HTA CG | MEMBER STATE COORDINATION GROUP ON HEALTH TECHNOLOGY ASSESSMENT

Annex 1 to Guidance on filling in the JCA dossier template – Medicinal products
Table template collection

V1.0

8 October 2024

Adopted on 28 November 2024 by the HTA CG pursuant to Article 3(7), point (d), of Regulation (EU) 2021/2282 on Health Technology Assessment

This collection of empty tables is a supplement to the guidance on filling in the joint clinical assessment (JCA) dossier template to provide further details and to support data presentation. Please select the appropriate tables taking into account the type of information, study or data to be presented. Tables may be adapted according to the specific requirements of the data and analyses to be presented.

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1 Results

1.1 Results from the information retrieval process

Table 1: Studies performed or sponsored by the HTD in the therapeutic indication for which the dossier is prepared

Study reference/ID	**Study for marketing authorization of the medicinal product under assessment**	**Study status**	**Study duration** **Data cut-off, if applicable**	**Study arms**
<Study A>	*yes / no*	*(completed / terminated / ongoing* (incl. expected completion date)*)*	*X months, MM/YYYY*	*Intervention A, intervention B, placebo*
footnotes (delete this row, if it is not needed)				
abbreviations (delete this row, if it is not needed)				

Table 2: Studies performed or sponsored by the HTD in the therapeutic indication for which the dossier is prepared and which are excluded

Study reference/ID	**Reasons for study exclusion**
footnotes (delete this row, if it is not needed)	
abbreviations (delete this row, if it is not needed)	

Table 3: <PRISMA flow chart to be included>

Table 4: Relevant studies from the search in bibliographic databases

Study reference/ID	**Reference**
footnotes (delete this row, if it is not needed)	
abbreviations (delete this row, if it is not needed)	

Table 5: Relevant studies from the search in study registries

Study reference/ID	**Identification locations (Name of the study registry and references[a])**	**Study included in the study list of the HTD (yes/no)**	**Study identified based on search in bibliographic databases (yes/no)**	**Status (completed/ discontinued/ ongoing**
<Study 1>	*NCT 12345 [6, 7]* *EudraCT 1223456 [8, 9]*	*yes*	*no*	*completed*
a: reference of the study registry entry, number (NCT-Number, EudraCT-Number) and, if available, reference of the reports on study design and/or results listed in the study registry				
HTD: health technology developer				

Table 6: Studies from searches in study registries that are not included in the submission dossier

Study reference/ID	**Reasons for study exclusion**
footnotes (delete this row, if it is not needed)	
abbreviations (delete this row, if it is not needed)	

Table 7: HTA reports on the medicinal product subject to the JCA in the indication under assessment

HTA report title	**Country affiliation**	***Reference***
<Report 1>	*<specify>*	*<specify>*
<Report 2>		
footnotes (delete this row, if it is not needed		
abbreviations (delete this row, if it is not needed		

Table 8: Studies from submission files to the EMA

Studies included in the JCA	**Applicable PICO question**
<Study 1 ID>	PICO <X>
<Study 2 ID>	
Studies not included in the JCA	**Reasons for study exclusion**
<Study 3 ID>	*<specify>*
<Study 4 ID>	
footnotes (delete this row, if it is not needed	
abbreviations (delete this row, if it is not needed	

Table 9: Included studies – list of relevant studies by PICO question

Study reference/ID **Study type** **Study interventions**	**Study for marketing authorization***	**Sponsored[a] or third-party study of the medicinal product under assessment**	**Available documentation in the submission dossier**
PICO 1			
Studies providing direct evidence [Intervention] vs. [Comparator]			
Study ID (Acronym[b]) *e.g., RCT / cohort study* Study intervention vs. Comparator	yes/no	sponsored / not sponsored	▪ CSR: [ref] ▪ Registry entry[c]: [ref] ▪ Publication or other reference: [ref]
Study ID (Acronym[b]) *e.g., RCT / cohort study* Study intervention vs. Comparator	yes/no	sponsored / not sponsored	▪ CSR: [ref] ▪ Registry entry[c]: [ref] ▪ Publication or other reference: [ref]
etc.			▪
PICO x			
Studies providing indirect evidence [Intervention] vs. [Comparator]			
Study ID (Acronym[b]) *e.g., RCT / cohort study* Study intervention vs. Comparator	yes/no	sponsored / not sponsored	▪ CSR: [ref] ▪ Registry entry[c]: [ref] ▪ Publication or other reference: [ref]
etc.			▪
* if yes, please provide information such as date and commission implementing decision in footnote a: study sponsored by the HTD or in which the HTD participated financially in some other way b: in the following tables, the study is referred to with this abbreviated form c: study registry entry, number (NCT-Number, EudraCT-Number)			
CSR: clinical study report; HTD: health technology developer; RCT: randomised controlled trial			

1.2 Characterisation of included studies

Table 10: Characteristics of the included studies

Study reference/ID	**Study type and design**	**Study population**	**Study arms (number of randomised/ included patients)**	**Study duration, data cut off(s) and locations**	**Study endpoints**
<Study 1>	*RCT, blind/ open, parallel/ cross-over, etc.*	*Relevant characteristics, e.g. degree of severity including respective key inclusion/ exclusion criteria in footnotes*	*Group 1 (N = XX)* *Group 2 (N = XX)* *Group 3 (N = XX)*	▪ *Study duration: (e.g., time from first-patient-in to last-patient-out).* ▪ *Completion date (estimated, if study is ongoing): XX XX 20XX* ▪ *1. Data cut-off: XX XX 20XX (planned interim analysis)* ▪ *2. Data cut-off: XX XX 20XX (requested by EMA; not planned)* *(if complex can be described in separate paragraph)* ▪ Number of centres by continent	*Primary:* *Key secondary[a]:* *Other[b]:* *(if complex can be described in separate paragraph)*
<Study 2>				▪	
a: only secondary endpoints controlled for multiplicity b: only if included in at least one PICO					
N: number of included patients; RCT: randomised controlled trial					

Table 11: Characterisation of the interventions of included studies

Study reference/ID	**Study intervention**	**Study comparator**
Study XXX	*e.g. 250 µg, 1* *Inhalation bid* *+* *Placebo 2* *Inhalations bid*	*e.g. 200 µg, 2* *Inhalations bid* *+* *Placebo 1* *Inhalation bid*
	<Additional content of treatment characteristics, if applicable i.e. pre-treatment, treatment during the run-in phase, concomitant/prohibited therapies, follow-up treatment after progression etc.>	
footnotes (delete this row, if it is not needed)		
abbreviations (delete this row, if it is not needed)		

Table 12: Subsequent therapy after withdrawal of the study medication; (specifically in oncology studies: information about the first subsequent therapy)

Study reference/ID	**Subsequent therapy**	**Patients with follow-up therapy n (%)**	
		Study intervention **N =**	**Study comparator** **N =**
Study XXX	*Total* *Therapy a* *Therapy b*	n (%) n (%) n (%)	n (%) n (%) n (%)
		<Additional content of treatment characteristics>	
footnotes (delete this row, if it is not needed)			
N: number of randomised patients; n: number of patients in the category			

1.3 Information on the course of included studies

1.3.1 For direct comparisons

Table 13: Information on the course of included studies – planned follow up times

Study reference/ID **Outcome**	**Planned follow-up**
<Study 1>	
<Outcome 1>	<Until disease progression/x days after end of treatment, …>
<Outcome 2>	
<Study 2>	
<Outcome 1>	
<Outcome 2>	
footnotes: (delete this row, if it is not needed)	
abbreviations: (delete this row, if it is not needed)	

