Imagine what it could be...

"Increasing the pool of researchers who can access data and decreasing the time it takes for them to review and find new patterns in that data is critical to speeding up development of lifesaving treatments for patients."

Joe Biden, Former Vice President, U.S.

**THE CLINICAL RESEARCH TRAGEDY**

**SELF-INFLICTED COMPLEXITY**

- Siloed neighborhoods lack understanding of customer’s needs
- Many manual handoffs increase time and reduce quality
- Tower of Babel: disconnected languages, tools, and processes

**REGULATORY HurdLES**

- Submission gauntlet that penalizes innovation at every step
- Piles of black box, vague, and confusing regulations
- Rigidness, risk averse, and fear of change

**DATA HERE, THERE, & EVERYWHERE**

- Collection data, raw data, SDTM data, ADaM data, your data, my data
- Copies and copies and copies of data for every milestone
- Misperception that quality data and traceability exist

**DATA DEVOID OF CONTEXT**

- Clinical information is complex, but our data is two dimensional
- Relationships are in people’s heads and not in their data
- Misdirected focus on the transformation and not on the patient

**Solving 21st Century Problems with 20th Century Tools**

"In the real world, we want to capture the complexity and diversity of the standard of care without forcing it into an artificial structure. The current framework forces researchers to constrain data to a structure that is not intuitive and limits the value of the data."

Florence Barkats, RWE Expert

"Instead of twisting data to fit into rigid, disconnected formats, we must learn to fit analytics directly to the data as captured. This is how analytics are applied throughout the modern world - why not research too?"

Wayne Kubick, CTO HL7

"Design"  "Collect"  "Analyze"  "Share"

Medical Director: “Alexa, what are the top five exploratory objectives in all active breast cancer trials?”

Clinical Research Associate: “Alexa, what data is missing for Thalia’s week 12 visit?”

Statistician: “Alexa, is there a statistically significant difference in progressive disease between our drug and the comparator?”

FDA Reviewer: “Alexa, show me the methods used to confirm my drug reduces the occurrence of progressive disease relative to the comparator.”

tinyurl.com/y92kuju9