

Innovative Solutions Opening (ISO)

SURPASS: Simulation-augmented, Real-time Platform Adaptive Seamless Trials

Proactive Health Office (PHO)

ARPA-H-SOL-26-164

30 September 2026

Amended 13 November 2026

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1.0 Innovative Solutions Opening (ISO) Summary Information

Federal Agency: Advanced Research Projects Agency for Health (ARPA-H), Proactive Health Office (PHO)

Program Title: Simulation-augmented, Real-time Platform Adaptive Seamless Trials (SURPASS)

Announcement Type: Solicitation, Amendment

- Amendment 01: 13 November 2026

ISO Solicitation Number: ARPA-H-SOL-26-164

Dates:

- Informational Webinar (online): 15 OCT 2026, 12-1pm ET
- Proposers' Day: hybrid format, Washington, DC
    - Day 1: 6 NOV 2026, 9am – 5pm ET (in-person and virtual)
    - Day 2: 9 NOV 2026, 9am – 12pm ET (virtual)
- Questions Due: 2 NOV 2026
- Solution Summary Due Date (ISO Closing Date): 30 NOV 2026 by 5pm ET
- Solution Pitch Package Due Date*: 22 JAN 2027 by 5pm ET
- Solution Pitches*: 1-5 FEB 2027

Anticipated awards: Multiple Other Transaction (OT) Agreements

Agency Contact: All inquiries shall be sent to SURPASS@ARPA-H.GOV

*These due dates are estimates. The final due dates will be confirmed in Solution Summary Feedback letters.

1.1 ISO Purpose

ARPA-H seeks proposals from all eligible entities (see Section 3, *Eligibility Information*) to accomplish the SURPASS program goals as described in this solicitation package. Ultimately, ARPA-H intends to negotiate multiple OT Agreements with Proposers whose proposals are most advantageous to the government.

1.2 ISO Questions and Answers

All questions regarding this ISO must be submitted to SURPASS@ARPA-H.GOV. ARPA-H will post Q&As to the SURPASS program webpage on an on-going basis and will not respond to questions directly, except when appropriate. All questions must be submitted in English and

must include the name, e-mail address, and telephone number of a point of contact. Proposers submitting questions to individual government team members (e.g., Program Manager) should not expect a response. ARPA-H will attempt to answer questions in a timely manner; however, questions submitted after the Q&A due date may not be answered. Further, duplicative questions may be combined and rephrased to streamline responses.

1.3 Informational Webinar and Proposers' Day

ARPA-H will host an informational webinar on Thursday October 15th at 12-1pm ET and a hybrid Proposers' Day on November 6th and 9th 2026 in support of the SURPASS program. The purpose of these events is to provide potential Proposers with information on the SURPASS program, promote discussion, and encourage team networking. Interested Proposers are not required to attend; materials formally presented at the webinar and at the Proposers' Day will be posted to arpa-h.gov. ARPA-H will not reimburse potential Proposers for participation at the Proposers' Day (nor for time and effort related to the submission of Solution Summaries or Solution Pitch Packages, or virtual presentations). Registration and additional details will be posted to the SURPASS program webpage and https://sam.gov.

2.0 The Program

2.1 SURPASS Overview

2.1.1 SURPASS Goals

SURPASS envisions a future in which clinical development operates as a continuous learning system rather than as a sequence of disconnected trials. In doing so, SURPASS directly advances the goals of HHS's Operation TrialBlazer to modernize clinical research, reduce unnecessary delays in drug development, and accelerate the delivery of new therapies while preserving scientific rigor. SURPASS seeks to shorten the clinical development of drugs and biologics by establishing Simulation-augmented, real-time Platform Adaptive Seamless Trials. These persistent, multi-arm trials will share operational infrastructure and control information, integrate validated predictions with accumulating patient data, support valid adaptive decisions as evidence emerges, and reuse regulatory and operational assets as intervention arms enter, stop, or graduate from the platform.

To achieve the goals of the program, SURPASS combines three integrated Technical Areas (TA) as described in Sections 2.2.3–2.2.5. Integration across the three TAs is also intended to make the SURPASS approach reproducible beyond the initial ARPA-H-funded platform trials. SURPASS seeks to produce a reusable blueprint for establishing future adaptive seamless platform trials, including transferable design and simulation methods developed under TA1, validated statistical and regulatory frameworks developed under TA2, and repeatable operational infrastructure and workflows

developed under TA3. Successful Core Platform Teams should therefore demonstrate not only that these capabilities function within their proposed platform, but that the resulting methods, tools, processes, and regulatory precedents can reduce the effort required to establish similar platforms in other disease areas or institutions.

2.1.2 The Clinical-Development Bottleneck.

Clinical development of a drug or biologic currently takes approximately 10 years, costs approximately $1 billion to $2 billion, and fails more than 90% of the time. Today, interventions generally progress through sequential Phase 1, Phase 2, and Phase 3 trials before submission of a New Drug Application or Biologics License Application. Each stage may require a new protocol, start-up process, control group, site network, contract structure, data system, and regulatory submission.

This multi-phase, multi-stop model creates repeated pauses and restarts. Infrastructure is rebuilt instead of maintained, control participants are recruited separately for each intervention, and clinical, statistical, regulatory, and operational learning is not systematically carried forward across phases or across drugs. Even when a candidate therapy is scientifically promising, the time, cost, and uncertainty associated with conventional development may make the program financially non-viable.

SURPASS aims to replace this fragmented process with a persistent adaptive platform capable of supporting first-in-human, efficacy, and, where appropriate, confirmatory evaluation within a single seamless clinical-development framework.

2.1.3 Patient Impact.

Long clinical-development timelines delay access to treatments and may prevent promising therapies from reaching patients at all. Treatments with lower projected commercial returns may not generate sufficient investment to survive conventional development, while limited clinical-trial capacity is consumed by repeated start-up activities and duplicative control groups. Patients may spend years waiting for effective treatments while interventions that do not work remain in development longer than necessary.

