



CAM-Cancer Methodology

Executive Committee of CAM-Cancer <http://www.cam-cancer.org>

Manual for Writing and Reviewing CAM Cancer Summaries

Editorial Process

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1. Introduction

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

The CAM-Cancer¹ project was originally 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).

From September 2007, The National Research Center for Complementary and Alternative Medicine (NAFKAM/NIFAB) at the University of Tromsø in Norway has taken the responsibility to continue the CAM-Cancer project. The project is aimed at improving evidence-based cancer care 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 CAM used in cancer. These 'CAM summaries' (CAM summaries) 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
- Providing a freely available website hosting the various publications detailed above at www.cam-cancer.org

¹ Concerted Action for Complementary and Alternative Medicine (CAM) Assessment in the Cancer Field

2. CAM summaries – definition and aims

CAM summaries are evidence-based articles synthesizing the best available scientific information on CAM in cancer. The selection criteria for CAM summary topics include 1) related safety issues 2) expressed patient interest and, if data are available, reported prevalence of use.

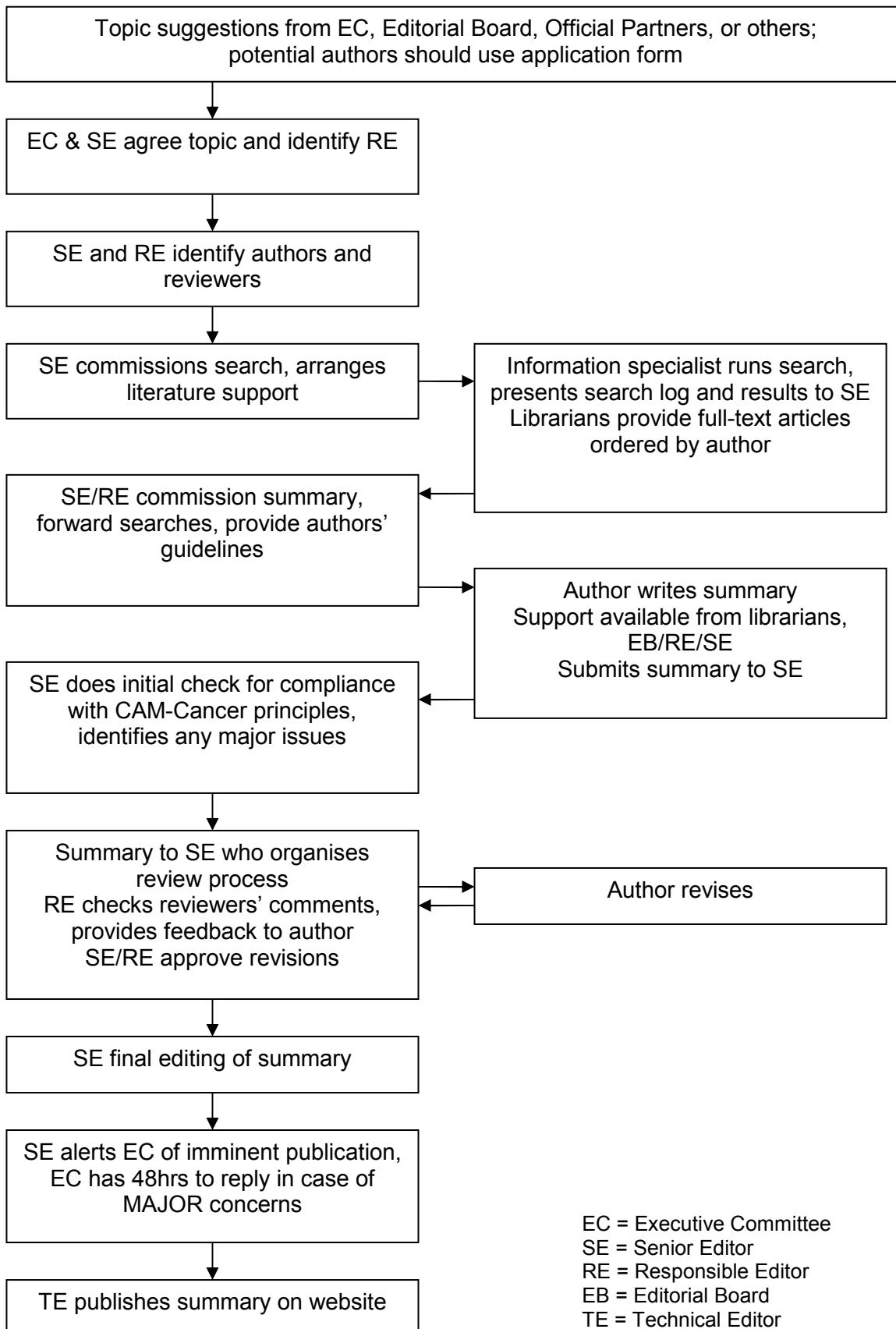
For each CAM summary, background information on the intervention and evidence for or against its clinical effectiveness, efficacy and safety are systematically prepared. Both are presented in a clear and easily accessible format. CAM summaries are peer-reviewed and regularly updated. By providing clear statements they are aimed at assisting health professionals in making shared decisions with their patients.

