

AI IN HEALTHCARE

EU LAW

HEALTHCARE

- [Regulation \(EU\) 2017/745](#) of the European Parliament and of the Council of 5 April 2017 on *medical devices*, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
- [Decision No 1082/2013/EU](#) of the European Parliament and of the Council of 22 October 2013 on *serious cross-border threats to health* and repealing Decision No 2119/98/EC Text with EEA relevance.
- [Directive 2011/24/EU](#) of the European Parliament and of the Council of 9 March 2011 on the *application of patients' rights in cross-border healthcare*.

EU INSTITUTION

EUROPEAN
COMMISSION

- [Communication](#) from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *A European strategy for data*, COM(2020/66 final, 19.2.2020.
- [Communication](#) from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats*, COM/2020/724 final, 2020.
- [Proposal for a Regulation](#) of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a *European Centre for disease prevention and control*, COM(2020) 726 final, 2020.
- [Proposal for a Regulation](#) of the European Parliament and of the Council on *serious cross-border threats to health* and repealing Decision No 1082/2013/EU, COM(2020) 727 final, 2020.
- The Commission [Roadmap](#), [Digital health data and services – the European health data space](#), 2020.

- [Communication](#) from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Pharmaceutical Strategy for Europe*, COM/2020/761 final, 2020.
- Annexes to the [Communication](#) from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Commission Work Programme 2021*, COM(2020) 690 final, 2020.
- European Commission, [Evaluation and revision of the general pharmaceutical legislation](#), 2021.
- Commission [Implementing Decision](#) 2019/1765 of 22 October 2019 providing the rules for the establishment, the management and the functioning of the network of national authorities responsible for *eHealth*, and repealing Implementing Decision 2011/890/EU, 2019.
- Commission [Communication](#) accompanying the Declaration of Cooperation on AI (10 April 2018), the *White Paper on AI, the Ethics Guidelines for Trustworthy AI* (8 April 2019) and the 2018 Coordinated Plan.

EU INSTITUTION

EDPB

OPINION

- EDPB [Opinion 3/2019](#) concerning the *Questions and Answers* on the *interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR)*
- EDPB-EDPS [Joint Opinion 1/2019](#) on the *processing of patients' data* and the role of the European Commission within the *eHealth Digital Service Infrastructure (eHDSI)*

OTHER DOCUMENTS

- EDPB [Document](#) on response to the request from the European Commission for clarifications on the *consistent application of the GDPR*, focusing on *health research*