[Sudan]
YELLOW FEVER DIAGNOSTICS REQUEST FORM

This template is for countries requesting Gavi support for procurement of yellow fever diagnosticreagents, supplies, and equipment under the Gavi Board-approved Yellow Fever Diagnosticsinitiative.The following are mandatory requirements to be submitted alongside this request form:

- Signatures required to endorse this request before submission to Gavi: i) Minister of Health, ii) Director of national yellow fever laboratory, and iii) Director of Finance for Ministry of Health. The signature of the Minister of Finance (or their delegated authorities) is recommended but not required.
- The Coordination Forum (ICC, HSCC or equivalent body) is required to endorse this requestbefore submission to Gavi. This can be done also through the ICC/HSCC endorsement of the Joint Appraisal (JA) and should be reflected in ICC/HSCC minutes.

Yellow fever diagnostic procurement support is provided to allow more timely, reliable identification and laboratory confirmation of yellow fever cases for more rapid containment of outbreaks and better prioritisation of preventive yellow fever vaccination efforts.Specifically, this support is intended to assist countries' efforts to follow World Health Organization (WHO) recommendations when conducting yellow fever diagnostic tests on all samples received from suspected yellow fever cases. The support is only available to Gavi-eligible countries in Africa that are classified as "high-risk" for yellow fever by WHO under the Eliminate Yellow Fever Epidemics (EYE) strategy[1].The countries that currently meet those criteria are listed in the **Yellow Fever Diagnostics Support Guidelines**.

The request will be reviewed by members of the Independent Review Committee (IRC) who will make a recommendation to Gavi[2]. Following the independent review there will be a clarification period (30 working days) for countries to respond to any 'issues to be addressed' ahead of final Gavi approval and disbursement.

Submit this request form and the aforementioned requirements to: proposals@gavi.org

Countries requesting Gavi support for the introduction of yellow fever vaccine into the routine immunisation schedule oryellow fever preventive mass campaigns should consult the Application guidelines(section 5.3.8) for more information on the process and requirements.Countries requesting Gavi support for rapid outbreak response for yellow fever (via the International Coordinating Group (ICG)), should consult the yellow fever Application guidelines in the ICG site.

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[1]*The list of Gavi-eligible countries is provided in **Annex 1 Yellow Fever DiagnosticsGuidelines**. For the full list of WHO classification, see 'World Health Organization. Eliminate Yellow Fever Epidemics(EYE): A Global Strategy, 2017-2026. WklyEpidemiol Rec 2017;92:193-204."*

[2] *The requests for consumable reagents and supplies will be reviewed separately from requests for equipment, so support for requested consumables may be recommended even ifsupport for requested equipment isnot recommended.*

Gavi Grant Terms and Conditions

Gavi terms and conditions

The terms and conditions of the Partnership Framework Agreement (PFA) between Gavi and the Country, including those provisions regarding anti-corruption and anti-terrorism and money laundering, remain in full effect and shall apply to any and all Gavi support made pursuant to this application. The terms and conditions below do not supersede those of the PFA. In the event the Country has not yet executed a PFA, the terms and conditions of this application shall apply to any and all Gavi support made pursuant to this application.

GAVI GRANT APPLICATION TERMS AND CONDITIONS

SUPPLIES AND EQUIPMENT USED SOLELY FOR APPROVED PROGRAMMES

The applicant country ("Country") confirms that all material provided by Gavi will be used and applied for the sole purpose of fulfilling the programme(s) described in the Country's application. Any significant change from the approved programme(s) must be reviewed and approved in advance by Gavi. All decisions for the supply application are made at the discretion of Gavi and are subject to IRC processes and the availability of funds.

AMENDMENT TO THE APPLICATION

The Country will notify Gavi in its Joint Appraisal, or in any other agreed annual reporting mechanism, if it wishes to propose any change to the programme(s) description in its application. Gavi will document any change approved by Gavi according with its guidelines, and the Country's application will be amended.

CONFIRMATION OF LEGAL VALIDITY

The Country and the signatories for the Country confirm that its application, or any other agreed annual reporting mechanism, is accurate and correct and forms legally binding obligations on the Country, under the Country's law, to perform the programme(s) described in its application, as amended, if applicable.

COMPLIANCE WITH GAVI POLICIES

The Country confirms that it is familiar with all Gavi policies, guidelines and processes relevant to the programme(s), including without limitation the Transparency and Accountability Policy (TAP) and complies with the requirements therein. All programme related policies, guidelines and processes are available on Gavi’s official website and/or sent to the Country.

ARBITRATION

Any dispute between the Country and Gavi arising out of or relating to its application that is not settled amicably within a reasonable period of time, will be submitted to arbitration at the request of either Gavi or the Country. The arbitration will be conducted in accordance with the then-current UNCITRAL Arbitration Rules. The parties agree to be bound by the arbitration award, as the final adjudication of any such dispute. The place of arbitration will be Geneva, Switzerland. The languages of the arbitration will be English or French.

For any dispute for which the amount at issue is US$ 100,000 or less, there will be one arbitrator appointed by Gavi. For any dispute for which the amount at issue is greater than US $100,000 there will be three arbitrators appointed as follows: Gavi and the Country will each appoint one arbitrator, and the two arbitrators so appointed will jointly appoint a third arbitrator who shall be the chairperson.

Gavi will not be liable to the country for any claim or loss relating to the programme(s) described in the application, including without limitation, any financial loss, reliance claims, any harm to property, or personal injury or death. The Country is solely responsible for all aspects of managing and implementing the programme(s) described in its application.

REPORTING

The Country's national yellow fever laboratory will report information on yellow fever testing activity and performance as requested by the WHO yellow fever laboratory network in a timely and accurate manner, including on the number of samples received and tested, the results of that testing, the timeliness of the overall testing process and the different steps of that process, and problems encountered with performing yellow fever testing. To simplify reporting and avoid duplication, Gavi will be relying on information from WHO to inform future decisions on whether to renew support for procurement of yellow fever reagents, supplies, and equipment to individual countries.

1. Review and update country information

1.1. Country profile

1.1.1. Country profile

Eligibility for Gavi support

Eligible

Date of Partnership Framework Agreement with Gavi

10 December 2013

1.1.2. National customs regulations

Please describe local customs regulations that are instrumental for the delivery of importedlaboratory supplies and equipment.

- The validity of diagnostics reagent should be at least six months.
- Medical devices and equipment should be new.

Please describe requirements for pre-delivery inspection of imported goods that are instrumental for the delivery of laboratory supplies and equipment.

No requirements

Please describe any special documentation requirements that are instrumental for the delivery of imported laboratory supplies and equipment.

1. Final invoice containing items to be cleared per quantities and price.
2. Packing list (in case the items are in the form of kits it should be in details.
3. Shipping documents.
4. Certificate of Origin.
5. Certificate of Analysis.

1.1.3. National Regulatory Agency

Please provide information on the National Regulatory Agency in the country, including status (e.g., whether it is WHO-certified).

National Medicines and poisons Board (Recognized as a regulatory authorization by WHO) is responsible official regulatory body. NMPB accepts WHO pre-qualified medical supplies. Supplies from the list of the countries with good manufacturing practices are also accepted. Suppliers who request pre-acceptance for supplies that are not registered could obtained for items in on-by-one cases.

Please identify at least one point of contact with phone number and e-mail address at the National Regulatory Agency. UNICEF will help work withregulatoryprocesses where relevant and may need to communicate licensing requirements to laboratory supply manufacturers.

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2. Yellow fever laboratory supplies and equipment

2.1. Number of samples from suspected yellow fever cases expected to be tested for which supplies will be needed

Number of samples received for testing in 2016	245
- Yellow fever outbreak in 2016?	Yes ☐ No ☒
Number of samples received for testing in 2017	157
- Yellow fever outbreak in 2017?	Yes ☐ No ☒
Number of samples received for testing in 2018	610
- Yellow fever outbreak in 2018?	Yes ☐ No ☒
Number of samples expected to undergo ELISA testingover a 12-month period[3]	354
Number of samples received for testing in 2016 that were collected ≤10 days after onset of illness	45
Number of samples received for testing in 2017 that were collected ≤10 days after onset of illness	108
Number of samples received for testing in 2018 that were collected ≤10 days after onset of illness	256
Currently testing for yellow feverwith polymerase chain reaction (PCR)?	Yes ☒No ☐
- If yes, what type of PCR machine is used?	Qiagen , Rotor Gene Real Time PCR machine
- If no, please describe any plans for starting testing for yellow with PCR in the next 12 months, including description of PCR testing already	

