European Commission

Horizon **Prize**

BIRTH DAY

The Birth Day Prize is brought to you in collaboration with: BILL & MELINDA GATES foundation MSD for mothers

RULES OF THE CONTEST

The 'Birth Day' Prize is an initiative of the European Commission. The Bill & Melinda Gates Foundation (or the Foundation) and Merck Sharp & Dohme Corp., subsidiary of Merck & Co. Inc., Kenilworth, NJ USA (or MSD) have committed to award prizes to winners following evaluation of entries by the Commission.

1. THEME: HORIZON BIRTH DAY PRIZE

1.1 Objectives pursued

The objectives of the prize are to:

(a) Reduce maternal and/or new-born deaths, stillbirths and/or maternal and new-born morbidity rates related to giving birth in facility-based deliveries

(b) Improve quality and outcomes of care surrounding facility-based delivery

1.2 Expected results

A novel solution to improve the outcome of facility-based deliveries, which might be of a clinical, technological or managerial nature, or a combination of these. The selected solution must take full account of relevant social factors and have the potential of scaling up rapidly.

2. PRIZE AMOUNT

The European Commission will award a prize of 1 Million EUR.

3. ADDITIONAL PRIZES

The Bill & Melinda Gates Foundation and Merck Sharp & Dohme Corp. have each committed to award the winning contestants[1] selected by the European Commission.

The additional funding envisaged by the Bill & Melinda Gates Foundation is 1 Million EUR

The additional funding envisaged by Merck Sharp & Dohme Corp. is 500 000 EUR

Up to 2 (two) additional prizes may be awarded.

[1] Disclaimer: The payment of the additional prizes is under the sole responsibility and independent responsibility of the Foundation and MSD. The European Commission cannot be held liable for the payment of the additional prizes. Additional information can be accessed on MSD website through the following link: www.MSDforMothers.com

4. DEADLINES & ADMISSIBILITY

Deadlines	
Opening date of the submission:	28 April 2016
Closing date for submission:	06 September 2017 at 17:00:00 CET[2]

Applications must be submitted by the (lead) contestant via the Participant Portal 'Submission Service', accessible via the call page.

Applications must be readable, accessible and printable. Incomplete applications may be considered inadmissible if essential elements are missing (e.g.: mandatory documents as outlined in the application guide).

The page-limit for this application to compete in the prize is 70 pages. Sample application forms are available as reference documents on the Participant Portal.

5. ELIGIBILITY CRITERIA

The contest is open to all legal entities (i.e. natural or legal persons, including International organisations) or groups of legal entities regardless of place of establishment

Please note however that special rules apply for Israeli entities[3] and for Crimean legal persons and that entities from non-EU Member States that are covered by Council sanctions are not eligible to participate[4] (see General Annex C to the Main Work Programme).

Moreover, contestants that have already received an EU or Euratom prize cannot receive a second prize for the same activities.

6. AWARD CRITERIA

The prize will be awarded to the application that in the opinion of the jury demonstrates a solution that best addresses the following cumulative criteria:

(a) Demonstrated (through scientifically sound and well-established methods) reduction of maternal and/or new-born morbidity and mortality and/or number of stillbirths in facility-based deliveries. The main focus of the Birth Day Prize is improving outcome of a facility based delivery.

(b) Absence of clear safety concerns (also with respect to the potential effect in the longer term – no adverse effects) documented over a period of at least six months

(c) Potential for rapid scalability, demonstrated by the affordability, acceptability and simplicity in use of the proposed application.

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2 Central European Time = Brussels local time.

3 See Commission Guidelines on the eligibility of Israeli entities and their activities in the territories occupied by Israel since June 1967 for grants, prizes and financial instruments funded by the EU from 2014 onwards (OJ C 205 of 19.7.2013, pp. 9-11).

4 For the list of persons, groups and entities subject to EU financial sanctions, see http://eeas.europa.eu/cfsp/sanctions/consol-list_en.htm.

6.1 Evaluation guidance

This part is a clarification of the award criteria that will be used for evaluating the applications. Sub-criteria have been added to clarify what is expected from contestants.

A. Reduction of maternal and/or new-born mortality/morbidity and/or stillbirths: The contestants will have to provide evidence on the positive impact of the submitted application on the health outcomes in the intervention facility(-ies). The evidence should highlight how the application has improved the health outcomes in terms of mortality and/or morbidity of mothers and/or new-borns and/or stillbirths. The main focus of the Birth Day Prize is on delivery and the neonatal period (i.e. 28 days after birth); the outcomes measures of submitted applications should thus specifically address this period of time.

