



The EU Framework Programme for Research and Innovation

HORIZON 2020

Ethics Review Data Sharing – Bridging Legal Environments

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European Commission



Research and
Innovation



Overview

1. How is EU Research Policy designed?
2. Vision, legal basis, rules, procedures
3. Why this Ethics Review?
4. Breakdown of the Ethics Procedure
5. Data Privacy: a New Framework
7. Conclusion : Ethics – an advantage



Unromantic but essential



*Demonstrates scientific
purpose and technical ambition
and foresight*

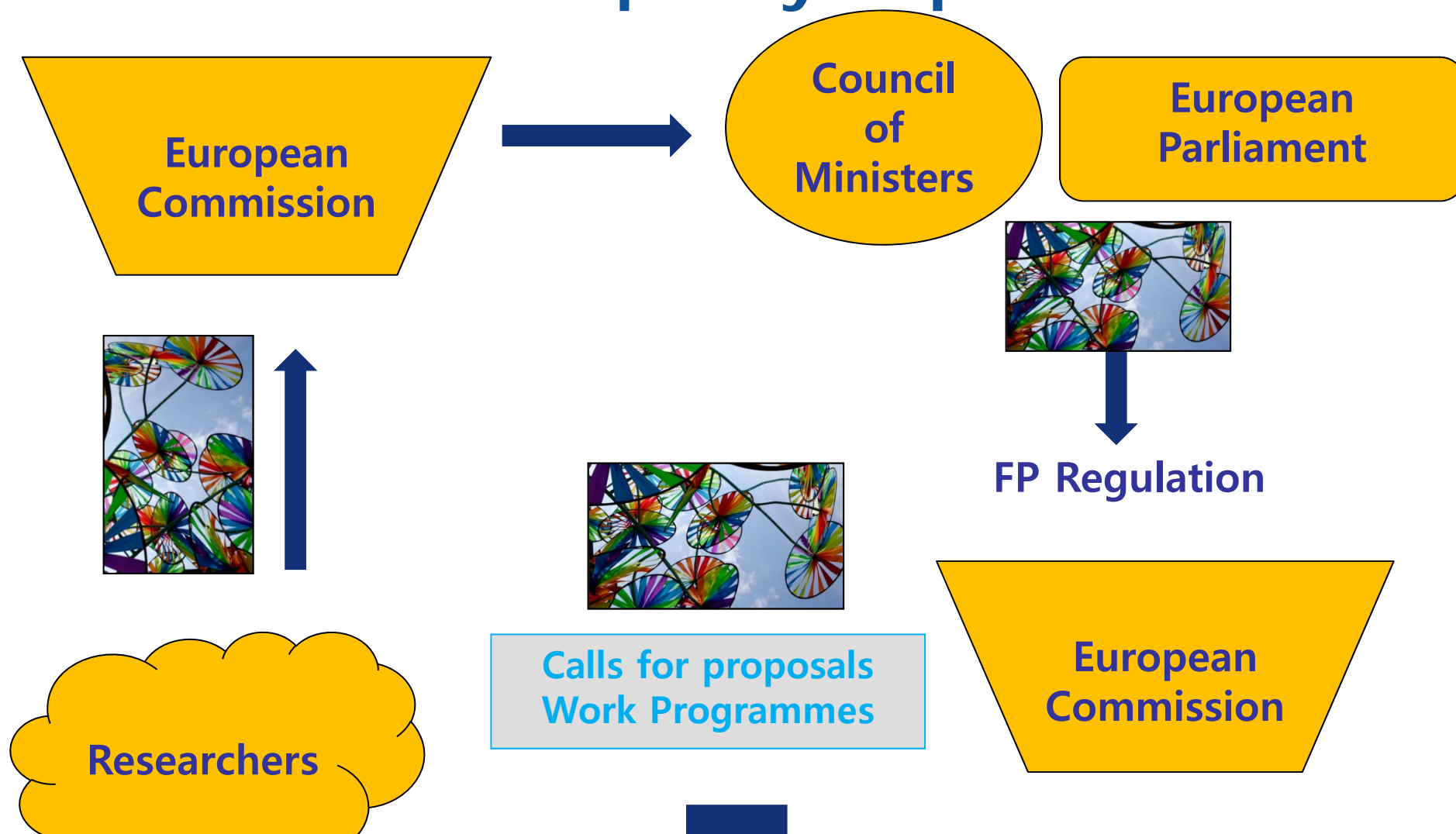
Ethics in Science and Health
Research:

All the projects need to have a
uniformly excellent ethics from
beginning to end of the research.

