The Growing Maturity of Digital Health Tools

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HIMSS21

Welcome

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Conflict of Interest

Murray Aitken, MBA

Has no real or apparent conflicts of interest to report.

Agenda

- Background to this research
- Key messages
- Research findings
- Q&A

Learning Objectives

- Summarize the landscape of digital health tools including wearables, digital biomarkers and health/medical apps focused on wellness and disease prevention/treatment
- Contrast the evidence requirements of health apps versus an emerging class of digital therapeutics and their commercial models
- Discover the novel means of remote patient monitoring being used both within clinical trials and in real-world settings that are emerging and being accelerated by COVID-19
- Compare the barriers to, and facilitators of, adoption including shifting government policies worldwide, payer and employer adoption and reimbursement approaches

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The Growing Maturity of Digital Health Tools

Key messages

- **Consumer health apps** proliferate, become more disease specific, and more are of higher quality
- **Digital Therapeutics and Digital Care products**, backed by outcomes evidence, grow in number and endorsement by healthcare professionals
- **Validated wearables and digital biomarkers** are expanding and gaining adoption in clinical trials and clinical care delivery, enabling remote monitoring of patients
- **Evidence** of the impact on health outcomes from use of digital health tools is mounting and more robust, and supports inclusion in treatment guidelines for an expanded set of health indications
- **Commercialization** is also maturing with multiple pathways to market now established and propelled by pandemic-driven efforts to accelerate use of digital health tools – growing investment capital flowing into the digital health space suggests increased confidence in the opportunity for digital health tools to yield meaningful results for patients, health systems and investors

Digital Health Tools in the Patient Journey During COVID

Care Team Email and Text Messages
helped patients communicate with their care team while at home

Health System Disease Management Apps
enabled remote patient monitoring outside traditional healthcare settings

Consumer Mobile Apps
provided information about COVID-19, tracked symptoms, provided home fitness programs

Digital Therapeutics
delivered interventions through software for select conditions

Consumer Wearables
monitored activity and various digital biomarkers of health

Connected Biometric Sensors
tracked vitals including oxygen saturation and helped patients self-monitor

Smartphone Cameras
to capture skin lesions and other health images and enable remote patient exams via telemedicine

Patient receiving care at home

Web-based Interactive Programs
delivered digital care programs, physical therapy, CBT programs for insomnia and other therapeutic interventions

Personal Health Records
were more accessible than ever online, facilitating care continuity

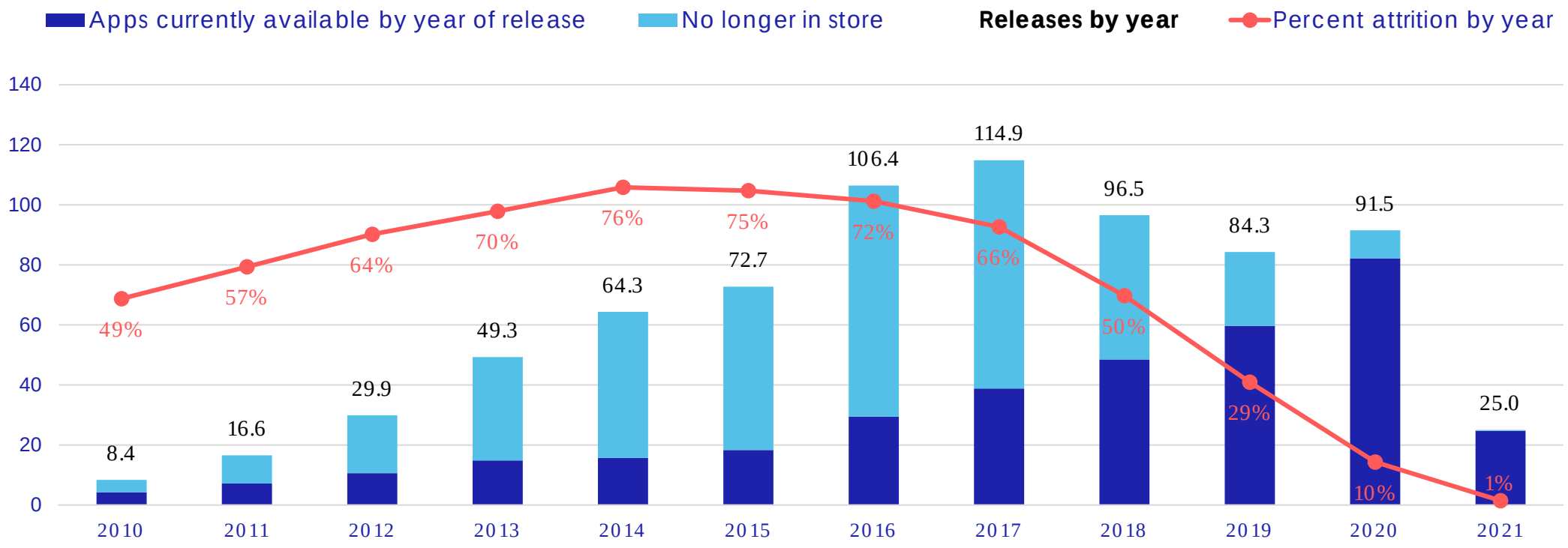
Telemedicine and Virtual Physician Visits
supported remote clinician contact and care

In-Home Connected Virtual Assistants
were still little used but can guide patients to health information, office numbers and EHR data, or push reminders

Clinical Trial Tools
collected patient information and enabled virtual trials or trials with virtual elements

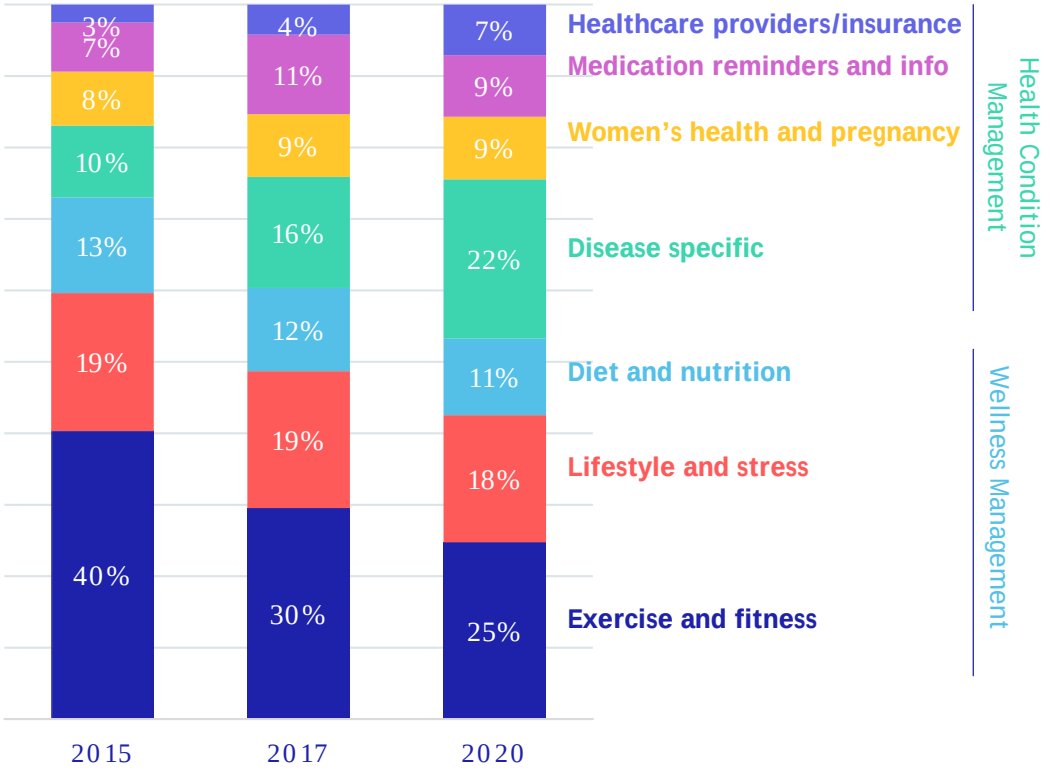
Source: IQVIA Institute, Jun 2021

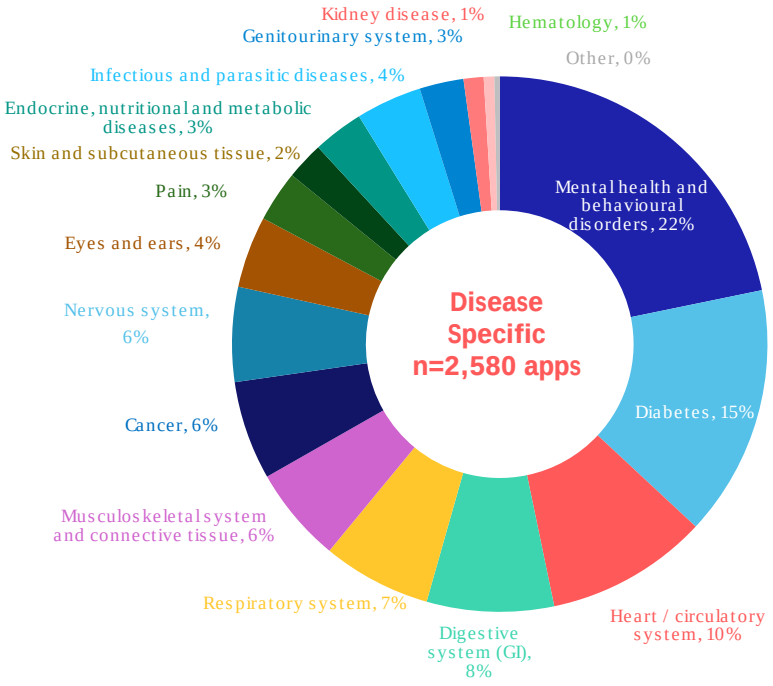
The Release and Removal of Health Apps from Stores Over Time



Source: 42 Matters, Jun 2021 and Jul 2017; Mevvy, Jun 2015; IQVIA AppScript App Database, Jun 2021; IQVIA Institute, Jun 2021
Note: Includes digital health apps that are publicly available to consumers and categorized as Health & Fitness or Medical.

