Emergency Medical Drone Delivery Project: Final Report
Location: Puerto Rico and Bahamas
Duration: July 2018 through June 2019
Key Partners: Merck & Co, Inc., Direct Relief, Volans-i, Softbox Systems, AT&T

I: Background

After Hurricane Maria, which struck Puerto Rico in September of 2017, nearly 3000 people lost their lives. The majority of deaths post-Maria did not happen as a result of traumatic injury or as direct consequence of the storm. Rather, they were attributable to the inability of residents, primarily those located in the island's more rural, mountainous or remote offshore areas, to access essential medicines and/or a healthcare provider. A significant number of those deaths were people who suffered from chronic illnesses prior to the storm, and experienced acute shocks due to their disconnection from the health system after the storm. In those cases, the elevated risk of mortality in the post-crisis context was largely attributable to the uneven geographic distribution of access to healthcare.

To reduce the risks that residents in Puerto Rico and similar locations experience due to the adverse effects of geographic limitations on access to healthcare during and after disaster situations, Merck & Co., Inc. initiated in early 2018 an effort to test the use of small unmanned aerial vehicles ("drones") to deliver essential medicines. The proof of concept aimed to traverse key routes from locations where medications may be stored, to areas that have high risk of experiencing reductions in physical access to medicines due to disaster. The supply hub for the initial flights in Puerto Rico was Merck's manufacturing facility at Las Piedras. The proposed recipient health center locations were Salud Integral en la Montana in Comerio and Adjuntas, as well as one of the sites of Health ProMed on Vieques Island. These sites were selected for their relative needs, their experience of being cut off from logistical assistance following Hurricane Maria, and their diversity of geography. Follow-up flights in The Bahamas traveled from the cargo hangar at the Abaco island airport to a landing spot on Green Turtle Cay, one of the "family islands" where citizens of The Bahamas live as full-time residents and receive health care from small community health centers.

Given the specific needs for proper management of cold chain medications, including such products as insulin and vaccines, the proof of concept flights in Puerto Rico transported a cold box produced by Softbox Systems to maintain small amounts of medication between 2C and 8C for several hours. The Softbox Systems Skypod is a validated container for cold chain medical transport, designed specifically to match the size and weight requirements of a small drone. A sensor package produced by AT&T was installed in the cold box to allow for remote monitoring of the onboard conditions of the temperature-controlled product. During The Bahamas flights the Softbox Skypods were loaded with dry ice to test their capability to maintain consistent temperatures between -60C and –80C, the temperature zone for "ultra cold" transport, which is required for some vaccines.

Over the course of three rounds of flight testing, three total point-to-point deliveries using the Volans-i VOLY C-10 hybrid vertical-takoff-and-landing (VTOL) aircraft to carry the Softbox Skypod with appropriate temperature controls and sensors were completed. These deliveries took place on Abaco Island in The Bahamas. They built upon a significant set of lessons learned from the initial two flight testing rounds which took place in Puerto Rico. This report details those lessons learned and makes a number of recommendations for implementation of future emergency drone delivery projects.

Figure 1: Softbox Systems Skypod with dry ice for -60C to -80C

(**NOTE:** For additional information specifically on the performance of the Softtbox Skypod please see the attached Appendix produced by Softbox Systems.)

II: Implementation Summary – Bahamas (June, 2019) and Puerto Rico (August, 2018 – January, 2019)

The proof of concept for connected-cold-chain delivery by drone took place in three phases: two flight testing rounds in Puerto Rico and one in The Bahamas.

Round 1: Flight route was intended to run on August 21-23, 2018 between Las Piedras, Comerio and Adjuntas. Permission could not be secured for beyond-visual-line-of-sight (BVLOS) flight so the flights we rescheduled to take place locally within Las Piedras and Comerio.

Round 2: Flight route was run on January 22nd, 2019 from mainland Puerto Rico to a landing spot on the island of Vieques. Drone flight was carried out successfully, but without the Softbox Skypod, which exceeded the allowable weight for vehicle and cargo combined under US FAA Part 107 regulations.

