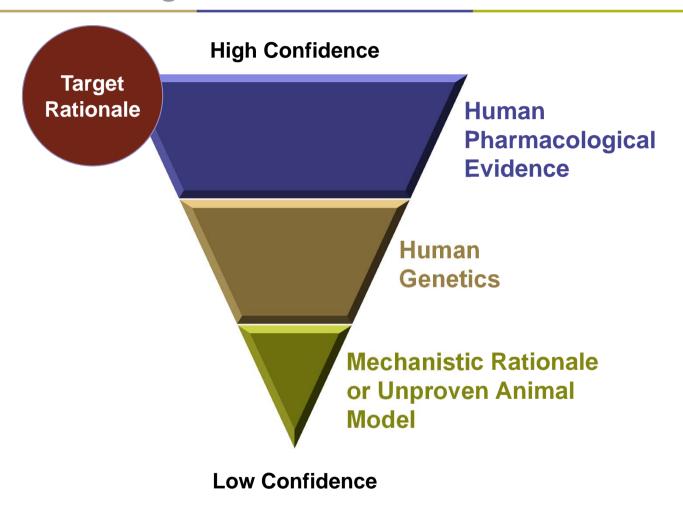
Convergence des Sciences de la Santé et du Big Data - Impact sur l'Industrie Pharmaceutique

Aurélie Grienenberger



The Most Important Decision We Make Choice of Target





The **PARADOX**

In spite of remarkable scientific progress, our capacity to translate those advances into health benefits has decreased

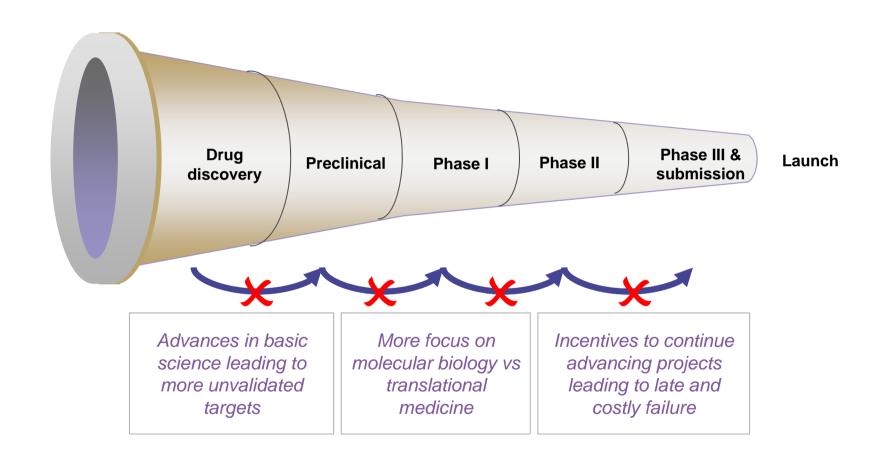
The number of biological targets has dramatically increased thanks to progress made in the field of genomics

In the biopharmaceutical sector success rate has dropped from 1/8 to 1/14 and the length of development has doubled



