



## **Research data as non personal data: the state of the art and the way ahead**

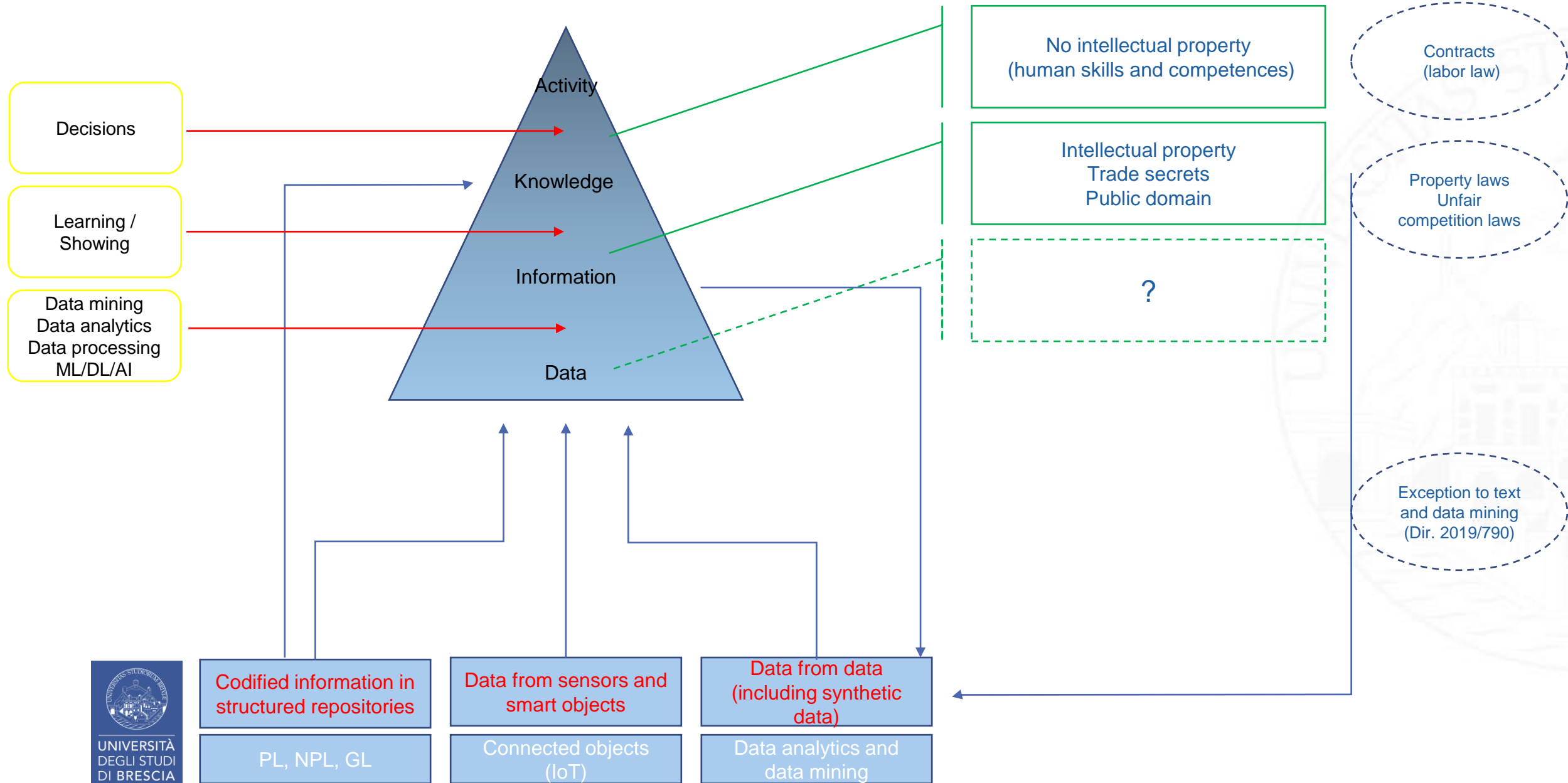
La comunità prima della commercializzazione  
Scienza aperta, proprietà intellettuale e dati

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# Prelude

14. Public sector information represents an extraordinary source of data that can contribute to improving the internal market and to the development of new applications for consumers and legal entities. Intelligent data usage, including their processing through artificial intelligence applications, can have a transformative effect on all sectors of the economy.

