

PROJECT STATUS REPORT (PSR)

10/01/2024 - 09/30/2025 - PSR-10400

PROJECT SUMMARY

Operation number
BR-T1623

Suboperation number
ATN/JF-21483-BR

Project Name
Remote OBGYN Monitoring Leveraging the iCTG Wearable Platform

Team Leader
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Executing Agency
Fundação Faculdade de Medicina

Purpose



Project cycle



PSR SCORE



- 0 - 1 Red Flag
- 1 - 2 Yellow Flag
- 2 - 4 Green Flag

LEARNINGS

1. Implementation

1.1. Brief Summary

1.1.1. Please provide a brief summary on the overall status of this operation and the relevant events that have occurred during execution. This may include the main activities realized, overall results achieved, relevant changes in context, and next steps contemplated. If desired, this section can be organized by component.

During its first year, the Remote OBGYN project, also known as the VITAL project, advanced from its contracting and fund transfer stages to the full initiation of the Phase 1 pilot. The project aims to test and validate a telemonitoring solution based on cardiotocography (iCTG) for pregnant women, particularly those in vulnerable situations, in order to develop a model for remote fetal telemonitoring and expand access to quality prenatal care for populations with limited healthcare services. Phase 1 focuses on evaluating the solution developed by Melody International Ltd. in a controlled and secure hospital environment, within the Obstetrics Ward of HCFMUSP, to ensure reliability and suitability prior to broader implementation. Launch The official launch event took place on May 21, 2025, at Japan House in São Paulo, gathering over 100 participants, including representatives from the IDB, the Embassy of Japan, Brazil's Ministries of Health and Science, hospital leadership, and Melody International. The event marked the formal start of the initiative, with the delivery of three iCTG devices to the hospital. Following the event, the project team was selected and fully onboarded to begin preparatory activities for implementation. Pilot Design and Preparation The research project was developed and approved by the hospital Research Ethics Committee, ensuring compliance with institutional and ethical standards. Connectivity assessments conducted prior to the pilot identified the need for infrastructure upgrades, leading to the contracting of seven Wi-Fi antenna kits, currently in installation. A training and demonstration session on the iCTG device was conducted for hospital professionals, including professors, physicians, and residents, with the participation of Melody's representative in Brazil. An online and scalable training tool was also developed and validated to facilitate future dissemination of the iCTG training among hospital professionals. The project and hospital teams collaborated to design a detailed Service Blueprint to guide pilot operations. After completing all legal and IT validations, the project officially initiated Phase 1 on July 29. Pilot implementation - Phase 1 During the first months of implementation, 28 exams were performed on 14 pregnant women. The number of exams was below the expected target, mainly due to the limited pool of eligible patients, as several had a Body Mass Index (BMI) above the inclusion criteria defined in the research project. As of September 30, a research addendum to broaden patient eligibility has been submitted and is awaiting approval. The team also addressed technical instability in the devices, including signal quality issues and occasional noise or static in some exams, prompting continuous adjustments to improve performance and exam quality. Melody's representative in Brazil observed the tests on September 19 and prepared a report, which was discussed during a meeting with Melody on September 26. A monthly coordination meeting has been established with Melody to monitor progress and follow up on technical and operational matters. The AI development roadmap is being jointly defined with Melody to ensure alignment with the clinical needs of the Obstetrics team, and the company has committed to deploying replacement devices and continuing to monitor device performance. Summary In summary, the first year of the VITAL project established the foundations for Phase 1 implementation, with key milestones achieved, including research project approval, iCTG device delivery, team onboarding and training, and the start of pilot testing. Although initial technical and operational challenges affected the pace of exams, mitigation measures were implemented to address these issues and support steady progress in project activities. With ongoing adjustments and coordinated efforts, the project is progressing toward the Phase 1 targets of 432 exams and 180 patients by 2026.

1.1.2. Based on these activities specify at least two Lessons Learned, Findings and Recommendations *

Phase	Dimension	Finding	Recommendation
Execution	Organizational Dimensions	Effective collaboration between the partner's technical team and the hospital pilot team is essential, and lack of structured communication can slow problem-solving and adaptation.	Establish regular coordination meetings and build a trusting relationship between teams to monitor pilot progress, address issues promptly, and adjust procedures when necessary. On-site visits by the partner team, whenever possible, make a significant difference in monitoring the tests effectively.
Design	Organizational Dimensions	The inclusion criteria defined in the research project can significantly limit the pool of eligible patients for the pilot, making it difficult to achieve the established indicators.	Before defining the inclusion criteria, conduct a preliminary study to evaluate the typical patient population and ensure the criteria are realistic for the pilot setting.

