



Recasting Trial Designs with Digital Endpoints

Key Considerations from Design to
Reporting



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Kishore Shyamala
Head of Data Standards
Algorics

Agenda

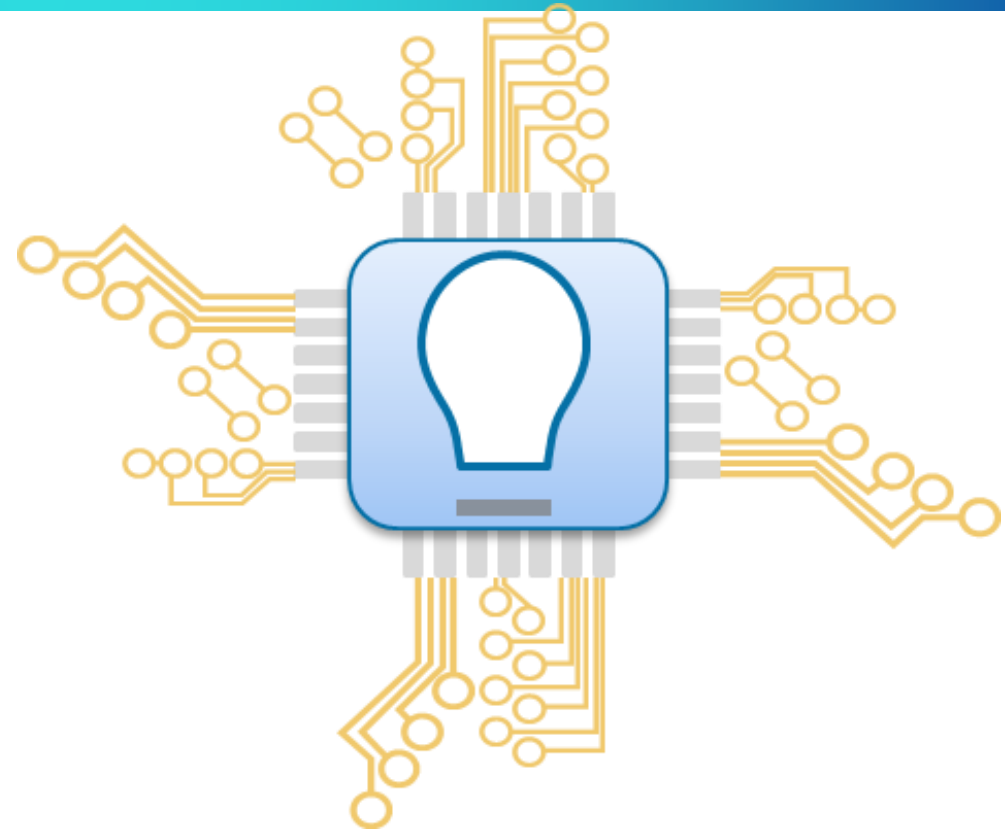
1. Digital Trials Landscape- Need & Key Area

