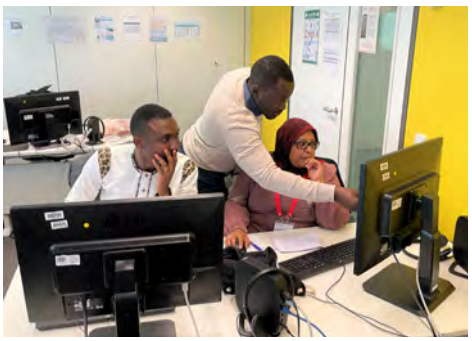
Federal Institute
for Drugs
and Medical Devices

The GHPP Projects at the BfArM

The Global Health Protection Programme
How the BfArM is globally promoting safe and effective medicines

June 2024


Content

The „Global Health Protection Programme“ 3
Medicines Regulation in Africa 5
The LabTrain projects at BfArM. 7
The PharmTrain projects at the BfArM. 15
Cooperation of the GHPP projects at the BfArM 23
Successfully completed GHPP projects 24

The „Global Health Protection Programme“

What does GHPP stand for?

Health crises of the past decades, such as the COVID-19 pandemic, demonstrate how pathogens can rapidly spread across borders in our globalised world, severely affecting the people's health. The impact on lives and livelihood of such crises are significant, long-lasting, and globally evident. Health protection and security are therefore global challenges that require cross-border solutions and close cooperation of the international community.

Health crises caused by (emerging) infectious diseases and the increasing number of antimicrobial resistances further highlight the interconnections between human, animal and environmental health. Consequently, interdisciplinary and cross-sectoral approaches in line with the „One Health“ concept are necessary to effectively address and prevent the causes of epidemics and pandemics.

The Global Health Protection Programme (GHPP) was launched in 2016 as a strategic initiative of the Federal Ministry of Health (BMG) in response to the Ebola epidemic in West Africa. The initiative aims to leverage the expertise and core competencies of specialised German institutions internationally. Seven German institutes implement the GHPP, including the Federal Institute for Drugs and Medical Devices (BfArM), the Bernhard Nocht Institute for Tropical Medicine (BNITM), the Paul-Ehrlich-Institut (PEI), the Robert Koch Institute (RKI), the German Central Committee against Tuberculosis (DZK), the Research Center Borstel (FZB), and the Friedrich-Loeffler-Institut (FLI).

The programme promotes networking, exchange and collaboration between German and international public health actors, thereby fostering global health protection. In the current second funding phase (2023-2025), approximately 40 projects are being supported.

The aim of the programme is to strengthen health systems at national, regional and international level in order to support partner countries worldwide, particularly in the prevention and management of epidemics and pandemics. The partnerships and projects play a critical role in the protection of public health and contribute significantly to the achievement of the United Nations Sustainable Development Goals, especially sub-goal 3: „Ensure healthy lives and promote well-being for all at all ages.“

GHPP Global Health Protection Programme

Supported by:

Federal Ministry of Health

on the basis of a decision by the German Bundestag

GHPP Projects at the BfArM

The Federal Institute for Drugs and Medical Devices (BfArM) is actively engaged in a range of projects under the Global Health Protection Programme (GHPP) to enhance drug safety and combat the growing threat of antimicrobial resistance in Africa. The GHPP projects are located within different divisions at the BfArM. Key elements of these projects are hands-on training for regulatory professionals, research projects in Sub-Saharan Africa, and the close collaboration with African partner institutions to develop and strengthen regulatory structures. The overall goal is to enhance local capacities and achieve sustainable improvements in healthcare systems.

The World Health Organization (WHO) and the African Union Development Agency – New Partnership for Africa's Development (AUDA-NEPAD) constitute supranational project partners. These collaborations ensure that BfArM's activities are internationally aligned and supported, thereby significantly increasing the projects' effectiveness and outreach.

LabTrain

The LabTrain project aims to strengthen the capacity and infrastructure for drug quality assurance in African countries. By providing training and supporting the establishment of high-capacity laboratories, the project facilitates proper monitoring of drug quality. It builds on the successful DQA/DQA PLUS project from the first GHPP funding phase. Separate projects conducted in the first GHPP funding phase, i.e. CPA/CPA PLUS and LEARN, have provided further valuable insights, such as the use of anti-infectives in Africa and the application of e-learning platforms, which play a crucial role in planning and implementing LabTrain.

PharmTrain2 project

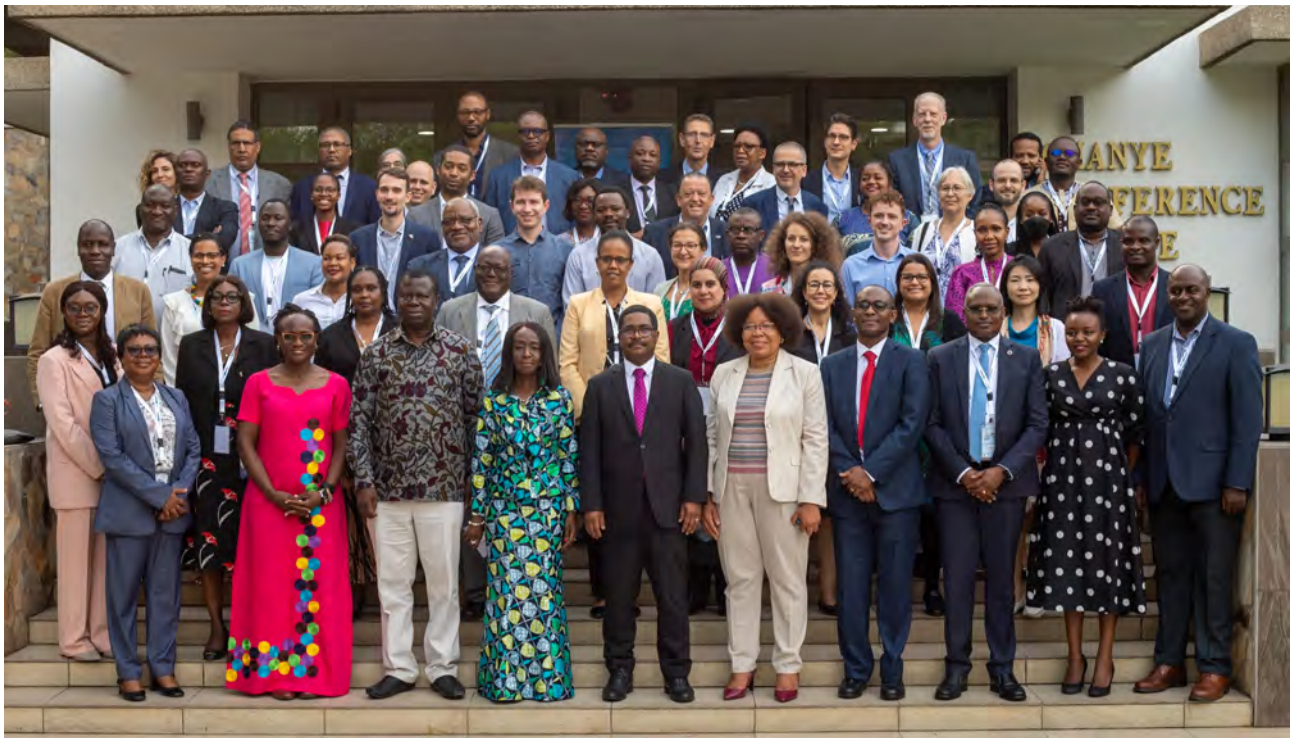
The PharmTrain2 project focuses on developing regulatory capacity and infrastructure in the area of marketing authorisation. By creating and implementing robust regulatory frameworks, the project enhances the capability of African partners to approve safe and effective medicines and ensure adherence to quality standards. The PharmTrain2 project builds on the experiences and outcomes of the successful RegTrain-PharmTrain project from the first funding phase.

