

~~IMAGINE~~ DISRUPT
THE FUTURE...

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AT INSTEM

Chris serves as the Vice President, Clinical Solutions at Instem. Chris has 25+ years of experience within the clinical data lifecycle including design and implementation of clinical systems, processes, and innovation. He has driven initiatives within pharmaceutical biometrics organizations solving problems and driving innovation by leveraging technology and transforming process. Outside of d-wise, Chris serves on the CDISC Board of Directors and as a member of PHUSE CSS Steering Committee. Chris brings a diverse background of knowledge and experience with an overall passion to enable innovation for a healthier world.



IN OUR PERSONAL LIFE...

WHAT IF...?

HOW WOULD YOU...?

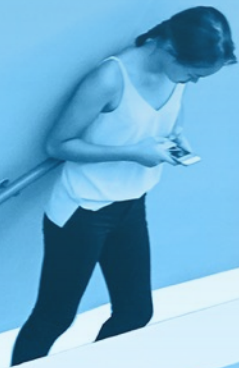


INFORMATION AT OUR FINGERTIPS...



A screenshot of a Google search for "alzheimer's disease". The search bar shows the query and the Google logo. Below the search bar, there are tabs for "All", "News", "Images", "Videos", "Books", and "More". The search results show "About 29,000,000 results (1.08 seconds)". The first result is "Alzheimer's Disease & Dementia | Alzheimer's Association" with a link to "www.alz.org/alzheimers_disease_what_is_alzheimers.asp". The second result is "Alzheimer's Disease Fact Sheet | National Institute on Aging" with a link to "https://www.nia.nih.gov/alzheimers/publication/alzheimers-disease-fact-sheet". Below the search results, there is a "Top stories" section with three articles: "Scientists Have Uncovered The Atomic Structure of a Key Alzheimer's Protein F...", "Can poor sleep lead to Alzheimer's?", and "Your Insomnia Could Actually Lead To Alzheimer's, Study Says". To the right of the search results, there is a summary card for "Alzheimer's disease" with a red border. The card includes a title, a subtitle "Also called: senile dementia", and three tabs: "ABOUT", "SYMPTOMS", and "TREATMENTS". The "ABOUT" tab is selected, showing a description of the disease, a "Very common" section, and a "People also ask" section.

THE CURRENT PARADIGM



“SILOS BUILD THE WALL IN
PEOPLE’S MINDS AND
CREATE THE BARRIER IN
ORGANIZATIONS’ HEARTS.”

