REQUEST FOR EXPRESSIONS OF INTEREST
CONSULTING SERVICES
BANK-EXECUTED OPERATIONS
FULL COMPETITIVE SELECTION PROCESS

PROJECT NAME: *Regional legal framework for cross-border clinical data exchange and data sharing agreements*
Selection Process #: RG-T4546-P002

SELECTION METHOD: Full Competitive
COUNTRY: Regional
SECTOR OR DEPARTMENT: Health
TC NAME: *Paving the Pan-American Highway for Digital Health*
FUNDING – TC #: ATN/OC-20850-RG
LINK TO TC DOCUMENT: IDB | Paving the Pan American Highway for Digital Health (iadb.org)

The Inter-American Development Bank (the Bank) was established in December of 1959 to help accelerate economic and social development in Latin America and the Caribbean. Today, the Bank is a major catalyst in mobilizing resources for the region (For more information about the Bank, please refer to the Bank's website at www.iadb.org.)

Section 1. Purpose of this Request for Expression of Interest

1.1 The Bank is executing the above-mentioned project. The Bank intends to contract consulting services described in this Request for Expressions of Interest (REOI). The purpose of this REOI is to obtain sufficient information to enable the Bank to evaluate if the eligible consulting firms (CF) have the experience and qualifications relevant to provide the consulting services requested by the Bank.

1.2 As defined in the Corporate *Procurement Policy* (GN-2303-33), participating CF must be from a Bank's Member Country[1] or Territory[2] to be eligible to submit an Expression of Interest (EOI). The Bank will conduct the shortlisting process of the CF that expressed interest. The shortlisted CF will then be invited to continue further in the procurement process.

1.3 This REOI is not to be construed as either an RFP or an offer to contract and in no way

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[1] **Member Countries:** Argentina, Austria, Bahamas, Barbados, Belgium, Belize, Bolivia, Brazil, Canada, Colombia, Costa Rica, Chile, Croatia, Denmark, Dominican Republic, Ecuador, El Salvador, Finland, France, Germany, Guatemala, Guyana, Haiti, Honduras, Israel, Italy, Jamaica, Japan, Mexico, Netherlands, Nicaragua, Norway, Panama, Paraguay, People's Republic of China, Peru, Portugal, Republic of Korea, Slovenia, Spain, Suriname, Sweden, Switzerland, Trinidad & Tobago, United Kingdom, United States, Uruguay and Venezuela.

[2] **Eligible Territories:** a) Guadeloupe, French Guiana, Martinique, Reunion – as Departments of France; b) U.S. Virgin Islands, Puerto Rico, Guam – as Territories of the USA; c) Aruba – as a constituent country of the Netherlands; and Bonaire, Curacao, Saint Marten, Saba, St Eustatius – as Departments of the Netherlands; d) Hong Kong – as a Special Administrative Region of the People's Republic of China.

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obligates the Bank to contract anyone. The Bank reserves the right to reject any and all participating CF for any or no reason without having to provide an explanation. The Bank does not bind itself in any way to select any participating consulting firm. No debrief will be provided as to why CF have or have not been shortlisted.

Section 2. Instructions to the eligible consulting firms

2.1 Expressions of interest must be delivered using the *Bidder Portal for the Selection and Contracting of Consulting Firms for Bank-Executed Operations* (the Portal) (http://beo-procurement.iadb.org) by: *[2nd September 2024]*, 5:00 P.M. (**Washington, D.C., Time**) in PDF format only (Max. 45MB).

2.2 To access the Portal, the CF must generate a registration account, including **all** the data requested by the Portal. In the event that any of the information requested is not included, the consulting firm will not be able to participate in this or any other Bank-executed selection process for operational work. If the consulting firm has been previously registered, please validate that you have **all** the consulting firm's information updated and complete before submitting an EOI.

2.3 Eligible CF may partner in the form of a Consortium/joint venture (JV) to enhance their qualifications. Such Consortium/JV shall appoint one of the CF as the representative responsible for the communications, the registration in the Portal, and the submission of the corresponding documents.

2.4 Interested CF may obtain further information during office hours, 09:00 AM to 05:00 PM (**Washington, D.C. Time**), by sending an email to: *adrianh@iadb.org*

Inter-American Development Bank
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Web site: www.iadb.org

2.5 The Bank hereby invites eligible CF to indicate their interest in providing the services described below in the draft Terms of Reference for the consulting services. Interested CF must provide information establishing that they have the necessary experience and are qualified to perform the services. So that all responses may be properly evaluated,

eligible CF must include in their submissions the information requested in the following section, with full and clear explanations.

