TBM Score Grid

Table 1: Score grid for the scientific assessment (S-Axis)

Scientific value S	Unacceptable (U)	Poor (-2)	Reasonable (-1)	Positive (0)	Excellent (+1)
S1. Project focus on the development of a new therapy, diagnosis and or specific prevention of a particular disease or a comparison of existing procedures	The TBM programme is aimed at projects whose objective is to contribute to (i) the further development of a **new or improved** therapy, diagnosis (including prognostic and theranostic tools), or prophylactic treatment of a particular human disease or medical issue or (ii) a comparison of **existing** procedures (therapies/diagnostics/preventive methods) in order to find out their relative efficacy and cost-effectiveness. Examples of research that does NOT fit in the TBM programme: (i) evaluations of health organisations, (ii) epidemiologic studies without a feedback to a new therapy/diagnosis/specific prophylactic treatment, (iii) research aimed at generally improving health (without aiming at a particular disease), (iv) the mere introduction into Flanders of existing therapies and/or diagnosis techniques from abroad that do not need further research and (v) comparison of interventions that are out-of-date or for which the efficacy and cost-effectiveness is already known. This criterion examines the *objective* that the applicants seek to reach. The way the applicants want to reach this objective is NOT assessed.				
	❑ The project is mainly NOT aimed at the development of a new therapy, diagnosis and/or specific prevention of a particular disease/medical issue or at the comparison of existing therapies/diagnostics/preventive methods. ❑ The targeted application is already out-of-date. ❑ The targeted application is already in practice abroad; no further research is required to introduce the application in Flanders. ❑ The relative efficacy and cost-effectiveness of the targeted interventions is already known. No further research is required.	❑ The proposal is only <u>partly</u> aimed at the development of a new therapy, diagnosis and/or specific prevention of a particular disease/medical issue or at the comparison of existing therapies/diagnostics/ preventive methods. It is not the primary objective of the proposal.	❑ The proposal is for the most part aimed at the development of a new therapy, diagnosis and/or specific prevention of a particular disease/medical issue or at the comparison of existing therapies/ diagnostics/preventive methods.	❑ The project is entirely aimed at the development of a new therapy, diagnosis and/or specific prevention of a particular disease/medical issue or at the comparison of existing therapies/diagnostics/ preventive methods.	**No possibility for scoring**
S2. Position of the project in the path from discovery to a specific application	The TBM programme is directed at <u>research</u> that is positioned late in the path from discovery to a specific application and aims at <u>translating and developing scientific findings into clinical applications</u> rather than creating knowledge from scratch. Research that is positioned too early in the process of discovering a clinical application does not qualify for support under the TBM programme. Here are some examples: (i) fundamental research that is mainly directed at the creation of knowledge, (ii) basic research that is still far from a clinical application and/or for which no proof-of-concept has been reached as yet. Pure implementation activities of acquired knowledge from the past without the need for further research are positioned too late in the discovery process to qualify for support. Examples include market studies, registration studies, development of SOPs.				
	❑ The proposal includes **mainly** activities that are not positioned correctly on the path from discovery to application.	❑ The proposal includes for a significant part activities that are not positioned correctly on the path from discovery to application.	❑ The proposal includes mainly activities that are positioned correctly on the path from discovery to application.	❑ The proposal consists (almost) entirely of activities that are positioned correctly on the path from discovery to application.	**No possibility for scoring**

