

Supplementary information form

To be completed by Drug and Therapeutics Committee delegate in consultation with applicant.

Evidence Supporting Application

Include all relevant randomised controlled trials and/or systematic reviews (meta-analyses).
(Copy following page if more space is required.)

Notes:

1. Copies of key papers should be included with the submission.
2. Unpublished studies may be considered (reason for non-publication should be provided). For unpublished studies, sufficient detail must be provided to allow independent assessment of results.
3. If no head-to-head studies are available for drug and comparator, other studies may be considered if they are likely to assist with decision-making, eg randomised, controlled studies with arms that include the various comparators.
4. Indicate if comparators, dosing regimens and duration of trial are relevant to local practice.
5. Indicate if study population(s) are relevant to local practice.
6. Indicate if benefits are likely to extend beyond the period of the trial.
7. If post-hoc sub-group analysis is included, highlight the limitations of the analysis so that risks associated with decision-making can be assessed.

Grading for Level of Evidence*

Level I	Evidence obtained from systematic review of relevant randomised controlled trials
Level II	Evidence obtained from one or more well-designed, randomised controlled trials
Level III	Evidence obtained from pseudo-randomised controlled trials (III-1), from well-designed comparative studies with concurrent controls: non-randomised, experimental trial, or cohort, case control or interrupted time series studies (III-2), or from a comparative study without concurrent controls (III-3)
Level IV	Case series with either post-test or pre-test/post-test outcomes

* From NHMRC additional levels of evidence and grades for recommendations for developers of guidelines 2009:
[https://www.nhmrc.gov.au/sites/default/files/images/NHMRC%20Levels%20and%20Grades%20\(2009\).pdf](https://www.nhmrc.gov.au/sites/default/files/images/NHMRC%20Levels%20and%20Grades%20(2009).pdf)

(Please copy and attach additional pages as required)

Reference number: Click or tap here to enter text.

Title:

Click or tap here to enter text.

Author(s):

Click or tap here to enter text.

Journal:

Click or tap here to enter text.

Date/Year: Click or tap here to enter text.

Drug and Comparators(s):

Click or tap here to enter text.

Number of patients in each arm:

Click or tap here to enter text.

Dose regimens:

Click or tap here to enter text.

Duration of trial: Click or tap here to enter text.

Outcome measure(s):

Click or tap here to enter text.

Study type:

Meta-analysis Yes No

Randomised Trial Yes No

Non-Randomised Trial Yes No

Case study with no controls Yes No

Efficacy:

Absolute Risk Reduction vs control: Click or tap here to enter text.

Statistically Significant ($p < 0.05$): Yes No

95% Confidence Interval: Click or tap here to enter text.

Number Needed to Treat: Click or tap here to enter text.

Evidence of clinical improvement:

_____ % Active vs _____ % Control

Safety:

Number Needed to Harm: Click or tap here to enter text.

Evidence of safety improvement:

_____ % Active vs _____ % Control

Evidence grading* I II III IV

* See notes on page 1

Comments (please refer to notes on page 1):**

** In particular, please comment on generalisability of trial data to specified hospital patient population