## The Evolution of DATAcc by DiMe's Library of Digital Endpoints

Jan 2018 The Centers for Medicare & Medicaid (CMS) for remote patient monitoring (RPM) services officially allows CPT 99091 for separate reimbursement

Apr 2019 European Medicines Agency (EMA) qualifies stride velocity 95th centile (SV95C) as a secondary endpoint in Duchenne Muscular Dystrophy (DMD) measured by wearables

Nov 2019 STAT publishes an article on the Library of Digital Endpoints aiding in clinical trials

Mar 2020 The COVID-19 pandemic drives widespread lockdown

Dec 2021 The FDA releases draft guidance on Digital Health Technologies (DHTs) for Remote Data Acquisition in Clinical Investigations

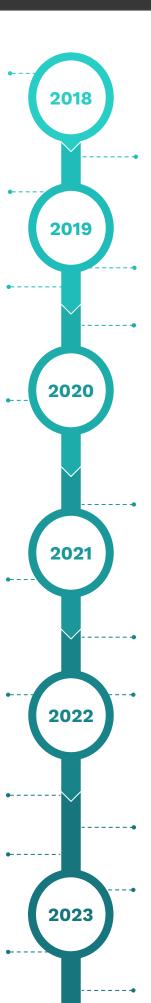
Mar 2022 The White House Office of Science and Technology Policy (OSTP) requests input on how DHTs can transform community health, individual wellness, and health equity

Jan 2023 AMA updates the RTM code set released in 2022 to include CPT 98978

**June 2023** Bellerophon Therapeutics clinical trial fails despite using innovative digital endpoints

Sept 2023 DiMe's Digital Measures and Diagnostics Portfolio, including the Library of Digital Endpoints, strategically shifts under <u>DATAcc</u> by <u>DiMe</u>, a <u>collaborative</u> community with the FDA's Center for Devices and Radiological Health







Jan 2019 The American Medical Association (AMA) introduces three new current procedural terminology (CPT) codes for RPM: 99453, 99454, and 99457

Oct 2019 <u>DiMe</u> publishes the <u>Library</u> of Digital Endpoints

Jan 2020 The remote monitoring code set expands to include CPT 99458

May 2021 Launch of the Digital Health Measurement collaborative community (DATAcc) with FDA participation

Jan 2022 AMA releases five new remote therapeutic monitoring (RTM) codes: 98975, 98976, 98977, 98980, and 98981

Mar 2022 DiMe launches the 3Ps of Digital Endpoint Value for using digital endpoints in clinical trials



May 2023 FDA publishes its "Decentralized Clinical Trials for Drugs, Biological Products, and Devices" guidance

Jul 2023 EMA qualifies SV95C as a primary endpoint in DMD measured by wearables

Nov 2023 DATAcc by DiMe's Library of Digital Endpoints celebrates its fourth anniversary with 63 sponsors and 405 endpoints

