# DRAFT PROGRAM SOLICITATION
# PLATFORM ACCELERATING RURAL ACCESS TO DISTRIBUTED & INTEGRATED MEDICAL CARE (PARADIGM)

## RESILIENT SYSTEMS OFFICE (RSO)
## ADVANCED RESEARCH PROJECTS AGENCY FOR HEALTH
## ARPA-H-SOL-24-02
## January 16, 2024

This is a DRAFT Program Solicitation. This is not an invitation for abstracts or proposals. Any such response will be disregarded. ARPA-H will not comment nor provide feedback on questions related to proposal technical approaches. Questions and Comments should be directed to PARADIGM@arpa-h.gov.

## PROGRAM SOLICITIATION OVERVIEW INFORMATION

**FEDERAL AGENCY NAME:** Advanced Research Projects Agency for Health (ARPA-H)

**FUNDING OPPORTUNITY TITLE:** Platform Accelerating Rural Access to Distributed & InteGrated Medical care (PARADIGM)

**ANNOUNCEMENT TYPE:** PROGRAM SOLICITATION (PS), Initial Announcement

**FUNDING OPPORTUNITY NUMBER:** ARPA-H-SOL-24-02

**DATES:** (All times listed herein are Eastern Time)

- ***Anticipated Proposer's Day***: Week of February 12, 2024
- ***Anticipated Program Solicitation Posting Date***: 3/13/24
- ***Anticipated Program Solicitation Questions & Answers (Q&A) submission due date***: 3/16/24
- ***Anticipated Proposal Due Date:*** *4/26/24*
- ***Estimate Period of Performance start date:*** *9/24/2024*

**CONCISE DESCRIPTION OF THE FUNDING OPPORTUNITY:** Sixty million Americans live in rural areas with limited access to essential health services. This population is more likely to die from five leading causes —heart disease, cancer, trauma, lung disease, and stroke—than urban Americans. These geographic health disparities are likely to grow as approximately one third of rural hospitals are at risk of closing. When hospitals close, patients cannot access advanced imaging, laboratory testing, and specialty medical services. **Platform Accelerating Rural Access to Distributed & Integrated Medical care (PARADIGM) will deliver hospital-level care via a multi-purpose Care Delivery Platform (CDP) that is as convenient as telehealth.** The CDP will pioneer new developments in point-of-care diagnostics, ensure seamless data exchange between medical devices and electronic health records (EHRs), and offer real-time guidance for medical tasks. The CDP is designed for large-scale deployment by healthcare systems, particularly in rural and resource-limited settings. Achieving this goal will involve multiple parallel work streams including the development of a miniaturized self-shielded CT scanner that achieves >80% reduction in size, weight, and power from standard scanners; software that connects remote medical devices with EHRs; and intelligent task guidance systems to provide real-time, interactive decision support for healthcare workers to perform functions beyond their usual training. These innovations will be integrated into a rugged electric vehicle (EV) platform to create a seamless and efficient environment for advanced and customized care delivery. Health systems will deploy CDPs across the country to evaluate CDP-based care in a broad range of use cases for clinical effectiveness and financial sustainability.

**ANTICIPATED INDIVIDUAL AWARD:** Multiple awards are anticipated.

**PROGRAM BUDGET:** Proposer funding will depend on the quality of proposals received.
**TYPES OF INSTRUMENTS THAT MAY BE AWARDED:** Other Transactions

**ANY COST SHARING REQUIREMENTS:** Cost sharing may be requested in certain situations for Other Transactions awarded under the authority of 42 U.S.C. § 290c(g)(1)(D). Specifically, cost sharing is required for performers operating in Technical Area 1, described below.

**POINTS OF CONTACT (POC):**
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The PS Coordinator for this effort can be reached at: PARADIGM@arpa-h.gov.
ATTN: PARADIGM

ATTACHMENT 1: OT BUNDLE TEMPLATES (TO BE PROVIDED WITH FINAL PROGRAM SOLICITATION)

(1) Attachment 2, Volume 1 – Task Description Document (TDD)
(2) Attachment 2, Volume 1 – Technical and Management
(3) Attachment 2, Volume 2 – Price
(4) Attachment 2, Volume 3 – Admin & National Policy Requirements

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# 1. PROGRAM INFORMATION

## 1.1. BACKGROUND

Rural Americans are more likely to die from the leading causes of death than urban Americans. Still, over 100 rural hospitals have closed in the last decade[1] and 600 additional rural hospitals (30% of total) are at risk of closure[2], which exacerbates access barriers to advanced healthcare services. Due to these closures, patients in rural communities are losing their local health system infrastructure and face high barriers to accessing healthcare services. The Platform Accelerating Rural Access to Distributed & InteGrated Medical care (PARADIGM) Program will mitigate this urgent problem by creating a new system to deliver acute and chronic hospital-level care to these communities where and when it is needed. Through earlier detection and clinical management, this program aims to reduce morbidity and mortality from cancers and other high prevalence diseases in rural populations.

While several non-traditional care models such as pharmacy-based clinics and mobile health vehicles address the challenge of extending care into rural settings, **there is no scalable platform to deliver hospital-level care aside from the outdated model of facility-based care. The goal of PARADIGM is to build a distributed care delivery model that can be seamlessly and sustainably adopted by health systems.** This new model will enable health systems to deliver high quality health care to rural communities and areas with health care shortages.

## 1.2. PROGRAM DESCRIPTION/SCOPE

PARADIGM will create a multifunctional, scalable care delivery platform (CDP) that enables health systems to extend their services beyond the walls of a hospital. At its core, the program will deliver robust clinical services typically associated with brick-and-mortar health care facilities ranging from advanced medical imaging to emergency/critical care; establish real-world settings for demonstrating and evaluating CDP-based care; and demonstrate the financial sustainability of this care model. The new platform will feature a multifunctional rugged electric vehicle (EV) that can integrate the next generation of advanced portable imaging including a miniaturized CT scanner and dozens of medical devices (e.g., ultrasound, MRI). The platform will support numerous clinical services that comprise a wide range of medical subspecialities and ancillary services that cater to acute and chronic disease management. CDPs will not be siloed from the existing healthcare infrastructure but integrated with the current workflows of rural providers through development of a medical internet of things (IoT) software that enable smooth transfer of medical data to the electronic health record (EHR) system of regional medical centers and clinics. This medical IoT platform will assist hospital-based rural healthcare providers by remotely expanding their services throughout multiple counties. Recognizing the dire shortage of doctors, nurses, and technicians in rural areas as well as advances in computer vision, deep learning-based technologies, and embedded sensors, the platform will also enable just-in-time interactive decision support for existing healthcare workers to perform tasks on the CDP beyond their usual training.

ARPA-H is uniquely positioned to advance a new distributed care delivery model in rural America as PARADIGM requires coordinated advances in multiple technical areas along with an integration plan for the hardware and software innovation. Progress in component technologies would result in innovations in the following domains:

[1] https://www.aha.org/system/files/media/file/2022/09/rural-hospital-closures-threaten-access-report.pdf
[2] Rural hospitals at risk of closing. Center for Healthcare Quality and Payment Reform. 2023

1. *Distributed rural healthcare network system.* Advancements in portable medical device technology, remote patient monitoring, satellite internet connectivity, and electric vehicle engineering that will allow for hospital-level quality of care in remote areas.
2. *Medical IoT platform for connecting remote medical devices.* Enhancements in cloud/edge computing and open-source EMR systems that would enable more efficient flow of medical data. A single unified platform where users easily install medical devices would lead to innovations in real-time connectivity thus improving patient experience and provider workflows.
3. *Advanced imaging in rural radiology deserts.* Creating a new miniaturized stationary CT scanner, integrating portable MRI, and implementing other imaging technologies will lead to earlier disease detection, improved medical diagnosis accuracy, and better disease management.
4. *Upskilling rural healthcare workers.* Revolutionary advancements in deep learning-based technologies would enable the creation of just-in-time intelligent task guidance tools for enhancing capabilities of the diminishing healthcare workforce by allowing existing staff to perform functions within the care delivery platform.

Although solutions to each of these technical challenges have been conceptualized, it is unlikely that any of these solutions will undergo development, come to market, or integrate with each other unless developed in parallel with the common objective of distributed care delivery. Successful demonstration of clinical effectiveness of an advanced multifunctional CDP will dramatically extend capabilities of the shrinking number of hospitals in rural areas in a cost-effective manner and reduce the demand for healthcare workers with advanced skills in remote areas by upskilling the medical professionals who are already there. Scaling this distributed care platform will lay the foundation for delivering convenient, affordable, and equitable access to healthcare services across rural communities.

**Pathway to Improve Health Outcomes**

A self-sustaining and distributed CDP will act as a force multiplier for hospitals and fundamentally change the paradigm of where and how rural Americans access healthcare services. Rural health outcomes continue to be worse than urban, and the economic impact of rural health inequity is ~$64 billion per year[3]. Many rural counties have an annual lung cancer incidence of almost twice that of metropolitan areas (1.7X)[3]. Rural areas also have 20% higher mortality overall. Cervical cancer has 13% higher mortality and colorectal cancer has 16% higher mortality in rural communities[4]. Further, rural Americans are at higher risk of dying from stroke, heart disease, and respiratory disease. Lack of access to high quality healthcare services is a major contributor to these health inequities[3]. The PARADIGM program will address health inequities by targeting zip codes with underserved populations. Mortality rates and cost of cancer care are directly linked to stage of disease at diagnosis[5] and PARADIGM will help to improve this by increasing screening rates thus leading to earlier diagnoses, more effective treatment, lower mortality, and decreased costs.

PARADIGM will provide an innovative health care delivery modality benefiting numerous stakeholders including patients, physicians, healthcare systems, and payers. If 500 CDPs equipped with CT scanners were deployed, PARADIGM would save an estimated 14,000 lives and recapture $3.8B of economic productivity every year from lung cancer screening alone. Screening will save lives by diagnosing cancer at earlier stages among at-risk individuals who would otherwise go undiagnosed thereby preserving years of productive life for each of these people. Lung cancer screening requires a CT scanner, an imaging modality that is not widely accessible to rural populations. Advances in pulsing x-ray source technology and AI imaging software can lead to development of a portable CT scanner that will increase lung cancer screening services in rural areas. If 1,500 CDPs with portable CT scanners for lung cancer screening were deployed to rural and suburban areas (1 CDP for every two counties), the impacts of lung cancer screening alone would climb to an estimated 41,000 lives saved and $11.4B in economic productivity gained every year. Expanding the use cases to other diseases such as colorectal cancer, cervical cancer,

heart disease, and lung disease would further increase economic and lifesaving benefits. The technical advances unlocked by PARADIGM would also positively impact other patient populations and stakeholders including non-rural populations, U.S. military, humanitarian efforts, disaster response, and space exploration.

## 1.3. PROGRAM STRUCTURE

The PARADIGM program will require advances in several Technical Areas (TAs) including integration across multiple interoperable technologies. The first three TAs establish novel decentralized clinical care settings and use cases, the multifunctional care delivery platform itself, and an interoperable device data system that agnostically links EHRs and medical devices. TA4 and TA5 expand the capacity of the CDP further by enabling first-in-class miniaturized CT imaging and intelligent, adaptive just-in-time skills training to enhance capacity of locally available clinical staff. The TAs are detailed below:

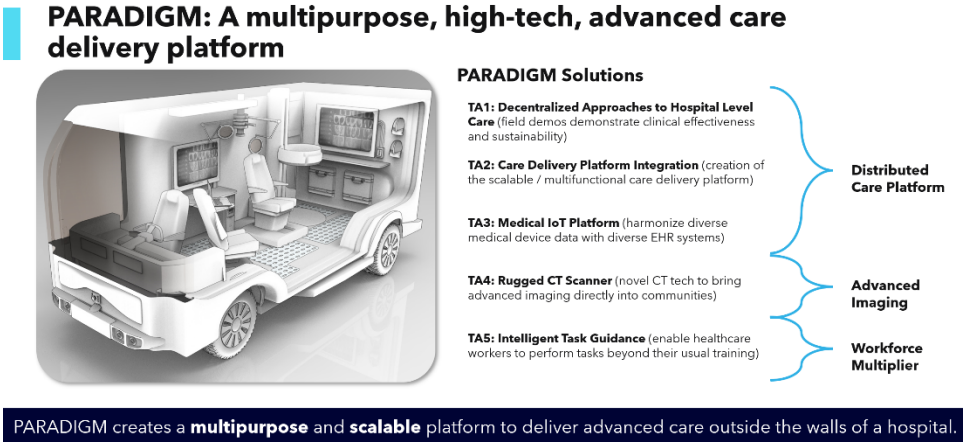
**TA1: Decentralized Approach to Hospital-Level Care.** Provide clinical care in a CDP that is currently only available in a hospital, and evaluate the clinical effectiveness, financial sustainability, and patient/staff user acceptability of CDP-based care.

**TA2: Care Delivery Platform Integration.** Develop a multipurpose scalable CDP to deliver advanced care outside the walls of a hospital.

**TA3: Medical Internet of Things (IoT) Platform.** Develop a low-cost software platform that enables seamless data ingestion, normalization, and translation between common medical devices and commercial or open-source EHR.

**TA4: Rugged & Miniaturized CT Scanner.** Fundamentally redesign and miniaturize a CT scanner for use in out-of-hospital settings to enable utilization of this essential imaging modality in remote rural populations.

**TA5: Intelligent Task Guidance.** Develop and equip CDP staff with an easy-to-use and interactive intelligent task guidance system that will provide real-time task guidance and decision support and turn a generalist into a just-in-time specialist.




### 1.3.1. Proposal Scope

Each proposal responsive to this PS may address **only one** of the five TAs detailed below. An organization **may** submit multiple independent proposals to different TAs, which will be evaluated separately. An organization **may** act as a primary performer on a proposal to one TA **and** a primary performer or subcontractor on additional proposals to different TAs. An organization **may not** act as a primary performer on one TA **and** a primary performer or subcontractor on a separate proposal addressing the same TA.

