

Call for proposals



Smart BioMaterials Center

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Smart BioMaterials Center program

Version 2.3

Date January 12, 2026

Website: www.smartbiomaterials.nl

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Date of Publication: January 12, 2026

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Background

Regenerative medicine (RM) aims to develop new treatments that make smart use of our body's self-repairing ability. This involves the use of gene, cell and tissue therapy products. The purpose of RegMed XB¹ is, on the one hand, to prevent or cure chronic diseases in the long term and, on the other, to enable Dutch businesses to develop innovative products and processes and to respond to a strongly growing foreign market.

One of the pillars of the RegMed XB ecosystem initiative is the development of a manufacturing infrastructure. This responds to major challenges in making RM therapies available and affordable to patients, namely the development and industrialization of manufacturing. This is complex (working with living material), must meet high standards (Good Manufacturing Practice) and is currently still labor intensive and not automated. RegMed XB and its partners will use Growth Fund² resources to realize a national RM infrastructure in the Netherlands, consisting of an ecosystem of pilot lines that support companies and research institutions in developing and valorizing new RM therapies, production technology and production services. Together they cover the entire chain from biomaterials to cells, micro tissues and whole organs, and every possible scale from personalized applications to the development of industrial production. Each link provides both products and services that are directly applicable in RM therapies and intermediate or auxiliary products for other steps in the chain.

Smart BioMaterials Center (SBMC)³ is one of the aforementioned pilot lines. Biomaterials play a major role in the production and delivery of RM therapies. Hydrogels are used to accelerate cell culture and to deliver drugs and/or cells and tissues into the body. The latter also applies to biodegradable implants. These are biomaterials specifically constructed to support the growth of new functional tissue in the body.

A total of € 6,8 million in financing has been budgeted by SBMC for a program, intended to stimulate and support R&D projects geared towards developing products and services that serve the regenerative medicine & biomaterials roadmaps directly, or enable derivative products in the value chain. SBMC distinguishes smaller *feasibility studies* and more extensive *R&D collaboration projects*. These projects will allow SMEs to make financially attractive use of the SBMC facilities and expertise and play a role at the national level but also at the European level.

Proposal for feasibility study sizes can vary between € 5,000 and a maximum of € 50,000. The SBMC contribution can amount to a maximum of € 25,000 per project. This contribution is 50% of the total project. The remainder is contributed by applicant(s), either in cash and/or in-kind. Proposals for R&D collaboration project sizes can vary between € 50,000 and a maximum of € 1,000,000. The

¹ RegMed XB stands for Regenerative Medicine Crossing Borders. RegMed XB is a public-private partnership.

www.regmedxb.com

² www.nationaalgroefonds.nl

³ www.smartbiomaterials.nl

SBMC contribution can amount to a maximum of € 500,000 per project. This contribution is 50% of the total project. The remainder is contributed by applicant(s), either in cash and/or in-kind.

Proposals can be submitted by an individual company (feasibility study) or on behalf of a consortium (R&D collaboration project). Project partners must comply with the conditions set forth in Article 25 of the GBER and ensure compliance with the conditions of Chapter 1 of the GBER and Article 25. When requesting the determination of co-financing, SBMC will review compliance with this State aid obligation.

Please note that this Call for Proposal takes its guidance from the: [Kaderregeling betreffende staatssteun voor onderzoek, ontwikkeling en innovatie \(2014/C 198/01\) en algemene groepsvrijstellingenverordening \(Verordening \(EU\) nr. 651/2014.](#)

Available budget and timetable

SBMC has a total of € 6,800,000 available for the period 2021-2028 to finance projects, which fall under the rules of the GBER (in dutch: AGVV⁴) article 25. Applications for the SBMC program may be submitted at any time during the period 2021-2027. Projects are ultimately limited by the program deadline - December 31, 2028.

Upon receipt of an application, an admissibility check will be performed. All admissible proposals are then submitted to the Program Council for its opinion, which is sent to the Executive Committee. Subsequently, the Executive Committee determines the funding. A conclusion by the Executive Committee will be taken within a maximum of 12 weeks after receipt of a complete application and all related documents. This term can be postponed once by 12 weeks.

