

Checklist for application documents – Clinical Trials

Documents required for concept review (CR) of SAKK proposals

- SAKK Core Trial Proposal Form (highlighted fields only)
- 4-5 important publications relevant to the proposed project (please be aware that we need references for the assumption concerning the primary endpoint)

Documents required for initial assessment

SAKK trial

- Completed SAKK Full Trial Proposal Form
- List of participating sites and committed accrual
- 4-5 important publications relevant to the proposed project (please be aware that we need references for the assumption concerning the primary endpoint), if not already provided for CR
- Completed Conflict of Interest Policy of the designated Coordinating Investigator

Trial of a cooperative group

- Protocol or trial synopsis of the cooperative group
- List of participating sites and committed accrual
- Completed Conflict of Interest Policy of the designated Coordinating Investigator

In case of **initial re-assessment**: All conditions from previous discussions in the Board fulfilled or non-compliance explained

Documents required for final assessment

SAKK trial or trial of a cooperative group

- Conditions of the board from previous assessments are fulfilled
- Written commitment for financing (Letter of Intent from companies)
- If applicable, written commitment for guaranteeing drug/device supply
- If required, statement to comments of international reviewers
- Budget and a suggestion for the compensation for inclusion of patients (Patient fee) is compiled by the SAKK CC and discussed with the Coordinating Investigator before submission to the board

In case of **final re-assessment**: All conditions from previous discussions in the Board fulfilled or non-compliance explained

Please find all the documents mentioned in the text on our website under: www.sakk.ch/en/sakk-submission