



BBMRI-ERIC[®]

Biobanking and
BioMolecular resources
Research Infrastructure

A Code of Conduct for Health and Life science in Europe

Professor Jan-Eric Litton

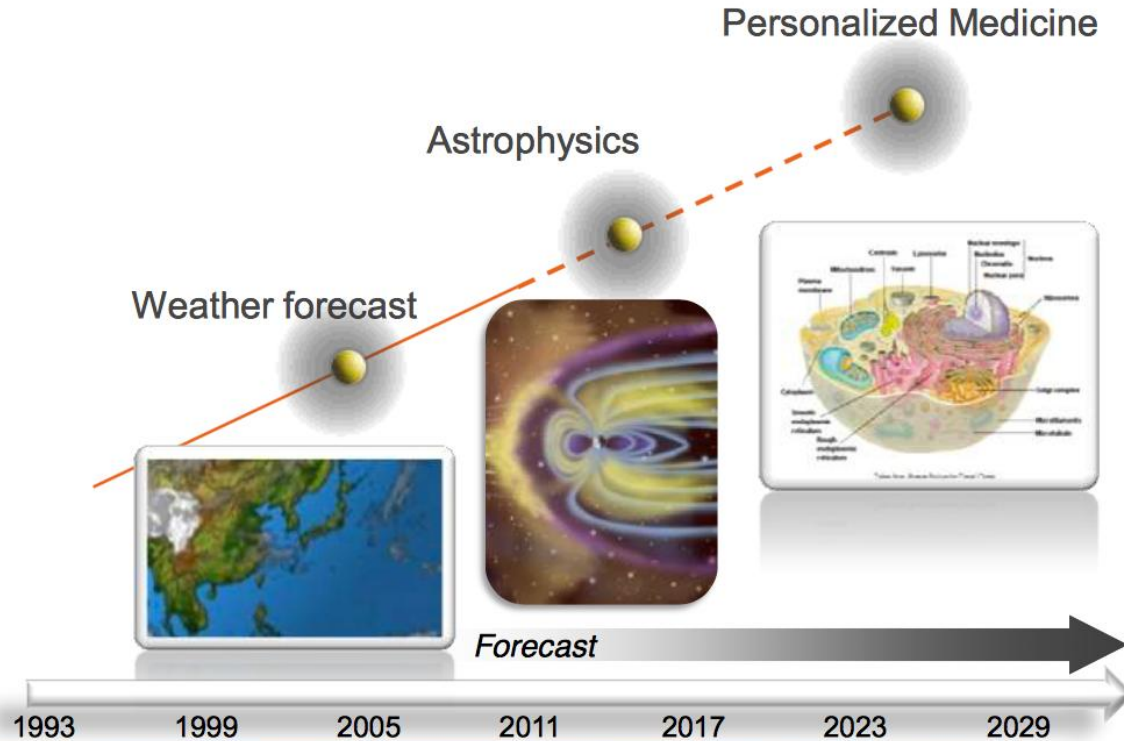
2017-11-08

General Data Protection Regulation - 25 May 2018



Big data - driven Health ?

- 1 ZFlops
- 100 EFlops
- 10 EFlops
- 1 EFlops
- 100 PFlops
- 10 PFlops
- 1 PFlops
- 100 TFlops
- 10 TFlops
- 1 TFlops
- 100 GFlops
- 10 GFlops
- 1 GFlops
- 100 MFlops



Personalized Medicine a key driver for Exascale ICT

from Intel 2012

BBMRI-ERIC - largest infrastructure for health in Europe



Members

Austria
Belgium
Czech Republic
Estonia
Finland
France
Germany
Greece
Ireland
Italy
Latvia
Malta
Netherlands
Norway
Poland
Sweden
United Kingdom

