TC Document/Appendix

I. Basic Information for TC

▪ Country/Region:	BRAZIL / CSC - Southern Cone
▪ TC Name:	Remote OBGYN monitoring leveraging the iCTG wearable platform
▪ TC Number:	BR-T1623
▪ Team Leader/Members:	OKUMURA, MASATO (LAB/DIS); OKAHASHI, KOTA (LAB/DIS): GUEVARA, XIOMARA PATRICIA (LAB/DIS); ROCHA, MARCIA GOMES (SCL/SPH); GOES SHIBATA, LEONARDO (SCL/SPH); DANIELE BARRA, CARLA MARIA (DSP/DVF); VILLALOBOS ALFARO, ANDREA; DAPHNE MORRISON (OII/OII); GARCIA DE PAREDES, MARGARITA RAQUEL; FRIEDMAN AROSEMENA, CAROL ESTEFANIA (GCL/FML); GREIN DEL SANTORO, BRUNO (GCL/FML); URENA SOLIS, LAURA; Laguyas, Natalia (LAB/EBA)
▪ Taxonomy:	Client Support
▪ Operation Supported by the TC:	N/A
▪ Date of TC Abstract authorization:	11/06/2024
▪ Beneficiary:	Brazil, State of São Paulo and potentially in the third phase a municipality in the Northern region of Brazil, HCFMUSP (Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo)
▪ Executing Agency and contact name:	FFM - Fundação Faculdade de Medicina (Foundation Faculty of Medicine) Contact name: Luciana Lischewski Mattar
▪ Donors providing funding:	Japan Special Fund (JSF) Japan Enhanced Initiative for Quality Infrastructure, Resilience against Disaster and Health (JEI)
▪ IDB Funding Requested:	US$ 700,000.00
▪ Local counterpart funding, if any:	US$ 175,000.00 (in-kind)
▪ Disbursement period (which includes Execution period):	36 months
▪ Required start date:	March1, 2025
▪ Types of consultants:	Not applicable
▪ Prepared by Unit:	MIF - Multilateral Investment Fund
▪ Unit of Disbursement Responsibility:	CSC/CBR - Country Office Brazil
▪ TC included in Country Strategy (y/n):	Yes
▪ TC included in CPD (y/n):	Yes
▪ Alignment to the IDB group country strategy with Brazil 2024-2027	Yes. The project is aligned with Brazil's country strategy 2024 - 2027, contributing to the strategic objective of improving the quality of health and education spending.

II. Objectives and Justification of the TC

2.1 Maternal and neonatal deaths are still social and health problems, especially in underdeveloped and developing countries such as Brazil. One of the main actions to reverse this situation was the inclusion in the UN Sustainable Development Goals (SDGs) of the reduction of global maternal mortality and the eradication of preventable deaths of newborns and children under 5 years of age by 2030 in order to encourage discussion of measures to achieve this goal in participating countries, including Brazil.

2.2 The death of children under one year of age is associated with the care provided during pregnancy, childbirth, and the puerperium, since 52% occur in the neonatal period, i.e., the first 28 days of a child's life. Therefore, one of the main strategies to reduce perinatal mortality (the death of a fetus or newborn around the time of delivery) is the consolidation of prenatal care, with better access to health professionals and additional tests[1].

2.3 Brazil's Fetal Mortality Rate (FMR) stood at 10.1 per 1,000 births in 2019, significantly higher than that of developed countries (2 to 7 per 1,000)[2]. This disparity is largely attributed to insufficient prenatal monitoring, particularly in poor and vulnerable (P&V) communities, which would contribute to reducing maternal and infant mortality. In the country, fetal deaths have a heterogeneous distribution, with higher rates in the North and Northeast regions, which are higher than the national average. Between 2017 and 2019, the FMR in the Northeast was 13.4 deaths for every thousand live births[3][4].

2.4 One of the main complementary tests to be performed during this period, especially in the follow-up of high-risk pregnancies, is cardiotocography. However, the lack of resources, including medical devices and trained professionals, limits access to early detection of complications during pregnancy. Specifically, cardiotocography is often unavailable due to its expense and the scarcity of qualified healthcare professionals to interpret the results. Therefore, pregnant women must often travel to specialized centers where there is an obstetric medical team, which is not always possible due to the cost and difficulties of travel, especially considering a country with continental dimensions like Brazil, where health resources are poorly distributed and concentrated in the south and southeast regions. As a result, P&V populations experience increased perinatal mortality and substandard maternal care.

2.5 The project proposes testing and introducing advanced mobile cardiotocography technology (iCTG), to provide an economical telemonitoring solution that could

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[1] Prezotto et al. Tendência da mortalidade neonatal evitável nos Estados do Brasil. Rev. Bras. Saude Mater. Infant. 21 (1). Jan-Mar 2021.

[2] Brasil. Ministério da Saúde. Datasus. Estatísticas vitais [Internet]. 2022 [cited 2022 Oct 01]. Available at: https://datasus.saude.gov.br/informacoes-de-saude-tabnet/

[3] Barros PS, Aquino EC, Souza MR. Mortalidade fetal e os desafios para a atenção à saúde da mulher no Brasil. Rev Saude Publica. 2019; 53:12. Available at: http://doi.org/10.11606/S1518-8787.2019053000714.

[4] Ministério da Saúde. Boletim Epidemiológico 37: Mortalidade infantil no Brasil. Available at: https://www.gov.br/saude/pt-br/centrais-de-conteudo/publicacoes/boletins/epidemiologicos/edicoes/2021/boletim_epidemiologico_svs_37_v2.pdf.

potentially decrease perinatal mortality rates, improve access to care and women's health, as well as establish new protocols and public policies for remote monitoring of high-risk pregnancy in *Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo* (HCFMUSP) and in the Brazilian Healthcare System (SUS).

