

Qradioval

An International Clinical Validation of Radiomics Artificial Intelligence for Breast Cancer Treatment Planning

Deliverable D7.4: Communication material

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Executive Summary

This deliverable describes the communication materials that are available for the partners of the the RadioVal project. Using these communication materials (abstracts, Work Package descriptions, ppt and social media templates, the website and promotional videos) serves the goal to streamline communication efforts, ensure a unified message, and facilitate smooth collaboration among all involved parties.



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1. Introduction

The RadioVal project develops and implements a comprehensive validation of artificial intelligence solutions in breast cancer treatment. RadioVal is the first multi-centre, multi-continental and multi-faceted clinical validation of radiomics driven estimation of NAC response in breast cancer.

Deliverable 7.4 "Communication material" serves as a comprehensive resource for project partners, providing them with the necessary materials and guidelines to effectively introduce, present, and promote the RadioVal project. The deliverable contains a range of items, including project summaries, branding guidelines, templates for presentations and social media, and more. The goal of this deliverable is to streamline communication efforts, ensure a unified message, and facilitate smooth collaboration among all involved parties.

2. Scientific Abstract

The RadioVal communication material includes the scientific abstract that succinctly outlines the objectives, methodology, and expected outcomes of the project. The abstract serves as a comprehensive yet concise summary, making it an invaluable resource for project partners who need to quickly familiarize themselves with the project's details or share information with external stakeholders. It is written in a technical and precise language to cater to a more specialized audience, ensuring that the project's intricacies are accurately conveyed. Please refer to the scientific abstract at the end of this section for a brief overview of the RadioVal project.

Breast cancer is now the most common cancer worldwide, surpassing lung cancer in 2020 for the first time. It is responsible for almost 30% of all cancers in women and current trends show its increasing incidence. Neoadjuvant chemotherapy (NAC) has shown promise in reducing mortality for advanced cases, but the therapy is associated with a high rate of over-treatment, as well as with significant side effects for the patients. For predicting NAC respondents and improving patient selection, artificial intelligence (AI) approaches based on radiomics have shown promising preclinical evidence, but existing studies have mostly focused on evaluating model accuracy, all-too often in homogeneous populations. RadioVal is the first multi-centre, multi-continental and multi-faceted clinical validation of radiomics driven estimation of NAC response in breast cancer. The project builds on the repositories, tools and results of five EU-funded projects from the AI for Health Imaging (AI4HI) Network, including a large multi-centre cancer imaging dataset on NAC treatment in breast cancer. To test applicability as well as transferability, the validation with take place in eight clinical centres from three high-income EU countries (Sweden, Austria, Spain), two emerging EU countries (Poland, Croatia), and three countries from South America (Argentina), North Africa (Egypt) and Eurasia (Turkey). RadioVal will develop a comprehensive and standardised methodological framework for multi-faceted radiomics evaluation based on the FUTURE-AI Guidelines, to assess Fairness, Universality, Traceability, Usability, Robustness and Explainability. Furthermore, the project will introduce new tools to enable transparent and continuous evaluation and monitoring of the radiomics tools over time. The RadioVal study will be implemented through a multi-stakeholder approach, taking into account clinical and healthcare needs, as well as socio-ethical and regulatory requirements from day one.

3. Summary for the lay audience

In addition to the scientific abstract, the RadioVal communication material provides a summary tailored for a lay audience. This summary aims to effectively communicate the project's goals, progress, and significance to non-experts or individuals outside the field of medical research and imaging. Written in clear, non-technical language, it ensures that the project's key aspects are easily understood by a broader audience, facilitating wider outreach and engagement. The lay



audience summary can be particularly useful when communicating with the general public, media, or non-specialized stakeholders.

The RadioVal project aims to develop and implement a very comprehensive validation of artificial intelligence solutions in breast cancer treatment. Such AI solutions enhance precision medicine and will help clinicians perform a more individualised treatment adjusted to the patients' need.

