



Terms and Conditions for the accreditation of imaging live educational events and e-learning materials

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I. GENERAL STATEMENT

- 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) and accreditation of elearning materials (ELMs) in imaging.
- 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 LEEs and e-learning materials in imaging. These Terms and Conditions mirror the documents <u>UEMS 2016/20</u> for the accreditation of LEE and <u>UEMS 2016/21</u> for the e-learning materials 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.
- 7. The scope of the accreditation granted accordingly to these Terms and Conditions is limited to:

<u>Live Educational Events or LEEs</u> defined as meetings/events, 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, in order to use it in practice with patients. By extension, live webinars are considered LEEs. A webinar is a live online educational presentation during which participation by viewers can be confirmed and they can submit questions and answers.

The recording of a live educational event made available online after the event has taken place is not considered a LEE. It is therefore not permissible to transfer the credits granted to a LEE to a viewer of an online recording to the LEE.

The recording however may be considered an e-learning material if it complies with the criteria for the accreditation of e-learning materials.

<u>Imaging field</u> defined as the discipline of medicine dealing with all kinds of medical imaging for diagnostic and/or therapeutic purposes.

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

- 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 and Part IV) and specific provisions (Part II and III, essentially), the most specific provision must always prevail.
- 9. All Applicants must familiarize themselves with the Terms and Conditions before applying for the accreditation.
- 10. By paying the accreditation fee established in sections II.5 and III.4 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 and ELMs in imaging, including the final decision on the eligibility of applicants.
- 12. 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: http://www.myebr.org/aci
 - ii. Once this short form has been fulfilled and sent by the Applicant, the ACI will check if the event 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 II.1 for LEEs and in section III.1 for ELMs) that must be completed and sent by email to the ACI, in order to formally begin the application process. The model forms attached as





annexes to the present document are only for information purposes. As indicated above, 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 above.
- 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.

13. Who is eligible to apply for CME accreditation?

The EACCME® considers for accreditation events and e-learning materials submitted by:

- An individual medical specialist
- A university or hospital department
- A scientific medical society
- A national medical association
- A medical communication agency
- A professional congress organiser (PCO) for LEE
- A medical publisher for ELM
- Applications by other types of providers will be considered on a case by case basis as long as the application is supported by an appropriated medical specialist who will take responsibility for the application. This person must be registered with his/her National Regulatory Authority.

The EACCME® will NOT consider for accreditation LEEs or ELMs where the content, format or faculty is influenced by industry.





PART II - SPECIFIC PROVISIONS FOR THE ACCREDITATION OF LIVE EDUCATIONAL EVENTS (LEEs)

II.1 APPLICATION STEPS AND REQUIRED DOCUMENTATION

- 1. The documents and information required under this section, and detailed below, are deemed essential for applying for accreditation (hereinafter, "Essential criteria of application").
- 2. The essential criteria of application are listed in **Annex 1** (check-list of criteria to be met by the Applicant).
- 3. In order to have an application for accreditation considered by the UEMS/EBR, the Applicant must submit fully completed and drafted in English the following documents:
 - a) The "Accreditation information" form, attached as **Annex 2**
 - b) The "Scientific and/or Organising Committee" description using the form attached as **Annex 3** to these Terms and Conditions;
 - c) The "Conflict of Interest Disclosure Form" completed and signed separately by each member of the Scientific and/or Organising Committee, including the head of the scientific and/or organising committee using the form attached as Annex 4 to these Terms and Conditions;
 - d) The "Director's Declaration" completed and signed by the senior medical practitioner who will take responsibility for the application, who can be the same person as the head of the scientific and/or organising committee, using the form that will be provided to you after completing the Scientific and/or Organising Committee form;
 - e) The confirmation of the full payment of the application fees according to section II.5 of these Terms and Conditions.
- 4. The Applicant has to ensure that suitable responses have been provided for each section of all above mentioned documents.
- 5. The only application form that will be accepted is that made available at the ACI website: http://www.myebr.org/aci.





- 6. No applications sent on paper or by email will be considered. The UEMS/EBR will not accept late applications. As applications can only be received in English, applicants will be responsible for the translation of all submitted materials.
- 7. Applicants are responsible for the validity of all documents and application data.

II.2. PROMOTIONAL MATERIAL

1. All educational material must be free of any form of advertising and any form of bias, defined as 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 (Please refer to **Annex 5** for further instructions).

Bias may be scientific, political, economic and financial, religious, genderrelated, 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.

- 2. The UEMS/EBR will reject any application that, in its opinion, includes advertising of any product or company directly related to any educational material, as for example 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 company logos in scientific lectures or in the scientific programme. The EACCME® will only consider for accreditation LEEs that fulfil specific requirements related to their funding. Accordingly, events provided by the pharmaceutical and medical equipment industries will not be considered for accreditation.
- 3. The UEMS/EBR will accept a single page acknowledgement, in the scientific programme, where all sponsors are recognised for their support of the LEE and programmes that include the names of satellite symposia only if they are clearly identified as industry-sponsored. 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.

II.3. APPLICATION DEADLINE

- 1. All required documentation must be submitted fully completed to the ACI no less than 13 weeks from the planned starting date of the LEE, and preferably more than 15 weeks before.
- 2. For this reason, the Applicant must have completed the application form available on the ACI web page at least 13 weeks before the planned starting date of the LEE (hereafter "the application deadline"), and preferably more than 15 weeks before, in order for the ACI to send to the Applicant all the documents mentioned in the section II.1.3.

The whole evaluation process should take no more than 7 weeks from the moment the EACCME has the application out for review. The application will be then sent out for review by the ACI specialist reviewers and afterwards by the relevant National Accreditation Authority (NAA). 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.

II.4. 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 in one or two. 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 section IV.3), this decision by the EACCME® shall be final.





3. 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).

II.5. FEES AND PAYMENT POLICY

Fees:

The fee for an application to the UEMS/EBR for the accreditation of LEEs under these Terms and Conditions is determined in accordance with the expected total attendance of learners during the event 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:

From 1 to 100 participants	192,5€ (accreditation fee= 167,5€ + processing fee 25€)
From 101 to 250 participants	412,5€ (accreditation fee= 337,5€ + processing fee 75€)
From 251 to 500 participants	742,5€ (accreditation fee= 667,5€ + processing fee 75€)
From 501 to 1,000 participants	1,100€ (accreditation fee= 1,000€ + processing fee 100€)
From 1,001 to 2,000 participants	1,430€ (accreditation fee= 1,330€ + processing fee 100€)
From 2,001 to 5,000 participants	2,805€ (accreditation fee= 2,655€ + processing fee 150€)
More than 5,000 participants	4,840€ (accreditation fee= 4,640€ + processing fee 200€)





The above fees are VAT excluded.

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

UEMS/EBR 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.

Payment Policy:

- 1. Full payment must be received by the application deadline.
- 2. Only applications for which full payment has been received will be accepted.

