Terms and Conditions for the Accreditation of Imaging live educational events (LEE), e-learning materials (ELM) and blended learning (BLD)

*This Terms and Conditions, mirror the latest version of the EACCME requirements

I. INTRODUCTION

I.1. AGREEMENTS WITH EUROPEAN AND NON-EUROPEAN ACCREDITATION BODIES

Europe

The EACCME® has signed agreements with the majority of European countries. For a full and updated list of signed agreements in Europe please visit https://eaccme.uems.eu.

The countries with which the EACCME® has signed agreements will recognise EACCME® credits.

All the other countries may recognise EACCME® credits on a voluntary basis. For these countries you will also need to apply to the central or relevant regional accreditation authority.

USA

The UEMS-EACCME® has had an agreement of mutual recognition of credits with the American Medical Association (AMA) for live educational events and for e-learning materials and blended learning since the year 2000.

The issue of territoriality is very important; both organizations are fully responsible for the activities taking place or organized within their remit. The UEMS-EACCME® is the central body for accrediting events in Europe and the AMA is the central body for recognition of CME credits in the USA.

E-learning activities need to be certified for credit by the process in place where the CME/CPD provider is based, i.e., AMA PRA Category 1 Credit™ for U.S. CME/CPD providers and ECMEC® credit for organizations in countries that are represented by the UEMS.

Canada

The UEMS-EACCME® has an agreement of mutual recognition of credits with the Royal College of Physicians and Surgeons of Canada (RCPSC) for live educational events since the year 2011.

The issue of territoriality is very important; both organizations are fully responsible for the activities taking place or organized within their remit. The UEMS-EACCME® is the central body for accrediting live educational events in Europe and the RCPSC is the central body for accrediting live educational events in Canada through its accredited providers.

CONFEMEL (Confederación Médica Latinoiberoamericana y del Caribe)

CONFEMEL is the organization that represents and is made up of all the titular medical institutions with national representation, the founding institutions and the adherents of the countries of Latin America and the Caribbean.
The countries of Latin America and the Caribbean within the scope of the agreement between UEMS-EACCME®, CONFEMEL and CGCOM-SEAFORMEC will be divided by regions for the operation of CONFEMEL, being the same: Andean Region: Bolivia, Colombia, Ecuador, Peru and Venezuela; Central American and Caribbean Region: Costa Rica, Guatemala, Haiti, Honduras, El Salvador, Mexico, Dominican Republic, Nicaragua, Panama and Puerto Rico, among others; South Region: Argentina, Brazil, Chile, Paraguay and Uruguay; European region: Spain and Portugal.
The EACCME® shall grant ECMEC® credits to national events taking place in Latin America and organised by Latin American providers part of or belonging to CONFEMEL. The applications related to national events shall be submitted through the SEAFORMEC/SMPAC platform for accreditation according to the agreement entered between UEMS-EACCME® and CGCOM.

I.2. DEFINITIONS

Actual conflict of interest:

A real conflict of interest occurs when an individual or institution has two competing interests, one of which is likely to interfere with or undermine a researcher's/institution's ability to fulfil its responsibilities as a researcher or research institution.

Bias:

Bias is a term used to describe a tendency or preference towards a particular perspective, ideology or result, especially when the tendency interferes with the ability to be impartial, unprejudiced or objective. Bias may be scientific, political, economic and financial, religious, gender-related, ethnic, racial, cultural or geographical. Bias may occur in relation to a particular industry or commercial product such as a mechanical device or pharmaceutical agent, or in relation to a particular intellectual, political or other view, in situations where a range of products or views may be equally useful or valid.

Blended learning:

An educational programme that combines obligatory participation in a LEE and completion of an associated e-learning component.

CME/CPD provider:

Individual / organisation whose mission is the development and provision of CME/CPD. They may receive independent financial support from various organisations including the pharmaceutical and medical devices industry (the sponsor). The sponsoring pharmaceutical/medical devices industry must have no input into or influence, at any point, on the educational programme. The scientific content of the educational material a CME/CPD provider delivers is developed by medical doctors independently of the sponsor and the content is not reviewed and controlled by the sponsor.

Commercial Interest:

Any entity producing, marketing, re-selling, or distributing healthcare goods or services consumed by, or used on, patients.

Conflict of Interest (COI):

A set of conditions in which judgment or decisions concerning a primary interest (for example a patients' welfare, the validity of research and/or quality of medical education) is unduly influenced by a secondary interest (personal or organizational benefit including financial gain, academic or career advancement, or other benefits to family, friends, or colleagues).

Continuing Medical Education (CME)

Continuing Medical Education (CME) refers to the process through which healthcare professionals participate in activities aimed at advancing their ongoing professional growth. These activities span various instructional methods, prioritize the learner's needs, and enhance the professionals' ability to deliver high-quality, comprehensive, and continuous care to patients, as well as serve their community or profession. CME content encompasses not only clinical care but also the attitudes and skills essential for excelling as administrators, educators, researchers, and collaborative team members within the healthcare system.

Continuing Professional Development (CPD):

Continuing Professional Development for physicians designates all the professional development activities that occur after specialist qualification has been obtained. It includes many forms of education and training that allow individual doctors to maintain and improve standards of medical practice through the development of knowledge, skill, attitude and behavior.

Educational app:

The word "app" is the abbreviation for application. An app is an element of software that has to be downloaded and run on a computer, on a phone or any other electronic device. An educational app is a means of delivering educational material that meets the EACCME® criteria for accreditation of ELM.

Educational e-platform:

A set of interactive and complementary online educational materials that provide learners with on-demand content to support the delivery and management of teaching and learning activities. An educational e- platform needs to have at least 10 individual modules that meet the EACCME® criteria for accreditation of ELM.
An e-platform is different from an ELM Course in which it is not mandatory for learners to go through all of the elements of the platform to claim credits. The learners may take any number of E-platform modules and in any order. The credits are awarded for each individual module completed.

E-Learning Material (ELM):

E-learning is learning utilizing electronic technologies to access an enduring educational content at a time convenient to a learner. In most cases, it refers to a course or programme delivered completely online. It should utilise modern available IT options.

E-learning material described as "on-demand" refers to digital educational resources that are accessible anytime and anywhere, allowing learners to engage at their convenience rather than following a fixed schedule.

The accreditation of ELM is only for the educational content of the ELM and not the e-media used to deliver it.

For further information, see “Part IV. Specific regulations on the accreditation of e-learning materials (ELM)” of this document.

ELM Course:

A course is a set of related individual modules aimed at providing education on a specific field of knowledge. In order to claim CME/CPD credits from a course, it is mandatory for learners to complete the entirety of the course.

Faculty:

Faculty includes: invited speakers, session chairs, workshop trainers, round-table moderators, discussion facilitators, developers and presenters of educational content and format of e-learning material etc. It does not include abstract/open paper/slide/poster presenters, speakers in non-CME sessions, speakers in industry symposia and other non-accredited sessions.

Hybrid event:

Educational event taking place at physical venue and streamed/broadcasted live simultaneously.

Independent Support Grant:

Monetary or in-kind contributions given by a commercial interest to a CME/CPD provider that is used to pay all or part of the costs of a CME/CPD activity where the education is independent of their control. The commercial interest is not allowed to have control or influence over the content of the CME/CPD activity nor is it allowed to receive any “benefits” for providing the support.

Individual module:

An individual module is the basic unit of an ELM. It lasts between 30 minutes and 3 hours. To be considered an individual module, the content of the ELM has to be under the scope of the same medical specialty. Individual modules are self-paced learning experiences that may include a combination of written content, audio, video, or other visual elements.

The content and format of an accredited module cannot change once accredited or for the period for which it is accredited. If the provider wishes to change the content or format, a new application needs to be submitted.
Individual modules lasting more than 3 hours must be split into smaller components with a maximum duration of 3 hours in order to be accredited.
Individual modules lasting less than 30 minutes must be combined to create a new module with a minimum duration of 30 minutes to be accredited.

Individuals involved in preparing the content:

The people responsible for or who have contributed to the design of the ELM, selection and preparation of the format and the content of the programme, selection of the faculty etc. This does not include the non-medical staff responsible for the logistical part of the development of the ELM, nor does it include the ELM faculty who have not been involved in the preparation of the ELM.

Institutional organisation:

Organisation linked to a national governmental or European/international institution.
Eg. IAEA, national health ministries, European Commission DG Santé…

Live Educational Events or LEEs defined as a live physical/ virtual/ hybrid meeting or webinar, the primary purpose of which is the provision of educational material of a medical nature to medical specialists, with the aim that they will achieve educational benefit. It requires of a participant on the event's site or a tele-presence when an event takes place via live-streaming. Each form of presence/participation requires a robust mechanism allowing confirmation of participation. It is expected that, as a result of this educational process, patients also will benefit from the lessons, applied in practice, that their specialist doctors have learned.

A live educational event can therefore be:

- ✓ held at a physical venue/on site;
- ✓ streamed live (virtual event or live webinar);
- ✓ hybrid (on site and via live-streaming).

All these formats must allow participants to submit questions and answers.

Medical officer (MO) taking responsibility for the application:

This person must be a specialist doctor registered with his/her Medical Regulatory Authority.

The medical officer (MO) taking responsibility for the application may be the Head of the Organising and/or Scientific Committee, one of its members or any specialist doctor willing to take responsibility for the application. This person will be the one completing and signing the director's declaration to be provided at the time of the application by the ACI office.

Medical Regulatory Authority:

By Medical Regulatory Authority we mean the authority in a country that delivers to doctors the license to practice medicine in that country.

Micro-learning:

A CME activity (LEE or ELM) lasting between 30 minutes and an hour.

Perceived conflict of interest:

A perceived conflict of interest occurs when an individual or institution may reasonably be understood by a third party as having two competing interests, one of which is likely to interfere with or undermine a researcher's/institution's ability to fulfil its responsibilities as a researcher or research institution.

Physician organisation:

Entity or group formed by physicians to collaborate, represent their interests, deliver healthcare or education services.

Principal intended recipients

Specific group or groups of specialist doctors identified as the intended recipients of a CME/CPD activity.

Professional Congress Organiser (PCO):

Individual / organisation who has been contracted out by a CME provider to organise the logistics of the event.

Quality control of educational e-platforms and apps:

Due to the dynamic character of educational e-platforms and apps, providers are entitled to change/upgrade the educational content after the initial accreditation without submitting a new application. Providers need to make sure that the changed/upgraded content will stay within the scope and remit of the initial accreditation. Also, backend technologies and cosmetic changes may undergo updates as long as requirements for obtaining EACCME® accreditation are met.

For this reason, there is a mandatory quality control of educational e-platforms and apps by EACCME® reviewers to ensure that their content remains within the scope and remit of the initial accreditation. This quality control procedure takes place one year after accreditation has been granted. Providers need to inform the EACCME® of any changes/upgrades made to the content of the educational e-platform or app.

Failure to comply with the quality control procedure may lead to removal of the accreditation.

Recording:

Recording of a whole live educational event made available on-demand during or after an EACCME®- accredited event.

The EACCME® does not accredit recordings per se but as the extension of an EACCME®- accredited live educational event.

Scientific and Organising Committee:

The people responsible for or who have contributed to the design of the event, selection and preparation of the format and the content of the programme, selection of the faculty etc. This does not include the non- medical staff responsible for the logistical part of the organisation of the event, nor does it include the event faculty members who have not been involved in the preparation of the event.

Sponsor:

An individual, group, corporation or organization (for-profit and not for-profit) who provides financial support (exhibition booth, commercial symposium, advertisements outside the scientific programme, among others) of educational activities. For further details on the type of sponsorship, see Annex 1, point 17 for LEE; Annex 5, point 20 for ELM

Sponsorship:

Monetary contribution given in exchange for a specific benefit e.g., exhibition booth, space for a commercial symposium, and advertisements outside the scientific programme. The sponsor is not allowed to influence the CME/CPD activity at any level and not allowed to have control over the content. The "benefit" in exchange for the sponsorship must relate to a non-educational component of the meeting.

Virtual event:

Educational event streamed/broadcast live in real time lasting more than 2 hours.

Webinar:

Educational event streamed/broadcast live in real time lasting between 30 minutes and 2 hours.

II. GENERAL STATEMENTS

1. The European Union of Medical Specialists (henceforth, UEMS) established the European Accreditation Council for Continuing Medical Education (EACCME®), in January 2000, with the aim of encouraging the highest standards in development, delivery and harmonisation of Continuing Medical Education (CME) and Continuing Professional Development (CPD). This was to be achieved through the international accreditation of CME events and e-learning materials, and the establishment of a system for the international acceptance of CME credits.

2. The European Board of Radiology (henceforth, EBR) and the UEMS are cooperating since 2015 to organize jointly the accreditation of international live educational events (LEEs), accreditation of e-learning materials (ELMs) in imaging and since 2023 accreditation of blended learning.

3. The specialist body of the EBR, which is carrying out the proceeding of the accreditation in collaboration with the EACCME®, is called Accreditation Council in Imaging (hereafter, ACI). The ACI is operating under the umbrella of the Spanish entity named European Board of Radiology (EBR).

4. Within the framework of this collaboration, during the Content Review Process of Application, the EBR will assume the role of reviewing all contents and documents provided by the Applicant, through its specialist body and the EACCME® will ensure that the Application is duly reviewed by the National Accreditation Authority (NAA) of the country in which the LEE will be held, or the e-learning material used, for national approval.

   Once the Application has been checked and evaluated by the NAA and by the ACI, the EACCME® will decide accordingly the number of European CME Credits (ECMECs) to be awarded.

   The EACCME® is the final decision maker and will always grant CME Credits (ECMECs) following its own criteria.

5. During the whole accreditation procedure, the EBR will receive from the Applicant the information and documentation required, and manage all communications exchanged, keeping a direct contact with the Applicant throughout all steps of the process.

6. As a result of the aforementioned, UEMS and EBR have implemented and approved these Terms and Conditions that describe the criteria and mechanisms for the accreditation of live educational events, e-learning materials in imaging and blended learning. These Terms and Conditions mirror the documents UEMS 2023.07 for the accreditation of LEE, UEMS 2023.08 for the e-learning materials and UEMS 2023.09 for Blended Learning and are thus based on the criteria set out in the mentioned documents. The UEMS and the EBR, hereinafter are referred to as UEMS/EBR.

   In 2009, the EACCME® implemented criteria for the accreditation of e-learning materials.

   In 2016, the EACCME® implemented EACCME® 2.0 including the accreditation of new forms of CME/CPD activities.

   In 2023, the EACCME® implemented EACCME® 3.0 including the accreditation of blended learning and new forms of CME/CPD activities

7. The scope of the accreditation granted accordingly to these Terms and Conditions is limited to: Live Educational Events (LEE), E-learning Materials (ELM) and Blended Learning.

8. These Terms and Conditions contain the updated criteria and mechanisms applied by UEMS/EBR during the accreditation process and serve as a binding contract between the UEMS/EBR and the Applicant for the accreditation (hereafter, the "**Applicant**").

   These Terms and Conditions include general provisions to be applied to any accreditation process, and specific ones depending on the accreditation´s

object: Live events or a different type of e-learning material. In case of any conflict or inconsistency between general provisions (Part I, Part II and Part VI) and specific provisions (Part III, IV and V, essentially), the most specific provision must always prevail.

9. All Applicants must familiarize themselves with the Terms and Conditions before applying for accreditation.

10. By paying the accreditation fee established in sections III.7 and IV.3 of this document, the Applicant agrees to these Terms and Conditions.

11. The EACCME® reserves the right to make the final decision in all matters relating to the accreditation of LEEs, ELMs in imaging and Blended Learning, including the final decision on the eligibility of applicants.

12. Who is eligible to apply for CME/CPD accreditation?

The EACCME® considers for accreditation events submitted by a physician organisation such as:

- An individual medical specialist;
- A university or hospital department;
- A scientific medical society;
- A national medical association;
- a CME-CPD provider;
- an institutional organisation
- applications by other types of providers will be considered on a case by case basis.

As long as the application is supported by an appropriate medical specialist in activity who will take responsibility for the application. This person must be registered with his/her National Regulatory Authority.

For any other types of providers not listed above, and who do not participate in the marketing or promotion of pharmaceuticals and/or medical devices, it is possible to co-develop an event: co-development is when two or more

organizations, at least one of which must be a physician organisation, work together to develop a CME/CPD activity to be accredited.

Examples of organisations that must co-develop a CME/CPD activity with a physician organisation:

- a professional congress organiser (PCO).

> The EACCME® will **NOT** consider for accreditation events where the content, format or faculty is influenced by industry, submitted by industry or where the industry is the CME/CPD provider.

Types of organizations that are not considered for accreditation:

In case of LEE, ELM and BLD:

- Pharmaceutical companies or their advisory groups;
- Medical/surgical devices companies;
- Medical technology companies;
- Medical/surgical software companies;
- Other industry;
- Medical communication agencies.

13.Types of CME/CPD Activities:

Which process do I use?

Type of application	Format	Duration	Number	Criteria
LEE*	- Live on site - Streamed - Hybrid - Individual live webinar	Min. 30 minutes	1 application per LEE/live webinar	UEMS 2023.07rev
WEBPACK*	- Streamed live	Min. 30 minutes Max. 2 hours	Minimum 2 webinars per application	UEMS 2023.07rev
ELM*	On-demand only	Min. 30 minutes Max. 3 hours	See types of ELMs in UEMS 2023.08	UEMS 2023.08rev
BLD*	Combination of two components: ELM + LEE	Min. 1 hour in total	1 application per blended learning	UEMS 2023.09rev

* Possibility to add the Recording option at any stage of the process of accreditation.

Live educational event (LEE)

- ✓ For all live educational events, either held at a physical venue,

streamed live, or hybrid, or for individual webinars;
- ✓ The Recording option can be requested at any stage of the process of accreditation.

Webinar Package (WEBPACK)

- ✓ For live webinars lasting between 30 minutes and 2 hours;
- ✓ All in the same medical specialty;
- ✓ Minimum 2 webinars;
- ✓ The Recording option can be requested at any stage of the process of accreditation.

E-learning material (ELM)

For on-demand material – please refer to PART IV - SPECIFIC REGULATIONS ON THE ACCREDITATION OF E-LEARNING MATERIALS (ELM), which mirror the ELM criteria (UEMS 2023.08).

Blended learning (BLD)

- ✓ For CME/CPD combining one/several LEEs and one/several ELM module(s);
- ✓ Minimum one hour in total;
- ✓ ELM is linked to the specific LEE and is available for a maximum period of 12 months;
- ✓ One single registration fee for the entire educational material;
- ✓ Participants must attend all sessions;
- ✓ The educational activity takes place within a period of 12 months
- ✓ The Recording option can be requested at any stage of the process of accreditation.

14. EACCME® General principles

The UEMS-EACCME® provides accreditation for medical education of the highest quality, thus supporting the best and most up-to-date patient care in

Europe. In order to guarantee this high-level education, the EACCME® has set the following principles:

Commercial influence and bias

- the education provided must be free of any commercial influence or bias;
- the education provided must be free of any form of advertising;

- commercial funding must be provided in the form of an independent support grant. The EACCME® will also accept funding from other sources, eg. fees for exhibition booths; (see full list in Annex 1 under criterion 17);

- educational materials provided entirely by a pharmaceutical or medical equipment industry will not be considered for accreditation;
- as a general principle, all scientific content of an activity must be clearly separated from the commercial component.

Educational needs and learning objectives

- a needs assessment has to be performed prior to the LEE;
- learning needs and educational outcomes have to be defined.

Conflict of interest and resolution of conflict of interest

- perceived or actual conflicts of interest will need to be disclosed by the Scientific and Organising Committee and the faculty;
- any actual conflict of interest will need to be resolved prior to the LEE.

- **Learners' monitoring and feedback**

- learners' attendance will need to be monitored by the provider;

- learners are expected to provide feedback on the educational material;

- the provider must submit an event report based on the learners' feedback.

Quality control

- the UEMS-EACCME® will randomly perform quality controls of any type of accredited events to ensure compliance with EACCME® accreditation criteria. The provider will need to provide free access to the entire event for the persons indicated by the EACCME® as its representatives.

