

ET14: Digital Health Technologies:

Evolution, Insights, and Future Directions



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Digital Health Technology

***FDA** defines Digital health technologies (DHTs) are systems that use computing platforms, connectivity, software, and/or sensors for healthcare and related uses.*

***Clinical Trials Transformation Initiative** (CTTI) refers to digital technologies as digital applications and other wearables, ingestibles, implantables, and portable technologies containing sensors for capturing outcomes data.*

*The **WHO** defines digital health as the field of knowledge and practice associated with the development and use of digital technologies to improve health. This encompasses a wide range of technologies, including mobile health (mHealth), health information technology, wearable devices, telehealth, and telemedicine, aiming to enhance the efficiency of healthcare delivery and make medicine more personalized and precise.*

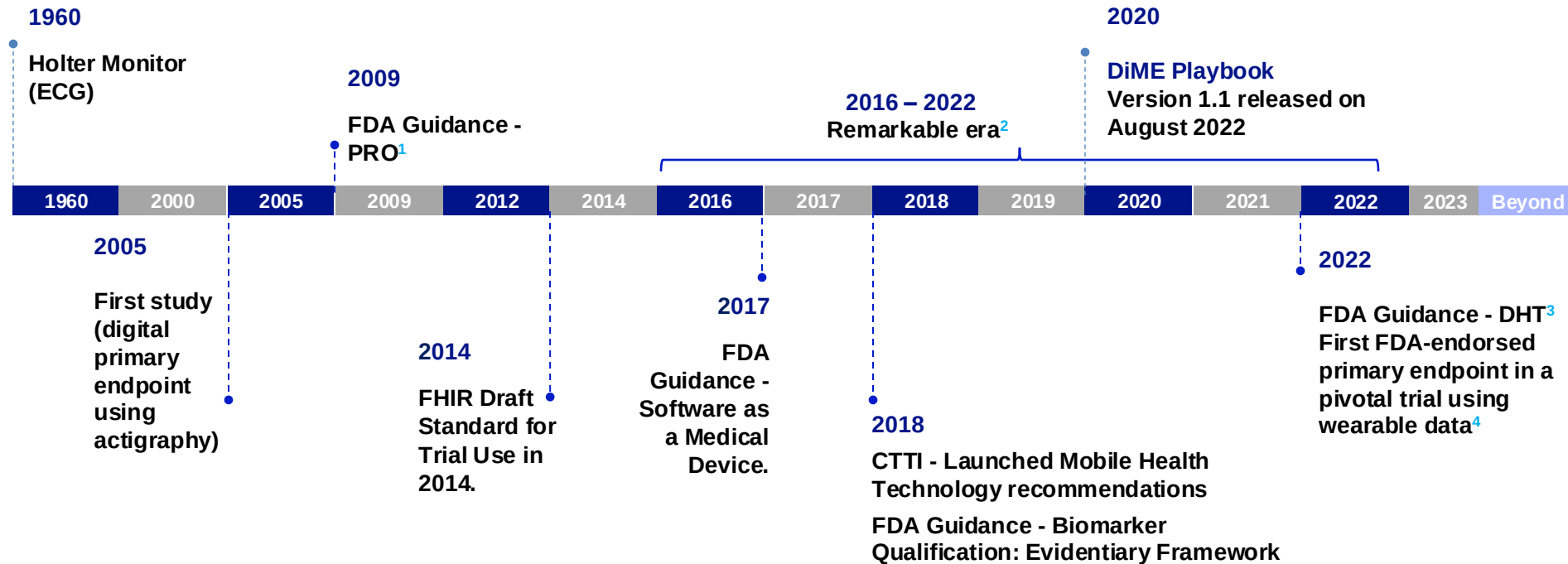
The convergence of digital innovations with healthcare delivery



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**Working
Groups**

History and Evolution



¹ Patient Reported Outcomes

² Out of 366 studies mentioned in DiME Library of digital endpoint; 341 are listed between this timeframe.