II.6. TRUSTED PROVIDER STATUS

Trusted Provider status

The EACCME® does not support the concept of accredited provider status as it offers no assurance regarding the robustness and fairness of the process when a provider has the right to accredit its own educational activities; this by itself undermines the quality of accreditation.

However, the EACCME® recognises the outstanding quality of CME 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 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, from the moment the EACCME





sends the application out for review.

- 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 Organising/ Scientific organisation 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.

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)

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 Organising and/or Scientific 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® Governance Board for decision. The Trusted Provider status is granted for a defined period of 3 years.

In recognition of the high quality of the LEEs 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. 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 Board's decision. The Secretary General can ask the Board for reconsideration of the application within 2 weeks or confirm the decision in which case the decision becomes final. The decision taken by the Board 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®





Governance Board that will consider retraction of the Trusted Provider status. The Board 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.

II. 7. ALLOCATION OF CREDITS

The EACCME® awards ECMECs® on the following basis:

One hour of LEE CME activity: 1 ECMEC®

One accredited hour of LEE= 60 minutes of actual educational activity

A participant can claim a maximum of 8 ECMEC®s per day of the LEE

It must be emphasized that:

- The EACCME® does not award fractions of credits.
- These are maximum allocations, i.e. no more than 8 ECMECs per day can be awarded, even if the LEE lasts longer than 8 hours.

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

PART III - SPECIFIC REGULATIONS ON THE ACCREDITATION OF E-LEARNING MATERIALS

III.1 APPLICATION STEPS AND REQUIRED DOCUMENTATION

- 1. The documents and information required under this section, and detailed below, are deemed essential for applying for accreditation (hereinafter, "Essential criteria of application").
- 2. The Essential and desirable criteria of application are listed in **Annex 6**.





- 3. In order to have an application for accreditation considered by UEMS/EBR, the Applicant must submit fully completed and drafted in English the following documents:
 - a) A link to the complete material with three sets of logins for the reviewers to access the material
 - b) A fully completed application form, which is attached as **Annex 7**, signed by the medical practitioner who is taking responsibility for the Material
 - c) Full payment of the application fee
- 4. The only application form that will be accepted is that made available at the ACI website: http://www.myebr.org/aci.

III.2. APPLICATION DEADLINE

All required documentation must be submitted fully completed to the ACI at least 11 weeks from the planned launch of the online material.

- 1. For this reason, the Applicant must have completed the application form available on the ACI website at least 12 weeks before the planned launch of the online material (hereafter "the application deadline"), in order for the ACI to send to the Applicant all documents mentioned in section III.1.3.
- 2. The whole evaluation process should take no more than 7 weeks from the moment the EACCME has sent the application out for review. 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.

III.3. 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.

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

3. 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.

III.4. FEES AND PAYMENT FOR INDIVIDUAL E-LEARNING MODULES

The fee for application to the UEMS/EBR for its accreditation of an e-Learning material in Imaging under these Terms and Conditions, will be:

- € 550 For 1 module
- € 1,100 for up to 10 accredited modules
- € 1,650 for up to 20 accredited modules
- € 2,200 for up to 30 accredited modules
- € 3,300 for up to 40 accredited modules
- € 5,500 for up to 50 accredited modules
- € 8,250 for up to 100 accredited modules
- € 11,000 for more than 100 accredited modules

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 € 375.





The UEMS/EBR 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.

Payment Policy:

- 1. Full payment must be received for the application process to begin
- 2. Only applications for which full payment has been received will be accepted.

III.5. ALLOCATION OF CREDITS

Allocation of European CME Credits (ECMECs) for e-learning materials:

1 hour (60 minutes of educational activity) = 1 ECMEC[®] Each additional full hour will be granted 1 ECMEC[®].

The EACCME[®] does not award fractions of credits.

III.6. SPECIAL PROVISIONS FOR THE ACCREDITATION OF EDUCATIONAL E-LEARNING PLATFORMS

1. The EACCME® will accredit educational e-learning platforms and not websites. The accreditation is for the 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. The e-platform must meet the criteria that apply to ELM (see Annex 6).
- d. 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 (see sections III.1/.2/.3 and IV.1/.2/.3) with two exceptions:
- Instead of completing the application form (see Annex 7) 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 elearning 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® website.

4. Modifications and quality control

Modifications of e-platforms are allowed according to principles stated in the definition of a modification.

There is periodical quality control of the educational e-platforms, by the EACCME® designated reviewers to ensure that their content remains within the scope and remit of the initial accreditation. The reviewers will report to the EACCME® for any concerns raised by the quality control appraisal.

5. Fees

- € 1,100 for up to 10 accredited modules
- € 1,650 for up to 20 accredited modules
- € 2,200 for up to 30 accredited modules
- € 3,300 for up to 40 accredited modules
- € 5,500 for up to 50 accredited modules
- € 8,250 for up to 100 accredited modules
- € 11,000 for more than 100 accredited modules

In addition to the fees above, there will be a flat fee of € 275 to be paid every year for the quality control review of the platform by EACCME[®].

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 platform will be 1 credit for every hour (60 minutes of actual e-learning excluding introductions etc.) of use as evaluated by EACCME® assessors and stated in the EACCME® confirmation of accreditation, provided that the users have completed a module and have passed the relevant assessment.

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.

III.7. SPECIAL PROVISIONS FOR THE ACCREDITATION OF E-LEARNING MODULES OF APPS

Accreditation of the e-learning modules delivered through apps 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.





III.8. SPECIAL PROVISIONS FOR THE ACCREDITATION OF THE USE OF EDUCATIONAL E-LIBRARIES

1. Scope of accreditation

The UEMS/EBR will not accredit the inclusion of an article in an e-library but the use of the e-library as a CPD/CME vehicle.

For example: A medical specialist can use the time already spent researching clinical questions with the library toward continuing professional development requirements. In order to use the library for accreditation, a user logs into the database with their personal account. When a clinical question is researched in the database, the library tracks both the search activity and the time spent researching. In order to apply for accreditation, the user generates an activity assessment of topics researched. For each topic searched, the user ticks how the information found was applied to their clinical practice (for example, this modified my treatment plan, this reinforced my treatment plan or generated ideas for searching for new treatments in the future). Once completed the system awards the credits to the user.

2. Submission/ evaluation/ accreditation/ appeal processes

The submission, evaluation, accreditation and appeal processes will be identical to the ones described for the educational e-platforms

3. Fees

Flat fee of € 5,000

In addition to the fee above, there will be a flat fee of € 250 to be paid every year for the quality control review by the UEMS/EBR.

The above fee is VAT excluded.

The UEMS/EBR reserve 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.





4. Credits

The credits for the users of the library will be 1 credit for every hour (60 minutes of actual use of educational material excluding technical introductions etc.) of use of the accredited educational e-library provided that the users have completed a search and have passed the relevant assessment.

