Closing the gap - validating and implementing new approach methodologies in a regulatory context

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1. Background

Investigating toxicity and safety of substances like additives, commercial chemical products and pharmaceuticals is an important part of ensuring the required safety of products. New chemical products and pharmaceuticals may only be approved once possible toxic effects and hazards for humans have been assessed adequately. In addition, efficacy of newly developed pharmaceuticals needs to be established in a human relevant fashion. Such assessments are facilitated by national and international legislation. However, both science and society are more and more aware of the necessity for humanized models to mimic human biology. Thus, developing innovative humanized test systems will not only be a key factor in replacing animal testing but also will benefit society and the environment due to the use of models that resemble the human situation more closely, eventually leading to safer and more efficacious products.

In the testing of substances, animal testing has long been the gold standard. In recent years, however, it has become increasingly clear that the so-called "translational failure", i.e. the low success rate in transferring animal tests to humans, is an urgent problem and must be addressed. New approach methodologies (NAMs[1]) can therefore be beneficial. Numerous alternative approaches have already been developed that have the potential to replace animal testing. Often, these new methods promise a gain in drug development efficiency because they are faster or less expensive than animal testing. Additionally, they have the added benefit of a potentially higher translational success rate. However, these new methods have not yet become mainstream or established as new scientific standards. This is primarily because most of these methods have not yet been validated or qualified for regulatory approval, thus hindering their widespread use in industry. With the rapid development of new human-based models, regulatory procedures need to be adapted to these models. This, along with the need for standardization and validation efforts for these models, highlights the need for scientific experts and regulators, to join forces. This way, the incorporation of regulatory requirements can be included in experimental designs and project set-ups, ensuring the suitability of NAMs for regulatory safety assessments. Furthermore, it is of great benefit if regulators are involved early on in the process and are thus able to provide valuable feedback and adapt existing procedures accordingly so that NAMs can be included in safety and/or efficacy assessments.
That being said it is key that NAMs are fit for purpose, with assays being validated as appropriate for the intended use of the data and the associated regulatory requirements. In case the intended use changes, additional validation may be required[2]. To be fit for purpose e.g. the following aspects should be considered:

[1] This term was coined at ECHA in 2016 as abbreviation of ‘New approach methodologies’. ECHA’s definition of NAMs is: "NAMs include in silico approaches, in chemico and in vitro assays, as well as the inclusion of information from the exposure of chemicals in the context of hazard assessment. They also include a variety of new testing tools, such as “high-throughput screening” and “high-content methods” e.g. genomics, proteomics, metabolomics; as well as some “conventional” methods that aim to improve understanding of toxic effects, either through improving toxicokinetic or toxicodynamic knowledge for substances.” The US Environmental Protection Agency (EPA) defines NAMs as follows: “it is broadly descriptive reference to any non Vertebrate Animals technology, methodology, approach, or combination thereof that can be used to provide information on chemical hazard and risk assessment.”

[2] https://link.springer.com/article/10.1007/s00204-022-03365-4

- The NAM should provide information that is needed by end users to draw specific conclusions about the substance under consideration (e.g., qualitative classification, a point of departure, or additional mechanistic information).
- The information measured by the NAM should relate to the regulatory endpoint of interest.
- The acceptable quantitative and qualitative level of uncertainty should be defined for the specified purpose.
- The context of use that the NAM is intended for should be predefined (e.g., for screening, hazard identification, hazard characterization, quantitative risk assessment, etc.)

