



BIOMAN^{4R2}

BioManufacturing Eurocluster for Recovery and Resilience in EU

D3.5 Final evaluation report

Author: STERN – BioRegio STERN Management GmbH

Grant Agreement: No. 101074495



BIOMAN^{4R2}

**BUSINESS
TURKU**



BioRegioSTERN 



MedSilesia
European Medical Cluster



Co-funded by
the European Union

I. Document Information

Grant Agreement Number	101074495	Acronym	BioMan4R2
Full title	BioManufacturing Eurocluster for Recovery and Resilience in EU		
Project URL			
Project Officer	Arianna Dellaca		

Deliverable number: 3.5		Title	Final Evaluation Report		
Work Package number: 3		Title	SME Support programme implementation		
Delivery date		Contractual	31/08/2024	Actual	31/08/2024
Status	Final	Version number: 1		Final	
Nature		R — Document, report			
Dissemination level		PU - Public			

Project Coordinator	Tero Piispanen	Email: tero.piispanen@turkubusinessregion.com
Partner	Turku Science Park Oy Ab	Phone:

Author(s) Partner(s)	BioRegio STERN Management GmbH		
Responsible partner	Dr. Margot Jehle	Email	jehle@bioregio-stern.de
		Phone	+49-173 1808924
Contributor		Email	
Contributor		Email	

Deliverable description	Document where the final evaluation results of the SME support programme are described.
Key words	Financial support scheme, Innovation Financial Support, Business Transformation Financial Support

II. History of Versions

Version	Date	Changes	Page (if applicable)
V1	29/08/2024	Initial draft generated	N/A

III. Disclaimer

The content of this document represents the views of the author only and is his/her sole responsibility; it cannot be considered to reflect the views of the European Commission and/or the European Innovation Council and SMEs Executive Agency (EISMEA) or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.

IV. Executive Summary

The present Deliverable 3.5 Final Evaluation Report has been developed within the framework of **WP3 SME Support Programme Implementation**.

The Final Evaluation Report is a document to be shared with stakeholders interested in the implementation and impact of Financial Support for Third Parties (FSTP) as part of BioMan4R2 Support Programme which supported small and medium-sized enterprises (SMEs) in the adoption of new technology or making use of services to become more resilient, sustainable and/or digital. Increasing the resilience of companies through direct financial support should also help to strengthen the entire BMT ecosystem and build more reliable, less disruptive supply and value chains. The document provides all details for the whole final evaluation process and the referring requirements for projects received FSTP through the BioMan4R2 Support Programme, such as project timeline, contribution of project partners or service providers, status of key performance indicators (KPIs) and amendments made to achieve envisaged KPIs. In addition, the impact according to several key aspects defined in the application process is evaluated to get insights on how the FSTP helped the companies to improve their current status.

The BioMan4R2 Support Programme aimed 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.

About the BioMan4R2 Support Programme

The BioMan4R2 project within the European SMP COSME programme launched an open call on April 27, 2023 providing financial support via lump sums, and networking for SMEs in the biomanufacturing and medical technology manufacturing sectors that want to increase their resilience, sustainability and competitiveness. The application process and guidelines for applicants are summarized in D3.1 SME Support Programme Implementation Plan. The call was closed on July 2, 2023. In total 118 proposals were submitted of which 26 were selected and announced on July 18, 2023. The list of winners was published on the [BioMan4R2 Matchmaking Platform](#) and the [ECCP website](#). 16 projects were awarded Innovation Financial Support (IFS, see Annex I) with a maximum amount of 60,000EUR and 10 were awarded Business Transformation Financial Support (BTFS, see Annex II) with a maximum amount of 15,000EUR. In total, the winning projects were awarded a sum of 1,050,000EUR. The Open Call process, the level of interest from different European countries and the list of winners are published in the [D3.2 Open Call Report](#). Before the start of the projects, the awarded SMEs signed a Grant Agreement which was a prerequisite to receive the FSTP. In beginning of August 2023, 50% of the FSTP was transferred to the awarded SMEs; max. 30,000EUR per IFS and 7,500EUR per BTFS resulting into a total amount of 525,000EUR. The approved projects started in the time period between August 1, 2023 and October 1, 2023. The duration of the projects was between 3 – 6 months. All awarded SMEs have been obliged to provide an Intermediary Report for a mid-way quality check after half of the project time, verifying the completion and/or status of the project's key performance indicators (KPIs) which were validated by the BioMan4R2 Financial Support Scheme Coordinator. Applicants had to describe in the application form the KPIs that should be measurable and achievable within six months. Applicants therefore had to indicate a deadline for each KPI. In the case of the IFS, the applicant had to specify three planned KPIs and in the case of the BTFS, two planned KPIs. The KPIs served as a basis for the BioMan4R2 Financial Support Scheme Coordinator to assess the progress of the project activities and to find solutions together with the applicant in case of delays in meeting the KPIs as planned. After the mid-way quality check, the distribution of funding was changed since one SME withdrew their grant agreement and retransferred the funding of an IFS project. The available FSTP was partially allocated to a new BTFS project (15,000EUR) which was the next applicant in the ranking list who was not on the list of winners and to an already awarded IFS project that received remaining funding (1,425EUR) for which the lead applicant SME had not applied for the maximum budget of 60,000EUR, but for 45,000EUR. This resulted in 15 projects awarded with IFS and 11 projects awarded with BTFS. The results of the mid-way quality check are summarised in D3.4 Intermediary evaluation report which will be published on ECCP.

BioMan4R2 Final Evaluation - Overview

Upon completion of the project or service, the selected SMEs were required to submit a final report on the activities and KPIs. This report had to demonstrate that the work undertaken was in line with the grant agreement and the criteria for impact, implementation and excellence as outlined in the application form. The BioMan4R2 Financial Support Scheme Coordinator evaluated the completion of KPIs, impact of FSTP brought to the European biomanufacturing and medical technology (BMT) ecosystem and future activities planned after the completion of the projects.

The lead applicants received the Final Report form on August 10, 2023 which were different for IFS and BTFS in terms of the KPIs (see Annex III). The lead applicant SME had to report on the following items:

- Timeline: status of the project and deviation from the envisaged timeline (if any)
- Contribution of partners or service providers: status of the contribution and possible changes
- Key performance indicators: 3 KPIs for IFS and 2 KPIs for BTFS and deviation from envisaged KPIs (if any)
- Budget: status of the budget spent by mid of project on an optional basis.
- Impact: in total 12 impact criteria were defined. Beneficiaries had to provide information on 3 most important factors for IFS, and 2 most important factors for BTFS.
- Project's contribution to sustainability of business growth: SMEs enabled to leverage additional investments, funding and/or resources
- Project status and potential developments: future actions planned after completion of the project

The BioMan4R2 Financial Support Scheme Coordinator received in total 26 completed final reports between October 30, 2023 and August 6, 2024 provided by the lead applicant SMEs: 15 for IFS and 11 for BTFS. The project status achieved for the final evaluation was assessed on the basis of the information provided in the submitted applications. The Financial Support Scheme Coordinator checked the quality of the report as well as the completion of the set KPIs on individual project-basis. In case of insufficient information provided within the final report, the Financial Support Scheme Coordinator returned the report to the SME with request for revision. As part of the final report evaluation, SME provided a one-pager to spread the success stories on project's achievements in the wider BioMan4R2 Eurocluster as well as within biomanufacturing & medtech ecosystems across the partnership (see Annex IV). The key messages of the success stories are summarized in D3.6 The Financial support scheme execution report and will be published on the BioMan4R2 LinkedIn channel and ECCP. The awarded SME only received the second half of the FSTP when the final report and one-pager met the quality requirements. Once the final report and the one-pager was approved the lead SME received an official letter of approval (see Annex V).

Evaluation of Timeline

The maximum duration of an IFS or BTFS project should not exceed six months, as specified in the grant agreements between the applicant SME and the Financial Support Scheme Coordinator. In practice, the project duration was between three and six months. Over the course of the project, eight of the fifteen IFS and three of the eleven BTFS lead applicant SMEs requested an extension to their respective projects. According to the Guidelines for Applicants an extension of the project duration of more than 6 months in total 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. The extension was granted in all cases, since they were in line with the rules set out in the Guidelines for Applicants. Actually, 6 IFS and 3 BTFS indicated in the final report that they needed the project extension of one month (Figure 1).

