DoD's Distributed Bioindustrial Manufacturing Program

Biomanufacturing Overview January 23, 2024

Controlled by: OUSD(R&E)

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POC: Peter Emanuel, Biotechnology





DoD Principal Director for Biotechnology

MISSION STATEMENT

Provide an enduring source of biologically-based solutions while ensuring the U.S. military maintains a lasting advantage to deter conflict and secure the Nation through investment in a self-sustaining, domestic biomanufacturing ecosystem.

VISION STATEMENT

Support domestic biomanufacturing to fill capability gaps in critical military supply chains; solve challenges in logistics, especially in contested regions, and provide materials with novel properties.

- Delivering biotechnology-enabled capabilities that address key missions and capability gaps
- Rapid prototyping to advance technology readiness through a common foundation that enables shared data, standard workflows, and scalable capacity
- Leading in bioethics, biosafety, and biosecurity
- Fostering a diverse, multi-disciplinary workforce
- Partnering effectively with industrial, academic, and international allies and partners



Biomanufacturing is National Security

NATIONAL MISSION

Executive Order on Advancing
Biotechnology and
Biomanufacturing Innovation for a
Sustainable, Safe, and Secure
American Bioeconomy

BRIEFING ROOM > PRESIDENTIAL ACTIONS

Executive Order on Protecting Americans' Sensitive Data from Foreign Adversaries

136 STAT. 1372 PUBLIC LAW 117–167—AUG. 9, 2022
CHIPS Act DIVISION A—CHIPS ACT OF 2022







Executive Order on Ensuring Robust Consideration of Evolving National Security Risks by the Committee on Foreign Investment in the United States





DoD RESPONSE

Increase Bioindustrial Manufacturing
Innovation and Infrastructure
Through Federal Investment

DoD is Strategically Investing to Build a Biomanufacturing Pipeline and Achieve Industrial Scale Biotechnology

- Tri-service Biotechnology for Resilient Supply Chains program (T-BRSC), FY22-27
- DoD's Distributed Bioindustrial
 Manufacturing Program (MEMBR), FY23-28



Manufacturing Enabled by Modular Bioindustrial and Reusable Assets

Distributed Bioindustrial Manufacturing Program's Themes



BUILD

Repurpose, expand, & construct facilities to engender an ecosystem of biomanufacturing to serve as a domestic testbed to accelerate commercialization of biotechnology, increase sustainment activities domestically, and facilitate enhanced education and training of the emerging biotechnology workforce.



INNOVATE

Design flexible domestic manufacturing facilities to expand current biomanufacturing infrastructure, develop technologies for flexible product fermentation and separation processes of diverse molecules, and mitigate logistics bottlenecks in forward-operating environments or disaster recovery operations.



TRANSITION

Identify and foster the integration of biomanufactured products and precursors into acquisition pathways for DoD and commercial partners.



Five-F's of Biomanufacturing for Defense



DoD Bioindustrial Manufacturing Primary Focus Areas



FOOD

Bio-generated foodstuff ingredients that adhere to military specifications and improve supply chain considerations



FUEL

Drop-in-ready fuel components and additives for, and production of, high-energy-density or endothermic fuels



FITNESS

Products or material precursors that increase operational robustness by maintaining operational fitness of fielded systems



FABRICATION

Platform materials and molecules for construction of defense products or performance-enhancing additives



FIREPOWER

Platform molecules or materials for production of energetics, munitions, and propellants



Distributed Bioindustrial Manufacturing Objectives



Primary objectives of DoD's Distributed Bioindustrial Manufacturing Program are to:

- Spur innovations in the bioproduction of a wide array of materials
- Backstop vital supply chains
- Counter supply chain shock
- Neutralize supply chain exploitation
- Allow for sustained military operations
- Strengthen the U.S. bioeconomy



Bioindustrial Manufacturing Actions The Next 24 Months



- 1. MAP & MEASURE: DoD's Distributed Bioindustrial Manufacturing Program will pollinate nascent commercial U.S. biotechnology and incentivize industrial biomanufacturing by investing in the <u>development of strategic plans</u> and technoeconomic assessments of bio-product markets
- 2. CONVENE & TEAM: DoD's Biotechnology office shall <u>convene stakeholders</u> across the inter-agency to facilitate partnering opportunities and foster innovation in biomanufacturing
- 3. BUILD: DoD's Distributed Bioindustrial Manufacturing Program shall strengthen U.S. Biomanufacturing capacity through <u>strategic investments</u> in commercial capacity across America.



