May 2024

Defense Health Agency Strategic Research Plan: Military Infectious Diseases (MID)



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1. OVERVIEW AND ORGANIZATION

The Defense Health Agency (DHA) Research and Engineering (R&E) Directorate leads the discovery and development of innovative medical solutions responsive to the needs of Combatant Commands, the Military Services, and the Military Health System (MHS). DHA R&E provides oversight and management of a Science and Technology (S&T) annual budget of approximately $500 to $800 million to support research across critical investment areas. The cornerstones of the DHA S&T management approach are as follows:

- Portfolio Managers directly accountable for the health and performance of their research Portfolios
- Alignment of research investments to validated and prioritized Joint Capability Requirements
- Identification of the Capabilities needed to work toward fulfilling priority Capability Requirements
- S&T (Budget Activity [BA] 6.1, 6.2, and 6.3) efforts that focus on areas where Defense Health Program (DHP) investments can make the most impact and accelerate delivery of knowledge and materiel products to product development and other transition partners or end users
- Informing multi-year research investment plans that allow adaptation to emerging (or declining) requirements

The DHA Deputy Assistant Director (DAD) for R&E employs Strategic Research Plans (SRPs) to inform and describe how Department of Defense (DoD) medical capabilities will be developed over time. These SRPs will drive investment recommendations for Future Years Defense Program (FYDP) plans and serve as a critical tool for aligning investments with military medical health priorities. SRPs include information that will enable the Portfolio Manager to perform the following activities:

- Develop, on an annual basis, the FYDP plans in alignment with Capability Requirements and anticipate the resources that will be required for the respective Program Objective Memorandum (POM) cycle
- Provide the oversight and concurrence of Year of Execution (YOE) spend plans that Program Managers (PMs) will be responsible for developing as a recommendation to the Portfolio Manager
- Facilitate discussion with leadership (e.g., DHA and Assistant Secretary of Defense – Health Affairs) and stakeholders regarding the research activities required to address Capability Requirements

SRPs are organized into four levels:

- **Capability Areas** (CAs) reflect the highest structural elements that encompass broad areas of medical research within a Portfolio
- **Capability Requirements** (CRs) are derived from key source documents (e.g., Joint Capabilities Integration and Development System – JCIDS) and outline Capabilities (knowledge or materiel) required to meet current or future military medical needs

- **S&T Paths** (STPs) describe the high-level research activities needed to support the transition of Capabilities to product development, other transition partners, or end users
- **Capabilities** describe the S&T knowledge and/or materiel products to be transitioned to product development or end users

Figure 1-1 shows the hierarchical relationship between the components of the SRP with the associated reference schema.

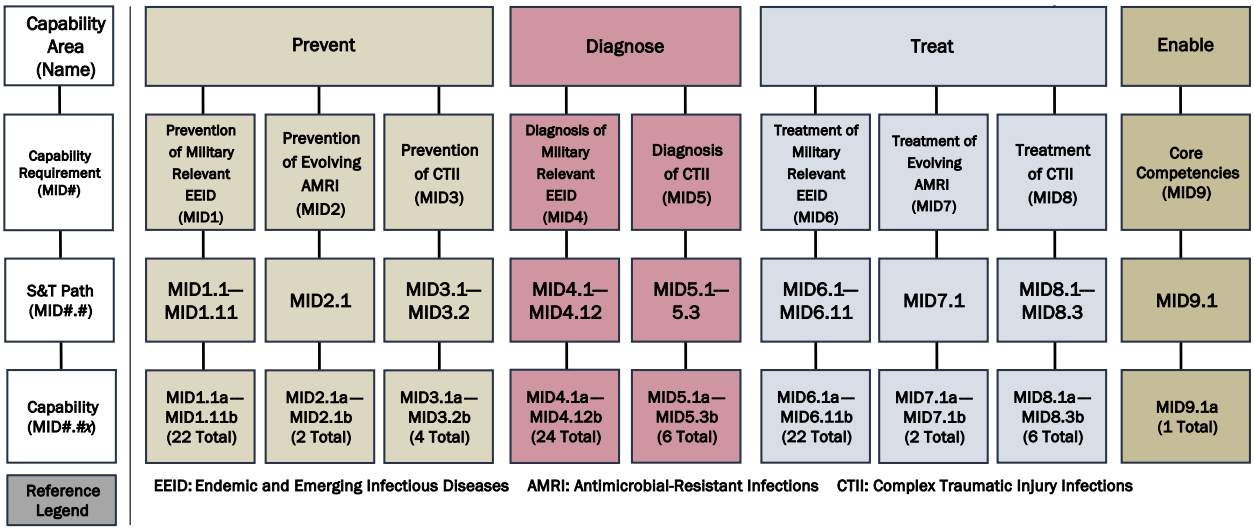


Figure 1-1 SRP Hierarchy

The scope of the DHA Military Infectious Diseases (MID) SRP includes CRs relating to the prevention, diagnosis, and treatment of military-relevant infectious diseases, to include combat-associated wound infections, as well as the core research competencies that enable research into those areas. These CRs serve the overall goal of maintaining unit and individual readiness, preserving operational effectiveness, and accelerating return to duty following infection. SRPs only outline the CRs deemed as priorities. These priorities have been identified based on assessment of the current and future medical and operational needs and/or existing research gaps of the military medical community. Inclusion of a CR in the SRP does not guarantee that funding will be aligned to its respective STPs.

The priority MID CRs are organized into the following Capability Areas, as shown in Table 1-1:

Table 1-1 Capability Areas Included in the SRP

Capability Area	Capability Area Description
Prevent	Develop solutions to prevent endemic and emerging infectious diseases, to include combat associated wound infections, to maintain readiness and preserve operational effectiveness.
Diagnose	Develop solutions to diagnose endemic and emerging infectious diseases, to include combat associated wound infections, to maintain readiness, preserve operational effectiveness, and accelerate return to duty.

Capability Area	Capability Area Description
Treat	Develop solutions to treat endemic and emerging infectious diseases, to include combat associated wound infections, to maintain readiness, preserve operational effectiveness, and accelerate return to duty.
Enable	Establish enabling capabilities to support medical countermeasure development against endemic and emerging infectious diseases.

The priority CRs are listed in Table 1-2, with each CR noted via a MID number (i.e., MID1, MID2, etc.). Section 2 describes the STPs leading to defined Capabilities for each CR. The numeric labeling schema (MID1–MID9) is not meant to represent relative priority and is only intended to organize the CRs for ease of reference.

