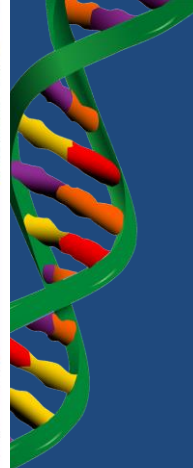


Big Data, the Internet of Things and Dr. Watson in the Era of Precision Medicine: Governance and Regulatory Opportunities and Challenges

Amalia M. Issa, PhD, MPH, FCPP
Professor & Founding Director
Personalized Medicine & Targeted Therapeutics









The New York Times

Big Data

Big Data Picks Up the Pace

By QUENTIN HARDY

March 5, 2014, 1:00 pm

We may be heading into the next phase of big data. The early bets and stand-one products seem to be moving rapidly into more sophisticated uses and

The New York Times

Policy

Big Data Means Big Questions on How That Information Is Used

By NATASHA SINGER

M

BBC NEWS

BUSINESS

THE TECHNOLOGY OF BUSINESS

3 March 2014 Last updated at 19:13 ET

Big Data: Are you ready for blast-off?

By Matthew Wall
Business reporter, BBC News

As Technology of Business begins a month-long series of features on the theme of Big Data, we kick off with a Q&A backgrounder answering some of those basic questions you were too afraid to ask.

P²MT²



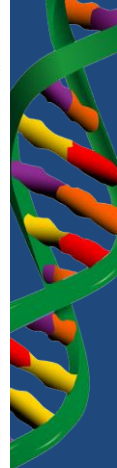
Big Data: Volume, Variety, Velocity, Veracity, Value

Rx

Dx



1,000,000,000,000,000,000,000



BYTE



To help visually compare different amounts of data, we ask you to consider 1 byte as equal to 1 inch.



KILO

A kilobyte, or 1,000 bytes, would then be as long as six cars stacked end to end.



MEGA

Riding your bike around the block 60 times.



GIGA

Four times back and forth between Chicago and London.



TERA

Round trip to the moon and back—33 times.



PETA

The distance between Earth and Pluto in two round trips.



