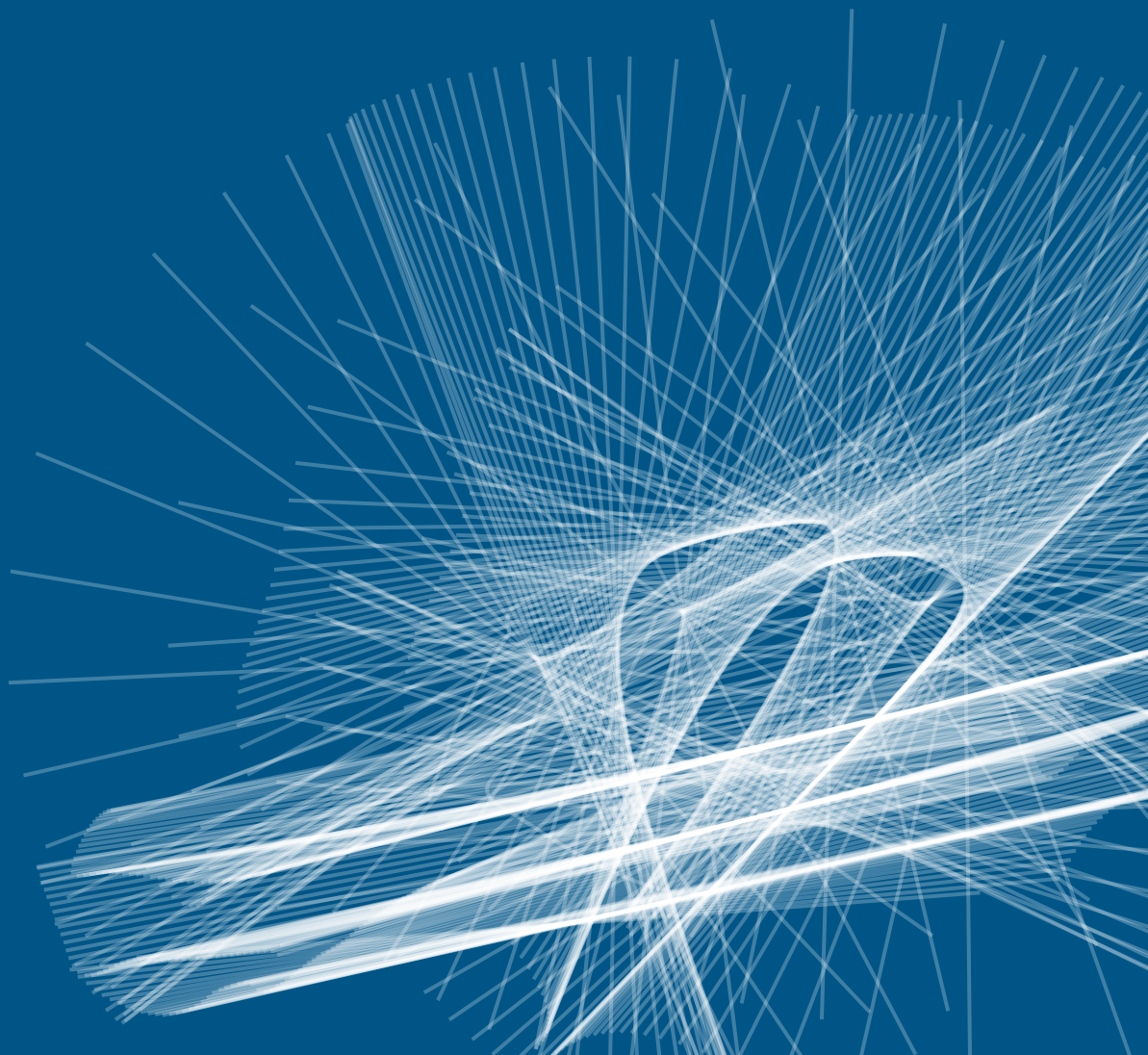
IQVIA INSTITUTE FOR HUMAN DATA SCIENCE

Pathway to Success in Cancer Treatment

ACHIEVING RADIOLIGAND CAPACITY AND READINESS IN EUROPE – A PUBLIC WORKING SESSION

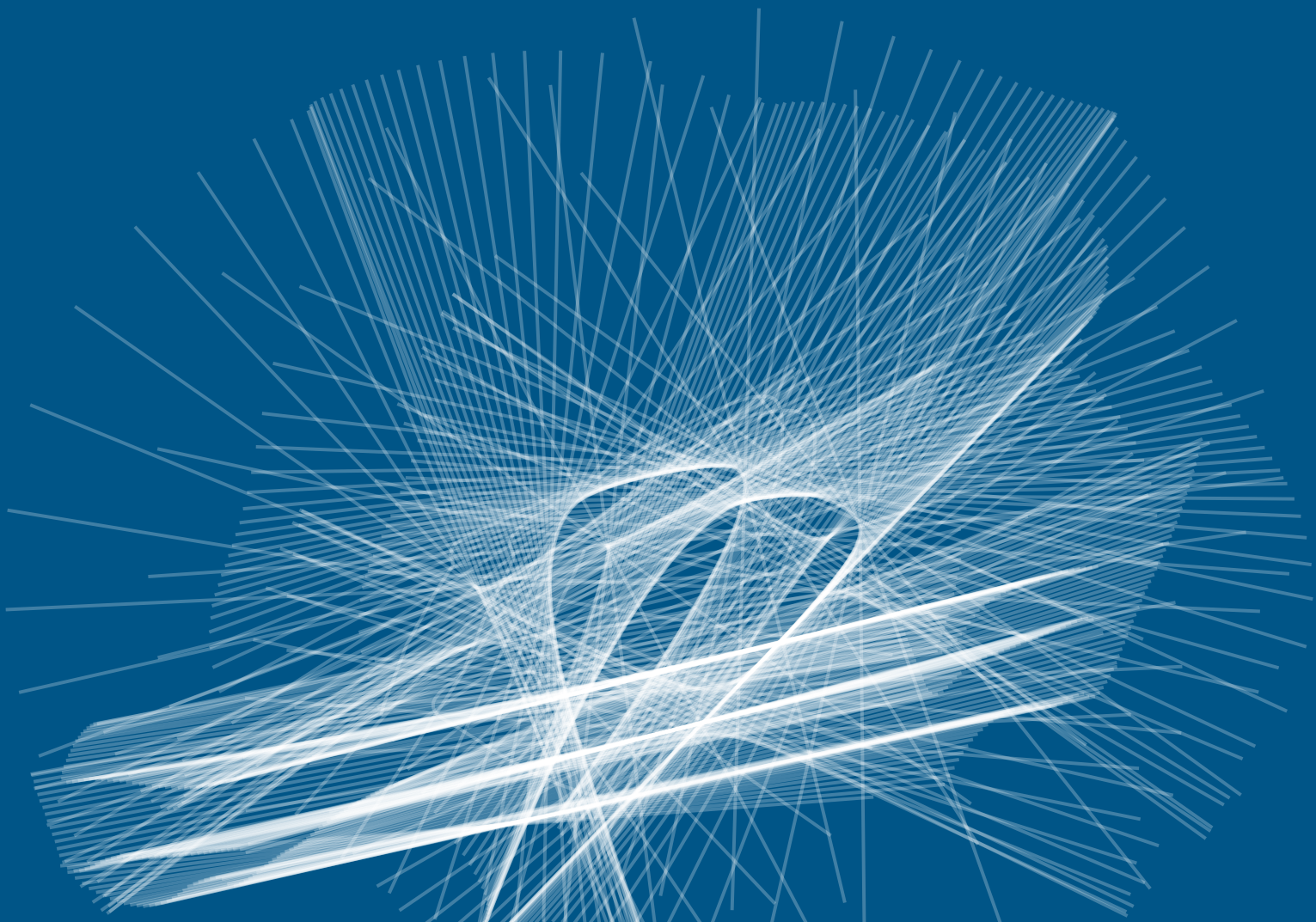
Summary highlights from a multi-stakeholder public working session held at The European Parliament On April 11, 2024, and subsequent discussions



