



# **BioManufacturing Eurocluster** for Recovery and Resilience in EU

**D3.4 Intermediary evaluation report** 

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Grant Agreement: No. 101074495





















### I. Document Information

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### **II. History of Versions**

Version	Date	Changes	Page (if applicable)
V1	27/03/2024	Initial draft generated	N/A
V2	29/08/2024	Reviewed initial draft generated	
		Added "key performance indicators"	Page 6
		Corrected "Once the Grant Agreements were signed by all awarded SMEs in beginning of August 2023"	Page 6
		Added "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."	Page 6
		Added "key performance indicators"	Page 7
		Added "applied for the maximum budget of 60,000EUR, but for 45,000EUR only. This was the simplest way to distribute the remaining funds. Due to the small amount, it would have been difficult to support a next ranked project where the benefit of this funding would not have led to a significant improvement in the resilience of the company's business or the BMT ecosystem."	Page 10
		Added "Which means that applicants from outside the partner countries (partner countries involved in BioMan4R2 Eurocluster: DE, FI, FR, ES, NL, PL) or applicants from an EU-13 country (Bulgaria, Croatia, Cyprus, Czechia, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia, and Slovenia) received an extra point to ensure a higher ranking in the evaluation process. In addition, applicants with partnerships from two different European countries were given an extra point to encourage transnational cooperation, defined as projects with a European dimension. This could be transnational cooperation between applicants from two countries in the territorial	Page 10 - 11



area of the BioMan4R2 Eurocluster, or between one partner from this area and one from outside this area, or both partners from outside the area but from two different European countries."  Added "Four applications from EU-13 countries: Poland	Page 11
(3), Slovenia (1). Three applications from outside the partners countries: Austria (1), Belgium (1), Slovenia (1). Other EU means EU countries except EU-13 countries. List of EU-13 countries is provided in main text."	
Added: "Five applications from EU-13 countries: Poland (4), Slovenia (1). Two applications from outside the partners countries: Belgium (1), Slovenia (1). Other EU means EU countries except EU-13 countries. List of EU-13 countries is provided in main text."	Page 12
Added: partners from "at least two" different countries	Page 12
Replaced number in main text:European dimension, i.e. "12" transnational co-operation between partners from at least two different countries, has changed after Mid-Way Quality Check.	Page 12
Replaced numbers in table 2 "13   50%"	Page 12
Replaced numbers in table 2 "12   46 %"	Page 12
Added "Out of the 26 granted applications a total of 14 applications had no "European dimension" meaning the lead applicant and collaborator(s) are not from two different EU countries, which could be classified under various categories, including EU-13 countries or outside the partner countries. For example, an application may come from the lead applicant and partner both from Slovenia, but from an EU-13 country. Alternatively, an application may come from the lead applicant and partner both from Belgium, not from an EU-13 country but from outside the partner countries. For further details, refer to Annexes 1 and 2, which provide overviews of applications indicating countries of lead applicants and partners."	Page 13



### III. Disclaimer

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### **IV. Executive Summary**

The present Deliverable 3.4 Intermediary Evaluation Report has been developed within the framework of **WP3 SME Support Programme Implementation**.

The Intermediary Evaluation Report is a document to be shared with stakeholders interested in the implementation of Financial Support for Third Parties (FSTP) and the BioMan4R2 Support Programme's progress on the half-time are described. The document provides all details for the whole Mid-way quality check 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.

The BioMan4R2 Support Programme 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.



### **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 small and medium-sized companies in the biological products 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 will be 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.

### BioMan4R2 Mid-Way Quality Check

Once the Grant Agreements were signed by all awarded SMEs in beginning of August 2023, 50% of the FSTP was transferred to the lead applicant 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 lead applicant SMEs have been obliged to provide an Intermediary Report for a mid-way quality check after half of the project time, verifying the completion 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.

The awarded lead applicants received the Intermediary 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.

