Plan of Operations

INDIVIDUAL PROJECT OF THE FACILITY RG-O1676
LINE OF ACTIVITY FOR INNOVATION PROTOTYPES
"TC PROTOTYPES"

DELEGATION OF AUTHORITY TO COUNTRY OFFICES

BRAZIL
(BR-T1459)

I. GENERAL INFORMATION

Title	Laura Digital Emergency Department (Laura Digital ED) with Artificial Intelligence (AI)		
Executing Agency:	Associação Laura Fressatto de Apoio a Saúde (Laura Institute).		
Focus Area:	Knowledge Economy		
Project Beneficiaries:	(i) Over 50 thousand people who will have access to a remote monitoring system application for detecting early signs of patient deterioration by COVID-19; (ii) 10 hospitals; (iii) Health Departments of 3 cities.		
Financing:	IDB Lab Cooperation:	US$ 128,000	80%
	Counterpart:	US$ 32,000	20%
	TOTAL PROJECT BUDGET:	US$ 160,000	100%
Execution and Disbursement Period:	15 months for execution and disbursement.		
Objective:	The main objective of this project is to contribute to the health of patients from 10 hospitals and 3 different cities in Brazil, by increasing their access to health services through high impact technology and by improving the patient pathway management using artificial intelligence algorithms.		
Environmental and Social Impact Review	This operation was screened and classified as required by the IDB's safeguard policy (OP-703) on 03/july/2020. Given the limited impacts and risks, the proposed category for the project is C.		
Project Team	Carolina Carrasco (DIS/CCH), Melissa Sendic (DIS/CBR), Felipe Cresciulo (INV/CBR), Jéssica Leite (DIS/CBR), Padydeh Eghbali (LAB/FIA), Catherine Pinto (SCL/SPH), Eduardo Azevedo (KIC/ICD), Juan Pedeflous (FML/LAB)		
Unit responsible for disbursements	CBR		

II. BACKGROUND AND JUSTIFICATION

A. Problem Description

2.1. In the last two decades the number of visits to the emergency department (Emergency Room) has increased by approximately 50% in the USA, with 138 million visits in 2014. This increase has contributed to the agglomeration in the emergency room and delays in care and, consequently, greater morbidity and mortality. Emergency screening presents the first opportunity to identify high-risk patients early and efficiently allocate finite resources. Among several screening algorithms, the Emerging Severity Index (ESI) and the Manchester System (MTS) are the most used. Despite their wide adoption, they depend heavily on subjective judgment, leading to high inter-examiner variability and suboptimal predictive capacity. The advent of Artificial Intelligence (AI) promises to improve predictive capacity in various conditions (for example, sepsis, unplanned transfers to intensive care unit and clinical deterioration). These approaches offer advantages for having high-order nonlinear interactions between predictors, obtaining more stable predictions.

2.2. Globally, the current crisis with the Coronavirus pandemic is causing a collapse in the health system: overcrowded emergency rooms, unnecessary visits to hospitals, overload of health professionals, and deviation of resources to low-risk patients, are some of the situations that affect citizens, especially the most vulnerable.

2.3. A more efficient and scalable screening tool allied with a robust dashboard with updated information of incoming patients for both the Emergency and City Health Departments would be a powerful tool to ameliorate the patient workflow, tailor government operations, and save lives.

2.4. Hospitals are using different kinds of tools to resolve questions about COVID and the development of remote triages in order to avoid unnecessary agglomerations and ensure an efficient use of resources in high risk patients. The use of AI to help patients' self-triage can dramatically increase the number of initial screenings, making a rapid differentiation between symptoms and providing appropriate recommendations to those probably developing COVID-19.

2.5. In Brazil, Laura AI platform has been operating since 2016, applying predictive analysis of patients in risk. Currently, the technology is preset in 30 Brazilian hospitals, attending an average of 10,000 hospital beds per monthly. Between the period of October 2016 to Abril 2020, the AI RL platform already had access to data of 3.9 million attendants and 1.7 million unique patients, which makes the AI model more robust and reliable.

2.6. The platform can be integrated with any Electronic Medical Record (EMR) system operating in health institutions. Once integrated, it will perform the retrospective analysis of the database in order to: (i) refine the prediction models of clinical deterioration; and (ii) generate reports on demographic data and local outcomes (mortality rate, length of stay). The platform use has proven to have a positive impact on the mortality rate (decrease of 25%), length of stay (decrease of 10%) and consequent hospitals cost reduction (US $ 1.2 million in just 1 year). The performance of the AI model for predicting patient's clinical deterioration was also shown to be superior to the scores used as state of the art, with an accuracy

greater than 90%. The current model in use was developed with data from 211,298 patients and 14 million collections of vital signs, reaching AUROC[1] curve of 0.97, sensitivity[2] of 92.6% and specificity[3] of 92.2%.

2.7. Laura AI experience was selected as Top Two Abstracts in SAIL 2020 (Symposium on Artificial Intelligence for Learning Health Systems) and will receive the New England Journal of Medicine (NEJM) travel scholarship. Moreover, Laura also had a scientific paper accepted in the CBMS 2020 (International Symposium on Computer-Based Medical Systems) comparing different machine learning approaches for healthcare.

III. THE INNOVATION PROPOSAL

A. Description of the Solution being Tested

3.1. Based on Laura's experience, the prototype will test a new application of Laura technology, providing virtual screening of patients, supported by a AI-based virtual assistant AI, that will be trained applying World Health Organization's and Brazil's Ministry of Health guidelines. The virtual assistant will be powered by Natural-Language Processing (NLP) technology in order to meliorate the user experience.

3.2. The main objective of this project is to contribute to improve/support the health of patients from 10 hospitals and 3 different cities in Brazil by increasing their access to health services through high impact technology and by improving the patient management pathway using AI algorithms for virtual screening.

3.3. The Executing Agency identified the cities of Curitiba, Ponta Grossa and Piçarras for the deployment of the virtual screening prototype, in alliance with corresponding Health Departments, which already confirmed their interest for this solution. Regarding hospitals, a pre-identification of 10 health centers, 9 of them public or philanthropic, will be part of the pilot experience.

3.4. If the patients show no signs of severity of clinical symptoms secondary to COVID-19, they shall receive prevention and follow-up guidance by the virtual assistant itself for 14 days. If this virtual screening identifies severity criteria or changes in the patient's clinical conditions, the patient should confirm that he/she will go to the hospital/Emergency Departments (ED) and he/she will appear in the demand forecast dashboard so that the hospital management team will be able to distribute and reallocate existing resources to offer the best possible clinical assistance to the patient.

B. Description of the Beneficiaries

3.5. The project will benefit: (i) over fifty thousand people who will have access to a remote monitoring system application for detecting early signs of patient clinical deterioration by COVID-19; (ii) ten hospitals, that will take advantage of an end-to-end solution which will store data on patient experience, from the presentation of symptoms, collected remotely, to attendance in the ED this will enable medical services to predict patient outcomes such as hospital admission, need for intensive care admission and mortality risk; and (iii) Health Departments of 3 cities that will

[1] In machine learning the term AUROC (Area Under the Receiver Operating Characteristics) is used to explain the model's performance (a value near to 1 is desirable)

[2] Percentage of sick people who are correctly identified as having the condition

[3] Percentage of healthy people who are correctly identified as not having the condition

be able to deploy remote monitoring of citizens at risk, detecting early signs of patient clinical deterioration by COVID-19 and directly guide those patients at risk to Public Emergency Departments. Moreover, it will be possible to have a holistic view of epidemiological data, clustering by region, most common symptoms and comorbidities, as well as clinical outcomes insights.

C. THE PROTOTYPE EXECUTION STAGES

A. Definition Stage:

3.6 During this stage, the machine learning algorithm for virtual screening of patients, supported by a virtual assistant will be developed considering the Principles for digital development[4]. This process will be documented by the Execution Agency.

3.7 A training kit (short manuals & videos) for hospitals, healthcare professionals (nurses and doctors), and Health Departments, will be developed and tested.

3.8 Severity criteria will be defined based on recent publications and scientific committee composed by Infectious Diseases and Emergency Department Physicians.

B. Implementation Stage:

3.9 During implementation stage, a differentiated strategy for hospitals and cities will be deployed:

3.10 **Hospitals Implementation:** (i) training on how to use Laura Remote Monitoring System for both healthcare professionals working on emergency departments and those developing solutions for improved healthcare system administration; (ii) fine-tuning of Laura's solution for each hospital and their emergency rooms; (iii) installation of Laura's virtual assistant on the website of each hospital; and (iv) remote monitoring of patients from each hospital.

3.11 **Cities Implementation:** (i) training on how to use Laura Remote Monitoring System for Cities Departments of Health; (ii) implementation of Laura Remote Monitoring System in each Department of Health, including a fine-tuning of Laura's solution in each Department; (iii) installation of Laura's virtual assistant on the website of each Department of Health; (iv) remote monitoring for patients from each Department of Health; and (v) implementation of Laura Epidemiological and Clinical Outcomes Dashboard in each Department of Health.

C. Evaluation and Knowledge Dissemination Stage:

3.12 The Executing Agency will prepare a final monitoring report will be released in January 2021 as a white paper. The main objective of this report is to share knowledge gathered along the project. The report will systematize the project's experience from its conception (how it was designed and conceived), implementation (what was the main factors that made it scalable, what were the main challenges), and the key performance indicators achieved. Taking into account the results of the prototype experience, the report will also include a scale strategy at national and regional levels.

3.13 The results of the algorithm tested, will be audited by an independent consultant or entity.

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[4] https://digitalprinciples.org/principles/

3.14 Once the algorithm receives scientific validation a Scientific Research Paper, describing technical aspects of the Machine Learning models used in addition to their performance in the identification of patients at risk of clinical deteriorating by COVID-19 (accuracy, sensitivity, specificity, F1 Score, Matthews correlation coefficient), will be developed by the Executing Agency. The study will be published as a preprint on MedRxiv/ ARxiv[5] and we also be sent to a high impact factor journal.

IV. EXECUTION AGENCY AND ARRANGEMENTS FOR EXECUTION:

A. Executing Agency

4.1 The prototype will be executed by Associação Laura Fressatto de Apoio a Saúde (Laura Institute), which is the social innovation institution of the Laura Group. The main goal of Laura Institute is to provide affordable high impact technology for improving healthcare services offered by the public sector as well as by philanthropic institutions. The Laura Institute have a cooperation agreement with the Ministry of Science, Technology, Innovations and Communications (MCTIC) in Brazil for introducing Artificial Intelligence systems to public hospitals in Brazil. Laura Group has been in the market since 2016 and have been providing platforms built to meet the needs of two major purposes: (i), to identify the patient who needs more attention and (ii) to provide health care teams with an early warning system about at risk patients, providing insights generated by machine learning algorithms and big data. Since then, Laura Group has assisted different care teams, from different clinical specialties, helping to save more than 12,289 lives, have analyzed more than 1.7 million patients and conducted more than 3 million unique visits, supporting decision making, which allows diagnosis and actions to be more tailored and appropriate to individual patient care, supported by predictive algorithms.

4.2 Laura has been recognized in several awards like the IET - The Institution of Engineering and Technology - Innovation winner, Pfizer challenge, 1776 Challenge Cup, Digital Healthcare Award Brazil & Latin America, Innovation & Tech Day: France - Brazil Chamber of Commerce, Deutsch-Brasilianische Industrie- und Handelskammer - Award, Accelerate2030 from United Nations.

B. Implementation Mechanism

4.3 The definition and execution stages will be developed by Laura Startup, the artificial intelligence company which develops healthcare software for the Laura Group. Laura Institute will contract Laura Startup for developing a single source consultancy contract, definition and execution stages. The terms of reference of this direct contract are available in Annex V.

4.4 The knowledge and evaluation component will be developed by Laura Institute.

4.5 **Principles for digital development[6].** The algorithms developed by the project will consider the following principles:

(a) **Design with the User.** Dialogue with actual users to understand the user experience and the important issues for the development of a new product. Digital tools to collect direct and indirect feedbacks to visualize behaviors like

[5] Open Access health publications platf\forms

[6] https://digitalprinciples.org/principles/

Heatmaps, Visitor Recordings, Feedback Polls, and Conversion Funnels, are also used.

(b) **Understand the Existing Ecosystem** and the adoption of pertinent communication channels.

(c) **Design for Scale,** based on microservices architecture and Kubernetes infrastructure, which means Laura services are ready for scale regardless of the number of users.

(d) **Build for Sustainability,** ensuring formal partnership agreements with local governments integrating national strategies for intelligent health system.

(e) **Be Data-Driven.** Making real-time dashboards available, so that hospitals and the city health institutions can use data to support rapid decision-making and intelligent resource allocation.

(f) **Use of Open Standards, Open Data, Open Source, and Open Innovation.** Most of the technologies used in Laura´s services development are open sources, such as Python, R, Kubernetes, Rancher and TensorFlow.

(g) **Reuse and Improve.** The microservices technology structure provides flexibility to develop new or rebuilt modules as needed, smaller and faster deployments continuous deployment, and a huge impact on scalability.

(h) **Address Privacy and Security.** The infrastructure services are based on non-open-source technologies. Laura uses Amazon Web Services (AWS), considered one of the most well-known cloud providers, which is in compliance with Health Insurance Portability and Accountability Act (HIPAA).

(i) **Be Collaborative.** Since the beginning of Laura´s developments diverse experts have been engaged (doctors, nurses, infectologists, biologists, biomedical, designers, engineers, developers, data scientists, health secretaries, mayors, and social workers).

V. ALIGNMENT WITH IDB GROUP, SCALABILITY, AND RISKS

A. Alignment with IDB Group

5.1 The Prototype is aligned with SDG 3 “Good Health and wellbeing” and with the Bank´s country strategy priorities for 2019-2022 (iv) reduce inequality of opportunity by enhancing public policy efficiency giving access to primary care to more people. As cross-cutting issues, the strategy will address challenges related to (c) innovation and digital transformation. The project is also aligned with IDB Group response to COVID-19, in the area of public health.

5.2 The project will contribute to the objectives of IDB Group fAIr Lac initiative, which aims to promote an efficient public management, using the opportunities arise from AI application, enhancing dialogue between public and private actors.

B. Scalability / Replicability

5.3 The prototype has a clear and scalable business model oriented to both, new health centers and departments, at the national and international level, and new medical specialties that could benefit of predictive models usage, as monitoring of pregnant mothers in order to reduce maternal mortality ratio, monitoring of diseases such as Malaria, dengue, yellow fever, stroke, tuberculosis, hepatitis B and C, HIV / AIDS, flu etc., for treatment improvements, etc.

C. Risks

5.4 The main envisaged risks and their mitigation strategies are:

Risks	Probability	Impact	Mitigation Strategy
Low product adherence by users	Low	High	Expand forms of disclosure to ensure understanding and access to the solution
Difficulty in accessing the solution	Low	High	Expand forms of disclosure to ensure understanding and access to the solution
Lack of adherence to the institutional process	Medium	Medium	Mapping of pre-implantation processes and development of generic systems for institutions
Customizations	Medium	Low	Development of platform with possibilities for customization of the screening flow by the institution itself
Data security	Low	High	Analysis of the current architecture to identify risks, development of security layers in the cloud network to secure services.
Data Ethics	Low	High	The Project will develop clear Terms and Conditions regarding data collection, data use, anonymization for research purposes, and any other relevant issue identified during definition and implementation stages.

VI. SUMMARY BUDGET

6.1 The project has a total cost of US$160,000, of which US$128,000 (80%) will be provided by IDB Lab, and US$32,000 (20%) by the counterpart.

6.2 The instrument to be used is a non-reimbursable technical cooperation given the coronavirus pandemic and urgent implementation needed.

6.3 Retroactive Recognition of Counterpart Funds. Counterpart resources from eligibility date, 14/April/2020, will be retroactively recognized.

