

# Big Data meets Medicines Regulation:

## Which Data and when?

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# Public Declaration of transparency/interests\*

The view and opinions expressed are those of the individual presenter and should not be attributed to AIFA / EMA

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

# Type and Size of Data

By 2020 Health Information Will Double Every 73 Days

**60%**  
Exogenous Factors

**30%**  
Genomics Factors

**10%**  
Clinical Factors



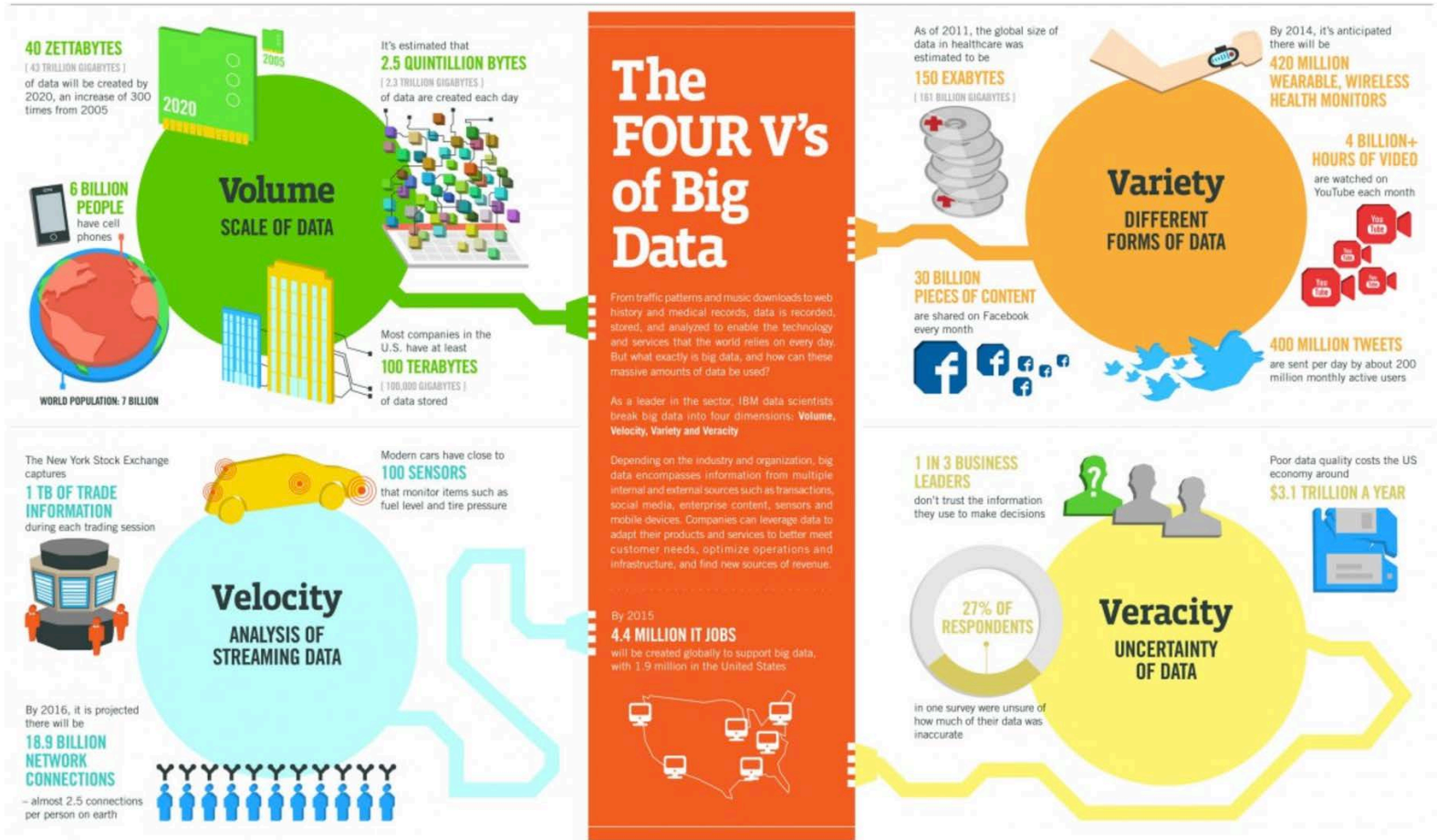
**1100 Terabytes**  
Generated per lifetime

