Fondazione Regionale per la Ricerca Biomedica

Regione Lombardia

Presentazione Call Europee 2020

EUROPEAN JOINT PROGRAMME RARE DISEASES

Joint Transnational Call (JTC 2020)

ERAPerMed

Joint Transnational call (JTC 2020)

19 Dicembre 2019

Sala Convegni, Palazzo Sistema
Via Taramelli 26
20124 Milano

Si ricorda che l'evento è videoregistrato. Per informazioni: www.frrb.it/it/privacy-policy

European Joint Programme on Rare Diseases
Joint Transitional Call (JTC 2020)

- *Scientific aim*
- *Evaluation and Scientific review*
- *General provisions*
- *Timeline*
- *FRRB rules*
- *Pre-proposal template*

www.ejprarediseases.org

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Scientific aim

"*PRE-CLINICAL RESEARCH TO DEVELOP EFFECTIVE THERAPIES FOR RARE DISEASES*"

Malattia rara: patologia che affligge non più di 5 persone ogni 10.000 persone nella Unione Europea, nei paesi EC associati e in Canada

Attenzione!!! USA e Giappone per es. utilizzano criteri differenti per definire se una patologia sia rara o no!

I progetti possono essere su 1 sola patologia rara o su un gruppo di patologie rare

NON POTETE PRESENTARE PROGETTI SU (*"Approaches and topics excluded from the scope of the call"*)**:**

- Malattie infettive rare
- Tumori rari
- Rari eventi avversi alla somministrazione di un farmaco
- Interventional clinical trials
- Terapie bastate sulla chirurgia o sulle radiazioni
- Studi su metodi per accelerare la diagnosi di malattie rare (topic dello scorso anno!)
- Malattie neurodegenerative rare → potete fare demenze infantili o malattie neurodegenerative infantili

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Scientific aim

At least one of the following areas:

Development of novel therapies in a preclinical setting (including small molecules, repurposing drugs, cell and gene advanced therapies) focusing on condition(s) with unmet medical needs	Use of disease models suitable for medicinal product's development according to EMA guidelines
Development of predictive and pharmacodynamics (PD) biomarkers (with appropriate analytical methods e.g. OMICS) in a preclinical setting (e.g. in the validated model or in pre-collected human samples) for monitoring the efficiency of the therapy. The model chosen must mimic the human diseases and be transposable so that the biomarker identified in animals can be valid for humans	Proof of principle studies fostering an early (pre-clinical) stage of drug development (excluding interventional clinical trials of phase 1-4).

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Scientific aim

Novel therapies or proof of principle studies:

- ODD: orphan drug designation planning
- Scale up feasibility for clinical trials and manufacturing
- For new targets: validation in preclinical models should be the first step

Validation or development of predictive and pharmacodynamics biomarkers:

- Ensure that the biomarker undergoes analytical validation using high quality samples from an independent collection → samples from BIOBANKS!!!

Disease models:

- Describe how the model replicates the pathology
- Describe if and how the model replicates aspects of the therapy target
- If you use animals, describe why you use them, if there is no alternative method, how many animals you use and how you defined the number, the choice of sex
- Describe how the preclinical model aligns with future stages in humans

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Scientific aim

Additional elements – Read very carefully page 8:

- Study design
- Bioinformatics
- Preliminary data
- Risk management
- Feasibility
- If relevant – intellectual property management
- Information on other studies on the same target
- Use of existing European health research infrastructures, or IRDiRC recognised resources
- FAIR principles: Findable, Accessible, Interoperable, Reusable → to be included in the data management plan
- PATIENTS ORGANIZATIONS AND PATIENTS REPRESENTATIVES

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Evaluation and Scientific revision

La valutazione viene effettuata da due organi distinti:

Call Steering Committee (CSC) = 1 rappresentante per ogni Funding Agency che partecipa alla Call.

