



BioManufacturing Eurocluster for Recovery and Resilience in EU





BioMan4R2 Financial Support Scheme

Version 1.0

27 April 2023

Disclaimer:

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HISTORY OF CHANGES			
Version	Changes		
1.0	27 April 2023	Initial version.	



BioMan4R2 SME Financial Support Scheme

The BioMan4R2 project within the European SMP COSME program offers financial support via lump sums, and networking for small and medium-sized companies in the biological products and medical technology manufacturing sectors that want to increase their resilience, sustainability and competitiveness.

The BioMan4R2 program aims to improve manufacturing processes, transfer disruptive medical technologies, strengthen the competitiveness and sustainability of the European healthcare ecosystem by fostering long-term collaboration among SMEs, investment funds, research, clinical and knowledge-intensive organizations, science and technology parks and other companies in these sectors.

BioMan4R2 Eurocluster consortium

The <u>BioMan4R2 Eurocluster</u> connects 7 partners from various regions across Europe (see table below), that collaborate to make improvements in the health ecosystem and strengthen the supply chains in Biotechnology and MedTech sector, as well as make them more resilient and innovative. The BioMan4R2 Eurocluster will provide targeted support to EU SMEs and build new partnerships outside the EU.

Table 1: Overview of BioMan4R2 partner consortium

Region/Country	Partner	
Finland	BioMan4R2 Eurocluster website Turku Science Park Ltd	SCIENCE PARKE
Catalonia, Spain	BioMan4R2 Eurocluster website BIOCAT	biocat
Germany	BioMan4R2 Eurocluster website BioRegio STERN	BioRegio STERN **
The Netherlands	BioMan4R2 Eurocluster website LifetecZONe	LIFETECZONE
Poland	BioMan4R2 Eurocluster website GAPR	MeuSvissia GAPR Upper Silesion Accelerator for Commercial Enterprises Ltd.
France	BioMan4R2 Eurocluster website MEDICEN Paris Region	ME
Europe	BioMan4R2 Eurocluster website CEBR	CEBR OUNGLO DECEMBER ONS



Applicants' requirements

SMEs from the EU, and SMP-countries, based within the ecosystems of the BioMan4R2 project partners and SMEs from EU regions different from the countries of individual Euroclusters' partners, in the biomanufacturing and medical technology area may apply to participate in the BioMan4R2 Open Call. An overview of the Eurocluster partners (including contact details) can be found within the overview table 2 of regional partner contacts below. Please check if your company meets the SME definition of the EU (more details via SME self-assessment).

Coordinator of Financial Support Scheme

The details of the BioMan4R2 Financial Support Scheme Coordinator are:

BioRegio STERN Management GmbH | Margot Jehle, Friedrichstrasse 10, 70174 Stuttgart, Germany

E-Mail: jehle@bioregio-stern.de

Lead applicants based in Finland, Spain, Germany, The Netherlands, Poland, or France are welcome to contact their referring regional consortium partner. Lead applicants based outside of these countries, are welcome to contact the Financial Support Scheme Coordinator.

The BioMan4R2 Eurocluster will organize informational online seminars for potential interested applicants to explain the application process and the different available financial support measurements. The dates of these informational online seminars will be published BioMan4R2 matchmaking platform

The different contact details for each regional partner can be found within Table 2 below:

Table 2: Overview of regional partner contacts

Region/Country	Partner Contact	Email address	
Finland	<u>BioMan4R2 Eurocluster</u> website / <u>Turku</u> <u>Science Park Ltd</u> , Tero Piispanen - Project Coordinator	tero.piispanen@turkubusinessregion.com	
Catalonia, Spain	BioMan4R2 Eurocluster website / BIOCAT, Alba Jimenez	ajimenez@biocat.cat	
Regions of Stuttgart, Tübingen, Reutlingen, Neckar Alb Germany	BioMan4R2 Eurocluster website / BioRegio STERN, Margot Jehle - Financial Support Scheme Coordinator	jehle@bioregio-stern.de	
LifetecZONe The Netherlands	BioMan4R2 Eurocluster website / LIfetecZONe, Ingrid Relou	irelou@lifeteczone.nl	
Poland	BioMan4R2 Eurocluster website / GAPR, Izabela Czeremcha	medsilesia@gapr.pl	
France	BioMan4R2 Eurocluster website / MEDICEN Paris Region, Silvia Paolella	spaolella@medicen.org	



Disclaimer

Purpose: This guide is explaining the BioMan4R2 Financial Support Scheme opportunity for information purposes only. No rights can be claimed on the basis of this document. This document does not reflect the views of the European Commission.

Mistakes or inconsistencies: The BioMan4R2 Consortium is not responsible for any mistakes or misinterpretations that this text may cause.

Modification of Guidelines for Applicants: The BioMan4R2 partners, represented by the Project Coordinator are entitled to modify the Guidelines for Applicants (including re-opening/closing dates of the calls, in case of non-granting of funds and/or early depletion of the available funds, or as they see fit) at any time without notice. The most recent version of the Guidelines for Applicants will be provided on the website of the BioMan4R2 matchmaking platform, always mentioning the version number and highlighting the changes.

