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ISPOR Special Interest Group

Collaborating With Patients to Define Digital Endpoints and Biomarkers That Truly Matter

Monday May 18, 2026 | 3:15PM – 4:15PM

Discussion Topics

	Topic	Presenter(s)
1	Welcome, Introductions (10 mins)	Anita Burrell
2	Digital COA acceptance (10 mins)	Bryan Bennett
3	Developing digital technologies (10 mins)	Arturo Cabra
4	Co-creating with patients (10 mins)	Angie Botto van Bemden
5	Q&A (15 mins)	All
6	Closing remarks	Anita Burrell

Today's Panel

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Chair, Past Chair Clinical Outcome Assessment SIG and Head Patient Centred Outcomes Jazz Pharmaceuticals, UK

Arturo Cabra
Medical Devices & Diagnostics SIG, HEOR Global Leader, GE Healthcare

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Author's Disclosure

Bryan Bennett is an employee of Jazz Pharmaceuticals and holds stock in Jazz Pharmaceuticals.

Anita Burrell has no conflicts of interest relating to digital endpoints or biomarkers to disclose

Arturo Cabra is an employee and shareholder of GE HealthCare, which commercializes Medical Devices and Diagnostics globally.

1

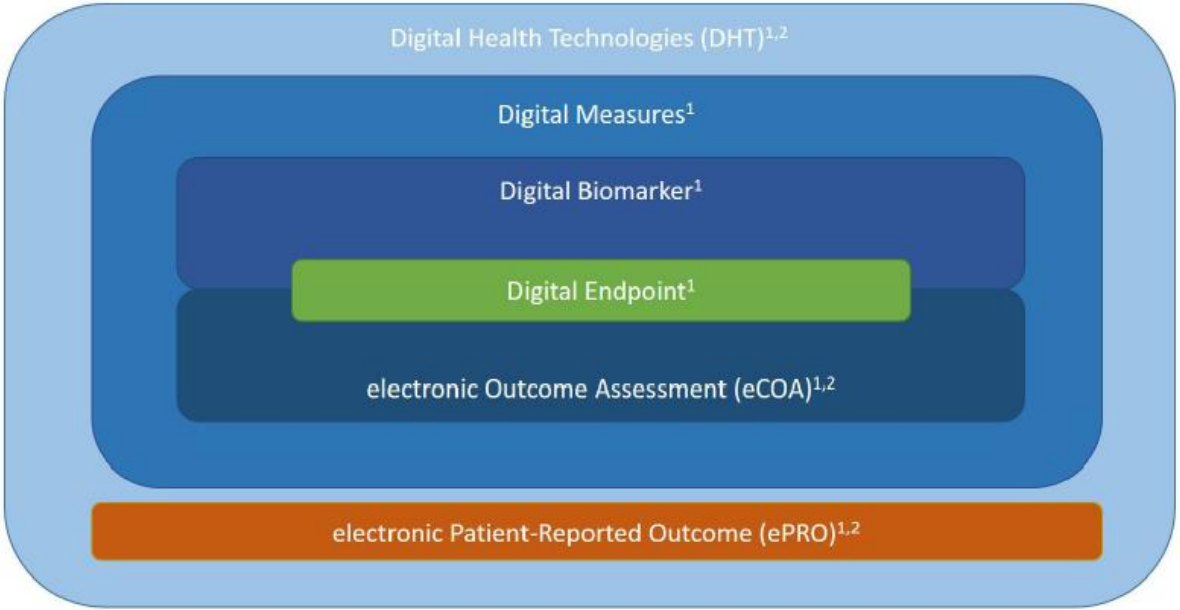
What defines a digital endpoint or biomarker?

What is a Digital Endpoint?

