LIST OF DELIVERABLES

Deliverables

Grant Preparation (Deliverables screen) — Enter the info.

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EU classified —RESTREINT-UE/EU-RESTRICTED, CONFIDENTIEL-UE/EU-CONFIDENTIAL, SECRET-UE/EU-SECRET under Decision 2015/444

Deliverable No	Deliverable Name	Work Package No	Lead Beneficiary	Type	Dissemination Level	Due Date (month)
D1.1	Guidance/algorithm in response to evaluation	WP1	8 - Rwanda FDA	R — Document, report	R-UE/EU-R - EU Classified	5
D1.2	Guidelines and SOP for evaluation	WP1	8 - Rwanda FDA	R — Document, report	R-UE/EU-R - EU Classified	8
D1.3	Joint evaluation of clinical trials	WP1	9 - TMDA	R — Document, report	R-UE/EU-R - EU Classified	24
D1.4	Post-approval Joint inspections of clinical trials	WP1	9 - TMDA	R — Document, report	R-UE/EU-R - EU Classified	30
D2.1	Baseline assessment report	WP2	2 - NIMR	R — Document, report	R-UE/EU-R - EU Classified	6
D2.2	Developing guidance documents for conducting performance evaluation	WP2	9 - TMDA	R — Document, report	PU - Public	12
D2.3	Performance evaluation of diagnostics and critical medical devices	WP2	9 - TMDA	R — Document, report	R-UE/EU-R - EU Classified	24
D2.4	Developing Protocols for conducting performance verification studies	WP2	9 - TMDA	R — Document, report	R-UE/EU-R - EU Classified	12
D3.1	Establishing a regulatory framework on health data and material sharing during the emergency periods	WP3	2 - NIMR	R — Document, report	R-UE/EU-R - EU Classified	28
D3.2	Data Managment Plan	WP3	2 - NIMR	DMP — Data Management Plan	SEN - Sensitive	6

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Deliverable No	Deliverable Name	Work Package No	Lead Beneficiary	Type	Dissemination Level	Due Date (month)
D4.1	Post-marketing protocol and plan developed	WP4	5 - ZFDA	R — Document, report	R-UE/EU-R - EU Classified	10
D4.2	Sample collections and perform product information reviews	WP4	5 - ZFDA	R — Document, report	R-UE/EU-R - EU Classified	20
D5.1	Training Needs Assessment	WP5	4 - MUHAS	R — Document, report	R-UE/EU-R - EU Classified	10
D5.2	Customization of short ethics course for Rwanda	WP5	3 - GSF KCMC	R — Document, report	R-UE/EU-R - EU Classified	16
D5.3	Preparation of training curriculum and materials for assessors	WP5	4 - MUHAS	R — Document, report	R-UE/EU-R - EU Classified	16
D5.4	Training of clinical trial assessors on in-vitro and medical devices CTs evaluation	WP5	4 - MUHAS	R — Document, report	R-UE/EU-R - EU Classified	30
D5.5	Training on rapid evaluation of therapeutic or vaccine trial	WP5	4 - MUHAS	R — Document, report	R-UE/EU-R - EU Classified	30
D6.1	Regulatory Capacity building of other SSA countries, and Sharing Scientific experience within consortium countries	WP6	9 - TMDA	R — Document, report	R-UE/EU-R - EU Classified	33
D7.1	Monitoring and Evaluation of the project	WP7	1 - KI	R — Document, report	R-UE/EU-R - EU Classified	36
D8.1	Awareness creation on the existence of the Project	WP8	3 - GSF KCMC	R — Document, report	PU - Public	36
D8.2	Launching of the project	WP8	3 - GSF KCMC	R — Document, report	PU - Public	2

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Deliverable No	Deliverable Name	Work Package No	Lead Beneficiary	Type	Dissemination Level	Due Date (month)
D8.3	Dissemination of reports to all stakeholders	WP8	3 - GSF KCMC	R — Document, report	PU - Public	36
D8.4	Website of the project	WP8	9 - TMDA	R — Document, report	PU - Public	4
D8.5	Exploitation and Dissemination plan	WP8	3 - GSF KCMC	R — Document, report	PU - Public	6

Deliverable D1.1 – Guidance/algorithm in response to evaluation

Deliverable Number	D1.1	Lead Beneficiary	8. Rwanda FDA
Deliverable Name	Guidance/algorithm in response to evaluation		
Type	R — Document, report	Dissemination Level	R-UE/EU-R - EU Classified
Due Date (month)	5	Work Package No	WP1

Description
Guidance and or algorithm in response to Evaluation and comments during an emergency outbreak in place.

Deliverable D1.2 – Guidelines and SOP for evaluation

Deliverable Number	D1.2	Lead Beneficiary	8. Rwanda FDA
Deliverable Name	Guidelines and SOP for evaluation		
Type	R — Document, report	Dissemination Level	R-UE/EU-R - EU Classified
Due Date (month)	8	Work Package No	WP1

Description
Guidelines and SOP for the evaluation of therapeutic and vaccine trials in a period of public health emergency

Deliverable D1.3 – Joint evaluation of clinical trials

Deliverable Number	D1.3	Lead Beneficiary	9. TMDA
Deliverable Name	Joint evaluation of clinical trials		
Type	R — Document, report	Dissemination Level	R-UE/EU-R - EU Classified
Due Date (month)	24	Work Package No	WP1

Description
A joint evaluation of clinical trials applications which are submitted to the Regulatory Authority and Ethics Committee will be conducted. Joint evaluation will be conducted by a group of assessors from TMDA, ZFDA, Rwanda FDA, NIMR, ZAHRI. Conducting joint evaluation of clinical trial protocols will reduce waiting time

Deliverable D1.4 – Post-approval Joint inspections of clinical trials

Deliverable Number	D1.4	Lead Beneficiary	9. TMDA
Deliverable Name	Post-approval Joint inspections of clinical trials		
Type	R — Document, report	Dissemination Level	R-UE/EU-R - EU Classified
Due Date (month)	30	Work Package No	WP1

Description
Conducting post-approval joint inspections of clinical trials to ensure they are conducted ethically. Joint inspection between TMDA, ZFDA, Rwanda FDA, ZAHRI and NIMR will be done. The TMDA and NIMR twining team of inspectors will be created and assigned for a site inspection of the approved

clinical trials. The inspection will be conducted at 18 and 30 months. The inspections will also be done in other consortium countries.

Deliverable D2.1 – Baseline assessment report

Deliverable Number	D2.1	**Lead Beneficiary**	2. NIMR
Deliverable Name	Baseline assessment report		
Type	R — Document, report	**Dissemination Level**	R-UE/EU-R - EU Classified
Due Date (month)	6	**Work Package No**	WP2

Description
The baseline assessment for evaluation of diagnostics and critical medical devices will be conducted and report should be prepared

Deliverable D2.2 – Developing guidance documents for conducting performance evaluation

Deliverable Number	D2.2	**Lead Beneficiary**	9. TMDA
Deliverable Name	Developing guidance documents for conducting performance evaluation		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	12	**Work Package No**	WP2

Description
Developing guidance documents for applicants and manufacturers on requirements for conducting a performance evaluation of diagnostic test kits

Deliverable D2.3 – Performance evaluation of diagnostics and critical medical devices

Deliverable Number	D2.3	**Lead Beneficiary**	9. TMDA
Deliverable Name	Performance evaluation of diagnostics and critical medical devices		
Type	R — Document, report	**Dissemination Level**	R-UE/EU-R - EU Classified
Due Date (month)	24	**Work Package No**	WP2

Description
Conducting performance evaluation of diagnostics and critical medical devices. The performance evaluation verification will be conducted by assessors

Deliverable D2.4 – Developing Protocols for conducting performance verification studies