Figure 2: Volans-i VOLY C-10 vertical takeoff & landing aircraft

Round 3: Flight route was run from Marsh Harbour airport to Green Turtle Cay in The Bahamas. The initial plan was for flights to take place on June 5-6, 2019. However, due to significant customs clearance issues on all materials, the project needed to be delayed to allow for arrival of all materials into The Bahamas. Full customs clearance was obtained the following week. Three successful flights carrying the Softbox Skypods and dry ice cargo, maintaining temperature in the boxes effectively between -60C and -80C, were then completed on the 19th and 20th of June.

III. Implementation Detail – Bahamas

The flight route on Abaco Island in The Bahamas stretched from the cargo hangar at the Marsh Harbour airport to a small park on Green Turtle Cay. Total distance flown was just over 40km each way. Batteries were swapped out in Green Turtle Cay for the return flight to the Marsh Harbour airport. Each flight transported a Softbox Skypod loaded with dry ice and IoT device to maintain and monitor temperatures for deep frozen vaccines.

Figure 3: Flight route in The Bahamas – Marsh Harbour Airport to Green Turtle Cay

Once all customs and logistics issues could be resolved, the first day of flights was scheduled for Wednesday, June 19th at 9:30am. The core team from Merck, Softbox, Volans-i and Direct Relief was joined for these flights by representatives from The Bahamas National Emergency Management Agency (NEMA) and the Ministry of Health local office on Abaco, as well as two local health practitioners. One of the key actors present for these flights was the local company Hogfish Ventures, Ltd., a strategic operating partner of Volans-i based in The Bahamas. Hogfish, through their Fli Drone arm, was largely responsible for securing all flight permissions, managing significant portions of customs clearance procedures, establishing a base of operations at the Marsh Harbour airport, and maintaining an open channel of communication with air traffic control to ensure that drone flights could take place safely from the airport. It is worth noting that basing drone operations out a functioning airport rarely, if ever, occurs in humanitarian or commercial drone operations given the complexity of coordination. The role of Hogfish demonstrated the central importance of having strong local partners in drone delivery operations. The role of the local partner would have been even more substantially magnified during the event of an actual emergency.

Basing the flights out of the Marsh Harbour airport was an important decision in its own right. Drone flights are rarely if ever coordinated out of an active airport, which increased significantly the need for strong communications with air traffic control. These communications were managed very effectively by the combined efforts of the Hogfish Ventures and Volans-i teams.

Flight arrivals into Green Turtle Cay likewise had significant planning and coordination requirements. The landing area had to be scouted in advance by ground teams to assure that no obstacles existed which might pose a safety hazard. (Note: In the event of actual emergency operations, ground scouting may well not be possible, and would have to be substituted with some form of imaging solution, either via satellite or drone imagery.) One of the arrival flights into Green Turtle Cay was met with a DJI Phantom being piloted in the area, which meant ground teams had to manage deconfliction of the landing space by finding the operator and making a friendly request.

Basic Flight Data:

Leg 1- 19JUN19- Outbound From Marsh Harbor Airport to Green Turtle Cay- 25 NM leg- 32mins for leg- 48kts speed- 300' altitude
Leg 2- 19JUN19- Return from Green Turtle Cay to Airport- 25 NM leg - 35 mins- 48kts speed - 300' altitude
Leg 3- 20JUN19- Outbound from Marsh Harbor Airport to Green Turtle Cay- 25 NM leg - 33mins - 48kts speed - 300' altitude

The first set of flights on the morning of Wednesday, June 19th was successfully executed by the Volans-i team. Temperature in the Skypod was likewise maintained at a highly consistent -70C throughout the duration of loading, round-trip flight, unloading and preparation for subsequent flights. The afternoon flights had to be suspended given precautions regarding thunderstorm weather systems in the proximate area of the flight route. Although the thunderstorms did not end up crossing into the projected flight path, the Volans-i team prudently managed potential weather hazards. The outbound flight on Thursday morning was likewise executed successfully; however, the return flight had to be suspended due to a mechanical error in the transition from vertical to horizontal flight. Overall though the VOLY C-10 vehicle performed capably all aspects of flight operations, and displayed no discernible effects of wind or other environmental risks during the pivotal transition from vertical to horizontal flight patterns.

