2012

Defense Threat Reduction Agency
RD Enterprise CB Directorate
STRATEGIC VISION

create collaborate communicate

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DIRECTOR'S MESSAGE

Dynamic and emerging threats present great challenges to our Nation, both at home and abroad. Although their form is unpredictable, we can be assured that they are likely to stem from the known fronts of adversarial intent, unintended consequences, or natural evolutionary processes. Intensifying these challenges, the globalization of interdisciplinary science and technology (S&T) and widespread information-sharing tools have facilitated the proliferation of potential chemical and biological threats. According to the 2010 Department of Defense Chemical Biological Defense Program Annual Report to Congress, "[t]he world has never been at more risk to [Weapons of Mass Destruction (WMD)] use by regional powers hostile to American interests, or to the widespread effects of disease-causing pathogens." Regardless of source, the advances in and proliferation of chemical and biological threats demands that we protect our military forces and contribute to our national security interests against these threats to the fullest extent. It is clear that the offensive nature of the threat is proceeding at a pace that requires us to be prepared to defend our warfighter and our Nation from the inevitable emergence of a new threat from biological and chemical agents and that we move rapidly in response. Our current inability to accurately predict the future threat therefore recognizes that knowledge is more actionable than incremental technology development. Knowledge and the speed and agility to act upon it are the 'tip of the spear' and our ability to evaluate and understand the threat and our preparedness to respond with agility are keys to our success.

Our commitment is to create a world-class S&T organization that is prepared to respond to the next chemical or biological threat. As an organization dedicated to innovation and critical thinking, we will dedicate our enterprise to delivering needed and useful technological solutions. Further, through the power of teaming—establishing and exploiting translational teams that include diverse groups of stakeholders throughout the S&T lifecycle, from early discovery to downstream acquisition and fielding—we will ensure that our areas of emphasis effectively transition capabilities that fill critical capability gaps. Translational teaming will also identify early risk and milestone achievements that will enable efficient pruning of investments to ensure focus on those that will deliver. It is imperative that we create an ecosystem of knowledge creation and translation that moves with agility to respond dynamically to the challenge presented by chemical and biological threats.

No single organization or agency can address this threat in isolation. According to the 2009 National Strategy for Countering Biological Threats, "[r]educing the risk presented by the deliberate or accidental release of a biological agent requires the use of all instruments of national power, close coordination among all sectors of government, and effective partnerships among public and private institutions both nationally and internationally." Based on the pervasive chemical weapons threat by state and non-state actors, the same close coordination among all partners is required to combat chemical threats. We will work closely with interagency efforts to ensure efficient expenditure of resources and to complement innovations necessary to provide whole-of-government solutions, where appropriate.

The best S&T to protect the warfighter and the Nation from threats must be our goal, and today's technical landscape requires that we proactively engage with the scientific communities operating on the leading edge of that S&T. Only through openly innovating with key partners—such as defense and national laboratories, academia and industry—can we ensure that we create sustainable paths to delivering actionable technologies. Seeking and nurturing 'the best' ensures that we satisfy our responsibilities as described in the 2008 Chemical and Biological Defense Program Strategic Plan and the 2011 Defense Threat Reduction Agency Strategic Plan.

As we continually challenge ourselves to do better, we will not only help to save lives but we will also clearly articulate our vision, goals, and expectations for what is possible and for how we intend to realize our potential for preparedness. We are committed to providing innovative solutions in support of the Nation's warfighters and beyond.

This strategic plan for the Joint Science and Technology Office (JSTO) is intended to provide a dynamic guide for who we are, what strategic focus will embody our investments, and how we will execute that strategy to meet a challenging and evolving mission. We will return to it often to validate its relevance and impact in providing such guidance. It will also provide an important tool for assessing the impact of and return on our investment in knowledge creation and translation for the Chemical and Biological Defense Program (CBDP). This strategic plan provides an important milestone in the future S&T directions we will take. Our challenge is to implement a new culture of innovation and translation and to use this strategic plan to realize our potential, providing a robust S&T organization prepared to respond to future threats.

Dr. Alan S. Rudolph
Director
Chemical & Biological Technologies Directorate

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MISSION

"To invest in transformational ideas, innovative people, and actionable technology development for Chemical Biological Defense solutions"

- ★ Accountable Investment Processes: making right decisions based on vision and diligence, cultivating a portfolio of programs that enables us to discover and nurture ideas and deliver technology in order to defeat chemical and biological threats
- ★ Transformational ideas: ideas that hold the potential to reset expectations about what is possible in chemical and biological defense and which enable new solution paradigms that radically alter the level of threat posed by chemical and biological agents
- ★ Innovative people: people who, unconstrained by convention, apply new concepts and strategies to solve problems, and whose efforts may have applicability to chemical and biological defense
- ★ Actionable technologies: developing technologies that have real-world, practical utility to warfighters and that transition to field development supporting the Nation's whole-of-government approach to homeland defense

VISION

"Create…Collaborate…Communicate"

In order to accomplish our mission, we will nurture a vibrant S&T organization that **CREATES** programmatic vision in **COLLABORATION** with intramural and extramural communities, and **COMMUNICATES** impact to the warfighter as revolutionary products and capabilities are achieved.

MISSION/VISION

The Defense Threat Reduction Agency's Chemical and Biological Technologies Directorate (DTRA CB) functions as the Joint Science and Technology Office for Chemical and Biological Defense which was established in 2003 to manage and integrate the Chemical and Biological Defense S&T portfolio. Its purpose was to develop scientific knowledge and technical solutions to reduce the chemical and biological threat to the military and the Nation.

Advances in science and technology, as well as the broadening of JSTO's charge to encompass whole-of-government capabilities that contribute to DoD's role in the safety of the American civilian population, has led to an expansion of the JSTO mission space. Accordingly, this expanded mission space compels us to look beyond current approaches and proactively seek out and nurture innovations in expanded performer bases, actively manage technology development, and transition actionable technologies and solutions to the warfighter. We recognize that when we invest in innovation, we are also investing in people, both our own committed workforce and other innovators who will help bring these solutions forward for Defense and National Security.

To execute this mission, we will create an ecosystem of creativity, collaboration and communication. This will require contributions from our entire workforce, including those with vision for both knowledge creation and knowledge translation and those with responsibility for program management of collaborative teams, comprised of stakeholders and performers, which will enable the realization of our goals. Innovative business practices will be required to ensure agility in sourcing ideas and contracting actions that enable their active management and timely development. Most importantly, we will need to communicate our vision and progress to a wider stakeholder community as well as to the warfighter to ensure that our vision is aligned with operational needs and that our impact is realized as we progress with novel solutions. These concepts are captured in the mission and vision statements on the previous page.

CREATING AN ENTERPRISE OF KNOWLEDGE CREATION AND TRANSLATION

Transforming discoveries into advanced development and ultimately solutions for our customers is an important outcome of our enterprise. We recognize that this requires the sustainment of knowledge creation and the ability to translate knowledge into actionable technology development. Industry sectors across disciplines are seeking ways to increase the efficiency of their research investments to end products. One approach that is being implemented in research and development organizations is to integrate innovators with developers across a product pipeline of investment and time. This translational paradigm is active and has demonstrated that teaming of interdisciplinary interests and practices can dramatically improve the efficiency of research and development and mitigate risks across the pipeline.

JSTO will adopt these translational product and research principles as the foundation for our S&T efforts. As a result, we will focus on improving our integration with CBDP members and including appropriate stakeholders as team members throughout the discovery, development, manufacturing, acquisition, and fielding phases of our S&T programs. By using translational research and development principles and integrated team structures and investments, we intend to improve the predictability of success for JSTO CB S&T programs.

We also expect to achieve the following important benefits:

- ★ Reduce attrition by removing unlikely successes earlier
- ★ Increase the success of investments by identifying and amplifying winners earlier
- ★ Increase the efficiency of moving discoveries to development and transition
- ★ Increase the value of S&T programs to deliver capabilities to mission

As part of this translational approach, we will aggressively modify our internal processes to emphasize critical thinking, innovation, and competition, and we will use a teaming process led by our S&T Managers (STMs) during all phases of the S&T program lifecycle. We intend to form and lead teams with external stakeholders that bridge the standard 6.1 through 6.5 budget categories.

