

IMPORTANCE OF DIGITIZATION IN THE EMERGENCE OF NEW TECHNOLOGIES



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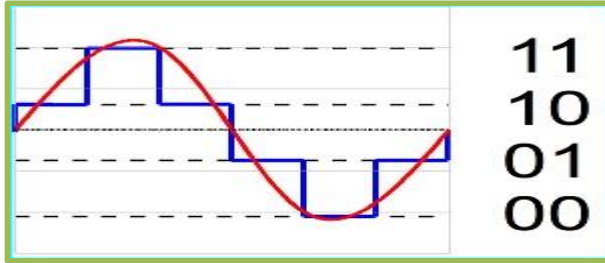
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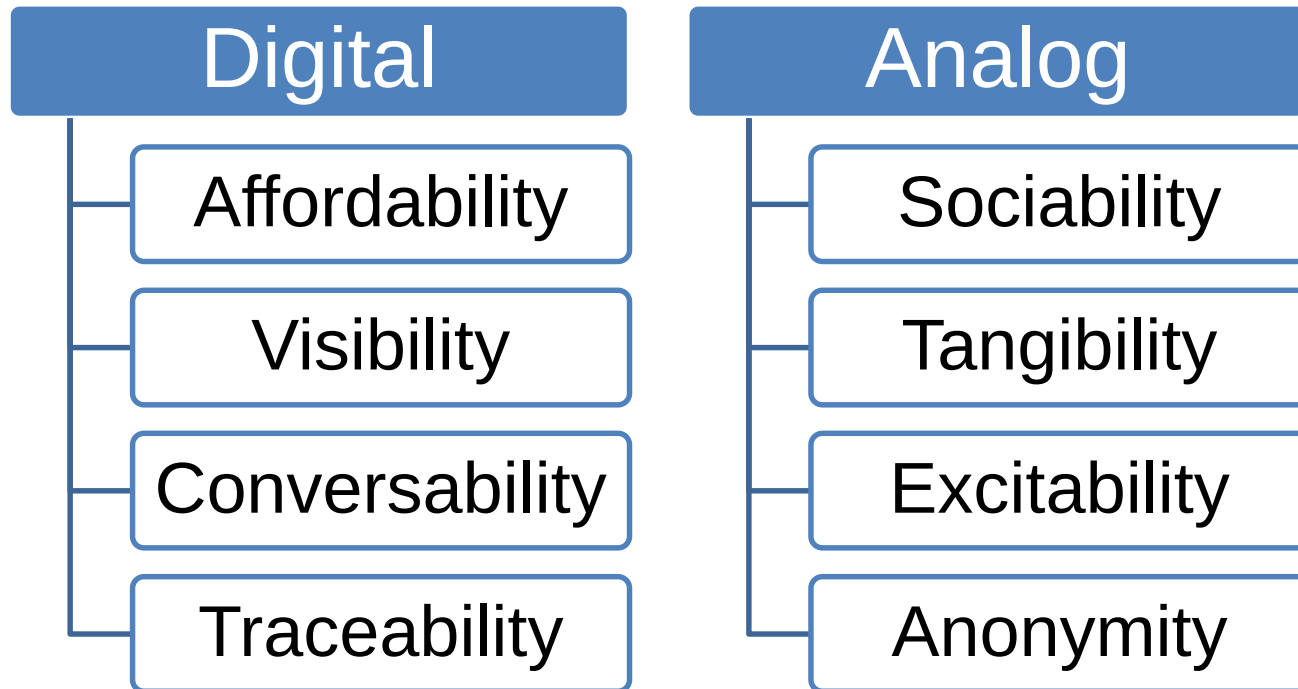
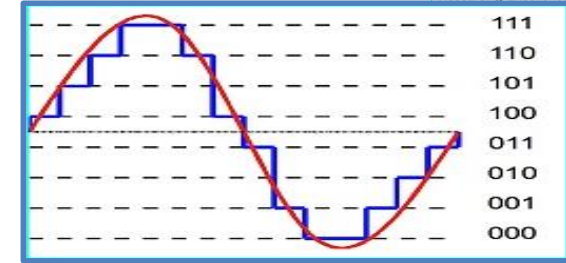
Agenda

