

Devices, Big Data and Real World Evidence

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Devices, Big Data and Real World Evidence

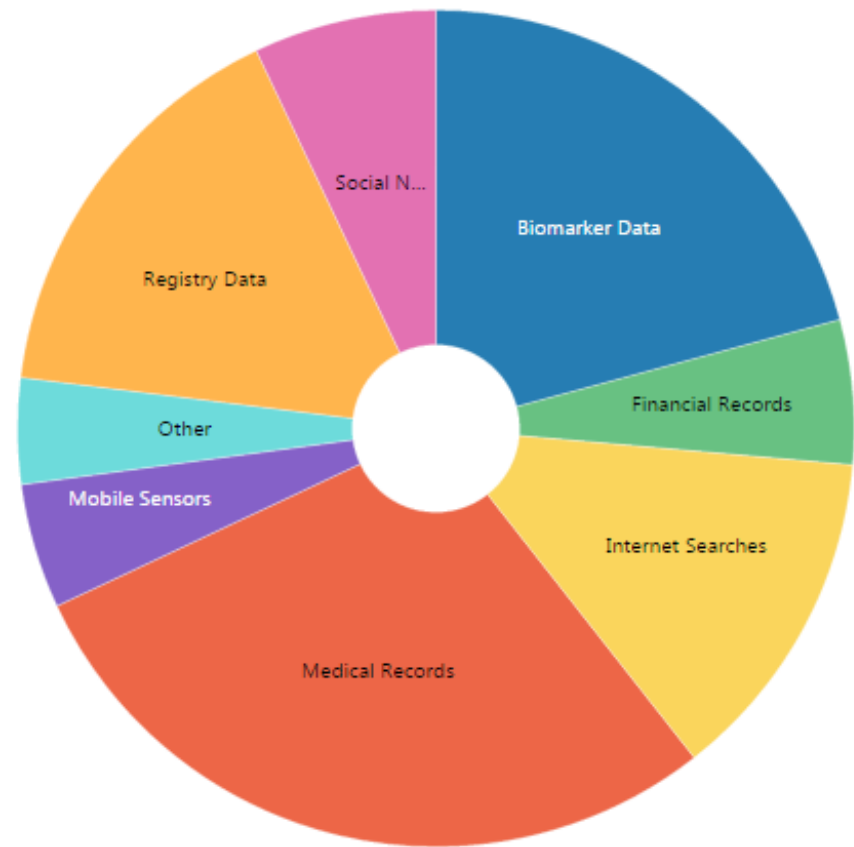
The world of clinical research is experiencing a revolution with a huge range of **connected devices** growing in popularity, with wearable and implantable devices across healthcare, fitness tracking and diet.

Pharmaceutical companies sponsoring clinical trials are incorporating these devices into ever more elaborate trial designs, while sorting through social media streams, registries and their own big data sources.