Volume, Variety, Velocity,  
Veracity

**6 Terabytes**  
Per lifetime

**0.4 Terabytes**  
Per lifetime

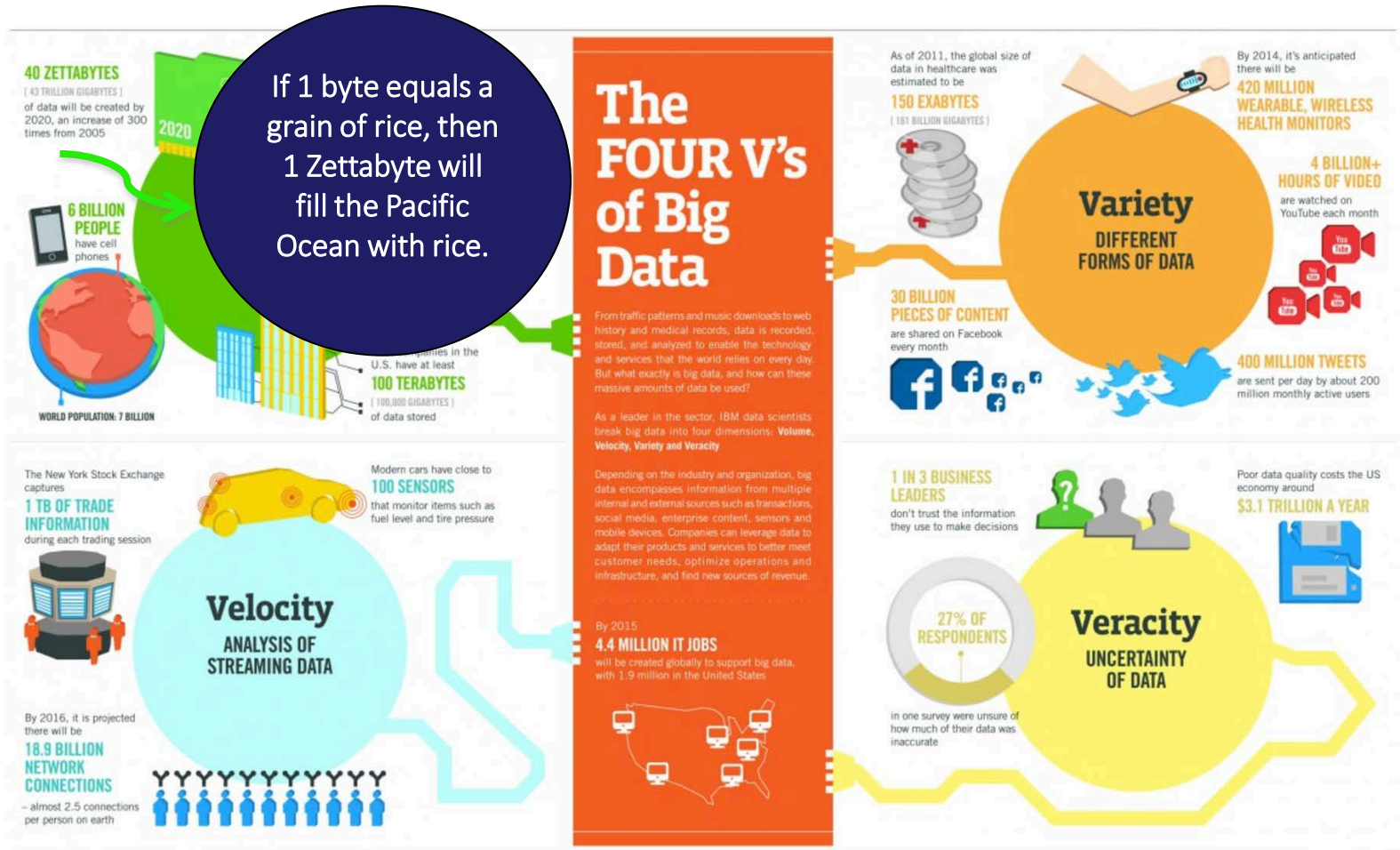
# What are we talking here really?



Sources: McKinsey Global Institute, Twitter, Cisco, Gartner, EMC, SAS, IBM, MEPTec, QAS



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# Data ≠ Information ≠ Knowledge

**58%**

TRANSITIONING FROM  
DATA TO KNOWLEDGE IS  
A MAJOR CHALLENGE<sup>1</sup>

**41%**

SYSTEMS CANNOT  
PROCESS LARGE  
VOLUMES OF DATA FROM  
DIFFERENT SOURCES

**62%**

GROWTH OF  
UNSTRUCTURED, NON-  
CONTEXTUALIZED DATA<sup>2</sup>

# Pillars of Exponential Data Paradigmatic Shock

Unprecedented volumes of public data



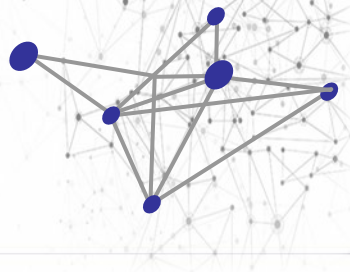
World Health Organization



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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

