



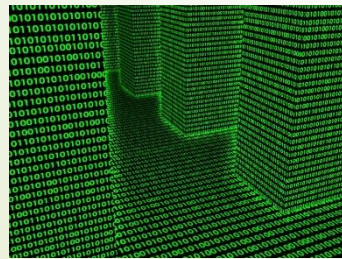
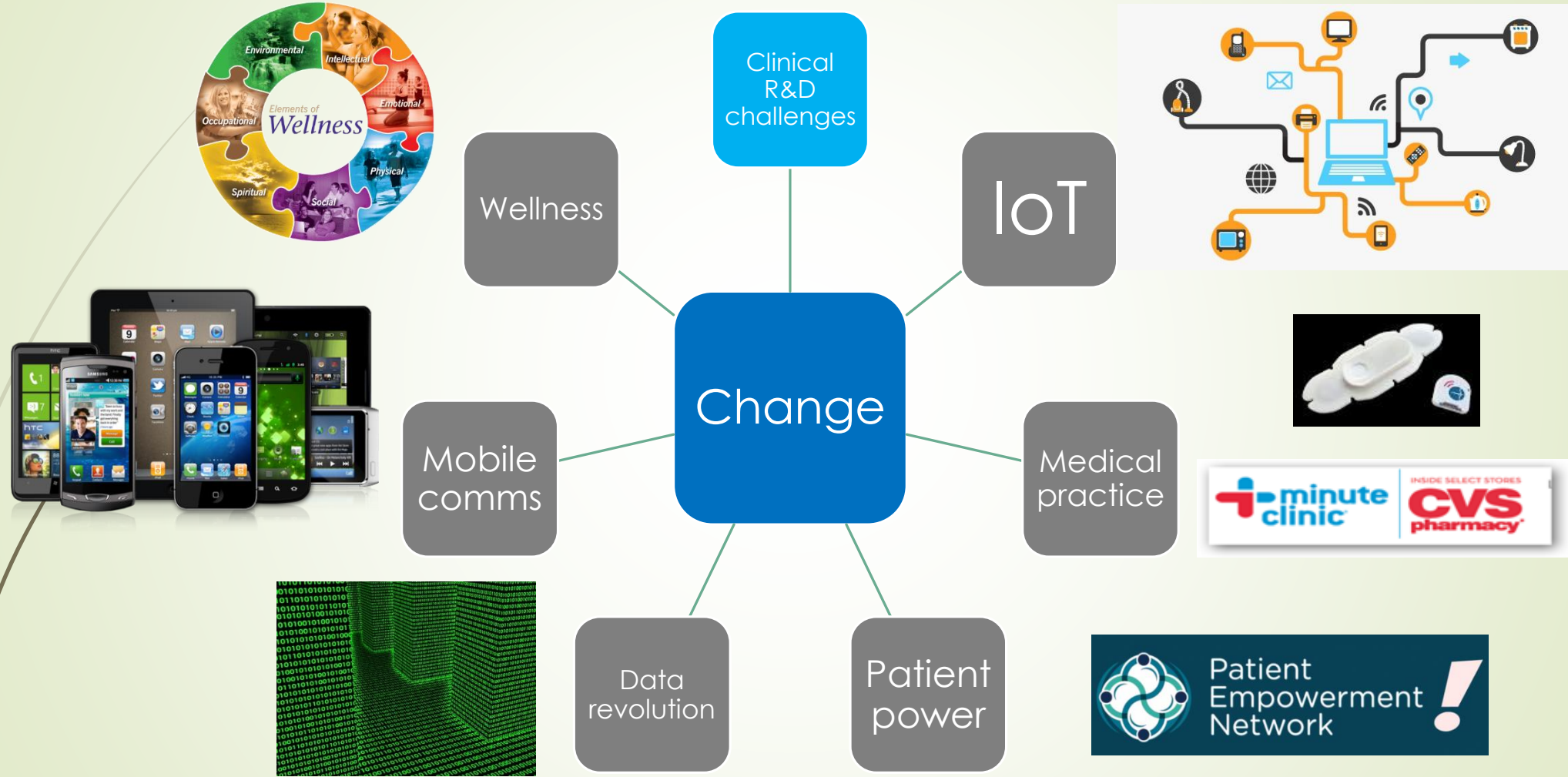
Connected Healthcare

