





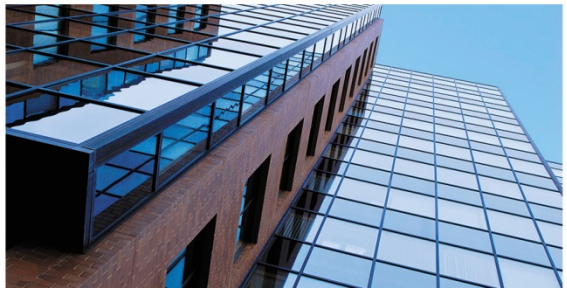


ENGAGING WITH THE NEW EU REGULATORY LANDSCAPE FOR MEDICAL DEVICES

CLINICAL EVIDENCE FOR MEDICAL DEVICES

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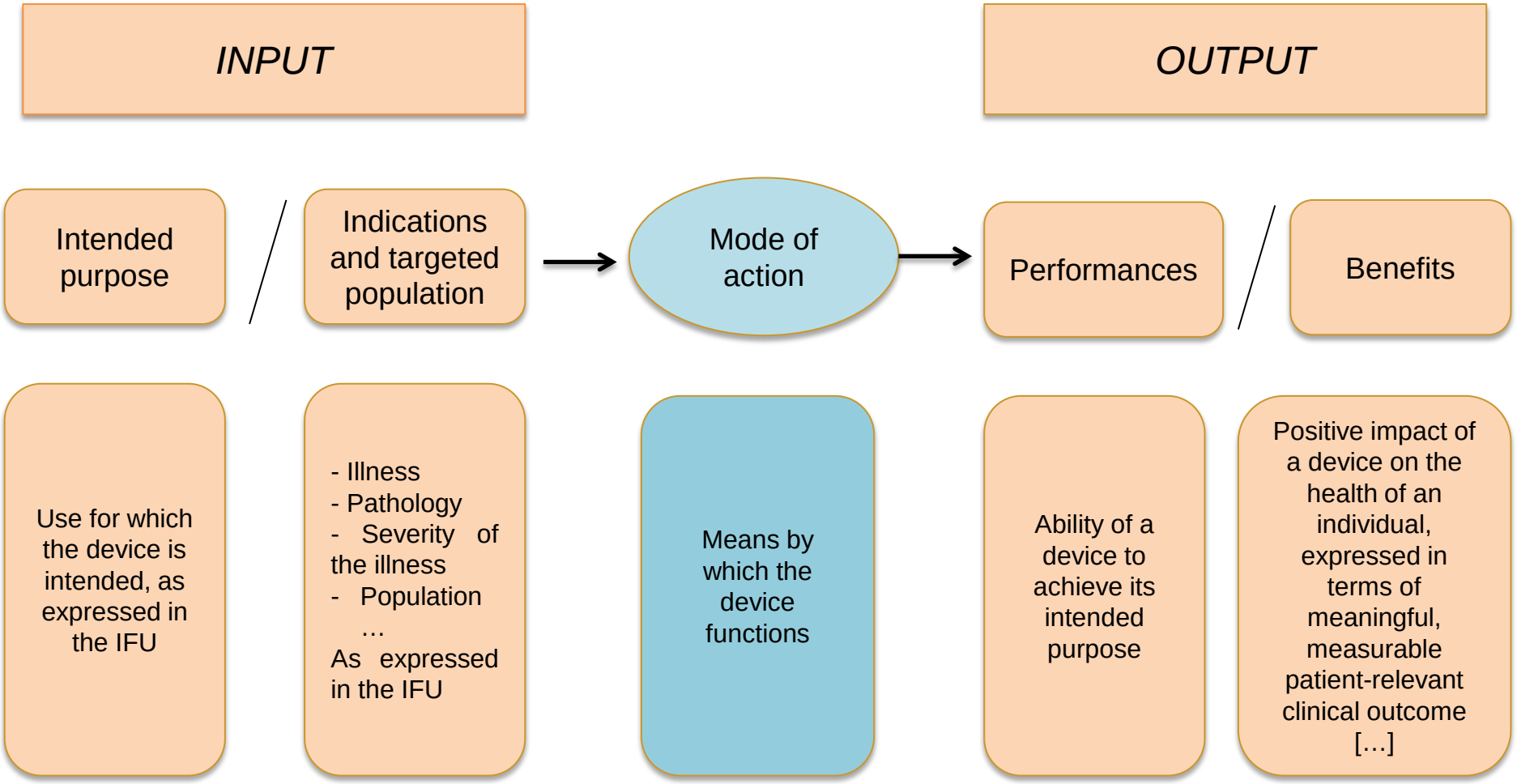
Brussels - April 6, 2018