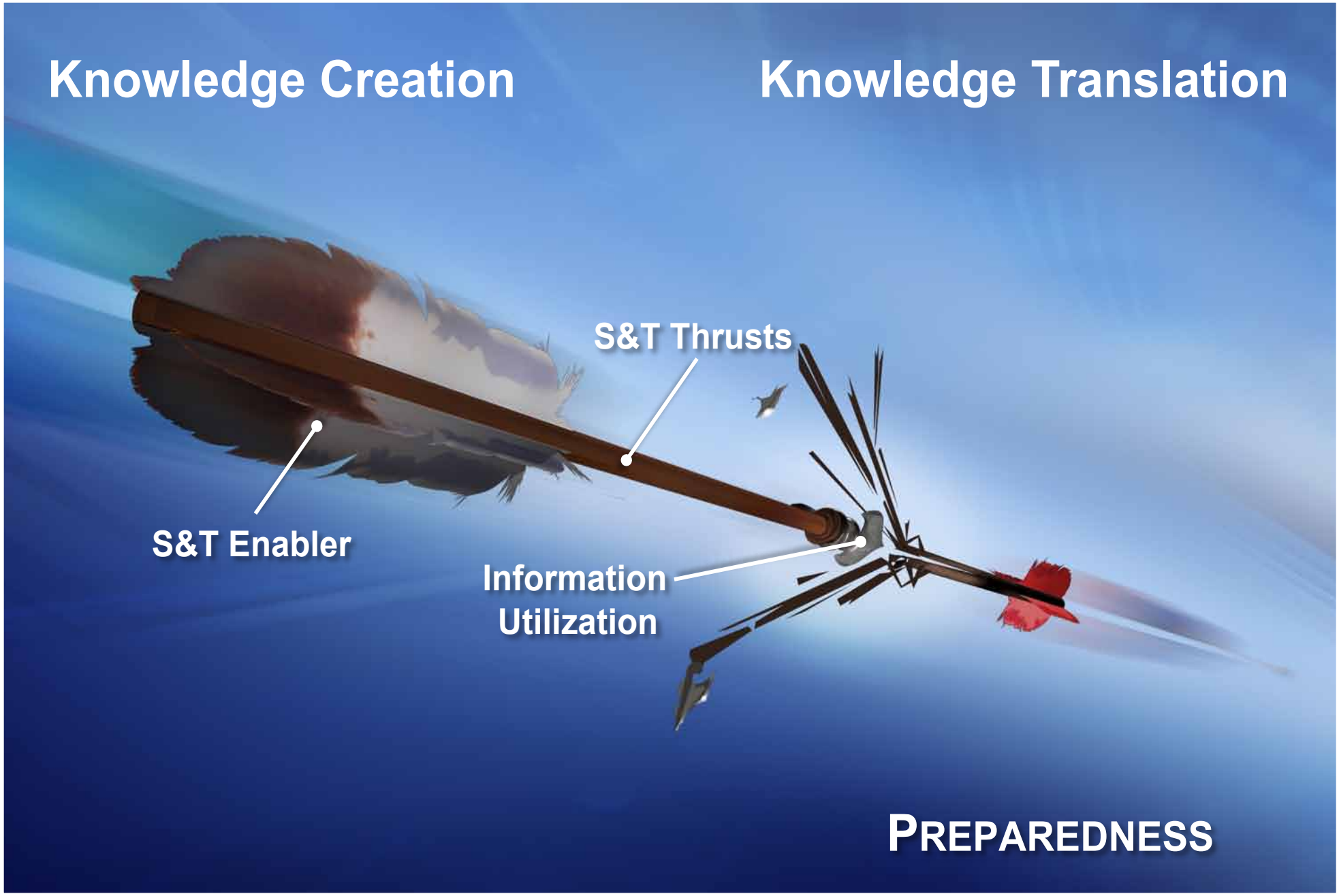
We recognize that some ideas require time before they are ready for translational approaches. We will provide seed investments for new ideas that are high risk and require more time to mature before they are integrated into more focused innovative technology programmatic investments. These seed investments will also be used to sustain core investments in key basic research areas that will be required to provide subject matter expertise and advise to the DoD and the national security infrastructure.

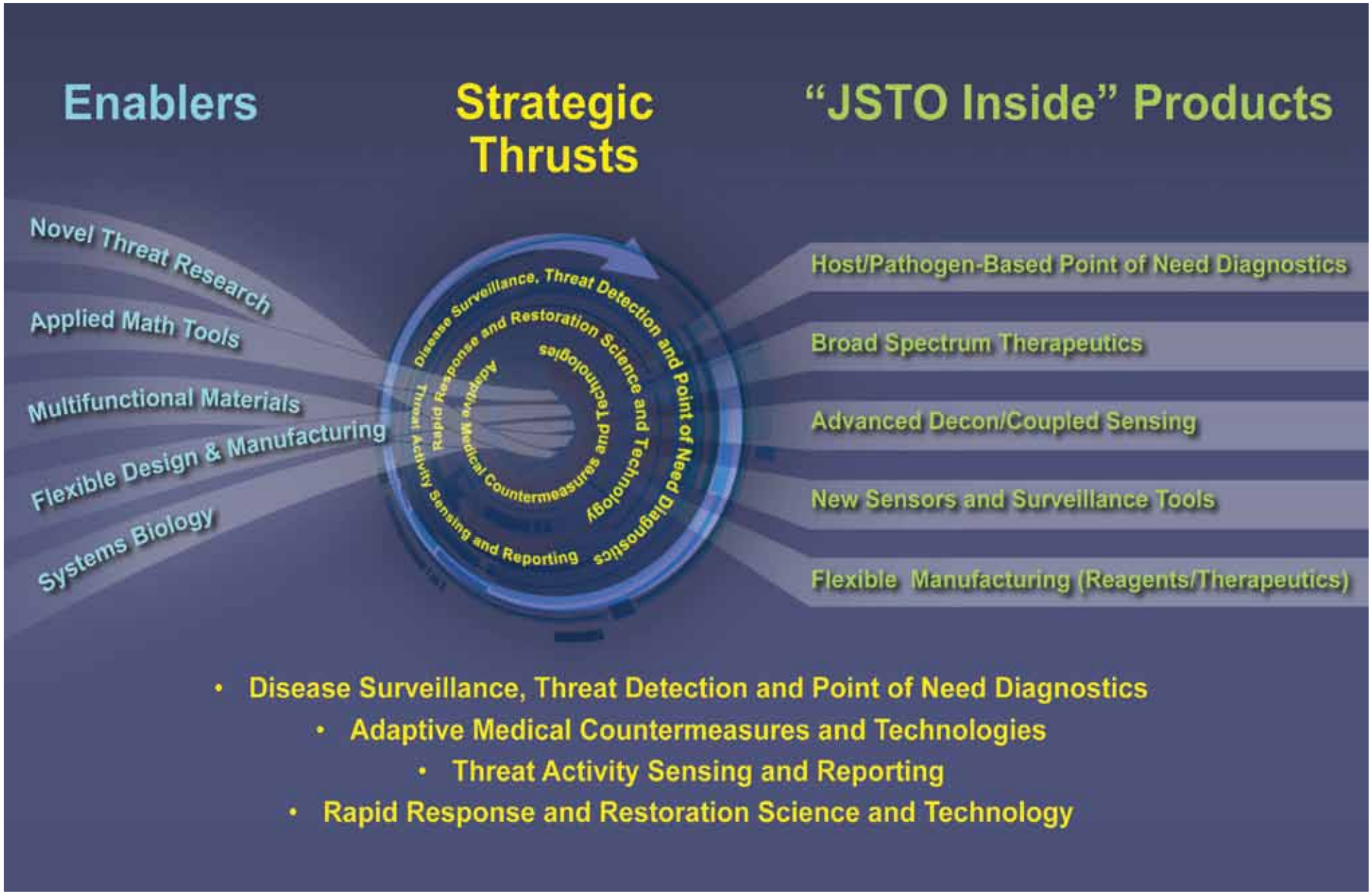
CULTURAL IMPERATIVES

As we create an ecosystem of innovation and translation we recognize that it is important to articulate both who we are and the values and behaviors that we embrace. These cultural imperatives will be a useful guide for us to consistently address our workforce, providing opportunities and incentives in human resource planning and development, and establishing principles for interactions within our organization and with our many enterprise stakeholders. We will hold ourselves accountable to these imperatives and use them to build and sustain a world-class S&T organization that recognizes the challenges we face.

