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The Swiss Oncology Research Network

SAKK Publication Guideline

This revised SAKK Publication Guideline has been approved by the SAKK General Assembly on May 4, 2022. This version is effective May 5, 2022 and supersedes the previous version (July 2019).

1 Purpose

This guideline defines the timing, authorship and SAKK review process for the preparation and release of publications based on data collected for SAKK trials and other trials with SAKK involvement. Furthermore, the procedures and the format for presentations are described.

For registries within SCORED, the SCORED publication guideline applies.

The responsibilities are shared by the coordinating investigators, clinical project managers, SAKK head of statistics, trial statisticians, SAKK Chief Scientific Officer (CSO), presidents of the project/working groups or sections, other participating investigators (e.g. quality of life, health economics, pathology or translational research), the SAKK scientific committee and the SAKK directors' committee.

The purpose of this guideline is to help everyone involved to proceed in an appropriate, efficient and timely way as well as to avoid conflicts. The competence center of SAKK provides assistance to investigators in order to facilitate the respective processes.

The SAKK guarantees the freedom of reporting to the participating physicians. This statement is based on the World Medical Association Declaration of Helsinki [1].

2 General considerations

2.1 Release of trial results

SAKK as sponsor has the duty to make the results of their research on human subjects publicly available and is accountable for the completeness and accuracy of their publications. All results, whether negative, inconclusive, or positive should be published or made publicly available.

Inappropriate publications (e.g. press releases) or presentations of trial results at closed sessions to persons outside the trial team should not jeopardize publications or presentations of results at public meetings.

Statistical analyses should be performed on data that have been reviewed by the coordinating investigator.

A publication plan detailing the type and timing of publications of the trial is to be implemented within the trial team. Results should be timely evaluated and published; hence early initiation of the process is essential. See section 2.1.1 about timing of publications. Detailed planning of the timing of analysis and submission of the manuscript or abstract is to be determined within the trial team as well. The publication plan should also include the planned author list (see 2.4).

SAKK encourages the (re-)use of data related to its trials by making them available to researchers. For the procedure see also section 3.3

2.1.1 Timing of publications

For phase I trials publication/presentation of interim results is permitted at any time during the course of the trial after consultation with an external contract partner, if appropriate. For phase I/II trials, phase I results may be published separately.

For stratified trials with parallel strata for different subgroups of patients, each stratum is considered as an independent trial. After reaching the primary and selected secondary endpoints in one stratum, a separate publication pertaining to that stratum is thus allowed.

For randomized trials with multiple parallel treatment arms within the same patient population, data of all treatment arms will usually be analyzed simultaneously for a comprehensive publication.

For phase II/III trials or phase III trials with a feasibility part, separate publications of results are permitted after reaching the primary endpoint of the phase II (or the feasibility part) of the trial, as long as results pertaining to or hinting at the primary endpoint of the phase III trial are not presented. Such publications/presentations will report results only on patients enrolled in the phase II or on the feasibility part of the trial.

Generally results are only released after reaching the primary endpoint. However, publications of early findings that are possible without jeopardizing the scientific integrity of the trial are allowed and encouraged under the following conditions:

- Results of pre-planned interim analyses may be published, however the results of the primary endpoint and any related secondary endpoints that could hint at results of the primary endpoint

cannot be included in the publication. Other results of any number of patients may be analyzed and included in the publication. After abstract submission updated results may be presented at the conference. If the primary endpoint and the related secondary endpoints have been reached in the meantime, the corresponding results may also be presented.
- Safety data may be released at any time without a planned interim analysis if deemed necessary. Such action is to be approved by the coordinating investigator, the medical advisor and the SAKK scientific committee.
- Results of pre-planned analyses of secondary endpoints or subprojects like e.g. quality of life, translational research, outcome research, pathology, quality assurance that are available before the primary endpoint may be published in advance. Such publications should not include results of endpoints potentially hinting at the primary endpoint

In case of doubt the SAKK directors' committee will decide whether or not such results may be released before the primary analysis.

2.2 Publication recommendations

It is recommended that publications in peer-reviewed journals and presentations at scientific conferences follow the established reporting standards, such as CONSORT [2-12] for randomized controlled trials, REMARK [13] for tumor maker prognostic studies, STARD [14] for studies of diagnostic accuracy, TREND [15] for nonrandomized evaluations, STROBE [16] for observational studies, PRISMA [17] for reviews and meta-analyses, ICMJE [18] for submission to biomedical journals, ASA statement on p-values [19].