In response to the COVID-19 pandemic, the PharmTrain-CoronaGlobal project (first funding phase) was launched, positively impacting structural development activities during the second funding phase and contributing to the expansion of structure development on a continental scale.

Collaborating with international partners, the sustainable development and improvement of healthcare infrastructure represents a crucial step towards global health equity.

Medicines Regulation in Africa

The (not so long) Journey towards Harmonisation



The participants of AMRH Week 2022: Heads of African regulatory authorities, members of the various AMRH technical committees, representatives of AUDA-NEPAD and WHO as well as African and international partners, including representatives of the PharmTrain2 project (Source: AUDA-NEPAD).

Although all African countries, except the Republic of Sahara, have a national medicines regulatory authority (NMRA) or a government administrative unit with relevant responsibilities, a WHO report shows that only 7% of these countries have sufficiently developed regulatory capacity with more than 90% of them having minimal or no capacity (see Ndomondo-Sigonda et al., Pharmaceut Med, 2017). As a result, many patients do not have access to safe, effective and affordable quality medicines. This has been a major challenge for public health in Africa for decades. It is therefore crucial to strengthen and connect NMRAs through structure and capacity development and to harmonise standards in order to ensure the supply of quality medicines across the continent. In this context, it is vital to develop standardised processes and scientifically sound regulatory guidelines. These provide also a foundation for training personnel for developing role-specific expertise and skills.

There are various political initiatives and support programmes to increase the competency level of the NMRAs and foster their cooperation. The African Medicines Regulatory Harmonisation (AMRH) programme was launched in 2009 by the New Partnership for Africa's Development (NEPAD) in order to overcome the fragmented regulatory landscape and to transition from a purely national to a cooperative, regional approach. In 2012, the East African Community (EAC) initiated a five-year regional initiative to harmonise medicines regulation as a pilot project for the broader AMRH programme. The EAC initiative has contributed to setting regulatory standards and promoting joint

medicines assessments of a number of NMRAs. Thereby, the time to marketing authorisations was halved (see Mashingia et al., PLoS Med, 2020). Cooperation programmes in other Regional Economic Communities (RECs) followed, particularly in the Southern African Development Community (SADC), improving likewise the situation for the NMRAs, patients and pharmaceutical manufacturers. Monitoring the quality of medicines is also an integral part of medicines regulation: the AMRH's African Medicines Quality Forum (AMQF), which exists since 2017, is a powerful continental cooperation that helps national drug quality control laboratories (NDQCLs) to expand their capabilities for the quality testing of medicines and supports countries in preventing falsified and substandard medicines from reaching patients.

In 2016, NEPAD developed the African Union (AU) Model Law on Medical Products Regulation in order to create a harmonised legal framework for the efficient regulation of medicines at national level. It facilitates the harmonisation of legislation and policies as well as cooperation within and between regions. The model law and the successful cooperation within the RECs form the basis for the implementation of the African Medicines Agency (AMA) that is currently taking place. The treaty establishing the AMA was adopted by the AU in February 2019 and its headquarter was later established in Rwanda. Since November 2022, concrete steps have been taken towards AMA's operationalisation. For example, the pilot phase for the continental assessment of medicines is currently ongoing.

The development of the AMA is currently being supported by the activities of the two BfArM GHPP projects in technical committees such as the Technical Committee for the Evaluation of Medicinal Products (EMP-TC), the Technical Committee for Regulatory Capacity Development (RCD-TC) and soon also the African Medicines Quality Forum (AMQF). The AMA is due to commence its work in the next few years. Compared with developments in Europe, pharmaceutical harmonisation in Africa is progressing at a rapid pace.

During the 'AMRH Partnership Platform Meeting' in Ghana in December 2022, Regine Lehnert, PharmTrain and PharmTrain2 project lead, was elected vice chair of the AMRH Partnership Platform Technical Partners Group. The BfArM's GHPP projects are thus making a significant contribution to the medicines regulation harmonisation on the African continent at both the technical and strategic levels.

Scientific Conference of Medicines Regulatory Authorities (SCoMRA VI) 2023: Three technical partners of the PharmTrain2 project from Ghana, Madagascar and Tanzania present the project activities to an international audience and meet colleagues of the PharmTrain team. (Source: PharmTrain)

Chimwemwe Chamdimba, Chair of the African Medicines Regulatory Harmonisation Initiative of AUDA-NEPAD, meets Regine Lehnert, PharmTrain2 project lead, at the '1st Meeting of the Continental Heads of Medicines Registration' in Nairobi 2024. (Source: PharmTrain)

The LabTrain projects at BfArM

From DQA to LabTrain

Substandard and counterfeit medicines pose a significant threat to individual and public health. This can be due to factors such as incorrect labeling, potentially toxic or incorrect active ingredients, and product contamination. Particularly concerning are substandard anti-infectives, as they promote the development of antimicrobial resistances, potentially rendering treatments ineffective or even harmful. In many African countries, the pharmaceutical quality of medicines unfortunately still falls short of the desired standards. This is often due to insufficient capacities and lack of technical equipment in national drug quality control laboratories (NDQCLs), which are responsible for monitoring and ensuring drug quality. Without proper training and modern technologies, these laboratories are unable to reliably perform the necessary quality tests. This leads to an increased prevalence of substandard or counterfeit medicines, which endangers public health and undermines trust in health systems.

The LabTrain projects are situated within the Pharmacopoeia Unit 45 of Division 4 and the Research Division 5 at BfArM. Since the beginning of the Global Health Protection Programme (GHPP), these two divisions have been working closely together, combining their expertise in research and laboratory work. LabTrain is one of 36 GHPP projects in the second funding phase (2023-2025) and builds upon the DQA project from the first funding phase (2016-2022).

The DQA project and its extension, DQA PLUS, were initiated during the first funding phase to enhance the capabilities of NDQCLs in Africa by strengthening the expertise of laboratory staff, introducing modern analytical methods, and establishing standardized procedures for quality testing, as outlined in national or international pharmacopeias. The aim is to enhance the laboratories‘ ability to assess drug quality and thus contribute to patient safety.

- **DQA Training**

The DQA training program was developed in collaboration with the WHO to train African laboratory staff from national drug control laboratories in drug quality monitoring and the identification of quality defects. The program integrates training into laboratory operations, promotes long-term knowledge transfer, and facilitates the establishment of a quality management system according to WHO and ISO 17025 standards. From 2017 to 2019, nine twelve-week in-person trainings were held at BfArM in Bonn and at InphA in Bremen. Due to the COVID-19 pandemic, these trainings were converted to a virtual format from 2020 to 2022. A total of 46 laboratory staff from 20 African countries received training in modern analytical methods and quality control standards over 13 training sessions. The trainees were able to successfully transfer and apply the acquired knowledge in their home countries.

- **DQA Alumni**

The DQA project has established an extensive network of specialists in drug analytics. To support this network, an alumni platform was created and various activities were organized for the alumni. Additionally, during the project period, two DQA alumni meetings were held, attended by alumni as well as representatives from BfArM, InphA, and WHO. The alumni network has stimulated new ideas and fostered collaborations. Alumni continue to maintain direct contact to exchange experiences and support each other.

- **DQA PLUS**

In the supplementary DQA PLUS project, support was provided to the WHO for updating the International Pharmacopoeia (Ph. Int.) and conducting analytical investigations for drafting a monograph for ciprofloxacin tablets. Additionally, new testing procedures for miltefosine were developed. The project was part of a WHO group that reviewed safety data on the side effects of miltefosine and provided recommendations for risk mitigation. In another study, antimalarial preparations were examined and near-infrared spectra analyzed to assign reference formulations. This laid the foundation for developing rapid screening methods to identify substandard and counterfeit medicines.