The following are specific cultural imperatives we will adopt to embrace this vision:

- ★ Prepare for surprise from fast moving fields and widening dynamic threats
- ★ Be proactive in seeking the best ideas and practices in both S&T and business activities
- ★ Focus on key critical areas of need and delivery of capability and products for development
- ★ Openly innovate with DoD labs, academia, and industry
- ★ Recognize that speed matters; we will save lives
- ★ Create and embrace translational teaming to enhance actionable technology and optimize transition potential for innovations and solutions
- ★ Create an ecosystem of innovation and constructive challenge


Knowledge Creation
Knowledge Translation
S&T Thrusts
S&T Enabler
Information
Utilization
PREPAREDNESS


Enablers
Strategic Thrusts
"JSTO Inside" Products
Novel Threat Research
Applied Math Tools
Multifunctional Materials
Flexible Design & Manufacturing
Systems Biology
Disease Surveillance, Threat Detection and Point of Need Diagnostics
Rapid Response and Restoration Science and Technology
Adaptive Medical Countermeasures and Technologies
Threat Activity Sensing and Reporting
Host/Pathogen-Based Point of Need Diagnostics
Broad Spectrum Therapeutics
Advanced Decon/Coupled Sensing
New Sensors and Surveillance Tools
Flexible Manufacturing (Reagents/Therapeutics)
• Disease Surveillance, Threat Detection and Point of Need Diagnostics
• Adaptive Medical Countermeasures and Technologies
• Threat Activity Sensing and Reporting
• Rapid Response and Restoration Science and Technology

THE FOCUS IMPERATIVE

The ability to translate knowledge into technology will require focus. It is imperative we focus on key areas of investment and remain diligent in focusing these investments toward actionable transition. This graphic outlines the process by which our investments in key enablers will integrate with our investments in focused strategic thrusts that will ultimately transition our research and development efforts into products and capability areas of need.

ENABLERS

Enablers are key areas of investment essential for establishing a strong foundation for knowledge creation and translation. They will comprise a portfolio of risk and innovation across a spectrum that provides an underlying base needed for realizing capabilities and technologies that can be mapped into strategic thrust areas for further research and development. They can include truly revolutionary science and technology, with the goal of discovering 'game-changing' enabling capabilities for chemical and biological defense.

They can work to develop new tools or platforms that could be transformative across a number of potential application areas. They can also be areas of basic research investments to grow a knowledge base from which to enable future capability and important archival information. The following enablers therefore guide a portion of our efforts, yet are structured to accommodate specific stakeholder needs, as appropriate. We will continually examine this foundation to ensure it provides a strong base for knowledge creation and translation that remains relevant to both our current mission and future needs.

ENABLER #1: NOVEL THREAT RESEARCH

JSTO is committed to pursuing discovery science to prepare for surprise from fast-moving disciplines that could present new threat scenarios. We will continue to invest in basic research to better understand and characterize current chemical and biological threats and evaluate new threats in order to find and develop new approaches to mitigate or defeat them.

We will explore novel areas emerging in interdisciplinary realms that could present new challenges and potential threats. These include broad areas such as synthetic biology where new tools are being rapidly developed and widely disseminated to create new genetic constructs that are being engineered in novel ways. This global community is growing fast due to socioeconomic drivers in a variety of sectors: energy, health, and environment. We will monitor and engage this community in new ways to assure we evaluate opportunities and challenges that could arise from synthetic biology. Engaging new communities, such as the DIY Bio, will help us to better understand the ease by which new threats could emerge.

Other areas of interest in novel threat research include understanding complex molecular and cellular interactions. Examples of such areas of investment include biofilms, which are each a complex matrix from which biological elements like bacteria and viruses interact, evolve, and express events that we do not clearly understand. We will explore new ways to characterize and engineer biofilms and other complex molecular and cellular communities to drive new understanding and application in biological and chemical defense. This has application across many areas, including quorum sensing, decontamination, and personnel protection. The biofilm area is an example of our overall lack of understanding of surface interactions between living and non-living systems. Continued characterization that drives novel ways to engineer or effect surface interactions will be a fruitful area for novel threat research activities and application.

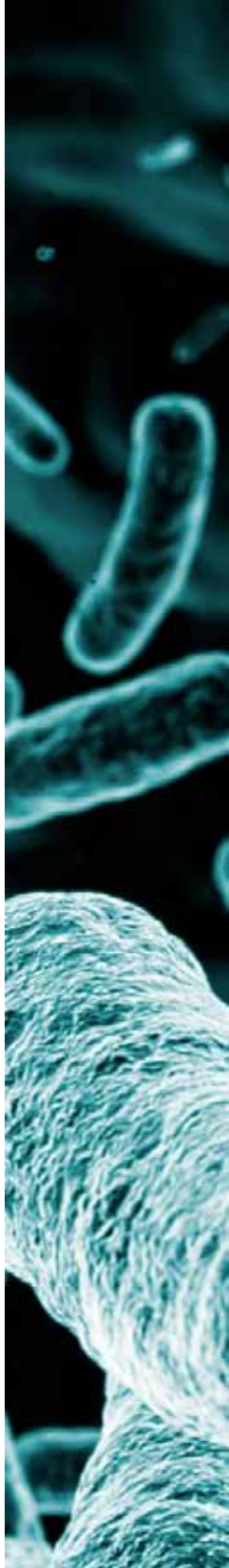
We recognize that investing in novel threat research includes understanding new tools and how they can be applied in new ways.

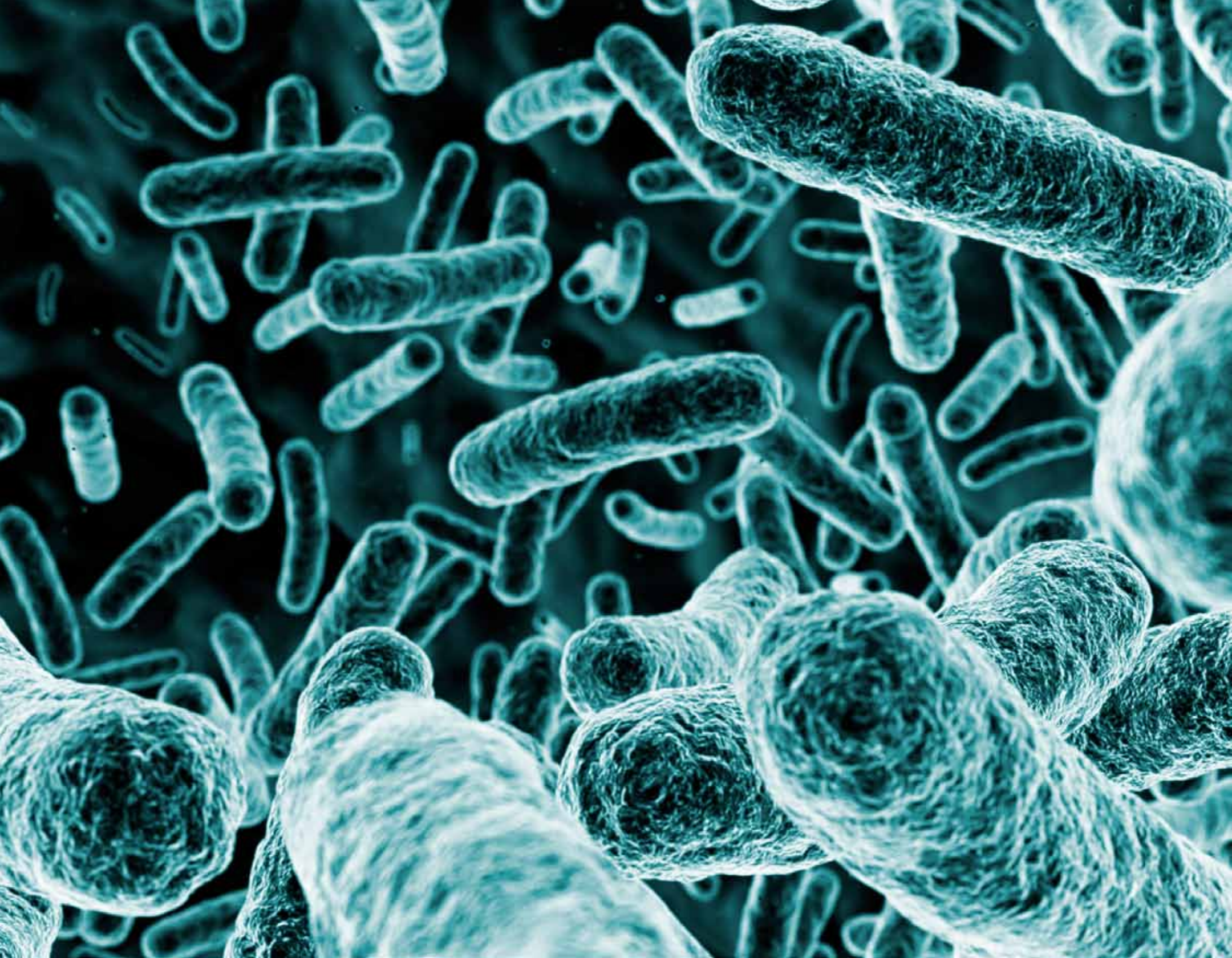
The advance in combinatorial methods of synthesis to generate novel chemical and biological molecules presents a rich area for investment in novel threat research. We will continue to examine novel methods of chemical synthesis to identify new potential chemical threats that could be used against the U.S. and its allies.

