Access to monoclonal antibodies in Africa: A call to action

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Acronyms

Africa CDC	Africa Centres for Disease Control and Prevention
AIDS	acquired immunodeficiency syndrome
AMA	African Medicines Agency
AMP	antibody-mediated prevention
AMR	antimicrobial resistance
AOCs	antibody oligonucleotide conjugates
BARDA	U.S. Biomedical Advanced Research Development Authority
bNabs	broadly neutralizing antibodies
DOD	U.S. Department of Defense
EC	European Commission
EMA	European Medicines Agency
EUA	emergency use authorization
FDA	Food and Drug Administration
Gates Foundation	Bill & Melinda Gates Foundation
HICs	high-income countries
HIV	human immunodeficiency virus
IDs	infectious diseases
LMICs	low- and middle-income countries
mAbs	monoclonal antibodies
NCDs	non-communicable diseases
NIH	U.S. National Institutes of Health
NSCLC	non-small cell lung cancer
PPCs	Preferred Product Characteristics
R&D	research and development
RSV	respiratory syncytial virus
STIs	sexually transmitted infections
UK MRC	UK Medical Research Council
VILI	ventilator-induced lung injury
WHO EML	World Health Organization Model List of Essential Medicines

Foreword

The transformative potential of monoclonal antibodies (mAbs) in modern medicine is undeniable. These advanced therapeutic agents have revolutionized the treatment of diseases ranging from cancers and autoimmune disorders to, increasingly, infectious diseases. However, this healthcare revolution has largely bypassed Africa, where access to these life-saving therapies remains critically limited. As this report highlights, the global mAb landscape has expanded significantly since 2020, nearly doubling the number of licensed products. Yet, Africa accounts for just 1% of global mAb sales, despite representing 20% of the world's population.

This stark disparity underscores a deeper issue in global health equity. Africa's dependence on external manufacturing and supply chains for essential medicines is both unsustainable and unacceptable. The COVID-19 pandemic exposed the vulnerabilities of this dependency, with African nations relegated to the back of the queue for critical medical countermeasures. This experience, coupled with ongoing challenges in accessing essential medicines, highlights the urgent need for robust pharmaceutical manufacturing capabilities on the continent, particularly for sophisticated biologics like mAbs.

The African Union's call for a New Public Health Order, which emphasizes expanding local manufacturing of vaccines, diagnostics, and therapeutics, offers a critical framework for addressing this gap. However, realizing this vision requires more than political commitment—it demands significant investment in technology transfer, infrastructure, and human capital. Building sustainable mAb manufacturing in Africa necessitates support across the entire value chain, from research and development to commercial production, to ensure an end-to-end approach to mAbs, which represents both a complex market dynamic and intricate Research and Development process.

Investing in African mAb manufacturing is not just about replicating existing therapies; it is also about addressing Africa's unique health challenges. The global mAb R&D pipeline disproportionately targets diseases prevalent in high-income countries, while those affecting African populations often receive insufficient attention. Strengthening local R&D capacity would enable African scientists to prioritize mAbs for diseases of regional importance, such as endemic infectious diseases and cancers with unique genetic profiles in African populations.

Technology transfer is pivotal in this transformation. Establishing mAb manufacturing capabilities requires not only production technologies but also the transfer of knowledge, expertise, and best practices. This includes bolstering regulatory frameworks, quality control systems, and workforce development. Genuine international partnerships—public and private—must embrace technology transfer that fosters independence rather than perpetuating dependency.

The economic rationale for investing in African mAb manufacturing is equally compelling. Beyond improving health outcomes, local production creates high-skilled jobs, stimulates economic growth, and reduces foreign exchange dependency on imported medicines. Regional manufacturing enhances supply chain reliability and can lower costs through shorter distribution networks and alignment with local healthcare needs.

This report provides a comprehensive analysis of the current state of mAb access in Africa and outlines a path forward. The findings serve as both a wake-up call and a roadmap for action. While the disparities in access are stark, the opportunities for transformation are clear. Growth in African clinical trials, local biosimilar development, and regulatory harmonization initiatives provide a strong foundation for progress.

Moving forward, investment must target physical infrastructure, human capital development, and supportive regulatory environments. Only through

such comprehensive efforts can the benefits of mAb therapies reach those who need them, irrespective of geography or economic status.

The journey toward pharmaceutical independence in Africa is challenging but achievable. Successfully establishing mAb manufacturing capabilities would not only enhance access to essential medicines but also serve as a model for achieving pharmaceutical sovereignty in other regions. This report marks a significant step on this journey, offering an evidence base and strategic direction to advance with urgency and purpose.

Sincerely,

Dr. Abebe Genetu Bayih, Acting Head of Manufacturing Division, Africa Centres for Disease Control and Prevention (Africa CDC)

Executive Summary

Monoclonal antibodies (mAbs) have transformed modern medicine [1]. However, their impact is limited as they are not accessible to all. In 2020 IAVI and Wellcome published a joint report "Expanding access to monoclonal antibody — based products: a global call to action" [2] which highlighted the gaps and opportunities to expand access to mAbs in low- and middle-income countries (LMICs). The report revealed that few, if any, mAbs were available in LMICs.

The world has changed dramatically in the last four years, not least because of the COVID-19 pandemic. In this report, we take a deep dive into mAb availability in Africa — the region that had fewest mAbs in 2020 — to explore trends in mAb access and research and development (R&D) for mAbs of regional relevance since the original report was released. Progress in tackling major barriers to mAb access in Africa could serve as a bellwether for progress globally.

To explore this, we reviewed the status of monoclonal R&D and access globally, and in the Africa region in 2024 compared to 2020. In 2020, there were just over 650 mAbs in development for various medical conditions, with 570 in clinical testing, more than 60% of which targeted oncology indications. By 2024, the clinical pipeline had nearly doubled, with over 1,000 innovative candidates, and with cancer mAbs still dominating the landscape.

In Africa, encouragingly, the current landscape of approved mAb-based products has also grown compared to 2020, although access gaps remain relative to the U.S. and Europe. More mAbs are being developed for high-priority African diseases, such as HIV and malaria, but fewer than a quarter of existing mAbs are available in Africa. In all, Africa accounts for only 1% of overall mAbs sales globally, despite accounting for 20% of the global population. Funding for mAbs for endemic infectious diseases (IDs) has increased but still pales in comparison to that for infectious diseases with epidemic potential, such as those for COVID-19 and Ebola. COVID-19 mAb R&D investment in the three-year period from 2020 to 2022 is more than double (US$1,167m) that for HIV and malaria combined since 2007 ($466m). Some clinical trials for monoclonal antibodies are being conducted in Africa, with the majority (77%) taking place in South Africa. However, the overall number of active mAb trials between 2023 and 2024 on the continent remains modest compared to those conducted in high-income countries, despite an overall increase in African clinical trial capacity. Nonetheless, Africa's clinical trial capacity is steadily growing, expanding the potential for more mAb trials in the region.

While progress has been made in the last four years, more is needed to ensure that mAbs are accessible for all and to ensure real world health gains for those most in need.

Methodology

Scope

This report evaluates the current state of R&D and access for monoclonal antibodies and related products (e.g., nanobodies) following the 2020 global call to action issued by IAVI and Wellcome to improve mAbs access in low- and middle-income countries. It examines the global landscape of approved mAbs and biosimilars, with a deep dive into the current situation in Africa. It also provides insights into mAbs in development for diseases that impact Africa significantly, including both non-communicable diseases (NCDs), such as cancer and autoimmune diseases, as well as infectious diseases, such as HIV, malaria, Ebola, respiratory syncytial virus (RSV), and COVID-19. Disease indications, availability, inclusion on Essential Medicines Lists, price, and the funding landscape for mAbs are considered. The report provides an overview of the progress made in advancing R&D and access in Africa since 2020, while highlighting areas requiring critical attention in a renewed call to action.

Data collection and analyses

The pipeline assessment in this report covers both mAbs for infectious diseases and NCDs. We sourced data on the mAbs landscape from publicly available databases including Clinicaltrials.gov, the Pan African Clinical Trials Registry, the Antibody Society, national regulatory agencies and manufacturers' websites (see Appendix). Data searches were conducted in April — May 2023 and March 2024, and cross-referenced with information on mAbs approved or in development for infectious diseases from Impact Global Health's (formerly Policy Cures Research) Infectious Disease (ID) R&D tracker [3], developed as part of the Evidence for Impact project [4]. The tracker's detailed methodology for pipeline curation and the mapping of active clinical pipeline candidates for disease and product areas is outlined on the Impact Global Health website [5].

R&D funding data was obtained via online and offline reporting tools through Impact Global Health's G-FINDER survey [6], which collects disbursement information from public, private, and philanthropic organizations involved in global health R&D. Grants were verified through automated and manual review processes [7]. Grants were categorized into two main groups — basic research and product development — based on definitions from the G-FINDER survey. The search terms "mAb," "monoclonal," "antibod*," and "nanobod*" were used to identify mAb-related products within the G-FINDER data. We excluded grants that focused on polyclonal antibodies or convalescent plasma, as well as any grants that were focused on vaccine or diagnostic development. The analysis included overall funding, year-to-year funding changes, and leading funders and funding sectors for each disease area.

Limitations

The scope of our analysis was limited to presenting data on the global and Africa regional R&D and access landscapes for mAbs, based on a cross-section of countries for which there was data available. While we present data on the current mAbs ecosystem, we do not systematically evaluate the underlying causes of access barriers in this report. For further insights on key drivers of access barriers and novel approaches to enable equitable access to monoclonal antibodies in low- and middle-income countries, see Malhotra, et al (2024) [8, 9].

The monoclonal antibody landscape: Approved products

Global mAbs landscape

The number of globally licensed mAbs almost doubled from 99 in 2019 to 172 in 2024. While oncology mAbs continue to be most prominent, mAbs for other disease indications are expanding **(Figure 2)**. The number of infectious diseases mAbs licensed has more than doubled, increasing from 7 to 18. This includes mAbs for SARS-CoV-2, which received emergency use authorization (EUA) during the pandemic, as well as for Ebola, respiratory syncytial virus (RSV), anthrax, HIV, rabies, and Clostridium difficile.

High-income countries (HICs) continue to comprise the greatest market share for mAbs, with the 80/20 split being roughly maintained from the last report: 77% of mAbs sales occur in the United States (U.S.), Canada and Europe versus 23% in the rest of the world [10].

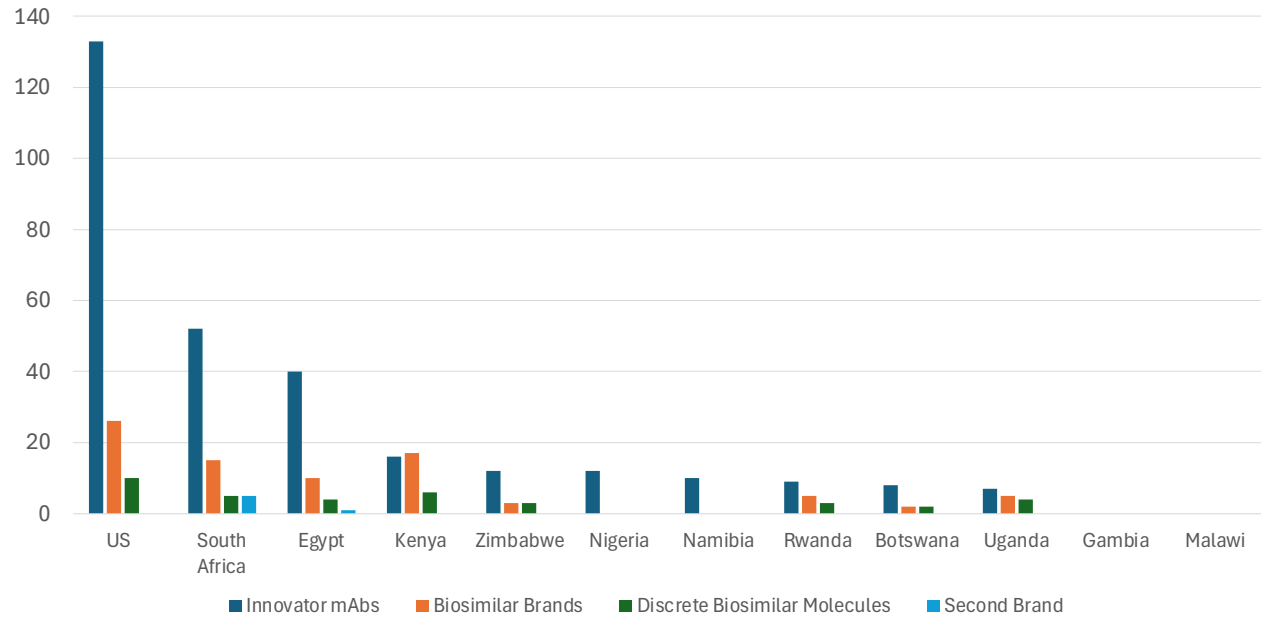
African mAbs landscape

Market share data for Africa is limited, with roughly 1% of sales value estimated to occur in African markets [10]. Although the lower overall sales value is in part related to differential pricing in African settings, the market share discrepancy also relates to gaps in the availability of and broad access to mAbs in Africa [11].