1.1.3. Describe the outcome(s) accomplished this year and their relation/contribution to the objective of the TC. If the outcome(s) were not completed as planned, please explain how this will affect progress towards achievement of the operation's objective.

The main outcomes accomplished this year were: Pilot design and preparation: This included the elaboration and approval of the research project, delivery of the iCTG devices, onboarding of the project team, and enhancement of the hospital's connectivity infrastructure to support pilot testing. Full initiation of Phase 1 at HCFMUSP's Obstetrics Ward: A total of 28 exams were performed on 14 pregnant women. While the number of exams is below expected, considering the target of 432 exams and 180 patients by 2026, the team has already implemented strategies to accelerate progress, including submitting a research project addendum and deploying replacement devices. The Phase 1 pilot consists in performing cardiotocography exams in pregnant women using both the iCTG device and the hospital's traditional cardiotocography system. The goal is to verify through comparisons performed on the same patients using both systems, the agreement between the iCTG device and the hospital's gold standard, as defined in the project's result matrix. This validation is critical to build confidence with the healthcare team, ensure the device is suitable for the Brazilian clinical context, and advance toward the overarching objective of the TC: to pilot and roll out Melody International's state-of-the-art iCTG device within the Obstetrics and Gynecology Department at HCFMUSP and, subsequently, in less complex or resource-limited health units in P&V communities, providing a cost-effective telehealth solution that enables cardiotocography examinations to be performed remotely and efficiently.

1.1.6. Stories from the field Provide a relevant story related to this TC, which may include: a success or failure story; a description of an event that has affected or steered the project; a description of unintended positive and/or negative effects of the intervention; and issues for policy dialogue that have emerged and how.

Type of Story	Story Text	Link (If available)
	During the project's onboarding meeting, a senior obstetrics professor from the hospital, a key sponsor of the project with extensive experience and recognition in her field, attempted to	

Challenge	<p>perform an exam using the iCTG device. However, she was unable to complete the test due to an interference-like noise that prevented proper device positioning. It was later verified that the room where the test took place was a connectivity shadow zone, which is now being addressed through the installation of improved network coverage.</p>	<p>https://docs.google.com/file/d/1DBdracF9hzxh-Nky2eguY6pcaU1hci1m/preview</p>
Success	<p>Following some technical challenges during the initial tests, including occasional signal instability and background noise in certain exams, Melody International's representative in Brazil conducted an on-site visit to observe the tests in person. A detailed report was later prepared and discussed with Melody's technical team. This collaborative review led to the decision to replace the devices and strengthened mutual confidence between the teams, reinforcing a shared commitment to improving the project's technical and operational performance.</p>	<p>https://drive.google.com/file/d/1Jgtue5wo5h9TD4OuNxIBhgEu111dJnNI/view?usp=drive_link</p>

2. Scalability

2.1.a Results MVP/Venture/Solution/Process

2.1.1. In the last calendar year, have your costs been fully covered by your sales or program funding? If "yes", please select how much of your costs are being covered to continue providing your solution/model/service.

[Yes. Costs were covered and we could still finance up to 6 months of operations (1-6 months)]

2.1.2. In the last calendar year, did the number of clients (individuals, households, companies, organizations, or others) using your solution/model/service increase? If "yes", did you achieve or exceed the number of clients you were expected to reach?

[Yes. but did not achieve the annual target]

Individuals or households

14

Individuals or households

14

2.1.b Institutional Capacity for Scaling

2.1.3. Does your organization have a scaling up plan that specifies key elements needed to scale the solution/model/service being financed?

[Yes]

2.1.4. Indicate the primary scaling up pathway the project/initiative is pursuing to reach scale

[Solution will be scaled through a joint effort (partnership) involving my company or organization and other entities]

2.1.5. Are you actively seeking and/or engaging with partners to take your solution/model/service to scale?

[Yes]

2.1.5.1. If "yes", select the degree of engagement (if multiple partners, select all that apply)

[Still seeking partner(s) but with no agreement reached]

2.1.c Factors

2.1.6. Which of these external factors are facilitating the scaling-up of your solution/model/service? Only select those that apply, and list them in order of priority.

[Solution/model/service addresses a need sharply felt by clients, Scaling partners see value in funding/adopting/acquiring the solution/model/service]

2.1.7 Which of these external factors are hindering the scaling-up of your solution/model/service? Only select those that apply, and list them in order of priority.

[Clients (individuals; households; companies; organizations) are not familiar and/or using similar solutions/models/services which might facilitate adoption]

2.1.8 Which of these internal factors are facilitating the scaling-up of your solution/model/service? Only select those that apply, and list them in order of priority.