LABORATOIRE NATIONAL DE MÉTROLOGIE ET D'ESSAIS

Clinical evidence for medical devices



Clinical evidence for medical devices

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

Clinical evidence for medical devices

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 scientic literature on other clinical experience of either the device in question or a device for which equivalence to the devic in question can be demonstrated
- Clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up

Clinical evidence for medical devices

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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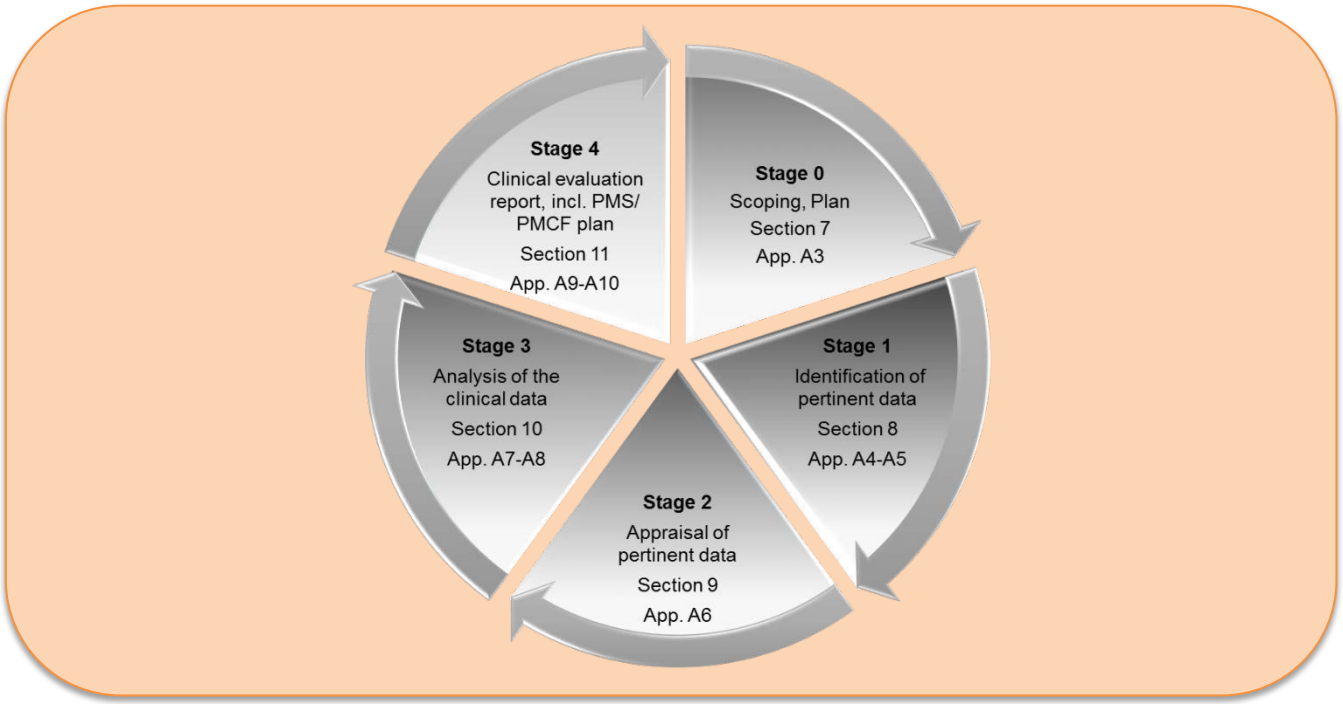
Methodology of MEDDEV 2.7.1 revision 4



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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 !