Section 3. Consulting Services

3.1 The consulting services include
1. Assessment of the Current State
- Conduct interviews with representatives of RACSEL, IDB and other regional and national actors.
- Conduct a survey and interview country representatives.
- Review existing national laws, policies and standards.
- Analyse global good practices and successful examples of regional health information exchange.
- Develop a report summarising the use cases and identifying possible regulatory impediments.
2. Proposed Regulatory Framework
- Propose a regional regulatory framework to enable health information exchange.
- Participate in outreach activities with countries to receive feedback.
3. Development of Framework Agreements and Templates
- Propose a framework of agreements to enable immediate health information exchange.
- Create template agreements to support health information exchange.
- Engage in socialisation activities with countries.
4. Create Executable Version of Agreements
- Create agreements based on the developed templates to enable the exchange of International Patient Summary (IPS) and vaccinations.
- Participate in meetings with country representatives to socialise the data sharing agreement.
5. Project Management and Reporting
- Develop an initial project plan.
- Provide bi-weekly status reports on project progress.

3.2 Although there is no standard format for presenting an Expression of Interest, eligible CF must submit an EOI containing the following information:
1) Basic Information—Provide the official name of CF, the contact's name, email address, phone numbers, and office address (es) of the key contact (s) responsible for the EOI.
2) Background—Provide a description of the CF. The CF may include brochures or documents that provide information about its organization, history, mission, structure, and number of staff.

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3) Experience related to the requested consulting services—Provide all kinds of evidence the CF considers appropriate to show its experience and expertise in delivering services similar to those described in Annex A, Terms of Reference (e.g., brochures, reports, studies, description of similar assignments, references to cases in which it has provided similar services, experience in similar conditions, availability of appropriate skills among staff, etc.)

3.3 Estimated budget: *$200,000*

Annex A. Draft Terms of Reference

Please note that the attached Terms of Reference may be subject to changes by the Bank. The CF that have been shortlisted will be notified of these changes.

ANNEX A – Terms of reference

1. **Background and Justification**

   1.1. **The COVID19 pandemic exposed and accelerated new challenges and vulnerabilities that decision-makers must address including ensuring proper continuity of care for individuals within and among countries.** The need for timely and accurate information during public health emergencies is well documented; based on research ranging past emergencies such as Ebola, Cholera, MERS, and others, access to quality data and insufficient data use was the most frequently encountered challenge (Park et al, 2020). Issues such as the informal market for health certificates and inadequate vaccination coverage pose threats to public health and raise concerns regarding authenticity and security. Additionally, the lack of coordination and interoperability in digital health initiatives hinders the exchange of crucial health data and limits cross-border healthcare services, exacerbating the situation. According to the Pan American Health Organization (PAHO) there is a significant vulnerability in the LAC region caused by the "lack sustainable integrated and interoperable information systems for health that allow them to capture, process, and share open and disaggregated data in real time (…) Access to this information is essential for public health insight, and digitized systems can provide greater opportunities for interoperability." Data interoperability and connectivity among countries in the region not only enable a continuous flow of medical information but also establish the foundation for a coordinated and agile response in times of need (World Health Organization - Global Vaccine Action Plan 2011-2020, 2016). Additionally, there is a critical need to improve the digital health workforce competencies in the public sector to ensure adoption and application of interoperability and cybersecurity standards.

   1.2. **Globally, there is recognition of a persistent need for a global mechanism to verify health document origins, crucial for pandemic readiness and uninterrupted healthcare.** Based on discussions in the Indonesia and India G20, in June 2023, the WHO launched the Global Digital Health Certification Network (GDHCN). The GDHCN is an open-source platform based on solid and transparent standards, establishing the first pillar of digital public health infrastructure to develop a

wide range of digital products aimed at strengthening pandemic preparedness and providing better health for all, and it is available for free use by WHO member states (WHO, 2023). Following the COVID-19 pandemic, the need for health certificates was recognized, and the GDHCN was created, which can support various uses, such as digitization of vaccination certificates, verification of medical prescriptions, sharing of the international patient summary (IPS), and certification of healthcare professionals. The WHO established the GDHCN, based on regional experiences and the certification system of the European Union, DIVOC (Digital Infrastructure for Verifiable Open Credentialing), LACPASS (Digital Vaccination Certificate for the Countries of Latin America and the Caribbean), and ICAO (International Civil Aviation Organization), and seeks interoperability, based on standards, with other existing networks (WHO, 2023). Various LAC countries have started the process to join the GDHCN, a crucial first step to enable cross-border digital health services.