AUGUST
2024

Table of contents

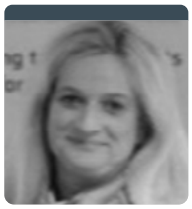
Participants	**1**
Introduction	**2**
Overview	**2**
Levers impacting radioligand therapy capacity	**5**
Pathway to success for radioligand therapy	**7**
Conclusion	**14**
References	**16**
About the Institute	**17**



Participants

JEAN-YVES BLAY, MD, PH.D.
UNICANCER,
Centre Léon Bérard

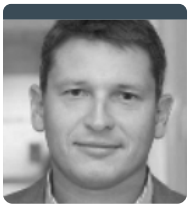
FRÉDÉRIC COURBON
French Society of Nuclear Medicine,
Toulouse University Institute of
Cancer - Oncopole



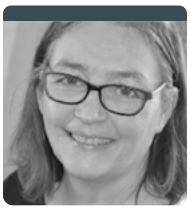
ULLA ENGELMANN, PH.D.
European Commission Joint
Research Centre

PAOLA ERBA, MD, PH.D.
University of Milan Bicocca,
European Association of Nuclear
Medicine (EANM)

ERIC GUEDJ, MD, PH.D.
Aix-Marseille University,
Marseille Timone Hospital



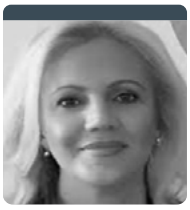
KEN HERRMANN, MD
University Hospital Essen



NIKIE JERVIS
International Neuroendocrine
Cancer, Alliance (INCA),
Neuroendocrine Cancer UK

BENGT JÖNSSON, PH.D.
Stockholm School of Economics

RICHARD PRICE
European Cancer Organisation



JASMINKA TALESKA
Novartis

REFERENCING THIS REPORT
Please use this format when referencing content from this report:
Source: IQVIA Institute for Human Data Science. Pathway to Success in Cancer Treatment: Achieving Radioligand Capacity and Readiness in Europe – A Public Working Session. August 2024. Available from www.iqviainstitute.org

Introduction

Global cancer treatment is a top priority for healthcare stakeholders, with the overall burden increasing at an alarming rate. The International Agency for Research on Cancer estimates that about 35 million new cancer cases will occur in 2050, a 77% increase from the estimated 20 million cases in 2022. Thus, there is a need for therapeutic innovation to meet this challenge and for healthcare systems to ensure that pathways exist for eligible patients to receive the appropriate treatment in a timely manner. In this public working session, we discussed the state of readiness in Europe to administer one such innovation, radioligand therapies, along with policies and actions needed to enhance the implementation of these therapies in a timely manner.

The introduction of innovative treatments in the healthcare system can lead to challenges for timely and effective diagnosis and treatment. In December 2023, the IQVIA Institute published a report on *The State of Radioligand Therapy Readiness in Europe*. This report established key data quantifying the readiness and highlighted the challenges that could restrict this treatment from reaching eligible patients on time, as well as key levers that need to be improved upon. Building on this report, a public working session was organized at the European Parliament on April 11, 2024, hosted by European Parliament Member Niels Geuking.

The objective of this session was to discuss recommendations and actions that can help overcome the previously identified challenges. This discussion took place with a multi-stakeholder panel representing key interest groups. A set of recommendations and actions were reviewed by the panelists prior to and during the public working session, and panelists discussed perspectives and actions building on the initial set of recommendations.

This proceedings document provides a short background of the key issues and challenges with the implementation of radioligand therapies. Subsequently, it summarizes the discussions and recommendations from prior meetings with panelists and from the session. The learnings from the sessions apply not only to radioligand therapies but also highlight the types of policies and actions that need to be considered as innovative therapies continue to enter the cancer care paradigm. Funding for this research, report, and symposium has been provided by Novartis.

Overview

Radioligand therapy (RLT) is an innovative type of treatment that delivers radiation primarily to affected tumor cells and components of the tumor microenvironment using specific radiopharmaceuticals, while minimizing unwanted effects on surrounding healthy cells. RLT is often combined with PET/SPECT imaging procedures which allow the selection of patients who will benefit from the treatment.[1,2] RLTs are already effective in treating cancers such as neuroendocrine and advanced prostate tumors. Research is currently ongoing for the treatment of several other advanced cancers. Given the anticipated increase in demand to treat patients with RLT, there is a critical and urgent need for healthcare systems to ensure readiness and build capacity for equitable access to RLT innovation across Europe.