ABAJOURNAL.COM



P²MT²



The Revenant



The Revenant

Rx

Dx





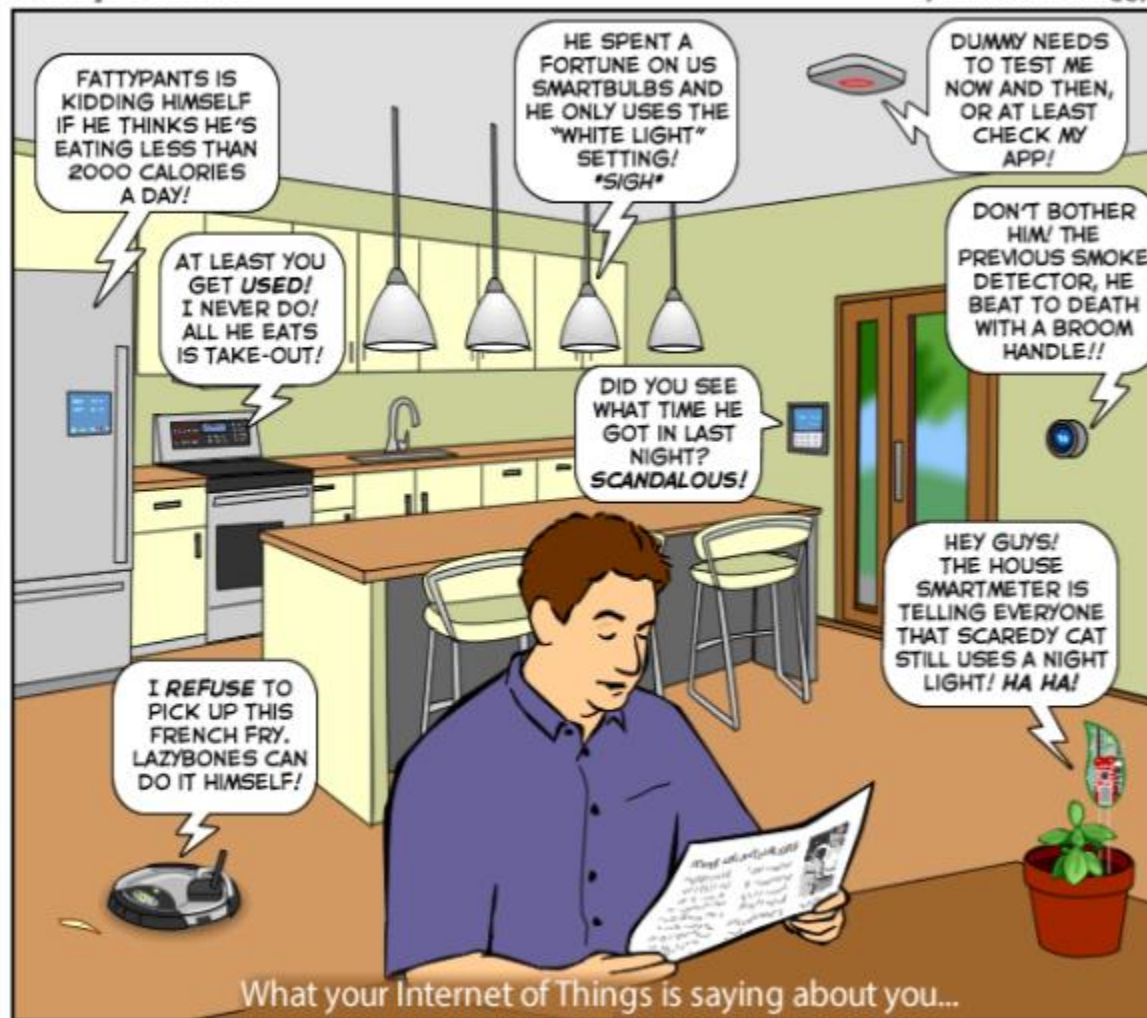
Rx

Dx



The Joy of Tech™

by Nitrozac & Snaggy



What your Internet of Things is saying about you...

