

The background of the slide features a blurred office setting. In the foreground, a man with short blonde hair, wearing a light blue button-down shirt, is seated at a wooden table. He is smiling and gesturing with his hands while looking towards another man on the right. The second man, who is Black, is wearing a blue and white plaid shirt and has a white headset with a microphone. On the table, there is a silver laptop and a brown paper coffee cup. In the background, other people are visible but out of focus.

ORACLE®

HEALTH SCIENCES

DV07 Clinical Data in Business Intelligence

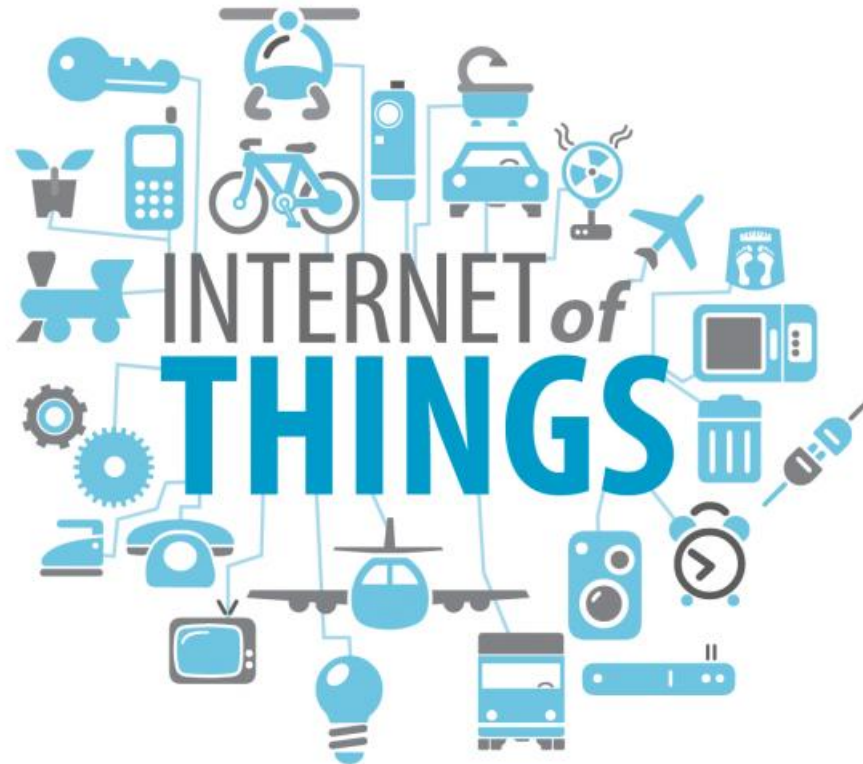
Mike Collinson
Life Sciences Architect
Oracle Health Sciences Consulting (HSC)
Oct 2016

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Safe Harbor Statement

The following is intended to outline our general product direction. It is intended for information purposes only, and may not be incorporated into any contract. It is not a commitment to deliver any material, code, or functionality, and should not be relied upon in making purchasing decisions. The development, release, and timing of any features or functionality described for Oracle's products remains at the sole discretion of Oracle.

Clinical Data in Business Intelligence



The Future is Connected!

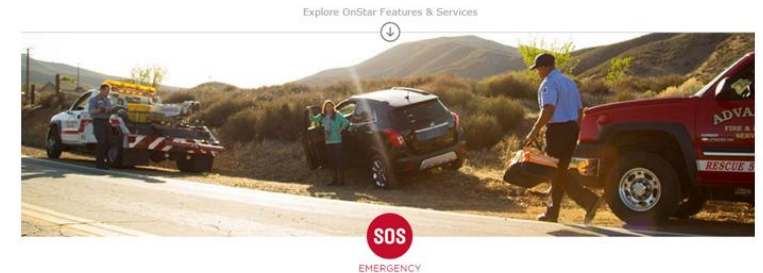
Clinical Data in Business Intelligence

BY THE YEAR 2020, THERE WILL BE

50,000,000,000 connected devices,
creating and sharing

40,000,000,000,000 GB

worth of data across the Internet of Things.



