# Change History Table: Original – Amendments (6)

**Amendment 6 (May 29, 2025): BARDA BAA-23-100-SOL-00004 List of Changes:**

| Amendment 6 (May 29, 2025) |
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| 1. Updates to Introduction<br>• Updated language under Introduction<br>• Added additional Disclaimer<br>2. Updates to Overview Information<br>• Updated language under Eligible Offerors<br>3. Updates to Background<br>• Updated language under Background<br>• Updated Table 2<br>4. Updates to Part I: Development and Technical Objectives<br>• Updated language to Development and Manufacturing Approach<br>5. Updates to Part VI: Proposal Instructions (Stage 3) – Volume II – Cost Proposal Attachments<br>• Rescinded Vol. II, Attachment 13: Procurements Involving Synthetic Nucleic Acid and Screening<br>6. Updates to Part VII: Proposal Evaluation<br>• Updated language under Program Relevance<br>• Added additional Other Evaluation Factors and Considerations for:<br>i. Gain of Function Research<br>ii. Domestic Based Manufacturing<br>7. Updates to Part VII: Research and Development Areas of Interest<br>• Added definitions<br>8. Updates to Area of Interest #1: CBRN Vaccines<br>• Updated language under introductory paragraph to AOI<br>• Updated AOI 1.2. Sudan Virus and Marburg Virus<br>• Updated AOI 1.3. Flexible Vaccine Manufacturing Platform Technologies<br>• Updated AOI 2.2. Botulism Antitoxins<br>• Updated AOI 2.4. Filovirus Antivirals<br>9. Updates to Area of Interest #3: Antimicrobials<br>• Updated language under introductory paragraph to AOI |

| Amendment 6 (May 29, 2025) |
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| • Updated AOI 3.1. MDR Bacteria and Biothreat Pathogens<br>• Updated AOI 3.2. MDR Fungal Infections<br>• Updated language under Qualities That Strengthen the Competitiveness of a Proposal<br>10. Updates to Area of Interest #4: Radiological/Nuclear Threat Medical Countermeasures<br>• Updated language under introductory paragraphs to AOI<br>• Updated AOI 4.1. Acute Radiation Syndrome (ARS)<br>• Updated AOI 4.2. Uncontrolled Hemorrhage<br>• Updated AOI 4.3. Radiation Injury and Trauma Pathophysiologies<br>• Updated AOI 4.4. Enabling Technologies and Platforms<br>• Suspend AOI 4.5. Decorporation Agents<br>• Updated language under Qualities That Strengthen the Competitiveness of a Proposal<br>11. Updates to Area of Interest #5: Chemical Medical Countermeasures<br>• Updated language under Qualities That Strengthen the Competitiveness of a Proposal<br>12. Updates to Area of Interest #6: Burn and Blast Medical Countermeasures<br>• Updated language under introductory paragraphs to AOI<br>• Updated AOI 6.1. Burn and Blast Traumatic Injuries Management, including:<br>i. Updated language under Enabling technology products<br>• Updated AOI 6.2. Management of Head Injuries in Trauma<br>• Updated AOI 6.3. Hemorrhage Control<br>• Updated AOI 6.5. Management of Thoracoabdominal Trauma Injuries<br>• Updated AOI 6.6. Musculoskeletal Injuries<br>• Suspend AOI 6.7. Special Instruction for Health Economic Impact Assessment of Burn MCMs<br>• Updated AOI 6.8. Platform Agnostic Software for AI Augmentation of Ultrasound Imaging Data, including:<br>i. Deleted AOI 6.8.1 Final Product – Device-Agnostic Ultrasound Algorithm<br>ii. Deleted AOI 6.8.2 Proposal Requirements<br>iii. Deleted AOI 6.8.3 Sustainability Planning<br>• Updated language under Qualities That Strengthen the Competitiveness of a Proposal<br>13. Updates to Area of Interest #7: Diagnostics<br>• Updated language under introductory paragraphs to AOI, including:<br>i. Updated language under Definitions for the purpose of this AOI<br>ii. Technology Readiness Level (TRL) Requirement<br>iii. Development of Instrumentation |