© 2014 Geek Culture

joyoftech.com

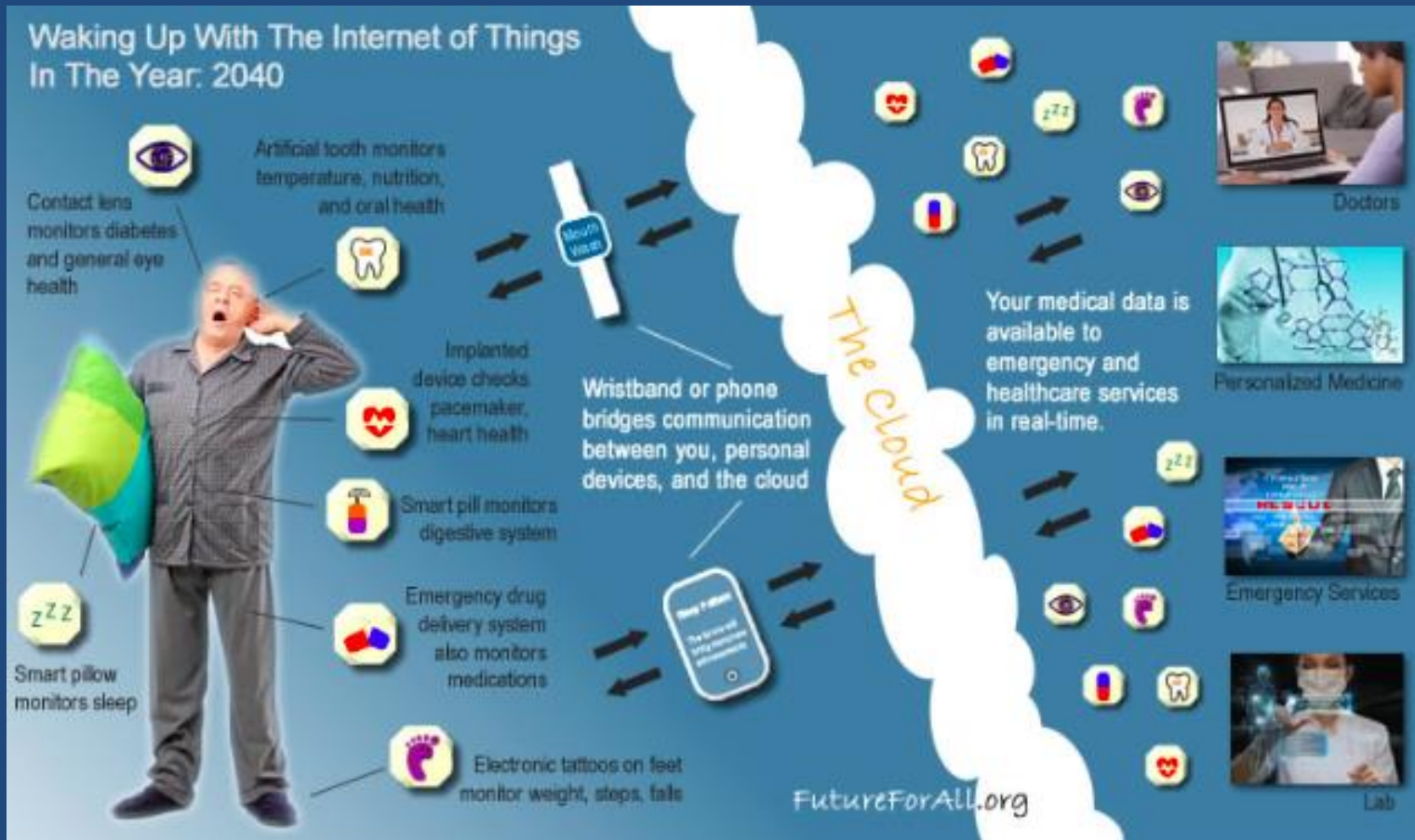
P²MT²



Internet of Things and Precision Medicine

Rx

Dx

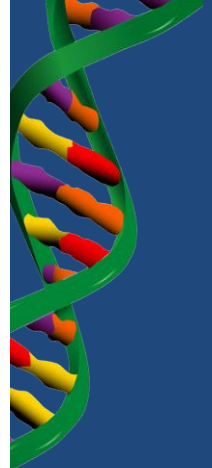


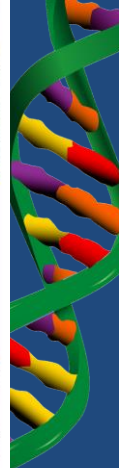


Rx



Dx

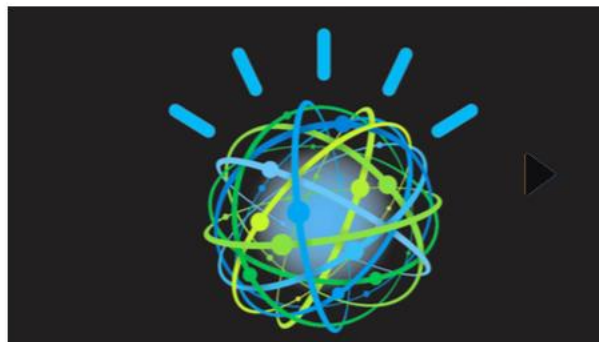




On Cancer

Memorial Sloan Kettering Trains IBM Watson to Help Doctors Make Better Cancer Treatment Choices

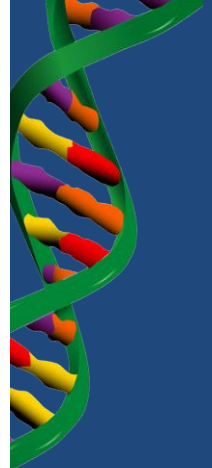
on Friday, April 11, 2014

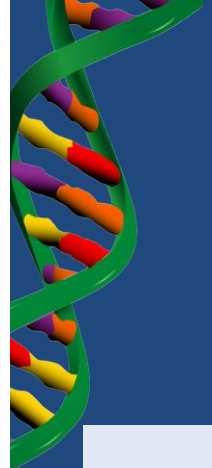


A team of physicians and analysts at Memorial Sloan Kettering has been "training" IBM Watson for more than a year to develop a tool that can help medical professionals choose the best treatment plans for individual cancer patients.



Eyjafjallajökull volcanic eruption Iceland, 2010







Critical Question:

What concentration of volcanic ash is harmful to jet engines?

