



Data Privacy Case Study: Evolving requirements for data protection and transfers

Pharmaceutical Compliance Congress and Best Practices
Forum, May 10 – 12, 2016, Warsaw, Poland

Panel

2

- **Tanya Daniels**, Senior Legal Director, EU Head of Data Protection at Quintiles, UK
- **Madina Plieva**, Legal Counsel at Bristol Myers-Squibb, Russia
- **Agata Szeliga**, Partner, Soltysinski, Kawecki and Szelzak, Poland
- **Daniela Fábíán Masoch**, Founder of FABIAN PRIVACY LEGAL, Switzerland (Moderator)

Agenda

3

- Introduction of major privacy developments
- Panel discussion on selected topics
- Case study on data transfers

Data Privacy Landscape

4

- Data privacy is regulated in more than 80 countries around the world.
- Common principles in general data protection laws and sectorial laws



Two major developments in the EU

- New General Data Protection Regulation
- Invalidation of Safe Harbor and agreement of Privacy Shield for the transfer of personal data between the EU and the US



5

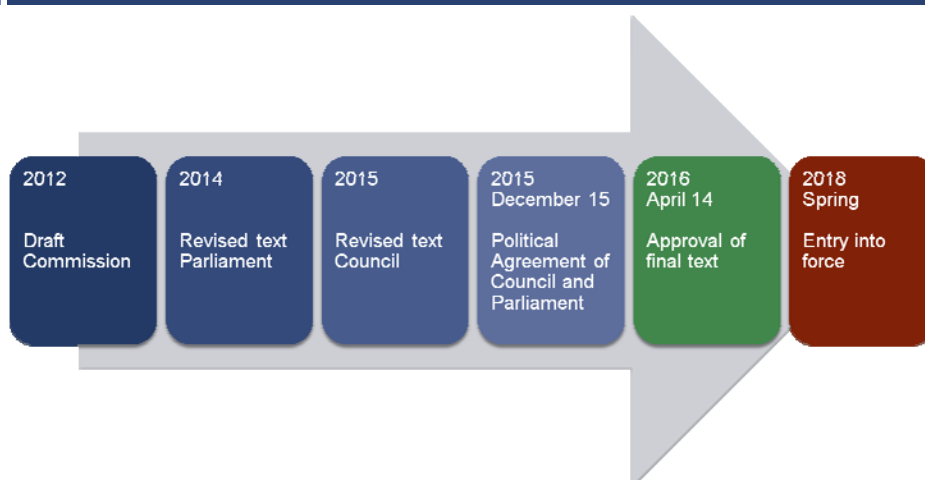
EU General Data Protection Regulation (GDPR)

FABIAN PRIVACY LEGAL | Pharmaceutical Compliance Congress and Best Practices | Warsaw, May 10-12, 2016



Process of EU GDPR

6



FABIAN PRIVACY LEGAL | Pharmaceutical Compliance Congress and Best Practices | Warsaw, May 10-12, 2016



Companies outside of the EU may be subject to the GDPR

7

- Controller or Processor is established in the EU
- Controller or Processor is established outside of the EU, but
 - Offers goods or services to data subjects in the EU, or
 - Monitors the (online) behaviour of data subjects in the EU
- Obligation to appoint a representative in EU Member State

FABIAN PRIVACY LEGAL | Pharmaceutical Compliance Congress and Best Practices | Warsaw, May 10-12, 2016



New definitions and concepts

8

Personal data and consent

- **Personal data**
 - Genetic and biometric data, which allow or confirm the unique identification of a natural person
 - Online identifiers and location data (cookies, IP addresses)
- **Consent**
 - Freely given, specific, informed, unambiguous and explicit – distinguishable from other matters, revocable at any time

Pseudonymization

- **Pseudonymization**
 - Personal data is processed in such a way that it can no longer be attributed to a specific individual without use of additional information that is kept separately and is subject to technical and organizational measures to ensure non-attribution

FABIAN PRIVACY LEGAL | Pharmaceutical Compliance Congress and Best Practices | Warsaw, May 10-12, 2016



