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RESEARCH ARTICLE

Strengthening pharmacovigilance systems through Africa-Europe collaboration: Insights from a regulatory roundtable discussion

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Abstract

Background

Many African countries have established national pharmacovigilance (PV) centers under their medicines regulatory authorities, but multiple barriers still limit system performance. Comprehensive, well-enforced PV regulations are often lacking, and the reporting culture among healthcare professionals and patients remains weak due to limited awareness, heavy workloads, and fear of legal consequences. The limited uptake of digital tools also leads to continued reliance on paper-based reporting, undermining data management and analysis. This manuscript summarizes an Africa–Europe roundtable where regulators discussed experiences, challenges, and priorities for

strengthening PV systems.

Methods

The Center for Medical Ethics at the University of Oslo, in collaboration with Gispen4Regulatory Science, organized an in-person, two-day Europe-Africa roundtable discussion on June 5-6, 2025, focusing on global reflections on PV. This manuscript synthesizes discussions from a high-level Africa-Europe drug regulators, researchers and policy experts on the development and integration of PV. The roundtable brought together 30 experts for a cross-regional dialogue on drug regulation. This exchange illuminated common goals and significant asymmetries in infrastructure, capacity, and policy implementation across regions.

Results

The event fostered critical discussions on real-world safety monitoring, regulatory practices, and differences in health systems through short, problem-focused presentations based on active research and field practice. The roundtable discussion revealed disparities in technological and infrastructural capacity, human-resource challenges and sustainability, funding stability, community and patient engagement, and the utilization of data. It also highlighted gaps in regional harmonization, and institutional models. The study also emphasized shared values, the development of mechanisms for mutual learning and coordinated approaches.

Conclusion

Drawing on shared experiences, participants formulated a series of actionable recommendations aimed at fostering sustainable, collaborative, and technology- supported PV systems in Africa. The insights inform future strategies for harmonization and mutual learning within global drug safety governance.

Plain Language summary

African countries have set up national pharmacovigilance centers as part of their responsibility to regulate medicines, but many systems are still not working as well as they should. In several countries, PV laws and guidelines are either incomplete or not well enforced. Reporting of side effects by health workers and patients remains low, partly because of limited awareness, heavy workloads, and fear of legal consequences. Digital tools for collecting and analyzing safety data are not widely used, so many places still rely on paper-based reporting, which makes data management slower and less reliable. To address these challenges, the Center for Medical Ethics at the University of Oslo, together with Gispen4Regulatory Science, held an in-person, two-day Europe–Africa roundtable discussion on June 5-6,

2025, focusing on global reflections on PV. This paper summarizes the discussions from that meeting, which brought together 30 experts, including regulators, researchers, and policy specialists from Africa and Europe. The roundtable highlighted both shared goals and clear differences in infrastructure, capacity, and how policies are put into practice. Participants discussed real-world safety monitoring, regulatory practices, and differences in health systems, and identified gaps in technology, staffing, funding, community and patient involvement, data use, regional coordination, and institutional models. At the same time, they emphasized shared values and the importance of learning from one another. Together, they developed practical recommendations to support sustainable, collaborative, and technology-enabled PV systems in Africa, offering guidance for future efforts to improve coordination and mutual learning in global drug safety.

Keywords
Pharmacovigilance system, development, integration, Europe, Africa, Regulators



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Introduction

Africa, the world's second-largest continent and home to 1.5 billion people in 2024, continues to face profound health and socioeconomic challenges despite considerable variation among countries.[1] In Sub-Saharan Africa (SSA), a large proportion of the population lives below the poverty line, while healthcare systems in many countries are weakened by inadequate infrastructure, limited equipment, and insufficient facilities.[2] These systemic gaps are compounded by a severe shortage of healthcare personnel, limited specialist capacity, and difficulties in recruiting and retaining personnel, constraining responses to the region's combined burden of communicable and noncommunicable diseases.[3]