Observers

Cyprus
Switzerland
Turkey
IARC



Directory 3.2

100M samples



Tools Connector



BBMRI-ERIC Directory



RD Connect
makes your Registry / Biobank visible

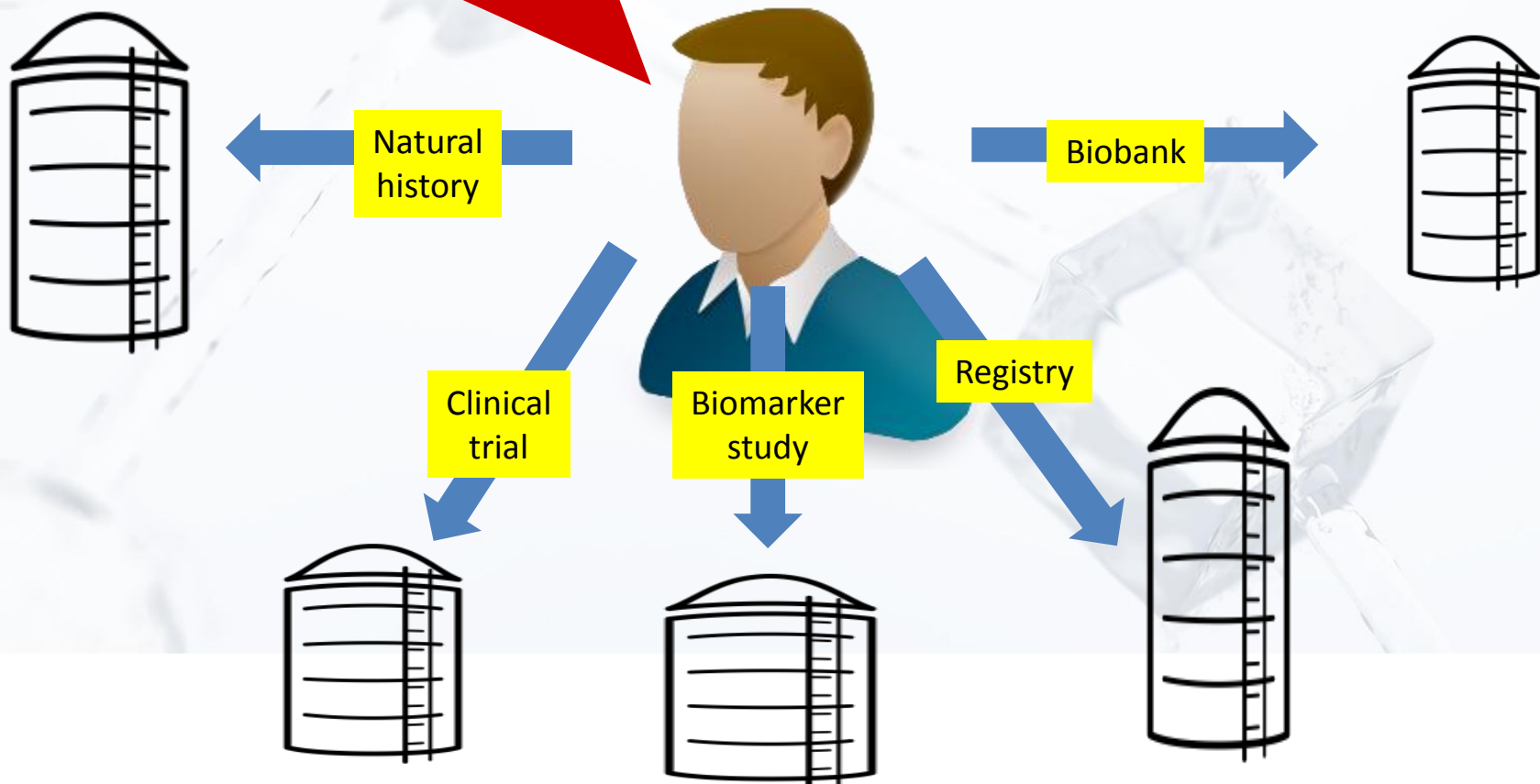
PROPOSE - Registry/Biobank

BROWSE - The RD Connect Network

The image shows a 3D network diagram with several large green cubes and many smaller white cubes connected by lines, representing a global network of registries and biobanks. The background is a light yellow-green gradient.

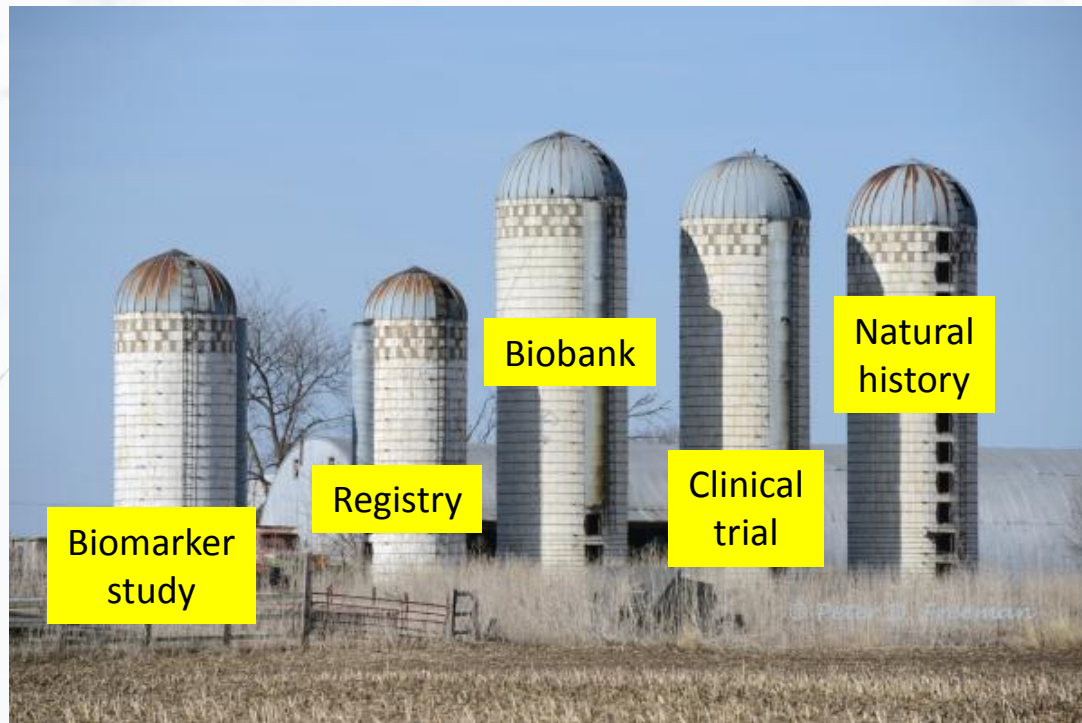
What happens to the data of a rare disease patient?