LabTrain – A Comprehensive Approach to Strengthening NDQCLs

Towards the end of the first GHPP funding phase, it was recognized that in addition to improving personnel capacity, the operational structure of weaker NDQCLs also needed strengthening. The GHPP LabTrain project was designed to build upon the successful GHPP DQA project and to pursue a comprehensive approach to strengthening NDQCLs in Africa.

The project is based on three pillars: structural development, training, and monograph work.

Project visit by the LabTrain team to the partner authority PBSL in Sierra Leone (Source LabTrain).

• **Structural Development**

This pillar focuses on the development and enhancement of organizational and operational structures within the NDQCLs in the West African partner countries of Ghana, Liberia, Sierra Leone, and The Gambia. This includes the introduction and optimization of management processes, the development of clear workflows, and the implementation of effective quality management systems. The goal is to create stable and efficient structures that ensure the long-term success and sustainability of the laboratories. This enables the drug regulatory authorities to carry out their monitoring duties more effectively, ensuring that the medicines distributed in their countries meet the required quality standards. As part of a comprehensive, collaborative assessment of the individual needs of the involved national regulatory authorities, all critical aspects of capacity building for quality control laboratories were thoroughly examined. This included infrastructure, availability of personnel resources, required equipment, legal frameworks, and current challenges. Based on the results of the needs assessment, tailored structural development programs were created to address the specific needs of each country. These programs aim to address the individual challenges and priorities of each laboratory and maximize the effectiveness of capacity building efforts.

• **Training**

LabTrain aims to enhance the personnel capacity of it partner NPQCLs in Africa. It offers structured training programs tailored to the individual needs and development stages of the laboratories. These training programs aim to provide the necessary expertise for setting up and operating laboratories and to promote the use of modern technologies to improve drug monitoring and quality assurance in the QCLs. The training programs offered include:

1. DQA Lab-Trainings for Alumni: Alumni of the GHPP DQA project who had only completed virtual training were able to participate in four-week practical training sessions at BfArM and the Institute for Pharmaceutical and Applied Analytics (InphA) in 2023. The focus of the training was on validating analytical methods, modern spectroscopic techniques for identifying substandard medicines, and the management of chemicals and laboratory materials.

2. Basic Training for QCLs: A four-week Basic Training for staff from national drug regulatory authorities of The Gambia, Liberia, and Sierra Leone supports the development and enhancement of QCLs. Conducted by the Food and Drugs Authority (FDA) Ghana, it provides foundational knowledge in pharmaceutical analytical

methods as well as in the maintenance and qualification of laboratory instruments.

3. Advanced Trainings for Established QCLs: These training modules are aimed at partner countries that already have established QCLs. They offer specific training on advanced topics to these labs. The training aims to enhance the long-term productivity of the laboratories or to address current challenges.

• **Monograph Work**

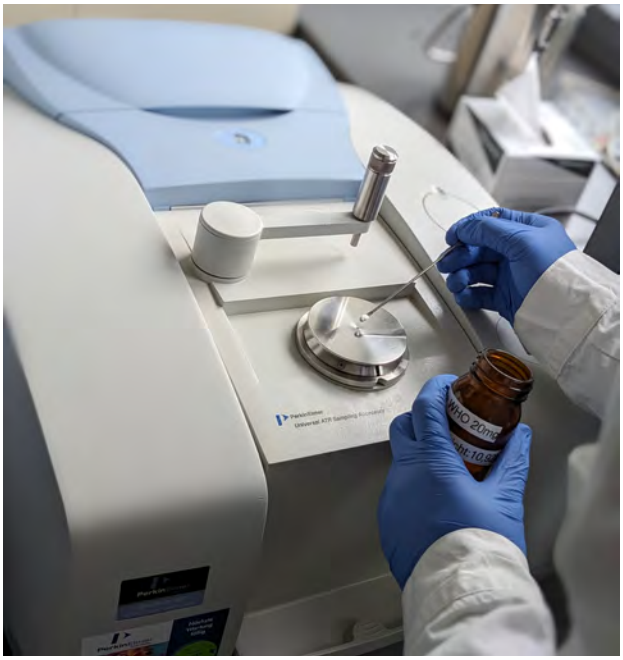
The GHPP LabTrain project supports the WHO in updating and developing monographs for the International Pharmacopoeia (Ph.Int.) and other quality guidelines. This enables quality control laboratories worldwide to apply correct analytical methods and assess the quality of medicines according to international standards. Potentially dangerous or substandard products can thus be identified and removed from circulation before they reach patients. The monograph work includes:

1. Monographs for Anti-Infectives

The Ph. Int. provides standard analytical methods and specifications for medicines throughout their entire shelf life. It includes monographs for many pharmaceutical active ingredients (APIs) and finished pharmaceutical products (FPPs). These freely accessible standards serve as guidelines for quality control laboratories and can be adopted by WHO member states as national standards. A particular focus is placed on medicines listed in the WHO Essential Medicines List and those important for WHO health programs, as other pharmacopoeias may not provide testing specifications for them. The project conducts experimental investigations to develop and validate analytical methods for specific anti-infectives and establishes quality requirements for these medications. It focuses on pharmaceutical products that are critical for health systems in low-income countries, for which monographs are often lacking or outdated.

2. Pharmacopoeial Standards for Excipients in mRNA Vaccines

Novel mRNA vaccines play a central role in global efforts against COVID-19. Ensuring the quality and effectiveness of these vaccines requires robust analytical methods and internationally harmonized specifications. The LabTrain project is developing monographs for lipids used as excipients in mRNA vaccines to establish standardized quality requirements for these substances and to enable better control over the manufacturing processes of mRNA vaccines. By building production facilities and ensuring high-quality excipients, the project aims to achieve local production and supply of vaccines, thereby improving availability and accessibility in previously underserved regions.



Identity testing of an active pharmaceutical ingredient as part of the monograph work (Source: LabTrain)

Interview: GHPP LabTrain Project Partner Dr. James Komeh, PBSL (Sierra Leone)

How would you describe the collaboration with the GHPP LabTrain project at BfArM? Could you provide insights into how this collaboration has developed?

The collaboration with the GHPP LabTrain project at BfArM has enhanced the laboratory capacities of quality control laboratories in West Africa. The project improves laboratory infrastructure, implements quality management systems, trains laboratory analysts, and optimizes quality assurance protocols. It was initiated to combat substandard medicines and strengthen regulatory agencies. The Pharmacy Board of Sierra Leone (PBSL) already benefited from the predecessor project GHPP DQA through our participation in training on medicine quality assurance for laboratory analysts. In the LabTrain project, PBSL also received support from a team of BfArM and InPhA to improve laboratory infrastructure and quality management systems. A needs assessment was conducted on-site to develop a tailored capacity-building program that addresses the specific challenges and priorities of the laboratory. We are currently working on implementing the recommendations from this needs assessment, which have been converted into structural development plans to optimize laboratory setup and processes for ISO 17025 accreditation and WHO prequalification..

What specific contributions has GHPP LabTrain made to support your institution in achieving its goals?

The GHPP LabTrain project has made several important contributions to support PBSL and its laboratory. A comprehensive survey of quality management and internal processes identified areas for improvement in our laboratory. Issues were found with documentation and outdated laboratory equipment, as well as financial constraints and knowledge gaps in instrument maintenance and existing management structures. Training programs help staff meet quality standards and achieve accreditation. An on-site visit in October 2023 provided the LabTrain team with detailed insights into daily operations, allowing for targeted adjustments in project support..

Dr. James Komeh, Head of the Pharmacy Board of Sierra Leone

In your opinion, what differences has GHPP LabTrain made for your institution?

The LabTrain project has already made significant improvements for PBSL. It has worked with staff and management to develop a structural development plan aimed at optimizing quality control through improved laboratory infrastructure and equipment, enabling more reliable testing of pharmaceutical products. Training programs have and will continue to enhance staff expertise, allowing them to perform their duties more effectively and according to international standards. Adjusting management structures to international guidelines improves compliance and strengthens internal processes, contributing to overall efficiency and reliability of operations.

