

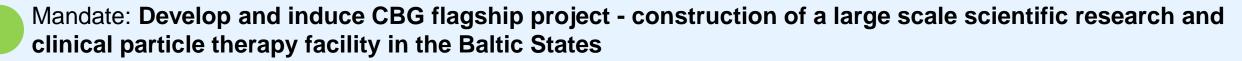
Advanced Particle Therapy center for the Baltic States Overview of the Feasibility Study

CERN Baltic Group's "Advanced Particle Therapy center for the Baltic States working group





On April 12th 2022 within CERN Baltic Group 9th general meeting at CERN the Advanced Particle Therapy Center in Baltic States Working Group has been established



To achieve this initial goal:

- establish Expert Team composed by medical professionals nominated by professional associations in the fields of radiology, therapeutic radiology, nuclear medicine, medical physics and others, researchers from CBG institutional members and experts of the NIMMS collaboration;
- facilitate the work of the Expert Team in order to evaluate the feasibility of the proposed project initiative
- establish Stakeholder Advisory Panel comprised by the relevant stakeholders in political, economical, social and other involved fields, as well as industry partners;
- regularly inform Stakeholder Advisory Panel from Expert Team side, with the inclusion in the decision making process and overall development of the project.

Mandate: On March 22nd 2024 within CERN Baltic Group 13th general meeting, "Advanced Particle Therapy center for the Baltic States" working group received the mandate to prepare a proposal for implementation plan of the Feasibility Study of the facility

Today – we report on the Prepared Proposal for future steps within CERN Baltic Group



- Latest status update
- Stakeholder engagement activities
- General overview of the Feasibility Study
- Proposal for Feasibility Study Implementation Plan
 - Future outlooks



Workshop report

Approved in 12th CERN Baltic Group General meeting (*October 11-12th, 2023*)



Report on workshop

Particle therapy – future for the Baltic States? State-of-play, synergies and challenges

Status update: Workshop outcomes

https://link.springer.com/article/10.1007/s12553-024-00875-2

Health and Technology (2024) 14:965-972 https://doi.org/10.1007/s12553-024-00875-2

ORIGINAL PAPER



"Particle therapy - future for the Baltic states?" – synthesis of the expert workshop report

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Abstract

Background Baltic States remains one of the few regions in the Europe without a dedicated particle therapy center. An initiative since 2021 has been started by CERN Baltic Group on a novel particle therapy center development in the region in partnership with CERN NIMMS collaboration. With a conceptual design idea in early 2022 and stakeholder engagement activities in late 2022 - next step forward was necessary for the initiative for a more in-depth analysis.

Methods A dedicated workshop "Particle therapy - future for the Baltic States? State-of-play, synergies and challenges" was held. The workshop was attended by medical community from the Baltics, as well as CERN technical experts and particle therapy practicing clinicians, with scientific programme split in 5 main areas of investigation.

Results Current cancer epidemiology statistics and RT technological possibilities in the region were analyzed, with first estimates of eligible number of patients calculated. Technological development level of the proposed accelerator complex was discussed, as well the clinical needs and synnergy possibilities with the nuclear medicine field.

Conclusions The current state and calculated first estimates presented here have shown a promising starting point, which prompts even further in-depth work – a feasibility study for development of a novel particle therapy center in the Baltic States.

Publication «Health and Technology»
«Hadrontherapy and BNCT: Current Status and
Future Trends»

https://indico.cern.ch/category/16259/attachments/2838075/4960020/REPORT 25 05 2023.pdf



Workshop of 2023: Moderators, speakers and participants



Erika Korobeinikova (Lithuanian Society of Radiation Oncology, LSMU, Clinic of Kaunas) Anna Maria Camarda (CNAO)

Dace Bogorada-Saukuma (Latvian Association of Therapeutic Radiology) Maija Radzina (Latvian Radiology Association, University of Latvia)

Andreis Ērglis (University of Latvia)

