EuroNanoMed

Joint Transnational Call for Proposals (JTC2020) for

"European Innovative Research & Technological Development Projects in Nanomedicine"

Call Text

DEADLINES

January 21st 2020 (17:00, CET) - SUBMISSION OF PRE-PROPOSALS
June 10th 2020 (17:00, CEST) - SUBMISSION OF INVITED FULL-PROPOSALS

Link to electronic proposal submission
https://ptoutline.eu/app/euronanomed2020
The submission system will be open by December 2nd, 2019

EuroNanoMed III Joint Call Secretariat

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INTRODUCTION & MOTIVATION

Nanotechnology is a strategic priority for Europe. Technologies related to this sector have a vast potential for developing public welfare and economic growth, as well as for changing the way of life of citizens in many fields of application: healthcare, Information and Communication Technologies (ICT), environment, etc.

Nanomedicine *is the application of nanotechnology to achieve breakthroughs in healthcare. It exploits the improved and often novel physical, chemical and biological properties of materials at the nanometer scale (from one nanometer to hundreds of nanometers). Nanomedicine has the potential to enable early detection and prevention of diseases, and to essentially improve diagnosis, treatment and follow-up of diseases. It was perceived as embracing five main sub-disciplines that in many ways are overlapping and underpinned by the following common technical issues: analytical tools, nanoimaging, nanomaterials and nanodevices, novel therapeutics and drug delivery systems, clinical, regulatory and toxicological issues.*

Over the last few years, Europe has successfully contributed to many of the achievements of the basic research dedicated to nanotechnologies. However, regarding the nanomedicine field in Europe, a critical issue concerns the capability of the research and technology development players to effectively move innovation from basic knowledge into either industrial or clinical applications, i.e. translational research*. In order to bridge this gap between research and clinical/commercial applications in nanomedicine it is essential that the efforts are made at the European level, so that a critical size in terms of R&D projects portfolio and scientific excellence is reached, and a sufficient level of competitiveness is achieved.

In this context, the European Union has supported the **ERA-NET EuroNanoMed in the field of nanomedicine** since 2008. Based on its success, support to the European Nanomedicine research community is continuing through a third **EuroNanoMed ERA-NET initiative under Horizon 2020, EuroNanoMed III (2016-2021).** Please visit our website for more information about this initiative: www.euronanomed.net

This ERA-NET serves as a platform for funding agencies and ministries to develop joint activities and programmes in order to coordinate high quality research in nanomedicine across national borders. The funding organisations listed below, have decided to launch the 11th

**Translational research* *transforms discoveries arising from "the bench" to the patients "bedside",* i.e. *from basic research – in which scientists study disease at a molecular or cellular level – to the clinical and/or industrial level. Its purpose is to improve and strengthen collaboration spanning various research fields.*

EuroNanoMed transnational call, to fund multinational innovative research projects in nanomedicine. The present Call for proposals will be conducted simultaneously by the participating funding organisations in their respective country/region and coordinated centrally by the **Joint Call Secretariat (JCS)**.

The call is opened and promoted simultaneously by the following funding organizations in their respective countries:

Funding agencies involved

- **Belgium (French speaking community) (FRS-FNRS), Belgium**
- **Bulgarian National Science Fund (BNSF), Bulgaria**
- **Fonds de Recherche du Québec- Santé (FRQS), Canada**
- **Technology Agency of the Czech Republic (TACR), Czech Republic**
- **Egyptian Academy of Scientific Research and Technology (ASRT), Egypt**
- **Estonian Research Council (ETAg), Estonia**
- **Agence Nationale de la Recherche (ANR), France**
- **General Secretariat for Research and Technology (GSRT), Greece**
- **Italian Ministry of Health (IMH), Italy**
- **Israel Ministry of Health (CSO-MOH), Israel**
- **State Education Development Agency (SEDA/VIAA), Latvia**
- **Research Council of Lithuania (RCL), Lithuania**
- **The Research Council of Norway (NCR), Norway**
- **National Centre for Research and Development (NCBR), Poland**
- **Executive Agency for Higher Education, Research, Development and Innovation Funding (UEFISCDI), Romania**
- **Academie Slovaque des Sciences (SAS), Slovakia**
- **Centro para el Desarrollo Tecnológico Industrial, E.P.E (CDTI), Spain**
- **Instituto de Salud Carlos III (ISCIII), Spain**
- **Agencia Estatal de Investigación (AEI), Spain**
- **Ministry of Science and Technology (MoST), Taiwan**
- **The Scientific and Technological Research Council of Turkey (TUBITAK), Turkey**