According to the good publication practice of Graf et al. 2009 [20], the key points are:

- Articles and presentations should be complete, balanced and clear.
- Reference to the unique study identification number should be included in all articles and presentations that report research from applicable clinical studies.
- Interpretation of results should be unbiased, based on findings, and relevant to the audience.
- Discussion of results should be unbiased, placed in the context of other relevant literature, and the evidence cited should be balanced. Studies with related findings should be cited, especially when previous results conflict with the results being reported.
- Limitations (and strengths) of the study design and methodology should be described.

Open access publication is encouraged for all results (both positive or negative) that are deemed to immediately impact on clinical practice and on research methods. Open Access publication fee should be integrated into the study budget.

2.3 SAKK representation

Every attempt should be made to have major publications in the name of SAKK. The following options should be considered:

- The number of the trial should appear in the title of the publication … *trial SAKK XX/YY…..*.
- The name "SAKK" should appear in the title of the publication: *A trial of the SAKK*.
- If this is impeded by the journal's publication policy, the name "SAKK" should appear at the end of the author list as "*for the Swiss Group for Clinical Cancer Research SAKK*"
- If none of the above options is acceptable by the target journal, all authors should be affiliated to both their institution and SAKK.

2.4 Authorship

2.4.1 Authorship principles

Authorship should be credited according to the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical publication" (updated December 2014). The two most important principles are:

- Authorship credit should be based on 1) substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND 2) drafting the work or revising it critically for important intellectual content; AND 3) final approval of the version to be published; AND 4) agreement to be accountable for all aspects of the work in ensuring that

questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Authors should meet all 4 criteria. Contributors who meet fewer than all 4 of the above criteria for authorship should not be listed as authors, but they should be acknowledged.

- Acquisition of funding, general supervision of a research group or general administrative support; and writing assistance, technical editing, language editing, and proofreading do not constitute authorship, but should be acknowledged.

It is the responsibility of the coordinating investigator (CI) to ensure that these principles are adhered to.

If authors move from one institution to another in the course of the trial, those authors will be listed with the institution to which they were affiliated at the time of starting trial participation and with "(now at <new affiliation>)" at the end.

No honorary authorship will be granted. Authorship will not be granted for compensation for other services or contribution to other trials.

2.4.2 First author

The CI is usually the first author of the primary manuscript. Secondary manuscripts/abstracts shall be authored by specific individuals directly responsible for the particular projects. For such manuscripts/abstracts the CI is usually last author, if adequately involved.

If the CI is inadequately involved in the trial, he/she may lose authorship after discussion in the respective project group/working group/section and by decision of the SAKK directors' committee.

If the CI has left the institution where he/she started the trial participation, but continues to stay affiliated with SAKK and to lead trial activities, he/she may maintain his/her rights as the first author with the permission of the president of the respective project group/working group/section and the scientific committee liaison person of the group.

If the CI has substantial delay in preparing the manuscript, he/she may lose the rights as the first author by decision of the SAKK directors' committee.

2.4.3 Selection of authors

First authors are responsible for proposing author selection and order. They have to give justifications for individual authorship.

Before the first draft of the manuscript/abstract is written, the first author submits the proposed author list to the trial statistician, who forwards it to the head of statistics for approval. The head of statistics may involve the SAKK directors' committee if deemed necessary.

The selected authors have to review and comment on the draft manuscript and receive the final version before submission to the journal.

2.4.4 Participating institutions

Authorship for participating institutions (members and sites) is based on accrual. Each member having enrolled ≥5% of patients in the primary analysis population may receive a position in the author list. If a member has enrolled a larger number of patients in the trial, that member may get an additional authorship for every additional 10% of the patients accrued, with a maximum of three authors. I.e. a member recruiting 5.0–14.9% patients may have one author, 15.0–24.9% patients two authors, and ≥25.0% patients three authors. The CI counts as an additional author for his/her site independent of the number of patients. Supporting coordinating investigators are included in the number of authors per site. For members consisting of several sites the number of authors will be distributed among the sites again according to the accrual of the individual sites. The trial statistician will inform the CI how many authors of each participating member and site may be included. The head of statistics may adapt these thresholds depending on the number of contributing institutions and the length of the author list accepted by the target journal/conference.

The trial-specific principal investigator of each site is responsible for assigning authorship to the appropriate individual(s) at that site. In case the responsibility of the principal investigator has been handed over to another person during trial conduct, the superior at the institution makes the assignment.