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Kristis	Krivičius	LSMUL Kauno Klinikos
LAIMONAS	JARUSEVICIUS	The Hospital of Lithuanian University of Health Sciences Kauno klinikos
Laura	Grikke	Medical physicist in Latvian Oncology center (nuclear medicine)
Lina	Lazdina	Dr
Maija	Radzina	Latvian Radiology Association
Māris	Mežeckis	Sigulda Hospital Center of Stereotactic Radiosurgery
Sigrid	Kuuse	



Status update: Stakeholder engagement activities 2024



March 22nd 2024: CERN Baltic Group 13th general meeting, "*Advanced Particle Therapy center for the Baltic States*" working group received the mandate to prepare <u>a proposal</u> for implementation plan of the Feasibility Study of the facility

Spring 2024 Publication of workshop outcomes in Health and Technology special edition



January and October <u>CERN Medical Applications Steering Committee meeting</u> – highest engagement level



April Presentation and discussions with Heidelberg Ion-Beam Therapy center - potential collaborator



July Presentation for Latvian Health Minister during visit of RTU



September Workshop with Lithuanian stakeholders



October 11th Short overview within PMNET forum



During 2024 Working towards radiotherapy statistics publication for December 2024 (*M.Dosanjh, E.Korobeinikova, E.Gershkevitsh, K.Palskis*)



November Participation in *The Nordic-Baltics as a European pilot region for cross-country cooperation in health data* conference (*K.Palskis, E.Korobeinikova, E.Gershkevitsh*)

accelerator technology toolbox for



Step of the feasibility study is necessary for this technology transfer into a facility - there Study) – a deare existing success cories ricle CERN with a goal of new particle

CERN as a possible host institution has long history of fostering international collaboration – such as the one Dedicated finalization studies necessary here he

accelerator technology development for

We should not take the willingness of CERN involvement for granted! MedAustron





Research institution

51 % of time for scientific research

49 % of time for clinical treatment



51:49 is what we would currently propose based on consensus

A scientific research facility WITH a clinical functionality

NOT



Towards the future . . . Motivation for Feasibility Study



Report on workshop

Particle therapy – future for the Baltic States? State-of-play, synergies and challenges

Workshop article therapy - future for the Baltic States

«Particle therapy - future for the Baltic States? Stateof-play, synergies and challenges»

« . . . In order to proceed with this promising idea, **a full-scale feasibility study of the project is needed.** It shall assess feasibility of the facility of this research infrastructure **from financial** (business case), **clinical** (medical case), **technological** (technical outline, availability and R&D required) **and multi-disciplinary scientific research perspective**. In each of these segments, feasibility study would need to have involvement of experts from every Baltic State and CERN researchers, as well as representatives of European particle therapy centers. The best existing platform for such feasibility study is CERN based NIMMS collaboration »



What **IS** the Implementation Plan Proposal?

- Above all, definition of core questions to be answered and areas of investigation necessary
- Briefly outlining organizational structure, working plan, stakeholder involvement necessary etc.
- It is a proposal NOT a definitive plan as of yet
- Aim of the proposal a document to approach political stakeholders, funding agencies etc.
- Raise institutional interest and awareness among stakeholders

What the Implementation Plan Proposal **IS NOT**?

- NOT the final version of the plan of whole Feasibility Study - a proposal to discuss for further actions to be taken
- NOT the expected outcome of the Feasibility Study: answering key areas of investigation is part of the Feasibility Study itself, just brief factual basis is provided in the "Motivation" section, paving way to investigations themselves



Throughout 2024, part of working group has been working on proposal of Feasibility Study Implementation plan

Plan Preparatory Working group:

- Convener of the WG: Prof. Toms Torims (Riga Technical University, LV)
- Deputy Convener of the WG: Prof. Diana Adlienė (Kaunas University of Technology, LT)
- Kristaps Palskis (Riga Technical University, LV)
- Dr. Erika Korobeinikova (Lithuanian University of Health Sciences, LT)
- Dr. Alberto Degiovanni (Riga Technical University, LV)
- Dr. Maurizio Vretenar (CERN, CH)
- Dr. Andris Ratkus (Riga Technical University, LV)
- Prof. Saulė Mačiukaitė-Žvinienė (Vilnius University, LT)
- Dr. Eduard Gershkevitsh (North Estonia Medical Centre, EE)

"Proposal of Implementation Plan" – proposal for discussions with CBG member institutions and other relevant stakeholders

Proposal is finalized; first rounds of comments collected after initial reviews of CBG members for edits already



Plan preparatory Working group

 Prepare the Proposal for consideration by CBG and its member institutions

- Extensive work done within the areas of expertise and competence of the members
- No financial support during this initiative for the Working Group

Plan preparatory Working group IS NOT . . .

