

ST10: Digging Deep into Digital Biomarkers: Empowering Clinical Trials

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Introduction

What is Digital Biomarker

- Unique features
- Digital vs. Traditional
- Use case of digital biomarker in clinical trials

Benefits & Challenges

Benefits

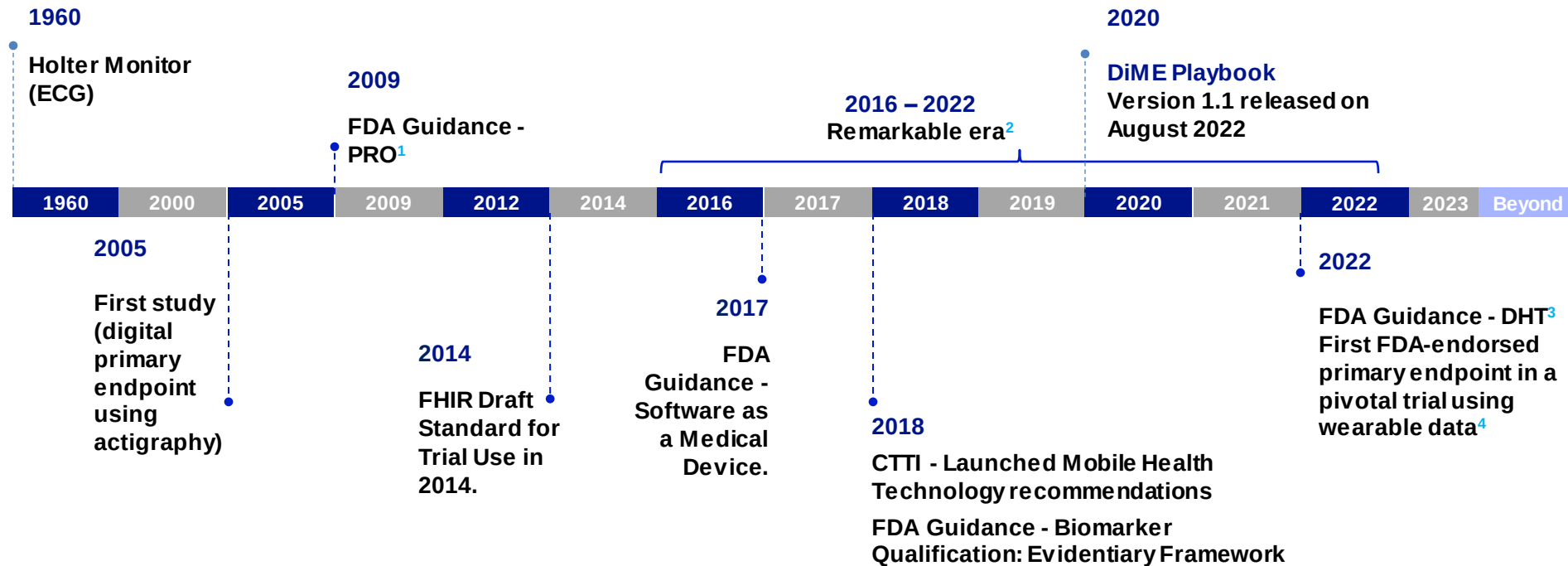
- New range of endpoints
- Rich data, real-time monitoring
- Lower cost and reducing patient burden

Challenges

- Scientific and technical
- Operational
- Regulatory submission



Timeline



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First Draft Guidance released on 21Jan2022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](#)

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.