Scientific value S		Unacceptable (U)	Poor (-2)	Reasonable (-1)	Positive (0)	Excellent (+1)
S3.	**Contribution to the state-of-the-art/scientific importance**	Under this criterion, an assessment is made as whether the project can, during the implementation, contribute to the scientific state-of-the-art. In other words, the scientific importance of the project is examined.				
		❑ The technology used is entirely out-of-date. ❑ The current knowledge was insufficiently taken into account. The project is clearly behind the current scientific state-of-the-art.	❑ The proposal shows the characteristics of a catching-up effort relative to the international state-of-the-art.	❑ The project is in line with the scientific state-of-the-art, but does not contribute to this state-of-the-art.	❑ The project builds on and makes a limited contribution to the scientific state-of-the-art.	❑ The project builds on and makes a clear contribution to the scientific state-of-the-art AND the proposal is for the most part positioned correctly (at least a reasonable score on previous criterion).
S4.	**Relevance of the scientific approach in the attainment of the scientific objectives**	This criterion assesses whether the proposed research approach is clear and whether this approach is relevant, suitable, and efficient to reach the targeted scientific objectives.				
		❑ There is a clear mismatch between the scientific objectives and the research approach.	❑ The research approach shows serious weaknesses or shortcomings. ❑ The harmonisation between objective and approach must be improved substantially.	❑ The research approach is reasonable.	❑ The proposed scientific approach is relevant and suitable to reach the targeted scientific objectives.	❑ The proposed scientific approach is the most relevant, effective and efficient approach to reach the scientific objectives.
S5.	**Balance between risks and feasibility of the scientific project objectives**	In the TBM programme the projects that are targeted are those where the project implementation goes hand in hand with an intrinsic scientific risk (otherwise this is not research anymore), but where the feasibility of achieving the targeted objectives is nonetheless sufficient. The balance between risks and feasibility is assessed under this criterion. The questions that must be asked include: i) Is the project associated with intrinsic scientific/technological risks (these are risks that are intrinsic to the problem to be solved; they are not the risks that are introduced through an erroneous approach!)? Do the applicants need to solve technological or scientific problems? (ii) What is the feasibility of the scientific project objectives? Are the applicants introducing additional risks through an erroneous approach? (iii) Are the applicants aware of the main risks and are “fall back scenarios” anticipated if necessary?				
		❑ The targeted scientific project objectives are not feasible because the intrinsic risk is much too high or because the wrong scientific approach is used.	❑ The project proposal includes only a very limited intrinsic technological or scientific risk. ❑ The feasibility of the scientific project objectives is low.	❑ The balance between risks and feasibility of the scientific project objectives is reasonable.	❑ The balance between risks and feasibility of the scientific project objectives is good. The project proposal has a clear intrinsic risk; however the feasibility of the project objectives is good.	❑ Optimum balance between scientific risks and feasibility of the scientific project objectives.

Scientific value S	Unacceptable (U)	Poor (-2)	Reasonable (-1)	Positive (0)	Excellent (+1)
S6. Quality project plan + management	In the TBM programme the projects targeted are those with a clear work programme and a sound project plan. The work programme must be sufficiently feasible within the given period and the cost efficiency (value for money) of the proposal must be sufficient. The questions that must be asked in relation to this criterion include: (i) Is the work plan clearly defined, with well defined and planned tasks that correspond to the project objectives? (ii) Are the different tasks/responsibilities shared clearly among the different partners, with a good estimation of the necessary personpower per partner? (iii) Are the major milestones and "deliverables" identified? (iv) Is the implementation of the proposed work programme feasible within the project duration? (v) What is the cost-efficiency of the project? In particular for projects that request a budget higher than 1M euro (which is only allowed for large or multicentric trials), the cost-efficiency of the project is an important aspect of this criterion.				
	❑ The project proposal does not include any work programme or project plan. ❑ The work programme cannot be implemented within the set timeframe. ❑ There is a substantial mismatch between the research workload and the requested level of personpower and resources. The appropriate adjustment amounts to more than 50% of the requested budget.	❑ The project plan is insufficiently developed. Structural adjustments are necessary. ❑ The feasibility of the implementation of the work programme within the set time frame is low. ❑ The research is insufficiently focussed. ❑ There is an important unbalance between the research workload and the requested level of personpower and resources. The appropriate adjustment amounts between 33% and 50% of the requested budget.	❑ The project plan is sound. ❑ The feasibility of the implementation of the work programme within the set time frame is reasonable. ❑ The level of requested personpower and resources is acceptable, provided that the budget is moderately adjusted (between 20 and 33%).	❑ The project plan is sound and the implementation of the work programme is feasible within the set time frame. ❑ There is a good balance between the research workload and the requested level of personpower and resources (less than 20% adjustment required).	❑ The project plan is sound and the implementation of the work programme is feasible within the set time frame AND the cost efficiency of the project proposal is high.
S7. Competence and infrastructure	This criterion assesses whether the necessary scientific and clinical expertise and infrastructure are indeed present and whether there is not any superfluous, irrelevant expertise present within the consortium. The possible synergy between the various research groups is also examined. Remark: It is possible to obtain a bonus point if a significant cross-institutional cooperation is initiated.				
	❑ Essential expertise or infrastructure is lacking.	❑ Important adjustments to the composition of the consortium or to the infrastructure are considered necessary in order to be able to implement the project. ❑ The expertise of one or more participating groups is not relevant for the project proposal. ❑ There is an excessive fragmentation of the resources.	❑ The overall expertise or infrastructure of the consortium is reasonably good, but gives rise to some concerns or shortcomings as to whether the project can be implemented optimally.	❑ The required expertise and infrastructure is available. The expertise of each of the partners (where there are several research groups) is complementary.	❑ The required expertise and infrastructure is available AND there is a relevant cooperation across institutions AND there is a good synergy in the consortium.

