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### Conforming intellectual property and privacy restraints to the right to health and the right to information in clinical trials data

The study aims to define a legal framework of clinical trials data, by testing International European rules of data secrecy against the expanding demands for disclosure. We argue that information embedded in clinical trial protocols turn out to be a precious source for the evaluation of drug's safety and efficacy, the awareness of which is thus to be considered essential for protecting patient's and consumer's health. However, apart from the public informational value, clinical trials data also appear to have an intrinsic regulatory-and therefore commercial-value, being key to the granting of drugs marketing license. We compare the general disclosure provision provided by art. 81(4) of the recent European Clinical Trials Regulation EC n.536/2014, establishing a publicly accessible European clinical trials database, with specific intellectual property measures, providing guarantees of exclusivity to clinical testing data used to obtain marketing approval. Research-based companies aiming to protect their "sweat of the brow" from competitors free-riding have invoked art. 39.3 TRIPS and the European data exclusivity regimes, as a legal basis for regulatory agencies non-disclosure obligation. Also privacy concerns have been called upon as a legal barrier to disclosure, due to the vast amount of personal data embedded in the results of test data. The conflict of competing interests- the once of transparency and of protection of commercially valuable information has become a conflict of opposite rights, and thus of opposite bodies of law, as the 2007 European Ombudsman's decision EMAvs, Cochrane Collaboration Research Group, and the two 2013 ECJ rulings AbbVie and Interment show. We illustrate how drug's safety information disclosure is not prevented by both clinical trials protection rules and the privacy normative framework. To the contrary we demonstrate a systemic justification for disclosure. In respect of privacy concerns, clinical trials transparency platforms could find legal grounds in light of the general exemption provided for the processing of personal data, when it is necessary to "reconcile the right to privacy with the rules governing freedom of expression". Secondly and most importantly, disclosure of test data is to be legally defended through an accurate analysis of the ratio of the sui generis intellectual property protection of data exclusivity regimes, specifically protecting data submitted by pharma companies to regulatory agencies for the granting of marketing license. Thus, the definition of the "structural" weight of data exclusivity regimes appears to be essential for solving the contrast between the two opposite regulatory frameworks, concerning both disclosure of test data and protection of commercially valuable information. Only on these premises, other areas of law can be invoked as interpretational grounds for the strengthening of disclosure rules. In this light, the public interest of transparency and accountability in clinical trials information must be read through the lenses of the human right to health and information, as defined by International Human Rights Treatises and the Human rights case law; of the public goods dimension of research and knowledge production; and finally of the legal framework protecting consumer rights as defined by the correspondent European Directives.

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