- Supervisiona tutto il processo
- Definisce le procedure della Call
- Dà la raccomandazione finale sui progetti da finanziare sulla base della graduatoria
- TUTTE LE PROCEDURE SULLA CALL VENGONO DECISE DAL CSC

Scientific Evaluation Committee (SEC) = panel di scienziati indipendenti riconosciuti a livello internazionale

- Scienziati riconosciuti a livello internazionale che valutano i progetti
- Firmano una dichiarazione di non-conflict of interest

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Treshold
3/5
12/15

5 p.ti

Excellence

Involvement of PAOs

Clarity and pertinence of the objectives

Credibility of the proposed approach and methodology

Soundness of the concept

Innovative potential

Feasibility of the project (adequate requested resources, time schedule, access to patients or patient's data and/or material)

Competence and experience of participating research partners in the field(s) of the proposal (previous work in the field, specific technical expertise)

5 p.ti

Quality and efficiency of the implementation

Appropriateness of the management structures and procedures, including risk management, contingency plans and innovation management

Plan for sustainability of infrastructures or resources initiated by the project

Budget and cost-effectiveness of the project (rational distribution of resources in relation to project's activities, partners' responsibilities and time frame)

Complementarity of the participants within the consortium, including the integration of PAOs where possible

Coherence and effectiveness of the work plan, including appropriateness of the allocation of tasks, resources and time-frame

5 p.ti

Impact

Added-value of transnational collaboration: gathering a critical mass of patients/biological material, sharing of resources (models, databases, diagnosis, etc.), harmonization of data, sharing of specific know-how and/or innovative technologies, etc

Involvement of industry (when appropriate/applicable/available)

Inclusion of Early Career Scientists as Principal Investigators

Benefit to patients, their families, and carers developed through the involvement of patient's organizations and patient representatives where possible

Potential of the expected results for future clinical, public health and/or other socio-economic health relevant applications, including patients' needs;

Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), to communicate the project, and to manage research data. A data management strategy in the full proposal is mandatory

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Evaluation and Scientific revision

Il processo di sottomissione è composto da 4 fasi:

1 **STAGE 1**
Pre-proposal

2 **STAGE 2**
Full proposal

3 **STAGE 3**
Rebuttal stage

4 **STAGE 4**
Consensus meeting

Le proposte che hanno passato l'eligibility check vanno al SEC
→ 2 membri/proposal
Commento + score per ogni criterio

Consensus meeting del SEC e graduatoria delle pre-proposal

Meeting del CSC e decisione finale sulle pre-proposal

Invio delle valutazione e possibili raccomandazioni del SEC

Underrepresented countries possono unirsi alle proposal

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Evaluation and Scientific revision

Il processo di sottomissione è composto da 4 fasi:

1. **STAGE 1**
   Pre-proposal
2. **STAGE 2**
   Full proposal
3. **STAGE 3**
   Rebuttal stage
4. **STAGE 4**
   Consensus meeting

Le proposal che hanno passato il pre-proposal stage vengono invitate a sottomettere il Full Proposal

Le Full Proposals vengono inviate almeno a 2 revisori specializzati esterni al SEC

non c'è votazione prima del rebuttal stage

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Evaluation and Scientific revision

Il processo di sottomissione è composto da 4 fasi:

1. **STAGE 1**
   Pre-proposal
2. **STAGE 2**
   Full proposal
3. **STAGE 3**
   Rebuttal stage
4. **STAGE 4**
   Final decision

Prima di arrivare di nuovo al SEC, le Full Proposal tornano ai PI che possono chiarire alcuni punti rispetto ai commenti dei revisori esterni

NON si possono aggiungere parti mancanti
NON E' OBBLIGATORIO

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Evaluation and Scientific revision

Il processo di sottomissione è composto da 4 fasi:

1. **STAGE 1**
   Pre-proposal
2. **STAGE 2**
   Full proposal
3. **STAGE 3**
   Rebuttal stage
4. **STAGE 4**
   Final decision

Il SEC si incontra per dare le votazioni e definire la graduatoria finale tenendo conto di:

- Evaluation criteria
- External reviewer comments
- Rebuttal discussion
- Discussione in sede di consensus meeting

Il SEC ha a disposizione anche:

- Valutazioni da parte di expert patient reviewers
- Valutazione da parte di statistici (no score)
- Valutazioni etiche

Il CSC prende atto della graduatoria del SEC e si incontra per stabilire quali progetti verranno finanziati **IN BASE ALLA GRADUATORIA E AI FONDI DISPONIBILI**

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General provisions

The maximum duration of the project is three years.

Attenzione alle regole nazionali e regionali!

Eligible partners:

- academia
- clinical/public health sector
- enterprise (all sizes of private companies). Participation of small and medium size enterprises (SMEs) is encouraged when allowed by national/regional regulations
- patient advocacy organisations (PAO)

The inclusion of a non-eligible research partner (principle investigator) in a proposal leads **to the rejection of the entire proposal** without further review.