Table 1-2 Capability Requirements Included in the SRP

CR #	CR Name	Capability Requirement Description
MID1	Prevention of Military Relevant Endemic and Emerging Infectious Diseases	Develop safe and effective prevention for military relevant endemic and emerging infectious diseases, to include in austere or contested environments [1].
MID2	Prevention of Evolving Antimicrobial-Resistant Infections	Develop safe and effective prevention for antimicrobial-resistant infections, to include in austere or contested environments [1].
MID3	Prevention of Complex Traumatic Injury Infections	Develop safe and effective prevention for infections and/or sepsis following complex traumatic wounds, to include in austere or contested environments [1][2].
MID4	Diagnosis of Military Relevant Endemic and Emerging Infectious Diseases	Develop a consistent ability to diagnose military relevant endemic and emerging infectious diseases, to include in austere or contested environments [1][2].
MID5	Diagnosis of Complex Traumatic Injury Infections	Develop a consistent ability to diagnose infections and/or sepsis following complex traumatic wounds, to include in austere or contested environments [2][3].
MID6	Treatment of Military Relevant Endemic and Emerging Infectious Diseases	Develop safe and effective treatments for military relevant endemic and emerging infectious diseases, to include in austere or contested environments [1].
MID7	Treatment of Evolving Antimicrobial-Resistant Infections	Develop safe and effective treatments for antimicrobial resistant infections, to include in austere or contested environments [1].
MID8	Treatment of Complex Traumatic Injury Infections	Develop safe and effective treatments for infections and/or sepsis following complex traumatic wounds, to include in austere or contested environments [1][2][3].
MID9	Core Competencies	Establish enabling capabilities to support medical countermeasure development against infectious diseases [1].

The Joint Force operates in areas of the world where endemic and emerging infectious diseases present substantial and immediate health risks to U.S. personnel. Future operational scenarios, to include large scale combat operations (LSCOs), pose an increased risk of infectious diseases due to degraded natural environmental disease barriers and public health infrastructure, as well as the potential for delayed evacuation times. Current national, military, and biodefense strategies and subsequent requirements documents specify a worldwide force protection capability to prevent, diagnose, and treat endemic and emerging infectious disease threats to protect the Joint Force.

Likewise, wound infection resulting from complex traumatic injuries in a prolonged care environment poses a substantial threat to the operational effectiveness of deployed forces. During prolonged care scenarios to include LSCO environments, infection and complications secondary to injury will develop in the prehospital setting through Role 3. While recent conflicts typically managed infection at higher roles of care, future conflicts in contested environments with near-peer adversaries will require management in-theater due to delayed casualty evacuation and/or treatment. While most infected wounds during insurgency operations over the last 20 years were not initially colonized with multi-drug resistant organisms (MDROs), the prevalence of MDRO infections significantly increased as casualties moved through higher roles of care. The inability to prevent, delay, or treat wound infections in a prolonged care environment will increase the prevalence and severity of infected wounds. Similarly, a concomitant increase in MDRO wound infections will occur across the continuum of care. Therefore, closing the gap on the impact of wound infections on the Joint Force requires countermeasures to prevent, diagnose, and treat both initial wound infections and MDRO infections across the continuum of care.

To address the distinct challenges associated with the different types of military relevant infections, the CRs in this SRP have been parsed into three areas of focus: military relevant endemic and emerging infectious diseases; evolving anti-microbial resistant infections; and complex traumatic injury infections. These focus areas cover requirements within both the Military Infectious Diseases and Combat Casualty Care Initial Capabilities Documents (ICDs) [1-3]. Within each focus area are requirements for prevention, diagnosis, and treatment, which are delineated as distinct but complimentary potential countermeasure approaches to mitigate the risk of these infectious disease threats.

2. CAPABILITY REQUIREMENTS, S&T PATHS AND CAPABILITIES

This section outlines the DHA Military Infectious Diseases Portfolio priority CRs, STPs, and Capabilities. The Capabilities described are expected to transition to product development or other end users (e.g., members of the clinical or operational community) to aid in fulfillment of the requirement when they reach the appropriate Technology Readiness Levels/Knowledge Readiness Levels (TRL/KRL). Product development will then perform, as appropriate, additional development activities required to mature these Capabilities to the extent to which they can be delivered for full clinical or operational use by the intended end user. Each CR in the sections that follow is depicted as a figure in the format shown in Figure 2-1.

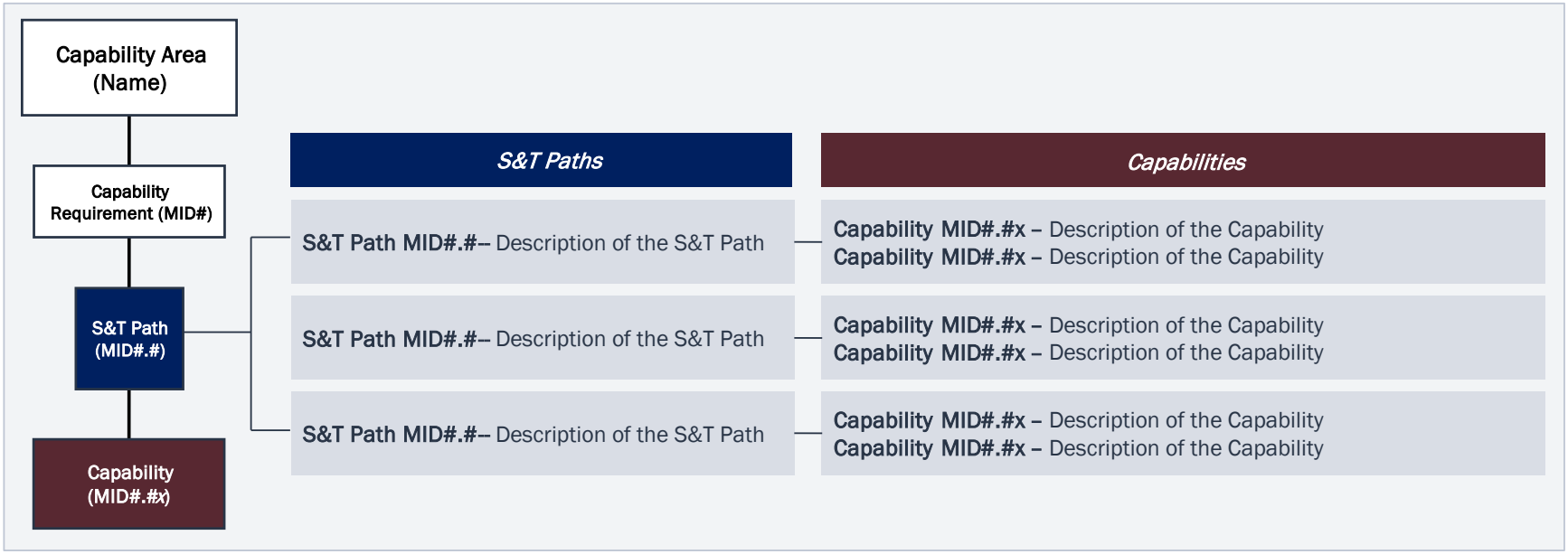


Figure 2-1 Capability Requirement Graphic Example

The CRs, STPs, and Capabilities outlined in this section focus on addressing DoD-specific, validated Joint/Service medical S&T requirements. The SRP is limited to activities that are unlikely to be resolved through S&T activities outside of the DHA—specifically, the SRP captures where military exposures or injuries are unique, or where potential solutions may differ from, or not be adequately addressed by, efforts elsewhere. The content of the SRP was significantly influenced by the results of the 2023 Threat Prioritization Panel (TPP), a triennial forum for Combatant Commands and other infectious disease stakeholders to identify infectious

disease threats of greatest concern to the Joint Force. The TPP output serves as a tool to guide medical research and development investments toward efforts of greatest value, leading to impactful solutions for the Joint Force. The goal of the TPP is to identify infectious disease threats to operational forces and prioritize their potential impact on the Joint Force. The result is a tiered global list of infectious diseases based on risk (Tiers 1, 2, and 3: high risk, medium risk, and low risk, respectively). A countermeasure maturity assessment was conducted to further down-select infectious disease threats for inclusion in the SRP. All high priority diseases were included regardless of whether countermeasures were available, while medium priority diseases were only included within the SRP if adequate countermeasures were not available.

