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Study Day In-House Medical Software for
Healthcare Institutions

CLINICAL INVESTIGATIONS

Benedicte NUYTTENS

Head of Clinical Investigation Unit

Federal Agency for Medicines and Health Products



.be

DO I NEED TO SUBMIT MY STUDY UNDER MDR FOR APPROVAL?

1. Is a device used with an intended medical purpose?
2. Does the study qualify as a clinical investigation?
3. Which regulatory submission pathway applies?



1. IS A DEVICE USED WITH AN INTENDED MEDICAL PURPOSE?

Examples:

- CE-marked medical devices
- Products in development for becoming a medical device
- Products used with a medical purpose within the study
- MDR Annex XVI products



2. DOES THE STUDY QUALIFY AS A CLINICAL INVESTIGATION?

Definition of a clinical investigation according to MDR:

any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance (including clinical benefits) of a medical device.



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Definition of a clinical investigation according to MDR:

any **systematic investigation** involving one or more human subjects, undertaken to assess the safety or performance (including clinical benefits) of a medical device.

Retrospective studies do not qualify as clinical investigations.



2. DOES THE STUDY QUALIFY AS A CLINICAL INVESTIGATION?

Definition of a clinical investigation according to MDR:

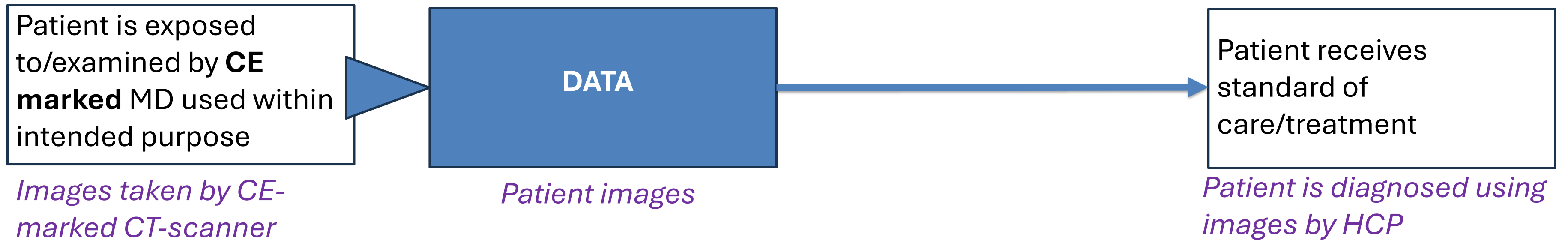
any systematic investigation involving one or more **human subjects**, undertaken to assess the safety or performance (including clinical benefits) of a medical device.

When does a study not involve human subjects?

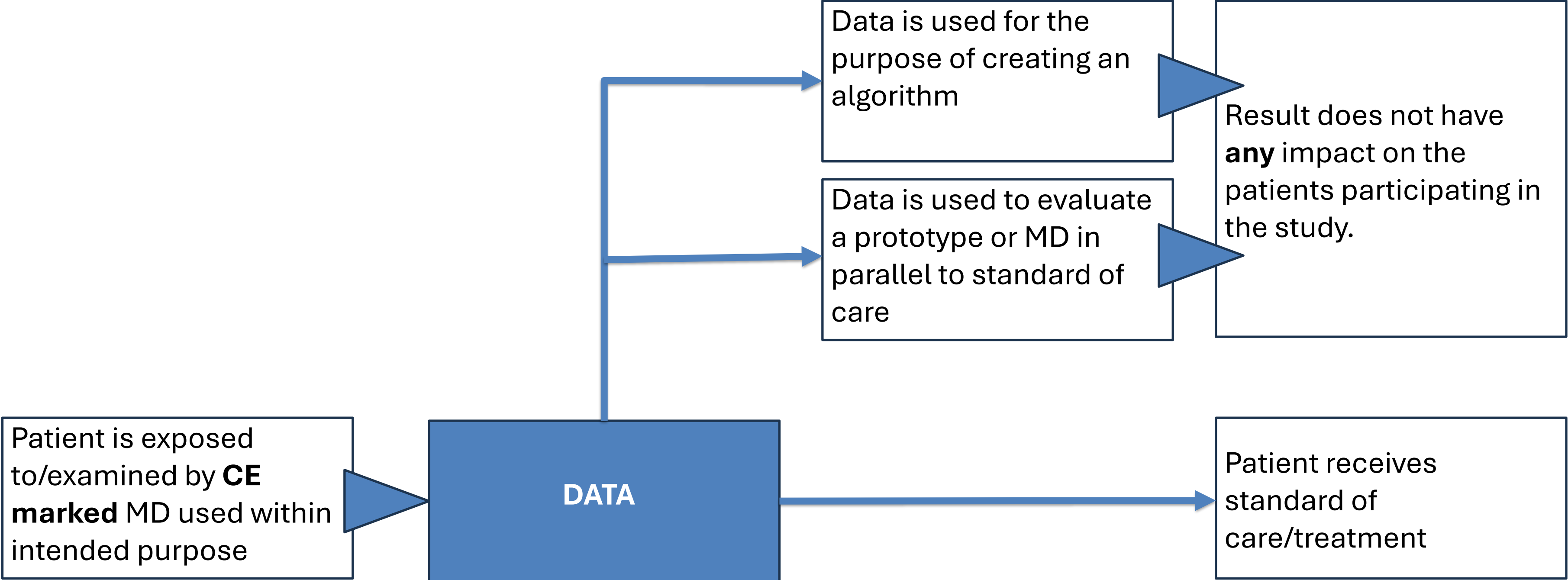
- *Fake datasets*
- *Certain exceptions for software (see example)*



