Project idea form - small projects

Version 2.1

Registration no. (filled in by MA/JS only) _____

Project Idea Form

Date of submission 28/05/2025

1. Project idea identification

Project idea name	AI-Optimised Cryoprobe for Opioid-Free Pain and Spasticity Treatment
Short name of the project	CryoAI
Previous calls	yes ◯ no ◉
Seed money support	yes ◯ no ◉

2. Programme priority

	1. Innovative societies

3. Programme objective

	1.2. Responsive public services

4. Potential lead applicant

Name of the organisation (original)	Copenhagen Medical Cryo ApS (technical coordinator until public lead is confirmed) Lead partner to be identified from public institution in BSR
Name of the organisation (English)	Copenhagen Medical Cryo ApS (technical coordinator until public lead is confirmed) Lead partner to be identified from public institution in BSR
Website	*(max. 250 characters incl. spaces)*

Country	DK
Type of Partner	Small and medium enterprise
	micro, small, medium enterprises
Contact person 1	
Name	René Kestenholz
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Contact person 2	
Name	*(max. 100 characters incl. spaces)*
Email	*(max. 100 characters incl. spaces)*
Phone	*(max. 100 characters incl. spaces)*

Which organisation(s) in the planned partnership take part in a project within the Interreg Baltic Sea Region Programme for the first time? Please list the respective partners.

All currently confirmed partners-Copenhagen Medical Cryo ApS (DK), Copenhagen Cryo Center (DK), Hvidovre Hospital (DK), and Technical University of Denmark (DTU)- are first-time participants in the Interreg Baltic Sea Region Program.

5.1 Specific challenge to be adressed

Chronic pain and spasticity impact not just bodies, but entire lives. In the Baltic Sea Region, many people live with constant pain that limits movement, interrupts sleep, and erodes daily functioning. Often, they are offered little more than morphine-based medication – fast-acting, but long-term problematic. Opioid dependency has quietly become a secondary crisis for people who never asked for anything but relief.We believe there must be a better way. Cryoneurolysis – the targeted freezing of overactive nerves – has shown great promise as a non-opioid method. But it is held back by inconsistent results, outdated technology, and lack of clinical validation. Public hospitals need safer, smarter tools.A 2025 editorial in Anesthesiology points to the core issue: current cryo systems fail to control thermal effects precisely, leaving clinicians uncertain and patients underserved.Our challenge is clear:To test and validate an improved cryoprobe system in real clinical settings, with feedback from professionals and patients;To develop standardised, CE-aligned protocols that can help public clinics adopt the method responsibly.This is not just about devices. It’s about dignity. About helping people move without fear, sleep without pills, and reclaim their everyday life.Sources: EFIC, European Pain

Alliance, Global Burden of Disease Study (2019), ECDC Opioid Reports, Ilfeld & Prologo (Anesthesiology, 2025).

5.2 Focus of the call

This project is for the people who fall through the cracks – those whose pain is not urgent enough for surgery, but too severe to ignore. For the nurses and clinicians who want to offer more than pills, but lack the tools. For regional hospitals looking for safe, effective therapies that don't come with addiction risks.We want to bring a validated cryotherapy solution into public clinics. The cryoprobe system is based on newer technology, with improved thermal control and usability. But even the best tools need the right conditions to work – which is why this project focuses on developing shared clinical protocols, user guidance and CE-aligned documentation.Through cross-border pilot testing, we aim to validate not just the device, but the pathway: how to introduce cryoneurolysis responsibly into care routines for chronic pain and spasticity. The method is non-invasive, repeatable and relatively low-cost – but it must be proven under realistic public healthcare conditions.Responsive public services mean more than digital dashboards. They mean helping people manage their pain before it becomes a lifelong dependency. That's the future we want to help build.

6. Transnational relevance

Chronic pain and spasticity affect millions of people across the Baltic Sea Region, and the burden is growing. Despite differences in healthcare structures, all BSR countries face a shared challenge: to help patients who live with persistent pain while reducing dependence on opioids.This project addresses that challenge by enabling a shared clinical protocol for cryoneurolysis – a non-opioid method that has shown promise but remains underused. Cryoneurolysis is often limited to private practice or experimental use due to inconsistent outcomes and lack of thermal control. In public hospitals, clinicians lack access to validated systems, protocols or data. This results in unnecessary suffering, reduced function, and opioid-based treatment as the default.The project cannot be solved within national borders. Protocols must be developed collaboratively and validated under different public healthcare conditions – urban and rural, large hospitals and smaller clinics – to ensure broader relevance.Beyond technical impact, the human goal is clear: to give clinicians a safe, evidence-based tool that can relieve pain, restore function, and reduce reliance on morphine-based medication. It is a shared responsibility we believe can best be tackled together.

7. Specific aims to be adressed

Building trust that could lead to further cooperation initiatives

Public trust in new therapies grows when results are predictable, methods are transparent, and systems are easy to implement. By working across borders, and combining expertise from hospitals, SMEs and academia, we aim to build a shared clinical model for non-opioid cryoneurolysis. The cryoprobe system will be tested under realistic conditions, with full documentation and feedback from public-sector professionals.

