

European Union





CALL FOR PROPOSALS FOR THE CREATION AND DEVELOPMENT OF THE VALLE D'AOSTA HUMAN TECHNOPOLE (HTVDA) ABSTRACT





GENERAL CLAUSES

General framework

The Valle d'Aosta region intends to create a research centre supporting personalised, preventive and predictive medicine, to be known as the *Valle d'Aosta Human Technopole* (HTVDA).

This research centre, on a scale appropriate to the size of Valle d'Aosta, is intended to boost the region's research and health sector in an innovative way, implementing the specialisation zones and technology transfer model set out in the *Valle d'Aosta regional research and innovation strategy for smart specialisation for the period 2014/2020.*

The main objective of this measure is to improve health by the creation of a research centre dedicated to personalised, preventive and predictive medicine, with particular reference to various neurodegenerative and oncological diseases. The research will also focus on building the genome profiles of samples of the population in order to establish a regional bioinformatics database.

The operation also aims to:

- enhance the region's research capacity;
- support the creation and structural strengthening of research laboratories with a possible impact on clinical/care services;
- further the professional development of the researchers involved;
- create employment opportunities for young people who have gone into the research sector or intend to do so;
- develop new competences in the research sector and in technological development;
- encourage knock-on effects for the region in terms of the impact on employment, the competitiveness of the system of production, the quality of the research system, as well as by the creation of start-up and spin-off businesses;
- create a "magnet", an energising hub in the region, boosting the research centres and centres of excellence already operating in the Valle d'Aosta region through cooperation with the HTVDA;
- create a specialist skills centre at local level, its purposes being to provide training and disseminate scientific knowledge, being open to collaboration at national and international level.

Implementation process

The Regional Authority intends to obtain proposals from partnerships comprising research bodies, public bodies and businesses which, in response to this call for proposals, wish to establish a research centre specialising in personalised, preventive and predictive medicine, located in the Valle d'Aosta region.

Funding available

This Call for Proposals has available a total funding amount of 15,000,000 Euros.

The partnership must ensure co-financing in cash of at least 2,680,000 Euros

Strands

The call has two different strands, each with its own funding sources, management procedures and applicable regulations, but having integrated approaches converging towards the same objective. The first strand provides for the provision of funding, co-financed by the European Regional Development Fund (ERDF) for research projects which are part of a Research Programme to be conducted from the HTVDA.

Specifically, it is intended for funding staff costs, costs relating to instrumentation and equipment, costs for research consultancy, costs for acquiring technical skills and patents, costs of materials for research, supplies and other similar products, and additional expenses in general, in relation to Research projects developed by the HTVDA.

The maximum amount that can be granted and paid in relation to the first strand (ERDF) is equal to 13,400,000 Euros.

The second strand is for the provision of Research grants, co-financed by the European Social Fund (ESF), up to a maximum amount of 23,600 Euros per Research Grant, per year, for the development of human resources involved in the HTVDA who, through its scientific activities, are specialising to a high level, starting off on professional pathways in the research sector.

The Research Grants have training objectives: by carrying out research activities alongside senior researchers and research experts, under the supervision of a scientific manager, within HTVDA, recipients of the Research Grant will be able to acquire new scientifically and technically important specialist skills and knowledge; at the same time, by engaging with scientific matters at national and supranational level and participating in managing projects, they will also have the opportunity to gradually acquire managerial, professional and entrepreneurial skills. These skills, including transversal skills, represent the scientific and managerial benefits of the Research Grants offered in the Call for Proposals.

The maximum amount that can be granted and paid under the second strand (ESF) is equal to 1,600,000 Euros.