³ Digital Health Technologies for Remote Data Acquisition in Clinical Investigations - Guidance for Industry, Investigators, and Other Stakeholders
First Draft Guidance released on 21Jan2022

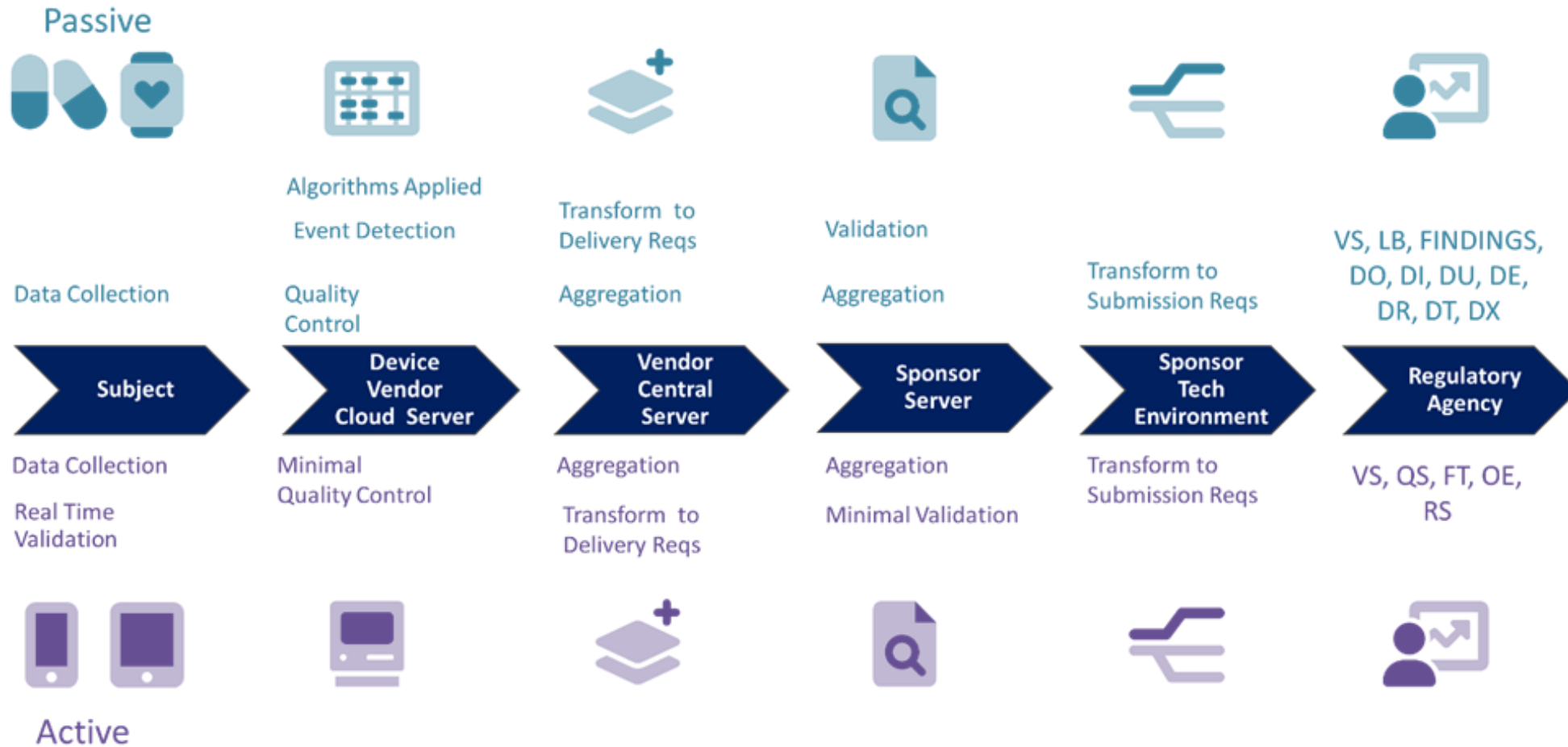
⁴ Case study- [Link](#)

