EASA
European Union Aviation Safety Agency

EASA Medical Section activities - research studies in progress, standardization in aviation medical certification

CCAA AME Refresher Training

14 December 2024

Mateja KOTNIK KERBEV, EASA Medical Expert

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Facts and figures

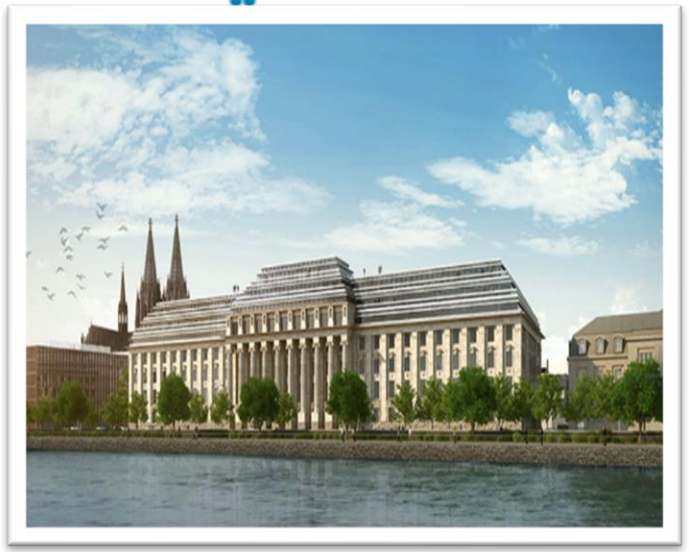
Established
2002

22 years
in operation

800+
aviation experts
& administrators

Headquarters in
Cologne
Office in
Brussels

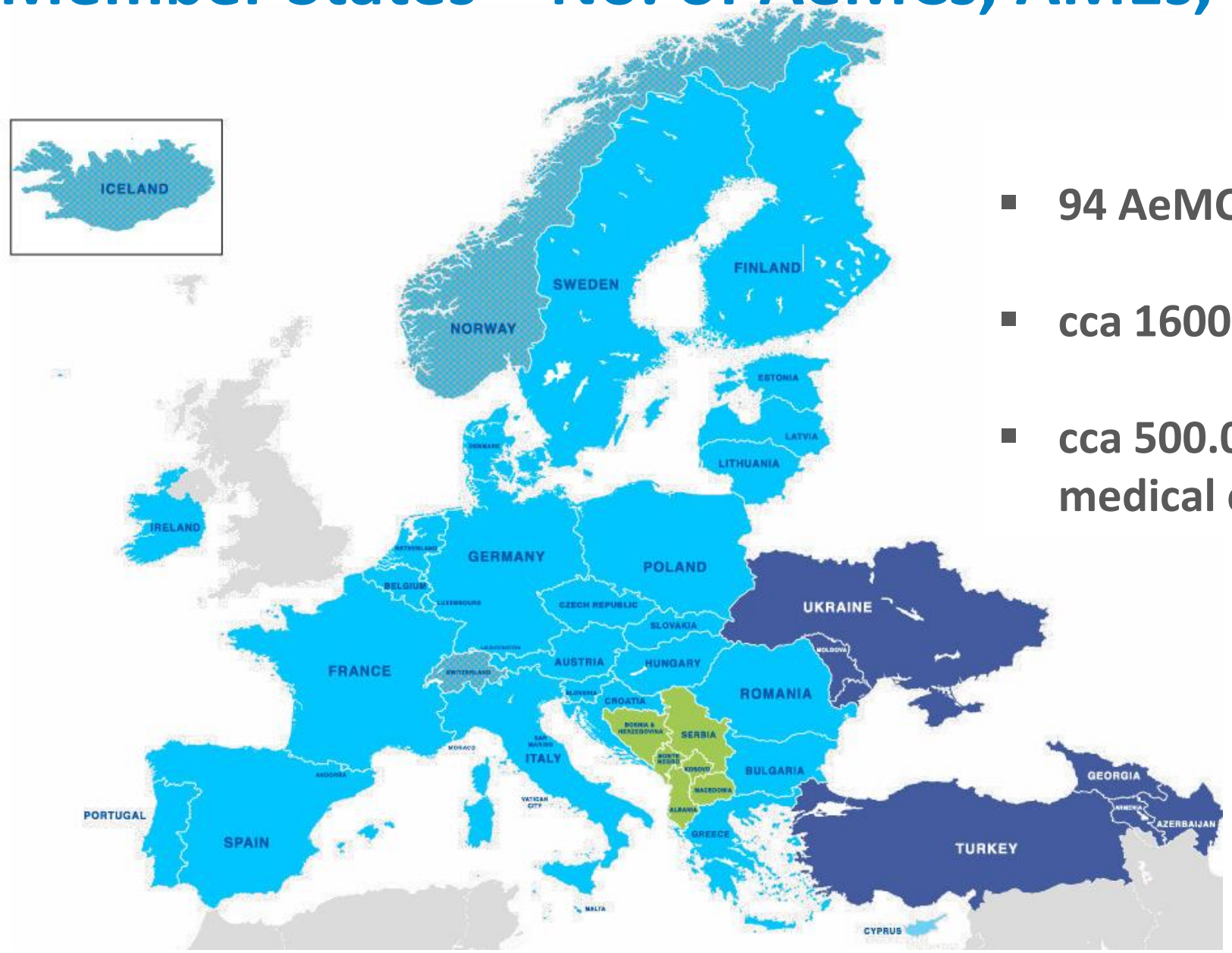
31 EASA member states
= 27 + 4
EU + Switzerland, Norway
Iceland, Liechtenstein



