



# **Manual for Writing and Reviewing CAM Summaries**

## **CAM-Cancer Project**

**Concerted Action for Complementary and Alternative Medicine  
Assessment in the Cancer Field**

<http://www.cam-cancer.org>

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Updated by Barbara Wider and Markus Horneber, July 2009

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## 1. Introduction

Complementary and Alternative Medicine (CAM) is frequently used by cancer patients in all countries. However, there are significant gaps in how much we know about the safety and efficacy of CAMs.

The CAM-Cancer project was funded by the European Commission within the framework of the "Quality of Life and Management of Living Resources" program during its set-up phase (October 02 - September 05).

Since September 2007, The National Research Center for Complementary and Alternative Medicine (NAFKAM/NIFAB) at the University of Tromsø, Norway has been responsible for the website.

The CAM-Cancer projects aims to improve evidence-based cancer care in Europe by:

- Developing and sustaining a network of experts in the field of CAM research.
- Providing summarised and synthesized information about the efficacy and safety of complementary and alternative medicines used in cancer. These 'CAM summaries' will cover a wide range of CAM topics
- Ensuring that the best available research evidence concerning CAM interventions is presented in a way which is accessible and usable to health care professionals.
- Ensuring that CAM summaries are written in an independent and non-judgemental way to maximise their use amongst health professionals and the general public.
- Authoring guidance which documents the processes used to produce evidence-based summaries and systematic reviews for CAMs in cancer.
- Build an accessible, usable and reliable web site to host the various publications detailed above: [www.cam-cancer.org](http://www.cam-cancer.org) The web site also features an eCommunity to encourage discussion amongst researchers, policy makers, health professionals and the general public.

## 2. CAM summaries – definition and aims

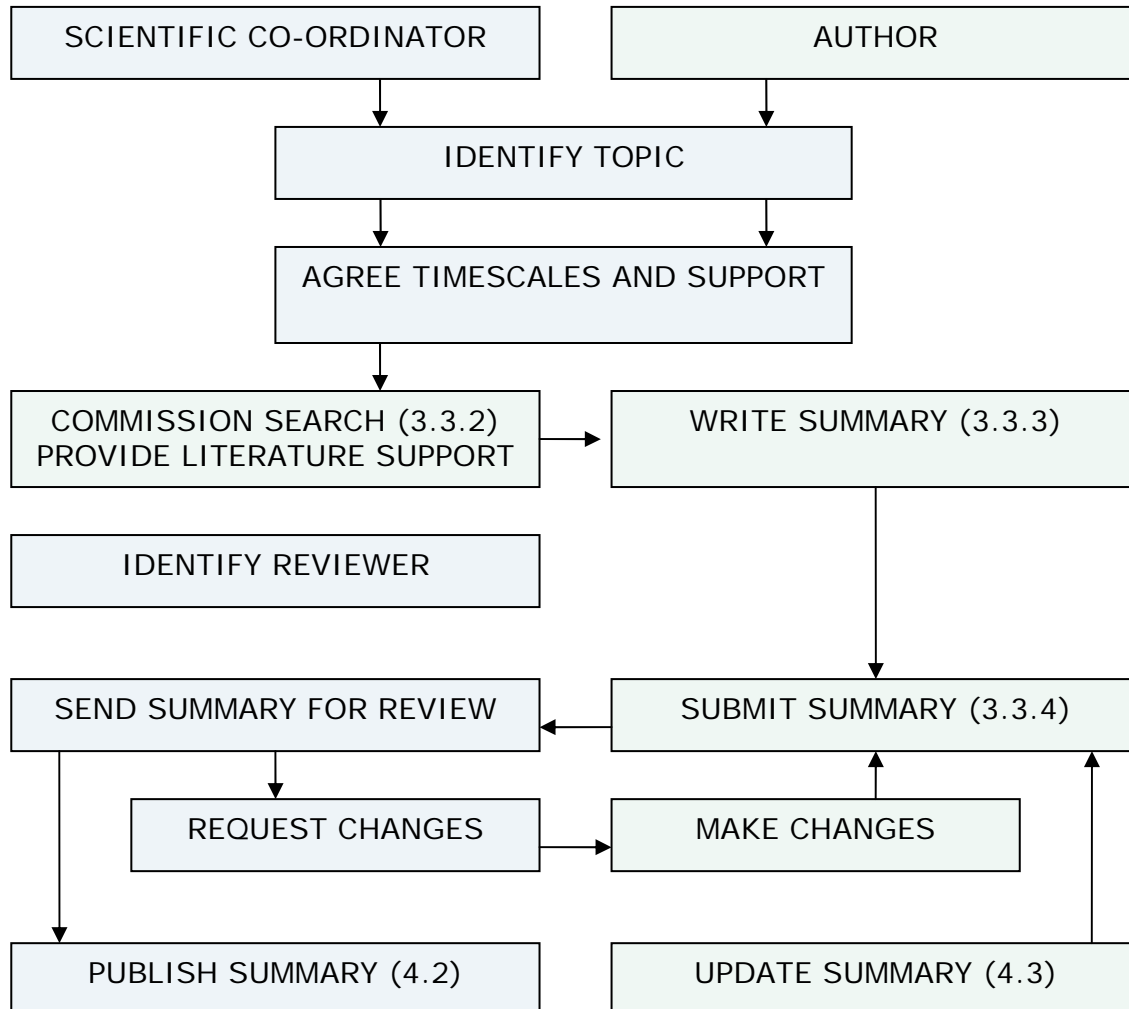
The CAM Summaries are evidence-based articles synthesizing the best available scientific information on CAM for cancer. For each CAM modality, background information (history, promoter claims, description of treatment methods and mechanism of action, prevalence of use, legal issues, costs) and documentation with regards to efficacy and safety are prepared systematically and presented in a clear and easily accessible format. The CAM summaries are peer-reviewed and regularly updated. By providing clear statements they are aimed at assisting health professionals in making shared decisions with their patients.