SOURCE: PHUSE CONNECT 2023 - ST10: Digging Deep into Digital Biomarkers: Empowering Clinical Trials



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Data Flow



SOURCE: PHUSE CONNECT 2023 - ST10: Digging Deep into Digital Biomarkers: Empowering Clinical Trials

Digital Health Technology – Key Domains



Digital Health Technology – Key Domains

- **Digital Intervention:** Technology-based solutions for health support (e.g., mental health apps like "Woebot").
- **Digital Biomarker:** Data from devices to assess health (e.g., Apple Watch ECG).
- **Digital Measurement:** Tools for precise health data collection (e.g., Fitbit).
- **Digital Endpoint:** Measures of treatment outcomes via digital devices (e.g., continuous glucose monitors in diabetes trials).
- **Digital Therapy:** Treatments delivered through digital platforms (e.g., "reSET" for substance use disorder).
- **Digital Medicine:** Technologies for data-driven, personalized care (e.g., AliveCor KardiaMobile).
- **Digital Prescription:** Prescribing medications and therapies digitally (e.g., Omada Health for weight loss).

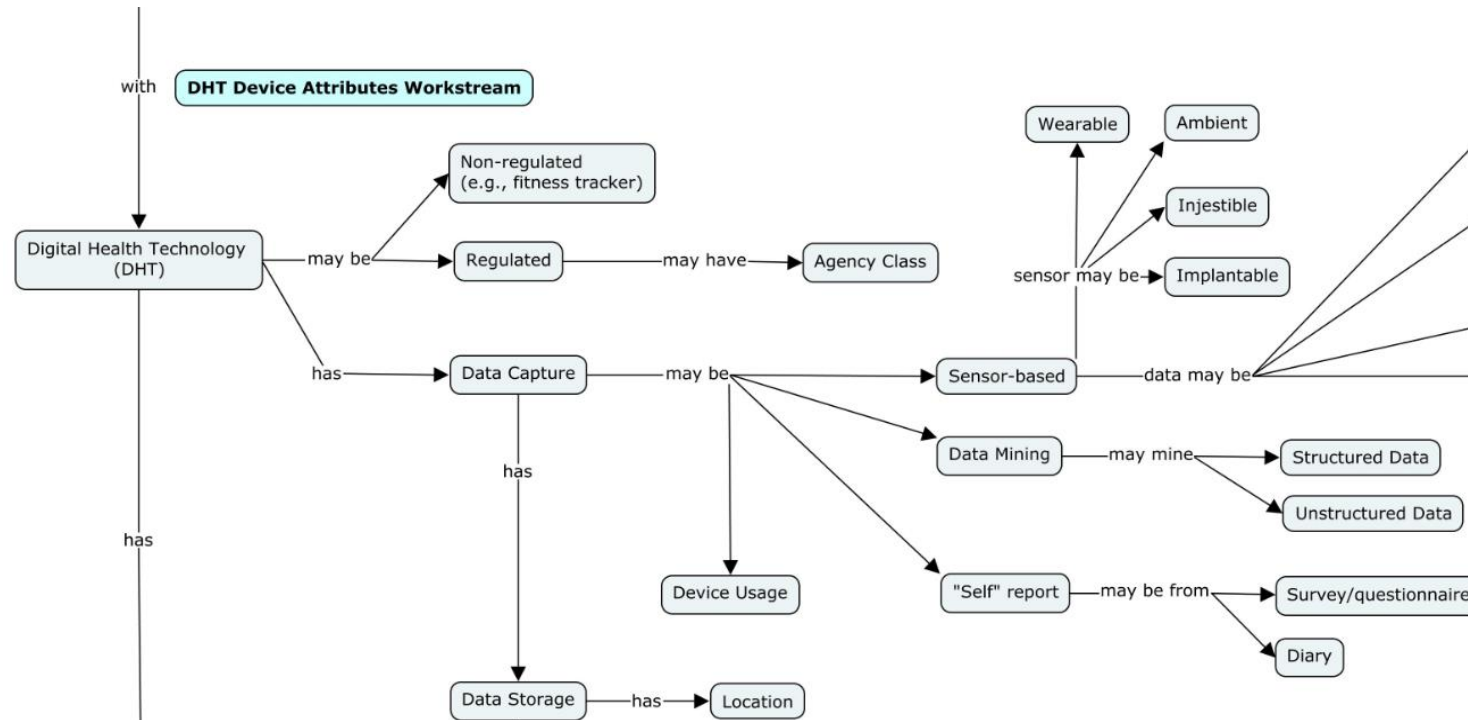
Digital Health Technology – Key Domains

- **Digital Health Platforms:** Integrated systems for patient engagement, telehealth, and remote monitoring (e.g., Epic MyChart, Teladoc Health).
- **Digital Twin in Healthcare:** Virtual replica of a patient for simulations and personalized treatment (e.g., Siemens Healthineers Digital Twin, GE Healthcare's Digital Twin).
- **Digital Diagnostics:** AI-powered tools for early disease detection (e.g., IDx-DR, Viz.ai).