2. Digital Endpoint

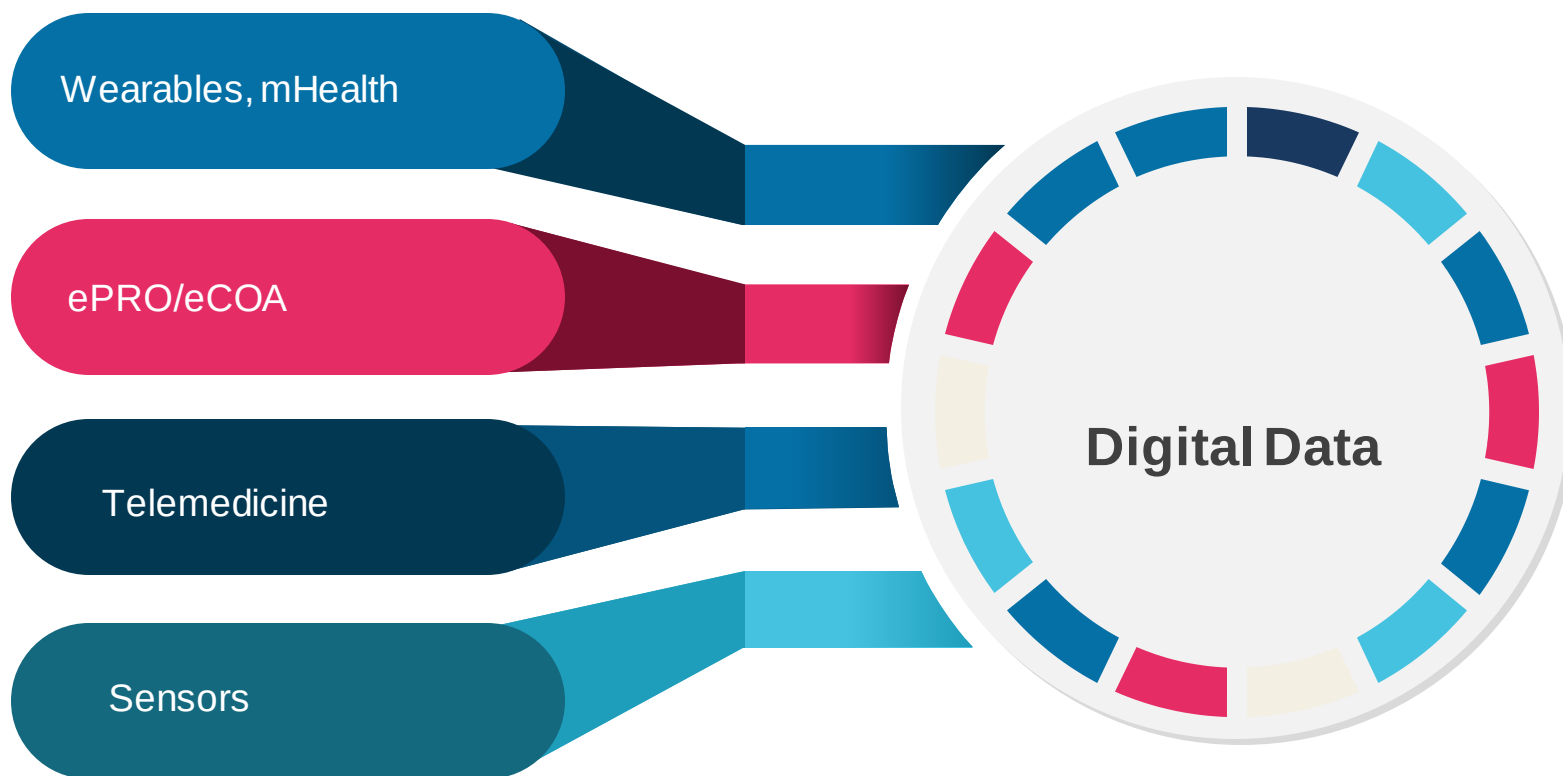
- Adoption
- Diversity
- Strategy

3. SWOT

4. Key Takeaways



Digital Trials Landscape- Need & Key Areas



Other data sources: eConsent, EHR, Images, Social, genetic profiles, phenotypic data, audio data, video data

- Recruitment Challenges- Moving away from Traditional pitfalls
- Novel Endpoints/Redefining a better endpoint
- Patient Population & Diversity
- Use of IoMT (Each person in the world would have at least 1 smart device)
- Patient Monitoring outside of the trial set-up (E.g., Daily monitoring)- Improve Patient Care

