

## **Clinical Research Organization (CRO) to support an Inactivated Influenza Vaccine Clinical Trial in Serbia**

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*Request for Proposals (RFP)*  
*Bid Reference 2015/HIS/PHI/001*

## TABLE OF CONTENTS

<b>TABLE OF CONTENTS.....</b>	<b>2</b>
<b>1. INTRODUCTION.....</b>	<b>4</b>
<b>1.1 Objective of the RFP .....</b>	<b>4</b>
<b>1.2 About WHO .....</b>	<b>4</b>
1.2.1 WHO Mission Statement.....	4
1.2.2 Structure of WHO .....	4
1.2.3 Description of Cluster/Service/Unit .....	4
<b>1.3 Definitions, Acronyms and Abbreviations.....</b>	<b>5</b>
<b>2. DESCRIPTION OF SUBJECT / PRESENT ACTIVITIES.....</b>	<b>5</b>
<b>2.1 Overview.....</b>	<b>6</b>
<b>2.2 Objectives of the activity .....</b>	<b>6</b>
<b>2.3 Activity coordination.....</b>	<b>6</b>
<b>3. REQUIREMENTS .....</b>	<b>7</b>
<b>3.1 Introduction.....</b>	<b>7</b>
<b>3.2 Characteristics of the provider .....</b>	<b>7</b>
3.2.1 Status .....	7
3.2.2 Accreditations.....	7
3.2.3 Previous experience.....	7
3.2.4 Logistical capacity .....	7
3.2.5 Staffing .....	7
<b>3.3 Work to be performed .....</b>	<b>7</b>
3.3.1 Key requirements .....	13
3.3.2 Reporting requirements.....	13
3.3.3 Finance and accounting requirements.....	13
3.3.4 Performance monitoring.....	14
3.3.5 Further Capacities .....	14
<b>4. INSTRUCTIONS TO BIDDERS .....</b>	<b>15</b>
<b>4.1 Language of the Proposal and other Documents .....</b>	<b>15</b>
<b>4.2 Intention to Bid .....</b>	<b>15</b>
<b>4.3 Cost of Proposal.....</b>	<b>15</b>
<b>4.4 Contents of the Proposal.....</b>	<b>15</b>
<b>4.5 Joint Proposal.....</b>	<b>15</b>
<b>4.6 Communications during the RFP Period .....</b>	<b>16</b>
<b>4.7 Format and Signing of Proposals.....</b>	<b>16</b>
<b>4.8 Sealing and Marking of Proposals.....</b>	<b>17</b>
<b>4.9 Exclusion of Submission of Offers by E-mail .....</b>	<b>17</b>
<b>4.10 Period of Validity of Proposals .....</b>	<b>17</b>
<b>4.11 Closing Date for Submission of Proposals .....</b>	<b>17</b>
<b>4.12 Modification and Withdrawal of Proposals.....</b>	<b>17</b>
<b>4.13 Receipt of Proposals from Non-invitees .....</b>	<b>18</b>
<b>4.14 Amendment of the RFP.....</b>	<b>18</b>
<b>4.15 Proposal Structure .....</b>	<b>18</b>
4.15.1 Acceptance Form .....	18
4.15.2 Executive Summary .....	19
4.15.3 Information of Firm/Organization submitting Proposal.....	19
4.15.4 Proposed Solution .....	20
4.15.5 Approach/Methodology .....	20
4.15.6 Proposed Time line .....	20
4.15.7 Financial Proposal.....	20

<b>5.</b>	<b>OPENING AND EVALUATION OF PROPOSALS</b>	<b>21</b>
5.1	Opening of Proposals	21
5.2	Clarification of Proposals	21
5.3	Preliminary Examination of Proposals	21
5.4	Evaluation of Proposals	21
5.4.2	Financial Evaluation	22
5.5	Bidders' Presentations	22
<b>6.</b>	<b>AWARD OF CONTRACT</b>	<b>22</b>
6.1	Award Criteria, Award of Contract	22
6.2	WHO's Right to modify Scope or Requirements during the Evaluation/Selection Process	23
6.3	WHO's Right to Extend/Revise Scope or Requirements at Time of Award	23
6.4	WHO's Right to enter into Negotiations	23
6.5	Signing of the Contract	23
<b>7.</b>	<b>GENERAL AND CONTRACTUAL CONDITIONS</b>	<b>24</b>
7.1	Conditions of Contract	24
7.2	Responsibility	24
7.3	Source of Instructions	25
7.4	Warranties	25
7.5	Legal Status	26
7.6	Relation Between the Parties	26
7.7	No Waiver	26
7.8	Liability	26
7.9	Assignment	26
7.10	Officials not to Benefit	26
7.11	Indemnification	27
7.12	Contractor's Responsibility for Employees	27
7.13	Subcontracting	27
7.14	Place of Performance	27
7.15	Language	27
7.16	Confidentiality	27
7.17	Title Rights	28
7.18	Termination and Cancellation	28
7.19	Force Majeure	29
7.20	Surviving Provisions	29
7.21	Use of WHO name and emblem	29
7.22	Successors and Assignees	29
7.23	Payment	30
7.24	Title to Equipment	30
7.25	Insurance and Liabilities to Third Parties	30
7.26	Settlement of Disputes	31
7.27	Observance of Laws	31
7.28	Authority to Modify	31
7.29	Privileges and Immunities	31
7.30	No Terrorism or Corruption	31
<b>8.</b>	<b>PERSONNEL</b>	<b>32</b>
8.1	Approval of Contractor Personnel	32
8.2	Project Managers	32
8.3	Foreign Nationals	33
8.4	Compliance with WHO's Policies	33
8.5	Ethical Behaviour	33
8.6	Engagement of Third Parties and use of In-house Resources	33

## 1. INTRODUCTION

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### 1.1 Objective of the RFP

The purpose of this Request for Proposals (RFP) is to enter into a contractual agreement with a successful bidder and select a suitable contractor to carry out the following work: ***Clinical Research Organization (CRO) to support an Inactivated Influenza Vaccine Clinical Trial in Serbia.***

WHO is an Organization that is dependent on the budgetary and extra-budgetary contributions it receives for the implementation of its activities. Bidders are therefore requested to propose the best and most cost-effective solution to meet WHO requirements, while ensuring a high level of service.

### 1.2 About WHO

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#### 1.2.1 WHO Mission Statement

The World Health Organization was established in 1948 as a specialized agency of the United Nations. The objective of WHO ([www.who.int](http://www.who.int)) is the attainment by all peoples of the highest possible level of health. Health, as defined in the WHO Constitution, is a state of complete physical, mental and social well being and not merely the absence of disease or infirmity. WHO's main function is to act as the directing and coordinating authority on international health work.

#### 1.2.2 Structure of WHO

The World Health Assembly (WHA) is the main governing body of WHO. It generally meets in Geneva in May of each year and is composed of delegations representing all 194 Member States. Its main function is to determine the policies of the Organization. In addition to its public health functions, the Health Assembly appoints the Director-General, supervises the financial policies of the Organization, and reviews and approves the proposed programme budget. It also considers reports of the WHO Executive Board, which it instructs with regard to matters upon which further action, study, investigation or report may be required.

The Executive Board is composed of 34 members elected for three-year terms. The main functions of the Board are to give effect to the decisions and policies of the WHA, to advise it and generally to facilitate its work. The Board normally meets twice a year; one meeting is usually in January, and the second is in May, following the World Health Assembly.

The WHO Secretariat consists of some 8,300 health and other officers at the Organization's headquarters in Geneva, in the six regional offices and in countries. The Secretariat is headed by the Director-General, who is appointed by the WHA on the nomination of the Executive Board. The current Director-General is Dr Margaret Chan. The head of each regional office is a Regional Director. Regional directors are appointed by the Executive Board in agreement with the relevant regional committee.

#### 1.2.3 Description of Cluster/Service/Unit

The Technology Transfer Initiative (TTi) within the unit of Public Health Innovation and Intellectual Property (PHI) in the Cluster on Health Systems and Innovation (HIS) works to facilitate the transfer of health-related technologies to improve access to medicines in all parts

of the world. The activities conducted by this programme serve to implement specific components of the *Global Action Plan for Influenza Vaccines* (GAP). Within this activity WHO is promoting the establishment of influenza vaccine production in developing countries to address the inequitable and short supply of vaccine anticipated during an influenza pandemic. In this programme WHO is supporting Torlak Institute of Virology, Vaccines and Sera in Belgrade, Serbia in the development and testing of influenza candidate vaccines.

