



# How European RIs can boost Open Science & Open Innovation

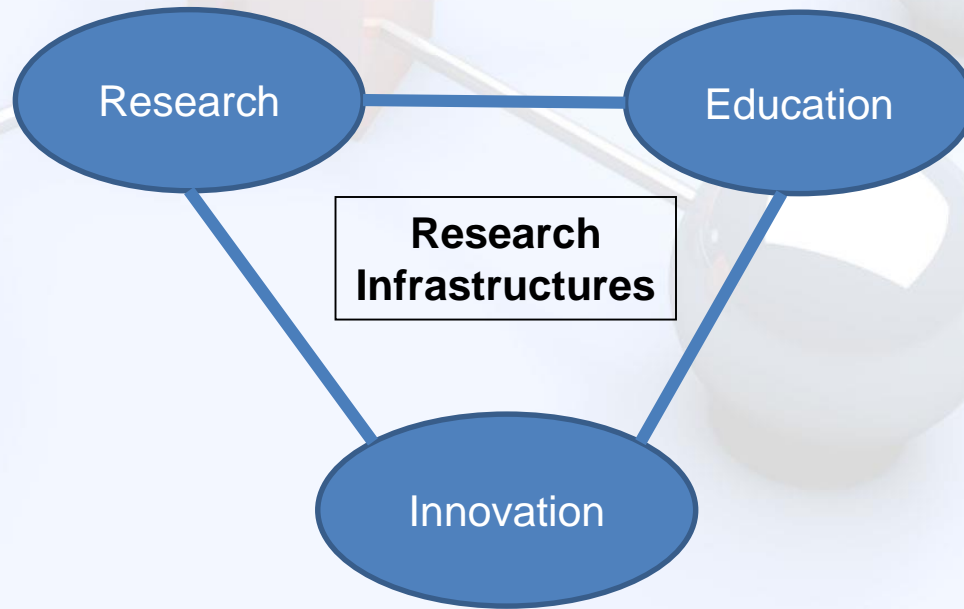
Kurt Zatloukal, Medical University Graz, Austria

Corbel Innovation Meeting  
Brussels, June 20th, 2017



Grant agreement  
No 654248

# *Research Infrastructures are at the Centre of the Knowledge Triangle*



„The quality of public research infrastructures may be one of the most important national assets for supporting innovation“

# *BMS Research Infrastructures and the Health Innovation Chain*



**Health Innovation Chain**

# BMS Research Infrastructures and the Health Innovation Chain



**Disease**



**Biospecimens  
Med. data**



**Molec. data**



**Knowledge**



**Diagnostics  
Therapies**

**Health Innovation Chain**

# BMS Research Infrastructures and the Health Innovation Chain



## Health Innovation Chain

**RIs contribute:** Resources  
Technologies  
Services  
Data/knowledge

# *How can BMS RIs boost Innovation?*



## The BBMRI-ERIC Expert Center Example

# *Industry Needs Access to Biosamples*



Without access to biosamples essentially

- no insight into molecular disease mechanisms,
- no new biomarkers,
- no new drugs,
- no advancement of personalized medicine.



# Biobanks need pharma

Which is why Europe's citizens need reassurance that their donations will be in the public interest.

Medical geneticist Thomas Meitinger remembers when biobanking was a simple craft. As a postdoc thirty years ago, he travelled from Oxford to Yugoslavia to track down a family afflicted with a rare disease causing blindness. The family listened enthusiastically as he explained his research over a fish dinner. He returned with blood samples and over the next decade used them to identify the single gene defect that caused the condition.

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cal good". But the large majority of healthy donors will need more persuading that profit-making industry should get access to their voluntary tissue donations.

The concept of expert centres, unveiled by the BBMRI at the meeting, should help. These would do all the molecular analyses

aimed at linking the biobanks into one distributed infrastructure. Now Meitinger, who currently works at the Institute of Human Genetics in Neuherberg, Germany, and the rest of the scientific consortium driving the effort, called the Biobanking and Biomolecular Resources Research Infrastructure (BBMRI), must find stable funding for the project and arrange access for the scientific community.

That's a lot of tough challenges at a time when the general public is sensitive to any issue involving genes and biological material. Key concerns in biobanking are those of anonymity and whether true informed consent can be given by individual donors now too numerous to be educated over dinner.

