Airspace Change Proposal ACP-2021-002 2.0 14/07/2022

Summary of Stakeholder Engagement ACP-2021-002 TDA extension

Version 2.0 of this document was created in support of the application for a TDA extension that was shared with stakeholders on 29/06/2022. To that end, further engagement with targeted stakeholders was required to ensure that the potential impacts of an extension to the TDA were fully understood, acknowledged and mitigated with local aviation users.

This document details the stakeholders engaged as part of the request for an extension to the TDA. It details the duration, lists of engaged stakeholders and summary of their responses. The evidence of engagement is included along with an analysis of the responses and a conclusion on the TDA extension request.

On submission of this report ACP-2021-002 EG D096 A-C has been activated for a total of 7 days in the last TDA period (5/5/2022 - 5/7/2022). We have had no stakeholder feedback to date, although this is as expected, given the low level of activation.

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1. Introduction

The following evidence was published by Apian and SkyLift UAV in support of a TDA

extension for ACP-2021-002, with stakeholders emailed on 29th June 2022:

Dear Stakeholder,

We would be grateful for your support for an extension to ACP-2021-002 which

currently expires on 5 July 2022.

First of all, thank you to all those who have helped us research the value of delivering

chemotherapy by drone to cancer patients. Apian is a medical drone startup founded by NHS doctors with support from the NHS Clinical Entrepreneur Programme. We work on behalf of

the NHS to operationalise drone technology and research the impact it has on patient health

outcomes and staff wellbeing.

We have activated the TDA for the first time this week (27th June) in anticipation of flight

trials to St Mary's Hospital on the Isle of Wight. We will be optimising the remaining TDA period up to the 5th July, and have increased resources within the project by onboarding an

additional drone operator to do so. However, even with this additional support, we are

unlikely to complete the required 90 flights within the current timelines and as a result, we are

seeking your support for an extension to our TDA. We will be asking for a 60 day extension

from the 22nd Sept, to allow us to complete the remaining flights (max of 90 flights in total).

All aspects of the current TDA will remain the same.

Given the AIC cycle, the next available start date is 22nd Sept. This requires us to begin our

formal application to the CAA for an extension to ACP-2021-002 by 14 July. Before we do so, we wanted to update you and ask for your support. Would you kindly let us know if we have

it? Please call or email me directly. I'm happy to answer any questions and can arrange a

briefing if you prefer. I am at your service.

Attached is a letter from the Chief Pharmacist of Isle of Wight NHS Trust explaining why this

work is so important and thanking you for your support of it.

Yours gratefully,

Louisa Smith Head of Aviation

Apian Limited

E: Louisa@apian.aero

T: 07824882039





St. Mary's Hospital
Parkhurst Road
Newport
Isle of Wight
PO30 5TG

01983 822099 www.iow.nhs.uk

5 Nov 2021

To whom it may concern,

Support for Isle of Wight NHS Trust and partners to complete research of chemotherapy delivery by Drone

For the past year, together with colleagues at Portsmouth University Hospitals NHS Trust, we've been researching the potential benefits of using drones to deliver chemotherapy and are finally in position to carry out the actual flights across the Solent to test the vibration impact on medicines in their real-world environment.

To ensure patient safety, we must gather enough evidence over a suitable period of time. We need 2 months of concurrent operations to achieve this. The TDA (temporary danger area) expires on 23 November, we request an extension to the TDA to ensure that we have enough time to carry out extensive testing on the most commonly used monoclonal antibody drugs. Without an extension to the TDA we can only certify a small fraction of the most commonly used monoclonal antibody drugs. A period of less than 2 months will reduce the number of data points gathered to 1 month, in most instances this is unhelpful for trend analysis. Therefore 2 months will provide enough operational procedure validation, spanning several staff shift variations, which is necessary for pharmacy team resource consideration. It will also provide more opportunities for Air Ambulance/HM Coastguard procedure integration and allow us to better determine the long-term economic sustainability of a drone delivery service.

Although there are now several published articles regarding the transport of drugs in drones, none demonstrate what the effect of this new mode of transport has on the stability of chemotherapy and immunotherapy products. In the month of October 2021, we transported via hovercraft a combination of over 200 chemotherapy and immunotherapies. It is therefore of vital importance that we have enough time to complete stability studies of these products by drone. An extension will ensure we secure robust scientific evidence.

Moving items by drone across the Solent can ensure we receive a great range of prescribed chemotherapy drugs in a more timely and efficient manner. The Pharmacy Department and the wider Isle of Wight NHS Trust are extremely grateful to you for the part you play in helping us best serve our patients.

Yours sincerely

Mr Thomas E H Cox

Chief Pharmacist and Associate Director Medicines Optimisation

2. Stakeholder Engagement Approach

All stakeholders engaged during this proposal to extend the TDA have been previously engaged in the design of ACP-2021-002 on numerous occasions. This document supports the methodology and approach described in 'Airspace Change Proposal ACP-2021-002 Summary of Stakeholder Engagement and Final Proposal' V2.0 dated 03/06/2021 in which the final design of the TDA complex was agreed.

Advice was sought from the CAA Airspace team, 32 target stakeholders were engaged on 29/06/2022 and were asked to provide responses for submission to the CAA by 14/07/2022, allowing over 2 weeks to provide feedback on the extension request.

Apian sent selected stakeholders, by e-mail where possible, the engagement material as per section 1.

A follow-up email was sent on 11/07/2022 (which can be seen in section 3.3) to those stakeholders that were yet to respond where 1:1 update briefings were offered. The desire was to ensure all stakeholders had the opportunity to understand the request, ask any questions and share their feedback.

The engagement material was uploaded to the CAA Airspace Change Portal so that any potential stakeholders that were missed had the opportunity to make their views known. Table 1 provides a list of all stakeholders that were contacted, whether they responded, and confirmation that their response has been closed.

Table 1.

