EU-MDR/GDPR: From complex regulation to impactful change

31-Jan-2018 / Mieke Roelants
Disclosure

Speaker name:
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I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
CE-Mark: Key to the EU Market

€110 Billion Market

28% of the world market

EU level:
Medical Device Directive (MDD)

National level:
Translation of the MDD into the local law
From MDD to MDR - Key changes

- Market surveillance
- Clinical data
- Distribution chain
- Definition & classification rules
- Conformity assessment
- Transparency & traceability
- Re-designation of NB
- Liability
- Better coordination
- Person responsible
From MDD to MDR

**PAST:**
MEDDEV 2.7/1rev. 3 & MDD
- Much information from literature
- Often referring to **non-equivalent** devices

**NOW:**
MEDDEV 2.7/1rev. 4, MDD & (MDR)
- Data AND methodology
- Critical assessment
- Benefit-risk evaluation
- Equivalent device – compliance with requirements

**FUTURE:**
New MEDDEV 2.7/1 and MDR

**Evaluation of clinical data** needs to be documented in a **Clinical Evaluation Report (CER)**

**Scientific literature**

**State of the Art**

**Clinical Investigation**
All clinical investigation information shall be:
• recorded,
• processed,
• handled, and
• stored
by the sponsor or investigator, as applicable, in such a way that it can be accurately reported, interpreted and verified while the confidentiality of records and the personal data of the subjects remain protected in accordance with the applicable law on personal data protection.
GDPR Scope related to health data

• Identifiable personal data, including pseudonymised data

• Processing of data concerning health is **prohibited**

1. Consent
   - Explicit consent – active consent
   - Freely given
   - Right to withdraw
   - Clearly distinguishable!

2. Processing for **scientific and historical research purposes** or statistical purposes
   - Obligated appropriate safeguards must be taken for the rights and freedoms of the data subject
   - Technical and organisational measures to respect the principle of data minimisation, inc. pseudonymisation

3. Others
Data Subject Rights

- Data Portability
- Information
- Erasure
- Access
- Rectification
- Object
- Restrict processing

Cartoon: Google would like permission to use your location.
Data Subject Rights

- **NO Right to Erasure**
- **Right to Erasure**

- Processing is necessary *scientific* or historical research *purposes*
- Erasure will render *impossible or seriously impair* the achievement of the objectives of the processing
Change is here & inevitable

• Both EU regulations were published with the aim to protect the public

• MDR: Forces manufacturers to evaluate available Clinical Data

• GDPR: Forces everyone in contact with personal data to evaluate whether everything is in place to protect confidentiality
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