



EDCTP

The power of sharing science

COVID-19 research in low- and middle-income countries: EDCTP experience

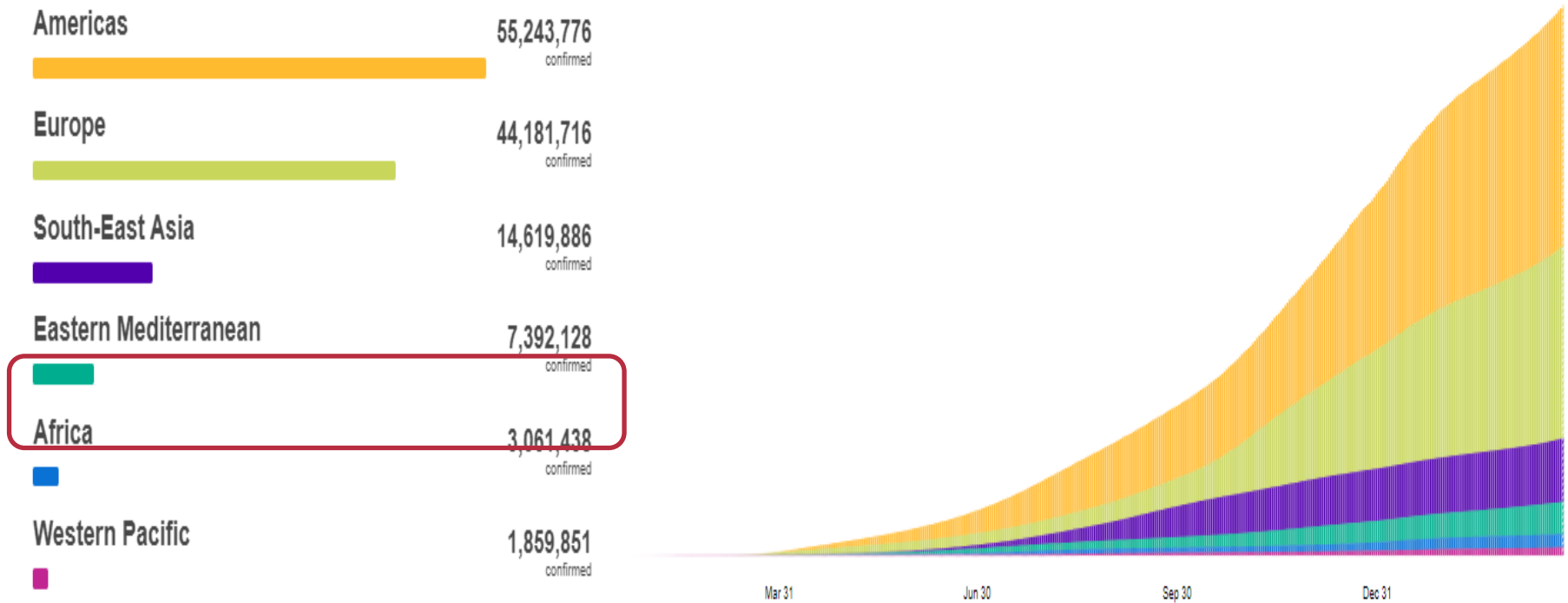
GloPID-R, UKCDR and COVID-19 Clinical Research Coalition
Online Meeting, 29-30 Mar 2021

Dr Michael Makanga | EDCTP Executive Director



Cases globally

As of 28 Mar 2021 - Globally, 126,359,540 confirmed cases of COVID-19, including 2,769,473 deaths, reported to WHO.

