HEALTH DATA ETHICS

MORE TRUST, MORE DATA, BETTER HEALTH

European Health Forum Gastein
21 September, 2018

FIPRA

Robert Madelin,
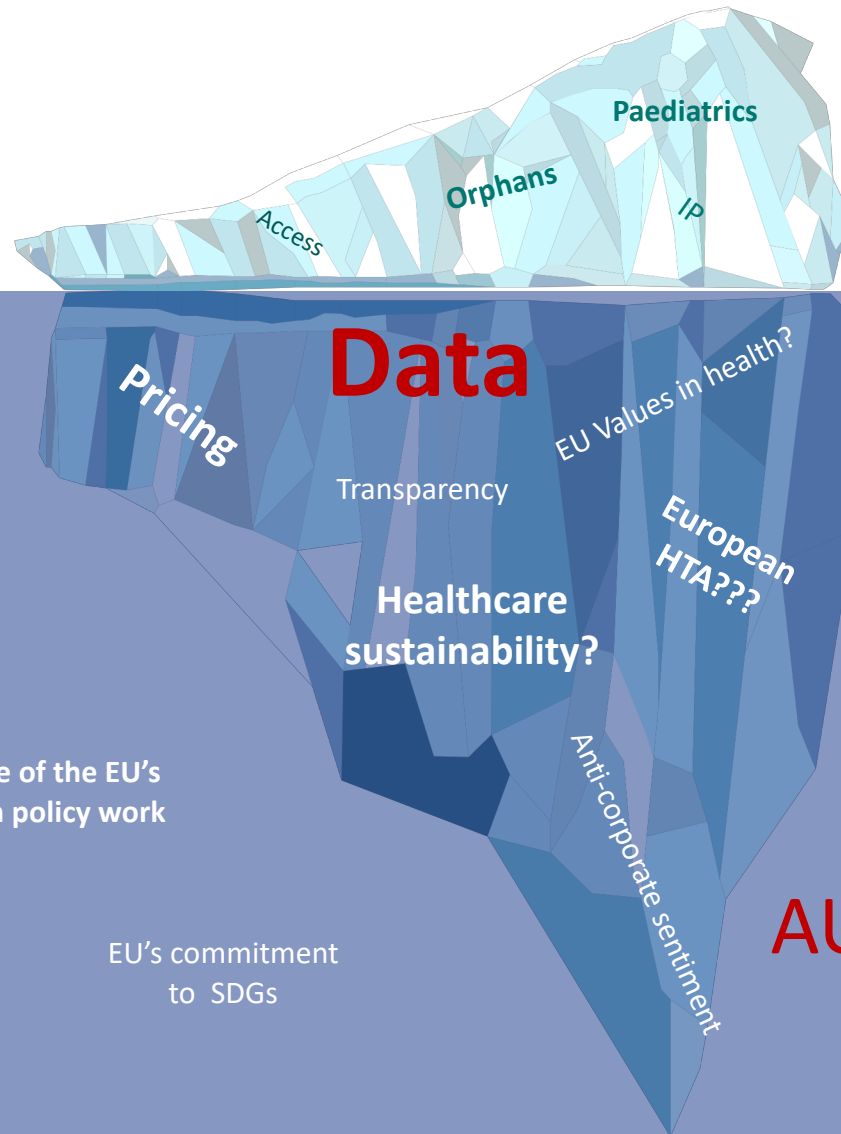Fipra International Ltd.

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

Today's debate

COSTS

Paediatrics

Orphans

Access

IP

The debate we need

Data

VALUE

Pricing

EU Values in health?

Transparency

Health outcomes

European HTA???

Healthcare sustainability?