GHPP LabTrain: Interviews with Deputy Project Leads Andrea Stanglmair und Dr. The Hung Vu

Andrea Stanglmair, Deputy Project Lead and Project Coordinator GHPP-LabTrain, Division 5 'Research'.

How do you see the connections and functions of the project in relation to the activities and commitments of BfArM?

Stanglmair: Health crises such as Ebola and the spread of antibiotic-resistant pathogens highlight that diseases do not respect international borders. Therefore, it is essential to think beyond purely national measures and promote close international collaboration. An example of this is the joint agreement of heads of state and government at the G7 summit in 2015 to strengthen global health systems, particularly in low- and middle-income countries where infectious diseases like HIV/AIDS, malaria, tuberculosis, and neglected tropical diseases are widespread. A crucial component in tackling these diseases is ensuring the quality of medicines for the population. National pharmaceutical quality control laboratories play a key role in this regard. In Germany, BfArM is the central authority that intensively deals with the testing and evaluation of the quality of pharmaceutical products. As such, our institute has extensive knowledge and laboratory infrastructure for pharmaceutical research and analytics. With this expertise, the LabTrain project, a collaboration between the Pharmacopoeia Division and the Research Division of BfArM, aims to support national drug regulatory authorities, particularly in West Africa, in building and developing their quality control laboratories. LabTrain focuses on optimizing quality management structures and enhancing the skills of laboratory staff to ensure the safe monitoring of medicines in the region.

What is your professional background as deputy project manager of LabTrain?

Stanglmair: Following my training as a pharmaceutical technical assistant in Munich, I studied International Relations at Regensburg University of Applied Sciences with stays abroad in Latin America and Southeast Asia and completed my Master's degree in Global Health, specialising in pharmacy, at the University of Copenhagen, Denmark. I was able to deepen my expertise by working at the Institute of Tropical Medicine and International Health, Charité - Universitätsmedizin Berlin. I have been working at the BfArM since 2021.

To what extent does BfArM benefit from the partnership and collaboration in the LabTrain project? Are there specific examples of successes or positive impacts??

Vu: The partnership and collaboration activities within the LabTrain project allow BfArM to gain deep insights into pharmaceutical quality monitoring in the partner region. Through this cooperation, we obtain a comprehensive understanding of global drug manufacturing and quality assurance. This knowledge is crucial for accurately assessing the impact on the German and European health systems. Consequently, BfArM and the Federal Ministry of Health (BMG) can respond to incidents in a timely and appropriate manner. Moreover, BfArM's increased presence in African partner countries and in international committees creates

further opportunities for collaboration and contributes to improved healthcare and a more stable global health system in the long term.

The project has developed a thorough understanding of the current situation in several African countries through various measures such as assessments and on-site visits. It has also enhanced cooperation between BfArM and international organizations like the WHO in developing guidelines and monographs. These documents are specifically tailored to address the deficiencies and challenges faced by African quality control laboratories and have been received very positively by them. Additionally, the project has helped establish a network of professionals to continuously exchange experiences and work together on solutions. This network has improved communication between the involved institutions and countries and enables a faster and more efficient response to health crises.

How did you become deputy project manager of LabTrain, Mr Vu?

Vu: I started with a Bachelor of Science in Chemistry at the University of Cologne and then successfully completed a Master of Science in Drug Research at the Rheinische Friedrich-Wilhelms-Universität Bonn. This was followed by a doctorate at the Pharmaceutical Institute at the Rheinische Friedrich-Wilhelms-Universität Bonn, specialising in pharmaceutical and analytical chemistry: Pharmaceutical and analytical chemistry. I have been working at the BfArM since 2019.

3. What are your long-term wishes and visions for the future, both for BfArM and for the support of the African continent through your agency?

Vu: I am firmly convinced that BfArM will continue to play a leading role in the evaluation and implementation of innovations in the field of pharmaceuticals. This leadership position will drive the use of modern technologies and set new standards in pharmaceutical regulation. Looking ahead, I envision BfArM not only as a national authority but also as a global player, improving global drug safety and quality through international cooperation and the exchange of knowledge and best practices. Our goal is to build close partnerships with health authorities worldwide to address global health threats together.

Dr The Hung Vu, Deputy Project Lead and Scientist GHPP-LabTrain, Subject Area 45: 'Pharmacopoeia' in Division 4.

Stanglmair: We also hope that our collaborations will contribute to the sustainable strengthening of health systems on the African continent. In the long term, African countries should have the necessary resources and capabilities to set and monitor their own high-quality standards for medicines and medical products. Ultimately, we wish for BfArM, through its work and international collaboration, to contribute to promoting health equity worldwide. Every person, regardless of where they live, should have access to safe and effective medicines. Achieving this goal is our vision for the future.

The LabTrain Team

Dr. Yvonne Urbach

Project Lead, Division 4, Unit 45

Pharmacist, Pharmacy Degree from the Albert Ludwig University of Freiburg; PhD at the University Hospital Erlangen; Postdoc at the University Hospital Bonn; Employed Pharmacist/Branch Manager at Esther Volmer Pharmacies e.K.

Prof. Dr. Britta Hänisch

Project Lead, Division 5, Division Head 5

Pharmacist, Pharmacy Degree, Bonn University; PhD in Pharmacology and Toxicology; Habilitation, Medical Faculty of Bonn University; Specialized Pharmacist for Drug Information; Specialist in Pharmacology (DGPT); Scientific work at the Institute of Pharmacology and Toxicology and at the Institute of Human Genetics, Division of Genomics, Bonn University; Since 2012, Group Leader of Pharmacoepidemiology in Neurodegenerative Disorders at the German Center for Neurodegenerative Diseases (DZNE); Since 2018, Head of the Research Group Pharmacoepidemiology (Unit 52) at the BfArM; Since 2018, University Professor of Pharmacoepidemiology, Bonn University; Since 2021, Head of the Research Division at BfArM

Benjamin Winnerling

Scientist, Division 4, Unit 45

Bachelor of Science in Molecular and Applied Biotechnology from RWTH Aachen University; Master of Science in Molecular and Applied Biotechnology from RWTH Aachen University; PhD at the Institute of Pharmaceutical Microbiology, University Hospital Bonn/Bonn University; PhD Focus: Biology – Pharmaceutical Microbiology

Claudia Stärk

PhD Candidate, Division 5

Pharmacist, Pharmacy Degree from the University of Marburg; PhD Project: Developing quality control procedures and specifications for lipid derivatives used as excipients in mRNA vaccines

The PharmTrain Projects at the BfArM

RegTrain-PharmTrain, PharmTrain2 and PharmTrain-CoronaGlobal

The PharmTrain projects are located in Division 'Regulatory Affairs 3', in Division 32 at the BfArM. This is due to the fact that the Global Health Protection Programme initially focused on infectious diseases and the core of these projects lies in marketing authorisation. The aim of the BfArM's PharmTrain projects is to strengthen the structures and capacities of African regulatory authorities. The RegTrain-PharmTrain project (January 2019 - December 2022) and the PharmTrain-CoronaGlobal project (May 2021 to March 2023) were successfully completed. Out of the 54 GHPP projects in the first funding phase, the German Federal Ministry of Health selected eight projects as so-called lighthouse projects due to their special model character with regard to the objectives of the GHPP. The RegTrain-PharmTrain project was one of these. The current PharmTrain2 project (January 2023 - December 2025) is one of 36 GHPP projects in the second funding phase and builds on the RegTrain-PharmTrain project. The PharmTrain-CoronaGlobal project was a distinct activity carried out in connection with the corona pandemic. Its results are feeding into the PharmTrain2 project in the area of structure development/scale-up. The PharmTrain2 project consists of three pillars, which are described in more detail on the following pages. Various partner authorities are involved in different ways:

I. Structure development
Supporting partner authorities in, Ghana, Liberia, Sierra Leone and The Gambia in developing harmonised regulatory guidelines and standard operating procedures. These are based on the results of WHO (self-) benchmarkings in order to promote the institutional development of the regulatory authorities in a tailored manner.