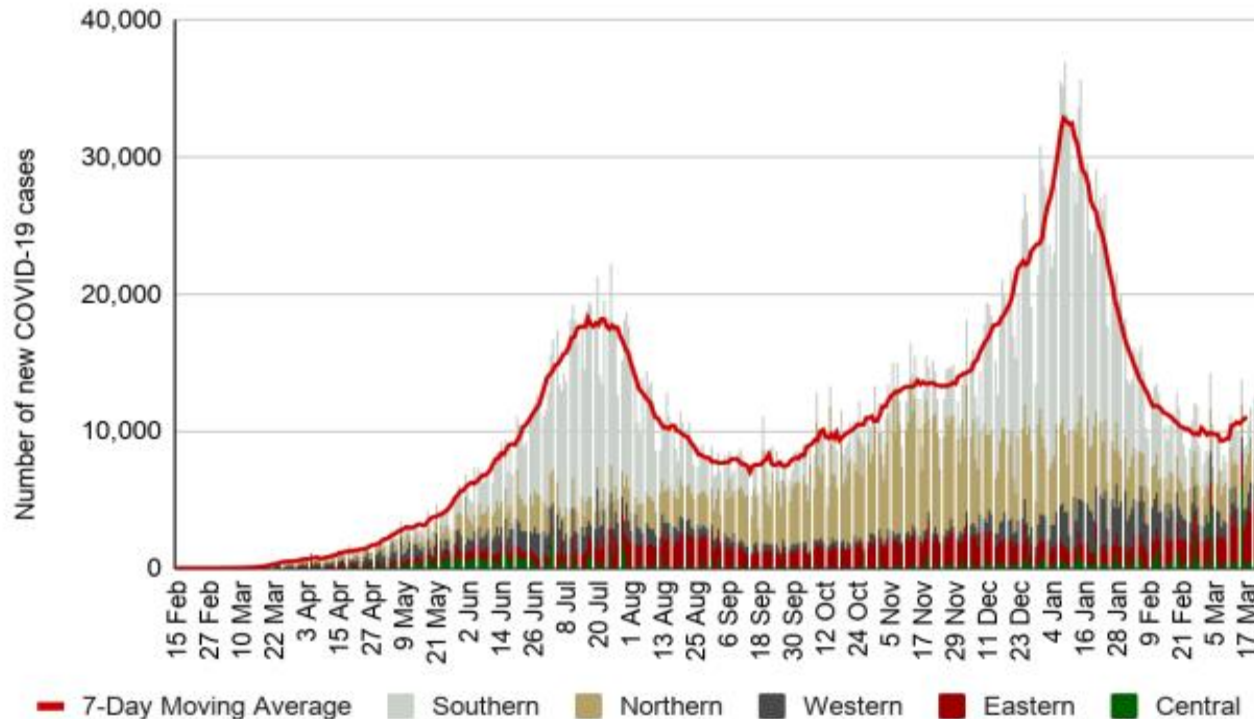


Source: [WHO Coronavirus \(COVID-19\) Dashboard](#) | [WHO Coronavirus Disease \(COVID-19\) Dashboard](#)

*Data may be incomplete for the current day or week.

Cases in Africa

Cases between Feb 2020 to Mar 2021



Between epi weeks 8 - 10, the epicurve trended downward to the level reported in October 2020. However, in the past epi week, the curve has begun to trend upward.

The new variants leading to a surge?

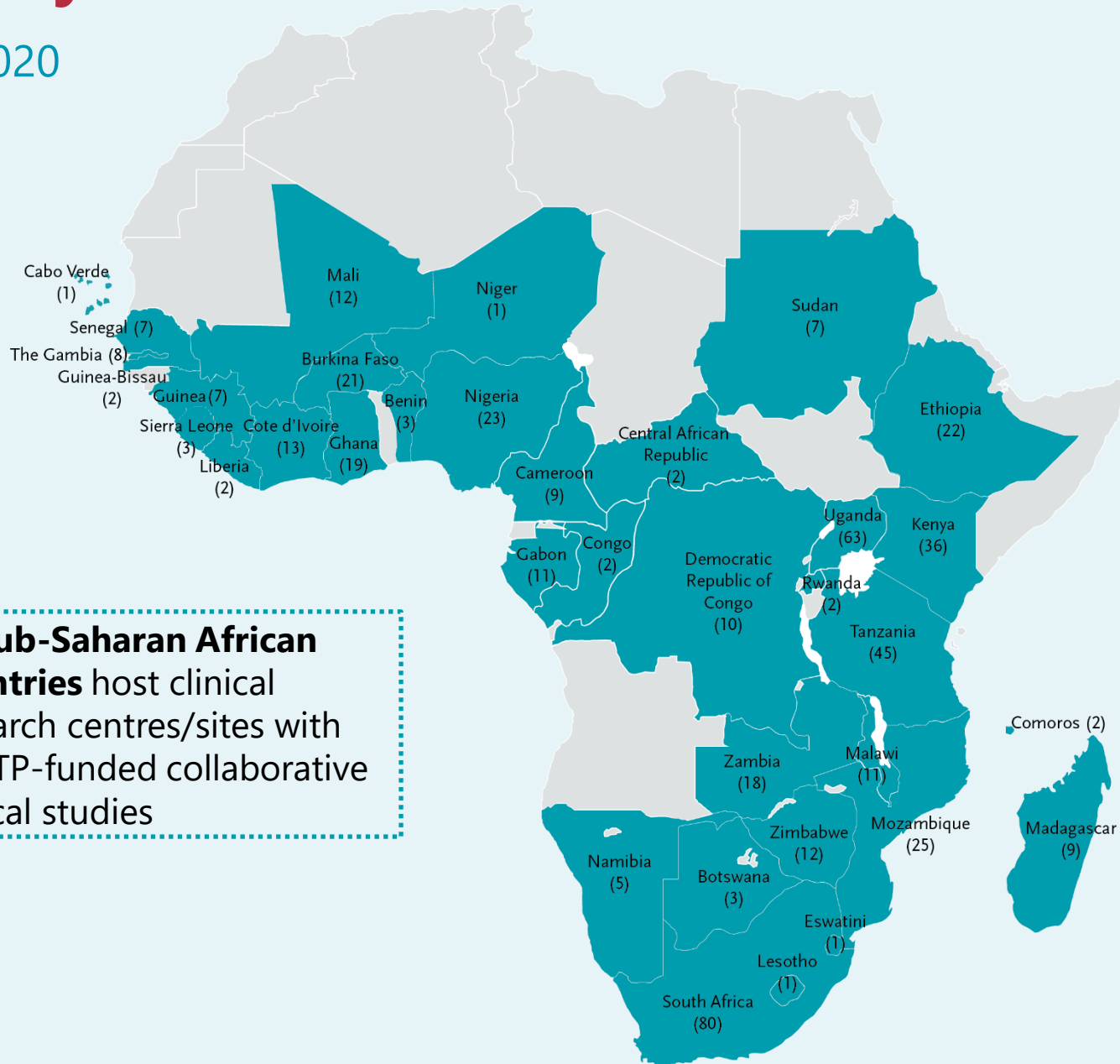
Figure: New COVID-19 cases reported by day in Africa by African Union region, 15 Feb 2020 - 23 Mar 2021.

