Readiness for radioligand therapy

Radioligand therapy: preparing for the future of targeted cancer care

International workstream Terms of Reference

7 March 2022

1 Project background

In 2019, The Health Policy Partnership (HPP) began a project to raise awareness of radioligand therapy among European policymakers and the broader cancer community. This culminated in the launch of a policy report in early 2020, which outlined barriers to the integration of radioligand therapy across Europe. During this first phase of work, HPP, with guidance from a Multidisciplinary Advisory Group, also developed a website, an explanatory video, and an editorial.

Over the course of 2020 and 2021, HPP developed the Radioligand Therapy Readiness Assessment Framework as a tool to define what is needed across all domains of a health system to support integration of and readiness for radioligand therapy. With guidance from national advisory groups, the framework was applied to the UK and US, and policy action blueprints were developed to encourage system readiness for appropriate integration of radioligand therapy within each country. The framework is publicly available, alongside a series of tools to support its independent application in other countries, regions or healthcare settings.

The planning required to integrate radioligand therapy into cancer care is an example of why we need to take a systems approach to ensure readiness in healthcare. Building on this example, HPP has undertaken work to explore health system readiness more broadly. Part of this work included the development of a policy brief which outlines how assessment frameworks can help explain how we can best define, evaluate and operationalise readiness in cancer care.

1.1 Continuation of the work in 2022

HPP wishes to build on the momentum of this work by strengthening existing collaborations while also engaging with new partners to apply our methodology to other geographies. Additionally, we would like to explore applying our approach to other areas of healthcare.

Our work in 2022 will be divided into an international workstream and national workstreams specific to different countries. There are currently active workstreams for the UK and US, which focus on building momentum and disseminating findings from the national-level applications of the Radioligand Therapy Readiness Assessment Framework. We anticipate that new national workstreams will emerge as the framework is applied in new settings, with active support from HPP. As this occurs, specific Terms of Reference will be developed for each national workstream and updated accordingly.

This document provides Terms of Reference for the continuation of this project for the international workstream only.

2 Aims

The initial aims of the radioligand therapy project were to:

- increase awareness of radioligand therapy and the importance of taking a systems approach to assessing its integration into cancer care
- define what is needed across the health system to support appropriate integration of radioligand therapy at both the international and national levels
- ingrain radioligand therapy into ongoing discussions around readiness in wider cancer care and healthcare
- engage a multidisciplinary network of stakeholders to expand ownership of the approach, implement proposals for policy change and achieve optimal system readiness.

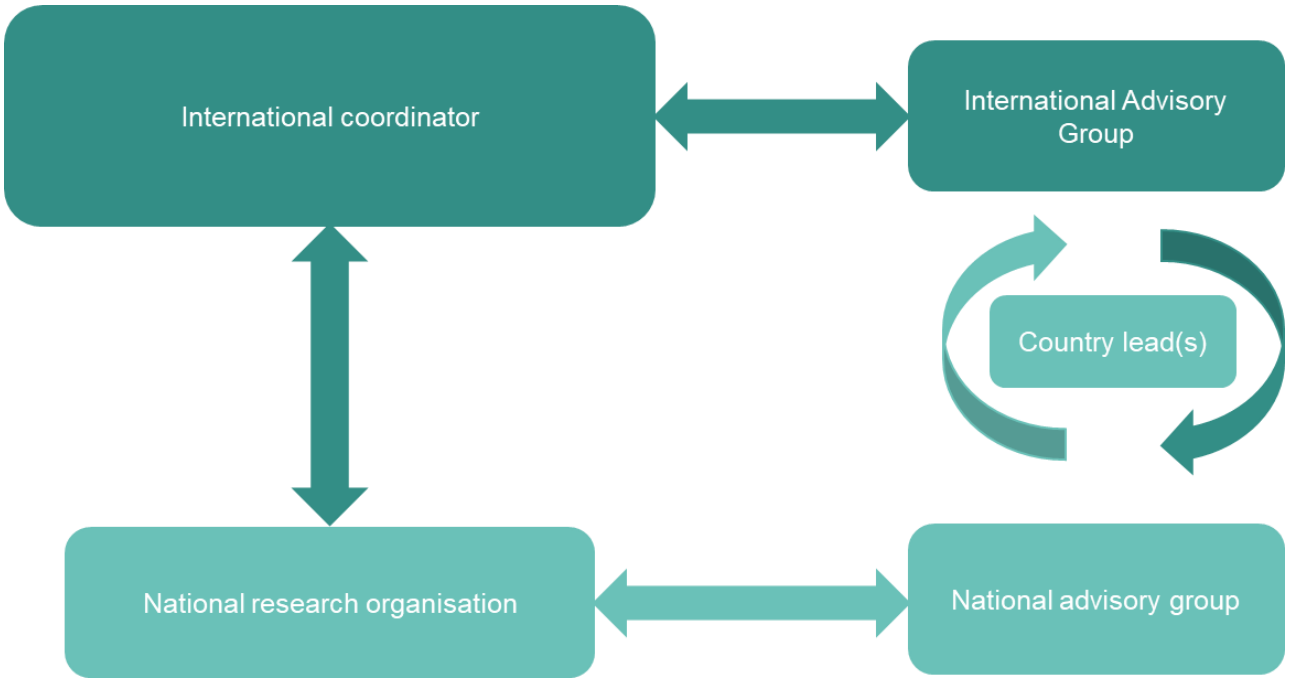
These initial aims remain relevant to the current phase of work for the project. Over the course of 2022, the international workstream will continue to act as a foundation to the project and specifically aims to:

- build momentum and multistakeholder awareness of and support for appropriate integration of radioligand therapy.
- grow leadership in health system readiness.
- drive change to improve appropriate integration of and readiness for radioligand therapy.
- support independent applications of the radioligand therapy framework to specific settings, indications or geographies.

3 Project governance

The radioligand therapy project is comprised of a series of advisory groups and research organisations (*Figure 1*).

Figure 1. Organigram of the project organisation[1]



3.1 International coordinator

HPP is the international coordinator to the project, with the role of managing and coordinating the project through the international workstream.

National research organisations will lead on national-level workstreams with support from the international coordinator. These research organisations will also feed back to the international coordinator to help further develop the overall project and inform the international-level work.

The international coordinator will seek to deliver the project aims and activities, and will be responsible for:

- **Organising and coordinating the International Advisory Group**: running the group in line with these Terms of Reference, leading stakeholder outreach and engagement in addition to organising, managing and facilitating all virtual and face-to-face meetings. The international coordinator will hold a minimum of one International Advisory Group meeting a year.
- **Managing the project**: being responsible for work planning, processing expenses, administration, financial reporting and liaison.
- **Leading on research and drafting of outputs**: collating comments from all involved experts and ensuring group consensus is represented in all final outputs. Being responsible for international outputs and supporting national outputs via consultation with national research organisations.

[1] Depending on the setting in which the framework is being applied, a regional or institutional research organisation or advocacy group may fill the role of the national equivalent.

- **Disseminating outputs**: developing a dissemination plan, with the aim of ensuring the project outputs reach relevant stakeholders. Being responsible for international outputs and supporting dissemination of outputs from national research organisations and findings from independent applications of the framework, as appropriate.
- **Upholding transparency and high ethical standards**: ensuring all key outputs and correspondence contain clear information on the project, including a funding declaration in line with these Terms of Reference. The international coordinator will only use endorsements and permissions in strict accordance with pre-agreed terms.

3.2 International Advisory Group

The International Advisory Group guides the international coordinator in the research, development and dissemination of international outputs. All members of the group have equal voices and voting rights. The International Advisory Group has ultimate editorial control of all international outputs. The international coordinator will support requests that come from the members of the International Advisory Group.

Participation in the International Advisory Group is by invitation from the international coordinator, which is responsible for ensuring that members are representative of all relevant stakeholder groups, and aims to ensure equality, diversity and inclusivity within the group. The International Advisory Group will include country leads from each national advisory group to act as a bridge between the international and national work.

