PROGRAM SOLICITATION OVERVIEW INFORMATION

- **Federal Agency Name** – Defense Advanced Research Projects Agency (DARPA), Biological Technologies Office (BTO)
- **Funding Opportunity Title** – Switch
- **Announcement Type** – Initial Announcement
- **Funding Opportunity Number** – DARPA-PS-24-16
- **Dates – All times are Eastern Time Zone (ET)**
  - Proposers Day: June 7, 2024
  - Posting Date: July 8, 2024
  - Q & A Submission Deadline July 24, 2024, 4:00 PM (ET)
  - Abstracts Due Date and Time: July 31, 2024, 4:00 PM (ET)
  - Oral Proposal Package (OPP) (By Invitation Only from the Government): Estimated August 21, 2024
  - OPP Due Date: Estimated September 11, 2024
  - Oral Presentation (In-Person): Estimated September 16-20, 2024
- The Defense Advanced Research Projects Agency (DARPA) is soliciting innovative proposals to develop biomanufacturing platforms for run-time reprogramming of chemical synthesis operations, which will enable new Concepts of Operations (CONOPS) that provide novel capabilities for national security. Switch is focused on bringing programmability and long-term stability to biomanufacturing processes, with the goal of enabling more flexible chemical manufacturing operations that can toggle between different feedstocks or products over continuous production runs.
- **Multiple awards are anticipated**
- **Total Funding** – Not to Exceed (NTE) $300K per award for Phase 0. DARPA anticipates multiple awards for Phase 1 that are approximately $8M per award.
- **Types of instruments that may be awarded** – Other Transaction (OT) for Prototype Agreements
- **Attachments**
  - Attachment A: Abstract Summary Slide Template
  - Attachment B: Abstract Template
  - Attachment C: Model Other Transaction for Prototype Agreement
  - Attachment D: Cost Spreadsheet Template
  - Attachment E: Schedule of Milestones and Payments
  - Attachment F: Representations and Certifications
  - Attachment G: Switch CUI Guide
- **Agency Contact**

  The Solicitation Coordinator for this effort can be reached at:
  Switch@darpa.mil
  DARPA/BTO
  ATTN: DARPA-PS-24-16
  675 North Randolph Street
  Arlington, VA 22203-2114

PROGRAM SOLICITATION
Defense Advanced Research Projects Agency (DARPA)
Switch

1. PROGRAM INFORMATION

1.1 Background

The goal of the Switch program is to develop a run-time reprogrammable biomanufacturing platform that affords flexible biosynthesis processes, which can toggle between ingest of various organic feedstocks or production of various chemicals, thereby enabling robust, rapidly repurposable manufacturing.

The U.S. Department of Defense (DoD) currently relies on petrochemicals as the source of organic (carbon-containing) molecules for virtually every aspect of operations including energetics, food, pharmaceuticals, textiles, and more. Unfortunately, petrochemicals increasingly depend on foreign supply chains, which are vulnerable to environmental and geopolitical events. Moreover, current petrochemical manufacturing practices cannot readily adapt to make different products, which limits the ability of highly optimized manufacturing workflows to respond to changing market conditions or DoD needs. Although some chemistry-based methods for distributed manufacturing are demonstrably versatile in their capacity to synthesize a wide-array of different products, these methods all rely on organic precursors that are themselves petrochemical derivatives, which means these technologies are still fundamentally tethered to petrochemical supply chains. Given the diversity of useful commodities that are made with petrochemicals, there is dire need for alternative petrochemical-independent production processes that can manufacture these same commodities in an agile, reprogrammable manner.

As the name implies, petrochemicals are derived exclusively from petroleum, and thus, the manufacture of important organic commodities lacks flexibility for accepting different inputs when the petroleum supply is compromised. Alternative emerging technologies, like biomanufacturing, can produce similar organic commodities to petrochemicals, but these technologies are still developed to optimize yield at the cost of flexibility. In general, biomanufacturing approaches are designed to produce a single type of product from a single feedstock input. Given that even non-petroleum feedstock supplies can be disrupted by natural, market, or geopolitical events, flexible processes would enable supply chain resilience and maintain production of important materials by consuming whatever feedstock is available at a given moment in time.

One possible approach to enabling flexible production of organic molecules is to build bespoke production facilities that allow input of different feedstocks or output of different products. However, this strategy requires significant capital expenditures and neglects to take advantage of extant infrastructure, such as the current biomanufacturing capacity for corn-derived ethanol and biopharmaceutical production. To this end, technologies that could be deployed in this existing infrastructure, particularly in a crisis-response scenario, would represent an immediate solution to establishing domestic resilience in chemical supply chains.

Finally, continuous processing is largely recognized as a superior approach to optimize yield compared to batch methods, but biomanufacturing today is almost exclusively practiced as a batch process. A major limiting factor for continuous biomanufacturing processes is the non-stationary nature of biological systems, which evolve over time and are susceptible to selection pressure that favors the propagation of the fittest organisms. As a result, a decrease in yield occurs when

metabolic resources are diverted from producing the desired molecule towards survival and replication. Additionally, contamination is a common challenge. Exogenous microorganisms can be introduced into a bioreactor via feed lines or other sources, and these organisms can outcompete the desired, engineered strain. Thus, technological approaches that increase the long-term stability of continuous biomanufacturing platforms could enable production modes that are better able to compete commercially with petrochemicals outside of a crisis (i.e., in periods of competition versus conflict).

1.2 Program Description

Switch aims to wed the diverse palette of chemical synthesis operations available to biological systems to recently developed engineering tools that enable external control over their expression. Natural biological systems have innate capacity to catabolize different materials they encounter in their environment, and they can use these materials to synthesize an enormous variety of chemical metabolites (10^3 to 10^4 different chemical species per organism). Moreover, natural biological systems can dynamically regulate their metabolism by altering gene expression in response to external chemical or physical signals. For instance, the lactose (*lac*) operon in *E. coli* gates the expression of genes involved in lactose metabolism as a function of ambient lactose concentration. Recent developments in synthetic biology have demonstrated that is possible to engineer novel genetic switches that selectively respond to a variety of chemical and physical signals, and it is also possible to multi-plex these genetic switches together with genetic logic elements that enable external control over the expression of large numbers of individual genes or pathways. Additionally, separate lines of research focusing on recombineering and horizontal/phage-based gene delivery could enable reversible, efficient introduction of gene cassettes into microbial communities. Thus, modern synthetic biology has set the stage for developing biosynthetic platforms that can be reprogrammed during run-time to adjust cellular metabolism – an approach that is antithetical to the historical strategy of optimizing solely for yield without consideration of flexibility. If successful, research on the Switch program will enable the development of flexible and stable biomanufacturing platforms and improve chemical supply chain resilience.

By engineering run-time reprogrammable platforms, Switch aims to enable new CONOPS that provide novel capabilities for national security. Specifically, such a reprogrammable system would enable four CONOPS of interest: (1) "opportunistic consumption" by switching between feedstocks, (2) "need-driven manufacturing" by switching between different products, (3) "co-opting capacity" by temporarily and reversibly adapting existing biomanufacturing platforms, and (4) "long-term stability" for continuous production. Proposals to the Switch program must address how the technical approach aligns to at least one of these CONOPS. Proposers that seek to address more than one of these CONOPS must discuss how a unique innovation in their approach applies to the CONOPS they wish to address, and to this end, proposers are discouraged from attempting to address multiple CONOPS by pursuing distinct technical approaches without a clear plan for integration. Proposals shall not seek to address both "opportunistic consumption" and "need-driven manufacturing".

While it is understood that eventual biomanufacturing systems incorporating Switch technologies may require innovation in upstream and/or downstream processing steps, research on the Switch program emphasizes work towards engineering the biological component of the system. Consequently, proposals should only include tasks associated with hardware and software development that are necessary to implement laboratory-scale design, build, test, learn cycles appropriate for generating run-time reprogrammable microorganisms that are the focus of the

Switch program. Specifically excluded are proposals that will result primarily in evolutionary or incremental improvements to the existing state of practice.