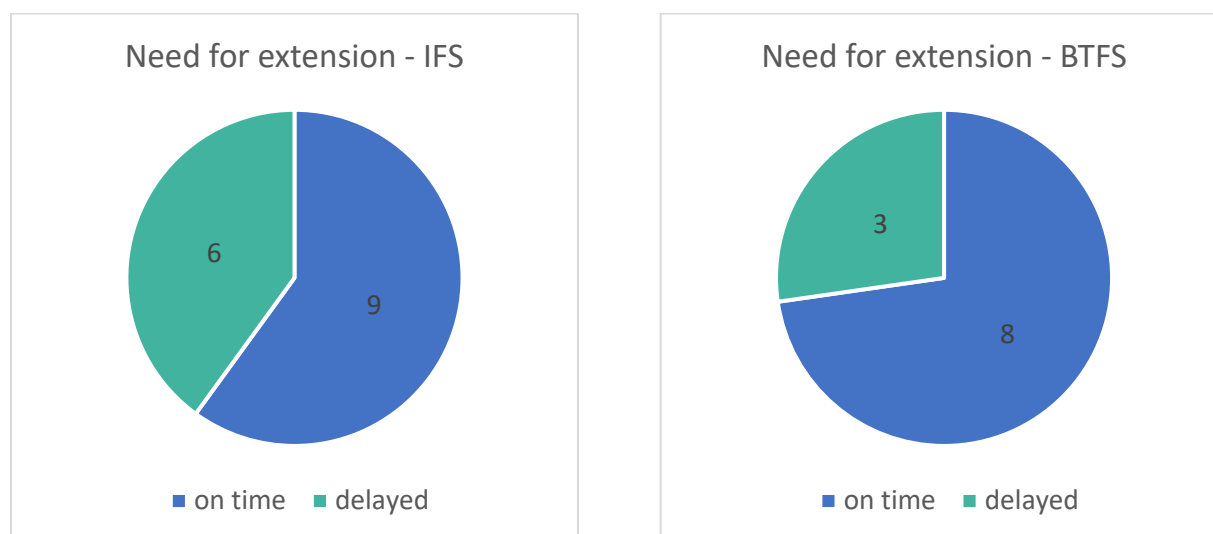


Figure 1: For project completion, 6 out of 15 Innovation Financial Support (IFS) projects and 3 out of 11 Business Transformation (BTFS) projects required a longer project duration than the specified 6 months.

The reasons for the project extensions are the same as reported in the intermediary report (Figure 2). Since, one IFS project was cancelled due to severe delays the number of affected projects slightly changed. A total of 6 different reasons were reported, all of which were unforeseeable. The three main reasons for project extensions were the delayed involvement of co-operation partners or service providers, manufacturing issues of components and issues with clinical study set up. Some delays occurred in the drafting of contracts or difficulties with the timely provision of services. In addition, problems related to upstream manufacturing led to an extension request, as some processes in biological manufacturing are complicated and require customisation due to the very specific requirements of biological materials. This may involve fermentation processes or the production of gene expression constructs. The regulatory requirements for the approval of medical devices represent a major hurdle, particularly for SMEs. Clinical trials are part of the approval process, which includes ethical voting, agreements with hospitals/clinics as test sites or the recruitment of the right patient groups. All these steps have an impact on the timeline of a project and the outcome is unpredictable for clients. Another reason for a project extension is the small number of employees in SMEs, where any loss of staff can have a negative impact on the project results.

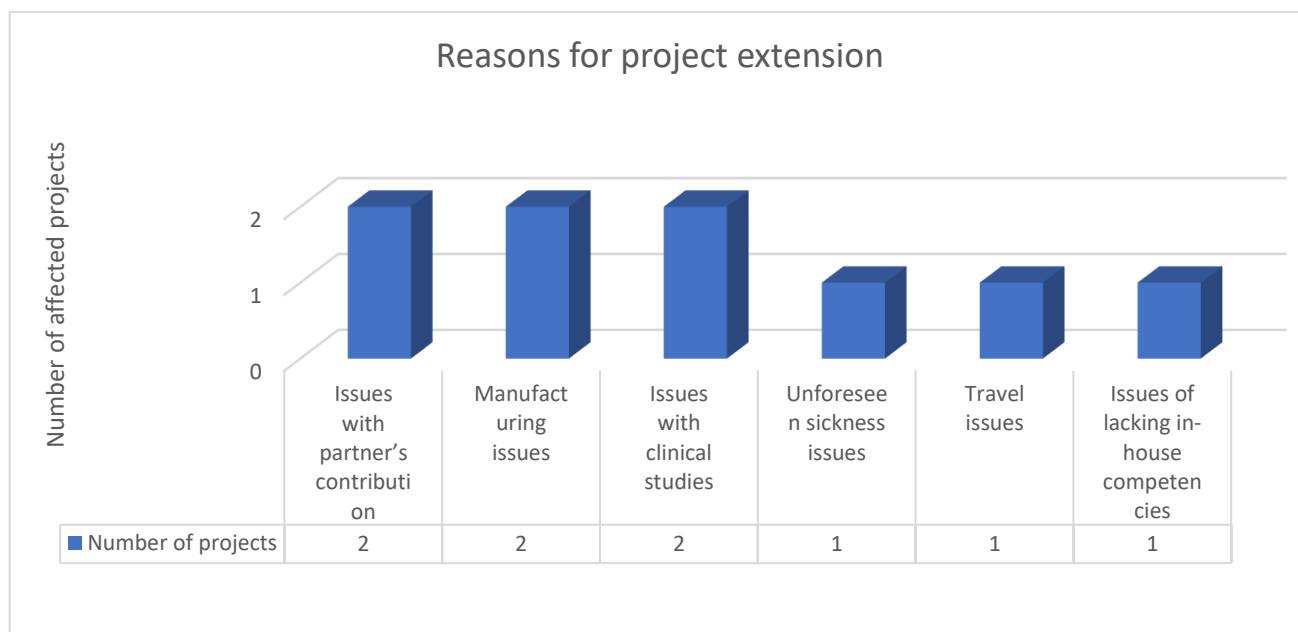


Figure 2: In total, 6 categories of reasons for project extensions were specified related to 9 projects.

Thanks to the close cooperation between the lead applicant SMEs and the Financial Support Scheme Coordinator, most of the problems were overcome via the support of one month project extensions. According to the final reports almost all projects were on track as described in the applications. Only in the case of two IFS projects and one BTFS project was the lead applicant SME unable to complete the activities as planned even after project extension (see next chapter). In such cases, the SME was asked to provide further information in the final report on the expected completion of the planned activities and KPIs. Once the activities and KPIs had been completed, the SME sent an addendum to the final report summarising the relevant information on the completed activities. The Financial Support Scheme Coordinator received the additional information from the three SMEs concerned.

According to the feedback in the final report provided by SMEs, there were no delays in 17 of the 26 projects, with 2 projects being completed ahead of schedule.

Evaluation of activities planned in the project

In order to ascertain the status of the projects, the SMEs were requested to indicate whether the activities outlined in the project plan had been carried out and completed in accordance with the original schedule. With regard to the IFS project, 13 projects were successfully completed. In the case of two projects, it was not feasible to complete the planned activities (Figure 3). The completion of the activities was duly communicated to the Financial Support Coordinator in the addendum. In one instance, the SME provided final data regarding the recruitment of patients to a clinical study. In another instance, the SME was able to scale up the purification process of a human-derived protein that was expressed in a newly established fermentation procedure.