[3]Number of samples expected to undergo ELISA testing over a 12-month period may be estimated to be equivalent to the largest number of samples received for testing in a single year over the last three years, excluding years with yellow fever outbreaks. For example, if no outbreaks occurred in 2016, 2017, and 2018 and more samples were received for testing in 2017 than in 2016 or 2018, the number of samples expected to be tested over a 12-month period can be estimated to be the same as the number of samples received for testing in 2017. If an outbreak occurred in 2017 and more samples were received for testing in 2018 than 2016, then the number of samples expected to be tested over a 12-month period can be estimated to be the same as the number of samples received for testing in 2018. Alternative approaches can be used if justification is provided.

being done for other viruses	
Number of samples expected to undergo PCR testing over a 12-month period[4]	256

2.2. Equipment

Does your laboratory receive at least 50 samples a year for yellow fever testing and need an enzyme-linked immunosorbent assay (**ELISA**) **reader** for yellow fever testing?	Yes ☒ No ☐
If yes:	
- Please provide justification, including referring to the findings from 2018 Gavi-funded yellow fever laboratory capacity assessment report or World Health Organization yellow fever laboratory capacity assessments.	Currently, there are three ELISA readers, one is not functioning and two are functioning that are shared between all laboratory diagnostic activities of Haemorrhagic Fevers, Influenza and Rotavirus. Another ELISA reader is needed to cover the high work load especially during outbreaks
- Please provide a description of the capacity for installing, operating, and maintaining the ELISA reader that will be available to your laboratory.	The Biomedical Engineering Department at NPHL is responsible of installing, operating, and maintaining the ELISA reader
Does your laboratory receive at least 50 samples a year for yellow fever testing and need an **ELISAwasher** for yellow fever testing?	Yes ☒ No ☐
If yes:	
- Please provide justification, including referring to the findings from 2018 Gavi-funded yellow fever laboratory capacity assessment report or World Health Organization yellow fever laboratory capacity assessments.	Currently, there is one functioning ELISA washer that is shared between all laboratory diagnostic activities of Haemorrhagic Fevers, Influenza and Rotavirus. Another ELISA washer is needed to cover the high work load especially during outbreaks
- Please provide a description of the capacity for installing, operating, and maintaining the ELISA washer that will be available to your laboratory.	The Biomedical Engineering Department at NPHL is responsible of installing, operating, and maintaining the ELISA washer

[4]If capacity to test for yellow fever with PCR is available, the number of samples expected to undergo PCR testing over a 12-month period may be estimated to be equivalent to the largest number of samples collected ≤10 days after onset of illnessand received for testing in a single year over the last three years, excluding years with yellow fever outbreaks. For example, if no outbreaks occurred in 2016, 2017, and 2018 and more samples collected ≤10 days after onset of illness were received for testing in 2017 than in 2016 or 2018, the number of tests expected to be run over a 12-month period can be estimated to be the same as the number of samples collected ≤10 days after onset of illness and received for testing in 2017. If an outbreak occurred in 2017 and more samples collected ≤10 days after onset of illnesswere received for testing in 2018 than 2016, then the number of samples expected to be tested over a 12 month period can be estimated to be the same as the number of samples collected ≤10 days after onset of illness and received for testing in 2018. Alternative approaches can be used if justification is provided.

Does your laboratory receive at least 50 samples a year for yellow fever testing collected no more than 10 days after patients' onset of illness and need a **PCR machine** for yellow fever testing?	Yes ☒ No ☐

If yes:

- Please provide justification, including referring to the findings from 2018 Gavi-funded yellow fever laboratory capacity assessment report or World Health Organization yellow fever laboratory capacity assessments.	Currently, there are two functioning PCR machines that are shared between all laboratory diagnostic activities of Haemorrhagic Fevers, Influenza and Rotavirus. Another PCR machine is needed to cover the high work load especially during outbreaks
- Please provide a description of the capacity for installing, operating, and maintaining the **PCR machine**that will be available to your laboratory.	No available capacity for installing, operating, and maintaining the PCR machine in our laboratory, so we need all the installing, operating, and maintaining services to be provided by specialized company

Does your laboratory need a **biosafety cabinet**?	Yes ☒ No ☐

If yes:

- Please provide justification, including referring to the findings from 2018 Gavi-funded yellow fever laboratory capacity assessment report or World Health Organization yellow fever laboratory capacity assessments.	Currently, there is one functioning biosafety cabinet that is uncertified and shared between all laboratory diagnostic activities of Haemorrhagic Fevers, Influenza and Rotavirus. Another biosafety cabinet is needed to cover the high work load especially during outbreaks
- Please provide a description of the capacity for installing, operating, and maintaining the Biosafety cabinet that will be available to your laboratory.	The Biomedical Engineering Department at NPHL is responsible of installing, operating, and maintaining the biosafety cabinet No capacity for certification, need to be done by specialized company

2.3. Logistics

2.3.1. Supply delivery

What isthe address and, if available, geocoordinates of the national public health yellow fever reference laboratory that is the ultimate destination for yellow fever laboratory supplies and equipment?