These methods also represent opportunities to produce novel molecular recognition elements for use in detection or mitigation of chemical or biological threats. We will exploit these new tools for rapid synthesis of novel molecules for new applications.

Novel threat research will also require looking over the horizon for those areas that could emerge in the future as threats that we either currently underestimate or that are created by new discoveries in interdisciplinary life sciences. An example of one such area is cognitive and neuroscience and engineering. We have traditionally defined this area as involving neurotoxins from known chemical agents, historically used in conflict, or non-traditional agent derivatives. The growing area of neuroscience and technology and its broad application to key human performance elements such as learning, behavior, and decision making represent future areas that will demand continued scanning. Interactions with key physiological systems such as the immune system or cognitive or behavioral deficits are ripe areas for evaluation. Another example is bioinspired and biomimetic engineering, where extracting discoveries in interdisciplinary life sciences continues to present broad opportunities for emerging areas of investment in novel threat research. We will be diligent in examining such new areas by scanning emerging discoveries that intersect with potential challenges and opportunities that could develop into new threats.

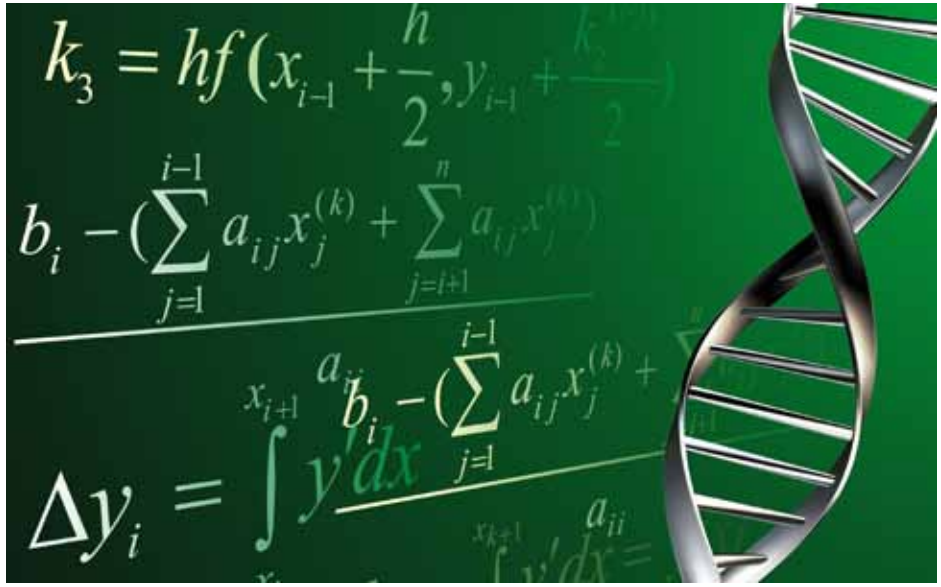
Another important activity we will undertake in novel threat research is to continually examine current systems and how they can be easily defeated. This 'red teaming' activity will be an important component in our efforts to evaluate current investments in advanced research or development and to explore how new discoveries could impact their defeat. We will apply new knowledge creation to continually challenge the technology we create and evaluate any ability to defeat or disable it as a means to understand novel threats to our own defense systems and their deployment.





ENABLER #2: APPLIED MATH TOOLS

The ability to integrate and analyze data is key to driving successful knowledge creation and translation. Our world is becoming awash in data and we are continually challenged to understand what is important, to know how to manage data, and to rapidly translate data into useful information and knowledge. We experience this problem across our enterprise in every application area and in every investment we make in basic or applied research. The challenge of transforming data into decisions has been recognized at the highest levels of DoD and across government. JSTO will use and develop advanced analytical, mathematical, and information management tools across our directorate to generate synthetic environments and predict CBRN effects and countermeasure performance. These toolsets will employ advanced predictive modeling and other mathematical analytic approaches in diverse areas such as atmospheric transport and diffusion, disease propagation, and biomarker target identification.



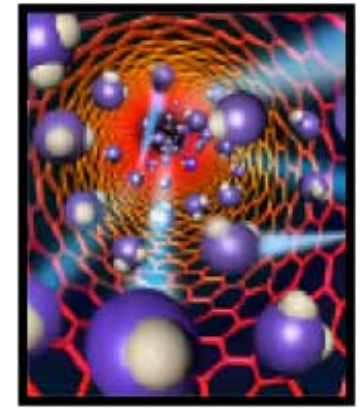
Our ability to tackle the ever demanding and increasing collection of data requires an aggressive investment in applied mathematical and statistical tools. We will target novel mathematical methods and improvements in noise and background analysis, breakthroughs in the use of incomplete datasets, advances in classification methods, and heuristic approaches for prediction and mirroring human predilection and intuition. Each of these will be investigated through a variety of techniques, including those based upon advanced understanding of topology, non-linearity, fractals and chaotic systems.

This will also require a complementary investment in information architectures that can accommodate the use of these novel methods to integrate data sources in a user-friendly manner (which recognizes the human interface with data), and that can evolve as necessary. The use of autonomous systems that are also integrated with new methods of data analysis will present future opportunities to advance a number of application areas as we learn and recognize how computational tools can supplement human interfaces in important ways.

ENABLER #3: MULTIFUNCTIONAL MATERIALS

Materials development has traditionally created static, uni-functional materials that do not change over time. The development of dynamic multifunctional materials represents a significant opportunity to create novel applications for future chemical and biological defense. This strategy mimics biological systems, such as skin, that have a number of dynamic material properties and functionalities. The environment is ripe for creating novel and multifunctional materials not only for protective purposes, but also for a host of other uses including, but not limited to, detection, diagnostics, decontamination, and therapeutic delivery.

We will focus on developing and integrating functional, multi-component materials for a variety of purposes. We will pursue bioinspired and biomimetic integrated materials for application as coatings, elastomers, and structural and sensing materials. We will seek advances in nanomaterials, dopants, quorum-sensing materials, nano- and quantum-dot materials, as well as materials for various purposes, such as drug delivery and imaging. We will also explore materials at the biotic-abiotic interface (e.g., biocompatible, regenerative, and reconfigurable). This will require evaluating new materials and methods of using existing structural materials (such as ceramics, electronic materials, polymers, and liquid crystals) and their integration with components that will enable multifunctional and dynamic capability and system application.