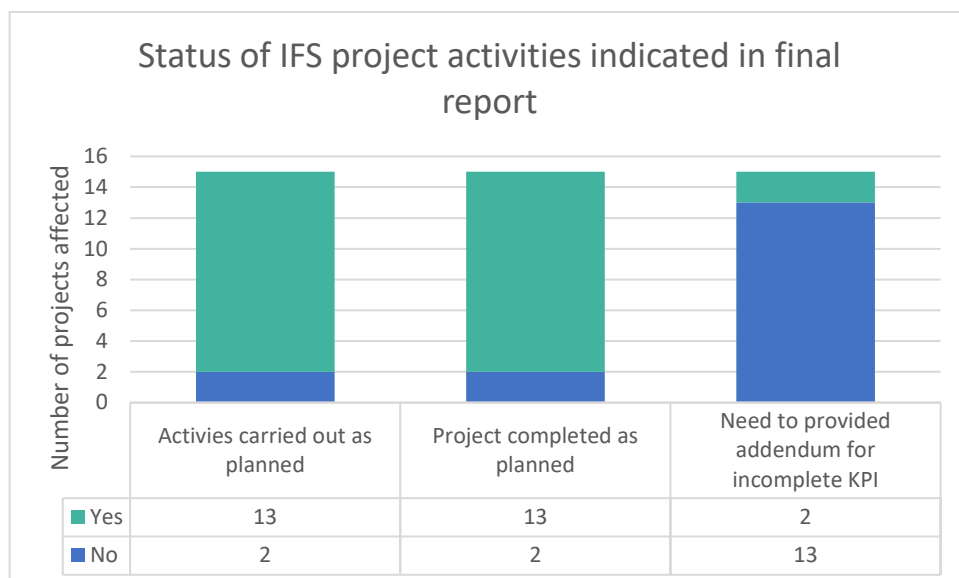


Figure 3: Status of Innovation Financial Support (IFS) project activities as reported by lead applicants and number of projects that have submitted an addendum to the final report on activities completed after the end of the project.

Nearly half of the BTFS project activities were not carried out as planned (Figure 4), which was also reported in the intermediary report. With support through project extension from the Financial Support Coordinator 3 of the SMEs were enabled to complete the project activities as planned. Only one SMEs struggled to complete the project activities within the 6-month duration. The completion of the project activities was reported about one month after the submission of final report in the addendum. The SME was able to complete the missing part of the project activities which was due to delays in the planned gap analysis for marked access in USA caused by the service provider.

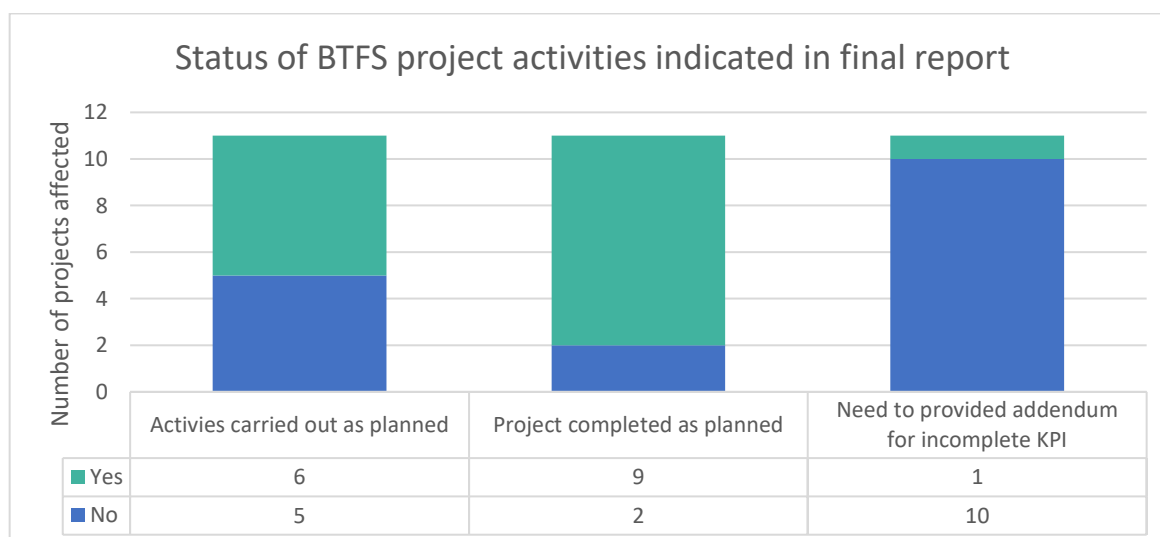


Figure 4: Status of Business Transformation Financial Support (BTFS) project activities as reported by lead applicants and number of projects that have submitted an addendum to the final report on activities completed after the end of the project.

In summary, 22 out of 26 SMEs were able to complete their project as planned with some minor adjustments regarding the activities. Only, three SMEs needed to complete their project some further time. At the end all

projects were completed as outlined in the application form with some minor deviation such as replaced partner or unexpected outcome of material characteristics (see next chapters).

Evaluation of partners' or service providers' contributions

At the final evaluation, the lead applicant SMEs reported on whether the partners had carried out the relevant activities described in the application. The final reports for the IFS projects indicated that in 12 cases the cooperation partner contributed to the project as planned, while two cooperation partners led to delays in the planned schedule (Figure 5). Two lead applicant SMEs decided to replace the partner in order to carry out the project and achieve the KPIs. The reason for replacing the partner in one case was the high cost of the clinical trial and the potentially low number of patients recruited to participate in the clinical trial. Replacing the partner enabled the SME to reach the planned number of subjects and stay within the planned budget. The second lead applicant SME opted for an alternative software company whose services are better suited to the needs of the platform to be used for processing and computing patient data. In the case of one SME, it was not possible to replace the partner, as the collaborator had already completed the relevant part of the process, which involved structuring the surface of an object, which did not result in the expected properties required for the subsequent process. The company decided to continue this process with improved parameters after the project ended.

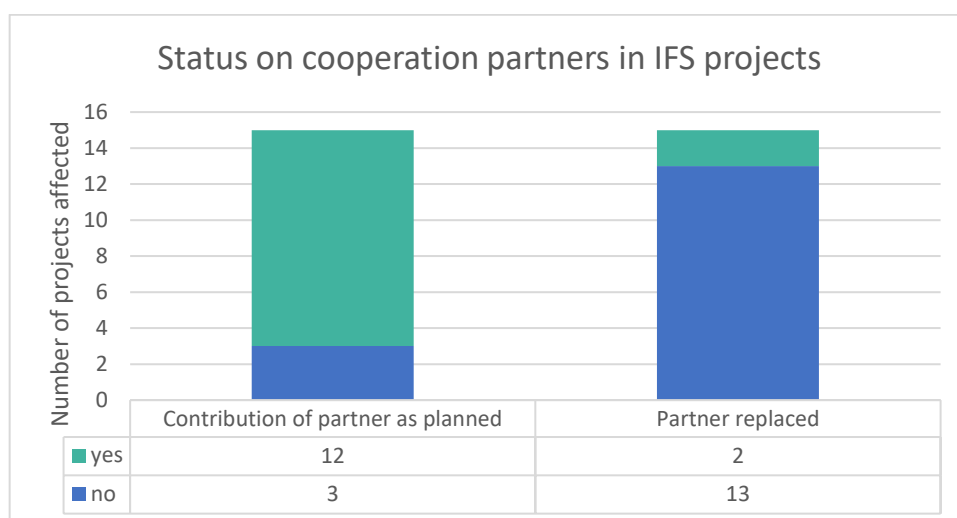


Figure 5: Partners contribution in Innovation Financial Support (IFS) projects as reported by lead applicants.

The final reports for the BTFS projects show that in three cases the partner did not contribute to the project as originally planned, while eight co-operation partners contributed to the activities as planned (Figure 6). Two of the applicants concerned decided to replace the partners in order to implement the project and achieve the KPIs. The reason for replacing the partner in one case was that the new software specialist was able to provide more comprehensive services than the first one specified in the application form. As a result, the lead applicant SME was able to achieve the targeted KPIs as planned. The second lead applicant SME replaced the service provider as the latter was unable to adapt its approach to the project's requirements. In one project, the service provider was no longer involved in the planned activities due to being unavailable at the start of the project. The activities (intern training on Medical Device Regulation, ISO standards, quality and risk management) were taken over by a second service provider that had already been specified in the application

form and was competent to carry out the activities. It was therefore not necessary to replace or acquire a new service provider.