Digital Health Technologies promoted in the industry

Digital Data used as Endpoint

FDA/EMA supports Digital trials

Digital Endpoint- Adoption

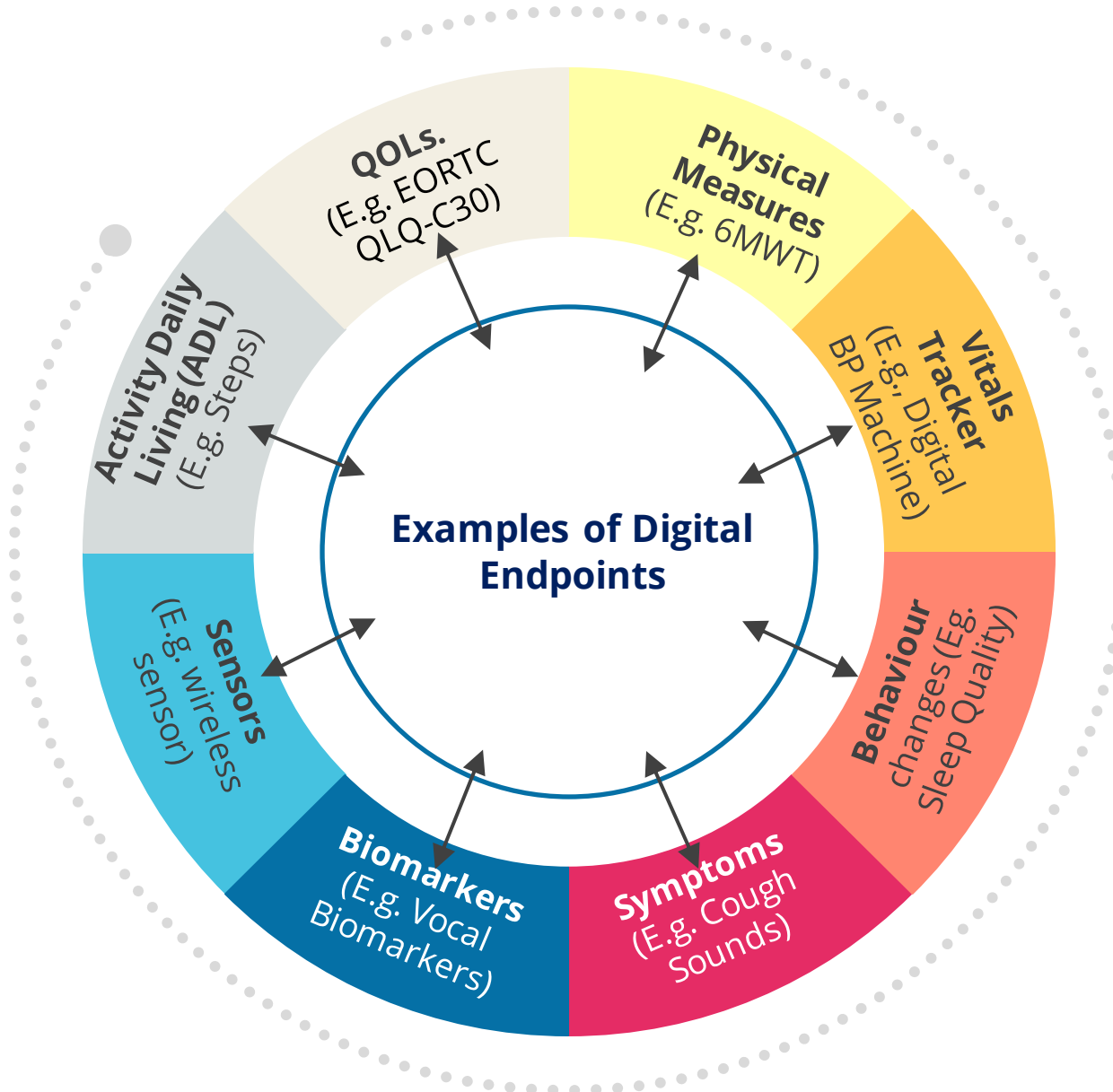
Digital Endpoint in the Spin Off (104 Sponsor's Survey)

