12th International Pharmaceutical & Medical Device Compliance Congress

CLOSING PLENARY SESSION
Embracing Change in the Digital Health Era

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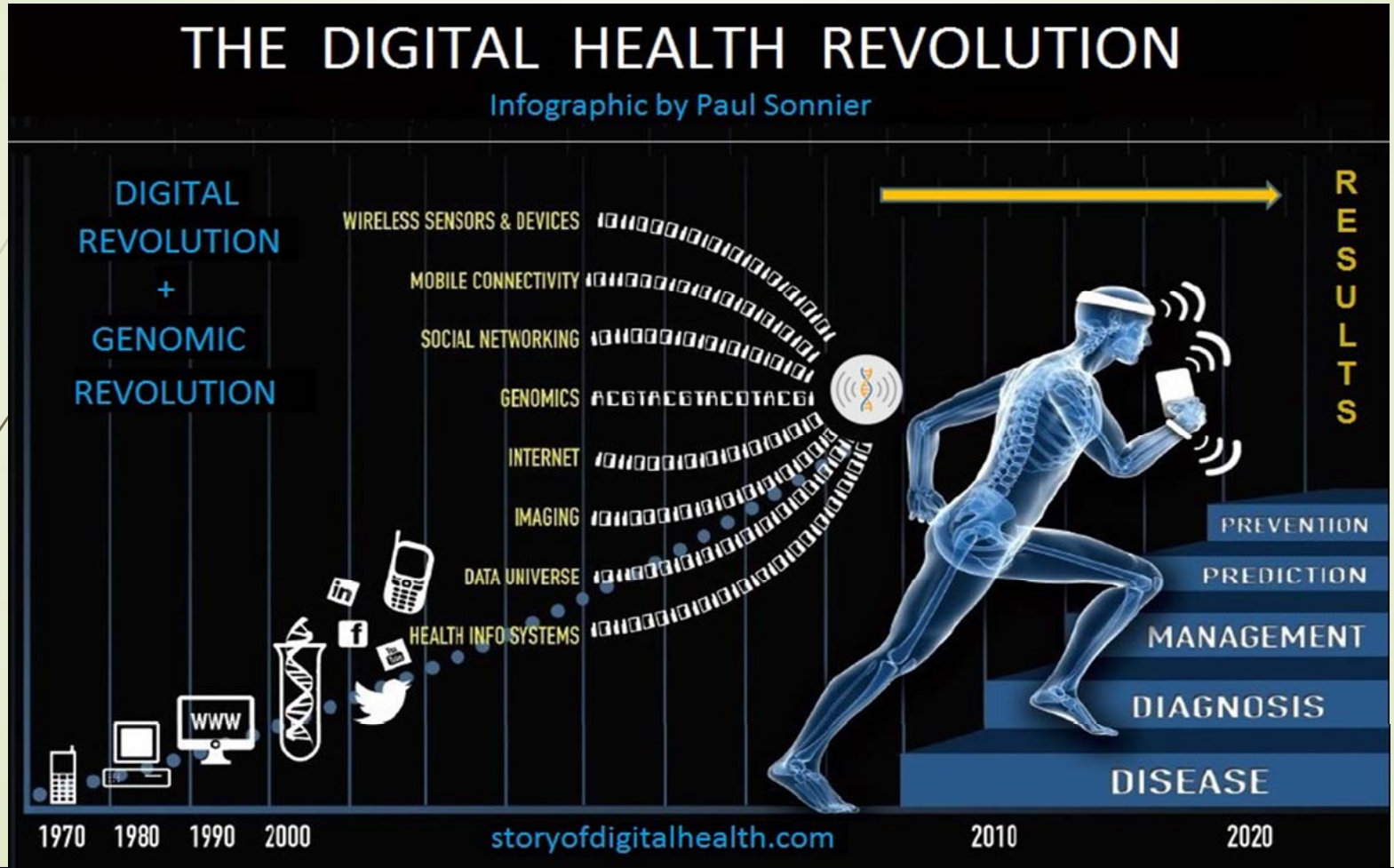
Introduction & Declaration of Interest

- Marie-Claire Pickaert is an **expert in health systems and policies** and has **in-depth knowledge of the pharma industry in Europe**, with 40-year experience in leading positions in associations. She is an Economist by training.
- For the bigger part of her career with pharma, she was involved in many platforms, round tables and reflections around **pricing**, **value-based reimbursement**, **outcomes research** and **healthcare reforms**, both at European (with EFPIA) and national (with AGIM) levels.
- In the latter part of her career, she engaged in projects **imagining the future of medical learning**.
- For 10 years, she coordinated **ethics and compliance** activities for the pharmaceutical industry in Europe and served as EFPIA's Chief Compliance Officer.
- Marie-Claire declares having **no direct / indirect financial interest** in any life science company.