The provider will be responsible for ensuring that there is a mechanism in the e-library to ensure the hours of use and searches made, the assessments passed and subsequently award the relevant credits. Compliance of the provider with this process will be checked during the annual review of the educational e-library by the UEMS/EBR.

5. Validity of the accreditation

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

PART IV - GENERAL DISPOSITIONS OF THE PROCEEDIN G FOR THE ACCREDITATION OF LEES AND E-LEARNING MATERIALS

IV.1. ACCREDITATION REGULATIONS

The EBR commits to:

- Provide, on its website, two application forms, one for LEEs and one for ELMs, based on the criteria set out in this document;
- Ensure confidentiality regarding the application submitted;
- Confirm to the Applicant the following dates:
 - a. on which the EACCME® application was made by the ACI,
 - b. on which the EACCME® application was complete,
 - c. on which the application fee was cleared,
 - d. the "starting date" on which the EACCME® has begun its evaluation which will be determined by the above two criteria (b & c) having been met,
 - e. completing the accreditation process within seven weeks of the





"starting date", except in the case of an appeal being lodged, when the process will take no longer than ten weeks;

- For ELM's: Choosing, from a pool of suitably-trained specialists, two assessors who have expertise appropriate to the material submitted;
- Provide the Applicant with answers regarding their accreditation process, when required;
- Publishing, through a link to the EACCME® website in the ACI website, the list of accredited events as well as the list of accredited modules.

IV.2. REVIEW PROCESS

- 1. The Review Process is divided in two parts: a) The "Administrative Review Process", and b) The "Content Review Process".
- 2. During the "Administrative Review Process", the fulfilment of all criteria listed in sections II.1 and III.1 will be checked by the ACI and the EACCME®/UEMS.
- 3. During the "Content Review Process", the material and the application form will be reviewed by the two designated evaluation bodies:
 - a) The Accreditation Council in Imaging (ACI) as relevant speciality-based organisation.
 - b) The National Accreditation Authority (NAA) of the country in which the LEE will be held.

The EACCME® is responsible of the national review part of the Content Review Process described (point b), and so EACCME® will ensure that the Application is duly reviewed by the National Accreditation Authority (NAA). 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.

4. For a positive decision by the EACCME® for a LEE, all essential criteria set out in this document must be met. The two designated evaluation bodies also will be required to confirm whether, according to their assessment of the information provided, the application is 1) for an activity that fits within the definition of a LEE (see definitions in Annex





- 8), 2) for an ELM all essential criteria, and at least one desirable criterion must be confirmed as 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.
- 5. Once the Application has been checked and evaluated by the ACI and the NAA, the EACCME® will decide accordingly the number of European CME Credits (ECMECs) to be awarded on a case-by-case basis.
- 6. Major causes of rejection of an application at the level of initial review:

a. LEEs:

- 6.1. Failure by a provider to disclose the means of funding of an LEE will lead to rejection of the application
- 6.2. Grossly or significantly inaccurate attendance declarations will lead to automatic rejection of the application and any future application
- 6.3. 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 fees
- 6.4. The use of any statement by the Applicant 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
- 6.5. Any unauthorised/inappropriate use of the UEMS and/or EBR logo will result in action being taken by the UEMS and/or the EBR accordingly.

b. ELMs:

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 fees

If an Applicant cannot meet all criteria by the application deadline, their application for accreditation will not be processed.





IV. 3 APPEAL PROCEDURE

Should both evaluation bodies, the ACI and the corresponding NAA, reject the application, the Applicant may still appeal. A decision to appeal must be lodged within one week/s and must be accompanied by full payment of the appeal fee. The appeal process will require a further two weeks from the date in which the appeal was received.

The fee will be 250 euros for LEE and 375€ for e-learning materials for all such appeals.

- 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 and any additional permissible correspondence. The Secretary General will then discuss with the ACI and the NAA;
- The three will vote on the Application, with a majority (2:1) decision being permitted to confirm accreditation; the appeal decision of the EACCME® will be final. The ACI will have an advisory role in the Appeal procedure.

IV.4. DATA PROTECTION AND PRIVACY

- 1. In accordance with the Spanish Data Protection Regulation (Law 15/1999 of December 15, on Personal Data Protection), the personal data collected by the EBR will be incorporated into a file of its ownership. 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, 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





IV.5.OUTCOME

- Until confirmation of accreditation has been sent to the Applicant, the only permissible statement that can be made by the Applicant on material related to the LEE or to the e-learning material is "An application has been made to the UEMS/EBR for CME accreditation of this event/material".
- 2. Confirmation of accreditation of the LEE or ELM by the UEMS/EBR will permit the Applicant 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 ECMECs (granted will be stated. Only after confirmation of accreditation has been received can the Applicant use the UEMS- EACCME® and EBR logos on material related to the LEE or to the e-learning material. The 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 logo cannot be used in notices, advertising, or promotion of activities other than in association with the EACCME® accreditation statement.
- 3. Accreditation by the UEMS/EBR of a LEE/e-learning material will be for the specific event or the e-learning material designated on the application form. It is not permissible to transfer this accreditation to any other event or e-learning material.
- 4. Where a website, an electronic communication or a printed material lists EACCME® accredited LEEs or ELM along with non-accredited LEEs or ELM, the Applicant must assure that the learners can easily recognise the accreditation status. Listing a ELM and LEE not accredited by the EACCME® in a misleading way, suggesting the EACCME® has also accredited it, will lead to withdrawal of accreditation.
- 5. EACCME® accreditation of e-CPD/CME 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 ACI website, and the confirmation of accreditation will be removed from the website after this period has elapsed.





- 6. 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. This extension of accreditation will be permitted at no extra charge.
- 7. 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.
- 8. 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.

IV.6. 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.

IV.7. 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.

IV.8. PRICES

The fee for a EBR/UEMS accreditation application relating to a live event and to an e-learning module, e-platform, app, e-library 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)" documents that are available through the following link: https://www.uems.eu/uems-activities/accreditation/eaccme.

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.

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.

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.

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IV.9. 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 five 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.

IV.10. 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.





IV.11. 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.

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 that accredited by EACCME® for this LEE and is not compliant with the ACI Terms and Conditions, the provider will be fined (€ 500) 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

IV.12. 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. The Applicant will be charged with a processing fee amounting to 75 EUR 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.

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IV.13. 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/EBR will not accept any postponement anymore, except in exceptional circumstances to be duly justified by the Applicant and upon written acceptance of the UEMS/EBR.

IV.14. 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.

IV.15. 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.

IV.16. 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.

IV.17. 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.

IV.18. 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 <u>Contact Us</u> 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

IV.19. 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.

IV.20. 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.



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Annex 1

All the criteria below are ESSENTIAL criteria. THE PROVIDER MUST:

1. Structure the LEE to fulfil defined educational needs.

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. Define the "target audience" for whom the LEE is most likely to be suitable.

