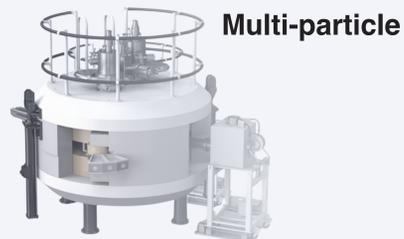


Introduction

Accelerate.EU involves 17 European partners that aim to develop novel (pre)clinical radiotheranostic pairs incorporating the alpha emitter Astatine-211 (²¹¹At) for the radiotherapeutic agent with companion diagnostics radiolabeled with either Fluorine-18 (¹⁸F) or Iodine-123 (¹²³I) for PET and SPECT imaging, respectively. The primary cancer indications will be pancreatic, brain and breast cancer. One of the major technological endeavors of the project is to develop a novel dedicated cyclotron to produce ²¹¹At cost-effectively for a robust and economically viable supply chain.

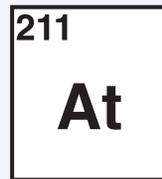
Cyclone® ALPHA

2010: From R&D machine... **2027:** to an industrial tool



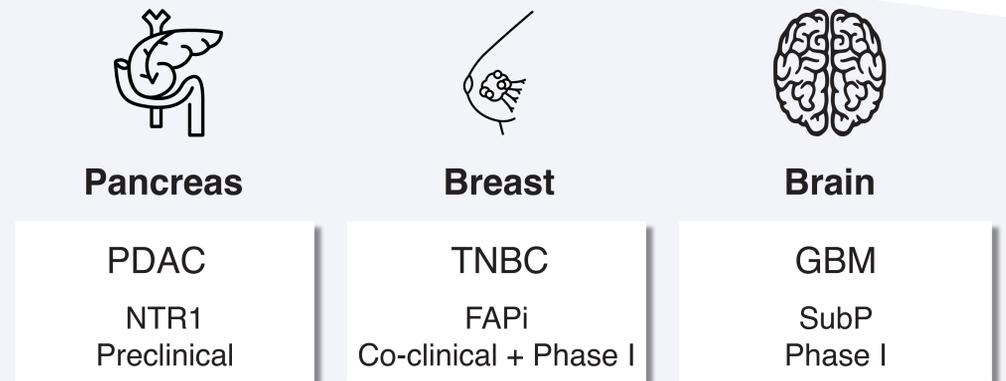
Cyclone® 30XP

Leveraging on IBA's 30 years of expertise in accelerator technology



28 MeV alpha beam dedicated to the production of alpha emitting isotope

Cancer Applications



From Bench to Bedside

Method

The project will establish a production capacity for ²¹¹At by integrating a complete value chain to develop ²¹¹At therapeutic agents and companion diagnostics. By ensuring timely coordination between different partners in the ²¹¹At network, the project will allow for a just-in-time production and supply of ²¹¹At to support the development of (pre)clinical pipeline focusing on neurotensin receptor 1 (NTR1)¹, fibroblast activation protein (FAP)², and Substance P (Sub P)³, for pancreatic, breast and brain cancers, respectively. These (pre)clinical activities will also involve compliance with the regulatory requirements. In addition, the project will explore potential methods for accelerating and improving the robustness of image quantification and dosimetry, including AI-based deep learning models for denoising images and automating image delineation.

In parallel, a novel cost-effective α-beam only cyclotron for ²¹¹At production with internalized targets and ion sources will be developed considering reduced installation and operating costs when compared to existing solutions.

Results

The anticipated outcomes include setting up a dedicated hub for developing ²¹¹At-based radiotheranostic pairs with optimal properties, leading to better identification of patients who can benefit from TAT, improved quality of life, and extended survival. In-depth radiobiological characterization of ²¹¹At-FAPi will be performed, and all required pre-clinical data on ¹²³I-FAPi and ²¹¹At-FAPi/NTR1i, as well as preliminary efficacy data of ²¹¹At-FAPi/Sub P, will be obtained for their introduction in clinical trials. Clinical validation of the safety, tolerability, and imaging characteristics of ¹²³I-FAPi and the safety and tolerability of ²¹¹At-FAPi/Sub P will also be conducted. The project also aims to develop a dedicated industrial cyclotron to produce ²¹¹At.

References
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Transversal Collaboration to Accelerate Alpha-therapy Uptake Across EU



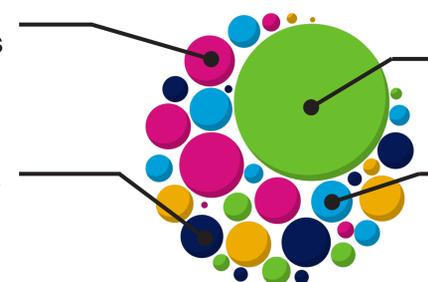
17 Partners	9 Countries	5 Years	16 M€ budget
99 ManPower	3 Industry Partners	3 Unmet Clinical Needs	30+ Patients Treated

Production of ²¹¹At every week over 5 years

Innovative co-clinical approach to boost alpha theranostic uptake

Dedicated alpha-cyclotron to enable ²¹¹At production network

Clinical trials for unmet clinical needs



● Early Supply ● Ligand & radiolabeling ● Preclinical & co-clinical ● Clinical trials ● Production scale-up

Conclusion

Accelerate.EU represents a significant advancement in cancer care by pioneering the development of ²¹¹At α-radiation-based radiotheranostic pairs for highly aggressive cancers. Novel cost-effective cyclotrons for TAT will be developed to support the future increased demand of ²¹¹At in EU and reinforce European strengths in Nuclear Medicine through a solid and stable supply chain.