Another, potentially incendiary, issue is whether the pharmaceutical industry should have the same access rights to biobanks as academic researchers. Europe's citizens could easily turn against biobanking if they start to feel exploited for financial gain. The BBMRI must accommodate industry while avoiding such a backlash.

Biobank resources may be fundamental to understanding the molecular bases of common complex diseases, but it is the pharmaceutical industry that will develop the treatments for such ailments. Companies generate their own biobanks, but these cannot reach the scale necessary to move forward. Industry wants access to large public biobanks, and the BBMRI recognizes its obligation to facilitate new medicines. The consortium hopes that relentless outreach and appropriate control of banked materials will achieve this without

infrastructure, and data would be stored for re-use in other studies, so industry could not gain exclusive rights.

Industry must also be prepared to give something back, in the form of access to its own biobanks and their richly financed expertise. Research departments across all companies believe that biobanks and the molecular information generated from them are outside the competitive realm, but their managers tend to be wedded to secrecy. So managers must be persuaded to follow their researchers' instincts, before the public gets the idea that industry is there only to exploit, gets deterred from donating, and the whole enterprise becomes tainted with distrust. ■

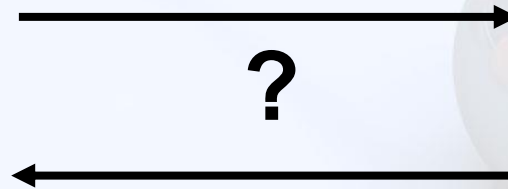
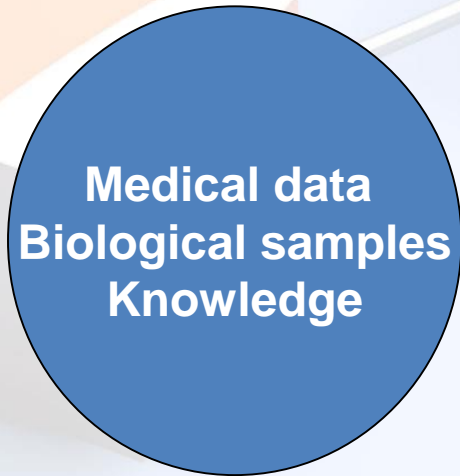


