

HEU-EFS Harmonised approach to Early Feasibility Studies for Medical Devices in the European Union

Progress and preliminary results

Giuditta Callea (PI | Bocconi University)

MDCG Clinical Investigation and Evaluation Working Group | 15 November 2024

Agenda

1

Progress of the project

2

Preview of upcoming deliverables results

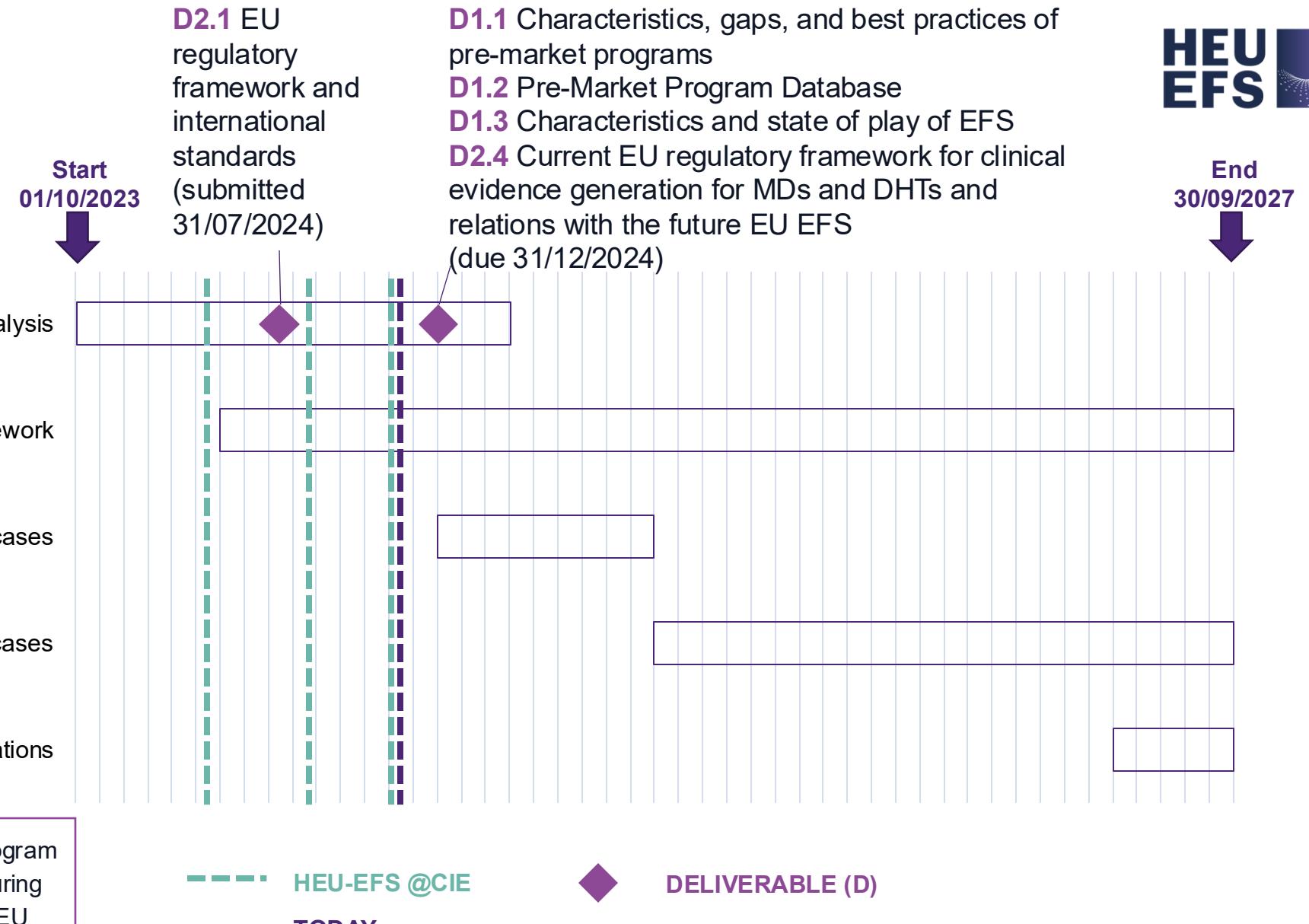
3

What's next

4

Q&A

Progress of the project



Pre-Market Approval Pathways



AIM

Understand the characteristics of pre-market clinical investigations for MDs approval pathways in 56 selected countries.



Created with mapchart.net

METHODOLOGY

- 1 Design Pre-Market Approval Pathways DB (PMAP-DB)
- 2 Data collection from public sources and compilation of the DB
- 3 Validation
 - By NCA for EU & EEA (13 out of 30)
 - Additional validations are welcome
 - By HEU-EFS partners for non-EU (26/26)
- 4 Analyses
- 5 Discussion of results and recommendations
- 6 Scientific paper: NCAs are invited to be coauthors

We want to sincerely thank DG SANTE and CIE members for their contribution to the research

Pre-Market Approval Pathways



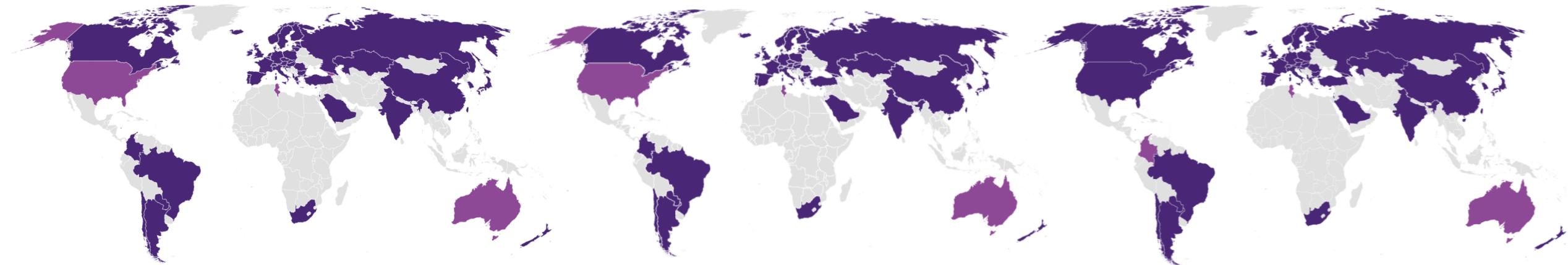
Mandatory documents accompanying the application for clinical investigation

- Yes, mandatory
- Yes, optional, No, or n/a

Application form (n=52)

Investigator's Brochure (n=54)