Epidemiology Laboratory, NPHL, Quaser Street, Khartoum, P.O box 287

What is the Port of Entryclosest to the national public health yellow fever reference laboratory?

Khartoum International Air Port for Air (for Air shipments); Port Sudan (for Sea shipments)

How many shipments should the needed supplies be spread across and why?[5]
Two shipments, to avoid the reagents to be expired

To facilitate timely delivery of supplies, laboratory staff will be responsible providing proof of customs clearance and other import authorizations prior to scheduling a shipment with UNICEF Supply Division. What is the laboratory's plan for securing the necessary customs clearance and any other import authorizations?
FMoH supplies are exempted from custom by Ministry of Finance. Annual waiver received by February each year. The consignee for all Ministry of Health is the International Health Department. Focal person for supply clearance. Pre-shipment notification required 2 weeks in advance to shipment arrival. Pre-alert should include Certificate of Origin (CoO), Certificate of Analysis (CoA) if applicable, Packing list and Airwaybill.

2.3.2. Logistical technical assistance

Does the laboratory staff need stock management training? If yes, please provide details
There is a system for stock management in the NPHL, but it need to be strengthened so we request training for the haemorrhagic fever laboratory staff.

2.4. Strategic considerations

2.4.1. Rationale for the request

Briefly describe howyellow fever diagnostic capacity fits into your country's plan for eliminating yellow fever epidemics.

The eliminating yellow fever epidemics Country Plan 2018-2020consists of strengthening the Surveillance, and Laboratory, implementation of Preventive mass vaccination campaigns, introduction of yellow fever vaccine in the routine immunization, strengthening Case management, Vector surveillance and control, timely Outbreak response,Training and supervision, Monitoring and evaluation, and Risk communication.

The laboratory component of the Elimination Yellow Fever Epidemics (EYE) country plan emphasized on building the Public health laboratory capacities in Sudan through:

1) developing and disseminating SOPs for collection and transportation and shipping of specimens
2) Evaluationof the needs and acquiring sufficient lab reagents and equipment including PPE, containers.
3) Providing Capture IgM ELISA & Real-time PCR Kits
4) Training of lab staff on Sequencing new CDC MAC ELISA, Home-made ELISA, Primer Design, Bioinformatics.
5) Participating in EQA program

According toGavi Yellow Fever Laboratory Capacity Assessment – Sudan, conducted in October 2018 there aremany gaps in the yellow fever laboratory including:

- lack of funding for the YF diagnostic laboratory
- There is no standardized, validated YF MAC-ELISA kit available to replace the in-house assay comprised of 10 commercially available and in-house produced components, which are procured and distributed separately.

[5]*Gavi will fund a maximum of three shipments for supplies used in routine yellow fever testing over a 12-month period (additional shipments are possible in response to outbreaks, if feasible). Exact shipment dates, times, and other details to be confirmed with UNICEF Supply Division.*

- Stockouts of one or more of the critical reagents or supplies which can result in delayed testing or substitution with a different reagent, perhaps of lower quality.
- Delay of sample transport at district and/or regional units compounds the situation.
- YF molecular testing is not currently supported by WHO AFR. Because of this NPHL has purchased YF IgM assays that are not validated by WHO.
- Because of the lack of budget, WHO laboratory training specific for YF diagnostic techniques is provided on an ad hoc basis, and there is no sustained proficiency testing program.
- Training workshops that do exist are not attended by participants of all the YF laboratory network countries. As a result, there is a lack of clarity on WHO recommended testing algorithms or updates to protocols, and gaps in YF specific technical proficiency among laboratory staff.
- There is currently no coordination between NPHL and EPI and WHO.
- The electric power supply needs upgrading and/or a back-up generator, as electricity outages can delay and/or disrupt testing and reagents and samples in the freezers may be degraded as they go through multiple freeze-thaw cycles.
- Biosafety cabinets and other equipment is not certified or calibrated, and other routine IQC is not implemented.
- NPHL should designate staff to coordinate biosafety and quality management policies. Only validated and WHO recommended protocols should be used and SOPs should be validated in the laboratory.

