



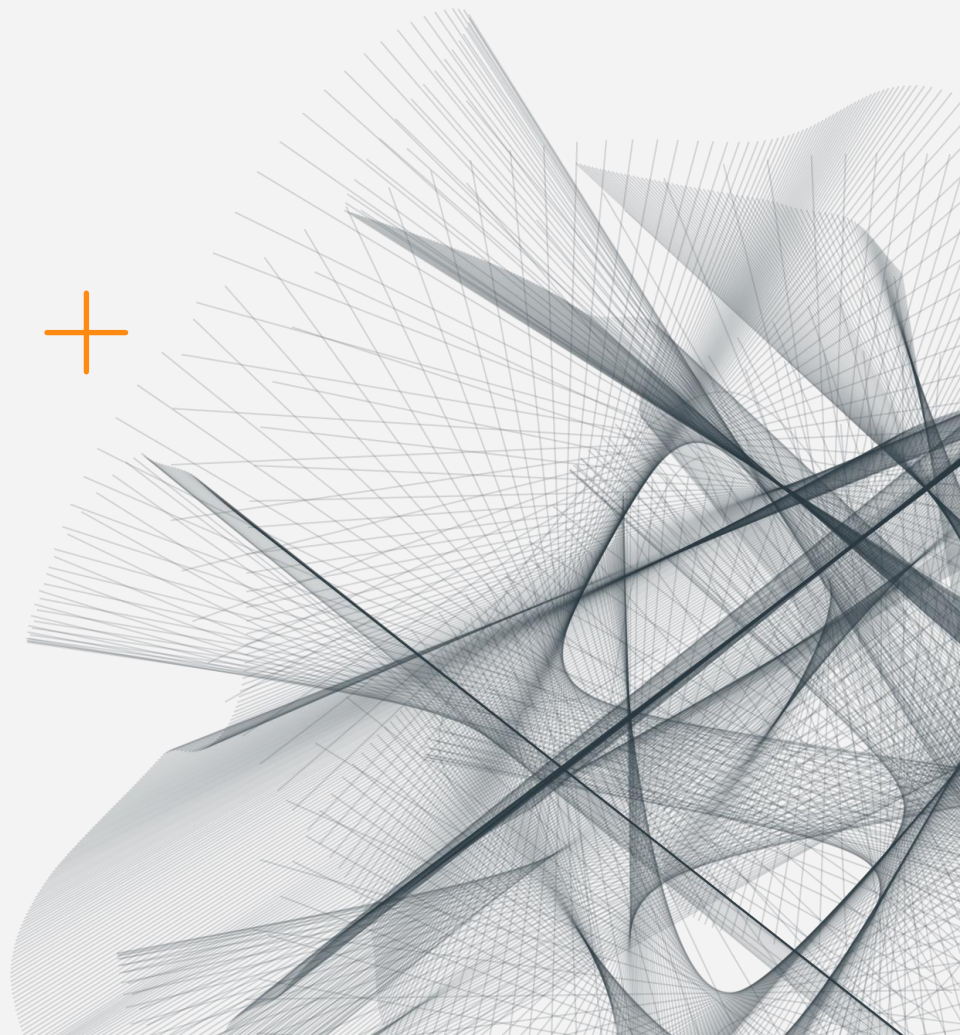
# Patient W.A.I.T Indicator 2023 LATAM

*Costa Rica*

AN ASSESSMENT OF  
INNOVATIVE MEDICINES  
AVAILABILITY ACROSS LATIN  
AMERICA



MARCH  
**2024**



# Table of contents

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<b>Costa Rica Executive Summary</b>	<b>1</b>
<b>Regional Availability, Time to Availability and Availability Over Time</b>	<b>2</b>
<b>Key Drivers of Availability</b>	<b>5</b>
<b>About the authors, Acknowledgements, Notes on Sources &amp; Definitions</b>	<b>6</b>
<b>Appendix-Methodological Considerations included</b>	<b>11</b>



# Summary of key findings from the study

## Availability in Costa Rica vs LATAM region

- 57% of molecules are globally approved in at least one country in LATAM, 20% are privately available, 34% have limited availability, and 45% are fully available
- In Costa Rica, 70% of molecules that are approved have at least private, limited or full availability with a majority (93% or 26 molecules) having limited availability
- More orphan molecules are approved (85 orphan vs 67 oncology) in at least one country in LATAM- this trend carries does not through to Costa Rica (19 orphan vs 24 oncology)
- With a smaller number of orphan molecules available, oncology molecules boast higher rates of availability in Costa Rica
  - 75% of oncology molecules vs 70% orphan molecules that are approved in Costa Rica have at least private limited or fully availability with a majority (92% oncology and 89% orphan) maintaining limited availability



***Though many molecules face reimbursement restrictions and uncertainty surrounding systemic changes exists, Costa Rica performs lower than LATAM regional averages***

## Availability Timelines in Costa Rica vs LATAM region

***Time to availability*** represents the length of time from both global and local market authorization until full or limited availability is reached

