



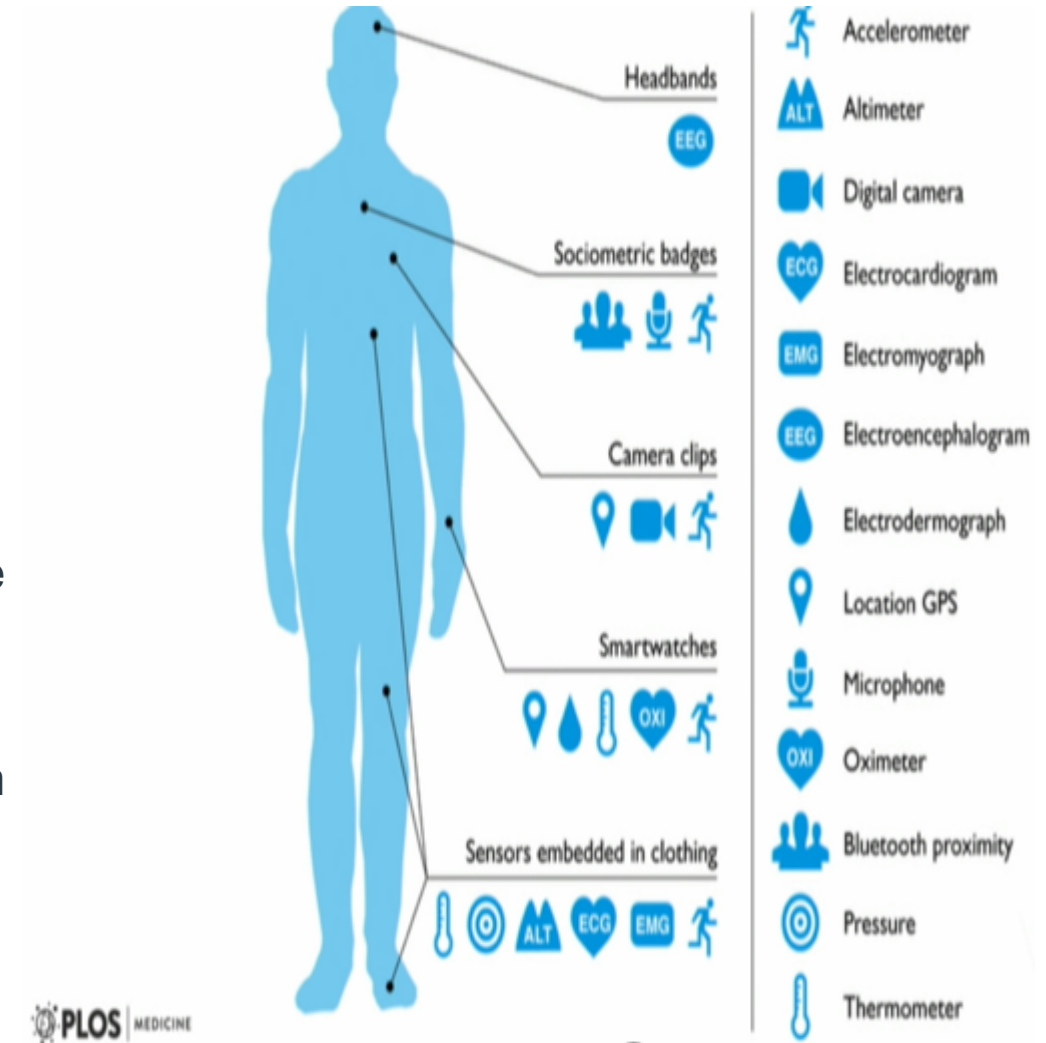
Managing Data Flow for Wearables, Apps & Sensors