1. AIM OF THE CALL

The aims of the call are:

- To support **translational research projects** that combine innovative approaches in the field of nanomedicine and;
- To encourage and enable **transnational collaboration between public and private Partners** from academia (research teams from universities, higher education institutions, public research institutions) and clinical/public health research (research teams from hospital/ public health, healthcare settings and other healthcare organisations) or research teams from industrial enterprises (all size). **The participation of Medical Doctors from research organizations and SMEs (Small and Medium-size Enterprises) is strongly encouraged**. Please note that, for some funding organizations, industrial enterprises are not eligible for funding.

Project proposals will address multidisciplinary and translational research. The project proposals must cover at least one of the following areas that are equal in relevance for this call:

a) **Regenerative medicine**
b) **Diagnostics**
c) **Targeted delivery systems**

According to the WHO, non-communicable diseases – such as cardiovascular diseases, cancer and chronic obstructive pulmonary diseases – account for 80 % of deaths in the European Region. Diseases of the circulatory system (ischaemic heart disease, stroke, etc.) are currently the most important causes of premature death (before the age of 65) in the EU, accounting for nearly 50 % of the total.

Cancer is the second leading cause, accounting for nearly 20 % of deaths and with the ageing population, the risk of cancer is rising. The disease is currently the main cause of premature death in 28 of the 53 countries in the EU, and is predicted to further increase by 2020.

A wide variety of nanomedicine have been developed and approved for use in clinical practice (including Abraxane, Doxil, DaunoXome, Evacet, Lipo-Dox, MyCareAssays, NanoTherm) and there are also a number of nanomedicines in clinical trials. As of 2016, 78 nanomedicines were on pharmaceutical markets across the world and 63 nanomedicines were approved as drugs or were in the approval process[1].

[1] Choi, Y.H. & Han, HK. Journal of Pharmaceutical Investigation (2018) 48: 43.

Oncology is the first therapeutic area covered by Nanomedicine products. The main developments concern drug delivery systems, including liposomes, micelles, emulsions and a diverse set of nanoparticles, gold particles or polymeric particles to reduce the toxicity of harmful compounds used in oncology; this is caused by the fact that nanomedicine products allow for a lower therapeutic dose of the anticancer agents due to improved bioavailability. However, there is much more to gain in this area. Recent insights have shown that treatment can be strongly improved if first patient susceptibility to nanomedicine is established via a theranostic approach. Furthermore, a better understanding of biological processes such as opsonization, active targeting and immunological responses have provided nanomedicine scientists with a much more detailed view which design criteria are important for an effective therapy.

In order to use nanopharmaceuticals in clinical practice, additional advances and further understanding are therefore still needed and achievable.

ENM is committed to advance nanomedicine toward any translational focus with anticipated impact relative to the risk and investment and also invites applications that focus on improving outcomes and/or reducing the costs of cancer treatment.

At the end, projects should fall within, but are not limited to, Technology Readiness Levels (TRL)[2] 3-6, although for being realistic and coherent with the characteristics of the call, projects should propose advancements for a maximum of two TRL levels during their lifetime. TRL level must be understood as the level achieved by the end of the three-year-project. Industry engagement should be appropriate for the TRL range being investigated.

For a better understanding of the objectives and a more efficient evaluation, applicants are asked to specify to which of the two categories described below the project falls, according to its TRL, degree of innovation and expected time to market:

1) **Innovation applied research projects**: Proof of concept projects for innovative applications with analytical/experimental research and/or implementation and integration of components and test in laboratory and/or animal models. Safety and nanotoxicity should be taken into account when relevant. The viability of a path that may lead the experimental and/or analytical results (for TRL 3) and/or

[2] Horizon 2020 scale for TRL: https://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2018-2020/annexes/h2020-wp1820-annex-g-trl_en.pdf

demonstrators (for TRL 4) to a future application at medium/long term shall also be demonstrated.

