



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Workshop on personalised medicines: role of
patients, consumers and healthcare professionals

Societal implications of personalised medicine

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London March 14th 2017



Healthcare Innovation Hub

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Biology has now become a science of information and we must change our cultural reference framework (Leroy Hood, 2003)



M. Dayhoff
1925-1983

$$D_{ij} = 10 \log_{10} \frac{(M^{250})_{ij}}{f_i}$$

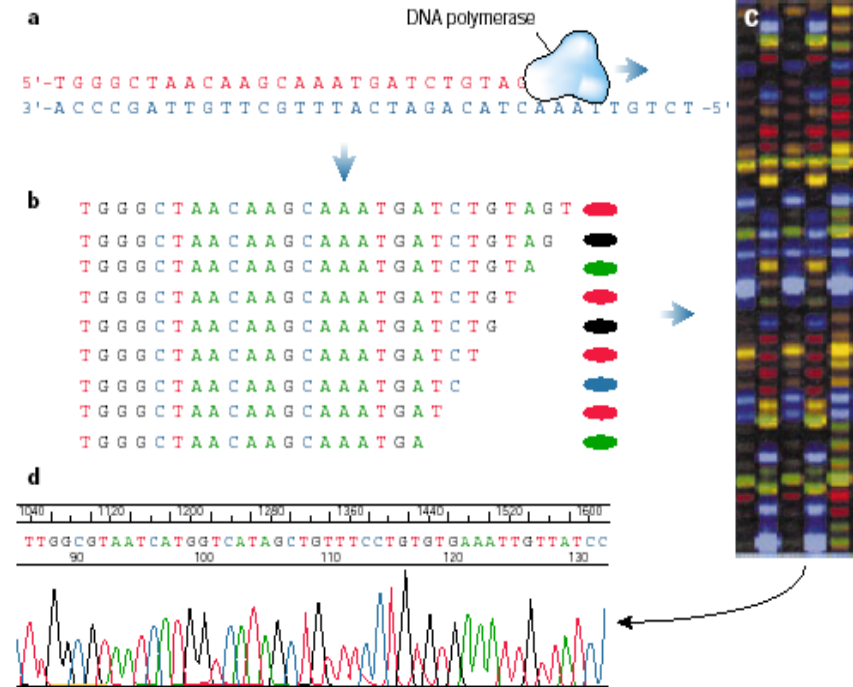
The PAM250 Matrix

	C	S	T	P	A	G	N	D	E	Q	H	R	K	M	I	L	V	F	Y	W	
C	12																				C
S	0	2																			S
T	-2	1	3																		T
P	-3	1	0	6																	P
A	-2	1	1	1	2																A
G	-3	1	0	-1	1	9															G
N	-4	1	0	-1	0	0	2														N
D	-5	0	0	-1	0	1	2	4													D
E	-5	0	0	-1	0	0	1	3	4												E
Q	-5	-1	-1	0	0	-1	1	2	2	4											Q
H	-3	-1	-1	0	-1	-2	2	1	1	3	6										H
R	-4	0	-1	0	-2	-3	0	-1	-1	1	2	6									R
K	-5	0	0	-1	-1	-2	1	0	0	1	0	3	5								K
M	-5	-2	-1	-2	-1	-3	-2	-3	-2	-1	-2	0	0	6							M
I	-2	-1	0	-2	-1	-3	-2	-2	-2	-2	-2	-2	2	5							I
L	-6	-3	-2	-3	-2	-4	-3	-4	-3	-2	-2	-3	-3	4	2	6					L
V	-2	-1	0	-1	0	-1	-2	-2	-2	-2	-2	-2	2	4	2	4					V
F	-4	-3	-3	-5	-4	-5	-4	-6	-5	-5	-2	-4	-5	0	1	2	-1	9			F
Y	0	-3	-3	-5	-3	-5	-2	-4	-4	-4	0	-4	-4	-2	-1	-1	-2	7	10		Y
W	-8	-2	-5	-6	-6	-7	4	-7	-7	-5	-3	2	-3	4	-5	-2	-6	0	0	17	W
	C	S	T	P	A	G	N	D	E	Q	H	R	K	M	I	L	V	F	Y	W	

- **Atlas of Protein Structure:**
- 1965 1 year work (720 Kb), all the world's lab
- 2003 30' (1 Gb), 1 Robot
- 2017 0.001' (127.352 macromolecules) <http://www.rcsb.org/>
- **DNA Sequence:**
- 1986 250 bp a day, 1 Robot
- 2003 1.500.000 bp a day, 1 better Robot (98 M\$ genome)
- 2017 3.000.000.000 bp a day 1 HT-Sequencing (1,000 \$)

The digital code of DNA

NATURE | VOL 421 | 23 JANUARY 2003 |



Toward Precision Medicine

Building a Knowledge Network for Biomedical Research
and a New Taxonomy of Disease



Committee on A Framework for Developing a
New Taxonomy of Disease

Board on Life Sciences

Division on Earth and Life Studies

NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

Biology and Medicine are now dead Sciences,
they have become Information Sciences

THE NATIONAL ACADEMIES PRESS
Washington, D.C.
www.nap.edu

2011

Predictive, personalized, preventive, **participatory** (P4) ...

