African PPR deep-dive

THE 100 DAYS MISSION SCORECARD GIVES A GLOBAL VIEW of how prepared the R&D ecosystem is to respond quickly to a pandemic. Since its inception, there have been calls for more Low- and Middle-Income Countries (LMIC)-focused indicators – especially around pandemic preparedness and response (PPR) capacity. In response, this year we have created an African capacity deep-dive to accompany the third Scorecard. This spotlight visually illustrates African laboratory, clinical trial, regulatory and manufacturing capacity to track regional skills needed to support the 100 Days Mission.

LABORATORY CAPACITY

In the event of an outbreak, high containment laboratory capacity is critical for pandemic response. Biosafety Level 4 (BSL-4) laboratory capacity – the highest level of biocontainment – is essential for studying the most dangerous pathogens such as filoviruses. For this pilot review of African capacity, publicly available data from Global Biolabs was used to identify countries with laboratories operating at BSL 4 containment level[17]. This targeted scope provides an initial benchmark for understanding where the most secure laboratories are located in Africa and to highlight gaps.

Currently, Africa has only two BSL-4 laboratories: the Emerging Viral Diseases Unit (UMVE) in Gabon and the Special Viral Pathogens Laboratory (SVPL) in South Africa. A third laboratory is under construction at the Institut Pasteur de Côte d'Ivoire's BSL-4 within the Center for High-Risk Infectious Pathogens (CEPRIS).

While BSL-4 labs are critical for handling the most lethal pathogens, many pathogens with pandemic risk could be managed in BSL-3 facilities, which play a role in supporting diagnosis, sequencing and product development. Therefore, we recognise that a coordinated network of BSL-3 and BSL-4 facilities, supported by robust biosafety and biosecurity practices, is needed for preparedness and R&D. However, this pilot highlighted the challenges of mapping BSL-4 capacity; there is no global mechanism tracking BSL-4 laboratories, there are no universal standards governing these labs and there is a dearth of centralised publicly available information. The data available from the Global Biolabs database dates from 2023, which represents an important time lag and further supports the need for a coordinated mechanism to collate this information on a regular basis. Regional initiatives like the African Society for Laboratory Medicine's (ASLM) LabMap, in partnership with the Africa Centres for Disease Control and Prevention (Africa CDC), aims to map continental laboratory capacity and will serve as a vital future resource.

CLINICAL TRIAL CAPACITY

Robust clinical trial capacity is a cornerstone of global health security and product development for diseases with pandemic or epidemic potential. Africa's unique epidemiological profile – marked by high pathogen diversity, frequent outbreaks, and a large, genetically diverse population – makes it critical that vaccines, therapeutics, and diagnostics are tested in the populations where they will ultimately be deployed. Without adequate trial infrastructure and leadership on the continent, products may lack locally relevant safety and efficacy data, hinder regulatory approval and delay the deployment of interventions during health emergencies putting everyone at higher risk. Since the COVID-19 pandemic, there have been a number of calls to strengthen and expand African clinical trial capacities. This pilot sought to capture the current African clinical trials capacity to support pandemic R&D.

Defining clinical trial capacity is complex and multifaceted encompassing physical infrastructure (sites, labs, storage, data systems), skilled personnel (principal investigators and research staff), organisational sponsorship, regulatory and ethics oversight, operational readiness for interventional trials, sustainable funding and partnerships, and transparent data management. For this pilot review, due to limitations of publicly available data, clinical trials capacity was defined as capacity to conduct interventional trials for 100DM Scorecard pathogens across DTVs from 2020-2025. A combination of data sources were used. Our primary source was the Clinical Trials Community Africa Network (CTCAN) platform – supported by the Science for Africa Foundation and NuvoteQ – which curates clinical trial information from the continent. This was supplemented by additional data extracted from the Pan African Clinical Trials Registry (PACTR) and ClinicalTrials.gov.