1.3.2 For indirect comparisons

Table 14: Information on the course of included studies – planned follow up times

Comparison **Study reference/ID** **Outcome**	**Planned follow-up**
Intervention vs. (Common) comparator	
<Study 1>	
<Outcome 1>	<Until disease progression/x days after end of treatment, …>
<Outcome 2>	
<Study 2>	
<Outcome 1>	
<Outcome 2>	
PICO comparator vs. (Common) comparator	
<Study 3>	
<Outcome 1>	<Until disease progression/x days after end of treatment, …>
<Outcome 2>	
<Study 4>	
<Outcome 1>	
<Outcome 2>	
footnotes: (delete this row, if it is not needed)	
abbreviations: (delete this row, if it is not needed)	

1.4 Study results on relative effectiveness and relative safety

Table 15: Studies included in the assessment of patient population <X> per PICO question

Study reference/ID **Relevant study arms (number of randomised/included patients)**	**Analysed population** **(number of randomised/included patients)**
PICO <X>	
<Type of comparison (e.g., direct, indirect)>: <XXX> vs. <YYY>	
<Study x> <Group 1> (N = XX) <Group 2> (N = XX)	<Characteristics x/y/z (if applicable)> Complete study population / relevant subpopulation[a]: <Group 1> (n = XX) <Group 2> (n = XX)
<Study x> <Group 1> (N = XX) <Group 2> (N = XX)	Complete study population

Study reference/ID **Relevant study arms (number of randomised/included patients)**	**Analysed population** **(number of randomised/included patients)**
<Study x> <Group 1> (N = XX) <Group 2> (N = XX)	<Characteristics x/y/z> Relevant subpopulation[a]: <Group 1> (n = XX) <Group 2> (n = XX)
PICO <X>	
<Type of comparison>: <XXX> vs. <YYY>	
<Study x> *<Group 1> (N = XX)* *<Group 2> (N = XX)*	<Characteristics x/y/z (if applicable)> Complete study population/relevant subpopulation[a]: <Group 1> (n = XX) <Group 2> (n = XX)
<Study 1> *<Group 1> (N = XX)* *<Group 2> (N = XX)*	Complete study population
<Study 2> *<Group 1> (N = XX)* *<Group 2> (N = XX)*	<Characteristics x/y/z> Relevant subpopulation[a]: <Group 1> (n = XX) <Group 2> (n = XX)
a: In the case that a subpopulation of the study is analysed for the assessment, specify the number of included patients and describe the characteristics of the relevant subpopulation.	
N: number of randomised patients; n: number of patients	

1.4.1 Patient characteristics

1.4.1.1 Table version for RCTs

Table 16: Patient baseline characteristics including treatment/study discontinuations for population <x> (Table for direct comparisons)

Study reference/ID **Characteristics** **Category**	**<Intervention>** **N =**	**<Comparator>** **N =**
<Study 1>		
Age [years], mean (SD)		
Sex [f/m], %		
<More characteristics>, n (%)		
<Category 1>		
<Category 2>		

Study reference/ID **Characteristics** **Category**	**<Intervention>** **N =**	**<Comparator>** **N =**
<Category 3>		
…		
Treatment discontinuation, n (%)		
Study discontinuation, n (%)		
<Study 2>		
…		
footnotes (delete this row, if it is not needed)		
f: female; m: male; N: number of randomised patients; n: number of patients in the category; ND: no data; RCT: randomised controlled trial; SD: standard deviation		

Table 17: Patient baseline characteristics including treatment/study discontinuations for population <x> (Table for indirect comparisons)

Characteristics **Category**	**<Intervention> vs. <Common comparator>**		**<PICO comparator> vs. <Common comparator>**	
	<Study 1>		**<Study 2>**	
	<Intervention>	**<Common comparator>**	**<PICO comparator>**	**<Common comparator>**
	N =	**N =**	**N =**	**N =**
Age [years], mean (SD)				
Sex [f/m], %				
<More characteristics>, n (%)				
<Category 1>				
<Category 2>				
<Category 3>				
…				
Treatment discontinuation, n (%)				
Study discontinuation, n (%)				
footnotes (delete this row, if it is not needed)				
f: female; m: male; N: number of randomised patients; n: number of patients in the category; ND: no data; RCT: randomised controlled trial; SD: standard deviation				

1.4.1.2 Table version for study types other than RCTs

Table 18: Patient baseline characteristics including treatment/study discontinuations for population <x>

Study reference / ID **Characteristics** **Category**	**<Intervention>** **N =**	**<Comparator>** **N =**	**Standardized difference**
<Study 1>			
Age [years], mean (SD)			
Sex [f / m], %			
<More characteristics>, n (%)			
<Category 1>			
<Category 2>			
<Category 3>			
…			
Treatment discontinuation, n (%)			
Study discontinuation, n (%)			
<Study 2>			
…			
footnotes (delete this row, if it is not needed)			
f: female; m: male; N: number of randomised patients; n: number of patients in the category; ND: no data; RCT: randomised controlled trial; SD: standard deviation			

1.4.2 Outcomes

1.4.2.1 For direct comparisons

Table 19: Matrix of outcomes in the included RCTs for PICO <x-1> – direct comparison: <Intervention> vs. <PICO comparator>

Outcomes	**Study reference/ID**		
	<Study 1>	**<Study 2>**	**<Study 3>**
<Outcome 1>, <OMI if applicable>	*<yes/no>*	*<yes/no>*	*<yes/no>*
<Outcome 2>, <OMI if applicable>			
<Outcome 3>, <OMI if applicable>			
<Outcome 4>, <OMI if applicable>			
footnotes (delete this row, if it is not needed)			
OMI: Outcome Measurement Instrument			

Table 20: Information on the course of included studies – actual treatment duration and observation periods

Study reference/ID **Outcome category**	**Study intervention**	**Relevant comparator**
<Study 1>	**<Study intervention>** **N = / n[a] =**	**<Relevant comparator>** **N = / n[a] =**
Treatment duration [<months/weeks>]		
Median [Min; Max]		
Mean (SD)		
Observation period [<months/weeks>]		
<Outcome>		
Median [Min; Max]		
Mean (SD)		
<Outcome>		
Median [Min; Max]		
Mean (SD)		
<Study 2>	**<Study intervention>** **N = / n[a] =**	**<Relevant comparator>** **N = / n[a] =**
Treatment duration [<month/weeks>]		
Median [Min; Max]		
Mean (SD)		
Observation period [<months/weeks>]		
<Outcome>		
Median [Min; Max]		
Mean (SD)		
<Outcome>		
Median [Min; Max]		
Mean (SD)		
a: if applicable: relevant subpopulation (<specify>)		
abbreviations: (delete this row, if it is not needed)		

1.4.2.1.1 Effectiveness outcomes

Table 21: Relative effectiveness results (dichotomous outcomes) – direct comparison: <Intervention> vs. <Comparator>

