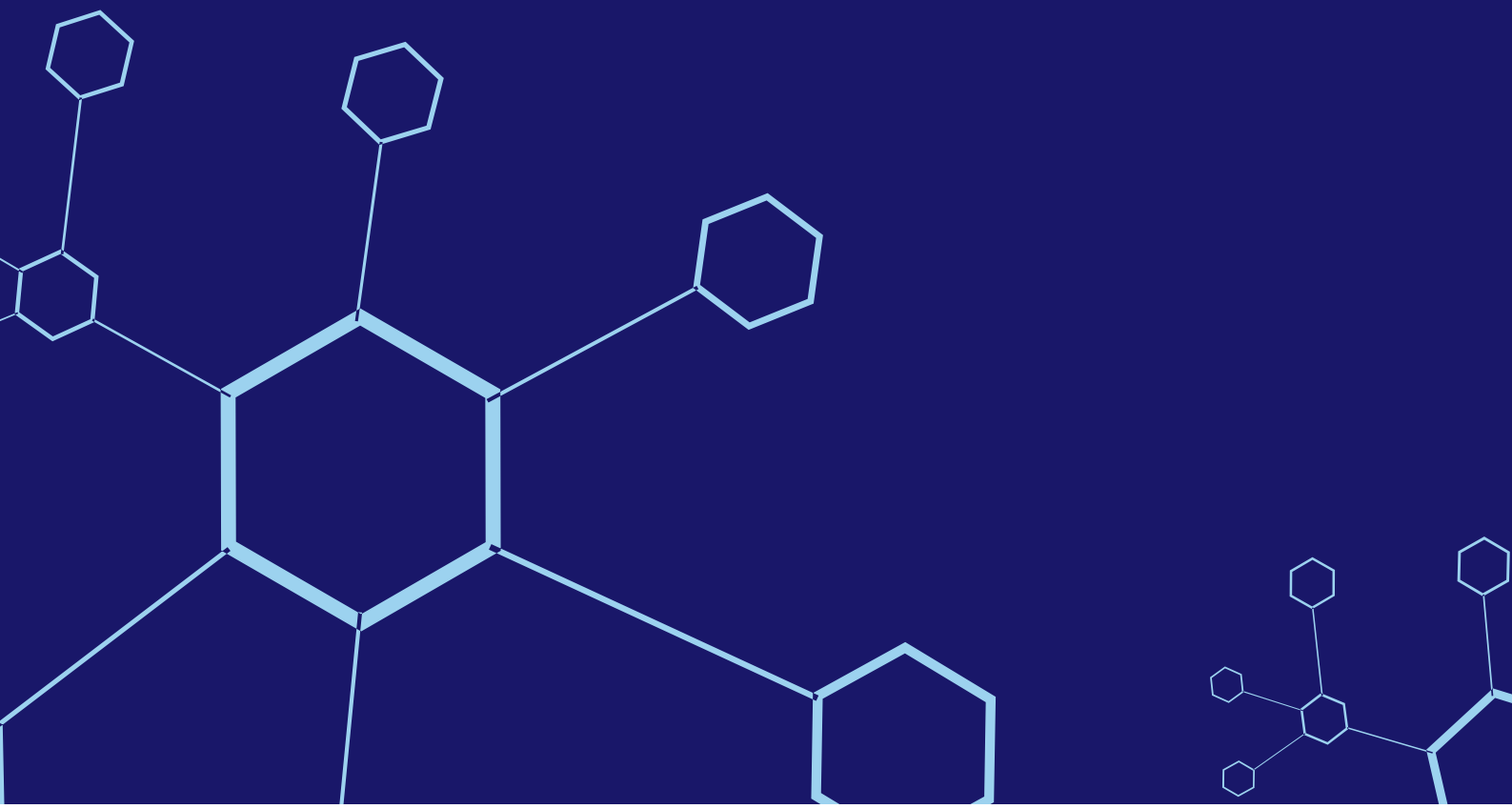
Radionuclides For Health UK

RADIONUCLIDE SUPPLY IN THE UK: A PATH TO A CANCER BREAKTHROUGH



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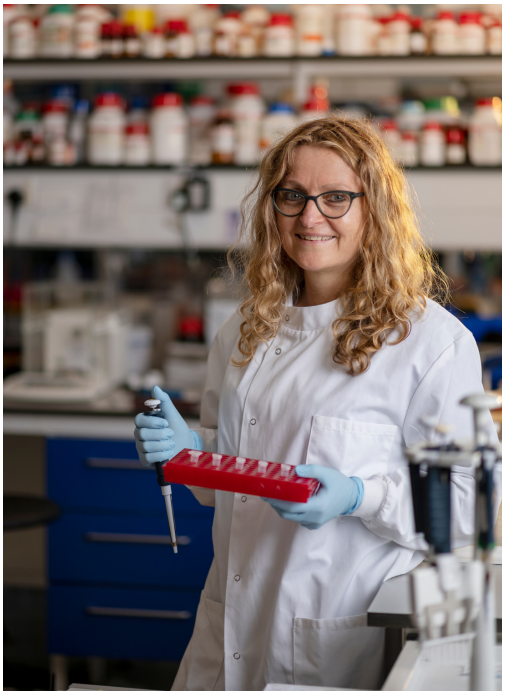
Executive summary

The UK's Life Sciences Vision set a bold vision for the future of UK science, building on the world leading success in finding a viable COVID-19 vaccine. Molecular radiotherapy offers a tangible route to delivering against these ambitions, with the opportunity to establish the UK as a world leader in expanding this innovative and highly personalised medicine.

Molecular radiotherapy treatment is dependent on a stable supply of radionuclides. The supply of radionuclides into the UK has been impacted by a combination of factors, including decommissioning of nuclear reactors, trade barriers and international conflict. Some radionuclides are so new and innovative that supply chains do not currently exist.

Poor access to radionuclides has implications not just for research and development but for more conventional diagnostics and therapies.

As health security comes to the fore as a policy issue, we believe that the time is right for the UK to invest in radionuclide production and associated infrastructure to overcome these challenges and place the UK's life sciences sector in a world-leading position in beating cancer.



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This paper sets out the big challenges for UK science and what is needed to address the immediate obstacles and become a science superpower in the future.

A golden opportunity for UK science

When the Government published its new Life Science's vision in July 2021, it set out an ambitious and compelling goal: for the UK to become a science super power.

