



Horizon Prize

BETTER USE OF
ANTIBIOTICS

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RULES OF CONTEST



1. OBJECTIVES PURSUED

The objectives of the prize are to:

- Reduce the unnecessary use of antibiotics in case of viral upper respiratory tract infections;
- Reduce costs and side effects linked to the use of antibiotics;
- Delay the emergence of antibiotic resistant organisms;
- Enable health-care providers to take early decisions in the management of upper respiratory tract infections (rapid initiation and cessation of treatment) and to facilitate the health care provider's decision not to prescribe antibiotics in case of viral infections and to facilitate patients' acceptance of not taking antibiotics for viral infections;
- Tackle the widespread and significant health care issue of respiratory infections; an ageing population, antibiotic resistance and increasing health care costs make this a particularly challenging problem.

2. EXPECTED RESULTS

Development of a rapid point-of-care test that will reduce the use of antibiotics in a safe way in patients with upper respiratory tract infections.

In this context "Upper Respiratory Tract Infections" include pharyngitis, sinusitis, otitis as well as bronchitis.

3. AWARD CRITERIA

The rapid point-of-care test may be part of an approach that includes clinical parameters/algorithms but it cannot be limited to such clinical parameters/algorithms.

While the impact of a solution (see criteria below) naturally increases with the size of the target population, solutions that apply only to limited target populations (e.g. children vs. adults) are also eligible.

Please note that the solution must be both developed by the contestant and be novel

3.1. Award Criteria

The prize will be awarded, after closure of the contest, to the entry that in the opinion of the jury demonstrates a solution that fulfils at least the minimum requirements and best addresses the following cumulative criteria.

- 1. Potential to reduce the use of antibiotics and magnitude of antibiotic use reduction:** contestants should include a robust estimation of the antibiotic courses that would be avoided in cases of upper respiratory tract infections as a consequence of the application of this test;
- 2. Accuracy and safety:** contestants should provide a risk/benefit analysis of giving or not giving antibiotics in the case of upper respiratory tract infections based on the result of this test. The test should identify with high accuracy patients with upper respiratory tract infection, who can safely be managed without antibiotics.

The accuracy and safety of the solution must be confirmed by an appropriate validation. The validation must have been performed in a clinical research or routine laboratory using a number of patient samples that is justified statistically as providing reasonable validation. The validation report must include details on number of patient samples, number of targets/pathogens/markers analysed per sample, randomisation strategy, sensitivity and specificity, gold standard used (addressing also the distinction between colonising agents and causative pathogens), time to result under 'real world' conditions and whether (and how many) samples have been analysed in parallel. Gender-specific differences should be taken into account. The validation must demonstrate a sensitivity and specificity that supports the use of the test to reduce the use of antibiotics in a safe way in patients with upper respiratory tract infections. The test should be ready for use at the time of submitting the application: as a minimum, a working

device or demonstrator method should exist that is suitable for deployment to test sites (i.e. acceptable to a manufacturer for scale-up for beta-testing and then to market).

Applicants may use the "[STARD Checklist for the reporting of studies of diagnostic accuracy](http://www.stard-statement.org/pdf%20and%20word%20documents/Checklist.PDF)"¹ indicating on which page of the application the STARD checklist items are addressed.

- 3. Minimal/non-invasive:** it is preferred that the sampling requirements are minimal/non-invasive.
- 4. Low cost and affordable:** cost of device, infrastructure requirements for device (water, electricity, waste disposal), cost of consumables, supply chain and storage requirements for consumables. Lower cost for device and consumables, room-temperature supply chain and storage as well as substantial tolerance for temperature excursions will be preferred.
- 5. Rapid:** ideally the total turn-around time of the test should be less than 30 minutes.
- 6. Easy to use:** the test must be useable by healthcare workers at primary care level. Simplicity and limited training requirements are preferred.

3.2. Evaluation process

The evaluation of applications will be carried out on the basis of a review of the written applications by independent evaluators during September and October 2016. There will be first a remote evaluation where the experts evaluate the applications individually at home; followed by a central evaluation in Brussels. Up to the five best applications that have passed the threshold of the central evaluation might be invited for a hearing that may include a demonstration of their method.

At the evaluation phase, the expert panel will assess each submitted solution against the six award criteria and will then mark each solution up to a maximum number of 30 points. The thresholds and maximum scores are indicated in the table below.