Dx

11010100
01010101
01101010
10100100

Na143 K
3.7 BP
110/70
HCT32 BUN
12.9 Pul

11010100
01010101
01101010
10100100

11010100
01010101
01101010
10100100

GCGTAG
ATGCGTA
GGCATGC
ATGCCAT



UUAGUG
AUGCGU
CUAGGC
AUGCAU

arg-his-pro-
gly-leu-ser-
thr-ala-trp-
tyr-val-

11010100
01010101
01101010

11010100
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01101010

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11010100
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10100100

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A photograph of a server room with rows of yellow server racks. A person is walking in the background, slightly out of focus. The text "What Can We Do With All This Data?" is overlaid in white on the left side of the image.

**What
Can We
Do With
All This
Data?**



Current Regulation and Laws Inadequate

- ✧ Health Insurance Portability and Accountability Act
- ✧ FDA Medical Device Regulation
- ✧ Electronic Communications Privacy Act
- ✧ Private Law (Contractor Tort)
- ✧ Fourth Amendment



HIPAA (45 C.F.R. 160.103)

- “Protected Health Information” includes individually identifiable health information that (1) is created or received by covered entities, (2) relates to past, present or future physical or mental health or condition . . . provision of healthcare . . . or payment for care and (3) identifies the individual, or with which there is reasonable basis to believe the information can be used to identify the individual.

FDA Medical Device Regulation



Private Law (Tort)