We conducted an analysis of licensed mAbs across eleven countries in Africa reflecting diverse geographies and economic profiles for which public data were available: Botswana, Kenya, South Africa, Egypt, Zimbabwe, Nigeria, Namibia, Rwanda, Uganda, The Gambia, and Malawi. In all, we identified 58 discrete mAbs licensed across these countries. Some countries — including Nigeria, South Africa, and Zimbabwe — have seen increases in the numbers of licensed mAbs since 2019 **(Figures 2 and 3)**. However, other countries in Africa, including The Gambia and Malawi, still have no approved mAbs on the market domestically. While there are over 170 mAbs approved globally for diseases and disorders such as cardiovascular diseases, respiratory diseases, cancers, HIV/AIDS, enteric infections, neglected tropical diseases, and hematological disorders which are among the leading causes of deaths in Africa [11], fewer than a quarter are licensed in Africa.

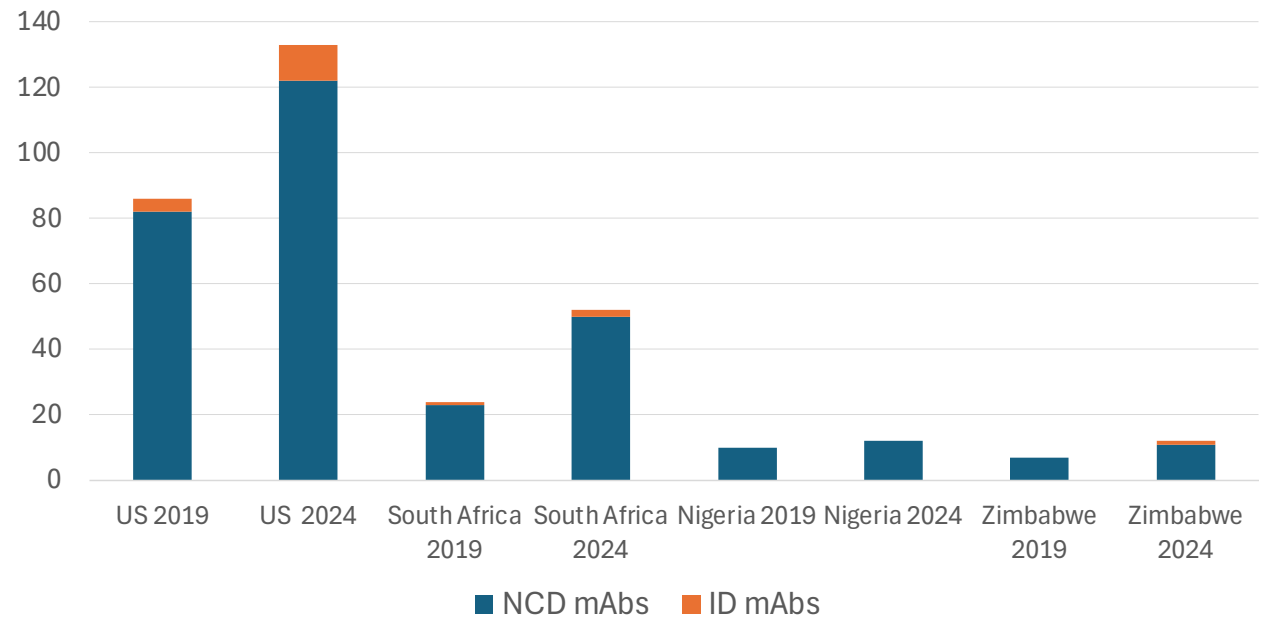
There are significant country-specific differences in the numbers of approved mAbs, including innovator, second brand and biosimilar mAbs, in Africa **(Figure 3)**. South Africa, Egypt, and Kenya are regional leaders in availability of these products **(See Figure 1)**.

Figure 1: Approved mAbs in the U.S. versus Africa, 2024[i]



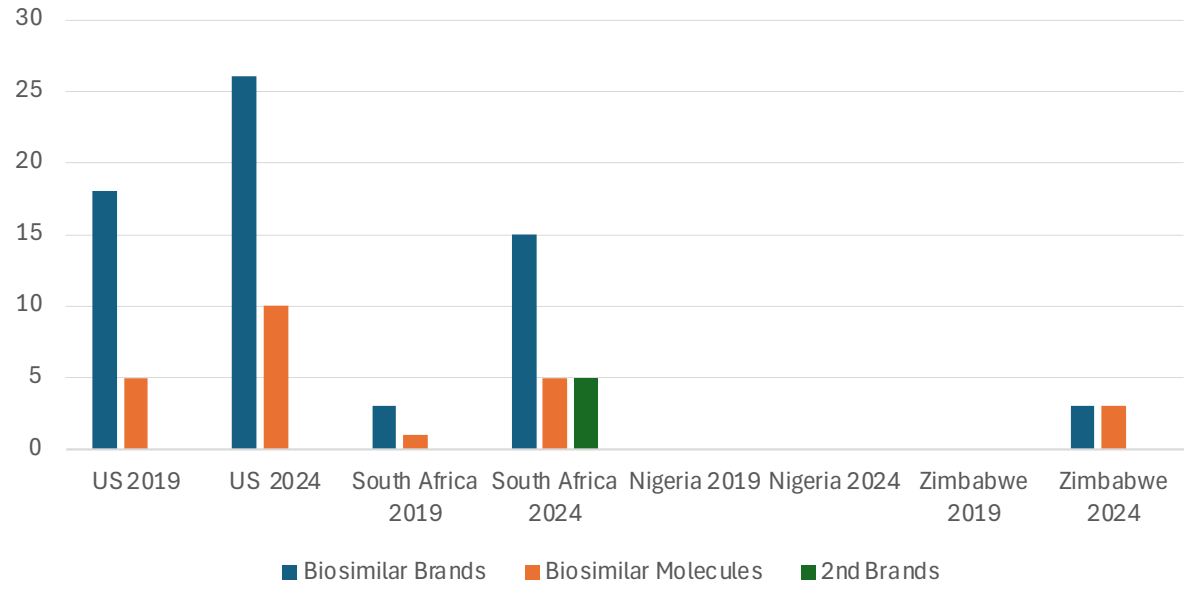
Seven discrete new biosimilars were registered globally since the last report in 2019, none of which are known to be registered in Africa. Promisingly, an Egyptian company, Minapharm, has a biosimilar of adalimumab in Phase 1 clinical development, paving the way for a localized supply solution for that mAb [12].

Figure 2: Approved innovative mAbs by disease category, 2019 versus 2024



[i] Second brand products are lower priced than innovator mAbs marketed specifically in specific LMICs. Biosimilars are versions of innovator licensed mAbs with no clinically meaningful differences compared with the originator product in terms of mechanism of action, safety, purity and potency that are often lower priced. There may be many biosimilar brands for one innovator mAb, the number of unique mAbs are represented by the Discrete Biosimilar Molecule.

Figure 3: Approved biosimilars and second brands by geographical location, 2019 versus 2024 [ii]



Availability of monoclonal antibodies

In addition to product registration, inclusion of mAbs in essential medicines lists can facilitate reimbursement through national health insurance schemes and serve as a critical enabler of access. The World Health Organization Model List of Essential Medicines (WHO EML) plays an important role in the adoption of medicines into national financing and procurement platforms for many nations. Unfortunately, the pace of inclusion of new mAbs in the WHO EML has been slow. Globally, of the 172 mAbs licensed in 2024, only 7 mAbs or mAb combinations appeared on the WHO EML, up from 5 mAbs in 2020 **(Table 1)**. Notable additions to the WHO EML included the first mAbs for infectious diseases — ansuvimab and the combination of atoltivimab, maftivimab, and odesivimab — for the treatment of Ebola virus.

Table 1: mAbs in the WHO Essential Medicines List [13]

mAb	Indication	WHO EML 2019	WHO EML 2023
Adalimumab	Arthritis, Crohn's	√	√
Ansuvimab	Ebola		√
Atoltivimab + maftivimab + odesivimab	Ebola		√
Bevacizumab	Cancer	√	√
Nivolumab	Melanoma	√	√
Rituximab	Multiple sclerosis + lymphomas	√	√
Trastuzumab	Breast cancer	√	√

[ii] Second brand products are lower-priced innovator mAbs marketed specifically in specific LMICs. Biosimilars are versions of innovator licensed mAbs with no clinically meaningful differences compared with the originator product in terms of mechanism of action, safety, purity and potency that are often lower priced.

Table 2: Regulatory status of cancer mAbs

mAb	Indication	First global approval	Year added to WHO EML	WHO Prequalified	*African national regulatory approval
Nivolumab	Melanoma	U.S., 2014	2019	No	Egypt, Kenya
Pembrolizumab	Melanoma	U.S., 2014	2019 (alternate)	No	Botswana, Egypt, Kenya, South Africa
Rituximab	Multiple sclerosis + lymphomas	U.S., 1997	2015	Yes (Originator and 2 biosimilars)	Botswana, Egypt, Kenya, Namibia, Nigeria, South Africa, Uganda, Rwanda, Zimbabwe
Trastuzumab	Breast cancer	U.S., 1998	2015	Yes (Originator and 4 biosimilars)	Botswana, Egypt, Kenya, Namibia, Nigeria, South Africa, Uganda, Rwanda, Zimbabwe

**Analysis covered Botswana, Egypt, Gambia, Kenya, Malawi, Namibia, Nigeria, Rwanda, South Africa, Uganda, and Zimbabwe*

Spotlight: Infectious disease access case study: Ebola mAbs

Past Ebola outbreaks catalyzed investment in the development of more effective medical countermeasures, including the U.S. Food and Drug Administration (FDA)-approved and WHO-recommended monoclonal antibodies Inmazeb and Ebanga for treatment of Zaire ebolavirus [15]. Since 2014, there has been steady growth in Ebola R&D funding, peaking at $208m in 2019. However, funding has since dropped to only $33m in 2022, reflecting both control of major outbreaks and the advancement of products through the pipeline. A large drop in funding in recent years followed the successful registration of two mAbs that were used to stem African outbreaks under expanded-access protocols, Inmazeb and Ebanga. These treatments reduced mortality significantly — from 54% to 6% with Inmazeb and to 11% with Ebanga — and effectively prevented disease in close contacts [16].

However, access to Ebola mAbs remains a major issue in the most highly affected regions. Between 2020 and 2022, only a third of Ebola patients received Inmazeb. The majority of Regeneron's Inmazeb supply was reserved in a stockpile by the U.S. government, and the product was never licensed, prequalified, or made widely available in the highest risk settings [17]. In August 2022, WHO raised concerns about the difficulty of accessing these therapeutics given supply barriers [15].

Ridgeback Biotherapeutics has partnered with Emergent BioSolutions for Ebanga manufacturing, sale and distribution in the U.S. and Canada [18-21]. In the interim, in the event of a major outbreak, there is no defined purchasing or delivery pathway for African governments and emergency responders from groups such as the WHO or the Africa Centres for Disease Control and Prevention (Africa CDC). This highlights the need for robust, sustainable access strategies as opposed to reliance on the benevolence of commercial entities.