Why Africa-specific COVID-19 research is needed

- COVID-19 epidemiology in Africa: the spread and response
- Biological responses: Immune responses to SARS-CoV-2
- Demographics: differences in age profiles, other potential vulnerabilities (socioeconomic factors and high levels other infections such as malaria, HIV, TB, NTDs) and growing NCDs.
- Control measures: classic public health responses difficult to practise hygiene promotion, isolation, restrictions on movement and lockdowns.
- Testing: PCR is expensive and limited capacity for PCR exists affordable and simple-to-use alternatives are therefore required.
- New challenges: new variants (the 501Y. V2 variant and new one identified from Tanzanian travelers); long COVID, etc.

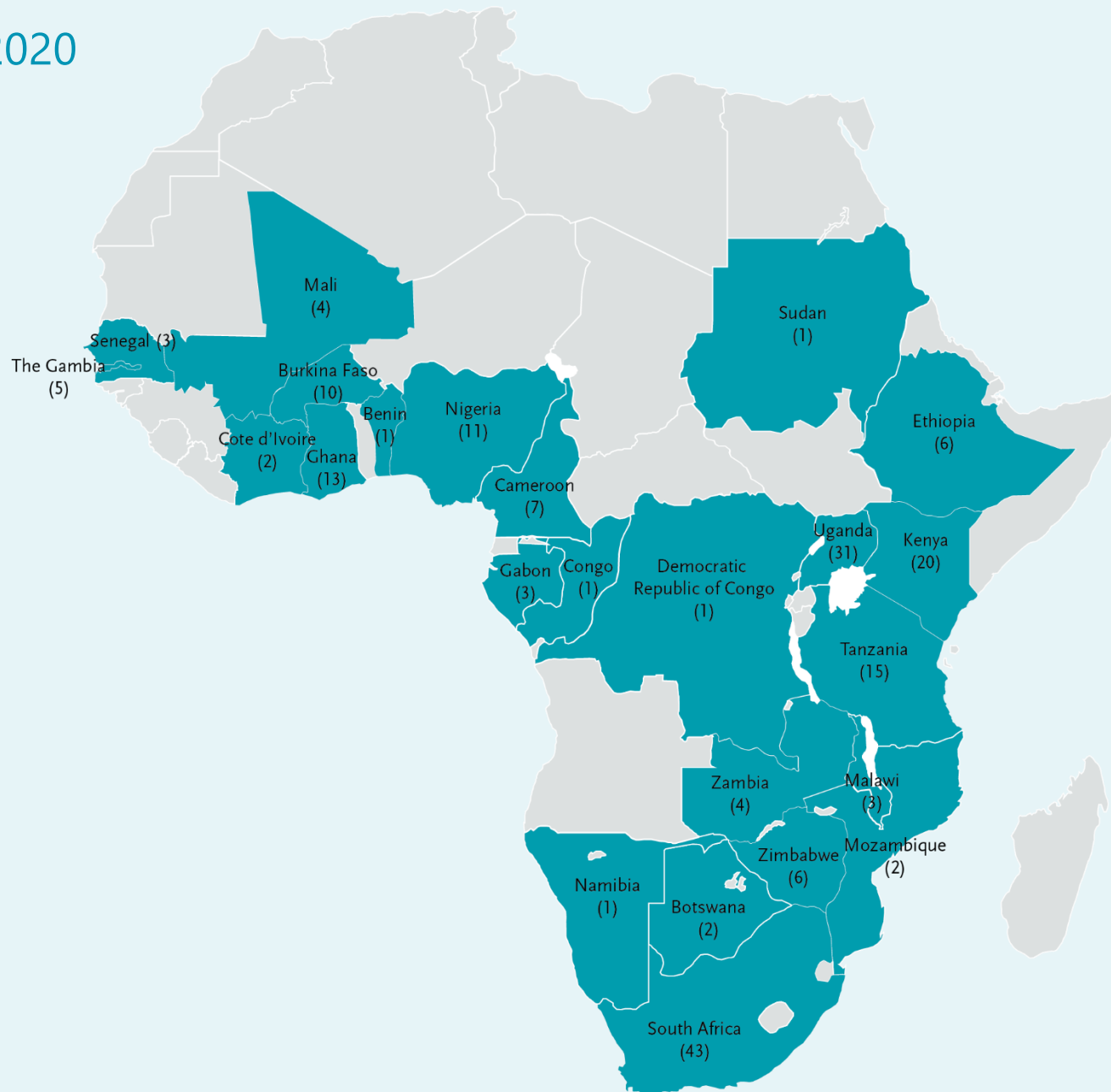
Country involvement in clinical studies

2014-2020



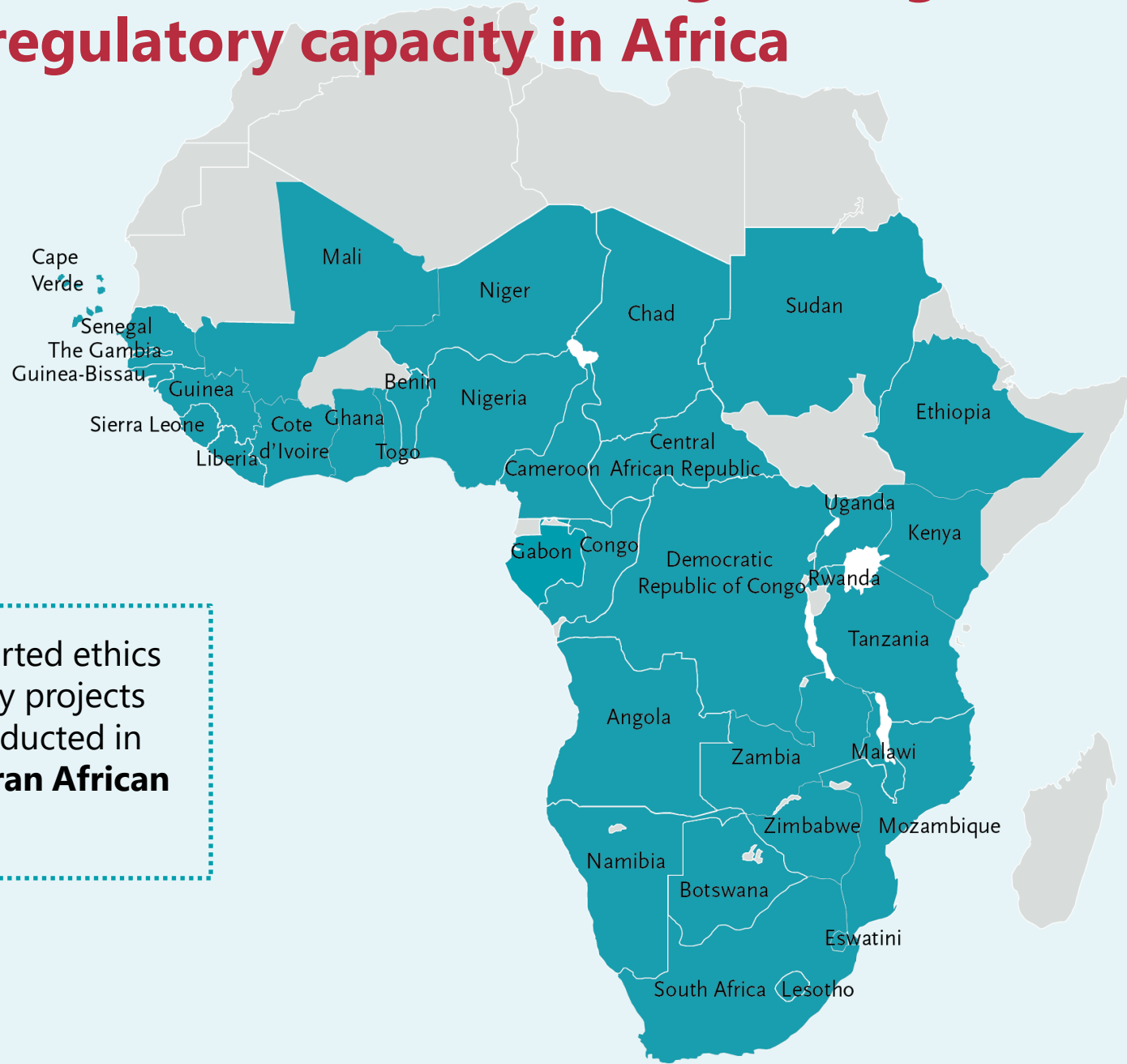
EDCTP2 Fellowships – by country

2014-2020



EDCTP's contribution towards strengthening ethics and regulatory capacity in Africa