The test guideline programme for the testing of chemicals of the Organisation for Economic Co-operation and Development (OECD) is used to test the safety of chemicals. Each member state of the OECD has the possibility to develop test procedures further or to introduce new procedures as well as to decide whether submitted proposals meet its own regulatory requirements. In order to coordinate and harmonize the national contributions and, above all, to comment on international drafts from the perspective of the respective member state, national coordinators (NCs) have been set up. The NCs represent their member states national position and are allowed to introduce new methods for approval. At an annual meeting of the NCs, proposals for test guidelines are being discussed from a technical point of view and may be adopted or commented on for further information. This way potential test methods are reviewed for suitability at the international level by the OECD and, where appropriate, adopted as test guidelines. The goal of OECD activities is to develop test guidelines that reflect current knowledge, regulatory needs, and strengthen animal welfare.
Both developers of NAMs and the corresponding NCs are increasingly willing to collaborate in this process, however, funding for the implementation of NAMs remains limited. Thus, this call in particular aims to fill this gap to support existing validation, implementation, and dissemination efforts for methods that have already been developed as an alternative to animal testing, but still need to be validated, qualified, and accepted for regulatory safety and/or efficacy assessment purposes. Coordinating NCs or experts from regulatory authorities such as the European Medicines Agency (EMA) or the national equivalents BfArM (German Federal Institute for Drugs and Medical Devices), PEI (Paul-Ehrlich Institute, Federal Institute for Vaccines and Biomedicines) and CBG (Dutch Medicines Evaluation Board Agency), that are involved in the approval and/or authorization of chemical substances or pharmaceutical products need to be consulted during project design and execution. Interdisciplinary projects as well as the collaboration between relevant stakeholders in Europe is an additional focus of this call. The overall objective is the further implementation of NAMs that are currently part of the approval process for pharmaceutical or chemical products, particularly in a regulatory context throughout Europe, by promoting and consolidating sustainable research consortia.
We aim for a step-by-step approach to validation thus moving from prediction to protective applications of NAMs.

Making regulatory decisions based on data generated using agreed standards at the global level saves time. Moreover, data generated using validated methods are less prone to rebuttal and dispute, give greater legal certainty, and help maintain a level playing field across countries. For that purpose, validation and validated methods are potent instruments to ensure the availability of standardised methods in the longer term.

To further strengthen the field in Europe and to foster and consolidate sustainable research cooperation of Germany and the Netherlands , a joint call for interdisciplinary research projects with a focus on validation is launched by the BMBF (German Federal Ministry of Education and Research) and ZonMw (The Dutch organisation for knowledge and innovation in health, healthcare and well-being).

To be eligible for funding, projects have to establish a minimal technology readiness of level (TRL) 3 and maximum of level 7 at the start of the project[3]. Please refer to the table below for specifications.

TRL	Expected achievement
1	Basic principles observed
2	Technology concept formulated
3	Experimental proof of concept
4	Technology validated in a lab
5	Technology validated in a relevant environment (industrially relevant environment in the case of key enabling technologies)
6	Technology demonstrated in a relevant environment (industrially relevant environment in the case of key enabling technologies)
7	System prototype demonstration in an operational environment
8	System complete and qualified
9	Actual system proven in an operational environment (competitive manufacturing in the case of key enabling technologies, or in space)

2. Objectives and Considerations for the Call

Main Objectives

Validation of new approach methods in a regulatory context, with the ultimate goal to implement new animal-free, human relevant methods as OECD guidelines or establish qualified methods for the use in efficacy testings for new pharmaceuticals.
In this regard, projects are expected to increase in TRL during the duration of the project, thus enabling them to prepare documentation for a timely (2-3 years post project finalisation) regulatory evaluation and approval, if feasible.

Considerations

1. *Modules*
   Projects may apply to one of two different modules. Modules only vary in their requested method readiness and thus ask for different work packages and outputs. Depending on the anticipated time frame and progress, projects that start in Module I can progress towards Module II. In this case, a milestone-based approach is mandatory and requirements of both modules may apply.

   - Module I
     Applications submitted in this module are expected to offer a TRL of 3-4.Thus, projects within this module may conduct transferability and reproducibility studies to establish the reliability of the method. It is strongly advised to consult with relevant regulatory authorities e.g. EMA, BfArM, PEI or CBG. The approval of an OECD guideline is not a necessary endpoint within module I.

   - Module II
     Applications submitted in this module are expected to offer a technology readiness level (TRL) of 5-7. Thus, projects within this module may conduct a ring trial or similar efforts according to established regulatory procedures to validate the method at hand and thus enable a timely regulatory acceptance or approval as a new guideline by the OECD.

[3] Please refer to the following website for further information on TRLs:
https://horizoneuropencpportal.eu/sites/default/files/2022-12/trl-assessment-tool-guide-final.pdf

Consulting regulatory bodies prior to submission of the application is mandatory to ensure readiness of the method. Regulatory bodies may be consulted throughout the project and funds may be specifically allocated for their services.