White Paper on the future of Europe: *Avenues for unity for the EU at 27*

Maltese Council Conclusions on rare diseases

Future of the EU's health policy work

Anti-corporate sentiment

Brexit

EU's commitment to SDGs

AUSTERITY

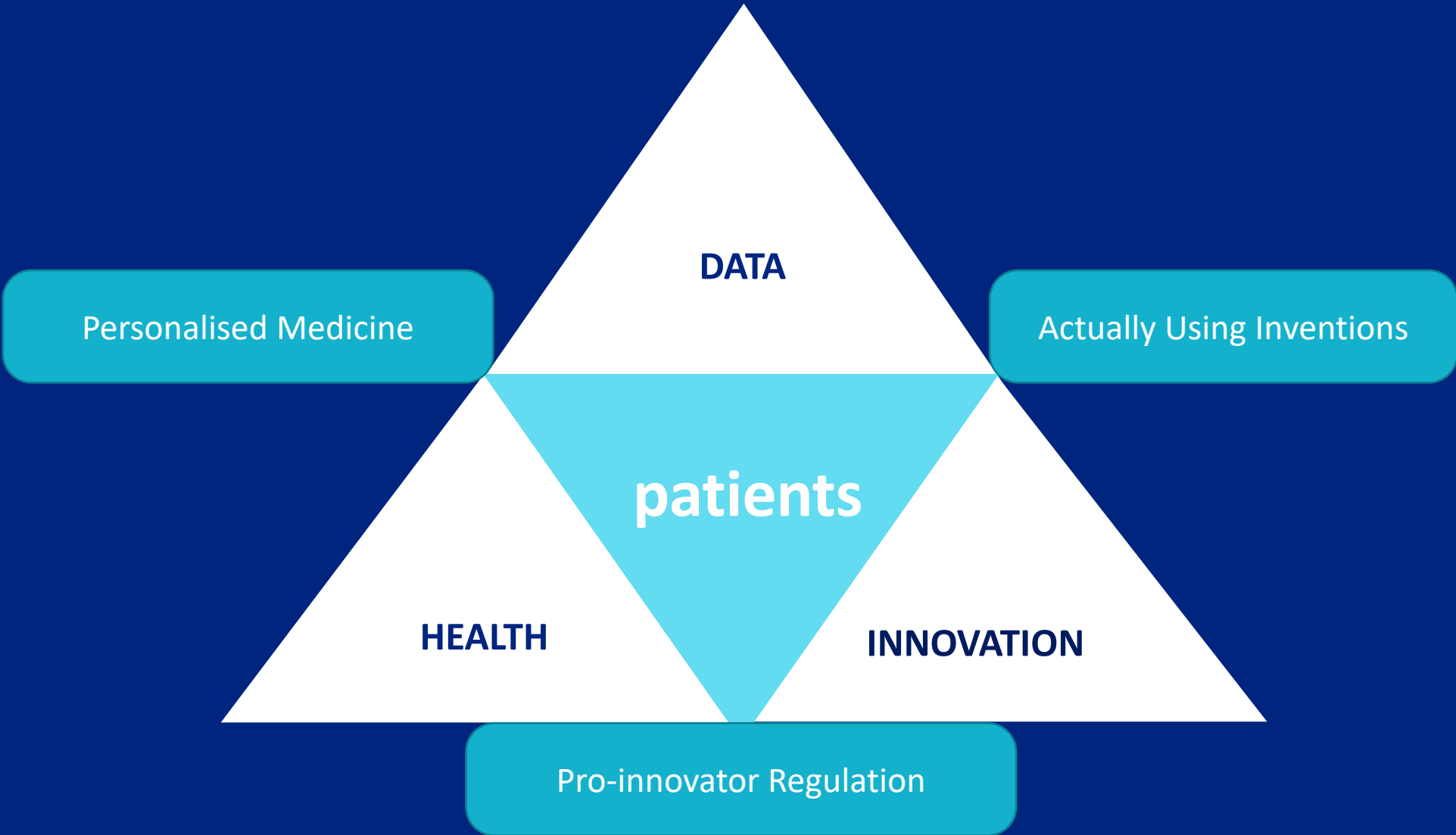With thanks to EURORDIS ☺

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WHAT VALUE DO WE REALLY PUT ON HEALTH?

"cost-effective for routine use" ?????????????????????