Other healthcare professionals

- the EACCME® will consider supporting accreditation for other healthcare professionals (other than medical specialists) in collaboration with their relevant professional bodies

II. GENERAL PROVISIONS FOR THE ACCREDITATION OF LIVE EDUCATIONAL EVENTS (LEE), E-LEARNING MATERIALS (ELM) AND BLENDED LEARNING

APPLICATION STEPS AND REQUIRED DOCUMENTATION

a) Previous and mandatory steps before application:

i. Before beginning the formal application process, the Applicant must complete, the application form available on the web page: https://www.myebr.org/aci/application-for-ecmec.

ii. Once this short form has been fulfilled and sent by the Applicant, the ACI will check if the event and/or e-learning material proposed seems to fit in the scope of the accreditation process organized by EBR/UEMS being related to the imaging field.

iii. Once this point has been checked and confirmed, the Applicant will receive an email from the ACI with all official documents (as listed in the following section III for LEEs, section IV for ELMs and section V for Blended Learning) that must be completed and sent by email to the ACI, in order to formally begin the application process. All official documents to be filled in will be provided by the ACI via email.

iv. Therefore, the ACI will not accept any application or document presented in any other way than the one described by the ACI Accreditation department by email as soon as the Application has been received.

v. By making an application, the Applicant, to the fullest extent permitted by laws, waives irrevocably and unconditionally the application of its own terms and conditions on the accreditation application.

PART III - SPECIFIC REGULATIONS FOR THE ACCREDITATION OF LIVE EDUCATIONAL EVENTS (LEEs)

III.1. REQUIREMENTS FOR THE ACCREDITATION OF A CME/CPD ACTIVITY

The essential criteria of application are listed in **Annex 1** (essential criteria to be met by the Applicant).

1. The only application form that will be accepted is that made available at the ACI website: https://www.myebr.org/aci/application-for-ecmec#lee-form

III.2. SUBMISSION/EVALUATION/ACCREDITATION/APPEAL PROCESSES

The deadline for receipt of a fully completed application form, all supporting documents and confirmed payment of the EACCME® fee is as follows:

- 6 weeks before the event for a complete and paid application

- 5 weeks before the event for a complete and paid application, with late fees applied

- 5 weeks before the event for trusted providers for a complete and paid application

- 4 weeks before the event for trusted providers for a complete and paid application, with late fees applied

These deadlines apply to ensure timely processing ahead of the event's scheduled start date.

For submissions at 5 weeks or 4 weeks for trusted providers, a late fee will be applied.

IMPORTANT NOTICE

Every time there is a delay in the process for which the applicant is responsible (i.e. the reviewer(s) have questions for the applicants for which an answer is pending...), the clock stops and the delay is not included in the above ~~7 weeks~~ schedule

Moreover if an application is not complete and paid at the latest 2 weeks prior to the start of the CME activity, the application will be automatically rejected with no refund and no possibility to appeal

Submission process

- The only application form that will be accepted is that made available at the ACI website: https://www.myebr.org/aci/application-for-ecmec#lee-form
- No applications sent on paper will be considered.

- As applications can only be received in English, applicants will be responsible for the translation of all submitted materials;
- For some countries or specialties, specific regulations might apply. Please check the EACCME® website for further information.

In order to have an application for accreditation considered by the ACI/EACCME®, the Applicant must:

- submit a fully completed application, in English (applicants will be responsible for the translation of all submitted materials), using the specific application form as provided by the ACI Accreditation department with all relevant attachments and full payment for the application;
- ensure that suitable information has been provided for each of the essential criteria;
- provide confirmation by the medical officer who is taking responsibility for the application.
- provide confirmation by the Head of the Scientific and Organising Committee who is taking responsibility for the scientific programme.

The ACI/EBR and EACCME® commits to:

- providing, on its website, an ACI application form, based on the criteria set out in this paper;
- ensuring confidentiality regarding the application submitted;
- confirming, at the request of the Applicant, the following dates:
    - on which the EACCME® application was made by the ACI,
    - on which the EACCME® application was complete,
    - on which the application fee was cleared,
    - the "starting date" – on which the EACCME® has begun its evaluation
    - completing the accreditation process within the time specified
- following the accreditation process;
- providing, at the request of the Applicant, a progress record of the application;
- publishing, on the EACCME® and ACI website, the list of accredited events.

Criteria and decision-making for accreditation

1. The material and the application form will be reviewed simultaneously by the two EACCME® designated evaluation bodies:

    a. the National Accreditation Authority (NAA) of the country within which the LEE will be held; and
    b. the relevant Speciality-based organisation, whether UEMS Section and Board, or partner European Speciality Accreditation Board (ESAB), in this case the Accreditation Council in Imaging (ACI)

    The EACCME® will be solely responsible for appointing these designated evaluation bodies.

2. **For a positive decision** by the ACI/EACCME® designated evaluation bodies, **all essential criteria set out in this document must be confirmed**. The two designated evaluation bodies also will be required to confirm whether, according to their assessment of the information provided, the application

is for an activity that fits within the UEMS definition of a LEE, and whether the stated learning objectives are likely to be achieved.

The NAA role is first and foremost to check if the application is compatible with the regulations in place where the LEE is held while the UEMS Section/Board or relevant ESAB conducts the scientific specialist review.

3. In order for the EACCME® to accredit the material, both designated evaluation bodies must support the application.

Amendment Procedure

1. The EACCME® recognises that some applications will fulfil almost all the criteria needed for accreditation but may not achieve the standard required for a small number of criteria. In accordance with its remit to encourage the improvement of the quality of CME/CPD, the EACCME® will permit the applicant, following request by the ACI, one opportunity to provide additional information.

2. Following activation of the amendment procedure, the clock for the processing time will stop pending receipt of the requested information or documents from the applicant, and the deadline for ACI to provide their decision will be extended accordingly. Other than through the mechanism of appeal (see below), this decision by the EACCME® shall be final.

Automatic Reconsideration

Should the two EACCME® designated evaluation bodies differ in their assessments, an automatic reconsideration will be triggered by the EACCME® system. This automatic reconsideration will be performed at no further cost to the applicant and will be completed within the timescale applicable for a regular review. Automatic reconsideration will involve review by the two EACCME® designated evaluation bodies and the Secretary-General of the

UEMS (or his/her nominee).

Appeal

1. Should both EACCME® designated evaluation bodies reject the application, the applicant may still appeal. A decision to appeal must be lodged within one week and must be accompanied by full payment of the appeal fee. The appeal process will require a further two weeks from the date that the appeal was received.

The fee will be **€ 310,20** for all such appeals. In the case of a positive appeal, the appeal fee will be refunded.

2. The mechanism of the appeal will be:

- the Secretary General of the UEMS (or his/her nominee) will review all the information provided on the application form, any supplementary permissible correspondence and may ask for additional information to all parties involved. The Secretary General will discuss the application with the two EACCME® designated evaluation bodies for the initial review, if needed;
- the appeal decision of the EACCME® will be final

III.3. SUBMISSION OF A WEBINAR PACKAGE APPLICATION

Conditions:

- ✓ The WEBPACK system is designed for the accreditation of live-streamed webinars only;
- ✓ **Live Educational Events (LEE)** Criteria apply;
- ✓ All submitted webinars must be in the **same medical specialty** (e.g. all in oncology, or all in paediatrics etc.);
- ✓ They must be **minimum 30 minutes each and maximum 2 hours** each;
- ✓ The minimum **fee** is for 5 webinars;

- ✓ The minimum number of webinars to be submitted is 2;
- ✓ Submission deadlines: see Chapter VIII taking into account the **starting date of the first webinar**;
- ✓ All webinars included in the WebPack must take place within 12 months from the starting date of the first webinar.
- ✓ The detailed programme, as well as all other supporting documents (Director's Declaration, COI forms, Participant's feedback form, which will be made available by the ACI) must be provided **for each webinar.**
- ✓ The Recording option can be requested when applying for a webinar series.
- ✓ The appeal option is not applicable to webinar packages. It will therefore not be possible to appeal the rejection of a webinar package or of an individual webinar of the package.

N.B. If your webinars are in different medical specialties, or if they last longer than 2 hours, you will have to submit them using the Live Educational Event (LEE) procedure (one LEE application per live webinar).

III.4. ACCREDITATION OF THE FULL RECORDING OF A LEE

1. Principle.

- It is an "extension" of the accreditation of a live event to its full recording made available on a website or platform.
- Partial recording will have to be submitted as an e-learning material once this partial recording has been transformed into e-learning module(s). For further information regarding e-learning materials, please consult "PART IV – SPECIFIC REGULATIONS ON THE ACCREDITATION OF E-LEARNING MATERIALS (ELM)" of the present document, which mirror the EACCME® Criteria for the Accreditation of ELM (UEMS 2023.08).
- The recording of an industry-sponsored satellite symposium will not be eligible for credits

2. Validity

- The validity of this accreditation is for a maximum of six months after the live event has taken place.

3. Submission process

- The recording option is requested by the ACI when the accreditation for the live event is requested. The recording option can also be requested at any stage of the accreditation process. Please note that this option will be activated at a later stage only upon receipt of the payment;
- The fee for the recording option amounts to 25% of the total fee.

4. Credits

- People viewing the recording during the six-month period after the event has taken place are entitled to CME/CPD credits, in the same way as the participants to the live event;
- The credits are granted, as for the live event, on the basis of actual "participation", i.e., how many hours of CME/CPD the participants have viewed;
- The provider will therefore have to keep track of the use of the recorded material;
- The ACI/EACCME® recommends that providers implement some interactive elements within the recording to promote learner engagement;
- The participant will have to submit a participant's feedback form before he/she is entitled to his/her credits, just like the participant at the live event;
- The maximum number of credits granted for watching the recording will be the same as for the live event and cannot exceed this number whatever the number of sessions attended or viewed;
- A participant may not obtain credits for participating at the live event and watching the same sessions as recordings.

III.5. OUTCOMES

1. Until confirmation of accreditation has been sent to the provider, the only permissible statement that can be made by the provider on material related to the LEE is **"An application has been made to the UEMS/EBR for CME/CPD accreditation of this event".**
2. Confirmation of accreditation of the LEE by the UEMS/EBR will permit the provider to use a statement to this effect (prepared by the EACCME®) on and within the material. This will be confirmed on the EACCME® website, where the maximum number of ECMEC®s granted will be stated. Only after **confirmation of accreditation has been received can the provider use the UEMS-EACCME® and EBR-ACI logos on material related to the LEE.**

   The UEMS-EACCME® logo may only be used in conjunction with, and in proximity to, the EACCME® accreditation statement and must not be associated with any commercial logo.

   The UEMS-EACCME® logo cannot be used in notices, advertising, or promotion of activities other than in association with the EACCME® accreditation statement.

3. **Accreditation by the EACCME/ACI of a LEE will be for the specific event designated on the application form**. It is not permissible to transfer this accreditation to any other event.
4. Where a website, an electronic communication or a printed material lists EACCME®-accredited LEEs along with non-accredited LEEs, the provider must assure that learners can easily recognise the accreditation status. Listing a LEE not accredited by the EACCME® in a misleading way, suggesting that EACCME® has also accredited it, will lead to withdrawal of accreditation.

III.6. MAJOR CAUSES FOR REJECTION OF AN APPLICATION AT THE LEVEL OF INITIAL REVIEW

1. Failure by a provider to disclose the means of funding of a LEE will lead to rejection of the application.

2. Grossly or significantly inaccurate attendance declarations will lead to automatic rejection of the application and any future application.

3. The Applicant must not attempt to influence the decision of the EACCME®. Specifically, any attempt to contact the reviewers of the application will result in automatic rejection of the application and forfeiture of the fee.

4. The use of any statement by the provider that suggests that accreditation has been granted, or has been provisionally granted while the application review process is not yet completed with positive outcome will result in automatic rejection of the application.

5. Any unauthorised/inappropriate use of the UEMS- EACCME® logo or EBR-ACI will result in action being taken by the UEMS or EBR respectively.

III.7. Allocation of European CME Credits (ECMEC®s)

The EACCME® awards ECMEC®s on the following basis:
30 minutes (30 minutes of educational activity) = 0.5 ECMEC®

Each additional half hour will be granted 0.5 ECMEC® with a maximum of 8 ECMEC® per day of the LEE.

Doctors must only claim ECMEC®s for those LEEs, or parts of LEEs that they have attended, and should ensure that they do so in accordance with their home country's criteria.

III.8. Fees and payment policy

Fees:

The fee for an application to the EACCME/ ACI for the accreditation of LEEs under these Terms and Conditions is determined in accordance with the expected total attendance of learners and is not dependent on the number of ECMECs® awarded.

As with any contractual agreement, all invoices that will be issued by the EBR must be paid by the Applicant.

The scale of fees is:

The EACCME® scale of fees for a Live Educational Event is:

From 1 to 50 participants:	**247,50 €**
From 51 to 100 participants	**372,90 €**
From 101 to 250 participants:	**493,90 €**
From 251 to 500 participants:	**895,40 €**
From 501 to 1,000 participants:	**1.359,60 €**
From 1,001 to 2,000 participants:	**1.852,40 €**
From 2,001 to 5,000 participants:	**3.699,30 €**
More than 5,000 participants:	**6.164,40 €**

The EACCME® scale of late fees for a Live Educational Event is:

From 1 to 50 participants:	**372,90 €**
From 51 to 100 participants	**562,10 €**
From 101 to 250 participants:	**740,30 €**
From 251 to 500 participants:	**1.331,00 €**
From 501 to 1,000 participants:	**2.041,60 €**
From 1,001 to 2,000 participants:	**2.781,90 €**
From 2,001 to 5,000 participants:	**5.550,60 €**
More than 5,000 participants:	**9.248,80 €**

The EACCME® scale of fees for a WebPack (Webinars Package) is:

From 2 to 5 webinars:	**1.233,10 €**
From 6 to 10 webinars:	**1.852,40 €**
Up to 20 webinars:	**2.712,60 €**
Up to 30 webinars:	**3.699,30 €**
Up to 40 webinars:	**4.684,90 €**
Up to 50 webinars:	**5.550,60 €**
Up to 100 webinars:	**9.989,10 €**
More than 100 webinars:	**13.193,40 €**

The EACCME® scale of late fees for a WebPack (Webinars Package) is

From 2 to 5 webinars	**€ 1.359,6**
From 6 to 10 webinars	**€ 2.041,6**
Up to 20 webinars	**€ 2.959,0**
Up to 30 webinars	**€ 4.134,9**
Up to 40 webinars	**€ 5.366,9**
Up to 50 webinars	**€ 6.480,1**
Up to 100 webinars	**€ 11.840,4**
More than 1000 webinars	**€ 16.278,9**

The **Recording option** is available for a regular application, a late application and for a WebPack application and amounts to **25% of the total fee**.

The above fees are VAT excluded.

The EACCME® reserves the right, in its sole discretion, to change its fees at any time. An application already submitted will be charged at the rate applicable at the time that it was made.

The Applicant will have no right to reduce the expected number of participants after submission of the application.

EACCME® reserves the right, at its sole discretion, to change the fees at any time. Applications already submitted will be charged at the rate applicable at the time they were made.

In some specialties, the UEMS-EACCME® has particular agreements with European Specialty Accreditation Boards (ESABs). Through mutual agreements with each of these, the UEMS-EACCME® will submit all eligible applications in these fields to the relevant ESAB for their specialist review see EACCME® website). Accordingly, ESABs are entitled to issue an invoice to providers in order to cover for their specific administrative tasks and provisions for quality assurance in their CME/CPD events.

Annex 2 contains a quick checklist for providers of a LEE with the necessary information to complete the application form.

III.9. TRUSTED PROVIDER STATUS

Trusted Provider status

The EACCME® recognises the outstanding quality of CME/CPD LEEs organised by a number of providers over many years and trusts that such providers will continue to maintain a record of excellence in CME/CPD activities. Therefore, providers with sufficient experience and a satisfactory history of EACCME® applications may apply for the status of Trusted Provider.

The Trusted Provider status is about a faster and simpler process, and not about lowering the EACCME® standards and the quality of the accreditation process.

Benefits of Trusted Provider status:

The trusted providers will benefit from an expedited process for some fields of the criteria. The Applicant enjoying the Trusted Provider status will be relieved from providing certain documents during the submission process but will need to have these available at the time of the event.

For trusted providers:

- The evaluation process is reduced to 4 weeks
- COI forms do not need to be submitted at the time of the application, but must be available at the time of the event for possible monitoring. This applies to the members of the Scientific and Organising Committee and to the faculty;
- Application sent for review without waiting to receive the payment. However, the payment must be received before the finalisation of the procedure. In case of cancellation, if the application is already reviewed, the payment is due.

Criteria to be fulfilled in order to obtain the status of "Trusted Provider"

1) Minimum of 10 applications/year during the last 2 years

The applicant for Trusted Provider status will have to provide the UEMS-EACCME®

with their track record of applications submitted. The UEMS-EACCME® will check the applicant's list against its own records.

2) Consistent record of high quality applications

- Application form completed correctly
- Application accurately completed and paid on time
- All supporting documents complete and submitted on time
- Positive final UEMS-EACCME® decision for all applications received
- Event material (booklet, website, app…) compliant with UEMS-EACCME® criteria

3) If amendments have been required to the Applicant's applications

- These have been performed rapidly (consistently in less than one week)
- The amendments fully addressed the concerns raised

4) The applicant has provided feedback on his/her applications to the EACCME®.

- Scientific programme distributed to participants at the meeting in a printed or electronic form
- Event feedback report provided for every accredited activity (within one month) For events with Recording option, event report provided within seven months.

In addition to these criteria, the applicant must answer the following questions:

a) How can/do participants register in advance for an event?

b) Demonstrate that for each activity a needs assessment process has been completed, how that process was performed and what relevant educational needs have been identified from that process.

c) Explain how actual conflicts of interest are resolved in the case of an actual conflict of interest of a member of the Scientific and Organising Committee and/or of a speaker.

d) Explain how attendance is monitored at each session of an event and how EACCME® certificates are delivered to participants.

GRANTING OF THE "TRUSTED PROVIDER" STATUS

When the application for Trusted Provider status is complete, it is presented to the UEMS EACCME® for decision. The Trusted Provider status is granted for a defined period of 3 years.

In recognition of the high quality of the LEEs, ELMs and BLDs organised by trusted providers, the EACCME® offers a bronze (up to 10 applications per year), silver (more than 10 and up to 20 applications per year), gold (more than 20 and up to 30 applications per year) and platinum (more than 30 applications per year) Trusted Provider status. The EACCME® will present the trusted providers and their status (bronze, silver, etc..) in a prominent page on its website and the trusted providers can also present their status on their own websites and LEEs, ELMs and BLDs.

If the Board's decision is negative the Applicant can submit a written reasoned appeal to the UEMS Secretary General within 2 weeks of receiving the EACCME®s decision. The Secretary General can ask the EACCME® for reconsideration of the application within 2 weeks or confirm the decision in which case the decision becomes final. The decision taken by the EACCME® after reconsideration of the application is final.

If the UEMS EACCME® decision on trusted provider status is negative, a renewed application can be submitted no earlier than after 1 year.

LOSS OF THE STATUS OF "TRUSTED PROVIDER"

The UEMS-EACCME® will monitor randomly selected activities organized by a Trusted Provider. Should the outcome of monitoring of the activity not be satisfactory, the report from the monitoring will be submitted to the EACCME® that will consider retraction of the Trusted Provider status. The EACCME® may ask the provider in question to provide additional information and explanations. If the Board finds the provider in breach with the UEMS EACCME® rules, the provider

will lose the status of Trusted Provider for a defined period, not shorter than 1 year.

Annex 3 contains a quick checklist for Trusted providers with the information needed to complete the application form.

III. 10. SANCTIONS

Sanction if the final programme of the LEE is not compliant with EACCME® criteria.

If the final programme that will be distributed to the participants at the LEE in a printed or electronic form differs from the accredited by EACCME® for this LEE and is not compliant with the EACCME®´s criteria, the provider will be fined (€ 550) and will not be allowed to apply for accreditation for:

- The following edition of its event in the case of an annual event;
- The next 6 months in the case of any other event.

III. 11.- INSTRUCTIONS REGARDING EVENT MATERIAL SUCH AS ANNOUNCEMENTS, POSTERS, PROGRAMME BOOKLETS, WEBSITES, WEBSITE PROGRAMMES, ETC.

Annex 4 contains the instructions regarding sponsors and event material.