Deliverable Expectations

EFFORTS WILL

- Develop tools to mature the business
- Design pathways for transition of development products to manufacturing
- Market products across military and commercial markets

The development of prototype business and technical plans as the foundation for large investments

- 1. (R) Prototype the strategic business plan
- 2. (R) Prototype the strategic marketing plan
- 3. (R) Prototype the production plant and equipment design
- 4. (O) Business process evaluations
- 5. (O) Technical process evaluations
- 6. (O) Chassis evaluation and sampling
 - (R) Required (O) Optional

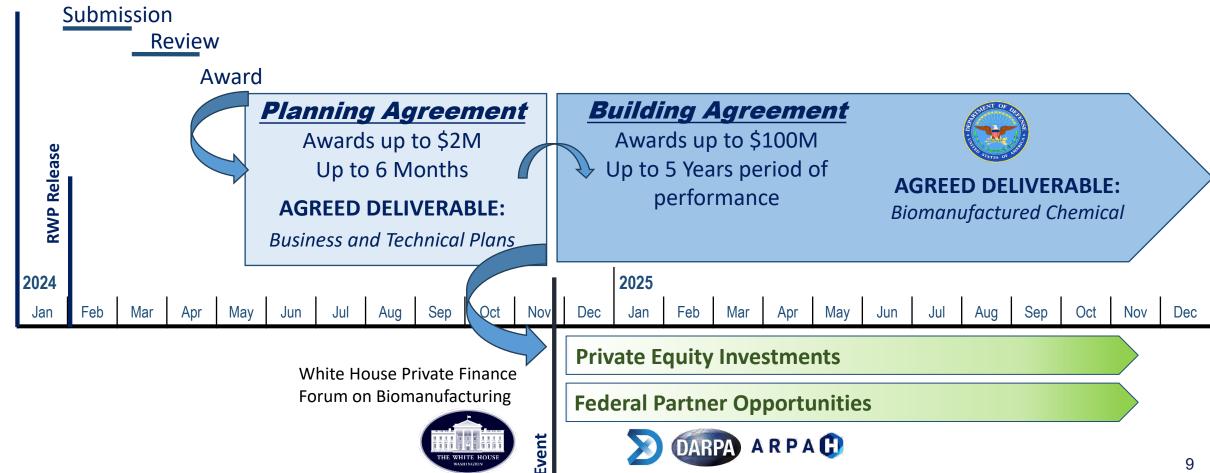


DoD's Distributed Bioindustrial Manufacturing Program The Next 24 Months



Defense Industrial Base Consortium: Open call 2024 Request for White Paper for Prototyping in Biomanufacturing



