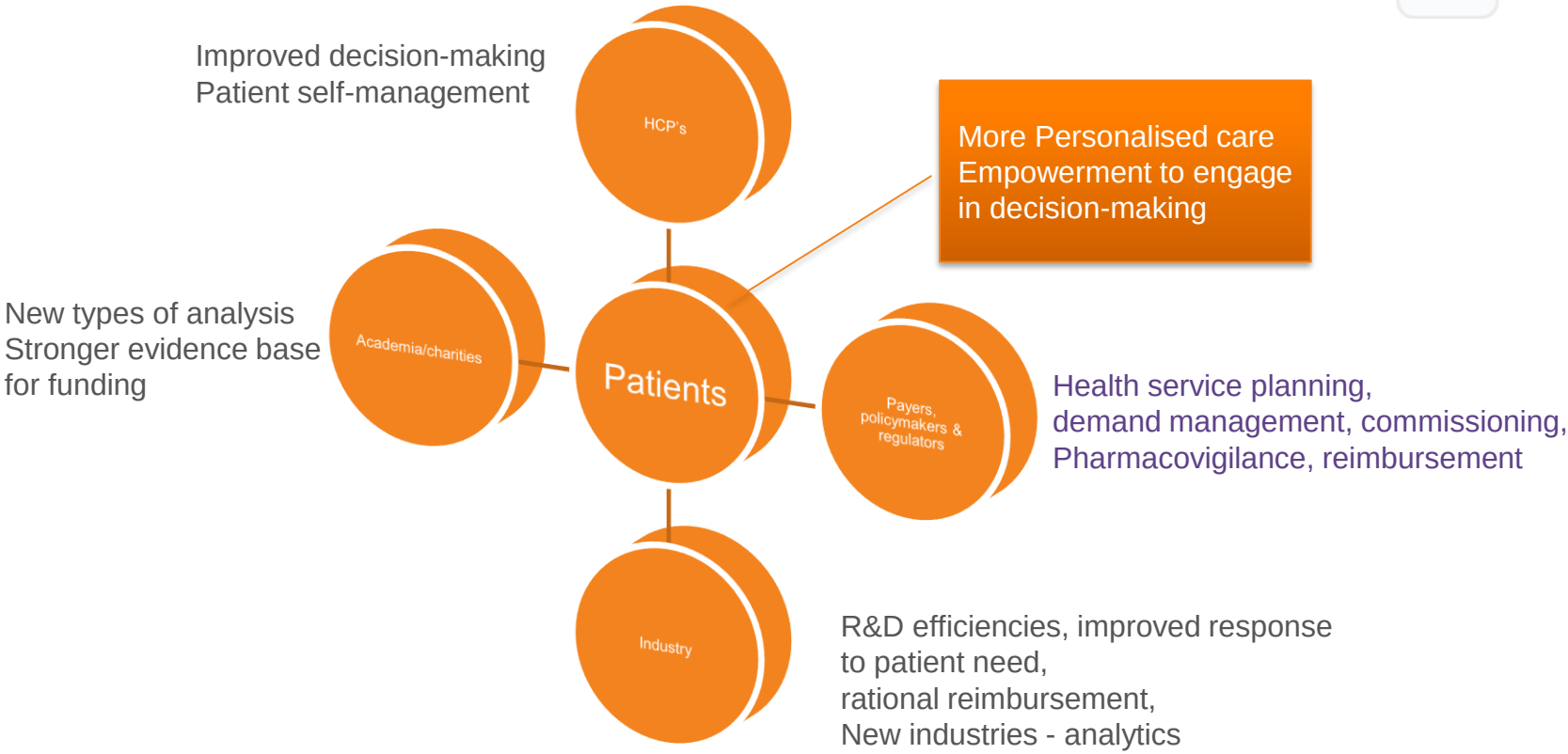
The EFPIA Perspective on the GDPR

FEAM Forum – November 2017

European Federation of Pharmaceutical Industries and Associations

www.efpia.eu

Key Benefits of Health Data



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EFPIA supports harmonisation of requirements for research