# Access for Industry



**Common good**  
(donations)

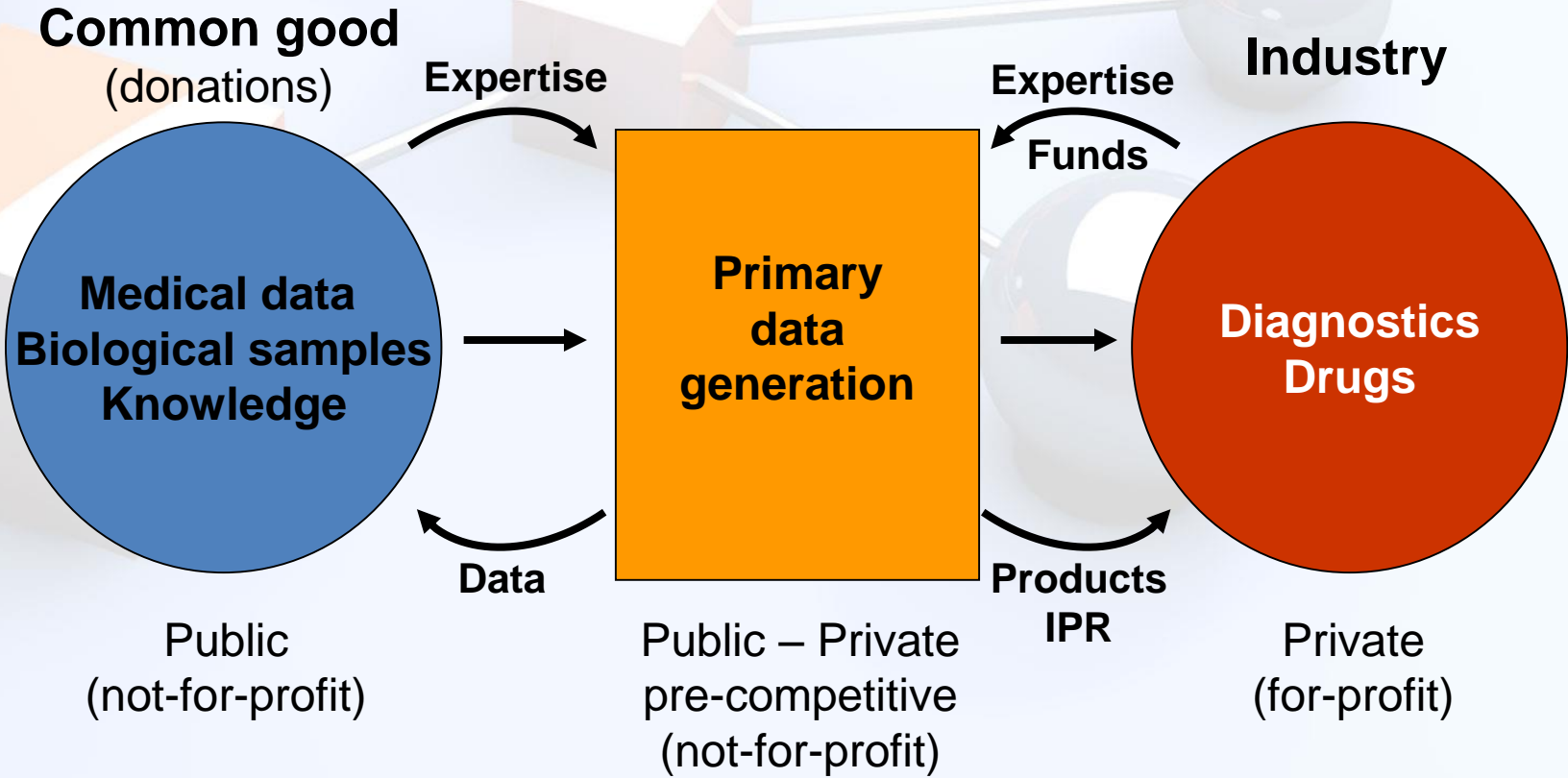