2) **Projects with high potential of applicability at short/medium term**: Projects closer to the market for the validation of demonstrators and prototypes in a realistic laboratory (for TRL 5) and/or relevant simulated operational field environment (for TRL-6). The viability of a path that may lead the validated systems and results to real products shall be demonstrated. Industrial engagement is crucial in this type of projects. Medical regulatory aspects have to be properly considered.

In both categories (1 and 2) it is highly recommended to underline the technical risks and required effort to advance to the next TRL levels, as an assessment of the level of development achieved at the end. Performance indicators must be proposed to evaluate it.

Proposals may include, but are not limited to: identification, characterisation and validation of biomarkers, early diagnosis, convergence of nanotechnology and stem cell technology, cell biology applied to nanomedicine, multimodal imaging agents or techniques, point of care diagnostics (on site sensors), standardised procedures for preparation & characterisation of drug delivery systems, regenerative, gene or cell therapies using nanotechnology and development and use of nanomaterials for medical purposes. Pre-clinical and early clinical studies are eligible subject to national/regional regulations. Proposals developing diagnostics and targeted delivery systems for cancer detection and therapy are encouraged, subject to national/regional regulations.

Proposals **must clearly demonstrate the potential health impact and/or economic impact** as well as **the added-value of transnational collaboration**: sharing of resources (models, registries, diagnosis, etc.), harmonisation of data, sharing of specific know-how and/or innovative technologies.

Furthermore, additional elements must be taken care of in the application:

- The design of the study (sample collection, statistical power, interpretation, relevant models for hypothesis validation) must be well justified and should be part of the proposal;
- When appropriate: strategies for patient recruitment, retention, assessment, and analysis must be included. The study design and objectives should take into consideration the population that would be needed in order to pursue clinical trials or other health care related studies in that disease. Data supporting the recruitment numbers is recommended.

- Appropriate bioinformatics and statistical skills should constitute, whenever justified, an integral part of the proposal;
- In case of an exploratory animal/clinical study, a detailed description is required as part of the Proposal Application Form. The review panel will scrutinize this information as part of the formal evaluation criteria (1-Excellence) of full proposals. Assistance for provision of the information on experimental design can be found in the general ARRIVE guidelines[3].

The new research data resulting from the project should be treated permissible according to the FAIR[4] principles, and deposited and shared, according to the national rules of the countries involved. It is strongly advised to make data accessible through Elixir (https://www.elixir-europe.org/platforms/data/elixir-deposition-databases - compiling a list of resources for the deposition of experimental, biomolecular data). To make research data findable, accessible, interoperable and re-usable (FAIR), a Data Management strategy for the proposed full project is mandatory in the second evaluation stage. Projects selected to receive funding in the current call, will be requested to present a more detailed Data Management Plan before month 6 from the official start of the project. Guidelines will be available in EuroNanoMed website (http://euronanomed.net/).

Projects are required to discuss and respond to **Responsible Research and Innovation (RRI)** aspects[5], including co-creating, co-design and co-production. Projects are required to include a plan to disseminate results/outcomes and how to achieve higher levels of technological readiness.

The individual project partners of the joint applications should be complementary and the proposed work should contain novel, innovative, ambitious ideas with high application potential for the end users.

Active participation of junior researchers in project proposals is encouraged. A junior investigator has been awarded his/her first PhD/MD or equivalent doctoral degree, at least 2 and up to 10 years prior to the proposal submission deadline[6].

[3] The ARRIVE Guidelines: Animal Research: Reporting of In Vivo Experiments. Originally published in PLOS Biology, June 2010
[4] FAIR: Findable, Accessible, Interoperable, Reusable (for more information; see "The FAIR Guiding Principles for scientific data management and stewardship" (https://www.nature.com/articles/sdata201618)
[5] H2020 website: http://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation. EuroNanoMed RRI guidelines: http://euronanomed.net/joint-calls/enmiii-rri-guidelines/
[6] PhD equivalence and eligible extensions to this period in case of career breaks are detailed in Annex II.

