

TC Document/Appendice

I. Basic Information for TC

▪ Country/Region:	CHILE/CSC - Southern Cone ¹
▪ TC Name:	Early Diagnosis of Diabetic Retinopathy in Chilean Health Service Using Medical Devices and Artificial Intelligence-based Pre-reports
▪ TC Number:	CH-T1284
▪ Team Leader/Members:	CARRASCO, CAROLINA (DIS/CCH), Team Leader; OKUMURA, MASATO (LAB/DIS), Alternate Team Leader; NARITA, TETSURO (LAB/INV), DIAZ ORDONEZ, JARA, PATRICIA (SCL/SPH), CHRISTIAN DIAZ (GCL/FML), LANZALOT, MARIA LAURA (DVF/DSP)
▪ Taxonomy:	Client Support
▪ Operation Supported by the TC:	N/A
▪ Date of TC Abstract authorization:	January 23 rd , 2023
▪ Beneficiary:	1,800 diabetic patients from Chile's public Health Service, at least 50% belong to vulnerable population (FONASA type A and B), 180 patients with disability will be treated at their homes
▪ Executing Agency and contact name:	Soluciones Tecnológicas e Informáticas Chile-Japón Spa (ALLM Latam)
▪ Donors providing funding:	Japan Enhanced Initiative for Quality Infrastructure, Resilience against Disaster and Health (JEI)
▪ IDB Funding Requested:	US\$308,000.00
▪ Local counterpart funding, if any:	US\$83,000.00
▪ Disbursement period (which includes Execution period):	42 months
▪ Required start date:	-
▪ Types of consultants:	Not Applicable
▪ Prepared by Unit:	IDB Lab in collaboration with SPH
▪ Unit of Disbursement Responsibility:	CSC/CCH
▪ TC included in Country Strategy (y/n):	Y
▪ TC included in CPD (y/n):	N
▪ Alignment to the Update to the Institutional Strategy 2010-2020:	Social inclusion and equality, and Productivity and innovation

II. Objectives and Justification of the TC

- 2.1 The increasing number of diabetic retinopathy (DR) cases and the lack of efficient and effective healthcare services has been one of the most concerning issues in Chile, especially for lower-income populations which this disease affects more.
- 2.2 DR is an eye disease caused by diabetes that affects the blood vessels, causing vision loss. It is the leading cause of blindness among adults of productive age in

¹ The non-objection of the country was received on May 30th, 2022.

developing countries and ranks third in Latin America after cataracts^{2,3}. In Chile, the prevalence of DR reported in various studies represents approximately 24-28% of the diabetic population⁴. Based on statistics in the country regarding the number of diabetic patients in 2016-2017⁵ – 1,468,818 patients- it is estimated that currently at least 350,000 people have a diagnosis of DR. Diabetic retinopathy (DR) is the leading cause of non-recoverable visual loss in industrialized countries in patients between 20 and 64 years of age, being responsible for 10% of new cases of blindness each year, being of vital importance to make an early diagnosis of this pathology, to establish the appropriate treatment as soon as possible and to avoid progression to more severe stages that cause irreversible blindness. On the other hand, the appearance of diabetic retinopathy is considered a marker of the general condition of the diabetic patient. The presence of proliferative diabetic retinopathy indicates that the patient has a higher cardiovascular risk, with an increased rate of acute myocardial infarction, amputation, and death. Thus, as a guideline, it is estimated that the risk of death at 5 years in diabetic patients can be associated with the severity of DR; if there is no DR, the risk will be 4% and if there is proliferative retinopathy it will be 68%⁶. In addition, the prevalence and incidence of DR are constantly increasing due to the worldwide epidemic of Diabetes Mellitus (DM), which is one of the principal causes of DR, and Chile is no exception. Accordingly, it is expected that by the year 2030 the number of patients with this ophthalmologic condition will double the current number of diagnosed patients.

