Hadrontherapy

and

EU clinical networks:

status and perspectives

Lisa Licitra & Ester Orlandi





European Reference Networks

European Commission

EpiCARE . BOND . CRANIO . ENDO . ERKNet . EYE . ERNICA . VASCERN . LUNG . RND . SKIN . EURACAN . GUARD-HEART . EuroBloodNet . eUROGEN . GENTURIS . ITHACA . MetabERN . PaedCan . RARE-LIVER . ReCONNET . EURO-NMD . TRANSPLANT-CHILD . RITA

Share. Care. Cure.



GOVERNANCE









- promote good quality and safe care to patients by fostering proper diagnosis, treatment, follow-up and management of patients across the Network
- empower and involve patients
- offer and promote multi-disciplinary advice for complex cases
- develop and implement clinical guidelines and cross-border patient pathways
- exchange, gather and disseminate knowledge evidence and expertise within and outside the Network
- promote collaborative research within the Network
- reinforce research and epidemiological surveillance, through setting up of shared registries
- exchange and disseminate knowledge and best practices, in particular by supporting national centres and networks





- 1. Head & neck cancers
- 2. Sarcomas
- 3. Digestive rare cancers
- 4. Neuroendocrine tumours
- 5. Rare thoracic cancers
- 6. Endocrine gland tumours
- 7. Central nervous system tumours
- 8. Rare female genital cancers
- 9. Rare urological and male genital tumours
- 10. Rare skin cancers & non-cutaneous melanoma

Registry Model



Performing an analysis across multiple decentralized data sources, without exchanging their data.





- ERNs' model in rare cancers
- Sustainability
- Integration between healthcare & research
- Integration between EU networking & MSs
- Integration between IT tools and EHR (incl. AI tools)
- Patient involvement



Brussels, 3.2.2021 COM(2021) 44 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

Europe's Beating Cancer Plan

{SWD(2021) 13 final}



High tech medical innovation

1. Nuclear Medicine



2. Radiomics





3. Innovative Radiotherapies



CNAC/ Centro Nazionale di Adroterapia Oncologic 4. Innovative Surgery





5. Physical Methods of Ablation







6. Cell Therapies





7. Ex-vivo Testing of Agents





EONIKO IAPYMA EPEYNAN National Hellenic Research Foundatio



Focus of NoEs...

- Guidelines/recommendations
- Advocacy/policy/awareness
- Healthcare organizational models
- Education (professionals, patients)
- Research promotion
- Quality criteria
- Patient and public engagement

....



Call: EU4H-2023-JA-3-IBA (Joint Actions third wave) Topic: EU4H-2023-JA-3-IBA-08 Type of Action: EU4H-PJG (EU4H Project Grants) Proposal number: 101183265 Proposal acronym: JANE-2 Type of Model Grant Agreement: EU4H Action Grant Budget-Based

Coordination from Istituto Nazionale Tumori in Milan, Italy





MEMBER STATES REPRESENTATION IN THE NOE

	Domain							
21 countries involved	Nuclear medicine	Radiomics	Innovative radiotherapies	Innovative surgery	Physical methods of ablation	Cell therapies	Ex-vivo testing of agents	TOTAL
Belgium	2	2	3	1	1	2	2	13
Bulgaria								0
Denmark	1		1	1	1	1	1	6
Estonia			1					1
France	1	2	3	1	2	2	1	12
Greece		1	1		1	1	1	5
Hungary				1		1		2
Italy		3	2	2	1	3		11
Latvia			1		2	2	1	6
Lithuania	1	1	1	2	2	1	2	10
Luxembourg	3		2		3	2	3	13
Moldova			1					1
Netherlands	1							1
Norway	1	1	1	1		1		5
Poland	1	1	1	1	1	4	3	12
Portugal						1	1	2
Romania		2	1		1			4
Slovenia	1			1	2	2	1	7
Spain	1	1	3	2		4	1	12
Sweden			1		1	2		4
Ukraine				1				1
Croatia								0
Cyprus								0
Czech Republic								0
Germany								0
Iceland								0
Ireland								0
Malta								0
TOTAL	13	14	23	14	18	29	17	