Developing a resilient and equitable healthcare system requires planning for the innovation in advance through policy and actions, funding and resource allocations, and workforce capacity building in addition to legislative or regulatory policies. Several barriers that hinder the readiness for RLT and possible recommendations and actions are summarized below (Exhibit 1).

Exhibit 1: General recommendations and actions needed

CATEGORY	BARRIERS TO RLT READINESS	GENERAL RECOMMENDATIONS	ACTIONS NEEDED/UNDERWAY
DIAGNOSTIC CAPACITY AND WORKFLOWS	• Low overall diagnostic capacity and varying access to diagnostic tools	• Implement and enhance the visibility of funding options for Member States to invest in PET/CT/MRI equipment and hospital facilities • Enhance access (including reimbursement) to imaging (including PET/CT and SPECT/CT scanners)	● Identify funds at EU level (such as the EU4Health or EU Cohesion Funds) and at national level which could be used to upscale the diagnostic capacity ● Identify funding mechanisms to support Member State, particularly after the 2024 EU parliamentary elections ● Conduct audits to estimate the current state of diagnostic capacity for RLT and identify workflow efficiencies to enhance capacity without additional costs. Future needs with potential required investments can also be estimated
REFERRALS	• Lack of appropriate and efficient standardized referral pathways	• Create efficient and effective referral networks to ensure timely referral and equitable access to RLTs exploring the hub and spoke model • Establish clear national or international pathway guidelines for patients so that all patients have reliable access to a consistent standard of care in each EU region • Ensure the consideration of the key role of multidisciplinary teams to improve patients' outcomes and in providing a more efficient diagnosis and treatment within the referral network	● Establish harmonized clinical guidelines to assist physician clinical decision making from diagnosis to treatment and developing integrated system at a national/regional level to guide physicians through the process ● Support and value multidisciplinary clinical care teams within organizations as standard of care at individual and/or a network of hospitals (i.e. hub and spoke model) ● Convene multidisciplinary group of experts to create a framework for developing overarching referral process to be applied to all radiopharmaceutical therapies (e.g., initiative can be lead by EANM) ● Enhance awareness of RLTs to all relevant stakeholders associated with multi-disciplinary decision making
CENTRES PROVIDING RADIOLIGAND THERAPY	• Limited number of centres with capacity to administer RLTs • Lack of investment and funding for specialized facilities (i.e., imaging equipment, shielded waiting and monitoring rooms and allocated areas for the dispensing of radio-pharmaceuticals)	• Deploy EU funding mechanisms to support upscaling of infrastructure for the treatment of relevant patients through investments in radioprotection rooms, waste disposal and storage facilities • Invest in specific infrastructure for nuclear medicine referrals and services, as well as in technical equipment and trained workforces for performing imaging) and RLT delivery and administration • Establish guidelines and standards to assist in the initiation of new RLT centers and the maintenance of quality for those already established • Include RLT in the certification for a comprehensive cancer center • Ensure relevant organizations apply for the use of policy funds to improve regional research and healthcare infrastructure and promote balanced development in different regions • Include a nuclear medicine department radiopharmacy when setting up global, regional, and national networks for cancer care	● Establish collaboration between policymakers and country level associations to identify areas where funding is more appropriate ● Identify how to efficiently utilize current funds (e.g., EU4Health, ESF+, ETC/Interreg) to enhance facility capability across Member States ● Establish Europe Cancer Moonshot coalition to bring innovative treatments such as RLTs to the forefront of cancer care by facilitating new collaboration, driving progress, and strengthening infrastructure ● Conduct initial audits to determine current capacity to diagnose and administer RLT to establish a baseline and model future needs based on anticipated demand ● Establish a national and/or subnational dashboards that is regularly updated to track RLT center capacity, and key bottlenecks, and project future demand ● Increase visibility to programs such as the EANM Theranostics Center of Excellence to ensure a harmonized theranostic approach of the highest possible quality across a network of centres ● Increase discussion amongst oncology and nuclear medicine stakeholders regarding inclusion of nuclear medicine department at cancer care networks, e.g. EU network of Comprehensive Cancer Centers (CCCs) in the context of Europe's Beating Cancer Plan ● Establish advisory boards by bringing oncologists, nuclear medicine physicists, nurses, patient organizations, and healthcare administrators to exchange RWE findings and best practices, and to standardize facility

● Member State Policymaker ● EU Policymaker ● EU and Regional Hospital/Association ● Industry

Exhibit 1: General recommendations and actions needed *continued*

CATEGORY	BARRIERS TO RLT READINESS	GENERAL RECOMMENDATIONS	ACTIONS NEEDED/UNDERWAY
REGULATORY AND PATIENT RELEASE FRAMEWORKS	• Variations in patient release frameworks across countries • Outdated definitions for radio-pharmaceuticals and inadequacy of Directive 2001/83 EC resulting in heterogeneity in interpretation by countries and producers • Lack of alignment of the Directive 2001/83/ EC with this requirement in the BSS Directive 2013/59/Euratom • Lack of integration/ coordination of "dual governance" (pharmaceutical and radiation safety) for Nuclear Medicines	• Deploy EU funding mechanisms to support upscaling of infrastructure for the treatment of relevant patients through investments in radioprotection rooms, waste disposal and storage facilities • Invest in specific infrastructure for nuclear medicine referrals and services, as well as in technical equipment and trained workforces for performing imaging) and RLT delivery and administration • Include RLT in the certification for a comprehensive cancer center • Include a nuclear medicine department when setting up global, regional, and national networks for cancer care	● Advance discussions around acknowledging radiopharmaceuticals as a separate class of medicinal products with its own regulatory framework integrating/coordinating the "dual governance" and reach consensus on clearly defined terminology ● Establish a multi-level forum concerning radiopharmaceuticals to promote interactions between regulators working in the fields of pharmaceutical supervision and radiation protection both at the EU and national levels (see SIMPLERAD project guidelines)[4] ● Support the development of registries to collect and analyze data on different models of patient release frameworks as well as for developing a consensus on evidence-based patient-centric radio-safety requirements which can be useful for supporting associations at EU and national level with decision making ● Promote proper absorbed-dose reporting in phase 1–2 clinical trials during the radiopharmaceutical clinical development process including activity-based prescription, patient-specific dosimetry, and dosimetry-guided patient-specific prescription ● Convene advisory board of experts across stakeholders to build a consensus on patient-centric radio-safety regulations and to standardize requirements for hospital licensing (e.g., initiative lead by NM associations)
WORKFORCE, TRAINING AND STAFFING	• Limited workforce with appropriate training	• Include specific RLT training as part of the broader medical training and encouraging nuclear medicine as a specialty • Harmonize training curricula and standards for the education of nuclear medicine specialists and members of the multidisciplinary team within the framework of policy initiatives • Develop funding programs (e.g., EU4Health Program) and platforms (e.g., European Reference Networks) to strengthen training for stakeholders across the healthcare system • Deploy training programs foreseen in Europe´s Beating Cancer Plan and the SAMIRA initiative to improve education around nuclear medicine in Europe and reach homogenous high-quality management for all European countries – with priority on those countries with basic need for improved HCP training • Support the educational and professional needs of specialist nurses and technologists	● Set up policy roundtables hosted within the context of relevant key congresses or by key national policymakers within countries to discuss workforce crisis. Enhancing the awareness of policymakers is crucial as national budgets and health plans are developed ● Plan for funds within the EU budget to support educational and professional needs ● Develop materials addressed to healthcare professionals and patient communities to support educational efforts and alleviate fears and apprehensions around nuclear medicine and the use of radioisotopes ● Establish advisory board at EU level led by Nuclear Medicine Societies to discuss RLT training and harmonization as part of medical training for nuclear medicine ● Establish an observatory to monitor the status of the nuclear medicine workforce, current and future staffing needs ● Develop awareness campaigns to target policymakers on informing RLT as an innovative approach to cancer care and its added value for patients and HCS in terms of safety and efficacy