The target audience must fall within the remit of the UEMS-EACCME® (fully qualified medical specialists). The target audience must therefore be explained in terms of specialty and seniority of the learner.

An EACCME® accredited event is open to all interested medical and other healthcare professionals, not only those fitting the described target audience.

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 on a voluntary basis.

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. 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.

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

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: 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

Union Européenne des médecins specialistes – International non-profit organization, rue de l'Industrie, 24 BE-1040 Brussels BELGIUM – registered in Brussels with VAT number BE 0469.067.848 European Board of Radiology, S.L.U., Avinguda Diagonal 383 SA 1º, 08008 Barcelona, SPAIN Inscrita en el Registro Mercantil de Barcelona, Tomo 42.942, Folio 117, Hoja B-420225, NIF-B65668006 Bank Data: European Board of Radiology, S.L., ACCOUNT NR. 0182 1797 37 0201622775 IBAN ES 1401821797370201622775, SWIFT BBVAESMMXXX 1 / 7



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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.

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. The application and programme must be submitted in English.

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

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

- Congress
- Conference
- Course
- Satellite symposium
- Hands-on workshop
- Other: applicant needs to clarify...

The EACCME® will **NOT** consider for accreditation commercial symposia.

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) with European participants/faculty attending and without European participants/faculty attending 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 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.



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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, 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.

You 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 Provider must submit a short description of its own organisation, and any other(s) with which they are working with regard to the LEE. Where the Provider is a CME company producing a programme on behalf of or supported by another organisation (e.g. pharmaceutical or device manufacturer) their relationship must be fully disclosed and any financial sponsorship must be under the form of an unrestricted educational grant.

11. State the name and job title of the individual responsible for preparing the LEE.

This person cannot be a doctor/professor/member of staff working for the industrial sponsor or educational company of the LEE.

12. Provide the name, title and contact details of a senior medical specialist who will take responsibility for the application for accreditation of the LEE. This doctor must be registered with a Medical Regulatory Authority, and his/her registration details must be provided.

This person must be a doctor and his/her registration number (with a Medical Regulatory Authority) must be provided. By Medical Regulatory Authority we mean the authority that delivers to doctors the right to practice medicine. The medical practitioner who will take responsibility for the application is the person who will complete and sign the director's declaration to be provided at the time of the application.

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

See template "Organising/Scientific Committee" to be completed and provided at the time of the application. No member of the industrial sponsor's (of the LEE) staff is allowed to be on the Scientific/Organising Committee.



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accreditation@myebr.org

https://www.myebr.org/aci/application-for-ecmec

14. Ensure that all members of the Organising and/or Scientific Committee provide written declarations of potential or actual conflicts of interest.

Each member of the Scientific/Organising Committee must state its financial interests for the last three years. The COI forms must be dated and signed. The COI forms of the members of the Scientific/Organising Committee must be provided at the time of the application.

The COI forms of the members of the Organising/Scientific Committee must be made available online on the event website and in the printed scientific programme.

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®.

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

This criterion is applicable to members of the Organising/Scientific Committee and is the personal responsibility of the scientific head of the faculty (including chairmen, moderators, presenters...). The provider must ensure that any actual conflict of interest has been resolved. This can be done in several ways:

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

16. Ensure that all members of the Faculty provide written declarations of potential or actual conflicts of interest.

All members of the faculty must provide written declarations of COI. These declarations must not be submitted at the time of the application but must be made available in case of on-site control by the EACCME®.

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

The programme must contain as a minimum:

- details of faculty members
- titles of lectures, etc.
- start and end time of individual lectures, workshops and sessions
- overall expected learning outcomes

It is not permissible for a member from the industry to be on the scientific programme.

The EACCME® will not permit major changes to the programme following confirmation of accreditation. Major changes will require a new application to be submitted.

Following the LEE, the Provider will send the final version of the programme to the EACCME®, highlighting any differences from the version submitted with the original application for accreditation.



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18. 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.

Funding can occur via:

- provider's own funds
- participants' registration fees
- unrestricted educational grant from sponsor
- 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
- if other: please specify

Sponsorship (from one or more sponsors) of an event can only be considered as long as the grant is in the form of an "unrestricted educational grant" and all other EACCME® LEE criteria are met.

The EACCME® reserves the right to ask for the contractual arrangement between the provider and the sponsor.

THE ORGANISING AND/OR SCIENTIFIC COMMITTEE MUST:

19. Ensure that the LEE 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.

20. 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.

In the case the sponsor is a pharmaceutical or medical device industry, the sponsor cannot be directly involved in the provision of the event. **The sponsor therefore cannot:**

- Invite participants and speakers
- Cover travel/accommodation 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 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...)...





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21. 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 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 EACCME® will accept a single page acknowledgement, at the end of the scientific programme, where all sponsors are recognised for their support of the LEE. 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. 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). Full instructions on the acknowledgement of sponsors and sponsored symposia in the event material are available in chapter XVI.

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 PROVIDER MUST:

22. Submit information regarding the expected total number of participants attending the LEE and 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 LEE may be provided free of charge but only if all participants are admitted without fee (supported for example from an unrestricted grant or subsidised by a scientific society...) and there is no sponsorship from industry.

23. 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 are encouraged to ensure that a feedback form is completed by the participants at the end of the event. The feedback form must include questions on the lecturer, presentation, content, value of each session and possible bias.

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The Applicant will provide the blank Feedback Questionnaire that will be distributed to participants at the event.

Participants will only be able to receive their certificate of attendance 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 submit a feedback report (better known as "event report") to the EACCME® within four weeks of the completion of the event. This report must include the participants' feedback, information on the total number of participants and any perception of bias by participants. Failure to provide feedback could jeopardise recognition of any future applications.

Annex 9: provider's feedback report Annex 10: participant's evaluation form

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 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 responsibility to make sure that participants, particularly local participants, will have their CME credits recognised.





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Annex 2

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PLEASE FILL OUT THE FOLLOWING FORM AND RETURN BY E-MAIL TO ACCREDITATION@MYEBR.ORG UNTIL XXXXX, XXXXX XX, 20XX AT THE LATEST.

EVENT INFORMATION	
Title of the event	
Event Website	
City of the event	
State/ Province	If the CME event is organised in Germany, this field is mandatory.
Country	
Start date of the event	
End date of the event	
Main speciality	Radiology
Active participants	Pick a category: (the accreditation fee which is collected by the UEMS is determined by the number of participants and listed here) From 1 to 100 participants: €192.50 From 101 to 250 participants: €412.50 From 251 to 500 participants: €742.50 From 501 to 1,000 participants: €1,100.00 From 1,001 to 2,000 participants: €1,430.00 From 2,001 to 5,000 participants: €2,805.00 More than 5,000 participants: €4,840.00 You will receive the invoice by e-mail up to five days after we have received from you the completed information for your event, including all additional documents. * A complementary invoice will be issued for the possible additional number of participants upon submission of the event report.