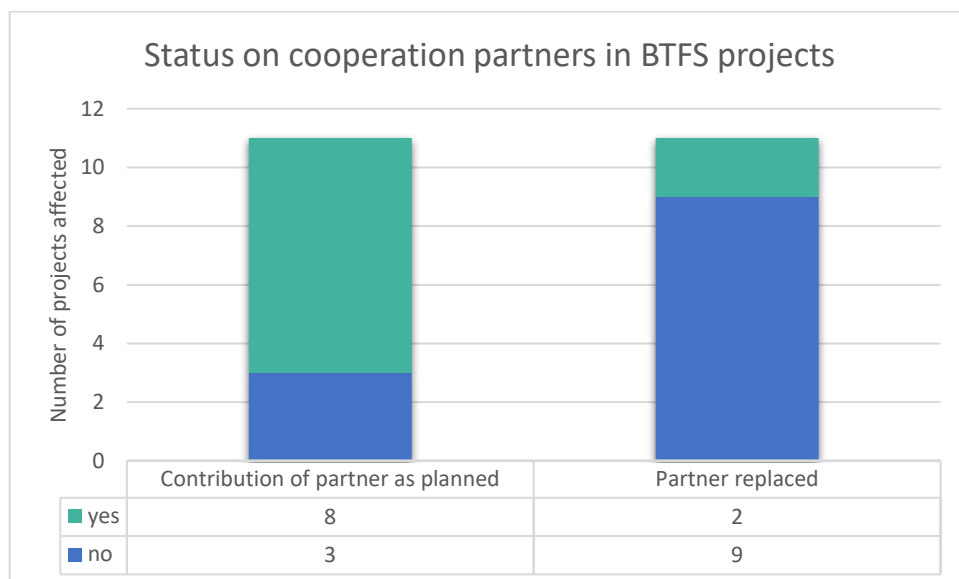


Figure 6: Partners contribution in Business Transformation Financial Support (BTFS) projects as reported by lead applicants.

Regarding the cooperation with projects partners and/or service providers, 22 projects were successfully completed with the partners/service providers as indicated in the application forms. Only in four cases the lead applicant SME decided to replace the partner/service provider to achieve the KPIs and completed activities as planned.

Evaluation of key performance indicator status

In the 26 final reports completed by the lead applicant SMEs, the KPI status achieved at the final evaluation was indicated. In the case of delays, the applicant provided information on the reasons for the delay. For the KPI delays, the same reasons apply as described in the section on timeline delays.

Within the final reports related to IFS projects the lead applicant SME had to provide information about the status (timeline) of their three envisaged KPIs according to the provided information within the submitted application. The status of the KPIs as stated in the final report is shown in Figure 7. At the final evaluation, the status of KPI1 was as follows: "done" (14 projects), or "incomplete" (1 projects). For KPI2 and KPI3, the status was "done" (13 applications), or "incomplete" (2). In case of five projects the KPIs deviated from originally expected outcome. Only in one case was the lead applicant SME unable to complete the KPI defined in the application form, which related to two versions of the newly structured material. One version fulfilled the characteristics as planned, the other version failed. As this KPI was half completed, the entire project was considered complete without the need to submit an addendum. The other two projects with incomplete KPIs delivered the addendum as described above in the chapter on partner contributions.

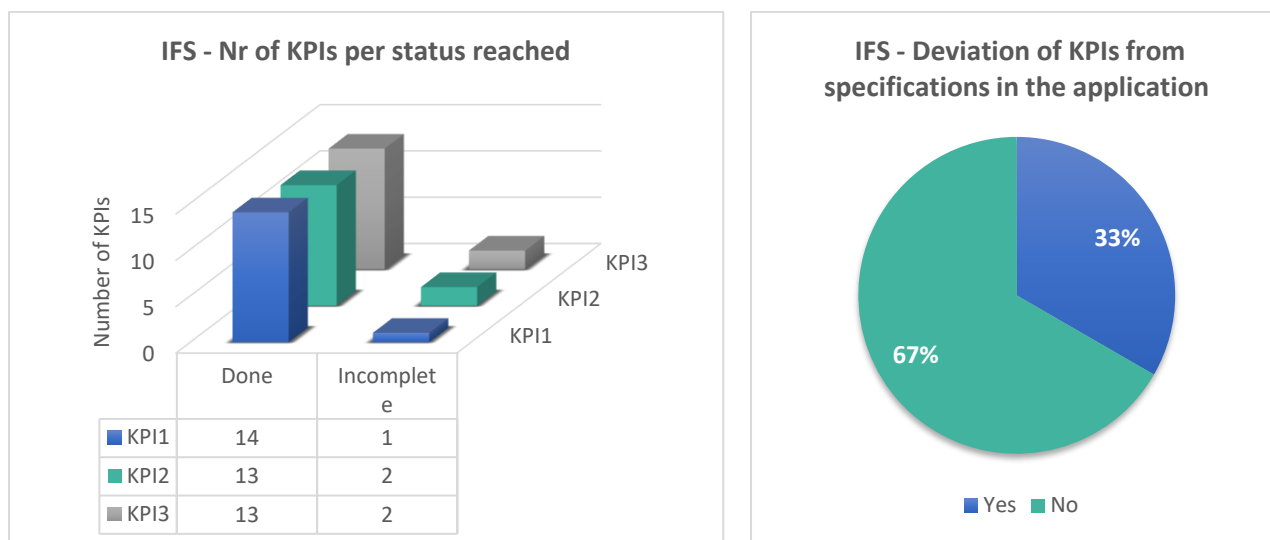


Figure 7: The status of the key performance indicators (KPIs) as indicated in the final report for Innovation Financial Support (IFS) by the lead applicant SMEs.

Within the final reports related to BTFS projects the lead applicant SME had to provide information about the status (timeline) of their two envisaged KPIs according to the provided information within the submitted application. The status of the KPIs is shown in Figure 8. At the final evaluation, the status of KPI1 was as follows: “done” (11 projects) as planned or “incomplete” (0 projects). For KPI2, the status was “done” (10 projects), or “incomplete” (1 project).

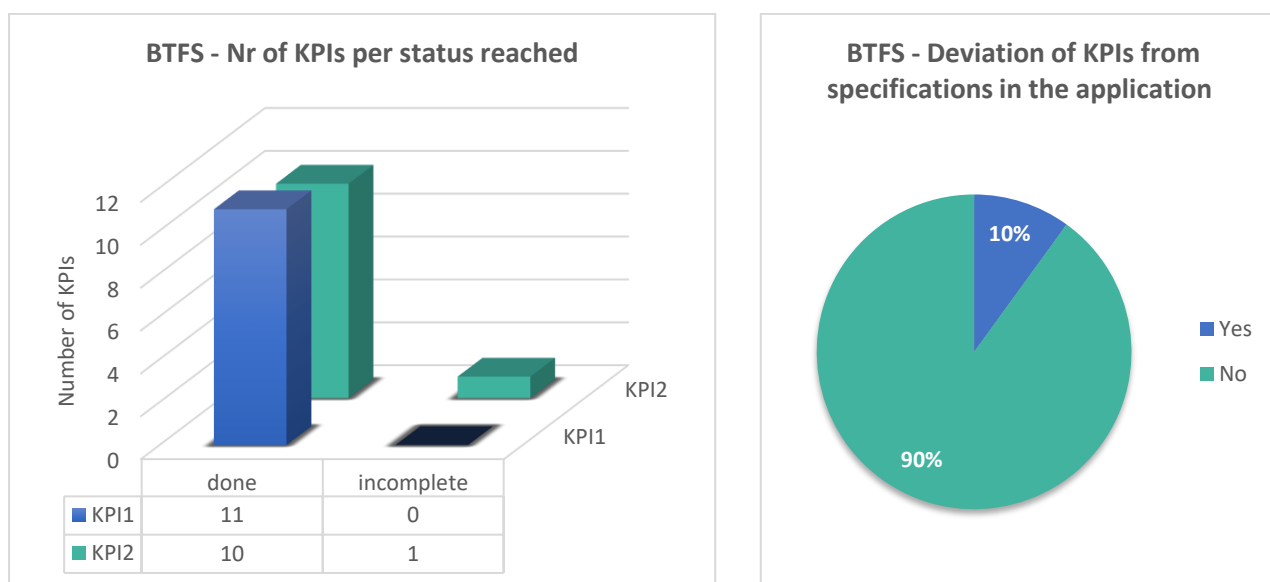


Figure 8: The status of the key performance indicators (KPIs) as indicated in the final report for Business Transformation Financial Support (BTFS) by the lead applicant SMEs.