**Industry**



**Public**  
(not-for-profit)

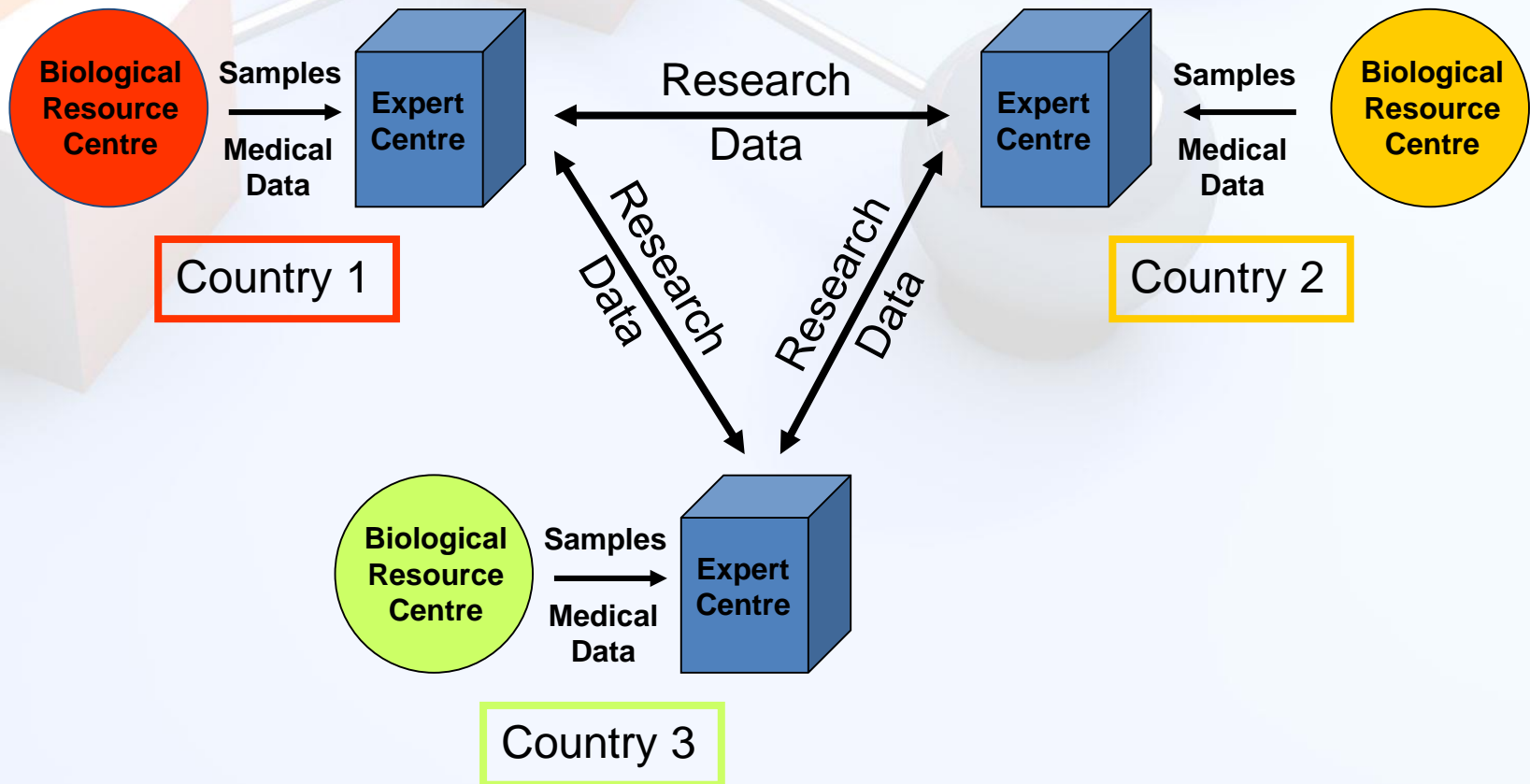
**Private**  
(for-profit)

