

RESEARCH Funding Program

Call Life Sciences 2021

Open Call

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1. Name of Open Call

Call Life Sciences 2021

2. Legal Framework

This open call — administered by the Vienna Business Agency. A service offered by the City of Vienna. (henceforth referred to as: "Vienna Business Agency") — is based on the City of Vienna funding guidelines "Research/18 21+ guidelines". These guidelines (henceforth referred to as such) are available for download at: www.wirtschaftsagentur.at. The Life Sciences R&D Call will be administered from within the framework of the RESEARCH funding program. The funding program will be treated in accordance with the provisions of the General Block Exemption Regulation (henceforth referred to as GBER), section 4 of the European commission and the Treaty on the Functioning of the European Union to de minimis aid (in short: "de minimis reg.").

3. Content and Objectives

3.1 Challenges in the Healthcare Sector

Even as the negative impacts of COVID-19 are still seriously restricting daily life, they made more clear the fundamental need for technological advances and innovation in the field of life sciences. A number of effective vaccines were approved after less than a year, a great success in overcoming this pandemic. Because of extremely complex production processes and high regulatory demands, it normally takes five to ten years to develop a vaccine. ³

With the pandemic omnipresent in the media, many other medical challenges of the 21st century are receiving very little attention at present despite the fact that they are no less relevant. For example, reductions in routine clinical operations since the outbreak of the

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¹Commission Regulation (EU) no. 651/2014 (GBER 2014: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0651&from=FE) of 17 June 2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty, published in the Official Journal of the European Union L 187/1 on 26.06.2014 (in short: "GBER 2014") together with the Commission Regulation (EU) 2017/1084 (regulation 2017: http://eur-lex.europa.eu/legal-

content/EN/TXT/PDF/?uri=CELEX:32017R1084&from=DE) of 14 June 2017 amending Regulation (EU) No 651/2014, published in the Official Journal of the European Union L 156/1 on 20.06.2017 (in short: "AGVO regulation 2017") – together in short: "GBER". The following sections are particularly relevant: article 22 and 25, paragraph 2, sections b and c, 28 as well as 29 of the GBER.

² Commission Regulation (EU) no. 1407/2013 (de minimis reg.: http://eur-

<u>lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:352:0001:0008:DE:PDF</u>) of 18 Dezember 2013 on the application of Articles 107 and 108 of the EC Treaty to de minimis aid; published in the Official Journal of the European Union L 352/1 on 24.12.2013 (in short: "de minimis reg.").

³ https://www.ages.at/themen/krankheitserreger/coronavirus/entwicklung-und-zulassung-von-impfstoffen/



pandemic last year have led to the postponement and missing of preventive cancer examinations, which has led to a significant reduction in the number of newly diagnosed cancer cases. ^{4 5} These incidences of cancer that are present but undiagnosed or diagnosed too late may lead to numerous additional but avoidable deaths in the coming years. A similar problem has been identified with cardiovascular diseases, where the number of patients with acute heart attacks decreased by 26%. ⁶ A significant increase in the time between the first occurrence of symptoms and arrival at the hospital has also been identified.

In addition to cancer, bacterial infections are also a source of significant challenges for the public healthcare system due to increasingly rapid and frequent antibiotic resistance. ⁷ Infections that were once easy to treat can now lead to life-threatening illnesses. Demographic change is also continuing, and the share of the population over the age of 65 will increase by 70% by the year 2050.8 This will lead to a further increase in the need for care and related services, which has already risen substantially over the past years, and will present another significant challenge for public budgets. ⁹

3.2 Potential in the Life Sciences

Few sectors have been driven as significantly by research and innovation as healthcare, where numerous groundbreaking findings from fundamental research such as the use of CRISPR gene editing " and the approval of mRNA vaccines " were documented for the first time in recent years.