Table 2: Score grid for the utilisation assessment (U-Axis)

Utilisation value U		Unacceptable (U)	Poor (-2)	Reasonable (-1)	Positive (0)	Excellent (+1)
U1.	**Relevance of the project in the attainment of the utilisation objective**	This criterion assesses whether the research approach is relevant, suitable and efficient to reach the utilisation objectives. The criterion also assesses whether the set scientific objectives are the most relevant to reach the utilisation objectives.				
		❑ There is a clear mismatch between the research approach (and/or the scientific objectives) and the utilisation objectives.	❑ The research approach shows serious weaknesses or shortcomings to be able to reach the utilisation objectives. ❑ The harmonisation between approach (and/or the scientific objectives) and utilisation objective must be improved substantially.	❑ The relevance and efficiency of the research approach (and/or scientific objectives) are reasonable as regards the attainment of the utilisation objectives.	❑ The proposed scientific approach (and/or scientific objectives) is relevant and suitable to reach the targeted utilisation objectives.	❑ The proposed scientific approach (and/or scientific objectives) is the most relevant, effective and efficient approach to reach the utilisation objectives.
U2.	**Intrinsic feasibility of the utilisation objective**	Under this criterion is assessed whether the societal objectives can be attained. The intrinsic feasibility of the utilisation objectives can be influenced by a number of bottlenecks such as scientific problems during and after the project implementation, ethical objections, regulation aspects, freedom to operate, etc. Neither the quality of the planning for the transfer of the results to the patient, nor the applicants' competence for the transfer of the results to the patient are taken into account here. These two aspects are assessed under the U6 and U7 criteria.				
		❑ The societal objectives are (almost) not feasible.	❑ The feasibility of the societal objectives is low in comparison with other projects in the sector.	❑ The feasibility of the societal objectives is reasonable/acceptable.	❑ The feasibility of the societal objectives is good.	❑ The feasibility of the societal objectives is very good.
U3.	**Anticipated impact for the individual patient**	This criterion assesses the extent of the anticipated medical impact/added value of the project for the individual patient, taking into account the intrinsic (inherent) feasibility of the targeted societal application. The following question needs to be answered under this criterion: What is the extent of the anticipated medical impact/added value of the project for the individual patient, taking into account the intrinsic feasibility of the targeted application? The difference that this project will mean for the patients compared to these patients' situation when the project would not be performed (e.g., life-saving, change from serious inconvenience to light inconvenience, reduction of light inconvenience) is examined. The difference that the project can mean obviously depends on the severity of the medical problem, the treatment methods already available, and the efficacy of the proposed solution. The scope of the patient group is not taken into account under this criterion. This aspect is assessed under criterion U4.				
		❑ Negative medical impact anticipated for the patient.	❑ (Quasi) no medical impact expected.	❑ The feasibility of the societal objectives is at least acceptable. AND the anticipated medical impact for the patient is limited (e.g., avoidance of light to average inconvenience during a limited time frame) to average (e.g., avoidance of light to medium inconvenience during many years).	❑ The feasibility of the societal objectives is at least acceptable AND the anticipated medical impact for the patient is high (e.g., prolongation of life with months/years of good quality, avoidance of serious inconvenience during many years).	❑ The feasibility of the societal objectives is at least acceptable AND the anticipated medical impact for the patient is very high (e.g., life-saving).