The data revealed clusters of clinical trial capacity in regions; Southern Africa makes up the largest portion, with 429 trials (42%), this is almost entirely concentrated in South Africa (407). While North Africa has almost no

clinical trials with the exception of Egypt and Tunisia, while East Africa accounts for 323 trials, (31%). There are also some hotspots where a number of trials are occurring within certain countries, but these are largely linked to single institutions with trial sponsorship often sitting with high income country organisations showing the need for improved African ownership of clinical trial leadership. For example, among the trials included in this analysis, only 5 of 107 in Kenya was led by a Kenyan institute while 14 trials were led by the University of Oxford. This can be linked back to institutional connections at the KEMRI- Wellcome Trust Research Programme and the University of Oxford– while clinical trial capacity is being developed in-country by these programmes, the organisational oversight is still removed. The picture was only slightly better in the case of Mali and Uganda, where 4 out of the 30 and 8 out of 88, respectively, were led by local institutes. There are pros and cons to having this type of trial capacity. There is benefit in having capacity routinely used for other disease areas to ensure sites are maintained and ready to be activated in the event of a pandemic. On the downside, a number of these institutions have high-income country or colonial ties, action is needed to support the transition away from this model.

Assessing clinical trial capacity is complex and available data is limited. Better information is needed to inform decision-making, but what current evidence does show is that capacity is concentrated within countries within each region and at specific institutions within countries. Further investment is needed to develop physical infrastructure, transfer knowledge and change funding mechanisms to empower African ownership and elevate African principal investigators. The European and Developing Countries Clinical Trials Partnership (EDCTP) has been pivotal in building African clinical trials capacity and the recent Memorandum of Understanding between Global Health EDCTP 3, and CEPI will focus on building capacity epidemic preparedness[18]. More broadly, the African Clinical Research Network (ACRN) is building an African-led, globally connected network of high-quality trial sites, laboratories, and trained personnel to strengthen clinical research capacity across the continent[19].

MANUFACTURING CAPACITY

The need for local manufacturing capacity in Africa – highlighted during COVID-19 and reaffirmed by mpox – remains critical. Diversified and harmonised regional DTV manufacturing capacity in Africa would strengthen preparedness, enable equitable access and create a more resilient supply chain, paving the way for faster progress towards the 100 Days Mission.

Similar to clinical trial capacity, defining manufacturing capacity is multifaceted and includes physical sites, line and dose capacity, drug substance vs drug product capacity, capacity to produce products utilising different platform technologies, technology transfers and more. However, comprehensive data on all these aspects is not publicly available limiting the ability to measure capacity holistically. For this analysis, we used the best publicly available data, collected by Africa CDC, PATH and CHAI for vaccines and IAVI for mAbs, aligning with their respective methodologies. Vaccine manufacturing capacity is captured in two ways; first, by identifying manufactures with sites that are either currently producing vaccines or have the potential to do so; and second, by assessing which sites have initiated or signed technology transfer agreements (TT's) and which are still awaiting TT's. For mAbs, capacity is based on information reported by sites themselves.

Ten manufacturers spread across six countries were identified as having vaccine manufacturing capacity. Five of these manufacturers have signed, or started, technology transfers to support production, including: Marbio (Morocco), Vacsera (Egypt), Institut Pasteur de Dakar (Senegal), Aspen Pharmacare (South Africa) and Biovac (Egypt). Five more vaccine manufacturers have the facilities and capacities to produce vaccines but are awaiting technology transfers: Eva Pharma (Egypt), Minapharm (Egypt), Biogeneric (Egypt), Saidal (Algeria) and Atlantic Biotech (Ghana).

For monoclonal antibodies (mAbs), 19 manufacturers were identified across Algeria, Egypt, Morocco, Tunisia, Ethiopia, Kenya, Rwanda, Uganda, Ghana, Nigeria and South Africa. This is higher than that of vaccines but reflects methodological differences in how mAbs data was captured. For mAbs, manufacturing information was captured through stakeholder consultations, landscape assessments, and digital mapping rather than detailed per-site capacity and technology transfer tracking used for vaccines.

