

CASE STUDY

GDPR Implementation Support



Expert assistance from the Kinetiq regulatory team enabled iSpecimen to implement GDPR with no service interruption to their Eurozone customers .

Case Study: GDPR Implementation Support Moves Research Forward

The Challenge:

The General Data Protection Regulation (GDPR), which recently took effect as the first significant update in the European Union (EU) privacy framework in 20 years, **imposes stringent data protection requirements for all personal data derived from the EU**. This includes new rights related to personal data, new responsibilities related to technical and organizational measures, and new penalties for breaches in compliance. GDPR also includes a new extra-territorial applicability to **any company offering goods and services to EU citizens regardless of that company's physical location**.

The Ask:

Support iSpecimen in becoming fully GDPR compliant. The goal was to **educate about the new compliance landscape, assess current policies and procedures** versus future requirements and provide recommendations for remediation, and work collaboratively to adopt a compliance strategy appropriate to the business need.

The Solution:

Kinetiq provides an executive stakeholder summary for how best to approach "adequate safeguards" requirements for non-EU companies, conducts a crosswalk and gap analysis of the US Health Insurance Portability and Accountability Act (HIPAA) privacy and security requirements with the EU GDPR requirements, and reviews and recommends tailored revisions to privacy policy, End-User License Agreements (EULAs), and other business-related materials.

The Result:

The iSpecimen marketplace was able to continue its worldwide activities without any service interruption during GDPR implementation. The iSpecimen Marketplace services are offered with a commitment to data protection that is compliant with all applicable laws and regulations.



“We needed a fast evaluation of our GDPR compliance situation. The team at Kinetiq provided clear guidance on what we needed to do, and then they helped us execute the plan. Our organization is now well prepared to satisfy the new GDPR requirements and continue our very important work in the EU and beyond.”

-Jill Mullan, COO
iSpecimen

About iSpecimen

iSpecimen was founded to address a critical challenge: how to connect life science researchers who need human biospecimens with the billions of specimens available in healthcare organizations worldwide. The company's ground-breaking iSpecimen Marketplace solves this problem, reinventing the biospecimen procurement process to accelerate medical discovery.

Kinetiq Collaboration Delivers Exceptional Results:



Does Your Organization Do Business in the Eurozone? Kinetiq Has You Covered.

Kinetiq is the research and technology consulting division of Quorum Review IRB. Kinetiq moves your international research forward with services that enhance and optimize compliance, clinical research, and administrative processes. We deliver collaborative custom solutions of the highest quality to match your processes with our expertise.

Regulatory Consulting

Kinetiq consultants provide expert advice to clients around the world on a wide array of issues **related to research and clinical trial oversight**, including:

- Ethics Review Board Requirements
- Institution Preparation for Single IRB Review
- Research Using Mobile Technology
- Social Media
- **US, Canadian, and Global Regulatory Requirements**
- Informed Consent
- eConsent
- HIPAA Compliance
- Good Clinical Practice (GCP) Compliance
- Unanticipated Problem and Noncompliance Interpretation
- Recruitment Plans and Campaigns

Regulatory Compliance

Kinetiq experts in GCP can help ensure that you **understand and navigate the changing regulatory landscape**. We provide support and training in:

- HRPP Advice, Evaluation, and Management
- Accreditation Evaluation and Support
- Agency Inspection Readiness
- Audit Readiness
- Compliance Assessment of Research Sites and Ethics Review Boards



Where does your organization stand?

Contact us today at info@kinetiqrideas.com for a free compliance assessment.



Move Your Research Forward™

Kinetiq is the foremost leader in life sciences and clinical research consulting. As the research and technology consulting division of Quorum Review IRB, Kinetiq moves your research forward with services that enhance and optimize the clinical research process. We deliver collaborative custom solutions of the highest quality to match your processes with our expertise.

Our leadership team comprises industry leaders, regulatory experts, and medical professionals with decades of research and technology development.

Plus, Kinetiq maintains a worldwide network of independent consultants, who specialize in areas including IBCs and biologic IND applications, mHealth and research application development, international accreditation, and more.

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