NHSF Efficacy Assessment Checklist
For Pivotal Clinical Trial

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

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 eight 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:

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 _____

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:

11.3 Were the outcomes set for non-inferiority?

Yes : ◯ No : ◯

Comments:

11.4 Were the outcomes set for superiority?

Yes : ◯ No : ◯

Comment:

11.5 Describe any secondary outcomes:

12.0 Non-completion

12.1 What was the non-completion rate?

12.2 How were the dropouts handled?

13.0 Statistics

13.1 What statistical methods were used?

13.2 Were statistical power calculations utilised?

14.0 (Optional) Please provide a synopsis of other clinical trials that you would like to be considered (100-word maximum):

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 _____