The role that UK scientists played in the development of a novel vaccine for Covid-19, demonstrated the vibrancy and potential of the UK's Life Sciences sector, after years of decline. The Life Science Vision outlines perfectly why the sector must look to the future, with the foreword written by Professor Sir John Bell, Rt Hon Sajid Javid MP, Rt Hon Kwasi Kwarteng MP, Lord David Prior and Sir Jonathan Symonds, stating:

> ***"The research and development that leads to innovative new healthcare products will underpin a globally successful industry. There is a race on to determine which countries will lead this Sector over the next decade and the prize both in terms of economic growth and human health is large. The UK is ideally positioned to compete successfully in this field with outstanding science, and globally successful pharma, biotechnology and medtech sectors."***

Molecular radiotherapy involves the administration of radiopharmaceuticals for therapeutic effect. These innovative therapies use radioactive targeting molecules to deliver a radiation dose specifically to cancer sites while minimising the effect on normal tissues and organs.

This emerging therapy, being researched at Barts Cancer Institute at Queen Mary University of London and King's College London and others, offers an example of how the bold ambition of the Life Sciences Vision could be realised.

At the heart of making this emerging cancer treatment a scalable, world leading therapy is the issue of re-establishing UK production of the essential radioactive component of these treatments - radionuclides.

The big challenges

The United Kingdom faces a cascade of potential challenges which must be addressed or overcome to achieve a reliable and accessible domestic supply of radionuclides. Many of these challenges are interlinked and can be rectified, and turned into a clear opportunity for the United Kingdom to lead the world in life sciences, driving forward skills and clinical trials for cancer treatments.