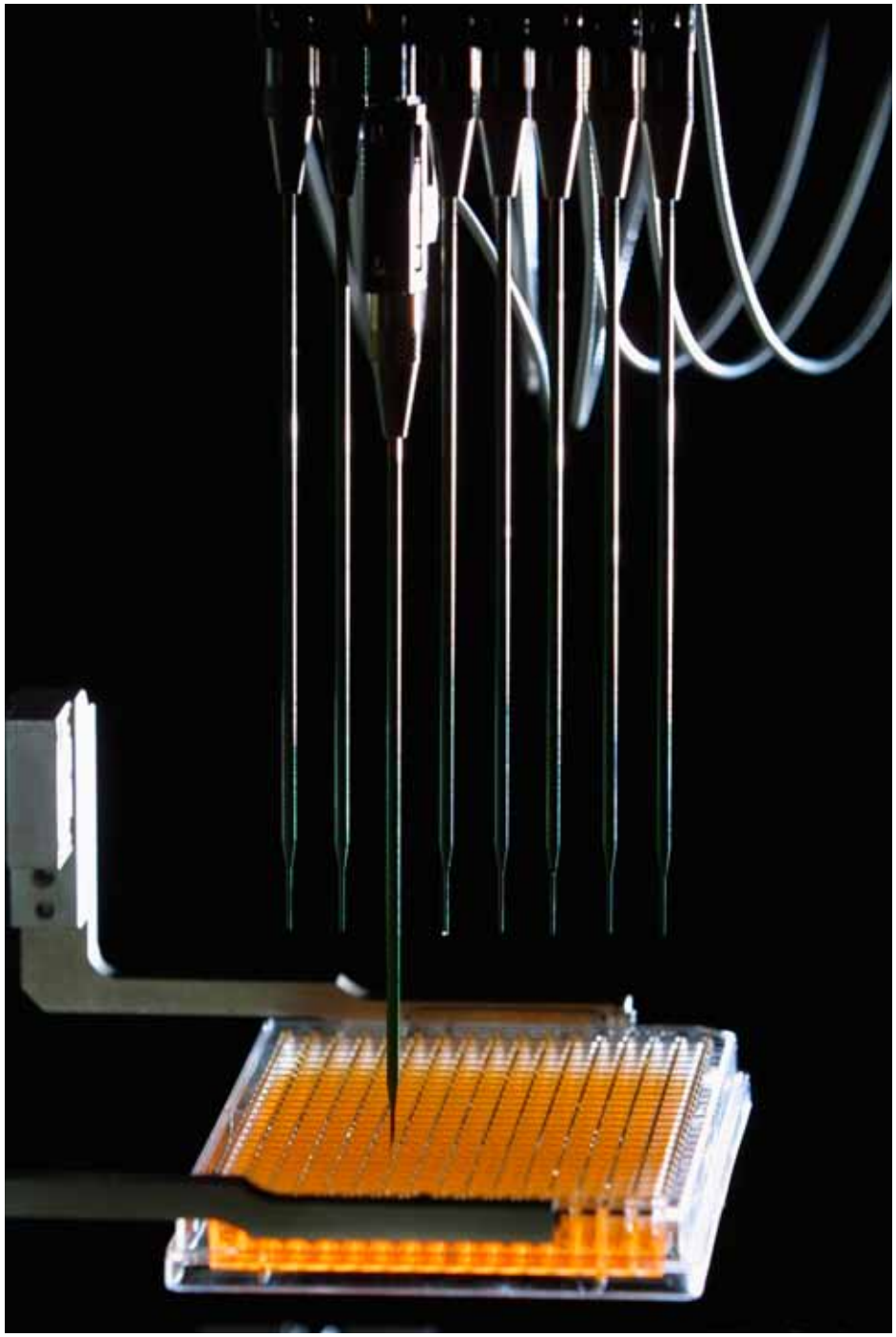


ENABLER #4: FLEXIBLE DESIGN & MANUFACTURING

Our Nation has seen an erosion in its manufacturing capability. This is particularly unacceptable when it comes to manufacturing needed technologies for biological and chemical defense. Accordingly, we will focus enabling investments in flexible design manufacturing across the capabilities and needs in our enterprise. We acknowledge that not only can we not depend on foreign manufacturing for producing products of need, but a strong future defense that mitigates fast-moving offensive threats will require flexibility and adaptability in manufacturing. This will demand a paradigm change in our current manufacturing methodology. Design flexibility will need to be built into the process up front to enable our agility and adaptability in manufacturing defense needs in response to a rapidly identified new or emerging threat.

We will seek to develop a variety of adaptive and modular designs for manufacturing platforms that will provide a strong future foundation for manufacturing development for chemical and biological defense.

These will include platforms that will employ molecular and cellular means of producing novel elements for manufacturing and that will address applications, such as production of materials, diagnostic reagents, therapeutic cells and tissues, and others. These agile and adaptable platforms will enable rapid reconfiguration based on an identified new threat. This emphasis will also support technical solutions that leverage chemical synthesis and synthetic biological approaches to increase yields and improve product selection of needed components. Additionally, we will focus on creating and demonstrating novel adaptive manufacturing designs that will support scaling from small- to large-scale production lots. Ultimately, our aim is to enable just-in-time production capability for both technology and medical chemical and biological defense solutions. These 'just-in-time' manufacturing platforms will also position our investments in future defense postures that trend toward small mobile agile units where such manufacturing methods may be highly distributed and localized to areas of conflict or operational need.