Utilisation value U	Unacceptable (U)	Poor (-2)	Reasonable (-1)	Positive (0)	Excellent (+1)
U4. Anticipated societal impact for Flanders	This criterion assesses the anticipated impact of this project for public health in Flanders. Besides the anticipated medical impact for each patient (see criterion U3), this criterion also assesses how many patients in Flanders will experience this impact and whether a cost reduction for the Flemish/Belgian healthcare system is to be expected. If the feasibility of reaching the societal applications is considered very low (criterion U2) or if there are NO patients in Flanders, this criterion is rated as unacceptable. For all other situations, this criterion should be rated taking into account the following subaspects: - medical impact for the individual patient (see U3); - number of patients in Flanders experiencing this positive medical impact (rule of thumb: small number: less than 50 patients; medium number: between 50 and 3000 patients; large number: more than 3000 patients); - anticipated cost reduction for the healthcare system/patient that is well substantiated in the proposal.				
	❑ Almost no societal impact is anticipated for Flanders.	❑ The anticipated scope of the societal impact for Flanders is low.	❑ The anticipated scope of the societal impact for Flanders is reasonable.	❑ The anticipated scope of the societal impact for Flanders is good.	❑ The anticipated scope of the societal impact for Flanders is excellent.
U5. Absence of industrial interest	This criterion assesses -based on the current knowledge- whether a company (existing or new, in Flanders or abroad) could at present (or in the near future) be interested to finance this project. After all, the TBM programme targets projects in which the industry does not have any interest at the time of submitting the application (or in the near future) due to a commercial or legal (e.g., no obligation for efficacy testing before marketing) reason. This absence of industrial interest should be thoroughly substantiated in the proposal.				
	❑ Research that could logically be supported through the support channel for companies (if submitted by a company). ❑ Research in which the industry is already logically interested. ❑ Insufficient arguments are provided to convince the panel about the absence of industrial interest. ❑ Insufficient evidence is provided that guarantees the independence of the researcher from commercial actors.	**No possibility for scoring**	❑ At the moment, the industry has only a very limited interest.	❑ At the moment the industry has no interest due to commercial and/or legal (e.g., no obligation for efficacy testing before marketing) reasons.	**No possibility for scoring**

Utilisation value U		Unacceptable (U)	Poor (-2)	Reasonable (-1)	Positive (0)	Excellent (+1)
U6.	**Quality and feasibility of the utilisation approach**	Under this criterion a score is given for the quality and feasibility of the approach suggested by the applicants in order to make the results of the project effectively available to the targeted patient group. The questions that should be asked here include: (i) Are the applicants aiming at the relevant target group(s)? (ii) Was a relevant advisory committee composed with clear engagement, and have patients been involved? Do the applicants adequately use the expertise and commitment of the members of the advisory committee in order to reach the proposed utilisation objectives? (iii) Is the targeted utilisation strategy suitable to translate the project results into the targeted utilisation objectives? (iv) Are the applicants aware of possible bottlenecks for the transfer of the results to the patient and are they planning strategies to resolve this? (v) Will the results be disseminated widely and on a non-discriminatory basis in the European Union?				
		❑ No utilisation strategy has been formulated. ❑ The strategy cannot lead to the targeted societal applications in Flanders. ❑ The results will not be made available broadly in the European Union on a non-discriminatory basis.	❑ The utilisation plan is insufficiently developed. Structural adjustments are necessary. ❑ The utilisation approach is not very feasible. ❑ Significant obstacles, hurdles or risk factors are clearly present, yet they are not acknowledged, nor are they tackled with an action plan.	❑ The vision and approach regarding utilisation shows definite shortcomings. ❑ For certain parts or aspects the chosen utilisation approach is not good. ❑ Potential obstacles, hurdles or risk factors were mentioned in a superficial manner, but can be considered as manageable.	❑ The proposal features a good perspective and approach as regards utilisation. The utilisation plan is developed properly and soundly and takes possible obstacles into account. The results will be made available broadly in the European Union on a non-discriminatory basis.	❑ Best possible approach to transfer the results to the patient. AND The results will be made available broadly in the European Union on a non-discriminatory basis.
U7.	**Competence and track record with regard to transfer and utilisation**	This criterion assesses to what extent the applicants and the members of the advisory committee together have the competence and experience to transfer the results to the targeted patient group. Have previous and/or ongoing TBM projects led to a significant transfer? **The focus in this criterion lies in the track record of the applicants with regard to utilisation and translation of research results to the clinical practice (difference with S7).**				
		No possibility for scoring	❑ The competence and track record to contribute to the translation of research into societal applications are very limited. ❑ The transfer of results from previous and/or ongoing TBM projects is very limited.	❑ The competence and track record to contribute to the translation of research into societal applications are reasonable. ❑ The transfer of results from previous and/or ongoing TBM projects is limited.	❑ The competence and track record to contribute to the translation of research into societal applications are good. ❑ Previous and/or ongoing TBM projects have not yet led to a transfer with a significant societal impact. However, they are oriented towards societal implementation.	❑ The competence and track record to contribute to the translation of research into societal applications are exceptionally good. ❑ Previous and/or ongoing TBM projects have led to a transfer with a significant societal impact.