One such issue is the decommissioning of reactors capable of producing the radionuclide used in innovative cancer treatments such as radionuclide therapy. All of these reactors are located overseas with many planned to be decommissioned in the coming years.[1] This represents both a challenge, but also an opportunity for the United Kingdom to fill the gap that will be left in the market, by creating a domestic supply for use within the UK, but also internationally. The more reactors that are decommissioned, the greater is the opportunity for other countries to step in and fill the gap.

Interlinking into the issue of immediate supply, are the trade barriers that have been thrown up as a result of the United Kingdom's departure from the European Union.

Decreased international cooperation, combined with the issue of trade barriers and increased cost of transport and customs procedures[2], as well as the ongoing situation in Ukraine and the associated sanctions placed on Russia, have resulted in a situation where potential shortages are far more likely than in the past.[3]

[1] The Foundation for Science and Technology, Need for UK to secure a sustainable supply of future medical radioisotopes, Dr Robert Hoyle, 9 December 2020 https://www.foundation.org.uk/Blog/2020/Need-for-UK-to-secure-a-sustainable-supply-of-futu
[2] https://www.healthpolicypartnership.com/app/uploads/Health-system-readiness-for-radioligand-therapy-in-the-UK-situation-analysis-report.pdf
[3] Co-ordinated Approach to the Development and Supply of Radionuclides in the EU; https://op.europa.eu/en/publication-detail/-/publication/4599de47-3ac6-11ec-89db-01aa75ed71a1/language-en

The overarching goal of investing in the United Kingdom's domestic infrastructure to create radionuclides, is to ensure access and lower the burden on the NHS in procuring them for healthcare purposes. The challenge in this space is that all radiopharmaceuticals have very short half-lives, with many having to be manufactured within days, or even hours of patient administration.[4]

Because these are used both in diagnostic and therapeutic settings, it means that the NHS requires a constant supply, which requires a seamless supply chain that is not encumbered by slow customs procedures, and issues in trade. The current model employed by the UK for manufacturing, transporting and preparing molecular radiotherapy is suitable for administering the therapy for a small number of people per week.[5] However, with the Government's intention to make the UK a Life Science superpower, this needs to be stepped up in order to accommodate the new vision.

The UK supply of radiopharmaceuticals are managed by pharmaceutical companies, who due to the short half-lives of the radionuclides and the large distances they have to travel, often have to produce more than is needed. This increases the cost of procurement and in turn the financial burden on the NHS.[6]

[4]Co-ordinated Approach to the Development and Supply of Radionuclides in the EU; https://op.europa.eu/en/publication-detail/-/publication/4599de47-3ac6-11ec-89db-01aa75ed71a1/language-en
[5] Review of Molecular Radiotherapy Services in the UK; https://www.rcr.ac.uk/publication/review-molecular-radiotherapy-services-uk
[6] Co-ordinated Approach to the Development and Supply of Radionuclides in the EU; https://op.europa.eu/en/publication-detail/-/publication/4599de47-3ac6-11ec-89db-01aa75ed71a1/language-en

> If we are to make the UK a life science superpower, we need to step up our ability to conduct clinical trials.

At a time when our NHS has been under large financial strain, cost saving initiatives looking at the long-term should be the focus, and investing in our own domestic capabilities in producing radionuclides and radiopharmaceuticals forms part of this.

If we are to make the UK a life science superpower, we need to step up our ability to conduct clinical trials. Clearly demonstrated by the development of a novel vaccine for Covid-19, the UK's Life Sciences sector, our medicines regulator the Medicines and Healthcare products Regulatory Agency (MHRA) can move quickly to adapt their internal mechanisms when necessary for the public good.

The Government should look at its regulatory framework and assess whether it is fit for purpose to allow for the effective development and implementation of new medicines and treatments. While this is a challenge for the Government to overcome, it presents an exceptional opportunity, not just in the radionuclide therapy space, but for the wider health sector allowing the UK to become a world leader in Life Sciences.

The UK as a pioneer in molecular radiotherapy

The post war years saw the use of radionuclides from Harwell being pioneered as therapies in the UK. Now, the UK could allow other countries or global pharmaceutical companies to lead the way, but this would fail to address the ambition of the Life Sciences Vision and some of the challenges set out above.

