PARTNER PROJECT AGREEMENT STCU P364 / DTRA UP-1

between

U.S. Department of Defence/Defence Threat Reduction Agency/Biological Threat Reduction Project,

the Science and Technology Center in Ukraine

and

Lviv Research Institute of Epidemiology and Hygiene Ministry of Health of Ukraine
Ukrainian Research Anti-Plague Institute Ministry of Health of Ukraine
Central Sanitary Epidemiological Station Ministry of Health of Ukraine

Kyiv

Operative Commencement Date: 1 November, 2008

The Science and Technology Center in Ukraine (STCU) (hereinafter referred to as **"the Center"**),
the U.S. Department of Defence/Defence Threat Reduction Agency/Biological Threat Reduction Project (hereinafter referred to as **" the Partner"**), and
the leading Institution Lviv Research Institute of Epidemiology and Hygiene Ministry of Health of Ukraine,
the Ukrainian Research Anti-Plague Institute Ministry of Health of Ukraine,
Central Sanitary Epidemiological Station Ministry of Health of Ukraine,

(hereinafter referred together as **"the Recipient(s)"**)
represented for the purpose of the signature of this Partner Project Agreement (hereinafter referred to as **"the Agreement"**) by their authorized representatives, (with the Center, the Partner, and the Recipient(s) hereinafter referred to collectively as **"the Signatory Parties"**),

TAKING INTO ACCOUNT THE FOLLOWING CONSIDERATIONS:

The United States of America, Canada, Sweden and Ukraine signed the agreement establishing the Science and Technology Center in Ukraine on October 25, 1993 (referred to as **"the STCU Agreement"**),

The European Union has acceded to the STCU Agreement on November 26, 1998, and in so doing, replaced Sweden as a Party to the Agreement,

Additional States may accede to the STCU Agreement to participate in the activities of the Center. Georgia acceded to the STCU Agreement on March 18, 1998; Uzbekistan acceded to the STCU Agreement on December 29, 1997, Azerbaijan acceded to the STCU Agreement on June 27, 2003, Moldova acceded to the STCU Agreement on December 7, 2004),

The Center is a legal entity and has been accredited by the Ministry of Foreign Affairs of Ukraine as an intergovernmental organization with its headquarters in Kiev,

The Partner, established under the law of United States of America is a legal entity that has been approved by the Center's Governing Board to participate in Center activities,

The Recipient(s) is a legal entity within Ukraine,

The Governing Board of the Center approves a project to be funded by the Partner through the Center in the domain covered by the Agreement,

The Partner has agreed to provide financial support for such project,

As set forth in the STCU Agreement, funds received by a legal entity in connection with the Center's projects shall be excluded in determining the profits of that organization for the purpose of tax liability, and funds received by persons in connection with the Center's projects shall not be included in these persons' taxable incomes,

HAVE AGREED AS FOLLOWS:

Article 1 - Scope of the Agreement

The Recipient(s) shall carry out the work plan set forth in Annex 1 according to the conditions of the Agreement, subject to the provisions of the STCU Agreement, and the Statute of the Center (hereinafter referred to as **"the STCU Statute"**) which govern in case of conflict. The activities carried out under the Agreement are entitled Evaluation of arthropod-borne infections in Ukraine (hereinafter referred to as **"the Project"**). The scopes of work and relevant budget lines for each recipient entity are identified in the Annex 1. All Project Activities subject to this Agreement are to be executed by the Recipient(s), using only funding provided by the Center and/or sources approved by the Center. The Recipient Entity(ies) shall notify the Center immediately if it and /or other participating institutions determine at any time to utilize any other funding sources to execute such Project activities.

Article 2 - Duration of the Project

The duration of the Agreement shall be from the date of entry into force of the Agreement (hereinafter referred to as "the Operative Commencement Date") until completion of the Agreement. Subject to the applicable requirements in Article 6 "Audit and Monitoring of the Agreement", Article 7, "Ownership and Exploitation of Results from the Agreement," and Annex III herein, the Agreement shall be deemed to have been completed upon approval by Partner of all deliverables required by the

Agreement and final payment to Recipient or termination of the Agreement pursuant to Article 11 herein, whichever is earlier. The duration of the Agreement is estimated to be 9 months.

Article 3 - Financial Contribution of the Partner through the Center

3.1 The total cost of the Project to the Center shall not exceed 125000$. This total includes the cost of items described in Articles 3.2, 3.3, and 3.4 below.

3.2 The Center shall pay for items ordered by the Recipient, represented by the project manager: equipment, materials, subcontracts, other direct costs, and travel. The amount of such payments is estimated to be 57205$.

3.3 The Center shall make grant payments directly to individual participants in the Project. The amount of such payments is estimated to be 57067$. This total amount may be increased with the concurrence of the Partner and Center provided that such increase results from additional time worked on the project, rather than an increase in the rate of pay, and an offsetting reduction is made to the cost of items in article 3.2.

3.4 The Center will pay overhead to the Recipient(s), represented by its Director(s), in the amount of 9.39% of the direct project costs.

3.5 The Center will receive a fee for its service in the amount of 0% of the total project costs. This amount should be calculated in addition to the total cost of the project.

3.6 The Partner will deposit to Center's account the entire amount of its commitment, equal to 125000$ that is the total cost of the project plus STCU's fee, in accordance with Articles 3.1, 3.5, and Article 7 of Annex 2.

3.7 Within Ukraine, all cash payments will be made in the national currency of Ukraine. Conversion of US dollars to the national currency of Ukraine will be according to the exchange rate of the Interbank Rate of Ukraine. Within Georgia, Uzbekistan, Azerbaijan, and Moldova all cash payments will be made in U.S. Dollars or Euros where possible.