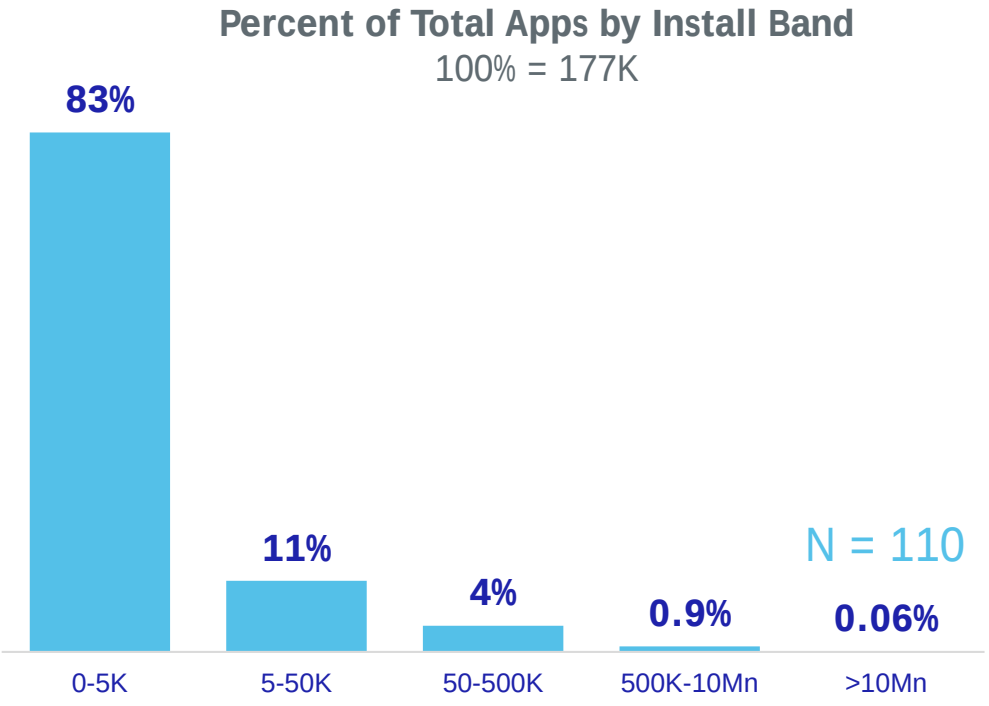
Digital Health Apps by Category and Disease State 2020

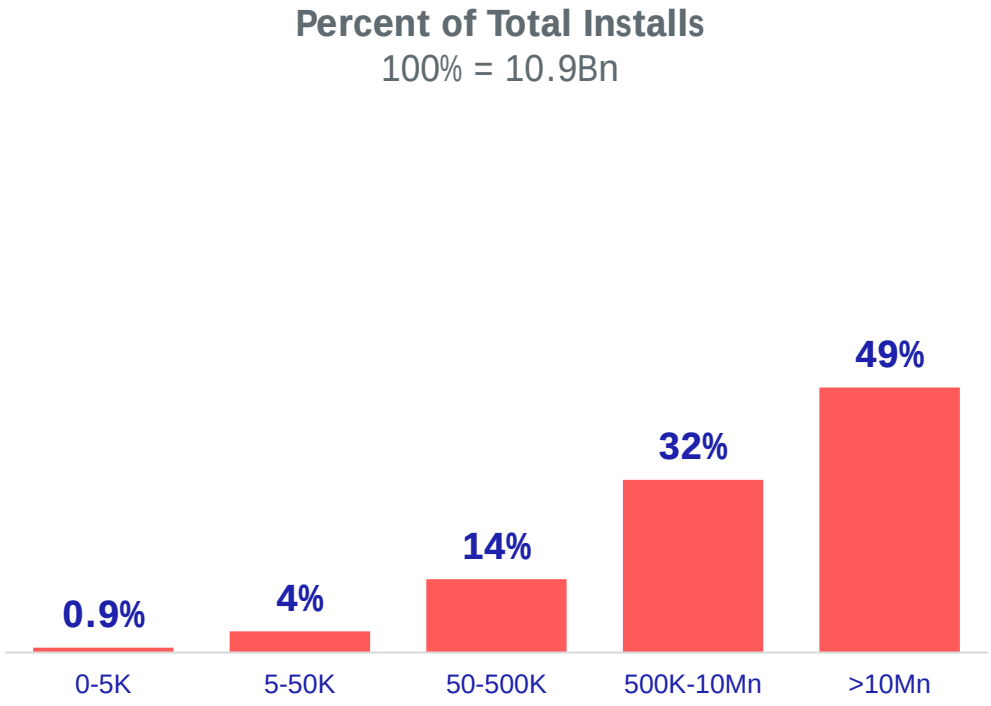




Source: 42 Matters, Jun 2021 and Jul 2017; Mevvy, Jun 2015; IQVIA AppScript App Database, Jun 2021; IQVIA Institute, Jun 2021
Note: Chart displays percent of categorizations. Numbers may not sum due to rounding; 2020 data includes 11,543 unique apps with 11,569 categorizations. 2017 data includes 11,216 unique apps with 11,249 categorizations. 2015 data includes 24,012 apps with 24,088 categorizations. View removes uncategorized apps from 2015 published numbers. 2020 view removes apps not in store, rejected as not health apps by AppScript and pending review.

Digital Health App Downloads
Top Apps Account for Nearly Half of Installs 49.3%

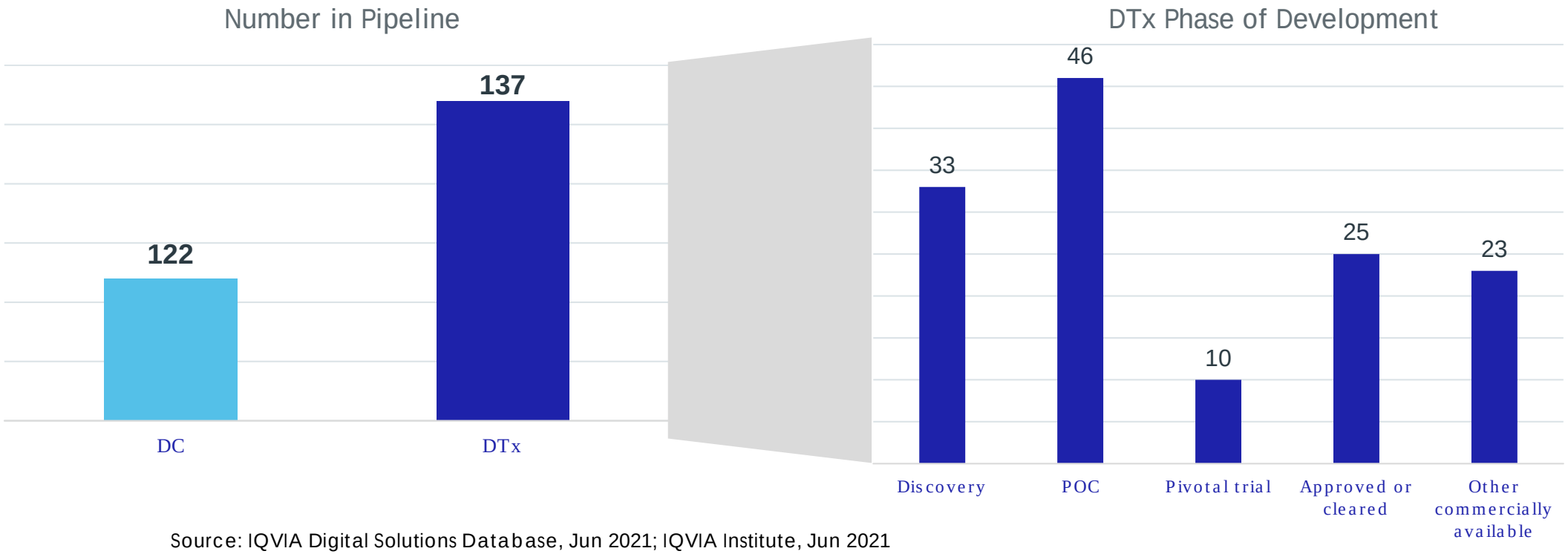




Source: 42 Matters, Jun 2021, Sep 2017; IQVIA AppScript Database, Jan 2021, Sep 2017; IQVIA Institute, Sep 2017
Note: Install data shown is from the Google Play app store only. Apple store install data not available.