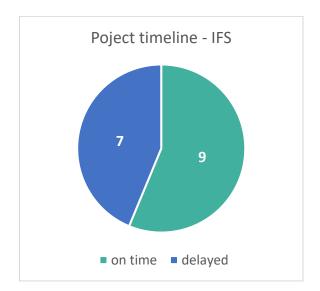
The BioMan4R2 Financial Support Scheme Coordinator received in total 26 completed intermediary reports between September 9, 2023 and January 12, 2024 provided by the lead applicant SMEs: 16 for IFS and 10 for BTFS. The project status achieved for the mid-way quality check was assessed on the basis of the information provided in the submitted applications. To discuss the status of the projects and potential improvements to achieve the envisaged KPIs within the project's timeline, the BioMan4R2 Financial Support Scheme Coordinator arranged online meetings with each lead applicant SME. As a follow-up, the SMEs received guidance on how to proceed with the project in terms of preparing the final report and completing 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.

### **Evaluation of Timeline**

Within the first half of the project duration 7 out of 16 IFS and 3 out of 10 BTFS lead applicant SMEs asked for extension of their project (Figure 1). 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.



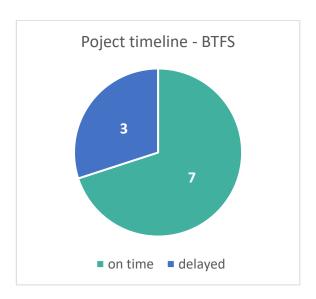


Figure 1: Evaluation of project timeline. 7 out of 16 IFS projects and 3 out of 10 BFTS project had issues to achieve envisaged key performance indicators (KPIs) within the planned timeline.

The reasons for the project extensions are shown in Figure 2. A total of 6 different reasons were reported, all of which were unforeseeable. The main reason for project extensions was the delayed involvement of cooperation partners or service providers. Most delays occurred in the drafting of contracts or difficulties with the timely provision of services. Only in one case the SME was not successful in finalising a contract with its partners. As an extension of more than 30 days was required, the lead applicant decided to withdraw the grant agreement and transfer the first half of the funds back to the Financial Support Scheme Coordinator (see section Reallocation of FSTP). 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. Thanks to the close cooperation between the lead applicant SMEs and the



Financial Support Scheme Coordinator, all problems were overcome via the support of one months project extensions and thus almost all projects are on track as described in the applications.

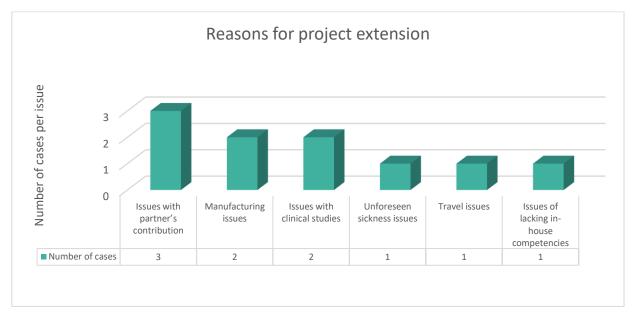


Figure 2: In total, 6 categories of reasons for project extensions were specified related to 10 projects.

There were no delays in 16 of the 26 projects, with 2 projects being completed ahead of schedule.

### Evaluation of partners' or service providers' contributions

At the mid-way quality check, the lead applicant SMEs reported on whether the partners had carried out the relevant activities described in the application. The intermediary reports for the IFS projects indicated that in 12 cases the cooperation partner contributed to the project as planned, while four cooperation partners led to delays in the planned schedule. One lead applicant decided to replace the partner in order to implement the project and achieve the KPIs. One applicant was unable to work with their original partner or find a new partner in time to complete the activities, as previously stated. Therefore, the funding was allocated to two other companies (see section "Reasons for reallocation of financial support for third parties").

The intermediary reports for the BTFS projects indicated that in one case the partner did not contribute to the project as originally planned while 9 co-operation partners contributed to the activities as planned. The respective applicant decided to replace the partner in order to implement the project and achieve the KPIs.

### Evaluation of key performance indicator status

In the 26 interim reports completed by the lead applicant SMEs, the KPI status achieved at the mid-way quality check 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 intermediary 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 is shown in Figure 3. At the mid-way quality check, the status of



KPI1 was as follows: "done" (7 applications), "in progress" as planned (4 applications) or "delayed" but started (5 applications). For KPI2, the status was "done" (2 applications), "in progress" as planned (9 applications), "delayed" but started (3 applications) or "not started" (2). Finally, the status of KPI3 was "done" (1 application), "in progress" as planned (8 applications), "delayed" but started (2 applications) or "not started" (4 applications).

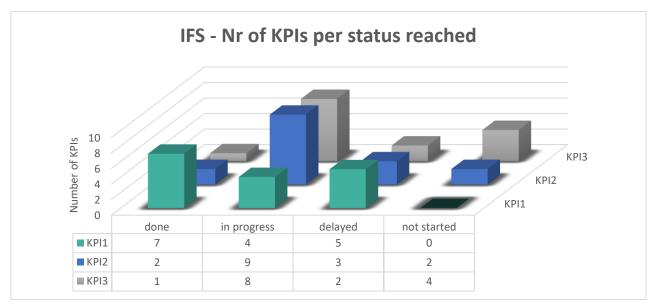


Figure 3: The status of the key performance indicators (KPIs) as reported for Innovation Financial Support (IFS) by the lead applicant SMEs.

Within the intermediary 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 4. At the mid-way quality check, the status of KPI1 was as follows: "done" (5 applications), or "in progress" as planned (5 applications). For KPI2, the status was "done" (1 application), "in progress" as planned (5 applications), or "not started" (4 applications).

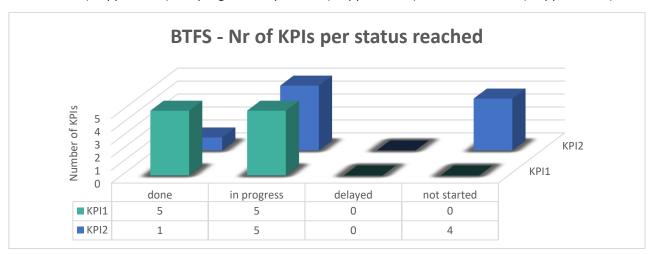


Figure 4: The status of the key performance indicators (KPIs) as reported for Business Transformation Financial Support (BTFS) by the lead applicant SMEs.



### Reasons for reallocation of financial support for third parties

One SME having received an IFS grant had major difficulties in realising the planned project. This was caused by the cooperation partner, who did not sign the cooperation agreement on time, resulting in a delay of more than 30 days. The applicant therefore decided to withdraw from the BioMan4R2 Grant Agreement and repay the received 50 % of financial support with an amount of 8,212.50EUR which means that a total amount of 16,425EUR was available for funding a new project. The BioMan4R2 consortium was able to grant one more IFS application than planned due to the fact that some lead applicant SMEs haven't requested the maximal amount for the referring FSTP within their applications (see D.3.2 Open Call Report). In accordance with the Guidelines for Applicants, the refunded budget was transferred to the next applicant in the ranking list who was not on the list of winners. The BioMan4R2 partners decided to support a BTFS with an amount of 15,000EUR. The lead applicant of the additionally nominated BTFS grant accepted to receive the funding and started the project on March 8, 2024, which will be subject of Mid-Way Quality Check and the final report. Since the remaining amount of 1,425EUR was not enough to fund a complete project, the BioMan4R2 partners decided to transfer it to an IFS winner whose project had not applied for the maximum budget of 60,000EUR, but for 45,000EUR only. This was the simplest way to distribute the remaining funds. Due to the small amount, it would have been difficult to support a next ranked project where the benefit of this funding would not have led to a significant improvement in the resilience of the company's business or the BMT ecosystem. The additional funding was accepted by the lead applicant of the IFS.

### **Amendments resulting from Mid-Way Quality Check**

After the completion of the Mid-Way Quality Check only minor changes compared to envisaged timeline, partner contribution and KPIs were monitored. Only one lead applicant withdrawn their application, which however resulted in a different number related to the FSTP categories (see Table 1) and in an altered geographical distribution of the applications.

Table 1: Changed number of of IFS applications and BTFS applications granted after Mid-Way Quality Check.