Table indicating the award criteria and their respective thresholds and maximum scores

Criterion	Threshold	Maximum points
1. Potential to reduce the use of antibiotics and magnitude of antibiotic use reduction	3	5
2. Accuracy and safety	3	5
3. Minimal/non-invasive	3	5
4. Low cost and affordable	3	5
5. Rapid	3	5
6. Easy to use	3	5
Total	18	30

Upon completion of their work, the members of the panel shall sign a record of all the entries examined, containing an assessment of their quality and identifying those to which the prizes may be awarded.

All contestants will be informed about the outcome of the evaluation at the end of 2016.

¹ <http://www.stard-statement.org/pdf%20and%20word%20documents/Checklist.PDF>

4. ARRANGEMENTS AND FINAL DATES FOR THE REGISTRATION OF CONTESTANTS, IF REQUIRED, AND ARRANGEMENTS AND FINAL DATES FOR THE SUBMISSION OF ENTRIES

Deadlines	
Opening of the submission of applications	10 March 2015
Deadline for the submission of applications	17 August 2016 at 10:00 CET ²

Applications are submitted through the Participant Portal.

5. AMOUNT OF PRIZE(S) INCLUDING SPECIFIC AMOUNT FOR EACH PRIZE, IF APPLICABLE

A single prize of €1 million.

6. ARRANGEMENT FOR THE PAYMENT OF THE PRIZE TO THE WINNER AFTER ITS AWARD

The award will be paid in one instalment. Prize money (€1 million) will be paid after the award ceremony (planned to be held in the last quarter of 2016) by bank transfer, provided the winner has submitted the required evidence as regards eligibility.

7. CONDITIONS FOR CANCELLATION OF THE CONTEST, IF ANY

The Commission has the right to terminate the contest before its closing date without any obligation to indemnify contestants in case the objective of the contest has been achieved by a non-registered or non-eligible contestant.

The Commission has the right to decide not to award any prize if no applications are received or if no applications are to be awarded by the contest jury.

8. CONDITIONS FOR PARTICIPATION

The contestant must not have previously received any other Union prize that is the subject of the current competition. All information given by the contestant in the application must be correct and complete.

8.1. Eligibility criteria

The contest is open to any legal entity (including natural persons) or group of legal entities established in an EU Member State or in a country associated to Horizon 2020.

8.2. Exclusion criteria

Contestant will be excluded from participating in the competition if they fall under any of the following situations:

² Central European Time

The contestant:

a) is bankrupt or being wound up, is having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, is the subject of proceedings concerning those matters, or is in any analogous situation arising from a similar procedure provided for in national legislation or regulations;

b) has been convicted of an offence concerning professional conduct by a judgment of a competent authority of a Member State which has the force of *res judicata*;

c) has been guilty of grave professional misconduct proven by any means which the European Union bodies can justify including by decisions of the European Investment Bank and international organisations;

d) is not in compliance with all its obligations relating to the payment of social security contributions and the payment of taxes in accordance with the legal provisions of the country in which it is established, with those of the country of the authorising officer responsible and those of the country where the activity is to be implemented;

e) has been the subject of a judgement which has the force of *res judicata* for fraud, corruption, involvement in a criminal organisation, money laundering or any other illegal activity, where such activity is detrimental to the Union's financial interests;

f) is subject to an administrative penalty for being guilty of misrepresenting the information required as a condition of participation in a procurement procedure or another grant award procedure or failing to supply this information, or having been declared to be in serious breach of its obligations under contracts or agreements covered by the Union's budget. Natural persons with power of representation, decision-making or control over one of the contestants that are legal entities, must not be in the situations referred to in b) and e) above:

Contestants must:

g) have no conflict of interests in connection with the prize; a conflict of interests could arise in particular as a result of economic interests, political or national affinity, family, emotional life or any other shared interest;

h) inform the European Commission, without delay, of any situation considered a conflict of interests or which could give rise to a conflict of interests;

i) have not been granted, and will not grant, have not sought and will not seek, have not attempted and will not attempt to obtain, and have not accepted and will not accept any advantage, financial or in kind, to or from any party whatsoever, where such advantage constitutes an illegal practice or involves corruption, either directly or indirectly, inasmuch as it is an incentive or reward relating to the award of the prize;

In case of award of a prize, the following evidence shall be provided upon request and within the time limit set by the European Commission:

For situations described in (a), (b) and (e), production of a recent extract from the judicial record is required or, failing that, a recent equivalent document issued by a judicial or administrative authority in the country of origin or provenance showing that those requirements are satisfied. Where the contestant is a legal person and the national legislation of the country in which the contestant is established does not allow the provision of such documents for legal persons, the documents should be provided for natural persons, such as the company directors or any person with powers of representation, decision making or control in relation to the contestant.