1.3. **The countries in the Latin America and Caribbean (LAC) region have prioritized data exchange at both national and regional levels.** For example, the Roadmap for the Digital Transformation of the Health Sector in the Region of the Americas CD 59/6 aims for countries to participate securely, ethically, equitably, inclusively, and cost-effectively in the digital transformation process by adopting and implementing interoperable digital health solutions through a multi-actor approach. Integrated health information systems are required to support the leadership and governance function of health ministries. Likewise, in the Inter-American Development Bank's regional health policy dialogue in 2022, countries identified several priorities for cross-border digital health, including optimizing available human resources through international telehealth, validating digital certificates, ensuring continuity of care, and regional resilience to face health emergencies by sharing data for public health. During the IDB-PAHO co-led event, RELACSIS 4.0, a plan was launched to strengthen regional digital health services and resilience, through regional data exchange and policy harmonization. Sixteen countries successfully exchanged digital vaccine certificates (COVID-19, Polio, Measles, and Yellow Fever) and critical clinical information (diagnosis, allergy, and prescription information) using international standards during the 2nd Regional LACPASS Connectathon.1

1.4. **Establishing regional agreements regarding health information exchange accelerates national adoption and improves healthcare.** Interoperability processes and data management systems can optimize how actors within a country share data with the health system. This can help governments make better decisions about the health of their population. A health system that is interoperable can: 1) Reduce health care costs associated with redundant diagnostic testing, unnecessary hospitalizations, and preventable readmissions; 2) Make better use of resources and management to know how, when, and where those resources are used; 3) Effectively monitor notifiable diseases, seasonal diseases, communities' disease burden, and other aspects; 4) Aid public health research; and 5) Strengthen disaster response (Bagolle et al, 2022). A systematic literature review of 25 studies on health information exchange (HIE) systems found positive outcomes for the quality and cost-effectiveness of health care, while fifteen of the HIE studies (60%) demonstrated positive economic effects due to significant savings related to reducing duplicated diagnostics (medical images,

laboratory tests) (Bagolle et al, 2022). Interoperability is also important for global public health; the COVID19 pandemic demonstrated that the current global health architecture is slow to respond to the current pandemic and ill-prepared to prevent future public health emergencies. To increase regional resilience, it is critical to prioritize regional foundations for data exchange that serve beyond the COVID19 use case, such as yellow fever vaccination certificates or the International Patient Summary. Regional agreements can assist governments in selecting standards and use-cases that are pertinent to their specific contexts, thereby accelerating the adoption process at the national level and optimizing investments. Additionally, regional training initiatives can promote mutual comprehension in this domain. In order to accelerate this process, coordination and investments in regional governance, agreements, policies, information standards, knowledge sharing and digital public goods2 are critical.

1.5. **Global Health and Universal Health Coverage.** To address the challenges described, it is essential for the countries of LAC and the international community to implement policies that ensure equitable access to healthcare for all. The use of digital technologies and accessibility to clinical data through mobile devices and shared information systems allow for informed and precise decision-making during health emergencies. With electronic health records available in real-time, healthcare professionals can quickly assess patients' situations, administer appropriate treatments, and coordinate care efficiently, even in situations of displacement or resource scarcity (Bashshur et al., 2018). Additionally, access to vaccination records and medical histories in a cross-border setting is crucial to ensure timely immunization during epidemic outbreaks (Nagata et al., 2019). Just as the Pan-American Highway plays a fundamental role in promoting regional integration, economic development, cultural exchange, and resilience in the Americas, a Digital Pan-American Highway for health can improve public health and continuity of care, enabling reliable exchange of health information in LAC, as well as empowering patients to securely access and share their health data, regardless of the city, province, or country they are in.

1.6. **Inclusive digital health by design.** The Latin America and Caribbean (LAC) region stands out globally for its significant inequality, marked by stark income gaps and entrenched disparities based on gender, race, and ethnicity. Access to essential social services like healthcare, education, and employment often hinges on these factors. Amidst this backdrop, there's a pressing debate regarding the role of technology in either reduce or intensifying these inequalities. The digital and data poverty gap permeate all levels of the healthcare sector, impeding access to preventive tools and care services for many individuals. Moreover, they hinder healthcare providers' capacity to serve the entire population efficiently. Additionally, they pose challenges to unbiased decision-making and equitable resource allocation. Furthermore, the increasing reliance on algorithmic decision-making, often based on biased or incomplete data, perpetuates these disparities. Without deliberate efforts to deploy digital technologies equitably and inclusively, these disparities will likely worsen. (Bagolle et al., 2022). In 2021, the countries of the region approved the Principle of Inclusive Digital Health, which implies appropriate access, digital skills, and usability and navigability aspects in the development of technological solutions, among others (PAHO, 2021). A digital highway for health

has the potential to transcend boundaries if designed with this principle in mind.