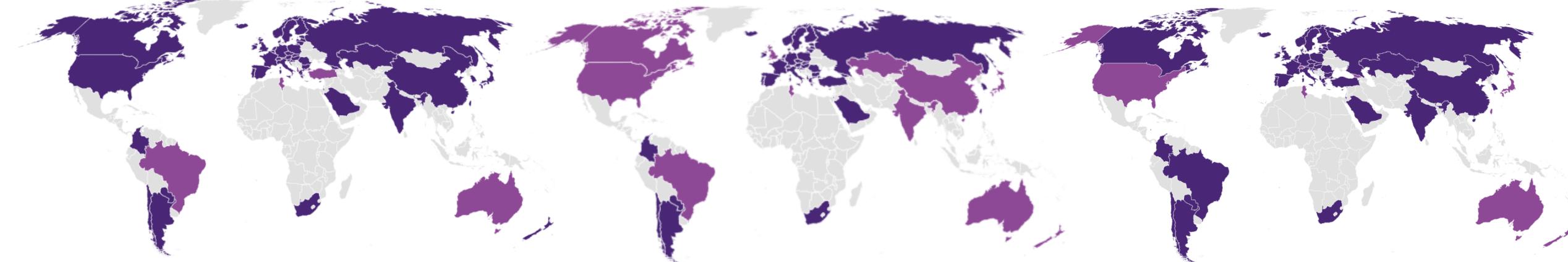
Clinical Investigation Plan (n=53)



Informed Consent Form (n=50)

Proof of insurance cover (n=44)

Copy of ethics committee opinion (n=47)

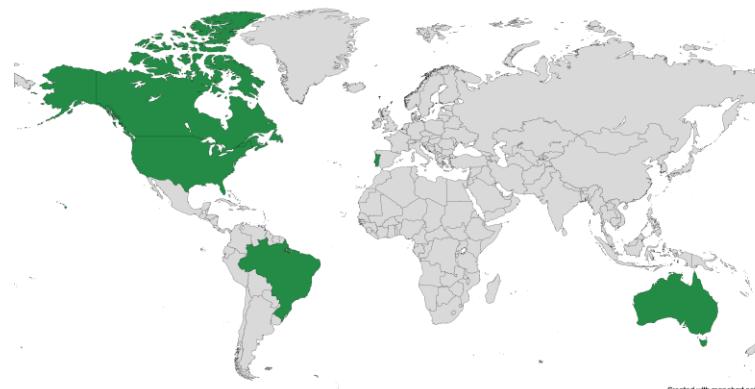


Pre-Market Approval Pathways

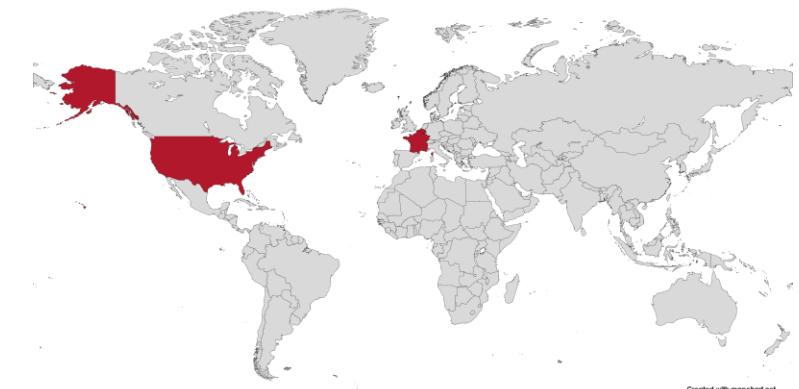
Existence of public database of pre-market CI of MD (n=15)



Existence of performance monitoring system of pre-market CI of MD (n=5)



Possibility to reimburse investigational devices (n=3)



APAC Australia, New Zealand, Japan, Republic of Korea, Taiwan

EMEA Israel, Russia (only approved studies), Kazakhstan

EU Croatia,* Germany,* Netherlands, Czechia

LATAM Argentina, Brazil, Paraguay

* Not validated

APAC Australia

EU Portugal

LATAM Brazil

NAFTA Canada (only for trade association), USA

EU France, Belgium

NAFTA USA

Challenges of pre-market CI of MDs in Europe

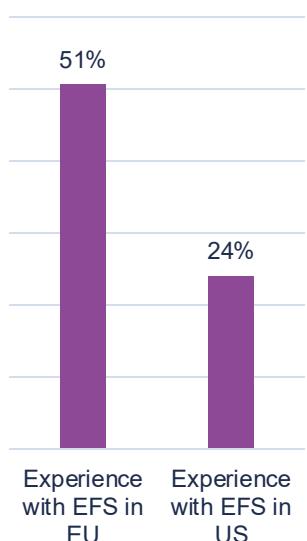
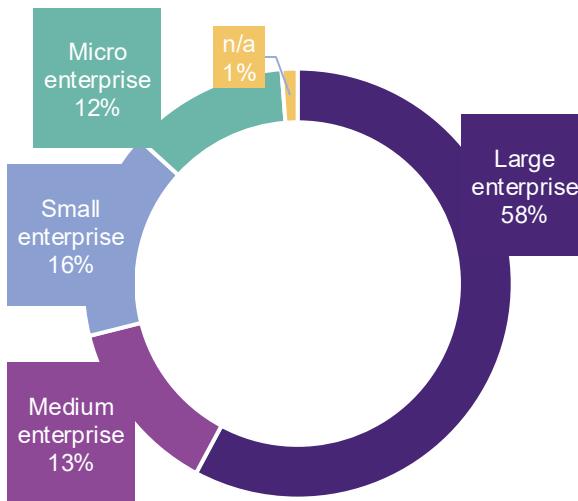
FOCUS

- Challenges of planning and conducting pre-market CI of MDs in the pilot phase in Europe

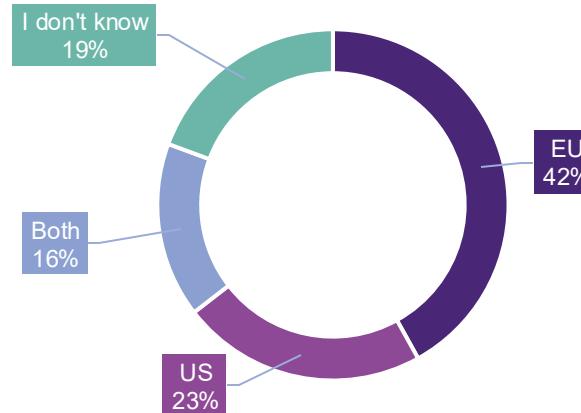
METHODOLOGY

- Anonymous, online survey implemented on Qualtrics, open from 18 Oct-11 Nov 2024
- Approved by Bocconi University Ethics Committee
- Distributed through HEU-EFS website, social media and consortium, and trade associations

