Summary Template for the Benefit-Risk Assessment of Medicines

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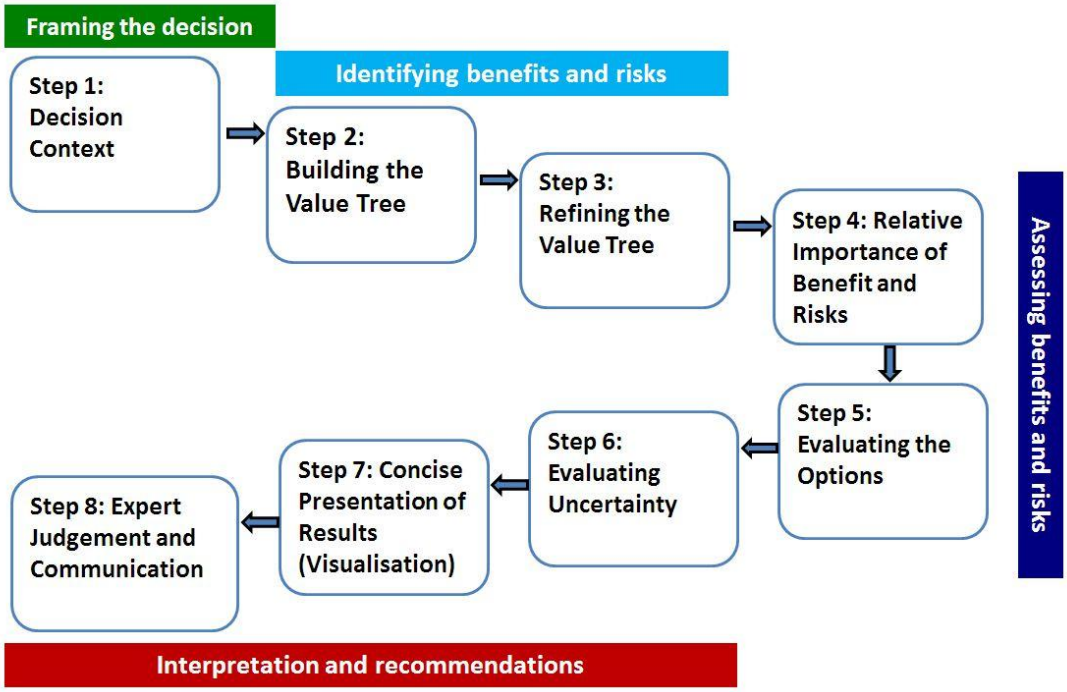
Compound Identifier(s):	Click here to enter text.	
Product name/ Brand name / Generic name:	Click here to enter text.	
Active Ingredient(s)/ Strength(s)/ Dosage form:	Click here to enter text.	
Proposed Indication by the company:	Click here to enter text.	
Approved Indication:	Click here to enter text.	
Regulatory History Please specify reference agencies that have reviewed the product and outcome	Reference agency Name	Outcome
	Click here to enter text.	Choose an outcome
	Click here to enter text.	Choose an outcome
	Click here to enter text.	Choose an outcome
	Click here to enter text.	Choose an outcome
	Click here to enter text.	Choose an outcome

Please complete a new summary form for each indication

All data will be treated in strict confidence.

No data or information will be revealed to any third party

The UMBRA Eight Step Benefit Risk Framework



The diagram shows the common elements of the UMBRA eight step Benefit Risk Framework that make up a systematic approach to benefit-risk assessment for medicines

At the CIRS annual workshop, 2012 (20-21 June) there was a consensus from those who are developing Benefit Risk methodologies for assessing medicines that there are four key stages namely;

- Framing the decision;
- Identifying the benefits and risks;
- Assessing the benefits and risks;
- and Interpretation and recommendation.

Underpinning these was an overarching eight step framework;

1. Decision context;
2. Building the Value Tree;
3. Value Tree refinement;
4. Assessing relative importance;
5. Evaluating options;
6. Evaluating uncertainty;
7. Concise presentation of results – visualisation;
8. Final recommendation.

All the methodologies currently being developed by regulators and companies have these steps whether explicitly or implicitly undertaken.

The UMBRA overarching framework provides the basis for a common agreement on the principles for benefit risk assessment of medicines.

Table of Contents

BENEFIT RISK SUMMARY:

This section provides a summary of the key outcomes of Benefit Risk analysis undertaken.

