

A Visualization approach for Clinical Trials with Digital Data



March 8th–11th
Renaissance Orlando at
SeaWorld Florida

US 2020

The Clinical Data
Science Conference



Agenda

- Need for new ways to handle data and what is Big data?
- Patient focused modern clinical trials
- Making sense of data – Structured and Unstructured data
- Data visualizations



Common Industry Pain Points:

- ✦ Increase in study complexity
- ✦ Age old enrollment challenges
- ✦ Timeline overrun
- ✦ Out of control budget
- ✦ 10% product approval
- ✦ 51% post approval success
- ✦ Silos mentality

\$98B
Sales and
Marketing
Spend

\$66B
R&D Spend

Total Market Spend

\$127B
2016 R&D
Spend

5-6%

\$148B
2020 R&D
Spend



Cost of RCTs



Cost Pressures

\$1B Avg. cost of RCTs

\$1M +1 day to a trial

\$10M +1 submission delay

72%

Studies are 1
mo. behind

70%

Of studies
experience
patient
Enrollment
delays

30%

Of time spent
on patient
recruitment

20%

Never recruit a
single subject

\$86M

Full Study
9mo. - 2yrs
to complete
enrollment



\$10B+/yr.

Wasted due to poor
site selection
(SSD-SSU)

What is BIG DATA?

Big Data is defined as the following three V's:

- ❑ Volume – various forms of data storages.
- ❑ Velocity – handling of data streams with in situ methods
- ❑ Variety – various forms of data

Why do we need BIG DATA?

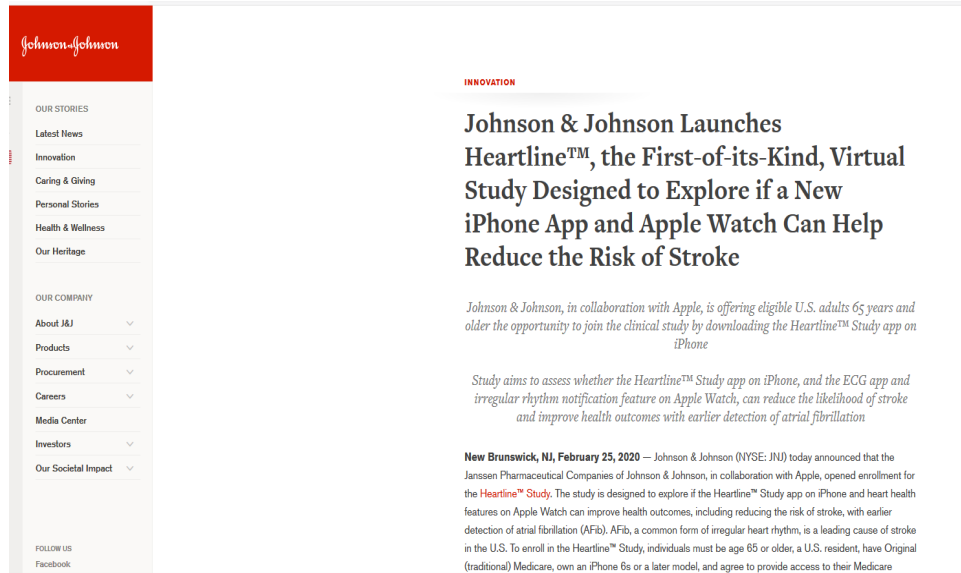
- The utilization of big data has revolutionized industries such as telecommunications, advertisement, healthcare, and finance. Similarly, the pharmaceutical industry is also evolving with the increasing utilization of big data.
- The emergence of big data in the pharmaceutical industry is helping in streamlining multiple complicated business procedures and improving efficiency across the board.
- Big data can enable businesses to gain insights from historical and real-time data sources such as social media, IoT sensors, log files, and patient data.
- Big data analytics can help in finding hidden patterns in such data that can be used to generate informative analytics.
- Leveraging big data, pharmaceutical companies can take a data-driven approach to several business procedures. Therefore, business leaders must stay informed about big data and its applications to benefit from the technology.