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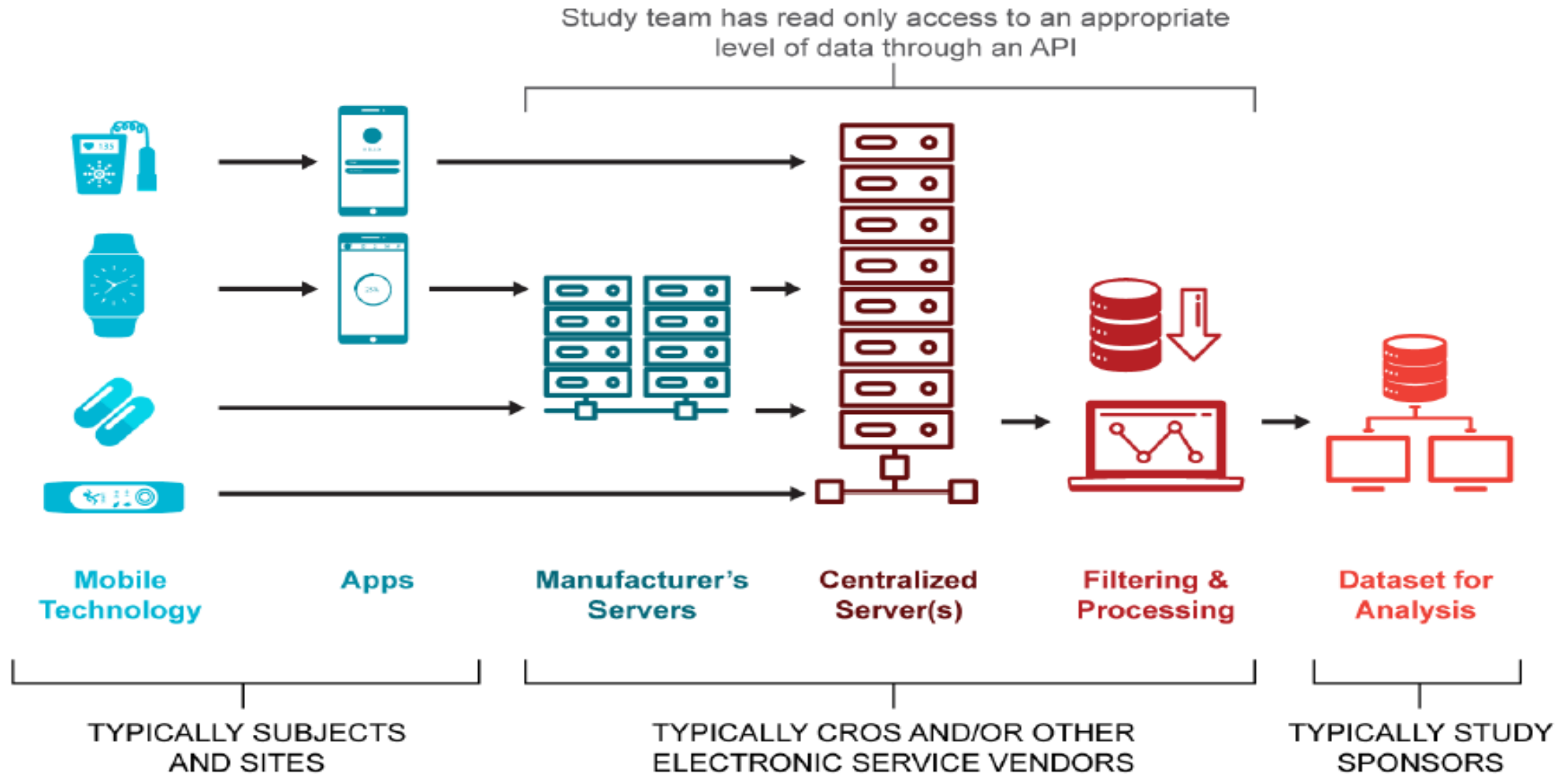
- + Industry Paradigm
- + Data Flow in Wearables, Apps and Sensors
- + Setting up Systems for Virtual / Hybrid trials
- + Best Practices – Data Security & Integrity
- + Data Quality Principles
- + Best Practices – Data Collection, Cleaning and Analysis
- + Contemplating Metrics
- + Regulatory Aspects