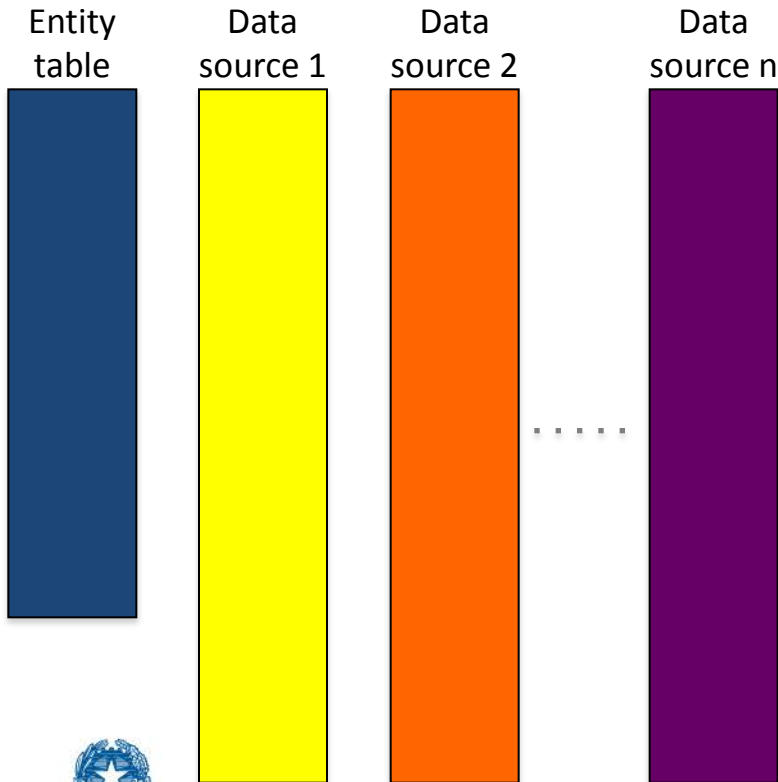
Level of engagement with industry



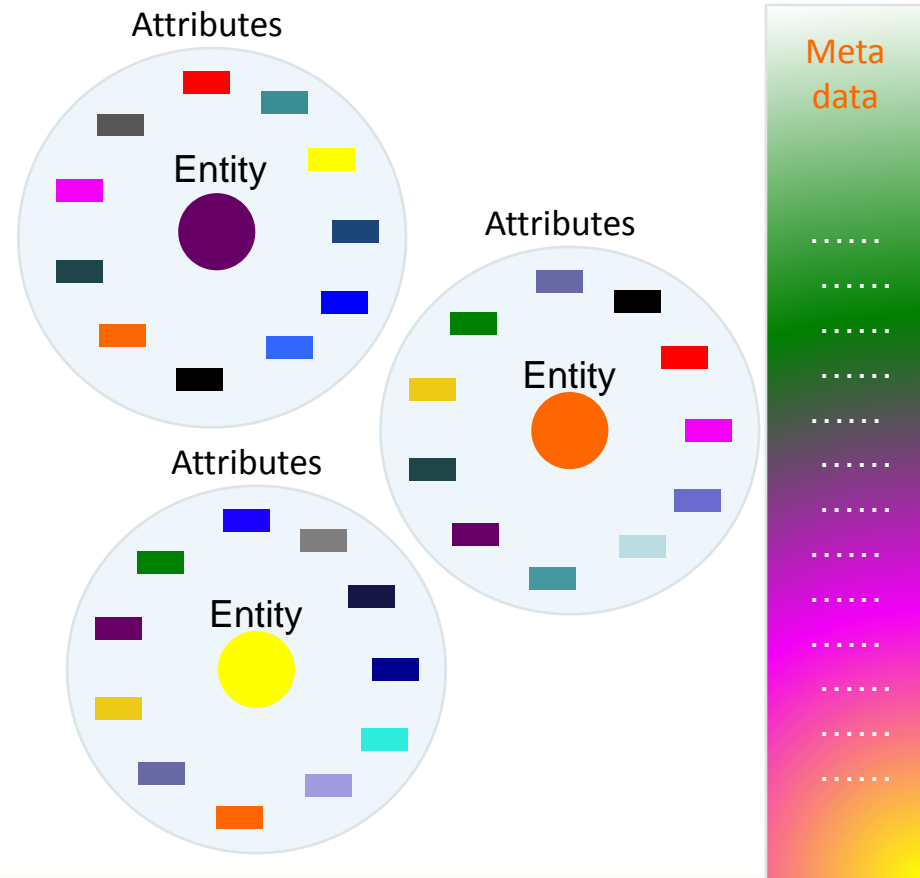
Examples: Monocles; Zephyr Health

# Innovative data models could be game changer

## Traditional, relational model



## Entity centric model





# In summary we are still dealing with...



Ease-of-Use



Regulation



Clinical Benefit

**Challenges**

## Lessons Learned?



Feasibility



Value > Burden



Objective Measurements

A word cloud featuring the phrase "thank you" in many languages and scripts. The central and largest word is "thank you" in a red, bold, sans-serif font. Surrounding it are numerous other words, including:
   
 - "danke" (German) in blue
   
 - "謝謝" (Chinese) in black
   
 - "teşekkür ederim" (Turkish) in pink
   
 - "gracias" (Spanish) in green
   
 - "dziękuję" (Polish) in purple
   
 - "obrigado" (Portuguese) in green
   
 - "sukriya" (Javanese) in purple
   
 - "kop khun krap" (Lao) in green
   
 - "terima kasih" (Indonesian) in yellow
   
 - "merci" (French) in orange
   
 - "thankyou" (English) in red
   
 - "bedankt" (Dutch) in yellow
   
 - "спасибо" (Russian) in red
   
 - "bajarlalaa" (Burmese) in red
   
 - "rahmat" (Arabic) in red
   
 - "ngiyabonga" (Shona) in red
   
 - "xinxiexie" (Vietnamese) in red
   
 - "ευχαριστώ" (Greek) in blue
   
 - "taikou" (Vietnamese) in blue
   
 - "mochchakkeram" (Bengali) in blue
   
 - "maith agat" (Marathi) in blue
   
 - "trugarez" (Breton) in blue
   
 - "muruuru" (Zulu) in blue
   
 - "chokrane" (Swahili) in yellow
   
 - "murakoze" (Swahili) in yellow
   
 - "tapadh leat" (Irish) in orange
   
 - "xhala" (Zulu) in red
   
 - "asante" (Swahili) in blue
   
 - "manana" (Swahili) in blue
   
 - "tenki" (Hindi) in blue
   
 - "obrigada" (Portuguese) in green
   