- **Digital Coaching:** AI-driven platforms providing real-time health support & lifestyle guidance (e.g., Lark Health, Omada Health).
- **Digital Therapeutics (DTx) for Mental Health:** Software/digital programs for treating mental health disorders (e.g., EndeavorRx, Woebot).
- **Digital Pharmacovigilance:** AI-driven systems monitoring medication safety (e.g., MedWatcher, Aetion).

Standards Development

- The Clinical Data Interchange Standards Consortium (CDISC) Digital Health Technologies (DHTs) project
- Collaboration with experts from CDISC and the Digital Medicine Society (DiMe)
- **Goals and Initial Phase**
 - Defining project boundaries
 - Mapping the DHT concept landscape

Standards Development



Draft DHT Concept Map (CDISC DHTs Project)

Standards Development

- **Use Case Development**
 - Identified based on feasibility
 - Data availability
 - Alignment with project goals
- **The DiMe Library of Digital Endpoints was utilized to prioritize endpoints, such as Continuous Glucose Monitoring (CGM)**

Endpoint identifier

125

Trial identifier

NCT03668808

Endpoint positioning

Secondary

Endpoint description (per trial registration record)

CGM % Time 70-180 mg/dl, % time 70-180 mg/dl by CGM, In flight period of time and for 72 hours at each destination

Health concept/s

Blood/skin/other biomarkers

Technology type

Wearable

Trial phase

Phase 4

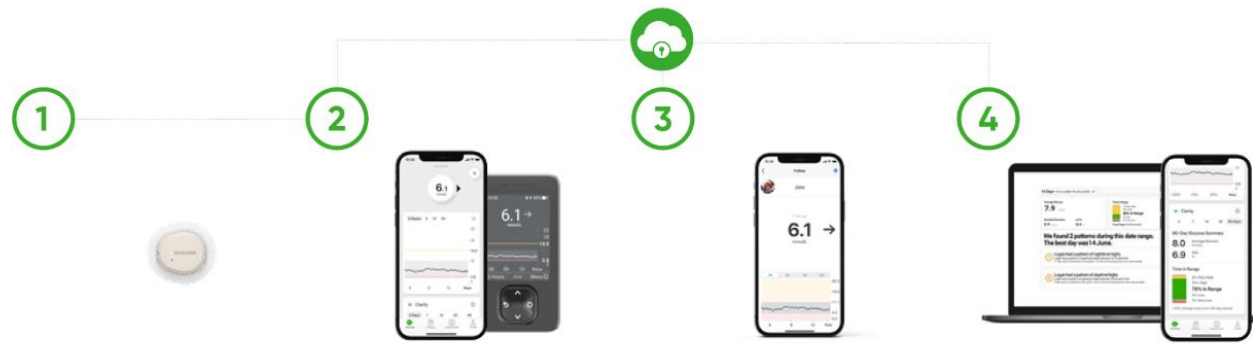


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Standards Development

- **Dexcom G7 system**, leveraging anonymized real-world data to model how it aligns with CDISC standards



