

Industry 4.0

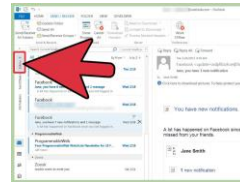
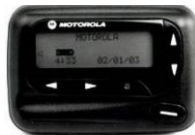
Are we ready for the change?



Varsha Mahajan



What is Industry 4.0?



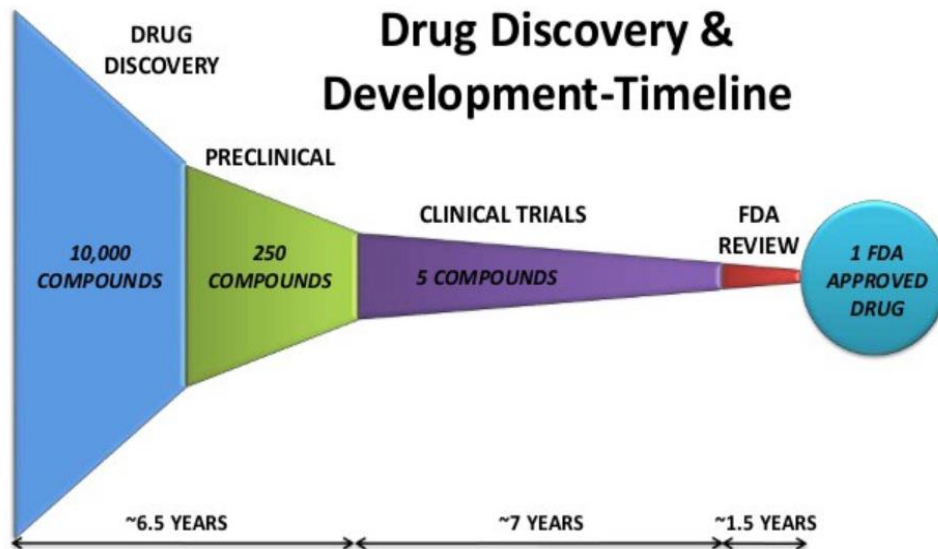
Mail
Talk
E-Mail
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Siri
Alexa

What led to Industry 4.0?

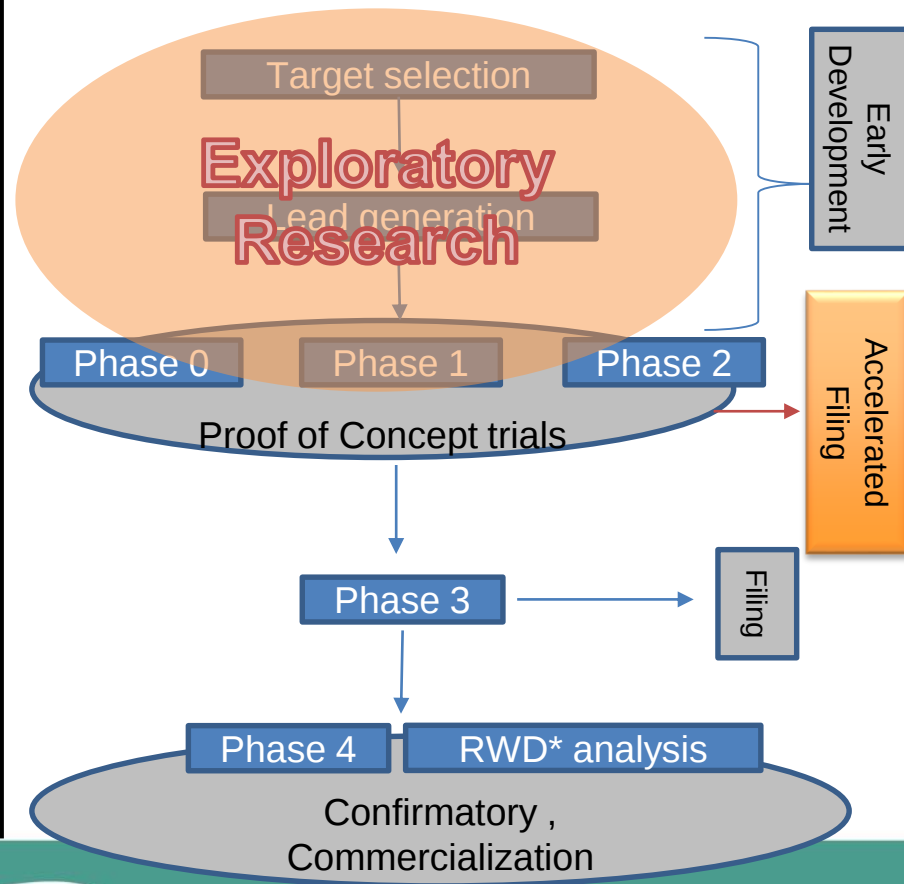
- ❑ Mass production – quality compliance
- ❑ Standardization – regulatory compliance
- ❑ Provide quick and continuous delivery – available for community
- ❑ To remain competitive – business acumen
- ❑ Manage complexity – personalized and specific delivery

