SINGLE SHIELD PRIZE

Concept Stage submission instructions

This document explains how to submit an entry to the Single Shield Prize Concept Stage.

If you encounter any technical issues, email Hello@SingleShieldPrize.com with a description of the problem, a screenshot (if available), and the date and time of the occurrence.

Please review the official rules, terms, and conditions for complete submission requirements and eligibility criteria.

Step 1: Submit a Declaration of Intent

Before submitting a concept paper, prospective entrants must submit a Declaration of Intent (DOI). The DOI collects basic entrant information and a short description of the proposed vaccine candidate.

To submit a DOI, prospective entrants must register at SingleShieldPrize.AwardsPlatform.com. When registering your team, provide the name and email address of the designated team lead.

The DOI deadline is 4:59 p.m. Eastern Time on Tuesday, January 5, 2027. Please submit at least one hour before the deadline to ensure your completed submission is received.

DOIs will be reviewed on a rolling basis throughout the submission period. Eligible entrants with in-scope vaccine candidates will be invited to submit a concept paper.

Step 2: Submit a concept paper

Entrants invited to submit a concept paper must complete submission details and upload a concept paper.

The deadline for concept papers is 4:59 p.m. Eastern Time on Friday, January 15, 2027. Please submit at least one hour before the deadline to ensure your completed submission is received.

Complete the submission details

The submission form will include:

- Entrant and partner information
- Submission title (15 words maximum)
- Submission headline (100 words maximum)
- Technical abstract (500 words maximum)

- Product profile checklist
- Submission checklist

Prepare the concept paper

Concept papers must:

- Be uploaded as a PDF.
- Be no more than 15 pages.
    - References do not count toward the page limit.
    - Additional content may be included in an appendix. The appendices do not count toward the page limit. Appendices are not guaranteed to be reviewed, but may provide helpful context or clarification.
- Use 1-inch (2.5 cm) margins.
- Use an easy-to-read typeface with minimum 12-point font size for prose and 10-point font size for tables and charts.

Each entrant must clearly delineate any confidential commercial information contained in a submission that the entrant wishes to protect as proprietary data.

Entrants must also demonstrate within their submission documentation that they possess, or have a viable pathway to obtain, all requisite intellectual property rights. This encompasses both the vaccine antigen component and any other technology needed for the single-administration vaccine candidate.

Concept paper requirements

Concept papers must address the following:

- **Concept summary.** A summary of the proposed innovative vaccine candidate and nonclinical development plan.
- **Product description**. A description of the proposed single-administration vaccine candidate, including information on antigen, formulation, delivery approaches, and adjuvant if relevant. Entrants should demonstrate alignment with the Desired Product Attributes, and the innovative nature and scientific feasibility of the product's ability to elicit a protective, safe, and tolerable immune response through a single-administration event, including any supporting evidence.
- **Past progress and current status**. A summary of current development status and description of past progress, including any supporting evidence from development and

evaluation efforts to date. The paper should also include details of any past funding and how it has been used to advance development to date, as well as a description of any prior interactions with the FDA regarding the proposed product.

- **Nonclinical development plan**. A clear roadmap for engineering, formulation development and optimization, and validating the proposed product through nonclinical studies, with a sound rationale for model selection aligned with the Desired Product Attributes.
- **Regulatory engagement plan**. A roadmap detailing a viable plan to engage with the FDA in preparation for seeking Investigational New Drug (IND) authorization to enable use of the proposed product in a Phase I trial.
- **Risk management plan**. A summary risk register and an overview of the organizational or program-based mechanisms that will be used during the execution of product development to assess, monitor, mitigate, and manage risks. Submissions should consider risks relating to: nonclinical development, regulatory processes, manufacturing, partnerships and intellectual property.
- **Manufacturing plan**. A manufacturing roadmap aligned with FDA guidance on Good Manufacturing Practice (GMP) and Chemistry, Manufacturing and Controls (CMC) for Investigational New Drug (IND) applications. Submissions should consider manufacturing processes, controls for manufacturing uniformity and consistency of formulation for clinical use; and manufacturing capabilities required to scale.
- **Organizational capabilities**. A summary of the team's key personnel, roles, responsibilities, decision-making processes, expertise, access to required technology, ability to conduct research in a BSL3 facility, and ability to comply with regulatory requirements for working with select agents*. Any gaps in expertise and capabilities required for product development should be identified and addressed.

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*The current exemption of H5 avian influenza viruses from the requirements of the regulations listed in 9 C.F.R. Part 121 expires June 2027 - Read the Guidelines for Avian Influenza Viruses (https://www.selectagents.gov/compliance/guidance/avian/docs/AIV-Guidelines-Exemption-2024-August_508.pdf)