### 1.3 Definitions, Acronyms and Abbreviations

AE	Adverse Event
BARDA	US Biomedical Advanced Research and Development Authority
CRA	Clinical research associate
CRF	Case Report Form
CRO	Contract Research Organization
CSR	Clinical Study Report
DSMB	Data Safety and Management Board
EMP	WHO Department of Essential Medicines and Health Products
ERC	Ethics Review Committee
FWA	Federalwide Assurance for the protection of human subjects
GAP	Global Action Plan for Influenza Vaccines
GCP	Good Clinical Practice
GLP	Good Laboratory Practices
HIS	WHO Cluster on Health Systems and Innovation
ICH	The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IIV	Inactivated influenza vaccine
IND	Investigational New Drug
IP	Investigational product
IEC	Independent ethics committee
IRB	Institutional Review Board
PATH	Program for Appropriate Technology in Health
PHI	WHO Unit on Public Health Innovation and Intellectual Property
RFP	Request for Proposals
SAE	serious adverse event
SOP	Standard Operating Procedure
TIV	Trivalent influenza vaccine
TTi	Technology Transfer Initiative
WHA	World Health Assembly
WHO	World Health Organization

## **2. DESCRIPTION OF SUBJECT / PRESENT ACTIVITIES**

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### **2.1 Overview**

WHO is supporting the Torlak Institute of Virology, Vaccines and Sera in Belgrade, Serbia in the development and testing of candidate influenza vaccines. Torlak has a fully GMP compliant influenza production facility at its offices in Belgrade. A candidate inactivated seasonal trivalent vaccine has been produced and evaluated in preclinical animal studies and is now ready to be taken into clinical trials.

In addition, WHO is supporting Torlak in the development of a candidate H5N1 influenza vaccine as a pre-pandemic preparedness measure.

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### **2.2 Objectives of the activity**

This request for proposals is being issued primarily to seek CRO support in clinical trial management, including regulatory support, site and data management, safety and clinical monitoring, study report writing, etc. for a phase I clinical trial in healthy Serbian adults. The investigative product for this phase 1 is a candidate inactivated trivalent seasonal influenza vaccine produced at Torlak. A detailed budget should be prepared for this study, according to the scope of work and study synopsis outlined in section 3.

A secondary purpose of this RFP is to seek CRO interest in supporting the same scope of work for a phase 2/3 trial of seasonal influenza vaccine and a phase I clinical trial of a candidate H5N1 pandemic influenza vaccine.

The contract will be awarded to cover only the scope of work of the phase I seasonal influenza vaccine trial. Excellent CRO performance in the Phase 1 seasonal influenza trial will confer a preferential status for consideration for the phase 2 study and for the H5N1 future work.

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### **2.3 Activity coordination**

WHO has received funding from the US Biomedical Advanced Research and Development Authority (BARDA) to support the conduct of these trials. In addition, BARDA is also funding PATH to provide process development, manufacturing and clinical management support to implement these trials.

### 3. REQUIREMENTS

#### 3.1 Introduction

WHO requires the successful bidder, the Contractor, to support selection and preparation of clinical site(s) and laboratory, support preparation of regulatory dossier for EC/NRA approval and carry out the study monitoring, data management and clinical study report writing of a seasonal trivalent influenza vaccine phase I clinical trial in healthy Serbian adults. The CRO is expected to work closely with the vaccine manufacturer, Torlak and our collaborating partner PATH. In addition the CRO will be expected to work closely with the selected clinical site(s) and the laboratory.

Please note, that the selected site(s) and laboratory will be contracted separately by WHO, but the bidding CRO is requested to list any recommended sites and laboratories which it has successfully collaborated with in the past or supports based on expertise and interest.

WHO will consider proposals from CROs proposing to conduct the clinical trials in neighbouring countries in later phases, however the phase I study should be conducted in Serbia and preference will be given to these CROs.

#### 3.2 Characteristics of the provider

##### 3.2.1 Status

- The provider shall be a Contract Research Organization operating in the field of clinical trials, with proven expertise in the conduct of clinical trials in Serbia and of vaccine clinical trials in general.

##### 3.2.2 Accreditations

- An accreditation or an on-going accreditation process by a certified accreditation body will be an asset.

##### 3.2.3 Previous experience

- Previous work with WHO, other international organizations and/or major institutions in the field of clinical trials.
- Proven experience in clinical trial management, including regulatory support, site and data management, safety and clinical monitoring, study report writing, etc. of clinical trials, particularly vaccine trials.

##### 3.2.4 Logistical capacity

- The CRO shall have the ability to operate in Serbia and to conduct all activities listed in section 3.3.

##### 3.2.5 Staffing

- Contractor staff dedicated to the project must have appropriate qualifications, training, and experience.

#### 3.3 Work to be performed

The following services and tasks are requested to be performed for the phase I study of Torlak's candidate seasonal influenza vaccine.

## **Pre-Study, Study Start-Up and Initiation Activities**

- Plan and execute kick-off meeting with CRO, Torlak and PATH.
- Review draft Case Report Form (CRF) provided by PATH/Torlak, provide recommendations and finalize CRF. Review other study documents and provide recommendations.
- Prepare randomization plan, generate dummy patient randomization/allocation schedule for approval by PATH/Torlak prior to going live, develop/maintain subject randomization/allocation. Schedule, set up system for randomization.
- Plan and execute Investigator Meeting prior to study initiation.
- Support project planning.
- Provide team-specific training on the project.
- Perform start-up activities for project management and clinical management.
- Review other study documents and provide recommendations. Secure translations and back translations of relevant English/Serbian study documents into Serbian/English language and provide appropriate certifications when required.
- Prepare, complete and distribute initiation package (documents) to the site including Investigator Brochure.

## **Regulatory Activities**

- Coordinate with PATH/Torlak to request, receive, review and forward to PATH/Torlak designee site documents required for NRA submissions within mutually agreed upon timelines.
- Ensure that all documents required as per ICH-GCP are in place at CRO and Designee study site.
- Assist performance sites with preparation and submission of documents to the local IEC, including safety notifications, as needed. Track status of regulatory and study initiation documents at/from sites. Track IEC approvals, renewals and payments. Review IEC standard operating procedures to ensure compliance with local regulatory authorities.
- Review all correspondence to and from local IECs to determine that it is accurate and complete within 5 working days of receipt. Apprise site and PATH/Torlak of any documents that require modification to meet regulatory requirements. Ensure regulatory correspondence is appropriately forwarded to sites, PATH and Torlak.
- Coordinate with PATH to request and receive site documents required for WHO ERC submissions; Coordinate subsequent communications as needed and ensure WHO ERC correspondence filed appropriately at site.

## **Clinical Operations, Site Management and Study Monitoring**

- Prepare, complete and distribute initiation package to the site, including Site Master Files (protocol, master Informed Consent Document, and Investigator Brochure will be provided by PATH/Torlak).
- Assist site in preparation for trial initiation by conducting a site assessment and preparation visit, developing recommendations based on findings, and monitoring progress and site-readiness status.
- Conduct site initiation visit and train the site personnel in ICH-GCP, study purpose and design, and study procedures. Ensure investigator is able to perform tasks required for the conduct of this study.
- Review site SOPs to ensure completeness and compatibility with protocol and study operations manual.
- Maintain in-house files.



- Procure and distribute study supplies, monitor inventory at sites, and provide sites with study supplies including but not limited to ICD and diary cards in appropriate language, paper case report forms, reporting forms and study logs, digital thermometers and materials for specimen collection (e.g., cryo vials and tubes, syringes).
- Conduct routine site monitoring visits to:
  - Review validity of subject information sheet/informed consent forms.
  - Review subject eligibility and study procedures.
  - Review significant changes to study facilities and team members.
  - Review laboratory sample collection, labeling and dispatch.
  - Perform source data verification, where applicable.
  - Process and resolve on-site data queries and clean CRFs.
  - Verify randomization procedures.
  - Monitor vaccine storage temperature logs at study site, track vaccine temperature excursions and report to sponsor/COM.
  - Review the reconciliation/accountability of clinical supplies at site and report deviations to the study sponsor.
  - Review and document protocol violations.
  - Verify adverse events and reporting
- Ensure completeness of regulatory binders at site on a regular basis.
- Provide immediate notification (within 24-36 hours or as specified) of significant findings at a monitoring visit by email to designated Torlak and PATH Operational Team contact(s). Significant findings would include unreported deaths, unreported SAEs, unreported major deviations from protocol procedures, disruptions in proper vaccine handling or unanticipated events likely to impact the safety or rights of participants or integrity of the study.
- Prepare visit reports and follow-up letters, ensure follow-up and closure of visit report findings.
- Prepare and distribute site status records regularly to all key team members.
- Track all IRB/EC approvals/renewals/payments.
- Monitor all IRB/EC approvals/renewals/payments
- Maintain Telephone Contact with the study site; maintain record of communications / conversations related to study conduct (telephone, faxes, etc.).
- Develop a study closeout plan including timing and essential documents to be returned.
- Conduct study site closeout visit, ensure completeness of regulatory binders at site at end of study.
- Return unused supplies to sponsor or approved destruction facility.
- Ensure site preparedness for audits.

