Big Data meets Medicines Regulation: Which Data and when?

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Public Declaration of transparency/interests*

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Interests in pharmaceutical industry	NO	Current	From 0 to 3 previous years	Over 3 previous years
DIRECT INTERESTS:				
1.1 Employment with a company: pharmaceutical company in an executive role	X	☐	☐	☐ mandatory
1.2 Employment with a company: in a lead role in the development of a medicinal product	X	☐	☐	☐ mandatory
1.3 Employment with a company: other activities	X	☐	☐	☐ optional
2. Consultancy for a company	X	☐	☐	☐ optional
3. Strategic advisory role for a company	X	☐	☐	☐ optional
4. Financial interests	X	☐	☐	☐ optional
5. Ownership of a patent	X	☐	☐	☐ optional
INDIRECT INTERESTS:				
6. Principal investigator	X	☐	☐	☐ optional
7. Investigator	X	☐	☐	☐ optional
8. Grant or other funding	X	☐	☐	☐ optional
9. Family members interests	X	☐	☐	☐ optional

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Type and Size of Data

By 2020 Health Information Will Double Every 73 Days

60%
Exogenous Factors

1100 Terabytes
Generated per lifetime

Volume, Variety, Velocity, Veracity

30%
Genomics Factors

6 Terabytes
Per lifetime

10%
Clinical Factors

0.4 Terabytes
Per lifetime

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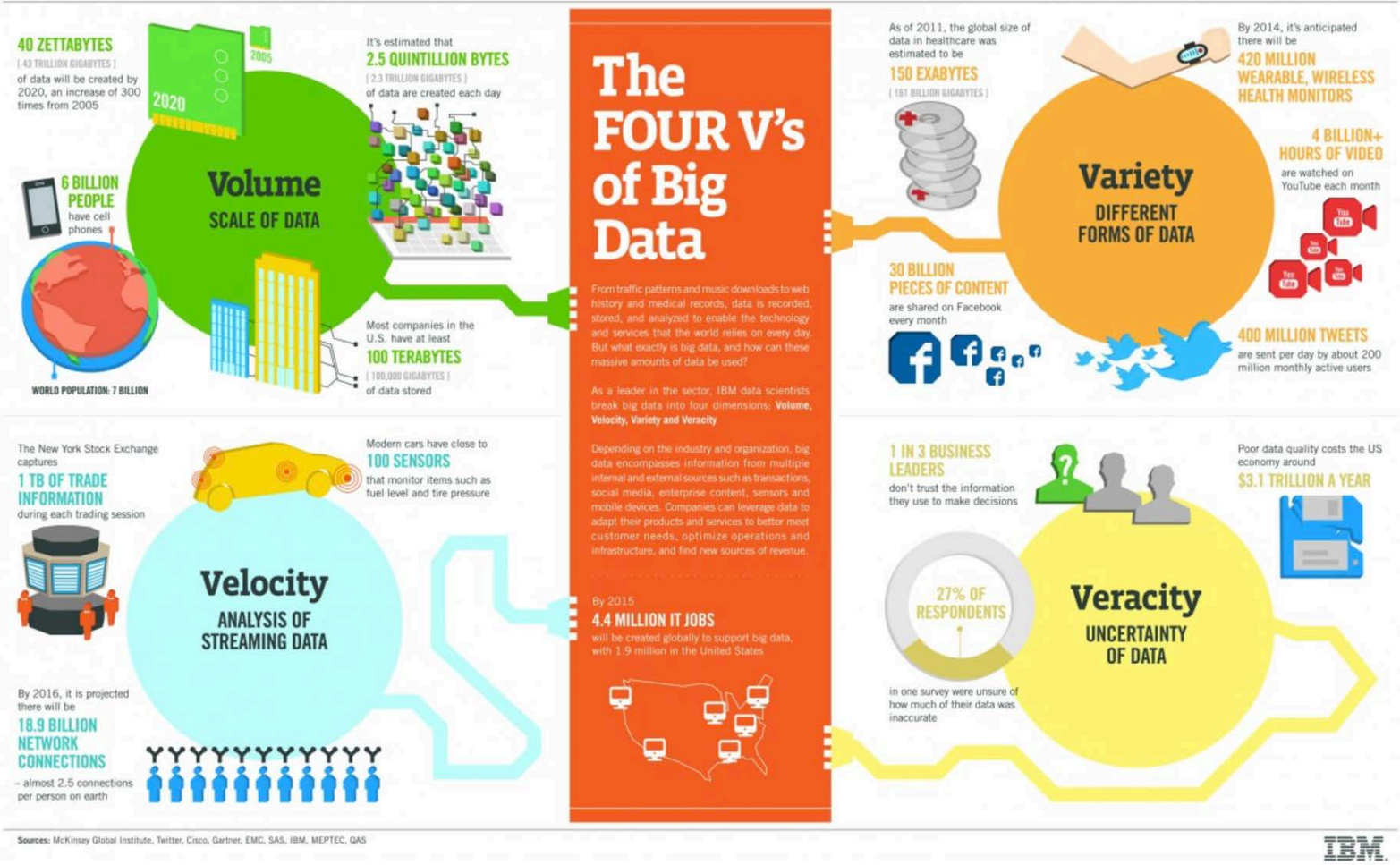
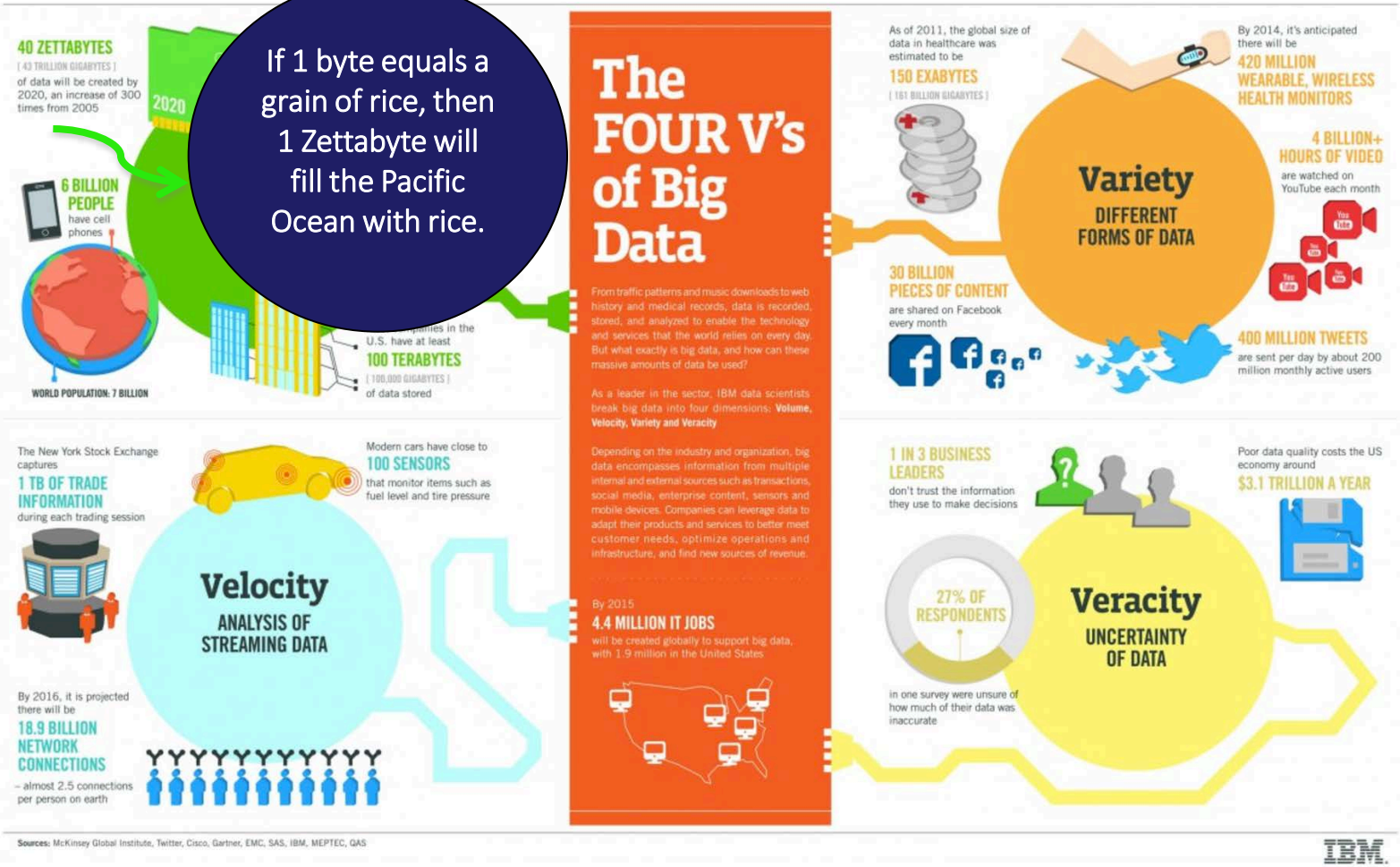
What are we talking here really?



