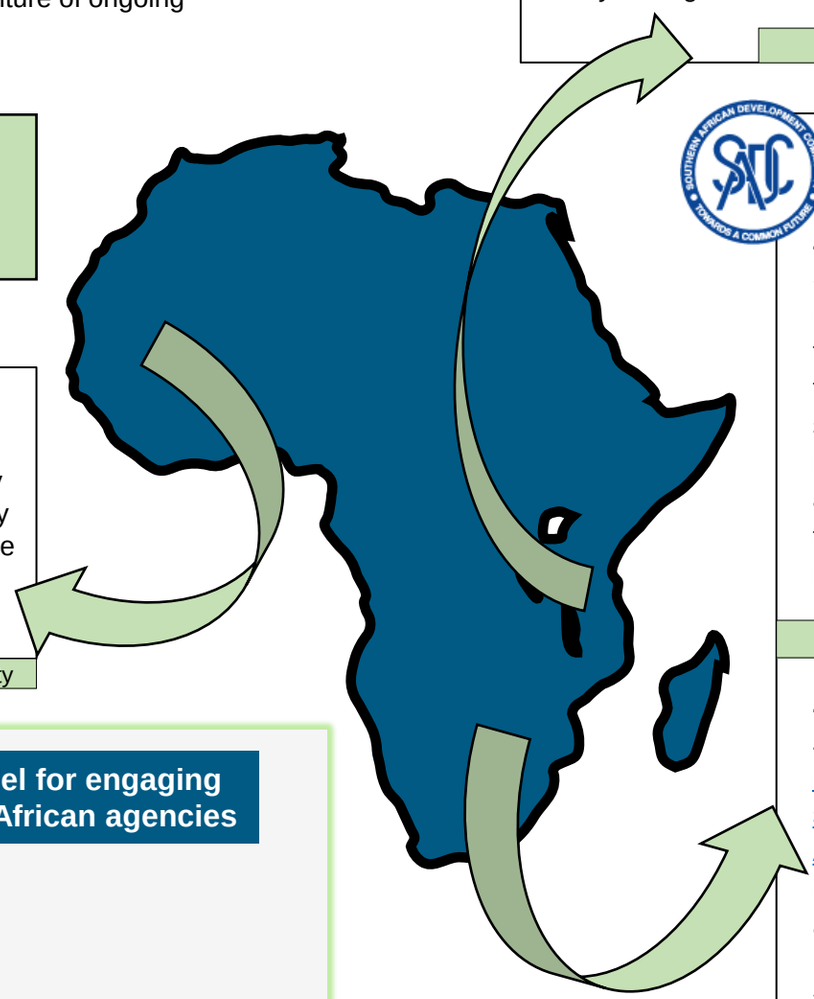
Impact case study: supporting the establishment of the African Medicines Agency through performance metrics

CIRS strategic pillars addressed: Metrics | Quality | Alignment

There are 55 regulatory agencies that govern medicines regulation across Africa. Many of these agencies have limited resources and do not have a robust complement of systems, skills and capabilities in place to provide effective and efficient regulatory support. This results in delays in medicines reviews and approvals, an increased likelihood of poor-quality medicines entering the market, and delays in patient access to critical medicines.

Over the last decade, much work has been done to improve regulatory capacity, capability and collaboration across Africa. CIRS has played a key part in this by giving African regulators and regional regulatory initiatives in the Optimising Efficiencies in Regulatory Agencies (OpERA) programme the tools to measure their efficiency and effectiveness. This has allowed barriers and opportunities for improvement to be identified and helped to embed a culture of ongoing performance monitoring and self-assessment.

The overall aim of the OpERA programme within Africa is to evaluate the regulatory performance of agencies and regional assessment initiatives to support the treaty for the establishment of the African Medicines Agency.



East African Community (EAC)

Seven agencies in the region have completed a questionnaire that rates their efficiency and effectiveness. These data have been analysed and are currently being put into a manuscript for publication, which will include recommendations for the region to improve its performance. In 2022, CIRS hopes to investigate what companies think of the efficiency and effectiveness of the EAC joint assessment by asking them complete a modified version of the agency questionnaire.

