European Commission

Development of a novel alternative to existing cold-chain technologies for vaccine formulation, preservation and transportation.

Prize competition rules

Introduction

- The FP7 Cooperation Work Programme Health 2012[1] (WP Health 2012) provides for a prize competition – Development of a novel alternative to existing cold-chain technologies for vaccine formulation, preservation and transportation.
- The rules mentioned herein are published with the purpose to further clarify the award criteria[2] set out in the WP Health 2012 and therefore should be read only in conjunction with the latter document. Therefore, where any conflict arises between the rules herein and the WP Health 2012, this document will prevail.
- The prize is intended to induce and reward innovation which addresses weaknesses in the current cold-chain approach for maintaining the integrity of vaccines. This is particularly relevant in regions experiencing temperature extremes and infrastructural weaknesses.
- Further information on the award criteria are provided below. It is important to note that approaches to be taken by the participants in the competition are not prescribed and may include alternate formulations, novel packaging and/or transportation techniques, or significant improvements over existing technologies, amongst others.

Competition deadlines, judging panel and announcement of winner

- The competition is officially open from the 16 April, 2012. Participants in the competition will be able to register their intention to compete on the competition website (http://ec.europa.eu/research/health/vaccine-prize_en.html) shortly thereafter and must do so by 30 April 2013 (17:00:00 Brussels time). The deadline for the submission of proposals is 03 September 2013 (17:00:00 Brussels time).
- Applications must include a summary of no more than 20 pages[3]. The judging panel will be instructed to disregard any pages exceeding this limit. Annexes in support of the summary may also be provided[4]. Applicants are encouraged to

[1] http://ec.europa.eu/research/participants/portal/page/cooperation?callIdentifier=FP7-HEALTH-2012-INNOVATION-1

[2] WP Health 2012 provides that the award criteria are subject to further clarification in the competition rules which will be released at competition launch.

[3] Times New Roman, minimum font size 10.

[4] The annex must not exceed 20 pages.

present their applications in as concise a manner as possible but are otherwise free to present their applications in the way that they consider best satisfies the award criteria (see below).

- The names of the members of the judging panel, which will provide advice to the European Commission on which application should be declared the winner, will be announced later in 2012. Participants in the competition should not contact the judging panel for any reason in connection with the competition. Any questions related to the competition may be addressed to RTD-VACCINE-PRIZE@ec.europa.eu. Q&A will be posted periodically on the competition website.
- In order to ensure the representation of all necessary expertise in the judging panel (as well as to communicate updates), participants in the competition may be contacted between 30 April 2013 and 03 September 2013 by the European Commission.
- The European Commission may invite participants in the competition to be involved in publicity of the prize during the entire period, from 16 April 2012 to the awarding of the prize.
- The announcement of the prize winner will be made at an event in the fourth quarter of 2013. There will be only one winning proposal, with a prize of €2 million to be awarded. If no application is in the opinion of the judging panel of sufficient quality, no prize will be awarded.

Eligibility criteria

- Participants must be legally established in an EU Member State or in countries associated with the Seventh Research Framework Programme. If the competing legal entity represents a group of individuals or organisations, the establishment of an agreement between the parties is highly recommended, though this will not be examined nor mandated by the European Commission.

Award criteria

- The prize will be awarded to the legal entity (representing either an individual or group) which satisfies the judging panel that it has best demonstrated achievement of the award criteria.
- These award criteria are the following:
  - Proposals which demonstrate applicability to a wide range of vaccines which themselves have the potential for a significant impact in terms of global health will be preferred to proposals which are applicable to a limited set of vaccines with limited impact.
  - Proposals must demonstrate a significant improvement over the state of the art and must have been developed by the proposer.

- All proposals must present data, with specificity depending on the nature of the proposal, demonstrating the retention of full potency and effectiveness of the vaccines under field conditions of transport and storage (for instance stability and efficacy data).
- Further, if the proposal concerns a novel formulation, or other modification that would require regulatory approval, safety data must also be provided. As the time frame of the competition may not permit a full safety assessment (i.e. should an idea be started at the time of the launch of the competition), relevant late pre-clinical or early clinical data will be acceptable.
- Proposals demonstrating the greatest range and scope of protection against the variability of field conditions (extremes of temperature, humidity, power consumption etc.) will be preferred, as will proposals demonstrating the potential for implementation at reasonable cost (for example through the presentation of a product development plan)[5].

- Participants in the competition retain the right to the intellectual property generated during, or presented as part of, their participation in the competition. In case the prize is awarded, the rules on protection, publication, dissemination and use of foreground developed by the winning participant in the competition shall apply mutatis mutandis[6].

[5] For example, but not exclusively, indicating potential marketability of the solution at a cost per unit vaccine not greatly exceeding existing solutions.
[6] According to art. 44-46 of Regulation (EC) No 1906/2006 of the European Parliament and of the Council Of 18 December 2006 laying down the rules for the participation of undertakings, research centres and universities in actions under the Seventh Framework Programme and for the dissemination of research results (2007-2013).