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| iv. Qualities that Strengthen the Competitiveness of a Proposal to AOI #7 (Diagnostics)<br>• Updated AOI 7.1. Biothreat Agent Diagnostics<br>• Updated AOI 7.2. Antibiotic Resistance Diagnostics for Priority Bacterial Pathogens<br>• Updated AOI 7.3. Influenza Diagnostics<br>• Updated AOI 7.4. Threat Agnostic Diagnostics<br>14. Updates to Area of Interest #8: IEID Vaccines<br>• Updated AOI 8.2. Innovative Vaccine Product and Production Enhancements, including:<br>i. Updated language under AOI 8.2.1 Platform technologies<br>• Updated language under Qualities That Strengthen the Competitiveness of a Proposal<br>• Updated Technical POC<br>15. Updates to Area of Interest #9: IEID Therapeutics<br>• Updated language under introductory paragraph to AOI<br>• Updated AOI 9.1. Broad Spectrum Antiviral Therapeutics for Influenza<br>• Updated AOI 9.2. Immune Modulators or Therapeutics Promoting Lung Repair<br>• Updated language under Additional Assessment Factors for the Specific Topic AOIs<br>16. Updates to Area of Interest #10: ImmuneChip+<br>• Updated language under introductory paragraphs to AOI<br>• Updated language under Overview<br>• Updated language under Submission Requirements and Desired Attributes<br>• Updated language under Out-of-Scope Project Attributes<br>• Deleted language under Chem MCM Program Interest Areas |

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

| Amendment 5 (December 18, 2024) |
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| 1. Updates to Background<br>• Updated language under BARDA's Detection, Diagnostics, and Devices Infrastructure (DDDI) Division<br>2. Updates to Part I: Development and Technical Objectives<br>• Updated language under Development and Manufacturing Approach – Manufacturing Development Activities<br>3. Updates to Part VI: Proposal Instructions (Stage 3)<br>• Added Vol. II, Attachment 12: Supply Chain Risk Assessment<br>• Added Vol. II, Attachment 13: Procurements Involving Synthetic Nucleic Acid and Screening<br>4. Updates to Part VII: Proposal Evaluation<br>• Added Additional Information – Prospective Contractor Responsibility and Eligibility Standards: Supply Chain Risk Assessment<br>5. Updates to Area of Interest #1: CBRN Vaccines<br>• Suspend AOI 1.1. Needle-Free Technologies to Administer Licensed Vaccines<br>6. Updates to Area of Interest #2: CBRN Antivirals and Antitoxins<br>• Updated language under introductory paragraphs to AOI<br>7. Updates to Area of Interest #5: Chemical Medical Countermeasures<br>• Updated AOI 5.1. Pulmonary Agents<br>• Updated AOI 5.2. Pharmaceutical-based Agents, including Opioids and Other Respiratory Depressants<br>8. Updates to Area of Interest #6: Burn and Blast Medical Countermeasures<br>• Updated language under introductory paragraphs to AOI<br>• Updated AOI 6.1. Burn and Blast Traumatic Injuries Management<br>• Updated AOI 6.2. Management of Head Injuries in Trauma<br>• Updated AOI 6.3. Hemorrhage Control<br>• 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)<br>• Updated AOI 6.5. Management of Blunt Trauma Injuries<br>• Updated AOI 6.6. Musculoskeletal Injuries<br>• Suspend AOI 6.7. Special Instruction for Health Economic Impact Assessment of Burn MCMs<br>• Updated AOI 6.8. Platform Agnostic Software for AI Augmentation of Ultrasound Imaging Data, including:<br>i. Updated AOI 6.8.1 Final Product – Device-Agnostic Ultrasound Algorithm<br>ii. Updated AOI 6.8.2 Proposal Requirements – 6.8.2.1 through 6.8.2.8<br>iii. Updated AOI 6.8.3 Sustainability Planning<br>iv. Deleted AOI 6.8.4 Deadlines and USG Response Time |