- **Digital Endpoint** "A precisely defined variable intended to reflect an outcome of interest that is 1) collected digitally with a sensor, and 2) statistically analyzed to address a particular research question." DiME

- **Digital Endpoint**: "A Digital Endpoint (a precisely defined variable intended to reflect an outcome of interest that is statistically analysed to address a particular research question) is derived from or includes a digital measurement. Digital endpoints can be ***clinical outcome assessments*** (clinical relevance established De Novo) or ***biomarkers*** (reliable relationship with existing clinical outcome can be established). EMA Q&A June 2020

Overlap of terms



(1) EMA: https://www.ema.europa.eu/en/documents/other/questions-answers-qualification-digital-technology-based-methodologies-support-approval-medicinal_en.pdf
(2) FDA: https://www.fda.gov/media/155022/download

Figure 3 Semantic overview of terminology used by EMA and FDA. Digital health technologies obtain digital measures, which include digital biomarkers and electronic clinical outcome assessment (eCOA). Digital biomarkers and eCOAs both can provide digital endpoints. EMA, European Medicines Agency; FDA, Food and Drug Administration.

Macias Alonso AK, *et al. BMJ Health Care Inform* 2024;31:e100914. doi:10.1136/bmjhci-2023-100914

Pros and cons of digital measures

- Pros
  - Can be collected outside of a clinical setting
  - Offers more relevant data to be collected
  - More frequent/real time assessment
  - Can reduce burden on patients
  - Can reduce trial costs
- Cons
  - May lead to data privacy and security risks
  - Current lack of consistency in regulatory guidance
  - Need to consider technical validation and clinical validation
  - May lead to access inequity
  - Potential for compliance and selection bias

2

Evolving Journey of Digital COA

POLLING QUESTION

- When was the last time you developed a COA strategy with a recommendation for using paper questionnaires?
  - A - <2 years ago
  - B - 2-5 years ago
  - C - >5 years ago
  - D - Never
  - E - Not my role

The Path to Perfection...?

Shift to patient-centric outcomes

PROs moved the focus from purely clinical or laboratory endpoints to how patients feel and function in daily life..

Regulatory formalization

The 2009 FDA PRO Guidance and subsequent PFDD work, along with EMA and ISPOR initiatives, turned PRO development into a rigorous, evidence-based discipline tied directly to labeling and benefit–risk decisions..

Digital transformation

ePRO addressed long-standing issues with paper (back-filling, missing data, poor time-stamping) and enabled real-time, high-quality data capture, but required robust validation and regulatory-grade system controls

Expansion beyond clinical trials

Standardized ePROs are now central to value-based care, outcomes-based contracting, and large-scale observation studies, blurring the line between research and routine care.

Early Development

Regulatory Milestones and Industry Good Practices

Digital Transformation And Data Integrity

nto Healthcare Ecosystems

The Evolution – A Long (a Continuing) Journey

- Emergence of QoL research in oncology and chronic disease.
- Development of early generic instruments and some disease-specific scales.
- Psychometrics standards begin to formalize.

- Growth of structured PRO instruments and cross-cultural validation.
- Outcomes-research societies and journals begin setting methodological expectations.
- Recognition that PROs can influence treatment evaluation, not just academic research.

- Increased use of PROs in pivotal trials.
- 2006 FDA PRO Guidance (Draft).
- 2009 FDA PRO Guidance
- Establishes PROs as regulatory-grade evidence

- Rapid adoption of ePRO to address paper diary issues
- ISPOR publishes ePRO system validation and migration equivalence.
- EMA increases engagement with HRQoL/PRO scientific advice and qualification procedures

- FDA releases Patient Focused Drug Development Guidance's (Draft + Final)
- 1. Collecting Patient Experience Data
- 2. Methods to identify what is important to patients
- 3. Selecting/developing or modifying fit-for-purpose COAs
- 4. Incorporating COAs into endpoints

- ePRO becomes standard in hybrid and decentralized trials
- Integration with wearables, sensors and remote monitoring
- Expansion into routine care, registries, and outcomes-based contracting
- Initiatives like Health Outcomes Observatory (H2O) push for standardized PRO use across health systems

Case Study 1: Standardization Era (1990s)

Context: A widely used clinician-reported and patient-reported outcome measure was migrated from paper to digital by a vendor without involving the instrument developer.

What Went Wrong

- Response options were reformatted into a scrolling list instead of a single visible set
- Instructions were shortened to '*Select your answer*'
- Items intended to be grouped were separated across screens
- Navigation changed the cognitive flow of the measure

Impact

- The instrument developer rejected the digital version
- Sponsor had to rebuild the digital version and repeat usability testing
- Trial timelines were delayed
- Additional costs incurred for reprogramming and revalidation

Lesson Learnt

- Digital migration must preserve the **content validity**, **layout** and **cognitive burden** – even small changes can invalidate a validated instrument

Case Study 2: Modern Digital Era (2020s)

Context: A Phase II study used multi-sensor wearables to capture mobility and sleep endpoints alongside ePRO.