PERSPECTIVES OF THE FUTURE

Being Disruptive or Being Disrupted

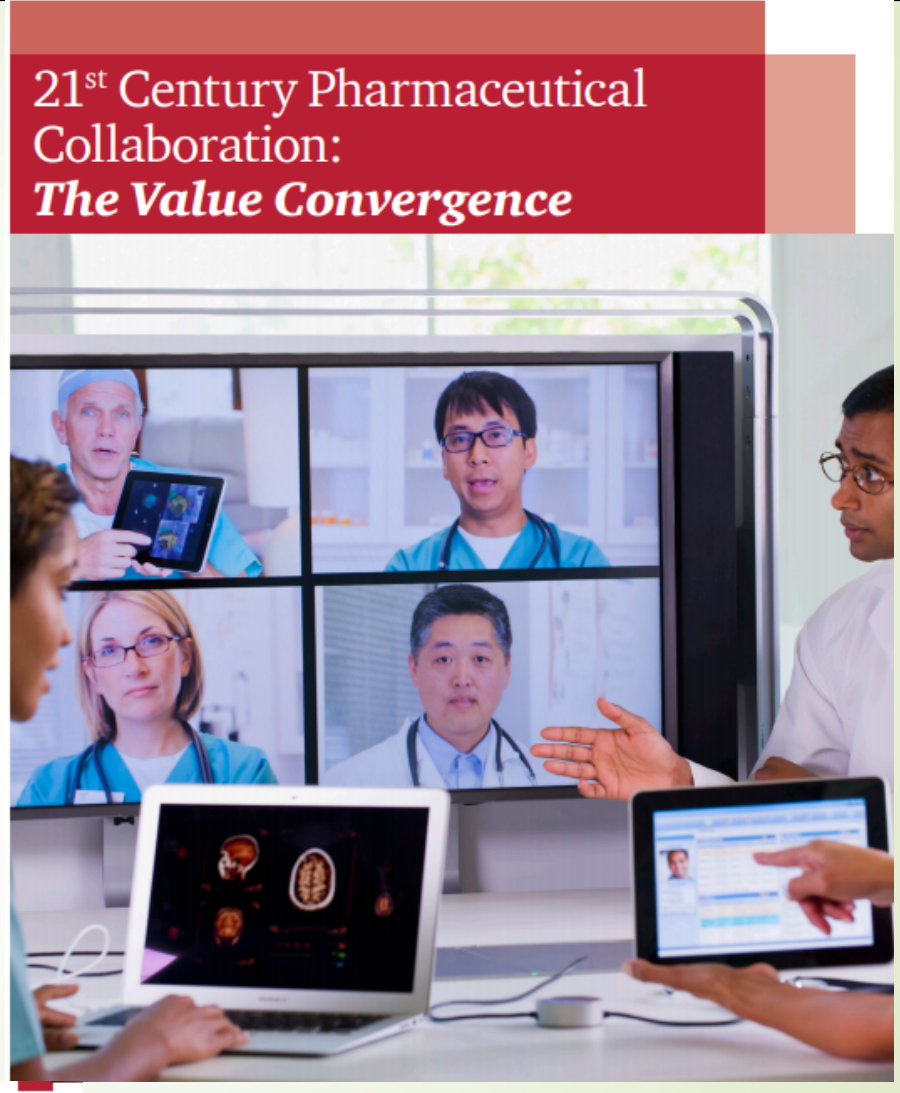
Embracing trends towards a new health ecosystem


THE DIGITAL HEALTH REVOLUTION
Infographic by Paul Sonnier
DIGITAL REVOLUTION + GENOMIC REVOLUTION
WIRELESS SENSORS & DEVICES
MOBILE CONNECTIVITY
SOCIAL NETWORKING
GENOMICS
INTERNET
IMAGING
DATA UNIVERSE
HEALTH INFO SYSTEMS
RESULTS
PREVENTION
PREDICTION
MANAGEMENT
DIAGNOSIS
DISEASE
1970
1980
1990
2000
storyofdigitalhealth.com
2010
2020

Health Research Institute
July 2015

Personal health information is the new currency of drug development and commercialization.

Novel collaborations are helping pharmaceutical and life sciences companies maximize the value of new medicines.



pwc

Abilify MyCite (aripiprazole tablets with sensor)

First digital pill – a system that includes an **ingested sensor**, **wearable patch**, **smartphone application** and **online portal to track medication compliance**.

For doctors, Abilify MyCite represents an opportunity to track adherence to prescribed drug therapy in a way that hasn't been available before, which could **improve the overall coordination of care**.