Phase	P0	P1	P2	P3	P4
% of Sponsor	2%	7%	35%	18%	38%
IPs	Drug	Device	Biologic	Other	Genetic
% of Sponsor	51%	34%	8%	6%	0.3%
Endpoint	Primary	Secondary	Label Claim	Exploratory	Other
% of Sponsor	51%	34%	8%	6%	0.3%

- Early Phase (P2) & Post Marketing Surveillance (P4)
- Digital Trials- used as Primary & Secondary Endpoint
- Drug & Devices – Both segments use Digital Endpoints very effectively

Digital Endpoints Diversity

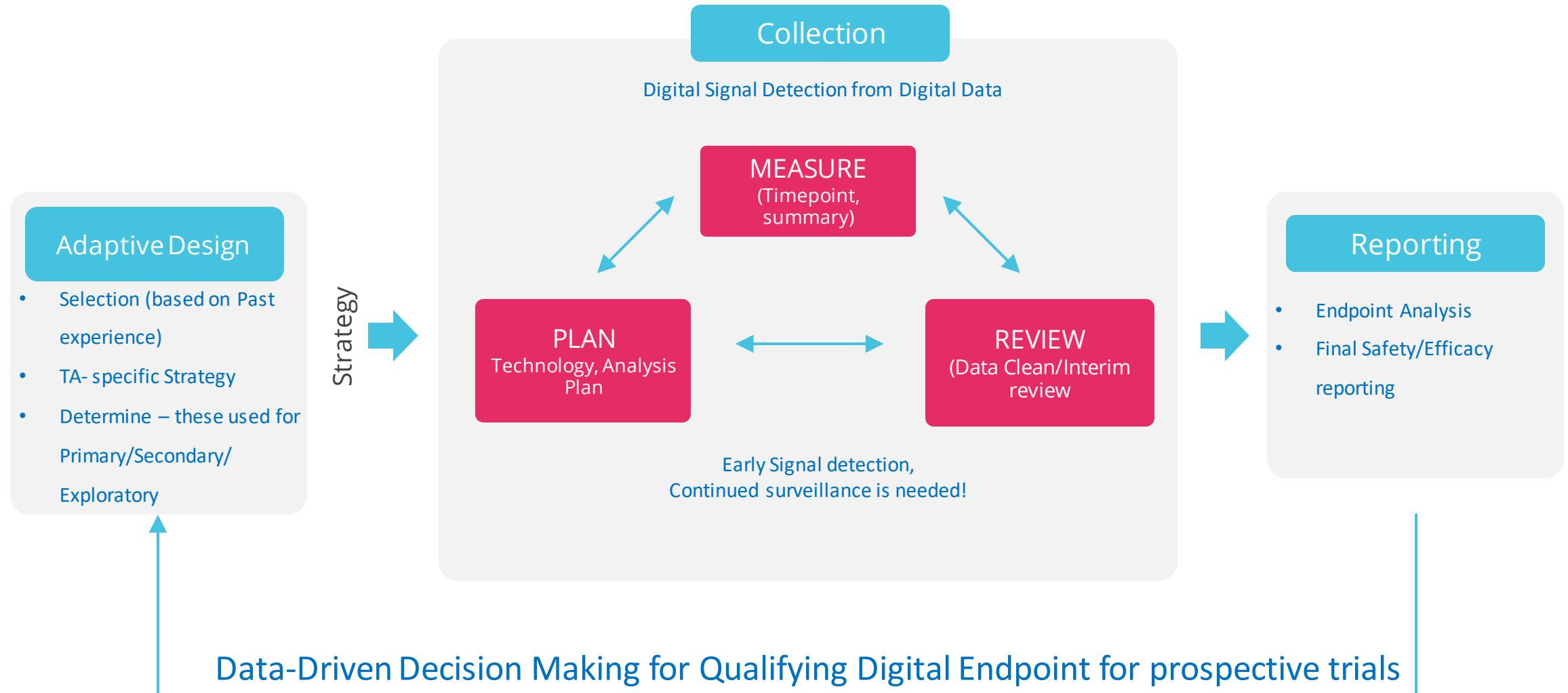
Patient-Centric Data Collection



Examples of Indications:

- Rheumatoid Arthritis
- COVI-19
- Axial Spondylarthrosis
- Asthma
- Heart Failure
- Neurocognitive changes- ADHD
- Parkinson's
- Alzheimer's disease

Qualified Digital Endpoint- End-to-End Strategy



Digital Endpoint Design

Using Adaptive Trial Designs in Digital Trials- Key pointers

Design Considerations



- Disease landscape
- New indications
- Protocol optimization
- Trial simulation
- Synthetic control arms

Data Considerations



EHR

Direct Data Capture

EHR such as Demog, MH, and Subgroup help with patient data for the selection of Patient populations

Use of EHR could be critical for designing the adoption and augmenting the Digital trials

ePRO

Wearables & mHealth

Digital Biomarkers

Sensors

ADAPTIVE CLINICAL TRIALS

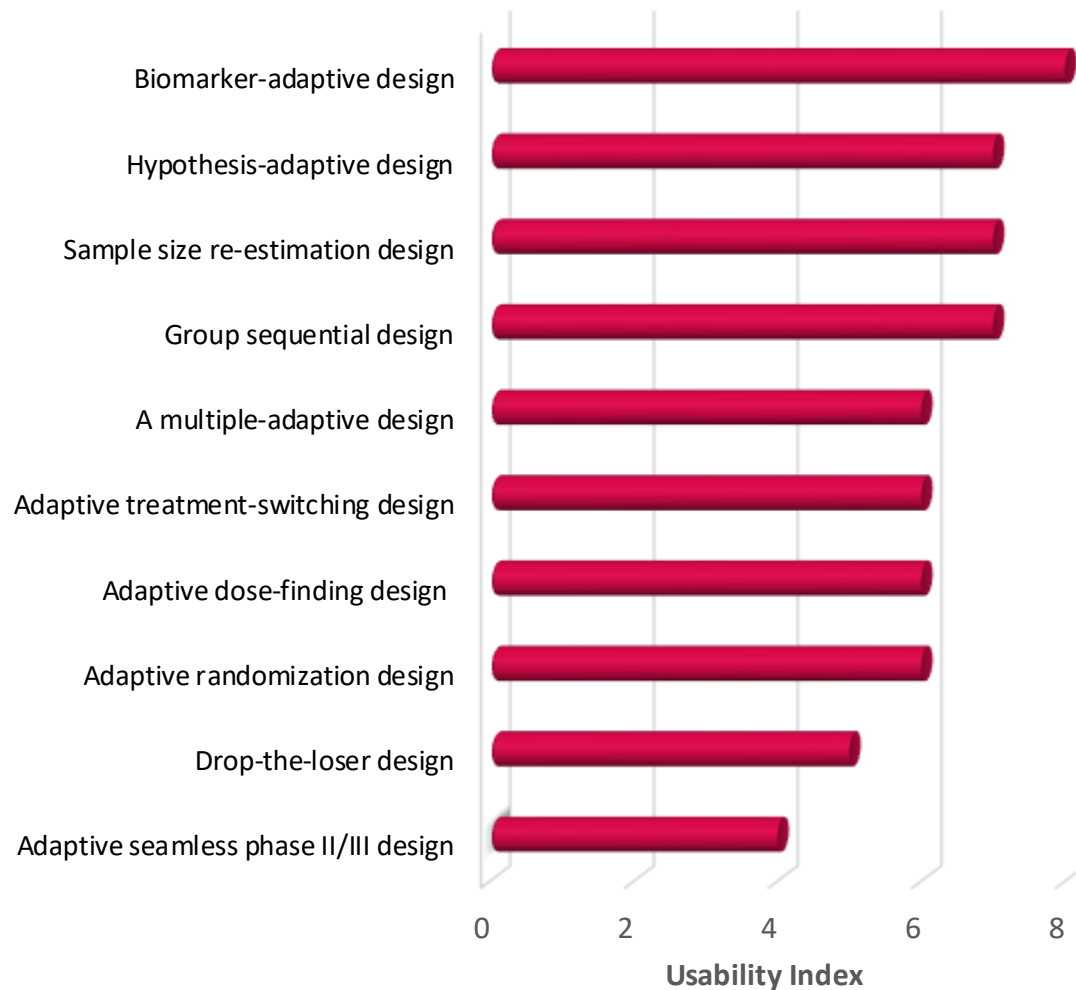


Digital Endpoint Design

Recasting considerations based on the usability Index



Usability Index of Digital End Points in Adaptive Trial Designs



Usability Index scale:

0 – 2	Less Likely