The impact of this JA will stem from the impact of the NoEs which it will give rise to. That said, their effectiveness will be mostly dictated by how far the new kind of EU health networking can overcome some of the challenges currently being experienced. This is why this project is equipped to assess such problems and work out possible solutions. The ambition here is to root these solutions in the European oncology community as deeply as possible. Indeed, the idea behind the concept of JAs is to involve communities of stakeholders, together with MSs and EU bodies, as widely as possible. We understand that if the launching of new NoEs was not envisaged merely as an administrative endeavour, and a dedicated JA was conceived, the reason is exactly to tackle some problems of EU health care networking by addressing them through a wide involvement of the European oncology community. Thus, the ambition of this JA is actually to be able to involve the whole European oncology community pragmatically, i.e. In an attempt to bring about the creation of a new kind of network, as anticipated by the Commission, capable of being effective, appropriate, and sustainable.

The ambition of the new NoEs, as far as their mandates are concerned, will obviously be to bring the added value of EU networking to some crucial oncology areas. Health care networking can be exceedingly important in Europe, since it gives the EU the potential to target its citizens in a coordinated fashion. In a sense, Europe is privileged by being able to exploit health care networking to an extent which is not accessible to most other areas of the world. In fact, the EU has the unique opportunity to drive healthcare providers in so many countries to collaborate with each other on a networking basis, provided that they operate in an environment which, although different from country to country, is reasonably homogenous, with special regard to the universal access to health care which it allows. Thus, healthcare networking is an organizational solution which seems very distinctive to Europe, and the EU can really exert a specific added value. All the more, since the expected outcome may be tremendous, it is vital to address all problems and obstacles. By launching JAs on healthcare networking, complementing the current networking in the rare cancer area through existing ERNs, the EU is sending a clear signal to its citizens and to the health systems of its MSs. This JA has the ambition to take on the challenge, within the scope of the NoEs to which it will give rise.

- Eu healthcare networking
- Challenges/solutions
- Wide involvement of the EU oncological community
- Eu as driving force for an universal access to care

Work Package 10: NoE on Hi-tech medical resources							
Duration:	M1 – M48	Lead Beneficiary:	Lead FR-Unicancer Co-lead DA - Region Zealand - Zealand University Hospital				

Objectives

The NoE on Hi-tech medical resources focuses on technologies that work across all cancers and are highly specialised and innovative. This network aims at finding solutions allowing patients across the EU to benefit from increased knowledge and expertise and more accessible health services. As emerging resources tend to be expensive and rare, particular attention will be paid to their equal access for EU citizens. This network contains 7 domains:

- Nuclear Medicine. This modality is well established across Europe in cancer centres. However, current developments with novel tracers reveal hitherto unseen possibilities for precise diagnostics and consequently treatment. Lead / co-lead: Unicancer (FR) - CLB & CHB; CSGV (SP) Participants: IJB-ULB (BE); REGIONH (DK), SAM (LT), INC (LU), HRS (LU), CHL (LU), OUS (NO), MSCI (PL), UKCL (SL); KU Leuven (BE); Mater Misericordiae University Hospital (IE)
- Radiomics. This novel discipline allows an extension of imaging not only to describe disease morphology, but also to decipher information about cancer biology. Lead / co-lead: Unicancer (FR) – IUCT; NKUA (GR) Participants: IJB (BE), FHF (FR), IRCC AOUBO (IT), LSMUL KK (LT), IOCN (RO), CSGV (SP); UGent (BE), CRO-Aviano (IT), IRCCS ISNB (IT), OUS (NO), MSCI (PL)

Innovative radiotherapy. Radiotherapy is a cornerstone of cancer therapy. Novel, innovative and highly specialized techniques such as hadron therapy allow new advances in treatment efficacy. Lead / co-lead: CNAO (IT); Unicancer (FR) - CLB

Participants: IJB-ULB (BE), USHATO (BU) NHRF (GR), PSCUH (LV), LSMUL KK (LT); RM (DK), PERH (ES), FHF (FR), CRO-Aviano (IT), CFB (LU), INC (LU), PMSI IO (MO), OUS (NO), MSCI (PL), IOCN (RO), IDIVAL (SP), SoS (SW), CSGV (SP); KU Leuven (BE), INCa (FR), HSJD (SP), St Lukes Radiation Oncology Ntwk (IE)

