

EASD Guidelines, Position Statements and Consensus Reports

MEMORANDUM OF UNDERSTANDING (MOU)

between

EUROPEAN ASSOCIATION FOR THE STUDY OF DIABETES e.V.,
hereinafter called **EASD**

and

**EASD Members, any Study Group, Society or Societies requesting joint
guidelines/statements/reports**
hereinafter called **Writing Group**

each party hereinafter called a "Party" and both parties collectively called the "Parties"

1. Subject and Purpose of this MOU

- a) The purpose of this MOU is to identify clearly the roles and responsibilities of each party as they relate to the guideline/position statement/consensus report entitled:

- b) Please tick the appropriate box:

- | | |
|--|---|
| <input type="checkbox"/> EASD guideline | <input type="checkbox"/> joint guideline |
| <input type="checkbox"/> EASD position statement | <input type="checkbox"/> joint position statement |
| <input type="checkbox"/> EASD consensus report | <input type="checkbox"/> joint consensus report |

For joint projects please indicate the cooperating society/societies:

- c) The MOU is a declaration of intent and is, except the No. 7, 8 and 11, not binding on either party. This declaration does not create any rights or obligations. In particular, the parties shall not be entitled to claim damages for non-performance.

2. Definition guideline, position statement and consensus report

- a) Guidelines are systemically developed statements, algorithmic in approach, to support the decision-making of persons working in the health care system. They are evidence-based, as well as grounded on procedures proven in practice; they are intended to take economic aspects into account in addition to safety and transparency in medicine. Guidelines serve only as a decision-making aid and are therefore not legally binding.

- b) A position statement is the written determination of a certain view or position and often deals with complex contentious issues; in some instances, the existing evidence may be limited or not (yet) available. In contrast to a guideline, position statements do not include an algorithmic approach and are rarely implemented by committees.
- c) A consensus report is a public statement on an aspect of medical knowledge at the time the statement is made that a representative group of experts agree to be evidence-based and state-of-the-art knowledge. Its main objective is to inform healthcare professionals on the best possible and acceptable way to prevent, predict, diagnose and treat a certain disease or how to address a decision-making area.

3. Procedural requirements:

- a) The document must address a matter relating to clinical diabetes, and should consider medical practice. It should contribute to decision-making on the relevant issues.
- b) Before the work commences by the Writing Group, the EASD Board should be contacted for their agreement concerning:
 - the remit and the constitution of the Writing Group,
 - the proposed publication and dissemination plans of the final document.
- c) The proposed document should be planned to be the length of a paper likely to be published in *Diabetologia* or other major journals; in general, this means under 6000 words. Long, in-depth reviews, papers with chapters (books), and discursive documents will not normally be considered. However, an abbreviated and/or executive summary of these documents may be produced, and considered for publication. In *Diabetologia*, the final decision on acceptance of texts generated under this MOU lies with the Editor-in-Chief.
- d) Guidelines, position statements and consensus reports should be evidence-based as far as possible.
- e) Guidelines, position statements and consensus reports should have a wide collateral review by others outside the Writing Group.

4. Constitution and remit of the Writing Group

The proposed constitution of the Writing Group should be outlined. The number of EASD representatives must be adequate, i.e. if diabetes should be the major topic at least equal representation is necessary; if diabetes should represent a minor part of the topic this can be waived. The provenance, committee selection procedures and authority of the group need to be explicit and transparent, and guidance should be sought from the EASD Board.

The Writing Group shall:

- a) delineate the remit,
- b) summarise the topic, the main purpose of the guideline, statement or report, and to whom it is being addressed,
- c) declare conflicts of interest,
- d) propose a timeline,
- e) follow the AGREE principals (<https://www.agreetrust.org>) for guidance on formulating guidelines,

- f) submit draft, revised and final versions of the paper as well as every other material on which the name or the logo of the EASD should be used, to the EASD executive office in a timely manner so that they can be noted,
- g) include the costing envisaged together with any pharma or other support available,
- h) define the authorship etc. but note that this needs to be done prior to the agreement of EASD to have its name and logo on the paper.