PART IV - SPECIFIC REGULATIONS ON THE ACCREDITATION OF E-LEARNING MATERIALS (ELM)

IV.1 REQUIREMENTS FOR THE ACCREDITATION OF AN E-LEARNING MATERIAL

1. **Annex 5** contains all the **essential criteria** for the accreditation of an e-learning material.

2. The only application form that will be accepted is that made available at the ACI website: https://www.myebr.org/aci/application-for-ecmec#elm-form

3. Types of E-Learning Materials

Individual module	The module - must last **minimum 30 minutes** - **maximum 3 hours** The content and format of an accredited module cannot change once accredited or for the period for which it is accredited. If the provider wishes to change the content or format, a new application needs to be submitted.	**<u>One application per module</u>** Accreditation valid for two years 0.5 ECMEC® per 30 min (30 min of education)
Series of individual modules	Each module - must last **minimum 30 minutes** - **maximum 3 hours** The content and format of an accredited module cannot change once accredited or for the period	**<u>One application per module</u>** Accreditation valid for two years

	for which it is accredited. If the provider wishes to change the content or format, a new application needs to be submitted.	0.5 ECMEC® per 30 min (30 min of education)
E-platform	- must have a **minimum of 10 modules available from the start** - modules must last ▪ **minimum 30 minutes** ▪ **maximum 3 hours** - modules must be ▪ **complementary** ▪ be part of the **same educational scope** - - the educational content of an accredited ELM can be changed/upgraded after the initial accreditation without submitting a new application, but providers have to make sure that the content will stay within the scope and remit of the initial accreditation.	**One application for the whole platform** Accreditation valid for two years. **Quality control review after 1 year** 0.5 ECMEC® per 30 min (30 min of education)

App	- the app must be already available at the time of the submission.
	- possibility to apply for
	  o an individual app
	  o a series of individual apps
	  o an e-platform app (**minimum 10 modules available from the start**)
	- can be multi-specialty
	- individual app or series of individual apps: the content and format of an accredited module cannot change once accredited or for the period for which it is accredited. If the provider wishes to change the content or format, a new application needs to be submitted.
	- e-platform app: the educational content of an accredited ELM can be changed/upgraded after the initial accreditation without submitting a new application, but the content must stay within the scope and remit of the initial accreditation.
		One application per individual app
		
		One application for the whole e-platform app
		
		Accreditation valid for two years
		
		Quality control review after 1 year for the e-platform app
		
		0.5 ECMEC® per 30 min (30 min of education)

ELM Course	- Set of related individual modules aimed at providing education on a specific field of knowledge. In order to claim CME/CPD credits from a course, it is mandatory for learners to complete the entirety of the course. - The content and format of an accredited ELM course cannot change once accredited or for the period for which it is accredited. If the provider wishes to change the content or format, a new application needs to be submitted.	**<u>One application for the whole ELM course</u>** Accreditation valid for two years 0.5 ECMEC® per 30 min (30 min of education)

IV.2. SUBMISSION/EVALUATION/ACCREDITATION/APPEAL PROCESSES

If there is a fixed date when the e-learning material will go live and will be available for use to learners, the recommended time for submission of an application is at least **11 weeks** from the planned launch of the online material.

The whole evaluation process should take no more than 7 weeks from the moment the application has been sent out for review. An application will be sent out for review when the EACCME® office considers the application to be complete and has received payment of the accreditation fee.

Every time there is a delay in the process for which the applicant is responsible (cf. amendment procedure), the clock stops and the delay is not included in the above 7 weeks' schedule.

Submission process:

- The only application form that will be accepted is that made available at the ACI website: https://www.myebr.org/aci/application-for-ecmec#elm-form
- No applications sent on paper will be considered.
- ACI and the EACCME® will not accept late applications;
- As applications can only be received in English, applicants will be responsible for the translation of all submitted materials.

On application for accreditation by the ACI/EACCME®, the Applicant will provide:

- A link to the complete material with three sets of logins for the reviewers to access the material;
- The final product of the material needs to be available online;
- A fully completed ACI application form (shall be provided by ACI via email), confirmed by the medical officer who is taking responsibility for the material (see Annex 5, criterion 17);
- Full payment of the application fee.

In dealing with the application, ACI/EBR and EACCME® commits to:

- provide, on its website, the application form, based on the criteria (essential and desirable) set out in this paper;
- ensuring confidentiality regarding the application submitted;
- confirming, at the request of the Applicant, the following dates:
    - on which the material was received,
    - on which the application was complete,
    - on which the application fee was cleared,
    - the "starting date" – on which the EACCME® has begun its evaluation – which will bedetermined by the above two criteria (b & c) having been met,
    - choosing, from a pool of suitably-trained specialists, two assessor who have expertise appropiate to the material

submitted;

- providing, at the request of the Applicant, a progress record of the application;
- ensuring that a decision is provided to the applicant within seven weeks of the starting date, except in the case of an appeal being lodged, then the process will take no longer than ten weeks;
- publishing, on the EACCME® website and the ACI website, the list of accredited ELMs.

Criteria and decision-making for Accreditation

1. The Material and the application form will be reviewed by the designated ACI and EACCME® assessors.
2. **For a positive decision** by the ACI and EACCME® assessors, in favour of the accreditation, all essential criteria, and at least one desirable criterion must be confirmed and achieved by the submitted material. As a specific point, the assessor also will be required to confirm whether, according to their use of the material, the stated learning objectives have been fulfilled.
3. In order for the EACCME® to accredit the material, the assessors must support the application.

Amendment Procedure

1. The EACCME® recognises that some applications may fulfil almost all the criteria needed for accreditation but be lacking in a small number. In accordance with its remit to encourage the improvement of the quality of CME/CPD, the EACCME® will provide feedback and recommendations for amendments to the material submitted by the Applicant.

2. The EACCME® will permit the applicant one opportunity, at no additional charge, to submit a revised version of the material for accreditation. This amended submission must be provided within three weeks of the EACCME®'s request for amendment or the EACCME® reserves the right to

reject the application without further assessment.

3. The EACCME® commits to providing a decision within two weeks of receipt of the amended submission. Other than through the mechanism of appeal (see below), this decision by the EACCME® shall be final.

Appeal

1. Automatic appeal/automatic reconsideration – should the two designated EACCME® assessors differ in their assessment, an automatic appeal will be triggered, and the applicant will be informed that this has occurred. This automatic appeal will be completed within the timescale applicable for any application and will be performed at no further cost to the Applicant.

2. Appeal by the Applicant – should both designated ACI/EACCME® assessors reject the application, the Applicant may appeal. This will require a further two weeks from the date that the appeal, and the clearance of the appeal fee, is confirmed as having been received by the EACCME®. The appeal fee will be €465,30 In the case of a positive appeal, the appeal fee will be refunded.

3. The mechanism of the Appeal will be:

   - the Secretary General of the UEMS (or his/her nominee) will review all the information provided on the application form, any supplementary permissible correspondence and may ask for additional information to all parties involved. The Secretary General will discuss the application with the two EACCME® designated evaluation bodies for the initial review, if needed;
   - the appeal decision of the EACCME® will be final.

IV.4. FEES AND PAYMENT FOR INDIVIDUAL E-LEARNING MODULES/APPS

The fee for application to the UEMS/EBR for its accreditation of an individual module/app or series of individual modules/apps, will be:

1 module	€ 683,1
up to 10 modules	€ 1.359,6
up to 20 modules	€ 2.036,1
up to 30 modules	€ 2.712,6
up to 40 modules	€ 4.071,1

The above fees are VAT excluded.

Should an Applicant appeal, in accordance with the procedure set out in this document, the UEMS/EBR will charge an additional appeal fee of €465,30

The EACCME® reserves the right, in its sole discretion, to change its fees at any time. An application already submitted will be charged at the rate applicable at the time that it was made.

In some specialties, the UEMS-EACCME® has particular agreements with European Specialty Accreditation Boards (ESABs). Through mutual agreements with each of these, the UEMS-EACCME® will submit all eligible applications in these fields to the relevant ESAB for their specialist review. Accordingly, ESABs are entitled to issue an invoice to providers in order to cover for their specific administrative tasks and provisions for quality assurance in their CME/CPD events.

IV.4. ACCREDITATION OF EDUCATIONAL E-LEARNING PLATFORMS

1. UEMS/EBR will accredit **educational e-learning platforms** and **not websites**. The accreditation is for educational content of the platform and not the e-media used to access and use it.

2. **For an educational e-platform to be accredited:**

   a. The educational material must be complementary and part of the same educational scope.
   b. The platform has to have different teaching e-learning modules addressing from different angles the same overarching topic of specialist practice.
   c. Please note that a single course even if composed of 10 educational modules or more is not an e- platform and must be submitted as separate individual modules.
   d. The e-platform must meet the criteria that apply to ELM (see Annex 5)
   e. It is up to the provider to ensure that the material submitted for accreditation is compatible with UEMS/EBR criteria for ELM.

3. **Submission/ evaluation/ accreditation/ appeal processes**

   a. The submission/ evaluation/ accreditation/ appeal processes will be as described for EACCME® ELM (see Annex 5) with two exceptions:

   - Instead of completing the application form for the single ELM, the provider will need to complete it for the whole platform he/she wishes to have accredited.
   - The EACCME® review will not cover each and every single one of the e-learning modules of the platform but it will be a selective review of no less than 10% of the submitted modules.

   b. The list of accredited e-platforms will be published on the EACCME® and ACI websites.

4. **Modifications and quality control**

Modifications of e-platforms are allowed according to principles stated in the definition of “Quality control of educational e-platforms and apps”.

There is periodical quality control of the educational e-platforms by ACI and EACCME® to ensure that their content remains within the scope and remit of the initial accreditation.

This quality control procedure takes place one year after accreditation has been granted. Providers need to inform the EACCME® of any changes/upgrades made to the content of the educational e-platform or app.

The reviewers will report to the EACCME® for any concerns raised by the quality control appraisal.

Failure to comply with the quality control procedure may lead to removal of the accreditation.

5. Fees

Up to 10 modules	€ 1.668,7
Up to 20 modules	€ 2.345,2
Up to 30 modules	€ 3.021,7
Up to 40 modules	€ 4.381,3
Up to 50 modules	€ 7.092,8
Up to 100 modules	€ 10.481,9
More than 100 modules	€ 13.871,0

The above fees are VAT excluded.

EACCME® reserves the right, in its sole discretion, to change its fees at any time. An application already submitted will be charged at the rate applicable at the time that it was made.

6. Credits

The credits for the users of the platform will be 0.5 credit for every half hour (30 minutes of actual e- learning excluding introductions etc.) of use, provided that the users have completed a module and have passed the relevant assessment.

It is the provider's responsibility to assess the duration of the ELM and to determine the number of credits accordingly following the principle stated above.

The provider will be responsible for ensuring that there is a mechanism in the platform to ensure that a module has been completed, an assessment has been passed and for awarding the relevant number of credits. Compliance of the provider with this process will be checked during the annual review of the platform by the EACCME®.

7. Validity of the accreditation

The accreditation will be valid for 2 years. After two years, if the provider wishes for the platform to be re- accredited, a new application has to be submitted to the ACI.

IV.5 Accreditation of apps (e-platforms)

Accreditation of the e-learning modules delivered through apps (e-platforms) is possible as long as the apps don't serve for example as "tools" for attending a Congress or just means of communication. As long as the providers can prove that the app contains educational material in the modular form that meets the same criteria as the applications for educational e-platforms, the educational content of the app can be accredited following the same process, pricing and award of credits as for the educational e-platforms.

Up to 10 modules	€ 1.668,7
Up to 20 modules	€ 2.345,2
Up to 30 modules	€ 3.021,7
Up to 40 modules	€ 4.381,3

Up to 50 modules	€ 7.092,8
Up to 100 modules	€10.481,9
More than 100 modules	€13.871,0

The above fees are VAT excluded.

The EACCME® reserves the right, in its sole discretion, to change its fees at any time. An application already submitted will be charged at the rate applicable at the time that it was made.

IV. 6 Accreditation of an ELM course

1. The EACCME® will accredit **ELM courses** made up of several individual modules.

2. For an ELM course to be accredited

a. The educational material must be complementary and part of the same educational scope.
b. The ELM course must meet the criteria that apply to ELM.
c. It is up to the provider to ensure that the material submitted for accreditation is compatible with EACCME® criteria for ELM.

3. Submission/ evaluation/ accreditation/ appeal processes

a. The submission/ evaluation/ accreditation/ appeal processes will be as described for EACCME® ELM with two exceptions:

- Instead of completing the application form for each individual module of the ELM course, the provider will need to complete it for the whole ELM course he/she wishes to have accredited.
- The EACCME® review will not cover each and every single one of the ELM course but it will be a selective review of no less than 10% of the submitted modules.

b. The list of accredited ELM courses will be published on the EACCME® website.

4. Modifications

The content and format of an accredited ELM course cannot change once accredited or for the period for which it is accredited. If the provider wishes to change the content or format, a new application needs to be submitted.

5. Fees

up to 10 modules	€ 1.359,6
up to 20 modules	€ 2.036,1
up to 30 modules	€ 2.712,6
up to 40 modules	€ 4.071,1

The above fees are VAT excluded.

The EACCME® reserves the right, in its sole discretion, to change its fees at any time. An application already submitted will be charged at the rate applicable at the time that it was made.

6. Credits

The credits for the users of the ELM course will be 0.5 credit for every half hour (30 minutes of actual e-learning excluding introductions etc.) of use, provided that the users have completed a module and have passed the relevant assessment.
It is the provider's responsibility to assess the duration of the ELM and to determine the number of credits accordingly following the principle stated above.
The provider will be responsible for ensuring that there is a mechanism in the platform to ensure that a module has been completed, an assessment has been passed and for awarding the relevant number of credits. Compliance of the provider with this process will be checked during the annual review of the platform by the EACCME®.

7. Validity of the accreditation

The accreditation will be valid for 2 years. After two years, if the provider wishes for the ELM course to be re-accredited, a new application has to be submitted to EACCME®.

IV.7. OUTCOMES

1. Confirmation of accreditation of the material by the UEMS/EBR will permit the provider to use a statement to this effect (prepared by the EACCME®) on and within the material. This will be confirmed on the EACCME® website, and the number of ECMEC®s (as 0.5 ECMEC® per 30 minutes of education) will be stated. **Only after confirmation of accreditation has been received can the provider use the UEMS-EACCME® or EBR/ACI logo on material related to the e-learning module(s).**

The UEMS-EACCME® logo may only be used in conjunction with, and in proximity to, the EACCME® accreditation statement and must not be associated with any commercial logo.

The UEMS-EACCME® logo cannot be used in notices, advertising, or promotion of activities other than in association with the EACCME® accreditation statement.

2. Accreditation by the UEMS/EBR of e-CME/CPD materials will be time-limited for a period of two years from the date of confirmation of accreditation. This date, and the expiry date, will be displayed on the EACCME® website, and the confirmation of accreditation will be removed from the website after this period has elapsed.

3.The EACCME® will permit, on request by the provider, the accreditation

of translated versions of the originally accredited material as long as this does not involve any alteration of the content.

4. Accreditation of the material will not be transferable, and will only be permitted for the defined material, in the particular format, by the specified provider. Any breach of this rule will lead to the withdrawal of accreditation.

5. An application shall be limited to a single process of assessment for accreditation. As indicated in this document, this process normally will incorporate the assessment by assessors, one opportunity for improvement if deemed appropriate (amendment procedure), and the potential for one appeal. Beyond these steps, and the timescales set out above, should the EACCME® reject the application, no further opportunity for re-assessment will be offered, other than by a new application.

6. Where a website, an electronic communication or a printed material lists EACCME®-accredited ELM along with non-accredited ELM, the provider must assure that learners can easily recognise the accreditation status. Listing an ELM not accredited by the EACCME® in a misleading way, suggesting that EACCME® has also accredited it, will lead to withdrawal of accreditation.

IV.8. MAJOR CAUSES FOR REJECTION OF AN APPLICATION AT THE LEVEL OF INITIAL REVIEW

The Applicant must not attempt to influence the decision of the EACCME®. Specifically, any attempt to contact the reviewers of the application will result in automatic rejection of the application and forfeiture of the fee.

IV. 9. ALLOCATION OF EUROPEAN CME CREDITS (ECMEC®S)

The EACCME® awards ECMEC®s on the following basis:
30 minutes (30 minutes of educational activity) = 0.5 ECMEC®

Each additional half hour will be granted 0.5 ECMEC® with a maximum of 3 ECMEC® per module.

PART V – SPECIFIC REGULATIONS ON THE ACCREDITATION OF BLENDED LEARNING

V.1 REQUIREMENTS FOR THE ACCREDITATION OF A CME/CPD ACTIVITY

1. **Annex 6** contains all the **essential criteria** for the accreditation of a CME/CPD activity.

V.2. SUBMISSION/EVALUATION/ACCREDITATION/APPEAL PROCESSES

The deadline for the receipt of a fully completed application form, all supporting documents, and confirmed payment of the EACCME® fee is as follows:

- **6 weeks** before the event for a complete and paid application.
- **5 weeks** before the event for a complete and paid application, with late fees applied.
- **5 weeks** before the event for trusted providers for a complete and paid application.
- **4 weeks** before the event for trusted providers for a complete and paid application, with late fees applied.

These deadlines apply to ensure timely processing ahead of the event's scheduled start date.

For submissions at 5 weeks or 4 weeks for trusted providers, a late fee will be applied.

IMPORTANT NOTICE:

Every time there is a delay in the process for which the applicant is responsible (i.e. the EACCME® admins/reviewer(s) have questions for the applicants for which an answer is pending…), the clock stops and the delay is not included in the above schedule.

Moreover if an application is not fully complete at the latest 2 weeks prior to the start of the CME/CPD activity, the application will be automatically rejected with no refund and no possibility to appeal.

Submission process

- ✓ The only application form that will be accepted is that made available at the ACI website: https://www.myebr.org/aci/application-for-ecmec#blended-form
- ✓ No applications sent on paper will be considered.
- ✓ As applications can only be received in English, applicants will be responsible for the translation of all submitted materials.
- ✓ For some countries or specialties specific regulations might apply. Please check EACCME website for further information.

In order to have an application for accreditation considered by the ACI/EACCME®, the applicant must:

- ✓ submit a fully completed application, in English, using the specific application form made available by the ACI Accreditation department via email with all relevant attachments and full payment for the application;

- ✓ ensure that suitable information has been provided for each of the essential criteria;
- ✓ provide confirmation by the medical officer who is taking responsibility for the application.

- ✓ provide confirmation by the Head of the Scientific and Organising Committee who is taking responsibility for the scientific programme.

The ACI/EBR and EACCME® commits to:

- ✓ providing, on its website, an ACI application form, based on the criteria set out in this paper;
- ✓ ensuring confidentiality regarding the application submitted;
- ✓ confirming for the applicant, at his/her request, the following dates:
  - on which the EACCME® application was made by the ACI,
  - on which the EACCME® application was complete,
  - on which the application fee was cleared,
  - the "starting date" – on which the EACCME® has begun its evaluation
  - completing the accreditation within the time specified
- ✓ following the accreditation process;
- ✓ providing, at the request of the Applicant, a progress record of the application;
- ✓ publishing, on the EACCME® and ACI website, the list of accredited educational materials.

Criteria and decision-making for accreditation

1. The Material and the application form will be reviewed simultaneously by the two EACCME® designated evaluation bodies:

a) the National Accreditation Authority (NAA) of the country within which the LEE will be held; and
b) the relevant Speciality-based organisation, whether UEMS Section and Board, or partner European Speciality Accreditation Board (ESAB), in this case, the Accreditation Council in Imaging (ACI).

The EACCME® will be solely responsible for appointing these designated evaluation bodies.

2. **For a positive decision** by the EACCME® designated evaluation bodies, **all essential criteria set out in this document must be confirmed.** The two designated evaluation bodies also will be required to confirm whether, according to their assessment of the information provided, the application is for an activity that fits within the UEMS definition of a BLD, and whether the stated learning objectives are likely to be achieved.

The NAA role is first and foremost to check if the application is compatible with the regulations in place where the LEE is held while the UEMS Section/Board or relevant ESAB conducts the scientific specialist review.

3. In order for the ACI/EACCME® to accredit the material, both designated evaluation bodies must support the application.

Amendment Procedure

1. The EACCME® recognises that some applications will fulfil almost all the criteria needed for accreditation but may not achieve the standard required for a small number of criteria. In accordance with its remit to encourage the improvement of the quality of CME/CPD, the EACCME® will permit the applicant, following request by the EACCME®, one opportunity to provide additional information.