Consortia:

Each consortium submitting a proposal must **involve four to six eligible principal investigator from at least four different participating countries.**

No more than two eligible partners from the same country can be present in each consortium.

The number of partners can be increased to 8 in two cases:

a) The inclusion of partners from participating countries usually underrepresented in projects (Czech Republic, Slovakia, Hungary, Lithuania, Poland, and Turkey).

b) The inclusion of Early Career Researchers as full partners (see section 4.5).

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General provisions

Early Career Researchers

v. Guidelines

ECRs are defined as per the regulations of the European Research Council criteria for starting grants. In short, the researcher must have been awarded their **first doctoral degree (PhD) two to seven years prior** to the pre-proposal submission deadline. Extensions to this period are allowed (with documentation) in the case of reasonably justified career breaks: absence for maternal, paternal or long-term sick leave, and compulsory military service.

For medical doctors (or applicants holding a degree in medicine), an MD is not by itself considered equivalent to a PhD award. To be considered an ECR, these applicants must provide the certificates of both a medical doctor degree and a PhD, or proof of an appointment that requires doctoral equivalency (e.g. post-doctoral fellowship or professorship appointment). MD applicants that do not hold a PhD must have been awarded their **MD four to nine years prior** to the pre-proposal submission deadline. For medical doctors who have been awarded both an MD and a PhD, the date of the earliest degree that makes the applicant eligible will be used to calculate eligibility. Extensions to this period will be given (with documentation) for clinical training periods up to a maximum of four years.

General provisions

Each partner (with their respective research groups) must contribute substantially to at least one of the project work packages. Consortia may include collaborators that secure their own funding. **Collaborators** do not count toward the limit of 8 partners requesting research funding. Each transnational proposal must nominate a **project consortium coordinator** among the project partner principal investigators. The coordinator must be an eligible project partner from an EJP RD JTC 2020 funding country/region.

Double funding of research projects is not permitted. The JCS and national/regional funding organisations will perform cross-checks of submissions against other joint transnational (e.g. NEURON, JPND, EuroNanoMed, ERA PerMed etc.) and national calls. Partners may not apply for funding for the same research activities in different calls.

Consortia are strongly advised to include **patient representatives and patient advocacy organizations (PAOs),** which are eligible to receive funding for their activities. If patient involvement is not deemed appropriate within a research project, this should be explained and justified.

Verificate le risorse suggerite

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General provisions

Research consortia who intend to submit a transnational project proposal should register via the electronic proposal system: https://ptoutline.eu/app/ejprd20 .

Please fill in the data sheet in the system.

Two-stage submission procedure for joint applications:

- pre-proposal
- full proposal.

One joint proposal document (in English) shall be prepared by the partners of a joint transnational proposal, and must be submitted by the coordinator **only** to the JCS via the electronic submission system. The proposals must strictly follow the instructions in the proposal form.

In general, no fundamental changes between the pre- and full proposals concerning the composition of the consortia, objectives of the project or requested budget will be accepted. The CSC, however, may allow such changes if detailed justification is provided to the JCS.

*The Call Steering Committee (**CSC**) and the Scientific Evaluation Committee (**SEC**), will manage the evaluation process of the call with support of the Joint Call Secretariat (**JCS**) (ANR, France). The process includes the evaluation procedure of pre- and full proposals and the final selection and award of research projects.*

Verificate con le Funding Agencies di riferimento

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General provisions

Eligibility check

The JCS will check all pre-proposals to ensure that they meet the call's formal criteria. The JCS will forward the proposals to the CSC members who will perform a check for compliance to country/regional/PAO eligibility rules. **Please note that proposals not meeting the formal criteria or the national/regional eligibility criteria and requirements will be declined without further review.**

The adherence to the national/regional regulations in the "Guidelines for Applicants" document is mandatory

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FRRB rules

ITALY, FRRB

Country / Region	Italy
Funding organisation	Fondazione Regionale per la Ricerca Biomedica - Regional Foundation for Biomedical Research (FRRB)
National contact person	Via Taramelli 12, 20124 – Milano Tel: +39 02 67650174 Miss Paola Bello Mrs. Carmen De Francesco Dr. Paola Larghi, PhD Mail to: bandi@frrb.it
Funding commitment	€ 1.000.000
Overheads	Up to 20% flat rate calculated on direct costs – Subcontracting costs excluded from this calculation.
Anticipated number of fundable research partners	2-3
Maximum funding per grant awarded to a partner	Maximum € 500,000 **per project** MAXIMUM TWO PARTNERS PER PROJECT
Eligibility of project duration	Maximum 3 years
Eligibility of a partner as a beneficiary institution	Public or Private IRCCS (Scientific Institutes for Research, Hospitalization and Health Care), Public Health Care Providers (ASST), Universities and Research Institutes located on the Lombardy territory. It is COMPULSORY that at least one IRCCS (public or private) or ASST is partner in the project proposal. Other types of organisation are eligible ONLY in partnership with them. Enterprises and for profit Organisation are NOT eligible.