- Analog versus Digital a brief approach
- Challenges in Clinical Trials
- Recruitment Failure
- Reason for Dropouts
- Choosing appropriate technology (Algorithm)
- Journey of Devices
- Devices and Applications
- Types of Devices
- Data Security
- Mitigate the security threats

Analog Vs Digital – A brief approach



Continuous & Sine wave
Real & Natural
Discrete & Square wave
Amplified and Converted



Challenges in Clinical Trials

*Complex trial
protocols*

Recruitment

*Drug candidate
selection/
Convenience*

*Engagement and
Retention*

Data Collection

Accuracy in result

*Increased regulatory
requirement*

Access to a query

*Increased cost
Decreased success rate
Slowdown in R&D process*

Time to market

Challenges in Recruitment

Failures

The protocol is too complex

Not being well prepared

Materials not motivating participants

Not trying new methods

Not tracking the results of recruitment

Solution

Protocol design, IE criteria, Population definition

Customizable general templates, Online Presence

Recruitment material – Intent of the study

Targeted advertise on social media, providing simple IE cards

How subjects heard about the study? what has/hasn't worked? Data to increase advertising budget

Reason for Dropouts

Inconvenient location



Schedule conflicts



Personal/family matters



Physically unable



Financial constraints



Lack of appreciation



Forgetting visits



Fear and anxiety



Condition not improving



Side effects



Refusal to comply



Misunderstood expectations



Better Retention

Minimize burdens during protocol design



Set expectations up-front during ICF discussion



Explain importance of their participation



Promptly respond to inquiries



Send reminders for upcoming visits



Provide a comfortable and patient-friendly environment



Show appreciation and recognition



Accommodate their schedule as much as possible



Cloud based technologies

- ❖ Model for enabling Universal, Convenient and On-demand network access to a shared pool of configurable computing resources.
- ❖ Virtual machines with minimal maintenance

