

Clinical investigation – application form under Medical Device Regulation.

Application form version 1.0

Section 1: Clinical investigation identification

1.1 Sponsor identification

Name:		
Address	Street name:	Street number:
	Postal code:	City:
	Country:	
Telephone number:		
Email:		

Contact person of the sponsor

First name:
Last name:
Telephone number:
Email:

Sponsor's legal representative identification

Do you have a legal representative?	
Yes	No
If yes, complete the information related to the legal representative (section 1.2)	

1.2 Legal representative identification

Organisation name:		
Address	Street name:	Street number:
	Postal code:	City:
	Country:	
Telephone number:		
Email:		

Contact person of the legal representative

First name:
Last name:
Telephone number:
Email:

Contact person for the clinical investigation

**Same as contact
person of sponsor**

**Same as contact
person of legal representative**

Other

If you selected other, please fill in the section below related to the other contact person for this clinical investigation.

Other contact person for the clinical investigation

First name:		
Last name:		
Address	Street name:	Street number:
	Postal code:	City:
	Country:	

1.3 Clinical investigation type

Select the appropriate regulatory pathway for the application :

Clinical investigation application (MDR Art. 62(1)/IVDR Art. 58(1))

PMCF investigation notification (MDR Art. 74(1))

**Other clinical investigation application/notification - national application
(MDR Art. 82(1))**

1.4 Submission type

First submission in the EEA

First submission at the national level (clinical investigation has been already submitted in EEA)

In this case, please provide the clinical investigation ID (CIV-ID) provided

Resubmission

Please provide the CIV-ID if already available

1.5 Participating countries within the EU/EEA/UK (Northern Ireland), Turkey and Switzerland

Select the participating countries for the clinical investigation

1.6 Participating countries outside EU/EEA/UK

If this study is part of a multi-site clinical investigation outside the EU/EEA/UK, please provide a list of all the non EU/EEA countries the study plans to be carried out in.

1.7 Clinical investigation plan (CIP)

CIP code:

CIP version:

CIP date:

1.8 Clinical investigation title

Full title :

Short title :

Title for lay people:

Section 2: Clinical investigation description

2.1 Scientific opinion

Has the manufacturer consulted with an expert panel as outlined in Art. 61(2) of Regulation (EU) 2017/745.

Y Yes No

2.2 Design of the clinical investigation

Exploratory investigation Confirmatory investigation
Observational investigation

First in human Not first in human
investigation

2.3 Design methodology

Case Contro Controlled Cross-sectional Double blind
Parallel Randomised Open
Other:

2.4 Development stage

Pilot stage Pivotal stage Post-market stage

2.5 Objectives and endpoints

Primary objective(s):

Secondary objective(s):

Other objective(s):

Primary endpoint(s):

Secondary endpoint(s):

Other endpoint(s):

2.6 Synopsis of the clinical investigation

Overall synopsis:

2.7 Planned number of subjects

In Europe:
In Asia:
In Africa:
In North America:
In South America:
In Oceania:
<i>Total planned number of subjects:</i>

2.8 Duration of clinical investigation

Estimated start date:
Estimated end date:

2.9 Population

2.9.1 Medical condition

Is there an associated medical condition?
Yes No
Is the medical condition considered to be rare?
Yes No

