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WEBINAR

# *Life Sciences Companies and European Privacy Requirements—An Overview of Recent Guidance Regarding the GDPR*

APRIL 2, 2019

*Attorney Advertising*

# *Webinar Guidelines*

- Participants are in listen-only mode
- Submit questions via the Q&A feature
- Questions will be answered as time permits
- Offering 1.0 CLE credit in California and New York*

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WEBINAR

# *Speakers*

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# *Overview*

- Background and Key Concepts
- Territorial Scope of the GDPR
- International Data Transfers
- Breach Response
- Consent vs. Legitimate Interests
- Joint Controllers
- Specific Guidance Regarding Clinical Trials
- EDPB Guidance Documents 2018 and 2019
- EDPB Planned Guidance Documents

# *Background and Key Concepts I*

- The European Union's General Data Protection Regulation ("GDPR") has full legal effect since May 25, 2018
- It replaced the EU Data Protection Directive 95/46/EC
- "Evolution, not revolution", but some important changes
- Fines
- Omnibus approach: all "processing" of "personal data" is regulated
- General prohibition of all processing, unless there is a specific purpose and legal basis for the processing, Art. 6 GDPR
- Additional protections for certain categories of personal data, e.g. health-related data, Art. 9 GDPR

# *Background and Key Concepts II*

Additional relevant obligations, e.g.

- Notice requirements, Art. 12, 13, 14 GDPR
- Documentation, Art. 30 GDPR
- Breach notification obligations, Art. 33, 34 GDPR
- Response to data subject requests, Art. 15-22 GDPR
- Data protection officers, Art. 37-39 GDPR

# *Major Topics since May 2018 – Territorial Scope of the GDPR*

- Art. 3 GDPR:
  - If “established” in the EU, irrespective of where processing takes place
  - If not “established” in the EU, where processing related to offering of goods and services to EU data subjects, or where data subjects’ behavior in the EU is monitored

- European regulators have published a guidance document in November 2018, final version expected soon https://edpb.europa.eu/our-work-tools/public-consultations/2018/guidelines-32018-territorial-scope-gdpr-article-3_en

- Several cases regarding the global scope of the “right to be forgotten” are pending before the Court of Justice of the European Union

# *Major Topics since May 2018 – International Data Transfers*

- Status of Privacy Shield
  - Review by the European Union
  - Court case(s)
- Status of the Standard Contractual Clauses,
  - Update of the text, alignment with Art. 28 GDPR (duties of processors)
  - CJEU case
- Interpretation of Art. 49 GDPR (derogations for specific situations),
  - Guidance document of the EDPB https://edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-22018-derogations-article-49-under-regulation_en
  - E-Discovery and transatlantic investigations

# *Major Topics since May 2018 – Breach Response*

GDPR has notified breach notification requirements, Art. 33/34

- Regulators
- Data subjects

Guidance document was published in August 2018, endorsed by the EDPB in May 2018
https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=612052

Authorities are overwhelmed by number of breaches, hints by some regulators of “over-reporting”

# *Major Topics since May 2018 – Consent / Legitimate Interests*

Most prominent example: “Cookie walls”

- Austrian authority: Newspaper website with cookie wall
- UK ICO: Washington Post
- Advocate General in *Planet 49* case

Complaints by various activists

Marketing based on legitimate interests

# *Major Topics since May 2018 – Joint Controllers*

- Controllers and processors both are caught by GDPR; heavier duties of controllers leads to discussion as to which is which
- Proliferation of situations where parties to processing are all considered joint controllers (Requirements of Art. 26 GDPR)
- CJEU decisions in *Wirtschaftsakademie Schleswig-Holstein (C-210/16) and Jehovan todistajat* (C-25/17)
- Upcoming CJEU decision in Fashion ID (C-40/17)
- Relevance for internal data transfers

# *Recent Developments: Clinical Trials and GDPR*

- January 2019 guidance document by the European supervisory authorities ("EDPB") regarding the relationship between the EU Clinical Trials Regulation 536/2014 and the GDPR https://edpb.europa.eu/our-work-tools/our-documents/opinion-art-70/opinion-32019-concerning-questions-and-answers-interplay_en
- Consent is usually not an appropriate legal basis for the processing of personal data, controllers have to rely on other legal bases (legitimate interests, legal obligations, public health).
  - Legitimate interests not available for health data; public interest must be framed by EU legislation (EU level or national)
  - Need to review current approach
- WH blog posts:
  - Data Protection Rules Could Seriously Impede Clinical Trials in Europe – February 11, 2019
  - The Legal Basis for Processing Personal Data in the Context of Clinical Trials in the EU: The European Data Protection Board Provides Some Clarifications, but Questions Remain – February 19, 2019

# *EDPB Guidance 2018*

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| Guidelines 2/2018 on **derogations of Article 49** under Regulation 2016/679 |
| EDPB statement on ePrivacy |
| **Endorsement of certain GDPR WP29 guidelines by the EDPB** |
| EDPB PSD2 letter |
| EDPB Statement on Market Concentration |
| Opinion on Commission proposals on European Production and Preservation Orders for electronic evidence in criminal matters |
| **Guidelines 3/2018 on the territorial scope of the GDPR** (Article 3) - version for public consultation |
| Rules of Procedure of the EDPB |
| Guidelines 4/2018 on the accreditation of certification bodies under Article 43 of the General Data Protection Regulation (2016/679) |
| Opinion 28/2018 regarding the European Commission Draft Implementing Decision on the adequate protection of personal data in **Japan** |

# *EDPB Guidance 2019*

EU - U.S. Privacy Shield - Second Annual Joint Review

Guidelines 1/2018 on certification and identifying certification criteria in accordance with Articles 42 and 43 of the Regulation 2016/679

Opinion 3/2019 concerning the Questions and Answers on the **interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation** (GDPR) (art. 70.1.b))

Opinion 4/2019 on the draft Administrative Arrangement for the transfer of personal data between European Economic Area ("EEA") Financial Supervisory Authorities and non-EEA Financial Supervisory Authorities

Information note on data transfers under the GDPR in the event of a **no-deal Brexit**

EDPB Work Program 2019/2020

Information note on BCRs for companies which have ICO as BCR Lead Supervisory Authority

EDPB Statement 01/2019 on the US Foreign Account Tax Compliance Act (**FATCA**)

First overview on the implementation of the GDPR and the roles and means of the national supervisory authorities

Opinion 5/2019 on the **interplay between the ePrivacy Directive and the GDPR**, in particular regarding the competence, tasks and powers of data protection authorities

Statement 2/2019 on the use of personal data in the course of **political campaigns**

Statement 3/2019 on an **ePrivacy regulation**

# *EDPB Work Plan 2019/2020 – Planned Guidelines*

- PSD2 and data protection laws.
- Certification and Codes of Conduct
- Connected vehicles
- Data protection by design and by default
- Legitimate interests
- Territorial scope of the GDPR (final version)
- Guidelines on reliance on Art. 6(1)(b) (“contractual necessity”) in the context of online services
- Guidelines on targeting of social media users
- Individuals’ rights

# *Thank You for Your Attention – Any Further Questions?*

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