SURPASS aims to improve the clinical-development experience for patients by:

1) Testing more candidate treatments within standing platform infrastructure;
2) Identifying ineffective or unsafe intervention arms earlier;
3) Adaptively allocating more participants to better-performing arms while maintaining valid inference;

4) Sharing control information across concurrent intervention arms;
5) Graduating validated in silico information into the control strategy when scientifically and regulatorily justified; and
6) Reducing the time required to move effective treatment from initial human testing toward approval.

The platform-trial architecture also provides a reusable testbed in which new predictive models, statistical methods, and operational tools can be evaluated without requiring a separate clinical-trial infrastructure for each capability.

2.1.4 U.S. Competitiveness and Economic Impact

The cost and duration of conventional clinical development threaten U.S. leadership in biomedical innovation. Clinical trials and associated business activity increasingly move to locations where studies can be conducted more quickly and at lower cost. When trial activity moves outside the United States, scientific expertise, investment, operational infrastructure, and valuable business transactions may move with it.

The current model also wastes capital by delaying the identification of ineffective drugs, requiring duplicative infrastructure, and preventing data and operational learning from being reused. High development cost and investor risk may contribute to high launch prices and discourage investment in therapies for smaller or less commercially attractive patient populations.

SURPASS seeks to strengthen the U.S. clinical-trial ecosystem by establishing domestic expertise and infrastructure for first-in-human and advanced adaptive trials, lowering the marginal cost of adding a new intervention arm, and making sophisticated platform capabilities more accessible to startup and small biotechnology companies that may not be able to build comparable standalone trials. In this way, SURPASS directly advances HHS's Operation TrialBlazer by developing scalable infrastructure and methods intended to make the United States a faster, more efficient, and more attractive environment for clinical development while maintaining rigorous standards for evidence generation.

2.2 Technical Approach and Structure

2.2.1 Platform Trial Requirements

The SURPASS program will develop, integrate, and clinically validate the capabilities necessary to operate simulation-augmented, real-time platform adaptive seamless trials. Each Core Platform Team will establish a platform trial to study a single disease area. Key features of the platform trial include:

Master Protocol design with the capability to evaluate multiple interventions simultaneously and add new interventions as they become available. The platform must support multiple simultaneous interventions under a common operational structure while preserving intervention-specific scientific, safety, regulatory, and statistical requirements. Platform-level processes, documents, data structures, and decision rules must be established before initial trial launch. Regimen-, drug-, or arm-specific appendices and associated operational documents must be designed for efficient modification and incorporation as new arms join the platform.

Randomized, controlled trial designed to support sharing of control information across investigational arms. Shared controls are a key source of platform efficiency; proposals should be designed to maximize sharing of control information wherever appropriate. Individual arms may use different control strategies, such as different placebos, but these strategies should be selected so that control information can be combined across arms. Similarly, investigational arms should study similar patient populations; the impact of arm-specific inclusion and exclusion criteria should be addressed when it impacts the ability to share controls.

Seamless/phaseless design that supports drug development from first-in-patient to evaluation of efficacy. For purposes of this ISO, the terms seamless and phaseless are considered synonymous and refer to the integration of clinical trial phases. While recognizing that clinical trial phases may differ with each program, broadly speaking Phase 1 studies focus on initial safety and tolerability, PK/PD, dose finding, and proof of mechanism; Phase 2 studies further characterize dose and exposure-response relationships and provide preliminary evidence of efficacy, and may use sensitive, shorter-term, biomarker, or other endpoints that may not themselves support registration; and Phase 3 studies provide confirmatory evidence of efficacy and safety using endpoints appropriate to support regulatory approval.

At a minimum, each Core Platform Team must propose a seamless design that supports development of each investigational arm from first-in-patient safety evaluation through preliminary efficacy evaluation. For an ultra-rare disease, the proposed design should encompass clinical Phases 1, 2, and 3 and be capable of supporting registration unless commercial drug supply makes that approach infeasible and the proposer clearly describes the limitation and an alternative plan.

The design need not formally define or gate progression according to traditional clinical trial phases; however, the general objectives of each relevant phase should be addressed within the platform. Proposers are encouraged to integrate confirmatory or registrational evaluation into the seamless design.

End-to-end clinical operations framework capable of supporting the activities of multiple concurrent intervention arms within the persistent platform. Sponsors must establish a governance framework with defined roles and responsibilities, decision rights, escalation pathways, and interfaces among the lead platform operator, sponsors, sites, functional departments, and vendors. The framework must distinguish between platform level and intervention arm specific responsibilities and identify activities that may be standardized, shared, or automated across the intervention arms. The governance framework should also include how operational capacity will be scaled without compromising safety, integrity, compliance or quality.

2.2.2 Disease, Intervention, Sponsor, Operations, and Platform Selection

Proposers may select any disease area if they demonstrate substantial unmet patient need, suitability for a self-sustaining adaptive platform, and the ability to meet all program requirements. Neurodegenerative diseases are of particular interest for SURPASS platforms; however, these diseases often have prolonged follow-up times and proposers in these areas should demonstrate the proposed platform can achieve its objectives within the program timeline.

Proposers must demonstrate that the selected disease area has a sufficiently deep and diverse pipeline of candidate drugs or biologics, together with sufficient sponsor demand, to sustain continued platform use for approximately a decade after SURPASS funding ends. Proposers must also demonstrate the ability to establish a multi-site clinical network and open the first site to enrollment no later than program year 2.

The ideal disease-area selection will balance the magnitude of the unmet patient need with the ability to prove out the SURPASS thesis during the program execution (e.g., availability of supporting elements at the start of the program, and a fast enough disease progression to read out during the program). For example, Alzheimer's disease has a large, affected population and substantial unmet need, but the long follow-up required to evaluate clinical endpoints may make it difficult to demonstrate the value of innovative design elements within the program timeline. Other considerations include: the potential benefit of faster clinical development; the availability of relevant natural-history, clinical, biomarker, and other data needed for predictive modeling, trial simulation, and prospective validation; regulatory, operational, and drug-supply feasibility; and the economic rationale for ARPA-H investment in establishing the platform.

