

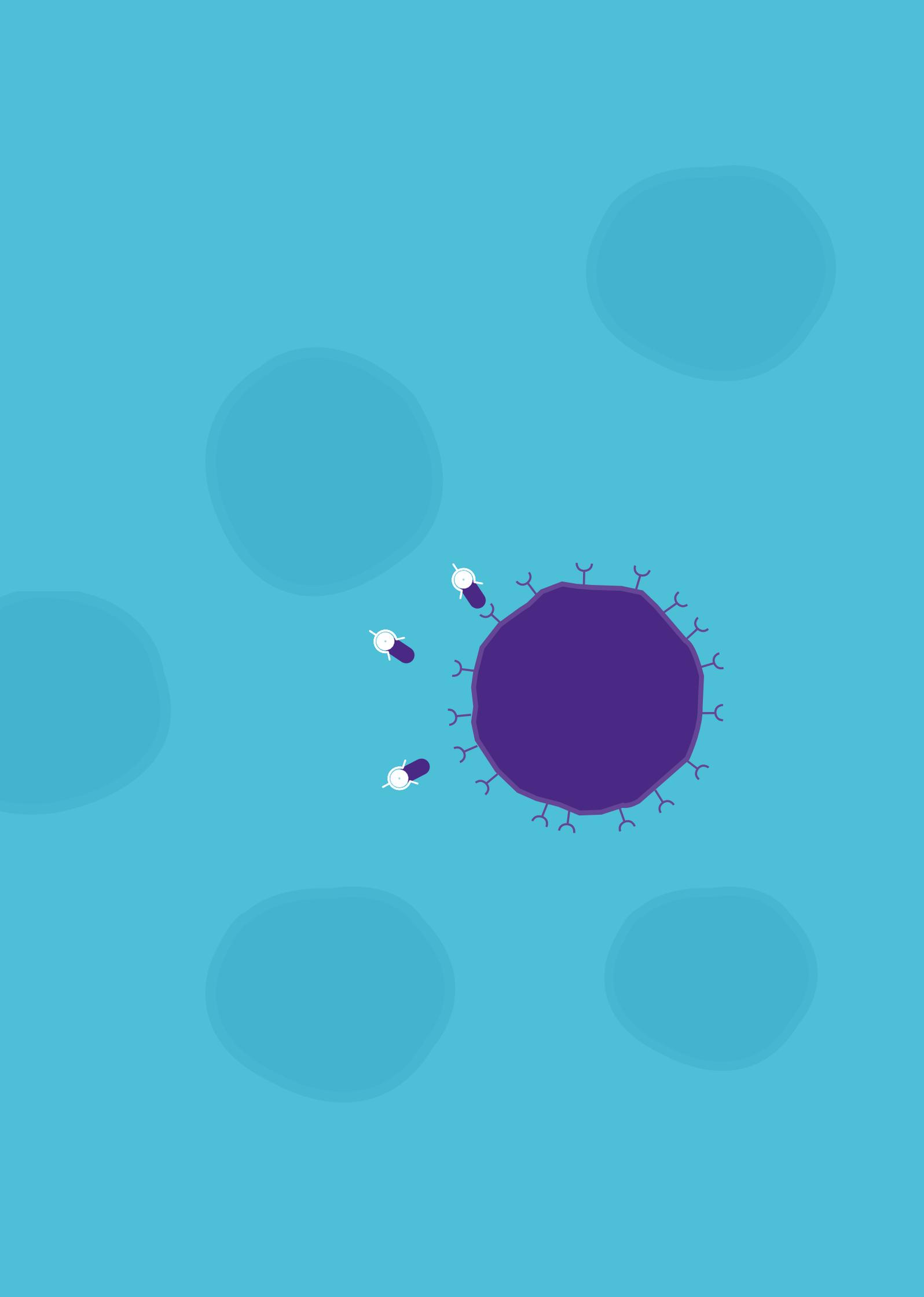
Radioligand therapy policy project

A YEAR IN REVIEW

This report has been drafted by The Health Policy Partnership. It is part of a project funded by Advanced Accelerator Applications, a Novartis Company. Additional support was provided by Curium (stage 1 of the project) and Nordic Nanovector (stage 2).