Leroy Hood & Stephen H. Friend

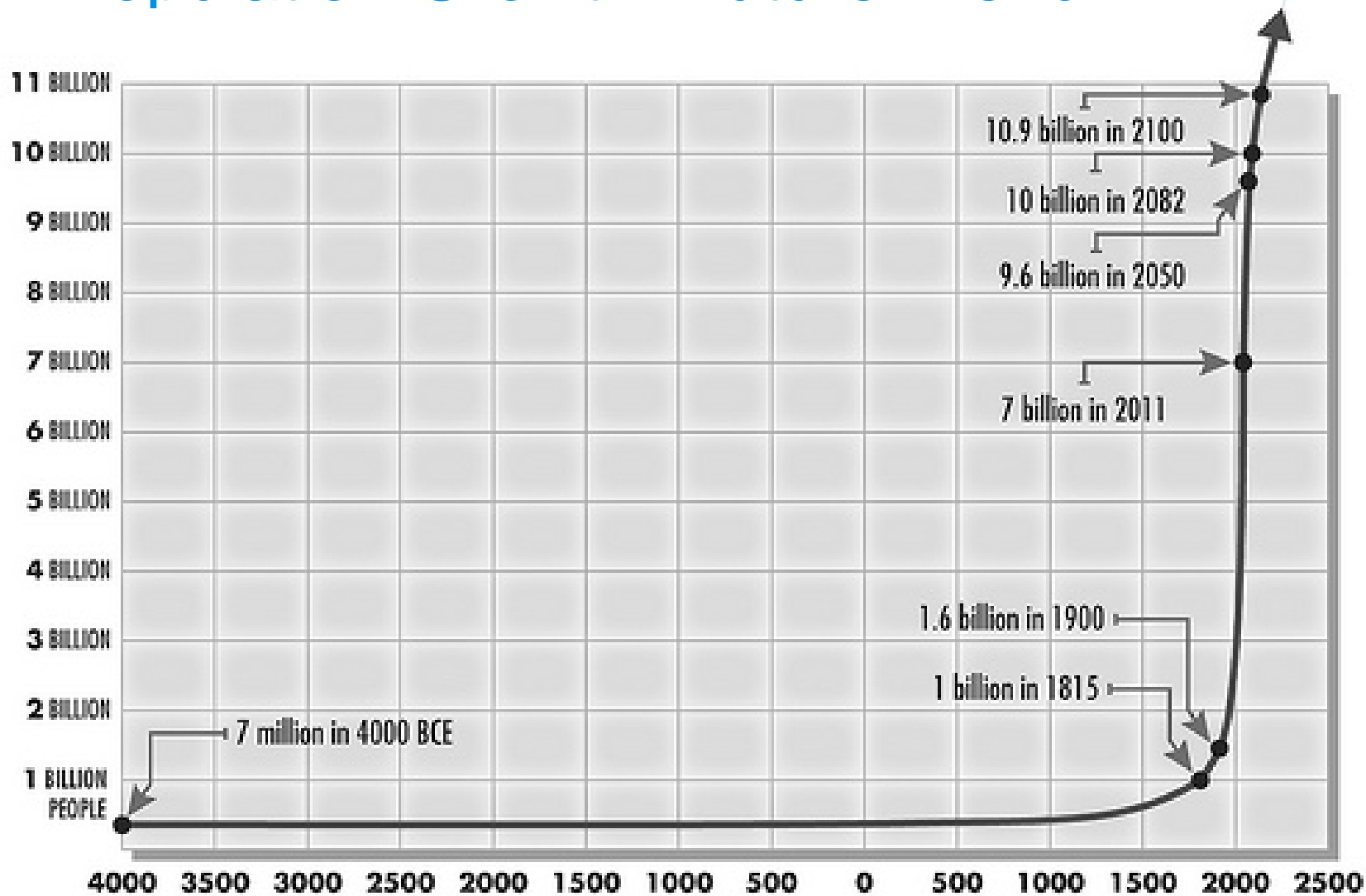
Nature Reviews Clinical Oncology **8**, 184-187 (March 2011)

