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Engineering & Scientific Consulting

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Professional Profile

Ariel Dowling, Ph.D., is a principal in the Biomechanics practice at Exponent with more than 15 years of experience in wearable technology, medical devices, and digital health solutions. She specializes in digital biomarker development and FDA endpoint approval, decentralized clinical trial design and execution for drug development, verification and validation for digital health technologies (DHTs) and algorithms, AI algorithms for health metrics in wearable devices, and IP disputes involving healthcare wearables.

Dr. Dowling is a data science subject-matter expert with extensive experience in 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.

Dr. Dowling is one of the founding members of the Digital Medicine Society (DiMe), a global nonprofit driving the adoption of digital approaches to advance medicine and improve public health. She is a co-author 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.

Digital biomarker development and FDA endpoint approval

Dr. Dowling has created and validated digital biomarkers for use as clinical trial endpoints, including in rare disease indications. Her work has focused on translating high-frequency digital signals into clinically meaningful endpoints through rigorous analytical methods and confirmatory validation studies. Her understanding of Food and Drug Administration evidentiary requirements and qualification processes helps these digital biomarkers meet regulatory standards for reliability, clinical relevance, and patient benefit.

Decentralized clinical trial design and execution for drug development

Dr. Dowling has led a variety of drug-development decentralized clinical trials (DCTs). She has designed and executed both hybrid and fully virtual clinical trial protocols that leverage telemedicine, remote monitoring with digital devices, and digital data capture while maintaining data quality and regulatory compliance. She has also developed biostatistical analysis plans to validate digital endpoints in DCTs.

Verification and validation for digital health technologies and algorithms

Dr. Dowling has developed digital health 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 has designed and executed rigorous testing frameworks for test devices/algorithms, established acceptable performance metrics, and applied statistical and clinical validation methods to confirm technical functionality and clinical relevance. Dr. Dowling has also overseen algorithm performance endpoint testing and documentation for successful FDA 510(k) submissions.

AI algorithms for health metrics in wearable devices

Dr. Dowling's extensive expertise in data science includes the use of machine learning and AI for wearable device data. Her previous AI algorithm design work combines data science, biomedical signal processing, and embedded system design to develop algorithms that extract accurate, meaningful health insights from continuous sensor data. She has designed machine learning and physiological models that detect, classify, and predict health metrics in real time, such as classifying activities of daily living, identifying disease status, and predicting future disease symptoms. Her deep understanding of clinical validation, regulatory expectations, and device integration helps ensure that her AI-driven algorithms are reliable, interpretable, and suitable for use in both consumer and clinical settings.

IP disputes involving healthcare wearables

Dr. Dowling has experience in intellectual property (IP) disputes involving both consumer and medical wearable devices. She has analyzed wearable device algorithms and output data for issues involving patent originality, infringement, and reduction to practice within the complex patent landscape of digital health. Her knowledge supports litigation cases involving strategic IP protection and dispute resolution by bridging the technical nuances of algorithm design with the legal frameworks that govern healthcare technology innovation.

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

Digital biomarker development and FDA endpoint approval

- Led retrospective proof-of-concept study of 40 participants to develop a digital biomarker to detect sweat initiation for Fabry disease.
- Contributed to the development of digital biomarkers to detect multiple sleep metrics in patients with narcolepsy from wearable device data, including sensors that measure brain activity, movement, and heart rate, in the TAK-861 drug development program.
- Advised DECODE industry consortium focused on developing novel digital biomarkers to detect nocturnal scratching in patients with psoriasis.
- Contributed to regulatory filings with the Food and Drug Administration and the European Medicines Agency on the development and acceptance of endpoints derived from wearable device data in late-stage clinical trials.

Decentralized clinical trial design and execution for drug development

- Led development of decentralized clinical trials involving digital devices for multiple clinical programs, including writing the DCT technology sections of drug development clinical trial protocols (phase I, II, and III).
- Evaluated multiple DCT platforms to determine fit-for-purpose based on specific clinical trial protocol requirements for TAK-861 and other clinical programs.
- Created and maintained internal SOP to evaluate, select, and manage the qualification and contracting of digital technology vendors for DCTs.

- Coordinating study-startup, execution, and data analysis of large-scale (300+ patients) hybrid DCT across multiple sites focused on measuring body composition in participants with obesity for the FNIH REAL-BODY program.

Verification and validation for digital health technologies and algorithms

- Oversaw multiple studies focused on evaluating and deploying digital health technologies in clinical trials, including conducting internal feasibility/capability assessments of multiple devices.
- Expertise in testing and validating an extensive range of digital health technologies, including wearable EEG systems to measure sleep, at-home vital signs devices for heart rate, blood pressure, and oxygen saturation, smartwatches and phones that measure activities of daily living, pediatric-focused monitors, and hearing loss wearable devices.
- Head of on-site testing and simulation laboratory focused on conducting usability and validation testing with digital devices and simulating clinical site visits.

AI algorithms for health metrics in wearable devices

- Created novel machine learning algorithm based on wearable device data from Parkinson's Disease patients to identity which features best predict disease status and severity.
- Served as PI and subject matter expert in algorithm design and digital device selection for algorithm work package of the IMI MOBILISE-D and IMI COVID-RED consortiums.
- Oversaw the development and testing of AI-based cardiac and daily living activities algorithms cleared by the FDA through the 510(k) submission process.

IP disputes involving healthcare wearables

- Expert witness for patent infringement and originality disputes based on health algorithms from fitness-focused smartwatches.

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