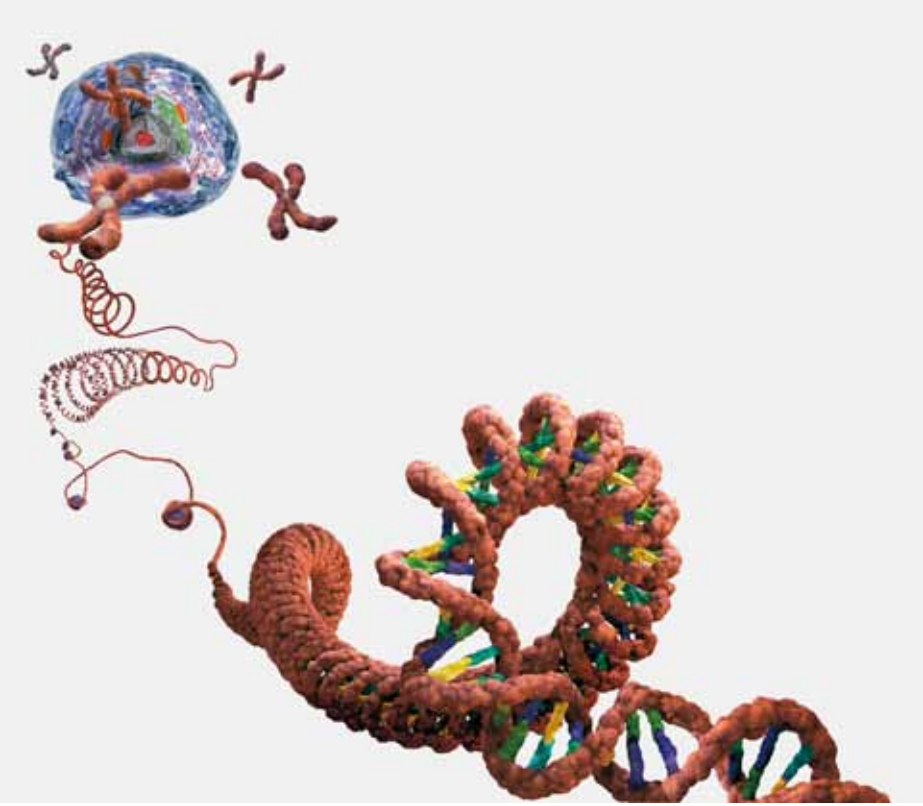
ENABLER #5: SYSTEMS BIOLOGY

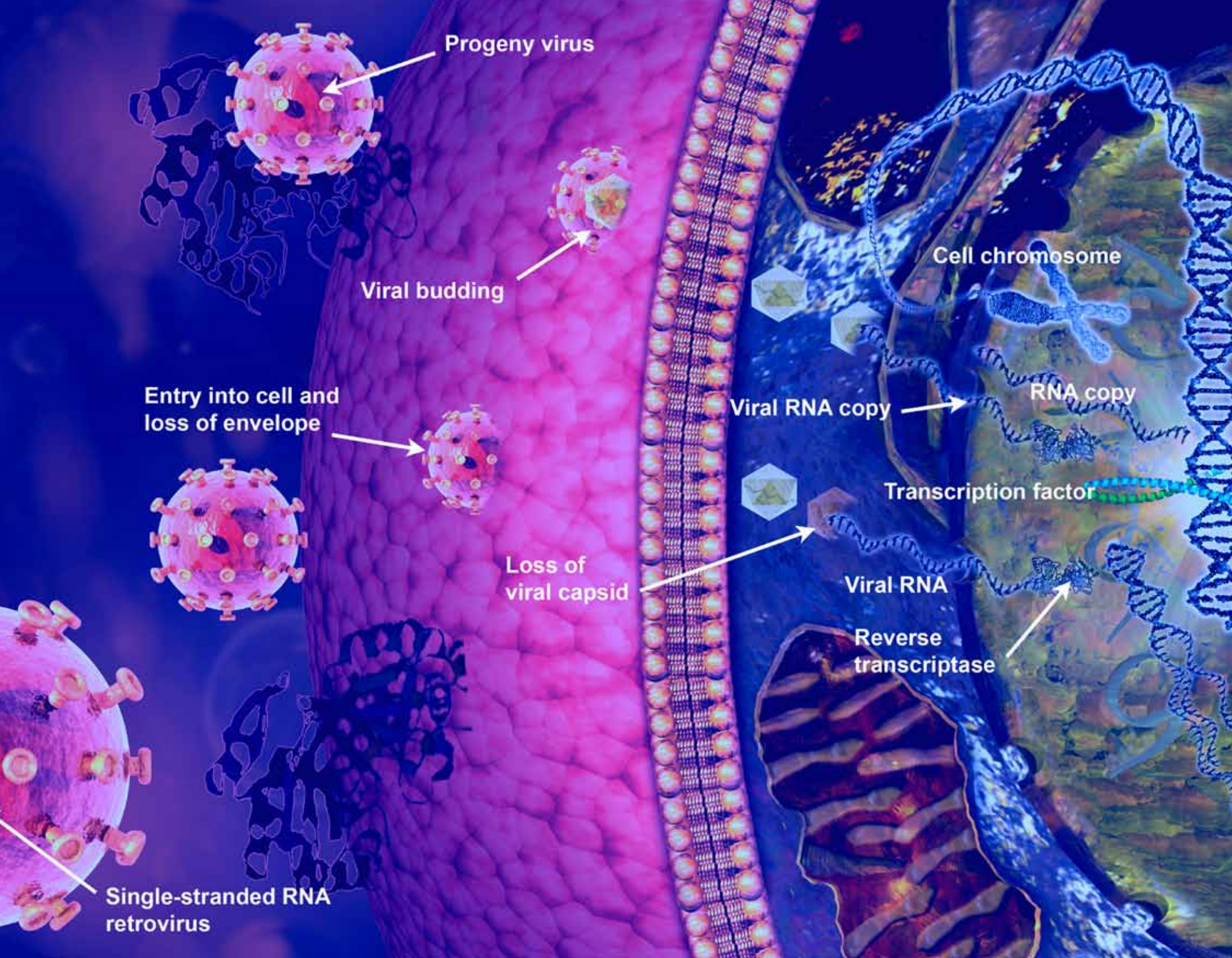
The reductionist trend in interdisciplinary life sciences is coming to an end. The emergence of systems biology over the last decade recognizes that understanding and exploiting complexity in living systems requires a systems understanding of events across scale and time. This emergence is characterized by the expanding 'omics' revolution that appreciates the inherent value of multivariate sources of knowledge (e.g., from genes, proteins, metabolism, physiology, and the connections that these information sources produce) in building a living system that is created by design and evolves through adaptive pressures.

Our challenge—and our opportunity—is to actively participate in the 'omics' revolution and emphasize efforts to understand pathogens, novel threats, and host responses (zoonotic and human) to such threats. The data and information developed will provide a rich foundation for knowledge creation and translation. We will be diligent to use key assets that enable investigation and evaluation of systems biological responses following exposure of living systems to threat chemical and biological agents.
This will require an active philosophy to mine genome, proteome, transcroptome, methabolome, connectome, physiome, and other information from experimental designs involving pathogens, chemicals, and hosts. This data stream will provide new biomarkers and targets that can be exploited for many applications.

An underlying enabling investment in systems biology will create rich data backbones that can be exploited for understanding pathogenesis, host immunity and toxicology, and for identifying key targets for applications, such as sensors, decontamination, diagnosis and therapeutic application. We will engage and employ the rich systems biology community to aid in the sustainment and growth of this important area of enabling investment, and we will continue to mine increasing information-rich datasets from biological systems following exposure to chemical and biological threats.

We will also exploit the information derived from systems biology investments to explore engineering new systems that could drive new capabilities. An example of such an effort could be to use information exploited from extremophile systems to engineer new capabilities into chemical and biological defense systems that would impart greater environmental stability in austere environments. Other examples include the use of cellular and organismal systems to create new opportunities in sensors, diagnostics and therapeutics. Such systems could create engineered biological systems, or 'canaries' that could report on functional consequences or react in ways that provide novel solutions to application areas of interest.




Progeny virus
Viral budding
Entry into cell and
loss of envelope
Loss of
viral capsid
Single-stranded RNA
retrovirus
Cell chromosome
Viral RNA copy
RNA copy
Transcription factor
Viral RNA
Reverse
transcriptase

STRATEGIC THRUSTS

Our ability to deliver key capabilities and technologies for our mission will require focus. We have identified four key areas for particular emphasis, each one an area of key need that provides a focused imperative to accomplish the JSTO mission. These strategic thrusts will support multiple goals, objectives, and investments, and they will provide a framework: to assess the success of our investments in delivering capability and technology to product development, to ensure the alignment of our investments with current requirements and known future needs, and to encourage and guide our investments in discovery and S&T innovations in promising new areas, as they are uncovered.

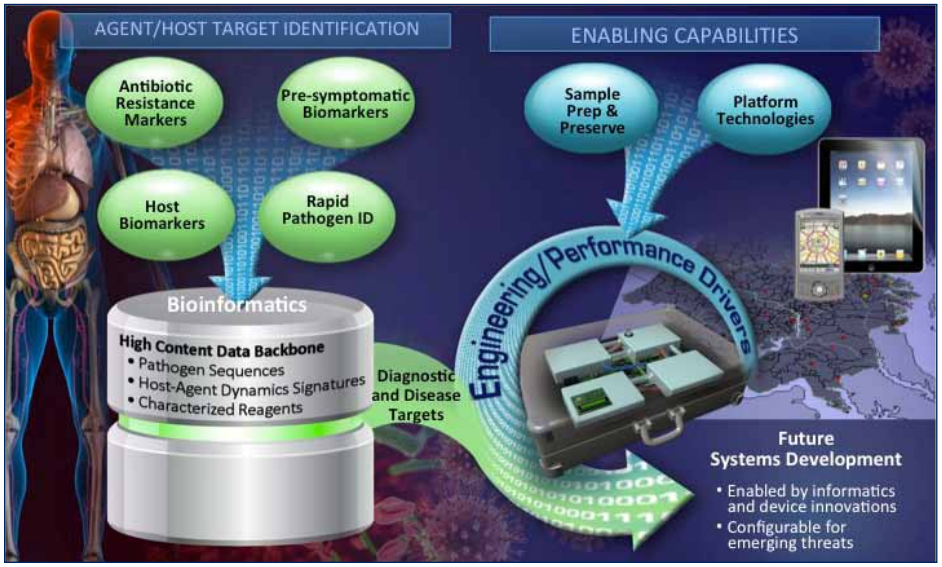
Strategic thrusts also serve to align efforts to ensure needs are met by fully integrated solutions and not by single or unsustainable products or approaches. Prudent investment demands a complete understanding of acquisition, fielding, and sustainment challenges earlier in discovery and development to better inform selection of those paths worthy of pursuit.

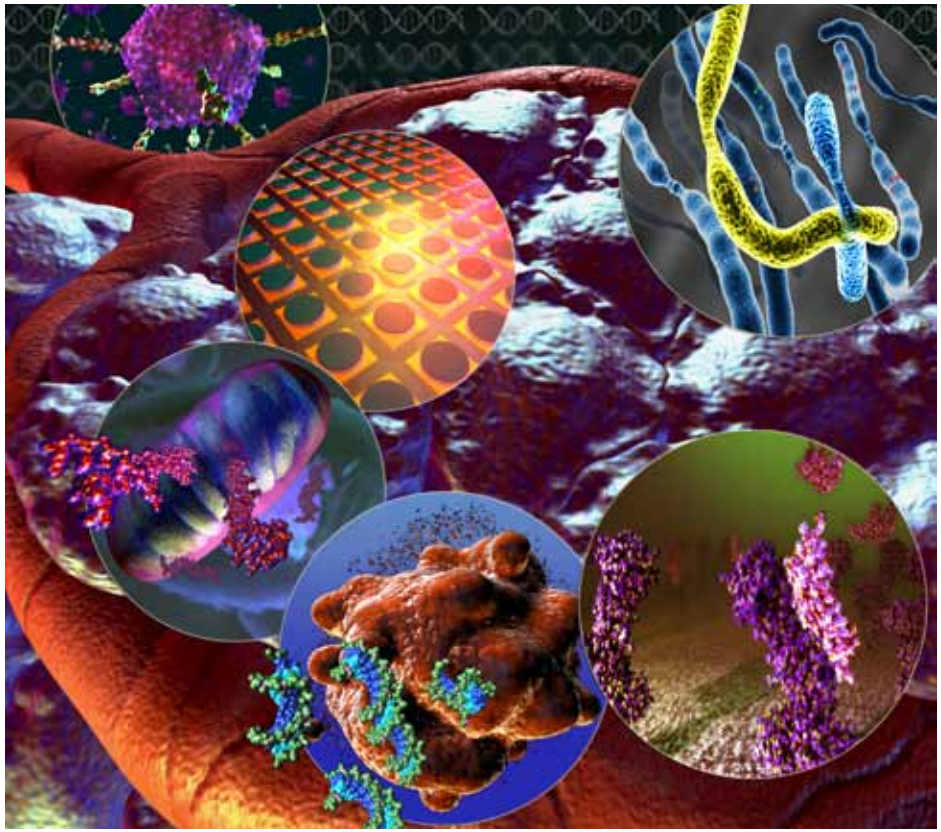
The following strategic thrusts will therefore guide a significant portion of our investments and efforts. These thrusts address critical stakeholder needs as well as provide a target for the exploration of potentially disruptive, revolutionary advances in science and technology.