2.6 Cardiotocography (CTG), also known as electronic fetal monitoring (EFM), is a medical procedure that tracks a baby's heart rate and uterine contractions during pregnancy and labor, to assess the baby's well-being, identify problems, and monitor the baby's response during labor. An ultrasound transducer is placed on the mother's abdomen to continuously record the baby's heart rate. It has the advantage of being an easy-to-install, non-invasive method that poses minimal risk to the fetus and pregnant woman.

2.7 One of the smallest models on the market is the one produced by the Japanese company Melody International Co. Ltd ("Melody"), a Japan-based startup specializing in creating and commercializing wearable, digital, and cloud-integrated fetal monitoring devices. It is a compact, lightweight device, independent of cables and sockets, which can be easily installed by the patient herself or any non-medical health professional, either at home or in less complex health units[5]. For this project, the device will always be used in conjunction with a health service and with a health professional. Melody was selected as part of the TSUBASA[6] open innovation challenge in 2022, a joint initiative organized by JICA and IDB Lab. This innovative device tracks fetal heart rate and uterine contractions, transmitting the data to a cloud server.

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[5] In previous studies, the iCTG device produced by Melody proved to be effective.

(1) In a 2019 study conducted at the University of Poland by Pilarczyk et al., the correspondence between the iCTG and a traditional cardiotocography device was even numerically higher. A total of 164 records were collected, including 82 from a conventional device (Corometrics model 172; GE Healthcare, Chicago, USA) and 82 from a mobile device installed by the patient herself (Pregnabit; Nestmedic, Wrocław, Poland). The analysis showed 97.1% agreement between the two types of examinations.

(2) In the study led by Pilarczyk et al, cited above, most pregnant women (80% in the intrapartum groups and 70% in the antepartum groups) and all nurses and obstetricians preferred the mobile CTG device to the standard CTG device. Eighteen completed questionnaires were collected. Most patients reported that CTG self-examination using the mobile device was easy (28%) or quite easy (61%), and 85% of them stated that the possibility of performing the examination at home would increase their feeling of safety, especially on weekends and holidays when access to the doctor is limited (72%), in identifying high-risk factors that do not require hospitalization (72%), and in the postpartum period (56%).

(3) Remote fetal monitoring was shown to be safe in a study in Mexico involving 153 high-risk pregnant women, which compared maternal and infant outcomes in patients who received remote monitoring (n = 74) with those who received standard hospital care (n = 79) (7). The study reported no differences in term gestation, birth weight, or obstetric complications between the two groups, and the rate of patient adherence to fetal monitoring was high (94.3%).

References:

Pilarczyk, Renata et al. Diagnostic equivalency of mobile CTG devices and remote analysis to conventional on-site nonstress test. Adv Clin Exp Med. 2020;29(1):33–44

[6] For more information about TSUBASA, visit: https://tsubasa-jica.com/.

2.8 The introduction of mobile cardiotocography technology will represent a shift towards a more equitable healthcare system where state-of-the-art care is not a privilege but a standard, substantially reducing disparities in fetal health outcomes. Therefore, the project addresses IDB's core objective of reducing poverty and inequality and improving medical care for pregnant women from poor and vulnerable communities. As a matter of fact, Melody's device can be an economical solution for the public health system in Brazil since it can be up to 20% cheaper than conventional cardiotocography devices. The device (one-time payment of USD 1,000), combined with the SaaS (monthly fee of USD 25), costs approximately USD 2,500 for a 5-year contract (prices don't include taxes). Regular cardiotocography device prices range from USD 2,500 to USD 4,000, or sometimes higher prices depending on the model.

2.9 The project has the objective of piloting and rolling out iCTG state-of-the-art device developed by Melody, a Japanese startup, within the Obstetrics and Gynecology Department HCFMUSP and later in less complex or resource-poor health units in P&V communities to provide a cost-effective telehealth solution by allowing cardiotocography examinations to be performed remotely and efficiently. The project beneficiaries include over 600 high-risk pregnant women from the Brazilian Unified Health System (SUS), as well as over 50 patients in a remote P&V municipality.

2.10 The project's high-level contribution is to support the establishment of a better monitoring protocol and solution for the reduction of fetal mortality rates in Brazil and the region and to promote constant prenatal monitoring across geographies. This will be accomplished by the wider adoption of affordable telehealth solutions, enhanced accessibility, and the enabling of remote monitoring in rural areas, which is important because it helps overcome distance challenges in a continental country like Brazil. By providing world-class health care and patient monitoring in the most remote areas and to underserved patients, the project aims to reduce fetal mortality rates closer to the level of developed countries through improved preventive care.

2.11 This project is innovative in its approach to democratizing access to advanced healthcare technology by leveraging digital and cloud-based solutions and developing telehealth protocols to support less complex or resource-poor health units from the Brazilian Health System (SUS) to provide adequate prenatal care. It will be the first case of using a mobile cardiotocography device in the Brazilian public health system. The iCTG platform combines wearable technology with real-time data transmission, allowing healthcare professionals to monitor fetal health data remotely. This approach not only circumvents the geographical and financial challenges but also creates a new model for prenatal care, where consistent monitoring is available even in the most resource-constrained environments. The innovation lies in the fusion of cloud-based health monitoring, mobile-accessible IoT technology, and the availability of remote support from the Obstetrics and Gynecology Department (OBGYN) specialists from Hospital das Clínicas - bringing cutting-edge care to communities that traditionally lack such resources. Also, the device is GDPR (General Data Protection Regulation) and LGPD (Brazilian General Data Protection Law) compliant and focuses on privacy and security according to data protection regulations.

2.12 The project is expected to enhance the capacity of public healthcare providers to detect and respond to complications during prenatal care, ultimately reducing the incidence of elective preterm births (PTBs) and reducing perinatal morbidity and mortality. In the long term, this initiative will contribute to establishing new standards

and protocols for remote monitoring of prenatal care in Brazil's public healthcare system, ultimately increasing equity in maternal healthcare access.

