

Life sciences organisations with operations in both the EU and the UK must comply with two data protection regimes: EU GDPR and UK GDPR. These are (known collectively as 'GDPR'). The General Data Protection Regulation (GDPR) imposes legal obligations on life sciences organisations relating to how personal data is processed, transferred and managed.

Given that the fields of research, pharmaceuticals, therapeutics, biotech, and medical devices are continuously evolving, life sciences organisations can encounter significant difficulties in adhering to both GDPR and local privacy regulations.

For many clinical trial sponsors and other life sciences organisations, appointing a data protection officer (DPO) and a data protection representative (DPR) are now not only a legal requirement but also a prerequisite for obtaining trial approval from ethics boards and other relevant stakeholders.

This fact sheet explains what the legislation means for organisations operating in the life sciences sector and the key areas they need to consider when managing and protecting personal data.



It is based on The DPO Centre's experience gained from working with a broad range of life sciences and medical device organisations within this specialist sector.

WHAT DOES DATA PROTECTION LEGISLATION MEAN FOR LIFE SCIENCES?

Like all organisations, life sciences organisations must:

- ✔ Be transparent about how you process personal data
- ✔ Understand the categories of personal data being processed, who has access to it and the international data transfers involved
- ✔ Implement appropriate agreements between each controller and processor processing your personal data
- ✔ Understand the conditions for processing and the transfer safeguards required
- ✔ Implement appropriate technical and organisational measures to protect your personal data
- ✔ Identify, respond to and where necessary, report data breaches
- ✔ Be familiar with relevant EU and UK life sciences legislation (e.g. the EU Clinical Trials Regulation)
- ✔ Where necessary, appoint a data protection officer and EU and UK representatives



IMPORTANT DATA PROTECTION CONSIDERATIONS FOR LIFE SCIENCES ORGANISATIONS

Life sciences organisations must protect personal data in a range of areas throughout their organisation and research activities. They must also be aware of multiple regulations and industry standards. Some of the major considerations include:

Sharing data with others

- ✔ Research partners, CROs and investigator sites
- ✔ Other controllers and processors who have an interest in your product development or clinical studies
- ✔ Clinicians and researchers
- ✔ Cloud storage

Complimentary regulations

- ✔ UK/EU GDPR
- ✔ Swiss FDAP
- ✔ Life sciences legislation
- ✔ National laws and guidance

Policies and agreements

- ✔ Privacy notices
- ✔ Data sharing, data processing and data transfer agreements
- ✔ Informed consent forms
- ✔ Records of processing activities

Data management

- ✔ Data pseudonymisation and anonymisation
- ✔ Automated processing and automated decision making
- ✔ Mergers, acquisitions and divestitures data transfers

Managing sensitive information

- ✔ Data protection impact assessment (DPIAs)
- ✔ Transfer impact assessments
- ✔ Selecting a lawful basis for processing appropriate to each jurisdiction

Marketing and communications

- ✔ Trial and post-trial marketing
- ✔ Investor and funding communications
- ✔ Social media posts
- ✔ Academic publications

OUTSOURCED DATA PROTECTION FOR LIFE SCIENCES AND CLINICAL TRIALS



The DPO Centre's outsourced data protection officer service delivers flexible, tailored data protection support, advice and expertise to your life sciences organisation.

The service provides your organisation with a highly experienced data protection officer (DPO) who works as an integral member of your team.

You will benefit from the proactive support of a knowledgeable, hands-on data protection professional who undertakes all the responsibilities you would expect from a DPO and all delivered extremely cost-effectively. This expertise is then backed up by the vested knowledge within The DPO Centre's large international team, along with the support, shared best practice and model documentation developed from the experience we have gained from working with many hundreds of clients globally, including a wide variety of clinical trial sponsors, medical device manufacturers and other life sciences organisations.

HOW DOES THE SERVICE WORK ?

Phase 1 of our 3-phrased approach begins with a discovery session relating to the particular data protection concerns within your organisation or study. The deliverable from this exercise is a gap analysis report identifying the required actions and mitigations.

Phase 2 is a mitigation phase, where we allocate an agreed number of days to address as many of the highest priority issues identified in phase 1.

Phase 3 is the on-going service that delivers the level of support and guidance required by your organisation or throughout the length of the trial.

The ongoing service is delivered based upon our "continuous support framework" that utilises three tiers of support to provide full month-round cover, fulfilling the statutory requirements of the DPO role.

Tier 1

A designated DPO, working as an integral member of your team at the required resource level.

Tier 2

A secondary DPO, to guarantee continuity of service by stepping in to cover sickness, absence and increased workload.

Tier 3

Month-round telephone and email support service delivered by the members of our extensive DPO team.

BENEFITS OF THE SERVICE

- ✔ Highly cost effective
- ✔ Designated DPO working with your team at the required resource level
- ✔ Ability to share best practice from the life sciences sector
- ✔ Pragmatic, straightforward solution driven advice
- ✔ Experience and shared best practice gained from working with many hundreds of organisations globally
- ✔ Pre-existing model documentation tested and validated across a variety of life sciences organisations
- ✔ UK and Pan-European expertise delivered to clients globally

Ability to provide EU and/or UK data protection representative (DPR) services alongside outsourced DPO.

WHO WE WORK WITH

- ✔ Sponsors of clinical trials
- ✔ Medical device companies
- ✔ Genomic-research organisations
- ✔ Clinical research organisations
- ✔ Pharmaceutical and therapeutics organisations
- ✔ MedTech and biotech companies