Accountability

Controller must demonstrate compliance with GDPR

9

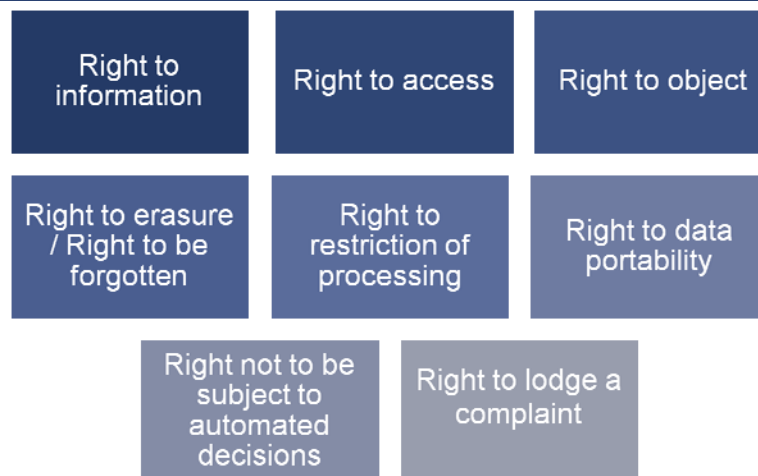


FABIAN PRIVACY LEGAL | Pharmaceutical Compliance Congress and Best Practices | Warsaw, May 10-12, 2016



Rights of data subjects

10



FABIAN PRIVACY LEGAL | Pharmaceutical Compliance Congress and Best Practices | Warsaw, May 10-12, 2016



New obligations for processors

Direct statutory compliance

11

Maintain records of processing activities

Cooperate with Supervisory Authorities

Implement appropriate security measures

Notify controller in case of a data breach

Comply with cross-border restrictions

Assist controller to comply with GDPR

Become joint controller, if data is processed beyond instructions

Enter into written data processing agreement with controller

FABIAN PRIVACY LEGAL | Pharmaceutical Compliance Congress and Best Practices | Warsaw, May 10-12, 2016



Data breach notifications

12

Personal data breach

- Breach of security leading to accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, personal data transmitted, stored or otherwise processed

Notification to DPA

- Without undue delay and, where feasible within 72 hours after having become aware of the breach, unless breach is unlikely to result in a risk to the rights for individuals (encryption)
- Content: nature of data breach, contact details of DPO, likely consequences and measures taken or planned

Notification to affected individual

- Without undue delay, if the breach is likely to result in a high risk to individual's rights and freedoms

FABIAN PRIVACY LEGAL | Pharmaceutical Compliance Congress and Best Practices | Warsaw, May 10-12, 2016



Cross-border data transfers

13



FABIAN PRIVACY LEGAL | Pharmaceutical Compliance Congress and Best Practices | Warsaw, May 10-12, 2016



Enforcement

14

- Investigative and enforcement powers for SAs
- Sanctions and penalties prescribed by GDPR with discretion of SAs
- Right of individual to obtain compensation for damage suffered
- Sanctions must be effective, proportionate and dissuasive:
 - Up to **Euro 10 m or 2%** of annual worldwide turnover for failures to
 - Obtain parental consent
 - Comply with general obligations / appoint a DPO
 - Implement data security measures, PIA
 - Up to **Euro 20 m or 4%** of annual worldwide turnover for failures against
 - Basic principles to data processing (consent)
 - Data subjects rights
 - Data transfer restrictions

FABIAN PRIVACY LEGAL | Pharmaceutical Compliance Congress and Best Practices | Warsaw, May 10-12, 2016





15

Privacy Shield

FABIAN PRIVACY LEGAL | Pharmaceutical Compliance Congress and Best Practices | Warsaw, May 10-12, 2016