2. *Human relevance*

All methods proposed should be fit for purpose and human relevant. Projects need to provide evidence for the human relevance of their method (preferably already established or to be established early in the project). Hence, projects should emphasize on biologically relevant and protective applications, with a focus on toxicity or efficacy, using NAMs and/or combining NAMs with traditional methods.

Projects may apply for a wide range of topics (please refer to examples below). You may also contact the organizers for further information on possible topics.

Applicable topics are e.g.

- neurotoxicity,
- oral toxicity,
- reproductive toxicity,
- endocrine disruptors,
- immunotoxicity,
- immunogenicity,
- inhalation sensitization,
- and others.

3. *If applicable - contribution to replacement*

If applicable, projects are encouraged to present arguments for the impact of the project on the replacement of animal testing using NAMs. It must be clearly stated for which application(s) the replacement method is to be used.

4. *Application of research results*

The joint projects have to contribute to a concrete, targeted and timely transfer of results and data into broad application. Existing NAMs are to be significantly developed further and prepared for a timely and broad implementation into applied sciences. If applicable, projects should aim for OECD approval within their guideline program within the project duration or latest within 2 years after the end of project (applicable for module II).

5. *Readiness criteria*

Projects should provide sufficient information regarding the readiness of their methods, enabling a thorough evaluation by the reviewers. Reference substances should be established before the start of the validation and hence be part of the readiness criteria. Validation endpoints need to be defined ahead of the project start!

Method readiness may be evaluated based on the following criteria:

- Context of use defined
- Scientific purpose and relevance (biological or mechanistic)
- SOPs or optimized protocols (please refer to 5.1 for further information) are available, which enables the implementation of methods in-other (naive) labs
    - Interoperability was shown at least in house (applicable for module II)
- Transfer possibilities exist
- Method description
    - Exposure scheme
    - Endpoints measure
    - Characterization of the test system (authentication, stability, metabolic competence, etc.)
- Shown for multiple reference substances (applicable for module II)

- Intra-laboratory reproducibility and if available (preliminary) inter-laboratory transferability (applicable for module II)
- Validation endpoints defined
- Others

6. *Interdisciplinary partnerships*
   Collaboration between industry and regulatory bodies, coupled with practical experience-sharing initiatives, is deemed essential for enhancing regulatory acceptance and fostering innovation. Thus, the joint project must be based on an international partnership in a broad strategic consortium.
   - Each consortium must contain partners eligible for funding by both funding organisations participating in this call (ZonMw and BMBF).
   - The consortium should consist of at least one public and at least one private partner; a regulatory partner is recommended. Visits between consortium partners are highly encouraged. Involvement of the relevant OECD National Coordinators (NCs) as well as other validation partners or consultants is strongly recommended.
   - A private partner may be any international company. Please note that there are differences in national criteria concerning the eligibility of private partners for funding. Please read the National Annexes!
   - Participants from countries outside Germany and the Netherlands may only be involved in a project if they secure their own funding and if their expertise is indispensable for achieving the project objectives.
   - The possibility for awarding subcontracts and services in the context of validation should be clarified in advance at the respective national level.

7. *Data management*
   Open data sharing is advocated to avoid reproducibility issues and to ensure method transferability. Openness and transparency in data acquisition and analysis are important, as they are a requirement for regulatory acceptance.
   A data management plan (DMP) and data handling protocols according to internationally state-of-the-art standards (FAIR[4] and GDPR[5] compliant and secure) must be provided as an integral part of the application. A data management plan should address criteria such as data accessibility, format and storage, stewardship/curation, time plan and schedule for the submission date, quality of meta data, and data security. For this, it may help to refer to the Horizon 2020 DMP template[6] or the institutional templates acknowledged by ZonMw[7]. A reliable concept concerning data storage, data/model exchange and data/model sharing should be available at the time of application and be part of the consortium agreement (see below). The use of existing infrastructure (e.g. ELIXIR[8]) should be taken into consideration.

