IDDI Scientific Symposium
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"Open Sharing of Clinical Trial Data"

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The last five years mark the beginning of a revolution in clinical research: data collected on patients treated in clinical trials to support approval of new drugs and devices, which for a long time were considered confidential, will from now on be shared with a view to enhancing public health and informing future research.

The European Medicines Agency (EMA, 2013) set a new standard for clinical trial data transparency by enabling interested parties to request data from clinical trials submitted for marketing authorization of medicinal products, including patient-level data. Other proposals to enable access to clinical trial data were made by the Pharmaceutical Research and Manufacturers of America (PhRMA, 2011), the European Federation of Pharmaceutical Industries and Associations (EFPIA 2011), the Institute of Medicine (IOM, 2015), the International Committee of Medical Journal Editors (ICJME 2016), among many others.

The two speakers will explore the possibility of open sharing of clinical trial data. Topics discussed will include benefits and challenges of open data sharing, a critical review of platforms offering access to clinical data from pharmaceutical industry and NIH-sponsored trials, the impact of the European General Data Protection Regulation (GDPR, 2018), and the involvement of patients in data sharing policies.