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Clinical Data in Business Intelligence

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ABSTRACT

Clinical organizations are under increasing pressure to execute clinical trials faster with higher quality. Subject data originates from multiple sources; CRFs collect data on patient visits, implantable devices deliver data via wireless technology. All this data needs to be integrated, cleaned and transformed from raw data to analysis datasets. This data management across multiple sources is on the critical path to successful trial execution, and submission. Oracle's Business Intelligence platform is integrated with the our best in class data management platform, allowing trial sponsors to automatically load and control data from EDC and various external sources, transform this from the collection standards into SDTM without user input, and provide the SDTM data to dynamic, near real time analyses which can be compiled into internet facing dashboards.

SDTM data provides a powerful tool for cross study analysis, and can include various types of external data such as labs, ecg and medical devices. Wearable devices are becoming more popular, and can even be included in patient treatment regimens. Once conformed, these data can provide fantastic insights into populations. This 'big' data can allow researchers to observe drug reactions in larger populations than those under study, and aligning with genetic data could even reduce wasted treatment cycles.

In the digital age, our attitude to information is changing. The traditional model of data capture and supply, using an EDC system with multiple integrations has shifted downstream. Rather than being at the very centre of this picture, EDC has shifted left slightly: companies now expect their clinical systems to act as a hub for all of the information relevant to their drug on trial, and are searching for a single source of the truth, whatever the data source.

INTRODUCTION

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Our warehouse can also be integrated with a wide range of wearable technologies. These can be integrated using Oracle's Internet of Things (IoT) service, which can accept information from a wide range of devices, such as Pulse Axiometry, Blood Pressure and Activity monitors. This data can be pushed to and EDC system, and owing to the tight integration with EDC, providing near real time data to patient and population dashboards. These data are automatically updated, accessible anywhere, and can real insight and drill down capabilities on these novel types of data. Figure 1 highlights some of these novel data types.
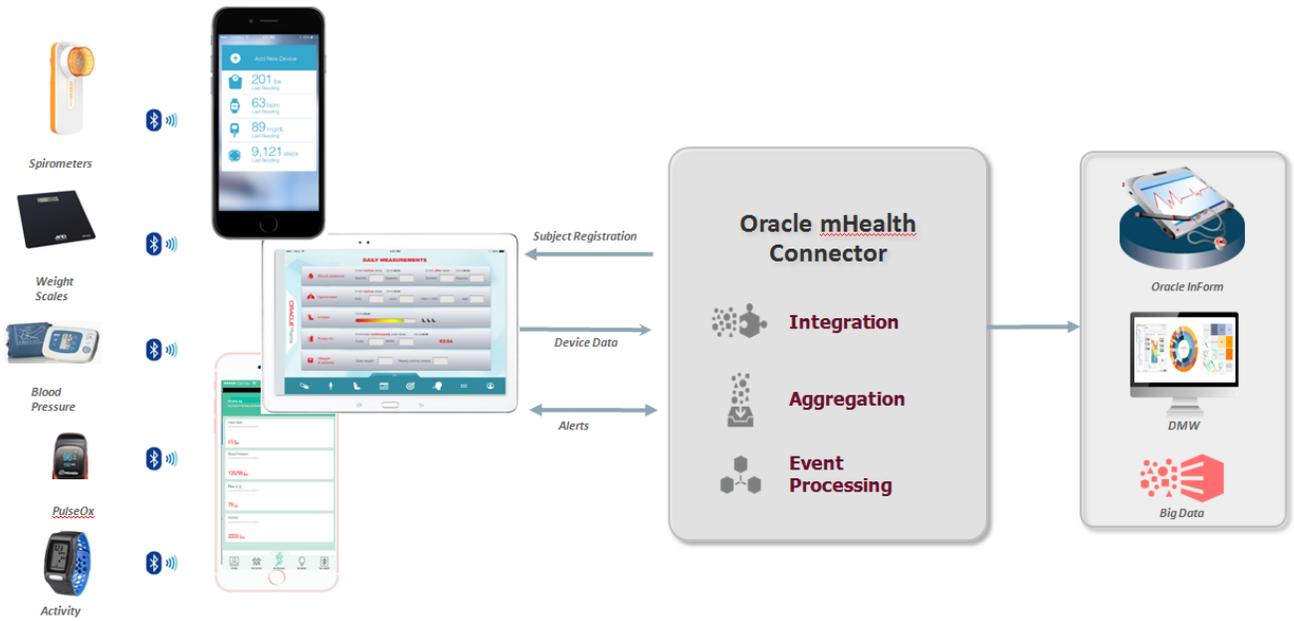
Figure 1 Integration of mHealth data