Increased interest and investment have led to both academic and commercial expansion of radiopharmaceutical research and development, including emerging molecular radiotherapies that are being researched by Barts Cancer Institute, Queen Mary University of London and King's College London amongst others.

These treatments offer an exciting example of the kind of breakthrough science to which is referred in the Life Sciences Vision. Molecular radiotherapy is a highly personalised way of treating cancer. The effectiveness of the treatment can be determined before treatment begins. Molecular radiotherapy offers significant benefits for patients - significantly reducing tumour burden with fewer side effects than chemotherapy, and the amount of time needed for treatment.

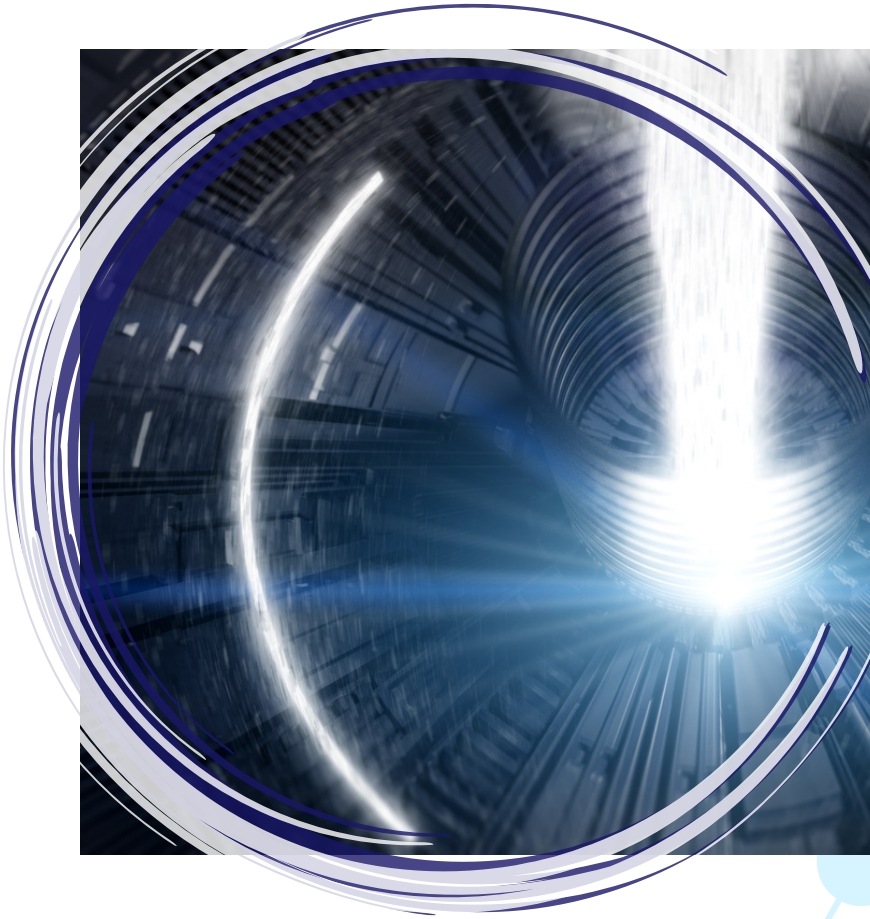
This treatment, which is already available on a small scale, offers a workable and scalable route to addressing a core Life Sciences Vision disease mission, through the UK's world leading specialisms.

> **Molecular radiotherapy is a highly personalised way of treating cancer.**

What do we need to make this a reality?

Re-establishing the UK's radionuclide supply is at the heart of expanding the UK's research and development capabilities in nuclear medicine. Whilst the UK could allow the pharmaceutical industry to lead the way using external supply chains, this would be a missed opportunity to build on the reputation UK science developed during the pandemic and to help drive NHS costs down, while improving the patient experience. There is potential for the UK to become a world leader in this space but investment is required across infrastructure and skills.