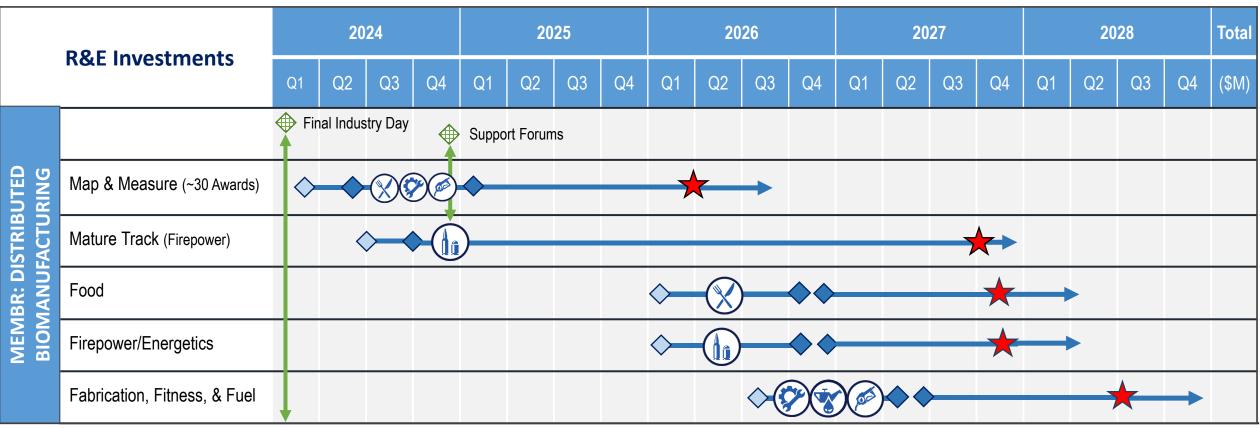




DoD's Distributed Bioindustrial Manufacturing Program



The Next 5 Years



RFP Release
 Award
 Stakeholder Engagement/Industry Day Event
 Milestone



www.USBiomanufacturing.com





Agenda

1300-1320	DoD's Distributed Bioindustrial Manufacturing Program	Dr. Peter Emanuel ST for Bioengineering, OUSD(R&E)
1320-1330	Acquisition Office Announcements	Ms. Kimberly Kozlowski Agreements Officer, WHS
1330-1430	The Defense Industrial Base Consortium and Award Timeline	Advanced Technology International (ATI) Consortium Manager
1430-1450	Q&A	Moderated by ATI
1450-1500	Closing Remarks	Ms. Kimberly Kozlowski Agreements Officer, WHS





Acquisition Office





What We Do

The Washington Headquarters Services (WHS) Acquisition Directorate (AD) is responsible for the planning, coordination, and management of supplies and service procurement programs. Knowledge-based services, research and development, and facility support account for more than 80 percent of AD's total dollars awarded, providing a consistent capability to connect people and process information.

Who we are

Under the Rapid Prototyping Acquisition Branch (RPAB) my team supports both acquisition portfolios for the OUSD Acquisition & Sustainment (A&S) and Research & Engineering (R&E) Offices. Kimberly (Kim) Kozlowski, Lead Contracting and Agreements Officer Guinevere (Guin) Bruner, Contracting and Agreements Specialist Representing A&S COL Leilani Tydingco-Amarante (COL T), Agreement Officer's Representative (AOR)

<u>Acquisition Directorate - Home (sharepoint-mil.us)</u>

New Other Transaction Agreement Vehicle Defense Industrial Base Consortium (DIBC)



"The Defense Industrial Base Consortium Other Transaction Agreement will not only help stimulate the growth of the defense industrial base, but it will also enable more rapid execution of Defense Production Act funding," said Dr. Laura Taylor-Kale, Assistant Secretary of Defense for Industrial Base Policy. "Additionally, this helps us execute the National Defense Industrial Strategy, address defense supply chain pain points, develop the industrial workforce, sustain critical production, and allow for complementary investments from other federal agencies to build a robust, resilient, and modernized defense industrial ecosystem."

<u>DOD to Accelerate Investments in Defense Industrial Base With New Other Transaction Agreement Vehicle > U.S. Department of Defense > Release</u>

DIBC Award



- Competitive process resulting in the selection of Advanced Technology International (ATI) as the Consortium Management Organization (CMO).
- Awarded on December 31, 2023
- Period of Performance: 5 year Base + 5 Year Option Period
- Ceiling: Unlimited
- This consortium has the ability to award projects under the authorities 10 U.S.C. § 4022 for prototypes, 10 U.S.C. § 4021 for research, and production OTs under 10 U.S.C. § 4022(f).

ATI Team



- As the CMO, ATI will serve as your primary interface for consortium and contractual matters
- WHS is working behind the scenes with ATI
- If awarded a project, a government Technical Point of Contact (TPOC) will be assigned as the primary interface for technical matters
- Contact ATI at: DIBConsortium@ati.org



Chris Bergner Program Manager



Erin PhalenContracts Director



Virginia Sheppa Shupe
Sr. Program Assistant



Advanced Technology International (ATI)

DoD's Distributed Bioindustrial Manufacturing Program Industry Day

23 January 2024

Agenda

- 1. Introduction to ATI and Other Transaction Agreements (OTA)
- 2. DIBC website and how to join
- 3. DD 2345 (Militarily Critical Technical Data Agreement), Sam.gov, Commercial and Government Entity (CAGE), and Unique Entity Identifier (UEI)
- 4. Upcoming opportunities
- 5. Process flows and templates

DIBC Mission/Vision

• Mission:

• To coalesce and expand the Defense Industrial Base (DIB) in support of the Manufacturing Capability Expansion & Investment Prioritization (MCEIP) critical subsectors. MCEIP is focused on addressing defense supply chain issues, developing the industrial workforce, sustaining critical production, commercializing R&D efforts, and rapidly scaling emerging technologies to build a robust, resilient DIB.

Vision:

• To deliver a resilient U.S. supply chain and workforce able to respond in times of national security crisis without reliance on foreign sources.

