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Professional Profile

With more than 15 years of experience in wearable technology, medical devices, and digital health solutions, Dr. Dowling brings extensive expertise in the evaluation, protocol design, data analysis, and regulatory requirements of digital health technologies (DHTs). She has developed digital technology strategies for clinical programs across multiple therapeutic areas and conducted verification and validation testing of novel digital devices against gold standards for use in clinical investigations.

She is also a subject-matter expert in data science as well as the development and deployment of digital biomarkers for drug development clinical trials. Her skills include creating novel machine learning algorithms for digital device data, conducting usability and validation testing with digital devices for fit-for-purpose applications, assessing the feasibility/capability of device vendors, and advising on regulatory considerations for digital health applications . She has overseen algorithm performance endpoint testing and documentation for successful FDA 510(k) submissions and developed biostatistical analysis plans to validate digital endpoints.

In addition, Dr. Dowling is one of the founding members of the Digital Medicine Society (DiMe), a global nonprofit that is driving the adoption of digital approaches to advance medicine and improve public health. She is a co-author and technical expert of the V3 framework (verification, analytical validation, and clinical validation), which is the primary international resource for evaluating DHTs to determine fit-for-purpose applications in clinical use cases throughout the healthcare value chain. She also serves on the external advisory committee for the Stanford Mobilize Center.

Academic Credentials & Professional Honors

Ph.D., Mechanical Engineering, Stanford University, 2011

M.S., Mechanical Engineering, Stanford University, 2007

B.A., Engineering Sciences, Dartmouth College, 2005

11/2020 Takeda DSI Summit 2020: Best Parallel Talk

01/2016 2015 JOSPT George J. Davies - James A. Gould Excellence in Clinical Inquiry

03/2010 Whitaker International Foundation Post-Doctoral Research Scholarship

03/2010 Fulbright Foundation Post-Doctoral Research Fellowship (declined due to acceptance of Whitaker)

08/2009 Veterans Administration Predoctoral Associated Health Rehabilitation Research Fellowship

05/2006 National Science Foundation Graduate Research Fellowship

06/2005 Tau Beta Pi National Engineering Honor Society

Professional Affiliations

Digital Medicine (DiMe) Society: 2019-present

Publications

Shanbhag NM, Padmanabhan JL, Zhang Z, Harel BT, Jia H, Kangarloo T, Yin W, Dowling AV, Laurenza A, Khudyakov P, Galinsky K, Latzman RD, Simuni T, Weintraub D, Horak FB, Lustig C, Maruff P, Simen AA. “An Acetylcholine M1 Receptor–Positive Allosteric Modulator (TAK-071) in Parkinson Disease with Cognitive Impairment: A Phase 2 Randomized Clinical Trial.” JAMA neurology, 2025.

Grossmann K, Risch M, Markovic A, Aeschbacher S, Weideli OC, Velez L, Kovac M, Pereira F, Wohlwend N, Risch C, Hillmann D, Lung T, Renz H, Twerenbold R, Rothenbühler M, Leibovitz D, Kovacevic V, Klaver P, Brakenhoff TB, Franks B, Mitratza M, Downward GS, Dowling AV, Montes S, Veen D, Grobbee DE, Cronin M, Conen D, Goodale BM, Risch L; COVID-19 remote early detection (COVID-RED) consortium. “Sex-specific differences in physiological parameters related to SARS-CoV-2 infections among a national cohort (COVI-GAPP study).” PLoS One, 2024; 19(3): e0292203.

Roussos, G., et al. “Identifying and characterizing sources of variability in digital outcome measures in Parkinson’s disease.” npj Digital Medicine, 2022; 5: 93.

Risch M, Grossmann K, Aeschbacher S, Weideli OC, Kovac M, Pereira F, Wohlwend N, Risch C, Hillmann D, Lung T, Renz H, Twerenbold R, Rothenbühler M, Leibovitz D, Kovacevic V, Markovic A, Klaver P, Brakenhoff TB, Franks B, Mitratza M, Downward GS, Dowling AV, Montes S, Grobbee DE, Cronin M, Conen C, Goodale BM, Risch L. “Investigation of the use of a sensor bracelet for the presymptomatic detection of changes in physiological parameters related to COVID-19 (COVI_GAPP).” BMJ Open, 2022; 12: e058274.