Computer Business Review – 10 of the Biggest IoT Data Generators, Joao Lima, 28 May 2015

Clinical Data in Business Intelligence

- Growing volumes of data, global operations and increasing regulatory scrutiny are encouraging pharmaceutical companies and healthcare providers to develop Clinical Data Warehouses.
- Data warehouses can be a mine of information in a data rich business environment, and can greatly enhance data transparency and visibility.
- The interoperability of systems is increasing along with interchange standards, and real world data is being collected more widely than ever before.

Next Generation Data Management

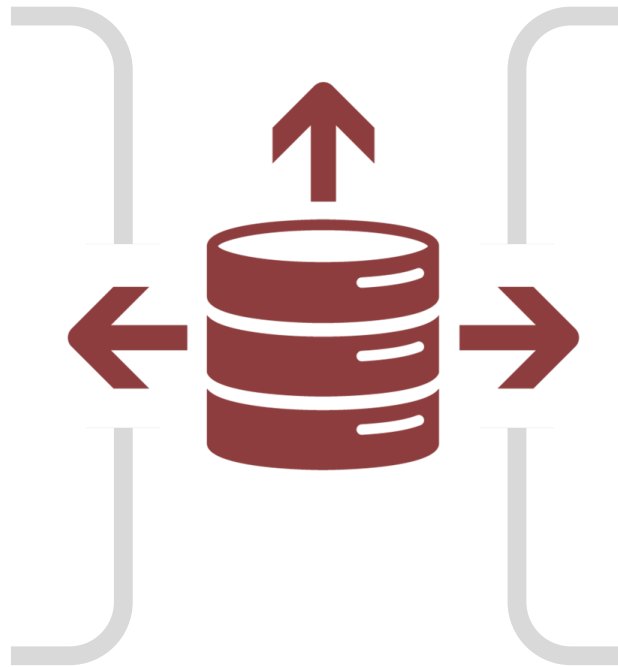
Oracle **Data Management Workbench** - Source to Submission

Single source of truth

- One database for all your clinical data
- All users access the same data
- Provides data blinding, security and scalability

Easy to use

- One click study setup
- Intuitive data dashboards
- Browser based



Saves you time

- Automated data loads
- Automated data transformations
- Automated discrepancy management workflows

Complete traceability

- Audit and traceability from data point capture to final submission deliverable
- Round trip discrepancy management

Next Generation Data Management

Automated Clinical Data Flow -
Data Collection:

sdeuat1601 - Case Report Forms - 10000001/--- Subject: 10000001/---

Home Enroll Subjects Queries Signatures Documents Admin

VIS 1 LOGS UNPL DISP FUP

Visit: DEMOGRAPHY

VIS 1 Demography

Forms:

- DOV
- DM
- PREVIOUS
- CONSENT
- MH
- ORAL
- CENTRAL ECG
- ETRK
- VS
- LABS HEM
- CENTRAL LAB

1.* Subject ID 10000001

2.* Birth Date (DD-MMM-YYYY): Jul / 26 / 1980

3.* Birth Year (YYYY): 1980

4. Birth Month (MMM):

5. Birth Day (DD):

6.* Sex / Gender: ☐ Male ☒ Female

7.* Ethnicity: ☐ HISPANIC OR LATINO ☐ NOT HISPANIC OR LATINO

Data Management:

ORACLE DMW SDEUAT1605 - Study Template 2 (Cardiology) Development Mike Collins

Home | Listings | Discrepancies | Study Configuration | Library | Administration

Studies

Filter Studies: SDEUAT1605

SDEUAT1605 - Study Template 2 (Cardiology)

Data Loads Transformations Validation Checks Files Not Processed

View

Target Model	Type	Install Status	Job ID	Submit Date/Time
21 - SDTM3.2	Transform	Success	17654405	01-SEP-2016 06:14:40
10 - Review	Transform	Success	17478691	08-AUG-2016 08:09:40
99 - SubjectVisit	Transform	Success	17508566	11-AUG-2016 08:00:40

