

**Grand Challenge:
Innovations in Vaccine Manufacturing for Global Markets**

FAQ

Grant Objectives

Is \$0.15/dose cost a per-vaccine target or per-disease target? In other words, can pentavalent vaccine come in at a total cost of \$0.75/dose because it targets 5 diseases?

The cost of \$0.15/dose is a per-vaccine target.

Does \$0.15/dose cost include packaging?

Yes, the cost includes packaging and labelling, ready to move the product into a distribution channel.

Can you provide unifying assumptions about any of the cost categories encompassed in the target \$0.15/dose (consumables, direct and indirect labor, facility, equipment and related costs, QA/QC costs, fill-finish, and licensing costs)?

This Grand Challenge values innovative thinking. Any attempt on our part to offer cost assumptions has the potential to constrain thinking. Proposers should develop sound arguments to support any assumptions made in parsing out cost categories.

Can I develop a new vaccine to manufacture?

No. This Grand Challenge is focused on development of innovative platform technologies for the production of existing vaccines and not discovery of novel untested vaccines. The vaccine(s) selected must be one(s) for which there are established quality standards and clinical endpoints so that a quality comparison may be made between the existing and novel platform technologies.

What team structure are you looking for? Am I required to designate an integrator or contact PI?

The foundation requires that one lead principal investigator be designated for the project. Beyond that, the foundation is open to whatever team and leadership structure the proposer deems best suited to accomplish the objectives stated within the Challenge. The makeup and strength of the team will be evaluated in the initial letter of intent review phase, after which the foundation may offer comments or suggestions.

Should the 5 year plan include human studies?

No. While it is the foundation's expectation that this platform may require a clinical study, this 5 year project is not expected to include that study. By the end of year 5, an IND submission must be made to the appropriate national regulatory agency to begin clinical trial testing of vaccine produced using the new process

Can the foundation assist me in getting access to bulk product?

No. For work that requires access to virus strains, proposers should consider with whom to engage as well as how that access requirement affects the critical path to development.

What steps might the foundation take in support of Global Access?

To ensure Global Access, the foundation may:

- Conduct due diligence and/or request an IP Report to determine the ability of the Applicant to effectively manage the IP Rights associated with the Grand Challenge in such a way that will achieve Global Access.
- Require a *Global Access Strategy* or *Global Access Commitment Agreement* from the Applicant, explaining their plans to achieve their goals and further the foundation's charitable objectives of Global Access, including the identification of third party IP Rights and relationships arising in connection with the research, development, use, manufacturing, marketing, commercialization and/or distribution of the Funded Developments, and the related IP management strategies, licensing structures, data management plans, and pricing frameworks.
- Require periodic updates of the *Global Access Strategy* to detail progress and ongoing efforts to achieve Global Access.
- Reserve IP Rights in Funded Developments. In those cases where the foundation does reserve IP Rights, it does so as necessary to ensure that either the foundation (and/or its grantees, partners or collaborators) has the IP Rights necessary for the research, development, use, manufacturing, marketing, commercialization and/or distribution of Funded Developments (as applicable) to achieve Global Access.

More information about the foundation's global access approach can be found at:

<http://www.gatesfoundation.org/Global-Access>

Application

How do I submit a Letter of Intent?

Please submit your LOI through the Unison application portal, found [here](#) (applicants must first create a log-in for Unison.) For reference, the RFP number is SOL1139572. Please see the Grand Challenge for specific guidance on what information your LOI should include.

Who is eligible to submit a Letter of Intent?

Please refer to page 8 of the Grand Challenge for eligibility information.

Does the 3 page limit include...(e.g., graphs, tables, references, contact information)?

All information submitted must be contained within 3 pages for the Letter of Intent. LOIs should communicate the proposer's core objectives and plan. Please refer to page 9 of the Grand Challenge for specific elements to address.

I submitted my response but did not receive a confirmation. How do I know if my LOI/Proposal went through?

You will receive an email confirmation when your application is submitted. If you do not receive this confirmation, please contact us at vaccineinnovations@gatesfoundation.org to confirm your application was received. Please first check your junk/spam folder to ensure the proposal confirmation was not accidentally sent there.

Review and Selection

What qualities are common to successful Grand Challenges proposals?

Compelling proposals typically feature the following attributes:

- Tell a good story
- Focus on the problem at hand and how to solve it, rather than the past accomplishments of the team members
- Give an honest and thorough assessment of the risks involved and provide a plan to mitigate those risks
- State assumptions and provide rationale
- Identify success metrics, particularly those that indicate the project is on track far in advance of achieving the end goal
- Assemble the best team possible, which may mean reaching out beyond the typical circle of collaborators

Will you give preference to proposals that plan to produce more than one of the priority diseases: human papillomavirus vaccine, inactivated poliovirus vaccine, measles-rubella vaccine, pentavalent vaccine (diphtheria, tetanus, whole-cell pertussis, hepatitis B, Hib), pneumococcal vaccine, and rotavirus vaccine?

Priority will be given to those proposals that either validate with multiple priority vaccines or show clear rationale for extension to additional vaccines. Work with non-priority vaccines will also be considered for funding, but only in conjunction with work that includes a priority vaccine.

How many applicants will be invited to submit a full proposal? How many will be awarded funding?

The number of applicants invited to submit a full proposal and the number awarded funding will depend on the quality and diversity of proposals received.

Who will be reviewing the responses?

LOIs and full proposals will be reviewed by a broad range of experts, including but not limited to foundation staff and independent subject matter experts.

Award

How many grants are you willing to fund, and for how much? What budget range are you expecting to see in the proposal?

The foundation will not provide specific funding limits or expectations. The number of awards and quantity of each award amount will depend upon the quality of the proposals received. Proposers are expected to develop a budget commensurate with the scope and scale of the work necessary to achieve the objectives laid out therein.

What milestones or criteria must be met to trigger Phase 2 funding, and when will that decision be made?

Applicants who are selected for funding will work closely with their foundation program officer to carefully define and agree upon milestones and timelines that must be met for Phase 2 funding. These milestones and timelines will be entirely customized to the objectives and workplan of the project(s).

When will applicants be notified?

Please see page 8 of the Grand Challenge for the planned review and announcement schedule

When will funding commence?

Should the foundation choose to move forward with an applicant after the full proposal review, due diligence and grant negotiations would begin in the second quarter of 2016 and will take approximately 1-3 months, after which final award decisions and payments would be made.

Other

Who can I contact if I have a question about a particular topic?

Please note that we are unable to provide specific feedback on draft proposals, given the volume of applicants. All other questions should be directed to vaccineinnovations@gatesfoundation.org