2. Following activation of the amendment procedure, the clock for the processing time will stop pending receipt of the requested information or documents from the applicant, and the deadline for EACCME® to provide their decision will be extended accordingly. Other than through the mechanism of appeal (see below), this decision by the EACCME® shall be final.

Automatic Reconsideration

Should the two EACCME® designated evaluation bodies differ in their assessments, an automatic reconsideration will be triggered by the EACCME® system. This automatic reconsideration will be performed at no further cost to

the applicant and will be completed within the timescale applicable for a regular review. Automatic reconsideration will involve review by the two EACCME® designated evaluation bodies and the Secretary-General of the UEMS (or his/her nominee).

Appeal

1. Should both EACCME® designated evaluation bodies reject the application, the applicant may still appeal.

   A decision to appeal must be lodged within one week and must be accompanied by full payment of the appeal fee. The appeal process will require a further two weeks from the date that the appeal was received.

The fee will be €310,20 for all such appeals. In the case of a positive appeal, the appeal fee will be refunded.

2. The mechanism of the appeal will be:
   - the Secretary General of the UEMS (or his/her nominee) will review all the information provided on the application form, any supplementary permissible correspondence and may ask for additional information to all parties involved. The Secretary General will discuss the application with the two EACCME® designated evaluation bodies for the initial review, if needed;
   - the appeal decision of the EACCME® will be final.

V.3. OUTCOMES

1. Until confirmation of accreditation has been sent to the provider, the only permissible statement that can be made by the CME/CPD provider on material related to the educational material is **"An application has been made to the UEMS/EBR for** CME/CPD **accreditation of this educational material".**

2. Confirmation of accreditation of the educational material by the UEMS/EBR will permit the Provider to use a statement to this effect (prepared by the EACCME®) on and within the material. This will be confirmed on the EACCME® website, where the maximum number of ECMEC®s granted will be stated. **Only after confirmation of accreditation has been received can the provider use the UEMS-EACCME® and EBR logos on material related to the educational material.**

   The UEMS-EACCME® logo may only be used in conjunction with, and in proximity to, the EACCME® accreditation statement and must not be associated with any commercial logo.

   The UEMS-EACCME® logo cannot be used in notices, advertising, or promotion of activities other than in association with the EACCME® accreditation statement.

3. **Accreditation by UEMS/EBR of an educational material will be for the specific educational material designated on the application form**. It is not permissible to transfer this accreditation to any other educational material.
4. Where a website, an electronic communication or a printed material lists EACCME®-accredited educational materials along with non-accredited educational materials, the provider must assure that learners can easily recognise the accreditation status. Listing an educational material not accredited by the EACCME® in a misleading way, suggesting that EACCME® has also accredited it, will lead to withdrawal of accreditation.

V.4. MAJOR CAUSES FOR REJECTION OF AN APPLICATION AT THE LEVEL OF INITIAL REVIEW

1. Failure by a provider to disclose the means of funding of an educational material will lead to rejection of the application.

2. Grossly or significantly inaccurate attendance declarations will lead to

automatic rejection of the application and any future application.

3. The Applicant must not attempt to influence the decision of the EACCME®. Specifically, any attempt to contact the reviewers of the application will result in automatic rejection of the application and forfeiture of the fee.

4. The use of any statement by the provider that suggests that accreditation has been granted, or has been provisionally granted while the application review process is not yet completed with positive outcome will result in automatic rejection of the application.

5. Any unauthorised/inappropriate use of the UEMS-EACCME® or EBR-ACI logo will result in action being taken by the UEMS or EBR respectively.

V.5. ALLOCATION OF EUROPEAN CME CREDITS (ECMEC®s)

Live educational events (LEEs):

The EACCME® awards ECMEC®s on the following basis:

30 minutes (30 minutes of educational activity) = 0.5 ECMEC®

Each additional half hour will be granted 0.5 ECMEC® with a maximum of 8 ECMEC® per day of the LEE.

Doctors must only claim ECMEC®s for those LEEs, or parts of LEEs that they have attended, and should ensure that they do so in accordance with their home country's criteria.

E-learning materials (ELMs):

The EACCME® awards ECMEC®s on the following basis:

30 minutes (30 minutes of educational activity) = 0.5 ECMEC®

Each additional half hour will be granted 0.5 ECMEC® with a maximum of 3 ECMEC® per module.

V.6. FEES AND PAYMENT POLICY

The fee for an application to the EACCME® for the accreditation of Blended Learning is determined in accordance with the expected total attendance of Learners and is not dependent on the number of ECMEC®s awarded. As with any contractual agreement, all invoices must be paid.

The EACCME® scale of fees for Blended Learning is:

From 1 to 50 participants	€ 929,5
From 51 to 100 participants	€ 1.049,4
From 101 to 250 participants	€ 1.175,9
From 251 to 500 participants	€ 1.577,4
From 501 to 1000 participants	€ 2.036,1
From 1001 to 2000 participants	€ 3.205,4
From 2001 to 5000 participants	€ 5.057,8
More than 5000 participants	€ 7.522,9

The EACCME® scale of late fees for Blended Learning is:

From 1 to 50 participants	€ 1.056,0
From 51 to 100 participants	€ 1.238,6
From 101 to 250 participants	€ 1.422,3
From 251 to 500 participants	€ 2.013,0
From 501 to 1000 participants	€ 2.718,1
From 1001 to 2000 participants	€ 4.134,9
From 2001 to 5000 participants	€ 6.910,2
More than 5000 participants	€ 10.608,4

The **Recording option** is available for the regular application fee and the late application fee and is **25% of the total fee**.

The above fees are VAT excluded.

The Applicant will have no right to reduce the expected number of participants after submission of the application.

The EACCME® reserves the right, in its sole discretion, to change its fees at any time. An application already submitted will be charged at the rate applicable at the time that it was made.

In some specialties, the UEMS-EACCME® has particular agreements with European Specialty Accreditation Boards (ESABs). Through mutual agreements with each of these, the UEMS-EACCME® will submit all eligible applications in these fields to the relevant ESAB for their specialist review see EACCME® website). Accordingly, ESABs are entitled to issue an invoice to providers in order to cover for their specific administrative tasks and provisions for quality assurance in their CME/CPD events.

The applicant will have no right to reduce the expected number of participants after submission of the application.

The EACCME® reserves the right, in its sole discretion, to change its fees at any time. An application already submitted will be charged at the rate applicable at the time that it was made.

V.7. APPLICATION FOR PROVIDERS

The information to complete the application form are listed in **Annex 7** (check list of information to be met by the Providers)

V.8. SANCTIONS

Sanction if the final programme of the educational material is not compliant with EACCME® criteria.

If the final programme that will be distributed to the participants in the educational material in a printed or electronic form differs from that accredited by EACCME® for this educational material and is not compliant with the EACCME®'s criteria, the provider will be fined (€ 550) and will not be allowed to apply for accreditation for:

- The following edition of its event in the case of an annual event
- The next 6 months in the case of any other event

V.9. INSTRUCTIONS REGARDING EVENT MATERIAL SUCH AS ANNOUNCEMENTS, POSTERS, PROGRAMME BOOKLETS, WEBSITES, WEBSITE PROGRAMMES, ETC.

Annex 4 contains the instructions regarding sponsors and event material.

PART VI- GENERAL DISPOSITIONS OF THE PROCEEDING FOR THE ACCREDITATION OF LEEs, E-LEARNING MATERIALS AND BLENDED LEARNING

VI.1. TERMINOLOGY AND INTERPRETATION

Unless the context otherwise requires, each of the following words and expressions in these Terms and Conditions shall have the following meaning:

"**Terms and Conditions**" refers to the present terms and conditions with all schedules and annexes (if any).

"**Applicant**", "**You**" and "**Your**" refer to the natural person or legal entity accessing this website and applying for the UEMS-EACCME® accreditation system of educational materials pursuant to the online process provided on the website https://eaccme.uems.eu.

"**The UEMS-EACCME®**", refer to the Belgian international non-for-profit organization Union Européenne des Médecins Spécialistes AISBL, having its registered seat at B-1040 Brussels (Belgium), Rue de l'Industrie, 24 and registered under the legal entity register (RPR Brussels) of the Crossroads Bank for Enterprises under no. 0469.067.848.

"**Party**", "**Parties**", or "**Us**", refer to both the Applicant and Ourselves, or either the Applicant or Ourselves.

Unless the context otherwise requires, (i) words importing the singular shall include the plural and vice versa, (ii) all references to a provision of law include a reference to that provision as amended or re-enacted, (iii) all references to a "party" include references to its permitted assigns and transferees and its successors in title, and (iv) headings contained herein are for ease of reference only.

VI.2. SCOPE

These Terms and Conditions shall apply to the accreditation application made by the Applicant through the ACI/EBR website https://www.myebr.org/aci/application-for-ecmec and shall govern any service or any product supplied by the ACI/EBR to the Applicant in this framework, unless specifically agreed otherwise in writing by the Parties.

By making an application, the Applicant, to the fullest extent permitted by law, waives irrevocably and unconditionally the application of its own terms and conditions to the ACI/EBR accreditation application launched by it.

VI.3. INTELLECTUAL PROPERTY RIGHTS

Copyrights and other relevant intellectual property rights exist on all texts relating to EBR/UEMS and/or EACCME® and the full content of the website of EBR shall always remain the exclusive and entire property of EBR/UEMS and/or EACCME®.

The EBR, UEMS and EACCME®´s logos, brands names and specific features in the website of the EBR are registered trademarks of the EBR, UEMS and/or EACCME® in the European Union.

Only after the confirmation of accreditation has been made the Applicant is allowed to use the EBR/UEMS and EACCME® logos on material related to the LEE or ELM. Any unauthorized use of these logos will result in action being taken by the EBR/UEMS, including, but no limited thereto, legal proceedings.

VI.4. CONFIDENTIALITY

The Applicant commits not to inform or disclose to third parties any confidential information regarding the EBR/UEMS and/or EACCME®, its contractors, employees, suppliers, representatives, advisors, agents and/or any related company, except in case of a prior express consent in writing by the EBR/UEMS and or EACCME®. This obligation shall apply throughout the duration of the contract between EBR/UEMS and the Applicant a well as for a period of five years following the end of the contract.

Confidential information is all information and documents that are exchanged between the EBR/UEMS and the Applicant, either oral or spoken, regardless of their nature, and whether or not these are marked as confidential.

VI.5. PRICES

The fee for a EBR/UEMS accreditation application relating to a live event and to an e-learning module and blended learning is determined according with the principles set forth in the "Accreditation of Live Educational Events by the EACCME®"(LEE)" and the "EACCME® Criteria for the Accreditation of E-Learning Materials (ELM)" and the EACCME® Criteria for the Accreditation of Blended Learning documents that are available through the following link: https://eaccme.uems.eu.

These documents are an integral part of the present Terms and Conditions. The Applicant acknowledges that it has real such documents and undertakes to comply with their applicable terms.

The fee for a EBRS/UEMS accreditation application relating to an **e-learning material** is determined in accordance with the number of modules. The Applicant shall submit in good faith the number of modules for the accredited e-learning material. When the Applicant submits a number of modules below the number of actual modules, the EBRS/UEMS will send an additional invoice based on the actual number of modules.

The fee for a EBRS/UEMS accreditation application relating to **an educational material** is determined in accordance with the expected total attendance of learners. The Applicant shall submit in good faith the number of learners expected to attend the accredited educational material. When the Applicant submits a number of learners below the number of actual learners, the EBRS/UEMS will send an additional invoice based on the actual number of learners who attended the educational material.

The fee for a EBRS/UEMS accreditation application relating to **a live event** is determined in accordance with the expected total attendance of learners. The Applicant shall submit in good faith the number of learners expected to attend the accredited live educational event. When the Applicant submits a number of learners below the number of actual learners, the EBRS/UEMS will send an additional invoice based on the actual number of learners who attended the live educational event.

Any tax of any kind on the fee payable to EBR/UEMS shall be borne by the Applicant in accordance with any applicable regulation.

The Applicant shall provide correct billing information, and in case of a VAT exemption, the certifying documents proving such exemption.

The UEMS/EBR reserve the right, in its sole discretion, to change its fees at any time. An accreditation application submitted before a modification of the fee will be charged at the rate applicable at the time that it was made.

The Applicant acknowledges and agrees that the review by UEMS/EBR of accreditation application shall only start if the fee has been entirely paid.

VI.6. PAYMENT

Bank transfers are acceptable methods of payment. In the case of a bank transfer our terms are payment in full and free of bank charges within seven days of the date of receipt of the invoice. Provision of service by the UEMS /EBR will only be performed upon receipt of the full payment upon submission.

Any delay in payment shall give rise to interests on the account of late payment, according to Spanish Law. EBR reserves the right to seek recovery of any monies remaining unpaid sixty days from the date of invoice via debt collection agencies and/or through court. In such circumstances, Applicant shall be liable for any and all additional administrative and/or court costs.

If the Applicant fails to pay an invoice at its due date, the UEMS/EBR reserves the right to suspend the processing of any pending or future application until full payment.

VI.7. LIABILITY

To the fullest extent permitted by law, except in the case of intentional negligence or misconduct on its part, UEMS/EBR excludes all liability for damages arising out of or in connection with your application and/or the use of ACI website. This includes, without limitation, direct loss, loss of business or profits (whether or not the loss of such profits was foreseeable, arose in the normal course of things or Applicant have advised of the possibility of such potential loss), damage caused to your computer, computer software, systems and programs and the data thereon or any other direct or indirect, consequential and incidental damages.

To the fullest extent permitted by law, the Parties agree that the total liability of the UEMS/EBR for damages that are the consequence of its failure to fulfil the contract shall, in any case, be limited to DATA.

The Applicant shall indemnify and hold harmless the UEMS / EBR and EACCME®, its employees and its contractors and agents from and against any and all liability to a third party, if exceeding or different from its liability to the Applicant.

VI.8. TERMINATION OF AGREEMENTS AND REFUNDS POLICY

The Applicant has the right to terminate any service agreement for any reason, at any time, including the ending of services that are already underway in accordance with the rules contained in this section of the Terms and Conditions. No refund will be provided.

In case of serious breach of these Terms and Conditions which is not remedied within 5 days of notice by UEMS/EBR to the Applicant, the UEMS/EBR shall have the right to terminate a service agreement without compensation. This termination shall be notified in writing to the Applicant. No refund shall be offered, and the UEMS/EBR reserves the right to claim an additional compensation from the Applicant by reason of any loss caused by his/her/its misconduct.

VI.9. CANCELLATION POLICY

The UEMS/EBR will permit an application to be withdrawn within one week of submission for any reasonable reason provided by the Applicant and will return the application fee if it was already paid, unless the application has already been sent to review . The Applicant will be charged with a processing fee and any bank charges that are incurred.

After one week, it will not be possible to withdraw the application or receive reimbursement for cancellation except in exceptional circumstances to be duly justified by the Applicant and upon written acceptance of EBR/UEMS. However, in accordance with the amendment procedure it will be permissible to make necessary and appropriate changes to the information submitted.

If an application is not fully complete at the latest 2 weeks prior to the start of the CME/CPD activity, the application will be automatically rejected with no refund and no possibility to appeal.

If an application is not fully complete prior to the start of the ELM activity, the application will be automatically rejected with no refund and no possibility to appeal.

VI.10. REJECTION POLICY

In the case of a rejection of an application, UEMS/EBR will not refund the paid fee at the time of application.

VI.11. POSTPONEMENT POLICY

Before an application has been sent to review, whether it has already been paid or not, it is possible to postpone it upon written notice to the UEMS/EBR, without any additional charge or fee.

Once the application has been sent to review, the UEMS-EACCME® will not accept any change except for one postponement. Any other change will be evaluated on a case-by-case basis and may require a new submission.

VI. 12. INCOMPLETE APPLICATION POLICY

If the Applicant does not complete his/her/its application within the deadlines set by this Terms and Conditions, the application will be automatically rejected without any reimbursement.

VI. 13. DATA PROTECTION AND PRIVACY

1. EBR agrees and undertakes to comply with all applicable EU and national legislation in the field of personal data protection and privacy laws and in particular Spanish Fundamental Law 15/1999, dated December 13th, on Protection of Personal Data and its corresponding regulations (Law 3/2018 of December 5, on Personal Data Protection), and from May 25, 2018, the Regulation (EU) 2016/679 of the European Parliament and of the Council, of 27 April 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation, GDPR).

2. Providers allow the EBR to store and treat their personal data. The EBR shall not use such personal data for purposes other than those related to the ACI /EACCME accreditation herein listed:

    a. Purpose I: management of the providers applications for the accreditation of their live educational events or e-learning materials.
    b. Purpose II: EBR communications relating information and advertising of products and services of the company, under the express consent of the candidate.

3. Any provided data will be kept for the period of duration of the accreditation process in which it was collected and during the period in which the contractual relationship between the user and EBR remains in

force, as well as for as many required years as to comply with legal obligations. Any data processing relating Purpose II (advertisement and communications) shall not exceed a period of THREE (3) years since the date the event/ e-learning material was accredited.

4. The provided data will not be transferred to third parties except in cases in which there is a legal obligation to do so or in which we have obtained your previous and express consent. EBR ensures that its employees and subcontractors who obtain or have access to such personal data comply at all times with the applicable legislation in terms of privacy and protection of personal data and have undertaken the same obligations as the relevant Party has under the present Agreement; supervises the Data Processing, which shall be performed under a legitimate interest; and undertakes to conduct, when applicable, Risk Analysis or Impact Assessment (DPIA) on Data protection.

5. Providers may exercise their right of information, access, rectification, cancellation, opposition, deletion, transmission, limitation of the processing and to not be subject to automatic individual decisions in relation with their personal data. The exercise of these rights must be made in writing, to the following contact details:

   Responsible: EUROPEAN BOARD OF RADIOLOGY, S.L.

   NIF: B-65668006

   Mailing address: Av. Diagonal, 383, SA. 08008 Barcelona (Spain)

   Email: administration@myebr.org

VI.14. FORCE MAJEURE

Neither party shall be liable to the other for any failure to perform any obligation under any agreement which is due to an event beyond the control of such party including but not limited to any terrorism, war, political insurgence, insurrection,

riot, civil unrest, act of civil or military authority, uprising, earthquake, flood or any other natural or man- made eventuality outside of his/her/its control, which causes the failure to perform any obligation or the termination of an agreement or contract entered into, nor which could have been reasonably foreseen.

Any Party affected by such event shall forthwith inform the other Party of the same and shall use all reasonable endeavours to comply with the terms and conditions of any agreement contained herein. The obligations of the affected Party shall be reduced and deadlines shall be prolonged for the duration of the force majeure. Both Parties shall use all reasonable endeavours to limit the consequences of the force majeure on the contract or the agreement as much as possible.

VI.15. WAIVER

Failure of either Party to insist upon strict performance of any provision of this or any agreement contained in these Terms and Conditions or the failure of either Party to exercise any right or remedy to which it is entitled hereunder shall not constitute a waiver thereof and shall not cause a diminution of the obligations under this or any agreement. No waiver of any of the provisions of these Terms and Conditions or any agreement shall be effective unless it is expressly stated to be such and signed by both Parties.

VI.16. SEVERABILITY

If any of the present provisions are deemed invalid or unenforceable for any reason (including, but not limited to the exclusions and limitations set out above), then the invalid or unenforceable provision will be severed from these Terms and Conditions and the remaining provisions will continue to apply. The Applicant and UEMS/EBR shall negotiate in good faith in order to replace the invalid or unenforceable provision by a valid and enforceable one, which should be as close to the purpose of the original one as possible.

Failure of the UEMS/EBR to enforce any of the provisions set out in these Terms and Conditions and any agreement, or failure to exercise any option to terminate, shall not affect the validity of these Terms and Conditions.

VI.17. COMMUNICATION

The **EBR** registered office is located at Av. Diagonal 383, SA 1a, 08008 Barcelona, SPAIN. The EBR is registered in Spain in Barcelona. Commercial Register, under book 42.942, page 117, number B-420225, NIF-B65668006.

Email: accreditation@myebr.org

Other contact information, can be requested on our Contact Us link on our website.

