General Remarks

This template of a data extraction form is intended to help you to start developing your own data extraction form, it certainly **has to be adapted** to your specific question. Delete unnecessary information and include all information important for your field.

- It is advisable to use one data-extraction form for one study, so that one data-extraction form may contain the information gained from several publications on the same trial.
- If several different trials are mentioned in one publication, the data of each should be extracted in a separate data extraction form.
- Fill in **every** field as it must be obvious from the form if a certain information is missing or uninterpretable (versus forgotten to extract)
- Extract all information that you will need for further analysis (e.g. subgroup analysis) and which allow you to classify or group several studies with common features (e.g. study quality, protocol of intervention)
- Specify which information is unclear or name conflicting details in order to avoid duplication of effort
- Extraction of statistics: extract all information on variables on location and variability, standard error, confidence interval and p-values. Extract exact figures of p-values (instead of “[not] significant”) and add niveau of confidence (95 or 99%)

Abbreviations:

REF	References
ID	Identification
NR	Not reported
IN	Included
EX	excluded
DB	Database

STUDY ELIGIBILITY FORM

FACTORS	ASSESSMENT	COMMENTS
TYPE OF STUDY		
1. Is the study described as randomized? NB. Please answer “No” if the study is a crossover or quasi-randomized trial.	Yes ⇩ Unclear ⇩ No ⇩ **Exclude**	
PARTICIPANTS		
2. Were participants diagnosed as patients with disease of interest?	Yes ⇩ Unclear ⇩ No ⇩ **Exclude**	
3. Were participants of the prespecified age? NB: Please answer „Yes“, If mix age participants i.e. both >18 years and < 18 years are included and state it as comments. No: If only < 18 years.	Yes ⇩ Unclear ⇩ No ⇩ **Exclude**	Subgroups available?
INTERVENTIONS		
4. Were comparison groups treated with prespecified intervention in one group and control intervention in other group? NB: study can have 3 arms e.g. CT arm, CT+RT (CMT) arm or RT arm, if so please cross „Yes“ and state it as comments.	Yes ⇩ Unclear ⇩ No ⇩ **Exclude**	
OUTCOMES		
5. Did the study report prespecified outcomes?	Yes ⇩ Unclear ⇩ No ⇩ **Exclude**	
FINAL DECISION 1 X “No” = EXCLUDE 1 X “Unclear” = UNCLEAR		

ORGANISATIONAL ASPECTS				**EX**		**IN**	
REF ID		Reviewer, Date		Checked by			
Author, Year							
Journal/Source				Study ID	NR /		
Country of origin							
Publication type	Fulltext ☐ / Abstract ☐ / Book chapter ☐ / internal progress report ☐ other (please specify) ☐						
Other relevant publications in DE-form							
Fate	Decision pending ☐ / Check references ☐ / Use for discussion ☐ / EX without listing ☐ / EX with listing ☐ / Other (please specify) ☐						
Notes / Short description							

REASONS FOR EXCLUSION OF STUDY FROM REVIEW (PLEASE SPECIFY according to protocol	
Methods	No RCT ☐ / Inadequate concealment of allocation ☐ / Other ☐
Patients	Different disease ☐ / stage ☐ / pretreatment schedule ☐/ age ☐ Subgroups available?
Outcomes	No clinically relevant outcomes assessed ☐ No data for relevant subgroup extractable ☐
Other	Duplicate publication ☐ / Other
NONE	Included

CURRENT STATUS: *(NAME OF REVIEWER + DATE)*
Question to clinician
Question to author **Status verified with study investigators or sponsors: Yes** ☐ / **No** ☐ Enter name of the source (e.g. PI, sponsor, etc.) _____
Contact address:

STUDY INTERVENTION BASICS	
Disease(s)/stage(s) studied	
Category of treatment investigated	First line therapy ☐ / Consolidation therapy ☐ Salvage therapy ☐ Other:
Inclusion criteria	
Exclusion criteria	Specials:
Experimental Intervention	*If more than two, please specify/add further rows*
Intervention Control	
Type of control	Active ☐ / Placebo ☐ / Active + placebo ☐ / No therapy ☐
Additional treatment	Balanced between treatment arms? Y / N
Compliance	Evaluated? Y / N
Planed treatment in case of failure/as long-term treatment?	
Outcomes assessed	☐ Infection related mortality ☐ Infection incidence ☐ Neutropenia incidence ☐ Neutropenia duration ☐ Treatment-related mortality ☐ Response ☐ Overall survival ☐ Event-free survival ☐ Progression-free survival ☐ Adverse events ☐ Quality of life ☐ Other (please specify)
Treatment arms comparable?	Significant differences between arms:
Subgroup evaluated	*(extractable data for these subgroups)*
Confounders	*(were confounders mentioned? A priori / a posteriori? Which? Multivariate analysis?)*