- Time to local approval/market authorization on average in LATAM is 953 days, where time to availability (between marketing authorization and availability) is on average 1,641 days
- Costa Rica is the fourth country with the longest regulatory approval timelines overall, though availability timelines
- Time to availability for orphan molecules are slightly faster in LATAM on average (1,637 days vs 1,700 days), and Costa Rica follows a similar trend with 963 days to availability for orphan molecules and 1,454 days to availability for oncology molecules

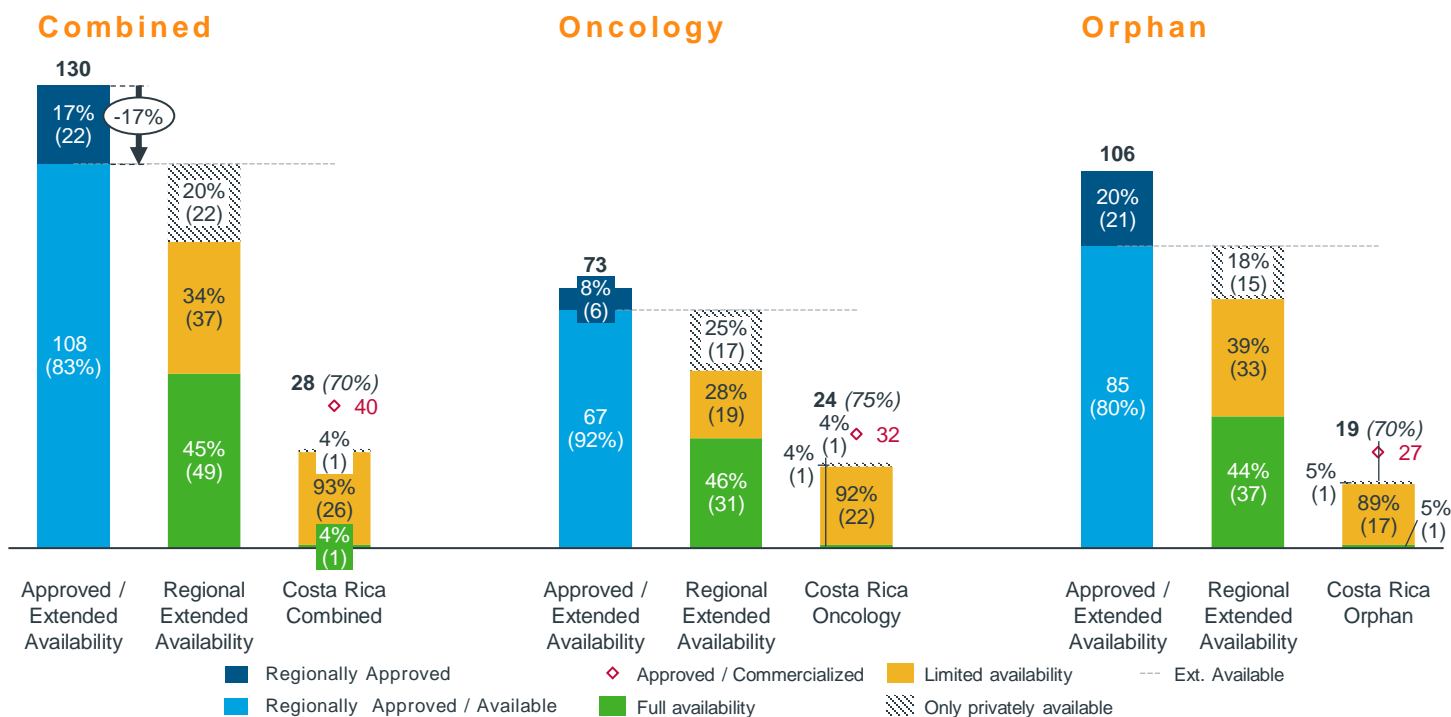
***Availability over time*** pinpoints the degree of availability according to global market authorization year to estimate the maturity of available molecules

- Availability over time reflects these trends and is likely to also have been affected by COVID: most molecules with full availability status were approved in Costa Rica between 2014-2017 (100%) and similar trends are seen for at the oncology (75%) and orphan (70%) level



## Costa Rica boasts a higher number and higher percentage of oncology molecules available vs orphan molecules

### Regional extended availability (2014-2021) – Regional and Costa Rica



- Of the 108 molecules approved in at least one country in LATAM, 20% are privately available, 34% have limited availability, and 45% are fully available
- In Costa Rica, 70% of molecules that are approved have at least private, limited or fully availability with a majority (93% or 26 molecules) having limited availability
- 67 oncology molecules are approved in at least one country in LATAM, while 25% are privately available, 28% have limited availability, and 46% are fully available
- 75% of oncology molecules that are approved in Costa Rica have at least private, limited or full availability with a majority (92% or 22 molecules) having limited availability
- More orphan molecules are approved (85 orphan vs 67 oncology) in at least one country in LATAM, while 18% are privately available, 39% have limited availability, and 44% are fully available
- Unlike LATAM regionally, there are more oncology molecules available than orphan molecules (24 vs 19) and higher rate of available oncology molecules as well (75% vs 70%)