 - "mesa" (Portuguese) in green
   
 - "sagolun" (Icelandic) in green
   
 - "najis tuke" (Icelandic) in green
   
 - "kam sah hamnida" (Icelandic) in green
   
 - "didi madloba" (Icelandic) in green
   
 - "nansi" (Icelandic) in green
   
 - "nandri" (Icelandic) in green
   
 - "kiitos" (Finnish) in green
   
 - "dhanyavad" (Sinhalese) in green
   
 - "gracie" (French) in green
   
 - "hvala" (Slovak) in green
   
 - "maururu" (Zulu) in blue
   
 - "koshonom" (Zulu) in blue
   
 - "vinaka" (Tongan) in blue
   
 - "spasibo" (Tongan) in blue
   
 - "blagodaram" (Sinhalese) in blue
   
 - "kua oia" (Sinhalese) in blue
   
 - "barka" (Sinhalese) in blue
   
 - "welalin" (Sinhalese) in blue
   
 - "tack" (Sinhalese) in blue
   
 - "misaotra" (Sinhalese) in blue
   
 - "matondo" (Sinhalese) in blue
   
 - "paldies" (Lithuanian) in blue
   
 - "grazzi" (Italian) in blue
   
 - "mahalo" (Hawaiian) in blue
   
 - "djiere dieuf" (Creole) in blue
   
 - "tau" (Creole) in blue
   
 - "djakou" (Creole) in blue
   
 - "mamnun" (Burmese) in blue
   
 - "sulpay" (Tibetan) in blue
   
 - "arigatō" (Japanese) in purple
   
 - "shukriya" (Urdu) in blue
   
 - "merce" (Catalan) in blue
   
 - "merci" (French) in orange
   
 - "dziękuję" (Polish) in purple
   
 - "sobodi" (Polish) in purple
   
 - "dekuji" (Polish) in purple
   
 - "chrorakaloutioun" (Greek) in green
   
 - "gracias ago" (Greek) in green
   
 - "gracies" (Greek) in green
   
 - "ariahtou" (Greek) in green
   
 - "tanemirt" (Sinhalese) in blue
   
 - "rahmet" (Sinhalese) in blue
   
 - "diolch" (Welsh) in blue
   
 - "dhanyavadagalu" (Sinhalese) in blue
   
 - "shukriya" (Urdu) in blue
   
 - "merci" (French) in orange



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