# Data ecosystems and use



# What is the current status of research data in EU?

‘Research data’ appear in the Open Data Directive (OPD) and are defined as **documents in a digital form**, other than scientific publications, which are collected or produced in the course of scientific research activities and are used as evidence in the research process, or are commonly accepted in the research community as necessary to validate research findings and results.

Research data as open data are subject to the provisions of the OPD on re-use and might be part of the high-value datasets pursuant to art. 13 OPD.

# Legal regime under the Open Data Directive

Research data are digital documents (not scientific publications)

Research data are collected or produced (documentary datadases?)

Research data underly significant (not only economic) value

Even if research data are digital documents in general, the OPD does not apply when such documents are covered by third parties' intellectual property rights (art. 1, par. 2, lett. c) and in a number of other situations (way too many, probably).

When documents are part of a dataset subject to Directive 96/9/EC held by public sector bodies exercise of exclusive rights is limited.

# Again on the notion of data as document

According to the OPD, **documents are:**

(a) **any content** whatever its medium (paper or electronic form or as a sound, visual or audiovisual recording); or

(b) **any part of such content**

There appears to be **a conceptual overlap between document and content of the document**, which might have severe implications (e.g., if IP rights exists in the document, would that mean that also its content is subject to exclusive rights?).

# Principles that apply to open data under the OPD

Art. 10 of the OPD encourages Member States to make research data available by adopting national policies and relevant actions aiming at making **publicly funded research data openly available** ('open access policies'), following **the principle of 'open by default'** and compatible with the **FAIR (Findable Accessible Interoperable Reusable) principles**.

Research data **shall be re-usable for commercial or non-commercial purposes** pursuant to the provisions of the OPD, but:

- without prejudice to third parties' IP rights on documents
- data are publicly funded
- "researchers, research performing organisations or research funding organisations have already made them publicly available through an institutional or subject-based repository"

In the same context, "legitimate commercial interests, knowledge transfer activities and pre-existing intellectual property rights shall be taken into account".

# Other principles on research data

Re-use of open data (including research data) is subject to the principles set forth by the OPD: format, charging, transparency, licenses, non-discrimination and **prohibition of exclusive arrangements**.

When dealing with research data that are instrumental or relevant to technology transfer by public research institutions and public funding institutions, **access to research data cannot be exclusive even if the main transaction involving a given technology is exclusive**. Are public bodies (and public research organizations) aware of this principle?

Re-use of research data and an “**open by default policy**” should take into account concurring values, such as privacy, protection of personal data, confidentiality, national security, legitimate commercial interests (such as trade secrets) and intellectual property protection. Then the principles becomes “**as open as possible, as closed as necessary**” (whereas 28 OPD).



# Can research data be also “other” data?

A conceptual question arises from concurrent definitions of data in different legal texts.

Under the forthcoming EU Data Act, industrial data means “any **digital representation of acts, facts or information** and any compilation of such acts, facts or information, including in the form of sound, visual or audio-visual recording” (art. 1, n. 1, EU Data Act, draft)

Are industrial data digital documents?

Overlap can be caused by the fact that industrial data are simply non personal data and might well be caught under the definition of research data. Which regime would then apply?

# What if research data are personal data?

Very relevant issue for public funded medical/clinical research generating collections of personal data for several purposes.

Personal data in GDPR means “any information relating to an identified or identifiable natural person (‘data subject’); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person” (art. 4, n. 1, Reg. EU 2016/679).

Personal data in a mixed dataset trigger the application of the GDPR to the whole set. If the same principle applies to research personal data, then the GDPR pre-empts the OPD.

# Some open questions on open data

Is the “open by design” principle operation actually prevented by the limitations and the restrictions laid down in the OPD?

Will this piecemeal approach to data regulation benefit or hinder the exploitation of open data?

Why the EU rulemakers did not consider coordinating sources on data with sources about “documents” covered by IP rights (the TDM exception of Directive 2019/790 applies here)

Will internal management practices of research institutions overwrite or expand to open data framework (...as necessary)?

# Let us think more about this!

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