

The Belgian integrated radioligand therapy plan for cancer treatment as a blueprint for other EU countries

The Belgian multi-stakeholder approach

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INOVIGATE

achieving outcomes





There is a huge influx of promising radioligand therapies (RLTs) for cancer
RLTs pose specific challenges to benefit patients

How can we balance innovation, access and future preparedness?



- During its **presidency of the Council of the European Union**, Belgium will strive towards a brighter future for medical radioisotopes
- The aim is to discuss and give inspiration on **access to radioisotopes for all European cancer patients**

- **We have developed in multi-stakeholder collaboration an integrated RLT plan for Belgium, to be future prepared**
- **The plan can serve as a blueprint for other countries and support alignment across EU, for optimal patient benefit**

Outline

- 1 The Belgian preparedness for RLTs and what we need**
- 2 The approach we took to build the plan**
- 3 The Belgian RLT plan as a blueprint for the EU**

Belgium has a rich RLT landscape, covering the full value chain

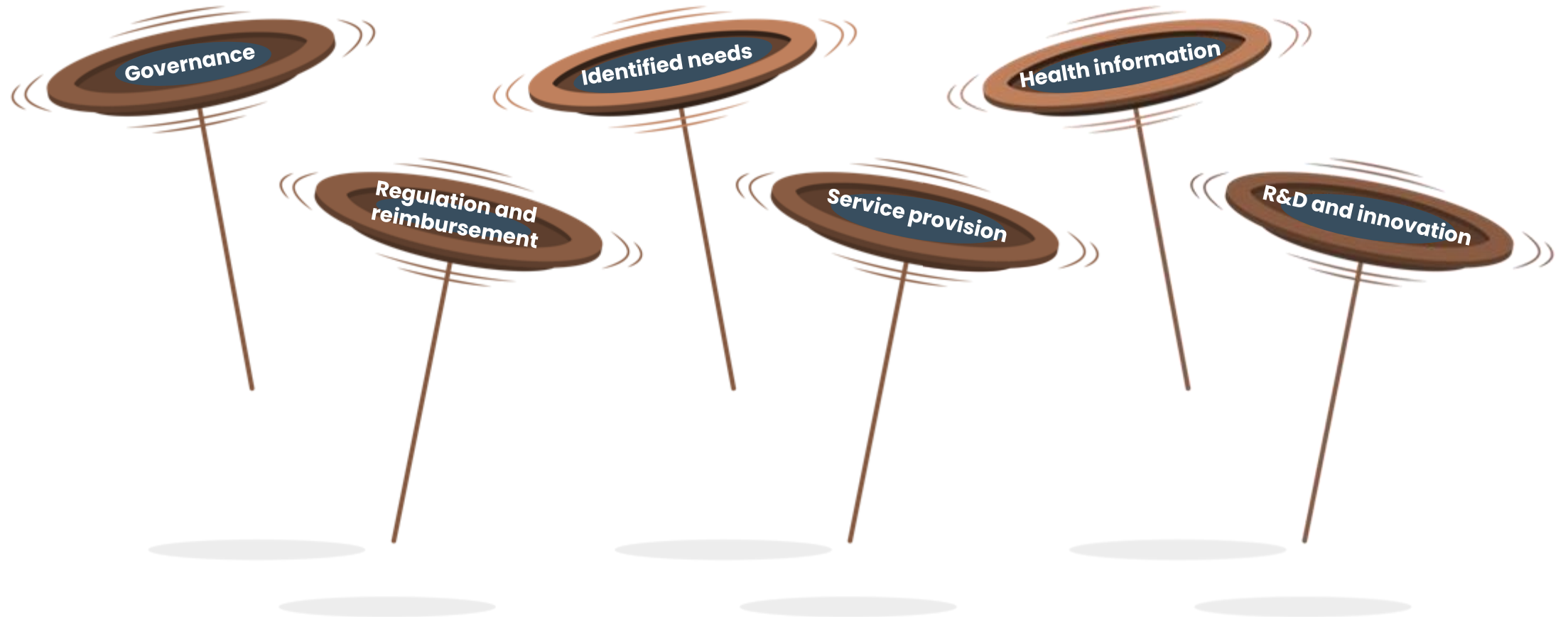


A horizon scan shows a tsunami of RLTs coming our way

Radioisotope	Preclinical	Phase 1 & 1/2	Phase 2	Phase 3/Reg	Approved	
