-dependent glucose dehydrogenase with acquired ability to utilize hexaammineruthenium(III) as an electron acceptor. *Bioelectrochem.* (In preparation).
- 190) Umpierrez GE, **Klonoff D.C.** Use of Insulin pumps and continuous glucose monitoring in the hospital. (in preparation).

Publications – Abstracts

- 191) **Klonoff D.C.**, Young C.W., Bohannon N.V., Burns A., Chan E.T.Y., Karam J.H. and Forsham P.H.: Advantages of fructose as a dietary sweetener in insulin dependent diabetes. *Clin. Res.* 1981; 29:55A.
- 192) Andrews, B.T., **Klonoff D.C.** and Obana W.G.: Stroke and intracranial hemorrhage associated with cocaine use. Abstract presented at the 38th Annual Meeting of the Congress of Neurological Surgeons in Seattle, Washington, September 24 to 29, 1988.
- 193) 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.
- 194) **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.

- 195) **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.
- 196) **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.
- 197) **Klonoff D.C.:** Rehabilitation from work disability due to chronic fatigue syndrome. Abstract presented at the American Association for Chronic Fatigue Syndrome Fourth National Meeting in Cambridge, Massachusetts, October 10 to 12, 1998.
- 198) **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.
- 199) 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.
- 200) **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.
- 201) **Klonoff D.C.:** Hazards of Hypoglycemia. Abstract presented at the Glucose Monitoring and Control Meeting in La Jolla, California. February 16 to 18, 2001.
- 202) Dawson C., Parker N., **Klonoff, D.C.**, Miller S.S., Gavin L., and Percival D.A.: Monitoring %HbA1c in the home. First Annual Diabetes Technology Meeting in San Francisco, California, November 2 to November 3, 2001.
- 203) 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.
- 204) Hopmeier M., Glenn J.F., Goldstein R., Hines J., Friedl K., Hunter-Schaedle K., Laughlin M., Loew M., and **Klonoff D.C.:** The joint DOD / NASA / NIH / JDRF Technologies for Metabolic Monitoring (TMM) Program. Second Annual Diabetes Technology Meeting in Atlanta, Georgia, October 31 to November 2, 2002.

- 205) 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.
- 206) **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.
- 207) 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.
- 208) Nayberg I, Ruano T, and **Klonoff D.C.**: Patient Attitudes towards Continuous Glucose Monitoring. Fifth Annual Diabetes Technology Meeting in San Francisco, California, November 10 to November 12, 2005.
- 209) Buse J, **Klonoff D.**, Nielsen L, Guan X, Holcombe J, Maggs D, Wintle M. Exenatide Reduced Weight and Decreased Elevated Hepatic Alanine Transaminase (ALT) in Patients with Type 2 Diabetes Mellitus (T2DM). American Diabetes Association 66th Scientific Sessions in Washington, D.C. June 9 to June 13, 2006.
- 210) Flacke F.M., **Klonoff D.**, Sethi B., Forst T., Simms P., Heinemann L., Pfuetzner A., Steiner S.S. Insulin VIAject™ and regular human insulin in patients with type 1 diabetes: efficacy and safety in an open-label multicenter clinical trial. European Association for the Study of Diabetes in Rome, Italy September 8 to September 11, 2008.
- 211) Pfuetzner A., Sethi B., Forst T., **Klonoff D.**, Simms P., Pohl R., Flacke F., Steiner S.S. Insulin VIAject™ and regular human insulin in patients with type 2 diabetes: efficacy and safety in an open-label multicenter clinical trial. European Association for the Study of Diabetes in Rome, Italy September 8 to September 11, 2008.
- 212) **Klonoff D.C.**, Nayberg I, Aratow SL, Zatarain, E, Shea L, Nelson N: Patency evaluation of an automated ex vivo whole blood glucose analyzer. Ninth Annual Diabetes Technology Meeting in San Francisco, California, November 5 to November 7, 2009.
- 213) 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.
- 214) Brazg R, Garg S, Bailey T, Buckingham B, Slover R, **Klonoff D.**, Kaufman FR, Uhrinak AN, Shin J. An Interim Analysis of an In-Clinic, Randomized, Cross-Over Study to Assess the Efficacy of the Low Glucose Suspend Feature of the Paradigm Veo System with Hypoglycemic Induction from exercise. Eleventh Annual Diabetes Technology Meeting in San Francisco, California, October 27 to 29, 2011.
- 215) 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.
- 216) 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.

- 217) **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*)
- 218) Pfützner 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.
- 219) **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.
- 220) 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.
- 221) 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.
- 222) 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.
- 223) **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.
- 224) **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.
- 225) **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.
- 226) 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.

- 227) **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.
- 228) 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 ASPIRE In-Home Study. European Association for the Study of Diabetes 50th Annual Meeting in Vienna, Austria. September 15-19, 2014.
- 229) **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.
- 230) 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.
- 231) **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.
- 232) **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.
- 233) 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-naïve people with type 2 diabetes. American Diabetes Association Meeting in Boston, Massachusetts, June 5-9, 2015.
- 234) Andelin M, Kropff J, Matuleviciene V, Joseph JI, 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.
- 235) 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.
- 236) 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.
- 237) **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.

- 238) **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.
- 239) 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.
- 240) King F, Ahn D, Hsiao V, Porco T, and **Klonoff D.** Performance of cleared blood glucose monitor systems. American Diabetes Association Meeting in Orlando, Florida, June 22-26, 2018 (Accepted for oral presentation - pending).
- 241) 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, Levvy BL. American Diabetes Association Meeting in Orlando, Florida, June 22-26, 2018. (Accepted for poster presentation - pending).
- 242) 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, Levvy BL. American Diabetes Association Meeting in Orlando, Florida, June 22-26, 2018. (Accepted for poster presentation - pending).
- 243) 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. (Accepted for poster presentation - pending).

Publications - Book Chapters

- 244) **Klonoff D.C.** and Greenspan F.S.: The Thyroid Nodule. Adv Intern. Med. 1982; 27:101-126.
- 245) **Klonoff D. C.** and Karam J.H.: Hypothalamic and pituitary hormones. In Basic & Clinical Pharmacology. pp. 396-406. (Katzung, B.G., Ed.) Los Altos, CA: Lange Medical Publications, 1982.
- 246) **Klonoff D.C.**: Hirsutism. In Basic & Clinical Endocrinology. pp 408-413. (Greenspan, F.S. and Forsham, P.H., Eds.) Los Altos, CA: Lange Medical Publications, 1983.
- 247) **Klonoff D.C.**: Syndromes affecting multiple endocrine glands. In Basic & Clinical Endocrinology. pp 609-625. (Greenspan, F.S. and Forsham, P.H., Eds.) Los Altos, CA: Lange Medical Publications, 1983.
- 248) **Klonoff D.C.** and Karam J.H.: Hypothalamic and pituitary hormones. In Basic & Clinical Pharmacology. 2nd Edition, pp 427-440. (Katzung, B.G., Ed.) Los Altos, CA: Lange Medical Publications, 1984.
- 249) **Klonoff D.C.** and Karam J.H.: Hypothalamic and pituitary hormones. In Basic & Clinical Pharmacology. 3rd Edition, pp 423-435. (Katzung, B.G., Ed.) Los Altos, CA: Appleton & Lange, 1987.

