जैव प्रौद्योगिकी विभाग
Department of Biotechnology
Ministry of Science & Technology
Government of India

EUROPEAN UNION

India-EU Research and Innovation Action
Towards A Next Generation Influenza Vaccine to Protect Citizens Worldwide

Guidelines for Submission of Joint Proposal

The European Union (EU) and India have agreed on a flagship call topic for international cooperation on the next generation influenza vaccine aiming at advancing the efficacy and safety, duration of immunity, and reactivity against an increased breadth of influenza strains. Improved influenza vaccines should ease a significant global health burden, and also help the international community to better prepare in the event of an influenza pandemic. In engaging jointly on this topic, India and the EU are also contributing to an important global public health challenge.

For this call, the European Commission (EC) through the EU funding programme for research and innovation 'Horizon 2020' has committed EUR 15 million and the Department of Biotechnology (DBT), Government of India, agreed to match that amount. In total, funding of EUR 30 million will thus be available.

The call text and the opening and closing date are the same for applicants from both Europe and India. Applicants from other countries may also join EU-India consortia. Evaluation of the proposals will take place as per independent peer review process. For funding the Indian participants, DBT will check the eligibility and budgetary requirements of the applicants. It is thus of utmost importance that guidelines hereunder are closely followed in preparing and submitting the proposal.

Contents

1. Snapshot

Call Focus	Towards a next generation influenza vaccine to protect citizens worldwide – an EU -India collaboration.
Eligible Applicant(s)	Minimum THREE applicants from Europe (from three different Member States/Associated Countries) and minimum THREE applicants from India. Eligibility for European applicants will be as per Horizon 2020 rules of participation; and for Indian applicants as per Indian law specified in guidelines hereunder.
Types of action	Research and Innovation Action (RIA)
Deadline Model	Single-stage
Submission opens	26 July 2018
Submission deadline	16 April 2019- 17h00 - Central European Time (CET) = 20h30 Indian Standard Time (IST)
Announcement of Results	August 2019
Scope	This call aims at further advancing the next generation influenza vaccine candidate(s) with improved efficacy and safety, duration of immunity, and reactivity against an increased breadth of influenza strains. Proposal should make use of new and multidisciplinary knowledge. It should bring together all vital stakeholders of complete value chain i.e. from vaccine research to pre-clinical and/or clinical development in a joint effort towards vaccine development to global cause. See complete text of call in Annex 1 and also on websites of: • **European Commission Horizon 2020 Participant Portal:** http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/topics/sc1-bhc-32-2019.html • **Department of Biotechnology (DBT):** http://www.dbtindia.nic.in/funding-mechanism/call/
Project Duration	Up to Five years
Award Amounts	Estimated between EUR 6 to 10 million per project from European side and matched by funding from DBT covering Indian applicants. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.
Proposal Forms	Proposal must be prepared according to Horizon 2020 requirements. In addition Indian applicants need to comply with the administrative & financial requirements as per DBT format (see Annex 2).

How to Apply	Complete text of proposals must be submitted to **both** funding agencies: 1) Horizon 2020 - Participant Portal: Electronic Proposal Submission portal: http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/topics/sc1-bhc-32-2019.html 2) Project Proposal via email to DBT (see section 8.2)
Contact DBT	• Dr Shailja V. Gupta, Scientist-'G', Division of International Cooperation, Department of Biotechnology, New Delhi, India • Dr Amit P. Parikh, Scientist-'E', Division of International Cooperation, Department of Biotechnology, New Delhi, India

2. Participation

Proposals for a collaborative Research and Innovation Action (RIA)[1] should be submitted by a consortium of at least **three** legal entities from India and **three** legal entities from three different EU Member States and/or Associated Countries.

2.1 Participants from India:

- At least **three** legal entities/ organizations (see section 3.1) established in India with expertise in relevant and distinct disciplines. All three legal entities shall be independent of each other.

- The call is open to all career groups (i.e. early, intermediate and senior); however, we expect that investigators will have adequate service tenure to accommodate key research, coordination and outreach responsibilities. Coordinator may also see that early career investigators are encouraged to participate.

2.2 Participants from EU:

- **Entities from Member States of the European Union**[2], including their overseas departments and outermost regions[3]; and

- Entities from **Associated Countries** (AC)[4] to EU R&I Programme 'Horizon 2020'.

Jointly called hereafter participants from **'Europe'.**

[1] http://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2016_2017/annexes/h2020-wp1617-annex-d-ria_en.pdf

[2] https://europa.eu/european-union/about-eu/countries_en

[3] http://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2018-2020/annexes/h2020-wp1820-annex-a-countries-rules_en.pdf

[4] As of 1 May 2018, the following countries are associated to Horizon 2020: Iceland, Norway, Albania, Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia, Montenegro, Serbia, Turkey, Israel, Moldova, Switzerland, Faroe Islands, Ukraine, Tunisia, Georgia, Armenia.

All three legal entities shall be independent of each other within the meaning of Article 8 of Horizon 2020 Rules for Participation[5].

Note:

As specified in the Participant Portal "Until the UK leaves the EU, EU law continues to apply to and within the UK, when it comes to rights and obligations; this includes the eligibility of UK legal entities to fully participate and receive funding in Horizon 2020 actions. The eligibility criteria must be complied with for the entire duration of the grant. If the United Kingdom withdraws from the EU during the grant period without concluding an agreement with the EU ensuring in particular that British applicants continue to be eligible, you will cease to be eligible to receive EU funding (while continuing, where possible, to participate) or be required to leave the project on the basis of Article 50 of the grant agreement."

UK Government Statement: UK businesses and universities should continue to bid for competitive EU funds while we remain a member of the EU and we will work with the Commission to ensure payment when funds are awarded. The Government will underwrite the payment of such awards, even when specific projects continue beyond the UK's departure from the EU."

2.3 Composition of Consortium:

This Research & Innovation Action (RIA) will be carried out by a consortium of organisations working together on specific research and innovation areas identified in the call text.