Personal and Human Population Numbers

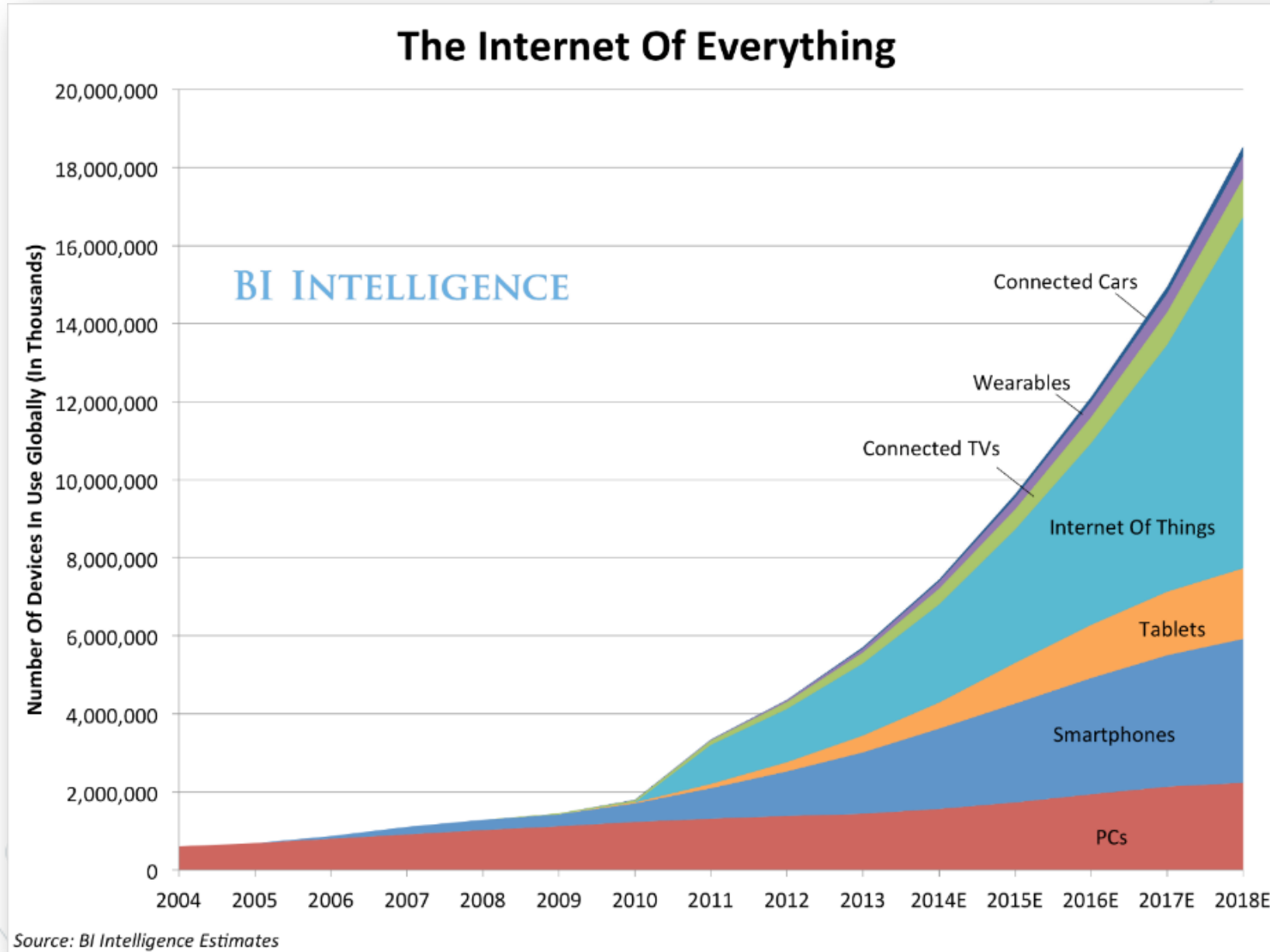
- ⊙ Earth's population = **7 billion people**
- ⊙ Exponential growth started only **200 years ago**
- ⊙ Between year 1000 and 2000 it grew **3 times faster**
- ⊙ In the last 100 years it increased **from 1,5 billion to 6**
- ⊙ Life expectancy increased **by more than 35 years**