2.1 Prevention of Military Relevant Endemic and Emerging Infectious Diseases (MID1)

The MID1 Capability Requirement supports the development of solutions to prevent endemic and emerging infectious diseases to eliminate their impacts on operational effectiveness. Prevention is the most desirable infectious disease countermeasure because it prevents disease from occurring (vs. treatment post-infection), is the most cost-effective approach, and reduces unit loss rate. Activities within this Capability Requirement include discovery, optimization, and development of animal models; efficacy testing in vitro; efficacy and safety testing in validated preclinical animal models; cGMP manufacture; and safety and efficacy testing in clinical trials of prophylactics. This includes repurposing of existing countermeasures and/or evaluating existing standard of care approaches for military-specific use cases.



Figure 2-2 Prevention of Military Relevant Endemic and Emerging Infectious Diseases (MID1) S&T Paths and Capabilities

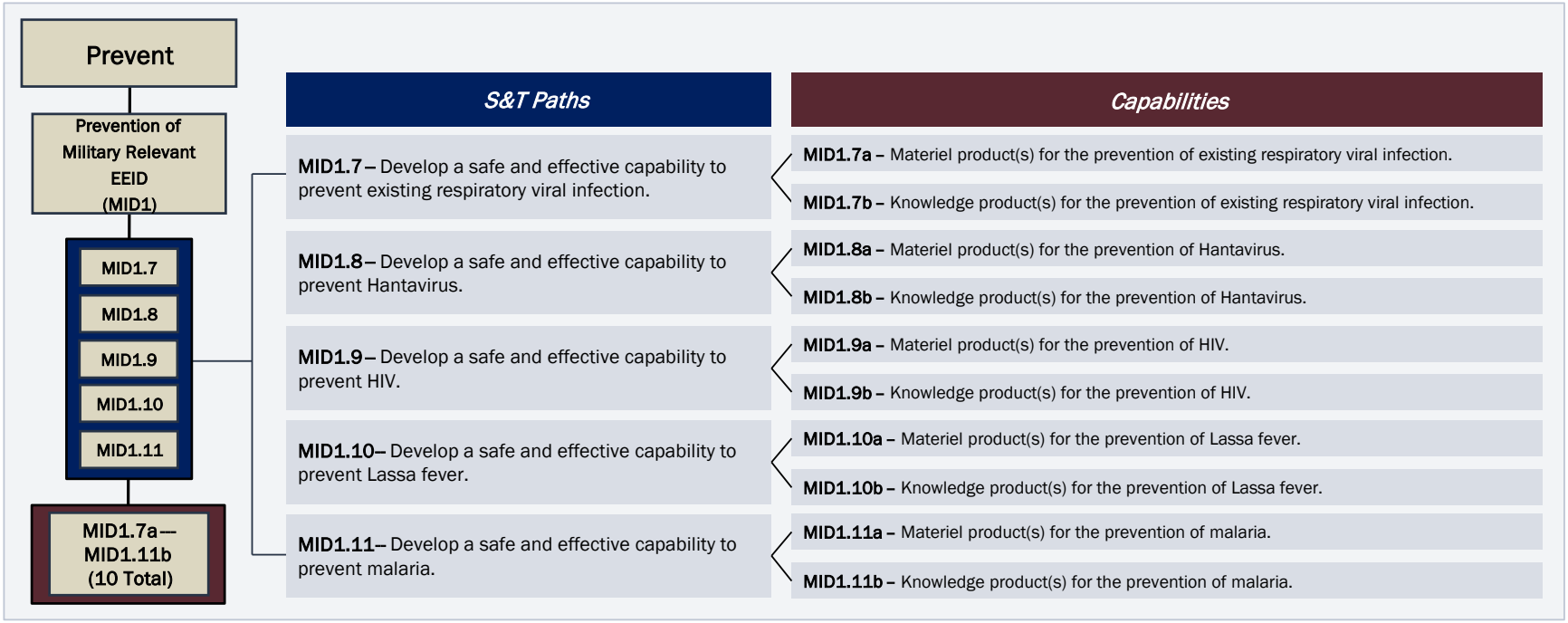


Figure 2-3 Prevention of Military Relevant Endemic and Emerging Infectious Diseases (MID1) S&T Paths and Capabilities, cont.

2.2 Prevention of Evolving Antimicrobial-Resistant Infections (MID2)

The MID2 Capability Requirement supports the development of solutions to prevent antimicrobial-resistant infections to eliminate their impacts on operational effectiveness. Prevention is the most desirable infectious disease countermeasure because it prevents disease from occurring (vs. treatment post-infection), is the most cost-effective approach, and reduces unit loss rate. Activities within this Capability Requirement include discovery, optimization, and development of animal models; efficacy testing in vitro; efficacy and safety testing in validated preclinical animal models; cGMP manufacture; and safety and efficacy testing in clinical trials of novel prophylactics.

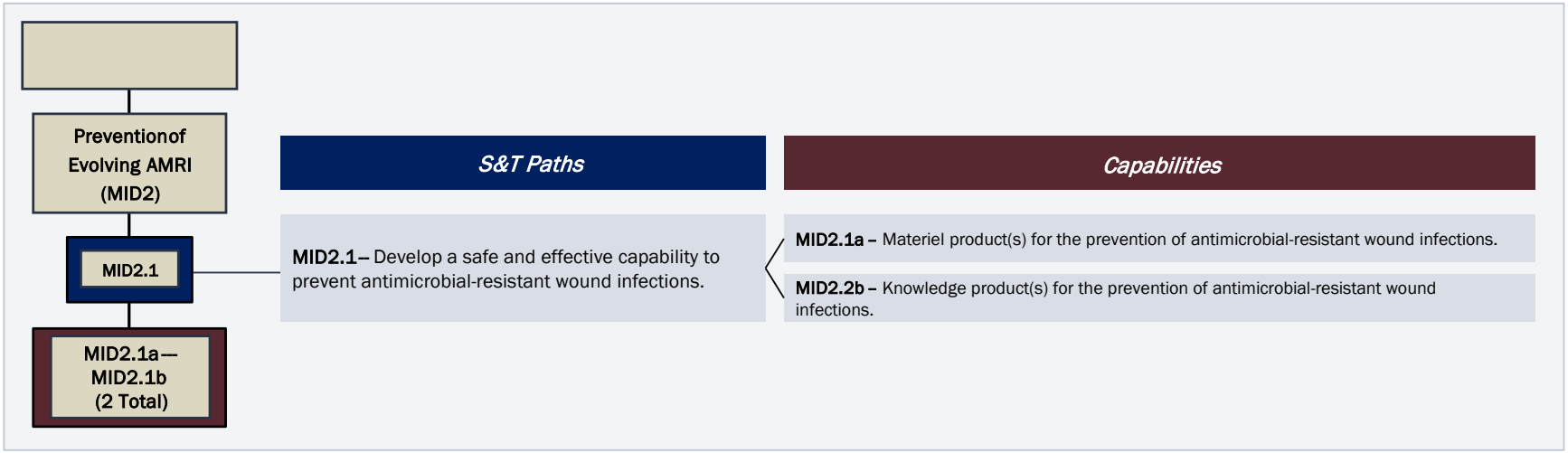


Figure 2-4 Prevention of Evolving Antimicrobial-Resistant Infections (MID2) S&T Paths and Capabilities