Pharmacovigilance (PV), the science and activities related to the detection, assessment, understanding, and prevention of adverse drug reactions of medicines is a cornerstone of public health.[4] The European Medicines Agency (EMA), US Food and Drug Administration (FDA), and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) are the major regulatory stakeholders driving global PV regulations,[5] evidenced by the fact that the FDA, the European Commission representing the EU regulatory system, and Japan's Ministry of Health, Labour and Welfare together with the PMDA are the three founding regulatory members of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.[6–8] Pharmacovigilance frameworks now exist in many countries across levels, but their scope, implementation, enforcement, and overall performance remain highly variable. In low-resource settings, PV is a dynamic and evolving field with continued debate about how best to develop systems, respond to constraints, and leverage emerging opportunities. Building resilient PV structure that can generate reliable data to inform health policy and clinical practice is particularly demanding in low- and middle-income countries (LMICs). Although some SSA regional economic communities have made progress in harmonizing PV regulations, many LMICs still lack cohesive, robust surveillance mechanisms.[9] Documented challenges include the need to tailor reporting tools into local languages, very high patient-to-healthcare provider ratios, shortages of adequately trained PV personnel, limited and often non-recurrent government funding, high staff turnover, and generally low awareness of PV among healthcare workers, decisionmakers, and patients.[10–12]

Compared with high-resource settings where PV structures are more established, implementation in many African contexts remains relatively weak, which constrains efforts to protect public health and ensure medicines are used safely.[5] Many Africa countries also depend heavily on imported products and raw materials,[13,14] heavy reliance on imports can overload already fragile pharmacovigilance systems, making it harder to detect, investigate, and act on safety issues arising from substandard and falsified medicines, medication errors, and poor-quality medicinal products.[15–17] The PV structures in SSA countries are still largely based on spontaneous reporting, increasingly supported by tools such as VigiFlow, which enable national management safety data and contributes reports to international databases.[9,18]

Submissions of individual case safety reports to VigiBase, the WHO global database of individual case safety reports, indicate substantial growth in pharmacovigilance activity in Africa. African countries had cumulatively submitted 103,499 reports by September 2015, representing 0.88% of the global database. By the end of 2024, reports from Africa were estimated to account for approximately 2% of the roughly 40 million reports in VigiBase, equivalent to about 800,000 reports. Nevertheless, Africa remains considerably underrepresented relative to its population and burden of disease.[19,20] Substantial work remains to consolidate and expand PV capacity on the continent, with the need for sustained investment in resources, infrastructure, and expertise. The roundtable discussion was crucial in bringing regulators and other stakeholders from both Africa and Europe together to share expertise, experiences, and explore future collaborations. This discussion forum intended to enable participants to learn from each other and work collectively to help guide and shape future PV priorities, with the aim of combining efforts in establishing regional harmonized safety guidelines, and building stronger, self-sustaining regulatory networks across the European and African continents. This manuscript reports on a recent Africa-Europe roundtable where regulators exchanged experiences, challenges, and aspirations for improving PV systems.

Methods

Settings and participants

The Strengthening Clinical Trial Regulatory and Ethical Review oversight in East Africa Project (AccessAfrica2), The Center for Medical Ethics at the University of Oslo, and the Gispen4Regulatory Science, organized an in-person, two-day roundtable discussion on June 5 to 6, 2025 entitled, "Global Reflections on Pharmacovigilance: A Europe-Africa Roundtable on Regulation, Culture, and Practice".

The roundtable was a policy/practice dialogue. The organizing team invited an initial group of 15 regulators (from Norway, The Netherlands, UK, Ethiopia, Tanzania, Uganda, Rwanda, South Africa, and Kenya) via email, based on their institutional roles, responsibilities, and experience with PV. The 15 invited regulators recommended additional colleagues with relevant expertise, which expanded the group to 30 experts. The PV roundtable event was also announced to the public on the AccessAfrica 2 website (https://www.accessafrica.uio.no/), including abstracts on discussion topics.

