



POST-TRIAL ACCESS DURING THE COVID-19 PANDEMIC:

A KENYA CASE STUDY

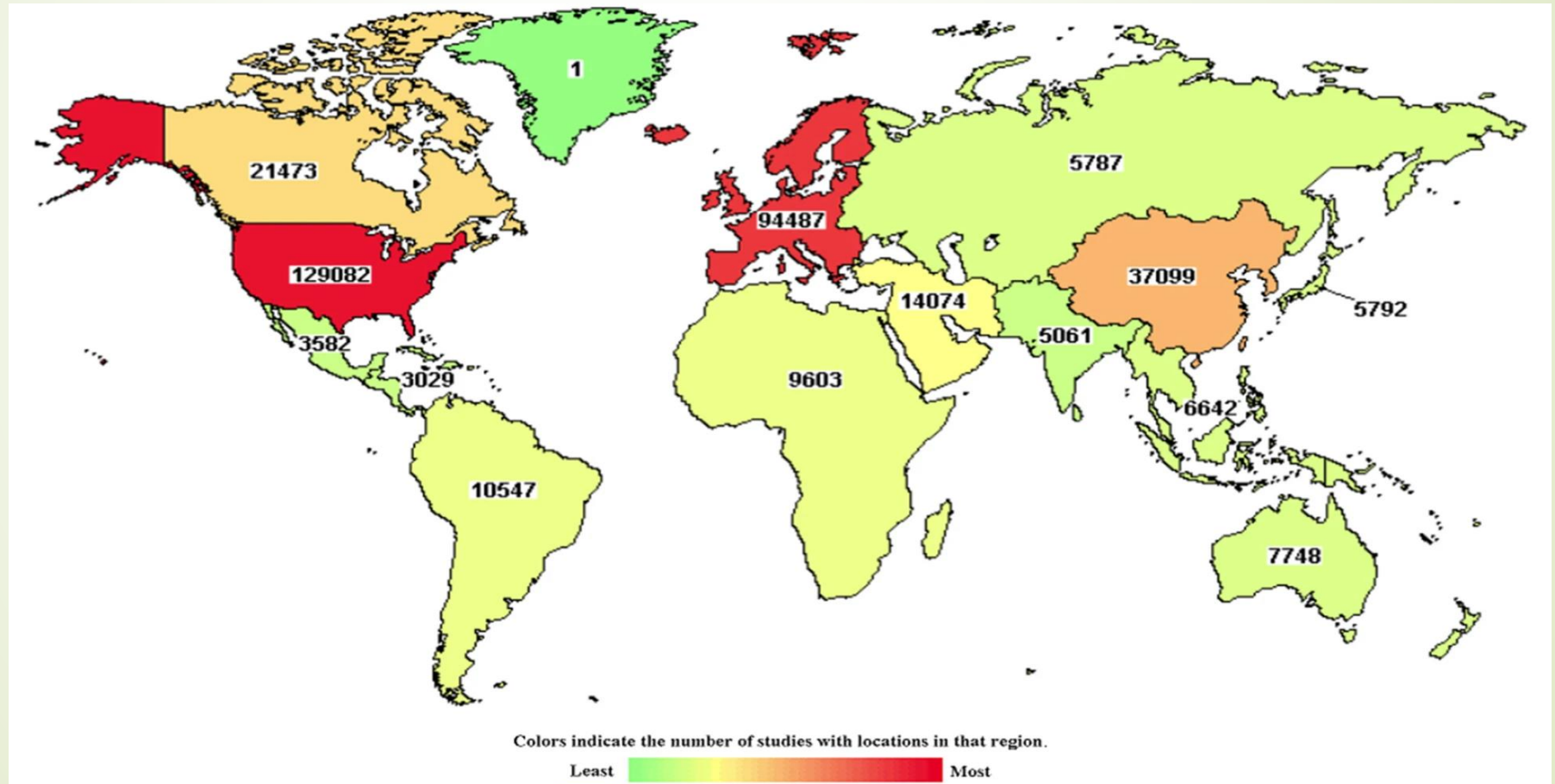
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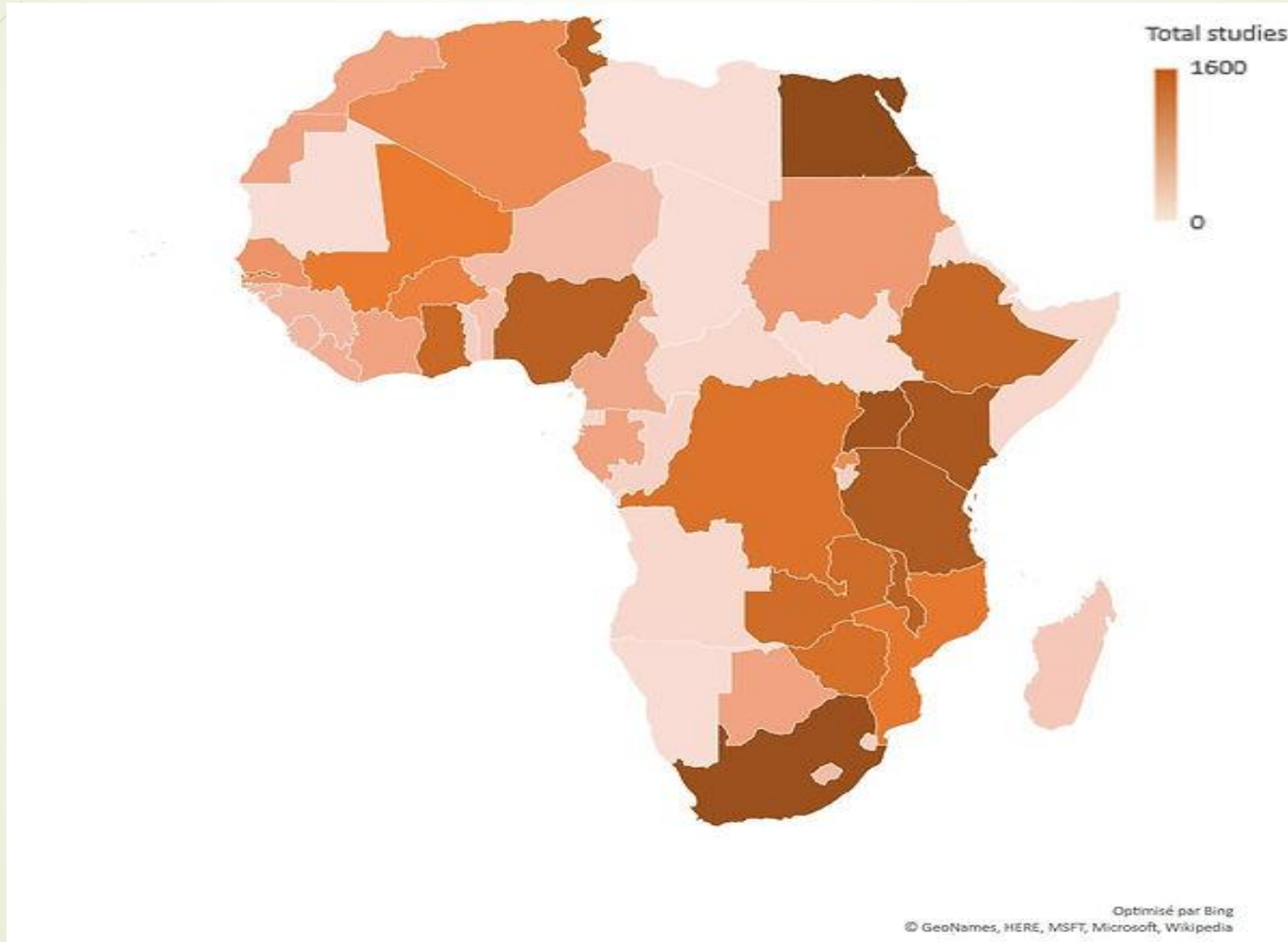
KENYA