All group participants must share the project goals and agree to respect the values of multidisciplinary working. With respect for external demands on time, and agreed level of involvement, we ask that International Advisory Group members aim to make themselves available for scheduled meetings and provide feedback on documents as requested. For a list of international outputs planned for 2022, see section 6.

If a member of the group wishes to step down from their role, they are free to do so at any time by notifying the international coordinator in writing.

4 Project funding

The radioligand therapy project is currently supported by a grant from Advanced Accelerator Applications, a Novartis Company, with additional support provided by Nordic Nanovector. Funding for the US outputs is in the form of an unrestricted grant. HPP is engaged in an ongoing process of outreach and discussion with other potential funders to obtain additional support. As new funders are brought into the project in the future, these Terms of Reference will continue to be updated accordingly.

A maximum of two representatives from each funding company may act as observers in the International Advisory Group and national advisory groups. The representatives will be invited to attend and observe all meetings, and provide feedback on all core outputs. However, they do not have any decisional power on any aspect of work. Outputs will not have to undergo internal review, and ultimate editorial control and the intellectual property rests with HPP under the guidance of the project advisory groups.

The above benefits and restrictions apply equally to all funding partners, regardless of the level of their financial contribution to the project. No funder will be granted greater benefits than another. To ensure transparency, all funders are listed on all project materials in alphabetical order.

Each funder is requested to abide by the principles contained in these Terms of Reference.

5 Ways of working

HPP, research organisations, advisory groups and funders will work in a way that demonstrates four core values:

- **Consensus:** all outputs from the project will aim to accurately represent a consensus among the involved experts.
- **Independence:** all outputs will be strictly non-promotional, and no specific products or technologies will be listed. Outputs will not be subject to legal or scientific review by any funding partner.
- **Transparency and adherence to public standards:** all outputs will have a clear declaration naming all funding partners. Major outputs will provide declaration of payments to any contributors (e.g. honoraria or paid advisers), as appropriate. Outputs will also be clear and transparent about any therapies that are currently under clinical investigation and/or currently unlicensed.
- **Objectivity and balance:** all outputs are for educational purposes and will be based upon a balanced review of the available evidence.