Privacy Shield shall replace Safe Harbor

16

- October 6, 2015: EU Court of Justice (CJEU) declared the EU – US Safe Harbor framework invalid as a mechanism to legitimize transfers of personal data from the EU to the US
- February 29, 2016: Agreement between EU and US on Privacy Shield framework designed to heighten protection for transatlantic data transfers
- Final framework is expected by June, 2016
- Organizations certifying their compliance with the Privacy Shield Principles will be authorized to transfer personal data of EU residents to the US

FABIAN PRIVACY LEGAL | Pharmaceutical Compliance Congress and Best Practices | Warsaw, May 10-12, 2016



Data Privacy in Practice

1. Demonstrating accountability
2. Data subjects rights
3. Roles and responsibilities for controllers and processors
4. Data security breaches
5. Further processing of data for research purposes



Case study 1: Clinical trials

Clinical Trial Data

19

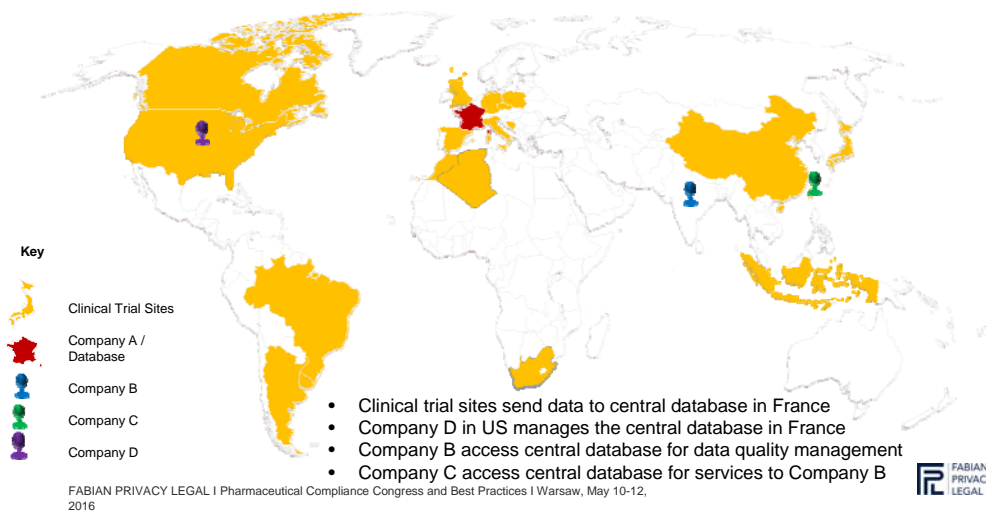
- ❑ **Company A** located in France conducts and sponsors a global clinical trial with sites in Europe, US, Canada, Africa, Latin America and Asia.
- ❑ Trial data (participant's code and medical information; data relating to the site investigator (such as name, CV, contact information, etc.) is sent from each of these sites to the global clinical trial database in Paris, France managed by **Company D**, an external service provider located in the US.
- ❑ **Company B**, an affiliate of Company A located in India provides data management services for the trial on behalf of Company A. For this purpose, Company B accesses the global database in France.
- ❑ Company B contracts with a sub-processor (**Company C**) in Taiwan to provide some services in relation to the data management and provides for this purpose access to the central database in France.

FABIAN PRIVACY LEGAL | Pharmaceutical Compliance Congress and Best Practices | Warsaw, May 10-12, 2016



Clinical trial data moves cross-border

20



Questions to the audience and the panelists

21

1. Is the data regarding clinical trial subjects – that is key coded patient data – personal data? (Yes / No / It depends)
2. Is the data regarding site investigators (names, professional information, contact information) personal data? (Yes / No / It depends)
3. What roles do the parties have?
 - Company A (Controller / Processor / Other)
 - Company B (Controller / Processor / Other)
 - Company C (Controller / Processor / Other)
 - Company D (Controller / Processor / Other)
 - Site investigators (Controller / Processor / Other)
4. Are the transfers of these data allowed? What measures must be in place? Options?
 - Transfer from clinical trial sites to central database in France?
 - Transfer from central database in France to processor in India?
 - Transfer from central database to sub-processor in Vietnam?
 - Transfer from central database to processor in US?
5. What responsibilities do the parties involved have?