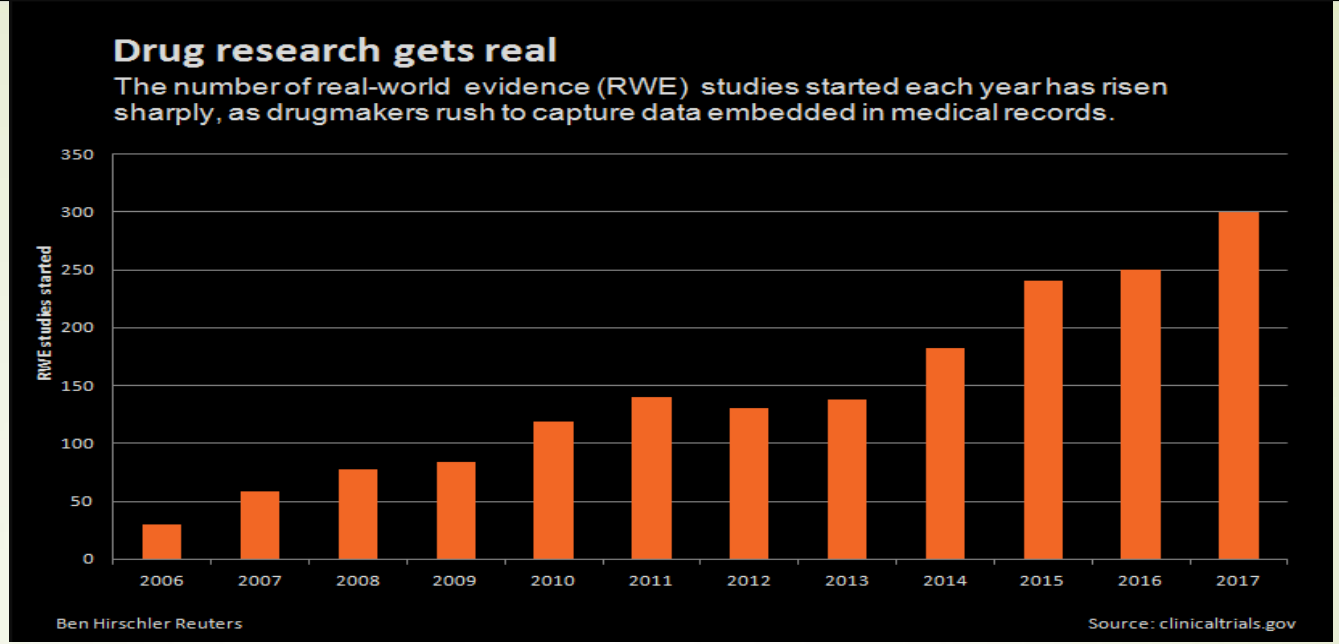
Source: SCRIP (electronic) November 14th, 2017

The digital health revolution: tech giants and their impact on pharma- **Drug discovery**, quicker clinical trial recruitment, **real word data generation**, better patient adherence and improved diagnostics/monitoring. Dramatic change is underway as companies such as **Google, Apple and Dell** expand use of their digital health platforms. What are the **organisational/cultural challenges** industry must overcome and are **tech giants** friends or foes?

Designs on the future of Healthcare: the ambitions of Google, Apple et al provides a detailed 360-degree scan of current and upcoming digital technologies and technology players that will radically alter the way pharma conducts its business.

"Technology is forcing us to go beyond how we traditionally do things in terms of healthcare delivery, but also in terms of life sciences development. We are going much faster through the enabling technologies." – Michael Greenberg, Sanofi Pasteur

Source: Insight Pharma Reports: "Designs on the Future of Health: the Ambitions of Google, Apple, et al; Executive Summary; November 20th, 2017



The **ability to capture the experience of real-world patients**, who represent a wider sample of society than the relatively narrow selection enrolled into traditional trials, is increasingly useful as medicine becomes more personalized.
However it also opens a new front in the **debate about corporate access to personal data** at a time when tech giants Apple, Amazon and Google's parent Alphabet are seeking to carve out a healthcare niche.