- "Fixed entity", it can be adapted based on suggestions from CERN Baltic Group itself
- Representative of Feasibility Study Implementation group – personnel and institutions to work within the Feasibility Study itself.



Towards the future . . . Motivation for Feasibility Study

Motivation from **RESEARCH perspective**

- Particle accelerator based scientific centers broad spectrum of research possibilities and disciplines
- Envisioned scientific activities: clinical, natural and technical sciences, towards helium ion clinical translation
- Create a regional scientific center of excellence, broad, world-class scientific research attractive to the international community
- 2/3 economic growth of EU: research and innovation –
 infrastructure crucial. Aligns with the National
 Development Strategies, innovation-led economic growth

Motivation from **CLINICAL** perspective

- Proton therapy shown benefits in the reduction of normal tissue complications in selected types of cancer
- Helium-4: recent re-emergence with a clear research interest in ion therapy centers both in Europe and Asia
- Increased the dose conformality and biological effectiveness.
- Provide a novel tool for cancer treatment the clinically established proton therapy with a long-term ambition of developing helium ion therapy for full

Motivation from **ECONOMIC** perspective

Macro-economic benefits in terms of healthcare cost savings, increased labor productivity and innovation development, job creation and contribution to national economic growth.

Reduced side effects and increased QoL: increased labor productivity and reduced healthcare costs

Infrastructure investments lead to the development of local ecosystems, including healthcare clusters and innovation hubs

Motivation from **COLLABORATION** perspective

Enable potential for the cooperation with CERN for the development of science, research and technology in the Baltic States

Excellent demonstration of the impact on society of the particle physics research promoted by CERN

Very good example of regional initiatives of CERN Member and Associate Member states

CERN has agreed to host this Feasibility Study within its collaborative framework.





CERN Baltic Group

Proposal for

Feasibility Study

of

Advanced Particle Therapy Centre for the Baltics Implementation plan

Document has been prepared by CERN Baltic Group "Advanced Particle Therapy Centre for the Baltic States" Working Group:

Convener of the WG: Prof. Toms Torims (Riga Technical University, LV)

Deputy Convener of the WG: Prof. Diana Adlienė (Kaunas University of Technology, LT)

Working group members:

Kristaps Palskis (Riga Technical University, LV)

Dr. Erika Korobeinikova (Lithuanian University of Health Sciences, LT)

Dr. Alberto Degiovanni (Riga Technical University, LV)

Dr. Maurizio Vretenar (CERN, CH)

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CENTER

ADVANCED PARTICLE THERAPY CENTER FOR THE BALTIC STATES



INSTITUTION









INDUSTRY INVOLVEMENT **INFRASTRUCTURE**

Main goal: decision making "tool-box"

Expected duration: 2 **years.** As this is not a commercial machine and is more focused on the scientific research infrastructure development, shorter duration would be deemed insufficient (based on previous CERN experience)

To envision the facilty and consider any future developments - scientifically and factually driven

FEASIBILITY STUDY

- Main goal: investigate the feasibility and possible scenarios of facility's implementation
- **Expected duration:** 2 years
- Expected launch: 2025