2. APPLICATION

2.1 ELIGIBILITY CRITERIA

Only transnational projects will be funded. Joint research proposals may be submitted by applicants belonging to one of the following categories (according to national/regional regulations, please see "Guidelines for applicants"):

A. **Academia** (research teams working in universities, other higher education institutions) **or research institutes;**
B. **Clinical/public health sector** (research teams working in hospitals/public health and/or other health care settings and health organisations). Participation of **Medical Doctors is encouraged;**
C. **Enterprise** (private companies of all sizes). Participation of **Small and Medium-size Enterprises (SMEs) is encouraged.**

Each application must include partners from at least two of the three categories A, B and C. The number of participants and their research contribution should be appropriate for the aims of the transnational research project and be reasonably balanced in terms of international participation. Each transnational collaborative project should represent the critical mass to achieve ambitious scientific goals and should clearly demonstrate an added value from working together.

Each consortium submitting a proposal must involve a **minimum of three eligible and a maximum of five eligible partners from at least three different countries participating to the call** (see list above). The maximum number of partners can be increased from five to seven under certain circumstances (see below). No more than two eligible partners from the same country participating in the call will be accepted in one consortium.

Partners not eligible to be funded by one of the organisations participating in this Joint Transnational Call (e.g. from non-funding countries or not fundable according to national/regional regulations of the participating funding organisations) may participate in transnational projects if they are able to secure their own funding (self-funded partners). Such partners should state in advance the source of funding for their part in the project and are considered as full project partners. A letter of commitment must be included as an annex to the full proposal submitted at the second stage summarising the commitment of this partner to the project and demonstrating the source of funding. However, no more than one self-funded partner can be included in a consortium and the Partner coordinator must be eligible to be funded by the participating funding organisations (budget requesting partner) (see Annex I). **In any case, the maximum number of participants in a project consortium is seven (including budget-requesting partner and self-funded partner)**.

Applicants are encouraged to include partners from the following participating countries, whose scientific community has been under-represented in past EuroNanoMed calls**: Bulgaria, Czech Republic, Egypt, Estonia, Latvia, Lithuania, Romania, Slovakia, Taiwan, and Turkey**. If they include such partners, the maximum number of partners can be increased up to seven (see table below).

Number of partners requesting funding (eligible partners)	3	4	5	6 (only with at least one underrepresented)	7 (only with at least 2 underrepresented)
Maximum number of additional partners with own funding	1	1	1	1	0

Each consortium must nominate a **project coordinator** among the project's principal investigators. The coordinating partner must be an eligible project partner for the national/regional funding organisation from which it requests support. The project coordinator will represent the consortium externally and towards the JCS and **Call Steering Committee**[7] **(CSC)**, and will be responsible for its internal scientific management such as controlling, reporting, intellectual property rights (IPR) issues and contact with the JCS.

Each project partner will be represented **by one (and only one) principal investigator**. Within a joint proposal, each project partner's principal investigator will be the contact person for the JCS and the relevant national/regional funding organisation.

Each principal investigator can submit only one proposal as project coordinator or up to two proposals as mere partner (e.g. the coordinator of a proposal cannot be partner in another proposal). Please note that this rule is subject to national/regional regulations, therefore applicants are strongly encouraged to contact their national/regional contact points to check their national/regional eligibility rules before submission (see also "Guidelines for applicants").

Whilst proposals will be submitted jointly by Partners from several countries/regions, budget requesting partners will be funded by the individual funding organisation of the respective country/region from which applicants have applied. The applicants are therefore subject to eligibility criteria of relevant funding organisations of the respective country/region. It is highly

[7] Call Steering Committee: funding organisations' representatives.

recommended to read carefully the funding rules and eligibility criteria of the relevant funding organisation.

Applicants are strongly advised to contact their relevant funding organisation contact person before submitting an application; please note that for some countries/regions it might be mandatory.

Please note that if a **partner** is found to be non-eligible at any step of the process by one of the funding organisations, the entire proposal will be rejected without further review. For a definition of eligible partners see "Guidelines for applicants", the national/regional regulations, and contact your national/regional contact person.

2.2 FINANCIAL AND LEGAL MODALITIES

Funding is granted awarded as a grant for a maximum of three years according to EuroNanoMed funding organisation regulations (notwithstanding any potential no cost extension, subject to each funding organisation applicable regulations). **Eligible costs and funding provisions may vary according to the respective funding organisation's regulations**. Applicants must refer and adhere to the specific regulations and scientific remits of the funding organisation from which they seek support, as detailed in the National Announcements. Clarification may be obtained from the individual funding organizations (see Annex I).

