SCOPE OF PRESENT PRESTATION

- Inform clients of Ad Hoc Clinical of existence of the GPDR
- All clients are involved in collecting data for clinical trials
- Introduction to the European GPDR 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 GPDR 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 the **25 May 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 residents

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?

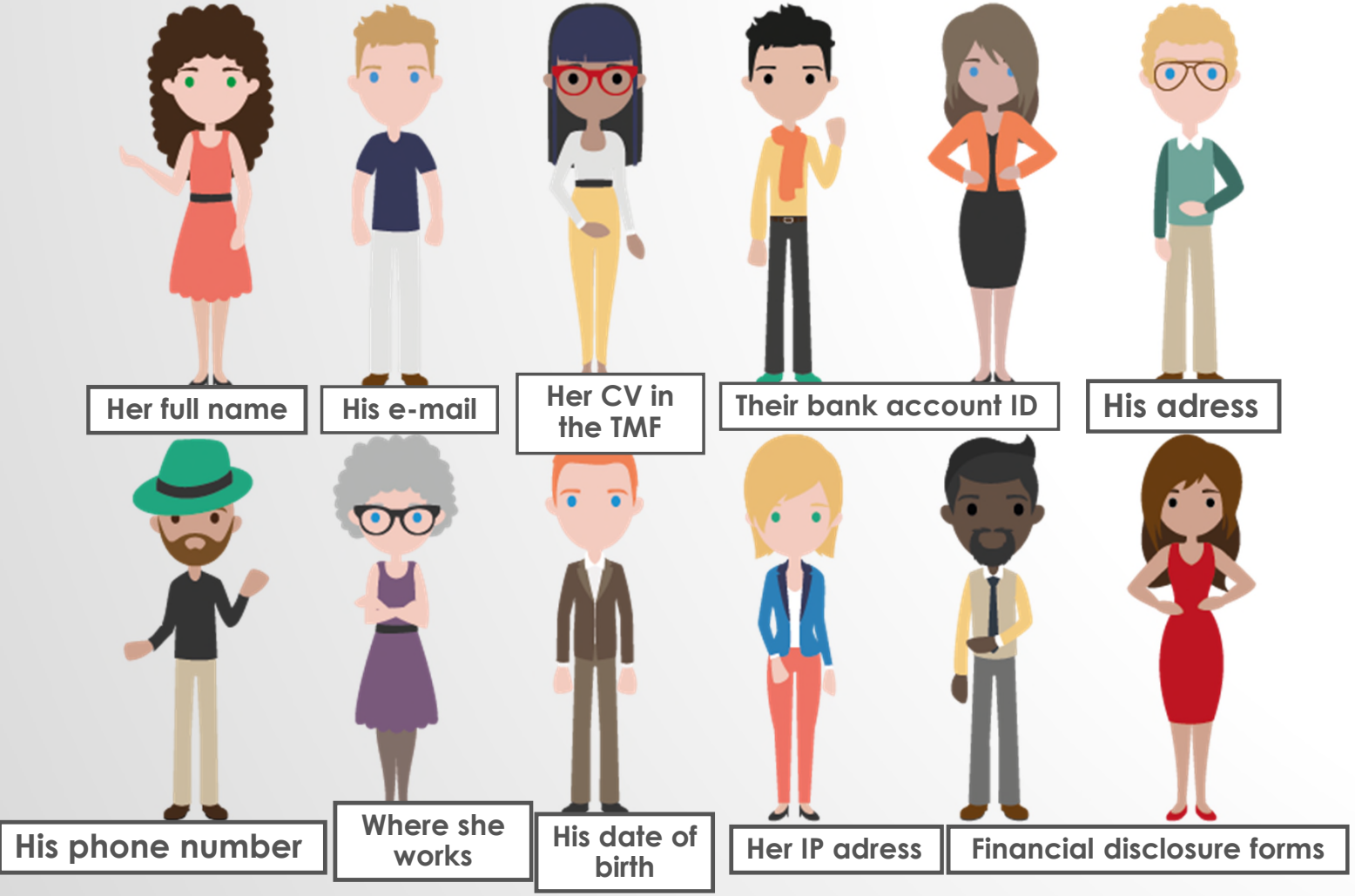
- **"Processing" of personal data =**

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, structuring

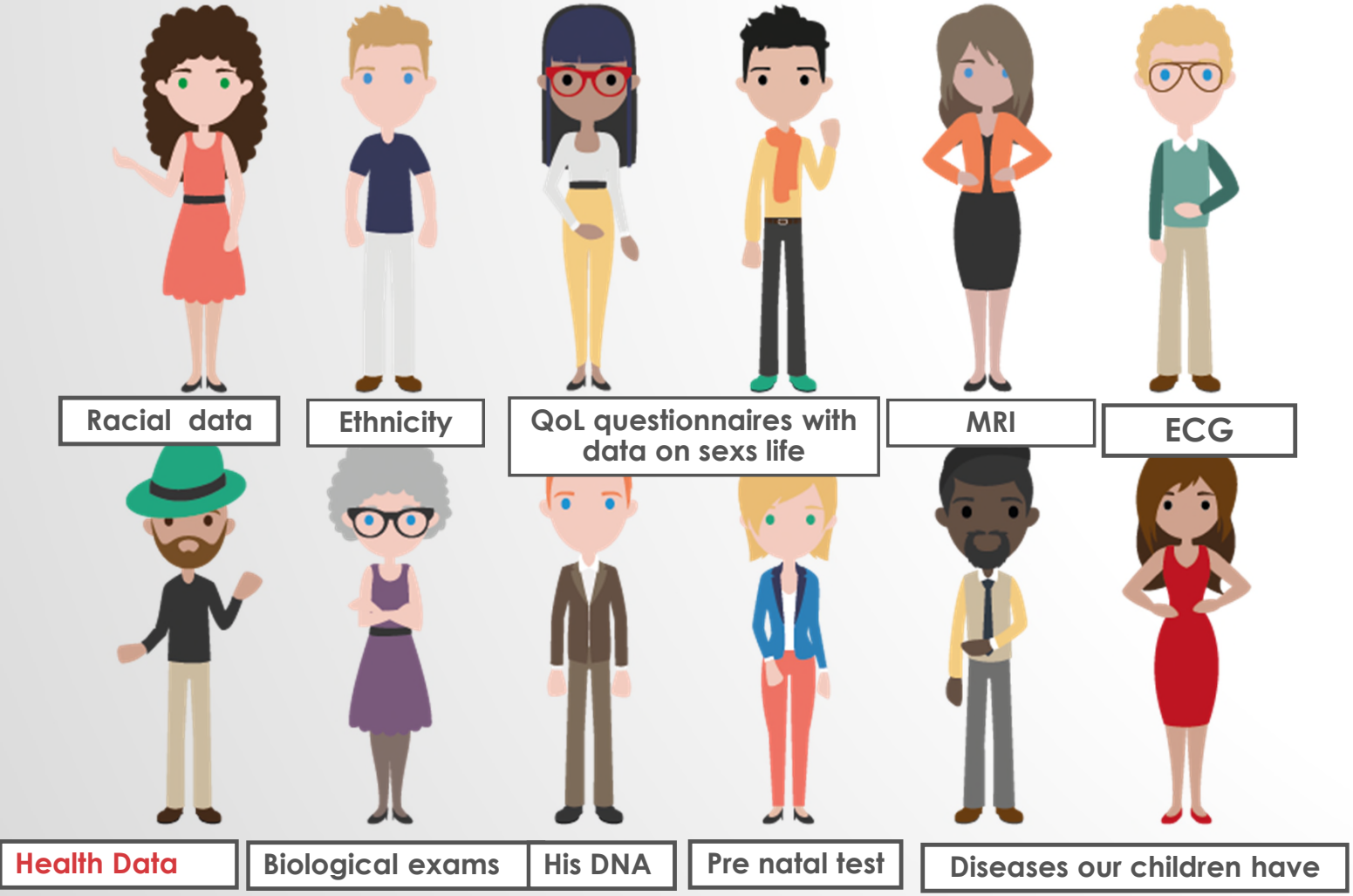
What is personnal data ?