DESCRIPTION OF THE VALLE D'AOSTA HUMAN TECHNOPOLE

Minimum requirements for the HTVDA

The HTVDA may have various legal and administrative configurations and may involve a range of different shapes/profiles, but must meet the following minimum specifications:

- have an organisational structure divided into at least two Departments, namely a <u>Medical</u> <u>Genomics Department</u> and a <u>Computational Genomics Department;</u>
- provide for there to be a Scientific Manager for the HTVDA, who will also be the Manager of the *Medical Genomics Department*, responsible for achieving the objectives of the Research programme and for verifying the activities of the students. The HTVDA manager will enter into a work contract with the lead body for a period of not less than 5 years (and in any case not less than the duration of the HTVDA Development Programme), such contract being able to ensure there is a stable, continuous, professional relationship, and guaranteeing their constant presence in the research activities of the HTVDA. In particular, they must be present for coordination meetings, internal assessment activities and self-monitoring, and monitoring activities by the Regional Authority, and must guarantee their productive and assiduous presence at the HTVDA. Their presence will be subject to monitoring by the Monitoring Committee;
- provide for there to be a Manager for the Computational Genomics Department and data management. The manager will enter into a work contract for a period of not less than 5 years (and in any case not less than the duration of the HTVDA Development Programme), such contract being able to ensure there is a stable, continuous, professional relationship, and guaranteeing their constant presence in the research activities of the

HTVDA. In particular, they must be present for coordination meetings, internal assessment activities and self-monitoring, and monitoring activities by the Regional Authority and must guarantee their productive and assiduous presence at the HTVDA. Their presence will be subject to monitoring by the Monitoring Committee;

- provide for there to be a **Technology Transfer Manager**;
- provide for there to be an Administrative, Management and Reporting Manager for the Research Programme and Research Grants, responsible for liaising between the Regional Authority, the partners, and the Managers of the HTVDA. The administrative manager will enter into a work contract for a period of not less than 5 years (and in any case not less than the duration of the HTVDA Development Programme), such contract being able to ensure there is a stable, continuous, professional relationship, and guaranteeing their constant presence in the research activities of the HTVDA. Their presence will be subject to monitoring by the Monitoring Committee;
- provide for there to be full time researchers, as well as the presence (including on a parttime basis) of other resources originating from project partners, as well as, if necessary, external resources of various provenance, such as researchers from universities, research centres public research bodies, research fellows and post-graduate students, in the following minimum numbers: at least 5 research fellows and 15 students, in line with a Human Resources Recruitment Programme and a Student Employment Programme;
- develop a 5-year Research Programme, with a total value of not less than 13,4 million Euros, including several Research projects, which must have a Technical Readiness Level (TRL) of at least 5 and which must relate to genome sequencing, for patients from the Valle d'Aosta Health Authority (AUSL VdA) as a minimum. The phases of identification, stratification, collection of samples and production of clinical data must be planned and implemented in collaboration with the AUSL VdA. The project must also specify how the clinical data were acquired, the medical history of patients, and supply data relating to life style, in collaboration with the AUSL VdA. These processes must also be followed if the research is extended to the healthy population.
- have available a System for **Management**, **self-monitoring and assessment** of the quality of the scientific activities carried out;
- develop a Develop an availability/ acquisition plan for equipment and scientific / technological instrumentation required in order to carry out the research projects; as a minimum, the following equipment must be acquired: a whole genome sequencer with a sequencing capacity of at least 24 whole human genomes per day, laboratory benches, local server storage, a gene expression profiling platform;
- have available an on-site storage system for liquid and tissue biological samples (biobank);
- have the ability to store scientific data in a **data centre**, classified as TIER IV;
- ensure that personnel conducting the research are trained / updated in accordance with a Training Plan;
- establish a Strategy to provide the HTVDA with its own access in order to ensure it has "visibility" in the relevant scientific contexts (and not only these), as well as for disseminating the results of the research to the region and to promote regional gatherings, including via a specific high level training course (Masters Level II), to be delivered in collaboration with the University of Valle d'Aosta. This training must also involve the employees of the Valle d'Aosta AUSL;
- establish a **Plan for relationships with universities, the IRCCS [Institute for Research** and Health Care] and research centres (national, European and international) with high

level scientific skills in these fields of knowledge, sometimes complementary fields as well, and with parties involved in similar human genome sequencing projects;

- develop a Plan for a stable and structured relationship with the AUSL Valle d'Aosta, especially with regard to ways of integrating the research activity of the HTVDA with that of this organisation, the processes for sample collection, the steps to create a Regional Bioinformatics data bank to be owned by AUSL VdA, the exchange of know-how and the training of employees and specification of mutual responsibilities around information for patients, the ownership and processing of data;
- establish a Strategy to ensure financial sustainability in the medium/long term and to allow the acquisition of other funding for their research projects, especially by accessing national and European funding strands;
- establish a Strategy for Technology Transfer and the creation of start-up and spin-off businesses. For example, it could be possible to support the creation of businesses which would focus their activity on identification of the diagnostic bio-markers which are needed for the development of new diagnostic kits which could be used by medical analysis laboratories, hospitals, clinics and care homes.