2.13 This proposal is expected to leverage the iCTG platform provided by Melody. This innovative device tracks fetal heart rate and uterine contractions, transmitting the data to a cloud server. The collected data is accessible to the expectant mother, her doctor, and other healthcare professionals from any location with internet connectivity using a tablet included in the kit.

2.14 This initiative also aligns with the IDB Group's core objectives of reducing poverty and inequality by improving access to quality healthcare services for disadvantaged populations, especially women in P&V communities. As mentioned above, fetal mortality rates are particularly higher in poorer regions and states in Brazil, such as the Northeast, and the decrease in FMR over the years in Brazil was heterogeneous. In the Brazilian Public Health System (SUS), it became evident that fetal mortality was higher in groups with a lower socioeconomic status, evidencing profound inequalities in health[7].

2.15 For this reason, the project will include remote monitoring of patients via telehealth in a P&V municipality. This service will be provided in a health unit where there is no cardiotocography device available and/or specialized staff to interpret the test results. The objective is to show how telemonitoring can improve care for high-risk pregnancies of patients who are hospitalized in services where there is no cardiotocography or a professional with the skills to interpret the test and reduce the travel costs of pregnant women who need to undergo outpatient vitality assessment but live far from the referral hospital where this resource is available.

III. Description of activities/components and budget

3.1 Key activities will include the deployment of iCTG devices in high-risk pregnancy cases to verify its accuracy; implement a test operation at HCFMUSP and later in a remote and P&V location (preferably a municipality in the Northern region of Brazil); assess the patient and physicians satisfaction and acceptability on the use of the device; develop telemonitoring protocols to use the iCTG device; train professionals at HCFMUSP and in remote locations to use the device; develop an AI model to support medical activities (i.e., predictions or diagnoses); carry out a needs assessment study of wearable iCTG solution in Brazil and submit the iCTG solution to regulatory approval by Melody International to Brazilian regulatory agencies.

3.2 The project consists of three subsequent phases: (1) comparing results between mobile and conventional cardiotocography on the same patient at the HCFMUSP ward, (2) training pregnant women to use the mobile device and evaluating their experience and satisfaction at the HCFMUSP clinic, and (3) remote fetal monitoring through telehealth, with tests analyzed by professionals from HCFMUSP in regions with scarce resources and difficulty accessing obstetrics reference centers.

[7] Barbeiro FM, Fonseca SC, Tauffer MG, Ferreira Mde S, Silva FP, Ventura PM, Quadros JI. Fetal deaths in Brazil: a systematic review. Rev Saude Publica. 2015; 49:22. doi: 10.1590/s0034-8910.2015049005568. PMID: 25902565; PMCID: PMC4390075. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC4390075/#fn3.

Phase 1 - HCFMUSP Ward (2025)	Phase 2 - HCFMUSP Clinic (2026)	Phase 3 - Remote Telehealth (2027)
Compare results between mobile and conventional cardiotocography on the same patient at the HCFMUSP ward.	Train pregnant women to use the mobile device and evaluate their experience and satisfaction at the HCFMUSP clinic.	Monitor fetal remotely through telehealth, with exams analyzed by professionals from HCFMUSP in P&V municipalities.

3.3 **Component I: Wearable technology:** This component focuses on developing and validating iCTG technology in close partnership with Melody during the project. It includes equipment acquisition (iCTG transducers and tablets), software setup, and AI development to support physicians. The budget covers cloud services, monthly user support, and maintenance. Training activities will reach at least 75 professionals, supported by manuals, documents, and instructional videos. Resources are allocated for international travel, field visits by Melody's representatives, and a needs assessment study of iCTG solutions in Brazil. Additionally, the component ensures regulatory compliance (ANVISA[8], Inmetro[9], Anatel[10]), targeting approval in 2026 to meet Brazilian health and safety standards.

3.3.1 As outlined in the Result Matrix, Component I aims to achieve the following outputs: an AI to support physicians accuracy rate of at least 80% by 2027, validated by trained OBGYN doctors; training of at least 75 professionals in the use of the device over the course of the project; the development of a needs assessment study for the wearable iCTG solution in Brazil by 2027; and the successful submission of regulatory approvals (ANVISA, Anatel, Inmetro, etc.) by Melody International in 2026.

3.4 **Component II: Clinical infrastructure:** The second component defines the required infrastructure preparation to implement the project, as well as overall project management, implementation, and coordination. This component is structured to provide knowledge and resources to test the technology with patients at HCFMUSP and remote locations during the project.

3.4.1 The Budget Table for Component II allocates resources to key activities necessary for the project. This includes the purchase of materials and supplies such as equipment for Wi-Fi, connectivity, data storage services, and networks, ensuring functionality in both outpatient clinics and wards. For the third phase, additional equipment and infrastructure for telemedicine may

[8] Anvisa is the Brazilian Health Regulatory Agency, which is responsible for the approval and supervision of products and services that impact health. For more information, please visit: https://www.gov.br/anvisa/pt-br/english.

[9] INMETRO is Brazil's National Institute of Metrology, Quality and Technology, which is the country's main accreditation body. One of its responsibilities is to ensure that products, services, and testing labs meet safety and quality standards. For more information, visit: https://www.gov.br/inmetro/pt-br.

[10] ANATEL, or Agência Nacional de Telecomunicações, is Brazil's National Telecommunications Agency. For more information, visit: https://www.gov.br/anatel/pt-br.

be acquired, including computers, cables, 5G connectivity equipment, and headsets. The budget also covers service fees for project management and coordination, including a Project Coordinator and two Senior Analysts, as well as technical support from OBGYN researchers and health professionals, consisting of two Lead Researchers and four health professionals (nurses and physicians). Additionally, service fees for one Data Scientist to implement the project are included.