DATA WAREHOUSING AND STANDARDIZED DATA

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.

Data warehouses are often used to aggregate data from multiple transactional systems. Such systems may have data structures designed for collection, and not be aligned with the reporting standard. Typically this data is transformed and then loaded into a central data model that has been optimized for analysis, for example market research or data mining. It is possible to design a Clinical Data Warehouse that follows the model of a traditional data warehouse with a single well-defined data model into which all clinical data are loaded. This can create a powerful tool allowing cross study analysis at many levels. Data is never deleted or removed from the warehouse, and all changes to data over time are recorded.

The main features of a reporting standard must be ease of use and quick retrieval. SDTM is a mature, extensible and widely understood reporting standard with clearly specified table relationships and keys. The key relationships can be used to allow users to select data from different reporting domains without an understanding of the relationships. between domains. SDTM also allows users to create their own domains to house novel and as yet unpublished data types, so we can maintain the principles above for any data type, allowing powerful cross domain reports to be created interactively – see Figure 2, where demographic and adverse event data is combined into a simple report.
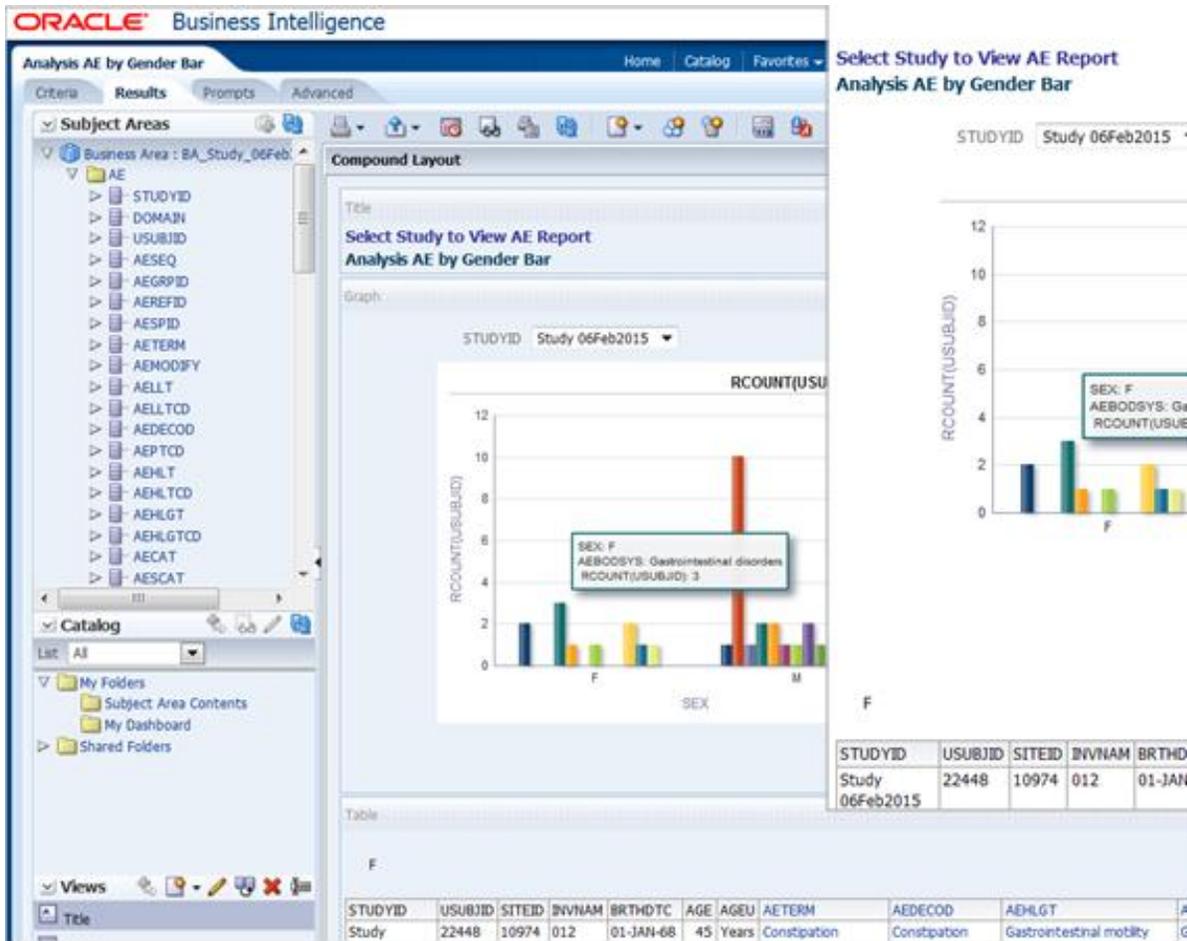
Figure 2. Simple Business Intelligence Analyses using SDTM

