

GRADE Ontology Detailed Protocol

This document describes the process the Working Group will follow to create a standardised vocabulary for GRADE concepts. This is a draft document. Last updated: 14 Jul 2025

Updated versions of this document should be posted to <https://zenodo.org/records/11002448>

1. Define the project team: GRADE Vocabulary Working Group

- a. GRADE Vocabulary Working Group membership will be open to any individual who self-identifies as a relevant expert for the GRADE Vocabulary. Relevant expertise for a code system may include, but is not limited to, experience evaluating or expressing the concepts to be included in the code system, either for human interpretation or for machine interpretation.
- b. The GRADE Working Group will be notified about the ability to join the GRADE Vocabulary Working Group.
- c. Process decisions will be made by the GRADE Vocabulary Working Group members who are present at an open meeting at the time of the decision (herein referred to as the 'steering group').

2. Scope of terms to cover certainty of evidence and evidence-to-decision judgments (103 terms)

- a. draft term list derived from <https://fevir.net/resources/CodeSystem/27833> - prior GRADE project work
- b. 18 Certainty of Evidence Domain terms - Overall certainty, Risk of bias, Inconsistency, Indirectness (5 types), Imprecision, Publication bias, Dose response gradient, Plausible confounding, Large effect, Direct effect estimate, Indirect effect estimate, Incoherence, Intransitivity

- c. 5 Certainty of Evidence Rating terms - High certainty, Moderate certainty, Low certainty, Very low certainty, No evidence
 - d. 12 Certainty of Evidence Domain Rating terms - no serious concern, serious concern, very serious concern, extremely serious concern, present, absent, no change to rating, reduce rating -1, reduce rating -2, reduce rating -3, increase rating +1, increased rating +2
 - e. 2 Recommendation Domain terms - Strength of Recommendation, Direction of Recommendations
 - f. 6 Recommendation Rating terms - Strong, Weak, For, Against, Good practice statement, Recommendation to use intervention only in research
 - g. 16 Decision Factor terms - Problem Importance, Desirable Effects, Undesirable Effects, All critical and important effects, Values Variability, Balance of Effects, Resources Required, Cost-effectiveness, Equity, Acceptability, Feasibility, Test Accuracy, Test's Effects, Natural Course (Prognosis), Intervention Effects (Management Effects), Link between Test results and Management
 - h. 24 Decision Factor Rating terms - 10 'magnitude rating' terms, 4 'variability rating' terms, 5 'direction of effect rating' terms, 5 'cost rating' terms
3. **Identify all the GRADE publications which may contain definitions of the relevant terms.**
 4. **For each term, from each publication, extract the relevant text to support preferred term, alternative terms, definitions, and guidance for application of the term.**
 5. **Draft for each term the preferred term, alternative terms (if any), definition, and guidance for application of the term.**
 - a. **A preferred term is**
 - b. **An alternative term is**
 - c. **A definition is**
 - d. **Guidance for application is**

6. For each term (for voting for approval): consensus process re: term definitions (attempts will be made iteratively to achieve 100% agreement and if unable then a deliberative process with at least 80% agreement will be required for term approval)

- a. When the steering group determines the draft term is “ready for vote”, voting will be open to members of the expert working group and the GRADE Vocabulary Working Group will be emailed a notice that the term is open for voting.
- b. Voters will either select YES for approval of the term (including display, alternative terms, definition, comment for application, and hierarchical listing regarding parent term) or select NO with the addition of a comment suggesting the change that would make the term acceptable. The voting process will be online and asynchronous.
- c. The content of individual votes (YES or NO selection, comments, and name of voter) will be visible to code system editors and may be shared during steering group meetings but will not be generally posted for open viewing outside steering group meetings and active editing of the code system.
- d. If a term has been open for vote for at least six days and has at least five votes and all votes are YES, the term will be considered provisionally approved (pending GRADE Guidance Group approval) and closed for voting.
- e. If a term has a NO vote, the steering group will review the comments, determine if any changes to the term are warranted, then:
 - i. If changes are made, when the steering group considers the term “ready for vote” the voting start date will be reset and the term will be open for vote as noted above.
 - ii. If the steering group determines no changes are warranted, the term will remain open for vote, the negative comment will be shared with the expert working group, and GRADE Vocabulary Working Group voters may change their vote by voting again.
 - 1. If on repeat steering group review all votes are YES, the term will be considered approved and closed for voting.

2. If on repeat steering group review there are new NO votes, the steering group will review the comments and determine if changes are warranted.
 3. If on repeat steering group review there are no new NO votes and the original NO vote persists, the person recommending changes will be asked to provide a rationale for deliberation as described below and if not provided within 1 week the term will be considered approved and closed for voting.
- f. If term does not achieve universal agreement (cycling through steps a-e above with conflicting suggestions):
- i. Each person recommending changes will write a rationale.
 - ii. The rationales will be shared with the expert working group prior to a group meeting.
 - iii. The group meeting will discuss and prepare the preferred version. The preferred version and meeting discussion will be shared with the group.
 - iv. Group members will have 48 hours to vote for the presented version.
 - v. The preferred version will become the included version if it achieves at least 80% agreement with at least 5 people voting.
 - vi. If unable to achieve at least 80% agreement with at least 5 people voting, options may include extending the voting period, dropping the item, or preparing for another group discussion.