3.4.2 According to the Result Matrix, Component II aims to achieve the following outputs: at least 912 iCTG measurements of high-risk patients over the three phases of the project; assistance for at least 634 high-risk patients during this period; the signing of a Technical Cooperation Agreement with one P&V municipality to provide remote hospital services in the third phase of the project; carry out assessment studies with patients and professionals in the second phase and third phases of the project in order to analyze their satisfaction and acceptability on the use of the device.

3.4.3 The criterion for considering the municipality as P&V will be the "per capita household income", which should be below the Brazilian average as of 2021 (726.83)[11]. The third phase of the project will focus on remote monitoring via telehealth. This service will be provided in a health unit where there is no cardiotocography device available and/or specialized staff to interpret the test results. The objective is to show how telemonitoring can improve care for high-risk pregnancies of patients who are hospitalized in services where there is no cardiotocography or a professional with the skills to interpret the test and reduce the travel costs of pregnant women who need to undergo outpatient vitality assessment but live far from the referral hospital where this resource is available.

3.4.4 The third phase will be, thus, focused on a P&V population, and the team will assess this information ex-post to verify it. In the first two phases, P&V patients will also be assisted, but the Hospital cannot discriminate their care based on income or vulnerability. Therefore, a significant percentage of the patients will come from poor and vulnerable backgrounds. To track this percentage, the Result Matrix has a monitoring indicator to evaluate the percentage of P&V patients.

3.5 **Component III: Sustainability and scalability:** The last component concerns the project's sustainability and scalability, including research articles, dissemination materials, and expansion planning reports. This component is structured to support dissemination activities during the project.

3.5.1 The Budget Table for Component III allocates resources to support key dissemination and communication activities. These include the production of materials such as reports, institutional videos, and publications. The budget also covers travel, event organization, and language-related expenses. Additionally, contingency funds are allocated to address potential risks during the project's execution.

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[11] Source: PNUD. Available at: https://app.powerbi.com/view?r=eyJrIjoiODNmZjdhNzgtMTFmOC00Y2Y0LTk3N2EtYWE5YjI2MTIxYWJlIiwidCI6ImIzZTVkYjVlLTI5NDQtNDgzNy05OWY1LTc0ODhhY2U1NDMxOSIsImMiOjh9.

3.5.2 According to the Result Matrix, Component III is expected to achieve the following outputs: the establishment of a database by 2027 containing information generated from iCTG measurements to support clinical research at HCFMUSP; the publication of at least three articles or papers presenting the project's results; and the development of two remote monitoring protocols—one for HCFMUSP and another for telemonitoring in a remote municipality.

3.6 **The project's expected results:** The project is designed with specific indicators to ensure measurable progress toward key outcomes. These indicators align with IDB Lab's commitment to fostering innovation and scaling impactful solutions in sectors like healthcare and women's health. The main focus areas include AI development, professional training, market strategy, regulatory approval, and using Melody International's iCTG device in clinical settings. Below is a breakdown of the output indicators according to the Result Matrix:

a. **AI Development and Validation (1.1):** The AI accuracy rate validated by trained OBGYN doctors (80% accuracy) directly feeds into innovation and knowledge economy goals by advancing AI solutions for healthcare.
b. **Capacity Building (1.2):** Training 75 healthcare professionals throughout the project on the use of the iCTG, improving local knowledge capacity.
c. **Needs assessment study (1.3):** Carry out a needs assessment study of wearable iCTG solutions in Brazil to validate its feasibility and scalability in the country.
d. **Regulatory Milestone (1.4):** Submission of regulatory approvals (ANVISA, Anatel, Inmetro, etc.) in 2026, ensuring the device meets health and safety standards in Brazil.
e. **iCTG Utilization (2.1, 2.2):** Assisting 634 patients during the three phases of the research, recording 912 measurements of these patients using the iCTG device according to the tables below, contributing to healthcare innovation and service delivery improvements to P&V communities.

	Phase 1 (2025)	Phase 2 (2026)	Phase 3 (2027)
Number of patients	180	384	70
Number of measurements	432	384	96

Activity		Duration*
Phase 1	Planning	**2 months**
	Execution	**7 months**
	Result Analysis	**3 months**

Phase 2	Planning	**2 months**
	Execution	**6 months**
	Result Analysis	**3 months**
Phase 3	Planning	**3 months**
	Execution	**6 months**
	Result Analysis	**4 months**
Article	Writing and publishing the final article/paper	**4 months**

* Durations may vary during the project implementation.

f. **Technical Cooperation (2.3):** A cooperation agreement with a municipality for remote hospital services, enhancing the project's scalability and offering better healthcare access for underserved populations.
g. **Qualitative Assessment of wearable solutions from patients and professionals (2.4, 2.5):** assessment study with patients and professionals in the second phase and third phases to analyze their satisfaction and acceptability of the use of the device.
h. **Clinical Research and Dissemination (3.1, 3.2, 3.3):** Establishing a structured database, producing at least 3 publications, and setting up remote monitoring protocols to scale the project and its impact.

3.7 It is expected that the project will ultimately achieve these main outcomes:

a. **5% Decrease in the incidence of elective preterm births (PTBs)** recommended by cardiotocography (CTG) alterations;
b. **At least 80% agreement between iCTG and the gold standard** (traditional cardiotocography system in the hospital). The project hypothesizes that cardiotocography exams performed using mobile devices offer diagnostic value equivalent to conventional equipment, enabling remote evaluation of records as reliable as in-hospital analysis. A proof of concept will take place to validate this hypothesis, and the results of cardiotocography exams using a standard hospital device/gold standard (Kolplast cardiotocograph) and a mobile device/iCTG (Melody) will be compared. The comparison will be conducted as follows: the same patient will undergo the exam using both the standard device and the mobile device. The tracings from both cardiotocographies will be evaluated by two independent medical examiners. The exams from the same patient will be compared and classified as concordant (matching reports) or non-concordant (non-matching reports).

