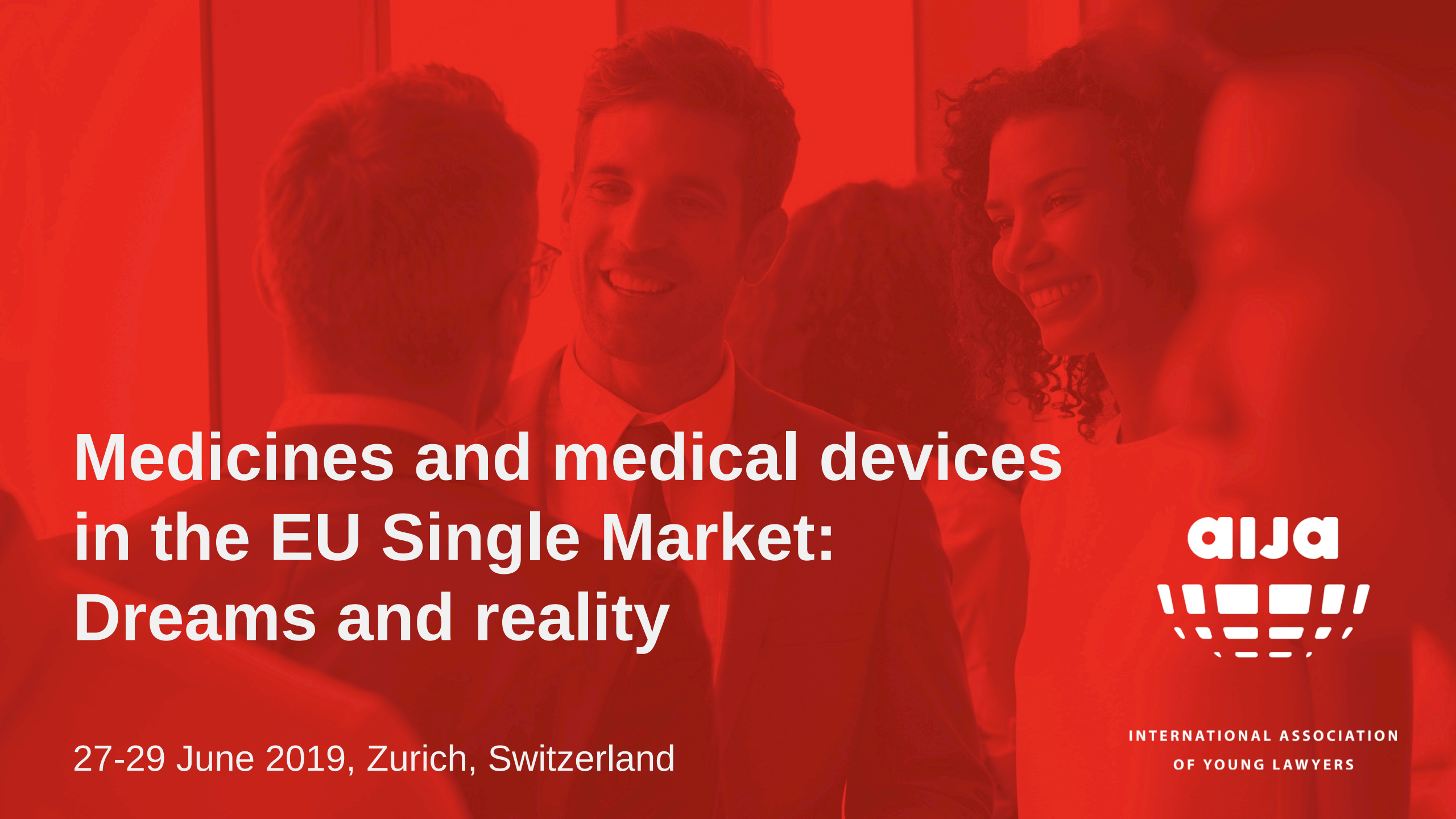

Medicines and medical devices in the EU Single Market: Dreams and reality

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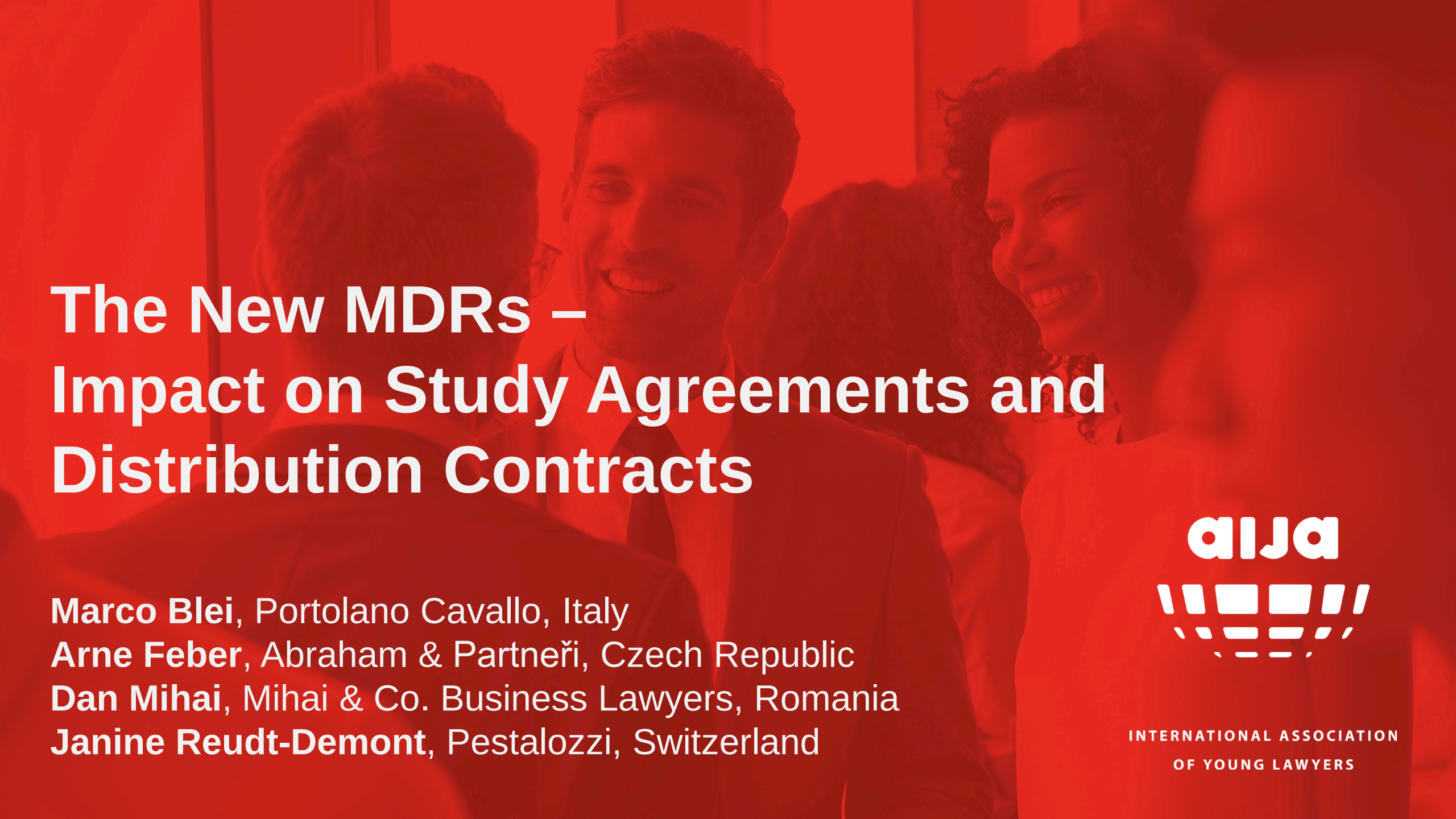

The New MDRs – Impact on Study Agreements and Distribution Contracts

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IP and Data Protection Impacts

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General Introduction to the Swiss Perspective

- MDR and IVDR **not** directly applicable (transposition into Swiss law ongoing)
- GDPR **not** applicable, but similar principles apply under the Swiss Data Protection Act
- **Specific** data protection provisions to observe in the context of research involving human beings

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IP Impacts

- Basis: Transparency Provisions and Information Disclosure through EUDAMED
- IP and Trade Secret Protection Clauses in Distribution Contracts
- IP and Trade Secret Protection Clauses in Study Agreements

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Basis: Transparency Provisions and Information Disclosure through EUDAMED

- Transparency Provisions: e.g. disclosure of technical documentation
- EUDAMED: e.g. disclosure of information on clinical investigations

→ create **increased need for IP and trade secret protection**, both with regard to distribution contracts and study agreements

! Protection is necessary even if the MDR / IVDR provide for confidentiality **!**
(see e.g. Articles 73 para. 3 lit. b MDR, Articles 102 and 109 MDR and IVDR)

IP and Trade Secret Protection Clauses in Distribution Contracts (I)

Annex II Para. 3 MDR

Disclosure of design and manufacturing information

- **Design information:**

Information to allow the design stages applied to the device to be understood

- **Manufacturing information**:

➢ Information to allow the manufacturing process to be understood

➢ Identification of all manufacturing sites, including suppliers and sub-contractors

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IP and Trade Secret Protection Clauses in Distribution Contracts (II)

Inclusion of IP and trade secret protection clauses in distribution contracts

→ was a MUST before; and

→ has now even become more important, because

the MDR transparency rules require **suppliers** to disclose some **process know-how** to their customers and require manufacturers not established in a Member State to disclose the full technical documentation to the authorized representative (who might be the manufacturer's distributor), which could be problematic due to the **business secrets** it contains.