TRIAL CHARACTERISTICS	
Sample size	Randomised ☐ / recruited ☐
Number of excluded patients	
Recruitment method	☐ consecutive inclusion
Setting	in-patient ☐ / out-patient ☐/ unclear ☐ / NR ☐
Location of trial	
Dates of Recruitment	
Trial Design	Phase _____ Parallel ☐ / cross-over ☐ / Factorial ☐ Single center ☐ / Multicenter trial: international ☐ / national ☐ / # centers:__ Equivalence/Non-inferiority ☐ Multi-arm study: Yes ☐ / No ☐ If yes:, how many? _____
Length of follow-up	From _____ till _____ Median (range): Mean:
Funding	Industry ☐ / Public ☐ / mixed ☐ (industry supported: drug ☐/ data management ☐/ travel ☐ / salary ☐/ other ☐ unclear ☐ / NR ☐
Conflict of interest statement	Yes ☐ / No ☐ / NR ☐
Number of groups	
Flow diagram?	
Method of randomisation	Central ☐ Methods NR ☐ / Minimization ☐ / Inadequate ☐ *(e.g. date of birth, visit)* Stratified by _____
Method of concealment of allocation	Adequate ☐ (please specify): Done +unclear ☐ / Not done ☐ / inadequate ☐ *(e.g. differently coloured envelopes)*
Blinding	Single ☐ / double ☐ / triple ☐ …/ not possible ☐ *(1: patient only; 2: + physician; 3: + outcome-assessor)*
Primary study aims	NR ☐ *(if not reported, leave out primary and fill in secondary study aims)*
Secondary study aims	NR ☐

Outcomes	Statistically significant for primary end-point: Yes ☐ / No ☐ / Enter p-value: _____ Statistically significant for secondary end-point: Yes ☐ / No ☐ / Enter p-value: _____ If outcome was NOT statistically significant is it because due to ☐ Evidence of absence of treatment effect (true negative study) (i.e. clearly defined based on primary outcomes in the trial), or ☐ No evidence for absence of treatment effect (i.e. inconclusive, or low-powered study) (i.e. not clearly defined or not based on primary outcomes in the trial) ☐ Unclear
Power calculation?	No ☐ / Yes ☐ (expected effect: _____) Expected difference on primary outcome: Yes ☐ / No ☐ Enter Value:_____ Alpha (α) pre-specified: Yes ☐ / No ☐ Enter value:_____ Beta error (β) pre-specified: Yes ☐ / No ☐ Enter value:_____ Calculated sample size: Yes ☐ / No ☐ Enter value:_____ Sample Size achieved? Yes ☐ / No ☐
Statistical methods	
Analysis (+ definition)	☐ ITT ☐ as treated ☐ per protocol ☐ unclear Definition: ☐ available and acceptable ☐ not available Different endpoints with different analysis? Please specifiy
Stopping rules	
Drop outs stated	No ☐ / Yes ☐

BASELINE CHARACTERISTICS OF PATIENTS				
	Experimental Arm	**Control Arm**	Others	Notes;p-values
Overall comment	No significant differences			Reports how to transform units, all ± values = means
Number of patients				
Age	--	--		
mean/±	±	±		
median/±	±	±		
Ethnicity No. %	NR	NR		
Gender No. %	Male: Female:	Male: Female:		

Diagnosis				
Definition of Diagnosis				
Extent of disease				
Organ involvement				
Additional diagnoses in group				
Stage				
Staging system				
Status of patients at Rdx	*e.g. untreated*			
Previous treatment				
Concurrent conditions				
Considered as high risk patients				
Considered as low risk patients				
Laboratory parameter (UNITS)	--	--		
Cytogenetics				
Performance status				

BASELINE CHARACTERIZATION OF PATIENTS (continued)			
Source	Often, the patients’ characteristics are summarised in a table – to very different extent in different studies. Instead of extracting every single figure, it might be useful only to extract the type and the number of baseline characteristics that have been evaluated and if there were differences between groups. If you want to use the figures for the formation of subgroups, however, it is advisable to extract them and to let them be checked for accuracy!		
Information	**Evaluated**	**Statistically significant differences between groups**	**Notes**
Important prognostic factor A			
Info 1			

Info 2				

Treatment Details according to STUDY PROTOCOL (as planned)				
	Experimental Arm	**Control Arm**	Others	Notes;
Primary intervention (Medication, dosage, administration)	*The form can be adapted to list expected medication and or schedules in order to reduce the amount of necessary writing.*			
Timing of treatment				
Duration of treatment (days, cycles)				
Important treatment information	*e.g. bone marrow or peripheral blood stem cells*			
Treatment specials				
Supportive treatment				

Patient flow according to PUBLICATION (as it really happened)				
	Experimental Arm	**Control Arm**	Others	Notes; p-values
No. of patients screened				
No. of patients recruited				
No. of patients allocated				
No. of patients evaluated				
No. of patients receiving planned treatment				
Reasons for not receiving treatment				
No. of drop-outs				
Reasons for drop-outs				

No. of protocol-violations				
Type and percentage of salvage / unplanned treatment				

OUTCOMES

The following tables have to be copied as many times as there are outcomes assessed.