AUTOMATED DATA LOADING AND CONFORMANCE TO SDTM

Data may be loaded from the source transactional systems in a number of ways. With EDC, new studies are continually brought online, and may be uploaded repeatedly. Most warehouse systems include a number of interfaces to load data. Many also supply APIs to allow external programs to control the warehouse in the same way as an interactive user. A combination of robust metadata, consistent data standards and naming conventions can allow automated creation of template driven warehouse structures, and dedicated listener programs can automatically detect files, and automate data loading.

The SDTM table keys enable incremental loading, where only records changed in the source system are updated in the warehouse, saving disk space. We can also use the SDTM keys in our audit processing, and use them to identify deleted records in incrementally loaded data pools.

SDTM conversion, data pooling at Therapeutic Area and Compound level, and Medical Dictionary re-coding can be handled automatically in the warehouse in the reporting standard. Use of SDTM facilitates the pooling of studies to the maximum version available, accommodating all of the studies in previous versions without destructive changes which would affect the warehouse audit trail.

Figure 3 shows a range of data management activities supported by the warehouse system, including transformation to SDTM.

Figure 3. Typical Data Management processes

DASHBOARDS AND DELIVERY

Uses of a Clinical Data Warehouse include:
- Ongoing medical review
- Wearable Device data review
- Data reconciliation
- Streamline statistical analysis for submission
- Modeling of protocol design and trial simulation
- Responding to regulatory queries
- Safety monitoring and signal detection
- Cross-study analysis

Each of these can deliver value to a customer, but each requires consistent data structures, in a format that is easily understandable by the warehouse consumers.

Figure 4 shows two views of wearable device data over time, with blood pressure results correlated with activity monitor data.
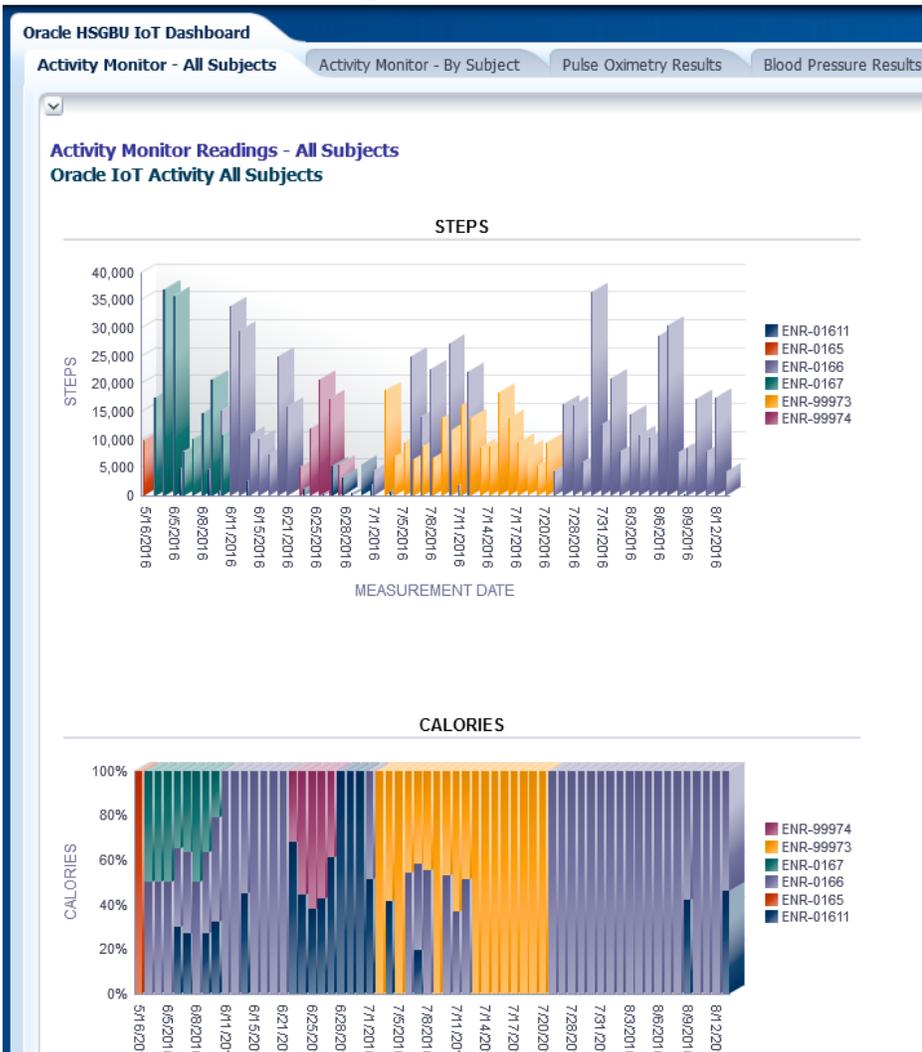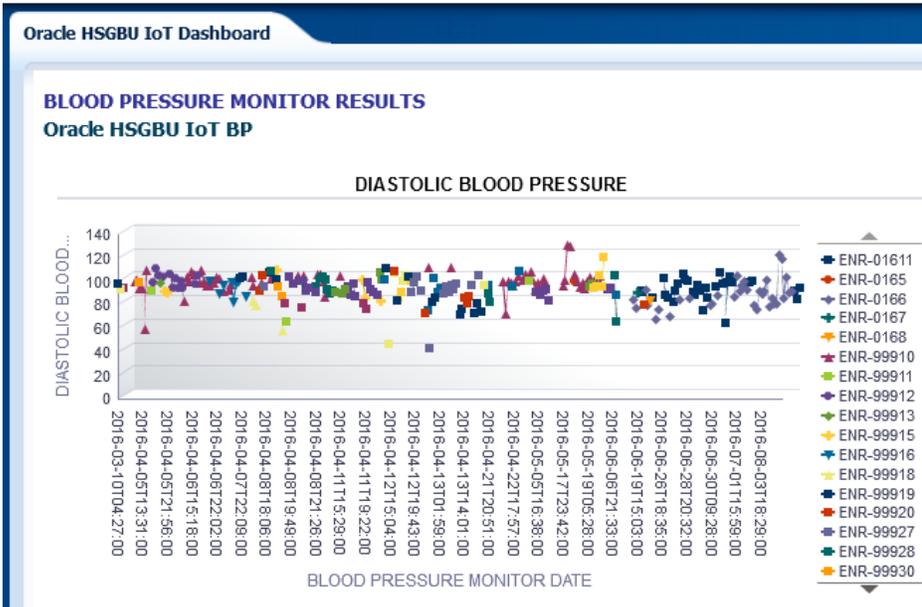
Figure 4. Oracle Business Intelligence dashboards of mHealth data

INTEGRATION AND RECONCILIATION OF SAFETY AND DEVICE DATA

Our Clinical Data Warehouse may also be connected to a transactional Safety system. This, coupled with the SDTM data warehouse can allow reconciliation of the two datasources, a crucial task as the Clinical studies are locked and reported.. Automated transformations can account for the different vocabularies in the two systems, and the records can be paired together in a dashboard.

The dashboards themselves can be configured to highlight non-matching records, and also to allow data entry to track comments, and acceptance of insignificant differences.

Reconciliation involves both the Clinical and Safety groups, but could also be carried out by CRO users responsible for the studies. This enhances collaboration between the sponsor and CRO, and provides an audited central secure location to capture comments. Security is paramount in an open system, and the warehouses security model is designed to allow CRO users to only see the studies they have been assigned to, hiding other studies from the dashboards and selection prompts.

As a serious adverse event must be reported within 24 hours, it is possible that that event could be reconciled against the clinical data the following day.

MHealth data can be integrated automatically using the IoT Cloud service, with patients automatically enrolled into and EDC study. This can be reconciled with CRF data and automatically loaded to the Business Intelligence layer:
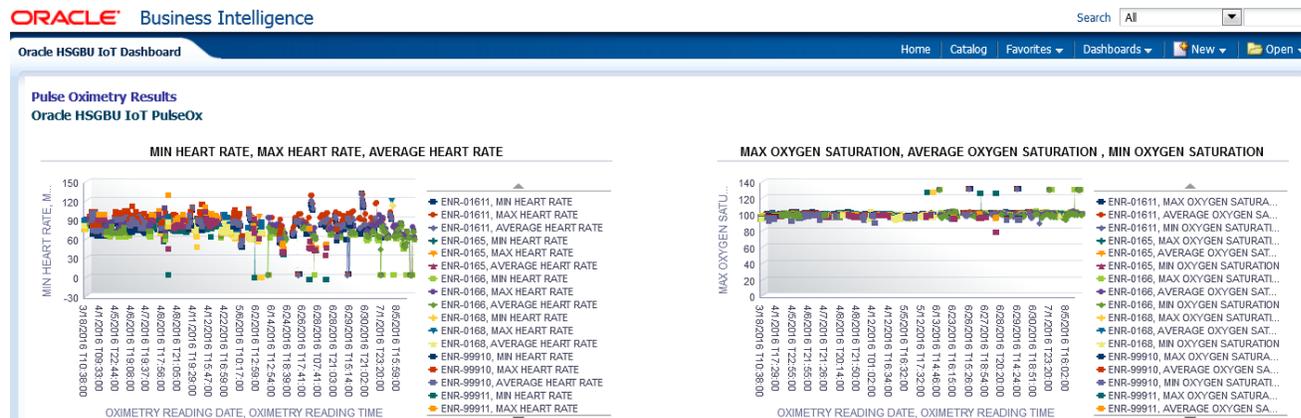

Figure 5. Oracle Business Intelligence dashboards of mHealth data

CONCLUSION

SDTM can be of huge benefit to the users of a Clinical Data Warehouse system, allowing data pooling for storage, audit and reporting. Use of data standards has already transformed Clinical research. The next generation of eClinical Software should place those standards in front of me, inside the tools I use every day, and allow me to automate transformations to and from review and submission models, respond quickly to regulatory enquires on current and historical data, generate automated definition documents and support a wide range of data visualization tools.

Study component reusability and automatic documentation together enable clinical organizations to have greater clarity on what has been done to get from source (e.g. EDC, labs data) to target (e.g. SDTM) – to turn on the light in the black box. Ultimately, leveraging standard, re-usable objects accelerates study setup, and combined with automation reduces manual processes, and increases traceability.

- Standards can streamline and enhance data collection
- End to end traceability can only improve review
- Increase regulatory compliance with comprehensive security, audit trail, and two-way traceability across the discrepancy lifecycle

Wearable devices are now being included in up to 50% of clinical protocols. These integrations present challenges for data collection and cleaning, but present sponsors with opportunities to:

- Improve data quality
- Novel methods of data collection
- Improve patient trial adherence
- Improve patient engagement

Recommended Reading: www.oracle.com

CONTACT INFORMATION

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