2 – 4	Moderate Likely
4 – 6	Likely
>6	Most Likely

Adaptive Design	Possible Type of Data/Outcome
Biomarker – adaptive	Digital Biomarkers
Hypothesis-adaptive	EHR / ePRO
Sample size re-estimation	Event / Symptom monitoring
Group sequential	Estimating Treatment Responses

(Usability Index: based on our expertise & published papers)

Digital Endpoint Collection

Study Conduct Considerations



- Use the validated source
- What & how to collect

**Define the
data Strategy**



**Recruitment &
Engagement**

- Optimization of Patient/site experience,
- Community Engagement



**Data
collection**

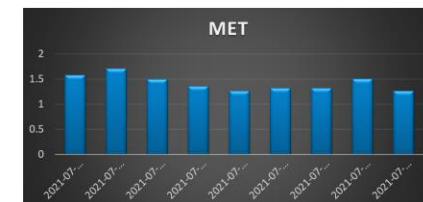
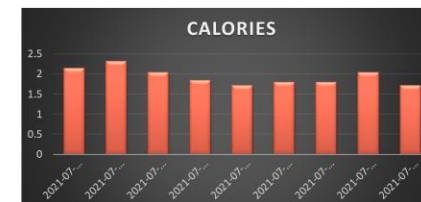


**Manage
Data**

- Data Review Surveillance
- Data Quality

- Data Flow
- Data Linkage & integration

Use of Analytics for Continuous monitoring



Digital Endpoint Reporting

Statistical Analysis & Reporting



- Statistical Analysis Plan (SAP)
- Selection of Target Variables
- Reporting Specs