2. **Objectives**

2.1. The purpose of this consultancy is:

2.1.1. To propose a regulatory framework to support countries in Latin America and the Caribbean (LAC) exchange health information and shared related digital health infrastructure across borders for the Pan-American Highway for Health. This includes but is not limited to exchanging data for healthcare purposes (e.g., continuity of care) and "secondary" purposes (e.g., public health surveillance, research) as well as verification of digital health certificates for vaccination, health worker credentials and other use cases as defined by countries.

2.1.2. Develop templated agreement(s) to support health information exchange and related digital health infrastructure sharing across borders for the variety of potential purposes.

2.2. As part of developing the regulatory and agreement frameworks, the consultant will need to review existing regional and national laws, policies, and standards related to privacy, security, interoperability, data governance, and digital health to identify potential barriers to and opportunities for information exchange (e.g., legal restrictions against a particular country disclosing patient information to an organization in another jurisdiction). The consultant will also need to draw on good practices globally (e.g., from the EU) to inform the proposed regulatory and agreement frameworks. The regulatory framework and agreement(s) will need to address countries' sharing the related digital health infrastructure in addition to the health information exchange for healthcare and secondary purposes.

3. **Scope of Services**

The following services are required as part of this engagement

3.1. Stakeholder engagement and communications

3.2. Legal analysis

3.3. Legal drafting

3.4. Project management

4. **Key Activities**

More specifically, the required activities are:

4.1. **Conduct a current state assessment**

4.1.1. Interview representatives from RACSEL, IDB, and other regional and national stakeholders as required to learn more about the current and potential use cases for health information sharing through the Pan-American Highway for digital health

4.1.2. Conduct a survey and interview representatives identified within countries (e.g., Ministries of Health) to gather information about the regulatory frameworks within countries and the potential use cases for the regional health information exchange

4.1.3. Review existing, publicly-available laws, policies, and national standards to create an inventory of laws, policies, and national standards and identify potential impediments to health information sharing or

sharing related digital health infrastructure across borders

4.1.4. Review existing global good practice standards for health information and digital health regulation particularly those developed by WHO, PAHO as well as examples of successful regional health information exchange such as the European Union

4.1.5. Review key, existing treaties, agreements, and other legal vehicles that could be leveraged to enable regional health information sharing and sharing related digital health infrastructure

4.1.6. Develop a brief yet comprehensive report summarizing the use cases for health information exchange and identifying potential regulatory impediments to achieving them

4.1.7. Develop and deliver a plain-language, executive-level presentation summarizing the report

4.2. **Proposing a regulatory framework**

4.2.1. In consideration of the above, propose a potential, regional regulatory framework that could be implemented across to enable health information exchange and sharing related digital health infrastructure required to enable it. Note that the framework does not need to include draft legislation or regulation but should identify the potential legal vehicles that could be used (e.g., legislation, shared policies, treaties, etc.), the key regulatory domains that need to be addressed, and guidance on the key principles to be addressed in those domains.

4.2.2. Participate in townhalls, workshops, and other engagement activities with countries to socialize the regulatory framework and receive feedback

4.2.3. Receive feedback on and edit the report based on the feedback

4.2.4. Refine and deliver an edited presentation if required

4.3. **Developing an agreement framework and agreement template(s)**

4.3.1. Assuming that any regional regulatory framework will require time to implement, propose an agreement framework enabling more immediate health information exchange and sharing of related digital health infrastructure. Note that the agreement framework must be flexible to accommodate adding new use cases for health information exchange as they arise. Specifically, the Government of Japan is funding a number of initial use cases (TBD) under RG-T4546 that must be enabled using the agreement framework.

4.3.2. Develop and deliver a plain-language, executive-level summary of the recommended framework

4.3.3. Revise the agreement framework as necessary

4.3.4. Refine and deliver an edited presentation if required

4.3.5. Create a templated agreement(s) to support health information exchange and sharing related digital health infrastructure. Note in addition to the commercial and legal terms the agreement template should the describes the purposes for health information exchange or sharing related digital health infrastructure, data elements to exchanged, data standards to be supported, participating countries, and other necessary elements. It should further be flexible to add additional use cases and signatories.