Note! CAM summaries are NOT systematic reviews but are aimed at summarising the existing evidence for or against CAM used in the prevention, treatment and palliative/supportive care of cancer patients.

Summaries produced to date can be found on the CAM-Cancer web site at www.cam-cancer.org

3. Authoring CAM summaries

Figure 1: CAM summary editorial process



3.1 Selecting topics and applying to write a CAM summary

The Executive Committee decides about topics and Responsible Editors for new summaries. The respective Responsible Editor then identifies together with the Senior Editor authors and reviewers for a topic.

If you wish to write a CAM-summary you can express your interest by filling in a topic proposal form (available on request from the Scientific Coordinator at contact@cam-cancer.org) Firstly, you should identify a CAM topic which has not yet been covered on the project website or is currently under development. The selection criteria include 1) the related safety issues 2) the expressed patient interest and the reported prevalence of use, if data are available.

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

Once approved, authors should follow the instructions in this manual to produce your CAM summary (sections 3.3. ff writing and submitting a CAM summary) using the CAM summary template (appendix 1).

3.2 Authorship and ownership

For each summary it is stated on the website that the summary is “written and reviewed by [author name(s)] and the CAM-CANCER Consortium”. Readers will also be referred to a list of author and reviewer names posted on the project website. The ownership of the CAM summary and the related methodological documents will remain with the respective authors and the CAM-CANCER Consortium.

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 methods 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
- user-oriented.

CAM summaries are not full systematic reviews. The primary audience for CAM summaries are health care professionals. Summaries should be written with this readership in mind and an independent and non-judgemental tone should be used.

4.2 Searching

The CAM-Cancer Scientific Co-ordinator provides authors with literature searches conducted by an experienced information specialist. The searches are all performed in Medline and the Cochrane Library and are available in bibliographic software. They are fully documented (search terms, databases, interfaces, 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 may be provided by the Scientific Co-ordinator.

In addition, authors need to perform their own searches for general background information and general safety information. If an author's search does not provide any useful references, they can contact the Scientific Co-ordinator to enquire whether the Editorial team or the Executive 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 resulting from your searches.

4.3 CAM summary template and guidelines

CAM summaries must be a maximum of 2000 words long with no more than 40 references.

4.3.1 Abstract

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

Summarise your findings in a way that will enable health care professionals to make unbiased and informed decisions. Although CAM summaries are written for professionals, do consider how the summary will be understood and interpreted by lay persons.

- **Do not make any recommendations:** Avoid wording the summary in a way which may be interpreted as making a recommendation. CAM summaries should summarise existing evidence, but not provide advice.

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, as well as any used common name where this is available) 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 is the direction for the conclusion regarding the, effectiveness, efficacy and safety of this CAM modality?

4.3.2 What is it?

Please limit this section to a maximum of two pages. Please always reference your sources.

Firstly, you must generate an **overview** of the CAM therapy which you are writing about. In this overview the following issues should be **briefly** presented using the following headings:

- Description
- Scientific name(s)/brand name(s)/common name(s)²
- Ingredient(s)/Components
- Application and dosage
- History/provider(s)³
- Claims of efficacy/mechanism(s) of action/alleged indication(s)⁴

² For taxonomy of plants please use: http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl

- Prevalence of use⁵
- Legal issues⁶
- Cost(s) and expenditures

4.3.3 Does it work?

To write this section, you must be able to **critically appraise and summarise** relevant articles identified through the literature search. Factors that warrant assessment are those related to internal (study design and conduct) and external validity (applicability and generalisability of results) of individual investigations.

Please summarise the evidence in a clinically meaningful way. Consider sorting the evidence according to cancer type or outcome measures, if appropriate. Provide evidence from the following study types using them as subheadings:

- systematic reviews, meta-analyses
- narrative reviews
- controlled clinical trials
- uncontrolled clinical trials – only if no or very few controlled trials are available
- case series/studies – only if no reviews or controlled trials available
- pre-clinical studies – please summarise very briefly in 2-3 sentences

For each of the above **categories**, you should **very briefly** describe the evidence:

- Type (i.e. systematic review, RCT, pre-clinical trial, case series, individual case reports, guidelines, 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)

³ When was the intervention first used in cancer care? Who discovered it and in which country? 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.