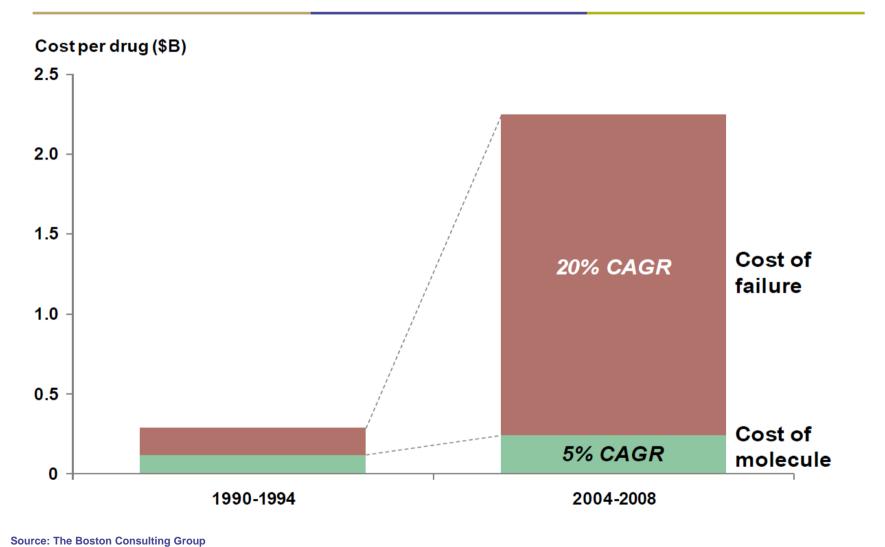


It is a **SEARCH** problem





It is a **NOISY** problem





In a bigger storm

Patient needs

- Acute to chronic
- Personalized
- Generics

Payer driven market

- Differential medical value
- Rise of formularies
- Payment restrictions
- Price controls

Regulation

- Regulatory burden
- Safety thresholds
- Postmarketing requirement
- Longer R&D cycles

Science

- Low predictability in humans
- Low success rates
- Low overall efficiency

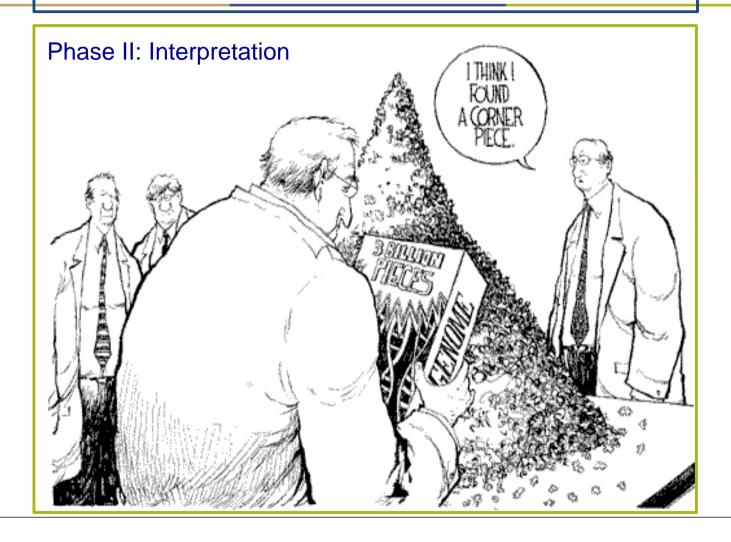


Its About the Human Biology – So let's start There!

- Disease Relevance need systems to access or collect patient/population data and materials to define medical need
- The human disease and how it is/will be treated must guide even early development
- The capacity to develop, use and interpret phenotypes, signatures and markers that are pragmatic and integral to all levels of discovery, development and commercialization
- Start with the patient/population and work backwards until you fall onto the target



Phase I: Sequence Human Genome



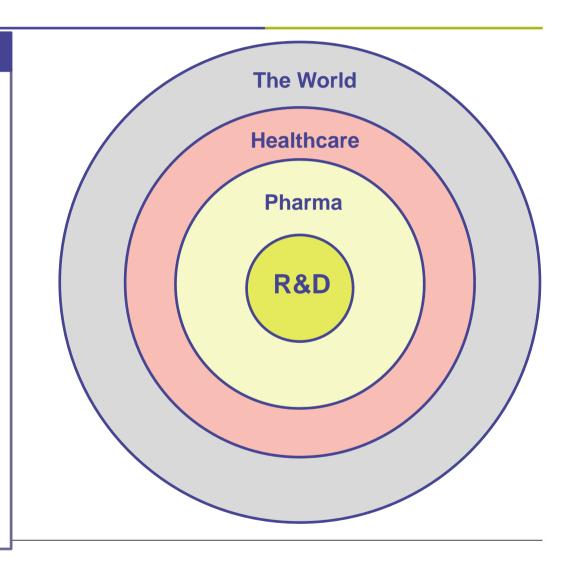




What do we mean by Big Data?