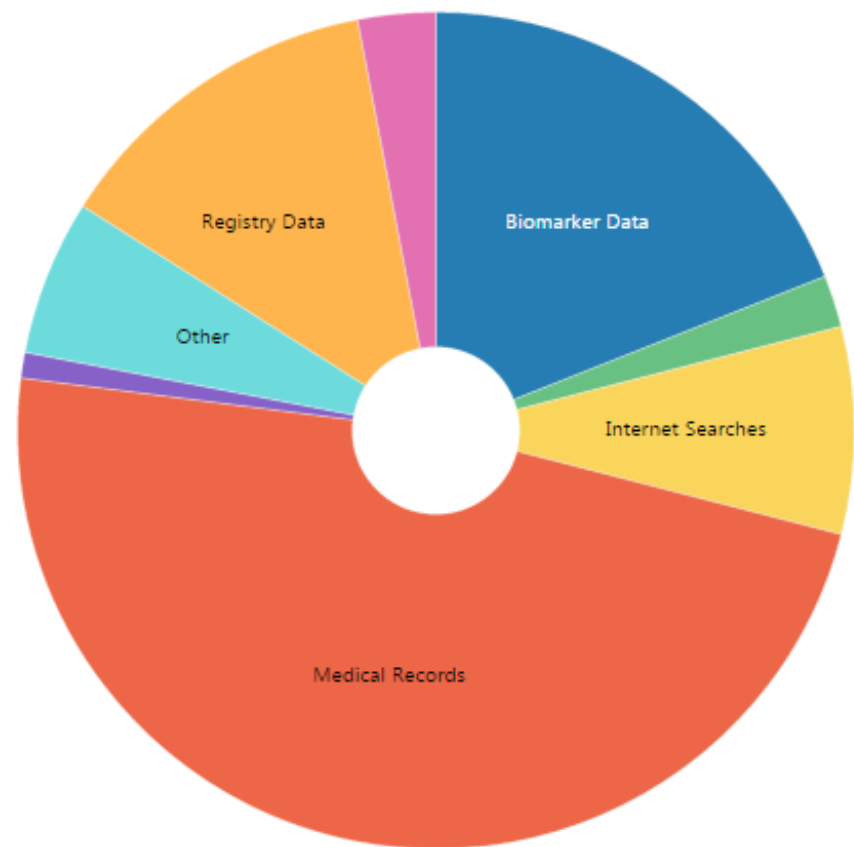
- What strategies will we use to integrate these external sources with their EDC data?
- How can data standards assist in information gathering?
- How do we define the distinction between big data and smart data?

Devices, Big Data and Real World Evidence

What is your big data comprised of?



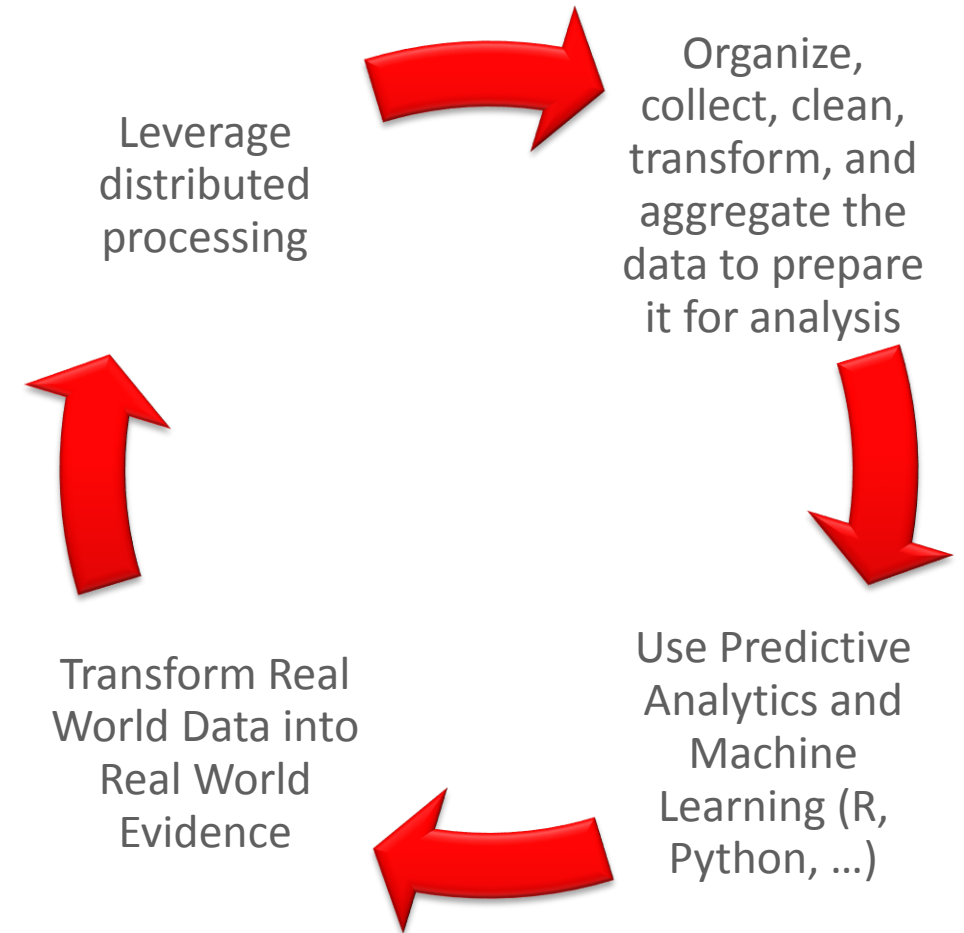
Which is most beneficial to you?



