ICON
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Clinical Research

Wearable Devices

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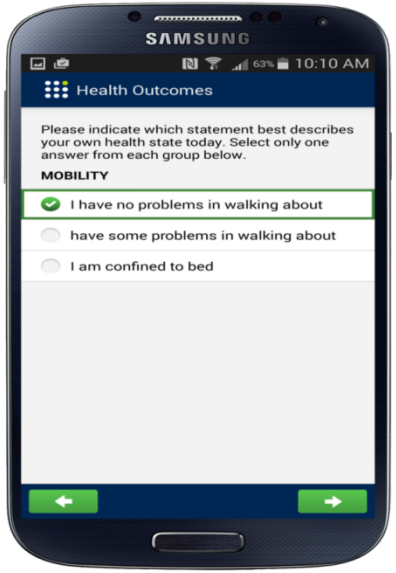
Agenda

- Wearables, categories, and how they work
- Potential uses and future ahead for wearables
- Feasibility in clinical trials
- Big Data
- Barriers
- Standardization
- Case Study

Wearable devices – Better model for engaging with subjects

User friendly, convenient instruments and diaries



Integrated mobile tools

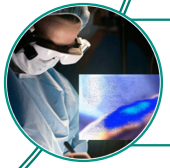
Biosensors / wearables

Wearable Categories

Health and fitness tracking

Early detection

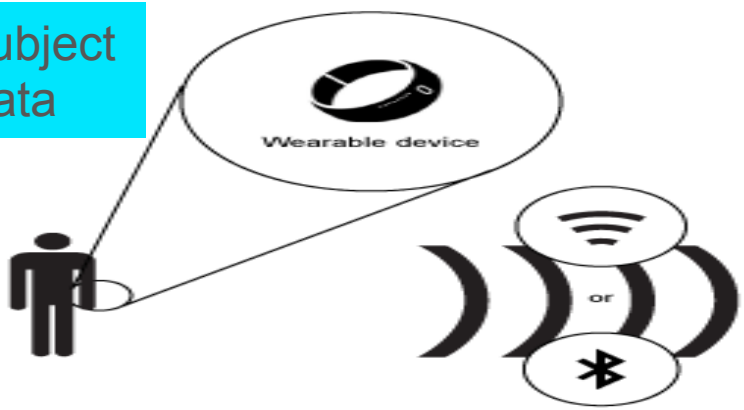
Personalized care for illnesses



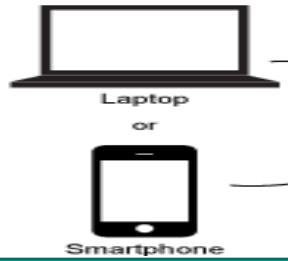
Amplified surgical precision

How do they work?