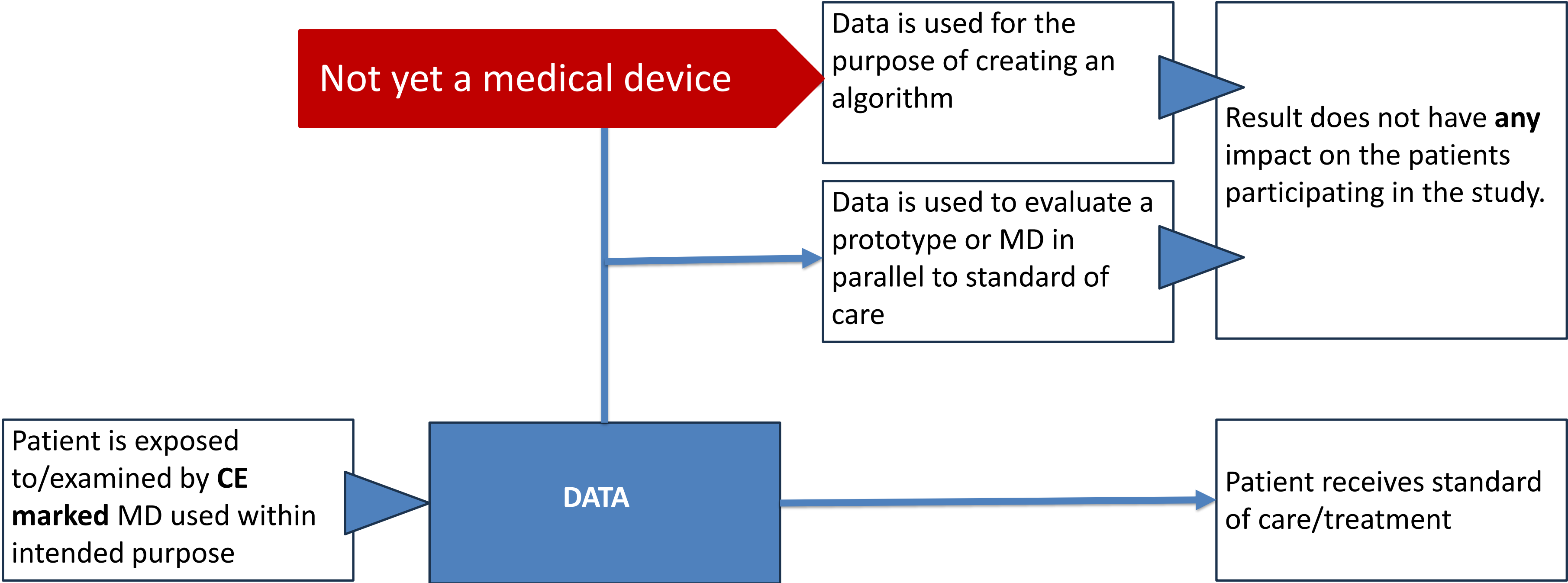
Example



Example



Example



Example

Not yet a medical device

Data is used for the purpose of creating an algorithm

Investigation does not involve human subjects, only "their data"

Data is used to evaluate a prototype or MD in parallel to standard of care

Result does not have **any** impact on the patients participating in the study.

