HM Hospitales Medical Research Ethics Committee

HM hospitales Medical Research Ethics Committee (CEIm) acts independently to ensure compliance with regulations and to prioritize the safety and well-being of patients participating in clinical trials
In order to carry out its activity, CEIm has Internal Operating Rules, pursuant to Spanish regulations, which detail, among other aspects, the documentation to be submitted to request the evaluation of a study or a modification of a trial.

Members:

The CEIM is composed according to the Good Clinical Practice Normative (CPMP/ICH/135/95) and the Royal Decree 1090/2015.

Chair
Dr. Alfonso Moreno González, Medical Doctor Specialized in Clinical Pharmacologist.

ViceChair
Dr. Santiago Ruiz de Aguiar, Medical Doctor Specialized in Clinical Pharmacologist Medical Director at Hospital Universitario HM Puerta del Sur.

Thecnical and Administrative Secretary
Dra. Almudena Lage Moreda. Head Technical Secretary. Medical Doctor, Surgery and Medical Degree
Dña. Raquel Alcántara Partido. Assistant Technical Secretary, Pharmacy Degree
Dña Carmen Lastras Menayo. Administrative Secretary

Members
Dra. María José Ferreiro, Medical doctor Specialized in Pneumology. Member of CEAS of HM Hospitales, Master in Bioethics
Dr. José Felipe Varona Arche, Medical Doctor Specialized in Internal Medicine. Hospital Universitario HM Monteprinicipe. Clinical Practice
Dr. Eduardo García Rico Fernández, Medical Doctor Specialized in Oncology, Hospital Universirario HM Torrelodones. Clinical Practice
Dr. Miguel Ángel Reina, Hospital Universitario HM Monteprincipe. Medical Doctor Specialized in Anesthesiology and Reanimation. Clinical Practice
D. Juan Carpio Jovani, Nursing Degree. HM Investigation Commission Member
Dra. Elena Sevillano, Medical Doctor Specialized in Oncology, Hospital Universirario HM Sanchinarro. Clinical Practice
Dr. Cesar G. Muñoz Sánchez-Miguel, Medical Doctor Specialized in Oncology, Hospital Universirario HM Sanchinarro. Clinical Practice
Dr. Jordi Remón Masp, Medical Doctor Specialized in Oncology, Hospital Universirario HM Delfos, Barcelona. Clinical Practice

Dña. María Ortiz, Pharmacy Degree, Specialized in Hospital Pharmacy
Dña Maria Teresa Curiel, Medical Doctor Specialized in Oncology, Hospital Universirario HM La Esperanza. Clinical Practice
Dña. María Teresa Espina Castrillo, Law Degree, Legal department at HM Hospitales and Vicepresident of CEAS at HM Hospitales
D. Ignacio García Gómez. Law Degree. Independent member. Patient Representative
Dña. Ofelia de Lorenzo, Law Degree, member of CEAS at HM Hospitales. Independent member
Dña. Gema Jiménez Jiménez, Law Degree, Fundación de Investigación HM Hospitales
Dña Noelia Perez Dominguez. Pharmacy Degree, Specialized in Primary Care
Dña. Estrella Blanco Patiño, Law Degree, Delegate of Data Protection

Contact information:

For any information you need you can contact:

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Dña. Raquel Alcántara Partido. Assistant Techincal Secretary
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Meetings and deadlines

The meetings take place twice a month, on Wednesdays
In order to complain the mandatory RD deadlines, we hold a third meeting if applicable

YEAR 2020	Day	Day
January	**15th**	**29th**
February	**12th**	**26th**

March	**11th**	**25th**
April	**15th**	**29th**
May	**13th**	**26th**
Jun	**10th**	**24th**
July	**8th**	**22nd and 29th***
September	**2nd* and 9th**	**23rd**
October	**6th**	**20th**
November	**4th**	**18th**
December	**2nd**	**16th**

*We will confirm the meeting in case we have to review either allegations or urgent documentation. The meeting will take place if we keep to the required quorum

Evaluation and approvals deadlines

Once we have received the complete package, and completed the validation process, we will review the documentation in the upcoming meeting

Submission package

1. Clinical trials with Investigational Medicinal Product / Medical Devices

1.1 Initial submission

Prior to filing the submission by ECM portal, a Cover Letter must be sent by email to CEIm. The Cover Letter must include

- Reason why you have requested
- Title, EudraCT, Code, Sponsor.
- A list with the documentation that you will file.
- A list with the name of the Principal Investigators, departments and sites involved in the clinical trial
- Contact information (from the person who applied)
- The documentation must be uploaded at ECM platform. It is important that every file expresses clearly what it is. Otherwise, we will request an email with the documentation.

Documentation Part I: It must be submitted to AEMPS and CEIm at the same time

- Cover letter (see above)

- Clinical Trial Application Form
- Authorization of the sponsor granted to the applicant (if applicable)
- Authorization of the promoter or manufacturer prior clinical trial product if Cross Reference to PEI.
- Study protocol synopsis.
- Study protocol.
- Investigator's Brochure, Investigational Medicinal Product and auxiliaries
- Pediatric Investigation Plan, Scientific Advice (if applicable)
- Benefit-risk assessment

The Part I documentation may be submitted in English, however the text free boxes on the CTA have to be in Spanish as well as in English.