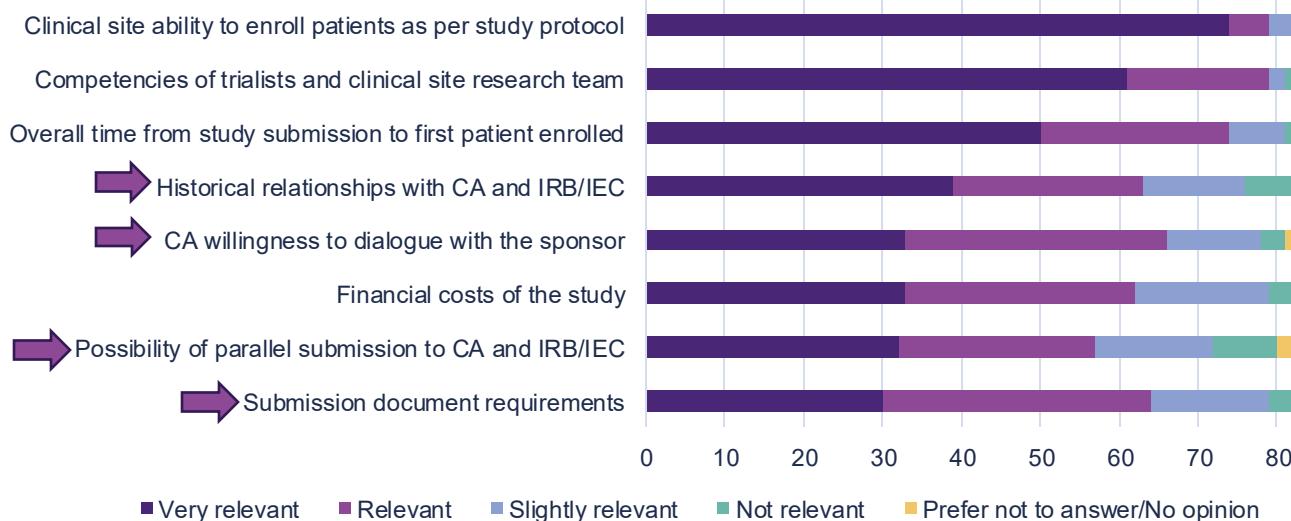
The sample (n=83)



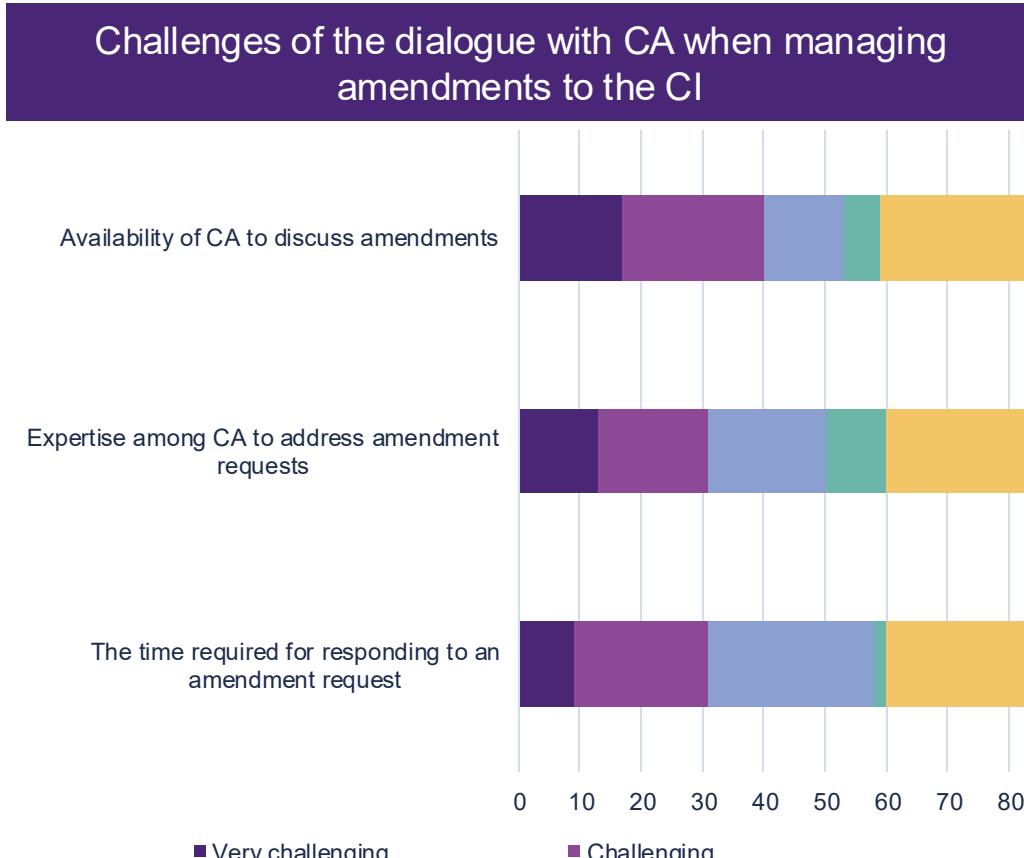
Favourite location for conducting pilot CI



