

## **NHSF Efficacy Assessment Checklist**

For Pivotal Clinical Trial



### 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

- a. 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
- b. 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
- c. 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
- d. 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 Timelines

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

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**Name of Product:**

**Name of Applicant Company:**

**Date:**

**Title of study:**

- 1.0 Was the Clinical Trial:  
Independent (Investigator Initiated)  
Industry sponsored  
Other Please explain
- 2.0 What was the type of intervention?  
Registered herbal product  
Dietary Supplement  
Probiotic  
Fish oil  
TCM  
Ayurvedic medicine  
Other Please specify
- 3.0 Is an Ethics Committee / Institutional Review Board Approval Certificate available?  
Yes  
No
- 4.0 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  
If no English publication or trial report is available, please paste in the box an authorised translation of study synopsis:

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5.0 Primary Area of Research

Treatment

PK / PD / safety

Prevention

Diagnosis

Palliation

Rehabilitation

Basic science

Other

Please specify

6.0 Synopsis: Please paste the synopsis into this box

7.0 Publication Reference(s):

8.0 Year of Publication(s):

9.0 Timing

Trial Initiation date

Trial completion date

10.0 Design (please complete any of the below if not already included in the synopsis):

10.1 Patient population:

Number of intent to treat

Number of completed subjects

Age range

Sex: no. of Males

no. of Females

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10.2 Inclusion criteria:

10.3 Exclusion criteria:

10.4 Allocation

Randomised controlled trial

Non-randomised controlled trial

Not applicable

10.5 Masking Technique

Open

Single-Blind

Double-Blind

10.6 Type of control

Placebo

Active

Before-after (historic)

Dosage comparison

None

10.7 Arms/Distribution

Single-armed

Parallel groups

Cross-over

Factorial

Other or N/A

11.0 Outcomes:

11.1 Versus placebo or standard of care:

11.2 Primary outcomes:



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15.0 Which claim area(s)/indication class(es) do you think the study justifies

– please document general and not specific claims e.g. mood (not depression), cognition (not dementia), digestive health (not IBS)

16.0 Form Submission

Please provide a list of the names of all documents you are submitting in addition to this form

Document 1
Document 2
Document 3
Document 4
Document 5
Document 6

Please provide your name, title and contact details of the authorised person that is submitting this application:

**Name**

**Job Title**

**Email Address:**

**Phone**