- Harmonised data requirements will enhance cross-border research and enhance the development of pan-European research networks
- Larger data sets facilitated by harmonised data privacy requirements will enable research into rare diseases and personalised medicines
- Re-using and sharing healthcare data reduces unnecessary and redundant research
- Enhances healthcare including use of medicines
- Individuals are usually supportive of data-sharing with appropriate safeguards

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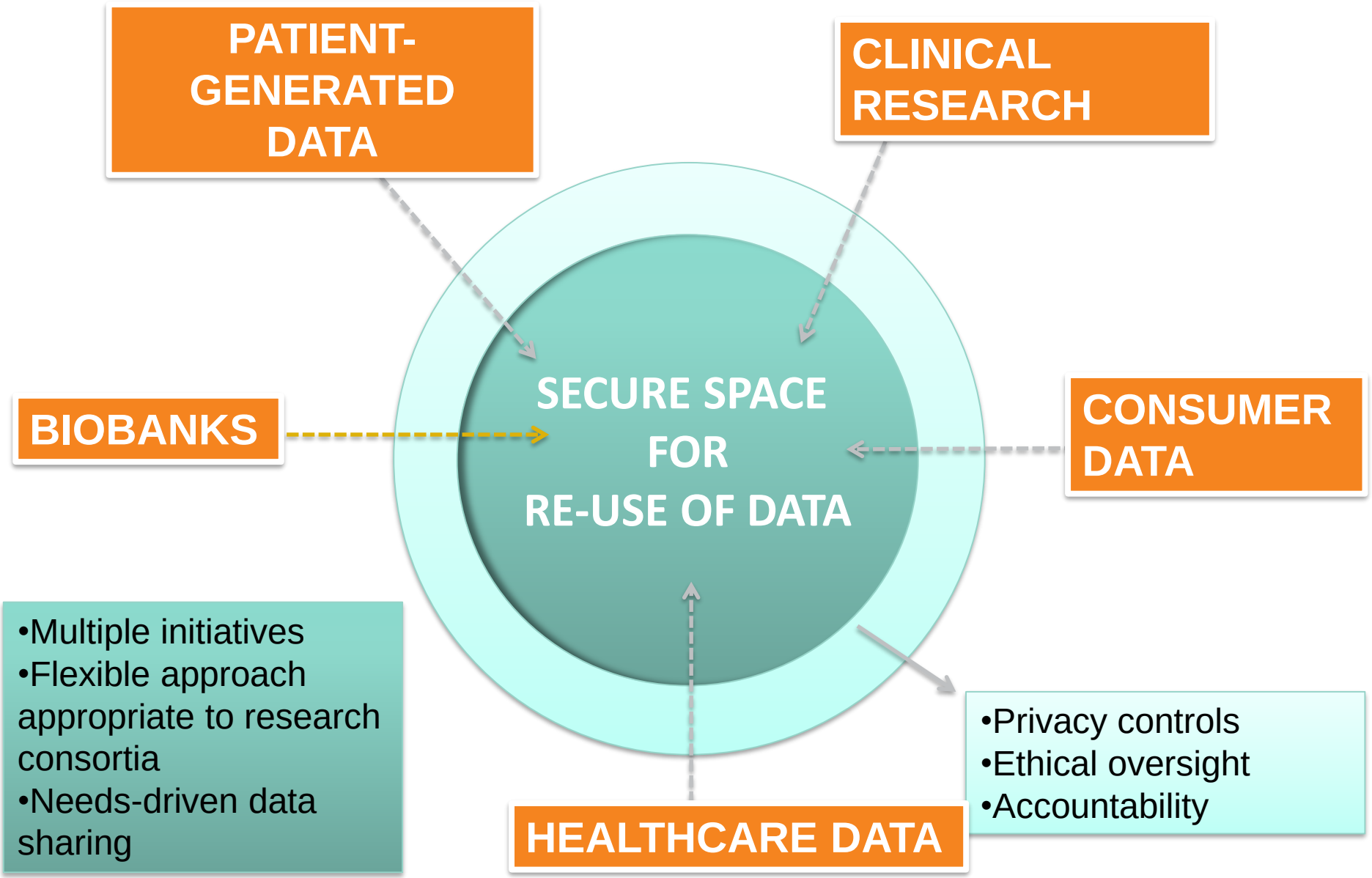
PATIENT-GENERATED DATA
CLINICAL RESEARCH
BIOBANKS
SECURE SPACE FOR RE-USE OF DATA
CONSUMER DATA
HEALTHCARE DATA
•Multiple initiatives
•Flexible approach appropriate to research consortia
•Needs-driven data sharing
•Privacy controls
•Ethical oversight
•Accountability