The technical activities of this 36-month program are structured into two phases as shown in Table 1.

Table 1 Phase-specific goals of Switch

Phase (Duration)	Goals
Phase 0 (6 months)	• Generate a technoeconomic analysis (TEA) of the Phase 1 approach and refine the proposed Phase 1 design of benchtop switchable biomanufacturing platform. The TEA should be performed on the proposed Phase 1 endpoint based on the CONOP a proposal is seeking to address (see Table 2). The TEA should be constructed around sufficiently granular sets of assumptions to enable teams to justify their design choices for Switch Phase 1. • Present revised Phase 1 plans, including rationale based in part on the TEA, at a preliminary concept review.
Phase 1 (30 months)	• Develop prototype, benchtop systems for switchable biomanufacturing platforms. • Iteratively refine and update the TEA based on Phase 1 platform development. • Develop and refine notional business strategies for commercial development of switchable biomanufacturing prototypes, including via interactions with finance professionals at program "pitch events" managed by an Independent Commercialization Consulting Group (ICCG; see Section 1.6.2 below).

1.3 Acquisition Strategy and Program Structure

The Government's aim is to lower the administrative burden of entry, reduce program risk, foster competition, and have performing teams get to work quickly. To facilitate these objectives, the Government will use the acquisition process described below. In preparing abstracts and Oral Proposal Packages, proposers are encouraged to use the checklist in Appendix A: Checklist of this document) to ensure their proposal conforms to the guidelines of the Switch solicitation.

i. **Abstracts:** Through this Program Solicitation, the Government requests proposers to submit Abstracts (see Section 3.2) for Phase 0. The Government will review all submitted abstracts for technical comprehension and ability (see Section 3.3). Selected proposers will be invited to provide an Oral Proposal Package and participate in an oral presentation (see Sections 3.4 & 3.5) to the Government.

ii. **Oral Presentations:** Upon the Government's request, proposers will have the opportunity to present their proposal to the DARPA program team. The Government will review all oral presentations (see Section 3.5) and anticipates that selected proposers will be given a Phase

0 award with a 6-month period of performance using an Other Transaction (OT) for Prototype agreement to conduct a technoeconomic analysis (TEA) and refine their proposed technical approach for Phase 1.

i. **Phase 0 (6 months):** Performers will revise their work plan for Phase 1 and perform a TEA to inform these refinements. The revised work plan will be provided to DARPA in a written form (i.e., a Task Description Document, TDD, that may be included in the OT agreement; see Attachment C) as well as in an oral presentation. Phase 0 performers will be provided details regarding the expectations in an invitation to brief their revised Phase 1 plans at the Preliminary Concept Review, including cost estimates. Based on performance in Phase 0, DARPA may or may not select teams for Phase 1 of the program. It is anticipated that only a subset of Phase 0 performers will advance to Phase 1. Switch Phase 0 program execution will include regular collaborative meetings and teleconferences to inform the Switch program team of development status. Predicated on a revised TDD and cost proposal, OT agreements will be modified and agreed upon prior to the initiation of Phase 1.

ii. **Phase 1: (30 months)** This phase will be negotiated using an OT agreement. Performers will execute their technical work plan.

The process and requirements for Abstract and Oral submissions are detailed in Section 3 of this Program Solicitation. Complete descriptions of the Switch program objectives and structure are provided within this Program Solicitation to give proposers as much context as possible to inform Abstract and Oral submissions.

1.4 Program Metrics

Switch is focused on bringing programmability and long-term stability to biomanufacturing processes, so that they can be switched between different feedstocks and products over continuous production runs. To that end, program metrics (Table 2) are generally agnostic to performer-specific approaches. Proposers are encouraged to recommend additional metrics that are specific to their technical approach. Successful efforts on the Switch program will result in a suite of tools and approaches with demonstrable capability to engineer run-time reprogrammable microorganisms at a BioManufacturing Readiness Level (BioMRL[1]) 4, indicating these technologies are at an appropriate level of maturity for continued development needed to scale up. However, proposals should not include planned effort to demonstrate pilot scale-up on the Switch program.

A major risk in biomanufacturing arises when attempting to engineer microorganisms to consume new feedstocks or to make new products. Today, this can take years to accomplish. The Switch program is focused on reprogrammability, which will not be demonstrated by consuming or producing novel feedstocks or molecules that lack evidence of tractability in biomanufacturing systems. As such, efforts on Switch will be limited to using feedstocks and products that have been

[1] Smanski, M. J., Aristidou, A., Carruth, R., Erickson, J., Gordon, M., Kedia, S. B., ... & Tomczak, M. (2022). Bioindustrial manufacturing readiness levels (BioMRLs) as a shared framework for measuring and communicating the maturity of bioproduct manufacturing processes. Journal of Industrial Microbiology and Biotechnology, 49(5), kuac022. https://academic.oup.com/jimb/article/49/5/kuac022/6712705

previously demonstrated as productive systems. Choices of individual feedstocks and individual products which have each already achieved BioMRL 8-10 will be considered low-risk and are preferred starting points for the development of reprogrammable biomanufacturing systems. Feedstocks and products which have already achieved BioMRL 4-7 will be considered high-risk starting points for reprogrammable systems but are still within the program description for Switch. For the "co-opting capacity" CONOP, proposals should be anchored on engineering a commonly used industrial strain at the BioMRL 8-10 level that will be engineered to co-opt a commodity feedstock. Proposals must include justification of feedstocks or products of choice, including estimated BioMRL levels for each. Additionally, to establish baseline levels of production in their own laboratories, proposers must articulate plans to quantify titer (g/L) and rate (g/L/h) for each of the BioMRL 4-10 feedstocks, strains, and/or products they intend to use for starting points and/or experimental controls in developing switchable biomanufacturing platforms.

A second major risk in biomanufacturing arises from challenges related to downstream processing, which ultimately is needed to purify a chemical product out of culture and assess the overall yield (g/g) of the process. To mitigate that risk, downstream processing will not be within the program description for Switch, and instead the program will focus on in-line measurements of titer and rate to assess productivity of a given system.

Switch is an unclassified fundamental research program. DARPA is not interested in chemicals that are listed on the US Munitions List (https://www.ecfr.gov/current/title-22/chapter-I/subchapter-M/part-121) or the Commerce Control List (CCL) https://www.bis.doc.gov/index.php/regulations/export-administration-regulations-ear. If any proposal selected includes the manufacturing or use of a chemical that is controlled in either the U.S. Munitions list or the CCL or considered Controlled Technical Information (CTI) those chemicals will be replaced with alternatives during contract negotiations. If you are unsure if the chemical is listed on the CCL or US Munitions List, work with your export control team, and reach out to the Bureau of Industry and Security at the U.S. Department of Commerce or BTO_Security@darpa.mil to obtain guidance.

Switch program metrics are listed in Table 2. The programmability metric will preserve baseline levels of production while introducing the ability to switch between different feedstocks or different products. A single combination of feedstock and product will comprise one "pathway," and the goal of Switch is to enable programmability between at least 16 pathways. This could consist of switching between different feedstocks (e.g., 16 feedstocks and 1 product) or different products (e.g., 1 feedstock and 16 products). Of note, proposals that seek to develop purely omnivorous platforms for "opportunistic consumption" that lack switchable control over genes responsible for the metabolism of distinct feedstocks will be deemed non-conforming and not considered for review. Similarly, proposals that aim only to valorize multiple products for "need-driven manufacturing" without controllable production will be deemed non-conforming. Lastly, proposals focusing on "co-opting capacity" will be deemed non-conforming if they do not identify an approach that can be reversed to the original industrial process. Proposals to Switch are not constrained to strategies focused on engineering cellular monocultures, and other strategies for engineering switchable biomanufacturing into microorganisms will be considered.