Summaries produced to date can be found on the CAM-Cancer web site at [www.cam-cancer.org](http://www.cam-cancer.org).

### 3. Authoring CAM summaries

Authors who wish to become involved in producing a new summary should follow the instructions below.

**Figure 1 – CAM summary production process**



#### 3.1 Applying to write a CAM summary

Getting involved in the CAM-Cancer project is very straightforward. Firstly, you should identify a CAM topic which has not yet been covered on the project web site. You can then submit your expression of interest by contacting [contact@cam-cancer.org](mailto:contact@cam-cancer.org). Once approved, you should follow the instructions in this manual to produce your CAM summary (sections 3.3. ff writing and submitting a CAM summary).

#### 3.2 Authorship, ownership and copyright

It is stated that the summary is “written and reviewed by [author name] and the CAM-CANCER consortium”. Readers are also referred to a list of authors and reviewers posted on the project

website. The ownership of the CAM summary and the related methodological documents remains with the respective authors and the CAM-CANCER consortium. All content on the CAM-Cancer website is published using the "Creative Commons Attribution-Noncommercial-No Derivative Works 3.0 Unported" licence.

## 4. Writing a CAM summary

The aim of a CAM summary is to synthesize and summarise the best available evidence that exists about a specific intervention when used in the management or treatment of cancer. Summaries should all be produced following the evidence-based methodology set out in this document, so that usability and reliability are maximised.

### 4.1 General guidance for authors

Keep in mind that a CAM summary should have the following qualities:

- completeness and comprehensiveness
- topicality
- unbiased tone (personal and scientific experience)
- user-oriented.

The primary audience for CAM summaries are health professionals, but it is likely that they will be used by a wide range of people, including members of the general public. For this reason, summaries should be written in a user-friendly and accessible way. Complex terminology and jargon should be kept to a minimum and an independent and non-judgemental tone should be adopted throughout.

Once a CAM summary has been produced, a reviewer and proof reader will check it for accuracy and readability.

CAM summary documents need to be double-spaced, Arial or Times New Roman, font size 12 and must be a minimum of 5 and maximum of 15 pages long.

Please have a look on the CAM Summaries available from the web site at [www.cam-cancer.org](http://www.cam-cancer.org) in order to have a concrete example about what we are looking for.

### 4.2 Searching

The CAM-Cancer Scientific Co-ordinator provides authors with literature searches on evidence conducted by an experienced information specialist. The searches are all performed in Medline and the Cochrane Library and are available in bibliographic software (e.g. Endnote). They are fully documented (search terms, databases, interface, dates, filters, result log) in order to ensure they are systematic, transparent and reproducible. The search documentation is available upon request from the Scientific Co-ordinator. Full-text articles can be requested via the Scientific Co-ordinator.