Brakenhoff TB, Franks B, Goodale BM, van de Wijgert J, Montes S, Veen D, Fredslund EK, Rispens T, Risch L, Dowling AV, Folarin AA, Bruijning P, Dobson R, Heikamp T, Klaver P, Cronin M, Grobbee DE; COVID-RED Consortium. “A prospective, randomized, single-blinded, crossover trial to investigate the effect of a wearable device in addition to a daily symptom diary for the remote early detection of SARS-CoV-2 infections (COVID-RED): a structured summary of a study protocol for a randomized controlled trial.” Trials. 2021; 22(1): 412.

Goldsack JC, Dowling AV, Samuelson D, Patrick-Lake B, Clay I. “Evaluation, Acceptance and Qualification of Digital Measures: From Proof-of-Concept to Endpoint.” Digital Biomarkers, 2021; 5(1): 53-64.

Stephenson D et al. “Precompetitive Consensus Building to Facilitate the Use of Digital Health Technologies to Support Parkinson Disease Drug Development through Regulatory Science.” Digital Biomarkers, 2020; 4(1): 28-49.

Goldsack JC, Coravos A, Bakker J, Bent B, Dowling AV et al. “Verification, analytical validation, and clinical validation (V3): the foundation of determining fit-for-purpose for biometric monitoring Technologies (BioMeTs).” npj Digital Medicine, 2020; 3(1): 1-15.

Lee SI, Adans-Dester CP, Grimaldi M, Dowling AV, Horak PC, Black-Schaffer RM, Bonato P, Gwin JT. “Enabling stroke rehabilitation in home and community settings: a wearable sensor-based approach for

upper limb motor training." IEEE Journal of Translational Engineering in Health and Medicine, 2018; 6: 2100411.

Dowling AV, Eberly V, Maneekobkunwong S, Mulroy SJ, Requejo PS, Gwin JT. "Telehealth monitor to measure physical activity and pressure relief maneuver performance in wheelchair users." Assistive Technology, 2016; 1-8.

Dowling AV, Stamler D, Felong TJ, Harris DA, Wong C, Cai H, Reilmann R, Little MA, Gwin JT, Biglan KM, Dorsey ER. "Wearable sensors in Huntington disease: a pilot study." Journal of Huntington's Disease, 2016; 5: 199-206.

Favre J, Clancy C, Dowling AV, Andriacchi TP. "Modification of Knee Flexion Angle Has Patient-Specific Effects on Anterior Cruciate Ligament Injury Risk Factors During Jump Landing." The American Journal of Sports Medicine, 2016; 44(6): 1540-1546.

Benjaminse A, Gokeler A, Dowling AV, Faigenbaum A, Ford KR, Hewett TE. Onate JA, Otten B, Myer, GD. "Optimization of the anterior cruciate ligament injury prevention paradigm: novel feedback techniques to enhance motor learning and reduce injury risk." Journal of Orthopaedic & Sports Physical Therapy, 2015; 45(3): 170-182.

Dowling AV, Barzilay O, Lombrozo Y, Wolf A. "An adaptive home-use robotic rehabilitation system for the upper body." IEEE Journal of Translational Engineering in Health and Medicine, 2014; 2: 1-10.

Dowling AV, Favre J, Andriacchi TP. "Characterization of Thigh and Shank Segment Angular Velocity during Jump Landing Tasks Commonly Used to Evaluate Risk for ACL Injury." Journal of Biomechanical Engineering, 2012; 134(9); 091006.

Dowling AV, Favre J, Andriacchi TP. "Inertial sensor-based feedback can reduce key risk metrics for ACL injury during jump landings." The American Journal of Sports Medicine, 2012; 40(5): 1075-1083.

Dowling AV, Favre J, Andriacchi TP. "A wearable system to assess risk for anterior cruciate ligament injury during jump landing: measurements of temporal events, jump height, and sagittal plane kinematics." Journal of Biomechanical Engineering, 2011; 133(7); 071008.

Dowling AV, Corazza S, Chaudhari AMW, Andriacchi TP. "Shoe-Surface Friction Influences Movement Strategies during a Sidestep Cutting Task: Implications for Anterior Cruciate Ligament Injury Risk." The American Journal of Sports Medicine. 2010; 38(3): 478-485.

