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16. Abstract					
The Federal Aviation Administra	ition (FAA) Office of Aei	ospace Medic	ine (AAM) tasked the	MITKE .	
Corporation's Center for Advance	ed Aviation System Deve	lopment (MIT	RE CAASD) to contin	nue connecting	
stakeholders to explore establishing an Aeromedical Certification Collaborative (ACC) that takes a data-					
driven fresh look at the role of aeromedical certification in aviation safety risk management. This report is a					
follow-on to prior foundational efforts (reference https://doi.org/10.21949/1529621). MITRE CAASD					
designed and executed ACC stakeholder engagement with commercial aviation nilots mainline and eargo					
airling. Aviation Medical Examinary, other professionals involved in rilet health issues, trade or d rilet?					
animes, Aviation interference Examiners, other professionals involved in prior nearth issues, trade and priors					
associations, and FAA AAM. MITKE CAASD engagement included:					
• Continued support for ACC and ACC Mental Health Working Group (MHWG) workshops, including					
ideation, prioritization, and refinement of mental health study ideas from April 2024 – June 2024.					
• Engaged in one-on-one pre-briefings and follow-ups with participants as requested/needed					
These activities, notably the work of the ACC MHWG, results in a set of prioritized possible studies					
aligned with the ACC concept, formalized expectations, and potential data needs associated with each					
study As a result FAA AAM will be able to improve safety risk management activities using sensitive					
collaborative data sharing to identify aviation safety risks associated with rilet health. The future immed					
of this work will allow EAA to develop performance based standards for medical fitness for fight and					
of this work will allow FAA to develop performance-based standards for medical fitness for flight and					
sate operation of the airspace based on analysis of operational and medical data. FAA will be able to					
balance aviation safety needs wh	ile minimizing cost and b	urden on pilot	s and other stakeholde	rs.	
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# **Aeromedical Certification Collaborative (ACC)**

### **Progress Report**

April 2024 – June 2024



#### Federal Aviation Administration

# **Contractual Scope and Outputs**

The Federal Aviation Administration (FAA) tasked The MITRE Corporation Center for Advanced Aviation System Development (MITRE CAASD) to advance aeromedical data-driven collaboration with industry.

#### Purpose

- This task continued prior efforts to research establishing an Aeromedical Certification Collaborative (ACC) with industry. The goal for <u>ACC</u> is to co-design the future aeromedical safety system through information sharing and collaborative research regarding aeromedical safety risks.
- MITRE CAASD is uniquely suited to be the trusted connector among ACC stakeholders based on our experience as the CAASD Federally Funded Research and Development Center (FFRDC) operator (i.e., deep knowledge of FAA and aviation safety) combined with expertise as an independent, conflict-free convener of dozens of collaboratives established in the public interest. As a Trusted Third Party, we fairly manage participant equities, protect data, and foster a safe space for collaboration (i.e., mitigate competitive/defensive dynamics among participants).

#### **Outputs** – Progress Report and Briefing

- 1. A summary of stakeholder engagement activities.
- 2. A summary of efforts to execute an operational collaboration concept prototype, including enablers, safeguards, roles, expectations for contributions and benefits.
- 3. A summary of potential research projects suitable for stewardship by the collaborative concept.

## **Background and Drivers of the ACC**

Shared challenge of improving aviation safety risk management drives need for collaboration.

- Prior research<sup>1</sup> shows aeromedical certification stakeholders such as pilots, pilots' and trade associations, airlines, providers/Aviation Medical Examiners (AMEs), and the FAA see and feel shared challenges with the current state and seek a fresh look:
  - Pilots seek a more timely and transparent process that supports their livelihood and health.
  - Airlines seek to sustain safety while boosting operational efficiency and flexibility.
  - Unions seek to enhance pilot retention, careers, and availability as well as future pilots.
  - FAA seeks a data-driven future for aeromedical certification as part of a shared risk model for aviation safety.
- Achieving these outcomes requires data-driven insights on the performance-based aviation safety risk associated with a condition, which are not currently available, consideration of ecosystem-wide risk mitigations, and cross-sector collaboration.
- Since no single entity has all the needed data or the ability to completely mitigate associated risks, parties
  must work together to share and analyze sensitive data with appropriate safeguards.
  - Pilots and the FAA have medical (i.e., diagnosis, treatment) data.
  - Airlines have operational and safety performance data.