Headed by
Mr Florian Guillermet

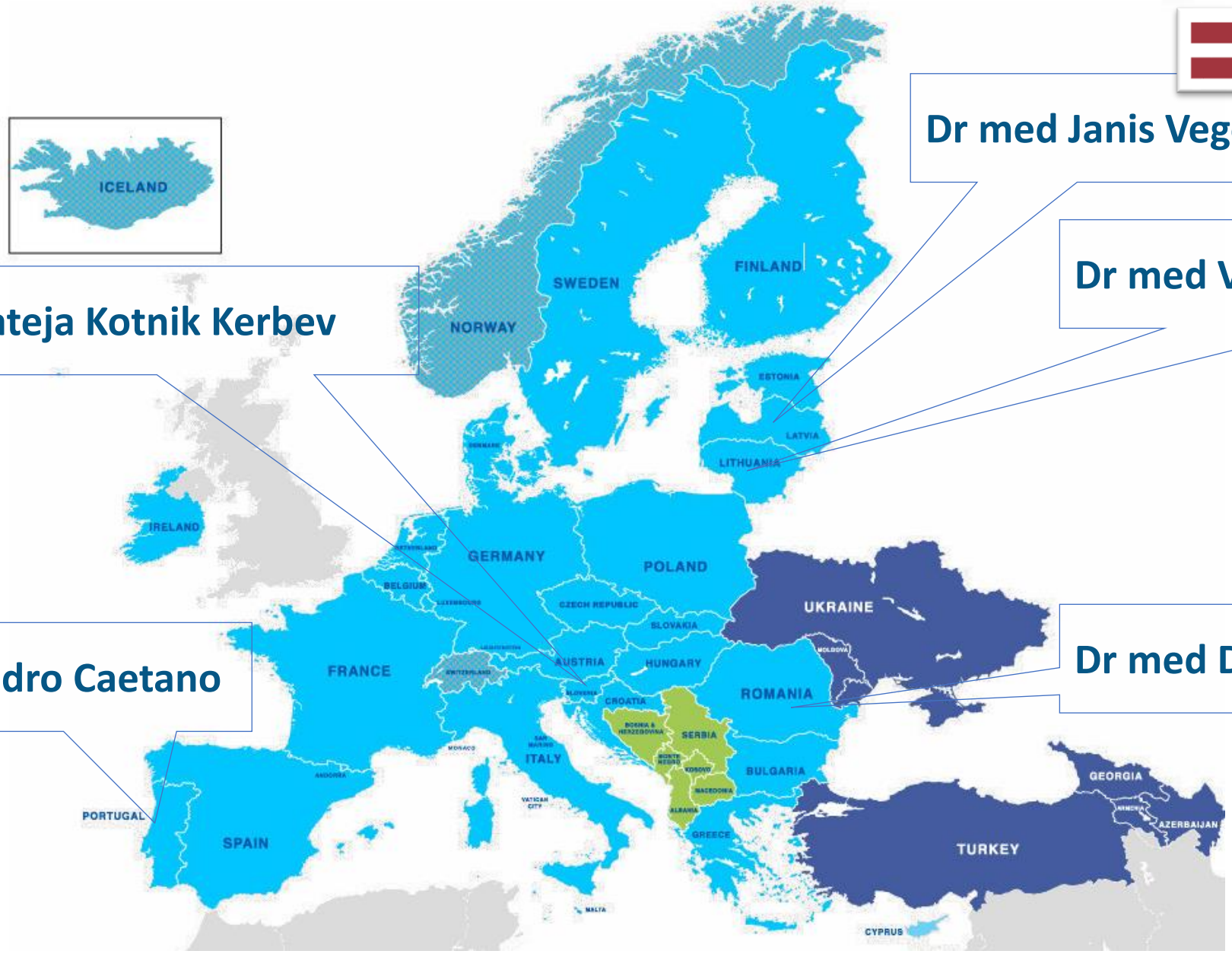
EASA

EASA Member States – No. of AeMCs, AMEs, medical cert.



- 94 AeMCs
- cca 1600 AMEs
- cca 500.000 holders of EASA medical certificate

EASA FS.3.2 Medical experts in Aviation Health & Medicine Section



Dr med Janis Vegers

Dr med Virgilijus Valentukevicius

Dr med Mateja Kotnik Kerbev

Dr med Pedro Caetano

Dr med Dr Cristian Ionut Panait

EASA Medical Activities

- Standardization
- Rulemaking
- International Cooperation
- Certification Support
- Representing EU Aviation Medicine
- Competent Authority 3rd countries
- Research

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European Union Aviation Safety Agency

Aviation Medicine - research activities

MEG 2024

5.12.2024

Mateja KOTNIK KERBEV

EASA Medical Expert

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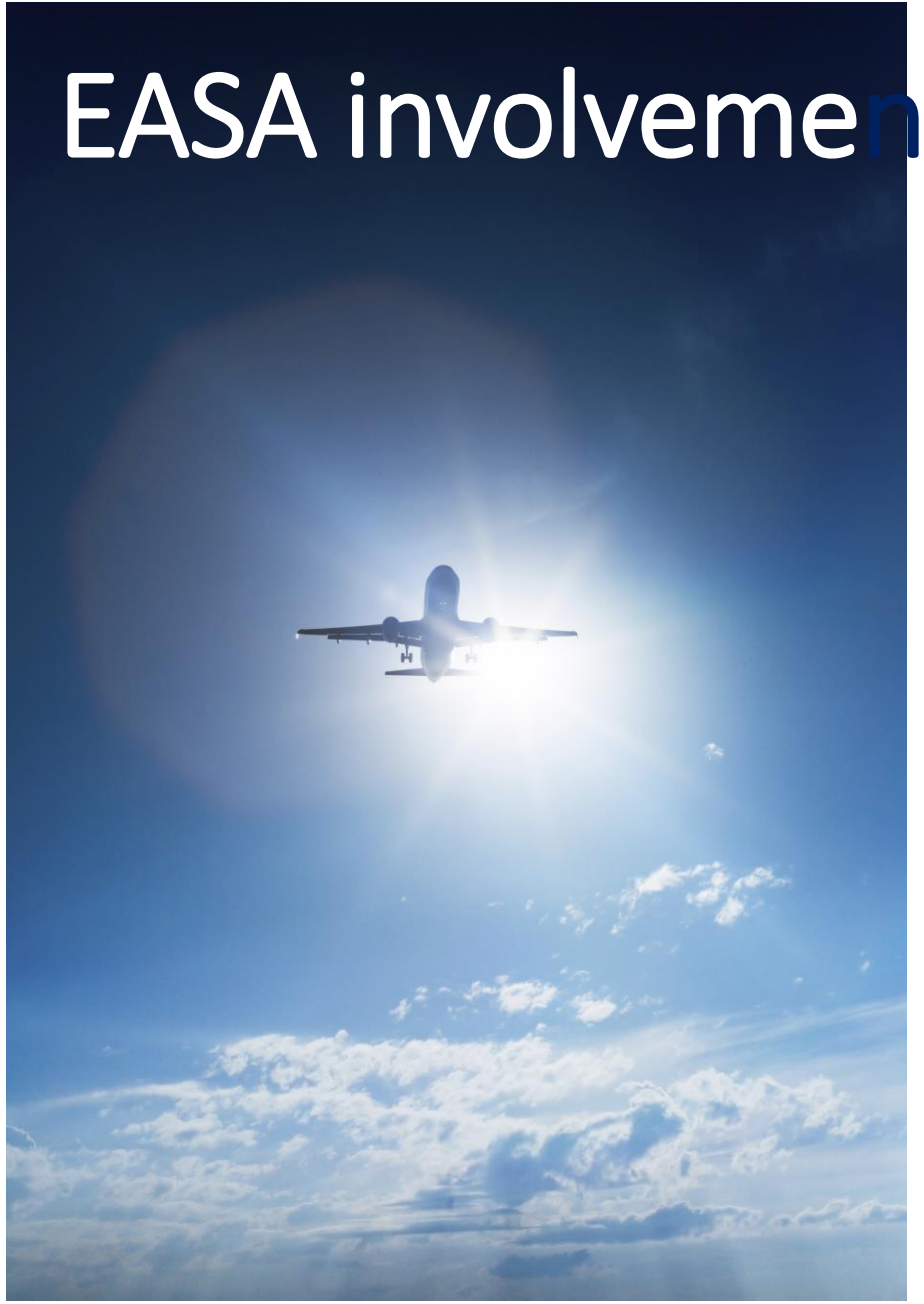
EASA involvement in R&I