Where does my data go? Who can access my data? Is my data safe? Will my data be useful?



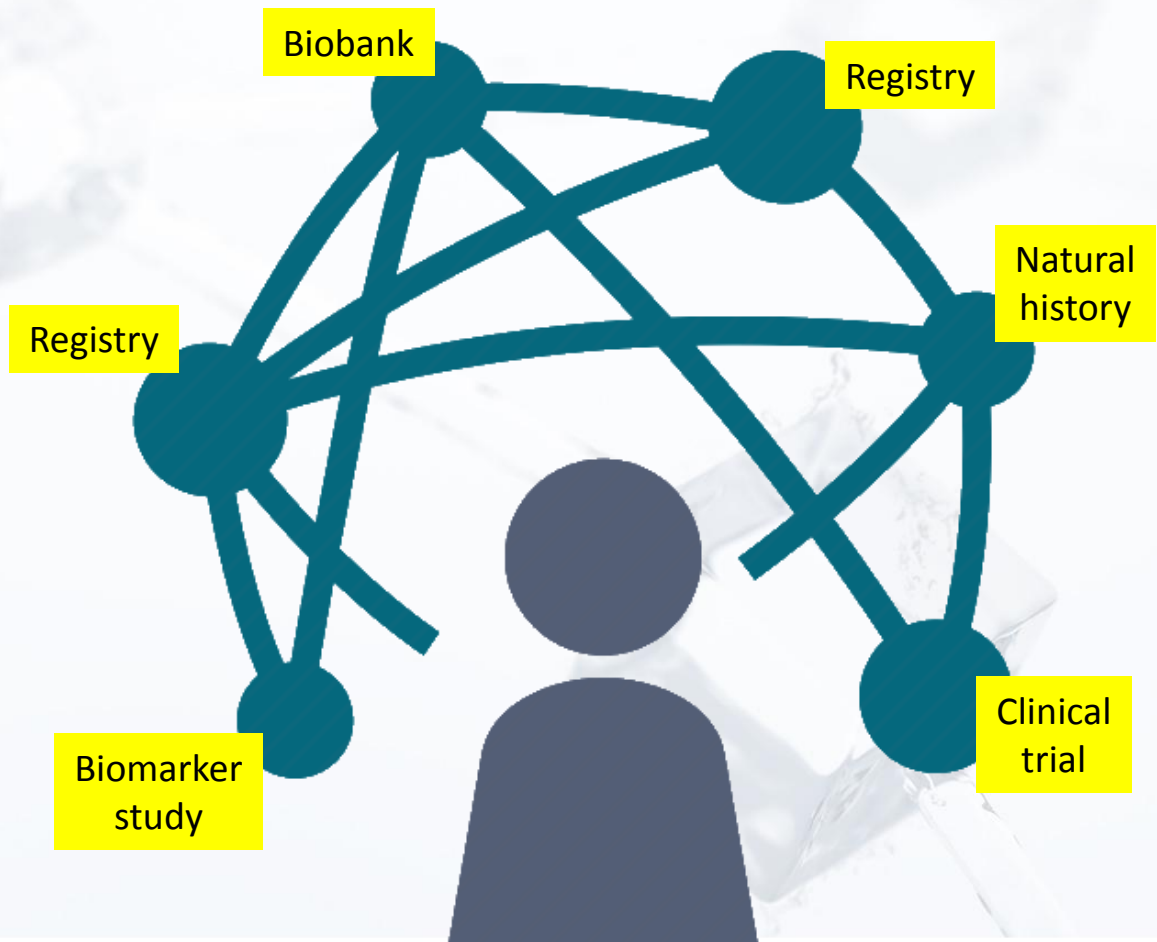
RD-Connect's guiding principle

Overcoming silos

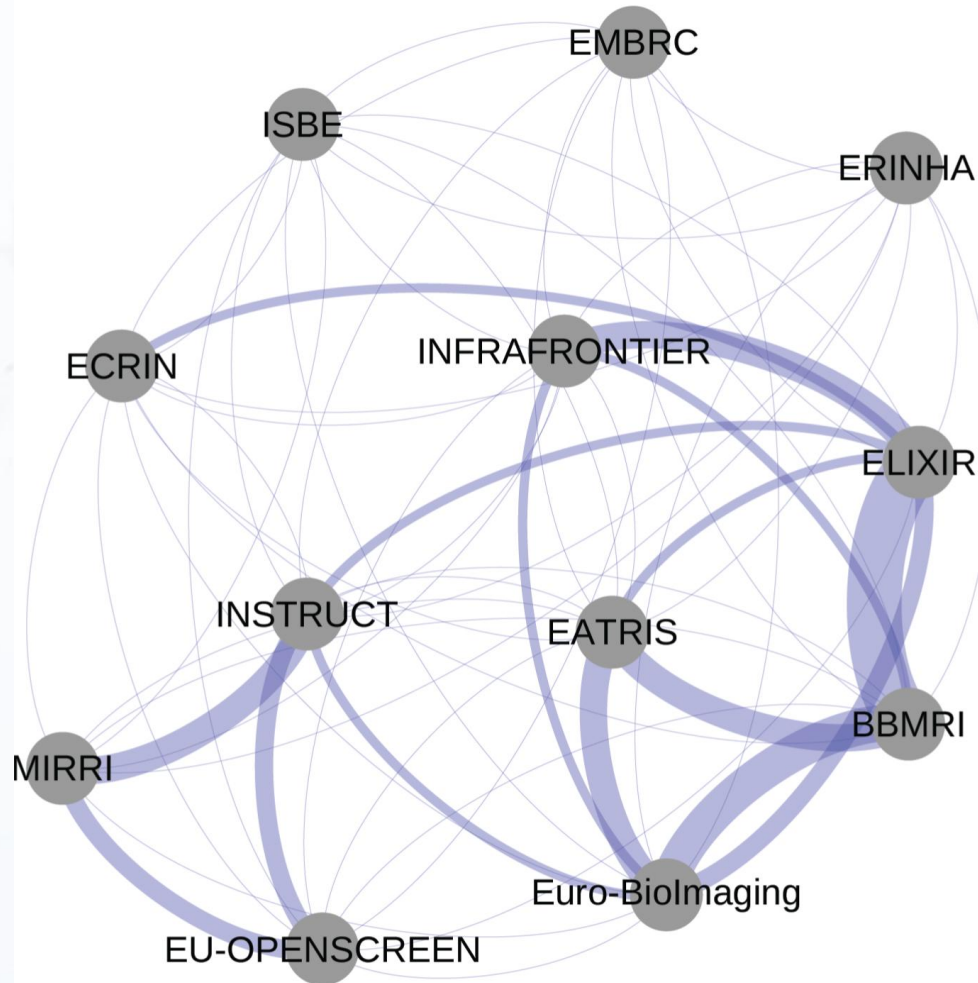


Data sharing for research and better data analysis

Enabling data linkage and reuse



EOSC



Concern: Health research is not specifically addressed



- (a) Conditions for consent
- (b) Secondary use of data
- (c) Personal data versus anonymised data
- (d) Defining and dealing with genetic data
- (e) Data/sample transfer to 3rd countries and international organisations
- (f) EO/SC

- Interpretation and implementation of the EU data protection framework could differ considerably

Recitals and Articles in the GDPR which provide some latitude to Member States to shape the GDPR in relation to research

- Recitals 33,34,53,159,161
- Articles 1,4,5,6,9,13,14,15,16,17,18,19,20,21,22, 32,34,89
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- Articles 1,4,5,6,9,13,14,15,16,17,18,19,20,21,22, 32,34,89
- **Early signs are of considerable diversity in national implementation**

Nature editorial

24 January 2017



nature International weekly journal of science

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Archive > Volume 541 > Issue 7638 > Column: World View > Article

NATURE | COLUMN: WORLD VIEW



We must urgently clarify data-sharing rules

Scientists have worked hard to ensure that Europe's new data laws do not harm science, but one last push is needed, says [Jan-Eric Litton](#).