The Regulation allows Member States to adjust the rules to local preferences

Room for national rules	
Additional conditions	For processing genetic data, e.g., development of particular safeguards
Further limitations	For processing health data, e.g., processing limited to certain types of entities or purposes
Derogations to subject's rights	Data subject's right to be forgotten, right of access, etc., e.g. for scientific research
Consent requirements	Exact scope of consent and possibility of opt-outs, e.g. for clinical trials

Definitions to be clarified	
Health data	Recital suggests broad interpretation, but legislative definition is less clear
Scientific research	Recital suggests broad interpretation, including privately sponsored research, but no definition in actual legislation
Public interest	Left to Member States to define

The GDPR failed to harmonise rules across the EU and may not improve on existing disharmony

GDPR Mapping Exercise – priority areas

- Consent
- Subject rights
- Legal basis for secondary use of data
- Safeguards
- Definitions

→ Preserve possibility of broad consent

→ Achieve balance between individual rights and wider interest in advancing research

→ High level of flexibility to re-use data with appropriate safeguards

→ Recognition of safeguards/ avoidance of mandatory processing requirements

→ Consistent definitions of key terms

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Conclusions from Mapping exercise

- Many MS's will carry out minimal transposition
- Most member states will rely on a range of secondary measures to set the rules for research. These vary from legislation to self-regulation to regulatory guidance
- We are seeing examples of best practice
- Most complex area is the legal basis for secondary use and the interaction with consent
- Implementation process has highlighted role and capacities of research ethics committees

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Supporting a harmonized implementation of GDPR

- **What can the EU do?**

- Promote alignment through
  - EU-MS dialogue (Expert Committee)
  - Guidance from the Article 29 Committee
  - Harmonised practices within research networks

- **What can other stakeholders do?**

- Lead the debate and support best practice in GDPR implementation
- Improve Public Education/Awareness
- Engage on Self-Regulation

BBMRI code of conduct:

BBMRI-ERIC

We must urgently clarify data-sharing rules

Scientists have worked hard to ensure that Europe's new data laws do no harm science, but one last push is needed, says Jan-Eric Litton.

24 January 2017

PDF | Rights & Permissions

In a little over 12 months, the European Commission will roll out a new legal framework to govern the protection of personal data. There were many debates and discussions about the controversia regulations, which passed last year, and scientists and scientific bodies raised concerns over restrictions that the framework could have placed on the use of research data. We won several concessions, but the fight is not over yet. Scientists must now come together to work out a consistent way to implement the rules, and they must do so quickly.

- GDPR supports Codes – Commission supports stakeholder-driven solutions
- 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
- Sectoral Code
  - Can respond to sectoral specificities
  - Offer solutions to Member States
  - Addresses the need for “representativeness” of codes

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In Summary

- The better use of healthcare data will improve patient outcomes, make our healthcare systems more sustainable, drive innovation in research and help Europe to remain a centre for investment in medical research.
- The ability to capture and share personal health data among researchers will advance the understanding of diseases. Allowing re-use of data will avoid duplication of studies, guarantee the verification of clinical trials results and enable individuals who wish to, to share their data to benefit others with the same or other medical conditions.
- Robust and harmonised rules in Europe on the processing and use of patient data will reduce delays and duplication allowing new medicines to be developed and brought to market quickly for the benefit of patients.
- This will lead to better outcomes for individual patients, improve population health in general, contribute to the sustainability of health systems and preserve the EU's place as a global centre of research
- The industry and its partners are pioneering new uses of data. We recognize the need for this work to proceed in tandem with enhanced technical safeguards and forms of accountability to those whose data we use.
- We call on the member states to commit to the development of an aligned approach to these issues and to avoid undermining such efforts through an uncoordinated implementation of the research provisions of the General Data Protection Regulation.

Thank You