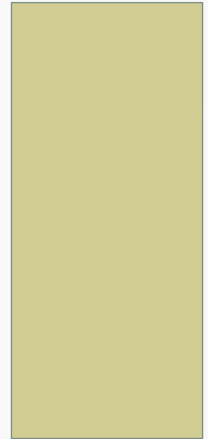


PERSONAL PRIVACY AND RE-USE OF CLINICAL DATA: A BALANCING ACT

MRS. LOES MARKENSTEIN, LL.M
CBP (DATA PROTECTION AUTHORITY), THE NETHERLANDS



DATA PROTECTION LAWS

Distinction in regime for:

- **personal data (within the scope of data protection laws); any information concerning an identified or identifiable person (recital 26, Dir. 95/46/EC)**
- **anonymized data (outside the scope of data protection laws); data rendered anonymous in such a way that the data subject is no longer identifiable (recital 26, Dir. 95/46/EC)**

A CLEAR DISTINCTION?

Recital 26, Dir. 95/46/EC

‘whereas, to determine whether a person is identifiable, account should be taken of all the means likely reasonably to be used, either by the controller or by any other person to identify the said person’

Focus on: outcome of de-identification process: result must be irreversible prevention of identification

A WORKABLE DISTINCTION?

WP29 (Opinion 05/2014) robustness of each anonymisation technique:

- is it still possible to single out an individual
- is it still possible to link records relating to an individual
- can information be inferred concerning an individual

Which technique(-s) can meet these requirements?

CLINICAL TRIAL DATA SHARING

Challenge: maintaining high utility versus requirements for de-identification (defensible, taking into account residual risks)

Impediments:

- different interpretations and criteria, also among authorities**
- different techniques, different assessments of outcome**

A ROAD FULL OF POT-HOLES?

- **Consensus?** Will it be feasible to reach an agreement on interpretations, criteria, techniques and assessment of outcomes and reach one single set of demands?
- **Stability?** How long will this consensus last, given the pressure of ongoing technological developments and consequent new risks?

A DIFFERENT ROUTE?

Clinical trial data sharing within the scope of data protection laws?

Explicit consent of data subjects/participants

- participants in clinical trials in the past (explicit enough?)
- future participants in clinical trials (general or specified?)

Waiver on requirement of consent?

- research that serves (exceptionally) high public interest
- additional safeguards to protect privacy (de-identification with residual risks)
- prior authorisation by competent authority

CBP'S POSITION

- Taking into account recital 26, dir 95/46/EC and Opinion WP29: techniques for de-identification/anonymisation are not likely to meet the requirements
- Clinical trial data sharing within the framework of data protection laws
- Techniques for de-identification valuable to reduce privacy-risks
- Guidance will be necessary on how the requirements of data protection laws can be met