

## Research Programme

# Antiviral therapies April 2023

### Content

1	Preamble .....	2
2	Aim and subject of the call.....	3
3	Eligibility .....	4
4	Terms and conditions.....	4
5	Application process .....	6
6	Deadlines .....	6
7	Scope and content of applications.....	6
8	Project management.....	7

## 1 Preamble

Antiviral therapies and the associated research and development suddenly came into focus worldwide with the COVID 19 pandemic. In addition to (newly emerging) human-pathogenic viral pathogens with epidemic or pandemic potential, resistance in already circulating pathogens also leads to a continuing need for innovative antiviral therapeutics. In addition, there are still viral infectious diseases that cannot be treated causally. The undiminished high clinical need for new antiviral therapies was just recently demonstrated during the wave of respiratory infections caused by the human respiratory syncytial virus (RSV) in 2022/2023. Favoured by the warmer summers, invasive mosquito species that can transmit pathogens previously unknown in Germany, such as the chikungunya or dengue virus, continue to spread nationally, especially in Baden-Württemberg. In addition, there are diseases caused by viral pathogens that can be passed on by ticks, such as the early summer meningoencephalitis (FSME) virus, which is also widespread in Baden-Württemberg. Experts worldwide are already warning of the next pandemic and are calling for increased research efforts to be better prepared in the future. Viral pathogens that require special attention in this context were first listed as priorities by the World Health Organisation (WHO) in 2017. A revised list is expected in the first half of 2023.

With its universities, universities of applied sciences, non-university research institutions and industrial companies, Baden-Württemberg is excellently positioned in the areas of research, development and innovation in virology and drug discovery and is making a significant contribution to the further development of these subject areas. The Supervisory Board of the Baden-Württemberg Stiftung has therefore decided to set up a new research programme in the field of antiviral therapies.

New opportunities for innovative antiviral therapies could particularly lie in interdisciplinary approaches that link the latest methods and findings from different fields of work and research disciplines. With its "Antiviral therapies" programme, the Baden-Württemberg Stiftung would like to strengthen research and development in particular on innovative antiviral drug candidates in Baden-Württemberg. The existing competence of the Baden-Württemberg research groups is to be expanded, thereby improving the researchers' ability to network even better with structures and stakeholders in this field of activity on a national and international level in the medium term.

## 2 Aim and subject of the call

The aim of the research programme is to strengthen the development of innovative platform technologies or (broad-spectrum) therapeutics for the treatment of human-pathogenic viral infectious diseases in outstanding projects. Different approaches are possible: In addition to antivirals for the causal treatment of viral infectious diseases, drugs that modulate cellular processes or the immune system, for example, are also conceivable.

Funding will be provided for early and late preclinical research projects. Projects may include activities from identification and validation of the therapeutic approach and high-throughput screening of drug molecules to the point of hit-to-lead development. Projects can include both synthetic compound and natural product libraries. If therapeutic approaches are already known, projects may include their further optimisation and development. The subject of the projects can be further investigations in suitable in vitro and in vivo models, pharmacological-toxicological tests as well as proof of concept studies. Where possible, initial mode of action and efficacy data should be provided by the applicants. For advanced projects, the patent situation should be researched and presented, including a statement as to whether property rights stand in the way of exploitation of the intended results. Early projects should investigate the property rights situation in the course of the project.

The research work as well as the project management should be carried out according to the standards of industrial development. The validity of the survey procedures must be guaranteed in relation to the chosen research question. Here, compliance with good laboratory practice (GLP) and good clinical practice (GCP) should be continuously monitored, depending on the relevance for the project, in order to facilitate the subsequent transition from independent, university-based to regulated, industrial research. Suitable alternative methods to in vivo studies are welcomed. A prerequisite for funding is the high quality of the methodology of the proposed project. The national and international state of research must be adequately taken into account in the project planning.

Regulatory framework conditions should be explicitly taken into account in the work plan if required. If necessary, an exchange with the regulatory authority should be planned at an early stage. The involvement of mentors from the clinical, regulatory, and industrial sectors is possible under certain conditions and is recommended for projects that can benefit from mirroring their project goals and results to existing requirements and needs due to their proximity to application.

Generally, applicants must have relevant previous scientific achievements. An essential selection criterion will be that the relationship of the approach to a viral disease is demonstrated in preliminary scientific work (if possible through initial publications).

*Excluded from funding are:*

- Pure basic research
- Research on SARS-CoV-2
- Research on plant viruses and animal pathogenic viruses (exception: viruses with zoonotic and high pandemic potential, such as H5N1).
- Preclinical work intended to expand the indications of already approved active substances ("repurposing")
- Production of GMP-conform investigational drugs for clinical trials
- Clinical studies
- Vaccines
- Diagnostics
- Medical technology products
- Surveillance

### **3 Eligibility**

Universities in Baden-Württemberg and non-profit non-university research institutions based in Baden-Württemberg are eligible to participate.