2.3 Prevention of Complex Traumatic Injury Infections (MID3)

The MID3 Capability Requirement supports the development of solutions to prevent infections resulting from traumatic wounds to eliminate their impacts on operational effectiveness. Prevention is the most desirable infectious disease countermeasure because it prevents disease from occurring (vs. treatment post-infection), is the most cost-effective approach, and reduces unit loss rate. Activities within this Capability Requirement include discovery, optimization, and development of animal models; efficacy testing in vitro; efficacy and safety testing in validated preclinical animal models; cGMP manufacture; and safety and efficacy testing in clinical trials of novel prophylactics.

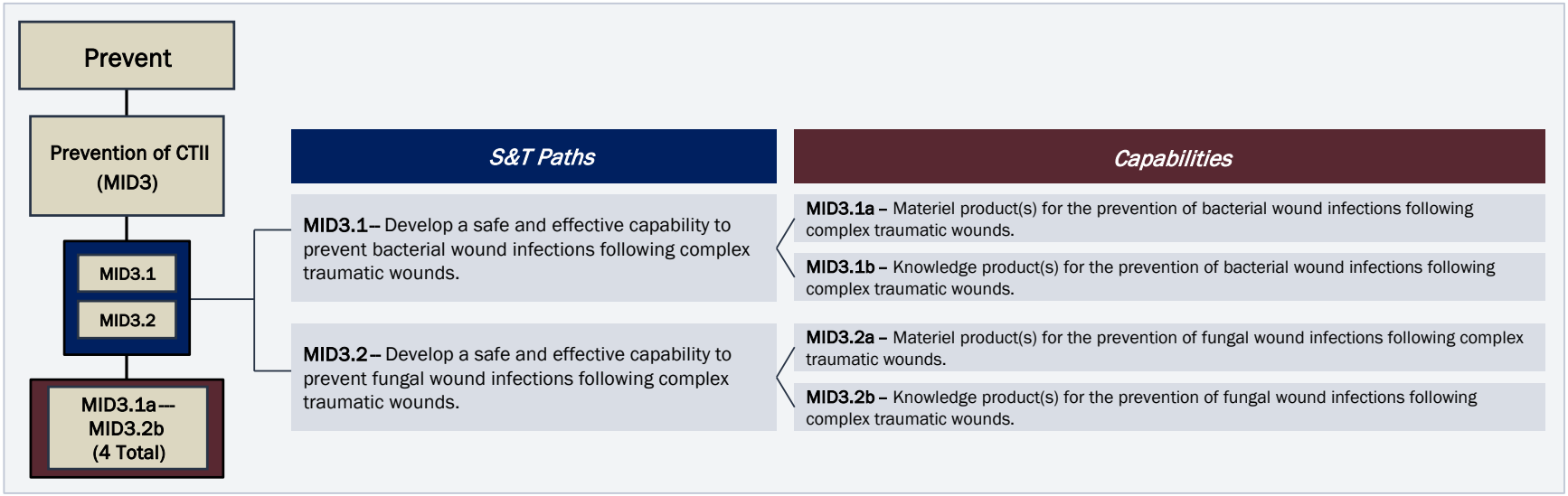


Figure 2-5 Prevention of Complex Traumatic Injury Infections (MID3) S&T Paths and Capabilities

2.4 Diagnosis of Military Relevant Endemic and Emerging Infectious Diseases (MID4)

The MID4 Capability Requirement supports the development of solutions to diagnose infectious diseases to mitigate their impacts on operational effectiveness. Improved diagnostic solutions for infectious disease casualties are necessary to accurately inform treatment decisions and ultimately return Service members to duty. Activities within this Capability Requirement include the identification of targets for diagnostic assay design; optimization of assays; and validation and testing of diagnostic assays and platforms.

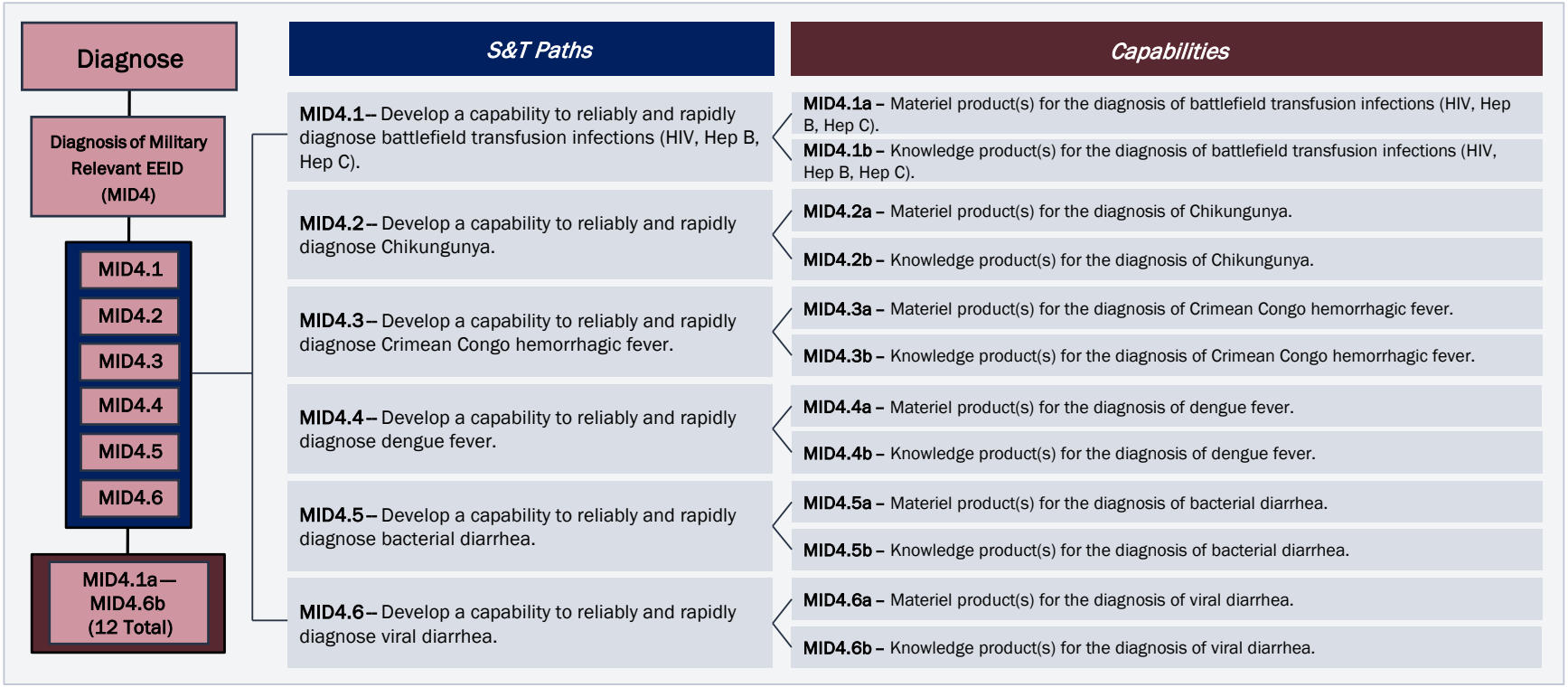


Figure 2-6 Diagnosis of Military Relevant Endemic and Emerging Infectious Diseases (MID4) S&T Paths and Capabilities