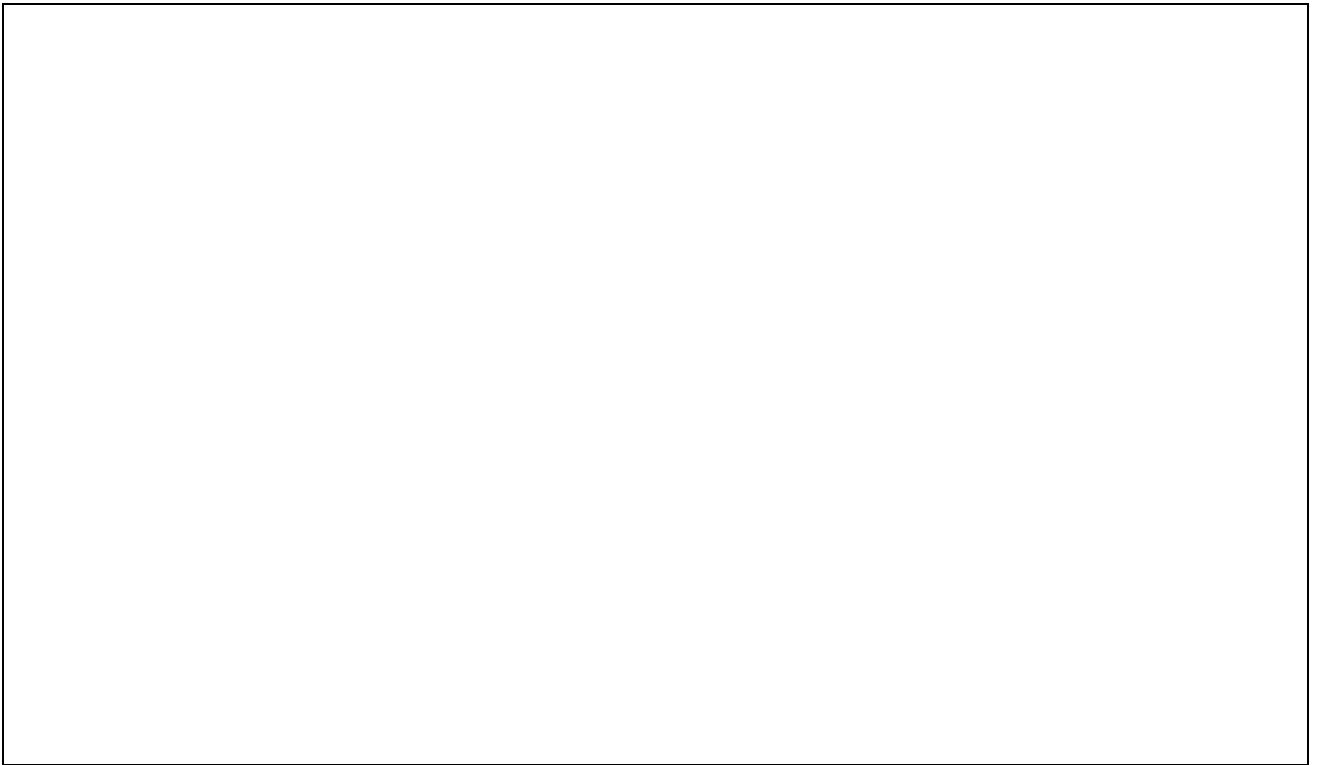
2.9.2 Therapeutic area

Select the therapeutic area that the clinical investigation falls under

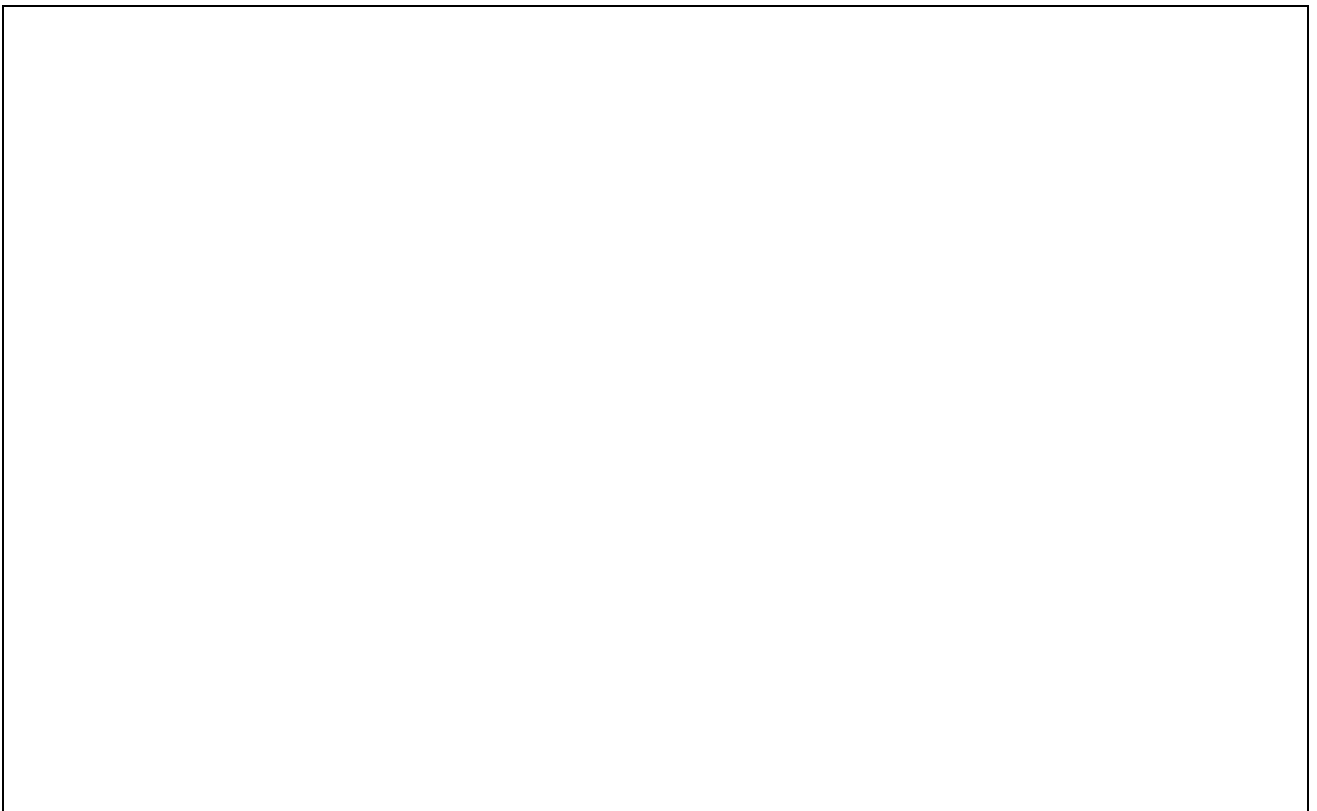
2.9.3 Gender of subjects

Female Male Other

2.9.4 Inclusion criteria

A large, empty rectangular box with a thin black border, intended for the user to enter the inclusion criteria for the study.

2.9.5 Exclusion criteria

A large, empty rectangular box with a thin black border, intended for the user to enter the exclusion criteria for the study.

2.9.6 Type of subjects that the clinical investigation plans to recruit

Healthy	Patients	Vulnerable population	Incapacited subjects
Minors	Pregnant women	Breastfeeding women	Patients in emergency situations
Other (please specify)			

2.9.7 Age range of the participants that the clinical investigation plans to include

In utero	Adults (from 18 to 84 years)
Newborns (from 0 to 27 days)	Elderly (from 85 years)
Infants and toddlers (from 28 days to 23 months)	
Children (from 2 to 5 years)	
Adolescents (from 12 to 17 years)	

2.10 Scope of the investigational device

2.10.1 Combined investigation Medical Device/In Vitro Diagnostic?

Yes	No
If yes, please provide the related IVD performance study identification number	

2.10.2 Is the application submitted in parallel with an application for a clinical trial on medicinal products?

Yes	No
If yes, please provide the EU Clinical Trial Number:	

2.11 Coordinating investigator

First name:		
Last name:		
Address	Street name:	Street number:
	Postal code:	City:
	Country:	
Telephone number:		
Email:		

3.1.4 Device Identifiers

Generic denomination:	
Device trade name:	Model:
Device name:	
European Medical Device nomenclature	
Medical device classification:	
Classification rule:	
Device description:	
Intended (clinical) purpose:	
Does the device contain or incorporate medicinal substance(s)?	
Yes	No
If yes, please provide the medicinal substance(s) name(s):	
The device incorporates, as an integral part, or it is manufactured using:	
Non-viable tissues of human origin or their derivatives with an ancillary action	
Non-viable cells of human origin or their derivatives with an ancillary action	
Non-viable tissues of animal origin or their derivatives with an ancillary action	
Non-viable cells of animal origin or their derivatives with an ancillary action	
Non-viable biological substance other than those referred to in the previous points	
None of these proposals/Not applicable	

Is the Investigational Device CE marked?

Yes No

If yes, please provide the information in the box below.