<sup>1</sup> See for example: Dienst J, Sienknecht T, Graf V, Lehner B, Roessner S (2023). Aeromedical Collaboration Outreach. <u>https://doi.org/10.21949/1529621</u>

### **Better Data can Reduce Uncertainty**

#### By analogy to separation, reducing health-related performance risk yields many benefits



# **Summary of Stakeholder Engagement**

Multiple engagement activities during this phase continue to define collaborative research.

- Continued support for ACC and ACC Mental Health Working Group (MHWG) workshops:
  - April 16, 2024 MHWG: Ideated studies and discussed FAA Mental Health and Aviation Medical Clearances Aviation Rulemaking Committee <u>report</u>.
  - May 15, 2024 MHWG: Refined and initially prioritized mental health study ideas.
  - May 29, 2024 ACC: Reviewed MH study ideas and explored physical health and other/process studies, inviting input from the full ACC.
  - June 19, 2024 ACC: Refined prioritized studies' alignment with ACC purpose and initially identified data that supports studies.
- Engaged in one-on-one pre-briefings and follow-ups with participants as requested/needed.
- Scheduled meetings into early summer.



## **Co-design Process: Iterative Concept Refinement**

Built on initial ACC concept from kickoff – refined use cases and expected safeguards



Context

Concept

Research

Engagement

# **Participants Sought MNDAs to Codify Safeguards**

Mutual Non-Disclosure Agreement based on standard from other collaboratives

MNDA intended to safeguard discussions and exploration of possible studies (not for actually sharing data for studies)

- Hold information in strict confidence
- Limit distribution within org / need to know
- Use information only for permitted purpose

#### **ACC Ground Rules**



# MNDA status: 5 of 15 signed

-	NDAN <sup>®</sup>
	MUTUAL NON-DISCLOSURE AGREEMENT
	Between
	The MITRE Corporation
	and
TI Co bu ''),	HIS Mutual Non-Disclosure Agreement (the "Agreement") made by and between The MITRE rporation, ("MITRE"), a not-for-profit Delaware corporation, having a principal place of siness at 7515 Colshire Drive, McLean, VA 22102-7539, and("
int de tha	minimums. Both Mill KE and(individually a Party of collectively the Parties ), end to disclose to each other proprietary/confidential information ("Information") as further scribed below, and in consideration of the receipt thereof, each Party hereby agrees to protect at Information as required hereunder.
Ba the Ae rol the dis res sat	ckground and Purpose. The Information to be disclosed by each Party (as the Discloser), and e purpose for its disclosure, are described as follows: As voluntary participants of an romedical Certification Collaborative ("ACC") that is taking a fresh, data-driven look at the le of aeromedical certification in aviation safety risk management, including but not limited to e performance-based aviation safety risk associated with pilot medical conditions, Parties will close Information such as their expectations for the ACC mission and operating model; related search and practices; and potential studies and the nature and availability of related data (e.g., fety, human factors, crew scheduling, medical diagnosis and treatment).
Th	e Parties further agree as follows:
1.	Use. Each Party (as the "Recipient") shall hold the Discloser's Information in strict confidence and shall use it only for the purpose described above. The Recipient shall limit distribution of the Discloser's Information only to those individuals within its organization who have a need to know such Information in groger, to accomplish the purpose defined above. The Recipient shall not disclose any of the Discloser's Information to a third party without the Discloser's prior written approval. Notwithstanding this restriction, MITRE may disclose ACC progress or status that does not attribute the source of any Information received from to MITRE's U.S. Government Customer, as required for its support.
2.	Protection. Each Party shall protect the Discloser's Information at least with the same degree of care that it protects its own Information, provided, however, that this obligation shall not apply to any nortion of the Information that:

Lead to

## **ACC Participants Refined Study Ideas**

Participants refined and prioritized study ideas by category

- Participants identified possible research studies in three categories:
  - Mental health: 9 studies.
  - Physical health: 6 studies.
  - Other/process-related: 5 studies.
- Studies, such as many of the other/process studies, may be optimally suited to be addressed in other forums such as the FAA Summit focusing on near-term aeromedical process changes.

Context

Concept

Research

Engagement

The top 5 priority study ideas aligned with ACC are profiled on following slides.

The participants' role in identifying and exploring possible studies is deeply appreciated. ACC recognizes that does not necessarily imply participants' endorsement of nor commitment to execute any study. Additional work is expected to clarify any possible voluntary role in future ACC efforts/studies.