⁴ <https://europadecentraal.nl/onderwerp/staatssteun/vrijstellingsmogelijkheden/algemene-groepsvrijstellingenverordening/>

Scope

Two types of project can be applied for under this call: **Feasibility Studies** and **R&D Collaboration Projects**. Both types of projects have their own characteristics.

Feasibility Study means the evaluation and analysis of the potential of a project, which aims at supporting the process of decision-making by objectively and rationally uncovering its strengths and weaknesses, opportunities and threats, as well as identifying the resources required to carry it through and ultimately its prospects for success (definition 87, GBER).

A **R&D Collaboration Project** consists of industrial research or experimental development or a combination thereof, carried out in actual collaboration and at shared expense and risk by a R&D partnership; An R&D partnership is an R&D association that does not have legal personality, consisting of two or more entrepreneurs not affiliated in a group, which has been established for the purpose of carrying out an R&D collaboration project. Representatives from research organisations can also be part of a partnership.

Industrial research Industrial research is critical research aimed at acquiring new knowledge and skills necessary for developing new products, processes, or services, or to significantly improve existing products, processes or services. It includes the creation of parts for complex systems and may also include the construction of prototypes in a laboratory environment and/or in an environment with simulated interfaces to existing systems, as well as pilot lines- when necessary for industrial research- and in particular for the validation of generic technology. Industrial research spans Technology Readiness Levels⁵ (TRL) 2-4 (definition 85, GBER).

Experimental development comprises the acquisition, design and use of all existing knowledge and skills aimed at developing new products, processes or services. This includes activities aimed at the conceptual formulation, planning and documentation of new products, processes or services.

Experimental development may include prototyping, demonstration, pilot development, testing and validation of new products, processes or services in environments representative of functioning under real-world conditions, aimed at making further technical improvements. This may include the development of a commercially viable prototype or pilot considering that this would otherwise be too expensive to manufacture.

Experimental development does not include routine or periodic changes to existing products, production lines, manufacturing processes, services and other current activities, even if such changes lead to improvements. Experimental development spans Technology Readiness Levels (TRL) 5-8 (definition 86, GBER).

⁵ https://en.wikipedia.org/wiki/Technology_readiness_level



Intellectual property

To strengthen the European regenerative medicine ecosystem, filing intellectual property is encouraged, if this improves the potential for future commercial applications. If relevant, parties are responsible for making their own arrangements and negotiating the necessary agreements. The SBMC can be an advisor in this process, but is formally no party to such arrangements and/or agreements.



Duration

Feasibility studies have a maximum duration of 12 months, following the start of the project. The project should start within 4 months after approval by the Executive Committee of SBMC.

R&D Collaboration Projects should start within 6 months after approval by the Executive Committee of SBMC and have a maximum duration of 24 months.

Projects are ultimately limited by the program deadline - December 31, 2028. As such, feasibility studies awarded in this call for proposals that start later than December 31, 2027 have less time until completion. And, R&D Collaboration Projects awarded in this call for proposals that start later than December 31, 2026, have less time until completion.

A grace period of 1 year is allowed in case of project delays related to calamities, sickness and/or maternity leaves. Project extensions must be applied for in writing prior to the initial project deadline, motivating the reason for extension. This can be sent to info@smartbiomaterials.nl

In any event, all projects need to be completed by the program deadline - December 31, 2028. This includes those that have been granted a grace period.

Who can apply?

Representatives of **Small and Medium** sized enterprises or **Large companies** can apply on their own for feasibility studies.

A consortium applying for a R&D collaboration project consist of at least two companies, one of which belongs to the category of Small or Medium sized enterprises. Representatives from **research organisations**⁶ can also be part of a consortium but cannot receive a financial contribution.

Company categorie	Staff headcount	Turnover	Or	Balance Sheet total
Medium-sized	<250	< €50 m		< €43 m
Small	<50	< €10 m		< €10 m

Source: https://ec.europa.eu/growth/smes/sme-definition_en

Companies must be registered as a legal entity at the Chamber of Commerce or similar institution in the Netherlands or abroad. Their activities in the Netherlands must be substantial, or the eligible activity benefits the Dutch economy. SBMC's Executive Committee will decide on this.