The PV Roundtable was held at the Fredrik Holsts Hus at the Department of Public and Global Health, Institute of Health and Society, University of Oslo. The roundtable brought together 30 experts from Europe and Africa for an intensive, cross-regional dialogue on drug regulation. Participants included regulators, researchers, and policy experts from various institutions, specifically from the European Medicines Agency, Norwegian Medical Products Agency; Dutch Medicines Evaluation Board; University of Oslo; Gispen4Regulatory Science; Africa Centre for Disease Control (Africa CDC); African Union Development Agency-New Partnership for Africa's Development (AUDA-NEPAD); Concilium (UK); the Pharmacy and Poisons Board (Kenya); Concilium (UK); the Tanzanian Medicines and Medical Devices Authority (TMDA); the Ugandan National Drug Authority (NDA); the Ethiopian Food and Drug Authority (EFDA); the Rwandan Food and Drugs Authority (RFDA); the Utrecht Centre for Pharmaceutical Policy and Regulation; The Uganda National Council for Science and Technology (UNCST); University of Groningen; and the Julius Centre for Health Sciences of the University Medical Center Utrecht, Netherlands.

Data collection and analysis

The event was originally planned to be physical; however, since there were a few others who were only available virtually, a hybrid format was eventually used. The language of the discussion was English. The roundtable was preceded by presentations on cross-cultural norms and practices; the European clinical trial application landscape and Clinical Trials Information System (CTIS); safety surveillance in clinical trials; sponsor and regulatory authority responsibilities; benefit–risk monitoring throughout a medicinal product's life cycle; data integration for signal management during pandemics; lessons from the COVID-19 pandemic; safety monitoring of vaccines and medicines used for compassionate purposes during pandemics and other emergencies; unintended consequences of regulatory interventions; home-based and decentralized clinical trials; contributions of patients and their support networks to pharmacovigilance and the safer use of medicines; perspectives from the Gravitate-Health public–private partnership; the potential and limitations of clinical trials for assessing drug safety; pharmacovigilance in Uganda; the clinical trial and pharmacovigilance regulatory landscape in Rwanda; pharmacovigilance activities and the role of the Tanzania Medicines and Medical Devices Authority (TMDA) in mainland Tanzania; and safety report monitoring in Ethiopia.

The roundtable emphasized reflection and practical insights rather than formal presentations, promoting collaborative learning and engagement to help shape future PV priorities. Since this was a professional dialogue, we used the recordings and transcripts as quantitative materials. The transcripts were analyzed using thematic analysis, which involved repeated review to become familiar with the content, the identification and generation of initial codes, the exploration and refinement of themes, and the formulation and naming of final themes. The transcripts were returned to participants for comments, and the findings were shared with the participants to provide their feedback. The themes are presented and discussed in the findings.

Ethical consideration

The roundtable was organized as a professional dialogue among pharmacovigilance stakeholders, with the primary purpose of mutual learning and exchange rather than as a formally designed research study. In line with institutional guidance for this type of stakeholder event, formal ethics committee approval was not required. All participants provided verbal consent for the use of anonymized content from the roundtable to develop the manuscript and for its publication. Verbal consent was obtained rather than written consent because the roundtable was conducted as a professional stakeholder dialogue with minimal risk to participants, and only anonymized content from the discussion was used in the manuscript. In accordance with institutional guidance for such events, formal written consent forms were not required, and verbal consent was documented in the study records. Most participants are listed as co-authors of this article, and all co-authors took part in the roundtable. Individuals who did not wish to be listed as co-authors or to fulfill all tasks required of authors were not included in the author group.

Results

The PV roundtable event fostered critical discussions and presentations on real-world safety monitoring, regulatory practices, and differences in health systems through short, problem-focused talks based on active research and field practice. The roundtable discussion revealed disparities in technological and infrastructure capacity, human-resource sustainability, fragile funding, community and patient engagement, and underutilization of data. It also highlighted gaps in regional harmonization, institutional models, shared values, and the potential for mutual learning and coordinated approaches.

Disparity in PV system

Technology and infrastructure capacity

Participants from Africa reported a substantial gap in technology and infrastructure, noting that some countries are "behind" in adopting advanced or automated computer systems for clinical trial data analysis. They explained that this

limits their ability to work effectively and take visible roles, as PV activities depend on stable internet access, dedicated computers, and specialized reporting software such as VigiFlow. They further noted that where PV responsibilities are not clearly defined and legally mandated in national regulations, stakeholders lack the authority and obligation to perform safety monitoring activities, leading to gaps in reporting, oversight, and risk management. Participants also mentioned that although electronic reporting tools such as MedSafety App, ODK, VigiMobile, the SQRT app, and USSD-based reporting are expanding, their usefulness remains limited in many African settings due to persistent internet connectivity challenges. Consequently, paper-based reporting is still common in rural areas, making it harder to reach patients and accurately capture and assess medicine-related problems

