SCOPE OF PRESENT PRESENTATION

- Inform Ad Hoc Clinical clients of existence of the GDPR law
- All clients are involved in collecting data for clinical trials
- Introduction to the European GDPR law

WAIVER

This information is an introduction to GDPR only and is not intended to be used for training purposes.

Information provided is synoptic and sometimes incomplete.

Please refer to applicable regulations/guidelines and standards for detailed information.

OUTLINE

- What law you say?
- When will it be applicable?
- Does it apply to me?
- What if I "forget" to be compliant?
- What do I need to do?
  - Risk analysis + documentation
  - Appoint DPO/ DPR
- Reference to the GDPR law

GDPR: GENERAL DATA PROTECTION REGULATION

REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016

on the protection of natural persons with regard to the processing of

personal data and on the free movement of such data

(repealing Directive 95/46/EC)

WHEN WILL IT BE APPLICABLE?

Will take effect on **May 25th, 2018** and will be directly applicable in all Member States without the need for implementing national legislation.

WHO IS CONCERNED?

- **EU companies**, with EU activities.

- **non-EU companies** collecting Personal Data of EU citizens

From companies like Google to a vendor of French fries

A large range of companies dealing with personal data are concerned - NOT ONLY those involved in clinical research!

WHAT ACTIVITIES ARE REGULATED BY THE DATA PROTECTION ACT?

"Processing" of personal data

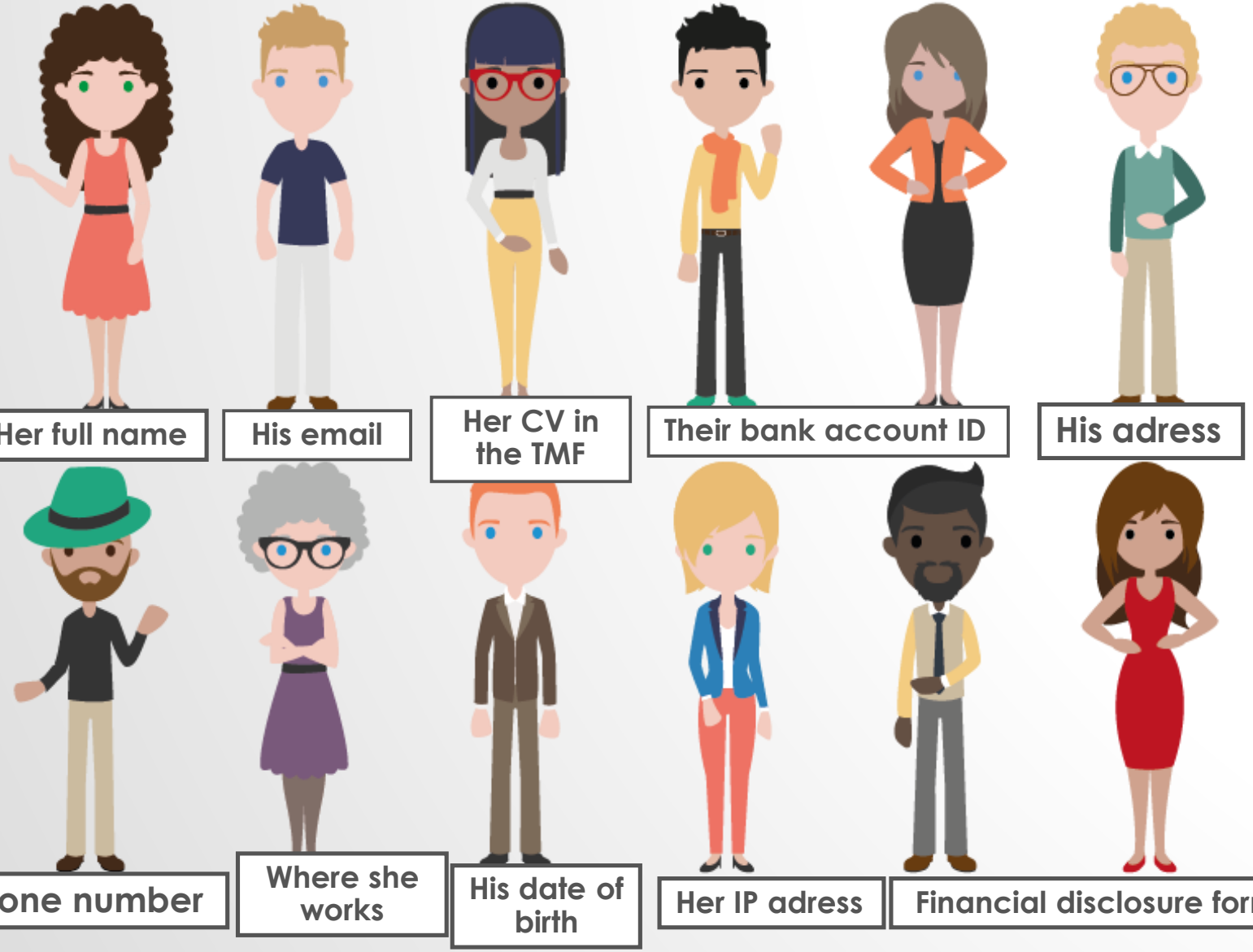
=

obtaining, recording or holding the information or data or carrying out any operation or set of operations on the information

→ The definition of processing is very wide and it is difficult to think of anything an organisation might do with data that is not considered as processing.