Human Population Growth: Future Trend

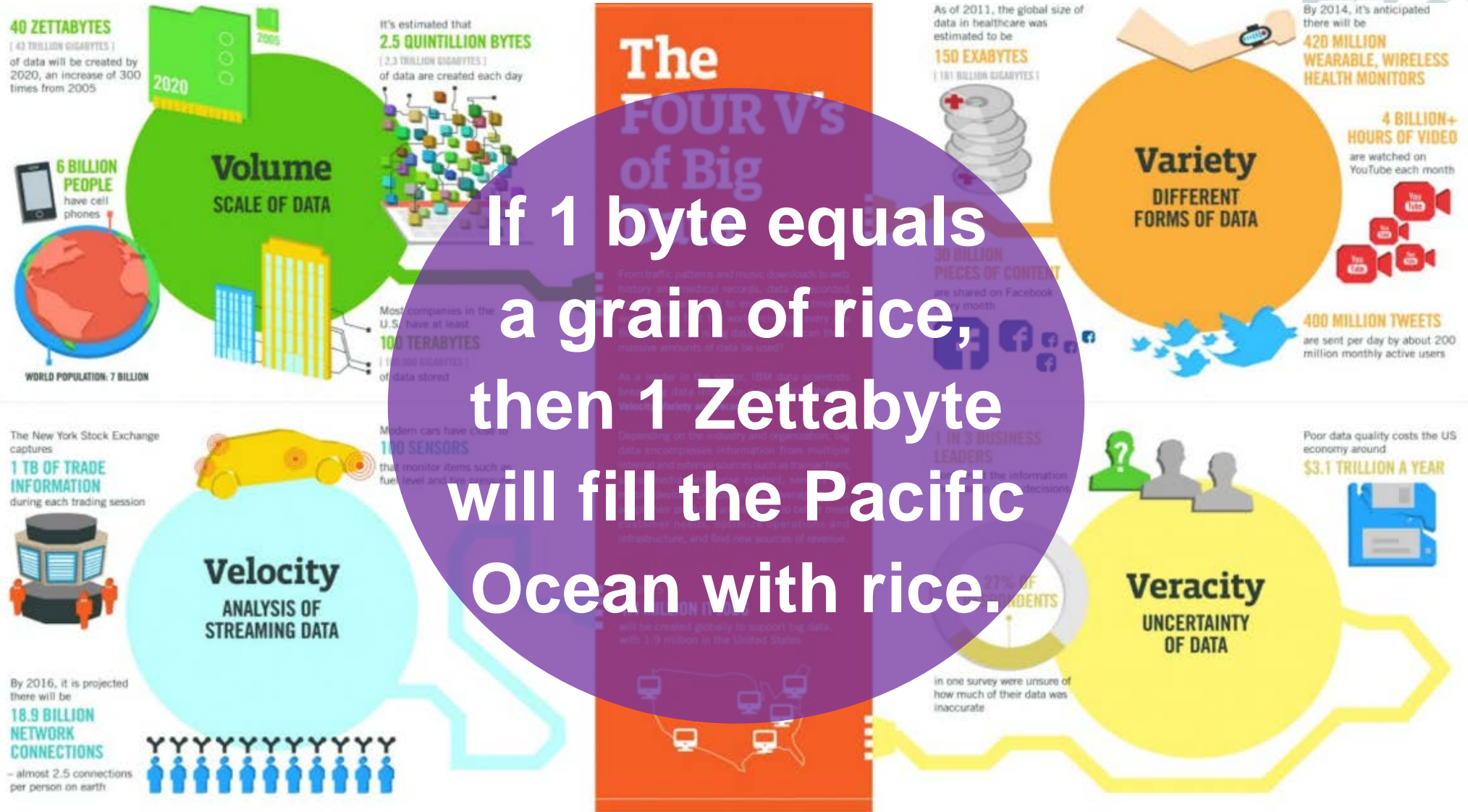


The personal revolution: number and types of devices



Will generate 40 ZettaBytes of Healthdata by 2020

What are we talking here really?

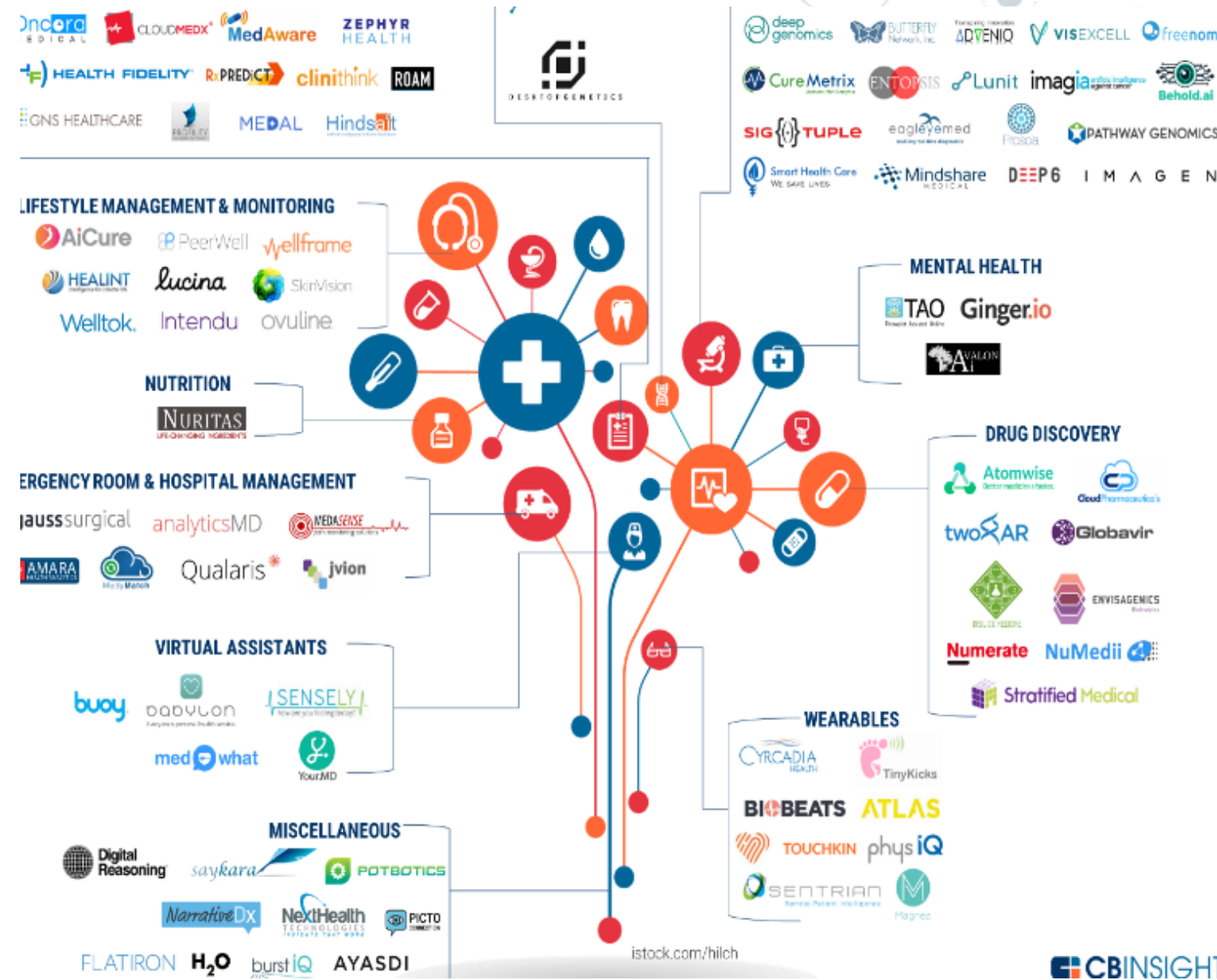


If 1 byte equals a grain of rice, then 1 Zettabyte will fill the Pacific Ocean with rice.