II. Capacity development
Training of personnel from the African partner authorities in Ghana South Africa, Tanzania, and Zimbabwe in the field of drug assessment, focussing on biosimilars and the clinical evaluation of pharmaceuticals. Experiencing the European approach - based on harmonisation, worksharing and reliance - is a relevant part of the fellowships. BfArM experts are supporting by giving trainings. In the particularly involved divisions, project team members in turn support the assessors in their technical and regulatory tasks. The targeted fellowship programmes are based on the train-the-trainer concept, putting particular emphasis on ensuring an efficient knowledge transfer. Training manuals for the clinical evaluation of medicinal products and the evaluation of biosimilars are developed jointly and serve for standardisation of the trainings. The development of e-learning courses complements the overall concept.

III. Harmonisation (Scale-up)
The activities of project pillars I and II feed into the harmonisation of medicines regulation in Africa via the supranational project partner, the African Union Development Agency - New Partnership for Africa's Development (AUDA-NEPAD). An important aspect of this scale-up is the support for the establishment of the African Medicines Agency (AMA), which is striving for harmonised continental medicines assessment and approval.

Providing sustainable support for the project partners is key. This includes their institutional development as well as harmonisation in improving both, regulatory structures and staff expertise, aiming at stable and effective regulatory systems. These, in turn, strengthen international health protection, which counteracts uncontrolled outbreaks and spread of (infectious) diseases. We would like to take this opportunity to thank the senior management of the BfArM, Prof. Dr. Broich and Prof. Dr. Knöss, as well as all colleagues involved, for their support of this BfArM activity - very important, also beyond Africa!

Interview with the Project Lead Regine Lehnert

Where do you see a connection between your project and the legal mandate of the BfArM?

With the GHPP and the incorporation of its institutes in this segment, the German Federal Ministry of Health has recognised that investing in global health protection is not a luxury, but is directly linked to the stability of the German healthcare system. The programme was launched after the devastating Ebola outbreak in West Africa. It was recognized that the combination of vulnerable healthcare systems, increasing population density and global mobility constitutes a risk, also for Germany. Life-threatening infectious diseases such as Ebola, other viral haemorrhagic fevers or highly pathogenic coronaviruses can spread easily. Some of these disease outbreaks predominantly or exclusively occur in less developed countries in Africa and in most cases there are no effective therapies. In addition, innovative medicines often take long to reach the African markets. Contributing factors are weak structures in some areas, understaffing and insufficient competencies in the regulatory authorities. It is precisely at these interfaces that the legal mandate of the BfArM and the activities of the PharmTrain2 project meet.

To what extent does the BfArM benefit from the cooperation with the African project partners?

The study visits by African colleagues to the BfArM in particular provide numerous opportunities for mutual exchange. One of our fellows, Mr Owusu from Ghana, studied the authorisation requirements for fixed dose combinations in some detail, while he was at the BfArM. Approximately one year later, a regulatory expert from Africa was sought for the Scientific Advice Working Party (SAWP) as part of an European Medicines Agency (EMA) Article 58 Scientific Advice on a combination medicinal product. Mr Owusu happily agreed to support. We subsequently received feedback from the EMA and BfArM coordinators about how helpful his participation had been. Moreover, the international visibility of the BfArM enhanced significantly by its participation in the GHPP.

Regine Lehnert, Project Manager GHPP PharmTrain2 of the BfArM, Clinical Assessor in Unit 32: 'Infectiology/Dermatology/Allergology'

What are your hopes for the BfArM's role in promoting global health protection?

I hope that the GHPP projects will continue beyond 2025 with the appropriate funding from the German Federal Ministry of Health and further support. Long-term, reliable partnerships are essential for sustainable projects. In response to numerous requests from our partners, I have realised that the available expertise at the BfArM could be used in many other areas when it comes to projects that promote the regulation of medicinal products outside the EU. I would like to thank my project team, my colleagues at the BfArM, the heads of the divisions, unites and the institute as well as the German Federal Ministry of Health for the support I have experienced so far!!

What is your professional background?

After studying human medicine at the FU Berlin, I worked clinically in an HIV outpatient clinic and in infectiology. Since 1997, I have been working as a clinical assessor in various divisions at the BfArM, and since 2019 also as project lead for the GHPP PharmTrain projects in Division 3.

The PharmTrain2 Team

Kornelia Flämig

Deputy Project Lead GHPP PharmTrain2 and project coordinator Biosimilar Fellowship (project pillar capacity development) and guideline development for the AMA (project pillar structural development).

At the BfArM since 2021. Pharmacist; studied Pharmacy at the University of Leipzig, Master in Global Health at Maastricht University; experience in patient-centered HIV medication supply at 'Doctors Without Borders' in South Africa; worked in public pharmacies in Germany and South Africa.

Dr. Henrike Bühl

Second deputy project lead and project coordinator for the structural development pillar of the GHPP PharmTrain2 project; guideline development in West Africa (TWG-MAG) and at continental level (AMA).

Working at the BfArM since 2020. Studied biology and obtained a doctorate in pharmaceutical microbiology at the University of Bonn. Experience in knowledge exchange and research in West Africa in cooperation with the Bernhard Nocht Institute (BNITM) Hamburg.

Dr. Tobias Siefen

Project coordinator for the Clinical Fellowship of the GHPP PharmTrain2 project (project pillar capacity development, development of e-learning units); clinical assessor in Unit 32 'Infectiology/Dermatology/Allergology'.

At the BfArM since 2022. Pharmacist, studied pharmacy at the University of Münster, doctorate at the Institute of Pharmaceutical Technology and Biopharmacy at the University of Bonn.

Dr. Magdalena Schilling

Project coordinator for the Biosimilar Fellowship of the GHPP PharmTrain2 project (project pillar capacity development and e-learning assessment of biosimilars) and quality assessor in Unit 35 'Pharmaceutical Biotechnology, Quality Inspections'.

At the BfArM since 2021. Studied biomedical chemistry at the University of Mainz; Doctorate in protein biochemistry at the University of Cologne - graduate of the Cologne Graduate School of Ageing Research; experience in science management.

Dr. Michael Marleaux

Project coordinator of the GHPP PharmTrain2 project (project pillar capacity development, e-learning biosimilar assessment) and assessor in Unit 23 'Diabetes mellitus/cardiovascular system'.

Since 2023 working as a parental leave replacement for Dr. Charlotte Norkus at BfArM. Studied biology at the University of Bonn; Master in Life and Medical Sciences at the University of Bonn. Doctorate in the field of structural biology at the University Hospital Bonn.

Anna Weiss

Project assistant of the GHPP PharmTrain2 project.

Working at the BfArM since May 2019. Specialist for office communication, organisation, administration and controlling to support project coordination.

.

PharmTrain2 Project Pillar I: Strengthening African Medicines Regulatory Authorities through Development of Structures

A unique process for the development of regulatory documents in the West African region was established. Since 2020 the four National Medicine Regulatory authorities (NMRAs) of Ghana, Liberia, Sierra Leone, and the Gambia have been collaborating with the GHPP PharmTrain project team to develop harmonised guidelines for marketing authorisation. The partnership with the young regulatory authorities of Liberia, Sierra Leone and the Gambia already began in 2019. Comprehensive reviews of existing regulatory frameworks for marketing authorisation, including legal provisions, guidelines, and standard operating procedures (SOPs) were carried out at the three West African authorities. Documents identified as missing were prioritized based on their importance to ensure an efficient and stable drug regulation. The priorities of the three West African authorities were found to be very similar, leading to collaborative working group called „Technical Working Group for Guidelines in Marketing Authorization (TWG-MAG)". In addition, the PharmTrain team engaged with FDA Ghana, one of the most advanced regulatory authorities in West Africa, to act as mentor for this working group. Beyond developing harmonised documents, this multilateral collaboration, supported by the PharmTrain team, fosters a stable network for mutual exchange, incorporating regional requirements into the guidelines. FDA Ghana benefits by critically evaluating its existing structures, identifying strengths and weaknesses, and optimising accordingly.