Time point **Outcome** **Study reference/ID**	**<Intervention>**		**<Comparator>**		**<Intervention> vs. <Comparator>**			
	N	**Patients with event n (%)**	**N**	**Patients with event n (%)**	**[e.g. RR] [95 %-CI] p-value**	**Hypothesis testing**	**RD [95 %-CI] p-value**	**Hypothesis testing**
<Time point>								
<Outcome 1>								
<Study XXX>						1: <x> - 2: <x> - 3: <x>		
<Study XXX>								
Total[a] (p_H = <XXX>; I^2 = <YYY>)								
<Outcome 2>								
<Study XXX>								
<Study XXX>								
Total[a] (p_H = <XXX>; I^2 = <YYY>)								
Reading the "Hypothesis testing" columns: 1: Statistical significance: S = Statistically significant against the alpha level specified in the statistical analysis plan of the corresponding study or protocol for evidence synthesis NS = Non-significant, NO = Nominal p-value 2: Prespecification: P = Statistical test was prespecified according to the statistical analysis plan of the corresponding study, NP = Not prespecified 3: Multiple hypothesis testing. C = Appropriate control for multiplicity according to the statistical analysis plan and clinical study report of the corresponding study, NC = Not controlled								
a: calculated from meta-analysis								
CI: confidence interval; N: number of patients in the analysis; NI: no information; p_H: p-value from test for heterogeneity <specify>; RD: risk difference; RR: relative risk								

Table 22: Relative effectiveness results (time to event outcomes) – direct comparison: <Intervention> vs. <Comparator>

Time point **Outcome** **Study reference/ID**	**<Intervention>**		**<Comparator>**		**<Intervention> vs. <Comparator>**			
	N/ N^{Cen}	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**N/ N^{Cen}**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**HR [95 %-CI]** **p-value**	**Hypothesis testing**	**<add appropriate absolute difference>** **p-value**	**Hypothesis testing**
<Time point>								
<Outcome 1>								
<Study XXX>						1: <x> - 2: <x> - 3: <x>		1: <x> - 2: <x> - 3: <x>
<Study XXX>						1: <x> - 2: <x> - 3: <x>		1: <x> - 2: <x> - 3: <x>
Total[a] (p_H = <XXX>; I^2 = <YYY>)						1: <x> - 2: <x> - 3: <x>		1: <x> - 2: <x> - 3: <x>
<Outcome 2>								
<Study XXX>								
<Study XXX>								
Total[a] (p_H = <XXX>; I^2 = <YYY>)								

Reading the "Hypothesis testing" columns:
1. Statistical significance: S = Statistically significant against the alpha level specified in the statistical analysis plan of the corresponding study, NS = Non-significant, NO = Nominal p-value
2. Prespecification: P = Statistical test was prespecified according to the statistical analysis plan of the corresponding study, NP = Not prespecified
3. Multiple hypothesis testing. C = Appropriate control for multiplicity according to the statistical analysis plan and clinical study report of the corresponding study, NC = Not controlled

a: calculated from meta-analysis

CI: confidence interval; HR: hazard ratio; N: number of patients in the analysis; N^{Cen}: number of censored patients; NI: no information; p_H: p-value from test for heterogeneity <specify>

Table 23: Relative effectiveness results (continuous outcomes) – direct comparison: <Intervention> vs. <Comparator>

Time point **Outcome** **Study reference/ID**	**<Intervention>**			**<Comparator>**			**<Intervention> vs. <Comparator>**	
	N	**Values at baseline mean (SD)**	**Change/values at <time> mean (SD)**	**N**	**Values at baseline mean (SD)**	**Change/values at <time> mean (SD)**	**<Effect> [95 %-CI] p-value**	**Hypothesis testing**
<Time point>								
<Outcome 1>								
<Study XXX>								1: <x> - 2: <x> - 3: <x>
<Study XXX>								1: <x> - 2: <x> - 3: <x>
Total[a] (p_H = <XXX>; I^2 = <YYY>)								1: <x> - 2: <x> - 3: <x>
<Outcome 2>								
<Study XXX>								
<Study XXX>								
Total[a] (p_H = <XXX>; I^2 = <YYY>)								

Reading the "Hypothesis testing" columns:
1. Statistical significance: S = Statistically significant against the alpha level specified in the statistical analysis plan of the corresponding study, NS = Non-significant, NO = Nominal p-value
2. Prespecification: P = Statistical test was prespecified according to the statistical analysis plan of the corresponding study, NP = Not prespecified
3. Multiple hypothesis testing. C = Appropriate control for multiplicity according to the statistical analysis plan and clinical study report of the corresponding study, NC = Not controlled

a: calculated from meta-analysis

CI: confidence interval; N: number of patients in the analysis; NI: no information; p_H: p-value from test for heterogeneity <specify>; SD: standard deviation

1.4.2.1.2 Safety outcomes

Please note: In the main part of the dossier, the tables should only be descriptive including numbers and percentages of patients with events, but not effect estimates (see below). Tables with relative effects for adverse events should be provided in an appendix of the dossier. Furthermore, tables including adverse events by SOC and PT should only be provided in an appendix of the dossier (please see section on appendix tables).

Table 24: Safety outcomes (dichotomous outcomes) – direct comparison: <Intervention> vs. <Comparator>

Time point	**<Intervention>**		**<Comparator>**	
Outcome **Study reference/ID**	**N**	**Patients with event n (%)**	**N**	**Patients with event n (%)**
<Time point>				
At least one AE				
<Study XXX>				
<Study XXX>				
Serious AE				
<Study XXX>				
<Study XXX>				
Severe AE [insert scale used]				
<Study XXX>				
Grade ≥ 3				
Grade 3				
Grade 4				
Grade 5				
<Study XXX>				
Grade ≥ 3				
Grade 3				
Grade 4				
Grade 5				
Death related to AE				
<Study XXX>				
<Study XXX>				
Treatment discontinuation due to AE				
<Study XXX>				
<Study XXX>				
Treatment interruption due to AE				
<Study XXX>				
<Study XXX>				

Time point	**<Intervention>**		**<Comparator>**	
Outcome **Study reference/ID**	**N**	**Patients with event n (%)**	**N**	**Patients with event n (%)**
Specific AE A[a]				
<Study XXX>				
<Study XXX>				
Specific AE B[a]				
<Study XXX>				
<Study XXX>				
a: As requested by member state(s) in their PICOs				
AE: adverse event; N: number of patients in the analysis; n: number of patients with event; PICO: Population – Intervention – Comparator – Outcome				

Table 25: Safety outcomes (time to event outcomes) – direct comparison: <Intervention> vs. <Comparator>

Time point	**<Intervention>**		**<Comparator>**	
Outcome **Study reference/ID**	**N/ N^{Cen}**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**N/ N^{Cen}**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**
<Time point>				
At least one AE				
<Study XXX>				
<Study XXX>				
Serious AE				
<Study XXX>				
<Study XXX>				
Severe AE [insert used scale]				
<Study XXX>				
Grade ≥ 3				
Grade 3				
Grade 4				
Grade 5				
<Study XXX>				
Grade ≥ 3				
Grade 3				
Grade 4				
Grade 5				
Death related to AE				
<Study XXX>				

Time point	**<Intervention>**		**<Comparator>**	
Outcome **Study reference/ID**	**N/ N^{Cen}**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**N/ N^{Cen}**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**
<Study XXX>				
Treatment discontinuation due to AE <Study XXX> <Study XXX>				
Treatment interruption due to AE <Study XXX> <Study XXX>				
Specific AE A[a] <Study XXX> <Study XXX>				
Specific AE B[a] <Study XXX> <Study XXX>				
a: As requested by member state(s) in their PICOs				
AE: adverse event; N: number of patients in the analysis; N^{Cen}: number of censored patients; n: number of patients with event; PICO: Population – Intervention – Comparator – Outcome				

1.4.2.1.3 Subgroup analyses

Table 26: Subgroup analyses (dichotomous outcomes) – direct comparison: <Intervention> vs. <Comparator>