For trials with secondary manuscripts, representatives of participating institutions who were not included in the author list of the primary manuscript may be included in the author list of the secondary manuscripts.

2.4.5 Competence center of SAKK

In general, three authors from the competence center of SAKK should be included. The trial statistician should be included in the author list, generally as one of the first three authors, if adequately involved. The clinical project manager and clinical project developer should be included in the author list, but do not need to be in prominent positions.

Further persons from the competence center of SAKK may be included as authors, depending on their intellectual input and further indispensable contribution. In unclear cases, the head of statistics will decide together with the other heads within the competence center of SAKK.

The affiliation must be “Competence center of SAKK”.

2.4.6 Representatives of other disciplines

For multidisciplinary trials several investigators of different disciplines (surgeons, radiotherapists, etc.) in an institution might have made similarly important contributions. It is the responsibility of the principal investigator and CI to decide whether several authors from different disciplines of an institution are justified. In unclear cases, the issue is escalated to the directors’ committee via the head of statistics.

2.4.7 Foreign cooperative groups participating in SAKK trials

Each cooperative group should have the opportunity to include at least one author. Individual authors should be listed in the name of the cooperative group.

It may be required or wished that the conditions for authorship, the number of authors and their positions in the author list are prospectively agreed upon between the SAKK and the respective cooperative groups in the trial specific contracts.

2.4.8 Acknowledgments

An acknowledgment should be included, whenever permitted by the policy of the target journal.

All contributors who do not meet the criteria for authorship should be listed in the acknowledgments or in an appendix, also medical writers if applicable. The acknowledgment list should include the names of all participating institutions together with the corresponding names of the principal investigators.

Members of the Independent Data Monitoring Committee (or similar committees) should be acknowledged where applicable.

2.4.9 Funding sources

The Swiss State Secretariat for Education, Research and Innovation (SERI) and the Swiss Cancer Research Foundation (SCR) and Swiss Cancer League (SCL) should be acknowledged for funding, unless the trial is completely funded by external partners.

Funding by external partners (e.g. pharmaceutical companies or foundations) should be acknowledged appropriately, including grant numbers, if applicable.

Pharmaceutical companies which provided study drugs should also be acknowledged.

2.5 SAKK review process

The trial statistician is responsible for the SAKK review process, but the individual steps of the review process may be delegated to other SAKK personnel.

The draft publication will be sent for review to all co-authors, the 2nd statistician (if applicable), the SAKK head of statistics and the SAKK CSO for review. The timeline for review should be at least 5 days for abstracts, poster and presentations and at least 10 days for manuscripts.

The draft publications will also be sent to any involved pharmaceutical companies and other external partners, as agreed upon in the respective contracts.

For very similar publications, e.g. resubmissions of abstracts, the head of statistics may shorten or waive the review process.

3 SAKK trial publications

3.1 Primary manuscripts

Primary results of each SAKK clinical trial should be timely evaluated and published. Statistical analysis, preparation of the clinical study report or conference presentation, if applicable, and manuscript writing should proceed in parallel and are to be finished within 6-9 months from reaching the primary and selected secondary endpoints or within 3 months of presenting the data at a conference, as agreed upon by the trial team.

The statistical analysis is carried out at the competence center of SAKK by the trial statistician in close collaboration with other members of the trial team. The trial statistician provides a draft report as the basis for manuscript writing.

It is the task and the privilege of the coordinating investigators to draft and finalize the manuscript. They may delegate the writing of specific sections (e.g. other disciplines, substudies) to competent coauthors. Delegating a person other than the coordinating investigator to write the whole manuscript is allowed after obtaining approval from the president of the respective project group/working group/section.

The involvement of a professional medical writer to support the first author in manuscript preparation and/or submission is allowed and encouraged. The budget needs to be approved by the head of statistics.

The coordinating investigator must provide a draft for the first review and submit according to the consented time schedule. In case of revisions, the resubmission should normally be done within 4 weeks. In case of a rejection, the submission to the next journal should normally be done within 4 weeks as well.

All named authors must approve the content of the final manuscript and assume responsibility for it.

During the manuscript writing the coordinating investigator and trial statistician should remain closely in touch. If the pre-defined timelines are not met, the trial statistician will escalate to the head of statistics who may further escalate to the respective project group/working group/section president and scientific committee liaison person and/or SAKK directors' committee if the delays are persisting. If despite these measures the manuscript writing process is still delayed, the respective project group/working group/section president has to assign a new writer for the manuscript. As a consequence, the coordinating investigator will lose the rights as first author.