## **Medical and Scientific Services/Pharmacovigilance Activities**

- **Medical support and communications**
  - Provide medical support to the study team and advise on study reporting.
    1. Medical support for project staff and investigative site for protocol-related issues.
    2. Protocol clarifications for CRA and investigative site.
    3. Review/clarification of trial-related adverse events (AEs) other than serious adverse events (SAEs).
    4. Provide a weekly report of participant safety to the Protocol Safety Review Team (to be defined).
  - Prepare module / SOP to communicate with sites, DSMB and critical functioning bodies (to be defined) in the study.
  - Interacting with Investigators and/or Principal Investigator and communicating medical/safety information responses.
  - Attend DSMB meetings as appropriate.
  - Perform medical monitor review of the clinical study report for accuracy and completeness including SAE narratives.

- Attend kick-off meetings, weekly team meetings and client meetings as requested.
- **Management of Serious Adverse Events**
  - Appoint a qualified and experienced Medical Monitor to lead pharmacovigilance efforts for this project. Lead medical monitor should be experienced in clinical trials.
  - Establish and maintain safety (pharmacovigilance) database.
  - Prepare Standard Operating Procedures (SOPs) in English and Serbian, Serious Adverse Event form, and training module for the SAE reporting; SOP for SAE review, and coding procedures. Include 24-hour receipt of SAEs by email or fax.
  - Prepare SAE reconciliation guidelines in coordination with data management team.
  - Develop and maintain tracking system for all SAEs. Communicate relevant SAEs and AEs to PATH and Torlak.
  - Provide medical review of SAEs submitted by site, query site for clarification or additional information as necessary. Enter SAEs into Safety Database. Ensure that the SAE reporting guidelines are followed properly, that appropriate follow up information is obtained and that all the SAEs are properly closed. Prepare initial and follow-up SAE narratives to be submitted to Serbian NRA. Ensure all the SAE narratives are accurate, complete and signed. Communicate relevant SAEs and AEs to PATH and Torlak. Send completed reports to PATH/Torlak designees for review prior to submission.
  - Submit report of SAEs to the regulatory authorities. Maintain stamped acknowledgements from Serbian NRA and notifications.
  - Perform SAE reconciliation with the data management database.
  - Provide periodic line listings or reports to Torlak and PATH. Prepare line listings and narrative for DSMB at frequent pre-determined intervals.
- **Management of Adverse Events**
  - Medical monitor review of AE listings quarterly, noting and communicating any trends.
  - Perform quality check of adverse event study data.
  - Ensure all the AE are complete, data captured is accurate, and AE followed until appropriate time point as per the protocol.

### **Clinical Data Management Activities**

- Provide input into the data management and statistical sections in the clinical trial protocol and amendments, as needed.
- Review draft CRF provided by PATH/Torlak and make recommendations. Finalize CRF.
- Develop, test, deploy and release the database.
- Develop, finalize and update as needed Data Management Plan, Data quality control plan, and data validation plan. Include data validation/editing specifications, trial specific obvious correction guidelines, and data entry and handling guidelines for data collection, monitoring and cleaning.
- Develop, finalize and update Data Entry and Handling guidelines for data collection /monitoring /cleaning.
- Develop, finalize and update Data Validation Plan.
- Track timely submission of CRFs from sites.
- Track for timely resolution of DCFs.
- Set up the safety database.
- Enter SAEs into safety Database.
- Perform SAE Reconciliation with safety database.
- Generate, track, send and resolve data queries and discrepancies from both automatic and manual review.
- Maintain audit trail.

- Develop, finalize and update data coding guidelines.
- Code adverse events on an ongoing basis using MedDRA dictionary.
- QC database and document quality; ensure validation checks applied.
- Perform audit of database and report results to PATH/Torlak.
- Track and periodically report subject status including enrollment, progress in study, discontinuations and reason for discontinuation.
- Lock completed database.
- Create transport files (in pre-defined format).
- Perform final data freeze and final database transfer in pre-defined format to the sponsor.

### **Biostatistical Services**

- Develop and finalize Data Management Plan.
- Develop and finalize statistical analysis plan.
- Develop Table, Listing, and Figure (TLF) and analysis data set requirements specifications for CSR.
- Statistical Programming
  - Program statistical analysis data sets.
  - Program listings (unique/total).
  - Program figures (unique/total).
  - Program tables (unique/total).
  - QC analysis programs and output quality.
  - QC listings, tables, figures and output quality.
  - Facilitate a format review of complete set of blinded/blank TLFs prior to unblinding.
- Perform unblinding.
- Generate final analysis data sets.
- Produce and QC final TLFs post database lock/unblinding.
- Produce post hoc tables if requested.
- Integrate tables into report.
- Generate final statistical report.
- Supply all SAS transport files (including analysis data sets) and programs to sponsor/COM.

### **Project Management Activities**

- Prepare project management plan.
- Manage prompt resolution of identified problems with the appropriate project team members.
- Keep the PATH/Torlak informed of study progress through regular verbal and written communication including status reports and monthly reports.
- Plan and attend regular teleconferences and other face-to-face meetings (at least 2-3 during study duration).
- Prepare and maintain documentation of all project correspondence including all meetings (internal and external) status reports, monthly reports and teleconference minutes.
- Review visit follow-up letters and reports, correspondence and telephone contact reports.
- Coordinate clinical team training, conduct clinical team meetings.
- Prepare monitoring plan and other monitoring tools.
- Develop project communication plan.
- Coordinate activities within CRO to ensure that all systems are operational and function as per requirements.
- Day-to-day management of the study.
- Develop or coordinate development of presentations on study goals, design and progress for internal or external audiences as requested by PATH.

- Review all in-house study files, organize system audits, and perform audit at least once during the study. Identify, document and implement preventive and corrective actions as needed.

### **Tracking system for biological specimens**

- Development, implement and maintain tracking application with a comprehensive shipping and inventory system in order to:
  - Identify specimens with unique study identifiers (such a bar-coding).
  - Establish site inventories that connect to laboratory and repository (storage) inventories.
  - Track specimens from collection point to central laboratory.
  - Manage inventory in storage, with retrieval and subsequent tracking.
  - Provide access at multiple locations (e.g., site, data management center, and laboratory).
  - Generate shipping manifest.
  - Tracks specimen results.
  - Maintain verifiable custody chain.
- Provide necessary software, equipment and supplies (such as labels, bar-code readers)
- Provide necessary training on system and procedures to site and central laboratory staff.

### **Write Clinical Study Report (CSR) in English following regulatory requirements and specified timeframe**

- Report should follow ICH GCP requirements for CSR
- Share draft report with Torlak and PATH for review
- Finalize CSR

### **Project Archiving and Document Return**

- Return all study related documentation to sponsor at the end of the study.

### **Assumptions**

The proposed study is a Phase I, double-blind, placebo-controlled, randomized study to examine the Safety and Immunogenicity of a Seasonal Trivalent Inactivated Influenza Vaccine produced by Torlak in healthy volunteers in Serbia.

Trial initiation date: Q3'2015; Trial end date: Q1'2016

Period of enrollment: 2 months

Sample size: Enrolled subjects: 60

Duration of Involvement for CRO: 15 months

- CRO involvement starts: Q2 2015
- CRO involvement ends: Q3 2016
- Investigator Meeting prior to study initiation (to be held in Belgrade, or other major city).

Total number of sites: 1-3 sites to be identified

IP including Placebo vaccine would be provided by Torlak respectively.

Site(s) will provide required equipment and durable supplies including equipment required for separation of sera, refrigerators, freezers and portable carriers for vaccines and specimens.

CRO will provide other study supplies (ICD, CRF and disposables such as digital thermometers, specimen collection materials including specimen containers, labels, gloves, plastic sheeting, etc).