Consequential Damages: In no event shall either party be liable to the other or any of its affiliates for any consequential, incidental, indirect, special, punitive or exemplary damages (including, without limitation, lost profits, business or goodwill) suffered or incurred by such other party or its affiliates in connection with this Financial Support Scheme opportunity, even if advised of the possibility of such damages.



Financial support Scheme Overview

Note: Clicking on a specific kind of financial support will direct you to a detailed description:

- ·	ne kind of financial support will direct you to a det	,
Innovation Financial Support (IFS)		Value: € 60.000 per consortium (with one single lead applicant SME who will receive the funding solely and pay other stakeholders involved within the collaborative project such as research organisations, enterprises, service providers etc. ONLY if these stakeholders provide services to the SMEs. The services provided need to be within the context and requirements of this Open Call), in case of collaborative projects / per SME in case of prototyping, valorization or validation projects.
		Number of available IFS: 15 in total
		This financial support focuses on supporting SMEs in delivering new-to-firm products and services through focusing on technological, production or process innovation aimed at making the European BioManufacturing ecosystem more resilient, sustainable and digitalizing production.
		Types of actions within this financial support:
	Innovation Financial Support (IFS)	- Collaborative projects between an SME (the main applicant) and minimal one other SME, company or academic centre/R&D institute (RDOs, RTOs, private cofunders, public institutions, etc.) with common resilience, green or digital transformation challenges. Cross-border applications are welcomed and is reflected in the evaluation procedure.
		- Prototyping, valorization and validation of existing products by implementation of resilience, green or digital aspects. Examples of resilience issues are provided in chapter Example project Set ups
Business Transformation Financial Support (BTFS)		Value: € 15.000 per SME Number of available BTFS: 10 in total
	Business Transformation Financial Support (BTFS) Go greener/digital	Support for SMEs to acquire training on technology uptake, digitalisation, and sustainable business models from supported providers. Development of training programmes for SMEs on digitalization and digital skills. Value: €15 000 per SME



9	Business Transformation Financial Support (BTFS) Go International	Support for SMEs to implement and make the business agreements and joint collaborative projects commercially viable — e.g. support for travel, third-country -/ EU-market discovery, advice on market access, reimbursement or regulatory challenges in third countries (e.g. FDA in US market) Value: €15 000 per SME
	Transforrmation Financial Support Business and legal/financial analysis	Support for resilience analysis, business continuity plans, goto market strategies, advice on reimbursement or regulatory challenges Value: €15 000 per SME

The overall maximum funding available for any SME (SMEs as knowledge/service provider included) is € 60.000 (the sum of all BioMan4R2 financial supports awarded to this beneficiary).

GENERAL COMPULSORY ELIGIBILITY CRITERIA

All proposals received will be checked by the BioMan4R2 Financial Support Scheme Coordinator in following items:

- Matching the thematic Scope of Activity for the referring financial support
- **General eligibility of the applicant:** a) a single SME (<u>SME definition</u> of the EU and <u>SME self-assessment</u>), in case of IFS application for collaborative projects: the lead applicant must be a single SME and a consortium should be already in place by applying, for prototyping, valorization and validation projects as well as for BTFS applications: the service provider should be in place by applying, b) Located in EU and <u>SMP-countries</u> and c) Active in the Biomanufacturing and/or MedTech industry d) Each SME must be in alignment with the following situations:
 - Is no bankrupt or being wound up, is not having affairs administrated by the courts, has not entered into an arrangement with creditors, has not suspended business activities, is not the subject of proceedings concerning those matters or is not in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
 - Is in compliance with its obligation relating to the payment of social security contributions and the payment of taxes, in accordance with the legal provisions of the country in which it is established;
 - Is not subject to a conflict of interest in connection with the grant.
- Submission of application in English-language
- Application must be submitted via the email address: <u>bioman4r2.submission@bioregio-stern.de</u>
 After submission, the applicant will receive an automatically generated email. If the applicant does not receive the automatic email, the applicant is requested to inform immediately the BioMan4R2 Financial Support Scheme Coordinator <u>jehle@bioregio.stern.de</u> in order to receive a confirmation for the timely submission of the application.
- Submission of application until the given deadline



• Threshold of financial support value for a single SME (SMEs as knowledge/service provider included): max. EUR 60.000 in total, therefore in terms of combining financial support, only a combination of multiple Business Transformation Financial support up to the € 60.000 limit is possible.

EVALUATION PROCESS

The detailed evaluation criteria and process is described at the different financial support opportunities.

CONSENSUS MEETING

The 'Selection Committee', selected from the project Management Committee, will decide by consensus, and based on the ranking received as result of the Consortium Evaluation.

ANNOUNCEMENT OF THE AWARDED SMES

Applicants will be notified of the status of their application within 12 working days after call closure. Successful applicants will receive a confirmation letter. Applicants who did not succeed will receive a rejection letter.

RULES OF PROCEDURE AND DATA PROTECTION REGULATION

RULES OF PROCEDURE

Applicants have to agree to this procedure during the application process. Agreement to this procedure is given through the respective application form.

DATA PROTECTION REGULATION

Data submitted via application form to partners of the BioMan4R2 consortium will be treated according to the EU Regulation 2016/679 (General Data Protection Regulation - "GDPR").

OVERALL PROCESS

The flowchart below depicts the overall process for the BioMan4R2 Financial Support Scheme.