EU regulator (question): *"I mean, among the gaps that you identified between what we have in Europe and what you have in Tanzania, which do you think is the most pressing in your model?"*

African regulator (response): *"Regarding technology, especially digital systems, we are behind … .. Even in rural areas, the technology is still not good. In Tanzania, we have both electronic and paper-based reporting. Some electronic reporting methods require internet access … .. In rural areas, internet connectivity is sometimes not available, unlike in urban areas."*

Human resource challenges and sustainability

Participants from Africa described significant challenges related to the high turnover of healthcare professionals trained in PV. They noted that this turnover is driven by a complex interplay of structural, institutional, and economic factors, resulting in a work environment where specialized PV training does not necessarily lead to long-term retention within national PV systems. They reported that the high attrition of trained health personnel, the lack of PV integration into job descriptions and training curricula, and the frequent transfers of trained staff particularly from rural areas, often leave remaining health workers overburdened. This, in turn, makes it difficult for staff to complete detailed safety reports, and generates a continuous need for refresher training and sensitization. Participants emphasized that, although regulatory frameworks may appear similar on paper, across settings, generating and using locally relevant safety data is more important than relying solely on evidence from other regions.

Participants further noted that when PV focal persons and other key healthcare professionals receive training in reporting and are subsequently transferred to other facilities, they often lose their designated roles. These transfers disrupt reporting processes and require newly assigned focal persons to be trained. Finally, participants emphasized that the failure to integrate PV responsibilities into job descriptions and training curricula undermines the sustainability of PV activities.

African regulator*: "These staff movements interrupt reporting, and each time the PV focal person is reassigned, the facility has to nominate and train a replacement".*

Funding fragility

The participants noted that government healthcare financing in Africa is severely inadequate, with very limited insurance coverage, making it difficult for people to access essential health services. They mentioned that, although PV is resource-intensive and requires adequate sufficient funding, it is often given low priority in national budgets, resulting in insufficient allocations. Consequently, many PV systems in African countries operate as short-term, donor-dependent projects, raising concerns about their sustainability and local ownership.

African regulator: *"… We do not have sufficient resources. We must seek external funding because our resources are limited, and we are unable to cover all areas."*

Community and patient engagement

During the roundtable, African participants emphasized the importance of engaging patients and communities in PV. They noted the growing recognition of patients and citizens—particularly in the context of vaccines—as essential stakeholders and valuable sources of medicines safety data. Patients may experience adverse drug reactions that are not captured in clinical trials or through traditional reporting systems; direct patient reporting can therefore provide real-world evidence that supports the early identification of safety concerns. Participants further observed that the widespread use of mobile phones in many African countries offers a promising channel for patient-led adverse drug reaction (ADR) reporting. Patient and community involvement can also improve the collection of patient-reported outcomes (PROs), which provide insights into how medicines affect quality of life—dimensions that standard clinical measures may not capture. Such engagement also supports clearer and more effective communication about medicine-related risks,

enabling patients to better understand potential adverse effects and make informed decisions. Participants concluded that simplifying patient reporting processes could increase both the quantity and quality of safety data by strengthening patient participation in PV activities.

African regulator: *… by actively engaging with patients and communities in Africa, PV can take a more proactive approach and function more effectively."*

Underutilization of data

Participants contrasted the well-established PV systems in the European Union, which are supported by robust regulatory frameworks and collaboration among regulators, healthcare professionals, and researchers, with those in many African settings, where limited analytical capacity remains a major constraint. They explained that insufficient infrastructure, resources, and expertise for analyzing and interpreting PV data hinder health authorities' ability to generate actionable evidence on medicines safety and effectiveness, respond promptly to adverse events, and develop evidence-informed guidelines. Participants therefore emphasized the need to strengthen national analytical capacity so that PV data can be used more effectively in regulatory decision-making and to improve patient safety across the continent.

African regulator: *"Pharmacovigilance in Africa suffers from limited analytical capacity, which constrains its full integration into regulatory decision-making processes."*

"A lack of feedback to data providers has traditionally posed a major challenge."