Information and Internet of everything

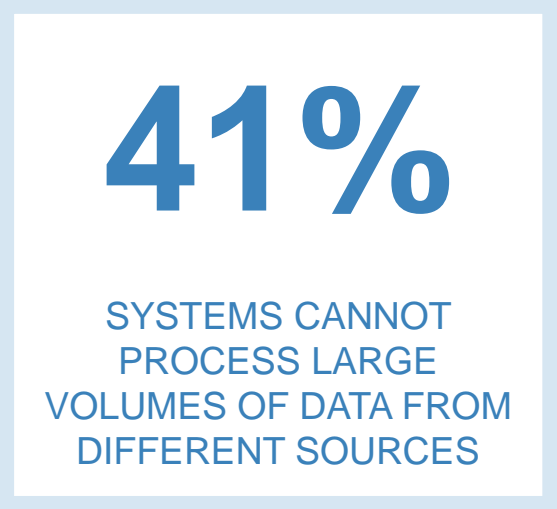
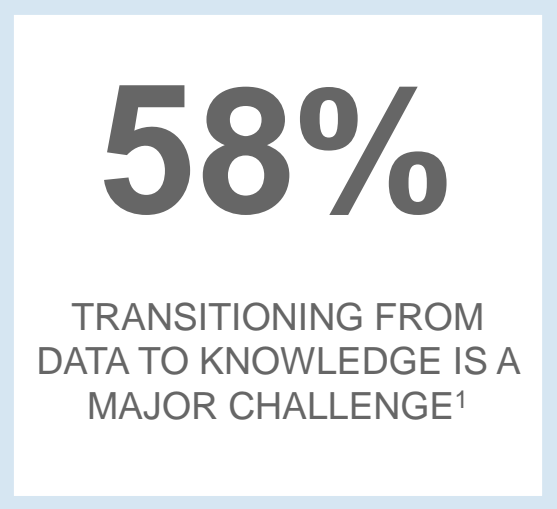
AI Applications in Healthcare Growing Dramatically

- Healthcare Research
- Drug Discovery
- Insights & Risk Mgt.
- Virtual Assistants
- Imaging & Diagnostics
- Wearables
- Lifestyle Mgt & Monitoring
- ER & Hospital Mgt.
- Mental Health