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Eligibility of principal investigator or other research team member	The Principal Investigator (PI) and all members of the research group must belong to eligible institutions. If an applicant has a currently funded FRRB grant, he/she cannot submit an application (neither as PI nor as WP leader) Coexisting FRRB awards and applications for new awards are not permitted
Eligibility of costs, types and their caps	Direct costs: • Personnel (for public IRCCS and ASST, ONLY temporary contracts): max 50% of the total direct costs (*overheads and subcontracting costs excluded*) • Consumables, animals purchase, maintenance and breeding; • Equipment (on hire or eligible amortization rate); • Travel: max 10% of the total direct costs(*overheads and subcontracting costs excluded*) • Publications: max 5% of the total direct costs (*overheads and subcontracting costs excluded*) • Overheads: 20% flat rate calculated on direct costs (*Subcontracting costs excluded from this calculation*). • Subcontracting: max 20% of the total direct costs (*overheads costs excluded*) FRRB will require the submission of a financial audit certificate together with the final financial report. This cost, to be included under the "Subcontracting category" will be eligible up to a maximum of € 8.000. Only costs generated over the lifetime of the project will be considered eligible.
Submission of other information at the regional level	According to internal procedures, Regional Foundation for Biomedical Research (FRRB) will grant an eligibility clearance to the potential applicants prior to the submission of the pre-proposals. The eligibility check will be based on the verification of a dedicated form ("Eligibility check form"), also available on the FRRB institutional website, to be returned, by email, to FRRB (bandi@frrb.it), duly completed and signed by the Principal Investigator at least 10 working days before the pre-proposal submission deadline. FRRB will provide feedback on the Eligibility check form ONLY in case of major issues or non-eligibility. PIs who submit a proposal without sending the "Eligibility check form" to FRRB beforehand will be automatically excluded. In addition, FRRB provides an excel sheet to help applicants abide by FRRB funding rules. This form is meant to support the PIs in the elaboration of the budget, but it does not need to be sent to FRRB.
Submission of financial and scientific reports at regional level	Lombardy beneficiaries will be requested to submit annual scientific and financial reports.
Further guidance	Administrative and financial guidelines will be provided by FRRB in due time to the contact persons of the funded organisations.