[Results on effectiveness have been documented and communicated]

2.1.8.1 Is there any other internal factor(s) facilitating the scaling-up of your solution/model/service? (If there is no other factor, leave blank)

We are still testing effectiveness, and will test usability in the next phase.

2.1.9 Which of these internal factors are hindering the scaling-up of your solution/model/service? Only select those that apply, and list them in order of priority.

[None]

3. Technology Deployment

3.1. Novel Technologies Factors

3.1.1. If the project/firm/fund makes use of novel technologies or methodologies, what factors have facilitated the implementation of the technological solution initially proposed by the project?

[Previous experience of the executing agency / client with the technology, Access to subject matter experts by executing agency/client, Public recognition of the innovation of the project]

3.1.2. If the project/firm/fund makes use of novel technologies or methodologies, what factors have hindered the implementation of the technological solution initially proposed by the project?

[Poor telecommunications network coverage]

4. Development Outcomes (Quantitative)

4.0 Has your project/firm/fund contributed to any of the following indicators in this calendar year (Ene-Sep)?

[4.6. Not contribute]

5. Sustainability and Innovation

5.1. Sustainability

5.1.1. Is the operation meant to be sustainable?

[Yes]

5.1.2. Describe the measures identified during execution to enhance project sustainability, if applicable. In the final report explain how benefits will continue to accrue once the operation has closed.

The first year of the project was implemented according to the procurement and contracting plan. The individuals for the project team (items 2 to 6) were acquired, as were the 3 iCTG kits (item 7). For the materials and supplies necessary for the test (item 13), 3 items were observed to be necessary: (i) installation of 7 wi-fi antennas to enhance connectivity in the obstetric ward (ii) gel to conduct the exam (iii) thermal paper to print exam results. Procurement of these materials is currently in progress.

5.2. Innovation

5.2.1. Did the TC introduce any key innovations (new processes or new products)?

[Yes]

INDICATORS

Overachieved Achieved Pending In process Overdue

C1: Wearable technology

Weight: 28%

Qualification: Satisfactory

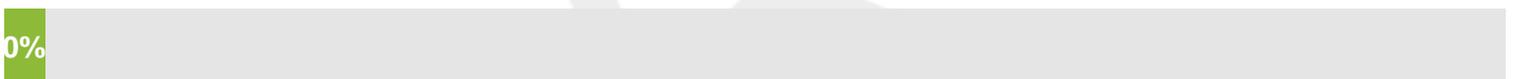


Indicators	Planned	Achieved	Status
I1 AI accuracy rate validated by trained OBGYN doctors	0 (2028-02-06)		
I2 Professionals trained to use the device	0 (2025-04-09)	47 (2025-09-10)	
I3 Needs assessment study of wearable iCTG solution in Brazil	0 (2028-02-06)		
I4 Submission of regulatory approval by Melody International (ANVISA, Anatel, etc.)	0 (2027-02-06)		

C2: Clinical infrastructure

Weight: 58%

Qualification: Satisfactory



Indicators	Planned	Achieved	Status
I1 Number of iCTG measurements of high-risk patients during the three phases of the research project	0 (2025-04-09)	28 (2025-09-30)	
I2 Number of high-risk patients assisted during the three phases of the project	634 (2028-04-09)	14 (2025-09-30)	
I3 Technical cooperation agreement with one P&V municipality to provide remote hospital services in the third phase of the project	0 (2028-02-06)		
I4 Qualitative Assessment of wearable solutions from Patients	0 (2028-02-06)		
I5 Qualitative Assessment of wearable solutions from Hospital Professionals	0 (2028-02-06)		

C3: Sustainability and scalability

Weight: 14%

Qualification: Satisfactory



Indicators	Planned	Achieved	Status
I1 Database with information generated by the iCTG measurements, for clinical research at HCFMUSP	0 (2028-02-06)		
I2 Publication with results from the project	0 (2028-02-06)		
I3 Remote monitoring protocols established (for HCFMSUP and for telemonitoring)	0 (2028-02-06)		

MILESTONES



Milestones	Achieved Value	Due Date	Achieved Date	Status
*Condiciones Previas / Prior Conditions	1	2025-10-09	2025-05-27	
*Professionals trained to use the device	50	2025-12-19		
*Agreement between iCTG and gold standard	1	2026-06-30		
*AI accuracy rate validated by trained OBGYN doctors	1	2026-12-21		
*Qualitative Assessment of wearable solutions from Patients and Professionals	2	2027-06-30		



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