Run History

View

Target Model	Type	Job ID	Submit Date/Time	Start Date/Time
21 - SDTM3.2	Transform	17654405	01-SEP-2016 06:14:40	01-SEP-2016 06:14:40
CM	Table	17654406	01-SEP-2016 06:14:40	01-SEP-2016 06:14:40
PR	Table	17654407	01-SEP-2016 06:14:40	01-SEP-2016 06:14:40
SUPPAE	Table	17654408	01-SEP-2016 06:14:40	01-SEP-2016 06:14:40
SUPPDM	Table	17654409	01-SEP-2016 06:14:40	01-SEP-2016 06:14:40
SUPPCM	Table	17654415	01-SEP-2016 06:14:40	01-SEP-2016 06:14:40
SUPPPR	Table	17654411	01-SEP-2016 06:14:40	01-SEP-2016 06:14:40
AE	Table	17654412	01-SEP-2016 06:14:40	01-SEP-2016 06:14:40
DM	Table	17654413	01-SEP-2016 06:14:40	01-SEP-2016 06:14:40

Lifecycle Mode:

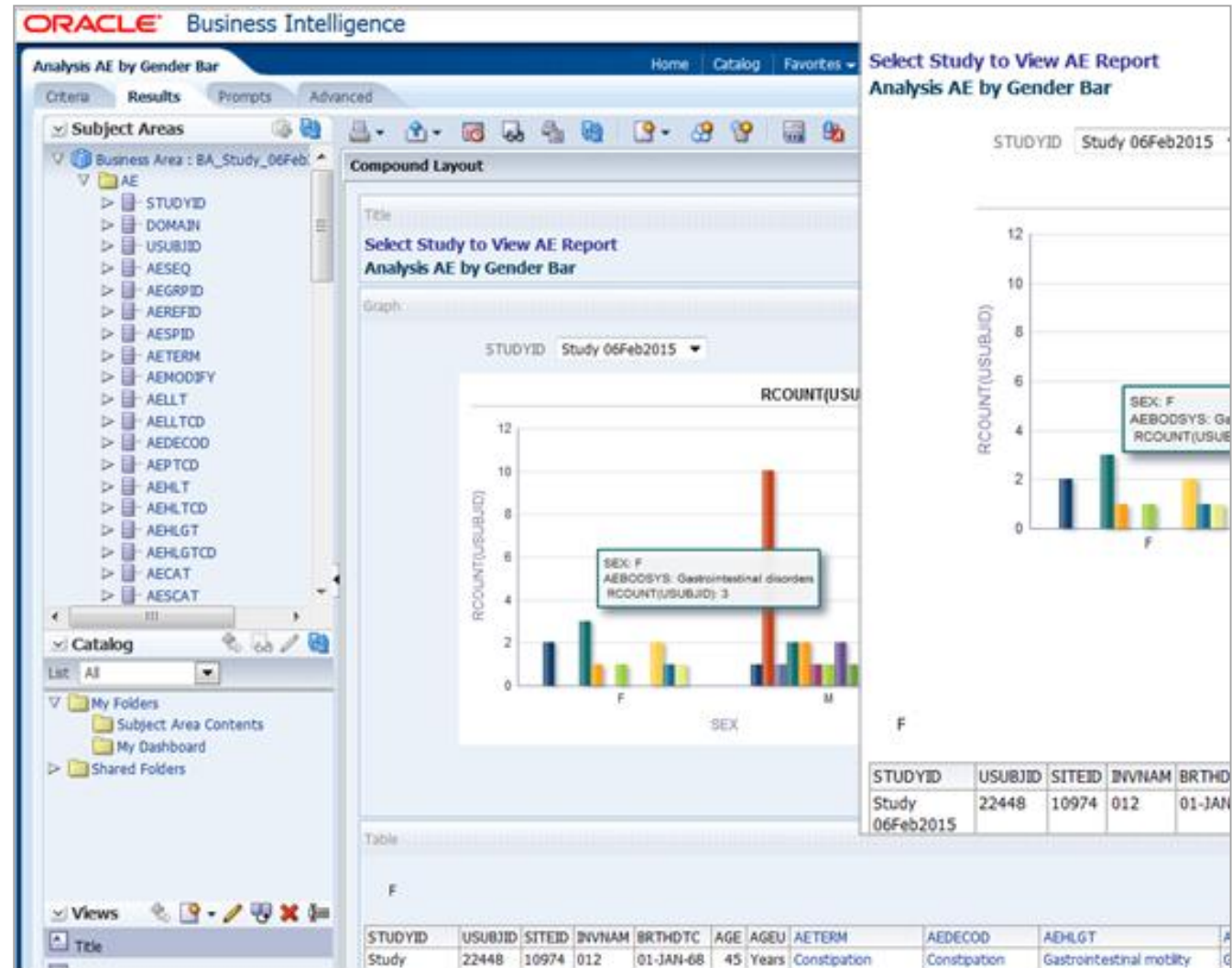
- Development
- Quality Control
- Production

