First time in Finland! 25.–26.10.2017 Helsinki

6th Conference on Clinical Trials in the Nordic Countries

Impact of the Regulatory Changes on the Clinical Data Expectations in Europe

Dr. Bassil Akra

Munich, 2017.10.26

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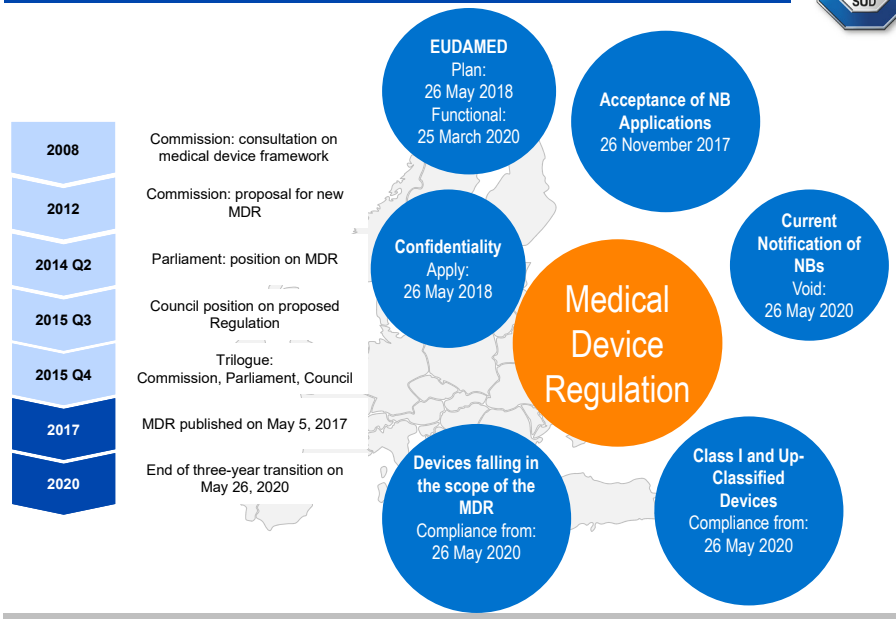
Disclaimer

This presentation is based on information available as of today and prepared to my best knowledge.
This presentation presents my personal understanding of the medical device requirements in Europe.
The presentation includes figures that were copied from public websites. A citation to the original source is included in the Footnote of this presentation.

What is happening when …

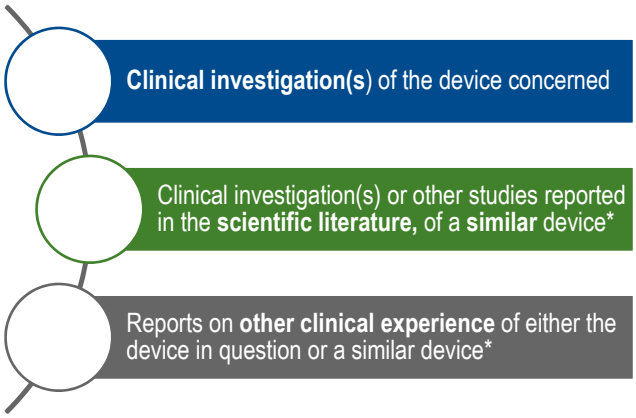


What are the current requirements of the Directive(s)?

2007/47/EC – Annex X: 1.1 As a general rule, confirmation of conformity with the requirements concerning…

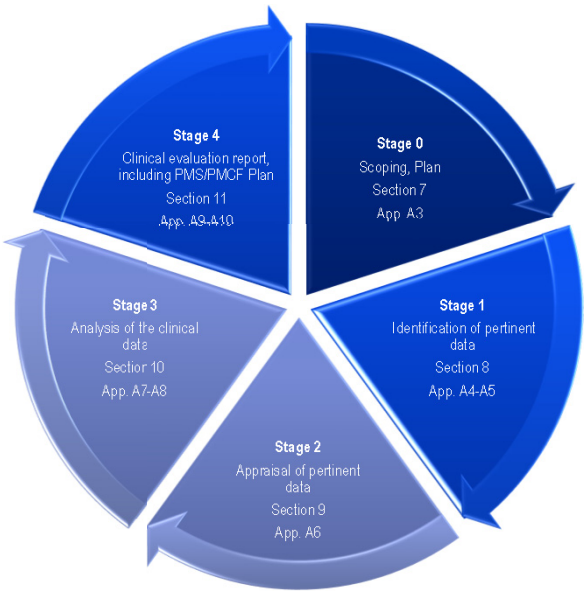
must be based upon clinical data

Sources to consider acc. 2007/47/EC – Annex X



* for which **equivalence** to the device in question can be demonstrated

How is a clinical evaluation performed?

