Is GDPR fit for purpose?

BBMRI – 28th January

European Federation of Pharmaceutical Industries and Associations

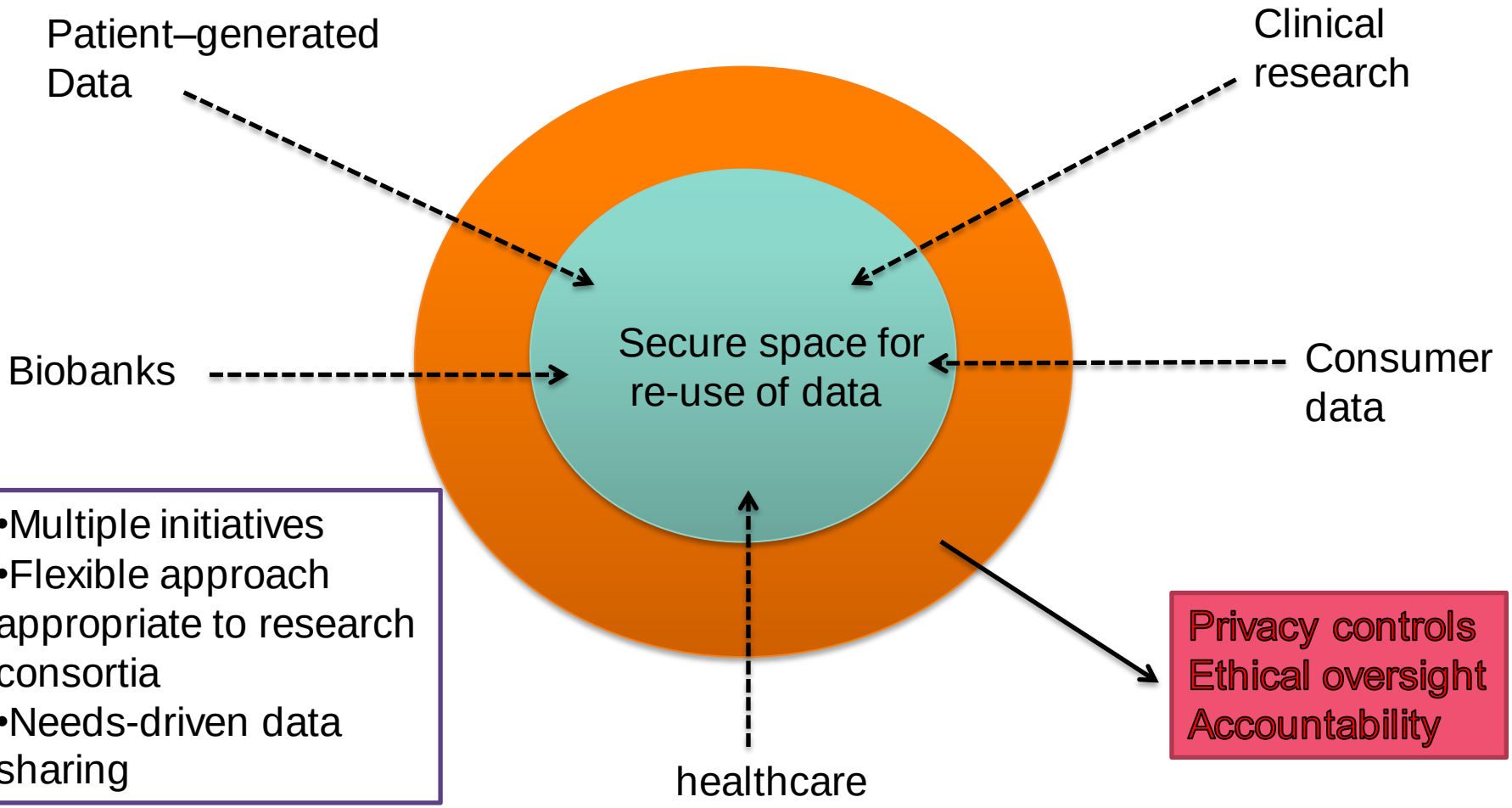
www.efpia.eu

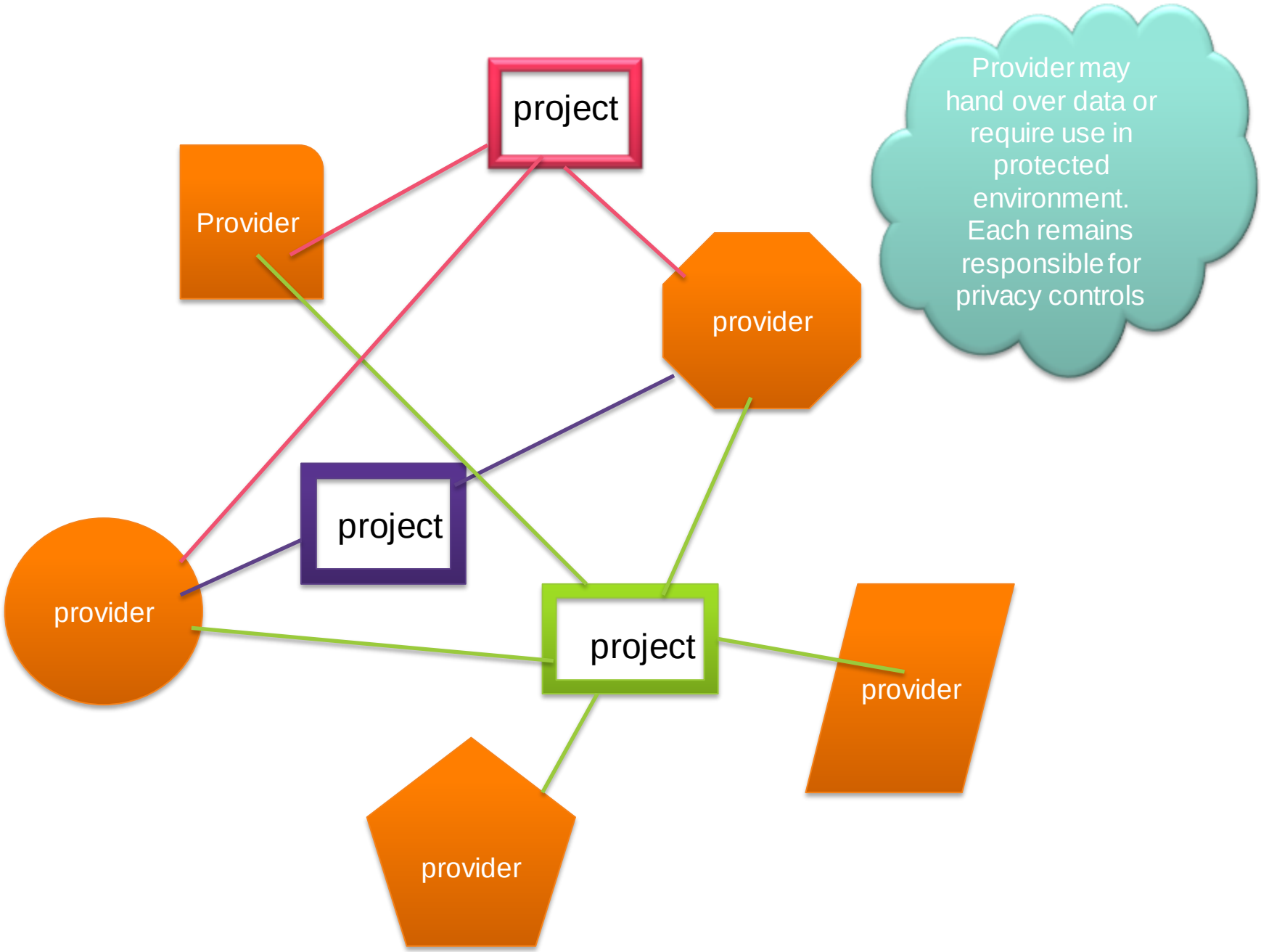
Scope

- Personal Data – both directly-identifiable and in coded form
  - Clinical trial data
  - biobanks
  - Pharmacovigilance data
  - Medical records
  - Prescription data
  - Consumer data
  - Patient-reported data
  - E-health data
  - M-health data
  - Organisational data (employees, etc)

Industry concerns

- General issues relevant to all industries
- Pharma/research-specific
  - Privacy impact assessments
  - Data breach notification
  - Transfers to third countries
  - Definition of genetic data
  - Legal basis for re-use of data for research purposes
  - What are identifiable/pseudononymised/anonymous data?


Patient–generated Data
Clinical research
Biobanks
Secure space for re-use of data
Consumer data
healthcare
•Multiple initiatives
•Flexible approach appropriate to research consortia
•Needs-driven data sharing
Privacy controls
Ethical oversight
Accountability


project
Provider
provider
project
provider
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provider
Provider may hand over data or require use in protected environment. Each remains responsible for privacy controls

Legislative procedure

Legislative procedure: State of play

- European Parliament
  - Adopted its report in plenary on 12 March 2014
  - EFPIA supports
    - Art. 4: Definition of genetic data in line with international standards
    - Art. 33: A single data protection impact assessment for similar activities
    - Art. 34: Deletion of the request for prior autorisation from the supervisory authority
    - Art. 38: Codes of conduct

Legislative procedure: State of play

- European Parliament
  - EFPIA strongly opposes
    - Art. 81 on processing of personal data concerning health
    - Art. 83 on processing for historical, statistical and scientific research purposes