Subject Data



Secure Storage



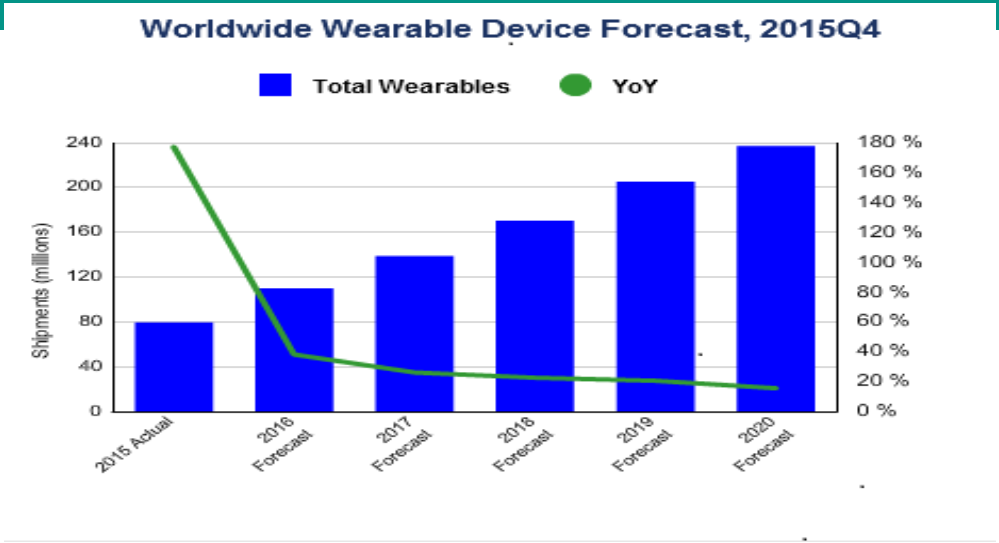
Clinical Record

Synchronization

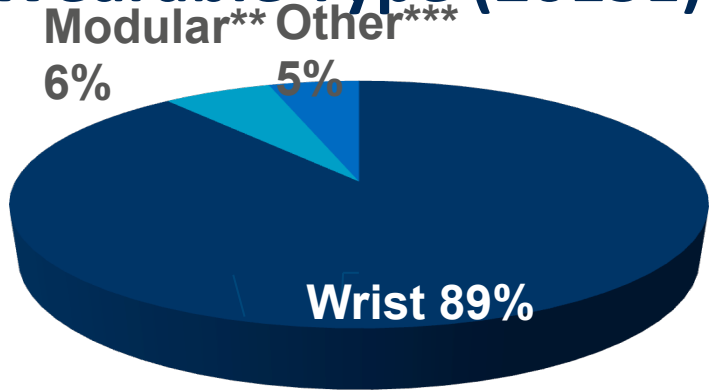
Study Monitoring

CDM Systems

Growth of wearable devices



Wearable Type (2015E)



