Data Protection and the Healthcare Sector: Key Updates in 2022

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Part three of the series: Digital round-up 2022

Read part one here, Read part two here

We are glad you're here for another blog post in our series where we round up the digital trends of 2022! In our last blog, we discussed some of the main legislative developments in European data regulation and digital markets regulation. In this blog, we're going to look at some of the most important EU legislative developments of 2022 when it comes to data protection and the healthcare sector, in addition to our new EIPA course on Data Protection and the Healthcare Sector.

Data Protection and the Healthcare Sector

- **European Health Data Space Regulation**

Background: **The European Health Data Space Regulation** aims to overcome the obstacles that exist regarding reaching the full potential of health data. It will establish clear rules, standards and a framework enabling better use of health data by patients and for research, innovation, and more. The better exchange of and access to health data could **save the EU €5.5 billion** over the next decade.

Key Aims of the European Health Data Space Regulation:

- Empower individuals with control of their health data
- Create an effective, regulated single market for health data
- Create an effective set-up for the use of health data for research, innovation, policy-making and regulatory activities

Impact of the European Health Data Space Regulation:

- Allows individuals and health professionals to have better control and use of health data (faster access, cross-border access, etc.)
- Will enable better healthcare policies, better research, and innovation
- Better diagnosis, treatment, patient safety, and healthcare continuity

Progress: The European Health Data Space Regulation is still in its early stages, having been proposed in May 2022

- **Clinical Trials Regulation**

Background: As of the 31st January 2023, the Clinical Trials Regulation has begun to replace the Clinical Trials Directive of 2004, simplifying and harmonising clinical trials within the EU.

Key aims of the Clinical Trials Regulation:

- Harmonise the process for assessing and supervising clinical trials within the EU
- Improve information sharing and collective decision-making on clinical trials
- Increase transparency on clinical trials data
- Ensure high standards of safety for all participants involved in clinical trials

Impact of the Clinical Trials Regulation:

- Creates the Clinical Trials Information System, a single online platform between Member States to evaluate and approve a multi-national trial and allows sponsors to submit only one application as

opposed to submitting separate applications to national competent authorities and ethics committees in each State to gain approval

- Foster innovation and research in facilitating the conduct of multiple clinical trials in the EU

Progress: As mentioned, the Regulation has become mandatory in its application as of 31st January 2023.

Want to know more?

If you're interested in following more on this topic, have a look at our upcoming Artificial Intelligence and Data Protection courses by clicking the button below:

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