⁶ an entity, such as a university or research organisation, regardless of its legal form (public or private law organisation) or financing method, which is principally engaged in carrying out basic research, industrial research or experimental development and disseminating the results thereof through education, publications or technology transfer; all profits are reinvested in those activities, in the dissemination of their results, or in education. Companies that can exert influence over such entity through, for example, shareholders or members, do not enjoy preferential access to such entity's research capacity or to the results of its research.

Cost eligibility

Feasibility study sizes can vary between € 5,000 and a maximum of € 50,000. The SBMC contribution can amount to a maximum of € 25,000 per project. This contribution is 50% of the total project.

R&D collaboration project sizes can vary between € 50,000 and a maximum of € 1,000,000. The SBMC contribution can amount to a maximum of € 500,000 per project. This contribution is 50% of the total project.

The following cost types are eligible for (partial) reimbursement.

Labour costs

For SME and large companies: project related labour costs for researchers, technicians and other support personnel to the extent they are engaged in the project to be accounted for by applying either:

- The salary costs plus surcharge method, whereby the direct wage costs per hour are increased by a fixed surcharge of 50% for indirect costs.
- The fixed hourly rate method, using an hourly rate of max. €60.
- For TNO- the integral cost system (IKS-rates).
- For other research institutions: labour costs are capped by the VSNU salary guidance per respective position i.e. for technicians, postdocs. See <https://www.nwo.nl/salaristatables> for an overview of current rates.

Other costs

Costs that are necessary and adequate in relation to the purpose of the project are eligible for reimbursement:

- Third party costs entail costs related to external services such as consulting- provided by companies or freelancers. Intermediate supplies between participants in a collaboration project are not covered by the concept of "third party costs".
- Costs for consumables, small instruments and aids.
- Investments in equipment for as long as they are used for the project. When such equipment is not used for their entire life for the project, only the depreciation costs corresponding to the project period, calculated according to generally recognized accounting principles, are considered eligible costs.
- Cost for travel and lodging.
- Costs for buying the rights to patents necessary for the project, for the duration of the project.
- Miscellaneous costs directly related to the project.
- *All costs stated must exclude VAT unless the beneficiary isn't VAT exempt. Only actual costs incurred post to the start and prior to the end of the project are eligible for (partial) reimbursement.*



For R&D collaboration projects, none of the participants in the partnership will bear more than 70% of the costs.

The maximum allowance for budget deviations between cost types is 15%. An excess of this percentage, prior written permission is required. Requests for permission must be motivated and can be sent to info@smartbiomaterials.nl



Applications

Applications for the SBMC program may be submitted at any time.

The full application comprises the following:

- a signed application form including a completed project plan, including appendices;
- project budget;
- declaration of no financial difficulties;
- relevant support letters (this is no obligation).

The subject of a feasibility study must fit within the objectives of SBMC and preferably offer the prospect of an R&D collaboration project as a follow-up. The objectives and ambition of SBMC are described in the project plan for a national pilot factory for regenerative medicine which has been honoured by the National Growth Fund⁷ (available upon request, in Dutch only). SBMC is never a formal project partner in the application. But using the SBMC facilities and expertise does underpin the requirement that the project must fit within the scope of SBMC. The cost of using SBMC facilities and/or expertise is made available at market rates and is budgeted as third party costs.

The subject of a R&D collaboration projects must fit within the objectives of SBMC. The objectives and ambition of SBMC are described in the project plan for a national pilot factory for regenerative medicine which has been honoured by the National Growth Fund (available upon request, in Dutch only). Making use of the SBMC facilities and expertise is preferred and does underpin the requirement that the project must fit within the scope of SBMC.

SBMC will appoint a project supervisor who will explore opportunities with applicants. If there are compelling arguments, facilities may be used elsewhere. SBMC is never a formal project partner in the application. The cost of using SBMC facilities and/or expertise is made available at market rates and is budgeted as third party costs.

Project applications that could create a conflict of interest within SBMC will not be selected.

Templates for the application form including project plan and project budget can be downloaded from <https://smartbiomaterials.nl/project-request/>

The full application can be sent to info@smartbiomaterials.nl

⁷ <https://www.nationaalgroefonds.nl/projecten-ronde-1/regmed-xb>

Proposal evaluation

The Smart BioMaterials Center program is coordinated by SBMC. The final decision on awarding a contribution lies with the Executive Committee of SBMC. A Program Council, as referred to in article 12 of the Foundations' articles of association, evaluates and recommends the proposals submitted to the program.