As far as morbidity is concerned, a greater value will be placed on applications that address conditions that represent a high risk to the individual or a high volume or a high cost to the health system and society.

A greater value will be placed on applications that have demonstrated an impact on the health outcomes of mothers AND new-borns AND stillbirths (including mortality and morbidity, if possible).

Method of measurement: health outcomes from the facility (-ies) covered by the application compared to baseline assessment; scientific arguments supporting the attribution of the reduction of maternal and/or new-born mortality/morbidity and/or stillbirths to the application.

- **With respect to the scientifically sound methodology**: contestants will have to provide data on the process underpinning the application. The contestants should provide a clear methods section with a description of measurements, tools for measurement, reasons for choosing tools, justification/rationale for choice of a particular site or sites for the pilot or intervention and - if relevant – description of sample and reasons for sample choice.

  Method of measurement: Quality and effectiveness of the S/T (Scientific and or Technological) methodology, used to describe the evidence, reliability of the data provided.

- **With respect to the Innovative aspect:** the application has to be novel and developed by the contestant. The novelty of the application can be either in the application itself or in the way it is being implemented (i.e. an already existing application that is being used in a novel manner, i.e. in a different context or at scale)

  Method of measurement: the extent to which the application is beyond the state of the art, and demonstrates innovation (e.g. novel concepts and approaches, new products, services or business and organisational models).

B. Absence of safety concerns. Contestants will include a risk-benefit analysis with a Risk intensity rating (low, medium high) and a Risk Management Plan for the medium to high identified risks of the application over a period of minimum 6 months.

Method of measurement: data on all potential adverse effects identified within the application and how each of them has been addressed, quality of the risk management plan.

Concerning medicinal products-related applications, the evidence will depend on the actual status of the products used. If these are still in trial, the contestant will provide copies of approval from national authorities and/or opinion of the ethical committees for the relevant clinical trials. For applications using medicinal products that have already been approved, the contestant will provide information on the regulation status of the products in this or other indication.

Important remark: applications showing clear safety concerns will not be considered for being awarded any of the prizes. In this view, the threshold and maximum points are identical: applications receive a score of 0 if clear safety concerns emerge from the evaluation or a score of 10 if no clear safety concerns arise.

C. Potential for rapid scalability. Contestants will have to provide data and/or arguments to defend the scalability of their proposed application. The application should thus be reproducible in settings of intended use. Supporting documentation can be real data on the implementation of the application in different settings or scientific arguments supporting the applicability of the application in settings of intended use.

A greater value will be placed on applications that have demonstrated their replicability in settings of intended use as opposed to those who only argue they are replicable. Should the application include (a) product (s) that is (are) intended to go to market, research data on the unmet need as well as a competitive situational analysis – both of which can either help or hinder market uptake should be included.

Method of measurement: data on the actual implementation of the application in different settings (if available) or scientific arguments supporting the replicability of the application in various settings of intended use.

- **with respect to affordability:** the contestants should provide evidence of how the application could be economically viable for the setting(s) in which it is intended.

  Method of measurement: description of the costs associated with building the application (Cost of Goods), description of the costs associated with the implementation of the application (including consumables, required ancillary items); an estimate of the cost-benefit of the application.

- **With respect to acceptability:** the application should be acceptable to end-users, health providers and payers from the setting(s) in which the application is intended. The contestants will provide data from research supporting the acceptability of the application or provide evidence or sound assumption-based arguments that the application will likely be acceptable to the population and the health providers of the setting.

  Method of measurement: research data on an actual end-user (and other users if applicable) and health professional acceptability in the intended facility (-ies) or evidence or sound assumption-based scientific arguments supporting the acceptability of the application for end-users and/or health professionals in the intended facility (-ies). Acceptability includes willingness to accept a unique application and/or replace a proven application with a new one.

- **With respect to simplicity in use**: the application should be usable by facility-based health workers within the setting(s) in which it is intended. Simplicity in use and re-use and limited need for training are preferred.

  Method of measurement: evidence that health workers of the facility have the necessary knowledge and training to use the application, a list of the necessary knowledge and training necessary to use the application in a satisfactory manner

7. DOCUMENTS

The mandatory supporting documents are set out in the application form.

Contestants may be asked at a later stage for further documents (for legal entity validation, bank account validation, ethics review, declaration of honour on exclusion grounds, etc.).