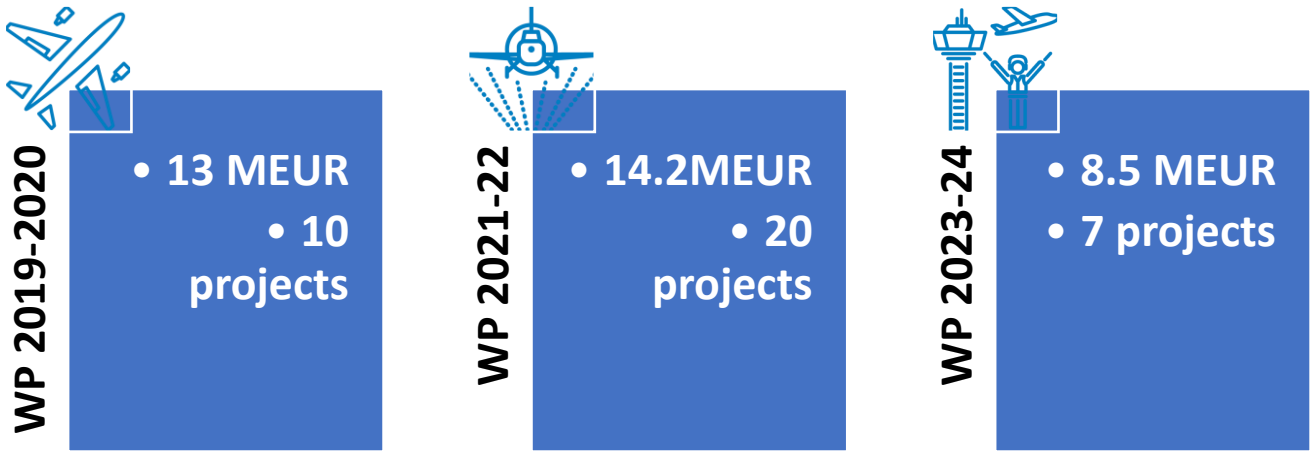
Aviation authorities **depend on research results** to perform their core activities (rulemaking, certification, standardisation) and **develop new competences**

R&I projects contribute to **improve safety and address existing and future challenges**

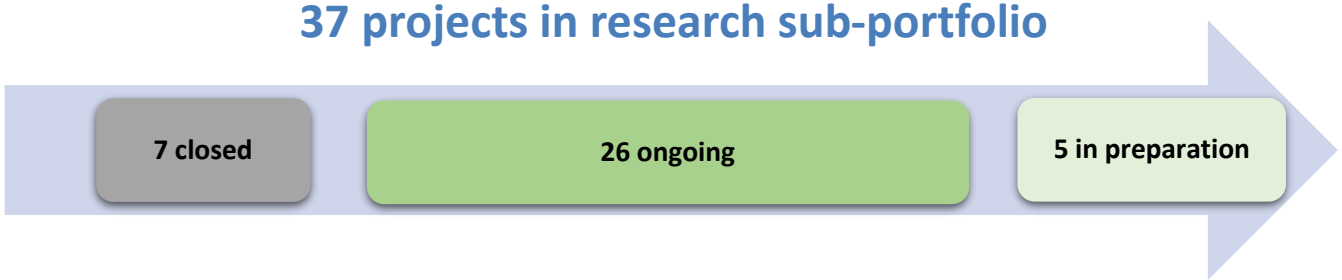
R&I projects play a key role to **identify and assess the impact of emerging risks** stemming from new technologies or new business models

R&I projects **accompany innovation** and the **introduction of new technologies and innovative operations** in a timely, efficient, safe manner

EASA-managed research projects from Horizon funds



37 projects in research sub-portfolio



Some of EASA Research projects

RWYMT, TRIPLE-ONE

Enhancing runway safety standards through new scientific evidence

FS, MGB, VRS

address rotorcraft safety standards with research on solutions of previous accidents

MLEAP

build up expertise for enabling the approval of safety-relevant artificial intelligence applications

NOISE, EMISSIONS, MbM

Advance sustainability through enhanced regulatory environmental tools

MODEL-SI, VIRTUA, DATAPP

Research on regulatory aspects to enable digital transformation

CaVD, DM, HEALTH, VISION

Addressing and enhancing health standards of critical aviation safety personnel

EASA - research needs

Environment
- New SAF production pathways

Security impacting safety
- AI aspects, conflict zones

Artificial intelligence
- Human factors

Data for Safety
- Future uses cases

Health / medical
- Obstructive sleep apnea, high air space operations

Automation
- Impact on responsibilities flight crew and air traffic controllers

ATM / ANS
- Performance of ground equipment, airspace classifications

Air operations
- Flight time limitations for emCO

Drones
- BVLOS operations

EASA Research Overview

OSA

- Obstructive Sleep Apnea (OSA) carries significant safety implications and affects individuals as early as 30 years old.

- The effects of OSA are even more important in the current context of **fatigue** both for **pilots and ATCOs** and on the verge of the **upcoming projects contemplating single pilot operations**.

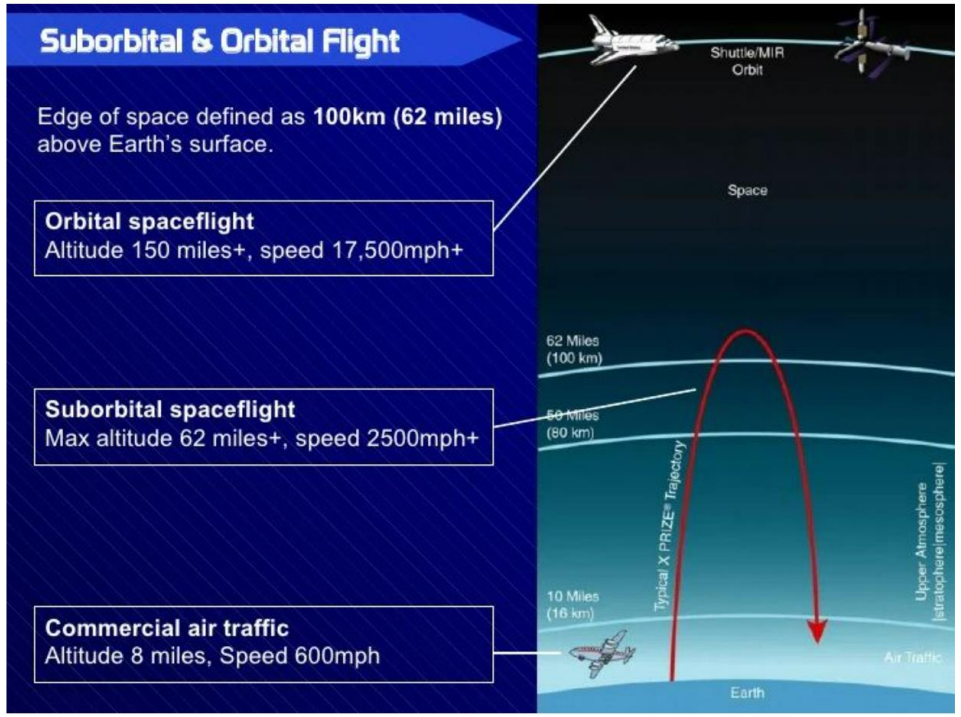
- The anticipated outcome of this research is to **provide solid evidence that can inform decision-making regarding regulatory needs** concerning the **assessment of the respiratory system for pilots and ATCOs**. The research report will allow rulemaking activities to further enhance safety and limit impact of fatigue caused by organic disorders.

