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TRANSPORT OF BIOLOGICAL MATERIALS AND MEDICINES WITH UAS

(Presented by Italy)

EXECUTIVE SUMMARY

This information paper presents the Italian National Initiative in the context of an Advanced Air Mobility (AAM) Ecosystem. It outlines the actions undertaken by Italy to develop advanced air mobility services within the national territory. Emerging technologies today, in particular Unmanned Aircraft Systems (UAS) are changing mobility in aviation. AAM and most recently referred to as Innovative Air Services, represents a new aeronautical paradigm for moving goods, people and innovative aerial services, which will improve the quality of citizens' lives. In particular drone medical delivery is playing an increasingly important role in both life-saving emergency operations and daily activities in urban and remote areas. The healthcare model sets specific logistical requirements for time-dependent procedures. In metropolitan areas, road congestion affects both time and safety. The transport of biological materials and medicines are time sensitive for successful clinical outcomes. This document describes a study conducted to validate the safety and integrity of transplant biological samples transferred by UAS versus traditional ground transport. Parameters of thermo-mechanical stresses, induced by the drone, were compared in pre-, peri- and post-transplant specimens. Italian Civil Aviation Authority (ENAC) envisions a new approach to create safe testing – sandbox to allow industry to perfect their products and business models by way of an open dialogue with the authority. In this context the specific study also addresses regulatory and technical aspects to transport medical and biological materials (blood samples) recognising the requirements for a Crash Protective Container (CPC). Finally the UAS therefore emerges as a fast, reliable, safe vector for medical transport logistics, with realistic end-to-end use in hospital networks.

1. INTRODUCTION

1.1 The current hub-and-spoke healthcare model makes biological transport a crucial clinical necessity, particularly for time-sensitive procedures such as transplants. In this scenario, transport quality requires control of time, temperature, mechanical stress and traceability, in full compliance with safety regulations. The limitations of traditional transport are accentuated in urban settings especially during the last mile, where delays and disruptions can affect the suitability of the biological sample.

1.2 The Unmanned Aircraft Systems (UAS) offers great potential for biomedical logistics; however, their deployment requires validation of the biological preservation of the sample while complying

with aviation regulations on flight safety and payload suitability. This study was developed by the Italian Civil Aviation Authority (ENAC) in collaboration with University Campus Bio Medico of Rome, UrbanV and the Lazio Regional Transplant Centre. Utilising a sandbox approach, it investigates the use of UAS for the urban transport of pre-transplant blood samples.

1.3 The aim is to validate their reliability through an experimental approach integrating regulatory analysis, flight campaigns and clinical evaluations. Particular attention is paid to payload stress analysis, telemetry data and the integrity and histocompatibility of blood samples upon arrival. Furthermore, guidelines for a Crash Protected Container (CPC) capable of ensuring compliance with health and aviation requirements are being evaluated for production.

2. DISCUSSION

2.1 ENAC published the National Strategic Plan for Advanced Air Mobility (NSP-AAM) which establishes a clear vision, mission and strategic objectives. One of the keys to actualizing the plan is gaining the commitment of the main players such as public institutions, cities, main aerodrome operators and air navigation service providers.

2.2 Medical delivery was identified as one of the practical applications that could garner public support and was chosen as an appropriate starting project. To actuate the NSP-AAM, ENAC published a Sandbox Regulation and established the first Regulatory Sandbox close to Rome Fiumicino Airport, called “Pianabella” where tests were developed by UrbanV, in collaboration with the Lazio Regional Transplant Centre and University Campus Bio Medico of Rome under the supervision of ENAC.

2.3 The study used blood samples to be transported by drone from a hub to a laboratory as a simulation. Ambulance was compared with a quadcopter drone carrying a polypropylene CPC prototype with vibration damping panels and sample housings. The reduction in time of delivery was going to be obviously shorter however the integrity of biological characteristics of the sample were in question.

2.4 The results confirm the feasibility and safety of UAS transport for biological material in transplantation: vibrations compromise neither molecular integrity nor lymphocyte viability, and clinical parameters remain equivalent to conventional transport. No histological or ultrastructural differences were found in organ tissues used for rejection diagnosis, UAS did not affect dd-cf DNA quantification. The analysis of critical failure scenarios drove the crashworthiness design of the CPC, ensuring geometric tolerances and containment. The drone therefore emerges as a fast, reliable, safe vector for transplant logistics, with realistic end-to-end applicability in hospital networks. This logistic model can be transferred effectively, efficiently and sustainably to other time-dependent healthcare sectors.

3. CONCLUSION

3.1 The results highlight the potential of UAS in advanced healthcare logistics and confirm the need for a multidisciplinary approach, in which flight safety, clinical quality and operational sustainability are considered in an integrated manner. It confirms that the regulatory sandbox approach allows for emerging technologies to be evaluated, with shared feedback and any regulatory adjustments to be made while providing industrial solutions for new business models.

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