8. PROCEDURE

Applications will have to pass an eligibility check. All eligible applications will be evaluated by an independent expert jury between September 2017 and October 2017 — first individually (by each expert separately) and then as a group (by the whole jury together).

The jury will evaluate each application against the 3 award criteria and score them as follows

Criterion	Threshold	Maximum points
a. Reduction of maternal and/or newborn mortality/morbidity and/or stillbirths	40	60
b. Absence of clear safety concerns	10*	10
c. Potential for rapid scalability	15	30
Total	**65**	**100**

* Please refer to the evaluation guidance for criterion B.

The 10 best applications will be invited as finalists in October 2017 for a hearing.

Upon completion of their work, the jury will sign a jury report of the applications examined, containing an assessment of their quality and identifying those to which the prizes may be awarded.

On the basis of the evaluation, the Commission will select the winner(s).

All contestants will be informed at the end of 2017.

9. OTHER CONDITIONS

9.1 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 contestant concerning the interpretation, application or validity of the rules of this contest, if such dispute cannot be settled amicably. For contestants that are International organisations such disputes with the Commission relating to the Contest must - if they cannot be settled amicably - be referred to arbitration.

The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Contest will apply.

9.2 Payment arrangements

The prize money (EUR 1 million) will be paid in one instalment after the award ceremony by bank transfer, provided all the requested documents have been submitted.

The payment of the additional prizes is under the sole and independent responsibility of the Foundation and MSD. The European Commission cannot be held liable for the payment of the additional prizes.

9.3 Publicity — Promoting the prize — Visibility of EU funding

9.3.1 Publicity by the winner(s)

The winner(s) must 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:

For the first winner "This action has been awarded the Horizon Birth Day Prize from the European Union's Horizon 2020 research and innovation programme".

For the winners of additional prizes "This action has been awarded an additional prize in the Horizon Birth Day Prize Contest by the Bill & Melinda Gates Foundation" or "This action has been awarded an additional prize in the Horizon Birth Day Prize Contest by the Merck Sharp & Dohme Corp."

The logo of the other funders participating in this initiative should be displayed together with the EU emblem in the event each of the funders has provided its written approval to do so and transmitted the relevant conditions and other information to the winner(s) of the additional prizes.

When displayed together with another logo, the EU emblem must have appropriate visibility.

For the purposes of its obligations, the winner(s) 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(s) may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

9.3.2 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 deliverables as well as any other material, such as pictures or audio-visual material that it receives from the winner(s) (including in electronic form).

The Commission will publish the name of the finalists and winner(s), their origin, the amount of the prize and its nature and purpose— unless the winner has requested to waive this publication (because 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.

9.4 Dissemination and exploitation of results

The winner(s) must comply with the obligations set out in Title III of the Rules for Participation Regulation No 1290/2013[5]

[5] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013 p.81).

9.5 Processing of personal data

9.5.1 Processing of personal data by the Commission

Any personal data will be processed by the Commission under Regulation No 45/2001[6] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the Commission (publicly accessible in the DPO register).

Such data will be processed by the 'data controller' of the Commission for the purposes of the award, implementation and follow-up of the prize or protecting the financial interests of the EU or Euratom (including checks, audits and investigations; see below).

The Commission will transfer the personal data of the second and third ranked winners, respectively to The Bill & Melinda Gates Foundation and to Merck Sharp & Dohme Corp., subsidiary of Merck & Co. Inc., for the purpose of (i) determining eligibility to receive the award[7] (ii) if eligible following such determination, awarding the additional prizes and making the payment of the committed amounts[8].

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the 'service specific privacy statement(s) (SSPS)' that are published on the Commission websites.

They also have the right to have recourse at any time to the European Data Protection Supervisor (EDPS). The winner(s) consent that the Commission publishes (in whatever form and medium) the following information:

(a) name

(b) Member State of origin (address or NUTS 2 region)

(c) their activities in relation to the award of the prize (via the summary for publication they provided)

(d) prize amount.

9.5.2 Processing of personal data by the contestants

The contestants must process personal data in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The contestants may grant their personnel access only to data that is strictly necessary for the award, implementation or follow-up of the prize.

The contestants must inform the personnel whose personal data are collected and processed by the Commission. For this purpose, they must provide them with the service specific privacy statement(s) (SSPS) (see above), before transmitting their data to the Commission.