# Expert Centres: Win-Win for Public and Private Sectors

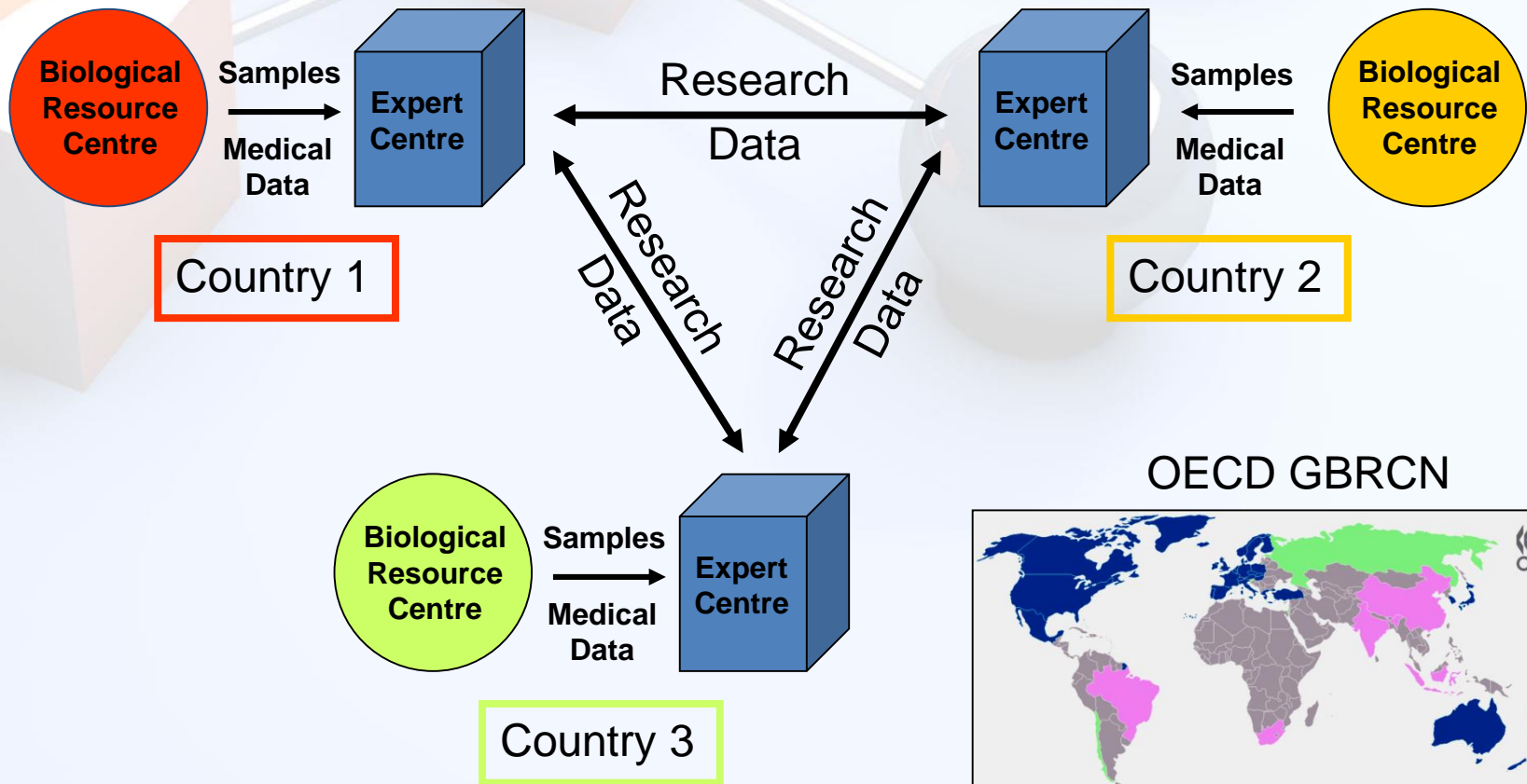


- Standardisation of data generation
- Basis for data sharing
- Better usage of finite resources
- Collaborative research to improve innovation

# *(public) Expert Centres as Highways for International Research Collaborations*



# *(public) Expert Centres as Highways for