

Early Warning System

# IADB-RG-T4948

## Development of Regional Integrated Drug Regulatory Data Repository of Latin American and Caribbean countries

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## Quick Facts

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| **Financial Institutions** | Inter-American Development Bank (IADB) |
| **Status** | Proposed |
| **Bank Risk Rating** | U |
| **Borrower** | not disclosed |
| **Sectors** | Communications, Education and Health, Technical Cooperation |
| **Investment Type(s)** | Advisory Services |
| **Investment Amount (USD)** | $ 0.55 million |
| **Project Cost (USD)** | $ 0.55 million |

## Project Description

According to the IADB, the objective of this technical cooperation (TC) is to develop the foundations for a regional, interoperable solution for the exchange of public regulatory data on medical products among the National Regulatory Authorities (NRAs) of Latin America and the Caribbean. The TC will encompass a diagnostic assessment of existing systems and capacities, in operational and technological terms; the identification and harmonization of regulatory terminology, data standards, and common definitions needed to sustain the regional exchange of information; the definition of governance arrangements; the identification of technical, legal, operational, and security requirements; the evaluation of information technology and architecture alternatives, including a feasibility analysis for using or adapting existing tools; and the development of a proof of concept. The scope of the operation is limited to the exchange of public regulatory data, given the substantially lower technical, legal, and institutional complexity involved relative to non-public or confidential data; mechanisms for exchanging non-public regulatory information will be explored separately, in a subsequent and stepwise phase, subject to further decision by the participating NRAs. Building on the diagnostic assessment, the NRAs will also co-design and pilot-test an AI-assisted prototype tool to support evaluation procedures, developed under an open, interoperable architecture that allows each agency to operate it independently.

## Investment Description

- Inter-American Development Bank (IADB)

## Contact Information

No contacts available at the time of disclosure

ACCOUNTABILITY MECHANISM OF IADB

The Independent Consultation and Investigation Mechanism (MICI) is the independent complaint mechanism and fact-finding body for people who have been or are likely to be adversely affected by an Inter-American Development Bank (IDB) or Inter-American Investment Corporation (IIC)-funded project. If you submit a complaint to MICI, they may assist you in addressing the problems you raised through a dispute-resolution process with those implementing the project and/or through an investigation to assess whether the IDB or IIC is following its own policies for preventing or mitigating harm to people or the environment. You can submit a complaint by sending an email to MICI@iadb.org. You can learn more about the MICI and how to file a complaint at http://www.iadb.org/en/mici/mici,1752.html (in English) or http://www.iadb.org/es/mici/mici,1752.html (Spanish).