Changing Industry Paradigms

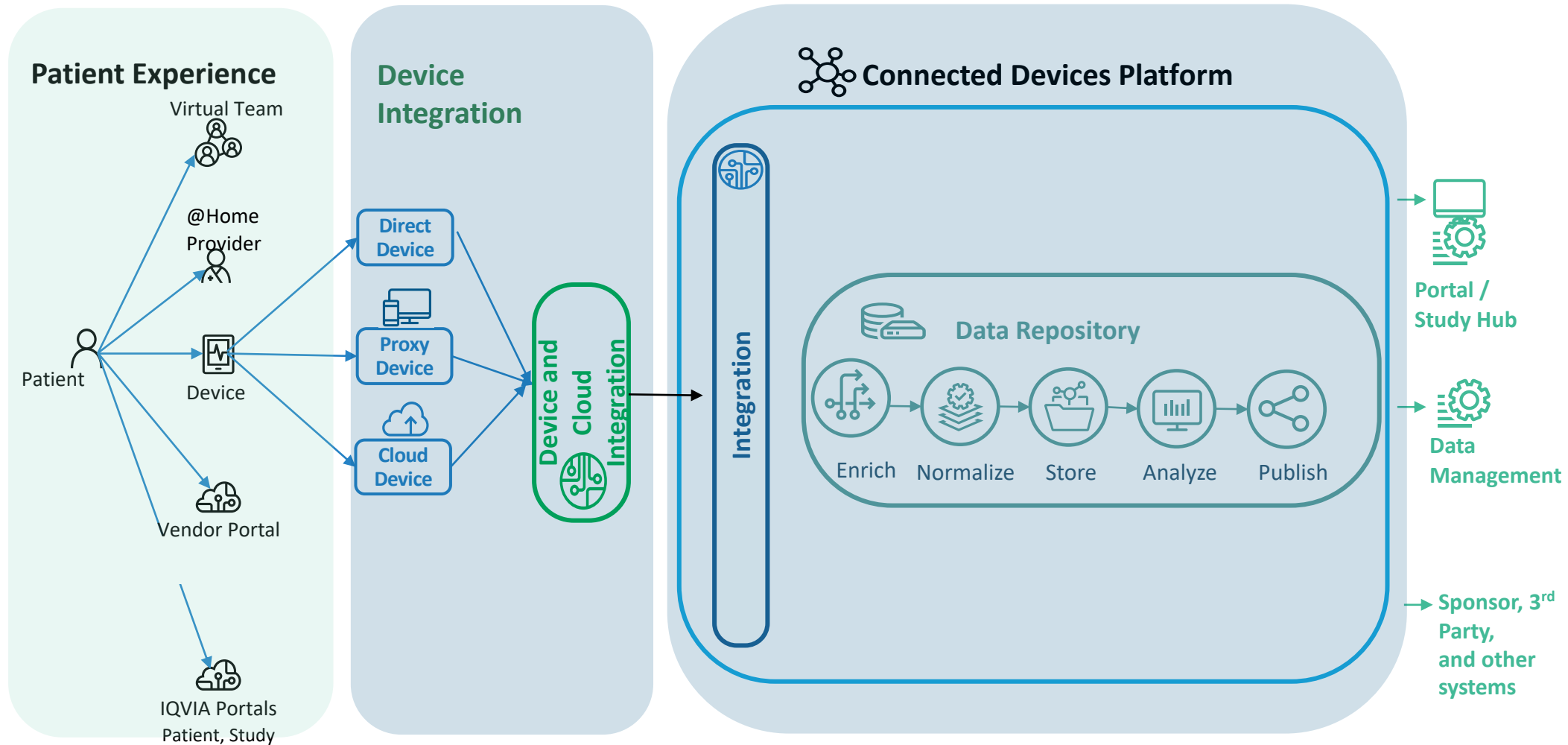
- ❑ A year's delay on a blockbuster costs 993 lives and approximately \$2.9 B in revenues [SOURCE: 1](#)
- ❑ Very few eligible subjects are participating in clinical trials. A patient shortage of 3.7 M as of 2015 [SOURCE: 2](#)
- ❑ 70% of patients live more than 2 hours from Clinical site, 80% of trials fail to complete on time.
- ❑ Just around 37% of companies involved in Clinical Trials are currently utilizing digital health technologies [SOURCE: 3](#)
- ❑ Clinical Trials and Healthcare space is undergoing paradigm change due to Digital Health Technologies (Virtual trials, Precision medicine, etc)