IV: Implementation Detail – Puerto Rico

The initial pilot flights were scheduled for the week of August 20, 2018. The plan for the week was to lead off on Monday, August 20 with a day-long conference / workshop on drone delivery for humanitarian aid and global health, followed by the Comerio and Adjuntas flights on Tuesday, August 21 and Wednesday, August 22, the Vieques flight on Thursday, August 23 and a brief wrap up seminar on Friday, August 24.

Volans-i, the drone manufacturer and operating team, was responsible for securing all permissions for the flights, including beyond visual line of sight (BVLOS), from the U.S. Federal Aviation Administration (FAA). Permissions became a significant issue, requiring rethinking of the flight plans and schedules.

BVLOS rights were not granted for any of the flights, which necessitated the use of spotters from the ground. The use of spotters over land between Las Piedras and either Comerio or Adjuntas proved to be logistically impossible. Therefore, the final flight configuration was to have only a single point-to-point delivery, between Las Piedras and Vieques (predominantly taking place over water), and then circular round-trip routes occurring entirely within Comerio and Adjuntas to simulate the terrain and distance which would have been required for the originally planned point-to-point flights at those locations. As originally planned, the one-way distances for each of these flights were roughly as follows:

- Comerio: 20km | Vieques: 43km | Adjuntas: 89km

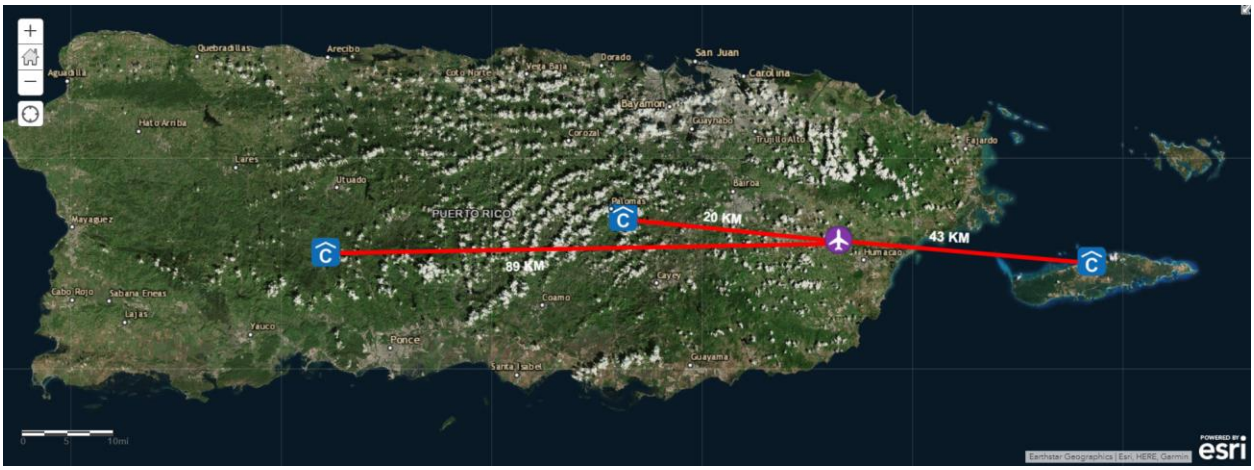

Figure 4: Planned flight routes in Puerto Rico from hub in Las Piedras

Direct Relief was required to determine how best to comply with the regulations specified by the *Drug Supply Chain Security Act* (DSCSA) to meet the pharmaceutical handling requirements of the test flights. Under DSCSA regulations any third-party logistics provider who wishes to transport pharmaceuticals must meet a set of common standards including employee background checks, standard operating procedures, and verifiable supply chain tracking. Two options were presented for the test flights – one, to on-board Volans-i as third-party logistics provider, or two, to operate receipt and handling of goods through an already certified third-party logistics provider in Puerto Rico. In early August Direct Relief decided that on-boarding Volans-i to meet DSCSA requirements would be too cumbersome to accomplish in the short term, and therefore that a third-party firm would need to receive the incoming drug shipment and provide storage of goods received until the flights take place. Cardinal Health, which operates a logistics facility outside of San Juan, was the third-party logistics firm selected. All drugs for drone delivery, as well as the Softbox units, were shipped to Cardinal Health for scheduled pickup by Direct Relief and handed off to Volans-i on the day of the flights.

Prior to the week of August 20th there was a last-minute complication when the Volans-i team reported that their VOLY C-10 platform vehicle was experiencing technical difficulties of an unspecified nature, most likely due to extreme heat at their testing facility in Arizona. The vehicle would not be ready for the upcoming week's flights. Its shipment to Puerto Rico was canceled. As of the morning of August 20 it was not clear whether Volans-i would be able to carry out any flights at all during the week. The group decided to have Volans-i bring a smaller multirotor drone capable of meeting the weight, but not the distance requirements, to Puerto Rico for the Comerio flight, and to postpone the Vieques flight until a