What Went Wrong

- Participants found the wearable uncomfortable
- Charging requirements were unclear
- Bluetooth synching failed intermittently
- Participants removed the device during daily activities
- Compliance dropped below 50% by Week 4

Impact

- Large gaps, missing data, in sensor derived endpoint data
- Inability to calculate pre-specified digital endpoints
- Regulators questioned the interpretability of the results
- Sponsor removed the digital endpoint from the final analysis

Lesson Learnt

- Digital COAs can fail when participant burden, usability, and device logistics are underestimated
- Modern digital endpoints require human-centred design and robust testing

Case Study 3: When Things Go Very Wrong

Context: A global Phase III trial provisioned devices for data capture.

What Went Wrong

- Devices were shipped late and to the wrong sites
- Sites lacked training on setup and troubleshooting
- Many patients did not complete baseline assessments
- No contingency plan (e.g. BYOD, web backup)

Impact

- ~40% baseline PRO data missing
- Baseline-adjusted endpoints were uninterpretable
- Trial required protocol amendments and additional monitoring (time and costs)
- Major delays in trial

Lesson Learnt

- Operational failures – not technology – can be the biggest risk to eCOA success.
- Device logistics must be treated as a critical path activity

Closing Thoughts

3

Developing Digital Technologies:

Author’s Disclosure

Arturo Cabra is an employee and shareholder of **GE HealthCare**, which commercializes Medical Devices and Diagnostics globally.

Content for informational purposes only. Opinions expressed are my own.

The Signal Exists. The Access Doesn't.

3.5 years

avg. time to Alzheimer's diagnosis

after first symptoms (Int J Geriatric Psychiatry, 2025)

3+ years

avg. time to Parkinson's diagnosis

non-motor symptoms triple referral delays (BMC Primary Care, 2025)

GATE 1

Regulatory Clearance

FDA / EMA acceptance

Clearance ≠ Coverage

›

GATE 2

Payer Coverage

Evidence of Value

Coverage ≠ Access

›

GATE 3

Patient Access

Diverse populations, real-world settings

This is the real finish line

Digital biomarkers can compress the diagnostic gap — but only if the evidence crosses **all three gates**.

ALZHEIMER'S DISEASE PATIENT PATHWAY

Biomarker-enabled, digitally supported care from very early suspicion to severe Alzheimer's disease

EVIDENCE BASE (Peer-reviewed)

- Alzheimer's Association. Alzheimer's & Dementia, 2024 (biomarker-based diagnosis & staging).
- Milà-Alomà M, et al. Lancet Neurology, 2024 (blood biomarkers guideline).
- Cummings J, et al. Alzheimer's & Dementia, 2023 (lecanemab AUR).
- Mintun MA, et al. J Prev Alz Dis, 2021 (A/T/N framework).
- Reavil J, et al. Nat Rev Neurol, 2024 (digital health review).