### **ACC Participants Prioritized Study Ideas**

Participants prioritized study ideas within each category

#### **Mental Health**

- 1. Effectiveness of peer support on managed, uncomplicated depression/anxiety
- 2. Effect of managed, uncomplicated depression/ anxiety on performance
- 3. Analysis of mental health medication stabilization evidence

#### **Physical Health**

- 1. Effect of managed physical condition on pilot performance
- 2. Effect of Obstructive Sleep Apnea (OSA) on fatigue/performance

### Mental Health Study Idea #1

Ideas prioritized by the ACC

#### Context Engagement Concept Research

#### Effectiveness of peer education/support in uncomplicated depression/anxiety

- **Problem**: Overcoming stigma of mental health and encouraging healthy lifespan through peer education (promote early detection/prevention and risk mitigation).
- **Objective**: Evaluate the efficacy of peer education to improve mental health and human performance among pilots.

### Mental Health Study Idea #2

Ideas prioritized by the ACC

#### Context Engagement Concept Research

#### Effect of managed, uncomplicated depression/anxiety on performance

- **Problem**: Insufficient information on the performance effect of MH much less the associated risk.
- **Objective**: If a cohort with depression or related medication (e.g., selective serotonin reuptake inhibitor) use can be identified/recruited, look back at performance data to see if different from others. Is there operational risk associated with each level of depression as assessed e.g., by PHQ-2/-9?

## Mental Health Study Idea #3

Ideas prioritized by the ACC

Context Engagement Concept Research

#### Analysis of mental health medication stabilization evidence

- **Problem**: FAA requirement for minimum 6 months grounding while medication stabilizes is not necessarily aligned with prevailing practice among peer CAAs or medical experts.
- **Objective**: Define a stabilization period for MH medications aligned with prevailing practice and evidence. How might pilots fly with additional safeguards (e.g., monitoring) during/after stabilization? How can short-term adjustment disorder/situational depression be addressed distinctly from continued conditions, such as those handled by Human Intervention Motivation Study?

# Physical Health Study Idea #1

Ideas prioritized by the ACC

Context
Engagement
Concept
Research

#### Effect of managed physical condition on pilot performance

- **Problem**: Guidance for conditions is not necessarily aligned with prevailing practice/evidence nor linked to performance/risk.
- **Objective**: Study the impact of physical health conditions, such as heart disease, cancer, and neurological conditions, on pilots' performance.

# Physical Health Study Idea #2

Ideas prioritized by the ACC

Context Engagement Concept Research

#### Effect of Obstructive Sleep Apnea (OSA) on fatigue/performance

- **Problem**: Relationship between updated guidance for OSA and performance/risk is unclear.
- **Objective**: Study the relationship of managed OSA (e.g., proper fit and usage of constant positive airway pressure device) on pilots' performance (e.g., fatigue).

# **MITRE CAASD's Recommendations**

Support momentum from initial meetings to shape collaborative concept

- To achieve the ACC vision and desired outcomes, MITRE CAASD recommends that:
  - MITRE CAASD continue to engage core participants in shaping the ACC concept and its enablers and safeguards, serving as trusted third party/connector.

Context

Concept

Research

Engagement

- MITRE CAASD work with FAA to develop a strategy for ACC that leverages prior FAA AVS investments.
- Industry contribute time/expertise to ACC and work to determine how they might shape expectations for and contribute (e.g., data, support) to collaborative research.
- The FAA strengthen internal relationships and coordination, particularly to enhance proactive engagement with industry, partnering with its FFRDC operator to that end.
- The FAA sustain focus and resourcing for what is reasonably attainable for ACC this year, as well as champion ACC and actively participate as appropriate. Some related activities (e.g., process study) may be funded by other FAA components and/or external entities. FAA-funded ACC activities would include:
  - Sustaining participation in ACC co-design workshops to clarify core concept, select viable/valuable studies
  - Co-designing agreements (e.g., charter/collaborative research agreement)
  - Conducting secure data fusion and analysis proof-of-concept per established safeguards (next phase)

### **Acronyms / Abbreviations**

ACC	Aeromedical Certification Collaborative
AME	Aviation Medical Examiner
CAASD	Center for Advanced Aviation System Development
FAA	Federal Aviation Administration
FFRDC	Federally Funded Research and Development Center
MITRE	The MITRE Corporation
MHWG	Mental Health Working Group
OSA	Obstructive Sleep Apnea

### **Notices**

#### Disclaimer

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