Source; Ben Hirschler, Reuters
March 1st, 2018

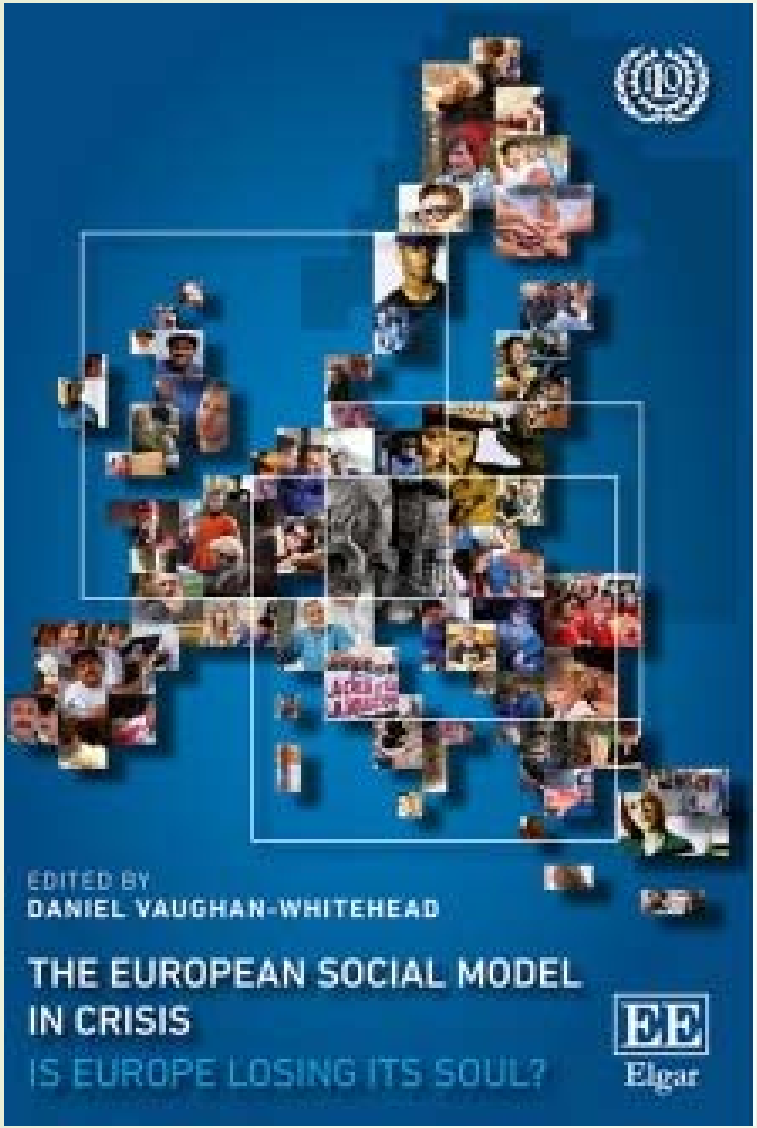
MOVING PIECES IN THE LANDSCAPE

renewed health eco-system, where digital will require anticipation and adaptation in life science sectors

Economic Realities

Social Shift

Technological Advances


EDITED BY
DANIEL VAUGHAN-WHITEHEAD
THE EUROPEAN SOCIAL MODEL IN CRISIS
IS EUROPE LOSING ITS SOUL?
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Elgar