> Enabling Next Generation Clinical Research

Julian Jenkins PhD, GlaxoSmithKline R&D

Mack Institute, Fall Conference 2016

Context – Drivers of Change



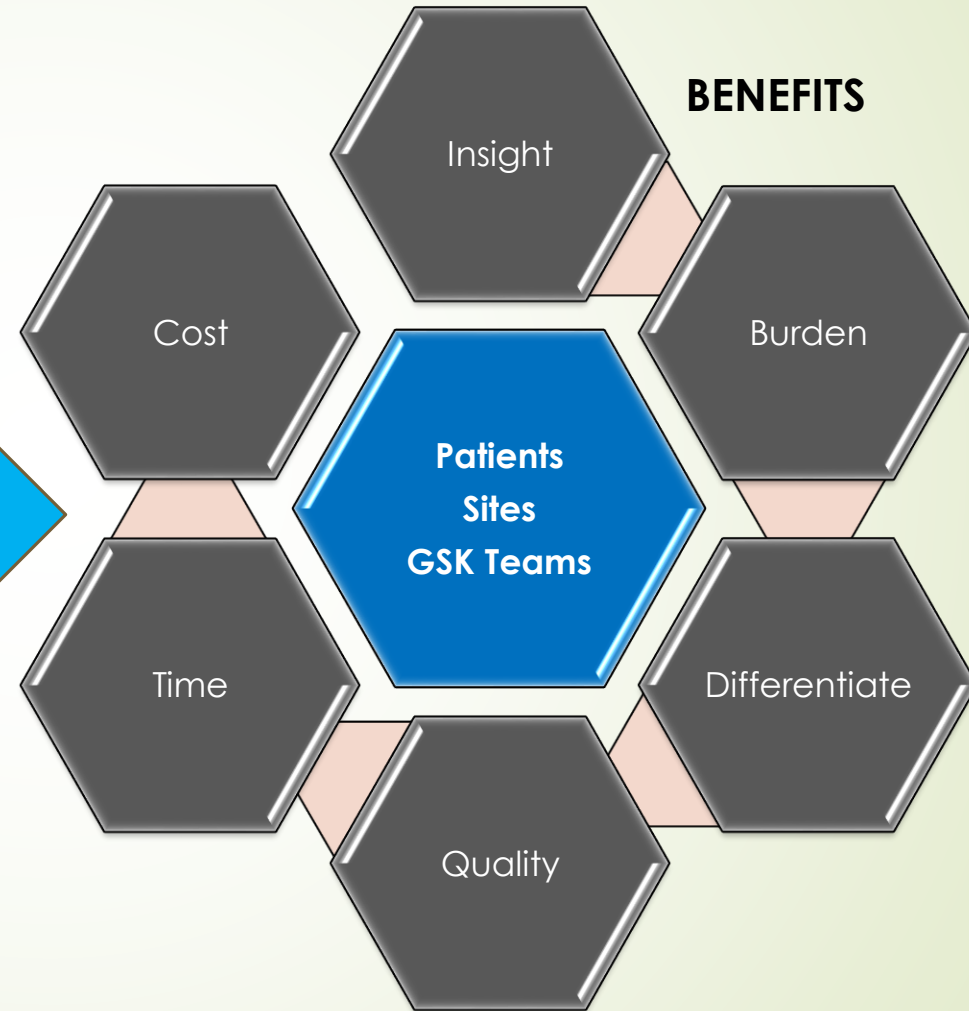
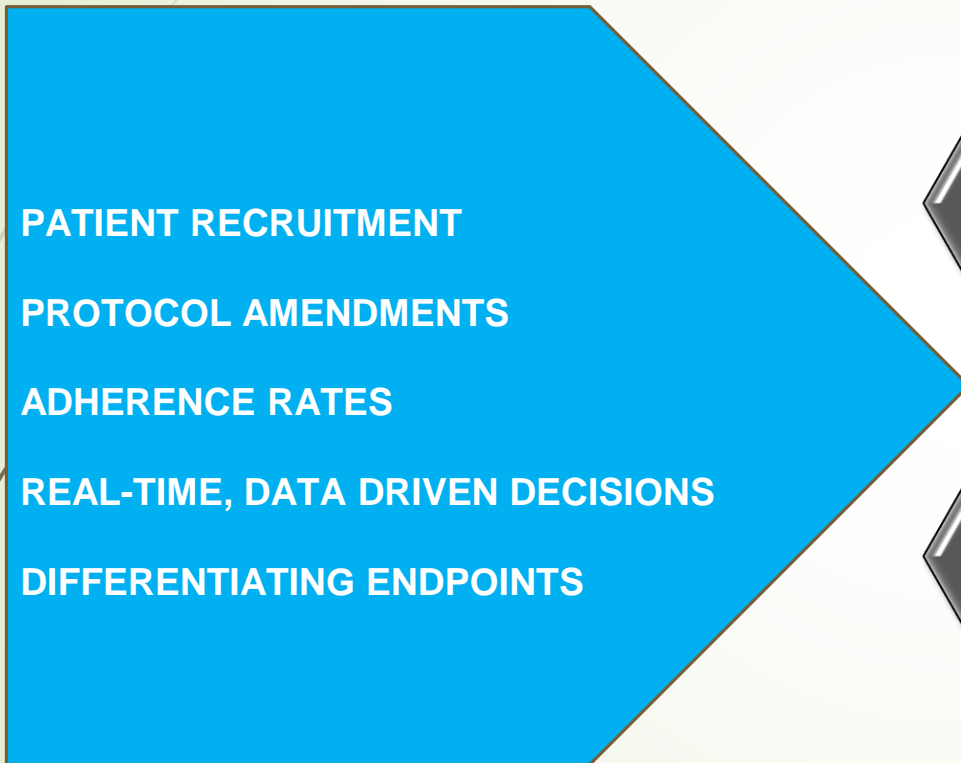
Evolution of Clinical Research