2.3 SUBMISSION OF JOINT PROPOSALS

There will be a **two-step submission and evaluation procedure** for joint applications: pre-proposals and full proposals. In both cases, one joint proposal document (in English) shall be prepared by the partners of a joint transnational proposal, and must be submitted to the JCS by uploading it on the electronic submission system (https://secure.pt-dlr.de/ptoutline/app/euronanomed2020) by one spokesperson, the project coordinator. The two-step application process will have the following timetable:

November 14th, 2019	Publication of the 11th joint transnational call
December 2nd, 2019	Opening of the submission system for pre-proposals
January 21st, 2020 (17:00, CET)	**Deadline for pre-proposal submission**
Early May, 2020	Communication of the results of the pre-proposal assessment (invitation for full proposal)
June 10th, 2020 (17:00, CEST)	**Deadline for full proposal submission**

31 August-7 Sept 2020	Rebuttal stage
September 15-16, 2020	Peer Review Panel Meeting and CSC meeting for funding recommendation to national funding agencies
October 2020	Communication of the funding decisions to the applicants
Beginning of 2021	**Expected project start** (subject to national procedures)

The pre-proposal template will be available on the EuroNanoMed website (www.euronanomed.net).

An application template of the full proposal will be sent to the project coordinator by the JCS at the same time as the invitation to submit a full proposal. Information on how to submit proposals electronically is available in the document "Guidelines for applicants". Invited full proposals submitted without using the relevant template will be declared non-eligible.

- If applicable, a proposal should be submitted with a legal/ ethical approval document according to the concerned country's/region's regulations;
- If applicable, a proposal should be submitted with a formal declaration of "Participation with own budget" of the Associated Research Partner.

For applicants from some countries/regions it might be mandatory to submit the additional national/regional proposal and/or other information, in some cases before the deadline of this call, directly to the national/regional funding organisations. Therefore, applicants are strongly advised to check their funding organisations specific regulations. See "Guidelines for applicants" for more details.

Ethical issues must be addressed in each application, and according to the concerned country's/region's regulations.

The consortium will take all lawful steps to ensure confidentiality of the information and documents obtained during the evaluation and selection procedure of the joint call.

2.4 FURTHER INFORMATION

If you need additional information, please contact the JCS, or your national/regional funding organisation Contact Person (see "Guidelines for applicants" or www.euronanomed.net).

3. FORMAL CHECK AND EVALUATION OF PROPOSALS

3.1 Formal check and evaluation of pre-proposals

The JCS will check all proposals to ensure that they meet the call's formal criteria (date of submission; number and category of participating countries; inclusion of all necessary information in English; appropriate limits on length). In parallel, the JCS will forward the proposals to the national/regional funding organisations, which will perform a check for compliance to national/regional rules.

Please note that if a budget requesting partner is not eligible for funding, the whole proposal could be rejected (for a definition of eligible partners see "Guidelines for applicants" and national/regional regulations and contact your national/regional representative).

Each proposal passing the eligibility check (call secretariat and country/region) will be provided to at least three reviewers for a first evaluation (see evaluation criteria below). The reviewers will perform the assessment of the pre-proposal and complete a written evaluation form with scores and comments for each criterion. Pre-proposals which are not passing this assessment will not be considered for full proposal stage. The CSC members will meet to decide which proposals will be invited for the full proposal submission based on the reviewers' recommendations and to ensure a reasonable balance of requested and available national/regional budgets.

3.2 Formal check and evaluation of full proposals. Rebuttal stage

Changes between pre- and full proposal are not allowed. The JCS will check the full proposals to ensure that they meet the call's formal criteria and have not changed substantially from the respective pre-proposals before sending them to the reviewers. Any fundamental changes between the pre- and full proposals concerning the composition of the consortium, objectives of the project or requested budget must be communicated to the JCS and to the national/regional funding organisations. In exceptional cases, these changes may be admitted if detailed justification is provided and if they are accepted by CSC.

