EU STUDY EXPANSION AND DATA PROTECTION COMPLIANCE:

How a US clinical trials sponsor mastered data protection compliance during their EU study expansion

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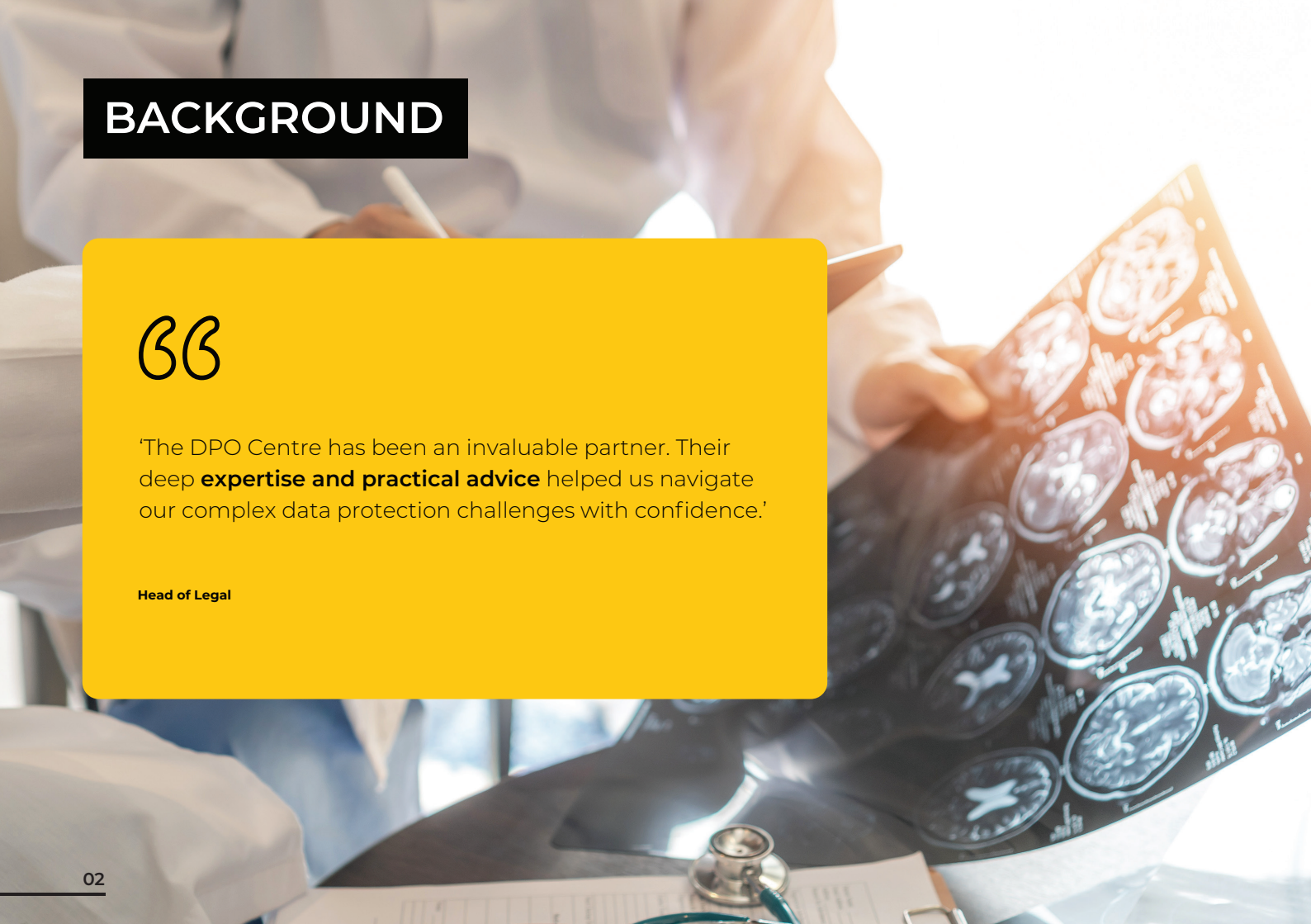
BACKGROUND



> ‘The DPO Centre has been an invaluable partner. Their deep **expertise and practical advice** helped us navigate our complex data protection challenges with confidence.’
>
> **Head of Legal**

This US-based company funds open-source research into one of the world's most prevalent neurodegenerative diseases.

Working with thousands of study participants, the organisation is responsible for large volumes of special category data. The open-source nature of their research requires novel techniques to preserve the confidentiality of participant data when shared with third-party researchers.

With a large network of sites, specialised vendors, and third-party researchers located around the globe, this organisation must coordinate a large number of differing contractual agreements and a complex system of data flows.