3.8 **Project's scalability:** the project, structured into three subsequent phases, is designed to scale the solution. The first and second phases will take place at the HCFMUSP as a test. The third phase, in turn, will take place at a remote location in order to determine how to scale this solution across different regions in Brazil. One of the main project outputs is to develop remote monitoring protocols — one for HCFMUSP and another for telemonitoring in remote locations. This is the project's plan to actively and continuously engage with key stakeholders to further scale the

project, as well as influence other hospitals and actors of the Brazilian public health system to adopt telehealth solutions.

3.8.1 After the project, HCFMUSP's goal is to expand the project, increasing the number of patients in the telehealth model. HCFMUSP wishes to continue working with Melody and other partners, such as the Japanese Government and the Brazilian Ministry of Health, to replicate this initiative and scale. The project can serve as a pilot to demonstrate its effectiveness, which will, in turn, be presented to policymakers in the Ministry of Health and State Secretariats of Health across different regions of Brazil. The dissemination materials, which are part of Component III, will be used to communicate and inform important actors in Brazil and influence policies and projects in the country. In fact, this year the Ministry of Health launched a program called Rede Alyne[12], focused on reducing maternal mortality of Black women in Brazil. One of the main actions is to invest more in prenatal care.

3.8.2 The General Hospital of the University of São Paulo (HCFMUSP) already has relevant experience implementing telehealth projects with nationwide repercussion and in partnership with the Brazilian Ministry of Health, such as:

a InCor's Telehealth Project[13], which is effectively improving public health services, allowing the introduction of 84 smart hospital beds at the HCFMUSP and, as a result, achieving a 20% reduction in mortality and a decrease in patient stay time in the ICU by 1 day. The solution was expanded to 7 cities in Brazil, with the Ministry of Health supporting the expansion plan for the entire network of the state of São Paulo, which has more than 30,000 beds. HCFMUSP expects the project to be included in this initiative in the future, supporting pregnant women and improving prenatal care in different cities. Therefore, the HCFMUSP has been collaborating with the Ministry of Health, and we hope this project with mobile cardiotocography can also be scaled with government support.

b Another ongoing project at the HCFMUSP is called OpenCare5G Teleradiology[14]. It uses open 5G networks to bring healthcare to the most remote locations in the country. The proposal to incorporate 5G technology, which enables greater speed and volume of data transmitted to serve the population through remote medicine, arises with the prerogative of accelerating the implementation of fifth-generation mobile data technology at lower costs than the traditional model in the industry. It is being used to perform consultations, ultrasounds, and even surgeries.

c A third telehealth project that was implemented by HCFMUSP was called Tele Obstetric ICU, which was implemented in 2022 in partnership with the

[12] For more information about Rede Alyne, visit: https://www.gov.br/saude/pt-br/assuntos/noticias/2024/setembro/rede-alyne-conheca-a-historia-da-jovem-negra-que-deu-nome-ao-novo-programa-de-cuidado-integral-a-gestante-e-bebe.

[13] For more information about the Telehealth project, visit: https://www.incor.usp.br/sites/incor2024/teleconsulta.

[14] For more information about the OpenCare5G Teleradiology project, visit: https://inovahc.hc.fm.usp.br/como-a-tecnologia-pode-promover-o-acesso-a-saude-em-comunidades-remotas/.

Brazilian Ministry of Health[15]. The essence of teleconsultations is to allow health professionals to obtain a second opinion from specialists in different areas, discuss clinical cases, and hold classes. In addition, it offered in-person training in skills and competencies to improve obstetric and hospital care in the monitoring of high-risk pregnancies. The initiative had nationwide scope and was initially offered in 27 hospitals, one in each Brazilian state and the Federal District. In two years, more than 1,500 pregnant women were assisted, and over 7,500 medical appointments took place.

3.8.3 In terms of sustainable funding for scaling the project after the first three years, the HCFMUSP will rely mostly on public funding from the Federal and/or State of São Paulo Governments to implement a telehealth solution for prenatal care or sign contracts with multilateral development banks or other stakeholders, including private corporations.

3.8.4 This pilot project will be crucial to determine the costs of scaling telehealth prenatal care to other regions. Costs may vary depending on the number of devices available, but ideally, each remote health unit would have one iCTG device connected to the 5G network and would need at least one physician and one nurse to offer prenatal care to the patient, while the team from HCFMUSP (at least one physician) would remotely support this process.

3.8.5 The estimated cost to assist remote hospital units would be approximately USD 67,000 per year, most of which would be used to hire professionals, one device per hospital unit, and 5G connectivity. The scale of the project would be modular since one physician can support and provide medical reports to up to three remote hospital units. Therefore, each module would consist of:

OBGYN Telehealth module	
1 physician working 40 hours a week	R$ 120,000/year (aprox. USD 20,652.98)
3 nurses working remotely (one for each hospital unit)	R$ 180,000/year (aprox. USD 30,979.47)
3 iCTG devices + connectivity (one for each hospital unit)	R$ 90,000/year (aprox. USD 15,489.73)
Total cost per module	**R$ 390,000/year (aprox. USD 67,122.18)**

3.8.6 With this funding, it would be possible to support at least 7,800 pregnant women annually and provide at least 31,200 cardiotocography exams. One device performs 4 exams per hour, so in 10 hours, it would amount to 40 exams/day. Considering 5 days a week, each device provided to a nurse would perform 200 weekly exams. Considering 4 exams per patient, a total of

[15] For more information about the Tele Obstetric ICU, visit: https://www.fm.usp.br/fmusp/noticias/-lancamento-tele-uti-obstetrica-uma-parceria-entre-a-fmusp-e-o-ministerio-da-saude-.

50 patients per week would be assisted, which accounts for 2,600 patients/year per device.