Data, Health and Innovation
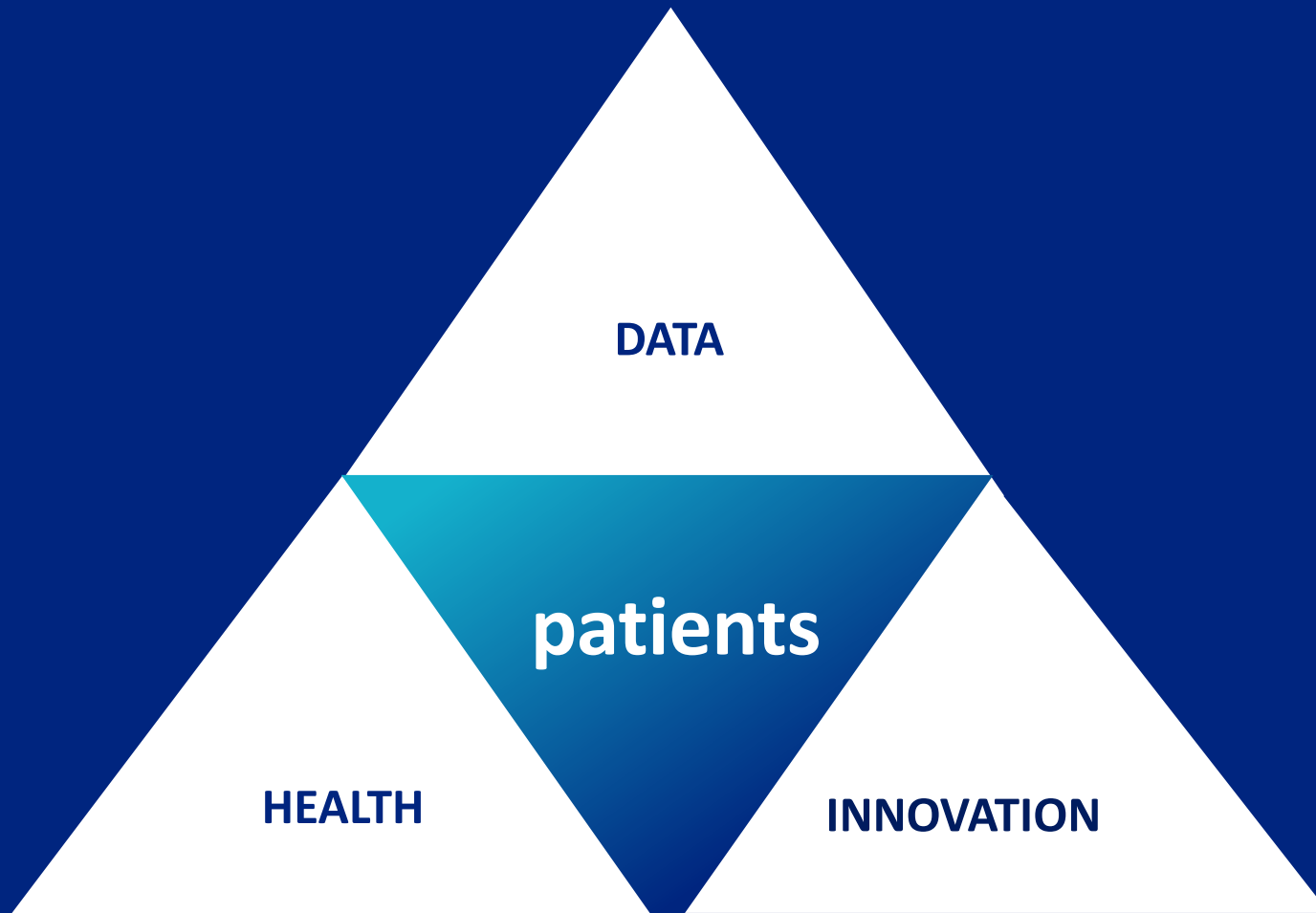
Data-Health-Innovation Linkages

DATA

Personalised Medicine

Actually Using Inventions

patients

HEALTH

INNOVATION

Pro-innovator Regulation

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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?

2017

ESTONIA
EU PRESIDENCY
JUL-DEC 2017

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

PRE-EVENT
DUBLIN SEP 2017

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

KICK-OFF EVENT
EU PARLIAMENT, BRUSSELS NOV 2017

| JUL | AUG | SEP | OCT | NOV | DEC |

BULGARIA
EU PRESIDENCY
JAN-JUN 2018

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

STOCKHOLM EVENT
June 2018

2018

| JUN | MAY | APR | MAR | FEB | JAN |

AUSTRIA
EU PRESIDENCY
JUL-DEC 2018

MILAN EVENT
SEP 2018

EHFG EVENT
OCT 2018

CLOSING EVENT
EU PARLIAMENT, BRUSSELS NOV 2018

2019

| JUL | AUG | SEP | OCT | NOV | DEC |

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

Co-create policy recommendations

Develop well-founded policy positions

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

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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.

THANK YOU!

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