Quality:

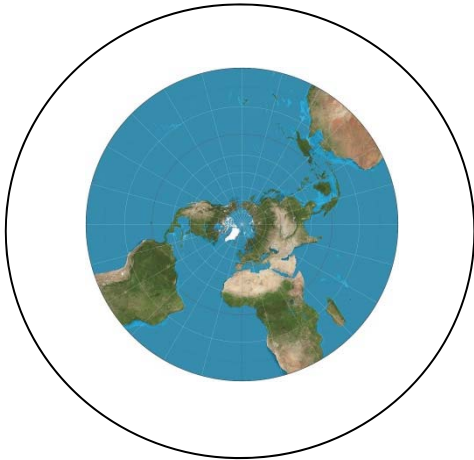
Research that demonstrates
scientific, technical and managerial
quality will have Ethics on an equal
level.

How is the EU policy implemented?



2 visions

Risk as legal hazard



Ex-post : some disadvantages

- Implies large budget provisions for lawsuits/litigations
- Internal review processes have NO VALUE in court
- Risk for researchers of being blocked by third parties – even at publication stage (cf. avian flu case)
- Advantage – no expense, might get away with it, but no deniability

Risk anticipation and mitigation



Ex-ante: advantages

- Unique process implemented by EU
- Identifies the issues, the risks
- Offers processes/solutions to mitigate them
- Protects the researcher, the project and the funding bodies

Disadvantage – perception of/and expense

- Requires risk management procedures
- Minimizes adverse impact
- large budget provisions for lawsuits/litigations

Results of the ex-post approach

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE AUTHORS GUILD, INC., THE AUSTRALIAN
SOCIETY OF AUTHORS LIMITED, UNION DES
ÉCRIVAINES ET DES ÉCRIVAINS QUÉBÉCOIS,
PAT CUMMINGS, ANGELO LOUKAKIS, ROXANA
ROBINSON, ANDRÉ ROY, JAMES SHAPIRO,
DANIÈLE SIMPSON, T.J. STILES and FAY WELDON;

Plaintiffs,

- against -

THE REGENTS OF THE
UNIVERSITY OF UTAH

The Chronicle
NEWS SPORTS OPINION RESEARCH
HEALTH & SCIENCE

**Updated: Anil Potti, Dr.
Accused of Misconduct,**
By Zachary Tracer, Taylor Doherty | November 1, 2012
Updated 6:30 p.m. with comments from Dr. Anil Potti,
Huntington Willard and Dr. Michael Cuffe, DUHS via
medical affairs.

The Duke cancer researcher who has been under investigation for
research misconduct since this summer has resigned.



Civ. No.

COMPLAINT

**According to the lawsuit, the
University of Utah incurred 3.3 million
in costs to remedy the security breach**

COLORADO CASUALTY INSURANCE
COMPANY, a Colorado corporation,

Plaintiff,

vs.

PERPETUAL STORAGE, INC., a
California corporation; UNIVERSITY OF
UTAH, a body politic and corporate of the
State of Utah, on behalf of UNIVERSITY
OF UTAH HOSPITALS AND CLINICS
and UNIVERSITY OF UTAH HEALTH
SCIENCES CENTER,

Defendants.

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE AUTHORS GUILD, INC., THE AUSTRALIAN
SOCIETY OF AUTHORS LIMITED, UNION DES
ÉCRIVAINES QUÉBÉCOIS,
LOUKAKIS, ROXANA
JAMES SHAPIRO,
LES and FAY WELDON

Plaintiffs,

- against -

HATHITRUST, THE REGENTS OF THE
UNIVERSITY OF MICHIGAN, THE REGENTS OF
THE UNIVERSITY OF CALIFORNIA, THE BOARD
OF REGENTS OF THE UNIVERSITY OF
WISCONSIN SYSTEM, THE TRUSTEES OF
INDIANA UNIVERSITY and CORNELL
UNIVERSITY

**"full responsibility for a series of anomalies
in data handling, analysis and management
that have come under scrutiny in the past
months."**



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BMJ 2012; 344: 10.1136/bmj.a440 (Published 2 February 2012)
Cite this as: BMJ 2012;344:a440

**US board says censoring research on
avian flu was necessary to prevent a
potential catastrophe**



Why this EU Ethics Review

- No funding for research forbidden in all MS and no funding in a MS where research is forbidden
- Support for initiatives that contribute to coordination & rationalisation of research with a responsible ethical approach
- Scientific evaluation and ethics review
- Approval on a case by case basis by Member States