Time point **Outcome** **Variable** **Study reference/ID** **Subgroups**	**<Intervention>**		**<Comparator>**		**<Intervention> vs. <Comparator>**			
	N	**Patients with event n (%)**	**N**	**Patients with events n (%)**	**[e.g. RR] [95 %-CI]** **p-value**	**Hypothesis testing**	**RD [95 %-CI]** **p-value**	**Hypothesis testing**
<Time point>								
<Outcome 1>								
<Variable X>								
<Study XXX>								
<Subgroup 1>						1: <x> - 2: <x> - 3: <x>		1: <x> - 2: <x> - 3: <x>
<Subgroup 2>								
Per study					Interaction[b]:		Interaction[b]:	
<Study XXX>								
<Subgroup 1>								
<Subgroup 2>								
Per study					Interaction[b]:		Interaction[b]:	
Total[a] (p_H = <XXX>; I^2 = <YYY>)					Interaction[b]:		Interaction[b]:	
<Subgroup 1>								
<Subgroup 2>								
<Outcome 2>								
<to be displayed as above>								

Time point	**<Intervention>**		**<Comparator>**		**<Intervention> vs. <Comparator>**			
Outcome **Variable** **Study reference/ID** **Subgroups**	**N**	**Patients with event n (%)**	**N**	**Patients with events n (%)**	**[e.g. RR] [95 %-CI] p-value**	**Hypothesis testing**	**RD [95 %-CI] p-value**	**Hypothesis testing**
Reading the "Hypothesis testing" columns: 1. Statistical significance: S = Statistically significant against the alpha level specified in the statistical analysis plan of the corresponding study, NS = Non-significant, NO = Nominal p-value 2. Prespecification: P = Statistical test was prespecified according to the statistical analysis plan of the corresponding study, NP = Not prespecified 3. Multiple hypothesis testing. C = Appropriate control for multiplicity according to the statistical analysis plan and clinical study report of the corresponding study, NC = Not controlled								
a: calculated from meta-analysis b: <specify>								
CI: confidence interval; N: number of patients in the analysis; NI: no information; p_H: p-value from test for heterogeneity <specify>; RD: risk difference; RR: relative risk								

Table 27: Subgroup analyses (time to event outcomes) – direct comparison: <Intervention> vs. <Comparator>

Time point	**<Intervention>**		**<Comparator>**		**<Intervention> vs. <Comparator>**			
Outcome **Variable** **Study reference/ID** **Subgroups**	**N/ N^{Cen}**	**Median time to event in <weeks/months> [95 %-CI] patients with event n (%)**	**N/ N^{Cen}**	**Median time to event in <weeks/months> [95 %-CI] patients with event n (%)**	**HR [95 %-CI] p-values**	**Hypothesis testing**	**<add appropriate absolute difference> p-value**	**Hypothesis testing**
<Time point>								
<Outcome 1> <Variable X> <Study XXX> <Subgroup 1>						1: <x> - 2: <x> - 3: <x>		1: <x> - 2: <x> - 3: <x>

Time point **Outcome** **Variable** **Study reference/ID** **Subgroups**	**<Intervention>**		**<Comparator>**		**<Intervention> vs. <Comparator>**			
	N/ N^{Cen}	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**N/ N^{Cen}**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**HR [95 %-CI]** **p-values**	**Hypothesis testing**	**<add appropriate absolute difference>** **p-value**	**Hypothesis testing**
<Subgroup 2>								
Per study					Interaction[b]:		Interaction[b]:	
<Study XXX>								
<Subgroup 1>								
<Subgroup 2>								
Per study								
Total[a] (p_H = <XXX>; I^2 = <YYY>)					Interaction[b]:		Interaction[b]:	
<Subgroup 1>								
<Subgroup 2>								
<Outcome 2>								
<to be displayed as above>								

Reading the "Hypothesis testing" columns:
1. Statistical significance: S = Statistically significant against the alpha level specified in the statistical analysis plan of the corresponding study, NS = Non-significant, NO = Nominal p-value
2. Prespecification: P = Statistical test was prespecified according to the statistical analysis plan of the corresponding study, NP = Not prespecified
3. Multiple hypothesis testing. C = Appropriate control for multiplicity according to the statistical analysis plan and clinical study report of the corresponding study, NC = Not controlled

a: calculated from meta-analysis
b: <specify>

CI: confidence interval; HR: hazard ratio; N: number of patients in the analysis; N^{Cen}: number of censored patients; NI: no information; p_H: p-value from test for heterogeneity <specify>

Table 28: Subgroup analyses (continuous outcomes) – direct comparison: <Intervention> vs. <Comparator>

Time point **Outcome** **Variable** **Study reference/ID** **Subgroups**	**<Intervention>**			**<Comparator>**			**<Intervention> vs. <Comparator>**	
	N	**Values at baseline mean (SD)**	**Change/values at <time> mean (SD)**	**N**	**Values at baseline mean (SD)**	**Change/values at <time> mean (SD)**	**<Effect> [95 %-CI] p-value**	**Hypothesis testing**
<Time point>								
<Outcome 1>								
<Variable X>								
<Study XXX>								
<Subgroup 1>								1: <x> - 2: <x> - 3: <x>
<Subgroup 2>								
Per study							Interaction[b]:	
<Study XXX>								
<Subgroup 1>								
<Subgroup 2>								
Per study							Interaction[b]:	
Total[a] (p_H = <XXX>; I^2 = <YYY>)							Interaction[b]:	
<Subgroup 1>								
<Subgroup 2>								
<Outcome 2>								
<to be displayed as above>								

Time point	**<Intervention>**			**<Comparator>**			**<Intervention> vs. <Comparator>**	
Outcome **Variable** **Study reference/ID** **Subgroups**	**N**	**Values at baseline mean (SD)**	**Change/values at <time> mean (SD)**	**N**	**Values at baseline mean (SD)**	**Change/values at <time> mean (SD)**	**<Effect> [95 %-CI] p-value**	**Hypothesis testing**
Reading the "Hypothesis testing" columns: 1. Statistical significance: S = Statistically significant against the alpha level specified in the statistical analysis plan of the corresponding study, NS = Non-significant, NO = Nominal p-value 2. Prespecification: P = Statistical test was prespecified according to the statistical analysis plan of the corresponding study, NP = Not prespecified 3. Multiple hypothesis testing. C = Appropriate control for multiplicity according to the statistical analysis plan and clinical study report of the corresponding study, NC = Not controlled								
a: calculated from meta-analysis b: <specify>								
CI: confidence interval; N: number of patients in the analysis; NI: no information; p_H: p-value from test for heterogeneity <specify>; SD: standard deviation								

1.4.2.2 For indirect comparisons

Table 29: Matrix of outcomes in the included studies for PICO <x-1> – indirect comparison: <Intervention> vs. <PICO comparator>

Outcomes	**Comparison Study reference/ID**				**Indirect comparison methods**
	<Intervention> vs. <Common comparator>		**<PICO comparator> vs. <Common comparator>**		
	<Study 1>	**<Study 2>**	**<Study 3>**	**<Study 4>**	
<Outcome 1>, <OMI if applicable>	<yes/no>	<yes/no>	<yes/no>	<yes/no>	*e.g. Bucher ITC, NMA, MAIC (anchored/unanchored), N/A*
<Outcome 2>, <OMI if applicable>					
<Outcome 3>, <OMI if applicable>					
<Outcome 4>, <OMI if applicable>					
footnotes (delete this row, if it is not needed)					
OMI: outcome measure instrument (add other abbreviations as required)					

Table 30: Information on the course of included studies – actual treatment duration and observation periods