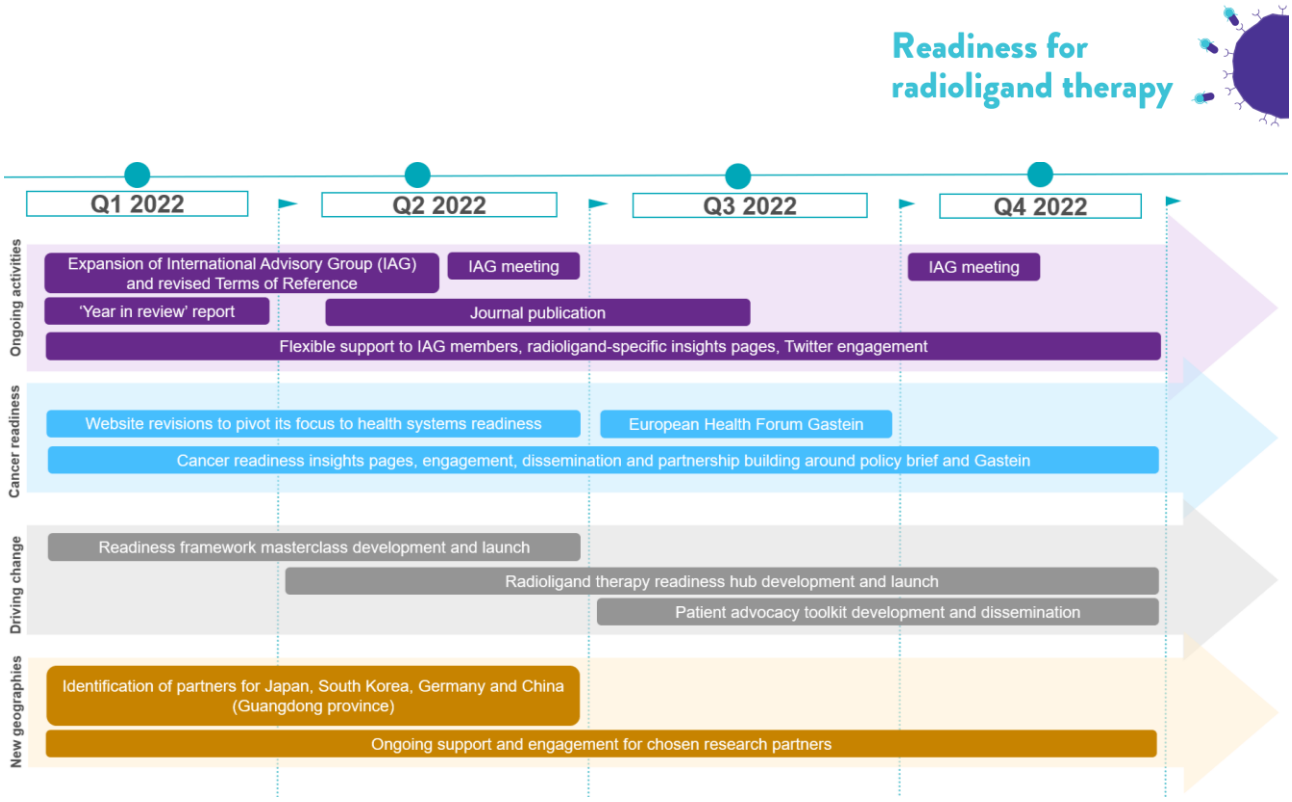
5.1 Reimbursement

To preserve the independence of the project, members of the International Advisory Group are asked to provide their time on a voluntary basis. However, the international coordinator will reimburse reasonable expenses incurred by any invited group members as a result of participating in project events or meetings, as appropriate. This includes standard-fare air or rail travel and business-standard accommodation. Any reimbursement must be compliant with national laws or regulations regarding industry funding as well as the European Federation of Pharmaceutical Industries and Associations guidelines in Europe or relevant guidelines in other countries, as appropriate. The international coordinator requests that the same principles be followed at the national level.

6 Activities in 2022

The international activities planned for 2022 are summarised in *Figure 2*.

Figure 2. Overview of 2022 international-level activities



As outlined in this figure, and with support from the International Advisory Group, the international coordinator will:

- Build momentum and increase awareness of radioligand therapy through activities including development of a:
    - **'Year in review' report:** a summary of the project's achievements in 2021 and next steps for 2022, which can be used for internal and external engagement.
    - **Journal publication:** a topic relevant to the radioligand therapy readiness assessment framework will be agreed in consultation with the International Advisory Group.
- Expand assessments of health system readiness beyond radioligand therapy, to wider cancer and health care, through activities including:
    - **Updating the project website:** redesigning the website home page to pivot its focus to health system readiness. This will support further discussions on readiness, attract new audiences and contributors, and enable the framework to be applied to other types of care.
    - **Developing a generic Readiness Assessment Framework:** a framework that is applicable to other innovative approaches in healthcare.
    - **Interactive meeting at European Health Forum Gastein on health system readiness:** using the policy brief as a stepping stone, the meeting will focus on the use of frameworks to improve planning for health system readiness.
- Drive change to improve readiness for appropriate integration of radioligand therapy through activities including development of a:

- **Masterclass video:** which will provide a simple and clear explanation of how to apply the Radioligand Therapy Readiness Assessment Framework. Building on the user guide and templates, we hope this resource will further facilitate independent applications of the framework.
- **Radioligand therapy readiness hub:** a resource that highlights best-practice examples of actions taken to improve the integration of and readiness for radioligand therapy, to support shared learning across different geographies, settings and cancer types.
- **Patient advocacy toolkit:** a resource to support patients in understanding the radioligand therapy pathway and the ways they can engage with policymaking.

- Support further applications of the framework in new geographies by providing guidance, support and information to appropriate external organisations applying the framework in Germany, Japan, South Korea and China (Guangdong province).

Activities at the national level will be agreed upon with the national research partner and relevant national advisory group.

7 Contact

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