7. The development version of the GRADE Vocabulary will be openly published throughout the effort for complete transparency. When approved by the GRADE Guidance Group, we will publish the ready-for-public-use version of the code system at fevir.net.

- a. **When the code system is published, attribution of contributorship will be shared by:**

- i. Listing authors based on anyone who contributed as a “term editor” on any of the terms which occurs through the weekly web meetings
- ii. Listing endorsers based on anyone who contributed as a “voter” on any of the final-approval votes for any terms
- iii. Listing reviewers based on anyone who contributed as a “commenter” or a “voter” on any of the disagreement votes on any of the terms
- iv. All of these listings may be ordered by decreasing the number of contribution instances across the code system.

- b. **When the code system is published, we will seek publication of introductory articles to the code system in the biomedical literature (as a GRADE Guidance paper).**

8. After the first published version of the code system (vocabulary with definition & preferred display) is available, for implementation and initial evaluation of the code system, we will:

- a. identify tools and systems that could use the code system, including consideration of the previously “identified 23 commonly used tools and systems for which the first version of code systems will be developed”
- b. offer support for implementation and measure the proportion of systems that get engaged.
- c. evaluate ease of use.
- d. generate code system change requests as needed.
- e. track systems that implement the code system and set a regular review interval to inquire about usefulness and change requests.

9. For ongoing maintenance and development of the code system:

- a. We will maintain an open invitation for code system users to join the expert working group for recognized contribution.

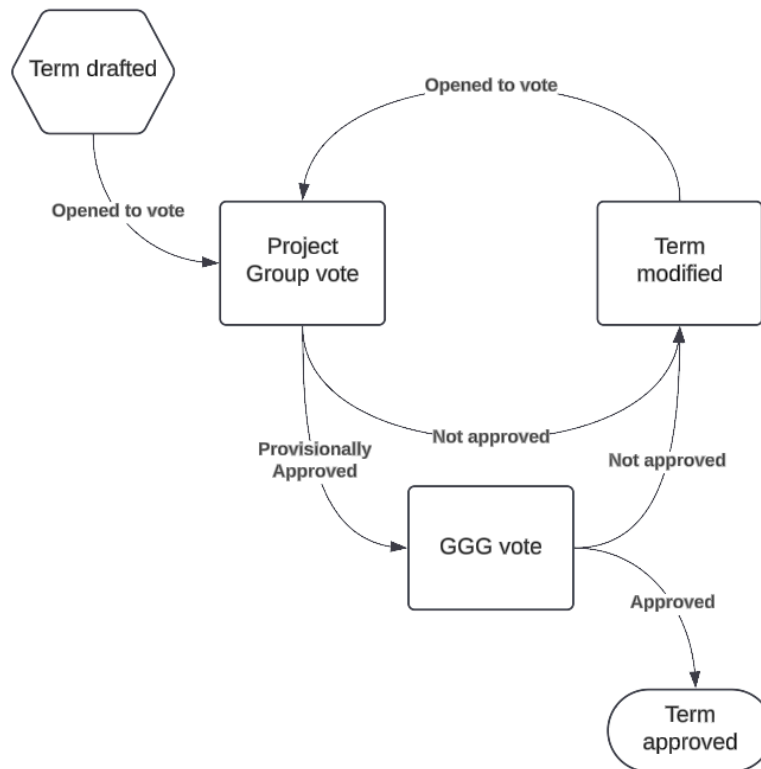
- b. We will maintain an open invitation for anyone to suggest additional tools or systems with common current use of concepts matching the code system.
- c. We will maintain an open invitation for anyone to share comments regarding specific code system terms for continued feedback.
- d. Code system changes may be initiated by change requests from the community.
- e. The steering group will validate that change requests are appropriate for group deliberation (e.g., fits the purpose of the code system, has sufficient rationale, avoids duplication).
- f. Valid change requests will lead to drafting a preferred display, synonym list, and definition. Voting on changes will then be processed as previously described.

10. If changes are requested after terms are approved while the code system is in development:

- a. The steering group may change Alternative terms and Comment for application through discussion in open meetings and changes will be reported to the Expert Working Group.
- b. Changes to the Preferred term or Definition for any term will result in setting the term back to draft and repeating the process for voting for approval. The prior “approval history” will be moved to a different term property but retained for documentation.

11. To ensure involvement of the GRADE Guidance Group (GGG) in validation of terms, definitions, and comments for application:

- a. Terms approved by the Expert Working Group will be considered “provisionally approved” until approved also by the GGG
- b. The GGG will vote and comment monthly on provisionally approved terms. Terms that are not unanimously approved by the GGG will be modified and reopened for vote by the Expert Group, as per the workflow illustrated below.



12. To ensure completeness of reporting of the ontology, documentation of the release version of the ontology (v1.0) will be compliant with the MIRO Guidelines (Matentzoglou, N., Malone, J., Mungall, C. et al. MIRO: guidelines for minimum information for the reporting of an ontology. J Biomed Semant 9, 6 (2018). <https://doi.org/10.1186/s13326-017-0172-7>)