### 1.3.2. Phase Structure

PARADIGM is a 5-year program that will rapidly prototype a platform and add functionality throughout three phases. The fully integrated CDP will include multiple innovative elements: miniaturized, rugged medical devices; open-source compatible software for device-system communication including EHR-agnostic medical records; and intelligent task guidance systems. Five Technical Areas (TAs) will be developed with associated program timelines, metrics, and milestones specific to each as outlined in detail in Section 1.2.2 below.

CDPs will be deployed to TA1 clinical evaluators on a rolling basis in months 18 through 36. In year 4, the program's miniaturized CT scanner research prototype will be integrated into a version 2 (v2) CDP to de-risk future commercial transition of CDP and CT technology. Intelligent task guidance systems will be prototyped and enhanced throughout the length of the program, with CDP integration and testing in year 4.

The description of phases follows:

1. **Phase I (months 1-12):** Performers will **validate** their proposed approaches by providing computational models, component prototypes, and landscape reports. TA1 performers will work with TA2-TA5 to quickly **launch** community and user engagement programs and mock clinical visits in simulated CDP settings.
2. **Phase II (months 13-48):** Performers will **develop** prototypes, **integrate** components, **present** demonstrations, and **assess** effectiveness and impact. In TAs 2-5, performers will be evaluated on their progress and a series of down-selections will result in a single performer for each TA. Independent Verification and Validation (IV&V) evaluations will inform down-selections; no additional proposals will be solicited in the process of IV&V or down-selection. See the **Program Timeline and Milestones** (**Figure 1**) for an overview of IV&V and down-selection events, and see individual TA sections for details.
3. **Phase III (months 49-60):** Performers will **refine** their components in the context of CDP field demonstrations and evaluations while working towards **commercial transition**.

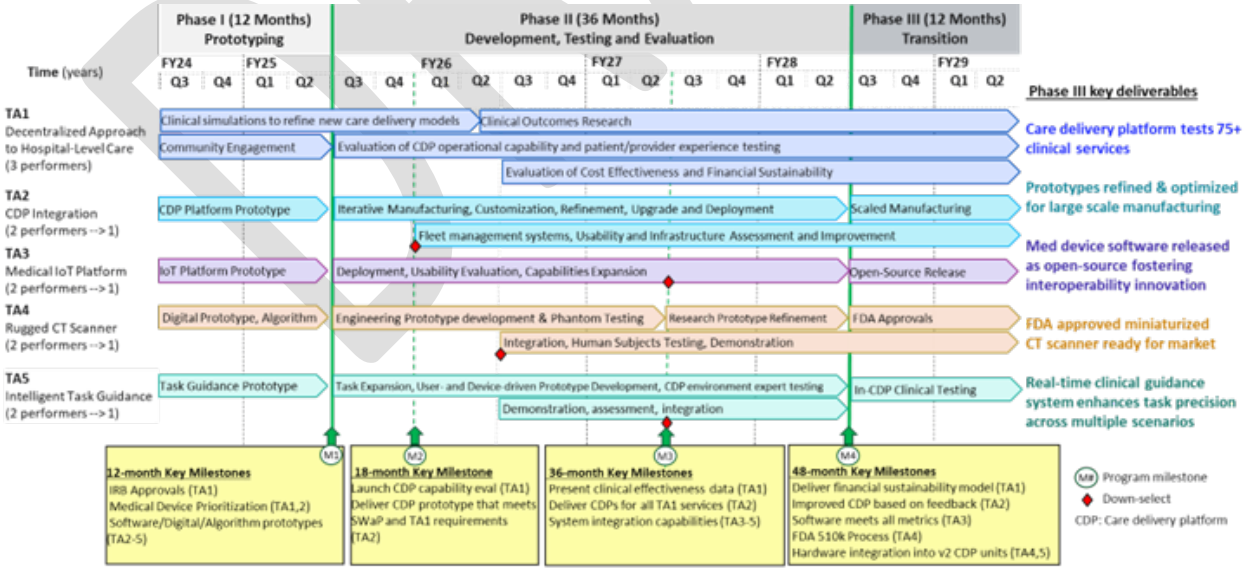



**Figure 1**: Program Timeline and Milestones

### 1.3.3. Independent Verification and Validation (IV&V)

IV&V will be conducted by an ARPA-H-identified Federally Funded Research and Development Center (FFRDC) with the necessary capabilities to evaluate TA2 to TA5. Performers are expected to work closely with the IV&V team to ensure timely delivery of models, calculations, data, and reports; establish acceptable formats for such materials; and provide access to prototypes as necessary. Regular calls and coordination meetings will be required.

### 1.3.4. Collaboration and Data Sharing

The ARPA-H PARADIGM program will be developed by several "performers" that include contractors and subcontractors, to include those with deep knowledge of key data assets as well as those selected through this announcement or through complementary funding mechanisms at partner organizations. **Therefore, it is expected that all performers will interact and work collaboratively with other performers in developing the care delivery platforms (CDPs), providing CDP-based care, and developing critical CDP infrastructure and devices, using open, timely, and effective communication, information exchange, and reporting.** Performers across all partner organizations will attend common meetings and technical exchanges to advance relevant technologies, bridge across data siloes, and move toward a common care delivery platform across numerous clinical use cases.

The major deliverable of the PARADIGM program is the creation, evaluation and validation of a customizable CDP that is effective and economically sustainable in delivering care to rural areas. Toward that end and consistent with the rapid prototyping model used by ARPA-H, the PARADIGM Performers evaluate and de-risk a set of technologies that then contribute to the development of the collective CDP-based care model. Multiple performer teams will collaborate to develop innovative tools and methods that can contribute across the TAs with some of these tools and methods being adopted for implementation into an executable architecture. In particular, collaboration with and between performers in TA1 and TA2 (Clinical Effectiveness and Workflow Evaluation, and CDP Integration, respectively) is essential to the Program's success. In addition, all TA3 to TA5 performers must remain engaged with TA1 and TA2 performers to maintain awareness of real-world care delivery operations, constraints, or requirements that these may impose on ongoing technical development. The FFRDC IV&V team will be entrusted with all data provided by performers for the purposes of evaluation and will keep such data secure.

To facilitate the open exchange of information described above, **performers will have Associate Contractor Agreement (ACA) language included in their award.** Each performer will work with other PARADIGM performers to develop an ACA that specifies the types of information that will be freely shared across performer teams. The open exchange of scientific information will be critical in advancing the software research required to achieve the PARADIGM objectives. The ACA will establish a common understanding of expectations to guide the open exchange of ideas and establish a collaborative foundation for the PARADIGM project. Each performer will also work with other performers to converge on open standards and APIs to ensure interoperability across prototype capabilities.

### 1.3.5. TA1: Decentralized Approach to Hospital-Level Care

**Technical area rationale**

Innovation in rural healthcare delivery services is profoundly needed and must maintain or exceed current hospital-based standards of care. Although existing platforms (e.g., mobile clinics) often already meet this minimum, this remains difficult to scale or siloed to one specific function (e.g., HIV testing in a specific at-risk population). Existing platforms are often funded through philanthropic sources or limited-term grants and subsidies, which threaten their sustainability and ability to innovate. To meet the diverse needs of underserved rural populations, the PARADIGM CDP must meet care standards for an array of clinical use cases and must be designed for financial sustainability.

Providing an excellent patient and community experience is central to PARADIGM's vision. High quality and financially sustainable care are irrelevant if the intended patient population is disinclined to seek care at a PARADIGM CDP. Reasons patients or staff may opt out of participation in CDP services include travel and waiting time, uncertainty about receiving services in a non-traditional setting, unfamiliarity with medical devices and staff, and stigma or cultural beliefs about care received in a CDP. To date, no other care delivery modality operating outside a hospital or clinic has optimized the combination of clinical effectiveness, financial sustainability, and user acceptability. PARADIGM will strive to achieve all three, and TA1 performers will design and conduct the systematic evaluation and reporting of each. TA1's research deliverables will provide strong evidence supporting future regulatory strategies in decentralized care delivery.

Strong TA1 proposers represent a diverse range of organizations capable of providing direct patient care and conducting the additional research and evaluation required by the program. Performers will integrate CDP usage into new or existing decentralized care models. Proposers may include academic medical centers, community/critical access hospitals, provider organizations, community health centers and healthcare service companies.

TA1 performers will increase the breadth of hospital-level care provided outside of a medical center setting and evaluate use of the multifunctional scalable CDP developed in TA2-TA5 to directly treat patients. Performers will collaborate with TA2 performers to configure CDPs to treat rural patients based upon the care use cases they plan to provide. For example, a CDP designed for a cancer screening use case may be utilized in one county while a separate unit outfitted for providing maternal health services may be employed in a different county.

**TA1 clinical use cases and services**

Proposers will identify use cases (e.g., cancer testing or intensive care) along with the associated clinical services that align with those use cases. A clinical service is considered a single procedure, diagnostic test (e.g., lab or imaging), specialized exam (e.g., obstetric, eye, or other), or treatment required to provide care for a given use case. For example, an ultrasound is a clinical service required for a prenatal care use case. Proposers will select three initial clinical services to provide in each CDP and propose a plan to increase the number of CDP services over time.

The selected **services** may be associated with one or more **use cases**. **Strong examples of use cases** include testing for multiple cancers, prenatal and/or postnatal care, emergency services, intensive care, or augmenting hospital-at-home care. The use cases and services selected by TA1 performers will define the set of devices that the TA2-developed CDP will contain. As a result, the selected use cases and services should drastically expand the breadth and quality of care available across the current ecosystem of decentralized care platforms. Services should be deployable in the setting of a healthcare provider shortage area (HPSA). Electric vehicle charging sites (see TA2 section below) in these areas should have enough existing infrastructure to feasibly install electric vehicle charging stations, and performers must coordinate with TA2 to install EV charging infrastructure if one currently does not exist.

**Strong proposals will describe multiple use cases that will accommodate an increasing number of clinical services** over time thus demonstrating the multifunctionality of the CDP. Over the course of the program, performers will commit to measurable increases in clinical health outcomes, patient satisfaction, community engagement, and the number of services provided to rural populations who have lost or are at risk of losing access to hospital-based services**.** In addition to an increasing number of services, **strong proposals will select hospital-level services that, when made available in a CDP, will uniquely and fundamentally revolutionize the quality and type of care available in a decentralized setting**. TA1 performers will bring a game-changing array of services to the TA2-developed CDP that will be

specifically designed to accommodate those services. TA1 proposers are encouraged to consider and describe regulatory challenges to effective use of CDP units for their chosen use cases and services and provide a strategy for managing those challenges.

**Strong proposals will describe how the chosen CDP use cases will result in financially sustainable business models.** For each proposed use case, performers should consider and present data assessing the target populations and needs, payment modes, regulatory changes, and CDP purchase, outfitting, and operating costs that would be necessary for success after the end of the program's support.

TA1 Clinical evaluation deliverables

To ensure that CDP-based care meets hospital quality standards, maintains financial sustainability, and is acceptable to staff and patients, **TA1 performers will produce four clinical practice-based deliverables:** (1) **Peer-reviewed clinical effectiveness research studies**; (2) **Deployment strategy report**; (3) **Community viability plan**; and (4) **Continuous user experience testing**. Together, these deliverables establish a deployment, practice, and evaluation framework to ensure CDP-based care is effective, sustainable, and acceptable.

1. **Clinical effectiveness research studies** will be conducted in health professional shortage areas (HPSAs) and measure patient outcomes specific to the performer's selected clinical use cases. For example, a CDP-based cancer screening program might be evaluated for percent of eligible population screened, cancer stage at diagnosis, and proportion of screen-positive patients referred to specialist cancer care compared to a clinic or hospital-based screening program. Clinical research studies must also include assessment of health disparities in the patient population and an evaluation of the program's impact on those disparities. Section III.D (Management Plan) should describe and demonstrate sufficient expertise and personnel time in clinical data analysis.

2. The Deployment Strategy Report has two key sections: CDP Workflow Playbook and a Financial Sustainability Report.

a. **The CDP Workflow Playbook** summarizes quantitative and qualitative insights into CDP clinical operations, from clinical studies, community engagement, clinical workflows, and user experience testing. It captures institutional wisdom and lessons learned during the first years of CDP care and evaluation, to enable faster and more efficient scaling to other geographies, settings, and markets. The Playbook should provide guidance and instructions for CDP operation including hardware/vehicle considerations (e.g., location selection, parking, power management, device-platform connections), clinical operations and best practices (e.g., staffing, scheduling, supply inventory, staff and patient access, registration, clinical workflows within the CDP interior, EHR use/health information management, and data security protocols), and ensuring applicable regulatory compliance with state and federal (including CMS) requirements for providing hospital level care outside a hospital, using or transporting medical equipment, waste, prescription medications and other products required for the proposed clinical services in the jurisdiction where the performer operates.
b. **The Financial Sustainability Analysis** will report on key performance indicators (KPIs) collected over the course of CDP operation at least annually including revenue metrics (e.g., total operating revenue, average revenue per day, service and payer-specific net revenue), profit metrics (e.g., operating margin, net profit margin), and cost metrics (e.g., total operating expenses cost per case). The financial sustainability report should evaluate the CDP's balance sheet and KPIs to make concrete recommendations for achieving and maintaining long-term financial sustainability from the perspective of the operating hospital, health system or organization. Proposers should describe the methods, data sources, and approach to producing the deployment

strategy report. This includes comments on the proposer's ability to gain access to the necessary financial statements and data required for the financial sustainability plan. Section III.D (Management Plan) should demonstrate sufficient expertise and personnel time allocated to CDP economic/financial analyses.

