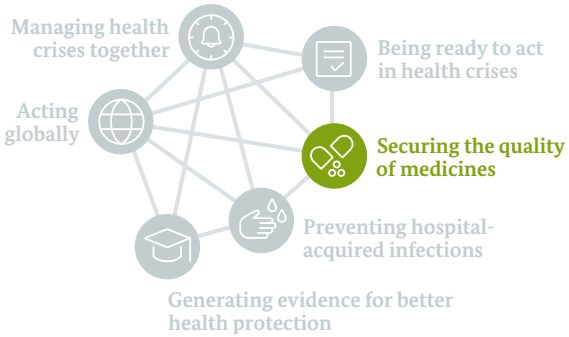


GHP Programme

Availability, Safety, and Quality of Blood and Blood Products

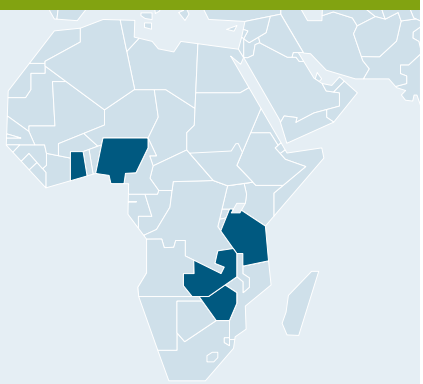
BloodTrain

Supporting the Development of a Regulatory Structure and its Adaptation to Crisis Situations in Partner Countries

Duration
2016–2021

Budget/year
BloodTrain I + II:
approx.
2016–2018: 450,000 EUR
2019–2021: 900,000 EUR

Partner countries
Ghana
Nigeria
Tanzania
Zambia
Zimbabwe



Challenges addressed by the project

In many African countries, blood supply is not available in adequate quantity and/or of acceptable quality. This is all the more critical, since the demand for blood components for transfusion is comparatively high in Africa due to infectious diseases, early childhood anaemia caused by malaria, or bleeding after giving birth. As a result, around 44 percent of maternal mortality is caused by postpartum bleeding. Safe blood components would help reduce this figure drastically. However, performing, processing and storage of a blood donation as well as testing strategies are often inadequately regulated or monitored, or these steps are not performed altogether. This, for example, dramatically increases the risk of a transfusion-related transmission of infectious diseases like HIV or hepatitis.

Objectives

A structured analysis of the status-quo in the areas of collection, manufacture, and supply of blood and blood components in the African partner countries revealed the weaknesses in the blood supply chain of the countries concerned. Customised working plans serve to determine supporting activities and set up suitable regulatory structures to create the preconditions for achieving the longer-term goal of BloodTrain, which is to establish a harmonised regulatory system for medicines throughout Africa in cooperation with AUDA-NEPAD. Altogether, the work of BloodTrain contributes to improving the quality, safety, and availability of blood and blood products in Africa. This will also strengthen health systems in the partner countries and beyond, thus supports the reduction of maternal and child mortality. Thanks to well-established structures, the countries will also be able to react adequately and more efficiently in the event of a disaster.

Overview of activities

Benchmarking

BloodTrain investigated the extent to which a regulation system for blood and blood products as well as related medicinal products and in vitro diagnostics (IVDs) is present across ten African countries. The results of this study demonstrated that manufacture and monitoring of blood and blood products are practically unregulated. For this reason, the BloodTrain team prepared customised development plans for each country.

Supported by:

Federal Ministry of Health

on the basis of a decision by the German Bundestag

BloodTrain team at the Paul-Ehrlich-Institut

BloodTrain trains the inspection of a blood establishment

Partner authorities are actively involved in the workshops through poster presentations or case studies

Group work for the analysis of real life case studies during a training workshop

Photos ©PEI

Pilot partner countries programme

BloodTrain supports five partner countries in developing and implementing regulatory structures for blood and blood products. To achieve this, individual training and indepth technical support for policies and guidance documents have been developed. This includes specialised training workshops such as the inspection of blood establishments, setting up a reporting system for adverse effects during blood transfusions (haemovigilance), the marketing authorisation of blood and blood products, and the regulation of in vitro diagnostics and plasma derivatives. During the pandemic, this interaction is maintained by online support and virtual workshops. To facilitate this collaboration appropriate e-learning structures have been developed.

African Blood Regulators Forum

BloodTrain was instrumental in supporting and driving the establishment of this platform for blood regulators to exchange their knowledge and experiences. BloodTrain together with PEI colleagues contributes its knowhow as associated partner on a long-term basis. The forum develops harmonised standards in blood regulation and is committed to implementing these standards across Africa. BloodTrain also supports their new working group on Convalescent Plasma, which is currently being discussed as a possible treatment option for patients with severe COVID-19.

Regulatory programme

In cooperation with AfSBT, the aim is to increase the acceptance for blood regulation in blood establishments. BloodTrain trains their staff and supports in facilitating contacts with the regulatory authorities.

Partner institutions

- National regulatory authorities in the partner countries: Ghana, Nigeria, Tanzania, Zambia, Zimbabwe
- Africa Society for Blood Transfusion (AfSBT), South Africa[1]
- African Union Development Agency – New Partnership for Africa's Development (AUDA–NEPAD), South Africa[2]
- World Health Organisation (WHO), Switzerland

Supporting institution in Germany/Contact

Paul-Ehrlich-Institut
Division of Haematology and Transfusion Medicine
International Coordination/Regulatory Service
Dr Anneliese Hilger, Dr Jens Reinhardt bloodtrain@pei.de
www.pei.de/en

1 Being a professional scientific organisation, AfSBT supports structures at the interface of regulation, blood establishments and hospitals
2 NEPAD is an important intra-regional partner in Africa, which is committed to a regulation system in the medicines sector in the African continent