- 2.3 The article "Chile needs better statistics and greater coverage in screening for diabetic retinopathy⁷", published in 2017, states that, when analyzing the proportion of people in treatment for DM with visual impairment, a clear gradient is observed across the different socioeconomic levels, which is that the lower the income quintile is, the higher the proportion with visual impairment goes. It is shown that Visual Impairment (including blindness) due to Diabetes is approximately three times higher in quintile I (lowest income population) than in quintile V (highest income population). (See Table 1) A similar situation occurs at the level of the social security system, with a higher proportion of people with DM affiliated to FONASA (public health insurance) than those with DM affiliated to ISAPRE (private health insurance).

² Klein BE. Overview of epidemiologic studies of diabetic retinopathy. *Ophthalmic epidemiology*. 2007;14(4):179-83.

³ Furtado JM, Lansingh VC, Carter MJ, Milanese MF, Pena BN, Ghersi HA, et al. Causes of blindness and visual impairment in Latin America. *Survey of ophthalmology*. 2012;57(2):149-77.

⁴ Verdaguer J, Vicencio C, Zúñiga C, Molina E, Grupo Panamericano, Chileno del Día-D. Tamizaje para Retinopatía Diabética en Latinoamérica (Día D). Resultados. *Arch Chil Oftalmol*. 2001;58(1-2):39-44.

⁵ Informe sobre Diabetes Melitus, Encuesta nacional de Salud 2016-2017, 2021(marzo); 9-12

⁶ Aliseda D, Berástegui L. Retinopatía diabética. *An Sist Sanit Navar* [Internet]. 2008 [citado el 14 de octubre de 2022]; 31:23–34.

⁷ T. Covarrubias et al, Chile needs better statistics and greater coverage in screening for diabetic retinopathy", *Revista Médica de Chile*, 2017 Dec;145(12):1633-1635.

Table 1: Diabetes Mellitus cases by income level⁸

Autonomous quintile of income level	Number of people with DM	% with visual impairment
I (lowest income)	188,668	9.9%
II	177,790	7.7%
III	169,404	7.6%
IV	149,689	5.1%
V (highest income)	99,586	3.5%

2.4 The lack of sufficient attention is also a critical issue. The national eye fundus examination coverage rate was 19.1% in 2011. In 2016, the figures became significantly higher, reaching 32.5%. In 2019, the highest value of 36.5% was recorded, although not significantly different from 2016⁹. Among the objectives of the Chilean Ministry of Health MINSAL's national health strategy is to reduce mortality associated with DM and improve the quality of care for diabetics. To this end, a target of 80% is set for the coverage rate (CR) of Eye Fundus for the age groups 15 to 24 years and over 65 years, while for the population between 25 and 64 years, a target of 90% is considered¹⁰. England recently achieved a similar CR, reaching 82.7%¹¹.

2.5 The latest study published by the National Disability Service (SENADIS), conducted on the population of people aged 18 years and older, considered representative at national, regional, and urban/rural levels, shows that eye diseases (72.7%) and circulatory system diseases (55.7%) are the most frequent among the adult population with disabilities¹². Patients with DR in more advanced stages present decompensation of diabetes, which increases the risk of presenting ischemic circulatory diseases such as diabetic foot, which depending on the management and progression can lead to amputation of limbs. On the other hand, blindness caused by advanced stages of DR also means high degrees of disability. Globally, people with disabilities are on the vertiginous rise and access to health care is a challenge due to different issues such as:

- The feeling of discrimination, stigmatization, misunderstanding, and lack of policies in place for their health care.
- Inadequate physical spaces, remote health care facilities with low frequency of transportation, poorly lit facilities that lead to accidents.

⁸ R.Silva-Jorquera, C. Zett, "Coverage rates of eye fundus examinations among Chilean patients with diabetes mellitus", Revista Médica de Chile, vol.149 no.7 Santiago jul. 2021

⁹ Ibid.