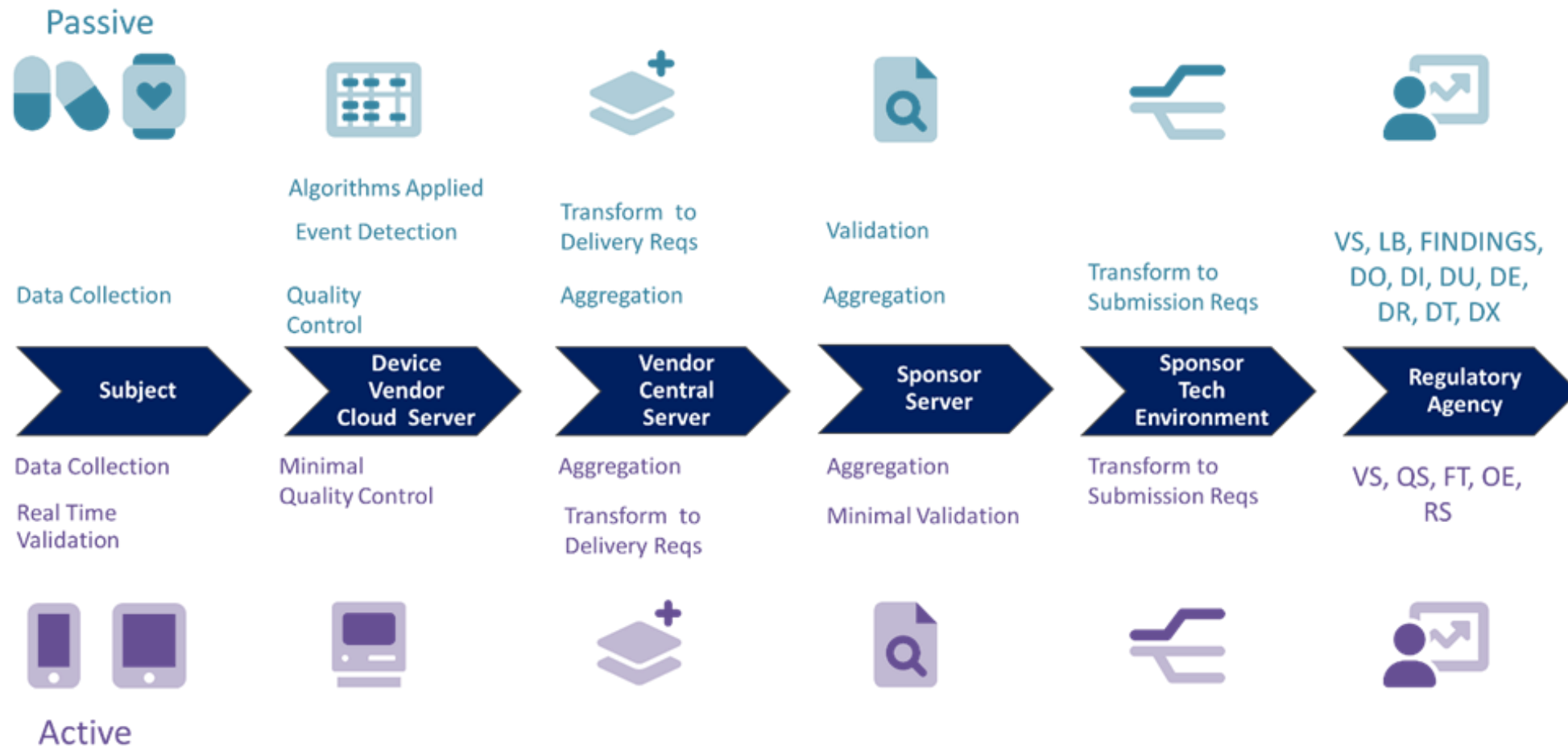


Statistical Modeling Consideration

Aspects to Consider

- Nature of the data
- Missing data
- Computational methods
- Bias

Data Flow

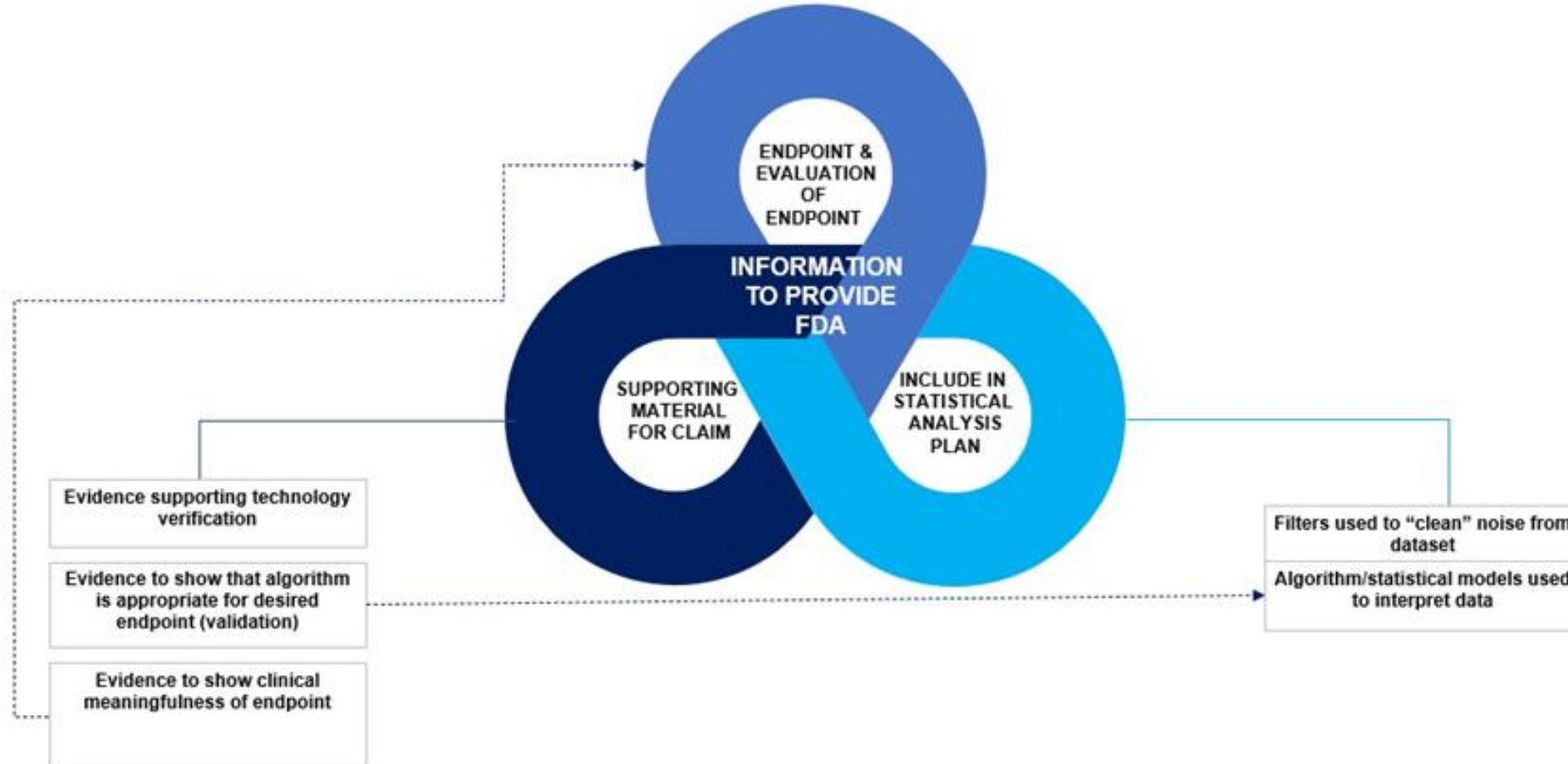


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Regulatory Submission



Source: [CTTI](#)

FDA Guidance on DHT

- Sponsor should provide fit-for-purpose for use of DHT (Digital Health Technology)
 - Commercially available DHTs
 - Technical specifications and user manuals
- Data integrity
 - Sponsors should include information about data management aspects
 - Data Collection, Storage, Transmission, Archive
 - Privacy and Security

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)

Forward Looking

The market for digital health technology is projected to grow significantly, reaching USD 27.17 billion by 2030 (Straits Research, 2022)