What is it?

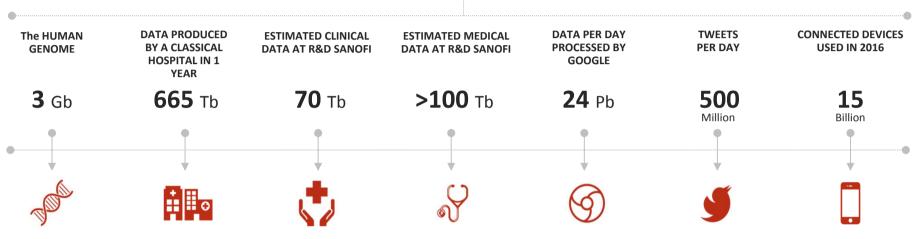
- All of the data, not just a sample
- Real World data, not just research output
- Collected in Real Time
- Collected for one purpose being used for another purpose
- Structured and unstructured
- Multiple formats images, audio, text...
- Curated & uncurated (messy) data



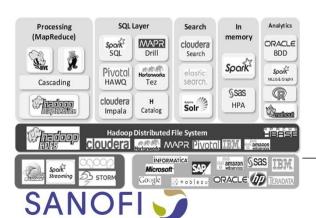


Big Data is a reality





Big Data Technology ecosystem overview



Companies are moving into that space in healthcare











'Information Sources That May be Linked to an Individual for Use in Health Care' Weber, Mandl, and Kohane; JAMA June 25, 2014, p. 2480

Examples of biomedical data		Ability to link data to an individual	Data quantity	
Pharmacy data	Health care center (electronic health record) data	■ Easier to link to individuals		
Claims data	Registry or clinical trial data	Harder to link to individualsOnly aggregate data exists		
Data outside of health care system			More	Less



THE AMOUNT OF DATA GENERATED BY ORGANISATIONS OR INDIVIDUALS



THE FREQUENCY AND SPEED AT WHICH IT IS GENERATED, CAPTURED AND SHARED



THE NEW TYPES OF DATA GENERATED



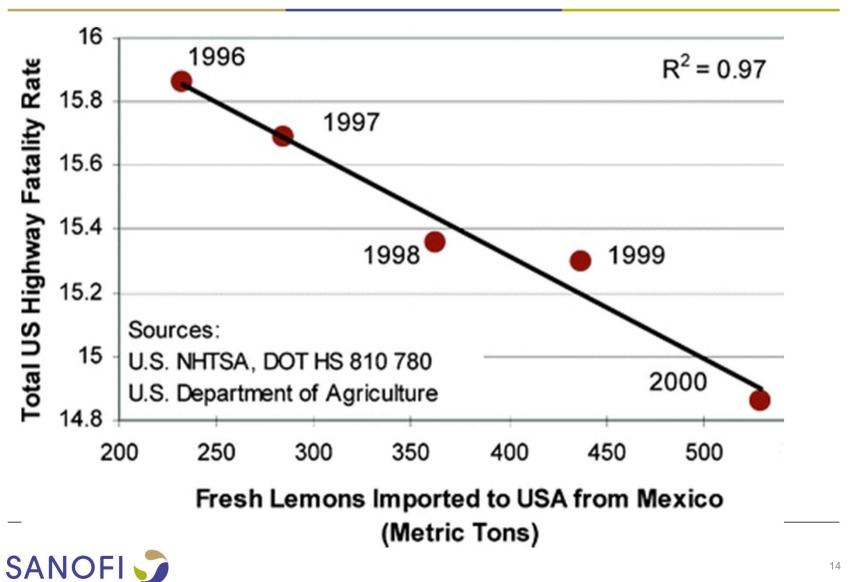
TO WHAT EXTENT CAN WE TRUST THE DATA AND THE OUTPUT?



HOW CAN WE ENSURE A RETURN ON INVESTMENT?