The stability metric will also preserve baseline levels of production while introducing the ability to maintain continuous production for longer durations. Genetic drift and microbial contamination are currently major contributors to stability issues in continuous fermentation processes. The stability metric for success will preserve titer and rate while increasing the duration of a continuous

run by 10-fold. Proposals focusing on the "long-term stability" CONOP must describe experimental approaches to test both stability against genetic drift and against microbial contamination, but these can be distinct experimental approaches. Proposals should also consider incorporating additional experimental strategies for demonstrating stability in the face of other mechanisms besides genetic drift and contamination.

Table 2 Switch Program Metrics

CONOP	Metric	Program Goal
Opportunistic consumption, need-driven manufacturing, and co-opting capacity	Programmability	≥16 pathways*
Long-term stability	Stability	10-fold longer duration*
*while maintaining product titer or rate equivalent to state-of-the-art batch process		

A visual presentation of the program timeline, milestones, and metrics is presented in Figure 1.

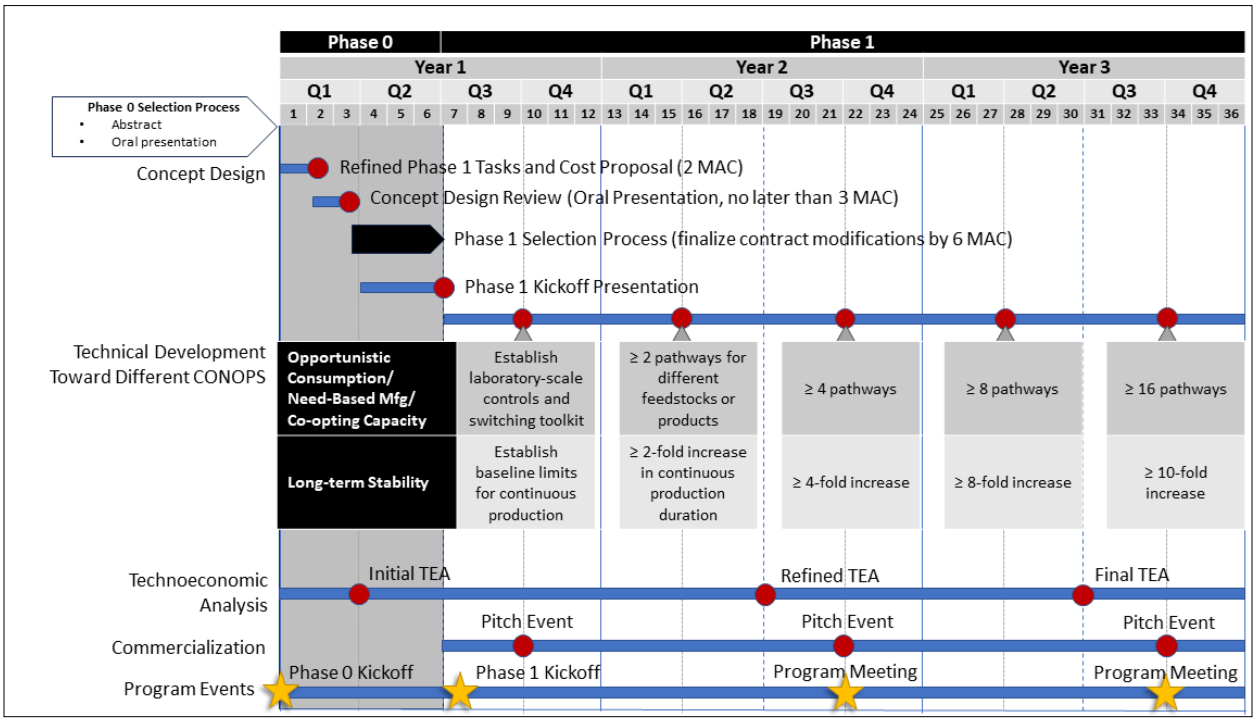

Figure 1 Switch - Program execution timeline and metrics

1.5 Program Tasks and Deliverables

A detailed breakdown of tasks, deliverables and reporting requirements are presented in Table 3. In addition to the Milestones listed below, performers will be expected to provide monthly status updates to DARPA, including technical and financial summary reports.

Table 3 Switch Milestones and Deliverables

	Month	Milestones	Deliverables
Phase 0 (6 mo.)	1	Phase 0 Kickoff	Slides summarizing initial Phase 1 plan as well as project plan for Phase 0.
	2	There is No Milestone Associated with this Deliverable	Revised Phase 1 TDD for pursuing one primary CONOP; Cost Proposal for Phase 1; Slides for revised Phase 1 plan including details for all experimental components such as feedstocks, products, strains, switching systems, bioreactor hardware, expected titers/rates, timeline for development, expected costs for Phase 1, potential risks and mitigation strategies, and transition plan for commercialization.
	3	Preliminary Concept Review	Review TDD and Cost Proposal with DARPA, including initial Technoeconomic Analysis (TEA); Note: favorable concept review is not predicated on favorable TEA results, but concept review will consider the rigor with which the TEA framework was constructed including its suitability for adaptation in Phase 1.
	6	For performers selected to advance for Phase 1, all agreements and subagreements required for Phase 1 work are fully executed	All performers: Phase 0 final report. For performers selected to advance to Phase 1, briefing slides for Phase 1 Kickoff.
Phase 1 (30 mo.)	7	Phase 1 Kickoff Meeting	Kickoff presentation of detailed technical plan, including control experiments and preliminary data generated in Phase 0
	9	Technical Milestone #1	Technical report on reprogrammability and stability, focused on performer-specific CONOPs. CONOPs: Opportunistic consumption, Need-based manufacturing, or Co-opting capacity. Report describing experimental design, apparatuses, control strains/pathways/conditions, and statistical methods for data analysis regarding test and assessment for systems that can switch between multiple (up to 16) pathways at run-time.

[redacted]			CONOP: Long-term stability. Report describing experimental design, apparatuses, control strains/pathways/conditions, and statistical methods for data analysis regarding test and assessment for maintaining the stability of continuous biomanufacturing systems using run-time reprogramming approaches.
		Pitch Event	Present a business hypothesis for how a particular system for switchable biomanufacturing could be commercialized, either by venture creation or integration into an existing business; identify a value proposition for switchable biomanufacturing that addresses a market need.
	15	Technical Milestone #2	Technical report on reprogrammability and long-term stability, focused on performer-specific CONOPs. CONOP: Opportunistic consumption. Reprogrammability is demonstrated by switching between at least two (2) pathways to consume at least two (2) different feedstocks for the production of a chemical product at baseline titer/rate. CONOP: Need-based manufacturing. Reprogrammability is demonstrated by switching between at least two (2) different pathways to produce at least two (2) different chemical products at baseline titer/rate. CONOP: Co-opting capacity. Reprogrammability is demonstrated by ability to successfully insert, delete, edit, or switch the genetic information of a commonly used industrial strain so that it can temporarily be used to create at least two (2) different chemical products at baseline titer/rate, and then return to the original process. CONOP: Long-term stability. Continuous fermentation is demonstrated for at least twice (2x) the duration of the state-of-the-art.
	21	Program-Wide Meeting	Slides: technical presentation on reprogrammability and stability, focused on performer-specific CONOPs.

[redacted]		Revised TEA	Refined TEA, specifically evaluating the manner in which unit operations for switchable biological systems relates to volatile market conditions and vulnerable supply chains
		Technical Milestone #3	Technical report on reprogrammability and stability, focused on performer-specific CONOPs. CONOP: Opportunistic consumption. Reprogrammability is demonstrated by switching between at least four (4) pathways to consume at least four (4) different feedstocks and make one chemical product at baseline titer/rate. CONOP: Need-based manufacturing. Reprogrammability is demonstrated by switching between at least four (4) different pathways to produce at least four (4) different chemical products at baseline titer/rate. CONOP: Co-opting capacity. Reprogrammability is demonstrated by ability to successfully insert, delete, edit, or switch the genetic information of a commonly used industrial strain so that it can temporarily be used to create at least four (4) different chemical products at baseline titer/rate, and then return to the original industrial process. CONOP: Long-term stability. Continuous fermentation is demonstrated for at least four times (4x) the duration of the state-of-the-art.
		Pitch Event	Present refined business hypothesis and value proposition for switchable biomanufacturing systems, including target market sizing and segmentation, possibilities for a minimum viable product, analysis of alternative approaches, and evaluation of partnership needs for advanced technology development.
	27	Technical Milestone #4	Technical report on reprogrammability and stability, focused on performer-specific CONOPs.