Comparison **Study reference / ID** **Outcome category**	**Study intervention**	**Relevant comparator**
Intervention vs. (Common) comparator		
<Study 1> Treatment duration [<months/weeks>] Median [Min; Max] Mean (SD)	**<Study intervention>** **N = / n[a] =**	**<Relevant comparator>** **N = / n[a] =**
Observation period [<months/weeks>] <Outcome> Median [Min; Max] Mean (SD) <Outcome> Median [Min; Max] Mean (SD)		
<Study 2> Treatment duration [<month/weeks>]	**<Study intervention>** **N = / n[a] =**	**<Relevant comparator>** **N = / n[a] =**

Comparison **Study reference / ID** **Outcome category**	**Study intervention**	**Relevant comparator**
Median [Min; Max] Mean (SD)		
Observation period [<months/weeks>] <Outcome> Median [Min; Max] Mean (SD) <Outcome> Median [Min; Max] Mean (SD)		
PICO comparator vs. (Common) comparator		
<Study 3> Treatment duration [<month/weeks>] Median [Min; Max] Mean (SD)	**<Study intervention>** **N = / n[a] =**	**<Relevant comparator>** **N = / n[a] =**
Observation period [<months/weeks>] <Outcome> Median [Min; Max] Mean (SD) <Outcome> Median [Min; Max] Mean (SD)		
<Study 4> Treatment duration [<month/weeks>] Median [Min; Max] Mean (SD)	**<Study intervention>** **N = / n[a] =**	**<Relevant comparator>** **N = / n[a] =**
Observation period [<months/weeks>] <Outcome> Median [Min; Max] Mean (SD) <Outcome> Median [Min; Max] Mean (SD)		
a: if applicable: relevant subpopulation (<specify>)		
abbreviations: (delete this row, if it is not needed)		

1.4.2.2.1 Effectiveness outcomes

Table 31: Relative effectiveness results (dichotomous outcomes) – indirect comparison: <Intervention> vs. <Comparator>

Time point **Outcome** **Study reference/ID**	**<Intervention> / <PICO comparator>**		**<(Common) comparator>**		**Group difference**			
	N	**Patients with event n (%)**	**N**	**Patients with events n (%)**	**[e.g. RR] [95 %-CI] p-value**	**Hypothesis testing**	**RD [95 %-CI] p-value**	**Hypothesis testing**
<Time point>								
<Outcome 1>								
<Intervention> vs. <(Common) comparator>								
<Study XXX>						1: <x> - 2: <x> - 3: <x>		1: <x> - 2: <x> - 3: <x>
<Study XXX>						1: <x> - 2: <x> - 3: <x>		1: <x> - 2: <x> - 3: <x>
Total[a] (p_H = <XXX>; I^2 = <YYY>)						1: <x> - 2: <x> - 3: <x>		1: <x> - 2: <x> - 3: <x>
<PICO comparator> vs. <(Common) comparator>								
<Study XXX>						1: <x> - 2: <x> - 3: <x>		1: <x> - 2: <x> - 3: <x>
<Study XXX>						1: <x> - 2: <x> - 3: <x>		1: <x> - 2: <x> - 3: <x>
Total[a] (p_H = <XXX>; I^2 = <YYY>)						1: <x> - 2: <x> - 3: <x>		1: <x> - 2: <x> - 3: <x>
Indirect comparison (<method used (e.g. Bucher, MAIC etc)>):								

Time point **Outcome** **Study reference/ID**	**<Intervention> / <PICO comparator>**		**<(Common) comparator>**		**Group difference**			
	N	**Patients with event n (%)**	**N**	**Patients with events n (%)**	**[e.g. RR] [95 %-CI]** **p-value**	**Hypothesis testing**	**RD [95 %-CI]** **p-value**	**Hypothesis testing**
<Intervention> vs. <PICO comparator>						1: <x> - 2: <x> - 3: <x>		1: <x> - 2: <x> - 3: <x>
<Outcome 2> <to be displayed as above>								
Reading the "Hypothesis testing" columns: 1. Statistical significance: S = Statistically significant against the alpha level specified in the statistical analysis plan of the corresponding study, NS = Non-significant, NO = Nominal p-value 2. Prespecification: P = Statistical test was prespecified according to the statistical analysis plan of the corresponding study, NP = Not prespecified 3. Multiple hypothesis testing. C = Appropriate control for multiplicity according to the statistical analysis plan and clinical study report of the corresponding study, NC = Not controlled								
a: calculated from meta-analysis								
CI: confidence interval; N: number of patients in the analysis; NI: no information; p_H: p-value from test for heterogeneity <specify>; RD: risk difference; RR: relative risk								

Table 32: Relative effectiveness results (time to event outcomes) – indirect comparison: <Intervention> vs. <Comparator>

Time point **Outcome** **Study reference/ID**	**<Intervention> / <PICO comparator>**		**<(Common) comparator>**		**Group difference**			
	N/ N^{Cen}	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**N/ N^{Cen}**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**HR [95 %-CI]** **p-value**	**Hypothesis testing**	**<add appropriate absolute difference>** **p-value**	**Hypothesis testing**
<Time point>								
<Outcome 1>								

Time point **Outcome**	**<Intervention> / <PICO comparator>**		**<(Common) comparator>**			**Group difference**		
Study reference/ID	**N/ N^{Cen}**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**N/ N^{Cen}**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**HR [95 %-CI]** **p-value**	**Hypothesis testing**	**<add appropriate absolute difference>** **p-value**	**Hypothesis testing**
<Intervention> vs. <(Common) comparator>								
<Study XXX>						1: <x> - 2: <x> - 3: <x>		1: <x> - 2: <x> - 3: <x>
<Study XXX>						1: <x> - 2: <x> - 3: <x>		1: <x> - 2: <x> - 3: <x>
Total[a] (p_H = <XXX>; I^2 = <YYY>)						1: <x> - 2: <x> - 3: <x>		1: <x> - 2: <x> - 3: <x>
<PICO comparator> vs. <(Common) comparator>								
<Study XXX>						1: <x> - 2: <x> - 3: <x>		1: <x> - 2: <x> - 3: <x>
<Study XXX>						1: <x> - 2: <x> - 3: <x>		1: <x> - 2: <x> - 3: <x>
Total[a] (p_H = <XXX>; I^2 = <YYY>)						1: <x> - 2: <x> - 3: <x>		1: <x> - 2: <x> - 3: <x>
Indirect comparison (<method used (e.g. Bucher, MAIC etc)>):								
<Intervention> vs. <PICO comparator>						1: <x> - 2: <x> - 3: <x>		1: <x> - 2: <x> - 3: <x>
<Outcome 2>								

Time point **Outcome** **Study reference/ID**	**<Intervention> / <PICO comparator>**		**<(Common) comparator>**		**Group difference**			
	N/ N^{Cen}	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**N/ N^{Cen}**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**HR [95 %-CI]** **p-value**	**Hypothesis testing**	**<add appropriate absolute difference>** **p-value**	**Hypothesis testing**
<to be displayed as above>								
Reading the "Hypothesis testing" columns: 1. Statistical significance: S = Statistically significant against the alpha level specified in the statistical analysis plan of the corresponding study, NS = Non-significant, NO = Nominal p-value 2. Prespecification: P = Statistical test was prespecified according to the statistical analysis plan of the corresponding study, NP = Not prespecified 3. Multiple hypothesis testing. C = Appropriate control for multiplicity according to the statistical analysis plan and clinical study report of the corresponding study, NC = Not controlled								
a: calculated from meta-analysis								
CI: confidence interval; HR: hazard ratio; N: number of patients in the analysis; N^{Cen}: number of censored patients; NI: no information; p_H: p-value from test for heterogeneity <specify>; RD: risk difference; RR: relative risk								