DEXCOM G7 SENSOR

The low-profile, all-in-one, wearable sensor sends real-time glucose readings to a user's compatible display device up to every 5 minutes, via Bluetooth.⁷

COMPATIBLE SMARTPHONE[®] (OR RECEIVER)

Smartphone sends glucose readings to Dexcom Cloud via WiFi or cellular data.⁷

The re-designed optional receiver is smaller, with a more vibrant, easier-to-read display.

FOLLOWER'S COMPATIBLE SMARTPHONE[®]

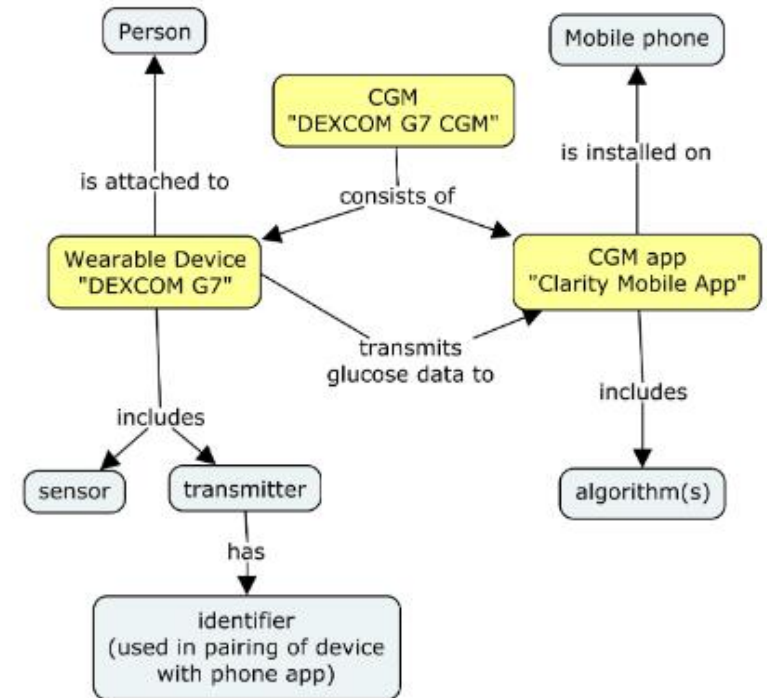
CGM data can then be sent to up to 10 followers via WiFi or cellular data.⁷

Having one or more followers is associated with lower mean glucose, less time in hyper- and hypoglycaemia, more time in range, and significantly higher CGM utilisation.¹¹

DEXCOM CLARITY (WEB OR MOBILE APP)

A user's CGM data may be sent to the Dexcom Clarity app, where they can choose to sync it with their healthcare provider's web portal.¹⁵

Clarity data and trends can now be viewed within the Dexcom G7 app.



Standards Development

- Modeling Process
- CDISC's (SDTM) standards to represent data from the Dexcom G7 system
- Laboratory test results (LB) and device identifiers (DI)
- Relationships between device components and algorithmically derived results

lb.xpt

Row	STUDYID	USUBJID	SPDEVID	LBSEQ	LBREFID	LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSPEC	LBMETHOD	LBANMETH	LBUTC
1	ABC	ABC-001	DEXCOM G7 CGM	1	3732xxxxxxx-1684	EGV	Estimated Glucose Value	82	mg/dL	INTERSTITIAL FLUID	BIOSENSOR	ALGORITHM	2023-06-15T08:00:56
2	ABC	ABC-001	DEXCOM G7 CGM	2	3732xxxxxxx-1984	EGV	Estimated Glucose Value	89	mg/dL	INTERSTITIAL FLUID	BIOSENSOR	ALGORITHM	2023-06-15T08:05:56
3	ABC	ABC-001	DEXCOM G7 CGM	3	3732xxxxxxx-1684	EGV	Estimated Glucose Value	94	mg/dL	INTERSTITIAL FLUID	BIOSENSOR	ALGORITHM	2023-06-15T08:10:57