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Recording of the LEE made available on-demand after it has taken place live, for a period of three months.	I wish to receive EACCME accreditation for the recording that will be made available on-demand after the event: Yes/ No If yes, an online tracking system must be put in place to monitor the attendance of participants who will take the recorded sessions ON-DEMAND and only the number of credits a participant is entitled will be granted, according to his/her actual attendance and only after receipt of the event evaluation questionnaire. The validity of the accreditation of recordings made available ON_DEMAND will only be for a period of 3 months after the event has taken place. *If the final number of participants provided in the event report is higher than the initially declared, the complementary invoice for the difference will also bear a 25% charge in the case of recording of LEE made available on-demand.
Main language	The primary language should be determined by the composition of the audience
Simultaneous translation	Yes/ No
Additional languages	
Description of the nature of the LEE	Short description of the course content
Duration of the event	Starting and ending time for each day of the Programme (including lunch and coffee breaks), together with the number of educational hours per day and for the whole event
Target and international audience	For example: radiologists, radiographers, physicians The target audience must be explained in terms of specialty and seniority of the learner.
International audience	Expected countries of origin of participants.
Educational needs	Short description of the needs assessment process and list of derived educational needs. A needs assessment must be carried out prior to the development of the LEE
Expected educational outcome(s)	List of educational outcomes for the LEE. An expected educational outcome is a formal statement of what participants are expected to learn in an event.
Methods to promote adult active learning	Methods used to promote adult active learning during the event (discussion time, quiz, Q§A session, training session, groups, open space, electronic communication, other (please clarify)

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Learner engagement	Explanation about how participants' attendance is monitored during the event
Means for feedback of learners	Explain how participants' attendance is monitored during the event. Mandatory: evaluation form (please find a template attached)
Source(s) of all funding	Disclose the name(s) of the sponsor(s), the type of funding and the details of pending applications for funding. The source of all funding must be declared. Funding can occur via: • provider's own funds • participants' registration fees • unrestricted educational grant from sponsor • exhibition booths during the event • commercial symposia organised during the event (not eligible for CME credits) • advertisements outside the scientific programme • provision of a range of tools during the event • if other: please specify Sponsorship (from one or more sponsors) of an event can only be considered as long as the grant is in the form of an "unrestricted educational grant" and all other EACCME LEE criteria are met. The EACCME reserves the right to ask for the contractual arrangement between the provider and the sponsor.
Schedule of fees for learners	List of the registration fees/categories
Name of the CME provider	Enter the exact official name of the CME event provider. Please note that this is the name of the CME provider (ie. the party who provides the educational content) that will appear on the Letter of Accreditation and on the participant's Certificate), and not the name of the party who might be submitting the application (like congress organizing agency) on behalf of the CME provider. Please do not use all capital letters, if not appropriate.
Short description of the Provider Organization	, , , , , , , , , , , , , , , , , , , ,
Lead individual responsible for preparing the LEE	Please state the name, affiliation, position, address, e-mail address, telephone and fax number. This person cannot be a doctor/professor/member of staff working for the industrial sponsor of educational company of the LEE.
Billing address (and reference, if necessary)	Please indicate the <u>customer name</u> , complete <u>billing address</u> and include the <u>VAT</u>

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	<u>number</u> , if available. VAT status: EU registered, EU not registered, EU exempt or Outside EU.
	Reference to be shown on your invoice, if necessary: e.g. Date and place, reference number, etc.
Trade register number	If available
Medical specialist who will take responsibility for the application	Please state the name, position, address, e-mail, telephone and fax number.
(can be same person as head of scientific committee and is the person signing the "director's declaration")	This doctor must be registered with a Medical Regulatory Authority: please provide the <u>registration</u> <u>number</u> and <u>the name of the registration authority</u> .
Head of the Scientific and/or Organising Committee	Please state the name, position, address, e-mail, telephone and fax number of the person responsible for the planning of the scientific programme.
	Organising committee: please state name, organization, address, e-mail and tel. number of each member of the scientific and/or organizing committee (copy the paragraph starting with "professional title" for each person).
DOCUMENTS TO BE SENT BY E-MAIL	 Point 3: Where there has been an actual or potential conflict of interest, there has to be an explanation of how this has been resolved. A Conflict of Interest may be resolved by informing the audience about it, for instance in providing the list of potential COI in the programme, publishing the list on the event website, projecting a slide with the COIs during lectures etc.
(please see e-mail attachment):	<u>Director declaration</u> : please fill out the form, Including the signature of the medical practitioner who will take responsibility for the application.
	Participants Evaluation form of the event under evaluation: if you use your own questioner, you need to include at least the questions contained in the template sent by us
	(Preliminary) programme
	COI (conflict of interest) disclosure: must be signed by each member of the scientific and/or organizing committee and any potential or actual conflicts of



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interest must be indicated. You will receive the COIs to be filled in by e-mail up after you have provided the completed information for your event, including all
documents.

After the event, it is necessary 1) to send an *event report of approx. 1 page by e-mail to accreditation@myebr.org up to one month after the event has taken place and 2) to send a copy of the final printed programme to UEMS-EACCME, Rue de l'industrie 24, B - 1040 Brussels (Please write the event reference number, which you will receive after having handed in the accreditation information, on the cover for easy identification).

*Once your event is officially accredited, you will receive by e-mail an Event Report template document which you can use.

If you have any questions concerning the information you need to send to us, please do not hesitate to contact us at accreditation@myEBR.org.

Annex 3

Professional title:
 First name:
 Last name:
 Organisation:
 Address:

E-mail address:

Tel.:

The scientific and/or organising committee

Please provide one single PDF document containing the information below:

1) Head of the Scientific and/or Organising Committee

>	Please add the completed and signed "Conflict of Interest Disclosure Form" of the head of the Scientific and/or Organising Committee using the appropriate EACCME form available for download on our website www.eaccme.eu.
2)	Members of the Scientific and/or Organising Committee
	Professional title: First name: Last name: Organisation: Address: E-mail address: Tel.: Please add the completed and signed "Conflict of Interest Disclosure Form" of each
	member of the Scientific and/or Organising Committee using the appropriate EACCME form available for download on www.eaccme.eu.
3)	Please explain how any actual conflicts of interest involving members of the Scientific and/or Organising Committee have been resolved
Organ EACCN	e there is an actual conflict of interest involving a member of the Scientific and/or ising Committee, the EACCME® must be informed of how this has been resolved. The ME® considers it a responsibility of the head of the Scientific and/or Organising ittee to ensure that actual conflicts of interest are addressed.