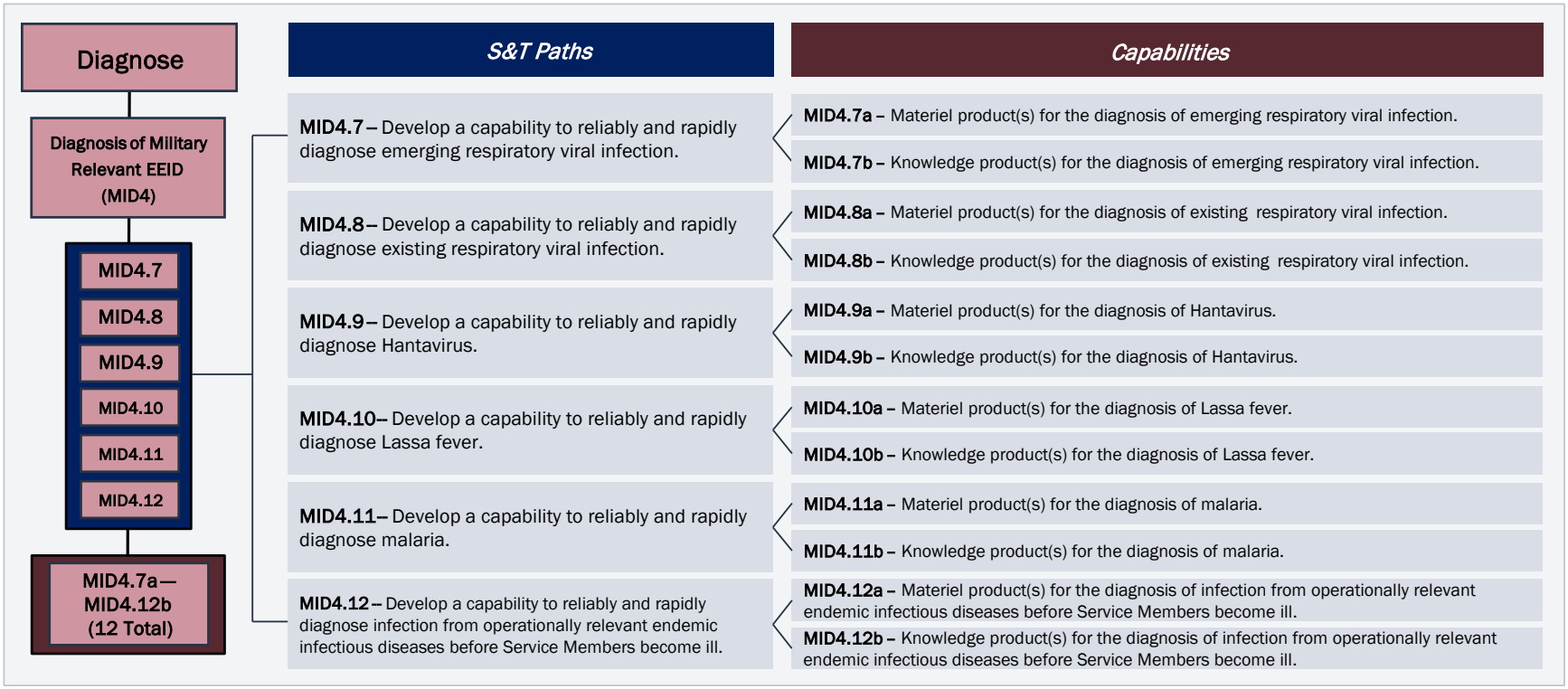


Figure 2-7 Diagnosis of Military Relevant Endemic and Emerging Infectious Diseases (MID4) S&T Paths and Capabilities, cont.

2.5 Diagnosis of Complex Traumatic Injury Infections (MID5)

The MID5 Capability Requirement supports the development of solutions to diagnose wound infections to mitigate their impacts on operational effectiveness. Improved diagnostic solutions for wound infection casualties are necessary to accurately inform treatment decisions and ultimately return Service members to duty. Activities within this Capability Requirement include the identification of targets for diagnostic assay design; optimization of assays on selected platforms; and validation and testing of diagnostic assays and platforms.

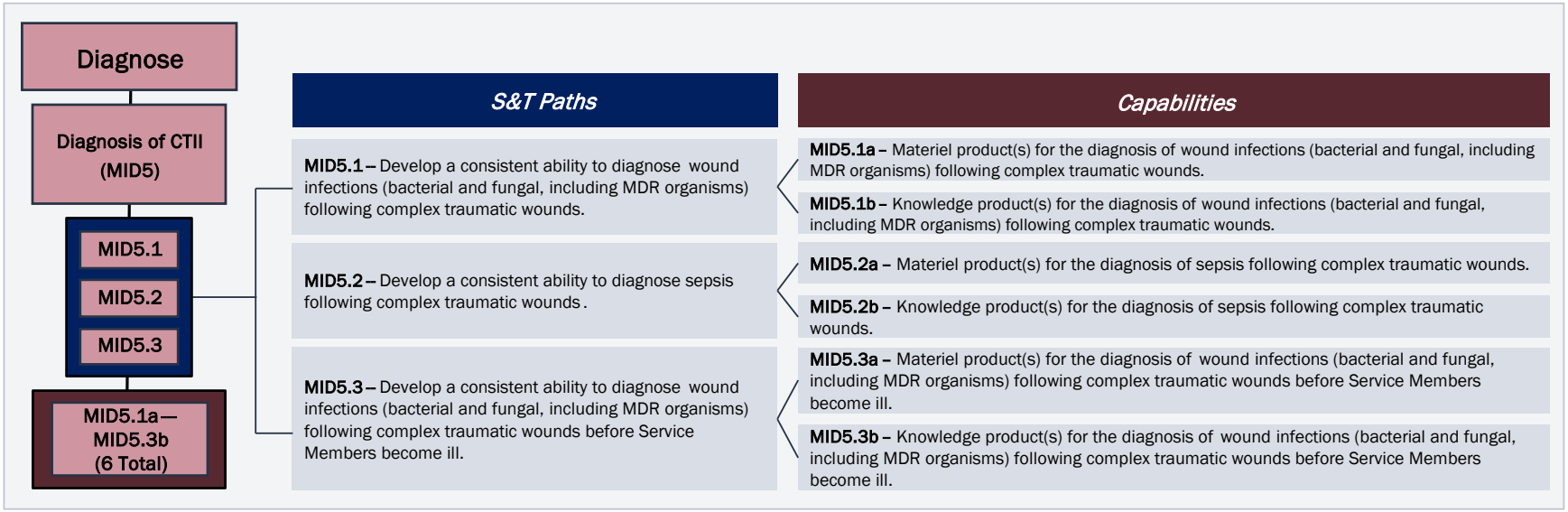


Figure 2-8 Diagnosis of Complex Traumatic Injury Infections (MID5) S&T Paths and Capabilities