Mexican Lemons Prevent Highway Death

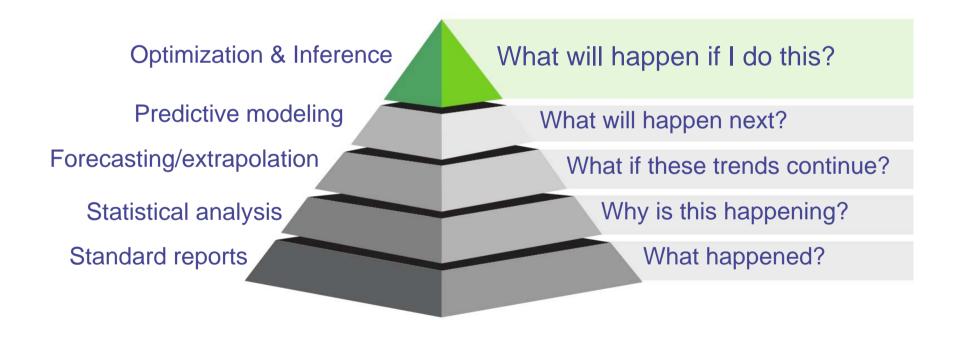


Big Data: the talk of the town! Critical importance of predictive analytics.



The Strategic Value of Big Data Analytics

Its not just about volume or speed, its about what it can tell you





The Perfect Opportunity

Interventions



Massive increase in number and cost of interventions

Machine Learning



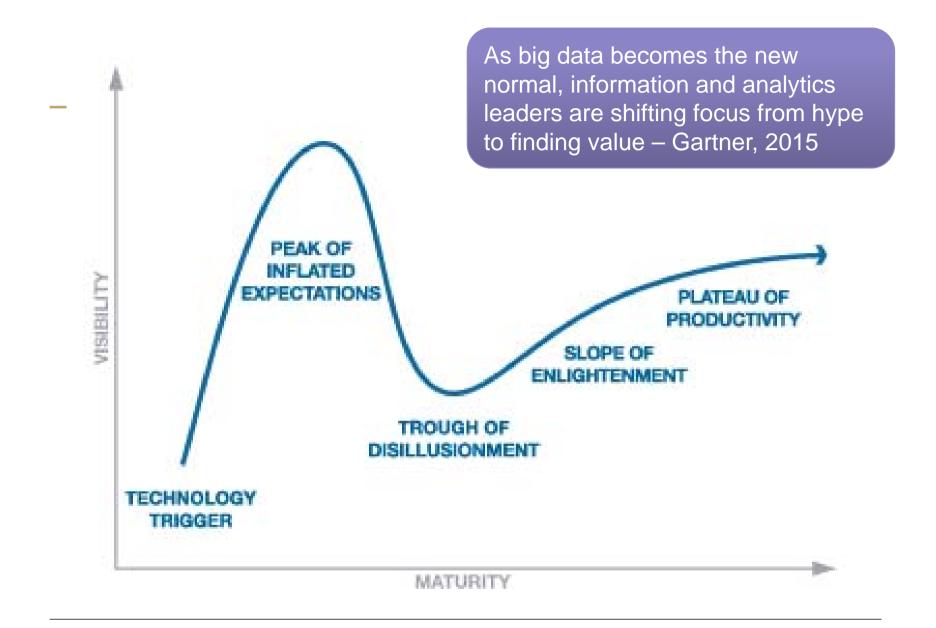
Breakthroughs in machine learning & cloud computing