	Stakeholder	Date sent	Response	Open/ Closed
1		29/06/2022	Υ	Closed
2		29/06/2022		
3		29/06/2022	Υ	Closed
4		29/06/2022	Υ	Closed
5		29/06/2022		
6		29/06/2022		
7		29/06/2022		
8		29/06/2022		
		29/06/2022		
		29/06/2022		
		29/06/2022	Υ	Closed
9		29/06/2022	Υ	Closed

10	29/06/2022		
11	29/06/2022		
12	29/06/2022	Υ	Closed
13	29/06/2022	Υ	Closed
2 0	29/06/2022		
14	29/06/2022		
	29/06/2022	Υ	Closed
15	29/06/2022	Υ	Closed
16	29/06/2022		
17	29/06/2022	9	
18	29/06/2022		
19	29/06/2022		
20	29/06/2022		
21	29/06/2022	Y	Closed
22	29/06/2022		
23	29/06/2022		
24	29/06/2022		
25	29/06/2022	Y	Closed
26	29/06/2022		
27	29/06/2022	Υ	Closed
28	29/06/2022	Υ	Closed
29	29/06/2022	Y	Closed
30	29/06/2022	Y	Closed
31	29/06/2022		
32	29/06/2022		

3. Stakeholder Evidence, Feedback and Conclusion

3.1 Engagement material

The email in section 1 was sent out to all stakeholders in table 1 on 29/06/2022 with attached supporting statements from Isle of Wight (IOW) NHS Trust. The following was sent to stakeholders that hadn't responded on 11/07/2022 from Louisa Smith:

Dear Stakeholder,

Following on from my email on the 29th June regarding the request for your support to extend ACP-2021-002, I wanted to contact you to offer further information or support if you wish.

This project is incredibly important to the NHS and aims to deliver critical chemotherapy treatment to individuals on the Isle of Wight. The requested extension would allow us to collect vital data from flights. We are not asking for any more flights, merely time to conduct the original 90 flights planned across all periods of TDA activation and complete initial research for the NHS.

We will be submitting our request, along with any feedback you provide to the CAA on Thursday 14th July, please do let us know if we have your support so we can inform the CAA. If you would like to discuss in more detail, please do not hesitate to contact me and I will be happy to arrange a call with you.

Regards

Louisa Smith

3.2 Summary of feedback

Apian received feedback from 15 of the 32 targeted stakeholders. 13 of the stakeholders were either supportive of the proposed extension or had no objection to it. 2 stakeholders opposed the proposal. The key elements of feedback are highlighted below:

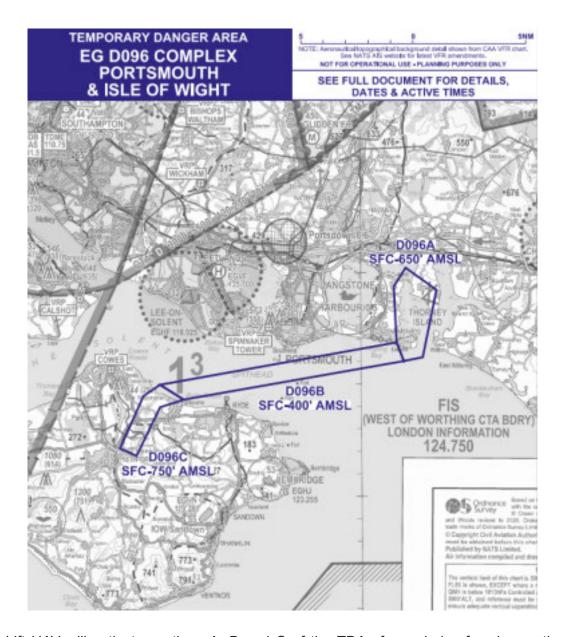
- Generally there was little in the way of questions or follow-up, likely given there was no change in the geometry of the airspace, number of flights or activation times for the TDA.
- A select few commented on the long term strategy for integration of new airspace users and the need to move away from TDAs, as these were not an appropriate long term solution. Apian reassured the individuals that we are working with the CAA innovation team to assist in identifying what the future solution might look like.
- We receive positive feedback about our stakeholder engagement and feedback requests

3.3 Analysis of responses and conclusion

Apian and Skylift UAV appreciate the feedback provided by stakeholders. Each response was analysed carefully to ensure a proposed extension to ACP-2021-002 can be managed

with minimal impact to local aviation users.

The trial outcome can be achieved with BVLOS operations from Thorney Island Baker Barracks to St Mary Hospital, Isle of Wight. The TDA complex design was updated to include 3 sections, A, B and C when the original extension was granted (31/01/2022 - 31/03/2022), the TDA complex is shown below:



SkyLift UAV will activate sections A, B and C of the TDAs for periods of no longer than 4 hours each day. This will typically be during afternoon hours and supports the current manufacturing schedule of the treatments required by the IOW NHS trust. The activation times are expected to be as follows: Monday - Thursday 14:00-18:00 local and Friday 10.30-14.30 local.

The letters of agreement that have been drawn up by Skylift UAV Ltd and, jointly, Chichester and District Model Aero club (CADMAC) and Thorney Island Microlight Club (TIMC) to specify deconfliction procedures within the TDAs remain in place if the TDA is extended. This has been acknowledged as part of the stakeholder feedback process and all issued LOAs will continue if an extension is agreed.

Skylift UAV will give priority to emergency services aircraft requiring access to active TDAs.

While HM Coastguard and the National Police Air Service were content with the information that will be provided by the TDA activation NOTAM, Hampshire and Isle of Wight Air Ambulance required a more detailed arrangement. To that end, Skylift UAV have signed an LOA with Babcock Onshore, the Air Ambulance operators, to specify deconfliction procedures within the TDAs, this will continue if an extension is agreed.

TIMC and The British Microlight Aircraft Association requested further information regarding the schedule of the operations. Apian anticipates having a more secure schedule in advance and is more than happy to send this on request. Requests should be made to airspace@apian.aero.

4. Summary and justification for extended TDA

The Isle of Wight NHS Trust's Pharmacy Manufacturing Unit (PMU) was decommissioned in July 2020. It has since been dependent on the mainland for the supply of its chemotherapy which must be delivered by ground courier to Portsmouth, then by ferry or hovercraft to the Isle of Wight, then by taxi to St Mary's Hospital. Disruptions to these services, including cancellations, delays and changing timetables complicate deliveries, leading to treatment delays and additional pressure on staff. It currently can take up to 3 or even 4 hours to transport chemotherapy from the nearest PMU at Portsmouth Hospitals University NHS Trust to St Mary's. Reducing this to a reliable, 30 minute flight will be transformative, making available to patients chemotherapy previously unobtainable on account of their short shelf lives, avoid unnecessary patient journeys to the mainland, minimise treatment delays and save staff time.