[redacted]			CONOP: Opportunistic consumption. Reprogrammability is demonstrated by switching between at least eight (8) pathways to consume at least eight (8) different feedstocks and make one chemical product at baseline titer/rate. CONOP: Need-based manufacturing. Reprogrammability is demonstrated by switching between at least eight (8) different pathways to produce at least eight (8) different chemical products at baseline titer/rate. CONOP: Co-opting capacity. Reprogrammability is demonstrated by ability to successfully insert, delete, edit, or switch the genetic information of a commonly used industrial strain so that it can temporarily be used to create at least eight (8) different chemical products at baseline titer/rate, and then return to the original industrial process. CONOP: Long-term stability. Continuous fermentation is demonstrated for at least eight times (8x) the duration of the state-of-the-art.
	33	Program Meeting	Slides - Technical presentation on performer specific CONOPs. Presentation clearly defines possibilities for advanced technology development including scale-up compatibility with upstream/downstream processing modules, possible integration of multiple CONOPs, and mobile systems to facilitate distributed or pre-placed functionality.
		Final TEA	Final TEA, including identification of exemplar conditions under which a performer's technology could provide an economic advantage over existing approaches.
		Technical Milestone #5	Technical report on reprogrammability and stability, focused on performer-specific CONOPs.

[redacted]			CONOP: Opportunistic consumption. Reprogrammability is demonstrated by switching between at least sixteen (16) pathways to consume at least sixteen (16) different feedstocks and make one chemical product at baseline titer/rate. CONOP: Need-based manufacturing. Reprogrammability is demonstrated by switching between at least sixteen (16) different pathways to produce at least sixteen (16) different chemical products at baseline titer/rate. CONOP: Co-opting capacity. Reprogrammability is demonstrated by ability to successfully insert, delete, edit, or switch the genetic information of a commonly used industrial strain so that it can temporarily be used to create at least sixteen (16) different chemical products at meaningful titer/rate, and then return to making the original industrial product. CONOP: Long-term stability. Continuous fermentation is demonstrated for at least ten times (10x) the duration of the state-of-the-art.
		Pitch Event	Polished pitch to potential investors, incorporating comprehensive feedback from the ICCG as well as a realistic forecast for technology transition and future funding strategy.
	36		Final Report. Content will include (but is not limited to) a detailed and comprehensive summary of approach to CONOP(s), data from all relevant milestones and metrics, limitations of technical solutions, and potential future directions.

1.6 Advisory and Working Groups

Switch will include both Independent Verification and Validation (IV&V) and an Independent Commercialization Consulting Group (ICCG) that will act as part of the government team. DARPA will establish the government team, and this solicitation is not seeking proposals for the Switch government team. Any proposals received in response to this solicitation that are seeking to participate on the Switch government team will be deemed non-conforming and will not be considered for review. Over the course of the Switch program, performers will be afforded the opportunity to interact with both the IV&V and ICCG.

1.6.1 Independent Verification and Validation (IV&V)

Proposing teams should plan to interact with the IV&V team over the course of the Switch program. This team will be composed of researchers with relevant expertise in synthetic biology and biomanufacturing from government US Government laboratories. Switch performers will engage with IV&V to consult on experimental design and relevant controls, in addition to TEA assumptions, calculations, and reporting. The interaction with IV&V, including early consideration of TEA results, is envisioned to de-risk and inform eventual transition pathways for industrial biomanufacturing. Additionally, IV&V will replicate key aspects of successful technologies, as possible, at laboratory scale. Consequently, proposals must plan for any required agreements needed to share background intellectual property (IP) with government IV&V partners that could be required for replication studies. These agreements should be appropriate for the proposed technology and replication studies, and they may necessitate material transfer agreements, data sharing agreements, contract research and development agreements (CRADAs), or other such agreements. DARPA is not responsible for negotiating these agreements because these terms must be agreed upon between the two parties exchanging information and/or materials (i.e., the IV&V partner and the contracted performer on Switch). Any foreground IP generated on Switch will be provided with Government Purpose Rights (GPR; see Sections 3.4, 3.5, and 4.5 as well as terms and conditions in the model Other Transaction for Prototype Agreement, Attachment C), and as such, this information will be shared with members of the government team, as necessary, for them to support the program.

1.6.2 Independent Commercialization and Consulting Group (ICCG)

Proposing teams should also plan to interact with the ICCG, which will be led by a contracted third-party to perform research and disseminate results on markets, business cases, and finance pathways required to support commercial/industrial transition of technologies developed on the Switch program. The ICCG will coordinate periodic "pitch events" where Switch performers brief professionals in finance on their technical progress and how that progress supports a notional business case. In turn, the ICCG members will provide feedback to Switch performers on refinements to their strategy and pitch that are predicated on their knowledge of market trends and opportunities. Switch proposals should include plans to attend and prepare for these "pitch events", including establishing any necessary agreements with the ICCG (e.g., non-disclosure agreements; NDAs) in advance of "pitch events". Again, while foreground IP generated on the Switch program will be provided with GPR, proposers should plan to establish necessary agreements with ICCG members if it is necessary to discuss background data with them. Proposals must include milestones relevant to establishing these agreements to allow for transparent discussions with the ICCG at all "pitch events". DARPA is not responsible for negotiating these agreements because these terms must be agreed upon between the two parties exchanging information; however, DARPA will facilitate introductions between entities that will be present at these events.

1.6.3 Ethical, Legal, and Societal Implications (ELSI) Group

An ELSI group will be formed to discuss Switch-specific topics throughout the course of this program. A proactive strategy to contemplate the implications of Switch will inform the government, academic, and industry teams on the potential ethical, legal, and societal issues of the program's technology. During programmatic events the DARPA team will convene discussions to consider how Switch technology could alter current paradigms of petrochemical manufacturing and biomanufacturing with respect to real-time reprogramming of chemical synthesis operations.

ELSI activities will be tracked in a working document, such as planned ELSI activities relative to program timelines and events, documenting relevant areas of expertise for program ELSI, and capturing outcomes of ELSI engagements. It is DARPA's intention to be fully compliant with the Biological Weapons Convention, the Treaty on Biological Diversity, and all applicable US statutory law governing biological weapons (e.g., 18 U.S.C. Chapter 10).

ELSI objectives may include:

- Identifying key non-technical limitations (e.g., public perception, political concerns) which could hinder adoption of Switch.
- Considering strategies for addressing biocontainment, biosafety, and biosecurity.
- Planning an ELSI consult to revisit and revise the ELSI Plan when evaluating whether to pursue expansion.

2 PROGRAM SOLICITATION AUTHORITY

This Program Solicitation may result in the award of Other Transaction (OT) for Prototype agreements, which can include not only commercially available technologies fueled by commercial or strategic investment, but also concept demonstrations, pilots, and agile development activities that can incrementally improve commercial technologies, existing Government-owned capabilities, and/or concepts for broad defense and/or public application(s). The Government reserves the right to award an OT for Prototype agreement under 10 U.S.C. § 4022, make multiple OT awards, or make no award at all. Follow-on production contracts or transactions may also be awarded pursuant to 10 U.S.C. § 4022. In all cases, the Government Agreements Officer shall have sole discretion to negotiate all agreement terms and conditions with selected proposers. The OT agreement will not require cost sharing unless the proposer is a traditional defense contractor who is not working with a nontraditional defense contractor participating in the program to a significant extent.