Critical sectors/subsectors:

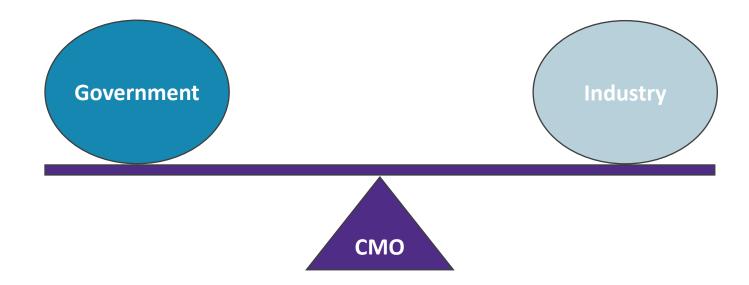
Kinetic Capabilities (Hypersonics)	Space Industrial Base
Microelectronics	Castings & Forgings
Critical Chemicals and Minerals	Submarine Industrial Base
Small Unmanned Aerial Systems (sUAS)	Rare Earth Elements
Batteries & Energy Storage	Critical Materials
Biomanufacturing	



ATI's CMO Role



ATI, as the "Consortium Management Organization (CMO)", serves as the critical pivot point between Government and Industry.



The CMO ensures the needs of both are balanced and met in an efficient and expeditious manner.

Other Transaction Authority

- A **streamlined contracting** vehicle used by the Government to engage innovative organizations that do not traditionally work with the federal government and partner them with defense industry and academia.
- An alternative to traditional acquisition methods when speed and simplified access to innovative non-traditional defense contractors is desired.
- And...

...the only path to go from successful R&D/prototype test outcome directly to production without further competition



10 U.S.C. § 4021 and 4022 authorizes DoD to carry out transactions for research and prototype projects

The Consortium Model Benefits Both Government + Industry Stakeholders and Prioritizes Innovation









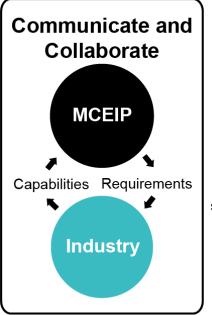




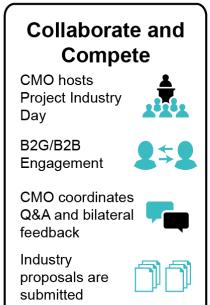


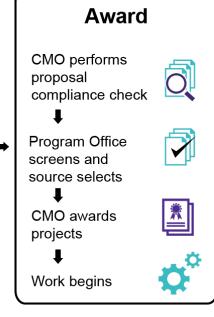
Problem Statements to Successful Outcomes

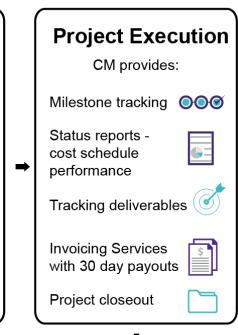












Prototypes deemed successful may move on to full-scale production

DIBC Public Website

- DIBC public website is live: dibconsortium.org
- Review the Membership tab and the How to Join page





About Membership v Opportunities v Resources v Events Contact Us Q



To coalesce and expand the defense industrial base (DIB) in support of the MCEIP critical subsectors.



To deliver a resilient U.S. supply chain and workforce able to respond in times of national security crisis without reliance on foreign sources.





Members Only Calendar



Documents Library



Announcement Awards and of RPPs Project Status

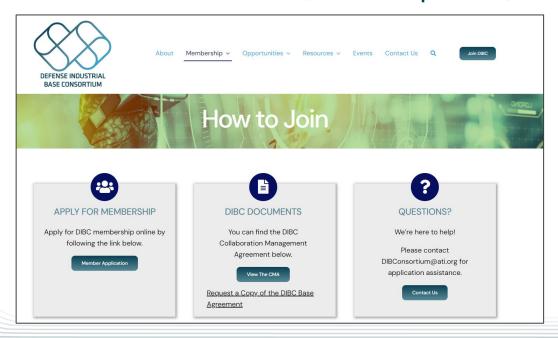


How to Participate

How to Apply

DEFENSE INDUSTRIAL BASE CONSORTIUM

- Review the application process at your earliest convenience
- Submit your application once you have all required documents
- Typically, must be a member to submit a white paper
 - Making exception for the Biomanufacturing solicitation due to recent DIBC launch
- Must be a member (no exceptions), in order to receive an award



+ Who should join?
+ How long does the process take?
+ When should my company join?
+ Can an international organization participate?
+ What do I need to apply for membership?
+ What is a consortium?
+ What is the Consortium Membership Agreement?
+ Is there a cost to participate in the DIBC?
+ What is a nontraditional defense contractor?
+ What is an Other Transaction Agreement?