March 2021

The
**Health Policy
Partnership**
[research, people, action]



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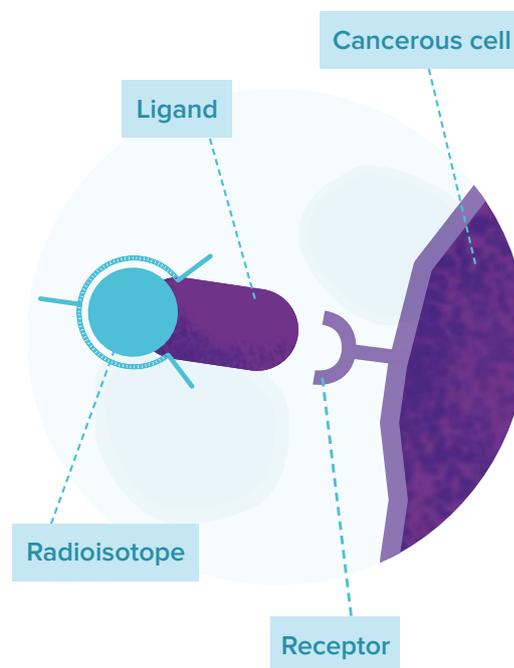
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Introduction

What is radioligand therapy?

Radioligand therapy is a highly targeted approach to cancer treatment.

A radioligand is made of two parts: a ligand, able to find cancer cells that present a particular tumour target, and a radioisotope that delivers the treatment. Put together, radioligands find and deliver radiation directly to cancerous cells, regardless of where they are in the body.



What is exciting about targeted treatments such as radioligand therapy is that they could potentially be applicable to multiple forms of cancer. Targeted radiation has existed for decades – radioiodine was first used to treat overactive thyroid glands in the 1940s. As radioligands bind to certain types of cancer cells, they can be used for targeted diagnosis and treatment in any cancer where a suitable receptor has been identified. So far, radioligand therapy has been approved for use in people with neuroendocrine neoplasms (NENs), a group of rare cancers, and is under evaluation for metastatic castration-resistant prostate cancer, blood cancers and other types of cancer.

As radioligand therapy uses internal radiation, making it available in clinical care requires a complex interplay of policies and practices that extend beyond the healthcare setting. Ensuring system ‘readiness’ for radioligand therapy is particularly complex, as it requires a fresh look at policy frameworks, capacity, infrastructure, resources, workforce and models of care needed to make radioligand therapy available to patients.

The need for appropriate system-level planning to protect the delivery of cancer care has been reinforced by the COVID-19 pandemic. The pandemic has laid bare the delays in diagnosis and referral, disruptions to cancer care services and ongoing pressures to deal with a backlog of people who require treatment. We hope that this project can play a small part in supporting efforts to plan for the ‘new normal’ of cancer care and encourage evidence-based investments to make radioligand therapy available to all people who need it.