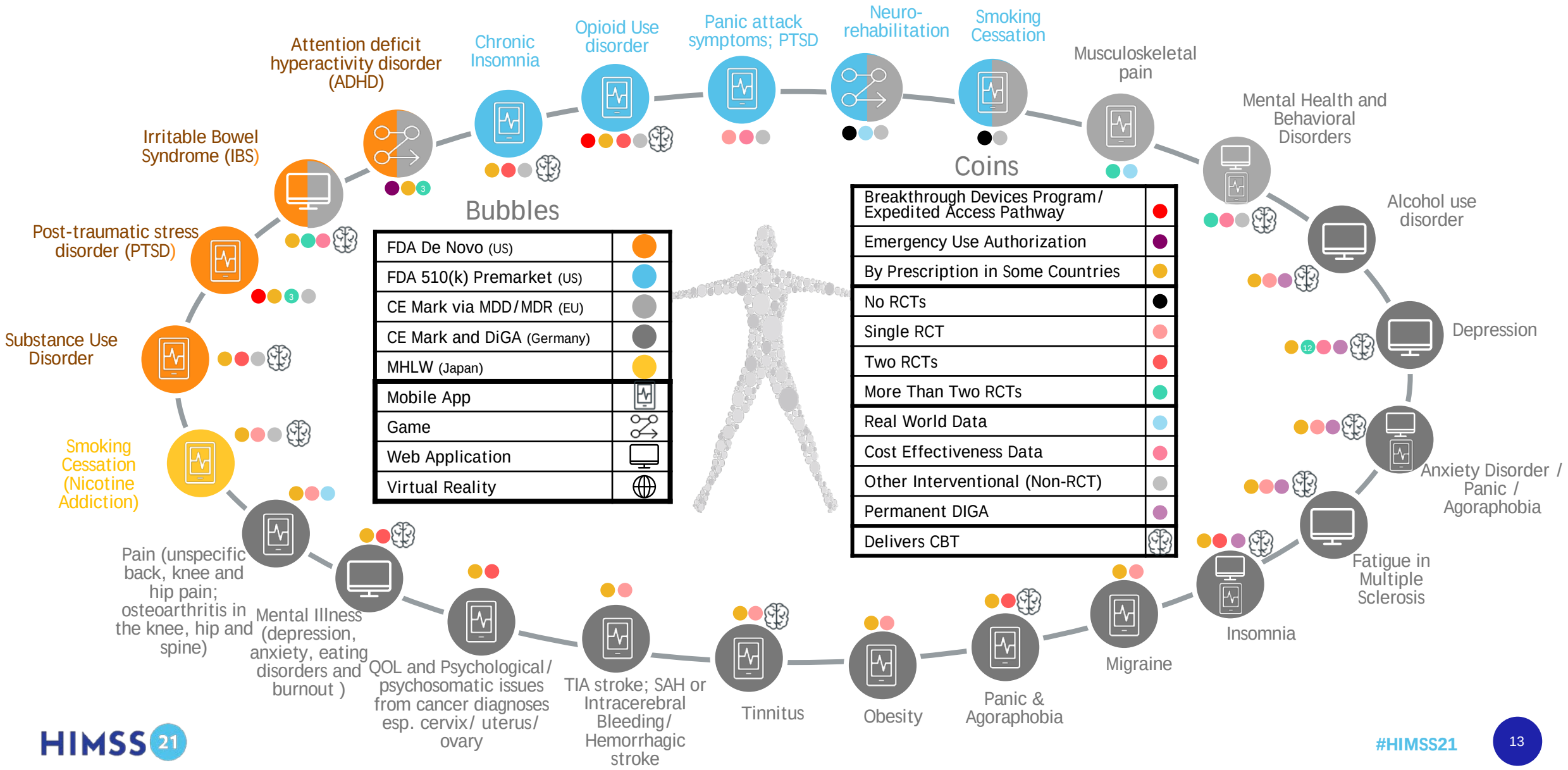
A Total of 259 Digital Therapeutics (DTx) and Digital Care (DC) Programs and Tools have been Identified Across all Phases

Number of Digital Therapeutics (DTx) and Digital Care (DC) Programs and Tools, and DTx Pipeline Status



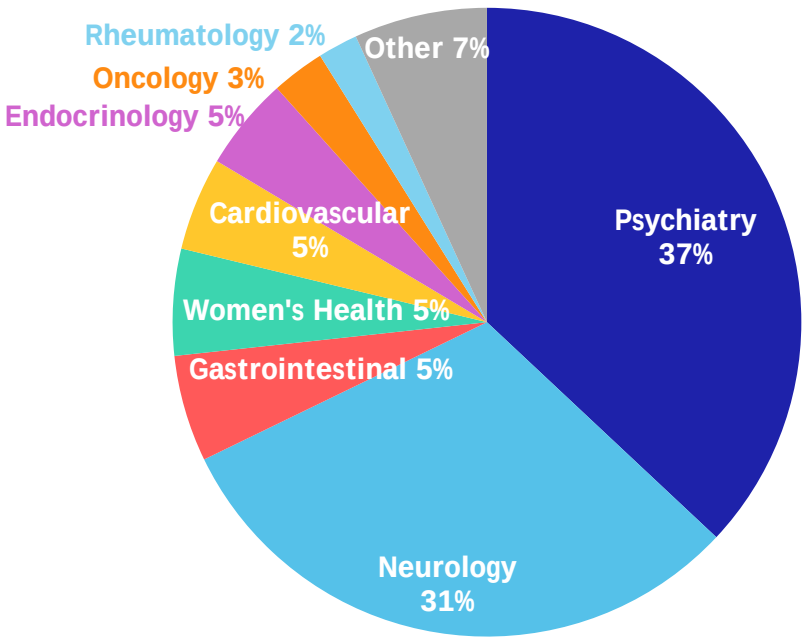
Source: IQVIA Digital Solutions Database, Jun 2021; IQVIA Institute, Jun 2021
Note: May underestimate the number of EU CE Marked devices that haven't gone through established reimbursement processes.
Other commercially available.

Digital Therapeutics with Market Authorization through Select Pathways and their Features