di.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	ABC	DI	Clarity Mobile App	1	DEVTYPE	Device Type	Mobile phone app
2	ABC	DI	Clarity Mobile App	1	MANUF	Manufacturer	Dexcom
3	ABC	DI	Clarity Mobile App	1	VERSION	Version Identifier	7
4	ABC	DI	DEXCOM G7	1	DEVTYPE	Device Type	Sensor/Transmitter
5	ABC	DI	DEXCOM G7	1	MANUF	Manufacturer	Dexcom
6	ABC	DI	DEXCOM G7 CGM	1	DEVTYPE	Device Type	CGM
7	ABC	DI	DEXCOM G7 CGM	1	MANUF	Manufacturer	Dexcom

reldev.xpt

Row	STUDYID	SPDEVID	PARENT	LEVEL
1	ABC	DEXCOM G7 CGM		1
2	ABC	DEXCOM G7	DEXCOM G7 CGM	2
3	ABC	Clarity Mobile App	DEXCOM G7 CGM	2

Standards Development

- **Future Directions**
- Additional use cases, such as actigraphy for physical activity and sleep measures, are under review.
- The project highlights the need for ongoing revisions to account for the complexity of real-world products and limitations in data granularity.
- This initiative represents a collaborative effort to standardize digital health data, enabling interoperability and accelerating innovation in clinical research.

Global Digital Health Landscape

United States (USA)

- **State-level Legislation:** As of 2025, 19 states have enacted comprehensive privacy laws, with some including health data provisions
- **Health Data-Specific Legislation:** Growing trend, with New York's Health Information Privacy Act (NY HIPA) being the most recent and comprehensive
- **Telehealth Flexibilities:** Ongoing efforts to make Medicare telehealth flexibilities permanent, with current extensions set to expire on March 31, 2025
- **Acute Hospital Care At Home (AHCAH) Program:** Advocates pushing for a five-year extension

Global Digital Health Landscape

European Union (EU)

- European Health Data Space (EHDS): Adopted in 2025, enhancing patient rights and data interoperability across EU Member States¹.
- Regulatory Framework: GDPR, MDR, AI Act, and IVDR governing various aspects of digital health¹.
- Key Initiatives: EU4Health 2021-2027, Digital Single Market Strategy, and European Health Union¹.

Global Digital Health Landscape

Japan

- **Online Pharmacy and Telemedicine:** Starting January 2025, licensed online pharmacies and telemedicine providers can advertise prescription drug services.
- **Regulatory Changes:** The Pharmaceutical Act of 2014 has propelled digital therapeutics, leading to approvals for innovative healthcare solutions.
- **"Japan Vision: Health Care 2035":** Promotes widespread use of telemedicine and integration of digital health solutions.
- **Digital Health Transformation:** As of February 2025, Japan is undergoing a digital revolution in healthcare, focusing on telemedicine, digital therapeutics, and AI-based diagnostic tools.

Global Digital Health Landscape

Global Initiatives

- Global Digital Health Partnership (GDHP): Collaboration of 33 countries and territories, WHO, OECD, and IDAIR to improve healthcare through digital services
- WHO Global Strategy on Digital Health 2020-2025: Provides guidance for global digital health transformation.