Table 1. Characteristics of 20th- vs 21st-Century Clinical Trials

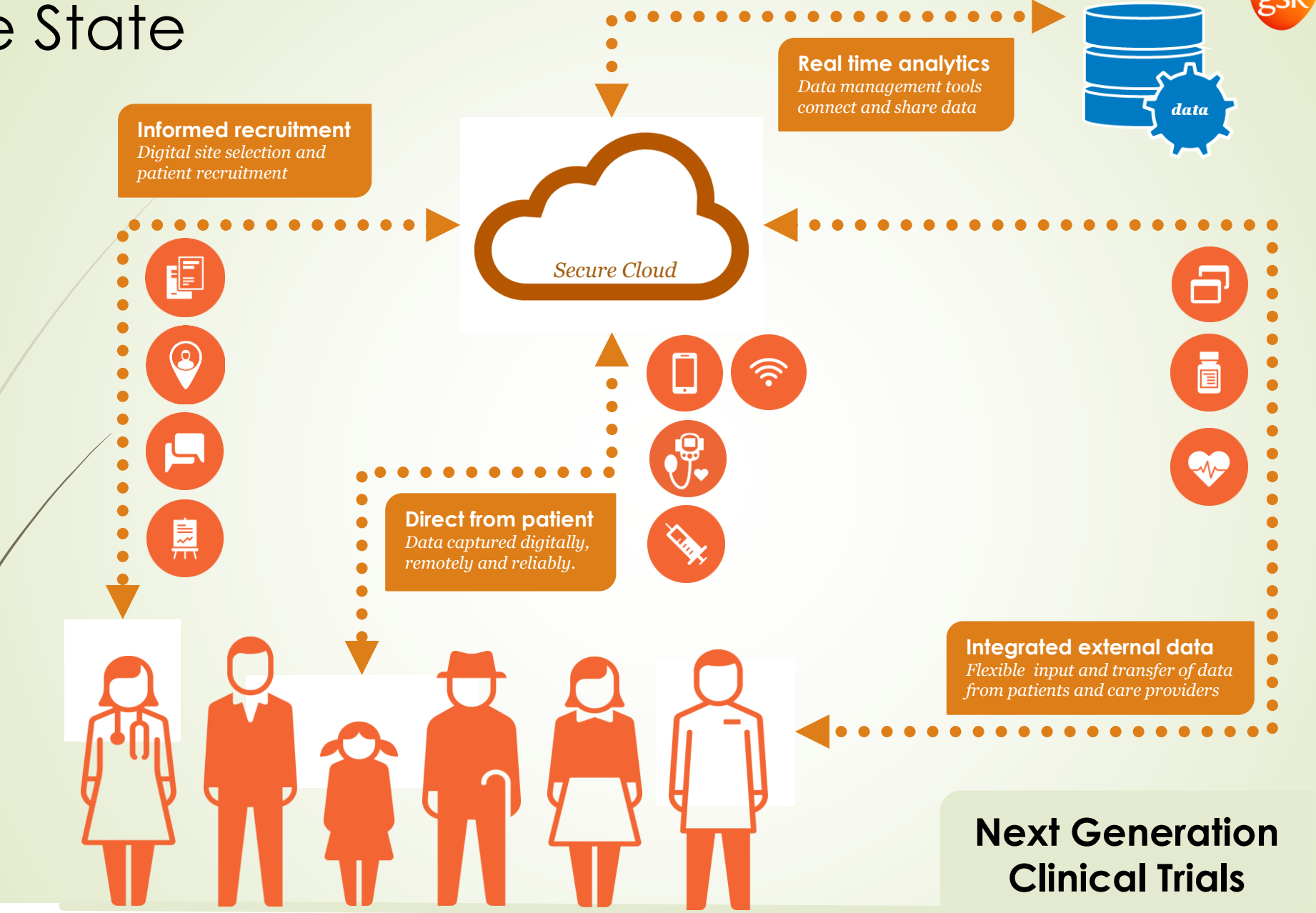
| Characteristic | 20th Century | 21st Century |
|----------------------|--|---|
| Study design | Randomized, double-blind, parallel-group, placebo-controlled trial | Randomized, double-blind, parallel-group, placebo-controlled trial using adaptive designs |
| Study population | All comers with a given disease | Individuals selected based on phenotypic and genetic results |
| Study recruitment | Clinical practices | Global clinical trial registries and social networks organized by individuals affected by the disease |
| Trial visits | In person and audio calls | In person and audio and video calls |
| Data management | Paper and electronic forms | Electronic forms |
| Participant feedback | Limited, delayed | Almost universal, approximately real time |
| Outcome measures | Insensitive | Sensitive |
| | Episodic | Frequent or continuous |
| | Subjective | Objective |
| | Provider centered | Patient centered |
| | In clinic | Remote |
| | Unidimensional | Multidimensional |

Clinical Research - Why Innovate?

