



SPA MDR CDR SCE

# RE08

## Wearable Technology: Enhancing Patient Monitoring and Real-World Evidence

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Science Conference

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# About the Presenters



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## Bio

Over the past 30 years, Bill has led many digital transformations in clinical trial analysis and reporting, optimizing trials through advanced data strategies and emerging technologies. He has partnered with leading pharma, CROs, & technology providers to modernize clinical research, integrating new tech & next-gen analytics. With expertise in statistical computing, biometrics, and regulatory, he helps organizations harness technology to improve efficiency & drive innovation.



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## Bio

Sridhar Vijendra has a Master's degree in Biomedical engineering and an inclination towards all things technical. He started his career doing programming and research in biomedical signal processing algorithms. After serving multiple roles including that of a statistical programmer, he believes he has found his calling working closely with business analysts and project managers on SCE implementations at Sycamore Informatics, India.

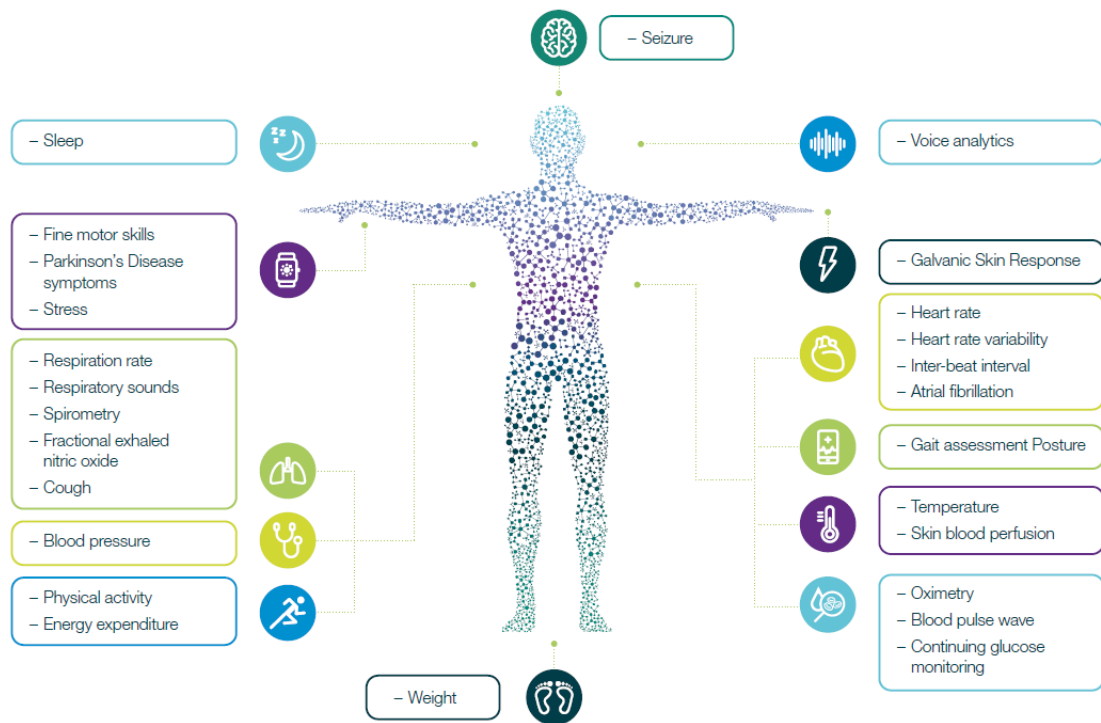


# Agenda

- What are Wearables
- Wearables in Clinical Trials
- Approved Wearables
- Challenges with Wearables
- Volume of Data: Technology Solutions
- Statistical Computing Environment (SCE) Considerations
- Elements of a Wearables Data Strategy
- Wearables in Clinical Trials: Opportunities
- Future Outlook



# Range of Physiological Parameters Captured by Digital Health Technologies (aka Wearables)



- Wearables are electronic devices designed to be worn on the body; accessories such as smartwatches, fitness trackers, smart glasses, and even smart clothing
- Devices integrate sensors, microprocessors, and wireless connectivity to collect, process, and transmit data in real-time
- Examples: Apple Watch, Fitbit, Garmin smartwatches, Oculus VR headsets, and medical-grade ECG monitors