Each Core Platform Team must propose at least three drug or biologic intervention arms. At least two proposed interventions should not be approved for any indication, including at least one drug or biologic with no prior patient data. The intervention without prior patient data may enter later in the program, and the platform may initially launch with interventions that already have patient data. Each Core Platform Team should include at

least two for-profit drug or biologic sponsors, including at least one startup or small company. Inclusion of an investigator-initiated intervention arm is encouraged.

Each platform must include at least six clinical sites by the end of the program. A single entity (organization or individual) must hold the master clinical protocol IND and Statistical Analysis Plan. Centralized or commercial Institutional Review Boards are preferred, and proposed processes must support IRB approval in less than one month. Proposers must describe the operational strategy for the clinical site network including site identification, feasibility, qualification, contracting, activation, training, and oversight. Site selection must consider patient population, experience, enrollment capability, capacity, competing trials and the ability to execute the platform requirements. This should also include performance measures and risk mitigations for escalations and underperforming sites.

Proposers must identify the critical operational activities and their dependencies to achieve readiness and describe the activities that will occur in parallel, which are critical path and how delays or challenges will be identified and mitigated.

Each Core Platform Team must identify a lead platform operator and describe why that entity has the expertise, infrastructure, authority, and long-term incentive to operate a persistent multi-sponsor platform. A disease-expert clinical institution or comparably durable organization is preferred. Alternative operating structures must be justified.

Proposals must describe the platform governance model, including:

a) Responsibility for the Master Protocol, IND, Statistical Analysis Plan, and common operational infrastructure.
b) Decision rights for adding, adapting, stopping, or graduating intervention arms.
c) Management of conflicts among participating sponsors.
d) Allocation of shared platform costs and arm-specific costs.
e) Data-access, confidentiality, publication, and model-governance policies.
f) Processes for incorporating follow-on sponsors and technology providers.
g) A transition plan for sustaining the platform after ARPA-H funding ends.
h) Clinical and operational decision rights and accountability across the platform operator, sponsors, investigators, and vendors.
i) Escalation pathways and timelines for any quality, safety, regulatory, data, supply or operational issues.
j) Vendor oversight of any third party that is supporting platform execution.
k) Processes to ensure continued integrity of safety, data, regulatory and inspection readiness as the platform scales.

2.2.3 Technical Area 1: Phaseless Design Engine

TA1 aims to develop a simulation-based design environment for adaptive seamless platform trials. The design engine must support integrated planning across first-in-patient, efficacy, and, where proposed, confirmatory clinical stages rather than optimizing each stage independently. The TA1 phaseless design engine should include:

a) Complete representation of the seamless adaptive platform design, to include stage-specific endpoints (as necessary), sharing of controls, and adaptive features defined under TA2.
b) Integration of in silico methods (additional detail below) with APIs that allow heterogeneous models to interoperate within a common trial-design environment.
c) Estimation of operating characteristics for investigational arms, such as average sample size, time-to-decision, statistical power, bias and estimation error.
d) Assessment of the platform-level performance, including throughput of investigational arms, time-to-first discovery, false positive/negative rate, and other applicable Program Metrics.
e) Simulator-construction tools that allow qualified non-developer trialists to construct, evaluate, and revise trial simulations.
f) Reproducible and auditable simulation workflows, including versioning of assumptions, designs, and simulation inputs and outputs.

The design engine must allow teams to evaluate alternative design choices before trial initiation and to revise the design as new interventions, data, or operating assumptions are introduced. Simulations must evaluate performance across a range of plausible operating scenarios, including uncertainty in investigational-arm and control outcomes, operational factors such as recruitment and the timing of new arm entry, and the performance of in silico models. Once the platform is underway, simulation assumptions and operating-characteristic estimates should be updated as relevant blinded information accumulates, including observed enrollment rates, arm-specific recruitment, control-event rates, and other factors that materially impact platform performance. Before the end of Year 5, performers should plan to re-simulate the platform design using simulation parameters informed by real-world information and, if necessary, refine the design to optimize performance under these more realistic conditions.

Outputs from the design engine may be used to support regulatory interactions, in which case they should be consistent with FDA guidance, including *Adaptive Design Clinical Trials for Drugs and Biologics*, *Interacting with FDA on Complex Innovative Trial Designs for Drugs and Biological Products*, and, where applicable, *Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products*. Simulation tools, assumptions, code, and outputs used to support regulatory decision-making must be

documented and shareable in a form that allows regulators to understand, reproduce, and interrogate the design.

TA1 also requires the platform trial include *in silico* capabilities, which are computer-based models that predict or simulate clinical patient, disease or clinical trial processes and outcomes. Examples of *in silico capabilities* include but are not limited to:

a) Digital twins or synthetic control approaches that predict individual patient outcome or simulate highly-realistic patient data.
b) Generative disease-progression models that align patients based on disease age.
c) Multimodal longitudinal models that integrate clinical, imaging, biomarker, omics, wearable, or other longitudinal data sources.
d) Pharmacokinetic and pharmacodynamic models.
e) Predictive safety and toxicity models that characterize the probability, timing, and severity of adverse events.
f) Models of patient eligibility, recruitment, enrollment, and retention that support realistic simulation of trial accrual and operational performance.

Predictive models proposed under TA1 must have a clearly defined role in the platform, for example, a PK model used for automatic dose selection, a biomarker-driven longitudinal model triggering a futility stop, or a digital twin used in the analysis of a clinical outcome. Teams must specify the data required by each model, its intended use, the decisions it informs, and the approximate computational time required to produce an output, which must be compatible with clinical-operations timelines. A model or design capability that cannot produce results quickly enough to inform the associated platform decision will not satisfy the program requirements.

The data used to develop and validate the in-silico models may be sourced externally, for example, from registries, EHRs, natural history studies, or prior clinical trials. The in-silico models should also incorporate data collected prospectively within the platform. Proposers should describe how external and platform-generated data will be combined, how model performance will be reassessed as new data accumulates, and what criteria will govern model updating, recalibration, and the decision to integrate it into the trial.