2014-2020



EDCTP-supported ethics and regulatory projects are being conducted in **37 sub-Saharan African countries.**

EDCTP funding of COVID-19 research

Schemes existing before COVID-19

- **Epidemic Preparedness Consortia:** research response by consortia funded through an earlier investment of **EUR 20M:**
 - the Pan-African Network for Rapid Research, Response, Relief and Preparedness for Infectious Diseases Epidemics (**PANDORA-ID-NET**), and
 - the African coalition for Epidemic Research, Response and Training (**ALERRT**).
- Activities include:
 - Immediate initiation of training in lab skills and cases management at points of entry
 - Implementation of Clinical Characterisation Protocol in several countries

- **Existing projects**

Amendments to incorporate COVID-19 research studies, sample collection

New investments

- **Emergency funding COVID-19** to support research activities in sub-Saharan Africa to manage and/or prevent the spread of COVID-19 (~**EUR 13M**)
- **Strengthening** sub-Saharan African research networks and establish an African cohort of epidemiologists and biostatisticians.
 - **EUR 18M** Regional Networks of Excellence
 - **EUR 6.5M** (jointly with Africa CDC) to train epidemiologists and biostatisticians (~150 candidates to be trained).
- COVID-19 included in the scope of programme.

COVID-19 Emergency response funding

Thematic areas being addressed by ongoing research grants

Topic 3: Studies contributing to the implementation of randomised, controlled **trials for diagnostics and therapeutics.**

3 RIA2020EF-2968: **BCG revaccination**
RIA2020EF-3049: **BCG revaccination**
RIA2020EF-2975: **platform for clinical trials**

RIA2020EF-2928: **Clin Characterisation**

RIA2020EF-2981: **household transmission**
RIA2020EF-2983: **PCR, influenza system repurpose**

1 RIA2020EF-2947: **COVID-19 Ag Respi-Strip™**

Topic 1: Studies contributing to better understanding of the natural history of infection; improving **surveillance capabilities** and understanding of the role of asymptomatic infection in transmission.

RIA2020EF-2905: **combination of RDTs**
RIA2020EF-2918: **POC-LAMP (PATHPOD) diagnostics**
RIA2020EF-2937: **RT-PCR in a suitcase**

2

Topic 4: Validation and adaptation of existing **serological tests** and establishment of **biobanks and serum panels** of well characterised COVID-19 sera.

RIA2020EF-3042: **antibody & other immunological assays**
RIA2020EF-2977: **Novel Serological Test**

4

RIA2020EF-2923: **active epi surveillance**
RIA2020EF-2926: **COVID in pregnant women**
RIA2020EF-2961: **PCR**
RIA2020EF-3008: **antibody evolution following exposure**
RIA2020EF-3012: **COVID-19 Ag Respi-Strip™**

RIA2020EF-3004: **Ag, Ab tests, Xpert® MTB/RIF-Covid and computer aided diagnostic software**
RIA2020EF-3026: **Dried Plasma Spot samples**
RIA2020EF-3030: **RT-LAMP diagnostic**
RIA2020EF-3031: **population-based surveillance**

Topic 2: Development, adaptation, evaluation, and implementation of **point-of-care diagnostic tests.**

The COVID-19 portfolio

AfriCoVER
Belgium, France,
Mozambique, Netherlands



COREP
Australia, Germany, Kenya,
South Africa, Spain, United
States



TREATS-COVID
France, Netherlands,
United Kingdom,
Zambia



AIDCO
Ethiopia, Gabon, Germany,
Netherlands, Senegal



periCOVID-Africa
The Gambia, Kenya, Malawi,
Mozambique, Norway,
Uganda, United Kingdom



Covid-19 HCW
France, South Africa,
United Kingdom



HALT_COVID-19
Denmark, Germany,
Netherlands, South Africa



CSIGN
Ghana, Spain, United
Kingdom



STREESCO
Benin, Burkina Faso, France,
Spain



ITAIL-COVID-19
Belgium, Congo, France,
Germany, United Kingdom



RADIATES Consortium
South Africa, Sweden,
United Kingdom



Africa_Suitcaslab
DR Congo, Germany,
Ghana, Madagascar, Nigeria,
Senegal, Sudan, Uganda,
United Kingdom