We encourage liasing with your referring regional BioMan4R2 contact in case of questions or unclarities, as well as for early stage review of your project idea and a quickscan as to whether it matches the goals of the Financial Support opportunity (see Overview of regional partner contacts).



Select Financial Support - SME

Check Eligibility and Evaluation Criteria for IFS

Check Eligibility and Evaluation Criteria for BTFS



Prepare the application - SME

Form your consortium or identify your service provider for the application for the IFS

Identify a suitable service provider for BTFS



Virtual Matchmaking - SME with Expert/Collaborator

SMEs meet with experts/collaborators on BioMan4R2 matchmaking platform for financial support implementation



Submit Application - SME

Contact the BioMan4R2 Financial Support Scheme Coordinator in case of questions.



Evaluation Meeting - BioMan4R2 Selection Committee

Selection of successful SMEs



Grant Agreement between SME & Financial Support Scheme Coordinator

Grant Agreement will be proof checked, accepted & signed



Financial Support Implementation

Project start: after signature of Grant Agreement | 50 % of IFS and/or BTFS are transferred



Mid-Way Quality Check - SME

SME has to provide information in the form of an Intermediary Report on KPI progress & impact after half time of the project



Reporting - SME

The SME needs to submit an online final report of the activity in accordance with the Grant Agreement, 50 % are transferred 30 days after approval of Final Report



ABOUT RESILIENCE

European clusters can be hindered in the effectiveness or level of innovation, valorisation and/or commercialization of biomanufacturing products and/or services by either regulatory, funding, infrastructure, technology, supply chain and/or market access barriers or complications.













Regulatory

Funding

Infrastructure

Technology

Supply Chain

Market Access

By overcoming this hindrance or barrier, the resilience of a cluster is improved. All aspects depicted in the figure in this section can hinder the flourishing of European clusters and thus can be targeted in your application. We encourage liasing with your referring regional BioMan4R2 contact for early stage review of your project idea and a quickscan as to whether it matches the goals of the Financial Support opportunity.

EXAMPLE PROJECT SET UPS

Challenge	Innovation Type	Example project	Collaborator examples	Impact
Worldwide value chains are prone to political and economic issues.	Process	Form consortium of component/material suppliers and/or support organisations.	Manufacturers, investors, materials R&D, incubators.	Shift sourcing to European/local partners and form more resilient value chains.
Sourcing small volumes of components for every manufacturing batch is costly.	Digital	forecasting algorithms implementation.	ICT company, manufacturing SMEs.	Increased insight into sourcing needs, opportunity for cost-effective sourcing and batch size negotiations to improve sourcing resilience.
Component obsolescence or prolonged lead time	Legal/Business	Find alternative and/or second suppliers in Europe.	SMEs with the same challenge, legal support in contracting second suppliers	More versatile supply chains built.
Waste must be reduced in the medical sector	Process and technological	Find European suppliers/developers of biobased/recyclable materials suitable for packaging and/or design expertise for smaller packaging.	Biomaterial companies, sterilization expertise, packaging expert, R&D expertise.	Less waste generated by the manufacturing of your product.
Less CO2 emission from your value chain.	Process	Optimize the logistic processes.	Logistics consultant, carriers.	Reduced CO2 emission.
Unwanted or high level of chemicals used in a processing step.	Pilot	Pilot project: design and test a new manufacturing process.	Process expertise.	More sustainable production process.
More resilient ecosystems	Pilot, Process	Build shared facilities for processes or support lacking in the ecosystem, e.g. a shared fill & finish facility, shared R&D labs, investment gap solutions.	Biomanufacturing companies, investors, pharmaceutical companies, academic centers.	More resilient ecosystems.





Innovation Financial Support (IFS)

This Financial Support focuses on supporting SMEs and collaborators from different sectors in delivering new-to-firm products and services through focusing on technological, production or process innovation aimed at making SMEs in the field of Biomanufacturing and Medical Technology (BMT) more resilient, sustainable and digitalizing production. The IFS is addressing SMEs with innovative changes to specific biomanufacturing value chain elements.

The IFS can be used for one of the following actions:

- 1. Collaborative projects between SMEs and collaborators of different sectors with common resilience, green or digital transformation challenges.
- 2. Projects targeting joint supply chain optimization, prototyping, valorization of existing products by implementation of resilience, green or digital strategies. Validation of novel supply chain products or processes across ecosystems are also within scope.

What you receive



Support from your regional ecosystem support organisation.



Find collaborators from any stakeholder type in our database



€ 60.000 financial support



Innovation Financial Support (IFS)

How it works

General guidelines for

1. Collaborative projects

Who should apply

The lead applicant must be

- A single SME (who will receive the funding solely to pay other stakeholders involved within the collaborative project such as research organisations, enterprises, service providers etc ONLY if these stakeholders provide services to the SMEs. The services provided need to be within the context and requirements of this Open Call)
- Located inthe EU and SMP-countries.
- Active in the biomanufacturing/medical technology/life sciences industry.
- Collaborate with minimal one other SME, company or academic centre/R&D institute (RDOs, private co-funders, public institutions, etc.) with common resilience, green or digital transformation challenges (collaborators should already in place by applying)

Scope of the IFS

The IFS can be used to implement innovative changes to specific biomanufacturing/medical technology value chain elements between SMEs and collaborators of different sectors with common resilience, green or digital transformation challenges.

