



Fostering global data sharing in the industry: legal challenges and practical tips

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Role of the data recipient

Scenario: Receiving data from a third party (e.g. hospital, company or biobank) including from third parties located abroad

Examples:

- Life sciences company seeking study data from a hospital or another life sciences company
- Life sciences company seeking access to a biobank



Role of the data recipient

Preliminary question: What kind of data do we aspire to? Aggregated statistical data or personal (identifiable or coded) data?

- ✓ Only ask for patient's coded or identifiable personal data if we really need this level of information
- ✓ Examples: research collaborations, investigator sponsored trials: the recipient may not need access to personal data but only aspire to statistical reports



Role of the data recipient

Need to check the other party's entitlement to share the data

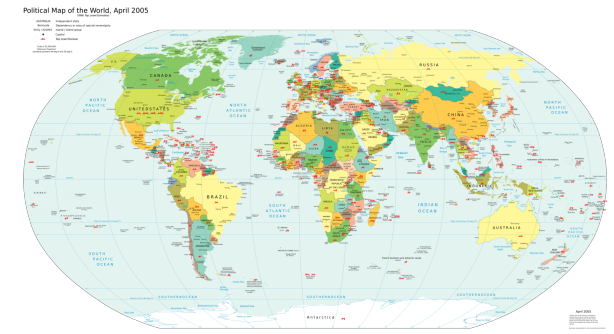
- ✓ Ask whether data subject agreed to the data sharing: terms of ICF signed?
- ✓ Request contractual warranty to this effect
- ✓ If not envisage possible alternatives: anonymization?
- ✓ Consider IP rights on the data
- ✓ Understand additional conditions under which access to data may occur e.g. biobank terms and conditions can be very strict



Role of the data recipient

Import of data from another country/region:

- ✓ Use appropriate legal transfer mechanism
- ✓ Offer adequate legal protection
- ✓ Examples:
 - Transfer within EEA, UK, CH
 - Transfer EEA-US or Transfer out of country X to country Y



Role of the data exporter

Scenario: Sharing data obtained in-house or through collaborations with researchers, or other companies which may be located abroad

Need to proactively ensure the possibility to share

- ✓ For data arising from studies, check ICF
- ✓ For data arising from research collaboration, check contract



Role of the data exporter

What to do if the underlying documentation is not sufficient?

- ✓ Difficulties to re-consent a posteriori or renegotiate collaborations
- ✓ Anonymization benefits limited

International transfer of data to another country or region:
need to respect legal framework in EEA and beyond



Follow up questions

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