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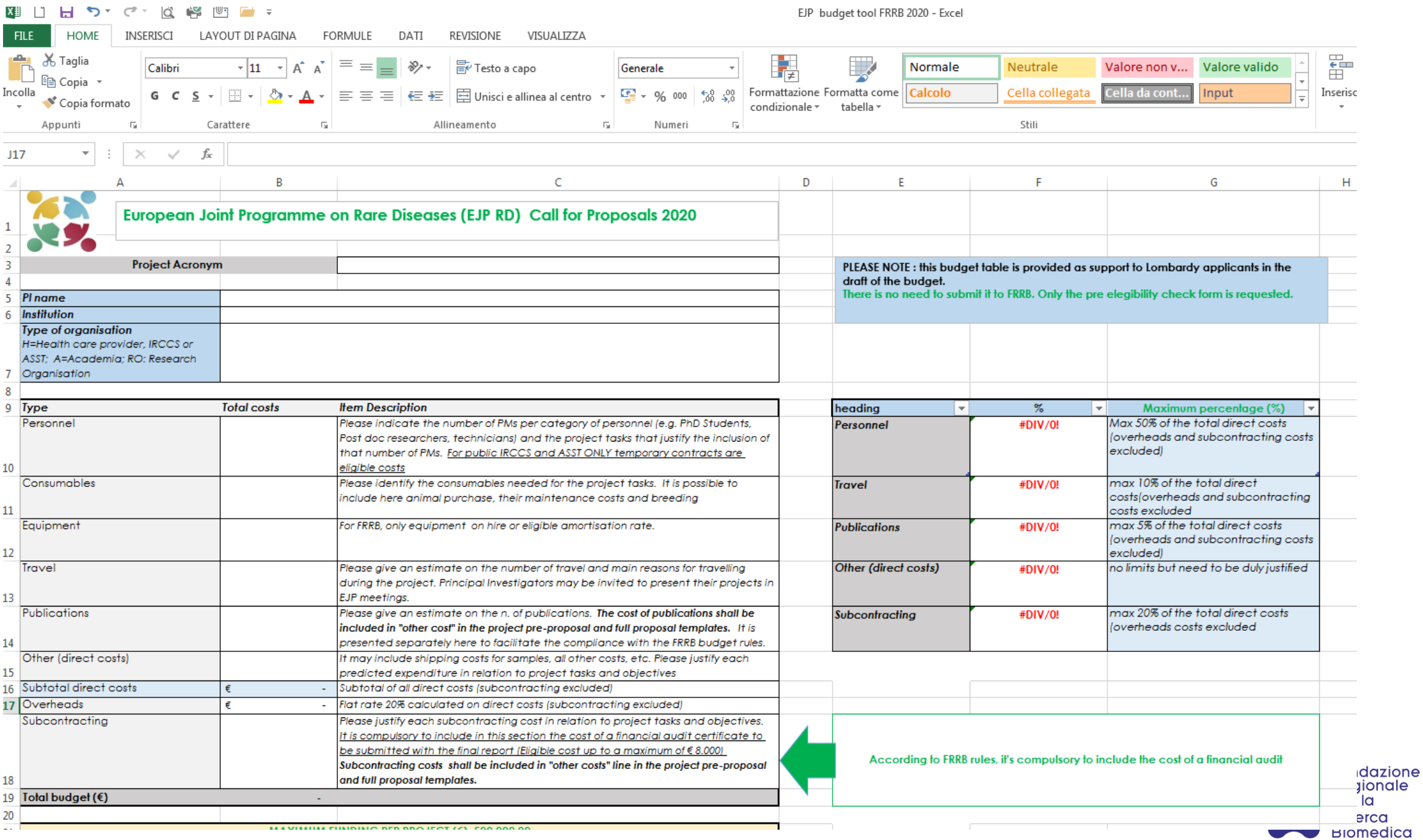
EJP budget tool FRRB 2020 - Excel
FILE
HOME
INSERISCI
LAYOUT DI PAGINA
FORMULE
DATI
REVISIONE
VISUALIZZA
Incolla
Taglia
Copia
Copia formato
Appunti
Calibri
11
Carattere
Testo a capo
Unisci e allinea al centro
Allineamento
Generale
Numeri
Formattazione condizionale
Formatta come tabella
Normale
Neutrale
Valore non v...
Valore valido
Calcolo
Cella collegata
Cella da cont...
Input
Stili
Inserisc
J17
European Joint Programme on Rare Diseases (EJP RD) Call for Proposals 2020
Project Acronym
PI name
Institution
Type of organisation
H=Health care provider, IRCCS or ASST; A=Academia; RO: Research Organisation
PLEASE NOTE : this budget table is provided as support to Lombardy applicants in the draft of the budget.
There is no need to submit it to FRRB. Only the pre elegibility check form is requested.
Type
Total costs
Item Description
Personnel
Please indicate the number of PMs per category of personnel (e.g. PhD Students, Post doc researchers, technicians) and the project tasks that justify the inclusion of that number of PMs. For public IRCCS and ASST ONLY temporary contracts are eligible costs
Consumables
Please identify the consumables needed for the project tasks. It is possible to include here animal purchase, their maintenance costs and breeding
Equipment
For FRRB, only equipment on hire or eligible amortisation rate.
Travel
Please give an estimate on the number of travel and main reasons for travelling during the project. Principal Investigators may be invited to present their projects in EJP meetings.
Publications
Please give an estimate on the n. of publications. The cost of publications shall be included in "other cost" in the project pre-proposal and full proposal templates. It is presented separately here to facilitate the compliance with the FRRB budget rules.
Other (direct costs)
It may include shipping costs for samples, all other costs, etc. Please justify each predicted expenditure in relation to project tasks and objectives
Subtotal direct costs
€ -
Subtotal of all direct costs (subcontracting excluded)
Overheads
€ -
Flat rate 20% calculated on direct costs (subcontracting excluded)
Subcontracting
Please justify each subcontracting cost in relation to project tasks and objectives. It is compulsory to include in this section the cost of a financial audit certificate to be submitted with the final report (Eligible cost up to a maximum of € 8.000) Subcontracting costs shall be included in "other costs" line in the project pre-proposal and full proposal templates.
Total budget (€)
-
heading
%
Maximum percentage (%)
Personnel
#DIV/0!
Max 50% of the total direct costs (overheads and subcontracting costs excluded)
Travel
#DIV/0!
max 10% of the total direct costs(overheads and subcontracting costs excluded
Publications
#DIV/0!
max 5% of the total direct costs (overheads and subcontracting costs excluded)
Other (direct costs)
#DIV/0!
no limits but need to be duly justified
Subcontracting
#DIV/0!
max 20% of the total direct costs (overheads costs excluded
According to FRRB rules, it's compulsory to include the cost of a financial audit