Clinical Data in Business Intelligence

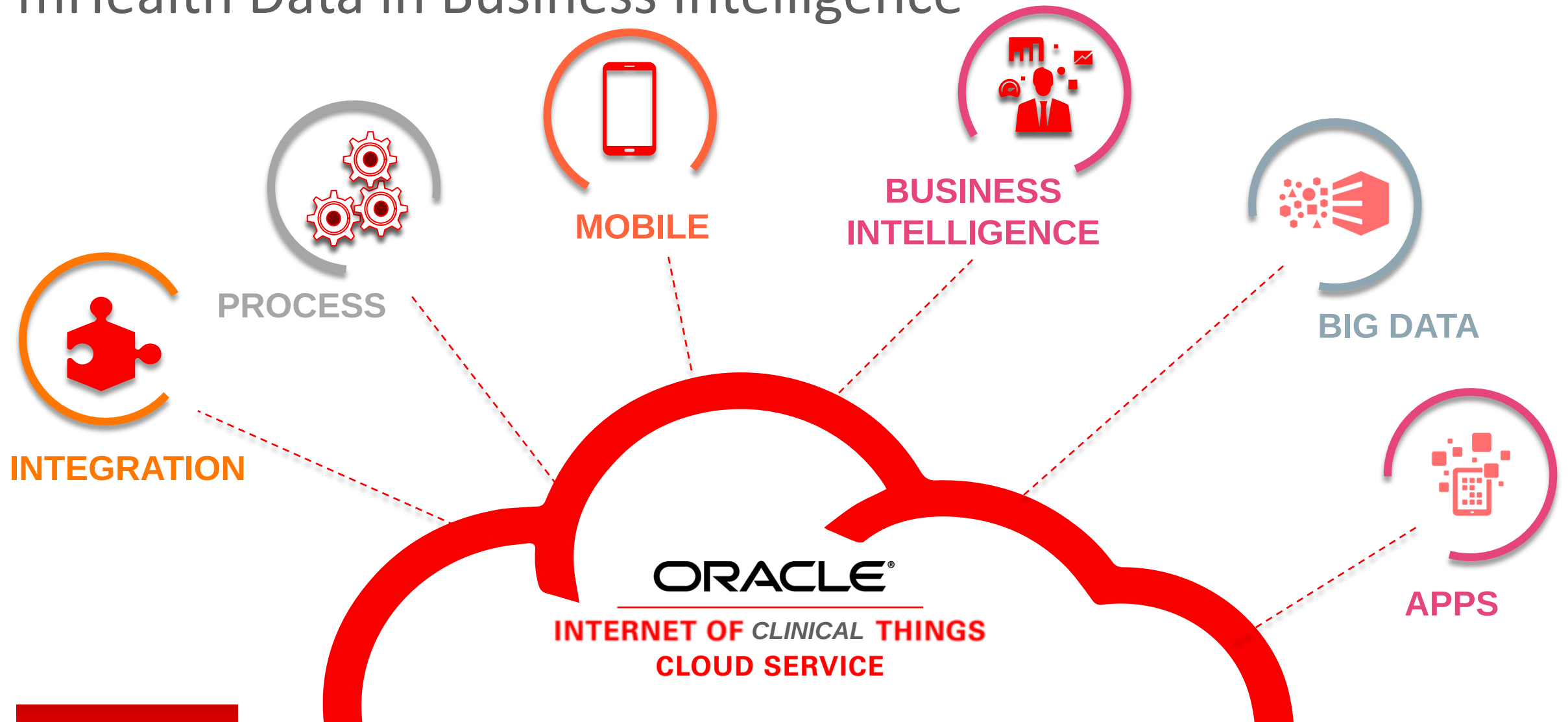
- SDTM data is useful for cross study analysis, and can include various types of external data such as labs, ecg and medical devices.
- SDTM is increasingly being mandated by regulatory authorities, including FDA and PMDA.
- Oracle DMW enables trial sponsors to automatically load and control data from EDC and various external sources and transform this from the collection standards into SDTM without user input.
- Oracle's Business Intelligence platform can be integrated with Oracle DMW.
- These tools can provide SDTM data to dynamic, near real time analyses which can be compiled into internet facing dashboards.