3. **The community viability plan** should describe the demographics, needs, disparities, and social determinants of health in rural communities served by the CDP as well as provide specific insights into community knowledge, attitudes, and anticipated practices around CDP-based healthcare utilization. The plan will also describe health equity gaps and ways that these may be addressed by CDP-based care. The plan must arise from direct engagement with key stakeholders including patients or individuals who could benefit from CDP care, clinical and ancillary staff, service personnel, host site owners, and local public health officials. Based on the information collected, the plan will offer recommendations on aligning CDP service delivery with the unique needs of its stakeholders thereby optimizing CDP-based care uptake. Proposers should describe the methods, specific stakeholder groups, and quantitative and qualitative analytic approaches to producing the community viability plan. In addition, proposers should describe any known existing or anticipated community viability challenges that they might encounter while providing CDP-based care and suggest strategies to query and address these issues during the program.

4. TA1 performers will evaluate the CDP user experience (UX) and define product requirements through ongoing UX testing while providing CDP-based care. PARADIGM's goal is to create a clinical CDP that provides a positive and human-centered experience for patients and staff. TA1 performers will provide regular, ongoing UX testing results to TA2 performers who will use the information to build and configure the CDP platform in a way that is acceptable for patients and providers. An example of UX testing includes accessing CDP interior workflows or configurations. In this example, TA1 performers would observe, survey, or interview patients during an exam using one of two different interior configurations of devices and furniture in the CDP. TA1 performers would solicit feedback to determine the preferred configuration then share these preferences and rationales with TA2 performers. TA1 performers must also define product requirements and distribute these to other TA performers tasked with building specific elements of the CDP. Product requirements may be derived from UX testing or from the clinical care itself. For example, product requirements may include the anticipated patient journey, required hardware, and regulatory requirements of clinical use cases. Proposers should describe their approach for UX testing as well as facilitate ongoing information exchange with TA2 and other performers throughout the duration of the program. Specifically, proposals should address ways to minimize added time and burden for patients and providers during UX testing. Proposal Section III.D (Management Plan) should demonstrate that the team has sufficient expertise in user experience design/evaluation and product management.

**TA1 performers will collaborate with all other performers continually throughout the program**, document resulting key takeaways, and indicate program implications. Specifically, and in addition to collaboration with TA2 as described above, TA1 performers must: 1) Share a description of clinical services and use cases with representatives from all other TA performers; answer questions; and clarify as needed to support technology development. 2) Share feedback and results of user experience assessments continuously and in real time to support user-centered design efforts across TA2-TA5. Ideally, TA2-TA5 performers will be invited to shadow TA1 teams as they perform clinical CDP simulations in Phase I as well as CDP-based patient care in Phases II-III.

**TA1 Metrics**

TA1 performers progress will be evaluated using five metrics (Table 1) to ensure that by the end of the program, the CDP model will be viable as a sustainable platform. Specifically, each performer will be expected to demonstrate CDP units with greater than 9 clinical services each, meeting the patient throughput and user acceptability targets established in year 1, and incurring operating costs less than one-half the amounts typically resulting from equivalent facility-based services. Additionally, each performer is expected to engage with a total of at least three partner community organizations directly impacted by the use cases addressed by their CDP units.

**Table 1:** TA1 metrics.

| | | Phase I (12 mo): Initial Prototype | Phase II (36 mo): Evaluation of Operational Capabilities | | | Phase III (12 mo): Transition |
|---|---|---|---|---|---|---|
| | **Metric** | **End of year 1** | **End of year 2** | **End of year 3** | **End of year 4** | **End of year 5** |
| **TA1: Decentralized Approach to Hospital-Level Care** | **Service breadth** (# of distinct clinical services delivered per CDP per performer, with ~3 CDPs per performer) | Finalize target services at 3 months | ≥ 3 | ≥ 5 | ≥ 7 | ≥ 9 |
| | **Scalability** (Patient throughput: i.e. # of visits per day as a % of total goal defined with performer. Ex: 1 CDP demonstrates 50 patients/day baseline capacity and recruitment, 100 by Phase III) | Target patients/day established during mock CDP workflow simulation | ≥ 25% target | ≥ 50% target | ≥ 75% target | ≥ 100% target |
| | **User-centered design** (Patient Net Promotor Score, likelihood of recommending CPD service, vs. hospital standard care) | Target set after initial UX feedback | ≥ 50% target | ≥ 70% target | ≥ 90% target | ≥ 95% target |
| | **Engagement** (# of partner community organizations per CDP community) | ≥ 1 | ≥ 2 | ≥ 3 | ≥ 3 | ≥ 3 |
| | **Yearly Operating Cost** (total annual recurring costs / CDP) | n/a | n/a | Same as clinical benchmark (equivalent facility based service) | <80% | <50% |

## TA1 Phases and Milestones

The program has three phases, each with key milestones and metrics. Throughout the program, **performers will submit frequent brief progress reports and intermediate deliverable drafts.** These milestones are listed below. Cost sharing must cover 25% of TA1 proposal budget in program year 4, and 50% in year 5.

### Phase I (Months 1-12)

**Performers will deliver a clinical research proposal describing at least 3 clinical services for evaluation**, and methods that enable quantitative conclusions on the quality and outcomes of CDP-based care**.** The proposal must also describe the outcomes for assessing clinical effectiveness, financial sustainability, and user acceptability. The list of 3+ clinical services will be shared early with TA2 system integrators. Specifically, **TA1 performers must provide TA2 performers with a comprehensive list of devices, equipment, and supplies** for each proposed clinical service and use case by the end of month 2. TA1 performers will also submit **a community engagement plan** that includes a **list of community partners** and organizations that will be included in outreach activities, and a **user experience testing plan** developed in consultation with TA2 performers. These two plans will form the foundations of the community viability plan and ongoing user experience testing deliverables. By the end of Phase I**, TA1 performers will secure human subjects research (institutional review board (IRB)) approval.** During Phase I and while the CDP is under development by TA2 performers, **TA1 performers will conduct clinical workflow simulations**, which are mock patient visits in simulated clinics that mirror dimensions and functions of the CDP. Simulations must include all proposed CDP services and involve representatives from key stakeholder groups (patients, providers, payers, clinical staff, CDP operations staff, etc.). Performers will use these mock patient visits to produce initial user experience feedback, which will inform subsequent CDP-based clinical care and TA2 CDP design.

### Phase II (Months 13-48)

**Performers will** make any requested revisions to research proposals and deliver a **project planning schedule of intermediate milestones** and roles/responsibilities matrix in support of the peer-reviewed

research, deployment strategy report, and community viability plan program deliverables. **Performers will launch community engagement and initiate CDP-based clinical services** once TA2 performers deliver the CDP. Performers will begin clinical research participant enrollment and study participant enrollment. Throughout this period, TA1 performers will document monthly meetings with TA2 performers to ensure hardware and power requirements for field testing are in place as well as to provide iterative user feedback to performers developing novel CDP technologies in TA2-TA5. By the end of this Phase, TA1 performers will deliver **12- and 24-month clinical effectiveness research endpoint data** and deliver **drafts of the community viability plan** and **deployment strategy report**.

**Phase III (Months 49-60)**
Performers will continue delivering CDP-based services in fully operational CDP units and submit clinical research studies for publication in peer-reviewed journals. Performers will also deliver final versions of the Deployment Strategy Report and Community Viability Plan. Documentation from regular meetings with TA2-TA5 performers will continue as ongoing user acceptability and customer feedback is required for technology commercialization and scaling. Finally, performers will engage at least one partner entity to pilot CDP-based care delivery. The purpose of this requirement is to support commercial transition and expand the reach of CDP-based care by leveraging the TA1 performer's experience delivering care and expanded network of clinical and community partners developed during the program.

**Table 2:** TA1 milestones.

| TA | Phase | Month | Milestones |
|---|---|---|---|
| TA1: Decentralized Approach to Hospital-Level Care | I | 12 | Deliver clinical research proposal including 3+ initial clinical services, study populations, methods and endpoints, and list of devices, equipment and supplies required for each clinical service. |
| | | | Deliver community engagement plan, community partner list, and user experience (UX) testing plan |
| | | | Complete clinical care workflow simulations of all proposed CDP services with representatives from each stakeholder group, and deliver initial UX feedback data based on simulated care |
| | | | Receive institutional review board (IRB) approval |
| | II | 24 | Deliver project planning schedule covering the peer-reviewed research, deployment strategy report and community viability plan projgram deliverables |
| | | | Launch community engagement program and initiate CDP clinical services |
| | | | Launch research study enrollment and data collection |
| | | 36 | Conclude 12-month endpoints in clinical effectiveness study |
| | | 48 | Deliver drafts of the Deployment Strategy Report and Community Viability Plan |
| | | | Conclude 24-month endpoints in clinical effectiveness study (or 2nd 12-month study) |
| | III | 60 | Submit study for publication in peer-reviewed journal |
| | | | Deliver final Deployment Strategy Report and Community Viability Plan |
| | | | Engage ≥1 transition partner entity to pilot and expand CDP care delivery |

### 1.3.6. TA2: Care Delivery Platform (CDP) Integration

**Technical area rationale and objectives**
The TA2 performer will design a rugged multifunctional CDP incorporating an electric vehicle that accommodates each TA1 performers' clinical services. In Phase I, TA2 performers will build prototypes for testing. Then in Phase II, they will build a fleet of vehicles to accommodate rigorous field testing for the full breadth of TA1 use cases. The TA2 performer will establish a fleet management system that will monitor the units' status as well as efficiently maintain, repair, and upgrade the vehicle as necessary. When onsite servicing of vehicles is not possible, the TA2 performer will rapidly configure a replacement unit to match and swap it out to minimize down-time. The TA2 performer will be responsible for outfitting the CDP units to operate in the local environment of the TA1 performer-specified use case providing suitable modifications and auxiliary equipment for operations in unique climates (e.g., desert, mountain, or cold below freezing terrains). The TA2 performer will be responsible for user acceptability by operating through the lens of human-centered design and utilizing user experience feedback collected by TA1 performers. As the integrator of all program components, TA2 performer assessment will focus

on the ability to build an integrated CDP that meets patient and clinician needs as well as by offering an excellent user experience.

**TA2 proposals may present concept designs responsive to one or more of three specific scenarios:** Scenario 1 (Pop-Up Clinic): The CDP will be capable of traveling by using electrical battery power for a maximum distance of 120 miles to a staging location. Proposers may assume that the location will provide a single level 3 charging plug and a dedicated parking space. Proposers may, if necessary for the optimal performance of their design, specify the need for a second level 3 charger. The CDP will provide services for up to a week before returning to its predetermined resupply location. Scenario 2 (Home Health Delivery): In a single day, the CDP will be capable of traveling using only battery power to two remote sites of service before returning to a home base. The total distance travelled will not exceed 100 miles. There will be no assurance of any recharging station except for the home base at the end of the sortie (i.e., home base to home base mission transit). Battery capacity must allow for up to 8 hours of up-time service (e.g., lighting; heating/cooling; air handling; and supporting medical devices, computers, and communications) in addition to travel requirements. Scenario 3 (Versatile Mission): The CDP will be capable of fulfilling the mission of either Scenario 1 or Scenario 2, as needed, and with no more than 24 hours required between sorties of different types for any needed reconfiguration of equipment. **Selected TA2 performers should expect that only one of their concept designs will be selected for development** and should calculate their budgets accordingly (e.g., indicating variable costs for different designs if needed). Should the program desire multiple designs to be developed by a single performer, they will be expected to create a combined budget at that time to allow for any cost savings this might afford.

**TA2 proposal concept designs must include the following:** (1) Clear and detailed graphics illustrating the components of the system. (2) Plans for addressing how the system will provide basic care equipment for use on all CDP units as well as specialized devices, and additionally how the units could be rapidly reconfigured to serve at least two distinct specialized clinical modalities (e.g., maternal health services and cancer screening). (3) Efficient space use plans for equipment, supplies, and furnishings. (4) Human factors design elements. (5) Estimates of the power supply and power use requirements for the vehicle during transport and when providing services. (6) Estimates of the total cost to produce the vehicle if done at scale. Strong proposals will demonstrate capabilities for wide-ranging clinical services as well as modular design supporting efficient reconfiguration and upgrade of equipment.

**All TA2 concept designs (and eventual products) must conform to the following constraints:** (a) Operation of the proposed CDP must not require any special licensure (e.g., a commercial driver's license[6]) due to its size, weight, or other factor, and must not require any non-trivial training on the part of the operator. (b) The CDP must be able to transport at least two people including the driver safely as well as conform to all laws and regulations regarding vehicle safety. (c) The CDP must provide sufficient usable size, weight, and power (SWaP) to allow for supplies, equipment, and operations as detailed in **Table 3**. (d) The CDP design must allow for the installation and safe transport of at least one piece of equipment weighing 500 lbs. that is deployed for use off-center (on the left-right axis) in the unit and considering transport on rural and mountain roads. Solutions allowing transport in a temporary on-center position are acceptable, so long as a system for easy repositioning of heavy equipment is included in the design. (e) The CDP must provide adequate heating and cooling that involves anticipating service operations in ungaraged extremes of temperature anywhere in the U.S. (f) The CDP design must include communications and networking hardware as well as computer systems sufficient to fulfill anticipated clinical services in the absence of working real-time communications. (g) The CDP unit must be fully compliant with the ADA[7](e.g., allowing access and service delivery to patients in wheelchairs)

**Table 3**: CDP Usable Size, Weight and Power (SWaP) constraints*

| | |
|---|---|
| Size | Total usable space: ≥600 cu ft; internal height: ≥8 ft; internal width: ≥7 ft |
| Weight (payload capacity) | Total >2000 lbs. |
| Power | Peak power delivery to equipment: ≥50kW; standard 120V outlets: ≥12 |

* Total CDP size and weight are limited by the constraint to not require any special license to operate (e.g., a commercial driver's license). Battery capacity is constrained by range, sortie duration, and charging availability requirements specified in the individual scenarios.