HAO – Higher Airspace Operations

- The existing medical regulations for pilots, as outlined in Regulation (EU) 1178/2011, do not consider the assessment of operational requirements specific to Higher Airspace Operations (HAO).

- To address this gap, there is a need to review the current aero-medical requirements, including any limitations, with due consideration to the stress associated with HAO.

- Research should also aim to evaluate potential medical requirements that may need to be applied to individuals, other than crew members on board of HAO aircraft, including passengers and observers.



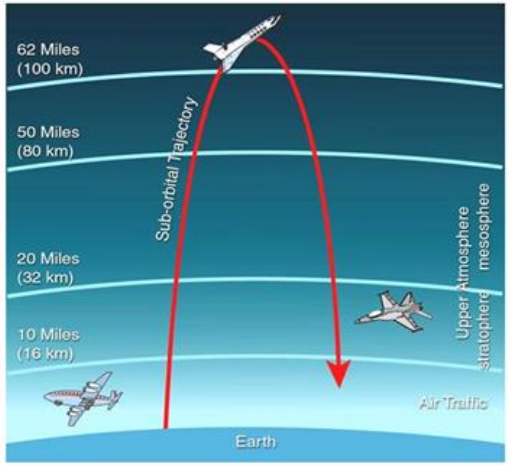


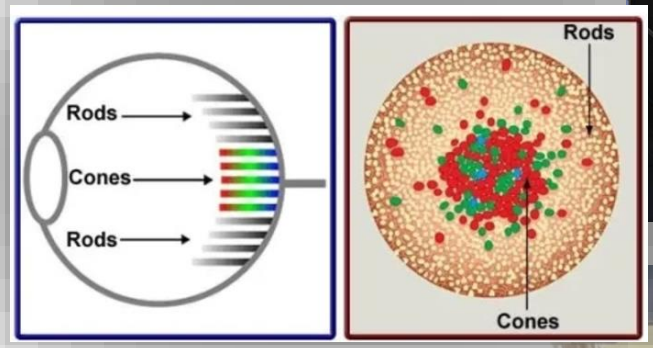
Figure 1. Suborbital trajectory [Reference 4]

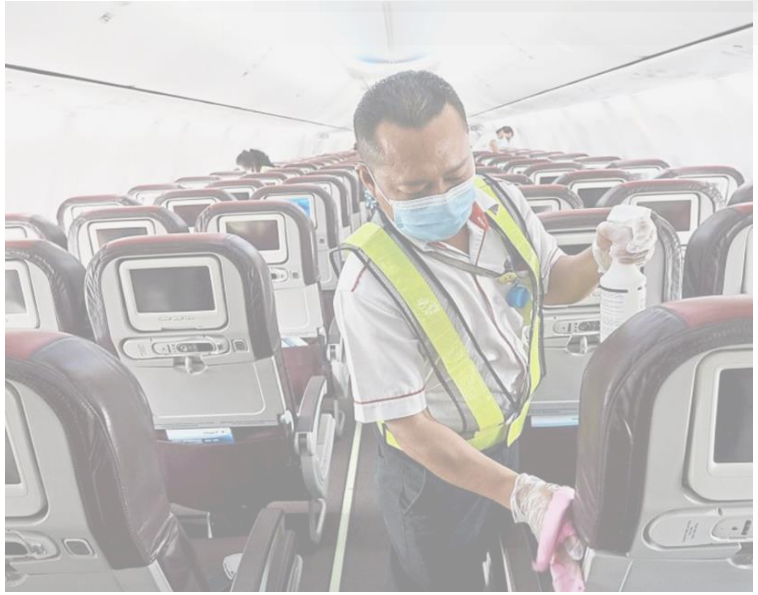
New Research Studies - 2024

→ **VISION** (colour vision)

→ **HEALTH** – Aircraft Surfaces

→ KoM – Q3&Q4 2024





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VISION – Colour vision

Research Project

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VISION – Colour vision

Introduction of consortium

- NLR - Royal Netherlands Aerospace Centre
- University of South-Eastern Norway
- University of Minho

- EASA

- KoM– 07.11.2024
- 1st TM January 2025
- 30 months

VISION – Colour vision

Colour vision requirements in the new full glass cockpit environment and modern ATCO consoles

→ The project will **assess the suitability of current colour vision requirements for pilots and ATCOs in modern working environments** and **provide scientifically based evidence** that will **support decision-making regarding regulatory needs for colour vision assessment.**

→ This will help to enhance safety and efficiency in air travel, by **ensuring that pilots and ATCOs have the necessary colour vision abilities to perform their duties effectively**.

https://www.easa.europa.eu/en/research-projects/vision

Required Output / Expected Outcome

The expected outcome of the project is to provide an updated assessment of the colour vision needs for pilots and ATCOs.

Main outputs:

- Comprehensive **assessment of the colour vision performances** required to safely perform pilot and ATCO professional duties,
- **Identification of suitable testing methods and thresholds** for the pilots and ATCOs.

The project will help to ensure that the colour vision assessment of pilots and ATCOs is based on the latest scientific evidence and that it is effective in identifying individuals who may have colour vision deficiencies that could negatively impact their professional duties.