# Familiar Examples of Wearables

## Continuous Glucose Monitoring

Traditional glucose monitoring requires frequent blood tests, modern CGM wearables, (e.g., Dexcom G7, Freestyle Libre) track blood glucose levels non-invasively while also integrating them with insulin pumps



## Cardiac & Blood Oxygen Monitoring

Devices originally built with a focus on fitness such as the Apple Watch Series 9 and Fitbit Sense are now FDA approved and now feature sleep apnea detection, atrial fibrillation (AFib) detection, SpO2 sensors, and real-time ECG readings



Pictures:

<https://zoe.com/learn/what-is-a-continuous-glucose-monitor>

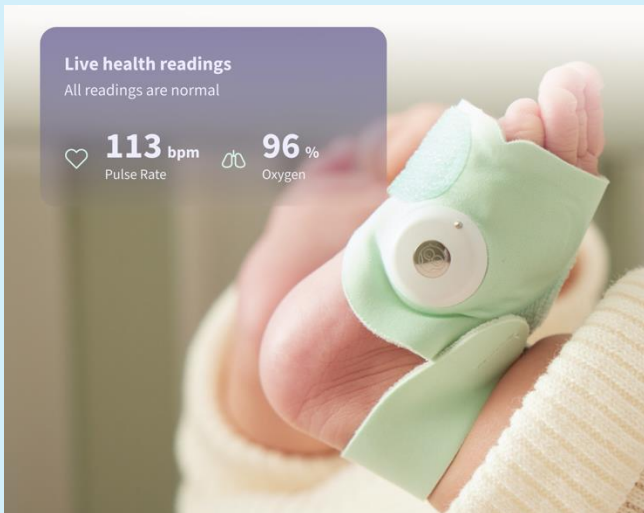
<https://www.cnet.com/health/personal-care/apple-watch-blood-oxygen-app-how-it-works/>



# Other Examples of Wearables

## Smart Fabrics and E-Textiles

Smart clothing integrates sensors directly into textiles. Companies like Hexoskin and Owlet have developed smart shirts and baby monitoring socks that measure heart rate, breathing, and activity



Pictures:

<https://hexoskin.com/pages/astroskin-vital-signs-monitoring-platform-for-advanced-research>

<https://owletcare.com/products/owlet-dream-sock>



# Interest in Wearables in Clinical Trails

Have you conducted/are conducting a clinical trial using wearables and other mHealth sensors?

|                             |                                                                                     |       |
|-----------------------------|-------------------------------------------------------------------------------------|-------|
| Considering/planning        |  | 24.0% |
| Yes – currently in progress |  | 7.5%  |
| Yes – already completed     |  | 15.5% |
| No                          |  | 34.0% |
| No response                 |  | 19.0% |

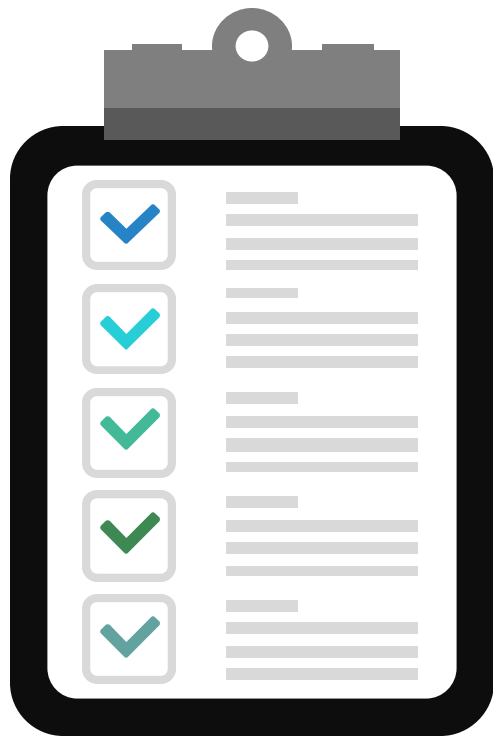
Which patient groups would most benefit from novel digital endpoints; patients living with

|                |                                                                                     |       |
|----------------|-------------------------------------------------------------------------------------|-------|
| Oncology       |  | 9.0%  |
| Rare Disease   |  | 20.0% |
| CNS            |  | 37.0% |
| Cardiovascular |  | 17.0% |
| Diabetes       |  | 17.0% |