OUTCOME	
Outcome	Primary ☐ Secondary ☐ not defined ☐
Definition of outcome *(Check definitions carefully and compare to definitions of outcome you have specified in your protocol for the meta-analysis)*	
Timing of assessment	
Statistics	
Length of follow-up	
No. of patients evaluated for this outcome	All randomised ☐ Unclear ☐ Less ☐ [%]
Reasons for drop-out	NR
Reasons for exclusion	NR
Source of information	

Dichotomous data

Outcome	Time	Intervention group		Control Arm		Notes
		Observed events	Sample size	Observed events	Sample size	
Source	☐ **text, p _____** ☐ **figure No. ____,** ☐ **table No. ____**					

Expert statistical attention needed? ☐ Y / ☐ N

Continuous data

Outcome	Time	Intervention group			Experimental Arm			Notes, p
		Sample size	Mean/ mean change (incl. Range)	Standard Deviation	Sample size	Mean /mean change (incl. Range)	Standard Deviation	

Notes								
Source	☐ text, p _____ ☐ figure No. ____, ☐ table No. ____							

Survival probabilities

Out-come	Time	Patients at risk	Intervention group (incl. CI)	Patients at risk	Control Arm	Notes P value
			Rate [%] of patients alive / SE / Sample size/ %CI		Rate [%] of patients alive / SE / Sample size/ %CI	
OS						
PFS						
Notes						
Source	☐ text, p _____ ☐ figure No. ____, ☐ table No. ____					

Median / Mean duration of survival

	Patients at risk	Intervention group Duration (months/years)	Patients at risk	Control Arm Duration (months/years)	Notes P value
OS					
PFS					
Notes					
Source	☐ text, p _____ ☐ figure No. ____, ☐ table No. ____				

Calculation of Hazard ratio for e.g. Death (table derived from [i] and [ii])				
	Arm 1 (CSF)	**Arm 2 (Control)**	**Arm 3**	**Arm 4**
Randomization ratio				
Patients randomised				
Patients analysed				
Observed Deaths				
Logrank expected events				
HR (CI 95% or standard error or variance from Cox)				
Logrank variance				
Logrank O-E				
test statistik (& test used, 1 or 2 sided?)				
Advantage to control or research?				
Kaplan-Meier curves or Actuarial curves?				
Numbers at risk reported?				
Follow up details				

Estimates for Death:

HR
Lower 95% CI
Upper 95% CI
ln(HR)
se(ln(HR))
Variance
O-E

Definition of death:

METHODOLOGICAL QUALITY - OVERVIEW						
REF ID		Reviewer, Date		Checked by		
Author, Year						
Journal/Source				Study ID	NR /	
Publication type	Fulltext / Abstract / Other (please specify)					
	yes	**unclear**	**no**	**Comments**		
Randomization						
Treatment allocation						
Similarity of groups						
Implementation of blinding						
Transparent patient flow?						
Completeness of trial						
ITT (less than 15% loss)				Loss to follow up symmetric in both arms?		
Different drop-out rates for different endpoints?						
Treatment preference (see below)						
Type of primary end-point	☐ Hard ☐ Soft					
Summarized validity:	Low risk of bias		Moderate risk of bias	High risk of bias		
Remarks:						

Randomization: ***Yes***: random numbers, etc. - ***No***: patient number, day of week, etc. ***Unclear***: method not stated

Allocation concealment: ***Yes***: central, ***No***: alternate, etc. ***Unclear***: not stated

Similarity of groups: Were the participant characteristics at baseline similar in both groups regarding the most important prognostic factors?

Blinding: Was the treatment allocation masked at the outcome assessments/to data managers?

Transparency: Were withdrawals, drop-outs and patients lost to follow-up stated for each group? (Yes if there were no drop-outs, withdrawals etc.)

Completeness: If transparent, drop-out rate per study < 15%?), if asymmetric, please specify in comments

ITT: Did the analysis include an ITT analysis and were there less than 10% of patients excluded in each group? Comment if appropriate definition of ITT

Treament preference: **1** standard treatment highly preferred - **2** standard preferred to innovation
3 about equal, innovation a disappointment - **4** about equal, innovation a success
5 innovation preferred to standard – **6** experimental treatment highly preferred

Type of endpoint: hard e.g. mortality, survival

---

[i] Parmar MK, Torri V, Stewart L. Extracting summary statistics to perform meta-analyses of the published literature for survival endpoints. Stat Med 1998; 17(24):2815-2834.

[ii] Tierney JF, Stewart LA, Ghersi D, Burdett S, Sydes MR. Practical methods for incorporating summary time-to-event data into meta-analysis. Trials 2007; 8:16.