8. *Quality management*
   Applicants have to ensure a thorough level of quality control/quality assurance (QC/QA) to guarantee consistent quality, especially with technically complex components. A quality management system should be in place, with a focus on robust technical component, thus conducting validation primarily on the biological aspects of the model. Working according to

[4] https://www.go-fair.org/fair-principles/

[5] https://gdpr-info.eu/art-5-gdpr/

[6] [http://ec.europa.eu/research/participants/data/ref/h2020/other/gm/reporting/h2020-tpl-oa-data-mgt-plan-annotated_en.pdf]

[7] https://www.zonmw.nl/en/acknowledges-institutional-data-managementplan-templates-dmp

[8] https://elixir-europe.org/

Good In Vitro Method Practices (GIVIMP)[9] is recommended. The existence of established SOPs is a mandatory requirement to be eligible for funding. SOPs may need to be provided upon request.

9. *Regulatory involvement*
   Applicants may choose the involvement of any suitable European regulatory authority depending on the nature of their project at hand, with it being mandatory to consult with at least one for module II.
   A cooperation with and/or the involvement of regulatory agencies should thus be outlined as a concept in the proposal. It is strongly recommended to involve the relevant NCs of the OECD at an early stage in order to receive valuable feedback about a potential new method for the OECD guidelines program. Further support, e.g. from national and/or international regulatory authorities (such as EURL-ECVAM, EMA, ECHA, PEI, BfArM, CBG, etc.), may be included in the proposal as well.

10. *Implementation plan*
    The proposal must contain a plan for a concrete, timely and broad implementation of research results with the installment of a new OECD guideline being one possible strategy. Time schedules with an approximated timeline for method uptake must be provided. Identification of key stakeholders as well as considerations regarding method scalability and economic viability should be included in the proposal.

11. *Coordination of validation efforts*
    Projects will have to ensure a successful coordination of validation studies, preferably including specific expertise in their validation management team. An experienced and specialized validation team is regarded as a key element for a successful planning, execution and analysis of a validation study. Thus, projects may apply for up to 20-25% of personnel capacity for coordination.

12. *Budgetary considerations*
    Applicants should account for 1-2 review meetings between project partners, reviewers and funding bodies to ensure needs-based and end user driven validation of NAMs.

13. *Consortium agreement*
    Within six months of the grant being awarded, the consortium partners must sign an agreement specifying, among other things, the approach to intellectual property rights (including data and models) derived from the results of the joint project. The consortium agreement should therefore include a set of rules and procedures to ensure fair protection for the IPR interests of the partners and their employees. The consortium agreement should also include conflict resolution procedures and mechanisms that maybe invoked if and when necessary.

Applicants are strongly advised to read the National Annexes for further specifications regarding the call.

4. Conditions

4.1 Project duration

Each joint project consortium may apply for a joint project time scale of a maximum of three years.

9 https://www.oecd.org/env/guidance-document-on-good-in-vitro-method-practices-givimp-9789264304796-en.htm

4.2 Who is eligible to apply?
Each consortium must contain partners eligible for funding by both funding organizations participating in this call (ZonMw and BMBF). Specific regulations are provided in National Annexes (www.valnam.eu).The consortium should consist of at least one public and one private partner, a regulatory partner is optional. A regulatory partner may be considered public depending on national regulations.

4.3 Available Funding
The contributed budget of the individual funding organizations is allocated to the respective national research groups. National funding regulations are provided in the National Annex of each funder (www.valnam.eu).

4.4 Policy on intellectual property
Each consortium must agree on a consortium agreement (CA), which must be signed by all public and private partners in the joint project within six months of the grant being awarded. The consortium agreement must specify the intellectual property policy of the consortium, which should include the arrangements for ownership rights to intellectual property in the form of knowledge, products, etc. developed during the project.
In this call ZonMw and BMBF have based their intellectual property policy on the principle of 'ownership follows inventorship'.
In compliance with the EC Framework for State Aid for Research and Development and Innovation (2006/C 323/01), specifically Article 3.2.2 'Collaboration of undertakings and research organizations', the intellectual property agreements must guarantee that:

- The results of joint projects from which intellectual property rights may be derived may be widely disseminated, and any intellectual property rights ensuing from the activities of the public partner(s) are awarded in full to the public partner(s).
- The public partner(s) receive remuneration from the private partner(s) in accordance with the market price for any intellectual property rights ensuing from the joint project that are transferred to the private partner(s). Any contribution by the private partner(s) to the costs incurred by the public partner(s) will be deducted from the remuneration.