Digitalisation and ICT are also steadily gaining importance in healthcare (digital health, e-health). Just some examples here are artificial intelligence, the Internet of Things, big data, and Industry 4.0, which are having an in part disruptive influence on the provision of healthcare. At the same time, companies in the healthcare sector must comply with increasingly complex laws and regulations (regulatory affairs). These trends are a source of

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⁴ The impact of the COVID-19 pandemic on cancer deaths due to delays in diagnosis in England, UK: a national, population-based, modelling study – The Lancet Oncology

⁵ Changes in the Number of US Patients With Newly Identified Cancer Before and During the Coronavirus Disease 2019 (COVID-19) Pandemic | Infectious Diseases | JAMA Network Open | JAMA Network

⁶ Coronavirus: Increased Number of "Silent" Heart Attacks | MedUni Vienna

⁷ https://www.who.int/antimicrobial-resistance/interagency-coordination-group/IACG final report EN.pdf?ua=1

⁸ https://ec.europa.eu/eurostat/documents/3217494/10166544/KS-02-19-681-EN-N.pdf/c701972f-6b4e-b432-57d2-91898ca94893

⁹ See OECD Health Data, p. http://stats.oecd.org/, 12.03.18.

¹⁰ Genome editing. The new frontier of genome engineering with CRISPR-Cas9 - PubMed (nih.gov)

¹¹ Understanding mRNA COVID-19 Vaccines | CDC



enormous challenges but also diverse opportunities for companies in particular and the public healthcare systems in general.

To support Viennese companies in developing new approaches for healthcare, the Life Sciences R&D Call 2021 is being conducted to promote private-sector research and development projects in the field of human health. Because of the multi-faceted nature of these challenges, the call is not exclusively targeted at new products, services, and processes for overcoming the coronavirus pandemic, but has a broader scope covering prevention, early detection, diagnosis, and treatment as well as improving quality of life for persons suffering from illnesses and persons requiring care.

3.3 Specific Focus of the Call

In order to be eligible, projects must primarily involve technological research and development and must exhibit recognisable risks of failure in realisation. A core objective of the call is to support projects with social relevance that address current challenges in human health and that are likely to bring a positive, tangible impact. A particular focus will be placed on projects that take the needs of the user into account. User for the purposes of this call is synonymous with customer, consumer, physician, patient, client, etc. and thus means anyone who applies, uses, purchases, or consumes the products, services, or methods in a business-to-business (B2B), business-to-government (B2G), or business-to-consumer/client (B2C) relationship. This also includes persons who use such products, services, or methods in the exercise of their profession or as an employee.

Project applications must also include plausible information about relevant regulations such as the Medical Devices Regulation, the In Vitro Diagnostic Regulation, and the General Data Protection Regulation in accordance with the content of the project.

3.4 Orientation of the Life Sciences R&D Call 2021 The following topics and technological fields are eligible:

- Medical biotechnology
- Pharmaceutical industry and methods and services for the production of medicinal products
- Medical technology and diagnostics
- Digital services in health and care (healthcare IT, digital health)



- Ambient assisted living (safety and protection, health and care 12)
- Bioinformatics (in the context of healthcare)
- Human medicine, e.g. personalised medicine, gender medicine

The following topics and technological fields are not eligible:

- Industrial biotechnology/agricultural biotechnology
- Veterinary medicine/livestock breeding
- Food technology projects
- Ambient assisted living projects with a low healthcare content (e.g. wellness category, lifestyle, fitness)
- Nutritional supplements/natural substances
- Projects containing no material changes to the current state of the art/of low complexity/without technical risk

4. Open Call Criteria

4.1 Basic Criteria

In accordance with the framework of the Life Sciences R&D Call 2021, the following R&D projects¹³ administered by Vienna-based businesses are eligible for funding:

- Projects that also address current research questions and thus reach beyond pure product development and the current state of technology;
- Projects that demonstrate a basic strategy for economic implementation from which the city of Vienna has the potential for future economic gain;
- Projects that directly or indirectly result in product, service or process innovations.

In any case, the projects must have a primarily technological research and development content, with discernible risks of failure during implementation.