Program Council

When assessing the applications, the Program Council provides advice to the Executive Committee of SBMC. The Program Council consists of research and innovation experts from business and science. To avoid a conflict of interest, the committee members adhere to a code of conduct as set out in the regulations for the Program Council, which can be found on www.smartbiomaterials.nl.

Admissibility check

Upon receipt of an application, a check will be performed taking note of the following criteria:

- the application has been drawn up correctly and completely;
- the application has been submitted by authorized bodies or persons (section 'who can apply');
- the project costs fall within the indicated bandwidths;
- the applicants for the project must not be in financial difficulty, as referred to in Regulation (EU) No 651/2014 of 17 June 2014 (Article 2.18).

If the application is deemed inadmissible, the applicant will be notified and provided with one opportunity to make the necessary alterations to the proposal and resubmit within 5 working days. Upon receipt the admissibility check will be performed again. Applicants will receive confirmation of admissibility.

Written evaluation

After the application has been declared admissible, it will first be assessed in writing by the Program Council on the basis of the set ranking criteria. A concise report will be sent to the Executive Committee of SBMC. The ranking criteria center on:

1. technological potential;
2. innovation;
3. business potential;
4. quality of the project plan and partnership;
5. alignment with the goal and ambition of SBMC, as shown in the project plan for a national pilot factory for regenerative medicine which has been honoured by the National Growth Fund;
6. use of SBMC facilities and/or expertise
7. potential economic and societal impact.

Each criterion carries equal weight.



Conclusion

The Program Council advises SBMC's Executive Committee on the quality of the project proposal. Subsequently, the Executive Committee determines the contribution. Applicants will be duly informed about the conclusions of the Committee

Decision challenge

In case of a decision challenge certain guidelines apply which can be found on www.smartbiomaterials.nl (coming soon).

Program terms

Payment

If awarded the contribution is paid out in two or more instalments to the main applicant. The first instalment will be transferred after all the stipulated funding conditions have been met. The hight of the first and following installments will be communicated to the main applicant in de allocation letter or contract. Subsequent tranches until the maximum of 75% is reached will be provided based on the liquidity needs of the project.

This includes a signed acceptance of the contribution and the associated terms. A final tranche of 25% will be paid upon completion of the project. A final report and a financial justification must be sent to info@smartbiomaterials.nl for approval. Reporting guidance and templates will be provided in due course.

Reporting

For feasibility studies and for R&D collaboration project reporting is required annually by 1 February for the period up to the end of December, and at the end of the project. Reporting should cover the status of the goals and milestones pursued by the project as well as the financial status.

In case the project is discontinued prematurely, applicants will be required to justify such decision and report on the final status. This can inherently lead to a reduction in the eligible contribution.

Reporting guidance and templates will be provided in due course.

Accountability

The determination of SBMC co-financing is made on the basis of a final report to be submitted by the applicant, accompanied by a final content report, which demonstrates that the activity or activities for which the contribution was granted have been carried out and that the activity or activities indicated when the co-financing was granted have been carried out in accordance with the obligations imposed.

The final report also includes an itemized statement of all actual costs directly attributable to the activities, prepared in accordance with the budget submitted. The eligible costs shall be supported by documentary evidence which shall be clear, specific and contemporary.

For collaboration projects, an audit opinion issued by an independent auditor is also requested. The goal of the audit is to establish whether the financial transactions as reported in the overall project financial statement comply with the framework as set out in this agreement. The audit subject is the overall financial report of the consortium, including own contribution(s) for the period being audited. The entire project period applies to the audit of the final report.

Ethical aspects

An applicant is responsible for determining whether an ethics statement or authorization is required to conduct the proposed study and for obtaining it in a timely manner from the relevant ethics committee. If deemed a requirement, the necessary ethics statement or permit will need to be in place before the starting date of the project, and after it has been awarded.



Disclaimer

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Stichting Smart BioMaterials Consortium cannot be held accountable for possible errors residing in this publication.

Applicants cannot derive any rights whatsoever from this document. Stichting Smart BioMaterials Consortium reserves the right to make alterations during the program if this is in the general interest of the foundation, bearing in mind that this is done in an equitable fashion.

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