| Amendment 5 (December 18, 2024) |
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| • Updated language under Qualities That Strengthen the Competitiveness of a Proposal<br>9. Updates to Area of Interest #7: Diagnostics<br>17. Updated AOI 7.1.3. Biothreat Agent Diagnostics: Filovirus Point-of-Care and Remote Settings<br>18. Updated AOI 7.2.1. Bacterial Antimicrobial Resistance (AMR) Testing Direct from Specimen<br>19. Updated AOI 7.3. Influenza Diagnostics<br>20. Updated AOI 7.3.1. Influenza Testing in an OTC and CLIA waived environment<br>21. Suspend AOI 7.3.2. Pan-Influenza Diagnostics: Point-of-Care or Laboratory<br>22. Suspend AOI 7.3.3. Point-of-Care Multiplex Assay for Detection of Influenza Virus<br>23. Updated AOI 7.4.1. Next-Generation Sequencing (NGS)-Based Diagnostic for Viral Pathogens, including:<br>v. Updated information under Out-of-Scope Topics for AOI 7.4.1<br>vi. Updated information under Qualities that Strengthen the Competitiveness of a Proposal to AOI #7 (Diagnostics)<br>10. Updates to Area of Interest #8: IEID Vaccines<br>• Updated Technical POC<br>11. Suspend Area of Interest #12: Flexible and Strategic Therapeutics (FASTx)<br>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) |
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| 1. Updates to Area of Interest #7: Diagnostics<br>24. Updated TRL Requirement<br>25. Updated AOI 7.1.3. Biothreat Agent Diagnostics: Filovirus Point-of-Care and Remote Settings<br>26. Updated AOI 7.2.1. Bacterial Antimicrobial Resistance (AMR) Testing Direct from Specimen<br>27. Updated AOI 7.3. Influenza Diagnostics<br>28. Updated AOI 7.3.1. Influenza Home-Use Testing (for OTC or Prescription At-home)<br>2. Updates to Area of Interest #12: Flexible and Strategic Therapeutics (FASTx)<br>• Updated Guidance for proposals pursuing a PEP or PrEP indication<br>• Updated Guidance for proposals pursuing a mAb platform<br>• 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) |
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| 1. Updates to Area of Interest #3: Antimicrobials<br>• Updated AOI 3.1. MDR Bacteria and Biothreat Pathogens<br>• Updated 3.2. MDR Fungal Infections<br>2. Updates to Area of Interest #5: Chemical Medical Countermeasures<br>• Updated AOI 5.2. Opioids and Other Respiratory Depressants<br>• Updated TRL Requirement<br>3. Updates to Area of Interest #6: Burn and Blast Medical Countermeasures<br>• Updated AOI 6.1. Enabling Technologies to Address General Burn & Blast Traumatic Injuries<br>• Updated AOI 6.2. Management of Head Injuries in Trauma<br>• Updated AOI 6.3. Hemorrhage Control<br>• Suspend AOI 6.4. Non-Autologous Topical Products to Prevent or Reduce Burn Wound Conversion<br>• Added new AOI 6.5. Management of Blunt Trauma Injuries<br>• Added new AOI 6.6. Advanced Imaging Technologies in Management of Trauma<br>• Added new AOI 6.7. Special Instruction for health economic impact assessment of Burn MCMs<br>• Added new AOI 6.8 Special Instruction for Platform Agnostic Software for AI Augmentation of Ultrasound Imaging Data.<br>4. Updates to Area of Interest #7: Diagnostics<br>• Updated AOI 7.1.3. Biothreat Agent Diagnostics: Filovirus Point-of-Care and Remote Settings<br>• Updated AOI 7.2.1. Bacterial Antimicrobial Resistance (AMR) Testing Direct from Specimen<br>• Suspend AOI 7.2.2. Bacterial vs. Viral Infections: Point-of-Care<br>• Updated TRL Requirement |

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

| Amendment 2 (Dec 22, 2023) |
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| 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) |
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| 1. Updates to Overview Information –<br>• Updated Research and Development Opportunity Description<br>• Updated General Market Research (TechWatch Program),<br>• Updated Application Process,<br>• Updated Contract and Submission Information,<br>• Updated Electronic Portal Submission Instructions<br>2. Updates to Background<br>3. Updates to Part I: Development and Technical Objectives<br>4. Updates to Part IV: Pre-Submission Call and Quad Chart/Market Research Abstract Instructions (Stages 1 & 2)<br>• Updated Figure 1. BARDA BAA Process Flow Chart<br>• Updated Stage 1: Pre-submission Call with Technical POC<br>5. Updates to Part VI: Proposal Instructions (Stage 3)<br>• Updates to Stage 3: Proposal Precreation<br>o Section M. Past Performance Information &<br>o Vol. II, Attachment 10: Past Performance<br>o Vol. II, Attachment 11: Reason for the Proposed Award Type<br>6. Updates to Part VII: Proposal Evaluation<br>7. Updates to Area of Interest #6: Burn and Blast Medical Countermeasures<br>• Updated TRL Requirement<br>8. Updates to Area of Interest #7: Diagnostics<br>• Updated AOI 7.1.3 Biothreat Agent Diagnostics: Filovirus Point-of-Care and Remote Settings<br>• Updated AOI 7.3.1 Influenza Home-Use Testing (for OTC or Prescription At-home)<br>• Updated AOI 7.3.3 Point-of-Care Multiplex Assay for Detection of Influenza Virus<br>9. Updates to Area of Interest #9: IEID Therapeutics<br>• Added new Area of Interest 9.4 COVID-19 Monoclonal Antibody Therapeutics for Treatment<br>• Updated Additional Assessment Factors for the Specific Topic AOIs<br>10. Suspend AOI #11: COVID-19 Immune Assay(s) Development and Implementation |