3.8.7 The scale means that the cost per patient is expected to be USD 50, and the cost per exam is USD 12.50.

3.9 Both output and outcome indicators align with IDB Lab and IDB Corporate Results Framework indicators (https://crf.iadb.org/en), including:

a. **Social inclusion and equality:**
   i. Level 1: Social Progress Index, since it is related to SDG 6 (Good Health and Wellbeing);
   ii. Level 2: Number of beneficiaries receiving health services and number of beneficiaries of targeted anti-poverty programs since the project will effectively offer better health services for pregnant women from P&V communities, especially during the third phase of the project;
   iii. Level 3: Projects supporting social inclusion and equality; Projects supporting gender equality;

b. **Productivity and innovation:**
   i. Level 1: Research and development expenditure as a percentage of GDP, since the project will be developed at public research institution;
   ii. Level 2: Micro, small, and medium enterprises financed since the project will support Melody's activities in Brazil;
   iii. Level 3: Projects supporting productivity and innovation;

c. **Gender equality and diversity:**
   I. Level 1: Global Gender Gap Index;
   II. Level 2: Number of women beneficiaries of economic empowerment initiatives; Strengthened gender equality and diversity policy frameworks since the project is focused on women's health and wellbeing;
   III. Level 3: Projects supporting social inclusion and equality;

IV. Indicative Budget

4.1 The total cost of the TC is US$875,000, of which US$700,000 will be financed by the resources of the Japan Special Fund (JSF) Japan Enhanced Initiative for Quality Infrastructure, Resilience against Disaster and Health (JEI). The remaining US$175,000 (in-kind) will be provided by the Executing Agency.

Indicative Budget* **

Component	IDB Funding (JSF)(JEI)	Counterpart Funding (In-kind)	Total Funding
Component 1 Wearable technology	$190,000.00	$50,000.00	$240,000.00

Component 2 Clinical infrastructure	$387,369.00	$96,842.00	$484,211.00
Component 3 Scalability and sustainability	$95,000.00	$23,750.00	$118,750.00
Contingencies	$27,631.00	$4,408.00	$322,039.00
Total	$700,000.00	$175,000.00	$875,000.00

**FFM is co-financing 20.00% of the project*
***The supervision of this technical cooperation will be under the IDB Brazil Country Office.*

V. Executing Agency and execution structure

5.1 *Fundação Faculdade de Medicina* (FFM) will be the executing agency of this project and will sign the agreement with the Bank. FFM is a non-profit foundation, private entity responsible for supporting the HCFMUSP Academic Health System and activities related to the collection, management, and application of resources. FFM is certified by the Ministry of Health as a Charitable Social Assistance Entity (*Entidade Beneficente de Assistência Social*) and qualified as a Social Health Organization (*Organização Social de Saúde*) in the State of São Paulo. FFM also has an agreement with HCFMUSP to implement these initiatives, according to the Brazilian Innovation Law (Law No. 10.973/2004). FFM and HCFMUSP have an agreement (nº 001/2021) for developing initiatives aimed at healthcare assistance, support for health surveillance, enhancement of scientific and technological development, and improvement of the hospital's operational capacity. FFM has a track record of working with the Bank on previous projects (Operation BR-T1457 – Open Innovation for the Health Sector in the Fight Against COVID-19).

5.2 The Academic Health System of the General Hospital of the Faculty of Medicine of the University of São Paulo comprises different organizations. The Faculty of Medicine of the University of São Paulo (FMUSP), the General Hospital of the Faculty of Medicine of the University of São Paulo (HCFMUSP), and its nine hospital institutions. The system also comprises InovaHC, the tech transfer office of HCFMUSP. InovaHC is responsible for implementing innovation projects at HCFMUSP.

5.3 This previous project's objective was to support the first edition of the Government of the State of São Paulo's open innovation program, IdeiaGov. This program focused on identifying challenges, receiving, and selecting proposals, financing, and validating technological solutions to address the needs of health networks in the fight against COVID-19.

5.4 To achieve this objective, the project had three lines of action: (i) Provide methodological support to prioritize challenges, find solutions, and manage their implementation for COVID-19; (ii) Offer technical and financial support to validate prototypes using HCFMUSP and IPT structure; and (iii) Develop a guide for regional implementation of innovative solutions for the pandemic crisis.

5.5 Other actors involved in the project include:

5.6 InovaHC, the technology transfer office of HCFMUSP. It was created in 2015 to serve as an agent of change by generating and driving innovation both within the

hospital complex and across the country. It brings together researchers, entrepreneurs, collaborators, and partners to advance healthcare. InovaHC is a department within the HCFMUSP. InovaHC is not a separate entity, and it will be responsible for managing the project and writing reports and presentations to IDB and IDB Lab. InovaHC implements several projects in partnership with FFM.

5.7 HCFMUSP is the largest hospital in Latin America and a teaching hospital directly affiliated with the University of São Paulo (USP), Brazil's largest and most prestigious academic institution. The Department of Obstetrics and Gynecology will be responsible for the research project and initiatives, including directly supporting the patients, testing, and using the iCTG devices, evaluating patients' and professionals' satisfaction with the device, and writing and publishing articles and reports. The General Hospital of the Faculty of Medicine of the University of São Paulo (HCFMUSP) has previous experience working in remote hospital services in remote regions in Brazil.[16]

5.8 Melody is a Japan-based startup specializing in creating and commercializing wearable, digital, and cloud-integrated fetal monitoring devices. The company was chosen as part of the TSUBASA open innovation challenge in 2022, a joint initiative organized by JICA and IDB Lab. This innovative device tracks fetal heart rate and uterine contractions, transmitting the data to a cloud server. The collected data is accessible to the expectant mother, her doctor, and other healthcare professionals from any location with internet connectivity using a tablet included in the kit. The startup will be responsible for providing the devices and platform, training professionals to use it, developing an AI solution to improve the platform, establishing a go-to-market plan, and providing regulatory approval with Brazilian authorities.