2.6 Treatment of Military Relevant Endemic and Emerging Infectious Diseases (MID6)

The MID6 Capability Requirement supports the development of solutions to treat infectious diseases to eliminate their impacts on operational effectiveness. Treatment solutions for infectious disease casualties are necessary to return Service members to duty. Activities within this Capability Requirement include discovery, optimization, and development of animal models; efficacy testing in vitro; efficacy and safety testing in validated preclinical animal models; cGMP manufacture; and safety and efficacy testing in clinical trials of novel treatments.

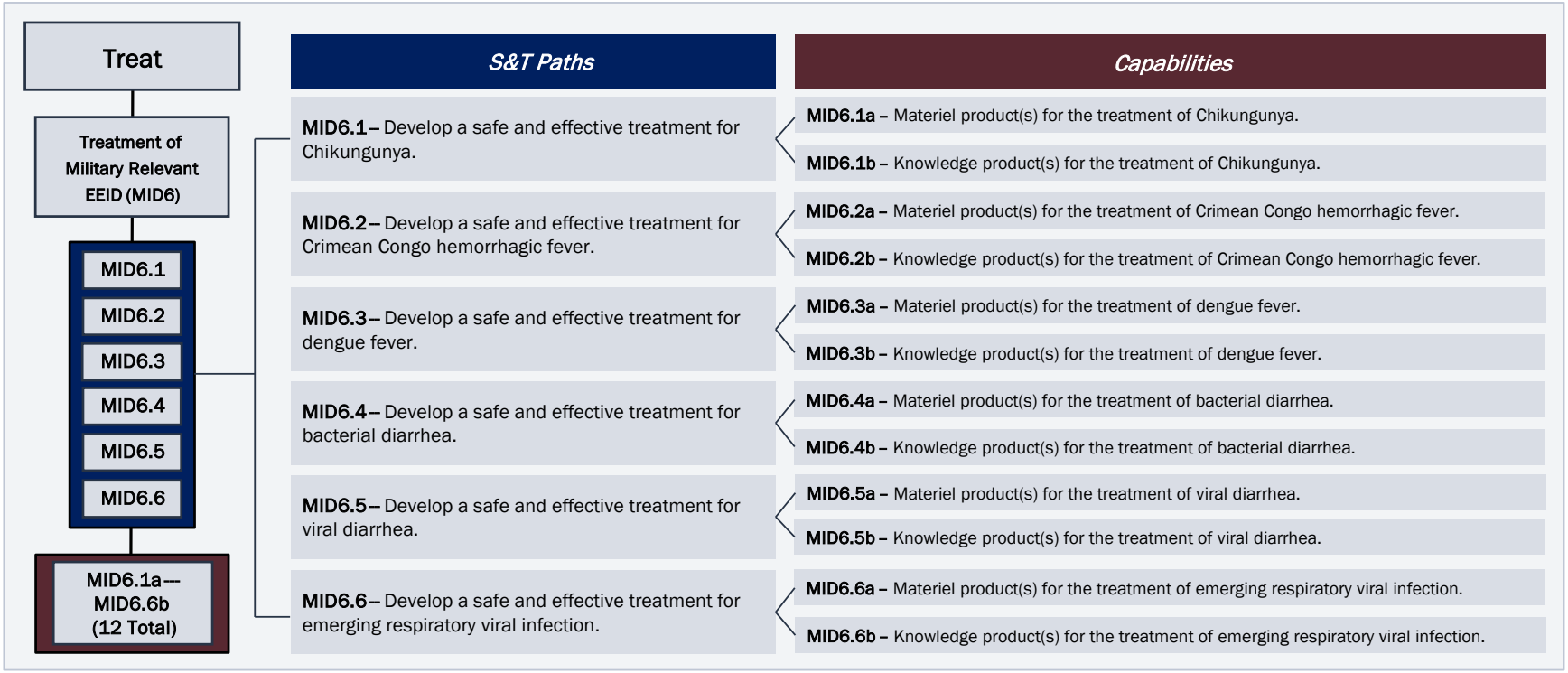


Figure 2-9 Treatment of Military Relevant Endemic and Emerging Infectious Diseases (MID6) S&T Paths and Capabilities

