



agentschap voor Innovatie
door Wetenschap en Technologie



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Toegepast Biomedisch Onderzoek met een Primair Maatschappelijke Finaliteit

Applied biomedical research with a primarily societal goal

TBM Call 2014-2015

Important change in program modalities: Advisory Committee

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Focus of the TBM-program

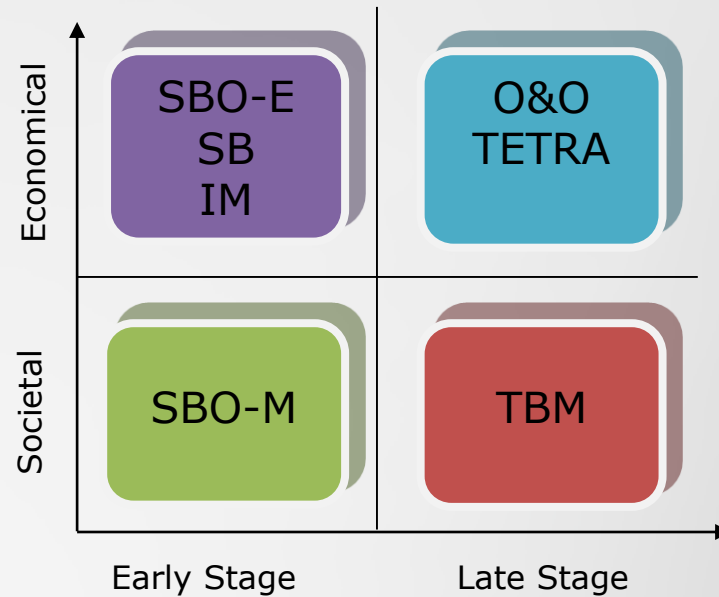


The TBM-program focuses on a **specific niche** within biomedical research:

Late-stage applied biomedical research that aims at improving the Flemish health situation (by means of developing an improved therapy, diagnosis and/or specific prevention), and in which **industry** is **currently not interested** due to a commercial reason.

Positioning towards other IWT programs

Positioning:



TBM Niche: Four criteria

1. Biomedical research aimed at the development of a **new therapy, diagnosis and/or specific prevention** of a disease.
2. **Late stage translational research** → focus on the translation of a scientific finding towards the clinic. Proof of concept has been reached (in patients).
3. **Added value for the Flemish health situation**, with at least a positive medical impact for a specific patient group.
4. **Lack of industrial interest.**

Criterion 1: Focus on the development of a new therapy, diagnosis and/or specific prevention

What kind of research does **NOT** fit in the TBM-program:

- Research to improve the *general* health situation
- Epidemiological studies
- Evaluation of health organisations
- Structural financing
- Comparative studies between *existing* medical procedures, therapies or diagnosis techniques
- Introduction into Flanders of a therapy or diagnosis used abroad
- ...

Criterion 2: Late stage translational research

What kind of research does **NOT** fit in the TBM-program:

- Fundamental research (*de novo* knowledge creation)
- Basic research (no *proof-of-concept* yet)
- Pure implementation activities
- Market research for the utilisation of the project findings
- ...

Criterion 3: Added value for Flemish health situation (positive medical impact for specific patient group)

What kind of research does **NOT** fit in the TBM-program:

- Research focused on a disease that has no incidence in Flanders
- Research focused on a development that has no *medical* impact (eg. only comfort improvement)

Criterion 4: Lack of industrial interest

What kind of research does **NOT** fit in the TBM-program:

- Research directed towards one specific company (R&D program).
- Research for which no collaboration with the industry has been sought in order to be able to achieve better transfer conditions in the future.
- Research without industrial interest due to a high scientific risk (conflict with criterion 2, SBO-program)
- Research that could lead to the establishment of a new spin-off company, once sufficient financial resources are available.
- Research for which reasonable industrial interest can be expected, but in which the industry refuses to invest because of the economic crisis.
- Research on development of medical devices, for which there is industrial interest.

Criterion 4: Lack of industrial interest

Possible **commercial reasons** for a lack of industrial interest:

- No possibility for patenting
- No possibility for a standardized product
(patient-specific products, eg. celtherapy, tissue engineering)
- Profit margins too low
- Commercial risk too high (eg. gene therapy, xenotransplant)
- Patient populations too small ('return on investment' too small)
- ...