Building Trust in the New Era

Moving from F2F to Connected Relationships

INCREASED NUMBER OF PARTNERS

Each insisting on their (exclusive) legitimacy

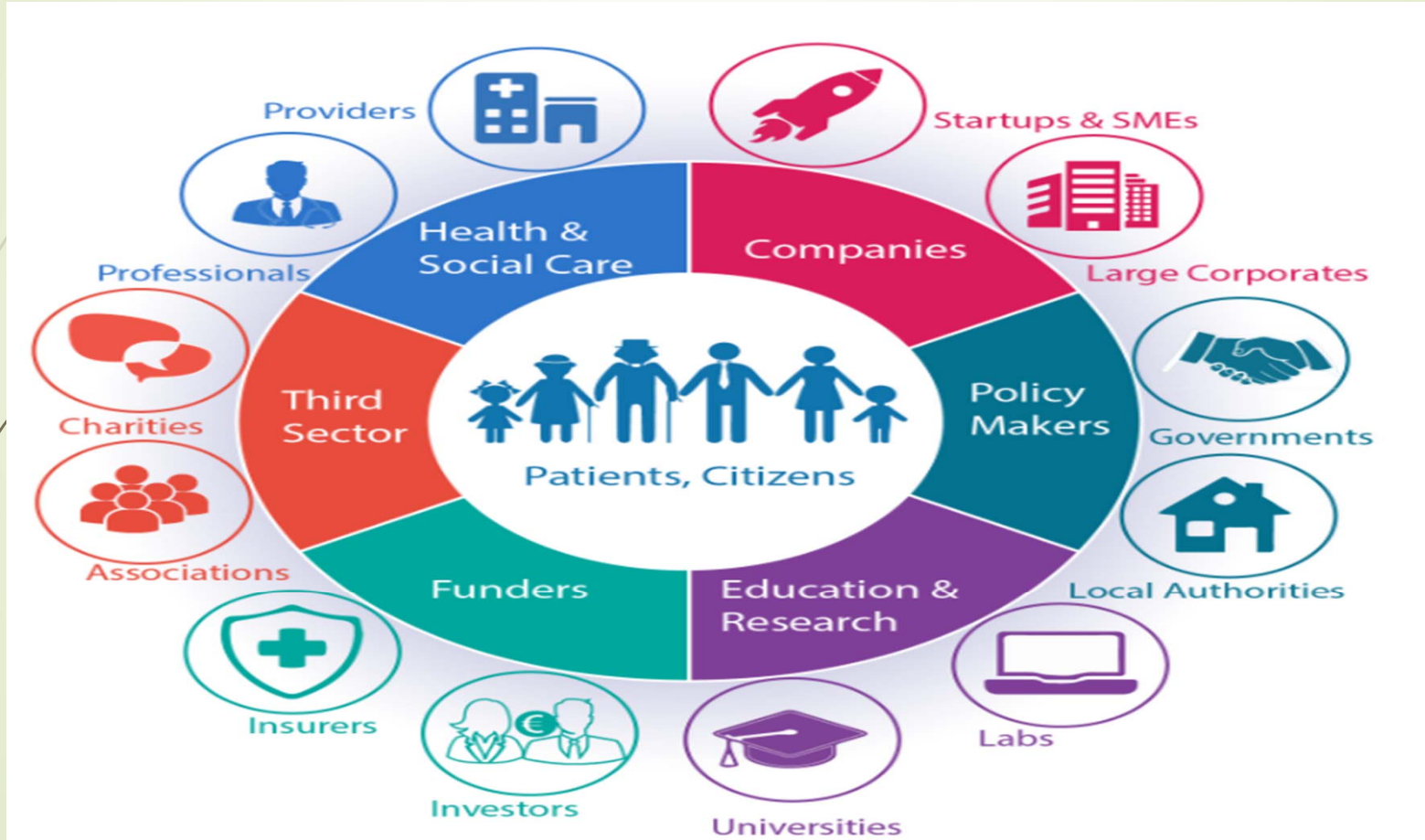


Fig. 1 The multi-stakeholders Digital Health Ecosystem

THE "SCIENCE WARS" STORY
Critical of the evidence-base

Source: "Are we all scientific experts now", Harry COLLINS, 2014 (published by Policy Press)

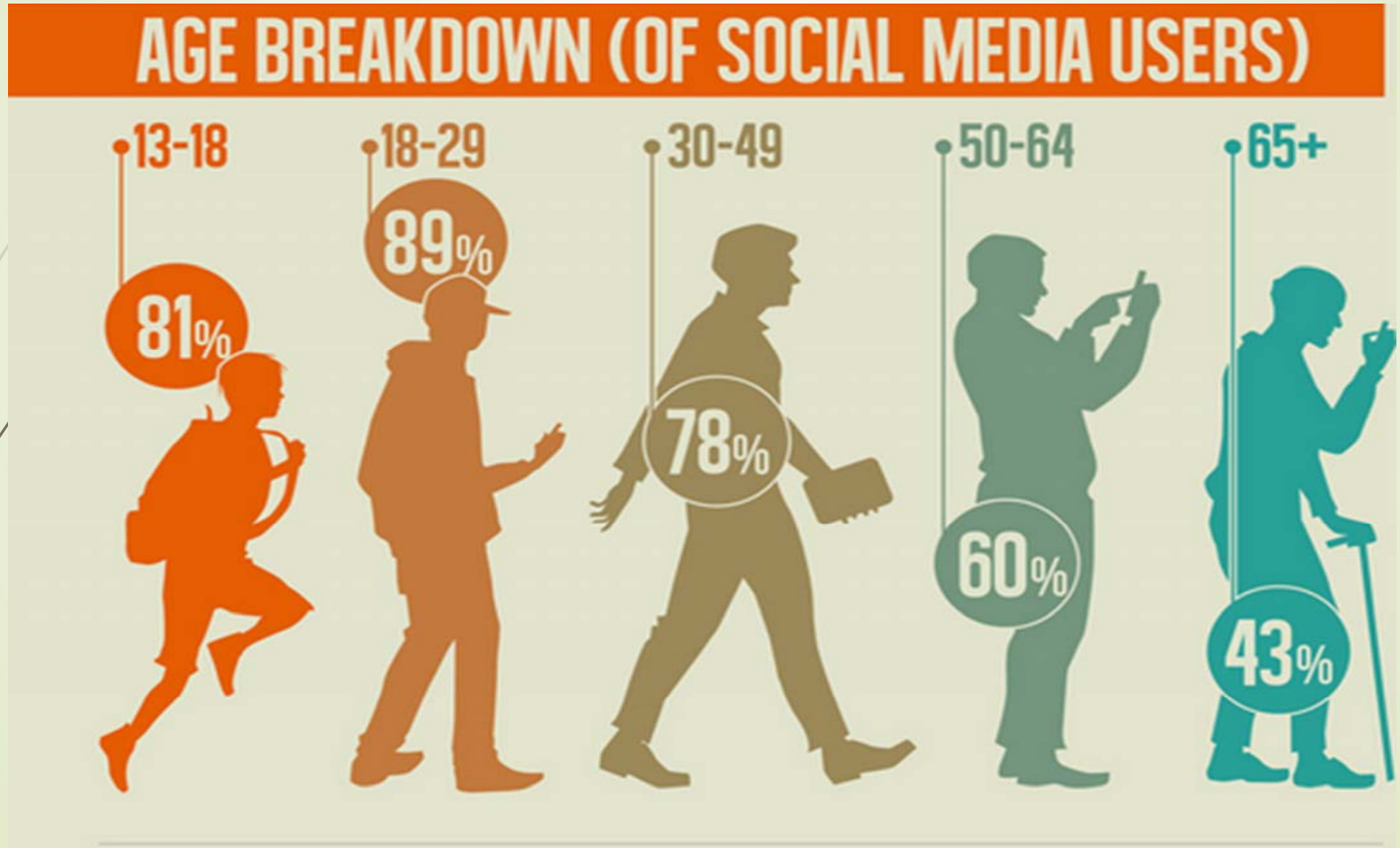
Scientists have no firmer a grip on facts and truth than anyone else: since science is a social activity, results could be coloured by who presented them and so could not represent ultimate truth.

Many different groups of people, **scientists and non-scientists alike, should contribute to decisions**.