- Innovative surgery. Novel surgical approaches are being developed, and integration with e.g. machine learning based decision support system or imaging-guided robotics, allows improved patient outcomes. Lead / co-lead: OI Ljubljana (SL); OUS (NO) Participants: UNICANCER (FR), IOV(IT), CSGV(SP); UGent (BE), ZEALCO (DK), OOI (HU), IOV(IT), LSMUL KK (LT), VULSK (LT), CHL (LU), MSCI (PL), UKCL (SL), NCI (UKR); HSDJ (SP); MMUH (IE)
- Physical methods of ablation. Ultrasounds, radiofrequency, electroporation, etc. Their rapid development and increasing use for oligometastatic disease allows more treatment options. Lead / co-lead: ZEALCO (DK); OIL(SL)

Participants: UNICANCER (FR), IRCCS AOUBO (IT), VGR (SW); UGent (BE), NKUA (GR), REUH (LV), SAM (LT), VULSK (LT), HRS (LU), CHL (LU), INC (LU), MSCI (PL), IOCN (RO), UKCL (SL); INCa (FR); St Vincent's University Hospital (IE)

- Cell therapies. Cell therapies encompass the use of immune cells from patients and donors to treat cancer and are gaining increasing relevance in cancer treatment. Cell therapies are highly specialized and require extensive lab facilities. Lead / co-lead: Unicancer (FR) – IPC; IRST (IT) Participants: IRCCS AOUBO (IT), PSCUH (LV), LU (LV), LSMUL KK (LT), IBB PAN (PL), MUL (PL), MUW (PL), AUH (SW), CSGVA (SP); REGIONH (DK), NKUA (GR), INC (LU), LIH (LU), OUS (NO), MSCI (PL), IPOP (PT), UKCL (SL), HSJD (SP), IDIVAL (SP), UPPSALA (SW); KU Leuven (BE), INCa (FR), OOI (HU); Galway University Hospital & St James' Hospital (IE)
- Ex-vivo testing of agents. Techniques involving patient-derived cell cultures as a platform to investigate cancer drugs efficacy in specific patients. The setup requires expertise and extensive lab facilities to grow samples from a larger number of patients. Lead / co-lead: Unicancer (FR) - Curie Institute; NHRF (GR) Participants: LU (LV), LSMUL KK (LT), IBB PAN (PL), MUW (PL), I3S (PT), CSGV (SP); UGent (BE), RSYD (DK), VULSK (LT), INC (LU), LNS (LU), LIH (LU), MSCI (PL), OI (SL); KU Leuven (BE)

These domains represent highly specialized and innovative technologies for which some challenges are common, thus, some tasks are set across all domains (T10.1, T10.2, T10.3). However, these technologies are also at different levels of maturity and possibilities for access across Europe, and needed infrastructure differs between them. Therefore, other tasks are domain-specific (10.4, 10.5, 10.6).

Specific objectives of the NoE (common to all domains) are the following:

- To organise of the governance of the network
- To establish recommendations for Member States regarding urgent needs and biggest gaps across Europe
- To position the network at the forefront of innovation

Specific objectives under the responsibility of each domain are:

- To support centres to better integrate innovative therapies
- To improve continuous medical education and enhancing patient and public literacy and involvement
- To ensure the visibility and the sustainability of the network through dissemination activities and evaluation criteria set-up
- To engage international and national scientific societies (e.g. ESMO, ESTRO) in these goals
- To identify and engage EU official bodies (EMA, EUnetHTA) in identifying obstacles to implementation and progress
- To address and collaborate with patient advocacy groups

D10.1	Recommendation paper for the future governance of the NoE on Hi-tech medical resources	10	UNICANCER (FR), ZEALCO (DK)	Document	PU - Public	M48	Word document, English Recommendations on: - Future governance of the NOE; - Tackling inequalities; - Implementation and access; - Training;
D10.2	Paper on emerging uses of hi-tech innovation in described domains and implications and strategies for access across Europe	10	Domain leaders & co-leaders	Document	PU - Public	M48	Scientific journal manuscript (English)
D10.3	Paper on information to patients	10	Domain leaders & co-leaders	Document	PU - Public	M48	Scientific journal manuscript (English)
D10.4	Paper on vision for development of hi-tech innovation in described domains	10	Domain leaders & co-leaders	Document	PU - Public	M48	Scientific journal manuscript (English)
D10.5	Policy paper on provision of access to hi-tech innovation in described domains	10	Domain leaders & co-leaders	Document	PU - Public	M48	Scientific journal manuscript (English)