AfriDx
Denmark, Ghana, Sweden,
United Kingdom



Profile-Cov
Ethiopia, Netherlands,
United Kingdom



COVADIS
Belgium, Burkina Faso, The
Gambia, Netherlands,
United Kingdom



ASCENT
Burkina Faso, France,
Guinea, Netherlands, South
Africa, Switzerland



ImmunoCoV
Kenya, Netherlands, Sweden



CAB
South Africa, Sweden,
Uganda, United Kingdom



RE-BCG-CoV-19
Netherlands, South Africa,
Spain, Sweden



BCG-COVID-RCT
Cape Verde, Denmark,
Guinea-Bissau,
Mozambique, Portugal



ANTICOV
DR Congo, Kenya, Spain,
Switzerland, United Kingdom



TraCE
Netherlands, South
Africa, United Kingdom



Intervention

- Drugs
- Diagnostics
- Vaccines

Other

- Product-focused implementation research

Disease

- HIV and HIV-associated infections
- Tuberculosis
- COVID-19
- Lower respiratory tract infections

Surveillance and response strategies (1)

Epidemic preparedness, Community engagement

- Countries, particularly in Africa, need to improve health infrastructure, human resources and medical technology using local resources to enable the continent respond adequately to public health emergencies.
- Improving health sector human resource capacity at the primary healthcare level such as community health workers has particularly proven to be an effective approach to early containment of global pandemics and must be prioritised as Africa's trump-card in pandemics response

[SAGE Open Med.](#) 2021; 9: 2050312121994360.

PMCID: PMC7887690

Published online 2021 Feb 11. doi: [10.1177/2050312121994360](https://doi.org/10.1177/2050312121994360)

PMID: [33633859](https://pubmed.ncbi.nlm.nih.gov/33633859/)

Urban health nexus with coronavirus disease 2019 (COVID-19) preparedness and response in Africa: Rapid scoping review of the early evidence

[Robert Kaba Alhassan](#),¹ [Jerry John Nutor](#),² [Aaron Asibi Abuosi](#),³ [Agani Afaya](#),⁴ [Solomon Salia Mohammed](#),⁴ [Maxwel Ayindenaba Dalaba](#),¹ [Mustapha Immurana](#),¹ [Alfred Kwesi Manyeh](#),¹ [Desmond Klu](#),¹ [Matilda Aberese-Ako](#),¹ [Phidelia Theresa Doegah](#),¹ [Evelyn Acquah](#),¹ [Edward Nketiah-Amponsah](#),⁵ [John Tampouri](#),⁶ [Samuel Kaba Akoriyea](#),⁷ [Paul Amuna](#),⁸ [Evelyn Kokor Ansah](#),¹ [Margaret Gyapong](#),¹ [Seth Owusu-Agyei](#),¹ and [John Owusu Gyapong](#)¹

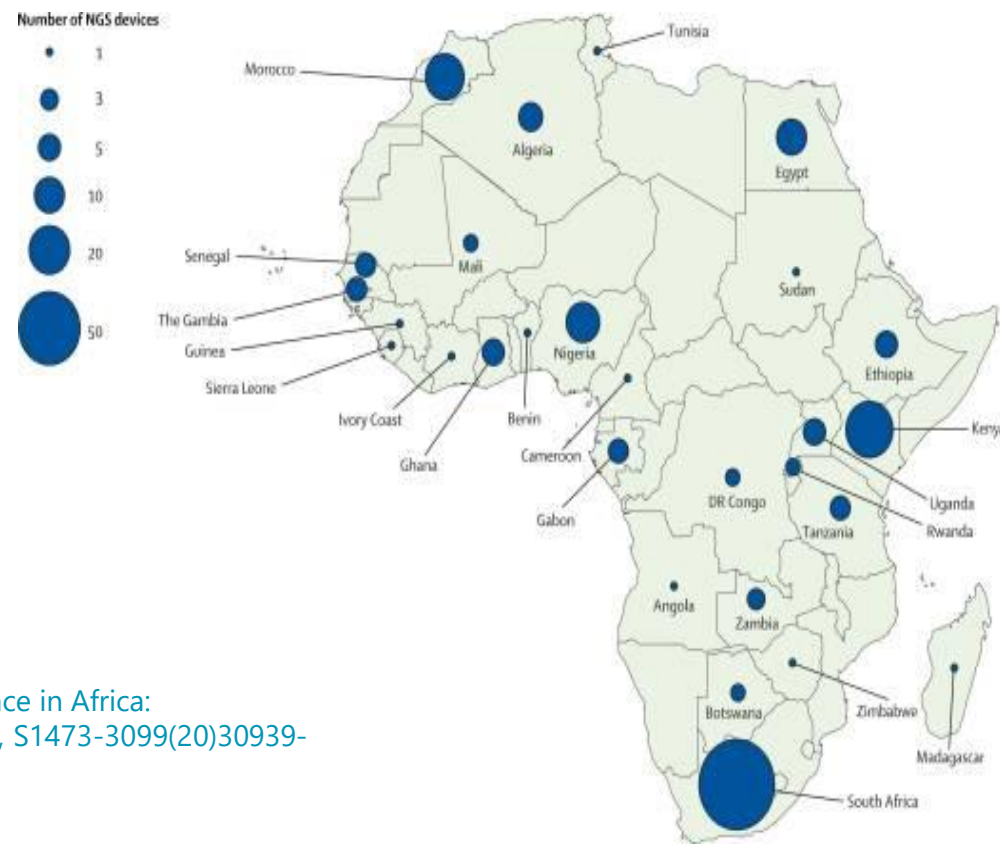
Surveillance and response strategies (2)