Utilizing big data in the pharmaceutical industry

- Research and development
- **Clinical trials**
- Drug discovery
- Drug reactions
- Precision medicine
- Sales and marketing
- Collaboration

Clinical Trials and Big Data

- Patient focused modern clinical trials - Usage of Health and Medical Devices.
 - Per National Center for Biotechnology information, there are over 318,000 health applications on various platforms and wearable devices.
 - More devices to come with the arrival of 5G.
 - Devices linked to health applications are bringing innovation in
 1. Digital Diagnostics and
 2. **Human-centered clinical trial designs.**



Two main advantages of digital devices and new methods

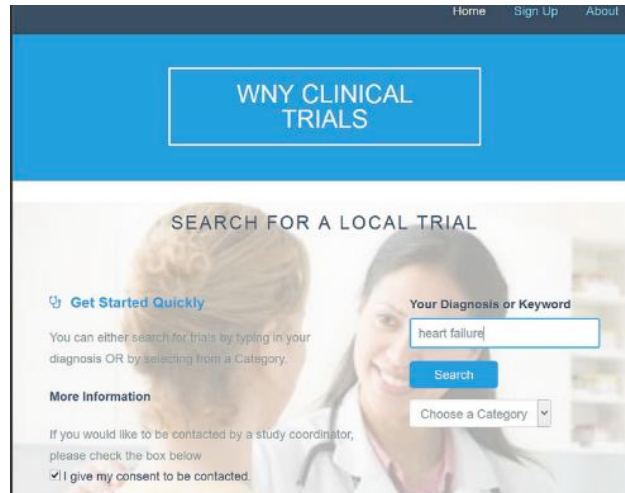
Patient Retention- Use of wearables allows patients work effortless and accurate collection of data. Technology will capture data instead of patient reporting the data by sticking to a schedule.

Drug Candidate Selection- Complex algorithms to screen large data pools containing biological, chemical and clinical information can help whittle down the probable candidate for testing.

Continued -

- This goes two ways. Patients can also look up for the most suited studies.

Example –A smartphone application is created by University at Buffalo (Jacobs School of Medicine and Biomedical Sciences at UB) that would allow patients to explore various clinical trials to see if they feel like they would be a good match for the trial. Once the subjects have found the suitable study, they are then able to enroll in it and be a part in the research just by pressing the button as shown below.



The screenshot displays the 'WNY CLINICAL TRIALS' website. At the top, there is a navigation bar with links for 'Home', 'Sign Up', and 'About'. Below this, a blue header contains the text 'WNY CLINICAL TRIALS'. The main section is titled 'SEARCH FOR A LOCAL TRIAL'. It features a 'Get Started Quickly' link and instructions: 'You can either search for trials by typing in your diagnosis OR by selecting from a Category.' There is a text input field labeled 'Your Diagnosis or Keyword' with 'heart failure' entered, and a blue 'Search' button. Below the search field is a dropdown menu labeled 'Choose a Category'. A 'More Information' section at the bottom includes a checkbox for consent, which is checked and labeled 'I give my consent to be contacted.'

Orphan drugs, rare diseases and drug repurposing-

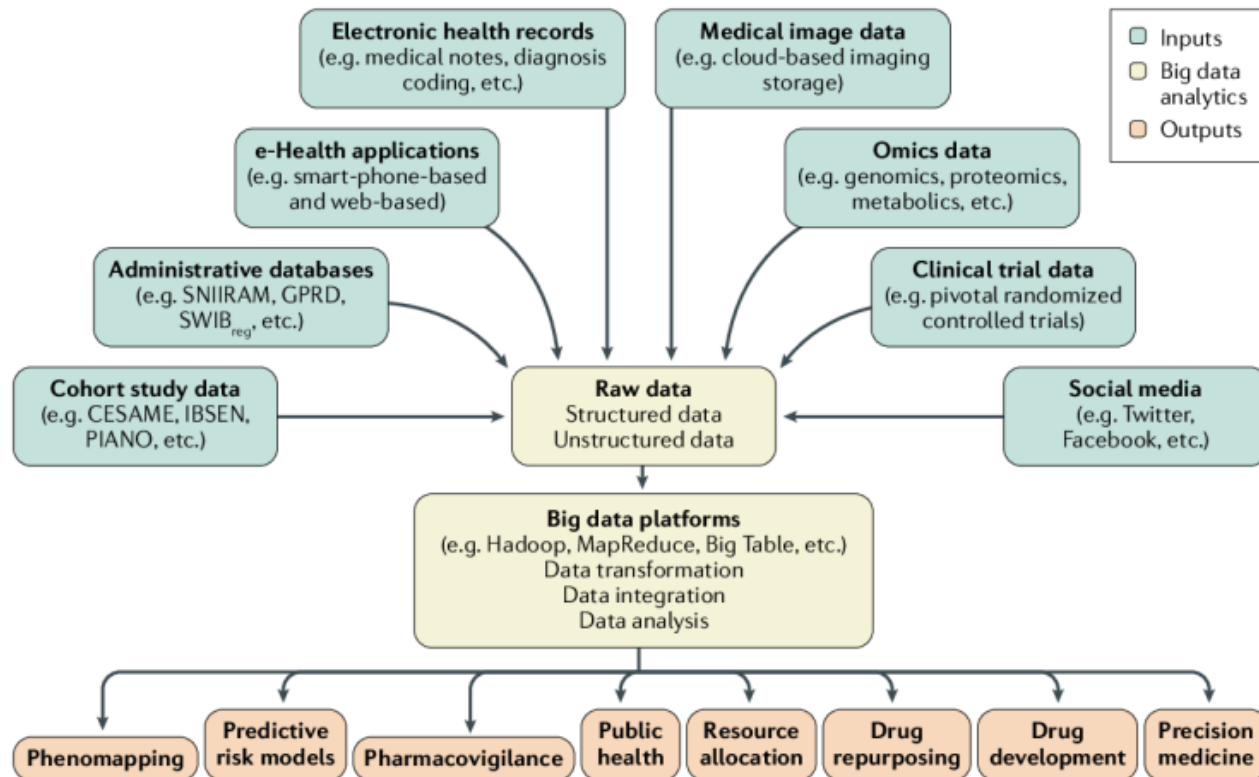
- During the course of a clinical trial, a drug candidate may not display the statistical significance to be effective, but it could be highly effective in particular subpopulations displaying a set of demographic, genetic or other commonalities.
- Big Data analytics can help identify specific subpopulations for which a “failed” drug can still be success.