In the case of incomplete KPIs, the lead applicant SME was requested to prepare an addendum to the final report providing information on the further results of the incomplete KPIs. As described in the sections on timeline, project activities and partners' contribution, the addendum was submitted by all concerned SMEs indicating that the KPIs had been completed.

Impact of Financial Support for Third Parties on SMEs' businesses and BMT ecosystem

The aim of the Bioman4R2 funding programme is to promote the resilience, sustainability and competitiveness of EU SMEs in the field of biomanufacturing and medical technology (BMT). A further objective is to support SMEs in becoming more digitalised, greener, internationalised and more skilled. In order to gain insight into the main impacts of the FSTP on SME businesses and the BMT ecosystem, SMEs were asked to select three out of 12 impact categories for IFS projects and two out of 12 for BTFS projects. In addition, SMEs were asked to explain why this category contributed to improvements in the BMT sector.

Figure 9 shows the main impacts of IFS on the SMEs' businesses. A total of 54 responses were received. The top three impact factors of IFS are "resilience for regional BMT ecosystem & beneficiary" (selected by 11 SMEs), "internal processes of beneficiary" (selected by 9 SMEs) and "technology" (selected by 7 SMEs). This reflects the use of the funding, which was mainly used to collaborate with research institutions to further develop or valorise existing products and services in order to extend their applications to wider or new areas. The categories related to go green (selected by 5 SMEs) and digitalised (selected by 3 SMEs) have not the highest impact on the SMEs businesses but are in the middle range.

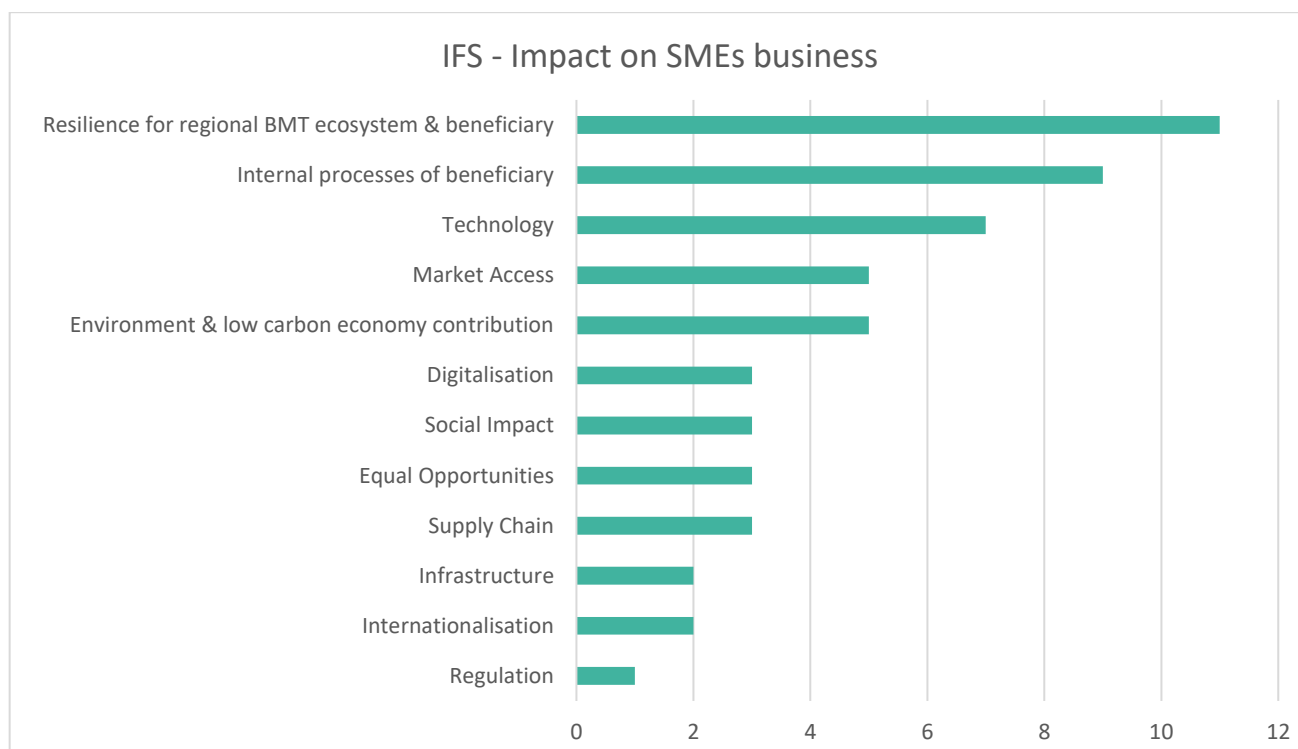


Figure 9: Impact of Innovation Financial Support (IFS) on small and medium sized enterprises' (SMEs) businesses selected by the lead applicant SME. Each SME was asked to provide feedback on the three main impact categories. Some SMEs provided feedback to more than three impact categories.

The top three impact categories of BTFS on the SMEs' businesses, as identified by the respondents, also included "internal processes of beneficiary" (selected by 6 SMEs). However, in contrast to IFS, the categories "market access" (selected by 5 SMEs) and "regulation" (selected by 4 SMEs) were considered to have the highest impact (Figure 10). On rank four, three SMEs indicated that the funding had also had an impact on the digitalisation of their businesses.

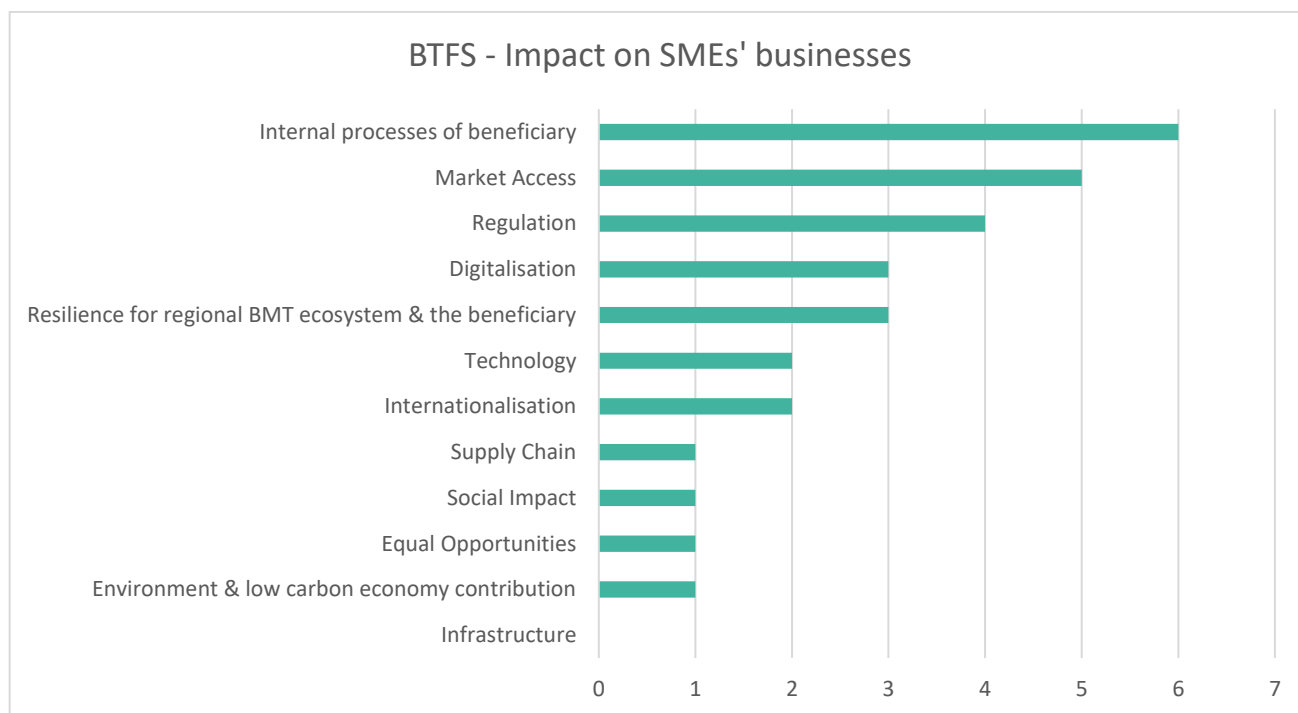


Figure 10: Impact of Business Transformation Financial Support (BTFS) on small and medium sized enterprises' (SMEs) businesses selected by the lead applicant SME. Each SME was asked to provide feedback on the three main impact categories. Some SMEs provided feedback to more than three impact categories.