Dowling AV, Fisher DS, Andriacchi TIP. "Gait modification via verbal instruction and an active feedback system to reduce peak knee adduction moment." Journal of Biomechanical Engineering. 2010; 132(7); 071007.

Presentations

ADDS. "Frome EEG to PPG to ACC: Usage of Digital Devices to Quantify Sleep in Clinical Trials." Actigraph, Pensacola FL, 2024.

CNS Summit. "Why Implement Digital Biomarkers in Clinical Trials." Roche Spotlight Session, Boston MA, 2023.

Digital Biomarkers and Digital Measurements Summit East. "From Analog to Digital: Reinventing Endpoints for Clinical Trials." Grey Green, Boston MA, 2023.

mHealth Research Seminar. "The V3 Framework in Action: case studies of analytical validation and clinical validation of digital health technologies." Washington University, St. Louis MO, 2023.

ISCTM Autumn Conference. “Verification, analytical validation, and clinical validation for biometric technologies.” Boston MA, 2022

DIA Global. “The Role of Sensors in Clinical Research: Integrating Sensor Generated Data into Data Platforms to Power Clinical Research and Patient Care.” DIA, Chicago IL, 2022.

Scope Summit. “Validating Digital Biomarkers and Endpoints”. Cambridge Healthtech Institute, Orlando FL, 2022.

Scope Summit. “Digital Ops: Integrating and Validating Multiple Digital Devices in a Clinical Trial.” Cambridge Healthtech Institute, Virtual, 2021.

CNS Summit. “Developing an Effective Data Asset Strategy for Wearable Devices in Clinical Trials.” ActiGraph Spotlight Session, Virtual, 2020.

Bio-IT World. “Wearable Devices in Drug Development Clinical Trials: Case Studies.” Cambridge Healthtech Institute, Virtual, 2020.

DIA Digital Technology in Clinical Trials. “Evaluation of Digital Technologies to Demonstrate Clinical and Analytical Validation.” DIA, Virtual, 2020.

PRISME Forum Tech Meeting. “GCP Compliant Data Transfer of Wearable Device Data in Clinical Trials: A Case Study in Parkinson’s Disease.” Alexion Pharmaceuticals, Boston MA, 2019.

Grace Hopper Celebration. “Wearable Technology in Clinical Trials for Parkinson’s Disease.” AnitaB.org, Houston TX, 2018.

EMBL-EBI Wearable Technologies Industry Workshop. “Machine Learning for PD: Identifying Bradykinesia.” Takeda Pharmaceuticals, Cambridge MA, 2018.

Project Experience

- Managed a team focused on evaluating and deploying digital health technologies in clinical trials: developed novel endpoints; conducted internal feasibility/capability assessments of multiple device vendors; oversaw verification and validation testing of novel digital devices against gold standards, including wearable EEG systems to measure sleep, at-home vital signs devices, and pediatric-focused monitors
- Led digital device strategies for clinical programs across all therapeutic areas: wrote digital technology sections of drug development clinical trial protocols (phase I, II, and III); primary business owner of the SOP to evaluate, select, and manage the qualification and contracting of digital technology vendors for clinical trials; core member of multiple clinical teams as SME for digital technology and biomarkers; created novel machine learning algorithms for digital device data from Parkinson’s Disease patients
- Head of internal testing and simulation lab: partnered with legal and HR to develop consent form to collect deidentified data from employees; wrote SOP for how to conduct internal usability and validation testing with digital devices; developed methods for internally simulating clinical site visits with digital devices
- Served as PI and subject matter expert in algorithm design and digital device selection for IMI MOBILISE-D and IMI COVID-RED consortiums (industry co-lead for algorithm work package)
- Contributed to regulatory filings with the FDA and the EMA on the development and acceptance of endpoints derived from wearable device data in late-stage clinical trials
- Oversaw development and testing of cardiac and biomechanics algorithms; managed algorithm testing and documentation for FDA 510(k) submission by creating and testing algorithm

performance endpoints and developing biostatistical analysis plan to validate performance endpoints

Advisory Appointments

Stanford Mobilize Center: External Advisory Committee, 2021 to Present

FDA: Digital Health Network of Experts, 2020 to 2023

DiMe Society: Strategic Advisory Board (founding member), 2019 to Present

Peer Reviews

npj Digital Medicine