● Member State Policymaker ● EU Policymaker ● EU and Regional Hospital/Association ● Industry

Levers impacting radioligand therapy capacity

RLT CAPACITY IS IMPACTED BY FIVE MAJOR LEVERS

IQVIA conducted research in 2023 using discussions and workshops with industry professionals with the aim to quantify these levers and to begin identifying the overall capacity for RLTs in different European countries. Some of the key highlights from this research are shown below. Additional details can be found in the full report.

Diagnostic capacity

- In the case of prostate cancer indication, we find that there are around 40 to 55 identified radioligand imaging centres with PSMA capability, i.e., a PSMA PET scan, in Germany, Italy and Spain.
- The share of mCRPC eligible patients that receive a PSMA test ranges between 12 and 14% in France and Spain, respectively, to 21 and 33% in Germany and Italy.

Referral pathway

- Based on discussions with industry professionals and hospitals, time from diagnosis to treatment is estimated at seven to eight weeks for Germany and Spain.

Patient release and regulatory frameworks

- Legal requirements for hospitalization can vary by country, with some countries considering no requirement for overnight hospitalization while others require one to two days. The average number of days of hospitalization ranges from two to three days for the countries assessed.

Capacity of identified centres

- Spain and Germany have relatively higher capacity with more than 55 identified treatment slots per 100,000 people — France and Italy have much lower capacity, suggesting a potential greater need to focus on readiness.
- Even within Spain and Germany, it is important to acknowledge that the number of treatment slots can vary by region.

Skilled workforce

- There are an estimated 8.9 nuclear medicine physicians per identified centres in Germany which is substantially higher than in Spain (6.6), Italy (6.3), and France (2.9)

"The consequences of [the entry of radioligand therapies] is that the number of patients who could be a candidate for such treatment is very large, much larger than what we have been facing recently with the development of targeted therapy of cancer."

Jean-Yves Blay

France audit of Nuclear Medicine Centre capabilities
In France, a survey audit of French Nuclear Medicine Centres Capability was conducted by the French Society of Nuclear Medicine (SFMN) and key highlights were presented by Prof. Frédéric Courbon and Prof. Eric Guedj. This survey covered 79 centres and 542 healthcare professionals.

The survey audit highlighted some of the key challenges to RLT readiness specific to France:

- **Diagnostics**: Challenges with diagnostic capacity were highlighted, as growth in diagnosis due to RLTs will need to be balanced with existing capabilities to perform PET scans daily for other conditions.
- **Workforce**: Lack of trained and dedicated human resources, including nuclear medicine physicians, nurses, and technicians, is a major issue across centres.
- **Investments**: Enhanced investments should be available for centres that have not yet received training in RLT use, as they currently lag behind those with established experience in nuclear medicine.
- **Care and patient workflow**: Set-up for efficient patient workflow is limited, particularly at centres with limited training.

The above example of France highlights the specific issues at a country level. Similar studies in other countries can help identify areas of focus to ensure readiness for current and future use of radioligand therapies. As these areas of focus are identified, an implementation pathway needs to be developed at a European and a country level with clear recommendations, actions, and collaboration across stakeholders.

A survey conducted of the audience at the public working session highlighted the urgent need for identifying and implementing this pathway. Sixty-four percent of the surveyed audience (n=100) noted a high degree of concern regarding the barriers to healthcare system readiness for treating eligible patients with radioligand therapy in a timely manner. Fifty-four percent of the surveyed audience noted that there is a low level of preparedness among countries in Europe to effectively treat eligible patients with radioligand therapy in a timely manner.

"The cornerstone and the bottleneck of RLT development is training people, and to get the right people it will take time. This is an issue even for a well-trained centre."

Frédéric Courbon

Pathway to success for radioligand therapy

SUCCESSFUL ADOPTION OF RLTS WILL DEPEND ON ACTIONS FROM MULTIPLE STAKEHOLDERS

Enhancing readiness and capacity for timely and widespread adoption of RLT in European cancer care will require targeted and fit-for-purpose solutions and collaboration across stakeholders.[3] The discussion across panelists at the public working session focused on key areas that these solutions should address. In some cases, actions are already being undertaken by key stakeholders while in other cases, further efforts are needed to accelerate this process. The key recommendations that were discussed with panelists prior to and during the session are summarized below.

WORKFORCE, TRAINING, AWARENESS AND STAFF

Main barriers

A limited number of healthcare professionals are adequately trained in administering RLT, restricting its availability to a select few specialized centres. Depending on country of practice, it takes four to five years of specialized training post medical school to become a nuclear medicine physician. Additionally, staff shortages exist at the level of trained nurses and technicians to administer RLT.[3] These shortages can lead to delays in diagnosis and treatment for patients, which has a direct impact on patient outcomes. Finally, awareness of these treatments across multidisciplinary teams, including patients, is crucial to efficient use, as shared decision-making is an important aspect of these therapies.

