

# **La comunità prima della commercializzazione**

## **Scienza aperta, proprietà intellettuale e dati**

*Clinical Trials Data and Data Exclusivity*

Università di Trento – 27 ottobre 2023

Giorgia Bincoletto

# Outline

1. Introductory remarks
2. The legal framework for clinical trials data
3. Data exclusivity
4. Future perspectives





# 1. Clinical research

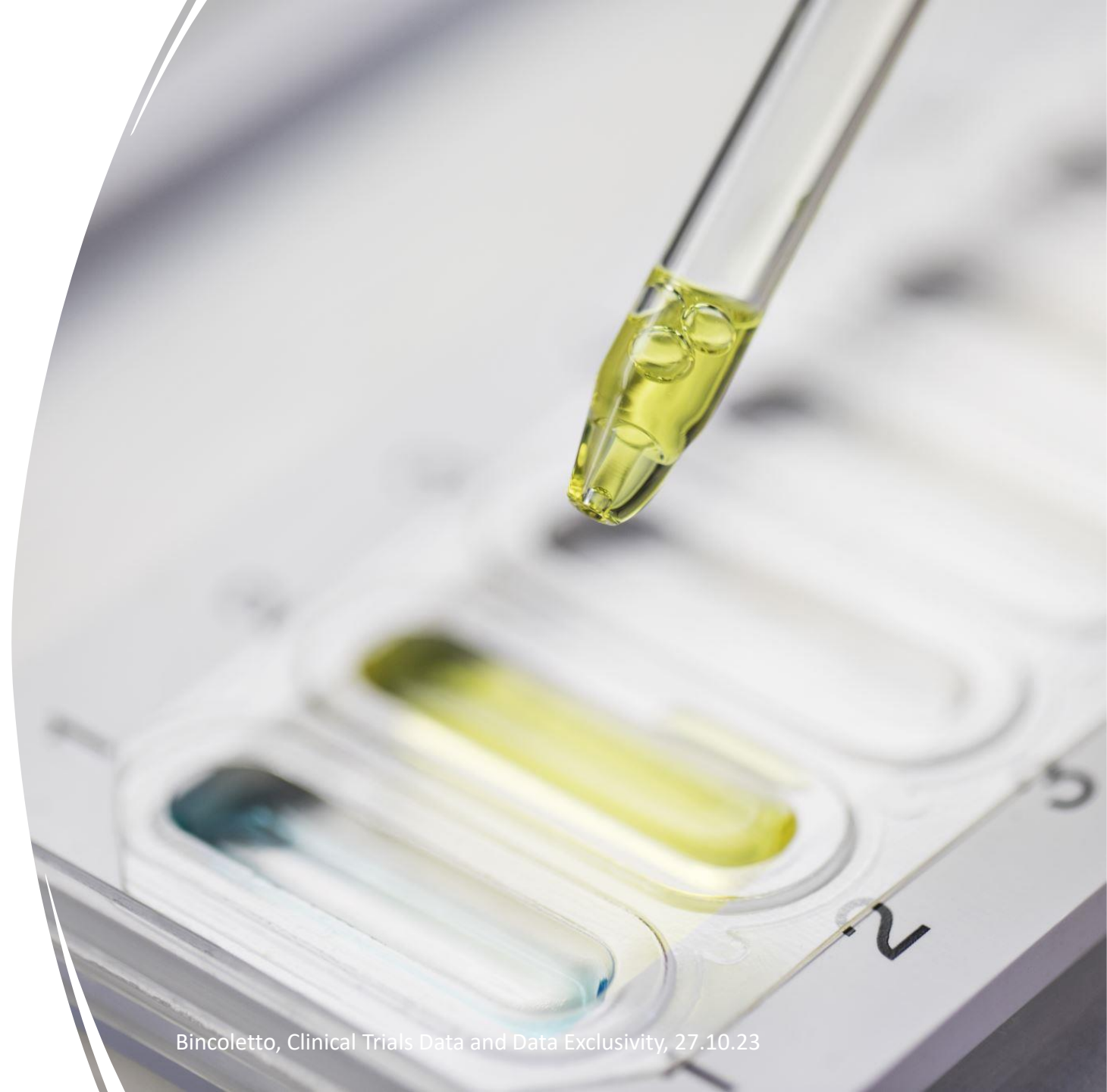
---

- Pharmaceutical field
    - vaccines, drugs
  - Research in the medical, biomedical, behavioral fields
    - Prospective and retrospective studies
    - Medical devices
- pre-clinical and clinical tests including data and samples