In 2020, the working group developed the „Guideline on Guidelines" as a foundation for guideline development, standardising development processes and document structures. This regulatory framework outlines the decision-making process and the steps required before and during the development and implementation of a guideline. A key element in the development of documents is to assess whether an existing guideline can be adopted (the „adoption approach") or a new document must be created („new development approach"). The collaborative approach of the working group and the adoption strategy save time and resources, build mutual trust, and prevent duplication of effort.

Prof. Dr. Karl Broich, President of the BfArM, together with the TWG-MAG and WHO, the project team as well as BfArM staff (Source: BfArM).

By December 2022, eight regulatory guidelines for marketing authorisation were developed. Each partner took the lead in drafting at least two guidelines, which were critically reviewed and discrepancies resolved by the working group. In the beginning, the TWG-MAG worked virtually due to the COVID-19 pandemic, which posed challenges such as connectivity issues and other technological challenges. In response to this, the PharmTrain team organised a hybrid workshop in November 2021 that led to an acceleration of the development process. For the first time the working group met the PharmTrain team in person during the workshop in Accra, Ghana in mid-September 2022.

The new project phase started with a kick-off workshop of the TWG-MAG at BfArM in spring 2023. Experts from BfArM and WHO representatives supported the work during this event. The current project phase focuses on continuing the guideline development, implementing the guidelines by the NMRAs, and creating NMRA-specific SOPs. A major success of this collaboration is the publication of all 17 jointly developed

guidelines intended for further use by other NMRAs. Beyond activities in West Africa, the PharmTrain team has been involved in the development of guidelines and SOPs on the continental level since 2023. The PharmTrain2 project is a technical partner of AUDA-NEPAD and an active member of the „AMRH Partnership Platform“ thereby supporting the establishment of the African Medicines Agency (AMA).

For further information, please visit the BfArM website: https://www.bfarm.de/EN/BfArM/EU-and-International/International-collaborations/GHPP-Global-Health-Protection-Programme/PharmTrain/Guidelines/_node.html

Members of the Technical Commitee for the Evaluation of Medicinal products (EMP-TC) and representatives of the PharmTrain team worked together on regulatory guidelines for the continental procedure in Cape Town in October 2023 (Source: AUDA-NEPAD)

PharmTrain2 Project Pillar II: Strengthening Regulatory Competencies through Capacity Development and Fellowships

The African Union Development Agency (AUDA-NEPAD) has established eleven Regional Centres of Regulatory Excellence (RCOREs) across the national medicines regulatory authorities (NMRA) in Africa, which play a key role in developing regulatory capacity in their respective regions and beyond. The RegTrain-PharmTrain/ PharmTrain2 project is partnering with four authorities from this pool for their fellowship programmes. With participants from Ghana, South Africa, Tanzania, and Zimbabwe these programmes are based on the train-the-trainer principle. In addition to scientific and regulatory content, also trainings on methods and didactics are included. The aim is to efficiently disseminate knowledge via the RCORE function of the respective national authorities and to ensure sustainability.

For the first time in 2019, assessors from Ghana and Zimbabwe came to the BfArM for an eleven-week workshop. They were trained in the clinical assessment of marketing authorisation dossiers and gained insights into these processes in Germany and Europe.

Despite the challenges posed by the COVID-19 pandemic, the switch to a virtual format in spring 2021 allowed the Clinical Fellowship programme to be continued and expanded to a total of ten participants (fellows) from three countries. The training content was continuously tailored to the needs of the fellows and their authorities. Each of these programmes had a duration of 200 hours. The PharmTrain team continued the programme in 2022 as ‘FellowshipPlus,’ which consisted of monthly virtual training sessions and a two-week workshop in Germany. Supported by BfArM experts, the fellows learnt about specific aspects of the assessment and how to apply them in practical exercises. During the practice-oriented workshop in Germany, they also remotely attended the CMDh (Coordination Group for Mutual Recognition and Decentralised Procedures - Human) and CHMP (Committee for Medicinal Products for Human Use) meetings at the European Medicines Agency (EMA). Regular, systematic tests proved the fellows‘ knowledge gain. The establishment of a solid network between the four authorities was another important objective.

PharmTrain clinical fellows with the PharmTrain team and Emer Cooke, Head of the EMA and Prof. Dr. Karl Broich, President of the BfArM. (Source: BfArM)

Starting with the second funding phase in 2023, two assessors from South Africa joined the programme. The twelve fellows regularly act as trainers themselves and develop together the 'Joint Training Manual for Clinical Assessment', a training programme on clinical assessment to provide less experienced assessors a basic yet comprehensive introduction to the complex topic. The fellows train their colleagues on relevant topics in their respective authorities or at regional meetings. These trainings facilitated by the PharmTrain project not only fulfil a relevant role at regional level, but are also important in preparing for harmonised drug approval in Africa. The African Medicines Agency (AMA) is currently being operationalised and the PharmTrain fellows already constitute an essential pool of clinical experts for the emerging agency. With their trainings, they contribute significantly to creating a common understanding of the regulatory requirements.

In addition to the need for training in clinical assessment, the partner authorities repeatedly expressed the demand for training on 'biosimilar products', i.e. generic products for biotechnologically manufactured medicinal products. Consequently, the PharmTrain team, in close collaboration with other BfArM experts, started another fellowship programme on the topic of 'Assessment of Biosimilars' as part of the second programme phase. Following a kick-off event in May 2023 and several virtual meetings, the ten biosimilar fellows from Ghana, South Africa, Tanzania and Zimbabwe visited the BfArM for the first time in October 2023 to receive three weeks of on-site training. On the occasion of this workshop, high-ranking representatives, e.g. of the WHO and AMRH were invited to a symposium held at the BfArM. Similar to the Clinical Fellowship, the biosimilar fellows also develop a "Joint Training Manual on the Assessment of Biosimilars" with the aim of creating a foundation for the standardised and harmonised evaluation of this special group of medicinal products in Africa.

Another milestone of the PharmTrain2 project is the development of an e-learning module on the evaluation of product information for medicinal products, which will be published in 2024. It consists of eleven units, some of which are specifically tailored to the situation in Africa. Professionally designed videos convey the content in an appealing way. Test questions consolidate the knowledge learnt. This eight-hour module will initially become available to our partner authorities over the next few months and contribute to further strengthening regulatory capacities. In addition, a second e-learning module on the assessment of biosimilars is currently being developed to provide the basics of this topic to a broader audience in a flexible format. For further information, please visit the BfArM website: https://www.bfarm.de/EN/BfArM/EU-and-International/International-collaborations/GHPP-Global-Health-Protection-Programme/PharmTrain/Pillar-Capacity-Development/_node.html

PharmTrain biosimilar fellows meet high-ranking representatives from the field of drug approval at the symposium 'Regulatory Landscapes in Africa, the EU and Germany' in October 2023. In addition to the PharmTrain team, the panel included Prof. Dr. Werner Knöss (Vice President BfArM), PD Dr. Harald Enzmann (CHMP Chairman) and international guests Farai Masekela (Chairman of EMP-TC), Dr. Murray Lumpkin (Bill and Melinda Gates Foundation, BMGF) and Dr. David Mukanga (BMGF) (Source: BfArM)

Interview Partner PharmTrain2: Dr. Mimi Delese Darko, CEO Food and Drugs Authority, Ghana

Dr. Mimi Delese Darko, CEO Food and Drugs Authority Ghana

How will you describe the collaboration with the PharmTrain project? Could you share how this collaboration unfolded?