⁴ When providing a description of the intervention method, please explore claims by the inventor, the theory of the intervention and the mechanism. What effects does the inventor / producer / originator claim the therapy has on cancer patients? How is the therapy supposed to prevent or treat cancer or be used in cancer palliation? How is the intervention delivered?

⁵ What is known about the prevalence of use of this CAM in cancer patients?

⁶ What is the legal position regarding intervention 'X' and/or what are the important legal issues to be considered generally? What qualifications are needed to practice as a therapist in various countries?

Summaries including five or more controlled clinical trials/reviews should present trial/review details in table format rather than describing them in the text.

- Please add a table containing the following details of **controlled trials** (see Appendix 1a below): First author, year, ref number; Study design; Participants (number, diagnosis); Interventions (experimental treatments, control); Main outcome measures; Main results; Comments.
- Please add a table containing the following details of **systematic reviews** (see Appendix 1a below): First author, year, reference number; Main outcomes; Number of studies; Type of studies; Number of patients included; Main results/Conclusion; Comments (quality of included studies, other).

Please also include a paragraph in the text summarising the main conclusions of the trials (number of trials, indications, main results and conclusion) and reviews (number of studies and patients, type of studies, main outcomes, main results and conclusion). Readers should be able to understand this summary paragraph and get enough information without having to read the table.

There is no need to obtain and analyse details of individual trials in the case where systematic reviews in a particular field exist. In such cases only additional publications should be added to the summarised results of the review. In cases where no systematic reviews exist, the existing evidence resulting from clinical trials should be **summarised**. Case series/studies only need to be included if no reviews or trials are available.

Results of pre-clinical trials and basic research should only briefly be summarised and be no longer than a few sentences.

Please consider including the following issues:

- **Evidence:** What is the level of evidence?⁷ Which methodological limitations of the underlying clinical research and the methods used in this summary might affect practical decisions about healthcare. What predictable variations might influence the applicability of the evidence to particular circumstances? Which other information should be considered by someone making a decision (current practice, compliance etc.)? Remember when presenting the statistical results of research to do it in a consistent way across your summary.

⁷ Please categorise according to the following system:

1 - (several, most rigorous etc) studies suggest (demonstrate, show etc) therapy x to be effective for condition y [the most positive result]

2a - no trial data are available [neutral because of lack of evidence]

2b - the data from the (most relevant, rigorous etc) trials are contradictory [neutral because of lack of agreement]

2c - the data from the (most relevant, rigorous etc) trials are of very low methodological quality [neutral because of lack of methodological rigour]

3 - (several, most rigorous etc) studies suggest therapy x to be not effective (better than placebo) for condition y [the most negative result]

- **Trade-offs:** Which trade-offs should be made between known/estimated benefits and known/estimated expenditures and harms, if decisions about the usefulness of a method are required.

- **Argumentation:** Do not confuse 'no evidence of effect' with 'evidence of no effect'.

Summarise your findings regarding the evidence found and the safety issues in an informative way. The facts should be repeated in order to allow the readers to reach their own conclusion about the CAM intervention. In addition, readers may go directly to the conclusion section and skip the intermediary sections.

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

4.4.4 Is it safe?

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

- Adverse reactions/effects⁸
- Contraindications
- Interactions with other drugs/therapies⁹
- Known problems or complications¹⁰
- Warnings

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

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

4.3.5 References

The summary should contain **a maximum of 40 references**. Please use numbers in the text for referencing the literature. The references should be numbered sequentially, according to their order in the text. The references listed in the bibliography should be sorted using the same order. For updates of existing summaries, references may be added at the end and numbered accordingly in the text. The Vancouver style should be applied (for full instructions refer to http://www.nlm.nih.gov/bsd/uniform_requirements.html).

⁸ How frequent, how severe?

⁹ If anything exists about herb-drug interactions mention it in this paragraph.

¹⁰ 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?

4.3.6 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 Submitting a CAM summary

After checking for compliance with the above guidelines, the author submits the CAM summary in electronic format to the Scientific Co-ordinator within the agreed deadlines. The Senior Editor and Responsible Editor then organise the peer review process.

5.2 Publishing a CAM summary

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

5.3 Updating CAM summaries

Summaries are updated on a regular basis. It is recommended that updating takes place on an annual basis. Updating should only be done in agreement with the Scientific Coordinator.

Summaries over two years old are archived and removed from the live web site.