Due to the short shelf lives, chemotherapy is currently manufactured and delivered by the PMU as bespoke doses a day in advance, before the patient has been clinically assessed and confirmed to be physically able to receive treatment. When a patient's health deteriorates such that they are unable to receive chemotherapy, their treatment is delayed and their dose is wasted. An on-demand drone delivery service will allow for a sequential process where manufacturing is only started after a positive patient assessment, enabling the PMU to deliver to St Mary's on the day of the patient's treatment. As some of these medicines cost several thousands of pounds per dose, this will save the NHS costs and bring care closer to patient homes, opening up the possibility for the provision of other treatments on the island such as potentially life-saving, clinical trial chemotherapy which have particularly short shelf lives.

Apian is not a drone company, it is a medical drone startup founded by NHS doctors in training with support from the NHS Clinical Entrepreneurs Programme. We work on behalf of the NHS to operationalise drone technology and research the impact it has on patient health outcomes and staff well-being. We are familiar with the various NHS drone related projects taking place across the country and agree with the feedback for better coordination of activities. This is Apian's directive and starting with the Solent, we are collaborating with NHS England, NHS Cancer Programme, NHS Greener Team and NHS Blood & Transplant, along with ten NHS Trusts to unify their healthcare needs, forming the basis for a single NHS-wide ACP.

As delivering chemotherapy by drone will be a world-first, the Medicines and Healthcare products Regulatory Agency (MHRA) requires evidence from real-world tests demonstrating chemotherapy is not negatively impacted by drone flight (vibration and temperature). This requires flying chemotherapy across the Solent and not simply within VLOS limits. In partnership with Southampton University and King's College London, we have begun researching the impact of drone flight on redundant chemotherapy and have shared initial results with Portsmouth Hospitals University NHS Trust's PMU on 09/11/21. Analysis showed no negative impact of hover flight on the first medication, and Bevacizumab, has been tested. We have now successfully completed the required vibration testing and obtained approval from the NHS Pharmacy Manufacturing Unit to deliver chemotherapy to St Mary's Hospital, Isle of Wight.

We need 60 days or 90 flights of real-world operations to ensure patient safety and inform NHS standards and best practice guidelines. This provides the time needed to research the

benefit of on-demand drone delivery to cancer patients, gathering enough data to gain reliable results and perform trend analysis. Working as best as we can within constrained NHS resources, 60 days or 90 flights provides the absolute minimum time required to validate operational procedures and test integration into the hospital environment, enabling the Isle of Wight NHS Trust to determine the long-term feasibility and sustainability of a drone delivery service.

Although there are now several published articles regarding the transport of medicines in drones, none demonstrate what the effect of this new mode of transport has on the stability of chemotherapy and immunotherapy products. In the month of October 2021, the Isle of Wight NHS Trust transported, via hovercraft, a combination of over 200 chemotherapy and immunotherapies. It is therefore of vital importance that the NHS has the 60 days it needs to complete stability studies of these products by drone. An extension to the TDA will ensure we secure robust scientific evidence.

We have activated the TDA for a total of 7 days during the last TDA period (May - July 2022), successfully flying BVLOS from Thorney Island to the Isle Of Wight. We have also increased resources within the project by onboarding an additional drone operator to do so, who has an approved OSC to ensure we fully utlise an extension to the TDA going forward. Unfortunately, we have not been able to complete the necessary number of flights with the required payload for this stage of the project. As a result, we are seeking your support for an extension to our TDA. We are not looking to increase the number of flights planned, merely the time in which they will take place. Given the impact of COVID-19 and the resulting NHS backlog, this work has never been more critical. It will be the first time chemotherapy has ever been delivered by drone and world firsts don't come easy.

If you would like to talk to the NHS and Apian further on our request to extend the TDA and why less than 60 days is not sufficient, we would happily do so.

5. Extending current temporary airspace arrangement

- 1. From 22/09/2022 through to 21/11/2022, a Remotely Piloted Aircraft System (RPAS) will operate between Baker Barracks, Emsworth and St Mary's Hospital in Newport, Isle of Wight to carry out operational flights for the purpose of transporting essential medical goods between the healthcare sites in direct support of the NHS and UK Government response to the COVID-19 pandemic. As the RPAS will be operating Beyond Visual Line of Sight, a Temporary Danger Area (TDA) complex will be established to facilitate the safe operation of the RPAS.
- 2. The TDA complex is sponsored by Skylift UAV Limited in accordance with Airspace Change reference ACP-2021-002.
- 3. The TDA complex will consist of 3 Danger Areas (DA) to facilitate the route between the healthcare sites. A chart of the area is included within this Aeronautical Information Circular.
- 4. Only the DA required for each flight or series of flights will be activated to minimise impact to other air users.
- 5. The required TDAs will be notified for activation no less than 24 hours prior to the planned flights. Activation of the TDAs could take place between the hours of 1400-1800 Monday to Thursday and 1030-1430 Friday, with actual dates and times of activation promulgated by NOTAM. All times referenced are UK local time.
- 6. EG D096A. When required from 22/09/2022 through to 21/11/2022, a Temporary Danger Area is established within the area bounded by straight lines joining successively the following points
 - a. 50°50'10"N 000°56'50"W
 - b. 50°49'10"N 000°54'40"W
 - c. 50°46'10"N 000°55'40"W
 - d. 50°46'00"N 000°57'00"W
 - e. 50°46'50"N 000°57'30"W
 - f. 50°49'20"N 000°57'40"W
- 7. Within EG D096A, Pre-Flight Information will be available from Skylift UAV via telephone number 0330 053 7600, which will be manned from 30 minutes before until 30 minutes after the notified activation period. When notified as active, requests for access to the TDA by emergency services aircraft shall be made by calling this number. Access to the TDA by emergency services aircraft will always be given priority over RPAS operations, which will be immediately suspended.
- 8. The TDA EG D096A is established between surface and 650 FT AMSL.
- 9. EG D096B. When required from 22/09/2022 through to 21/11/2022, a TDA is established within the area bounded by straight lines joining successively the following points
 - a) 50°46'00"N 000°57'00"W
 - b) 50°44'20"N 001°12'30"W
 - c) 50°45'00"N 001°14'10"W

