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Appendix

Authors: These minimum items of information are needed by our referees and Editors to evaluate your manuscript. Additional information may be appropriate, depending on your study design and objectives.

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   c. **Sample-size justification** appropriate for the study design and primary hypothesis. This should include details of adjustment for clustering (including the levels of clustering, the assumed cluster size, and either the design effect or the intracluster correlation) if clustering was present.
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   g. Declaration of the **experimental unit**
   h. Descriptions of the formal **random mechanism** (e.g., lottery or table of random numbers) and the list frame (enumerating every eligible subject and/or cluster) used at any step claimed to be “random”
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2. For **comparative studies** (including both observational and intervention studies):
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   b. Descriptions of how **blindness** was accomplished for all subjective evaluations

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b. Methods by which the owners of the animals gave informed consent for their animals to be in the trial

c. Methods used for allocation concealment after the animals were determined to be eligible for random assignment to the various experimental or control groups

d. Description and justification of the "control" group's "treatment" (e.g., standard therapy, placebo to mimic the delivery system in the absence of a standard therapy, or "do nothing" to mimic both the treatment and its delivery)

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4. For simulation studies and risk assessments:

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b. Descriptions of (and justifications for) all choices of distributions and their parameter values

c. Description of numbers, training, experience, and representativeness of any experts used to provide opinions

d. Declaration of the stakeholders for any risk assessment

e. Distinction between assumptions, input data, calculations from intermediate steps in the modeling process, and model predictions

f. Descriptions of the assumed chance variation and assumed knowledge uncertainty in the inputs, and methods used to deal with those sources of total uncertainty

g. Sensitivity analyses of key assumptions and of the input variables that had the greatest uncertainty

h. Descriptions of the variability in the "outputs" from stochastic models

5. For statistical-hypothesis tests:

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b. Alpha and tails, and any methods used to adjust for multiple comparisons (to protect experiment-wise alpha from the problem of multiplicity)

c. Methods used to adjust for clustering within the data

d. Methods used to determine that the statistical assumptions were met (e.g., that the data were Gaussian or that the odds ratio or hazards ratio was constant across the observed range of the risk factor)

e. Methods used to look for collinearities or other interrelationships among the risk factors being tested

f. Methods used to select or to retain risk factors within multivariable models (including the test criterion)

g. Clear declaration of any variables "forced into" the model (not allowed to drop out; this implies a need to account for that factor) or offered to the model on a priori grounds despite any screening results (this implies that the factor was part of a major hypothesis)

h. Description of the goodness-of-fit of any models

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