To illustrate the actual benefits of the FSTP for SMEs and their BMT ecosystem, the feedback from SMEs on the resilience category is summarised in Table 1. As indicated, the IFS not only has an impact on resilience within the company processes and business, but also on the regional and European BMT ecosystem. This demonstrates the high overarching benefits of the BioMan4R2 funding programme, which improves the entire BMT sector by strengthening the development of new materials and compounds, improving production and purification processes, driving digitalisation, e.g. through digital platforms for data processing, stabilising supply chains and introducing sustainable and environmentally friendly technologies. These results will improve bioproduction and lead to high-quality and innovative healthcare for society as a whole.

The BTFS has a greater impact on the internal processes of SMEs, which will improve their competitiveness and business growth. As indicated by the SMEs, they will implement the results of the services, such as business continuity plans, enter new markets and diversify their product portfolio to be better prepared for market fluctuations.

A detailed overview of the testimonials provided by lead applicant SMEs on the BioMan4R2 Support Programme is compiled in Del3.6 The Financial support scheme execution report.

In summary, feedback from participants in the BioMan4R2 support programme demonstrates a very positive impact on internal and external processes. This contributes to improving the resilience of EU industrial

ecosystems by developing value chains, building innovation capacities, adopting processes and technologies and improving access to global supply and value chains.

Table 1: Feedback on the impact of the Innovation Financial Support (IFS) and Business Transformation Financial Support (BTFS) on resilience reported by lead applicant small and medium sized enterprises (SMEs).

Resilience for regional Biomanufacturing and Medical technology ecosystem and the beneficiary as indicated by SMEs	
IFS	
✓	Increased resilience within Belgium's biomanufacturing environment through successful technology transfer and strategic alliance between industrial and academic partners driving advancements within the country's biomedical technology domain.
✓	Use of local suppliers to manufacture the raw part of our tooling and the material processing. The solution is an R&D platform which allows collaboration within the ecosystem to innovative smart material
✓	New production process of recombinant proteins in yeast serves as a pharmaceutical development platform for biologicals
✓	New sustainable, cost-efficient and environmentally friendly purification process will be provided as new services on production of clinical candidates for pharma companies developing drugs
✓	New vegan friendly production process of silk proteins for medical device developers and manufacturers as part of the material supply chain
✓	Related to AI-driven diagnostic device for dermatological care. Adhering to and influencing regulatory standards ensures sustainable operations and industry growth. Innovation in medical technology, facilitated by our project, bolsters the region's biomanufacturing capabilities.
✓	Integration of new software fosters resilience for the regional biomanufacturing and medical technology ecosystem by facilitating access to cutting-edge genomic analysis tools and enabling more efficient and effective patient care pathways
✓	BMT community will largely benefit from the AI Platform, which will enable technological transfer, new innovations and businesses within the BMT ecosystem
✓	Process development based on new technology is able to mass produce biotherapies at scale with limited resources
✓	Production automation of high-end consumables such as materials with activated surfaces
✓	Development of a supply chain for metal microparts in Europe reducing risks of supply chain failure
BTFS	
✓	Implementation of a Business Continuity Plan is expected to accelerate company's growth
✓	Company is prepared for global market challenges and compliance with international regulations
✓	Beneficiary gained up-to-date knowledge and skills that will enable them to introduce medical products to the market
✓	Beneficiary gained insights on crucial elements for market diversification positively impacting company growth and resilience against market fluctuations.

Impact of FSTP to enable SMEs in leveraging further funding, investment or resources

A key objective of the BioMan4R2 SME Support Programme was to facilitate the leveraging of further funding and/or investment, as well as new resources (e.g. equipment, staff) by SMEs. All SMEs that received an IFS grant indicated that the funding enabled them to be better prepared to access funding, investment and other resources (Table 2).

Table 2: Impact of Innovation Financial Support (IFS) indicated by small and medium sized enterprises (SMEs) enabling them to gain access to further funding, investment, or resources are presented here. The number of votes received for each category is shown in the final column.

SME enabled by IFS to	Indicated by
acquire further public funding/private investment with higher success rate	7 SMEs
identify new business partners	2 SMEs
acquire successfully public funding/private investment	2 SMEs
apply for public funding programme	1 SME
purchase new equipment/hire new staff/implement of new production line	3 SMEs

Eight of the 11 SME recipients of BTFS indicated that the assistance provided had facilitated the acquisition of additional investment or resources (Table 3).

Table 3: Impact of Business Transformation Financial Support (BTFS) indicated by small and medium sized enterprises (SMEs) enabling them to gain access to further funding, investment, or resources are presented here. The number of votes received for each category is shown in the final column.

SME enabled by BTFS to	Indicated by
acquire further public funding/private investment with higher success rate	4 SMEs
identify new business partners	1 SMEs
acquire successfully public funding/private investment	2 SMEs
apply for public funding programme	1 SME

As indicated by the lead applicant SMEs the FSTP facilitated the acquisition of subsequent funds and additional resources. In total, seven out of 26 SMEs successfully secured funding/investment (4 SMEs) or deployed new resources (3 SMEs) over the course of the project. The majority of SMEs will only benefit from the support once the project has reached its completion.

The next steps planned by lead applicant SMEs after project completion

In order to find out how the results will be processed after the end of the project, the main applicants were asked to provide an assessment.

As indicated in Table 4, the majority of lead applicants will continue with regulatory approval and clinical trials after project completion (as indicated by 8 SMEs), followed by improving processes, standards or user experience (as indicated by 5 SMEs) and validating and refining their processes, products or services (as indicated by 5 SMEs). This also reflects the impact of the IFS, where improving internal processes is identified as one of the top three factors.

Table 4: Next steps planned after the completion of the Innovation Financial Support (IFS) projects as indicated by the lead applicant small and medium sized enterprises (SMEs).

Next step plans after completion of IFS projects	Indicated by SMEs
Regulatory Approval, Clinical Trial	8
Improve processes, standards, user experiences	5
validation and refining system	5
Cooperations with new partners	4
Further develop platform, new models, software	3
Scaleup processes	3
Enter new markets/Internationalisation	3

Related to BTFS projects the lead applicant SMEs indicated as well that Regulatory approval (as indicated by 3 SMEs) will be required in the next step. In addition, implementation of systems, business or strategic plans will be followed after project completion (Table 5).

Table 5: Next steps planned after the completion of the Business Transformation Financial Support (BTFS) projects as indicated by the lead applicant small and medium sized enterprises (SMEs).

Next step plans after completion of BTFS projects	Indicated by SMEs
Implementation of systems or plans	3
Regulatory approval	3
Enter new markets/Internationalisation	2
Market access	2
Cooperation with new partners	2
Validation and refining system	1

Regulating the BMT sectors is a challenge for SMEs, as the authorisation of new products is associated with high hurdles. In addition, SMEs rarely receive public funding for this task. The results of the final report demonstrate the significant demand. Such support measures benefit not only the companies, but the entire healthcare sector. SMEs in particular were overwhelmed by the introduction of the MDR/IVDR and are therefore dependent on support. The BioMan4R2 funding programme presents an exemplary scenario that illustrates the usefulness of funding steps of the regulatory approval processes of BMT SMEs.