Important data limitations: There is no globally accepted standard for capturing manufacturing capacity. Measuring it remains a complex task, constrained by the limited availability of public data. The data presented here represents the best publicly available information. Data gaps must be addressed to better understand the true and potential manufacturing capacity in Africa. In this review, diagnostics were excluded due to the lack of publicly available data, however this presents a future opportunity for tracking. There are several ongoing initiatives which will further delineate the landscape and provide better data, including from Regionalized Vaccine Manufacturing Collaborative (RVMC) who are developing a dashboard on regional vaccine manufacturing capacity.

REGULATORY CAPACITY

Mapping regulatory capacity is essential to evaluate Africa's ability to rapidly approve, monitor, and deploy vaccines, therapeutics, and diagnostics during outbreaks- critical for achieving the 100 Days Mission. In this pilot, regulatory capacity was defined as the presence of national regulatory authorities (NRAs) that have reached WHO-recognised maturity level 3 (ML3) indicating capability to approve medical products. Data was sourced directly from WHO's List of National Regulatory Authorities (NRAs) operating at ML3 and maturity level 4 (ML4). This analysis focused on capacity for vaccine and therapeutic approvals, as publicly available data on diagnostic approvals was not available.

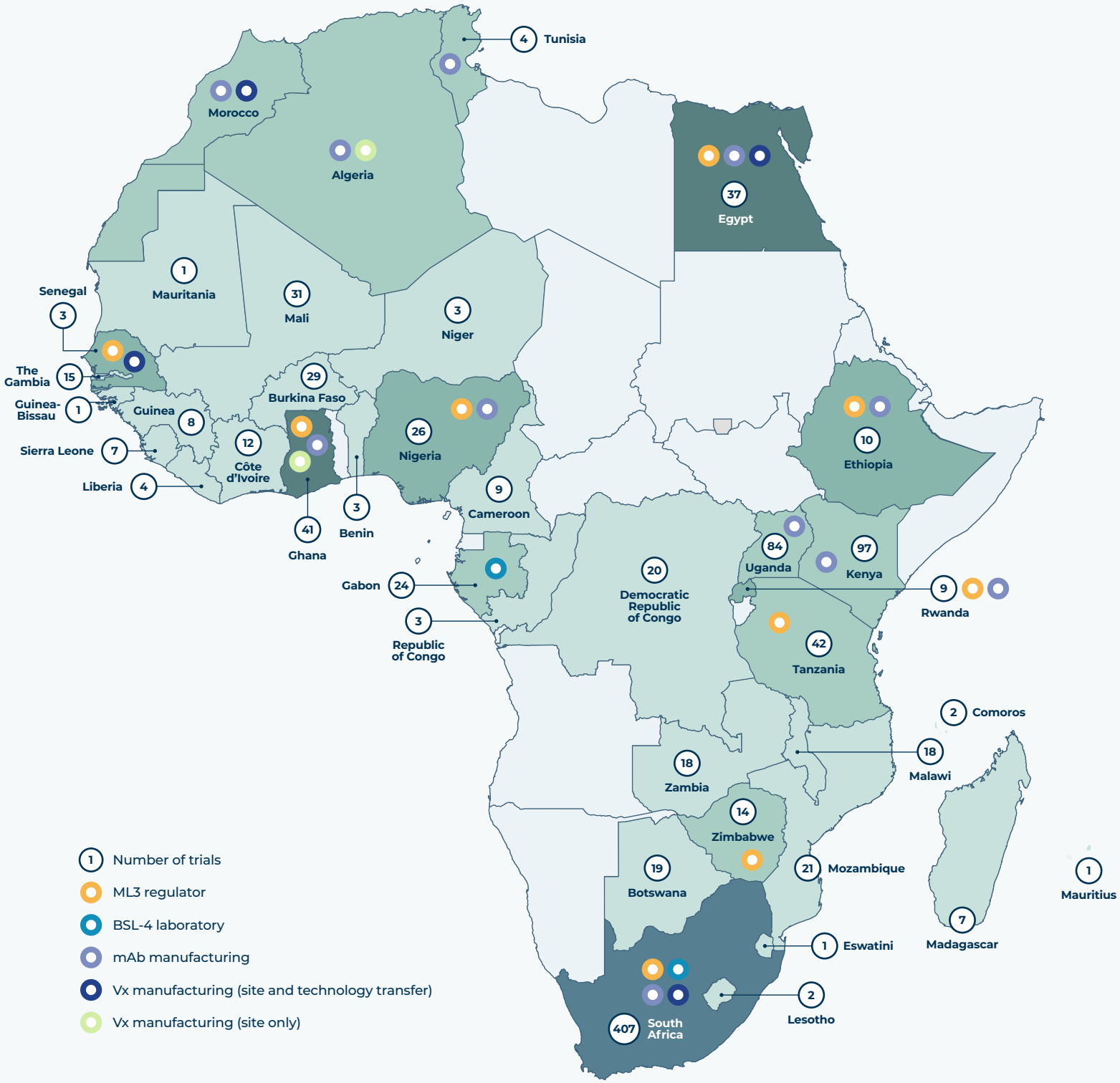
Regulatory capacity across Africa has grown since the COVID-19 pandemic, with several regulators achieving WHO ML3 status, including Ethiopia (Sept 2025), Senegal and Rwanda (Dec 2024), and Zimbabwe (June 2024). Notably, the Botswana Medicines Regulatory Authority (BoMRA) completed a self-benchmarking exercise with the WHO in August 2025 and is on track formal benchmarking in early 2027.