Several types of collaboration are anticipated:

- 1. Project between a biomanufacturing/medical technology/life sciences industry SME and a cross-sectoral SME.
- 2. Project between an SME and an academic centre and/or R&D institute, hospital.
- 3. Project between an SME and a large enterprise.

The applicant is expected to be the project leader and will be a SME from the BMT sector and will pay other involved project partners such as SME, academic centre or R&D institute, hospital, large enterprise etc. against the exchange of services for the benefit of the lead applicant SME as only SMEs are eligible to receive any financial support within BioMan4R2 Eurocluster. Any further SMEs involved within a collaborative project besides the lead applicant SME will receive the financial support from the lead applicant SME according to the provided information within the application form. It is recommended that the lead applicant SME, in case of a consortium, envisage internal arrangements regarding their operation and co-ordination to ensure that the project is implemented properly. These internal arrangements might be set out in a written 'consortium agreement' between the lead applicant SME and project partners before the signature of the Grant Agreement. These arrangements of this agreement are in the responsibility of the lead applicant SME only and NOT within the responsibility of the Financial Support Scheme Coordinator. An intermediary and final report will be required



to proceed with payments. An SME can submit more than one application but will be granted as team leader for only one application without exceeding the established € 60 000 financial limit.

About Resilience

Find more information in section ABOUT RESILIENCE.

Selection of collaborators Collaborators could be

SME, academic centre or R&D institute, hospital, large enterprise.

- Listed preferably within the BioMan4R2 network/Eurocluster <u>matchmaking</u> <u>platform</u>. If no suitable collaborator is available, the applicant may propose a collaborator that can be approved by the BioMan4R2 consortium via the referring regional BioMan4R2 <u>contact</u> for the financial support application.
- Collaborative partners will be partners that are either i) contracted by the applying SME to achieve the scope of the financial support project ii) partners that contribute in kind to this scope iii) SMEs with equal challenges and cooperating with the main applicant SME to achieve the scope.
- Matchmaking: The applicant has the opportunity to conduct virtual matchmaking sessions via the project's provided <u>BioMan4R2 matchmaking</u> <u>platform</u> with the selected collaborators/service providers to get to know each other and discuss further details of collaboration before submission of an application.

2. Prototyping, valorization or validation projects

Who should apply

The applicant must be

- A single SME (who will receive the funding solely to pay other stakeholders involved as service providers)
- Located inthe EU and <u>SMP-countries</u>.
- Active in the biomanufacturing/medical technology/life sciences industry.
- Collaborate with minimal one other SME, company or academic centre/R&D institute (RDOs, private co-funders, public institutions, etc.) as service provider with expertise in the resilience, green or digital transformation challenges the application targets. (service providers should already in place by applying)

Scope of the IFS

This IFS can be used for joint supply chain optimization, prototyping, valorization of existing products or services by implementation of resilience, green or digital strategies. Validation of novel supply chain products or processes across ecosystems are also within scope.

Selection of

Service provider could be

service provider

- SME, academic centre or R&D institute, large enterprise.
- Listed preferably within the BioMan4R2 network/Eurocluster <u>matchmaking platform</u>. If no suitable service provider is available, the applicant may propose a service provider that can be approved by the BioMan4R2 consortium via an evaluation procedure (fill in template for external service provider approval). No entity/staff of the BioMan4R2 Eurocluster is allowed to act as service provider.



Matchmaking: The applicant has the opportunity to conduct virtual matchmaking sessions via the project's provided <u>BioMan4R2 matchmaking</u> <u>platform</u> with the selected collaborators/service providers to get to know each other and discuss further details of collaboration before submission of an application

Value of IFS

Max. € 60.000 per consortium in case of collaborative projects / per SME in case of prototyping, valorization or validation projects

Applications

Interested SMEs will have to fill in an application form for the Innovation Financial support . Proposals need to be submitted before the given Deadline. Late proposals will not be admitted. English is the official language for the open calls. The proposal must be in English in all its mandatory parts in order to be eligible.

Application open

See submission dates below.

Number of

15 in total

available IFS



Contact

Find your regional support organization here.

Communication of results

The applicant will receive an email about the outcome of the assessment. In case of any questions regarding the evaluation results please contact the Financial Support Scheme Coordinator, Margot Jehle, jehle@bioregio-stern.de.

The validity of the Innovation Financial Support is 6 months starting from the contract date. Remuneration is further explained under 'Payment" below.

Reapplications

Reapplication is not possible.

Procurement

The main applicant follows the company's internal procurement guidelines.

Project initiation procedure

a. Grant Agreement:

Upon receipt of the confirmation that the application has been granted the lead applicant has to sign a Grant Agreement, which will act as the official agreement between the applicant (SME), and the BioMan4R2 Partnership. BioMan4R2 Partnership will proofcheck its accuracy and level of detailedness to assure the successful completion of the project. The Agreement regulates the transfer of the financial support.