24 January 2017

BBMRI-ERIC

Before the Summer 2017

1. Identify experts representing a certain range of organisations that can commit to the writing process:
 - Represented organisations are expected to cover their experts' travel & time in-kind
2. Determine sub-groups based on suggested topics and available experts
 - For drafting sections of the code to be presented and discussed
 - Keep log-book (explanatory memorandum) - **throughout**

After The Summer 2017-2018

3. Present and discuss results from sub-groups
 - Suggested format: online and/or in person discussions with stakeholders
 - Incorporate feedback – **autum 2017**
4. DPA consultation **Dec 2017 – Jan 2018**
5. Prepare draft of the whole document and ensure public consultation - **1 March 2018**
6. Code of Conduct proposal to be submitted to the EC (process yet to be defined) plus high level seminar – **25 May 2018**

Why Anonymous Data sometime isn't

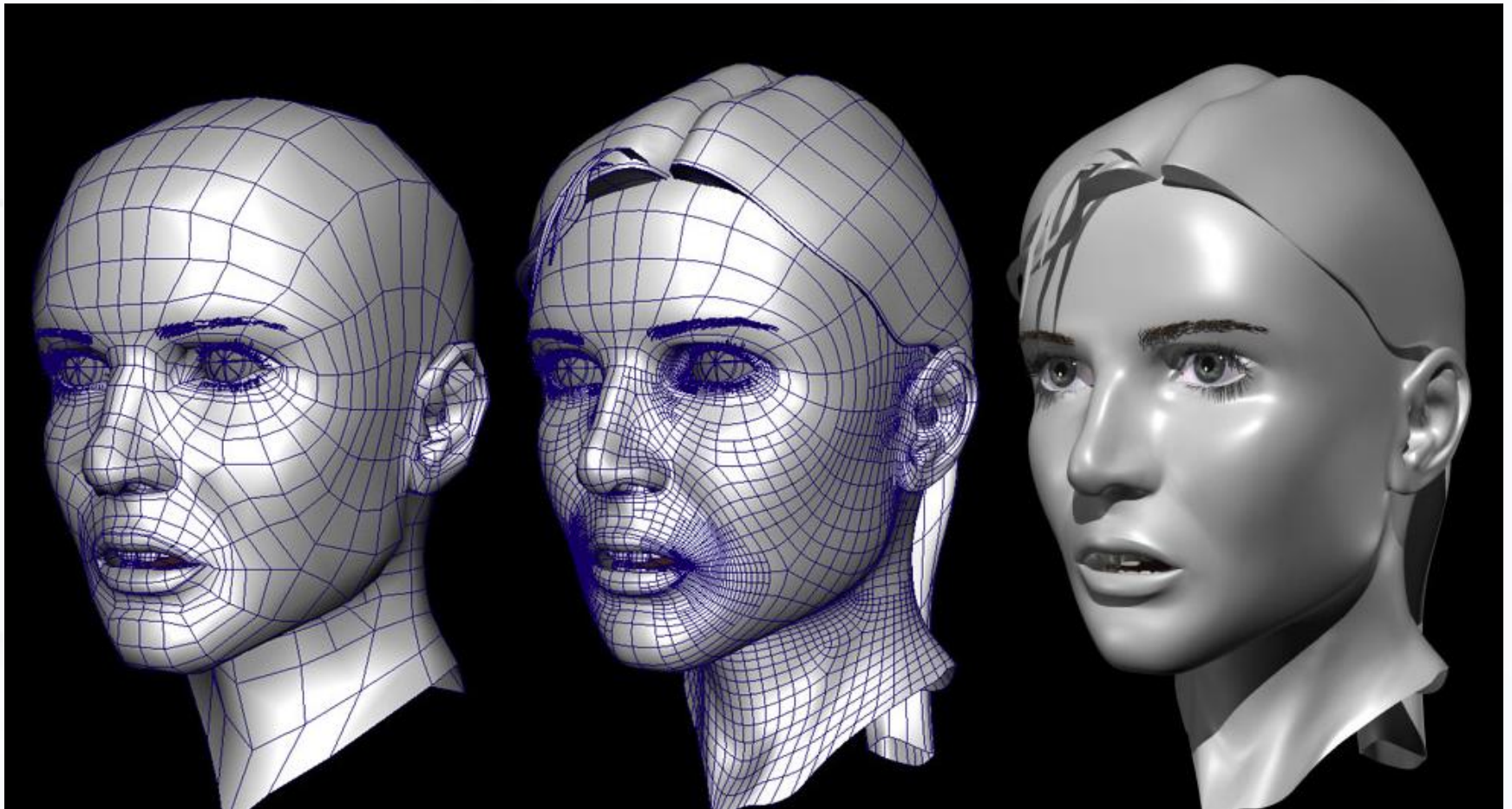
Each time you use a digital device and, for example, surf the Internet, use your mobile and visit websites, your activities leave small marks behind them.