The activities set out in the **Creation and Development Plan for the HTVDA**, such as investment in tangible items which have been subsidised, must be conducted at the operational premises of the HTVDA, located in the *Area Espace Aosta*.

SUBMISSION AND EVALUATION OF PROPOSALS

Parties eligible to submit proposals

Project proposals may be submitted by partnerships intending to establish a research centre specialising in personalised, preventive and predictive medicine, located in the Valle d'Aosta region, fitting the description provided in the Call for Proposals.

The partnership must necessarily be composed of at least one research body and one enterprise. It may include other research bodies, public bodies and/or enterprises.

The lead party in the partnership must be a research body.

Participating enterprises must have an operational base in Valle d'Aosta at the time of the release, including any partial release, of the grant.

The partnership must be formalised, within 30 days of receipt of the communication on the outcome of the assessment, by the establishment of a temporary special-purpose association or consortium, pursuant to Articles. 2612 et seq. Of the Civil Code (consortia with external activities).

In the event that a temporary special-purpose association is established, the articles of association must include how the proposal is shared, the agreement and commitment to work in conjunction, the processes and terms of the collaboration, with conferment of a special collective mandate, free and irrevocable, with reporting obligations and exclusive and legal representation being with the lead body, which must be authorised to represent the associates exclusively, including in court proceedings, in relations with the Regional Authority, for all operations and actions of any nature whatsoever.

The partnership must necessarily collaborate with the AUSL VdA, which will not claim expenses and will make its healthcare personnel available, including for the collection of liquid and / or tissue samples to be used for sequencing.

Regulations relating to State aid

The contributions referred to in the Call for Proposals for the Research projects are granted to businesses within the constraints of prevailing Community regulations on State aid, as set out in Art. 25 of (*EU*) Commission Regulation no. 651/2014 dated 17 June 2014 which declares some categories of aid to be compatible with the internal market within the terms of articles 107 and 108 of the treaty.

The contributions referred to in the Call for Proposals for the Research projects are granted to research bodies and public bodies in compliance with all the terms set out in the *Framework* for state aid for research, development and innovation (2014/C 198/01) for activities of a non-economic nature.

Recipients of research grants

The Research Grant may be accessed by young researchers, researchers, research fellows, graduates with a Master's Degree or old 4-year degree who, at the time research activity at the HTVDA begins, have not yet worked or are unemployed, and are domiciled in Valle d'Aosta.

Domicile in Valle d'Aosta must be maintained throughout the period of the Research grant.

Inspection

Applicants who intend to participate in the Call for Proposals must carry out an inspection at the premises intended to house the HTVDA.

Processes and conditions for submitting applications

In order to be considered, grant applications must be submitted via the SISPREG 2014 system, by 12:00 28 August 2018.

Evaluation of applications

Upon expiry of the deadline for submitting applications, their eligibility will be scrutinised by the appropriate regional body. Those applications deemed eligible will be assessed by an Assessment Committee composed of experts, to be nominated following expiry of the deadline for submitting applications.

Those HTVDA creation and development Projects which pass the assessment of their merits will then undergo an economic assessment, which will evaluate the amount of monetary resources which the applicant intends to allocate to the Research Programme to partially cover the costs thereof.

Establishment of milestones and payment of funds

Within 30 days of the assessment of applications being completed, by order of the director of the competent body, the milestones will be approved and notified to the applicants by certified email.

The beneficiary must sign a collaboration agreement with AUSL VdA

EXECUTION OF THE PROJECT

Project launch

Work in relation to the Creation and Development Project for the HTVDA must begin by 1 October 2018.

The commencement of work must be advised by the lead body to the Regional Authority.

The launch of the HTVDA's research activities must take place by 1 January 2019.

