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Transparency policies of the European Medicines Agency: Has the paradigm shifted?

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The presentation will draw on the controversial issue of clinical trial data disclosure and focus on the recent developments in the regulatory environment in the European Union. In 2014, the European Medicines Agency (EMA) adopted a landmark policy that provides for disclosure of clinical trial reports and individual patient-level data. Around the same time, the new EU regulation on clinical trials was adopted and set new standards for reporting clinical trial results and obligations on the trial sponsors for disclosure of clinical trial data. Meanwhile, several pharmaceutical companies have successfully challenged at the Court of Justice of the European Union (CJEU) the EMA's decisions to grant a third-party access to clinical trial data. The presentation will draw on the emerging case-law of the CJEU that illustrates main uncertainties of the EU regulatory environment regarding access to clinical trial data. In particular, the following issues/questions will be addressed: Access to non-summary clinical trial under the current EU regulatory framework; the legal basis for third-party access to data held by drug authorities; the legal basis for protection against disclosure; is clinical trial data (intellectual) property under EU law? Are there presumptions of confidentiality or overriding public interest in the case of clinical trial data under EU law? What are the main legal uncertainties for drug sponsors? I believe this topic will be of interest for the practitioners, who work with cross-border operations in the pharmaceutical sector, as well as legal scholars, who do comparative research in this field.

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