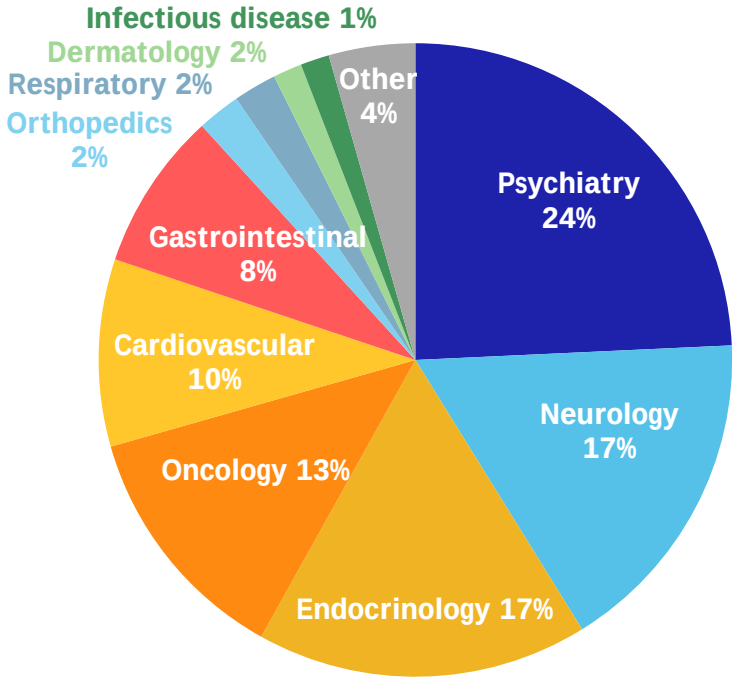


Therapeutic Focus of DTx and DCs Across All Phases of Development, 2021

N=137 Digital Therapeutics

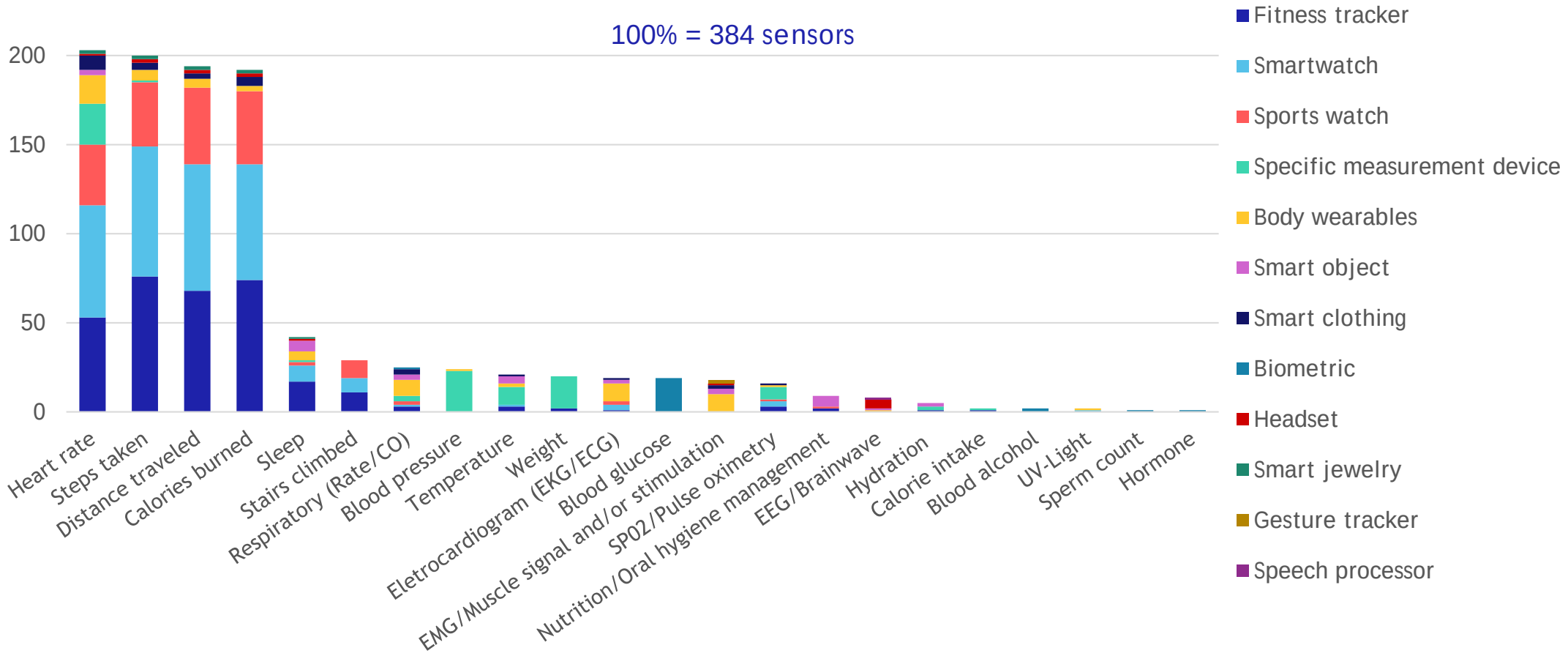


N=122 Digital Care Programs



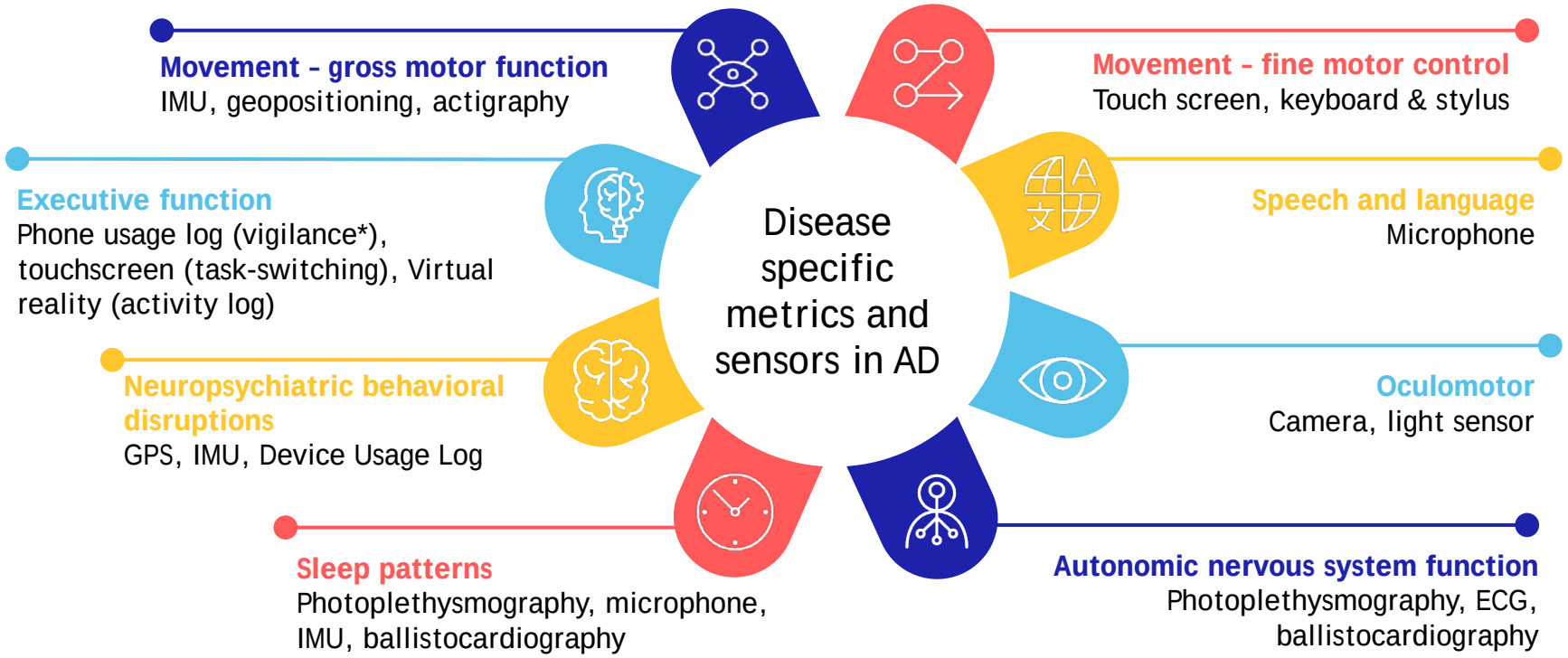
Source: IQVIA Digital Solutions Database, Jun 2021; IQVIA Institute, Jun 2021
Note: Other DCs include Rheumatology, Hearing Disorder, Urologic disease, Women's Health / Sexual Health. Other DTx includes Includes Dermatology, liver disease, Metabolic Disorder, Movement Disorder, Ophthalmology, Orthopedics, Respiratory, Transplantation, Vision disorders. DTx and DCs that treat multiple therapy areas are counted in each, such that DTx were mapped 146 times and DCs 136 times.

Parameters Measured by Consumer Digital Health Devices by Type



Report: IQVIA Institute for Human Data Science. Digital Health Trends 2020: Innovation, Evidence, Regulation and Adoption
Source: IQVIA AppScript Device Database, Mar 2021; IQVIA Institute, Mar 2021
Note: Chart includes data from 384 sensors. Total exceeds 384 due to multiple measures being tracked by a single sensor. Specific measurement devices include vitals measurement.

Mobile / Wearable Digital Consumer Technology Offers a Potential Path Towards Clinical Grade Digital Phenotyping in AD



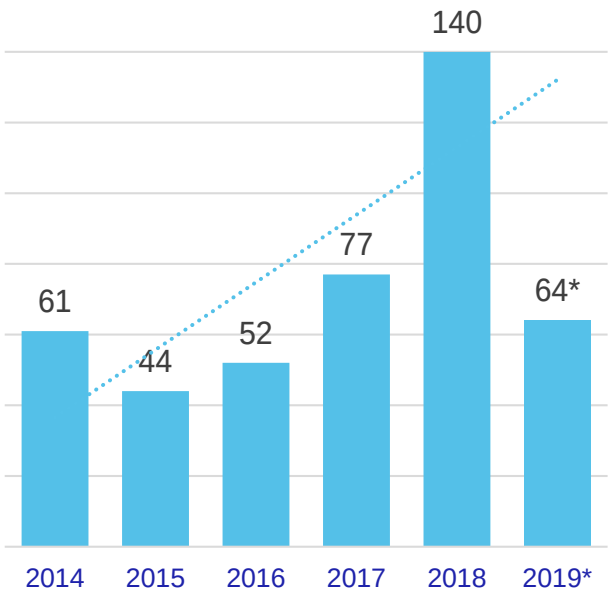
Source: Kourtis, L.C., Regele, O.B., Wright, J.M. et al. Digital biomarkers for Alzheimer's disease: the mobile/wearable devices opportunity. npj Digital Med 2, 9 (2019).
Notes: Vigilance refers to the ability to sustain attention on a task and is a measure of overall attention. IMU = Inertial measurement unit, ECG = Electrocardiogram, GPS = Global positioning system

The Number of Feasibility Studies to Improve the Value of Digital Biomarkers has been Growing Since 2014, with Neurology, Musculoskeletal Disorders and Sleep Accounting for Over Half of Studies

Feasibility Studies on Digital Biomarkers Since 2014 and by Therapy Area and Device Type

Total = 438 studies on 933 biomarkers

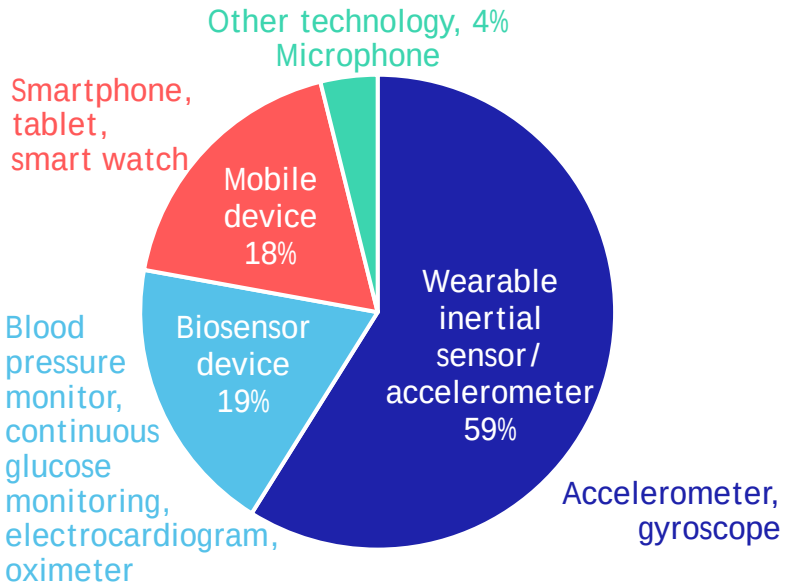
Number of published feasibility studies for digital biomarkers