2.1 Program Solicitation Procedure

DARPA will use the following process to facilitate the Switch solicitation procedures:

2.1.1 Proposers Day (Proposer Attendance/Participation Optional)

The Program Manager held a Proposers Day where he briefly described the program and its goals and solicited questions from the audience in real time. Where possible, the Government provided answers in real time, and a comprehensive list of questions and answers will be provided via a Questions and Answers (Q & A) document (see Section 2.1.2). Participation in the Proposers Day was not a requirement for proposers seeking to submit an abstract.

2.1.2 Questions and Answers (Q&As)

DARPA hosted a Questions and Answers (Q&As) session during the Switch Proposers Day and will post a consolidated Questions and Answers (Q&As) document. The Q&A document will be available online at http://www.darpa.mil/work-with-us/opportunities. Questions can be sent to Switch@darpa.mil. DARPA will respond to any relevant and/or PS clarification question(s) prior to the final abstract due date and update consolidated Q&As at the DARPA Opportunities page.

2.1.3 Abstracts (Required)

In response to this Program Solicitation, proposers are asked to submit a 10.5-page abstract as described in Section 3.2. This process allows DARPA to ascertain (1) whether the proposers understand the key challenges of the Switch program and (2) whether they can execute a proposed concept. Specific evaluation criteria used to make the assessment can be found in Section 3.3.

If DARPA finds that both of these conditions are met, it may request that the proposer provide DARPA with an oral presentation of their technical solution, as described in Section 3.4. These oral presentations will allow DARPA to further evaluate the proposed technical solution. Specific evaluation criteria used to make the assessment of oral presentations can be found in Section 3.5. After the oral presentations, DARPA will determine which proposers may participate in the program. The Government will not pay proposers responding to this Program Solicitation for the costs associated with abstract submissions or oral presentations. Abstracts shall be submitted as specified in Section 3.2 of this Program Solicitation. The Government will evaluate abstracts against the criteria stated in this Program Solicitation. It is important to note that proposers must submit an Abstract in response to this Program Solicitation to be considered for participation in the Switch program.

For Phase 0, proposers must only propose an OT for Prototype with fixed payable milestones. (Note – Milestones represent a completed event. Milestone schedule is based on key observable events in the critical path to accomplish program objectives. Payments are triggered by successful performance of observable technical events. Fixed payable milestones are payments based on successful completion of the milestone accomplishments agreed to in the milestone plan. A Schedule of Milestones and Payments is included as Attachment E.)

2.1.4 Awards

DARPA will review Oral Proposal Packages to determine which proposed solutions sufficiently meet the evaluation criteria stated in Sections 3.4 & 3.5. Upon favorable review, and subject to the availability of funds, the Government may award an OT for Prototypes pursuant to 10 U.S.C. § 4022. Phase 0 will be a 6-month period of performance with fixed, payable milestones and Phase 1 will be a 30-month period of performance with fixed, payable milestones.

2.2 Eligibility Information

2.2.1 Federally Funded Research and Development Centers (FFRDCs) and Government Entities (FFRDCs)

FFRDCs are subject to applicable direct competition limitations and cannot propose to this PS in any capacity unless they meet the following conditions: (1) FFRDCs must clearly demonstrate, with specific details, that the proposed work, expertise, and facilities are not otherwise available from the private sector, and (2) FFRDCs must provide a letter on official letterhead from their sponsoring organization citing the specific authority establishing their eligibility to propose to Government solicitations and compete with industry, and their compliance with the associated FFRDC sponsor agreement's terms and conditions. This information is required for FFRDCs proposing to be awardees or subawardees. FFRDC proposals that do not include these elements may be deemed non-conforming and removed from consideration.

FFRDCs proposing as prime awardees must be able to accept an OT for Prototype agreement as the award instrument. FFRDCs that can only be funded through their existing sponsor contracts should not submit an abstract directly to this PS.

2.2.2 Government Entities

Government Entities (e.g., Government/National laboratories, military educational institutions, etc.) are subject to applicable direct competition limitations. Government entities must clearly demonstrate that the work is not otherwise available from the private sector and provide written documentation citing the specific statutory authority and contractual authority, if relevant, establishing their ability to propose to Government solicitations, and compete with industry. This information is required for Government Entities invited to submit OPPs as either awardees or subawardees.

Government Entities submitting abstracts as prime awardees must be able to accept an OT for Prototype agreement as the award instrument. Government Entities that can only be funded through their existing sponsor contracts should not submit abstracts directly to this PS.

2.2.3 Authority and Eligibility

At the present time, DARPA does not consider 15 U.S.C. § 3710a to be sufficient legal authority to show eligibility. While 10 U.S.C. § 4892 (formerly 10 U.S.C. § 2539b) may be the appropriate statutory starting point for some entities, specific supporting regulatory guidance, together with evidence of agency approval, will still be required to fully establish eligibility. DARPA will consider FFRDC and Government entity eligibility submissions on a case-by-case basis; however, the burden to prove eligibility for all team members rests solely with the proposer.

2.2.4 Other Applicants

Non-U.S. organizations and/or individuals may participate to the extent that such participants comply with any necessary nondisclosure agreements, security regulations, export control laws, and other governing statutes applicable under the circumstances.

2.2.5 Organizational Conflicts of Interest (OCI)

Without prior approval or a waiver from the DARPA Deputy Director, a contractor cannot simultaneously provide scientific, engineering, technical assistance (SETA), advisory and assistance services (A&AS), or similar support and also be a technical performer. As part of the OPP, all members of the proposed team (including any potential subawardees or consultants) must affirm whether they (their organizations and individual team members) are providing SETA or similar support to any DARPA office(s) through an active award or subaward. All facts relevant to the existence or potential existence of Organizational Conflicts of Interest (OCI) must be disclosed in the Title Page of the Oral Proposal Package (see Section 3.4), should the proposer be invited to submit an OPP.

If SETA, A&AS, or similar support is being or was provided to any DARPA office(s), the OPP must include a disclosure in the Title Page of the Oral Proposal Package (see Section 3.4):

- The name of the DARPA office receiving the support;
- The prime contract number;

• Identification of proposed team member (subawardee, consultant) providing the support; and

• An OCI mitigation plan.

Under this section of the OPP, the proposer is responsible for providing this disclosure with each OPP submitted. The disclosure must include the proposer's, and as applicable, proposed team member's OCI mitigation plan. The OCI mitigation plan must include a description of the actions the proposer has taken, or intends to take, to avoid, neutralize, or mitigate such conflict, prevent the existence of conflicting roles that might bias the proposer's judgment, and prevent the proposer from having unfair competitive advantage. Prior to the start of OPP evaluations, the Government will assess potential conflicts of interest based on the OPPs submitted. DARPA will promptly notify the proposer if any appear to exist. The Government assessment does NOT affect, offset, or mitigate the proposer's responsibility to give full notice and planned mitigation for all potential organizational conflicts.

If, in the sole opinion of the Government after full consideration of the circumstances, a proposal fails to fully disclose potential conflicts of interest and/or any identified conflict situation cannot be effectively mitigated, the OPP will be rejected without technical evaluation and withdrawn from further consideration for award.

If a prospective proposer believes a conflict of interest exists or may exist (whether organizational or otherwise) or has questions on what constitutes a conflict of interest, the proposer should send his/her contact information and a summary of the potential conflict via the specific email address identified in this PS before time and effort are expended in preparing an OPP and mitigation plan.