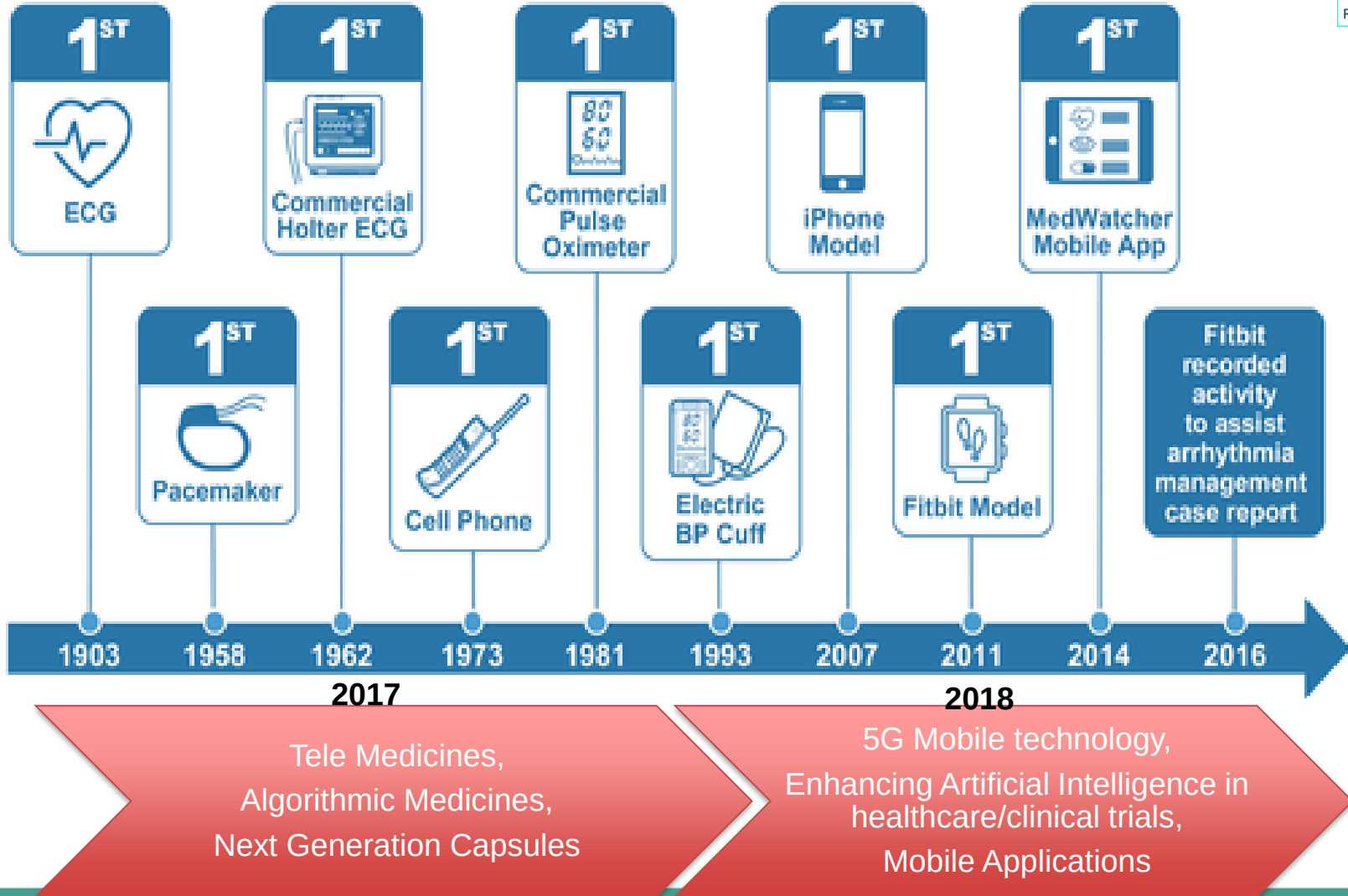
Benefits:

- Increased transparency and real-time visibility
- Enhanced collaboration between investigators, sponsors, and partners
- Increased efficiency and speed to conduct trials.
- Decreased frustration and costs in completing trials.