Regional harmonization and institutional models

Participants reported that, drawing on lessons from EMA, African regulators are pursuing work-sharing arrangements, harmonized guidelines, and a clearer definition of the AMA's role in streamlining PV activities across the continent. They identified the AU-3S initiative as a practical example of efforts to harmonize and strengthen PV through shared systems, regional and national collaboration, and sustainable approaches to data generation and signal detection that support regulatory decision-making. At the same time, participants expressed concern about historical patterns of data misuse, including breaches of local regulations in cross-border secondary data analyses, and emphasized the need for genuinely reciprocal partnerships between African and European institutions to safeguard trust and integrity. Regulators stressed that collaboration should be based on mutual exchange, with both regions learning from one another rather than relying on a one-directional teaching model. Such an approach could deepen understanding of each region's policies and promote respect for diverse regulatory approaches. Participants also emphasized the importance of collaborative training and capacity-building initiatives to strengthen national and regional capabilities to detect, assess, and manage medicines safety risks and to support the development of standardized safety-monitoring frameworks aligned with international standards. As a practical model, they cited the EMA's twinning projects with Eastern European countries, in which shared assessment dossiers enabled partners to learn from one another's experience and expertise.

Shared commitments

According to the participants, there are marked structural disparities in PV between European and African countries. They noted that Europe benefits from a sophisticated and largely unified regulatory framework, led by the EMA, which oversees drug assessment, approval, and post-marketing surveillance. Although different committees and bodies may separately handle clinical-trial PV and routine PV, EU/EEA member states work under uniform, binding regulations that standardize processes for the approval and monitoring of medicines. PV is integrated across the entire life cycle of medicinal products, with safety planning beginning early in development. Participants acknowledged that the EU system still has room for improvement, for instance in better coordinating the various oversight bodies to reduce fragmentation. In contrast, participants reported that African regulators, despite sharing similar regulatory ambitions, face substantial limitations in infrastructure, regulatory maturity, policies, funding, and trained personnel. They described PV systems in many African countries as less mature and frequently dysfunctional due to multiple, interacting barriers such as underfunding, weak regulatory capacity, human resource shortages and skills gaps, a poor reporting culture, fragmented health systems and coordination problems, poor data quality, limited PV legislation and governance, and broader global inequalities and data governance concerns.[9,11,21] Participants noted that although many African countries are members of the WHO Program for International Drug Monitoring, standardized and comprehensive legal frameworks for PV absent or incomplete in several contexts.[22] In some African settings, regulators still struggle with legal frameworks and operational procedures for inspections, including enforcing compliance with good PV practices and systematically following up on corrective and preventive actions.[22] Participants also observed that regulatory authorities across the continent are at very different stages of institutional development, which contributes to uneven and sometimes

inconsistent approaches to medicines regulation. Finally, they pointed out that the AMA is in the process of being operationalized, with the explicit goal of achieving regulatory harmonization along lines comparable to the European model.

Discussion

This paper explicitly reports on qualitative synthesis of an Africa-Europe roundtable, aim at highlighting the experiences, challenges, and aspirations for improving PV systems. The themes emerging from the findings align closely with, but also deepens, several strands in the existing PV literature on infrastructure, human resources, funding, community engagement, and harmonization.

Existing work has consistently noted that many low- and middle-income countries, including in Africa, struggle with weak PV infrastructure, such as limited electronic reporting, fragmented databases, and scarce analytical tools, leading to under-reporting and delayed signal detection.[9,23] This paper highlights these concerns. The regulators in this study are not only calling for "electronic systems" in general, but for field-appropriate, mobile-enabled, and AI-supported platforms that work in low-connectivity environments and can handle complex data streams (e.g., genomics, adaptive designs).

Existing literature documented shortages of trained PV staff and the reliance on a small number of PV focal persons within national centers.[24] The emerging theme in this paper shows that high attrition, the absence of formal PV roles in job descriptions, and weak integration of PV into pre-service curricula reflect that capacity is not just scarce, it is structurally unstable. This finding reinforces existing literature that PV competencies should be embedded within professional standards and pre-service training and ongoing continuing education.[4,8] It also indicates that even well-structured training programs are unlikely to deliver sustained improvements.

