HEALTH DATA ETHICS

MORE TRUST, MORE DATA, BETTER HEALTH
WHERE IS THE EU HEALTH DEBATE?
Focusing on costs, risk of missing out on value

Today’s debate

The debate we need

COSTS

VALUE

AUSTERITY

Health outcomes

Maltese Council
Conclusions on rare
diseases

Future of the EU’s
health policy work

Brexit

EU’s commitment
to SDGs

EU Values in health?

European HTA???

Healthcare sustainability?

Transparency

Access

Orphans

Paediatrics

Data

With thanks to EURORDIS 😊
WHAT VALUE DO WE REALLY PUT ON HEALTH?

“cost-effective for routine use”
Data, Health and Innovation

patients

DATA

HEALTH

INNOVATION
Data-Health-Innovation Linkages

- Personalised Medicine
- Actually Using Inventions
- Pro-innovator Regulation
DATA: HIGH VALUE ASSETS, HIGH STAKES

- Data4Health - offer knowledge tailored to personalized need.

- Secondary Use - my data to improve health for cohorts of patients.

- Do No Harm – Avoid over-regulation, chilling health-saving research and clinical practice.

- More research needed - on a new ethical framework for health data and “data donation”.

More Trust, More Data, Better Health
How does Europe grasp the innovation opportunity?

A first discussion held with stakeholders ahead of the roadshow, to identify areas of interest and to set the scene for further discussions.

Kick-off event hosted by Séan Kelly MEP, discussed key topics with stakeholders including the Commission, patients, regulators and innovators.

The Stockholm event centred around the secondary use of health data for health outcomes.

The Milan event will focus on research and clinical need, and will examine the health systems impact of health data.

An event at the European Health Forum Gastein will provide the link between ethical frameworks and health systems reform at national and regional level.

The roadshow aims to conclude with the launch of policy recommendations at an event in the European Parliament in November 2018.

Co-create policy recommendations
Develop well-founded policy positions
From the discussions

- A widely shared and **practical Health Data Ethic** is both necessary and within Europe’s grasp
- Commercial organisations must go **beyond regulatory requirements** in providing transparency and ensuring compliance
- Urgent need for **effective self- and co-regulation** which generates public trust
- **Reciprocal relationship** between citizens and their health data

Priority challenges:

- Lack of reliable data infrastructure and of interoperability (notably between and within health systems)
- Need for clearer best practices (e.g. in cybersecurity, data resilience and privacy-by-design)
Six principles for use of AI?

1. **Fairness**: we must understand and counter unconscious and intentional bias in AI systems.

2. **Reliability**: AI systems must undergo rigorous testing to ensure that they respond safely to unanticipated situations.

3. **Privacy and security**: AI systems must comply with privacy laws that regulate the collection, use and storage of personal data.

4. **Inclusiveness**: inclusive design practices must anticipate potential barriers to avoid unintentionally excluding people.

5. **Transparency**: contextual information about AI systems is needed so that people understand how decisions are made.

6. **Accountability**: People who design and deploy AI systems must be accountable for how their systems operate.
Lessons learned from a year-long initiative

Health as a leading case for a better Europe

1. **Europe must maintain a top-level commitment to the collective pursuit of great health.** European leaders should define the outcomes they seek together, and share their experience in working for health and well-being nationally and locally. This will create a strong connection, allowing the best of new innovation to support better health and well-being for all European citizens.

2. **Data ethics should frame data as the New Blood.** Data donation should become a social aspiration, and should be made at least as safe and easy as giving blood. Intuitive consent machinery and distributed ledger assurance of proper use should be top priorities. Data legacies for the end of life should also be framed as a valued contribution to our society. Big, anonymised and open (not necessarily public) data sets should be created for AI training.

3. **Participation is the key to success.** This is true of modern society in general, and of responsible innovation in all fields. But health is all about people, so it should be a leading case for study and experiment. Patients, their carers and family, and other lay people, need to be leading actors and not merely central objects of the health ecosystem. Patients will share data wherever they feel that they get regular access to fruits of the health research that they are enabling, and maybe also get a steering role in setting future priorities.

4. **Sustaining a data-driven health revolution depends on an educational revolution in the sector.** Patients should have a role in the education of health professionals fit for an age where empathy, resilience and creativity, rather than specialisation, will be the main determinants of great careers.
Lessons learned from a year-long initiative

Innovation as the leading enabler

5. **Europe can and should create a pro-innovation environment.** This alone will make the continent a talent magnet for next-generation ideas. There are plenty of policy reports out there: the next mandate should see implementation.

6. **Europe should lead the world in regulatory innovation.** This idea takes us well beyond law-making. The deployment of what are home-grown ideas around co-regulation can make the continent a living lab for Ethical Business Regulation, and should foster multistakeholder conversations around the challenges and benefits of these new ideas.

7. **Europe should be the first place to offer a continental framework for self-certification of new health (and, if it works, also other) data tools.** Trustworthy tools will be trustworthy by design, supported by top-flight pre-market testing protocols and real-time, cooperative techno-vigilance.

8. **Europe needs a sustained and ambitious Digital Programme to create world-class, open, secure data infrastructure.** This may be thought to go without saying, but as in so much of this exercise, the obstacles to progress are often not health-specific.
What are we missing?

- Certifying Health Applications
- Innovation
- Participation
- Digital Health
- Ethics
- Fulfilling Potential
- Holistic Approach
- Patient Involvement
- Data Quality
- Trust
- Privacy
- Artificial Intelligence
- Leadership
- Anonymous
- Decision Support
- Fragmentation
- Action
- Legal
- Dialogue
- Accountability
- Transparency
- Accountability
- Safety
- Reliability
- Security
- Open
- Education
- Reputation
- Secondary Use
- Human-Driven Solutions
- Innovation
- Sustainability
- Co-development
- Infrastructure
THANK YOU!

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