More particularly: data collection, archiving, extraction, consultation, transmission, lock, deletion, update and structuring.

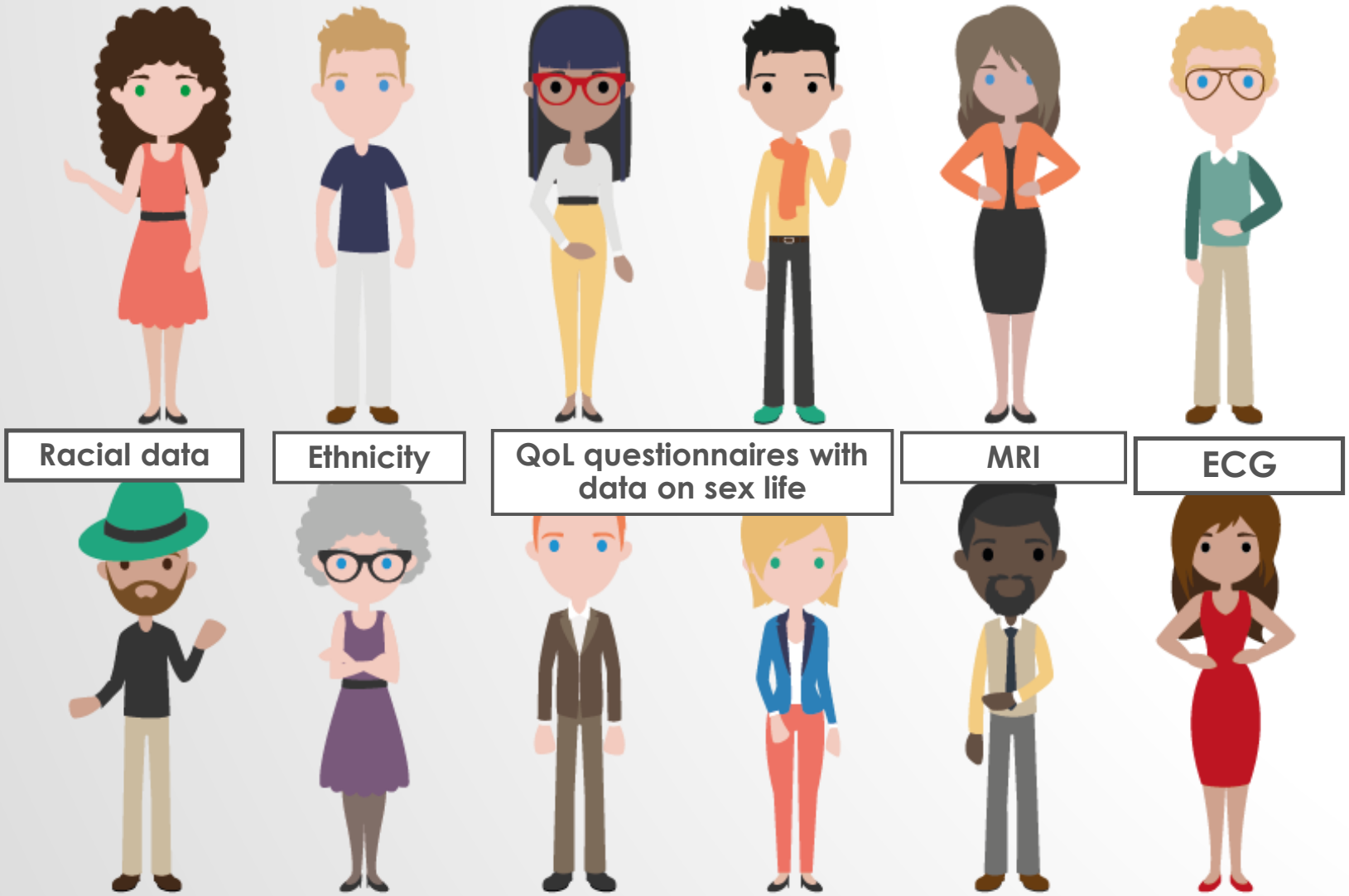
What is *personal* data?



Personal data = ANY information related to an identified OR identifiable individual.

Patient Data in clinical trials is never considered anonymous but identifiable through a code held by the investigator.