	Innovation Fin	ancial Support	Business Transformat	ion Financial Support		
	Mid-Way Quality Check					
	before	after	before	after		
Number of applications	16	15	10	11		

Through the BioMan4R2 Support programme it is intended to support 10% applications from outside the partner countries and/or 10% from EU-13 countries. Which means that applicants from outside the partner countries (partner countries involved in BioMan4R2 Eurocluster are DE, FI, FR, ES, NL, PL) or applicants from an EU-13 country (Bulgaria, Croatia, Cyprus, Czechia, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia, and Slovenia) received an extra point to ensure a higher ranking in the evaluation process. In addition, applicants with partnerships from two different European countries were given an extra point to encourage transnational cooperation, defined as projects with a "European dimension". This could be transnational cooperation between applicants from two countries in the territorial area of the BioMan4R2



Eurocluster, or between one partner from this area and one from outside this area, or both partners from outside the area but from two different European countries.

As reported in <u>D3.2 Open Call Report</u> the awarded applications were distributed as shown in Figure 5 where indicating the numbers of applications from outside the partner countries:

Austria: 1 awarded application
 Belgium: 1 awarded application
 Slovenia: 1 awarded application

#### and E13 countries:

Poland: 3 awarded applicationsSlovenia: 1 awarded application



Figure 5: Geographical spread of awarded applications before the Mid-Way Quality Check (NL = Netherlands). Four applications from EU-13 countries: Poland (3), Slovenia (1). Three applications from outside the partners countries: Austria (1), Belgium (1), Slovenia (1). Other EU means EU countries except EU-13 countries. List of EU-13 countries is provided in main text.

The geographical distribution of applications after the Mid-Way Quality Check are shown in Figure 6 which resulted in following changes for numbers of applications from outside the partner countries:

Belgium: 1 awarded applicationSlovenia: 1 awarded application

### and E13 countries:



Poland: 4 awarded applicationsSlovenia: 1 awarded application

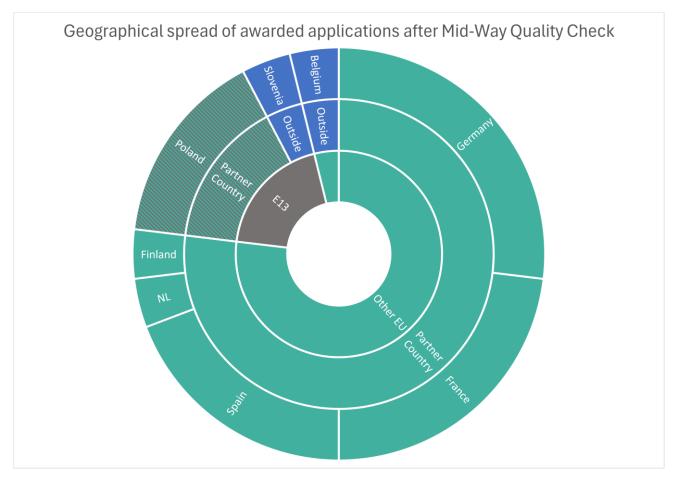


Figure 6: Geographical spread of awarded applications after the Mid-Way Quality Check (NL = Netherlands). Four applications from EU-13 countries: Poland (4), Slovenia (1). Two applications from outside the partners countries: Belgium (1), Slovenia (1). Other EU means EU countries except EU-13 countries. List of EU-13 countries is provided in main text.

The new ratio of 26 applications from outside the partner countries and/or from EU-13 countries is shown in Table 2. The number of applications with a European dimension, i.e. 12 transnational co-operation between partners from at least two different countries, has changed after Mid-Way Quality Check. Of the 26 applications, the portion of applications from outside the partner countries decreased slightly from 12% to 8% and is therefore below the target level of 10% of supported applications from outside the partner countries. In contrast, the portion of supported applications from the EU-13 countries increased from 15% to 19%.

Table 2: Changed number of applications from outside the partner countries and EU-13 countries after Mid-Way Quality Check. The percentage refers to the 26 approved applications.