The collaboration has been helpful in building capacity in the area of clinical assessment and recently biosimilar assessment. It has also impacted in structure building in the area of guideline development and review. This started with a meeting between the FDA Ghana and the project lead from BfArM where the proposal was shared and agreed with the FDA.

What specific changes has the PharmTrain project initiated within your agency, particularly in terms of regulatory process and collaboration?

In the area of capacity building a total of four assessors are being trained in clinical assessment and four in biosimilar dossier assessment. The first four staff who have been trained under the project have impacted other assessors within the marketing authorization department by organizing trainings internally and through their involvement in routine assessment and discussion. It has resulted in significant improvement in the capacity of the FDA Ghana for the assessment of the clinical part of the medicinal product dossiers. We have improved some existing guidelines through these collaboration and are working on adopting new guidelines that have been developed through this collaboration. A very good example is the guideline of guidelines which has been adopted by the FDA. All our existing and new guidelines are being aligned with the guideline on guidelines. It has therefore contributed to our preparation for WHO GBT level 4 status. It has also afforded us the opportunity to support other agencies within the subregion in building structures for proper regulatory function such as SOPs and guidelines development and review.

How do you envisage the future collaboration between your agency and BfArM, both within the context of your own institution and in support of the African continent (AMRH/AMA)?

We hope this collaboration continues. The collaboration will have a positive impact on the activities of WAHO (West African Health Organization) and AMA (African Medicines Agency). Clinical assessors that are being trained will be very useful in assessment of dossiers that are submitted for joint assessment at the regional and continental levels. The structure of the program enables staff of the FDA to work closely with their counterparts from other agencies on the continent. This enables knowledge sharing and improves the agenda for regulatory harmonization within regional blocks and the continent. Also based on the extensive work that some of our staff have done in the area of guidelines development through this collaboration, I believe they will be very resourceful to the AMA in developing very useful guidelines.

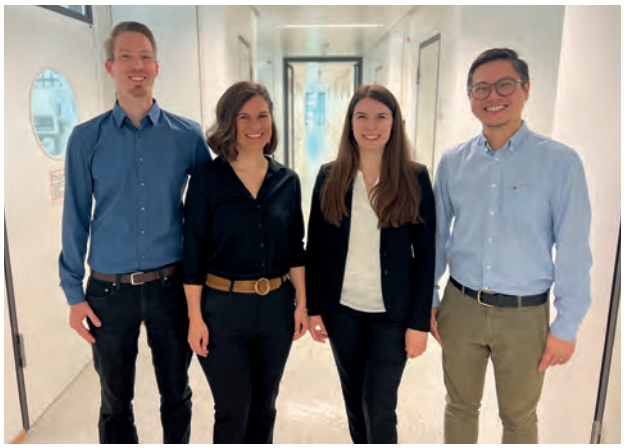
Cooperation of the GHPP Projects at the BfArM

PharmTrain2 team at the BfArM (Source: BfArM)

The GHPP project teams at the BfArM - LabTrain and PharmTrain2 - liaise regularly in order to coordinate their activities. The cooperation also extends to the selection of the partner countries and authorities supported. Through this close exchange, both projects can ensure that their activities are harmonised, which leads to a greater impact. An outstanding example of cooperation was the joint kick-off event in June 2023.

LabTrain and PharmTrain2 joint kick-off event with WHO and BfArM experts (Source: BfArM).

This important meeting marked the official start of the new project funding phase and provided a well-suited platform for the first visits by fellows, trainees and international partners. Participants were familiarised with the objectives and methods of the LabTrain and PharmTrain2 projects and the foundations for fruitful collaboration between the two GHPP projects at the BfArM were laid for the coming years.
The ongoing coordination of the LabTrain and PharmTrain teams makes it possible to identify synergies, learn and benefit from each other. Sharing best practices



LabTrain team at the BfArM (Source: BfArM)

and knowledge, ensures efficient use of resources for both projects. This does not only increase the effectiveness of the individual projects, but also builds trust and partnership within the entire project community. The interviews with the project leads in this edition illustrate how the projects relate to the tasks and legal mandate of the BfArM.

Successfully Completed GHPP Projects

GHPP CPA: Combatting Antimicrobial Resistance – Scientific Training for Rational Use of Anti-Infectives

Infectious diseases pose a significant challenge to healthcare in Africa and worldwide, particularly due to the increasing development and spread of antimicrobial resistance (AMR). These resistances often arise from improper medication choices or misuse, such as irregular intake or premature discontinuation. Although the availability of anti-infectives is secured in some African countries, proper use remains crucial to maintain their effectiveness. Training for healthcare professionals, public education, and monitoring programs are essential to prevent the emergence and spread of AMRs and to ensure successful treatments.

To address this need, the project "CPA - Combatting Antimicrobial Resistance – Scientific Training for Rational Use of Anti-Infectives" was initiated in 2017 as part of the Global Health Protection Programme (GHPP). In 2019, it was expanded with additional measures through the supplementary project "CPA PLUS." The focus of the project was on advancing the training of scientific personnel in Southern Africa and further developing knowledge transfer in the areas of personalized medicine and rational use of anti-infectives.

The overarching goal was to establish a network for clinical pharmacology in Southern Africa that could implement measures to prevent or mitigate antimicrobial resistance by optimizing the use of anti-infectives in clinics. Throughout the project, a particularly collaborative partnership developed between the partner organizations in Zimbabwe and Zambia, both in research and in training and education.

A significant factor in the successful establishment of this network was the collaboration in research on anti-infective therapy topics. Various questions with local relevance were addressed and published scientifically. At the same time, the research projects highlighted the continuing need in the countries for anti-infective therapy, clinical pharmacology, and pharmacogenetics. Within the network, the partner countries were supported in knowledge transfer and sustainable scientific education in clinical pharmacology. The project supported three PhD students in their research projects and the publication of scientific papers. An important outcome of the CPA/CPA PLUS project was the recognition that, in addition to generating knowledge through research, knowledge dissemination in clinical pharmacology in academic settings and the continuing education of healthcare personnel also needed to be expanded. This was addressed by developing training materials for academic education within the project.

Furthermore, the partner organizations supported the development of a master's program from needs assessment through concept development to curriculum creation and validation by university committees.

BfArm project team members, project partners from the University of Zambia and AiBST Zimbabwe (Source: LabTrain)

Interview with Prof. Collen Masimirembwa

Prof. Collen Masimirembwa: President and Chief Scientific Officer at the African Institute of Biomedical Science and Technology (AiBST)

How would you describe the collaboration with the GHPP CPA project at BfArM? Could you share insights into how this collaboration unfolded?

The collaboration started following Professor Julia Stingl (BfArM) and Professor Collen Masimirembwa (AiBST) meeting and discussing possibilities of research collaboration in their area of shared interest, pharmacogenetics (PGx) and pharmacokinetics (PK) in 2012. They proposed to work on a Europe-Africa project to increase awareness of pharmacogenetics among medical professional, patients and the public through use of various media tools, training of postgraduates in the field of PGx, and promoting the transition from population pharmacogenetic studies to clinical pharmacogenetics for health impact. This resulted in a Global Health Protection Programme (GHPP) grant from 2017-2021 entitled Combating Antimicrobial Resistance by Promoting Rational Use of Anti-infective Drugs (CPA). This work resulted in a strong collaboration involving institutions from Germany (BfArM), Zimbabwe (AiBST), and Zambia (UNZA). This collaboration produced three publications, a postdoctoral fellowship of Dr Mkombwe from Zambia (UNZA) at the AiBST in Zimbabwe, a visit by the BfArm team to AiBST and an internship of an AiBST PhD student at the BfArM.