Conclusion

The analysis of the final reports prepared by the SMEs indicates that most projects were completed in accordance with the original plan as outlined in the application forms. A minority of projects, specifically 40% of IFS and 27% of BTFS projects, required an extension of one month. Nevertheless, 85% of projects were able to fulfil the planned activities and KPIs. Only three projects (two IFS and one BTFS) required approximately one additional month after project extension to complete all project activities and KPIs. Cooperation with the project partners and/or service providers proceeded in accordance with the description in the application form in 77% of cases. Two partners in each of the IFS and BTFS projects were replaced by others who were better suited to achieving the project objectives in a reliable manner. The IFS and BTFS funding had the significant impact on resilience within the BMT ecosystem and the lead applicant SME, demonstrating the impact on both

external and internal processes. Moreover, the funding enabled the beneficiaries to secure additional funding, investment, resources and partners. Upon completion of the project, the majority of beneficiaries will prioritise product approval, process improvement and validation, and the initiation of new cooperation projects.

In conclusion, the direct financial support was highly beneficial for the entire BMT ecosystem, allowing stakeholders to utilise the BioMan4R2 Eurocluster's expert and service provider network to enhance the resilience of EU industrial ecosystems by developing new value chains and interlinkages in the EU Single Market, particularly relevant for the health sector and related biomanufacturing and medical technology sectors. This contributes to an increase in strategic autonomy. In order to build new capacities in enhanced technologies (such as AI, biomaterials and biotechnology), SMEs were enabled to adopt new processes and technologies to reinforce transformation into a greener and more digital economy (such as fermentation, vegan protein production, environmentally friendly purification processes, AI-based diagnostic tools or digitalised documentation processes and data analysis platform). In addition, the up-skill of the workforce and provision of training in regulatory and market entry aspects, and support in internationalisation to boost access to global supply and value chains was achieved thanks to the cooperation of the BioMan4R2 partnership.

Annexes

Annex I – List of IFS winners

Table 6: List of the winners received Innovation Financial Support (IFS) through the BioMan4R2 Support Programme.

IFS Winner	Country	Project Title	Category	Co-Partner (Country)	FSTP [€]
*Robeauté	FR	Microrobots for neurosurgery - revolutionising access to complex areas of the central nervous system	Neurology	FEMTIKA (LT) AMAROB (FR)	60,000
*Plantibodies	FR	Plant-Based Oral Immunotherapy for Gastrointestinal Diseases: A Resilient Bioproduction Approach	Gastroenterology	Prodigest (BE) CDMO (BE)	60,000
InSpek SAS	FR	On-chip Raman spectroscopy sensors to monitor in-line and in real time the bioproduction	Bioproduction	URD ABI AgroParisTech (FR)	60,000
Antleron NV	BE	3D-printing and beta-testing of customised 3D fixed bed (3D-FB) cell culture disposables	Manufacturing process	Leuven Viral Vector Core (LVVC) (BE)	60,000
*Fibrothelium GmbH	DE	Biosynthetic protein production in plants for bioabsorbable implants	Bioproduction	Aachen-Maastricht Institute for Biobased Materials (NL)	59,335
ATTOM	FR	New modular device to support other companies to create and test complex in vitro models for preclinical research purposes	Validation process	Healshape (FR) ICO (FR) UCBL labs (FR)	60,000
MindAhead UG	DE	Validation of digital therapy tool for improving brain health	Neurology	Medical Innovations Incubator	60,000

IFS Winner	Country	Project Title	Category	Co-Partner (Country)	FSTP [€]
				GmbH (DE)	
*ALTA sp. z o.o.	PL	Validation of a new psychological memory test	Neurology	Prometriks Ltd (BG)	59,760
*/**MIRA Vision Microscopy GmbH	DE	Scaling up AI-assisted image analysis for microscopy	Imaging	Jaydevs LLC (LT)	45,000 +1,425
Time is Brain SL	ES	Validation real-time brain monitoring tools of stroke patients	Neurology	University Hospital La Princesa (ES) University Hospital Sant Pau (ES) University Hospital Arnau de Vilanova (ES)	60,000
MAGIC GENOMIX	FR	Revolutionizing cancer treatment by developing a theragnostic solution, relevant in multiple cancer types	Oncology	ValoTec (FR)	60,000
*PolyAn GmbH	DE	Filling the gap: Automated production line for glass slides with reactive surface functionalization	Imaging	Eccom OÜ (EE) Herbert Stamm KG (DE)	60,000
*IntegraSkin GmbH	DE	Overcoming regulatory, economic, and market entry barriers for diagnostic device providing effective treatment plans for chronic skin conditions	Dermatology	Medical Innovations Incubator GmbH (DE)	60,000

IFS Winner	Country	Project Title	Category	Co-Partner (Country)	FSTP [€]
				ITSAN NGO (USA) Charité IFA (DE) Bestseller Verlag GmbH (DE)	
*Basic Pharma	NL	Reducing pharmaceutical development time and costs and increase the change of success by setting up a European joint supply chain for the GMP production of biologicals	Manufacturing process	ARTES Biotechnology GmbH (DE)	60,000
*Care4living Oy	FI	Validation of cost-effective fermentation and purification process for a cytotoxic small molecule drug	Manufacturing process	University of Turku (FI) NIHM BV (NL)	60,000

*Transnational cooperation

**Received reallocated FSTP

Annex II – List of BTFS winners

Table 7 List of winners received Business Transformation Financial Support (BTFS).

BTFS Winner	Country	Project Title	Category	Co-Partner (Country)	FSTP [€]
SITEC pharmabio	ES	Business Continuity Plan to aligned with the regulatory requirements of Pharma and Nutra sectors	Business legal / financial analysis	GENESIS Biomed (ES)	15,000
*Zeisberg GmbH	DE	Market Entry beyond Europe of a new video oculography system	Go International	AHK Kanada (CA) Emergo by UL (USA) DQS DE	15,000
*Egerton sp. Z o.o.	PL	Project B: Transitioning to MDR for class I medical devices, including gap analysis, clinical evaluation, and EMC testing	Train your worker-Go Greener/Digital	novineon CRO (DE) ELZAB Laboratory (PL)	15,000
Manitty	FR	Developing a headband in line with European regulations in terms of RGPD, CE marking and MDR	Business legal / financial analysis	SQI (FR)	15,000
JAFRAL d.o.o.	SI	Creating a specialized digital module for managing service providers to comply with GMP standards	Train your worker-Go Greener/Digital	Miran Janežič s.p. (SI)	15,000
*Breaz Medical SL	ES	Creating clinical evaluation plan under the provisions of the MDR for a lung disease diagnostic device	Business legal / financial analysis	novineon CRO GmbH (DE)	14,920
Earlab GmbH	DE	Implementation of the QMS and the commencement of compliant development of a medical device for hearing assessment	Business legal / financial analysis	Medical Innovations Incubator GmbH (DE)	14,760
Egerton sp. Z o.o.	PL	Project C: Legal, market, and resilience analysis to outline the regulatory landscape, market dynamics,	Business legal / financial analysis	Scheelite Sp. z o.o. (PL)	14,800

BTFS Winner	Country	Project Title	Category	Co-Partner (Country)	FSTP [€]
		and potential obstacles for a system for digitizing nursing rounds			
*Gate2Brain S.L.	ES	Strategic roadmap of Market Access to achieve the inclusion of a drug candidate to treat pediatric cancer patients in different Early Access Programs in the EU	Business legal / financial analysis	AliraHealth SAS (FR)	15,000
ONIRIA THERAPEUTICS, S.L.	ES	Market Access analysis to gain a comprehensive understanding of the four key European markets and the UK for melanoma treatment.	Go International	Alira Health SLU (ES)	15,000
*/**Egerton sp. Z o.o.	PL	Project A: Training of the human resources in risk management and post-market surveillance in order to be in compliance with the requirements of the Medical Device Regulation.	Train your worker- Go Greener/Digital	novineon CRO GmbH (DE)	15,000

*Transnational cooperation

***Received reallocated FSTP



Co-funded by
the European Union

BioMan4R2 Financial Support Scheme

Final Report

Innovation Financial Support

Disclaimer:

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or EISMEA. Neither the European Union nor the granting authority can be held responsible for them.