IP and Trade Secret Protection Clauses in Study Agreements (I)

Article 33 MDR

European database on medical devices

- **Purpose:**

«to enable the public to be adequately informed about clinical investigations […]» (para. 1 lit. c)

- **Eudamed includes**:

«the electronic system on clinical investigations referred to in Article 73» (para. 2 lit. e)

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IP and Trade Secret Protection Clauses in Study Agreements (II)

Inclusion of IP and trade secret protection clauses in study agreements and the conclusion of confidentiality / non-disclosure agreements with all external personnel involved in a study

→ was a MUST before; and
→ has now even become more important, because

the MDR transparency rules require **disclosure** of certain information regarding clinical investigations and clinical data.

IP and Trade Secret Protection Clauses in Study Agreements (III)

Example Clause:

The Institution and the Consultant ***agree and understand that MANUFACTURER is the owner of certain confidential information ("Confidential Information") related to its business and that during the Term of this Agreement the Institution and/or the Consultant will be given access to certain valuable proprietary information of a confidential nature belonging to MANUFACTURER****. The Institution and/or the Consultant* ***shall not****, during the Term of this Agreement,* ***disclose*** *any item of Confidential Information (as defined below) of MANUFACTURER to any third party or use any such item for the Institution's and/or Consultant's own benefit or for the benefit of any third party* ***without the prior written consent of MANUFACTURER****, until such time as such Confidential Information shall have properly become known to the general public.*

- Clause continues with **broad** definition of Confidential Information
- Clause may include the right of the manufacturer to request reviewing materials from time to time
- Finally: Do not forget to include a provision on the **return of Confidential Information** after completion of services and/or expiry and/or termination of the agreement

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Data Protection Impacts

- Enhanced Data Protection Requirements in General
- Typical Data Protection Clauses in Distribution Contracts
- Typical Data Protection Clauses in Study Agreements
- Informed Patient Consent in the Context of a Clinical Study

Enhanced Data Protection Requirements in General

→ strengthened conditions for consent

→ enhanced information rights

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Typical Data Protection Clauses in Distribution Contracts

Data storage and data security

Data processing clause
(copy of Data Protection Notice)

Clause regarding screening (e.g. of sales agents) and provision of respective data to supplier

**Regulation of roles:
Who is the controller?
Who is/are the processor(s)?**

Disclosure and data transfer clause

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Typical Data Protection Clauses in Study Agreements

Data security clause

Data processing clause or separate Data Processing Agreement (DPA)

Regulation on the processing of non-patient personal data

Regulation of roles:
Who is the controller?
Who is/are the processor(s)?

Regulation on obtaining an Informed Patient Consent

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Informed Patient Consent in the Context of a Clinical Study (I)

Privacy Information:

1) What **kind** of personal data are processed?
2) How are personal data used? (**purpose, pseudonymization** etc.)
3) What is the **legal basis** for processing personal data? (explicit informed consent)
4) How and to whom are personal data **disclosed**?
5) How are personal data **protected**? (organizational and technical measures)
6) How long are personal data **retained**?
7) How can use and disclosure of personal data be **limited**?
8) How are the data subject's rights **protected**? → information on rights to access, to obtain copy, to object processing, to correct/amend/delete data, to **withdraw consent (for the future)**, to have biological samples destroyed etc.
9) Where must **complaints** be addressed?
10) **Contact information** in case of questions

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Informed Patient Consent in the Context of a Clinical Study (II)

Consent form:

1) Confirming understanding of privacy information

2) Confirming understanding of **withdrawal right** → **! Effect only for the future !**

   Example Clause: «I understand that if I withdraw, data already collected on me will be retained and analyzed as part of the Study."

3) **Consent to the processing** of personal (health) data

4) Consent to the disclosure to and use by the MD-manufacturer of pseudonymized (coded) data and to disclosure abroad

5) Specific consent to the **collection of biological samples** (if applicable)

6) Specific agreement on the **further use of data for future scientific research**

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