What is *sensitive* data?



Sensitive data =

personal data, revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership**;** **data concerning health** or sex life and sexual orientation; **genetic data** or biometric data.

OOPS, I DID NOT KNOW. WHAT ARE THE RISKS I'M TAKING?

When a data breach occurs harming the data subject =

- Your organisation risks a financial sanction up to **4% of your global annual turnover.**

- Your organisation risks **to be forced to erase collected data.**

→ Risk of compromising the clinical trial.

Do I have your attention?

WHAT DO YOU NEED TO DO?

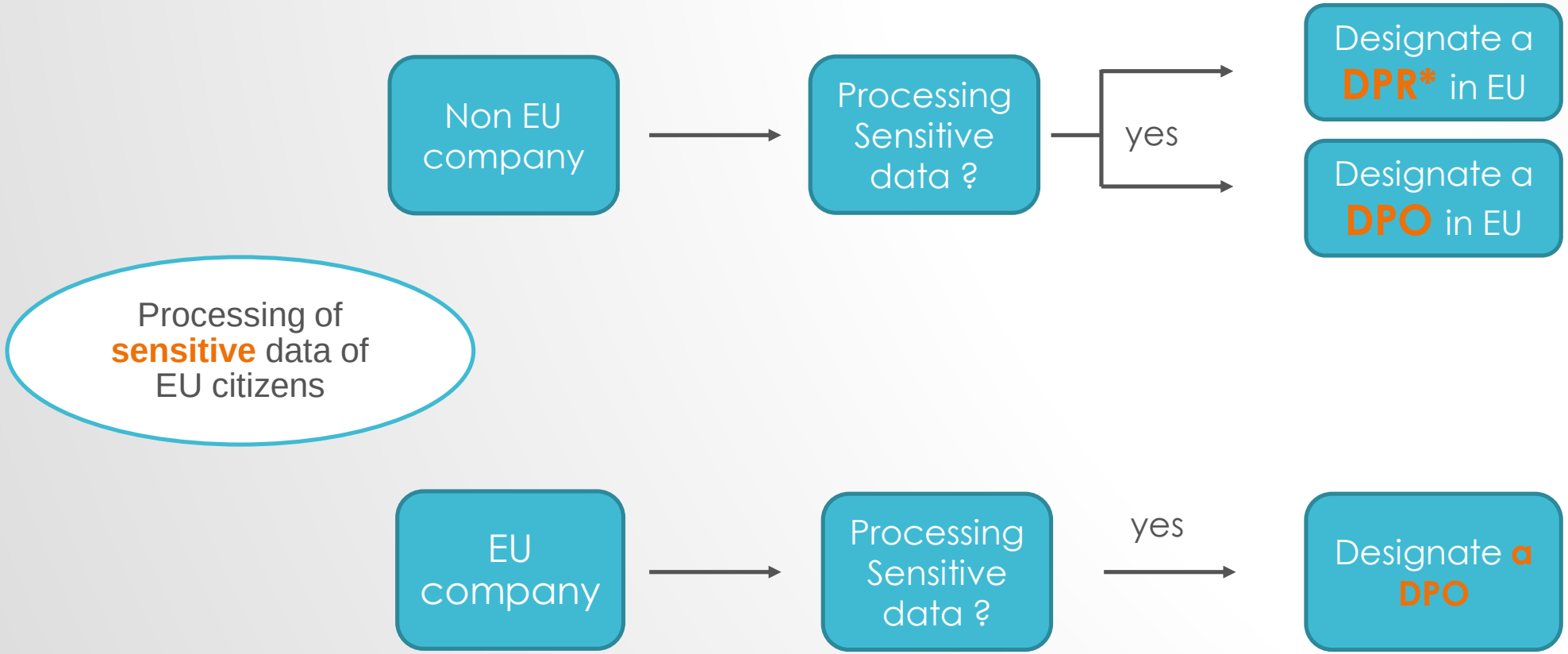
- Analyse if an **impact analysis** is required or not and do this for your various applications/business units.

- Appoint an EU based **DPO and**
- Appoint a **Data Representative if you are not EU based.**

IMPACT ANALYSIS REQUIRED OR NOT?

Check requirements per business unit

APPOINT A DPO / DPR



RESPONSABILITIES IN CASE OF DATA BREACH

DPO	SPONSOR (DATA CONTROLLER) CRO (DATA PROCESSOR)
• **DPO must report all Data Breaches to an EU Data Privacy Agency.**	**Sponsors and all CRO's must ensure all measures are taken and reporting processes are in place to inform the DPO in case of data breaches.** **Make sure you adapted your SOP's!** **Both data processor and controller can be held liable.**

REFERENCES

http://eur-lex.europa.eu/legal-content/FR/TXT/?uri=CELEX%3A32016R0679

QUESTIONS?

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