Main aims of the Feasibility Study

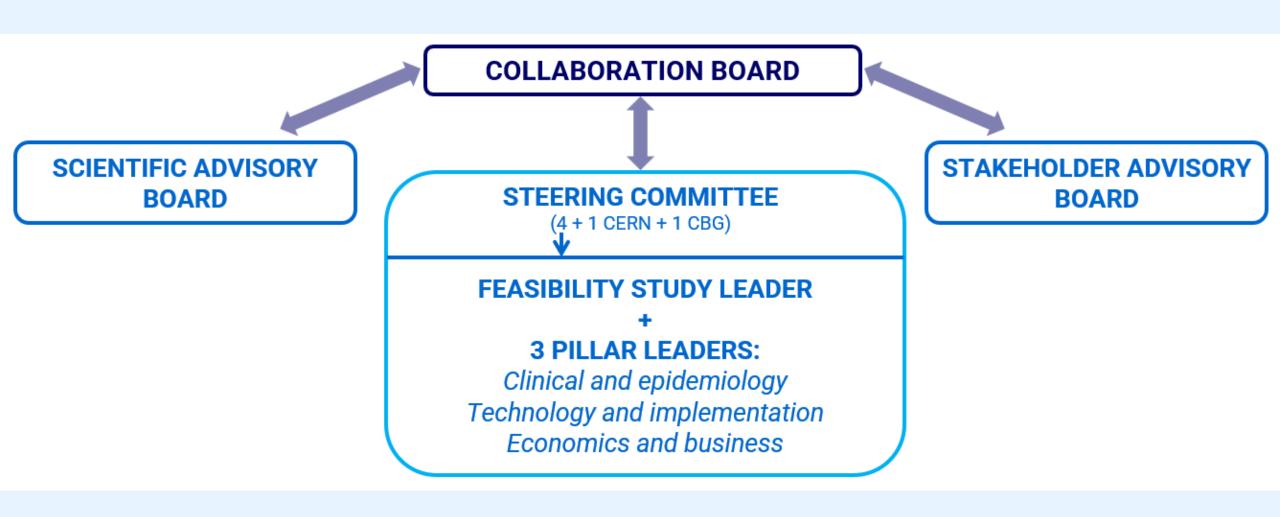
- to investigate the feasibility of the implementation of the APTCB facility to a certain level;
- to provide a factual based Feasibility Study Report to be used as tool for the decision making in the APTCB project continuation;
- through the Feasibility Study Report and associated documents to provide multiple possible scenarios for implementation at various levels: full, partial or no implementation, with possible alternatives.



FEASIBILITY STUDY IS TO BE DONE WITHIN FRAMEWORK OF CERN WITH INVOLVEMENT OF TECHNICAL EXPERTS



Implementation Plan Proposal: Expected organizational structure





Implementation Plan Proposal: Overview of proposed working packages

CLINICAL AND EPIDEMIOLOGY

Lead: Senior researcher with proven knowledge in field

- Research programme in clinical sciences
- Relevant medical statistics in the region
- Eligibility criteria for proton therapy
- Patient referral, connections with PT community

3 researchers or PhD students
from each of the Baltic countries

TECHNOLOGY AND IMPLEMENTATION

Lead: Senior researcher with proven knowledge in field



- Technical requirements of the facility
- Integration study and future upgradability
- Basis of cost estimates for accelerator and facility

3 researchers or PhD students from each of the Baltic countries

ECONOMICS AND INNOVATION

Lead: Senior researcher with proven knowledge in field



- Organizational structure and governance model
- Full cost estimation and economic benefit analysis
- Evaluation of revenue streams

3 researchers or PhD students from each of the Baltic countries

TRANSVERSAL TASKS

- Alternative solutions for the facility
- Aspects on regulatory and legal approvals

Risk analysis and evaluation

Information flow between pillars for cost estimates

Education and training necessities



Implementation Plan Proposal: Pillar of CLINICS AND EPIDEMIOLOGY

Table 2. Tasks and expected deliverables of "Clinical and Epidemiology" pillar.