¹⁰ Subsecretaría de Redes Asistenciales. Matriz de Cuidado a lo Largo del Curso de la Vida [Internet]. 2020. Available from: https://www.minsal.cl/wp-content/uploads/2020/09/20200908_MATRIZ-DE-CUIDADOSA-LO-LARGO-DEL-CURSO-DE-VIDA.pdf [cited on Dec 28th, 2020]

¹¹ Public Health England. NHS Screening Programmes in England 2017 to 2018. 2019 March p. 17.

¹² Servicio Nacional de la Discapacidad [Internet]. Gob.cl. Disponible en: https://www.senadis.gob.cl/pag/355/1197/ii_estudio_nacional_de_discapacidad

- In the case of blindness, there are usually no communication channels (loudspeakers, audios) with health information or innovative formats in documents such as medical prescriptions.
Disability in vulnerable populations means low incomes or pensions, which do not make it possible to afford health care or travel to health care centers.

2.6 MINSAL provides substantial financial coverage for a group of urgent illnesses based on a warrant stated in legislation named Garantías Explícitas de Salud (GES), which includes DR. For every GES-covered illness, the ministry regulates the maximum waiting periods for each procedure considered in the corresponding treatment. In the case of DR, the maximum period between the suspicion and the diagnosis is 90 days, while surgery should take up to 60 days from the medical order. The table below¹³ shows only the number of patients being treated in the public health system whose GES-warranted treatment was delayed at the end of 2021. As shown in the table below, out of all GES-warranted pathologies, visual impairment-related illnesses such as cataracts, refraction defects, and DR are in the top 5 of the waiting lists of patients. It is important to note that DM has a negative effect on the productive life of patients causing them to lose more than ten years of productive life. The main and most frequent complication is DR with 47.2%, followed by peripheral vascular insufficiency and neuropathy¹⁴.

Table 2: Number of patients with accumulated delay in GES-warranted treatment¹⁵

Health Problem	Number of patients with Delayed Opportunity Guarantees
Cataracts	12.485
Refraction defects	4.249
Integral Oral Health of Pregnant Women	2.714
Preventive Cholecystectomy	3.468
Diabetic Retinopathy	2.398
Breast Cancer	2.026
Hip Osteoarthritis	1.486
Cervical Uterine Cancer	2.731
Orthoses	4.212
Chronic Kidney Disease Stage 4 and 5	1.374

2.7 This proposal aims to promote fundus examinations of diabetic patients belonging to Chile's public Health Service to diagnose diabetic retinopathy and encourage its follow-up treatment, with a focus on vulnerable populations and a specific activity targeting people with disability.

¹³ Subsecretaría de Redes Asistenciales, "Glosa 06, Ley de Presupuesto 21.289", enero de 2022, <https://www.minsal.cl/wp-content/uploads/2021/05/ORD-495-09-02-2022.pdf>, p. 16

¹⁴ V. Ramos-Trujillo et al., "Labor invalidity: Result of the chronic complication of the Mellitus Diabetes type 2", REVISTA SALUD QUINTANA ROO, vol. 12, nro. 42, julio-diciembre 2019, p. 7-11

¹⁵ Ditto.