While these ML3 regulators approve medicines and vaccine, most countries do not have corresponding manufacturing capacity. This includes Ethiopia, Ghana, Senegal, Rwanda, Tanzania, and Zimbabwe. Currently, only two ML3 regulators oversee vaccine production: the Egyptian Drug Authority (EDA) and the South African Health Products Regulatory Authority (SAHPRA). In country vaccine production necessitates that regulators have oversight adding an additional layer of capacity. The lack of local vaccine manufacturing highlights the gap between regulatory maturity and vaccine production readiness which is needed to accelerate timelines under the 100 Days Mission.

The geographic distribution of ML3 regulators is relatively balanced across East, West and South Africa, but North Africa remains underrepresented apart from Egypt. Beyond national progress, the establishment of the African Medicines Agency (AMA) marks a pivotal shift toward regionalised regulation. In February 2025, a landmark Memorandum of Understanding (MoU) was signed by Africa's ML3 regulators under the African Medicines Regulatory Harmonization (AMRH) initiative. Once fully operational, AMA will coordinate joint assessments, enable mutual regulatory reliance, and support continent-wide approval pathways, positioning Africa to move from fragmented national oversight to a harmonised continental model.

Regulatory capacity has significantly improved on the continent in recent years, at both the national and regional level. The developments under AMA highlight how regionalisation of capacities can maximise available resources, streamline processes and avoid unnecessary duplication.

African PPR capacity deep-dive



COMPLEMENT OF CAPACITIES*

*The heat map colouring corresponds to a scale of 0-5 and represents how many capacities a country has: clinical trial capacity, ML3 regulator, Vaccine manufacturing capacity, mAbs manufacturing capacity, BSL-4 capacity

SYNTHESIS: COMPLEMENT OF CAPACITIES

To meet the 100 Days Mission coordination and harmonisation across the PPR ecosystem is needed. Rather than solely focusing on individual indicators, it is essential to consider the overarching complement of capacities at the national, regional and continental level and how these interact.

From both a research and implementation perspective, these capacities are intrinsically interlinked – having one without the other won't enable progress. For example, if a country can study a pathogen in a high-containment lab but lacks clinical trial networks or regulatory pathways, vaccine candidates cannot be tested or approved locally, and without manufacturing capacity, approved products cannot be produced at scale – showing how missing links stall the entire process.

Looking at individual countries, there are clear gaps. South Africa is the only country with all four capacities, followed by Egypt and Ghana with three each. However, the goal is not for every country to develop full end-to-end capabilities, as this would be duplicative and inefficient especially in resource constrained settings. Instead, broader coordination and harmonisation are needed to leverage existing infrastructure, fill strategic gaps and deliver benefit at scale.