To what extent is the intended purpose of the device in the clinical investigation covered by the CE-mark?

CE marked device will be used outside the scope of its CE mark

CE marked device will be used within the scope of its CE mark and no additional procedures are foreseen in the clinical investigation

CE marked device will be used within the scope of its CE mark, but additional procedures are foreseen in the clinical investigation

Are those additional procedures considered to be burdensome and/or invasive?

Yes No

Please, comment why do you consider as such?

Information related to the Notified body involved, if applicable:

Notified body number:

Notified body name:

3.2 Previous clinical investigation

Has this device been investigated in a clinical investigation within the EU previously?

Yes No

If yes, please provide the relevant reference number(s) (such as SIN, CIV-ID, other reference(s)) of the previous clinical investigations

3.3 Scientific opinion/view

Has the investigational/study device been subject to a national scientific view/opinion from an Expert Panel

Yes No

3.4 Manufacturer of the investigational device

Is the manufacturer the same as the sponsor?

Yes No

If no, please fill in the requested information in section 3.4.1 and 3.4.2.

3.4.1 Manufacturer information

Organisation name:		
Address	Street name:	Street number:
	Postal code:	City:
	Country:	
Telephone number:		
Email:		

Contact person of the manufacturer

First name:
Last name:
Telephone number:
Email:

3.4.2 Authorised representative

e

Organisation name:		
Address	Street name:	Street number:
	Postal code:	City:
	Country:	
Telephone number:		
Email:		

Contact person of the authorised representative

First name:
Last name:
Telephone number:
Email:

Additional devices could be added by using a duplicated section 3, in appendix to this application form.

Section 4: Comparator

4.1 Applicability of section 4

Is there a comparator included in the clinical investigation?.

Yes No

If yes, the section from 4.2 needs to be completed.

4.2 Type of comparator

Therapy
Placebo
No treatment
Medical device

4.2.1 Medical device as comparator

Is the comparator medical device CE marked?	Yes	No
If yes, will the CE marked comparator medical device be used in the clinical investigation within the scope of its CE mark?	Yes	No
Generic denomination:		
Device trade name:	Model:	
Device name:		
European Medical Device Nomenclature :		
Medical device classification:		
Device description:		

Intended (clinical) purpose:
<p>Does the comparator device contain or incorporate medicinal substance(s)?</p> <p>Yes No</p> <p>If yes, please provide the medicinal substance(s) name(s):</p>
<p>The comparator device incorporates, as an integral part, or it is manufactured using:</p> <p> Non-viable tissues of human origin or their derivatives with an ancillary action Non-viable cells of human origin or their derivatives with an ancillary action Non-viable tissues of animal origin or their derivatives with an ancillary action Non-viable cells of animal origin or their derivatives with an ancillary action Non-viable biological substance other than those referred to in the previous points None of these proposals/Not applicable </p>

Additional comparators could be added by using a duplicated section 4, in appendix to this application form

Section 5: National information

5.1 Study site information

Please provide the list of sites taking part in the clinical investigation

Name of institution	Site address	Investigator attached to this site	Contact information of investigators

Additional sites could be added by using a duplicated section 5.1, in appendix to this application form

5.2 Ethics committee information

Select the applicable option:

Ethics committee opinion available

Ethics committee opinion under review

Ethics committee opinion is not mandatory before submission to the competent authority

If an ethics committee has to be selected by the sponsor before submission, please provide the ethics committee information's below.

Organisation name:

Address	Street name:	Street number:
	Postal code:	City:
	Country:	

Telephone number:

Email:

5.3 Status of the clinical investigation

Is the sponsor considered as commercial according to national legislation?

Yes

No

5.4 Expected number of subjects recruited within the Member State

How many subjects are expected to be recruited into the study in the Member State you are applying to?

I hereby certify that the information and documentation submitted with this notification is correct in detail and all the information requested has been supplied. The investigated (medical) device complies with the applicable general safety and performance requirements, apart from those covered by the investigation and that every precaution has been taken to protect the health and safety of the patient and/or user.

I confirm that all the clinical investigations information collected for this application, has been done in compliance with the European data protection legislation (GDPR).

Name:

Position: