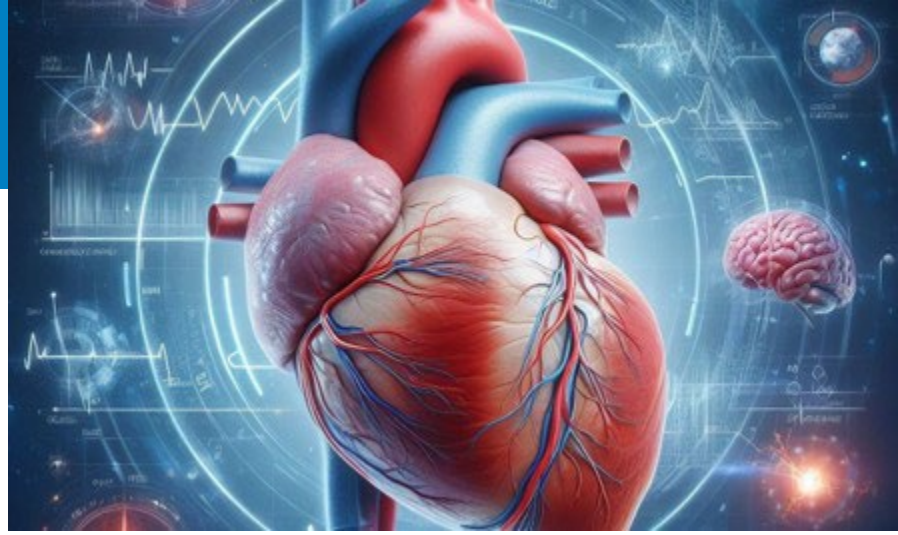


# CaVD-PACE – New treatments and diagnostic measures for cardiovascular diseases



## Contractor

DLR - Deutsches Zentrum für Luft- und Raumfahrt e.V.

## Consortium Members

None

## Contract period

17/11/2022 - 16/11/2025

## Budget

370 045€

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## Main objectives:

New technologies have been released on the market that provide for improved curative or supportive treatments in terms of medication and supportive equipment (implantable or external) that highly improve the quality of life for cardiac patients. Some types of equipment, although performing very well on the ground, are potentially affected by the inflight conditions such as humidity, vibration, pressure, and temperature, which may lead to inflight malfunctions (be it a regular flight or the case of sudden cabin decompression).

The objective of this research is to provide

- evidence-based recommendations for updating the cardiovascular requirements in line with the latest medical developments;
- an impact assessment of the recommended amendments to the cardiovascular requirements;
- guidance material for aeromedical examiners and medical assessors on the updates to the fitness assessment of applicants;
- material to support the management of the proposed amendments (e.g., presentation of the results obtained under this project and training material for professional audiences); and
- risk management promotion material for aeromedical certificate holders to allow them to early detect and self-manage their cardiovascular risk factors (CVRFs).

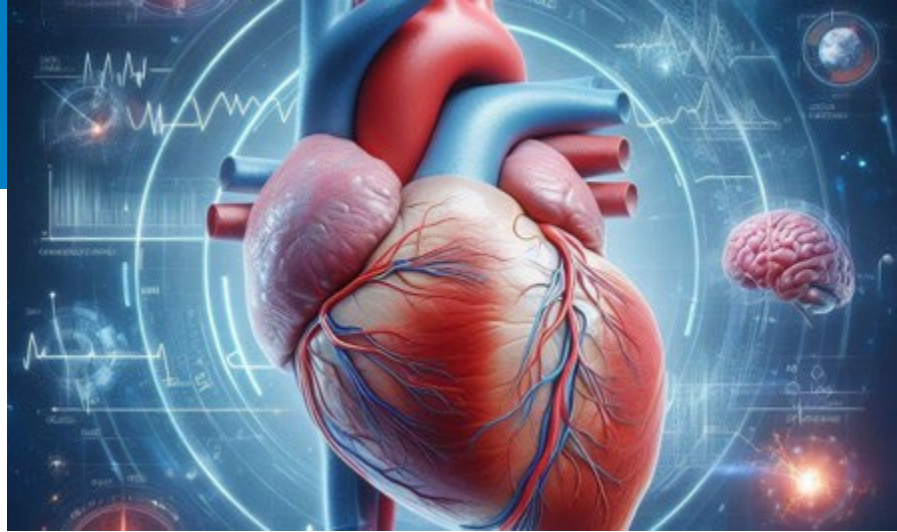
The study of such types of equipment will have an impact on crew members, particularly on their fitness to perform their duties, but also on passengers that have such devices, even if flying only occasionally. In a similar way, new treatments have been developed to alleviate certain pathological conditions; nevertheless, for some of these treatments the side effects may be further augmented by the cabin environment to the level of making them incompatible with flying. In the case of medication, the issue has a greater impact on the fitness of crew members rather than of occasional passengers.