The role of the European Commission in research (RTD)

1. As Policy maker

- European Research Area
- 3% of GDP spent on R&D

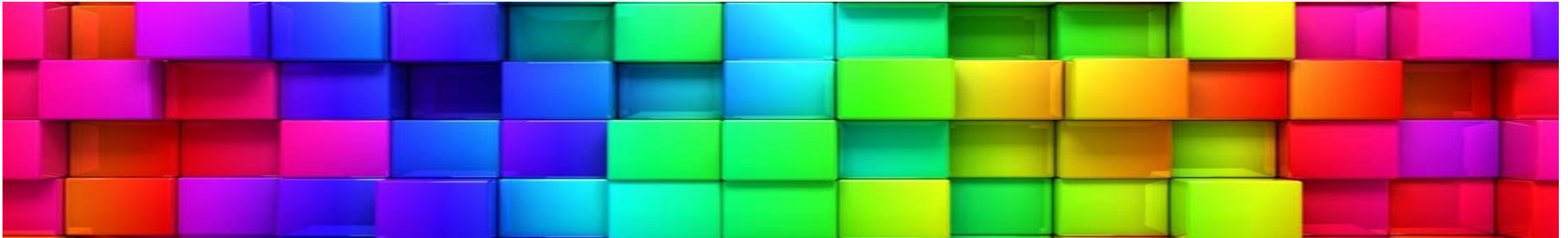
2. As Funding agency

- EC manages 6% of total public R&D investment in the EU (through the multiannual Framework Programme)
- Supporting research done by multi-national, multi-disciplinary teams in pre-defined thematic areas (e.g. Health)

3. As a Regulator

- EC proposes legislative initiatives RTD –
- Provides scientific evidence to Commission houses EGE (foresight)
- Piloting revision of existing legislation