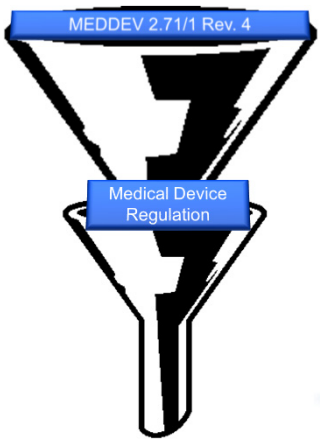


What is the impact of the MEDDEV during the MDR transition period?

A=100%

B= A – x%

C= B – x%



EU Regulation – Soft introduction

"The manufacturer shall specify and justify the level of clinical evidence necessary to demonstrate compliance with the relevant essential requirements on safety and performance which shall be appropriate to the characteristics of the device and its intended purpose."

MDD versus MDR – Conformity with Requirements

Demonstration of conformity with the essential requirements must include a **clinical evaluation** in accordance with Annex X.

Demonstration of conformity with the general safety and performance requirements shall include a **clinical evaluation** in accordance with Article 61.

MDD versus MDR – Clinical Data Expectations

As a general rule, confirmation of conformity with the requirements concerning the characteristics and performances referred to in Sections 1 and 3 of Annex I, under the normal conditions of use of the device, and the evaluation of the side-effects and of the acceptability of the benefit/risk ratio referred to in Section 6 of Annex I, must be **based on clinical data**.

Confirmation of conformity with relevant general safety and performance requirements set out in Annex I under the normal conditions of the intended use of the device, and the evaluation of the undesirable side-effects and of the acceptability of the benefit-risk- ratio referred to in Sections 1 and 8 of Annex I, shall be **based on clinical data providing sufficient clinical evidence**, including where applicable relevant data as referred to in Annex III.

MDD versus MDR – Definition Clinical Data

‘clinical data’ means the safety and/or performance information that is generated from the use of a device. Clinical data are sourced from:

clinical investigation(s) of the device concerned;	clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question **can be demonstrated**;	published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question **can be demonstrated**

‘clinical data’ means information concerning safety or performance that is generated from the use of a device and is sourced from the following:

clinical investigation(s) of the device concerned,	clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question **can be demonstrated**,	reports published in **peer reviewed** scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question **can be demonstrated**,	clinically relevant information coming from **post-market surveillance, in particular the post-market clinical follow-up**

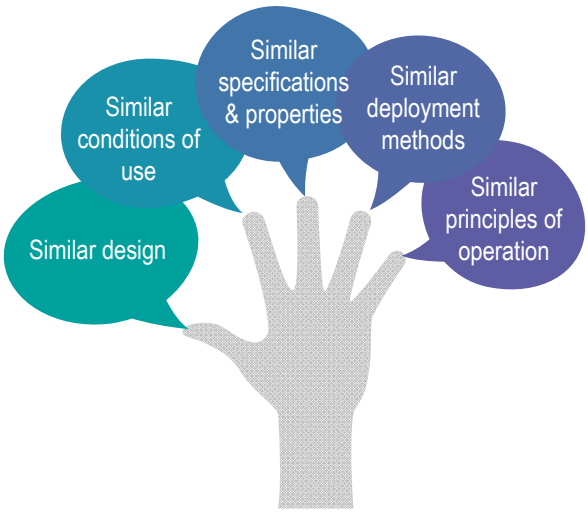
EU Regulation - Equivalence approach, only possible if clinically…

Same clinical condition or purpose, including similar severity and stage of disease, at the **same site in the body**, in a similar population, including as regards age, anatomy and physiology
has the **same kind of user**
has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose

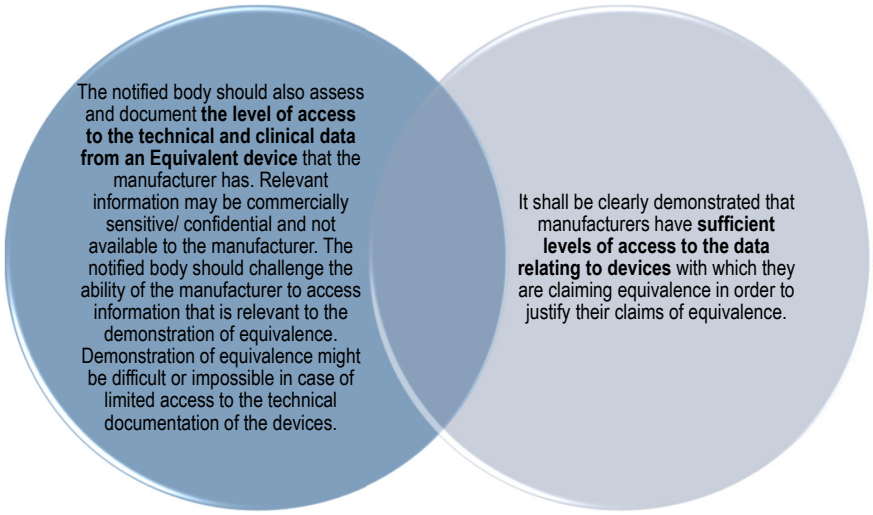
EU Regulation - Equivalence approach, only possible if biologically…

The device uses the **same materials or substances** in contact with the **same human tissues or body fluids** for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables

EU Regulation - Equivalence approach, only possible if technically…

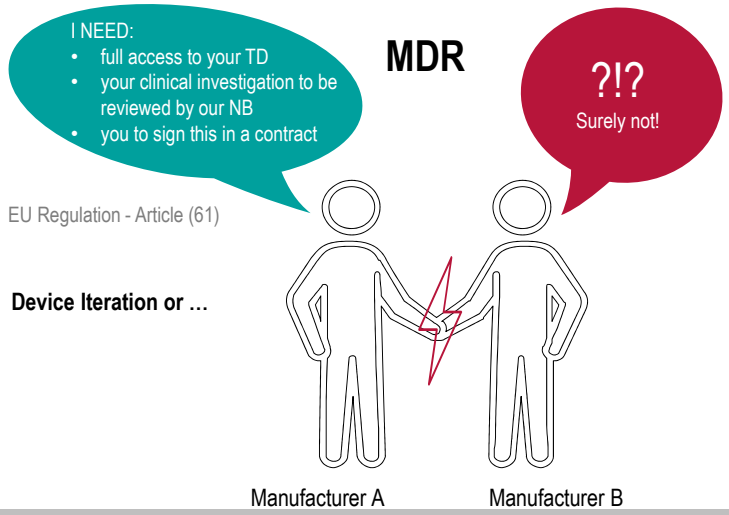


MDD versus MDR – Non-Implantable and Non-Class III Devices



MDD versus MDR – Class III and Implantable

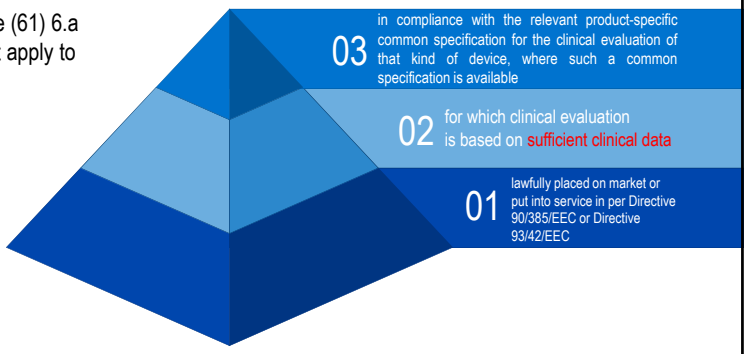
MDD - In the case of implantable devices and devices in Class III clinical investigations shall be performed **unless it is duly justified to rely on existing clinical data**. If demonstrated, equivalence is possible.