- d) 50°46'50"N 000°57'30"W
- 10. Within EG D096B, Pre-Flight Information will be available from Skylift UAV via telephone number 0330 053 7600, which will be manned from 30 minutes before until 30 minutes after the notified activation period. When notified as active, requests for access to the TDA by emergency services aircraft shall be made by calling this number. Access to the TDA by emergency services aircraft will always be given priority over RPAS operations, which will be immediately suspended.
- 11. The TDA EG D096B is established between Surface and 400 FT AMSL.
- 12. EG D096C. When required from 22/09/2022 through to 21/11/2022, a TDA is established within the area bounded by straight lines joining successively the following points
 - a. 50°44'20"N 001°12'30"W
 - b. 50°44'00"N 001°14'10"W
 - c. 50°41'50"N 001°15'50"W
 - d. 50°42'10"N 001°17'00"W
 - e. 50°44'30"N 001°15'20"W
 - f. 50°45'00"N 001°14'10"W
- 13. Within EG D096C, Pre-Flight Information will be available from Skylift UAV via telephone number 0330 053 7600, which will be manned from 30 minutes before until 30 minutes after the notified activation period. When notified as active, requests for access to the TDA by emergency services aircraft shall be made by calling this number. Access to the TDA by emergency services aircraft will always be given priority over RPAS operations, which will be immediately suspended.
- 14. The TDA EG D096C is established between Surface and 750 FT AMSL.
- 15. Further enquiries can be made to Airspace Regulation (Utilisation), Safety and Airspace Regulation Group, Civil Aviation Authority on telephone number 01293-983880.
- 16.As part of the ACP process requirements, Skylift UAV is collecting feedback regarding this TDA and its impact over its duration which will be shared with the CAA. All feedback regarding this may be sent via email to info@skyliftuav.co.uk

6. Appendix 1: Stakeholder Responses

Stakeholder responses were received from the following;







Yes you have our support 100% and best of luck from the 22nd of September.

Kind regards.



Let's give nature a home



The RSPB is the UK's largest nature conservation charity, inspiring everyone to give nature a home. Together with our partners, we protect threatened birds and wildlife so our towns, coast and countryside will teem with life once again. We play a leading role in BirdLife International, a worldwide partnership of nature conservation organisations.

The Royal Society for the Protection of Birds (RSPB) is a registered charity: England and Wales no. 207076, Scotland no. SC037654

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Dear Sponsor

It worries me that this Trial needs yet another extension. The project started almost 18 months ago in Jan 2021, and it was revised in April that year. You were given approval to go ahead one year ago and then in Nov 21 asked for an extension which was granted 3 months ago. As an experienced aviation trials manager, had one of my own organisation performed in this way it would have been considered a very poorly planned trial.

There seems to be little thought given to the impact on other airspace users of the frequent requests from NHS trial drone operators - inc Apian - for extensions and amendments to trials. To answer frequent requests takes valuable time for both individuals stakeholders and even for many of the GA organisations - a well thought-out, comprehensive plan at the start with a realistic timeframe would certainly be welcome in reducing that burden.

Moreover, many GA pilots plan their flying some time ahead in Summer/Autumn, looking to take part in various fly-ins to other aerodromes. Obviously the routes to be used are not fixed but they are often agreed in 'broad outline' so that several airfields can be visited over a short period of time - typically 1 or 2 days. Your requested extension only hinders that forethought, adding again an unnecessary burden.

You have provided no explanation for being unable to complete your own plan and absolutely no reason why this extension is required, relying on emotive language and a rather one-sided letter of support. I can see no reason why this

extension should be granted and I do not support it.

Kind regards



Thank you for taking the time to respond to our request. We are sorry to hear that you cannot offer your support for an extension to our TDA

We want to assure you that the TDA has been designed to minimise the impact on other airspace users, such as the height of the TDA which is 400AMSL over the solent and 750 AMSL over the Isle of Wight, and only activated when needed. We also have Letters of Agreement with the regular flyers on Thorney Island and HEMs to ensure they are still able to operate, as well as liaising with local aerodromes such as Goodwood and Solent.

As you mention you have experience as a trial manager in aviation, I am sure you appreciate the challenges a trial such as this can bring, and despite robust plans and with our best intentions there are often delays that cannot be foreseen at the start. We recently have recruited an additional drone operator to work alongside Skylift to ensure we can utilise the TDA (although we will still maintain a maximum of 90 flights in total across all TDA activations and drone operators). Unfortunately, the regulatory approval timelines have meant that they were unable to operate sufficient flights before the 5th July, but will be in a position to operate within the TDA extension.

If you would like to discuss this further, I am more than happy to schedule a telephone or video call with you.

Regards Louisa Louisa Smith Head of Aviation Apian Limited E: Louisa@apian.aero T: 07824882039

6 July 2022 at 16:14

Thanks Louisa

A kind offer but I'm sure we both have better things to do.

And just to be clear, I do understand the challenges such a trial can bring, but all my organisation's trials would be undertaken with very robust plans and a suitable contingency, so that whenever they started they finished on time. To do otherwise would impose considerable cost in time and money, and that would have been considered both unprofessional and career-limiting! It is for this reason that I will not support the request for an extension.

However, I do applaud your engagement which is an exemplar other ACP sponsors could well copy.

Kind regards

11

Dear Louisa.

Thank you for your below message and engaging the British Microlight Aircraft Association (BMAA).

I know that you are also in contact with the Thorney Island Microlight Club (TIMC) regarding this additional extension request and, whilst I am liaising with them as members of the BMAA, they will be responding directly. I am also copying the

Whilst the BMAA support assistance for cancer-related logistics we have some concerns about your additional TDA extension request, as detailed below.