Simple Business Intelligence Analyses using SDTM data:

- Simple cross tabulation of Adverse Event and Demography Data, showing segmentation of Adverse Events by SOC and Gender



mHealth Data in Business Intelligence



FDA Enthusiastic about Mobile Health Data

“FDA Enthusiastic about Mobile Health Data”¹

“From the regulatory point of view, we have to be sure that these devices are reporting a meaningful clinical benefit.”¹

“I doubt whether there'd be a requirement to audit every single data point”¹

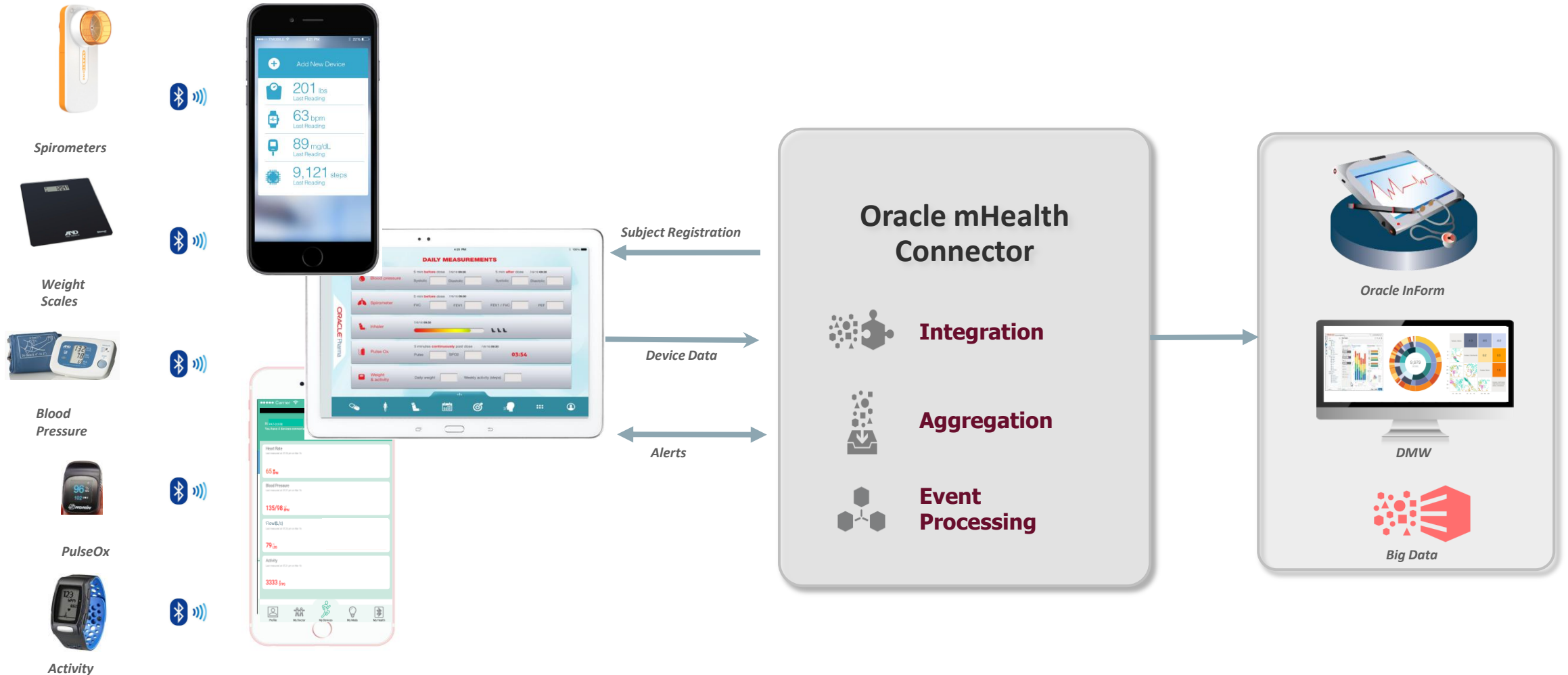
“There are no regulatory restrictions to using these technologies at all and certainly I think there's room for us at FDA to produce more guidance on this”¹

