



CLINICAL TRIAL KPIs

Harmonization across TMDA, Ethiopia FDA, Rwanda FDA, Uganda NDA

a part of the



**Grand Challenges: Enhancing Data Systems of
African National Regulatory Agencies**

Gates
Foundation

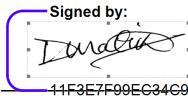
BROAD REACH™
group

Global Health
Analytics Group

Confirmation and Approval

The contents of this document have been reviewed, confirmed and approved by each of the four National Regulatory Agencies in Tanzania (TMDA), Ethiopia (EFDA), Rwanda (RFDA) and Uganda (UNDA).

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Background

As part of the Gates Foundation's Grand Challenges program ***Enhancing Data Systems of African National Regulatory Agencies***, the East African group of National Regulatory Agencies (NRAs) participating in this program committed to working together to arrive at a subset of KPIs across Marketing Authorization (MA), Clinical Trials (CT) and Good Manufacturing Processes (GMP) that they could all align around towards the goal of achieving harmonization. The East African NRAs are as follows:

- **TMDA:** Tanzania Medicines and Medical Devices Authority Home
- **EFDA:** Ethiopia Food and Drug Authority
- **RFDA:** Rwanda Food and Drugs Authority
- **UNDA:** Uganda National Drug Authority

On the basis of maturity level seniority, TMDA was elected to lead this group of NRAs in the technical discussions and collaborations. Providing additional support were technical advisory specialists from Global Health Analytics Group and the BroadReach Group, who also provided the Program Management Office (PMO) to oversee all efforts.

Approach

The teams utilized a highly collaborative approach based on mutual trust, transparency and integrity.

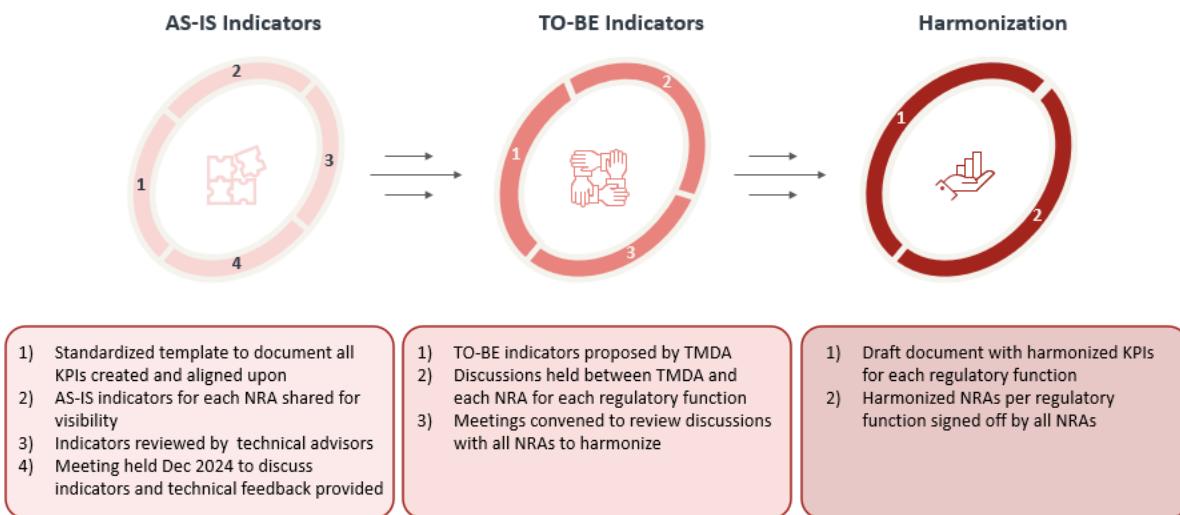


Figure 1: KPI harmonization approach

Each NRA initially shared their key indicators and processes for the regulatory functions (MA, CT, GMP) which were reviewed by Global Health Analytics Group, BroadReach and AMRH's MoE Community of Practice representatives. Based on the feedback, TMDA then proposed a set of KPIs that could be harmonized across the countries. As the KPIs fall across three different regulatory functions, the NRAs agreed to follow a staggered manner. CT KPIs would be harmonized first, followed by MA and then GMP.

The group then reported back on their individual discussions with TMDA and with BroadReach and Global Health Analytics Group advisory support, aligned on a final set of KPIs for Clinical Trials. Nuanced differences between NRAs have been noted.

These KPIs are designed to meet a minimum maturity level of 3, as outlined in the WHO Global Benchmarking Tool (GBT) framework. To achieve this, National Regulatory Authorities (NRAs) will as a part of this program, undertake a review of their processes to harmonize them and align with Maturity Level 3 requirements, which emphasize the standardization and documentation of processes. Additionally, clear process owners will be established to ensure accountability, and the effectiveness of these processes will be monitored through the identified KPIs. Following this, NRAs will focus on ensuring that staff receive regular training on these processes, enabling consistent execution across the organization.