CLINICAL TRIAL PERFORMANCE CHALLENGES

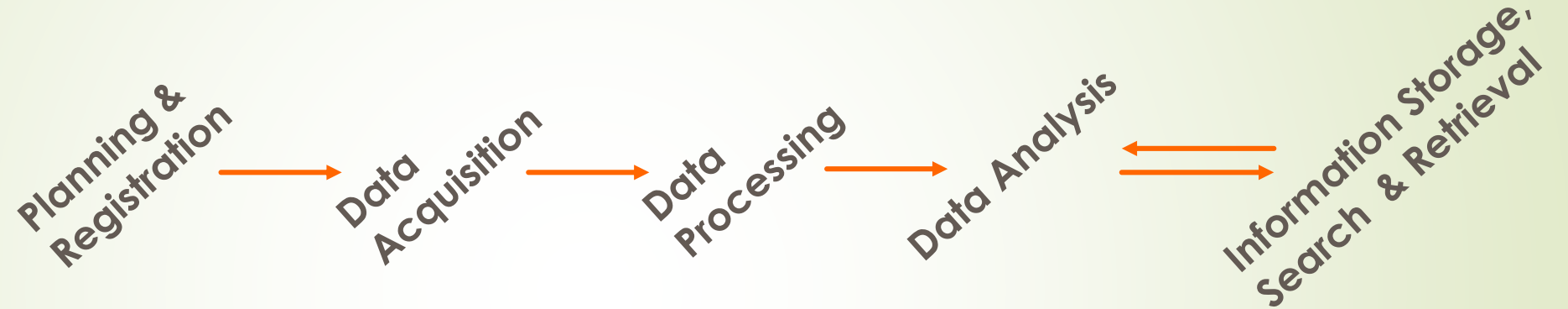


Future State



Clinical Research Technology Platform

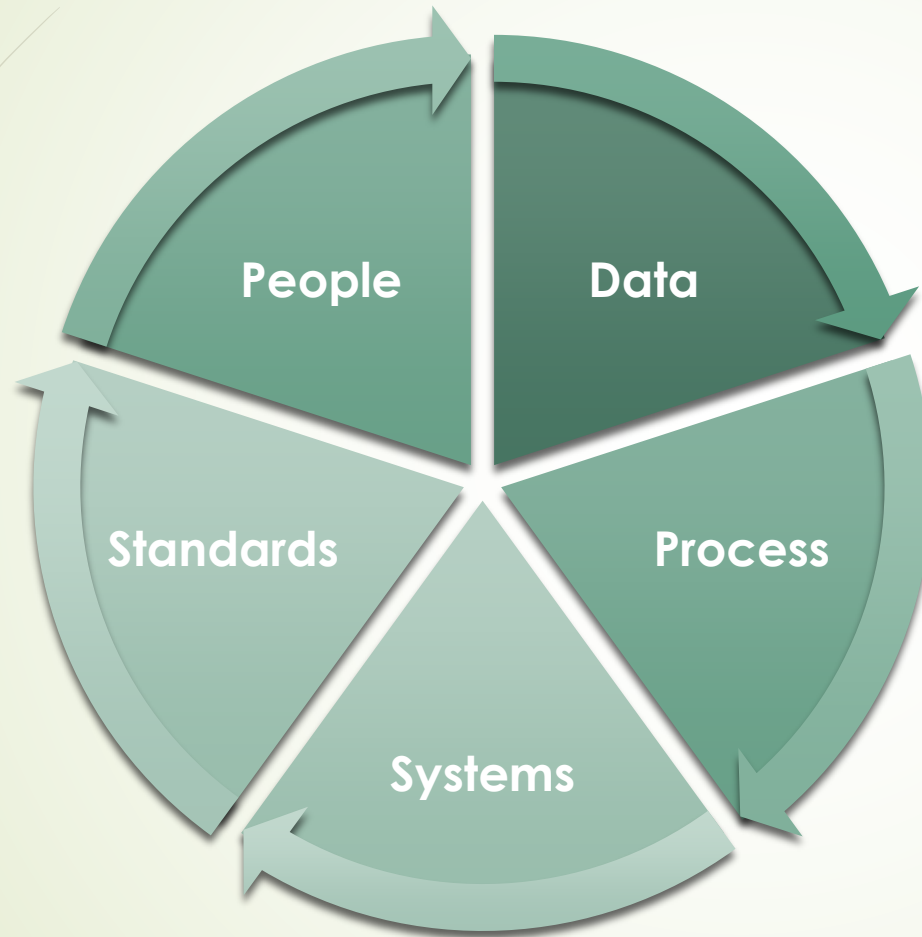
Validated and Audit Ready



30-100

- Clinical Data Systems
- Operational Data Systems
- Data visualization Systems
- Data Archives
- Collaborative Systems