Whilst answering the questions "*Are We All Scientific Experts Now?"* with a resounding 'no', those holding different kinds of expertise have a recognised role in scientific debate (for instance for **whistle-blowers who draw attention to perceived lapses in scientific process** – for example, when scientists are paid by companies for publishing favourable results).

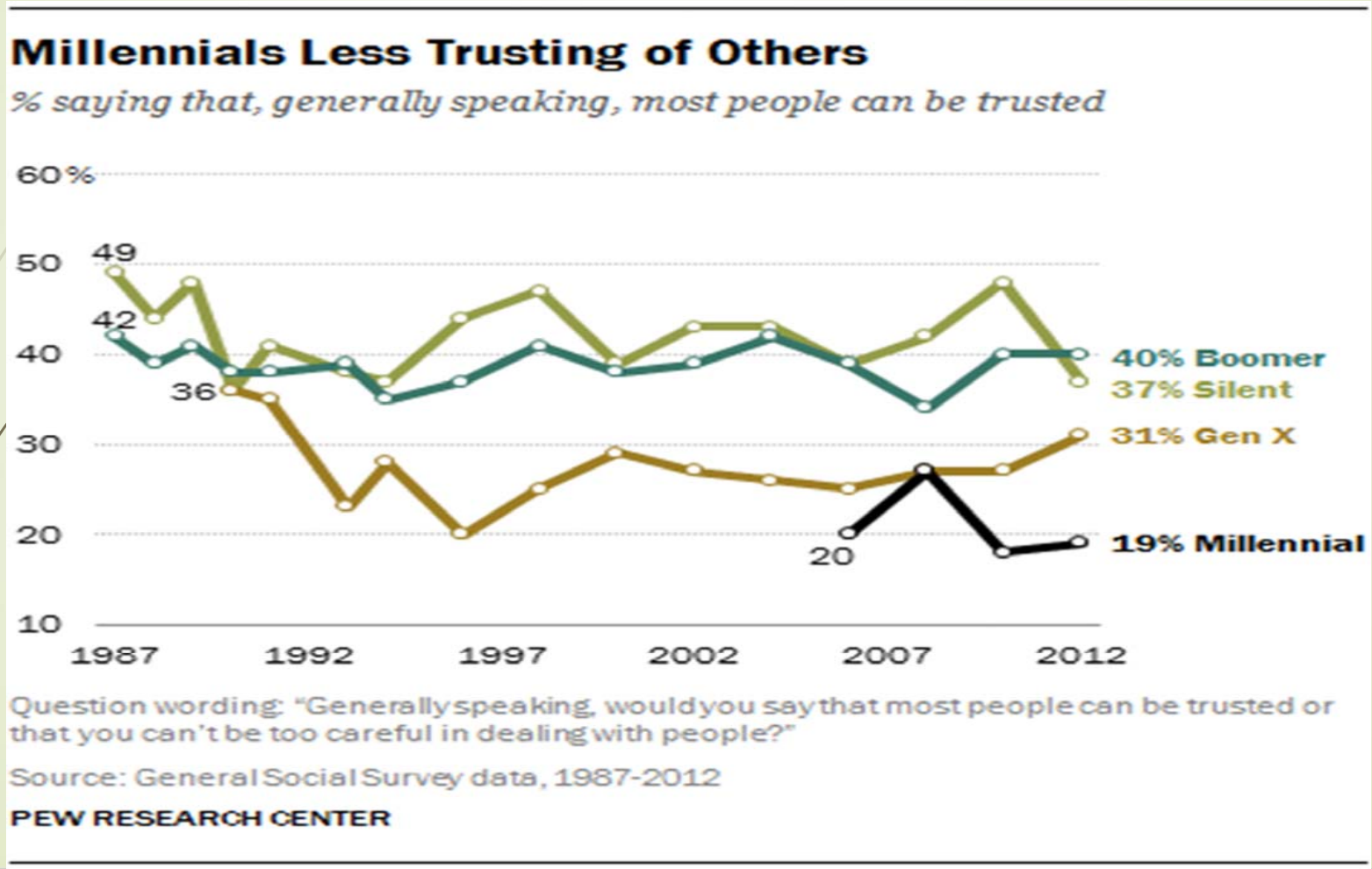
THE GENERATION GAP

Talking differently, Communicating differently



MISTRUST AS A RULE

Try to convince me



KEEPING THE BALANCE RIGHT

Call for caution: recognition of the benefits of the digital society , but also the dangers of the invading digital world

The "Buzz Court": the reign of the generalised presumption of guilt (whatever the source, whatever the evidence)

"Networks of Anger": social media protects the anonymity of the provider of information (with risk of – intended or not-intended – misrepresentation), but leaves those attacked defenceless

Source: Trends Tendances March 15th , 2018

The new Regulations on medical devices

On 5 April 2017, 2 new Regulations on medical devices were adopted, and they entered into force on 25 May 2017. These replace the existing Directives.

