

SAKK Publication Guideline

This revised SAKK Publication Guideline has been approved by the SAKK General Assembly on June 26, 2019. This version is effective July 1, 2019 and supersedes the previous version (November 2015).

| | | |
|----------|--|----------|
| 1 | Purpose | 2 |
| 2 | General considerations | 2 |
| 2.1 | Release of trial results | 2 |
| 2.2 | Publication recommendations | 3 |
| 2.3 | SAKK representation | 3 |
| 2.4 | Authorship | 3 |
| 2.5 | SAKK review process | 3 |
| 2.6 | Final approval | 4 |
| 3 | SAKK trial publications | 4 |
| 3.1 | Primary manuscripts | 4 |
| 3.2 | Abstracts and conference presentations | 5 |
| 3.3 | Secondary publications | 5 |
| 3.4 | Other types of SAKK publications | 5 |
| 3.5 | Other publications based on SAKK data | 5 |
| 4 | Collaborative group trial publications | 5 |
| 4.1 | Primary manuscript | 6 |
| 4.2 | Secondary publications | 6 |
| 5 | Non-trial publications | 6 |
| 6 | Attachments | 6 |
| 7 | References | 6 |

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. Checklists for guidance and documentation of these processes are provided in the appendix. The responsibilities are shared by the coordinating investigators, clinical project managers, the SAKK CEO, head of statistics, trial statisticians, presidents of the project/working groups or sections, other participating investigators (e.g. quality of life, health economics, pathology or translational research) and the SAKK board.

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 SAKK Coordinating Center (CC) 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.

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 board.
- 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 board 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 marker 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

See authorship guidelines.

2.5 SAKK review process

See checklists for manuscript, abstract and poster/presentation review in the appendix. 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 SAKK president, SAKK past president and 2 further SAKK board members selected by the head of statistics will review all abstracts.

The SAKK president, SAKK vice president, SAKK past president, liaison person and optionally another SAKK board member selected by the head of statistics will review all manuscripts.

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

2.6 Final approval

For all abstracts and manuscripts a final approval is required.

Board members contacted for review with an out of office reply coming back may be replaced. Similarly, board members indicating within 2 working days that they cannot do the review within the given time frame will be replaced. Board members may ask for a time extension if the submission of the abstract or manuscript is not jeopardized.

The selected board members have three options for classifying a draft:

- a) no comments;
- b) minor revisions required, no need to review again;
- c) major revisions required, need to review again.

No reply, i.e. not even out of office, within the possibly extended time frame will be counted as a). If all board members indicate a) the draft abstract/manuscript may be submitted without further ado. If the maximum indicated class is b) the first author has to resend the revised draft to the trial statistician who will check if all comments have been incorporated adequately and will give the final approval. If one or more board members indicate c) the respective board members have to contact the first author directly. The issue needs to be clarified and the board members need to give final approval and inform the trial statistician accordingly. In case of contradictory comments the final decision will be taken by the SAKK past president for abstracts and the SAKK vice president for manuscripts.

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 1 month of presenting the data at a conference, as agreed upon by the trial team.

The statistical analysis is carried out at the SAKK CC 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. 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.

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.

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 Board liaison person or SAKK president 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 SAKK CC and the coordinating investigator via the head of clinical project management. If deemed necessary, the SAKK board might be consulted. A short project description and the target journal/conference 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 president or board 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 president or board shall be requested.

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 the review process.

4 Collaborative group trial publications

This section pertains to publications based on data of trials lead by other collaborative groups 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 project group president and the SAKK coordinating investigator/representative are responsible for the scientific interpretation.

4.1 Primary manuscript

At least one SAKK representative should be named as author. Depending on contribution, further authors may be added. The SAKK co-authors have to be affiliated to both their institution *and* to the SAKK.

All participating SAKK institutions as well as the corresponding principal investigators should be acknowledged in the publication.

4.2 Secondary publications

In case substantial contribution has been provided to a substudy by SAKK investigators, authorship of an SAKK representative is requested. The SAKK co-author has to be affiliated to both his/her institution *and* to the SAKK.

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 president or board 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 Attachments

- Authorship (3 pages)
- Checklist for Abstract Review (1 page)
- Checklist for Manuscript Review (1 page)
- Checklist for Poster and Presentation Review (1 page)