Our results align with concerns raised in prior studies about reliance on donor funding and the exposure of African regulatory systems to short-term projects.[25,26] Disruption in digital platforms, difficulties retaining skilled analysts, and stalled expansion of PV and inspection activities together undermine the performance of the regulatory system. By drawing attention to mismatch between resource-intensive PV functions and their routine marginalization in health budgets, our work lends support to recent calls for dedicated domestic financing for PV and regulatory capacity[25] and adds weight to critiques of a predominantly "pilot and project" approach. The paper emphasized a shift from one-way donor–recipient relations to equitable partnerships that build self-reliance.

In Europe and globally, there is growing recognition of the importance of patient-reported outcomes and community engagement in PV,[27,28] whereas African studies have emphasized on healthcare professional reporting. Our data show that when user-friendly mobile tools are made available, patient reports can outnumber those submitted by healthcare professionals, positioning patients as an under-used but highly responsive source of safety information. This supports global advocacy for patient reporting and demonstrates its practicality and impact in African settings when supported by appropriate accessible digital apps and tailored communication approaches. The findings that surveillance remains incomplete and potentially biased without meaningful community involvement challenges prevailing models that frame PV as primarily a facility-based, expert-driven activity. Our findings therefore back debates for co-designed communication strategies that target audiences, preferred information channels, and resonant messaging.

An extensive body of work on regulatory harmonization in Africa, especially in relation to medicine registration, has documented benefits such as decreased duplication, pooled expertise, and faster access to quality-assured products.[25] The experiences of the participants in this study are consistent with and add empirical support to these documented reports. Work-sharing, harmonized guidelines, and supra-national coordination are presented as ways to improve signal detection, risk–benefit assessment, and complex regulatory decisions. Importantly, our participants emphasize mutual learning and contextual adaptation rather than one-directional capacity building. This study referenced twinning models (e.g. EMA with Eastern Europe; the Rwanda FDA experience) and illustrates how dossier sharing and joint training can lead to concrete outputs, updated guidelines, strengthened batch-release frameworks, enhanced laboratory capacity, while still respecting national ownership. It also emphasized that PV systems collect data but often lack the means to turn those data into timely, visible regulatory action. Previous studies suggest that under-reporting is partly fueled by reporters' perceptions that their submissions vanish with little feedback or visible impact on decision-making.[29,30] Our findings substantiate this by showing how slow, complex systems and absent feedback undermine motivation even among trained staff. This work complements technical discussions of signal detection with a more relational, trust-based perspective on PV practice.

In this paper, the participants described a clear power and capacity asymmetry between European and African PV systems. Participants described the roundtable as a valuable opportunity to share experiences and institutional histories but stressed that it should be treated as contextual reference material rather than a prescriptive blueprint. They were keenly

aware that most global benefit–risk assessments, and many multi-country trials, are still coordinated and led from Europe or North America. African regulators therefore called for the systematic inclusion of African-generated PV data in global benefit–risk deliberations and advocated for data governance arrangements that guarantee African visibility and influence, rather than merely extracting data from the region.

Twinning initiatives and dossier-sharing were repeatedly highlighted as practical mechanisms for mutual learning, and participants recognised that EMA-style harmonization can help reduce duplication and make better use of limited expertise. They also underscored the potential of "training-of-trainers" approaches in which African centers of excellence act as regional hubs for capacity building.

Limitation

This analysis draws on a single event (roundtable discussion) involving a selected group of participants, relies on their self-reported experiences, rather than on systematically sampled empirical data. It therefore cannot be taken as statistical representativeness, and its applicability across all African PV settings. The views captured may over-reflect the perspectives of particularly engaged regulators, while the experiences of the frontline staffs in more fragile settings or under resourced contexts may be less visible. Even so, these constraints do not diminish the usefulness of the material. The discussion provides detailed, practice-informed account of how experienced actors currently understand PV challenges and priorities and can serve as a starting point for generating hypothesis, shaping policy debate, and guiding the design of more systematic, comparative research.

