ENGAGING WITH THE NEW EU REGULATORY LANDSCAPE FOR MEDICAL DEVICES

CLINICAL EVIDENCE FOR MEDICAL DEVICES

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Clinical evidence for medical devices

**INPUT**

- Intended purpose
- Indications and targeted population

**OUTPUT**

- Performances
- Benefits

**Intended purpose**

Use for which the device is intended, as expressed in the IFU

- Illness
- Pathology
- Severity of the illness
- Population
  ... 
As expressed in the IFU

**Indications and targeted population**

 Means by which the device functions

**Mode of action**

Ability of a device to achieve its intended purpose

Positive impact of a device on the health of an individual, expressed in terms of meaningful, measurable patient-relevant clinical outcome [...]

**Performances**

**Benefits**
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*What is expected from the manufacturer?*

To perform a clinical evaluation: Systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device, in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer.
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**What are the clinical data?**

**Clinical data:** Informations concerning safety or performance that are generated from the use of a device.
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What are the sources of the clinical data?

- 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
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**What is the aim of this clinical evaluation?**

To demonstrate the clinical evidence of the MD: Clinical data and clinical evaluation results pertaining to a device of a sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s), when used as intended by the manufacturer.
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Is it a regulatory requirement?

Article 61.1 of MDR: Confirmation of conformity with relevant general safety and performance requirements [...] 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 [...] shall be based on clinical data providing sufficient clinical evidence.
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How to determine a sufficient clinical evidence?

1st item: methodology is expressed in the MEDDEV 2.7.1 revision 4

Definition of sufficient clinical evidence: an amount and quality of clinical evidence to guarantee the scientific validity of the conclusions.
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Methodology of MEDDEV 2.7.1 revision 4

Stage 4
Clinical evaluation report, incl. PMS/PMCF plan
Section 11
App. A9-A10

Stage 3
Analysis of the clinical data
Section 10
App. A7-A8

Stage 2
Appraisal of pertinent data
Section 9
App. A6

Stage 1
Identification of pertinent data
Section 8
App. A4-A5

Stage 0
Scoping, Plan
Section 7
App. A3
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**How to determine a sufficient clinical evidence?**

2nd item: It is a risk-based approach (with regards to the benefits) and thus, it is proportionate to the level of risk of each device, associated to the other available therapeutics alternatives.
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How to determine a sufficient clinical evidence?

3rd item: Is the quality of available clinical data sufficient to address the risks (with regards to the benefits)?
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How to determine a sufficient clinical evidence?

4th item: Is the quantity of available clinical data sufficient to address the risks (with regards to the benefits)?
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Thank you for your listening and participation!