In addition to the **six mandatory participants (3+3)**, there is **no restriction on additional number of participating** entities/organizations from India and Europe. Based on the principle 'Horizon 2020 Open to the World', entities located anywhere in the world are also eligible to join the project consortium, subject to specific Horizon 2020 funding rules.

The number of project partners should be optimum and correspond to the objectives of the project. Each project should clearly demonstrate the partner's essentiality, complementarities, and added value in jointly addressing the topic.

According to European Commission (EC) guidelines, a Horizon 2020 project proposal must appoint a consortium beneficiary to serve as the central contact point and represent the consortium towards the EC. This beneficiary is also known as the **'Project Coordinator'**[6]. It is advised to appoint project coordinator from among the European participants, who is familiar with the Horizon 2020 rules, requirements and procedures. By the same token, it is required to nominate a **'Lead Scientific**

[5] https://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/rules_participation/h2020-rules-participation_en.pdf

[6] **Project Coordinator**: A project coordinator is the individual who leads a Horizon 2020 project. Most often, the project coordinator will organize the consortium, prepare the proposal and manage the project. The coordinator signs the Grant Agreement for his or her organization with the European Commission and other beneficiaries accede to the Agreement. The coordinator is the only authorized representative of the consortium for any communication with the European Commission. https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/amga/h2020-amga_en.pdf (page 15)

Coordinator' among the Indian participants, to represent them in the consortium. The Lead Scientific Coordinator will conduct all official communication with DBT.

2.4 Gender Balance:

Applicants are encouraged to promote equal opportunities in the implementation of the action by ensuring a balanced participation of women and men at all levels of the research and innovation teams and in the management structures.

3. Eligibility

The participating entities/organisations have to be a legal entity as per Indian law (Indian applicants) and Horizon 2020 rules of participation (European and Indian applicants).

3.1 India - Entities eligible to participate:

- Government of India supported or recognised (Public or Private) academia; research organisations and urban or other local bodies;
- Government of India recognised not-for-profit, NGO(s)/ VO(s)/ Trust(s)/ Research foundations, having research as one of the imperative mandates;
- Indian Industry can be a partner in the consortium and are eligible for funding subject to fulfilment of DBT's technical, administrative and financial norms.

Note:
Academic/Research Partners:

- *Public and/or private universities and research organisations must have a well-established research support system, for basic or applied research; and*
- *Submission of proof of establishment under Indian statue; recognition documents and registration at Government of India's Public Finance Management System (PFMS) - https://pfms.nic.in shall be obligatory.*

Not-for-profit, NGO(s)/ VO(s)/ Trust(s)/ Research Foundations:

- *The Indian private R&D performing institutions and Not-for-profit, NGO(s)/ VO(s)/ Trust(s)/ Research foundations should have experience of at least 3 years in scientific research, teaching, training and extension activities; and*
- *Proof of registration at 'NGO DARPAN' of NITI Aayog (http://ngodarpan.gov.in/); Certificate of registration under Society Registration Act; certificate of DSIR in-house R&D recognition and registration at Government of India's Public Finance Management System (PFMS) (https://pfms.nic.in) shall be obligatory;*

***Industry partners**:*

- *Should be an Indian Company registered under the Companies Act, wherein 51% (or more) of the ownership/shareholding/partnerships shall be held by resident Indian citizen(s); and*
- *Submission of certificate of incorporation issued under Companies Act; Shareholding/ subscriber Particulars; certificate of DSIR in-house R&D recognition and registration at Government of India's Public Finance Management System (PFMS) - https://pfms.nic.in shall be obligatory.*

Ineligible organisations:

- *Companies headquartered and owned outside India and their subsidiaries in India, or vice versa, are not eligible to receive funding from DBT under this action; and*

- *Research centres and academic organisations headquartered and owned outside India and their subsidiaries in India, or vice versa, are not eligible to receive funding from DBT under this programme.*

3.2 Europe - entities eligible to participate[7]:

- Any natural or legal person (e.g. any company, big or small, research organisations, universities, non-governmental organisations, etc.) regardless of their place of residence or establishment in Europe;
- They must possess the operational and financial viability to carry out the research tasks that they propose.

4. Funding

Proposals requesting a contribution from the EU between EUR 6 and 10 million, to be matched by DBT funding, for a project duration up to 5 years will be supported under this Call.

Budget should be commensurate with the workload, objectives of the project and cost of participation.

4.1 Funding by DBT/ India:

4.1.1 DBT will support:

Budgeted costs of the project to legal entities subject to obligatory fulfilment of eligibility criteria:

i. DBT will support (Grant-in-aid) 100% of the approved budget costs to the following two categories of organizations:

   a. Government of India supported or recognised public or private academic institutions or research organisation, and urban or other local bodies;

   b. Not-for-profit, NGO(s)/ VO(s)/ Trust(s)/Research foundations, having research as one of the imperative mandates

Eligible costs for funding are: Capital expenditure (equipment's) || Manpower || Consumables || Travel (local and international travel) || Contingency || Overheads || Outsourcing || others. (*Academia can factor in additional sub heads (in other category) such as training & awareness; workshops; publications; review meetings, etc. under expenditure based on the requirement of the project).*

[7]http://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/applying-for-funding/find-partners_en.htm

ii. Grant-in-aid to Industry:

a. DBT's support to Industry shall not exceed 50% of the total project cost and the remaining 50% contribution shall mandatorily come from the Industry;

b. The cost breakup for the DBT component of the proposal shall be: Capital and Manpower costs each not exceeding 30% of the DBT supported project cost; and balance will cover consumables and travel costs. Contingency & overhead costs will not be permissible;

4.1.2 Non allowable cost from DBT:

i. Civil Construction costs
ii. Prosecution/litigation costs
iii. Salary of investigators

4.2 Funding by EU:

Funding of European partners as per Horizon 2020 rules of participation for the Research and Innovation Actions (RIA). For details, see:
http://ec.europa.eu/research/participants/data/ref/h2020/other/gm/h2020-grant-factsheet_en.pdf

5. Finding partners

The starting point is to consider partners with whom you already have direct or indirect connections. As participation in a Horizon 2020 call requires an interdisciplinary and/or inter-sectoral approach for a challenge to be addressed appropriately, it may become necessary to look for partners outside the usual circle of contacts.