Initiating and keeping networks that are important for the BSR

Pain care is complex, and sustainable innovation depends on strong, lasting relationships between developers and users. This project connects stakeholders who rarely collaborate: cryotech engineers, university researchers, frontline clinicians and regional innovation agents. Our goal is to form a cross-BSR alliance that can continue developing, refining and applying non-opioid interventions – even after the project ends.

Bringing the Programme closer to the citizens
In smaller hospitals and regional rehab units, patients often wait months for access to specialist care – or receive strong painkillers as a quick solution. Our project aims to bring precision therapy closer to where people live. By validating the system in local clinics and standardising training, we help empower healthcare workers with a tool that is safe, transportable and affordable.

Allowing a swift response to unpredictable and urgent challenges
Pain is unpredictable. It can appear suddenly, last for years, and spiral into dependency, isolation or loss of function. We want to give public health systems a faster, safer way to act before pain becomes crisis. With validated tools and ready-to-use protocols, local clinics can respond quickly and effectively – even without waiting for large-scale reforms. Our cryoprobe is just one tool, but we hope it can be part of a bigger shift: acting early, acting safely, and giving people back control over their bodies and lives.

8. Target groups

The primary target group is public hospitals and rehabilitation clinics treating patients with chronic pain and spasticity. These include large regional hospitals as well as smaller municipal facilities that often have limited access to advanced pain care methods.We aim to engage clinicians, physiotherapists and pain nurses who are directly responsible for patient care and protocol implementation.Universities and technical research institutions are also key. They help define clinical endpoints, validate sensor data, and co-develop standard operating procedures.DTU, for example, will provide thermal modelling and risk analysis. Such partners are crucial to ensuring that the technology works not only in theory, but in real clinical workflows.Regional innovation agencies and public health authorities represent another vital group. Their role is to ensure that validated methods can be adopted across systems, supported by CE documentation and aligned with health priorities.Finally, we consider patients and user organisations as core stakeholders. They are not passive recipients of care, but active participants. Their feedback on safety, usability and treatment effect will directly inform the final output – because at the centre of everything we do is the person we want to help.

	Please use the drop-down list to define up to five target groups that you will involve through your project's activities.	Please define a field of responsibility or an economic sector of the selected target group	Specify the countries and regions that the representatives of this target group come from.
1.	Hospital and medical centre	Public clinics for chronic pain and spasticity care; clinical test sites and validation partners	Denmark, Lithuania, Poland, Finland (regional hospitals and rehab centres)

2. Higher education and research institution	Thermal modelling, safety thresholds, CE-relevant data, cross-border protocol co-design	Denmark, Estonia, Finland
3. Regional public authority	Health service innovation, care integration, scale-up of validated methods	Estonia, Lithuania, Poland
4. Interest group	Patient advocacy, usability feedback, non-opioid rehabilitation pathways	Denmark, Poland

9. Contribution to the EU Strategy for the Baltic Sea Region

Please indicate if your project idea has the potential to contribute to the implementation of the Action Plan of the EU Strategy for the Baltic Sea Region (https://eusbsr.eu/implementation/).

yes ◉ no ◯

Please select which policy area(s) of the EUSBSR your project idea contributes to most.

PA Health
PA Innovation
PA Education

The MA/JS may share your project idea form with the respective policy area coordinator(s) of the EUSBSR. You can find contacts of PACs at the EUSBSR website (https://eusbsr.eu/contact-us/).

☐ If you disagree, please tick here.

10. Partnership

The partnership is initiated by Copenhagen Medical Cryo ApS (DK), a medtech SME developing the cryoprobe system and coordinating the overall project. CMC is supported by three confirmed partners:– Hvidovre Hospital (DK), a public rehabilitation clinic with expertise in chronic pain and spasticity– Copenhagen Cryo Center (DK), a private pain clinic with long-standing clinical experience in ultrasound-guided cryoneurolysis– Technical University of Denmark (DTU), a research institution providing thermal simulation, modelling and safety analysis related to ice zone control and CE-prepThese partners bring together technical, clinical and scientific expertise within Denmark. All are

first-time participants in Interreg Baltic Sea Region. While the initial focus is national, their skills, networks and outputs are designed to benefit the wider region.We are now preparing to expand the partnership to include public hospitals or research organisations in at least two other BSR countries – such as Lithuania, Estonia, Poland or Finland. These new partners will participate in pilot testing, help adapt protocols to local contexts, and provide insight into regulatory and clinical integration in their health systems.Our goal is not to build a large consortium, but a practical, committed and complementary one. Public lead partners are especially welcome, and we invite the Managing Authority and national contact points to advise and support this process.The rationale for this partner mix is simple: to ensure that both the technology and its application are grounded in real-world needs. We are combining the agility of an SME with the rigour of academic validation and the daily reality of front-line care. Together, we hope to create a shared model that can help public health systems respond to chronic pain with dignity, precision and less reliance on opioids.