SAM.gov, CAGE Code and Unique Entity ID (UEI)

SAM.gov



- DIBC Requires an active SAM.gov registration, Cage Code and UEI to become a member.
- SAM.gov is where prospective members will need to register (if the respective organization hasn't already) to get a UEI and CAGE code.
- Registration is free and questions about how to register on SAM can be found here:
 - https://sam.gov/content/entity-registration
- More information about CAGE codes can be found here:
 - https://cage.dla.mil/Home/UsageAgree

DoD Directive



"Export-controlled items marked Distribution Statement C or D shall not be disseminated outside the U.S. Government or to U.S. Government contractors without first verifying the recipient's eligibility and authority to receive export-controlled information by verifying they have a current, valid DD Form 2345 in accordance with Reference (d)."

https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523024p.pdf

The DD2345 Militarily Critical Technical Data Agreement



The <u>DD Form 2345</u> is used for the following purposes:

- Bid on a DoD solicitation or execute a DoD contract that involves access to export controlled technical information
- Conference/meeting attendance that discusses/shares export controlled material/data
- DoD export controlled technical data exchange between vendors
- Obtain Request for Proposal (RFP) details involving DoD export controlled data
- DoD Research/Development projects involving export controlled data

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admitted lawfully for permanent residence into: (X (1) or (2))		by the U.S. or Canadian Government a	gency that provided the	e technical data.		
militarily critical technical data on behalf of the co- admitted lawfully for permanent residence into:	ntractor, is a citizen or person	than their employees or eligible person behalf unless such access is permitted	s designated by the re	gistrant to act on their		
 CITIZENSHIP/RESIDENCY STATUS. The individual designated by name in Item 3. 	who will act as custodian of the	d. They will not provide access to milit	arily critical technical o	lata to persons other		
5. AS A CONDITION OF RECEIVING MIL	ITARILY CRITICAL TECHNICA	AL DATA, THE ENTERPRISE OR IN	IDIVIDUAL CERTI	FIES THAT:		
TO DECOMP THE OF NELEVANT BUSIN	COUNTY (CAM OF 1) DE)					
4. DESCRIPTION OF RELEVANT BUSIN	ESS ACTIVITY (Print or type)					
c. TITLE		d. E-MAIL ADDRESS				
				rec - musual area coos		
a. NAME (See Instructions)		b. TELEPHONE NUMBER (Primary Co	mpany Number prefer	red - include area code		
d. CAGE CODE (Mandatory for Enterprise) 3. DATA CUSTODIAN		1				
c. NAME OF SUBSIDIARY/DIVISION/DEPARTN	MENT	1				
NAME (Name of Enterprise or Individual)		b. ADORESS (Physical address, includ	ing m.u. box if applica	ioey		
2. ENTERPRISE OR INDIVIDUAL DATA	Referred to as a "certified contr					
TYPE OF SUBMISSION (X one)	a. INITIAL SUBMISSION	b. REVISION	c. 5-YEAR RE			
	BATTLE CREEK, N	MI USA 49037-3084				
	DLA LOGISTICS INF	ORMATION SERVICE ASHINGTON AVE., NORTH				
	U.S./CANADA JOINT O	CERTIFICATION OFFICE				
	TIFICATION FORM OR OTHER	R DOCUMENTATION WHICH VERI	HES THE LEGITIM	ACY OF THE		
BUSINESS LICENSE, SALES TAX IDEN'	MAIL THE ORIGINAL, COMPLETED FORM AND A COPY OF YOUR COMPANY'S INCORPORATION CERTIFICATE, STATE/ PROVINCIAL BUSINESS LICENSE, SALES TAX IDENTIFICATION FORM OR OTHER DOCUMENTATION WHICH YERIFIES THE LEGITIMACY OF THE			PROVINCIAL		
BUSINESS LICENSE, SALES TAX IDEN'	(Please read Agency Disclosure Notice and Instructions on back before completing this form.)		202205	proval expires		
MAIL THE ORIGINAL, COMPLETED FOR BUSINESS LICENSE, SALES TAX IDEN	ency Disclosure Notice and Insi	MILITARILY CRITICAL TECHNICAL DATA AGREEMENT				

https://www.dla.mil/Logistics-Operations/Services/JCP/

The JCP (Joint Certification Program)



- The JCP was created in order to allow DoD/DND to access unclassified export controlled information.
- The JCP reviews and certifies DD2345s.
- It is through the JCP that members fill out and send the DD2345 form.
- On the JCP site there are DD2345 instructions and a search engine to verify if a member has an active DD2345.
- Link to <u>instructions</u>
- Link to JCP <u>search</u>
 - You will need to register before you can login, and instructions on how to register and get a two way authenticator can be found here

JCP Requirements Cont'd



- The JCP is now requiring that members get a SPRS ranking
- The Government has started implementing DFARS 252.204-7019, Notice of NIST SP 800-171 DoD Assessment Requirement, and DFARS 252.204-7020, NIST SP 800-171 DoD Assessment Requirements.
- These clauses require all contractors subject to the implementation of the NIST SP 800-171 standard have a current (completed within the past 3 years) assessment on record in the DoD's Supplier Performance Risk System (SPRS).
- Additional information on these DFARS clauses and SPRS can be found here:
 - DFARS 7019 Resource Summit 7
 - DFARS 7020 Resource Summit 7
 - Supplier Performance Risk System
 - SPRS NIST SP 800-171 Quick Entry Guide

Other Resources



- We're here to help: DIBConsortium@ati.org
 - ATI available to engage via email, phone, or meeting
- DD2345 Certificate Training Page
 - DD2345 Instructions
 - Block 4 examples
 - And several other helpful tools for members who may have questions about the form.

Upcoming Opportunities



- RWP release targeted for Jan. 31 on DIBC website, DIBC listserv, and today's attendees
- ATI will host speed networking event
 - Companies register as presenter or listen-only
 - 3 minutes for interested companies to present and communicate their capabilities and interests in collaborating on a **specific** opportunity
- ATI will coordinate one-on-one industry-to-industry meeting sessions
 - Utilize survey and Meetup tools to streamline setup
- Utilize features of the Members-only site :
 - Collaboration Database: share POCs, collaboration interests, company information, etc.

Speed Networking



- ATI coordinates and hosts this for you
 - Tentatively scheduled for Feb. 6 from 1-3pm ET
- Zoom Meeting- participants register as a presenter or listener
 - Presenters must submit slides by COB day before
 - SLIDES CANNOT CONTAIN CUI
- One presenter per member
- Each presenter has three minutes to go over their slide
- ATI will host and run slides
- After the event, ATI will post slides on the member's only site

Example slide for Speed Networking



Company Profile

About the company

- Contact Name:
- Contact Position
- Contact Email
- Contact Number

Strengths/Capability Highlights

•

Core Capabilities

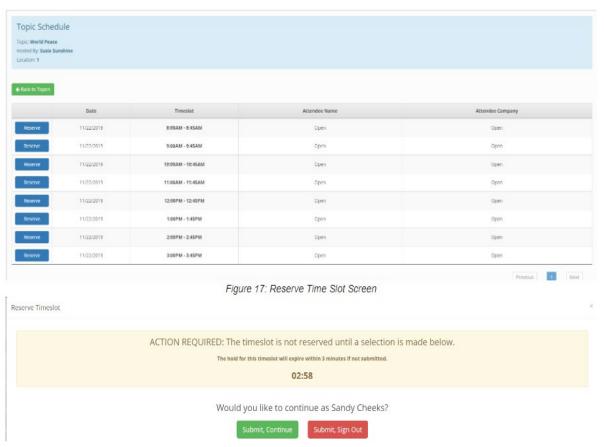
Teaming Interests

•

One-on-One Meetings with Industry

DEFENSE INDUSTRIAL BASE CONSORTIUM

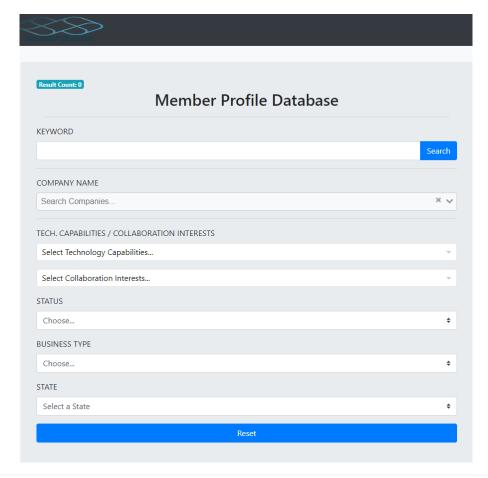
- ATI will send out a survey to see who is interested in <u>hosting</u> sessions
- ATI will coordinate with host to setup time slots in Meetup Tool
- Other DIBC members can then register in Meetup for a one-on-one with that company