Key criteria influencing the selection of the country



Challenges in pre-market CI of MDs in Europe



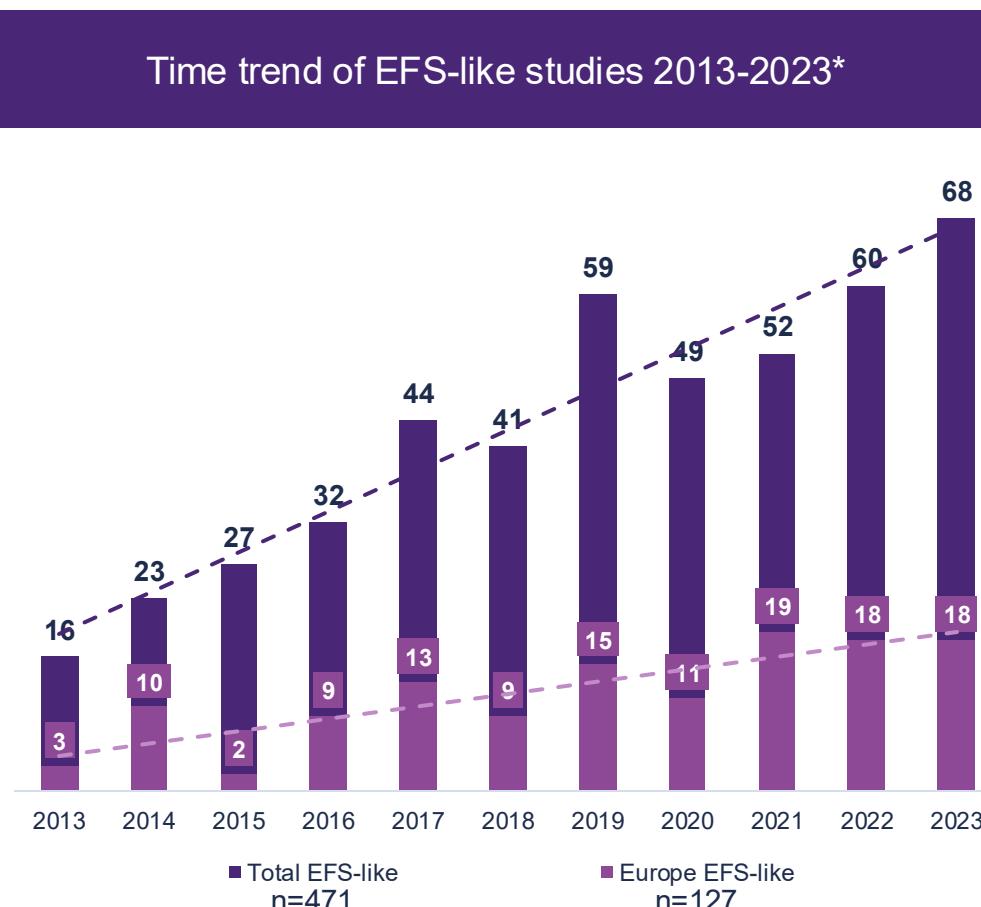
Diffusion of EFS-like studies

«EFS-LIKE» IDENTIFICATION STRATEGY IN CLINICALTRIALS.GOV

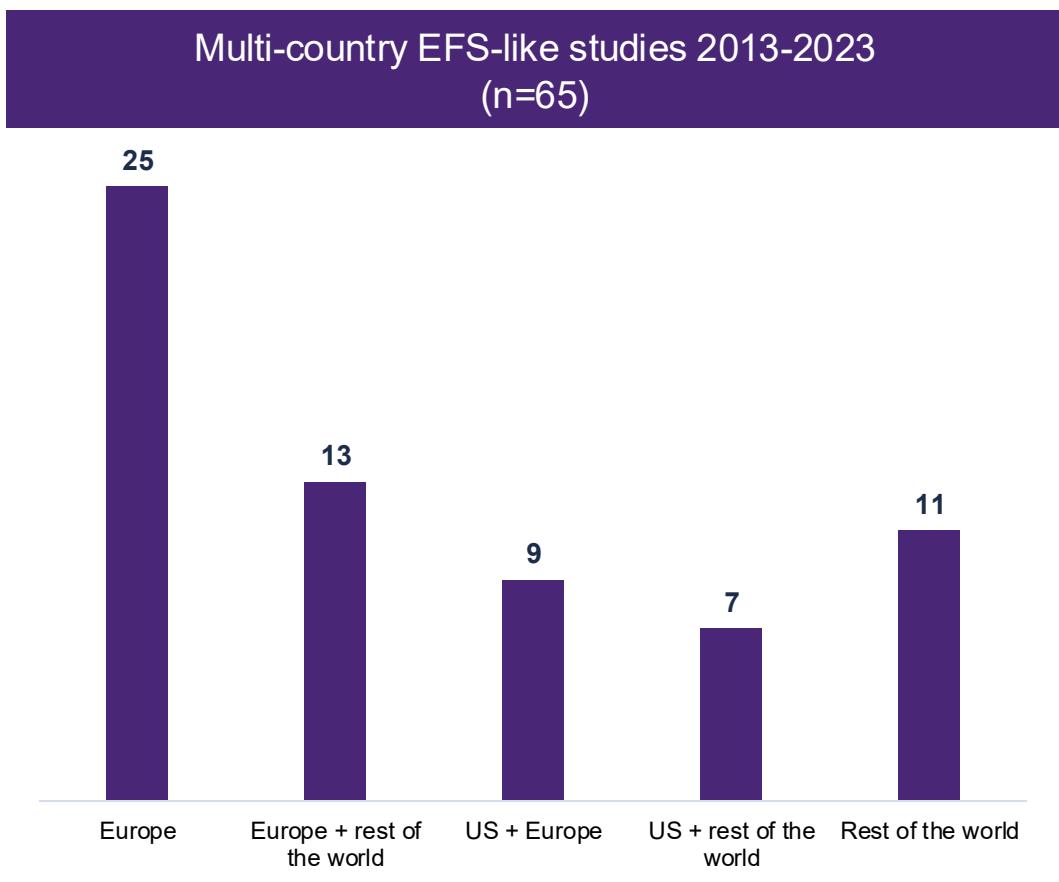
- «early feasibility» or «EFS» in title or summary of the study
OR
- Study type: **Interventional** AND Estimated sample size ≤ 30 AND
Interventional mode: **single group assignment** AND Masking:
None (Open label)



Time trend of EFS-like studies 2013-2023*



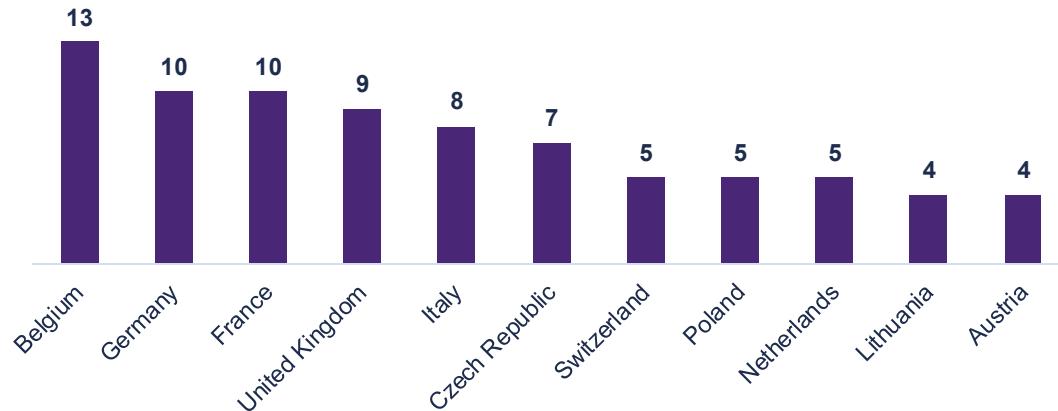
Multi-country EFS-like studies 2013-2023
(n=65)