The **UEMS** registered office is located at Rue de l'Industrie, 24, BE-1040 Brussels, BELGIUM. The UEMS-EACCME® is registered in Belgium under the registration number: 0469.067.848

VI.18. AMENDMENTS

These Terms and Conditions shall not be amended, modified, varied or supplemented except in writing and signed by duly authorized representatives of the UEMS/EBR.

UEMS/EBR reserves the right to change these Terms and Conditions from time to time as it sees fit it being specified that an accreditation application submitted before a modification of the present Terms and Conditions shall remain governed by the terms and conditions applicable at the time that it was made.

VI.19. CHOICE OF LAW AND JURISDICTION

The laws of Spain govern exclusively these terms and conditions and all relationships between the UEMS/EBR and the Applicant.

Any disputes arising from any agreement subject to these Terms and Conditions are under the exclusive jurisdiction of the courts and tribunals of Brussels.

ANNEX 1. Requirements for the accreditation of a CME/CPD activity (LEE)

All the criteria below are ESSENTIAL criteria.

THE PROVIDER MUST:

1. **Structure the LEE to fulfil defined educational needs.**

This confirmation must demonstrate that a "needs assessment" process has been performed, that these educational needs have been defined, and will be fulfilled.

A needs assessment must be carried out prior to the development of a CME/CPD activity. The process of aneeds assessment is designed to identify the gap between a current situation and a desired situation.

There are different types of needs assessment:
- Evaluation results from a previous activity
- Surveys of potential participants
- Publication of a new clinical guideline or new research
- Legislative/regulatory/organizational changes affecting patient care…

The discrepancy between the current situation and desired situation must be measured to appropriately identify the need. The need can be a desire to improve current performance or to correct a deficiency.

A short description of this needs assessment process and derived educational needs must be provided.

2. **Define the "principal intended recipients" for whom the LEE is most likely to be suitable.**

The principal intended recipients must fall within the remit of the UEMS-EACCME® (fully qualified medical specialist doctors). The principal intended recipients must therefore be explained in terms of medical specialty and seniority of the learner.

The UEMS (recognized) medical specialities can be found here: www.uems.eu.

In addition to fully qualified medical specialist doctors, an EACCME® accredited event is open to all interested medical and other healthcare professionals.

EACCME® certificates can therefore be distributed to any other healthcare professional attending the accredited event (i.e. nurses, pharmacists, clinical scientists …) who wishes to benefit from EACCME® credits. It is expected that the healthcare professional's association will recognise the EACCME® credits ona voluntary basis.

EACCME® certificates can also be distributed to speakers for the duration of their attendance as any other participant. They may also request credits for delivering a presentation (see UEMS 2023.10 "EACCME Recognition of CPD/CME activities" – Learning by Teaching).

3. **Identify and communicate the expected educational outcome(s) of the LEE.**

An expected educational outcome is a formal statement of what participants are expected to learn in an event. Expected learning outcome statements refer to specific knowledge, practical skills, areas of professional development, attitudes, higher-order thinking skills, etc. that faculty members expect participants to learn, develop or master after attending the event.

When defining an event's learning outcomes, action verbs must be used to express what participants will
be able to do, e.g., analyse, create, compare, evaluate.

Example: "After attending the event, participants will be able to + action verb + something."

A list of educational outcomes must be provided.

4. **Provide the title of the LEE, its venue, date(s), and a clear description of the nature of theevent.**

Title: must be identical with the title used in all materials related to the event. It is not permissible to have
an industrial sponsor's or a commercial product's name in the title of the event.

Venue:

- Town, country where the event will take place in the case of a physical event
- Town, country where the CME/ CPD provider is located in the case of a virtual event / webinar

Events held in the facilities of any commercial company, such as a pharmaceutical/medical/surgical devices/software companies, are not eligible for EACCME® accreditation.

When the LEE is virtual and taking place on a member-only website/platform, the provider must provide login details so that the EACCME® is able to assess the LEE content.

The EACCME® deals with the accreditation of international events in Europe and outside of Europe (with the exception of the USA and Canada with which the EACCME® has agreements of mutual recognition of credits).

For international events in Europe the EACCME® will seek to have the approval from the National Accreditation Authority of the country where the event takes place and with which the EACCME® has a signed agreement.

For all those countries with which the EACCME® does not have a signed agreement, the EACCME® strongly recommends to also apply for accreditation with the National Accreditation Authority of that country to ensure that local participants receive their credits.

The list of countries with which the EACCME® has signed an agreement is available on the EACCME® platform under the section related to "Collaborations".

For international events outside of Europe the EACCME® accepts to consider such applications if European participants and/or faculty attend the event.

However, the EACCME® encourages the accreditation of international events outside of Europe even though there are no European participants and no European faculty. In this case EACCME® accreditation is considered as a "mark of excellence". For those events the EACCME® will apply the ~~standard~~ EACCME® criteria. These events should attract participants from several countries.

Date: EACCME® will accept one set of consecutive dates per event. A separate application must be submitted for each repetition of the same event.

Courses run on non-consecutive dates will be accepted as one application if the course meets the following conditions:

- One single registration fee for the entire course
- Participants must attend all sessions
- The course takes place within a period of 12 months

All individual dates must be provided on the application form at the time of submission.

The EACCME® will not accept any change except for one postponement. Any other change will be evaluated on a case by case basis and may require a new submission.

The applicant will notify the EACCME about the postponement before the original dates of the event. The applicant will have to provide the new date(s) of the postponed event within 12 months of notifying the EACCME office of the postponement and at least 6 weeks before the new starting date of the event. The applicant will send the Director's Declaration with the new event dates and the new programme with changes highlighted (if any) at least 6 weeks before the new dates of the event. Failure to do this will result in the application being automatically rejected.

If the application is in review or in accredited stage and changes have been made to the programme, a new application will have to be submitted.

Nature of the event: You will need to state whether the event is a:

- Pre-congress activity
- Congress
- Post-congress activity
- Conference
- Course
- Hands-on workshop
- Webinar
- Other: applicant needs to clarify…

The EACCME® will **NOT** consider for accreditation commercial/industry-sponsored satellite symposia even if it is stated that they are supported by an independent support grant.

The applicant will also have to confirm whether the event is physical / virtual or

hybrid. Pre-congress and post-congress activities will require a separate

application per activity.

The EACCME® will not accredit parts of a live educational event. The application will have to be for the whole educational event.

The application and programme must be submitted in English.

If the application is submitted 6 weeks (or less) prior to the event, providers are required to submit the final programme booklet in PDF format as distributed to participants at the event.

THE LEE MUST:

5. **Be presented in a manner suitable for an international audience.**

The EACCME® will not consider for accreditation purely local/national events with only local/national participants attending. This is the remit of a National Accreditation Authority.

However, a national event attracting foreign participants may be considered for accreditation by the EACCME®.

The EACCME® accredits international events in the whole world (except for the USA and Canada) as long as the event attracts participants from several countries and the programme submitted with the application is available in English.

International terminology for procedures and therapeutic agents must be used.

6. **Include methods to promote active, adult learning.**

The EACCME® encourages the use of methods promoting adult active

learning.The methods used can be one or a combination of the following:

- Discussion time
- Quiz
- Q&A session
- Training session
- Groups
- Open space
- Electronic communication
- Other: applicant needs to clarify.

7. **Be conducted in compliance with all relevant ethical, medico-legal, regulatory, industry-based and legal requirements.**

THE PROVIDER MUST:

8. **Provide detailed information on the duration of the LEE.**

The provider will need to state the starting time and ending time for each day of the programme (including lunch breaks and coffee breaks), together with the number of educational hours per day and for the whole event.

Only purely scientific sessions will be considered for accreditation.

Therefore, commercial sessions, coffee/lunch breaks, non-scientific opening/closing ceremonies, assessments etc. will not be awarded ECMEC®s.

9. **Indicate the mechanism(s) by which it will be verified that the learner has engaged**

with the LEE in order to fulfil the educational objective(s).

Simple registration of attendance at the event is not sufficient.

As the CME/CPD provider must deliver the number of credits to participants based on their actual attendance, providers are required to monitor the presence of each participant for each session of the event. Differentmethods can be used: attendance list, scanning system, etc.

For virtual events, the participant's online attendance must also be monitored through a tracking system. Further methods could include pop up questions during the event, short evaluation questionnaire after each session, etc.

Providers will need to explain how the participants' attendance is monitored during the event and to include in the learner's feedback form questions related to the relevance of the content and speakers.

10. Provide a short description of the Provider organisation(s).

The applicant must submit a short description of the CME/CPD provider, and any other organisation the CME/CPD provider is working with in regard to the LEE. Where the provider is a CME/CPD company producing a programme on behalf of or supported by another organisation, their relationship must be fully disclosed and any funding should be in the form of an independent support grant although it is also acceptable for some funding to come from other sources, eg. fees for exhibition booths (see Annex 1 criterion 17).

Events submitted by a CME/ CPD provider on behalf of industry (e.g., pharmaceutical or medical device companies) **will NOT** be considered for accreditation by EACCME®.

Events submitted by industry (e.g., pharmaceutical or medical device companies) **will NOT** be consideredfor accreditation by EACCME®.

11. Provide the name, title and contact details of a medical officer who will take responsibility for the application for accreditation of the LEE and ensure that the medical officer provides a written declaration of perceived or actual conflicts of interest.

The medical officer must be a specialist doctor in activity and his/her registration number with a Medical Regulatory Authority must be provided as well as the name of that authority

By Medical Regulatory Authority we mean the authority in a country that delivers to doctors the license topractice medicine in that country.

The medical officer (MO) taking responsibility for the application may be the Head of the Scientific and Organising Committee, one of its members or any specialist doctor willing to take responsibility for the application.

From the EACCME®'s point of view, this person is responsible for the event.

This person will be the one completing and signing the director's declaration to be provided at the time of
the application.

The medical officer (MO) taking responsibility for the application declares, on behalf of the

Director of theCME/CPD programme, that:

- The scientific programme was developed under his/her supervision and responsibility, and presents a scientifically balanced perspective of the subjects included;
- The programme complies with all relevant ethical, medico-legal, regulatory, industry-based and legal requirements applicable in the country where it is being held;
- All members of the Scientific and Organising Committee have provided a declaration of perceived or actual conflict of interest;
- The Scientific and Organising Committee has determined the content of all aspects of the LEE to be free of any attempt by sponsors to influence the Committee's decisions;
- He/she is aware of the source and form of any funding received to develop this programme and confirms that any educational material is free of any form of advertising and any form of bias;
- All faculty and other speakers at this scientific event have disclosed, or will disclose, any perceived or actual conflict of interest. This will be published, and stated at the beginning of their presentation(s);
- He/she will ensure that the applicable national rules, regulations and industry standards regarding exhibition areas where companies are permitted to present their products will be enforced;
- He/she is a medical practitioner, registered with a Medical Regulatory Authority and has provided his/her registration details to the EACCME®.

12.Provide the name(s), job title(s) and contact details of the head, and all other members of the Scientific and Organising Committee.

This includes the members of the Scientific and Organising Committee listed on the event website. No member of staff/doctor/professor working for the industry is allowed to be on the Scientific and Organising Committee.

13. Ensure that all members of the Scientific and Organising Committee provide written declarations of perceived or actual conflicts of interest.

Conflict of interest: A set of conditions in which judgment or decisions concerning a primary interest (for example a patients' welfare, the validity of research and/or quality of medical education) is unduly influenced by a secondary interest (personal or organizational benefit including financial gain, academic or career advancement, or other benefits to family, friends, or colleagues).

A perceived conflict of interest: A perceived conflict of interest occurs when an individual or institution may reasonably be understood by a third party as having two competing interests, one of which is likely to interfere with or undermine a researcher's/institution's ability to fulfil its responsibilities as a researcher or research institution. Whereas **an actual conflict of interest** occurs when an individual or institution has two competing interests, one of which is likely to interfere with or undermine a researcher's/institution's ability to fulfil its responsibilities as a researcher or research institution.

At the time of application, only the Head of the Scientific and Organising Committee and the medical specialist responsible for the application must submit a completed conflict of interest form. The medical specialist in charge will declare, in the Director's declaration, that they have received and reviewed the conflict of interest forms from all other members of the Scientific and Organising Committee and the faculty.

Each form should include the individual's perceived or actual conflicts of interest for the last three years. The COI forms must be dated and signed by hand or an authenticated or certificate-based electronic signature. COI declarations signed more than 6 months before the date of the event will not be accepted.

The EACCME will accept documents electronically signed as long as they meet the European requirements for advanced electronic signatures AdES.

The list of perceived or actual conflicts of interest of the members of the Scientific and Organising Committee must be made available online on the event website. EACCME® reviewers may ask for the COIs of any of the known faculty at the time of submission if needed.

The COI template will be made available by the ACI.

Providers who have been granted the status of "Trusted Provider" do not need to supply the COI forms at the time of submission of the application but the forms have to be completed before the LEE takes place and have to be available for an on-site control by the EACCME®.

14. Ensure that all members of the faculty provide written declarations of perceived or actualconflicts of interest.

All members of the faculty must provide written declarations of COI. These declarations do not need to be submitted at the time of the application but must be made available in case of control by the EACCME® or its reviewers. Reviewers may ask for the COIs of any of all known speakers at the time of submission if needed.

15. Confirm that all actual conflicts of interest have been resolved.

This criterion is applicable to all members of the Scientific and Organising Committee and faculty (including chairpersons, moderators, presenters…) and is the personal responsibility of the Head of the Scientific Committee.

The provider must ensure that all actual conflicts of interest have been resolved. This can be done in several ways:

- Every faculty member must provide a declaration of perceived or actual conflicts of interest as a second slide of his/her presentation.
- The feedback form completed by participants must include a question on the faculty's bias.
- The list of perceived or actual conflicts of interest of all members of the Scientific and Organising Committee and faculty must be made available in the programme and on the event website.
- Member of the Scientific and Organising Committee or faculty is excluded from the preparation of the scientific programme.

16. Provide the latest version of the programme of the LEE at the time of application.

When applying, the programme that Providers have to upload is the document intended for the participants.

The programme must contain as a minimum:

- title of the event;

- venue of the event;
- date of the event;
- titles of individual sessions / lectures, etc.
- start and end time of individual lectures, workshops and sessions, etc. In cases in which the eventis held in more than one time zone, this information should be provided in the CET time zone;
- name and affiliation of faculty members (including chairpersons, moderators, presenters…) alongside their respective sessions. This information must also be provided in the application in the designated field.

Sessions for which these details have not been provided will not receive accreditation.

As a general rule, it is not permissible for a member employed by, in contractual relationship with or otherwise representing the industry to be on the scientific programme. In specific situations (ground- breaking scientific investigation, exceptional scientific merit, etc.), dependent on the approval of the EACCME®, a member employed by, in contractual relationship with or otherwise representing the industry may be exceptionally allowed to be on the scientific programme. In this case, the speaker's affiliation mustbe clearly presented at the beginning of the session, under the form of a COI declaration.

In specific situations, dependent on the approval of the EACCME®, representatives from industry may be exceptionally allowed to be on the scientific programme:

1. Where the content of the talk is not related to the business lines or products of their company, or
2. The content of the accredited activity is limited to basic science research, such as preclinical research and drug discovery, or the methodologies of research, and they do not make care recommendations.

In this case, the speaker's affiliation must be clearly presented at the beginning of the session, under the form of a COI declaration.

If the event is organised in parallel sessions, a summary programme at-a-glance (table form) needs to be submitted to clearly show how each day is organised.

Sessions developed for allied healthcare professionals (nurses, psychologists, physiotherapists, etc.) should be stated as such in the scientific programme.

Non-exhaustive examples of sessions that will not be entitled to credits:

- opening / closing sessions
- industry symposia / commercial sessions
- satellite symposia
- poster sessions (unless if part of the scientific programme with a clear timeframe, structure and monitoring)
- oral sessions (if no details are provided)
- awards sessions
- examinations / completion of evaluations forms
- coffee / lunch breaks
- hospital visits (unless if part of the scientific programme with a clear timeframe, structure and monitoring)
- committees or annual general meetings
- social events and/or networking opportunities
- sessions developed for allied healthcare professionals (nurses, psychologists, physiotherapists, etc.)

- etc.

It is the provider's responsibility to ensure that the latest version of the programme is, at all times, made available to the EACCME® via the application page.

Following confirmation of accreditation and before the beginning of the LEE, providers are obliged to inform the EACCME® of any changes made to the programme. The EACCME® will evaluate the new programme and, if deemed necessary, a new application will have to be submitted by the provider.

Once the final programme brochure is available, the provider will **send it to the ACI (accreditation@myebr.org)** no less than one week before the start of the event.

Once the final programme brochure is available, the EACCME® will not permit further changes to the programme. Changes made at this time might lead to removal of accreditation.

When an event website exists, it must contain the event programme.

17. The source(s) of all funding for the LEE must be declared, and be made available to Learners in a readily accessible manner.

The source of all funding must be declared. The name of the sponsor and the type of financial support and sponsorship confirmed or pending must be declared.

Funding can occur via:

- provider's own funds
- participants' registration fees
- an independent grant
- exhibition booths during the event
- commercial symposia organised during the event (not eligible for ECMEC®s)
- advertisements outside the scientific programme
- provision of a range of tools during the event (in-kind support)
- if other: please specify

Independent support grant: Monetary or in-kind contributions given by a commercial interest to a CME/CPD provider that is used to pay all or part of the costs of a CME/CPD activity where the education is independent of their control. The commercial interest is not allowed to have control or influence over the content of the CME/CPD activity nor is it allowed to receive any "benefits" for providing the support.

Sponsorship is a monetary contribution given in exchange for a specific benefit e.g., exhibition booth, space for a commercial symposium, and advertisements outside the scientific programme. The sponsor is not allowed to influence the CME/CPD activity at any level and not allowed to have control over the content. The "benefit" in exchange for the sponsorship must relate to a non-educational component of the meeting.

To ensure full transparency for learners, all sources of funding must be declared at the start of the activity (full instructions on the acknowledgement of sponsors in the event material are available in Annex 4).

The EACCME® reserves the right to ask for the contractual arrangement between the provider and the sponsor(s). Providers are entitled to redact any financial information.
Tobacco/alcohol industry sponsorship of CME/CPD activities will not be permitted.

As far as sponsorship items are concerned, the EACCME® places trust in providers to adhere to relevant ethical codes, such as the "EFPIA Code of Practice on Relationships Between the Pharmaceutical Industry and Patient Organizations" or the "MedTech Europe Code of Ethical Business Practice", just to cite two examples.

The EACCME®'s primary focus lies in ensuring the scientific integrity of events. This entails maintaining meeting rooms free from commercial influence, including advertising and sponsors' branding. For instance, sponsor-branded lanyards and advertisements between scientific sessions will not be permitted within meeting spaces. However, outside of these areas, providers can allow their sponsors to promote their products as desired.

THE SCIENTIFIC AND ORGANISING COMMITTEE MUST:

18. Ensure that the LEE will provide a programme that presents a scientifically balancedperspective of the subjects included.

This must include impartiality in the scheduling of subjects, lecturers and opportunity for discussion.

Where there is a valid evidence base for a specific therapy or agent, this may be stated, but this must be referenced in a manner that is appropriate for a scientific journal. Only generic names will be permitted.

The EACCME® encourages programmes using a number of speakers adequate to the size of the educational material. The EACCME® strongly encourages providers to promote diversity and inclusion when choosing the faculty of the educational material in order to adequately represent society.

Industry-sponsored symposia and/or social activities should not conflict with accredited activities. Industry-sponsored symposia should ideally be organised at the beginning / end of the day and during lunch breaks and should ideally not take place simultaneously with scientific sessions.

Industry-sponsored content must be delivered in a different physical environment from where the scientific content is delivered. When this is not possible, the industry-sponsored content should be delivered at the beginning/end of the day and/or during lunch break. In these situations, the industry-sponsored content should be clearly identified as such.

19. Confirm that it has determined the content of all aspects of the LEE to be free of any attempt
by sponsors to influence the Committee's decisions.

All funding must be provided free of any attempt to influence the programme, individual sessions, subjects for discussion, content or choice of faculty members.

The sponsor cannot be directly involved in the provision of the event. **The sponsor therefore cannot directly**:

- Invite or select participants and speakers
- Cover travel/accommodation/registration costs of participants and speakers
- Take part in the organisation of the event (invitation of participants, registration of

participants,
staffing, catering, speaker's fees…)

- Take part in the development of the scientific programme (no funding company member on the Scientific and Organising Committee, no influence on the choice of the speakers/selection of topics…)
- Be on the scientific programme (no speaker from the industry will be allowed on the scientificprogramme, except in the cases described above);
- Advertise and promote the event via mailing.