Regionally there are significant opportunities to sustain the momentum behind harmonisation initiatives. Africa CDC and AUDA-NEPAD are driving several initiatives to strengthen Africa's health preparedness ecosystem. These include building regional clinical trial networks, upgrading laboratory systems and biosafety standards, harmonising regulatory frameworks through the African Medicines Regulatory Harmonization program, and scaling vaccine and biotherapeutics manufacturing via mechanisms like the African Vaccine Manufacturing Accelerator and Regional Capability Networks. These initiatives are often in partnership – such as those with CEPI, EDCTP and ASLM – showing the need for collaboration to achieve this goal[20,21].

Together, these efforts aim to create an integrated, continent-wide capacity for research, regulation, and production to respond rapidly to future health threats.

SPOTLIGHT

H5N1

BACKGROUND & CURRENT STATE

The influenza A (H5N1) virus has circulated in wild birds and poultry for two decades, crossing repeatedly into mammals and occasionally humans. Worldwide, more than 950 human cases and ~475 deaths have been reported to WHO as of Aug 2025[22]. Between January 1 and August 25, 2025, 27 human infections with H5N1 viruses have been detected globally, of which 23 were identified in 7 countries outside of the United States, including 10 infections that resulted in death[22]. Recent data show that H5N1 is not only affecting birds but dairy cattle herds in the United States[23] – highlighting the significant potential economic consequences for agricultural systems and food supply chains. Traces of H5 (including H5N1) have also been detected in wastewater systems in North America[24].

CONCERNING VIRAL CHARACTERISTICS

- **Historically high CFR in human infections** (WHO reports ~52 % CFR among confirmed cases)[25].
- **Demonstrated ability to cross species barriers:** livestock involvement, wastewater detection[23].
- **Known mutations under surveillance that could enhance human transmissibility or adaptation** – though no clear evidence yet of a transmissible human-adapted variant.

SURVEILLANCE GAPS REVEALED

- The large-scale dairy herd outbreaks in the U.S. indicate **delayed detection and containment.**
- **Under-detection of human cases:** the true number of mild or sub-clinical infections is unknown.
- Wastewater surveillance in several states has detected H5 viral genetic material, **indicating possible broader environmental dissemination.**
- **Limited genomic sequencing and timely sharing to track viral evolution globally** – especially in LMICs and livestock reservoirs[26].

CURRENT STATE OF MEDICAL COUNTERMEASURES (MCMs)

DIAGNOSTICS:

PCR-based assays available in reference laboratories for H5 bird-flu viruses.

- **Gaps:** Limited point-of-care diagnostics in agricultural/ remote settings; delayed milk testing in affected dairy herds; need for rapid syndromic panels that differentiate H5N1 from seasonal influenza or other respiratory infections[27].

THERAPEUTICS:

Neuraminidase inhibitors e.g. oseltamivir and zanamivir and cap-dependent endonuclease inhibitors e.g. baloxavir are in contingency stockpiles.

- **Gaps:** Uncertain effectiveness of these antivirals specifically against current H5N1 clades; no completed human clinical trials of H5-specific therapeutic regimens; limited data on optimal treatment protocols for severe H5N1 illness.

VACCINES:

At least 20 H5 influenza vaccines have been licensed in some jurisdictions as of September 2025[28].

- **Gaps:** Many vaccines are egg-based, thus vulnerable to poultry supply disruption; global stockpiles (under the PIP framework) reserve only ~10% of total global antigen for LMICs; cold chain requirements limit deployment in rural/LMIC settings; limited paediatric safety/ efficacy data[29,30].

KEY TAKE-HOME POINTS FOR THE 100DM

1. **Maintain heightened surveillance** in avian, mammalian (especially livestock) and environmental reservoirs (e.g., wastewater) to detect early signals of adaptation.
2. **Update MCM contingency planning:** review antiviral stockpile effectiveness, accelerate DTV readiness plans for H5N1 and ensure equitable access frameworks for LMICs.
3. **Foster cross-sectoral coordination** (animal health, human health, agriculture, environment) under One-Health approach to manage spill-over risks while strengthening diagnostics deployment.