As soon as the agreement is set up it has to be signed by the applicant (SME) and BioMan4R2 Financial Support Scheme Coordinator within 10 working days before the start of the project. If the Agreement is not signed by the selected applicant within the indicated timeframe, the applicant with the next highest score on the ranking list will be awarded the grant. 50% of the financial support value being awarded will be transferred to the main applicant after the signing of the Agreement. The remaining 50% will be transferred 30 days after approval of the Final Report.

b. Monitoring activities:

The lead applicant SME has to provide information in the form of an **Intermediary Report** for a mid-way quality check after half of the project time, verifying the completion of the project's KPIs which will be validated by the BioMan4R2 Financial Support Scheme Coordinator. Within one month after completion of the project/service purchase, the applicant must submit an online **Final Report** on the activity in accordance with the Grant Agreement.

Note: The main applicant must inform the BioMan4R2 Financial Support Scheme Coordinator immediately about occurring problems, which may compromise the success of the project.



An Extension of the project duration of more than 6 months is only possible in case of unforeseen circumstances and for a maximum of one month extension. Applying for the extension is to be done via the Financial Support Scheme Coordinator and no later than in Month 3 of the project timeline.

Contractual obligation

The successful applicants agree to

- Sign the Grant Agreement
- Acknowledge the EU funding and BioMan4R2 project: For dissemination and use of results generated through the financial support from BioMan4R2, the recipient must credit the EU funding by acknowledging through proper citation and visibility of EU support, displaying the European flag (emblem) and funding statement (also include the disclaimer) as indicated below, and as well of the BioMan4R2 logo and the ECCP logo:







"This project has received funding from the European Union's Single Market Programme, via the Open Call BioMan4R2"

- Allow the BioMan4R2 consortium to use the name of the winners for communication purposes.
- Cooperate on establishing a best practice one-pager on the resilience action.

Applicants shall not have any potential conflict of interest with the selection process. All cases of potential conflict of interest will be assessed case by case.

Payment

50% of the financial support value being awarded will be transferred to the lead applicant at the start of the project within 30 days upon signature of the Grant Agreement (prepayment). The remaining 50% (final payment) will be transferred within 30 days only upon

- A successful performed mid-way quality check.
- Submission and approval of the final report.

In case the final report is not submitted on time, the prepayment must be reimbursed to the BioMan4R2 Financial Support Scheme Coordinator.



Eligible Costs

Eligible costs

Eligible costs are personnel costs, external costs (such as subcontracting costs including consultancy, legal, manufacturing expenditures), consumables and travel costs.

- The project period for each Innovation Financial Support starts upon signature of the Grant Agreement by the BioMan4R2 Financial Support Scheme Coordinator. Only costs generated during the lifetime of the project are eligible.
- Personnel costs relevant to the execution of the project are eligible.
- **External costs:** The costs incurred and invoiced by the service provider are eligible for direct funding via BioMan4R2 financial support.
- Prototype and material costs relevant to the execution of the project are eligible.
- Travel costs: Only costs incurred during the trip and related to the purpose of the trip are considered eligible.

Financial Support and VAT

- Deductible VAT <u>is not</u> considered as an eligible cost.
- Non-deductible and non-identifiable VAT <u>is</u> considered as an eligible cost.
- The de minimus rule does not apply to the Bioman4R2 financial support.

Ineligible Costs

- Personal Computers & Devices including phones, tablets, satnavs etc Overhead charges associated with the project
- Depreciation costs of equipment, infrastructure or other assets of the participating SME(s) and collaborators necessary for the project are not eligible.
- Project costs approved and/or incurred prior to the Issue Date of the Innovation
 Financial Support.



Payment Terms

- All payments will be made in EUR.
- Expenditures incurred before the Grant Agreement signature date, or after the project duration period are ineligible for remuneration.
- Costs incurred for the implementation of the project must be used for the sole purpose of achieving the objectives of the project and its expected results, in a transparent manner consistent with the principles of economy, efficiency and effectiveness.
- Beneficiaries have to set up internal contracts regulating their cooperation and any financial payments between the cooperation partners. Bioman4R2 will not be responsible for paying any costs applied for and incurred by the beneficiaries in case of non-compliance with the Guidelines for Applicants of the BioMan4R2 funding scheme.
- Submission of an application does not constitute an entitlement for funding.
- Submission of multiple applications for Innovation Financial Support is possible, but the overall maximum funding available for any SME is € 60.000 (the sum of all BioMan4R2 financial supports awarded to this beneficiary). Any funding received by an SME within the BioMan4R2 fincancial support scheme will be recorded in a list which will include all SMEs receiving financial support in order to ensure the maximum funding of € 60.000 will not be exceeded by a single SME.
- The recipients of the financial support from BioMan4R2 must ensure that the European Commission, the European Anti-fraud Office (OLAF) and the Court of Auditors (ECA) can exercise their powers of control, on documents, information, even stored on electronic media, or on the final recipient's premises.

The evaluation process

The BioMan4R2 Eurocluster will strive to support as many high-impact IFS as possible by aiming a diversification, gender equality and geographical spread of companies supported.

Evaluation Criteria

COVID-19 posed challenges and exposed critical risks in EU supply chains in the health sector. The BioMan4R2 program aims to improve manufacturing processes, transfer disruptive medical technologies, strengthen the competitiveness and sustainability of the European healthcare ecosystem by fostering long-term collaboration among SMEs, investment funds, research, clinical and knowledge-intensive organizations, science and technology parks and other companies in these sectors.