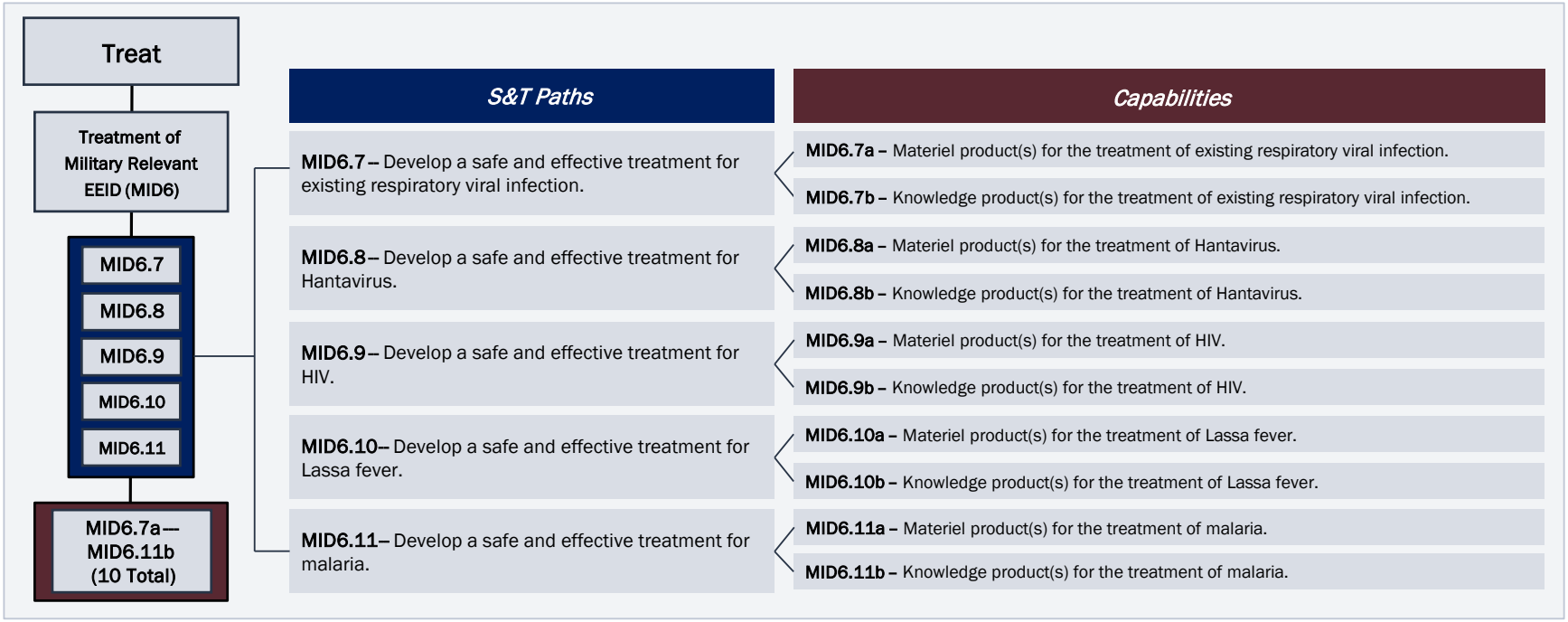


Figure 2-10 Treatment of Military Relevant Endemic and Emerging Infectious Diseases (MID6) S&T Paths and Capabilities, cont.

2.7 Treatment of Evolving Antimicrobial-Resistant Infections (MID7)

The MID7 Capability Requirement supports the development of solutions to treat antimicrobial-resistant wound infections to eliminate their impacts on operational effectiveness. Improved treatment solutions for infectious disease casualties are necessary to return Service members to duty. Activities within this Capability Requirement include discovery, optimization, and development of animal models; efficacy testing in vitro; efficacy and safety testing in validated preclinical animal models; cGMP manufacture; and safety and efficacy testing in clinical trials of novel treatments.

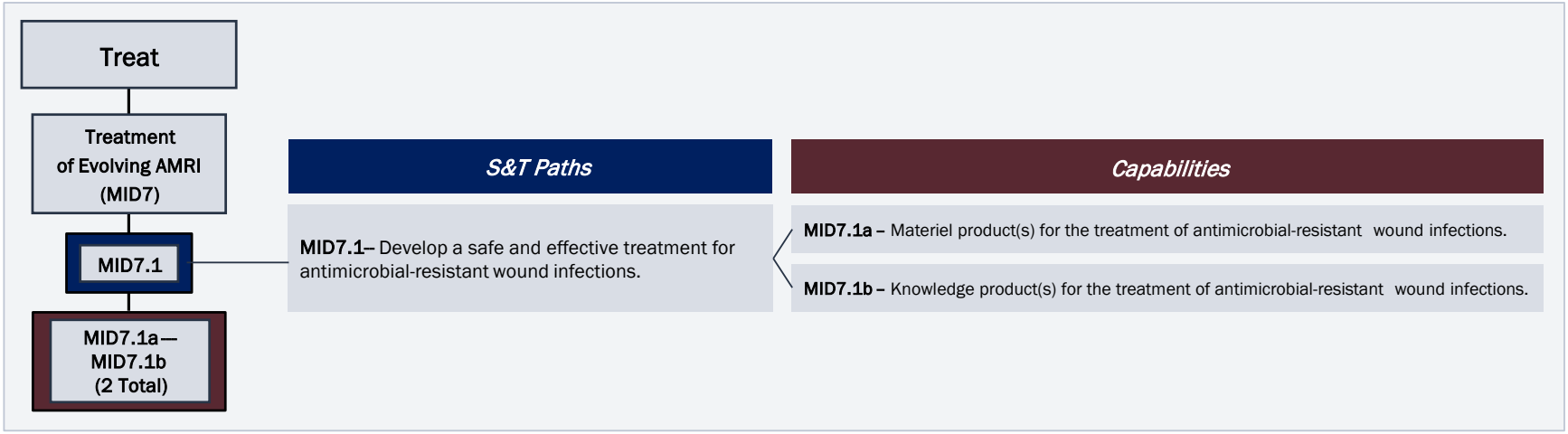


Figure 2-11 Treatment of Evolving Antimicrobial-Resistant Infections (MID7) S&T Paths and Capabilities

2.8 Treatment of Complex Traumatic Injury Infections (MID8)

The MID8 Capability Requirement supports the development of solutions to treat wound infections resulting from traumatic wounds to eliminate their impacts on operational effectiveness. Improved treatment solutions for infectious disease casualties are necessary to return Service members to duty. Activities within this Capability Requirement include discovery, optimization, and development of animal models; efficacy testing in vitro; efficacy and safety testing in validated preclinical animal models; cGMP manufacture; and safety and efficacy testing in clinical trials of novel treatments.

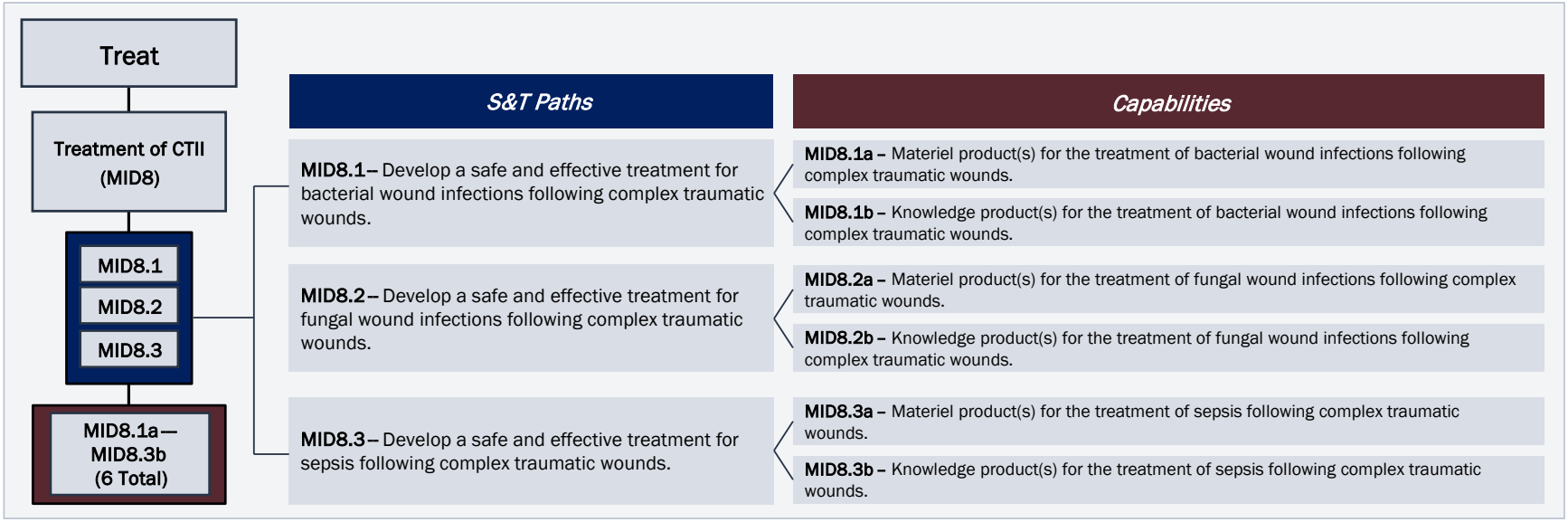


Figure 2-12 Treatment of Complex Traumatic Injury Infections (MID8) S&T Paths and Capabilities

2.9 Core Competencies (MID9)

The MID9 Capability Requirement is intended to support infectious disease-specific competencies (e.g., infectious disease drugs and biologics, infectious disease animal models, etc.) that are required across multiple Capability Requirements within this strategic plan to deliver Capabilities. By providing broad and adaptable competencies across the MID Portfolio, this requirement reduces redundancies within the Portfolio by concentrating efforts and offering support to deliver Capabilities across the entire breadth of the SRP.