Summary 1.1 Background (Decision Context):	
Summary 1.1.1 Specify the proposed therapeutic indication Click here to enter text.	
Summary 1.1.2 Treatment options evaluated in this submission Click here to enter text.	
Summary 1.1.3 Is this product for an unmet medical need? (Reviewer opinion): Please select Select.	
Reason: Please provide justification for your decision on the product fulfilling or not fulfilling an unmet medical need	Click here to enter text.
Summary 1.1.4 Please specify any local clinical, guideline or other issues which need to be considered to contextualize the decision context. Click here to enter text.	
Summary 1.1.5 Has this active substance been reviewed by the agency previously? Please select Select. If Yes - Please provide detail on the outcome of the review, the indication and any issues raised Click here to enter text.	

Summary 1.1.6: Reference Agency Regulatory History								
Reference agency	Please tick the information reviewed as part of this assessment:							
Reference agency Name:	Click here to enter text.							
Outcome at agency	Approved	_	Rejected	_	Withdrawn	_		
	If rejected what was the main reason? Click here to enter text.							
Approved Indication(s)	Click here to enter text.							
Approved doses	Click here to enter text.							
Contraindications	Click here to enter text.							
Warnings and precautions	Click here to enter text.							
Is the submitted product exactly the same for the CMC/ quality aspects?	Yes	_	No	_				
	If not please comment on differences:							
	Click here to enter text.							
Key Documents referenced Please 'X' the relevant ones	CPP	_	Public domain assessment report	_				
	Agency internal assessment reports	_	Risk mitigation plan	_				
	Agency/company Question/answers	_	Product Information Leaflet	_				
Please indicate here any other documents referenced	Click here to enter text.							

Add another agency

Summary 2.1 Overall Summaries:			
Summary 2.1.1 Quality Conclusion:			
If ticked - No relevant findings for the clinical benefit-risk assessment		_	
If there are relevant findings please comment	Click here to enter text.		
Summary 2.1.2 Non-Clinical Conclusion:			
If ticked - No relevant findings for the clinical benefit-risk assessment		_	
If there are relevant findings please comment	Click here to enter text.		

Summary 2.1.3 Human Pharmacology Conclusion:

Only the important results and issues that have an impact on the benefit-risk balance should be described. *In addition, unresolved issues or uncertainties should be identified and their impact on the balance assessment should be clearly stated. This includes Bioequivalence, Pharmacokinetic and Dynamic profile, as well as PK, & PD interactions, special populations, dose findings etc.*

Dose finding

Bioequivalence

Food Effect

Pharmacokinetics

Pharmacodymamics

Drug Interaction

Special Populations

Summary 2.1.4 Assessment of Ethnic Factors:

Click here to enter text.

Summary 3.1 Clinical Study Summary

Study Ref. **Type**	**Study Design (N)(duration)** R, C, DB, OL (N=)(weeks/months) ·Non-inferiority/Superiority/ Observational study ·State primary objective ·State primary efficacy parameter	**Treatment** ·Treatment arm Active (name, dose, freq, duration) ·Comparator arm Placebo / Active (name, dose, freq,duration)	**Conclusion** ·Results of primary efficacy parameter ·Results of other relevant efficacy endpoints ·Conclusion of study (outcomes, strength of study, weight of evidence, and clinical significance)	**Provide the key benefit(s) or risk(s) identified by this study**	Double click the "+" to add a study
Study Ref. Select a type	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	+
Study Ref. Select a type	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	+
Study Ref. Select a type	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	+
Study Ref. Select a type	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	+
Study Ref. Select a type	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	+

Legend

R: Randomised **C:** Controlled **DB:** Double blinded **OL:** Open label **N:** Number of subjects

Summary 3.2 Clinical Conclusion: *Only the important results and issues that have an impact on the benefit-risk balance should be described. In addition, unresolved issues or uncertainties should be identified and their impact on the balance assessment should be clearly stated. This includes study design, dosage, population and comparators.*
Click here to enter text.

Summary 4.1 RISKS: Overall Summary

Table of pooled overall incidence of events can be added below

Click here to enter text.

Summary 5.1 Identified Benefits and Risks

Summary 5.1.1 Benefits documented

List all **benefits** of treatment for this indication as inferred in the submission or identified by the reviewer	Please 'X' here if Benefit Identified by Reviewer but not by company	Please indicate which **benefits** you believe are justified to be included in the benefit risk assessment	Please explain your main reason **for inclusion or exclusion** of the benefit parameter
Enter Benefit 1	–	Yes	Click here to enter text.
Enter Benefit 2	–	Yes	Click here to enter text.
Enter Benefit 3	–	Yes	Click here to enter text.
Enter Benefit 4	–	Yes	Click here to enter text.
Enter Benefit 5	–	Yes	Click here to enter text.
Enter Benefit 6	–	No	Click here to enter text.
Enter Benefit 7	–	No	Click here to enter text.
Enter Benefit 8	–	No	Click here to enter text.
Enter Benefit 9	–	No	Click here to enter text.
Enter Benefit 10	–	No	Click here to enter text.