About the project

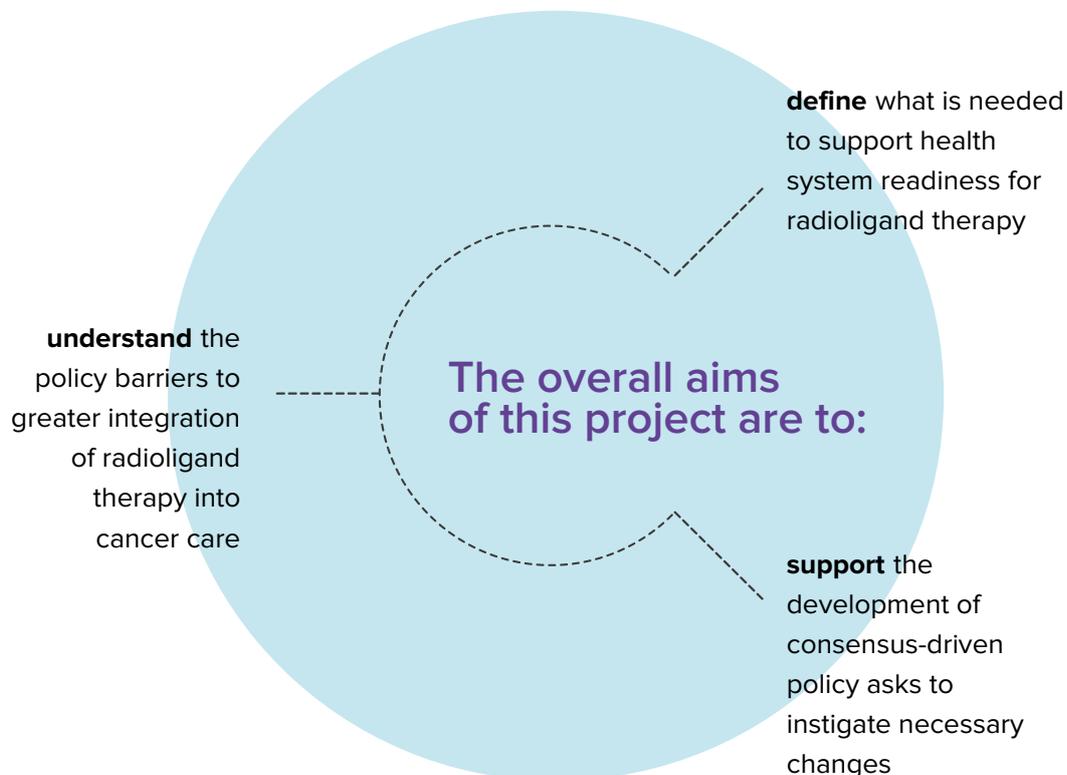
The Health Policy Partnership (HPP), an independent health policy research organisation, began a project in 2019 aiming to raise awareness of radioligand therapy among European policymakers and the entire cancer community.

We developed a report describing policy barriers to the wider integration of radioligand therapy into cancer care across Europe. After launching the report at the European Parliament in January 2020, HPP then initiated a second stage of research.

The second stage, health system readiness for radioligand therapy, aims to define what is needed to support the integration of radioligand therapy into cancer care. We will then work with policymakers to help ensure appropriate steps are taken to secure readiness. We see this work as an exemplar of how to take a whole-system approach to planning for the integration of a new type of treatment into cancer care, and hope that our methodology and findings may resonate with the cancer community at large.

This report presents an overview of what we have achieved so far.

Overall project aims



STAGE 1

Radioligand therapy: realising the potential of targeted cancer care

European policy report

We developed a policy report to raise awareness and support engagement around radioligand therapy among policymakers. The report was created in collaboration with a multidisciplinary expert group.

We identified six barriers to integration of radioligand therapy into cancer care:



Low awareness and understanding



Limited professional capacity, training and workforce planning



Unclear models of care



Inadequate physical capacity and resourcing in hospitals



Evolving legislation, regulation and policy



Lack of data and research

We then outlined ten actions that policymakers should take in order to address these barriers:

- Increase awareness of radioligand therapy and the role of nuclear medicine among decision-makers, people with cancer and the clinical cancer community.
- Harmonise education and training standards across Europe for nuclear medicine specialists and all members of the multidisciplinary cancer team.
- Ensure that nuclear medicine specialists have adequate capacity to participate in multidisciplinary cancer care processes.
- Develop clear processes and patient pathways for care in each national context.
- Ensure adequate hospital capacity and resources for delivery of radioligand therapy to meet current and future demand.
- Incorporate radioligand therapy into national, regional and local cancer plans.
- Establish clear, consistent regulatory frameworks for the use of radioisotopes spanning approval, funding and reimbursement.
- Ensure continued supply and appropriate disposal policies.
- Invest in real-world data on radioligand therapy to better understand patient outcomes and cost-effectiveness.
- Identify and share best practices to optimise and standardise care.

PROFESSOR KEN HERRMANN, University Hospital Essen:

I was pleased to be involved in developing the *Radioligand therapy: realising the potential of targeted cancer care* report. It emphasised that nuclear medicine physicians must be more involved in multidisciplinary cancer care teams, and that multidisciplinary working must happen in a meaningful way.

Launch and policy engagement

Launch at the European Parliament

The report was launched at the European Parliament in Brussels on 22 January 2020 at an event hosted by MEPs Tanja Fajon (Slovenia), Brando Benifei (Italy) and Ewa Kopacz (Poland). Speakers included experts in oncology, nuclear medicine, patient advocacy and specialist nursing. The event has led to ongoing engagement with MEPs and the European Commission.