Breast cancer is now the most common cancer worldwide, surpassing lung cancer in 2020 for the first time. It is responsible for almost 30% of all cancers in women and current trends show its increasing incidence. Neoadjuvant chemotherapy (NAC) has shown promise in reducing mortality for advanced cases, but the therapy is associated with a high rate of over-treatment, as well as with significant side effects for the patients. For predicting NAC respondents and improving patient selection, artificial intelligence (AI) approaches based on radiomics have shown promising preclinical evidence, but existing studies have mostly focused on evaluating model accuracy, all-too often in homogeneous populations.

RadioVal is the first multi-centre, multi-continental and multi-faceted clinical validation of radiomics driven estimation of NAC response in breast cancer. The project builds on the repositories, tools and results of five EU-funded projects from the AI for Health Imaging (AI4HI) Network, including a large multi-centre cancer imaging dataset on NAC treatment in breast cancer.

To test applicability as well as transferability, the validation will take place in eight clinical centres from three high-income EU countries (Sweden, Austria, Spain), two emerging EU countries (Poland, Croatia), and three countries from South America (Argentina), North Africa (Egypt) and Eurasia (Türkiye). RadioVal will develop a comprehensive and standardised methodological framework for multi-faceted radiomics evaluation. Furthermore, the project will introduce new tools to enable transparent and continuous evaluation and monitoring of the radiomics tools over time. The RadioVal study will be implemented through a multi-stakeholder approach, taking into account clinical and healthcare needs, as well as socio-ethical and regulatory requirements from day one.

The first half of the project is dedicated to a dialogue with clinicians, patients, AI developers and ethico-legal experts to design the evaluation study and understand the exact needs of all stakeholders. During the second half, we will perform the evaluation study on real-world data from eight hospitals all over the world.

Ultimately, we want to establish AI tools that provide insights into the decision-making (explainability), how certain or uncertain they are (uncertainty) and provide traceability tools to track AI performance through time.

4. Project leaflet

The RadioVal project leaflet is a compact, A5-sized informational resource designed to quickly convey the project's vision, mission, objectives, and key facts, such as runtime, start date, and project coordinator. This leaflet is an effective communication tool for project partners and stakeholders, providing an easily understandable and visually appealing summary of the project. It can be distributed at events, meetings, or shared electronically, making it an efficient and accessible means of introducing the RadioVal project to a wide range of audiences. A pdf copy of the leaflet will be attached at the end of this report as Annex 1, enabling project partners to utilize it as needed for their communication activities.



The leaflet was already distributed during the European Congress of Radiology, at different, wellattended sessions, as well as at the EIBIR booth.

5. Summaries of all Work Packages

Summaries of all Work Packages were prepared for easy-to-use assets for communication, that at the same time also help partner get a brief and easy-to-understand overview of the objectives of Work Packages they are not involved in.

WP1 - Multi-stakeholder engagement and social innovation

Work Package 1 develops the social innovation framework of RadioVal that compiles the multistakeholder requirements and pathways for enhancing radiomics evaluation and implementation in breast cancer. Later, this social innovation framework will be leveraged in the following areas: 1. clinical, patient and healthcare; 2. socio-ethical; 3. legal and regulatory. The Radiomics information and communication package will be created, which will be used during the social innovation and radiomics evaluation sessions by RadioVal's stakeholders.

WP2 - Multi-faceted evaluation framework, resources and guidelines

Work Package 2 focuses on identifying the criteria and metrics for multi-faceted evaluation of radiomics AI; defining the stages, timelines, and procedures for radiomics evaluation; and establishing an open-access reference dataset for comparative evaluation and community benchmarking of radiomics AI in the field of breast NAC. A cost-effectiveness analysis approach modelling the specificities of radiomics AI tools will also be introduced and new guidelines for the reporting of radiomics evaluation studies will be developed and disseminated.

WP3 - Tools for continuous evaluation, monitoring and traceability

Work Package 3 is responsible for developing the radiomics passport for standardised description and traceability of radiomics models; implement methods for both image and segmentation automated quality controls; and develop methods for automated failure detection. Furthermore,



the human-in-the-loop mechanisms will also be implemented by this Work Package that enables and ensures a degree of human oversight to radiomics AI.

WP4 - Preliminary evaluation and tool calibration

Work Package 4 builds on Work Package 1 and 2 and will perform the preliminary evaluation of the RadioTool taking into account fairness, robustness, explainability and usability. Depending on the results, the mitigation measures and suitable strategies will be evaluated. This Work Package is also in charge of integrating the radiomics tools and AI optimisation methods into a functional CDSS making it ready for clinical deployment and validation based on the commercial QUIBIM Precision platform.