5.9 InovaHC will establish an execution unit and the necessary structure to execute project activities and manage resources effectively and efficiently. InovaHC will also be responsible for submitting progress reports on project implementation. Details on the structure of the execution unit and reporting requirements are in Annex V in the project technical files.

5.10 Regarding technical expertise, FFM, through its agreement with HCFMUSP/InovaHC, is fully capable of meeting the project's needs/objectives, and it has qualified staff to do so. FFM hires personnel based on a regulation focusing on academic background, years of experience, and activities. FFM also has robust financial conditions, is adequately capitalized, and enjoys excellent financial liquidity, as demonstrated during the screening process[17].

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[16] For example, in April 2024, HCFMUSP trained Indigenous agents from Alto do Xingu, in the Amazon region, to perform point-of-care ultrasounds - another action from InovaHC's OpenCare 5G project, which intended to provide health services to remote areas. For more information: https://medicinasa.com.br/inrad-indigenas/.

[17] In terms of financial sustainability, FFM enjoys a very comfortable liquidity situation and does not depend on external financing to carry out its activities. For better evidence, more direct indicators determined according to the financial statements prepared on 12/31/2023 (attached) are provided below. The current (immediate) liquidity on 12/31/2023 was 4.75 (that is, for every 1 of debt, there was 4.75 available for settlement), while the general liquidity, of a broader nature and considering longer-term rights and obligations, was 4.68. These ratios indicate excellent capitalization, with a high capacity to settle its commitments. In 2024, despite the fiscal year still being ongoing, the general situation remains

5.11 The Executing Agency agrees to adhere to the standard IDB Lab arrangement for results-based disbursements, the procurement and financial management policies applicable to the private sector, in accordance with the Financial Management Guidelines for IDB-financed Projects (document OP-273-12) of 17 June 2019 and specified in the Guide for Milestones-based Management and Financial Supervision for IDB Lab and SEP Technical Cooperation Projects.

5.12 The Executing Agency shall prepare a procurement plan acceptable to the Bank that describes the contracts for goods and services required to carry out the project, including the estimated cost of each contract and the proposed methods for acquisition of its goods and services, including consultants' services. The Bank may request annual reports on the execution of the procurement plan by the Executing Agency. Implementation of the procurement policies, terms of reference, and contracts for the acquisition of goods and services, as well as the procurement plan and fulfillment thereof, may be subject to ex-ante review or ex-post supervision by the Bank at its discretion.

5.13 Melody will be contracted as principal solution providers through direct contracting for the following three reasons: (i) their iCTG wearable solutions devices have the potential to be delivered and used in rural areas efficiently and effectively with portable and easy-to-use devices. The solutions have been acknowledged in several international prizes and academic papers, as mentioned above in Section II; (ii) the Executing Agency has previously tested their solution as a demo and demonstrated interest in further testing its efficiency and usability on a larger scale; (iii) Also, Melody International was selected as part of the TSUBASA Open Innovation Challenge supported by JICA and IDB Lab in 2022.

5.14 Melody will be hired to implement the following activities under Component I of the project, including equipment acquisition (iCTG Transducers and Tablets), training activities and materials (Manuals, Documents, Videos), maintenance, cloud services, and support, as well as software setup, AI development, and regulatory compliance. Representatives from Melody may also travel to Brazil to follow the project implementation. IDB will make payments directly to Melody once the Executing Agency approves the products/deliverables according to the Result Matrix and Budget Table. Melody International will receive US$ 200,000.00 during the project. The procurement of goods cannot represent more than 30% of the total IDB financing.

5.15 The level of risk, as determined by the Diagnostic Assessment of Integrity and Institutional Capacity (DICI), is low, confirming that the Executing Agency has an acceptable financial management system for IDB Lab and has a monitoring and accountability structure for the presentation of its institutional financial statements to the Bank.

5.16 The Executing Agency will be responsible for carrying out the project's monitoring and tracking activities, taking the indicators agreed upon in the results matrix as a reference. The Executing Agency will annually submit to the Bank a summary of the project's status through the Project Reporting System (PSR). This report will specify the fulfillment of components, results, and impact indicators of the project, as well as the milestone report, among others. IDB Lab will hold working meetings and field

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the same. The general institutional cash position reached R$1.3 billion reais (approximately USD 234 million) on 10/31/2024, with no significant changes in the liability structure.

visits to verify the completion of activities in situ, the quality of services provided to the beneficiaries, and the results achieved.

5.17 An initial and final baseline study of the project has been planned to capture the initial and final indicators of the project's execution at the level of the project's results matrix, with the aim of validating the project's impact thesis.

VI. Alignment with IDB Group strategies

6.1 The proposal is aligned with the strategic objective of reducing poverty and inequality by improving access to quality healthcare services for disadvantaged populations, especially women in P&V communities. The project addresses the health disparities faced by P&V communities in Brazil, contributing to the IDB's focus on inclusive growth and healthcare innovation. Furthermore, the collaboration with Melody International - part of the TSUBASA Open Innovation Challenge supported by JICA and IDB Lab - demonstrates a commitment to fostering partnerships that drive technological advancement and social impact.

6.2 This proposal is aligned with the priorities of the Japan Special Fund (JSF) in the line of the Japan Enhanced Initiative for Quality Infrastructure, Resilience against Disaster and Health (JEI).

6.3 This project is aligned with two IDB operations led by SPH: BR-T1562 - Innovation and Digital Health to Improve Health in the Amazon region and BR-T1520 - Support for Digital Transformation in the Health Sector in Brazil. Operation BR-T1562 aims to design an inclusive digital health service for the Amazonian population, while Operation BR-T1520 aims to improve the quality, efficiency, and equity of health services by adopting digital interventions. As such, a device like Melody's iCTG and the medical protocol HCFMUSP can be key to helping achieve these goals by taking fetal monitoring to remote areas and as a tool to push for a more digital health service, not only in Brazil but for the whole region.