*Start year of the study

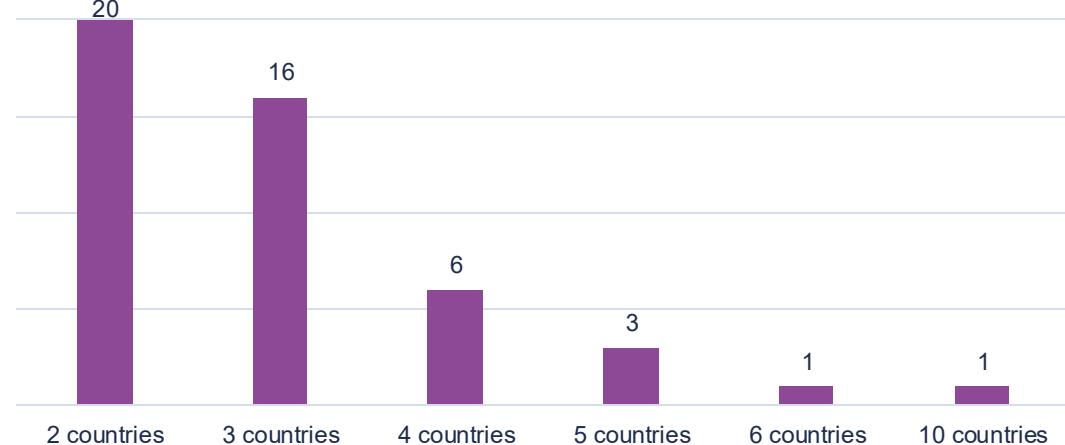
European multi-country EFS-like studies

Multi-country studies* by country

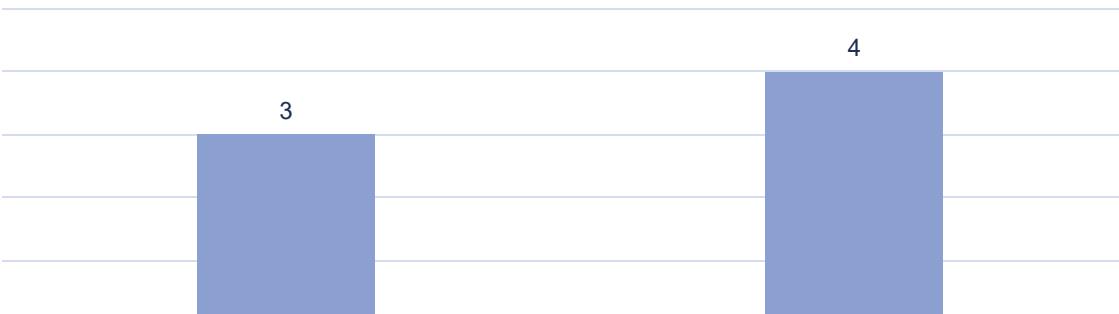


*Multi-country studies are counted in all countries

Number of collaborating countries per study

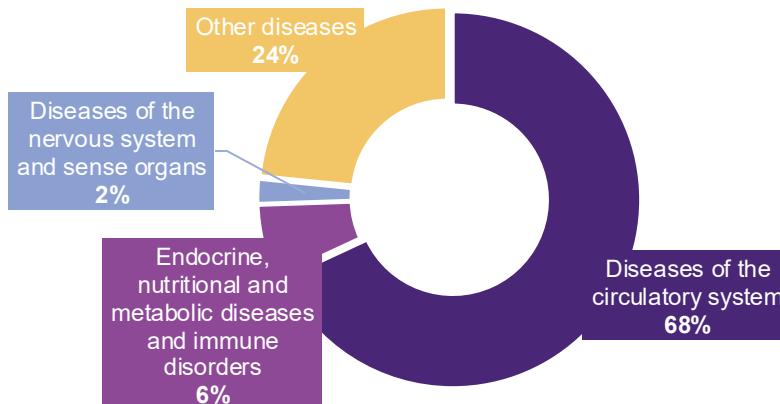


Most common collaborations among European countries



BE - LT; DE - IT;
DE - UK; ES - IL;
FR - NL; FR - UK;
IT - CH; IT - UK;
NL - US; UK - US

EFS-like conditions (ICD-10 classification)



Survey for National Competent Authorities



AIM

- Explore
 - NCAs experiences with pre-market exploratory clinical investigations (CIs) of MDs at the pilot stage (first-in-human, early feasibility, and traditional feasibility CIs)
 - Resources and training needs related to the assessment of CI applications to conduct pre-market clinical investigations

ETHICS APPROVAL

- Survey and informed consent already approved by Bocconi University Ethics Committee, under evaluation by Trinity College Dublin Ethics Committee

SURVEY

- Online survey implemented on Qualtrics platform
- Time required for completion: 15 minutes
- 28 questions
 - Validation by NCA of Ireland, Italy, and Portugal (members of HEU-EFS Advisory Board)
- Participation is entirely voluntary. You can provide the information you are comfortable with
 - Each question has a “Prefer not to answer/No opinion” option
- Informed consent and link to the survey distributed by DG SANTE

Survey for National Competent Authorities



ELABORATION OF INFORMATION

- All information collected in the survey will be kept confidential, in accordance with applicable laws
- Responses will be anonymized
- Results will be analysed in aggregate, ensuring that individual responses cannot be traced back to you
- Data will be stored securely and will be accessible only to the research team

USE OF THE RESULTS

- Results will be included in a confidential report for NCAs and a scientific deliverable
 - Level of disclosure to be discussed with NCAs
- Results will be shared only after presentation @CIE and validation by NCAs

NEXT STEPS

- 1 Bocconi University shares survey (pdf) and informed consent through DG SANTE 7 days after TCD ethics approval (second half of November)
- 2 NCAs send the signed informed consent to Tom Melvin
- 3 Link to online survey shared through DG SANTE
- 4 Survey open for 2-3 weeks
- 5 Half day virtual meeting with NCAs for discussion of results in mid January (doodle will be circulated)
- 6 Preparation of report and deliverable
- 7 Reviews and comments by NCAs
- 8 Submission of outputs