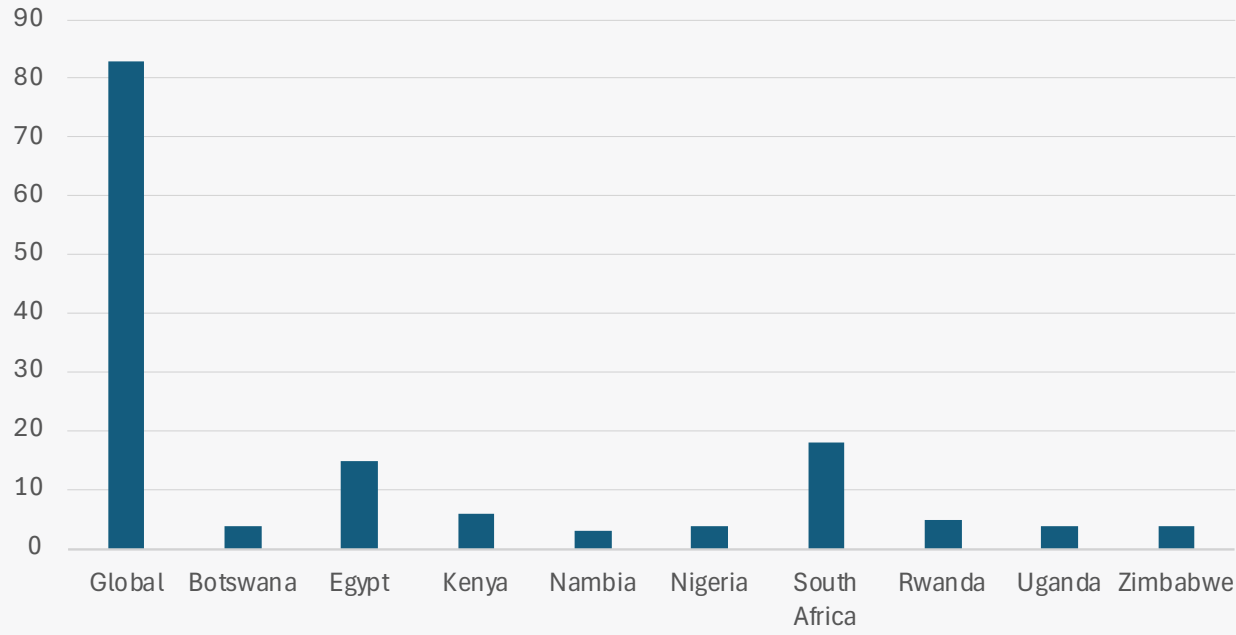
Alongside two licensed mAbs, remaining pipeline candidates are in early development. Priorities for future Ebola mAbs articulated in WHO's roadmap include mAbs that target and neutralize viral glycoproteins and provide post-exposure prophylaxis against multiple filoviruses, ideally through non-invasive methods [22]. Among the seven mAb candidates in development, three have entered Phase 1 trials: GamEmab and Gamezumab for emergency prevention and MBP134, a mAb cocktail for treatment of Sudan ebolavirus. MBP134 AF, a second-generation pan-ebolavirus therapeutic containing two broadly neutralizing antibodies, is undergoing preclinical evaluation for Zaire, Sudan, and Bundibugyo Ebola viruses [23].

Spotlight: Non-communicable disease access case study: Breast cancer mAbs

Cancer is one of the leading causes of death in Africa. From 2008 to 2020 cancer incidence increased by more than 50% and mortality increased by 30% in Africa [24]. Cancer in Africa is often characterized by early onset, aggressive disease, late-stage presentation, and poor survival rates [25].

mAbs have revolutionized cancer therapy, increasing survival rates with fewer side effects than alternatives. However, of 83 innovator mAbs licensed globally for cancer treatment, only 20 discrete antibodies are known to be licensed in Africa **(Figure 4).**

Figure 4: Licensed cancer mAbs in Africa, 2024



With approximately half a million new cases a year, breast cancer is the most frequently diagnosed cancer in Africa, representing 17% of new cancer cases and 11% of cancer deaths in 2023 [25]. First marketed in the U.S. in 1998 by Genentech/Roche under the brand name Herceptin, trastuzumab transformed the treatment of HER-2 positive breast cancer in high income settings, resulting in improved outcomes and survival rates for patients. However, it wasn't until 2012, in the face of imminent biosimilar competition, that Roche launched a second brand for Herceptin in two African countries — Egypt and South Africa. The launch of biosimilar versions of trastuzumab in 2013 helped to significantly expand access, with more than ten biosimilars for trastuzumab licensed globally, many of which were licensed throughout Africa.

Nonetheless, access to and affordability of trastuzumab remain limited in resource-limited settings. It took almost 20 years from the time of initial licensure for trastuzumab to be included on the WHO EML (in 2015) and more than 20 years for the first biosimilars of trastuzumab to be prequalified by WHO. Access to WHO prequalified trastuzumab biosimilars in countries such as Botswana, Kenya, and Egypt has driven down the cost of therapy; however, prices remain prohibitive for many relative to per capita income (**Table 3**).

Table 3: Herceptin/Trastuzumab biosimilar price per vial, USD

	Egypt	Kenya	Nigeria	South Africa	US
Herceptin	310	n/d	259	506	4129
***Herceptin SC**	516	1095	251	540	4932
****Herceptin 2nd brand**	252	n/a	n/a	n/d	n/a
Biosimilar 2nd brand	201	381-839	n/a	277	3602

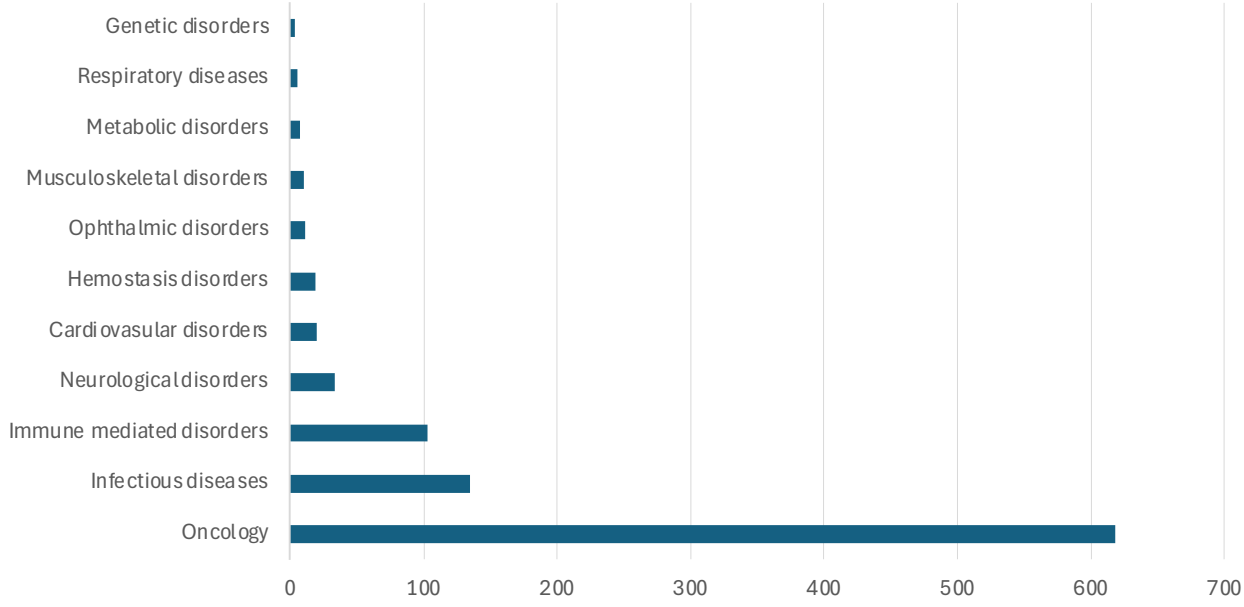
**Subcutaneous formulation, ** n/a not available, n/d no data*

Monoclonal antibodies in development

Monoclonal antibodies in the pipeline

Monoclonal antibody R&D constitutes one of the fastest-growing fields of biomedical research. In 2020, there were over 570 mAbs in clinical development for various medical conditions. By 2023, the clinical pipeline had nearly doubled, with over 1,000 investigational candidates. While there has been expansion of the global mAbs pipeline, this progress has primarily focused on diseases that significantly impact HICs, such as cancer and cardiovascular diseases, rather than those disproportionately affecting LMICs (**Figure 5**).

Figure 5: mAbs in clinical development by indication



Non-communicable diseases

Cancer mAbs continue to dominate the pipeline, accounting for 60% of the mAbs in development. There are 618 mAbs in clinical development targeting cancer indications **(Figure 5)**. In addition to new investigational mAbs, the pipeline includes expanded indications for already licensed mAbs. For instance, as of May 2024, there were 2,440 clinical trials registered in clinicaltrials.gov for Keytruda alone, covering 25 types of cancer [26].

Spotlight: Pembrolizumab (Keytruda®) and lung cancer in Africa

First marketed in the U.S. in 2014 by Merck & Co., Inc. for melanoma under the brand name Keytruda, this cancer mAb (pembrolizumab) is now approved by the U.S. FDA to treat 16 types of advanced cancers [27]. Pembrolizumab has significantly improved survival rates of many difficult to treat cancers, including lung cancers, and was added to the WHO EML list for melanoma in 2019.

- In sub-Saharan Africa up to 70% of cancer patients present with advanced stage cancer [28]
- Lung cancer is one the most common cancers in Africa, with incidence rates expected to rise [29]

Lung cancer has a low overall survival rate linked to late diagnosis and metastasis. Non-small cell lung cancer (NSCLC) makes up about 80% to 85% of all lung cancer cases [30]. African data for lung cancer is limited due to the lack of a clinical registry, financial constraints, and inadequate screening and treatment facilities. The overall two-year survival rate of NSCLC in one Kenyan hospital was 66.7% [31] while patients diagnosed with early-stage NSCLC in the U.S. have a two-year survival of 76%-97% [32]. Keytruda after chemotherapy for NSCLC reduced the risk of disease progression by 42% compared to chemotherapy alone [33].

Table 4: Keytruda prices per vial in USD

U.S.	11,337
Egypt	2,329
Kenya	1,969-3,803
Kenya biosimilar	1,820-2,189
South Africa	2,132

In 2023 Keytruda was the top-selling pharmaceutical product globally with sales of >$25 billion [34]. While sales data is not available for Keytruda in Africa, it is reported that Africa represents only 1% of the oncology drugs market [35]. While still under patent, there are two known biosimilars of Keytruda, both produced by pharmaceutical companies in Bangladesh, with at least one exported to Kenya with a modest drop in price relative to Keytruda. A biosimilar of Keytruda is possible now because Merck & Co, Inc., the developer of Keytruda, has publicly committed to not pursue patent protection for selected patents in specific LMICs. While the prices of Keytruda per vial are 4-5-fold less expensive in African countries, compared to U.S. prices, the cost of each vial is still thousands of dollars **(Table 4)**.

While mAbs hold promise for improving cancer treatment options in Africa, substantial efforts are needed to overcome the financial and infrastructure barriers to ensure equitable and broader impact on the continent.

Beyond cancer, mAbs for immune-related disorders have also garnered significant attention, accounting for 103 candidates in clinical development. As of 2024, the clinical pipeline included additional NCD areas, such as genetic disorders (n=3)[iii]; respiratory diseases (n=5)[iv], and metabolic disorders (n=7) **(Table 5)**.

Table 5: Metabolic disorders clinical mAbs pipeline

Name	Phase	Indication	Developer	Trial identifier
JR-171	Phase 1/2	Mucopolysaccharidosis I	JCR Pharmaceuticals	NCT04227600
AMG133	Phase 1	Obesity	Amgen	NCT04478708
AMG598	Phase 1	Obesity	Amgen	NCT03757130
GFB-024	Phase 1	Severe insulin resistant diabetic neuropathy	Goldfinch Bio, Inc.	NCT04880291
GMA-102/105; Glutazumab	Phase 3	Type II Diabetes mellitus	Gmax Biopharm	CTR20222558; CTR20211661
GMA-102/105; Glutazumab	Phase 2	Obesity	Gmax Biopharm	CTR20222558; CTR20211661
REGN4461	Phase 2	Generalized Lipodystrophy	Regeneron	NCT04159415

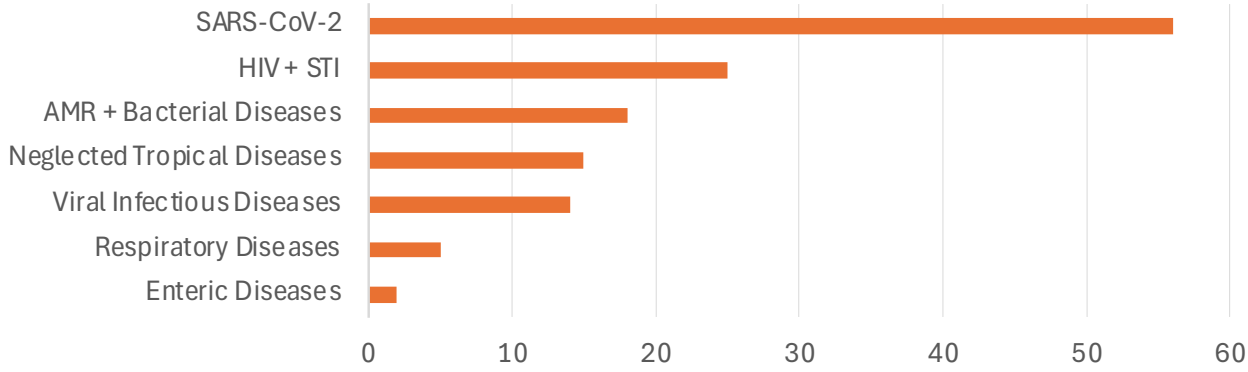
Infectious diseases

There are 135 mAbs candidates in clinical development for infectious diseases. The ID mAbs pipeline includes mAbs for endemic diseases and mAbs for epidemic-prone diseases. HIV, malaria, and dengue lead the endemic diseases mAbs pipeline, while COVID-19, Ebola, and Lassa fever top the list of epidemic-prone diseases being pursued for mAb development. The ID mAbs pipeline is also evolving to include bispecific antibodies and DNA-encoded monoclonal antibodies against SARS-CoV-2.[v]

There is insufficient attention dedicated to developing novel products tailored to regional needs or suitable for resource-constrained African health systems. Our clinical pipeline mapping reveals that of the 17 HIV mAb candidates in development, only eight (47%) align with WHO's Preferred Product Characteristics (PPCs) for HIV prevention [36]. For malaria, only one out of four clinical candidates meet WHO's PPCs for malaria prevention [37].[vi]

[iii] Alongside conventional mAbs, antibody oligonucleotide conjugates (AOCs) are advancing in clinical trials for three genetic disorders. These AOCs merge the targeting abilities of mAbs with the precision of oligonucleotide therapies, potentially offering new treatments for a range of cardiovascular and immunological diseases prevalent in Africa.
[iv] Among the five candidates for respiratory diseases, three late-stage mAbs are focused on chronic obstructive pulmonary disease. ALT-100, a new anti-inflammatory mAb, is currently in Phase 2A trials for acute respiratory distress syndrome and ventilator-induced lung injury, with potential applications in chorioamnionitis and prostate cancer, significant unmet medical needs in Africa
[v] Our analysis includes a review of Preferred Product Characteristics guidance for mAbs for infectious diseases. There are currently no PPC guidelines for mAbs for non-communicable diseases.
[vi] The COVID-19 pandemic accelerated mAb development, cutting trial times by 75% and showcasing rapid production capabilities. Early COVID-19 mAbs proved effective with good safety profiles but faced challenges with variants. These experiences are now shaping the development of next-generation COVID-19 mAbs, including pan-variant neutralizing antibodies and pan-betacoronavirus antibodies. Although the pipeline expanded rapidly due to the ongoing pandemic, there are currently 16 clinical candidates in development as of February 2024.