9.6 Ethics

The activities must be carried out in compliance with:

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[6] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 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 (OJ L 8, 12.01.2001, p. 1).

[7] Additional information on the eligibility criteria of MSD can be found using the following link www.MSDforMothers.com

[8] By applying to this contest the applicants agree to this transfer to the Bill & Melinda Gates Foundation and to the Merck Sharp & Dohme Corp., subsidiary of Merck & Co. Inc. in case of being considered for the award of these additional prizes, for the above mentioned purposes, in accordance with Article 9.6(b) of Regulation (EC)No 45/2001

(a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[9] — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

(b) applicable international, EU and national law.

No prize will be awarded for activities carried out outside the EU, if they are prohibited in all Member States.

The contestants must ensure that the activities have an exclusive focus on civil applications.

The contestants must ensure that the activities do not:

- aim at human cloning for reproductive purposes
- intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads) or
- intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

Research activities involving human embryonic stem cells (hESC) are moreover subject to the conditions set out in the Statement of the Commission related to research activities involving human embryonic stem cells.

For more information and best practice, see the Online Manual, the sample application form for prizes and the guidance 'How to complete your ethics self assessment'.

9.7 Conflict of interests

The contestants must take all measures to prevent any situation where the impartial and objective award of the prize is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('conflict of interests').

They must inform the Commission without delay of any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The Commission may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

9.8 Liability for damages

The Commission cannot be held liable for any damage caused to the contestants or to third parties as a consequence of the award or implementation of the prize, including for gross negligence.

The Commission cannot be held liable for any damage caused by any of the contestants, as a consequence of activities linked to the prize.

9.9 Checks, audits and investigations

The Commission, the European Anti-Fraud Office (OLAF) and the Court of Auditors may carry out checks, audits and investigations in relation to the prize.

[9] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.
http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

9.10 Withdrawal of the prize — Recovery of undue amounts

The Commission may withdraw the prize and recover all payments made, if it finds out that:

(a) false information or fraud or corruption was used to obtain the prize or

(b) the winner was not eligible or should have been excluded.

9.11 Exclusion and financial penalties

Contestants will be excluded if (or for points (a)(b) a natural or legal person that assumes unlimited liability for the debts of the contestant; or for points (c)(d)(e)(f) a natural person who is a member of the administrative, management or supervisory body of the contestant, or who has powers of representation, decision or control with regard to that contestant)[10]:

(a) it is bankrupt, subject to insolvency or winding up procedures, its assets are being administered by a liquidator or by a court, it is in an arrangement with creditors, its business activities are suspended or it is in any analogous situation arising from a similar procedure provided for under national legislation or regulations;

(b) it has been established by a final judgement or a final administrative decision that the contestant is in breach of its obligations relating to the payment of taxes or social security contributions in accordance with the law of the country in which it is established, with those of the country in which the authorising officer is located or those of the country of the performance of the contract;

(c) it has been established by a final judgement or a final administrative decision that the contestant is guilty of grave professional misconduct by having violated applicable laws or regulations or ethical standards of the profession to which the contestant belongs, or by having engaged in any wrongful conduct which has an impact on its professional credibility where such conduct denotes wrongful intent or gross negligence, including, in particular, any of the following:

(i) fraudulently or negligently misrepresenting information required for the verification of the absence of grounds for exclusion or the fulfilment of selection criteria or in the performance of a contract, a grant agreement or a grant decision;

(ii) entering into agreement with other persons with the aim of distorting competition;

(iii) violating intellectual property rights;

(iv) attempting to influence the decision-making process of the Commission during the award procedure;

(v) attempting to obtain confidential information that may confer upon it undue advantages in the award procedure;

(d) it has been established by a final judgement that the contestant is guilty of any of the following

(i) fraud, within the meaning of Article 1 of the Convention on the protection of the European Communities' financial interests, drawn up by the Council Act of 26 July 1995;

(ii) corruption, as defined in Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of EU Member States, drawn up by the Council Act

[10] Article 105a, paragraphs 1 to 4, 6 and 7, except point (b) of the first subparagraph and the second subparagraph of that paragraph, paragraphs 8, 9, 11 and 13 to 17 of Article 106 and Article 108 of the 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 repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 218, 26.10.2012, p.1) shall apply to participants and winners. Article 107 shall apply to participants.

of 26 May 1997, and in Article 2(1) of Council Framework Decision 2003/568/JHA, as well as corruption as defined in the legal provisions of the country where the authorising officer is located, the country in which the contestant is established or the country of the performance of the contract;

