Title of the Project: Clinical trial data between privatization of knowledge and Open Science (CLIPKOS)

PROGETTI DI RICERCA DI RILEVANTE INTERESSE NAZIONALE – Bando 2022 Prot. 2022K4HBFA

Description and objectives of the Project CLIPKOS

Clinical research produces enormous amounts of data. This especially in the pharmaceutical field during pre-clinical and clinical trials. These data represent an invaluable treasure from multiple points of views: scientific interests in creating new medicines and pursuing progress and innovation in the health domain; the necessity to verify the studies carried out; the purely commercial approach on protecting the effort to obtain a marketing authorisation of a new drug; and the public interest in access and disclosure. Access to this information is often severely limited by forms of exclusive rights and other forms of protection and controls that persist on various levels and make it impossible to take (public) advantage of such important resources. On the contrary, Open Science, findability, accessibility, interoperability, and reuse principles, transparency and flexibility needs, and the creation of public databases push forward the implementation of Open Access and Open Data. The recent pandemic has tragically brought this problem to bear and in this application context there is currently a lack of clarity and knowledge among the different stakeholders in the legal, philosophical and ethical fields.

The project CLIPKOS aims at investigating the interplay between privatization of knowledge by pharmaceutical developers and Open Science for clinical trial data from multiple perspectives.

The first objective of the research will be the comprehensive legal mapping of the regulatory framework for the protection of data in clinical research in the EU legal system and in some selected Member States, including Italy, while briefly considering the international context. It shall be also examined if and how this scenario may be consistent with the instances promoted by Open Science, Open Access and Open Data. The legal analysis uses a comparative methodology that takes into account the complex regulatory framework. This task is primarily assigned to the Principal Investigator, i.e. at the Faculty of Law at University of Trento.

The second objective will be the investigation of the different policies adopted by the public agencies (European and nationals) on data access and governance. This task is primarily assigned to the University of Turin.

Moreover, interdisciplinarity will be key to understanding a context that sees the intersection of many scientific fields. These theoretical approaches will be then combined with the approaches followed by two other partners of the project (University of Pisa and University of Bolzano): ethical and philosophical studies related to striking the balance between the fundamental rights to health and science with the individual data rights.

Ample space will also be dedicated to case studies based on health and clinical data and offered by the scientific partners: CNR- Istituto di Fisica Applicata. Researchers at CNR will be able to understand how data is managed with special reference to the concept of research integrity, data reproducibility and the attitude of communicating science in an open and transparent way.

The ultimate goals of the research are to provide a set of policy recommendations, guidelines, and proposals on legislation reforms on the use and disclosure of clinical test data that balance privatization and Open Science interests.

Main tasks of the University of Trento research unit

Data is not protected per se by the Intellectual Property Rights (IPRs). Although a reliable definition is not shared by the scientific fields, data can be considered units of facts and statistics that (as ideas) are not covered by the law. However, traditional IP rights (i.e. patents, trade secrets) and new *sui generis* and data rights (e.g. database protection, data and market exclusivity) can create direct or indirect exclusive forms of control over data. While on the one hand it may be necessary to protect the economic interests of those who carried out the experiments, providing incentives and benefits to those who work in the field, on the other hand the openness of information (e.g. through publication in public databases) would ensure greater transparency of scientific research and a more effective and efficient sharing of innovations for public health and scientific research.

The primary objective of the research at the University of Trento will be the comprehensive legal mapping of the regulatory framework for the protection of data in clinical research in the European Union (EU) legal system and in some selected Member States, including Italy, while briefly considering the international context. In this scenario, next to the fundamental rules provided by EU Reg. 536/2014, intellectual property rules, especially considering trade secrets and patent laws, are at play, while these also overlap with other forms of exclusive rights that outline a context strongly characterized by closure, i.e., considering data exclusivity as primarily informed by EU Reg. 726/2004, market exclusivity, supplementary protection certificates. It also worths to be taken into account the fact that the personal data protection can play an important role in this context: the consistent application of this legal regime, including additional measures that would apply to special categories of data, creates other forms of confidentiality (and control). The research will, then, analyse the impact of the data protection field over the issues of privatization and openness of clinical test data.

It shall be then examined how this scenario may be consistent with the instances promoted by the Open Science and Open Access, that advocate for greater access and transparency of scientific research. Considering publicly funded research, such instances seem partially welcomed in the latest reforms of EU. The research will cover the recent legal developments in the open data domain that have been recently implemented by the Member States.

The methodological approach for this analysis will be characterized by legal, comparative and interdisciplinary perspectives, aimed at verifying similarities and divergences across Member States, with primary reference to the implementation of EU rules in Italy, but also application rules adopted by the authorities.

The research will also be coordinated and combined with the other parts of the project, which will be carried out in the other universities: the legal analysis of the Open Science instances and the policies of the agencies (UNITO), ethical aspects (UNIPI), philosophical aspects (UNIBZ) and the case studies (CNR, Istituto di Fisica Applicata).

The final goal is contributing at the creation of a set of guidelines, recommendations and proposals able to balance the control over information with Open Science.