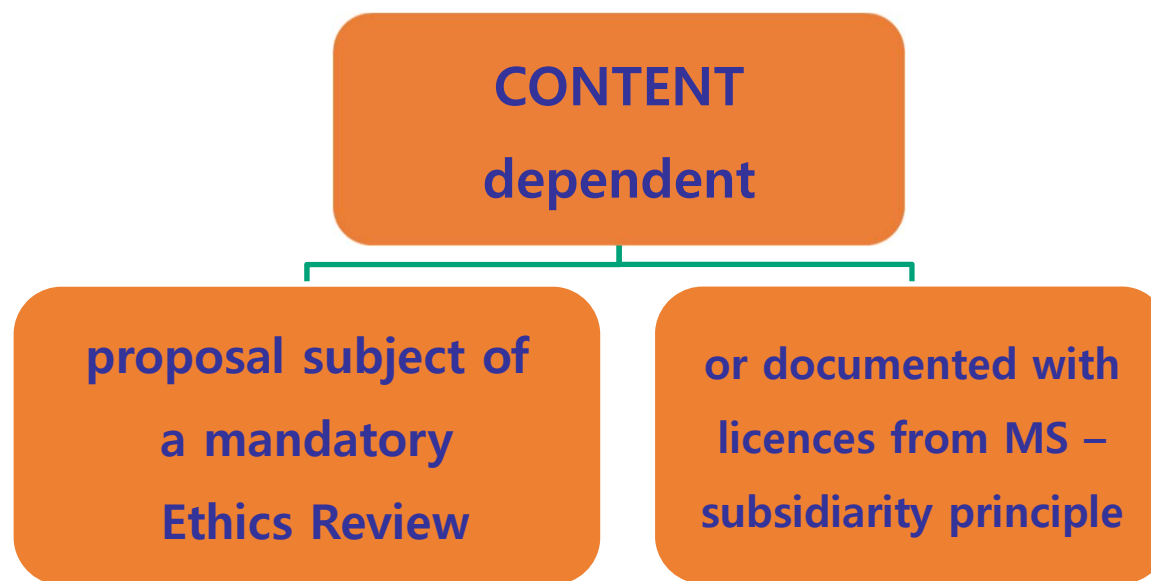
Ethics intensity low simple management

Ethics intensity High – Management of Risk

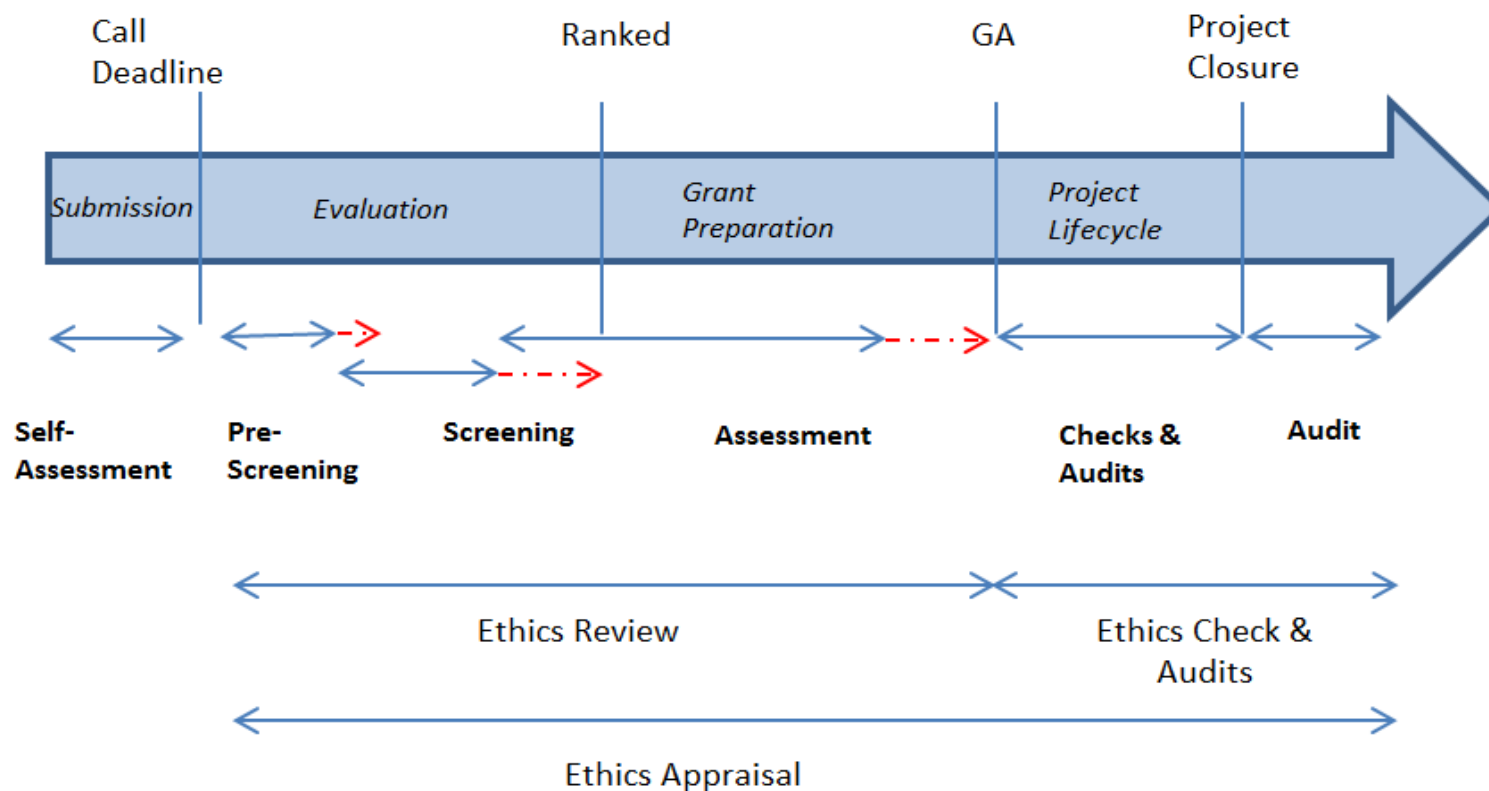
- Project – one participant, few ethics issues – basic research
- Project – one participant, many issues – ERC, REA
- Project – multiple participants, few ethics issues
- Project – multiple participants, many ethics issues – RTD
- Project – multiple participants, many ethics issues, in many states – HEALTH

Main steps of the Ethics Review follow-up process

1. After scientific evaluation
2. Ethics Review conducted in Brussels by ethics experts



Ethics Process in Horizon 2020





Rules and legislative basis

Specific FP (H2020)

- H2020 Regulation: Article 19 "Ethical principles"
- Rules for Participation: Article 13 "Ethics Review"
- Inclusive practise
- Grant Agreement (GA): Article 34 "Ethics"

Special focus hESC, Gene manipulation and Data

But also.....