20. All educational material must be free of any form of advertising and any form of bias.

The EACCME® will reject any application that, in its opinion, includes advertising of any product or company directly related to any educational material.

Specific examples that will lead to automatic rejection of an application include:

- the use of a sponsor's name, brand name or product name in the title of the scientific programme,
  a scientific session or a scientific lecture;
- the display of brand names and/or individual company logos in scientific lectures or in thescientific programme;
- the name of a speaker from industry in the scientific programme, a scientific session or a scientific lecture; except in specific circumstances as mentioned under criterion 16;
- the use of the brand or product name of the equipment/software used during hands-on sessionsin the title of the scientific programme, a scientific session or a scientific lecture.

Should medical devices/software/equipment appear in the LEE, it is mandatory to use the following statement at the beginning and at the end of the LEE:

> *"Commercial names of medical devices/software/equipment may appear in this content because they arelinked to specific medical procedures, which are the focus of this training material. Other products in themarket can be used to perform the aforementioned medical procedures. The educational provider does not endorse any particular product."*

The EACCME® strongly encourages providers to produce two programme booklets:

1. one for the scientific programme
2. one for the industry-sponsored events and industry acknowledgement/information

When this is not possible, the acknowledgement of sponsors for their financial or material support, the details of industry satellite symposia (title, speakers, sessions, sponsors…) and all advertising components (including the listing of exhibitors) must be placed at the end of the scientific programme booklet, on separate pages from the scientific content.

The event website cannot be hosted on any commercial company website and cannot bear any commercial company logo. The acknowledgement of sponsors for their financial or material support, the details of industry satellite symposia (title, speakers, sessions, sponsors…) and all advertising components (including the listing of exhibitors) will only be allowed under a separate tab clearly identified as dedicated to industry/commercial sponsors.

Full instructions on the acknowledgement of sponsors and sponsored symposia in the event material are available in Annex4.

THE PROVIDER MUST:

21. **Submit information regarding the expected total number of participants attending the LEEand the schedule of registration fees for these learners.**

Expected total number of participants:
This number includes all participants in the event whether they are specialist doctors or not. It also includes speakers and exhibitors/sponsors participating in the event.
The applicant will have no right to reduce the expected number of participants after submission of the application.

Registration fee:
A registration calendar and related fees must be provided upon submission of the application.
An LEE may be provided free of charge but only if all participants are admitted without fee (supported forexample by an independent support grant or subsidised by a scientific society…).

EACCME® does not allow providers to charge an additional fee to participants to issue the EACCME® certificate.

22. **Provide a reliable and effective means for the learners to provide feedback on the LEE, including the extent to which the educational objectives of the LEE were met. The provider must commit to make available to the EACCME® a report on this feedback and on the provider's responses to this.**

Providers must ensure that a feedback form is completed by the participants at the end of the event. Providers must use the EACCME® template of feedback form as a minimum for their post-event forms. Additional feedback questions may be added by the provider if deemed necessary.

The Applicant will provide a copy of the feedback form[1] that will be distributed to participants at the event upon submission of the application.

Participants will only be able to receive their EACCME® accreditation certificate once they have completedthe feedback form. They can only receive the number of ECMEC®s corresponding to their actual attendance.

Based on the participants' individual feedback, the provider must complete **and send to the ACI office.** the EACCME® event report"[1] within four weeks of the completion of the event. Failure to provide feedback could jeopardise recognition of any future applications.

If accreditation has been requested for the recording of the LEE, the event report will be submitted to EACCME® seven months after the completion of the LEE.

Upon completion of the EACCME® event report, if the number of participants reported exceeds by 10% or more the initial number provided at the time of submission, a complementary invoice will

[1] Appendix 1: feedback form to be provided by the ACI via email.

2 Appendix 2: event report form to be provided by the ACI via email.

be produced.

Providers cannot deliver a higher number of certificates than the number of feedback forms received.

Once the event report is sent, no further EACCME® certificates can be distributed to participants.

23. **Confirm that it will comply with the applicable national rules, regulations and industry standards regarding exhibition areas where companies are permitted to present their products.**

The provider has a duty to check if special arrangements regarding accreditation and recognition of CME/CPD credits apply in the country/region where the LEE takes place. The EACCME® strives to monitor local regulations but is not always notified of local changes in a timely manner and the provider has the responsibility to make sure that participants, particularly local participants, will have their CME/CPD credits recognised.

24. **All content within the educational material must be evidence-based. This includes but is not limited to notes on the level of evidence (where applicable), and suitable references.**

25. **The provider must ensure that the educational material is in accordance with the EACCME® criteria prior to application to the EACCME® for accreditation.**

26. **The UEMS-EACCME® will randomly perform quality controls of any type of accreditedevents to ensure compliance with EACCME® accreditation criteria. Ç**

The provider will need to provide free access to the entire event for the persons indicated by the EACCME® as its representatives.

An EACCME® representative is someone carrying an official UEMS-EACCME® document signed by the Secretary-General stating that they are appointed to control the quality of the event.

To perform the control, the EACCME® representative will be able to take pictures and videos. These contents will be for internal use only and not published.

Any identified breach of EACCME® criteria may lead to the removal of EACCME® accreditation after discussion with the Secretary General.

Once a quality control visit takes place, the EACCME® will provide feedback to the provider on any issue ofnon-compliance with EACCME® criteria noted.

ANNEX 2. Quick application checklist for providers

The following information is necessary to complete the application form:

Description of the live educational event

- Event title
  - Please note that the use of an industry sponsor's or a commercial product's name in the event title will lead to automatic rejection of your application.

- Event website
  - The event website cannot be hosted on the industry sponsor's website and cannot bear the industry sponsor's logo (except under a separate tab "sponsor" where the sponsor will be acknowledged).
  - If there is no website for the event, the provider must explain how they are promoting their LEE as well as how they are handling the registration.

- Venue
  - Multiple venues for the same educational event require separate applications.

- Start date – end date
  - Only one date or set of dates is permitted for each event.
  - A separate application must be submitted for each repetition of the same event.

- Duration of the event
  - Please state starting time and ending time for each day of the programme (including lunch breaks and coffee breaks), together with the number of educational hours per day and for the whole event.

- Principal intended recipients
  - Specify the specialty and seniority of the doctor(s) most likely to benefit.

- Main specialty of the event
  - Please select the main specialty of the event. The EACCME® reserves the right to change the specialty of the event.

- Expected total number of participants

- Educational needs

- Expected educational outcomes

- Clear description of the nature of the event

- Methods to promote active, adult learning

- Confirmation of learner engagement

- Compliance with all relevant ethical, medico-legal, regulatory, industry-based and legal requirements

- International audience

- Main language of the event

- Simultaneous translation

Details of the provider

- Short description of the provider organisation(s)
    - The provider must submit a short description of their own organisation, and any other(s) with which they are working

- Medical officer who will take responsibility for the application
    - This specialist doctor must be registered with a Medical Regulatory Authority and his/herregistration details must be provided

Scientific and Organising committee

- Name, professional affiliation(s) and contact details of the Head of the Scientific and Organising Committee who will be personally accountable for the educational content of the event.
- Name professional affiliation(s) and contact details of the members of the Scientific and Organising Committee
- Please explain how any actual conflicts of interest involving members of the Scientific and Organising Committee have been resolved

Faculty

- Confirmation that all members of the faculty have provided written declarations of perceived or actual conflicts of interest

Funding of the LEE

- Sources of all funding
    - Name of sponsor(s) (confirmed and unconfirmed)
    - Type of funding
    - Details of pending applications for funding
- Schedule of fees for learners
- Confirmation that all funding is provided free of any attempt to influence the programme, individual sessions, subjects for discussion, content or choice of faculty members

Promotional material

- Confirmation that all the educational material is free of any form of advertising and any form of bias
- Confirmation that the event complies with the applicable national rules, regulations and industry standards regarding exhibition areas where companies are permitted to present their products

Review by learners

- Means for the learners to provide feedback on the LEE
- Commitment to making available to the EACCME® a report on the learners' feedback and on the provider's responses to these

Contact and billing information

- Contact person for the application
- Billing information

<u>Documents to be uploaded in addition to the application form:</u>

- Latest version of the **programme** including
    - details of faculty members;
    - titles of sessions;
    - start and end time of individual lectures, workshops and sessions;
    - name of every speaker(s)/teacher(s) for each lectures, workshops and session;
    - overall expected learning outcomes.
- **Programme overview** (if available)

- **Director's declaration**
    - To be completed and signed by the medical practitioner taking responsibility for the application
- **Conflict of interest disclosure form**
    - To be provided, completed and signed, for the Head of the Scientific and Organising Committee and the medical practitioner taking responsibility for the application
- **Learner's feedback form**
- **Event report**
    - To be submitted no later than 4 weeks after the event has taken place (or after the recording option is no longer available)
- **Final version of the programme to be submitted no less than one week before the start of the event** (highlighting any differences from the version submittedwith the original application)

ANNEX 3. Quick application checklist for Trusted Providers

Please see “quick application checklist for providers”.

Trusted providers do not need to provide:

- COI disclosure forms for all the members of the Scientific and Organising Committee at the time of the application. However, these must be available at the time of the event for possible control by the EACCME®.
- Payment of the accreditation fee at the time of the application. However, the payment must be received before the finalisation of the evaluation procedure. In case of cancellation, if the application is already reviewed, the payment is due.

ANNEX 4. Instructions regarding event material such as announcements, posters, programme booklets, websites, website programmes, etc.

INDUSTRIAL SPONSORS

All educational material must be free of any form of advertising and any form of bias.

The EACCME® will reject any application that, in its opinion, includes advertising of any product or company directly related to any educational material (essential criterion).

Specific examples that will lead to automatic rejection of an application include:

- the use of a sponsor's name in the title of the scientific programme, a scientific session or a scientific lecture;
- the display of brand names and/or individual logos in scientific lectures or in the scientific programme.

The EACCME® will accept a single page acknowledgement, in the scientific programme, where all sponsors are recognised for their support of the LEE at the end of the programme booklet after the scientific programme. The details of industry satellite symposia (title, speakers, sessions, sponsors…) may only be published in a separate section after the scientific programme. All advertising components (including the listing of exhibitors) must be clearly separated and distinguished from the scientific/educational components of the programme and identified as such.

In case of sponsorship being in the form of material used for hands-on courses (i.e. surgical instruments and equipment etc.), the providers are authorized to mention the equipment that will be used in the industry section of the event material. Providers also need to include a statement informing the participants that there is a variety of different similar products that they can use beyond the ones provided at the event.

EACCME® does not require that brand names are erased from the physical material used for hands-on courses.

1. Programme booklet

Adverts and names of companies must not appear next to scientific and educational information. The booklet should be divided into two parts:

I. A first section for all the scientific/educational information, such as:

- President's foreword, invitation, scope of the event, Scientific and Organising Committee, list of faculty, programme overview, scientific programme etc.
- Within the scientific programme and overview, sponsored symposia should be identified as such, but the names of the sponsors must not be mentioned, neither the details such as title, speakers, etc. You therefore indicate them with a formula such as "industry-sponsored symposium";
- Within this first "scientific" section, must not appear adverts, acknowledgements of sponsors etc.

II. A second section for all the other information, such as:

- Registration, venue, etc.
- Acknowledgement of sponsors, where the names and logos of sponsors may appear;

- (detailed) list of sponsored sessions, with the titles, speakers, names and logos of sponsors;
- Advertisement from industry.

Industry names/logos may also not appear in the vicinity of the EACCME® accreditation statement.

Sponsors' names and logos as well as commercial adverts may not be printed on the front/back covers, on the second page (inside front cover) and inside the first section (scientific/educational information section) of the programme booklet.

2. Online content (Website, social media, etc.)

The same principle applies, whereby industry names/logos may not appear alongside scientific/educational information. In this respect:

I. All versions of the programme (pdf and other "uploads", as well as programmes as webpages) must respect the rules above;
II. Sponsors' names and logos, as well as adverts from industry, may not appear on the home page, on all the pages with scientific/educational information, and ideally should be placed under a separate tab dedicated to sponsors; again, do not have commercial logos where you will place the EACCME® accreditation statement.

Regarding the communication about the event from external parties, the EACCME© accepts that when a commercial company supports a LEE, they can announce the event via their website or social media but not via mailing.

ANNEX 5. Requirements for the accreditation of an e-learning material(ELM)

All the criteria below are ESSENTIAL criteria.

Educational Objectives and Fulfilment of Learning Needs:

1. **The provider must state, in a readily-accessible manner, that the ELM has been prepared in order to fulfil stated educational needs, and indicate how this will be achieved**.

This confirmation must demonstrate that a "needs assessment" process has been performed, that these educational needs have been defined, and will be fulfilled.

A needs assessment must be carried out prior to the development of a CME/CPD activity. The process of a needs assessment is designed to identify the gap between a current situation and a desired situation.

There are different types of needs assessment:
- Evaluation results from a previous activity
- Surveys of potential participants
- Publication of a new clinical guideline or new research
- Legislative/regulatory/organizational changes affecting patient care…

The discrepancy between the current situation and desired situation must be measured to appropriately identify the need. The need can be a desire to improve current performance or to correct a deficiency.

A short description of this needs assessment process and derived educational needs must be provided.

2. **The provider must state, in a readily-accessible manner, the expected educational outcome(s) of the ELM.**

These must be explained in terms of the knowledge, skills, attitudinal or behavioural, or ethical lessons that can be learned, and whether these are clinical or non-clinical.

When defining an ELM's learning outcomes, action verbs must be used to express what participants will be able to do. eg. analyse, create, compare, evaluate.

Example: "After attending the ELM, participants will be able to + action verb + something."

A list of educational outcomes must be provided.

3. **The provider must clearly define, and state in a readily-accessible manner, the "principal intended recipients" for whom the ELM is most likely to be suitable.**

The principal intended recipients must fall within the remit of the UEMS-EACCME® (fully qualified medical specialist doctors). The principal intended recipients must therefore be explained in terms of medical specialty and seniority of the learner.

The UEMS (recognized) medical specialities can be found in the UEMS website (www.uems.eu).

In addition to fully qualified medical specialist doctors, an EACCME® accredited activity is open to all interested medical and other healthcare professionals.

EACCME® certificates can therefore be distributed to any other healthcare professional attending the

accredited ELM (i.e. nurses, pharmacists, clinical scientists …) who wishes to benefit from EACCME® credits. It is expected that the healthcare professional's association will recognise the EACCME® credits on a voluntary basis.

Description of Material

4. **The provider must clearly explain, and state in a readily-accessible manner, in a brief summary, the content of the ELM.**

The content of an ELM needs to be interactive and the use of voice-recording is encouraged. As such the content of an ELM can be a recording, a video, a practical case study, a clinical case or any other format or combination of formats provided that interactivity tools are implemented.

Any ELM deriving from an industry-sponsored satellite symposium will not be eligible for accreditation.

Translations of an accredited ELM will benefit from automatic accreditation if the provider provides a certificate from an official translation agency/translator stating that the translated version is a true copy of the original accredited version

5. **The provider must respect and confirm the privacy and confidentiality of the learner, and confirm that any information provided by the learner will only be utilised for the specific purposes of completing the ELM.**

The only permitted exception to this will be with the valid consent of the learner

6. **The provider must clearly state, in a readily-accessible manner, the likely duration that the learner will need to engage with the ELM in order to fulfil the educational objective(s).**

This must be a minimum of 30 minutes (30 mins of actual educational activity excluding introductions etc.) and a maximum of three hours.

It is the provider's responsibility to determine the time needed to go through the ELM and to determine the corresponding number of credits. No rounding-up of EACCME® credits will be allowed (eg. 45 min is equal to 0.5 credits and not 1 credit).

7. **The Provider must clearly state, in a readily-accessible manner, compliance of the ELM with all relevant ethical, medico-legal and legal requirements.**

Where applicable, these must include: consent by patients and other participants to inclusion in the ELM, confirmation of confidentiality for patients and other participants, compliance with research ethics requirements, compliance with data-protection legislation, and copyright arrangements for the ELM. It is essential to ensure that patients are not, and cannot be identified in any of the materials presented.

8. **Both in the application and in the e-learning material, the provider must clearly state, in a readily-accessible manner, the date of preparation of the ELM, any substantial revisions to its content, and expiry date.**

9. **Both in the application and in the e-learning material, the provider must clearly state, in a readily-accessible manner, the required format for use of the ELM, (e.g. Windows/MacOS), and must provide contact details for the provision of assistance.**

Nature of Material

10. **All content within the ELM must be evidence-based, with notes on the level of evidence (where applicable), and suitable references.**

This must be to the standard required for a publication in a scientific journal

11. **The ELM must encourage the learner to employ methods of active, adult learning to achieve the educational objective(s).**

These may include: problem-orientated learning, task-based learning, case-based learning, reflective learning, and performance improvement CME/CPD. The EACCME® also strongly recommends feedback be provided on the learner's engagement with the material, such as an explanation of why a response to the self-assessment component was incorrect.

12. **The ELM must include a means of confirming learner engagement and achievement of the educational objective(s)**

The assessment component must be of quality, duration and content appropriate to the ELM and the educational objective(s), and it must be integral to the ELM and available online. It may be based on multiple-choice questionnaire or other self-assessment methodologies, but must have clearly stated assessment criteria (e.g. pass mark). This should be set by the provider of the educational content (as distinct from the provider of the product).

This self-assessment component must comprise a minimum of 10 minutes per educational hour (i.e. 5 questions per half-hour).

The assessment component must be available at the end of each individual module of the ELM.

Learners will only be able to receive their EACCME® accreditation certificate once they have completed the EACCME® learner's feedback form and reached the assessment's set pass-mark. They can only receive the number of ECMEC®s corresponding to their actual participation.

No modification of the EACCME® certificate is allowed, except for the addition of the provider's logo.

13. **All content must be free from any form of advertising and any commercial or other forms of bias (see "definitions").**

The EACCME® will reject any application that, in its opinion, includes advertising of any product or company directly related to any educational material.

Where there is a valid evidence base for a specific therapy or agent, this may be stated, but must be referenced in a manner that is appropriate for a scientific journal. The EACCME® will reject any application that, in its opinion, includes biased information.

Specific examples that will lead to automatic rejection of an application include:

- The use of a sponsor's name, brand name or product name in the title of the ELM;
- The display of brand names and/or individual company logos in any component of the ELM;
- The presence of a speaker from industry in any component of the ELM (see exceptions below).

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The material can therefore not be hosted on the sponsor's website, nor contain the sponsor's logo on any page of the material. The EACCME® will allow one single page acknowledgement at the end where the sponsor is recognised for their support.

Regarding the communication about the ELM from external parties, the EACCME© accepts that when a commercial company supports an ELM, they can announce the ELM via their website or social media but not via mailing.

Should medical devices/software/equipment appear in the ELM, it is mandatory to use the following statement at the beginning and at the end of the ELM:

> *"Commercial names of medical devices/software/equipment may appear in this content because they are linked to specific medical procedures, which are the focus of this training material. Other products in the market can be used to perform the aforementioned medical procedures. The educational provider does not endorse any particular product."*

14. **All content should be suitable for an international audience.**

This refers to the use of international terminology for procedures and therapeutic agents.

Details of the Provider

15. **The provider must provide, in a readily-accessible manner, a short description of the provider organisation.**

While the use of the provider's logo(s) will be permitted (and not the use of the sponsor's logo), there must not be any attempt at using this description for advertisement.

16. **The ELM must state, in a readily-accessible manner, the names and qualifications of the individual(s) involved in preparing the content.**

The EACCME® requires that all individuals who have contributed to the preparation and presentation of the material(s) are mentioned.

As a general rule, it is not permissible for a member employed by, in contractual relationship with or otherwise representing the industry to be involved in the ELM. In specific situations (ground-breaking scientific investigation, exceptional scientific merit, etc.), dependent on the approval of the EACCME®, a member employed by, in contractual relationship with or otherwise representing the industry may be exceptionally allowed to be involved.