- 2.8 This project will pilot the implementation of a Japanese solution based on the use of portable retinal cameras and an artificial intelligence (AI) tool for the performance of fundus examination in 1,800 diabetic patients from Chile's Public Health Service, at least 50% belong to a vulnerable population (FONASA type A and B)¹⁶, and 180 patients with a disability will be treated at their homes. The level of innovation of this project in Chile is considered quite high because it proposes a novel way to help the public health system to strengthen the detection of diabetic retinopathy (DR) at early stages in vulnerable populations based on artificial intelligence and agile deployment of low-cost portable eye exam equipment. Considering that DR is the number one cause of blindness in the working-age population, its early detection is vital for any developing country's society. In Brazil, Allm had some previous experience with the eye exam equipment considered in this project with very good results on massive eye screening programs in search for pathologies such as glaucoma, cataract, DR, etc. organized by city halls.
- 2.9 For this purpose, in the framework of the national home care program, aimed at the vulnerable population affected by chronic diseases, the health personnel will be provided with a combination of technologies that will enrich and complement clinical evaluations in general and, in particular, that of diabetic patients. The innovation of this proposal is related to the virtuous combination of the technologies to be implemented:
- 2.9.1 The communication application, "JOIN", certified as a medical device in Japan, which has been successfully developed and tested in different countries. JOIN allows medical staff to exchange patient clinical information, including real-time video, images under DICOM viewer system, geo-referencing, and other relevant data, optimizing diagnosis, treatment, operational costs, and efficiency. JOIN is certified under HIPAA, EU GDPR, and ISO27001, its communications are encrypted, and all patient information is anonymized.
- 2.9.2 Portable retinal cameras which consist of camera-equipped devices that weigh a few kg and are small. The cameras are high resolution and specialized in taking eye fundus images according to ophthalmological standards. One of the main benefits that this type of portable format brings to the care model is the possibility of moving them even to remote areas, bringing health and technology closer to people who have greater access barriers to this type of services.
- 2.9.3 Incorporation of an artificial intelligence (AI) tool that provides in a matter of minutes an automated report that predicts, with 85% accuracy, DR findings.
- 2.10 The combination of these three technologies will allow health professionals and the patients themselves to have an expeditious and timely diagnosis, without having to wait for a report, which in conventional terms can take a month or more, speeding up the referral of patients with pathological findings to the ophthalmologists of the corresponding Health Service, scheduling their consultation hours, and treatments, more quickly.

¹⁶ FONASA type A and B population corresponds to patients with monthly income below [\\$320.500 as of 2020](#), therefore, those patients have a monthly income below the national median income ([\\$457.690 as of 2021](#)).

- 2.11 The final beneficiaries of this project will be 1,800 diabetic patients in the selected region/city/area who will be able to receive treatment in a timelier fashion by a quicker diagnosis and prompter specialist appointment. At least 50 % of those patients will belong to the vulnerable segment of the population. By choosing a low-income area with low eye-fundus coverage rates the team aims to target poor or vulnerable populations. The intermediate beneficiaries will be the public health care services of the region, and more specifically the Unidades de Atención Primaria Oftalmológica (Ophthalmological Primary Care Units), which will be able to reduce their long waiting lists of patients waiting for an eye-fundus exam. The corresponding Servicio de Salud (Health Network) will also be a beneficiary as it will be able to reduce the gap of the yearly retinal exams requested by the Ministry of Health. The project incorporates, within the target population, diabetic people with some degree of disability which does not allow them to travel to mobile care devices or health centers. In order to overcome this access barrier, a particular care model will be defined to bring the eye fundus service closer to homes, institutions such as nursing homes, etc. The staff of professionals will travel to the places of residence, with necessary equipment and supplies, ideally accompanied by the home care team of the corresponding health center.
- 2.12 It is important to note that the idea is to pilot a scalable model so that the solution will be replicated in other regions in Chile or in other countries of Latin America and the Caribbean to benefit a larger number of patients. Also, a scale-up path in collaboration with IDB's public sector will be considered. The detailed scale-up planning is included in Component II of the project.

III. Description of activities/components and budget

- 3.1 The project is organized around three components: (i) Design and implementation of the pilot; (ii) Expansion strategy development/Analysis and dissemination of results; and (iii) Project management and coordination. Criteria for selection of regions:
- Percentage of coverage below the national average according to the most recent MINSAL statistics.
 - Region other than the Metropolitan Region where the capital city is located.
 - To have a waiting list for eye fundus examination (diabetic patients under control with non-current examination) that represents at least 60% of the patients under control.
 - To have staff that performs home care.
 - To be equipped with UAPOS.
- 3.2 **Component I: Design and implementation of the pilot (IDB Funding: US\$161,900, Counterpart: US\$78,000).** The objective of this component is to design and implement the pilot. The use of portable medical equipment (retinography) will be made available, which after the fundus examination, will deliver an automated artificial intelligence pre-report. The result will be communicated to the ophthalmology specialists through an instant messaging application for medical use. The pilot will begin with approximately 450 fundus examinations in the first year, which will be increased annually throughout the project, to conclude with approximately 1,800 tests executed for diabetic patients with non-current exams who belong to the most vulnerable population of the public health system, thus generating

a prioritization in the referral to the secondary hospital level. In addition, the following actions are planned within this component:

- Acquisition and provision of equipment and software infrastructure (portable retinography with data card, mobile application licenses, tablets).
- Coordination between the executing agency and the Health Service on issues such as the definition of activities, schedule of care, selection of patients according to previously established criteria, places of care, and required documentation, among others.
- Determination of the patient care process in conjunction with the Health Service. Home care procedures will be defined for patients with reduced mobility.
- Training of professional and administrative regarding equipment use, requirements, mobile applications (manuals, documents, audio-visual files).
- Recruitment of ophthalmologists by the executing agency (IA validation, referral of patients).
- Generation of statistical reports and progress reports.

3.3 Currently, the project team is considering the region of Valparaíso-San Antonio by applying the following criteria. The area is subject to change depending on several aspects such as the capacity of local partners, etc.

- High percentage of coverage below the national average according to the most recent MINSAL statistics.
- Region other than the Metropolitan Region where the capital city is located.
- To have a waiting list for eye fundus examination (diabetic patients under control with non-current examination) that represents at least 60% of the patients under control.
- To have staff that performs home care.
- To be equipped with UAPOS.

3.4 **Component II: Expansion strategy development/analysis and dissemination of results (IDB Funding: US\$46,000, Counterpart: US\$5,000).** The objective of this component is to develop a strategic plan to replicate the solution at national and international levels with a sustainable and scalable business model. At the domestic level, the executing agency will seek expansion through the public sector by leveraging the IDB's projects and connections. It will also include the aspects such as the identification of other local partners or international partners in other countries in the LAC region with low coverage rates for fundus examination in diabetic patients, the access population's access to fundus examination, and the possibility of incorporating the model in the systems of care currently in operation. Preliminarily, countries such as Peru, Uruguay, Dominican Republic, and Panama are the candidates for expansion. The principal actions that will be carried out in this component will include:

- Conducting a feasibility study in Chile and in other Latin American countries with similar health contexts to the pilot.
- Planning of an expansion strategy (pricing table, regions, countries, partners, etc.).
- Preparation of a report with the analysis of the pilot results (indicators, lessons learned, etc.).

- Dissemination of results and marketing campaigns through audiovisual material.

3.5 **Component III: Project Management (IDB Funding: US\$100,100, Counterpart: US\$-).** The objective of this component is to support overall management and coordination during the implementation of the project.

3.6 **Indicative Budget.** The total cost of the TC is US\$391,000 of which US\$308,000 will be financed by the resources of the Japan Enhanced Initiative for Quality Infrastructure, Resilience against Disaster and Health (JEI). The remaining US\$83,000 will be provided by the Executing Agency or any other partners.

Indicative Budget

Activity/Component	IDB Funding (JEI)	Counterpart Funding	Total Funding
I. Design and implementation	US\$161,900	US\$78,000	US\$239,900
II. Expansion strategy development/analysis and dissemination of results	US\$46,000	US\$5,000	US\$51,000
III. Project management	US\$100,100	US\$0	US\$100,100
Total	US\$308,000	US\$83,000	US\$391,000