later date when the VTOL platform met all maintenance and safety checks. A local Puerto Rican drone company (Drones de Puerto Rico) was recruited to perform an alternate set of flights at the Comerio location and at the Las Piedras facility, carrying the Softbox with a modified DJI 100 platform in order to provide redundancy in the event of additional technical issues with Volans-i and the ability to make a separate claim about the drone platform independent of the Softbox.

The Monday conference / workshop accomplished all core requirements. The agenda for this event included a range of in-person and invited guest speakers who joined by Skype, including:

- *Andrew Schroeder* of Direct Relief, who covered the global history and emergent best practices of medical and humanitarian drone delivery
- *Sid Rupani* of Llamasoft, who focused on the economics of sustainable drone delivery systems
- *Jennifer Fluder and Sara de la Rosa* of USAID who recounted the creation of USAID's drones for global health coordination mechanism
- *Olivier Defauwes* of Village Reach, who relayed a drone delivery case study from Malawi
- *Hannan Parvizian* of Volans-i, who detailed the regulatory and safety requirements for drone delivery including the authorization for flight beyond visual line of sight (BVLOS)
- *Richard Wood* of Softbox, who detailed the cold chain and internet-of-things dimensions of the project

With the decision to reorganize the week's flights to accommodate technical issues with Volans-i, Tuesday was devoted to logistical reorganization, visitation to the Cardinal Health facility to determine best medical material handling practices, and close attention to the AT&T IoT platform. Wednesday was devoted to the Comerio flights, including media coverage on site. Thursday was devoted to brief demo flights and a media event at the Las Piedras facility. Friday was then spent manually transporting the AT&T Softbox to Vieques to complete the test monitoring of the sensor, as well as debrief at Las Piedras. The longer Vieques flight was postponed until technical and scheduling issues could be sorted out.

The flight around Comerio was the only one worth noting from a cargo delivery point of view. The launch point in Comerio was a soccer field near the main town. Volans-i located spotters in the hills above the field. The VOLY C-5 multi-copter (drone with 8 propellers) was loaded with the Softbox which contained four vials of insulin in their original packaging. The material remained constantly between 2C and 8C throughout all parts of the flight procedure. The drone flew an automated route around the circumference of the hills. No technical failures were reported. Unfortunately Drones de Puerto Rico was unable to complete a flight in Comerio due to lack of propellers on hand; however, they were able to demonstrate a method for attaching the Softbox to an M100 drone in place of the VOLY C-10. Later during the Las Piedras demo flights they demonstrated that the M100 can fly with the Softbox attached, opening up the possibility of a localized, platform-independent approach to aerial cold chain logistics.