Collaboration Database



- A great networking tool
- Access through the DIBC member's only site
 - Step by Step instructions are located on the Member's only Site under New Members
- Search for other DIBC members with similar interests





Process Flows

Project Pathways

- One Step: Full Cost & Technical Proposal
- Two Step: Enhanced White Paper (10-15 pages)
 - Enhanced White Paper
 - If selected, full cost proposal
- Three Step Approach
 - Enhanced White Paper
 - After evaluations, selectees invited to pitch
 - If selected after pitch, full cost proposal



RWP Template



- 1. Introduction
- 2. Enhanced White paper submission and format
- 3. Enhanced White paper submission content
- 4. Evaluation process
- 5. Selection process
- 6. Cost submission process (only if selected)

4.1 White Paper Evaluation

The Government will evaluate the WP to assess each Offeror's understanding of the work and its ability to accomplish the stated tasking and successfully deliver a prototype(s). The White Paper will be assigned pros, cons, and associated risks which will be used to determine award. All Phase I white papers will be evaluated by a team of Government evaluators against the following criteria:

- 1. Does the White Paper present a prototype solution that meets the requirements of the Problem Statement and does the proposed Prototype solution present a technology and/or technological process advancement?
- 2. Does the White Paper present a technology and/or technological process approach that is feasible?
- 3. Does the White Paper provide a ROM and schedule/timeframe that is realistic and feasible?
- Based upon the feedback provided in questions 1-3, please summarize the Pros, Cons, and Associated Risks for this proposal.

4.2 WP Rating

White Papers will be assigned the following ratings:

Rating	Description
Met	The proposed solution is responsive to the technology need in the problem statement, compatible with the DoD environment, provides technology advancement, and is technically possible. The listed Pros outweigh the Cons, and associated risks are low.
Not Met	

Enhanced White Paper Template



Cover Page

Section 1: Technical

SECTION 1: TECHNICAL

Section 1.0: Executive Summary (est. 1 page)

Provide an overview of the company, technology, and capability to be addressed. Summarize items such as: the technical baseline, key efforts to be undertaken, business/market targets, and the risks to be addressed. Identify the long term (~3-5 year) capability goals.

Section 1.1: Background/Problem to be Addressed (est. 2 pages)

This section provides a summary of what problem the proposed business and technology plans address. Cover items such as: organization and past fundraising; material and process (feedstock through DSP); technology ownership; production to-date, process, scale, and metrics; customers and applications; and business and technical gaps.

Section 1.2: Proposed Milestones (est. 1 page)

Provide an overview of key milestones and deliverables, and state: "The total proposed project duration is [insert proposed period of performance in months] months from award." A tabular presentation of this information may be used to provide this information. If selected for award, a Performance Work Statement (PWS) will be negotiated based on these proposed milestones.

Section 1.3: Technical Strategy/Solution and Key Innovations (est. 3 pages)

Provide a brief overview of how the project will approach the problem, and the key capability advancements for which the results of the project will create a foundation. Cover items such as: product form and characteristics; production characteristics; production scale and manufacturing capability; product test and evaluation requirements; infrastructure - capital and operations expense planning; sales, revenue, and profitability planning; operations and infrastructure funding requirements and sources.

Section 1.4 Technical Maturity (est. 2-3 pages)

Provide a summary of the current level of maturity of the technology your project intends to address. Cover items such as: chassis status and technical pathway; organizational business, marketing, technical, and manufacturing expertise; business, market, and technical gaps and risk mitigation/goals;

Section 1.5: Success Metrics (est. 1 page)

Provide the capability improvement <u>metrics</u> that will be developed for the project and how they will be measured. May include items such as: business/financial assessment and planning metrics; marketing assessment metrics; technical design completion metrics; product and/or process capability metrics (for optional tasks).