Hereunder you will find a list of European services that assist in finding the right partners:

Partner search tools	
Expressed Interest	H2020 – Participant Portal: search by call topics where organisations have participated or expressed interest in participating in the future.
euMatch 2.0	Partner Search and Matchmaking platform to find partners and project initiatives to participate in H2020 supported health related projects.
Participant portal partner search platform	Search among partners of existing projects.
Enterprise Europe Network cooperation	Includes both business and technology offers and requests

opportunities database	
Social media	
LinkedIn group "Environment projects & partner search – EASME"	In particular for applicants for Horizon 2020 and LIFE projects
Partnering events	
Info Days in Brussels	DG RTD (Health) occasionally organises information and networking days in Brussels. Details of these events will be available online and will be distributed through the NCP network. Info about the last Info Day webinar is available here
Information days & networking events in India	DBT and the Delegation of the European Union to India will be organising networking events in a number of cities in India. Details of these events will be available online and distributed in Europe through the NCP network(s). DBT: http://www.dbtindia.nic.in/events/ EU DEL: https://eeas.europa.eu/delegations/india_en .
Brokerage events organised by the Enterprise Europe Network	Often back-to-back with key trade fairs and conferences.
National Contact Points	
National Contact Points	Personalised support & assistance in partner search in applicants' respective countries.
Euraxess India	Partnering tools for Horizon 2020 calls.
Databases of previous and ongoing projects	
CORDIS project database	Projects funded under Horizon 2020 as well as previous research framework programmes.
Horizon 2020 SME Instrument	Innovation by small and medium-sized companies in the fields of eco-innovation & sustainable supply of raw materials, and environment & climate action.

6. Preparation of joint proposal:

The Indian and European participants must formulate a joint proposal according to the requirements and templates provided by the Horizon 2020 – Participant Portal format[8] and DBT's administrative and financial requirements.

The format and components of the proposal are compulsory. The proposal itself consists of two main parts:

- **Part A:** the **Administrative Forms** containing general information on the project (title, abstract, and keywords), the consortium (basic administrative data, contact persons, declarations) and the budget overview.

- **Part B**: the Technical Annex containing the detailed description of the **planned research and innovation project**. The structure is based on the evaluation criteria (cite them here) as provided in the proposal template for a RIA.

In addition, the administrative and financial requirements specifically for Indian applicants must be provided according to DBT templates (see Annex 2). These documents shall be added to the Horizon 2020 online proposal as an Annex.

Further mandatory or optional annexes (e.g. supporting documents for regulatory and ethics issues) required by the call and the given topic, as shown in the submission system.

It is essential that the project consortium makes a thorough analysis of the project strengths, weaknesses, opportunities and threats, prior to filling out technical section. It is equally important to address properly the project management and provide for a detailed time and cost plan as well as the exploitation and dissemination of results.

Note:
IPR legislation and other rules are often crucial for participants in research projects, as they may have a deep influence on the way in which the knowledge can be shared during a project resulting, and in which project results can be commercially used.

The participants shall jointly develop a Consortium Agreement (CA)[9]. The CA is a specific agreement to be concluded between the participants in joint research defining, among other things, ownership, protection, user rights for research and development purposes, exploitation and dissemination, including arrangements for joint publication, the rights and obligations of visiting researchers and dispute settlement procedures. The CA shall also address foreground and background information, licensing and deliverables.

The IPR issues for all the proposals need to satisfy the S&T agreement between EU and India[10] and should also be in conformity with the Annotated Model Grant Agreement [11] [12].

[8] https://ec.europa.eu/research/participants/data/ref/h2020/call_ptef/pt/2018-2020/h2020-call-pt-ria-ia-2018-20_en.pdf
[9] http://ec.europa.eu/research/participants/data/ref/h2020/other/gm/h2020-guide-cons-a_en.pdf
[10] http://trade.ec.europa.eu/doclib/docs/2003/july/tradoc_113341.pdf
[11] http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/amga/h2020-amga_en.pdf
[12] http://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/grant-management_en.htm

6.1 Preparation of Budget

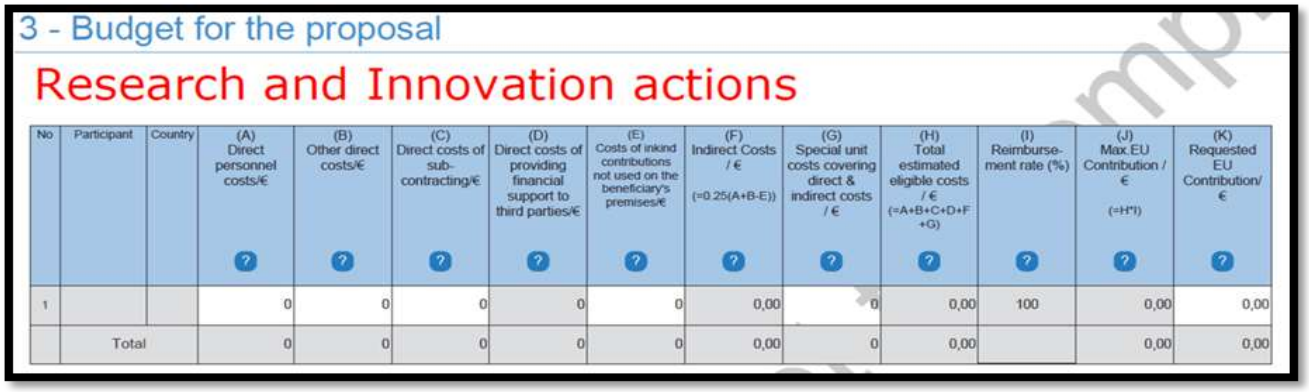
The "Project Coordinator" must ensure that the financial budget in the joint proposal to the EU is presented in EUR (€), while the "Lead Scientific Coordinator" must ensure that the proposal submitted to DBT is presented in Indian Rupees (₹).

