

Clinical Content Validity Guidelines

These guidelines are to establish the validity of clinical content to be shared in a CME activity.

A. CME Program Office ensures the above by:

1. Working closely with the Activity Director so that activity is planned and the content is controlled in compliance with the Policy on Clinical Content Validation of CME.
2. Reviews the content of the CME activity and documents the evidence of recommendations, treatments and manners of practicing medicine transmitted in CME activities.
3. Assessing the content of the activity matching the learners' current professional practice.
4. Appraising the content of activity developed in the context of desirable physician attributes (e.g., IOM competencies, ACGME competencies).
5. Sharing the content of the activity with the independent reviewer prior to the activity.
6. Separating the Independent Reviewer from planning or execution of that specific activity.
7. Sharing the approved result regarding the content of the activity with speaker for further actions, if required.
8. Revisiting the enduring material content from time to time so that the content is up-to-date with the new scientific developments.
9. Communicating the learning objectives/ goals of the activity to learners.

B. Activity Director ensures above by:

1. Involving the faculty with the wide range of opinions and perspectives; and have an objective view of research and treatment options in the CME activity.
2. Encouraging the speakers to keep the appropriate room for discussion, debate and for exploring new and evolving topics while presenting.
3. Facilitating the learners' engagement with new and evolving topics without advocating for, or promoting practices that are not, or not yet, adequately based on current science, evidence and clinical reasoning.

C. Independent Reviewer ensures above by:

1. Validating that the recommendations for patient care are based on current science, evidence and clinical reasoning, while giving a fair and balanced view of diagnostic and therapeutic options.
2. Reviewing the scientific research referred to, reported or used in CME activity is in support of a patient care recommendations.
3. Determining that the content does not advocate for unscientific approaches to diagnosis or therapy or promotes recommendations, treatment or manners of practicing healthcare that are determined to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients.
4. Reviewing the content of activity involves appropriate room for discussion, debate and exploring new and evolving topics.
5. The Independent Reviewer is the subject expert who remains unknown in the activity and cannot have any relationship with any Corporate Entity supporting the activity.
6. An Independent Reviewer will ensure that the activity materials are fair, balanced and free from bias towards the commercial supporter (s) of the activity (if any) or manufacturers of products discussed in the activity.

7. He or she would further scrutinize patient treatment recommendations to ensure they represent a standard practice for the profession.
8. In addition, an Independent Reviewer has to review the studies cited in these materials upon which recommendations are made to ensure that they are scientifically objective and conform to research principles generally accepted by the scientific community.
9. If confused, he or she should call a committee or take opinion from a second expert. This should be reported to CME Program Office.