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