Documentation Part II: To be submitted only to CEIm

- Cover Letter (see above)
- Recruitment and Informed Consent Procedure
- Informed Consent Form
- Investigator's Suitability
- Investigator's CV and declaration of interest. GCP
- Site and Facilities Suitability
- Insurance certificate.
- Study Budget
- Fees Payment proof, invoice request or documentation to waiver

Sponsor data Protection Commitment: It is not mandatory as an independent document. It can be in the confidentiality section of the ICF where the Sponsor commits complying with Spanish law on data protection.

The patient document's Part II, such as ICF, must be written in Spanish. Nevertheless, if the ICF is in a different language than Spanish, a certified translation must be submitted by Sponsor.

At HM Hospitales' site, the patients can exercise their rights through Principal Investigator
At HM Hospitales' site, the Facilities Suitability must be signed by either Foundation HM Hospitales director or HM Hospitales Subdirector.

For **Medical Devices** clinical trials, the documentation must be sent through email.

1.2 Substantial Amendments

Prior to filing the submission by ECM portal, a cover letter must be sent by email to CEIm. The Cover Letter must include

- Amendment number and date
- Affected part, if the amendment concerns Part I, II or both
- Cause and reason of the amendment.
- List of the documentation included, classified by Part I and Part II
- List of Principal investigators and sites.

Documentation

- Cover letter (see above).
- Substantial Amendment Notification Form.
- Final version and version with tracked changes of every amendment document.
- Reason of the modifications.
- Document that includes the summary of changes (Protocol and IB only).
- Principal investigator agreement.
- Fees Payment proof, invoice request or documentation to waiver.

If the clinical trial title changed, the new one must be clearly identified in the cover letter as well as in all the documents submitted.

Principal investigator amendment:

- Cover letter. It must include a complete list of the clinical sites and investigators.
- An updated Investigator Suitability (New version).
- CV, GCP and Conflict of interest of the new investigator.
- Insurance certificate updated with the new PI.
- Fees Payment proof, invoice request or documentation to waiver.

New site amendment:

- Cover letter. It must include a complete list of the clinical sites and investigators.
- An updated Investigator Suitability (New Version).
- CV, GCP and Conflict of interest of the new principal investigator.
- Site Suitability.
- Insurance updated with the new PI and site.
- Fees Payment proof, invoice request or documentation to waiver.

The documentation must be uploaded at ECM platform. It is important that every file expresses clearly what it is. Otherwise, we will request an email with the documentation.

For medical devices submission, the documentation must be sent to us by email.

1.3 Responses to Clarification Requests.

A Cover Letter must be sent by email to CEIm. The Cover Letter must include

- Reason why you have submitted
- Title, EudraCT, Code, Sponsor.
- A list with the documentation that you will file. (Part I, Part II or both)

Documentation:

- Cover letter mentioned above.
- Document of responses.
- Modified Documentation. Final Version and version with tracked changes.

The files must be uploaded at ECM portal. It is important that every file expresses clearly what it is. Otherwise, we will request an email with the documentation.

For **Substantial Amendments** and Medical Devices clarifications, the documentation must be sent to us by email

2. Post Authorization Studies (EPAs) with medicines

A Cover Letter must be sent by email to CEIm. The Cover Letter must include title, sponsor, code, Principal Investigator and site. It also must contain a list of the documentation included in the submission package. In addition, the submission packet must include:

- Cover letter (Mentioned above)
- Study protocol
- ICF
- Study budget.
- Commitment of Investigator
- AEMPs classification
- Fees Payment proof, invoice request or documentation to waiver
- Approval Letter from other CEI, if applicable

3. Investigational projects

A Cover Letter must be sent by email to CEIm. The Cover Letter must include title, sponsor, code, Principal Investigator and site. It also must contain a list of the documentation included in the submission package (see Foundation cover Letter HM template). In addition, the submission packet must include:

- Cover letter (Mentioned above)
- Study protocol
- ICF
- Study insurance (if applicable)
- Study budget
- Any other document which would be necessary for approval
- Fees Payment proof, invoice request or documentation to waiver

4. Responses to Clarification Requests (point 2 and 3):

A Cover Letter must be sent by email to CEIm. The Cover Letter must include
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- Cover letter

- Document of responses.
- Modified Documentation. Final version and version with tracked changes.

Clinical trials follow up

Since the approval letter has been sent to the sponsor, the annual progress report must be sent to the secretary. For clinical trials point 1, Addenda XI of AEMPS must be used. For the rest of the studies, there is no template, but Addenda XI can be used as a model if necessary.

Fees

Fees must be requested by email to secretariaceic@mail.hmhospitales.com, cc to Ana Laguia (alaguia@hmhospitales.com) indicating the following project information clearly

- Title
- Code
- EudracT (if applicable)
- Number sites
- Principal investigator
- Reason why you have requested: New Clinical Trial Substantial Amendment, Medical Device, EPA
- Substantial modification # (if applicable)
- Tax data and any other relevant information must be included in the same email (e.g. purchase order)

2020 Fees

Clinical Trial	Initial submission	Amendment
From 1 to 5 sites	2.684,00 € + VAT	777 € + VAT
From 6 to 10 sites	3.199,00 € + VAT	929 € + VAT
11 or more sites	3.714,00 € + VAT	1.139,00 € +VAT

Post Authorization Studies fees: 2.684 € + VAT

There are no fees for projects which Sponsor is the Principal Investigator.

Either way, if you apply for fees exemption, you must email the document of exemption of fees

Agreement management, Contact

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