- 250) **Klonoff D.C.** and Karam J.H.: Hypothalamic and pituitary hormones. In Basic & Clinical Pharmacology. 4th Edition, pp 451-465. (Katzung, B.G., Ed.) Los Altos, CA: Appleton & Lange, 1989.
- 251) **Klonoff D.C.** and Karam J.H.: Hypothalamic and pituitary hormones. In Basic & Clinical Pharmacology. 5th Edition, pp 513-528. (Katzung, B.G., Ed.) Norwalk, CT: Appleton & Lange, 1992.
- 252) **Klonoff D.C.:** Chronic fatigue syndrome. In MKSAP (Medical Knowledge Self-Assessment Program) 10 Reprint Collection, Volume 1. American College of Physicians. Chevy Chase, MD: Nelson Information Systems, 1994.
- 253) **Klonoff D.C.** and Karam J.H.: Hypothalamic and pituitary hormones. In Basic & Clinical Pharmacology. 6th Edition, pp 561-577. (Katzung, B.G., Ed.) Norwalk, CT: Appleton & Lange, 1995.
- 254) **Klonoff D.C.:** Noninvasive blood glucose monitoring. In Annual Review of Diabetes 1997, pp 206-211. (Kelley, D.B., Ed.) Alexandria, VA: American Diabetes Association, Inc., 1997.
- 255) **Klonoff D.C.:** A doctor's approach to treating chronic fatigue syndrome. In Chronic Fatigue Syndrome, pp 168-176. (Fisher, G.C., Ed.) New York, NY: Warner Books, 1997.
- 256) Fitzgerald P.A. and **Klonoff D.C.:** Hypothalamic and pituitary hormones. In Basic & Clinical Pharmacology. 7th Edition, pp 603-618. (Katzung, B.G., Ed.) Norwalk, CT: Appleton & Lange, 1998.
- 257) **Klonoff D.C.:** Noninvasive blood glucose. In Annual Review of Diabetes 1998, pp 382-384. (Kelley, D.B., Ed.) Alexandria, VA: American Diabetes Association, Inc.
- 258) McGrath M., Shafer S.T., Albright A., **Klonoff D.C.**, Sulander G., and Thigpen J.: Type 2 Diabetes and Fitness. San Bruno, CA: StayWell/Krames, 1999.
- 259) **Klonoff D.C.:** Chronic fatigue syndrome. In Conn's Current Therapy. 52nd edition, 110-113. (Rakel, R.E., Ed.) Philadelphia, PA: W.B. Saunders Company, 2000.
- 260) **Klonoff D.C.** and Schwartz D.M.: An economic analysis of interventions for diabetes mellitus. In Annual Review of Diabetes 2000, pp 238-257. (Kelley D.B., Ed.) Alexandria, VA: American Diabetes Association, Inc., 2000.
- 261) **Klonoff D.C.:** In Living with Juvenile Diabetes: A Practical Guide for Parents and Caregivers of Children with Type 1 Diabetes Mellitus. (Peurrung, V). Long Island City, NY: Hatherleigh Press, 2001.
- 262) **Klonoff D.C.:** Emerging Technologies for Glucose Monitoring and Insulin Delivery. In Diabetes and Carbohydrate Metabolism (Goldfine ID and Rushakoff RJ, Eds.) <<http://www.endotext.org/diabetes>>. Endotext.com. 2002.
- 263) **Klonoff D.C.:** Novel Technologies for the Treatment of Diabetes. In Regulatory Affairs Focus. Rockville, MD: Regulatory Affairs Professional Society. November, 2003.
- 264) **Klonoff D.C.:** Chronic fatigue syndrome. In Conn's Current Therapy 2004. (Rakel, R.E. and Bope, E.T., Eds.) Philadelphia, PA: W.B. Saunders Company, 2004. Pages 118-122.