What are we talking here really?

If 1 byte equals a grain of rice, then 1 Zettabyte will fill the Pacific Ocean with rice.



Data ⋦ Information ⋦ Knowledge

58%

TRANSITIONING FROM DATA TO KNOWLEDGE IS A MAJOR CHALLENGE[1]

41%

SYSTEMS CANNOT PROCESS LARGE VOLUMES OF DATA FROM DIFFERENT SOURCES

62%

GROWTH OF UNSTRUCTURED, NON-CONTEXTUALIZED DATA[2]

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[1] PwC 5TH annual IQ survey
[2] International Data Group Research

Pillars of Exponential Data Paradigmatic Shock

Unprecedented volumes of public data

NPPES National Plan & Provider Enumeration System

PubMed

CMS Centers for Medicare & Medicaid Services

ClinicalTrials.gov A service of the U.S. National Institutes of Health

World Health Organization

National Institutes of Health

NHS British National Health Service

FDA

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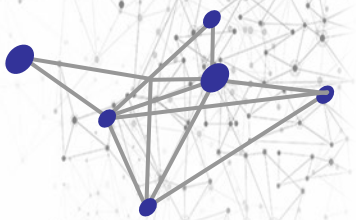
Programmatic data transformation:

Deep Learning

Billions of data connections made



Automated categorization

Relative prominence of research activities

Perceived influence on other health care providers

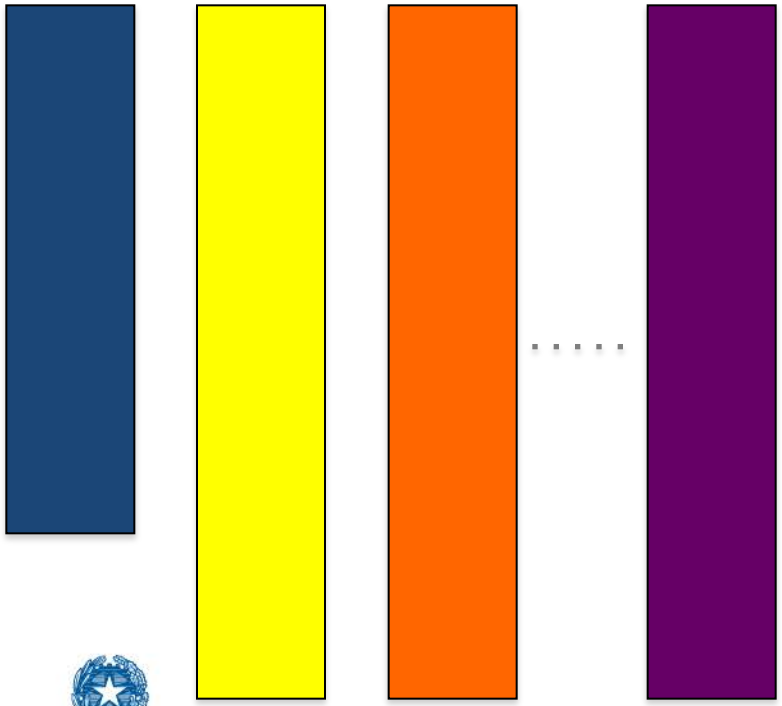
Comparative clinical behavior

Level of engagement with industry

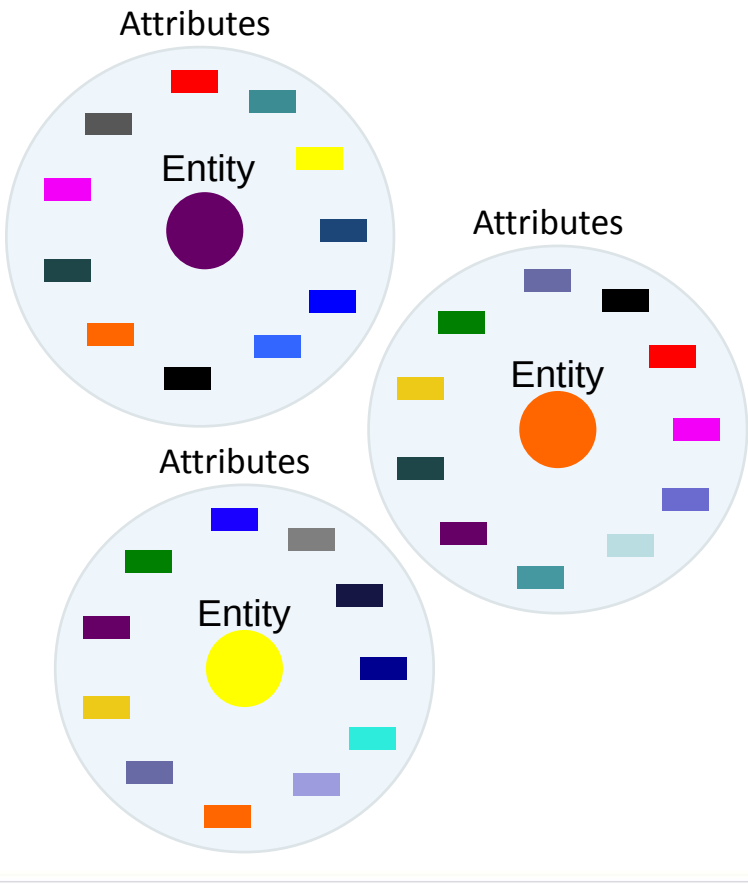
Examples: Monocles; Zephyr Health

Innovative data models could be game changer

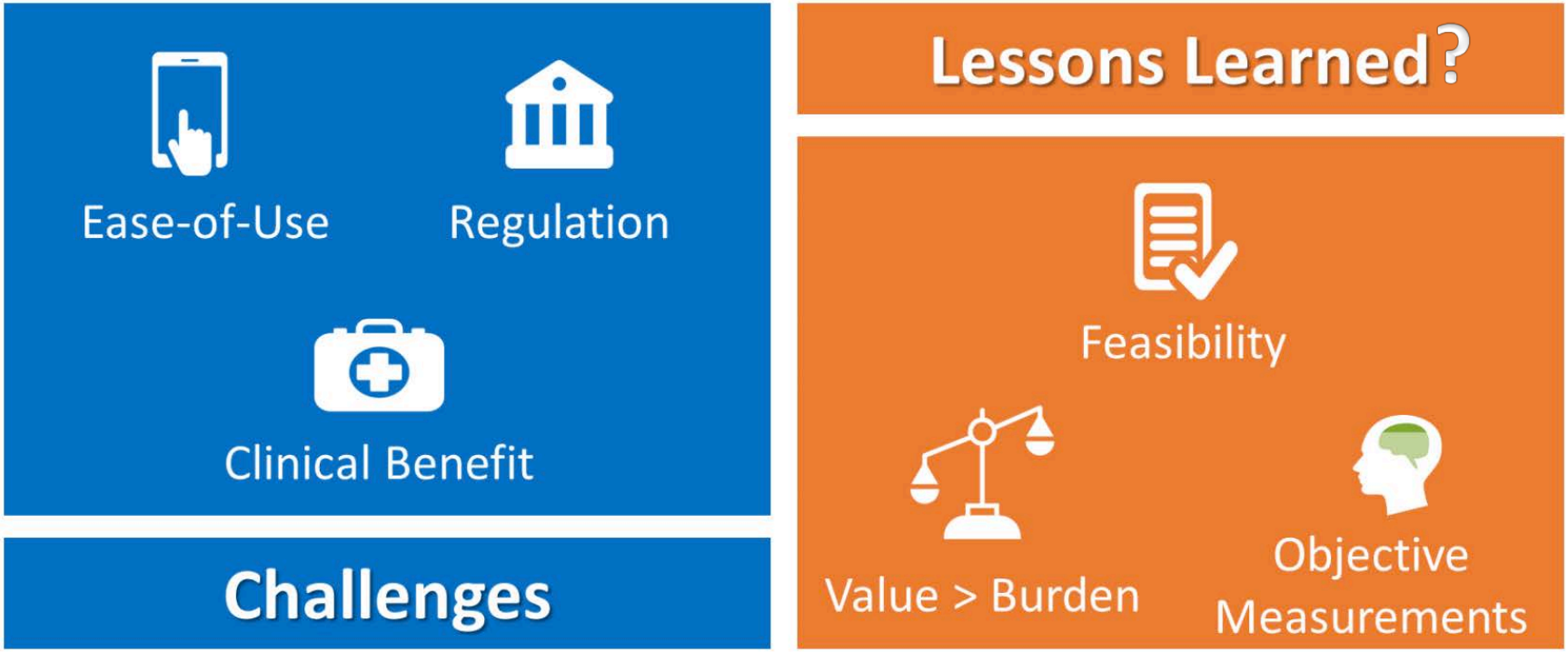
Traditional, relational model



Entity centric model



In summary we are still dealing with…



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