Planned visits:

- Initiation visit of 2 days duration.
- Interim monitoring visits (each visit of 2 days duration): 4 visits.
- Visits schedule to be determined.
- Closeout visit of 2 days duration at site.

Source data verification: 100% of subject eligibility, informed consent documents, solicited and unsolicited adverse events immediately post vaccination, Serious Adverse Events, other unanticipated events. Additionally, 20% of all study subjects records will be selected for complete source document verification. To be further discussed with monitoring group.

Investigator's Brochure, final protocol, final template consent form, participant diary cards, draft case report forms, and draft manual of operations will be provided by Torlak and/or PATH. Documents will require review by CRO for its own purposes and modifications as needed to CRF and manual of operations.

CRO will be responsible for securing required translations. Assume site will require translation into Serbian and back translation to English of multiple documents with appropriate documentation: Informed Consent Document, and Post Immunization Reactogenicity Diary Card.

CRO will author Clinical Study Report.

CRO will assist Torlak as necessary obtaining the required approvals for study conduct from the Serbian NRA.

Clinical trial Insurance and cost of treatment of adverse events may be provided by Torlak, but a CRO should specify whether they can procure the insurance and stipulate the costs in a separate budget line in the proposal.

### **3.3.1 Key requirements**

The trial must be carried out in accordance with Good Clinical Practice (GCP) as required by applicable rules of the Republic of Serbia.

The study will be in line with the World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (CIOMS, 2008), the International Guidelines for Biomedical Research Involving Human Subjects (CIOMS, 2002), and the International Guidelines for Ethical Review of Epidemiological Studies (CIOMS, 2009).

The study informed consent documents will embody the elements of consent as described in the Declaration of Helsinki.

### **3.3.2 Reporting requirements**

The Contractor will provide a full clinical study report as a deliverable for this contract which will be reviewed and approved by PATH and WHO.

### **3.3.3 Finance and accounting requirements**

The Contractor will provide a detailed financial report, based on the budget lines of the proposal.

#### **3.3.4 Performance monitoring**

The Contractor will indicate the mechanism by which its own performance is monitored.

#### **3.3.5 Further Capacities**

N/A

## 4. INSTRUCTIONS TO BIDDERS

Bidders should follow the instructions set forth below in the submission of their proposal to WHO.

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### 4.1 Language of the Proposal and other Documents

The proposal prepared by the bidder, and all correspondence and documents relating to the proposal exchanged by the bidder and WHO shall be written in the English language.

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### 4.2 Intention to Bid

**No later than 06 February 2015** the bidder shall complete and return by both email or fax to WHO:

1. The enclosed *RFP\_2015\_HIS\_PHI\_001\_Acknowledgement.doc* form signed as confirmation of the bidder's intention to submit a *bona fide* proposal and designate its representative to whom communications may be directed, including any addenda; and
2. The enclosed *RFP\_2015\_HIS\_PHI\_001\_Confidentiality.pdf* form signed.
  - Email for submissions of acknowledgement: [sparrowe@who.int](mailto:sparrowe@who.int)
  - Fax number for submissions of acknowledgement: **+41 22 791 49 09 (Attn: E. Sparrow Bid Ref 2015/HIS/PHI/001)**

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### 4.3 Cost of Proposal

The bidder shall bear all costs associated with the preparation and submission of the proposal, including but not limited to the possible cost of discussing the proposal with WHO, making a presentation, negotiating a contract and any related travel.

WHO will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the selection process.

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### 4.4 Contents of the Proposal

Proposals must offer the total requirement. Proposals offering only part of the requirement may be rejected.

The bidder is expected to follow the proposal structure described in paragraph 4.15 below and otherwise comply with all instructions, terms and specifications contained in, and submit all forms required pursuant to, this RFP. Failure to follow the aforesaid proposal structure, to comply with the aforesaid instructions, terms and specifications, and/or to submit the aforesaid forms will be at the bidder's risk and may affect the evaluation of the proposal.

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### 4.5 Joint Proposal

Two or more entities may form a consortium and submit a joint proposal offering to jointly undertake the work. Such a proposal must be submitted in the name of one member of the consortium - hereinafter the "lead organization". The lead organization will be responsible for undertaking all negotiations and discussions with, and be the main point of contact for, WHO.



The lead organization and each member of the consortium will be jointly and severally responsible for the proper performance of the contract.

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#### 4.6 Communications during the RFP Period

A prospective bidder requiring any clarification on technical, contractual or commercial matters may notify WHO via email at the following address no later than **Friday 13 February 2013** prior to the closing date for the submission of offers.:

Email for submissions of all queries: [sparrowe@who.int](mailto:sparrowe@who.int)  
(use subject: WHP Bid Ref. Bid Ref 2015/HIS/PHI/001)

The WHO Responsible Officer at WHO will respond in writing (via email only) to any request for clarification of the RFP that it receives by the deadline indicated above. A consolidated document of WHO's response to all questions (including an explanation of the query but without identifying the source of enquiry) will be sent to all prospective bidders who have received the RFP. Questions are to be submitted through use of the form "Questions from Bidders".

There shall be no individual presentation by or meeting with bidders until after the closing date. From the date of issue of this RFP to the final selection, contact with WHO officials concerning the RFP process shall not be permitted, other than through the submission of queries and/or through a possible presentation or meeting called for by WHO, in accordance with the terms of this RFP.

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#### 4.7 Format and Signing of Proposals

The bidder shall submit four (4) hard copies each of the complete proposal by the closing date set forth in section 4.11 to the address in section 4.8. Each complete proposal should include the following:

- Hard copy of proposal and supporting documents (marked clearly **Bid Ref 2015/HIS/PHI/001**)
- Signed Acceptance Form RFP\_2015\_HIS\_PHI\_001\_Acceptance\_Form.doc
- CD-ROM or USB stick containing electronic copy of proposal and supporting documents

Please also note the following instructions for preparation of the Proposal:

- 1) The four (4) copies shall be labelled "Master Copy" and "Copy1", "Copy2" and so on, as appropriate. The bidder must ensure that the content of all copies is identical. If at any time a difference is discovered between any copies of the proposal then the "Master Copy" will prevail as the official copy.
- 2) The four (4) hard copies shall be unbound, provided in binders from which pages may be removed easily. Dividers may be used to separate sections of the document, if needed.
- 3) All pages of the proposal shall be numbered in the format 'Page X of Y'.
- 4) All four (4) copies of the proposal shall be typed or written in indelible ink and shall be signed by a person or persons duly authorized to represent the bidder, submit a proposal and bind the bidder to the terms of the RFP. A proposal shall contain no interlineations, erasures, or overwriting except, as necessary to correct errors made by the bidder, in which case such corrections shall be initialled by the person or persons signing the proposal.



- 5) The electronic copies of the proposal and supporting documents on the four (4) CD-ROMs or USB sticks should be in PDF, or MS Word compatible format.

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#### 4.8 Sealing and Marking of Proposals

Four (4) copies of the complete proposal must be sent by registered mail, via courier or hand delivered, in a **sealed** envelope or parcel to the following address:

**Office 3032  
Bid Ref: Bid Ref 2015/HIS/PHI/001  
Attn: E. Sparrow  
World Health Organization  
20, Avenue Appia  
CH-1211 Geneva 27  
Switzerland**

**NOTE:** If the envelopes are not sealed and marked as per the instructions in this clause, WHO will not assume any responsibility for the misplacement or premature opening of the proposal and may – at its discretion – reject the proposal. If the envelopes are delivered by hand, it shall be the bidder's responsibility to ensure that they are dated and signed for receipt (with an indication of the time of receipt) by an employee of WHO upon their delivery.

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#### 4.9 Exclusion of Submission of Offers by E-mail

Only hard copies are acceptable as official bid entries. Under no circumstances shall offers be submitted to WHO by E-mail.

Any and all bidders submitting an offer by such means shall be disqualified and their offer rejected.

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#### 4.10 Period of Validity of Proposals

The offer outlined in the proposal must be valid for a minimum period of 120 calendar days after the closing date. A proposal valid for a shorter period may be rejected by WHO. In exceptional circumstances, WHO may solicit the bidder's consent to an extension of the period of validity. The request and the responses thereto shall be made in writing. Any bidder granting such an extension will not, however, be permitted to otherwise modify its proposal.