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

The new rules will only apply after a transitional period. Namely, 3 years after entry into force for the **Regulation on medical devices (spring 2020)** and 5 years after entry into force **(spring 2022) for the Regulation on in vitro diagnostic medical devices**.

50 years of pharmaceutical legislation

The **requirements and procedures for marketing authorisation**, as well as the rules for monitoring authorised products, are primarily laid down in Directive 2001/83/EC and in Regulation (EC) No 726/2004. They also include **harmonised provisions for the manufacture, wholesale or advertising** of medicinal products for human use.

Additionally, EU legislation provides for **common rules for the conduct of clinical trials** (to test the safety and efficacy of medicines under controlled conditions) in the EU. Various rules have also been adopted to address the particularities of certain types of medicinal products and promote research in specific areas:

- Medicinal products for **rare diseases** ('Orphan medicines') (Regulation (EC) No 141/2000
- Medicinal products for **children** (Regulation (EC) No 1901/2006
- **Advanced therapy** medicinal products (Regulation (EC) No 1394/2007

Self-regulation in Medical Products

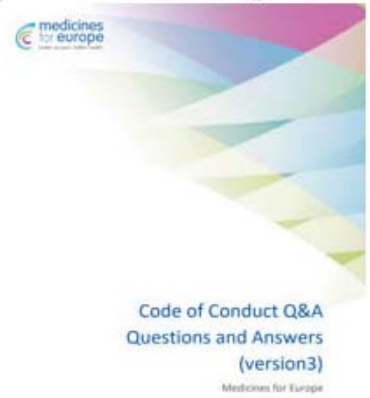
efpia
European Federation of Pharmaceutical Industries and Associations

Patient organisations

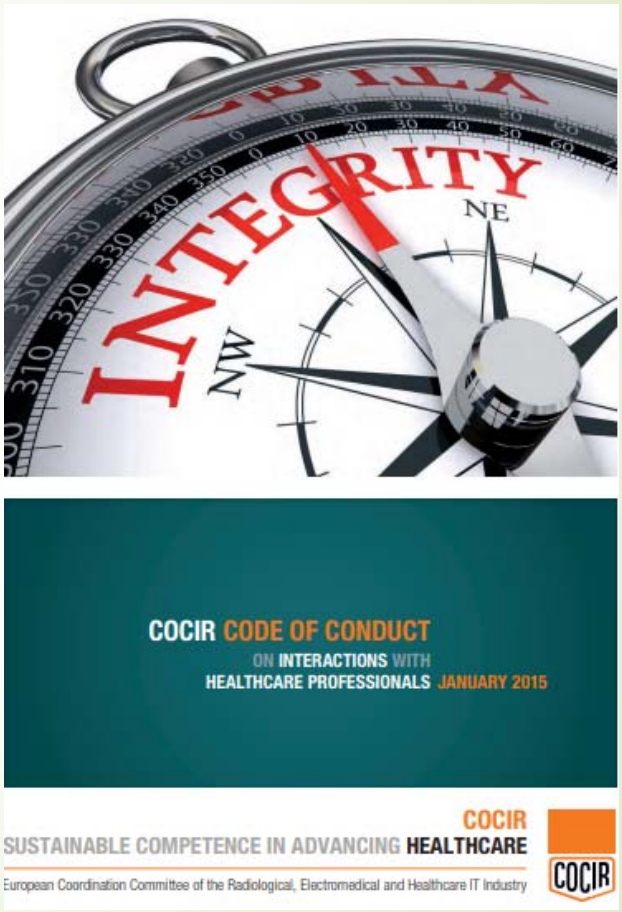
Healthcare professionals (HCPs)

Disclosure of payments to HCPs

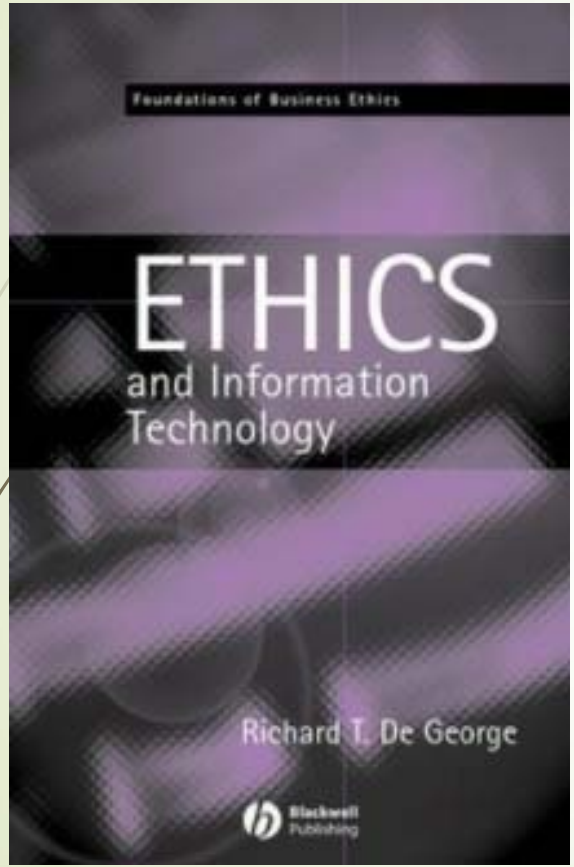
medicines for europe
better access. better health.