### **4 Terms and conditions**

The research is carried out on behalf of the Baden-Württemberg Stiftung gGmbH on the basis of a commissioned contract with the research institution (contract research). The Baden-Württemberg Stiftung gGmbH is entitled to the rights of the research results.

Applications can be submitted by individual working groups/research institutions as well as by consortia of different research institutions. Interdisciplinary approaches to address complex problems are welcomed. In any case, it must be demonstrated that all the competences required to work on the research project are available to the applicants or are guaranteed by the involvement of external expertise.

If several research institutions are involved, a coordinator must be appointed who acts as the contact person for the Baden-Württemberg Stiftung, coordinates between the research institutions and is responsible for the overall project management towards the Stiftung.

Financing is provided for personnel and material costs, travel expenses, subcontracts, and - in duly justified cases - investment costs in the form of depreciation incurred during the term of the project.

A single-stage application procedure is planned. The applications, which have to be submitted within the deadline specified below, will be evaluated by an independent, external review panel, which will submit recommended funding decisions to the Baden-Württemberg Stiftung.

The most important evaluation criteria are:

- Level of innovation and differentiation from the state of the art
- Innovation effect and application relevance
- Quality of the scientific-technical approach and work plan (excellence)
- Qualification of the working group/research institution or consortium
- Adequacy of the financial plan

No reasons will be given for rejection of the project under this call for proposals. There is no entitlement to funding. By submitting the project description, the applicants agree to these terms and conditions.

The projects should not exceed a duration of 3 years. The Baden-Württemberg Stiftung gGmbH has up to 5 million euros available for the research programme.

## 5 Application process

All applications from universities must be submitted by their rectorates. Applications from non-university research institutions must be submitted by their management.

## 6 Deadlines

Applications must be submitted electronically in German or English to the project management organisation by **30.06.2023**, 23:59 (deadline). Applications are submitted via the submission portal listed under 8.

## 7 Scope and content of applications

The following structure is provided for the proposals:

1. *General information* (title of the project; applying institution; other participants, if applicable; project leader or coordinating person in the case of consortia; project duration; total costs)
2. *Summary* (short, generally understandable description of the project with objectives, procedure, expected results and their benefits, max. 1600 characters), a summary also in German for applications in English.
3. *Topic and objective* (introduction; problem; objective and approach; relevance (e.g. for Baden-Württemberg))
4. *State of science and research* (international status as well as differentiation of the project from this and its added value)
5. *Patent situation*
6. *Project-relevant own preliminary work/expertise* (of all participants; incl. publications; patent applications)
7. *Information on equipment and personnel*
8. *Planning* (work plan divided into coherent work packages; time schedule; six clear, binding, semi-annually reviewable, quantitatively defined milestones; description of possible risks and their minimisation; Gantt chart). Work packages that take into account regulatory frameworks (e.g. Scientific Advice Meeting) are welcomed. For collaborative proposals, submit a joint proposal. Clearly outline the division of tasks.
9. *Exploitation plan* (scientific-technical/economic; benefit for Baden-Württemberg)
10. *Financial plan* (net cost statement, indicating VAT separately; if no VAT is shown, it is assumed to be a gross cost statement including VAT):
  - Personnel costs (incl. person months and pay groups). A maximum of 80,100 euros/year for postdocs, 74,100 euros/year for PhD students and

- 54,300 euros/year for technical staff (based on 100% positions; plus VAT in each case) will be funded. The inclusion of mentors from the clinic/industry/regulatory sector is possible, but not eligible for funding.
- Itemised material costs (small equipment up to 5,000 euros, consumables, patent research for "early" projects, travel expenses)
  - In justified exceptional cases, investment costs (applies to new investments of 5,000 euros or more, depreciation period according to the official depreciation (AfA) table, deductible depreciation only for the period of use during the project).
  - Summarised total costs
  - In the case of collaborations, there must be a clearly differentiated financing plan that conclusively shows which posts and funds are earmarked for each project participant.
11. *Legally binding signature* (see section 5, incl. place, date and legally binding address as well as contact person in charge, if applicable)

The entire application document (incl. title page and appendices as well as bibliography) must not exceed **20 A4 pages** (Arial font, 12pt font size, 1.15 line spacing, minimum 2 cm margins). Please note that the application must be unencrypted. Applications that do not meet these requirements may be excluded from the evaluation and rejected without further justification.

## **8 Project management**

The Baden-Württemberg Stiftung gGmbH has commissioned the project management organisation VDI/VDE Innovation + Technik GmbH (VDI/VDE-IT) with the implementation and monitoring of the research programme. The project management organisation is responsible for the organisational management of the programme and is the central point of contact for applicants. It is recommended to contact the project management organisation prior to submission.

The application is submitted via the submission portal (<https://www.vdivde-it.de/submission/bekanntmachungen/2310>). An application in PDF format signed by the rectorate of the university or the management of the research institution must be uploaded to the submission portal. The digital signature in the PDF document is sufficient. Original submission by post or fax is not required.

**VDI/VDE Innovation + Technik GmbH**

PT Antiviral therapies

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