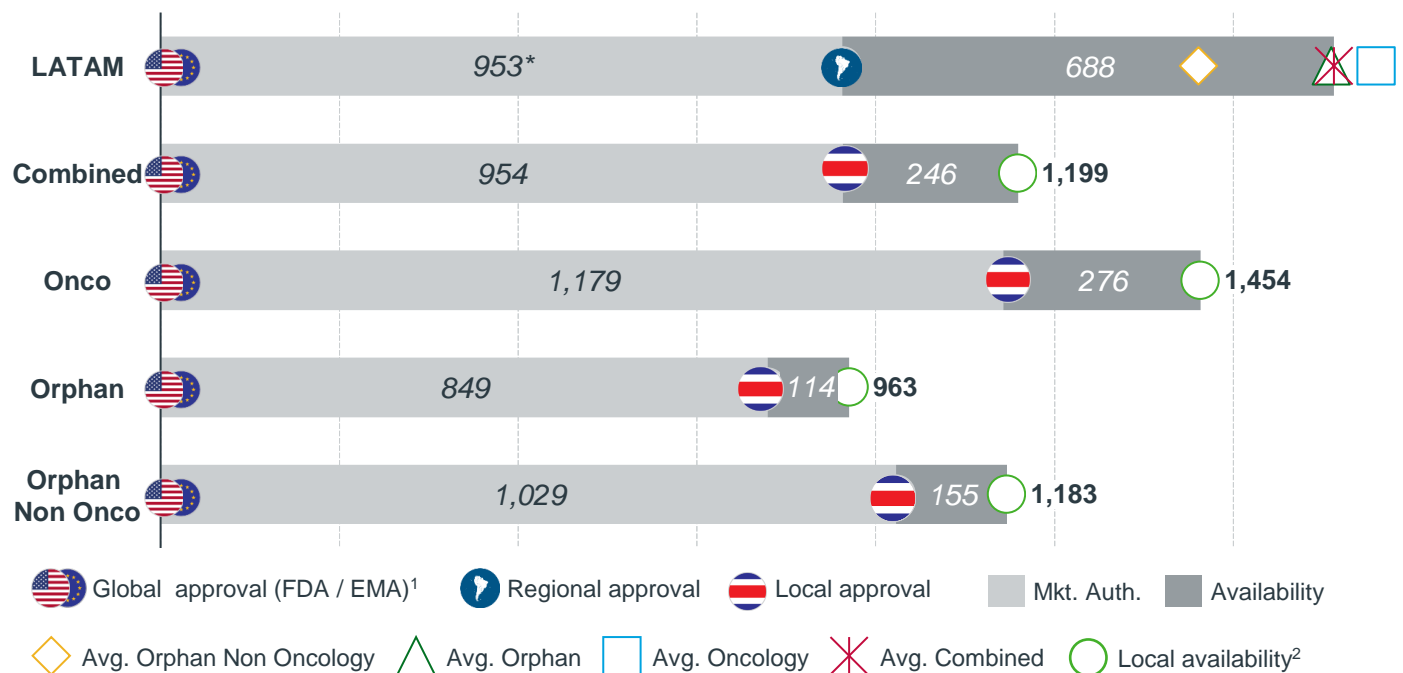


*Although availability regionally reaches 83%, Costa Rica performs below average with just 28 molecules available*

Note: Global availability is defined as a molecule that has regulatory approval in the USA, or in Europe; \*Approved in at least one LATAM country  
 † Not considering Argentina extended availability as a result of its fragmented private market based on case-by-case decisions

## Length of time to availability varies regionally in LATAM, with Costa Rica having short availability timelines

Average time to availability (2014-2021) – Regional and Costa Rica, FDA / EMA, marketing auth., and local availability dates



- Wide disparities exist between countries in terms of time to availability, with Argentina on the low end at an average of 966 days, Colombia towards the middle with 1,673 days, Brazil with 1,604 days and Mexico on the high end, with an average of 2,073 days, which reflects the total of time to marketing authorization and time to reimbursement (pub / pri), as of FDA/EMA approval

- Time to local approval/market authorization on average in LATAM is 953 days, where time to availability (between marketing authorization and availability is on average 1,641 days)

- Costa Rica is the fourth country with the longest regulatory approval timelines overall, though availability timelines are short; data gaps may account for this in part

<sup>1</sup> Global approval date considered the earliest date between FDA or EMA

<sup>2</sup> Considering molecules with Full and / or Limited Availability

<sup>2</sup> ARG / CRI: Limited number of Fully / Limited Availability date of reimbursement information resulted in shorter timelines

\*Orphan category includes Orphan Oncology molecules

- Time to availability for orphan molecules are slightly faster than oncology molecules in LATAM on average (1,638 days vs 1,700 days), and Costa Rica follows a similar trend with 963 days to availability for orphan molecules and 1,454 days to availability for oncology molecules



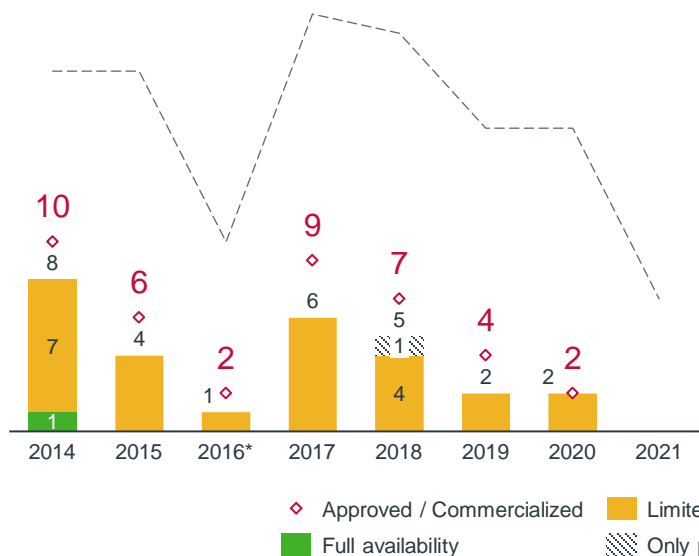
**Time to availability is relatively short, though data gaps exist that may be influencing this trend**

## The overall trend observed regionally in LATAM remains similar in Costa Rica for both oncology and orphan molecules over time

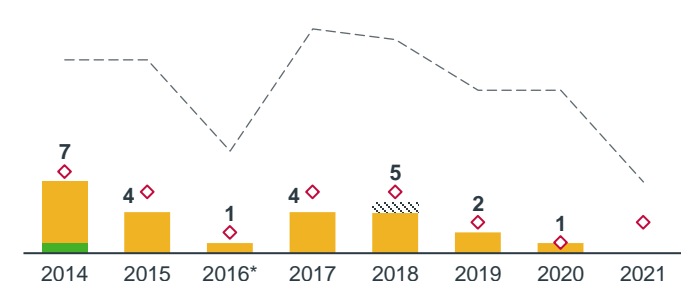
### Extended availability over time (2014-2021) – Regional and Costa Rica

#### Combined

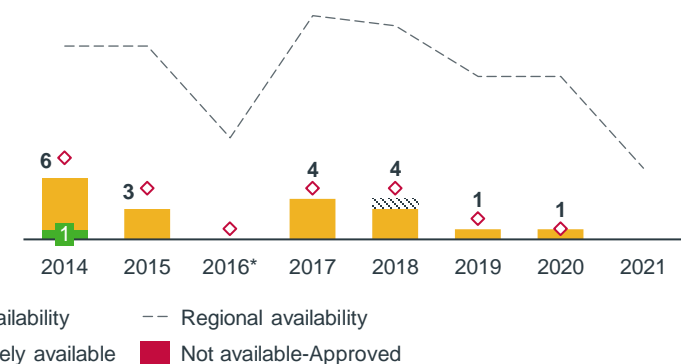
**The only molecule with full availability status was approved in Costa Rica between 2014-2017**



#### Oncology



#### Orphan



- As was observed regionally in LATAM, most molecules with full availability status were approved in Costa Rica between 2014-2017 (100% of the total molecules with full availability)
- Similar trends are seen for molecules that are fully available between 2014-2017 in Costa Rica in both oncology and orphan drugs
- A number of potential drivers can explain this; in addition to the generally long, fragmented path to availability, three additional potential issues are:
  - The COVID-19 pandemic and associated strain on healthcare system likely

exacerbating underlying systemic challenges e.g., budget impact

- Increases in investment coupled with clinical innovation in oncology/rare disease in recent years has led to new standards of care e.g., PD1s, CDK4/6 inhibitors (2014-2015), but also more gradual increments of clinical benefit, and lesser priority for reimbursement
- Expanding indications, going from most niche or smallest patient population to broader more prevalent conditions

In recent years, the number of fully available molecules has decreased, together with molecule approvals

# Key drivers of availability in Costa Rica

## Four main drivers emerge when analyzing availability of orphan and oncology molecules in Costa Rica



1

There are various **market size and communication considerations** that influence availability in Costa Rica. Costa Rica has very few molecules approved within LOM. Although, there are **3 other access channels in Costa Rica to consider**: special approval requirements (AMPARO), internal approvals outside LOM (approved by local committees) and the 117 law that allows for importation of non-registered products.

2

The approval process of oncology versus orphan products is **not differentiated by molecule designation**. Although, the special approval requirements (AMPARO) **prioritizes orphan approvals** since usually there are very limited treatment options for rare diseases vs oncology.

3

Recently , the CCSS has reached a risk sharing agreement **Innovative Healthcare Agreements (IHA)** which grants access for **oncology molecules** (atezolizumab was the first molecule to reach this agreement).

4

**International pharmaceutical companies** have regulatory facilities and incentives which lead them to usually have their Central America headquarters in Costa Rica or Panama as well. As for **emerging pharma companies**, they generally leverage a commercial partnerships to obtain access in Costa Rica.



# About the authors

## Overall Project Leader



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André Ballalai is a researcher in the field of International Health Systems and Policy and Global Director of Value and Access Consulting at IQVIA in New York, USA.

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Dr. Diego Guarin is the Regional Market Access Lead for LATAM and is a founding member of the ISPOR Colombia chapter, also having served as chair of the ISPOR Latin American Consortium Industry Committees and Advisory Board. Dr. Guarin graduated as Medical Doctor from Universidad del Rosario-1653 (Colombia) and holds various master's degrees.



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# Acknowledgements

*The completion of this study could not have been possible without the support of numerous stakeholders across all countries included on the research*

## FIFARMA Leadership



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**Ecuador**

**Mexico**

**Peru**

**Regional LATAM**

# Notes on Sources

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## **THIS REPORT IS BASED ON THE SOURCES DETAILED BELOW**

**IQVIA MIDAS™** is a unique platform for assessing worldwide healthcare markets. It integrates IQVIA's national audits into a globally consistent view of the pharmaceutical market, tracking virtually every product in hundreds of therapeutic classes and provides estimated product volumes, trends and market share through retail and non-retail channels. MIDAS data is updated monthly and retains 12 years of history. IQVIA MIDAS was used by each local IQVIA team to provide the existing data

**PUBLIC AVAILABLE INFORMATION** for each market was incorporated in the study from HTA agencies and regulatory bodies

**Costa Rica:** [CR Ministry of Health Registry](#)

**MANUFACTURERS' INTERNAL DATA** was asked via a Smartsheet survey and collected from each of the manufacturers included in the study

**MANUFACTURERS ASSOCIATIONS' DATA** as well as MNFs data, was asked and collected from associations included in the study. Associations also participated in the local definition's alignment. Associations that participated are:

**Costa Rica:** FEDEFARMA

**2022 W.A.I.T INDICATOR STUDY** data was also leveraged to include and validate for the 2023 W.A.I.T Indicator results. Data was included in order to expand the cohort to 7 years (2014-2021)

**Data was validated and QCed across all sources by a data analysis model generating comprehensive and visual results**

# Definitions & Methodologies

## Molecules were selected from US/EU approvals for novel oncologics and molecules indicated in rare disease from 2014-2021

1. Molecules with global approval from 2014-2021 were first identified via IQVIA's global list and EFPIA WAIT list
2. List was narrowed to include only orphan and oncology molecules
3. Some molecules were further excluded if they fell into the following categories: diagnostic tools, vaccines, drugs used in symptom relief (e.g., nausea) associated with oncologic treatment, molecules launched outside of the US/EU
- A few additional points were noted: (a) Molecules can have up to three marketing authorization dates: FDA, EMA, and (b) local Orphan status may be determined by either the FDA or EMA

## Results from the study are shown in terms of different levels of availability and compared across countries

1. **No Availability: Not submitted, or in regulatory evaluation process**
  - Time required by local regulatory bodies evaluating market authorization submissions to make a final approval publicly available.
2. **Approved, not available: Commercially available, but not reimbursed**
  - As being approved by regulatory bodies, medicines are authorized to be commercialized in the country. In this stage, there is reimbursement from neither private nor public payers; patients typically pay full OOP. This is inclusive of managed access schemes.
3. **Privately available: Private market reimbursement**
  - Medicines available only in the private market for a limited number of patients. Typically, medicines are reimbursed by private payers (e.g., HMOs) or have total or partial coverage by private insurance policies.
4. **Limited availability: Reimbursement but not for a broad population**
  - Medicines available only in the private market for a limited number of patients. Typically, medicines are reimbursed by private payers (e.g., HMOs) or have total or partial coverage

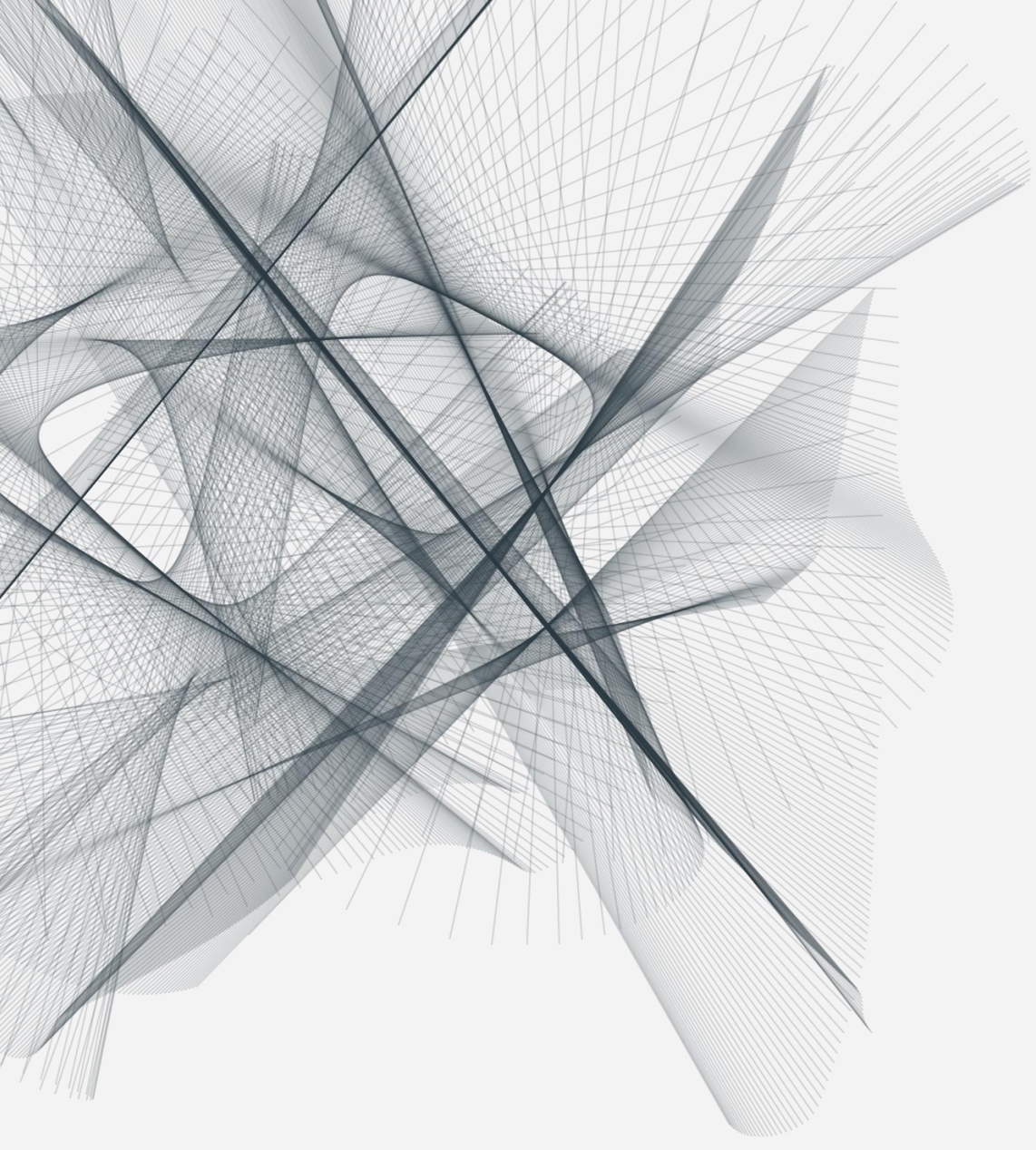
by private insurance policies.