Consortia are strongly advised to contribute publications and information on data, tools and technologies generated by their research to the public domain where it should be made widely available. Access must be provided to other bona fide research groups, with the necessary arrangements in place.
It is the responsibility of each project partner to ensure that intellectual property rights ensuing from the accomplishment of the joint research projects are efficiently and properly protected and distributed.

5. Assessment procedure

Grants will be awarded based on an assessment of a joint written proposal. If applicable, a presentation and interview with the committee is also part of the procedure.
The proposal evaluation will be organized and executed by a joint call secretariat (JCS).

5.1 Procedural criteria
Applicants are required to submit one joint transnational proposal. With regard to the international review process, joint project proposals have to be written in English.
The consortium leader must submit the following attachments:

- The full application form which includes an itemized budget for each project partner.
- Applicants may also include an optional attachment of no more than two A4 pages containing figures and tables.
- Applicants may also submit an additional GANTT chart outlining the proposed project timeline in detail.

- Applicants should also submit SOPs[10] that support the method readiness, which can be used by other (naive) labs as well.
- Applicants are not eligible for funding if they already receive funding for individual work packages or the entire project proposed by third party funders.
- In the event that a grant is awarded, joint project coordinators are expected to:
    - submit a final report summarizing the achievements of the project (templates will be made available) according to national funding regulations;
    - attend at least one status review meeting (to be scheduled and hosted by the JCS) and present the project results.

5.2 Proposal Evaluation

Proposals that are not eligible will be rejected and cannot be re-submitted in this call. All eligible proposals will be peer-reviewed by a reviewer panel selected and installed by the JCS, the peer reviewer panel (PRP). The panel members will evaluate the proposal using a standardized written form.

JCS will coordinate reviewer comments and host a panel meeting. Proposals will be invited based on the written reviews. Participation will be on a voluntary basis.
Selected projects will then be discussed in the following way during the PRP meeting: the project coordinator will be given the opportunity to present the project and address critique, followed by a Q&A with the PRP. The PRP will establish a ranking list of high-quality and relevant applications recommended for funding.
The final project selection is incumbent to the participating funding bodies (ZonMW and BMBF).

JCS will communicate the funding decision to the applicants.

5.3 Assessment criteria

Each joint proposal will be assessed for the 5 criteria below:

Relevance: Contribution to the objectives of the call (weighed double)

- Suitability with regard to the context of the call, especially with regard to human relevance
- It replaces an animal test or is part of a battery to capture the information required for a relevant biological or toxicological process, thus having implications for chemical safety or pharmaceutical efficacy with relevance for humans.
- Transferability of the findings from the intended replacement model to humans or the previous animal model
- Potential impact on scientific domains, regulatory conditions, public health economics, etc, addresses an urgent regulatory need, shows sufficient regulatory expertise
- Bi-Nationality substantiates the main objectives of the call.

Project readiness level (weighed double)

- Quantity and quality of existing data with regard to readiness criteria and standardization
- Clarity of the objectives and research hypothesis to substantiate a fit for purpose application of the NAM
- Realistic and coherent outline of steps planned to progress this project towards implementation in a regulatory framework
- Effectiveness of the implementation plan and experimental validation of the method

[10] Please be advised that SOPs will be considered confidential information and specific instructions will be provided to the reviewers. Please contact JCS before submission, if there are any additional concerns. SOPs are expected to be structured according to OECD and EPA guidance (https://doi.org/10.1787/9789264304796-12-en and https://www.epa.gov/sites/default/files/2015-06/documents/g6-final.pdf). You may also refer to Hollmann et al. (https://doi.org/10.1371/journal.pcbi.1008095) for further instructions.

- Outlines a potential or anticipated increase in TRL during the project
- Distinctive considerations for module I or module II apply.
- An appropriate module selection by the applicants will be evaluated based on the readiness level of the project.