Number of feasibility studies for digital biomarkers by therapy area

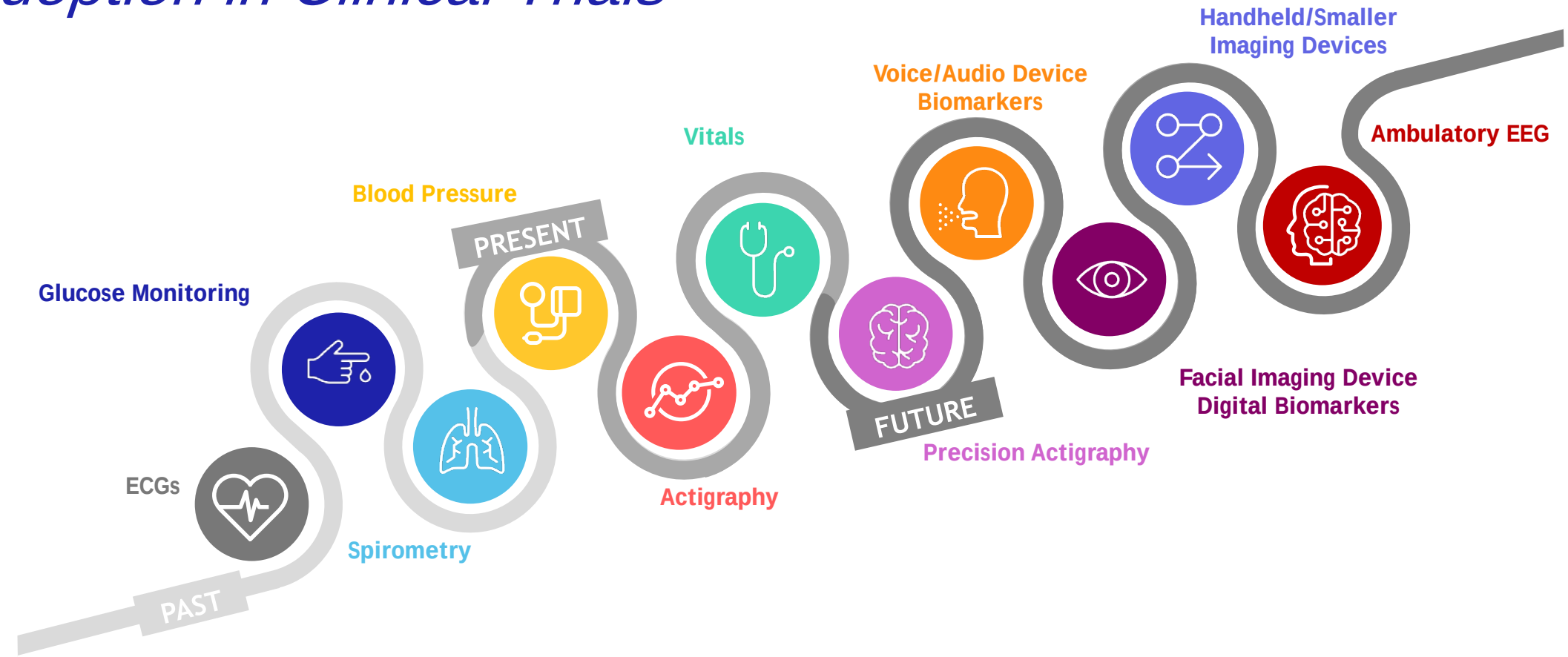
Therapy area	# (n%)
Neurology	178 (26%)
Musculoskeletal	168 (24%)
Sleep	49 (7%)
Pulmonary/Respiratory	49 (7%)
Cardiology	44 (6%)
Endocrinology	38 (5%)
Pediatrics	37 (5%)
Orthopedics	19 (3%)
Psychiatry	14 (2%)
Oncology	13 (2%)
Women's Health/Sexual Health	13 (2%)
Obesity/Weight Loss	12 (2%)
Aging	11 (2%)
Ophthalmology	11 (2%)
All others	37(5%)

Number of feasibility studies for digital biomarkers by type of device



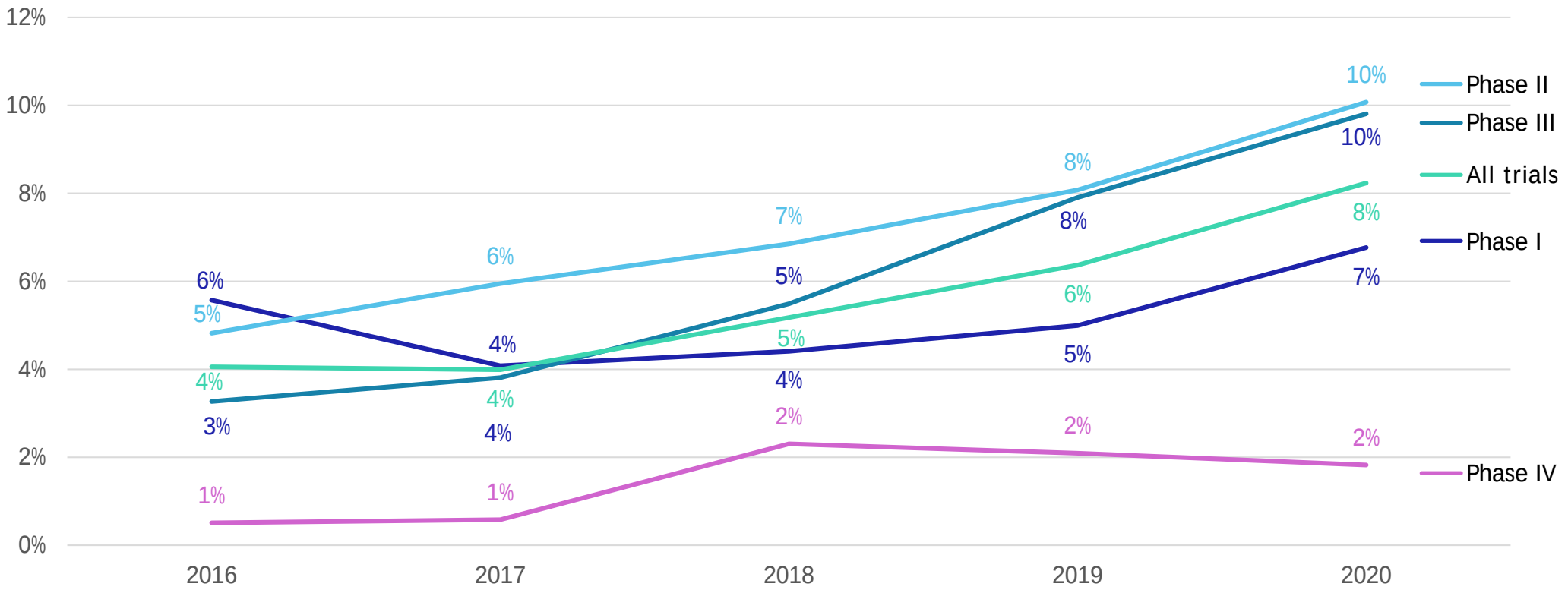
Source: CTTI, Nov 2020, https://feasibility-studies.ctti-clinicaltrials.org. IQVIA Institute, Jun 2021
Notes: Database includes a systematic search of scientific literature indexed in PubMed and published between January 2014 and June 2019. The term "pilot" was not in the original search from January 2014–May 2018 dataset but was included in the review from June 2018–June 2019. One study from 2013 removed and one duplicate title.