**TA2 proposals must include fleet management plans.** CDP units manufactured by the TA2 performers will be deployed in diverse rural locations throughout the U.S. Where needed, TA2 performers will provide expert advice and coordination with TA1 performers and site owners to ensure that needed EV charging infrastructure is correctly configured for CDP use. TA2 performers will be expected to remotely monitor the CDP vehicle's battery performance and hardware systems status as well as perform maintenance, repairs, and upgrades as needed.

**Strong proposals will include plans for minimizing downtime** and will indicate the number of replacement units and staff needed, where replacement units and upfitting supplies should be warehoused or pre-positioned, and efficient processes for rapidly configuring and re-configuring CDP units to match TA1 performers' use cases, or for making repairs, performing maintenance and doing upgrades.

**TA2 performers are expected to collaborate** with all other TA performers to incorporate user-driven design elements that will facilitate successful integration of their components. Proposals must include plans for interaction with other performers through virtual meetings and, if deemed necessary, site visits. Importantly, TA2 performers must work closely with TA1 performers to implement UX feedback collected during clinical operations. The proposal should describe tactical plans for effective ongoing collaboration with other TA performers including expected goals and outcomes. Proposal section III.D (Management Plan) should describe the team's sufficient expertise for user experience design and evaluation.

**TA2 Metrics**

TA2 performers will be evaluated based on 7 distinct metrics (Table 4) to ensure that by the end of the program, the CDP model will be viable as a sustainable platform. By the end of the program, the CDP units will be capable of supporting, through incorporation of devices, space configuration and supplies, twice the number of clinical services initially proposed by TA1 performers. By the end of year 2, preferably earlier, at least 3 CDP units, outfitted to carry out the clinical services of each TA1 performer's stated initial use case, will have been delivered (one each) to the TA1 performers. This will increase to at least 3 CDP units per performer by the end of year 3. TA2 performers will assess, using feedback from users, the CDP reliability, fleet management performance, and usability, and meet 95% quality metrics by the end of the program. TA2 performers are expected to minimize production and maintenance costs and will meet the indicated metrics targets. The production cost metric sets requirements for cost of a CDP at scale, outfitted with interior and exterior features required to accommodate devices specific to TA1 clinical use cases, but not including those devices. Outfitting refers to all features required to operate the CDP and accommodate specific devices, but not including those devices. Overall, the goal is to make the production cost of a CDP comparable to that of an ambulance.

**Table 4:** TA2 metrics.

| | Metric | Phase I (12 mo): Initial Prototype<br>End of year 1 | Phase II (36 mo): Evaluation of Operational Capabilities<br>End of year 2 | <br>End of year 3 | <br>End of year 4 | Phase III (12 mo): Transition<br>End of year 5 |
|---|---|---|---|---|---|---|
| **TA2: Care Delivery Platform** | **Multifunctionality** (# of distinct clinical services supported by CDP as a multiple of services proposed by TA1 performers) | Baseline set at 6 months through "needs assessment report" | 0.95X | 1.25X | 1.5X | 2X |
| | **Production and Deployment** (# of CDPs produced and deployed to TA1 performers) | n/a | ≥ 3 total CDP (v1) | ≥ 9 total CDP (v1) | ≥ 9 total CDP (v1) & 2 CDP (v2) w/tech integrated (if avail) | ≥ 9 total CDP (v1) & 2 CDP (v2) deployed |
| | **Reliability** (CDP service up-time as a % of days scheduled for use/unit) | n/a | ≥ 80% (30 days post-deployment) | ≥ 90% | ≥ 95% | ≥ 95% |
| | **Fleet management** (Likert scale assessment of performance and UX of mgmt. tool) | Target set at 3 months | ≥ 50% target (30 days post-deployment) | ≥ 75% target | ≥ 90% target | ≥ 95% target |
| | **Useability** (Likert scale assessment of useability by staff) | Target set at 3 months | ≥ 50% target (30 days post-deployment) | ≥ 75% target | ≥ 90% target | ≥ 95% target |
| | **Production Cost** (per v1 CDP manufactured & outfitted) | ≤$750K | ≤$700K | ≤$600K | ≤$500K | ≤$400K |
| | **Maintenance Costs** (EV vs internal combustion engine-ICE) | n/a | n/a | Same as ICE | <80% | <50% |

## TA2 Phases and Milestones

The program has three phases, each with key milestones and metrics. Throughout the program, performers will submit frequent brief progress reports and intermediate deliverable drafts. These milestones are listed below.

### Phase I (Months 1-12)

Up to two proposers will be selected in TA2 to develop a CDP prototype. At 6 months and after consultation with TA1 performers, TA2 performers will present a report detailing how they will address all the various TA1 use cases (the "needs assessment report"). This report will incorporate all needed equipment within the available SWaP space of the proposed CDP units and will identify the equipment shared across all configurations (core) versus those that will be needed for specialized use cases. Near the end of Phase I, performers will deliver a detailed virtual computerized 3-D (CAD/VR) renderings of their designated CDP prototype that meets all **design constraints** and the relevant vehicle **scenario parameters**. This prototype will enable as many **TA1 clinical use cases** as possible by including adequate equipment, supplies, and power. Performers will also produce an accompanying report detailing features of the design. The form and content requirements of this report and its deadline will be specified by the IV&V team at least 2 months before it is due near the end of the Phase. Ahead of the Phase II down-select at month 18 (which will be based on evaluation of a physical prototype), performers are expected to begin planning and preliminary construction activities during Phase I.

### Phase II (Months 13-48)

Performers will receive feedback based on their Phase I designs and will make suitable revisions prior to construction and delivery of a physical prototype by month 18. Following evaluation by the IV&V team, there will be a down-select to a single prototype design concept and performer. By month 24, the selected TA2 performer will have delivered to TA1 performers at least 3 CDP units that meet all design constraints and vehicle use case parameters listed above. These units will be ready to use and will meet all regulations for safe and legal travel on public roads. The TA2 performer will cooperate with the TA1 performers and the IV&V team and gather information through surveys of CDP unit staff to evaluate the reliability, fleet management acceptability, and usability (UX) metrics. For these metrics, each CDP unit will be evaluated by the IV&V team after data covering 30 service days have been collected. Throughout the remainder of Phase II (and Phase III), the TA2 performer will provide fleet management services and support for EV charging infrastructure as needed. By month 36, the TA2 performer will have expanded the CDP fleet to at least 11 units. At least 9 of the units will be deployed to TA1 performers, and one each will be supplied to TA4 and TA5 for integration and testing with their technologies. By month 48, TA2

performers will have incorporated the feedback on reliability, fleet management and UX, and made any needed upgrades to the fleet to address any issues.

When a working CT scanner prototype produced by TA4 and a working skills augmentation system produced by TA5 are ready, the TA2 performer will collaborate in the integration and testing of those systems. This will prepare CDP v2 units for field testing and demonstrations during Phase III. TA2 performers are expected to develop a business plan by investigating and collecting data for transition of CDP units as sustainable products beyond the end of the PARADIGM program. Performers will work with the IV&V team to provide all requested reporting and data as well as arrange site visits and demonstrations as necessary to accommodate the IV&V team's end-of-Phase evaluation.

**Phase III (Months 49-60)**
Performers will continue to provide fleet management services and support for EV charging infrastructure as needed. By month 52, the TA2 performer will deploy two upgraded v2 CDP units, one equipped with the compact CT scanner developed under TA4 and the other with the skills augmentation technology developed under TA5 (if those technologies are ready for field testing and demonstrations). Additionally, these v2 units will incorporate feedback collected from TA1 performers to enhance their effectiveness and usability. By the program's end, the performer will deliver a final technology transition plan that supports dissemination of CDP units and associated technological, design, and systems integration innovations that would enable large scale manufacturing of advanced CDP vehicles. Performers will deliver a final report summarizing all activities and achievements over the course of the program as well as provide data demonstrating that all end-of-program metrics have been met.

**Table 5:** TA2 milestones.

| TA | Phase | Month | Milestones |
|---|---|---|---|
| TA2: Care Delivery Platform Integration | I | 6 | Deliver needs assessment report describing all equipment and SWaP requirements with justification and priority for all unique and shared TA1 use cases |
| | | 12 | Deliver *in silico* prototype (computational 3D model and SWaP estimates) |
| | II | 18 | Deliver CDP prototype meeting SWaP and TA requirements |
| | | 24 | Deploy intial CDPs that meets all DOT requirements for operations and safety on public roadways & consult with TA1 performers on installation of EV infrastructure in select locations |
| | | | Collect initial reliability, acceptability and usability data from TA1 |
| | | 36 | Build and deploy fleet: 16 total CDPs outfit with remote fleet management system activated |
| | | | Confirm EV power infrastructure at key sites as needed |
| | | 48 | Incorporate feedback from TA1 for UX testing |
| | III | 52 | Design and build 2 CDP v2 units that compiles feedback from TA1, 1 that integrates CT scanner from TA4, and 1 that integrates skills augmentation from TA5 (or as soon as made available for integration). |
| | | 60 | Deliver commercial transition report |

### 1.3.7. TA3: Medical IoT Platform

**Technical area rationale and objectives**
PARADIGM seeks to create a software toolbox for ingesting, normalizing, and translating data from medical devices (including all devices chosen by TA1 and TA2 for use in the CDP) into formats that are compatible with existing commercial and open-source EHR systems, as well as work to improve standards through demonstration of solutions to gaps in current health data standards. **Strong proposals will describe a scalable, extensible approach to connect hundreds of devices to multiple EHR systems, in a way that consolidates and integrates across existing standards** (e.g., IEEE, HL7, FHIR, LOINC, SNOMED). TA3 solutions should create a plug-and-play capability that enables users to add new devices with minimal effort. Strong proposals will describe the architectural and algorithmic approaches to enable interoperability for hundreds of devices. Proposers should explain what methods will be used to minimize the amount of software development and user configuration time that will be

needed to add each new device and should focus on architectural principles such as loose coupling. Innovative architectural approaches to minimize time for software development and end user configuration are highly encouraged. Approaches that support dynamic mapping of device data fields to EHR data fields using standard data models and ontologies are also highly encouraged. **Strong proposals will include a strategy to communicate bidirectionally with multiple EHR systems in a manner that tracks data provenance using a small set of standardized Application Programming Interfaces (APIs) founded on standard data models and ontologies.**

The TA3 approach should develop a cutting-edge commercial internet of things (IoT) platform that operates with permissive open-source licenses to foster innovation and accessibility in medical device interoperability; viral or copyleft licenses are not suitable. The platform should be sufficiently open that it enables developers from many organizations to extend and add to the IoT capabilities. A modular, scalable IoT solution integrated in the CDP will contribute to the platform's multifunctionality by enabling future increases in the number and types of medical devices supported by the platform. The use of a small set of standardized APIs founded on consistent and well-defined data models and ontologies will ensure high levels of extensibility and evolvability.

**Proposals must address key needs in each of the following categories:** (i) ***Device integration:*** Manage the diversity of data coming from common medical devices found in clinical care environments. (ii) ***Data normalization:*** Leverage existing ONC encoding standard recommendations (e.g., SNOMED, LOINC, and RxNorm) as a foundation for all data encoding and support new required data elements as compatible extensions to those encoding representations. Develop techniques to normalize data representations that use these encodings, such as normalizing HL7 FHIR Observation resources on ingestion into an analytic data store, so that the same test or observation is represented the same way, every time. (iii) ***Data interoperability:*** Enable bidirectional, secure communication with commercial and open-source EHRs. In addition, the proposal must address patient data privacy and security along with scalability and maintenance considerations. (iv) ***Data security and privacy:*** Receive and transmit patient data in a way that maintains privacy, supports HIPAA compliance, and limits the potential for unwanted transmission of personally identifiable information (PII) and is consistent with National Institute for Standards and Technology (NIST) Risk Management Framework (RMF) principles as articulated in multiple NIST Special Publications including considerations across Confidentiality, Integrity and Availability factors e.g. protecting the environment from ransomware type attacks as well as protecting privacy. (v) ***Systems Thinking Applied to Safety and Data quality****:* Ensure that the IoT Platform—as well as the systems that the IoT platform integrates with—are well described with a comprehensive system description and control structure.[8,9] Establish processes to enable ongoing data quality assessment and independent verification and validation of data, with a goal that all data will be accompanied with sufficient information to answer the question: "Why should I trust this data?" Validate Data Interoperability by ensuring that there is no degradation in data quality and data completeness across all data exchanges. (vi) ***Content and knowledge syndication****:* IoT devices are necessarily simple yet require mechanisms to keep their ability to properly collect and encode data up to date across a very large system of devices with different versions of firmware and dynamic software. In addition, IoT devices are susceptible to the 8 Fallacies of distributed computing.[10] Proposers must design a system that can be managed in a way that ensures up-to-date data collection instruments and encoding of responses such that when IoT devices are available and have bandwidth, they must be able to synchronize knowledge assets (new questionnaires, updated questionnaires, terminology changes, value sets, and value set changes). The Medical IoT Platform should support periodic synchronization in a manner that provides credible solutions to the 8 distributed computing fallacies. These solutions may include modular cooperating services that are fault tolerant, and that utilize reliability and consistency mechanism such as store and forward or distributed ledger architectures, with eventually consistent distributed transactions.

**Commercial-friendly open-source licenses (e.g., Minimum BSD License) are preferred.** For those who elect to propose a proprietary aspect, the solution should leverage or extend open standards for each class of medical device chosen by TA1 and TA2. If an open standard does not yet exist, proposers should identify the devices that lack an open standard, describe a plan to generalize a common data model across those devices, and prototype a new open standard. **Strong proposals will explain how the performer will enhance data interoperability (including syntactic and semantic interoperability)** and expand the usage of open standards and data models throughout the program. Development or use of open-source data translators, expansion of existing open standards, and interoperability enhancements for open data models are all of interest.