Data types and Big Data Framework

Data is heterogeneous, where data is collected in

1. **Structured** - Predefined standard based data and it ready for analyses. Common examples of structured data are Excel files or SAS Datasets.
2. **Unstructured Databases** - Unstructured data is information that either does not have a predefined data model or is not organized in a pre-defined manner. Unstructured information is typically text-heavy and does not follow an easily identifiable pattern.

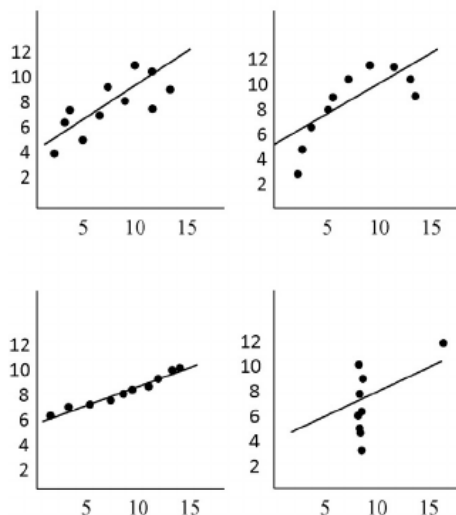
BIG DATA Framework



BIG DATA AND Data Visualizations

- With the amount of data available it is very easy to misinterpret the data. In order to make accurate decision, it has become very important for the pharmaceutical companies to understand these vast data repositories.

Anscombe's Quartet



Property	Value
Mean of X (average)	9 in all 4 XY plots
Sample variance of X	11 in all four XY plots
Mean of Y	7.50 in all 4 XY plots
Sample variance of Y	4.122 or 4.127 in all 4 XY plots
Correlation (r)	0.816 in all 4 XY plots
Linear regression	$y = 3.00 + (0.500x)$ in all 4 XY plots

Data sets for the 4 XY plots

I		II		III		IV	
x	y	x	y	x	y	x	y
10.0	8.04	10.0	9.14	10.0	7.46	8.0	6.58
8.0	6.95	8.0	8.14	8.0	6.77	8.0	5.76
13.0	7.58	13.0	8.74	13.0	12.74	8.0	5.76
9.0	8.81	9.0	8.77	9.0	7.11	8.0	8.84
11.0	8.33	11.0	9.26	11.0	8.81	8.0	8.47
14.0	9.96	14.0	8.10	14.0	8.84	8.0	7.04
6.0	7.24	6.0	6.13	6.0	6.08	8.0	5.25
4.0	4.26	4.0	3.10	4.0	5.39	19.0	12.50
12.0	10.84	12.0	7.26	12.0	8.15	8.0	5.56
7.0	4.82	7.0	7.26	7.0	6.42	8.0	7.91
5.0	5.68	5.0	4.74	5.0	5.73	8.0	6.89

Advantages of Data Visualizations

1. Better monitoring and investigating data,
2. Identifying data issues, areas that require special attention, outliers,
3. Increasing quality of clinical trial reporting,
4. Investigating potential covariates and performing ad-hoc analyses, and
5. Sharing and presenting results in greater detail.

A Real Life Application of Big Data Visualization

MRSA - PCU Geospatial Analysis



MRSA - PCU Patient Days



Source: Augusta Health

Acknowledgements



Questions