Recommendations

Drawing on the roundtable discussions, participants stressed the importance of strategic investment in technology and innovation for PV. They argued that national regulators and ministries of health in SSA should give priority to scaling up digital ADR reporting tools and electronic safety databases and collaborate with regional initiatives such as AfriVigilance to build shared data infrastructure. Participants also encouraged exploring AI-supported platforms and e-learning tools to support data analysis and capacity building, particularly in contexts with staff turnover. The further highlighted the importance of mutual learning and cross-country collaboration are central to developing PV systems that are sustainable, responsive, and effectively supported by technology. These reflections outline a forward-looking agenda for harmonizing PV practices and strengthening global drug safety governance.

Invest in technology and innovation

Regarding investing in technology and innovation, regulators recommended that a broad coalition of stakeholders work jointly to reinforce PV systems through technology (digital tools). They emphasized expanding the use of digital ADR reporting tools and AI-supported analytical platforms, including MedSafety App, ODK, VigiMobile, The SQRT app, and USSD-based reporting, to speed up and improve data capture, processing, and feedback.

They further suggested that national regulators, ministries of health, AMA, RECs, EMA, and donors should, through combined efforts: a) Lead the adoption and integration of these tools into national and regional PV systems. b) Allocate adequate budgets and resources for deployment, maintenance, and scale-up. c) Develop and harmonize guidelines and technical standards and promote cross-country interoperability and data sharing. d) Provide technical support for the development, integration, and use of AfriVigilance as a continental PV database to consolidate and enhance PV data management. e) Leverage technology, including AI, to create innovative training solutions for health workers, thereby helping to address challenges related to high staff attrition.

Institutionalizing human capacity

Regulators recommended that a wide range stakeholders, including Ministries of Health, and NRAs should formally embed PV training into preservice curricula and job profiles and career pathways. They called for policies that support the creation of national and regional centers of excellence underpinned by sustainable training-of-trainers (ToT) models. At health facilities level, both public and private care providers should be tasked with appointing one or two PV focal persons per facility, charged with overseeing safety reporting and orienting new staff to help reduce the impact of high turnover and workload. Regionally, institutions such as AMA and the RECs were identified as key conveners to endorse and coordinate regional centers of excellence and harmonized ToT models, while donors and global health agencies were urged to provide financial and technical backing to make these structures operational as part of broader health system strengthening.

Ensure financial sustainability

Participants also highlighted the need to move PV financing from ad hoc, project-based support to stable domestic funding. National authorities and parliaments were encouraged to establish predictable budget lines for PV, including earmarked proportions within national health budgets, and lock these commitments in legislation and national strategies.

Ministries of Finance and Health, together with NRAs, should treat PV funding as an integral element of health system funding rather than a temporary, externally supported activity. Donors and international partners, in turn, were asked to shift from traditional one-directional funding relationships towards co-created partnerships that enhance local stewardship and capacity, recognizing shrinking external resources and prioritizing practical implementation support on ground over purely high-level policy engagement.

Empowering patients and communities

The regulators point to multiple stakeholders. They emphasized that Regulators and Ministries of Health should promote and institutionalize the use of mobile technologies (such as the MedSafety App) for patient ADR reporting and safety awareness, and leverage platforms like ISOF meetings as venues for African regulators to share expertise and coordinate approaches. Together with regional bodies and patient organizations, they should develop inclusive communication strategies that clearly identify target audiences, preferred information channels, and tailored messages, thereby fostering public understanding of PV and empowering patients as key stakeholders. Health facilities and professional associations should actively encourage patients to use widely available mobile phone applications to report safety issues and integrate these tools into routine care and community outreach. Donors and technical partners should support the design, scaling, and evaluation of such mobile and communication initiatives, recognizing their potential to significantly increase public awareness and engagement, as demonstrated by the growing number of ADR reports submitted by patients via mobile applications, which now exceeds those from healthcare providers in some contexts.