	Mid-Way Quality Check				
	before % after				
European dimension	13	50%	12	46%	
Outside partner countries	3	12%	2	8%	
EU13 countries	4	15%	5	19%	



Out of the 26 granted applications a total of 14 applications had no "European dimension" meaning the lead applicant and collaborator(s) are not from two different EU countries, which could be classified under various categories, including EU-13 countries or outside the partner countries. For example, an application may come from the lead applicant and partner both from Slovenia, but from an EU-13 country. Alternatively, an application may come from the lead applicant and partner both from Belgium, not from an EU-13 country but from outside the partner countries. For further details, refer to Annexes 1 and 2, which provide overviews of applications indicating countries of lead applicants and partners.



### The next steps

### 1. Mid-Way Quality Check

The newly granted BTFS project started in March 2024 is also obliged to provide an Intermediary Report until half time of the project duration (July 8<sup>th</sup>, 2024). This report should include information on the Key Performance Indicators (KPIs) progress and the impact achieved up to that point as provided within this evaluation report. The aim of this check is to assess the project's performance and make any necessary adjustments for the successful completion of the project. However, the results will not be part of the D3.4 Intermediary evaluation report.

### 2. Final Step - Reporting

The SMEs must submit an online final report in line with the Key Performance Indicators (KPIs) mentioned in the application. This report should highlight the project's activities, achievements, and outcomes. Once approved, 50% of the remaining funds will be transferred.

### 3. One-pager for communication purposes

The SMEs must complete a so-called one-pager which contains non-confidential information on their company, project aims and testimonials on the BioMan4R2 Support Programme. The information will be disseminated via the LinkedIn channel and the partners' ecosystem to show the impact of the financial support to third parties in the biomanufacturing and medical technology sectors.

#### Conclusion

The high demand for financial support, as offered under the BioMan4R2 Support Programme, with 118 project applications, shows the need to help companies from the biomanufacturing and medical technology sectors with tailored measures. This may involve digitalisation, production of biological compounds or regulatory requirements. The number of applicants from all over Europe also emphasises that the outreach work was extremely successful – and that the high number of applicants indicates a true financing need of innovation in biomanufacturing.

Based on the evaluation results, it is clear that a project duration of 6 months is insufficient for companies operating in the biomanufacturing and medical technology sectors. Therefore, it is recommended that companies allow for longer project durations or greater flexibility to extend the project duration to enhance their ability to adapt to unexpected delays, such as production delays in the upstream phase, delayed contribution of partners or working days lost to illness.

The planned activities and KPIs are generally running as planned. There are only minor deviations that affect the timeline of the project or the composition of the partners. Thanks to the Mid-Way Quality Check and the one-to-one meetings with the lead applicants, all projects that deviated from the project plan were successfully guided back onto the originally planned schedule, with one exception. By reallocating the funding received back from the failed IFS project, another BTFS project with a greater chance of success was funded and an ongoing IFS project received valuable additional funding. For this reason, it is expected that all projects funded by BioMan4R2 will achieve their objectives as planned. The final results and impact of the BioMan4R2 Support Programme will be evaluated on the basis of the final reports and the results will be published on ECCP.

### **Annexes**

Annex 1

Table 3: List of the winners received Innovation Financial Support (IFS) through the BioMan4R2 Support Programme.

IFS Winner	Country	Project Title	Category	Co-Partner (Country)
*Robeauté	FR	Microrobots for neurosurgery - revolutionising access to complex areas of the central nervous system	Neurology	FEMTIKA (LT) AMAROB (FR)
*Plantibodies	FR	Plant-Based Oral Immunotherapy for Gastrointestinal Diseases A Resilient Bioproduction Approach	Gastroenterology	Prodigest (BE) CDMO (BE)
InSpek SAS	FR	On-chip Raman spectroscopy sensors to monitor in-line and in real time the bioproduction	Bioproduction	URD ABI AgroParisTech (FR)
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)
*Fibrothelium GmbH	DE	Biosynthetic protein production in plants for bioabsorbable implants	Bioproduction	Aachen-Maastricht Institute for Biobased Materials (NL)
АТТОМ	FR	New modular device to support other companies to create and test complex in vitro models for preclinical research purposes	l Validation process	Healshape (FR) ICO (FR) UCBL labs (FR)
MindAhead UG	DE	Validation of digital therapy tool for improving brain health	Neurology	Medical Innovations Incubator GmbH (DE)