During the week of January 21, 2019, a final attempt was made to carry out inter-island delivery between mainland Puerto Rico and a health center on Vieques. The intent of this effort was to use Volans-i's VOLY C-10 platform to carry the Softbox along with IoT device and 8 vials of insulin primarily over water, landing in the middle of Vieques island. The completion of this delivery would have demonstrated a key post-disaster use case given that remote islands are among the most at risk of supply disruptions due to extreme weather and other disasters. Unfortunately, although the VOLY C-10 itself was air worthy and capable of making the flight, the weight of the aircraft and batteries was 54.9

pounds. Given the legal limit according to US FAA Part 107 regulations of 55 pounds for commercial drone flights there was no possibility to carry the medical cargo in and around Puerto Rico.

V: Lessons Learned and Recommendations

The key areas for lessons learned from test flights in The Bahama and Puerto Rico have to do with regulation, preparation, localization, available data, and coordination.

- Unmanned Flight Regulations

    - Drone Flight: The ability to secure permissions to fly, including BVLOS, in a quick and efficient manner is a significant stumbling block to any implementation of emergency drone cargo flights. Outside of FAA airspace, in The Bahamas, BVLOS permissions were not a problem, based on coordination through Volans-I's local partner. Although Volans-i was able to secure line of site permissions in Puerto Rico, no BVLOS permission was granted in the case of Puerto Rico, which in turn necessitated the use of spotters. There are diminishingly few reasonable circumstances in actual emergency situations where the use of spotters would be preferable to figuring out an alternate ground or water based logistical method. Presumably some form of waiver could be agreed to with the FAA to authorize flights during an emergency. However, as of now no such waivers have been granted, nor is there a clear process for obtaining them.

      Action item: Development of a standard process for issuance of emergency drone flight waivers should be a priority in the upcoming year. Identification of the proper actor to negotiate such waivers should also be considered a priority. NGOs could conceivably apply for FAA waivers individually, or an organization like the Partnership for Quality Medical Donations (PQMD) could in theory advocate across individual cases for broader waiver provisions.

- Logistics and Customs Clearance

    - Emergency drone delivery, much like the proof of concept activities, may involve significant logistical coordination of technology and other goods coming into the country where operations will take place. During emergency response activities in particular, logistical blockages alone are often the difference between success and failure. Although Puerto Rico did not raise the issue of customs clearance given that everything was sourced from the United States, in the case of The Bahamas PoC significant customs issues arose with virtually every part of the project.
    - Drone Technology: During The Bahamas PoC, Volans-i encountered customs constraints on the export level from US Customs and Border Patrol based on their third-party logistics provider having failed to obtain proper export control permissions. The lack of these permissions blocked the drone technology from departing the US in Miami, despite having secured appropriate import permissions in The Bahamas.
    - Medical Material: The Merck donated vaccines were blocked upon entry into Marsh Harbour, Bahamas. This was due to the lack of a pre-established partner in the country and the related lack of an official letter of approval from the MoH prior to arrival.

- Softbox Skypods: The cold boxes were held in customs at Marsh Harbour, largely due to their association with the vaccines and the project overall. The vaccines were held the previous day, therefore when the Skypods were noted as part of the same project customs officials exercised an unusually strict level of caution in blocking the boxes from entry as well.
- Dry Ice: The dry ice could not be obtained locally and therefore had to shipped in to coincide with the arrival of all other materials. The ice was detained briefly in Nassau customs and had to be sent separately to Abaco, delaying its arrival.

  Action Item: All emergency drone delivery projects should establish a detailed logistics and customs plan and checklist, shared between all relevant parties who may be responsible for different aspects of logistics and customs, well prior to arrival of teams and goods in country. Not all customs issues can be resolved beforehand, but a detailed understanding of what risks may exist can be a significant help in flagging and resolving them in a timely manner.