3.7 The supervision of this technical cooperation will be under the IDB Chile Country Office.

IV. Executing Agency and execution structure

4.1 The executing agency of this project will be Soluciones Tecnológicas e Informáticas Chile-Japón Spa (ALLM Latam), a Chilean subsidiary of ALLM, a Japanese start-up based in Tokyo. ALLM was founded in 2014 with the main goal of saving one million lives per year as a result of better treatment for acute vascular diseases such as brain stroke and acute myocardium infarcts. To achieve it, ALLM develops and offers healthcare services and their staff technical platforms that enhance their clinical coordination and optimize their clinical processes, thus reducing valuable time in the treatment of patients. It was selected through JICA-IDB Lab open innovation challenge TSUBASA (Transformational Start Ups' Business Acceleration for the SDGs) organized in 2021. ALLM Latam is based in Santiago, Chile, and represents ALLM for a major part of the Latin-American market. ALLM Latam has been working with public and private hospitals in Chile, Peru, Dominican Republic, and Argentina for the last couple of years, focusing in particular on building along with their customers Clinical Networks for Brain Stroke Networks, Diabetic Foot, Sexually Transmitted Diseases and Acute Myocardial Infarct. ALLM played a key role as a technology provider in a prototype project of IDB Lab in Brasil (BR-T1453, "Allm: Cross-border Telemedicine to Strengthen Responses to COVID-19 with an Existing Digital Health Solution for Stroke Care") where the same communication application JOIN was used for telemedicine treatment of COVID-19 patients. This track record shows the effectiveness and the applicability of the software in the region. In September 2022, the large public Japanese company DeNA acquired 45.8% of the shares of ALLM Inc becoming its main shareholder. DeNA is well-known in Japan

for being one of the largest IT companies. Recently it has created a large healthcare division investing in several companies in the industry. ALLM has become its main acquisition so far and the founder and CEO of ALLM Inc., Mr. Teppei Sakano, has become the general manager of that healthcare division in DeNA from October 1st, 2022.

- 4.2 The AI vendor selected for the project will be Phelcom, a Brazilian company founded in 2016 that unites technology and health. It creates portable, connected, and smart devices, with the purpose of democratizing access to visual health. Eyer is the first product of the company, and it aims to help combat severe visual impairment and blindness, which affects more than 250 million people worldwide and occurs in more than 75% of cases due to a lack of prevention and correct treatment. Phelcom will be contracted directly as it is the only supplier in the global market that satisfies all the needs of the project. Those needs include the following:
- Portable or static (convertible to tabletop retinography with conventional support).
 - No Internet connection is required to operate.
 - FDA and ANVISA certifications.
 - AI tool with 97.8%/61.4% sensitivity/specificity to support the diagnosis.
 - Very easy to use (30-min training)
 - Very fast (eye fundus exams with AI analysis in less than 3 minutes)
 - High-quality Images: it is the only portable device with image quality as good as desktop eye fundus cameras.
- 4.3 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.
- 4.4 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.
- 4.5 The level of risk, as determined by the Diagnostic Assessment of Integrity and Institutional Capacity (DICI), was 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.

V. Alignment with IDB Group strategies

- 5.1 The project is aligned with IDBG Country Strategy with Chile 2019-2022 (document GN-2946), specifically with the strategic objective of improving the health of the Chilean people from the priority area of “Improve the quality of life for the population”.
- 5.2 The project is also aligned with the Bank's Health Sector Framework in its objective of contributing to the integration of health services through the prevention and management of chronic diseases. It also aims to contribute to universal health coverage through digital health and the incorporation of information technologies into healthcare processes, including the increased adoption of telemedicine. The project is also aligned with the Bank's Social Protection and Poverty Sector Framework in its third line of action “Support services for the inclusion and autonomy of PwD (Persons with Disabilities)” given that the project incorporates, within the target population, diabetic people with some degree of disability which does not allow them to travel to mobile care devices or health centers.
- 5.3 The project will complement the efforts of the IDB's Social Protection and Health Division through project CH-T1248 "Support for the Continuity of Essential Health Care with an Emphasis on the Management of Waiting Lists and Care for Chronic Patients in the Context of the COVID-19 Crisis"; and project CH-T1270 "Strengthening the recovery and response capacity of the post-COVID-19 health system", both projects aimed at expanding access to health services and contributing to the preventive approach to chronic diseases. In addition, together with these technical cooperation operations, it will contribute to the dialogue for the formation of future IDB loans in Chile and other countries.
- 5.4 The project focuses on Global Health and Universal Health Coverage, which is one of three priority sectors of IDB Group's Japan Special Fund (JSF), including the Japan Enhanced Initiative for Quality Infrastructure, Resilience against Disaster and Health (JEI).
- 5.5 It will contribute to the Sustainable Development Goals (SDGs) 3 - Good health and well-being (Target 3.8) by improving access to health services (fundus examinations in diabetic patients); SDG 1 – No Poverty (Target 1.4) because the project is expected that at least half of the project beneficiaries will be vulnerable individuals; and SDG 10 – Reduced Inequalities (Target 10.2) because the project has a specific activity targeting people with disability.
- 5.6 The project's implementation will be based on [the Principles for Digital Development](#), endorsed by the IDB and other multilateral organizations.