Distribution of clinical studies registered on ClinicalTrials.gov on April 2019



Clinical trials distribution in Africa



Necessity of clinical trials in Africa

- ▶ The testing of COVID-19 vaccines in Africa **was part of global efforts** to ensure their **efficacy and safety for diverse populations**.
- ▶ To address health equity, as vaccines can sometimes interact differently depending on genetic, environmental, and other population-specific factors.
 - ▶ *“We may have different strains; we have other disease profiles as well. For instance, we have a big population of people with HIV.” [African Researcher]*
- ▶ The topic of **post-trial access (PTA)** in the context of **COVID-19 vaccine trials in Africa** raises important ethical, logistical, and health equity considerations

COVID 19 Vaccine Trials- EXPERIENCES IN KENYA

- **Recruitment of participants** - In early stages of COVID- 19 pandemic, many Kenyans were willing to participate [**ALTRUISM**]

'Even if it doesn't help us as individuals, it will help the doctors learn something that may help others' (media reports)

- Later, **Uproar** over Covid -19 trials in Kenya-

- Two French doctors discussing during a TV debate possibility of a trial in Europe and Australia, both agreed the trial should be tested in Africa too, one saying:

"If I can be provocative, shouldn't we be doing this study in Africa, where there are no masks, no treatments, no resuscitation? (BBC).