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HEALTH
Research Project

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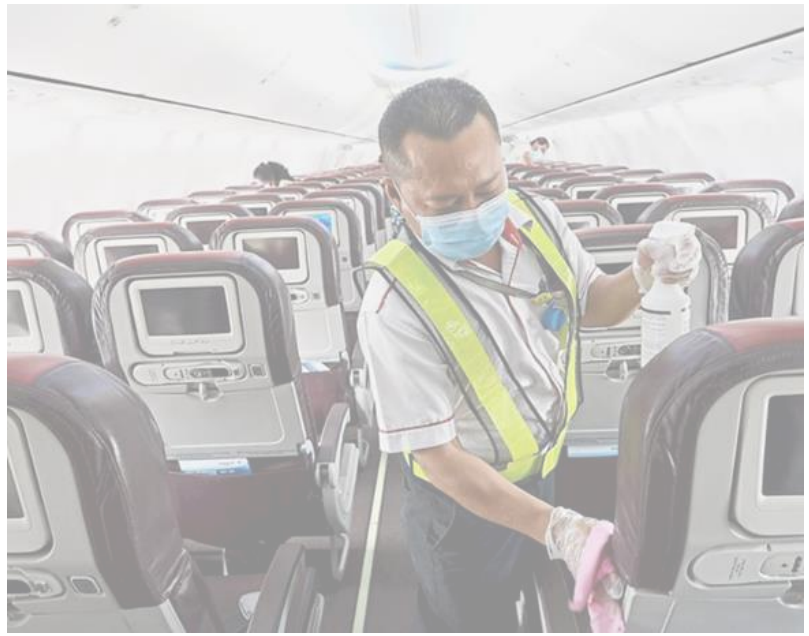
HEALTH - *New health safety measures in aircraft*

- DLR
- Supported by Lufthansa and Airbus

- EASA

- KoM– 20.09.2024
- 1st TM – 27.11.2024
- 36 months

Deutsches Zentrum für Luft- und Raumfahrt



HEALTH - *New health safety measures in aircraft*

This research project is expected to analyse scientifically proven solutions to reduce the spread of airborne infectious agents within the aircraft environment.

The objectives of the project are to investigate the possibilities to further reduce the spread of a series of airborne infectious agents (viruses, bacteria, fungi) within the aircraft environment by improving filtration systems, recirculation systems and cabin airflow.

https://www.easa.europa.eu/en/research-projects/health

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Pilot and ATCO fitness research

CaVD & Diabetes

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ATCO and Pilot Fitness research

- New development in medicine may have an impact on the assessment of fitness of pilots and ATCOs:

- **Diabetes**
- **Cardiovascular**

- Contracts signed in Q4 2022

- Duration: **36 months**
- **Expected final deliverables Q4 2025**

Horizon Europe Project: Pilot and ATCO aeromedical fitness – Lot 2: “New treatments and diagnostic measures for cardiovascular diseases”

CaVD-PACE

CaVD-PACE

Pilots and ATCOs Cardiovascular Evaluation

AIM OF THE PROJECT

- Produce **evidence-based recommendations** for updating the cardiovascular requirements for pilots and ATCOs in line with the recent medical developments;
- To evaluate and analyze advantages and disadvantages of **new diagnostic methods and treatment options** for cardiovascular conditions taking job demands into account;
- To indicate opportunities and make **recommendations** where aeromedical decision making can be improved in order to enhance safety;
- To perform an **impact assessment** of the recommended amendments to the cardiovascular requirements.

Stakeholders – Communication, dissemination, engagement, training, promotion

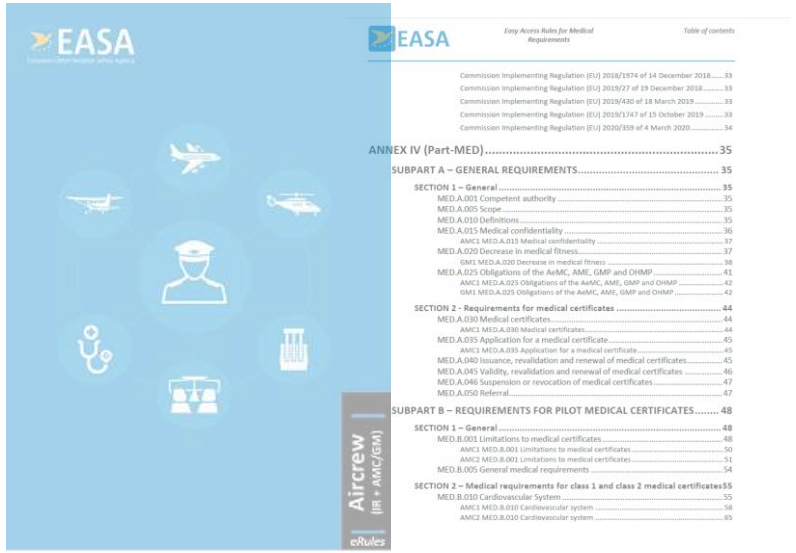
- To produce **guidance material for AMEs and MAs** on the updates to the fitness assessment of applicants;
- To produce **material for dissemination** of the results and training material for professional audiences to support the management of the proposed amendments;
- To produce risk management **promotion material** tailored for pilots and ATCOs to stimulate their awareness for self-detection and self-management of their cardiovascular and metabolic risk factors.

EXPECTED RESULTS

POLICY MAKING RECOMMENDATIONS

→ Evidence-based **recommendations** for updating the cardiovascular requirements in Part-MED and Part ATCO-MED;

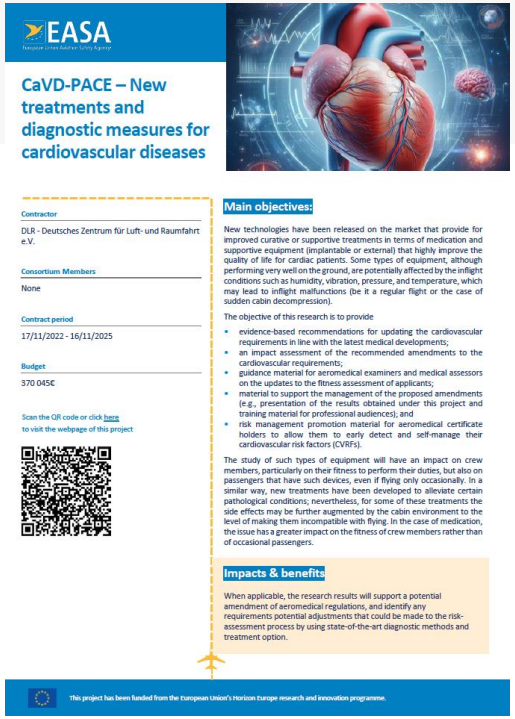
→ Impact assessment of the recommended **regulatory changes.**



PUBLISHED DELIVERABLES

https://www.easa.europa.eu/en/research-projects/new-treatments-and-diagnostic-measures-cardiovascular-diseases-pilots-and-atcos

- D-1.1/D-1.2 — Review of diagnostic measures and treatment options
- D-2.1 — Report on the cardiovascular diagnostic methods and treatments suitable for use in aeromedical fitness assessments
- CaVD-PACE — Leaflet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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€

