NCGC National Clinical Guideline Centre

Crohn's disease

Appendix K

Clinical Guideline <...>

5-ASA call for evidence

10 October 2012

Commissioned by the National Institute for Health and Clinical Excellence

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Setting higher medical standards

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Call for evidence to all Stakeholders

NICE guidance on Crohn's disease

11 April 2011

Dear Stakeholder,

The National Institute for Health and Clinical Excellence (NICE) has commissioned the National Clinical Guideline Centre (NCGC) to develop guidance on Crohn's disease.

Your organisation is invited to submit data (as specified in the checklist attached) specifically comparing sulfasalazine, mesalazine, olsalazine and balsalazide to placebo or to each other, so that they may be considered during the guideline development process. We have already carried out extensive literature searches in this area to cover publications from the clinical literature and health economic literature. Upon reviewing the literature in this field, the NCGC have reason to believe there may be relevant and important data unavailable in published form. Data will be considered as evidence dependent upon how closely the comparisons match the following:

For induction of remission in adults or children diagnosed with Crohn's disease:

Dichotomous data, comparing sulfasalazine, mesalazine, olsalazine and balsalazide to placebo or to each other in the following outcome measures:

- Efficacy as assessed by Crohn's disease activity index (CDAI) score, Paediatric Crohn's disease activity index (PCDAI) score or other validated index
- Withdrawal due to adverse events
- Significant adverse events including event numbers or incidence rates
- Health-related quality of life as assessed by Inflammatory Bowel Disease Questionnaire (IBDQ) or IMPACT questionnaire, EQ-5D and SF36

Please read the instructions below to identify the types of information that can be submitted.

A full description of the national guideline development process and guidance for stakeholders is available from the NICE website.

If you wish to make a submission please preferably email it to celia.pincus@rcplondon.ac.uk or post it to Celia Pincus at 11 St Andrew's Place, Regent's Park, NW1 4LE, to arrive by 12 noon on Wednesday 11 May. Please acknowledge receipt of this letter by email indicating whether your organisation will be submitting evidence for consideration.

Yours sincerely

Celia Pincus

Project Manager in Guideline Development

Instructions to stakeholders for submitting evidence for a call for evidence

Before submitting details of suggested evidence, please check the relevance of the information against the clinical comparisons and the criteria mentioned below.

- Stakeholders may wish to submit details of specific databases, including those outside the public domain that are likely to capture relevant information. The Cochrane Library, Medline, CINAHL and EMBASE databases are routinely searched by the NCGC.
- Relevant, published, peer-reviewed reviews or cost-effectiveness analyses that appropriately address the question posed by the scope of the guideline will be found by the NCGC by systematic literature searching. Generally there is no need to submit such papers unless you are aware that the journal in question is not indexed on any of the above databases or that the specific data we seek are not reported within the paper which is indexed on any of the above.
- Submissions should include sufficient information about methods to allow them to be quality assessed. Abstracts, posters or data tables alone will be considered to provide insufficient methodological information and should be accompanied by a technical report or draft paper.
- Relevant 'academic in confidence' or 'commercial in confidence' data can be submitted, however it must be clearly labelled as such and a completed checklist submitted. Its submission must adhere to the principles contained within the guidelines manual.

Evidence which generally will not *be considered includes:*

- Promotional literature.
- Secondary papers interpreting results.
- Representations or experiences of individuals (e.g. anecdotal evidence).

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Clinical Guidelines – evidence submission

Checklist of confidential information

Section 1 - Guidance on identification of confidential information

To ensure that the guideline development process is as transparent as possible, the Institute considers it highly desirable that evidence pivotal to the Guideline Development Group's (GDG) decisions should be publicly available. Ideally, all the evidence seen by the GDG should be available to all stakeholders. Under exceptional circumstances, unpublished evidence is accepted under agreement of confidentiality. However, the Institute expects stakeholders to keep confidential material within a submission to an absolute minimum. Types of information that can be classed as confidential include:

- data that are 'Commercial in Confidence' (CIC)
- data that are intellectual property awaiting publication ('Academic in Confidence').