FABIAN PRIVACY LEGAL | Pharmaceutical Compliance Congress and Best Practices | Warsaw, May 10-12, 2016



Your poll will show here

1

Install the app from
pollev.com/app



2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help

or

[Open poll in your web browser](#)



Your poll will show here



1

Install the app from
pollev.com/app



2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help
or
[Open poll in your web browser](#)



2



Your poll will show here



1

Install the app from
pollev.com/app



2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help
or
[Open poll in your web browser](#)



2



Your poll will show here



1

Install the app from
pollev.com/app



2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help
or
[Open poll in your web browser](#)



2



Your poll will show here



1

Install the app from
pollev.com/app



2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help
or
[Open poll in your web browser](#)



2



Your poll will show here



1

Install the app from
pollev.com/app



2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help
or
[Open poll in your web browser](#)



2



Your poll will show here



1

Install the app from
pollev.com/app



2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help
or
[Open poll in your web browser](#)



2



Your poll will show here





1

Install the app from
pollev.com/app

2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help
or
[Open poll in your web browser](#)



Your poll will show here



1



Install the app from
pollev.com/app

2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help
or
[Open poll in your web browser](#)





Your poll will show here





1

Install the app from
pollev.com/app

2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help
or
[Open poll in your web browser](#)



Your poll will show here



1



Install the app from
pollev.com/app

2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help
or
[Open poll in your web browser](#)





Your poll will show here





1

Install the app from
pollev.com/app

2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help
or
[Open poll in your web browser](#)



Your poll will show here



1



Install the app from
pollev.com/app

2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help
or
[Open poll in your web browser](#)





Your poll will show here





1

Install the app from
pollev.com/app

2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help
or
[Open poll in your web browser](#)



Your poll will show here



1

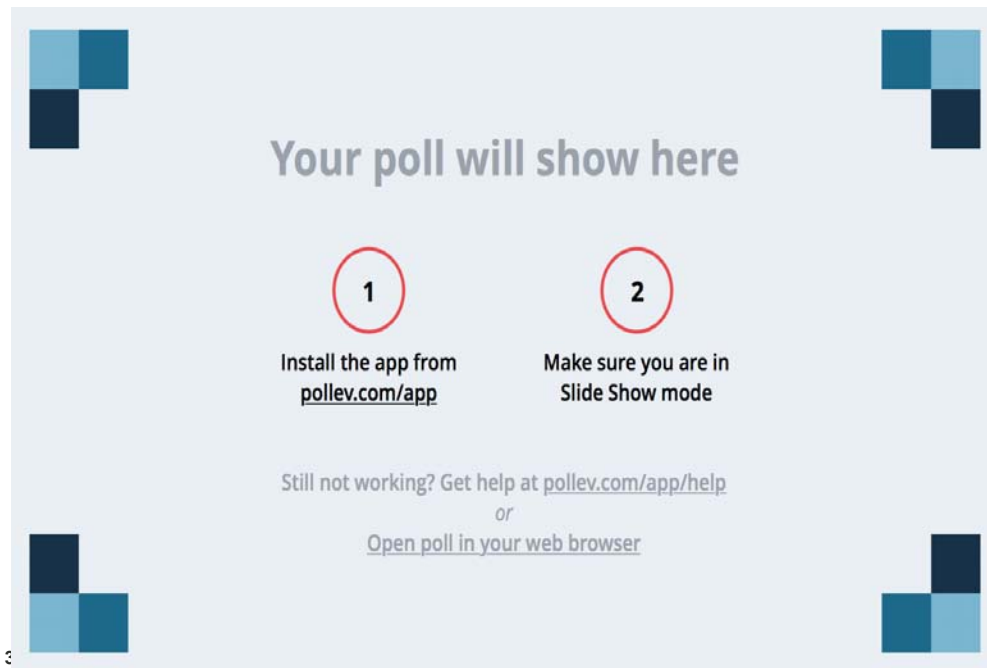
Install the app from
pollev.com/app

2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help
or
[Open poll in your web browser](#)