6.4 This project is aligned with IDB's Country Strategy with Brazil 2024-2027, in its strategic objective of improving the quality of spending on health and education, by expanding the access to basic health care through the provision of quality remote cardiotocography, especially for high-risk pregnancies in vulnerable social contexts.

6.5 The project is aligned with the Sustainable Development Goals (SDGs), especially Goal 3: Ensure healthy lives and promote well-being for all ages, contributing to the targets 3.1: By 2030, reduce the global maternal mortality ratio to less than 70 per 100,000 live births; Target 3.2: By 2030, end preventable deaths of newborns and children under 5 years of age, with all countries aiming to reduce neonatal mortality to at least as low as 12 per 1,000 live births and under-5 mortality to at least as low as 25 per 1,000 live births; Target 3.7: By 2030, ensure universal access to sexual and reproductive healthcare services, including family planning, information, and education, and the integration of reproductive health into national strategies and programs; Target 3.8: Achieve universal health coverage, including financial risk protection, access to quality essential healthcare services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all; and Target 3.c: Substantially increase health financing and the recruitment, development, training, and retention of the health workforce in developing countries, especially in least developed countries and small island developing State.

6.6 Finally, as stated in the previous item, the project is focused on achieving the SDGs targets and indicators related to ensuring healthy lives and promoting well-being for all at all ages (Goal 3). Most of the United Nation's targets for 2030 in this goal are related to women's health, reducing the global maternal mortality ratio, and ending preventable deaths of newborns and children under 5 years of age. The project is also aligned with Brazilian strategies and policies. In September 2024, the Federal Government launched a new strategy to reduce maternal mortality by 25% by 2027, so this project can influence and serve as a best practice to support this new Brazilian strategy.

VII. Major Risks

7.1 **Partnership:** For the successful execution of the project, the partnership between FFM and Melody is of utmost importance. If such a partnership is not documented prior to, or terminated during, the project implementation, the project goals will not be achieved. To control this risk, IDB Lab will be requesting, as a **condition before the first disbursement**, a partnership agreement or any other form of documentation evidencing the establishment of a partnership between FFM and Melody. Additionally, the technical cooperation agreement to be signed between IDB Lab and FFM will include a clause of notification of early termination, indicating that FFM must inform IDB Lab of an early termination of its partnership with Melody.

7.2 **Equipment theft or loss:** The iCTG's wearable nature introduces the risk of loss or theft, especially due to its small size, which makes it easier to misplace. Mitigation measures include security protocols such as user training on device care, secure storage when not in use, and tracking capabilities for the devices.

7.3 **Connectivity in remote areas:** In remote or rural areas, reliable connectivity for transmitting data could be challenging, potentially leading to gaps in monitoring and delayed response to emergencies. If some of the areas covered in the project do not have good connectivity, it may affect the solution's performance. To mitigate these risks, the Executing Agency will contract data plans with telecoms and provide each device with a SIM card for all data communication.

7.4 **User compliance and training:** There may be risks related to the patients' and medical staff's ability to properly use and interpret the technology. Insufficient training can lead to user errors, impacting the reliability of the data. To mitigate it, Melody will offer training to staff and patients during the project implementation. There will also be a user manual for the people involved in the project.

7.5 **Information management and data protection:** The Executing Agency and its partners will manage the sensitive personal information of the participants principally online, and any mismanagement of the information may cause legal issues. The collection and storage of health data pose significant risks if not properly secured. Important measures will be taken to mitigate this risk. The team will carry out a thorough project planning and assess with Melody whether they collect and process personal and sensitive personal data (including storage and sharing). The team will align with InovaHC and HCFMUSP's legal departments on compliance with the GDPR (General Data Protection Regulation) and LGPD (Brazilian General Data Protection Law) and project risks. The contract must also include clauses regarding the non-sharing of data and subsequent deletion of data. The team will include

security protocols such as user training on device care, secure storage when not in use, tracking capabilities for the devices, and encryption to protect stored data. In addition, the project's implementation will be based on the Principles for Digital Development endorsed by the IDB and other multilateral organizations.

7.6 **Technology and logistics:** The project will demand important prevention measures to avoid technological and logistical risks, such as a) equipment not approved by ANVISA. To mitigate this risk, the team will approve a research project within the HCFMUSP Ethics Committee to enable the use of the device in a research context, eliminating the need for regulatory approval upfront. This process usually takes up to three months and will be approved before the beginning of the project; b) difficulty integrating data into the HCFMUSP medical record. To mitigate this risk, the team will evaluate integration requirements with IT personnel, including HCFMUSP IT (NETI), as well as carry out tests. If integrating is not viable, the EA will evaluate alternatives for the project that do not involve integration with the medical record system if the risk materializes.

7.7 **Access to information.** The information contained in this document is classified as public upon approval under the Bank's Access to Information Policy[18]**.**

7.8 **Intellectual property**. The Executing Agency and the solution providers will retain ownership of all intellectual property rights to the products developed and studies conducted under the project and will grant IDB Group a nonexclusive, free license to use them for non-commercial purposes in Brazil and throughout the region except for the app and algorithms. This will ensure that the lessons learned from the project are disseminated as widely as possible throughout the region.

7.9 The project team, with the support of the Office of Institutional Integrity (OII), conducted integrity due diligence (IDD) on the project (including FFM, HCFMUSP, and Melody International) and found no indicators of integrity or related reputational risks for IDB Lab that merit disclosure.

VIII. Exceptions to Bank policy

8.1 None.

IX. Environmental and Social Strategy

9.1 This operation was screened and classified in accordance with the IDB´s Environmental and Social Policy Framework (document GN-2695-21) on June 10, 2024. Given the limited impacts and risks, the project has been proposed as a category C operation. This operation was also screened for Paris Alignment on June 12, 2024, by the project team and is deemed to be aligned with BB1 and BB2.

[18] https://www.iadb.org/en/access-information/home