IFS Winner	Country	Project Title	Category	Co-Partner (Country)
*ALTA sp. z o.o.	PL	Validation of a new psychological memory test	Neurology	Prometriks Ltd (BG)
*/***MIRA Vision Microscopy GmbH	DE	Scaling up AI-assisted image analysis for microscopy	Imaging	Jaydevs LLC (LT)
				University Hospital La Princesa (ES)
Time is Brain SL	ES	Validation real-time brain monitoring tools of stroke patients	Neurology	University Hospital Sant Pau (ES)
				University Hospital Arnau de Vilanova (ES)
MACIC CENIONALY ED	FR	Revolutionizing cancer treatment by developing a theragnostic	Oncology	ValoTec (FR)
MAGIC GENOMIX	ΓK	solution, relevant in multiple cancer types	Oricology	valorec (FK)
*PolyAn GmbH	DE	Filling the gap: Automated production line for glass slides with	n Imaging	Eccom OÜ (EE)
r oly All Gilloll	DL	reactive surface functionalization	iiiagiiig	Herbert Stamm KG (DE)
				Medical Innovations Incubator GmbH (DE)
*lata and Clair Cooks	D.F.	Overcoming regulatory, economic, and market entry barriers for		ITSAN NGO (USA)
*IntegraSkin GmbH	DE	diagnostic device providing effective treatment plans for chronic skin conditions		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 join supply chain for the GMP production of biologicals		ARTES Biotechnology GmbH (DE)



IFS Winner	Country	Project Title	Category	Co-Partner (Country)
*Care4living Oy	FI	process for a cytotoxic small molecule drug	Manufacturing process	University of Turku (FI) NIHM BV (NL)
*/**EVOMEDIS GmbH	АТ	EVOCornea – validation of a cell-based therapy for the treatment of corneal defects	Ophthalmology	University Clinic Düsseldorf (DE)

<sup>\*</sup>Transnational cooperation

**Annex II** 

Table 4 List of winners received Business Transformation Financial Support (BTFS).

BTFS Winner Cou	untry	Project Title	Category	Co-Partner (Country)
SITEC pharmabio	ES	Business Continuity Plan to aligned with the regulatory requirements of Pharma and Nutra sectors	Business legal , financial analysis	/ GENESIS Biomed (ES)
*Zeisberg GmbH	DE	Market Entry beyond Europe of a new video oculography system	Go International	AHK Kanada (CA) Emergo by UL (USA) DQS DE
*Egerton sp. Z o.o.	PL	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)

<sup>\*\*</sup>Lead applicant withdrawed grant agreement due to issues with cooperation partner and retransferred FSTP