PhD student: Nancy Ngum, New Partnership for Africa Development

West African Health Organisation (WAHO)

Work is underway to evaluate the effectiveness and efficiency of seven agencies who are active in the Economic Community of West African States (ECOWAS). Similar to the studies in the EAC and ZaZiBoNa regions, companies' perspectives of the WAHO joint assessment will also be investigated.

PhD student: Mercy Acquaye Owusu-Asante, Ghana Food and Drug Authority

Southern African Development Community (SADC)

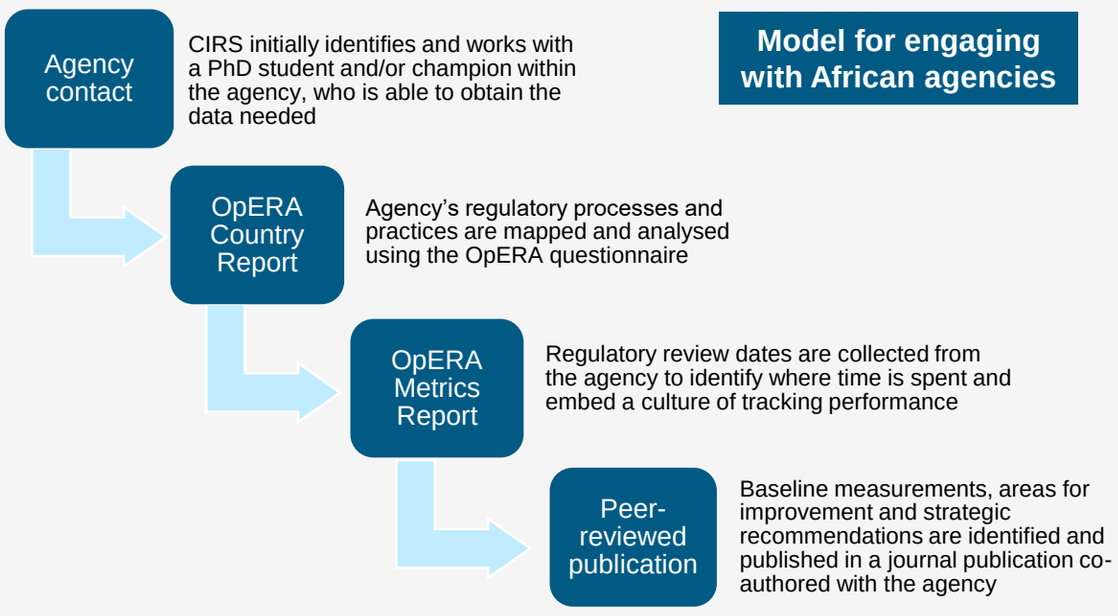
ZaZiBoNa - six agencies who are active in ZaZiBoNa, the Southern African Development Community (SADC) collaborative medicines registration initiative, have been evaluated in terms of their Good Review Practices, review models and approval timelines, resulting in two peer-reviewed publications. A further study of all nine active ZaZiBoNa agencies is currently being prepared for publication; this evaluated the region's efficiency and effectiveness, both from the agencies' perspective and from the perspective of companies. This is the first time ZaZiBoNa has been evaluated in such a way by both stakeholders.

PhD student: Tariro Sithole, Medicines Control Authority of Zimbabwe

Zimbabwe – In 2021 two peer-reviewed publications on Zimbabwe were published; the first assessed OpERA-collected metrics from the Zimbabwe agency for 2017-2019, while the second compared the Zimbabwe agency with the agencies in Australia, Canada, Switzerland and Singapore. Both publications included recommendations for improvement, such as developing a decision-making framework and enhancing transparency.

South Africa – a key aspect of CIRS' work with South Africa has been around the implementation of reliance pathways. The introduction of abridged and verification reliance pathways has successfully helped the South African agency to address its backlog of marketing authorisation applications, reducing approval timelines for these applications by 68%. CIRS continues to work closely with the South African agency on various aspects of its performance as it looks to achieve the next maturity level of the WHO Global Benchmarking Tool (GBT) indicator.

Model for engaging with African agencies



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