- 265) **Klonoff D.C.:** Technology for the Measurement of Blood Lactate. In Monitoring Metabolic Status: Predicting Decrements in Physiological and Cognitive Performance, pp 280-283. Committee on Metabolic Monitoring for Military Field Applications. Standing Committee on Military Nutrition Research. Food and Nutrition Board. Institute of Medicine of the National Academies. 2004. Washington, DC: The National Academies Press.
- 266) **Klonoff D.C.:** Monitoring technologies - continuous glucose monitoring, biomarkers of glycemic control, artificial pancreas. In Diabetes and Carbohydrate Metabolism (Goldfine, ID and Rushakoff, RJ, Eds.) <<http://www.endotext.org/diabetes>. Endotext.com, 2007.
- 267) **Klonoff D.C.:** Promising Technological Frontiers in Monitoring and Treatment. In Diabetes Public Health: From Data to Policy (Narayan K.M.V., Williams D., Gregg E., and Cowie C. Eds.) New York City: Oxford University Press. 2011.
- 268) **Klonoff D.C.:** Introduction. In Pumping Insulin, Fifth Edition. (Walsh J and Roberts R) La Jolla, CA. Torrey Pines Press, 2012.
- 269) **Klonoff D.C.:** Blonde L, Gabbay R, Polonsky W, Seley J, Vigersky R. Self Monitoring of Blood Glucose in Non Insulin Treated Type 2 Diabetes. Foster City, CA: Diabetes Technology Management, Inc. 2012.
- 270) **Klonoff D.C.,** Tamborlane W. Diabetes technology for monitoring. In The American Diabetes Association/JDRF Type 1 Diabetes Sourcebook. (Peters A and Laffel L Eds.) American Diabetes Association Press, 2013.
- 271) **Klonoff D.C.:** Clinician Needs in Urgent Care, Emergency Medicine, and Disaster Preparedness for Diabetes Patients. In Global Point-of-Care Strategies for Disasters, Complex Emergencies, and Public Health Crises: Enhancing Standards of Care at the Site of Need. Chapter 3. (Kost G and Corbin C Eds.) American Association of Clinical Chemistry Press. 2014.
- 272) **Klonoff D.C.:** Foreword. In Insulin Pumps and Continuous Glucose Monitoring Made Easy (Hussain S and Oliver N). Elsevier. Oxford, UK. 2016.
- 273) Horwitz D, **Klonoff D.C.:** New Technologies for Insulin Administration and Glucose Monitoring. In Textbook of Diabetes 5th Edition. (Holt R, Flyvbjerg A, Goldstein B, and Cockram, C. Eds.). Wiley-Blackwell (In press).

(*) = Featured on the CDC website: Infection Prevention During Blood Glucose Monitoring and Insulin Administration.

(**) = Featured on the 2017 US Department of HHS Assistant Secretary for Preparedness and Response (ASPR), Technical Resources, Assistance Center, and Information Exchange (TRACIE) Cybersecurity Topic Collection

CONTRACT AS PRINCIPLE SCIENTIFIC OFFICER

United States Air Force. Personalized Medicine for Diabetes: Scientific, Translational, and Commercial Factors. 2008 - 2009.

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.
- 7) Mercury Diagnostics, Incorporated, (Amira Medical), *Protocol #M98-001 WIRB*: An open-label, subject-controlled, clinical study of Mercury Diagnostics' blood glucose measurement system ("Mercury Gold System"). 1998.
- 8) Orbon Corporation, *Protocol RA 9801*: Glucagon eye drops. Phase 1. 1998 – 1999.
- 9) Pfizer, *Protocol 106*; *Protocol 110*; *Protocol 111*: Inhaled insulin. (Extensions). 1998 – 2003
- 10) Provalis Diagnostics UK Ltd., *Protocol 200G1-002-PDL-Glyco*: Evaluation and reproducibility of the Glycosal HbA1c test using office staff participants. 2000.
- 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.
- 18) Amylin Pharmaceuticals, *Protocol 2993-113*: 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 a sulfonylurea alone. 2002 – 2003.
- 19) Amylin Pharmaceuticals, *Protocol 137-150*: A randomized, triple-blind, placebo-controlled multicenter study to investigate the safety of Pramlintide treatment employing Pramlintide dose-titration followed by insulin dose optimization in subjects with type 1 diabetes mellitus who have not achieved glycemic targets with intensive insulin therapy. 2002 – 2003.
- 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.