Do you see digital endpoints primarily as

|                       |                                                                                     |       |
|-----------------------|-------------------------------------------------------------------------------------|-------|
| Supplementary         |  | 45.0% |
| Stand alone           |  | 19.0% |
| Composite (with COAs) |  | 36.0% |

# Benefits of Wearables in Clinical Trials



1

## Enhanced Data Quality and Objectivity

Real-time, high-frequency data that reduces reliance on patient-reported outcomes (PROs) & improves data accuracy

2

## Improved Patient Engagement & Compliance

Reduces patient burden & real-time feedback, wearables increase adherence to study protocols and improve long-term engagement

3

## Operational Efficiency and Cost Reduction

Automates patient monitoring and data collection lowers trial costs, reduces site visits, and can accelerate clinical trial timelines

4

## Decentralized Clinical Trials (DCTs)

Wearables enable remote participation, making trials more accessible and improving participant diversity and retention

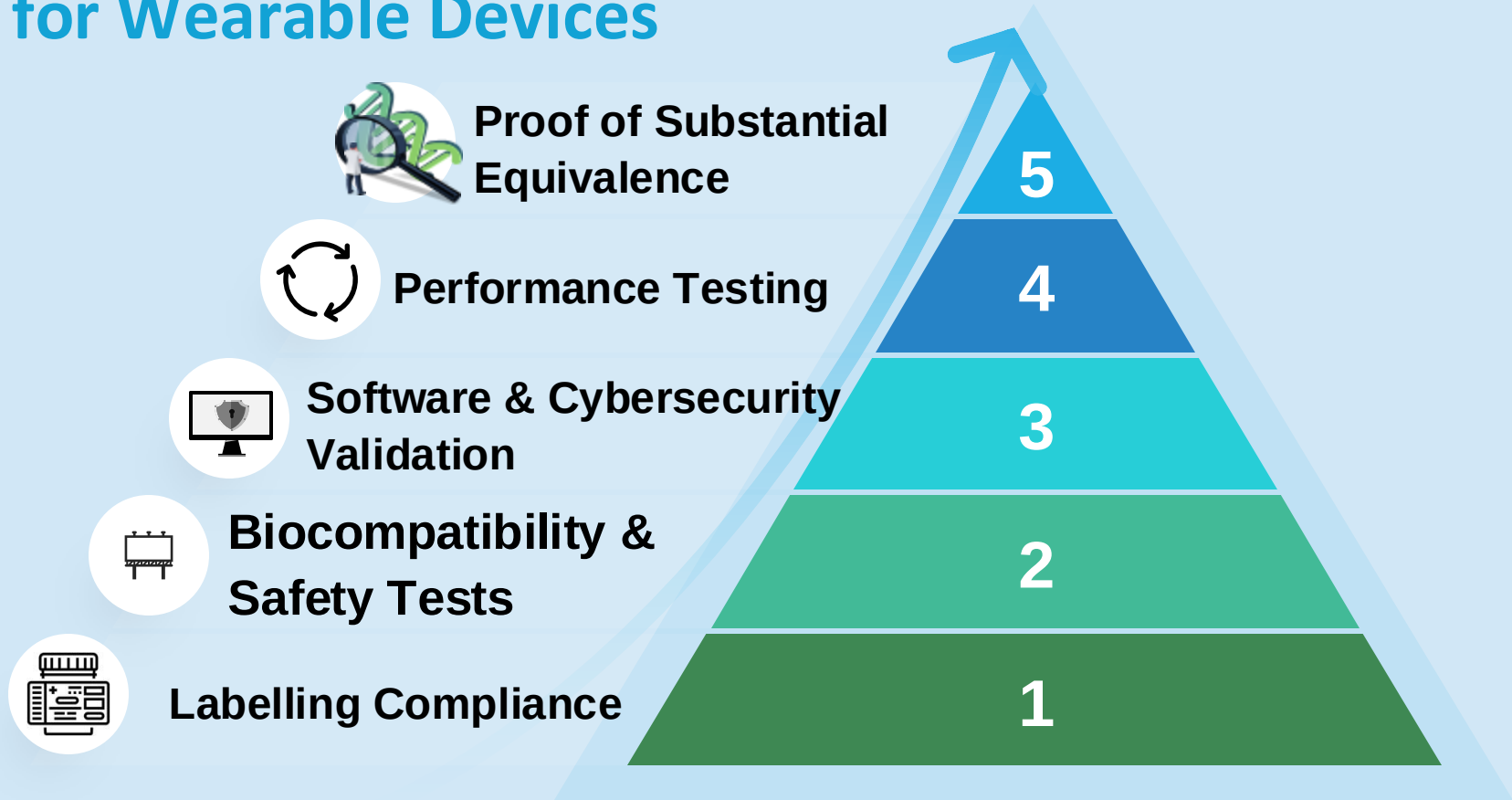
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## Regulatory Considerations & Future Potential