Waves of Connected Medical Device Technology Adoption in Clinical Trials



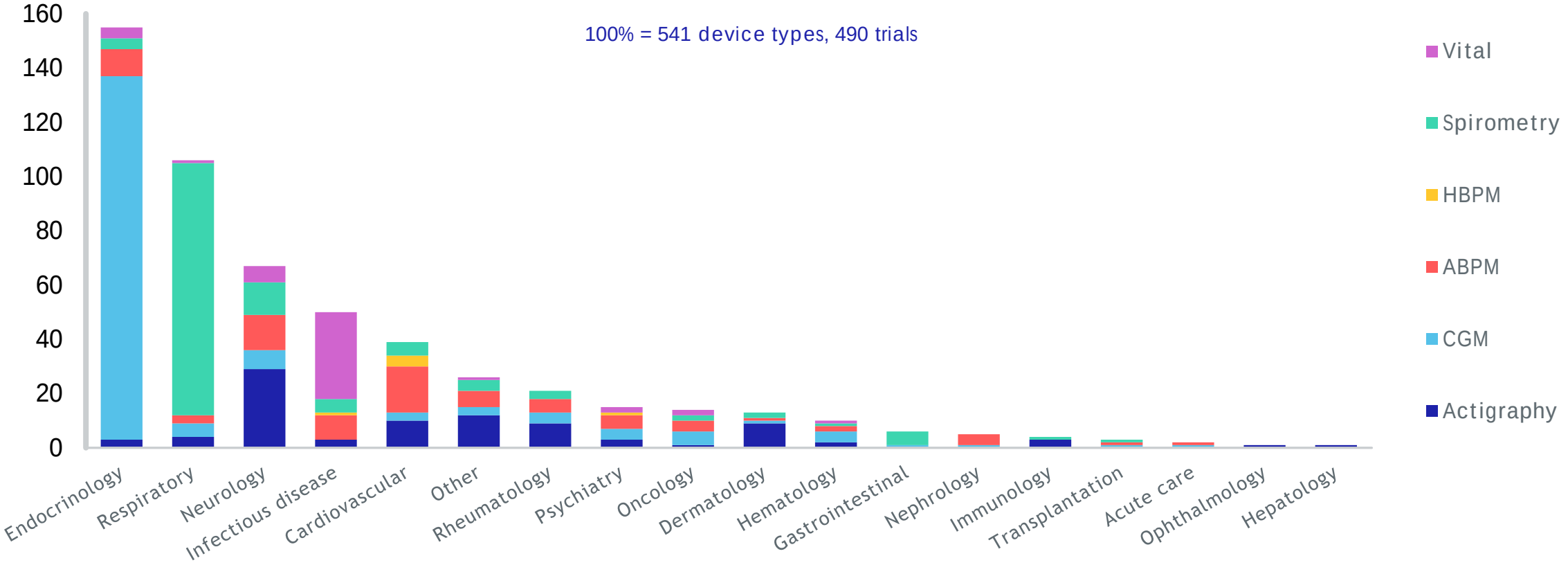
Source: IQVIA Institute, Jun 2021
Note: Includes devices used for safety as well as efficacy evaluations . 1 = MDPI. How to Select Balance Measures Sensitive to Parkinson's Disease from Body-Worn Inertial Sensors—Separating the Trees from the Forest. Available from: https://www.mdpi.com/1424-8220/19/15/3320/html

Connected Devices as a Percent of All Trials



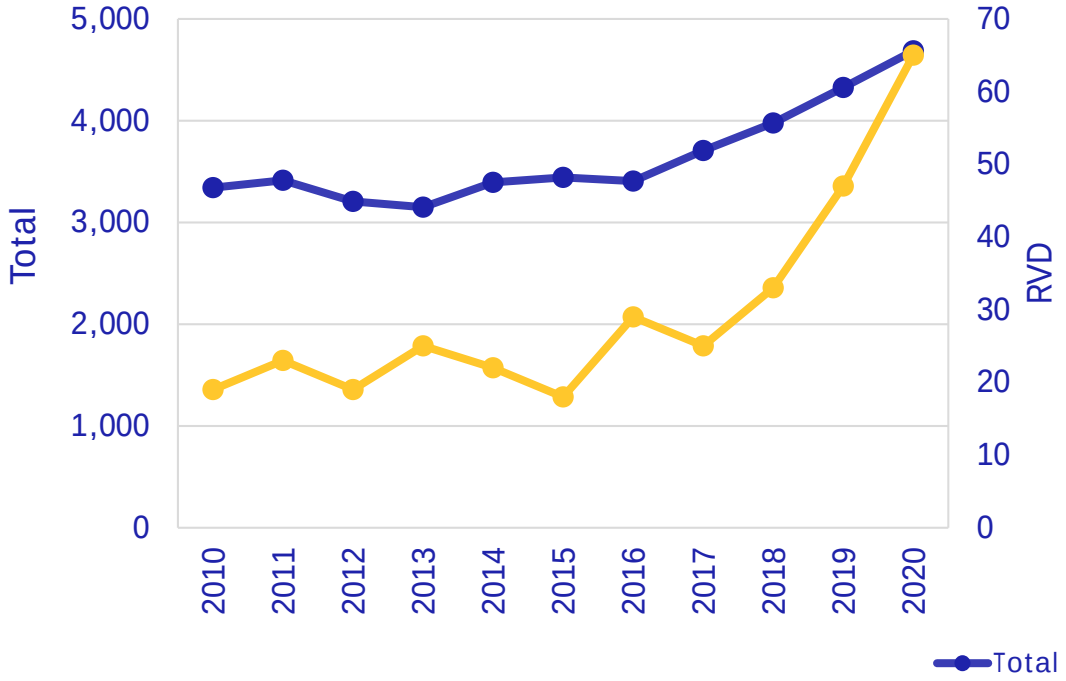
Source: IQVIA Institute, Jun 2021
Notes: Slide shows trials IQVIA is aware of in each year. Connected device trials include those for ECG, vital sign capture, actigraphy, spirometry, blood pressure and glucose monitoring, where a life sciences company intends to outsource the device trial component in Phase I-IV. Excludes trials where the company is directly insourcing devices

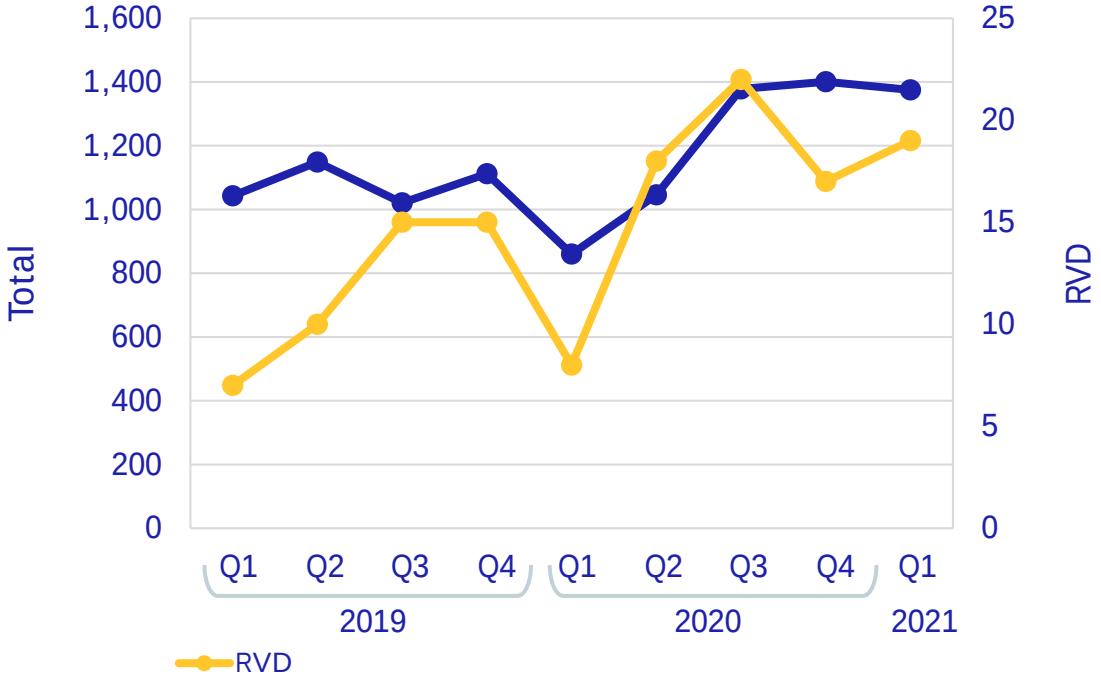
Connected Device Types Excluding ECG Used in Trials by Therapy Area, 2017-2021



Source: IQVIA Institute, Jun 2021
Notes: Slide shows trials IQVIA is aware of since 2017 where a life sciences company intends to outsource the device trial component in Phase I-IV. Excludes trials with ECG. Excludes trials where the company is directly insourcing devices. Large imaging devices were excluded. Data as of May 5, 2021