Exemptions from clinical investigations for…

For implantable & Class III medical devices:

EU Regulation - Article (61) 6.a requirements shall not apply to devices…



Exemptions from clinical investigations for…

EU Regulation - Article (61) 6.b

Sutures	Staples	Dental fillings
Dental braces	Tooth crowns	Screws
Wedges	Plates	Wires
Pins	Clips	Connectors

→ Clinical evaluation based on sufficient clinical data
→ Clinical evaluation in compliance with relevant product-specific common specification, where such common specification is available

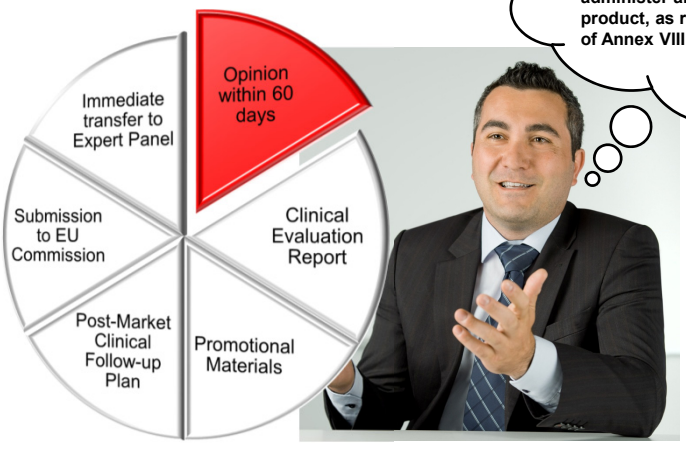
EU Regulation – Article 61 (2)

For class III devices and for certain class IIb devices, a manufacturer should be able to consult voluntarily an expert panel, prior to that manufacturer's clinical evaluation and/or investigation, on its clinical development strategy and on proposals for clinical investigations.

Clinical evaluation consultation procedure for certain class III and class IIb devices – Article 54

Applicable for innovative devices or innovative technologies

Applicable for implantable devices classified as class III, and for Class IIb active devices intended to administer and/or remove a medicinal product, as referred to in section 6.4 of Annex VIII (Rule 12)



Mechanism for scrutiny of conformity assessments of certain class III and class IIb devices

Article 55

- A notified body shall notify the competent authorities of certificates it has granted to devices
- Notification shall take place through the electronic system
- Notification shall include:
  - the summary of safety and clinical performance information
  - the assessment report by the notified body
  - the instructions for use
  - the scientific opinion of the expert panels
  - where applicable, a justification in case of divergent views between notified body and expert panel

Major Elements of the Post-Market Surveillance Requirements

*The post-market surveillance system shall be suited to **actively and systematically** gathering, recording and analyzing relevant data on the quality, performance and safety of a device **throughout its entire lifetime**, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions.*

Summary of safety and clinical performance (SSCP)

EU Regulation – Article 32

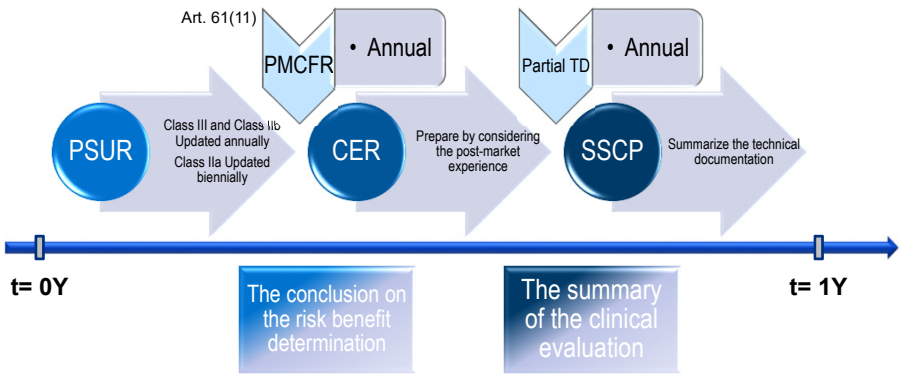
In case of class III & implantable devices, other than custom-made or investigational devices, manufacturer shall draw up a SSCP

Manufacturer shall mention on label or IFU where the summary is available

EU MDR Regulation
Applicable for Class III and Implantable Medical Devices

PSUR: Periodic Safety Update Report
CER: Clinical Evaluation Report
SSCP: Summary of Safety and Clinical Performance
PMCFR: Post-Market Clinical Follow-Up Evaluation Report

For class III devices and **implantable devices**, the PMCF evaluation report and, if indicated, the summary of safety and clinical performance referred to in Article 32 shall be updated at least annually with such data.



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Dr. Bassil Akra
Vice President
Global Focus Teams
Bassil.Akra@tuev-sued.de
Phone: +49 89 5008 4421
Fax: +49 89 5008 4403

Contact us:
www.tuv-sud.com
info@tuv-sud.com

Follow us on social media:
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