177-Lu	RAD CONNECT SPAGO AIP	IPSEN curasight CELL Akirama Therapeutics	Blue Earth Therapeutics Cancer Targeted Technology CTT CLOVIS ONCOLOGY Debiopharm GIY Therix M.T.T.I NOVARTIS	ARICEUM NORDIC NANOVECTOR FUTURECHEM	CURIUM itm Sinotau LANTHEUS NOVARTIS Telix POINT	NOVARTIS
225-Ac	RAD itm Blue Earth Therapeutics	Fusion PRECIRIX ARICEUM	POINT OncoTab Ratio Modulation Therapeutics, Inc. NOVARTIS LANTHEUS	Jaf Telix Fusion CONERGENT	RayzeBio	
131-I	Cereius	Pacific Meinuoke	PRECIRIX	CELLECTAR Telix Therapeia JUBILANT	Actinium Pharmaceuticals, Inc.	LANTHEUS
90-Yt	ANDARIX OncoTherapy Science, Inc. ALISSAPHARMA	Ashvattha oranomed	FUJIFILM Telix	PPMX PENTIXAPHARM		ACROTECH
Other	RAD alpha9 3B Pharmaceuticals	Abdera Therapeutics Atonco VIEWPOINT Nami Therapeutics AKTIS Radionetics TREVARX	AdvanCell NOVARTIS mAbs Therapeutics, Inc. CLARITY ANDARIX NANOMAB PLUS PENTIXAPHARM OSAM Biosciences	onco invent RadioApeX oranomed Serene		Bayer BioMed

Source: Andrew Pannu

There are many challenges that must be addressed, to ensure patient access to all RLTs available in the future



The pathway for the future is a shared responsibility



... All stakeholders should take responsibility in

... A **transparent dialogue** based on all available information

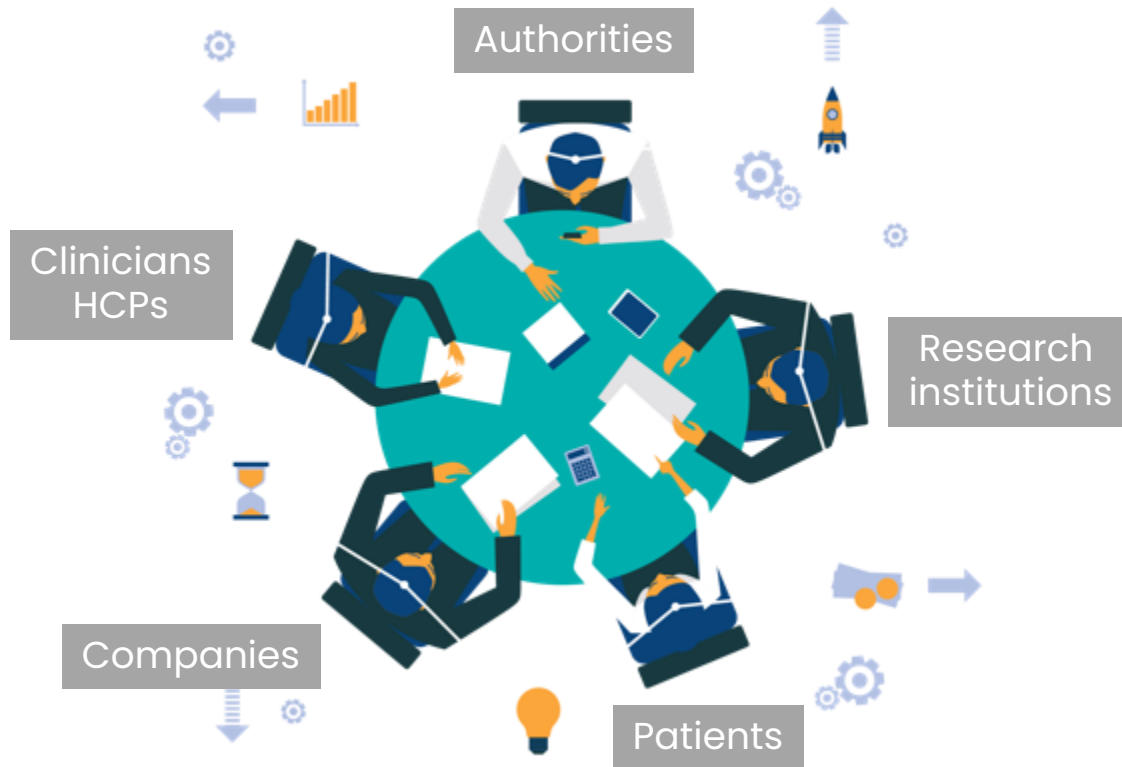
A person in a blue jacket and tan pants is performing a handstand on a rocky cliff edge. The background features a wide fjord with steep, forested mountainsides under a cloudy sky. The scene is captured from a high angle, emphasizing the height and risk of the activity.