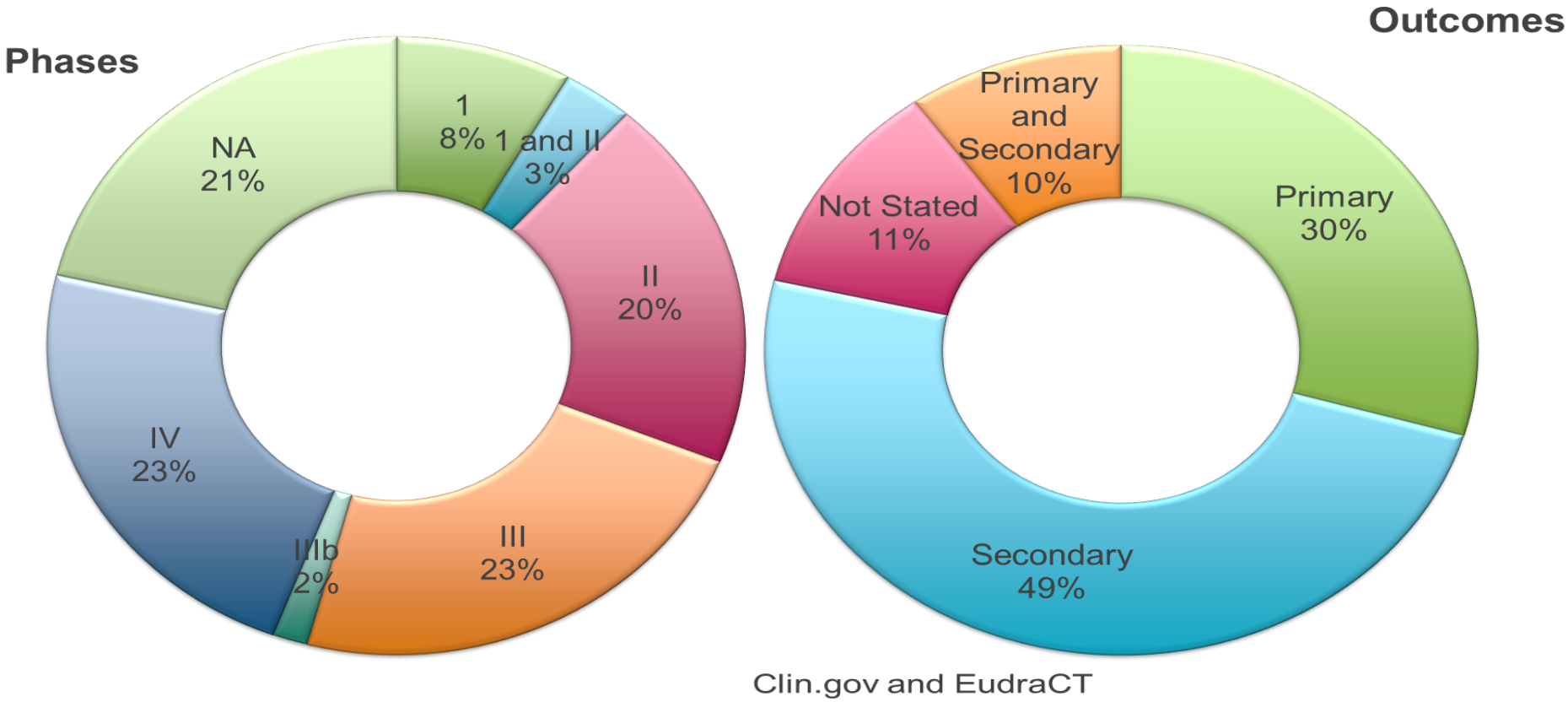
Global 5-year CAGR: 45

** Modular can be worn with clip, strap or patch
*** Other includes eyewear, earwear, clothing

*** Num of clinical trials using mobile apps more than doubled in the past 2 years, rising from 135 to 300**
***One in 10 mHealth apps now has the capability to connect to a device or sensor, providing biofeedback and physiological function data from the patient and greatly extending the accuracy and convenience of data collection**

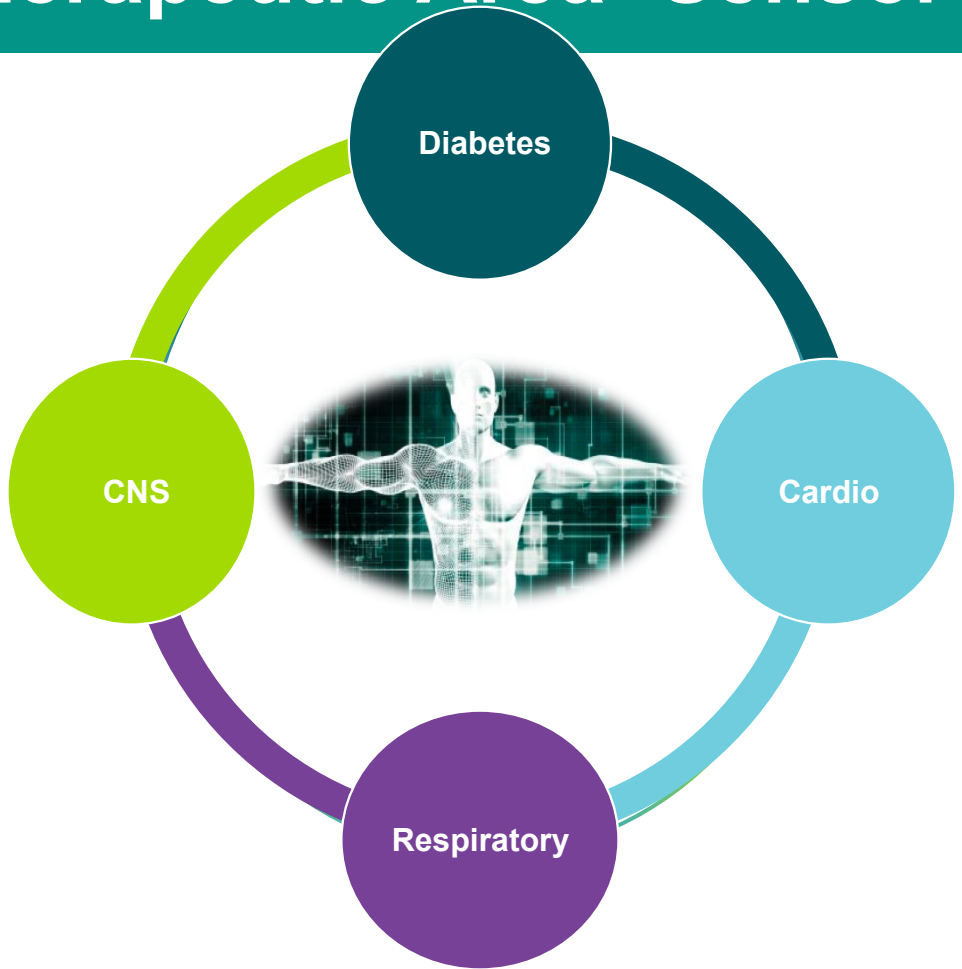
Source: IDC Worldwide Wearable Device Tracker March 2015