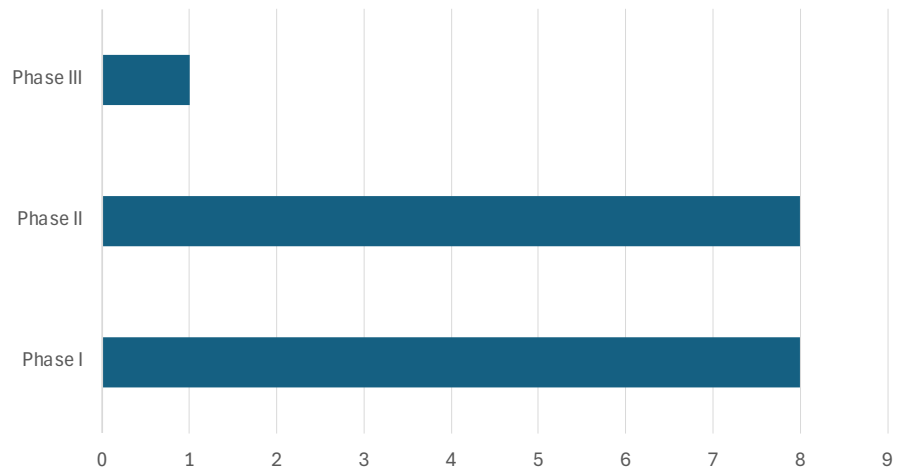
Figure 6: Infectious Disease mAbs in clinical development



Endemic diseases mAbs

There are 17 clinical candidates in the HIV pipeline **(Figure 7)**. The pipeline features mostly broadly neutralizing antibodies (bnAbs) at various stages of development, a Phase 3 anti-domain 1 CD4 antibody, and a bispecific antibody, 10E8.4/iMab, that has completed Phase 1 trials [38].

Figure 7. HIV mAb candidates per R&D stage



Decades of HIV antibody research have contributed valuable insights into mAb development for other viruses, highlighting the importance of addressing highly divergent co-circulating viruses for long-term effectiveness and of using mAbs in combinations to prevent viral escape [39, 40].

For malaria, seven mAbs are in the pipeline, with four being evaluated in clinical trials. Details can be found in the case study below. Dengue remains a growing concern in Africa, where countries face outbreaks with no cure and limited diagnostics. We identified seven Dengue candidates in the pipeline, including a Phase 2 candidate and two in Phase 1.

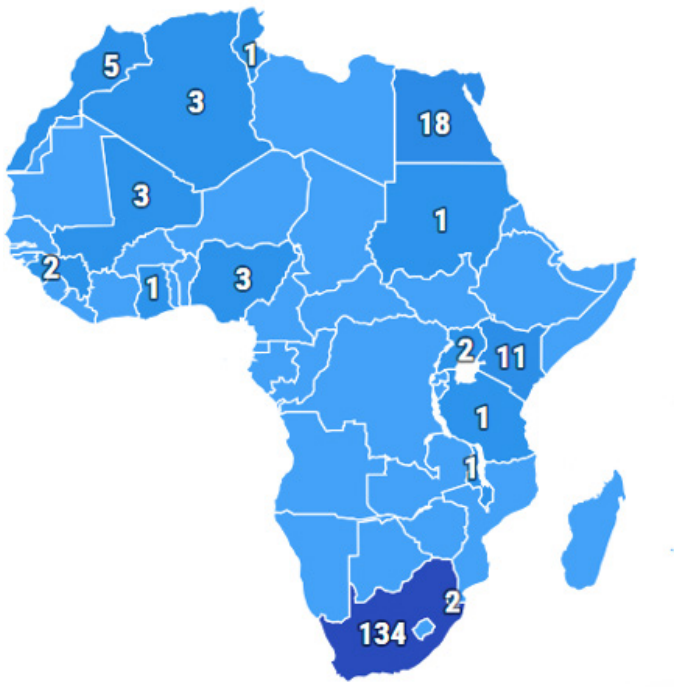
Epidemic-prone diseases mAbs

There has been progress in the mAbs pipeline for regionally endemic diseases that mainly cause outbreaks in LMICs including Ebola (West Africa), Lassa fever (West Africa) and Zika (South America). There are three Ebola candidates undergoing Phase 1 testing, and seven Ebola candidates in preclinical development. The entire pipeline for Lassa fever (7) and Zika (10) mAbs is in preclinical development. This stands in contrast to the significant progress in R&D for diseases with broader geographic footprint and pandemic potential, like SARS-CoV-2.

While a broad range of ID mAbs are being investigated, mAbs for diseases that mainly cause outbreaks in Africa are advancing slowly compared to mAb development for diseases of global pandemic potential.

Monoclonal antibody trials in Africa

Figure 8. Active mAb trials in Africa, by geographical location



From 2019 to 2023, approximately 200 mAb trials were conducted across 15 African countries, spanning all clinical phases **(Figure 8)**. The majority of these trials were concentrated in South Africa, which hosted 134 trials (72%). Kenya conducted 11 trials, while North Africa saw a total of 28 trials distributed among Egypt (18), Sudan (1), Algeria (3), Tunisia (1), and Morocco (5).

In South Africa alone, over half (55%) of the 134 clinical trials were for cancer. These were predominantly targeting lung and breast cancer, which are the leading causes of invasive cancers reported in South Africa in 2022 among males and females, respectively, and which are both on the rise[vii] [41, 42]. Most clinical trials targeting immunological disorders took place in North Africa — Egypt (7), Tunisia (4), Morocco (1), and Sudan (1), with additional trials in Kenya and Mauritius for multiple sclerosis and lupus nephritis, respectively.

Table 6. Active mAb trials in Africa, by therapeutic area ~ all phases ~

Selected Therapeutic Area	Trials in Africa	Number of unique mAbs	Unlicensed Globally (innovative)
Cardiovascular	**2**	**2**	**2**
Hematological	**11**	**6**	**4**
Immune Mediated	**52**	**23**	**10**
Infectious	**16**	**23**	**8**
Oncology	**83**	**32**	**10**

[vii] Between 2008 and 2018, male deaths due to lung cancer increased by 29.1% and breast cancer deaths increased by 42.4%.

Most of these trials (almost 90%) were for cancer indications (83) **(Table 6)**. The 16 mAb trials for infectious diseases were initiated in five countries and targeted COVID-19, Ebola, HIV, malaria, and RSV infection. South Africa is host to all five ongoing RSV mAb clinical trials, along with three COVID-19 trials (two of which also include Mali and Kenya), and three HIV mAb trials in Africa (which also include Kenya, Uganda, and Rwanda). There are three malaria clinical trials underway, two in Mali and one in Kenya. Guinea is host to two Ebola virus mAb trials, focusing on Ebanga and Inmazeb. Meanwhile, the three novel Phase 1 Ebola mAb trials mentioned earlier in the pipeline are being conducted outside of Africa, in Russia and the U.S.

Most of these trials are supporting expanded indications or protocols for globally licensed mAbs, with fewer trials for novel investigational mAbs. While disease burden is an essential metric for determining where trials take place, the distribution of mAb clinical trials in Africa suggests that trials are frequently (but not always) conducted in countries with more established human resources capacity, infrastructure, and integrated regulatory systems capable of ensuring quality in clinical trials.

Spotlight: Malaria mAbs in development

WHO reports that progress in reducing malaria incidence and mortality has stalled [43]. In 2022, global cases rose to 249 million, with most occurring in Africa [44]. Further, the region has not delivered on targets of reducing malaria incidence and mortality by 40% by 2020 and is set to miss 2025 targets of achieving a 70% reduction in incidence as well. Alongside long-standing measures — such as insecticide-treated nets, chemoprevention, diagnostic tests for early detection and treatment with Artemisinin-based combination therapies — new malaria vaccines have expanded current prevention options [45]. Malaria monoclonal antibodies offer an additional prevention alternative that is anticipated to afford high-level protection against malaria infection and onward transmission [46]. It is anticipated that, if made available at an affordable price, these mAbs could offer higher efficacy than existing vaccines and that in highly seasonal settings, a single mAb injection could protect against malaria for the entire season, addressing adherence issues and averting concerns about resistance to currently available drugs [47].

Four notable mAbs are advancing through clinical trials. Three mAbs, CIS43LS, L9LS, and MAM01, target the Circumsporozoite protein 1 (CSP-1) of *P. falciparum* [48]. The first, CIS43LS, has shown 88.2% efficacy when administered as an IV infusion in a Phase 2 trial conducted in Mali gainst intense seasonal transmission. The first, CIS43LS, has shown 88.2% efficacy when administered as an IV infusion in a phase II trial conducted in adults in Mali against intense seasonal transmission [49]. L9LS shows 2-3 fold greater potency compared to CIS43LS in mouse models [50]. In Phase 2 trials, L9LS achieved 77% effectiveness over 24 weeks with a single subcutaneous dose in children 6-10 years of age [51]. Ongoing and planned studies for L9LS include post-discharge prevention for hospitalized children with severe malaria and use during pregnancy. Efforts are ongoing to optimize cell line production of L9LS for cost-effective utilization. MAM01 has also shown strong preclinical efficacy and holds the potential to be cost-effective and more readily accessible in LMICs, given process optimization to maximize productivity while keeping production costs low [52]. An additional transmission-blocking mAb, TB31F, is in Phase 1 development [53]. Modeling studies indicate that community-wide administration of TB31F could reduce malaria cases by 75% in high-transmission areas, showing great promise for malaria control and elimination [54].

Spotlight: RSV mAbs

RSV is the most common cause of acute lower respiratory infection in young children. More than 95% of RSV-associated acute lower respiratory infection episodes and more than 97% of RSV-attributable deaths across all age groups were in LMICs [55]. Currently there are two licensed mAbs available for the prevention of RSV infections in infants. Synagis (palivizumab) has been approved since the late 1990s but is still unavailable in most of Africa. Even where available, palivizumab's high costs and the need for five monthly intramuscular injections throughout the RSV season limit its use. One injection of palivizumab costs roughly $1,000 USD in South Africa [57].

Figure 9: Africa is disproportionately affected by RSV; age-standardized mortality rate in 2019

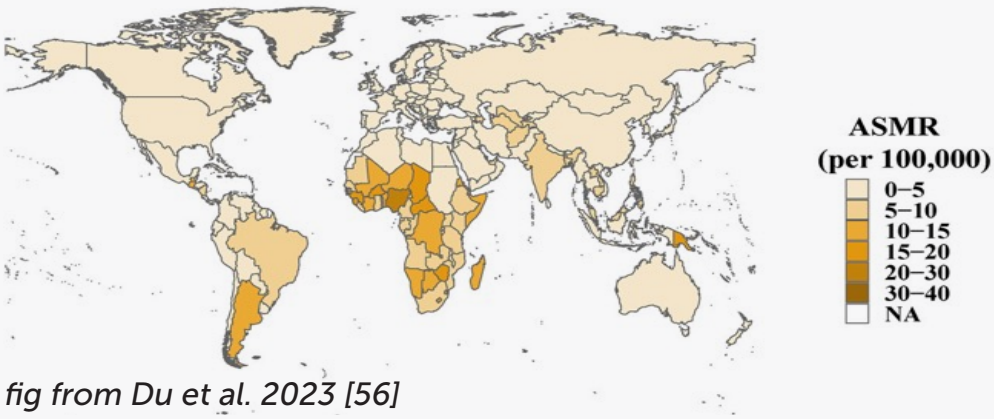


fig from Du et al. 2023 [56]

Synagis' patent protection expired almost a decade ago [58], however there are no licensed biosimilars, despite RSV's devastating impact on infants in LMICs. In 2016, the Utrecht Centre of Excellence for Affordable Biotherapeutics for Public Health created a consortium of local manufacturers working to make affordable palivizumab biosimilars available for low-income countries. The consortium completed Phase 1 clinical trials (NCT04540627 & NCT05121246) of a palivizumab biosimilar in 2023, with the goal of producing the product at $50 per dose, a fraction of the current price of the innovator drug.