- Treaties (TEU, TFEU)
- Charter EU
- Rules for Participation: Article 13 "Ethics Review"
- Grant Agreement (GA): Article 34 "Ethics"
- Specific Regulations
- Specific Directives
- Decisions
- Internaytional Agreements and Conventions
- And
- The Staff Regulation

Setting the Stage for Ethics in Science: The basis

- *Issues?*
 - *Actions?*
 - *Legal docs?*
 - *Practical steps?*
 - *Can we do better?*
- The Particular case
of ICT in
HEALTHCARE***

- *Data often electronic, Collected, stored, processed, in e-format*
- *Nature of Data – Polymorphic, patient, personal, contextual, pathology, etc*
- *Interpretation – What is sensitive and personal – IT is a whole PROFILE*
- *Use, re-use, save , merge, derive, re-merge, move, migrate*
- *Can we delete?*

Data Protection Directive to Regulation?



"Paying my fee will also help as evidence for our insanity defense."

- One rule for EU – "One stop shop"
- One only DPA for each subject
- National DPAs valid through the EU
- National DPAs outside the EU
- Consent explicit rather than implicit
- Easier access to own data
- A 'right to be forgotten'
- EU rules apply to PD abroad when service provider is active in the EU
- DPA authorities can fine violation of EU rules
- Penalties up to €1 million or 2% of global annual turnover
- The rules will apply to both domestic and **cross-border transfers** of data

Setting the Stage for Ethics in Science



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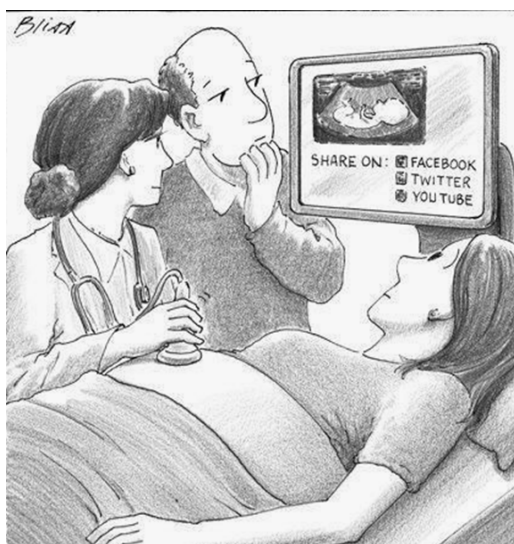
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*The Particular case of
ICT in HEALTHCARE*

The Public trust as "consumers"

But hesitate to share as Citizens?



- Data quality, collection, storing, mining need à priori ethics for confidence
- Privacy data sharing policies at the centre of Research generates trust
- ER of projects - important for trust
- Collaboration doesn't equal complication
- Trust on Data protection directive now transferred to new Regulation
- Proof of compliance favours clarity
- Public cannot accept failure in this

Flexible Orchestration



*Demonstrates purpose ,
technical ambition and
foresight*

All parts of ethics fit together
seamlessly

All the projects have ethics from
beginning to end of the research and
the unknown is part of science

Quality:

Research demonstrates quality of
Ethics on an equal level with
science and budget





Sharing Data in EU – a paradigm?

- Big data for research and health care – the ethical way to go
- Personal data (private by default) in the EU Charter no way around it
- EU GDPR (May 2018) mirrors Data Protection Directive (95/46/EC)..but
- Data protection enforced by EU ethics review
- Generated TRUST within EU- respect for ownership
- Ethics compliance as condition for funding



Big Data – Challenge and Opportunity

- Ethics oversight for Big data in research – challenge because
 - processing of data
 - anonymization techniques
 - special conditions apply for transfer outside EU
- Protect good research and support the researchers
- Ethics from start
 - the use of new mining algorithms to
 - ensure ownership
 - Research cannot alter principles, standards and regulations
- Conditions a new context, opportunities
- But needs an imaginative solution
 - Ethics as honest broker?

Thank you

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<http://ec.europa.eu/research>



Challenge

- Health systems, information databases are diverse and fragmented
- Same for many health research databases
- Data formats, analysis, and transfer heterogeneity leads to incompatibilities
- Health data sharing is necessary for reliable data for research and health policies



Opportunity: Ethical use of data is possible

- Big-data researchers should have safe technical/methodological tools for :
 - Storage
 - Maintenance of quality data in repositories and databases
 - requires the active management of data over its lifecycle: collection, cleaning, transformation (metadata), validation and preservation
 - Analysis for new solutions (big- analytical tools and computational methods to combine heterogeneous data making sense of it)
 - Usage/Share: making it usable & exploitable by a variety of actors.
But maintaining privacy by default
- Consequences of Privacy by Default not all joy
- Compliance with the European Legislation, means more European storage capacity structured in conformity.
- **Ethics platform -An honest broker/gatekeeper and arbitrar of Fairness?**