Applications submitted until given deadline are evaluated and rated along three elements:

1. Excellence

a. Ambition: The applicants should provide information about the degree of resilience that this project will bring to the BMT ecosystem respectively to the lead applicant SME in EU and their region and how the project is aligned with their Regional Smart Specialization Strategy.



- b. Soundness of the approach: the applicants should try to explain the resilience gaps the project considers to fill and the need for this kind of financial support.
- c. **European dimension:** One additional point will be given to cross-border collaborations (e.g. at least if one collaborator will come from another European region than the main applicant SME).

2. Impact

- a. **Transversal impact criteria:** The applicants need to demonstrate the level of 'Environment and low carbon economy contribution', 'Equal Opportunities' and/or 'Social Impact' the project will expect to generate.
- b. Economic impact criteria: The applicants need to demonstrate how the output/impact of the financial support will be leveraged in the own organization and describe the expected economic impact (on the BMT Eurocluster's resilience).
- c. Market opportunity criteria: The applicants have to provide information about how the region's BMT innovation ecosystem and local industries will benefit from the innovation / business development / technology transfer as well as will contribute to the degree of European resilience
- d. **Sustainability criteria:** The applicants have to demonstrate their capacity to leverage additional funding and resources to support medium-term participation of the region in BMT ecosystem.
- e. **EU-13** and other regional criteria: One additional point will be given to projects to be implemented in EU-13 regions, and specifically the regions from outside of partner ones, to weigh their participation higher.

3. Implementation

- a. Team: The applicant has to demonstrate that the team will have solid management and leadership qualities, technical comptences and commercial skills needed for successful execution of the project. The team should be balanced and cross-functional team, with a strong background and skill base.
- b. Competences: Solid technical competences of the team providing local technology services is to be demonstrated. Commercial skills of the applicant, meaning its capability to deliver services beyond just executing projects, will be evaluated.
- c. **Budget:** The SMEs will present a budget calculation for the different cost categories (according to template) to justify the requested lump sum.
- d. **Regional alignment:** The match with the Regional Smart Specialization Strategy is to be confirmed.
- The evaluation of the received applications will be done by the BioMan4R2 consortium partners on a rolling basis. Each proposal will be evaluated by two partner experts (out of the BioMan4R2 consortium) from different partner regions. A partner expert based in the same region as one or more of the

The process



- beneficiaries cannot evaluate the referring application to guarantee an objective and fair evaluation
- Applications will be evaluated according following criteria: Impact, implementation and excellence.
- Each of the 3 criteria will be scored out of 15 for impact, 10 for implementation,
 10 for excellence
- Thresholds apply to individual criteria and to the total score. The threshold for impact is 8, for implementation 6 and for excellence 6 and the total overall threshold is 20.
- The final score on each criterion will be given by the average scoring of all Evaluators. If scores on a project show significant divergence between the two Evaluators, a third Evaluator will be involved to provide an additional independent assessment of this proposal.
- The ranking of the applications will be formed by the joint average scoring on Impact, Implementation and Excellence. One extra point maximum will be assigned to projects who have an European dimension (e.g. at least if one collaborator will come from another European region than the main applicant SME, independently from the number of involved European regions) or/and when EU-13 partner and other regional criteria will be met (to projects implemented in EU-13 regions, and specifically the regions from outside of BioMan4R2 project partner ones, to weigh their participation higher, (independently from the number of involved EU-13 regions or involved regions from outside of project partners' regions).
- Maximum score for a proposal is 35 (plus 2 extra points, see above)
- In case of equal scoring the referring applications will be ranked by applying following order:
 - Impact score (0-15)
 - Implementation score (0-10)
 - Excellence score (0-10)
 - An (EU-13 partner) and other regional criteria (+1)
 - Cross-border collaboration (+1)

Reallocation

- The call will be re-opened if insufficient applications or applications that do not meet the criteria are submitted in the BioMan4R2 call.
- If the Grant Agreement is not signed by the selected applicant by the date indicated to the SME via email by providing the Grant Agreement, the applicant with the next highest score on the ranking list will be awarded the grant.
- The BioMan4R2 consortium has the right to award a lower budget to an application in case the milestones described in the application are not met and the reason for this is not clearly provided in the final report. The Financial Support is based on the Lump Sum approach and can only be fully awarded if either achieving the milestones or the effort to achieve the milestones and lessons learned from non-feasible milestones is clarified in the final report.



 When an awarded project is discontinued or when other reasons lead to a nonexhausted budget for the FSTP, the application that was initially highest ranked but fell outside the budget limit, will be rewarded.

Call date

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Please note: the SME applicant cannot apply for and/or receive funding outside of BioMan4R2 for a similar project that could lead to a potential double funding of the same action. The BioMan4R2 Consortium may carry out the necessary control actions with other SMP Eurocluster Consortia and other EU-funded projects to verify that there is no double funding ongoing.





Business Transformation Financial Support (BTFS)

Categories: Go Greener/Digital, Go International & Business legal/financial analysis

Train your worker - Go Greener/Digital: Support for SMEs to acquire training on technology uptake, digitalisation, and sustainable business models from supported providers. Develop training programmes for SMEs on digitalization and digital skills.

