Research project: **Designing Regulation of Access to Clinical Research Data in the Context of Competition in Innovation in the Pharmaceutical Sector**

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Abstract

In my current project, I explore the controversial issue of disclosure of clinical research data in the context of cumulative innovation and dynamic competition in the biopharmaceutical sector.

The issue of access to clinical trial reports submitted by pharmaceutical companies for drug marketing authorization has been subject to a long-standing debate. Most recently, the idea of opening access to industry-sponsored clinical trial data has been brought to the fore by several prominent initiatives including the European Medicines Agency (EMA) 2015 policy for data disclosure,[1] the WHO 2014/2015 public consultations,[2] and the 2015 Report of the Institute of Medicine of the National Academies "Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk".[3] As of January 1, 2015, the EMA provides access to clinical dossers submitted for regulatory review after the corresponding drug has been authorised for the EU market. Access can be granted without the authorization of and remuneration to drug sponsors, upon the condition that the released data are used for *scientific*, *non-commercial research* purposes and, explicitly, not for the purpose of generic drug approval.

Pharmaceutical innovation is science-driven and cumulative in a way that new research endeavours rely and build on previous knowledge. Evidence collected during clinical trials on newly established and verified properties of tested drug candidates presents one of the major sources of new biomedical knowledge. Since the advent of evidence-based medicine, the major share of clinical research has been sponsored by the pharmaceutical industry. For the most part, industry-generated clinical trial data remain tacit: pharmaceutical companies view research data as a source of competitive advantage, claim property rights in datasets and adopt restrictive data sharing policies.

In broad terms, benefits of data sharing are associated with healthcare improvement and scientific progress. Proponents of the EMA policy have argued that the disclosure of clinical dossiers can reduce the risk of publication and reporting bias and contribute to the greater transparency of drug authorities. In terms of new drug development, evidence gathered in previous trials can facilitate exploratory research, support R&D activities and guide discovery and development of new drug molecules and targets.

Against this background, I formulate the main innovation-related controversy over clinical data disclosure as the dilemma over balancing innovation incentives of multiple drug developers in the context of the cumulative research. The overall concern is that confidentiality protection over clinical research data can generate inefficiencies in drug R&D resources allocation at the sector level and,

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[1] The EMA, *The European Medicines Agency Policy on Publication of Clinical Data for Medicinal Products for Human Use*, EMA/240810/2013 (Oct. 2, 2014) *available at* http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf (last visited Feb. 26, 2016).

[2] The World Health Organization, *Call for public consultation: WHO Statement on Public Disclosure of Clinical Trial Results, available at* http://www.who.int/ictrp/results/en/ (last visited Feb. 26, 2016).

[3] The Institute of Medicine of the National Academies, *Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk* (2015) *available at* http://www.iom.edu/Reports/2015/Sharing-Clinical-Trial-Data.aspx (last visited Feb. 26, 2016).

potentially, deter the development of new medicine. From a broader public policy perspective, the access/confidentiality dilemma pertains to the question of governance of innovation resources. Is the society better-off in terms of the supply of innovative medicines if the regulator protects interests of data originators by safeguarding data confidentiality, or enables access to data for follow-on drug developers? In addressing this question, the study analyzes how principles of intellectual property and competition law – the two areas of economic law that intend to promote innovation – can inform regulation of access to clinical data.

The research starting point is that clinical dossiers are protected as a category of intellectual property in the meaning of Article 39 of the TRIPS Agreement. The *hypothesis* is that

> although mandatory disclosure of clinical data contradicts the essence of confidentiality protection, under certain circumstances, it can be consistent with the principles of IP protection.

In particular, I consider principles of IP that determine the scope of legal protection and intend to balance the interests of multiple innovators. Principles of interference with IP protection by *competition law* are considered as secondary checks and balances addressing concerns regarding overprotection. As a guiding principle, the analysis adopts the postulate that IP promotes competition by *substitution* at the expense of a temporary limitation on competition by *imitation*.

The study does not intend to prove whether disclosure of clinical data is *legitimate* under IP or competition law of a particular jurisdiction. It takes a normative approach and assumes that, by integrating principles underlying intellectual property and competition law, regulation of access to clinical dossiers can promote drug innovation in a more balanced way as compared to the blanket data disclosure by drug authorities.