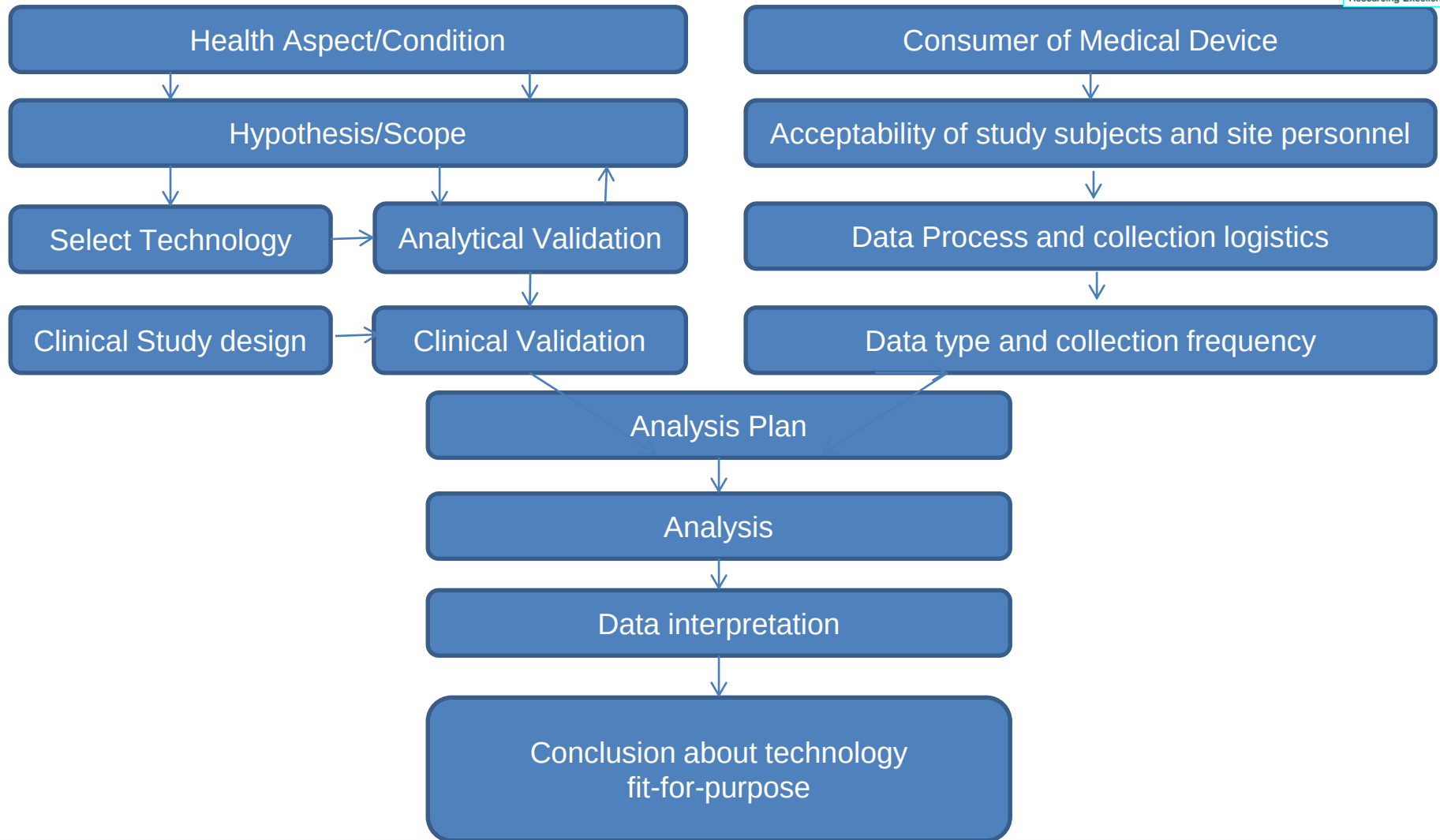
Challenges:

- **Service Provider Capabilities:** Existing clients, Experienced staff, Issue management
- **Data Security:** Where Data will process and get store, Sufficient physical and electronic security, Data encryption, Robust backup, Data isolation, Access hierarchy

Journey of Devices



Choosing Appropriate Technology



Devices and Applications

Electronic Clinical Outcome Assessment

Smartphone/Health Wearable

Interactive Voice Response

Web Browser

Digital Pen

Tablet

Applications

Widely Available, frequent /episodic events, touch screen, reminders, Images, Applications

Easy to use, Reminders, mid-study changes

Visuals and scales, Complex and lengthy dairies, FAQs, compliance issues, out-of range data

Easy to use, Images and visual scales

Touch screen, stylus data entry, Wide screen, portability

Types of Devices

Device Type

Wrist Worn

Skin Patch

Cuffs

Finger Worn

Clothing Embedded Sensor

Headband

Data Collected and Examples

Heart Rate, Blood Pressure, Electro Dermal Activity
Ex: Fitbit, Actiwatch Spectrum, E4, Apple