PEARL ZHU



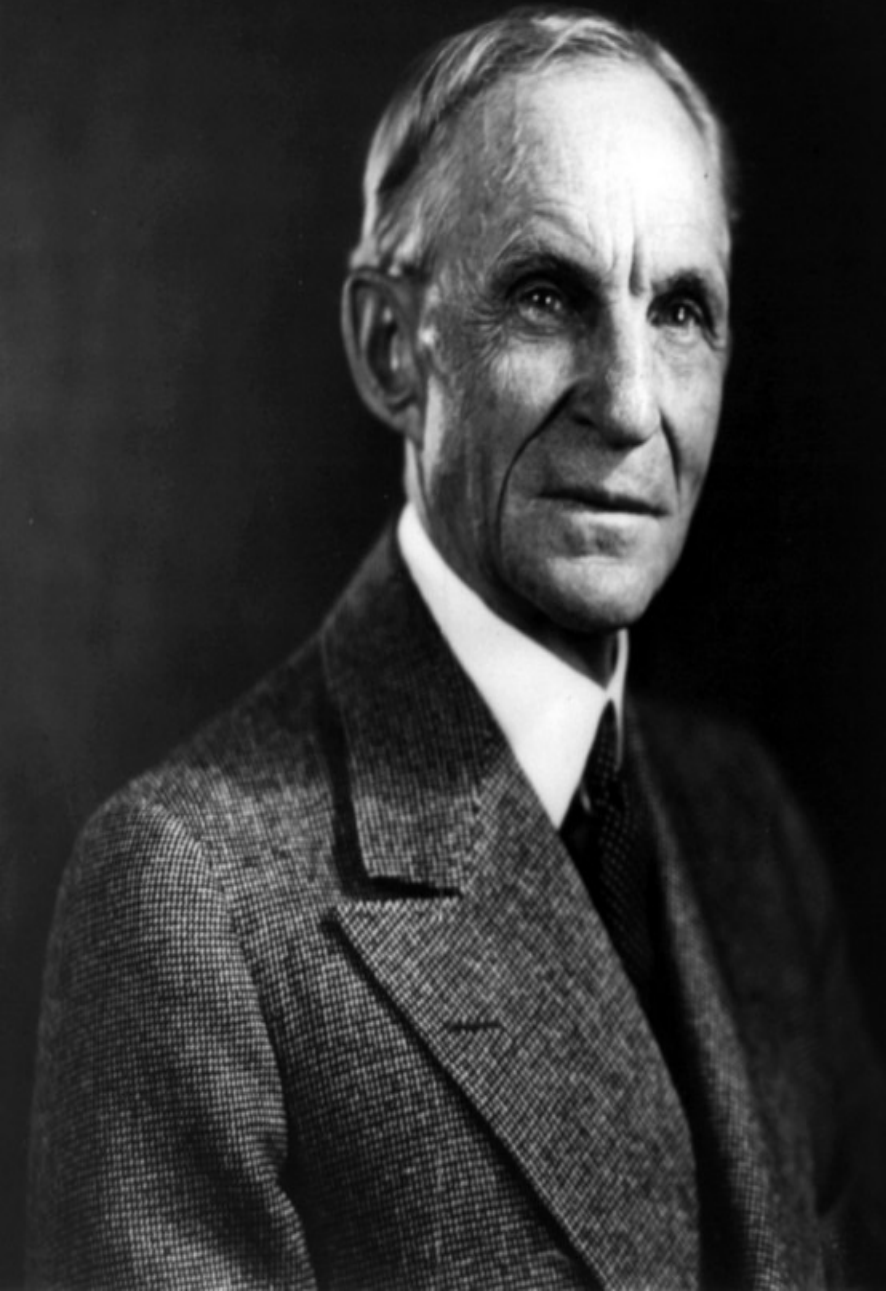
“WE ARE DROWNING IN INFORMATION
BUT STARVED FOR KNOWLEDGE.”

JOHN NAISBITT



“IF THE ONLY TOOL YOU HAVE IS A
HAMMER, YOU TEND TO SEE EVERY
PROBLEM AS A NAIL.”