Self-regulation in Medical Devices, Diagnostics & Medical Equipment



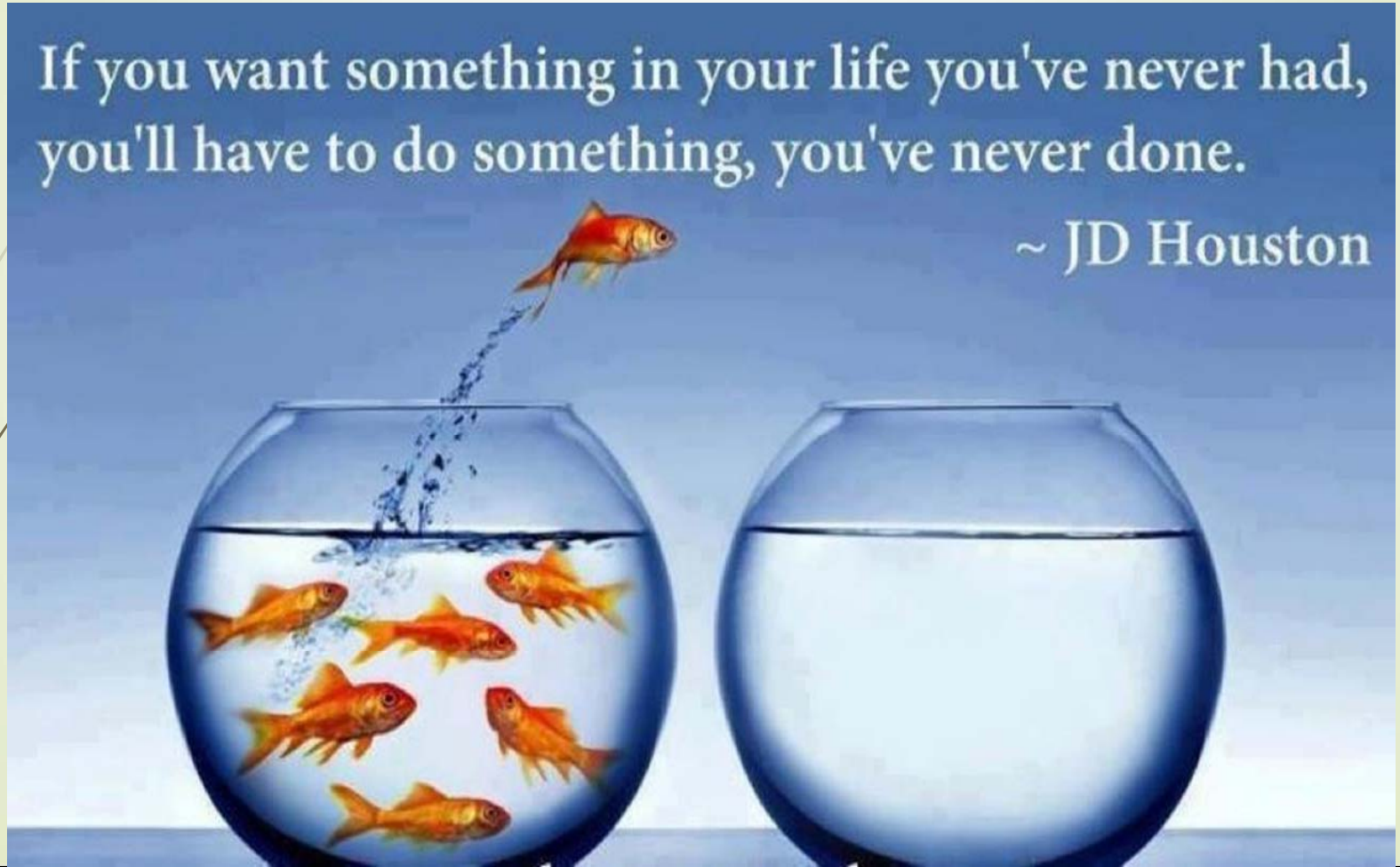
Ethics & Business Integrity in non life-science sectors



- **2002: First study of business ethics to take into consideration the plethora of issues raised by the Information Age.**
- Explores a wide **range of topics** including: marketing, privacy, and the protection of personal information; employees and communication privacy; intellectual property issues; the ethical issues of e-business; Internet-related business ethics problems; and the ethical dimension of information technology on society.
- Uncovers **previous ignored ethical issues**.
- Underlines the **need for public discussion** of the issues.
- **Argues that computers and information technology have not necessarily developed in the most ethical manner possible.**

Consolidation of general ethical principles that all sectors embrace and areas of convergence of code provisions, and

increasing **readability of applicable standards** and reducing divergences that may "discredit" self-regulation.


If you want something in your life you've never had,
you'll have to do something, you've never done.
~ JD Houston

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