5. Remit of the EASD

EASD shall undertake the following activities:

- a) On receipt of a proposal, the EASD Committee on Clinical Affairs (CCA) will nominate official representatives to be part of the Writing Group. These representatives are obliged to send a written report to the executive office to be forwarded to the Board, when the first draft has been successfully completed and stating that they are in agreement with the guidelines/statements/reports. It is the duty of the EASD representatives to alert the EASD Board in a timely manner if, during the writing phase, there are major dissonances which cannot be overcome to their satisfaction, making an eventual positive recommendation to accept the guidelines/statements/reports difficult (problematic) for them.
- b) The executive office of EASD will forward the draft guidelines/statements/reports to CCA for their review, comments and recommendations. The CCA will particularly check that the new guidelines/statements/reports do not contradict previously endorsed guidelines/statements/reports. Where contradictions occur, the CCA may ask the Writing Group to amend the paper or justify the contradiction, for example based on new knowledge. Afterwards, the CCA will send the reviewed, commented and recommended draft of the guidelines/statements/reports to the EASD Board through the EASD executive office. The Board needs to agree or disagree before the Writing Group/authors will be informed accordingly and, in the case of recommendations/amendments, asked to implement them.
- c) When all recommendations have been implemented with accordance of the Board, the guidelines/statements/reports will be endorsed by the Board. A final decision on dissemination/publication can only be made after the guidelines/statements/reports have been approved. Then CCA would make a recommendation about the dissemination, including the possibility of publication in *Diabetologia*, of the finished article. The Editor-in-Chief of *Diabetologia* has the decision right whether such publication is approved.

6. Consequences of the recommendation

In case the EASD Board, based on CCA's recommendation(s), requests modifications to the draft guidelines/statements/reports, the Writing Group can either

- a) decline to implement the recommendations, or
- b) implement the recommendations.

In the case of a), EASD will not endorse the guidelines/statements/reports and they will not be considered as such.

In case of b), once the guidelines/statements/reports have been approved by CCA and by the EASD Board, an official letter conveying this decision signed by the President and the Chair of CCA will be passed on to the Writing Group via the executive office. A final certified version

of the guidelines/statements/reports will be sent to the executive office by the Chair of CCA for dissemination and publication as appropriate.

7. Confidentiality

- a) The parties agree to keep confidential information confidential beyond the termination of the cooperation. This applies to all persons involved in this cooperation. Information shall be considered confidential if it is expressly marked as confidential.
- b) Information shall in principle remain the property of the respective party regardless of the nature of the embodiment. The transmission of information does not confer any rights to the Writing Group.

8. Costs

EASD will cover the costs (travel and accommodation) incurred by its nominated representative(s) on the Writing Group. Any further costs arising in connection with this MOU should in principle be born independently by each party and must be discussed.

9. Contradicting MOUs

- a) In the case of contradicting MOUs of the parties in individual points or completely, initially only those points which coincide in content shall apply. All contradictory points should be renegotiated so that all parties' perspectives reconcile adequately.
- b) If the Writing Group does not show any willingness to compromise, the CCA and the Board of EASD reserve the right to refuse the cooperation without stating further reasons.
- c) In case that MOUs or contracts need to be signed for a joint cooperation, these must be sent to the CCA in due course.

10. Miscellaneous

- a) If any provisions of this MOU are found to be invalid, or if any regulatory gap should arise, this shall not affect the validity of the remaining provisions. In such cases, the parties shall endeavour to find a solution that comes as close as possible to the economic result of the invalid provision and to what the parties actually intended.
- b) German law applies exclusively and the place of jurisdiction is Düsseldorf, Germany.
- c) Amendments of this MOU must be made in writing.

11. Effective Date and Signature

This MOU shall be effective upon the signature of EASD and the Writing Group’s authorised official. It shall be in force from to

In the event that the project underlying the MOU does not begin or is not finished by the end date, the MOU shall lose its validity and the Writing Groups will need to submit a new MOU for further approval by the EASD.

EASD and the Writing Group indicate agreement with this MOU by their signatures.

Place, Date

Place, Date

Signature EASD

Signature Writing Group