Information designated as either commercial or academic in confidence should be consistent with the following principles:

- information that has been put into the public domain, anywhere in the world, may not be marked as confidential
- the results of clinical trials submitted relating to products that have received regulatory approval should be available for scrutiny. When it has been decided that release of trial results will occur through a journal publication, at a date later than the first release by the Institute of documentation quoting data from the trial, as a minimum, a structured abstract should be made available for public disclosure. The content of the structured abstract should be a synopsis derived from a recognised format for a full trial report such as that provided by the CONSORT statement (http://www.consort-statement.org).
- The same principles apply to the release of information in the form of economic models. The full economic model, in electronic format, should be available for scrutiny by the NCC and the Institute. A structured abstract of the economic model submitted by the stakeholder should, as a minimum, be made available for public disclosure.

Confidential information submitted by stakeholders is made available for review by the National Collaborating Centre (NCC) and the GDG and – when necessary – the expert advisers invited to attend the particular GDG meetings.

- If information in a submission is designated confidential by the manufacturer or sponsor, then any specific mention of that information will be removed or 'blanked out' from the draft clinical guideline released to stakeholders and later published on the NICE website. In addition, unless

the confidential status is removed during the period of the guideline, the confidential information will not appear in the final guideline.

- The Institute asks stakeholders to reconsider restrictions on release of data where either there appears to be no obvious reason for the restrictions, or such restrictions would make it difficult or impossible for the Institute to show the evidential base for its guidance.

Section 2 – Important notes to consider before completing the checklist of confidential information

- Before completing the checklist and marking their submission, manufacturers and sponsors should read carefully section 5.10 of the Guidelines Manual 2009.

- Submissions of evidence are only needed when it is decided by the developers to make a call out for evidence during development. Stakeholders are not routinely required to provide a submission of evidence.

- Marking a whole submission confidential is not acceptable.

- For each submission, stakeholders should complete the checklist of confidential information below.

- The checklist must be completed clearly and in full and submitted as a separate file to your submission dossier by the deadline.

- In addition to the checklist, the relevant confidential sections of the submissions should be underlined and/or highlighted. Please take care to ensure that the checklist is completed accurately and corresponds to the highlighted and/or underlined text in your submission.

- Results derived from calculations incorporating confidential data will not be considered confidential unless releasing those results would enable back-calculation to the original confidential data.

- If the status of information changes during guideline development, a new checklist of confidential information must be completed as soon as possible.

- Where the confidential status of information is expected to change during the course of the guideline, exact embargo dates (e.g. following a conference presentation) or approximate dates (e.g. after an article has been accepted for publication) should be given.

- In the event that no checklist of confidential information is received with a submission, all information in that submission and any accompanying appendices or attachments will automatically be considered not to be confidential.

Section 3 – Completed checklist of confidential information

To be completed in full and returned to the NCC Project Manger, preferably in electronic format, as a separate file to your submission dossier by the submission deadline.

If the NCC does not receive a completed checklist all information contained in your submission will be considered as not confidential

Stakeholder:

Guideline:

Summary of the evidence submitted:

Does your submission contain any confidential information?* (please check appropriate box)

No ☐ If no, please proceed to section 4: declaration (below)

Yes ☐ If yes, please complete the table below in full (insert additional rows or delete unnecessary rows as necessary) and ensure that relevant sections of your submission are clearly highlighted and / or underlined and correspond to the information provided in the table.

Page ^	Nature of Confidential information	Rationale for Confidential status	Time Frame of confidentiality restriction ⊗
	* ☐ Commercial in confidence * ☐ Academic in confidence		
	* ☐ Commercial in confidence * ☐ Academic in confidence		
	* ☐ Commercial in confidence * ☐ Academic in confidence		

^ reference page(s) of your submission where the confidential information appears
* Check box as appropriate

* See guidance above for more information.
⊗ Please state whether the timeframe given is exact or approximate. For Academic in Confidence material, please state either the date and title of the conference at which the information will be made public, or the date of submission and title of the journal to which the relevant paper has been submitted, together with the journal's stated turn around time.

Section 4: Declaration

I confirm that all relevant material pertinent to the call for evidence have been disclosed to the NCC

I confirm that any confidential sections of the submission have been underlined and/or highlighted and that if any change occurs to the above information a new checklist will be submitted.

Name of person completing checklist:

Contact details (tel/email):

Date: