



Projeto
Rede Colaborativa Brasil de Pesquisa
Clínica sobre Covid-19 e Covid longa

Integrante da Plataforma Clínica Global da OMS

Seminário Internacional Plataforma Clínica Global Covid-19 e Pós-Covid/ Organização Mundial da Saúde- OMS: Resultados da Pesquisa, Desafios e Lições Aprendidas

COLOMBIA

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Coordinador Nacional estudios clínicos

Brasília-DF, 05 de dezembro/22

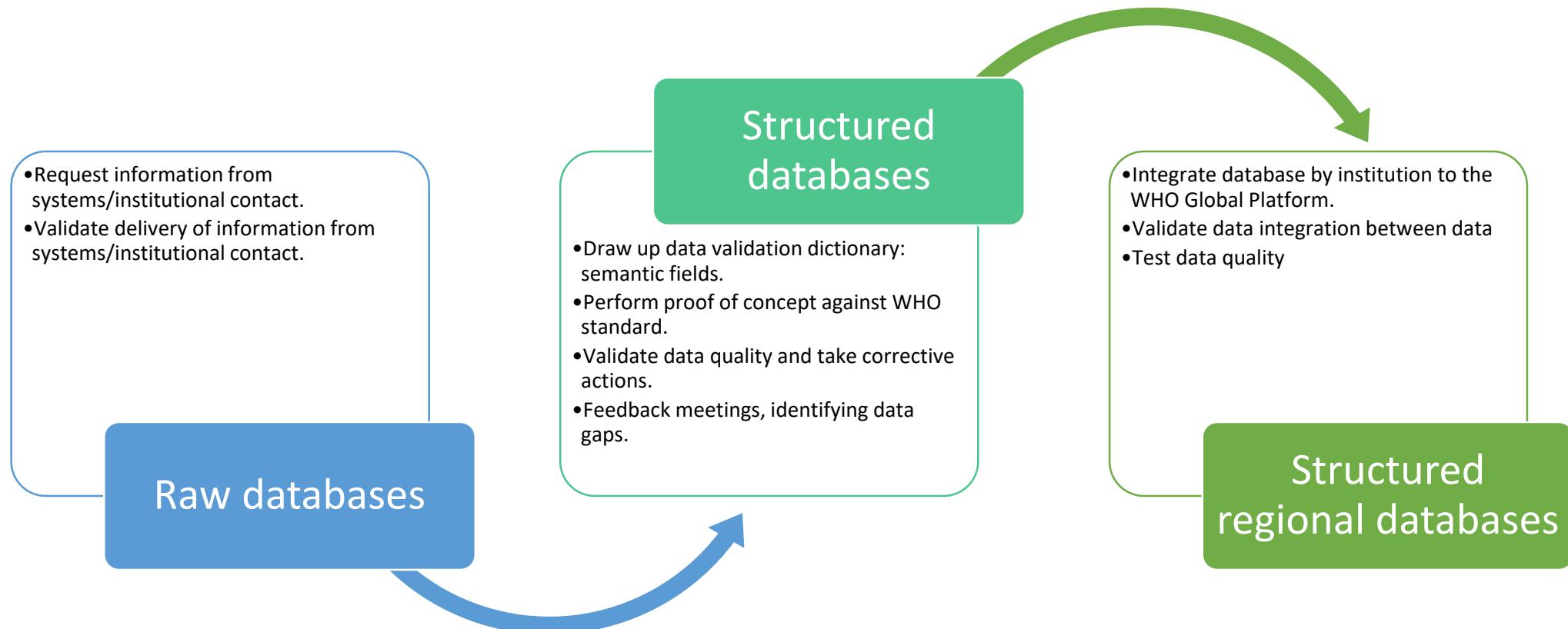


OPAS OPAS 120 Aniversario



**MINISTÉRIO DA
SAÚDE**

Data workflow in the COVID and Postcovid Global Platform Projects.



TOPICS

1

Plataforma Clínica Global COVID-19

2

POST COVID-19 Platform

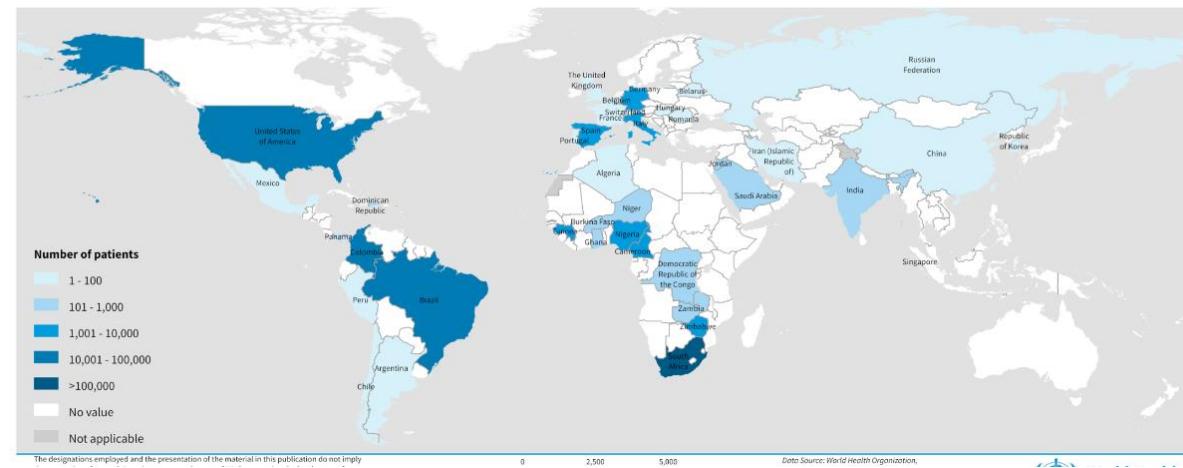
3

Estudio EPICO

Clinical Trials Registry Platform



Countries contributing data to the WHO Platform (September, 2021)



With the support of PAHO in Colombia and Washington, it was possible to quickly implement.

Plataforma Clínica Global COVID-19

Goal

1. To describe the key clinical features and prognostic factors of **hospitalized cases of suspected or confirmed COVID-19**, thereby increasing understanding of the severity, spectrum, and impact of the disease in the hospitalized population globally, in different countries.
2. Characterize clinical interventions, thus facilitating global and national operational planning during the COVID-19 pandemic.

Plataforma Clínica Global COVID-19

Para armonizar la recopilación de datos en diversos entornos mundiales, la OMS ha desarrollado un formato estándar.

- Contiene un conjunto mínimo de variables clave y establece la base de tres tipos de CRF:

- CRF base

- CRF de embarazo

- CRF multisystem inflammatory syndrome MIS-C

- Data can be recorded directly on the platform electronically or in CRF printed on paper, then entering the data on the WHO platform.

Core CRF: hospitalized children and adults with COVID19

Pregnancy CRF: core CRF + specific sections/variables in hospitalized pregnant women

Multisystem inflammatory syndrome (MIS): Children and Adolescents

Case Report Forms (CRFs)

MODULE 1 Admission

- Clinical inclusion criteria
- Demographics
- Date of onset and admission vital signs
- Co-morbidities
- Medication
- Signs and symptoms on admission
- Supportive care received
- Lab results
- Pregnancy Status upon Admission

MODULE 2 Inpatient stay (Daily Follow Up)

- Vital signs
- Daily clinical features
- Lab results
- Medication
- Supportive care received
- Fetal Heart Rate

MODULE 3 Discharge or death (Outcome)

- Diagnostic/ pathogen testing
- Complications
- Medication
- Supportive care received
- Outcome
- Pregnancy Outcomes

7 Feb 2020 - 11 Jun 2021

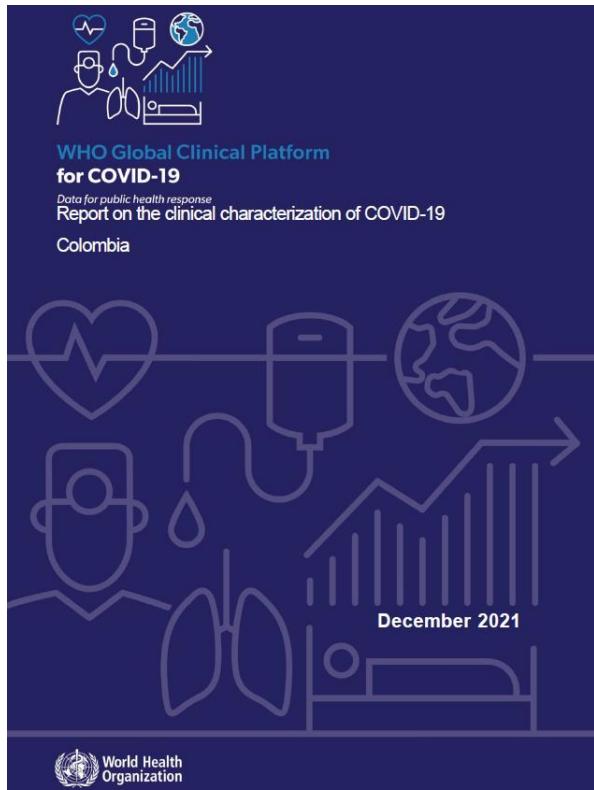
Phase 1

Plataforma Clínica Global COVID-19

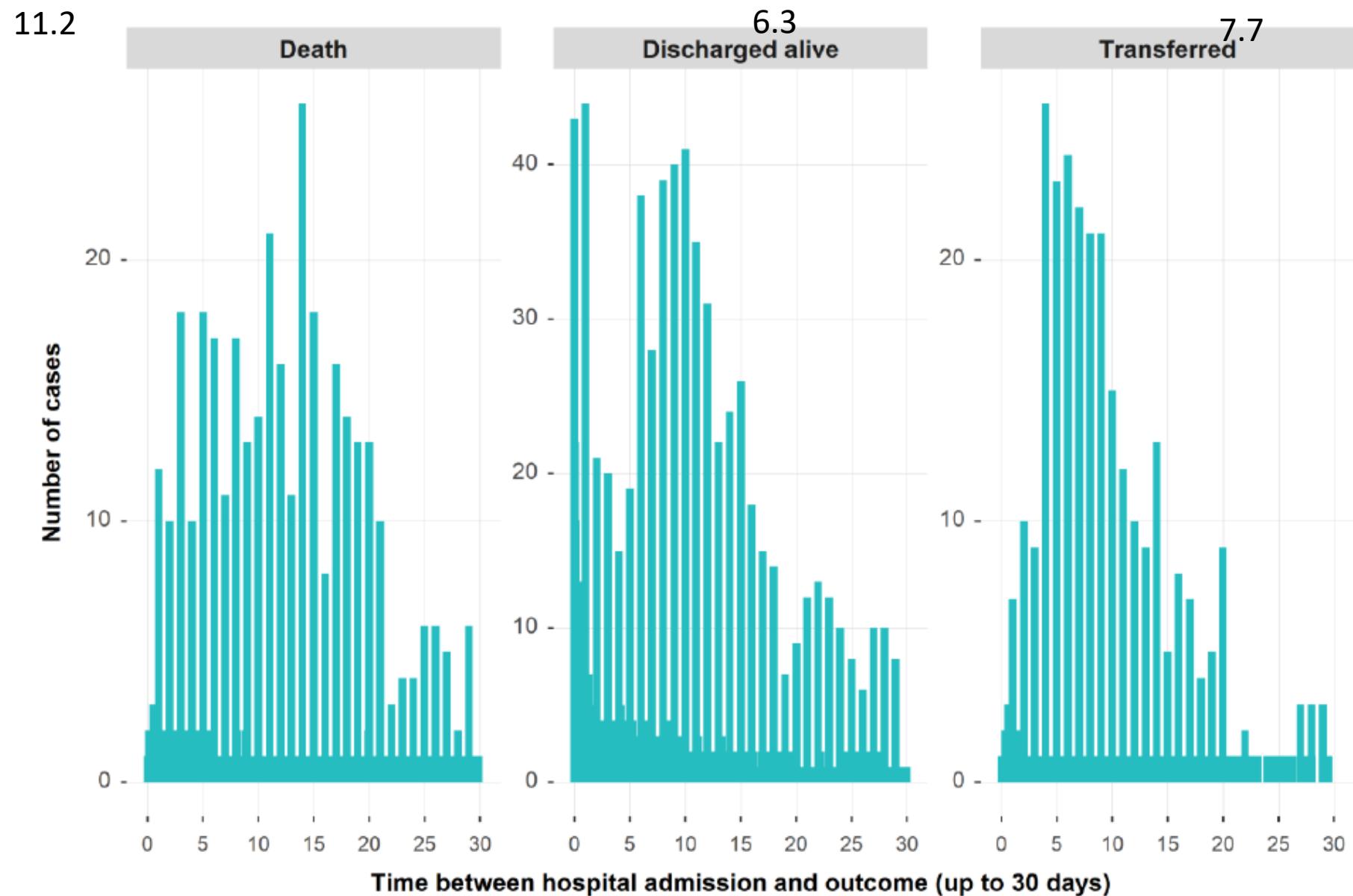
- Fundación Cardioinfantil, Bogotá
- Clínica Infantil Colsubsidio, Bogotá
- Hospital Universitario San Ignacio, Bogotá
- Clínica Iberoamérica, Barranquilla
- Clínica Colsanitas-Clínica Sebastián de Belalcázar, Cali
- Hospital Militar Central, Bogotá
- Hospital Universitario Nacional de Colombia, Bogotá
- Clínica El Carmen, Barranquilla
- Clínica Colsanitas - Clínica Reina Sofía, Bogotá
- Clínica Colsanitas-Clínica Universitaria Colombia, Bogotá
- Clínica Colsanitas-Clínica Infantil Santa María del Lago, Bogotá



Gestión Científica y de Investigación

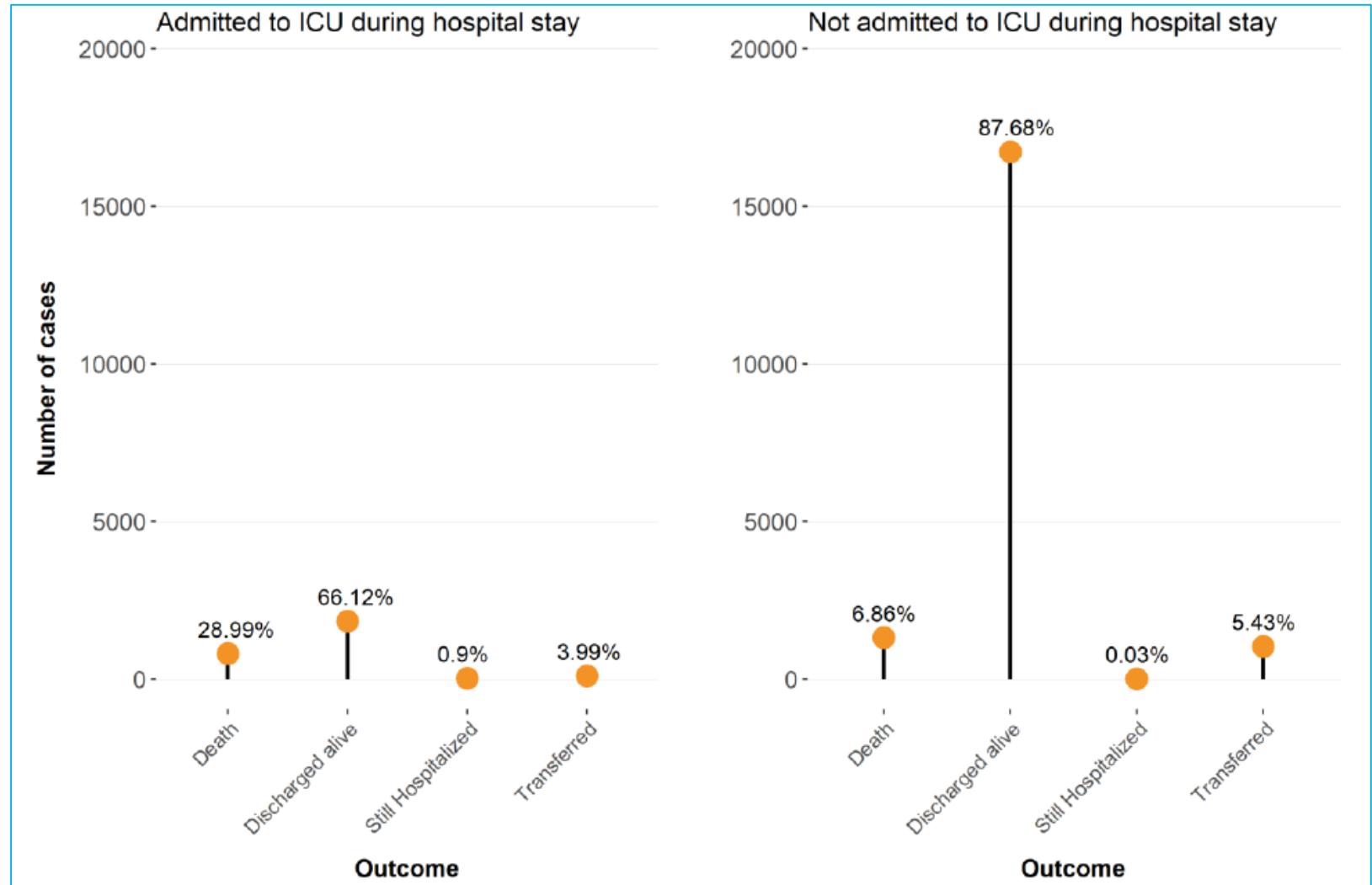


27.881 Registered Patients



Gestión Científica y de Investigación

Proporción de resultados para pacientes con COVID-19 por nivel de atención hospitalaria recibida (UCI VS No UCI)



Associated Factors for mortality in a SARS-CoV-2 COVID-19 Colombian Cohort by

Epidemic wave: is the Predominance of Mu Variant relevant?

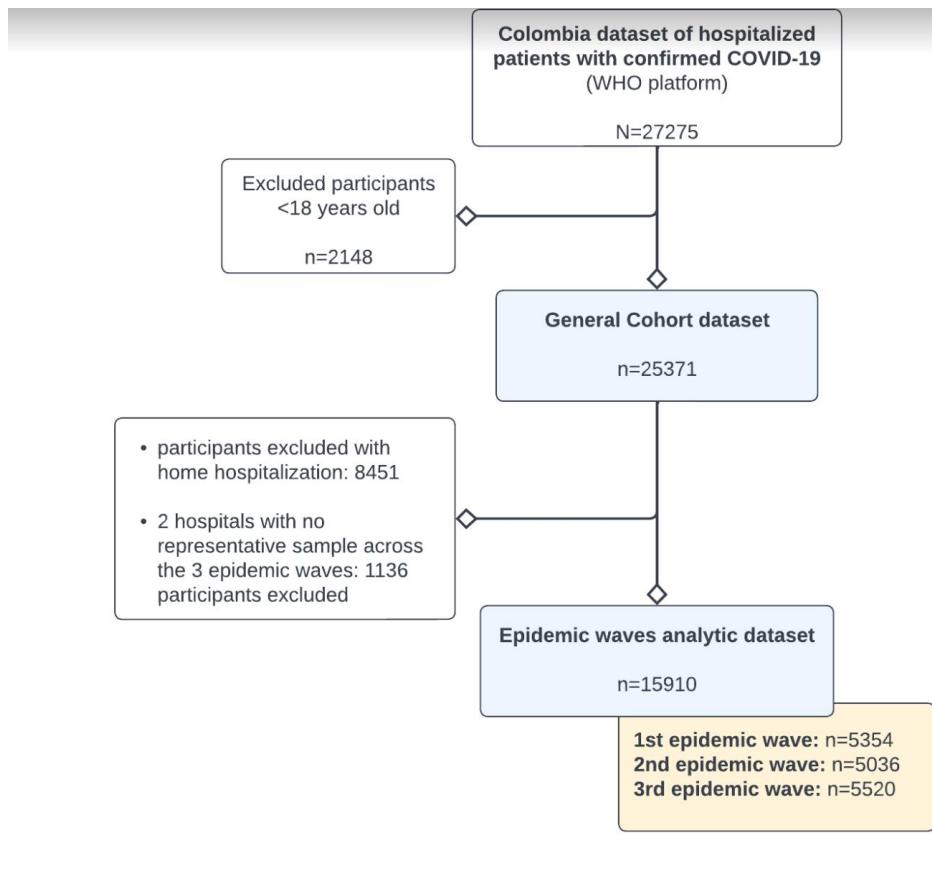


Table 3. Description of the Clinical Characteristics, Clinical Management, and Outcomes of the Colombian cohort by an epidemic wave from March 2020 to September 2021. WHO World Platform.

Clinical Characteristics, Clinical Treatment, and Outcomes	First (N=5354) ¹	Second (N=5036) ¹	Third (N=5520) ¹	P value
Age (years)	59.7 (47.0-71.6)	63.2 (50.5-74.4)	56.7 (42.5-68.7)	< 0.01
Age (years)				< 0.01
< 45	1208 (22.6%)	903 (17.9%)	1597 (28.9%)	
45 to 65	2251 (42.0%)	1952 (38.8%)	2274 (41.2%)	
66 to 75	932 (17.4%)	1081 (21.5%)	875 (15.9%)	
> 75	963 (18.0%)	1100 (21.8%)	774 (14.0%)	
Sex				0.03
Male	3057 (57.1%)	2959 (58.8%)	3104 (56.2%)	
Female	2297 (42.9%)	2077 (41.2%)	2416 (43.8%)	
Signs and symptoms on admission				
Altered consciousness/confusion	663 (12.4%)	589 (11.7%)	1173 (21.2%)	< 0.01
Fever	2644 (49.4%)	2164 (43.0%)	3229 (58.5%)	< 0.01
Cough	2880 (53.8%)	2089 (41.5%)	2933 (53.1%)	< 0.01
Shortness of breath	2767 (51.7%)	2865 (56.9%)	3118 (56.5%)	< 0.01
Headache	510 (9.5%)	347 (6.9%)	1089 (19.7%)	< 0.01
Nausea or Vomiting	232 (4.3%)	108 (2.1%)	120 (2.2%)	< 0.01
Loss of taste	186 (3.5%)	153 (3.0%)	156 (2.8%)	0.14
Loss of smell	161 (3.0%)	145 (2.9%)	162 (2.9%)	0.93

1048

Postcovid: Goal

1098

Postcovid already collected

7056

COVID: Goal

2022

10022

COVID already collected

Phase 2

1065

Monkeypox: Goal

1002

First Monkeypox already collected

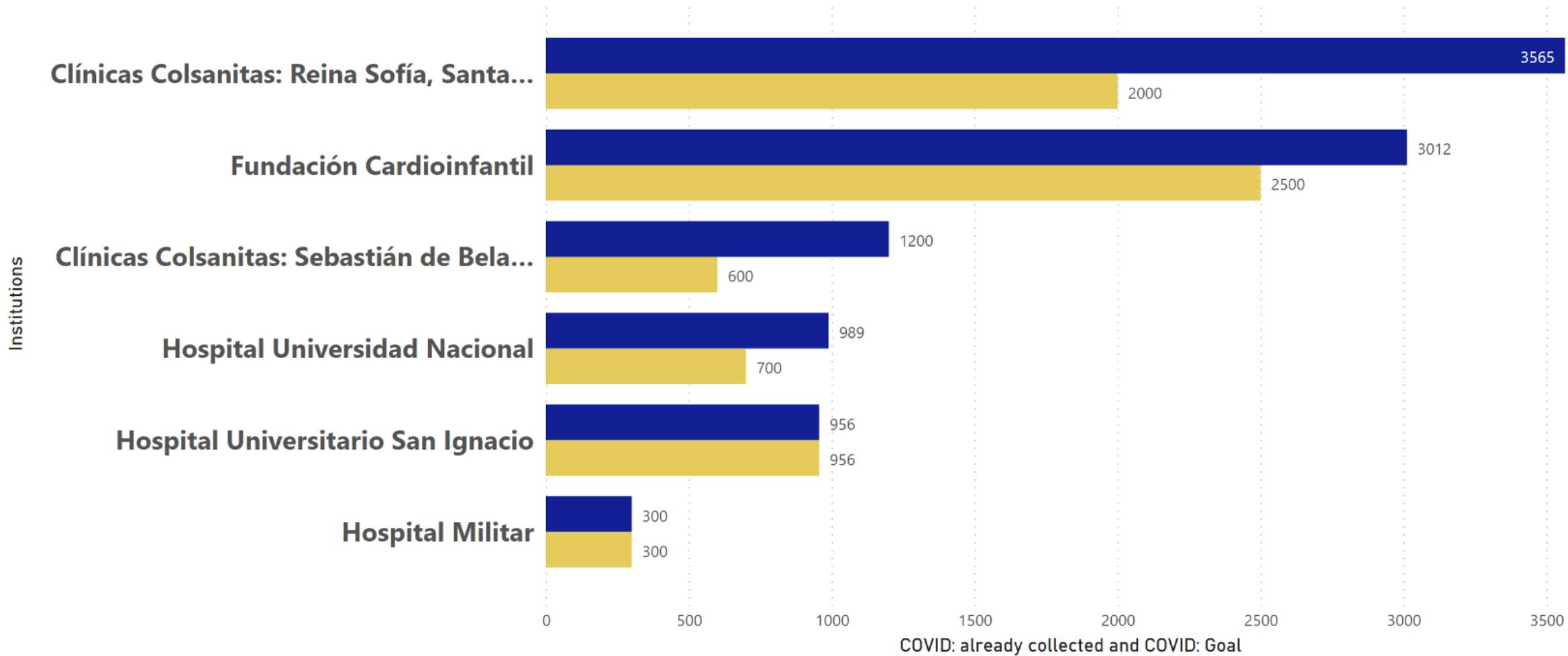


Iniciativa Rede Colaborativa Brasil

Estudo de caracterização clínica e manejo de pacientes hospitalizados com Covid-19: contribuindo com o SUS e a Plataforma Clínica Global da OMS



● COVID: already collected ● COVID: Goal



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Estudio EPICO

Plataforma Clínica Global COVID-19

Post COVID-19 Condition

- Designed to assess the mid and long-term sequelae of COVID-19
- **CRF Post COVID-19 includes 3 modules:**
- **Module 1:** Acute COVID-19 episode. Clinical Record, demographics and symptoms related to the acute episode of COVID-19.
- **Module 2:** Questions related to the period of post-acute illness to identify patients who require further clinical attention.
- **Module 3:** Follow up. Includes the medical evaluation and the results of the examinations, tests or diagnoses made during the follow-up visit.
- It can be a clinical tool to document the medium and long-term sequelae of COVID-19. This will ensure that rehabilitation needs are identified, and pa

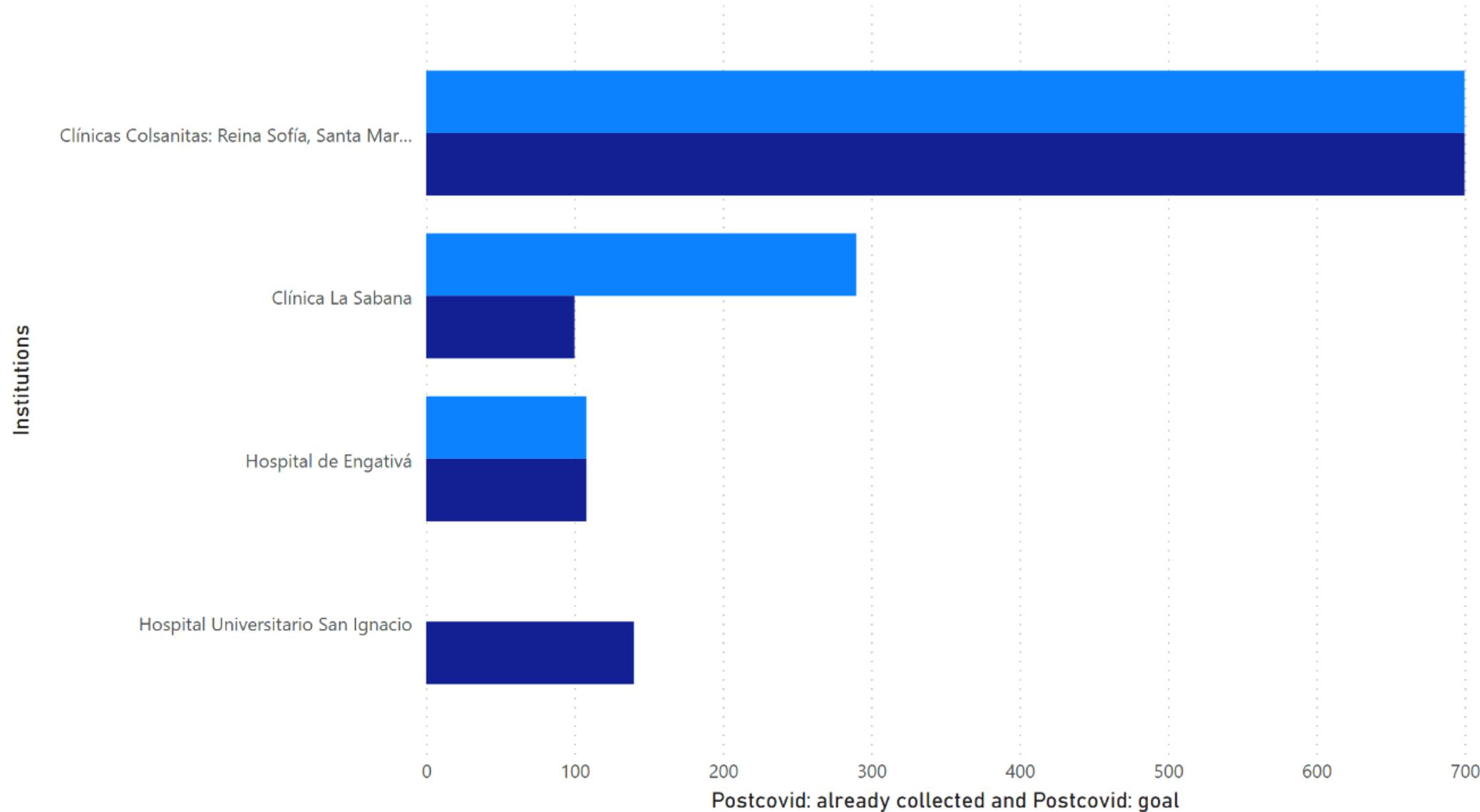


WHO Global Clinical Platform for COVID-19
Case Report Form (CRF) for COVID-19 sequelae ("Post COVID-19 CRF")



Postcovid: already collected and Postcovid: goal by Institutions

● Postcovid: already collected ● Postcovid: goal



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EPICO

CORONAVIRUS (SARS-COV-2) IN PEDIATRIC POPULATION IN COLOMBIA: EPIC GROUP.



Estudio Epidemiológico de las Infecciones pediátricas
por el nuevo Coronavirus (SARS-CoV-2)

COLOMBIA CORE TEAM

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Martha Báez, MD.

Oscar Ovalle, MD.

Pablo Vasquez Hoyos, MD, MSc.

Sandra Beltran, MD.

Camilo Andrés Cristancho, MD,

Daniela Duarte Montero

Luis Miguel Navarro.

Equipo
multidisciplinario
EPICO COLOMBIA

Diferentes
especialidades,
enfoque clínico y
metodológico

Representación de
diferentes
Sociedades
Científicas

OBJETIVES

To describe the spectrum of disease associated with confirmed SARS-CoV-2 infection that requires hospital management in the different areas of pediatrics, including its evolution, severity factors, and outcomes.

GENERAL PEDIATRICS

Newborn population

METHODS

Tipo de estudio	Población	Recolección información
Estudio observacional descriptivo, multicéntrico	Menores 18 años (incluye neonatos) con infección confirmada por SARS CoV2.	Red Cap: variables sociodemográficas, clínicas, evolución y desenlaces 159 Variables compartidas, 28 pediátricas y 61 neonatales exclusivas respectivamente
Tamaño de muestra	Duración	Seguimiento
Se espera incluir el mayor número posible de cada uno de centros participantes (se estima por lo menos 200)	24 meses	Intrahospitalario, sin seguimiento ambulatorio
Análisis estadístico Limitaciones		

EPICO Colombia

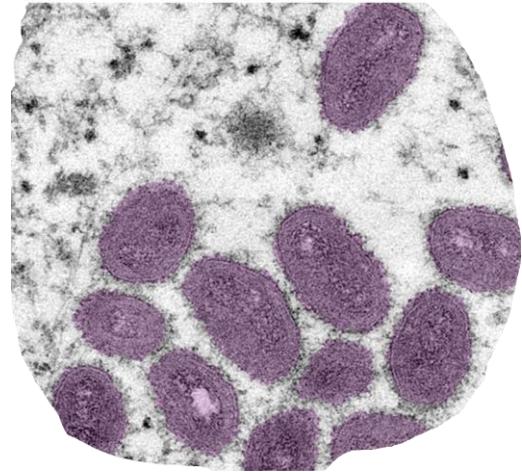
- Clínica Infantil Colsubsidio (CIC)
- Hospital Regional de la Orinoquia
- San José Centro
- Clinica Materno Infantil San Luis
- Instituto Roosevelt (IR)
- Clínica Colsanitas Pediátrica
- Clínica Colsanitas S.A. Sede Santa María del Lago
- Hospital Militar
- San José Infantil
- Hospital Universitario Fundación Valle del Lili
- Hospital Universitario Fundación Santa Fe de Bogotá (HUFSCB)
- Clínica SOMA
- Clínica del Rosario



EPICO Colombia

HOSPITAL	# PACIENTES	% PACIENTES	Total solicitudes CC	Solicitudes último CC	% Solicitudes pendientes*	Pacientes CC completo
Clínica Infantil Colsubsidio (CIC)	198	27,42	2947	1824	62%	54
Hospital Regional de la Orinoquia	110	15,24	878	53	6%	84
San José Centro	73	10,11	260	78	30%	57
Clinica Materno Infantil San Luis	71	9,83	222	81	36%	14
Instituto Roosevelt (IR)	48	6,65	594	336	57%	13
Clínica Colsanitas Pediátrica	46	6,37	647	1	0%	45
Clínica Colsanitas S.A. Sede Santa María del Lago	45	6,23	1282	0	0	45
Hospital Militar	38	5,26	759	18	2%	27
San José Infantil	30	4,16	987	4	0%	26
Hospital Universitario Fundacion Valle del Lili	29	4,02	593	25	4%	13
Hospital Universitario Fundación Santa Fe de Bogotá (HUFSA)	17	2,35	144	29	20%	11
Clinica SOMA	13	1,80	417	403	97%	1
Clinica del Rosario	3	0,42	36	15	42%	1

Fecha de corte: 31 de diciembre 2021



COLOMBIA

Global Clinical Data Platform

Monkeypox

CASE REPORT FORM (CRF)

Institutions	Confirmed Participation	Cases already collected
Hospital Universitario del Valle	No	
Hospital Universitario Nacional	Pendiente	
Hospital Universitario San Ignacio	Pendiente	
Clínicas Colsanitas	Sí	600
Fundación Shaio	Sí	
Infectologos Clínicos de Colombia	Sí	200
Secretaría de Salud Valledupar	Sí	
Virrey Solís	Sí	202

Institutions	Monkeypox: Goal
Clínicas Colsanitas	698
Fundación Shaio	6
Hospital Universitario del Valle	30
Hospital Universitario Nacional	5
Hospital Universitario San Ignacio	20
Infectologos Clínicos de Colombia	200
Secretaría de Salud Valledupar	6
Virrey Solís	100
Total	1065





CHALLENGES

the administrative processes are being more difficult than expected

At the beginning, solidarity and resilience surpassed the bureaucracy, but...

NEEDS

- More agile administrative processes, including ethical processes, but maintaining its seriousness.
- Focal points for clinical and observational studies.
- Big data handling capacity

Muito obrigado



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