6.1.1 Part A: budget in EUR

- Part A is partially pre-filled with proposal data on: (1) General information, (2) Participants and contacts, (3) Budget; (4) Ethics and (5) call specific questions;

- Each participant (European and Indian) to indicate cost of their action in EUR **in Part A section 3 - Budget for the proposal**;

- The total budget corresponds to the total cost of the project (Colum H).



3 - Budget for the proposal

Research and Innovation actions

No	Participant	Country	(A) Direct personnel costs/€	(B) Other direct costs/€	(C) Direct costs of sub-contracting/€	(D) Direct costs of providing financial support to third parties/€	(E) Costs of inkind contributions not used on the beneficiary's premises/€	(F) Indirect Costs / € (=0.25(A+B-E))	(G) Special unit costs covering direct & indirect costs / €	(H) Total estimated eligible costs / € (=A+B+C+D+F +G)	(I) Reimburse-ment rate (%)	(J) Max.EU Contribution / € (=H*I)	(K) Requested EU Contribution/ €
1			0	0	0	0	0	0,00	0	0,00	100	0,00	0,00
	Total		0	0	0	0	0	0,00	0	0,00		0,00	0,00

Note:
Indian applicants should indicate "zero" under columns (I), ((J) and (K) concerning EU contribution requested from EU Horizon 2020, since funded by DBT.

6.1.2 Part B: Indian participants prepare budget (in Rupees) according to DBT format:

- Indian participants **MUST** submit detailed financial plan in **Indian Rupees (₹)** for duration of the project.

- The detailed Indian financial plan for each Indian participant in the project must be specified according to format provided by DBT in Annex 2: Indian academic partners must use "Budget Format - Academic Partner" (*at para G.10)* and Indian industry partners must use "Budget Format - Industry Partner" (*at paraG.11).*

6.1.3 DBT's budget calculation for Indian participants:

The Lead scientific coordinator from India must ensure that each Indian participant follows budget format proposed by the DBT.

Direct Costs:

1) **Manpower cost**: As per the requirements of the project (emoluments will be as per prevailing Gov. of India norms);
2) **Mobility of investigator(s) & project staff(s):** For visit(s) and work related to project to be undertaken by Indian investigator(s) & project staff(s) **in Europe**; the cost of travel and man-days of stay in European countries (i.e. round-trip international travel by economy class, admissible insurances, local transport, boarding and lodging) must be justifiably budgeted by respective Indian organisation for each year, at G. 9, 10, 11 (as applicable) of Annex 2 as well as at Horizon 2020 Participant Portal.

   It is expected that institution hosting the collaborating investigator(s) & project staff(s) of other consortium participants, shall provide research facility and research resources to accomplish defined objectives and if required, it can also be reflected in each participant budget adequately.
3) **Overhead/Indirect Cost:** overhead expenses payable to institute for Indian partners, up to 10% of the total project cost for educational institutions and up to 8% for laboratories and institutions under central Government Departments/Agencies as per prevailing Gov. of India norms.

Note:
The budget that DBT provides to Indian participants does not cover expenses incurred by the European and other countries' applicants in the consortium.

7. Regulatory and Ethical Considerations

7.1 Research using hazardous microorganisms, genetically engineered (GE) organisms & products thereof for R&D purpose:

In India, research using hazardous microorganisms, genetically engineered (GE) organisms & products thereof are governed under Rules, 1989 (Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/ Genetically Engineered Organisms or Cells) of Environment (Protection) Act, 1986, according to which, necessary intimation/ recommendation/ authorization from concerned Institutional Biosafety Committee (IBSC), Review Committee on Genetic Manipulation (RCGM) & Genetic Engineering Appraisal Committee (GEAC) is obligatory based on type & scale of research operations.

Further guidance on regulatory considerations can be obtained from:

- Guidelines and Handbook for IBSCs, 2011
  http://www.dbtindia.nic.in/wp-content/uploads/9.-Guidelines-_Handbook_2011.pdf
- Regulations and Guidelines on Biosafety of Recombinant DNA Research & Biocontainment, 2017
  http://www.dbtindia.nic.in/wp-content/uploads/Draft-Biosafety-Regulations-and-Biocontainment-Guidelines-2017-FF.pdf
- Recommendations for Streamlining the Current Regulatory Framework, 2005
  http://www.moef.nic.in/divisions/csurv/geac/draftreport_rpharma.pdf

7.2 Human and Animal Subjects Research:

DBT and the European Commission are committed to ensure that projects involving human or animal subjects are protected from research risks in compliance with the rules and policies in respectively the EU and India (ICMR/DBT policies).

All projects recommended for award that involve human or animal subjects will undergo Horizon 2020 ethics review[13] as well as a review by the Indian Bioethics Committees prior to award request.

For information on ICMR policies, please consult:

- National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017
  http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf

India PIs of the consortium should apply to their institutional review boards (IRBs)/ institutional ethics committees (IECs) **at the time of submission of proposal** to obtain necessary bioethics approvals from all involved institutions. If selected, Indian PIs are required to submit proof of their institution's IRB/IECs approval to DBT by no later than 30 November 2019.