Contacts



Giuditta Callea

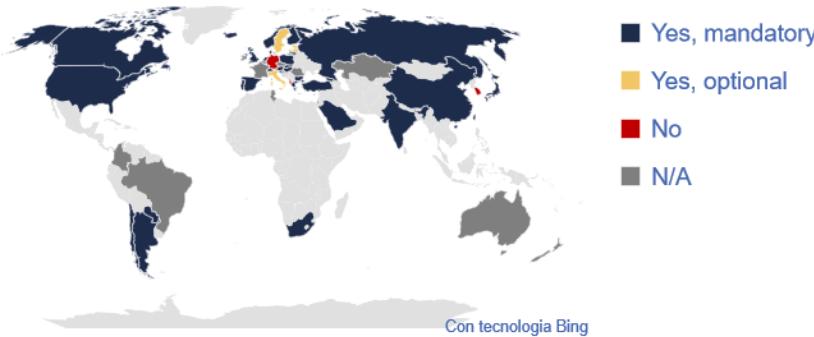
Associate Professor of Practice

SDA Bocconi School of Management – Bocconi University

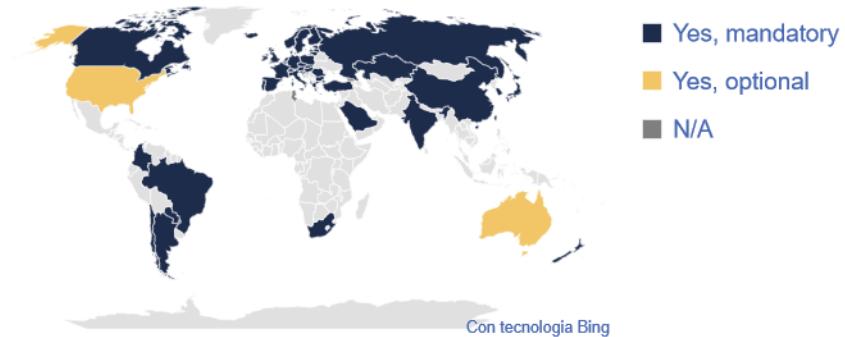
<mailto:giuditta.callea@unibocconi.it>

Documents accompanying the application for clinical investigation

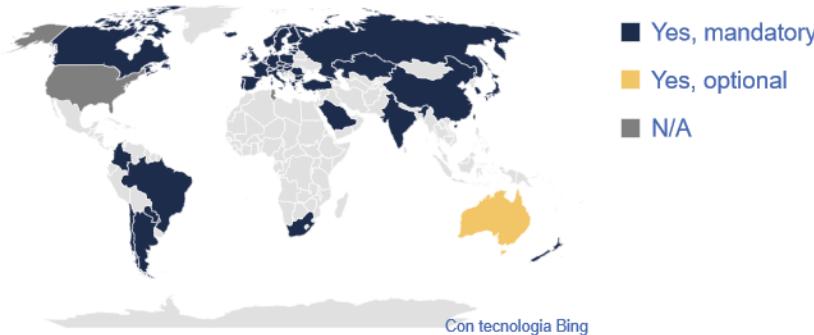
Cover letter



Application form



Investigator's Brochure (IB)

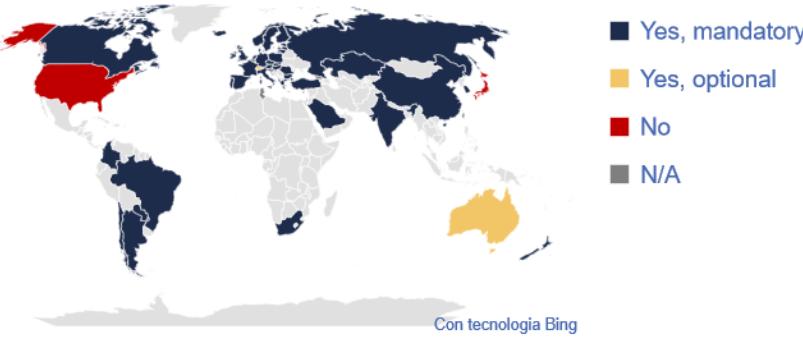


Clinical Investigation Plan (CIP)

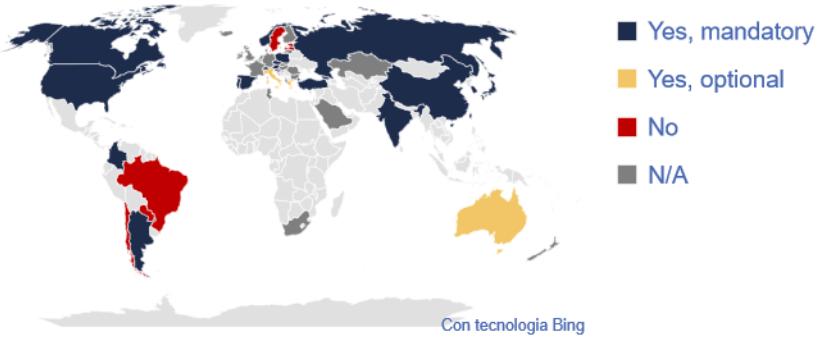


Documents accompanying the application for clinical investigation

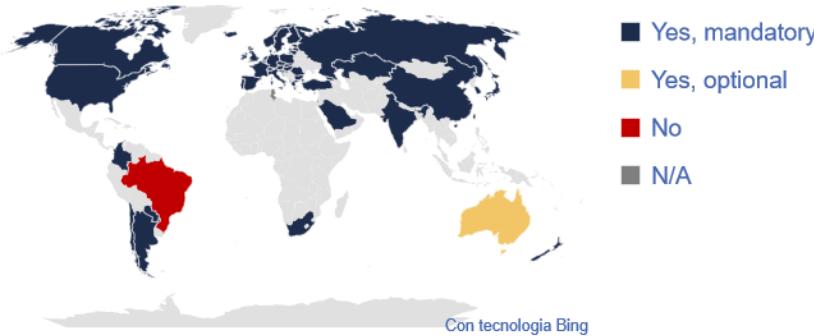
Copy of the opinion of the ethics committee



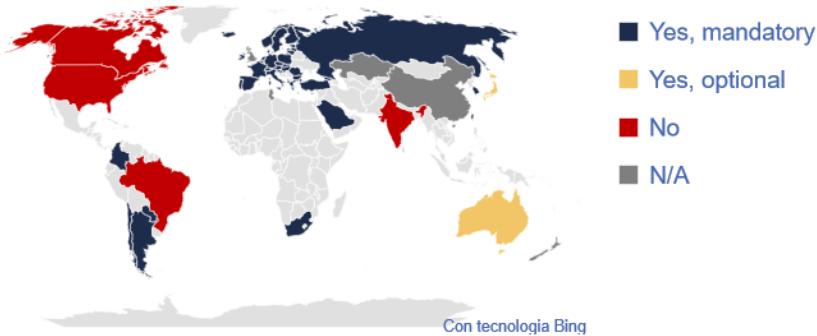
Case Report Form (CRF)



Informed Consent Form (ICF)