# 1. Clinical trials data

---

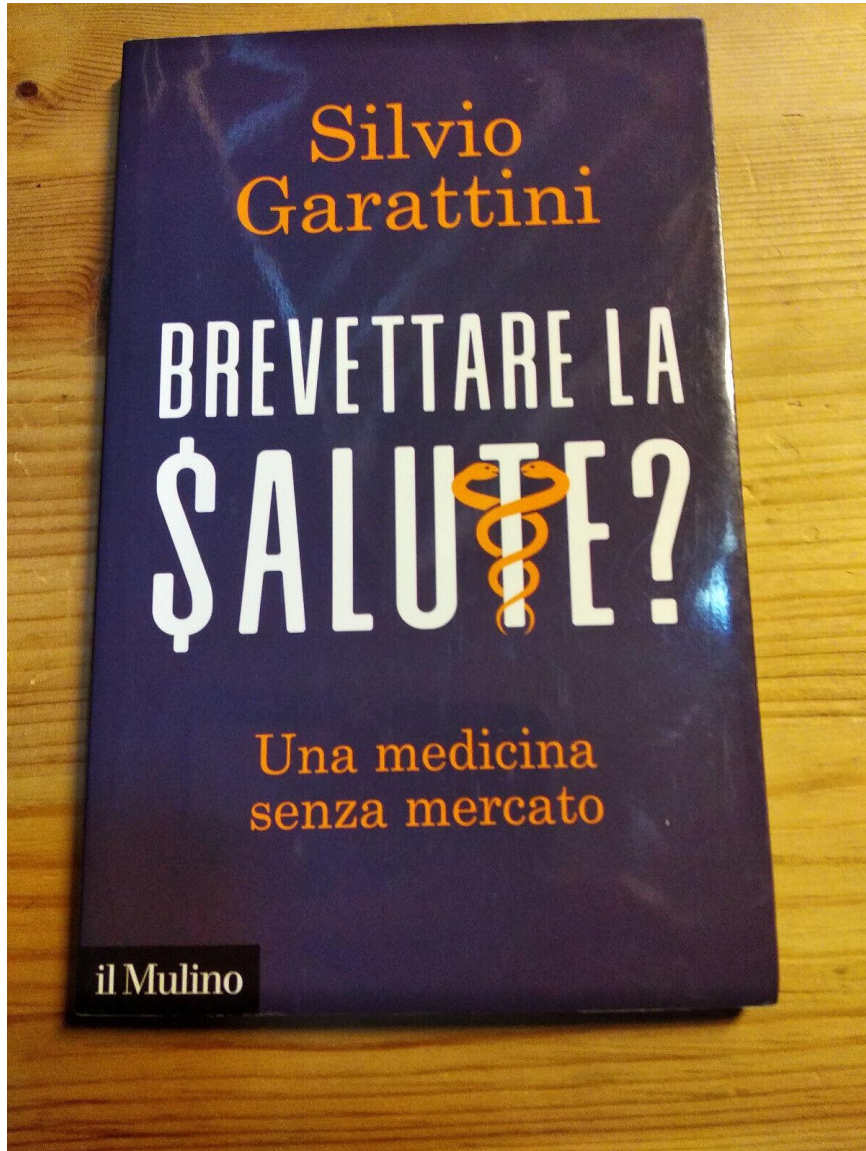
- Collection of personal and non-personal data
  - Repositories
- Samples (blood, urine, tissue samples, surgical pieces, organ fragments, tumors...)
  - biobanks
- **Data on the trial – clinical study reports:** including safety, efficacy...