7 References

- (1) World Medical Association (WMA). Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (64th WMA General Assembly, Fortaleza, Brazil, October 2013).
- (2) Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BMJ* 2010; 340:c332.
- (3) Piaggio G, et al. for the CONSORT Group. Reporting of Noninferiority and Equivalence Randomized Trials: An Extension of the CONSORT 2010 Statement. *JAMA* 2012; 308(24):2594-604.
- (4) Boutron I, et al., for the CONSORT group. Methods and Processes of the CONSORT Group: Example of an Extension for Trials Assessing Nonpharmacologic Treatments. *Ann Intern Med* 2008: W60-W67
- (5) Boutron I, et al. for the CONSORT Group. Extending the CONSORT Statement to Randomized Trials of Nonpharmacologic Treatment: Explanation and Elaboration. *Ann Intern Med* 2008: 295-309
- (6) Zwarenstein M, et al. for the CONSORT and Pragmatic Trials in Healthcare (Practihc) groups. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. *BMJ* 2008; 337:a2390
- (7) Hopewell S, et al. for the CONSORT Group. CONSORT for Reporting Randomized Controlled Trials in Journal and Conference Abstracts: Explanation and Elaboration. *PLoS Med* 2008;5(1): e20. doi:10.1371/journal.pmed.0050020.
- (8) Hopewell S, et al. and the CONSORT Group. CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet* 2008: 371: 281-283
- (9) Campbell MK, Elbourne DR, Altman DG. CONSORT 2010 statement: extension to cluster randomised trials. *BMJ* 2012; 345:e5661.

- (10) Ioannidis JP, et al. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004;141(10): 781-788.
- (11) Gagnier JJ, et al. Reporting randomized, controlled trials of herbal interventions: an elaborated CONSORT statement. *Ann Intern Med* 2006;144(5): 364-367
- (12) Gagnier JJ, et al. Recommendations for reporting randomized controlled trials of herbal interventions: explanation and elaboration. *J Clin Epidemiol* 2006; 59(11):1134-1149.
- (13) McShane et al. for the Statistics Subcommittee of the NCI-EORTC Working Group on Cancer Diagnostics. Reporting Recommendations for Tumor Marker Prognostic Studies (REMARK). *JNCI* 2005;97(16):1180-1184
- (14) Bossuyt et al for the STARD Group. STARD 2015: An Updated List of Essential Items for Reporting Diagnostic Accuracy Studies. *BMJ* 2015;351:h5527
- (15) Des Jarlais DC, Lyles C, Crepaz N and the TREND Group. Improving the Reporting Quality of Nonrandomized Evaluations of Behavioral and Public Health Interventions: The TREND Statement. *American Journal of Public Health* 2004;94(3):361-366
- (16) Vandembroucke JP, et al. STROBE Initiative. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): explanation and elaboration. *Epidemiology* 2007;18(6):805-835. PMID: 18049195
- (17) Moher D, et al., for the PRISMA Group. Preferred Reporting Items for Systematic Reviews and Meta-Analyses. The PRISMA Statement. *BMJ* 2009;339:b2535, doi: 10.1136/bmj.b2535
- (18) International Committee of Medical Journal Editors (ICMJE): Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication. Updated December 2018.
- (19) Wasserstein RL et al. The ASA's statement on P-values: Context, process, and purpose. *Am Stat.* 2016 70:129–33
- (20) Battisti WP, et al. Good publication practice for communicating company-sponsored medical research: GPP3. *Ann Intern Med.* 2015 Sep 15;163(6):461-4

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 SAKK board and 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.

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 board.

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 SAKK board.

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 board.

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 initial approval. The head of statistics may involve the SAKK president 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. The final approval of the author list will be made by selected members of the SAKK board while reviewing the manuscript/abstract.

Participating institutions

Authorship for participating institutions (members and sites) is based on accrual. Each member having enrolled $\geq 5\%$ 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 $\geq 25.0\%$ 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.

SAKK CC

In general, three authors from the SAKK CC should be included.

The clinical project manager should be included in the author list.

The trial statistician should be included in the author list, generally as one of the first three authors, if adequately involved. Not all SAKK CC co-workers should have prominent positions.

Further persons from the SAKK CC (e.g. head of clinical project management, head of statistics, head of CTM, medical advisor, CEO) may be included as authors, depending on their intellectual input and further indispensable contribution.

The affiliation must be “SAKK Coordinating Center”.

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.

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.

Collaborative group trial publications

For publications of trials lead by other collaborative groups (e.g. HD, Hovon), the president of the respective project group/working group/section should make sure that authorship is allocated equitably. SAKK representatives should give the affiliation of both their institution *and* to the SAKK.

Acknowledgments

Contributors

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.

Funding sources

The Swiss State Secretariat for Education, Research and Innovation (SERI) and the Swiss Cancer Research Foundation (SCS) should be acknowledged for funding.

External sources should be declared additionally if applicable (information can be obtained from the Fundraising & Communications unit).

Pharmaceutical companies which provided study drugs should also be acknowledged.