## Impacts & benefits

When applicable, the research results will support a potential amendment of aeromedical regulations, and identify any requirements potential adjustments that could be made to the risk-assessment process by using state-of-the-art diagnostic methods and treatment option.



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## Further reading

The research will be carried out in five tasks:

In Task 1, the project team will conduct a **review of the state-of-the-art diagnostic methods**, including severity assessment, and treatment options available by assessing recent scientific literature and publication of clinical trials as well as the latest guidelines of competent national and international organisations involved in the diagnosis and treatment of cardiovascular diseases. This review will consider the most frequent comorbidities and cardiovascular risk factors (CVRFs), as well as family and personal medical history.

Based on the literature review, the main objective of Task 2 will be to analyse the diagnostic tests in terms of suitability to positively identify cardiovascular pathologies and assess the severity and their value in **assessing the risk of pilot/ATCO incapacitation**, cost effectiveness, and availability of state-of-the-art tests at EU Member State level. In addition, the suitability of readily available test options taking into consideration the class of aeromedical certification and the acceptable risk of incapacitation will also be assessed.

Task 3 will focus on the development of a **populational study protocol** looking at the conditions for which the guidelines, including diagnostic methods and treatment options, have been updated after 2015. The populational study will determine the proportion of aeromedical certificate holders that suffer from cardiovascular conditions for each class of aeromedical certification; and include a relevant multi-ethnic and multi-cultural sample that covers all classes of aeromedical certification, and assess its condition, including the severity, treatment and relevant comorbidities using state-of-the-art diagnostic methods and comparing the results with its latest aeromedical assessment.

*To be noted that in the performance of this tasks, medical confidentiality will be respected at all times, and personal data will be processed in accordance with the applicable EU regulations, in particular the General Data Protection Regulation (GDPR).*

For task 4, the project team will analyse the **risk of pilot/ATCO incapacitation** for each class of aeromedical

certification, taking into account the acceptable risk level depending on the risk of their incapacitation relative to the severity of their condition and potential treatment. Where the risk level is not acceptable, analyse whether certain limitations applied to the aeromedical certificate may mitigate the higher-to-acceptable risk considering the class of aeromedical certification.

In light of the outcomes of the previous tasks, the existing **requirements for pilot/ATCO cardiovascular aeromedical fitness** will be reviewed in task 5. In addition, the project team will analyse the acceptable risk of pilot/ATCO incapacitation and identify any potential adjustments that could be made to the risk-assessment process by using state-of-the-art diagnostic methods and treatment options.

Lastly, task 6 will draw general conclusions from the research study and make **recommendations for potential adjustments of the existing requirements** in the light of the newly developed diagnostic measures and treatment options for cardiovascular diseases that would allow the improved assessment of the risks as well as maintaining the competence within the aviation system by allowing prevention, early detection and a better follow-up of the medical certificate holders that have cardiovascular risk factors (CVRFs) or have developed cardiovascular pathologies. An impact assessment of the implementation of the proposed recommendations will also be developed.



*This project is part of the portfolio of EASA managed research projects funded under the European Research Programmes. Projects under this portfolio address research needs of civil aviation authorities and are geared to generate mid-term benefits after the successful completion of the project to enhance safety, security and sustainability.*