ECG, Actigraphy, skin temperature.
Ex: BioStampRC, HealthPatch

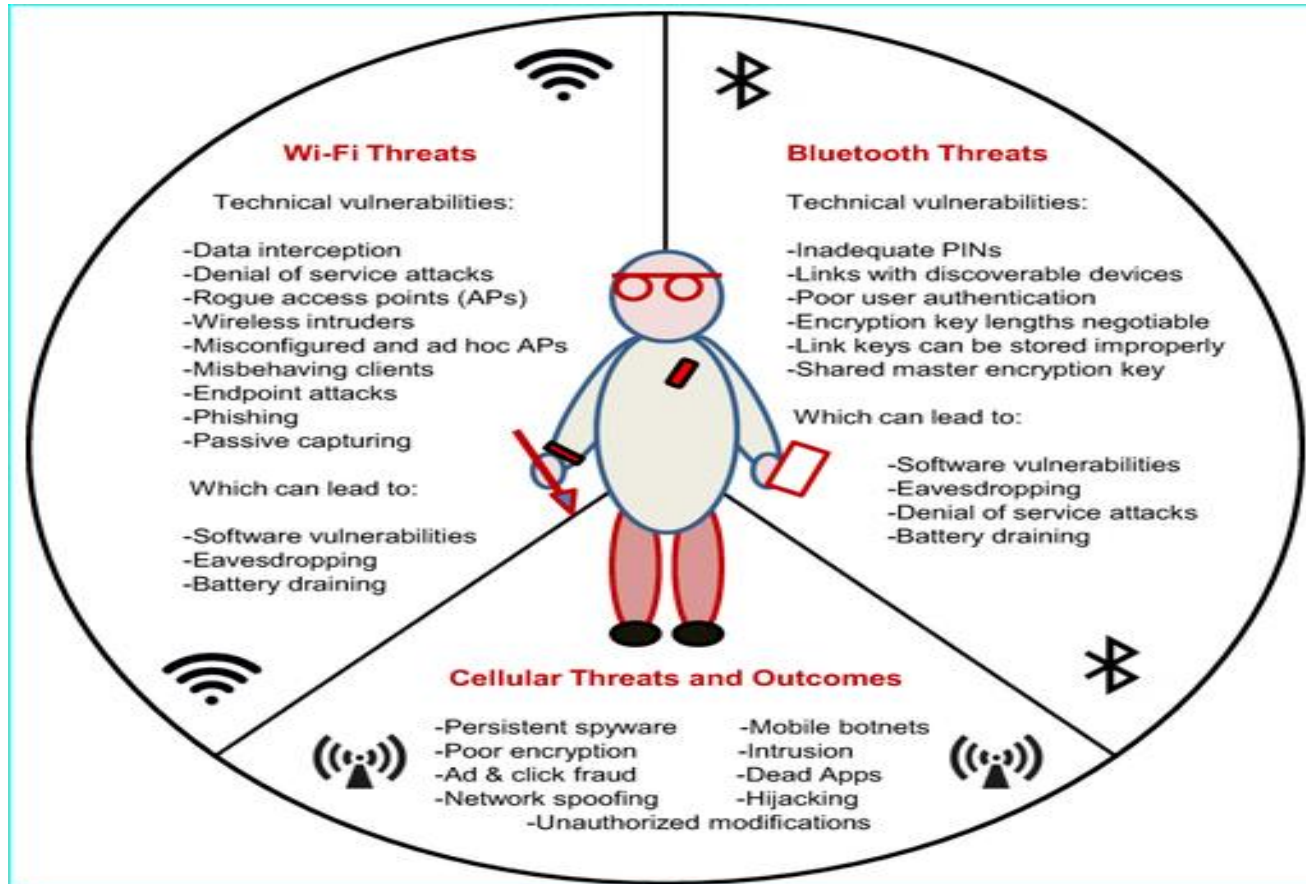
BP, HR
Ex: Intellisense Digital BP Monitor

HR, SpO2
Ex: iSpO2 Pulse Oximeter

HR, HRV (Variability), ECG, Breathing Rate
Smart Shirts by Hexoskin

EEG (Electroencephalogram), EMG (Electromyography)
Ex: EMOTIV EPOC, 4D FORCE

Data Security



To mitigate the Security threats

Access Control	Account Management, Access Enforcement
Awareness/Training	General Awareness/Role-based training
Audit/Accountability	Audit review analysis and reporting
Maintenance	Controlled maintenance, Management tools
Privacy Authorization	Authority to collect, purpose and sharing
Planning	Security and Privacy plans, Updates, Rules, Behavior
Risk Assessment	Security Categorization, Assessment and Vulnerability Scanning
Media Protection	Media access, Storage and Transport

Any Question?



Thank you