- Personalized medicine
- Clinical trial design
- Early detection of drug efficacy
- Improved safety monitoring
- Development of new novel digital medicinal products, combination therapies
- Better understanding of disease progression
- Reduced time to market



Acknowledgments

- Digital Biomarkers in Clinical Submission project members
- PHUSE Emerging Trends and Technologies working group
- Katie Warren

Back-up

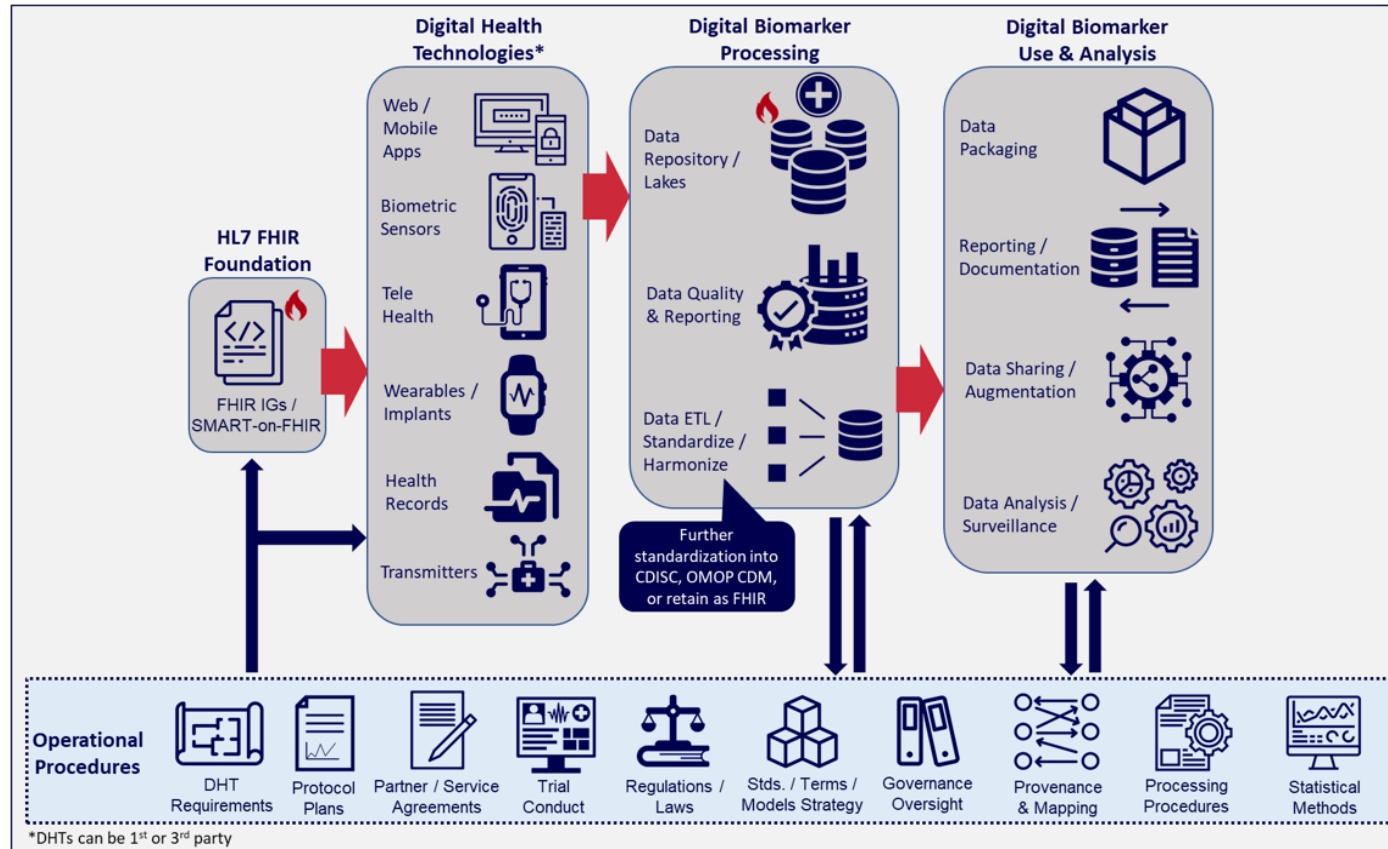


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**Working
Groups**



FHIR - enabled DHTs for Digital Biomarker Conceptual Data Flow



21st Century Cures Act – TMAP (Technology Modernization Action Plan) - DSPAP (Data Standards Program Action Plan) - API – HL7-FHIR (FDA, EMA, Health Candata, PMDA)

Questions?