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Annex 4

Conflict of Interest Disclosure Form

(to be completed by scientific/organising committee members)

NAME:		
AFFILIATION:		
n accordance with criterion 24 of document UEMS 2012/30 "Accreditation of Live Educational Events by the EACCME", all declarations of potential or actual conflicts of interest, whether due to a financial or other relationship, must be provided to the EACCME® upon submission of the application. Declarations also must be made readily available, either in printed form, with the programme of the LEE, or on the website of the organiser of the LEE. Declarations must include whether any fee, nonorarium or arrangement for re-imbursement of expenses in relation to the LEE has been provided. DISCLOSURE		
lacksquare I have no potential conflict of interest to report		
$oldsymbol{\square}$ I have the following potential conflict(s) of interest to rep	port	
Type of affiliation / financial interest	Name of commercial company	
Receipt of grants/research supports: Receipt of honoraria or consultation fees: Participation in a company sponsored speaker's bureau: Stock shareholder: Spouse/partner:		
Other support (please specify):		
Signature:	Date:	



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Annex 5

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. 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 need to include in the programme 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.

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/organising committees, list of faculty, programme overview, scientific programme etc.

Within the scientific programme and overview, sponsored symposia should be <u>identified</u> 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;





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(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. Commercial adverts may not be printed on the second page (inside front cover) and inside the first section (scientific/educational information section) of the programme booklet. Sponsors' names and logos may not appear on the front cover of the programme.

2. Website

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.



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Annex 6

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.

- 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.
- 3) The provider must clearly define, and state in a readily-accessible manner, the "target audience" for whom the ELM is most likely to be suitable.

The target audience must fall within the remit of the UEMS-EACCME® (fully qualified medical specialists). The target audience must therefore be explained in terms of specialty and seniority of the learner.

EACCME® certificates may be distributed to any other healthcare professional completing an e-learning module (i.e. nurses, pharmacists, clinical scientists...) who wishes to benefit from EACCME® credits. It is up to the healthcare professional's association to 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.
- 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.

This is particularly relevant in the case of interactive ELM (such as online websites). 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 one educational hour (60 mins of actual educational activity excluding introductions etc.), with each hour of educational time expected to count as one ECMEC®.
- 7) The Provider must clearly state, in a readily-accessible manner, compliance of the ELM with all relevant ethical, medico-legal and legal requirements.



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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) 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) 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. 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).

This must be of quality, duration and content appropriate to the ELM and the educational objective(s), and it must be integral to the ELM. 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 within the duration expected for the accreditation of each educational hour (1 ECMEC®).

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

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.

14) All content must be free of any form of advertising.

The EACCME® will reject any application that, in its opinion, includes advertising of any product or company.

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.



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15) 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

16) 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.

17) 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 identified.

- 18) The ELM must provide the name and title of a medical practitioner who will take responsibility for its content. This doctor must be registered with a Medical Regulatory Authority, and his/her registration details must be provided.
- 19) There must be a full declaration of actual or potential conflict of interest of the individual(s) involved in preparing the content of the Material.

It is essential that the medical practitioner who will take responsibility for the material provides and the individual(s) involved in preparing the content of the material provide a full declaration of actual or potential conflict of interest. Earnings from the sale or marketing of the Material itself will not be considered a conflict of interest. Each ELM must contain authors' COI declaration provided as a slide or oral statement in the introductory part of the ELM.

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.

Sponsorship (from one or more sponsors) of an ELM can only be considered as long as the grant is in the form of an "unrestricted educational grant" and all other EACCME® ELM criteria are met.

The EACCME® reserves the right to ask for the contractual arrangement between the provider and the

sponsor.

Quality Assurance by the Provider

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

As a minimum, the EACCME® requires the provider to have assessed its material using the criteria set out in this document.



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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 evaluation form to be completed by learners after completion of the module.

In order to maintain accreditation, this feedback must be submitted to the EACCME® within 12 months of accreditation having been granted.

23) The provider's evaluation record for previous or on-going modules or programmes must be satisfactory or, where not, reasons for unsatisfactory ratings must have been addressed.

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.

Where these links are to commercial sites, this must be made clearly identifiable.

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





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Annex 7

APPLICATION FORM FOR THE ACCREDITATION OF E-LEARNING MATERIALS Title of the ELM (ELearning Material) Main speciality Radiology Individual Module □ E-Platform module * Nature of the ELM □ E-Library ** □ App. □ Website: (please provide URL) Mobile device □ Other: (please specify) Please provide three sets of login details (eg. Username and Means by which the ELM is password): made available Username: Password: Username: Password: Username: Password: **Overall description** Name of the CME Provider This is the name that will appear on the letter of accreditation and on the participant's certificate Start date (launch of the ELM) End date (of the ELM)



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Main language of the ELM	
Translations available into (specify into which language (in the event there is any)	
Billing address	Please indicate the <u>customer name</u> , complete <u>billing address</u> and include the <u>VAT number</u> , if available. <u>VAT status</u> : EU registered, EU not registered, EU exempt or Outside EU.
Trade register number	If available
Fees info:	*Accreditation of individual e-learning modules or e-learning modules of apps: - € 550 For 1 module - € 1,100 for up to 10 accredited modules - € 1,650 for up to 20 accredited modules - € 2,200 for up to 30 accredited modules - € 3,300 for up to 40 accredited modules - € 5,500 for up to 50 accredited modules - € 8,250 for up to 100 accredited modules - € 11,000 for more than 100 accredited modules *Accreditation of educational e-learning platforms: - € 1,100 for up to 10 accredited modules - € 1,650 for up to 20 accredited modules - € 2,200 for up to 30 accredited modules - € 3,300 for up to 40 accredited modules - € 3,300 for up to 50 accredited modules - € 8,250 for up to 100 accredited modules - € 11,000 for more than 100 accredited modules (in addition there will be a fee of € 275 to be paid every year for the quality control review by the UEMS/EBR) *E-library: flat fee of € 5,500 (in addition there will be a fee of € 275 to be paid every year for the quality control review by the UEMS/EBR)

^{*} 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® will not accredit the inclusion of an article in an e-library but the use of the e-library as a CPD/CME vehicle.

For example: A medical specialist can use the time already spent researching clinical questions with the library toward continuing professional development requirements. In order to use the library for accreditation, a user logs into the database with their personal account. When a clinical question is researched in the database, the library tracks both the search activity and the time spent researching. In order to apply for accreditation, the user generates an activity assessment of topics researched. For each topic searched, the user ticks how the information found was applied to their clinical practice (for example, this modified my treatment plan, this reinforced my treatment plan or generated ideas for searching for new treatments in the future). Once completed the system awards the credits to the user.

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CHECKLIST

In order to be validly submitted, all essential and desirable criteria must be completed.

ESSENTIAL CRITERIA

1. State how the ELM has been prepared in order to *fulfil stated educational needs*, and explain 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.

Open response box

2. What are 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.

Open response box

3. What is the "target audience" for whom the ELM is most likely to be suitable?

The target audience must fall within the remit of the EACCME (fully qualified medical specialists). This must therefore be explained in terms of the speciality and seniority of learner. EACCME certificates may be distributes to any other healthcare professional completing an e-learning module (i.e. nurses, pharmacists, clinical scientists...)