How does it impact us?

Traditional Drug Development process

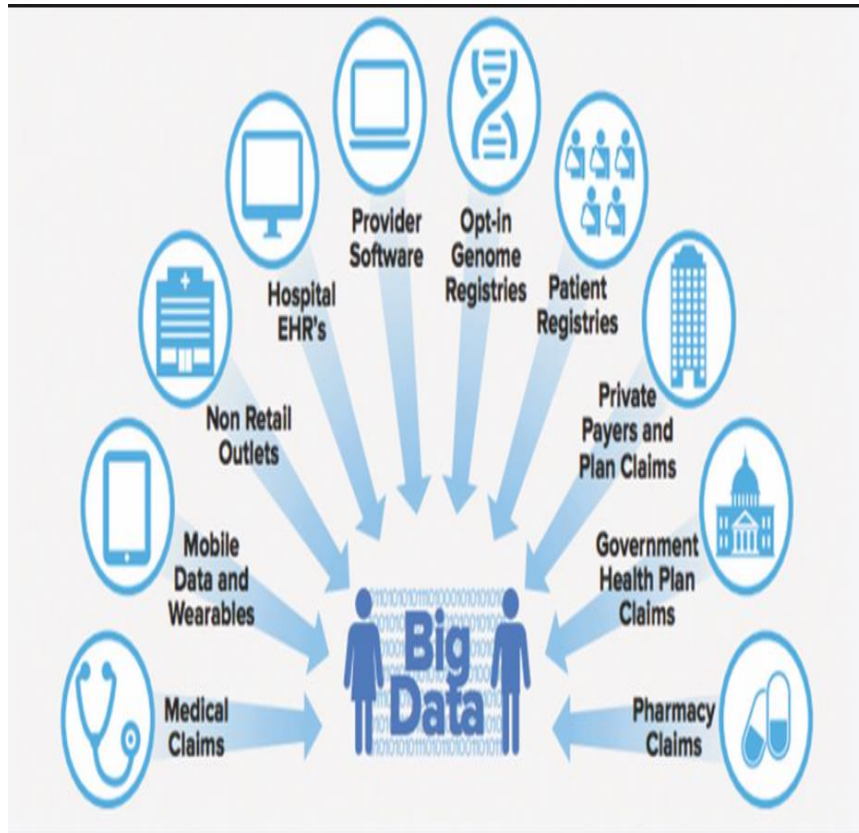


Accelerated Drug Development process



* Real World Data

New paradigm – Data enabled



Challenges

- Unstructured data
- Different / variable data
- New data – connected devices (fitbit, chip in helmet, bats...)
- Missing data – data cleaning

Opportunities

- Re-usability / Re-packaging of data
- Lot available for exploring
- Find un-identified / un-explored areas
- Do more in less – advanced technology
- Advanced analytics – smart analytics