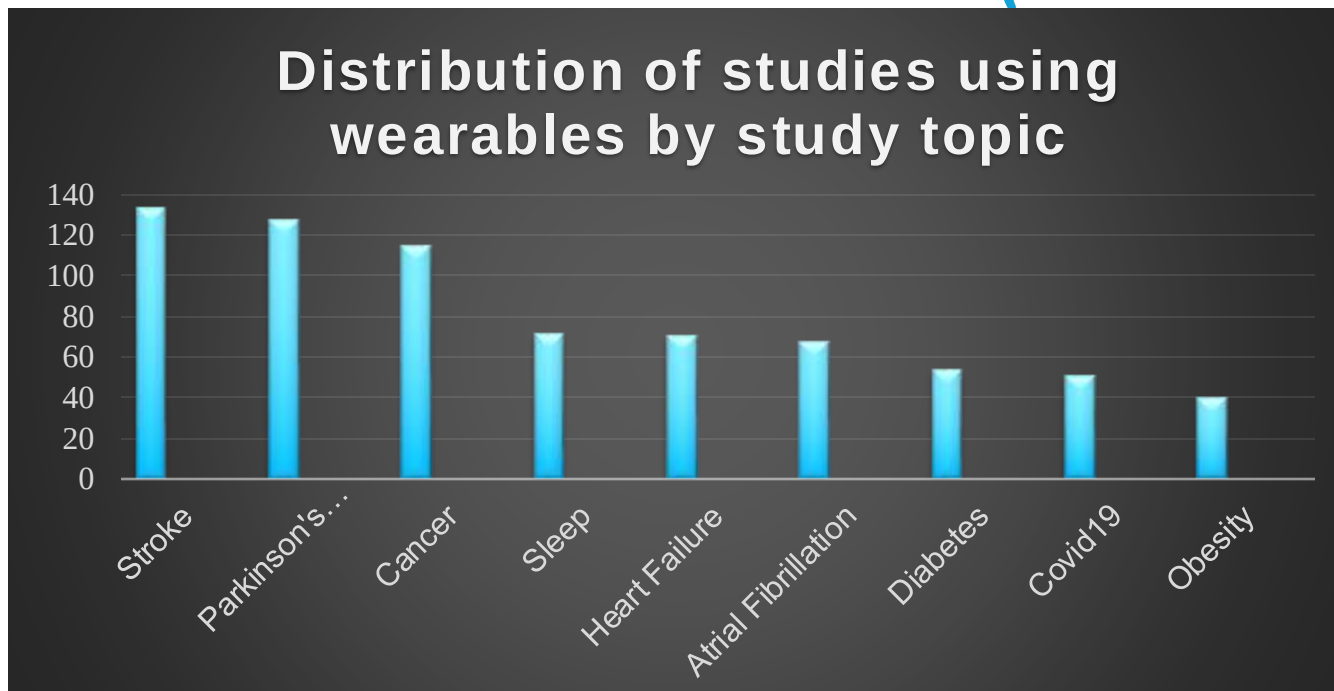
FDA, EMA, and Health Canada are developing guidelines to ensure data integrity, patient privacy, and wearable validation