3.8 Title to the property purchased for performance of this Agreement in accordance with Article 3.2 shall be determined in Annex 1 by applying one of the following clauses:
3.8.1 title will vest in the participation institution at the time of delivery or
3.8.2 title will remain with the Center until termination or completion of the project, at which time title will be vested in accordance with Article 8 - Special Conditions or following to additional agreement between the STCU, Partner and Recipient(s) replacing Special Conditions.

3.9 Title to any goods (deliverables) purchased by Partner under this Agreement shall pass directly from Recipient to Partner at the time of delivery, subject to Partner's right of rejection upon inspection.

Article 4 - Cost Statements, Reports, and other Project Outputs

Quarterly cost statements shall be submitted by the Recipient to the Center. The quarterly cost statements will include a representation that all projects activities conducted by the Recipient during the preceding quarter were funded only with funding provided by the Center and that no other source of funding was utilized in carrying out such activities.

Quarterly progress reports shall be submitted by the Recipient to the Center, to the Partner and/or to the Technical Monitor as designated by the Partner and identified in Annex I - Work Plan (in English and Ukrainian (optional) or Russian (optional, if the project is located only in other CIS states)), in hard copy and in electronic format in accordance with Annex 3 - Reports. The format of the cost statements and quarterly progress reports will be provided by the Center.

Technical reports and other deliverables that are requested by the Partner shall be submitted by the Recipient to the Partner and/or Technical Monitor in accordance with Annex I and Annex III.

Article 5 - Confidentiality

5.1 All reports or portions of reports properly marked as invention information or Business Confidential Information by the Recipient in consultation with the Partner shall be protected from public dissemination unless otherwise agreed by the Recipient(s) and the Partner.

5.2 Subject to any obligations under this Agreement and in accordance with applicable laws and regulations, the Signatory Parties agree to keep confidential any invention information or Business Confidential Information communicated to them by other Signatory Parties or third parties in relation to

the execution of this Agreement, unless such information so disclosed is or becomes legitimately available to the receiving Signatory Party through other sources without any covenant as regards its confidentiality.

Article 6 - Auditing and Monitoring

6.1 Access by the Center and the Partner, through the Center, to the project site to carry out on-site monitoring, for the evaluation and the verification of the progress of the Project activities, and to do audits of costs shall be granted by the Recipient(s) including access to (a) portions of facilities where the Project is being carried out and to all equipment, documentation, information, data systems, materials, supplies, personnel, and services which concern the Project, and (b) technical and cost information concerning the management and progress of the Project.

6.2 The Center will give the Recipient(s) up to 10 days advance notice of any intended on-site monitoring of the project.

6.3 The Recipient(s) has the right to protect those portions of facilities that are not related to the Project.

6.4 All documentation and records, including those associated with equipment, data systems, materials, supplies, and services utilized on the project must be maintained and made available for review by the Center, the Partner, or their representatives, for up to two years following the project's completion or termination.

Article 7 - Ownership and Exploitation of Results

7.1 The allocation of intellectual property arising from this Agreement and the responsibilities for protecting and exploiting such intellectual property should be established between the Recipient(s) and the Partner or Technical Monitor, on behalf of the Partner, in the form of Annex 4.

7.2 Exploitation of results shall be limited to applications for peaceful purposes. In this regard, the Recipient(s) and the Partner shall ensure that any results which could result in concerns over proliferation of weapons technology and transfer of sensitive technologies will be protected in accordance with relevant laws of Ukraine, and international agreements and conventions to which Ukraine, is a party.

Article 8 - Special Conditions

8.1 The special conditions specified in this Article shall prevail over other conditions specified in the Agreement.

8.2 Partner, upon agreement with Center and Recipient(s), may at any time, by written notice, make changes within the scope of this Agreement. If any such change causes an increase or decrease in the cost of, or the time required for, performance of any part of the work under this Agreement, whether or not changed by the order, or otherwise affects any other terms and conditions of this Agreement, Partner shall make an equitable adjustment in the Project Price, the delivery schedule, or both, and shall modify the Agreement.

Article 9 - Liability

9.1 The Signatory Parties accept the project team for the execution of the project and accept the project manager as the leader of the project team. The project manager shall be responsible for scientific, technical, personnel and financial activities related to the project, and shall have exclusive rights to handle all goods and services related to the project during its term. The director(s) of the institution(s) is liable for provision of general administrative and legal support to the project manager in connection with the execution of the Agreement.

9.2 The Center shall not be liable for nonperformance by the Partner or the Recipient(s) of their obligations under the Agreement.

9.3 The Center and Partner shall not be liable for any material loss, damage, or injury of any nature arising from, or in connection with, the performance of the work under the Agreement.

Article 10 - Disputes

Disputes arising during performance of the Agreement including, in particular, (1) a claim by the Recipient(s) for any payments deemed due; (2) an interpretation of a provision of the Agreement; or (3) a request for relief or approval related to the Agreement, shall be subject to the following procedure.

The Recipient(s) shall submit any claim, demand, or request in writing to the Partner and to the Center. The Partner and the Center will prepare a joint response. The written decision of the Partner and the Center shall be delivered to the Recipient(s) within four weeks of the receipt of the submission.

Exceptionally, the Recipient(s) may appeal the Partner's and Center's decision in writing through the Executive Director of the Center to the Governing Board of the Center within four weeks of the communication of the Partner's and Center's decision.