Capabilities – More Than Just Systems



- ❑ **Data**
 - ❑ E2e flow
 - ❑ Retrieve and re-use easily
- ❑ **Process**
 - ❑ Integrated, streamlined
- ❑ **Systems**
 - ❑ Fewer and better
 - ❑ See requirements
- ❑ **Commitment to Standards**
 - ❑ Process (e.g. TransCelerate)
 - ❑ Data (e.g. CDISC, HL7)
 - ❑ System
- ❑ **People**
 - ❑ Involved in the change
 - ❑ Simple user experience

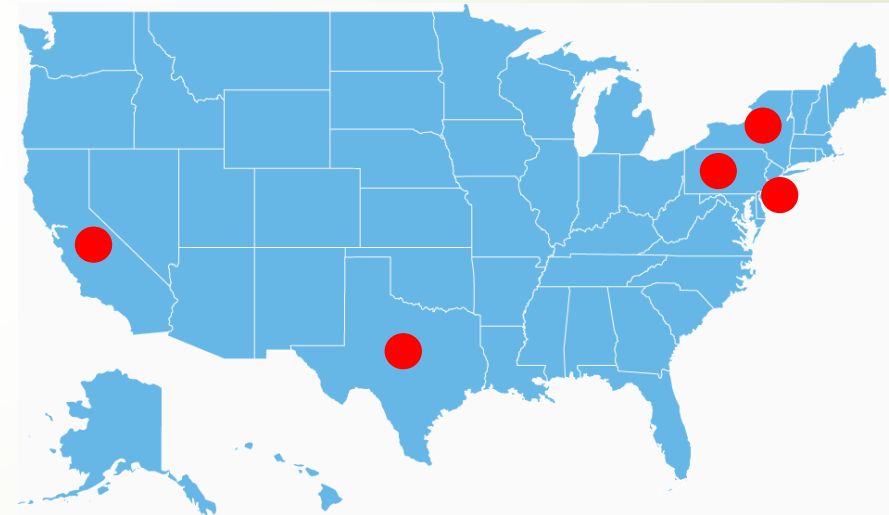
Consortia – Collaboration is Essential



PARADE Epidemiology Study in Rheumatoid Arthritis

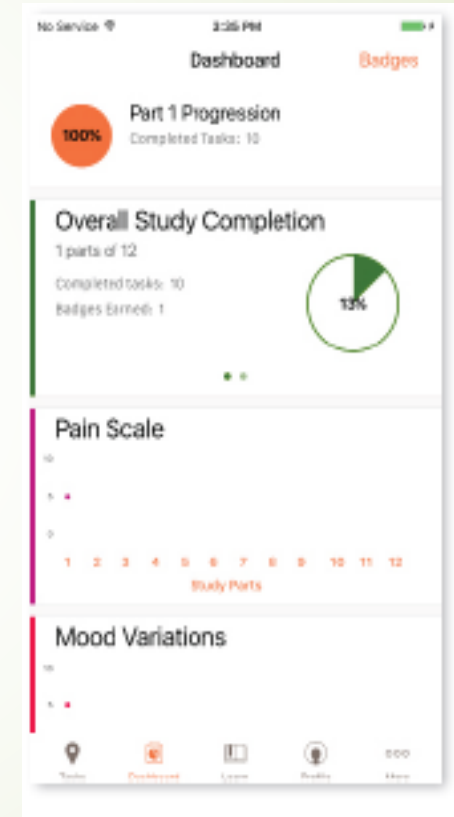
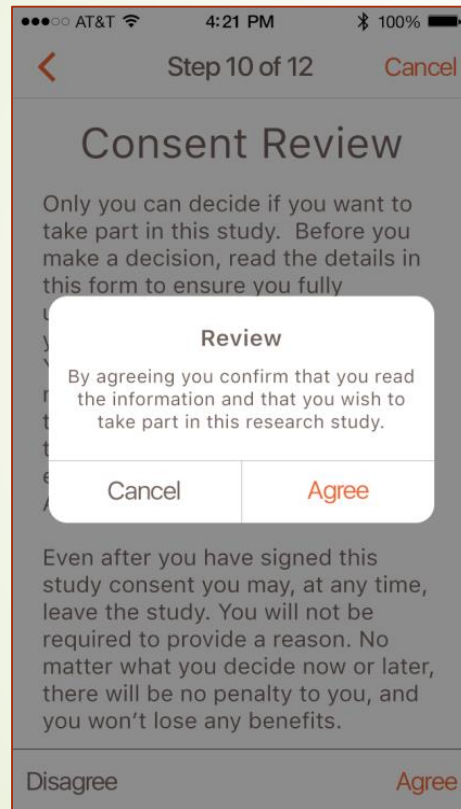
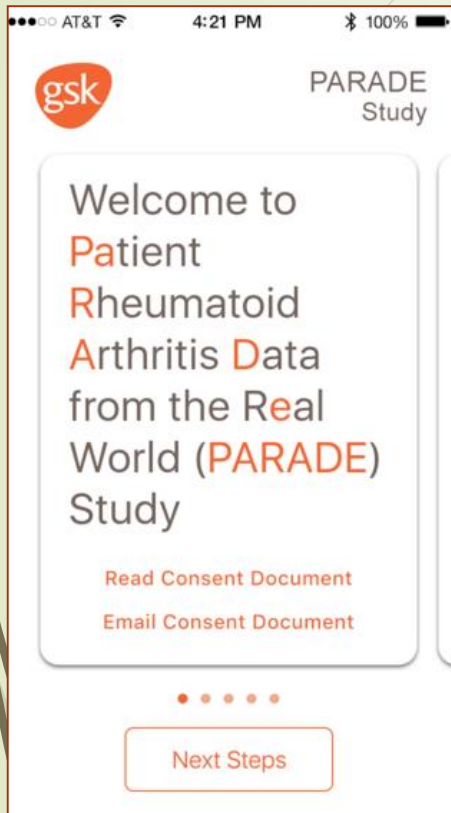
GSK – Medidata – Possible Mobile – Alphanumeric Collaboration