Table 33: Relative effectiveness results (continuous outcomes) – indirect comparison: <Intervention> vs. <Comparator>

Time point **Outcome** **Study reference/ID**	**<Intervention> / <PICO comparator>**			**<(Common) comparator>**			**Group difference**	
	N	**Values at baseline mean (SD)**	**Change/values at <time> mean (SD)**	**N**	**Values at baseline mean (SD)**	**Change/values at <time> mean (SD)**	**<Effect> [95 %-CI]** **p-value**	**Hypothesis testing**
<Time point>								
<Outcome 1>								
<Intervention> vs. <(Common) comparator>								

Time point **Outcome** **Study reference/ID**	**<Intervention> / <PICO comparator>**			**<(Common) comparator>**			**Group difference**	
	N	**Values at baseline mean (SD)**	**Change/values at <time> mean (SD)**	**N**	**Values at baseline mean (SD)**	**Change/values at <time> mean (SD)**	**<Effect> [95 %-CI] p-value**	**Hypothesis testing**
<Study XXX>								1: <x> - 2: <x> - 3: <x>
<Study XXX>								
Total[a] (p_H = <XXX>; I^2 = <YYY>)								
<PICO comparator> vs. <(Common) comparator>								
<Study XXX>								1: <x> - 2: <x> - 3: <x>
<Study XXX>								
Total[a] (p_H = <XXX>; I^2 = <YYY>)								
Indirect comparison (<method used (e.g. Bucher, MAIC etc)>):								
<Intervention> vs. <PICO comparator>								1: <x> - 2: <x> - 3: <x>
<Outcome 2>								
<to be displayed as above>								

Time point	**<Intervention> / <PICO comparator>**			**<(Common) comparator>**			**Group difference**	
Outcome **Study reference/ID**	**N**	**Values at baseline mean (SD)**	**Change/values at <time> mean (SD)**	**N**	**Values at baseline mean (SD)**	**Change/values at <time> mean (SD)**	**<Effect> [95 %-CI] p-value**	**Hypothesis testing**
Reading the "Hypothesis testing" columns: 1. Statistical significance: S = Statistically significant against the alpha level specified in the statistical analysis plan of the corresponding study, NS = Non-significant, NO = Nominal p-value 2. Prespecification: P = Statistical test was prespecified according to the statistical analysis plan of the corresponding study, NP = Not prespecified 3. Multiple hypothesis testing. C = Appropriate control for multiplicity according to the statistical analysis plan and clinical study report of the corresponding study, NC = Not controlled								
a: calculated from meta-analysis								
CI: confidence interval; N: number of patients in the analysis; NI: no information; p_H: p-value from test for heterogeneity <specify>; RD: risk difference; RR: relative risk; SD: standard deviation								

1.4.2.2.2 Safety outcomes

Please note: In the main part of the dossier, the tables should only be descriptive including numbers and percentages of patients with events, but not effect estimates. Tables with relative effects for adverse events should be provided in an appendix of the dossier. Furthermore, tables including adverse events by SOC and PT should also only be provided in an appendix of the dossier (please see section on appendix tables).

Table 34: Safety outcomes including effect estimates (dichotomous outcomes) – indirect comparison: <Intervention> vs. <Comparator>

Time point	**<Intervention> / <PICO comparator>**		**<(Common) comparator>**	
Outcome **Study reference/ID**	**N**	**Patients with event n (%)**	**N**	**Patients with event n (%)**
<Time point>				
At least one AE				
<Intervention> vs. <(Common) comparator>				
<Study XXX>				
<Study XXX>				
<PICO comparator> vs. <(Common) comparator>				
<Study XXX>				
<Study XXX>				
Indirect comparison (<method used (e.g. Bucher, MAIC etc)>):				
<Intervention> vs. <PICO comparator>				
Serious AE				
<to be displayed as above>				
Severe AE [insert used scale]				
<to be displayed as above>				
Death related to AE				
<to be displayed as above>				
Treatment discontinuation due to AE				
<to be displayed as above>				
Treatment interruption due to AE				
<to be displayed as above>				
Specific AE A[a]				
<to be displayed as above>				
Specific AE B[a]				

Time point	**<Intervention> / <PICO comparator>**		**<(Common) comparator>**	
Outcome **Study reference/ID**	**N**	**Patients with event n (%)**	**N**	**Patients with event n (%)**
<to be displayed as above>				
a: As requested by member state(s) in their PICOs				
AE: adverse event; N: number of patients in the analysis; n: number of patients with event; PICO: Population – Intervention – Comparator – Outcome				

Table 35: Safety outcomes including effect estimates (time to event outcomes) – indirect comparison: <Intervention> vs. <Comparator>

Time point	**<Intervention> / <PICO comparator>**		**<(Common) comparator>**	
Outcome **Study reference/ID**	**N**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**N**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**
<Time point>				
At least one AE				
<Intervention> vs. <(Common) comparator>				
<Study XXX>				
<Study XXX>				
<PICO comparator> vs. <(Common) comparator>				
<Study XXX>				
<Study XXX>				
Indirect comparison (<method used (e.g. Bucher, MAIC etc)>):				
<Intervention> vs. <PICO comparator>				
Serious AE				
<to be displayed as above>				
Severe AE [insert used scale]				
<to be displayed as above>				
Death related to AE				
<to be displayed as above>				
Treatment discontinuation due to AE				
<to be displayed as above>				
Treatment interruption due to AE				
<to be displayed as above>				

Time point	**<Intervention> / <PICO comparator>**		**<(Common) comparator>**	
Outcome **Study reference/ID**	**N**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**N**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**
Specific AE A[a] <to be displayed as above>				
Specific AE B[a] <to be displayed as above>				
a: As requested by member state(s) in their PICOs				
AE: adverse event; N: number of patients in the analysis; n: number of patients with event; PICO: Population – Intervention – Comparator – Outcome				

1.5 Appendix tables

Adverse events tables including effect estimates and tables of adverse events by SOC and PT

Data presentation of AE by SOC and PT should include the summary measures (all AE, serious AE, severe AE, discontinuation due to AE, interruption due to AE). Analyses estimating RR or time-to-event analyses estimating HR should be provided as appropriate. Below are example tables for the presentation of RR analyses. Tables for the presentation of time-to-event analyses by SOC and PT should be adapted accordingly.

Table 36: Safety outcomes including effect estimates (dichotomous outcomes) – direct comparison: <Intervention> vs. <Comparator>

Time point	**<Intervention>**		**<Comparator>**		**<Intervention> vs. <Comparator>**	
Outcome **Study reference/ID**	**N**	**Patients with event n (%)**	**N**	**Patients with event n (%)**	**RR [95 %-CI]** **p-value**	**RD [95 %-CI]** **p-value**
<Time point>						
At least one AE						
<Study XXX>						
<Study XXX>						
Total[a] (p_H = <XXX>; I^2 = <YYY>)						
Serious AE						
<Study XXX>						
<Study XXX>						
Total[a] (p_H = <XXX>; I^2 = <YYY>)						
Severe AE [insert used scale]						
<Study XXX>						
Grade ≥ 3						
Grade 3						
Grade 4						