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#### 4.11 Closing Date for Submission of Proposals

**Proposals must be received at WHO at the address specified in section 4.8 no later than 20 February 2015 at 17:00 hours, Geneva time.**

WHO may, at its own discretion, extend this closing date for the submission of proposals by notifying all bidders thereof in writing.

Any proposal received by WHO after the closing date for submission of proposals may be rejected.

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#### 4.12 Modification and Withdrawal of Proposals

The bidder may withdraw its proposal any time after the proposal's submission and before the opening of the bids, provided that written notice via email and fax of the withdrawal is received by WHO prior to the closing date.

The bidder's withdrawal notice shall be addressed, sealed and marked in accordance with section 4.8 to be received before the closing date referred to in section 4.11. An advance copy of the withdrawal notice may also be sent by email but must be followed by a signed confirmation copy received by the closing date.

- Email for withdrawal of proposal: [sparrowe@who.int](mailto:sparrowe@who.int)

No proposal may be modified after the closing date for submission of proposals, unless WHO has issued an amendment to the RFP allowing such modifications (see section 4.14).

No proposal may be withdrawn in the interval between the closing date and the expiration of the period of proposal validity specified by the bidder in the proposal in accordance with section 4.10.

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#### 4.13 Receipt of Proposals from Non-invitees

WHO may, at its own discretion, if it considers this necessary and in the interest of the Organization, extend the RFP to bidders that were not included in the original invitation list.

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#### 4.14 Amendment of the RFP

WHO may, at any time before the closing date, for any reason, whether on its own initiative or in response to a clarification requested by a (prospective) bidder, modify the RFP by written amendment. Amendments could, *inter alia*, include modification of the project scope or requirements, the project timeline expectations and/or extension of the closing date for submission.

All prospective bidders that have received the RFP will be notified in writing of all amendments to the RFP and will, where applicable, be invited to amend their proposal accordingly.

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#### 4.15 Proposal Structure

The contents of the bidder's proposal should be concisely presented and structured in the following order to include, but not necessarily be limited to, the information listed in sections 4.15.3 to 4.15.7 below.

Any information which the bidder considers confidential, if any, should be clearly marked confidential.

##### 4.15.1 Acceptance Form

The bidder's proposal must be accompanied by a transmittal letter signed by a duly authorized representative of the bidder and stating:

- That the bidder undertakes on its own behalf and on behalf of its possible partners and contractors to perform the work in accordance with the terms of the RFP;
- The total cost of the proposal, indicating the United Nations convertible currency

used (preferably US Dollars);

- The number of days the proposal is valid (from the date of the form) in accordance with section 4.10.

#### 4.15.2 Executive Summary

The bidder's proposal must be accompanied by an Executive Summary/Proposed Solution.

#### 4.15.3 Information of Firm/Organization submitting Proposal<sup>1</sup>

Information of Firm/Organization submitting Proposal	
<b>1</b>	<b>Company Information</b>
1.1	<b>Corporate information</b>
1.1.1	Company <b>mission statement</b>
1.1.2	<b>Service commitment</b> to customers and measurements used
1.1.3	<b>Organization</b> structure
1.1.4	<b>Geographical</b> presence
1.1.5	Relevant <b>experience</b> (include description of those parts of your organization that would be involved in the performance of the work)
1.2	<b>Staffing information</b>
1.2.1	<b>Number and Geographical</b> distribution of staff
1.2.2	<b>Number of consultants</b> employed on similar projects in each of the past three years
1.2.3	<b>Staff turnover</b> rate for the past three years
1.3	Audited <b>financial statements</b> for the past three (3) years
1.4	<b>Legal information</b>
1.4.1	History of <b>Bankruptcy</b>
1.4.2	Pending major <b>lawsuits</b> and <b>litigations</b> in excess of USD 100,000 at risk (indicate particularly those by licensees or patent infringement)
1.4.3	Pending <b>Criminal/Civil lawsuits</b>
1.5	<b>Relevant Contractual relationships</b>
1.5.1	<b>Relevant Contractual projects</b> (with other UN agencies or contractors)
1.6	Proposed <b>sub-contractor</b> arrangements including <b>sub-contractor information</b> (as above for each sub-contractor)
<b>2</b>	<b>Experiences and Reference Contact Information</b> (list and provide five (5) detailed examples of relevant experience gained within the past five years of the issuance of this RFP that demonstrate the contractor's ability to satisfactorily perform the work in accordance with the requirements of this RFP)
2.1	<b>Project Name</b>
2.1.1	<b>Project Description</b>

<sup>1</sup> Bidders will be excluded if:

- they are bankrupt or being wound up, are having their affairs administered by the courts, have entered into an arrangement with creditors, have suspended business activities, are the subject of proceedings concerning those matters, or are in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
- they have been convicted of an offence concerning their professional conduct by a judgment which has the force of *res judicata*; have been subject of a judgment which has the force of *res judicata* for fraud, corruption, involvement in a criminal organization or any other illegal activity;
- it becomes apparent to WHO that they are guilty of misrepresentation in supplying, or if they fail to supply, the information required under this RFP and/or as part of the bid evaluation process; or
- they give rise to a conflict of interest.

Information of Firm/Organization submitting Proposal	
2.1.2	<b>Status</b> (under development/implemented)
2.1.3	<b>Reason for Relevance</b> (provide reason why this project can be seen as relevant to this project)
2.1.4	<b>Roles and responsibilities</b> (list and clearly identify the roles and responsibilities for each participating organization)
2.1.4.1	<b>Client</b> Role and Responsibility
2.1.4.2	<b>Contractor</b> Role and Responsibility. Previous contractor role in project
2.1.4.3	<b>Third party contractors</b> Role and Responsibility. Previous specified 3 <sup>rd</sup> party role in project.
2.1.5	<b>Team members</b> (indicate relevant members of the team that will also be used for this project)

#### 4.15.4 Proposed Solution

Not Applicable

#### 4.15.5 Approach/Methodology

Not Applicable

#### 4.15.6 Proposed Time line

The proposal must indicate the delivery time between commencement of the clinical trial and the delivery of the final report.

#### 4.15.7 Financial Proposal

The bid must include a financial proposals for the conduct of the phase I seasonal trivalent influenza vaccine trial as laid out in the assumptions of section 3.3. This will be a detailed proposal and the basis of subsequent contract.

## 5. OPENING AND EVALUATION OF PROPOSALS

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### 5.1 Opening of Proposals

WHO will open the proposals in the presence of a Committee formed by WHO at the Headquarters office in **Geneva, Switzerland on 23 February 2015 at 11:00 am Geneva time.** Each proposal will be opened during the session, each bidder will be announced and, in case of fixed-price offer, the total cost of each Financial Proposal will be read aloud. Bidders may attend the session (at their own cost) and should inform WHO in advance via email if they plan to attend. Non-attendance has no implication on the evaluation of the bids.

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### 5.2 Clarification of Proposals

WHO may, at its discretion, ask any bidder for clarification of any part of its proposal. The request for clarification and the response shall be in writing. No change in price or substance of the proposal shall be sought, offered or permitted during this exchange.

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### 5.3 Preliminary Examination of Proposals

WHO will examine the proposals to determine whether they are complete, whether any computational errors have been made, whether the documents have been properly signed, and whether the proposals are generally in order. Proposals which are not in order as aforesaid may be rejected.

**Please note that WHO is not bound to select any bidder and may reject all proposals.** Furthermore, since a contract would be awarded in respect of the proposal which is considered most responsive to the needs of the project concerned, due consideration being given to WHO's general principles, including economy and efficiency, WHO does not bind itself in any way to select the bidder offering the lowest price.

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### 5.4 Evaluation of Proposals

A two-stage procedure will be utilized in evaluating the proposals, with technical evaluation of the proposal being completed prior to any focus on or comparison of price.

The technical and financial evaluations of proposals will be accomplished by a Selection Panel composed of (a) Scientist, WHO Technology Transfer Initiative (b) Technical Officer, WHO Technology Transfer Initiative, (c) Administrative Officer, Technology Transfer Initiative (d) Project Manager, PATH (e) Clinical Trial Specialist, PATH

The Selection Panel will evaluate all proposals which have passed the Preliminary Examination of Proposals.

#### 5.4.1 Technical Evaluation

The technical evaluation of the proposals will include:

- the extent to which WHO's requirements and expectations have been satisfactorily addressed;
- the quality of the overall proposal;
- the appropriateness of the proposed approach;
- the quality of the technical solution proposed;
- the management strategy/plan detailed in the document;
- the experience of the firm in carrying out related projects;
- the qualifications and competence of the personnel proposed for the assignment;
- the proposed timeframe for the project;

The number of points which can be obtained for each evaluation criterion is specified below and indicates the relative significance or weight of the item in the overall evaluation process.