Data



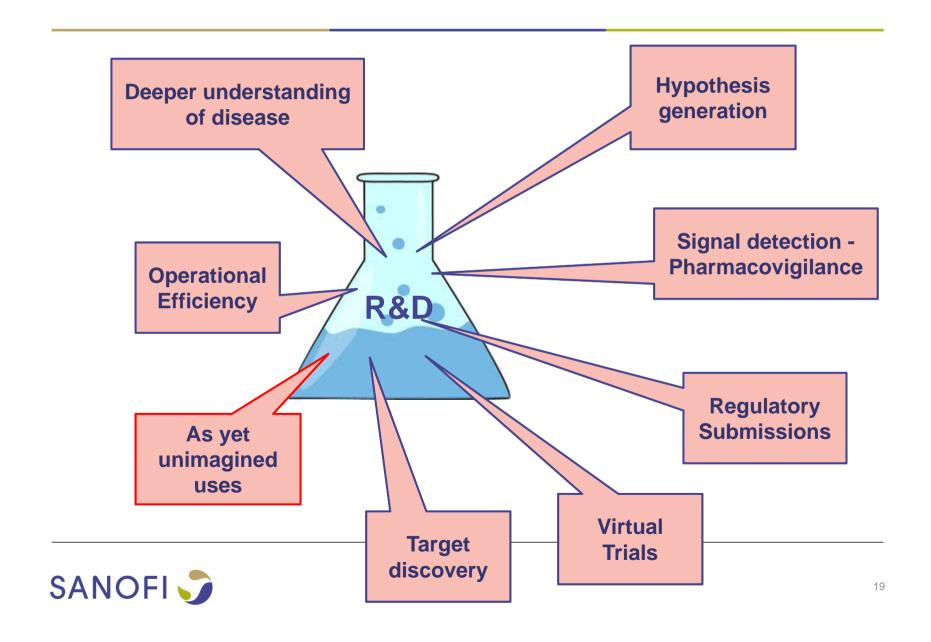
Exponential increase in data and investments to leverage it