**Reporting
Strategy**

Data Specs

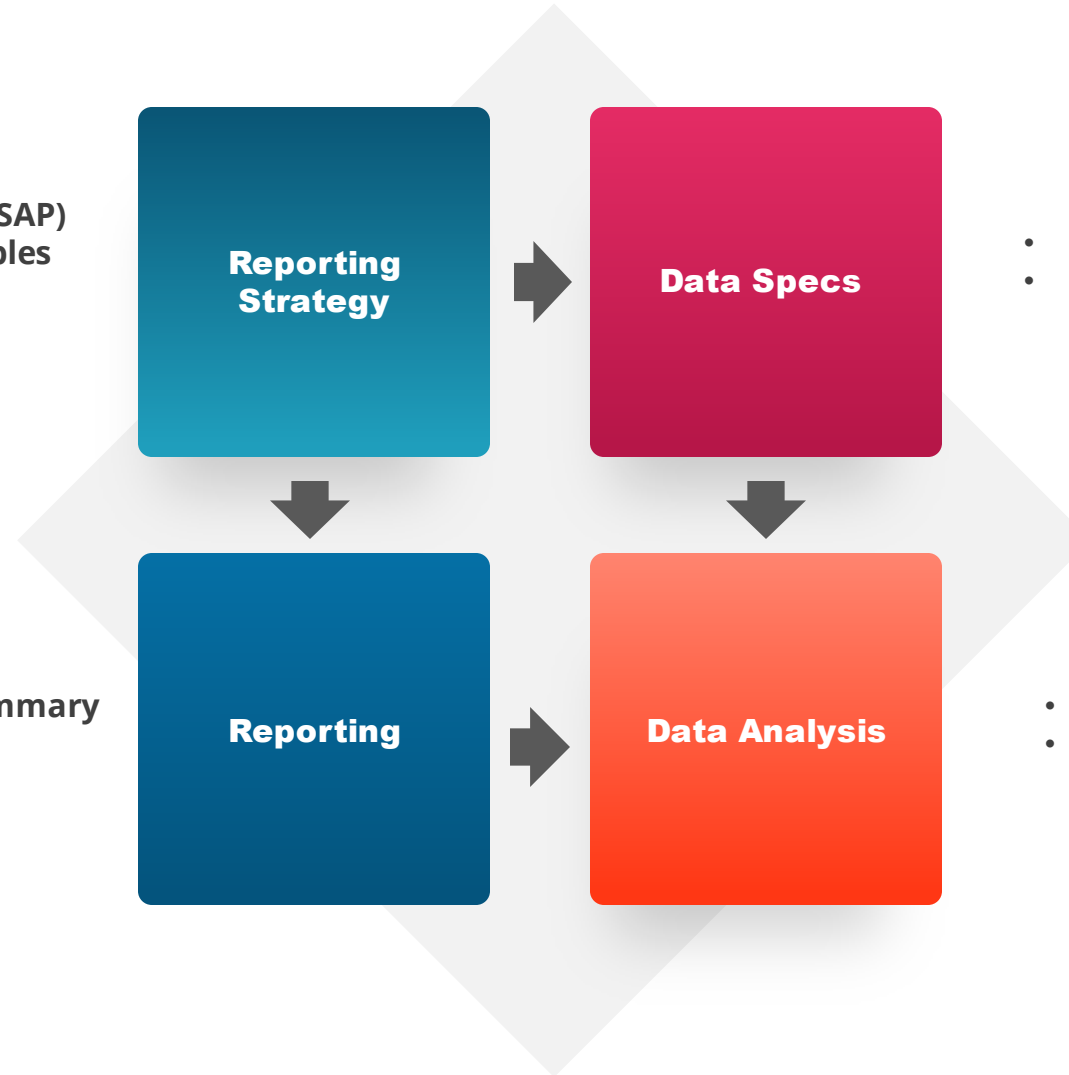
- Mapping the data with the SDTM model
- Specific Focus on the Target variables