Because in silico capabilities may initially be experimental, they may first be deployed in an exploratory capacity which does not impact the main statistical analyses or formal decision rules of the platform. However, as evidence accumulates, each Core Platform Team must conduct at least one evaluation of a predictive model such as a digital twin using the platform architecture, for example by evaluating the same intervention with and without the model-enabled capability. Progression from development to formal use must be supported by pre-specified validation evidence and coordinated with TA2 and applicable regulatory authorities.

At least one Model Master File (MMF) must be made publicly available after it is submitted to FDA for review and after the FDA has acknowledged the MMF as acceptable for cross-reference in regulatory submissions for the stated and intended purpose. Additional MMFs may remain confidential when necessary to protect sponsor or performer intellectual property. Performers must participate in standards-development activities as directed by ARPA-H.

TA1 will be evaluated using the following interim and final metrics:

Metric	Interim Success Criterion	Final Success Criterion
Number of phases combined into one phaseless/continuous/seamless design	Phase 1+2 or Phase 1+2+3	n/a
Simulator construction time for a non-programmer trialist	≤3 months	≤1 month
Time to re-simulate valid operating characteristics after changing a design parameter or simulation input.	≤1 day	≤5 hours
In silico models validated using data from the platform trial. Validation method to be established during Year 1 of the program.	Evaluation using blinded/holdout data from any source.	Prospective evaluation using platform data.
Number of major decisions per arm informed by an in silico model; major decisions include randomization, dose selection, go/no-go, success or futility.	N/A (used pre-trial)	≥2
Reduction in control allocation due to incorporation of in silico methods.	Year 3: ≥33%; Year 4: ≥50%	Year 5: ≥80%

2.2.4 Technical Area 2: Continuous Inference

TA2 aims to develop a continuous-inference and adaptation-validity engine that permits clinically meaningful decisions on accumulating data without compromising inferential validity. "Continuous" or "real-time" inference does not mean unrestricted or undocumented examination of trial data. Analyses and adaptations must occur through authorized, reproducible, and auditable procedures defined in the Master Protocol, regimen-specific appendices, and Statistical Analysis Plan (SAP).

TA2 methods may combine adaptive-platform methods with anytime-valid, group sequential, Bayesian or other inferential approaches. Regardless of methodological framework, performers must demonstrate that the proposed system produces calibrated and decision-relevant outputs and preserves the operating characteristics required for the intended regulatory use.

The TA2 engine should support:

a) Seamless transitions from safety evaluation to efficacy and confirmatory evaluation.
b) Addition or removal of intervention arms.
c) Integration of prognostic scores, digital-twin outputs, and other information from in silico models.

The TA2 engine should include prespecified adaptive elements, for example:

a) Earlier go/no-go decisions between nominal development phases.
b) Formal futility, efficacy, and safety stopping rules.
c) Modification of sample size through sample size re-estimation or selection.
d) Enrichment of the patient population through modified eligibility criteria.
e) Response adaptive randomization or other innovative allocation approaches.
f) Augmentation/replacement of randomized controls with in silico methods.

Where the regulatory objective requires control of Type I error, the proposed methods must demonstrate those properties under the complete set of planned adaptations. Bayesian quantities should be calibrated and supported by simulation sufficient to permit interpretation by statistical reviewers, Data and Safety Monitoring Boards (DSMBs), sponsors, and regulators. Bayesian designs should meet the operating characteristics, documentation, and reporting requirements outlined in the FDA Draft Guidance *Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products*.

Performers are encouraged to consider methods for augmenting, and potentially replacing, control information with in silico methods such as digital twins, synthetic controls, or disease progression models informed by external data sources. Replacement of human control information with in silico information must be graduated and evidence-based. Performers must demonstrate that each proposed level of replacement preserves the statistical and regulatory validity of treatment-effect estimates.

An independent statistical analysis committee (SAC) must be responsible for conducting and monitoring ongoing interim analyses, ensuring that adaptations are implemented as planned, and producing an interim-analysis report for the DSMB after each interim analysis. Proposing teams must describe the structure and operating procedures for the SAC, including membership, composition and expertise; reporting and communication

structure; and procedures for escalating concerns to the DSMB and platform sponsor. Proposing teams must include a blinding plan, describing which stakeholders (platform sponsor, arm sponsors, DSMB, SAC, investigators etc.) may access sensitive interim trial information and under what circumstances. The plan must describe any unblinding procedures needed to evaluate the performance of each in silico model using data gathered within the platform.

Core Platform Teams must define the safety operations for the platform and intervention arms. The plan must define responsibilities for adverse event and serious adverse event collection, reporting, database management, reconciliation, signal detection and aggregate reporting, investigator notification, regulatory reporting and DSMB expectations. The framework of the plan must also define the responsibilities and if any safety information is relevant to more than one intervention arm will be evaluated and acted upon.

The TA2 system must maintain complete, traceable, and version-controlled records sufficient to reconstruct each interim analysis, adaptive decision, and the resulting change to trial conduct, consistent with the principles of ICH E6(R3) Good Clinical Practice and other applicable regulatory requirements.

TA2 capabilities should satisfy the applicable Program Metrics for analysis frequency, calibration, earlier correct go/no-go decisions, participant allocation, trial-redesign time, control replacement, bias and error control, and regulatory readiness.

TA2 will be evaluated using the following metrics:

In the first year of the program, performers will propose and establish reference designs for each investigational arm which will be a set of independent/separate, non-adaptive clinical trial designs by which the relative performance of the platform design will be measured. The reference designs will be based on recent clinical trials in the same disease area and phases of clinical development, representing a traditional clinical trial development paradigm. Comparisons to reference designs may be evaluated using clinical trial simulation and/or real-world platform performance, to be determined when the reference designs are proposed.

Metric	Interim Success Criterion	Final Success Criterion
Frequency of prespecified interim analyses while maintaining operating characteristics that are acceptable to regulators.	More frequent than every three months	Monthly or more frequently

Reduction in sample size relative to reference designs.	≥33%	≥50%
Earlier correct go/no-go decisions for each arm relative to its reference design.	1.5× faster	2.5× faster
Reduction in time-to-discovery of the first effective drug at the platform level, relative to reference designs.	≥33%	≥50%

2.2.5 Technical Area 3: Agentic Operations

TA3 aims to develop and validate AI–enabled operational systems including an integrated clinical operations framework that allow a persistent platform and its intervention arms to start, enroll, execute, adapt, and generate decision-ready data at speed while maintaining participant safety, data integrity, regulatory compliance, quality, and inspection readiness.