Beyfortus (nirsevimab) received EMA approval in 2022 and secured U.S. FDA and Chinese National Medical Products Administration (NMPA) approvals in 2023. Nirsevimab has a significantly improved product profile from palivizumab, aligning well with the WHO PPC as a single dose, long-acting, highly potent mAb. In the Phase 3 HARMONIE trial, conducted in France, Germany and the United Kingdom, nirsevimab demonstrated 83.2% efficacy in preventing hospitalization due to RSV-associated lower respiratory tract infections among infants under 12 months [59]. However, Nirsevimab has not yet been registered in Africa and plans to pursue equitable access to the mAb in LMICs remain undefined [8].

Clesrovimab (Merck) is another long-acting mAb in the pipeline, currently being studied in a Phase 3 trial in South Africa. Clesrovimab has demonstrated promising results. In a Phase 1/2 study, a single dose of clesrovimab provided 74% efficacy for the prevention of RSV infection for a duration of five months in infants [60].

The introduction of biosimilar competition for first-generation mAb products has been slow but could broaden accessibility. As improved, single dose, longer-acting RSV mAbs advance in the pipeline, forging a timely pathway to access in LMICs is imperative.

Global investment in mAbs research and development

The African Union called for a New Public Health Order which will safeguard the health and economic security of the continent by expanding the local manufacture of vaccines, diagnostics, and therapeutics as part of Agenda 2063 [61]. Presently, less than one percent of vaccines administered on the continent are manufactured in Africa. Infectious diseases contribute to over 227 million years of healthy life lost annually in Africa and result in more than $800 billion in productivity losses each year [62]. Africa bears the highest burden of endemic diseases. It also bears a significant burden from outbreak-prone diseases, with the continent accounting for the majority of the estimated 10 million annual deaths from these conditions [63].

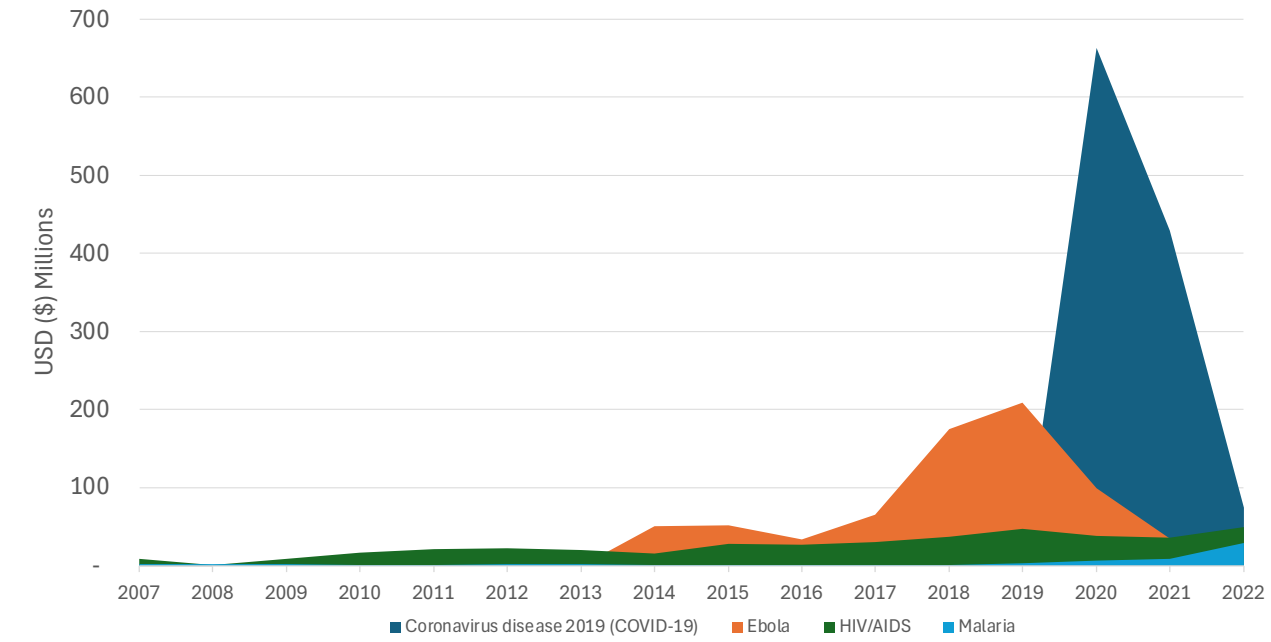
Leveraging the G-FINDER survey[viii], which tracks global annual investment in neglected, emerging infectious diseases and sexual and reproductive health R&D, we examined funding for mAbs R&D from basic research to post-registration activities for HIV/AIDS, malaria, Ebola, and COVID-19, four high burden infectious diseases in Africa.

Following a peak of $807m in 2020 in the height of the COVID-19 pandemic, global R&D funding from preclinical through clinical development for mAbs targeting COVID-19, Ebola, HIV/AIDS, and malaria, has declined, reaching $185m in 2022. This was less than one-quarter of 2020's peak and marked the second consecutive year of decline, with funding falling by almost two-thirds from 2021 (down $323m, -64%). Both the peak and the subsequent decline were almost entirely driven by decreasing COVID-19 mAb investment. COVID-19 mAbs received $664m of funding in 2020, after which funding tumbled to $74m in 2022 (down $589m, -89% from 2020). Despite these recent trends, COVID-19 still received the largest share of investment in 2022 at 40% ($74m). Over this period, funding for Ebola mAbs also dropped, continuing its year-on-year decline from a peak of $208m in 2019 to $33m in 2022 (down $176m, -84% from 2019). These funding trends likely reflect the reactive nature of R&D investment in response to outbreaks.

Funding for HIV/AIDS mAbs rose to a new peak of $49m in 2022 (up $14m, 38%), surpassing its previous 2019 peak, and sitting well above its yearly average of $24m over the preceding 15 years. Moreover, malaria mAb funding more than tripled to $28m in 2022 (up $20m, 248%), following five consecutive years of steady growth. Nonetheless, funding for endemic infectious diseases such as HIV and malaria is dwarfed by funding for epidemic diseases. COVID-19 mAbs have received $1,167m since 2020, which is more than double the combined investments for HIV/AIDS and malaria since the start of our data collection in 2007 ($466m). Total mAb funding for Ebola since 2014 ($751m) also sits well above funding totals for HIV/AIDS ($406m) and malaria ($60m)-related mAbs research and development.

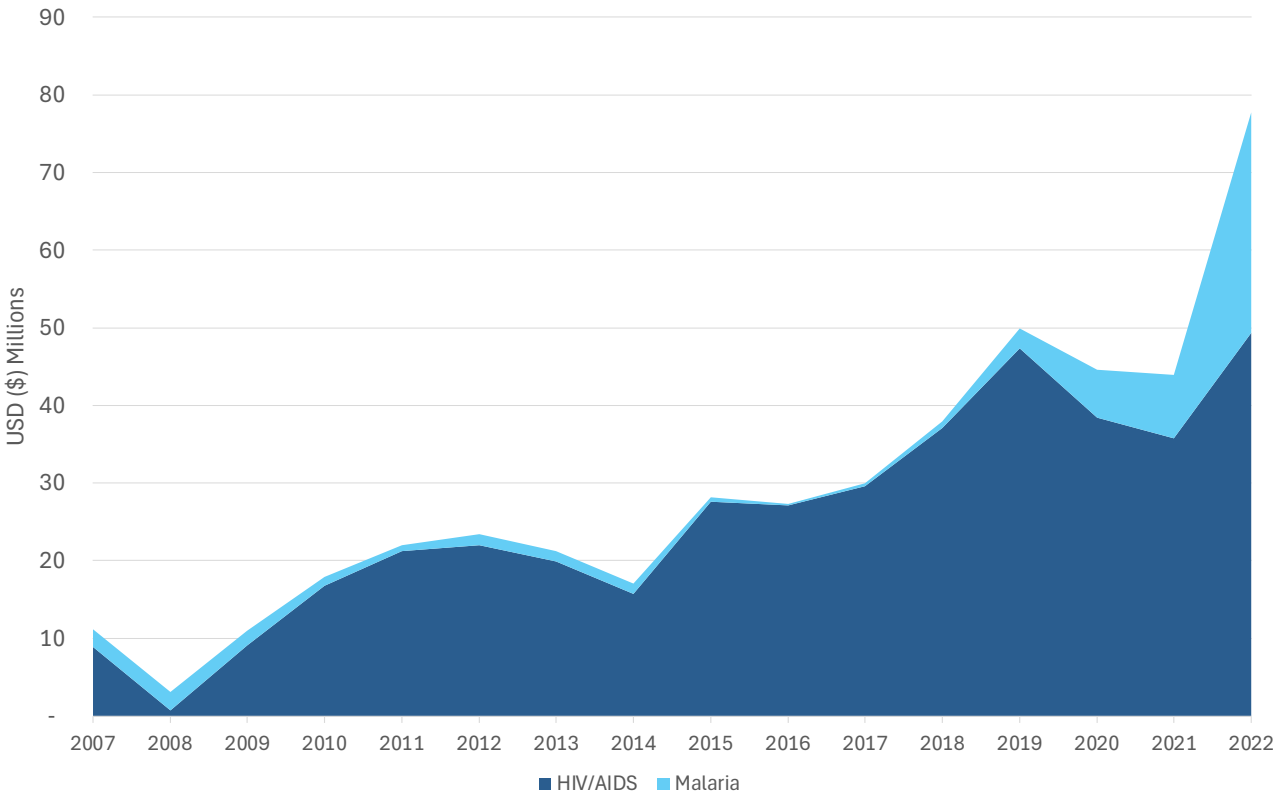
[viii] G-FINDER grants which focused on discovery or development of mAbs, or mAb-related products (e.g. nanobodies) were identified and divided into two broad categories: basic research studies that seek to improve scientific knowledge and understanding of disease, disease processes, pathogen or its vector to aid development of mAbs and actual product development encompassing discovery and preclinical, clinical, and post-registration studies.

Figure 10a. Global mAb funding for HIV/AIDS, malaria, Ebola and COVID-19 2007-2022*



**Ebola was added to the G-FINDER survey in 2014 and COVID-19 was added in 2020. Therefore, funding data is only available for these diseases from these years onwards.*

Figure 10b. Global mAb funding for HIV/AIDS and malaria 2007-2022



There is a striking difference between the level and urgency of investment in mAb research and development for diseases of pandemic potential compared with endemic diseases.

Monoclonal antibody funding for diseases with epidemic potential has focused on later-stage R&D, with 99% of Ebola mAbs funding and 95% of COVID-19 mAbs funding directed towards clinical development, from 2007 to 2022 (Figure 11a). In contrast, just 18% of HIV/AIDS mAb funding has gone towards clinical development, with 82% of HIV/AIDS mAbs funding going towards earlier-stage basic research. Before 2022, 74% of malaria mAb funding similarly went to basic research, however, with the progression of pipeline candidates, most of the 2022 growth in malaria funding was directed towards clinical development ($24m, 54%). Across all four diseases, development accounted for 80% of mAbs funding, however basic research funding has been trending upwards, doubling in five years to hit $70m in 2022.