Wearables and Clinical Trials



Clin.gov and EudraCT

Therapeutic Area- Sensor Suite



- Activity and Sleep Monitors
- Glucometers
- Oximetry
- Blood Pressure Devices
- Heart Rate Monitors
- Weighing Scales
- Medical Adherence

Potential areas for wearable use

	Current	Opportunities
Pain	Pain intensity scales (PRO), e.g., visual analog scale, brief pain inventory	Level of activity and/or sleep quality
Stroke	NIHSS (National Institutes of Health Stroke Score) or Rankin Scale	Gait, cadence, balance of steps between left foot and right foot
Parkinson's	Unified Parkinson's Disease Rating Scale (UPDRS)	Level of vocal tremor during phone conversations
COPD	6-minute walk test	Daily steps for trial duration
Asthma	PRO surveys on number of night awakenings	Number of night awakenings detected by wearable device
Obesity/ Diabetes	Weight, blood pressure and hypoglycemic events	Active minutes / steps walked

Big Data

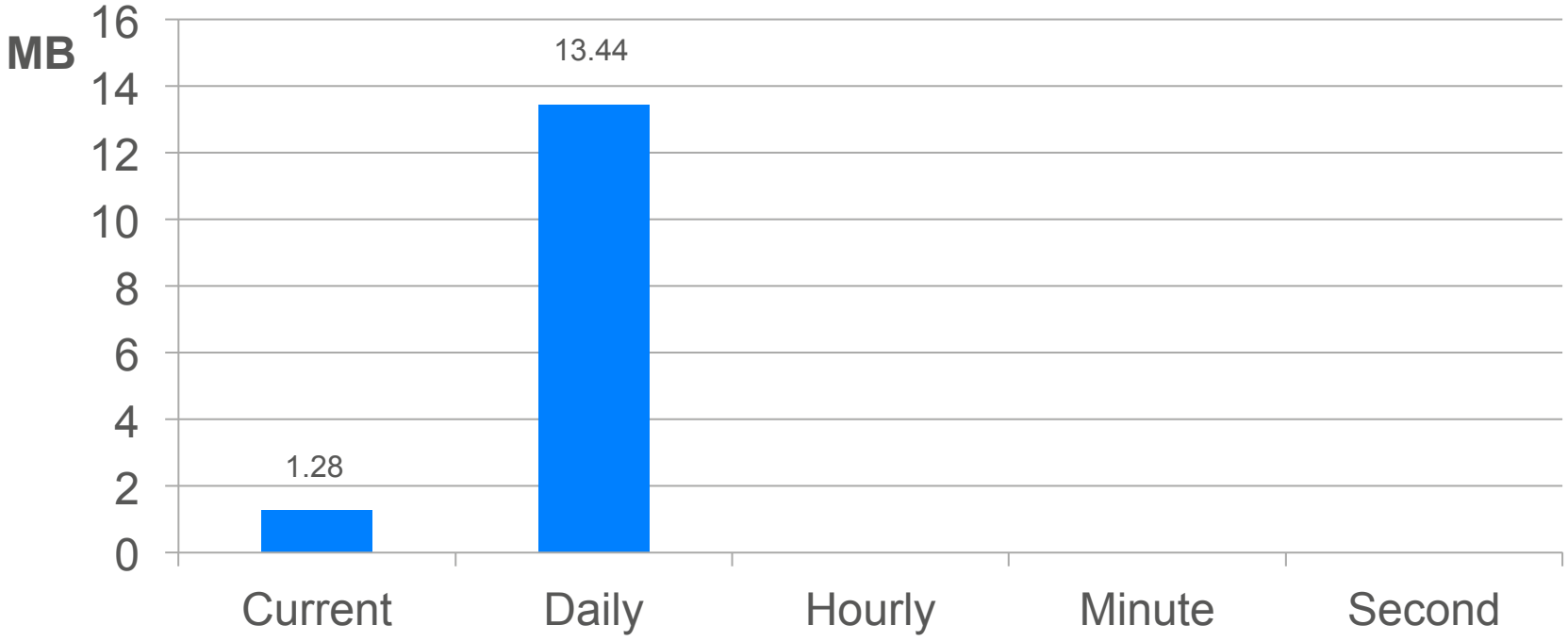
- Big Data are the collection of large amounts of unstructured data.
- They are enormous amount of data, such large that it is difficult to collect, store, manage, analyze, predict, visualize, and model the data.

Big Data

Assumptions

12 week study, 8 visits, 200 patients

Vitals + Labs = approx. 800 data points / patient / visit



Courtesy: **Mike Bartlett,** Senior Enterprise Architect, Lundbeck

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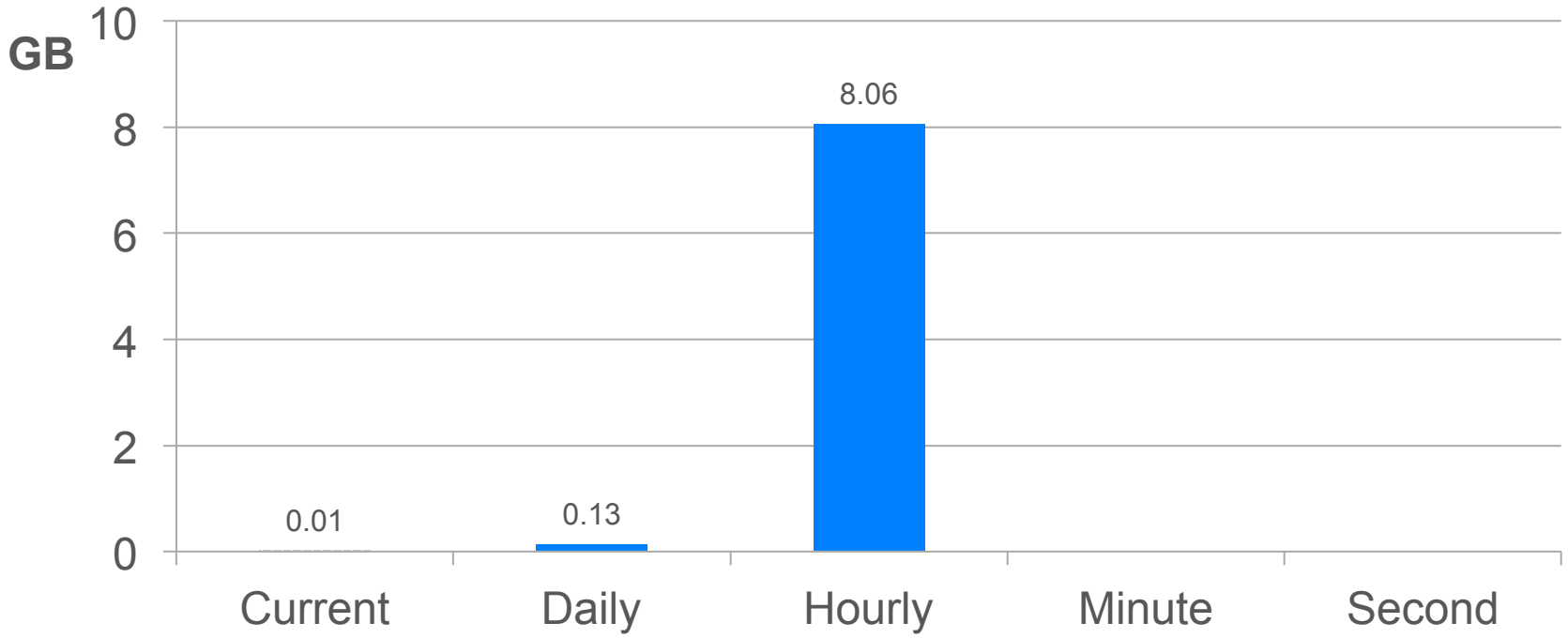