Recommendations

- Include specific RLT training as part of the broader medical training and encourage nuclear medicine as a specialty.
- Harmonize training curricula and standards for the education of nuclear medicine specialists and members of the multidisciplinary team (e.g., nurses, nuclear medicine technicians) within the framework of policy initiatives.
- Develop funding programs (e.g., EU4Health Program) and platforms (e.g., European Reference Networks) to strengthen training for stakeholders across the healthcare system.
- Deploy training programs foreseen in Europe´s Beating Cancer Plan and the SAMIRA initiative to improve education around nuclear medicine in Europe and reach homogenous high-quality management for all European countries – with priority for countries with basic need for improved HCP training.
- Support the educational and professional needs of specialist nurses and technologists.

Actions needed/being undertaken

EU and regional hospital/association: Key stakeholders (for example, patient organizations, HCPs, medical societies, nursing societies, and policy organizations) can collaboratively develop materials addressed to healthcare professionals and patient communities to support educational efforts and alleviate fears and apprehensions around nuclear medicine and the use of radioisotopes. Efforts are already being led by organizations such as EANM at the EU level.

An advisory board at the EU level led by nuclear medicine societies can be convened to discuss RLT training and harmonization as part of medical training for nuclear medicine. This can be done in conjunction with the European Commission, which is already taking action in this direction (see below).

Hospitals and/or organization at the EU and regional level can also establish an observatory to monitor the status of the nuclear medicine workforce, current and future staffing needs which can help with effective planning.

Additional awareness campaigns can also be developed to target policymakers on informing RLT as an innovative approach to cancer care and its added value for patients and the healthcare system in terms of safety and efficacy.

EU policymaker: At the EU level, the European Commission can help plan for funds within the EU budget to support educational and professional needs.

The European Commission can also provide coordination at the EU level across Member States. Some steps are already being taken in this direction; for example, the European Commission JRC is already hosting discussions for forming a community of training institutions to exchange on training audiences on gaps and needs, interoperability, and accreditation, and a possible future network of EU network of training institutions across member states. There is also a proposal to endorse a European level accreditation or recommended gold standard model of education training in radioisotope protection by different professional societies.

Member State policymaker: Informed stakeholders can set up policy roundtables hosted within the context of relevant key congresses or by key national policymakers within countries. Enhancing the awareness of policymakers is crucial as national budgets and health plans are developed.

"We are hosting discussions toward forming a community of training institutions to exchange on prevailing gaps and needs to provide comprehensive training as well as on interoperability and accreditation with the aim to establish a possible future network of EU training institutions across Member States."

Ulla Engelmann

"EANM is the main reference for our corresponding associations in order to increase the level of education and training and promote the daily collaboration that is happening in every single hospital."

Paola Erba

"The time bomb of the workforce crisis has already gone off. So I hope that in the next parliament, the next commission, that can be picked up because it seems to be the number one lesson from the COVID-19 pandemic that we haven't addressed. If you look at something like the Europe's Beating Cancer Plan, which was a new form of policy, what it's done is provided a great framework to pick up on lots of other issues that may not have actually been named in the plan, but things like an EU network of cancer centres or an inter-specialty cancer training program, these are great ways to help pick up new and emerging issues."

Richard Price

Main barriers

RLT use requires centres to have up-to-date, well-maintained imaging equipment (lifespan typically limited to eight years) for appropriate patient selection, treatment monitoring, and follow-up.[3] Comprehensive imaging is necessary during the diagnosis phase to identify all tumour sites and optimise therapeutic management. Access to diagnostic tools needed to administer RLTs (such as PSMA PET scans) varies across geographies, with many patients needing to travel large distances to a specialist for diagnosis. Additionally, the use of these diagnostic tools for RLT purposes at hospitals that have availability needs to be balanced with their use for other conditions.

Recommendations

- Develop standardized diagnostic procedures across Member State health networks.
- Enhance access (including reimbursement) to imaging/diagnostics (including PET/CT and SPECT/-CT scanners).
- Implement and enhance the visibility of funding options for Member States to invest in PET/CT/MRI equipment and hospital facilities.

Actions needed/being undertaken

Member State policymaker: Europe's Beating Cancer Plan calls for greater access to diagnostics. Efforts need to be made at the Member State level to enhance this access. Member States can identify funds at the EU level (such as the EU4Health or EU Cohesion Funds) and at the national level that could be used to upscale the diagnostic capacity.

"With respect to RLTs and diagnostics, you have to keep in mind that you have to preserve capabilities to perform routine diagnostics such as PET studies and cardiac studies while building capacity for RLT related diagnostics."

Frédéric Courbon

EU policymaker: At the EU level, funding mechanisms to support Member State efforts can be identified, particularly after the 2024 EU parliamentary elections.

EU and regional hospital/association: At a hospital and association level, audits can be conducted to estimate the current state of diagnostic capacity for RLT, anticipated future needs, and potential investments required. Hospitals and associations can also identify efficiencies in the current system in terms of workflows to enhance the capacity for diagnosis without additional costs. These best practices can then be shared within countries and across EU Member States.

"When it comes to radioligand therapies, you also need diagnostic equipment, and you need special equipment for treatment. And I think that the countries are probably very happy if they could get EU funds for investing in this equipment. But you must be [planning] a little in advance here because if you're investing in this equipment and don't really have the money to run them and don't have the manpower to run them, they will not be of big use."

Bengt Jönsson

CENTRES PROVIDING RLT

Main barriers

Infrastructure requirements and administrative processes for setting up a center that can administer RLTs can be burdensome. A well-equipped nuclear medicine centre requires a trained workforce, lead-protected rooms, proper radioisotope storage, a waste disposal system, up-to-date imaging equipment, and protective equipment for healthcare personnel to adequately deliver care.[3] These requirements limit the centres with capacity to administer RLTs with additional funding required to develop these specialized facilities.

Recommendations

- Deploy EU funding mechanisms to support upscaling of infrastructure for the treatment of relevant patients through investments in radioprotection rooms, waste disposal, and storage facilities.
- Invest in specific infrastructure for nuclear medicine referrals and services, as well as in technical equipment and trained workforces (e.g., for performing imaging) and RLT delivery and administration.
- Establish guidelines and standards to assist in the initiation of new RLT centers and the maintenance of quality for those already established.
- Include RLT in the certification for a comprehensive cancer centre.
- Ensure relevant organizations apply for the use of policy funds to improve regional research and healthcare infrastructure and promote balanced development in different regions.
- Include a nuclear medicine department and radiopharmacy when setting up global, regional, and national networks for cancer care.
- Standardize requirements for facilities across countries.