Figure 11a. Global mAbs funding by disease and R&D stage (basic research vs clinical development) 2007-2022^

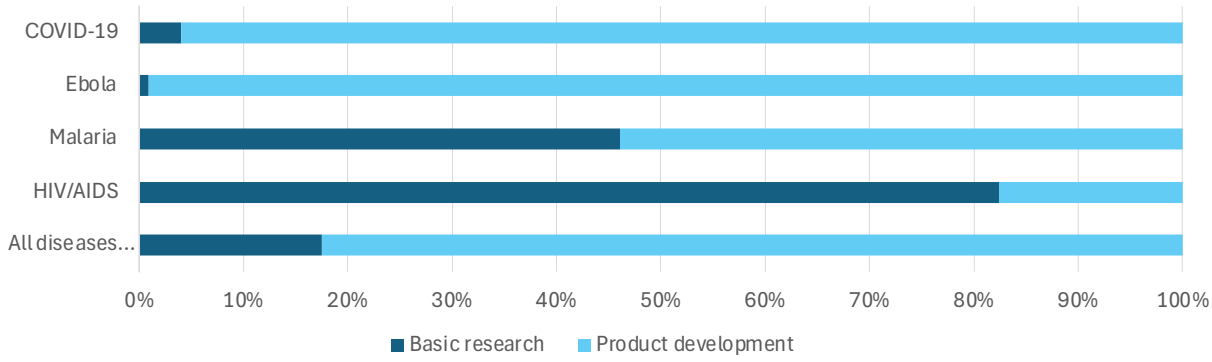
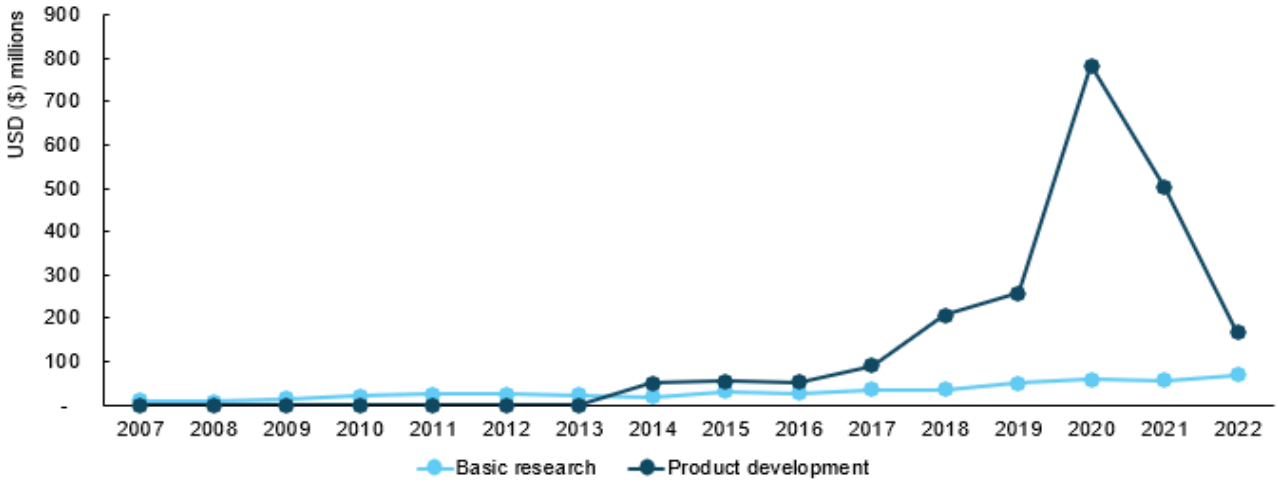


Figure 11b. Global mAbs funding by R&D stage (basic research vs clinical development) 2007-2022^



^<1% of mAb investment was not categorized as either basic research or clinical development ('unspecified' funding). This funding has not been included in figures 2a and 2b.

In 2022, over 90% of mAbs funding across the four diseases was provided by just five funders: the U.S. National Institutes of Health (NIH), U.S. Biomedical Advanced Research Development Authority (BARDA), the Bill & Melinda Gates Foundation (Gates Foundation), European Commission (EC) and U.S. Department of Defense (U.S. DOD) **(Table 7)**.

Table 7. Top mAb funders (USD millions) 2007-2022+

Funder	COVID-19	Ebola	HIV/AIDS	Malaria	Total mAb Funding
U.S. BARDA	228	653	-	-	881
Aggregate industry	753	0.1	-	-	753
U.S. NIH	67	56	284	17	423
Gates Foundation	25	1.5	98	28	153
U.S. DOD	11	38	0.2	-	49
EC	35	-	5.2	1.3	41
Other funder (combined)	49	2.6	19	1.4	84
Total	1,167	751	406	60	2,384

+The six top funders of mAb R&D across all four diseases combined were not necessarily the top six funders for each individual disease. Funding totals for Ebola and COVID-19 only includes funding from 2014 and 2020 onwards, respectively.

COVID-19

The U.S. NIH, BARDA, the Gates Foundation, the EC, and the U.S. DOD have been the top funders of COVID mAbs R&D over the years, alongside industry, which provided 65% of total COVID-19 mAbs funding.

Investment in COVID-19 mAbs was swiftly mobilized when the pandemic first began, however funding fell steeply in the following two years to one-eighth of its initial level. Industry funding for COVID-19 mAbs plummeted to just $0.1m in 2022 (down $345m, -99% from 2021). This left BARDA as the top funder of COVID-19 mAbs R&D in that year, accounting for 23% of funding.

These funding declines occurred on the backdrop of the EUA of first generation COVID-19 mAbs in late-2020, the subsequent revocation of the EUAs for these products due to poor performance against emerging viral variants, the approval and roll-out of COVID-19 vaccines, and the transition out of the acute phase of the pandemic [64, 65].

Ebola

BARDA also provided 71% of Ebola funding in 2022 and has accounted for an even greater 87% of total Ebola mAb funding since 2014. This heavy reliance on a single source of funding leaves the Ebola mAbs R&D landscape vulnerable to even small shifts in funding priorities. Since peaking in 2019, funding for Ebola mAbs has dropped for three consecutive years to one-sixth of its previous high. This drop occurred in the context of the approval of the first Ebola vaccine for the Zaire strain at the end of 2020, and the approvals of Inmazeb, a triple mAb cocktail and Ebanga, a human mAb, in 2020 [66-69].

HIV/AIDS

In contrast to infectious diseases with epidemic potential, R&D for mAbs to combat HIV/AIDS and malaria relied heavily on the U.S. NIH and philanthropic investment from the Gates Foundation. Funding for HIV/AIDS mAbs rose to $49m in 2022 (up $14m, 38%), reversing the previous two years of decline from a previous peak of $47m in 2019. In 2022, the NIH and the Gates Foundation provided 95% of HIV/AIDS mAbs funding, with U.S. NIH investment hitting a new peak of $36m in 2022, accounting for 72% of mAbs HIV/AIDS investment in 2022, following years of steady growth. In early 2021, the results of the high-profile Phase 2b Antibody-Mediated Prevention (AMP) studies, which investigated the NIH's broadly neutralizing antibody VRC01, were published, which shaped future priorities for HIV antibody research and development [70, 71].

Malaria

The malaria funding landscape has traditionally been more diversified than that for other diseases, with contributions from a broader range of organizations including the UK Medical Research Council (MRC) and the Australian National Health and Medical Research Council, who together account for one-quarter of total funding for malaria mAbs since 2007. That said, the Gates Foundation accounted for three-quarters of malaria mAbs funding in 2022 (75%), driving most of the funding increase that year (an increase of 813% from $3 million to $21 million). The NIH contributed another 22% ($6.3) of malaria funding in 2022.

Funding for malaria mAbs has grown for five consecutive years, reaching a high of $28m in 2022 (up $20m, 248%). There is building momentum in this field, evidenced by the recent publication of WHO's Monoclonal Antibodies for Malaria: Preferred Product Characteristics and Clinical Development Considerations to galvanize efforts for the development of mAbs with high impact and optimal suitability for use globally [37] and announcements from NIH on successful early-stage clinical testing of respective malaria mAbs in 2023 [49, 72].

Spotlight: mAbs for STIs to combat antimicrobial resistance

Antimicrobial resistance (AMR) poses a significant and growing threat to public health, particularly in Africa, where the burden of infectious diseases is high, and access to effective treatments is often limited [73]. The rapid spread of drug-resistant pathogens undermines progress in managing common infections and calls for innovative solutions to stay ahead of this escalating challenge. mAbs have emerged as a promising alternative, offering targeted therapeutic options that can bypass resistance to commonly used small molecule medicines [74].

In this context, sexually transmitted infections (STIs) represent a critical area of concern. The prevalence of drug-resistant Neisseria gonorrhoeae, the bacterium responsible for gonorrhea, has surged, reducing the efficacy of existing treatments and making it imperative to develop new approaches to prevention and therapy. To address this, research into mAbs for STIs is gaining momentum. We highlight ongoing R&D efforts focusing on STI monoclonal antibodies, illustrating how these innovations could transform the fight against AMR in Africa and beyond.

Toscana Life Sciences' MAD Lab is developing mAbs from individuals vaccinated with the meningococcal group B vaccine Bexsero, which show protection against gonorrhea, supported by €2.5 million from the European Research Council [75]. Additionally, a collaboration between the University of Massachusetts Medical School and biotech firms has produced mAbs targeting drug-resistant gonorrhea. This project, running from 2018 to 2022 with $4.2 million in NIH funding, developed two promising immunotherapeutics, including a chimeric mAb, which have shown promise in mice and potential for human use in intravaginal rings.

These projects investigating mAbs for drug-resistant gonorrhea take place in the wider context of an additional $3m (in 2022 USD) for mAbs against other STIs. This funding — like the chimeric mAb project outlined above — comes mostly from the U.S. NIH ($2.7m, or 88% of the total) and supports biologics for drug-resistant syphilis ($2.3m over four years, 77% of the total). The remainder ($0.3m) funds basic research and early-stage product development for Human T-lymphotropic virus 1 and herpes simplex virus 2 mAbs.

Conclusions

Progress made but more needed to make mAbs accessible to all

Since the 2020 IAVI/Wellcome report was published, there has been significant progress in the global mAb landscape. The number of licensed mAbs has nearly doubled, with a growing pipeline targeting a range of disease indications, including several which predominantly impact African populations, such as Ebola, HIV and malaria. However, mAb access and availability remains largely concentrated in HICs, with 77% of global sales occurring in the U.S., Canada, and Europe, and only 1% of sales reported in Africa. Less than a quarter of globally approved mAbs are licensed in Africa, despite the continent's high burden of cardiovascular conditions, HIV/AIDS, neglected tropical diseases, and cancers. Countries like South Africa, Egypt, and Kenya lead in mAb approvals, while others, including The Gambia and Malawi, have yet to license any mAbs. It remains to be seen if advancements in mAbs R&D will lead to improved access across the continent. Encouragingly, biosimilar approvals in Africa are increasing, which could lower prices and enhance accessibility, although no biosimilars for infectious diseases have been approved thus far.

There are significant disparities in funding for mAbs targeting diseases endemic to Africa, such as malaria and HIV, compared to those perceived as biosecurity threats in HICs. R&D funding for COVID-19 and Ebola, prompted by recent outbreaks, was significantly quicker and more substantial compared to funding for diseases that have long been prevalent in Africa [6]. The mAbs R&D funding landscape for endemic diseases like HIV and malaria is largely supported by the public and philanthropic sectors, with minimal or no investment from industry. This contrasts starkly with the COVID-19 and Ebola experiences. While it is encouraging to see large-scale mAb development as part of global response efforts, this trend highlights the reactive nature of disease prevention and control, where resources are more readily available for diseases perceived to be a threat to HICs or those with a shared burden, like cancers, than for diseases primarily affecting LMICs. Addressing these funding imbalances could significantly accelerate the development of mAbs for Africa-specific health challenges. Greater investment and long-term commitment are essential to ensure innovations for endemic priorities are delivered and lead to better access and health outcomes for African populations.

While progress has been made in developing and approving mAbs, particularly with biosimilars, since the initial Expanding Access to mAbs-based Products report was issued in 2020, more is needed to make mAbs accessible to all. Overall, mAbs remain largely inaccessible across much of Africa, limiting their potential to address the significant healthcare needs on the continent. To expand access to mAbs in Africa, several key actions are needed:

Advance novel business models that prioritize accessibility of mAbs in LMICs:

Investment in developing fit-for-purpose mAbs for conditions that disproportionately affect LMICs has been limited. Systemic challenges hinder widespread access to mAbs in Africa, including a lack of commercial incentives to target LMIC markets and complexity in manufacturing and regulatory processes. New business models are needed to incentivize development and manufacturing of mAbs that are optimized with a target product profile and cost that enable use in diverse LMIC settings. Additionally, commercialization models must be advanced that prioritize broad accessibility in the LMIC markets in which the majority of the global population resides. Lessons can be applied from voluntary

licensing strategies and product development partnerships that have demonstrated success in catalyzing development, affordable supply, and equitable availability for innovations addressing a range of infectious diseases. Technology transfer will be key to expand LMIC research, development, and manufacturing capacity and to enable sustainable and diversified supply in Africa and all regions of the world [8]. Recent investments by funders such as Unitaid, the Gates Foundation, and LifeArc in forging innovative business models and optimized production approaches will help support the goal of making mAbs more accessible [9, 76].

Establish access pathways for pathfinder mAbs to pave the way for broader access: Pilot projects to expand access to mAbs could focus initially on a small number of pathfinder products, which could provide early impact and proof-of-concept for optimized product profiles and business model approaches to expand access. Pathfinder candidates could be NCD or ID mAbs that are already approved in HICs and align with PPCs but are not yet affordably and equitably available, such as nirsevimab for RSV or mAbs used to treat cancer or other immunological disorders.