Data Flow – Wearables, Apps And Sensors



Setting up Systems for Virtual / Hybrid Trials



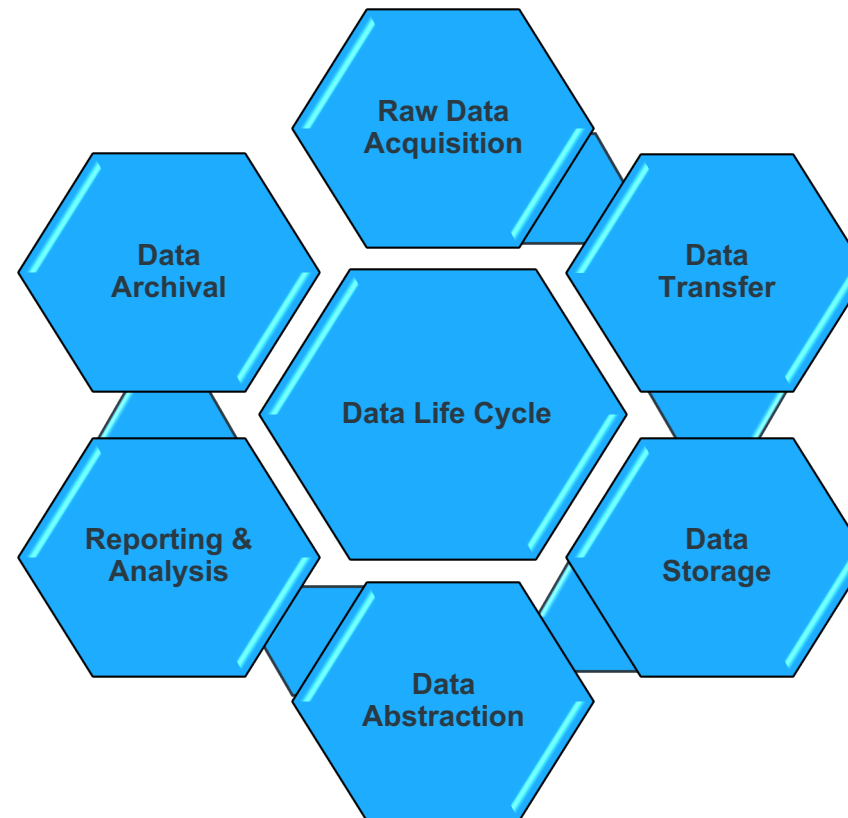
Best Practices – Data Security and Integrity

Additional considerations

- 1) Educate participants on data security
- 2) Refrain capturing personally identifiable data on mobile technology. Provide a unique identifier during enrolment
- 3) Maintain a log of who accessed the server and when

Securing data during storage

- 1) Use only internal servers or servers accessible only through VPN
- 2) VPN should require multi-factor authentication to access
- 3) Encrypt data at storage
- 4) SOPs for server access, data back-up



Securing data on mobile technologies

- 1) Secure Device Access - Authentication & Authorization
- 2) Automatic timeouts requiring re-login
- 3) Automatic Data Encryption when locally stored on mobile

Securing data during transfer

- 1) Hard wired transfer preferred
- 2) If wireless, transmit data through HTTPS or SFTP
- 3) Use secure network encryption certificate – SSL(Secure Socket Layer) / TLS(Transport Layer Security)
- 4) Certificate pinning ensures mobile communicates with servers only when pin matches