- 22) Amylin Pharmaceuticals, *Protocol 2993-113E*: An open-label extension study of protocol 2993-113 to examine the long-term effect on glucose control (HbA1c) and safety and tolerability of AC2993 given two times a day to subjects treated with a sulfonylurea alone. 2003 – 2004.
- 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.
- 24) Amylin Pharmaceuticals, *Protocol 2993-119*: An open-label study to examine the long-term effect on glucose control (HbA1c) and safety and tolerability of AC2993 given two times a day to subjects with type 2 diabetes mellitus. 2003 – 2004.
- 25) OptiScan Biomedical Corporation, *Protocol 0301*: OptiScan Biomedical Corporation clamp study. 2003.
- 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 Sulfonylurea and Metformin. 2003 - 2004.
- 27) Genex 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.
- 30) Eli Lilly & Company, *Protocol F3Z-US-IOOQ*: A Comparison of Prandial Insulin Lispro Mixtures Therapy to Glargine Basal-Bolus Therapy With Insulin Lispro on the Overall Glycemic Control of Patients with Type 2 Diabetes Previously Treated With Oral Agents Combined With Insulin Glargine. 2004 – 2005.
- 31) Eli Lilly & Company, *Protocol H80-MC-GWAP*: Safety and Efficacy of Exenatide in Patients with Type 2 Diabetes Using Thiazolidindiones or Thiazolidindiones and Metformin. 2004 – 2005.
- 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.
- 33) Provalis Diagnostics Limited, *Protocol H01010PD02P*: Evaluation of the G5 HbA1c Test Using Office Staff Participants. 2004.
- 34) Amylin Pharmaceuticals, *Protocol 2993-119LTM*: An open-label study to examine the long-term effect on glucose control (HbA1c) and safety and tolerability of AC2993 given two times a day to subjects with type 2 diabetes mellitus. 2004 – 2006.
- 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) Biodel, 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) Biodel, *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.

- 76) InsuLine Medical. *Protocol G080106/B*. Protocol for Evaluation of the safety use of the InsuPatch Device in daily life conditions. 2010 – 2012.
- 77) Novo Nordisk Inc., *Protocol NN9068-3697*. DUAL™ I. DUal Action of Liraglutide and insulin degludec in type 2 diabetes. A trial comparing the efficacy and safety of insulin degludec/liraglutide, insulin degludec and liraglutide in subjects with type 2 diabetes. A 26-week randomised, parallel three-armed, open-label, multi-centre, multinational treat-to-target trial comparing fixed ratio combination of insulin degludec and liraglutide versus insulin degludec or liraglutide alone, in subjects with type 2 diabetes treated with 1-2 oral anti-diabetic drugs (OADS). 2011 – 2012.
- 78) Eli Lilly & Company. *Protocol I2R-MC-BIAJ*. A Comparison of LY2605541 Versus Insulin Glargine as Basal Insulin Treatment In CoMbinatiOn with OrAl Anti-HyperGlycemia Medications in INsulin NaïvE Type 2 Diabetes Mellitus: A Double-Blind, Randomized Study: The IMAGINE 2 Study. 2011 – 2014.
- 79) MannKind. *Protocol MKC-TI-171*. A Phase 3, Multicenter, Open-label, Randomized, Forced-titration Clinical Trial Evaluating the Efficacy and Safety of Technosphere® Insulin Inhalation Powder in Combination with a Basal Insulin Versus Insulin Aspart in Combination with a Basal Insulin in Subjects with Type 1 Diabetes Mellitus Over a 24-week Treatment Period. 2011 – 2013.
- 80) Eli Lilly & Company. *Protocol I2R-MC-BIAN*. The Impact of LY2605541 versus Insulin Glargine for Patients with Type 1 Diabetes Mellitus Treated with Preprandial Insulin Lispro: An Open-Label, Randomized, 78-Week Study (The IMAGINE 1 Study). 2011 – 2014.
- 81) Medtronic MiniMed, Inc. *Protocol CEP237/Z25/D*. ASPIRE (Automation to Simulate Pancreatic Insulin Response): Pivotal In Home study to determine safety and efficacy of the LGS feature in sensor-augmented pumps. 2011 – 2013. (Lead National Investigator).
- 82) Home Access Health Corporation. *Protocol 040412*: Clinical Chemistry Analysis Utilizing Micro-Serum/Micro Blood (Fingerstick) Specimen Collection. 2012.
- 83) Novo Nordisk Inc., *Protocol NN9068-3851*: DUAL™ III - GLP-1 Switch - The efficacy of insulin degludec/liraglutide in controlling glycaemia in adults with type 2 diabetes inadequately controlled on GLP-1 receptor agonist and metformin therapy. 2012 – 2014.
- 84) Novo Nordisk Inc., *Protocol NN9068-3951*: The efficacy of insulin degludec/liraglutide as add-on therapy in controlling glycaemia in adults with type 2 diabetes inadequately controlled on sulphonylurea with or without metformin therapy. 2012 – 2013.
- 85) Novo Nordisk Inc., *Protocol NN2211-3917*: The effect of liraglutide versus placebo when added to basal insulin analogues with or without metformin in subjects with type 2 diabetes. A 26-week double-blind placebo-controlled randomised multicentre, multinational parallel-group trial. 2012 – 2013.
- 86) Biodel, Inc. *Protocol 3-201*: A randomized, parallel group trial evaluating safety and efficacy of BIOD-123 compared to insulin lispro (Humalog®) in subjects with type 1 diabetes using basal-bolus insulin injection therapy. 2012 – 2013.
- 87) Amylin Pharmaceuticals, LLC. *Protocol BCB120*: A Randomized, Long-Term, Open-Label, 3-Arm, Multicenter Study to Compare the Glycemic Effects, Safety, and Tolerability of Exenatide

