Project Pitch Document

Project name

Carbon monoxide poisoning treatment, research and development of production technique

Fellow(s)

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Contribution: Tarek will contribute the entire budget (USD$100,000)

Short description

The ClearMate is an off-patent device by Thornhill Medical that represents a novel way to treat carbon monoxide poisoning. This device has undergone nearly 20 years of development, with the first paper describing its action by anaesthesiologist and inventor Joe Fisher in 1999. Thornhill Medical is prepared to allow Glia to document the bill of materials, production steps and quality assurance tests so that the device is more widely accessible and can be available, especially in low-resource settings. This project will seek to turn this commercial device into an open source medical device.

Objective(s)

- Complete legal work required to allow the transfer of ClearMate into an open source repository
- Document Bill of Materials
- Document all necessary regulatory requirements for Health Canada, FDA and potentially CE
- Document production process
- Document quality assurance testing required to ensure the device is well-functioning
- Document maintenance requirements
- Certify device via Health Canada for use in Canadian hospitals
- Use the device in clinical trials for the Pulse Oximeter’s carbon monoxide sensor (carboxyhemoglobin)

- Co-train Gaza office engineers in device engineering and production
- Co-train Tunisia office engineers in device engineering and production
- Create and sell devices where agreed by Thornhill Medical under a specific non-compete

Link to scope of fellowship(s)

The fellowship scope includes providing access for high-quality low-cost mission-critical devices for the improved health of patients. The ClearMate is an innovative way to treat carbon monoxide poisoning, and its confluence of expired patent and socially conscious inventor makes it an ideal test case for transitioning a commercial device to open.

Context

The use of a carbon dioxide–oxygen mixture known as carbogen appeared in the literature in the early 20th century as a response to increased carbon monoxide poisonings from urbanization and the use of combustible fuels domestically and industrially. The efficacy of this treatment was proved at the time and remained the standard of care until the 1960s.

During the 1950's and 1960's, a body of literature developed demonstrating the comparative superiority of hyperbaric oxygen to carbogen or pure oxygen. In this setup, a victim is placed in a sealed chamber with high-pressure oxygen at up to three times the atmospheric pressure (304 kPa). While the standard of care shifted to hyperbaric oxygen, it became clear over the proceeding decades that the real-world conditions, long preparation times and high costs involved in initiating hyperbaric oxygen made the actual treatment outcomes no better than no treatment at all.

Starting in the late 1990s, several independent teams began to speculate and prove experimentally that carbogen delivered with the patient in a hyperpneic state (breathing quickly) was equally effective to hyperbaric oxygen while reducing barriers to treatment. The ClearMate was subsequently developed by Thornhill Medical to capitalize on these research findings.

The ClearMate was poorly received by the FDA because it represented a new treatment modality for a serious condition. It took until March, 2019 for the ClearMate to finally be approved for use by the FDA. During this time, the patent on the ClearMate (US8459258B2) was abandoned.

With the Patent abandoned, Thornhill Medical stands to gain significantly by allowing the Glia project to partner with them and release the device as open source. In so doing, more understanding, use and demand will be created for the device, which will drive sales to Thornhill Medical. As well, the device will be available to other care providers and researchers who do not have access to Thornhill Medical products.

Intended beneficiaries

- Ministry of Health (Gaza) – creation of needed medical devices for treating a critical condition
- Ministry of Health (Tunisia) – creation of needed medical devices for treating a critical condition
- Glia Gaza office – co-training in device engineering and production
- Emergency Department, London Health Science Centre – field testing and utilization of devices
- Southwestern Ontario Base Hospital Program – field testing and utilization of devices on ambulances.
- Thornhill Medical – increased demand for an abandoned device as well as increased incentive to release further devices.
- General public due to improved care with carbon monoxide poisoning

Strategic partners

- Ministry of Health (Gaza)
- Ministry of Health (Tunisia)
- Glia (Gaza)
- Emergency Department, London Health Science Centre
- Institute IRNAS in Slovenia for development and documentation of processes
- Thornhill Medical for providing process and material information

Boundary players

Boundary players are listed below in order of disruption as a function of ability and likelihood.

- Coordination of Government Activities in the Territories (COGAT) – Israeli unit responsible for blockade
    - Might deny project members entry to Gaza
    - Might deny equipment entry into Gaza
- Ministry of Interior (Israel)

    - Might deny project members visas to enter Israel
- Israel Security Agency (aka Shin Bet aka Shabak)
    - Might declare project members as terrorists
- Canadian Security Intelligence Service / Royal Canadian Mounted Police (CSIS/RCMP)
    - Might define work in Gaza as falling within Bill C51 (The Antiterrorism Act)
    - Might order confiscation of laptops / electronics
- Canadian / Gazan physicians
    - Might consider device unusable or "amateur" as compared to commercial offerings
- Health Canada
    - Licensing barriers might create down-time in projects in Canada and Gaza
- Food and Drug Administration (US FDA)
    - Licensing barriers might create down-time in projects internationally
- Conformité Européenne (CE)
    - Licensing barriers might create down-time in projects internationally

Methodology and activities

Production research and development

The ClearMate's original manufacturer, Thornhill Medical, is willing to participate in the open-sourcing of the ClearMate. As such, Glia will engage with Thornhill Medical and IRNAS to clearly document in an accessible and reproducible way the following:

- Bill of Materials
- Production process
- Manufacturing files (CAD, etc.)
- Legal requirements
- Regulatory requirements
- Post-production quality assurance tests
- Post-production maintenance
- Usage and instructions manuals
- Training guide

Validation

The device is already validated, but will be field-tested to ensure that the quality of the devices produced by the open process meet the same requirements as the proprietary device.