Scan the QR code or click here to visit the webpage of this project

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

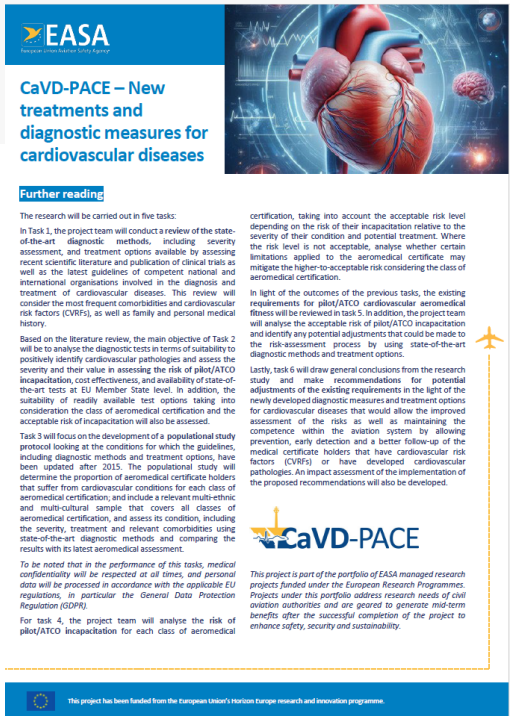
- evidence-based recommendations for updating the cardiovascular requirements in line with the latest medical developments;
- an impact assessment of the recommended amendments to the cardiovascular requirements;
- guidance material for aeromedical examiners and medical assessors on the updates to the 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.

This project has been funded from the European Union's Horizon Europe research and innovation programme.


EASA

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

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.

CaVD-PACE

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.

This project has been funded from the European Union's Horizon Europe research and innovation programme.

EASA

CAVD-PACE and DM Final Dissemination Conference

EASA HQ, Cologne, Germany

12-14 November 2025

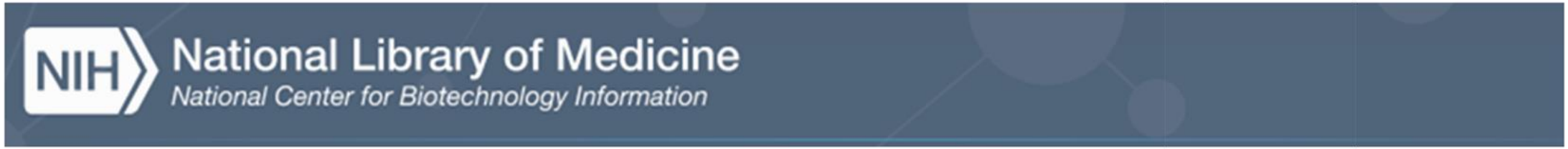
DIABETES MELLITUS Research

- University of Graz - Austria
- University of Leuven – KULeuven – Belgium
- University of Surrey – UK

- EASA

- Kick-off meeting in December 2022
- 36 Months

Diabetes in Aviation – current status in literature



MESH search: *(("Aircraft"[Mesh] OR "Aviation"[Mesh]) AND (("Blood Glucose"[Mesh]) OR "Diabetes Mellitus" [Mesh] OR ("diabetes Mellitus"[Mesh] AND "complications"[Mesh]) OR "Hypoglycemia" [Mesh] OR ("Hypoglycemia"[Mesh] AND "complications" [Mesh]) OR ("Hypoglycemic Agents" [Mesh]) OR ("Insulin" [Mesh]))) 149*

Free term search: *(((pilots[Title/Abstract]) OR (aviation[Title/Abstract]) OR (flying[Title/Abstract]) OR (aircraft[Title/Abstract]) OR (airplane[Title/Abstract])) AND ((diabetes[Title/Abstract]) OR (insulin[Title/Abstract]))) 164*

- **54 articles related to diabetes and aviation**
  - **14 related to diabetes technology and aviation**

DIABETES MELLITUS in Pilot and ATCO aeromedical fitness

- Provide **evidence-based recommendations** for updating requirements related to diabetes mellitus, in line with the latest medical developments.

- Produce **guidance materials** for aeromedical examiners and medical assessors regarding updates to fitness assessments for applicants.

- Generate **supporting materials** to manage the proposed amendments, including presenting project results and creating training materials for professional audiences.

- Create **risk management materials** to help aeromedical certificate holders to detect and self-manage their metabolic risk factors early.

https://www.easa.europa.eu/en/research-projects/diabetes-mellitus-dm

DIABETES Research Status

- Focus on **insulin treated diabetes**
- Conduct a review and critique of the **state-of-the-art diagnostic methods and treatment options for diabetes mellitus** (recent scientific literature, analytical methods, as well as methods to assess and compare)
- Identify diagnostic and monitoring methods for diabetes mellitus that are suitable for use in aeromedical fitness assessments
- Hypobaric chamber tests - (positive results!)
- Continuous Monitoring Devices - (positive results!)