Time point **Outcome** **Study reference/ID**	**<Intervention>**		**<Comparator>**		**<Intervention> vs. <Comparator>**	
	N	**Patients with event n (%)**	**N**	**Patients with event n (%)**	**RR [95 %-CI]** **p-value**	**RD [95 %-CI]** **p-value**
Grade 5						
<Study XXX>						
Grade ≥ 3						
Grade 3						
Grade 4						
Grade 5						
Total[a] Grade ≥ 3 (p_H = <XXX>; I^2 = <YYY>)						
Death related to AE						
<Study XXX>						
<Study XXX>						
Total[a] (p_H = <XXX>; I^2 = <YYY>)						
Treatment discontinuation due to AE						
<Study XXX>						
<Study XXX>						
Total[a] (p_H = <XXX>; I^2 = <YYY>)						
Treatment interruption due to AE						
<Study XXX>						
<Study XXX>						
Total[a] (p_H = <XXX>; I^2 = <YYY>)						
Specific AE A[b]						

Time point **Outcome** **Study reference/ID**	**<Intervention>**		**<Comparator>**		**<Intervention> vs. <Comparator>**	
	N	**Patients with event n (%)**	**N**	**Patients with event n (%)**	**RR [95 %-CI]** **p-value**	**RD [95 %-CI]** **p-value**
<Study XXX>						
<Study XXX>						
Total[a] (p_H = <XXX>; I^2 = <YYY>)						
Specific AE B[b]						
<Study XXX>						
<Study XXX>						
Total[a] (p_H = <XXX>; I^2 = <YYY>)						
a: calculated from meta-analysis b: As requested by member state(s) in their PICOs						
AE: adverse event; N: number of patients in the analysis; n: number of patients with event; PICO: Population – Intervention – Comparator – Outcome; RD: risk difference; RR: relative risk; SAE: serious adverse event						

Table 37: Safety outcomes (time to event outcomes) – direct comparison: <Intervention> vs. <Comparator>

Time point **Outcome** **Study reference/ID**	**<Intervention>**		**<Comparator>**		**<Intervention> vs. <Comparator>**	
	N/ N^{Cen}	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**N/N^{Cen}**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**HR [95 %-CI]** **p-value**	**<add appropriate absolute difference>** **p-value**
<Time point>						
At least one AE						
<Study XXX>						
<Study XXX>						

Time point	**<Intervention>**		**<Comparator>**		**<Intervention> vs. <Comparator>**	
Outcome **Study reference/ID**	**N/ N^{Cen}**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**N/N^{Cen}**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**HR [95 %-CI]** **p-value**	**<add appropriate absolute difference>** **p-value**
Total[a] (p_H = <XXX>; I^2 = <YYY>)						
Serious AE						
<Study XXX>						
<Study XXX>						
Total[a] (p_H = <XXX>; I^2 = <YYY>)						
Severe AE [insert used scale]						
<Study XXX>						
Grade ≥ 3						
Grade 3						
Grade 4						
Grade 5						
<Study XXX>						
Grade ≥ 3						
Grade 3						
Grade 4						
Grade 5						
Total[a] Grade ≥ 3 (p_H = <XXX>; I^2 = <YYY>)						
Death related to AE						
<Study XXX>						
<Study XXX>						

Time point	**<Intervention>**		**<Comparator>**		**<Intervention> vs. <Comparator>**	
Outcome **Study reference/ID**	**N/ N^{Cen}**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**N/N^{Cen}**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**HR [95 %-CI]** **p-value**	**<add appropriate absolute difference>** **p-value**
Total[a] (p_H = <XXX>; I^2 = <YYY>)						
Treatment discontinuation due to AE						
<Study XXX>						
<Study XXX>						
Total[a] (p_H = <XXX>; I^2 = <YYY>)						
Treatment interruption due to AE						
<Study XXX>						
<Study XXX>						
Total[a] (p_H = <XXX>; I^2 = <YYY>)						
Specific AE A[b]						
<Study XXX>						
<Study XXX>						
Total[a] (p_H = <XXX>; I^2 = <YYY>)						
Specific AE B[b]						
<Study XXX>						
<Study XXX>						
Total[a] (p_H = <XXX>; I^2 = <YYY>)						

Time point	**<Intervention>**		**<Comparator>**		**<Intervention> vs. <Comparator>**	
Outcome **Study reference/ID**	**N/ N^{Cen}**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**N/N^{Cen}**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**HR [95 %-CI]** **p-value**	**<add appropriate absolute difference>** **p-value**
a: calculated from meta-analysis b: As requested by member state(s) in their PICOs						
AE: adverse event; HR: hazard ratio; N: number of patients in the analysis; N^{Cen}: number of censored patients; n: number of patients with event; PICO: Population – Intervention – Comparator – Outcome; SAE: serious adverse event						

Table 38: Safety outcomes including effect estimates (dichotomous outcomes) – indirect comparison: <Intervention> vs. <Comparator>

Time point	**<Intervention> / <PICO comparator>**		**<(Common) comparator>**		**Group difference**	
Outcome **Study reference/ID**	**N**	**Patients with event n (%)**	**N**	**Patients with event n (%)**	**RR [95 %-CI]**	**RD [95 %-CI]**
<Time point>						
At least one AE						
<Intervention> vs. <(Common) comparator>						
<Study XXX>						
<Study XXX>						
Total[a] (p_H = <XXX>; I^2 = <YYY>)						
<PICO comparator> vs. <(Common) comparator>						
<Study XXX>						
<Study XXX>						
Total[a] (p_H = <XXX>; I^2 = <YYY>)						

Time point	**<Intervention> / <PICO comparator>**		**<(Common) comparator>**		**Group difference**	
Outcome **Study reference/ID**	**N**	**Patients with event n (%)**	**N**	**Patients with event n (%)**	**RR [95 %-CI]**	**RD [95 %-CI]**
Indirect comparison (<method used (e.g. Bucher, MAIC etc)>): <Intervention> vs. <PICO comparator>						
Serious AE <to be displayed as above>						
Severe AE [insert used scale] <to be displayed as above>						
Death related to AE <to be displayed as above>						
Treatment discontinuation due to AE <to be displayed as above>						
Treatment interruption due to AE <to be displayed as above>						
Specific AE A[b] <to be displayed as above>						
Specific AE B[b] <to be displayed as above>						
a: calculated from meta-analysis b: As requested by member state(s) in their PICOs						
AE: adverse event; N: number of patients in the analysis; n: number of patients with event; PICO: Population – Intervention – Comparator – Outcome; RD: risk difference; RR: relative risk; SAE: serious adverse event						

Table 39: Safety outcomes including effect estimates (time to event outcomes) – indirect comparison: <Intervention> vs. <Comparator>

Time point **Outcome** **Study reference/ID**	**<Intervention> / <PICO comparator>**		**<(Common) comparator>**		**Group difference**	
	N	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**N**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**HR [95 %-CI]**	**<add appropriate absolute difference>** **p-value**
<Time point>						
At least one AE						
<Intervention> vs. <(Common) comparator>						
<Study XXX>						
<Study XXX>						
Total[a] (p_H = <XXX>; I^2 = <YYY>)						
<PICO comparator> vs. <(Common) comparator>						
<Study XXX>						
<Study XXX>						
Total[a] (p_H = <XXX>; I^2 = <YYY>)						
Indirect comparison (<method used (e.g. Bucher, MAIC etc)>):						
<Intervention> vs. <PICO comparator>						
Serious AE						
<to be displayed as above>						
Severe AE [insert used scale]						
<to be displayed as above>						