To support a vision of medical device interoperability with a strong unifying regulatory framework, **strong proposers will** develop and/or integrate existing open-source solutions aligning with existing national standards and regulatory guidance. **Proposals must** include a technical plan to align with the Office of the National Coordinator for Health Information Technology's (ONC) Health IT Certification Standards & Regulations for EHR systems, including support for Fast Healthcare Interoperability Resources (HL7 FHIR) and Digital Imaging and Communications in Medicine (DICOM). **Strong proposals** will outline integration with the Trusted Exchange Framework and Common Agreement (TEFCA). Adhering to international standard ISO/IEEE 11073 will enable broad support for current and future devices, especially those developed internationally. Section III.D (Management Plan) of the proposal should describe sufficient expertise in medical device software engineering, clinical informatics, health IT, and cybersecurity.

### TA3 Metrics

TA3 performers will be evaluated based on 5 distinct metrics (Table 6) to ensure that by the end of the program, the CDP model will be viable as a sustainable platform. By the end of the program, the CDP units will incorporate a fully mature data exchange system that will be capable of handling data from 3.5 times as many medical devices and 2 times as many supported data types as initially needed to fulfil the needs of TA1 performers' proposed use cases and will work with six or more individual EHR systems including at least one open source EHR system. TA3 performers will assess, using feedback from users, the usability of the system, and meet the 95% quality metric by the end of the program.

**Table 6:** TA3 metrics.

| | | Phase I (12 mo): Initial Prototype | Phase II (36 mo): Evaluation of Operational Capabilities | | | Phase III (12 mo): Transition |
|---|---|---|---|---|---|---|
| | **Metric** | **End of year 1** | **End of year 2** | **End of year 3** | **End of year 4** | **End of year 5** |
| **TA3: Medical IoT** | **Device multifunctionality** (# medical devices that system can draw data from as a multiple of # of devices proposed by TA1) | Baseline set at 6 months | 0.95X | 1.5X | 2.5X | 3.5X |
| | **Extension of ONC-specified health data encoding standards** (number of data types supported as compatible extensions to existing ONC encoding standards, relative to what is proposed by TA1 performers) | Baseline set at 6 months | 0.95X relative to TA1 use cases | 1.2X relative to TA1 use cases | 1.6X relative to TA1 use cases | 2X relative to TA1 use cases |
| | **EHR compatibility** (# EHR systems) | ≥ 1 | ≥ 3 | ≥ 4 (including open source EHR) | ≥ 5 (including open source EHR) | ≥ 6 (including open source EHR) |
| | **Useability** (Likert scale assessment of useability by staff) | Target set at 3 months | ≥ 70% target | ≥ 80% target | ≥ 90% target | ≥ 95% target |
| | **Maturity** (Technology Readiness Level #) | ≥ 3 | ≥ 4 | ≥ 5 | ≥ 6 | ≥ 7 |

### TA3 Program Phases and Milestones

The program has three phases, each with key milestones and metrics. Throughout the program, performers will create a software stack or toolbox that will enable ingesting, normalizing, and translating data to/from medical devices using different vendors within TA2 performers' CDP into formats that are compatible with existing commercial and open-source EHR systems. Throughout the program,

performers will be expected to take an agile continuous integration continuous delivery (CI/CD) approach in which software iterations are regularly updated in response to continuous feedback from TA1 to TA5 and IV&V performers.

**Phase I (Months 1-12)**
Performers will request and receive a list of clinical services, associated medical devices, EHR systems being implemented, and existing ARPA-H designated open-source projects that the performer will either build upon—or be interoperable with—in TA1. Using this list and information gathered from device vendors, EHR providers, and other stakeholders, performers will design a software codebase prototype that is ready to be tested in different clinical use cases. The prototype should demonstrate connectivity between selected devices and EHR systems. It should also demonstrate the foundations required for HIPAA compliance of the final IoT product. Performers will source research and development (R&D) devices corresponding with the TA1 list along with EHR licenses as needed for R&D.

**Phase II (Months 13-48)**
**Performers will deploy the software** in a clinical environment of the CDP where it can be accessed by end-users (presently, TA1 performers). The software will be tested for seamless exchange of data between medical devices of different manufacturers and EHRs of different vendors. The number and types of medical devices will increase during this Phase. Performers will develop a caching strategy to mitigate latency and downtime during times of intermittent internet connectivity. TA3 Performers will conduct user testing in collaboration with TA1 and TA2 performers. By end of Phase II, performers will demonstrate a software toolbox ready for commercialization.

**Phase III (Months 49-60)**
**Performers will develop and document a transition and commercialization strategy** then deliver a final report. The report should include a detailed description of progress, achievements, and breakthroughs made during the program and include strategies to reach other healthcare markets beyond those identified in this program. The report should cover any intellectual property created, licensing agreements, or partnerships with external organizations for commercialization. Note that all software IP first created in the performance of the contract will conform to a permissive open license. The government will maintain unlimited rights to data and software products first produced in the performance of this PS, according to FAR 52.227-14. In this context, data means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and computer software. In addition, proposers may not build on top of limited rights components (i.e., existing proprietary software) unless they have prior approval in writing from the program manager and the contract officer.

Performers will be expected to complete iterations of the software version based on continuous feedback from providers and staff and demonstrate that software iterations have greater integration and interoperability capabilities. An open-source version of the software will serve as a platform for community-driven enhancements and ensure that final software toolbox meets critical demand of clinical use cases. Finally, **performers must** describe any barriers or challenges anticipated during transition and commercialization as well as strategies to address these issues. The report should contain quantifiable metrics and outcomes for measuring commercialization success (e.g., sales targets, partnerships, licensing and technology adoption by health systems and device manufacturers).

**Table 7:** TA3 milestones.

| TA | Phase | Month | Milestones |
|---|---|---|---|
| TA3: Medical IoT Platform | I | 12 | Gather requirements from device and EHR vendors and other stakeholders |
| | | | Design and code a software prototype |
| | II | 24 | Deploy software in the clinical environment of CDP |
| | | | Develop caching strategy for intermittent internet connectivity |
| | | | Conduct user testing in collaboration with TA1 and TA2 performers |
| | | 36 | Demonstrate that software iterations have greater integration and interoperability capabilities |
| | | 48 | Ensure that final software toolbox meets critical demand of clinical use cases |
| | III | 60 | Create an open source version of software and deliver commercial transition report |

### 1.3.8. TA4: Rugged & Miniaturized CT Scanner

**Technical area rationale and objectives**
The Computed Tomography (CT) scanner is one of the most common advanced medical imaging devices, and over 80 million CT scans are performed in the U.S. per year. This device is an irreplaceable imaging modality for diagnosing both acute and chronic conditions. While other advanced imaging modalities like ultrasound and MRI have been miniaturized, the size, weight, and power requirements of body CT scanners have not changed in the past 50 years. The CT scanner must be redesigned for use in out-of-hospital settings to make this essential imaging modality available to rural populations. PARADIGM will build a miniaturized, ruggedized, self-shielded CT scanner by reimagining both the hardware and software design elements of the device. Several technical challenges must be overcome to succeed. An approach for decreasing device size, weight, and power (SWaP) constraints may require innovating a non-rotating, stationary ring gantry with a rapidly pulsing x-ray tube to generate a series of images from multiple angles. Existing x-ray source hardware would need to be redesigned to obtain needed images while generating minimal heat. The generated series of two-dimensional images would require validation and implementation of novel software reconstruction algorithms to generate a high-quality three-dimensional image from such a source. Overcoming these technical hurdles would reduce size, weight, and power requirements of the CT scanner by 80-90% and facilitate rural access to CT imaging by creating a portable CT scanner that can be used in various environments.

**TA4 proposers must include plans to develop a CT scanner** that meets the requirements and metrics indicated below. They must also perform on schedule as detailed in the milestones table at the end of this section. The planned device and any accessories or attachments must have a footprint no larger than 32 square feet and a total weight of no more than 500 pounds. Designs must include plans for protecting the device from vibrations, lateral swaying, and tilting expected from being transported in a mobile CDP unit over rural roads. Designs must include plans for protecting the device from extremes of temperature when the CDP unit is not in use (e.g., when parked overnight outdoors). The planned device must be self-shielding to meet FDA radiation safety limits for both patients and technicians.

**Strong proposals** will include designs that are more compact than these baseline requirements. One option is to design the device considering a standing patient. If a standing patient is targeted, accommodation must be designed (supports, grab bars, etc.) for a patient who is unable to stand unaided. If a supine or seated patient is targeted, proposals may design a multipurpose patient table or chair that can reasonably serve the other diverse clinical procedures to be expected in a CDP unit as well as the CT scanner. If so, the table or chair need not be considered in the calculation of the devices' size or footprint, and in this case the footprint of the CT scanner alone must not be larger than 16 square feet. Proposed scanners must not exceed 50 kW of peak power draw and must use less than 1 kWh of total power per scan.

**Proposers must produce at least two working research prototypes of the CT scanner** capable of performing diagnostic quality full-body scans and body region scans on human subjects. One of these

devices must be integrated within a CDP unit provided by the TA2 performer, ruggedized to survive travel on typical rural roads, and be capable of enduring large changes of temperature between periods when the device is not in use (overnight), and when the CDP unit's heating/cooling system is operational. This integrated device will be used for *in situ* testing and evaluation so it must remain within the unit for the duration of the program. The other prototype may be used for human subjects' testing (e.g., non-inferiority studies).

**TA4 performers are expected to collaborate** with TA2 performers to ensure that the CT scanner and CDP unit designs are mutually compatible for eventual integration and use. Proposals will include plans for interactions with TA2 performers through virtual meetings and, if deemed necessary, site visits. TA4 performers will collaborate with the PARADIGM IV&V team while establishing methods for evaluating program metrics including image evaluation software, digital and physical phantoms, and radiologist's scoring of human subjects' scans.

### TA4 Metrics

TA4 performers will be evaluated based on metrics of quality, safety and technology maturity (Table 8) to ensure that the CT device developed will be ready for commercial transition by the end of the program.

**Table 8:** TA4 metrics.

| | | Phase I (12 mo): Initial Prototype | Phase II (36 mo): Evaluation of Operational Capabilities | | | Phase III (12 mo): Transition |
|---|---|---|---|---|---|---|
| | **Metric** | **End of year 1** | **End of year 2** | **End of year 3** | **End of year 4** | **End of year 5** |
| **TA4: CT Scanner** | **Quality** (image noise, accuracy, inter-reader reliability) | Digital prototype 50% target in digital phantom study | Digital prototype 90% target in digital phantom study | Research prototype 75% target in phantom study | Research prototype 100% target in phantom study | Final prototype 100% American College of Radiology standards |
| | **Safety** (FDA maximum radiation exposure thresholds for patients and operators) | n/a | ≤ 5 | ≤ 1 | ≤ 1 | ≤ 1 |
| | **Maturity** (Technology Readiness Level #) | ≥ 3 | ≥ 4 | ≥ 5 | ≥ 6 | ≥ 7 |

### TA4 Phases and Milestones

#### Phase I (months 1-12)

Two proposers will be selected, and each performer will work closely throughout the Phase with the CDP integrator of TA2 and other program stakeholders focusing on CDP integration planning and program use cases. In the first year, key metrics and milestones will focus on **building an *in silico* digital prototype (Technology Readiness Level 3)** that will meet or exceed SWaP requirements while delivering image quality suitable for diagnostic needs. This effort will include developing new image reconstruction algorithms. Performers will work closely with the IV&V team to **establish testing software requirements**, **digital phantoms, and scenarios for evaluation** of their models and algorithms, and to establish image quality metrics. At 6 months, the **TA4 performers will demonstrate the capabilities of their image reconstruction algorithm and procedures**. The IV&V team will validate these demonstrations and may request input data, code, output data, and other materials as needed. Near the end of Phase I and on a schedule set by the IV&V team, **performers will deliver their digital prototype models, algorithms, and all required data and documentation** to the IV&V team. **Performers will initiate contact with FDA and, if appropriate, make a Q submission (Q-Sub).** Performers will prepare an end of Phase I report detailing progress to date and updated plans for meeting all future program requirements, metrics, and milestones.

#### Phase II (months 13-48)

Performers will develop, integrate, and test multiple subsystem components and **create an engineering-level (i.e., sub-systems integrated but not ready for human testing) prototype** before the end of program month 24. At this time, performers will work with the IV&V team to **arrange site visits, demonstrations, and presentation of any required data** including updated computer models and algorithms to demonstrate adequate progress toward future milestones and metrics. With input from the

IV&V team, **the program will down-select to a single performer**. During the remainder of Phase II, **the performer will plan and execute a market research study** to determine demand for the commercialization of their device and begin to develop a business plan for that transition.
The performer will progress to create two research-level prototypes capable of being integrated into a model CDP and being used for human subjects testing. By the end of program month 36, they will have completed initial testing of the research prototype and obtained regulatory permission to begin human subjects' testing. Once permissions have been obtained, the TA4 performer will begin human subjects' testing of the scanner research prototype's performance. Beginning at month 36, the performer will work with the IV&V team to provide demonstrations showing that all metrics have been or will be met by the end of the Phase. The TA4 performer will collaborate with the TA2 performer to integrate one of their two research prototypes into a provided CDP unit and begin testing of the installed scanner including testing of ruggedness and usability. The performer will prepare an end of Phase report detailing progress to date and plans for meeting Phase III requirements.

**Phase III (months 49-60)**
**ARPA-H and the TA4 performer will equally share costs incurred in Phase III**. During this Phase, the performer will continue making prototype refinements and move towards regulatory approval. The performer will test the CDP-integrated and stand-alone research prototypes with human subjects. Depending on the performer's approach to technologic innovation, the regulatory approval process may involve different pathways. By the end of Phase III, the performer will have achieved either of the following: (1) The performer received an investigational device exemption along with Institutional Review Board (IRB) approval to conduct a human subjects' study or clinical research study **and** have gathered safety and effectiveness data required to submit a premarket approval. (2) The performer received FDA medical device approval. The TA4 performer will support refinement of CT integration into the CDP, initiate or continue discussions with the FDA, and deliver a transition plan outlining a roadmap for regulatory approval and marketplace transition. The performer will provide demonstrations of the CDP-integrated CT scanner to interested parties as requested by PARADIGM's Program Manager (PM). The performer will provide an end of program report summarizing all activities and achievements throughout all phases of the program.