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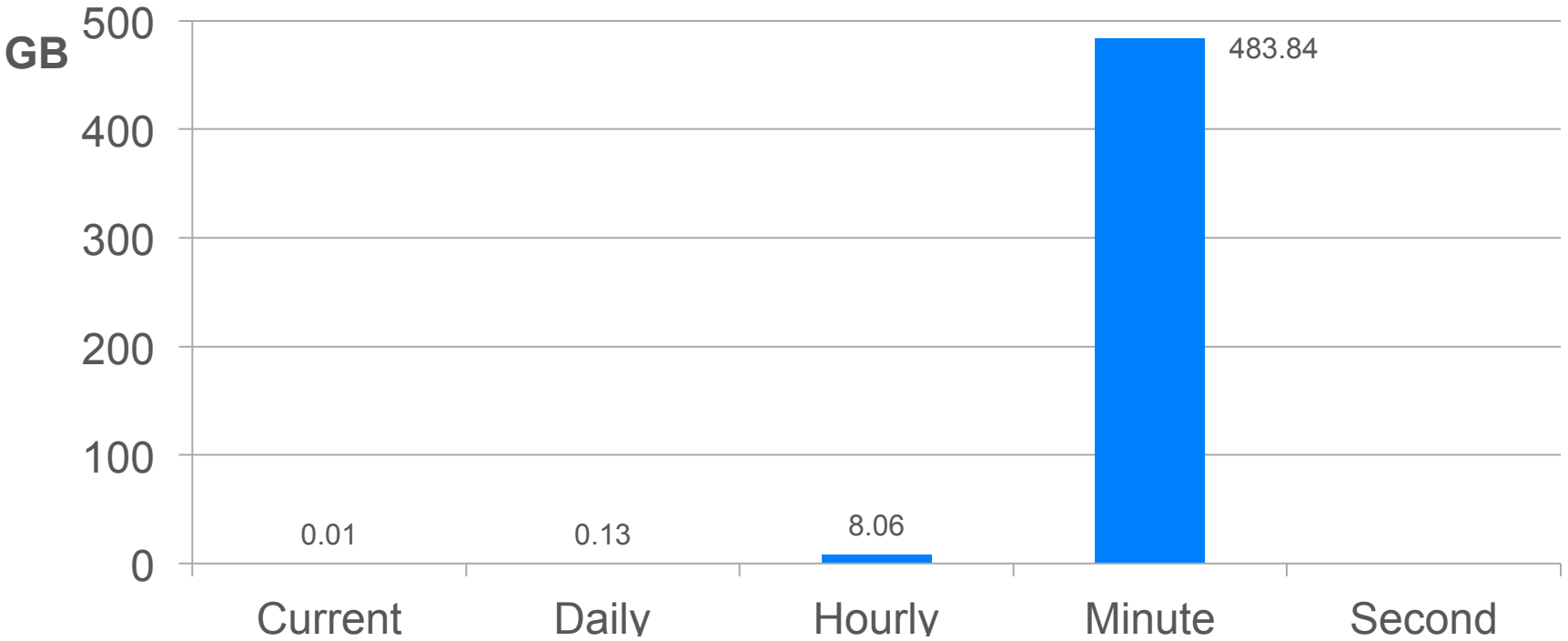