Harmonized set of Clinical Trial KPIs

Five KPIs were proposed by TMDA under the Clinical Trial function for harmonization across the four NRAs. Post discussions, this set of KPIs was expanded to a total of 8 indicators that have been widely agreed upon. However, specific nuances and exceptions have been noted.

Table 1: KPIs discussed for harmonization and final agreements

| | | | | | | | | |
|--|---|---|---------|---|--|-----|------|-----------|
| 8. | Average turnaround time to complete evaluation of CT applications | 3 | Process | Sum of times taken to complete evaluation of each application | Total number of evaluated applications | N/D | Days | Quarterly |
| <ul style="list-style-type: none"> ✓ Harmonized between Rwanda FDA, TMDA and Uganda NDA. ● Modification for Ethiopia FDA: Reporting frequency will be semi-annual ✗ | | | | | | | | |

To note: KPI 8 (Average turnaround time to complete evaluation of CT applications) is a supplementary indicator that will help NRAs to set the “specified” timeline in KPI 1 appropriately. This will help the NRA to continuously improve their timelines. Outliers in the datasets however should be analyzed and actioned as these can skew the average.

Supplemental Clinical Trial KPIs tracked by NRAs (not harmonized)

The NRAs also discussed other KPIs that they thought helpful to either support the KPIs being discussed above or to strengthen specific areas of their clinical trials processes. These are listed below for reference and may form the basis of future discussions to expand the harmonization journey.

Ethiopia FDA will track the following as well:

Table 2: Supplemental indicators proposed by Ethiopia FDA

| # | KPI Name | Maturity Level | Indicator Type | Indicator calculation rules | | | Unit of Measure | Reporting Frequency |
|-----|---|----------------|----------------|---|---|-----------|-----------------|---------------------|
| | | | | Numerator (N) | Reporting Frequency | Formula | | |
| 2.1 | Percentage of received amendments of clinical trials evaluated | 3 | Output | Number of clinical trial amendment applications evaluated | Total number of amendment applications of clinical trial received | (N/D)*100 | % | Quarterly |
| 3.1 | Percentage of regulatory measures taken on clinical trials due to GCP inspection findings and safety concerns | 3 | Outcome | Number of regulatory measures taken on clinical trials | Total number of clinical trials conducted | (N/D)*100 | % | Quarterly |

| | | | | | | | | |
|-----|--|---|--------|-----------------------------------|---|-----------|---|-----------|
| 4.1 | Percentage of received safety reports that were assessed | 3 | Output | Number of safety reports assessed | Total number of safety reports received | (N/D)*100 | % | Quarterly |
|-----|--|---|--------|-----------------------------------|---|-----------|---|-----------|

These indicators are expected to supplement the KPIs numbered in Table 1. KPI 2.1 for example is the output indicator version of KPI 2 which is the process indicator version.

To note: Rwanda FDA can adopt KPI 3.1. It is a disagg of their KPI 3.3 shown in Table 3.

Rwanda FDA will track the following as well:

Table 3: Supplemental indicators proposed by Rwanda FDA

| # | KPI Name | Maturity Level | Indicator Type | Indicator calculation rules | | | Unit of Measure | Reporting Frequency |
|-----|---|----------------|----------------|---|----------------------------------|-----------|-----------------|---------------------|
| | | | | Numerator (N) | Reporting Frequency | Formula | | |
| 3.2 | # of triggered inspections conducted within the defined timelines | 3 | Process | Number of triggered inspections conducted within set timeline | N/A | N | Number | Quarterly |
| 3.3 | % of follow-up of regulatory actions within set timeline | 3 | Process | Number of regulatory actions followed-up within set timeline | Number of all regulatory actions | (N/D)*100 | % | Quarterly |

KPI 3.3 is the monitoring of follow-on actions of those inspections that did not meet requirements.

Way Forward

Following the acceptance of this document that lays out the indicators that have been aligned upon between the four NRAs, TMDA will take the lead in developing the User Requirement Specifications (URS) and thereafter the Design Specification for the CT component of the KPI Monitoring Tool that all NRAs have committed to building out as an enhancement to their existing Regulatory Information Management System (RIMS). While the tool will not be the exact same across all NRAs, given that their RIMS are all at different levels of customization, aligning on the URS and Design will help to further the goals of harmonization of KPIs across NRAs. This will also be shared with other NRAs beyond this group as needed.

The KPIs chosen to harmonize across the NRAs are high-level; each NRA will have more granular indicators that support the details behind each of these KPIs. As a future roadmap item, NRAs can work together to harmonize several of these indicators as well.

While all of the 8 indicators agreed upon will be added into the KPI monitoring tool, each NRA may add other indicators their organization needs visibility of. These additions will be done in alignment with the principles employed in the agreed upon URS and Design specifications.