	0 AWARENESS & EARLY CONCERN	1 PRIMARY CARE DETECTION	2 TRIAGE	3 DIAGNOSTIC CONFIRMATION	4 TREATMENT ELIGIBILITY & RISK ASSESSMENT	5 TREATMENT INITIATION & ARIA MONITORING	6 RESPONSE ASSESSMENT & PET FOLLOW-UP	7 TREATMENT DISCONTINUATION OR LONG-TERM CARE
	Very early changes noticed by patient or family (memory, speech, behavior, navigation, daily function)	Initial evaluation in primary care for cognitive concern	Determine likelihood of Alzheimer's pathology and need for specialist referral	Confirm etiology and stage; rule out alternative causes	Confirm amyloid pathology and estimate risk to guide treatment decision	Start anti-amyloid therapy and monitor safety (ARIA) and tolerability	Evaluate treatment effect and ongoing risk to guide continuation	Discontinue if not benefiting or not tolerating; continue holistic care & support
KEY CLINICAL QUESTION	Should I be concerned and seek evaluation?	Is there objective cognitive/functional impairment?	Is AD pathology likely and does the patient need specialist referral?	Is this Alzheimer's disease and what stage is it?	Is the patient eligible for anti-amyloid therapy and what is their risk (e.g., ARIA)?	Is treatment safe and is ARIA occurring?	Is the treatment working (amyloid reduction & clinical stability)?	Should treatment be continued or stopped? How do we provide ongoing care?
TOOLS & DIAGNOSTICS	• Digital cognitive screeners • Speech & language analysis • Passive data (activity, sleep, phone use) • Family questionnaires	• History (patient & informant) • Cognitive tests (MoCA, MMSE) • Depression, sleep, meds, vitals • Labs: B12, TSH, CBC, CMP	• Blood-based biomarkers (p-tau217 or p-tau181, Aβ42/40, NfL, GFAP)* • Risk scores (age, APOE ε4, family history)	• Amyloid-PET • CSF Aβ42/40 • p-tau PET (if needed for staging) • FDG-PET (if unclear) • MRI (structural) • Detailed neuropsychological testing • Differential diagnosis (FTD, LBD, vascular, etc.)	• Amyloid status (PET or CSF) • Tau PET (if needed for staging) • APOE genotyping • Baseline MRI • Risk calculators (ARIA risk)	• MRI per protocol for ARIA-E/H • Clinical assessments • Infusion/administration monitoring • Labs as indicated	• Amyloid-PET (quantitative) • Clinical scales (CDR-SB, ADAS-Cog, ADCS-iADL) • Safety labs • MRI as indicated	• Clinical trajectory • Amyloid-PET (quantitative) • Tolerability & patient preference • Care planning & supportive services
DIGITAL HEALTH OPPORTUNITIES	• Mobile apps for awareness & education • AI algorithms for early risk detection • Speech & language analysis (baseline screening) • Passive monitoring (activity, sleep, phone)	• Remote pre-visit cognitive testing • EHR alerts for cognitive risk • Digital questionnaires (PHQ-9, sleep, meds) • Telehealth visits	AI algorithms integrating clinical data + blood biomarkers • Automated triage to specialist • Decision support	AI-enhanced MRI (atrophy, WMH) • Speech & language analytics • Digital neuropsych platforms • Differential diagnosis support tools	• AI risk prediction for ARIA • Eligibility checklists • Shared decision aids • Patient education portals	AI MRI for ARIA detection • Remote symptom monitoring • ePROs & adverse event reporting • Infusion tracking	Quantitative PET analytics (Aβ SUVR) Longitudinal dashboards • Trend visualization & alerts • Digital cognitive follow-up	Care coordination platforms • Caregiver support tools • Telehealth follow-up & palliative support

DISEASE CONTINUUM (CLINICAL STAGE)

AT RISK / PRECLINICAL
No symptoms
Biomarker changes may be present

SUBJECTIVE COGNITIVE DECLINE
Self or informant concern, normal objective testing

MCI DUE TO AD (EARLY STAGE)
Objective impairment, preserved independence

MILD AD DEMENTIA
Functional impairment in complex IADLs

MODERATE AD DEMENTIA
Assistance needed for basic ADLs

SEVERE AD DEMENTIA
Dependent in all ADLs, advanced disease

KEY PRINCIPLES

Biomarker-based Diagnosis
Use fluid and imaging biomarkers to confirm AD and stage disease.

Early Detection Matters
Earlier identification enables more treatment options and planning.

Right Test, Right Time
Use stepwise approach to balance accuracy, access, and cost.

Safety First
Monitor ARIA closely with MRI and digital tools.

Patient-Centered Care
Shared decision-making, value-based care, caregiver support.

Continuous Monitoring
Integrate clinical, biomarker, and digital data for ongoing decisions.

*Blood biomarkers are evolving. Use assays with demonstrated clinical performance and per local regulatory guidance.

Abbreviations: AD = Alzheimer's disease; ARIA = Amyloid-Related Imaging Abnormalities; PET = Positron Emission Tomography; CSF = Cerebrospinal Fluid; Aβ = Amyloid beta; p-tau = phosphorylated tau; NfL = Neurofilament light chain; WMH = White Matter Hyperintensities; IADLs = Instrumental Activities of Daily Living; ADLs = Activities of Daily Living; EHR = Electronic Health Record; ePROs = electronic Patient-Reported Outcomes.