# Regulatory Approval Process: FDA-Cleared Class II for Wearable Devices



# Wearables in Clinical Trials (ClinicalTrials.gov)



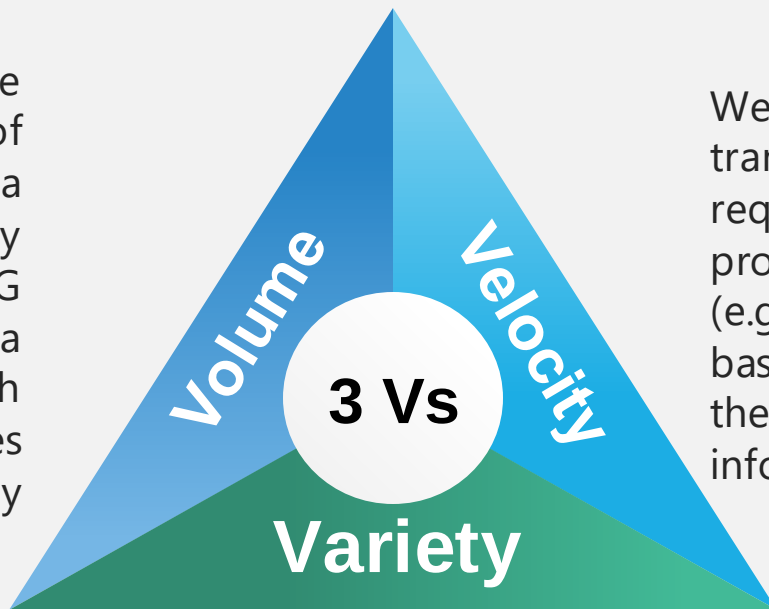
| Time Period  | # of Studies |
|--------------|--------------|
| Before 2000  | 2            |
| 2001-2010    | 6            |
| 2011-2020    | 1,125        |
| 2021-Present | 1,602        |
| Other        | 51           |

- As of February 12, 2024, there have been a total of 2,786 "wearables" studies
- The number of studies has exploded starting in 2011



# Data Strategy for Wearables: The 3 Vs

Wearable devices generate **vast amounts** of **continuous** health data (e.g., heart rate, activity levels, glucose levels, ECG readings); data accumulation can reach terabytes or even petabytes during a study



Wearables collect and transmit data in **real-time**, requiring **advanced** data processing **architectures** (e.g., cloud computing, AI-based analytics) to manage the high-speed influx of information

**Structured** data (heart rate readings, timestamps) and **unstructured** data (raw sensor outputs, accelerometer data, sleep patterns); harmonizing this data across different devices and platforms presents a major challenge in **interoperability**



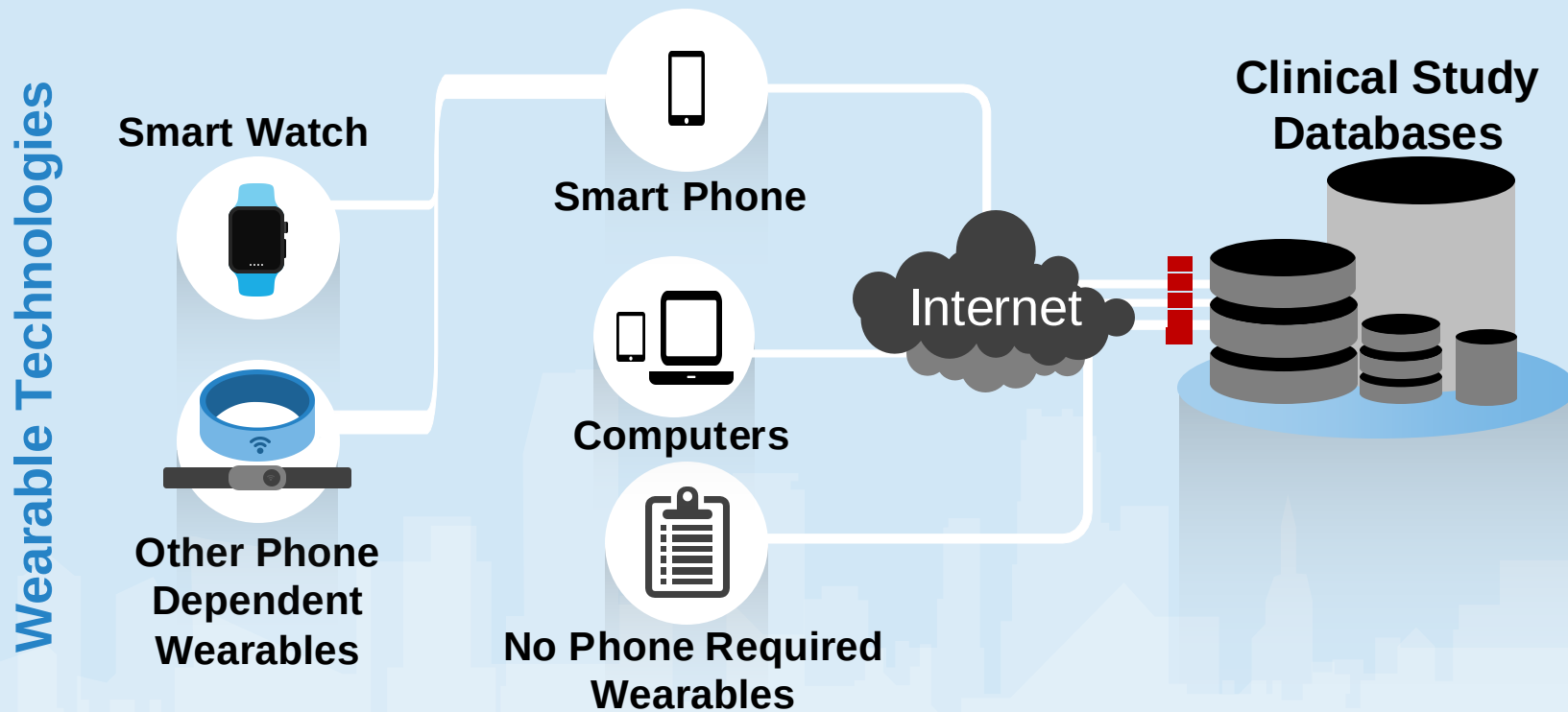
# Elements of a Data Strategy for Wearables, Continued