The stakes are high We must be able to reconcile all the interests

Manufacturers

Payers

Three multi-stakeholder round tables were organised to create common ground for a future-proof Belgian RLT plan



- 3 sessions, 2023
- 37 representatives of key stakeholders
- Complemented by external expert opinions, scientific literature review, and in-depth interviews

Chaired by Jo De Cock

Organised by Inovigate in full independency

The Belgian RLT plan is created based on a multi-stakeholder engagement approach



First round table on October 4th 2023

Benefits of a multi-stakeholder approach

- **Exchange experience** and concerns by stakeholders with different backgrounds contributes to better mutual understanding
- **Fast** methodology to reach a solution that is widely supported
- **Co-creation and co-design** of the essential building blocks of the RLT plan

We structured the RLT plan building blocks in 6 domains, as a framework to facilitate dialogue and co-create solutions

Domains:	Description:
Governance	<ul style="list-style-type: none">• Rule-making functions• Policy and plans (incl. guidelines and best practices)
Regulation and reimbursement	<ul style="list-style-type: none">• When and how RLTs should be provided and paid• Ensures safety, efficacy and sustainability
Identified needs	<ul style="list-style-type: none">• Potential RLTs need and/or demand
Service provision	<ul style="list-style-type: none">• Healthcare workforce and infrastructure required
Health information	<ul style="list-style-type: none">• Data to support decision-making• Understand RLT use and improvements
R&D and innovation	<ul style="list-style-type: none">• Research, clinical trials and innovations in RLT• Public and private funding instruments

In each domain, we have developed solutions in multi-stakeholder agreement

Domain & description

Challenges identified by stakeholders during interviews

Domains:	Main challenges & barriers prioritised by stakeholders:	Solution building blocks based on RT:	
<p>Governance</p> <p>Governance refers to a range of steering and rule-making functions carried out by decision-makers that directly impact the availability, accessibility and standards of delivery of RLT. Governance comes from health decision-makers in the form of policy and plans, including guidelines and best practices from the clinical community</p>	<p>Belgium should stay at the RLT forefront, preserving and even further reinforcing its strong legacy in RLT</p>	<p>RLT hotspot & leadership vision</p>	<p>The Belgian RLT value chain should be evaluated and strengthened to support RLT across all actors to increase strength and impact and to reinforce the position of Belgium as RLT hotspot. A Belgian RLT leadership vision and plan is required to keep our top position</p>
	<p>RLT has a lot of complexities involving multiple dimensions (resources, regulations, supply aspects, etc.) and stakeholders. Today, harmonisation and alignment is missing and there are no objectives and goals</p>	<p>RLT strategic plan (national multi-stakeholder) aligned with cancer plan</p>	<p>An integrated, multi-stakeholder supported RLT vision, strategy and plan for Belgium is needed with clear objectives and evaluation metrics. The RLT plan should be aligned and integrated with the national (revisited) cancer plan.</p>
	<p>RLT is poorly integrated into cancer planning and there is limited political recognition and leadership</p>	<p>Long-term central planning & management (horizon scanning)</p>	<p>A Belgian RLT task force could ensure long term equal patient access by future preparedness and proactive planning. Tasks could be (to be confirmed) a central planning and management role in e.g. infrastructure occupation and investment, production, supply chain and management planning</p>
		<p>Involve patients & all stakeholders</p>	<p>Involving patients and all stakeholders to take part in defining the RLT plan for Belgium, the priorities and decision-making. Patients and patient organisations should be heard in the debate vs. medical community, authorities, agency, ...</p>
		<p>Governance for fast approval or modification</p>	<p>Legislation, regulations, compliance and administrative pathway allowing for fast approval or modification</p>