3 GUIDELINES FOR ABSTRACTS AND ORAL PROPOSAL PACKAGES

3.1 General Guidelines

a. Do not include elaborate brochures or marketing materials; only include information relevant to the submission requirements or evaluation criteria.

b. Use of a diagram(s) or figure(s) to depict the essence of the proposed solution is permitted.

c. All abstracts and Oral Proposal Packages shall be unclassified.

d. Proposers are responsible for clearly identifying proprietary information. Submissions containing proprietary information must have the cover page and each page containing such information clearly marked with a label such as "Proprietary" or "Company Proprietary." NOTE: "Confidential" is a classification marking used to control the dissemination of U.S. Government National Security Information as dictated in Executive Order 13526 and should not be used to identify proprietary business information.

e. Questions regarding abstracts can be sent to Switch@darpa.mil by July 24, 2024 at 4:00 PM (ET).

f. Submit Abstracts to Switch@darpa.mil by July 31, 2024, 4:00 PM (ET).

g. Submissions sent through other mediums, channels, or after the prescribed Program

Solicitation deadline will not be considered, reviewed, or evaluated.

h. Proposers providing Abstracts that are not invited to an oral presentation will be notified in writing as soon as practical.

i. Abstracts and oral presentations should inherently address all of the Heilmeier questions as described here: https://www.darpa.mil/work-with-us/heilmeier-catechism

j. Proposers are encouraged to review "Appendix A: Checklist" to ensure their proposal conforms to the Switch solicitation.

3.2 Abstract Content

a. Abstracts should not exceed ten and one-half (10.5) single-sided written pages using 12-point Times New Roman font with 1" margins all around. Abstracts that do not conform to these requirements may not be evaluated.

b. Abstracts must include the following components, identified with the section headings as shown in Table 4:

Table 4 Abstract Content

Section Headings	Required Content
Abstract Summary Slide	See Attachment A: Abstract Summary Slide template.
Title Page (Excluded from 10.5-page limit)	See Attachment B: Abstract Template Proposer Name Title Date E-Mail Addresses Phone Numbers, and Addresses for Technical Point of Contact and Administrative Point of Contact. The proposer should include a statement that no persons on the proposer's team work for DARPA as Scientific Engineering Technical Assistance (SETA), Advisory and Assistance Services (A&AS), or similar support services, as DARPA has a policy prohibiting such individuals/organizations from working as a technical performer.
Executive Summary	Provide a summary of your technical approach and execution strategy to address the goals of their proposal to Switch program. The goal is for the proposer to demonstrate clear understanding of this program's purpose and goals. This summary shall be specific to the proposer's own technical approach and not simply restate the program goals listed in this Program Solicitation. The summary should also include a

(No more than 1 page and is counted towards the 10.5-page limit)	statement of anticipated rough order-of-magnitude (ROM) costs for Phase 1.
Proposed Approach (No more than 6 pages and is counted towards the 10.5-page limit)	Provide a summary of the following: • Your technical vision to achieve the goals of this program • Approach during Phase 0/Plan for refinement of Phase 1 tasks • Overall approach to meet the goals and milestones of Phase 1 • Outlines specific tasks to meet the milestones of Phase 1 • Presentation of, not just reference to, unpublished data that establishes technical feasibility of Phase 1 work
Technology Challenges (No longer than 2 pages and counted towards the 10.5-page limit)	This section should identify specific technical challenges associated with the proposed approach. The proposer should include what they think the primary risks are to successful development in the Switch program and the envisioned mitigations for those risks.
Technical Expertise (No more than 1 page and is counted towards the 10.5-page limit)	Detail why the proposer believes their team has the ability to be successful at achieving program goals, if selected to participate in Switch. The proposer may include past experience, organizational capabilities, team members' qualifications, or anything else that demonstrates competence in designing and building run-time reprogrammable biomanufacturing platforms.
Phase 0 Budget Estimation Table (BET) (No more than 0.5 page table and is counted towards the 10.5-page limit)	See 'PHASE 0 BET' tab in Attachment D for the table to be completed. All applicable cost categories in the table need to be estimated. Total cost must not exceed $300k.
References (References are not included in the 10.5-page limit)	Provide a list of citations, references, or end notes. The reference list must include 1-2 sentences per citation regarding the relevance of the cited reference for the proposal. Proposers should also annotate their perception of the relative importance of cited research for the proposed work (***critical; **important; *informative)

3.3 Abstracts – Process and Basis of Evaluation

Abstract evaluation criteria are listed in Table 5 below in descending order of importance. Individual abstracts will be evaluated by DARPA using the evaluation criteria listed below and not against other Abstracts submitted in response to this Program Solicitation. DARPA will respond to the 10.5-page Abstract with a statement as to whether DARPA requests submission of an Oral Proposal Package. If DARPA is not interested in obtaining an Oral Proposal Package, it will state this in a communication to the proposer. Upon review of Abstracts, the Government may elect to invite all, some, or none of the proposers to submit Oral Proposal Package Content. *Only abstract proposers invited by DARPA to participate in the oral presentations are eligible to provide one.*

Table 5 Review Criteria for Proposal Abstracts

Evaluation Criteria	Required Content
Technical Comprehension	The proposed technical understanding accurately reflects Switch goals, and key technical challenges and risks are identified.
Technical Ability	The proposer's team and organization are capable of developing run-time reprogrammable biomanufacturing platforms, and the proposers convey a plausible strategy to design, build, test, and refine such a platform.
Past Performance	The proposers demonstrate an ability, if selected, to achieve the goals of the Switch program. Of particular interest and aspects to consider including would be, but are not limited to, highlighting key personnel who will work on the program, providing examples of past performance or projects in this technical domain, and demonstrating capability to develop industrial cell lines or strains of microorganisms for biomanufacturing.

3.4 Oral Proposal Package (OPP)

If DARPA expresses interest in an oral presentation, the proposers will be asked to provide further details on their proposed solution. Specific instructions for the Oral Proposal Package (including content submission guidelines), in addition to oral presentation details, will be provided in the invitation letter. Oral Proposal Packages must include:

a. **Title Page**: Proposer Name, Title, Date, Point of Contact (POC) Name, E-Mail Address, Phone, and Address. (The title page does not need to be briefed). The title page must also include the following:

- A statement that no people on the proposer's team work for DARPA as SETA, A&AS, or similar support services on an active contract or subcontract (including those awarded through DARPA agents); or list which offices the proposer supports and identify the prime contract numbers. DARPA policy prohibits support contractor individuals and entities from concurrently working as research and development performers, unless potential organizational conflicts of interest are identified, eliminated, or appropriately mitigated, and granted a waiver.

- A statement that identifies and substantiates which of the following condition(s) are met to permit use of OTs for Prototypes in accordance with 10 U.S.C. § 4022(d)(1): (A) There is at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the prototype project; (B) All significant participants in the transaction other than the Federal Government are small businesses (15 U.S.C. § 638) or nontraditional defense contractors; (C) At least one third of the total cost of the prototype project is to be paid out of funds provided by sources other than the Federal Government; or (D) The senior procurement executive for the agency determines in writing that exceptional circumstances justify the use of a transaction that provides for innovative business arrangements or structures that would not be feasible or appropriate under a contract, or would provide an opportunity to expand the defense supply base in a manner that would not be practical or feasible under a contract.

b. Oral Presentation

Refer to the information in Table 6. This table will also be provided in the invitation letter. Please note, these oral presentations will be in-person only at a location to be determined. No virtual presentations will be allowed.

Table 6 Oral Presentation – Expected Details

Requirement	Description
Duration	60 minutes (45 minutes for presentation, 15 minutes for questions)
Executive Summary	• 8 slides (recommended); 15 slides (max) • Technical approach overview • Facilities and personnel qualification
Oral Presentation	• 25 slides (recommended); 30 slides (max) • Detailed Switch technical approach (no animations) • Detailed risks and mitigation plan • Description of facilities available to execute proposed work • Budget estimation table for Phase 1 ('PHASE 1 BET' tab in Attachment D) • Teaming/subcontractors, including plans for establishing agreements and/or subcontracts during Phase 0 that are germane to program execution in Phase 1 • Data Rights and Intellectual Property; between the government and the proposing team, and within the proposing team

	• Notional commercialization strategy: business model canvas (1 slide; template will be provided to teams selected for oral presentations)
Accompanying Materials	• Complete draft OT agreement with a task description document (TDD) filled in for Phase 0 (see Attachment C) • Detailed cost spreadsheet for Phase 0, not to exceed $300K (see Attachment D) • Schedule of Milestones and Payments (see Attachment E) • Completed Representations and Certifications (see Attachment F)

In addition to the above-required areas, the Government may request the proposer provide clarifying information in addition to the Oral Proposal Package. Submission instructions, due date for submitting the Oral Proposal Package, date and time of Oral Presentation will be provided with the invitation. Any questions asked by proposers must be submitted to Switch@darpa.mil.

c. **Model OT for Prototype Agreement (Attachment C):** Proposers must complete and submit the Model Prototype Other Transaction (OT) provided as Attachment C as part of the Oral Proposal Package. DARPA has provided the model OT in order to expedite the negotiation and award process.