Open response box

4. What is the *content* of the ELM?

This must be clearly explained, and stated in a readily-accessible manner, in a brief sumamry

Open response box



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5.	Confirm how the <i>privacy and confidentiality</i> of the Learner will be respected, and how
	you will make sure that any information provided by the Learner will only be utilised for the
	specific purposes of completing the ELM.

This is particularly relevant in the case of interactive ELM (such as online websites). The only permitted exception to this will be with the valid consent of the Learner.

Open response box

6. What is the *expected 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 one educational hour (60m min. of actual educational activity excluding introductions, etc.), with each hour of educational time expected to count as one credit.

Open response box

7. State how will compliance of the ELM with all relevant **ethical**, **medico-legal and legal requirements** be met.

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.

Open response box

8. Please specify the *date of preparation* of the ELM, any substantial revisions to its content, and *expiry date*.

Open response box

9. What is the required *format for use* of the ELM, (eg. Windows/MacOS...) and contact details for the provision of assistance?

Provide contact details for the provision of assistance.

Open response box



10. Please specify the level of evidence of the content

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10.	Thease specify the level of evidence of the content.
	All content must be evidence-based, with notes on the level of evidence (where applicable)
	and suitable references, at the standard required for a publication in a scientific journal.

Open response box

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

Open response box

12. Please specify the extent to which the ELM includes a means of confirming Learner engagement, and achievement of the educational objective(s).

This must be of quality, duration and content appropriate to the Material and the educational objective(s), and it must be integral to the ELM. It may be based on multiple-choice questionnaire or other self-assessment methodologies, but must have clearly stated assessment criteria (eg. 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 within the duration expected for the accreditation of each educational hour (1 credit).

Open response box

13. Please specify the extent to which the content is *free from any commercial or other forms of bias*.

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.

Open response box

14. Please specify the extent to which the content is *free of any form of advertising*.

Open response box





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15. Please specify the extent to which the content is suitable for an *international audience*. This refers to the use of international terminology for procedures and therapeutic agents.

Open response box

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16. Please provide a short description of the Provider organisation.

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

Open response box

17. Please state, in a readily-accessible manner, the *names and qualifications of the individual(s) involved in preparing the content*.

The UEMS-EACCME® requires that all individuals who have contributed to the preparation and presentation of the ELM(s) are identified.

Open response box

18. Please state the *name of the senior medical specialist who will take responsibility for the content of the ELM*.

State the complete name, title, affiliation, position, address, country, email address, telephone and fax number.

This doctor must be registered with a Medical Regulatory Authority, and his/her registration details (registration number and name of the registration authority) must be provided.

Open response box

19. Please provide a *full declaration of actual or potential conflict of interest* of the individual(s) involved in preparing the content of the ELM.

It is essential that the medical practitioner who will take responsibility for the ELM and the individual(s) involved in preparing the content of the ELM provide a full declaration of actual or potential conflict of interest. Earnings from the sale or marketing of the ELM itself will not be considered a conflict of interest. Each ELM must contain authors' COI declaration provided as a slide or oral statement in the introductory part of the ELM.

Open response box

20. Please declare and state the source of all funding provided for the preparation of the ELM. If an educational grant or other financial support has been obtained by the developers of the Material, the source and nature of this must be declared.

Open response box



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21.	Please provide confirmation that the ELM is <i>quality-assured</i> prior to application to the UEMS-EACCME® for accreditation.
	As a minimum, the UEMS-EACCME® requires the provider to have assessed its ELM using the criteria set out in the document UEMS2016/21.
	Open response box
22.	Please specify which reliable and effective means for the Learner to provide feedback on the ELM is provided and how the report on this feedback and on its responses to this will be made available to the UEMS-EACCME [®] .
	This feedback must be submitted within 12 months of accreditation having been granted. Failure may affect future recognition.
	Open response box
23.	Please confirm that your evaluation record for previous or ongoing modules or programmes is satisfactory. Where not, please specify how the reasons for unsatisfactory ratings have been addressed.
	Open response box
	DESIRABLE CRITERIA
24.	Please specify the extent to which the content is easy to use.
	Open response box
25.	Please specify whether and which "hot-links" to further relevant information are provided.
	Where these links are to commercial sites, this must be made clearly identifiable.
	Open response box



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26. Please specify the extent to which <i>technical support</i> related to the ELM was made available.)
Open response box	



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Annex 7.2

Understanding the concept of "pre-paid applications" for the accreditation of E-learning materials (ELM)

A new concept of pre-paid module applications for ELMs has been introduced.

With this new concept, you will be able to apply for several modules at a package price. This allows you to submit your applications at your own pace during the course of one year (from the date of purchase of the pre-paid applications). This new concept applies to either a single or series of ELM module(s)/app(s), or an e-platform which hosts a series of modules.

When you want to submit an ELM application, it is important to determine beforehand which type of ELM it concerns. This will determine the type of pre-paid applications you will need to purchase.

In case of doubt as to the type of ELM, please contact the ACI office (accreditation@myebr.org).

Please see the definitions of the different ELM types (also available in UEMS 2016/21) below:

E-learning module:

A complete unit of e-learning material that meets on its own right the <u>ACI Terms and Conditions</u> for accreditation of an ELM.

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.

Educational e-platform:

An integrated set of interactive online services that provide a community of learners and facilitators with information, tools and resources to support the delivery and management of teaching and learning activities. An educational e-platform needs to have at least 10 e-learning modules that meet the <u>ACI Terms</u> and <u>Conditions</u> criteria for accreditation of ELM.

Educational app:

The word "app" is an abbreviation for application. An app is an element of software that can be run on the internet, on a computer, or on a phone or any other electronic device. While the word "app" has gained popularity in the context of mobile devices, it still applies more broadly to programs in general. An educational app is an app that is used as a medium for the delivery of educational material modules that meet the <u>ACI Terms and Conditions</u> for accreditation of ELM.

Educational e-library (or digital library):

An organised collection of selected digital resources created to support learning, scholarship, research and teaching. Through the use of appropriate technological standards, a digital library is created to facilitate permanent access to and resource discovery of selected digital resources.



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[In the case of an e-library, you do not need to buy pre-paid applications, as the fee for e-libraries is a fixed amount. You can just complete the application form and you will receive the invoice after it. The definition has been included above for information purposes.]

Pre-paid applications in the case of:

Individual module(s)/app(s):

For example, if you expect to submit 10 applications during the course of a year, you can purchase pre-paid applications at a package price "for up to 10 modules".

This allows you to spread the submission of your 10 individual applications during the course of one year. You therefore do not need to submit all applications at the same time. In this case you need to submit a filled out application form for each individual module each time (you however have the possibility to duplicate previously filled out application forms).

E-platform:

The same principle applies to e-platforms, however in this case, you only need to submit one application form. The application form will contain slots for up to as many pre-paid applications as you have bought.