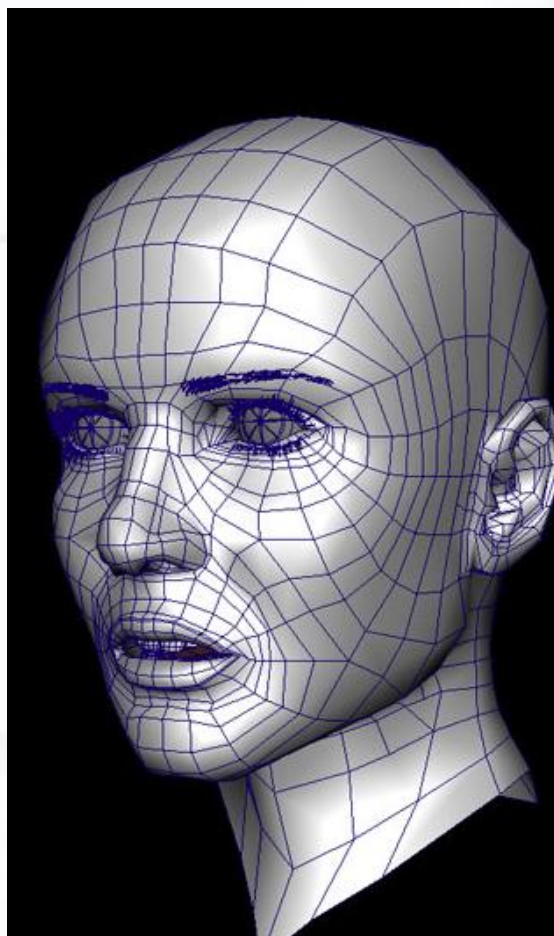
Why Anonymous Data sometime isn't

INTERNET OF THINGS SOLUTIONS FOR HEALTHCARE

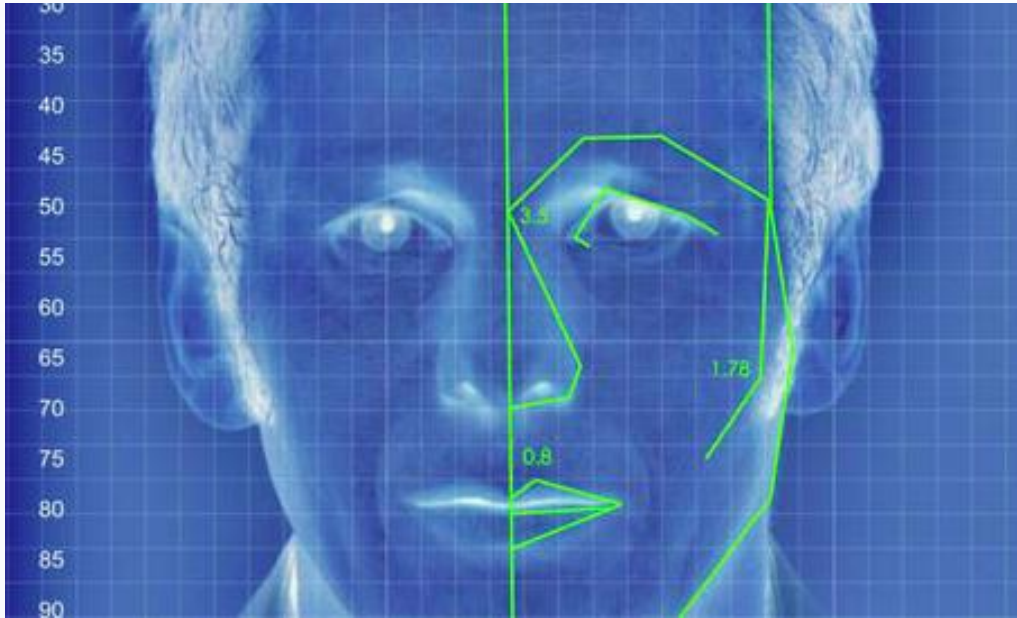
NURBS 1986



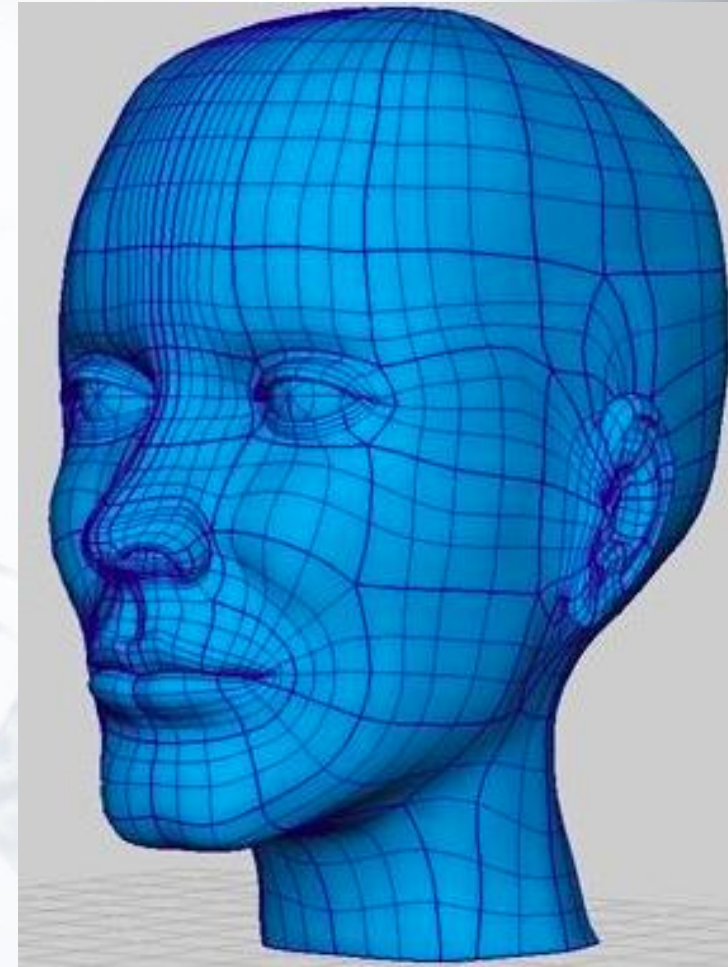
NURBS 1986



NURBS 2017



iPhone X
Say hello to the future.



Why Anonymous Data sometime isn't

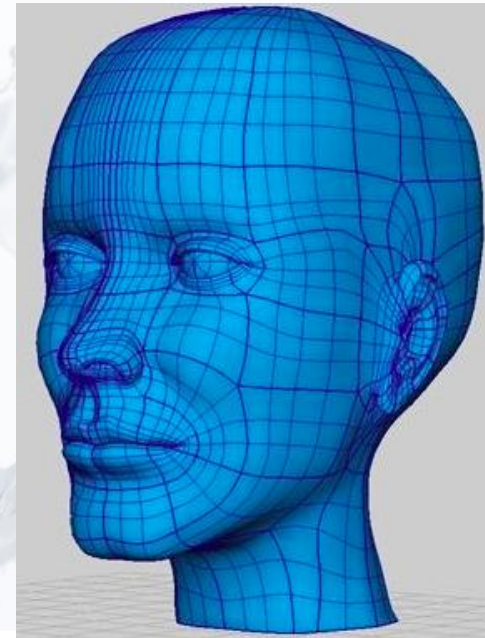
No matter how high the data protection standards are set, there will always remain some risk of (re-)identification of individuals and disclosure of sensitive information about them.

What is needed is the tightening of rules to protect against privacy violation in health and life science

.. such as discrimination based on genetic information like U.S. Genetic Information Non-discrimination Act (GINA) is a good starting point

Why Anonymous Data sometime isn't

Given the use of human material and data in medical research, we might need *privacy-protecting principles* related to compliance with data protection regulations.



Concern: Health research is not specifically addressed



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The Road to Health & Life Science GDPR Code of Conduct



