NIHR | National Institute for Health Research

MRC | Medical Research Council

19/23 NIHR Themed Call: Specification Document
Cannabis-based products for medicinal use

Close date: 1:00 pm, 31st July 2019 (two stage)

This National Institute for Health Research (NIHR) call welcomes proposals for primary clinical research to evaluate the safety and clinical efficacy or clinical effectiveness of cannabis-based products for medicinal use in humans.[1]

Proposals are eligible that investigate their use for the management of difficult to treat epilepsy, or other disorders unresponsive to existing treatments where there is sufficient existing evidence to justify further, more definitive, research.

Applications should meet all the professional and legal requirements within which cannabis based products for medicinal use may be prescribed and lead to robust clinical evidence that will inform practice (e.g. through randomized controlled trials, though other robust research designs may be appropriate in some circumstances).

Applicants will need to show a track record of delivering high quality clinical research and proposals must demonstrate access to the full range of skills needed to undertake the proposed research.

Additional issues of interest include:

- for treatments shown to be efficacious, clarification of therapeutic levels/ appropriate range of dose
- the inclusion of nested mechanistic and pharmacokinetic research (where appropriate)
- reporting of short and longer term (≥12 months) adverse events
- clarification of the role of combinations of cannabis derivatives
- the standardisation of therapy and its mode of delivery
- reporting of drug interactions
- reporting of outcomes relevant to carers, immediate relatives or partners
- where relevant, proposals should explain how they would minimise the risk of confounding from the use of cannabis and any derivatives obtained outside the study.

Applicants should justify the importance of their proposed research and identify how its findings will contribute to an understanding of the science and potential clinical use of cannabis derived medicines for the treatment of patients.

Supporting information:
During 2018 the Chief Medical Officer to the UK Government was asked to examine the evidence of the medicinal benefit of cannabis based products and advise on the appropriateness of their place within Schedule 1 of the Misuse of Drugs Regulations 2001 and subject to designation under s7(4) of the Misuse of Drugs Act 1971.

[1] Cannabis-based medicinal products for use in humans as set out by the Home Office: https://www.parliament.uk/business/publications/written-questions-answers-statements/written-statement/Commons/2018-10-11/HCWS994/

The review considered a range of evidence from a number of international sources and recommended that the whole class of cannabis based medicinal products be moved out of Schedule 1 of the Misuse of Drugs Regulations 2001.

The Advisory Council on the Misuse of Drugs responded to the consultation on cannabis-derived medicinal products with a number of recommendations concerning their definition, the routes of access for prescribing and guidance to support practitioners.

The response of the Home Secretary and the Secretary of State for Health and Social Care indicated their support for the use of the existing frameworks of professional standards; medicines regulation and legislation and the development of new guidance within which cannabis based products for medicinal use may be the prescribed.

How to apply:

Research proposals must be within the remit of at least one of the two participating NIHR programmes. Applications which span the remit of both programmes will be welcomed. In these cases, proposals should be submitted to the programme within whose remit the major part of the work lies. The inclusion of patient, service user, carer and public views and experiences are considered important by each participating programme.

Applicants who are unsure which programme to apply to may wish to send a short summary (maximum 1 page) of their research proposal to themedcalls@nihr.ac.uk

Applicants should note that this call is not a time limited opportunity and signals an on-going interest in receiving applications.

All applicants should:

- take note of the remits of the two participating programmes (see below)
- ensure they have taken account of and referenced relevant completed and ongoing studies to avoid duplication of research

Participating Programmes:

The following NIHR managed research programmes:

Efficacy and Mechanism Evaluation (EME)
Health Technology Assessment (HTA)

EME Programme:

Applications to the EME Programme should examine the efficacy of interventions, and may explore the mechanisms underlying possible efficacy.

HTA Programme:

Applications to the HTA Programme should examine the clinical and/or cost effectiveness of the proposed intervention compared to the current standard, where some evidence already exists to show that the proposed intervention can be effective.