Time point	**<Intervention> / <PICO comparator>**		**<(Common) comparator>**		**Group difference**	
Outcome **Study reference/ID**	**N**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**N**	**Median time to event in <weeks/months> [95 %-CI]** **patients with event n (%)**	**HR [95 %-CI]**	**<add appropriate absolute difference>** **p-value**
Death related to AE <to be displayed as above>						
Treatment discontinuation due to AE <to be displayed as above>						
Treatment interruption due to AE <to be displayed as above>						
Specific AE A[b] <to be displayed as above>						
Specific AE B[b] <to be displayed as above>						
a: calculated from meta-analysis b: As requested by member state(s) in their PICOs						
AE: adverse event; HR: hazard ratio; N: number of patients in the analysis; n: number of patients with event; PICO: Population – Intervention – Comparator – Outcome; SAE: serious adverse event						

Table 40: Adverse events (all) by SOC and PT including effect estimates

Time point **Study reference/ID** **Safety outcome** **SOC** **PT**	**<Intervention>** **N =** **Patients with event n (%)**	**<Comparator>** **N =** **Patients with event n (%)**	**<Intervention> vs. <Comparator>** **RR [95 %-CI]; p-value**	**<Intervention> vs. <Comparator>** **RD [95 %-CI]; p-value**
<Time point>				
<Study XXX>				
Total AE				
System Organ Class A				
AE1 PT				
AE2 PT				
System Organ Class B				
AE1 PT				
AE2 PT				
System Organ Class C				
AE1 PT				
AE2 PT				
footnotes (delete this row if it is not needed)				
AE: adverse event; CI: confidence interval; N: number of patients in the analysis; n: number of patients with event; PT: Preferred Term; RD: risk difference; RR: relative risk; SOC: System Organ Class				

Table 41: Adverse events (serious) by SOC and PT including effect estimates

Time point **Study reference/ID** **Safety outcome** **SOC** **PT**	**<Intervention>** **N =** **Patients with event n (%)**	**<Comparator>** **N =** **Patients with event n (%)**	**<Intervention> vs. <Comparator>** **RR [95 %-CI]; p-value**	**<Intervention> vs. <Comparator>** **RD [95 %-CI]; p-value**
<Time point>				
<Study XXX>				
Total SAE				
System Organ Class A				
SAE1 PT				
SAE2 PT				
System Organ Class B				
SAE1 PT				
SAE2 PT				
System Organ Class C				
SAE1 PT				
SAE2 PT				
footnotes (delete this row if it is not needed)				

Time point **Study reference/ID** **Safety outcome** **SOC** **PT**	**<Intervention>** **N =** **Patients with event n (%)**	**<Comparator>** **N =** **Patients with event n (%)**	**<Intervention> vs. <Comparator>** **RR [95 %-CI]; p-value**	**RD [95 %-CI]; p-value**
CI: confidence interval; N: number of randomised patients; n: number of patients with event; PT: Preferred Term; RD: risk difference; RR: relative risk; SAE: serious adverse event; SOC: System Organ Class				

Table 42: Discontinuation due to adverse events by SOC and PT including effect estimates

Time point **Study reference/ID** **Safety outcome** **SOC** **PT**	**<Intervention>** **N =** **Patients with event n (%)**	**<Comparator>** **N =** **Patients with event n (%)**	**<Intervention> vs. <Comparator>** **RR [95 %-CI]; p-value**	**RD [95 %-CI]; p-value**
<Time point>				
<Study XXX>				
Total discontinuation due to AE				
System Organ Class A				
AE1 PT				
AE2 PT				
System Organ Class B				
AE1 PT				
AE2 PT				
System Organ Class C				
AE1 PT				
AE2 PT				
footnotes (delete this row, if it is not needed)				
AE: adverse event; CI: confidence interval; N: number of randomised patients; n: number of patients with event; PT: Preferred Term; RD: risk difference; RR: relative risk; SOC: System Organ Class				

Table 43: Studies included in the description of relative effectiveness and relative safety within the assessment scope

Study reference/ID	**Treatment arm(s) (relevant for the assessment)**	**Study design**
Studies on the medicinal product under assessment		
RCTs		
<Study A>	*<Intervention> vs. <Comparator>*	*RCT*
…		
Non-RCTs		

Study reference/ID	**Treatment arm(s) (relevant for the assessment)**	**Study design**
<Study B>	*<Intervention> vs. <Comparator>*	*<e.g. non-randomised, controlled / single-arm>*
…		
…		
Additional studies on comparators (if required)		
RCTs		
<Study C>		RCT
…		
Non-RCTs		
<Study D>	*<Intervention> vs. <Comparator>*	*<e.g. non-randomised, controlled / single-arm>*
…		
footnotes (delete this row, if it is not needed)		
abbreviations (delete this row, if it is not needed)		

Table 44: Study design and methodology for study <Study name>

CONSORT Item	**Characteristic**	**Study information**
-	Study objective	
2b	Precise objectives, problem and hypotheses	
-	Methods	
3	Study design	
3a	Description of the study design (e.g. parallel, factorial) including allocation ratio	
3b	Relevant changes in the methodology after the study has started (e.g. inclusion/ exclusion criteria, with justification	
4	Test subjects / patients	
4a	Inclusion/exclusion criteria for test subjects/patients	
4b	Study organization and location where the study is conducted	
5	Interventions Precise information on the planned interventions in each group and on the administration, etc.	
6	Target criteria	

CONSORT Item	Characteristic	Study information
6a	Clearly defined primary and secondary target criteria, survey times, possibly all survey methods used to optimize the quality of results (e.g. multiple observations, training of the examiners) and possibly information regarding the validation of survey instruments	
6b	Changes in the target criteria after the study has started, with justification	
7	Case number	
7a	How were the case numbers determined?	
7b	If necessary, description of interim analyses and criteria for premature discontinuation of the study	
8	Randomization, generation of treatment sequence	
8a	Method for generating random allocation	
8b	Details (e.g. block randomization, stratification)	
9	Randomization, allocation concealment, execution of allocation (e.g. numbered containers; central randomization by fax/ phone), information if concealment was ensured until allocation	
10	Randomization, execution Who conducted the allocation, who entered the test subjects/patients in the study and who allocated the test subjects/patients to the groups?	
11	Blinding	
11a	Were the a) test subjects/patients and/or b) those who conducted the intervention/ treatment, and/or c) those who assessed the target variables blinded or not blinded, how was blinding performed?	
11b	If relevant, description of the similarity of interventions	
12	Statistical methods	
12a	Statistical methods for assessing the primary and secondary target criteria	
12b	Additional analyses, such as subgroup analyses and adjusted analyses	
-	Results	
13	Patient flow (including flow chart for illustration after the table)	

CONSORT Item	Characteristic	Study information
13a	Number of study participants for each of the treatment groups formed through randomization, who a) were randomised, b) actually received the planned treatment/intervention, c) were considered in the analysis of the primary target criterion	
13b	For each group: Description of lost and excluded patients after randomization including justification	
14	Inclusion/recruitment	
14a	More details on the time period the test subjects/patients started the study and on follow-up monitoring	
14b	Information why the study ended or was terminated	
a: according to CONSORT 2010		

Table 45: Present the patient flow in a flow chart for each study

<e.g. CONSORT flow chart>

Table 46: Main study/studies from the clinical development programme (if not addressed by any of the PICO questions)

Main study/ies from the clinical development programme (if not addressed by any of the PICO questions)		
Study reference/ID	**Treatment arm(s)**	**Study design**
RCTs		
<Study A>	*<Intervention> vs. <Comparator>*	*RCT*
…		
Non-RCTs		
<Study B>	*<Intervention> vs. <Comparator>*	*<e.g. non-randomised, controlled / single-arm>*
…		
footnotes (delete this row, if it is not needed)		
abbreviations (delete this row, if it is not needed)		