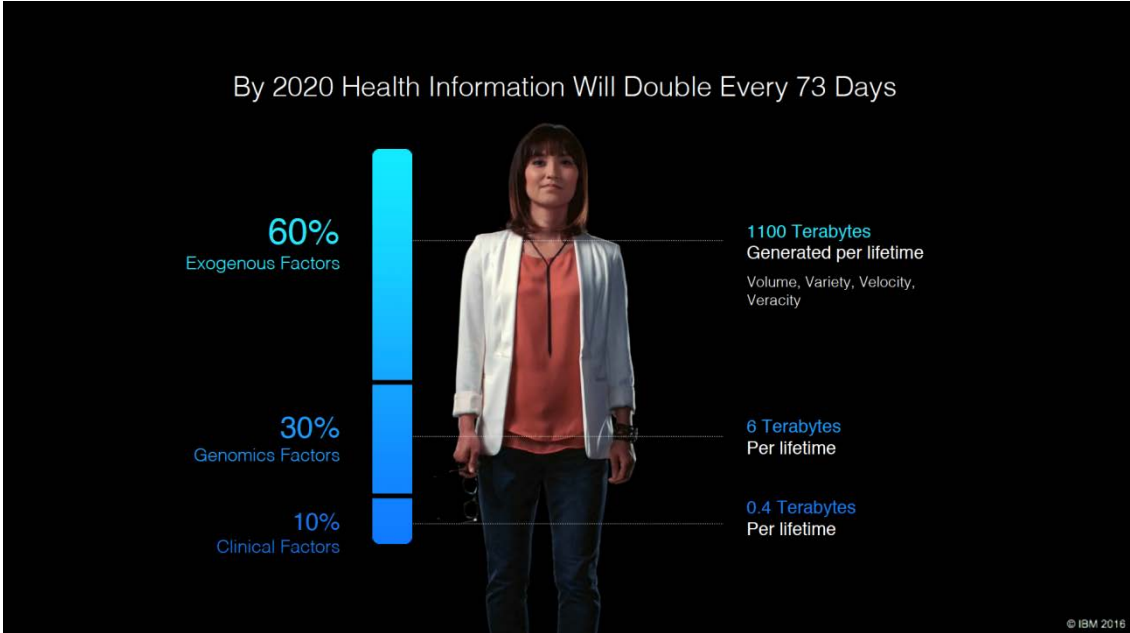
Type and size of data

Data ≠ information ≠ knowledge

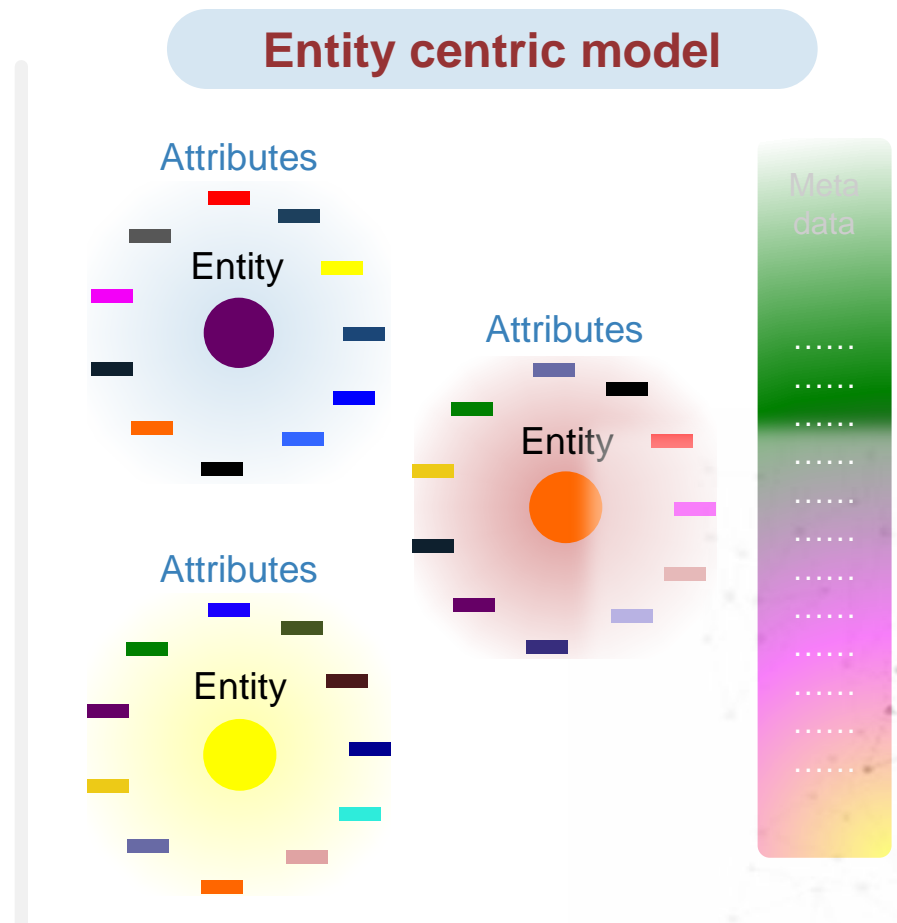
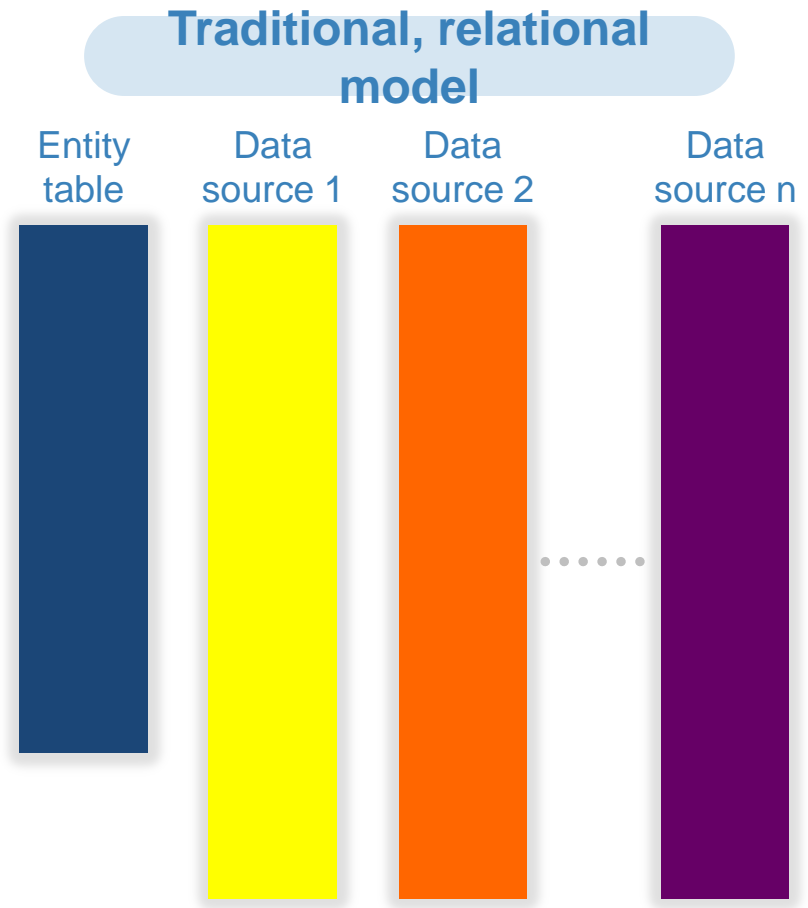


Courtesy of William King, CEO of Zephyr Health (modified)

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



Innovative data analysis models could be game changer



Programmatic data transformation:
Deep Learning



Billions of data connections made



Courtesy of William King, CEO of Zephyr Health (modified)

From internet of everything to customerization of everybody What is one of the Giant thinking and doing?

Scoop: Emails between Apple and FDA hint at future plans

By **Jonah Comstock** | November 28, 2016

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Since its well-publicized meeting with the FDA in 2013, Apple has continued to meet with the agency regularly as well as to correspond by phone and email, according to emails obtained by MobiHealthNews via a Freedom of Information Act request to the FDA.



