



d-data exChange

DIABETESMINE™  
INNOVATION PROJECT

"AN INCREDIBLE GATHERING OF INNOVATORS IN THE DIABETES SPACE"

AN ONLINE EXPERIENCE

Friday  
June 18, 2021

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# AGENDA

**8:15 am** | **Login & Chat**

**8:30** | **Welcome to #DData**  
Amy Tenderich, DiabetesMine

**8:50** | **"Consumer Adoption of Digital Tech + What's Next with 5G"**  
Brian Cooley, CInet

**9:20** | **Exploring FDA's Diabetes Innovation Pathways**  
Prabhu Raghavan and Alberto Guiterrez

**9:50** | **Diabetes DIY in 2021**  
Katarina Braune, OPEN Project Berlin

**10:20** | **Smart Pens Go Big**  
Medtronic/Companion Medical,  
Novo Nordisk, Eli Lilly

**11:05** | **Stretch Break**

**11:20** | **Hot #DData DEMOS (Round 1):**

- Bigfoot Unity
- Tidepool Loop
- DiaMon Tech
- Thrivable

**12:00 pm** | **Lunch Break**

**12:30** | **"Beyond Telehealth": Data-Driven Self-Care**

- New Research Results: One Drop, DiabetesMine & Thrivable
- Discussion: One Drop, Stanford Medicine, Crossover Health

**1:30** | **"Expanding Education & Support for CGM"**  
Molly Tanenbaum, Stanford Medicine

**1:45** | **"New Toolkits for Closed Loop Systems"**  
Laurel Messer, Barbara Davis Center

**2:00** | **"Access Is Everything"**  
Erika Emerson, National Diabetes Leadership Council

**2:30** | **The 'Other' Access Issue: Disaster Preparedness**  
BIPOC Video + Table Discussions

**2:45** | **Stretch Break**

**3:00** | **Hot #DData DEMOS (Round 2):**

- Agamatrix/Waveform
- Levels
- Nudge BG

**3:25** | **Closing Remarks**

**3:30 pm** | **Happy Hour / Facilitated Networking**

# EVENT HOST



## AMY TENDERICH, DIABETESMINE

Amy is Founder and Editor-in-Chief of DiabetesMine.com, a leading online information destination for people with diabetes that she launched after her diagnosis with type 1 diabetes in 2003. Since 2015, DiabetesMine has been part of San Francisco-based Healthline Media, where Amy also serves as Editorial Director, Diabetes & Patient Advocacy.

Amy is a journalist / blogger and nationally known patient advocate who hosts her own series of thought leadership events (the annual [DiabetesMine Innovation Summit](#) and biannual [DiabetesMine D-Data ExChange](#)) that bring patient entrepreneurs together with the medical establishment to accelerate change.

Amy was one of the early pioneers in the Diabetes Online Community (DOC), and has conducted numerous patient community research projects that have appeared in peer-reviewed journals, including the Journal of Diabetes Science and Technology. She serves as an advisor to the ADCES (Association of Diabetes Care and Education Specialists).

Amy holds an MA in Communication Studies from UC Santa Barbara. She has become a well-known public speaker at national diabetes, healthcare and health technology events, and periodic guest lecturer at Stanford University on health design topics.

# FEATURED SPEAKERS



## BRIAN COOLEY, CNET

Brian Cooley is editor at large at CNET, the largest publisher of consumer technology information. He's charged with following the consumer tech trends that drive today's modern lifestyle and demystifying what underlies hits and misses in the history of consumer tech adoption.



## PRABHU RAGHAVAN, MDQR

Prabhu Raghavan is a medical device quality and regulatory professional with over 20 years of experience in R&D, regulatory, and operations. He has held senior leadership positions in both startups and large organizations and now is a consultant helping medical device companies with regulatory affairs and quality assurance. Most recently he was Vice President of Regulatory and Quality at AliveCor, a startup utilizing artificial intelligence to help patients manage their arrhythmia.

Prior to that, Prabhu was Vice President of Regulatory, Quality and Clinical at Jan Medical, a startup focused on developing non-invasive techniques to detect brain abnormalities, including ischemic stroke. Before that, Prabhu was at Stryker where he held several leadership roles including Director of Global Supplier Quality for the MedSurg Group, and Director of Quality responsible for the quality operations for several manufacturing plants. Prabhu started his career as an R&D staff engineer at Bell Labs developing machine learning algorithms for automatic speech recognition and speech signal processing. Prabhu has 5 issued patents. He has an MS in Electrical Engineering from Rutgers University and a joint MBA from University of California Berkeley and Columbia University.

