RIAT Audit Record (RIATAR)

*A tool for documenting the transformation from regulatory documents to journal publication, based on the CONSORT 2010 checklist of information to include when reporting a randomised trial**

Section/Topic	Item No	Checklist item	Reported on page No of RIAT manuscript	Source section(s) of the Clinical Study Report (CSR): page No. and paragraph	PDF page No (for PDF files)	Notes
Title and abstract						
	1a	Identification as a randomised trial in the title				
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)				
Introduction						
Background and objectives	2a	Scientific background and explanation of rationale				
	2b	Specific objectives or hypotheses				
Methods						
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio				
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons				
Participants	4a	Eligibility criteria for participants				
	4b	Settings and locations where the data were collected				
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were				

Section/Topic	Item No	Checklist item	Reported on page No of RIAT manuscript	Source section(s) of the Clinical Study Report (CSR): page No. and paragraph	PDF page No (for PDF files)	Notes
		actually administered				
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed				
	6b	Any changes to trial outcomes after the trial commenced, with reasons				
Sample size	7a	How sample size was determined				
	7b	When applicable, explanation of any interim analyses and stopping guidelines				
Randomisation:						
Sequence generation	8a	Method used to generate the random allocation sequence				
	8b	Type of randomisation; details of any restriction (such as blocking and block size)				
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned				
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions				
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those				

Section/Topic	Item No	Checklist item	Reported on page No of RIAT manuscript	Source section(s) of the Clinical Study Report (CSR): page No. and paragraph	PDF page No (for PDF files)	Notes
		assessing outcomes) and how				
	11b	If relevant, description of the similarity of interventions				
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes				
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses				
Results						
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome				
	13b	For each group, losses and exclusions after randomisation, together with reasons				
Recruitment	14a	Dates defining the periods of recruitment and follow-up				
	14b	Why the trial ended or was stopped				
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group				
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups				
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the				

Section/Topic	Item No	Checklist item	Reported on page No of RIAT manuscript	Source section(s) of the Clinical Study Report (CSR): page No. and paragraph	PDF page No (for PDF files)	Notes
		estimated effect size and its precision (such as 95% confidence interval)				
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended				
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory				
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)				
Discussion						
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses				
Generalisability	21	Generalisability (external validity, applicability) of the trial findings				
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence				
Other information						
Registration	23	Registration number and name of trial registry				
Protocol	24	Where the full trial protocol can be accessed, if available				
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders				

* The aim of this audit tool is provide a permanent record of the parts of text, tables and figures of the source Clinical Study Report (CSR) selected for inclusion into the RIAT manuscript submitted for publication. This tool is based upon checklist items described in the CONSORT 2010 statement, which is a widely adopted standard for reporting randomised trials. RIAT authors should consult the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. Similar audit records can be created for other types of trials by adapting other CONSORT extensions, e.g. for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. See www.consort-statement.org for more details.