Change History Table: Original – Amendments (5)

Amendment 5 (December 18, 2024): BARDA BAA-23-100-SOL-00004 List of Changes:

Amendment 5 (December 18, 2024)
1. Updates to Background • Updated language under BARDA's Detection, Diagnostics, and Devices Infrastructure (DDDI) Division 2. Updates to Part I: Development and Technical Objectives • Updated language under Development and Manufacturing Approach – Manufacturing Development Activities 3. Updates to Part VI: Proposal Instructions (Stage 3) • Added Vol. II, Attachment 12: Supply Chain Risk Assessment • Added Vol. II, Attachment 13: Procurements Involving Synthetic Nucleic Acid and Screening 4. Updates to Part VII: Proposal Evaluation • Added Additional Information – Prospective Contractor Responsibility and Eligibility Standards: Supply Chain Risk Assessment 5. Updates to Area of Interest #1: CBRN Vaccines • Suspend AOI 1.1. Needle-Free Technologies to Administer Licensed Vaccines 6. Updates to Area of Interest #2: CBRN Antivirals and Antitoxins • Updated language under introductory paragraphs to AOI 7. Updates to Area of Interest #5: Chemical Medical Countermeasures • Updated AOI 5.1. Pulmonary Agents • Updated AOI 5.2. Pharmaceutical-based Agents, including Opioids and Other Respiratory Depressants 8. Updates to Area of Interest #6: Burn and Blast Medical Countermeasures • Updated language under introductory paragraphs to AOI • Updated AOI 6.1. Burn and Blast Traumatic Injuries Management • Updated AOI 6.2. Management of Head Injuries in Trauma • Updated AOI 6.3. Hemorrhage Control • Suspend AOI 6.4. Non-Autologous Topical Products to Prevent or Reduce Burn Wound Conversion (Defined as a Worsening of a Burn Wound From its Original Depth) • Updated AOI 6.5. Management of Blunt Trauma Injuries • Updated AOI 6.6. Musculoskeletal Injuries • Suspend AOI 6.7. Special Instruction for Health Economic Impact Assessment of Burn MCMs • Updated AOI 6.8. Platform Agnostic Software for AI Augmentation of Ultrasound Imaging Data, including:

Amendment 5 (December 18, 2024)
i. Updated AOI 6.8.1 Final Product – Device-Agnostic Ultrasound Algorithm ii. Updated AOI 6.8.2 Proposal Requirements – 6.8.2.1 through 6.8.2.8 iii. Updated AOI 6.8.3 Sustainability Planning iv. Deleted AOI 6.8.4 Deadlines and USG Response Time • Updated language under Qualities That Strengthen the Competitiveness of a Proposal 9. Updates to Area of Interest #7: Diagnostics • Updated AOI 7.1.3. Biothreat Agent Diagnostics: Filovirus Point-of-Care and Remote Settings • Updated AOI 7.2.1. Bacterial Antimicrobial Resistance (AMR) Testing Direct from Specimen • Updated AOI 7.3. Influenza Diagnostics • Updated AOI 7.3.1. Influenza Testing in an OTC and CLIA waived environment • Suspend AOI 7.3.2. Pan-Influenza Diagnostics: Point-of-Care or Laboratory • Suspend AOI 7.3.3. Point-of-Care Multiplex Assay for Detection of Influenza Virus • Updated AOI 7.4.1. Next-Generation Sequencing (NGS)-Based Diagnostic for Viral Pathogens, including: i. Updated information under Out-of-Scope Topics for AOI 7.4.1 ii. Updated information under Qualities that Strengthen the Competitiveness of a Proposal to AOI #7 (Diagnostics) 10. Updates to Area of Interest #8: IEID Vaccines • Updated Technical POC 11. Suspend Area of Interest #12: Flexible and Strategic Therapeutics (FASTx) 12. Added Appendix 3: HHSAR Referenced Clause

Amendment 4 (June 4, 2024): BARDA BAA-23-100-SOL-00004 List of Changes:

Amendment 4 (June 4, 2024)
1. Updates to Area of Interest #7: Diagnostics • Updated TRL Requirement • Updated AOI 7.1.3. Biothreat Agent Diagnostics: Filovirus Point-of-Care and Remote Settings • Updated AOI 7.2.1. Bacterial Antimicrobial Resistance (AMR) Testing Direct from Specimen • Updated AOI 7.3. Influenza Diagnostics • Updated AOI 7.3.1. Influenza Home-Use Testing (for OTC or Prescription At-home) 2. Updates to Area of Interest #12: Flexible and Strategic Therapeutics (FASTx) • Updated Guidance for proposals pursuing a PEP or PrEP indication • Updated Guidance for proposals pursuing a mAb platform • Deleted Important guidance for proposals for SARS-CoV-2

Amendment 3 (Mar 29, 2024): BARDA BAA-23-100-SOL-00004 List of Changes:

Amendment 3 (Mar 29, 2024)
1. Updates to Area of Interest #3: Antimicrobials • Updated AOI 3.1. MDR Bacteria and Biothreat Pathogens • Updated 3.2. MDR Fungal Infections 2. Updates to Area of Interest #5: Chemical Medical Countermeasures • Updated AOI 5.2. Opioids and Other Respiratory Depressants • Updated TRL Requirement 3. Updates to Area of Interest #6: Burn and Blast Medical Countermeasures • Updated AOI 6.1. Enabling Technologies to Address General Burn & Blast Traumatic Injuries • Updated AOI 6.2. Management of Head Injuries in Trauma • Updated AOI 6.3. Hemorrhage Control • Suspend AOI 6.4. Non-Autologous Topical Products to Prevent or Reduce Burn Wound Conversion • Added new AOI 6.5. Management of Blunt Trauma Injuries • Added new AOI 6.6. Advanced Imaging Technologies in Management of Trauma • Added new AOI 6.7. Special Instruction for health economic impact assessment of Burn MCMs

Amendment 3 (Mar 29, 2024)
• Added new AOI 6.8 Special Instruction for Platform Agnostic Software for AI Augmentation of Ultrasound Imaging Data. 4. Updates to Area of Interest #7: Diagnostics • Updated AOI 7.1.3. Biothreat Agent Diagnostics: Filovirus Point-of-Care and Remote Settings • Updated AOI 7.2.1. Bacterial Antimicrobial Resistance (AMR) Testing Direct from Specimen • Suspend AOI 7.2.2. Bacterial vs. Viral Infections: Point-of-Care • Updated TRL Requirement

Amendment 2 (Dec 22, 2023): BARDA BAA-23-100-SOL-00004 List of Changes:

Amendment 2 (Dec 22, 2023)
1. Suspend AOI 9.4 COVID-19 Monoclonal Antibody Therapeutics for Treatment

Amendment 1 (Nov 9, 2023): BARDA BAA-23-100-SOL-00004 List of Changes:

Amendment 1 (Nov 9, 2023)
1. Updates to Overview Information – • Updated Research and Development Opportunity Description • Updated General Market Research (TechWatch Program), • Updated Application Process, • Updated Contract and Submission Information, • Updated Electronic Portal Submission Instructions 2. Updates to Background 3. Updates to Part I: Development and Technical Objectives 4. Updates to Part IV: Pre-Submission Call and Quad Chart/Market Research Abstract Instructions (Stages 1 & 2) • Updated Figure 1. BARDA BAA Process Flow Chart • Updated Stage 1: Pre-submission Call with Technical POC 5. Updates to Part VI: Proposal Instructions (Stage 3) • Updates to Stage 3: Proposal Precreation

Amendment 1 (Nov 9, 2023)
○ Section M. Past Performance Information & ○ Vol. II, Attachment 10: Past Performance ○ Vol. II, Attachment 11: Reason for the Proposed Award Type 6. Updates to Part VII: Proposal Evaluation 7. Updates to Area of Interest #6: Burn and Blast Medical Countermeasures • Updated TRL Requirement 8. Updates to Area of Interest #7: Diagnostics • Updated AOI 7.1.3 Biothreat Agent Diagnostics: Filovirus Point-of-Care and Remote Settings • Updated AOI 7.3.1 Influenza Home-Use Testing (for OTC or Prescription At-home) • Updated AOI 7.3.3 Point-of-Care Multiplex Assay for Detection of Influenza Virus 9. Updates to Area of Interest #9: IEID Therapeutics • Added new Area of Interest 9.4 COVID-19 Monoclonal Antibody Therapeutics for Treatment • Updated Additional Assessment Factors for the Specific Topic AOIs 10. Suspend AOI #11: COVID-19 Immune Assay(s) Development and Implementation