ABRAHAM MASLOW



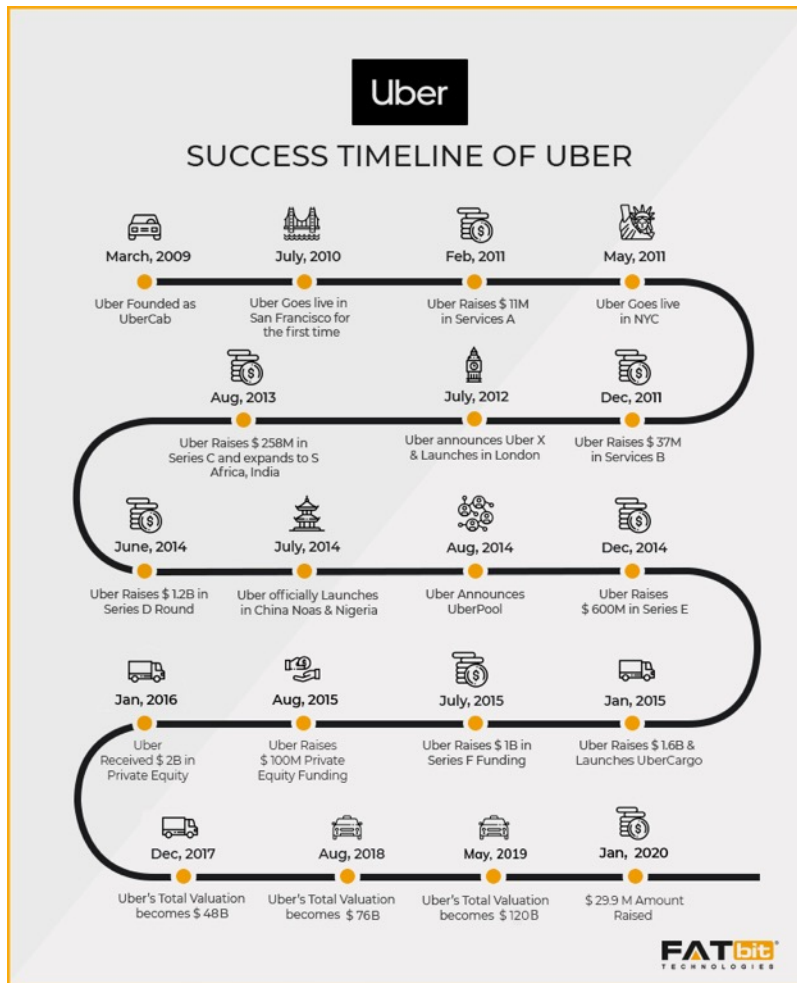
“IF I HAD ASKED
PEOPLE WHAT THEY
WANTED, THEY WOULD
HAVE SAID A FASTER
HORSE.”

HENRY FORD



DISRUPTION IN THE LAST DECADE

WHAT IF YOU COULD REQUEST A RIDE FROM YOUR PHONE?



HOW DID UBER SUCCEED IN OWNING THE TRANSPORTATION MARKET?

- » Global transportation network
- » Ease of user experience
- » Convenient and Cheap



WHAT IF I COULD HAVE SOMETHING DELIVERED IN A DAY?



WHAT ENABLED AMAZON TO DOMINATE PERSONAL SHOPPING?

- » Rethought supply chain
- » Embraced the "have now" culture
- » Motivated users to spend more
- » Exploded through partnerships and vendors

HOW DID WE DELIVER COVID VACCINES IN <12 MONTHS?

The COVID-19 Pipeline: Vaccines Could Begin to Receive Emergency Use Authorization Based on Phase 3 Data as Early as September 2020

Firm/Treatment Vaccines	Timeline		
	Enter Clinic (data)	Start Phase 3	Approval
Moderna's mRNA-1273 (mRNA code for spike protein)	March (Phase 1 top line data)	July	December (EUA)
Oxford/AstraZeneca's ChAdOx1 nCoV-19 (AZD1222) (viral vector with spike protein code)	April (no clinical data)	August (May U.K. phase 2/3)	September (EUA)
Pfizer/BioNTech's BNT162 b1, b2: modified mRNA (RBD, full spike protein) a1: uRNA for RBD c2: self amplifying RNA for full spike protein	April (Phase 1/2 preprint, more data July 2020E)	July	October (EUA)
Johnson & Johnson's Ad26.COV2-S (intranasal, viral vector with spike protein code)	July	September	Q1 2021
Novavax's NVX-CoV2373 (nanoparticle-bound spike protein antigen)	May (July 2020E)	September	Q1 2021
CureVac's CVnCoV (self-amplifying mRNA based on spike protein)	June	October	Q1 2021
Sanofi/Glaxo (spike protein antigen)	September	Early 2021	Mid-2021

Source: Morningstar, company reports. EUA=emergency use authorization, RBD=receptor binding domain. Several other clinical-stage vaccine programs with smaller manufacturing capabilities are not included here.

HOW DID WE REDUCE YEARS OF THE R&D PROCESS INTO LESS THEN A YEAR?

- » Decade of technology and research
- » Improbable collaboration between governments, regulatory, and pharma
- » Commitment to the cause

WHAT DOES DISRUPTION LOOK
LIKE FOR US?