We have developed a new five point plan to help accelerate this ambition:



1. Investing in nuclear infrastructure for medical radionuclides in the UK

We believe the UK needs a long-term infrastructure plan for nuclear research, which will ultimately deliver a research reactor for the UK. In the shorter term, we would like to see expanded accelerator and processing capacity in the UK, and the creation of a centralised radiopharmacy dedicated to research and clinical trials. This would have the dual effect of helping secure a domestic supply, and allowing for clinical trials and research to continue, further helping patient lives. There needs to be greater accelerator capacity for the creation of nuclear medicine and diagnostic tools. In Birmingham there is a facility with a high energy accelerator, however it does not have processing facilities and has a limited amount of time dedicated to radionuclide research.

2. Develop enhanced nuclear processing capabilities

At present, the UK is reliant on radionuclides produced elsewhere, specifically for medical use. However existing UK nuclear waste stocks could be used to create a range of molecular radiotherapies. Waste material would require treatment and conditioning processes to convert it into a form that is suitable for its subsequent end-use.

The National Nuclear Laboratory is developing an inventory to ensure that we know what material we have and we need the government to ensure that useful material is kept in the UK and used for the benefits of UK patients.

We would like to see the Government facilitate access to the Nuclear Decommissioning Authority and Ministry of Defence's nuclear material so that its suitability for nuclear medicine can be assessed.

Materials which are suitable for use in nuclear medicine should be reserved for this specific use rather than being sold on or sent for disposal.

We would also like to see Government support for an expanded National Nuclear Laboratory research programme to process this waste into usable material.

This creates the opportunity to generate UK-owned intellectual property.

3. Create a new research friendly regulatory framework for nuclear medicines

Nuclear medicine could benefit from the type of regulatory reform described in the Life Sciences Vision - removing bureaucratic barriers, while prioritising patient safety. This could include a fast-tracked, MHRA risk based assessment for radiopharmaceuticals,

compatible with short half lives of the materials we produce. This might also include specific good manufacturing guidelines designed for our sector. We would like to see a new open dialogue between researchers, industry and the regulator around clinical trials with a view to making the UK more receptive to research & development in nuclear medicine.

4. Create a centralised, nationally accessible appropriately resourced radiopharmacy dedicated to research and trials

Currently, UK radiopharmacies are multi-purposed, used to produce patient doses as well as undertake research and development. Understandably, patient needs take priority, but this limits the capacity for research and the expansion of breakthrough treatments like molecular radiotherapy.

We are calling for the creation of a dedicated research and development radiopharmacy that can be used exclusively for trials. [7]

5. Close the UK skills gap through expanded training opportunities and regulatory reform allowing more people to train to work in the sector

There is currently a shortage of nuclear and radio-chemists in the UK, despite a surge in interest in nuclear medicine. New courses need to be developed and supported to help train the next generation of nuclear and radio-chemists and nuclear medicine specialists.

We need regulatory reform to change the Qualified Person (QP) training process to align with European standards. This would expand opportunities for nuclear and radio-chemists to be involved in clinical trials and become fully qualified. At present there is a shortage of Qualified Persons which in turn is hampering the number of people who are able to train and qualify.

Greater investment could expand capacity at a scale which would deliver against many of the ambitions set out in the Life Sciences Vision.

[7] We have made a start by setting up national pilot facilities for research with radionuclides from waste (NNL) and cyclotron-produced radionuclides (King's College London)

Investment impact

The benefits that nuclear infrastructure investment could deliver

	Nuclear waste processing	Accelerator capacity	Standalone research reactor	Investing in nuclear infrastructure for medical radionuclides in the UK
Security of supply				
New clinical products				
Research opportunities				
Creation of new UK industry				
Value to current health provision				
Impact on local economy				
Employment benefit				
Logistics				

How you can help

Sign up to support our 5 point plan: email **rad4healthuk@qmul.ac.uk** to register your support.

Contact the Minister for Science, to call on them to support efforts to re-establish radionuclide supply in the UK

Follow us on social media and share our content

- **@radionuclidesuk**
- **www.linkedin.com/company/radionuclides-for-/health**

Join our mailing list **rad4healthUK@qmul.ac.uk** to hear more about this campaign and the important work being undertaken by Radionuclides for Health UK