Two Tracks. No Bridge.

DIGITAL BIOMARKER TRACK

→ Developers build

Raw signal → Digital Biomarker → Endpoint

→ Validated against

Cognitive scores, clinical benchmarks, each other

→ Language

AUC, sensitivity, signal fidelity

GAP

CLINICAL / PAYER TRACK

→ Payers and clinicians trust

Clinical diagnostics (UPDRS, MMSE), Gold Standard, Biomarkers

→ Guidelines require

Concordance with established gold standards and validation

→ Language

Guideline concordance, Budget Impact, Accuracy, Diagnostic and Clinical Utility

Until digital health validates against what payers and clinicians already trust, the bridge does not exist.

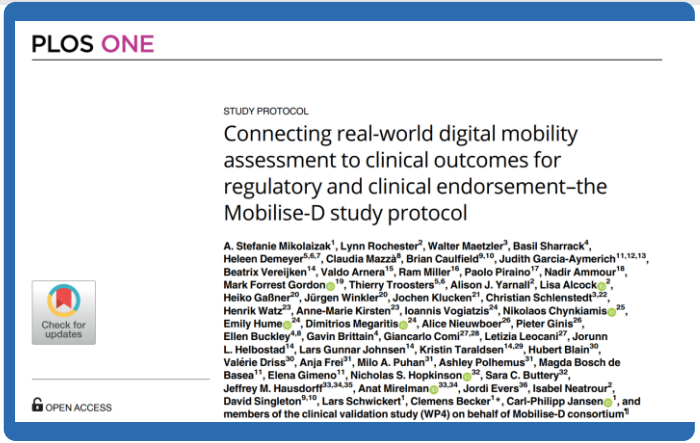
What Bridging the Gap Looks Like

The Mobilise-D Case

- One wearable sensor (lower back). One algorithmic pipeline.
- 24 validated Digital Mobility Outcomes (DMOs)
- Validated alongside UPDRS — not instead of it
- Enables real-time, continuous monitoring between clinic visits
- >90% patient adherence across 5 disease cohorts

Same device. Same pipeline. Five diseases: Parkinson's • COPD • Multiple Sclerosis • Heart Failure • Hip Fracture Recovery

Mobilise-D consortium (2023–2024). Innovative Health Initiative


PLOS ONE

STUDY PROTOCOL

Connecting real-world digital mobility assessment to clinical outcomes for regulatory and clinical endorsement–the Mobilise-D study protocol

A. Stefanie Mikolaizak[1], Lynn Rochester[2], Walter Maetzler[3], Basil Sharrack[4], Heleen Demeyer[5,6,7], Claudia Mazzà[8], Brian Caulfield[9,10], Judith Garcia-Aymerich[11,12,13], Beatrix Vereijken[14], Valdo Arnera[15], Ram Miller[16], Paolo Piraino[17], Nadir Ammour[18], Mark Forrest Gordon[19], Thierry Troosters[5,6], Alison J. Yarnall[2], Lisa Alcock[2], Heiko Gaßner[20], Jürgen Winkler[20], Jochen Klucken[21], Christian Schlenstedt[3,22], Henrik Watz[23], Anne-Marie Kirsten[23], Ioannis Vogiatzis[24], Nikolaos Chynkiamis[25], Emily Hume[24], Dimitrios Megaritis[24], Alice Nieuwboer[26], Pieter Ginis[26], Ellen Buckley[4,8], Gavin Brittain[4], Giancarlo Comi[27,28], Letizia Leocani[27], Jorunn L. Helbostad[14], Lars Gunnar Johnsen[14], Kristin Taraldsen[14,29], Hubert Blain[30], Valérie Driss[30], Anja Frei[31], Milo A. Puhan[31], Ashley Polhemus[31], Magda Bosch de Basea[11], Elena Gimeno[11], Nicholas S. Hopkinson[32], Sara C. Buttery[32], Jeffrey M. Hausdorff[33,34,35], Anat Mirelman[33,34], Jordi Evers[36], Isabel Neatrour[2], David Singleton[9,10], Lars Schwickert[1], Clemens Becker[1]*, Carl-Philipp Jansen[1], and members of the clinical validation study (WP4) on behalf of Mobilise-D consortium[¶]

Check for updates

OPEN ACCESS

The word that mattered:

Additive

not replacement.