Technologies potentially affected in aviation

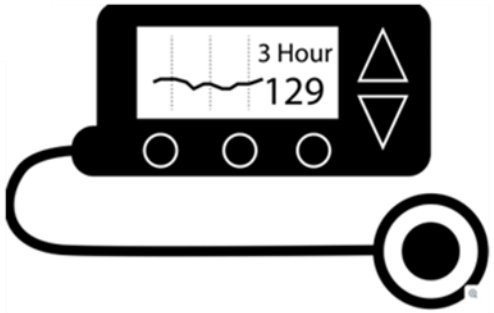
CGMs

Accuracy of glucose measurement

Insulin pumps

Accuracy of insulin delivery

AID systems



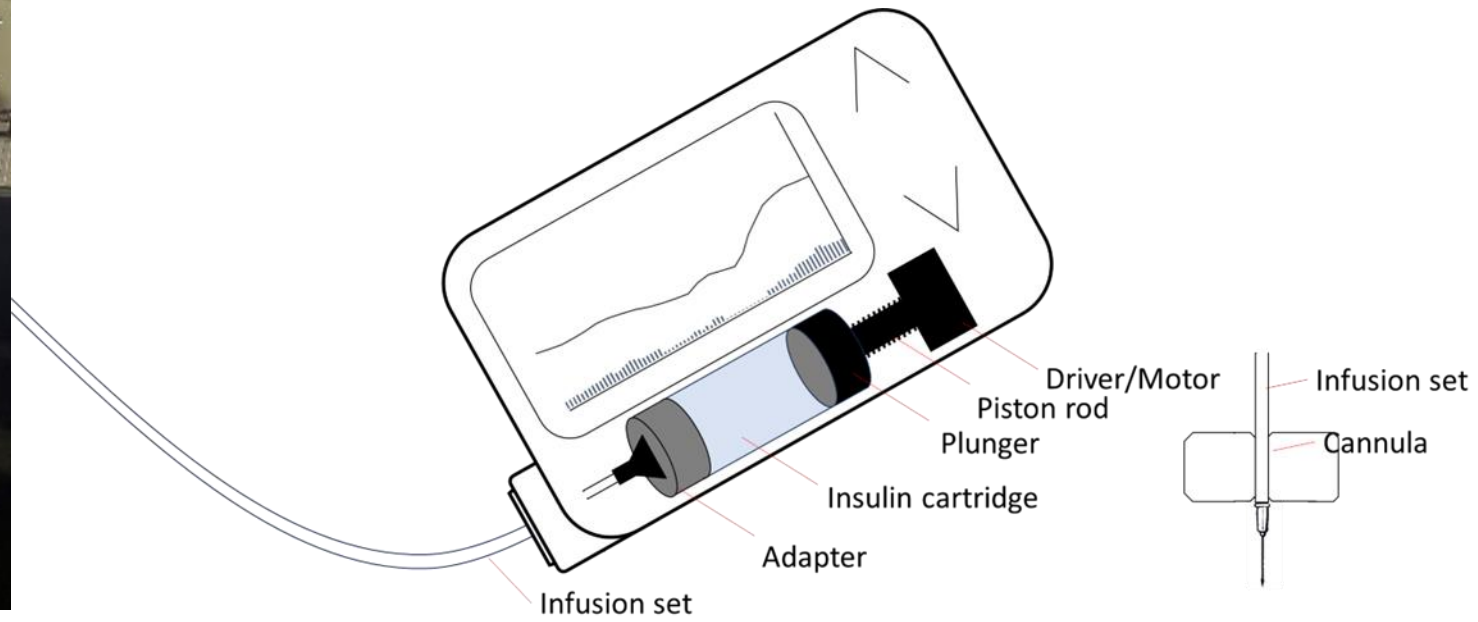
Accuracy of glucose measurement and insulin delivery

CGM – Continuous Glucose Monitor, AID – Automated Insulin Delivery

DIABETES Research Status

- **Hypobaric chamber studies** of Continuous Glucose Monitoring (CGM) demonstrated a strong to very strong correlation with self-monitoring blood glucose measurements across both ground and simulated-flight conditions, providing an alternative and effective means to monitor diabetes within aviation.
- The use of **CGMs** by insulin-treated pilots and air traffic control officers was found to greatly improve on-duty glycaemic controls.
- Surveyed pilots reported that the integration of CGMs was both convenient and provided accurate measurements to inform their diabetes management in-flight.
- Further **literature review** on macrovascular and microvascular complications supports the monitoring and management approach as outlined by EASA.

Impact of atmospheric pressure changes on insulin pumps



Paterson M, Fan KS, Shojaee-Moradie F, Manoli A, Edwards V, Lee V, Hutchison E, Koehler G, Mader JK, King B, Russell-Jones D. The effects of atmospheric pressur experienced during routine airline flight on infusion rates of insulin pump. Diabetes Technol Ther [Internet]. 2024;26(2):113. Available from: https://www.liebertpub.com/doi/epub/10.1089/dia.2024.2525.abstracts

In-flight study

The Use of the Automated Insulin Delivery Systems During Commercial Airplane Flights - a PILOT Study (AID_PILOT)

- Monocentric, comparative, within subject, field, pilot study
- 20 otherwise healthy volunteers with type 1 diabetes experienced in AID
- Mid-haul flight (4-5 hours, Vienna-Reykjavik)
- Inbound – standardized meal
- Outbound – fasted
- Ground phase (for comparing)

- Medtronic MiniMed 780G
- Insulet Omnipod 5
- Tandem Control-IQ or CamAPS FX with Ypsomed YpsoPum

- additional CGM sensors
  - Abbott Libre 3
  - Dexcom G7
  - Medtronic Simplera

  not interfering with the AIDs

- Capillary BG measurement

Diabetes Mellitus in Pilot and ATCO aeromedical fitness

→ D1.1: Review of Diagnostic Measures

→ The purpose of this “Review of Diagnostic Measures” is to give an overview of existing evidence regarding the classification and diagnostic measures for DM.

→ D1.2: Review of Treatment Options

→ A report provides an overview of the existing evidence in regard to the management and treatment measures for DM.

→ D2.1: Analysis of the suitability of diagnostic tests

- Diabetes Mellitus Analysis of the suitability of diagnostic tests
- Diabetes Mellitus Review of Diagnostic Measures
- Diabetes Mellitus Review of Treatment Options
- DM — Leaflet

https://www.easa.europa.eu/en/research-projects/diabetes-mellitus-dm

Mental health research activities

MESAFE

MEntal health for aviation SAFEty

Mental health - Scope

- The scope of the project includes:
  - Assessment of existing tools used around Europe
  - Identifying new medical diagnostic tools suitable for use in the aviation environment
  - Provide recommendation on its implementation
  - Provide training materials for AMEs and members of the peer support groups
  - evidence-based recommendations for updating the mental health requirements in line with the medical developments

- The tool should consider both pilots and ATCOs looking at the need to further customize the use for each category of applicants

Mental health - deliverables

- Final deliverables are be published on EASA Website:

https://www.easa.europa.eu/en/research-projects/mesafe-mental-health#group-downloads

MESAFE Conference – 23 & 24th April 2024 at EASA HQ

Next steps

Task	Timeline
Initial discussion with the Medical Experts' Group (MEG) about the project results and recommendations	16-17 May 2024
Internal assessment of the input received during the final dissemination event and MEG feedback	Q3 2024
Insert a placeholder for a potential EPAS action in EPAS 2025	Q3-Q4 2024
Potential rulemaking reviewing and updating the mental health requirements, AMC, and GM in Part-MED and Part-ATCO.MED taking into account the new scientific evidence of the MESAFE project	Q2 2025 – Q4 2027
Implementation support and safety promotion activities including related information to the relevant ICAO working groups and panels	2025 - 2030

Research – ideas for the future?

- VR training for pilots – assessing the impact on fitness
- Medication
- Risk assessment matrix
- Unmanned Aircraft systems and air mobility
- Radiation
- Neurology (epilepsy, migraine)

Rulemaking

RM in the Basic Regulation — Working methods

Article 115

Procedures for the development of opinions, certification specifications and other detailed specifications, acceptable means of compliance and guidance material

Rulemaking Procedure

1. The Management Board shall **establish transparent procedures for issuing opinions, certification specifications and other detailed specifications, acceptable means of compliance and guidance material** referred to in Article 76(1) and (3). Those procedures shall:

Advisory Bodies

   (a) **draw on the expertise of the civil and, where appropriate, military aviation authorities of the Member States;**