You can read more about the launch on the [HPP website](#) and in this [press release](#).



STAGE 1

Submission to Europe’s Beating Cancer Plan

Building on the policy discussions at the launch event, [HPP contributed](#) to the European Commission’s public consultation for Europe’s Beating Cancer Plan. Aligning with the report findings, we highlighted the following priorities for consideration in the Plan:

6 PRIORITIES		
<ul style="list-style-type: none"> › Greater public and professional awareness of the use of radioactive substances in healthcare 	<ul style="list-style-type: none"> › Additional training and better integration of specialists delivering radioligand therapy into multidisciplinary care teams 	<ul style="list-style-type: none"> › Adaptation of regulatory frameworks at the European Union and Member State level
<ul style="list-style-type: none"> › Alignment of nuclear energy and health policies 	<ul style="list-style-type: none"> › Secure and consistent supply of radioisotopes 	<ul style="list-style-type: none"> › Advance planning to secure sufficient infrastructure for delivery of radioligand therapy

Dissemination

Dedicated website

Radioligandtherapy.com was launched in January 2020 to act as a home for the project. As of 1 January 2021, the website has achieved:



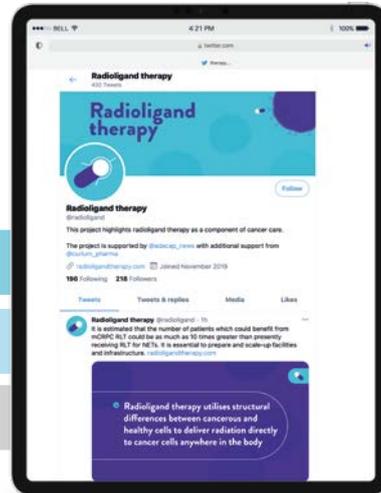
- over **7,500 visits**
- almost **6,000 unique visitors**
- 1,465 views** of the animation
- over **600 downloads** of the policy report
- over **300 downloads** of the various translated report summaries

Twitter

To help create an ongoing presence for the project on social media, we launched the [radioligand therapy Twitter account](#) in January 2020.

The channel has performed well and has become a major voice in this area, achieving:

- over **210,000** views of our posts
- over **900** likes
- over **400** retweets



Publications and conference presentations

During 2020, we developed a series of posters and publications to help us disseminate our findings among the clinical community. Highlights included:



[Editorial](#) in the *European Journal of Nuclear Medicine and Molecular Imaging*

[Poster](#) at the European Neuroendocrine Tumour Society conference, 11–13 March

[Poster](#) at the European Conference on Rare Diseases, 14–15 May

[Virtual booth and narrated presentation](#) at the European Association of Nuclear Medicine congress, 22–30 October

Radioligand therapy readiness assessment framework

What is the readiness assessment framework?

Considering the barriers to integration of radioligand therapy into cancer care identified in the policy report, we built an assessment framework to evaluate the situation in different countries and help guide change. The framework asks:

- ❓ Are all the necessary policies, processes and resources in place to ensure full integration of radioligand therapy into cancer care in different countries?
- ❓ What components need to be in place for systems to be ready to implement this approach in any other cancer types in the future?
- ❓ What lessons can be learnt from the integration of other therapies and applied to radioligand therapy?
- ❓ What lessons can be learnt across different countries?

Scoping research

We evaluated several existing frameworks and tools to help us understand how to build a credible tool that can assess system-level readiness for radioligand therapy. We also spoke to experts in nuclear medicine, clinical oncology, cancer planning and framework development, and drew from existing work.^{1,2}

The radioligand therapy readiness assessment framework that we created as a result is the first framework of its kind to focus specifically on this form of therapy.