The decision of the Governing Board shall be final and binding (unless otherwise provided). Pending the final settlement of disputes, the Recipient(s) shall, nevertheless, proceed diligently with the performance of the Agreement.

Article 11 - Suspension and Termination of the Agreement

11.1 Each Signatory Party shall reserve the right to suspend the Project or its part by issuing to the other Signatory Parties a notification of suspension which specifies the problem, the effective date, and the period of the suspension.

11.2 When the Project is suspended by the Center, and the period of the suspension expires and the Center and the Recipient are unable to find a solution, the Center shall, in consultation with the Partner, terminate the Project or a part of the Project.

11.3 When the Project is suspended by the Recipient, and the period of the suspension which is specified in the Recipient's notification expires and the Recipient and the Center are unable to find a solution, the Recipient shall terminate the Project.

11.4 Notwithstanding the termination, the Recipient shall submit reports and cost statements covering the period up to the termination and the following provisions of the Agreement shall continue to apply: Article 7, Article 10, and Annex 2.

11.5 When Force Majeure situations occur which make the Project implementation impossible, the Center in consultation with the Partner and the Recipient(s) may terminate the Project with application of similar procedures as specified above.

11.6 When the Recipient(s) has committed actions which obviously violate the national laws of the Ukraine, or which obviously are contrary to the objectives specified under the STCU Agreement, the Center shall terminate the Project with immediate effectiveness upon written notification of termination to the Recipient. In this case, the Recipient(s) shall promptly return to the Center all payments and goods previously provided to the Recipient(s).

Article 12 - Amendments, Variations, or Additions

The provisions of the Agreement and its annexes may be amended or supplemented by means of a written agreement signed by authorized representatives of the Signatory Parties. However, operational changes in Annex 1, other than changes in the project manager, the institution, and the overall schedule, can be made by agreement between the Center and the Recipient(s) upon approval by Partner requested in accordance with applicable clauses of Annex 1.

Article 13 - Annexes

The Annexes are an integral part of the Agreement. They are:
Annex 1 - Work Plan
Annex 2 - Financial Provisions
Annex 3 – Reports
Annex 4 – Intellectual Property

Article 14 - Entry into Force of the Agreement

The Agreement shall enter into force on the first of the month following the date this Agreement is signed by the last signature of Signatory Parties or the date Partner deposited its commitment in accordance with Article 3.6 to Center's account, whichever is later, i.e. on "the Operative Commencement Date".

Prepared in Kyiv in the English and Ukrainian languages (Russian optional, if the project is located only in other CIS State). In the event of inconsistencies between the English and other texts, the English text shall take precedence.

For the Center

5.11.2008

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2.6.3. Підходи до діагностики лептоспірозу.

Лабораторно гострий лептоспіроз людини може бути діагностовано за допомогою ПЛР та серологічних досліджень, зокрема ELISA та реакції мікроаглютинації (МАТ) [14, 39]. Однак антитіла до лептоспір рідко виявляються методом МАТ у перші сім днів перебігу захворювання, а чутливість залишається значно нижчою від 100%, особливо протягом перших 14 днів хвороби [39]. Нещодавно було розроблено метод на основі ПЛР для виявлення ДНК лептоспір в сечі, що дозволяє діагностувати інфекцію в зразках, отриманих на ранньому етапі перебігу хвороби до того, як з'являється можливість виявляти антитіла. Як МАТ, так і ПЛР є доступними в Україні, і попередні дані зі Львова свідчать про те, що лептоспіроз можливо підтвердити за допомогою ПЛР, МАТ або обох методів приблизно у 85% пацієнтів з клінічним діагнозом гострого лептоспірозу (Зубач О., особисте спілкування).

III. ПЛАН ДОСЛІДЖЕННЯ

3.1. Цілі

3.1.1. Основні цілі:

1. Визначити серопревалентність антитіл до хантавірусів серед 4000 і вірусу ККГГ серед 400 здорових добровольців, залучених установами військових частин та медичних закладів Міністерства оборони України, розташованих у Львові, Харкові, Одесі та Києві, і порівняти ці дані з інформацією у їх медичних картках, розроблених анкетах.

Захворювання, викликані хантавірусами, були вперше виявлені під час Корейської війни, коли близько 1500 військовослужбовців ООН захворіли на невідому фібрильну хворобу з ознаками ураження нирок та геморагічними симптомами. Як показали результати досліджень за період багатьох років, військова діяльність (риття окопів, земельні роботи в полі) призводять до вищого ризику для солдатів, ніж будь-які інші види діяльності. Таким чином, ця популяція може пролити світло на поширеність хантавірусів у навколишньому середовищі та потенціал виникнення захворювання, оскільки Міноборони має військові частини на всій території країни. Окрім того, збір зразків МОЗ локалізований у двох областях з метою забезпечення інформативних оціночних даних про інтенсивність захворювання, у той же час, за результатами діяльності Міноборони будуть отримані оціночні дані щодо рівня ризику інфікування збудниками ККГГ та ГГНС в Україні. Ці дані також дадуть відповідь на запитання про те, чи екстраполяція даних про гризунів та кліщів на національний рівень може надати цінну цільову інформацію.

2. Ідентифікувати антитіла до вірусу ККГГ та хантавірусів у сироватках крові людей використовуючи цільовий підхід до вибірки зразків добровольців.

- Дослідження припиняє Міністерство оборони США, інша регуляторна структура уряду США або будь-який регуляторний орган в Україні.

Якщо учасник вирішує відмовитися від участі в дослідженні або виходить із нього, будь-які зібрані в ході дослідження дані, включаючи зразки для лабораторних досліджень, будуть вилучені з аналізу та знищені.