**Table 9:** TA4 Milestones.

| TA | Phase | Month | Milestones |
|---|---|---|---|
| TA4: Rugged & Miniature CT Scanner | I | 6 | Demonstration of image reconstruction algorithm |
| | | 12 | Demonstrate *in silico* prototype including computational model of combined product, image quality metrics and SWaP estimates |
| | II | 24 | Demonstrate an engineering prototype including with tested and integrated subsystem components |
| | | 36 | Demo a research prototype (safety testing and initial human / phantom testing) & initiate regulatory approval engagements |
| | | 48 | CDP integration into CDPv2 and image quality, ruggedness and usability testing |
| | | | Continue FDA pre-meetings / non-inferiority studies underway, obtain IDE or file for 510K with FDA |
| | | | Complete market research study, begin business/transition plan |
| | III | 60 | Completion of CT refinement and integration into CDPv2, testing, evaluations and demonstrations |
| | | | Human subjects research / clinical trial underway OR FDA approval received |
| | | | Deliver commercial transition report |

### 1.3.9. TA5: Intelligent Task Guidance

**Technical area rationale and objectives**
TA5 will equip CDP staff with an **easy-to-use and interactive intelligent task guidance system that will provide real-time task guidance and decision support**, which will help turn a generalist into a just-in-time specialist. Currently, healthcare workforce shortages impact multiple geographic regions across the country and disproportionately affect rural areas. The limited number of specially trained personnel is

further exacerbated by high employee turnover leading to a perpetual inability to meet growing healthcare demand. Mobile health programs can help bridge this gap by bringing critical healthcare capacity to under-resourced communities and through extending the existing broad skillset of locally based staff to include specialized procedures and diagnostic tests. While CDPs expand the reach of hospitals, they require staff to perform a broad range of tasks with varying frequency and degree of difficulty, which contrasts with a large diversely trained hospital-based staff. Maximizing the value of CDPs will require expanding the number of services a CDP worker can provide while optimizing the quality and efficiency of that care.

PARADIGM's CDPs will be deployed across a wide spectrum of rural and under-resourced communities offering different clinical use cases and procedure types from cancer screening to perinatal care to home-hospital services provided by personnel with varying levels and domains of expertise (e.g., midwives, technicians, nurses, etc.). CDP locations and clinical services will be proposed by TA1 performers. **TA5 performers must propose a specific clinical service that is divided into clearly defined subtasks** for the intelligent task guidance system. **Strong proposals** may include services such as performing an ultrasound in one or more anatomical regions or doing a standard medical procedure (e.g., venous blood draw). Proposers are encouraged to suggest a service (e.g., procedure, diagnostic test, operating a medical device, or specialized exam) that aligns with their technical background then to engage with TA1 performers to align on clinical use cases and services. Intelligent task guidance systems will direct users through discrete basic tasks in Phase I as proof-of-concept that will increase in complexity through Phase II towards the complete clinical service as outlined in Table 11: TA5 milestones. An intelligent task guidance system must be able to interpret and navigate continually changing and variable CDP environments to track steps in complex processes, incorporate explicit and implicit knowledge, and support user decision-making in real-time. To accomplish this goal, **TA1 performers must consider four critical areas in their guidance system design and development**: (1) component models leveraging datasets of varying sizes and sources; (2) hardware that guides a user within the CDP environment; (3) assessments that measure the system's impact on task proficiency and user trust; and (4) strategies for addressing bandwidth limitations.

TA5 proposals must describe the types of component models used and their interactions. Such models may include the following:

- ***Environment models*** that spatially map and localize objects within a given surrounding. Performers may consider good engineering controls (e.g., equipment labels, tags, interlocks, access controls, barrier curtains, etc.) and nominal operating conditions (e.g., heating, ventilation, and air conditioning (HVAC) controls, lighting controls, etc.).
- ***Task models*** that understand when a procedure has commenced and when it will reach completion—successfully or unsuccessfully. Performers may consider human action recognition (HAR) over different time intervals considering variations in pose, shape, and motion (anthropometric variations), fusion of motion and appearance (multi-view variations), image quality and frame-rate issues, camera motion, illumination variation, and dynamic and cluttered backgrounds.
- ***User state models*** that know the physical state of a user in relation to the environment or task. Performers may consider pose-estimation, gaze-estimation, depth ambiguities, and occlusion.
- ***Cognitive models*** with explicit knowledge required to conduct tasks and implicit knowledge assumed. Performers may consider interaction with the task, user, and environment models to get the data necessary for evaluating the degree of correctness that needs to be achieved for attaining the best measurement.
- ***Recovery models*** that know when results from a procedure are insufficient or unsuccessful as well as how to resolve issues. Performers may consider human-computer interaction errors, task order errors, equipment failure, and whether a closed-loop recovery is sufficient for a desired

behavior. A closed-loop recovery means that error signals are used as inputs (e.g., task and environment models for resetting task). An open-loop recovery behavior means that the error is reported, and human performers reset functions.

- ***Interaction models*** that know how, when, and what to communicate visually and verbally. Performers may consider text-to-speech synthesis, pre-recorded audio, and video instruction.

Limited datasets pose a technical risk by hindering the development of intelligent task guidance system models capable of accurately directing users through rare or unpredictable situations. Incorporating expert training through audio/visual data and creating innovative methods for using sparse data would mitigate such risks. **To this end, performers must describe how training datasets will be acquired and managed as well as potential challenges and proposed solutions** that take into consideration the size and sources of data (e.g., textbooks, videos of experts, pictures, etc.). Proposers should describe the methods and approaches for developing or collecting a training dataset. Section III.D (Management Plan) should describe and justify adequate personnel capacity that accounts for the needs of prototype research & development and systems integration.

**TA5 proposals must describe how the intelligent task guidance system enables information transfer within the CDP environment** including real-time interaction with CDP personnel. Proposals must describe essential hardware (e.g., audio and video), positioning within a CDP-like environment, and ways in which different modalities (e.g., sound, sense, and sight) will be used to communicate through different interfaces (e.g., projector) with CDP personnel in a way that minimizes ambiguity. **Strong proposals will consider design features that avoid the risk of overloading the user with too much information** and inadvertently hindering decision-making. Proposers should describe the hardware, data sources, and approaches for enabling information transfer for model training and real-time communication.

The central goal of TA5 is to create a task guidance system that users trust and that significantly improves proficiency of task execution without compromising accuracy or safety. To this end, **proposals must describe methods for performing the following tasks**: (1) obtain baseline metrics (e.g., efficiency, speed, and accuracy) before and after standard training for performing the clinical procedure (e.g., number of errors made by a trainee at day 1, halfway through, and at graduation); (2) measure human-machine teaming performance; and (3) assess trust and usability (e.g., confidence in reliability of guidance system) with the test practitioner. Proposers should describe in the proposal the quantitative and qualitative approaches for assessing the aforementioned user-related metrics. In addition, proposers should describe any known existing or anticipated challenges they might encounter when setting baselines or measuring human-machine teaming performance then suggest strategies to query and address these during the program. Section III.D (Management Plan) should describe and justify adequate personnel capacity that accounts for the needs of user interface design and performance testing. TA5 performers will make all reasonable efforts to assure that bias on the basis of race, gender, or other protected classes is excluded from training data and function of systems especially regarding language (i.e. communication between task guidance system and users) and the use of images.

Due to potential availability constraints of consistent Starlink or mobile broadband-based connections, **proposals must describe strategies for addressing bandwidth limitations in austere environments**. Such performance conditions may include edge-computing solutions, federated learning, and other data architectures. Proposers should describe in Section II.A (Technical Approach) and Section III.C (Technical Plan) detailed strategies for overcoming bandwidth limitations and projected constraints of each approach. Section III.D (Management Plan) should describe and justify adequate personnel capacity that accounts for the needs of user information storage, processing, and exchange.

**TA5 performers will maintain ongoing information exchange** with other TAs throughout the duration of the program. TA5 performers are expected to collaborate with TA1 performers to ensure that intelligent task guidance systems are serving a clinically relevant need in a way that is ethical, equitable, and incorporates a user-centered design approach. TA5 performers will work with TA1-TA3 performers regarding specific hardware and software requirements for the CDP operability from initial prototype v1 through CDP integration and demonstration of effectiveness study.

### TA5 Metrics

TA5 performers will be evaluated based on 4 distinct metrics (Table 10) to ensure that the task guidance system will be ready to deploy on CDP units and be ready to transition as a sustainable technology by the end of the program. Starting with at least 2 clinical tasks and increasing to seven or more by the end of the program, performers will demonstrate proficiency, technological maturity, and various measures of user satisfaction meeting the indicated targets.

**Table 10:** TA5 metrics

| | | Phase I (12 mo): Initial Prototype | Phase II (36 mo): Evaluation of Operational Capabilities | | | Phase III (12 mo): Transition |
|---|---|---|---|---|---|---|
| **Metric** | | **End of year 1** | **End of year 2** | **End of year 3** | **End of year 4** | **End of year 5** |
| **TA5: Intelligent Task Guidance** | **Skill breadth** (# of component tasks guided in each clinical service) | ≥ 2 | ≥ 3 | ≥ 4 | ≥ 5 | ≥ 7 |
| | **Maturity** (Technology Readiness Level #) | ≥ 3 | ≥ 4 | ≥ 5 | ≥ 6 | ≥ 7 |
| | **Useability** (Likert scale assessment of useability by staff, including novice adoption and satisfaction) | ≥ 50% operator satisfaction | ≥ 60% operator satisfaction | ≥ 70% operator satisfaction | ≥ 90% operator satisfaction | ≥ 95% operator satisfaction |
| | **Proficiency** (Procedural skills assessment based on expert designed competency assessment tool for each clinical service) | Target set by 12 months | ≥ 50% target competency | ≥ 60% target competency | ≥ 75% target competency | ≥ 95% target competency |

### TA5 Program Phases and Milestones

The program has three phases with key milestones and metrics. Throughout the program, **performers will submit frequent brief progress reports and intermediate deliverable drafts**. Milestones and associated accomplishments are listed below.

### Phase I (months 1-12)

Two proposers will be selected, and each will work closely with TA1 performers to align prospective task guidance systems with anticipated CDP clinical use cases and services. TA1 performers will engage TA2 performers to ensure that task guidance systems effectively integrate within the physical CDP environment and are operable with CDP electronic systems and data storage architecture. Performers will work closely with an IV&V team to establish data acquisition and model training plans as well as set validation baselines, endpoints, and scenarios for evaluation of their models and prototype task guidance systems, which will be presented as a strategic plan by 6 months. **By 12 months, performers must demonstrate an intelligent task guidance system prototype incorporating both physical (e.g., interactive hardware) and computational (e.g., novel training algorithms) component technologies.** This first prototype must guide a user through two or more simple tasks involved in a specific CDP-based service as chosen by the TA5 performer and in collaboration with TA1 performers. This prototype will be used for preliminary testing of task guidance system useability. By the end of Phase I, performers must have target metrics to evaluate their task guidance system's impact on user proficiency.

### Phase II (months 13-48)

By 18 months, performers will present an assessment of anticipated bottlenecks and technological barriers along with a strategic roadmap for meeting metrics by end of the program. **By 24 months, performers will demonstrate a user-driven prototype** (e.g., responds to voice, movements, or other actions taken by the user) within an instrumented mock-up of a CDP interior as well as present a quantitative and qualitative assessment of skill augmentation measuring user task proficiency, user satisfaction, and other

predefined metrics. **By 36 months, performers will demonstrate a device-driven prototype** (e.g., system interprets the environment and correct/incorrect actions to direct users towards the end goal) within an instrumented mock-up of a CDP interior along with continued performance assessments. **A down-select will occur at the end of year 3** as informed by IV&V on the performer's ability to meet key metrics, milestones, and progress towards a working prototype. Starting in year 4, the selected performer will integrate a refined prototype into CDP for a Phase III effectiveness study. In parallel to CDP integration, the performer will scale intelligent task guidance functionality by incorporating one or more clinical services.

**Phase III (months 49-60)**
During Phase III, performers will work with a contracted group to conduct an effectiveness study that evaluates the CDP-integrated prototype. Performers will publish results of the effectiveness study and assemble a commercial transition plan.

**Table 11:** TA5 milestones.

| TA | Phase | Month | Milestones |
|---|---|---|---|
| TA5: Intelligent Task Guidance | I | 6 | Deliver strategic plan outlining model training and system evaluation |
| | | 12 | Deliver intelligent task guidance system prototype for simple task(s) |
| | II | 18 | Deliver assessment of bottlenecks and barriers along with roadmap for meeting metrics |
| | | 24 | Deliver user-driven prototype integrated in mock-CDP and assess performance metrics |
| | | 36 | Deliver device-driven prototype integrated in mock-CDP and assess performance metrics |
| | | 48 | Scale system to guide user through an additional one or more clinical service(s) |
| | | | Complete CDP integration |
| | III | 60 | Perform demonstration effectiveness study and deliver commercial transition report |

### 1.3.10. Integration

All components developed under the TAs must be integrated into a single care delivery unit. **Proposals must identify a team member as the primary integrator** tasked with representing the performer's work on their specific TA and interfacing with integrators on other performer teams. Note that this person does not need to be the Principal Investigator (PI).