Patient is exposed to/examined by **CE marked** MD used within intended purpose

DATA

Patient receives standard of care/treatment

2. DOES THE STUDY QUALIFY AS A CLINICAL INVESTIGATION?

Definition of a clinical investigation according to MDR:

any systematic investigation involving one or more human subjects, undertaken to **assess the safety or performance** (including clinical benefits) of a medical device.

There need to be device related endpoints assessing the safety or performance.



2. DOES THE STUDY QUALIFY AS A CLINICAL INVESTIGATION?

Case example:

In a clinical trial, a non-CE marked software application, provided by a third-party, is used to support dosing decisions of the investigational medicinal product based on patient-specific data.

The software provides treatment recommendations but has no study endpoints or objectives and is not evaluated as a device.

Nevertheless, its use may influence patient management and indirectly affect the clinical trial outcomes.



Is this a clinical investigation?

2. DOES THE STUDY QUALIFY AS A CLINICAL INVESTIGATION?

Case example:

No, there is no aim to assess the safety and/or performance.

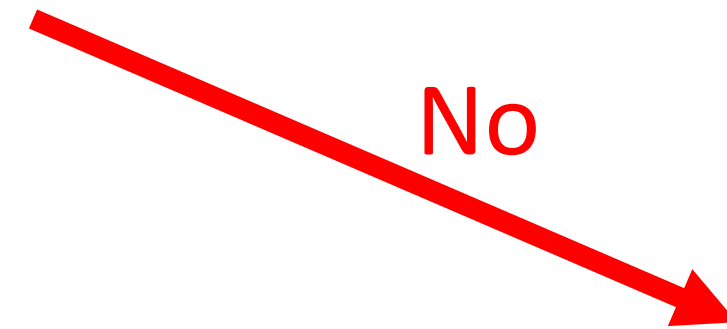
However:

- The software is not CE-marked and does not qualify as an in-house device.
- The sponsor can only use this medical device in the context of a clinical investigation.
- Endpoints related to safety and/or performance will need to be added.



DO I NEED TO SUBMIT A CLINICAL INVESTIGATION UNDER MDR FOR APPROVAL?

1. Is there an intended medical purpose?
2. Does the study qualify as a clinical investigation?



Out of scope of MDR

3. Which regulatory submission pathway applies?



3. WHICH REGULATORY PATHWAY APPLIES?

CLINICAL INVESTIGATION	OPINION FROM	PROCESS FLOW	REGULATORY PATHWAY
<ul style="list-style-type: none"> PMCF studies with additional burdensome and/or invasive procedures 	EC	FAMHP – COLLEGE - EC	VALIDATION FAMHP OPINION EC
<p>Clinical investigations:</p> <ul style="list-style-type: none"> with non-CE-marked medical devices with CE-marked medical devices used “out of scope” with custom-made medical devices for which data will be used for conformity assessment 	FAMHP + EC	FAMHP – COLLEGE - EC	CONSOLIDATED OPINION FAMHP AND EC
<ul style="list-style-type: none"> Clinical investigations with CE-marked devices used “in scope” 	EC	EC	EC ONLY
<ul style="list-style-type: none"> Clinical investigations with in-house medical devices 	FAMHP EC	FAMHP EC	SEPERATE OPINION FAMHP AND EC



WHAT ABOUT IN-HOUSE MEDICAL DEVICE SOFTWARE?

Article 5(5) MDR provides a derogation from CE-marking and market access requirements for in-house medical devices.

However, in-house medical device software is not exempted from clinical investigation requirements **when the software itself is the object of the investigation.**

If you systematically investigate an in-house software's safety and/or performance you are conducting a clinical investigation.

-> Application through the “separate opinion” regulatory pathway is needed



KEY TAKEAWAYS

The intended purpose of the device in the study determines if the device qualifies as a medical device.

Not all studies qualify as clinical investigations under the MDR.

Non-CE-marked medical devices may not be used on patients outside a clinical investigation.

In-house medical devices are not exempt from clinical investigation requirements.

Consult our national guidances for detailed instructions and examples.



MORE INFORMATION...

Clinical Investigations Unit – R&D

ct.rd@fagg-afmps.be

Website

- [Guideline on Submission Procedures of Clinical Investigations according to MDR in Belgium](#)
- [Clinical Investigations – Guidance on Dossier Content](#)

MDCG guidelines



QUESTIONS?



CONTACT

Federal Agency for Medicines and Health Products - FAMHP

Avenue Galilée/Galileelaan 5/03
1210 BRUSSELS
tel. + 32 2 528 40 00

welcome@fagg-afmps.be
www.famhp.be

Clinical Investigations Unit – R&D Devison – DG Pre
ct.rd@fagg-afmps.be

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