Building blocks for solutions that resulted from the multi-stakeholder round tables

The optimal solutions for access to RLTs consist of many solution building blocks



No single solution will be sufficient to provide access to RLTs for patients

We need to **combine solution options** in order to achieve our ambitions

Over the six domains, we have developed 27 solutions in multi-stakeholder agreement

Governance	RLT hotspot & leadership vision	RLT strategic plan (national multi-stakeholder) aligned with cancer plan	Long-term central planning & management (horizon scanning)	Involve patients & all stakeholders	Governance for fast approval or modification
Regulation and reimbursement	Adaptive safety regulations	Adequate reimbursement budget	Outcomes-related reimbursement	Regulate hospital and industrial production (how)	Criteria for hospital and industrial production (what)
Identified needs	Awareness building & info dissemination	Inclusion in multidisciplinary cancer treatment	Centres of excellence	Clear criteria for referrals & care pathways	
Service provision	Short-term central planning & management of demand and supply	Inclusion of future technology evolutions	Companies to provide total solutions	Professional training & licensing for all HCPs	Ensure patient supply
Health information	Evidence-based decisions, guidelines, value	Predictive models based on registries, RWD/E			
R&D and innovation	Sufficient large clinical trials to be meaningful	Clinical trial framework to become hotspot	Adapted financing instruments	Data collection & re-use for R&D	Knowledge pooling

Each building block was created from stakeholder interviews, literature research and round table discussions

During the multi-stakeholder round tables, **each solution was agreed upon**

In the RLT report, each solution block is described in detail and paired with **concrete actions for each stakeholder group**

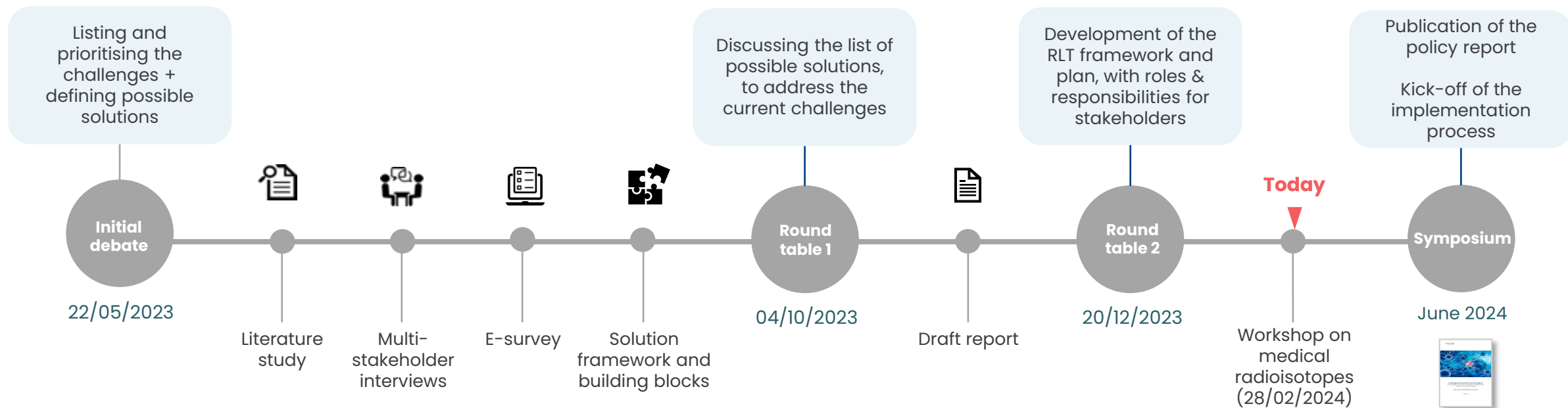
This multi-stakeholder approach offers win-win solutions for patients, hospitals & research institutions, authorities and companies