“Use of these technologies and methods allows for more flexibility for the sponsor and clinical investigator”²



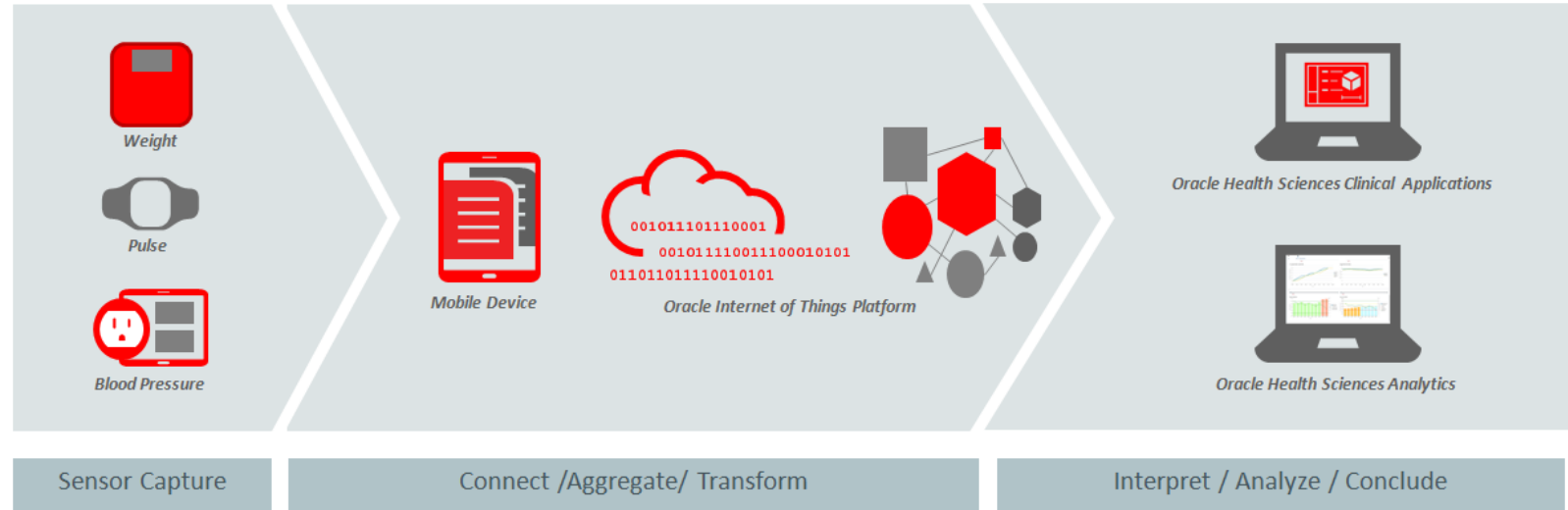
1- Posted in [Mddionline](#) by mthibault on Oct 2, 2015, Leonard Sacks Dir. Clinical Methodology FDA
2- Posted in [Mobihealthnews](#) by jcomstock on Nov, 4 2015, Leslie Kux Assoc. Commissioner Policy FDA