3.5. Процедури на випадок відхилення від протоколу

Весь медичний персонал, що проводить відбір зразків крові та персонал лабораторій Служби превентивної медицини МО України, який бере участь у лабораторних процесах, до початку дослідження проходитиме навчання з процедур та етики проведення досліджень, суб'єктом якого є людина. У разі ненавмисного включення осіб, що не відповідають критеріям включення, біологічні зразки від них не повинні відбиратися, будь-які зібрані мають бути вилучені з аналізу та знищені, а особа має бути проінформовано про це. Якщо зразки для лабораторних досліджень від осіб, що не відповідають критеріям включення, вже були відібрані, вони будуть вилучені, а особа – проінформована про це.

У цілому, про відхилення від протоколу, що не впливають на здоров'я учасників, буде повідомлено під час поточного перегляду протоколу та/або в остаточному звіті. Про відхилення від протоколу або неочікувані ситуації, що можуть вплинути на здоров'я, безпеку або благополуччя учасників дослідження, буде негайно повідомлено головному дослідникові / менеджеру зі збору даних, українському комітету з біоетики та Агентству зменшення загрози Міністерства оборони США (АЗЗ). Про незначні інциденти слід повідомляти протягом 72 годин, а про серйозні, включаючи випадки смерті – протягом 24 годин. Усі випадки смерті суб'єктів дослідження, підозрювані або відомі як такі, що пов'язані з процедурами дослідження, повинні бути доведені до відома комітетів із біоетики в США та Україні. Про будь-які відхилення від протоколу або неочікувані ситуації, які викликають занепокоєння щодо наукової обґрунтованості продовження дослідження, також буде негайно повідомлено головному дослідникові, головному співдослідникові, українському комітету з біоетики та АЗЗ.

Якщо очікується відхилення від протоколу, головний дослідник та головний співдослідник попередять комітет з біоетики в Україні, а також заздалегідь запросять дозвіл на виняток з протоколу у АЗЗ. Усі зміни в протоколі та згоді повинні бути схвалені комітетами з біоетики в Україні до початку їх впровадження.

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United States Army
Medical Research Institute
of Infectious Diseases

Biodefense solutions to protect our nation

Viral Hemorrhagic Fever Medical Countermeasures Clinical Trials Network 2015

United States Army Medical Research Institute of Infectious Diseases (USAMRIID)
and
Naval Medical Research Center (NMRC)

USAMRIID
United States Army
Medical Research Institute
of Infectious Diseases

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Bottom Line

- **World caught unprepared for a large Ebola outbreak**
- **DoD, USAMRIID, and entire USG was unable to execute clinical studies**
- **Advances in medical countermeasure (MCM) development restricted to Ebola *Zaire* – not other Filoviruses**
- **<u>Proposed Solution:</u> Deployable response unit and capability centered around Joint Advanced Technology Demonstrations (JATD) for viral therapeutics and diagnostics located within the AFRICOM AOR that can be expanded to other areas of interest**

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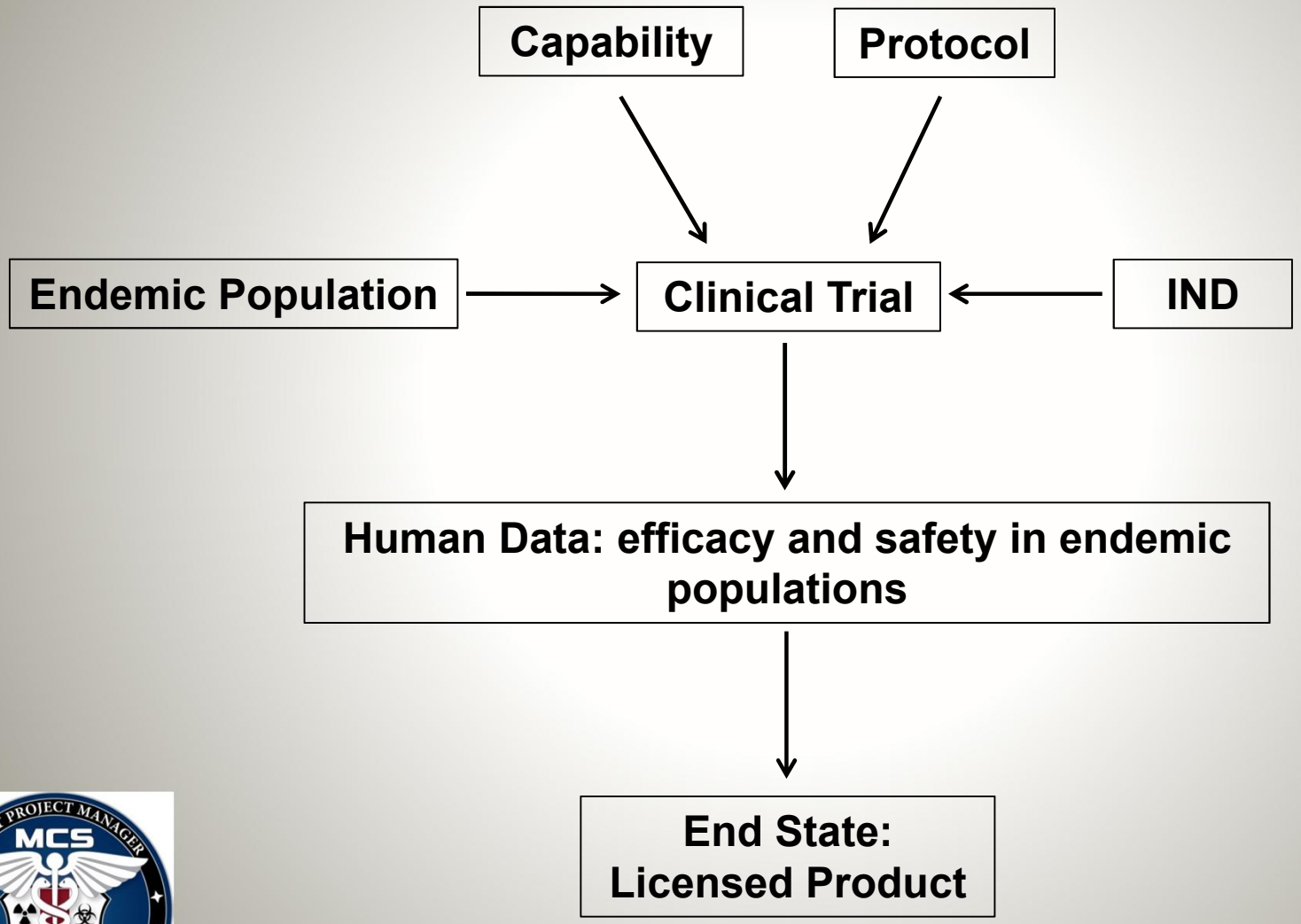
Bottom Line