In accordance with EU definitions, eligible projects must fall within the fields of either "industrial research" (IR) or "experimental development" (ED). ¹⁴

¹² https://wirtschaftsagentur.at/fileadmin/user_upload/Technologie/Factsheets_T-Reports/190325_Technologiereport_AAL_DE_Screen.pdf

¹³ The eligible minimum project duration is 1 year, the maximum is 5 years.

¹⁴ See article 2, clause 84-86 of the GBER or appendix VII of the Research/18 – 21+ guideline.



Applicant businesses must come up with significant parts of the project-related R&D in-house and must also shoulder the majority of the risk associated with the realization of the project, in particular the risk associated with the economic implementation of the obtained R&D results.

4.2 Eligible Costs

All project-related costs such as project-related personnel, such as R&D-related personnel costs, that the business (or business partners in case of a joint application) may incur as internal or external personnel expenses¹⁵ (and/or project-related material costs or investment expenses are eligible. A detailed list of these can be found under pt. 6 of the Research/18 –21+ guidelines.

It is particularly relevant to note that costs related to clinical studies for medicinal products (phase I, II, or parts thereof) and medical devices and in vitro diagnostic performance evaluations are also eligible. Costs related to regulatory affairs and the first-time installation of a quality management system are also eligible.

All expenses must naturally stand in direct relation with the project.

Expenses incurred by small and mid-sized businesses related to the protection of proprietary research and development results are also subject to funding.

4.3 Funding Rate

Funding rates are dependent on research-grade classification as defined by EU provisions: Project elements (working packages) that are classified as experimental development (ED), are subject to a funding rate of 25% for large businesses, 35% for mid-sized businesses and 45% for small businesses. All project elements (working packages) classified as industrial research (IR) are subject to a funding rate of 50% for large businesses, 60% for mid-sized businesses, and 70% for small businesses.

Endeavors should cause applying businesses to adopt maximum sustainability practices. Projects should furthermore be conducted using largely in-house research and development work, with the understanding that the applying business shall shoulder all associated technical

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¹⁵ Personnel costs are defined as the costs necessary to maintain employees for the applying business that are in direct relationship to R&D work. In the case of small businesses, the value of work performances by business owners and shareholders that are actively working on a project can be taken into consideration. Expenses for external services: see pt. 6 of the Research/18 –21+ guidelines.

¹⁶ Costs in connection with the attainment, validation, or defense of patents and other immaterial assets are subject to a funding rate of 50%. See pt. 8 of the Research/18 – 21+ guidelines.

¹⁷ For further information please refer to the Research/18 – 21+ guidelines.



and economic risks. Research facilities are thus only eligible as project partners. As knowledge transfer partners, research facilities are only eligible for a standard funding rate of 80%. Additional bonuses are not available to research facilities (see also pt. 8 of the Research/18 – 21+ guidelines).

5. Participants

Please review pt. 4 of the prevailing Research/18 - 21+ guidelines to determine if you are eligible to apply. In accordance with pt. 4.1. and pt. 4.2. of the prevailing Research/18 - 21+ guidelines, only Vienna-based business and founders are eligible to apply as lead partners.

5.1 Cooperation Projects

In the case of cooperation projects, businesses may receive a bonus of up to 15%18, provided they fulfill the following criteria:

Unlike contractual relationships, *cooperation projects* are not defined by the principal of paid service and service in return, but rather by *mutual interest*, whereby each partner within the framework of a cooperation contract predefines the rights and obligations assumed by each party. All partners of a jointly conducted research endeavor thus share the *costs of* and *rights* to all research results.

In instances of cooperation between at least two (independent) businesses, none of the individual businesses may bare more than 70% of the eligible costs.

The endeavor must furthermore either include cooperation with at least one SME or be international in nature or. In instances of cooperation between a business and a research facility, the research facility must shoulder at least 10% of eligible costs and, given that the investigation has been carried out in their facility, must be granted the right to publish results. In such cooperation arrangements, substantial portions of the engineering work and knowhow development must be completed by the lead applicant.

