ADHOC CLINICAL
GDPR AWARENESS

For full regulation please refer to GDPR

SCOPE OF PRESENT PRESTATION

- Inform clients of Ad Hoc Clinical of existence of the GPDR
- 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 do you say ?

Does it apply to me ?

What do I need to do?

- Risk analysis + documentation
- Appoint DPO/ DPR

What if I “ forget” to be compliant ?

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 ?

Has taken effect since **25th of May 2018** and is directly applicable in all Member States without the need for implementing national legislation.

WHO IS CONCERNED ?

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

- **non-EU companies** processing 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?

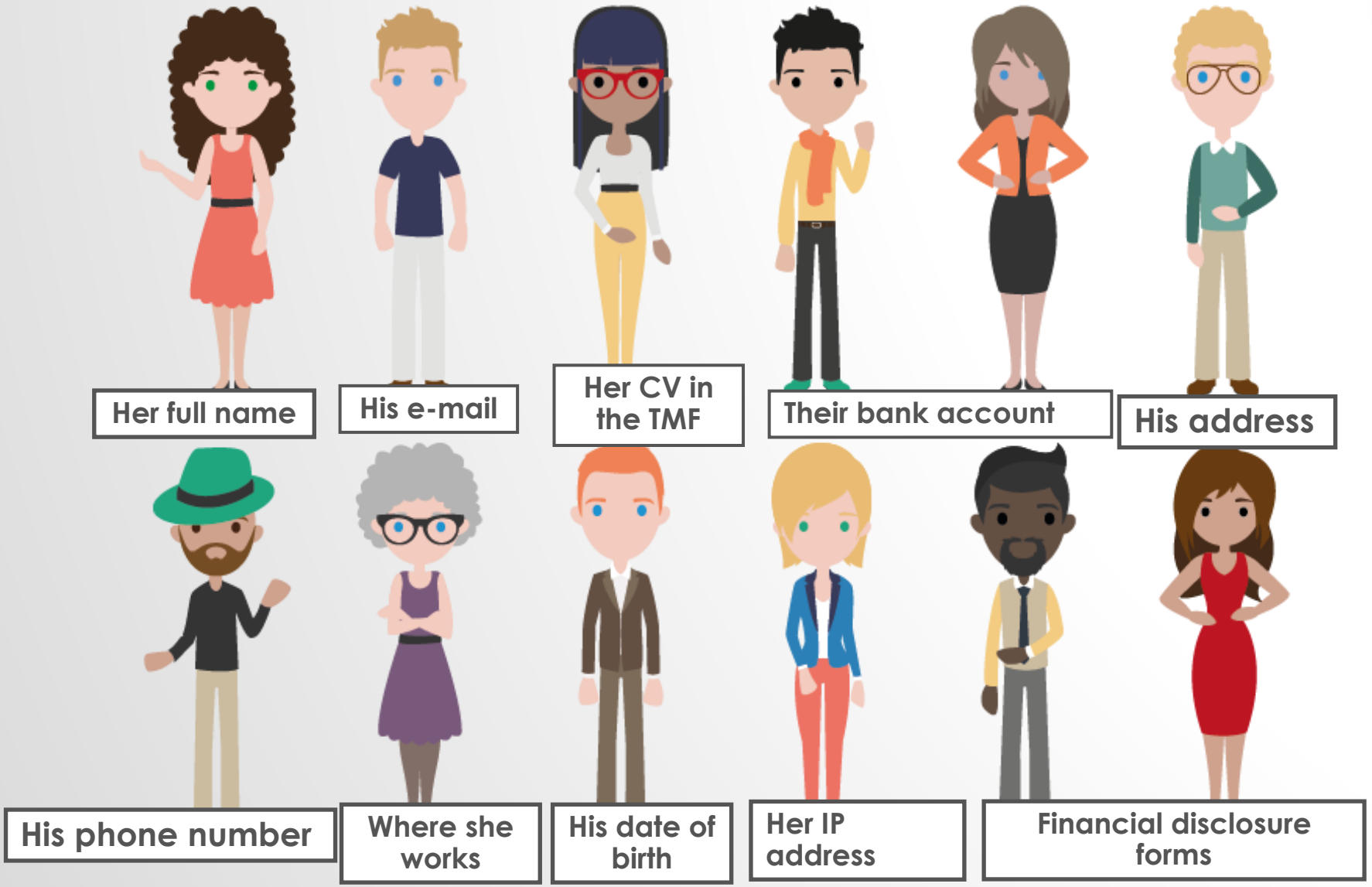
"Processing" of personal data =

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

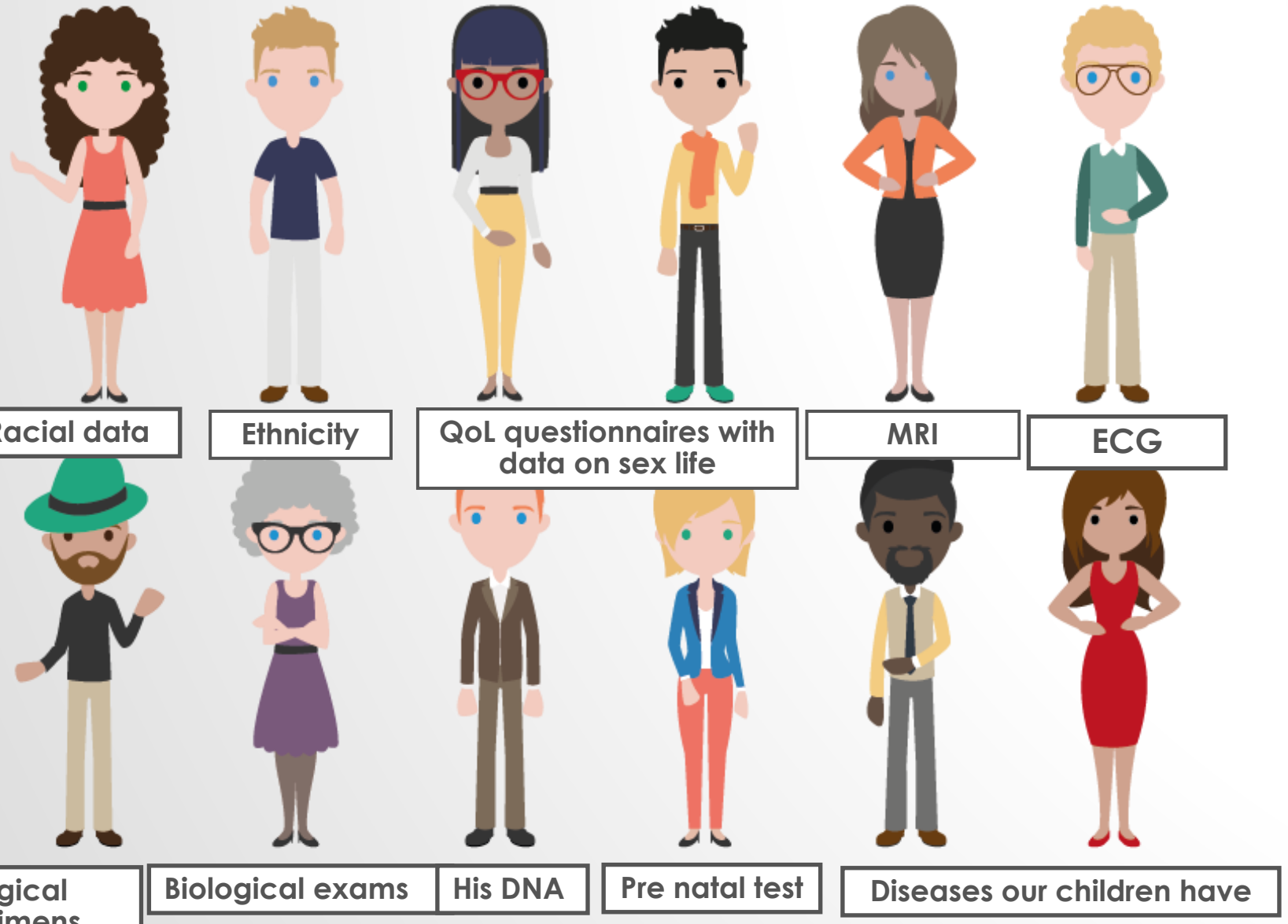
WHAT IS PERSONNAL DATA ?



personal data = ANY information related to an Identified OR identifiable individual

