# Manual: Instrument for rapid assessment of risk of bias in observational epidemiological studies on animal populations (raRoB-vet)

## Getting started


The structure of the tool follows the major steps in the critical assessment of risk of bias of an observational epidemiological study with animals. You can answer and complete the vertically arranged domains from top to bottom in order to proceed a complete risk of bias assessment. Each domain contains between 1-4 items that must be rated on a predefined scale.

Assign ratings to these items based on a predetermined scale, contributing to the comprehensive risk of bias assessment of the publication. Rating categories can be selected individually for each item.

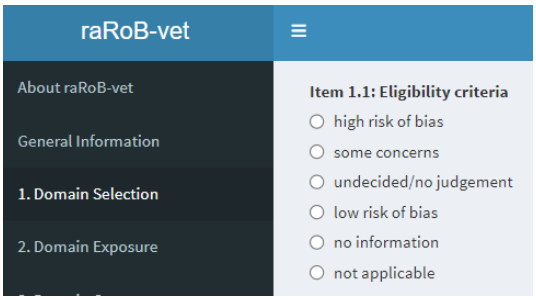
Assessment results can be downloaded in two formats: a MS-Word report (Microsoft Corporation, 2021), which includes item-based evaluations displayed in a spider plot, and an MS-Excel file (Microsoft Corporation, 2021), which presents individual assessment results in a tabular format. For systematic reviews, meta-analyses and/or weight of evidence approaches, it is recommended ton use the tabular format.

## Predefined rating categories

Each item is individually scored using one of the predefined categories.

**Low risk of bias** - A low risk of bias should be chosen if the questioned method component or the conduct or choice of essential parameters were appropriate to the study design and the research question, and possible biases were taken into account during the analysis.

**High risk of bias** - A high risk of bias is present if the chosen methods, study design, or essential parameters are unsuitable for addressing the research question, or if key components of the study were incorrectly implemented.




**Some concerns** - Select this category if there is some concern about bias, but it is not considered high.

**Undecided/No judgement -** Due to a lack of expertise, an assessment of this domain is not possible and would lead to false results.

**No information** - If no or only insufficient information is provided for a necessary method, study design or conduction step of the study, the category "no information" is selected. This category is rated equal to a high risk of bias in the overall risk of bias score.

**Not Applicable** - Choose this category if the item does not apply to the specific study being assessed.

## Steps - risk of bias analysis

### 1. General Information

- Specify the source that was assessed for risk of bias by entering the DOI of the publication to be assessed, its title and abstract.
- Identify the type of observational epidemiological study you are about to analyse under the section Study Design. Use the Help box if you are unsure about the study design, but in general, the study design is often mentioned within the publication.
- Indicate whether the present study design is suitable for answering the study question. Appropriateness of study design is the only non-domain-specific item in the tool and is collected at the very beginning of the assessment.
- Primary versus secondary data

Primary data is data collected exclusively for a specific research question, whereas secondary data refers to data that has already been collected for other purposes and is available through sources like registers, routine records, surveillance systems or databases. While primary data is more specific, up to date and tailored to the research question, secondary data can be more convenient and cost-effective but may not align perfectly with research question. The use of secondary data itself does not induce bias, but if the data has been collected for another purpose, there might be more challenges involved in using this data for the purpose of the current study. As a result this item does not contribute to the overall risk of bias score. However, both the choice of data to answer a specific question and the risk of selection bias and unmeasured confounding in using this particular data to answer the study question play an important role in study quality.

## 2. Domain - Selection

The selection domain deals with the process of selecting the study participants into the study or analysis. This includes the type, period and course of recruitment. Inappropriate procedures or selection criteria could lead to selection bias or even confounding.

In order to assess the potential bias for this domain, please rate the individual items according to the rating categories provided in the form. Items for the domain selection include:

- Eligibility criteria
- Comparability of groups
- Non-response rate
- Time Frames

Under the item time frames, assessors should also verify the temporality of exposure and outcome i.e. the exposure occurred before (the onset of) the outcome.