#### **Technical Scoring and Weighting System: 70%**

##### **5.4.2 Financial Evaluation**

During the Financial Evaluation, the price proposal of all bidders who have passed the Technical Evaluation will be compared, according to the following scoring and weighting system.

#### **Financial Scoring and Weighting System: 30%**

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### **5.5 Bidders' Presentations**

WHO may, during the evaluation period, at its discretion, invite selected bidders to supply additional information on the contents of their proposal (at such bidders' own cost). Such bidders will be asked to give a presentation of their proposal (possibly with an emphasis on a topic of WHO's choice) followed by a question and answer session. The presentation will be held at WHO's Headquarters in Geneva, or by tele/videoconference.

NOTE: Other presentations and any other individual contact between WHO and bidders is expressly prohibited both before and after the closing date.

## **6. AWARD OF CONTRACT**

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### **6.1 Award Criteria, Award of Contract**

WHO reserves the right to

- a) Award the contract to a bidder of its choice, even if its bid is not the lowest;
- b) Award separate contracts for parts of the work, components or items, to one or more bidders of its choice, even if their bids are not the lowest;
- c) Accept or reject any proposal, and to annul the solicitation process and reject all proposals at any time prior to award of contract, without thereby incurring any liability to the affected bidder or bidders and without any obligation to inform the affected bidder or bidders of the grounds for WHO's action;
- d) Award the contract on the basis of the Organization's particular objectives to a bidder whose proposal is considered to be the most responsive to the needs of the Organization and the activity concerned;

- e) Not award any contract at all.

WHO has the right to eliminate bids for technical or other reasons throughout the evaluation/selection process. WHO shall not in any way be obliged to reveal, or discuss with any bidder, how a proposal was assessed, or to provide any other information relative to the evaluation/selection process or to state the reasons for elimination to any bidder.

NOTE: WHO is **acting in good faith** by issuing this RFP. However, **this document does not oblige WHO to contract for the performance of any work, nor for the supply of any products or services.**

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## 6.2 WHO's Right to modify Scope or Requirements during the Evaluation/Selection Process

At any time during the evaluation/selection process, WHO reserves the right to modify the scope of the work, services and/or goods called for under this RFP. WHO shall notify the change to only those bidders who have not been officially eliminated due to technical reasons at that point in time.

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## 6.3 WHO's Right to Extend/Revise Scope or Requirements at Time of Award

WHO reserves the right at the time of award of contract to extend, reduce or otherwise revise the scope of the work, services and/or goods called for under this RFP without any change in the base price or other terms and conditions offered by the selected bidder.

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## 6.4 WHO's Right to enter into Negotiations

WHO also reserves the right to enter into negotiations with one or more bidders of its choice, including but not limited to negotiation of the terms of the proposal(s), the price quoted in such proposal(s) and/or the deletion of certain parts of the work, components or items called for under this RFP.

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## 6.5 Signing of the Contract

Within 30 days of receipt of the contract, the successful bidder shall sign and date the contract and return it to WHO according to the instructions provided at that time. If the bidder does not accept the contract terms without changes, then WHO has the right not to proceed with the selected bidder and instead contract with another bidder of its choice.

## 7. GENERAL AND CONTRACTUAL CONDITIONS

The contract between WHO and the selected bidder ("the Contract") will, unless otherwise explicitly agreed in writing, include the provisions as set forth in this section, and will otherwise *inter alia* address the following issues:

- responsibilities of the selected bidder(s) ("the Contractor(s)") and WHO;
- clear deliverables, timelines and acceptance procedures;
- payment terms tied to the satisfactory performance and completion of the work;
- notices.

The prices payable by WHO for the work to be performed under the Contract shall be fixed for the duration of the Contract and shall be in a UN convertible currency (preferably US Dollars), based on the UN exchange rate of the date of invoice. The total amount payable by WHO under the Contract may be either a lump sum or a maximum amount. If the option for payment of a lump sum applies, that lump sum is payable in the manner provided, subject to satisfactory performance of the work. If the option for payment of a maximum amount applies:

- the Contract shall include a detailed budget;
- the Contractor shall be held to submit a financial statement together with each invoice;
- any advance payments by WHO shall be used by the Contractor exclusively for the work in accordance with the budget and any unspent balance shall be refunded to WHO;
- payment by WHO shall be subject to satisfactory performance and the acceptance of the Contractor's financial statements; and
- all financial reports shall be subject to audit by or on behalf of WHO, including examination of supporting documentation and relevant accounting entries in the Contractor's books. In order to facilitate financial reporting and audit, the Contractor shall keep systematic and accurate accounts and records in respect of the work.

Unless otherwise specified in the Contract, WHO shall have no obligation to purchase any minimum quantities of goods or services from the Contractor, and WHO shall have no limitation on its right to obtain goods or services of the same kind, quality and quantity as described in the Contract, from any other sources at any time.

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### 7.1 Conditions of Contract

Any and all of the Contractor's (general and/or special) conditions of contract are hereby explicitly excluded from the Contract, i.e., regardless of whether such conditions are included in the Contractor's offer, or printed or referred to on the Contractor's letterhead, invoices and/or other material, documentation or communications.

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### 7.2 Responsibility

The Contractor will be responsible to ensure that the work performed under the Contract meets the agreed specifications and is completed within the time prescribed. The Contractor shall facilitate the operational audit related to the execution of the work and the compliance with the obligations set forth in the Contract, by persons so designated by WHO. In this regard, the Contractor shall make all relevant operational information, without restriction, available to persons so designated by WHO and provide satisfactory explanations to all queries arising in connection therewith.



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### 7.3 Source of Instructions

The Contractor shall neither seek nor accept instructions from any authority external to WHO in connection with the performance of the work under the Contract. The Contractor shall refrain from any action which may adversely affect WHO and shall fulfil its commitments with the fullest regard to the interests of WHO.

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### 7.4 Warranties

The Contractor warrants and represents to WHO as follows:

- 1) The deliverables shall meet the specifications called for in the Contract and shall be fully adequate to meet their intended purpose. The Contractor furthermore warrants that the deliverables shall be error-free. The Contractor shall correct any errors in the deliverables, free of charge, within fifteen days after their notification to the Contractor, during a period of at least one year after completion of the work. It is agreed, however, that errors and other defects which have been caused by modifications to the deliverables made by WHO without agreement of the Contractor are not covered by this paragraph.
- 2) The deliverables shall, to the extent they are not original, only be derived from, or incorporate, material over which the Contractor has the full legal right and authority to use it for the proper implementation of the Contract. The Contractor shall obtain all the necessary licenses for all non-original material incorporated in the deliverables (including, but not limited to, licenses for WHO to use any underlying software, application, and operating deliverables included in the deliverables or on which it is based so as to permit WHO to fully exercise its rights in the deliverables without any obligation on WHO's part to make any additional payments whatsoever to any party.
- 3) The deliverables shall not violate any copyright, patent right, or other proprietary right of any third party and shall be delivered to WHO free and clear of any and all liens, claims, charges, security interests and any other encumbrances of any nature whatsoever.
- 4) The Contractor, its employees and any other persons and entities used by the Contractor shall not violate any intellectual property rights, confidentiality, right of privacy or other right of any person or entity whomsoever.
- 5) Except as otherwise explicitly provided in the Contract, the Contractor shall at all times provide all the necessary on-site and off-site resources to meet its obligations hereunder. The Contractor shall only use highly qualified staff, acceptable to WHO, to perform its obligations hereunder.
- 6) The Contractor shall take full and sole responsibility for the payment of all wages, benefits and monies due to all persons and entities used by it in connection with the implementation and execution of the Contract, including, but not limited to, the Contractor's employees, permitted subcontractors and suppliers.

Contractor furthermore warrants and represent that the information provided by it to WHO in response to the RFP and during the bid evaluation process is accurate and complete. Contractor understands that in the event Contractor has failed to disclose any relevant information which may have impacted WHO's decision to award the Contract to Contractor, or has provided false information, WHO will be entitled to rescind the contract with immediate effect, in addition to any other remedies which WHO may have by contract or by law.

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## **7.5 Legal Status**

The Contractor shall be considered as having the legal status of an independent contractor vis-à-vis WHO, and nothing contained in or relating to the Contract shall be construed as establishing or creating an employer/employee relationship between WHO, on the one hand, and the Contractor or any person used by the Contractor in the performance of the work, on the other hand.