- 1. We are confused as to why Apian Ltd., are requesting this since you are not the sponsors of this ACP and, as I understand it, therefore not the responsible controller of the TDA. In the original SON Skylift UAV stated that they were conducting these trials on behalf of the Portsmouth Hospitals University NHS Trust and the IOW NHS Trust and Skylift UAV are listed as the sponsors of this ACP, so surely any notices regarding this TDA should come from them? What position do Apian have with regards to responsibility to and approval from the CAA with regards to this ACP?
- 2. The LOA covering the original and May-July extension TDA is between Skylift UAV and the TIMC. We expect that LOA should extended and be subject to any further TDA extension not preventing TIMC operations from that airfield and that this be a condition of any CAA approval for any further activation of the current TDAs.
- 3. Our understanding is that only five days were activated during the first 90 days TDA approved period and we have only seen the TDA activated for the last five days during the 60-day May-July extension. In our response to the request for the May-July TDA extension period we explained that we trusted the project would be sufficiently prepared to use the extension, since much CAA and stakeholder resources had been used. The response dated 07/03/22 was "Yes, everything has been done to ensure that the project is sufficiently prepared to make full use of a delayed TDA." Clearly that was not the case. Considering this further extension request we think it only fair that the ACP sponsor provides a full explanation to all stakeholders as to why this has happened. Furthermore, considering these facts, we feel the sponsor should demonstrate to the CAA that it is in compliance with its Operational Safety Case and technically capable of carrying out these trials (with the UAV approved by the OSC Skylift's v50 UAV was stated in your previous response) immediately at the start of any further TDA extension as a condition of approval.
- 4. Also, in response dated 07/03/22 you agreed that a schedule of planned days and times for operations (rather than just the intention to operate Mon-Thu 14:00-18:00 and Fri 10:30-14:30) during the TDA extension would be 'worked on with Skylift UAV and the NHS Trusts'. In the CAA approval for the May-July extension one of the conditions they sated was "As suggested in the engagement summary, you should develop and share with stakeholders a flying schedule covering the 2-month period in addition to publishing the NOTAM" We never received this. Considering this condition was broken how can stakeholders and the CAA be sure the ACP sponsor will carry this out for any further extension?

- 5. Whilst we understand the sponsor of this ACP is Skylift UAV and the TDAs have been approved for their use according to their OSC, we understand that a NOTAM activation was issued for the weekend of 02-03 July 22, days which are outside of the LOA between Skylift UAV and TIMC, for operations intended to be flown by another UAV operator named Modini. We also understand that this NOTAM was withdrawn after it was pointed out that this was in violation of the agreements. Once again, this does not give us confidence that procedures for responsible use of the existing TDA are being followed and, again, we seek clarification of who is responsible for administration of this ACP and operation of any TDA.
- 6. In the CAA approval for the May-July extension they also stated "We would also welcome and support the suggestion that the results of the project are shared and would encourage you to consider making this information available to a broader range of stakeholders by uploading it to the airspace change portal." We have not seen this information but would wish to see this statement in any future TDA extension approval from the CAA
- 7. The CAA have often stated that TDAs are not a long-term solution for this type of operation. Whilst actual activations of this TDA have been minimal we feel that these trials have seem to have been inadequately prepared. It would seem better that the technology is matured prior to use of the CAP1616 process and approved TDAs.



Thank you for taking the time to respond to our email request. We appreciate your support of our trials, as do the NHS and welcome your feedback. We will of course pass on your comments to the CAA. I met week whilst we were conducting some VLOS flights on the island, and understand that she will be responding separately.

You have raised a number of concerns below which I have responded to directly for ease of reference and hope you find suitable. If you would like to discuss anything in more detail with myself or my colleagues at Apian, please do not hesitate to contact me and I will be happy to schedule a time to do this.

Regards

Louisa

Dear Louisa,

Thank you for your below message and engaging the British Microlight Aircraft Association (BMAA).

I know that you are also in contact with the Thorney Island Microlight Club (TIMC) regarding this additional extension request and, whilst I am liaising with them as members of the BMAA, they will be responding directly. I am also copying their

Whilst the BMAA support assistance for cancer-related logistics we have some concerns about your additional TDA extension request, as detailed below.

- 1. We are confused as to why Apian Ltd., are requesting this since you are not the sponsors of this ACP and, as I understand it, therefore not the responsible controller of the TDA. In the original SON Skylift UAV stated that they were conducting these trials on behalf of the Portsmouth Hospitals University NHS Trust and the IOW NHS Trust and Skylift UAV are listed as the sponsors of this ACP, so surely any notices regarding this TDA should come from them? What position do Apian have with regards to responsibility to and approval from the CAA with regards to this ACP?
- Apian is leading the project on behalf of the IOW NHS Trust and Portsmouth Hospital University NHS Trust and represents them as sponsors. We have a close relationship with Skylift and therefore Apian is leading the ACP process to ensure Skylift can prioritise drone operations.
 - 2. The LOA covering the original and May-July extension TDA is between Skylift UAV and the TIMC. We expect that LOA should extended and be subject to any further TDA extension not preventing TIMC operations from that airfield and that this be a condition of any CAA approval for any further activation of the current TDAs.
- We agree and have reached out to those with LOA to ensure that we can continue with the same details. The LOA is with Skylift UAV and the TIMC, where Skylift UAV represents the project as the drone operator.
 - Our understanding is that only five days were activated during the first 90 days TDA approved period and we have only seen the TDA activated for the last five days during the 60-day May-July extension. In our

response to the request for the May-July TDA extension period we explained that we trusted the project would be sufficiently prepared to use the extension, since much CAA and stakeholder resources had been used. The response dated 07/03/22 was "Yes, everything has been done to ensure that the project is sufficiently prepared to make full use of a delayed TDA." Clearly that was not the case. Considering this further extension request we think it only fair that the ACP sponsor provides a full explanation to all stakeholders as to why this has happened. Furthermore, considering these facts, we feel the sponsor should demonstrate to the CAA that it is in compliance with its Operational Safety Case and technically capable of carrying out these trials (with the UAV approved by the OSC – Skylift's v50 UAV was stated in your previous response) immediately at the start of any further TDA extension as a condition of approval.