In addition, the following web sites may be useful when searching for information about the CAM topic you are tackling:

National Centre for Complementary and Alternative Medicine:

<http://nccam.nih.gov/>

National Cancer Institute's PDQ® Cancer Information Summaries: Complementary and Alternative Medicine:

<http://www.cancer.gov/cancerinfo/pdq/cam/>

American Cancer Society:

[http://www.cancer.org/docroot/eto/eto\\_5.asp](http://www.cancer.org/docroot/eto/eto_5.asp)

Memorial Sloan-Kettering Cancer Center

<http://www.mskcc.org/mskcc/html/1979.cfm>

University of Texas M.D. Anderson Cancer Center:

<http://www.mdanderson.org/departments/CIMER/>

If you find that after you have scanned the searches and these sources you have not found any useful references, you could also contact the Scientific Co-ordinator to enquire whether the Scientific Advisory Committee are aware of any evidence and/or other important issues (e.g. prevalence, legal issues, safety, cost etc). **PLEASE NOTE** – contacting the Scientific Co-ordinator should only be done as a **LAST RESORT** when you have found little or no evidence during your searches:

## 4.3 CAM summary template and instructions

*Please use the template provided in annex 1. Take note that the line numbering option in your text editor software should be enabled in order to make the reviewers' work easier.*

### 4.3.1 Abstract and key points

Leave the writing of the abstract to the end - once you have gathered all information it will be easier to summarise your work.

Structure the abstract as follows and answer each point with one sentence:

- What is the commonly used name for the CAM modality you are describing (if it is a herbal remedy, please mention the *Latin* name) and what does the CAM method entail?
- What are the **claimed** effects of the therapy? Make sure to state that these claims are made by the provider and should not be taken at face value.
- What does the research evidence tell us about the CAM modality (i.e. how many trials – if any – of what nature and quality and what are the results)?
- What are the safety aspects of this CAM modality?
- What is the direction for the conclusion regarding the efficacy and safety of this CAM modality (please do **not** make any recommendations)?

- Add a very short bullet point lists with the 3-4 key messages in telegrammatical style for the blue summary box on the website (see e.g. Co-enzyme Q10 on the website).

#### 4.3.2 What is intervention 'X'?

Firstly, you must generate an **overview** for the CAM therapy about which you are writing. In this overview the following issues should be considered/included:

- Scientific name(s)/brand name(s)/common name(s)<sup>1</sup>
- Ingredient(s)
- Application and dosage
- History/provider(s)<sup>2</sup>
- Claims of efficacy
- Mechanism(s) of action
- Alleged indication(s)<sup>3</sup>
- Prevalence of use<sup>4</sup>
- Legal issues<sup>5</sup>
- Cost(s) and expenditures

*Please use the template provided in appendix 1. Please always reference your sources.*

#### 4.3.3 Does intervention 'X' work?

- To write this section, you must be able to **critically appraise** the articles retrieved via the literature scanning (see 3.3.2). Additionally, try to contact 'experts' and providers of the intervention, e.g. clinics, anecdotal evidence and specific people who are working in this field.

The retrieved literature should be arranged into the following categories:

- Systematic reviews, meta-analyses
- Narrative reviews
- Clinical trials
- Case series/studies
- Guidelines, books (chapters), consensus statements etc.
- Pre-clinical trials
- other

<sup>1</sup> For taxonomy of plants please use: [http://www.ars-grin.gov/cgi-bin/npgs/html/tax\\_search.pl](http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl) (use the *Latin* name of the plant throughout the report)

<sup>2</sup> When was the intervention discovered in order to be used in cancer care? Who discovered it and in which country was that? How is the CAM therapy delivered? What are the main providers/companies? If it is a whole medical system (i.e. acupuncture) summarise the history and philosophical framework of the system in a few sentences.

<sup>3</sup> When providing a description of the intervention method, please explore claims by the inventor, the theory of intervention and the mechanism,. What effects does the inventor / producer / originator claim the therapy has on the cancer patient? How is the therapy supposed to work to prevent cancer / to treat cancer / to be used for cancer palliation? How is the intervention being delivered?