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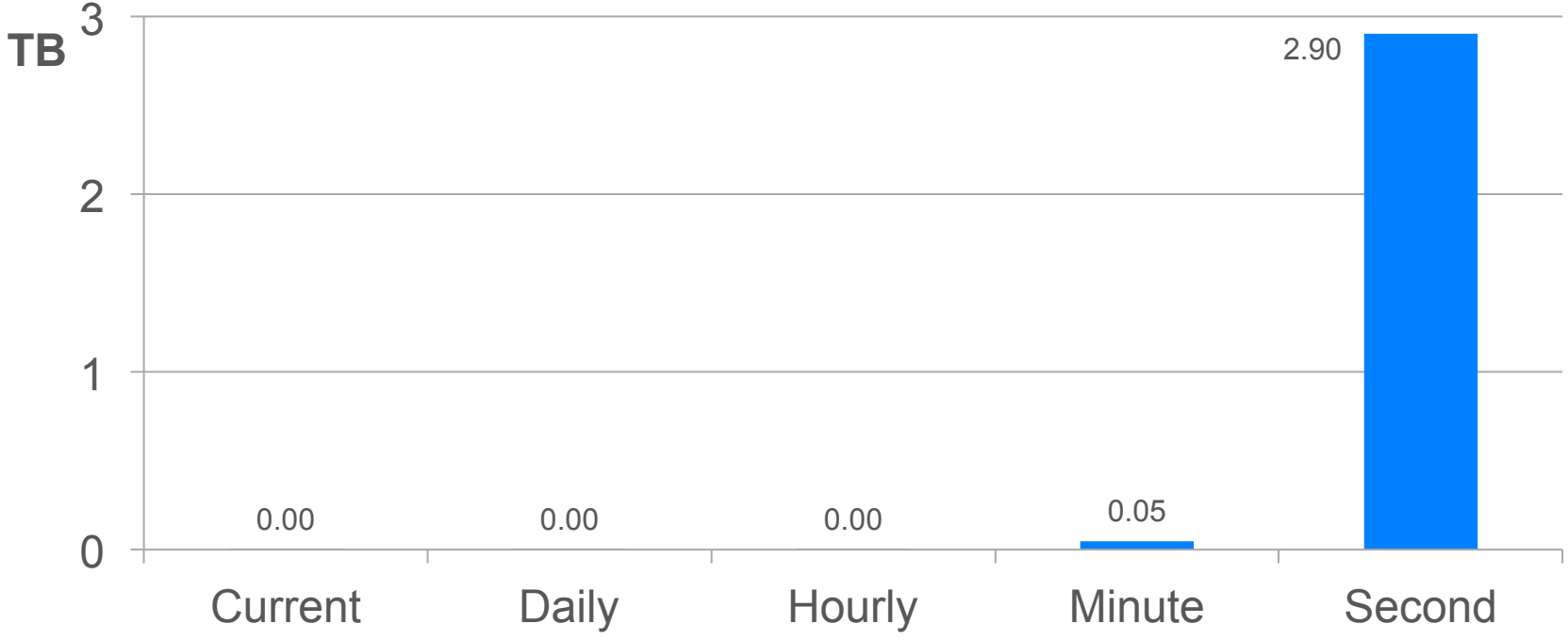