5.2 Joint Application / Partner Application

If the proposed project is to be undertaken in cooperation with one or more partners, it is generally permissible to choose partners from all sectors and all geographic regions. It is, however, only possible to include the project costs of said cooperation partners in the joint

 $^{^{18}}$ Eligible up to a maximum of 80%. See also pt. 8 of the Research/18 – 21+ guidelines.



funding application if the eligible partner is Vienna-based (for an exact definition see pt. 4.2 of the Research/12 - 21 + guidelines).

6. Maximum Funding

Maximum funding per project is € 500,000.

7. Available Budget

The total budget available for this open call is € 2,000,000.

8. Contracting Party

This open call is administered by the Vienna Business Agency, 1070, Mariahilfer Strasse 20. The funds available were provided by the Vienna Business Agency.

9. Application Period

Applications for this call can be submitted from Wednesday, May 05th 2021, until Friday, September 10th, 2021 at https://cockpit.wirtschaftsagentur.at.

Applications can be completed in German or English and must be submitted online to the Vienna Business Agency within the period mentioned above. Application materials will be supplied upon successful registration at https://cockpit.wirtschaftsagentur.at from the time that this call is announced until the end of the application deadline. The original copy of the "Certificate of Application Authenticity" (located on the last page of the online form), which must be signed by an authorized member of your business, is due by the application deadline and should either be sent by registered mail (date of postage stamp) or hand delivered to the Vienna Business Agency, 1070 Vienna, Mariahilfer Strasse 20. The certificate can also be sent via email to the Vienna Business Agency when a qualified electronic signature is used.

10. Evaluation

Applications must comply with the abovementioned objectives and requirements for submission. Applications will be evaluated according to evaluation criteria stated in pt. 14 of the Research/18 – 21+ guidelines, and according to a standardized evaluation system that can be found at www.wirtschaftsagentur.at. The evaluation will be made by an expert jury. Should there be doubts on behalf of an applicant regarding the impartiality of potential evaluators they have the option to exclude a maximum of two individuals or institutions by submitting the names and addresses of the same. The contents of the applications and the detailed evaluations



will be accessible solely by the contracting party (i.e. Vienna Business Agency) and the jury members. The contracting party reserves the right to publish the names of applicants who receive a positive grant decision. The project title, a short project description, the grant amount, and the jury's statement may likewise be published.

11. Further Procedure

Following the completion of the evaluations of applications that have met the open call requirements, applications will be ranked according to quality and recommended by the Vienna Business Agency committee for funding in accordance with the stipulations of the budgetary framework. In accordance with EU regulations, maximum aid intensities are hereby taken into consideration.

The municipal administration of the City of Vienna will award grants based on these recommendations. The specified subsidies are all maximum amounts.

12.Funds

12.1 Cash subsidies for R&D

Cash subsidies will be awarded for the realization of the best R&D projects. The allocation of funds will follow the rank assigned to the evaluated applications. Subsidies will be provided in the following amount until the budget for those subsidies has been depleted.

The subsidy amount will be calculated according to project type and the eligibility of project costs as determined during the evaluation process and pursuant to the Research/18 - 21+ guidelines.

12.2 Bonus for women

In the case of a positive funding decision, projects that can be proven to be led by qualified females who are employed by the Vienna-based applicant businesses (lead applicants) will receive a € 10,000 bonus.¹⁹

¹⁹ According to pt. 8.5. of the Research/18 – 21+ guidelines.



12.3 Payment

The 50% advance payment and final payment shall be disbursed upon successful completion of the final accounting statement and presentation of the final report. Installments are possible under certain conditions.²⁰

13. Further Information

Information about this open call as well as supporting documents (in particular the Research/18 – 22 guidelines and the evaluation system) can be found at www.wirtschaftsagentur.at. For additional information, please Dr. Jonas Ramoni or Dr. Petra Zwirn by email ramoni@wirtschaftsagentur.at or zwirn@wirtschaftsagentur.at or telephone T +43-1-25200-426 or DW 427.

 $^{^{\}rm 20}$ According to pt. 16.3., 17.4. and 17.5. of the Research/18 - 21+ guidelines