	Table 2. Tasks and expected deriverables of Children and Epideimology phila		
	TASKS	DELIVERABLES	
1.1	Definition of APTCB research programme in clinical sciences	D1: Report with proposed scientific research outline for clinically-oriented research fields - pre-clinical and clinical in radiation oncology, radiobiology and nuclear medicine (radiopharmaceuticals) - based on state-of-the-art and networking with relevant facilities. Report to include already active research groups in the relevant fields within the Baltic States.	
1.2	Relevant medical statistics in the region	D2: Conclusive report about current number of cancer patients, radiotherapy treatments and other relevant statistical parameters, as well as parameters relevant to assess capacity in nuclear medicine. Report is to provide also possible eligible fraction of cancer patients for particle therapy based on literature studies and also extrapolation of the trends over the coming 10-20 years.	
1.3	Patient eligibility criteria for proton therapy	D3: Report describing the options, approaches and models for patient eligibility for particle therapy based on international experience. Report is to also provide overview of existing clinical evidence as basis for eligibility. D4: Proposal for most suitable patient selection and eligibility estimation methodology for the Baltic States.	
1.4	Patient referral, connections with particle therapy community	D5: Report on existing methods of referral in Baltic States for other cancer treatment methods (conventional radiotherapy, chemotherapy etc.), provision of comparison with other relevant countries having particle therapy facility. D6: Proposal for most suitable patient referral methodology for Baltic States.	

- Research programme proposal not active development
- Use existing information sources (cancer registries etc.) NOT creating new already
- Eligibility criteria and referral system proposal not an active implementation



Implementation Plan Proposal: Pillar of TECHNOLOGY AND IMPLEMENTATION

Table 3. Tasks and expected deliverables of "Technology and Implementation" pillar.

	TASKS DELIVERABLES	
2.1	Definition of APTCB research programme in natural and technological sciences	D7: Report with defined research goals for research fields in natural and technological sciences – medical physics, dosimetry, accelerator physics and technologies, particle physics, material science and radiation chemistry (radiopharmaceutical production) – based on state-of-the-art and networking with relevant facilities. Report to include already active research groups in the relevant fields within the Baltic States.
2.2	Technical requirements for APTCB facility design	D8: Report with defined particle accelerator requirements based on the NIMMS HeLICS technology D9: Report of additional technologies necessary for clinical implementation: dose delivery methods and registration tools, general control system, integration with oncology information system, choice of pretreatment and in-room imaging options D10: Report on technical aspects of parallel radioisotope production: isotopes of interest, beam-time allocation
		and definition of additional technical requirements for this functionality
2.3	Integration study and outlooks of	D11: Baseline of Product Breakdown Structure (PBS) and main interfaces.
	future upgradability	D12: Report on the design of main systems and sub- systems with functional analysis.
2.4	Basis of cost estimates	D13: Report of base information needed for cost estimation of the accelerator system and facility as whole

- Research programme –
 proposal not active development
- Technology implementation not development – to assess NIMMS HeLICS technology and explore it's integration into a facility
- Possible identification of technical information gaps in HeLICS proposal



Implementation Plan Proposal: Pillar of ECONOMICS AND INNOVATIONS

Table 4. Tasks and expected deliverables of "Economics and Innovation" pillar.

	Table 4. Tasks and expected deliverables of Economics and innovation pillar		
	TASKS	DELIVERABLES	
3.1	Research on long term funding model, business engagement and economical aspects of research function	D14: Report on existing and possible industrial engagement opportunities. Report is to include a database of relevant companies. D15: Proposal of a novel funding model for the facility, while also identifying proper performance indicators for the scientific research activities.	
3.2	Definition of organizational structure and governance model	D16: Proposal of operational schedule and organizational structure for APTCB facility D17: Proposal of «organigram» and APTCB project resource plan.	
3.3	Full cost estimation for the facility and economic benefit analysis	D18: Report on full cost estimates, including construction, commissioning, installation and operational phases. Report is to be done based on data provided by second pillar for construction, while providing basis of estimates for other stages, also including additional experience from other centres. D19: Report on possible economic benefits of the facility and future projections, based on international experience and studies (impact on healthcare costs, increase of labour productivity, industry engagement and job creation)	
3.4	Identification and evaluation of revenue streams of the facility	D20: Report on the different revenue streams for the facility based on international experience of particle therapy centres and scientific research institutions (clinical and scientific research services, grants, collaboration and licensing agreements, medical tourism) D21: Report on evaluation of the different proposed revenue streams, focusing on the key metrics such as possible annual revenue per source and growth rate. Basis of the "breakeven analysis" and expected profitability timeline should be provided.	

