HEU EFS
HARMONISED APPROACH TO EARLY FEASIBILITY STUDIES FOR MEDICAL DEVICES IN THE EUROPEAN UNION

Harmonised approach to **E**arly **F**easibility **S**tudies for Medical Devices in the **E**uropean **U**nion **(HEU-EFS)**

WP5 Program monitoring system

DELIVERABLE 5.1

Assessing the Performance of Early Feasibility Studies in the EU – Annex VII - Application form

COCIR efpia EuropaBio MedTech Europe Vaccines Europe

Co-funded by the European Union

Disclaimer:

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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:	Australia	
Telephone number:			
Email:			

Contact person of the sponsor

First name:
Last name:
Telephone number:
Email:
☑ Check the box if the sponsor qualifies as a Small or Medium-sized Enterprise (SME) (according to the European Commission definition set out in Recommendation 2003/361/EC).

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:	Belgium	
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:	Belgium	

1.3 Clinical investigation type

Select the appropriate regulatory pathway for the application :

◯ Clinical investigation application (MDR Art. 62(1))

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

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

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

Austria
Belgium
Bulgaria
Croatia
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Iceland
Ireland
Italy
Latvia

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.

○ Yes ○ No

2.2 Design of the clinical investigation

○ Exploratory investigation ○ Confirmatory investigation

○ Observational investigation

☐ First in human investigation ☒ Not first in human

☒ Early Feasibility Study ☐ Traditional Feasibility Study

2.3 Design methodology

☐ Case Control ☐ Controlled ☐ Cross-sectional ☐ Double blind

☐ Parallel ☐ Randomised ☐ Open

☐ Other:

2.4 Development stage

○ Pilot stage ○ Pivotal stage ○ Post-market stage

Patients or patient associations involvement

Were patients or patient associations involved in the design of the clinical investigation?

◉ Yes ○ No

If yes, please briefly describe their role:

2.5 Objectives and endpoints

Primary objective(s):
Secondary objective(s):
Other objective(s):
Primary endpoint(s):

Secondary endpoint(s):
Other endpoint(s):
Use of Patient-Reported Measure(s): ☐ Patient-Reported Outcome Measures (PROMs) ☐ Patient-Reported Experience Measures (PREMs) ☐ Other:

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: [ ]
Total planned number of subjects: [ ]

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

- Circulatory system: cardiovascular / lymphatic
- Endocrinology and diabetes
- Gastroenterology & hepatology
- General and plastic surgery, dentistry
- Nephrology & urology
- Neurology
- Obstetrics & gynaecology including reproductive
- Opthalmology
- Orthopaedics, traumatology, rehabilitation,
- Other
- Respiratory, anaesthesiology, intensive care

2.9.3 Gender of subjects

☐ Female ☐ Male ☐ Other

2.9.4 Inclusion criteria

2.9.5 Exclusion criteria

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: Australia	
Telephone number:		
Email:		

Section 3: Investigational device(s)

3.1 Investigational medical device

3.1.1 Device purposes

Alleviation of an injury or disability
Alleviation of disease
Compensation for an injury or disability
Devices for the control or support of conception
Diagnosis of an injury or disability
Diagnosis of disease
Investigation of the anatomy or of a physiological or pathological process or state
Monitoring of an injury or disability Monitoring of an injury or disability
Monitoring of disease
No medical purpose, but device belongs to a group of devices listed in MDR Annex XVI
Prediction of disease
Prevention of disease
Products specially intended for the cleaning, disinfection or sterilisation of devices
Prognosis of disease
Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations
Replacement or modification of the anatomy or of a physiological or pathological process or state
Treatment of an injury or disability
Treatment of disease

3.1.2 Device type

- ☐ Implantable
- ☐ System
- ☐ Active device
- ☐ Non-medical purpose
- ☐ Measuring function
- ☐ Sterile
- ☐ Reusable surgical instrument
- ☐ Software
- ☐ Intended to administer or remove medicinal substance

3.1.3 Invasiness

Is it an invasive medical device?

◯ Yes ◯ No

3.1.4 Device Identifiers

Generic denomination:

Device trade name: Model:

Device name:

European Medical Device nomenclature

Medical device classification: Class I / Class IIA / Class IIB / Class III

Classification rule:

Rule 13 - All other active devices
Rule 14 - Devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product
Rule 15 - Devices used for contraception or prevention of sexually transmitted diseases
Rule 16 - Specific disinfecting, sterilising, cleaning, rinsing devices or hydrating contact lenses
Rule 17 - Devices intended for recording diagnostic images generated by X-ray
Rule 18 - Devices utilising tissues or celles of human or animal origin or their derivatives
Rule 19 - Devices incorporating or consisting of nanomaterial
Rule 20 - Invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation

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 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: Belgium	
Telephone number:		
Email:		

Contact person of the manufacturer

First name:
Last name:
Telephone number:
Email:

3.4.2 Authorised representative

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

Class I
Class IIA
Class IIB
Class III

Device description:

Intended (clinical) purpose:

Does the comparator device contain or incorporate medicinal substance(s)?

◯ Yes ◯ No

If yes, please provide the medicinal substance(s) name(s):

The comparator 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

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: Belgium	
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 application/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:

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