

# Standards & Guidelines for Accreditation of eLearning Materials

## *Scope and Standards*

1 Only CME materials that exclusively benefit hematologists and their patients are eligible for accreditation.

2 Only academic or scientific organizations are eligible to apply for accreditation. Only a trained specialist in hematology or related field is eligible to apply for accreditation on behalf of the academic or scientific organization.

3 The academic or scientific organization and its representative (together to be called ‘the organizer’) are fully responsible for adherence to these standards and guidelines.

4 The items referred to as “eLearning materials” are to be interpreted as the materials delivered to the learner via electronic means, such as but not restricted to: recorded audio, recorded visual, digital presentations, digital quizzes, distance learning available online via an educational website, or a mixture or technological development of the aforementioned media.

5 EBAH recognizes that some technologies go beyond conventional definitions and that eLearning can encompass learning via electronic media in combination with face-to-face interactions and those are also considered by means of applying the criteria for eligibility for accreditation of general eLearning materials. Such items, referred to as “blended learning”, include all the media listed above used also in combination formats in which the material is coupled with interactions between learners and teachers. This can be achieved via outlets that encompass but are not restricted to: asynchronous online platforms that allow peer-to-peer interactions and teacher’s interventions and online programs that include forms of face-to-face interactions between users.

## *Guidelines*

### **1 Commercial interest**

1.1. The eLearning materials that benefit the organizing institution or any commercial interest are not eligible for accreditation. The organizer must ensure that the educational and scientific content of the material is neither influenced by nor biased by commercial entities. This implies, but is not restricted to, the following:

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1.1.1. The organizer must select the topic and content of the eLearning material independent from (the review of) the donor(s) of the educational grant(s) or any commercial entity.

1.1.2. The organizer must develop the educational materials of the eLearning activity independent from (the review of) the donor(s) of the educational grant(s) or any commercial entity.

1.1.3. The eLearning material must be clearly distinguished from commercially organized materials (e.g. “hot links” to commercial websites). These must not compete with or be prominently placed over or mixed with the accredited eLearning material. The eLearning material must be apart from any commercially organized links, contents or commercial promotional efforts.

1.1.4. The use of logos, symbols, colors, etc. that refer explicitly or implicitly to the donor(s) of the educational grant(s) or any other commercial entity is not allowed (save conditions stated in paragraph 1.2.4.). All content must be free of any form of advertising.

1.1.5. The use of commercial product names is not allowed. Generic names must be used throughout all the material and content. Only in case no generic name is available the trade name may be used (e.g. Thalidomide).

1.1.6. Data relative to any unlicensed, investigational commercial product must be presented as such. Information must be of scientific peer review journal standard.

1.1.7. The material must ensure, respect and confirm the privacy and confidentiality of the user and the user information, and confirm that any information provided will only be used for the specific purposes of completing the material. This is particularly relevant in the case of interactive material, such as educational websites. Information on the user must not be shared with third parties or sponsors.

1.2. EBAH recognizes the importance of the contribution of financial resources from the healthcare industry to eLearning materials. To allow for good cooperation with the healthcare industry, the EBAH believes that it is necessary to adopt a balanced approach that will guarantee transparent CME materials. This implies, but is not restricted to, the following:

1.2.1. The financial contribution to the eLearning material by one or more commercial entity or entities is allowed only by a way of an unrestricted (i.e. substantively independent) educational financial grant. This contribution must be granted to the organizer. Contributions to eLearning materials other than financial support (e.g. development or organizational contributions) are not permitted.

1.2.2. The donor(s) of the unrestricted educational grant(s) must be acknowledged, in writing, by the organizer of the material to the users of the material and to EBAH.

1.2.3. Any communication material promoting the eLearning material distributed by the donor(s) of the unrestricted educational grant(s) must be reviewed beforehand by the organizer. Any written reference to the donor(s) of the unrestricted educational grant(s) must be prefixed by: **'supported by an unrestricted educational grant from [name of commercial entity].'**

1.2.4. Any communication material promoting the eLearning material distributed by the organizer (see paragraph 114) may include the statement **'supported by an unrestricted educational grant from [name of commercial entity].'** Only when preceded by this statement,

and only once, a discrete logo may be included (being the sole exception to the conditions stated in paragraph 117).

1.2.5. The only permitted promotion is the acknowledgement that the commercial entity has contributed to the eLearning material by way of an unrestricted educational grant.

1.2.6. Any relevant financial relationship of individuals involved in any way the preparation or carrying out of the eLearning material must be fully declared. A financial relationship is considered relevant in case the individual, or the individual's spouse or partner, benefits, or has benefited in the 12 months prior to the application of accreditation, by receiving salary, royalty, intellectual property rights, consulting fees, honoraria, ownership interest or other financial benefit from a commercial entity.