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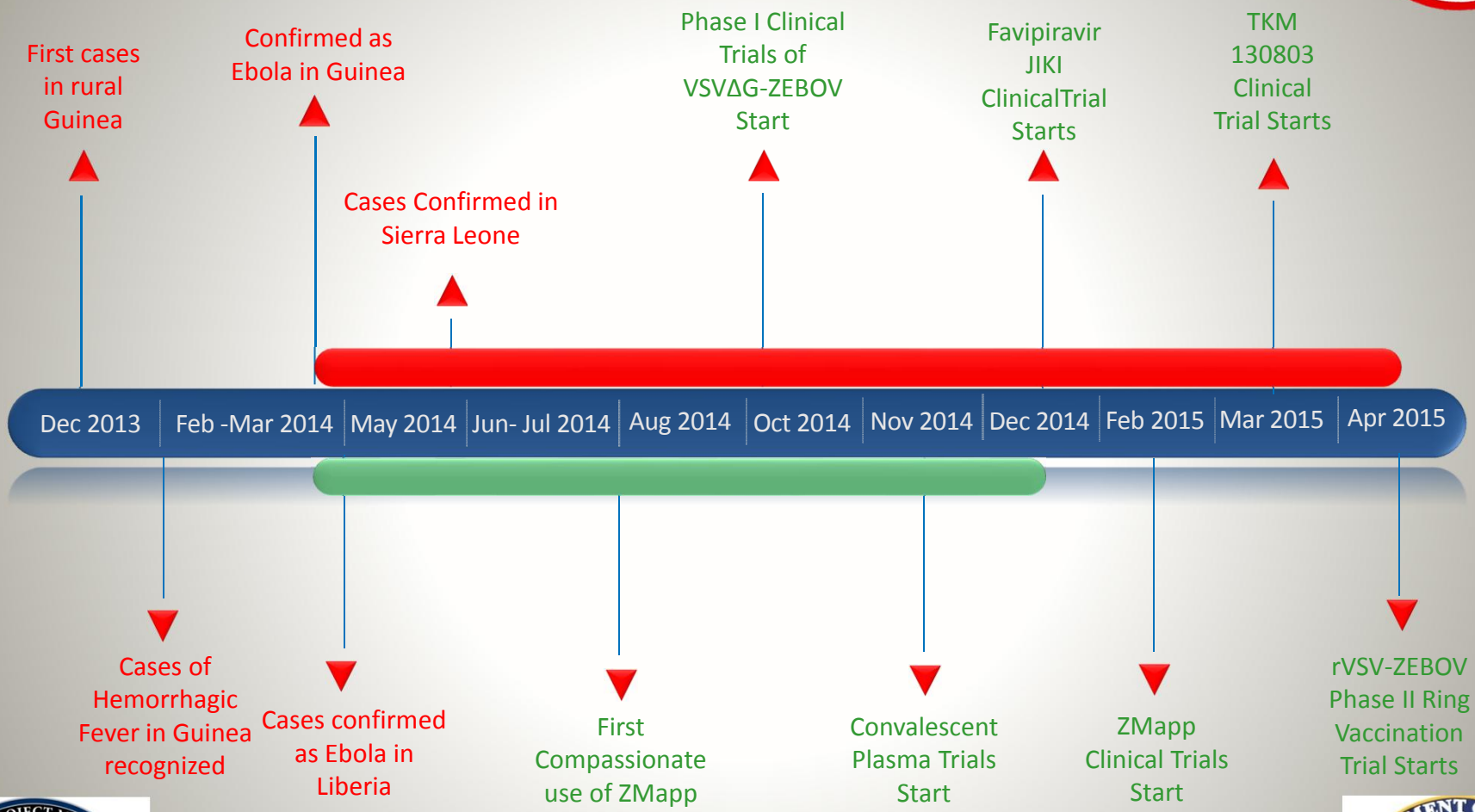
Background