**Working
Groups**

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Classification

Classification strategies

- **BEST** (**B**iomarkers, **E**ndpoint**S** and other **T**ools) categories
- Clinical status/outcome
- Patient interaction
- FDA device clearance

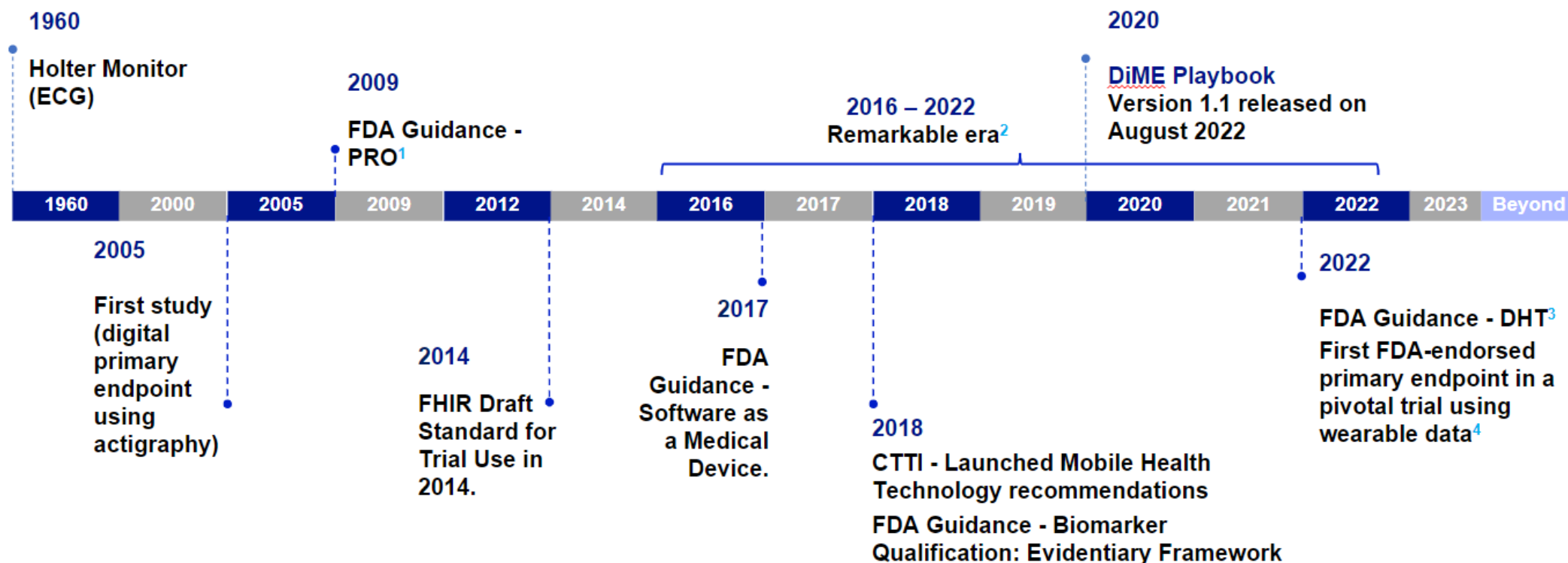
FDA guidance

*Digital Health Technologies for Remote Data Acquisition in Clinical Investigations
Guidance for Industry, Investigators, and Other Stakeholders 2021*

Statistical Modeling Consideration

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- Bias
- Computational methods
- Missing data
- Nature of the data



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