<sup>4</sup> What is known about how many cancer patients use this CAM ?

<sup>5</sup> What is the legal position regarding intervention 'X' in your country and/or what are the important legal issues to be considered generally? What qualifications are needed to practice as a therapist in various EU countries?

For each of the above **categories** (not individual trials), you should describe in plain language the evidence found:

- Quantity and type (i.e.: systematic review, RCT, pre-clinical trial, case series, individual case reports, guideline, other)
- Quality of the evidence/research findings
- Internal validity (study design and conduct)
- External validity (applicability and generalisability of results)
- Direction of evidence (positive, uncertain, negative).

As effects of healthcare interventions are often made up of **specific** (substance-related) and **unspecific** (meaning of the intervention, physician-patient relationship issues etc.) **effects**, please consider the following aspects in appraising the efficacy/effectiveness:

- System efficacy<sup>6</sup>
- Component efficacy<sup>7</sup>
- Biologic mechanism<sup>8</sup>

It is crucial to critically appraise the quality of the research findings that are synthesized in this summary. Factors that warrant assessment are those related to internal (study design and conduct) and external (applicability and generalisability of results) validity of individual investigations. Please use the provided appraisal tool.<sup>9</sup>

*Please use the template provided in appendix 1. Please always reference your sources.*

#### 4.3.4 Is intervention 'X' safe?

For this paragraph please summarise what you have found in regard to safety/applicability of the CAM modality. Please consider/include the following issues:

- Reported/possible adverse events (how frequent, how severe)
- Existing contraindications
- Reported/possible interactions with other drugs/herbs/therapies
- Warnings
- Other problems or complications<sup>10</sup>

Please consult Natural Medicines Comprehensive Databases: (<http://www.naturaldatabase.com>).

*Please use the template provided in appendix 1. Please always reference your sources.*

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<sup>6</sup> What is the effect of receiving a comprehensive treatment in the given CAM area? (Examples could be the effect of receiving a treatment from an acupuncturist, the effect of receiving treatment from a reflexologist. Please bear in mind that this is not intended to tease out the effect of every single component, which practitioners are using in their treatment.)

<sup>7</sup> What is the effect of receiving a unique component treatment? (Examples could be a specific homeopathic remedy, the acupuncture needle at point X, manipulation of the colon area of the right foot sole etc.)

<sup>8</sup> What is the plausible biologic explanation of mechanism for the effects described above?

<sup>9</sup> Critical appraisal checklists are available here ([http://www.cebm.net/critical\\_appraisal.asp](http://www.cebm.net/critical_appraisal.asp)). These will help CAM-summary authors to maximise consistency of the appraisal approach across all authors and to increase the transparency of the final CAM-Cancer resource (we can tell end-users how we produce our content).

<sup>10</sup> Is there any relationship between increasing doses of the drug and toxic effects? Are there significant risks for humans, especially indications of specific organ damage, mutagenicity, carcinogenicity, or teratogenicity?

### **4.3.5 Bibliography**

Please use numbers in the text for referencing to the literature. The references should be numbered sequentially, according to their order in the text. The references listed in the bibliography should be sorted accordingly, using the same order. For updates of existing review, the references can be added at the end and numbered accordingly in the text. The Vancouver style should be used (for full instruction see [http://www.nlm.nih.gov/bsd/uniform\\_requirements.html](http://www.nlm.nih.gov/bsd/uniform_requirements.html)).

### **4.3.6 Disclaimer**

The following standard disclaimer will be inserted “The present documentation has been compiled by the CAM-CANCER Project with all due care and expert knowledge. However, the CAM-CANCER Project provide no assurance, guarantee or promise with regard to the correctness, accuracy, up-to-date status or completeness of the information it contains. This information is designed for health professional. Readers are strongly advised to discuss this information with their physician. Accordingly, the CAM-CANCER Project shall not be liable for damage or loss caused because anyone relies on the information it contains”

## **5. Managing the production process**

### **5.1 Selecting topics**

The consortium experts have defined a list of CAM to be investigated in priority. The selection criteria are 1) the related safety issues 2) the expressed patient interest and the measured prevalence of use if data are available. The list of available CAM topics for CAM summary can be obtained from the Scientific Co-ordinator. Authors are also invited to propose new CAM topics.