- **End-to-End Architecture:** Design the data flow and business practices and standards from device to storage to analysis and reporting
- **Ensure Data Veracity:** Validate wearable data accuracy by assessing algorithm reliability, bias, & precision; ensure alignment with endpoints
- **Optimize Data Ingestion:** Choose between real-time streaming (for immediate clinical insights and safety monitoring) and batch processing (to reduce network strain and optimize resources)

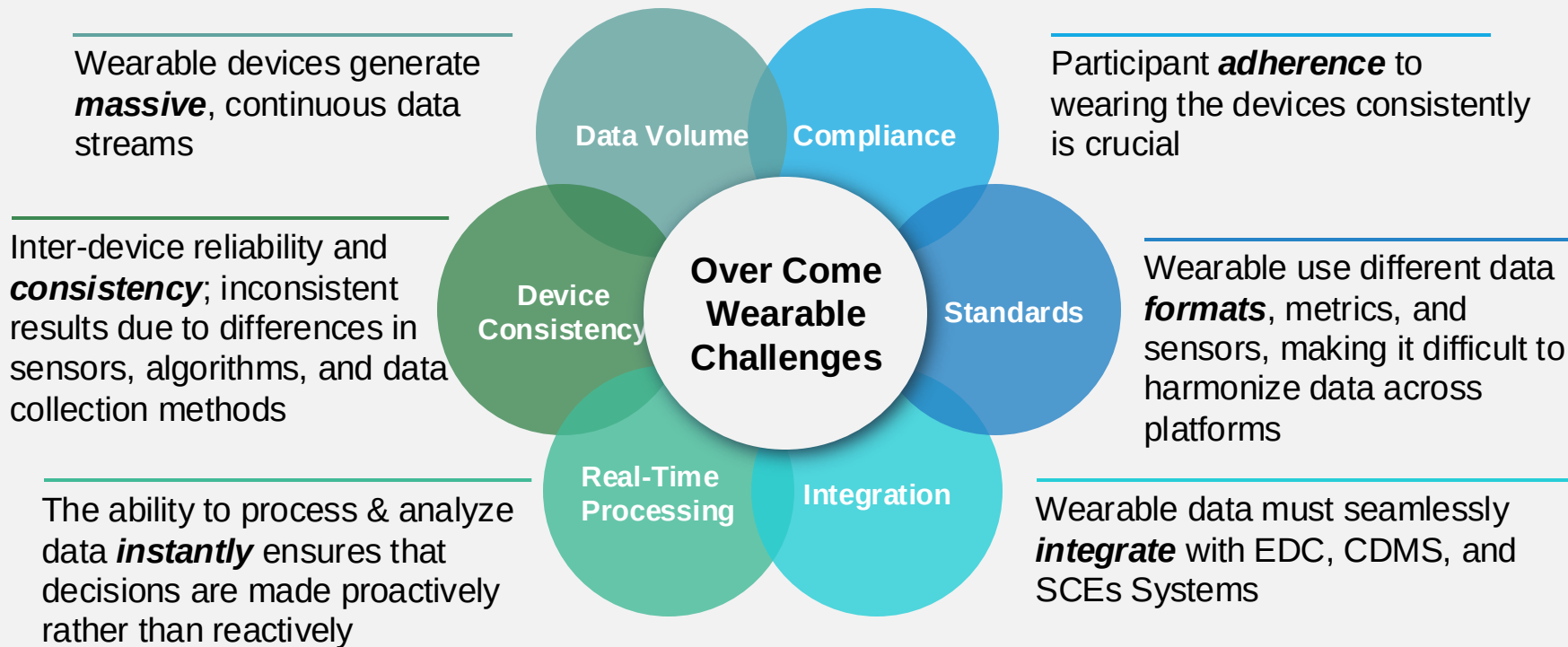
- **Enhance Data Integration:** Standardize wearable data formats and ensure compatibility with EHRs, EDC, and regulatory submission requirements
- **Plan for Data Continuity:** Device malfunctions, non-adherence, and environmental factors; implement imputation techniques, threshold definitions, and automated alerts
- **Implement Compliance & Security Measures:** With HIPAA, GDPR, and FDA/EMA regulations, enforce data encryption, audit trails, and traceability mechanisms



# The Long Road: From source to database



# Challenges with Wearables



# Volume of Data: Technology Solutions

## CLOUD-BASED PLATFORMS

**Scalable** infrastructure capable of handling large datasets  
Organizations must consider cost implications & healthcare **regulations** like HIPAA and GDPR

## DATA STORAGE & MGT

Data lakes built on platforms like AWS Lake Formation, allow researchers to **aggregate** and analyze large datasets, facilitating machine learning applications

1

2

Solving  
the data  
volume  
challenge

3

4

## DATA PROCESSING FRAMEWORKS

**Processing** large datasets requires **distributed** computing frameworks that analyze high-velocity data streams

## REAL-TIME DATA STREAMING

Real-time data **streaming** technologies for immediate analysis and response; implement platforms that have **low-latency** data ingestion



# Statistical Computing Environment (SCE): Key 'must have' system capabilities



Consume metadata standards including ***transformations*** and mappings



***Standardize*** handling of data (collection to locking to archiving)



***Data ingestion***: Handle data from any source, in any format



Define and manage ***role-based*** access across the lifecycle



Reliably ***audit*** access and changes



***Coordinate*** tasks, track work and enforce processes



Maintain ***traceability*** and ***lineage*** across programs, data and outputs with version control



***High-performance*** computing environment that is scalable to support the access, processing, analysis, and storage of large data



***Connect*** to data sources, up & downstream applications via integrations and REST APIs



# Transforming Data into Submission Ready Analyses

## Data Validation

- Ensure **accuracy**, completeness, and consistency of data
- Implement **automated** validation tools to detect and correct anomalies
- Establish **regular** calibration processes for long-term data reliability

## Reproducible Results

- Implement **lineage** and traceability across acquisition, processing, and analysis with built in version control
- Adopt standardized **data formats** & analysis programs to enhance study consistency
- Conduct regular **audits** to maintain protocol adherence and data integrity

## Standardized Reporting

- **Automate** report generation (global programs, tools)
- Define **clear and consistent** data handling, statistical analyses, and visualizations
- Adhere to regulatory reporting **standards**, including data anonymization & ethical considerations

## Regulatory & Compliance

- Good Clinical Practice (GCP) & FDA 21 CFR Part 11 for **data integrity**
- Implement robust **access controls**, audit logs, and data encryption
- Conduct internal **audits** & regulatory consulting to identify and mitigate risks



# Data & Dictionary Standards: Many collection standards and formats (transformations required)

RWD **must** be submitted consistent with the FDA Data Standards Catalog

*Result: RWD to be submitted using CDISC standards*

## CDISC

Data in Domains for regulatory submissions (SDTM & ADaM)