For example, if you have an e-platform with 30 modules, you buy pre-paid applications for an e-platform "for up to 30 modules". You will then be able to submit one application form with 30 slots (you will need to complete each slot with title of the individual module making up the e-platform). If you do not have all modules ready at the time you fill out the application form, the remaining module slots will remain available and can be completed later. For example, if you only fill out 20 modules at the time of submission, you will be able to add the remaining 10 modules later, but always during the course of one year.

First, buy the necessary pre-paid applications

Before being able to complete the application form and submit an application for an ELM, you need to buy the necessary pre-paid applications.

Pre-paid applications are necessary for the following e-learning materials:

- -Individual module or series of individual modules
- -E-platform
- -App or series of apps
- -In the case of an e-library, you do not need to buy pre-paid applications as the fee for e-libraries is a fixed amount. You can just complete the application form and you will receive the invoice after it.



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"Order Pre-paid applications"

All you need to do is select the type of ELM you wish to apply for. Please note that once the ACI office will have introduced the data provided by you in the system, the type of ELM cannot be changed. Please make sure that you indicate the right type of ELM to the ACI office. If in doubt, please do not hesitate to contact the ACI office (accreditation@myebr.org) for help.

You can choose between:

- -An individual module or a series of individual modules
- -An e-platform
- -An app or a series of apps

Once you have selected the type of ELM, you need to indicate the number of modules you wish to apply for.

Once the form is completed and the type of ELM and number of modules is chosen, you will receive an invoice which will be sent to the email address you have filled out in the Billing contact e-mail field of the pre-paid modules order form.





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Annex 8

Definitions

Live educational event (LEE):

A meeting/event, 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 presence of a participant on the event's site or a tele-presence when an event takes place. 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.

By extension, live webinars are considered LEEs. A webinar is a live online educational presentation during which participation by viewers can be confirmed and they can submit questions and answers.

The recording of a live educational event made available online after the event has taken place is not considered a LEE. It is therefore not permissible to transfer the credits granted to a LEE to a viewer of an online recording of the LEE.

The recording however may be considered an e-learning material if it complies with the criteria for the accreditation of e-learning materials.

E-learning material:

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.

Blended learning:

An educational programme that combines obligatory participation in a LEE and completion of an associated elearning component. To apply for the accreditation of a blended learning module, you will need to apply for the live educational component and also for the e-learning component of the module separately.

Continuing Professional Development (CPD) and Continuing Medical Education (CME):

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 behaviour.

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.





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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.

Organising/Scientific 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.

Unrestricted educational grant:

An unrestricted educational grant is financial sponsorship offered to a provider by the sponsor through a transparent contract. All funding must be provided free of any attempt of the sponsor to influence the programme, individual sessions, subjects for discussion, content or choice of faculty members.



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Annex 9

EACCME® Event Report

LACCIVIL	ent neport	
Event reports must be submitted at the latest 4 week	s after the accredited event has	taken place.
Event title:		
		••••••
Event date: Event city:		
EACCME® reference number:		
Actual number of participants:		
Please provide breakdown (in %) of international	participation:	
European participants		
American participants		
Canadian participants		
Other: please specify		
Number of evaluation forms submitted:		
Number of EACCME® certificates distributed:		
Summary of evaluation forms completed by the p	participants:	
Your feedback as a provider must include at least		Please refer to the
EACCME® participants' evaluation form for the inform	mation to be provided below:	
Category	Number of respondents	Mean score
Quality of the event		
Relevance of the event		
Suitability of formats used during the event		
Ways the event affected the participant's practice		
Commercial bias		





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Annex 10

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EACCME® participant's evaluation form

1) Quality of the event

How useful for your professional activity did you find this event?

Programme Organisation What was the best aspect of this event? What was the worst aspect of this event? Programme Organisation What was the best aspect of this event? Programme Organisation What was the best aspect of this event? Programme Organisation What was the best aspect of this event? Programme Organisation What was the worst aspect of this event? Programme Organisation What was the best aspect of this event? Programme Organisation What was the best aspect of this event? Programme Organisation What was the best aspect of this event? Programme Organisation What was the best aspect of this event? Programme Organisation Not at all Undecided How useful to you personally was each session?	Extremely use	eful	Usefu	ıl	Faiı	ly useful		No	t useful
Excellent Good Fairly good Poor Very poor	f this activity was	not useful, p	lease expl	ain why:					
Programme Organisation What was the best aspect of this event?	What was your ov	erall impress	ion of this	event?					
Programme Organisation What was the best aspect of this event?		Excellent	: (Good	Fairly g	ood	Poor		Very poor
What was the best aspect of this event? 2) Relevance of the event Did the event fulfil your educational goals and expected learning outcomes? Very much Somewhat Not much Not at all Undecided Was the presented information well balanced and consistently supported by a valid scientific evidence on the presented of the event fulfil was each session? Very much Somewhat Not much Not at all Undecided How useful to you personally was each session? Extremely Useful Fairly Not useful Undecided	Programme				-				•
2) Relevance of the event Did the event fulfil your educational goals and expected learning outcomes? Very much Somewhat Not much Not at all Undecided Was the presented information well balanced and consistently supported by a valid scientific evidence oase? Very much Somewhat Not much Not at all Undecided How useful to you personally was each session? Extremely Useful Fairly Not useful Undecided	Organisation								
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How useful to you personally was each session? Extremely Useful Fairly Not useful Undecided	pase?						·		
Extremely Useful Fairly Not useful Undecided	<u> </u>	-							
useful useful DNA	How useful to you	Ext	tremely			•	Not use	ful	Undecided
1 st session's title			ıseful		ι	ıseful			DNA

PRESIDENT: DR ROMUALD KRAJEWSKI SECRETARY-GENERAL: PROF VASSILIOS PAPALOIS

TREASURER: DR BERNARD MAILLET LIAISON OFFICER: DR ZLATKO FRAS

UNION EUROPÉENNE DES MÉDECINS SPÉCIALISTES EUROPEAN UNION OF MEDICAL SPECIALISTS

Association internationale sans but lucratif – International non-profit organisation

3) Suitability of formats used during the event

Was there adequate time available for discussions, questions & answers and learner engagement?

Yes, always/almost always	Yes, sometimes	Only rarely	Never	Undecided

Can you indicate any innov	ative elements	during the	activity?

4) Ways the event affects clinical practice

Will the information you learnt be implemented in your practice?

Very much	Somewhat	Not much	Not much Not at all	

Can you provide ONE example h	now this event	will influence	your future	practice?

5) Commercial bias

Did all the faculty members provide their potential conflict of interest declaration with the sponsor(s) as a second slide of their presentation?

Yes, all	Yes, for the majority	Yes, but only a small part	No	Undecided/ don't know

Can you provide an	example of biased	presentation i	n this activity?

Do you agree that the information was overall free of commercial and other bias?

Strongly agree	Rather agree	Rather disagree	Strongly disagree	Undecided/ don't know