- ❖ IRB-approved epidemiology study
- ❖ Social Media targeted enrolment, 5 States
- ❖ Virtual Informed Consent
- ❖ Demographic, health history
- ❖ Comprehensive medication list
- ❖ RA symptom questions
- ❖ RA validated questionnaires
- ❖ Tasks: walking, wrist Exercise, Joint Pain



Apple Research Kit Platform

Patient Rheumatoid Arthritis Data From Real World Study



ALS: Amyotrophic Lateral Sclerosis

Clinical gold standard measurements

Speech

Normal speech processes
Detectable speech disturbance
Intelligible with repeating
Speech combined with nonvocal communication
Loss of useful speech

Salivation

Normal
Slight but definite excess of saliva in mouth; may have nighttime drooling
Moderately excessive saliva; may have minimal drooling
Marked excess of saliva with some drooling
Marked drooling; requires constant tissue or handkerchief

Swallowing

Normal eating habits
Early eating problems — occasional choking
Dietary consistency changes
Needs supplemental tube feeding
NPO (exclusively parenteral or enteral feeding)

Handwriting

Normal
Slow or sloppy: all words are legible
Not all words are legible
Able to grip pen but unable to write
Unable to grip pen

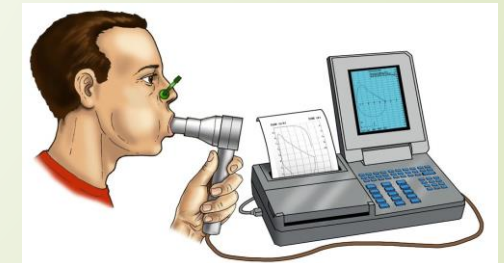
ALS Functional rating scale
–revised (ALSFRS-R)

Muscle power

(hand-held dynamometry)