The proposals would:

- create an additional layer of potentially conflicting regulation to the existing structure
- limit a research participant's right to consent to future research
- make important research impossible, where obtaining prior consent is not reasonably feasible
- make clinical research extremely difficult

Legislative procedure: State of play

- Council
  - Provides a legal basis to the processing of personal data for scientific purposes (Art. 6 para 2)
  - But allows MS to derogate from the various data controller obligations to the data subject individual rights (Art. 83 para 1)

    e.g. right of notice, access, rectification, to be forgotten and to erasure, to restriction of processing, data portability and the right to object.

- Timetable
  - June 2015: Council to reach General Approach
  - September 2015: Trialogues to start
  - 2015: Political Agreement

Overall……

- Pragmatic approaches to DP assessments and other issues are welcome
- Some hope that European harmonisation will be advanced through enhanced coordination
- Neither EP or Council texts provide a wholly-satisfactory solution to research needs
- Significant risk that Europe loses out as a location for research (is this already happening?)
- Important to ensure that Regulation is permissive of an implementation that is adaptive to future needs

For Discussion

- Overwhelming public support for re-use of data for research purposes provided appropriate protections are in place
- What do we want the Regulation to say?
- What do the right protections look like in the era of “big data”
- What role should ethical oversight play in supporting wider re-use of data?
- How should the research community respond to likely expectations of improved accountability in relation to re-use?
- How important is it that we have the same standards, principles across Europe and across the Research Community?
- Should we be developing a collective response?

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