TA3 capabilities include but are not limited to

a) Automation or acceleration of platform-level pre-trial activities;
b) Generation, review, and management of Master Protocol and arm-specific documents;
c) New-arm feasibility assessment and onboarding;
d) Contracting and site-activation workflows;
e) Regulatory-submission preparation and tracking;
f) Institutional Review Board submission and amendment workflows;
g) Participant pre-screening;
h) Clinical data collection and reconciliation;
i) Automated data cleaning and construction of analysis-ready datasets;
j) Monitoring of enrollment and operational performance against TA1 predictions;
k) AI-guided regulatory-path tools that identify required actions, dependencies, and evidence for upcoming milestones;
l) Clinical site identification, feasibility, qualification, activation, management and closeout;
m) Patient identification, recruitment, enrollment, and retention;
n) Risk based quality management and clinical monitoring;
o) Protocol deviation detection, escalation, trending and oversight;
p) Clinical supply management;
q) Safety reporting and reconciliation;
r) Vendor oversight;
s) Trial Master File (TMF) essential document management;
t) Training including documentation;

u) Operational implementation of adaptations authorized in TA2;
v) Resource forecasting with scalability;
w) Maintenance of inspection ready documentation across platform and each intervention arm.

Platform-level operational processes and documents must be implemented before initial trial launch. Arm-specific processes and documents must be sufficiently modular and adaptable to permit efficient onboarding of new drugs, biologics, sponsors, models, or other capabilities without rebuilding the platform.

TA3 must provide timely, traceable, and reproducible data flows to TA1 and TA2. Data used for model updating, interim analysis, adaptation, or regulatory evidence must have sufficient provenance, versioning, and transformation records to support reproducibility, auditability, and applicable regulatory requirements.

TA3 systems must operate within the platform's established clinical, statistical, regulatory, and governance structure. Use of AI-enabled automation does not alter or displace the responsibilities and decision-making authority assigned to sponsors, investigators, clinical sites, statistical committees, DSMB, IRB, or regulatory authorities. Proposers should describe a clinical operations oversight framework that explains how proposed innovations will be implemented and monitored, how oversight will be maintained as the platform scales to additional arms, and how compliance and inspection readiness will be ensured.

TA3 capabilities should satisfy the applicable Program Metrics for IND-to-first-subject-dosed time, new-arm onboarding, contracting, IRB approval, enrollment prediction, data collection, data cleaning, human labor, and cost per intervention arm.

TA3 will be evaluated using the following metrics

Metric	Interim Success Criterion	Final Success Criterion
IND submission to First Subject Dosed (FSD) for the platform	<6 months	<3 months
FDA “may proceed” to FSD for each new intervention arm	<3 months	<1 month
Contract execution for each new intervention arm	<1 month	<1 week
IRB approval for each new intervention arm	≤3 weeks	<1 week

Actual versus predicted enrollment rate, averaged across intervention arms	Within ±50%	Within ±25%
Data collection time	≤1 week	≤2 days
Data cleaning and dataset construction time	≤3 weeks	≤1 week
Human hours consumed, measured at first site activation, FSD, one arm fully recruited, the third arm fully recruited, and program end, and compared with historical single-trial records.	≤1/2 of historical FTE hours	≤1/4 of historical FTE hours
Sponsor cost per intervention arm compared with three CRO quotes for an equivalent standalone trial of the same size without compromising on quality or compliance.	Same as the lowest of three CRO quotes	Below the lowest of three CRO quotes

2.2.6 Program Stages and Performer Structure

SURPASS is a five-year program consisting of two program stages, Stage I: Platform and Capability Buildout (24 months) and Stage II: Capability Validation and Deployment (36 months).

During SURPASS Stage I, Core Platform Teams will develop and integrate TA1, TA2, and TA3 capabilities; establish the Master Protocol, SAP, clinical-site network, and platform-level operational infrastructure; engage FDA; onboard at least three drug or biologic intervention arms; and open the first clinical site to enrollment no later than Year 2.

During SURPASS Stage II, the remaining Core Platform Teams will prospectively validate the integrated SURPASS capabilities, add new intervention and in silico capabilities, implement and validate trial adaptations, and progress, terminate, or graduate intervention arms according to the approved trial framework.

Each Core Platform Team must propose to and perform work across all three Technical Areas. The prime performer will be responsible for the integrated technical and clinical outcome of the platform, including management of dependencies among TA1, TA2, and TA3. Performance will be evaluated based on successful integration of the Technical Areas and achievement of applicable Program Metrics, rather than completion of isolated Technical Area activities.

Core Platform Teams are not expected to possess all required capabilities within a single organization. Each team must include experienced project managers and experts in biostatistics, regulatory affairs, clinical medicine, AI and predictive modeling, and clinical operations, as well as participating drug or biologic sponsors. At least some biostatisticians must have experience integrating digital-twin simulations or other

sophisticated predictive models. Proposers may provide these capabilities through subcontractors, collaborators, vendors, or other partners, but are ultimately responsible for the entire project. Proposals must clearly identify responsibility for each Technical Area, describe coordination across organizational boundaries, and explain how the prime performer will manage integration and resolve technical dependencies.

For Core Platform Teams, ARPA-H will consider funding the trial expenses associated with the first three drug or biologic intervention arms in full and may consider partial funding for the fourth and fifth intervention arms. No later than the end of Year 2, the core platform teams will be expected to develop a detailed plan to scale up their platform in Year 3 to include at least 2 new arm sponsors. ARPA-H does not anticipate funding intervention arms beyond the fifth. Cost sharing by Core Platform Teams is strongly encouraged.