These emails show that Apple and the FDA have discussed the App Store review process, the 510(k) process, ResearchKit apps, diagnostic apps, working with the FDA in an “unregulated” way and more. The FDA even invited Apple to participate in regular briefings designed to help guide an international effort to harmonize medical software regulation. Though much of the sensitive information is redacted, the emails also point to three regulated medical devices that Apple is seriously pursuing: an app for diagnosing Parkinson’s disease and two separate but related cardiac devices.



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BRIEF

Emails shed light on Apple's healthcare musings

AUTHOR

Meg Bryant

PUBLISHED

Nov. 30, 2016

Dive Brief:

- A three-year trail of emails between Apple and the Food and Drug Administration sheds some light on the tech giant’s future plans in healthcare.
- The emails, [obtained by MobiHealthNews](#) from the FDA via a Freedom of Information Act request, include discussions about the 510(k) process, the App Store review process, Research Kit apps, diagnostic apps and keeping Apple apps in unregulated waters, among other things.

Apple: mHealth

- ⦿ ResearchKit, real-world research laboratory
- ⦿ 5 app of mHealth aimed to Parkinson's disease, diabetes, cardiovascular disease, asthma and breast cancer track
- ⦿ Recording information very useful post market studies involving large numbers of individuals over vast geographical areas
- ⦿ Data collected every second remotely



New Technologies: PatientsLikeMe

PatientsLikeMe

- ◉ A network and at the same time a research platform
- ◉ Through the network, patients may remain in contact with other patients
- ◉ Sharing the experiences
- ◉ Opportunity to learn from the aggregate data of others and see other types of treatments



With nearly 500,000 members, PatientsLikeMe is a **reliable source of information on diseases** and it allowed the publication of more than 80 research studies.

patientslikeme®

A recent study by PatientsLikeMe and Biogen monitored walking activity in people with Multiple Sclerosis (MS). Participants were also surveyed about their experience with the study and attitudes about using a fitness tracker.

Below are select results from the survey.

68%
say the device would help them manage and track their MS



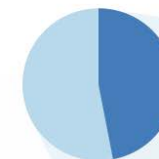
89%
believe activity tracking is important for health management



55%
believe that the device helped change their health routine



47%
had never tracked their activity levels



of 191 survey respondents

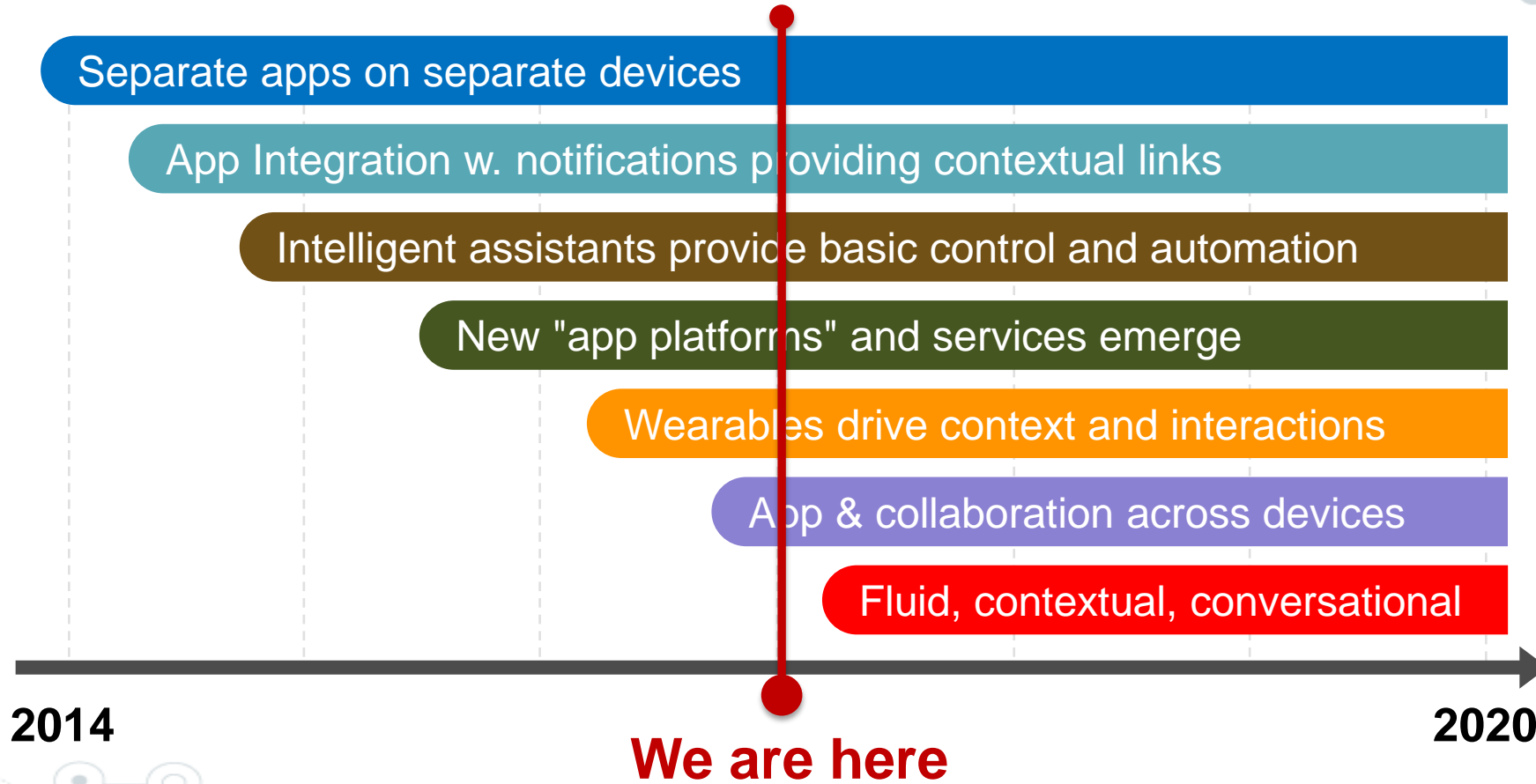
Societal Implications for new answers to new demands