11. Workplan

The workplan is structured around four main pillars:
(1) protocol development,
(2) clinical pilot validation,
(3) CE-preparation, and
(4) knowledge sharing and training.

1. Protocol development:
The partners will co-develop a shared, CE-oriented clinical protocol for cryoneurolysis in pain and spasticity care. This includes patient selection criteria, safety thresholds, standard procedures and documentation flows. DTU will support thermal modelling and system validation. CCC and Hvidovre Hospital will adapt clinical workflows for realistic public use. This work ensures the technology can be integrated into diverse health systems.

2. Clinical pilot validation:
The system will be tested at pilot sites in Denmark and at least one additional BSR country (e.g. LT, PL, FI). The aim is not to run a full RCT, but to generate evidence of safety, usability and user satisfaction. Professionals will use the cryoprobe during real procedures, provide structured feedback, and help define optimal parameters. This is crucial for building confidence among practitioners and demonstrating value under public care conditions.

3. CE-preparation:
Based on technical and clinical results, the partners will create key CE documents: clinical evaluation, risk assessment, usability evidence, and training protocols. While the system itself is developed outside this project (funded by Innobooster), the Interreg work will generate the regulatory and clinical input needed for market readiness. Without this step, adoption in public settings would remain fragmented or unavailable.

4. Knowledge sharing and training:
Outputs will be shared through workshops, open-access summaries, and clinical training materials. These will target small- and mid-sized hospitals, particularly in regions with limited access to advanced

pain care. The project is designed to produce tools that others can use – not just academic papers, but practical guides, decision flows, and validated procedures that make it easier to implement non-opioid pain therapy.

All technical development (hardware, gas control, AI) is completed before project start through national funding. The Interreg project focuses only on validation, documentation, and clinical implementation steps, helping public services adopt a safe and timely alternative to opioids.

12. Planned budget

ERDF budget (planned expenditure of partners from the EU)	EUR 450,000.00
Norwegian budget (planned expenditure of partners from Norway)	EUR 0.00
Total budget (including preparatory costs)	**EUR 450,000.00**

13. Project consultation

Please indicate if you wish to have a consultation (online meeting) with the MA/JS to discuss your project idea

yes ◉ no ◯

14. Questions to the MA/JS

Questions related to the content of the planned project	1. Can pilot-level clinical testing (without RCT) be considered eligible as a validation activity under this programme, when the focus is on usability, safety documentation and CE-preparation? 2. Can private clinics with strong clinical expertise (e.g. CCC) participate as full project partners if they contribute to protocol development and testing? 3. Can technical universities (e.g. DTU) be funded for activities related to thermal modelling, usability evaluation and data interpretation for CE documentation? 4. Is cross-border training of clinicians and development of shared Standard Operating Procedures (SOPs) considered eligible dissemination activities? 5. Can public health authorities or hospital districts act as lead partners, even if they are not yet fully confirmed at the time of this PIF submission?
Questions related to budgeting and expenditure	1. Can clinic infrastructure (e.g. test rooms, medical equipment) or in-kind contributions such as meeting space be included as part of the 10% co-financing? 2. Are services related to CE-preparation – such as risk analysis, usability reporting or protocol design – eligible project costs?

	3. Is it possible to allocate budget to clinical staff hours during non-invasive patient procedures, even if no medication or device implantation is involved? 4. Are travel and accommodation costs for cross-border training and pilot support eligible if directly tied to implementation? 5. Can budget be reserved for external advisory support (e.g. ethical/ regulatory advisors) during protocol finalisation? 1. Can clinic infrastructure (e.g. test rooms, medical equipment) or in-kind contributions such as meeting space be included as part of the 10% co-financing? 2. Are services related to CE-preparation – such as risk analysis, usability reporting or protocol design – eligible project costs? 3. Is it poss
Any other questions	Would the program be open to including feedback mechanisms from patient organisations or user representatives, even if they are not formal project partners? Could early-stage expressions of interest from commercial actors (e.g. future distribution partners) be mentioned in the full application to demonstrate post-project sustainability, without triggering concerns about private benefit? Lastly, would it be acceptable to involve potential lead partners in the co-design of the full application before they are formally confirmed, and still comply with the partnership rules?

15. Additional information

This project is driven by a strong personal and clinical motivation to offer patients safe and effective alternatives to long-term opioid use. It builds on years of experience with cryoneurolysis, now entering a new phase of cross-border validation. The development is supported by Innobooster (DK), and the partners are part of the EU-supported Life Science Academy. The project responds directly to the clinical concerns raised in Anesthesiology (2025) regarding cryo-system safety and reproducibility. The article can be shared during consultation or with the full proposal, if relevant.

Your account in BAMOS+

Please remember that to officially submit your application you need to access our electronic data exchange system BAMOS+. More information about the process of applying for your account in BAMOS+ you will find here:
https://interreg-baltic.eu/gateway/bamos-account