7.3 Authorizations for pre-clinical and/or human clinical trials:

While exploring vaccine developmental studies in India, Investigators must satisfy regulatory and ethical provisions adopted under:

- Drugs and Cosmetics Rules, 1945 (as amended from time to time) of Drugs and Cosmetics Act, 1940.
- Committee for the purpose of Control and Supervision of Experiments on Animals.
  http://cpcsea.nic.in/Auth/index.aspx

[13] http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm

- Schedule 'Y' of Drugs and Cosmetics Rules, 1945 || Requirements and Guidelines for Permission to Import and/or Manufacture of New Drugs for Sale or to undertake Clinical Trials: http://cdsco.nic.in/html/D&C_Rules_Schedule_Y.pdf
- Guidance for Industry on Preparation of Common Technical Document for Import/Manufacture and Marketing Approval of New Drugs for Human Use (New Drug Application-NDA): http://www.cdsco.nic.in/writereaddata/CDSCO-GuidanceForIndustry.pdf
- Handbook: Good Laboratory Practice (GLP). Quality practices for regulated non-clinical research and development, 2nd ed. Geneva, World Health Organization, 2009 || http://www.who.int/tdr/publications/documents/glp-handbook.pdf
- Clinical Trials Registry of India (CTRI) – India http://ctri.nic.in/Clinicaltrials/login.php

8. Process for submission of joint project proposal

8.1 Submission of proposal on Horizon 2020 Participant Portal[14]:

Proposals must be submitted electronically using the electronic submission system of the Horizon 2020 Participant Portal. This task is to be done by the designated Project Coordinator.

Access to the electronic submission system is available after selecting a topic and a type of action of a call. Click here to start submission:

http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/topics/sc1-bhc-32-2019.html

Proposals must be created and submitted by a representative/contact person of the coordinating organization. The electronic submission system is an online wizard that guides you step-by-step through the preparation of your proposal.

As explained above (Point 6), a proposal consists of 2 main parts: PART A relating to administrative forms (structured information of the basic administrative data, declarations of partners, organizations and contact persons, etc...) and PART B containing the technical specifications, the detailed description of the planned research and innovation project; outlining work packages, budget and costs, etc.
The documents relating to administrative & financial requirements of Indian applicants should also be part of the electronic submission.

Further mandatory or optional annexes (e.g. supporting documents for regulatory and ethics issues) may be required, as shown in the submission system.

[14] http://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/applying-for-funding/submit-proposals_en.htm

The **H2020 Online Manual**[15] provides a detailed step-by-step guide on how to electronically submit the proposal.

8.2 Submission to DBT by the Lead Scientific Coordinator from India:

The Lead Scientific Coordinator from India must submit the **complete proposal,** Part A + Part B + administrative and financial form (same as submitted on the Horizon 2020 Participant Portal) as single consolidated PDF file, by **19 April 2019** to email ID: **icone@dbt.nic.in**

Please note that the proposal will be disqualified, if not submitted to above email ID by indicated date or if any discrepancy is found in the proposal submitted at Horizon 2020 Participant Portal and to DBT.

After completion of peer review process, only selected applications will be requested to:

- Submit a duly signed (*by Lead Scientific Coordinator*) and transmitted (*by Utmost Authority of the organization*) short covering letter introducing the application, along with complete proposal to the concerned DBT contact point.
- Resubmit proposal at the electronic project submission portal of DBT.

8.3 Preparation to ensure successful submission to Horizon 2020 Participant Portal:

- Before submitting a proposal, any applicant (from Europe or India) needs to be registered and validated by the European Commission (see registration procedure in Annex 3).
- Online guidance is also provided on how to fill in the administrative forms (Part A).
- Proposal templates for the technical annex can be downloaded from the system. The technical annex and any additional annexes have to be uploaded as PDF documents.

For more details see: https://ec.europa.eu/research/participants/portal/desktop/en/funding/index.html

[15] http://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/applying-for-funding/submit-proposals/submission-tool_en.htm

Annex 1 Call text

Call Text: SC1- BHC-32-2019: Towards a next generation influenza vaccine to protect citizens worldwide – and EU-India collaboration

Type of Action: Research and Innovation action – single stage

Opening on	26 July 2018 00:00 (Brussels local time)
Deadline for proposal submission	16 April 2019 - 17:00 (Brussels local time) - 20:30 (Indian Standard Time)

SC1-BHC-32-2019: Towards a next generation influenza vaccine to protect citizens worldwide – an EU-India collaboration

Specific Challenge: Seasonal influenza is a major health burden, with an estimated 500,000 deaths around the world each year.[16] A further threat from influenza is the non-seasonal emergence of new strains, which have the potential to result in major influenza pandemics.

Despite the large danger posed by both seasonal and pandemic influenza, vaccines against flu are only moderately effective.[17] In addition, current influenza vaccines need to be developed every year, as they only work against a narrow range of the hugely variable influenza subtypes, and are also highly vulnerable to strain mutations after an annual vaccine has been developed. Improved influenza vaccines would simultaneously ease a significant global health burden, and help the international community to better prepare in the event of an influenza pandemic.

The burden of seasonal influenza, and the ever-present threat of a new influenza pandemic, is a high priority for both Europe and India. In recent years, significant progress has been made by teams in India and Europe on influenza vaccination. To build on this shared recognition of the importance of influenza, as well as significant expertise available in both regions, a renewed effort by India and Europe towards the development of a next generation influenza vaccine is needed. Furthermore, utilisation of the human challenge model of influenza, or work to improve the model itself, may be an important step to progress this essential field.

Scope: Proposals should further the advancement of next generation influenza vaccine candidate(s) with improved efficacy and safety, duration of immunity, and reactivity against an increased breadth of influenza strains. Proposals should make use of new knowledge of, for example, structural biology, immunology, genetics and genomics, influenza transmission modelling, vaccine production, formulation and delivery methods.

Proposals should cover at least pre-clinical and/or early clinical research, selecting promising vaccine candidate(s), supporting their proof of concept, showcasing new pre-clinical or clinical knowledge.

[16] World Health Organization seasonal influenza factsheet: http://www.who.int/mediacentre/factsheets/fs211/en/

[17] ECDC, Influenza vaccination: https://ecdc.europa.eu/en/seasonal-influenza/prevention-and-control/influenza-vaccination

The approach taken should include validation of one or more candidate vaccine(s) in a human challenge model[18] of influenza, and/or work to improve the influenza human challenge model itself. This latter work could include comparative testing of potential human challenge strains, and the responses they elicit in volunteers.

The suitability of the interventions to be developed should be addressed and assessed for different population groups, as should the suitability of the candidate(s) to low- or middle-income settings. The downstream constraints for the uptake of the intervention by national health systems should be taken into account.