Manufacturing

The Glia offices in Gaza and Tunisia will collaborate with the respective Ministries of Health in the two regions to manufacture devices for local hospitals and ambulances. In Canada, manufacturing will be done in collaboration with IRNAS and Thornhill Medical for use in the London, Ontario catchment area.

Because the number of units needed for a given hospital are low, it may not make sense to train other Canadian hospitals to create additional units. Instead, units for Canadian use will continue to be manufactured and marketed by Thornhill Medical.

Should Thornhill Medical completely abandon the device, Glia can produce it with the help of IRNAS.

Clinical training

The deployment of devices in Gaza and Tunisia will be coordinated with an educational program for paramedics, nurses and physicians through the Ministry's Human Resources Department, the department responsible for training and education of Ministry employees.

In London, Canada, the system will be deployed through the South West Ontario Base Hospital Program, the medical unit that trains and directs paramedic care in the region. Respiratory therapists, nurses and physicians in London Health Sciences and other affected hospitals will be trained on the device's use as well.

Outputs and deliverables

Carbon monoxide treatment device production

The main deliverable will be an open access carbon monoxide treatment device that is quality-controlled and ready for use in Canada and abroad. This will be done by collaborating with IRNAS and Thornhill Medical and will output the following:

- Bill of Materials
- Production process
- Manufacturing files (CAD, etc.)
- Legal requirements
- Regulatory requirements
- Post-production quality assurance tests

- Post-production maintenance
- Usage and instructions manuals
- Training guide

Personnel development

This project should help develop engineers in Tunisia and Gaza as part of the co-development process. It will also provide the Canada office with relevant experience on producing a mechanical class 2 medical device.

Time frame

Two years. Start date is effective immediately.

Resources and budget

Development by IRNAS in Slovenia

- 10,000EUR for coordination with Thornhill Medical
- 25,000EUR for documentation efforts for items in “Outputs” above
- 5,000EUR for project management

Collaboration by Thornhill Medical

- USD$10,000 for project management
- USD$10,000 for compensation of lost engineering time
- USD$15,000 for legal costs related to the project
- USD$10,000 for travel related to quality assurance in target countries

Development and deployment costs for Glia in Gaza and Canada

- USD$10,000 for prototyping and initial testing
- USD$5,000 for field trials-related costs
- USD$10,000 for Health Canada regulatory approval

Measures of success

What changes in behaviour do you expect to see?

1. Independence of the engineers in Gaza and Tunisia to manufacture devices
2. Use of carbon monoxide poisoning treatment early in the injury timeline in pre-hospital (ambulance) and emergency patients in Canada, Gaza and Tunisia

What changes in behaviour would you like to see?

1. Independence of the engineers in Gaza to create, research and engineer devices
2. Deprecation of hyperbaric chambers for carbon monoxide poisoning

What changes in behaviour would you love to see?

1. The wide manufacture of carbon monoxide treatment devices beyond the Glia team. That is, the carbon monoxide treatment device project adopted and built by projects that have no direct connection to our team
2. The demonstration of feasibility to allow other proprietary manufacturers to release their off-patent or abandoned devices as open source

Communication strategy

Intra-group communication will be done using Github, Mattermost, Kanboard, email and in-person meetings.

External communication will be via academic publication, twitter, facebook, instagram and public talks internationally.

Sustainability strategy

The low cost of carbogen-based carbon monoxide poisoning treatment as compared to hyperbaric chambers should make this project easy to adopt for most Ministries of Health. To ensure long-term success, it will be essential to leave behind a team of competent users and engineers in each region where devices are deployed.

So long as Thornhill Medical continues to manufacture ClearMate devices, there will be no specific need to manufacture them. However, the capacity to manufacture will allow Glia or its

affiliates to take over production if Thornhill Medical fails, discontinues the device, or increases the price dramatically.

Risks

The main risks for this project are:

1. Change in Thornhill Medical's willingness to participate in this project
2. Unexpected delays in creating the outputs
3. Change in IRNAS's ability to participate in this project
4. Gaza-based personnel being targeted by Israeli authorities for perceived anti-Israeli activities
5. Gaza-based personnel being targeted by Palestinian authorities for perceived anti-Palestinian activities
6. Lack of buy-in from paramedics, respiratory therapists, physicians, nurses or engineers in Gaza, Tunisia or Canada
7. Regulations and export limits on electronics components export and use for Gaza and Palestine

Our team intends to mitigate the risks in the following way:

1. Careful adherence to best practices in project management, including task lists, a dedicated project manager and regular follow-up meetings to assess progress through milestones
2. Ensuring that our objectives are clear and cannot be misinterpreted by potential adversaries and armed factions
3. Early, continuing and thorough engagement with stakeholders such as paramedics, respiratory therapists, nurses, physicians and biomedical engineering departments in all target institutions and ministries
4. Positively promoting Thornhill Medical's role in what appears to be a historic decision to release a previously closed device as open source