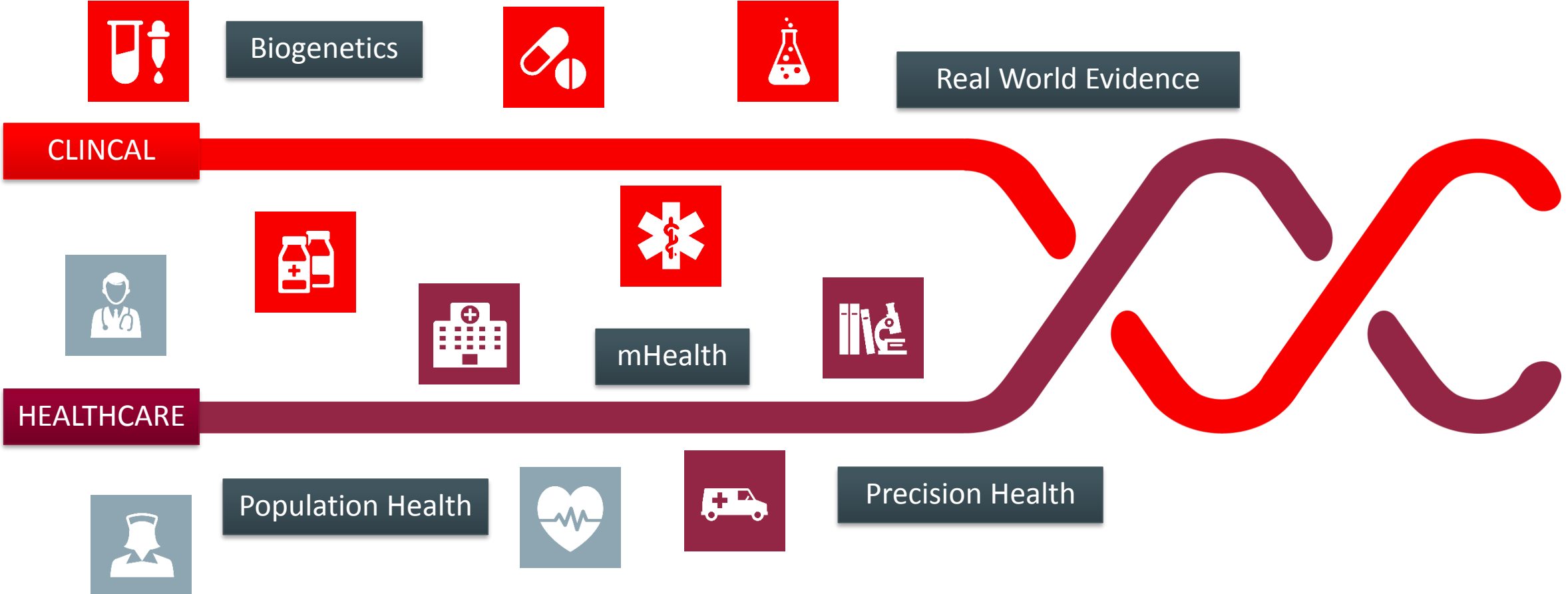
Source: <http://www.appliedclinicaltrials.com/big-data-survey-report-december-2016>

Cloud Services

- Cloud platforms provide lightning responses to queries from transactional systems, and these can now also be integrated with large scale indexed data stores, running a very different type of distributed processing query, asking unique questions.
- Databases and indexed data stores can complement each other, bringing transactional clinical data together with real world data from indexed systems:



Devices, Big Data and Real World Evidence



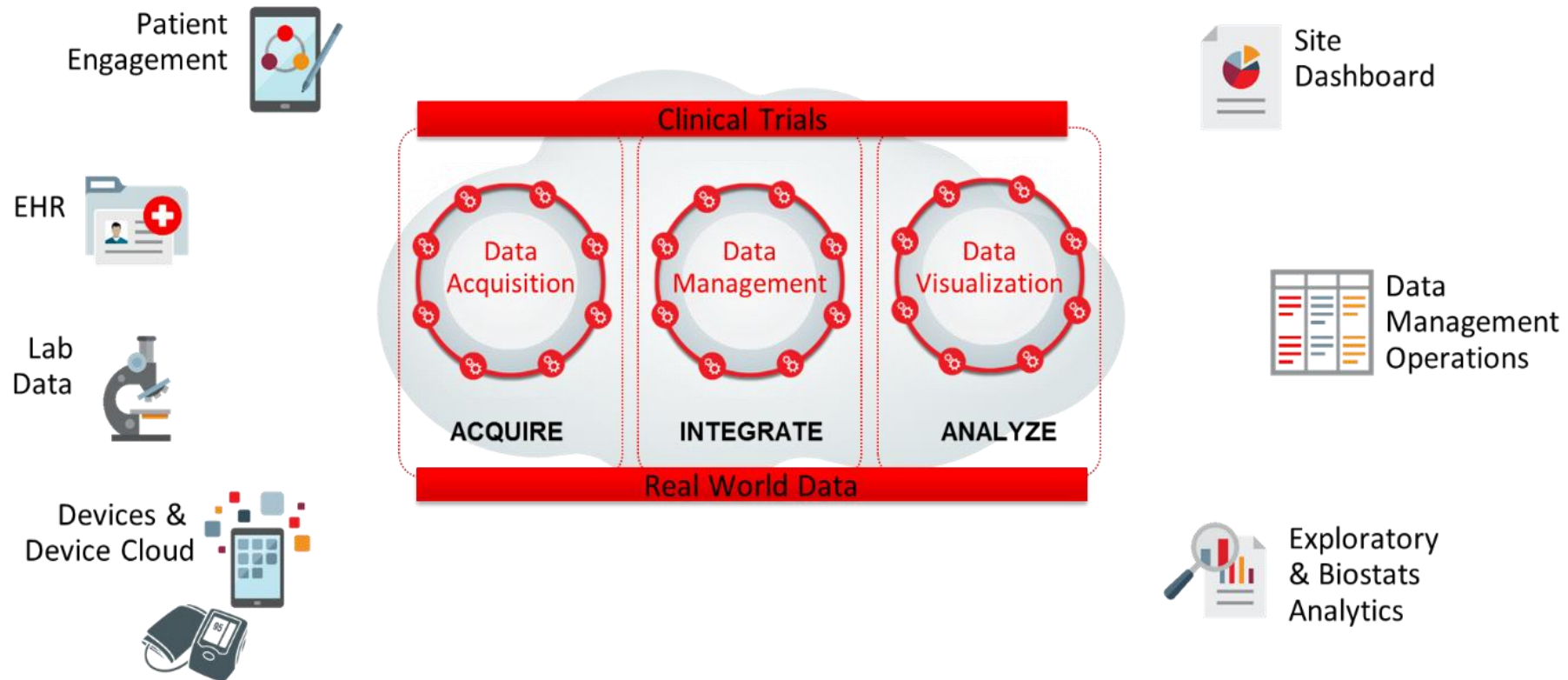
Devices

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

- Improve patient trial **adherence**
- Improve patient **engagement**
- Improve the granularity of patient **data**
- Extend the dimensions to describe subject's **characteristics**

Devices

How do we leverage the data from wearable and implantable devices and EHR?



Learn more: <https://www.youtube.com/watch?v=gVEz9icle2g>

EHR and Real World Evidence

- In addition, sponsors, technology providers and Standards Development Organizations (SDO)s are working towards Electronic Health Record (EHR) and Electronic Data Capture (EDC) integrations.
- Expected **time savings** and **reduced human error** from EHR to EDC integration:
 - 745,000+ data points collected and managed in a production trial.
 - ~300,000 data entry key strokes could be saved if as little as 40 percent (40%) of the EDC data could be mapped from EHR.