Utilize and respond to safety data

The participants highlighted that the NRAs and Ministries of Health should prioritize building local capacity for data analysis, signal detection, and regulatory response as core PV functions, working closely with universities and training institutions to develop specialized curricula and practical training programs. Health facilities should be engaged in strengthening feedback mechanisms so that reporters, whether healthcare workers or patients, receive clear, timely information about how their safety reports are used and what actions result. Donors should invest in tools, systems, and training that enable robust feedback loops and support national and regional capacity for analysis and signal detection. Across these stakeholders, enhancing the feedback loop for safety data is critical to foster greater engagement, sustain motivation to report, and improve the quality and accuracy of PV reporting

Promote harmonization and work-sharing

The participants emphasized that AMA and the RECs should lead the development of shared PV guidelines and cross-country dossier assessments, establishing structured frameworks for collaboration and mutual learning among African regulators. National authorities and Ministries of Health should engage actively in these processes, fostering interaction that enables better understanding of each other's policies, acceptance of differences, and steady progress toward harmonization. The EMA and EU member states, should support dossier sharing and twinning initiatives with African counterparts, drawing on successful models such as the EMA–Eastern Europe collaborations and the Rwanda twinning project, which helped Rwanda FDA to create a PV training plan, update key regulatory guidelines, strengthen staff capacity in safety analysis and core regulatory functions (including marketing authorization and vaccine lot release), develop legal frameworks and SOPs for batch release, and deliver targeted training in GCP, GDP, and GMP, alongside an action plan to reinforce RFDA laboratories. Donors should fund and facilitate these twinning and dossier-sharing efforts, ensuring they function as equitable partnerships that build sustainable regulatory capacity and advance harmonization between African and European PV systems.

Build equitable global partnerships

The participants stressed that African regulators, AMA, and RECs should champion fair data governance models that ensure African ownership, control, and visibility of locally generated PV data, and establish frameworks for how these data are shared and used internationally. European regulators and pharmaceutical companies should be encouraged, and, where possible, required, to formally integrate African-generated data into global benefit-risk assessments, recognizing its value for understanding the safety profiles of products in African contexts. EMA and EU countries should work with African counterparts on joint studies and data-sharing arrangements that strengthen real-world PV evidence across diverse populations and settings and enhance global medicine safety monitoring. Donors and technical partners should support the development and implementation of these governance frameworks and collaborative research initiatives, ensuring that African data are used equitably and transparently within global regulatory and industry decision-making.

Conclusion

This paper reports insights from an Africa–Europe roundtable on PV and shows that, while participants identified substantial differences in infrastructure, analytical capacity, financing, and regulatory maturity across settings, they also emphasized important shared commitments and opportunities for mutual learning. The discussions suggest that

strengthening PV in Africa will require coordinated attention to technology, human capacity, governance, and sustainable financing, supported by stronger analytical capacity and active patient and community engagement. At the same time, participants underscored that collaboration between African and European actors should be grounded in reciprocity, contextual sensitivity, and equitable partnership, not one-directional transfer of expertise. Together, these insights highlight the value of cross-regional dialogue as a basis for shaping more responsive, collaborative, and locally relevant PV systems that can better detect, interpret, and act on safety data.

Use of generative AI

During the preparation of this document, the authors utilized Grammarly, an artificial intelligence-based editing tool, to review the text for grammatical correctness, and spelling errors. After using this tool, the authors reviewed and edited the content as necessary and take full responsibility for the final formatting and overall accuracy of the text.

Ethics and consent

The roundtable was organized as a professional dialogue among pharmacovigilance stakeholders, with the primary purpose of mutual learning and exchange rather than as a formally designed research study. In line with institutional guidance for this type of stakeholder event, formal ethics committee approval was not required. All participants provided verbal consent for the use of anonymized content from the roundtable to develop the manuscript and for its publication. Verbal consent was obtained rather than written consent because the roundtable was conducted as a professional stakeholder dialogue with minimal risk to participants, and only anonymized content from the discussion was used in the manuscript. In accordance with institutional guidance for such events, formal written consent forms were not required, and verbal consent was documented in the study records. Most participants are listed as co-authors of this article, and all co-authors took part in the roundtable. Individuals who did not wish to be listed as co-authors or to fulfill all tasks required of authors were not included in the author group.

Disclaimer

We confirm that the funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Data availability statement

Data underlying this study are available from the Zenodo repository: Dataset supporting the study on strengthening pharmacovigilance systems through Africa–Europe collaboration (DOI: 10.5281/zenodo.21774603). The repository contains the dataset: Data on Strengthening Pharmacovigilance Systems through Africa–Europe Collaboration-Insights from a Regulatory Roundtable Discussion.docx.[31] The data are available under the terms of the Creative Commons Attribution 4.0 International (CC BY 4.0) License.

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