Go International: Support for SMEs to implement and make the business agreements and joint collaborative projects commercially viable – e.g. support for travel, third-country market discovery, advice on market access, reimbursement or regulatory challenges in third countries (e.g. FDA in US market)

Business legal/financial analysis and Resilience analysis, business continuity plans, go-to market strategies, advice on reimbursement or regulatory challenges

What you get



Find your partners in the matchmaking database.



Access to cutting-edge digital and green technologies.



Up to a €15000 .



Business Transformation Financial Support (BTFS), Categories: Go Greener/digital, Go international & Business legal/financial analysis

How it works

General guidelines

Who should apply

The applicant must be

- A single SME (who will receive the funding solely to pay other stakeholders involved as service providers)
- Located in the EU and SMP-countries.
- Active in the biomanufacturing/medical technology/life sciences industry.

Scope of the BTFS

The BTFS can be used for

- Category Go Greener/digital: the exploration and/or implementation of Green and Digital technologies with the aim to create a more resilient supply chain
- Category Go International: Implementation and commercial viability of the business agreements and joint collaborative projects
- Category Business legal/financial analysis and Resilience analysis, business continuity plans, go-to market strategies, advice on reimbursement or regulatory challenges

Resilience

Find more information in section ABOUT RESILIENCE

Selection of service provider

Service provider could be

- SME, academic centre or R&D institute, large enterprise.
- Listed preferably within the BioMan4R2 network/Eurocluster matchmaking platform. If no suitable service provider is available, the applicant may propose a service provider that can be approved by the BioMan4R2 consortium (a provided template for external service provider approval has to be filled). No entity/staff of the BioMan4R2 Eurocluster is allowed to act as service provider.
- Matchmaking: The applicant has the opportunity to conduct virtual matchmaking sessions via the project's provided BioMan4R2 matchmaking platform with the selected service providers to get to know each other and discuss further details of collaboration before submission of an application (service providers should already in place by applying)

Value of BTFS

Max € 15.000 per SME

Number of available

10 in total

services



Applications

Interested SMEs will have to fill in an application form for the Business Transformation

Financial support.

Proposals need to be submitted before the deadline. Late proposals will not be admitted. English is the official language for the open calls. The proposal must be in English in all its

mandatory parts in order to be eligible.

Application open

See call dates below.

Contact

Find your regional support organization here.

Communication of results

The applicant will receive an email about the outcome of the assessment. In case of any questions regarding the evaluation results please contact the Financial Support Scheme

Coordinator, Margot Jehle, jehle@bioregio-stern.de.

The validity of the Business Transformation Financial Support is 6 months starting from

the contract date. Remuneration is further explained under 'Payment" below.

Reapplications

Reapplication is not possible.

Project initiation procedure

a. Grant Agreement:

Upon receipt of the confirmation that the application has been granted the lead applicant has to sign a Grant Agreement, which will act as the official agreement between the applicant (SME), and the BioMan4R2 Partnership. BioMan4R2 Partnership will proofcheck its accuracy and level of detailedness to assure the successful completion of the project. The Agreement regulates furthermore the transfer of the financial support.

As soon as the agreement is set up it has to be signed by the applicant (SME) and BioMan4R2 Financial Support Scheme Coordinator within 10 working days before the start of the project. If the Agreement is not signed by the selected applicant within the indicated timeframe, the applicant with the next highest score on the ranking list will be awarded the grant. 50% of the financial support value being awarded will be transferred to the main applicant after the signing of the Agreement. The remaining 50% will be transferred 30 days after approval of the Final Report.

b. Monitoring activities:

The lead applicant SME has to provide information in the form of an **Intermediary Report** for a mid-way quality check after half of the project time, verifying the completion of the project's KPIs which will be validated by the BioMan4R2 Financial Support Scheme Coordinator. Within one month after completion of the project/service purchase, the applicant must submit an online **Final Report** on the activity in accordance with the Grant Agreement.



Note: The applicant must inform the Financial Support Scheme Coordinator immediately about occurring problems, which may compromise the success of the project.

An Extension of the project duration of more than 6 months is only possible in case of unforeseen circumstances and for a maximum of one month extension. Applying for the extension is to be done via the Financial Support Scheme Coordinator and no later than in Month 3 of the project timeline.

Contractual obligation

The successful applicants agree to

- Sign the Grant Agreement and Grant Agreement
- Acknowledge the EU funding and BioMan4R2 project: For dissemination and use
 of results generated through the financial support from BioMan4R2, the recipient
 must credit the EU funding by acknowledging through proper citation and visibility
 of EU support, displaying the European flag (emblem) and funding statement (also
 include the disclaimer) as indicated below, and as well of the BioMan4R2 logo and
 the ECCP logo:







"This project has received funding from the European Union's Single Market Programme, via the Open Call BioMan4R2"

- Allow the BioMan4R2 consortium to use the name of the winners for communication purposes
- Cooperate on establishing a best practice one-pager on the resielience action.

Applicants shall not have any potential conflict of interest with the selection process. All cases of potential conflict of interest will be assessed case by case.

Payment

50% of the financial support value being awarded will be transferred to the lead applicant at the start of the project within 30 days upon signature of the Grant Agreement has been signed (prepayment). The remaining 50% will be transferred within 30 days only upon

- A successful performed intermediary quality check
- Submission and approval of the final report.