ELM authors from commercial organisations
Ineligible organisations

1. Pharmaceutical companies
2. Device companies (manufacturers or distributors)
3. Biotechnology companies
4. Growers, distributors, manufacturers or sellers of medical foods and dietary supplements 5. Manufacturers of health-related wearable products
6. Reagent manufacturers or sellers
7. Companies developing or marketing health-related IT solutions

E-learning authors or editors
Accredited e-learning applications must have no authors or editors from commercial organisations (as defined above).

The only exceptions to this would be for authors where both A and B below are satisfied:
A. The ELM is organised by an independent educational provider (see eligible organisations).

B. One of the following criteria applies to the author concerned:

1. The topic is a recognised area of expertise for the speaker and the content of the talk is not related to the business lines or products of their company, or

2. The content of the activity is limited to basic science research, such as preclinical research, drug discovery, or the methodologies of research, and the author does not make care

recommendations.

Where a provider includes an author from a commercial organisation, they should submit a COI Declaration signed by the author concerned.

The EACCME® encourages programmes using a number of speakers adequate to the size of the educational material. The EACCME® strongly encourages providers to promote diversity and inclusion when choosing the faculty of the educational material in order to adequately represent society. The name and affiliation of these individuals must also be provided in the application in the designated field.

17. The ELM must provide the name and title of a medical officer who will take responsibility for its content.

This person must be a specialist doctor and his/her registration number with a Medical Regulatory Authority must be provided as well as the name of that authority.

By Medical Regulatory Authority we mean the authority in a country that delivers to doctors the license to practice medicine in that country.

The medical officer (~~MO~~) taking responsibility for the application may be involved in the preparation of the content or may be any specialist doctor willing to take responsibility for the application.

From the EACCME®'s point of view, this person is responsible for the ELM.

The medical officer taking responsibility for the application declares that:

- The scientific content was developed under his/her supervision and responsibility;
- The material complies with all relevant ethical, medico-legal, legal requirements;
- All individuals involved in preparing the content have provided a declaration of perceived or actual conflict of interest;
- He/she has determined the content of all aspects of the ELM to be free of any attempt by sponsors to influence his/her decisions;
- He/she is aware of the source and form of any funding received to develop this material and confirms that the educational material is free of any form of advertising and any form of bias;
- All individuals involved in preparing the content have disclosed, or will disclose, any perceived or actual conflict of interest. This will be published on the ELM website, and stated at the beginning of their presentation(s);
- He/she is a medical practitioner, registered with a Medical Regulatory Authority and has provided his/her registration details to the EACCME®.

18. There must be a full declaration of actual or perceived conflict of interest of the individual(s) involved in preparing the content of the material.

Conflict of interest: A set of conditions in which judgment or decisions concerning a primary interest (for example a patients' welfare, the validity of research and/or quality of medical education) is unduly influenced by a secondary interest (personal or organizational benefit including financial gain, academic or career advancement, or other benefits to family, friends, or colleagues).

A perceived conflict of interest: A perceived conflict of interest occurs when an individual or institution may reasonably be understood by a third party as having two competing interests, one of which is likely to interfere with or undermine a researcher's/institution's ability to fulfil its responsibilities as a researcher or research institution. Whereas **an actual conflict of interest** occurs when an individual or institution has two competing interests, one of which is likely to interfere with or undermine a researcher's/institution's ability to fulfil its responsibilities as a researcher or research institution.

The medical officer who will take responsibility for the material and the individual(s) involved in preparing the content of the material must provide a full declaration of actual or perceived conflict of interest for the last three years. The COI forms must be dated and signed by hand or using an authenticated or certificate-based electronic signature. The COI forms of the medical officer must be provided at the time of the application.

The list of perceived or actual conflicts of interest of the individuals involved in preparing the content must be made available online on the ELM page. EACCME® reviewers may ask for the COIs of any of the known individuals at the time of submission if needed.

The COI template will be made available by the ACI office.

The EACCME will accept documents electronically signed as long as they meet the European requirements for advanced electronic signatures AdES.

For more information on this requirement please visit What is eSignature (europa.eu) a la part de LEEs això ho han eliminat

19. Confirm that all actual conflicts of interest have been resolved.

This criterion is applicable to all individuals involved in preparing the content and is the personal responsibility of the medical practitioner in charge of the application.

The provider must ensure that all actual conflicts of interest have been resolved. This can be done in several ways:

- The EACCME® learner's feedback form completed by participants must include a question on possible bias on the content of the ELM.
- The list of perceived or actual conflicts of interest of all the individuals involved in preparing the content must be made available on the ELM page.
- Individual involved in preparing the content is excluded from the preparation of the scientific content.

20. The source of all funding provided for the preparation of the material must be declared, and stated in a readily-accessible manner.

The source of all funding must be declared.

The EACCME® reserves the right to ask for the contractual arrangement between the provider and the sponsor(s). Providers are entitled to redact any financial information.

Independent support grant: Monetary or in-kind contributions given by a commercial interest to a CME/CPD provider that is used to pay all or part of the costs of a CME/CPD activity where the education is independent of their control. The commercial interest is not allowed to have control or influence over the content of the CME activity nor is it allowed to receive any "benefits" for providing the support.

Sponsorship is a monetary contribution given in exchange of a specific benefit e.g., exhibition booth, space for a commercial symposium, and advertisements outside the scientific programme. The sponsor is not allowed to influence the CME activity at any level and not allowed to have control over the content. The "benefit" in exchange for the sponsorship must relate to a non-educational component of the meeting.

To ensure full transparency for learners, the source of funding MUST be declared upfront when registration occurs and at the start of the activity. Declarations must clearly list all funders and type of financial support received, logos are not allowed. For online activities, the declaration should not just be a pop-up as these are often blocked by firewalls or disabled.

Tobacco/alcohol industry sponsorship of CME/CPD activities will not be permitted.

As far as sponsorship items are concerned, the EACCME places trust in providers to adhere to relevant ethical codes, such as the "EFPIA Code of Practice on Relationships Between the Pharmaceutical Industry and Patient Organizations" or the "MedTech Europe Code of Ethical Business Practice", just to cite two examples.

Quality Assurance by the Provider

21. **The provider must provide confirmation that it has had the ELM quality-assured against the EACCME criteria prior to application to the EACCME® for accreditation.**

The EACCME® requires the provider to have assessed its material using the criteria set out in this document.

22. **The provider must provide a reliable and effective means for the learner to provide feedback on the ELM, and must make available to the EACCME® a report on this feedback and on its responses to this.**

Each ELM module must include an EACCME® learner's feedback form to be completed by learners after completion of the module. Providers must use the EACCME® template of feedback form as a minimum for their feedback forms. Additional feedback questions may be added by the provider if deemed necessary.

In order to maintain accreditation, this summary feedback must be submitted to the EACCME® within 12 months of accreditation having been granted, using the "ELM report" template.

All the criteria below are DESIRABLE criteria.

24. **All content should be easy to use.**

25. **The ELM should provide links to further relevant information**

Links to commercial sites are not allowed.

26. **The provider should make available for the learner technical support related to the ELM.**

ANNEX 6. Requirements for the accreditation of a CME/CPD activity (Blended Learning)

All the criteria below are ESSENTIAL criteria.

THE PROVIDER MUST:

1. Structure the educational material to fulfil defined educational needs.

This confirmation must demonstrate that a "needs assessment" process has been performed, that these educational needs have been defined, and will be fulfilled.

A needs assessment must be carried out prior to the development of a CME/CPD activity. The process of a needs assessment is designed to identify the gap between a current situation and a desired situation.

There are different types of needs assessment:

- Evaluation results from a previous activity
- Surveys of potential participants
- Publication of a new clinical guideline or new research
- Legislative/regulatory/organizational changes affecting patient care...

The discrepancy between the current situation and desired situation must be measured to appropriately identify the need. The need can be a desire to improve current performance or to correct a deficiency.

A short description of this needs assessment process and derived educational needs must be provided.

2. Identify and communicate the expected educational outcome(s) of the educational material.

An expected educational outcome is a formal statement of what participants are expected to learn in an activity. Expected learning outcome statements refer to specific knowledge, practical skills, areas of professional development, attitudes, higher-order thinking skills, etc. that faculty members expect participants to learn, develop or master after attending the activity.

When defining an activity's learning outcomes, action verbs must be used to express what participants will be able to do. eg. analyse, create, compare, evaluate.

Example: "After attending the event, participants will be able to + action verb + something."

A list of educational outcomes must be provided.

3. Define the "principal intended recipients" for whom the educational material is most likely to be suitable.

The principal intended recipients must fall within the remit of the UEMS-EACCME® (fully qualified medical specialist doctors). The principal intended recipients must therefore be explained in terms of medical specialty and seniority of the learner.

The UEMS (recognized) medical specialities can be found on the UEMS website (www.uems.eu).

In addition to fully qualified medical specialist doctors, an EACCME® accredited activity is open to all interested medical and other healthcare professionals.

EACCME® certificates can therefore be distributed to any other healthcare professional attending the accredited activity (i.e. nurses, pharmacists, clinical scientists ...) who wishes to benefit from EACCME® credits. It is expected that the healthcare professional's association will recognise the EACCME® credits on a voluntary basis.

EACCME® certificates can also be distributed to speakers for the duration of their attendance as any other participant. They may also request credits for delivering a presentation (see UEMS document UEMS 2023.10 rev "Recognition of CME/CPD activities" – Learning by Teaching).

4. Submit information regarding the expected total number of participants taking part in the educational material and the schedule of registration fees for these learners.

Expected total number of participants:

This number includes all participants in the educational material whether they are specialist doctors or not. It also includes speakers and exhibitors/sponsors participating in the educational material.

The applicant will have no right to reduce the expected number of participants after submission of the application.

Registration fee:

A registration calendar and related fees must be provided upon submission of the application.

A LEE may be provided free of charge but only if all participants are admitted without fee (supported for example by an independent support grant or subsidised by a scientific society…).

EACCME does not allow providers to charge an additional fee to participants to issue their EACCME certificate.

5. Provide detailed information on the duration of the educational material.

<u>For live educational events (LEEs):</u>

The provider will need to state the starting time and ending time for each day of the programme (including lunch breaks and coffee breaks), together with the number of educational hours per day and for the whole event.

Only purely scientific sessions will be considered for accreditation.

Therefore, commercial sessions, coffee/lunch breaks, opening/closing ceremonies, assessments etc. will not be awarded ECMEC®s.

<u>For e-learning materials (ELMs):</u>

The provider must clearly state, in a readily-accessible manner, the likely duration that the Learner will need to engage with the ELM in order to fulfil the educational objective(s).

This must be a minimum of 30 minutes (30 mins of actual educational activity excluding introductions etc.).

It is the provider's responsibility to determine the time needed to go through the ELM and to determine the corresponding number of credits. No rounding-up of EACCME® credits will be allowed (eg. 45 min is equal to 0.5 credits and not 1 credit).

6. Provide the title of the LEE, its venue, date(s), and a clear description of the nature of the whole educational material.

Title: must be identical with the title used in all materials related to the educational material. It is not permissible to have an industrial sponsor's or a commercial product's name in the title of the educational material.

Venue:

- Town, country where the event will take place in the case of a physical event
- Town, country where the CME/CPD provider is located in the case of a virtual event/webinar

In the case of multiple event dates, the town/country of the first event will apply to all event dates.

Events held in the facilities of any commercial company, such as a pharmaceutical/medical/surgical devices/software company, are not eligible for EACCME® accreditation.

When the LEE is virtual and taking place on a member-only website/platform, the provider must provide login details so that the EACCME® is able to assess the LEE content.

The EACCME® deals with the accreditation of international events in Europe and outside of Europe (with the exception of the USA and Canada with which the EACCME® has agreements of mutual recognition of credits).

For international events in Europe the EACCME® will seek to have the approval from the National Accreditation Authority of the country where the event takes place and with which the EACCME® has a signed agreement.

For all those countries with which the EACCME® does not have a signed agreement, the EACCME® strongly recommends to also apply for accreditation with the National Accreditation Authority of that country to ensure that local participants receive their credits.

The list of countries with which the EACCME® has signed an agreement is available on the EACCME® platform under the section related to "Collaborations".

For international events outside of Europe the EACCME® accepts to consider such applications if European participants and/or faculty attend the event.

However, the EACCME® encourages the accreditation of international events outside of Europe even though there are no European participants and no European faculty. In this case EACCME® accreditation is considered as a "mark of excellence". For those events the EACCME® will apply the EACCME® criteria. These events should attract participants from several countries.

The application and programme must be submitted in English.

Date: EACCME® will accept one set of consecutive dates per event. A separate application must be submitted for each repetition of the same event.

Courses run on non-consecutive dates will be accepted as one application if the course meets the following conditions:

- One single registration fee for the entire course;
- Participants must attend all sessions;
- The course takes place within a period of 12 months.

All individual dates must be provided on the application form at the time of submission.

The EACCME® will not accept any change except for one postponement. Any other change will be evaluated on a case-by-case basis and may require a new submission.

The applicant will notify the EACCME® about the postponement before the original dates of the activity. The applicant will have to provide the new date(s) of the postponed activity within 12 months of notifying the EACCME® office of the postponement and at least 6 weeks before the new starting date of the activity. The applicant will upload the Director's Declaration with the new activity dates and the new programme with changes highlighted (if any) at least 6 weeks before the new dates of the activity. Failure to do this will result in the application being automatically rejected.

If the application is in review or in accredited stage and changes have been made to the programme, a new application will have to be submitted.

Nature of the educational material: You will need to state whether the educational material is a combination of:

- Course
- Conference
- Hands-on workshop
- Webinar

with

- E-learning module
- E-learning app
- Other: applicant needs to clarify

The content of an ELM needs to be interactive and the use of voice-recording is encouraged. As such the content of an ELM can be a recording, a video, a practical case study, a clinical case or any other format or combination of formats provided that interactivity tools are implemented.

The EACCME® will **NOT** consider for accreditation commercial/industry-sponsored satellite symposia even if it is stated that they are supported by an independent support grant.

The applicant will also have to confirm whether the live event is physical / virtual or hybrid.

The EACCME® will not accredit parts of a blended learning activity. The application will have to be for the whole educational activity.

If the application is submitted 6 weeks (or less) prior to the event, providers are required to submit the final version of the programme as provided to participants at the event

7. Provide the latest version of the programme of the educational material at the time of application.

When applying, the programme that providers have to upload is the document intended for the participants.

The programme must contain as a minimum:

- ✓ title of the LEE/ELM
- ✓ venue of the LEE
- ✓ date(s) of the LEE
- ✓ link to the ELM
- ✓ duration of the ELM
- ✓ short description on how the ELM interacts with the LEE as a way to better achieve the learning outcomes
- ✓ titles of individual sessions / lectures, etc.
- ✓ start and end time of individual lectures, workshops and sessions, etc. In cases in which the event is held in more than one time zone, this information should be provided in the CET time zone.
- ✓ name and affiliation of faculty members (including chairpersons, moderators, presenters...) alongside their respective sessions. This information must also be provided in the application in the designated field.

Sessions for which these details have not been provided will not receive accreditation. It is not permissible for a member from the industry to be on the scientific programme.

As a general rule, it is not permissible for a member employed by, in contractual relationship with or otherwise representing the industry to be on the scientific programme.

In specific situations, dependent on the approval of the EACCME®, representatives from industry may be exceptionally allowed to be on the scientific programme:

1. Where the content of the talk is not related to the business lines or products of their company, or
2. The content of the accredited activity is limited to basic science research, such as preclinical research and drug discovery, or the methodologies of research, and they do not make care recommendations.

In this case, the speaker's affiliation must be clearly presented at the beginning of the session, under the form of a COI declaration.

If the event is organised in parallel sessions, a summary programme at-a-glance (table form) needs to be submitted to clearly show how each day is organised.

Sessions developed for allied healthcare professionals (nurses, psychologists, physiotherapists, etc.) should be stated as such in the scientific programme.

Non-exhaustive examples of sessions that will not be entitled to credits:

- opening / closing sessions
- industry symposia / commercial sessions
- satellite symposia
- poster sessions (unless if part of the scientific programme with a clear timeframe, structure and monitoring)
- oral sessions (if no details are provided)
- awards sessions

- examinations / completion of of participants' feedback forms

- coffee / lunch breaks
- hospital visits (unless if part of the scientific programme with a clear timeframe, structure and monitoring)
- committees or annual general meetings
- social events and/or networking opportunities
- sessions developed for allied healthcare professionals (nurses, psychologists, physiotherapists, etc.)

It is the provider's responsibility to ensure that the latest version of the programme is, at all times, made available to the EACCME® via the application page.

Following confirmation of accreditation and before the beginning of the educational material, providers are obliged to inform the EACCME® of any changes made to the programme. The EACCME® will evaluate the new programme and, if deemed necessary, a new application will have to be submitted by the provider.

Once the final version of the programme is available, the provider will send it to the ACI office no less than one week before the start of the event.

Once the final version of the programme is available, the EACCME® will not permit further changes to the programme. Changes made at this time might lead to removal of accreditation.

When an event website exists, it must contain the event programme.

THE EDUCATIONAL MATERIAL MUST:
8. Be presented in a manner suitable for an international audience.

The EACCME® will not consider for accreditation purely local/national events with only local/national participants attending. This is the remit of a National Accreditation Authority.

However, a national event attracting foreign participants may be considered for accreditation by the EACCME®.

The EACCME® accredits international events in the whole world (except for the USA and Canada) as long as the event attracts participants from several countries and the programme submitted with the application is available in English.

International terminology for procedures and therapeutic agents must be used.

9. Include methods to promote active, adult learning to achieve the educational objective(s).

The EACCME® encourages the use of methods promoting adult active learning. The methods used can be one or a combination of the following:

<u>For live educational events (LEEs):</u>

✓ Discussion time
✓ Quiz
✓ Q&A session
✓ Training session
✓ Groups
✓ Open space
✓ Electronic communication
✓ Other: applicant needs to clarify.

<u>For e-learning materials (ELMs):</u>

✓ Problem-orientated learning
✓ Task-based learning
✓ Case-based learning
✓ Reflective learning
✓ Performance improvement CME/CPD

The EACCME® also strongly recommends feedback be provided on the learner's engagement with the material, such as an explanation of why a response to the self-assessment component was incorrect.

THE PROVIDER MUST:

10. Clearly state, in a readily-accessible manner, compliance of all educational material with all relevant ethical, medico-legal and legal requirements.

Where applicable, these must include: consent by patients and other participants to inclusion in the ELM, confirmation of confidentiality for patients and other participants, compliance with research ethics requirements, compliance with data- protection legislation, and copyright arrangements for the ELM. It is essential to ensure that patients are not, and cannot be identified in any of the materials presented.

11. Indicate the mechanism(s) by which it will be verified that the learner has engaged with the educational material in order to fulfil the educational objective(s).

For live educational events (LEEs):

Simple registration of attendance at the event is not sufficient.

As the CME/CPD provider must deliver the number of credits to participants based on their actual attendance, providers are required to monitor the presence of each participant for each session of the event. Different methods can be used: attendance list, scanning system, ...

For virtual events, the participant's online attendance must also be monitored through a tracking system. Further methods could include pop up questions during the event, short evaluation questionnaire after each session, etc.

Providers will need to explain how the participants' attendance is monitored during the event and to include in the learner's feedback form questions related to the relevance of the content and speakers.

For e-learning materials (ELMs):

The assessment component must be of quality, duration and content appropriate to the ELM and the educational objective(s), and it must be integral to the ELM and available online. It may be based on multiple-choice questionnaire or other self-assessment methodologies but must have clearly stated assessment criteria (e.g. pass mark). This should be set by the provider of the educational content (as distinct from the provider of the product).

This self-assessment component must comprise a minimum of 10 questions per educational hour (i.e. 5 questions per half-hour).

The assessment component must be available at the end of each individual module of the ELM.

12. Provide a short description of the provider organisation(s).

The applicant must submit a short description of the CME/CPD provider, and any other organisation the CME/CPD provider is working with in regard to the LEE. Where the provider is a CME/CPD company producing a programme on behalf of or supported by another organisation, their relationship must be fully disclosed and any funding should be in the form of an independent support grant although it is also acceptable for some funding to come from other sources, eg. fees for exhibition booths (see full list under criterion 17).

Educational materials submitted by a CME provider on behalf of industry (eg. pharmaceutical or medical device companies) **will NOT** be considered for accreditation by EACCME®.

Educational materials submitted by industry (eg. pharmaceutical or medical device companies) **will NOT** be considered for accreditation by EACCME®.