FHIR and EHR

Over the last couple of years, there has been a focus on using **FHIR RESTful Services** to integrate patient care data into the clinical research process. A key use case has been populating EDC system CRFs from EHR systems.

This can help the biopharma company and its sites participating in a clinical trial to:

1. Reduce overall data entry **volume** for each clinical trial
2. Improve **quality** of entered data for each clinical trial, by removing redundancy of manual data transcription from one system to another
3. Reduce clinical trial **costs** as data populating the CRF from the EHR system does not have to be source data verified

Devices, Big Data and Real World Evidence

Machine learning now offers ready to use algorithms to detect patterns and make predictions which readily consume the large volume of data that is now available.

With the easy availability of highly scalable compute it is now easier than ever to identify signals across the wide variety of data sets and data structures.

This characterized by vibrant ecosystem of open source technologies, including:

- HDFS / Map Reduce technology to **store** data
- Query editors including Spark, Impala, HIVE, HUE, PIG to **query** data
- R / Python to **enable** Predictive Analytics and Machine Learning

Devices, Big Data and Real World Evidence

Big Data
Integration:
Distributed
processing and
map reduce
queries

Hive Editor

Query Editor

My Queries

Saved Queries

History

Assist

Settings

DATABASE

default

Table name...

attitude

budgetspent

budgetspent...

budgetspent...

campaign

car

car_1

comedores...

credit_d1

credit_d10

credit_depar...

cust

customer

ddm_campai...

ddm_custom...

dmz_custom...

1

`select * from test_attitude_xx`

Execute

Save

Save as...