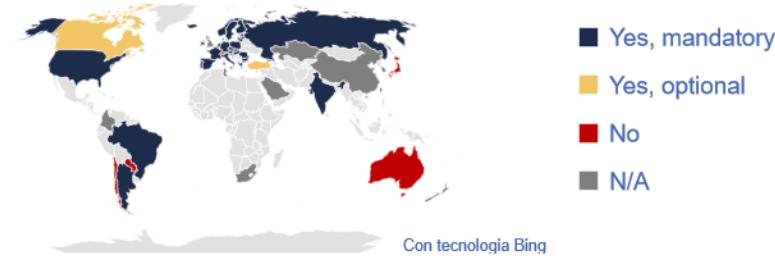


Proof of insurance cover

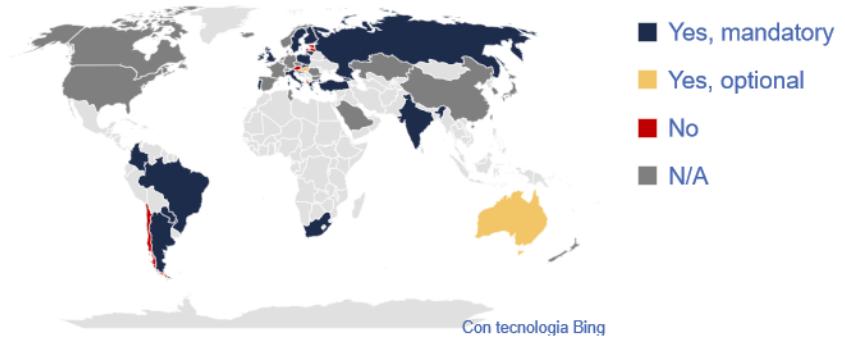


Documents accompanying the application for clinical investigation

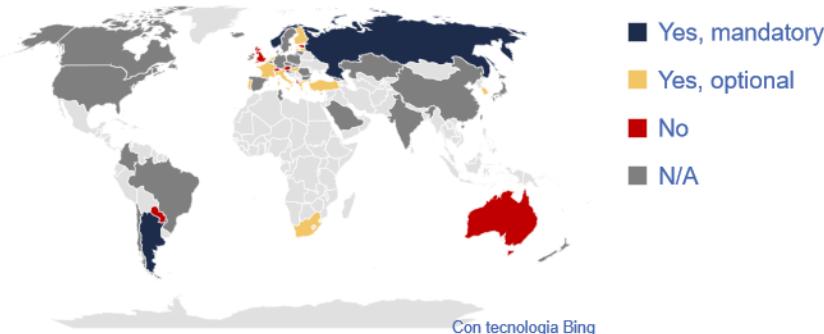
Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data and information



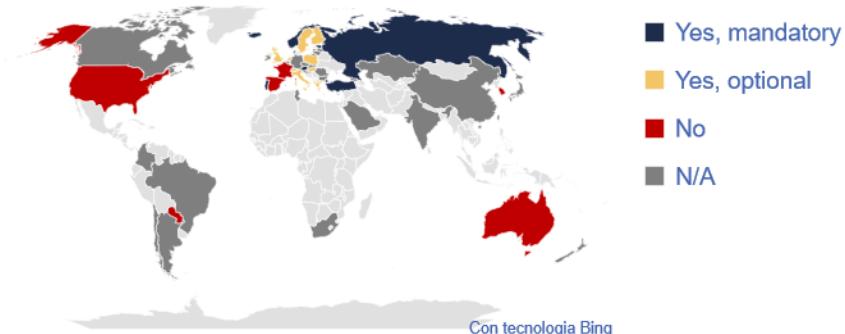
Proof of payment of the fee



Opinion of expert panels

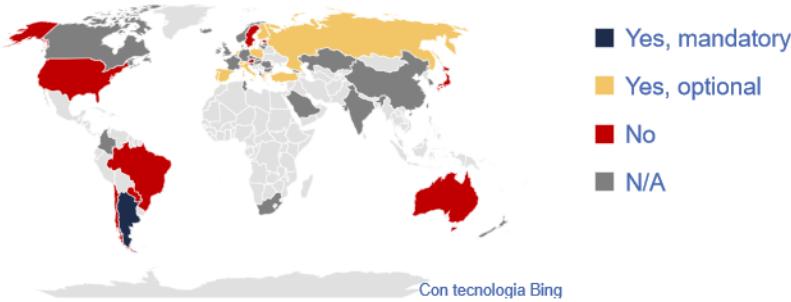


Notified Bodies CE certificates

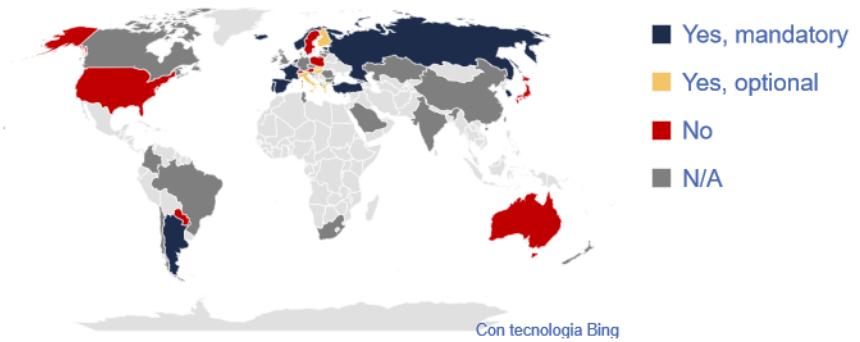


Documents accompanying the application for clinical investigation

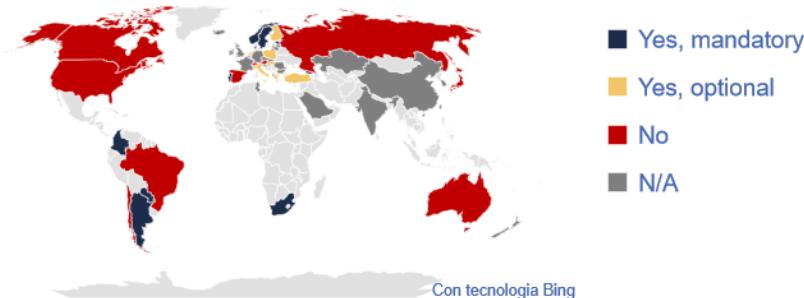
Decisions of other Competent Authorities concerned



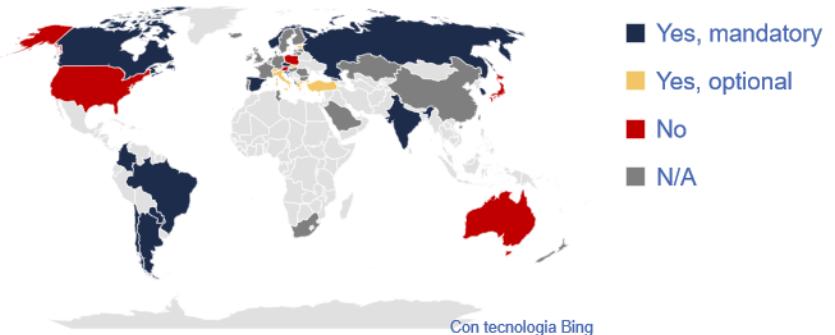
Post Market Clinical Follow-up (PMCF) plan