Regulatory Guidance

FDA

- The FDA released final guidance on "Digital Health Technologies for Remote Data Acquisition in Clinical Investigations" in December 2023
- Key aspects include:
 - Recommendations for selecting suitable DHTs for clinical investigations
 - Guidelines for describing DHTs in regulatory submissions
 - Verification and validation requirements for DHTs
 - Use of DHTs to collect data for trial endpoints
 - Risk management associated with DHT use
 - Data retention and protection
 - Roles of sponsors and investigators
 - Device safety considerations and the potential need for Investigational Device Exemptions (IDEs) for certain DHTs

Regulatory Guidance

EMA

- European Medicines Agency (EMA) is responsible for reviewing data generated by DHTs that support medicinal product development, use, or monitoring
- **Key aspects include:**
 - **Compliance with the General Data Protection Regulation (GDPR) for patient data**
 - **Regulation of DHTs that meet the definition of medical devices or in vitro diagnostics by national competent authorities**
 - **Implementation of new regulations on medical devices and in vitro diagnostics, progressively replacing existing directives**

Regulatory Guidance

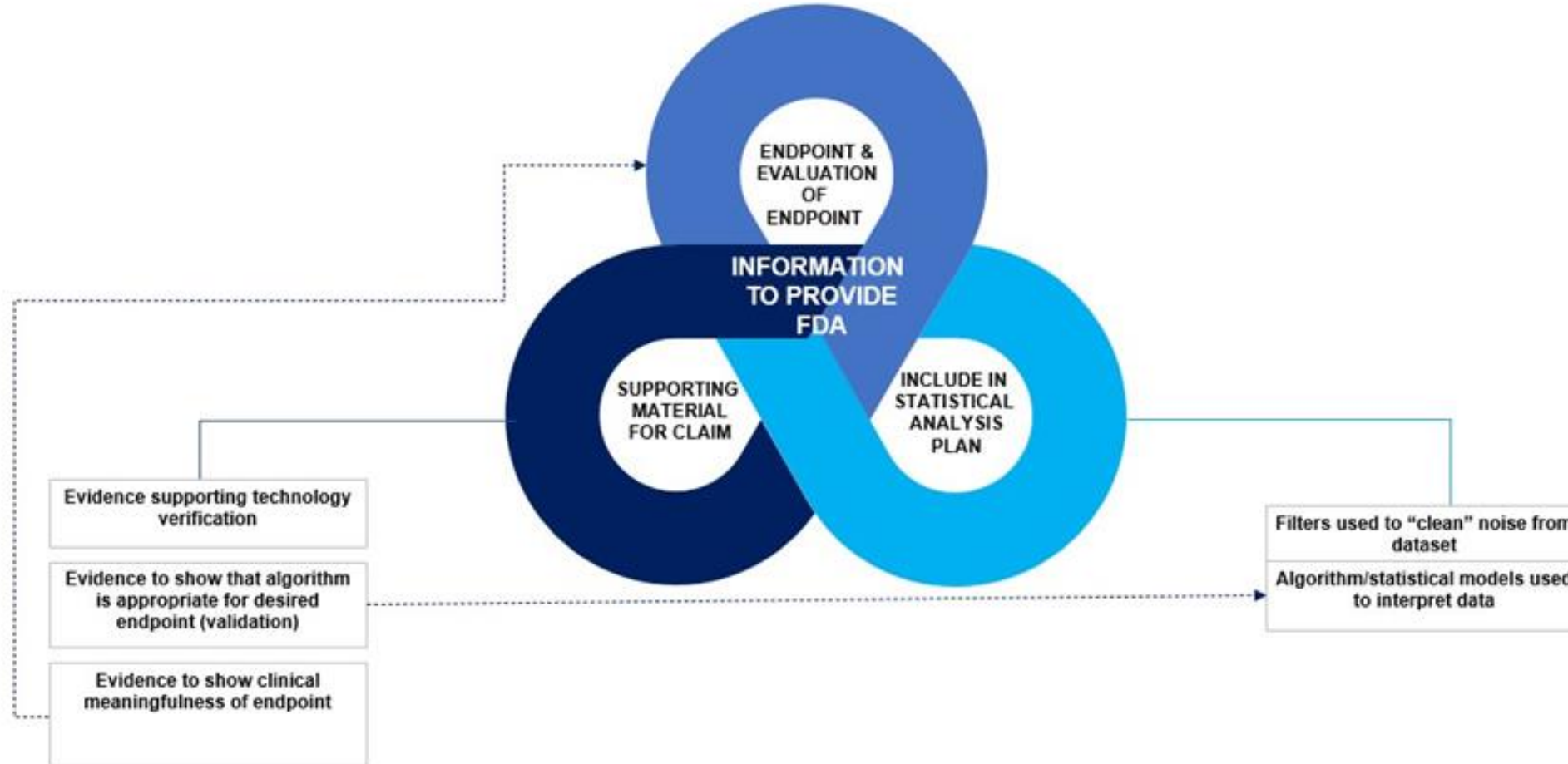
PMDA

- Japan's Pharmaceuticals and Medical Devices Agency (PMDA) has implemented several initiatives to expedite the commercialization of Software as a Medical Device (SaMD):
- Introduction of "DASH for SaMD 2" strategy in September 2023, building on the 2020 framework
- Implementation of a two-stage approval system for SaMD
 - Initial approval based on performance and safety, followed by a second-stage approval based on clinical data and real-world use
 - Establishment of a target review timeframe of six months for SaMD products under priority review
- Plans to restructure the organization to include a department dedicated to SaMD review
- Additionally, the PMDA has issued guidance on package insert digitization for medical devices and IVDs, effective since August 2021

DiME Playbook Guidance on Submission

- **Readily reconstructed**
- **Source documents**
 - **Earliest practically retainable record of the data.**
 - **Source data as the first level of data that is both clinically relevant and interpretable**
- **Audit trails**
 - **Track the data (including any modifications made to the data)**
 - **Point of creation by the sensor in the connected sensor product through to the first practically retainable record of the data (durable media)**