# 1. Clinical trials on drugs

---

- Target identification (e.g. gene)
- Pre-clinical research (e.g. *in vitro* test)
- Clinical research to test efficacy and safety





# 1. Clinical trials on drugs: research phase

---

- Study 1 on a limited set of participants to verify safety and parameters
- Study 2 on a larger set to test efficacy
- Studies 3 on even larger set to test clinical validity and usability
- Study 4 or post-marketing

# 1. Clinical trials

---

- Health Authority's and/or ethics Committee's approvals
    - Local ethical committee
  - Authority for the drugs' approval
    - European Medicines Agency
    - Agenzia Italiana del Farmaco
    - Food and Drug Administration
- Data is key part of the authorisation

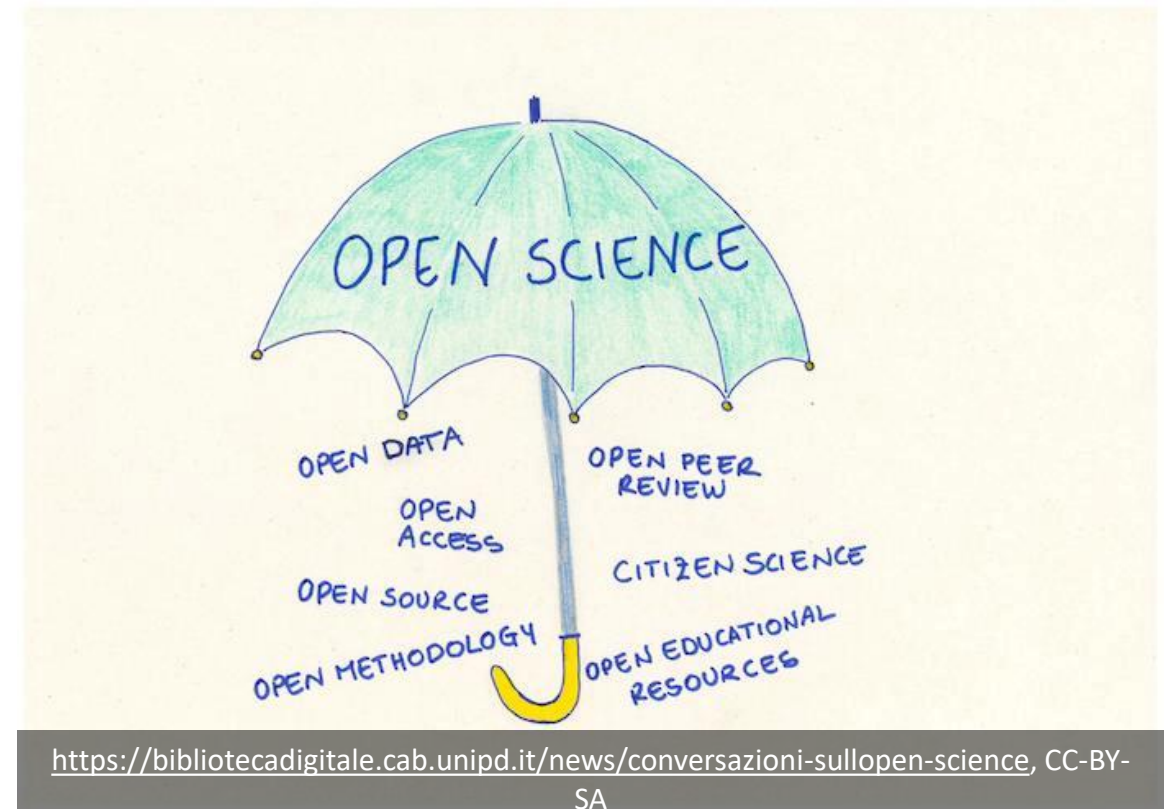


# 1. Access to clinical trials data

---

Access benefits:

- Participants
- Society as a whole to assess safety and efficacy, and to ensure transparency
- Scientific progress: reducing duplication and ensuring reproducibility