- To ensure we minimise the impact to other airspace users we have only activated the TDA for 7 days (27th June to 5th July excluding the weekend).
- This trial is delivering world firsts, which, as I am sure you appreciate, can bring a number of challenges and despite robust plans and with our best intentions there are often delays that cannot be foreseen at the start. One of our mitigations was that we recruited an additional drone operator (Modini) to work alongside Skylift to ensure we can utilise the TDA (although we will maintain a maximum of 90 flights in total across all TDA activations). Unfortunately, the regulatory approval timelines have meant that they were unable to operate sufficient flights before the 5th July, however the approval process will be complete to ensure they can conduct flights in the TDA extension timelines.
- Skylift have an operational authorisation based on their submitted OSC for BVLOS operations using VTOL
 aircraft in the TDA and VLOS anywhere in the UK, and have, as standard, undergone and passed an audit
 from the CAA in February which confirms their compliance with their OSC and CAA regulations. Apian,
 Skylift and Modini pride themselves on their attitude to safety and have held the highest standards
 throughout all flight operations.
- 4. Also, in response dated 07/03/22 you agreed that a schedule of planned days and times for operations (rather than just the intention to operate Mon-Thu 14:00-18:00 and Fri 10:30-14:30) during the TDA extension would be 'worked on with Skylift UAV and the NHS Trusts'. In the CAA approval for the May-July extension one of the conditions they sated was "As suggested in the engagement summary, you should develop and share with stakeholders a flying schedule covering the 2-month period in addition to publishing the NOTAM" We never received this. Considering this condition was broken how can stakeholders and the CAA be sure the ACP sponsor will carry this out for any further extension?
- To date it has been challenging to have a stable schedule of operations due to platform testing, met conditions and regulatory approvals that would offer you the details for advanced planning (outside that that is offered from a NOTAM).
- We will submit a NOTAM as far in advance as possible to allow the aviation community to see this in advance.
- Subject to approval for an extension of the TDA, given we have now completed a point-to-point flight, we
 anticipate having a more secure schedule in advance and are more than happy to send this on request.
 Requests should be made to airspace@apian.aero.
- 5. Whilst we understand the sponsor of this ACP is Skylift UAV and the TDAs have been approved for their use according to their OSC, we understand that a NOTAM activation was issued for the weekend of 02-03 July 22, days which are outside of the LOA between Skylift UAV and TIMC, for operations intended to be flown by another UAV operator named Modini. We also understand that this NOTAM was withdrawn after it was pointed out that this was in violation of the agreements. Once again, this does not give us confidence that procedures for responsible use of the existing TDA are being followed and, again, we seek clarification of who is responsible for administration of this ACP and operation of any TDA.
- As mentioned above, Modini are our second operator, they were planning to complete some operations
 (VLOS) subject to approval from Baker Barracks. They proactively submitted the NOTAM as per the time
 recommendation on the NOTAM site, pending permission to fly over the weekend. This was done with the
 best intentions, but unfortunately led to some confusion with the local TI users. Apian have directly emailed
 all parties apologising for the miscommunication and the NOTAM was removed as soon as possible.
- · Activation of the TDA, as to date, will be through Skylift.
- 6. In the CAA approval for the May-July extension they also stated "We would also welcome and support the suggestion that the results of the project are shared and would encourage you to consider making this information available to a broader range of stakeholders by uploading it to the airspace change portal." We have not seen this information but would wish to see this statement in any future TDA extension approval from the CAA.
- We still support this statement and will share results when available once all the data is collected. We
 are more than happy that this statement is included in any approval.
- 7. The CAA have often stated that TDAs are not a long-term solution for this type of operation. Whilst actual activations of this TDA have been minimal we feel that these trials have seem to have been inadequately

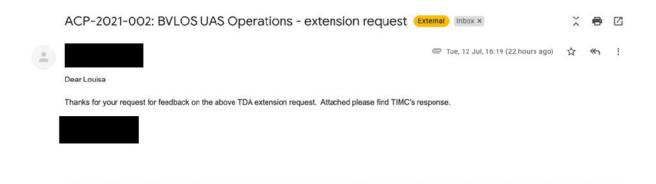
prepared. It would seem better that the technology is matured prior to use of the CAP1616 process and approved TDAs .

We agree that TDAs are not a long-term solution and have been working with the CAA innovation team to
help identify a more suitable solution for the future. Unfortunately a TDA is required to ensure the aircraft is
safely segregated whilst we test and mature the technology.

[Quoted text hidden]

Kind Regards Louisa

1



Thorney Island Microlight Club (TIMC)

Feedback to ACP-2021-002 extension proposal (60 days from 22 September 2022)

Thank you for the request for feedback on the latest extension request for the above ACP. We have the following comments to make on this application:

- 1. We note that there have been 3 approved requests for a TDA relating to this activity:
 - a. 26/08/2021 23/11/2021 during which the TDA was activated for 5 days
 - b. 31/01/2022 31/03/2022 during which the TDA was not activated
 - c. 05/05/2022 05/07/2022 during which the TDA was activated for 7 days
 - d. 22/09/2022 22/11/2022, the subject of this additional approval request

The impact of these TDAs on TIMC's operations has been minimal, which is not surprising given the activity levels noted above. TIMC therefore has no comment to add for the operational aspect of the September – November 2022 extension, provided it is conducted under the same terms and Letter of Agreement as the May – July 2022 TDA.

2. TIMC would like to comment on the administrative resource which has been committed to all of these TDA requests. Two different versions of the Letter of Agreement have been defined and agreed (in order to take account of the change in operating locations used by Skylift on Thorney Island), encompassing three signed agreements. These have been agreed on a three-party basis with TIMC, Chichester and District Model Aircraft Club, and Skylift. In all cases, TIMC members have been fully briefed in advance of TDA approval periods on the agreed deconfliction. So, whilst there has been little operational impact in reality, the preparation and administration risk the 'boy crying wolf' scenario for another potential TDA activation. For this reason, we would highlight the comment made in response to stakeholder engagement in March 2022:

"We welcome your excellent suggestion to publish a schedule of planned days and times for operations during the TDA extension and will work closely with Skylift and our NHS partners to complete this. This would be in addition to the NOTAM that is conducted 24hrs in advance of TDA activation."

We also note one of the CAA's conditions in granting the May – July TDA extension: "As suggested in the engagement summary, you should develop and share with stakeholders a flying schedule covering the 2-month period in addition to publishing the NOTAM"

This condition was not met; however we would strongly recommend that it remains an <u>implemented</u> condition of any TDA extension, in order to effectively inform third party users in advance of planned activity and reduce the risk of "TDA fatigue".

3. We note that Apian have applied for this TDA extension, rather than Skylift, the previous sponsors. In Skylift's email of 15 July 2022 it refers to 'Apian Ltd, who are responsible for the service provision to the NHS'

TIMC's Letter of Agreement is with Skylift, not Apian, as the responsible operator of the technology. A change in TDA sponsor should logically require a new ACP for a TDA, rather than a TDA extension. Apian have made reference to an additional drone operator with which TIMC have had no contact, and only an application to operate in direct contravention of the LoA which was agreed with Skylift. To save having multiple agreements with different operators, we would suggest that TDA activity which takes place, if

not by Skylift, is directly supervised by Skylift (assuming the relevant safety case and operating requirements are satisfied).