Recent queries

Query

test_attitude_xx.custom

0 95541321

1 95541322

2 95541323

3 95541324

4 95541325

5 95541326

input HDFS

split 0

map

sort

split 1

map

split 2

map

copy

merge

reduce

part 0

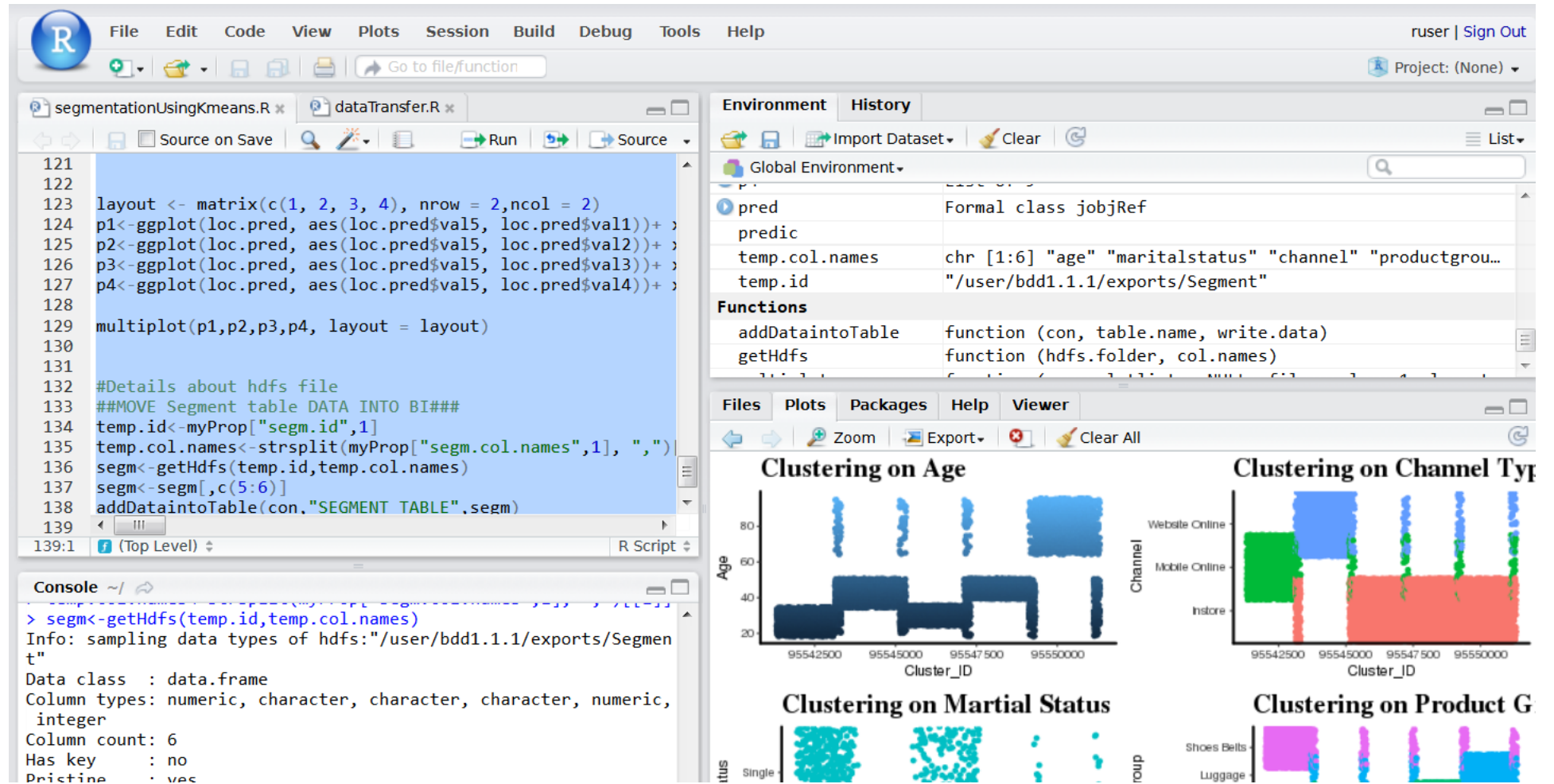
HDFS replication

Source: Hadoop, The Definitive Guide, Tom White, O'Reilly 2009



Devices, Big Data and Real World Evidence

Integrated cluster and outlier analysis, using a standard R distribution



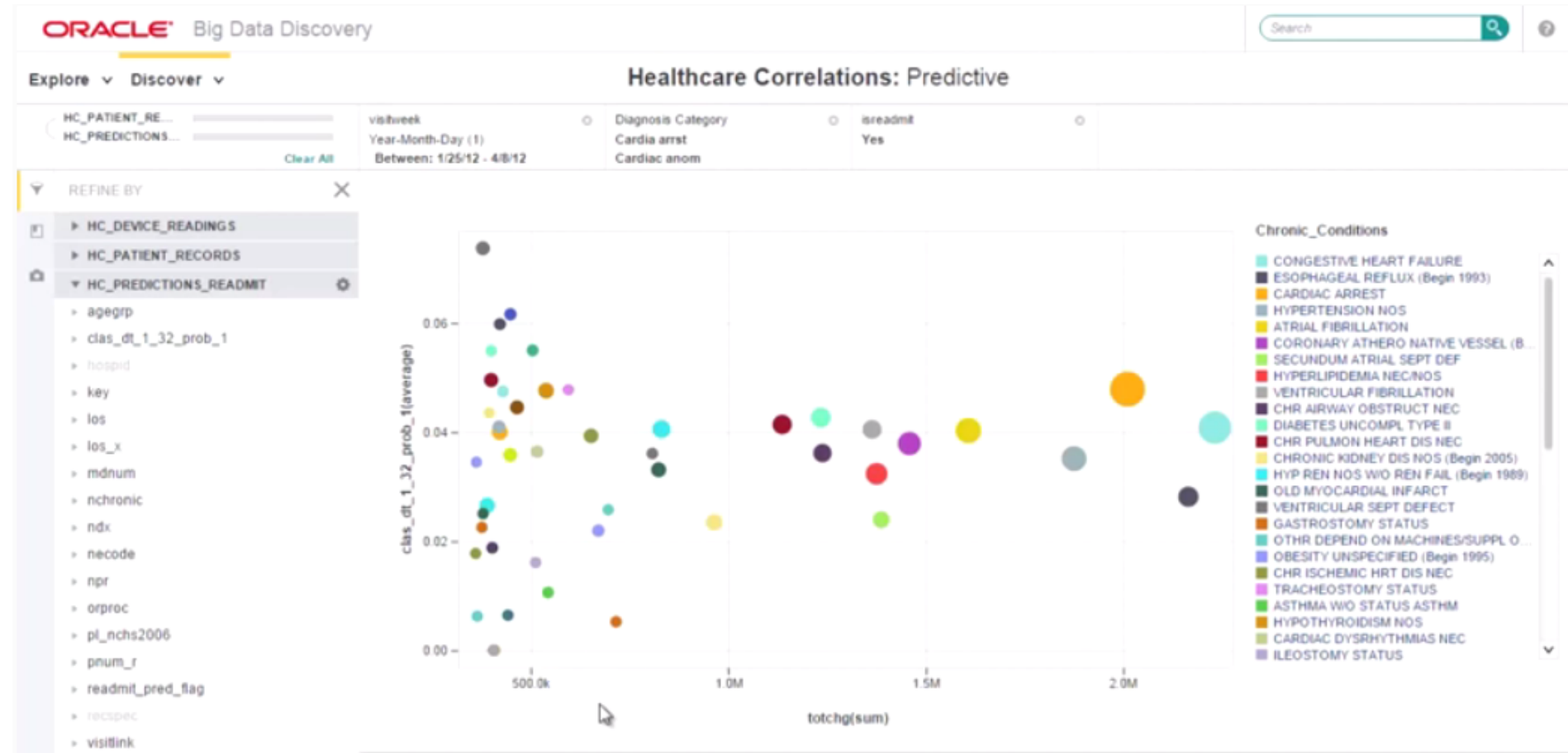
Predictive Analytics

Integrating the vast volume, velocity and variety of big data will allow users to exploit machine learning and artificial intelligence. Machine learning techniques can create predictive analytical models, as in a recent example assessing risk of hospital re-admission.

These analyses can predict the relative rate of re-admission for patients, based on their initial diagnosis. The analysis gives Healthcare Professionals **quantifiable insight** regarding likely re-admission, which can assist in resource planning.

Predictive Analytics

Machine learning techniques can create predictive analytical models, as in this example assessing risk of hospital re-admission