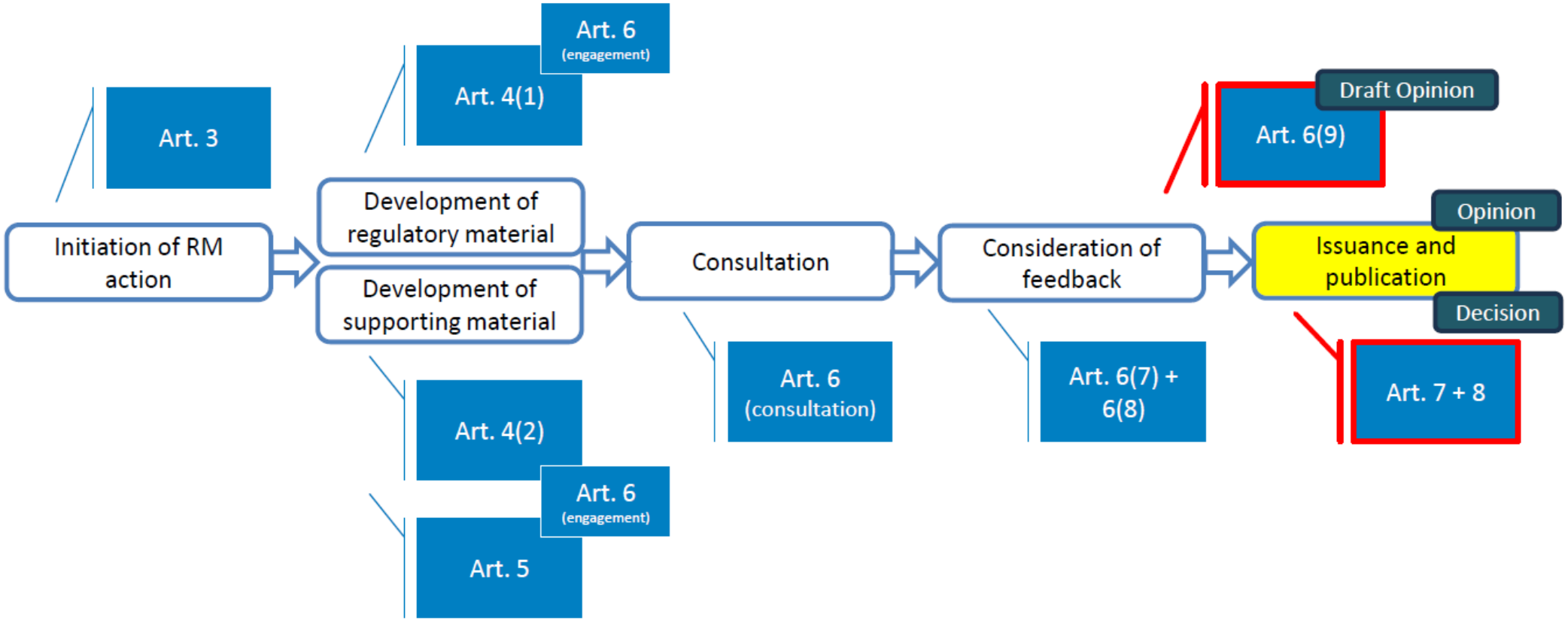
   (b) **whenever necessary, involve experts from relevant interested parties or draw on the expertise of the relevant European standardisation bodies or other specialised bodies;**

   (c) **ensure that the Agency publishes documents and widely consults interested parties**, in accordance with a timetable and a procedure which includes an obligation on the Agency to give a written response to the consultation process.

2. When the Agency, pursuant to Article 76(1) and (3), develops opinions, certification specifications and other detailed specifications, acceptable means of compliance and guidance material, it shall establish a procedure for the prior consultation of the Member States. To that effect, it may create a working group in which each Member State is entitled to designate an expert. When consultation relating to military aspects is required, the Agency shall, in addition to Member States, consult the European Defence Agency and other competent military experts designated by the Member States. When consultation relating to the possible social impact of those measures of the Agency is required, the Agency shall involve the Union social partners and other relevant stakeholders.

3. **The Agency shall publish the opinions, certification specifications and other detailed specifications, acceptable means of compliance and guidance material** developed pursuant to Article 76(1) and (3) and the procedures established pursuant to paragraph 1 of this Article **in the official publication of the Agency.**

Overview RM procedure

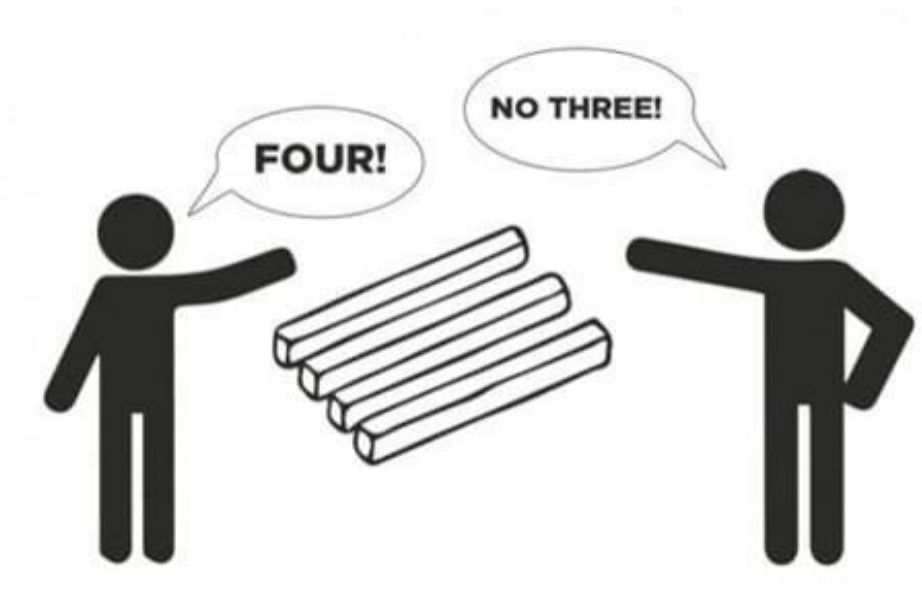


Rulemaking

Consultation

Externals need to be informed that their comments/contributions are made public (as part of EN) or may be disclosed in the context of public access to documents (MBD Art. 6(5))

Standardisation & harmonisation



Standardisation

Reg 2018/1139 Art. 85(1) : Monitoring of Member States

The EASA shall assist the Commission in:

Monitoring the application by Member States of the Basic Regulation and of the delegated and implementing acts

Assist the Member States in **ensuring the uniform application** of the Basic Regulation and of delegated and implementing acts

Sharing best practices

Standardisation inspection

- Regulation (EU) No 628/2013
- EASA visits the National Competent Authorities (NAA) to assess
  - Implementation of Part ARA, Part ORA, Part MED and Part ATCO.MED
  - Implementation of authority requirements including,
    - Certification of AMEs, AeMCs, GMPs
    - Oversight over their AMEs, AeMCs, GMPs
    - Medical certification of Aircrew and ATCOs
- As part of the visit to the NAA, EASA visits undertakings to sample how the NAA is completing its tasks

EASA
European Union Aviation Safety Agency

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Your health is also our mission.

An Agency of the European Union