Exploitation and sustainability

- Coherent and plausible outline of steps planned to consolidate the results of the project beyond the funding period and implement the new method in a regulatory context.
- Appropriate description and consideration of regulatory requirements (where relevant), measures for IPR management (e.g. Fair, Reasonable and Non-Discriminatory (FRAND)[11]) and measure for access to data and samples
- Utilization concept with time horizon and economic and technical significance beyond the project duration
- Implementation strategy for a sustainable transfer of project results, scalability and economic viability

Organization, project management and expertise

- Scientific necessity and added benefit to the project of the effective cooperation of Dutch and German teams; quality and expertise of the selected consortium, including expertise on validation
- Concrete step-by-step plan, including task allocation, milestones and deliverables
- Effectiveness of the chosen approach, data and quality management in place, communication and implementation of the results, both during and after the project (including regulatory involvement)
- Appropriate management structures and procedures and reasonable and comprehensively structured work plan
- Level at which regulatory authorities have been consulted and contribute to the progress and regulatory implementation of the project (mandatory for module II)

Adequacy of resources and feasibility

- Requested human and financial resources (adequacy of means allocated to each work programme, clear justification of requested means, value for money, overall balance of resources, quality of the scientific environment and specific conditions for implementation/application)
- Feasibility of the project (work plan, realism of the timetable, risk assessment and contingency plan); The application file must jointly present the Dutch and the German parts of the research programme, including details about the roles of each team as well as the means defining their common work.

Each joint proposal is assessed for all criteria established. The PRP will rank the proposals using the scoring system below for each individual criterion, thus ranking applications. In addition, projects will be scored based on their funding eligibility and priority.

Scoring System

0 points: Failure - The proposal fails to address the criterion in question, or cannot be judged because of missing or incomplete information.

1 points: Poor - The proposal shows serious weaknesses in relation to the criterion in question. Concerning this criterion, the project cannot be recommended for funding.

[11] https://www.oecd.org/fr/securitechimique/essais/intellectual-property-in-oecd-test-guidelines.htm

2 points: Fair - The proposal generally addresses the criterion, but there are significant weaknesses and considerable deficiencies that need corrections.

3 points: Good - The proposal addresses the criterion in question comprehensively, but also presents deficiencies and improvements are necessary.

4 points: Very good - The proposal addresses the criterion very well, but small improvements could further strengthen the proposal.

5 points: Excellent - The proposal successfully addresses all aspects of the criterion in question.

6. Contact

National Contact Points
Applicants are encouraged to contact their respective National Contact Point for any queries related to content or national regulations:

ZonMw - The Netherlands

Dr. Martijn Nolte

Email: Nolte@zonmw.nl
Phone: +31 70 515 03 75

Laan van Nieuw Oost-Indië 334
2593 CE Den Haag
The Netherlands

BMBF / VDI/VDE-IT- Germany
BMBF has commissioned the following project management organization to implement the funding measure:

Dr. Sandra Paschkowsky
Dr. Anke Teichmann
Dr. Sophia Bauch

Email: valnam@vdivde-it.de
Phone: +49 30 310078-5585

VDI/VDE Innovation + Technik GmbH
Steinplatz 1
10623 Berlin
Germany

Joint Call Secretariat
For questions on the application procedure, please contact the Joint Call Secretariat:

Dr. Sandra Paschkowsky
Dr. Anke Teichmann
Dr. Sophia Bauch

Email: valnam@vdivde-it.de
Phone: +49 30 310078-5585

VDI/VDE Innovation + Technik GmbH
Steinplatz 1
10623 Berlin
Germany

7. Submission of proposals via online submission tool

One joint proposal document shall be prepared by the partners of a joint transnational consortium and submitted electronically by the coordinator via the online submission tool (https://ssl.vdivde-it.de/positrons-en/calls/2407). Only proposals using the template provided by the JCS will be accepted. No other means of submission will be accepted.
The submission deadline for proposals is no later than **28.04.2025.**

Detailed Information on how to submit joint proposals, required documents and other binding requirements for the project proposal can be found in the online submission tool (https://ssl.vdivde-it.de/positrons-en/calls/2407).

8. Downloads

The required documents can be found on the call website (www.valnam.eu) under call documents.

- Template grant proposal

8.1 ZonMw specific Documents (ZonMw applicants)

- Dutch National Annex

8.2 BMBF specific Documents (BMBF applicants)

- Richtlinie zur Förderung von Projekten zum Thema „Validierung und Implementierung humanbasierter neuer Methoden im regulatorischen Kontext - ValNAM“
- For eligible costs and further national regulations please refer to national guidelines applicable to applications to BMBF: https://foerderportal.bund.de/
- Merkblatt für Antragsteller/Zuwendungsempfänger zur Zusammenarbeit der Partner von Verbundprojekten, BMBF-Vordr. 0110/08.14