FDA authorization to proceed for the platform Master Protocol IND, as well as the same authorization for at least one investigational arm, by the end of SURPASS Stage I is a required programmatic Go/No-Go criterion for continuation into SURPASS Stage II. Achievement of individual Technical Area metrics does not substitute for successful integration of the three Technical Areas. Core Platform Teams must demonstrate TA1, TA2, and TA3 operate together within the platform trial and achieve the applicable Program Metrics.

3.0 Eligibility Information

3.1 Eligible Proposers

All responsible sources capable of satisfying the government's needs may submit a Solution Summary in response to this ISO. Additionally, the prime organization can be any organization if it has the ability to sustain the proposed platform trial after the SURPASS program is completed.

Note that an organization may submit no more than one proposal as the prime. An organization may be included in multiple Solutions/Proposals as a teaming member (e.g., subproposer). For large institutions, multiple independent PIs may be considered independent primes for the purpose of this provision. See 4.10 for additional information related to this circumstance.

3.1.1 Prohibition of Performer Participation from Federally Funded Research and Development Centers (FFRDCs) and other Government Entities

ARPA-H is primarily interested in responses to this solicitation from commercial Performers, academia, non-profit organizations, etc. In certain circumstances, FFRDCs

and government entities will have unique capabilities that are not available to proposing teams through any other resource. Accordingly, the following principles will apply to this solicitation.

a) FFRDCs and government entities, including federal government employees, are not permitted to respond to this solicitation as a prime or sub- Performer on a proposed Performer team.

b) If an FFRDC or government entity has a unique research idea that is within the technology scope of this solicitation that they would like considered for funding; OR, if an FFRDC or government entity, including a federal government employee, is interested in working directly with the government team supporting the research described by this solicitation, contact SURPASS@arpa-h.gov.

c) If a potential prime Performer believes an FFRDC has a unique capability without which their solution is unachievable, they may provide documentation as part of their Solution Summary submission demonstrating they have exhausted all other options. ARPA-H will consider the documentation to determine if inclusion of the FFRDC is necessary for the Solution.

3.1.2 Non-U.S. Entities

Non-U.S. entities may participate to the extent that such participants comply with any necessary non-disclosure agreements, security regulations, export control laws, and other governing statutes applicable under the circumstances. However, non-U.S. 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.

3.2 System for Award Management (SAM)

A Proposer must have initiated registration in SAM (www.sam.gov) and possess a Unique Entity Identifier (UEI) for its Solution Pitch package to be found conforming. A Proposer must have an active registration in SAM to be eligible for an Award with ARPA-H.

Proposers must maintain an active registration in SAM.gov with current information at all times during which a proposal is under consideration or a current award from ARPA-H is held. Information on SAM.gov registration is available at SAM.gov.

NOTE: New registrations and renewals may take more than 14 business days to process in SAM. The SAM is independent of ARPA-H and thus ARPA-H representatives have no influence

over processing timeframes.

4.0 SURPASS Submission and Evaluation Process

The SURPASS evaluation and selection process is based on the following steps:

a) Eligible entities submit Solution Summaries.
b) Government verifies eligibility and then reviews eligible Solution Summaries.
c) Proposers are notified whether they are encouraged to submit Solution Pitch packages or not.
d) Proposers submit Solution Pitch packages.
e) The government reviews Solution Pitch packages from eligible entities and schedules Solution Pitches with entities whose packages are conforming.
f) The government evaluates Solution Pitch packages and Pitches, selecting the most advantageous Solutions.
g) Proposers are notified of the Government's selection decision.

4.1 Solution Summary and Solution Pitch Package Submission Information

NOTE: Non-conforming submissions that do not follow ISO instructions may be rejected without further review at any stage of the process.

4.1.1 **General.** All Solution Summaries and Solution Pitch packages submitted in response to this solicitation must be submitted in English and must be consistent with the content and formatting requirements of Appendix B (Solution Summary Format and Instructions) and Appendix C (Solution Pitch Package Format and Instructions).

4.1.2 **Submission Portal.** All Solution Summaries and Solution Pitch packages shall be submitted via the ARPA-H Solutions site (https://solutions.arpa-h.gov/). Proposers must register in advance of submissions.

4.2 Solution Summary Submissions

Solution Summary submissions are required. See Appendix B *Solution Summary Format and Instructions*.

4.3. Solution Pitch Package Information

4.3.1. Eligible entities (e.g., those who submitted a Solution Summary and received feedback) may submit a Solution Pitch package. To be considered conforming, Pitch Packages must follow the instructions provided in Appendix C.

4.3.2. The estimated due date for the Solution Pitch Package Submission is provided in Section 1. The final due date and any additional guidance will be provided at the time of Solution Summary feedback.

4.4 Virtual Solution Pitches

Entities whose Solution Pitch package is determined to be conforming will be invited to provide a mandatory virtual Pitch (estimated for early February 2027).

Presentations will be conducted via Microsoft Teams and will include a 15-minute uninterrupted presentation followed by up to 45 minutes of questions from the Government.

4.5 Post Selection Proposal Information

Entities selected for negotiation of a potential award will be provided instructions related to additional Proposal Information required (e.g., Administrative and National Policy Requirements).

4.6 Proprietary Information

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".

4.7 Review and Evaluation

The Government intends to review and select Solutions for negotiations that are most advantageous. To determine most advantageous, the Government will consider the Solution's innovation, feasibility, and scientific and technical merit in the context of the Program requirements.

Ultimately, the Government intends to negotiate awards at reasonable prices with entities proposing the most advantageous Solutions.

4.8 Review and Evaluation Timelines

It is the policy of ARPA-H to ensure an impartial, equitable, and comprehensive scientific review process based on the criteria listed above, and to select for funding negotiations the Proposer(s) whose Solution (as proposed through a Solution Pitch package and Pitch) is most advantageous to the government. Awards will be made to Proposers whose Solutions are most advantageous at reasonable prices.

ARPA-H will review and respond to all Proposers submitting Solution Summaries by the Solution Summary deadline date. Solution Summaries will be reviewed on a high-level (given page limitations). Neither Solution Summaries nor Solution Pitch packages will be evaluated against each other but rather evaluated on their own individual merit to determine how well the submission meets the criteria stated in this ISO.