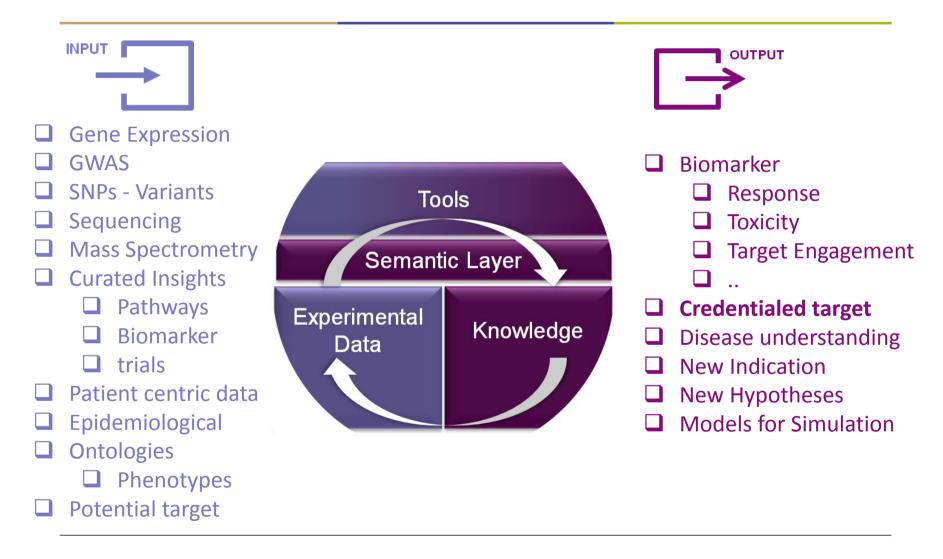




"Big Data" has great potential for R&D



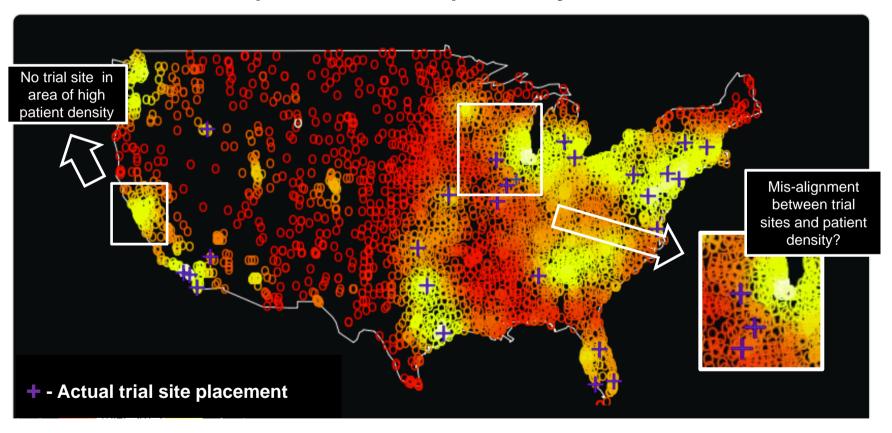
Sanofi's TM4P project in Translational Science:





Big Data Opportunities: running trials where the patients are

Patient Heat-map based on publicly-available information





Sanofi R&D Big Data Initiative



Start pilot projects with clear scientific or medical value



Use these pilots to build first common capabilities

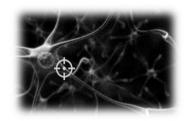


Build partnerships for implementation



6 Main Opportunity Areas Identified

Target identification and credentialing





Clinical Trials
Simulation

Pre-clinical Simulation and prediction (Chemistry, Toxicology...)





Predictive Pharmaco-Vigilance & Safety

Patient stratification



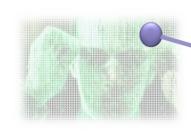


Real-World / Patient data for integrated care



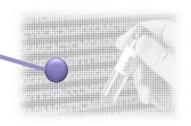
First projects cover a wide spectrum of areas





Improve the quality of Clinical Trial Simulation predictions and decisions by using hospital, real word payor and clinical study data

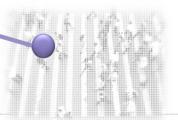
Develop methods to predict developmental and reproductive toxicity outcomes, by building a library of mechanistic "pathways of toxicity"





Assess the real ability of identifying relevant early signals from Patient forum data on 3 of our marketed products

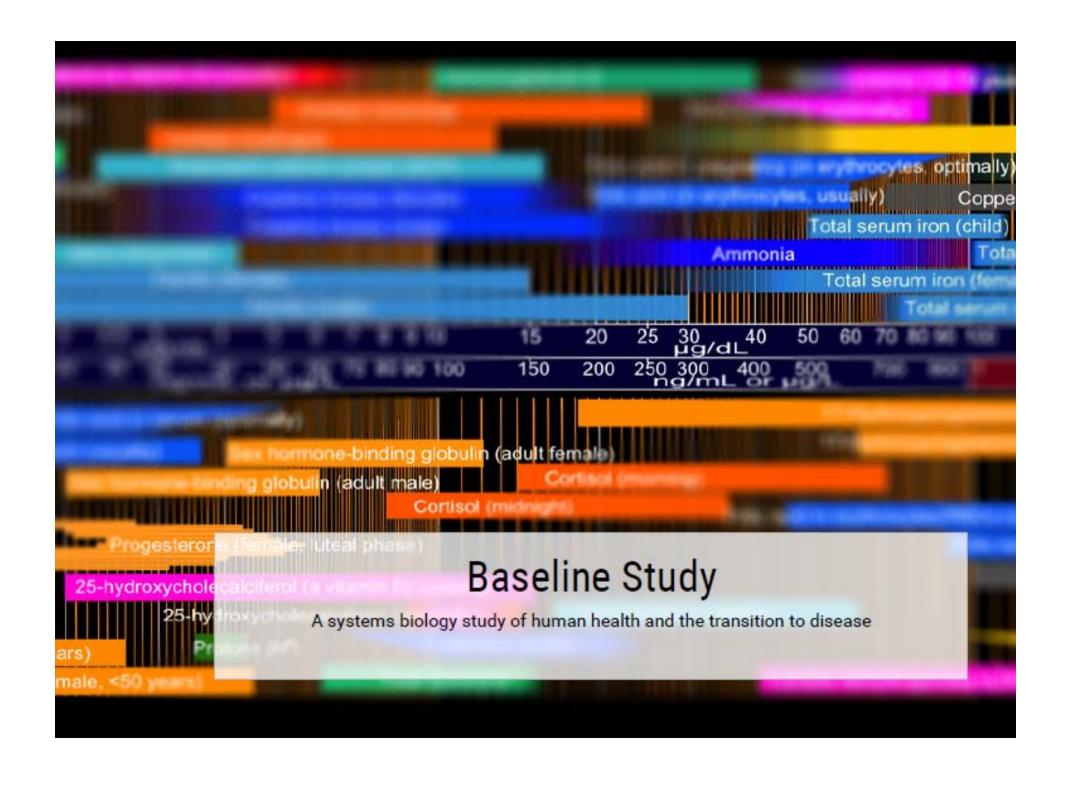
Discover novel differentially expressed genes between subpopulations and select the most appropriate populations for our clinical trials