INNOVATIVE RADIOTHERAPIES - DOMAIN 3 - PARTNERS



Acronym	Organisation name	Country	CA/AE	Contact person	Email	Domain 3 Innovative radiotherapies
CUSL	Clinique universitaire Saint-Luc	Belgium	AE	Prof. Jean-Pascal Machiels	jean-pascal.machiels@saintluc.uclouvain.be	OBSERVER
CUSL	Clinique universitaire Saint-Luc	Belgium	AE	Guillaume Dachy	guillaume.dachy@saintluc.uclouvain.be	OBSERVER
IJB-ULB	Institut Jules Bordet	Belgium	AE	Dirk Vangestel	dirk.vangestel@hubruxelles.be	HIGH
IJB-ULB	Institut Jules Bordet	Belgium	AE	Jonathan Cimino	jonathan.cimino@hubruxelles.be	HIGH
KU Leuven	KU Leuven	Belgium	AE	Evy Lobbestael	evy.lobbestael@kuleuven.be	OBSERVER
KU Leuven	KU Leuven	Belgium	AE	Johan Van Lint	johan.vanlint@kuleuven.be	OBSERVER
RM	Central Denmark Region - Aarhus University Hospital, Danish Center for Particle The	Denmark	AE	Cai Grau	cai.grau@rm.dk	LOW
ZEALCO	Region Zealand - Zealand University Hospital - Dept. of Clinical Oncology and Palliativ	Denmark	CA	Keld Hundewadt	kehun@regionsjaelland.dk	LOW
PERH	Põhja-Eesti Regionaalhaigla	Estonia	AE	Kätlin Tiigi	katlin.tiigi@regionaalhaigla.ee	LOW
FHF	Fédération Hospitalière Française	France	AE	Vincent Bourbonne	vincent.bourbonne@chu-brest.fr	LOW
FHF	Fédération Hospitalière Française	France	AE	Vincent Ollivier	v.ollivier@fhf.fr	LOW
INCa	Institut National du Cancer	France	CA	Caroline Le Dour	cledour@institutcancer.fr	OBSERVER
INCa	Institut National du Cancer	France	CA	Margaux Le Gall	MLEGALL@institutcancer.fr	OBSERVER
Unicancer	Unicancer - Centre Oscar Lambret (Lille)	France	AE	David Pasquier	d-pasquier@o-lambret.fr	LOW
Unicancer	Unicancer - Centre Oscar Lambret (Lille)	France	AE	Eric Lartigau	e-lartigau@o-lambret.fr	LOW
Unicancer	Unicancer - Institut Gustave Roussy (Paris)	France	AE	Eric Deutsch	eric.deutsch@gustaveroussy.fr	LOW
Unicancer	Unicancer - Centre Léon Bérard (Lyon)	France	AE	Vincent Grégoire	Vincent.GREGOIRE@lyon.unicancer.fr	Co-LEADER
NHRF	ETHNIKO IDRYMA EREVNON	Greece	CA	Dr Alexandros Pintzas	apint@eie.gr	HIGH
NHRF	ETHNIKO IDRYMA EREVNON	Greece	CA	Dr Theodora Katsila	thkatsila@eie.gr	HIGH
NHRF	ETHNIKO IDRYMA EREVNON	Greece	CA	Dr Dimitra Mitsiou	dmitsiou@eie.gr	HIGH
NHRF	ETHNIKO IDRYMA EREVNON	Greece	CA	Dr Christos Chochos	chochos@eie.gr	HIGH
CNAO	Centro Nazionale di Adroterapia Oncologica	Italy	AE	Ester Orlandi	ester.orlandi@cnao.it	LEADER
CNAO	Centro Nazionale di Adroterapia Oncologica	Italy	AE	Tiziana Golme	tiziana.golme@cnao.it	LEADER
CNAO	Centro Nazionale di Adroterapia Oncologica	Italy	AE	Lisa Licitra	lisa.licitra@istitutotumori.mi.it	LEADER
CNAO	Centro Nazionale di Adroterapia Oncologica	Italy	AE	Chiara Marazzi	chiara.marazzi@cnao.it	LEADER
CRO-Aviano	CRO Aviano IRCCS	Italy	AE	Maurizio Mascarin	mascarin@cro.it	LOW
CRO-Aviano	CRO Aviano IRCCS	Italy	AE	Lorenzo Vinante	lorenzo.vinante@cro.it	LOW
CRO-Aviano	CRO Aviano IRCCS	Italy	AE	Andrea Dassie	andrea.dassie@cro.it	LOW
CRO-Aviano	CRO Aviano IRCCS	Italy	AE	Paolo Chiovati	pchiovati@cro.it	LOW
CRO-Aviano	CRO Aviano IRCCS	Italy	AE	Michele Avanzo	mavanzo@cro.it	LOW
PSCUH	Pauls Stradins Clinical University Hospital	Latvia	CA	Reičela Heinrihsone	reicela.heinrihsone@stradini.lv	HIGH
PSCUH	Pauls Stradins Clinical University Hospital	Latvia	CA	Aija Geriņa-Bērziņa	aija.gerina-berzina@stradini.lv	HIGH