Each full proposal will be allocated to at least three reviewers who fit the profile of the application. The reviewers will perform the assessment of the full proposal and complete a written evaluation form with scores and comments for each criterion (see evaluation criteria below). The reviewers will meet in a PRP panel to discuss all proposals and produce a list of proposals recommended for funding in a ranking list. The composition of the PRP will be available on the EuroNanoMed website after the full proposal step.

Rebuttal stage: before the PRP members meet to discuss each **full proposal** in a PRP meeting, each coordinator is provided with the opportunity of studying the assessments and commenting on the arguments and evaluations of the reviewers, which remain anonymous. This stage allows applicants to comment on factual errors or misunderstandings that may have been committed by the referees while assessing their proposal and to reply to reviewers'

questions. However, issues which are not related with reviewers' comments or questions cannot be addressed and the work plan cannot be modified at this stage.

The applicants will have up to one week (**first week of September**) for this optional response to the reviewers' comments

Answers sent after the notified deadline, or not related with reviewers' comments or questions will be disregarded.

3.3 Evaluation criteria

Pre-proposals and full proposals will be assessed according to specific evaluation criteria using a common evaluation form as long as the proposals are within the scope of the Joint Transnational Call (proposals not fitting with the scope of the call will not be further evaluated). A scoring system from 0 to 5 will be used to evaluate the proposal's performance with respect to the different evaluation criteria.

Scoring system:

Score	Category	Definition
0	Failure	The proposal fails to address the criterion in question, or cannot be judged because of missing or incomplete information
1	Poor	The proposal shows serious weaknesses in relation to the criterion in question
2	Fair	The proposal generally addresses the criterion, but there are significant weaknesses that need corrections
3	Good	The proposal addresses the criterion in question well but certain improvements are necessary
4	Very good	The proposal addresses the criterion very well, but small improvements are possible
5	Excellent	The proposal successfully addresses all aspects of the criterion in question

Evaluation criteria:

1. Excellence:
    a. Scientific & technological quality of the proposal;
    b. Novelty; innovation potential; methodology; degree of technological maturity;
    c. "Nano value" of the proposed approach, clearly demonstrating the added value of the application of nanotechnology;

d. Quality of the project consortium: international competitiveness of participants in the field(s), previous work and expertise of the participants, benefit of the transnational collaboration, participation of junior researchers.

2. Impact
   a. Unmet medical need addressed and potential impact in clinics;
   b. Translatability and marketability of the proposed approach;
   c. Added value of the transnational collaboration;
   d. **Innovation applied research projects**: potential impact of expected results in different domains of nanomedicine or cross-KET applications, marketability potential, quality of the dissemination and exploitation plan;
   e. **Projects with high potential of applicability at short/medium term**: expected time for market/transfer to patient towards clinical/public health applications, pharmaceutical/health device applications, other industrial applications including market and end user's scenario, quality of dissemination, exploitation and business plan.
   f. Risk assessment, safety, regulatory, ethics and other **Responsible Research and Innovation (RRI) issues** properly addressed (fit to the type of research to be performed). For this point, refer to the Guidelines for RRI in proposals to EuroNanoMed III (v2.0) [8].

3. Quality and efficiency of the implementation
   a. Quality of project plan;
   b. Adequateness of the work package structure and work plan (tasks, matching events, time schedule);
   c. Balanced participation of project partners and integration of workload in the different work packages, quality and efficiency of the coordination and management;
   d. Scientific justification and adequacy of the requested budget;

4. FINAL DECISION ON FUNDING

Based on the ranking list established by the PRP and on available funding, the CSC will suggest the projects to be funded to the national/regional funding organisations. Based on these recommendations, final decisions will be made by the national/regional funding organisations,

[8] H2020 website: http://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation. EuroNanoMed RRI guidelines: http://euronanomed.net/joint-calls/enmiii-rri-guidelines/

subjected to budgetary considerations. The national/regional funding organisations will follow the ranking list established by the PRP members.

The project coordinator will be informed by the JCS about the final decision and he should inform his/her project partners.

5. PROJECT START, CONSORTIUM AGREEMENT AND DATA MANAGEMENT PLAN

Project partners of projects selected for funding must fix a common project start date, which will be the reference date for yearly and final reporting. This common project start date must be stated in the Consortium Agreement (CA).