### **5.2 Appointing authors**

Authors will be appointed on a case by case basis. Authors should be professionals working in the field of CAM, with experience of writing English language health care information. Knowledge of critical appraisal techniques and evidence-based research are essential.

### **5.3 Publishing CAM summaries**

Following peer review and any necessary amendments the final CAM summary is published on the CAM-Cancer web site.

### **5.4 Updating CAM summaries**

Summaries are updated on a regular basis to avoid them becoming out of date and unreliable. An update literature search is performed on an annual basis to identify summaries that need updating. The respective authors are then contacted, and the writing and reviewing process is initiated. Out-of-date summaries are archived and removed from the live web site.

## 6. Reviewing a CAM summary

### 6.1 The task of scientific reviewers

The goal is to ensure that the CAM summaries are prepared in accordance with the CAM-Cancer standards. For more information, please refer to the previous section of this manual.

### 6.2 Methods

The scientific reviewer will use the checklist (version 6) attached in appendix 2. This checklist was designed in order to allow an in-depth and structured assessment by the reviewer. The checklist assesses four quality criteria:

- completeness and comprehensiveness of the document,
- topicality,
- neutrality,
- user-friendliness.

The reviewer should go through the checklist and score all items. The reviewer shall make exhaustive comments and suggestions in order to help the author improve the CAM summary. Reviewers should make a difference between the scientific quality and the writing style of the document. The scientific quality is the priority of this review. The writing style should be addressed only if the text is confusing or not understandable. Special attention should be paid to the question no 6 “Overall conclusion of the reviewer. Can this CAM summary be published on the project website in its current version?” as it will inform the Scientific Co-ordinator whether this CAM summary can be published in its current version or it will need further modification, or finally is rejected.

The comments should be inserted in the electronic version of the checklist and sent to the Scientific Co-ordinator. The Scientific Co-ordinator will then integrate the reviewers' comments and suggestions into a single document “the reviewers' feedback”. The Scientific Co-ordinator will ensure the consistency between reviewers' comments and eventually add additional comments. In case of major disagreement between the author and the reviewers, or between the reviewers themselves, the Scientific Co-ordinator will first act in order to try to reach a consensus. If no agreement can be found, the Steering Committee shall take a decision.

Reviewer's overall conclusion	Explanation
Yes	The text is perfect and can be published after the review for the quality of the English.
Yes, with minor modification(s)	Some minor modification(s) (terminology, reference number, cosmetic rewording) have to be done. This type of modification can be done by the Scientific Co-ordinator without having to re-circulate the text for getting authors'/ reviewers' approval.
Yes, with major revision	Reviewers conclude to the omission of important data or there is disagreement regarding author's statement or conclusion. The text will have to be modified by the author accordingly. The modified version will have to get reviewers' approval.
No, rejected	This should not be used in first line. A CAM Summary draft may be rejected only if the author doesn't accept to follow the recommendations approved by the reviewers.

### 6.3 Review process

1. The Scientific Co-ordinator will provide the CAM summary to the appointed reviewers. The reviewers will provide their evaluation and eventual recommendations to the Scientific Co-ordinator within two weeks of submission
2. The Scientific Co-ordinator will pool the eventual scientific reviewers' comments and prepare the feedback for the author. Direct discussions between author and the reviewers can take place. The author will amend the summary and send it to the Scientific Co-ordinator. The modified version will have to be approved by the reviewers.
3. Once the document is considered as final by scientific reviewers, it will be submitted to the project Scientific Advisory Committee for approval. The documents will be considered as approved in the absence of comments within 5 working days.
4. The approved documents will then have to be checked for language and medical terminology correctness. After that, the document will be published.

