



Proposals for AIDA Clinical evaluation projects

Analytic Imaging Diagnostic Arena (AIDA) is a national arena for research and innovation on analytic image-based diagnostics. AIDA is a cross-disciplinary and cross-sectorial collaboration aiming for large-scale usefulness from Artificial Intelligence (AI) in healthcare. AIDA is part of the national Strategic Innovation Program Medtech4Health, a joint initiative by VINNOVA, Formas and the Swedish Energy Agency. More information can be found at medtech4health.se/aida.

A main part of the AIDA initiative is to host efforts from the entire country, aiming to contribute to development and adoption of AI methods in imaging diagnostics. We here describe an opportunity to participate in AIDA with clinical projects conducting evaluation efforts.

Opportunity for Clinical evaluation projects

This initiative is directed to clinical evaluation of commercially available AI solutions within AIDA's scope of imaging diagnostics. AIDA will here support care providers that wish to assess whether an existing solution is likely to perform well and provide substantial benefits if adopted. This evaluation can be a preparatory step before going into procurement or be a part of an innovation procurement process.

Examples of previous projects of this type can be found on the AIDA Clinical evaluation web page.

The condition that the AI solution is commercially available means that it needs to be an openly advertised product/service. It is strongly recommended that the solution has regulatory approval for clinical use in Sweden. If such regulatory approval does not yet exist, the application must in other ways show that the product/service is mature enough to be appropriate for clinical evaluation.

The proposals are recommended to adhere to the following setup. Deviations may be acceptable if well motivated.

- The data collection used for the evaluation is to be extracted from the clinical production of the proposing care provider(s). Care should be taken to ensure that it is representative for the clinical routine and the targeted patient group.
- The solution provider should follow their normal process for clinical implementations, which for instance may include calibration of the AI algorithm on a subset of the data collected.
- The care provider should have three roles represented in the project: a project manager, enduser representative(s) (typically diagnostic physicians), and IT staff. The project manager effort should amount to 20-30% of the total work hours.
- The evaluation protocol includes quantified assessments of benefits such as effects on productivity and diagnostic precision.
- The project is to include a written final report, describing evaluation results and lessons learned.

AIDA welcomes proposals from care providers in Sweden. The industrial vendor efforts are not a formal part of the project and no AIDA funds will go to the vendor, but the vendor must in writing confirm that they commit to making the efforts on their side necessary for the project to be conducted as planned.

If relevant, connections to other existing AIDA projects or parallel proposals, in particular clinical fellowships, are welcome. State such connections clearly in the application.

AIDA expects project proposals with a **total** cost budget between 100 - 300 kSEK (which AIDA funding would partially cover, see below).

Terms

The level of funding from AIDA/VINNOVA is 50% of the project cost. For care providers being private companies, the funding degree may be further limited by the general regulations for this type of project ("Process innovation") and the size of the proposing party, see the <u>VINNOVA guide</u>.

Whereas the industrial vendor cannot receive AIDA funds, other parties outside of the care provider can be engaged to support the evaluation, given that the overall 50% funding level is not exceeded. One option is to include them as regular project parties. This would, however, for commercial companies typically mean a limited funding level according to the rules for government subsidies, see the VINNOVA guide. There is also an opportunity to engage commercial partners (such as consulting firms) as sub-suppliers through the AIDA *Innovation check*. The check has a fixed format: the subsupplier firm receives 50 kSEK in return for a 100 man-hours effort.

The application must be approved and signed by the respective department manager of all clinical counterparts involved and a suitable manager of the vendor in question.

The project should start within 3 months from the call deadline (though vacation period exceptions are possible) and should not be longer than 12 months.

An allotment of AIDA technical resources is offered for free for approved projects, for clinical evaluations the AIDA PACS installation may for instance be useful.

The proposals will be evaluated according to the following meriting criteria:

- Potential
 - o Topic relevance for AIDA
 - Potential for clinical usefulness
 - Level of solution maturity
 - o Contributions to, and benefits from, the AIDA connection
- Actors
 - Constellation of organizations
 - Expertise of individuals
 - o Gender equality, both in terms of staffing and influence
- Practical feasibility
 - Time plan and budget
 - o Access to suitable expertise in given time frame

A foundational part of AIDA is knowledge exchange with all AIDA partners. Approved projects will be required to participate at the "AIDA Days" events (6-8 times per year) as follows: Participation means physical presence whenever an on-premise meeting is arranged, otherwise remote. At least one representative of the project should participate at each AIDA Days. All project members with substantial efforts in the project should participate in at least one AIDA Days during the project.

In order for a proposal being a continuation of a previous AIDA project to be approved, a final report for the previous project must have been filed before the proposal deadline.

In addition to the AIDA-specific rules, general VINNOVA terms apply for allowed cost types, cost levels, funding levels etc. The costs are defined according to the general VINNOVA standard, a full description is found here (in Swedish): <u>Guide om stödberättigade kostnader</u>.

Application procedure

Proposals should be described using the template available on medtech4health.se/aida. The proposal is submitted to the Arena Director at aida-director@medtech4health.se. Incoming proposals are then refined in a dialogue with the Arena Director – a dialogue that can include assistance to find suitable project partners including consulting firms. After the dialogue, the Arena Director brings the finalized proposal to the AIDA Steering Group for decision. The proposing party is entitled to request decision

from the Steering Group even if the Arena Director does not consider the proposal finalized. The AIDA Steering Group reserves the right to award a smaller amount of funding than what a proposal asks for or to make part of the funding dependent on a specific condition.

AIDA currently plans for recurring rounds of accepting proposals. The deadlines for submitting proposals will be announced on medtech4health.se/aida.

Please note that if a proposal is submitted close to the deadline, there may not be time for dialogue regarding the proposal. Therefore, we recommend submitting a first version well in advance of the deadline. Also note that AIDA will accept high-quality proposals until the budget is reached, which means that there is no guarantee of future rounds of accepting proposals.