VI. Major risks

- 6.1 **Equipment theft or damage.** Unfortunately, criminality in Chile is on the rise in recent years. The Executing Agency should consider the risk of having one of the portable retinography machines stolen or one of the team workers on the field assaulted. In addition, portable retinography may suffer some kind of physical damage in transport or handling. In order to mitigate this risk, the team will contract insurance for portable retinography, with national coverage against theft, damage,

and deterioration. Implementation of other measures such as metallic containers with restricted access for storage and transportation will be considered as well.

- 6.2 **Information management.** The Executing Agency and its partners will manage the sensitive personal information of the participants principally online. Any mismanagement of the information may cause legal issues. To mitigate this risk, the executing agency will make sure that all the process follows the local relevant laws and regulations and have the certifications in force for the safeguarding of sensitive health data in the applications to be used. In addition, the project's implementation will be based on [the Principles for Digital Development](#), endorsed by the IDB and other multilateral organizations.
- 6.3 **High staff rotation of health service partners.** In general, public health services in Chile present a high rotation of staff. The leaving or absence of key coordinators or collaborators in the partners' hospitals could affect the project's overall performance. To mitigate this risk, the Executing Agency will sign collaboration agreements with the highest authority of the health partner, detailing the scope, responsibilities, and duration of the project. In addition, there will be a continuous training program for the users, which will be delivered through audiovisual media, graphic material, and previously scheduled sessions.
- 6.4 **Connectivity.** Although the retinography equipment does not need internet connectivity for taking eye fundus exams or generating AI reports, Connectivity is necessary to generate automated AI analysis reports and to upload the exams' images for remote analysis review by ophthalmologists. If some of the areas covered in the project do not have good connectivity, it may affect the performance of the solution. To mitigate these risks, the Executing Agency will acquire the portable retinography from Phelcom, since this technology does not require an internet connection for taking the eye fundus exam for the artificial intelligence analysis. In addition, the Executing Agency will contract data plans with telecoms and provide each device with a SIM card for all data communication.
- 6.5 **Resistance from ophthalmologists who will be responsible for the follow-up treatments.** Due to the incorporation of AI and non-conventional equipment for RD diagnosis, who may not trust or want to support the execution of the project. To mitigate this risk, the Executing Agency will draw up a program of activities that involve the ophthalmologists of the secondary-level hospital(s) from the very beginning of the project. Besides, the program will also generate criteria for validation of the AI considering the opinions of the staff of ophthalmologists available to the executing agency.
- 6.6 **Access to information.** The information contained in this document is classified as public upon approval under the Bank's Access to Information Policy¹⁷.
- 6.5 **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 Paraguay and throughout the region.

¹⁷ <https://www.iadb.org/en/access-information/home>

This will ensure that the lessons learned from the project such as the applicability of the latest IT training models for poor and vulnerable populations are disseminated as widely as possible throughout the region.

VII. Exceptions to Bank policy

7.1 None.

VIII. Environmental and Social Strategy

8.1 Based on IDB's Environmental and Social Policy Framework (GN-2965-21), the classification for this operation is "C".