<sup>\*\*\*</sup>Received reallocated FSTP



Country	Project Title	Category	Co-Partner (Country)
FR	Developing a headband in line with European regulations i terms of RGPD, CE marking and MDR	n Business legal financial analysis	/ SQI (FR)
SI	Creating a specialized digital module for managing service providers to comply with GMP standards	eTrain your worker- Greener/Digital	Go Miran Janežič s.p. (SI)
<b>SL</b> ES	Creating clinical evaluation plan under the provisions of th MDR for a lung disease diagnostic device	e Business legal financial analysis	/ novineon CRO GmbH (DE)
DE	compliant development of a medical device for hearin assessment	Business legal financial analysis	/Medical Innovations Incubator GmbH (DE)
PL	landscape, market dynamics, and potential obstacles for system for digitizing nursing rounds	a financial analysis	/ Scheelite Sp. z o.o. (PL)
. ES	Strategic roadmap of Market Access to achieve the inclusio of a drug candidate to treat pediatric cancer patients i different Early Access Programs in the EU	n Business legal n financial analysis	/ AliraHealth SAS (FR)
s.L. ES	understanding of the four key European markets and the U for melanoma treatment.	KGo International	Alira Health SLU (ES)
PL	Training of the human resources in risk management and pos- market surveillance in order to be in compliance with th requirements of the Medical Device Regulation.	t- Train your worker- e Greener/Digital	Go novineon CRO GmbH (DE)
	FR SI SL ES DE PL . ES	Developing a headband in line with European regulations is terms of RGPD, CE marking and MDR  Creating a specialized digital module for managing service providers to comply with GMP standards  Creating clinical evaluation plan under the provisions of the MDR for a lung disease diagnostic device  Implementation of the QMS and the commencement of compliant development of a medical device for hearing assessment  Legal, market, and resilience analysis to outline the regulator landscape, market dynamics, and potential obstacles for system for digitizing nursing rounds  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  Market Access analysis to gain a comprehensive understanding of the four key European markets and the Use for melanoma treatment.  Training of the human resources in risk management and posmarket surveillance in order to be in compliance with the	FR Developing a headband in line with European regulations in Business legal terms of RGPD, CE marking and MDR financial analysis  SI Creating a specialized digital module for managing serviceTrain your worker-providers to comply with GMP standards Greener/Digital  SL ES Creating clinical evaluation plan under the provisions of the Business legal MDR for a lung disease diagnostic device financial analysis  Implementation of the QMS and the commencement of compliant development of a medical device for hearing financial analysis assessment  PL Legal, market, and resilience analysis to outline the regulatory landscape, market dynamics, and potential obstacles for a financial analysis system for digitizing nursing rounds  Strategic roadmap of Market Access to achieve the inclusion of a drug candidate to treat pediatric cancer patients in financial analysis different Early Access Programs in the EU  Market Access analysis to gain a comprehensive understanding of the four key European markets and the UKGo International for melanoma treatment.  Training of the human resources in risk management and post-Train your workermarket surveillance in order to be in compliance with the Greener/Digital

<sup>\*</sup>Transnational cooperation

<sup>\*\*\*</sup>Received reallocated FSTP

### **Annex III**







## BioMan4R2 Financial Support Scheme

## **Intermediary 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

Beneficiary details	21
Project timeline	
Partner or service provider contribution to the project	21
Key performance indicator (KPI) status	21
Budget details spent so far	21



### **Beneficiary details**

Name of organization	
Name of person who completes this intermediary report	
Date of completing this intermediary 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 on schedule?	□Yes
	□No
Please indicate schedule delays and how you plan to meet the timeline to finish 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 work to achieve the KPIs	
- KPI 1	
- KPI 2	
- KPI 3	
Do you expect any delays in achieving	□Yes
the KPIs	□No
If yes, please describe how you manage to achieve the KPIs as planned.	

### **Budget details spent so far**

Please, indicate the budget you have spent for each	Budget spent per partner	Date of budget transfer to
partner until the mid-term timeline of your project	and category (personnel,	partner / service provider



	external, consumable, travel costs)	
- Beneficiary		
- Partner / Service provider 1		
- Partner / Service provider 2		
- Partner / Service provider 3		
<ul> <li>Partner / Service provider 4 (please, extend if needed)</li> </ul>		
Are there any delays in spending budget as planned		



Signa	ature 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):









## BioMan4R2 Financial Support Scheme

## **Intermediary Report**

## **Business Transformation Financial Support**

#### **Disclaimer:**

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### Table of contents

Beneficiary details	26
Project timeline	26
Partner or service provider contribution to the project	26
Key performance indicator (KPI) status	26
Budget details spent so far	26



### **Beneficiary details**

Name of organization	
Name of person who completes this intermediary report	
Date of completing this intermediary 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 on schedule?	□Yes
	□No
Please indicate schedule delays and how you plan to meet the timeline to finish 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 work to achieve the KPIs	
- KPI 1	
- KPI 2	
Do you expect any delays in achieving the KPIs	□Yes
	□No
If yes, please describe how you manage to achieve the KPIs as planned.	

### **Budget details spent so far**

Please, indicate the budget you have spent for each	Budget spent per partner	Date of budget transfer to
partner until the mid-term timeline of your project	and category (external,	partner / service provider
	travel, other costs)	



- Beneficiary	
- Partner / Service provider 1	
- Partner / Service provider 2	
- Partner / Service provider 3	
<ul> <li>Partner / Service provider 4 (please, extend if needed)</li> </ul>	
Are there any delays in spending budget as planned	



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):	