CONSORTIUM AGREEMENT

It will be the responsibility of the project coordinator to draw up a Consortium Agreement suitable to their projects partners in order to manage the delivery of the project activities, finances, intellectual property rights (IPR) and to avoid disputes which might be detrimental to the completion of the project. The project coordinator is responsible for sending the CA signed by all partners to the JCS. This consortium agreement will be made available to the concerned funding organisations. The project consortium is strongly encouraged to sign this CA before the official project start date, and in any case the CA should be signed as soon as possible, but **no later than six months after the official project start date.** Please note that national regulations may apply concerning the requirement for a CA. Further instructions will be provided by the JCS to the coordinators of the projects selected for funding.

DATA MANAGEMENT PLAN

After the evaluation and selection procedures are completed, each consortium selected to be funded is required to draft a Data Management Plan and data handling protocols according to international state-of-the-art standards (FAIR[9] and GDPR[10] compliant and secure). Within six (6) months after the start of the project the DMP must be sent to the Joint Call Secretariat by the consortium coordinator. DMPs are living documents and can be updated throughout the runtime of the projects, at best with annual reports. After completion of the project, the DMP can be published.

[9] Wilkinson, M.D *et al*. The FAIR Guiding Principles for scientific data management and stewardship. *Sci Data* 3: 160018 doi: 10.1038/sdata.2016.18 (2016)

[10] https://ec.europa.eu/commission/priorities/justice-and-fundamental-rights/data-protection/2018-reform-eu-data-protection-rules_en

Where nationally required, a format for data storage, data/model exchange and data/model sharing agreements will be available by the national funder in due time to successful consortia.

6. RESPECT FOR RELEVANT EUROPEAN AND INTERNATIONAL STANDARDS

The submitted proposals have to respect relevant European and international standards like:

- The new EC Regulation (EC 2016/679) on the protection of natural persons with regard to the processing of personal data and on the free movement of such data. This Regulation applies in all Member States from May 25, 2018 and thus also for the ENM JTC 2020 granted projects (https://publications.europa.eu/en/publication-detail/-/publication/3e485e15-11bd-11e6-ba9a-01aa75ed71a1/language-en).
- European Research Council Guidelines on Implementation of Open Access to Scientific Publications and Research Data (referred to in http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/open-access-data-management/open-access_en.htm)
- To make research data findable, accessible, interoperable and re-usable (FAIR), a data management strategy is **mandatory in the full proposal**. For an example of questions for a data management strategy, see Annex 1 in http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf
- A data management strategy/plan should include information on:
    - the handling of research data during & after the end of the project;
    - what data will be collected, processed and/or generated and/or reused;
    - which methodology & standards will be applied;
    - whether data will be shared/made open access;
    - how data will be curated & preserved (including after the end of the project).

7. REPORTING REQUIREMENTS

Each project coordinator, on behalf of all participating partners, shall submit to the JCS an annual and final scientific progress report of the transnational project (in English) by filling out a template provided by JCS stating the scientific progress, the goals that have been met, and corrective measures set in case that the annual project plan has not been fulfilled. It may also be necessary for project partners' principal investigators to submit reports individually to their

national funding organisation in accordance with the respective national/regional regulations. In addition, project coordinators present the project results during EuroNanoMed meetings (Review Seminars coupled to Training Workshops for funded researchers). Accordingly, travel expenses to attend these meetings should be included in the proposal budget plans.

In case of ANY significant changes in the work program or the consortium composition, the coordinator must inform the JCS, who will inform the relevant funding organisations, who will decide upon the proper action to be taken.

Selected project coordinators, upon notification, are expected to deliver an abstract of their project suitable for communication and dissemination purposes.

In addition, the funding recipients are expected to participate and contribute to any communication activity initiated by ENM III in the funding period and beyond.

Importantly, all funding recipients must ensure that all outcomes (publications, etc.) of transnational EuroNanoMed III funded projects include a proper acknowledgement of ERA-NET EuroNanoMed III and the respective funding partner organizations. Publication with Open Access is encouraged.