That is how digital earns trust in clinical guidelines.

Design the Evidence Backwards — Start from the Patient

1. PATIENT

What does the patient experience?
What function or outcome matters in their daily life?

Co-create from day one

>

2. CLINICAL STANDARD

What gold standard does the clinician trust?

CSF, PET, UPDRS, MMSE

Validate your digital signal against this, not around it

>

3. EVIDENCE OF VALUE

Will the evidence (and the product) support any change in the patient outcomes
Additional Patients diagnosed, Diagnostic Accuracy, outcomes data

Pre-specify these before Phase III, not after

The evidentiary chain must be designed in reverse — from the patient's reality, through the clinical standard, back to the digital signal.

The signal is not the problem. Digital biomarkers and clinical biomarkers need to speak the same language

Payers fund what guidelines recommend. Guidelines trust what is validated against gold standards.

Digital biomarkers sometimes generate evidence and validated it against those gold standards — and when they do, it becomes news but, we need to think how we integrate the digital technologies in the patient pathway (not replacing biomarkers but as enablers).

"What evidence do digital technologies need to bridge the gap between signal and patient outcomes — and what can we build, together as a community, to improve those outcomes and achieve optimal patient access "

4

Co-Creating with Patients

From Digital Signal to Meaningful Outcome: Who Decides?

THE MEASUREMENT GAP

Digital ≠ Meaningful

Capturing a signal digitally does not make it patient-relevant

Continuous ≠ Relevant

More frequent data does not equal better clinical insight

Precise ≠ Patient-Centered

Algorithmic precision is worthless without lived-experience anchoring

130+

AI-powered digital endpoints deployed in trials 2008-2022 (HumanFirst Institute, 2022)

0

DHT-derived biomarkers formally qualified by FDA as DDT as of July 2024 (Bakker et al., CPT 2025)

"Who defines what matters?"

Without patient involvement in concept definition, digital endpoints risk measuring what is technically feasible rather than what is meaningful to patients

Conceptual Validity: The Missing First Step

Before any algorithm, there must be a concept- defined by patients living with the condition.

CONCEPT OF INTEREST

What truly matters to patients? Articulate lived experience.

PATIENT-DERIVED MODEL

Co-design the conceptual framework with patients before selecting any sensor.

DIGITAL SIGNAL MAPPING

Map candidate digital measures to the patient-defined concept.

MEANINGFUL CHANGE

Pre-specify thresholds of meaningful change anchored in patient experience.

KEY FRAMEWORKS | V3 Framework (DiME/BEST) • FDA PFDD Guidance Series (1-4) • EMA Context of Use (Q&A 2020) • ISPOR COA Good Practices

Regulatory & HTA Expectations Are Rising

FDA

- PFDD Guidance Series 1-4 (2018-2022): patient voice in COA development
- DHT for Remote Data Acquisition — Final Guidance (2023): fit-for-purpose standard
- Digital Health Advisory Committee established (Oct 2023)
- Real-World Evidence framework expanded to wearables & sensors (Dec 2025)
- Sponsors must justify DHT selection, demonstrate conceptual validity
- Diversity Action Plans required for equitable trial design (2024+)

EMA & HTA

- EMA Q&A: Qualification of Digital Technology-Based Methodologies (2020)
- Landmark: Stride velocity 95th centile qualified as primary endpoint in DMD (2024)
- EU Health Data Space (EHDS) 2025: patient data governance mandate
- NICE, G-BA, CADTH: patient-centric evidence increasingly required for HTA
- Conceptual validity + patient relevance now core evidentiary expectations
- ISPOR PICOTS-ComTeC framework: standardizing digital health evidence (2024)

*****Future is not digital endpoints. It is decision-relevant digital endpoints!**

Equity & the Risk of Digital Exclusion

Culture

Language, cultural norms & trust in technology shape who adopts/participates

Limiting Conditions

Disability, motor/cognitive impairment constrain device usability

Education & Health Literacy

Lower literacy correlates with lower DHT adoption & data quality

Age

Older adults 65+ systematically underrepresented in DHT trials

Residence

Rural & low-connectivity areas excluded by bandwidth-dependent devices

Socioeconomic Status

Device cost, data plans & time burden create access inequity

EVIDENCE: Only 4.96% of completed clinical trials used connected DHT for data capture (2013-2023).