New paradigm – Digital enabled

Virtual clinical trials

- Smart study designs
- Device connect (BYOD)
- Continuous monitoring of data
- Online clinical help – multilingual
- Online procurement of medicine – delivered at door step
- Dosing reminders
- Automatic reminders for health check / lab evaluations
- Standardized evaluations
- Mobile clinics for sample collection
- e-help in case of AEs
- Safety automation
- Regulatory automation

Hybrid clinical trials

- Long run clinical trials
- Virtual clinical trials +
- Certain visits at the site
 - ✓ Compliance check
 - ✓ Anxiety remediation
- Automate follow-up visit reminders

Data enabled to Digital enabled



Industry 4.0 - Principles

- ❑ Interoperability – Technology and Human connect
- ❑ Virtualization – Data available at anytime to contextualize information
- ❑ Technical assistance – Real time problem solving via technological support
- ❑ Decentralized decision-making – Autonomous decision making
- ❑ Customer oriented outcomes
- ❑ Modularity – Quick ability to adapt to change

What does Industry 4.0 mean to us?

Benefits

- ❑ Optimization – self optimize, zero down time
- ❑ Customization – meet the need
- ❑ Pushing research – natural intelligence
- ❑ Data transparency – anybody can analyze and infer

Concerns

- ❑ Data Security issues
- ❑ High degree of reliability on technology connect
- ❑ Maintaining integrity of the process with less human oversight
- ❑ Loss of high paying human jobs
- ❑ Technical outages leading to production outages
- ❑ Lack of experience and manpower to implement new changes



How to lead the change?

- ❑ Domain expertise – game changer
- ❑ Future-Proof by upgrading workforce – skill development
- ❑ Lead the change – new roles
- ❑ Being present and creative
- ❑ Innovation via partnership and collaboration
- ❑ Personalized and connected healthcare

The future for us...

- ❑ Big data analysis
- ❑ Robot assisted production
- ❑ Self managing systems:
 - Predictive maintenance
 - Smart problem-solving capacity
- ❑ Machines / tools as services
- ❑ Continued automation and real time solutions

Examples of industry 4.0

**Collect, analyze, summarize and
interpret data**



Interesting facts – life in numbers

- ❑ Total distance walked in a person's life, 80 years, 216,262,500 steps, 110,000 miles
- ❑ Total calories eaten (2000 females, 2500 males / day): 64,923,187
- ❑ Total sleep, 80 years lifespan: 10,000 days
- ❑ 8000 days sitting
- ❑ 200 days exercising



Modern big data examples

- ❑ Netflix / Amazon Big brands use big data analytics for targeted advertising



- ❑ UOB bank from Singapore is an example of a brand that uses big data to drive risk management



- ❑ Biomechanical analysis of the speed of Owens' joints shows that had he been running on the same surface as Bolt, he wouldn't have been 14 feet behind, he would have been within one stride.

*Jessie Owens: 1936
Berlin Olympics: 10.3 sec
Usain Bolt: 2013 World
championships: 9.77 sec*



Ibrance – approval - RWE

NEWS / U.S. FDA Approves IBRANCE® (palbociclib) for the Treatment of Men with HR+, HER2- Metastatic Breast Cancer

U.S. FDA APPROVES IBRANCE® (PALBOCICLIB) FOR THE TREATMENT OF MEN WITH HR+, HER2-METASTATIC BREAST CANCER

Approval of expanded indication based predominately on **real-world data**

Thursday, April 4, 2019 - 2:57pm EDT

Pfizer (NYSE:PFE) today announced that the U.S. Food and Drug Administration (FDA) approved a supplemental New Drug Application (sNDA) to expand the indications for IBRANCE® (palbociclib) in combination with an aromatase inhibitor or fulvestrant to include men with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer. The approval is based on data from electronic health records and postmarketing reports of the real-world use of IBRANCE in male patients sourced from three databases: IQVIA Insurance database, Flatiron Health Breast Cancer database and the Pfizer global safety database.