Trial/Project:

Journal:

CHECKLIST FOR MANUSCRIPT REVIEW

| | | |
|--|--|---|
| <input type="checkbox"/> <p style="text-align: center;">Author List</p> <p>The sequence of authors is to be proposed by the first author who must justify individual authorship. The first author submits the list to the trial statistician, who will forward it to the head of statistics for initial approval. The head of statistics may involve the SAKK president if deemed necessary. The final approval will be made by selected members of the SAKK board while reviewing the manuscript.</p> | | <p style="text-align: right;">due date date</p> |
| <input type="checkbox"/> <p>Second Statistician, Head of Statistics and Head of F&C</p> <p>The trial statistician forwards the draft manuscript to the second statistician to cross-check with the report or other output and check consistency, completeness and readability of the manuscript, to the head of statistics to check consistency, completeness and readability of the manuscript and the head of F&C to check the acknowledgements.</p> <p><i>Time for review: 10 days</i></p> <p style="text-align: right;">sent date due date end date</p> | <input type="checkbox"/> <p>Co-Authors and PG/WG President</p> <p>The trial statistician sends the draft manuscript for review to all co-authors, the president of the respective PG/WG and requests the required COI forms. The reviewers should provide comments on the manuscript as well as the names and tasks of contributors who should be acknowledged. If it is judged by the first author that co-authors did not make adequate contribution in the review process or did not send the COI form in time, they may lose authorship.</p> <p><i>Time for review: 10 days</i></p> <p style="text-align: right;">sent date due date end date</p> | <input type="checkbox"/> <p>Pharmaceutical companies and Collaborative groups</p> <p>The trial statistician sends the draft manuscript for review to all pharmaceutical companies and collaborative groups involved. In case of major changes, the SAKK board should receive an update.</p> <p><i>Time for review: as specified in contracts (usually 30 days)</i></p> |
| <input type="checkbox"/> <p style="text-align: center;">Revision</p> <p>The first author revises the manuscript before the trial statistician sends it to selected members of the SAKK board. <i>Time for revision: 10 days</i></p> | | <p style="text-align: right;">sent date due date end date</p> |
| <input type="checkbox"/> <p style="text-align: center;">Board Review</p> <p>The trial statistician sends the revised version including target journal to the president, vice president, past president, liaison person and optionally another SAKK board member for review. The trial statistician compiles the comments from the SAKK board for the first author, who finalizes the manuscript accordingly. In case of major changes, the pharmaceutical companies should receive an update. <i>Note: This step may be done in parallel to the other review steps in case of urgency</i></p> <p><i>Time for review: 14 days</i></p> | | <p style="text-align: right;">sent date due date end date</p> |
| <input type="checkbox"/> <p style="text-align: center;">Submission</p> <p>After final approval, the first author is responsible for submitting the manuscript to the target journal. The submission fee can be reimbursed by the SAKK CC. The final electronic version of the submitted manuscript must be sent to the trial statistician and other co-authors. The first author has to send a copy of the journal's editorial response (accompanying letter and comments of reviewers) to the trial statistician and revise the manuscript, if necessary. He/she should inform the co-authors if major revision is required. If the manuscript is rejected by the target journal, the first author chooses another journal for submission. The first author is responsible for checking the galley proof. The trial statistician can help in checking statistical methods, results, figures and statistical interpretations in the galley proof. The first author must send the respective PDF file of the published manuscript to the trial statistician and other coauthors as soon as available. The PDF file is saved electronically at the SAKK CC.</p> | | <p style="text-align: right;">submission date</p> |

CHECKLIST FOR PRESENTATION AND POSTER REVIEW

| |
|-------------------------------|
| Trial/Project: Conference: |
|-------------------------------|

| | | |
|--|--|--|
| <input type="checkbox"/> Format Whenever possible the SAKK poster and presentation templates should be used. These are available on the website or can be provided by the trial statistician. As a minimum requirement the SAKK logo should be placed on posters. For presentations, a big SAKK logo should be on the title and acknowledgment slide and a small logo in one corner of every slide. | | |
| <input type="checkbox"/> Request Permission and Author List due date date If the intended presentation/poster is due to an abstract submitted to and accepted by a conference, then the same authors as in the abstract should be used. If the intended presentation/poster is not due to an abstract submitted to and accepted by a conference, then a request for permission must be sent by the intended presenter or the coordinating investigator via the trial statistician to the head of statistics. The presenter has to propose the authors list, which is forwarded by the trial statistician to the head of statistics for approval. The head of statistics may involve the SAKK president if deemed necessary. | | |
| <input type="checkbox"/> Second Statistician, Head of Statistics and Head of F&C The trial statistician sends the draft presentation/poster to the second statistician to cross-check with the report or other output, to the head of statistics to check consistency, completeness and readability of the manuscript and the head of F&C to check the acknowledgements <i>Time for review: 3 days</i> sent date due date end date | <input type="checkbox"/> Co-Authors The trial statistician sends the draft presentation/poster for review to all co-authors <i>Time for review: 3 days</i> sent date due date end date | <input type="checkbox"/> Pharmaceutical companies and Collaborative groups If required in the contract, the trial statistician sends the draft presentation/poster for review to all pharmaceutical companies and collaborative groups involved. Otherwise, the trial statistician sends the final presentation/poster to all pharmaceutical companies and collaborative group involved for information. <i>Time for review: as specified in contracts</i> sent date due date end date |
| <input type="checkbox"/> Revision and submission deadline submission date The first author revises the presentation/poster according to the reviewer comments. The presenter is responsible for submitting the final presentation/poster in time to the intended conference/meeting and providing the electronic file of the presented version to the trial statistician. The printing of posters has to be organized by the presenter. The costs can be reimbursed by the SAKK CC. | | |