# FEATURED SPEAKERS



## ALBERTO GUTIERREZ, NDA PARTNERS

Alberto Gutierrez, Ph.D., is a partner with NDA Partners, a FDA regulatory consultant firm. Dr. Gutierrez retired from the FDA in 2017, after 25 years of working in research and regulation.

Dr. Gutierrez was the director of FDA's Office of In Vitro Diagnostics and Radiological Health for 8 years, responsible for the pre-market review and post-market regulation of in vitro diagnostics and radiology devices, as well as responsible for FDA's regulation of radiation-emitting products and regulation of mammography facilities in the US.

Dr. Gutierrez joined the FDA in 1992 as researcher and reviewer in FDA's Center for Biologics Evaluation and Research working on vaccine adjuvants and method development for determination of purity and structure of vaccine components. In 2000, he joined the Office of In Vitro Diagnostic Device Evaluation and Safety as a scientific reviewer, joining management in 2003.

Dr. Gutierrez received a bachelor's degree from Haverford College, and master and doctorate degrees in Chemistry from Princeton University. His research experience is in structural organic and organometallic chemistry.



## KATARINA BRAUNE, THE OPEN PROJECT

Dr. Katarina Braune is a medical doctor at Charité – University Hospital and digital clinician scientist of the Berlin Institute of Health in Germany. She is a pediatric endocrinology fellow, a digital health researcher with a focus on open-source and patient-led innovation.

She is also the co-chair of the Berlin chapter of the organization called Hacking Health. She also lives with type 1 diabetes herself for 20+ years and uses DIY looping, which she has studied extensively as a co-founder of the EU-funded "OPEN" project.



# FEATURED SPEAKERS



## DR. MOLLY TANENBAUM, STANFORD UNIVERSITY

Dr. Tanenbaum is a clinical health psychologist and clinical researcher with expertise in applying qualitative and mixed methods with the goal of improving health and quality of life. Her current research focuses on developing and evaluating interventions to improve uptake of continuous glucose monitoring technology for people living with type 1 diabetes.



## LAUREL MESSER, BARBARA DAVIS CENTER FOR DIABETES

Laurel Messer (Ph.D., RN, CDCES) is an Assistant Professor of Pediatrics at the Barbara Davis Center for Diabetes, University of Colorado School of Medicine. She is a clinical scientist who has specialized in the care of children, adolescents, and young adults with type 1 diabetes for over 16 years.

She is a research investigator in the PANTHER (Practical AdvaNced THERapies for Diabetes) research program at the BDC, conducting numerous clinical research studies related to insulin pumps, continuous glucose monitors (CGM), and automated insulin delivery/closed-loop systems.

She lectures and teaches about type 1 diabetes and diabetes technology at universities, hospitals, and national and international conferences, and has published over 40 peer-reviewed manuscripts related to implementation of diabetes technology.

Dr. Messer created the PANTHER Program ("Closing the loop on diabetes technology education) in order to provide freely accessible resources for clinicians and persons with diabetes related to diabetes technology: <http://BDCPantherDiabetes.org>.

# FEATURED SPEAKERS



## ERICA EMERSON, NATIONAL DIABETES LEADERSHIP COUNCIL

Erika B. Emerson is Executive Director of the Diabetes Leadership Council. She has more than 20 years of health policy and advocacy experience, including healthcare and pharmaceutical public policy, issues management, strategic communications and stakeholder relations.

Her biopharmaceutical industry experience and understanding of the U.S. healthcare system lend unique insight to state and federal policies impacting access, quality and value of care and coverage for people with chronic conditions.

Erika's health policy and patient advocacy experience is rooted in behavioral and mental health. A serendipitous introduction to the diabetes community sparked a heart-and-mind connection that expanded her policy interests and personal passion for patient-centered, individualized approaches to chronic disease care and coverage.

# FEATURED PANELISTS



## SØREN ØSTERGAARD, NOVO NORDISK

Søren has a passion for the interplay between pharmaceuticals and technology and how this can be used to improve people's lives. As an experienced leader with more than 15 years experience in the field of pharma, medtech and digital health, and a thought leader within the field of digital health, he has been able to unite and excite people towards how digital health can add value to big pharma, society and the health care system in general. He currently serves as Global Vice President, Digital Health for Novo Nordisk, a global leader in diabetes care.



## SEAN SAINT, MEDTRONIC

Sean Saint is Vice President, Medtronic Diabetes Business and InPen Founder. He is focused on ensuring a positive end-to-end customer experience across all Medtronic touchpoints, reimagining our engagements with healthcare providers and educators to broaden adoption of smart insulin pen technology and driving development of future smart insulin pen solutions that reduce the burden of living with diabetes.

Sean previously worked in roles of increasing responsibility at Tandem Diabetes Care, Alure Medical, Dexcom, and Medtronic/AVE.

He holds a Bachelor of Science degree in Mechanical Engineering from California Polytechnic State University – San Luis Obispo and is a registered Professional Engineer in the state of California. He has over 175 issued and pending patent applications.

Beyond his professional resume, Sean was diagnosed with type 1 as an adult and uses InPen today to manage his own diabetes.



# FEATURED PANELISTS



## CHALLIS IMES, ELI LILLY

Challis leads the commercial strategy and capability efforts for Lilly Diabetes' U.S. Connected Care and Insulins Business Unit. In her role, Challis is preparing for the launch of the connected platform that integrates connected insulin delivery devices, software, glucose sensing technology and digital decision support for open loop and closed loop platforms.

Challis joined Lilly in 2003 in the Musculoskeletal Business Unit and during her tenure has held multiple sales and marketing leadership roles in bio-medicines, diabetes and patient support.

Challis is actively involved in multiple Employee Resource Groups, including WILL (Women's Initiative for Leading at Lilly), PRIDE, OLA (Organization of Latinx at Lilly) and BE@Lilly (Black Employees at Lilly). She also serves as the President of the Zionsville Education Foundation, a nonprofit supporting academic excellence by funding teacher and student grants for the public school system. She currently lives in Zionsville, Indiana, with her husband Matt and two children. She enjoys most outdoor activities, watching her kids compete in multiple sports and traveling west to visit family.



## JAMILLAH HOY-ROSAS, ONE DROP

Jamillah Hoy-Rosas is a senior healthcare professional who has worked in the fields of nutrition and public health for over 20 years. Jamillah is a Registered Dietitian and Diabetes Educator who specializes in all areas of healthcare service delivery, particularly clinical operations, chronic disease self-management, health coaching, program and curriculum design, quality improvement, and HIPPA compliance. She has worked in the areas of clinical care coordination, medical case management, medical nutritional therapy, maternal and child nutrition, breastfeeding education, and worksite wellness. She is trained as a Lifestyle Coach for the National Diabetes Prevention Program, as a U.S. Diabetes Conversation Map® Program Facilitator, and as an Asthma Care Specialist.

Jamillah is currently the VP of Clinical Operations at One Drop, where she oversees the health coaching function to drive transformative behavior change for users living with chronic illnesses. Prior to that, she worked as the Chief Health Officer at City Health Works, a nonprofit health organization based in Harlem where they trained community health workers to provide health coaching and care coordination services to individuals living with chronic conditions.

Jamillah received her B.A. in Biological Basis of Behavior from the University of Pennsylvania and completed her RD and Master's Degree in Public Health Nutrition at New York University.

# FEATURED PANELISTS



## DR. STEPHEN EZEJI-OKOYE, CROSSOVER HEALTH

Dr. Stephen Ezeji-Okoye has served as Crossover Health's Chief Medical Officer since July 2019. Previously, he served as the Medical Director at Crossover's medical clinic at Facebook, Life @Wellness. Dr. Ezeji-Okoye came to Crossover Health in January 2019 from the VA Palo Alto Health Care System (VAP-AHCS), where he served for over 26 years, in the role of Deputy Chief of Staff for the last 12 years.

Dr. Ezeji-Okoye has also served as a Clinical Professor (Affiliated) at Stanford University School of Medicine, as a national consultant to the VA on the use of Integrative Medicine practices in VA care, and as an Advisory Council member to the National Institute of Health's National Center for Complementary and Integrative Health.

Dr. Ezeji-Okoye graduated magna cum laude from Harvard College where he earned an A.B. in Anthropology. He attended medical school at the University of Texas Health Science Center at Houston. He completed an internship, residency and chief residency in Internal Medicine at Stanford. He has a passion for population health and in redesigning systems to drive improvements in quality and efficiency. He was also recently diagnosed with type 1 diabetes himself.



## PRIYA PRAHALAD, STANFORD UNIVERSITY

Dr. Priya Prahalad is a Clinical Assistant Professor of Pediatrics and Pediatric Endocrinology at Stanford University and has an appointment with the Information Services department of Stanford Children's Health. She completed medical school and a Ph.D. in cell biology at Georgetown University. She completed a residency in Pediatrics and fellowship in Pediatric Endocrinology at Stanford University. She is also board certified in Clinical Informatics.

Dr. Prahalad's interests are in using technology to improve the quality of care delivery to children with diabetes. She is leading diabetes quality improvements in the division and is the Stanford lead for the T1DX-QI national registry and SWEET international diabetes registry. Dr. Prahalad participates in research efforts to use technology, such as continuous glucose monitors, insulin pumps, and telehealth, to improve outcomes in children with type 1 diabetes. She is also involved in research efforts to use technology to close health disparities in children with type 1 diabetes.

# DEMO COMPANIES



## BIGFOOT UNITY

Bigfoot Unity Diabetes Management System is a first-of-its-kind system integrating smart pen caps with continuous glucose monitor (iCGM) data and healthcare provider instructions to provide insulin dose recommendations for people with diabetes who use multiple daily injections (MDI) of insulin. It is the centerpiece of our larger Bigfoot Unity Diabetes Management Program, which takes a holistic approach to simplify and connect key aspects of insulin management. At its heart is the FreeStyle Libre 2 sensor that provides the Bigfoot Unity System with hypoglycemia alerts in real-time. The FreeStyle Libre brand is the #1 CGM worldwide. The Bigfoot Unity System is designed to clearly, and in real time, help answer the question, "How much insulin would my doctor recommend I take right now?"



## TIDEPOL LOOP

Built on the extraordinary foundation of the do-it-yourself diabetes community's original Loop app, Tidepool Loop is a first-of-its-kind project with the goal to take through FDA and bring to market cutting edge user-led innovations borne from this #WeAreNotWaiting community of innovators with the support of best-in-class medical device partners.

Tidepool Loop has been submitted to FDA as a controller (iAGC) that pairs with an ACE insulin pump and an iCGM using Bluetooth wireless communication. The app is designed to take in information about glucose and adjust a pump's basal insulin rates as often as every five minutes. Tidepool is working to make it possible for the app to be available for download from the App Store and compatible with commercially-available, in-warranty insulin pumps and CGMs.



## DIAMONTECH

DiaMonTech is a pioneering non-invasive glucose monitoring company. We have developed a medical device that measures blood glucose without a finger prick, drop of blood or test strip and provides results with comparable accuracy to commercial minimally-invasive CGM devices. By 2022, we will launch the mobile device that will drive our mission to increase the quality of life for the people affected by diabetes immensely.

# DEMO COMPANIES



## THRIVABLE

Thrivable connect patients and companies to create better products and services for the next generation of health care. Our real-time market research platform makes it easy for patients to be their own advocates by sharing their insights via surveys, interviews, usability studies and more.



## AGAMATRIX WAVEFORM

The WaveForm Continuous Glucose Monitor (CGM) is an easy, virtually pain-free way to monitor glucose for up to 14 days. This system is the only CGM on the market with a needle-less sensor insertion method, and multiple eco-friendly features, including a rechargeable transmitter and reusable sensor insertion tool. Gain insights with glucose readings measured every minute and transmitted directly to a smartphone application where glucose data, trends, alerts, and reports can be viewed. Customizable and predictive glucose alerts provide notifications when glucose is low or high, or other events that require the user's attention. We believe the combination of the long wear life of our sensor and our competitive cost profile can provide CGM access to a broader segment of people with diabetes.

Our system is commercially available through our distribution partner, A. Menarini Diagnostics S.R.L., under their GlucoMen Day brand in Western and Eastern Europe with expansion underway into Middle Eastern markets. For more information about the GlucoMen Day CGM visit: [www.glucomenday.com](http://www.glucomenday.com).

AgaMatrix Holdings d/b/a WaveForm Diabetes is a medical device company that develops, manufactures, and markets innovative glucose monitoring technology. With over 20 years of experience delivering high-quality, connected glucose monitoring products, we provide a suite of digital diabetes management solutions that we believe empowers people to build trust and confidence in managing diabetes.

# DEMO COMPANIES

## LEVELS

### LEVELS

Levels is the first consumer program that lets an individual know how food and lifestyle choices are directly affecting metabolic health, in real-time. We pair continuous glucose monitoring with intelligent software to support metabolic awareness for the general population. Our mission is to reverse the metabolic crisis by empowering individuals with personal health data so that they can make informed, personalized choices about diet and lifestyle.



### NUDGE BG

Nudge BG is an algorithm for AID (Automated Insulin Delivery) systems focusing on two principles: “simpler is better” and allowing users to choose their own levels of engagement.

Nudge BG’s goal is to create a system requiring less effort than existing sensor-augmented pumps and hybrid closed-loop systems, and with better outcomes than MDI or open-loop pump therapy.

To this end, Nudge BG will be a fully closed loop algorithm that does not require meal or exercise inputs. The system is designed to “nudge” basal insulin in response to CGM data.



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