INNOVATIVE RADIOTHERAPIES - DOMAIN 3 - PARTNERS



LSMUL KK	Hospital of Lithuanian University of Health Sciences Kauno klinikos	Lithuania	AE	Assoc. Prof. Sigita Liutkauskiene	sigita.liutkauskiene@kaunoklinikos.lt	LOW
LSMUL KK	Hospital of Lithuanian University of Health Sciences Kauno klinikos	Lithuania	AE	Gailė Venclovienė	gaile.vencloviene@kaunoklinikos.lt	LOW
LSMUL KK	Hospital of Lithuanian University of Health Sciences Kauno klinikos	Lithuania	AE	Viktoras Rudzianskas	viktoras.rudzianskas@kaunoklinikos.lt	LOW
LSMUL KK	Hospital of Lithuanian University of Health Sciences Kauno klinikos	Lithuania	AE	Laimonas Jarusevicius	laimonas.jarusevicius@kaunoklinikos.lt	LOW
LSMUL KK	Hospital of Lithuanian University of Health Sciences Kauno klinikos	Lithuania	AE	Erika Korobeinikova	erika.korobeinikova@kaunoklinikos.lt	LOW
CFB	Centre François Baclesse	Luxembourg	AE	Prof. Guillaume Vogin	guillaume.vogin@baclesse.lu	LOW
INC	Institut National du Cancer	Luxembourg	CA	Dr Nikolai Goncharenko	nikolai.goncharenko@inc.lu	LOW
INC	Institut National du Cancer	Luxembourg	CA	Dr Amélie Gaignaux	Amelie.Gaignaux@inc.lu	LOW
PMSI IO	PMSI Institute of Oncology	Moldova	CA	Horia Vulpe	horiavulpe@gmail.com	LOW
PMSI IO	PMSI Institute of Oncology	Moldova	CA	Minzatean Artiom	tiomat9@gmail.com	LOW
OUS	Oslo University Hospital, Department of Oncology	Norway	CA	Per Magnus	PEMM@ous-hf.no	х
OUS	Oslo University Hospital, Department of Oncology	Norway	CA	Jan Rødal	jro@ous-hf.no	LOW
OUS	Oslo University Hospital, Department of Oncology	Norway	CA	Marianne G. Guren	Marianne.Gronlie.Guren@ous-hf.no	LOW
MSCI	M. Sklodowska-Curie National Research Institute of Oncology - National Research Inst	Poland	CA	Tomasz Rutkowski	Tomasz.rutkowski@gliwice.nio.gov.pl	LOW
MSCI	M. Sklodowska-Curie National Research Institute of Oncology - National Research Inst	Poland	CA	Slwomir Blamek	Slawomir.blamek@gliwice.nio.gov.pl	LOW
IOCN	INSTITUTUL ONCOLOGIC PROF DR ION CHIRICUTA CLUJ-NAPOCA (IOCN)	Romania	CA	Andrei Roman	andrei.roman678@gmail.com	LOW
IOCN	The Oncology Institute, Cluj-Napoca	Romania	AE	Delia Nicoara	delianicoara13@gmail.com	LOW
CSGVA	Conselleria de Sanitat, Generalitat Valenciana	Spain	AE	Mariola Penadés Fons	penades_marfon@gva.es	HIGH
FSJD	Fundació Privada per a la Recerca i la Docència Sant Joan de Déu	Spain	AE	Andrés Morales La Madrid	andres.morales@sjd.es	OBSERVER
HUMV-IDIVAL	Fundación Instituto de Investigación Marqués de Valdecilla	Spain	AE	Fernando Rivera Herrero	fernando.rivera@scsalud.es	LOW
HUMV-IDIVAL	Fundación Instituto de Investigación Marqués de Valdecilla	Spain	AE	Ignacio José Durán Martínez	ignaciojose.duran@scsalud.es	LOW
HUMV-IDIVAL	Fundación Instituto de Investigación Marqués de Valdecilla	Spain	AE	Carlos López López	carlos.lopez@scsalud.es	LOW
HUMV-IDIVAL	Fundación Instituto de Investigación Marqués de Valdecilla	Spain	AE	Itziar Gardeazábal González	itziar.gardeazabal@scsalud.es	LOW
HUMV-IDIVAL	Fundación Instituto de Investigación Marqués de Valdecilla	Spain	AE	Fernanda Genre Romero	fgenre@idival.org	LOW
SoS	National Board of Health and Welfare (Socialstyrelsen)	Sweden	AE	Hillevi Rylander	Hillevi.Rylander@skandion.se	LOW
NCI	National Cancer Institute	Ukraine	CA	Andrii Horodetskyi	andriy.gorodetskiy@unci.org.ua	LOW