mHealth Clinical Data Flow



mHealth Data in Business Intelligence

- Continuous analyses using mHealth and SDTM data:

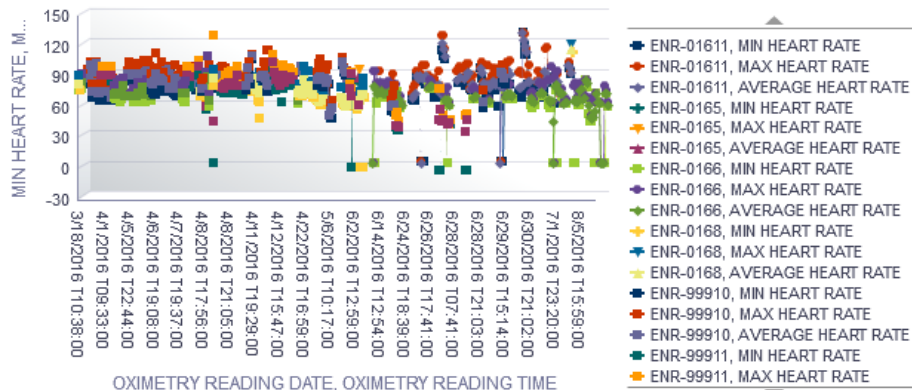


ORACLE Business Intelligence

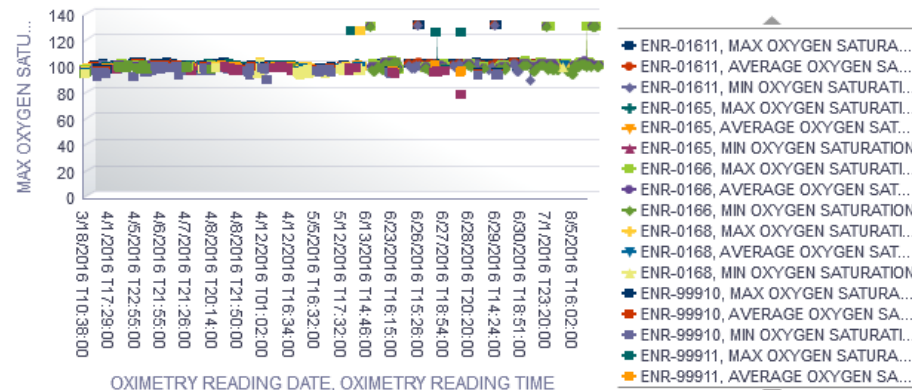
Oracle HSGBU IoT Dashboard

Pulse Oximetry Results Oracle HSGBU IoT PulseOx

MIN HEART RATE, MAX HEART RATE, AVERAGE HEART RATE



MAX OXYGEN SATURATION, AVERAGE OXYGEN SATURATION, MIN OXYGEN SATURATION



Clinical Data in Business Intelligence

- Standardized data can streamline data collection and increase data availability
- End to end traceability aids review and increases regulatory compliance
- Wearable devices are now being included in up to 50% of clinical protocols
- These integrations present sponsors with opportunities to:
 - Improve data quality
 - Improve patient trial adherence
 - Improve patient engagement

Thank you!

Want to find out more?

Watch this short video: [The Internet of Clinical Things](#)



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