Patient Data in clinical trials is almost 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

DATA TRANSFER OUTSIDE OF THE EU

Free data transfer inside EU

Transfer outside the EU is FORBIDDEN adequate levels of protection are in place

DATA TRANSFER OUTSIDE EU
IN SUMMARY

Legal basis to **Process** data

- Consent
- Contract
- Legal obligation
- Vital importance
- General interest (if you are a public authority!)
- Legitimate interest
- Exemption

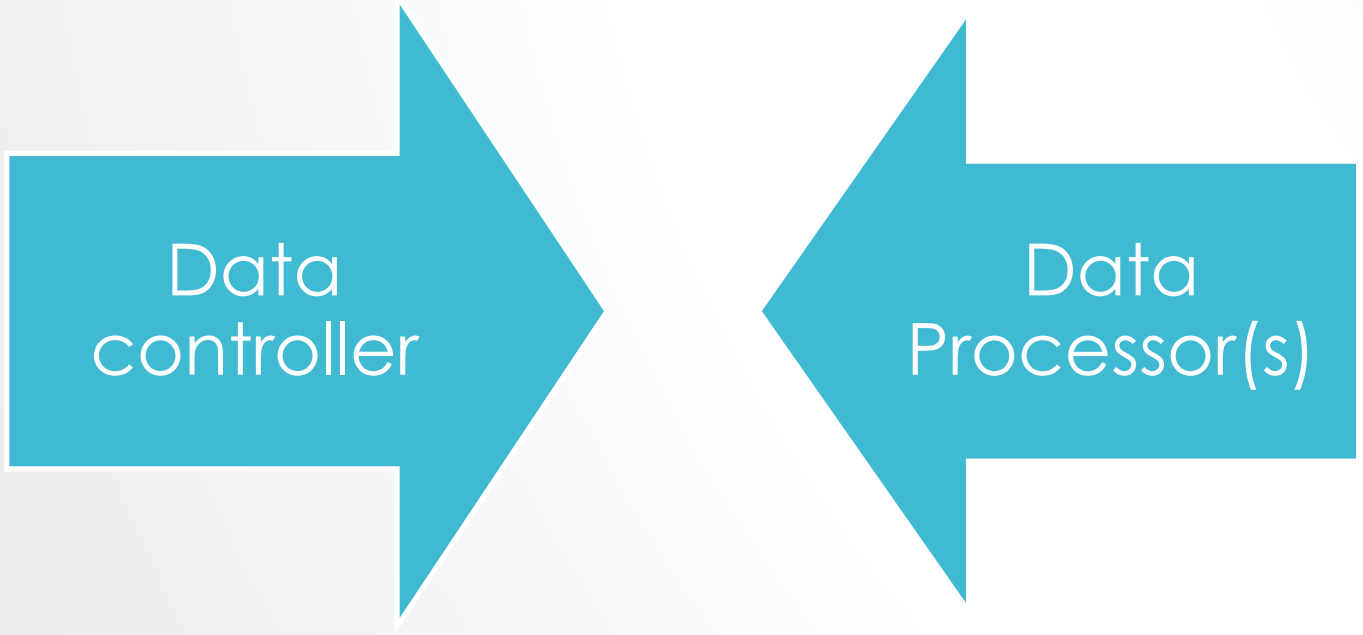
Legal basis to **transfer** data

- EEA countries
- List of “safe countries”
- B2B contract (EU binding contratual clauses)
- Binding corporate rules
- Exemptions art 49
- Or …. Consent….

WHAT DO YOU NEED TO DO ?

- Get **trained** and train your staff
- Check if you need to **appoint** a Data Protection Officer (DPO) and/or a Data Protection Representative (DPR)
- Verify **impact** on various departments off your organisation (HR-BD-Clin Ops-Quality- contracts- vendor managment…)
- Have **documentation** in place to demonstrate compliance(register – DPIA-SOP's- policies…)

RESPONSABILITIES



Sponsors and its vendors must ensure measures are taken
Both data processor and data controller can be held liable

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.

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 ?

Ad Hoc Clinical
Tel +32(0)57 400 530
info@adhoc-clinical.com
www.adhoc-clinical.com

Ter waarde 45 _1B_- 8900 Ieper-Belgium