## 2. The legal framework

- Clinical trials regulations
- Data protection law
- Biobanking law
- Pharmaceutical legislation
- Intellectual property law: patent, trade secrets, know-how, database protection
- Data and market exclusivity

# 3. Data Exclusivity

---

TRIPs Agreement, Article 39, par. 3

«Members, **when requiring, as a condition of approving the marketing of pharmaceutical** or of agricultural chemical products which utilize new chemical entities, **the submission of undisclosed test or other data,**

the origination of which involves **a considerable effort,**  
shall **protect such data against unfair commercial use.**

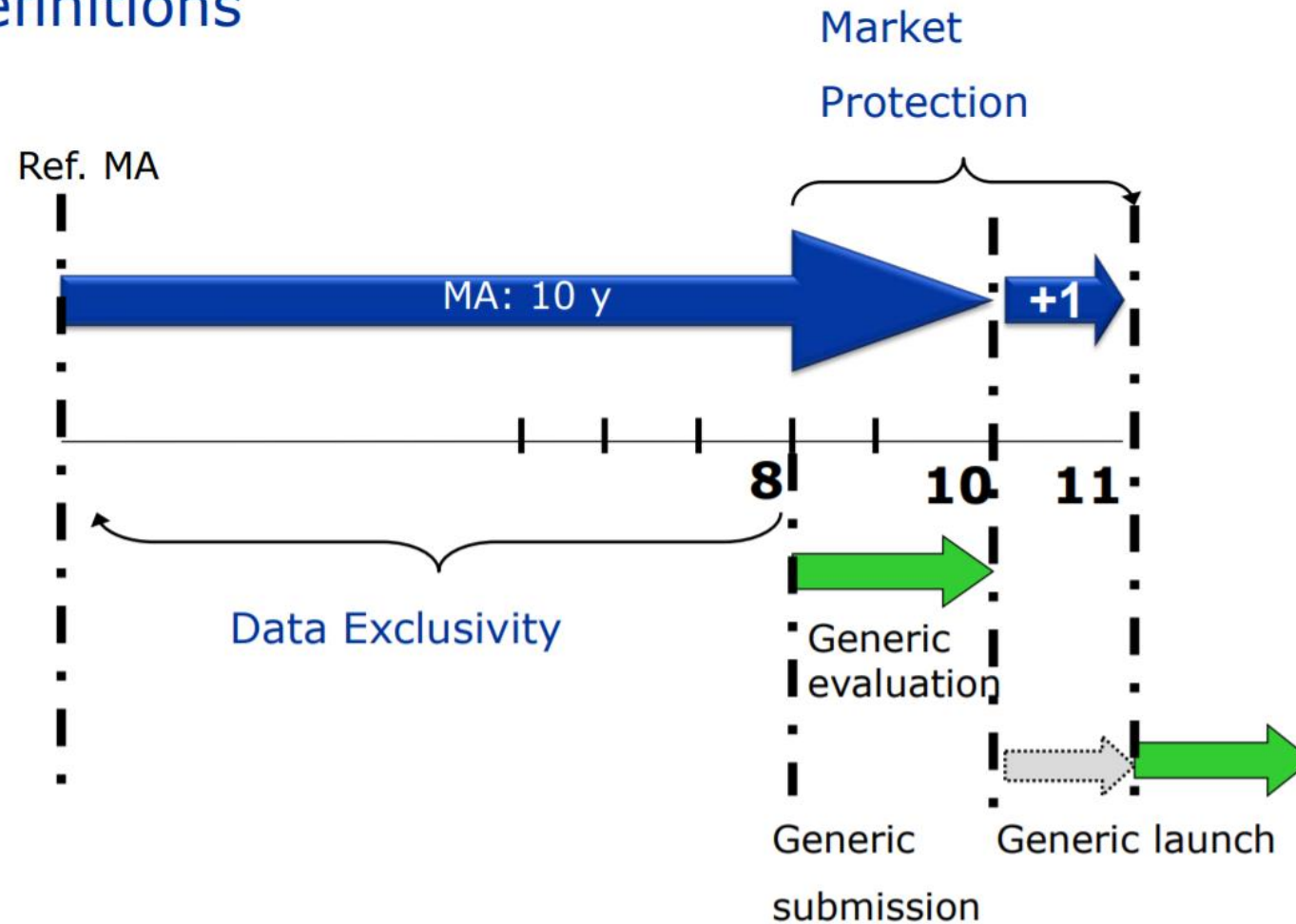
In addition, Members **shall protect such data against disclosure,** except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use»