Which stakeholders should we contact to join the project for this domain?

- Existing projects/tools/networks
- Relevant scientific societies
- Relevant industrial partners
- Missing relevant stakeholders, including from missing Member States
- Existing training programs

- Existing projects/tools/networks: Hitriplus (<u>https://www.hitriplus.eu/</u>), PIANOFORTE (<u>https://pianoforte-partnership.eu/</u>)
- Relevant scientific societies/ industrial partners : any other suggestions?
 <u>Link</u>
- Missing relevant stakeholders, including from missing Member States <u>A couple of considerations:</u>

NoE's Missing Countries: Germany, Cyprus, Austria, Finland, Croatia Among Domain 3 - WP10 MISSING there are: Slovenia, Netherlands, Moldova, Hungary, Ireland, Portugal, Germany, Cyprus, Austria, Finland, Croatia

How to involve them: Institutions? Clinical and Radiation Oncologist societies? Research group?

★ Existing training programs: Hitriplus (<u>https://www.hitriplus.eu/</u>), Euracan, Phd program (UPLIFT) → Ideas?





How can we envision this domain within 4 years?

- Based on the milestones and deliverables planned for your domain, what are the priorities in order to start working together?
- How will you connect with the 6 other networks of expertise JANE 2 and with the EUnetCCC (CraNE follow-up)?

Task 4 – Infrastructural Infrastructural and procedural support

- <u>Milestone:</u> Workshop on mapping Innovative Radiotherapy techniques and technologies, and country-based processes for implementation of innovative techniques
- <u>Milestone:</u> Workshop on designing a roadmap for Innovative Radiotherapy involves addressing clinical and technical state-of-the-art scenarios to aid less advanced centers in the implementation of innovations
- Deliverable: Document on mapping Innovative Radiotherapy: exploring future roadmap agendas for Radiotherapy Innovation, methods, and implementation
- Deliverable: Document on establishing a Values-Based framework for comprehensive evaluation of innovations in Radiotherapy

Task 5 – Education and training

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- <u>Milestone:</u> Developing a European platform for training exchanges and facilitating access to technical and clinical knowledge of Innovative radiotherapy
- <u>Milestone</u>: Creating a model to empower patients by providing a comprehensive overview of the available treatment options and technologies across Europe in close collaboration with patients associations
- <u>Deliverable</u>: Report on perspectives and training needs of clinical staff regarding Innovative Radiotherapy Resources
- <u>Deliverable</u>: Document on the role of patients associations in advancing Innovative Radiotherapy