Time until first vaccine trial in West Africa

Time until first novel therapeutic trial in West Africa

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Problem Points

- **Overall, the world was caught unprepared for outbreak:**
  - **Lack of Treatment/therapeutics**
  - **Lack of MCMs/vaccines**
  - **Lack of Standard of Care**
  - **Lack of General Outbreak Mitigation Infrastructure and Activity**
  - **Lack of Diagnostics**
- **DoD (and entire USG) was unable to execute clinical studies due to:**
  - **Absence of a viable health care infrastructure to support clinical trials**
  - **Lack of FDA-approved protocols, INDs, and adequate clinical drug supplies**
  - **Uncertainty of USG Research & Development leadership**
- **Recent potential advances in MCM development are mostly restricted to Ebola Zaire not Makona.**

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Problem Statement

- **Due to a number of factors linked to a lack of local health infrastructure, outbreak severity, unpreparedness, and leadership uncertainty, DoD was unable to execute any significant clinical studies to push forward MCMs while Ebola Viral Hemorrhagic cases existed in meaningful numbers.**

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Lessons Learned

- **Need ability to IMMEDIATELY implement key clinical trials in next outbreak response**
- **Requirements prior to an outbreak**
  - **Prepositioned healthcare and clinical research infrastructure**
  - **Trained and ready research teams**
  - **Pre-approved IND/human subjects research protocols**
  - **Established logistical tail, including available therapeutic product**

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Necessary Factors for Clinical Trial Success

- Filed INDs
- Flexible and pre-approved protocols;
- Clinical research infrastructure (including well-trained personnel, functioning laboratory support, logistical systems, human subjects research and regulatory oversight, and continuously exercised system function);
- Support/endorsement of senior DoD leadership, US Government MCM Enterprise leadership, and host-nation governments; and
- Functional integration into host-nation and international filovirus outbreak response plans and operations.

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Solution:
Deployable Clinical JATD

Mission

Deployable response unit and capability centered around Joint Advanced Technology Demonstrations (JATD) for viral therapeutics and diagnostics located within the AFRICOM AOR that can be expanded to other areas of interest. Primary mission will include:

- Conduct JATD of the ability to apply therapeutic and diagnostic products against viral targets.
- Develop CONUS test-bed capability for component/system validation.
- Provide training opportunities for both OCONUS host nation and US military outbreak response units.
- Support rapid response and deployment to emerging outbreaks and apply enhanced application of viral therapeutics and diagnostics.

- Provide the capability to evaluate MCM for FDA approval protecting the warfighter against Hemorrhagic Fever Viruses and other emerging threats worldwide.

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Partners

- **MCS: Provide U.S. military forces and the nation safe, effective, and innovative medical solutions to counter CBRN threats**
- **USAMRIID: U.S. Army's Center of Excellence for Medical Biological Defense Research**
- **NMRC: Lead institute for U.S. Navy medical research enterprise for infectious diseases**

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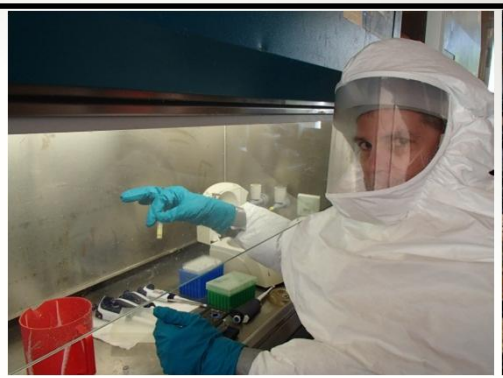
USAMRIID: Africa Experience






Liberia Ebola Outbreak: July2014-Present



East African/Uganda Clinician Training

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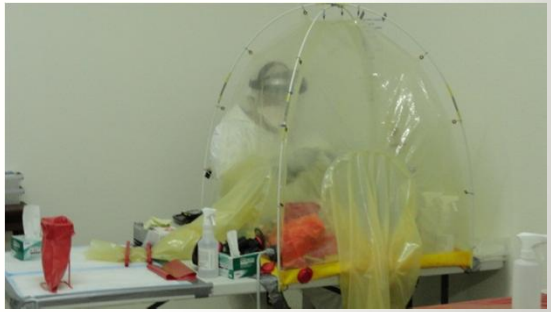
NMRC Experience

On-the-ground clinical/operational experience in multiple filovirus outbreak settings in West and Central Africa.

Kabale, Uganda. Marburg Outbreak, Oct 2012.

Conakry, Guinea. Ebola Outbreak, May 2014



Bong/Monrovia, Liberia. Ebola Outbreak, September 2014-April 2015

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Execution: ATD

Initial 3-phase spiral over 36 months

Deliverables:

Phase I: Develop CONUS capability and validation exercise (CAPEX) for test-bed operation

Phase II: Deliver first OCONUS site for basic trial capability in country

Phase III: Deliver additional OCONUS sites for advanced trial capability and execution of MCS products

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Phase I: CONUS Test-bed/CAPEX

Initial Operational Capability (IOC) Phasing and Capability Exercises (CAPEX), Fort Detrick, MD – Farm Site