4. I would reiterate my comments made on the original ACP application in April 2021:

A major safety benefit would be the ability of the remotely piloted aircraft which are the subject of the ACP, to listen and transmit position reports to microlights operating out of Thorney Island. Thorney Island Microlight Club uses SafetyCom in common with many other small airfields in order to transmit position and intentions in order to maximise safety. The technology exists to utilise aircraft transportable radios, the pilots of the remotely piloted aircraft are appropriately licenced to operate a radio, therefore there should be no barrier to UAV use of SafetyCom as part of this trial to prove interoperability with other air users. This may be against current policies for radio use, however if air users are expected to be responsive to enable solutions such as this proposal to aid the NHS, we would expect the policy application to be equally responsive to change.

In addition to Skylift, there is periodic activity using other remotely piloted aircraft at Thorney Island, for which activity is covered via NOTAM. These aircraft legitimately operate using SafetyCom, and therefore concurrent use with TIMC is both safer, and more straightforward than operating without the ability to communicate as with Skylift. So, for one operator TIMC members and other pilots may communicate with drone operations where necessary, and for the other operator rely on written procedures with no ability to communicate. This inconsistency in approach is clearly suboptimal and requires a change in approach to allow Skylift to communicate with other air users where required. The safety case for this should be self-evident.

ACP-2021-002: BVLOS UAS Operations - extension request



Thank you for taking the time to respond to our email request. We appreciate your support of our trials, as do the NHS and welcome your feedback. We will of course pass on your comments to the CAA.

You have raised a number of concerns below which I have responded to directly for ease of reference and hope you find them helpful. If you would like to discuss anything in more detail with myself or my colleagues at Apian, please do not hesitate to contact me and I will be happy to schedule a time to do this.

Regards

Louisa

Thorney Island Microlight Club (TIMC)

Feedback to ACP-2021-002 extension proposal (60 days from 22 September 2022)

Thank you for the request for feedback on the latest extension request for the above ACP. We have the following comments to make on this application:

- 1. We note that there have been 3 approved requests for a TDA relating to this activity:
- a. 26/08/2021 23/11/2021 during which the TDA was activated for 5 days
- b. 31/01/2022 31/03/2022 during which the TDA was not activated
- c. 05/05/2022 05/07/2022 during which the TDA was activated for 7 days
- d. 22/09/2022 22/11/2022, the subject of this additional approval request

The impact of these TDAs on TIMC's operations has been minimal, which is not surprising given the activity levels noted above. TIMC therefore has no comment to add for the operational aspect of the September – November 2022 extension, provided it is conducted under the same terms and Letter of Agreement as the May – July 2022 TDA.

- Thank you, we would like to conduct the trial under the terms and Letter of Agreement as
 previously agreed with yourselves and support this approach.
- 2. TIMC would like to comment on the administrative resource which has been committed to all of these TDA requests. Two different versions of the Letter of Agreement have been defined and agreed (in order to take account of the change in operating locations used by Skylift on Thorney Island), encompassing three signed agreements. These have been agreed on a three-party basis with TIMC, Chichester and District Model Aircraft Club, and Skylift. In all cases, TIMC members have been fully briefed in advance of TDA approval periods on the agreed deconfliction. So, whilst there has been little operational impact in reality, the preparation and administration risk the 'boy crying wolf' scenario for another potential TDA activation. For this reason, we would highlight the comment made in response to stakeholder engagement in March 2022: "We welcome your excellent suggestion to publish a schedule of planned

days and times for operations during the TDA extension and will work closely with Skylift and our NHS partners to complete this. This would be in addition to the NOTAM that is conducted 24hrs in advance of TDA activation." We also note one of the CAA's conditions in granting the May – July TDA extension: "As suggested in the engagement summary, you should develop and share with stakeholders a flying schedule covering the 2-month period in addition to publishing the NOTAM" This condition was not met; however we would strongly recommend that it remains an implemented condition of any TDA extension, in order to effectively inform third party users in advance of planned activity and reduce the risk of "TDA fatigue".

- We appreciate your support and resources to assist in completing the updated LoA, and understand your comments above.
- We would like to reassure you that we do not see TDAs as a long-term solution and have been
 working closely with the CAA innovation team to help identify a more suitable solution for the
 future which allows integration with other airspace users.
- To date it has been challenging to have a stable schedule of operations due to platform testing, Met conditions and regulatory approvals that would offer you the details for advanced planning (outside that that is offered from a NOTAM).
- However, subject to approval for an extension of the TDA, given we have now completed a point-to-point flight, we anticipate having a more secure schedule in advance and are more than happy to send this on request. Requests should be made to airspace@apian.aero.
- We will also ensure we submit a NOTAM as far in advance as possible to allow the aviation community to see this in advance.
- 3. We note that Apian have applied for this TDA extension, rather than Skylift, the previous sponsors. In Skylift's email of 15 July 2022 it refers to 'Apian Ltd, who are responsible for the service provision to the NHS' TIMC's Letter of Agreement is with Skylift, not Apian, as the responsible operator of the technology. A change in TDA sponsor should logically require a new ACP for a TDA, rather than a TDA extension. Apian have made reference to an additional drone operator with which TIMC have had no contact, and only an application to operate in direct contravention of the LoA which was agreed with Skylift. To save having

multiple agreements with different operators, we would suggest that TDA activity which takes place, if not by Skylift, is directly supervised by Skylift (assuming the relevant safety case and operating requirements are satisfied).