STRATEGIC THRUST #1: DISEASE SURVEILLANCE, THREAT DETECTION AND POINT OF NEED DIAGNOSTICS

Efforts to provide early warning of biological or chemical threats recognize that disease surveillance and diagnostics provide key sources of information. The data-rich information sources generated by enabling investments in systems biology and novel threat research will provide foundational information for detecting and classifying diseases. These include biomarkers associated with pathogen identification and host response, antibiotic resistance, and pre-symptomatic markers. We will provide resources and sponsorship to develop the molecular, epidemiological, and computational tools and discover the endemicity patterns necessary to rapidly identify natural and man-made biological and chemical threat agents through point-of-need diagnostics, disease surveillance and threat detection systems. We will continue to exploit pathogen identification and classification systems with increasing multiplexing and expanding detection capability from clinical samples. We will also aggressively push host-response diagnostics that are pathogen or threat agnostic and based entirely on host response.

We will also recognize that moving samples around in the future will become more difficult and that providing decentralized point-of-need systems which can feed diagnostic and detection information to a centralized data analysis architecture is the future trend. This will require attention to affordable sample collection and preservation media and data collection devices, such as cell phone technology. Integration of digital results from such devices into surveillance architectures will also be an important aspect of this investment.





Areas of emphasis:

- Pursuing advances in surveillance technologies that can be fielded at the point of need. These technologies will enable biosurveillance assessment of microbial ecosystems, disease emergence/re-emergence through zoonotic and insect vector surveillance, human and environmental characterization, and detection of microbial variants.
- Focusing on the identification of effective host biomarkers and their use in point-of-need diagnostic solutions, and supporting bioinformatic systems to drastically improve current disease surveillance and expedite effective response.
- Sample collection and preservation in tiered level systems from user-friendly, affordable, and high clinical value point-of-care diagnostics to more sophisticated technologies that provide data-rich information and will find application in the clinical diagnostic laboratory.

STRATEGIC THRUST #2: ADAPTIVE MEDICAL COUNTERMEASURES AND TECHNOLOGIES

The realization that the likelihood of surprise from biological and chemical threats is inevitable and that potential exposure of new or emerging threats to DoD personnel is likely demands that our investment strategy for medical countermeasures embraces agility and adaptability. This requires that we approach developing candidate pretreatments and post exposure therapeutics with broad spectrum platforms that can be easily modified to create countermeasures as new threats are identified. It also requires an integrated countermeasure research and development strategy of rapid threat identification, rapid target selection, and rapid lead candidate development. This strategy is embodied in our current medical countermeasure programs and is amplified by new investments in medical countermeasures directed by the White House and National Security Policy.

The application of translational medical principles to the development of needed medicines also represents an opportunity to bring greater efficiency to our programmatic investments in resource-intensive medical countermeasure efforts. We will actively exploit the principles of translational medicine, enabling the use of predictive pharmacodynamics and kinetics, robust demonstrations of absorption, deposition, metabolism and excretion, human safety microdosing (Phase 0) and Phase I safety trials to better predict the performance of needed candidates later in development.

Through translational teaming that will engage members who have an understanding of operational requirements/utility and those who have experience in advanced development and acquisition strategy, we will also perform pre-clinical safety and efficacy in accordance with DoD requirements and utility assessments. This will ensure that key elements of design, such as route of administration and product stability, meet product specifications before the product reaches advanced development.

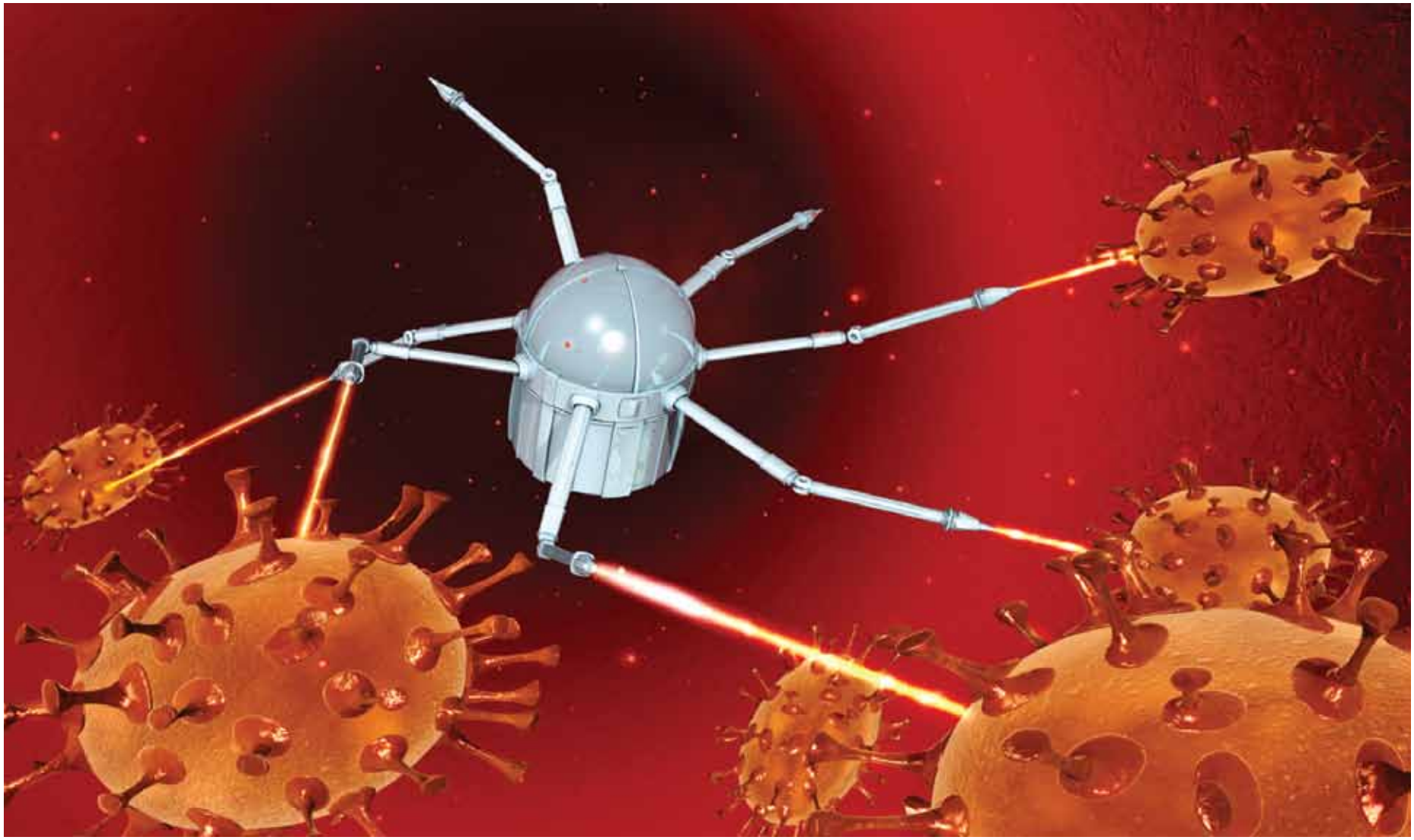
We will invest in new efforts to create flexible manufacturing capabilities for needed countermeasures. Borrowing from enabling investments in flexible manufacturing, we will seek to enhance our ability to adaptively manufacture countermeasures from new expression vehicles such as plants, cells, and de novo synthetic platforms. We will explore methods to demonstrate and develop such platforms for producing new capabilities both during advanced development and during large-scale production. The need to create flexible and adaptive countermeasure strategies will require the development of new regulatory paradigms that go beyond the use of the animal rule.