Between 1 October 2018 and 1 January 2019, all activities preparatory to the start of the HTVDA's activities on 1 January 2019 must be carried out, in relation to both the first and

second funding strands, such as, for example, the selection of human resources, including the students, in accordance with the Student Employment Programme, orders for equipment and instrumentation, preparation of the premises.

The Creation and Development Project for the HTVDA must have a duration of 5 years.

The Creation and Development Project for the HTVDA must plan for the centre to be fully operational by 1 January 2020 in the Human Resources Recruitment Programme and Student Employment Programme, which must ensure the employment of at least 20 individuals in training (postgraduate students, researchers, research fellows), at least 15 of whom are to be funded via Research grants paid by the ESF under the Call for Proposals. The students may be taken on gradually, based on progress on the relevant Research projects, but the minimum number of 15 Research grants funded under the second strand (ESF) must be achieved and, since the Research grants are co-funded by the ESF, the activities of the students must be completed in good time for all the payments to be made by 31 December 2023.

Monitoring

Beneficiary parties must consent to and support the performance of activity monitoring, which will be carried out by a Monitoring Committee established by a resolution of the Regional Council.

Checks

The Regional Authority carries out supervisory activity and monitoring on initiatives falling within the scope of the Call for Proposals, for verification purposes and to ensure that operations are running properly and that the established objectives are being achieved.

GENERAL TERMS OF THE CALL FOR PROPOSALS

Information and publicity

Beneficiaries are advised that their name will be included in the public register of beneficiaries of the *Investment Programme for Growth and Employment 2014/20* (ERDF) and the *Investment Programme for Growth and Employment 2014/20* (ESF).

Beneficiaries undertake to comply with requirements relating to information and publicity as set out in Art. 115 of (EU) Regulation no. 1303/2013 and Attachment 12 of (EU) Regulation no. 1303/2013 and, in particular, to inform the public of the subsidy obtained from European Funds.

Non-cumulation clause

The grant in question may in no case be accumulated with other public financing, of any description (European, national or howsoever granted by public bodies and institutions) in relation to the same costs, even if only partially allowable.

Intellectual property rights

The sharing of intellectual property deriving from activity carried out in the context of the Project, and the terms for exercising these rights, must be defined through an Agreement which the applicant parties must sign and submit to the Regional Authority with their application.

Ring-fencing

The beneficiary undertakes to comply with the ring-fencing requirements set out in Art. 71 of (EC)) Regulation no. 1303/2013, that is, to ensure that the ERDF contribution is applied

exclusively to the co-financed activities and that, with regard to these, the following do not occur:

- the termination of production activities or their relocation outside the region's territory;
- a change of infrastructure ownership resulting in undue advantage to a business or public entity,
- a substantial change which may alter the nature, objectives or implementation stages of the operation in such a way that the original objectives are compromised.

To enable verification of compliance with regulations, all equipment and instrumentation which is covered by a grant arising from this call for proposals must be installed in the operational unit located in the territory of the Valle d'Aosta region and be kept there for at least 5 years after the end of the HTVDA Creation and Development Programme.

Process manager

The manager of the process is the director of the Struttura Ricerca, innovazione e qualità.

Requests for information may be addressed to the offices of the "*Dipartimento industria*, *artigianato ed energia - Struttura Ricerca, innovazione e qualità*"- Piazza della Repubblica, 15 – Aosta - Telephone 0165 274726.

Final provisions

Communications relating to this call for proposals will take place via Certified Email or through the SISPREG 2014 computer system. Similarly, all official communications to the Regional Authority from the beneficiaries must be made via Certified Email at the address: industria artigianato energia@pec.regione.vda.it or through the SISPREG 2014 computer system.

The Process Manager retains the option to add to or modify this call for proposals to meet European, national or regional requirements arising before the deadline for submitting applications.

Where not expressly stated in the Call for Proposals, prevailing European, national or regional regulations will apply.

The Regional Authority reserves the right to issue further provisions where these become appropriate for the process to proceed more effectively.

The Regional Authority reserves the right to cancel or revoke this process, including after the establishment of the project milestones, where there are reasons of public interest. Specifically, the Regional Authority reserves the right to cancel this process if the proportion of co-financing is found to be excessively reduced. In such case, the applicant parties will not be able to submit any claim for compensation or damages.