Section 1.6: Implementation and Transition (est. 1 page)

Provide details of how the business and manufacturing solution proposed will be implemented and product brought to market in military and commercial supply chains and applications.

Section 1.7: Data Rights:

It is anticipated that all technical data and computer software delivered under this proposed effort would be delivered to the Government with Unlimited Rights. If this is not the intent,

Section 2: Participants

SECTION 2: PARTICIPANTS

Section 2.1: Project Team

Provide a brief overview of the project team, and their roles and responsibilities for the project.

Organization	Location	Role	Key Contributions

Section 2.2: Facilities

Provide a brief overview of the facility or facilities that will be used during the project.

Section 3: ROM

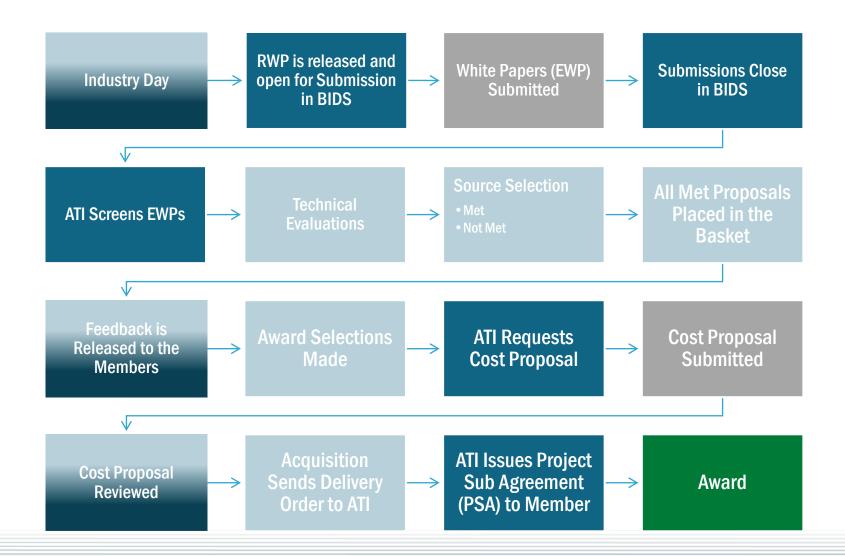
Section 3: ROM

The Offeror must provide a ROM estimate based on the technical approach proposed in the White Paper. The following chart (tailored as appropriate) shall be included in the White Paper.

Objectives	Estimate
Objective 1 – Strategic Business Plan	\$
Objective 2 - Market Planning and Business Development	\$
Objective 3 – Manufacturing Plans – Process and Equipment Design	\$
Objective 4 – Process Evaluation - Business	\$
Objective 5 - Process Evaluation - Technical	\$
Objective 6 - Chassis Improvement and/or Material Sampling	\$
TOTAL	\$

Two Step Process Overview: Enhanced White Papers



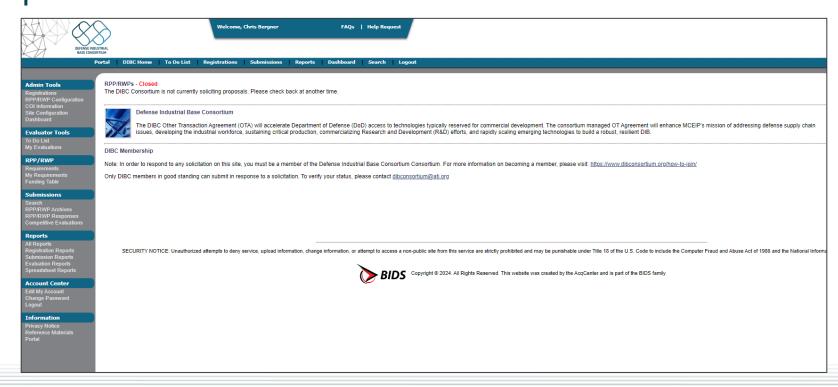


CMO Government Member

BIDS Overview



This BIDS Portal is a customizable tool used to manage the collection of requirements, white paper evaluation, and release white paper feedback.



Summary



- As the CMO, ATI will serve as your primary interface for consortium and contractual matters
- Review membership application process and submit application once all forms are in-hand
- Direct any questions to ATI at: <u>DIBConsortium@ati.org</u>
 - ATI available to engage via email, phone, or meeting



Q&A



Closing Remarks