Due to the specific challenge of this topic, in addition to the minimum number of participants set out in the General Annexes, proposals shall include at least three participants from India. For more information, interested entities in India shall consult the website of the Department of Biotechnology (DBT) http://www.dbtindia.nic.in/funding-mechanism/call/# , where DBT will indicate the eligibility conditions to Indian applicants. Proposals should include participants from a variety of different disciplines.

The Commission considers that proposals requesting a contribution from the EU of between EUR 6 and 10 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

- Further the development of a vaccine that could be effective against an increased breadth of seasonal strains and/or from the outset of a large-scale influenza pandemic.
- Utilisation of and/or further improvement of the human challenge model of influenza as a tool for candidate vaccine(s) assessment.
- Contribute to the reduction of the burden of influenza outbreaks worldwide, particularly in Europe and India. Contribute to the achievement of Sustainable Development Goal 3, to ensure health and well-being for all, at every stage of life.
- Specific to India, boost initiatives like the National Health Mission[19] and Biopharma Mission [Innovate in India (I^3)][20] of the Government of India by developing affordable biopharmaceuticals, including vaccines, for citizens the world over.

Type of Action: Research and Innovation action

[18] Human Challenge Trials for Vaccine Development, World Health Organization: www.who.int/biologicals/expert_committee/Human_challenge_Trials_IK_final.pdf

[19] National Health Mission, Government of India: http://www.nhm.gov.in/nhm.html

[20] Innovate in India (i3), Government of India: http://www.dbtindia.nic.in/press-release-for-launch-of-national-biopharma-mission/

Annex 2 Template for Indian Requirements

PROJECT'S ADMINISTRATIVE AND FINANCIAL CONSIDERATIONS (DBT'S REQUIREMENTS)

This document shall be completed for Indian Investigators by the Lead Scientific Coordinator, in consultation & Agreement with EU Counterparts

==========

A. Whether the Lead Scientific Coordinator and Principal Investigators have valid service tenures to accommodate key research and coordination responsibility? [-- YES/NO --]

If yes, provide valid answer for the same with date of superannuation *[NMT 30 words]*
If no, Provide details of precautionary approach to be followed in case of exigency *[NMT 80 words]*

_ _

B. Provide explicit objectives of each participating organization (Indian and EU counterparts) in bullet points

_ _

C. Details of ongoing projects with Project Lead Scientific Coordinator; Principal Investigators (PIs); Co-Investigators (Co-Is) as per the following format (*Funded by any funding agency*):

S. No.	Title of the project	Project Keywords	Approved Objectives	Funding agency	Project duration (Dates)		As (PI/ Co-I)	% of time devoted to each project
					From	To		
1.								
2.								
3.								
…								

D. Information for completed projects of Project Lead Scientific Coordinator; Principal Investigators (PIs); Co-Investigators (Co-Is) as per the following format (*Completed projects funded by any agency in last three years*):

S. No.	Title of the project	Project Keywords	Approved Objectives	Duration (Dates)		As (PI/ Co-I)	Date of Actual Completion
				From	To		
1.							
2.							
3.							
…							

E. Complementarities of participants and extent to which the consortium as a whole brings together the necessary expertise and appropriateness of the allocation of tasks *[NMT 80 words]*

F. Deliverable goal of the project *[NMT 50 words]*

G. Administrative & Regulatory Considerations:

1) Is there any possibility of use of information (in any form) resultant of the proposed work, which may impinge on India's national security? If yes, the nature of such a use may be indicated. *[NMT 50 words]*

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2) Give a list of the likely places of visit within the country planned by the EU collaborator. Also give a list of the institutions which the collaborator is likely to visit. *[NMT 70 words]*

---

3) Will any sensitive source material be referred to during the course of the research?
[-- YES/NO --]

If yes, provide explicit details of the same. *[NMT 70 words]*

---

4) Does this collaboration involve *(Explicitly highlight the same)*

a) Transfer of biological material(s): [-- YES/NO --]
b) Use of radioactive materials: [-- YES/NO --]
c) Use of hazardous material(s): [-- YES/NO --]
d) Use of Genetically Engineered Organisms: [-- YES/NO --]
e) Field trials or testing: [-- YES/NO --]
f) Pre-clinical and/ or Clinical trials or testing: [-- YES/NO --]
f) Ethical considerations: [-- YES/NO --]
g) Considerations related to Intellectual Property Rights (IPR): [-- YES/NO --]

5) If answer to the above question is yes, are the investigator(s) aware of the relevant regulations (*such as IBSC/IASC/IAEC/IEC/NBA/IC-SCR etc.*) **and have they agreed to abide by them?** [-- YES/NO --]

If YES, explain it in brief [NMT 40 words]
If NO, provide valid reason(s) to it [NMT 80 words]

_ _

6) If relevant, describe if and how the project results should be protected. Details of knowhow generated so far. Also IPR barriers or relations to others' intellectual properties must be described, including e. g. a brief summary of your freedom to operate analysis. Also, state if the methods chosen give rise to intellectual property problems or opportunities. *[NMT 160 words]*

_ _

7) Identify any additional critical considerations you would like to bring to the attention of the reviewer *[NMT 100 words]*

_ _

8) While submitting this grant proposal you are requested to note the following and upload/ enclose relevant information

a) In case of Academia (Public, Private, Not for profit Research foundations) submission of proof of establishment by Indian statue and recognition documents is obligatory. (*Kindly enclose relevant documents*)

b) In case of Private Institution(s)/ NGO(s)/ VO(s)/ Trust(s), submission of proof of registration at 'NGO DARPAN' at http://ngodarpan.gov.in/; Certificate of registration under Society Registration Act and certificate of DSIR in-house R&D recognition is obligatory. An Academic society must follow research as mandate. (*Kindly enclose relevant documents*)

c) In case of Public or Private Industry, submission of Certificate of Incorporation issued under Companies Act; Shareholding/ subscriber Particulars and certificate of DSIR in-house R&D recognition is obligatory. (*Kindly enclose relevant documents*)

9) Details of Consolidated budget proposed:

(Rs. In lakhs)

Heads	Year I	Year II	Year III	Year IV	Year V	Total
Equipment(s)						
Manpower						
Consumables						
Travel (Domestic || International)						
Contingency						
Overheads						
Outsourcing						
Other (Provide details)……						
Total						

(N.B: Academia can factor in additional sub heads (in other category) such as training & awareness; review meeting, etc. under expenditure based on the requirement of the project.)