Thus the Contractor shall be solely responsible for the manner in which the work is carried out. WHO shall not be responsible for any loss, accident, damage or injury suffered by the Contractor or persons or entities claiming under the Contractor, arising during or as a result of the implementation or execution of the Contract, including travel, whether sustained on WHO premises or not.

The Contractor shall obtain adequate insurance to cover such loss, accident, injury and damage, before commencing work on the Contract. The Contractor shall be solely responsible in this regard and shall handle any claims for such loss, accident, damage or injury.

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## **7.6 Relation Between the Parties**

Nothing in the Contract shall be deemed to constitute a partnership between the Parties or to constitute either Party as the agent of the other.

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## **7.7 No Waiver**

The waiver by either Party of any provision or breach of the Contract shall not prevent subsequent enforcement of such provision or excuse further breaches.

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## **7.8 Liability**

The Contractor hereby indemnifies and holds WHO harmless from and against the full amount of any and all claims and liabilities, including legal fees and costs, which are or may be made, filed or assessed against WHO at any time and based on, or arising out of, breach by the Contractor of any of its representations or warranties under the Contract, regardless of whether such representations and warranties are explicitly incorporated here in or are referred to in any attached Appendices.

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## **7.9 Assignment**

The Contractor shall not assign, transfer, pledge or make any other disposition of the Contract or any part thereof, or any of the Contractor's rights, claims or obligations under the Contract except with the prior written consent of WHO.

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## **7.10 Officials not to Benefit**

The Contractor warrants that no official of WHO has received or will be offered by the Contractor any direct or indirect benefit arising from the Contract or the award thereof. The Contractor agrees that breach of this provision is a breach of an essential term of the Contract.

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### **7.11 Indemnification**

The Contractor shall indemnify and hold WHO harmless, from and against the full amount of any and all claims and liabilities, including legal fees and costs, which are or may be made, filed or assessed against WHO at any time and based on, or arising out of, the acts or omissions of the Contractor, or the Contractor's employees, officers, agents, partners or sub-contractors, in the performance of the Contract. This provision shall extend, *inter alia*, to claims and liabilities in the nature of workmen's compensation, product liability and liability arising out of the use of patented inventions or devices, copyrighted material or other intellectual property by the Contractor, its employees, officers, agents, servants, partners or sub-contractors.

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### **7.12 Contractor's Responsibility for Employees**

The Contractor shall be responsible for the professional and technical competence of its employees and will select, for work under the Contract, reliable individuals who will perform effectively in the implementation of the Contract, respect the local laws and customs, and conform to a high standard of moral and ethical conduct.

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### **7.13 Subcontracting**

Any intention to subcontract aspects of the Contract must be specified in detail in the proposal submitted. Information concerning the subcontractor, including the qualifications of the staff proposed for use must be covered with same degree of thoroughness as for the prime contractor. No subcontracting will be permitted under the Contract unless it is proposed in the initial submission or formally agreed to by WHO at a later time. In any event, the total responsibility for the Contract remains with the Contractor.

The Contractor shall be responsible for ensuring that any and all subcontracts shall be fully consistent with the Contract, and shall not in any way prejudice the implementation of any of its provisions.

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### **7.14 Place of Performance**

The place of performance of the work under the Contract shall be in Serbia and in offices in other countries as used by the provider.

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### **7.15 Language**

All communications relating to the Contract and/or the performance of the work thereunder shall be in English.

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### **7.16 Confidentiality**

- 1) Except as explicitly provided in the Contract, the Contractor shall keep confidential all information which comes to its knowledge during, or as a result of, the implementation and execution of the Contract. Accordingly, the Contractor shall not use or disclose such information for any purpose other than the performance of its obligations under the Contract. The Contractor shall ensure that each of its employees and/or other persons and entities having access to such information shall be made aware of, and be bound by, the obligations of the Contractor under this paragraph. However, there shall be no obligation of confidentiality or restriction on use, where: (i) the information is publicly

available, or becomes publicly available, otherwise than by any action or omission of the Contractor, or (ii) the information was already known to the Contractor (as evidenced by its written records) prior to becoming known to the Contractor in the implementation and execution of the Contract; or (iii) the information was received by the Contractor from a third party not in breach of an obligation of confidentiality.

- 2) The Contractor, its employees and any other persons and entities used by the Contractor shall furthermore not copy and/or otherwise infringe on copyright of any document (whether machine-readable or not) to which the Contractor, its employees and any other persons and entities used by the Contractor have access in the performance of the Contract.
- 3) The Contractor may not communicate at any time to any other person, Government or authority external to WHO, any information known to it by reason of its association with WHO which has not been made public except with the authorization of WHO; nor shall the Contractor at any time use such information to private advantage.

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### 7.17 Title Rights

- 1) All rights pertaining to any and all deliverables under the Contract and the original work product leading thereto, as well as the rights in any non-original material incorporated therein as referred to in section 7.4.2 above, shall be exclusively vested in WHO.
- 2) WHO reserves the right to revise the work, to use the work in a different way from that originally envisaged or to not use the work at all.
- 3) At WHO's request, the Contractor shall take all necessary steps, execute all necessary documents and generally assist WHO in securing such rights in compliance with the requirements of applicable law.

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### 7.18 Termination and Cancellation

WHO shall have the right to cancel the Contract (in addition to other rights, such as the right to claim damages):

- 1) In the event the Contractor fails to begin work on the date agreed, or to implement the work in accordance with the terms of the Contract; or
- 2) In the event the progress of work is such that it becomes obvious that the obligations undertaken by the Contractor and, in particular, the time for fulfilment of such obligations, will not be respected.

In addition, WHO shall be entitled to terminate the Contract (or part thereof), in writing:

1. At will with the provision of thirty (30) days prior notice in writing; and
2. With immediate effect (in addition to other rights, such as the right to claim damages), if, other than as provided above, the Contractor is:
  - a. In breach of any of its material obligations under the Contract and fails to correct such breach within a period of thirty (30) days after having received a written notification to that effect from WHO; or
  - b. Adjudicated bankrupt or formally seeks relief of its financial obligations.

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### 7.19 Force Majeure

No party to the Contract shall be responsible for a delay caused by *force majeure*, that is, a delay caused by reasons outside such party's reasonable control it being agreed, however, that WHO shall be entitled to terminate the Contract (or any part of the Contract) forthwith if the implementation of the work is delayed or prevented by any such reason for an aggregate of thirty (30) days. Such termination shall be subject to payment of an equitable part of the Contract sum and/or other reasonable charges. In the event of such termination, the Contractor shall, in accordance with the ownership rights referred to in section 7.17 *Title rights*, deliver to WHO all work products and other materials so far produced.

In the event of and as soon as possible after the occurrence of any cause constituting *force majeure*, the Contractor shall give notice and full particulars in writing to WHO, of such occurrence or change if the Contractor is thereby rendered unable, wholly or in part, to perform its obligations and meet its responsibilities under the Contract. The Contractor shall also notify WHO of any other changes in conditions or the occurrence of any event which interferes or threatens to interfere with its performance of the Contract. The notice shall include steps proposed by the Contractor to be taken including any reasonable alternative means for performance that is not prevented by *force majeure*. On receipt of the notice required under this section, WHO shall take such action as it, in its sole discretion, considers to be appropriate or necessary in the circumstances, including the granting to the Contractor of a reasonable extension of time in which to perform its obligations under the Contract.

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### 7.20 Surviving Provisions

Those rights and obligations of the Parties as set forth in sections 7 and 8 that are intended by their nature to survive the expiration or earlier termination of the Contract shall survive indefinitely. This includes, **but is expressly not limited to**, any provisions relating to WHO's right to financial and operational audit, conditions of contract, warranties, legal status and relationship between the parties, breach, liability, indemnification, subcontracting, confidentiality, title rights, use of the WHO name and emblem, successors and assignees, insurance and liabilities to third parties, settlement of disputes, observance of laws, privileges and immunities, no terrorism or corruption, foreign nationals and compliance with WHO policies.

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### 7.21 Use of WHO name and emblem

Without WHO's prior written approval, the Contractor shall not, in any statement of an advertising or promotional nature, refer to the Contract or its relationship with WHO. In no case shall the Contractor use the name or emblem of the World Health Organization, or any abbreviation thereof, in relation to its business or otherwise.