Case study 2: Employee data



Employee Data

39

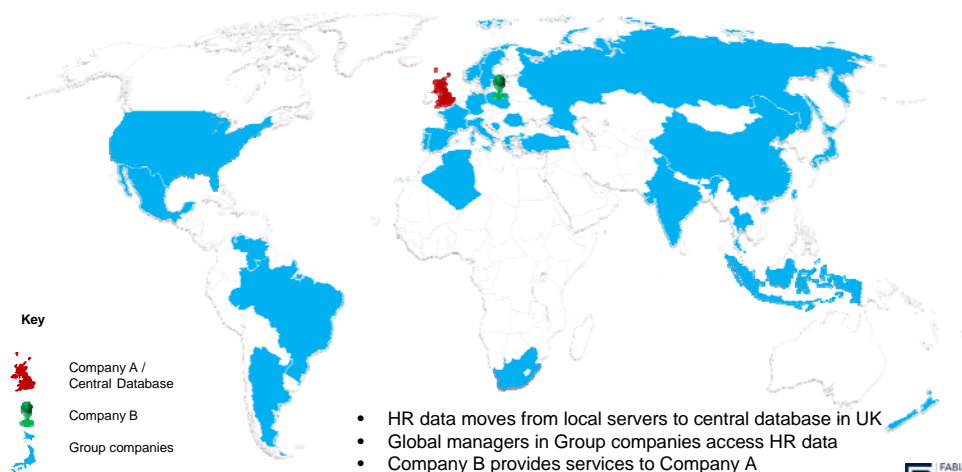
- **Company A** with headquarters in UK wants to set up and maintain a worldwide Human Resources (HR) database containing personal data relating to the Company's employees globally. The purpose is to store all the data centrally to facilitate staff administration and organization as well as for performance and talent management purposes. All local databases shall be eliminated and replaced by a central database.
- HR data is transferred from local servers to the central database in UK.
- Global managers in Group companies have access to employee data originating from all countries including the EU.
- A third party vendor located in Poland (**Company B**) provides payroll and other services and has access to all the data maintained in the global database.

FABIAN PRIVACY LEGAL | Pharmaceutical Compliance Congress and Best Practices | Warsaw, May 10-12, 2016



Employee data moves cross-border

40



FABIAN PRIVACY LEGAL | Pharmaceutical Compliance Congress and Best Practices | Warsaw, May 10-12, 2016



Questions to the audience and the panelists

41

1. Is HR data personal data? (Yes / No / It depends)
2. What are the roles of the parties?
 - Company A (Controller / Processor / Other)
 - Company B (Controller / Processor / Other)
 - Affiliates (Controller / Processor / Other)
3. Are the transfers of these data allowed? What measures must be in place? Options?
 - Transfer from affiliates to central database in UK
 - Access of data in central database in UK by Group companies
 - Access of data by third party service provider
4. What responsibilities do the parties involved have?

Your poll will show here

1

Install the app from
pollev.com/app



2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help

or

[Open poll in your web browser](#)



Your poll will show here





1

Install the app from
pollev.com/app

2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help
or
[Open poll in your web browser](#)



Your poll will show here



1



Install the app from
pollev.com/app

2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help
or
[Open poll in your web browser](#)





Your poll will show here



1

Install the app from
pollev.com/app



2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help
or
[Open poll in your web browser](#)



4



Your poll will show here



1

Install the app from
pollev.com/app



2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help
or
[Open poll in your web browser](#)



4



Your poll will show here



1

Install the app from
pollev.com/app



2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help
or
[Open poll in your web browser](#)



4



Your poll will show here



1

Install the app from
pollev.com/app



2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help
or
[Open poll in your web browser](#)



4



Your poll will show here



1

Install the app from
pollev.com/app



2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help
or
[Open poll in your web browser](#)



4



Your poll will show here



1

Install the app from
pollev.com/app

2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help
or
[Open poll in your web browser](#)



5