Ibrance – approval - RWE

Real-world data is playing an increasingly important role in expanding the use of already approved innovative medicines.¹ Due to the rarity of breast cancer in males, fewer clinical trials are conducted that include men resulting in fewer approved treatment options. In the U.S. in 2019, it is estimated that there will be 2,670 new cases of invasive breast cancer and about 500 deaths from metastatic breast cancer in males.² The 21st Century Cures Act, enacted in 2016, was created to help accelerate medical product development, allowing new innovations and advances to become available to patients who need them faster and more efficiently.³ This law places additional focus on the use of real-world data to support regulatory decision-making.⁴



Framingham heart study - 1948

BY THE NUMBERS: Uncovering the Mysteries of the Heart

By American Heart Association News

Years the Framingham Heart Study continues to break new ground on cardiovascular disease

70



5,209

Initial volunteer participants

3

Generations who have participated in the study

15,447

Participants over the past 70 years



3,698

Published journal articles based on Framingham Heart Study data



1960

Year the study pinned cigarette smoking as a risk factor for heart disease

802

Participants who have donated or registered to donate their brain for further study

Sources: Framingham Heart Study, Boston University

Published Oct. 10, 2018

Big study
Big findings

Simple design and follow-up of citizens

Big contributions
Milestones
Landmarks in heart diseases

Framingham heart study – contributions, main findings and landmarks

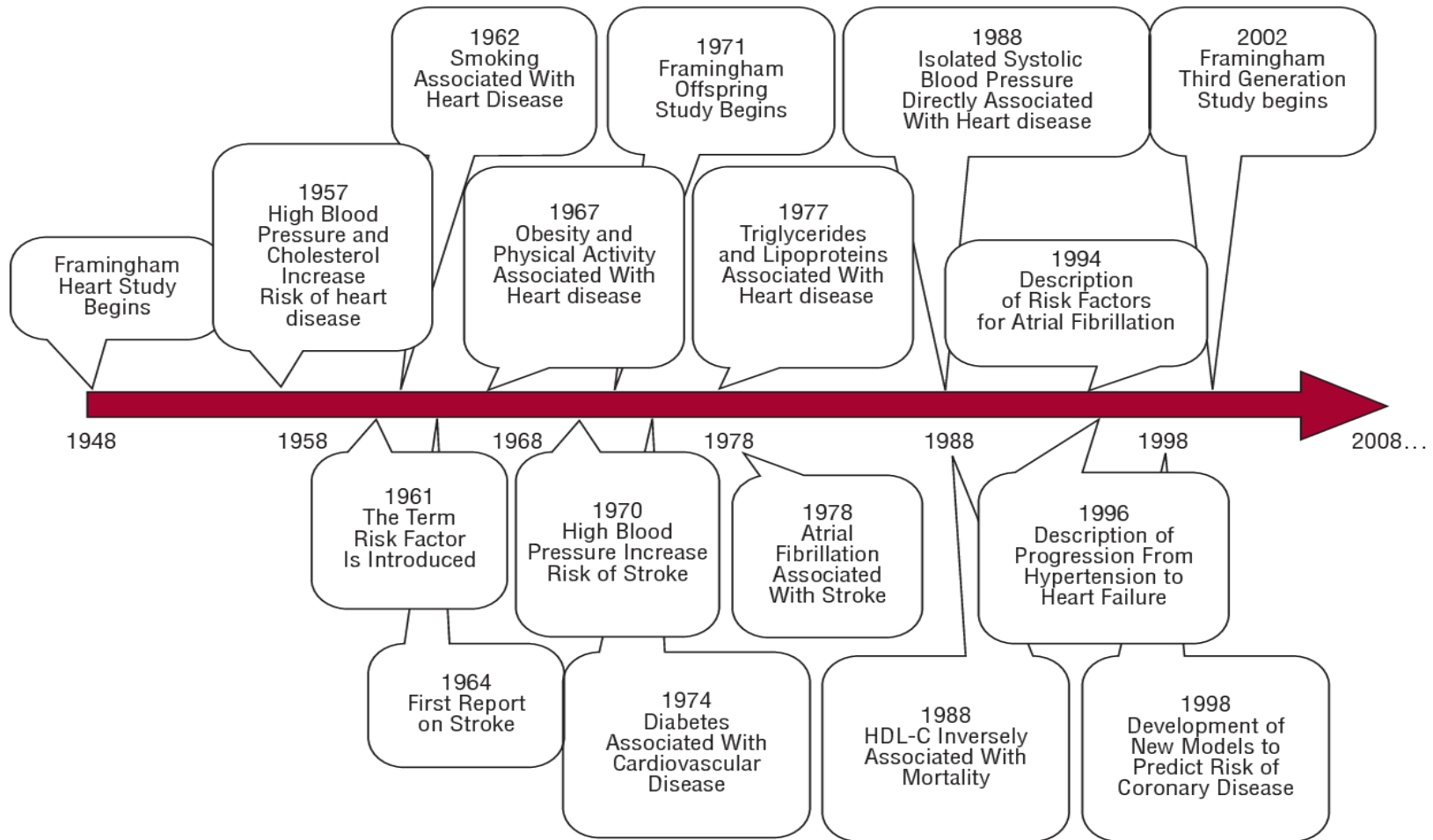


Figure 1 Summary of some of the main findings and landmarks of the Framingham Heart Study. HDL-C indicates high density lipoprotein

Beyond the clinical trial ... data analysis

POSEIDON Study

- ❑ Funding by Chest Research Foundation, Council of Scientific and Industrial Research—Institute of Genomics and Integrated Biology (CSIR-IGIB), and Cipla Ltd.

Objective

- ❑ Aimed to record the prevalence of symptoms and medical conditions for which patients visit a primary health-care practitioner in India.

Expected outcome

- ❑ A better understanding of what ails India will help policy makers plan appropriate health-care services and infrastructure development, design medical education curricula, and identify health research priorities that are relevant to the needs of the country.