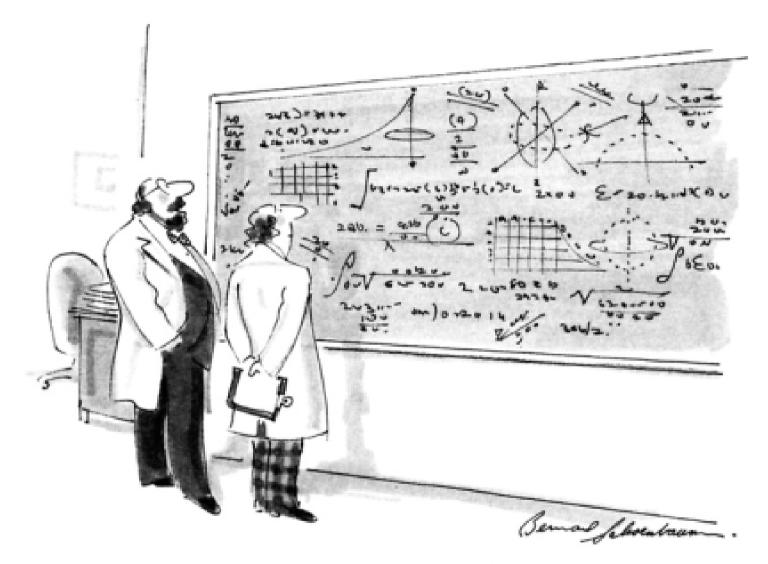




Sanofi-Google partnership







"Oh, if only it were so simple."



Big Data Policy to be addressed

- Boundary Challenges
 - Data standards & harmonization
 - Data localization
 - Access to non-public data (owned by others, particularly governments)
- Confidentiality Challenges
 - Individual Privacy and Data Confidentiality
 - Patient consent
 - Special considerations for genomic data
- Regulatory Challenges
 - Regulatory use of big data
 - Use of big data in submissions



Making use of Big Data – Are we ready change our mindset?

- Can we learn to start with the data, not the hypothesis?
- Are we comfortable with knowing there is a correlation without necessarily understanding the causality -- knowing 'what', not 'why'?
- Can we learn to change the tires on a moving car? Making good use of real-time big data demands analysis in motion.
- Are ready explore approaches that examine the whole population and not a controlled samples?
- How do we bring mathematics and engage mathematicians in our work?
- Are some big data tools and analytics pre-competitive?