Task 6 – Dissemination & Sustainability

- <u>Milestone:</u> Describing workflows for assessing patient needs in specific radiotherapeutic options and enhancing access
- <u>Milestone:</u> Implementing a model for patient empowerment to enhance patients' ability to make informed decisions about their healthcare, particularly regarding innovative radiotherapy
- <u>Deliverable:</u> Document on procedures for evaluating patient requirements in particular radiotherapy choices and improving accessibility to innovation
- Deliverable: Document on frameworks for patient empowerment



Mapping innovative radiotherapy techniques and technologies in Europe European radiation oncology perspective on value-based innovation high tech radiotherapy

- 1. Radiotherapy (RT) innovation is highly focused on the precision and accuracy of radiation planning and delivery.
- 2. Value-based oncology aims to optimize patient outcomes while also considering the cost-effectiveness of treatments. In the context of radiotherapy, it encompasses a broad concept that has yet to achieve a definitive definition.
- 3. In the context of radiotherapy, defining core endpoints and a value scale must primarily consider:
- I. Intervention types (e.g., stepwise versus incremental technological innovations);
- II. Methods for testing clinical evidence and different timelines for testing;
- III. Endpoint categorization (including survival-related endpoints, functional outcomes, acute and late toxicity and complications, as well as economic and operational endpoints such as resource use, costs, and quality).



GETTING PREPARED FOR JANE 2 start





Survey

Part 1: Snapshot of Techniques and Technology Available in your Center Part 2: A snapshot of radiation oncologist's perspectives on RT innovation Part 3: A snapshot of Cost and reimbursement policy

Part 2: Radiation Oncologist's perspectives on RT innovation

1.Several RT innovations have been developed in the recent years. For each choice consider the importance on a scale from 1 to 5, where 1=strongly disagree and 5=strongly agree, how would you rate the following statements? (*Likert scale 1 to 5****)

- MRI- photon beam radiotherapy
- Photon beam Adaptive radiotherapy
- Photon beam 4D CT/MRI planning
- Flash photon beam radiotherapy
- MRI-planning for brachytherapy
- US-planning for brachytherapy
- Implementation of LET analysis for particle beam planning
- Flash particle beam radiotherapy
- 4D CT planning particle beam radiotherapy
- 4D MRI planning particle beam radiotherapy
- Adaptive particle therapy
- 4D particle dose delivering
- Other ions (please specify)______
- Al auto-contouring tool
- Al auto-planning tool

How would you describe the characteristics of an innovative technique/technology applied to radiation oncology? (check all that apply): On a scale from 1 to 5, where 1=strongly disagree and 5=strongly agree, how would you rate the following statements? Improvement of therapeutic index (Likert scale 1 to 5***)

Improvement of clinical work-flow Reduction of human error Shorten treatment times Expansion of treatment options for difficult-to-cure cancer Use of advanced imaging modalities Integration of AI Improvement of tailored-based treatments Reduction time to achieve specific RT objective (i.e. to finalize the OARs contouring, to finalize plan optimization) Reduction of healthcare costs Reduction of toxicities Impact on disability-adjusted life-years (DALYs) Improvement of local control Enhancement of safety and quality of care Easily accessible worldwide Approved by regulatory groups Green Sustainable Increment of accessibility in clinical trials Other (please specify)

7. How long do you consider an innovation as such? (check all that apply): On a scale from 1 to 5, where 1=strongly disagree and 5=strongly agree, how would you rate the following statements?

- Until the achievement of clinical evidence
- Until the achievement of maximum enhancement of efficiency or RT delivery
- Until its results are able to change the guidelines and recommendations
- Until the achievement of evidence-based data
- For the time it is included in a trial
- Up to the achievement of global accessibility
- Other (please specify) _____

8.How can AI impact the RT clinical practice? (check all that apply): On a scale from 1 to 5, where 1=strongly disagree and 5=strongly agree, how would you rate the following statements?