In case the final report is not submitted and approved on time, the prepayment must be reimbursed to the BioMan4R2 Financial Support Scheme Coordinator.



Eligible Costs

Eligible costs

Eligible costs are external costs (such as subcontracting costs including consultancy, legal, manufacturing expenditures), and travel costs.

- Only costs generated during the lifetime of the project are eligible. The project period for each Innovation Financial Support starts upon signature of the Grant Agreement by the Financial Support Scheme Coordinator.
- **External costs:** the costs incurred and invoiced by the service provider are eligible for direct funding via BioMan4R2 financial support.
- Travel costs: Only costs incurred during the trip and related to the purpose of the trip.

Financial Support and VAT

- Deductible VAT <u>is not</u> considered as an eligible cost.
- Non-deductible and non-identifiable VAT is considered as an eligible cost.
- The de minimus rule does not apply to the Bioman4R2 financial support.

Ineligible Costs

- Personal Computers & Devices including phones, tablets, satnavs etc Overhead charges associated with the project
- Depreciation costs of equipment, infrastructure or other assets necessary for the project incurred and invoiced to the participating SME(s) and collaborators are not eligible
- Project costs incurred prior to the Issue Date of the Financial Support.



Payment Terms

- All payments will be made in EUR.
- Expenditures incurred before the Grant Agreement signature date, or after the project duration period are ineligible for remuneration
- Costs incurred for the implementation of the project must be used for the sole purpose of achieving the objectives of the project and its expected results, in a transparent manner consistent with the principles of economy, efficiency and effectiveness.
- Beneficiaries have to set up internal contracts regulating their cooperation and any financial payments between the cooperation partners. Bioman4R2 will not be responsible for paying any costs applied for and incurred by the beneficiaries in case of non-compliance with the Guidelines for Applicants of the BioMan4R2 funding scheme.
- Submission of an application does not constitute an entitlement for funding.
- Submission of multiple applications for Business Transformation Financial Support is possible, but the overall maximum funding available for any SME is € 60.000 (the sum of all BioMan4R2 financial supports awarded to this beneficiary). Any funding received by an SME within the BioMan4R2 fincancial support scheme will be recorded in a list which will include all SMEs receiving financial support in order to ensure the maximum funding of € 60.000 will not be exceeded by a single SME.
- The recipients of the financial support from BioMan4R2 must ensure that the European Commission, the European Anti-fraud Office (OLAF) and the Court of Auditors (ECA) can exercise their powers of control, on documents, information, even stored on electronic media, or on the final recipient's premises.

The evaluation process

The BioMan4R2 Eurocluster will strive to support as many high-impact financial support, as possible by aiming a diversification, gender equality and geographical spread of companies supported.

Evaluation Criteria

COVID-19 posed challenges and exposed critical risks in EU supply chains in the health sector. The BioMan4R2 program aims to improve manufacturing processes, transfer disruptive medical technologies, strengthen the competitiveness and sustainability of the European healthcare ecosystem by fostering long-term collaboration among SMEs, investment funds, research, clinical and knowledge-intensive organizations, science and technology parks and other companies in these sectors.

Applications submitted until given deadline are evaluated and rated along three elements:

- 1. Excellence will evaluate:
 - a. SME with proven track record in BMT field.
- 2. Impact will analyse:
 - a. Impact of the proposed service-purchase for the SME internal processes.



- b. Economic impact.
- c. Contribution to the degree of European resilience
- 3. Implementation will consider:
 - a. Budget. Costs justification. The Bioman4R2 evaluators remain the right to adjust the budget if the quality of the project is ranked high but the budget is judged to high in relation to the milestones and activities described.
 - b. Track record of the service provider.

The process

- The evaluation of the received applications will be done by the consortium partners on a rolling basis. Each proposal will be evaluated by two partner experts (out of the BioMan4R2 consortium) from different partner regions. A partner expert based in the same region as one or more of the beneficiaries cannot evaluate the referring application to guarantee an objective and fair evaluation
- Applications will be evaluated according following criteria: Impact, implementation and excellence.
- Each of the 3 criteria will be scored out of 15 for impact, 10 for implementation,
 10 for excellence
- Thresholds apply to individual criteria and to the total score. The threshold for impact is 8, for implementation 6 and for excellence 6 and the total overall threshold is 20.
- The final score on each criterion will be given by the average scoring of all Evaluators. If scores on a project show significant divergence between the two Evaluators, a third Evaluator will be involved to provide an additional independent assessment of this proposal.
- The ranking of the applications will be formed by the joint average scoring on Impact, Implementation and Excellence. One extra point maximum will be assigned to projects who have an European dimension (e.g. at least if one collaborator will come from another European region than the main applicant SME, independently from the number of involved European regions) or/and when EU-13 partner and other regional criteria will be met (to projects implemented in EU-13 regions, and specifically the regions from outside of BioMan4R2 project partner ones, to weigh their participation higher, (independently from the number of involved EU-13 regions or involved regions from outside of project partners' regions).
- Maximum score for a proposal is 35 (plus 2 extra points, see above)
- In case of equal scoring the referring applications will be ranked by applying following order:
 - Impact score (0-15)
 - Implementation score (0-10)
 - Excellence score (0-10)
 - An (EU-13 partner) and other regional criteria (+1)
 - Cross-border collaboration (+1)



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