

Einladung zum Biometrischen Kolloquium

DARIA KIM, Max-Planck-Institut für Innovation und Wettbewerb

22. März 2018, 10h s.t.

im Jugendstilhösrsaal der Medizinischen Universität Wien, Spitalgasse 23, 1090 Wien

ACCESS TO CLINICAL TRIAL DATA: IS THE PARADIGM SHIFTING?

ABSTRACT:

The presentation will reflect on the recent changes in the EU regulatory framework that governs access to clinical trial data. It will cover the aspects such as transparency requirements under the new EU Regulation on clinical trials; provisions related to health data under the new EU General Data Protection Regulation; access to clinical trial data as the exercise of the right of access to documents; legal sources of exclusive control over data by trial sponsors; recent decisions of the Court of Justice of the European Union regarding disclosure of clinical trial reports by the EMA. The overall objective is to define whether clinical trial data is becoming more accessible for scientific research.

The discussion will also touch upon the questions what policy instruments of access could provide for the greater realisation of the research potential of data, and whether there is cooperation or competition between industry and academia with regard to exploratory data analysis.

ABOUT THE SPEAKER:

Daria Kim (LL.M., MA) is a doctorate researcher at Max-Planck Institute for Innovation and Competition (Munich) and a PhD candidate at the University of Augsburg. Main areas of research include intellectual property law and policy; competition in innovation in the pharmaceutical sector; legal and regulatory framework for a data-driven economy in the EU.