The coordinating investigator should aim for the highest ranking realistic journal and adhere to the corresponding guidelines for authors.

3.2 Abstracts and conference presentations

The first author is responsible for good timing in abstract preparation, allowing sufficient time for the SAKK review and the review by contract partners (e.g. industry) involved, and submission.

Submission and presentation of the same abstract or results at two different conferences is allowed as long as different aspects are highlighted. Presentations may be given by coauthors at different conferences. Highest-ranking conferences should be considered first.

3.3 Secondary publications

Secondary publications include all non-primary publications using SAKK patients' data; e.g. quality of life, translational research, outcome research, pathology substudies, quality assurance or long-term follow-up publications.

Usually the investigator responsible for the secondary project is in charge of writing the manuscript. Secondary publications shall be authored by specific individuals directly responsible for the particular project, in the name of SAKK. The coordinating investigator and other key contributors are usually co-authors with the coordinating investigator as last author.

If a substudy or project is not mentioned in a protocol but planned retrospectively, the investigator must request permission from the competence center of SAKK and the coordinating investigator via the clinical project manager. If deemed necessary, the SAKK scientific committee and/or SAKK directors' committee might be consulted. A short project description, the target journal/conference and the planned author list must be included in the request. SAKK is committed to making the best use of the available data and therefore encourages secondary publications.

All contributors to the substudy must be properly acknowledged.

3.4 Other types of SAKK publications

This section refers to letters to the editor, single case reports, review papers, book chapters, trial protocols etc. written by SAKK investigators and based on SAKK trial data.

The first author must obtain permission for use of the data and SAKK affiliation from the head of statistics. If deemed necessary, further approval from the SAKK directors' committee shall be requested. The target journal/publisher must be mentioned in the request. The extent of the review process will be determined based on the type of publication.

3.5 Other publications based on SAKK data

This section pertains to publications based on data in part provided by SAKK upon collaboration requests (e.g. for meta analyses) and may be written by non-SAKK investigators/co-workers.

Such collaborations may be considered only after the primary manuscript of the respective SAKK trial has been accepted for publication.

The project leader must obtain permission to use data of a specific SAKK trial via the coordinating investigator, who will forward the request to the head of statistics for approval. If deemed necessary, further approval from the SAKK directors' committee shall be requested. The head of statistics with check with the SAKK legal team if a specific data sharing agreement needs to be set up and if special measures for data protection (e.g. anonymization) are required.

At least one SAKK representative must be included as author. Usually the coordinating investigator acts as the SAKK representative. If the coordinating investigator is no longer active in this context, then the president of the respective project group/working group/section selects the SAKK representative. Depending on contribution, further authors from SAKK (e.g. the trial statistician) may be requested.

The project leader submits the draft publication to the trial statistician, who is responsible for checking formal correctness.

4 Collaborative group trial publications

This section pertains to publications based on data of trials lead by other collaborative groups (e.g. HD, Hovon) and coordinated/supported by SAKK in Switzerland and may be written by non-SAKK investigators.

The publication policy must be agreed upon between the SAKK and the respective collaborative group in the trial specific contract.

The SAKK coordinating investigator/representative submits the draft publication to the responsible clinical project manager, who takes care of the review process and checks formalities. The SAKK coordinating investigator/representative is responsible for the scientific interpretation.

4.1 Authorship

The president of the respective project group/working group/section should make sure that authorship is allocated equitably. In unclear cases, the issue is escalated to the directors' committee via the head of statistics.

For the primary manuscript, at least one SAKK representative should be named as author. Depending on contribution, further authors may be added. For secondary publications, in case substantial contribution has been provided to a substudy by SAKK investigators, authorship of an SAKK representative is requested.

SAKK representatives should give the affiliation of both their institution *and* the SAKK. All participating SAKK institutions as well as the corresponding principal investigators should be acknowledged in the publication.

5 Non-trial publications

This section pertains to publications which do not use data of SAKK trials or of trials lead by other collaborative groups and coordinated/supported by the SAKK in Switzerland, but are written in the name of the SAKK or the SAKK is listed as the affiliation of some authors.

The first author, or for consulting cases the statistician, sends the draft version including authors list and the name of the conference/journal to the head of statistics (and co-authors as usual). If deemed necessary, further approval from the SAKK directors' committee shall be requested.

The first author has to provide electronic files of the submitted and the published versions to the statistician or head of statistics and co-authors..

6 References

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