Landscape assessment of sequencing capacity within Africa

- The use of genomics to support the response to COVID-19 in Africa is currently low
- Mobilisation of resources to support the epidemic response, incl. digital and genomic strategies
- Recognising the potential of genomic technology and computational power; pioneering novel approaches to advance public health surveillance systems

Tessema, Sofonias K et al. "Accelerating genomics-based surveillance for COVID-19 response in Africa." *The Lancet. Microbe* vol. 1,6 (2020): e227-e228. doi:10.1016/S2666-5247(20)30117-8

- Capacity is sparse and concentrated in a few countries
- Up to 71% of next-generation sequencers are concentrated in five countries: South Africa (n=79; 38%), Kenya (n=28; 14%), Nigeria (n=13; 6%), Morocco (n=18; 9%), and Egypt (n=10; 5%).
- 70% is found outside of national public health institutes



Inzaule, Seth C et al. "Genomic-informed pathogen surveillance in Africa: opportunities and challenges." *The Lancet. Infectious diseases*, S1473-3099(20)30939-7. 12 Feb. 2021, doi:10.1016/S1473-3099(20)30939-7

Focus on key populations

Feedback from discussions with EDCTP-funded researchers

- Risk, transmission and immunity in **pregnant women and infants**.
 - Inclusion of pregnant women in ongoing and planned clinical studies
 - Pregnant women and infants in planned safety studies that will accompany vaccines roll-out programs.
 - Address lack of vaccines safety data in pregnant women may affect vaccines acceptance.
- New vulnerable populations due to **stigma**
 - The impact of mistrust and stigma on research response activities, keeping key populations away from studies
- **Re-defining the concept of key populations** in the context of COVID-19
 - Patients with non-communicable conditions (e.g. obesity)
 - Front-line workers, depends on socio-economic context (e.g. police agents, banking sector in countries with limited digital banking)

COVID-19 & other major infectious diseases in sub-Saharan Africa (1)

Feedback from discussions with EDCTP-funded researchers

- Disruption in health services delivery
 - Increased focus on COVID-19
 - Decrease in care for patients with TB, malaria, HIV and NIDs.
 - COVID-19 cases overburdening health systems
 - Pandemic response measures limiting usual programmatic activities.
- Increased mortality driven by
 - Interruption of ART for HIV patients,
 - Late diagnosis and treatment of new TB cases and
 - Curtailment of mosquito net distribution for malaria.
- Risk for severe COVID-19
 - TB and HIV patients are at an increased risk of severe COVID-19
- To address major disruption of services
 - The need to increase local production for reagents and other products required prevention, diagnosis and treatment of major infectious diseases.
 - Encourage and support research on repurposing of drugs,
 - Collaboration across existing disease programs
- To manage the risk for severe COVID-19 due to other conditions
 - COVID-19 studies should integrate screening for other diseases.

COVID-19 & other major infectious diseases in sub-Saharan Africa(2)

DRC Case: COVID-19, Ebola, Measles

- Focus COVID-19 and Ebola virus disease,
- In the same period, 369 520 measles cases with 6779 deaths
- Suboptimal vaccination efforts due to disruptions of immunisation campaigns
- Potential threats of resurgence of other vaccine-preventable infectious diseases.

Jean B Nachega, Placide Mbala-Kingebeni, John Otshudiema, Alimuddin Zumla, Jean-Jacques Muyembe Tam-Fum, The colliding epidemics of COVID-19, Ebola, and measles in the Democratic Republic of the Congo, *The Lancet Global Health*, Volume 8, Issue 8, 2020, Pages e991-e992, ISSN 2214-109X, [https://doi.org/10.1016/S2214-109X\(20\)30281-3](https://doi.org/10.1016/S2214-109X(20)30281-3), <https://www.sciencedirect.com/science/article/pii/S2214109X20302813>

- Lessons Learned from the Ebola Virus Disease Outbreak in DRC
 - Capacity and experience used to respond to COVID-19
- Mobula, L. M., Samaha, H., Yao, M., Gueye, A. S., Diallo, B., Umutoni, C., Anoko, J., Lokonga, J., Minikulu, L., Mossoko, M., Bruni, E., Carter, S., Jombart, T., Fall, I. S., & Ahuka-Mundeke, S. (2020). Recommendations for the COVID-19 Response at the National Level Based on Lessons Learned from the Ebola Virus Disease Outbreak in the Democratic Republic of the Congo, *The American Journal of Tropical Medicine and Hygiene*, 103(1), 12-17. Retrieved Mar 29, 2021, from <https://www.ajtmh.org/view/journals/tpmd/103/1/article-p12.xml>

New emerging questions and knowledge gaps specific to sub-Saharan Africa (1)

Feedback from discussions with EDCTP-funded researchers

- Asymptomatic cases
 - What is the prevalence of asymptomatic cases?
 - What is the biology behind the observed non-progression to symptoms?
- Data accuracy
 - Uncertainty about levels of infections or deaths in rural versus. urban areas, and/
 - Difference between African Countries and the rest of the world
- Vaccines data
 - Currently developed vaccines are (will be) approved based on data collected mainly outside Africa.
 - Urgent need to collect and analyse post safety and efficacy/effectiveness data in African populations.