Laboratory Containment

Shelter/Treatment Area

Power/Environmental Control

Air Filtration

Clean Power Distribution

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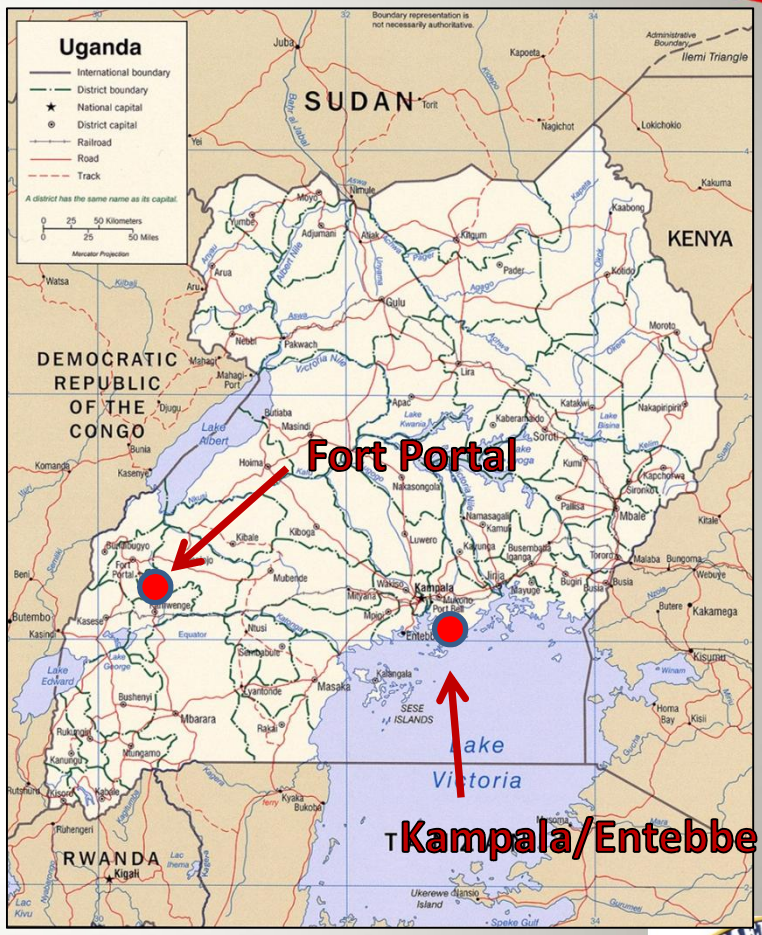
Phase II: Fort Portal Site

- **Well Established Relationships:**
  - **Uganda Infectious Disease Institute-USAMRIID clinician training partnership.**
  - **Partnership with Ugandan-MOH and Makerere University Walter Reed Project (MUWRP)**

- **Strategically located**
  - **Close to site of Bundibugyo Ebola outbreak and in highly active area for emerging infectious diseases (Western Uganda/ Eastern DRC)**



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Phase III: Additional Site Options

- **Numerous possibilities due to Army and Navy presence overseas**

- **Army:**
  - **USAMRU-K: Kenya**
  - **AFRIMS: Thailand**
  - **USAMRU-G: Republic of Georgia**

- **Navy:**
  - **NAMRU-3: Egypt**
  - **NAMRU-6: Peru**

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Command, Control and Logistics

In order to protect the Warfighter from deliberate and emerging ID threats

- **JPEO-MCS: Manages the JATD and CAPEX capabilities**
- **USAMRIID and NMRC: Provides field clinical trials management to the JATD to support FDA licensure of MCM products in an outbreak environment. This will be done through fixed and mobile capabilities in high threat areas**
- **USAMRIID and NMRC: Provides sustainment and ensures operational capability of the JATD**

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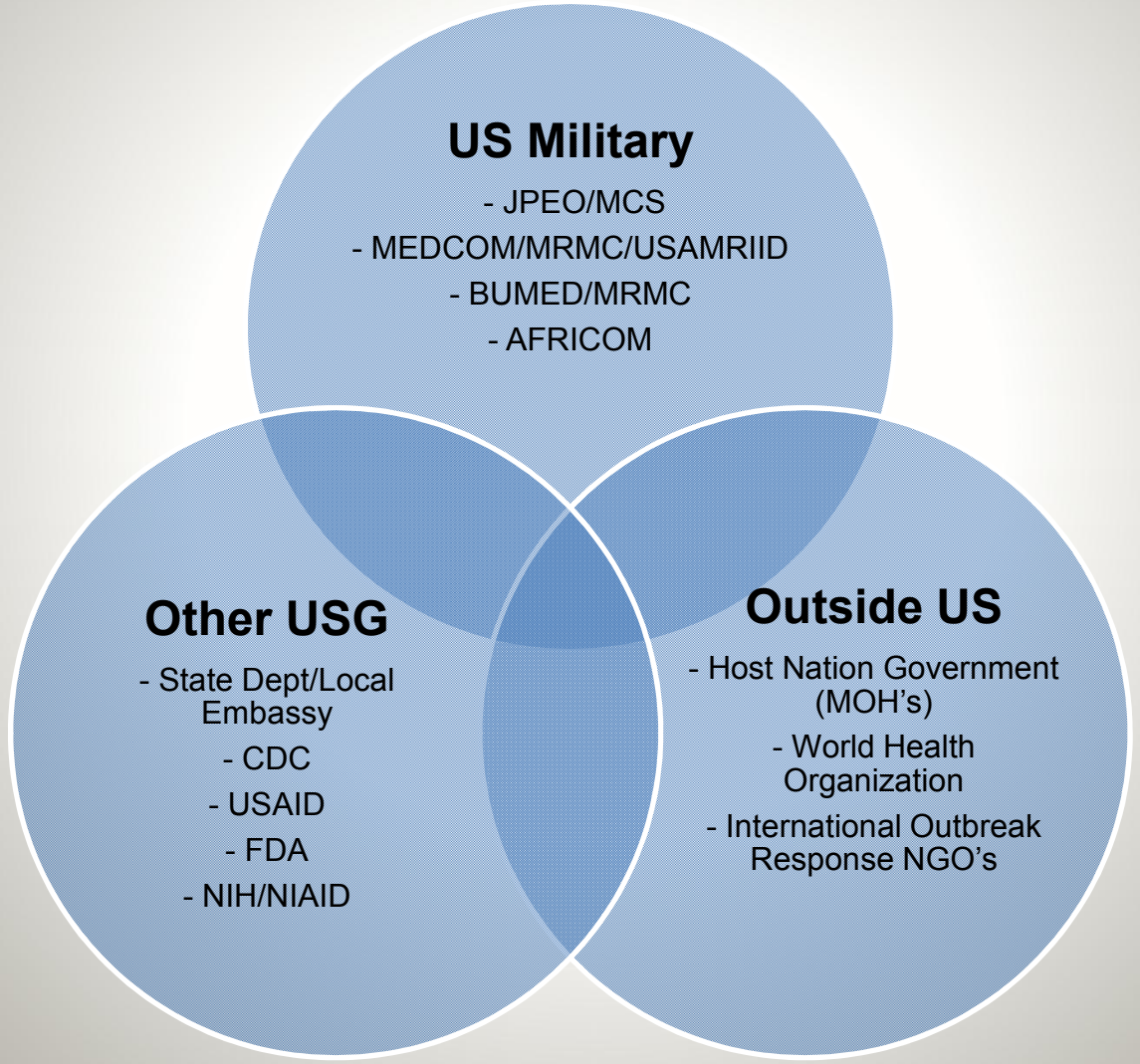
Coordination/Engagement