ARPA-H's intent is to review Solution Summaries and Solution Pitch packages as soon as possible after the applicable submission date.

4.9 Handling of Competitive Sensitive Information

It is the policy of ARPA-H to protect all submissions as competitive sensitive information and to disclose their contents only for the purpose of evaluation and/or 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 Solution Summaries and Solution Pitch packages 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.

4.10 Evaluation and Award Disclaimers

The government reserves the right to select for negotiation all, some, one, or none of the proposals received in response to this ISO. If warranted, portions of resulting awards may be segregated into pre-priced options. In the event 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 stages with options for continued work, as applicable. For large institutions with multiple independent PIs, the Government reserves the right to limit the number of selections within the institution to maximize diversity of investment.

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, price, and/or if the Proposer fails to provide requested additional information in a timely manner.

In all cases, the government will have sole discretion to negotiate all award terms and conditions with selectees. ARPA-H will apply publication or other restrictions, as necessary, if it is

determined 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, any information marked Sensitive but Unclassified (SBU), etc. Any award resulting from such a determination will include a requirement for ARPA-H concurrence before publishing any information or results on the effort. At a minimum, all awards will include a requirement for Performer teams to submit information for review to ARPA-H before publishing.

5.0 Policy Requirements and Miscellaneous Other Information

5.1 Organizational Conflicts of Interest (OCI)

Proposers are required to identify and disclose all facts relevant to potential or actual OCIs involving the Proposer's organization and any proposed team member (proposed sub-awardee). Although the Federal Acquisition Regulation does not apply to OTs or this ISO overall, ARPA-H requires OCIs be addressed in the same manner prescribed in FAR subpart 9.5. Regardless of whether the Proposer has identified potential or actual OCIs under this section, the Proposer is responsible for providing a disclosure with its proposal. If a potential or actual OCI has been identified, 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.

5.1.1 Agency Supplemental OCI Policy

In addition, ARPA-H restricts Performers from concurrently providing professional support 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 sub-awardee, 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.

Note: An OCI based on a Proposer currently providing professional support services, as described above, cannot be mitigated and will render the Proposer ineligible for further consideration for award.

5.1.2 Government OCI 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 based on the evaluation criteria and funding availability.

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.

5.2 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 entities 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 key personnel who will be 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.

5.3 Electronic Invoicing and Payments

Performers will be required to submit invoices in a designated electronic payment system as described in the award document.

5.4 Government-Furnished Property/Equipment/Information

Government-furnished property/equipment/information may be provided to selected Performers. Any instances of GFP/GFE will be specifically negotiated.

5.5 Research Security Disclosures

Conforming proposals selected for negotiation of a potential award will undergo a Research Security Review (RSR). The RSR involves a review of the proposer's disclosures made as part of the Administrative & National Policy Requirements document (see Section 4.5, Post Selection Proposal Information), and a validation and comparison of those disclosures utilizing publicly available information and commercially available information tools. Section 10631 of the CHIPS and Science Act of 2022 prohibits federal research agencies, such as ARPA-H, from providing R&D awards in response to any proposal in which a covered individual is participating in a Malign Foreign Talent Recruitment Program (MFTRP). It also requires federal agencies to require recipient institutions to prohibit covered individuals participating in MFTRPs from working on projects supported by federal R&D awards.

In accordance with NSPM-33, to receive federal funding, research organizations should identify and mitigate conflicts of commitment (COCs) and conflicts of interest (COIs). COCs and COIs involving foreign countries of concern (FCOCs), including the People's Republic of China, the Russian Federation, the Islamic Republic of Iran, and the Democratic People's Republic of Korea (also known as North Korea), will require risk mitigation plans. A research organization proposing in response to this ISO must provide research security disclosures as described in the Administrative & National Policy Requirements document and the Office of Science and Technology Policy-identified Common Forms. The Common Forms are required for all senior or key personnel.

After a proposal is selected for negotiations of a potential award, ARPA-H will conduct an RSR of each proposer and its senior or key personnel. The RSR is not part of the ARPA-H scientific merit review process. The RSR reviews include assessments of potential risks associated with covered individuals' disclosed or undisclosed participation in MFTRPs, funding received from FCOCs, collaboration with FCOC entities (including researchers and research institutions that have been identified on various entity lists), foreign ownership control or influence with regard to FCOCs identified in proposals, and the pursuit of foreign patents stemming from U.S. government funded research prior to obtaining U.S. patent protections.

If ARPA-H determines the proposer failed to provide all requisite research security disclosures or failed to reasonably provide information requested by ARPA-H to assist in evaluating the proposer's disclosures and/or research security mitigations, ARPA-H may eliminate the proposal from award consideration. ARPA-H may also eliminate the proposal from award consideration if ARPA-H determines the proposer did not or cannot properly mitigate research security-related risks.

5.6 Procurement of Synthetic Nucleic Acids or Benchtop Synthesizers

An award resulting from this ISO will include the requirement to comply with the Framework for Nucleic Acid Synthesis Screening per Executive Order (E.O.) 14110.

5.7 Dangerous Gain-of-Function Research

An award resulting from this ISO will include the requirement to comply with the E.O. 14292, Improving the Safety and Security of Biological Research and the United States Government Policy for Stopping High-Risk Research.

Appendix A: Acronyms

AI	Artificial Intelligence
ARPA-H	Advanced Research Projects Agency for Health
BOE	Basis of Estimate
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
COI	Conflict of Interest
DMSP	Data Management and Sharing Plan
DSMB	Data Safety and Monitoring Board
EHR	Electronic Health Records
FAR	Federal Acquisition Regulation
FDA	Food and Drug Administration
FTE	Full Time Equivalent
FFRDC	Federally Funded Research and Development Centers
GCP	Good Clinical Practice
HHS	Health and Human Services
IND	Investigational New Drug
IP	Intellectual Property
IRB	Institutional Review Board
ISO	Innovative Solutions Opening
MMF	Model Master File
OCI	Organizational Conflicts of Interest
OT	Other Transaction
PHO	Proactive Health Office
PD	Pharmacodynamics
PK	Pharmacokinetics
ROM	Rought Order of Magnitude
SAC	Statistical Analysis Committee
SAM	System for Award Management
SURPASS	Simulation-augmented, Real-time Platform Adaptive Seamless Trials
TA	Technical Area
U.S.	United States

Appendix B: Solution Summary Format and Instructions

A. General Instructions

All Solution Summaries must be submitted in English and use a non-serif font type with a readability like that of Public Sans, Avenir Next LT Pro Light, Arial, or New Century 11-point font. Smaller non-serif fonts may be used for figures, tables, and charts. Margins may be no less than one inch in width. Solution Summaries are limited to **4 pages**, exclusive of a cover page, Rough Order of Magnitude including basis of estimate (BOE), and References/Citations. No tables of content shall be provided. The government may not review pages beyond four (4) total; and any Solution Summary submitted that exceeds 4 pages will only be reviewed at ARPA-H's discretion.