- Comprehensive/Detailed Summary
- Final CSR

Reporting

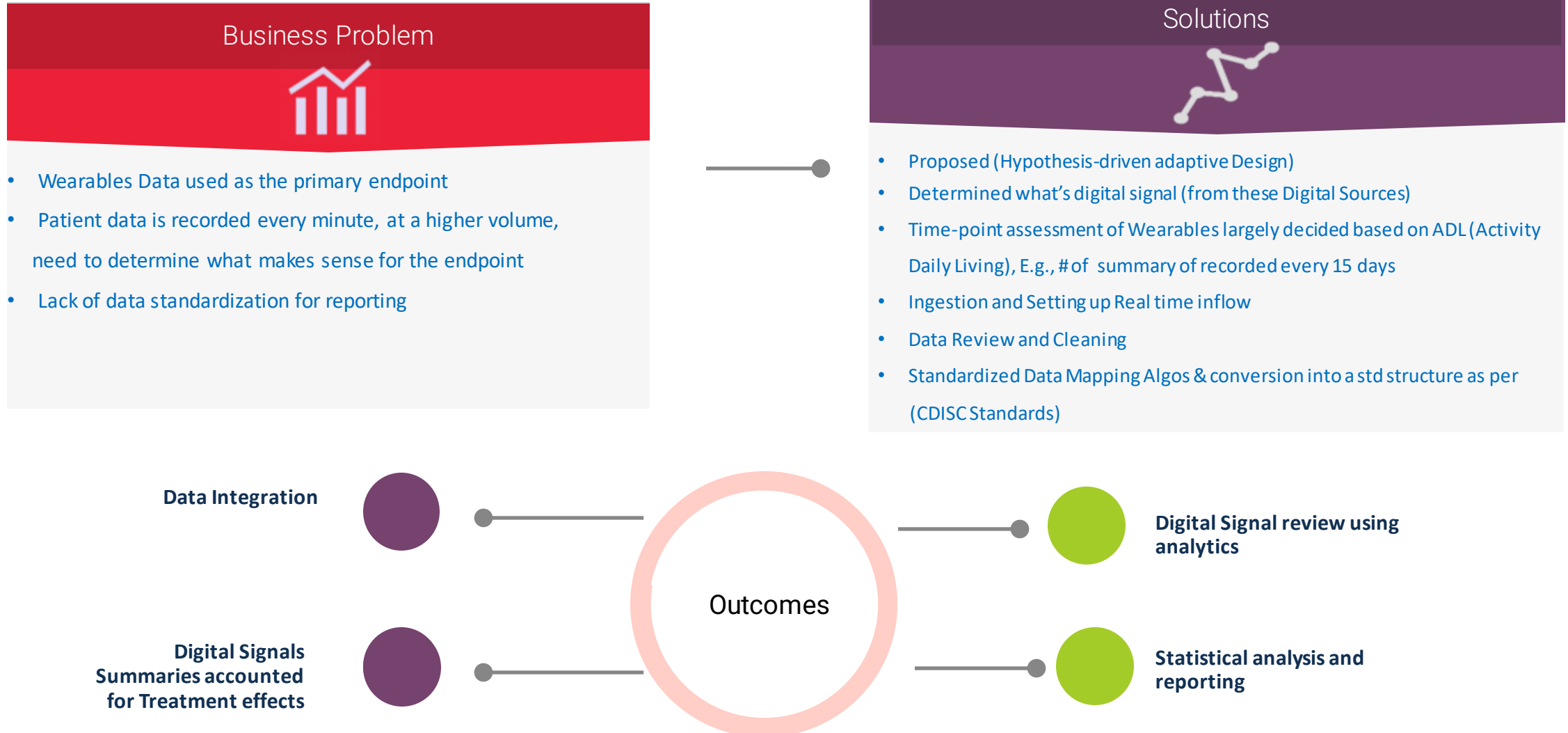
Data Analysis

- Statistical based Data Cleaning
- Data Analysis & generate TFL



Using Digital Endpoint

Case Study: Digital (Wearable Data)- From Design to Report



SWOT Analysis- Digital Trials & Endpoints



Strengths

- High Enrollment Rate- Enhance efficacy/Safety Endpoints
- Beyond the boundaries (Simple wearables to biosensors)
- Innovative Designs



Weaknesses

- Lack of Harmonization guidelines
- Transition from Traditional CTs to Digital CTs could be time-taking
- Digital Endpoints needs to be qualified
- Data Collection Errors- Loss of Data



Opportunities

- Wide use of IoMT- leading to wide Patients reach out
- Could help in Precision/Personalized Medicines



Threats

- Data Privacy and Security
- Moving away from Scientific intervention
- Patient might be overwhelmed of using devices (elderly population)

Key Takeaways

1. Digital Endpoints- take Clinical trials close to the patient, has huge advantages
2. Planning and Strategy is required- A Historic data analysis, a way forward for AI/ML capabilities
3. Clinical Trial Design considerations must be considered
4. Clinical Decision making could be faster and easier
5. SWOT help us to improve and be conscious of use of digital endpoints

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Thank you

Kishore Shyamala
Head of Data Standards & Programming
E: kishore.shyamala@algorics.com
www.algorics.com

Sugumaran Muthuraj
Manager – Statistical Programming
E: sugumaran.muthuraj@algorics.com
www.algorics.com