Once Weekly Suspension to Sitagliptin and Placebo in Subjects With Type 2 Diabetes Mellitus. 2012 – 2013.

- 88) Intarcia Therapeutics, Inc. *Protocol ITCA 650-CLP-103*: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Efficacy, Safety and Tolerability of ITCA 650 in Patients with Type 2 Diabetes. 2012 – 2013.
- 89) Intarcia Therapeutics, Inc. *Protocol ITCA 650-CLP-105*: A Phase 3, Randomized, Active Comparator, Double-Blind, Multi-Center Study to Compare the Efficacy, Safety and Tolerability of ITCA 650 to Sitagliptin as Add-on Therapy to Metformin in Patients with Type 2 Diabetes. 2012 – 2015.
- 90) Correlation Of Measurements Between In vivo Numerically Assessed blood glucose levels and Tear glucose levels In specimens Obtained Noninvasively (The COMBINATION Study). 2013 – 2016.
- 91) Halozyme, Inc., *Protocol: HALO-117-403 CONSISTENT I*: Evaluation of Metabolic Outcomes and Safety of Hylenex recombinant (hyaluronidase human injection) used as a Preadministration Infusion Site Treatment in Subjects with Type 1 Diabetes (T1DM) Using Continuous Subcutaneous Insulin Infusion (CSII). 2012 – 2015.
- 92) Novo Nordisk, Inc., *Protocol NN9211-3919*: The efficacy and safety of liraglutide as adjunct therapy to insulin in the treatment of type 1 diabetes: A 52-week randomized, treat-to-target, placebo-controlled, double-blinded, parallel group, multinational, multi-centre trial. 2013 – 2015.
- 93) Novo Nordisk, Inc. *Protocol NN1250-3995*: A randomised, double blind, cross-over trial comparing the safety and efficacy of insulin degludec and insulin glargine, both with insulin aspart as mealtime insulin in subjects with type 1 diabetes. 2013 – 2016.
- 94) Sanofi. Functional Evaluation of the Reusable JuniorSTAR® Half-Unit Insulin Pen. 2014-1015.
- 95) Eli Lilly & Company. *Protocol H9X-MC-GBDI*: A Randomized, Double-Blind Trial Comparing the Effect of Dulaglutide 1.5 mg with Placebo on Glycemic Control in Patients with Type 2 Diabetes on Basal Insulin Glargine. 2014 – 2016.
- 96) Novo Nordisk, Inc. *Protocol NN9211-4083*: The efficacy and safety of liraglutide as adjunct therapy to insulin treatment in type 1 diabetes: A 26-weeks randomised, insulin-capped, placebo-controlled, double-blinded, parallel group, multinational, multi-centre trial. 2014 – 2015.
- 97) Janssen Research & Development *Protocol 28431754DIA2004*: A Randomized Phase 2, Double-blind, Placebo-controlled, Treat-to-Target, Parallel-group, 3-arm, Multicenter Study to Assess the Efficacy and Safety of Canagliflozin as Add-on Therapy to Insulin in the Treatment of Subjects with Type 1 Diabetes Mellitus. 2014 – 2015.
- 98) Oramed. Protocol: Pharmaceuticals Inc. *Protocol: ORA-D-007*. Randomized, Double-Blind, Placebo-Controlled Study to Assess the safety and efficacy of Multiple Oral Bedtime Doses of ORMD-0801 (Insulin Capsules) in Adult Patients with Type 2 Diabetes Mellitus who are Inadequately Controlled with Diet and Metformin. 2015 – 2016.
- 99) Novo Nordisk, Inc. *Protocol NN9068-4185/ DUAL™ VII* - A clinical trial comparing efficacy and safety of insulin degludec/liraglutide (IDegLira) vs basal-bolus therapy in subjects with type 2 diabetes mellitus. 2015 – 2016.
- 100) Calibra Medical, Inc. Clinical Study *Protocol VP-00525*, Glycemic Control and Treatment Satisfaction Using Finesse Versus Pen for Initiating Bolus Insulin Dosing in Type 2 Diabetes