DIRECT TO PATIENT DATA COLLECTION...



For Division of STI and HIV
HIV/AIDS
Hepatitis
Date Rec'd: 4/15/20

Confidential Influenza-Associated Mortality
Case Report Form
State of Alaska, Section of Epidemiology

PATIENT INFORMATION
Last Name: _____ First Name: _____ Date of Birth: _____
Sex: _____ Race: _____ Ethnicity: _____
Address: _____ City: _____ State: _____ Zip: _____
Date of onset of symptoms: _____
Date of hospital admission: _____
Date of death: _____
Date of specimen collection: _____
Influenza type and strain: _____
Influenza vaccination history: _____
Clinical course: _____
Significant past medical history: _____

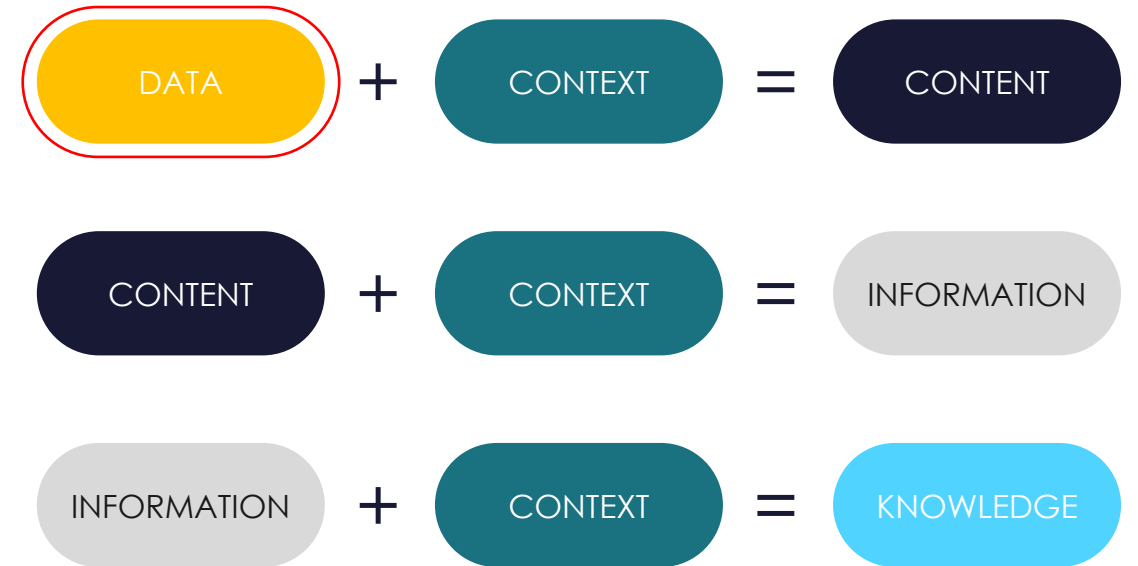
#KillCRFs

A background image showing three business professionals in a meeting. On the left, a man with a beard and a light blue shirt is looking towards the center. In the middle, a woman with blonde hair in a ponytail, wearing an orange blazer, is looking down at a laptop. On the right, a man with a beard and a red sweater is smiling and looking towards the camera. The image has a dark blue overlay.

REAL TIME REGULATORY COLLABORATION FROM THE BEGINNING...



EXPAND THE VALUE OF YOUR DATA THROUGH CONTEXT



“THE REASONABLE MAN ADAPTS HIMSELF TO THE WORLD;
THE UNREASONABLE ONE PERSISTS IN TRYING TO ADAPT THE
WORLD TO HIMSELF. THEREFORE, ALL PROGRESS DEPENDS
ON THE UNREASONABLE MAN.”

GEORGE BERNARD SHAW

IT'S TIME TO BE UNREASONABLE...





**The future transformed for the benefit
of everyone. Intelligent solutions
empower collaboration and life-
enhancing science**