(iii) participation in a criminal organisation, as defined in Article 2 of Council Framework Decision 2008/841/JHA;

(iv) money laundering or terrorist financing, as defined in Article 1 of Directive 2005/60/EC of the European Parliament and of the Council;

(v) terrorist-related offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA, respectively, or inciting, aiding, abetting or attempting to commit such offences, as referred to in Article 4 of that Decision;

(vi) child labour or other forms of trafficking in human beings as defined in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council;

(e) it has shown significant deficiencies in complying with the main obligations in the performance of a contract, a grant agreement or a grant decision financed by the Union's budget, which has led to its early termination or to the application of liquidated damages or other contractual penalties, or which has been discovered following checks, audits or investigations by an Authorising Officer, OLAF or the Court of Auditors;

(f) it has been established by a final judgment or final administrative decision that the contestant has committed an irregularity within the meaning of Article 1(2) of Council Regulation (EC, Euratom) No 2988/95;

(g) for the situations of grave professional misconduct, fraud, corruption, other criminal offences, significant deficiencies in the performance of the contract or irregularity, the contestant is subject to:

(i) facts established in the context of audits or investigations carried out by the Court of Auditors, OLAF or internal audit, or any other check, audit or control performed under the responsibility of an authorising officer of an EU institution, of a European office or of an EU agency or body;

(ii) non-final administrative decisions which may include disciplinary measures taken by the competent supervisory body responsible for the verification of the application of standards of professional ethics;

(iii) decisions of the ECB, the EIB, the European Investment Fund or international organisations;

(iv) decisions of the Commission relating to the infringement of the Union's competition rules or of a national competent authority relating to the infringement of Union or national competition law.

(v) decisions of exclusion by an authorising officer of an EU institution, of a European office or of an EU agency or body.

Contestants will also be excluded if they misrepresent the information required as a condition for participating in the procedure or fail to supply that information.

However contestants will not be excluded where:

(a) they have taken remedial measures11, thus demonstrating their reliability. This point shall not apply in the case referred to in point (d) above;

(b) such an exclusion would be disproportionate12.

If a contestant is in one of the exclusion situations referred the Commission may also impose:

- decisions excluding the contestants from all contracts, grants and contests financed from the EU or Euratom budget for duration not exceeding the duration, if any, set by the final judgement or the final administrative decision of a Member State and either five years for the cases referred to in paragraph 4.2 (d) or three years for the cases referred to in paragraph 4.2 (c), (e) and (f).and/or

- a financial penalty between 2% and 10% of the value of the prize on a contestant in one of the cases referred to in paragraph 4.2 (c), (d), (e) and (f).

9.12 Evidence upon request

Whenever requested by the Commission and where it is necessary to ensure the proper conduct of the procedure the contestant as well as other entities whose capacity the lead-contestant rely on, shall provide evidence that the contestant or a legal or natural person that assumes unlimited liability of debts of the contestant; a natural person who is a member of the administrative, management or supervisory body of the contestant, or who has powers of representation, decision or control with regards to that contestant is not in one of the exclusion situations referred to in paragraph 8.11.

9.13 Cancellation of the contest

The Commission may cancel the contest or decide not to award a prize — without any obligation to indemnify contestants — if:

- no applications are received
- the jury does not find a winner or
- the winner Is not eligible or must be excluded.

the objective of the contest has already been achieved.

10. CONTACT

For more information, please see the prize website.

In case of questions, please contact the Horizon 2020 Helpdesk.

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11 The measures which remedy the exclusion situation may include, in particular: measures to identify the origin of the situations giving rise to exclusion and concrete technical, organisational and personnel measures within the relevant business area of the economic operator, appropriate to correct the conduct and prevent its further occurrence; proof that the economic operator has undertaken measures to compensate or redress the damage or harm caused to the Union's financial interests by the underlying facts giving rise to the exclusion situation; proof that the economic operator has paid or secured the payment of any fine imposed by the competent authority or of any taxes or social security contributions.

12 In particular taking into account the seriousness of the situation, including the impact on the Union's financial interests and image, the time which has elapsed since the relevant conduct, its duration and its recurrence, the intention or degree of negligence, the limited amount at stake for point (b) above or any other mitigating circumstances, such as the degree of collaboration of the economic operator with the relevant competent authority and its contribution to the investigation as recognised by the contracting authority, or the disclosure of the exclusion situation by means of the declaration.