- Replacing the role of RT staff
- Supporting clinical decision
- Reducing workload
- Increasing workload
- I think AI will have no significant impact on clinical practice
- Other (please specify) _____

9.What are the possible barriers that negatively impact the European democratisation access to new technologies? (check all that apply): On a scale from 1 to 5, where 1=strongly disagree and 5=strongly agree, how would you rate the following statements?

- Lack of clinical evidence
- Highly costs of purchase and maintenance
- Lack of specific reimbursement policy dedicated to the RT departments
- Lack of specific reimbursement policy dedicated to patients to reduce the financial toxicity
- Imbalance in geographical distribution of facilities that allow access to new technology
- Absence of a European cooperative group dedicated to the implementation and integration of new RT technology
- Concerns about privacy and data security (i.e in the use of AI)
- It is more time-consuming compared to conventional technology
- Requiring dedicated staff
- Regulatory issues
- Longer learning curve compared to conventional technologies
- Other (please specify) ______
- •

10.How would you describe the accessibility applied to innovation in radiation oncology? (check all that apply): On a scale from 1 to 5, where 1=strongly disagree and 5=strongly agree, how would you rate the following statements?

- Strategical geographical location of RT innovation to serve a larger number of patients
- Implementation of telemedicine and mobile RT units to serve also low-income countries or rural areas
- Presence of reimbursement policies
- Ensuring access to high-quality care for all patients
- Lodging accommodation for patients who travel, especially for patients facing financial and logistical challenges
- Physical accessibility to RT departments for patients with disabilities
- Cost-effective value-based radiotherapy
- Other (please specify) ______

Criteria for network endorsement (1/2)

Cancer types:

- 1. frequent cancers
- 2. rare cancers
- 3. pediatric cancers

Field of application :

- 1. standard of care
- 2. clinical research
- 3. translational, basic research
- 4. public health...

Connection with clinical cooperative groups, CT:

- 1. Connected with cooperative groups,
- 2. Clinical Trials,
- 3. European networks/consortia partecipation

Human resources, expertise:

- 1. On-site/network with radiation oncologist, bio-IT, pathologist, medical oncologist, hematologist, surgeons, medical Physicist, Bio-ing, accelerator physicist, Clinical research support professionals, TTO
- 2. On-site/network with genetist, hemato-onco pediatrician, socialeconomist expert
- 3. Continous professional development

Available infrastructure / core facilities (equipment, TPS, AI, ...): - Minimal equipment/software: State of the Art linacs; CT scanners dedicated to treatment planning; State-of-the-Art treatment planning system (TPS), State-of the-Art Record and Verify System (RVS); three-dimensional RT; IMRT techniques (including VMAT, tomotherapy); State-of- the-Art Image guided radiotherapy (IGRT)

-Brachitherapy: High dose rate brachytherapy; Pulsed dose rate brachytherapy; Low dose rate brachytherapy

-Advanced equipment platform/software: stereotactic radiotherapy (SRT); Adaptive Radiotherapy (ART); atlas -based contouring; Albased contournig; MRI scanners dedicated to treatment planning; PET/CT scanners dedicated to treatment planning; US dedicated to treatment planning

-Continuous technological development: beam qualities and techniques other than photons-based ones both in clinical setting and clinical research, includind protons (carbon ion, helium, boron neitron capture therapy, BNCT, FLASH therapy, Proton arc therapy..);TPS with integrated biological function and /or LET optimization and/or AI-based planning

Criteria for network endorsement (2/2)

Clinical Practice guidelines, Training, Education:

- 1. Twinning program PHD
- 2. Involvment in setting up international CPG, in (inter)national teaching program (for scientists, technicians, bio-IT...)
- 3. Involvment / Organisation of seminars, paractical courses

Track record:

- 1. Number of publications/yr including open access (peer-review journal)
- 2. Number of interdisciplinar publications
- 3. Patent application
- 4. Medical device development

In summary:

The EU network on rare cancer (EURACAN) is a reality and opened the way for an innovative approach to health care.

- On the same path EU launched 2 JAs to support networking construction.
- Within the oncological NOE network construction, high tech innovative RT has the opportunity to conceptualise drive, shape and develop the way in which innovative RT will be implemented in the EU oncological community.