NHSF Efficacy Assessment Guide for Applicants

naturalhealth SCIENCE FOUNDATION

1.0 Background and basis of the efficacy assessment

Establishing that natural medicine products are efficacious is critical to defining their appropriate role in health care. To define such a role requires good quality clinical trial evidence together with certainty on which specific product has been trialled. This is due to the high variability of the active components of naturally sourced products which means that trial results are applicable to the specific product tested.

Following successful demonstration that the trial results are applicable to the product under assessment (the NHSF Quality and Equivalence Assessment) the Efficacy Assessment follows to substantiate that the clinical trial evidence broadly supports claims for the product.

The aim of the efficacy review is to establish whether or not, on appropriate and clearly stated criteria, a well-defined natural product is;

(a) Significantly more efficacious than placebo control; or
(b) Non-inferior to currently accepted evidence-based therapy; or
(c) Superior to currently accepted evidence-based therapy

in a *claim area* or *indication class*.

2.0 Disclaimers

1. It is assumed that the product has passed the Quality and Equivalence assessment of the Foundation, substantiating that the trials submitted are specifically on the product in question
2. As part of a successful Quality and Equivalence assessment, market approval of the product in a market such as the EU, Canada or Australia, will have been produced and authenticated to support product safety
3. The efficacy assessment provides no warranties or review of the safety of natural health products, specifically in relation to side effects, contraindications and interactions which will not be assessed by the Foundation as this is a matter for the regulatory authorities in each country
4. The assessment will not review specific claims on the product, which is the role of individual regulatory authorities, but will review whether the efficacy evidence substantiates an effect in a *claim area* or *indication class*.

3.0 Confidentiality and conflicts of interest

The Product Assessment Process is overseen by an Expert Advisory Board, who have designed and conduct the review process independently of any company. The submission will only be reviewed by assessors who are not conflicted and under strict confidentiality.

4.0 Process

Please complete the NHSF Efficacy Assessment Checklist for the pivotal clinical trial that you use to support the claim area/indication class you would like your product accredited for. Please provide a 100 word synopsis on other clinical trials you would like to use to support the pivotal clinical trial.

5.0 Time Lines

Submitted applications will be reviewed expeditiously, with advice to applicants forwarded within four weeks.

NHSF Efficacy Assessment Checklist
For Pivotal Clinical Trial

naturalhealth
SCIENCE FOUNDATION

Name of Product: _____

Name of Applicant Company: _____

Date: _____

Clinical trial data assessment, as applicable

1. Was the Clinical Trial:
   - Independent (Investigator Initiated) ☐
   - Done in-house ☐
   - Commissioned ☐
2. Is an Ethics Committee / Institutional Review Board Approval Certificate available?
   - Yes ☐ No ☐
3. Is a copy of the publication or a copy of the Clinical Trial Report in English available?
   - Publication Available Yes ☐ No ☐
   - Clinical Study Report Available Yes ☐ No ☐
4. What is the type of publication, if applicable:
   - Full Research Article ☐
   - Conference Proceedings ☐
   - Synopsis ☐
   - None of the above ☐
   - Other: ☐
5. Publication Reference(s): ☐
6. Year of Publication(s): ☐
7. Trial Initiation Date ☐ Trial completion date ☐

8. Synopsis:

9. Design:

9.1 Patient population:

Number of intent to treat | Number of completed subjects

Age range

Sex:

no of Males | no of Females

9.2 Inclusion criteria:

9.3 Exclusion criteria:

10. Outcomes:

10.1 Versus placebo or standard of care:

10.2 Primary outcomes:

10.3 Were the outcomes set for non-inferiority?

Yes ☐ No ☐

Comment:

10.4 Were the outcomes set for superiority?

Yes ☐ No ☐

Comment:

10.5 Describe any secondary outcomes:

11. What was the non-completion rate? How were the drop-outs handled?

11.1 Was Good Pharmacovigilance Practice applied during the clinical trial?

Yes ☐ No ☐

Comments

12. Methodology:

12.1 What power calculations were utilised to demonstrate significance?

12.2 What statistical method was used?

13. Justification of claim(s) validity:

Thank you. We will contact you in order to review the documents identified in this survey.