Define the African mAb market size to stimulate mAb commercial interest and product registrations in Africa: A comprehensive market analysis for priority mAbs is essential to highlight their value and potential return on investment for governments, health systems, insurance companies, and the broader community. The global mAbs market was valued at $200 billion in 2022 and is projected to grow at an annual rate of 11% from 2023 to 2030, driven by the rising prevalence of chronic diseases [10]. Additionally, the growing use of mAb therapies for different diseases and increasing awareness among patients and physicians are expected to boost market growth. While positive, the lack of specific data on the mAbs market size for priority mAbs in Africa limits commercial interest and government investment. To enhance the market's attractiveness and viability, it is essential to address this data gap.

Demonstrate the real-world impact of mAbs or biosimilars to justify investment: Analyses on the health and economic impact and cost-benefits of mAbs within African health systems are needed to highlight their potential value and return on investment. There is evidence that mAbs have significantly improved health outcomes, survival rates, and quality of life for various diseases, including for cancers and immunological disorders once considered untreatable. Broadening assessments to include a more comprehensive evaluation of the health, societal, and economic impacts of mAbs would better support decision making and enable greater investment in mAb initiatives in Africa.

Address the drivers of high mAbs prices: Improving the availability of biosimilars and second brands can create a more diverse and differentiated supply ecosystem that fosters more competitive and affordable pricing for African markets. Exploring additional innovative strategies to reduce the costs of developing and manufacturing antibodies is also essential to produce a step change reduction in cost [77].

Build awareness around mAbs: Trust in mAbs-based innovations is vital for their acceptance. This can be achieved through culturally appropriate community engagement and educational initiatives for clinical teams and patients [78,79]. Raising awareness about mAbs among the public, patients, clinical staff, and policymakers will eventually lead to making mAbs a recognized and expected component of medical care, enhancing their market acceptance. Evidence shows that increasing awareness among these stakeholders will drive market growth, ultimately improving uptake and access to these therapies.

Support and incentivize mAb R&D and manufacturing in Africa: The Africa CDC's Platform for Harmonized African Health Products Manufacturing initiative aims to advance regional production of vaccines, diagnostics, and therapeutics, which can have positive spillover effects for mAbs access and availability. Regional manufacturing can support supply sovereignty, lower distribution costs, facilitate supply chain resilience, and reduce reliance on international suppliers. A recently established MOU between IAVI and the Africa CDC includes efforts to collaborate in creating a sustainable ecosystem for regional mAbs manufacturing, to advance this agenda [80].

Regulatory harmonization to support broad mAbs registration across African countries by streamlining regulatory processes to facilitate faster approvals and market entry, ensuring that more countries have access to mAbs. The African Medicines Agency (AMA) could play a pivotal role in this effort. Furthermore, already established initiatives like the European Medicines Agency's (EMA) Medicines4All program can complement Africa's regulatory harmonization efforts when they come into effect. Collaborating with such programs can enhance the regulatory environment and accelerate the availability of mAbs in Africa.

Ensuring equitable access terms are enshrined in funding and distribution strategies. For diseases with outbreak potential, the funding landscape has often resulted in mAbs being developed and stockpiled in high-income countries, rather than being used in countries where these diseases are most prevalent. R&D companies and funding agencies play a crucial role in ensuring LMIC needs are addressed in distribution strategies so that these and other life-saving therapies are accessible where they are needed most. This can be accomplished by including equitable principles in development, manufacturing and supply mechanisms, along with enforceable clauses in agreements to ensure access for low- and middle-income countries.

Way forward: A renewed call to action

Monoclonal antibodies have revolutionized the treatment of diseases such as cancer and autoimmune disorders, becoming a cornerstone of modern medicine and offering hope to millions. However, for much of Africa and for many LMICs, this potential remains largely untapped due to significant access barriers related to prohibitive costs, limited availability, and lack of local production capabilities. This disparity is not just a medical issue but a profound ethical and public health challenge that demands immediate and sustained action.

The recommendations in this report are a reminder that we must sustain and amplify our call to action. To improve access to mAbs in Africa, a united effort from all stakeholders — governments, healthcare providers, pharmaceutical companies, the private sector, funders, civil society, and international organizations — is essential. By working together, these groups can develop innovative, scalable, and cost-effective models for mAbs R&D, manufacturing, and distribution tailored to the unique needs in different geographies. This collaborative approach will be crucial in creating sustainable solutions that ensure mAbs reach those who need them most.

Now is the time to elevate our commitment and take bold steps towards transforming access to mAbs across Africa. By investing in regional production capabilities and dismantling barriers to access, we can make these therapies more affordable and widely available. The stakes are high, and so is the potential impact. Together, we can turn mAbs from a symbol of inequity into a beacon of hope, ensuring they become accessible to all and not just a privilege for a few.

References

1. Kothari M, et al. (2024) A Comprehensive Review of Monoclonal Antibodies in Modern Medicine: Tracing the Evolution of a Revolutionary Therapeutic Approach. Cureus 16(6): e61983. https://doi.org/10.7759/cureus.61983
2. IAVI. (2020) Expanding access to monoclonal antibody-based products: a global call to action https://wellcome.org/reports/expanding-access-monoclonal-antibodies.
3. Research PC. (2024) R&D pipeline tracker https://www.impactglobalhealth.org/data/infectious-disease.
4. Research PC. (2024) The Impact of Global Health R&D https://impact.policycuresresearch.org/.
5. Research PC. (2024) RD-Pipeline-Methodology https://cdn.impactglobalhealth.org/media/Infectious_Disease_Tracker_Scope-1.pdf.
6. Policy Cures Research. (2024) G-FINDER data portal: tracking funding for global health R&D http://gfinder.impactglobalhealth.org/.
7. Research PC. (2024) Health areas https://www.impactglobalhealth.org/insights/health-areas.
8. Malhotra S, et al. (2024) Novel approaches to enable equitable access to monoclonal antibodies in low- and middle-income countries. PLOS Glob Public Health 4(7): e0003418. https://doi.org/10.1371/journal.pgph.0003418
9. UNITAID. (2023) Call for Proposals: Establish viable business models for access to monoclonal antibodies in low- and middle-income countries. https://unitaid.org/call-for-proposal/establish-viable-business-models-for-access-to-monoclonal-antibodies-in-low-and-middle-income-countries/#en.
10. Grand View Research. (2023) GLOBAL MONOCLONAL ANTIBODIES MARKET.
11. World Health Organization. (2024) Global health estimates: Leading causes of death Cause-specific mortality, 2000–2021 https://www.who.int/data/gho/data/themes/mortality-and-global-health-estimates/ghe-leading-causes-of-death.
12. MinaPharm. (2023) Minapharm Pharmaceuticals receives regulatory approval from the Paul-Ehrlich Institute for a phase 1 multi-center clinical trial in Germany for its Adalimumab biosimilar https://minapharm.com/News/PressReleaseDetail.
13. Organization WH. (2019) Report of the 22nd WHO Expert Committee on the Selection and Use of Essential Medicines https://iris.who.int/bitstream/handle/10665/325773/WHO-MVP-EMP-IAU-2019.05-eng.pdf?sequence=1.
14. World Health Organization. (2021) The Selection and Use of Essential Medicines 2021 Report of the 23rd WHO Expert Committee on the Selection and Use of Essential Medicine https://iris.who.int/bitstream/handle/10665/345554/WHO-MHP-HPS-EML-2021.01-eng.pdf
15. World Health Organization. (19 August 2022) WHO makes new recommendations for Ebola treatments, calls for improved access https://www.who.int/news/item/19-08-2022-who-makes-new-recommendations-for-ebola-treatments-----calls-for-improved-access.
16. GHTC Impact Global Health. (March 2024) Doing Well by Doing Good: Why Investing in Global Health R&D Benefits the United States and the World https://www.ghtcoalition.org/resources-item/doing-well-by-doing-good-why-investing-in-global-health-r-d-benefits-the-united-states-and-the-world.
17. Crozier I, et al. (2022) The Evolution of Medical Countermeasures for Ebola Virus Disease: Lessons Learned and Next Steps. Vaccines 10(8): 1213.

18. RidgebackBio. (2024) Ebanga™ https://ridgebackbio.com/pipeline/ebanga/.
19. Emergent. (July 7, 2022) Emergent BioSolutions and Ridgeback Biotherapeutics Enter Into Agreement for Ebanga™ Treatment for Ebola https://www.emergentbiosolutions.com/story/emergent-biosolutions-and-ridgeback-biotherapeutics-enter-into-agreement-for-ebanga-treatment-for-ebola/.
20. Carvalho C. (October 20, 2021) Ridgeback Biotherapeutics Responds to 13th Ebola Outbreak in Democratic Republic of Congo https://www.businesswire.com/news/home/20211020005683/en/Ridgeback-Biotherapeutics-Responds-to-13th-Ebola-Outbreak-in-Democratic-Republic-of-Congo.
21. Regeneron. (2024) Inmazeb https://www.inmazeb.com/.
22. Organization WH. (January 2019) Ebola/Marburg Research and Development (R&D) Roadmap https://www.who.int/publications/m/item/ebola-marburg-draft-r-d-roadmap.
23. Bornholdt ZA, et al. (2019) A Two-Antibody Pan-Ebolavirus Cocktail Confers Broad Therapeutic Protection in Ferrets and Nonhuman Primates. Cell Host Microbe 25(1): 49-58.e5. https://doi.org/10.1016/j.chom.2018.12.005
24. Sharma R, et al. (2022) Mapping Cancer in Africa: A Comprehensive and Comparable Characterization of 34 Cancer Types Using Estimates From GLOBOCAN 2020. Frontiers in Public Health 10. https://doi.org/10.3389/fpubh.2022.839835
25. Sung H, et al. (2021) Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. CA Cancer J Clin 71(3): 209-49. https://doi.org/10.3322/caac.21660
26. Ogilvy P. (Sept 2, 2020) Keytruda approved in SA for bladder cancer and non-small cell lung carcinoma. https://www.medicalbrief.co.za/keytruda-approved-in-sa-for-bladder-cancer-and-non-small-cell-lung-carcinoma/. Juta Medical Brief.
27. Fierce. (2024) Who's No. 1? With $25B in sales, Merck's Keytruda looks to be the top-selling drug of 2023. https://www.fiercepharma.com/pharma/whos-no-1-25b-sales-mercks-keytruda-appears-set-be-top-selling-drug-2023.
28. Olatunji E, et al. (2023) Utilization of cancer immunotherapy in sub-Saharan Africa. Front Oncol 13: 1266514. https://doi.org/10.3389/fonc.2023.1266514
29. Hamdi Y, et al. (2021) Cancer in Africa: The Untold Story. Front Oncol 11: 650117. https://doi.org/10.3389/fonc.2021.650117
30. American Cancer Society. (2024) Key Statistics for Lung Cancer https://www.cancer.org/cancer/types/lung-cancer/about/key-statistics.html#:~:text=Key%20Statistics%20for%20Lung%20Cancer,%25%20to%2085%25%20are%20NSCLC.
31. Said NS,Degu A. (2023) Assessment of survival outcomes among lung cancer patients at the National and Referral Hospital in Kenya. Cancer Med 12(8): 9194-201. https://doi.org/10.1002/cam4.5658
32. Morgan KK. (2024) Your Chances of Surviving Lung Cancer https://www.webmd.com/lung-cancer/lung-cancer-survival-rates. WebMD.
33. Merck. (2024) RESULTS FOR KEYTRUDA AFTER CHEMOTHERAPY https://www.keytruda.com/non-small-cell-lung-cancer/keytruda-clinical-trials-previously-treated/#:~:text=(partial%20response)-,Disease%20progression,months%20for%20patients%20on%20chemotherapy.
34. Verdin P. (2024) Top companies and drugs by sales in 2023. Nat Rev Drug Discov 23(4): 240. https://doi.org/10.1038/d41573-024-00041-3