# 3. Data Exclusivity

---

- Forms of **data and market protection** to safeguard the «effort»
  - ...and public-funded research?
- **X years** after the authorisation to prevent the generic drug
  - In the EU pursuant to Art. 14(11) Reg. 2004/726: 8 years of data protection and 10 years of marketing protection
  - In Italy Art. 98 (2) may add the protection of trade secrets
- Insisting on **information/data/results** of the clinical trial
- No limitation or exceptions

# Definitions



[https://www.ema.europa.eu/en/documents/presentation/presentation-data-exclusivity-market-protection-orphan-paediatric-rewards-s-ribeiro\\_en.pdf](https://www.ema.europa.eu/en/documents/presentation/presentation-data-exclusivity-market-protection-orphan-paediatric-rewards-s-ribeiro_en.pdf)

# 3. Clinical Trial Regulation

---

- Reg. 536/2014 entered into application on 31 January 2022
- Creation of a **database** at Union level
- data in an easily searchable format, with related documents linked together by the trial number and with hyperlinks (e.g. linking together the summary, the protocol and the clinical study report, Recital 67)
- Goals: **transparency, protecting public health and fostering innovation capacity** (Recital 67)

# 3. Clinical Trial Regulation

---

Art. 81(4): database **publicly accessible unless**, confidentiality is justified on:

(a) protecting personal data

(b) protecting **commercially confidential information**, in particular through taking into account the status of the marketing authorisation for the medicinal product, **unless there is an overriding public interest in disclosure**

# 3. Clinical Trials Information System

---

- From 31 January 2023 single-entry point for sponsors and regulators of clinical trials for the submission and assessment of data
- Searchable database for healthcare professionals, patients, and other interested parties





### **3. Reform of the EU pharmaceutical legislation**

- 26 April 2023 Proposal for a new directive and new regulation
- Transferable data exclusivity voucher



# 3. Critical aspects

---

- Monopoly privilege to Big Pharma
- Pseudo-IP protection
- Even when compulsory licence applies, data exclusivity remains
- Duplicability and reproducibility



## 4. Future Perspectives

- Following the EC's proposals in the pharmaceutical sectors
- Following the EC's proposal for the European Health Data Space
  - Secondary use of electronic health data



## 4. Future Perspectives

### **PRIN 2022 «Clinical trial data between privatization of knowledge and Open Science»**

- University of Trento (Prof. Caso)
- University of Pisa (Prof. Pievatolo)
- CNR – Consiglio Nazionale delle ricerche (Prof. Colcelli)
- University of Bolzano (Prof. De Gennaro)
- University of Torino (Prof. Borghi)



## 4. Future Perspectives

### **PRIN 2022, UNITN:**

- Drawing on the theoretical background on IP and data, how can the EU and Italian legal rules be modified to safeguard creativity and innovation, but also balance exclusivity with superior rights (right to health and science)?
- What guidelines and recommendations can be formulated to improve access to clinical test data?

# Giorgia Bincoletto

E-mail:

[giorgia.bincoletto@unitn.it](mailto:giorgia.bincoletto@unitn.it)

Web:

<https://webapps.unitn.it/du/it/Persona/PER0123289/>

# Copyright

Copyright by Giorgia Bincoletto



Licenza Creative Commons

Quest'opera è distribuita con [Licenza Creative Commons  
Attribuzione - Condividi allo stesso modo 4.0 Internazionale](https://creativecommons.org/licenses/by-sa/4.0/)

La citazione di testi e la riproduzione di immagini costituisce esercizio dei diritti garantiti dagli art. 2, 21 e 33 Cost. e dall'art. 70 l. 1941/633