Actions needed/being undertaken

EU and regional hospital/association: At country/regional level, initial audits to determine current capacity to diagnose and administer RLT to patients need to be undertaken to establish a baseline. These audits can then be utilized to understand current infrastructure capacity barriers and model future needs based on anticipated demand. Such audits can be led by country level nuclear medicine societies, like the one taken up in France. Similar efforts are also being undertaken by Belgium, Germany, and Italy.

Based on these audits, national and/or sub-national dashboards can be regularly updated to track RLT centre capacity and key bottlenecks, and project future demand. Such dashboards can also be aggregated at an EU level so that resources can be allocated efficiently based on anticipated requirements.

At the EU level, increasing discussion among oncology and nuclear medicine stakeholders is needed regarding inclusion of nuclear medicine department at cancer care networks, e.g., EU Network of Comprehensive Cancer Centres (CCCs) in the context of Europe's Beating Cancer Plan. Additionally, increasing visibility to programs such as the EANM Theranostics Center of Excellence can ensure a harmonized theranostic approach of the highest possible quality across a network of centres.

"Belgium has a very interesting initiative to map the landscape of theranostics in terms of limitations and opportunities. France, Italy, and Germany did the same. So I'm very happy to see that every national member state in a way or in the other is trying to provide data on this topic."

Paola Erba

"A major issue in building capacity is timing; not too early and not too late. Capacity is a tool to be used for a purpose. While RLT may be a very useful technology in the future, we still do not know when this future will come. We still lack data on patient outcomes and cost-effectiveness of different potential applications. I understand that there are clinical trials for first line use for first line prostate cancer, which would be a major indication, but the implementation of the results from those trials may not be so straightforward. In my view, evidence generation will be the major issue for driving capacity for and introduction of RLT."

Bengt Jönsson

Finally, at the EU level, advisory boards can be established by bringing oncologists, nuclear medicine physicists, nurses, patient organizations, and healthcare administrators to exchange RWE findings and best practices, and to standardize facility requirements.

EU policymaker: At the EU level, funding mechanisms to support member state efforts can be identified, particularly after the 2024 EU parliamentary elections. Discussions on how current sources of funds (such as EU4Health Program, European Regional Development Funds (ERDF), European Social Fund (ESF+), European Territorial Cooperation (ETC)/Interreg) can be efficiently utilized to enhance facility capacity across member states. Additionally, a Europe Cancer Moonshot coalition that would bring innovative treatments such as RLTs to the forefront of cancer care by facilitating new collaboration, driving progress, and strengthening infrastructure could be useful for future planning for RLT and other innovative treatments.

Member State policymaker: Member States are critical for the financing of infrastructure development and planning for appropriate funds directed efficiently toward benefiting the most patients. Policymakers need to work closely with country level associations to identify areas where funding is more appropriate.

REFERRAL

Main barriers

Referral workflow is an integral part of the RLT delivery value chain. Clear referral pathways and models of care are crucial given the intricacy of processes and interactions that are required for consistent RLT delivery. Currently, there are no standard referral pathways for RLT, therefore the process of prescribing and referring eligible patients and delivering RLT can vary substantially.[3] Furthermore, the absence of any overarching referral process makes it difficult for new centres to start offering the therapy. Additionally, referrals often require multi-disciplinary decision-making involving oncologists, nuclear medicine physicians, patients, and other stakeholders. Not all stakeholders may have the requisite awareness of RLTs to effectively participate in this process.

Recommendations

- Create efficient and effective referral networks to ensure timely referral and equitable access to RLTs utilizing the hub and spoke model.
- Establish clear national or international pathway guidelines for patients so that all patients have reliable access to a consistent standard of care in each EU region.

- Ensure the consideration of the key role of multidisciplinary teams to improve patient outcomes and in providing a more efficient diagnosis and treatment within the referral network.

Actions needed/being undertaken

EU and regional hospital/association: EU level associations (such as EANM) can lead the convening of a multidisciplinary group of experts in relevant fora to create a framework for developing an overarching referral process framework to be applied to all radiopharmaceutical therapies. This group can also focus on enhancing awareness of RLTs to all relevant stakeholders associated with multi-disciplinary decision-making.

Establishing harmonized guidelines to assist physician clinical decision-making from diagnosis to treatment and developing integrated systems at a national/ regional level to guide physicians through the process will be critical. These guidelines and systems will need to be sustainably integrated into the Member State's healthcare network. Standardizing scalable electronic medical records technology to enable seamless integration across health centres can aid in this process.

"Support from EU is needed in order to build up a consortium that try to build a model to teach and train specialists coming from different fields from general practioners because the referral pathways are very diverse and we need to cover every single step to the final medicine practitioner."

Paola Erba

"Collaboration between the nuclear medicine specialist and the oncologist must be dramatically changed in order to be able to deploy the full efficacy of the treatment and to be able to benefit from the expertise of the two specialties."

Jean–Yves Blay

These efforts require country and regional hospitals and associations linked to nuclear medicine to advocate with other stakeholders in the healthcare system (e.g., other oncologists, hospitals, and regional/national level healthcare leaders).

"The awareness piece is not really only for the treating physicians, it's for the wider healthcare team who are involved in those multidisciplinary discussions on treatment, but also very importantly, the patients themselves, and the patient organizations who are supporting them. If we're going to deliver shared decision-making, we have to address their needs in terms of knowledge and awareness about these new treatments."

Richard Price

REGULATORY AND PATIENT RELEASE FRAMEWORKS

Main barriers

There are substantial variations in patient release frameworks across countries. RLT is typically administered as an in-patient procedure, and hospitalization times vary across different countries due to differences in regulatory requirement and hospital practices.[3]

From a regulatory point of view, there is significant heterogeneity and discrepancies among countries regarding radioprotection and safety regulations. There is a lack of integration/coordination of "dual governance" (pharmaceutical and radiation safety) for nuclear medicines. An example can be seen in the lack of alignment of the Directive 2001/83/ EC with this requirement in the BSS Directive 2013/59/Euratom. The Council Basic Safety Standards Directive 2013/59/ Euratom (BSSD) has introduced the requirement to individually plan treatment involving ionising radiation, which includes treatment with radiopharmaceuticals. The missing alignment of the Directive 2001/83/EC with this requirement in the BSS Directive has caused an unclear situation in Member States and should be clarified with the revision.