TBM-program: target group

▪ **Applicants:**

- Non-profit O&O actors: universities, hospitals, research institutes, higher education institutes

Participation of non-Flemish applicants is limited to max. 20% of the total budget.

- Companies not allowed
- Consortium possible, but presence of a **Flemish hospital** is required

Due to focus on clinical translation

Min 10% of the total budget - motivate!

▪ **Large Subcontractors (> € 8.500):**

- Companies allowed
- Routine tasks, without any creative input

Max. 30% of the budget.

TBM-program: budget and subsidy

- Project budget: between € 250.000 and € 1.000.000
- Duration: 2 to 4 years
- Subsidy: 100%

TBM-program: **new:**

Cooperation with an advisory committee

For each TBM project, an **advisory committee** -consisting of actors that will be involved in the further utilization trajectory-needs to be assembled from the project preparation phase onwards.

Purpose:

- Stimulate **interaction** with relevant societal players from project preparation on
- Encourage and stimulate effective implementation and dissemination of project results
- Enlarge the impact of TBM projects
- Orient the TBM program (even) better towards its goal (contribute to the implementation of new therapy/diagnosis/prevention)

TBM-program: advisory committee

Role:

Support **translation** of results towards clinical practice, from regulatory as well as patient perspective

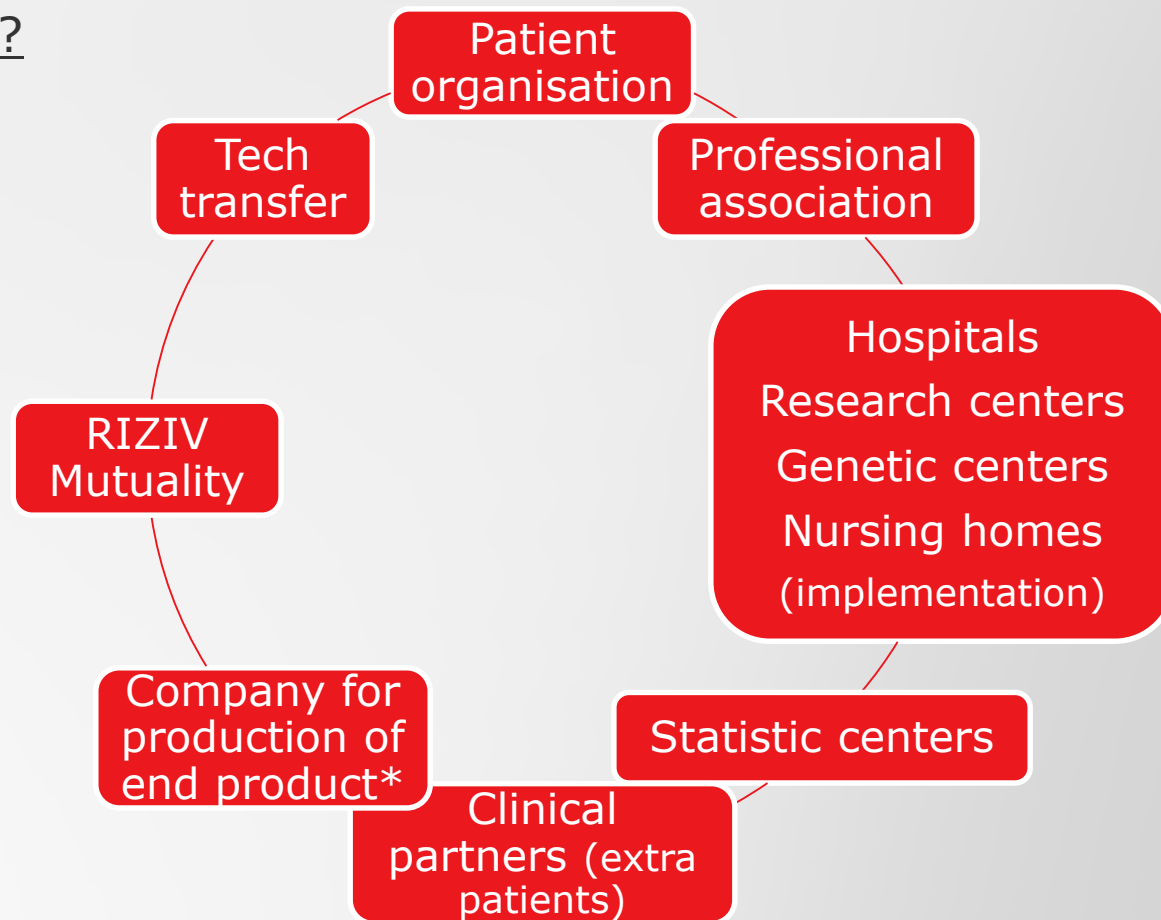
eg. define practical needs in clinical practice, discuss project approach, design and prepare translation to clinical practice, options for reimbursement, ...