- New organizational model
- Innovation in life sciences and biotech
- Possibility of avoiding recurrence of diseases
- Introduction and monitoring of selective drugs
- Preventive personalised medicine aimed at **healthy** individuals at risk



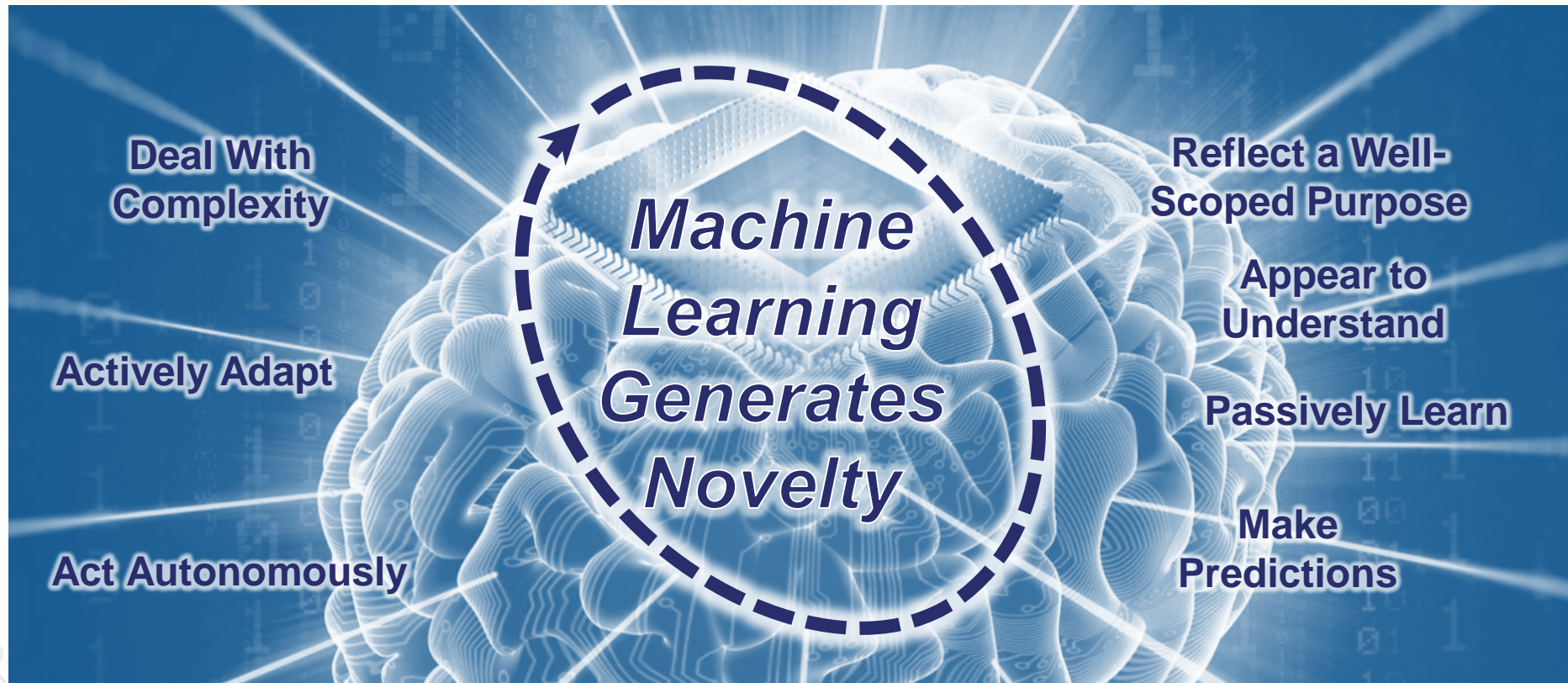
Continuous & ambient user experience

Moving toward a postApp Era



Information of everything + advanced machine learning + advanced systems

The Perfect Storm Ignited the Smart Machine Revolution



In conclusion: Societal Implications of Personalised Medicine

- The most important innovation disrupter: *i.e.* the ITC impact on an expanding set of end-user devices is here now
- This will challenge and force all of us to rethink how data-information-knowledge are being created and used
- Business models will evolve (fast) thanks to smart machine technologies
- We must augment perimeter defense and rule-based security detection with user and entity behavior analytics
- The difference, if any, between patients and consumers is fading away