WP5 - Multi-centre clinical evaluation study

Work Package 5 implements an international study for in-depth, multi-faceted evaluation of the radiomics tools for treatment planning in breast cancer. This Work packages also evaluates the radiomics models, compares the results between internal and external sites and gather feedback and report on the results of the study based on the reporting guidelines set in Work Package 2.

WP6 - Impact evaluation and maximisation

Work Package 6 performs an in-depth cost-effectiveness analysis of the radiomics tool. It evaluates the impact of the introduction of the radiomics based treatment planning, the socio-ethical implications of the radiomics tools and establishes the pathways of the regulatory certification of such tools. The final version of the RadioPack information package will be delivered via this Work Package and possible exploitation routes and sustainability plans will also be examined.

WP7 - Project management and outreach

Work Package monitors the successful implementation of the research activities taking place in the Work Packages, coordinates the administrative and financial aspects of the project and disseminates and communicates the results of the project.

6. Branding guidelines

The RadioVal project's visual identity plays a crucial role in maintaining a consistent and professional image across all communication materials. To ensure that all project partners adhere to the same design principles, a set of branding guidelines has been developed. These guidelines cover various aspects of the project's visual identity, including logo usage, typography, colour palette, and other design elements. By following the branding guidelines, partners can ensure that all RadioVal-related materials are easily recognizable and convey a unified message.

Logo usage

The RadioVal logo is an essential component of the project's visual identity. This section outlines the proper use of the logo, including placement, sizing, and any restrictions on altering its design. By adhering to these guidelines, partners can ensure that the logo is used consistently across all communication materials.

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RadioVal project logo

The project logo consists of a logotype and a wordmark.





RadioVal logomark

Colours

The RadioVal logo is available in four colourways:

- White
- White with coloured ribbon
- Dark blue with coloured ribbon
- Black

The dark blue logo with coloured ribbon is to be used whenever possible and legible.

The while with coloured ribbon logo is to be used on medium to dark coloured backgrounds.

The two monochrome coloured logos can be used if the colour palette must be limited, or for legibility reasons.



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Whenever the logo is used, it should be surrounded with clear space to ensure its visibility and impact. No graphic elements of any kind should invade this zone. The logo and the icon's exclusion zone are equal to half the height of the icon.





Typography

Typography plays a significant role in maintaining a consistent visual identity for the RadioVal project. This section provides details on the typefaces, font sizes, and font styles that should be used in project materials, as well as any recommended usage for headings, subheadings, and body text.

The typeface used in the logo is based on Montserrat. For web use, Montserrat typefaces should be used. In situations where Montserrat typefaces is not available (for example offline usage), the fall-back typeface is Arial.

Font sizes should be selected for optimal legibility and not condensed.

Increased font weights should be used for emphasis, together with a colour emphasis.

Headings, subheading, and body text can use the same typeface, or one of the recommended typefaces, which can be mixed and matched between headings and body text. The typefaces within one type of text should not be mixed, i.e., if headings are using a different typeface that the body, the heading should always use the same typeface and the body text should only use one typeface as well.

Colour palette

The RadioVal project's colour palette consists of a set of primary and secondary colours that have been carefully chosen to represent the project's values and goals. This section outlines the specific colour codes (HEX and CMYK) for each colour in the palette and provides guidelines on how to apply these colours to various communication materials.

Color	Electric pink	Purple	Purple Blue	Dark blue	Black	White
Swatch						
HEX	#FF52CE	#AD5BFF	#5727f3	#180054	#000000	#FFFFFF
СМҮК	0 / 76 / 0 / 0	44 / 69 / 0 / 0	75 / 78 / 0 / 0	100 / 100 / 2 4 / 39	100 / 100 / 100 / 100	0/0/0/ 0
Usage	Primary	Primary	Primary	Primary	Secondary	Secondary
Logo	х			х	х	x
Text	х	х	х	х	х	x
Graphs	х	х	х	х		
Gradient		х	х			

In the table below six colours are features, as well as their usage.