10) Details of Investigator wise and/or Institute wise & year wise final budget proposed: (*Critically review the budget requirements, ensuring every possibility of using existing resources & communication technologies or possibly sharing the same from alternative sources (outsourced) without impacting time and efforts to achieve the goal*)

(Rs. In lakhs)

Heads	Year I	Year II	Year III	Year IV	Year V	Total
Equipment(s)						
Manpower						
Consumables						
Travel (Domestic || International)						
Contingency						
Overheads						
Outsourcing						
Other (Provide details)……						
Total						

(N.B: Academia can factor in additional sub heads (in other category) such as training & awareness; review meeting, etc. under expenditure based on the requirement of the project.)

11) Details of Industry wise & year wise final budget proposed:

(*As per the agreed grant policy, DBT's support to Industry shall not exceed 50% of the total project cost, 50% of the contribution shall mandatorily come from the Industry.*

The cost breakup for the DBT component of the proposal shall be: Capital and Manpower costs each not exceeding 30% of the DBT supported project cost; and balance will cover consumables and travel costs. Contingency & overhead costs will not be permissible)

(Rs. In lakhs)

	Contribution from DBT						Contribution from Industry					
Heads	**Year I**	**Year II**	**Year III**	**Year IV**	**Year V**	**Total**	**Year I**	**Year II**	**Year III**	**Year IV**	**Year V**	**Total**
Equipment(s)												
Manpower												
Consumables												
Travel (Domestic || International)												
Total												

12) Details of Investigator wise and/or Institute wise equipment proposed:

(Rs. In lakhs)

Sr. No.	Name of the Proposed Equipment	Justification of the Proposed Equipment	Proposed Cost
1			
2			
3...			

a) Provide a list of equipment(s) available in your laboratory (*To be submitted for each participant investigator)*

_ _

13) Manpower details: *[NMT 80 words]*

a) Provide the desired qualification, experience and emoluments of the manpower proposed in the project. *(Justification for the need of each proposed project position must also be given)*

b) In case of desired qualification, experience and emoluments of the manpower proposed in the project is not as per DST guidelines, then provide details of the same and compulsorily enclosed the copies of relevant approved guidelines. *(E.g. ICAR/ ICMR/ Institutional guidelines/ Wage norms of State Govt. Labour Department etc).*

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14) Explicit justification for the consumables budget proposed: *[NMT 100 words]*

_ _

15) Justification for the contingency budget proposed: *[NMT 50 words]*

_ _

16) Explicit justification for the travel budget proposed: *(Domestic and international travel should be limited for project purposes only. In case of field visit etc. which are required for collection of samples and/or visit of patients etc, it should be separately mentioned and justified.*

Explicitly clarify the frequency & number of visits to be made by investigator(s) and/or project staff(s) to EU counterparts (and vice versa) each year along with the basis for the proposed cost). [NMT 110 words]

_ _

17) Whether any outsourcing of work (like genome sequencing, bioinformatics analysis etc.) is involved in the project? [-- YES/NO --]

If yes, please provide the details of the same [NMT 60 words]

– –

18) Explicit justification for budget proposed under 'Other' category: *[NMT 100 words]*

– –

19) Endorsement by the Head of the Organization: *(To be submitted on letter head in support of all participating investigators of the concerned organization(s) as per the proforma placed below)*

Endorsement by the Head of the Organization

To be submitted on letter head in support of participating Investigator(s)

Project Title:

I. Certified that the Institute welcomes participation of Dr.______________________________ as the Principal Investigator and Dr.______________________________ as the Principal Co-Investigator for the project and that in the unforeseen event of discontinuance by the Principal Investigator, the Principal Co-Investigator will assume the responsibility of the fruitful completion of the project (with due information to DBT).

II. Certified that all resources (infrastructure, techno-scientific, administrative, etc.) as per the terms and conditions of the grant, will be extended to investigator(s) throughout the duration of the project.

III. Institute assumes to undertake the financial and other management responsibilities of the project.

IV. Certified that comprehensive appraisal pertaining to administrative and financial requirements has been made towards participation of this organization through this project beforehand.

Date:

Name & Signature with stamp of Head of the Organization

Place:

Annex 3 How to use Horizon 2020 participant Portal

1. How to Participate:

https://ec.europa.eu/research/participants/portal/desktop/en/funding/index.html

By selecting the "How to Participate" tab on the Participate Portal "Home" page, researchers and innovators are directed to a page that provides easy access and instructions for using key parts of the portal (see screen shot below):

- Create an Account
- Register an Organization
- Find Partners
- Find a Call for Proposals
- Submit a Proposal

2. Online Manual and Reference Documents

http://ec.europa.eu/research/participants/docs/h2020-funding-guide/index_en.htm

From the page below, researchers and innovators can access the comprehensive user-friendly Online Manual (see screen shot below) and reference documents for all parts of Horizon 2020.

3. Support

The "Support" tab on the Participant Portal "Home" page provides access to the Horizon 2020 Helpdesk, the IT Helpdesk, a Glossary of Terms and FAQs as well as links to support organizations such as Horizon 2020 National Contact Points (NCPs) and the Enterprise Europe Network (EEN).