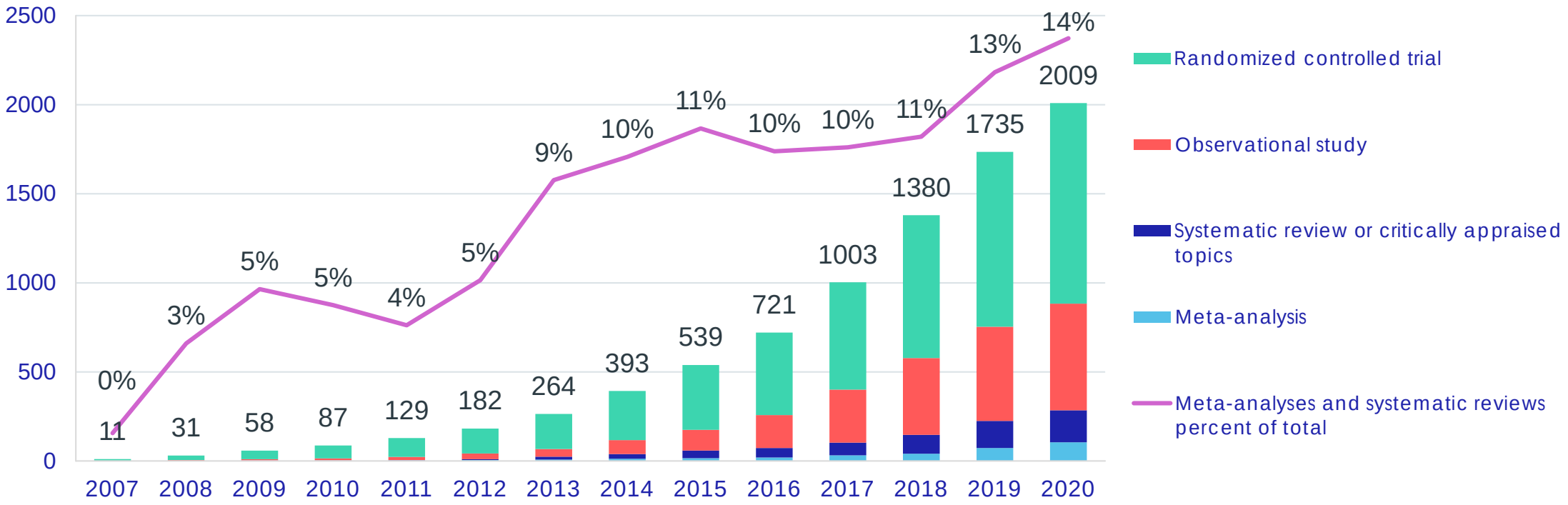
Trial Starts for All Trials and Remote, Virtual or Decentralized Trials (RVD)





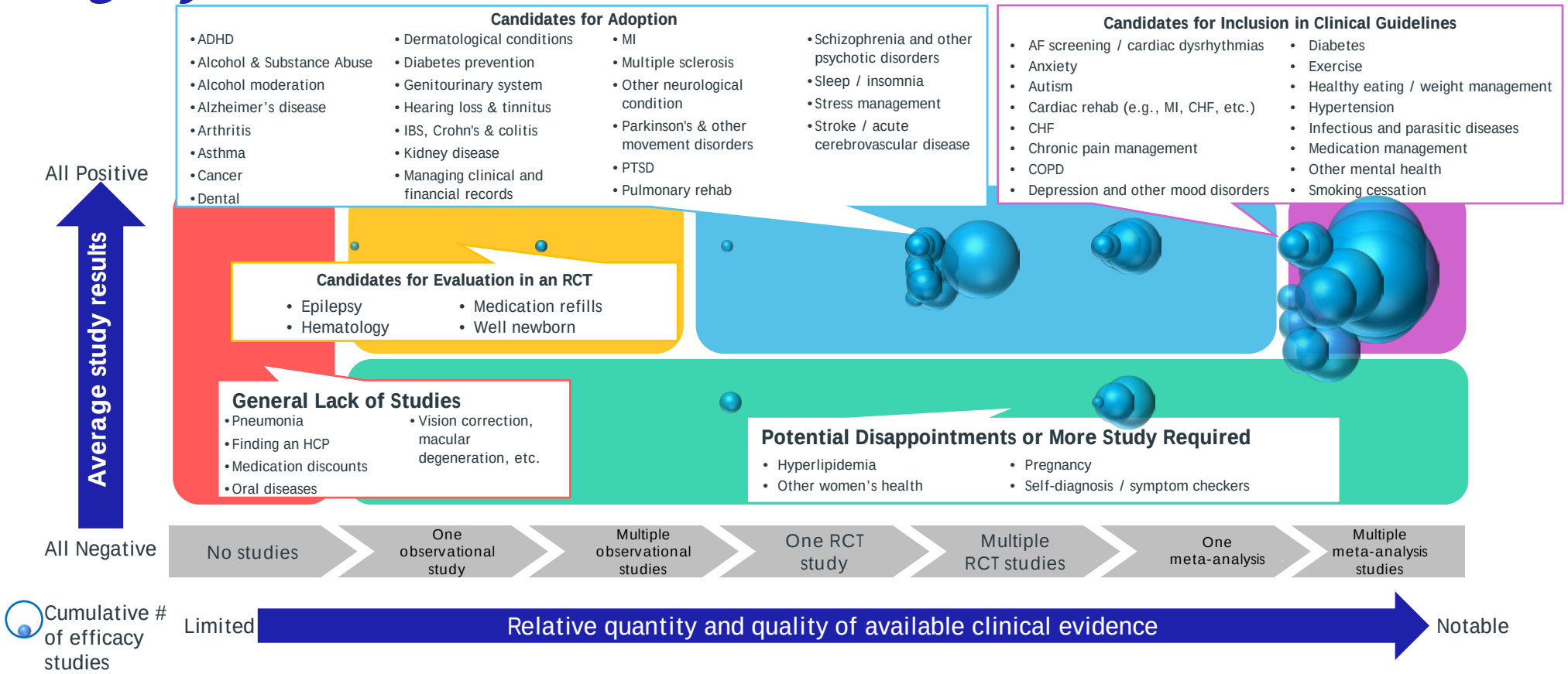
Report: Global Trends in R&D: Overview through 2020. Report by the IQVIA Institute for Human Data Science.
Source: Citeline Trialtrove, Apr 2021; IQVIA Institute, Apr 2021
Notes: This analysis includes remote, siteless, virtual and decentralized trials, but also trials including a single element typically included in these, such telemedicine, home health interactions, remote and virtual visits, mHealth, remote sensors (that might collect) digital endpoints and digital biomarkers, eCOA and ePRO, eConsent, medication use tracking devices, as well as those trials using medical event monitoring systems or medication event monitoring systems.

Cumulative Number of Published Digital Health Efficacy Studies and Percentage of Meta-analyses and Systematic Reviews



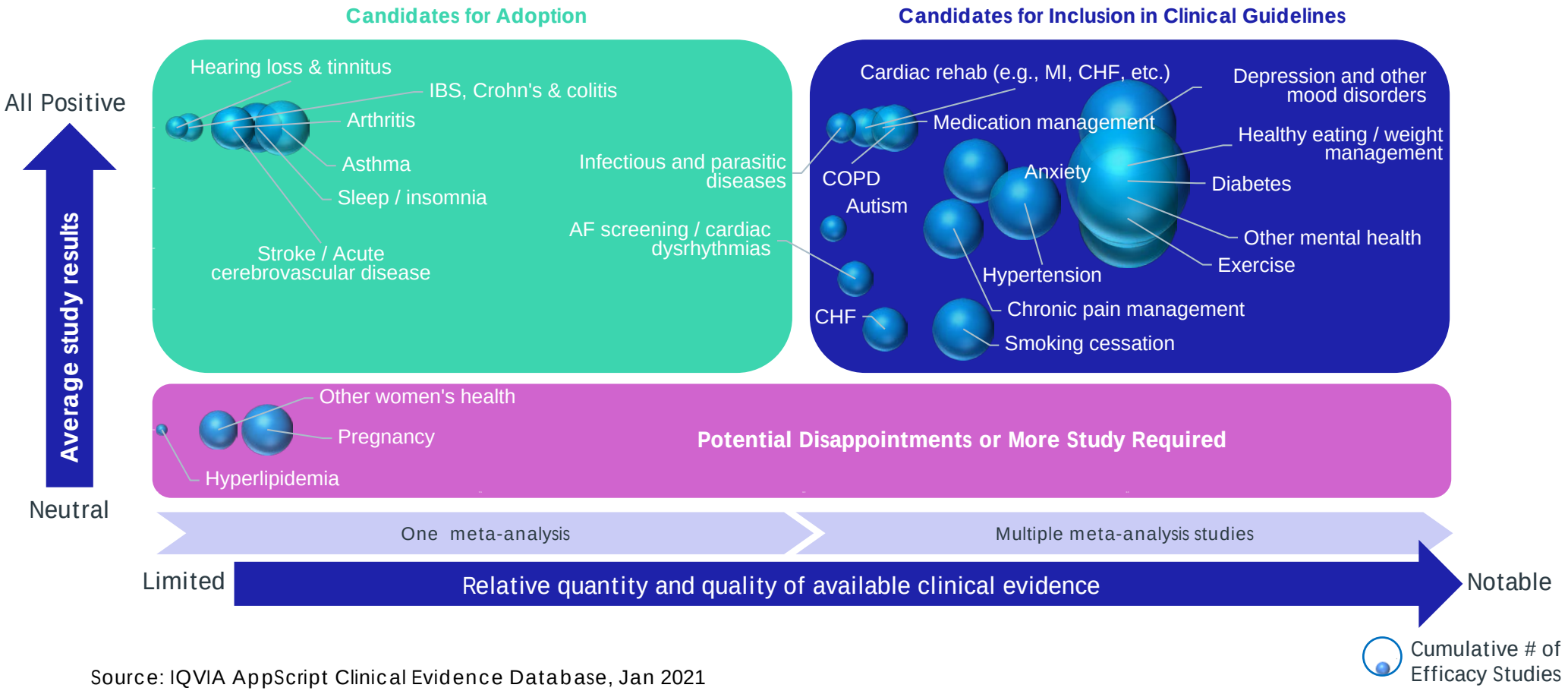
Source: AppScript Clinical Evidence Database, Jan 2021
Notes: Only includes studies that evaluated the interventional value of a digital health solution (mobile or web app, connected device, or other mobile intervention such as texting) on patient outcomes such as activity levels, lab results, or healthcare resource utilization.
'Observational Study' includes all trials examining the interventional value or impact of an app excluded from the other three categories regardless of design.