Methodology

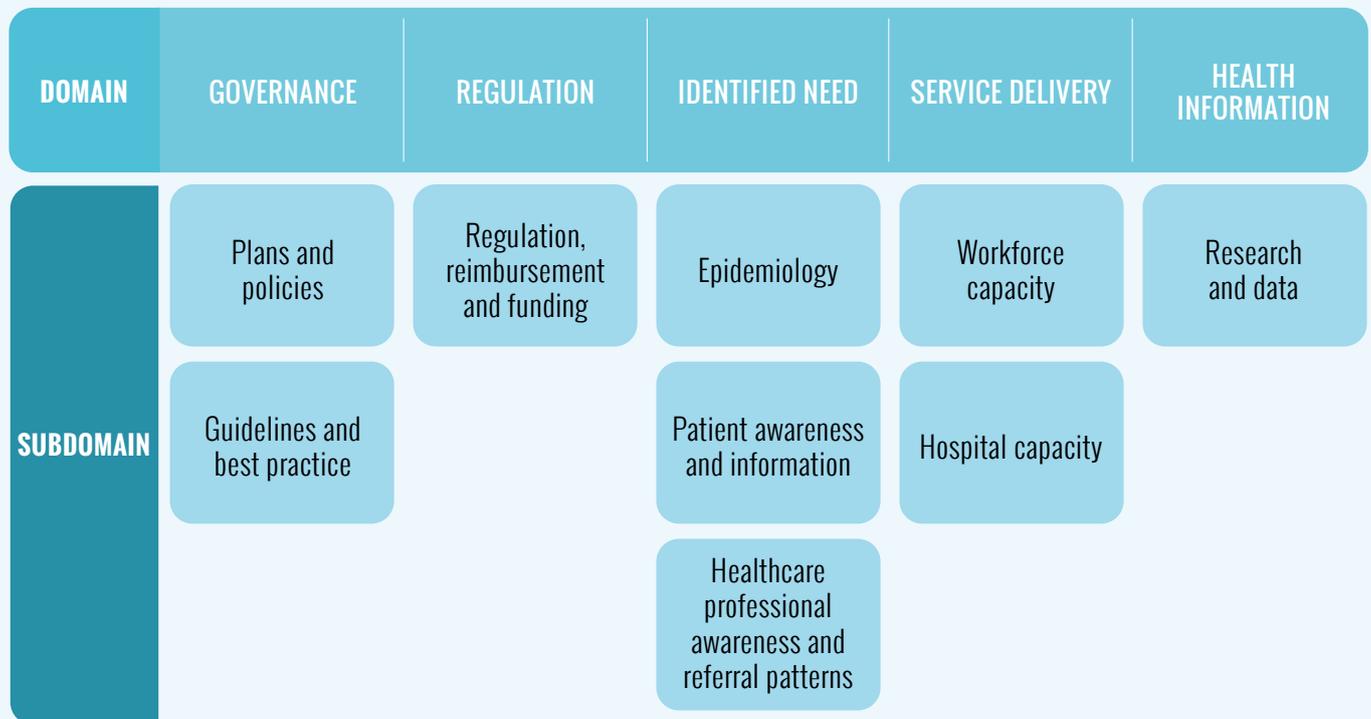
We identified five domains to assess system readiness. These domains form the backbone of the assessment framework and aim to guide us in uncovering best practice in terms of optimal system readiness (*Figure 1*).

The methodology for developing the assessment framework was presented as a [poster](#) at the European Society for Medical Oncology (ESMO) conference in October 2020.

1. Atun R, de Jongh T, Secci F, et al. 2010. *Health Policy Plan* 25(2): 104-11

2. Maser B, Force LM, Friedrich P, et al. 2020. *J Cancer Policy*: 10.1016/j.jcpo.2019.100208

FIGURE 1: Domains and subdomains for the radioligand therapy readiness assessment framework



A grounded theory approach

The framework has been developed to evaluate the current ‘state of play’ in different countries in terms of the potential integration of radioligand therapy into care pathways. It is being piloted in the UK and the US. We have adopted a grounded theory approach to developing it further, incorporating findings from country analyses to refine it over time. Once finalised, the framework can then be applied to other countries.

DR JOHN BUSCOMBE, President, British Nuclear Medicine Society (BNMS):

At the BNMS, we are aware of the need to prepare the UK for the new radioligands for cancer treatments, which will be coming soon. I applaud the work that The Health Policy Partnership has done over the past year to look at ways we can all be prepared to provide radioligand therapies to patients, where indicated, and to ensure we avoid a ‘postcode lottery’ with patients denied access because of where they live. Working with The Health Policy Partnership, we believe we can deliver equitable access to this exciting new way to effectively treat cancer.