Dark Blue is the primary colour for text. It is also featured in the logo.

Electric Pink is also featured in the logo and can be an alternative colour for text. However, it is recommended to use Purple as a secondary text colour for emphasis. Purple Blue is a secondary colour that can be also used for emphasis.

7. PowerPoint template for presentations

To ensure consistency in presentations related to the RadioVal project, a PowerPoint template has been developed for use by all project partners. This template includes pre-designed slide layouts, typography, and colour schemes that adhere to the project's branding guidelines. By using the PowerPoint template, partners can create professional and visually cohesive presentations that align with the RadioVal project's visual identity.



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8. Social media guidelines and templates

In addition to the project website, an online presence for RadioVal is established on social media. Currently, this includes a Twitter profile, a LinkedIn page and a YouTube channel. The partners will use social media platforms, such as <u>Twitter</u>, <u>LinkedIn</u>, and <u>YouTube</u> to raise awareness and disseminate information.

To facilitate effective communication and promote the RadioVal project on social media, we have prepared a set of guidelines and templates for project partners. These guidelines aim to ensure a consistent message and tone across various social media platforms while leveraging the existing reach of partners' institutional accounts.

The social media guidelines outline best practices for partners when sharing RadioVal-related content on their institutional accounts. These guidelines cover aspects such as tone, language, and the use of visuals, ensuring that all social media posts align with the project's overall communication strategy and visual identity.

Hashtags

The main hashtag that should be included in all RadioVal-related social media posts are **#RadioVal** and mentioning the project's official account (**@RadioVal_AI**) is also highly encouraged. By using these hashtags, partners can contribute to the online conversation surrounding the project and

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increase its visibility. Other recommend hashtags include: **#HorizonEurope, #AI, #breastcancer, #EUfunded #ArtificialIntelligence.**

Institutional Accounts

Partners are encouraged to use their institutional social media accounts to share updates about the RadioVal project. This approach takes advantage of the established audiences and reach of these accounts, ensuring that the project's messages reach a wide audience without the need to build a new follower base from scratch.

Social media templates

To streamline the process of creating social media content, we have provided a set of templates for social media posts. These templates include suggested post formats, imagery, and key messaging points that partners can customize to suit their specific needs and audiences.

The open design files are available to the consortium upon request.



Social media template

Social media presence

The social media accounts of the RadioVal project (Twitter, LinkedIn and YouTube) are active and, using the key messages and branding established at the beginning of the project, we are able to reach hundreds of potential stakeholders and keep them engaged in our posts. RadioVal's social



media accounts are used to reach out to potential stakeholders and to keep them informed about the latest updates of the project. On the Twitter account of RadioVal, partner introduction tweets were prepared and tweeted highlighting the partners' main responsibilities and key contacts.

9	Radio Val @RadioVal_AI · Apr 19 RadioVal presents the University of Barcelona (@UniBarcelona), and, very own Project Coordinators @KarimLekadir and @ooliverdiaz. Apar from overseeing the project, they are in charge of the data manageme and scientific coordination of RadioVal. #HorizonEurope #EUfunded				 rcelona), and, our liverdiaz. Apart ata management e #EUfunded
	The Un Coort the pro- activit ar coord	UNIVER BARCI niversity of B dinator of Ra oject manag ties, the data and the overa lination and the proj	RSITAT DE ELONA arcelona is the adioVal, leads rement-related management Il scientific monitoring of ect.		
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Introductory partner tweet example



Radio Val @RadioVal_AI · Mar 3 RadioVal at #ECR2023! #breastcancer #Artificial_Intelligence ...

connect.myesr.org/course/unlocki...



RadioVal tweet during ECR2023



9	Radio Val @RadioV Have you seen the Check out our latest of our team! #EUfunded #breast For the second	al_AI · Apr 27 his yet? t video of #RadioV tcancer #research youtube.com What is RadioVa This video introd main aims and o	(al explained by th #ArtificialIntellig I? - An Introduction luces the idea of F bjectives of the p	 ne scientific leads ence #horizoneu on RadioVal, the roject.
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9	Radio Val @Radio RadioVal is welch We are an #EUfund #ArtificialIntelliger Learn more about of stakeholder: radioval.eu/news/co	/al_AI · Apr 19 coming external stal ded project that aim nee solution for #br us via our website a	keholders! Is to validate an eastcancer treatm nd fill in the form #	••• ent planning. to become our

Tweet promoting external stakeholder sessions.