### 1.3.11. Independent Verification and Validation (IV&V) of the Technology

Throughout the program, performers will work with an IV&V team established by ARPA-H. The IV&V team will consist of subject matter experts from the Government, FRDCs, academia, and/or other relevant domains. The IV&V team will test and validate technology to confirm the performer's progress. The IV&V team will produce with cooperation of the selected Phase II TA2 performer, surveys and any other procedures needed to evaluate PARADIGM-related metrics (e.g., reliability, fleet management performance, and usability). Further, the IV&V team will test the ability of the PARADIGM technology to respond accurately to external communications and activation. Proposers should budget for monthly interactions with the IV&V team, plan for an in-person visit to key performer facilities for familiarization with techniques and anticipate provision of a sufficient number of devices to verify key program metrics. **Proposers should request the necessary funds to engage with IV&V teams.**

### 1.3.12. Open Software Standards

Performers will be expected to adhere to all relevant Government laws and policies applicable to data and information systems and technologies, including but not limited to:

- Common IT Security Configurations
- Federal information technology directives and policies
- Section 508 of the Rehabilitation Act of 1973 (29 USC 794d) as amended by P.L. 105-220 under Title IV (Rehabilitation Act Amendments of 1998)

- National Institute of Standards and Technology (NIST) Risk Management Framework Special Publications

A key goal of this program is to seed the establishment and growth of a fully interoperable system of medical device and records generation, transmission and storage. As such, all software IP first created in the performance of the contract will conform to a permissive open license, such as CC-BY, BSD, MIT, Apache 2.0 or similar.

All data generated by new devices and technology created in the PARADIGM program must be adherent to relevant standards established or endorsed by ONC (e.g., HL7, FHIR, DICOM, USCDI, and USCDI+).

Whenever an existing standard is available that meets technical needs of the program, performers must use the existing standard instead of creating their own. In cases where an existing standard provides only partial functionality, performers should extend the existing standard in a fully backwards compatible manner and create the documentation needed for ONC to evaluate extensions for inclusion in the national standard.

All Application Programming Interfaces (APIs) developed for PARADIGM must be founded on open standards and models such as REST, JSON, JSON-LD and utilize standard data models and ontologies if available. All data elements and structures in API calls must be mapped to a data dictionary that references the standards. APIs must be operable regardless of the data transmission technologies used, must be tolerant of unreliable data connections and must ensure consistency of data between remote devices and the EHR platform.

Finally, proposers may not build on top of limited rights components (i.e. existing proprietary software) unless they have prior approval in writing from the program manager and the contract officer.

### 1.3.13. Commercial Transition Support

Proposers who are selected for an ARPA-H award may apply for a team of non-government advisors known as Entrepreneurs in Residence (EIR) / Experts in Residence (XIR) or may apply to work with ARPANET-H Customer Experience Hub advisors in a similar capacity. In coordination with the PM, the EIR/XIR/IC Hub will provide commercial transition support to the awardee. The goal is to offer complementary capabilities to the team; hence, the extent of the work is flexible. Examples of tasks may include cost modeling, end-user engagement, market analysis and mapping, competitive analysis, techno-economic analysis, manufacturing and scale-up strategy, intellectual property (IP) securement strategy, and financial plan creation. All commercialization and transition activities should align to the technology's stage of maturity. EIRs/XIRs/IC Hub will work closely with ARPA-H's Project Accelerator Transition Innovation Office (PATIO) team to leverage its extensive network of U.S. investors, strategic partners, and mentors.

Proposers wishing to participate must do the following: (i) briefly (<1 page) describe a strategy for transitioning the technology into a product; or (ii) itemize EIR/XIR/ARPANET-H tasks with proposed costs for developing a viable Go-to-Market Strategy over the course of the program (<1 page included in total page count; example tasks are listed above). Participation in the program is voluntary but recommended. Performers are not expected to form a new company or leave their current research positions to pursue transition. Instead during the program, performers should identify appropriate partners for enabling transition.

### 1.3.14. Equity Requirements

ARPA-H is committed to equitable health care access irrespective of race, ethnicity, gender/gender identify, sexual orientation, disability, geography, employment, insurance, and socioeconomic status. Therefore, an Equity Officer (EO) will be involved in the expert review of proposals and performers throughout the program to ensure that assessments of metrics and milestones prioritize end-user needs. TA1 proposers must describe how they will engage specific stakeholder groups (e.g., patients and community organizations) to maximize health equity. **All performers must articulate how they will incorporate equity considerations** (e.g., diverse user demographics) into design, development, and testing of prototypes to ensure equal access and mitigation of bias. TA1 and other performers who may collect patient data in support of research deliverables must collect data elements that enable assessment of health equity and disparity indices[11,12](e.g., race, ethnicity, and other demographic data). **Performers must designate one team member as primary point of contact for equity activities** and considerations, then remain responsive to communication and coordination with the PARADIGM Equity Officer. Performers involved in the handling of personalized and/or identified demographics or health data must ensure appropriate privacy and security standards are met. All TA proposers should outline anticipated risks and potential ramifications of not meeting equity goals. The EO will be involved in review of all milestone reports and evaluations and will advise on how equity issues can be strengthened throughout the program.

### 1.4. PROGRAM METRICS & MILESTONES

ARPA-H will meet with PARADIGM performers at least monthly to review progress towards the metrics and milestones defined above. Performers should propose additional quantitative metrics and milestones appropriate to their specific approach for each Phase of the program that will demonstrate progress towards the program's goals. Achievement of all metrics as agreed to by ARPA-H is the basis for initiation of the optional Phases. Key overall program metrics and milestones are listed in Section 1.2.

### 1.5. GENERAL REQUIREMENTS

#### 1.5.1. Proposer Team Composition

Proposals are expected to include all the required expertise to achieve the goals the TA to which they are proposing. Specific content, communications, networking, and team formation are the sole responsibility of the proposing teams. Proposers must submit a single, integrated proposal led by a PI under a single prime contractor that addresses all program Phases relevant to proposed TA. Proposals must designate a project manager for the entirety of the effort. The project manager will serve alongside the PI as a primary point of contact for scientific and administrative matters, and he or she will ideally hold an advanced degree in a relevant field of study. Proposals should provide a detailed plan for coordination, including explicit guidelines for interaction among collaborators/subcontractors of the proposed effort.
ARPA-H will hold a Proposers Day (see Section 8, "Other Information") to facilitate the formation of proposer teams and enable sharing of information among interested proposers through the ARPA-H Opportunities Page and the Proposers Day registration website.

#### 1.5.2. Down-selects

Performers in TA2-5 will be evaluated on their progress and a series of down-selections will result in a single performer for each TA. Independent Verification and Validation (IV&V) evaluations will inform down-selections. See Figure 1 (Program timeline and Milestones) for schedule and timing of IV&V and down-selects.

## 2. PS AWARD INFORMATION

This PS may result in multiple awards of Other Transaction (OT) agreements. However, the number of awards selected will depend on the quality of the proposals received and the availability of funds. If warranted, portions of resulting awards may be segregated into pre-priced options. In the event that the Government desires to award only portions of a proposal, negotiations will commence upon selection notification. The Government reserves the right to fund proposals in phases with options for continued work, as applicable. The Government reserves the right to request any additional, necessary documentation to support the negotiation and award process. The Government reserves the right to remove a proposal from award consideration should the parties fail to reach agreement on award terms, conditions, cost, and/or the proposer fails to provide requested additional information in a timely manner. The Government Agreements Officer (AO) shall have sole discretion to negotiate all agreement terms and conditions with selected proposers.

A Model Agreement with basic terms and conditions will likely be posted with the Final PS. Proposers may submit red-line edits to the basic terms and conditions of the resulting instrument; however, the Government AO shall have sole discretion to negotiate any red-line edits that deviate from the basic terms and conditions. Further, a resulting OT Agreement will not require cost-sharing; however, ARPA-H reserves the right to negotiate cost-sharing as appropriate to the situation.

ARPA-H will apply publication or other restrictions, as necessary, if it is determined that the research resulting from the proposed effort will present a high likelihood of disclosing sensitive information including Personally Identifiable Information (PII), Protected Health Information (PHI), financial records, proprietary data, and any information marked Sensitive but Unclassified (SBU), Controlled Unclassified Information (CUI), etc. Any award resulting from such a determination will include a requirement for ARPA-H permission before publishing any information or results on the effort.

# 3. ELIGIBILITY INFORMATION

## 3.1. Eligible Applicants

All responsible sources capable of satisfying the Government's needs may submit a proposal to the PS. Specifically, universities, non-profit organizations, small businesses and other than small businesses are eligible and encouraged to propose to this PS.

## 3.2. Federally Funded Research and Development Centers (FFRDCs) and Government Entities

FFRDCs and Government Entities may not propose to this PS as a prime performer; however, subject to any restrictions (i.e., direct competition limitations as determined by the entity or potential limiting organizational conflicts of interest, etc.), FFRDCs and Government Entities may be included as part a prime performer's proposal, as a sub-awardee. As with all prime/sub-awardee teaming arrangements, the Government will only have privity of contract with the prime performer, and all payments will be made through the prime awardee.

If an FFRDC or Government entity is interested in working directly with the Government team supporting this program, please contact the PARADIGM Team at paradigm@arpa-h.gov.

## 3.3. Non-U.S. Organizations

Non-U.S. entities 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. However, Non-US entities are encouraged to collaborate with domestic U.S. entities. In no case will awards be made to entities organized under the laws of a covered foreign country (as defined in section 119C of the National Security Act of 1947 (50 U.S.C. § 3059)) or entities suspended or debarred from business with the Government.

### 3.4. Organizational Conflicts of Interest (OCI)

Proposers are required to identify and disclose all facts relevant to potential OCIs involving the proposer's organization and any proposed team member (proposed subawardee). Although the FAR does not apply to OTs, ARPA-H requires OCIs be addressed in the same manner prescribed in FAR subpart 9.5. Regardless of whether the proposer has identified potential OCIs under this section, the proposer is responsible for providing a disclosure with its proposal.[3] The disclosure must include the proposers, and as applicable, proposed team members' OCI mitigation plans. The OCI mitigation plan(s) must include a description of the actions the proposer has taken, or intends to take, to prevent the existence of conflicting roles that might bias the proposer's judgment and to prevent the proposer from having unfair competitive advantage. The OCI mitigation plan will specifically discuss the disclosed OCI in the context of each of the OCI limitations outlined in FAR 9.505-1 through FAR 9.505-4. The disclosure and mitigation plan(s) do not count toward the page limit.

### 3.5. Agency Supplemental OCI Policy

In addition, ARPA-H restricts performers from concurrently providing professional support services, including, Advisory and Assistance Services or similar support services, and being a technical performer. Therefore, as part of the FAR 9.5 disclosure requirement above, a proposer must affirm whether the proposer or any proposed team member (proposed subawardee, etc.) is providing professional support services to any ARPA-H office(s) under: (a) a current award or subaward; or (b) a past award or subaward that ended within one calendar year prior to the proposal's submission date.

If any professional support services are being or were provided to any ARPA-H office(s), the proposal must include:

- The name of the ARPA-H office receiving the support;
- The prime contract number;
- Identification of proposed team member (proposed subawardee) providing the support; and
- An OCI mitigation plan in accordance with FAR 9.5.

### 3.6. Government Procedures

The Government will evaluate OCI mitigation plans to avoid, neutralize, or mitigate potential OCI issues before award and to determine whether it is in the Government's interest to grant a waiver. The Government will only evaluate OCI mitigation plans for proposals selected for potential award under the PARADIGM PS evaluation criteria and funding availability.

[3] Entities are encouraged to reach out, via the Q&A process or by contacting the PS coordinator directly, prior to proposal submission if a potential OCI issue exists. The Government will not review a OCI mitigation plan at this time, but feedback regarding the potential OCI may be provided.

The Government may require proposers to provide additional information to assist the Government in evaluating the OCI mitigation plan.

If the Government determines a proposer failed to fully disclose an OCI; or failed to provide the affirmation of ARPA-H support as described above; or failed to reasonably provide additional information requested by the Government to assist in evaluating the proposer's OCI mitigation plan, the Government may reject the proposal and withdraw it from consideration for award.

# 4. PROPOSAL AND SUBMISSION INFORMATION

## 4.1. GENERAL GUIDELINES

- All submissions must be written in English with type not smaller than 12-point font. Smaller font may be used for figures, tables, and charts.
- Do not include elaborate brochures or marketing materials; only include information relevant to the submission requirements or evaluation criteria.
- Use of a diagram(s) or figure(s) to depict the essence of the proposed solution is permitted.
- All submissions shall be unclassified.
- 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.
- ARPA-H will post a consolidated Questions & Answers document on a regular basis. See Section 7.0.
- Files containing Controlled Unclassified Information (CUI) must be encrypted when sending over the Internet.
- Submissions sent through other mediums, channels other than what is prescribed herein, or after the prescribed PS deadline will not be considered, reviewed, nor evaluated.

## 4.2. PROPOSAL INSTRUCTIONS

### 4.2.1. Proposal Volume Templates

Proposers must provide the following information when submitting a proposal. Template documents and instructions for all volumes are provided as attachments to the PS (Attachment 2). Failure to utilize the templates and/or provide the information requested may result in a proposal being deemed non-conforming and/or delay the evaluation process discussed in Section 5.2. Proposals should express a consolidated effort in support of one or more related technical concepts or ideas addressing one TA.

**Volume 1 must consist of the following documents:**
TECHNICAL & MANAGEMENT
TASK DESCRIPTION DOCUMENT OR RESEARCH DESCRIPTION DOCUMENT

The maximum page count for the Technical & Management proposal is 40 pages. The Technical & Management proposal may include an attached bibliography (excluded from the page limit) of relevant technical papers or research notes (published and unpublished) that document the

technical ideas and approach upon which the proposal is based. Copies of not more than three relevant papers may be included with the submission. The submission of other supporting materials along with the proposal is strongly discouraged. These materials will not be considered for evaluation.

**Volume 2 must consist of the following documents** (*no page limit*):
PRICE/COST PROPOSAL
AGREEMENT CERTIFICATION
MODEL AGREEMENT

**Volume 3 must consist of the following documents:**
ADMINISTRATIVE & NATIONAL POLICY REQUIREMENTS

### 4.2.2. Model Other Transaction Agreement

Prior to submitting a proposal, proposers must review the model OT that is provided as an attachment to this PS (included within Attachment 2 – will be provided with the Final Solicitation). ARPA-H has provided the model OT to expedite the negotiation and award process. The model OT is representative of the terms and conditions that ARPA-H intends to include in the resulting award.