Ensuring a responsible roll-out into Europe in a manner compliant with the General Data Protection Regulation (GDPR) and EU Clinical Trials Regulation (CTR) was key for this high-profile clinical trial sponsor. They began working with The DPO Centre in 2020 to ensure the expansion of their study into Europe was compliant with multi-jurisdictional data protection legislation.

SOLUTION

Conducting Data Protection Impact Assessments (DPIAs) allowed the designated Data Protection Officer (DPO) to identify and prioritise the risks associated with the organisation's novel, high-risk processing activities across multiple studies. The DPO then advised on best practices for the compliant processing of special category data across EU jurisdictions and supported the implementation of effective risk mitigation measures.

By revising data protection policies and procedures, the DPO could ensure a consistent approach to complex data flows, boosting confidence in both external and internal data handling. The development of Privacy Notices ensured compliance with data protection laws across multiple EU jurisdictions, providing transparency to participants and demonstrating a strong commitment to the confidential safeguarding of their data.

Ensuring vendor and third-party compliance, the DPO performed thorough due diligence across multiple locations to confirm that these entities adequately safeguard the data entrusted to them. The DPO also established comprehensive agreements for cross-border transfers, including Clinical Trial Agreements (CTAs), Data Processing Agreements (DPAs), Standard Contractual Clauses (SCCs), and other relevant transfer mechanisms.

The DPO provided tailored training and expert guidance to all clinical staff. This increased the team's understanding of European data protection laws and ensured alignment with any updated company-specific processes.

A re-evaluation of the organisation's compliance framework, following the enhancement and implementation of these various data protection measures, allowed the organisation to assess their progress against the initial recommendations and keep pace with any legislative updates.

OUTCOME

‘The training and procedures they introduced have greatly **enhanced our understanding** of European data protection laws and solidified our relationships with partners across Europe. The improvements they've made to our compliance processes will continue to benefit our organisation long into the future, ensuring that our research practices remain **secure and compliant**.’

Head of Legal

RESULTS

- Increased understanding of data protection laws
- Reduced risk through accountability measures
- Fostering positive partnerships with European sites
- Facilitated privacy-safe research practices

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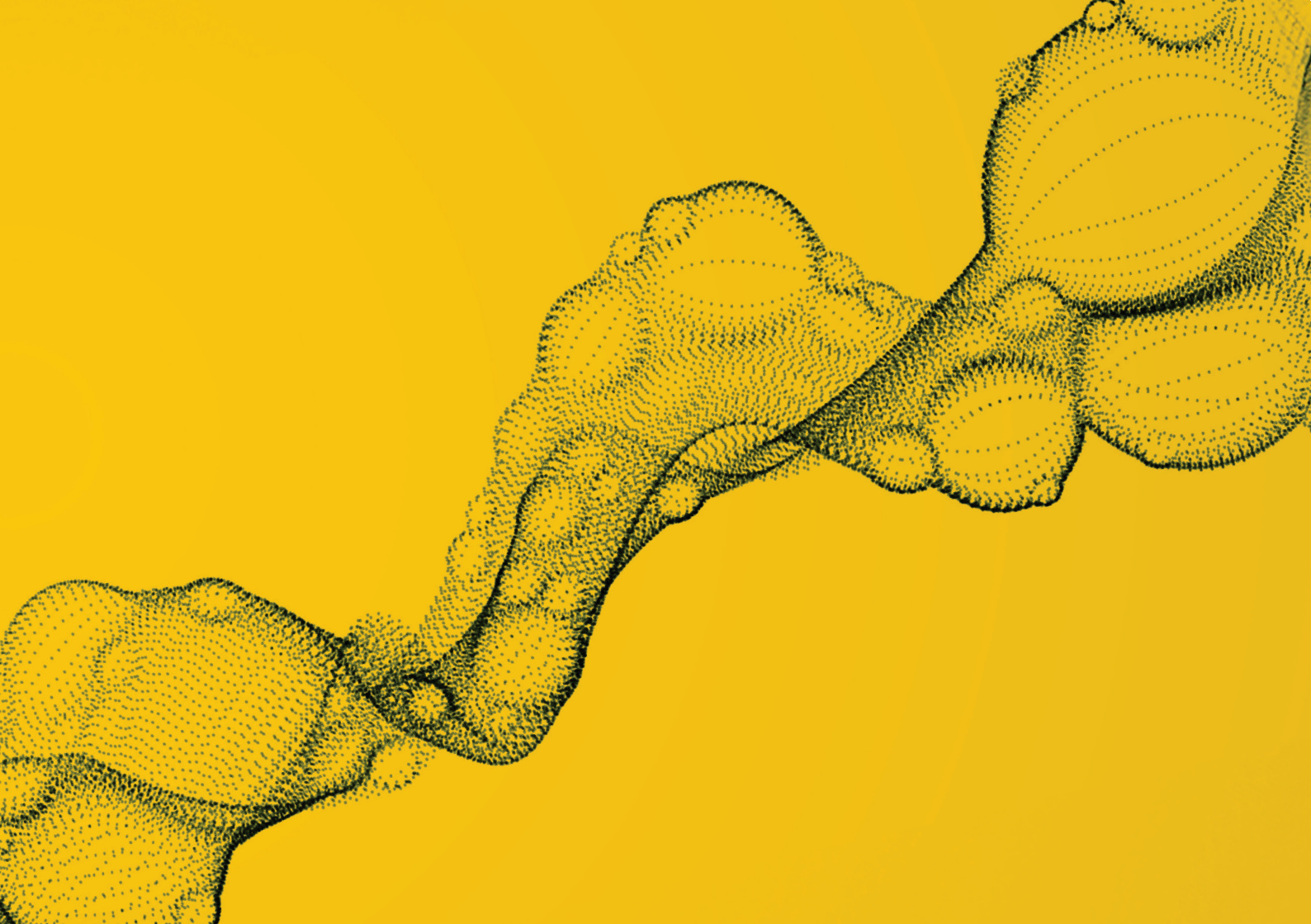
Life Sciences