New emerging questions and knowledge gaps specific to sub-Saharan Africa (2)

The Economy Factor

- Most fall into the category of LMICs with challenges of poor infrastructure, shortage of health workforce, diverse religious beliefs, and random distribution of population densities, combined with ongoing conflicts and displacements of people.
- Need to balance the investments made towards different measures addressing the pandemic (incl. cost for vaccines purchase and distribution) and costs directed towards other areas/diseases.



[Am J Trop Med Hyg.](#) 2021 Mar; 104(3): 794–796.

PMCID: [PMC7941795](#)

Published online 2021 Jan 7. doi: [10.4269/ajtmh.20-1506](https://doi.org/10.4269/ajtmh.20-1506)

PMID: [33427194](#)

Who Will Pay for the COVID-19 Vaccines for Africa?

[Don Eliseo Lucero-Prisno, III](#),¹ [Isaac Olushola Ogunkola](#),^{2,*} [Uchenna Frank Imo](#),² and [Yusuff Adebayo Adebisi](#)³

Collaboration with major initiatives

GloPID-R

- EDCTP – Observer member as of Sept 2020

WHO R&D Blueprint Global Coordination Mechanism

WHO Global Malaria Programme

- Workstreams addressing the double challenge of malaria & COVID-19

WHO-AFRO Expert Committee

COVID-19 Clinical Research Coalition - <https://covid19crc.org/>

- ANTI-COV consortium

Reconciliation of Cohort data in Infectious Diseases - <https://recodid.eu/>

- COVID-19 Data Portal

Africa CDC

- Consortium for COVID-19 Vaccine Trials (CONCVACT)

The CONCVACT's objective is to provide support for, and link, both clinical trial sites and vaccine developers

Support for clinical trial sites



Access to **global vaccine developers** with ambition to run vaccine clinical trials in Africa



Technical expertise to support the preparedness and execution of clinical trials from **global and local experts**



Capacity building for clinical trial sites –incl. seed funding for trials, lab capacity, GCP training, donor relationship building and technical support



Clinical trial sites will have political support of the African Union heads of state and ministers of health to ensure a **fast-tracked process of decision-making**

The **CONCVACT** will link high-potential clinical trial sites with vaccine developers

Support for vaccine developers



A list of **pre-vetted clinical trial sites** will be provided to developers



Initial **seed funding** for clinical trials will be provided to sites who are planning to partner with developers to ensure trials begin without delay



Developers will have the **political support of the African Union heads of state** and ministers of health for trials run using the CONCVACT network



The CONCVACT will work with regulatory agency and pan-African regulatory harmonisation initiatives to ensure a **fast-tracked process of decision-making and eventual market authorisation**

African Vaccine Regulatory Forum



WORLD HEALTH ORGANIZATION REGIONAL OFFICE FOR AFRICA SUPPORTS THE COVID-19 RESPONSE

- Contribution to COVID-19 R&D through:
 - AVAREF virtual forums for engagement of product developers, scientists, and key research centres in Africa
 - Capacity building of members through weekly updates on regulatory status of products developed for COVID-19; attracts 140 participants
 - Provides scientific advice to COVID-19 sponsors and product development partnerships
 - Provides expedited joint/assisted reviews of Clinical Trials for products against COVID-19
 - Provides common tools and guidelines to facilitate harmonized Call to Action.



EDCTP interactive portfolio: case studies

2014-2020



- Visual stories of EDCTP-supported grants
- Interactive elements (e.g. infographics, videos)
- Share publications through different channels (e.g. social media)
- Data updated on a 6-month basis
- Profiles of countries involved in EDCTP

EDCTP2's portfolio

- Collaborative clinical trials and clinical studies
- Clinical research capacity
- Fellowship programme

EDCTP2 portfolio:

- Collaborative clinical trials and clinical studies
- Clinical research capacity
- COVID-19 collaborative clinical research
- Fellowship programme

Collaborative clinical studies and clinical trials

- HIV & HIV-associated infections
- Tuberculosis
- Malaria
- Neglected infectious diseases
- Emerging diseases
- COVID-19
- Diarrhoeal diseases and lower respiratory tract infections

Thank you!

For more information: www.edctp.org