## 5. **Full availability: Broad and national reimbursement**

- Medicines are fully available at national level for a broad population in both public and private market. Full availability is frequently tied to national formulary listing, positive HTA recommendations, or central procurement.

**Each geography in scope has a local definition of availability such that, to the extent possible, results can be compared regionally**

- **Ecuador Definitions of availability:** full: Essential list e.g., MSP, IESS; limited: Typically exception processes; private: n/a



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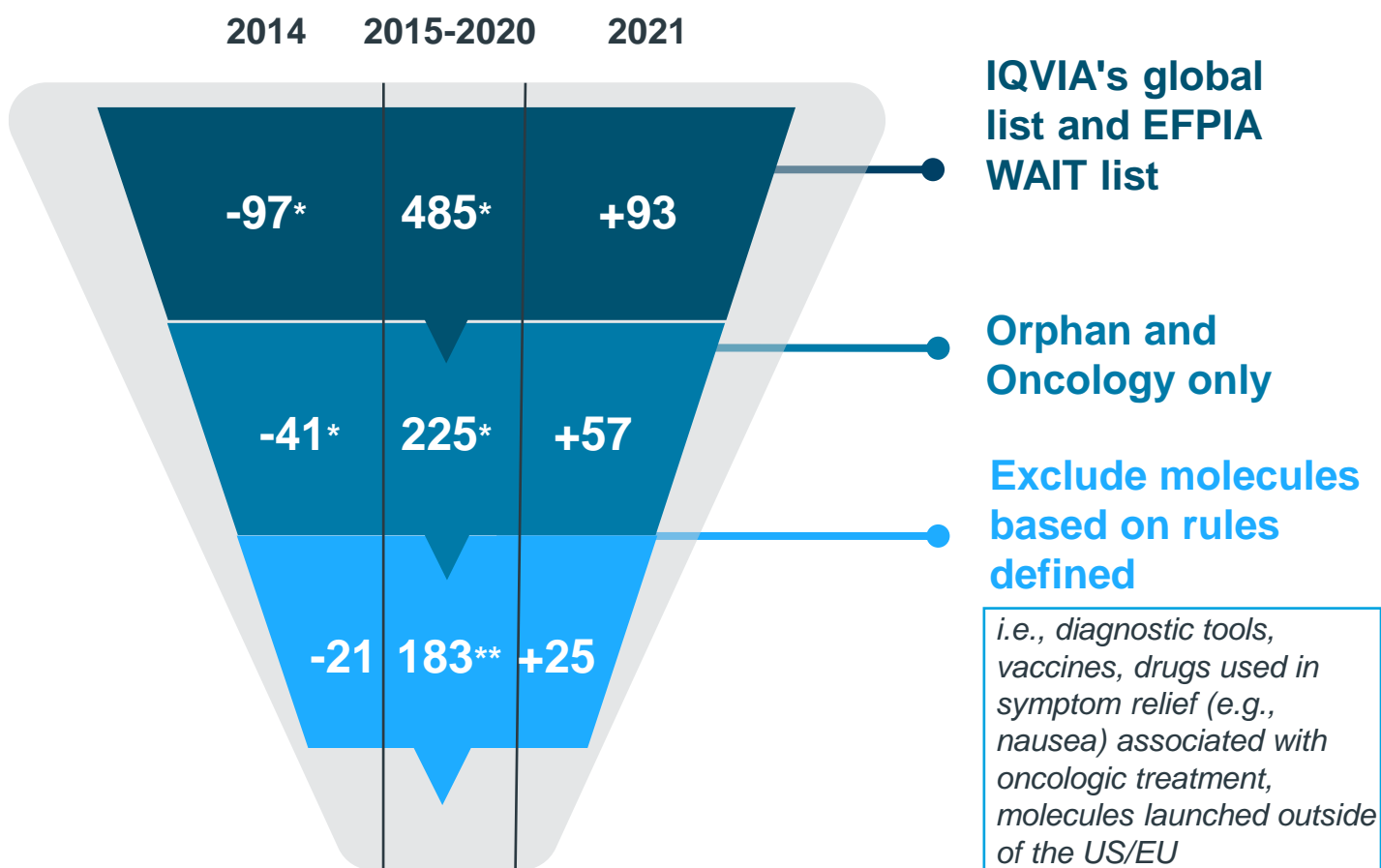
[oscar.courtney@iqvia.com](mailto:oscar.courtney@iqvia.com)



## Molecules were selected from US/EU approvals for novel oncologics and molecules indicated in rare disease from 2014-2021

### Study Cohort Selection Criteria

Molecules were selected from a universe from IQVIA's global and EFPIA WAIT list. Filters were used to identify only orphan and oncology molecules. Further exclusions were based on rules defined and aligned with FIFARMA



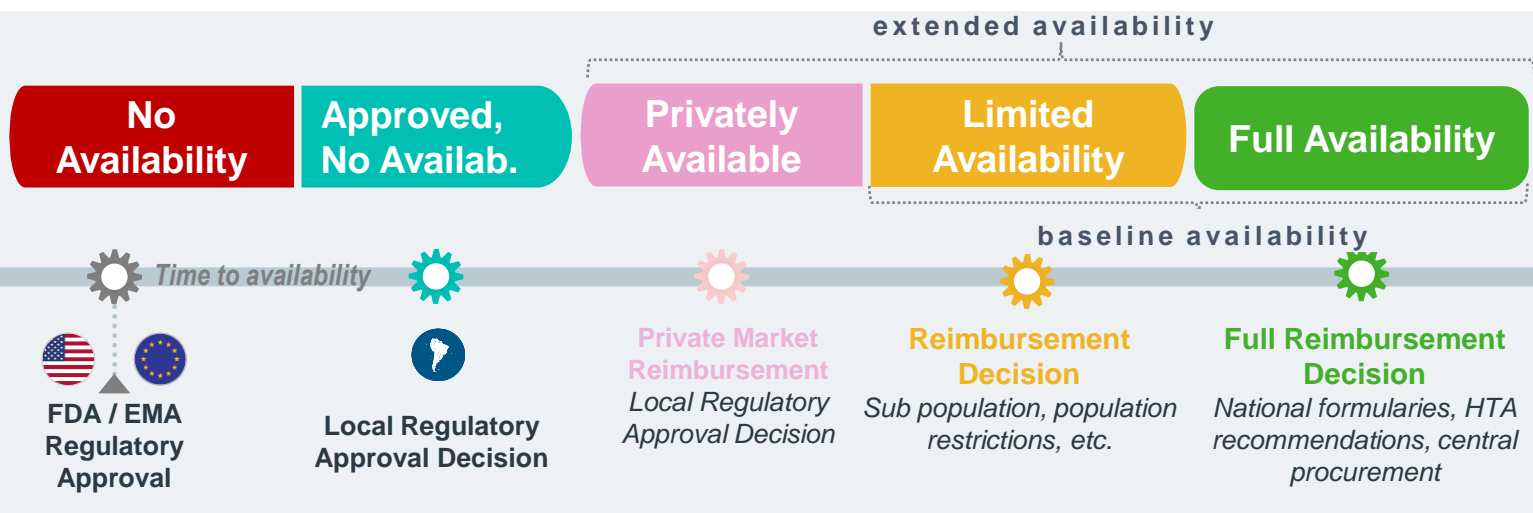
- Molecules can have up to three marketing authorization dates: FDA, EMA, and local
- Orphan status may be determined by either the FDA or EMA

\*Numbers used are for illustrative purposes only; \*\* Reflects the total after inclusions (+27) and exclusions (-9) based on updated exclusion rules

Acronyms: EFPIA: European Federation of Pharmaceutical Industries and Associations; WAIT: Waiting to Access Innovative Therapies; FDA: Food and Drug Administration; EMA: European Medicines Agency

## Results from the study are shown in terms of different levels of availability

### Availability Definitions



#### No Availability:

*Not submitted, or in regulatory evaluation process*

- Time required by local regulatory bodies evaluating market authorization submissions to make a final approval publicly available.

#### Approved, not available:

*Commercially available, but not reimbursed*

- As being approved by regulatory bodies, medicines are authorized to be commercialized in the country. In this stage, there is reimbursement from neither private nor public payers; patients typically pay full OOP. This is inclusive of managed access schemes.

#### Privately available:

*Private market reimbursement*

- Medicines available only in the private market for a limited number of patients. Typically, medicines are reimbursed by private payers (e.g., HMOs) or have total or partial coverage by private insurance policies.

#### Limited availability:

*Reimbursement but not for a broad population*

- The availability of medicines is limited to specific patient sub-populations, restricted to a limited number of treatment centers, or otherwise not granted access according to the full registered therapeutic indication.

#### Full availability:

*Broad and national reimbursement*

- Medicines are fully available at national level for a broad population in both public and private market. Full availability is frequently tied to national formulary listing, positive HTA recommendations, or central procurement.

## METHODOLOGICAL CONSIDERATIONS

Each geography in scope has a local definition of availability such that, to the extent possible, results can be compared regionally

	AR 	BR 	CL 	CO 	CR 	EC 	MX 	PE 	
Availability Def.	<b>Full</b>	PAMI/ SURGE or PAMI and PMO	CONITEC and centralized purchases	Ley Ricarte Soto or GES	PBS-UPC	CCSS (LOM)	Essential list e.g., MSP, IESS	Compendium, and federal inst. purchases	PNUME, and RENETSA /RM purchases
	<b>Limited</b>	1+ country formulary and broad coverage by OSN / prepaid	CONITEC, no centralized purchasing	Limited FONASA reimbursement, special programs	ADRES / MIPRES	Special purchases	Typically exception processes	Decentralized formularies	Not listed but with limited access
	<b>Private</b>	Broad prepaid coverage	ANS ROL placement	CAEC, ISAPRES	n/a	Prepaid plans	n/a	Large private formularies	n/a
Data	<b>Public</b>	SURGE, Drug Banks	CONITEC, ANVISA, ANS ROL	National websites, tenders	MinSalud, respective circulars	MOH, CCSS	MSP, IESS	Compendium, INEFAM, tenders	PNUME, IETSI, INEN
	<b>IQVIA*</b>	Retail, non-retail	Across channels	Retail, non-retail	Across channels	Retail, non-retail	Retail, non-retail	Across channels	Retail, non-retail
<b>Caveats</b>	Data coverage for sub-national plans not comprehensive	Relatively high visibility through available data	Private coverage data through CAEC is highly limited	Relatively high visibility through public data	Public data on approvals not available	Relatively high visibility through available data	Relatively high visibility through available data	Recent changes i.e., RENETSA and RM included	

**Definitions were aligned on and refined by the working group of local associations and IQVIA local teams**

Where not otherwise stated, date of first sale was used to indicate time to reimbursement

Acronyms: PAMI: Programa de Asistencia Médica Integral; SURGE: Sistema Único de Reintegros por Gestión de Enfermedades; PMO: Programa Médico Obligatorio; CONITEC: National Committee for Technology Incorporation; FONASA: Fondo Nacional de Salud; PBS-UPC: Plan De Beneficios En Salud Con Cargo A La UPC; CCSS: Caja Costarricense De Seguro Social; LOM: Lista Oficial de Medicamentos; MSP: Ministerio de Salud Pública; IESS: Instituto Ecuatoriano De Seguridad Social; PNUME: Petitorio Nacional Único de Medicamentos Esenciales; RENETSA: Red Nacional de Evaluación de Tecnologías Sanitarias; ANVISA: Agencia Nacional de Vigilancia Sanitaria; MOH: Ministry of Health; IETSI: Instituto de Evaluación de Tecnologías en Salud e Investigación; INEN: Instituto Nacional de Enfermedades Neoplásicas; CAEC: Cobertura Adicional para Enfermedades Catastróficas; GES: Garantías Explícitas en Salud



# Factors influencing availability across markets

Though this report does not aim to exhaustively identify and assess the impact of the multiple **factors that can influence availability across countries in LATAM**, there are several recurring themes that emerged through the research



## Commercial Partnerships

Oncology and Orphan drugs have a high number of emerging biotech's that have limited presence in the region, and typically require a local commercial partner to launch



## Indication Sequencing

The study considers the approval and reimbursement date of the first indication to arrive in each market; but the first indication may not fully represent the availability status of a molecule



## Role of the Private Market

Reimbursement in LATAM is bottoms-up, starting with private HMOs, then public sector before broad national formularies. In markets such as Brazil and Chile, a private market often delays public subnational access before broad public access




## COVID Impact

During the COVID period, a decrease in high cost / specialty care HTA activity was observed, resulting in fewer molecules being included in both subnational and national formularies



# Detailed Country Availability Definitions, as developed by FEDEFARMA - Costa Rica

Country	Availability	Definitions	Public Data	IQVIA Data
	Full	<i>CCSS Basic Formulary (LOM)</i>	MOH website CCSS Document	<b>Retail:</b> Available  <b>Hospital / Non-Retail:</b> Not broadly available
	Limited	<i>Purchased via Special purchases negotiations, and through judicialization initiated by the patient</i>		
	Only Private	<i>Broad coverage by prepaid plans, no special purchase negotiations, no CCSS formulary</i>		
	Not Available	<i>Ministerio de salud approval, no CCSS, no special purchases negotiations, no broad coverage by prepaid plans Only OOP sales, mostly in the Retail Setting</i>	INVIMA Website	