Those trials systematically underrepresented older adults & African American participants. Digital inclusion must be DESIGNED- not assumed. (ClinicalTrials.gov analysis; npj Digital Medicine 2022)

Data Governance & Trust: The Hidden Determinant of Adoption

Patients Ask...

- Who OWNS my data?
- How is it USED- and for what purpose?
- Who is it SHARED with (industry, insurers)?
- Do I BENEFIT from its use?
- Can I REVOKE consent- granularly?
- What happens to my data if I withdraw?

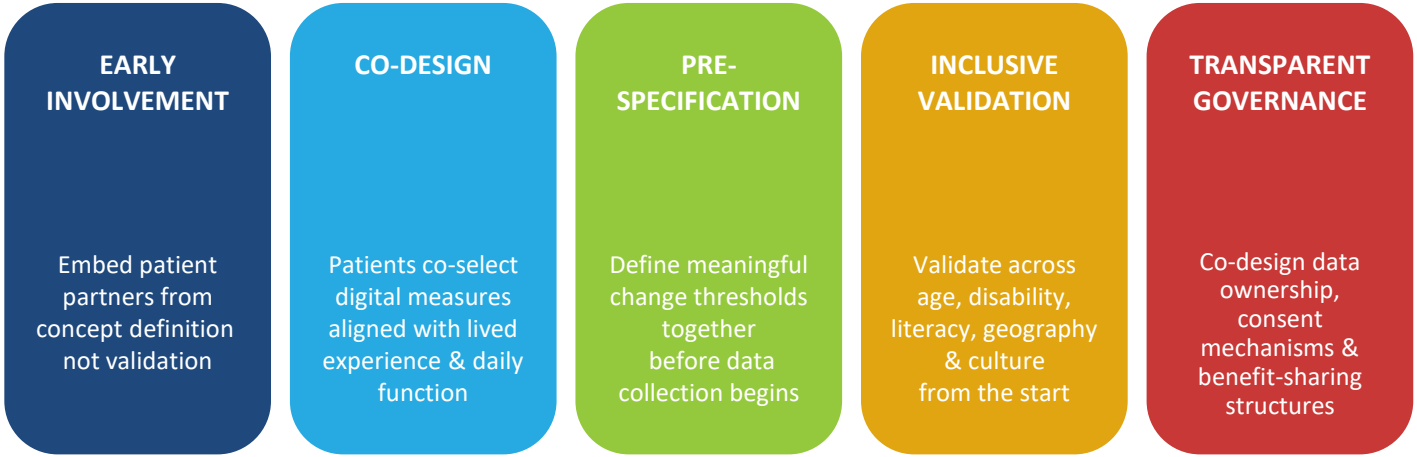
Framework Requirements

- GDPR / HIPAA / EHDS compliance- data minimization & purpose limitation
- Granular, dynamic, withdraw-able consent management
- Transparent data flow mapping & audit trails
- Patient access to their own data (Right of Access)
- Benefit-sharing mechanisms- co-ownership models
- De-identified tokens & blockchain consent tracking (npj Digital Medicine 2025)

⚠ KEY FINDING: 55% of digital health study consent forms are missing critical data governance disclosures

including rights around data sharing, secondary use, and withdrawal. Trust drives adherence- and adherence drives data quality. (PMC 2025; NIH DHT Guidance Analysis)

Moving From Promise to Practice: A Structured Co-Design Model



Digital technologies offer extraordinary opportunity.
But without methodological discipline and patient partnership, they risk widening disparities and weakening decision relevance.

Co-design is the mechanism by which digital endpoints earn the trust of patients, regulators, and payers alike.

5

Q & A

Polling Question

Which topic from today's session would you most like to see developed further? (Select all that apply)

- **A** Co-design and conceptual validity in digital endpoint development
- **B** Regulatory qualification pathways: FDA Drug Development Tools & EMA procedures
- **C** Health equity, digital access & inclusion-by-design strategies
- **D** Patient data governance, trust & consent management frameworks
- **E** From evidence to adoption: HTA and value-based assessment of digital endpoints

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