## 3. Domain - Exposure

In order to correctly assess the association between exposure and outcome, it is necessary to ensure an accurate data collection. Exposure measurements can be subject to measurement error or misclassification, hence a designated item in the assessment specifically addresses this bias in the subsequent evaluation.

In order to assess the potential bias for this domain, please rate the item according to the rating categories provided in the form. Item in the domain exposure:

Methodology of exposure measurements

## 4. Domain - Outcome

Measurement errors or misclassifications in outcome measurement can lead to bias. The bias is called non-differential if the outcome measurement error does not depend on the exposure status and differential if the outcome measurement error depends on the exposure status.

In order to assess the potential bias for this domain, please rate the item according to the rating categories provided in the form. Item in this domain:

Methodology of outcome measurements

## 5. Domain - Confounding

Confounding is a key issue in assessing the risk of bias of observational studies. If confounding is not prevented by the design of the study, remains undetected or is not taken into account in the analysis, the relationship between the exposure and the outcome would be biased. Appropriate analysis techniques may include stratified analysis, multivariable analysis, and propensity score matching.

In order to assess the potential bias for this domain, please rate the individual items according to the rating categories provided in the form. Items for this domain include:

- Accounting for confounding
- Confounding assessments

## 6. Domain - Censoring

In epidemiological studies generally, the withdrawal or drop out of study units for various reasons can have a notable impact on the validity of the study results.

In order to assess the potential bias for this domain, please rate the individual items according to the rating categories provided in the form. Items for this domain include:

- Adequacy of length of observation periods
- Relevance and handling of dropouts

## 7. Domain - Analysis

The choice of the statistical methods should be appropriate to the study question and study design, data collection, and limitations. It is also important that the amount of missing values is reported for the exposure, outcome, confounding variables and further variables. How the missing values were managed in the analysis also affects the risk of bias of the study.

In order to assess the potential bias for this domain, please rate the individual items according to the rating categories provided in the form. Items for this domain include:

- Statistical methods
- Handling of missing values

## 8. Domain - Selective reporting

Bias through selective reporting occurs when authors choose to report only certain outcomes or aspects of a study, while omitting others, leading to a distorted representation of the findings and/or an inaccurate or incomplete understanding of the true effects of an exposure. This distortion can have serious implications for evidence-based decision-making.

In order to assess the potential bias for this domain please rate the individual items according to the rating categories provided in the form. Items for this domain include:

Selective reporting of outcomes

## 9. Reviewer Information

Please enter your name in this section and, if you wish, a personal assessment of the bias risk of the individual publication, especially if you have missed an area for potential bias during the analysis or your personal assessment of the risk of bias for this study differs from the results of the guided assessment. Please give reasons for your entries.