Recruitment procedures and advertising materials



Opinion of other Ethics Committees concerned

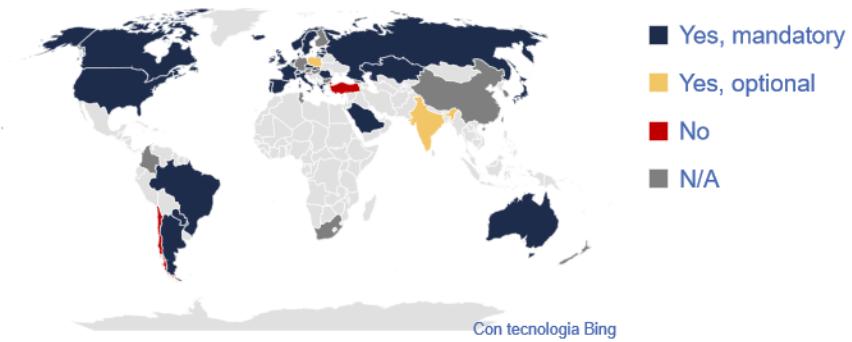


Documents accompanying the application for clinical investigation

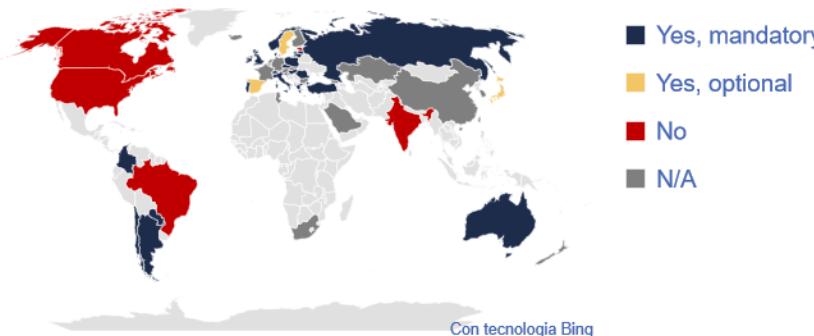
General Device Information



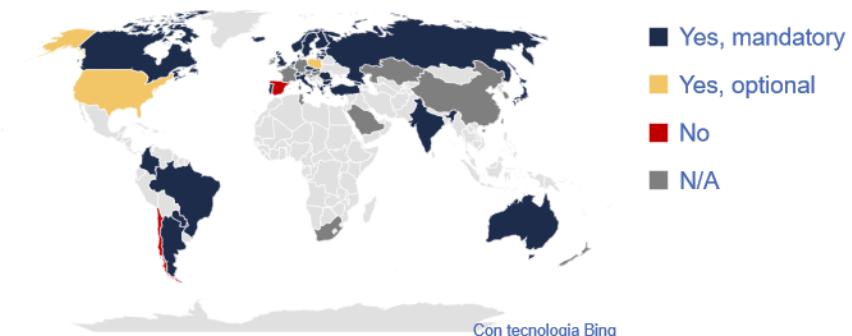
Medicinal products contained in the device



List of participating countries

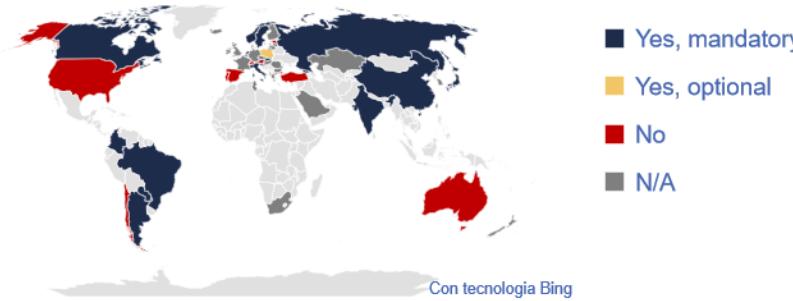


Trial centres list

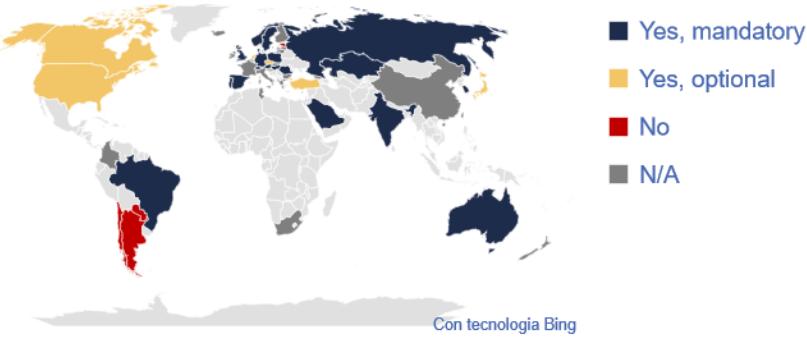


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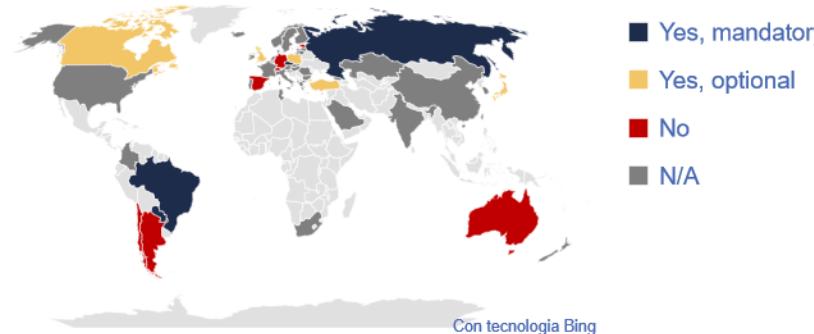
Declaration of possession of requirements for trial centres



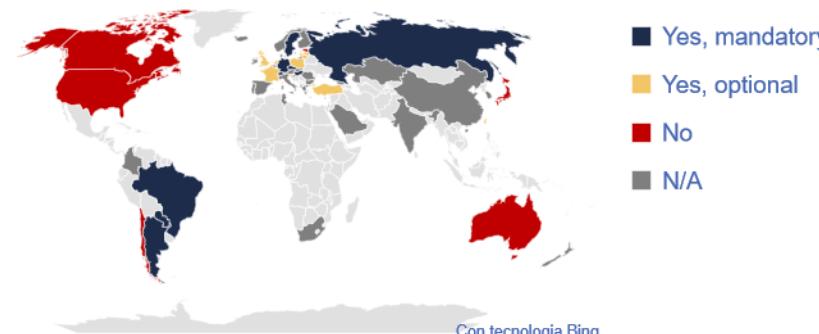
Compliance to ISO 14155



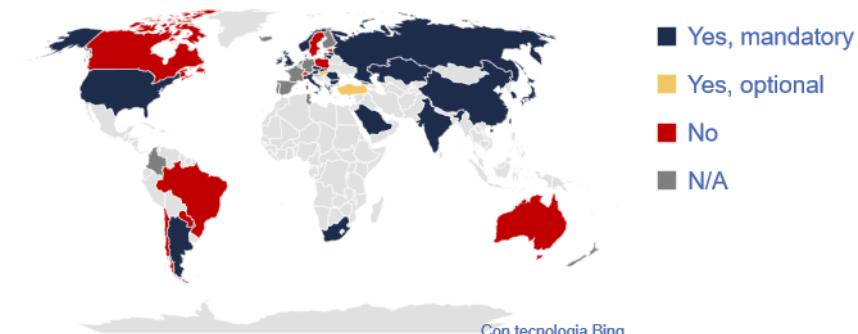
MRI checklist



Ionising radiation information



Serious Adverse Event (SAE) Report Form





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Thank you! Questions?

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