35. BIS. BIS Research. (September 28, 2017). Drug discovery market worldwide by segment in 2016 and 2025 (in billion U.S. dollars) [Graph]. In Statista. Retrieved May 23, 2024, from https://www-statista-com.ezproxy.cul.columbia.edu/statistics/765535/drug-discovery-market-worldwide-by-segment-globally/.
36. Organization WH. (22 July 2022) WHO preferred product characteristics for monoclonal antibodies for HIV prevention https://www.who.int/publications/i/item/9789240045729.
37. Organization WH. (20 April 2023) Monoclonal antibodies for malaria prevention https://www.who.int/publications/i/item/9789240070981.
38. Ho D. (March 6, 2023) 10E8.4/iMab Bispecific Antibody in HIV-uninfected and HIV-infected Adults https://ichgcp.net/clinical-trials-registry/NCT03875209.
39. Walker BD. (2021) The AMP Trials — A Glass Half Full. New England Journal of Medicine 384(11): 1068-9. https://doi.org/doi:10.1056/NEJMe2101131
40. Corti D, et al. (2021) Tackling COVID-19 with neutralizing monoclonal antibodies. Cell 184(12): 3086-108. https://doi.org/10.1016/j.cell.2021.05.005
41. Statistics South Africa. (28 March 2023) CANCER IN SOUTH AFRICA (2008 – 2019) https://www.statssa.gov.za/publications/03-08-00/03-08-002023.pdf.
42. Africa SS. (30 April 2024) Mortality and causes of death in South Africa: Findings from death notification 2020 https://www.statssa.gov.za/publications/P03093/P030932020.pdf.
43. World Health Organization. (2023) World malaria report 2023 https://www.who.int/teams/global-malaria-programme/reports/world-malaria-report-2023.
44. African Leader Malaria Alliance. (2023) 2023 Africa Malaria Progress Report https://alma2030.org/heads-of-state-and-government/african-union-malaria-progress-reports/2023-africa-malaria-progress-report/.
45. Praet N, et al. (2022) Assessing the safety, impact and effectiveness of RTS,S/AS01(E) malaria vaccine following its introduction in three sub-Saharan African countries: methodological approaches and study set-up. Malar J 21(1): 132. https://doi.org/10.1186/s12936-022-04144-3
46. Abboud KK. (21 May 2024) Will monoclonal antibodies be a new weapon in the fight against malaria? https://www.iavi.org/iavi-report/monoclonal-antibodies-for-malaria-prevention-iavireport/#:~:text=studies%20show%20that%20a%20monoclonal,development%20of%20the%20L9LS%20mAb.
47. Hamilton A, et al. (2023) Modeling of malaria vaccine effectiveness on disease burden and drug resistance in 42 African countries. Commun Med (Lond) 3(1): 144. https://doi.org/10.1038/s43856-023-00373-y
48. Wells T,Donini C. (2022) Monoclonal Antibodies for Malaria. New England Journal of Medicine 387(5): 462-5. https://doi.org/doi:10.1056/NEJMe2208131
49. Kayentao K, et al. (2022) Safety and Efficacy of a Monoclonal Antibody against Malaria in Mali. New England Journal of Medicine 387(20): 1833-42. https://doi.org/doi:10.1056/NEJMoa2206966
50. Souza HFd. (30 Apr 2024) New monoclonal antibody vaccine slashes malaria risk in children https://www.news-medical.net/news/20240430/New-monoclonal-antibody-vaccine-slashes-malaria-risk-in-children.aspx#:~:text=L9LS%20is%20a%20recently%20developed,epitopes%20(circumsporozoite%20protein)%20in%20adult.
51. Kayentao K, et al. (2024) Subcutaneous Administration of a Monoclonal Antibody to Prevent Malaria. New England Journal of Medicine 390(17): 1549-59. https://doi.org/doi:10.1056/NEJMoa2312775
52. Bill & Melinda Gates Medical Research Institute. (2024) MAM01: The Development of A Long Acting Intervention to Prevent P. falciparum Malaria https://www.gatesmri.org/.

53. van der Boor SC, et al. (2022) Safety, tolerability, and Plasmodium falciparum transmission-reducing activity of monoclonal antibody TB31F: a single-centre, open-label, first-in-human, dose-escalation, phase 1 trial in healthy malaria-naive adults. The Lancet Infectious Diseases 22(11): 1596-605. https://doi.org/10.1016/S1473-3099(22)00428-5
54. Eek A. (11 August 2022) New drug blocks transmission of malaria parasites. Radboudumc shows successful use of antibody in clinical trial https://www.radboudumc.nl/en/news-items/2022/new-drug-blocks-transmission-of-malaria-parasites.
55. Li Y, et al. (2022) Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in children younger than 5 years in 2019: a systematic analysis. Lancet 399(10340): 2047-64. https://doi.org/10.1016/s0140-6736(22)00478-0
56. Du Y, et al. (2023) Global burden and trends of respiratory syncytial virus infection across different age groups from 1990 to 2019: A systematic analysis of the Global Burden of Disease 2019 Study. International Journal of Infectious Diseases 135: 70-6. https://doi.org/10.1016/j.ijid.2023.08.008
57. Baleta A. (19 April 2023) New RSV vaccine can save thousands of lives, researchers say https://www.spotlightnsp.co.za/2023/04/19/new-rsv-vaccine-can-save-thousands-of-lives-researchers-say/. Spotlight.
58. Staton T. (Dec 17, 2014) The top 10 patent losses of 2015. https://www.fiercepharma.com/special-report/top-10-patent-losses-of-2015. FiercePharma.
59. Drysdale SB, et al. (2023) Nirsevimab for Prevention of Hospitalizations Due to RSV in Infants. New England Journal of Medicine 389(26): 2425-35. https://doi.org/doi:10.1056/NEJMoa2309189
60. Sun M, et al. (2023) Monoclonal Antibody for the Prevention of Respiratory Syncytial Virus in Infants and Children: A Systematic Review and Network Meta-analysis. JAMA Netw Open 6(2): e230023. https://doi.org/10.1001/jamanetworkopen.2023.0023
61. Africa Centres for Disease Control and Prevention. (3 March 2022) Partnerships for African Vaccine Manufacturing (PAVM) Framework for Action https://africacdc.org/download/partnerships-for-african-vaccine-manufacturing-pavm-framework-for-action/.
62. Organization WH. (2019) A Heavy Burden: The Productivity Cost of Illness in Africa https://www.afro.who.int/publications/heavy-burden-productivity-cost-illness-africa.
63. Nkengasong JN,Tessema SK. (2020) Africa Needs a New Public Health Order to Tackle Infectious Disease Threats. Cell 183(2): 296-300. https://doi.org/https://doi.org/10.1016/j.cell.2020.09.041
64. U.S. Food and Drug Administration. (2024) Emergency Use Authorization https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs.
65. Administration USFaD. (2024) COVID-19 Vaccines
66. Administration USFaD. (19 Dec 2019) First FDA-approved vaccine for the prevention of Ebola virus disease, marking a critical milestone in public health preparedness and response https://www.fda.gov/news-events/press-announcements/first-fda-approved-vaccine-prevention-ebola-virus-disease-marking-critical-milestone-public-health.
67. U.S. Food and Drug Administration. (2024) FDA's role in Ebola preparedness and response, and information about Ebola https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/ebola.
68. Administration USFaD. (14 Oct 2020) FDA Approves First Treatment for Ebola Virus https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-ebola-virus.
69. Mulangu S, et al. (2019) A Randomized, Controlled Trial of Ebola Virus Disease Therapeutics. New England Journal of Medicine 381(24): 2293-303. https://doi.org/doi:10.1056/NEJMoa1910993

70. Corey L, et al. (2021) Two Randomized Trials of Neutralizing Antibodies to Prevent HIV-1 Acquisition. N Engl J Med 384(11): 1003-14. https://doi.org/10.1056/NEJMoa2031738
71. Diseases NIoAaI. (26 Jan 2021) Antibody infusions prevent acquisition of some HIV strains, NIH studies find https://www.nih.gov/news-events/news-releases/antibody-infusions-prevent-acquisition-some-hiv-strains-nih-studies-find.
72. Lyke KE, et al. (2023) Low-dose intravenous and subcutaneous CIS43LS monoclonal antibody for protection against malaria (VRC 612 Part C): a phase 1, adaptive trial. Lancet Infect Dis 23(5): 578-88. https://doi.org/10.1016/s1473-3099(22)00793-9
73. Naghavi M, et al. (2024) Global burden of bacterial antimicrobial resistance 1990–2021: a systematic analysis with forecasts to 2050. The Lancet 404(10459): 1199-226. https://doi.org/10.1016/S0140-6736(24)01867-1
74. Chung C, et al. (2023) Expanding the Reach of Monoclonal Antibodies: A Review of Synthetic Nucleic Acid Delivery in Immunotherapy. Antibodies 12(3): 46.
75. Sciences TL. (2024) MONOCLONAL ANTIBODY DISCOVERY (MAD) LAB https://www.toscanalifesciences.org/en/la-ricerca-tls/monoclonal-antibody-discovery-mad-lab/.
76. Bill and Melinda Gates Foundation. (2024) Innovations for Exceptionally Low-Cost Monoclonal Antibody (mAb) Manufacturing https://gcgh.grandchallenges.org/challenge/innovations-exceptionally-low-cost-monoclonal-antibody-mab-manufacturing.
77. Dugdale C, et al. (2023) Cost-effectiveness of broadly neutralizing antibody prophylaxis for HIV-exposed infants in sub-Saharan African settings. Journal of the International AIDS Society 26(1):e26052. https://doi.org/10.1002/jia2.26052
78. Hood S, et al. (2023) Culturally Informed Community Engagement: Implications for Inclusive Science and Health Equity. RTI Press https://www.ncbi.nlm.nih.gov/books/NBK592587/
79.U.S. Centers for Disease Control and Prevention. (2024) Embracing Cultural Humility and Community Engagement https://www.cdc.gov/global-health-equity/php/publications/cultural-humility.html.
80. IAVI. (2024) Africa CDC and IAVI sign Memorandum of Understanding to enhance vaccine and antibody research capacity in Africa https://www.iavi.org/press-release/iavi-africa-cdc-sign-mou/.

Appendix

Approved products and pipeline methodology

Search method for mAbs for Africa landscape methods

Data from the Antibody Society: Therapeutic and preventative monoclonal antibodies approved or in review in the EU or US (June 2023); www.antibodysociety.org/resources/approved-antibodies Expanded by IAVI to include other known licensed mAbs. Emergency Use Authorization (EUA) COVID-19 mAbs are included.

African data searched from African regulatory authorities for approved medicines from Algeria, Botswana, Burkina Faso, Congo DRC, Egypt, Gambia, Ivory Coast, Kenya, Malawi, Morocco, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Sudan, Tunisia, Uganda, and Zimbabwe in Q1 2023. Data was also extracted from 11 regulatory authorities Botswana Medicines Regulatory Authority, Egyptian Drug Authority, Medicines Control Agency The Gambia, The Kenyan Pharmacy and Poisons Board, Malawi Pharmacy and Medicines Regulatory Authority, Namibia Medicines Regulatory Council, Nigeria National Agency for Food and Drug Administration & Control, Rwanda Food and Drugs Authority, South African Health Products Regulatory Authority, National Drug Authority Uganda, and Medicines Control Authority of Zimbabwe.

mAbs were categorized by broad therapeutic areas: Genetic Diseases, Hematological Disorders, Immune-mediated diseases, Infectious disease, Metabolic disorders, Musculoskeletal Disorders, Neurological disorders, Oncology, Ophthalmology, and Other.

Analysis of mAbs approved in Africa and the mAbs pipeline cross references against 2019 data from Institute for Health Metrics and Evaluation Global Burden of Diseases and WHO data for top causes of death in Africa.

Search method for clinical trials and pipeline

In clinicaltrials.gov we searched for all Recruiting, Active, not recruiting Studies Interventional Studies trials in the area or location indexed to an African nation (all Africa nations searched by name) in April 2023. All records were manually searched for the words monoclonal, mAbs, or drug names ending in 'mab'. This list was then analyzed, cross referenced, and indexed by county location, type of mAb (novel, licensed mAb, or biosimilar), and therapeutic area. The WHO International Clinical Trials Registry Platform and African Clinical Trials Registry were also searched using the monoclonal antibodies terms.

Searches were performed in clinicaltrials.gov for any mAb (using keywords) for a disease indexed to Infectious Disease (database indexing). Additional searches were performed in in clinicaltrials.gov for mAbs for the list of African CDC priority diseases: Anthrax, Avian Influenza, Chikungunya, Cholera, Crimean-Congo haemorrhagic fever, Dengue, Ebola, Hepatitis B, Hepatitis C, Hepatitis E, Lassa Fever, Malaria, Marburg, Measles, Meningococcal Meningitis, Middle East Respiratory Syndrome, Monkeypox, Plague,Poliomyelitis (Polio), Rift Valley Fever, Tuberculosis, Yellow Fever, Zika Virus. ID Trials were limited

to initiated in or after 2019 or active and to time of search in Q3 20023. The HIV list was taken from prior IAVI analysis. COVID-19 and non-communicable mAbs data were exported from list obtained from the Antibody Society 2019-2023. Trials were analyzed and indexed for Therapeutic Area.

WHO Essential Medicines List mAbs

Data obtained from WHO Model List of Essential Medicines — 23rd list, 2023, and the WHO Medicines (Finished Pharmaceutical Products/Biotherapeutic products) — Prequalification database in Q3 2023. The list was then cross referenced against the list developed for African approved mAbs. Data for national EML list inclusion taken from national lists.

Drug sales and prices

From Nature Reviews Drug Discovery 22, 260 (2023) doi: https://doi.org/10.1038/d41573-023-00039-3, Expanding access to monoclonal antibody-based products: A global call to action. Additional information was sought from literature, news, online pharmacy searches.