ANNEX I. SUMMARY OF THE EURONANOMED JTC 2020 PARTICIPANTS INDICATIVE FUNDING COMMITMENTS AND ELIGIBILITY

Participant organisation name	Country / Region	Funding academic or clinical/academic partners	Funding academic or clinical partners with private partners (please specify if is private for profit or non for profit)	Funding private partners only (please specify if is private for profit or non for profit)	Tentative initial funding commitment (Euros)	Envisaged number of teams potentially funded with the tentative initial funding commitment
Fonds de la Recherche Scientifique – FNRS (F.R.S.-FNRS)	BELGIUM	YES	NO	NO	200.000	1
Bulgarian National Science Fund (BNSF)	BULGARIA	YES	NO	NO	230.000	3
Fonds de rercherche du Québec –Santé (FRQS)	CANADA	YES	YES	NO	360.000	1-2
Technology agency of the Czech Republic (TACR)	CZECH REPUBLIC	YES	YES	YES	1.000.000	5-6
Egyptian Academy of Scientific Research and Technology (ASRT)	EGYPT	YES	YES	YES	400.000	3-4
Estonian Research Council (ETAg)	ESTONIA	YES	YES	NO	100.000	2
Agence Nationale de la Recherche (ANR)	FRANCE	YES	YES	YES	2.500.000	10-12
The General Secretariat for Research and Technology (GSRT)	GREECE	YES	YES	YES	1.000.000	4-5
Israel, Ministry of Health (CSO-MOH)	ISRAEL	YES	NO	NO	240.000	2-3
Italian Ministry of Health (IMH)	ITALY	YES	NO	NO	1.000.000	4

Valsts izglītības attīstības aģentūra (SEDA/VIAA)	LATVIA	YES	YES	YES	420.000	2
Lietuvos mokslo taryba (RCL)	LITHUANIA	YES: Lithuanian research and education institutions	YES: Public health care institutions	YES (2)	100.000-150.000	1
The Research Council of Norway	NORWAY	YES	YES	YES	750.000	2-3
National Centre for Research and Development (NCBR)	POLAND	YES	YES	YES	600.000	1-3
Executive Agency for Higher Education, Research, Development and Innovation Funding (UEFISCDI)	ROMANIA	YES	YES	YES	500.000	1-2
Slovak Academy of Sciences (SAS)	SLOVAKIA	YES	NO	NO	120.000	1
National Institute of Health Carlos III (ISCIII)	SPAIN	YES	YES	NO	500.000	3-5
Centro Tecnológico Industrial, E.P.E. (CDTI)	SPAIN	Only companies can be funded as beneficiaries. Other type of entities can participate as subcontractors of companies.			500.000	3-5
Agencia Estatal de Investigación (AEI)	SPAIN	Yes (1)	Yes, non-profit (1)	No	400.000	
Ministry of Science and Technology (MoST)	TAIWAN	YES	YES	NO	500.000	3-4
The Scientific and Technological Research Council of Turkey (TUBITAK)	TURKEY	YES	YES	YES	750.000	3-5

ANNEX II. DEFINITION OF JUNIOR RESEARCHERS

Junior researchers must have been awarded their first PhD/MD or equivalent doctoral degree, at least 2 and up to 10 years' prior the proposal submission deadline of the EuroNanoMed III JTC 2020. Extensions to this period may be allowed in case of eligible career breaks, which must be properly documented. However, there is **no need** to attach additional documentation when submitting the project proposal. Eligible career breaks are:

- For maternity: the effective elapsed time since the award of the first PhD/MD will be considered reduced by 18 months for each child born before or after the PhD/MD award
- For paternity: the effective elapsed time since the award of the first PhD/MD will be considered reduced by the actual amount of paternity leave taken for each child born before or after the PhD/MD award
- For long term illness (over ninety days), clinical qualification or national service the effective elapsed time since the award of the first PhD/MD will be considered reduced by the documented amount of leave taken for each event which occurred after the PhD/MD award

Eligible events that take place within the extension of the eligibility window may lead to further extensions. The cumulative eligibility period should not in any case surpass 14 years and 6 months following the award of the first PhD/MD. No allowance will be made for principal investigators working part-time.

Please note that in some countries MD may not be equivalent to PhD but equivalent to Bachelor of Medicine or Bachelor of Surgery. Doctoral or equivalent level, are designed primarily to lead to an **advanced research qualification**. For more details, you can see the International Standard Classification of Education (ISCED) of the UNESCO (page 59)
http://www.uis.unesco.org/Education/Documents/isced-2011-en.pdf