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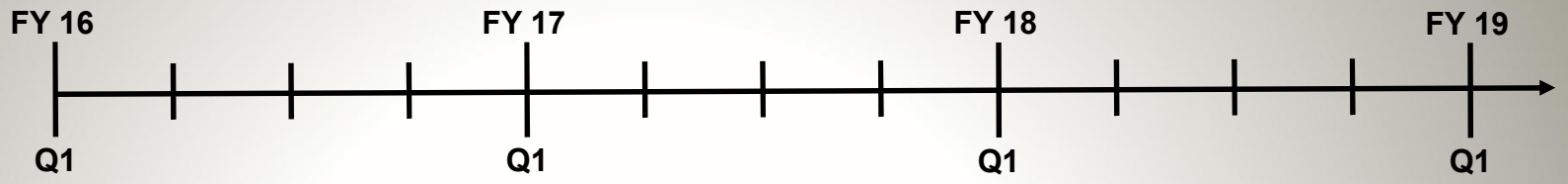
JATD Phase Schedule



MCS Contracting

Phase I
- **Test-bed CONUS**

Phase II
- **Pilot Site, Fort Portal Uganda, Basic Protocol Capability**
- **Additional Sites, Basic Protocol Capability**

Phase III
- **Pilot Site, Fort Portal Uganda, Advanced Protocol Capability**
- **Additional Sites Advanced Protocol Capability**

Additional Sites MCM Clinical Trial Ready

Represents CAPEX

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Investment

Deliverable	YR 1	YR 2	YR 3	3 YR Cost	10 YR O&M Cost
Core Deliverables					
CONUS Testbed	$2.0m			$2.0m	
OCONUS Site 1 MCM Clinical Trial Ready	$4.0m	$2.0m		$6.0m	
Optional Additional Sites					
OCONUS Site 2 *MCM Clinical Trial Ready*		*$3.0m*	*$3.0m*	*$6.0m*	
OCONUS Site 3 *MCM Clinical Trial Ready*		*$3.0m*	*$3.0m*	*$6.0m*	
Medical Sustainment	$2.0m	$2.0m	$2.0m	$6.0m	$20m
ATD Total Cost over 10 YRS	$8.0m	$10.0m	$8.0m	$26.0m	$40m
JPEO Total	**$6.0m**	**$8.0m**	**$6.0m**	**$20m**	**$0.0m**
Sustainment Total	**$2.0m**	**$2.0m**	**$2.0m**	**$6.0m**	**$20m**

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JATD Capability Enhancement

	Current Capability	New Capability
Lab	Basic clinical tests in fixed location, standard containment	Full operational clinical and microbiological diagnostic tests, Mobile ready, Advanced molecular and biochemical (PK/PD) testing, high-level field biocontainment
Patient Care	Consistent with Ministry of Health Standards	High-performance, validated supportive care protocols for clinical management of severe infectious diseases in resource-constrained setting
Clinical Facility	Fixed location using existing power and facilities	Fixed or mobile location with designed isolation, fully reliable power and facilities
Medical Logistics	Basic supply/transport with standard ordering and delivery times	Pre-positioned and active supply chain that provides quick ordering/deliveries with minimal lead time
Staff and Training	Qualified/willing staff for basic clinical studies (not FDA trials) of conventional pathogens; Basic training human subjects research	Staff qualified for FDA clinical trials with high-threat agents; Intensive Good Clinical Practice and Good Laboratory Practice training and frequent exercises
Human Subjects Research	Standard regulatory oversight and protocols	Advanced regulatory structure built and exercised to support FDA level review Flexible and pre-approved research protocols
Infection Prevention and Control	Universal precautions; Brief flex to elevated posture for small number of suspect or confirmed cases	Sustained high-level isolation care for multiple critically ill patients
Data Management /Informatics	Local data management and basic processes to secure and share data	Strengthened data management processes and systems to perform in mobile locations and provide more immediate access for research team in secure, remotely accessible environment

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Next Steps

- Letter of support from USAMRIID
- Discussion about USAMRIID contribution to sustainment
- Start discussions about INDs/protocols

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Goal: Until we can run an IND trial here, we will not be able to bring an Ebola MCM to licensure.

Donka Ebola Treatment Unit. Conakry, Guinea.