- Pharmaceutical Handling Regulations:

  - Compliance: The capability to act in accordance with all appropriate and relevant pharmaceutical handling regulations, including the development of standard operating procedures ensuring such compliance, is a core element of any emergency drone logistics effort that involves carrying pharmaceutical or other medical cargo. The method for accomplishing such compliance in the case of the initial Puerto Rico test flight was to route in country handling through a verified third-party logistics firm, Cardinal Health. This need not be the only way to accomplish effective regulatory compliance in the future.

    Action item: Develop a framework to normalize assurance that drone cargo providers meet DSCSA standards, and creation of workflows for NGO-based importation and handling which might internalize regulatory compliance all the way to the desired end point for drone flights.

- Project Preparation

  - Routine services: Perhaps the most challenging aspect of emergency drone flights is the lack of standard, regularly used, routes for delivery. In most cases, as of now at least, no standard services exist for medical (or non-medical) drone logistics. Therefore, in the event of emergency there is no pre-existing standard, such as exists for manned aviation, which can easily be applied to drone flights.
  - Regularization of activities: One of the key recommendations that emerges from this pilot project and should be fleshed out in detail in future projects is that **prior to emergency efforts, standard drone logistics systems should be implemented and thoroughly tested.** Such implementation requires broad multi-stakeholder cooperation, between regulators, drone logistics providers, emergency management, NGOs and healthcare providers. By developing systems for routine delivery, the threshold may be

lowered to the issuance of waivers in the event of emergency simply based upon the existence of an extensive and well-documented track record of safety and reliability.

- Emergency protocols: Parallel to the creation of routine systems prior to emergencies which may establish a formal track record upon which emergency waivers might be based.

  Action item: The creation of a preliminary set of emergency protocols ought to be considered. This set of emergency protocols might take the form of a checklist which contains an accounting of all key aspects, from technology to flight planning to regulations, communications and coordination. The checklist so developed should likewise be endorsed by major parties to the emergency drone logistics system and distributed widely to those likely to engage in such efforts in the future. One model for the development of such a standard which should be consulted in the Humanitarian UAV Code of Conduct (http://uavcode.org) which lays out a clear set of standards in the data collection and mapping fields for safe, ethical and effective use of drone technology during disasters and other humanitarian response events.

- Open Data and Transparency

  - Ease of Comparability: Drones are highly variable in terms of air frame, technical specifications, manufacturer reliability and other factors. Cargo delivery drones in particular are still at early stages of development where they are not cheap or ubiquitous enough to be considered a widespread commercially accessible technology. Reliable data on all key factors of cargo drone delivery operations is therefore in relatively short supply. Open data on drone operations should be considered a high priority to ensure that some reasonable measures of comparability across models and use cases can be established. (**NOTE**: Additional information may be available upon request.)
  - Expertise Gaps: One key point to recognize about drone technology as opposed to other types of (information and communications technology) ICT for aid and development is that despite significant recent gains in the safety and accessibility of this technology they do tend to fall outside of the common forms of technical understanding found within NGOs and other humanitarian agencies. This is perfectly understandable insofar as prior to the existence of small, cheap commercial drones NGOs, apart from perhaps the World Food Programme's humanitarian air service, have not had significant incentives to engage with aerospace technologies of any kind.

    Action Item: A database of drone vendors should be created that contains open data on their flight records for cargo operations to facilitate useful knowledge. A mutually agreed-upon set of key telemetry indicators should be conveyed from flight logs, as well as any possible emergency response experience. Additional data may be available upon mutual agreement.

    Action Item: An independent organization or consortium of experts should be engaged on an advisory capacity to guide decision-making around implementation of drone

cargo delivery projects. The role of this independent advisory group should be to provide input into immediate decision frameworks, for example guidance for evaluating appropriate partners based on needed skills and proven technology capabilities to meet project requirements, and to build knowledge and capacity within NGOs.