Maturity of Digital Health Efficacy Studies by Use Category, 2020



Source: IQVIA AppScript Clinical Evidence Database, Jan 2021
Notes: Only includes studies that evaluated the interventional value of a digital health solution (mobile or web app, connected device, or other mobile intervention such as texting) on patient outcomes such as activity levels, lab results, or healthcare resource utilization. Shows the average of study results for the highest quality evidence available (i.e., meta-analysis > RCT > observational)

Categories with One or More Meta-Analysis



Source: IQVIA AppScript Clinical Evidence Database, Jan 2021
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App Commercialization Pathways

Commercial Models

Direct-to-consumer

- App manufacturer sells directly to patients / end users, who pay a subscription fee
- Payment frequency may vary (monthly, annually, etc.) and some could pay with HSA/FSA
- User downloads disease management app, sometimes from the APP store

Value-based contracting

- App manufacturer contracts with payer, employer or IDN
- Contracts structured around improved outcomes or reduced costs
- Generally paid on a per members per month basis
- Payers may require a pilot and/or robust evidence & ROI before adopting
- Contract renewal/payment often based on usage/ engagement/KPIs

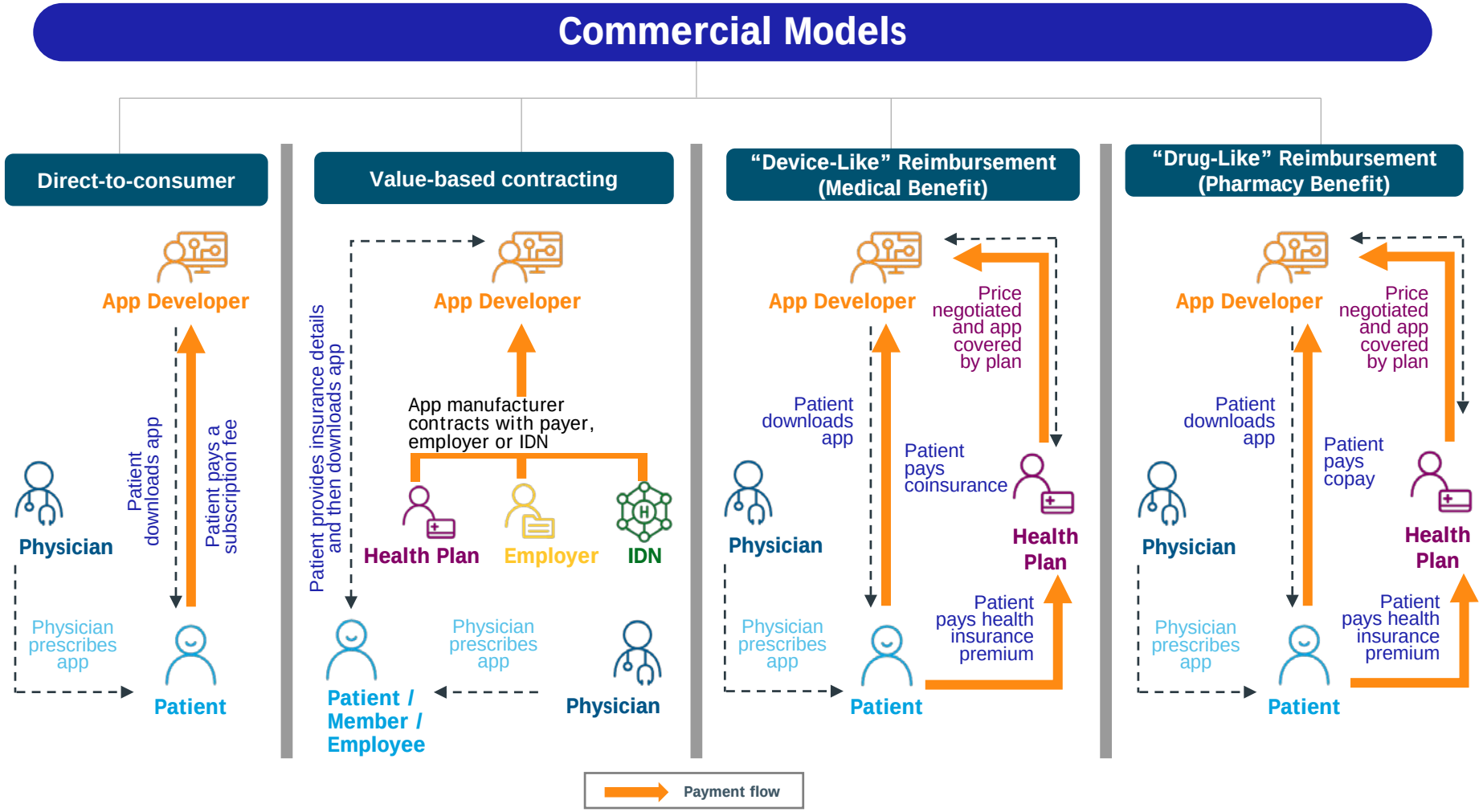
"Device-Like" Reimbursement (Medical Benefit)

- App manufacturer sets the price for solution, insurance covers up to a certain amount as part of core medical benefit or medical exception
- Patient pays coinsurance

"Drug-Like" Reimbursement (Pharmacy Benefit)

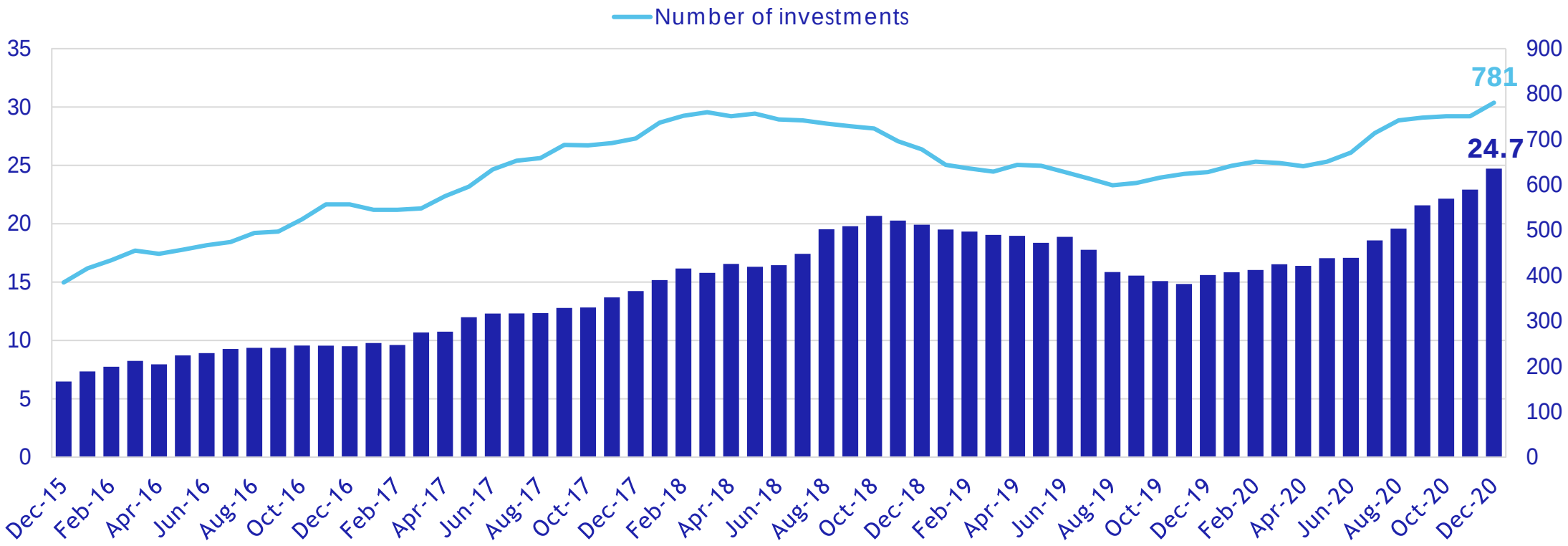
- Reimbursed price negotiated between app manufacturer and payer for the solution to be listed on pharmacy benefit or digital formulary
- Patient pays copay
- Typically, an NDC code exists/issued for app

App Commercialization Pathways



Source: IQVIA, Mar 2021; IQVIA Institute, Jun 2021
Notes: NDC – National Drug Code, HSA – Health Savings Account; FSA – Flexible Spending Account; IDN – Integrated Delivery Network; KPI – Key Performance Indicator

Investment in Digital Health Over Five Years Based on 12-Month Rolling Totals



Source: Sluijs M. DigitalHealth.Network. $24Bn invested: Don't look back! Digital Health Marketscan 118th Ed Dec 2020.
Notes: Chart displays global data (including US/EU/APAC) and12 month rolling totals in each period since 2015. Includes Digital Health broadly ranging from connected sensors, analytical technology, patient facing solutions including digital therapeutics, life science information technology (IT) and clinical trial data collection technology, healthcare IT. Includes Venture Capital Investment in private companies with a value above $1M and excludes private equity buyouts and IPOs.

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Questions?

Thank you!

- To download the report: www.IQVIAInstitute.org
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