## PCORnet

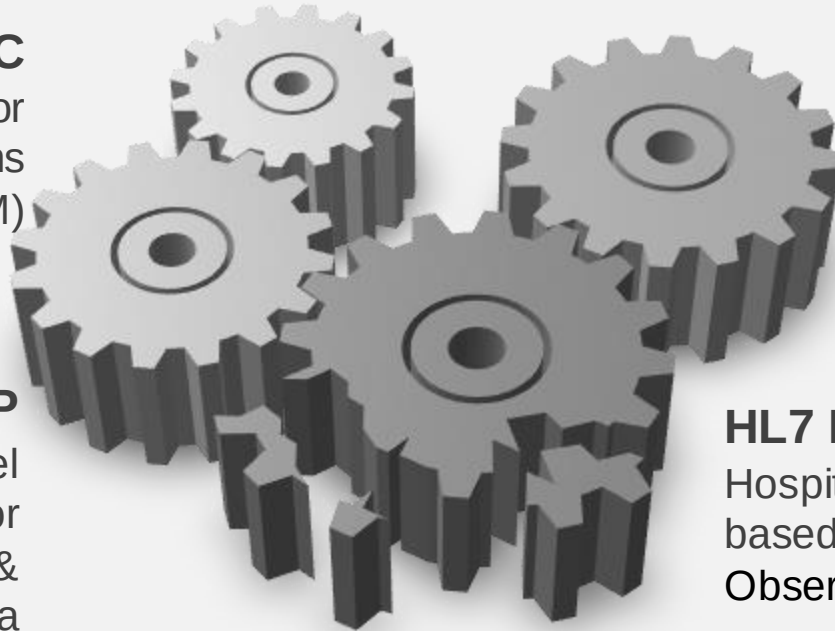
Another CDM standard for EHR and claims data for large-scale, multi-site research

## OMOP

Common Data Model (CDM) standard for EHR, claims, & registry data

## HL7 FHIR

Hospitals, EHRs, & app exchange based on resources (e.g., Patient, Observation, Medication)



# The Future....



*Image generated using AI (DALL·E, OpenAI)*

# Future Outlook – The next 5-years

- **AI-Powered Wearables with Real-Time Clinical Decision Support**
  - ***Real-time analytics***: Wearables will not only passively collect data but also use AI and machine learning to provide real-time, predictive analytics
  - ***AI-driven anomaly detection***: Wearables will be capable to flag irregular health events (e.g., cardiac arrhythmias, glucose spikes) and suggest interventions
  - ***Automated adverse event reporting***: Wearables will detect side effects and autonomously notify clinical investigators of potential drug interactions or adverse reactions.



# Future Outlook – Beyond 5-years

- Wearables to be fully integrated with EHRs, seamless bidirectional data exchange between clinical trials and real-world healthcare creating a unified digital health ecosystem
- Wearable data becomes regulatory-grade
  - **Interoperable health data sharing:** Standardized APIs (FHIR, HL7) will enable seamless sharing between hospitals, trial sponsors, and regulatory agencies.
  - **Regulatory agencies (FDA, EMA)** will accept wearable-generated health metrics as primary endpoints for drug approvals
  - **Standardized digital biomarkers:** Heart rate variability, SpO<sub>2</sub>, sleep patterns, and glucose trends will be considered valid endpoints
  - **Regulatory AI auditing:** AI-driven compliance tools to validate wearable data for FDA submissions, streamlining the approval process



# Another Part of the Future - Bring Your Own “Device” (BYOD)

- Participants to use their own technologies, leading to better compliance
- Participants have familiarity with and access to the technology they use in their daily lives
- Sponsors can design patient-centric studies with lower costs and burden on study sites
- Potentially expands participation in clinical trials for populations with limited access to clinical facilities, (e.g., older adults, people with disabilities, or living in remote locations)
- Potential challenges: introduction of biases, device and data inter-reliability just to name a few!



# Wrap-up



Wearables will become a key element of clinical trial data collection

Before you embark upon this journey:

- Develop a wearables **data strategy**
- **Engage** Regulatory Affairs for the latest guidance
- Architect and deploy a technology solution for the data collection (from **end-to-end**) enabling real-time collection
- **Frist class** data storage, processing, and analysis solution (e.g., SCE) with the supporting business processes



# Connect with the Presenters!

**Bill Qubeck**



**Sridhar Vijendra**



# Thank you!

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