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

- 101) Lexicon Pharmaceuticals Inc. *Protocol: LX4211.309*. A Phase 3, Randomized, Double-blind, Placebo controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of LX4211 as Adjunct Therapy in Adult Patients with Type 1 Diabetes Mellitus Who Have Inadequate Glycemic Control with Insulin Therapy. 2015 – present.
- 102) Boehringer Ingelheim Pharmaceuticals, Inc. *Protocol: 1245.69*: Phase III, randomised, double blind, placebo efficacy, safety and tolerability trial doses of Empagliflozin as Adjunctive to in 52 weeks in patients with Type 1 Diabetes. 2015 – present.
- 103) Lexicon Pharmaceuticals Inc. *Protocol: LX4211.1-312-T1DM*. A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Net Clinical Benefit of Sotagliflozin as Adjunct to Insulin Therapy in Type 1 Diabetes. 2016 – present.
- 104) Bristol-Myers Squibb on behalf of AstraZeneca. *Protocol: MB102-230*. A Multicenter, Randomized, Double-Blind, Placebo-controlled, Parallel Group, Phase 3 Study to Evaluate the Efficacy and Safety of Dapagliflozin as an Add-on to Insulin Therapy in Subjects with Type 1 Diabetes Mellitus - Study Two. 2016 - present.
- 105) Bristol-Myers Squibb on behalf of AstraZeneca. *Protocol: CV181-369*: A 24-week International, Multicenter, Randomized, Open-Label, Active-Controlled, Parallel Group, Phase 3b Trial with a 28-week Extension to Evaluate the Efficacy and Safety of Saxagliptin Co-administered with Dapagliflozin Compared to Insulin Glargine in Subjects with Type 2 Diabetes who have Inadequate Glycemic Control on Metformin with or without Sulfonylurea Therapy. 2016.
- 106) Dexcom Inc. *Protocol: PTL-902309*. Feasibility Session Study: Evaluation of the Dexcom® Continuous Glucose Monitoring (CGM) System Performance in Non-Intensive Insulin Therapy Type 2 Diabetes Mellitus (T2DM) Adults. 2016 - present.
- 107) Novo Nordisk, Inc. *Protocol NN1218-3854*: Efficacy and Safety of Continuous Subcutaneous Insulin Infusion of Faster-acting Insulin Aspart compared to NovoRapid® in Adults with Type 1 Diabetes. 2016 - present. (Signatory Investigator)
- 108) Novo Nordisk, Inc. *Protocol NN9924-4233*: Efficacy and safety of oral semaglutide versus placebo in subjects with type 2 diabetes mellitus treated with diet and exercise only. 2016 – present.
- 109) Diasome Pharmaceuticals, Inc. *Protocol Number: 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 Investigational Product: Oral Hepatic Directed Vesicle-Insulin (HDV-I). 2017 - present. (Lead Investigator)
- 110) Novo Nordisk, Inc. *Protocol Number: NN1250-4252*: A trial comparing the efficacy and safety of insulin degludec and insulin glargine 300 units/mL in subjects with type 2 diabetes mellitus inadequately treated with basal insulin with or without oral antidiabetic drugs. 2017 - present.
- 111) Dexcom, Inc. *Protocol Number PTL-901895*. Post Approval Study for Non-Adjunctive Use of Dexcom G5 CGM System for Diabetes Management: Continuous Monitoring And Control of Hypoglycemia: The COACH Study. 2018 – present.