Component	BID Lab	Local Contribution	Total
Component I: Definition	**0**	**10,000**	**10,000**
Development of training kit (short manuals, videos) for the healthcare professionals of how to use the platform	0	5,000	**5,000**
Training new intentions for chatbot according to WHO and Health Ministry guidelines	0	5,000	**5,000**
Component II.a : Implementation in hospitals	**120,000**	**10,000**	**130,000**
Implementation in hospitals	60,000	5,000	**65,000**

Implementation in cities	60,000	5,000	**65,000**
Component III	**8,000**	**12,000**	**20,000**
Impact evaluation report	0	2,000	**2,000**
Midterm and final evaluation report	0	3,000	**3,000**
Scientific Research Paper	0	5,000	**5,000**
External audit of algorithm's results	8,000	2,000	**10,000**
Total	**128,000**	**32,000**	**160,000**
Percentages	**80%**	**20%**	**100%**

VII. COMPLIANCE WITH MILESTONES, FIDUCIARY AND REPORTING ARRANGEMENTS

7.1 **Disbursement by Results.** In order for the results to be accepted, the EA will adhere to the IDB Lab disbursement standards established in the "Operational Guidelines for Management of Milestones and Financial Supervision for IDB Lab and PES Technical Cooperation Projects" (updated in 2019). Monitoring will be undertaken in accordance with the performance and risk management policies (fulfillment of milestones) established in these Operational Guidelines. The project disbursements will be contingent upon verification of the achievement of the milestones. These milestones will be verified using their means of verification, which will be agreed upon between the EA and the IDB Lab. The achievement of these milestones does not exempt the EA from the responsibility of reaching the logical framework indicators and the project objectives.

7.2 **Project Supervision.** The Project will be associated with the Line of Activity RG-O1676 in Bank systems. It will be supervised by the IDB Lab Specialist based in the Brazil IDB Country Office and executed in coordination with the Project Team for RG-O1676.

7.3 **Procurement**. The Executing Agency shall have a procurement policy in place to ensure that the project-related procurement is complete at competitive market prices. It shall also prepare a procurement plan (the "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 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 therefor may be subject to ex-ante review or ex-post supervision by the Bank, at its discretion.

7.4 **Financial Management:** Disbursements will be made in accordance with the Financial Management Guidelines for IDB-Financed Projects (OP-273-12) July 2, 2019 or future updates. The Executing Agency shall maintain *financial data and internal accounting and administrative control systems acceptable to the Bank* to provide the necessary documentation to permit verification by the Bank of the procurement and expenditures for the Project and to facilitate the timely preparation of financial statements, budgets, and reports. The Bank reserves the right to audit all financial statements, internal controls, procurement, or other aspects of the Project.

7.5 **Financial Statements.** The Executing Agency shall prepare and make available for the Bank its annual financial statements, which must be certified by an external auditor acceptable to the Bank and include a note on the use of the Contribution

and Counterpart Resources for the Project. The financial statements must be submitted to the Bank within 90 calendar days of the close of each fiscal year. Together with its annual financial statements, the Executing Agency must submit a certification of integrity, transparency and use of funds in the format to be outlined in the Technical Cooperation Agreement to the bank.

7.6 **Project Status Reports:** The Executing Agency is responsible for presenting a PSR to the IDB Lab within 30 days within 30 days following the end of each semester, or more frequently if required by IDB Lab. The PSR must include information about the implementation of the project, results obtained, and contributions to reaching the project objective as presented in the Result Matrix (Annex I) as well as other planning instruments. Additionally, the document must include information on challenges encountered during the implementation period and possible paths to address these challenges. Within 90 days of finishing the execution period, the Executing Agency will present to IDB Lab a Final PSR giving priory to reporting on key results achieved, a sustainability plan, scaling up strategy, and lessons learned.

7.7 **Project Coordinator:** The Executing Agency will appoint a Project Coordinator either from its existing staff or at its own cost. Expenses relating to project coordination and/or administration costs are not eligible under the IDB Lab contribution, rather such expenses must be financed by the counterpart contribution. The Project Coordinator shall have overall responsibility for the management of the project, including submission of PSRs, tracking milestones and results and coordination with IDB Lab.

APPROVAL

This Technical Cooperation Prototype is recommended and approved for funding under IDB Lab's Line of Activity for Innovation Prototypes MIF/GN-123 (project number RG-O1676, document number MIF/AT-1565, and resolution number MIF/DE-8/19).