

# Expanding the Scope: Utilizing Early Access/Compassionate Use Pathways to Generate Market-Specific Real-World Evidence Across LATAM Prior to Launch

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## INTRODUCTION

- Early access/ Compassionate Use programs (EAPs/CUPs) allow for patients to access therapies prior to marketing authorization
- These can be leveraged by manufacturers to generate RWE for the product prior to its launch and pose an opportunity for market-specific data generation, especially in countries that otherwise may not be included in the pivotal clinical trial, such as with LATAM countries
- This research evaluates EAPs available in major LATAM countries to determine whether they provide opportunities for RWE collection pre-launch






## METHODS

- Publicly available information up until June 2024 was screened to identify EAPs in Argentina, Brazil, Chile, Colombia, and Mexico using their respective websites to extract key information

## RESULTS

- Four countries offer EAPs (Table 1), with Argentina, Brazil, and Chile offering two pathways (Colombia offers 1, Mexico none)
- Inclusion criteria are broadly aligned across markets, allowing access to individuals or patient groups with severe, debilitating conditions with no effective therapeutic alternatives
- Reimbursement/ charging incentives can vary between countries
  - In 3/4 (Argentina, Brazil, Chile) countries that offer EAPs, manufacturers must provide their treatments at no cost
  - In 1/4 (Colombia), reimbursement may be provided in select cases, but decision criteria are unclear
- In the markets that offer EAPs, RWE-generated data can potentially be leveraged to supplement both regulatory and reimbursement evidence dossier submissions

Table 1: Overview of EAPs across select LATAM markets

Country	Agency	Scheme	Initiated by	Reimbursement offered?
	ANMAT	Expanded Access Program	Manufacturer	No
		Exceptional Access Program (RAEM)	Physician	
	ANVISA	Expanded Access Program	Manufacturer	No
		Compassionate Use Program	Physician	
	ISP	Expanded Access Program	Manufacturer	No
		Compassionate Use	Physician	
	INVIMA	Non-Available Vital Medications (VnD)	“Any legally constituted public or private entity”	In select cases
	COFEPRIS	No dedicated early access scheme available, with importation of special treatments available for low incidence diseases that may pose risk to vulnerable groups		

## CONCLUSIONS

- Four out of five major LATAM markets offer EAPs, providing manufacturers an opportunity to collect market-specific real-world evidence for their healthcare technology at the point of launch to support their regulatory and reimbursement submissions
- The lack of reimbursement incentives may pose a barrier, but this can be offset by the opportunity to collect data from countries that may be excluded from pivotal trials

**Abbreviations:** ANMAT: National Administration of Drugs, Food and Medical Devices of Argentina; ANVISA: Brazilian Health Regulatory Agency; ISP: Public Health Institute of Chile; INVIMA: National Institute of Drug and Food Surveillance of Colombia; COFEPRIS: Federal Commission for Protection against Health Risks of Mexico