Active involvement in **implementation** and **dissemination** of project results

eg. advice on feasibility of utilisation trajectory: protocol changes, help when inclusion problems, ...

TBM-program: advisory committee

Who?



TBM-program: advisory committee

Requirements:

- **At least 2 members** (~relevance & project needs)
- **Early pro-active interactie** with advisory committee is crucial, motivate:
 - Interactions before submission & impact on the project
 - Added value for each member
 - Final role in the utilisation
- For each member a **motivated letter of intent** by the deadline of submission, signed by legal representative
- Minimal interaction frequency: once/year

Previous TBM calls: overview

Overview supported TBM projects: www.innovatienetwerk.be (projects-TBM)

Call	Available budget (€)	Number of submitted projects	Total budget applied for (€)	Number of supported projects	Succes rate
2006-2007 I	5 M	23	12 M	7	42%
2006-2007 II	5 M	46	26 M	9	19%
2007-2008	6 M	42	23 M	11	26%
2008-2009	6 M	32	17 M	11	35%
2009-2010	5.7 M	45	27 M	9	20%
2010-2011	5.4 M	45	31 M	8	18%
2011-2012	6.7 M	31	21.5 M	9	32%
2012-2013	6.8 M	42	32 M	9	21 %
2014-2015	6.8 M	41	29 M	8	24%

TBM Call 2014-2015: Project submission

- Program budget: ca. € 6,8 million
- Deadline Submission: **February 18th, 2015** (12h00)
- Submission according to the template on the website ("Aanvraagtemplate")
 - **Electronic submission** (tbm@iwt.be or CD-rom)
 - In **English**
 - Max. 25-30 pages project description
 - **1 Word** file: project identification & description
 - **1 Excell** file: budget
 - **1 PDF** file: attachments

Project submission: Application form

- Part 1: Project identification

- ☐ Project summary
- ☐ Administrative data applicants (applicant=legal entity!!)

- Part 2: Project description


- ☐ "Fit" in the TBM program
- ☐ Positioning towards the state of the art & project goals
- ☐ Utilisation of the project results
- ☐ Work program
- ☐ Expertise

- Part 3: Project budget

- ☐ Project budget for each applicant
- ☐ Total project budget

- Part 4: Enclosure(s)

- ☐ Declaration of each applicant
- ☐ Declaration of project leader
- ☐ Motivated letters of intent from members of advisory committee
- ☐ Approval of the Ethical Commission (if relevant)
- ☐ A quote for each subcontractor > € 8.500 (if relevant)




Incl.
Added value / Relevance
Interaction with advisory committee
Impact
Role in utilisation trajectory

Project submission: Lay-out of the budget

- See documents on the website (www.iwt.be/subsidies/tbm)
 - **General IWT cost model**
 - Template: excel file
- Project budget = Sum of the budgets of each applicant
- The budget for each applicant is divided in:
 - Staffing costs
 - Other costs:
 - Direct costs: Working costs + equipment costs (depreciation)
 - Indirect costs: Overhead

Project submission: Lay-out of the budget



▪ Staffing costs:

- Only research staff working on the project objectives (other staffing costs, eg. secretary, have to be included in the overhead costs,...)
- Gross salaries (by salary scale)
- No double financing
- Costs for employees based on quotes (eg. consultants) have to be included in other costs or large subcontractors (> €8.500), unless in case of long-time engagement
- Doctors that work in the hospital on an independent basis are allowed in the staffing costs

