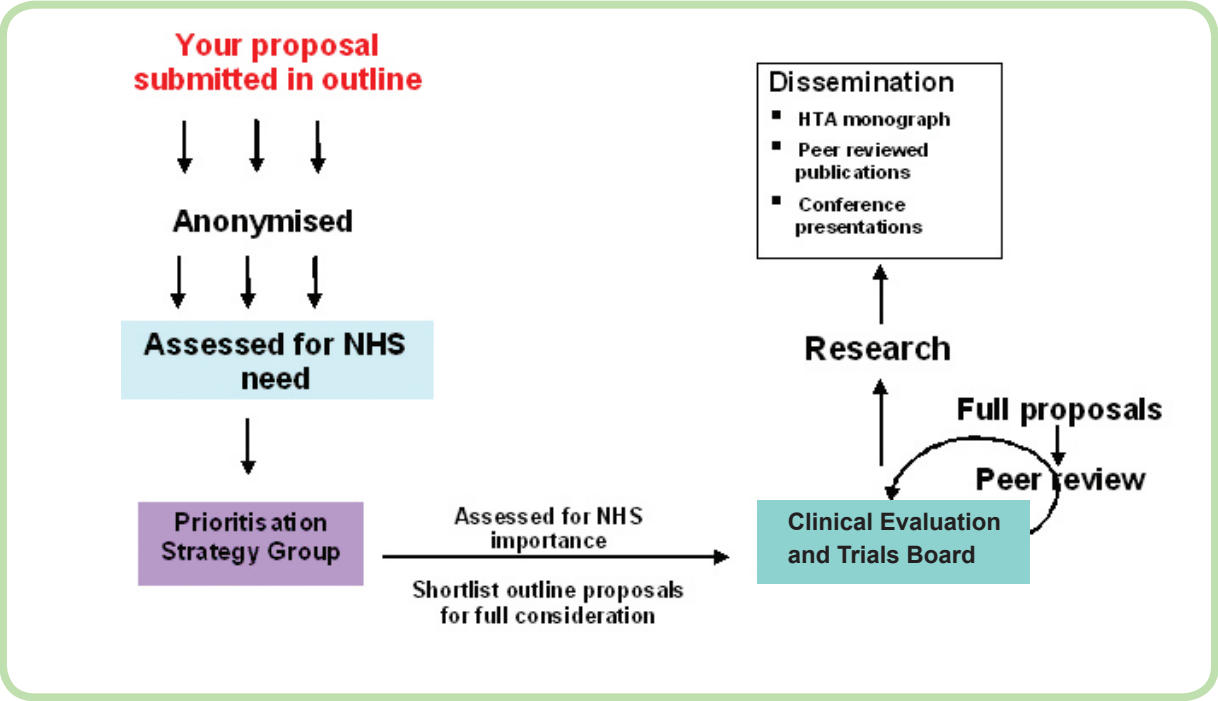
Submitting a successful application for HTA Clinical Evaluation and Trials funding

The HTA programme has two distinct stages for assessing trial proposals – assessing the importance of the topic to the NHS and evaluating whether the scientific methods will answer the research question.

Outline proposals for HTA Clinical Evaluation and Trials seeking to assess the effectiveness of treatments and interventions within the NHS are accepted throughout the year.

HTA Clinical Evaluation and Trials application process



The table on the back of this leaflet shows considerations to be made when submitting an application.

What else can you do to gain insight into submitting a successful application?

- **Ask for advice from the HTA programme**
- **Offer to peer-review** - see how others write grant applications
- **Speak to active HTA researchers, especially Clinical Trials Units**

For further enquiries on submitting applications for HTA funding, write to: htacet@soton.ac.uk or visit our website: www.hta.ac.uk

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Importance – deciding whether your topic is suitable for HTA

Applicants should consider:

- The *need* for research: How will patients and the NHS benefit from the proposed research?
- Consulting with panels of clinical and patient representatives
- Include a clear HTA research question using **'PICO'**:
  - **P**opulation: NHS target population i.e. real patients
  - **I**ntervention: A technology that is or could be used now in the NHS
  - **C**omparator: Usually next best treatment, but could be placebo
  - **O**utcome: Patient centred, leading to effectiveness and cost-effectiveness
- Include a summary of the burden of disease
  - Incidence or prevalence
  - Mortality and quality of life
- Describe the place of the technology in the care pathway
- Include a thorough summary of current research

Consider:

- How does this proposal relate to other HTA research e.g. has there been a previous Systematic Review?
- How would the proposal fit into the HTA portfolio?
- How does the proposal relate to NICE guidance?

Scientific quality of the proposal

Sample size:

- Credible effect size
  - From literature; by analogy; from experience
  - Include least important effect size

Outcomes:

- Patient centred
- Not composite, except by convention e.g. QALY
- Co-primary endpoints
- Not surrogates, except established

Preparation:

- Conduct systematic reviews
- Consider a pilot
- Explore existing developed technologies, especially for complex interventions

Comparators:

- Best alternative or TAU vs. placebos

Cost-effectiveness:

- Is it necessary?
- Consider including modelling
- Include a full description of methods of data collection and analysis

Value for money:

- This should be proportional to the cost of treatment and importance of outcomes

Feasibility:

- Not over-complex
- Describe recruitment rate, to include:
  - Number of centres
  - Number of eligible patients
  - Issues around patient consents
  - Method of patient follow-up
- Demonstration of the necessary skill mix, experience, project management and infrastructure for success.
- Clinical and methodological experts
  - Link with Clinical Trials Units
  - Links with Clinical Research Networks

Presentation:

- English for mixed audience – clinicians, methodologists, patients and the public
- Tell the story well for the non - expert
- Include a Plain English summary
- Follow standard writing guides here, not just in the publication.
- Use visible headings, e.g. sample size, outcomes, technologies
- Space the proposal well, using clear paragraphs
- Flow diagrams
  - Consort type – check these include sufficient detail
  - Use where appropriate to explain complex interventions
    - (e.g. Perera R, Heneghan C, Yudkin P. BMJ 2007;334:127)