Clinical Data in Business Intelligence

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Safe Harbor Statement

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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.
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:

Data Management:

Oracle DMW SDEUAT1605 - Study Template 2 (Cardiology) Development

Mike Colburn
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

INTEGRATION

MOBILE

BUSINESS INTELLIGENCE

PROCESS

BIG DATA

INTERNET OF CLINICAL THINGS
CLOUD SERVICE

APPS
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

Oracle mHealth Connector

- Integration
- Aggregation
- Event Processing
mHealth Data in Business Intelligence

- Continuous analyses using mHealth and SDTM data:
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