For the situation described in point (d) above, recent certificates or letters issued by the competent authorities of the State concerned are required. These documents must provide evidence covering all taxes and social security contributions for which the contestant is liable, including for example, VAT, income tax (natural persons only), company tax (legal persons only) and social security contributions.

For any of the situations (a), (b), (d) or (e), where any document described in the two paragraphs above is not

issued in the country concerned, it may be replaced by a sworn or, failing that, a solemn statement made by the interested party before a judicial or administrative authority, a notary or a qualified professional body in his country of origin or provenance.

If the contestant is a legal person, information on the natural persons with power of representation, decision making or control over the legal person shall be provided only upon request by the European Commission.

8.3. Sole liability of contestants

The Commission may not be held responsible for any claim relating to the activities carried out in the framework of the contest by the contestant. The Commission shall not be held liable for any damage caused or sustained by any of the contestants, including any damage caused to third parties as a consequence of or during the implementation of the activities related to the contest.

8.4. Checks and audits

The contestants accept that, if they are awarded a prize, the Commission, OLAF and the Court of Auditors may carry out checks and audits in relation to the contest and the received prize.

8.5. Publicity

8.5.1. Publicity by the winner of the prize

The contestants accept, if they are awarded a prize, to promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

Unless the Commission requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) must:

(a) display the EU emblem and

(b) include the following text: *“This action has been awarded the Horizon Prize for Better Use of Antibiotics from the European Union’s Horizon 2020 research and innovation programme”*.

When displayed together with another logo, the EU emblem must have appropriate prominence. For the purposes of its obligations, the winner of the prize may use the EU emblem without first obtaining approval from the Commission. This does not, however, give it the right to exclusive use. Moreover, the winner of the prize may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

8.5.2. Publicity by the Commission

The Commission may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material that it receives from the winner of the prize (including in electronic form).

The Commission will publish the name of the winner, its locality, the amount of the prize and its nature and purpose and that the contestant may request the Commission to waive such publication if disclosure risks threatening its security and safety or harm its commercial interest.

Photos and videos taken by the Commission either in preparation of the award ceremony or during the award ceremony are the sole property of the Commission.

8.6. Processing of personal data

Registration and submission of application shall be made in writing, which implies by letter or by electronic means (as specified in the rules of the contest), provided that they are non-discriminatory in nature and ensure integrity, confidentiality and protection of personal data. All personal data contained in the application shall be processed in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the

Council (OJ L8 of 12.01.2001, p1) on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. Such data shall be processed by the Controller solely in connection with the implementation and follow-up of the application of the winner, without prejudice to a possible transmission to the bodies in charge of a monitoring or inspection task in accordance with European Community and European Union legislation.

Contestants may, on written request, gain access to their personal data and correct any information that is inaccurate or incomplete. They should address any questions regarding the processing of their personal data to the Controller, via the contact person announced in the rules of the contest. Please send in addition a scanned copy of your letter to the email address announced in the rules of the contest.

Contestants may, at any time, lodge a complaint against the processing of their personal data with the European Data Protection Supervisor.

The Commission shall be authorised to publish, in whatever form and on or by whatever medium, the following information:

- The name of winner(s);
- The locality of winner(s);
- The general purpose of the activities of the winner(s) in relation to the award of the prize, in the form of the summary provided by the winner(s);
- The amount of the prize awarded.

8.7. Applicable law and competent jurisdiction

The contest is governed by the applicable Union law complemented, where necessary, by the law of Belgium. The General Court or, on appeal, the Court of Justice of the European Union, shall have sole jurisdiction to hear any dispute between the Union and any participant concerning the interpretation, application or validity of the rules of this contest, if such dispute cannot be settled amicably.

If international organisations are eligible, this general rule may be complemented by the special conditions proposed in the model grant agreement on dispute settlement - arbitration and applicable law.

8.8. Applicability of penalties

By virtue of Article 212 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and with due regard to the principle of proportionality, a contestant which has committed irregularities or fraud, has made false declarations shall be liable to:

(a) administrative penalties consisting of exclusion from all contracts, grants and contests financed by the Union budget for a maximum of five years from the date on which the infringement is established and confirmed following a contradictory procedure with the contestant; and/or

(b) financial penalties of 2% to 10% of the value of the prize.

In the event of another infringement within five years following the establishment of the first infringement, the period of exclusion under point (a) may be extended to 10 years and the range of the rate referred to in point (b) may be increased to 4% to 20%.

8.9. Dissemination and exploitation obligations

Obligations regarding dissemination of results laid down in Title III of the rules for participation and dissemination in Horizon 2020 (Regulation 1290/2013) apply, as well as any additional rules provided in the Work Programme.