What specific changes has GHPP CPA initiated within your agency, particularly in terms of (regulatory) processes and collaboration?

Our Institute, the African Institute of Biomedical Science and Technology, AiBST, is not a regulatory agency but a research and training institute that works closely with the regulatory authority in Zimbabwe, the Medicines Control Authority of Zimbabwe (MCAZ). The GHPP CPA has helped us conduct research in collaboration with MCAZ (Mbavha et al., 2021) that helped the Authority appreciate the potential importance of pharmacogenetics in the approval and procurement of medicines in Zimbabwe. The work has further resulted in Prof. Collen Masimirembwa getting funding from the Bill and Melinda Gates Foundation (BMGF) to conduct an implementation study on pharmacogenetics guided treatment in 6000 patients in South Africa, Zimbabwe, Kenya, and Nigeria. He also got a second BMGF grant to engage drug regulators across Africa including the African Medicines Agency (AMA) on developing an African genomic diversity policy framework on how drug developers and regulators should take African's genetic heterogeneity into account.

In your opinion, what significant differences has GHPP CPA made to the regulatory systems in your region, particularly in terms of (regulatory) processes and procedures?

The GHPP CPA has not yet made a difference but has set in motion activities that are expected to make a huge difference in terms of clinical pharmacogenomics.

What are your long-term goals and aspirations for the collaborative work between your agency and BfArM, both within the context of your own institution and in support of the African continent (AMA)?

The long-term goal in the collaboration between BfArM and AiBST is to build research capacity for drug analysis and genomic analysis to better understanding of the opportunities in implementing pharmacogenetics-guided treatment. In addition to methodological work, the collaboration aims to develop and deploy educational material to increase knowledge, aware-

ness, and guidelines to healthcare practitioners (nurses, lab scientists, pharmacists, and doctors) on the implementation of genomics guided medical practice. With respect to the African Medicines Agency (AMA), the collaboration aims to gather data on pharmacogenomics in Africa and present it to AMA in the form of a highly consultative policy framework which can help AMA come up with a policy on how the genomic diversity of African populations should be taken into account in the registration and clinical use of medicines in people of African ancestry.

LEARN: Cross-Project Evaluation of E-Learning Concepts to Support sustainable Capacity Building within the GHPP

With the onset of the COVID-19 pandemic, online tools and e-learning platforms became an integral part of the working culture in GHPP projects, being used across the entire spectrum of communication activities and project work. Prior to the COVID-19 pandemic, interaction within GHPP projects was primarily based on email correspondence and personal contacts such as training sessions and on-site visits. Only a few projects had started using online learning platforms at that time.

To gain an overview of new developments in electronic learning and communication methods, as well as the use and dissemination of online tools and e-learning platforms in GHPP projects, data was collected and analyzed through an online survey among all GHPP projects that had commenced before 2020.

During the COVID-19 pandemic, the use of online tools for project activities increased significantly, with the use of video conferencing growing particularly strong across all regions. These tools were used more frequently for communication, document exchange, and collaboration, and this trend is expected to continue post-pandemic. 92% of respondents rated their experiences with online tools as positive.

Virtual collaboration with African partners presents numerous challenges, often influenced by cultural, organizational, and technical factors. One of the major technical hurdles is infrastructure. In many African countries, internet connectivity can be unstable or slow, significantly hindering communication and collaboration. Additionally, frequent power outages can disrupt work continuity and stall projects.

Another aspect complicating virtual collaboration is the time difference. Coordinating meetings and deadlines across different time zones can be challenging and requires careful planning and flexibility from all parties involved. Building trust and maintaining relationships are also central challenges. Virtual collaboration can make it difficult to build trust and foster personal relationships, which are often crucial for the success of collaborative projects.

To address these challenges, several strategies can be implemented. Regular communication through video calls and virtual team activities can help strengthen personal relationships and build trust. Additionally, where possible, occasional in-person meetings on-site can further enhance trust and collaboration. By being aware of these challenges and implementing appropriate strategies, institutions and projects can make their collaborations with African partners more effective and successful.

The survey results and comprehensive context were discussed in online workshops organized by BfArM on digital collaboration in individual GHPP projects and e-learning in the context of digitalization and international cooperation with GHPP project partners. A final survey report summarized the results from the surveys, workshops, and research on suitable e-learning platforms, placing them in an international context. Consequently, recommendations for GHPP projects for a new funding phase were developed and issued.

The PharmTrain-CoronaGlobal Project: Health Crises Caused by Infectious Diseases – A Persistent Threat?!

Infectious agents do not respect borders, making their impact even more critical in our globalised world. Epidemics and pandemics affect health, society, and the economy on a large scale. Which measures can we take to mitigate these developments? Without a doubt, a robust healthcare system with effective emergency preparedness and response measures provides the best protection. The COVID-19 pandemic has highlighted the importance of an efficient drug supplies for securing the health and well-being of the population. In health crises, it is vital that prevention and treatment options are made available to the public as quickly as possible.

From May 2021 to March 2023, the PharmTrain-CoronaGlobal project, led by BfArM, aimed to strengthen NMRAs in the Southern African Development Community (SADC) region during health emergencies. The SADC region comprises 16 countries with a population of 380 million people. It is currently considered one of the most peaceful regions on the continent. Besides multinational collaboration among NMRAs in this region, a longstanding partnership with the GHPP PharmTrain project and SADC has been established.

The objective of the PharmTrain-CoronaGlobal project was to develop a regional framework for accelerating the approval of medicinal products during emergencies, known as the „Emergency Use Authorisation (EUA)." This document was drafted between September 2021 and October 2022 and endorsed by the SADC heads of agencies in November 2022. It outlines both the data requirements and steps required under this procedure for expediting regulatory decision-making in public health emergencies. It serves as a template for NMRAs in the SADC region to create harmonised national guidelines for Emergency Use Authorisation. The PharmTrain-CoronaGlobal team collaborated with representatives from the authorities of Angola, Botswana, Comoros, Lesotho, Madagascar, Mozambique, Namibia, South Africa, Tanzania, Zambia, and Zimbabwe. Based on the World Health Organization's (WHO) „Emergency Use Listing Procedure," the working group developed this regional framework, tailored to local needs and conditions of the SADC region (SADC-EUA Framework, or SADC-EUA-F). The framework is available on the BfArM's GHPP PharmTrain2 website under "Publications". This comprehensive document helps to close gaps in emergency preparedness at national level, thereby enhancing the capacity to respond to health crises. It also promotes harmonised processes and fosters trustworthy collaboration among authorities in Southern Africa. Its application may result in standardisation of the evaluation of candidate medicinal products and their expedited approval. In the second phase of the PharmTrain-CoronaGlobal project, the NMRAs of Madagascar, Namibia, Tanzania, and Zambia each developed country-specific guidelines based on the framework, while the South African authority updated its guideline accordingly. This demonstrates the framework's suitability as a model for national guidelines. Furthermore, the framework already formed the basis for the draft EUA guideline of the African Medicines Agency (AMA). This project, completed in just 23 months, has a profound and significant impact on Africa's preparedness for health crises.

The SADC-EUA framework in the hands of the working group (Source: PharmTrain team)

IMPRINT

Publications, including extracts, require the authorisation of the BfArM.

Published by
Federal Institute for Drugs and Medical Devices
Kurt-Georg-Kiesinger-Allee 3
53175 Bonn

Concept/editing
Lilian Pfender

Authors
Lilian Pfender, LabTrain team, PharmTrain team

Layout/graphics
Lilian Pfender, Alper Özer

Picture credits
Lilian Pfender, LabTrain team, PharmTrain team, AUDA-NEPAD

Published
June 2024