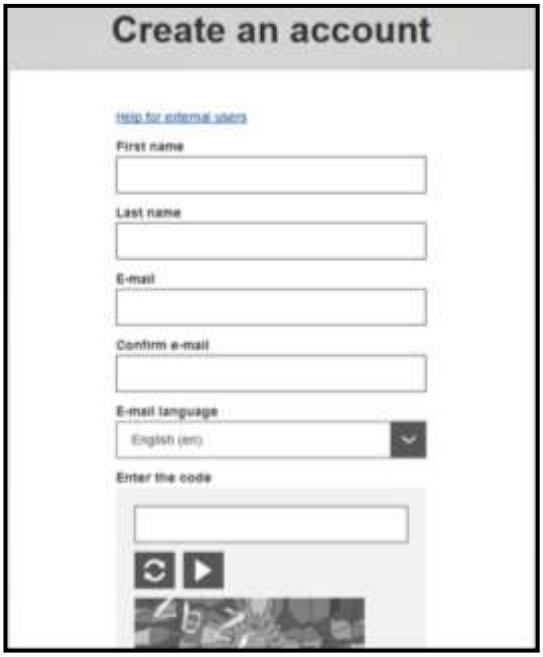
4. Opening an Account

A. Individuals: European Commission Authentication Service (ECAS)

https://webgate.ec.europa.eu/cas/eim/external/register.cgi

To enter the secure area in the Participant Portal, a person must first open an account with the European Commission Authentication Service (ECAS). The service acts as a firewall for the Participant Portal. Anyone may establish an account with ECAS and enter the Participant Portal. There is no limit on the number of individual accounts that can be affiliated with a given organization.

To open an ECAS account, select "Register" on the home page of the Participant Portal (see screen shot above) and enter the information required (username and email address). A password will be sent to your email address within minutes. Return to the home page of the Participant Portal and select "Login." You will be directed to the page in the screen shot below. When prompted to indicate a user "Domain," select "External" to indicate that you are not a Commission employee. Use the new password to gain access to the Participant Portal. This is the main gateway for registered people and organizations to the Portal.



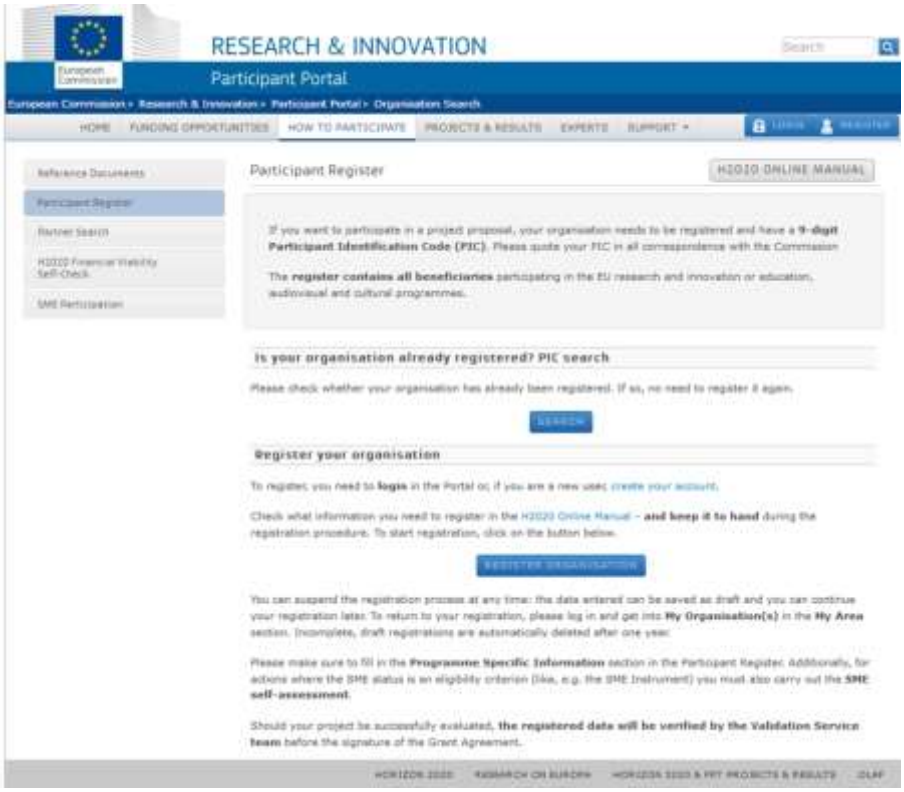
Once logged into the Participant Portal, one should complete the user account by identifying the organizations and/or proposals and projects with which they are associated and then establishing their role or roles in these.

B. Registering an Organization (Legal Entity) || Participant Information Code (PIC)

https://ec.europa.eu/research/participants/portal4/desktop/en/organisations/register_sec.html

To participate in a Horizon 2020 project, a researcher must be registered as legal entity at the Participant Portal of the European Commission. Once registered, organizations receive a unique nine digit "Participant Identification Code" (PIC) that is required for any organisation to submit a proposal. The Commission will use the PIC in all interactions with the organization and associated researchers.

If an organization has previously signed an EU Framework Programme Grant Agreement, it already has a PIC. If this is the case, then a researcher should contact the appropriate person or office within the organization (e.g. Office of Research Services, Office of International Research) to obtain the PIC. Alternatively, they can query the online PIC database by selecting the "Beneficiary Register" in the Participant Portal (highlighted in blue on the left side in the screen shot below) or by following the link above.



If an organization does not have a PIC, it must obtain one by registering in the Organization Register. It is hosted within the Participant Portal and can be accessed by selecting "Beneficiary Register." To complete the registration, information regarding the legal status and finances of the organization will be required. If it is not possible to complete the registration in one session, the information may be saved and re-opened by selecting "My Organizations" in the Participant Portal (highlighted in dark blue on the left side in the screenshot above). Once complete, a provisional PIC will be provided electronically within 48 hours.

Please note that, only if a proposal is successful, the European Commission will proceed with the validation of all information in the Organization Register, and provide a definitive PIC. Once validated, the organization will be required to designate a person to serve as its “Legal Entity Appointed Representative” (LEAR) who is authorized to sign legal documents for the organization. The European Commission will also proceed with a financial viability check at that time. These steps are taken regardless of the age, size or reputation of an organization.