Recommendations

- Adapt international and national regulatory frameworks developed for conventional medicines to make them suitable for the evaluation of RLT and radioisotopes.
- Acknowledge radiopharmaceuticals as a separate class of medicinal products with their own regulatory framework integrating/coordinating the "dual governance" (pharmaceutical and radiation safety).
- Adapt the Directive 2023/0132 (COD) to clarify the relation of BSSD and Pharma Directive.
- Develop a consensus on evidence-based patient-centric radio-safety requirements, with the aim of updating radioprotection and safety regulations (such as the European Basic Safety Standards Directive 96/29/Euratom) and ultimately optimizing hospital infrastructure.

"We need to explore the creation and funding of a European partnership to harmonize the requirements for clinical trials with radiopharmaceuticals at the EU Member State level. Its remit should address and harmonize key regulatory issues, such as timelines for approval of clinical trials and lengths of hospitalization after routine radiopharmaceutical treatments. In addition, it should work toward improving the availability of a competent workforce in the field based on a coordination at the European level for information related to nuclear education and training for health professionals."

Ulla Engelmann

- Create regional and national pathways for radiopharmaceuticals and introduce an evidence-based fixed-dose for safe administration in routine clinical cancer care, while optimizing scalability, capacity, and improving treatment accessibility.
- Assess hospital licensing to standardize requirements on licenses that hospitals need to obtain to perform radioligand imaging and treatment.
- Involve patients in all decision-making to ensure patient relevant outcomes drive decision making around treatment availability.
- Review and consider different models of patient release (inpatient vs. outpatient).

Actions needed/being undertaken

EU and regional hospital/association: Nuclear medicine associations at the EU level can lead the convening of an advisory board of experts across stakeholders to build a consensus on patient-centric radio-safety regulations and to standardize requirements for hospital licensing. Similar advisory boards can also be led by national and regional level nuclear medicine associations.

Additionally, advisory boards of experts can recommend approaches for proper absorbed-dose reporting in phase 1–2 clinical trials during the radiopharmaceutical clinical development process including activity-based prescription, patient-specific dosimetry, and dosimetry-guided patient-specific prescription.

Industry: Industry partners can support the development of registries to collect and analyze data on different models of patient release frameworks as well as for developing a consensus on evidence-based patient-centric radio-safety requirements, which can be useful for supporting associations at EU and national level with decision-making.

EU policymaker: Policymakers need to advance discussions around acknowledging radiopharmaceuticals as a separate class of medicinal products with its own regulatory framework integrating/coordinating the "dual governance."

This can be done by establishing a multi-level forum concerning radiopharmaceuticals to promote interactions between regulators working in the fields of pharmaceutical supervision and radiation protection both at the EU and national levels (see SIMPLERAD project guidelines).[4]

"We need these data to consolidate the effect of such therapies in real life, and also to demonstrate the impact in terms of medical economic measures and of quality of life. We also need these important data to better evaluate and manage our medical organization."

Eric Guedj

"When we talk about Europe, we always forget that we talk about many different countries with many different regulations, registration procedures, reimbursement procedures, challenges, and we need to focus on a certain homogenization. It doesn't make any sense that at one country the patient gets a therapy as an outpatient whereas in a different country the patient has to stay two, three or four nights in the hospital. From a radiation safety point of view it should be very similar among the different countries in Europe."

Ken Herrmann

"We are all part of the healthcare system either as individuals, as patients, caregivers or as the representatives of institutions and stakeholders who are involved in shaping the healthcare system environment. So it's important to partner because a couple of initiatives so far showed a best case of how together we can achieve more through innovation, which is important for healthcare systems."

Jasminka Taleska

Conclusion

There is a need for greater data collection in general to track real world efficacy, costs, capacity and other key variables

Over the course of the discussion, the importance of data to drive understanding of clinical benefit in real-world setting, assessment of capacity, and estimation of costs was repeatedly highlighted. This data would allow for efficient allocation of resources to optimize patient benefit. Efforts are already underway in France to collect real-world data to demonstrate medical and medico-economic outcomes through the Health Data Hub.

Ensuring that patients are kept at the centre of all decisions made to address the barriers highlighted at the public working session is critical

There is an urgent and pressing need to address issues surrounding the readiness for RLTs. The issues highlighted in this public working session can exacerbate existing inequities in the health system with only a limited number of eligible patients able to access the right treatment. Patients need to be kept at the centre of decision-making, with the aim to enhance their access, expand their awareness, and address their concerns.

Finally, strategic partnerships across all relevant stakeholders across the healthcare system will be needed to take actions in an appropriate timeframe to ensure that the value presented by RLT innovation is not lost due to a lack of preparedness. RLT provides an important opportunity to demonstrate how innovations in the healthcare system can be integrated with advance planning and collaboration across stakeholders. This case study will provide lessons for many subsequent innovations and can pave the way for more agile and thoughtful planning to ensure optimal patient outcomes.

"We've seen that from surveys and studies from reports that patients tell us there are inequities over every aspect from access to diagnostics - access to treatments from meeting healthcare professionals who do not understand either their disease or the pathway to the right diagnostics or know how to treat them. Patients are becoming experts in their own care and yet not involved in decisions about care."

Nikie Jervis

References

1. The Health Policy Partnership. Radioligand Therapy: Realizing the potential of targeted cancer. Jan 2020. Available from: https://www.healthpolicypartnership.com/app/uploads/Radioligand-therapy-realising-the-potential-of-targeted-cancer-care.pdf
2. Novartis. Radioligand therapy explained. Accessed Nov 2023. Available from: https://www.novartis.com/researchdevelopment/technology-platforms/radioligand-therapy
3. IQVIA Institute for Human Data Science. Succeeding with Innovation: The State of Radioligand Therapy Readiness in Europe.December 2023. Available from: www.iqviainstitute.org
4. Krause B.J., et al. SIMPLERAD: SAMIRA Study in the Implementation of the Euratom and EU legal Bases with Respect to the Therapeutic Uses of Radiopharmaceuticals. 2024. Available from: https://earl.eanm.org/wp-content/uploads/2024/03/D4.3_Workshop-proceedings_SIMPLERAD.pdf

About the Institute

The IQVIA Institute for Human Data Science contributes to the advancement of human health globally through timely research, insightful analysis and scientific expertise applied to granular non-identified patient-level data.