We will actively invest in regulatory sciences and technologies to enhance the transformation of regulatory guidelines for needed responses to chemical and biological threats. We recognize that emergency use authorization will likely amplify the need for agility, thereby increasing the need for regulators to be engaged with us and experienced with our broad spectrum approaches and new flexible manufacturing platforms. We will actively invest in regulatory sciences that explore new assays to determine human safety and efficacy and the quality of needed countermeasures produced from new manufacturing methods. These will include ex vivo technologies as well as post processing analytical tools to provide novel methods of assessment.

Areas of emphasis:

- Developing broad spectrum platform approaches that enable adaptive responses to chemical and biological threats. These will include both pretreatments and post exposure strategies as well as host immunomodulators.

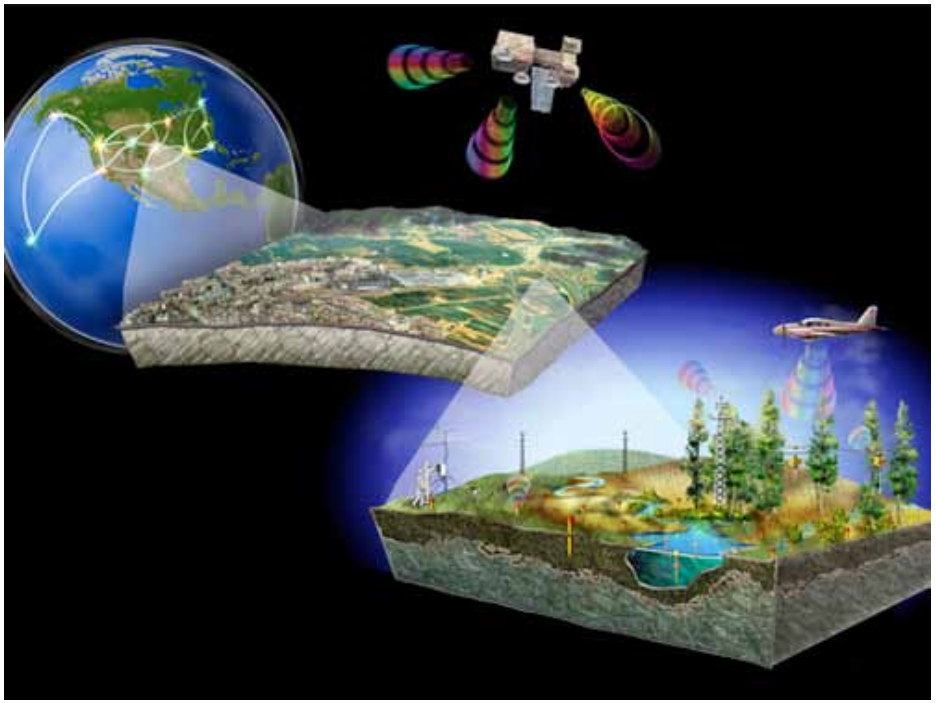
- Improving regulatory science—the science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products. Advances in the areas of assay development, efficacy in product development, quality in design, and statistical mathematical methods will provide the supporting evidence and approaches needed to transform the current, unnecessarily long process for medical therapeutic approval and use.
- Designing flexible and adaptive manufacturing paradigms to improve the agility of a DoD and/or National response to disease outbreaks or other biological threats.
- Employing translational medicine approaches, including medical discovery and delivery technologies, to improve efficiency and adaptability in fielding capabilities to preserve warfighter health and combat effectiveness.



STRATEGIC THRUST #3: THREAT ACTIVITY SENSING AND REPORTING

Historical investments in this area have striven to provide ever-increasing information on the physical detection of threats in the environment. JSTO will continue to pursue this strategy, but will also enhance our investments to include broad spectrum approaches to create systems that widely respond to chemical and biological threat 'activity.' These new sensors will provide new information on human exposure consequences and are natural extensions of our increasing knowledge regarding host response.

Our 'sense and report' strategy has also relied too heavily on static systems. The ability to move and seek out threats while sensing and reporting will also be an active area for exploration. The creation of robotic and autonomous systems that provide hunting capability and the ability to get up close to the threat will provide new alternative strategies to the historical investment in stand-off detection.



Areas of emphasis:

- Advancing current physical detection systems and materials/coatings to improve their sensing and reporting capabilities, and integrating them with complementary sensor modalities. We will enhance current capabilities by developing decontamination materials and coatings that actively report on functional biological or chemical threats upon detection or following exposure, and adaptively report on the status of remaining contamination in real-time.
- Developing complementary sensors that detect and classify host response activity in order to predict functional consequences of exposure and to classify threats. Additional sensors will integrate environmental fate and transport detection and prediction capabilities, zoonotic and epidemiology assessment capabilities, and topological and meteorological integration. Integrated sensor suites will provide improved prediction of physiological consequences of short-and long-term exposure to a variety of functional threats (e.g., neurotoxic, long-term cognitive, immunomodulation, immune, gastro intestinal, muscular skeletal).
- Exploiting mobile sensing and reporting by using ground, amphibious, and air unmanned robotic systems to seek out threats and provide orthogonal solutions to stand off detection.
- Revolutionizing approaches to assess threat activity by considering novel collection concepts that enable improvements in wide-scale or localized background monitoring and collection. These approaches will contribute to delivering capability to conduct operational missions, such as biosurveillance.

STRATEGIC THRUST #4: RAPID RESPONSE AND RESTORATION SCIENCE AND TECHNOLOGY

In accordance with our cultural imperative that speed matters, we recognize that our ability to rapidly respond to a threat across the spectrum of need is paramount to our defense against chemical and biological threats. We have made great strides in creating a community of scientists and technologists that recognize that our research investments are not passive exercises, but could be called on at any time to provide a solution to a real world problem. In that vein, we have initiated a rapid response capability focused on pathogen identification. We intend to expand this valuable practice and strategically invest in teams capable of creating rapid responses across the spectrum of need including decontamination, personnel and materiel protection, and rapid restoration of operations.

Areas of emphasis:

- Developing innovative materials that can protect people, electronics, and vehicles. These new materials will enable rapid regeneration and reconfiguration for multipurpose use and will be biodegradable and compostable. Not only will this emphasis provide greater levels of protection for personnel, it will also reduce the burden on personnel and support systems.
- Exploring technologies that provide small deployable units with self-contained, low-power and low-signature systems capable of rapidly producing potable water, safe food, and clean air so as to establish controlled and survivable clean and safe environments.
- Creating systems that rapidly identify all threat agent types and quickly attribute threats from known, modified, and newly emerged agents. This requires broad research and application of genomics, proteomics, transcriptomics, metabolomics, connectomes, informatics, and computational chemistry.
- Designing adaptable and flexible manufacturing approaches that enable surging the production of detectors, diagnostics, therapeutics, and decontamination solutions in response to an event that requires rapid scale-up.

IMPLEMENTATION

No strategic plan is effective without focused attention on its implementation. The guidance provided in this dynamic plan will consistently be evaluated and assessed for its relevance and ability to produce realizable gains in knowledge creation and translation. We will use our cultural imperatives to create a series of organizational behaviors, practices, and structures to realize this strategic plan. This will require recognition that we must partner with other key stakeholders in our success, including those with deep understanding of defense utility and operational realities and who are willing to accept that the investments we make today will take time to develop and, yet, may be needed quickly in response to a new emerging threat or conflict. We will also focus on our workforce and ensure it is optimized to achieve these goals.

We are actively creating a number of new initiatives to aggressively pursue this strategy and provide more specific goals and objectives in each of the identified enabling investments and strategic thrusts. These initiatives also recognize that agility in innovation requires attention to business practices and their effective implementation as key components of success.

We recognize that what we do today will save lives. In this regard, we are passionately committed to providing innovative solutions for the defense and national security community and will stand ready to be ever more prepared for the uncertain future ahead.

Chemical & Biological Defense
Science & Technology Strategy
Defense Threat Reduction Agency (DTRA)
1234 Walker Lane Road
Alexandria, VA 20049
571-123-4567

www.dtra@mil.gov