4.3.6. Develop and deliver a plain-language, executive-level presentation summarizing the agreement template

4.3.7. Participate in townhalls, workshops, and other engagement activities with countries to socialize the framework and receive feedback

4.3.8. Edit the agreement template as necessary

4.3.9. Refine and deliver an edited presentation if required

4.4. **Create an executable version of the agreement(s) required to support cross-border health information**

exchange vaccinations and the international patient summary

    4.4.1. Create the agreement(s) based on the templated developed above to enable participating countries to exchange an International Patient Summary (IPS) and vaccinations– assuming that it will be based on the data sharing agreement template / framework developed above

    4.4.2. Develop a plain-language, executive-level summary of the agreement that can be used to discuss terms with signatories

    4.4.3. Participate in meetings with country representatives as necessary to socialize the data sharing agreement

    4.4.4. Edit the agreement based on countries' feedback

    4.4.5. Refine and deliver an edited the executive-level summary if required

4.5. **Project management and reporting**

    4.5.1. Initial development of a project plan minimally including a workplan of activities, dates, and responsibilities; stakeholder engagement plan; and status reporting template

    4.5.2. Provide bi-weekly status reports on project progress

5. Expected Outcome and Deliverables

All deliverables are to be produced in the Spanish and English languages except where stated below.

The expected outcomes and deliverables of the activities include:

5.1. Project Plan

5.2. Current State Report and Executive-Level Presentation

5.3. Proposed Regulatory Framework and Executive-Level Presentation

5.4. Agreement Framework and Executive-Level Presentation

5.5. Agreement Template(s) to accommodate the variety of potential uses cases for health information exchange

5.6. Executable Agreement for prioritized services

5.7. Bi-weekly Status Reports

6. Project Schedule and Milestones

6.1. Project Plan: Q2 2024

6.2. Current State Report and Executive-Level Presentation: Q3 2024

6.3. Proposed Regulatory Framework and Executive-Level Presentation: Q3 2024

6.4. Agreement Framework and Executive-Level Presentation: Q4 2024

6.5. Agreement Template(s): Q1 2025

6.6. Executable Agreement for prioritized services: Q1 2025

7. Reporting Requirements

7.1. Status reports on progress are required bi-weekly. Status reports must include an update on progress against the workplan, work that is anticipated for the upcoming reporting period, and any key issues or risks that

require being addressed.

7.2. Other reports (e.g., executive reports) are listed in Section 5 and described more fully in Section 4.

8. Acceptance Criteria

8.1. The contents of each deliverable resulting from this TOR will be mutually agreed to in an annotated outline at the beginning of that work packet.

8.2. Acceptance of the deliverable will depend on:

8.2.1. Delivered content to address the scope of content identified in the relevant outline.

8.2.2. At least 2 rounds of review and revisions after a comprehensive draft has been delivered.

8.2.3. Acceptance to be provided by the person responsible for supervision identified in Section 10.

8.3. Acceptance of the executable agreement will be when the participating countries agree to signature.

9. Other Requirements

The consulting firm is required to have:

9.1. At least 8 years of experience in similar projects.

9.2. Personnel assigned to this consultancy must have at least 5 years of experience, working with the consulting firm, in similar projects in the region.

9.3. Travel permitted according to work plan.

10. Supervision and Reporting

10.1. The consulting firm will be reporting to the project Team Lead Jennifer Nelson, who will review and / or consult with the PH4H Steering Committee as needed and will provide comments to any reports, approve reports, documents and work, and / or any instructions for changes.

10.2. It shall be the consulting firm's responsibility to ensure that such reports are submitted to the Bank.

10.3. The frequency of communication will depend on the need for comments and approvals agreed upon at the beginning of the consultancy. It will be the responsibility of the Firm to ensure that such meetings take place.

11. Schedule of Payments

11.1. Payment terms will be based on project milestones or deliverables. The Bank does not expect to make advance payments under consulting contracts unless a significant amount of travel is required. The Bank wishes to receive the most competitive cost proposal for the services described herein.

11.2. The IDB Official Exchange Rate indicated in the RFP will be applied for necessary conversions of local currency payments.

Payment Schedule	
Deliverable	**%**
1. Project Plan	20%
2. Current State Report and Executive-Level Presentation Approved	10%
3. Proposed Regulatory Framework and Executive-Level Presentation Approved	20%
4. Agreement Framework and Executive Level Presentation Approved	20%
5. Agreement Template(s) Approved	10%
6. Executable agreement for RG-T4404 approved	20%
TOTAL	100%