## **2 Eligibility**

2.1. The organizer must provide a description of their association, society or organization. Scientific or academic organizations are eligible to apply for accreditation of their eLearning materials, commercial organizations are not.

2.2. The following materials are not eligible for eLearning accreditation: commercial presentations, sponsored hot links, and any other content not part of the scientific peer reviewed eLearning material.

2.2. Blended learning activities that allow users to learn using blended methods that include eLearning as described alongside a combination of face-to-face personal interactions and/or interactions on an asynchronous learning platform, forum or outlet are eligible to apply for accreditation. In case such blended learning activity outcomes depend heavily on levels of users engagement, this is only eligible for accreditation when the organizer agrees to monitor for user's activity and achievement of learning objectives for granting credit points.

## **3 Quality**

3.1. The quality of the eLearning material is subject to the review of scientific peers who will evaluate the material on the basis of the following criteria:

3.1.1. The individuals involved in the preparation of the eLearning material are specialists in hematology or related fields and are of high academic and scientific repute.

3.1.2. The eLearning material must recognize and meet the needs of hematologists and their patients. Therefore, the material must respond to a detected learning need, a lack of knowledge found and must specify its intended audience. The material should be created to cover the detected learning need(s). In order to identify the aforementioned needs, a "needs assessment" process should have been performed beforehand. The need(s) detected must be clearly defined by the organizer as well as the method used to detect them.

3.1.4. The learning objectives of the material must be defined according to the learning identified. Those objectives should respond to the learning needs detected and should be used to evaluate the success of the learning material. Therefore the material must be bound by expected learning outcomes. These learning objectives must be covered in terms of the knowledge, skills or any other relevant lessons that can be learned, and whether these are clinical or non-clinical. The learning objectives should be worded in both general terms, stating the general purpose of the activity and also worded in specific objectives, more detailed and tell what the students will be able to know once they complete the learning activity successfully. They must be assessable.

3.1.5. The material should encourage the user to utilize 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 improving learning.

3.1.6. The material should address the stated learning needs and also indicate how this will be achieved with the justification of the learning method selected. It is necessary to define which learning methods and will be used in the material. Teaching methodology applied throughout the material needs to be appropriate in order to cover the objectives. The teacher's role (passive or more active), the interaction between teachers and learners, the activities proposed are factors that should be considered to implement the appropriate method to achieve the learning objectives. The methodology must be clearly defined by the organizer and has to be related with the objectives of the program.

3.1.7. The eLearning materials must allow for the user to be assessed on their engagement with the material and provide some sort of feedback to the organizer. The material must include an assessment method or a means of confirming user engagement, and the achievement of the educational objective(s). It can consist of multiple-choice questionnaire, other self-assessment methodologies, contributions to forums, case studies, summaries, schemes, algorithms, virtual simulations, or user monitoring means by technological means (e.g. how much time was spent inside the platform) or teacher-centered (e.g. in the case of blended learning formats). This should be set by the organizer and be described upon application.

3.1.8. It is also highly encouraged the possibility to provide feedback on the user's assessment, e.g. with an explanation of why a response to a self-assessment question was incorrect, when this is possible.

3.2. The eLearning material has to be suited to the target audience. Such target audience should be stated, and match the needs assessment study that was conducted, detailed describing to which health care professionals the material is most likely to benefit.

3.3. The eLearning materials must be scientifically peer reviewed in the standard required for a publication in a scientific journal. Criteria for the review must include the assessment whether the material recognizes and meets the needs of hematologists and their patients. Furthermore, the materials must meet aforementioned needs of hematologists and their patients. The individuals involved in the review should be specialists in hematology or related fields and are of high academic and scientific repute.

3.4. The eLearning material must be linked under the relevant sections of the European Hematology Curriculum, for harmonizing purposes, as it is endorsed by 27 countries in and outside Europe.

## 4 Procedure

### 4.1 Submission

4.1.1. The application must be completed and submitted by the organizer (i.e. its representative) of the eLearning material, who will be the contact person for the entire accreditation process.

4.1.2. The organizer must demonstrate that the eLearning material corresponds to the needs of hematologists and their patients. The organizer must state what the needs are, how they were identified, and how the proposed activity meets them.

4.1.3. The organizer must state the learning objectives of the eLearning material, how they will be evaluated, and present the profile of the participants to whom the activity is addressed.

4.1.5 The organizer must describe the teaching methods to be used and how these are adapted to the needs of the users.

4.1.6. The organizer must present the scientific content of the eLearning material. The content submitted for accreditation must include all material to which the learners will be exposed.

4.1.7. The program must be open for review, without costs, to the reviewers of EBAH for assessment. For reviewing purposes, it must be possible to run through the program freely without fully completing tests and meeting other interactive requirements (skip-functionality). For that purpose, all details for direct access to the educational material and educational platform must be provided.

4.1.8. In case the eLearning material is sponsored by way of one or more grants provided by a commercial entity, the organizer must present a declaration signed by the commercial entity or entities and the organizer stating that the grant is of an unrestricted and educational nature.

4.1.9. Accreditation of eLearning materials will be valid for two years from the date of confirmation of accreditation. A reaccreditation application can be submitted after an update of the material has been undertaken. An update of the content of the program or any other changes, which do have an effect on the learning objectives, must be communicated to EBAH.

### 4.2 Fees

4.2.1. The organizer must transfer to EBAH a submission fee. Upon application an invoice will be issued which must be referred to in the transfer comments. Costs are as follows, according to the duration of the program:

Application

*First 30-min. Program: 425 Euros*

*First 1-hour program: 850 Euros*

*2-hour program: 1.000 Euros*

*3-hour program: 1.150 Euros*

4.2.2. Non-standard programs, including, but not restricted to, blended learning or closed courses and mixed formats, will be charged according to the policy for live events or will be charged according to a combination of the policy for live events and the policy for online events, depending on specifics.

### 4.3 The eLearning material

4.3.1. The organizer must inform all users of the EBAH CME accreditation and let them know credit points are granted upon successful completion of said material. This information text should also include instructions to create a user account on the EBAH CME system so their points can be included upon completion.

4.3.2 The organizer must collect disclosures of all authors and individuals in any way involved in the preparation of the eLearning activity and inform them of the obligation of providing up-to-date information, to be submitted along with the application in the EBAH CME system (see paragraphs 1.2.6-8). The material must provide the name and title of a medical practitioner who will take responsibility for its content. This hematologist must be registered with a Medical Regulatory Authority, and the relevant registration details must be provided.

4.3.3 The organizer must inform all users that the disclosures will be available on the EBAH website and provide a clear link to such disclosure file, for transparency purposes.

4.3.4 The material must contain the names and qualifications of the individual(s) involved in preparing its content. All individuals who have contributed to the preparation and presentation of the material(s) are identified and must disclose their affiliations. A full declaration of actual or potential conflict of interest of the individual(s) involved in preparing the content of the material must be provided upon application.

4.3.5. The organizer must inform all users about the CME accreditation by including the following statement in the eLearning material descriptions and communications:

**“The content of the [insert title of eLearning material] has been reviewed and approved for CME accreditation by the European Board for Accreditation in Hematology (EBAH). EBAH has approved this eLearning material for a determined number of CME credits. Each hematologist should only collect credits for time that she/he actually spent engaging with the eLearning material.”**

4.3.6. The organizer must make available to all users of the eLearning material a document (e.g. educational booklet) summarizing the material’s scientific content and providing references for further reading, linking it to the European Hematology Curriculum. The organizer must make this document available to EBAH.

4.3.7. The organizer must keep the announcement of the EBAH CME accreditation in the homepage or starting page of the eLearning material.

4.3.8. The organizer must provide technical information and support, stating the required format and possible system specifications for use of the material (e.g. Windows/MacOS; DVD region), and must provide contact details for the provision of assistance. Furthermore, the organizer must agree to install and cooperate to the technical developments pertaining to the link between the eLearning platform that supports the material and the web service that allows the granting of the points automatically to each user's EBAH CME account upon successful completion. Such technical support should also be available for the user in case any issues related to functionality of the accredited eLearning material.

4.3.9. One educational hour time expected to count as one EBAH CME credit point.

## ***5 Responsibility***

5.1. All views must be presented in a balanced and transparent manner. The organizer is fully responsible for the scientific impartiality, objectivity, quality, and balance of the scientific content of the eLearning material.

5.2. The organizer will assume complete and undivided responsibility for the adherence to these standards and guidelines. Failure to respect these standards and guidelines will lead to the ineligibility for or to the revocation of accreditation of the eLearning material.

5.3. The organizer must clearly state compliance of the eLearning materials with all relevant ethical, medico-legal and legal requirements. Where applicable, these must include: consent by patients and other participants to inclusion in the contents, confirmation of confidentiality for patients and other participants, compliance with research ethics requirements, compliance with data-protection legislation, and copyright arrangements for the material. It is essential to ensure that patients are not, and cannot be identified in any of the materials presented.