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9. RadioVal website

The RadioVal website (<u>www.radioval.eu</u>) has been developed as the main public-facing online presence.

It contains the most important information about the project and efforts were made to keep the information understandable for the general public.

The website is a constantly changing and evolving platform. The initial release provides basic functionality and information but will change substantially over the course of the project.

All separate pages are attached as an Annex 2 of this document.

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Landing page

The landing page features an attention grabbing hero element at the top of the page. This is followed by more details about the objectives of the project. Both sections link to more in-depth information about RadioVal.

This is followed by a section displaying the latest news items, which also links to a news archive.

As a next section, and overview of the consortium is included. All consortium partners are included with their logo.

A final attention-grabbing headline concludes the content of the main page, and links to the overview of work packages.

The menu at the top of the page remains at the top for easy navigation.

A footer at the bottom of the page includes information about the EC funding and the disclaimer regarding the public views of RadioVal. It also includes direct contact details and quick links to each main section.



About Us page

The About Us page provides more details about RadioVal, including the mission and vision, as well as some hard facts about the project such as runtime, number of partners, coordination teams etc.

Work Packages

The specific objectives and work packages are described on this page.

Consortium and partner-specific pages

This page provides a geographical overview of the consortium, showing its global nature, as a list of partners. Every partner can be clicked on for navigation to more details about each partner. This includes a general description of the organisation, their role in the project and the staff involved.

This page also includes information about the multidisciplinary nature of the consortium, and its complementary expertise.

Results

The results page features searchable and sortable tables for three categories of public results: scientific publications, public deliverables and press material. The respective tables will be populated with results as they become available.

Contact page

The contact page does not include any contact forms, but only provides details for direct contact means; a dedicated email address and a phone number.

The decision not to include a contact form was made for GDPR compliance reasons.

News items

The website has been regularly updated with news items, targeting the general stakeholders of the project. WP1 lead partner, SHINE, in collaboration with EIBIR, provided regular updates regarding its latest presentations, conferences and lectures about RadioVal.

10. Promotional videos

The RadioVal consortium prepared videos as part of RadioPack. The main aim of these videos are to provide details and context for different stakeholders. These videos are created in a collaborate effort between partners with the goal to inform the lay audience (primarily patients). Four introductory RadioPack videos have been produced and published. These videos feature English-language narration from actual researchers working on the project, with additional languages being provided as subtitles (Croatian, Polish, Portuguese. Spanish, Swedish and Turkish). These videos are published <u>on a separate section on the project website</u>, and <u>on the project's YouTube channel</u>:



Screenshots of the RadioPack "What is RadioVal?"





Screenshots of the RadioPack "Breast Cancer Oncology"



Screenshots of the RadioPack "Radiomics Artificial Intelligence for Breast Cancer Treament Planning"



Screenshots of the RadioPack "Ethics Considerations in Artificial Intelligence"



An additional promotional video was produced explaining the project and its importance. It features the leading researchers explaining the idea of RadioVal. Such promotional videos help raising awareness and inform the general public and stakeholders about the main aims and objectives of RadioVal. A longer version of the promotional video was made for the project's official <u>YouTube</u> <u>channel</u>, while a shorter version was also prepared specifically for social media.



11. Conclusion

In conclusion, in the first ten months of the projects, we've produced significant amount of communication materials to facilitate the dissemination of the project by all partners and we would continue to do so as results become available.

<u>Deliverable D7.4:</u> <u>Annex 1 – RadioVal Leaflet</u>

Empowering Personalised Treatment of Breast Cancer Patients

RadioVal implements the first international, clinical validation study of radiomics-based prediction of neoadjuvant chemotherapy treatment response from breast MRI.

RadioVal develops a comprehensive and standardised methodological framework for multi-faceted radiomics evaluation. We will promote precision medicine with tools that provide insights into decision-making and AI performance through time.

RadioVal will help clinicians develop treatment plans tailored to each patient, potentially reducing the costs of breast cancer care.