   The Model Prototype Other Transaction (OT) is representative of the terms and conditions that DARPA intends to award for Switch includes the following eight (8) attachments:

   - Attachment 1: Task Description Document (TDD)
   - Attachment 2: Report Requirements
   - Attachment 3: Wide Area Work Flow (WAWF) Instructions
   - Attachment 4: Definitions
   - Attachment 5: Agreement Administration
   - Attachment 6: Agreements Officer's Representative Appointment Memo
   - Attachment 7: Equipment and Property
   - Attachment 8: Performer Attestation

It is expected that the effort will leverage all available relevant prior research in order to obtain the maximum benefit from the available funding. For proposals that contain cost share, the proposer should provide sufficient rationale as to the appropriateness of the cost share arrangement relative to the objectives of the proposed solution (e.g. high likelihood of commercial application, etc.).

Proposers may suggest edits to the model OT for consideration by DARPA and provide a copy of the model OT with tracked changes as part of their proposal package. Please note that suggested edits may not be accepted by DARPA. Prior to the start of Phase 0, the Government reserves the right to remove a proposal from award consideration should

the parties fail to reach agreement on OT award terms and conditions. If edits to the model OT are not provided as part of the proposal package, DARPA assumes that the proposer has reviewed and accepted the award terms and conditions to which they may have to adhere and the sample OT agreement provided as an attachment, indicating agreement (in principle) with the listed terms and conditions applicable to the specific award instrument. DARPA explicitly reserves the right to terminate awards if negotiations are not completed in a timely manner.

d. **Determination of Process Improvements, Creating Value via OT for Prototype Agreement Vehicle**: Proposers are required to provide answers to all of the following questions as part of the Oral Presentation Package (Please note some these answers will be presented during the oral presentation and will be reviewed whether presented or not. Further, the answers to the questions are not subject to any oral presentation evaluation criteria). Questions to be answered are as follows:

    1. Please provide your understanding of current technology in this space, and how it has informed or influenced your proposed technical solution.
    2. How does your proposed solution deliver increased capability beyond what is possible today?
    3. How would your proposed solution, if successful, enable federal entities to do that they cannot already?
        a. How much time and money could the DoD / Federal Government save when compared to the current state of technology?
        b. What future value does this technology offer to the DoD / Federal Government?
        c. What commercial best practices or processes do you plan to instantiate to deliver value to the Government?
    4. How would your proposed solution, if successful, enable the commercial markets to do that they cannot already?
        a. What future value does this technology offer to the commercial sector?
        b. Is your solution disruptive to the market, or does it provide incremental improvements to current practices?
    5. Detail the technical risks in your proposal to be solved under the DARPA program. How does DARPA engaging in this program accelerate the timeline for value, schedule, technical debt, and transition to commercial or DoD marketplaces?

    Proposers are free to provide further detail outside of the answers to the above questions as to why and how an OT allows for the Government to realize cost savings and thereby create added value.

e. **Cost Spreadsheet (Attachment D)**: Proposers must fully complete Attachment D, Cost Spreadsheet, for Switch Phase 0. In addition, provide rough order of magnitude estimates for Phase 1 technical efforts as described in Section 3.2 above.

f. Completed Representations and Certifications (Attachment F)

3.5 Oral Presentations – Process and Basis of Evaluation

Oral presentation evaluation criteria are listed in descending order of importance. Individual presentations will be evaluated against the evaluation criteria described below. The government will provide final evaluation criteria in the oral presentation invitation.

Table 7. Review Criteria for Oral Presentations

Evaluation Criteria	Required Content
Technical Approach	The proposed technical approach is reasonable, feasible, and innovative. The approach demonstrates an innovative yet feasible approach to address the identified technical risks and challenges and meet program metrics.
Relevant Qualifications	Personnel and/or company experience and qualifications are accurate, relevant, and demonstrate the ability of the proposer to meet the technical goals of the program.
Budget	The proposed costs are realistic for the technical approach and accurately reflect the technical goals and objectives of the Program Solicitation.
Data Rights	The extent to which data assertions allow the Government to realize the objectives and progression of the Switch program. The Government will require Government Purpose Rights for the technology developed under this program.

Please note, these oral presentations will be in-person only at a location to be determined. No virtual presentations will be allowed. The Government reserves the right to record presentations. The Government will rely on information provided in the OPP, the Oral Presentation, and Q&A session as basis for evaluation. All material to be presented should be sent to the Government one week in advance of the presentation.

After the oral presentations, DARPA, at a later date, will either: 1) inform the proposer that its proposed concept/technology/solution is of interest and proceed into OT negotiations or 2) inform the proposer that its proposed concept/technology/solution is not of continued interest to the Government and they are no longer considered for participation in the program. If DARPA does not intend to issue an award to a proposer for the Phase 0 effort, proposers may request a brief informal feedback session with DARPA regarding their proposal.

3.6 Review and Selection Process

DARPA's policy is to ensure impartial, equitable, and comprehensive proposal evaluations based on the evaluation criteria listed above and to select the source (or sources) whose proposal meets the Government's technical, policy, and programmatic goals. DARPA will conduct a review of each conforming abstract and OPP. All evaluations will be based solely on the evaluation criteria.

4 AWARDS

4.1 General Guidelines

Upon favorable review of the proposal and subject to the availability of funds, the Government may choose to award an OT for Prototypes agreement for Phase 0.

The Agreements Officer (AO) reserves the right to negotiate directly with the proposer on the terms and conditions prior to execution of the resulting OT agreement, including payment terms, and will execute the agreement on behalf of the Government. Be advised that only a Government AO has the authority to enter into or modify a binding agreement on behalf of the United States Government.

In order to receive an award:

a. Proposers must have a Unique Entity Identifier (UEI) number and must register in the System for Award Management (SAM) at SAM.gov. Proposers who are considering submitting an abstract against this solicitation are advised to register on SAM.gov as early as possible.

b. Proposers must also register in the prescribed Government invoicing system (Wide Area Work Flow: https://wawf.eb.mil/xhtml/unauth/registration/notice.xhtml). Awardees will be required to submit invoices for payment electronically via the Wide Area Work Flow (WAWF) module in the Procurement Integrated Enterprise Environment at https://piee.eb.mil/ unless an exception applies. Registration in PIEE is required prior to any award under this Program Solicitation.

c. Proposers must be determined to be responsible by the AO and must not be suspended or debarred from an award by the Federal Government nor be prohibited by Presidential Executive Order and/or law from receiving an award.

4.2 Controlled Unclassified Information (CUI) and Controlled Technical Information (CTI) on Non-DoD Information Systems

Further information on CUI identification, marking, protecting, and control, to include processing on Non-DoD Information Systems, is incorporated herein and can be found at www.darpa.mil/work-with-us/additional-baa. A program-specific CUI Guide has been established and will be provided with the Program Solicitation to help proposers determine CUI thresholds for information relevant to and technologies developed under the program. As CTI is anticipated for this program, foreign proposers are encouraged to understand U.S. export laws and regulations, and to have a plan in place to obtain export licenses when necessary. Possible methods include teaming with a U.S. prime and/or having a U.S. subsidiary/parent company.

4.3 Representations and Certifications

All proposers are required to submit DARPA-specific representations and certifications for Prototype OT awards in order to be eligible to receive an OT award. See

http://www.darpa.mil/work-with-us/reps-certs for further information on required representations and certifications for Prototype OT awards and Attachment F.