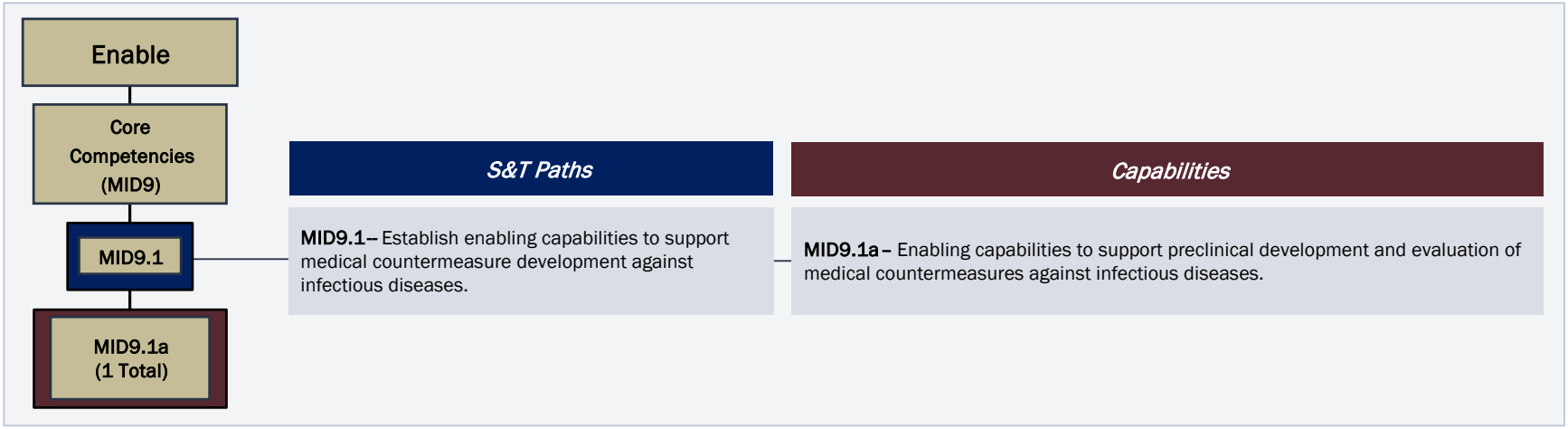


Figure 2-13 Core Competencies (MID9) S&T Paths and Capabilities

3. REFERENCES

[1] Director of Research and Development Policy & Oversight, “Initial Capabilities Document for Military Infectious Diseases,” November 30, 2020.

[2] Deputy Assistant Secretary of Defense, Force Health Protection & Readiness, “Initial Capabilities Document for Department of Defense Combat Casualty Care Devices and Products,” May 9, 2014.

[3] Director of Research and Development Policy & Oversight,” Initial Capabilities Document for Combat Casualty Care Support for Future Operations,” January 5, 2021.

[4] The Johns Hopkins University Applied Physics Laboratory, AOS-L-20-0230 Defense Health Agency Science and Technology Portfolio Management Concept of Operations,” Pre-decisional Draft, amended June 10, 2022.

[5] The Johns Hopkins University Applied Physics Laboratory, AOS-21-0929. “Science and Technology Portfolio Management Process Research Road mapping Methodology,” August 2021.

[6] Conduct of Chemical and Biological Defense Program, 50 U.S.C. §1522. (1994).

APPENDIX A. KEY DEFINITIONS (GLOSSARY)

Term	Definition
6.1	Budget Activity (BA) for Basic Research increases knowledge/understanding: discovery; hypothesis testing. ~TRL 1–2
6.2	Budget Activity (BA) for Applied Research is the refinement of concepts into solutions: pre-clinical studies; drug formulation; device defined in animal model. ~TRL 2–3
6.3	Budget Activity (BA) for Advanced Technology Development is candidate solution development; proof of concept and product safety demonstrated (e.g., Phase 1–2a trials). ~TRL 3–6
Budget Activity	Categories within each appropriation and fund account that identify the purposes, projects, or types of activities financed by the appropriation or fund.
Capability	The S&T knowledge and/or materiel products to be transitioned to product development or other end users.
Capability Area	Reflects the highest structural element that encompasses broad areas of medical research within a Portfolio.
Capability Requirement	Derived from key source documents, outlines capabilities (knowledge or materiel) required to meet current or future military medical needs.
Interdependency	Reliance of one S&T progression on the outcome of another or more S&T activities.
Joint Capabilities Integration and Development System	JCIDS is the process by which the military develops and validates capability requirements for Joint (more than one Service) use and interoperability.
Long-Term Rehabilitation	The potential capability to enable long-term rehabilitation of injured or wounded warfighter and mitigation of long-term and late effects that limit the RTD.
Medical Readiness	Ensuring warfighters are healthy, protected from potential threats, and ready for operations or contingencies.
Military Community	Warfighters, DoD civilians, and beneficiaries.
Operational Effectiveness	The ability of an individual warfighter, unit, or force to successfully conduct its assigned tasks and accomplish its mission.
Subject Matter Expert	An individual who has accumulated great knowledge in a particular field or topic.
S&T Path	Describe the high-level research activities needed to support the transition of Capabilities to product development or other end users.

APPENDIX B. ABBREVIATIONS

AMRI	Antimicrobial-Resistant Infections
BA	Budget Activity
CA	Capability Area
cGMP	Current Good Manufacturing Practices
CR	Capability Requirement
CTII	Complex Traumatic Injury Infections
DAD	Deputy Assistant Director
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
EEID	Endemic and Emerging Infectious Diseases
FY	Fiscal Year
FYDP	Future Years Defense Program
ICD	Initial Capabilities Document
ID	Infectious Disease
JCIDS	Joint Capabilities Integration and Development System
KRL	Knowledge Readiness Level
LSCO	Large Scale Combat Operation
MDRO	Multi-Drug Resistant Organism

MHS	Military Health System
MID	Military Infectious Diseases
MIDRP	Military Infectious Diseases Research Program
MRI	Military Relevant Infections
PD	Product Development
PM	Program Manager
POM	Program Objective Memorandum
R&E	Research and Engineering
S&T	Science and Technology
SM	Service Member
SRP	Strategic Research Plan
STEID	Science & Technology Enterprise Integration Division
STP	S&T Path
STPMB	Science & Technology Portfolio Management Branch
TPP	Threat Prioritization Panel
TRL	Technology Readiness Level
YOE	Year of Execution