- Localization of Services

    - Routine services: Importation of drone technology and services during emergencies is potentially at odds with the goal of establishing standard services prior to emergencies which provide a firm foundation of safety and reliability. Although the relative portability of drone technology is a strength and a selling point, in order to operate systems with confidence during emergencies the better option is to have ongoing local services which may be drawn upon or amplified during times of crisis. The business model, ownership structure and organizational form of such local services may be highly variable, just as is the case today with other shipping and logistics services, but nevertheless the emphasis should be placed upon localized services rather than importation of technology and expertise.
    - Reduced costs: Additionally, localization of routine services is far more likely to bring about needed reductions in costs, which under current circumstances may be quite high even for technology which has not been thoroughly tested or vetted under emergency conditions. The initial steps taken during the drone tests outlined above to engage local actors such as Drones de Puerto Rico might reasonably be built upon in the future by expanding the role of local actors in drone cargo services.

      Action Item: Develop and share a database of local drone operators per country.

- Project Coordination

    - Multi-stakeholder models: Emergency drone cargo logistics is an inherently multi-stakeholder process. As such, effective implementation requires effective coordination between key stakeholders. Coordination involves communications with and between public authorities including aviation and emergency management, deconfliction through air traffic management, and engagement between drone operators, healthcare providers, response agencies and affected communities. The World Food Programme (WFP), to cite one example, has been working over the past two years to develop models and protocols for effective drone coordination during humanitarian response operations. Likewise, USAID with the support of such organizations as UNICEF and the Bill & Melinda Gates Foundation has been working to establish a funding and donor coordination mechanism for drones in global health, which may also prove to be a forum for establishment of health cargo-specific coordination models.
    - Simulation exercises: To ensure that such coordination models may be understood and tested prior to emergencies it would make sense to conduct one or more simulation exercises aimed specifically at operating drone cargo logistics workflows as closely as

possible to the ways that such workflows would be operated during an actual event. Such simulation exercises, in addition to providing valuable data and feedback for the refinement of operational models also serve as effective testing grounds for coordination between key stakeholders, many of whom may never have engaged in this specific practice before.

Action Item: Either individually or through multi-stakeholder coordination NGOs should more directly engage with existing humanitarian UAV coordination efforts.

Action Item: One or more humanitarian UAV emergency simulations should be developed between multiple NGOs and other stakeholders in order to test proposed emergency protocols and develop new knowledge and capacity. Nethope's humanitarian ICT trainings and simulation exercises could be a good general model.

VI: Conclusion

Between the PoC activities in Puerto Rico and The Bahamas, and in the context of other projects undertaken in many other parts of the world, it is now safe to say that the technology required for useful emergency drone delivery projects is well on the way towards maturity. It is also safe to say, however, that the regulatory, coordination and logistical hurdles which need to be overcome in order to undertake drone delivery projects during emergencies remain substantial. During the round 3 flights which took place in Bahamas, Volans-i was able to demonstrate that with access to clear airspace, the presence of all necessary materials, and the on-site presence of a reliable ground control team, regular BVLOS drone delivery should not be considered a significant technical challenge any longer. Nevertheless, each of those requirements did in some way, throughout the PoC, pose quite significant operational challenges, and in some cases halted operations altogether. This was true for a well-defined and controlled proof of concept experiment. It would be even more true during emergency response.

What is clear then based on this PoC is that the next phase of drone delivery testing for emergencies needs to move forward from technical testing (i.e. – assurance that the flights themselves will work as planned) to operational testing (i.e. – assurance that workflows exist to control for the myriad of factors which will confront operators during emergency response activities). Key areas of focus in that operational testing environment should include workflows which approximate regular drone flights, including the ability to safely and efficiently set up logistics corridors; coordination with all key stakeholders for effective regulatory engagement; compliance with prevailing codes of conduct and laws governing supply-chain tracking; cultivation of community contacts to ensure bottom-up support; and regular, transparent evaluation based on open data. NGOs, governments, corporate donors and other actors can look forward to an exciting and in many ways path-breaking future for humanitarian logistics if these operational factors can be managed at the same level of which the technology itself is capable.