B. Cover Page

The cover page should follow the format below. The cover page does not count towards the page limit.

Solicitation #	ARPA-H-SOL-26-164
Solution Summary Title	
Submitter Organization	
Type of Organization	Choose all that apply: Large Business, Small Disadvantaged Business, Other Small Business, HBCU, MI, Other Educational, or Other Nonprofit
Technical Point of Contact (POC)	Name: Mailing Address: Telephone: Email:
Administrative POC	Name: Mailing Address: Telephone: Email:
Total Estimated Budget	Total: $ ARPA-H share: $ Performer share: $
Place(s) of Performance	
Other Team Members (subperformers, including consultants) if any	Technical POC Name: Organization: Organization Type:

C. Proposed Work

At a minimum, the Solution Summary should address the following items in sufficient detail:

1. Disease area, drug/biologic arms, potential sponsors, patient population, platform trial design and conduct. Clearly indicate prior experience related to the SURPASS program and operationalizing clinical trials in the disease area.
2. TA1, TA2, TA3 innovations and their deployment in the trial.
3. Regulatory strategy including planned meetings/milestones, risks, and risk mitigations (no more than one paragraph).
4. Economic sustainability of the platform trial after the SURPASS program, including evidence of a robust external research pipeline and plans for recruitment into the platform (no more than one paragraph).
5. Why is your solution better than any of your competitor's?

Solution summaries should include tables, schemas and charts as needed to illustrate the proposal.

D. Rough Order of Magnitude (ROM)

Please include a basis of estimate (BOE) to support the proposed project budget, as well as the total project cost including cost sharing, if applicable. The below table may be used for this breakdown:

Categories	Stage I Amount	Stage II Amount	Total
Platform trial setup cost			
Platform trial maintenance cost			
Budget for intervention arms			
TA1 budget			
TA2 budget			
TA3 budget			
Regulatory budget (if not included in rows above)			
Biostatistics budget (if not included in rows above)			
Total			
Cost Sharing (if applicable/appropriate)			

NOTE: Delete all formatting and content instructions prior to submission.

Appendix C: Solution Pitch Package Format and Instructions

Solution Pitch packages must follow the guidance in this Appendix. Conforming packages shall consist of the following:

1. Solution Pitch Deck (see requirements below)
2. Gantt chart in Excel (no template)
3. Preliminary master protocol with detailed description of the adaptive design elements and statistical details supporting the TA2 approach (no page limit).
4. 2-page description of in silico and AI models describing inputs, outputs, existing evidence of viability, and validation plans.
5. Scope of Work in Word (use provided template)
6. Cost Workbook in Excel (use provided template).
7. Optional Appendix in PDF: If relevant regulatory documents have been developed and shared with regulators, they may be submitted as an Appendix. ARPA-H is most interested in regulatory documents that support the proposed approach and/or demonstrate the team's competency to execute on the proposed plan.

All Word, PowerPoint and PDF documents shall be formatted for printing on 8-1/2 by 11- inch paper. Margins must be 1-inch on all sides, using a sans serif font with readability similar to that of 11 pt Arial, Avenir Next LT Pro Light, or Public Sans, with a page number at the bottom of each page.

Documents must be clearly labeled with the ISO number, Proposer organization, and proposal title/proposal short title (in the header of each page), and the name of the document (e.g., Master Protocol Synopsis, or in silico modeling).

Solution Pitch Deck Requirements

Solution Pitch Decks will be PowerPoint format and cannot exceed 21 slides. No template will be provided, but the below table outlines required content and slide numbers.

PowerPoint slide section	Slide limit	Description
Cover/title slide	1	n/a
Platform trial	2-3	Disease(s) area, study population, key endpoints/analyses, control, drug/biologic arms, adaptive platform design, in silico capabilities.
TA1	2	Address TA1 innovations
TA2	2	Address TA2 innovations
TA3	2	Address TA3 innovations
Integration of all TA w/	1	Describe how and when developments in

platform trial		TA1, 2, 3 will be integrated into the platform trial.
Patient enrollment	1	Evidence-based recruitment projections; site capacity, access to patient population, anticipated enrollment challenges and mitigations.
Regulatory	1-2	Regulatory pathway and strategy, planned interactions, evidence that will be used to support the inclusion of innovative design elements.
Integration of new arms and in silico capabilities	1	How new arms and in silico capabilities will be integrated
Standards	1	Discuss which standards will need to be developed and disseminated to increase adoption of the proposed approaches
Timeline	1	Show an overall timeline with all proposed components
Risks	0-1	Risks can be described in other sections or as a separate slide. Mitigation strategies must be provided.
Sustainability post SURPASS	1	How the platform will be economically sustained for 10 years after SURPASS; including availability of new, external investigational therapies and plan for their recruitment into the platform.
Team	1	Describe the team composition, governance, reporting. Please don't over-engineer governance and try to build lean and motivated teams.
Budget	Max 1 slide	Describe the main budget components, what drives what, budget by year, upfront expenditures, etc.
Total	Max 21	Do not exceed 21 slides in total including everything

ATTACHMENTS/TEMPLATES

(*The following Appendix C templates are provided as separate attachments to the ISO)*

Attachment 1: Scope of Work Template
Attachment 2: Cost Workbook