- Allegations of "testing on Africans first"
- 'Kenya being used for clinical trials even when Kenya was not an epicenter of the pandemic'
[media reports]

CONCERN: Exploitation and historical unethical medical practices in the Global South.

Resistance and misinformation around first Covid-19 vaccine trials.. Protests
Johannesburg July 01, 2021



PTA Regulatory landscape initiatives

Before

- The Sponsor shall put in place measures to ensure that the study participants have access to successful investigational products for their disease condition before the products have received a marketing authorization in Kenya, especially so for the Phase III clinical trials.
- Any effective interventions developed or knowledge generated are made available to the affected communities.

In response to pandemic

- Legal Framework change (Page vii, under Section 3 of the Health Laws (Amendment)
 - The drug regulator mandated to Approve the use of any unregistered medicinal substance for purposes of clinical trials and **compassionate use-**
- For studies that need to be closed , withdraw participants or temporary halts and involve provision of treatment to participants, careful consideration should be given to **post-study care.**
- Researchers have the ethical obligation to ensure benefit from and **access** to a new vaccine, medicine or technology for all **during and in a post-pandemic/emergency/disaster situation.** [BENEFICENCE]
- **Drugs and vaccines found to be effective from conducted research shall be made available to the country** at affordable costs. [JUSTICE]

Nonetheless....

- Several COVID-19 vaccine developers, including **AstraZeneca**, **Pfizer**, and **Johnson & Johnson**, conducted trials in African countries like South Africa, **Kenya**, and Egypt.
- The Oxford ChAdOx1-S vaccine was the first to be tested in Kenya amongst health care workers. Other types followed thereafter.
- After the initial clinical trials, with proof of appreciable efficacy and safety the vaccine was out for use but the rich countries bought all of it and there was none left for the Africans,”
 - *In mid July 2020, More than 5.7 billion COVID-19 vaccine doses had been administered globally, but only 2% in Africa, [World Health Organization (WHO)]*
- In Kenya, Owing to vaccine shortage, government aimed to vaccinate only those over 50 years of age, health care workers and those in the hospitality sector - deemed to be at high risk of infection.
 - No plan for vaccine coverage for the rest of the population was in place.

KEY ETHICAL CONCERNS

• Discrimination-

- Hoarding(pre-purchasing doses up to 6 times their population) of the vaccines by HICs, Having national agreements with pharma, buying vaccines at preferential prices, left the developing world, Kenya included to pay more for rich countries leftovers

➤ Hesitancy -

- Initially stemmed from mistrust due to colonial legacies and misinformation.
- Due to Inadequate citizen education, over 52% of youth were hesitant to get the vaccine until they see the effects in the vaccinated. Social media identified as main source of information -**infodemic**".

Lessons learnt

- The Importance of addressing **Trust and Awareness** through community engagement.
- Encouraging **culturally sensitive Informed Consent** for local Participants
- *Capacity building initiatives to **empower local researchers** to increasing Africa's representation in clinical trials.*
- Optimise **collaboration** between vaccine manufacturers and trial sponsors and local governments to ensure that **PTA commitments are honoured**.
- Providing post-trial benefits, **builds trust in clinical research**, which is crucial for encouraging participation in future trials.
- Participate in **global mechanisms** like COVAX Facility to address global vaccine inequity through pooling of procurement and equitable distribution of eventual interventions in a pandemic situation to ensure PTA for participants in Africa.

Way Forward- to improve PTA in Africa

- Global & Regional Organizations, such as the WHO & African Union, initiatives should **monitor and enforce PTA commitments**
- Through **policy advocacy**, strengthen legal and regulatory frameworks to ensure PTA is non-negotiable in trial agreements.
- Governments should **strengthen Health systems** essential for equitable vaccine access beyond trial participation.
- Establish **Local Production of medicines & vaccines** to reduce dependency on external suppliers during pandemics.
- African Countries should embark on **clinical trial readiness**- For example; improve on WHO global benchmarking maturity levels.
 - signifies established robust and integrated regulatory systems capable of overseeing and ensuring quality for either vaccines or medicines. Kenya working towards ML 3