Beyond the clinical trial ... data analysis

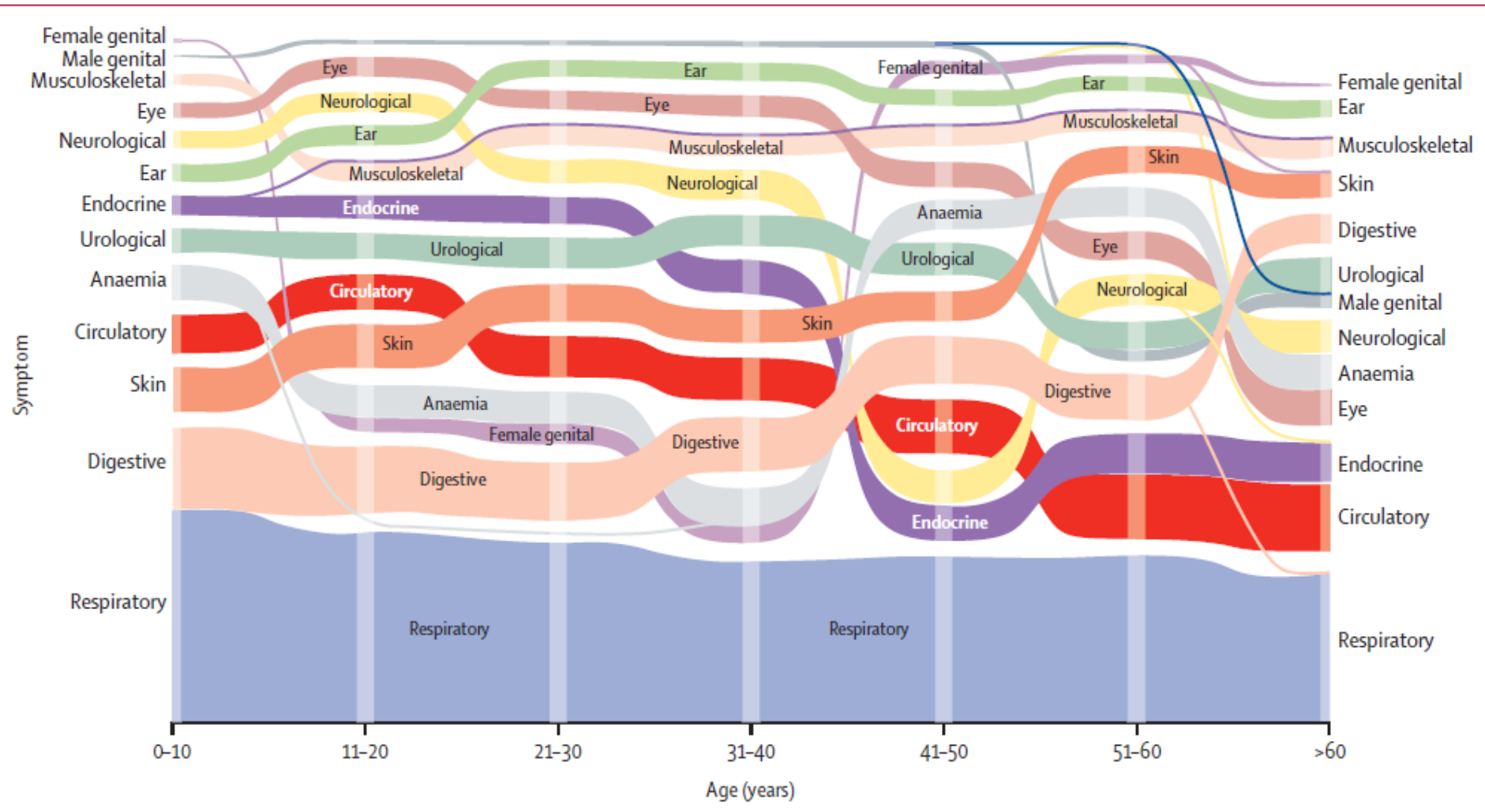
Data collection

- ❑ **1,20,00** general practitioners, general physicians, and pediatricians selected
- ❑ **880** cities and towns
- ❑ Data on **Feb 01, 2011** visit
- ❑ Addition **1,225** practitioners volunteered

Data included and analysis conducted

- ❑ Responses from **7,400** health-care practitioners
- ❑ **2,04,912** patient's data; **5,54,146** reasons for visit
- ❑ Descriptive analyses of prevalence rates and used χ^2 tests to study comorbid associations
- ❑ Inter-relations between organ involvement of diseases and symptoms and how these associations change with age and gender

Beyond the clinical trial ... data analysis



Salvi S. Symptoms and medical conditions in 204 912 patients visiting primary health-care practitioners in India: a 1-day point prevalence study (the POSEIDON study). Lancet 2015 (3)

Beyond the clinical trial ... data analysis

Findings

- ❑ Greater proportion of visits from male patients (54.1%)
- ❑ Only 7.9% of patients were older than 60 years
- ❑ Most frequent disease conditions:
 - Fever (35.5%), Respiratory diseases (~50%)
 - Common presentations:
 - Digestive system symptoms (25%),
 - Circulatory symptoms (12.5%),
 - Skin complaints (9%), and endocrine disorders (6.6%).
 - Hypertension (14.52%),
 - Obstructive airways diseases (14.51%), and upper respiratory tract infections (12.9%)
- ❑ 21.4% patients with hypertension reported were < 40 years old
- ❑ Anemia was the fourth most common disease and was most common in women of menstrual age living outside metro cities.

Food for thought...

- ❑ Is SAS the only option?
- ❑ R, Python – Big data analysis
- ❑ Tableau, SPOTFIRE – Data visualization
- ❑ Adaptive design, Bayesian analysis
- ❑ Basket trials
- ❑ Newer analysis R-comorbidities, QALY or DALY analysis
- ❑ More collaboration, industry connect, knowledge sharing
- ❑ Robust training and being relevant
- ❑ ...

