First publishable summary

31 October 2022



Our goals

PRISMAP - The European medical radionuclide programme, aims at providing emerging and non-conventional radionuclides for scientists across different disciplines in biomedical research.

Radionuclides, since their discovery 125 years ago, have shown their potential for medicine, and have been used in diagnostics and therapeutic applications. They are used either directly or in synthetic compounds, and serve as injectable solutions in diagnostics such as PET-CT scan imaging, and therapeutic compounds to treat cancers.

Cancer is a major cause of disease and mortality in Europe: in 2020 alone, 2.7 million persons in the European Union were diagnosed with cancer, and 1.3 million persons lost their lives to it. In the past twenty years, new efficient therapeutic drugs based on radionuclides that were previously not industrially available, obtained a marketing authorization and have been used to treat cancers that were lacking appropriate treatments. However, an imperfect match of the radionuclide properties and the targeted medical applications can lead to reduced efficacy, possible side-effects, higher treatment costs, or even the discontinuation of an already marketed drug.

PRISMAP's overarching goal is to overcome these bottlenecks for the benefit of European citizens and healthcare systems. This will be achieved by the selection of better radionuclides with appropriate properties, and the development of targeted treatments, notably by combining diagnostic and therapeutic radiopharmaceuticals in so-called theranostics approaches. It will support economic growth, as the field is evaluated to follow a double-digit growth and the overall economic impact of cancer in Europe is estimated to exceed €100 billion annually. It can also support other fields of medical research, such as molecular targeted therapies, neurological disorders, and new imaging technologies.



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PRISMAP's new web access platform, www.prismap.eu, is used to display public information, alongside a private consortium section for data sharing and communication. This platform covers to date 24 different radionuclides in our portfolio, that can be used as ingredients in diagnostics, treatment, or for theranostics. Our platform allows scientists interested in biomedical research to easily access important information, such as the type of diagnostic, imaging, or treatment modality, that directly depends on the chemical, physical and nuclear properties of a given radionuclide, notably its different modes of radioactive decay, and often their combination.

For each radionuclide we provide general data, together with the mode of production and general applications of the radionuclides in biomedical research with links to published articles when available. We also give full specifications of the quality grades supplied by PRISMAP allowing to clarify if the radionuclide with its properties, and the range of purity grades accessible are appropriate for a given field of biomedical research.



The PRISMAP flowchart illustrates production services provided by the project, as well as the different facilities involved and the medical application available to the users.

New terminologies and standards have been introduced to account for the novel methods of production made available across the PRISMAP consortium, notably combining isotope mass separation and more established accelerator (cyclotron) and reactor methods. Sometimes the data are insufficiently known or not available at all. We have therefore started to produce <u>new data</u>, that can be useful in the assessment of the physical and nuclear parameters, purity grades, or their application in biomedical research. Examples of application in targeted molecular therapies are particularly relevant, as some of our radionuclides can be supplied in high molar activities, which make the synthesis and use in radiopharmaceuticals targeting specific tumor receptors possible.

PRISMAP can provide <u>access</u>, free of charge, to new radionuclides and new grades of these to researchers across Europe and beyond, either directly in their laboratory, or by accessing one of our <u>biomedical research</u> centres licensed to handle these new radionuclides.

In a first call for proposals, 9 highly innovative user projects proposed by research teams active across Europe (BE, DE, ES, FR, IT) were selected by an expert panel. For a second call the evaluation is ongoing. The selected projects cover a wide range of disciplines in radiochemistry, radiation physics, radiopharmacy, preclinical and translational biomedical research, and target different types of cancer and experimental approaches. The results will be public once available, and reported at conferences, in scientific articles, and at PRISMAP's public events as already done, e. g. introducing new theranostics application for a mass separated Sm-153-DOTATATE radiobioconjugate or implementing a clinical translation of Tb-161-DOTATATE, allowing a possible comparison with the Lu-177-DOTATATE (Luthatera®) in the years to come.

Targeted alpha therapy, an efficient mode of treatment exploiting alpha emitters, also benefits from research and data produced in PRISMAP. This is particularly true for radionuclides which present short half-lives and require efficient dispatch and special licenses to handle. To this end, <u>synthetic guidelines</u> were edited to raise awareness of the regulatory framework for transport and use of radionuclides in biomedicine, be it in early preclinical research or for clinical translation.



The PRISMAP consortium

Our activities so far allowed PRISMAP to launch various interactions with other programmes in Europe and beyond, to maximise the output of PRISMAP, and integrate <u>new infrastructures</u> when they become available. Already part of the consortium, the SPES facility is expected to start operation before the end of our four-year project, and is already actively participating in research activities of the consortium.

We also interact with other European infrastructure projects, such as <u>EuroBioimaging</u> to maximise future synergistic actions in the medical field. Input from other programmes, such as those active in Japan and North America, has provided us with important insights in their programmes and will allow PRISMAP to develop future links with other geographically distributed programmes.

As we will soon begin the delivery of radionuclides to the <u>selected projects</u> and host the first users in our facilities, we hope that breakthroughs in all fields of research across the multidisciplinary community served by PRISMAP will contribute to a better, healthier future in Europe and in the world. From the infrastructure side, we will continue to develop new production methods and generate new opportunities for medical research, gather complementary nuclear data on the novel radionuclides, ensure the reliability of our supply through interlaboratory comparisons and supporting emerging infrastructures, to become a major stakeholder for the supply of medical radionuclides in Europe. We shall support our users and policy makers in the translational research on novel medical radionuclides via targeted position papers on ongoing developments, and through the production of monographs providing clear and accurate information on the radionuclides.

We are confident that these various elements, complemented by a comprehensive <u>survey</u> launched to understand the needs of industry partners, will help unite a currently dispersed community and make PRISMAP, as the European Medical Radionuclides Programme, a one-stop shop for biomedical researchers who need to develop research activities with non-conventional radionuclides in the years to come.



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101008571 (PRISMAP) www.prismap.eu MedRadionuclide PRISMAP Project In

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