Project goals



Country-level assessments and policy engagement

The year 2021 will see the development of country-specific outputs based on the research conducted throughout 2020. The situational analyses for both the UK and the US, and the accompanying frameworks, will serve to develop a policy action blueprint for each country. We will also build a readiness strand to the work, expanding our work in radioligand therapy to cancer care more broadly and contributing to wider discussions on readiness within healthcare.

JOSH MAILMAN, President of NorCal CarciNET and patient advocate:

Decision-makers and public policymakers at all levels need to work together to align policies that support the greater integration of radioligand therapy into existing cancer care pathways. We need this to ensure that the right people get the right care at the right time. Given the complexities of the US healthcare system, communication between public policymakers, healthcare professionals and patient communities across all disease types is vital to bring about change that can improve patient outcomes.

Outputs planned for 2021

📌 Situational analysis

In early 2021, we will develop a comprehensive situational analysis for the UK and the US. The findings will be used to develop nationally specific, consensus-driven policy recommendations for key decision-makers to drive optimal system readiness for radioligand therapy. We will seek to publish our findings in leading oncology and nuclear medicine journals.

📌 Nationally adaptable framework

We will launch the radioligand therapy readiness assessment framework as a nationally adaptable, publicly available resource. We hope it will assist researchers in understanding our overarching approach and encourage them to apply the framework independently in the future.

📌 Policy action blueprints

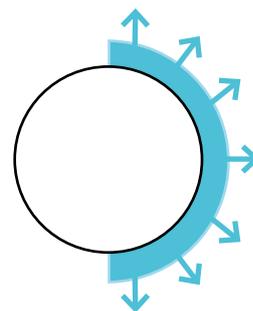
Policy action blueprints will be developed as starting points for policy engagement in the US and the UK, based on findings from their situation analyses. They will outline five to eight priority actions needed to shift policy in each country. The blueprints will be available both as web-based resources and as summary handouts.

📌 Building the readiness strand

The readiness strand will provide a general overview of what system readiness in cancer care means and why it is important. It will be developed in the form of a policy brief with an international focus. We will also develop a case study to showcase how system readiness can be applied in practice, including in other targeted cancer treatments.

Stakeholder engagement and dissemination

An important goal of our ongoing work is to continue to engage more stakeholders across the cancer community on the topic of radioligand therapy. We plan to launch the framework at the American Society of Clinical Oncology (ASCO) annual meeting in 2021. We will engage the cancer community through attendance at a range of high-profile conferences and meetings.



Engagement at major events will be accompanied by ongoing interactions via the radioligand therapy website, as well as Twitter and video outputs.

National political launches

We plan to host political launch events both in the UK and in the US in June and July 2021. These events will launch the situational analyses and policy action blueprints to raise awareness of key issues among a wider audience.

Further project development

PROFESSOR HEIN VAN POPPEL, Adjunct Secretary General for the European Association of Urology:

I am pleased to be involved in the readiness assessment project and represent the perspectives of the prostate cancer community. With any cancer, but particularly advanced prostate cancer, a smooth and timely integration of innovative and personalised treatments is essential. We need to make sure that this happens collaboratively, with patients and all members of the multidisciplinary cancer care teams working together with a shared vision for the future.

Expand the assessment to other countries

The end of 2021 will see us planning for further national assessments in other countries around the world. This will allow us to expand the scope of the research to make the framework more globally relevant.

Broaden the scope of readiness to other areas of cancer care

In building the readiness strand, we intend to host a round table on readiness in cancer care at ESMO 2021. This will take our work beyond radioligand therapy and into the broader healthcare research agenda. We will consider preparedness, resilience and sustainability when planning for the future of cancer care.

Secure further investment in the project from multiple funders

We have already secured funding from Advanced Accelerator Applications and Nordic Nanovector, and are in ongoing discussions with potential funders to expand the scope of the research to treatment modalities beyond radioligand therapy. We wish to secure sustainability and diversity of funding for the project, to ensure that we can deliver lasting impact.

Project governance

HPP leads the overall project, acting as Chief Researcher and Editor. The project is steered by an International Working Group consisting of HPP and Avalere, our US research partner.

A multidisciplinary International Advisory Group oversees and provides guidance on this work, with UK and US arms focusing on national-level work.

International Advisory Group

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