Deliverable Number	D2.4	**Lead Beneficiary**	9. TMDA
Deliverable Name	Developing Protocols for conducting performance verification studies		
Type	R — Document, report	**Dissemination Level**	R-UE/EU-R - EU Classified
Due Date (month)	12	**Work Package No**	WP2

Description
Developing specific protocols for conducting performance verification studies for selected diagnostics test kits used for testing Covid-19, HIV, Hepatitis, Syphilis, TB and Malaria and developing other working tools such as SOPs, flow charts

Deliverable D3.1 – Establishing a regulatory framework on health data and material sharing during the emergency periods

Deliverable Number	D3.1	**Lead Beneficiary**	2. NIMR
Deliverable Name	Establishing a regulatory framework on health data and material sharing during the emergency periods		
Type	R — Document, report	**Dissemination Level**	R-UE/EU-R - EU Classified
Due Date (month)	28	**Work Package No**	WP3

Description
A regulatory framework will be established on health data and material sharing during the emergency periods. Different guidelines will be developed and these will include guide for data collection tools (manual and electronic), data storage, accessing archived data for research, sharing data in-country and outside country. This will improve ethics requirements for health data and material access during emergency periods

Deliverable D3.2 – Data Managment Plan

Deliverable Number	D3.2	**Lead Beneficiary**	2. NIMR
Deliverable Name	Data Managment Plan		
Type	DMP — Data Management Plan	**Dissemination Level**	SEN - Sensitive
Due Date (month)	6	**Work Package No**	WP3

Description
Data management an will be developed

Deliverable D4.1 – Post-marketing protocol and plan developed

Deliverable Number	D4.1	**Lead Beneficiary**	5. ZFDA
Deliverable Name	Post-marketing protocol and plan developed		
Type	R — Document, report	**Dissemination Level**	R-UE/EU-R - EU Classified
Due Date (month)	10	**Work Package No**	WP4

Description
Post-marketing protocol and plan developed based on risk assessment of the medical products circulating on the market

Deliverable D4.2 – Sample collections and perform product information reviews

Deliverable Number	D4.2	**Lead Beneficiary**	5. ZFDA

Deliverable Name	Sample collections and perform product information reviews		
Type	R — Document, report	Dissemination Level	R-UE/EU-R - EU Classified
Due Date (month)	20	Work Package No	WP4

Description
Collecting samples from the market based on the approved sampling plan and product information review (PIR) will be conducted as per the established protocol. The results of Products information review (PIR) will be disseminated during stakeholders meeting Regulatory actions will be taken for those who will not comply with regulations

Deliverable D5.1 – Training Needs Assessment

Deliverable Number	D5.1	Lead Beneficiary	4. MUHAS
Deliverable Name	Training Needs Assessment		
Type	R — Document, report	Dissemination Level	R-UE/EU-R - EU Classified
Due Date (month)	10	Work Package No	WP5

Description
Training needs assessment for both therapeutic and vaccines protocol evaluation , and for performance evaluation of in-vitro diagnostics and critical medical devices will be conducted for staff from TMDA, ZFDA, Rwanda FDA, NIMR and ZAHRI

Deliverable D5.2 – Customization of short ethics course for Rwanda

Deliverable Number	D5.2	Lead Beneficiary	3. GSF KCMC
Deliverable Name	Customization of short ethics course for Rwanda		
Type	R — Document, report	Dissemination Level	R-UE/EU-R - EU Classified
Due Date (month)	16	Work Package No	WP5

Description
Short ethics course will be customized for Rwanda FDA

Deliverable D5.3 – Preparation of training curriculum and materials for assessors

Deliverable Number	D5.3	Lead Beneficiary	4. MUHAS
Deliverable Name	Preparation of training curriculum and materials for assessors		
Type	R — Document, report	Dissemination Level	R-UE/EU-R - EU Classified
Due Date (month)	16	Work Package No	WP5

Description
Preparation of training curriculum and materials for assessors will be done

Deliverable D5.4 – Training of clinical trial assessors on in-vitro and medical devices CTs evaluation