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 you 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 ?

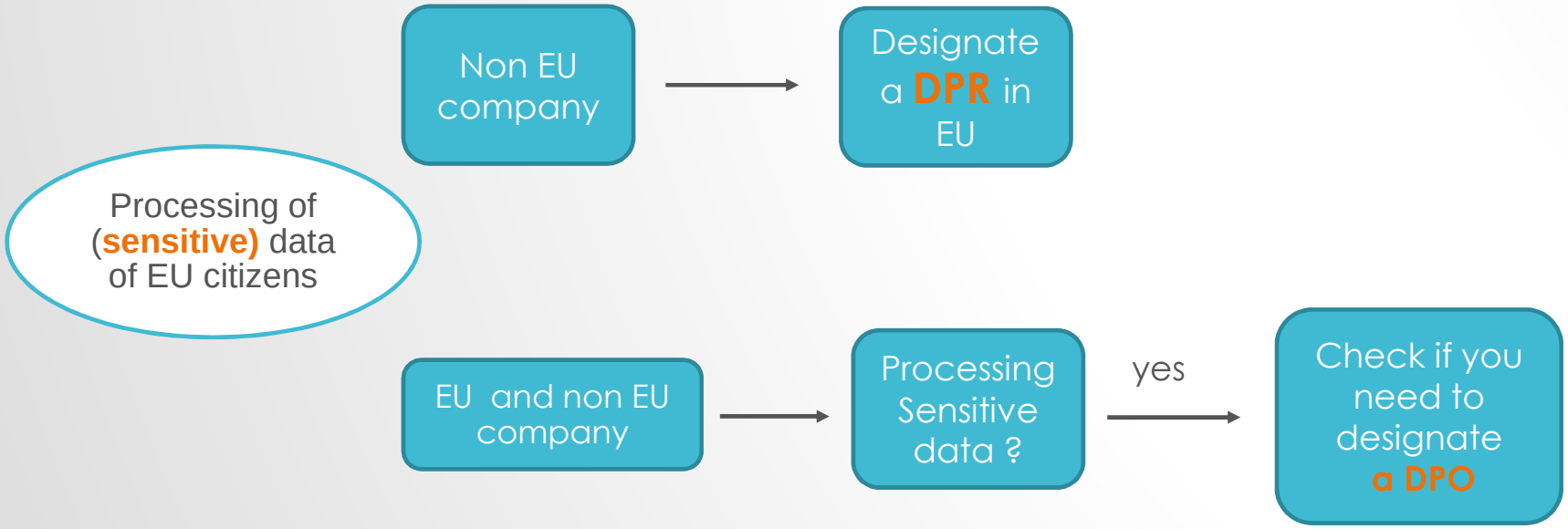
- Analyze if an **impact analysis** is required or not and do this for your various applications/ business units

- Check if you need to Appoint a **Data Protection Officer (DPO)**
- If you are not EU based BUT you collect data from EU residents
  (Check if you need to) Appoint a **Data Protection Representative (DPR)**

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 Data Breaches to a 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 breache** **Make sure you adapted your SOP's !** **Both data processor and controller can be held liable**

REFERENCES

- https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=FR
- https://ec.europa.eu/commission/priorities/justice-and-fundamental-rights/data-protection/2018-reform-eu-data-protection-rules_en

QUESTIONS ?

Nancy Cottigny
Managing Director
tel +32(0)57 400 530
fax+32(0)57 401 530
mob + 32(0)499 70 22 22
nancy.cottigny@adhoc-clinical.com
www.adhoc-clinical.com

Ter waarde 45 _1B_- 8900 Ieper-Belgium