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### 7.22 Successors and Assignees

The Contract shall be binding upon the successors and assignees of the Contractor and the Contract shall be deemed to include the Contractor's successors and assignees, provided, however, that nothing in the Contract shall permit any assignment without the prior written approval of WHO.

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### **7.23 Payment**

Payment will be made against presentation of an invoice in a UN convertible currency (preferably US Dollars) in accordance with the payment schedule contained in the Contract, subject to satisfactory performance of the work. The price shall reflect any tax exemption to which WHO may be entitled by reason of the immunity it enjoys. WHO is, as a general rule, exempt from all direct taxes, custom duties and the like, and the Contractor will consult with WHO so as to avoid the imposition of such charges with respect to this contract and the goods supplied and/or services rendered hereunder. As regards excise duties and other taxes imposed on the sale of goods or services (e.g. VAT), the Contractor agrees to verify in consultation with WHO whether in the country where the VAT would be payable, WHO is exempt from such VAT at the source, or entitled to claim reimbursement thereof. If WHO is exempt from VAT, this shall be indicated on the invoice, whereas if WHO can claim reimbursement thereof, the Contractor agrees to list such charges on its invoices as a separate item and, to the extent required, cooperate with WHO to enable reimbursement thereof.

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### **7.24 Title to Equipment**

Title to any equipment and supplies that may be furnished by WHO shall remain with WHO and any such equipment shall be returned to WHO at the conclusion of the Contract or when no longer needed by the Contractor. Such equipment, when returned to WHO, shall be in the same condition as when delivered to the Contractor, subject to normal wear and tear. The Contractor shall be liable to compensate WHO for equipment determined to be damaged or degraded beyond normal wear and tear.

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### **7.25 Insurance and Liabilities to Third Parties**

The Contractor shall provide and thereafter maintain:

- (i) insurance against all risks in respect of its property and any equipment used for the execution of the Contract;
- (ii) all appropriate workmen's compensation insurance, or its equivalent, with respect to its employees to cover claims for personal injury or death in connection with the Contract; and
- (iii) liability insurance in an adequate amount to cover third party claims for death or bodily injury, or loss of or damage to property, arising from or in connection with the performance of the work under the Contract or the operation of any vehicles, boats, airplanes or other equipment owned or leased by the Contractor or its agents, servants, employees, partners or sub-contractors performing work in connection with the Contract.

Except for the workmen's compensation insurance, the insurance policies under this section shall:

- a) Name WHO as additional insured;
- b) Include a waiver of subrogation to the insurance carrier of the Contractor's rights against WHO;
- c) Provide that WHO shall receive written notice from the Contractor's insurance carrier not less than thirty (30) days prior to any cancellation or material change of coverage.

The Contractor shall, upon request, provide WHO with satisfactory evidence of the insurance required under this section.

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## **7.26 Settlement of Disputes**

Any dispute relating to the interpretation or application of the Contract shall, unless amicably resolved, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absences of agreement, with the rules of arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final.

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## **7.27 Observance of Laws**

The Contractor shall comply with all laws, ordinances, rules, and regulations bearing upon the performance of its obligations under the terms of the Contract.

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## **7.28 Authority to Modify**

No modification or change of the Contract, no waiver of any of its provisions or any additional contractual relationship of any kind shall be valid and enforceable unless signed by a duly authorized representative of both parties.

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## **7.29 Privileges and Immunities**

Nothing in or relating to the Contract shall:

- be deemed a waiver of any of the privileges and immunities of WHO in conformity with the Convention on the Privileges and Immunities of the Specialized Agencies approved by the General Assembly of the United Nations on November 21, 1947 or otherwise under any national or international law, convention or agreement; and/or
- be construed as submitting WHO to any national court jurisdiction.

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## **7.30 No Terrorism or Corruption**

The Contractor warrants that:

- (i) it is not and will not be involved in, or associated with, any person or entity involved in terrorism, that it will not make any payment to any such person or entity and that it will not enter into any employment or subcontracting relationship with any such person or entity; and
- (ii) it shall not engage in any illegal, corrupt, fraudulent, collusive or coercive practices in connection with execution of the Contract.

The Contractor agrees that breach of this provision is a breach of an essential term of the Contract.

Any payments used by the Contractor for the promotion of any terrorist activity or any illegal, corrupt, fraudulent, collusive or coercive practice shall be repaid to WHO without delay.



## **8. PERSONNEL**

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### **8.1 Approval of Contractor Personnel**

WHO reserves the right to approve any employee, subcontractor or agent furnished by the Contractor and Contractor's consortium partners for the performance of the work under the Contract (hereinafter jointly referred to as "Contractor Personnel"). All Contractor Personnel must have appropriate qualifications, skills, and levels of experience and otherwise be adequately trained to perform the work. WHO reserves the right to undertake an interview process as part of the approval of Contractor Personnel.

The Contractor acknowledges that the qualifications, skills and experience of the Contractor Personnel proposed to be assigned to the project are material elements in WHO's engaging the Contractor for the project. Therefore, in order to ensure timely and cohesive completion of the project, both parties intend that Personnel initially assigned to the project continue through to project completion. Once an individual has been approved and assigned to the project, such individual will not, in principle, thereafter be taken off the project by the Contractor, or reassigned by the Contractor to other duties. Circumstances may arise, however, which necessitate that Personnel be substituted in the course of the work, e.g. in the event of promotions, termination of employment, sickness, vacation or other similar circumstances, at which time a replacement with comparable qualifications, skills and experience may be assigned to the project, subject to approval of WHO.

WHO may refuse access to or require replacement of any Contractor Personnel if such individual renders, in the sole judgment of WHO, inadequate or unacceptable performance, or if for any other reason WHO finds that such individual does not meet his/her security or responsibility requirements. The Contractor shall replace such an individual within fifteen (15) business days of receipt of written notice from WHO. The replacement will have the required qualifications, skills and experience and will be billed at a rate that is equal to or less than the rate of the individual being replaced.

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### **8.2 Project Managers**

Each party shall appoint a qualified project manager ("Project Manager") who shall serve as such party's primary liaison throughout the course of the project. The Project Manager shall be authorized by the respective party to answer all questions posed by the other party and convey all decisions made by such party during the course of the project and the other party shall be entitled to rely on such information as conveyed by the Project Manager.

The Project Managers shall meet on a monthly basis in order to review the status of the project and provide WHO with reports. Such reports shall include detailed time distribution information in the form requested by WHO and shall cover problems, meetings, progress and status against the implementation timetable.



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### **8.3 Foreign Nationals**

The Contractor shall verify that all Contractor Personnel is legally entitled to work in the country or countries where the work is to be carried out. WHO reserves the right to request the Contractor to provide WHO with adequate documentary evidence attesting this for each Contractor Personnel.

Each party hereby represents that it does not discriminate against individuals on the basis of race, gender, creed, national origin, citizenship.

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### **8.4 Compliance with WHO's Policies**

The Contractor shall at all times comply with and ensure that the Contractor and each of its partners, subcontractors and their employees and agents comply with any applicable laws and regulations and with all WHO policies and reasonable written directions and procedures relating to: (i) occupational health and safety, (ii) security and administrative requirements, including, but not limited to computer network security procedures, (iii) sexual harassment, (iv) privacy, (v) general business conduct and disclosure, (vi) conflicts of interest and (vii) business working hours and official holidays.

In the event that the Contractor becomes aware of any violation or potential violation by the Contractor, its partners, subcontractors or any of their employees or agents, of any laws, regulations, WHO policies or other reasonable written directions and procedures, the Contractor shall immediately notify WHO of such violation or potential violation. WHO, in its sole discretion, shall determine the course of action to remedy such violation or prevent such potential violation, in addition to any other remedy available to WHO under the Contract or otherwise.

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### **8.5 Ethical Behaviour**

WHO, the Contractor and each of the Contractor's partners, subcontractors and their employees and agents shall adhere to the highest ethical standards in the performance of the Contract. In this regard, the Contractor shall also ensure that neither Contractor nor its partners, subcontractors, agents or employees will engage in activities involving child labour, trafficking in arms, promotion of tobacco or other unhealthy behaviour, or sexual exploitation.

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### **8.6 Engagement of Third Parties and use of In-house Resources**

The Contractor acknowledges that WHO may elect to engage third parties to participate in or oversee certain aspects of the project and that WHO may elect to use its in-house resources for the performance of certain aspects of the project. The Contractor shall at all times cooperate with and ensure that the Contractor and each of its partners, subcontractors and their employees and agents cooperate, in good faith, with such third parties and with any WHO in-house resources.