Table of contents

<u>Beneficiary details</u>	26
<u>Project timeline</u>	26
<u>Partner or service provider contribution to the project</u>	26
<u>Key performance indicator (KPI) status</u>	26
<u>Budget details spent by end of project</u>	26
<u>Impact achieved through your project</u>	27
<u>Project's contribution to sustainability of business growth</u>	27
<u>Project status and potential developments</u>	27

Beneficiary details

Name of organization	
Name of person who completes this final report	
Date of completing this final report	

Project timeline

Were activities carried out as defined in application or were there any changes?	☐ Yes ☐ No
In case of changes, please describe	
Is the project completed?	☐ Yes ☐ No
Please indicate schedule delays and how you plan to complete the project.	

Partner or service provider contribution to the project

Did the partner(s) / service provider(s) contribute to the progress of the project as planned in the application?	☐ Yes ☐ No
In case of changes, please describe:	
What did the partner(s) / service provider(s) deliver to you?	Please describe per partner(s) / service provider(s) the contribution to the project. Also indicate any deviations from planned contribution.
Partner / Service provider 1	
Partner / Service provider 2	
Partner / Service provider 3	
Partner / Service provider 4 (please, extend if needed)	

Key performance indicator (KPI) status

Please describe the status of the KPIs	
- KPI 1	
- KPI 2	
- KPI 3	
Are there any delays/deviation in achieving the KPIs	☐ Yes ☐ No
If yes, please describe how you manage to achieve the KPIs as planned.	

Budget details spent by end of project

Please, indicate the budget you have spent for each partner by the end of your project	Budget spent per partner and category (personnel, external, consumable, travel costs)	Date of budget transfer to partner / service provider
--	---	---

- Beneficiary		
- Partner / Service provider 1		
- Partner / Service provider 2		
- Partner / Service provider 3		
- Partner / Service provider 4 (please, extend if needed)		
Are there any delays/deviation in spending budget as planned, please describe:		

Impact achieved through your project

What impact does funding have on the following categories?	Please, select 3 most important factors and briefly describe the impact (about <u>100 words</u>).
- Internal processes of beneficiary	
- Environment and low carbon economy contribution	
- Equal Opportunities	
- Social Impact	
- Resilience for regional Biomanufacturing and Medical technology ecosystem and the beneficiary	
- Digitalisation	
- Internationalisation	
- Regulation	
- Infrastructure	
- Technology	
- Supply Chain	
- Market Access	

Project's contribution to sustainability of business growth.

Has the financial support enabled you to leverage additional investments, funding and/or resources in or by your SME?	
---	--

Project status and potential developments.

Please summarize the progress of your project and indicate future actions planned to finalize (around <u>300-500 words</u>)	
--	--

Signature of BioMan4R2 Beneficiary (SME)

Name of the BioMan4R2 Beneficiary organisation:

Name of the legal representative:

☐ I confirm that the information indicated above is correct (please tick box)

Date and Signature (and stamp if available; digital provided signature is allowed):



Co-funded by
the European Union

BioMan4R2 Financial Support Scheme

Final Report

Business Transformation Financial Support

Disclaimer:

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or EISMEA. Neither the European Union nor the granting authority can be held responsible for them.

Table of contents

<u>Beneficiary details</u>	32
<u>Project timeline</u>	32
<u>Partner or service provider contribution to the project</u>	32
<u>Key performance indicator (KPI) status</u>	32
<u>Budget details spent by end of project</u>	32
<u>Impact achieved through your project</u>	33
<u>Project's contribution to sustainability of business growth</u>	27
<u>Project status and potential developments</u>	33

Beneficiary details

Name of organization	
Name of person who completes this final report	
Date of completing this final report	

Project timeline

Were activities carried out as defined in application or were there any changes?	☐ Yes ☐ No
In case of changes, please describe	
Is the project completed?	☐ Yes ☐ No
Please indicate schedule delays and how you plan to complete the project.	

Partner or service provider contribution to the project

Did the partner(s) / service provider(s) contribute to the progress of the project as planned in the application?	☐ Yes ☐ No
In case of changes, please describe:	
What did the partner(s) / service provider(s) deliver to you?	Please describe per partner(s) / service provider(s) the contribution to the project. Also indicate any deviations from planned contribution.
Partner / Service provider 1	
Partner / Service provider 2	
Partner / Service provider 3	
Partner / Service provider 4 (please, extend if needed)	

Key performance indicator (KPI) status

Please describe the status of the KPIs	
- KPI 1	
- KPI 2	
Are there any delays/deviation in achieving the KPIs	☐ Yes ☐ No
If yes, please describe how you manage to achieve the KPIs as planned.	

Budget details spent by end of project

Please, indicate the budget you have spent for each partner by the end of your project	Budget spent per partner and category (external, travel, other costs)	Date of budget transfer to partner / service provider
- Beneficiary		
- Partner / Service provider 1		

- Partner / Service provider 2		
- Partner / Service provider 3		
- Partner / Service provider 4 (please, extend if needed)		
Are there any delays/deviation in spending budget as planned, please describe:		

Impact achieved through your project

What impact does funding have on the following categories?	Please, select 1 - 2 most important factors and briefly describe the impact (about <u>50 words</u>).
- Internal processes of beneficiary	
- Environment and low carbon economy contribution	
- Equal Opportunities	
- Social Impact	
- Resilience for regional Biomanufacturing and Medical technology ecosystem and the beneficiary	
- Digitalisation	
- Internationalisation	
- Regulation	
- Infrastructure	
- Technology	
- Supply Chain	
- Market Access	

Project's contribution to sustainability of business growth.

Has the financial support enabled you to leverage additional investments, funding and/or resources in or by your SME?	
---	--

Project status and potential developments.

Please summarize the progress of your project and indicate future actions planned to finalize (around <u>100-200 words</u>)	
--	--

Signature of BioMan4R2 Beneficiary (SME)

Name of the BioMan4R2 Beneficiary organisation:

Name of the legal representative:

☐ I confirm that the information indicated above is correct (please tick box)

Date and Signature (and stamp if available; digital provided signature is allowed):

Annex IV – One-pager templates

BioMan4R2 best practice one -pager



■ About your company - What is your company providing? (product, service, etc.)

Please enter a non-confidential statement by replacing this text, which we can publish via social media and the project website (max. 570 characters)

■ What will be tackled with the funded project?

Please enter a non-confidential statement by replacing this text, which we can publish via social media and the project website (max. 570 characters)

■ Please indicate the impact of the financial support on your company?

Please enter a non-confidential statement by replacing this text, which we can publish via social media and the project website (max. 570 characters)

■ Overall Testimonial on the Financial Support Programme:

Please enter a non-confidential statement by replacing this text, which we can publish via social media and the project website (max. 570 characters)



BioMan4R2 best practice one -pager



- Describe the resilience for regional Biomanufacturing and Medical technology ecosystem and your company/business:

Please enter a non-confidential statement by replacing this text, which we can publish via social media and the project website (max. 570 characters)

- Additional Comments you wish to include in your testimonial/interview:

Please enter a non-confidential statement by replacing this text, which we can publish via social media and the project website (max. 225 characters)

- Please add your corporate logo in **high resolution** and with **transparent background**:

logo



Annex V – Approval Letter template



Co-funded by
the European Union

BioMan4R2 Financial Support Scheme

Approval of Final Report

Disclaimer:

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or EISMEA. Neither the European Union nor the granting authority can be held responsible for them.

Beneficiary details

Name of organization	
Name of person who completed the final report	
Date of receipt of the final report	DDMMYYYY
Total FSTP Grant	
Value of 2 nd payment (50 % FSTP Grant)	
Date of approval Final Report	

Information about approval of Final Report

The Coordinator of the Financial Support Scheme approved your final report. The payment will be transferred to you within the next 30 days at the latest.

Sincerely

The BioMan4R2 Coordinator of the Financial Support Scheme