International Research Collaborations*



# *BBMRI-ERIC Expert Centres*



Framework for collaborative research

Public – private partnership

Platform for sharing of biological resources, data and knowledge

Common QM: reference material and proficiency testing together with other ECs

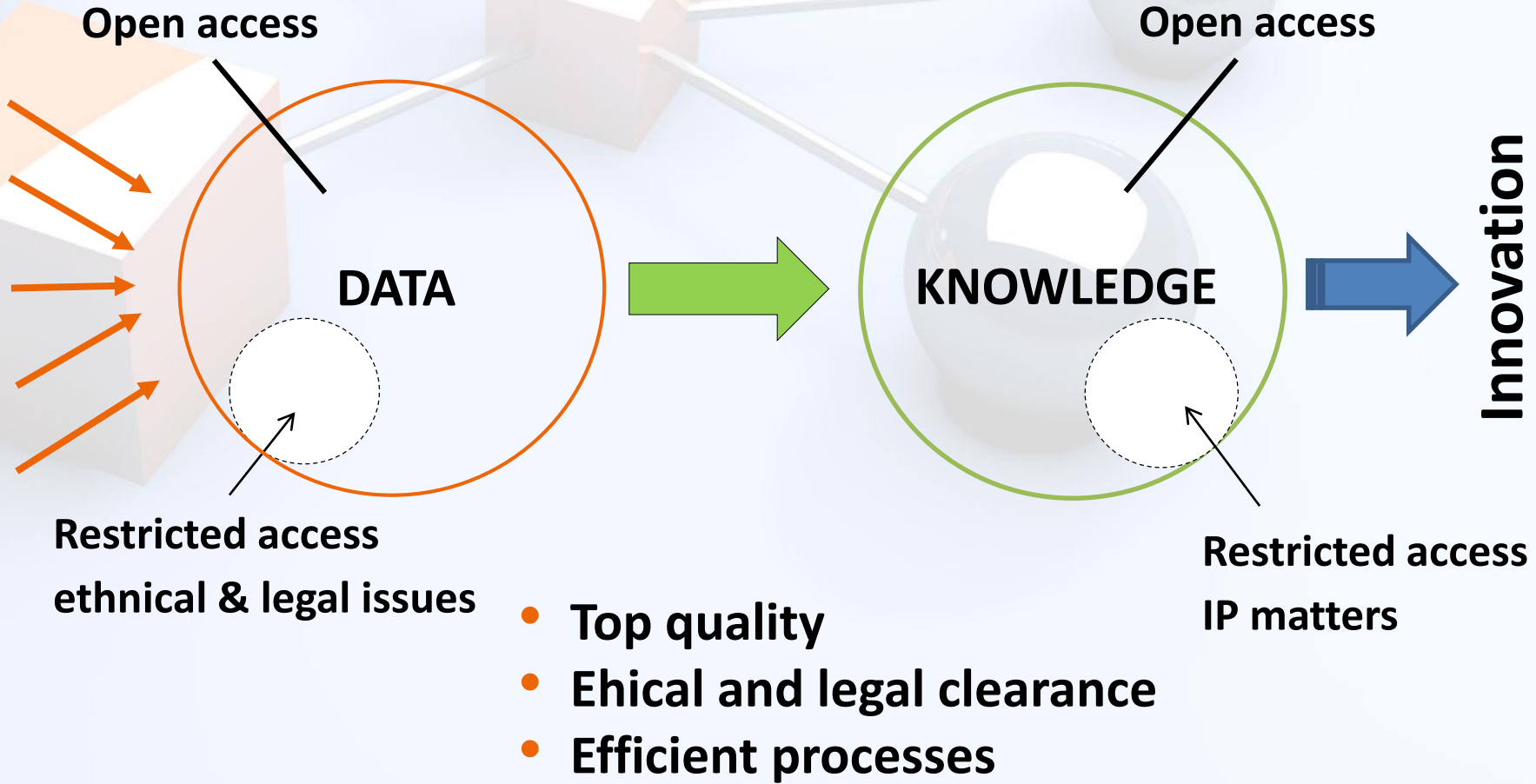
Building block of a global open data resource

Enabler for (open)innovation

# Expert Center Concept for Corbel: Open Data is a common product



Research Infrastructures



- Top quality
- Ethical and legal clearance
- Efficient processes



# Open Data on the Top Agenda



## Priorities of Commissioner Moedas:

### Open Science as part of an open approach

- **Open Innovation**
- **Open Science**
- **Open to the world**



# *The European Open Science Cloud*



Federating existing scientific data infrastructures

Provide secure environment, privacy, data protection

New market opportunities for health, environment, transport

Provide interoperability, data services, incentives, governance

All H2020 data should become open according to FAIR principle

European Data Infrastructure

3.5 bio € investment



Brussels, 19.4.2016  
COM(2016) 178 final

**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN  
PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL  
COMMITTEE AND THE COMMITTEE OF THE REGIONS**

**European Cloud Initiative - Building a competitive data and knowledge economy in  
Europe**

# The FAIR Principle



- F – Findable
- A - Accessible
- I – Interoperable
- R – Reusable

[www.nature.com/scientificdata](http://www.nature.com/scientificdata)

## SCIENTIFIC DATA

OPEN

SUBJECT CATEGORIES

- » Research data
- » Publication characteristics

**Comment:** The FAIR Guiding Principles for scientific data management and stewardship

Mark D. Wilkinson *et al.*#

# Some Caveats

# *Underestimated Issue: Specific Features of Health Data*



Sensitive data (identifiable personal data)

Highly regulated (GDPR, ethics, health care)

Potential high value, complex ownership

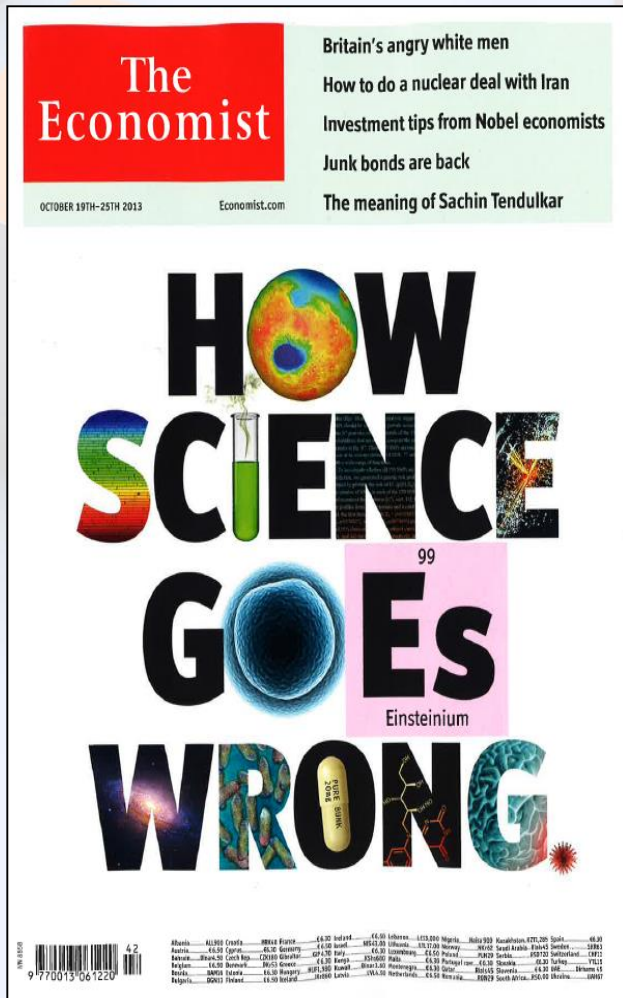
Heterogeneous data (plain text in national language, imaging, laboratory, life style, -omics etc.)

Heterogeneous quality

Data provenance, series (disease course, versioning, evolution)

Complex access procedures

# Limited Reproducibility of Scientific Data



Too many of the findings that fill the academic ether are the result of shoddy experiments or poor analysis (see pages 21-24). A rule of thumb among biotechnology venture-capitalists is that half of published research cannot be replicated. Even that may be optimistic. Last year researchers at one biotech firm, Amgen, found they could reproduce just six of 53 “landmark” studies in cancer research. Earlier, a group at Bayer, a drug company, managed to repeat just a quarter of 67 similarly important papers. A leading computer scientist frets that three-quarters of papers in his subfield are bunk. In 2000-10 roughly 80,000 patients took part in clinical trials based on research that was later retracted because of mistakes or improprieties.



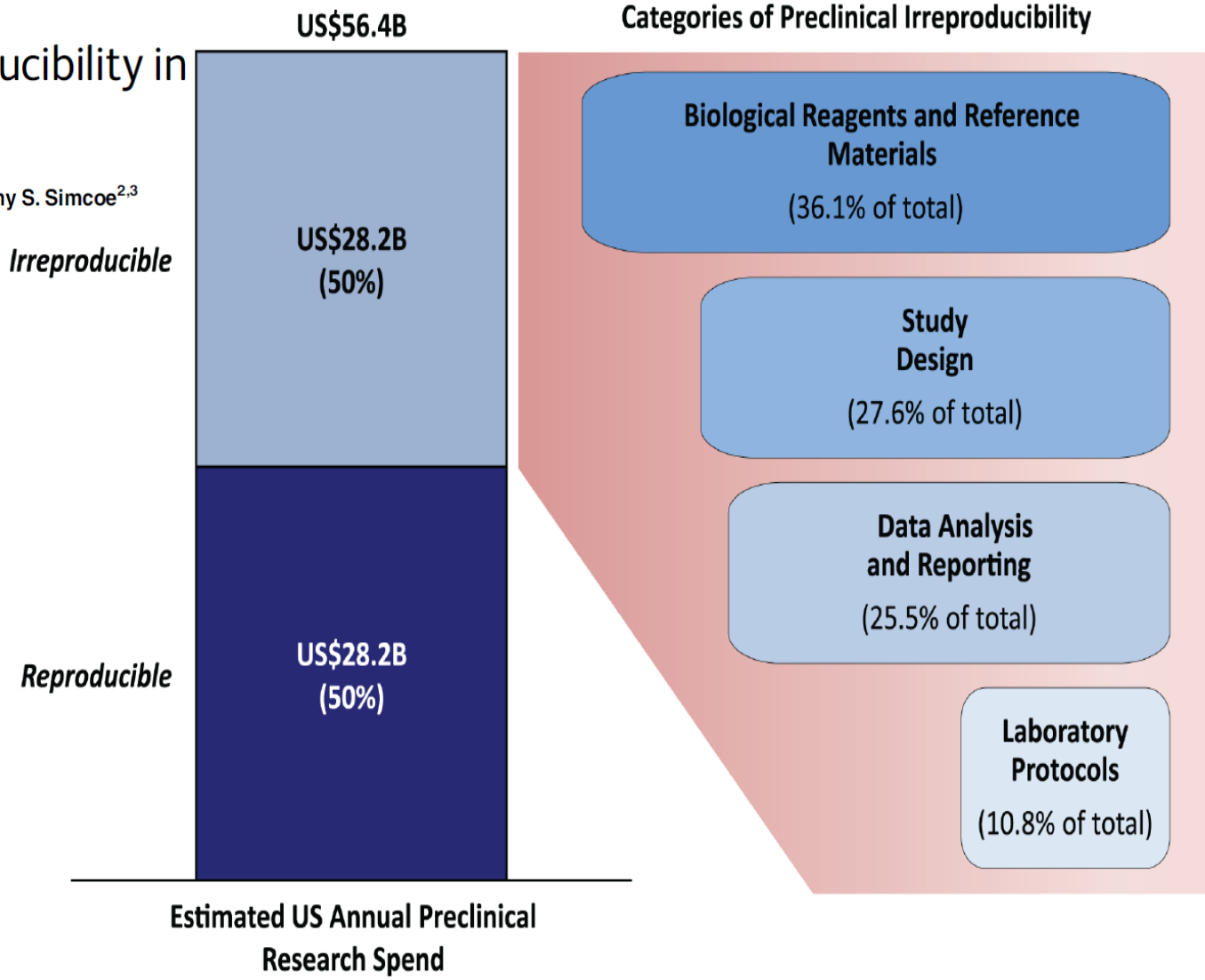
# A Case for Sample and Data Quality



PERSPECTIVE

## The Economics of Reproducibility in Preclinical Research

Leonard P. Freedman<sup>1\*</sup>, Iain M. Cockburn<sup>2</sup>, Timothy S. Simcoe<sup>2,3</sup>



# *Impact of Errors in Medical Diagnostics*



46% - 68% of diagnostic testing process errors are in the pre-analytical phase

Plebani M, Clin Chem Lab Med. 2006

5 percent of U.S. adults experience a diagnostic error

10 percent of patient deaths can be attributed to diagnostic errors

6 to 17 percent of adverse events in hospitals are related to diagnostic errors

Institute of Medicine  
SEPTEMBER 2015  
Improving Diagnosis in Health Care  
The National Academy of Sciences.

# Emerging European and ISO Standards

European IVD Regulation

SPIDIA

CEN/TC 140

ISO/TC 212

ISO15189

- ▶ Technical specifications for pre-examination processes

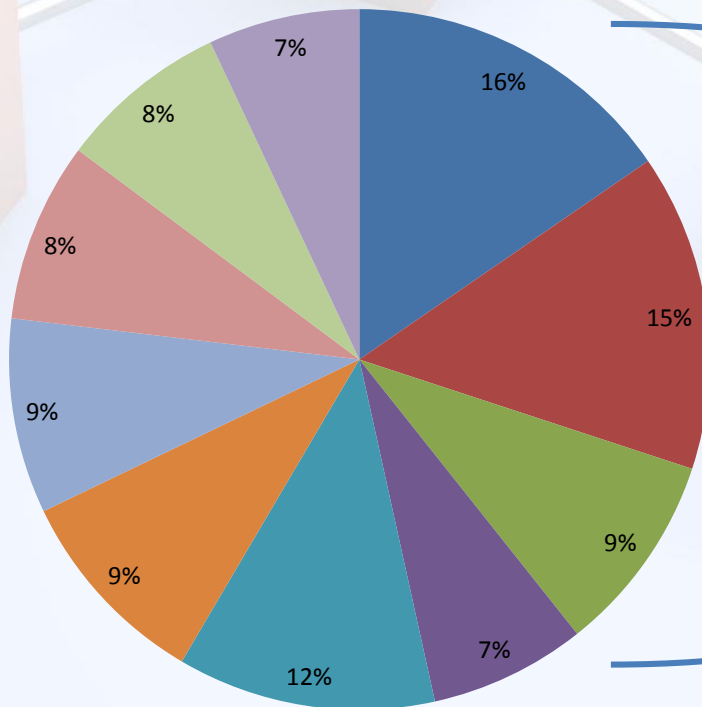
ISO/TC 276 Biotechnology

- ▶ Biobanks and Bioresources

# Open Access Created the Most Valuable Companies in the World

## Top 10 Companies in the world 2016

- ➔ Apple
- ➔ Alphabet
- ➔ Facebook
- ➔ Amazon
- ➔ Microsoft
- Exxon Mobil
- Berkshire Hathaway
- Johnson & Johnson
- General Electric
- Wells Fargo



Enabled by  
free access  
to internet

# THANK YOU!