2.4.2. Financial sustainability and budgeting of yellow fever laboratory

A cost sharing requirement will eventuallybe introduced for **yellow fever materials. This cost-sharing will not come into effectthrough at least the end of 2020.More information will be provided by your Gavi Senior Country Manager (SCM) as it becomes available. **

What is the current year's and, if available, the next year'sdomestic budget for yellow fever laboratory capacity needs, including yellow fever laboratory supplies and equipment?

There is annual budget for NPHL for supplies and consumables, but there is no special budget for the yellow fever supplies.

2.4.3. Anticipated future changes in yellow fever laboratory capacity

Aside from access to yellow fever diagnostic reagents, supplies, and equipment, does the laboratory expect its capacity to test for yellow fever to change over the next 2 years, e.g., new staff, training, new facility, etc.? If so, how?

- We are planning to have a functioning quickly responding laboratory at the national level through recruiting additional staff and training them in addition to the provision of the laboratory supplies, the national laboratory will work in liaise with the CDC Africa and WHO laboratory.
- Also we are planning to upgrade of the existing five regional laboratories for testing suspected cases of Haemorrhagic fevers for serology while the PCR will be conducted in the national public health laboratory in Khartoum. These regional laboratories will serve the post conflict areas, areas affected previously by epidemics of haemorrhagic fever, and the bordering high risk countries (e.g.South Sudan and Ethiopia) to ensure timely confirmation of cases.(see the attached map)

Contacts

Person(s) who should be contacted in case Gavi needs to ask for more information regarding the application.

Name	Position	Phone Number	Email	Organisation
BabikerMagboul	Director the health emergency and epidemic control directorate	+249123390000	babkerali@yahoo.com	FMoH
MubarkS Karsany	Head of Department of Epidemiology and Virology Lab	+249912307132	mubarak88@gmail.com	NPHL
Awad Omer	EPI manager	+24912133976	awadomer51@hotmail.com	FMoH
Ali Sayed Mohammed Elhassan	Gavi PMU	+249912298526	alisayed67@gmail.com	FMoH

Comments

Please provide any comments you have about this application and how to improve it

- In Sudan there is no separate yellow fever surveillance it works within the haemorrhagic fever surveillance they share the same suspected case definition, and the suspected cases are tested for all haemorrhagic fevers.

Version: July2019

Government signature form

The Government of (Sudan) would like to expand the existing partnership with Gavi for the improvement of the immunisation programme of the country, and specifically hereby requests Gavi support foryellow fever diagnostics (that is, laboratory reagents, supplies and equipment) as outlined in this request form.

The Government of (Sudan) commits itself to developing national immunisation services, including laboratory testing that helps guide immunisation services, on a sustainable basis in accordance with the national health and immunisation strategic plans. The Government requests that Gavi and its partners contribute financial and technical assistance to support immunisation of children as outlined in this application.

Please note that Gavi will not review this application without the signatures of the Minister of Health, the Director of the national yellow fever laboratory, and the Director of Finance for the Ministry of Health or their delegated authorities.