Win-win

- Patients must have fast access to the most optimal cancer treatment, incl. RLTs
- Pharmaceutical companies must find clear market access conditions and fair reward for innovative medicines, while payers want to keep healthcare budget under control
- Hospitals must receive correct reimbursement of patient RLT care pathway incl. data collection
- Hospitals, policy makers and pharmaceutical companies have to collaborate and manage supply, available care infrastructure, incl. visibility on care investments needed to cope with future RLT growth



The multi-stakeholder supported solutions will result in a policy report with recommendations for an RLT plan for Belgium



The report addresses the RLT landscape, challenges and solutions



The report addresses the following topics:

- The RLT potential and landscape
- European actions
- The objective: Belgian preparedness for RLT
- The approach
- RLT challenges and proposed solutions
- RLT solution framework for Belgium
- Integration of the Belgian RLT framework into the cancer plan
- Next steps

The report will be published at the symposium (and online)
In June 2024

The Belgian RLT plan is based on the EU recommendations

EU Key recommendations:

Translating radiotheranostic cancer research into clinical practice in Europe



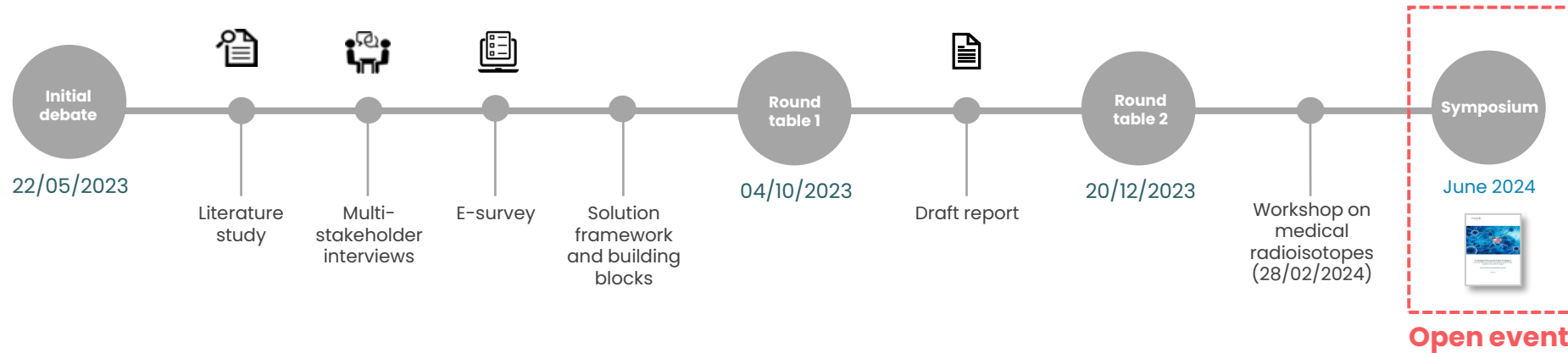
1. **Encourage a coordinated approach** between the research programmes, with solutions for scaling up to market demand and clinical use
2. **Strive for EU autonomy** for a continuous, stable and uninterrupted supply of medical radionuclides considering an increasing demand of use
3. **Harmonise the requirements for clinical trials** with radiopharmaceuticals across EU Member States, to enable multicentre European studies and agilise timelines for approval
4. **Address regulatory issues** concerning radiation protection, including harmonisation of guidelines for hospitalisation
5. **Joining forces on education and training** for radiopharmaceutical use to health care providers, radiation protection experts, regulators, decision makers, patients and respective care takers
6. **Encourage the integration of radionuclide technologies** in multidisciplinary clinical boards, addressing also pooling of data for harmonisation of clinical practice.
7. **Support health technology assessments and cost-effectiveness analysis** of radiopharmaceutical diagnosis and treatments in support of reimbursement decisions