▪ Other costs (incl. overhead costs!):

- Only real costs, related to the project (realistic estimation)
- Motivate direct costs (eg. materials, tools, IT-costs, traveling expenses, amortisations on research equipment, subcontractors, ...)
- Max. €40.000/FTE/year (of which indirect costs max. €20.000/FTE/year)

Project submission: Lay-out of the budget

- Large subcontractor (> €8.500):
 - No own valorisation rationale, no own risk, no right for results
 - Market price (full cost + margin)
 - Need cost driver (motivation and estimation of number of manmonths or specific tasks)

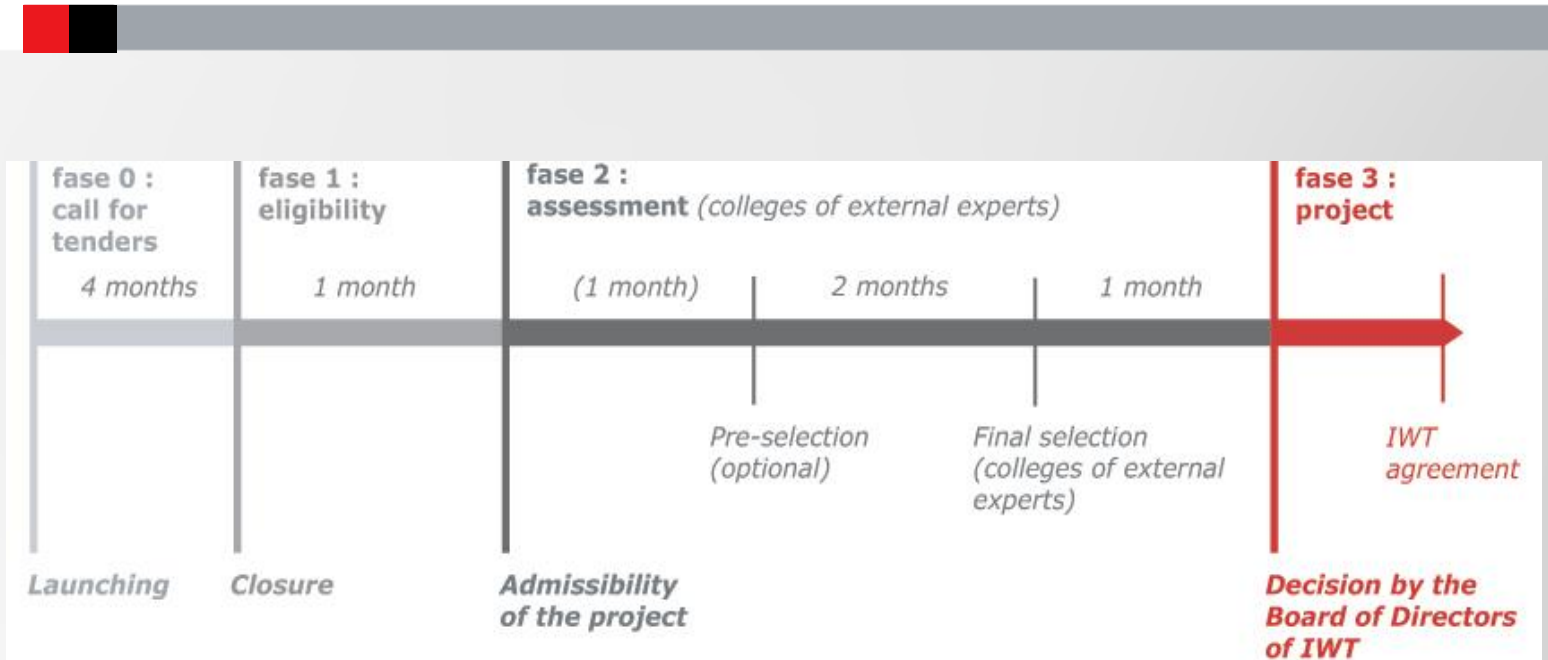
- Large cost:
 - **Exceptional** (very expensive tests: eg. imaging, sequencing, ...)
 - Has to be relevant en necessary for the project
 - Only accepted when this cost cannot be added to the project budget in previous categories
 - Needs detailed motivation (quotes)