Deliverable Number	D5.4	**Lead Beneficiary**	4. MUHAS
Deliverable Name	Training of clinical trial assessors on in-vitro and medical devices CTs evaluation		
Type	R — Document, report	**Dissemination Level**	R-UE/EU-R - EU Classified
Due Date (month)	30	**Work Package No**	WP5

Description
Training of clinical trial assessors on in-vitro diagnostics and medical device clinical trial evaluation. The TMDA-MUHAS RCORE will be strengthened by conducting different trainings for reviewers, assessors and inspectors on evaluation and inspection of new trials of both emerging and re-emerging diseases in the emergency period.

Deliverable D5.5 – Training on rapid evaluation of therapeutic or vaccine trial

Deliverable Number	D5.5	**Lead Beneficiary**	4. MUHAS
Deliverable Name	Training on rapid evaluation of therapeutic or vaccine trial		
Type	R — Document, report	**Dissemination Level**	R-UE/EU-R - EU Classified
Due Date (month)	30	**Work Package No**	WP5

Description
Training on rapid evaluation of therapeutic or vaccine trial protocol during a public health emergency. Training and Technical support will be provided to the responsible personnel on clinical trials evaluation in consortium African countries for them to improve and respond fast in the evaluation of the protocol during emergencies.

Deliverable D6.1 – Regulatory Capacity building of other SSA countries, and Sharing Scientific experience within consortium countries

Deliverable Number	D6.1	**Lead Beneficiary**	9. TMDA
Deliverable Name	Regulatory Capacity building of other SSA countries, and Sharing Scientific experience within consortium countries		
Type	R — Document, report	**Dissemination Level**	R-UE/EU-R - EU Classified
Due Date (month)	33	**Work Package No**	WP6

Description
Regulatory capacity building, Sharing scientific experience within the consortium countries Benchmarking and mentoring of SSA countries will be conducted.

Deliverable D7.1 – Monitoring and Evaluation of the project

Deliverable Number	D7.1	**Lead Beneficiary**	1. KI
Deliverable Name	Monitoring and Evaluation of the project		
Type	R — Document, report	**Dissemination Level**	R-UE/EU-R - EU Classified

Due Date (month)	36	**Work Package No**	WP7

Description
Monitoring and evaluation of the project will be done to ensure its smooth implementation. Resources of the project will be controlled to achieve specific project goals

Deliverable D8.1 – Awareness creation on the existence of the Project

Deliverable Number	D8.1	**Lead Beneficiary**	3. GSF KCMC
Deliverable Name	Awareness creation on the existence of the Project		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	36	**Work Package No**	WP8

Description
Awareness creation on the existence of the BREEDIME project by using different forum and social media

Deliverable D8.2 – Launching of the project

Deliverable Number	D8.2	**Lead Beneficiary**	3. GSF KCMC
Deliverable Name	Launching of the project		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	2	**Work Package No**	WP8

Description
The project will be launched to create awareness on its objectives and other issues pertaining to the project

Deliverable D8.3 – Dissemination of reports to all stakeholders

Deliverable Number	D8.3	**Lead Beneficiary**	3. GSF KCMC
Deliverable Name	Dissemination of reports to all stakeholders		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	36	**Work Package No**	WP8

Description
Dissemination of the reports to relevant stakeholders by conducting Stakeholders' forum annual project meetings including preparations for policy brief. The meeting will be convened to disseminate different information about the project and its progress and outcome.

Deliverable D8.4 – Website of the project

Deliverable Number	D8.4	**Lead Beneficiary**	9. TMDA
Deliverable Name	Website of the project		

Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	4	**Work Package No**	WP8

Description
Website of the project will established

Deliverable D8.5 – Exploitation and Dissemination plan

Deliverable Number	D8.5	**Lead Beneficiary**	3. GSF KCMC
Deliverable Name	Exploitation and Dissemination plan		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	6	**Work Package No**	WP8

Description
Exploitation and dissemination plan developed