Belgian RLT plan:



Translated to the Belgian context and integrated into the **Belgian RLT plan**

A symposium will be organised in June at NIHDI to present the report and launch the implementation of the RLT plan for Belgium



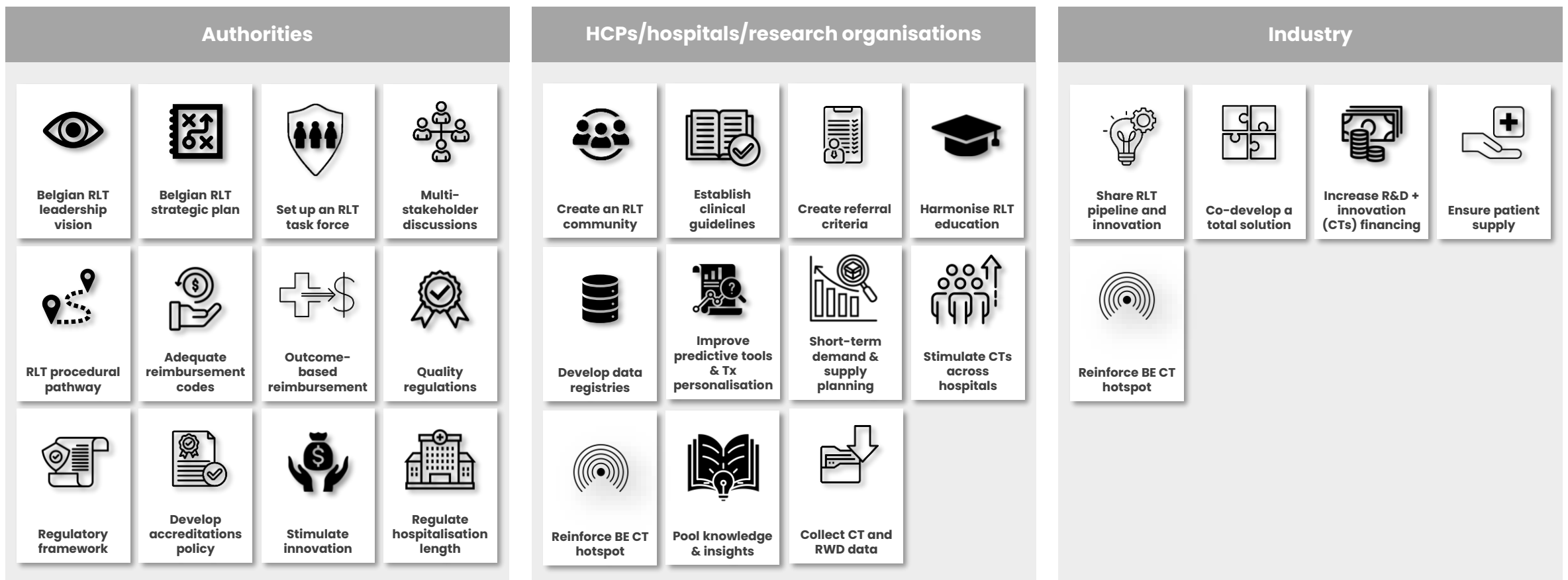
The report will be made available on our website after the symposium:



<https://www.inovigate.com/publications/>

Initiatives and actions have already been assigned to stakeholders to ensure implementation of the RLT plan in Belgium

RLT framework for Belgium



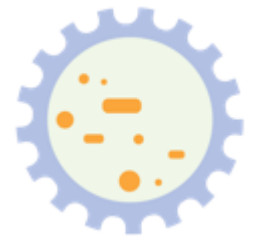
Future challenges



The Belgian RLT plan can inspire multi-stakeholder supported RLT plans in other countries to obtain EU-wide RLT future preparedness

Insights gained can serve as **inspiration** for future collaborative RLT solution-seeking initiatives in the EU

Talking, listening and **acting together** via an intellectually fair process is a key tool for collaboration and solving **multi-stakeholder challenges**



Thank you!

**Want to attend the symposium in June and be part of the implementation coalition?
Contact us!**

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