

# Pharmacological and Toxicological Studies

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### Legal topic of drugs digital support and digital therapeutics

The pharmaceutical industry is now heavily involved in medical software, significantly developing **Drug Digital Companion** (or Drug Digital Support), software that supports the patients navigating medications through their treatment journey, and **Digital Therapeutics**-evidence-based therapeutic interventions guided by software to prevent, manage or treat a medical disorder or disease.

In the European context, the main legal questions to be dealt with are:

- The correct qualification of the software in compliance with the recent Medical Device Regulation (EU Reg. 2017/745)
- The rules to be applied for data protection in the light of the GDPR (Reg. 2016/679) and the lawful utilization of data generated through the software use (for example, Real World Data)

Furthermore, the next AI Regulation and the recent proposal of a Directive on AI liability will substantially impact this sector.

#### Recent Publications

1. Silvia Stefanelli & David Vaccarella The marketing of medical devices in Switzerland following the non-agreement with the European Union 05/05/2022

2. Silvia Stefanelli & Gaspare Castelli Electronic instructions for use of medical devices: here's what you need to know 18/01/2022
3. Silvia Stefanelli & Maddalena Collini AI and data accuracy: is the legal framework adequate? 12/03/2021.

#### Biography

Silvia Stefanelli is the founder of Stefanelli&Stefanelli Legal Firm, based in Bologna, Milan, Rome. She specializes in health legislation, digital health, medical devices, advertising, PA contracts, and data protection. She has qualified as a "Privacy Officer and Privacy Consultant" and, in 2017 obtained a "Course on European Data Protection Law" Certificate issued by the Academy of European Law in Brussels. She works on several innovative digital projects with SmithKline Foundation and Clusit Association and is a member of the Scientific Committee of the Telemedicine Observatory of Altems-Unicattolica.

She lectures in II<sup>o</sup> Level Master in several Italian Universities, including Unitelma La Sapienza, Uni Roma 3, and Altems Unicattolica. In addition, she gives national-level courses for several training institutions, such as IQVIA and Il Sole 24 Ore. Since 2005 she has been a registered publicist at the Association of Journalists of Bologna. She writes for several magazines, including About Pharma, Il Sole 24 Ore Sanità, and Quotidiano Sanità, and is co-author of several publications and contributions, most recently "La Privacy in sanità" - Giuffrè.

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