GDPR CONSIDERATIONS FOR TRIAL SPONSORS

Privacy is paramount in the EU and the UK. As a clinical trial sponsor, you must focus on safeguarding the personal data you collect on trial participants, as well as vendors and even your own EU- and UK-based employees and on-site staff. Failure to do so could lead to study delays and interruptions to data flows.

EU and UK data protection laws have been around for decades. However, they've been significantly strengthened in recent years, especially with the implementation of the General Data Protection Regulation (GDPR) in 2018. Most notably for clinical trial sponsors, the GDPR introduced the concept of 'extraterritorial scope', which makes organisations in any country responsible for compliance whenever EU and UK residents are involved.

As a sponsor, you're generally considered a 'Data Controller' (as opposed to a 'Data Processor') under the GDPR. That means you're required to ensure compliance with the GDPR's 7 principles (shown on the right) throughout the data collection and processing chain. Failure to comply with the GDPR could mean application delays and loss of access to study data, not to mention the possibility of significant fines.

Accountability is foundational, as it requires you to be able to demonstrate at all times how you are accountable for your compliance with the other 6 principles.

Ensuring you meet the data protection standards set by the GDPR, and the requirements of the Clinical Trials Regulation (CTR) are of vital importance. This will contribute to study success and allow you to maximise the value of the data your trial generates.

7 Principles of GDPR

GDPR focuses on these key principles:

1. Lawfulness, fairness and transparency
2. Purpose limitation
3. Data minimisation
4. Accuracy
5. Storage limitation
6. Integrity and confidentiality
7. Accountability for the other 6 principles

A CHECKLIST FOR GETTING STARTED

These questions will help your clinical trials organisation ensure that you have everything in place before you begin. Have you:

- ☐ Appointed your DPO?
- ☐ Completed a DPIA and mitigated the identified risks?
- ☐ Implemented the necessary contracts and agreements with the other parties involved, including your CRO?
- ☐ If required, appointed an EU and/or UK Representative?
- ☐ Ascertained the appropriate lawful bases for processing that are accepted by the data protection authority within each jurisdiction your trial will be operating in?
- ☐ Created privacy notices for participants, partners, and employees?
- ☐ Trained your staff in respect of your policies and procedures?
- ☐ If relying on Consent, explained that consent given on an informed consent form is not the same as Consent to collect and process personal data?
- ☐ Considered the data protection requirements of the countries you will be operating in, especially if these include France and the UK?
- ☐ Gained an understanding of your trial data flows and completed TIAs or TRAs for each relevant international data transfer?

About The DPO Centre

The DPO Centre is an international privacy compliance consultancy and Data Protection Officer (DPO) resource centre, specialising in Life Sciences. The company delivers Data Protection Officer (DPO) and Data Protection Representative (DPR) services from its offices in London, Dublin, Amsterdam, and Toronto and its network of establishments across all 27 EU Member States.

The DPO Centre provides access to one of the largest teams of experienced and permanently employed DPOs available. Since 2017, the company has delivered its services to over 1,000 clients globally, including many health, Life Sciences, MedTech, and medical device organisations.

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