6. Reviewing a CAM summary

6.1 Task of scientific reviewers

The goal is to ensure that CAM summaries are prepared in accordance with the standards outlined in this manual.

6.2 Review process

- The Senior Editor sends the CAM summary to the respective Responsible Editor. If major issues are identified at this stage, the summary needs to be revised before peer review. Otherwise the summary is sent to the two appointed reviewers.
- The Responsible Editor checks the evaluation and recommendations provided by the two reviewers, and prepares the feedback for the author. Direct discussions between editors, reviewers and authors can take place.
- The author amends the summary; the modified version has to be approved by the reviewers and/or Responsible Editor.
- Once the document is considered as final by the reviewers and editors, it is sent to the Executive Committee who can raise major concerns within 48 hours.
- After that, the document is published on the website at www.cam-cancer.org

6.2 Reviewing methods

The reviewer uses the checklist provided 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.

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 Responsible or Senior Editor 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.

The reviewer should go through the checklist and score each individual item. The reviewer shall make exhaustive comments and suggestions in order to help the author improve the CAM summary. Reviewers should differentiate 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.

Comments should be inserted in the electronic version of the checklist and sent to the Scientific Co-ordinator. Specific comments can also be inserted directly into the summary.

The Responsible Editor ensures that there is consistency between reviewers' comments. In case of major disagreement between the author and the reviewers or between the reviewers themselves, the Responsible Editor will try to reach consensus. If no agreement can be found, the Senior Editor and/or the Executive Committee shall make a decision.

Appendix 1: Template CAM summary

CAM summaries must be a maximum of 2000 words long with no more than 40 references.

Title

- CAM-summary: name of the method

Abstract and key points

Summarize the following points (not more than 1-2 sentences per point):

- 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

What is it?

This section should be no longer than 2 pages. Always reference your sources.

Please use the following subheadings:

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

Does it work?

Please **summarise** the evidence in a clinically meaningful way. Consider sorting the evidence according to cancer type or outcome measures if appropriate.

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

- Systematic reviews, meta-analyses
- Narrative reviews
- Clinical trials
- Case series/studies (only if no reviews or clinical trials are available)
- Pre-clinical studies (only very briefly, summarise in 2-3 sentences)
- Other

For each category, please very briefly 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)

Summaries including five or more controlled clinical trials/reviews should present trial/review details in table format rather than describing them in the text. Please see Appendix 1a below for table templates. Please also include a short paragraph in the text summarising the main conclusions of the trials/reviews.

Is it 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 mutagenicity, carcinogenicity, 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

Please limit the number of references to 40.

List all sources used according to 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.

Appendix 1a: Tables

Table 1: Controlled clinical trials of xxx for xxx

First author, year, (ref)	Study design	Participants (number, diagnosis)	Interventions (experimental treatments, control)	Main outcome measures	Main results	Comments (critical evaluation, weaknesses, etc)

Table 2: Systematic reviews of xxx for xxx

First author, year, (ref)	Main outcomes	Number of studies Type of studies Number of patients	Main results/ Conclusions	Comments (quality of included studies, other).

Appendix 2: Reviewer's checklist

You can either list your comments and suggestions in the comment boxes provided on this form or insert them directly into the manuscript using track changes/comments. Please also complete tables 1 and 2 below.

1. Overall assessment of the CAM summary

	well	adequate	poor
complete and comprehensive	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
topicality	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
unbiased tone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
user-orientated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please comment on any particular weaknesses and suggest improvements.

2. Overall conclusion of the reviewer

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

	Explanation	<input type="checkbox"/>
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.	<input type="checkbox"/>
Yes, with major revision	Reviewers noting omission of important data or if 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.	<input type="checkbox"/>
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.	<input type="checkbox"/>

Please provide your general comment(s) and any particular remark(s)

**Please send this form back to the
Scientific Co-ordinator Barbara Wider Vellinga
e-mail: b.wider@exeter.ac.uk**

Appendix 3: History of the CAM-Cancer Manual

Document history

Version 1 drafted by K. Schmidt (Nov 2004) and updated by A. Tomlin (Dec 2004)

Version 2 completely revised by K. Schmidt and M. Horneber (Dec 2004/Jan 2005)

Version 3 updated and revised by K. Schmidt, M. Horneber; completed and submitted by A. Tomlin (Feb 2005)

Version 4 revised by S. Lejeune (Jul 2005)

Version 5 revised by B. Wider and M. Horneber (Jul 2009)

Version 6 revised by V. Fønnebø, M. Horneber, P. Viksveen, B. Wider (March 2011)

Version 7 revised by B. Wider (January and April 2012)