Source: https://www.youtube.com/watch?v=6YR_YPp70cU

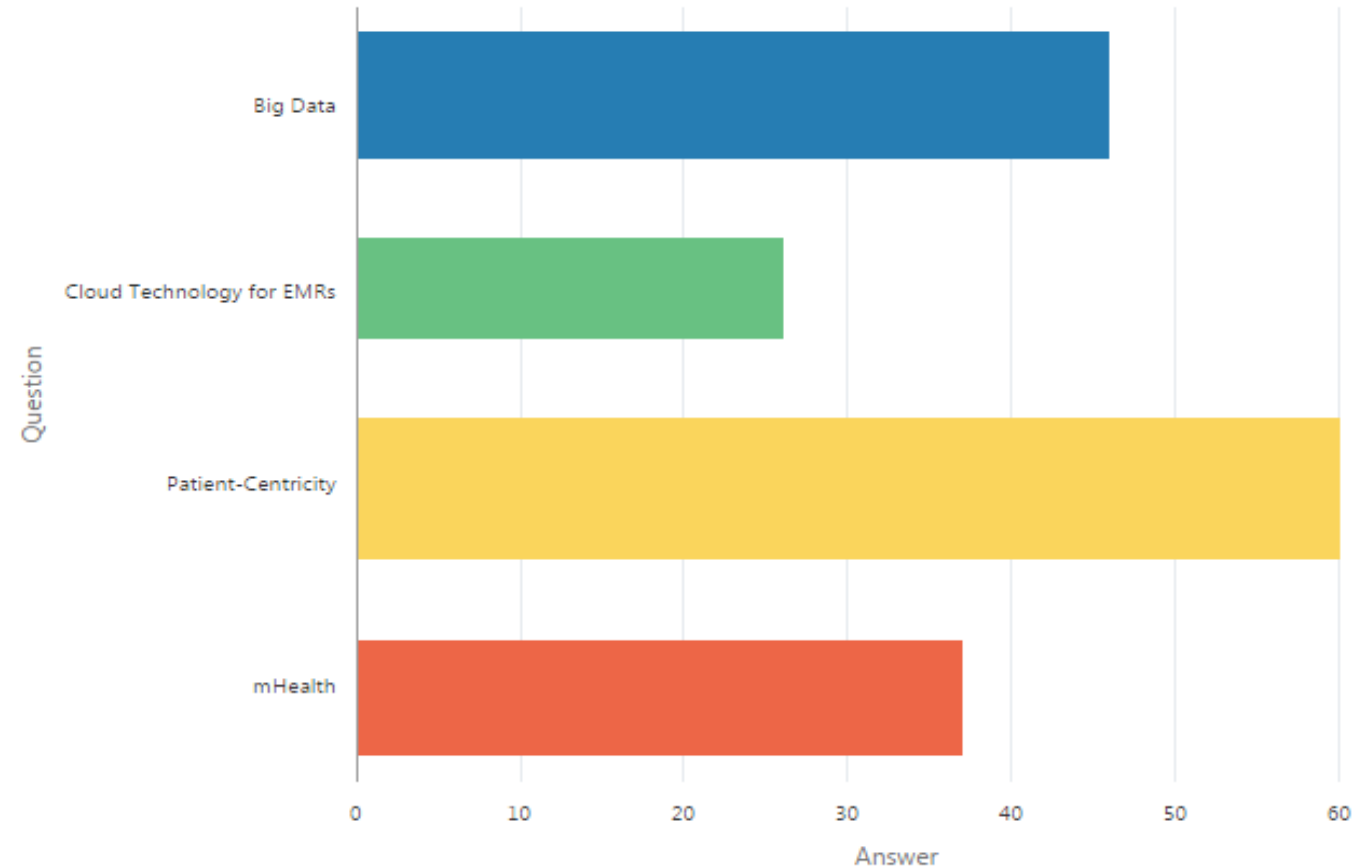
Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11

- When mobile technology is used in a clinical investigation to capture, record, and transmit study-related data directly from study participants, the data are collected and stored, perhaps for very short periods of time on the mobile technology before being transmitted to the sponsor's EDC system.
- In some cases, the data may pass temporarily through various electronic hubs or gateways before reaching the sponsor's EDC system.
- *FDA considers source data as data that are first recorded in a **permanent** manner.*
- *In general, for data collected directly from study participants through mobile technology, the first permanent record is located in the sponsor's EDC system or the EHR, and not in the mobile technology.*

Source: <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM563785.pdf>

Devices, Big Data and Real World Evidence

eClinical Strategies in Use in Industry Today



Source: <https://knect365.com/clinical-trials-innovation/article/e3d64458-2494-490a-b831-8f12abc467ad/eSource-clinical-trials-adoption>

Devices, Big Data and Real World Evidence Summary

New technologies will allow patients and sponsors to more closely monitor relevant data during a clinical trial

These technologies provide direct insight into a remote patient's condition, transforming Real World Data into Real World Evidence

Cloud technologies will transform Sponsor's access to technologies and processing types

We will use Big Data tools and distributed processing to organize, collect, clean, transform, and aggregate the data to prepare it for analysis

Devices, Big Data and Real World Evidence

Next Steps

Databases and indexed data stores complement each other, bringing transactional together clinical and real world data

Disparate systems will come closer together through use of interoperability standards and messaging protocols, bringing huge value to Clinical Research

Regulators and SDOs are keen to identify synergies and opportunities and further define how we react to the evolution of patient data

Predictive Analytics and Machine Learning?

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