References

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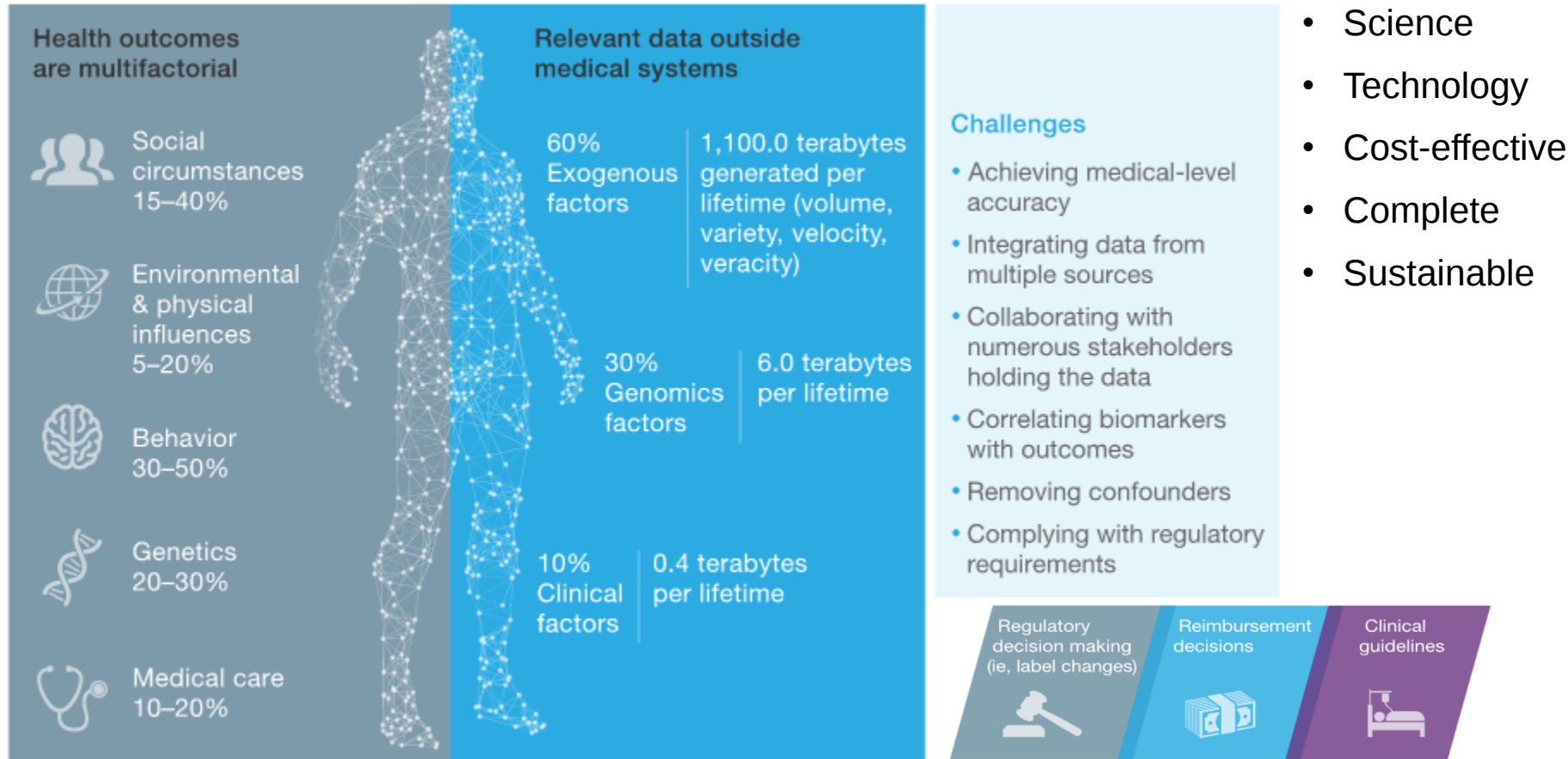
“We but mirror the world. All the tendencies present in the outer world are to be found in the world of our body. If we could change ourselves, the tendencies in the world would also change. As a man changes his own nature, so does the attitude of the world change towards him. This is the divine mystery supreme. A wonderful thing it is and the source of our happiness. We need not wait to see what others do.”

Mahatma Gandhi

Thank you!



Health Data



Source: "The relative contribution of multiple determinants to health outcomes," *Health Affairs*, August 21, 2014