

# RGPD 6 mois après l'entrée en vigueur : Jurisprudence CNIL, Témoignage d'une biotech, Questions et Idées fausses

GDPR 6 months after: Guidance from Data Protection  
Agencies, Testimonial from Abivax biotech, Questions and  
Myths

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# Agenda

PharMarketing: Who We Are, What We Do

Guidance from Data Protection Agencies (IX, MR...)

Lessons learned from Pharma Companies and CROs

Consistency with Industry Guidances

Myths

Impacts for Data Managers

Testimonial from Abivax biotech

# PharMarketing



## Services

- Training
- Audit, Gap Analysis
- Data Protection Impact Assessment
- Information Security Assessment, IT Audits
- Contracts Review
- Data Protection Officer External Service – all EU
- Business Process Reorganisation
- Citizens' Requests Capture and Tracking System



# PharMarketing



## Team



Spain



UK / Ireland



DACH



Benelux



France / UK



Nordics



Spain



Italy



DACH



Benelux



Belgium



Poland



# The GDPR Law

General Data Protection Regulation (GDPR)

Règlement Général sur la Protection des Données (RGPD)

**It's simple!**



EUGDPR.org



# Guidance from Data Protection Agencies (DPAs)

- ▶ When GDPR should be fully in place at your company
- ▶ When a Risk Analysis (PIA) needs to be done; White list, Black list
- ▶ When a Data Protection Officer (DPO) is mandatory
- ▶ What if the sponsor doesn't give any news?
- ▶ What will happen with Authorisations like AU-013?
- ▶ Consult your DPA if any doubt (severity of data leak, remaining risk after mitigating risks,...): in doubt, declare!



# Guidance from Data Protection Agencies (DPAs)

- ▶ Immediate penalty for big IT faults
  - ▶ Otherwise: usually notice, then second control, before penalty
- ▶ Small firms don't get specific indulgence
- ▶ Interpretation for employee data
- ▶ CNIL published guide for Medical Doctors
- ▶ ICO published guide for Healthcare sector
- ▶ DPO Certification
- ▶ Several good tools from DPAs and from ANSSI



**GUIDE PRATIQUE SUR  
LA PROTECTION  
DES DONNÉES PERSONNELLES**

# Lessons learned from pharma companies and CROs

- ▶ It's simple and it's about common sense!
- ▶ Important to have a privileged access to DPA/CNIL
- ▶ Few external requests from EU residents
  - ▶ False requests starting to arrive
- ▶ Human error is the most common source of risk



# Consistency with Industry Guidances

- ▶ Healthcare and Pharma Guidances
  - ▶ E.g.: EU PV Directive 2001, Code de la Santé Publique, CFR 21, GCP..
- ▶ ePrivacy EU Directive
- ▶ Local Patrimony laws

**Autorisation unique AU-013**

**Traitements de pharmacovigilance**

## GAMP 5 Guide



Regulation (EU) No 1027/2012



**CNIL.**

**Méthodologie de référence MR-004**



# Consistency with Industry Guidances

- ▶ Patient's right to remove its data from an interventional/obs study
- ▶ Same for AEs
- ▶ Same for Registries
- ▶ Subcontractors' audits and contracts
- ▶ Reuse of patient's data after death

# Myths / Beliefs

- ▶ « I'm a sub-contractor, I don't have to start the PIA, it's the Data Controller's job »
- ▶ « I'm a small CRO, I have been told I have 44 new SOPs to write »
- ▶ « We already comply with GXP and MR-00X so we are GDPR compliant »
- ▶ The sponsor: "by contract all responsibility is on the CRO, we have nothing to do"

# Myths / Beliefs

- ▶ The CRO or the Clinical Site: “it’s the responsibility of the sponsor”
- ▶ The sponsor or the CRO: “we don’t store patient identification, it’s the clinical site responsibility”
- ▶ “Pharmacovigilance is not subject to GDPR”
- ▶ “We do only Phase I or II trials with 100 patients max, so no large volume, no DPO needed”

# Beliefs around Anonymised Personal Data

- ▶ 'We process anonymised patient data'
- ▶ 'For our Market Access studies, we process Healthcare databases provided by Health Ministry, which are already anonymised, so we are GDPR compliant'

SNIIRAM

**SNDS**  
Système national des données de santé

**PMSI**



**THIN Database**  
The Health Improvement Network

 **CPRD**  
The Clinical Practice Research Datalink

**PHARM**ARKETING

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# Impacts for Data Managers

- ▶ Good Data Management is the essence of GDPR
- ▶ Data Managers can have a prominent role for Data Protection
- ▶ CSV
- ▶ Protocol / CRF Design: minimisation
- ▶ IT Security
- ▶ Potential for GDPR Referent role, career evolution
- ▶ Relay of Global DPO it its department
- ▶ Pooling of Data

# Testimonial from Abivax





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