Regulatory Submission



Source: [CTI](#)

Verification and Validation

- **Verification**

- The process of ensuring that a product, service, or system meets the specified requirements and design specifications.

- **Analytical validation**

- The process of evaluating the performance of analytical methods used in digital health technology.

- **Clinical validation**

- The process of evaluating the safety and effectiveness of digital health technology in real-world clinical settings.

Case Study - Verification and Validation

- **Predictive Biomarkers** – Utilizing algorithmic models on wearable device data to forecast health conditions and accelerate drug development
- **Regulatory Challenge** – Ensuring **consistency, accuracy, traceability, and validity** for clinical study compliance
- **Case Study Overview**
 - Developed a predictive biomarker based on **Heart Rate Variability (HRV)**.
 - Applied **verification and validation methods** to assess the algorithm's performance.
 - Proposed a **framework** for integrating DHT in clinical trials.
- **Access Full White Paper:** [PHUSE Case Study](#)

AI/ML in DHT

- **AI & ML are transforming DHTs by enabling predictive analytics, personalized treatment, and automation**
- **Key Applications:**
 - **Diagnostics & Imaging:** AI-powered tools detect diseases (e.g., tumor detection in CT scans)
 - **Virtual Assistants & Chatbots:** Enhancing patient engagement (e.g., WHO's SARAH AI)
 - **Remote Monitoring & Digital Biomarkers:** AI-driven insights from wearables
 - **Clinical Trials & Digital Twins:** Predicting treatment responses
- **Challenges:** Bias, data security, AI hallucinations, and ethical governance
- **Future Outlook:** Responsible AI frameworks, human-in-the-loop approaches, and balancing IQ vs EQ in AI-driven healthcare

Benefits & Challenges

Benefits

- New range of endpoints
- Rich data, real-time monitoring
- Lower cost and reducing patient burden

Challenges

- Scientific and technical
- Operational
- Regulatory submission



Additional Resources

- FDA: <https://www.fda.gov/medical-devices/digital-health-center-excellence>
- CDISC: <https://www.cdisc.org/standards/in-development/digital-health-technologies>
- DiMe: <https://dimesociety.org/>
- CTTI: <https://www.ctti-clinicaltrials.org/our-work/digital-health-technologies>
- WHO GDHP: <https://gdhp.health/>

Acknowledgements

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