## 10. Assessment results

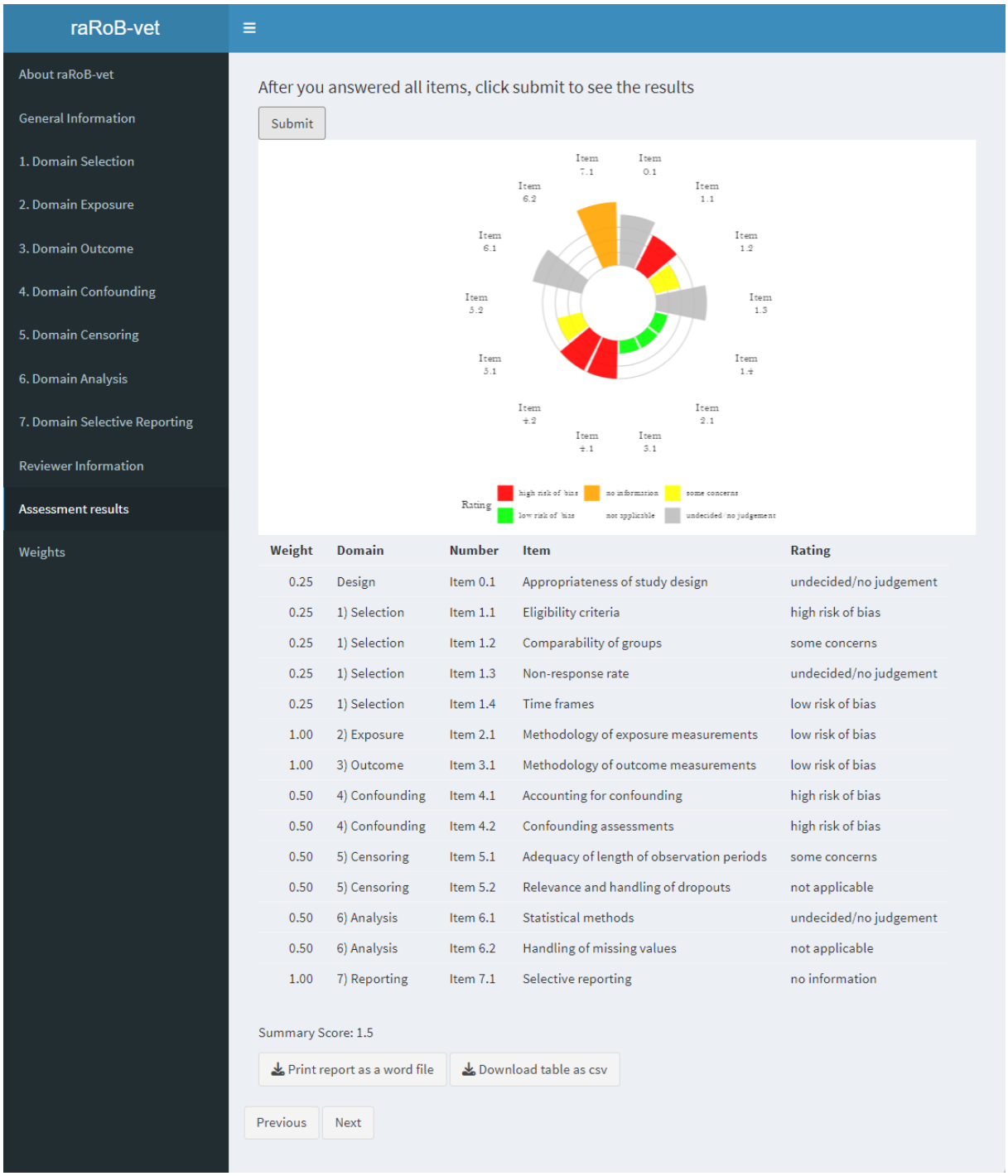
In order to obtain the report of your assessment, you have to answer all items and then you can click on the submit button and see the results in a circular bar plot. The legend underneath the plot shows what each colour is standing for. The table gives a list of your answers for all items. You can also save this table. This option is useful for example when you want to combine the assessment results of multiple papers (e.g. in a systematic review). All items and their corresponding comments together with reviewer information and their personal assessment can be saved as a stand-alone report in a word document.

The summary score beneath the table shows the semi quantitative assessment of the risk of bias. It is the weighted average of the assessment for each item, using numerical scores as follows: high risk of bias, some concerns, undecided/no judgement, low risk of bias, no information, not applicable. For more information on this score, please see the note in the Weights section.

## 11. Weights

In this section, you can set individual weights for each item, to calculate the summary score (see assessment results above).

**Important note:** The user-defined weights are required to calculate an overall numerical score. This feature was implemented in response to user requests. The default weights ensure that equal weights are placed on each of the domains, irrespective of the number of items assessed. The developers of this tool do not explicitly endorse the use of a sum score and advise users to consider the score only an indication of the magnitude of risk of bias (and not a quantitative measure of it) and use the results with caution. Studies with identical summary scores should not be assumed to have exactly the same risk of bias. Differences or ratios of sum scores for two studies are not necessarily proportional to differences or ratios of risk of bias.




Microsoft Corporation. (2021). Microsoft Word (2108) [Computer software]. Retrieved from: Office LTSC 2021

Microsoft Corporation. (2021). Microsoft Excel (2108) [Computer software]. Retrieved from: Office LTSC 2021