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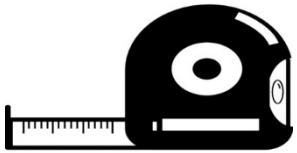
Key Activities



What to measure

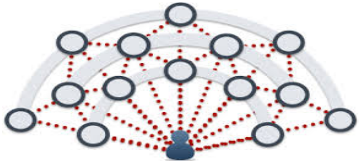
How to measure

How to integrate/manage big data

Standardization

How to analyze big data

Analytics



How to operationalize and interoperate

Lack of Standardization and need for analytics

- Large and still growing variety of wearables
- Include proprietary software interfaces
- Lack of standard and open software interfaces to interact with these devices

- *Prospective solutions??*
  - Model-driven approach for wearable system development
  - Similar model to CDISC/SDTM
  - Interoperable systems

Case Study: ACTIGRAPHY

Case Study: Actigraphy?

- Sleep/wake patterns
- Icon conducted a pilot trial using Actigraphy Device
- Traditional self-report measures of pain and activity cannot capture real-time data.
- Using Actiwatch®

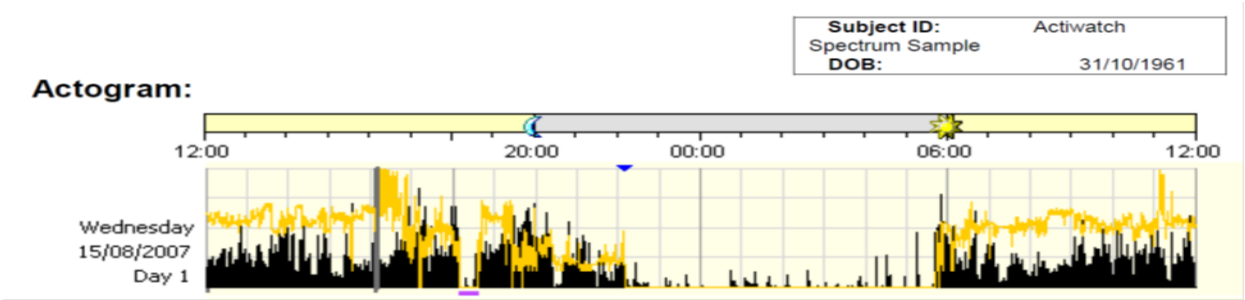


Figure 1. *Actogram*
Normal healthy adult has activity during the day and little or no movement during the sleep period.

ICON Management of Accelerometer Data

Derived Endpoints

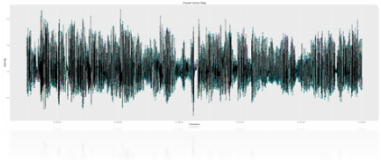
- EDC → ICONIK Immediate Knowledge

Activity Counts

- New Endpoints →

Raw Data

- Pattern recognition →



Actigraphy Data Outputs

Produces vast quantities of data

- 30 second epoch produces 2880 data points in a day
- 7 days study of 300 patients 6,048,000 data points.

Validated Algorithms identify clinically significant endpoints

Sleep endpoints are the most common Actigraphy endpoints used in Clinical Trials.

Barriers in the Operationalization of Wearables

Data Transfer

Data Privacy

HUB or App

Real time data

Remote data

Data Management

Data Reconciliation

Data is edit checked

Incorporated into the SDTM datasets for analysis

Device

Fit for Purpose

Medical Device or Consumer device depends on use case.

Data Integration

API

CSV

In Conclusion……..

Consideration needs to be given to :

- Required Endpoints (Clinical relevance).
- Interoperable systems
- Data Transfer and Analysis

Need for Standardization for this technology to become truly valuable in Clinical Trials.


Thank
you