Project submission: Lay-out of the budget

- Advisory committee:

- No rights on project results
- No financing possible for:
 - Interaction with possible members of advisory committee before submission
 - Participation in advisory committee (participation fee)
 - Activities after the project (further development / implementation activities & dissemination of project results)
- Activities during project execution -linked to utilisation afterwards- can be taken into account for support
 - Limited: eg. meetings with the advisory committee

Evaluation process



Evaluation process: Eligibility


1. Eligibility

- Scheduled for the meeting of the IWT board of directors of March 2015

Eligibility Criteria

- Submitted before deadline, according to requested format
- Formal criteria (budget, duration, consortium, ...)
- Attention: **Do not forget the declaration form(s)!**
- At least **advisory committee** of **2 members**, incl. motivated **letter of intent** for each member
 - **Signed** by legal representative
 - Specific added value of project results for each member (↔ general interest)

Evaluation process: Evaluation

- 
- 2. Pre-selection round** (Only when a large number of proposals have been submitted!)
 - Based on the "fit" of the projects in the TBM program (cfr. 4 criteria)
 - 1 commission of experts

- 3. Final selection round**
 - Based on the "fit" in the TBM program and quality criteria
 - One commission of experts per topic – short interaction with the applicants
 - Scheduled for the IWT Board meeting of June 2015

Evaluation process: Scoring

Scoring system

- The TBM scoring system consists of two dimensions of equal value:
 - Scientific quality
 - Societal utilisation perspectives

Evaluation process: Criteria scientific quality

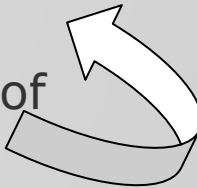
1. Focus of the project on the development of a new therapy, diagnosis and/or specific prevention of a disease (FIT)
2. Positioning of the project in the path from discovery towards an actual application (FIT)
3. Added value towards the state-of-the-art/scientific importance
4. Relevance of the scientific approach in order to achieve the scientific goals
5. Balance between the risks and the feasibility of the scientific project goals
6. Quality of the project plan + management
7. Competence and infrastructure

Evaluation process: Criteria social utilisation perspectives

1. Relevance of the project in order to achieve the utilization goal of the project
2. Intrinsic feasibility of the utilization goal
3. Expected impact for the individual patient (FIT)
4. Expected impact of the social potential for Flanders (FIT)
5. Lack of industrial interest (FIT)
6. Quality and feasibility of the utilization approach
7. Competence and track record with regard to transfer of the results towards an application

Advisory committee:

- Interaction
- Relevance/Added value
- Role in utilisation



Evaluation process: IWT contract

- The **IWT contract** handles:
 - Intellectual property rights: applicants are owner
 - Consortium agreements between applicants
 - Conditions for payments
 - Reporting towards IWT
 - Budget
 - "Innovation goal" of the project

Payments

- Half-yearly pre-payments
- Final payment is based on the verification of the costs (financial report)

Reporting

- **Half-yearly report:**

- Short scientific report
- **Yearly**, a prestation table (manmonths per person)

Coupled to **follow-up meeting**

Interaction with advisory committee & IWT advisor

- **Final report**

- Scientific report
- Report on the utilisation perspectives
- Financial report, incl. prestation table

- **Workshop**

- Presentation of TBM project results
- Non-confidential summary of the project results

Tips

- Carefully read the documents on the IWT website and contact IWT in case of questions (02/432 42 33; tbm@iwt.be)
- **Start interacting with the advisory committee early**
- Send an abstract of the proposal to tbm@iwt.be to get an idea about the 'fit' of the project in the TBM program
- Give a clear argumentation for the fit in the TBM program (e.g. why is industry not interested?...)
- Make sure your project has a clear focus
- Make sure the scientific goals are well aligned with the utilisation goals
- Contact supporting services in your organisation for help with utilisation planning, budget, statistics, ...

Tips

- Pay sufficient attention to
 - power analysis (clinical studies)
 - patient inclusion strategy (dropouts, feasibility)
 - utilisation planning
- Don't forget to include the overhead costs in the budget
- Make sure every "declaration" has been signed in time.

Team

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