## Annex 1: Template CAM summary

### Title

- CAM-summary: name of the method
- Name of the author, Address, phone, email

### Abstract and key points

Summarize the following points:

- Name (*Latin* name for herbs)
- What does the CAM method entail?
- **Claimed** effects by the provider
- Clinical evidence - results
- Safety - results
- Direction of the conclusion regarding efficacy and safety (no recommendations)

Summary box (not more than one line each)

- Description of the therapy
- Evidence of effectiveness
- Safety issues
- Conclusion

### What is “intervention X”?

Please use the following subheadings:

- Scientific name(s), brand name(s), common name(s)
- Ingredient(s)
- Application and dosage
- History/provider(s)
- Claims of efficacy
- Mechanism(s) of action
- Alleged indication(s)
- Prevalence of use
- Legal issues
- Cost(s) and expenditures

### Does “intervention X” work?

Provide evidence from the following study types using them as subheadings:

- Systematic reviews, meta-analyses
- Narrative reviews

- Clinical trials
- Guidelines, books (chapters), consensus statements etc.
- Case series/studies
- Pre-clinical studies
- Other

Please address the quality of the evidence/research findings:

- Internal validity (study design and conduct)
- External validity (applicability and generalisability of results)
- Direction of evidence (positive, uncertain, negative)

## Is “intervention X” safe?

Please use the following subheadings:

- Adverse events  
i.e. reported/possible adverse events (how frequent, how severe)
- Contraindications
- Interactions  
i.e. reported/possible interactions with other drugs/herbs/therapies
- Warnings
- Other problems or complications

Distinguish between pre-clinical toxicological data and clinical data, are there data on mutagenity, carcinogenity, use by pregnant women?

State the difference between 'existing data do not show any risk', 'no data available on certain risks' and 'theoretical risks'.

## Bibliography

List all sources used according Vancouver style. Use the same order, in which they appear in the summary. For updates: add new references at the end of the document and number the new references in the text accordingly. (This is to save you from having to renumber all references throughout the document when adding new references).

State the date of access for websites.

## Disclaimer

The present documentation has been compiled by the CAM-Cancer Project with all due care and expert knowledge. However, the CAM-Cancer Project provides no assurance, guarantee or promise with regard to the correctness, accuracy, up-to-date status or completeness of the information it contains. This information is designed for health professional. Laypersons are strongly advised to discuss this information with their physician. Accordingly, the CAM-Cancer Project shall not be liable for damage or loss caused because anyone relies on the information it contains.

## Annex 2: Reviewer's checklist

### CAM-Summary Checklist 5.0

#### 1. Abstract

	well	adequate	poor	not applicable
complete and comprehensive <sup>11</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
topicality	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
unbiased tone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
user-oriented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Please comment on any particular weaknesses of the chapter and suggest what should be done to improve them<sup>12</sup>:</b>				

#### 2. Chapter: *What is intervention 'X'?*

	well	adequate	poor	not applicable
complete and comprehensive <sup>13</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
topicality	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
unbiased tone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
user-oriented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Please comment on any particular weaknesses of the chapter and suggest what should be done to improve them<sup>14</sup>:</b>				

#### 3. Chapter: *Does intervention 'X' work?*

**Compared to what is recommended in the manual, how well meets the chapter the following criterion**

<sup>11</sup> see 2.2.1. *General guidance for authors* in the manual

<sup>12</sup> please fill in electronically

<sup>13</sup> see 2.2.1. *General guidance for authors* in the manual

<sup>14</sup> please fill in electronically

	well	adequate	poor	not applicable
complete and comprehensive	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
topicality	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
unbiased tone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
user-oriented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Please comment on any particular weaknesses of the chapter and suggest what should be done to improve them:</b>				

4. Chapter: *Is intervention 'X' safe?*

	well	adequate	poor	not applicable
complete and comprehensive	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
topicality	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
unbiased tone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
user-oriented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Please comment on any particular weaknesses of the chapter and suggest what should be done to improve them:</b>				

5. Chapter: *Conclusion about intervention 'X'*

	well	adequate	poor	not applicable
complete and comprehensive	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
topicality	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
unbiased tone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
user-oriented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Please comment on any particular weaknesses of the chapter and suggest what should be done to improve them:</b>				

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**6. Overall conclusion of the reviewer**

Can this CAM summary be published on the project website in its current version?

Yes	<input type="checkbox"/>
Yes, with minor modification(s)	<input type="checkbox"/>
Yes, with major revision	<input type="checkbox"/>
No, rejected	<input type="checkbox"/>

<p><b>Please provide your general comment(s) and any particular remark(s):</b></p> <div style="height: 150px;"></div>
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<p><b>Please send this form back to: Scientific Co-ordinator *****</b>  <b>e-mail: *****</b></p>
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