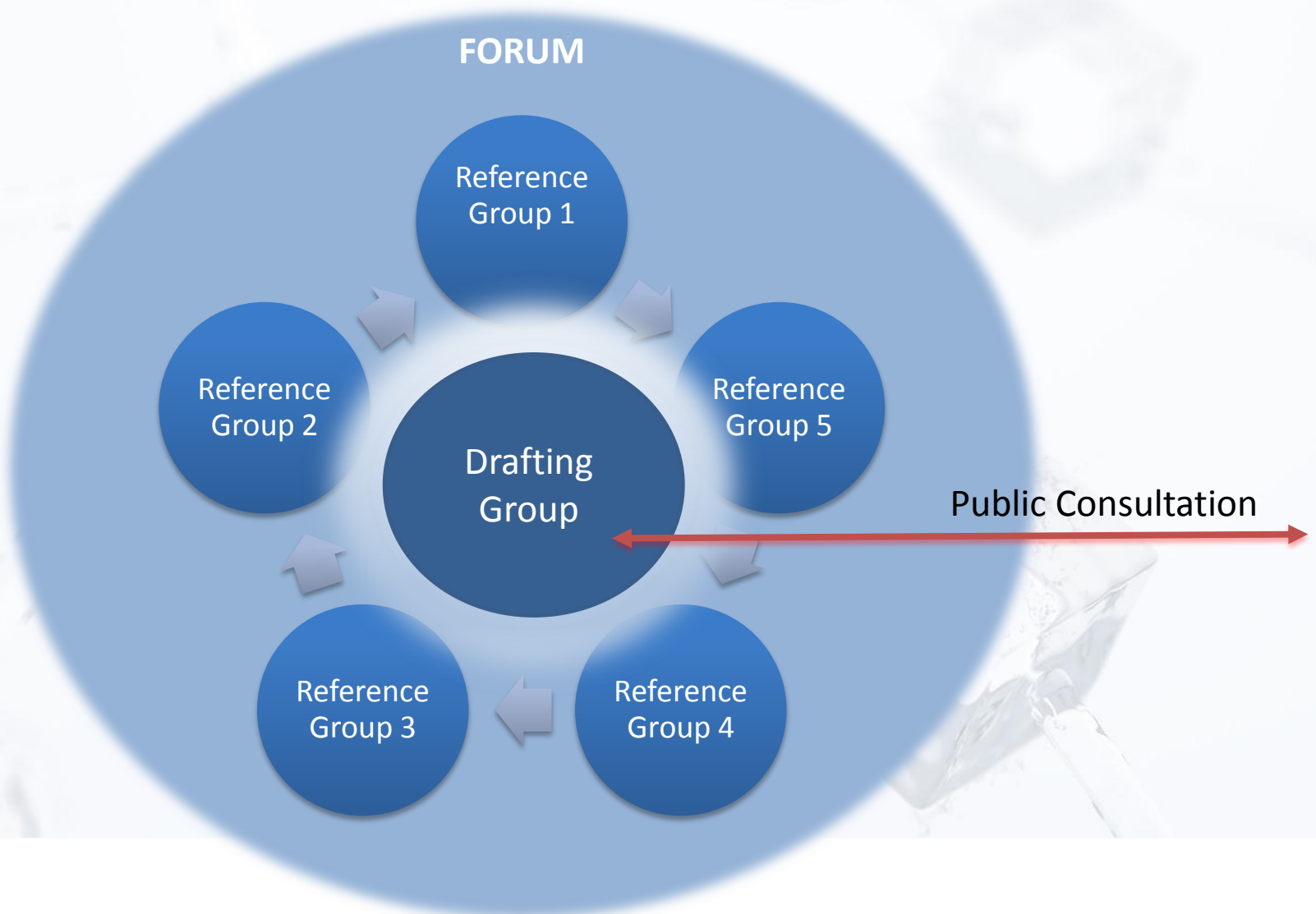
Article 40: Associations and *other bodies* representing categories of controllers or processors may prepare codes of conduct



Aim of the Code of Conduct for Health Research

- To develop a sector specific code that explains how the GDPR applies in practice in health research;
- To contribute to the proper application of the regulation, taking into account the specific features of processing personal data in the area of health;
- The code has to be comprehensive to non-legal experts;
- To clarify and specify certain rules of the GDPR for controllers who process personal data for purposes of scientific research in the area of health;
- To help demonstrate compliance by controllers and processors with the regulation;
- To help foster transparency and trust in the use of personal data in the area of health research.

Code of Conduct - Governance



Reasons a Code of Conduct

Consistency : Health Data is a complex multiple source/
multiple user environment

- Provider reassurance
- Support public/private collaboration
- External accountability to patients/citizens can be enhanced

The Commission has indicated the importance of the
“representativeness” of codes

Sectoral Code

- can respond to sectoral specificities
- Offer solutions to Member States

The road to a: *Code of Conduct for Health Research*



Governance of the Code

Code is a living document!

- Defining governing bodies
- Defining monitoring mechanisms

Governance of the Code

Code is a living document!

- Defining governing bodies
- Defining monitoring mechanisms

<http://code-of-conduct-for-health-research.eu/>

A Code of Conduct for Health Research

Why do we need a Code of Conduct for Health Research?

The EU General Data Protection Regulation comes into force on 25 May 2018, with direct effect in Member States. Given that legal texts are not always easily accessible, a Code of Conduct for Health Research is being developed that is as comprehensive as possible in order to:

- guide researchers and administrative staff;
- reduce unnecessary fear relating to compliance; and
- enhance data sharing for the purpose of stimulating progress in research.

COMING UP

6/11/2017: [GDPR Code of Conduct for Health Research and Implications for FP9](#)

Format: Seminar

Place: Brussels

Participants (affiliations): tbd

Summary: The seminar will focus on how the new data protection environment will determine and affect the use of (sensitive) personal data for health sciences in future research collaborations, especially with regards to FP9.

22-23/11/2017: CoC Drafting Group Meeting

Format: Drafting Session

Place: Paris

Thank you!

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<http://code-of-conduct-for-health-research.eu>