4.4 Competition Sensitive Information

DARPA policy is to treat all submissions as competition-sensitive and to disclose their contents only for the purpose of evaluation. Restrictive notices notwithstanding, during the evaluation process, submissions may be handled by support contractors for administrative purposes and/or to assist with technical evaluation. All DARPA support contractors performing this role are expressly prohibited from performing DARPA-sponsored technical research and are bound by appropriate non-disclosure agreements. Input on technical aspects of the proposals may be solicited by DARPA from non-Government consultants/experts who are strictly bound by the appropriate non-disclosure requirements.

4.5 Intellectual Property / Data Rights

The Government is open to flexible IP proposals from performers that are advantageous to the Government. IP proposals should, at a minimum allow DARPA to:

- Flexibly brief U.S. Government stakeholders regarding technical progress and accomplishments,
- Allow validation of technical performance, capabilities, and accomplishments by independent technical (potentially non-Government) experts, subject to NDA restrictions,
- Facilitate discussion of technical challenges and applications with the broader technical community – for example, by starting a new DARPA program that attempts to solve a serious technical challenge that limits further progress,
- Support analyses of alternatives, and
- Support transition opportunities, including design and performance data required to support other acquisition activities. These latter activities may require the Government to conduct an independent performance analysis.

The Government expects Government Purpose Rights for the technology developed under the Switch program.

4.6 Procurement Integrity Act (PIA)

All awards under this Program Solicitation shall be treated as Federal Agency procurements for the purpose of 41 U.S.C. Chapter 21. Accordingly, the Program Solicitation competitive solicitation process and awards made thereof must adhere to the ethical standards required by the former PIA.

Appendix A: Checklist

DARPA encourages the use of this checklist to ensure that your proposal conforms to the Switch solicitation. This checklist is for your own use only, do not submit it with the proposal and cost documents. For the purposes of this checklist, the term “proposal” refers to either the abstract or the oral presentation.

This checklist does not represent evaluation criteria that DARPA will use to review proposals received in response to the Switch PS. These evaluation criteria are listed and described in Sections 3.3 & 3.5 of the Switch PS. Rather, this checklist is only included as a tool to help respondents ensure their proposals conform to the Switch PS. Conforming proposals address all aspects of the PS, and this table calls attention to all instances where "must", "should", "shall", "all", and "encouraged to" language is used.

Abstract	Oral Proposal Package	Technical approach and execution strategy
X	X	The proposal addresses how the technical approach aligns to at least one of the CONOPS, i.e. opportunistic consumption, need-driven manufacturing, co-opting capacity, and long-term stability.
X	X	If addressing multiple CONOPS, the proposal discusses how a unique innovation in their approach applies to all the CONOPS they wish to address and there a clear plan for integration that is not reliant on distinct technical approaches.
X	X	The proposal **does not** address both opportunistic consumption and need-driven manufacturing.
X	X	The proposal emphasizes work towards engineering the biological component of the system. The proposal adequately justifies any tasks associated with hardware and software development, these tasks are only those necessary to implement laboratory-scale design, build, test, and learn cycles appropriate for generating the run-time reprogrammable microorganisms that are the focus of the Switch program.
X		The proposal includes a justification of feedstocks or products of choice.
	X	The proposal's justification of feedstocks or products of choice includes rationale based off projected BioMRL levels.
X	X	The proposal articulates a plan to quantify titer (g/L) and rate (g/L/h) for each of the feedstocks,

		strains, and/or products they intend to use for starting points and/or experimental controls in developing switchable biomanufacturing platforms.
	X	The proposed research plan aims to generate a demonstration of run-time reprogrammable biomanufacturing platform along one of the four CONOPS (need based manufacturing, opportunistic consumption, co-opting capacity, or long-term stability) that is at BioMRL 4 level of maturity.
	X	The proposal focuses on in-line measurements of titer and rate to assess productivity of their system and **does not** address downstream processing.
X	X	The proposal **does not** include the manufacturing or use of a chemical that is included on the U.S. Munitions List or the Commerce Control List. (If unsure if the chemical is listed, reach out to the Bureau of Industry and Security at the U.S. Department of Commerce or BTO_Security@darpa.mil to obtain guidance).
X		The proposal's executive summary is specific to the proposers' own technical approach and execution strategy and **does not** simply restate the program goals listed in this Program Solicitation.
X	X	The proposal **does not** include a planned effort to demonstrate pilot scale-up.
X	X	Additional metrics that are specific to the proposed technical approaches are considered and described.
X	X	The proposal identifies specific technical challenges associated with their proposed approach and addresses the primary risks.
		CONOP: Opportunistic consumption
X	X	The proposal addresses the programmability metric and plans to preserve baseline levels of production while introducing the ability to switch between different feedstocks.

	X	The proposal identifies at least 16 pathways, e.g. 16 feedstocks and 1 product.
X	X	The proposal aims to develop an approach to opportunistic consumption that is controllable.
		CONOP: Need-driven manufacturing
X	X	The proposal addresses the programmability metric and plans to preserve baseline levels of production while introducing the ability to switch between different products.
	X	The proposal identifies at least 16 pathways, e.g. 1 feedstock and 16 products.
X	X	The proposal aims to develop a controllable approach to need-driven manufacturing.
		CONOP: Co-opting capacity
X	X	The proposal addresses the programmability metric and plans to preserve baseline levels of production while introducing the ability to switch between different products.
X		The proposal is anchored on engineering a commonly used industrial strain at the **BioMRL 8-10** level, and notional partners for obtaining the specified industrial strain are identified.
	X	The proposal justifies a plan and explains how they will obtain and manage IP rights for engineering the BioMRL 8-10 industrial strain that will be executed during Phase 0.
	X	The proposal identifies at least 16 pathways to produce at least 16 products that start from a **commodity** feedstock.
X	X	The proposal aims to develop an approach to co-opting capacity that can be reversed to the original industrial process.
		CONOP: Long-term stability

X	X	The stability metric determined in the technical approach preserves baseline levels of production while introducing the ability to maintain continuous production for longer durations.
X	X	The proposal describes approaches to test both stability against genetic drift and against microbial contamination (these can be distinct experimental approaches).
		Advisory and Working Groups
	X	The proposal plans for any required agreements needed to share background intellectual property (IP) with government IV&V partners that could be required for replication studies.
	X	The agreements proposed are appropriate for the proposed technology and replication studies.
	X	The proposal includes plans to attend and prepare for the "pitch events" coordinated by the ICCG and establishing any necessary agreements with the ICCG in advance of the "pitch events".
	X	Proposals include milestones relevant to establishing agreements with the ICCG to allow for transparent discussions with ICCG at all "pitch events".
		General
X		The reference list must include 1-2 sentences per citation regarding the relevance of the cited reference for the proposal.
X		In the reference list, proposers should also annotate their perception of the relative importance of cited research for the proposed work (***critical; **important; *informative)
	X	Plans for establishing agreements and/or subcontracts during Phase 0 that are germane to program execution in Phase 1 are included.

	X	Data Rights and Intellectual Property are addressed between the government and the proposing team, and within the proposing team.
	X	There is a notional commercialization strategy described.
	X	A complete draft of the OT agreement (see Attachment C) with a task description document (TDD) is filled in for Phase 0.
	X	Complete Schedule of Milestones and Payments is included (see Attachment E)
	X	Complete Representations and Certifications (see Attachment F)
	X	Complete the Value Analysis Questions (see Section 3.4.d)
		Costs
X	X	Proposed Phase 0 cost does not exceed $300k.
X		The proposal includes a Budget Estimation Table (BET) for Phase 0 (see Attachment D).
	X	The proposal includes a detailed cost proposal for Phase 0 (see Attachment D).
X		The executive summary includes a statement of anticipated rough order-of-magnitude (ROM) costs for Phase 1.
	X	The proposal includes a Budget Estimation Table (BET) for Phase 1 (see Attachment D).