Proposers may suggest edits to the model OT for consideration by ARPA-H and provide a copy of the model OT with track changes as part of the proposal package. It is required that Proposers include comments providing rationale for any suggested edits of a non-administrative nature. Suggested edits may be rejected at ARPA-H's discretion.

## 4.3. PROPOSAL DUE DATE AND TIME

Proposals are due no later than 2:00 PM ET on April, 26, 2024. Full proposal packages as described in Section 4.4 must be submitted per the instructions outlined in the PARADIGM PS and in accordance with Attachment 2 and received by ARPA-H no later than the above time and date. Proposals received after this time and date will not be reviewed. Proposals shall be submitted to eCPS (https://ecps.nih.gov/).

Proposers are warned that the proposal deadline outlined herein is in Eastern Time (ET) and will be strictly enforced. When planning a response to this notice, proposers should consider that some parts of the submission process may take from one business day to one month to complete.

# 5. EVALUATION OF PROPOSALS

## 5.1. Evaluation Criteria for Award

Proposals will be evaluated using the following evaluation criteria, listed in descending order of importance.

- **Overall Scientific and Technical Merit**
  The proposed technical approach is innovative, feasible, achievable, and complete. Task descriptions and associated technical elements provided are complete and in a logical sequence with all proposed deliverables clearly defined such that a final outcome that achieves the goal can be expected as a result of award. The proposal identifies major technical risks and planned

mitigation efforts are clearly defined and feasible. In addition, the evaluation will take into consideration the extent to which the proposed intellectual property (IP) rights structure will potentially impact the Government's ability to transition the technology.

- **PROPOSER'S CAPABILITIES AND/OR RELATED EXPERIENCE**
  The proposed technical team has the expertise and experience to accomplish the proposed tasks. The proposer's prior experience in similar efforts clearly demonstrates an ability to deliver products that meet the proposed technical performance within the proposed budget and schedule. The proposed team has the expertise to manage the cost and schedule. Similar efforts completed/ongoing by the proposer in this area are fully described including identification of other Government entities.

- **POTENTIAL CONTRIBUTION TO RELEVANCE TO THE ARPA-H MISSION**
  Potential future R&D, commercial, and/or clinical applications of the project proposed, including whether such applications may have the potential to address areas of currently unmet need within biomedicine and improve health outcomes. Degree to which the proposed project has the potential to transform biomedicine is an important factor. Potential for the project to take an interdisciplinary approach is also valuable.

- **COST REALISM**
  Price and value analysis will be performed on each proposal to assess the reasonableness and value the overall proposed price provides the Government for the technical solution selected.

  When price and value analysis are inconclusive, cost realism analysis may be performed to ensure proposed costs are realistic for the technical and management approach, accurately reflect the technical goals and objectives of the solicitation, the proposed costs are consistent with the proposer's TDD and reflect a sufficient understanding of the costs and level of effort needed to successfully accomplish the proposed technical approach. The costs for the prime proposer and proposed sub-awardees should be substantiated by the details provided in the proposal (e.g., the type and number of labor hours proposed per task, the types and quantities of materials, equipment and fabrication costs, travel and any other applicable costs and the basis for the estimates).

  It is expected that the effort will leverage all available relevant prior research to obtain the maximum benefit from the available funding. **TA1 proposals must include a cost share strategy**. Mechanisms may include internal performer funding or external/other agency funding sources. Cost sharing must cover 25% of proposal budget in program year 4, and 50% in year 5. **For TA2-TA5 efforts with a likelihood of commercial application, appropriate direct cost sharing may be a positive factor in the evaluation**. Cost sharing is required in TA1 proposal budgets. ARPA-H recognizes that undue emphasis on cost may motivate proposers to offer low-risk ideas with minimum uncertainty and to staff the effort with junior personnel to be in a more competitive posture. ARPA-H discourages such cost strategies.

  Strong proposals will include a cost point that is commensurate with the scale and complexity of the proposed technical and management approach. Proposers should ensure that budgets align to the needs of the work being proposed. Budgets should focus on the tasks essential for achieving program goals and associated risk mitigation strategies. Budgets that are unrealistically high will require a full cost proposal (i.e., direct and indirect rates, labor hours, equipment, material, other direct costs, etc.) that must be substantiated by other than certified cost or pricing data. The

submission of a full cost volume will impact price/cost proposal review timelines and will likely be followed by extensive negotiations.

## 5.2. REVIEW AND SELECTION PROCESS

It is the policy of ARPA-H to ensure impartial, equitable, comprehensive proposal evaluations based on the evaluation criteria listed above and to select the source (or sources) whose offer meets the Government's technical, policy, and programmatic goals.

ARPA-H will conduct a scientific and technical review of each conforming proposal. All proposal evaluations will be based solely on the evaluation criteria in Section 5.1

Relative to the evaluation criteria, the Government will evaluate each conforming proposal in its entirety, documenting the strengths and weaknesses. Based on the identified strengths and weaknesses, ARPA-H will determine whether a proposal will be selected for award. Proposals will not be evaluated against each other during the scientific review process, but rather evaluated on their own individual merit to determine how well the proposal meets the criteria stated in PARADIGM PS.

An award will be made to a proposer(s) whose proposal is determined to be selectable by the Government, consistent with the instructions and evaluation criteria specified herein and based on the availability of funding. Given the limited funding available, not all proposals considered selectable may receive an award and funding.

For the purposes of this proposal evaluation process, a selectable proposal is defined as follows:

**SELECTABLE:** A selectable proposal is a proposal that has been evaluated by the Government against the evaluation criteria listed in the PS, and the positive aspects of the overall proposal outweigh its negative aspects. Additionally, there are no accumulated weaknesses that would require extensive negotiations and/or a resubmitted proposal.

For the purposes of this proposal evaluation process, a non-selectable proposal is defined as follows:

**NON-SELECTABLE:** A proposal is considered non-selectable when the proposal has been evaluated by the Government against the evaluation criteria listed in the PS, and the positive aspects of the overall proposal do not outweigh its negative aspects. Additionally, there are accumulated weaknesses that would require extensive negotiations and/or a resubmitted proposal.

**CONFORMING PROPOSALS:** Conforming proposals contain all requirements detailed in the PARADIGM PS. Proposals that fail to include required information may be deemed non-conforming and may be removed from consideration. Non-conforming submissions may be rejected without further review. A proposal will be deemed non-conforming if the proposal fails to meet one or more of the following requirements:

- The proposed concept is applicable to goal and objectives described in the PARADIGM PS.
- The proposers meet the eligibility requirements of the PARADIGM PS.
- The proposal met the submission requirements of the PARADIGM PS.
- The proposal met the content and formatting requirements in the attached templates to this PARADIGM PS.
- The proposal provided sufficient information to assess the validity/feasibility of its claims.

- The proposer has not already received funding or a positive funding decision for the proposed concept (whether from ARPA-H or another Government agency).

Non-conforming proposals may be removed from consideration. Proposers will be notified of non-conforming determinations via email correspondence.

### 5.3. HANDLING OF COMPETITIVE SENSITIVE INFORMATION

It is the policy of ARPA-H to protect all proposals as competitive sensitive information and to disclose their contents only for the purpose of evaluation and only to screened personnel for authorized reasons, to the extent permitted under applicable laws. Restrictive notices notwithstanding, during the evaluation process, submissions may be handled by ARPA-H support contractors for administrative purposes and/or to assist with technical evaluation.

All ARPA-H support contractors are expressly prohibited from performing ARPA-H sponsored technical research and are bound by appropriate nondisclosure agreements. Input on technical aspects of the proposals may be solicited by ARPA-H from non-Government consultants/experts who are strictly bound by appropriate non-disclosure requirements. No submissions will be returned.

## 6. AWARDS

### 6.1. GENERAL GUIDELINES

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

In order to receive an award:

- Proposers must register in the System for Award Management (SAM). See Section 6.3.1
- Proposers must be determined to be responsible by the Agreements Officer and must not be suspended or debarred from award by the Federal Government nor be prohibited by Presidential Executive Order and/or law from receiving an award.

### 6.2. NOTICES

#### 6.2.1. PROPOSALS

The following notices will be provided as applicable:

- Request for clarifying details (if applicable)
  *May occur at any time during the evaluation process after proposal submission. Will not include requests for proposal changes and changes will not be permitted.*
- Request for additional information (if needed)
  *Proposers will be advised of any deficiencies and/or major weaknesses in their proposals and given an opportunity to respond, to include offering proposal amendments.*
- Notice of non-selection
- Notice of selection

Once the evaluation of proposals is complete, the proposers will be notified that (1) the proposal has been selected for funding, subject to OT agreement negotiations. This notification may indicate that only a part of the effort has been selected for negotiation and may request a revised proposal for only those selected portions, if not apparent through the delineation of proposed tasks; or (2) the proposal has not been selected for funding.

The above listed notifications will be sent via electronic mail to the Technical and Administrative points of contact identified on the proposal coversheet.

## 6.3. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS

### 6.3.1. System for Award Management (SAM) Registration and Universal Identifier Requirements

All proposers must be registered in SAM and have a valid Unique Entity ID (UEI) number at time of proposal submission. Performers must maintain an active registration in SAM.gov with current information at all times during which they have an active Federal award or idea under consideration by ARPA-H. Information on SAM.gov registration is available at SAM.gov.

**NOTE**: New registrations can take an average of 7-10 business days to process in SAM.gov. Registration requires the following information:

- SAM UEI number
- TIN
- Commercial and Government Entity Code (CAGE) Code. If a proposer does not already have a CAGE code, one will be assigned during SAM registration.
- Electronic Funds Transfer information (e.g., proposer's bank account number, routing number, and bank phone or fax number).

### 6.3.2. Controlled Unclassified Information (CUI) or Controlled Technical Information (CTI) on Non-DoD Information Systems

Further information on Controlled Unclassified Information identification, marking, protecting and control is incorporated herein and can be found at 32 CFR 2002.

### 6.3.3. Intellectual Property (IP)

Proposers must provide a good faith representation that the proposer either owns or possesses the appropriate licensing rights to all IP that will be utilized for the proposed effort.

ARPA-H intends to maintain ownership and unlimited rights to data and software products first produced in the performance of this program. In this context, data means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and computer software. Proposers should appropriately identify any desired restrictions on the Government's use of any Intellectual Property contemplated under the award. This includes both noncommercial and commercial items. Respondents should utilize the prescribed format within the Administrative & National Policy Requirements Document Template (Volume 3 of Attachment 2 to this PS) when asserting restrictions. If no restrictions are intended, then the proposal should state "NONE."

### 6.3.4. Human Subjects Research

All entities submitting a proposal for funding that will involve engagement in human subjects research (as defined in 45 CFR § 46) must provide documentation of one or more current Assurance of Compliance with federal regulations for human subjects protection, including at least a Department of Health and Human Services (HHS), Office of Human Research Protection Federal Wide Assurance. All human subjects research must be reviewed and approved by an Institutional Review Board (IRB), as applicable under 45 CFR § 46 and/or 21 CFR § 56. The human subjects research protocol must include a detailed description of the research plan, study population, risks and benefits of study participation, recruitment and consent process, data collection, and data analysis. Recipients of ARPA-H funding must comply with all applicable laws, regulations, and policies for the ARPA-H funded work. This includes, but is not limited to, laws, regulations, and policies regarding the conduct of human subjects research, such as the U.S. federal regulations protecting human subjects in research (e.g., 45 CFR § 46, 21 CFR § 50, § 56, § 312, § 812) and any other equivalent requirements of the applicable jurisdiction.

The informed consent document utilized in human subjects research funded by ARPA-H must comply with all applicable laws, regulations, and policies, including but not limited to U.S. federal regulations protecting human subjects in research (45 CFR § 46, and, as applicable, 21 CFR § 50). The protocol package submitted to the IRB must contain evidence of completion of appropriate human subjects research training by all investigators and personnel who will be directly involved in the design or conduct of the ARPA-H funded human subjects research. Funding cannot be used toward human subjects research until ALL approvals are granted.

#### 6.3.5. Animal Subjects Research

Award recipients performing research, experimentation, or testing involving the use of animals shall comply with the laws, regulations, and policies on animal acquisition, transport, care, handling, and use as outlined in: (i) 9 CFR parts 1-4, U.S. Department of Agriculture rules that implement the Animal Welfare Act of 1966, as amended, (7 U.S.C. § 2131-2159); (ii) the Public Health Service Policy on Humane Care and Use of Laboratory Animals, which incorporates the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training," and "Guide for the Care and Use of Laboratory Animals" (8th Edition)." Proposers must complete and submit the Vertebrate Animal Section worksheet for all proposed research anticipating Animal Subject Research. All Animal Use Research must undergo review and approval by the local Institutional Animal Care Use Committee (IACUC) prior to incurring any costs related to the animal use research.

### 6.4. Electronic Invoicing and Payments

Performers will be required register in and to submit invoices for payment for invoicing in the Payment Management Services (PMS) system. PMS is a centralized payment and cash management system. ARPA-H other transaction are made by PMS, operated by PSC, in accordance with Department of the Treasury and OMB requirements. PMS guidance can be found here: https://pms.psc.gov/training/grant-recipient-training.html.

## 7. COMMUNICATIONS

ARPA-H intends to use electronic mail for all correspondence regarding the PARADIGM PS. Administrative questions regarding this PS should be emailed to the PARADIGM PS Coordinator. ARPA-H will post a Q&A document to SAM.gov regarding all administrative questions submitted to this

PS on an as needed basis. All questions must be in English and must include the name, email address, and telephone number of a point of contact.

ARPA-H will attempt to answer questions in a timely manner. In order to receive a response sufficiently in advance of the proposal due date, questions should be submitted on or before the Q&A deadline stated herein.