13. Provide the name, title and contact details of a medical officer who will take responsibility for the application for accreditation of the educational material.

The medical officer must be a specialist doctor in activity and his/her registration number with a Medical Regulatory Authority must be provided as well as the name of that authority.

By Medical Regulatory Authority we mean the authority in a country that delivers to doctors the license to practice medicine in that country.

The medical officer taking responsibility for the application may be the Head of the Scientific and Organising Committee, one of its members or any specialist doctor willing to take responsibility for the application.

From the EACCME®'s point of view, this person is responsible for the educational material.

This person will be the one completing and signing the director's declaration to be provided at the time of the application (template available on the EACCME® platform for download).

The medical officer taking responsibility for the application declares, on behalf of the Director of the CME/CPD programme, that:

➢ The scientific programme was developed under his/her supervision and responsibility, and presents a scientifically balanced perspective of the subjects included;

➢ The programme complies with all relevant ethical, medico-legal, regulatory, industry-based and legal requirements applicable in the country where it is being held;

➢ All members of the Scientific and Organising Committee have provided a declaration of perceived or actual conflict of interest;

➢ The Scientific and Organising Committee has determined the content of all aspects of the educational material to be free of any attempt by sponsors to influence the Committee's decisions;

➢ He/she is aware of the source and form of any funding received to develop this programme and confirm that any educational material is free of any form of advertising and any form of bias;

➢ All faculty and other speakers at this scientific event have disclosed, or will disclose, any perceived or actual conflict of interest. This will be published, and stated at the beginning of their presentation(s);

➢ He/she will ensure that the applicable national rules, regulations and industry standards regarding exhibition areas where companies are permitted to present their products will be enforced;

➢ He/she is a medical practitioner, registered with a Medical Regulatory Authority and has provided his/her registration details to the EACCME.

14. Provide the name(s), job title(s) and contact details of the head, and all other members of the Scientific and Organising Committee of the LEE and the names and qualifications of the individual(s) involved in preparing the content of the ELM.

<u>For live educational events (LEEs):</u>

This includes the members of the Scientific and Organising Committee listed on the event website.

No member of staff/doctor/professor working for the industry is allowed to be on the Scientific and Organising Committee.

<u>For e-learning materials (ELMs):</u>

The EACCME® requires that all individuals who have contributed to the preparation and presentation of the material(s) are mentioned.

As a general rule, it is not permissible for a member employed by, in contractual relationship with or otherwise representing the industry to be involved in the ELM. In specific situations (ground-breaking scientific investigation, exceptional scientific merit, etc.), dependent on the approval of the EACCME®, a member employed by, in contractual relationship with or otherwise representing the industry may be exceptionally allowed to be involved.

ELM authors from commercial organisations

Ineligible organisations

The EACCME® does not accept applications for CME/CPD accreditation from organisations involved in producing, marketing, re-selling or distributing healthcare goods or services consumed by or used on patients. These organisations include:

1. Pharmaceutical companies
2. Device companies (manufacturers or distributors)
3. Biotechnology companies
4. Growers, distributors, manufacturers or sellers of medical foods and dietary supplements
5. Manufacturers of health-related wearable products
6. Reagent manufacturers or sellers
7. Companies developing or marketing health-related IT solutions

E-learning authors or editors

Accredited e-learning applications must have no authors or editors from commercial organisations (as defined above).

The only exceptions to this would be for authors where both A and B below are satisfied:
A. The ELM is organised by an independent educational provider (see eligible organisations).

B. One of the following criteria applies to the author concerned:
1. The topic is a recognised area of expertise for the speaker and the content of the talk is not related to the business lines or products of their company, or
2. The content of the activity is limited to basic science research, such as preclinical research, drug discovery, or the methodologies of research, and the author does not make care recommendations.

Where a provider includes an author from a commercial organisation, they should submit a COI declaration signed by the author concerned.

15. Ensure that all members involved in the preparation and presentation of the educational material (Scientific and Organising Committee and faculty) provide written declarations of perceived or actual conflicts of interest.

Conflict of interest: A set of conditions in which judgment or decisions concerning a primary interest (example a patients' welfare, the validity of research and/or quality of medical education) is unduly influenced by a secondary interest (personal or organizational benefit including financial gain, academic or career advancement, or other benefits to family, friends, or colleagues).

A perceived conflict of interest: A perceived conflict of interest occurs when an individual or institution may reasonably be understood by a third party as having two competing interests, one of which is likely to interfere or undermine a researcher's/institution's ability to fulfil their responsibilities as a researcher or research institution. Whereas **an actual conflict of interest** occurs when an individual or institution has two competing interests, one of which is likely to interfere or undermine a researcher's/institution's ability to fulfil their responsibilities as a researcher or research institution.

Each member of the Organising and/or Scientific Committee must state its perceived or actual conflicts of interest for the last three years. The COI forms must be dated and signed by hand or using an authenticated or certificate-based electronic signature. COI declarations signed more than 6 months before the date of the event will not be accepted. The COI forms of the members of the Organising and/or Scientific Committee must be provided at the time of the application.

At the time of application, only the Head of the Scientific and Organising Committee and the medical officer taking responsibility for the application must submit a completed conflict of interest form. The medical officer in charge will declare, in the Director's declaration, that he/she has received and reviewed the conflict of interest forms from all other members of the Scientific and Organising Committee and faculty.

Each form should include the individual's perceived or actual conflicts of interest for the last three years. The COI forms must be dated and signed by hand or an authenticated or certificate-based electronic signature. COI declarations signed more than 6 months before the date of the blended activity will not be accepted.

The EACCME® will accept documents electronically signed as long as they meet the European requirements for advanced electronic signatures AdES.

The list of perceived or actual conflicts of interest of the members of the Scientific and Organising Committee must be made available by the provider to the ACI office.

The COI template will be made available by the ACI office.

Providers who have been granted the status of "Trusted Provider" do not need to supply the COI forms at the time of submission of the application but the forms have to be completed before the educational material takes place and have to be available for an on-site control by the EACCME®.

All members of the faculty must provide written declarations of COI. These declarations do not need to be submitted at the time of the application but must be made available in case of control by the EACCME® or its reviewers. Reviewers may ask for the COIs of any of the known speakers at the time of submission if needed.

16. Confirm that all actual conflicts of interest have been resolved.

This criterion is applicable to all members of the Scientific and Organising Committee and faculty (including chairpersons, moderators, presenters...) and is the personal responsibility of the Head of the Scientific Committee.

The provider must ensure that all actual conflicts of interest have been resolved. This can be done in several ways:

➢ Every faculty member must provide a declaration of perceived or actual conflicts of interest as a second slide of his/her presentation.

➢ The feedback form completed by participants must include a question on the faculty's bias.

➢ The list of perceived or actual conflicts of interest of all members of the Scientific and Organising Committee and faculty must be made available on the educational material's website.

➢ Member of the Scientific and Organising Committee or faculty who has a conflict is excluded from the preparation of the scientific programme.

17. The source(s) of all funding for the educational material must be declared, and be made available to learners in a readily accessible manner.

The source of all funding must be declared. The name of the sponsors and the type of financial support and sponsorship, confirmed or pending, must be declared.

Funding can occur via:

✓ provider's own funds
✓ participants' registration fees
✓ an independent support grant
✓ exhibition booths during the event
✓ commercial symposia organised during the event (not eligible for ECMEC®s)
✓ advertisements outside the scientific programme
✓ provision of a range of tools during the event (in-kind support) aqui no ho han afegit?? Jo ho afegiria, se'l shi ha passat, segurament
✓ if other: please specify

Independent support grant: Monetary or in-kind contributions given by a commercial interest to a CME/CPD provider that is used to pay all or part of the costs of a CME/CPD activity where the education is independent of their control. The commercial interest is not allowed to have control or influence over the content of the CME/CPD activity nor is it allowed to receive any "benefits" for providing the support.

Sponsorship is a monetary contribution given in exchange for a specific benefit e.g., exhibition booth, space for a commercial symposium, and advertisements outside the scientific programme. The sponsor is not allowed to influence the CME/CPD activity at any level and not allowed to have control over the content. The "benefit" in exchange for the sponsorship must relate to a non-educational component of the meeting.

To ensure full transparency for learners, all sources of funding must be declared at the start of the activity (full instructions on the acknowledgement of sponsors in the event material are available in Annex 4.

For the ELM, the EACCME® will allow one single page acknowledgement at the end of the module where the sponsor is recognised for their support.

The EACCME® reserves the right to ask for the contractual arrangement between the provider and the sponsor(s). Providers are entitled to redact any financial information.

Tobacco/alcohol industry sponsorship of CME/CPD activities will not be permitted.

As far as sponsorship items are concerned, the EACCME® places trust in providers to adhere to relevant ethical codes, such as the "EFPIA Code of Practice on Relationships Between the Pharmaceutical Industry and Patient Organizations" or the "MedTech Europe Code of Ethical Business Practice", just to cite two examples.

The EACCME®'s primary focus lies in ensuring the scientific integrity of events. This entails maintaining meeting rooms free from commercial influence, including advertising and sponsors' branding. For instance, sponsor-branded lanyards and advertisements between scientific sessions will not be permitted within meeting spaces. However, outside of these areas, providers can allow their sponsors to promote their products as desired.

18. All educational material must be free of any form of advertising and any commercial or other forms of bias.

Live educational events (LEEs):

The EACCME® will reject any application that, in its opinion, includes advertising of any product or company directly related to any educational material.

Specific examples that will lead to automatic rejection of an application include:

- the use of a sponsor's name, brand name or product name in the title of the scientific programme, a scientific session or a scientific lecture;
- the display of brand names and/or individual company logos in scientific lectures or in the scientific programme;

- the name of a speaker from industry in the scientific programme, a scientific session or a scientific lecture except in specific circumstances as mentioned under criterion 7;

- the brand or product name of the equipment used during hands-on sessions of the scientific programme.

The EACCME® strongly encourages providers to produce two programme booklets:

1. one for the scientific programme
2. one for the industry-sponsored events and industry acknowledgement/information

When this is not possible, the acknowledgement of sponsors for their financial or material support, the details of industry satellite symposia (title, speakers, sessions, sponsors...) and all advertising components (including the listing of exhibitors) must be placed at the end of the scientific programme booklet, on separate pages from the scientific content.

The event website cannot be hosted on any commercial company website and cannot bear any commercial company logo. The acknowledgement of sponsors for their financial or material support, the details of industry satellite symposia (title, speakers, sessions, sponsors...) and all advertising components (including the listing of exhibitors) will only be allowed under a separate tab "sponsorship".

Full instructions on the acknowledgement of sponsors and sponsored symposia in the educational material are available in Annex 4.

E-learning materials (ELMs):

The EACCME® will reject any application that, in its opinion, includes advertising of any product or company directly related to any educational material.

Where there is a valid evidence base for a specific therapy or agent, this may be stated, but must be referenced in a manner that is appropriate for a scientific journal. The EACCME® will reject any application that, in its opinion, includes biased information.

Specific examples that will lead to automatic rejection of an application include:

- the use of a sponsor's name, brand name or product name in the title of the ELM;
- the display of brand names and/or individual company logos in any component of the ELM;

- the presence of a speaker from industry in any component of the ELM–see exceptions above).

The material can therefore not be hosted on the sponsor's website, nor contain the sponsor's logo on any page of the material. The EACCME® will allow one single page acknowledgement at the end where the sponsor is recognised for their support.

Should medical devices/software/equipment appear in the LEE or ELM, it is mandatory to use the following statement at the beginning and at the end of the LEE/ELM:

> *"Commercial names of medical devices/software/equipment may appear in this content because they are linked to specific medical procedures, which are the focus of this training material. Other products in the market can be used to perform the aforementioned medical procedures. The educational provider does not endorse any particular product."*

THE PROVIDER MUST:

19. Provide a reliable and effective means for the learners to provide feedback on the educational material, including the extent to which the educational objectives of the educational material were met. The provider must commit to make available to the EACCME® a report on this feedback and on the provider's responses to this.

Providers must ensure that a feedback form is completed by the participants at the end of the educational material. Providers must use the EACCME® template of the feedback form as a minimum for their post- activity forms. Additional feedback questions may be added by the provider if deemed necessary.

The applicant will provide a copy of the feedback form[1] that will be distributed to participants at the end of the educational material upon submission of the application.

Participants will only be able to receive their EACCME® accreditation certificate once they have completed the feedback form. They can only receive the number of ECMEC®s corresponding to their actual attendance.

Based on the participants' individual feedback, the provider must complete the EACCME® event report"[1] within four weeks of the completion of the event on their application page. Failure to provide feedback could jeopardise recognition of any future applications.

If accreditation has been requested for the recording of the BLD, the event report will be submitted to EACCME® seven months after the completion of the BLD.

Upon completion of the EACCME® event report, if the number of participants reported exceeds by 10% or more the initial number provided at the time of submission, a complementary invoice will be produced.

Providers cannot deliver a higher number of certificates than the number of feedback forms received.

EACCME® certificates can be distributed up to 6 months after the event has taken place.

THE INDIVIDUALS INVOLVED IN THE PREPARATION OF THE WHOLE EDUCATIONAL MATERIAL MUST:

20. Ensure that the educational material will provide a programme that presents a scientifically balanced perspective of the subjects included.

This must include impartiality in the scheduling of subjects, lecturers and opportunity for discussion.

Where there is a valid evidence base for a specific therapy or agent, this may be stated, but this must be referenced in a manner that is appropriate for a scientific journal. Only generic names will be permitted.

The EACCME® encourages programmes using a number of speakers adequate to the size of the educational material. The EACCME® strongly encourages providers to promote diversity and inclusion when choosing the faculty of the educational material in order to adequately represent society.

21. Confirm that it has determined the content of all aspects of the educational material to be free of any attempt by sponsors to influence the Committee's decisions.

[1] Appendix 1: participant's feedback form to be provided by the ACI.

[2] Appendix 2: event report to be provided by the ACI.

All funding must be provided free of any attempt to influence the programme, individual sessions, subjects for discussion, content or choice of faculty members.

In the case the sponsor is a pharmaceutical or medical device industry, the sponsor cannot be directly involved in the provision of the educational material. **The sponsor therefore cannot:**

- Invite or select participants and speakers;
- Cover travel/accommodation/registration costs of participants and speakers;
- Take part in the organisation of the educational material (invitation of participants, registration of participants, staffing, catering, speaker's fees...);
- Take part in the development of the scientific programme (no funding company member on Organising/ Scientific Committee, no influence on the choice of the speakers/selection of topics...);
- Be on the scientific programme (no speaker from the industry will be allowed on the scientific programme, except in the cases described above);
- Advertise and promote the educational material via mailing;
- Be involved in any way in the preparation of the ELM...

THE PROVIDER MUST:

22. Ensure that all content within the educational material is evidence-based. This includes but is not limited to notes on the level of evidence (where applicable), and suitable references.

For the ELM, this means that it must be to the standard required for a publication in a scientific journal.

23. Provide confirmation that it has had the educational material assessed using the EACCME criteria prior to application to the EACCME® for accreditation.

24. Confirm that it will comply with the applicable national rules, regulations and industry standards regarding exhibition areas where companies are permitted to present their products.

The provider has a duty to check if special arrangements regarding accreditation and recognition of CME credits apply in the country/region where the LEE takes place. The EACCME® strives to monitor local regulations but it is not always notified of local changes in a timely manner and the provider has the responsibility to make sure that participants, particularly local participants, will have their CME credits recognised.

25. Respect and confirm the privacy and confidentiality of the learner, and confirm that any information provided by the learner will only be utilised for the specific purposes of completing the educational material.

The only permitted exception to this will be with the valid consent of the learner.

26. Clearly state, both in the application and in the e-learning material, in a readily-accessible manner, the date of preparation and expiry date of the ELM.

27. Clearly state, both in the application and in the e-learning material, in a readily-accessible manner, the required format for use of the ELM, (e.g. Windows/MacOS), and must provide contact details for the provision of assistance.

All the criteria below are DESIRABLE criteria.

28. All content of the ELM should be easy to use.

29. The ELM should provide links to further relevant information.
Links to commercial sites are not allowed.

30. The provider should make available for the learner technical support related to the ELM.

ANNEX 7. Quick application checklist for providers (Blended Learning)

The following information is necessary to complete the application form template:

Description of the educational material

- ✓ Educational material title
  - Please note that the use of an industry sponsor's or a commercial product's name in the event title will lead to automatic rejection of your application.

- ✓ Educational material website
  - The educational material's website cannot be hosted on the industry sponsor's website and cannot bear the industry sponsor's logo (except under a separate tab "sponsor" where the sponsor will be acknowledged).
  - If there is no website for the educational material, the provider must explain how they are promoting their LEE as well as how they are handling the registration.

- ✓ Venue
  - List each venue per LEE component.

- ✓ Start date – end date
  - Only one date or set of dates is permitted for each event.
  - A separate application must be submitted for each repetition of the same event.

- ✓ Duration of the LEE component
  - Please state starting time and ending time for each day of the programme (including lunch breaks and coffee breaks), together with the number of educational hours per day and for the whole event.

- ✓ Principal intended recipients
  - Specify the speciality and seniority of the doctor(s) most likely to benefit.

- ✓ Main specialty of the educational material
  - Please select the main specialty of the educational material. The EACCME® reserves the right to change the specialty of the educational material.

- ✓ Expected total number of participants

- ✓ Educational needs

- ✓ Expected educational outcomes

- ✓ Clear description of the nature of the educational material

- ✓ Methods to promote active learning

- ✓ Confirmation of learner engagement
- ✓ Compliance with all relevant ethical, medico-legal, regulatory, industry-based and legal requirements

- ✓ International audience

- ✓ Main language of the educational material

- ✓ Simultaneous translation

Details of the provider

- ✓ Short description of the provider organisation(s)
  - The provider must submit a short description of their own organisation, and any other(s) with which they are working

- ✓ Medical practitioner officer who will take responsibility for the application
  - This specialist doctor must be registered with a Medical Regulatory Authority and his/her registration details must be provided

Scientific and Organising committee

- ✓ Name, professional affiliation(s) and contact details of the Head of the **Scientific and Organising** Committee who will be personally accountable for the educational content of the event.
- ✓ Name professional affiliation(s) and contact details of the members of the **Scientific and Organising** Committee
- ✓ Please explain how any actual conflicts of interest involving members of the **Scientific and Organising** Committee have been resolved

Faculty

- ✓ Confirmation that all members of the faculty have provided written declarations of perceived or actual conflicts of interest

Funding of the activity

- ✓ Sources of all funding
  - Name of sponsor(s) (confirmed and unconfirmed)
  - Type of funding
  - Details of pending applications for funding
- ✓ Schedule of fees for learners
- ✓ Confirmation that all funding is provided free of any attempt to influence the programme, individual sessions, subjects for discussion, content or choice of faculty members

Promotional material

- ✓ Confirmation that all the educational material is free of any form of advertising and any form of bias
- ✓ Confirmation that the event complies with the applicable national rules, regulations and industry standards regarding exhibition areas where companies are permitted to present their products

Review by learners

- ✓ Means for the learners to provide feedback on the educational material
- ✓ Commitment to making available to the EACCME® a report on the learners' feedback and on the provider's responses to these (tick box)

Contact and billing information

- ✓ Contact person for the application
- ✓ Billing information

<u>Documents to be uploaded in addition to the application form template</u>

- ✓ Latest version of the **programme** including
  - o details of faculty members
  - o titles of lectures, etc.
  - o start and end time of individual lectures, workshops and sessions
  - o overall expected learning outcomes
  - o Name of every speaker(s)/teacher(s) for each lectures, workshops and session

- ✓ **Programme overview** (if available)

- ✓ **Director's declaration**
  - o To be completed and signed by the medical practitioner taking responsibility for the application

- ✓ **Template Organising/Scientific Committee**
  - o To be completed with the names and details of all the members of the Organising/Scientific Committee

- ✓ **Conflict of interest disclosure form**
  - o To be provided, completed and signed, for the Head of the **Scientific and Organising** Committee and the medical practitioner taking responsibility for the application

- ✓ **Learner's feedback form**
- ✓ **Event report**
  - o To be completed on the application page no later than 4 weeks after the event has taken place (or after the recording option is no longer available)
- ✓ **Final version of the programme** to be uploaded on the application page no less than one week before the start of the event)