Data Quality Principles

ATTRIBUTABLE

AUTHENTICATION -

- ✓ Password
- ✓ Biometrics –Fingerprint/Iris scan/face recognition
- ✓ Hybrid

MONITORING/STATISTICAL APPROACH

- ✓ Trend Analysis
- ✓ Clustering techniques

ORIGINAL

DATA ORIGIN

- ✓ Active: App based, data entry by Participant
- ✓ Passive: Without human intervention (CGM Sensors / Actigraphy / Heart Rate Monitor etc)

CONTEMPORANEOUS

- ✓ Data collection & recording is real time in wearables
- ✓ No pre/postdating possible

LEGIBLE

ALGORITHMS -

- ✓ Raw sensor data are machine readable
- ✓ Algorithms process them to human interpretable values
- ✓ Source data: The first level of data that is both clinically relevant to the trial and interpretable.
- ✓ Collect applicable metadata(Date & Time stamps)

ACCURATE

- ✓ VERIFICATION: Assures raw data collection and processing is Accurate, **Consistent** and Uniform across technologies
- ✓ VALIDATION: Assures “Analysis Algorithm Outputs” are accurate

Best Practices – Collection, Cleaning & Analysis

Data Collection

- Selecting the right technology and conducting feasibility study early on is critical
- Collect minimum data required for study endpoint
- Appropriate metadata are required to provide contextual information
- Avoid collecting patient identifier information

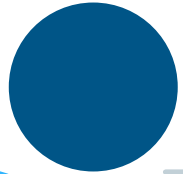
Data Cleaning

- Monitor and minimize data quality issues
- Minimize missing data
- Different manufacturers have different modes of data transfer to CROs/Pharma

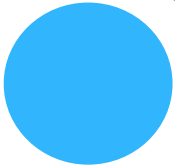
Data Analysis

- Epoch length and the optimal sampling frequency for a given outcome should be predetermined
- Big Data Solution – Volume | Velocity | Variety | Veracity

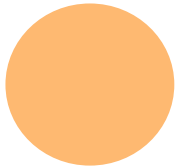
Metrics for Wearables, Apps and Sensors



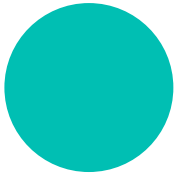
Compliance: Compliance to calibration(as applicable for device)



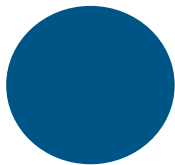
Compliance: Compliance related to upload / % of On-Time, Accepted file transfer



Quality: Data Acceptability report for % of data captured | % of Queries raised



Configurations: Device Status Report



App performance : Speed, Latency and Crashes



Visit time and screen views: Especially in unblinded studies

Regulatory Landscape

FDA's Pre-Cert program(Jan 2019):

- Focus is to certify digital technology Developer rather the product
- Products from 'Pre-certified' companies to meet safety and effectiveness standards

What does 21st Century Cures Act mean for Digital Health?

- Introduced in Dec 2016 by US Senate
- Better health data interoperability for those who support it and penalties for those who block it

Which Federal Laws applies for Mobile Health Apps?

Does your app collect, create, or share consumer information? Does it diagnose or treat a disease or health condition? This [Tool](#) will help you figure out which federal laws apply.

Case study

Situation

- Key client study in Parkinson's patients requiring collection of blood pressure in real time at home in addition to traditional ABPM and collection of patient activity data
- Requirement of 4 different devices (ECG device, Ambulatory Blood Pressure device (ABPM), Home Blood Pressure Monitor (HBPM), Axivity watch)

Solution

- ECG reading and ABPM data collection were available offerings
- For HBPM, we immediately identified a vendor that could support the requirement and created the end to end process, documents and solid training plan
- For Activity tracking, client had a preferred vendor. We worked closely with this vendor and implemented a process with support from our global logistics partner to meet the study teams need

Result

- All 4 offerings executed successfully. A happy client and study team
- First of its kind study for client where 4 major services managed by us creating efficiencies in communication, documents, processes
- Success on this study resulted in multiple new RFPs requiring similar services
- All offerings audited by client with no findings

THANK YOU