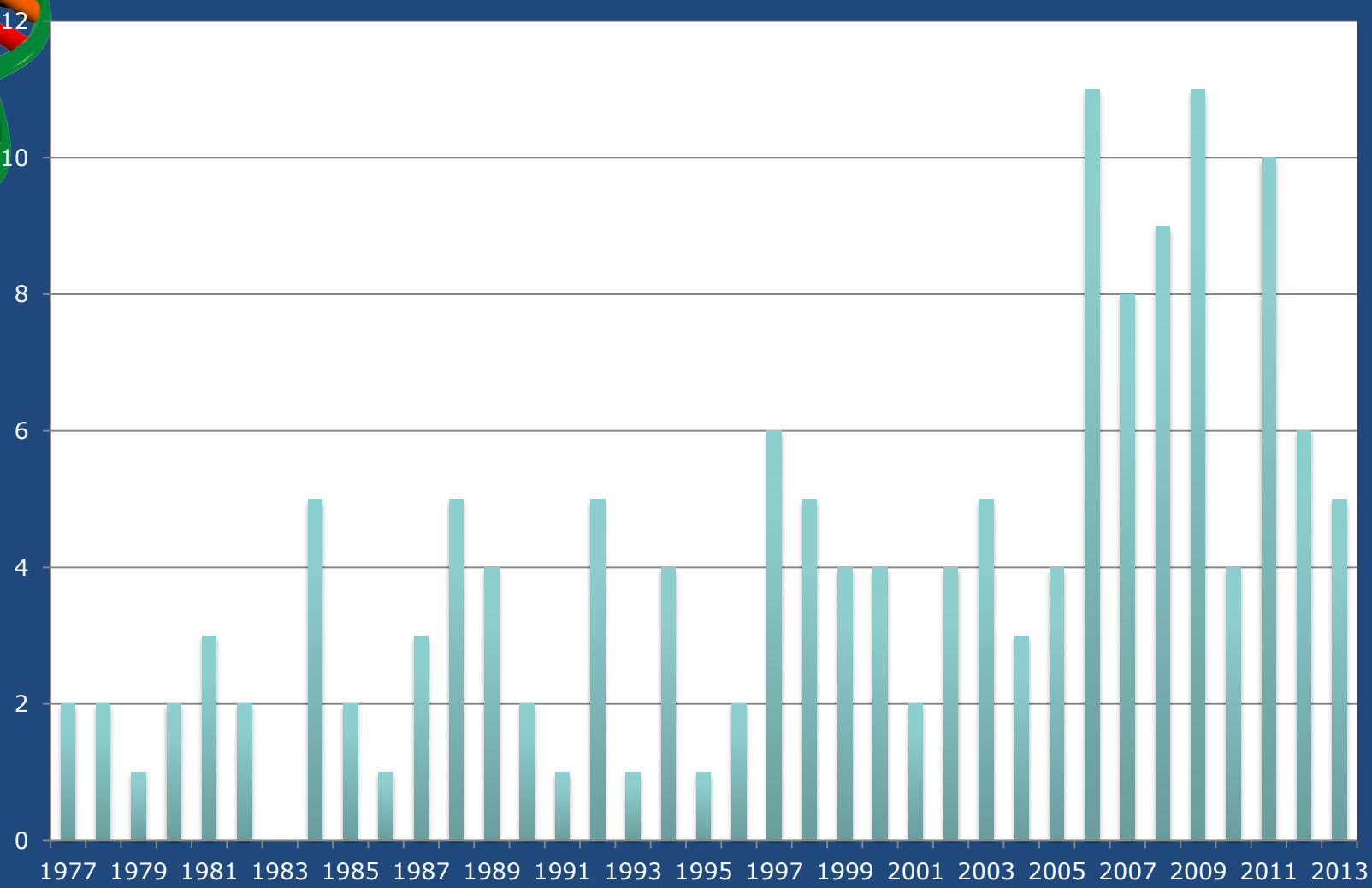


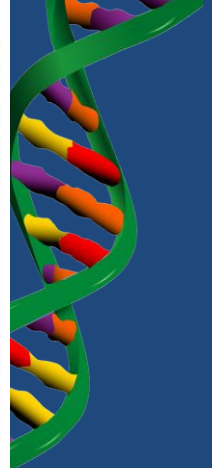
Liability Issues: Questions Not Answers

- Where will the data be stored and backed up?
- Who can access it?
- Adequate security controls and audits in place?
- Absolute right to get the data back without conditions?
- Can provider use or access the company's data?
- Do third parties have access to the data?
- Control of Data: Does control change as data moves?
- Disclosure and/or consent?
- Privacy policies in place, agreed to and meet regulations?



Reported Cases of Genetics Liability Litigation: 1977-2013





TECHNOLOGY

When Fitbit Is the Expert Witness

An upcoming court case will use fitness-tracking data to try and prove a plaintiff's claim, bringing us one step closer to the new age of quantified self incrimination.



Andrey Butskan/Shutterstock/Fitbit

KATE CRAWFORD | NOV 19, 2014

Self-tracking using a wearable device can be fascinating. It can drive you to exercise more, make you reflect on how much (or little) you sleep, and help you detect patterns in your mood over time. But something else is happening when you use a wearable device, something that is less immediately apparent: You are

Questions Not Answers

- Should a computer like Watson have decision authority?
- Will Watson-health (or a cognitive computing platform like it) be admissible as an expert witness in court?
- Can it set a new standard of care?
- Should you be able to “opt out” of data aggregation?
- Should you be required to “opt in” to data aggregation?
- Is there a “moral duty” to participate in some way if you want the benefits?
- Should there be hard limits on data collection, retention or sale?





Precision Medicine Big Data and Reducing the Possibility of Malpractice

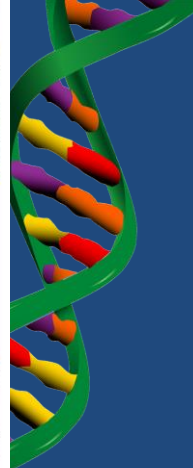
- Fewer adverse events
- Reduced variation in practice
- Early notification before problems arise
 - Provider level
 - Patient level



Rx

Item	Description	Quantity	Unit Price	Total Price
17	Office Visit	1	100.00	100.00
18	Office Visit	1	100.00	100.00
19	Office Visit	1	100.00	100.00
20	Office Visit	1	100.00	100.00
21	Office Visit	1	100.00	100.00
22	Office Visit	1	100.00	100.00
23	Office Visit	1	100.00	100.00
24	Office Visit	1	100.00	100.00
25	Office Visit	1	100.00	100.00
26	Office Visit	1	100.00	100.00
27	Office Visit	1	100.00	100.00
28	Office Visit	1	100.00	100.00
29	Office Visit	1	100.00	100.00
30	Office Visit	1	100.00	100.00

Dx





After a short stay in America, Michelangelo's
David Returned to Europe

Thank you to my team at the Personalized Medicine & Targeted Therapeutics Center and to the patients, providers, and others who participate in our studies!

Thanks to all our funders including the NHGRI R01 HG006145 (Marchant, Issa and Campos-Outcalt) which supported this work.