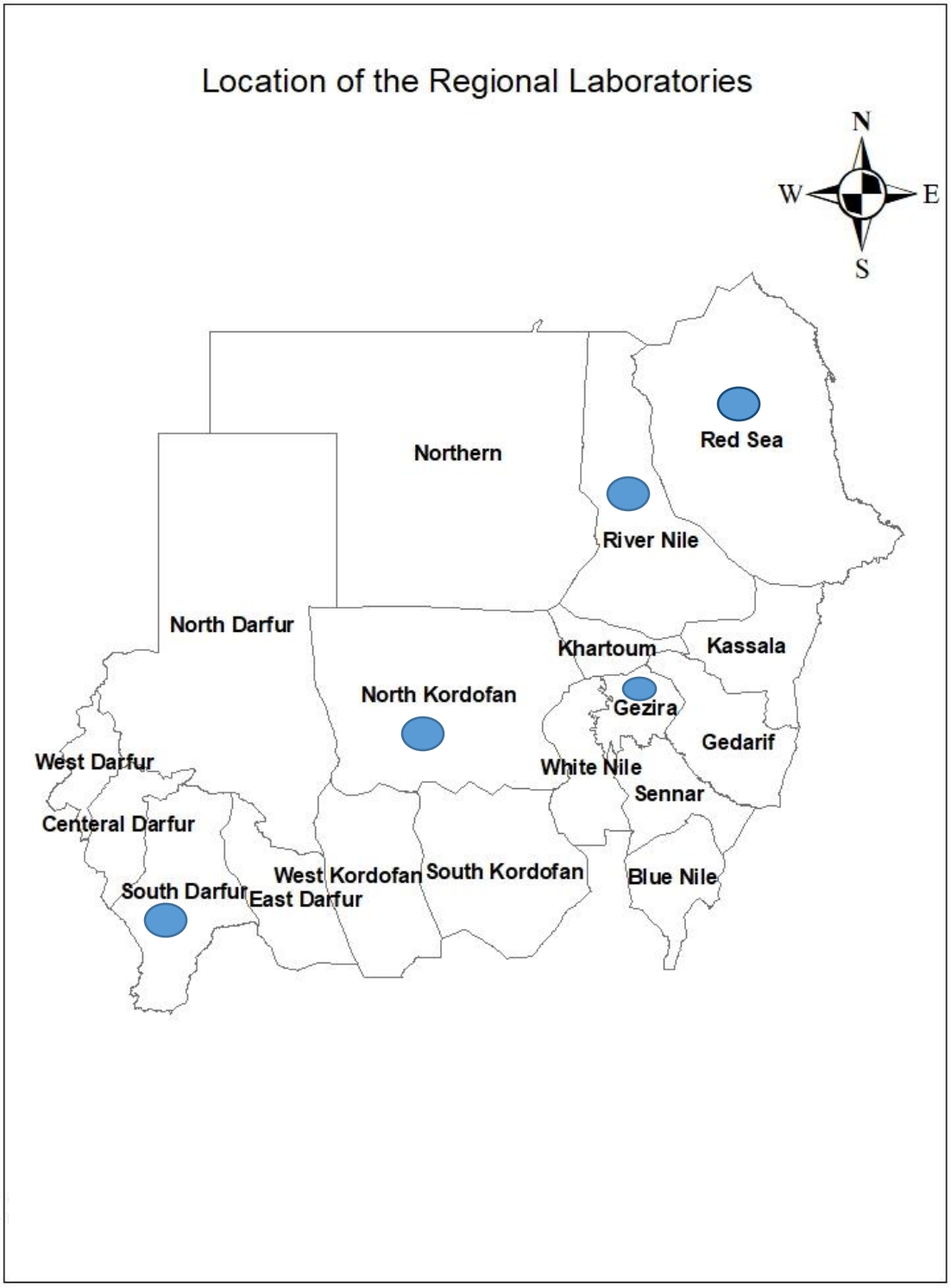
We, the undersigned, affirm that the objectives and activities in this request are fully aligned with the national health and immunisation strategic plans (or equivalent), and that funds for procuring yellow fever laboratory reagents, supplies, and equipment will be included in future annual budgets of the Ministry of Health, including funds for co-financing of future Gavi-supported procurement of suppliesonce the details of the Gavi co-financing requirements are available.

We, the undersigned, further affirm that the terms and conditions of the Partnership Framework Agreement between Gavi and the Country remain in full effect and shall apply to any and all Gavi support made pursuant to this application.[6]

Minister of Health (or delegated authority)	**Director of national yellow fever laboratory (or delegated authority)**
Name: Dr. Akram Al Eltom	Name: Dr. Mubarak S Karsany
Date: 16-9-2019	Date: 16-09-2019
Signature:	Signature:

Director of Finance for Ministry of Health (or delegated authority)	**Minister of Finance (or delegated authority) (recommended but not required)**
Name: EL FAKI MOHMEDELAMEIN	Name:
Date: 16.9.2019	Date:
Signature:	Signature:

[6] *In the event the Country has not yet executed a Partnership Framework Agreement, the terms and conditions of thisapplication shall apply to any and all Gavi support made pursuant to this application.*


Location of the Regional Laboratories
N
W
E
S
Northern
Red Sea
River Nile
North Darfur
Khartoum
Kassala
North Kordofan
Gezira
Gedarif
West Darfur
White Nile
Sennar
Centeral Darfur
West Kordofan
South Kordofan
Blue Nile
South Darfur
East Darfur