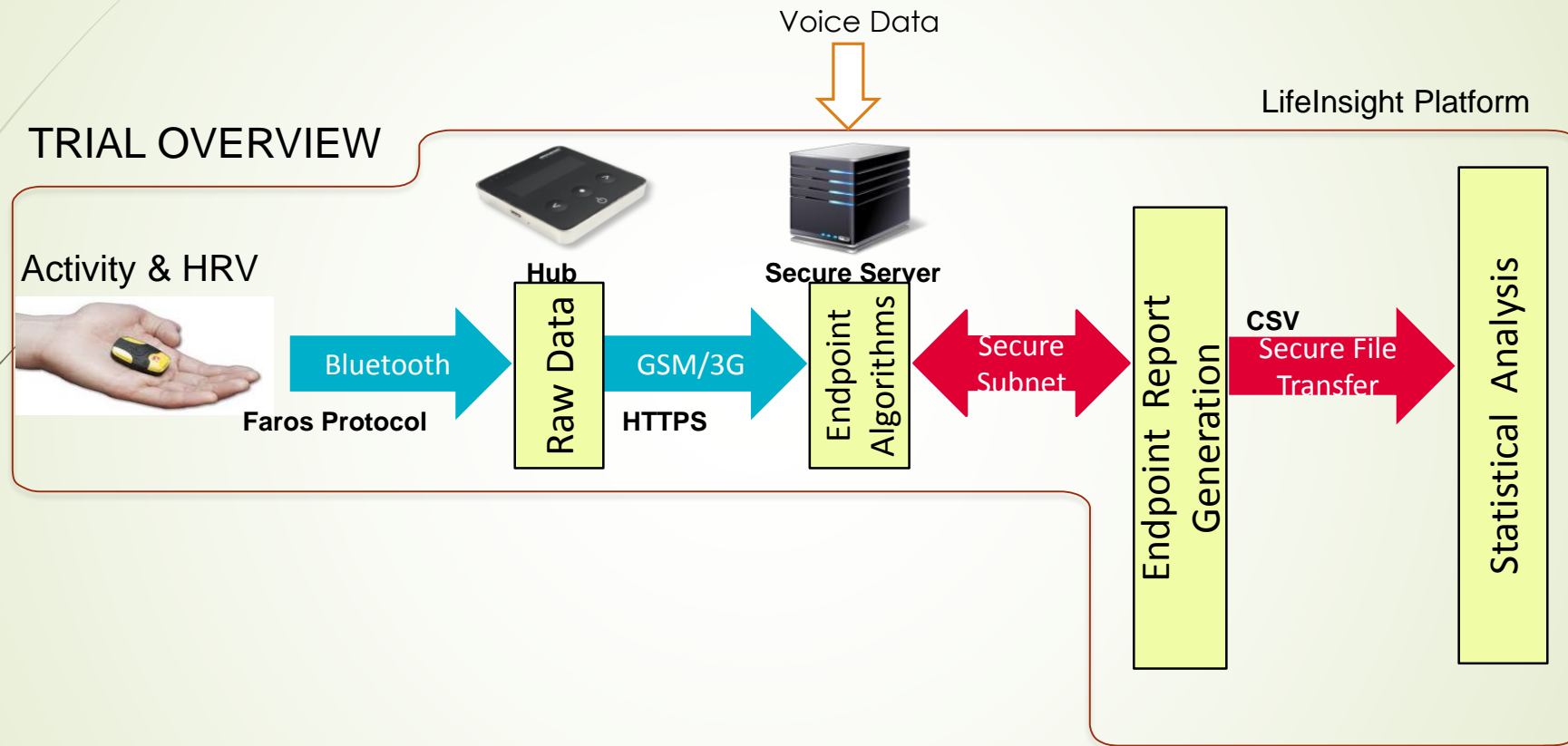
Spirometry

(slow/fast vital capacity)



ALS Biotelemetry Study: Speech & Activity

Novel Surrogate Endpoints



Challenges & Learnings

- Has to be a **'so what?'** – not just because its high tech
- **Regulatory** environment is evolving
- **Technical & operational** challenges of execution
- Dependent on **partnerships** – not a device or IT company
- Secure **data collection and transfer** – infrastructure needed
- **Data** algorithms, analytics and visualization are key
- **Change** management - varied adoption / acceptance

Thank You! Any Questions