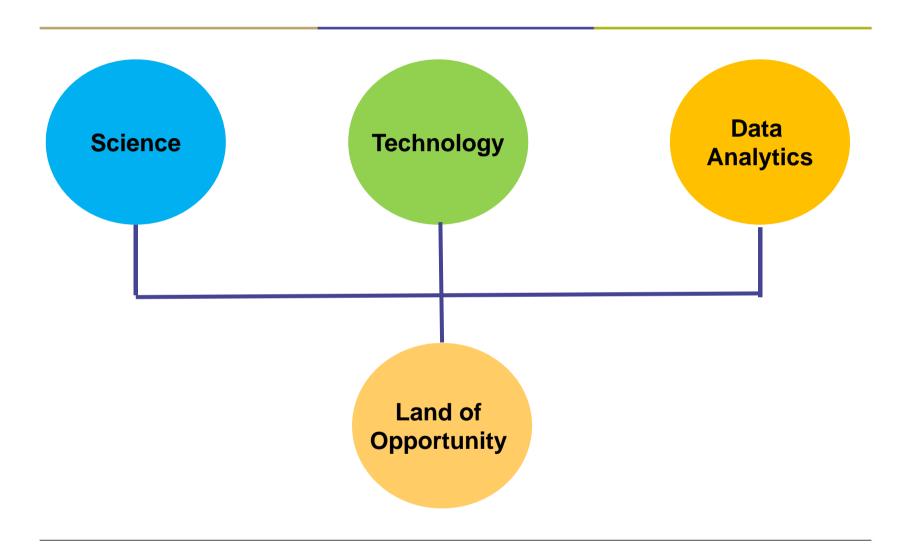
Not so fast! It's not without risk......

- Doesn't tell us which correlations are meaningful
- Risk of spurious correlations because of the magnitude of the data
- Rarely succeeds as a wholesale replacement for scientific enquiry
- Tools can be easily gamed
- Lack of accepted methodologies
- Can give scientific-sounding solutions to very imprecise questions
- Falls short when trying to analyze things that are not common
- Concerns about misuse of data about us and our products



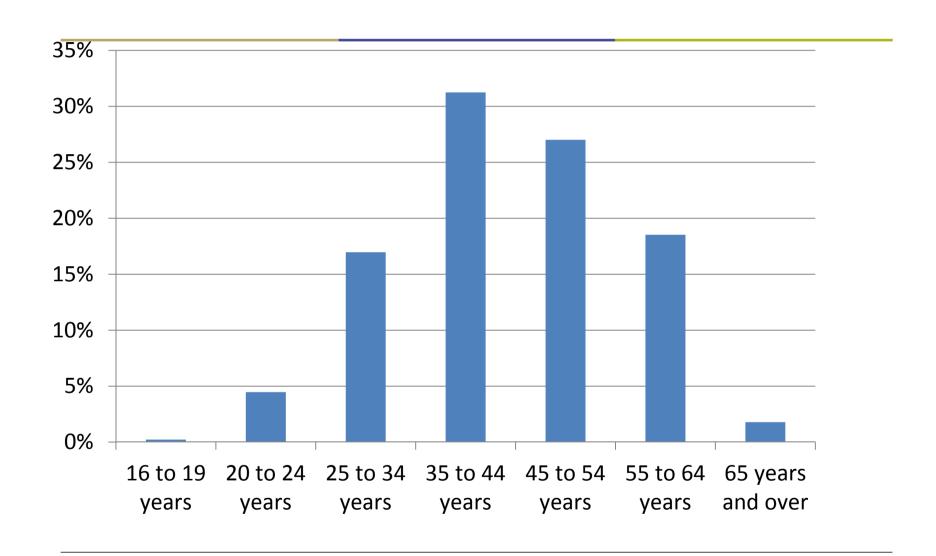


Convergence: New Frontier





Part of the solution will come from generation shift





Preparing for the transformational tidal wave

"Big data will deliver transformational benefits to enterprises within two to five years, and by 2015, will enable enterprises adopting this technology to outperform competitors by 20% in every available financial metric."

Gartner, 2012



Preparing for the transformational tidal wave

We tend to overestimate the effect of a technology in the short run and underestimate the effect in the long run thing data will deliver transformational benefits

'Big data will deliver transformational benefits to enterprises within two to five years, and by 2015, will enable enterprises adopting this technology to outperform competitors by 20% in every available financial metric."

Gartner, 2012



The future is here, it's just not evenly distributed William Gibson