Summary 5.1.2 Risks documented

List **Risks** of treatment (all relevant risks) for this indication as inferred in the submission or identified by the reviewer	Please 'X' here if Risk Identified by Reviewer but not by company	Please indicate which **risks** you believe are justified to be included in the benefit risk assessment	Please explain your main reason **for inclusion or exclusion** of the risk parameter
Enter risk 1	–	Yes	Click here to enter text.
Enter risk 2	–	Yes	Click here to enter text.
Enter risk 3	–	Yes	Click here to enter text.
Enter risk 4	–	Yes	Click here to enter text.
Enter risk 5	–	Yes	Click here to enter text.
Enter risk 6	–	No	Click here to enter text.
Enter risk 7	–	No	Click here to enter text.
Enter risk 8	–	No	Click here to enter text.
Enter risk 9	–	No	Click here to enter text.
Enter risk 10	–	No	Click here to enter text.
Enter risk 11	–	No	Click here to enter text.
Enter risk 12	–	No	Click here to enter text.
Enter risk 13	–	No	Click here to enter text.
Enter risk 14	–	No	Click here to enter text.
Enter risk 15	–	No	Click here to enter text.

Summary 6.1 Weights and values

Benefits	Relative Importance (weighting) High/Med/Low	Valuing the options Investigated product	Comparator	Placebo	Units	Comment on strength and uncertainty of benefit
Enter Benefit 1	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Enter Benefit 2	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Enter Benefit 3	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Enter Benefit 4	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Enter Benefit 5	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

Risks	Relative Importance (weighting) High/Med/Low	Valuing the options			Units	Comment on strength and uncertainty of each risk	Was the value or weight of this risk altered or mitigated by the ability to control the use of the medicine once on the market?
		Investigated product	Comparator	Placebo			
Enter risk 1	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Enter risk 2	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Enter risk 3	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Enter risk 4	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Enter risk 5	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

Summary 7.1 Conclusion

Summary 7.1.1: Effects table and conclusion

	Effect	Relative Importance	Units of Measurement	Valuing the Options			Comment on Strength and Uncertainty
				Investigator Product	Comparator	Placebo	
B	Enter Benefit 1	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
B	Enter Benefit 2	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
B	Enter Benefit 3	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
B	Enter Benefit 4	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
B	Enter Benefit 5	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
R	Enter risk 1	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
R	Enter risk 2	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
R	Enter risk 3	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
R	Enter risk 4	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

	Effect	Relative Importance	Units of Measurement	Valuing the Options			Comment on Strength and Uncertainty
				Investigator Product	Comparator	Placebo	
R	Enter risk 5	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

Summary 7.1.2 If the benefit-risk balance is assessed to be negative, describe the harm (e.g. in terms of lack of efficacy, toxicity) that the drug may cause if used in the proposed indication

Click here to enter text.

Summary 7.1.3 Describe how the benefit-risk balance is expected to evolve over time (e.g. when late side effects emerge or long-term efficacy decreases)

Click here to enter text.

Summary 7.1.4 Make reference to the evaluation of the pharmacovigilance plan and risk minimization plan if any. Describe any communication or particularly significant information to the medical profession, patients or the public that is required. Describe restrictions to product availability or usage

Click here to enter text.

Summary 7.1.5 Describe outstanding issues, and other significant information eg, submission of additional reports by the company to address those issues, hearings and advisory group recommendations, information from other jurisdictions (eg advisory committees, scientific experts, patients, consumers, consumer advocates and other stakeholders)

Click here to enter text.

Summary 7.1.6 Describe the need for further studies (e.g. the need for studies to improve the benefit-risk balance with further optimization studies, the need for intensive additional follow up measures or specific obligations, and the need for further development including any paediatric development plans.

Click here to enter text.

Summary 7.1.7 Please provide any other information considered by the agency relevant to the benefit risk decision that is not covered elsewhere in the template.

Click here to enter text.

Summary 7.1.8 Please provide a clear conclusion on the benefit-risk being positive or not for the proposed indication. Click here to enter text.
Summary 7.1.9 Please provide the indication recommended following the outcome of the benefit-risk balance. Click here to enter text.
Summary 7.1.10 Please indicate if the approved indication is the same as the reference agencies used for this review, if yes which agency(s) if no specify the rational Click here to enter text.

Reviewers Name	Click here to enter text.
Signature	Click here to enter text.
Date	Click here to enter text.
Manager sign-off or Peer review	
Reviewers Name	Click here to enter text.
Signature	Click here to enter text.
Date	Click here to enter text.