FRRB rules

- *Leggere attentamente le guidelines*
- *Ciascun ente interessato a richiedere un contributo a FRRB nell'ambito di una Call*

*dovrà obbligatoriamente inviare, all'indirizzo bandi@frrb.it il form di «**Pre-eligibility check form»** scaricabile dal sito internet di FRRB e dalla pagina ufficiale del singolo programma.*

- *Tale modulo dovrà pervenire agli uffici di FRRB **almeno 10 giorni lavorativi** prima dalla deadline di sottomissione del pre-proposal così da permettere alla Fondazione di verificare l'ammissibilità a partecipare alla Call degli enti proponenti.*
- *Soltanto nel caso in cui il controllo dovesse avere **esito negativo o dovessero essere necessarie maggiori informazioni** sarà cura di FRRB contattare l'ente interessato.*
- *Domande e quesiti dovranno essere inviati a bandi@frrb.it, specificando «EJP JTC 2020» nell'oggetto. Le domande, preferibilmente senza elementi identificabili, saranno pubblicate con la relativa risposta nelle **FAQ** pubblicate nella pagina web di FRRB dedicata alla call.*

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Timeline

Date	Stage
December 18, 2019	Publication of the JTC 2020
February 18, 2020	Submission deadline for pre-proposals
April 30, 2020	Communication selection of pre-proposals
June 16, 2020	Submission deadline for full proposals
October/November 2020	Final funding decision consortium
First half of 2021	Funded projects start

Pre-eligibility check form: FRRB requests to all Lombardy PIs applying for funding to submit this form, duly completed and signed, at **least 10 working days before the pre-proposal submission (February 4th 2020 at latest)**

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Pre-proposal template

PRE-PROPOSAL APPLICATION FORM

EUROPEAN JOINT PROGRAMME
RARE DISEASES

Call for Proposals 2020

"PRE-CLINICAL RESEARCH TO DEVELOP EFFECTIVE THERAPIES FOR RARE DISEASES"

Submission deadline for pre-proposals:
February 18th, 2020; 2 p.m. (CET)

Pre-proposal application form

Please note:

- **Proposals that do not meet national/regional eligibility criteria and requirements will be declined without further review.**
- **Format is Century Gothic font size 11, single-spaced, with margins of 1.27 cm. Incomplete proposals, proposals using a different format or exceeding length limitations of any sections will be rejected without further review.**
- **Once completed, the pre-proposal must be converted in a single PDF document before being uploaded to the submission website.**

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Project awarded!

FRRB: Successivamente all'approvazione della graduatoria, il Cda di FRRB riceve l'informativa dal Direttore generale e approva formalmente la graduatoria finale dei progetti ammessi e finanziati e non finanziati. Gli Enti interessati sono contattati da FRRB per le pratiche amministrative (accettazione del contributo, conferma da parte dell'ente finanziato che nell'ambito del progetto non si svolgano attività economiche, convenzione, modalità di erogazione...)

JCS: The project coordinator is the point of contact for consortia during the application procedure, and is responsible for forwarding relevant information from the JCS to their consortium members.

The **coordinators** of all funded projects must submit a **brief annual scientific project report** (due on the 28th of February 2022 and subsequent years) **and a final scientific project report** (due within six months of the end of the project). All reports must be in English and must use the reporting templates provided. The research partners are jointly responsible for delivery of the reports. Only reports delivered on behalf of the consortium, via the project coordinator, will be accepted.

Consortium members of projects selected for funding **must fix a common project start date**, which will be the reference date for yearly and final reports and extensions. This common project start date must appear in the **Consortium Agreement (CA).**

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Domande?

Fondazione Regionale per la Ricerca Biomedica