

GDPR for Medical Sector



April 14 & 15, 2021

SCOPE OF TRAINING:

1. Personal Data processing in the medical sector
 2. Diversified GDPR topics in the field of medical services, pharmaceuticals and clinical trials
 3. Interactive workshop based on practical examples in the medical field
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INTRODUCTION

The General Data Protection Regulation (GDPR) aimed, starting with the date of its application – May 25th, 2018, to ensure a consistent and high framework for personal data protection, harmonized in all member states of the European Union, and therefore in Romania too.

This has led to increased responsibilities for the entities that process personal data, in the sense of ensuring compliance with the principles and rules established by the GDPR, but also beyond this, an increased care to ensure that the personal data they process are protected effectively and the rights and freedoms of individuals are respected.

In particular, the data processing in the medical sector requires increased attention, not only due to the fact that health data and genetic data are considered special categories of data within the meaning of the GDPR, but also due to the fact that the manner in which the personal data are

processed and protected in this field is highly connected to the trust of patients and data subjects in general.

Our GDPR workshop aims to approach diversified topics in the medical services, pharmaceutical and clinical trials fields, covering the main notions, concepts and rules that have to be considered to ensure the compliance with GDPR requirements.

The workshop will be held during two days and it is addressed to all participants who want to gain or consolidate their knowledge in the field, especially data protection officers, legal advisors and employees from the medical sector who deal with personal data during their daily work activities.

TRAINING DETAILS:

Organizers: AVANTYO -Institute of Clinical Research and Filip & Company Law Firm

Date/Time: April 14 & 15, 2021

Location: Online

Language: Romanian

Online registration: online; Deadline: April 13 th , 2021.

Trainer: Ioan Dumitrascu & Raluca Puscas & Diana Gavra

Host: Cristina Florescu Moraid

Participation fee:

- March 18 - April 2 -> **Early Bird** for companies: 150 Euro or 750 Lei
-> **Early Bird** for individuals: 100 Euro or 500 Lei
- April 3 - April 13 -> Standard Registration for companies: 200 Euro or 1000 Lei
-> Standard Registration for individuals: 150 Euro or 750 Lei

Discounts: • 5% for over 3 participants registered by the same company;

- 10% for over 5 participants registered by the same company.



IOAN DUMITRASCUPartener - Filip & Company

- Ioan is a founding partner in Filip & Company and currently coordinates the Commercial Department, including the medical sciences & pharma practice.
- He regularly advises companies on all aspects of personal data protection compliance, including data protection policies and procedures, the use of data in the provision of consumer and business products, Big Data issues, data protection impact assessments, transfers of data in outsourcing projects and M&A transactions, cloud computing, data security breaches, cross border data transfers, customer relationship management, employee monitoring and website compliance issues. Ioan has also assisted clients concluding successful deals in pharma, automotive, energy, retail, food & consumer goods, telecom, financial services or IT. Recent projects include assistance for one of the largest private hospitals in Romania in the acquisition of a private medical unit comprising a pharmacy, hospital and medical analysis laboratory, as well as assistance in the drafting and negotiation of international clinical trials framework agreements.



RALUCA PUSCASPartener - Filip & Company

- Raluca is a partner in Filip & Company and a highly experienced lawyer in the personal data protection field, also being CIPP/E certified by the International Association of Privacy Professionals (IAPP).
- She regularly provides advice on complex projects involving processing of personal data, such as data loss prevention tools, aspects involving remote identification and other new technologies, innovative advertising using analytics /profiling, cross border transfers of

data, employee monitoring techniques, data protection due diligence in M&A transactions, as well as a wide range of personal data protection compliance aspects, including policies and procedures, data protection impact assessments, website compliance, assistance in case of data breaches and regular trainings/webinars. Raluca has assisted a large and complex range of international and domestic clients in various areas of activity such as pharma and medical, banking, automotive, retail, food & consumer goods, real estate or telecom. Some of the highlights include providing customized personal data protection trainings in several pharmacies, as part of a program developed by the client and the assistance provided from a personal data protection, contractual and consumer protection legislation for the implementation of a telemedicine website/mobile app.



DIANA GAVRA Senior Associate - Filip & Company

- Diana is part of Filip & Company's Commercial Department, which gathers several practices such as medical sciences & pharma, personal data protection, contracts, risk & compliance, consumer protection, employment, new technologies or energy and natural resources.
- Diana focuses on personal data projects, consumer protection, contracts and regulatory & compliance in various industries such as life sciences & pharma, IT, retail, tobacco etc. Some of her most recent highlights include assisting a large central laboratory active in the clinical trials and medical research industry on the drafting and negotiation of services agreements concluded with entities from different levels of the medical research process, on both clinical trials and data protection matters, providing assistance on regulatory matters for the opening of a phase I clinical trials medical unit, training sessions on the practical implementation of the GDPR for participants from various industries such as retail, banking, tobacco and automotive, conducting and coordinating the personal data protection compliance project for a large group of companies from the pharma industry and preparing the contractual and data privacy documentation for the implementation of a telemedicine website/mobile app.