- Apian is leading the project on behalf of the IOW NHS Trust and Portsmouth Hospital University NHS Trust and represents them as sponsors. We have a close relationship with Skylift and therefore Apian is leading this TDA extension process to ensure Skylift can prioritise drone operations.
- TDA activation, as to date, will be led by Skylift, who remain the ACP sponsor.
- The additional drone operator (Modini), which has been onboarded to ensure we utilise the TDA
 extension (subject to approval) and achieve the required flights (max of 90 over the all TDA
 activation periods). This drone operator's operations will be coordinated through skylift who are
 responsible for the TDA management.
- Modini has received an approved OSC from the CAA to operate in the TDA, and this includes
 measures to ensure only one drone will be operating in the TDA at any time.
- 4. I would reiterate my comments made on the original ACP application in April 2021:

 A major safety benefit would be the ability of the remotely piloted aircraft which are the subject of the ACP, to listen and transmit position reports to microlights operating out of Thorney Island. Thorney Island Microlight Club uses SafetyCom in common with many other small airfields in order to transmit position and intentions in order to maximise safety. The technology exists to utilise aircraft transportable radios, the pilots of the remotely piloted aircraft are appropriately licenced to operate a radio, therefore there

should be no barrier to UAV use of SafetyCom as part of this trial to prove interoperability with other air users. This may be against current policies for radio use, however if air users are expected to be responsive to enable solutions such as this proposal to aid the NHS, we would expect the policy application to be equally responsive to change. In acdition to Skylift, there is periodic activity using other remotely piloted aircraft at Thorney Island, for which activity is covered via NOTAM. These aircraft legitimately operate using SafetyCom, and therefore concurrent use with TIMC is both safer, and more straightforward than operating without the ability to communicate as with Skylift. So, for one operator TIMC members and other pilots may

communicate with drone operations where necessary, and for the other operator rely on written procedures with no ability to communicate. This inconsistency in approach is clearly suboptimal and requires a change in approach to allow Skylift to communicate with other air users where required. The safety case for this should be self-evident.

- · We will pass your comments on to the CAA.
- The CAA have confirmed with Skylift UAV: "The definition and requirements for a DACS and DAAIS are laid out in ENR 1.1 para 5.1.3.3 and 5.1.3.4. Both are inflight services where a DACS provides a clearance and thus must be by an ATCO whereas a DAAIS is not a clearance but is instead passing the status of the airspace and therefore can be provided by a FISO. There will be licensing requirements on the Unit (the service provider) as to what they would need to be able to provide AFIS or ATC."
- Skylift UAV can therefore only provide Pre-Flight Information over the phone. While Skylift UAV
 would gladly use a VHF radio installed on the aircraft, the CAA currently has no mechanism to
 provide Skylift UAV with a call sign, as they do not put uncrewed aircraft on the G-register. A Gregistration is required for an Ofcom aircraft radio licence. The CAA have informed Skylift UAV that
 they are addressing this issue internally. Skylift UAV intend to maintain at least a listening watch on
 SAFETYCOM



13

Dear Louisa,

I do not support your extension, I do not see any benefit in doing these tests, except to gain more of the abundant Government grant money being wasted on very many similar drone transportation "trials".

The first thing you should be doing is certifying an autonomous detect and avoid system for BVLOS drones, this is the only long term solution to drone use, it is not acceptable to continue to have multiple TDAs across the country. It is also not acceptable to try to make other airspace users subsidise drone operations by making them all fit certain equipment, which would mean the drone operators can use a cheaper detection system as has been suggested by one drone operator.

Certification of an autonomous detect and avoid system should be done in a dedicated drone testing area that already exists, such as Salisbury Plain or Aberporth/Llanbedr.

Once this is certified and equipped drones can be permitted to be flown BVLOS in class G airspace, then all these type of trials can be started.

On your specific trial, I do not understand why a BVLOS drone flight needs to be used to asses vibration effects, this should be able to be done in a laboratory, or with a drone flown on a representative flightpath remaining in line of sight. This could be done anywhere and cause no disruption to other airspace users.

Surely there should be a specification of vibration effects that each drug can withstand, which is defined by laboratory experimentation and applicable to all forms of transport. Then each form of transport should be tested to be within the specification required for the drugs, again this can normally be done on a test rig or in a laboratory or dedicated testing area.

Best regards



Thank you for taking the time to respond to our request. We are sorry to hear that you cannot offer your support for an extension to our TDA.

We agree that TDAs are not a long-term solution and have been working with the CAA innovation team to help identify a more suitable solution for the future. Unfortunately working with the current regulations a TDA is required to ensure the aircraft is safely segregated whilst we test and mature the technology. We will ensure your comments are passed onto the CAA.

This trial is researching the delivery of critical chemotherapy medication to individuals receiving treatment on the Isle of wight, which has a transit time of 3-4hrs, whereas this technology would reduce this to approx 32 minutes. For us to complete this research we need to perform end to end delivery, which cannot be achieved in a laboratory or dedicated testing area.

We want to assure you that the TDA has been designed to minimise the impact on other airspace users, such as the height of the TDA which is 400AMSL over the solent and 750 AMSL over the Isle of Wight, and only activate the TDA when needed. We also have Letters of Agreement with the regular flyers on Thorney Island and HEMs to ensure they are still able to operate, as well as liaising with local aerodromes such as Goodwood and Solent.

If you would like to discuss this further, I am more than happy to schedule a telephone or video call with you.

Louisa

14.

In response to your request for our support for the drone trials for delivering drugs to St Mary's hospital, I can only repeat the response we gave on 13/3/2022 to your colleagues Alexander Trewby and Dr Sophie Barrack when you requested our support for the initial extension to the trial:

"It is unusual to be asked to positively support a trial and the associated airspace restrictions. Normally, a lack of objection is considered a form of support. The Sky Surfing Hang Gliding and Paragliding club have not objected to this particular UAS trial being conducted under ACP-2021-002, especially as the reason for it is potentially life saving.

The reason why we are not willing to positively endorse any trials involving BVLOS or autonomous drones, however worthy the reason for them, is that we have a concern that the increasing number of BVLOS trials is the thin end of a wedge that could ultimately lead to severe restrictions and increased risk of midair collisions for the General Aviation community, and the foot launched free flying community in particular.

So for this reason we will not be providing a positive endorsement of the trial. I hope you understand our position."



13 July 2022 at 15:10



Thank you for taking the time to respond to our email request. We appreciate your support of the trial, as do the NHS and welcome your feedback, whilst understanding your reasoning for not providing a positive endorsement. We will of course pass on your comments to the CAA.

We want to assure you that we will continue to only activate the TDA when needed to ensure minimal impact to the aviation community. We continue to work closely with the CAA innovation team to help identify a more suitable solution for the future which allows drone operations to be integrated with other airspace users and do not see TDAs as a long-term solution. Unfortunately, working with the current regulations a TDA is required to ensure the aircraft is safely segregated whilst we test and mature the technology.

If you would like to discuss anything in more detail with myself or my colleagues at Apian, please do not hesitate to contact me and I will be happy to schedule a time to do this.

Regards

Louisa

SouthamptonAirport

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