 Provide initial estimates on all the aspects and solid foundational basis for further developments into a business plan etc.



Table 5. Transversal tasks and respectively expected deliverables.

		sversal tasks and respectively expected deliverables
	TASKS	DELIVERABLES
T.1	Alternative solutions for the facility Description: as different implementation scenarios of the APTCB facility are to be explored, for "implementation" scenario alternative solutions from existing dual- function (scientific research and clinical use) facilities are to be explored with the provision of data for comparative analysis in clinical, scientific research, technological and economical domains	D22: Factual basis of alternative solutions for the facility for comparative analysis in scenario of "no implementation" Results of the task are to be used as inputs for Risk Assessment
T.2	Regulatory and legal approvals Description: general investigation on existing and necessary regulatory, licencing and certification framework and creation of strategic approach to these aspects of the APTCB;	D23: Report on compliance of the facility with current relevant regulations at national and international level (healthcare research, medical treatments, environmental regulations and data protection) D24: Report on necessary licenses or certifications for the operation of the facility, with a roadmap for the process Results of the task are to be used as inputs for Risk Assessment
T.3	Information flow for cost estimates Description: clear definition of process inputs and outputs between the different pillars for the analysis of the costs for the different phases of the APTCB <u>life-cycle</u> ;	D25: Creation of information flow scheme between the pillars for cost estimates Results of the task are to be used as inputs for Risk Assessment
T.4	Risk analysis and evaluations Description: creation and management of a risk registry with a suitable risk management plan to be used as initial reference for all risk-related documentation for the APTCB. Risk analysis is to cover all major domains such as financial, operational, regulatory etc.	D26: Creation of Risk Assessment Matrix D27: Creation of Risk Management Plan
T.5	Education and trainings Description: exploration of required specialization and dedicated training programmes for the roles that will be needed for construction, commissioning, operation and maintenance of the APTCB	D28: Creation of human resource matrix D29: Creation of proposals for education and training plans Results of the task are to be used as inputs for Risk Assessment

Implementation Plan Proposal: Transversal tasks

- Areas of investigation which require inputs and expertise from all 3 main pillars
 - alternative solutions in "no implementation scenario"
 - regulatory and legal aspects
 - information flow
 - risk analysis and management strategy
 - education and training necessary
- To be done under coordination of Feasibility Study Leader

Implementation Plan Proposal: Expected outcomes of the Feasibility Study

Tool for decision making process for the future of this scientific research facility

- The main tangible outcome: the Feasibility Study Report. The information collected to be used as decision making tool made by CBG the future of the APTCB project
- Other documents will be created along with the Feasibility Study report by CBG:
 - risk analysis associated with APTCB proposal and overall risk management strategy;
 - finalized and factual-based proposal for layout of the APTCB facility;
 - finalized and factual-based beam-time usage proposal for the APTCB facility;
 - finalized and factual-based list of selection criteria for the choice of most suitable
 APTCB facility construction site;
 - initial proposal for the expected staging for full-scale development of APTCB facility;
 - initial basis for a business plan for the APTCB facility.



Multiple possible scenarios

- Feasibility Study report and other accompanying documents: to provide the basis for multiple possible scenarios, not a definitive solution, for the decision making stakeholders. Providing factual basis for comparison of the different alternative options.
 - full-scale implementation scenario, with varying weights of scientific research and clinical treatment functions;
 - partial implementation scenario, limiting certain technical functionalities of the proposed facility;
 - scenario of not implementing the facility, while identifying possible alternatives.



Let's discuss, few things identified already . . .

First feedback given to WG by CBG member institutions

- Clearer definitions in stakeholder identification and engagement plan
- More detailed milestone definition
- Additional considerations for tasks (addition of certain scientific directions etc.)
- **.** . . .
- Proposed expansion of the working group for second iteration of the document



As mentioned, "<u>first iteration</u>" of the document – let's discuss on how and if should we proceed further!