CRISTINA FLORESCU MOROID, MD, MSC, EUSPLM, MRQACEO AVANTYO Institute of Clinical Research, Romania President of Clinical Trials Symposium

- Dr Florescu Moraid got her Medical Doctor Diploma in 1998 from „Carol Davila” University of Medicine and Pharmacy in Bucharest, Romania and was accredited as Laboratory Medicine Specialist in 2005 and as Senior Laboratory Medicine Specialist in 2011, by the Romanian College of Physicians.
 - She got her Master of Science Diploma for Hospital and Medical Management in 2006, accomplished the Postgraduate School of Clinical Trials Management - Gdansk in 2012 and the Postgraduate Leadership Development Program at University of Sussex - UK, in 2014.
 - Dr Florescu Moraid was responsible for clinical trials operations at Synevo Central Lab, the clinical research wing of Swedish Medicover Group as Regional Director for Romania, Moldova, Bulgaria and Serbia between 2005 and 2018. She has been organizing Synevo Clinical Trials Symposium for 11 years.
 - Since the beginning of 2019, she is Co-founder of Avantyo - Institute of Clinical Research and CEO of Camina Medical Experts, developing tailored CT services for pharma sponsors, CROs and mid-size biotech companies. She is also a member of the Events and Training Working Group of EUCROF (European CRO Federation).
 - She is invited as a speaker for different scientific events and acts as an active advocate for increasing awareness over the importance of developing clinical trials for the patient’s benefit.
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AGENDA:

14 April 2021 - Day 1

10:00 - 10:30

1. Introduction and main concepts

- a. What is the purpose of the GDPR?
- b. What are the personal data? Who are the data subjects? What does processing of personal data mean?
- c. What does compliance with the GDPR mean? Introduction to the 6 principles and 8 individual rights

10:30 - 12:00

2. The lawful basis for processing personal data in the medical sector services

- a. Consent or legitimate interest? Practical examples: employees' recruitment, direct marketing, customer satisfaction studies, employees' health and safety
- b. Consent or other legal grounds? Practical examples in the context of clinical trials and medical and hospital care
- c. The processing of special categories of personal data (e.g. health data, biometrical data)
- d. How to perform a balancing test, if the processing relies on legitimate interest
- e. Marketing and GDPR
- f. Transfer of personal data abroad (non-EU countries)

12:00 - 12:30 - BREAK

12:30 - 12:45

3. Information to be provided to the data subject

- a. Various templates of information notices used in practice. Layered approach
- b. Practical discussion: exceptions from the obligation to inform and its potential applicability in the medical sector services

12:45 - 13:30

4. Relation with other entities that receive / send / process personal data in the context of medical sector services

- c. Core concepts and qualification. Examples for data controllers (joint or separate), processors, third parties
- d. Practical discussion: qualification of the entities involved in carrying out clinical trials and medical and hospital care

13:30 - 14:00

5. Q&A Session

End of the day one.

15 April 2021 - Day 2

10:00 - 10:30

6. Personal data storage periods

- a. How to establish the storage periods. What to do at the end of the storage period?
Practical examples in clinical trials and medical and hospital care

10:30 - 10:45

7. Technical and organisational measures

- a. Methods for reducing the risks and ensuring security
- b. Pseudonymization vs anonymisation of the personal data – differences and impact

10:45 - 11:15

8. Records of processing activities used by companies involved in the medical sector services

- a. Who has to fill in the records?
- b. What should the records contain and when should it be updated?

11:15 - 12:00

9. Data breaches

- a. How to identify a data breach and how to react?
- b. When is it necessary to notify the supervisory authority / data subjects?

12:00 - 12:30 - BREAK

12:30 - 12:45

10. Rights of the data subjects - most used

- a. The right of access
- b. The right to object to the processing of personal data
- c. The right to not be subjected to automated processing. Practical discussions about profiling
- d. The right to erasure

12:45 - 13:00

11. Data Protection Impact Assessment - DPIA

- a. When is it necessary?
- b. How to conduct a DPIA?

13:00 - 13:30

12. Investigations of the data protection supervisory authority

- a. How is an investigation conducted and what does the company have to do? Useful advice and rules to follow

13:30 - 14:00

13. Q&A Session

End of day two.

Note:

Online event | The ZOOM details and instructions will be sent a few days in advance!

Discounts and assistance | Please contact us: info@avantyo.com, diana.lupu@avantyo.com (0726 840 456), andrei.grigore@avantyo.com (0728 453 248)

Not sure how to book? [Click here for instructions in Romanian.](#)

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