Fulfilling an essential need within healthcare, the Institute delivers objective, relevant insights and research that accelerate understanding and innovation critical to sound decision making and improved human outcomes. With access to IQVIA's institutional knowledge, advanced analytics, technology and unparalleled data the Institute works in tandem with a broad set of healthcare stakeholders to drive a research agenda focused on Human Data Science including government agencies, academic institutions, the life sciences industry, and payers.

Research Agenda

The research agenda for the Institute centers on 5 areas considered vital to contributing to the advancement of human health globally:

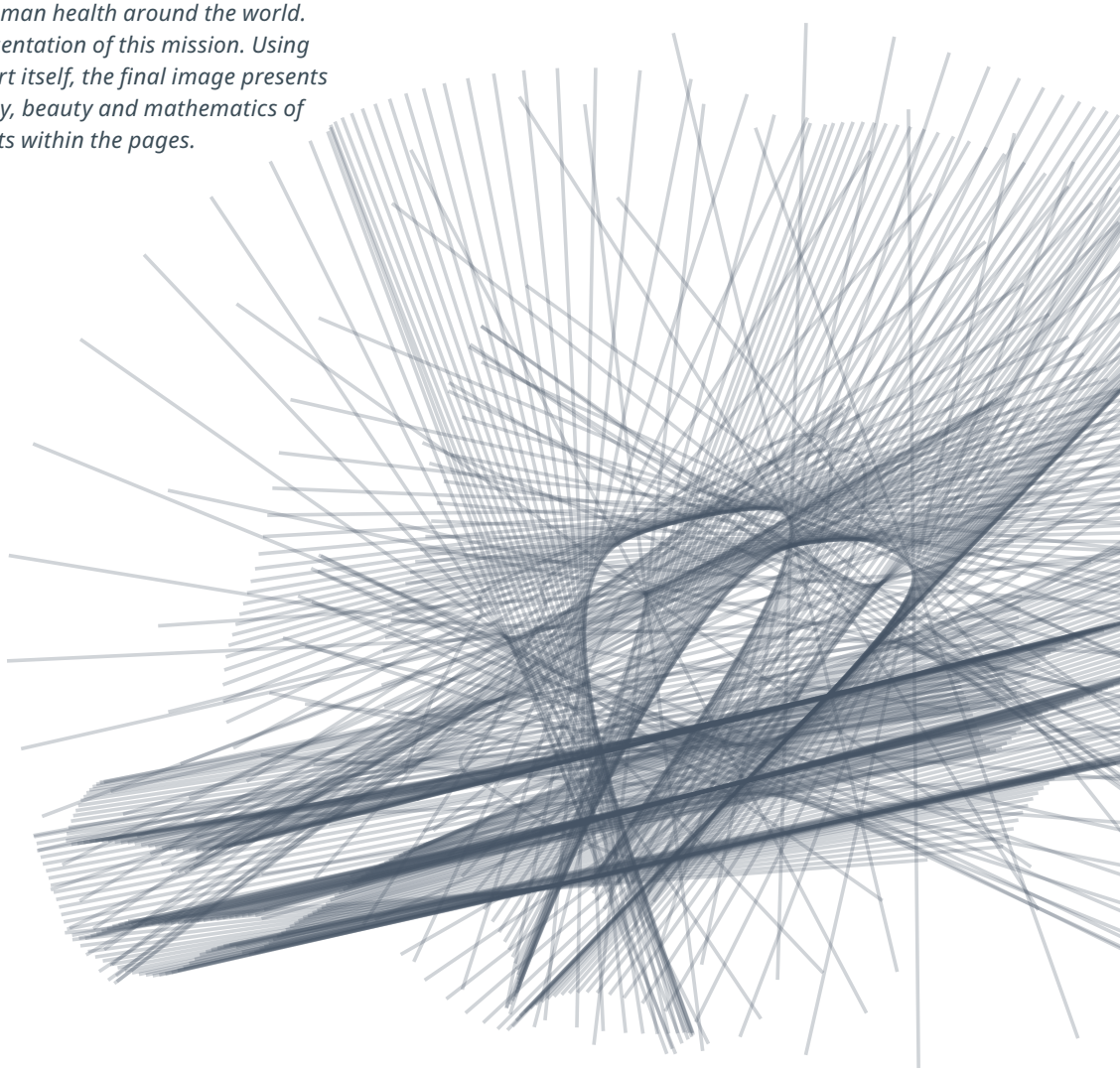
- Improving decision-making across health systems through the effective use of advanced analytics and methodologies applied to timely, relevant data.
- Addressing opportunities to improve clinical development productivity focused on innovative treatments that advance healthcare globally.
- Optimizing the performance of health systems by focusing on patient centricity, precision medicine and better understanding disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.
- Understanding the future role for biopharmaceuticals in human health, market dynamics, and implications for manufacturers, public and private payers, providers, patients, pharmacists and distributors.
- Researching the role of technology in health system products, processes and delivery systems and the business and policy systems that drive innovation.

Guiding Principles

The Institute operates from a set of guiding principles:

- Healthcare solutions of the future require fact based scientific evidence, expert analysis of information, technology, ingenuity and a focus on individuals.
- Rigorous analysis must be applied to vast amounts of timely, high quality and relevant data to provide value and move healthcare forward.
- Collaboration across all stakeholders in the public and private sectors is critical to advancing healthcare solutions.
- Insights gained from information and analysis should be made widely available to healthcare stakeholders.
- Protecting individual privacy is essential, so research will be based on the use of non-identified patient information and provider information will be aggregated.
- Information will be used responsibly to advance research, inform discourse, achieve better healthcare and improve the health of all people.

The IQVIA Institute for Human Data Science is committed to using human data science to provide timely, fact-based perspectives on the dynamics of health systems and human health around the world. The cover artwork is a visual representation of this mission. Using algorithms and data from the report itself, the final image presents a new perspective on the complexity, beauty and mathematics of human data science and the insights within the pages.



IQVIA INSTITUTE FOR HUMAN DATA SCIENCE

CONTACT US

100 IMS Drive

Parsippany, NJ 07054

United States

info@iqviainstitute.org

iqviainstitute.org