In dialogue with healthcare professionals, patients, AI developers and ethicolegal experts, we will design the evaluation study according to their needs and requirements. We will then perform the evaluation study on real-world data from eight hospitals all over the world.

"We noticed a lot of AI tools were of very good quality with interesting results, but not sufficiently translated into clinical practice because there was a lack of evidence they could be trusted in the real world." - Karim Lekadir, University of Barcelona, **RadioVal** Coordinator

Gradioval

www.radioval.eu

Gradioval

Visit www.radioval.eu for more information.

The **RadioVal** consortium is a highly experienced and ambitious consortium with a unique blend of assets and expertise suited to achieve the ambitious objective of a first multi-faceted, international validation study in the field of radiomics.

Contact us:

e-mail: radioval@eibir.org

Twitter: @RadioVal_AI

Website: www.radioval.eu

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or European Health and Digital Executive Agency (HADEA). Neither the European Union nor the granting authority can be held responsible for them.

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Funded by the European Union

<u>Deliverable D7.4:</u> Annex 2 – RadioVal website



THE RADIOVAL PROJECT

Empowering Personalised Treatment of Breast Cancer Patients

Raising the standard of breast cancer care with radiomics-based prediction

Learn More

RadioVal Objectives

The idea of the RadioVal project is to implement a very comprehensive validation of artificial intelligence solutions for breast cancer treatment.



Assess Performance Of AI Tools

We will evaluate the performance of artificial intelligence tools for breast cancer treatment by looking at multiple dimensions, including accuracy, robustness, fairness, usability, confidence and productivity.



Address Challenges In Medical AI

Our goal is to build and validate AI tools that overcome common challenges in medicine, such as population-based biases, uncertainty, explanability, usability and data harmonisation.



Help Clinicians Help Patients

The ultimate goal of RadioVal is to provide validated artificial intelligence tools that clinicians understand, trust and use in clinical practice so they more effectively treat breast cancer patients.

About RadioVal



Latest News

A description of your blog and what the visitor could expect to find in it.



RadioVal Website Launched

As of the 30th of November, the RadioVal website is going live!

Read More



Successful Launch Of RadioVal

The RadioVal project which is co-funded under Horizon Europe has started in October 2022 and runs until September 2025

Read More

Our consortium

The RadioVal consortium brings together 16 partners from 13 countries.

You can find out more about the consortium partners, the individual expertise and the involved staff on the consortium overview page.



Introducing radiomics Artificial Intelligence in breast cancer



treatment

Find out more about our Work Plan and how we are working to introduce radiomic artificial intelligence for the prediction of neoadjuvant chemotherapy treatment efficacy.

Gradioval

Increasing prospects of radiomics artificial intelligence in breast cancer treatment planning

This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement No 101057699.

Quick Links

Home About us Work Packages Partners Results Contact

Get In Touch

- ≥ pgordebeke@eibir.org
- Phone: +43-1-533-4064-323





Cradioval

Our Mission

The idea of the RadioVal project is to develop and implement a very comprehensive validation of artificial intelligence solutions in the breast cancer treatment.

We hope our projects promotes precision medicine with tools that will help clinicians to perform more precise medicine, individualised to the patient's need.

RadioVal will help clinicians help patients.



About the project

RadioVal implements the first international, clinical validation study of radiomics-based prediction of neoadjuvant chemotherapy treatment response from breast MRI. The project will develop a comprehensive and standardised methodological framework for multi-faceted radiomics evaluation based on the FUTURE-AI Guidelines, to assess Fairness, Universality, Traceability, Usability, Robustness and Explainability. Furthermore, the project will

introduce new tools to enable transparent and continuous evaluation and monitoring of the radiomics tools over time. The RadioVal study will be implemented through a multi-stakeholder approach, taking into account clinical and healthcare needs, as well as socio-ethical and regulatory requirements from day one.

Facts and Figures

Project name: International Clinical Validation of Radiomics Artificial Intelligence for Breast Cancer Treatment Planning

Project acronym: RadioVal Start Date: September 1, 2022 End Date: August 31, 2026 Coordinator: University of Barcelona Consortium: 16 partners from 13 countries

Funding: € 5,838,576

Context

Breast cancer is now the most common cancer worldwide, surpassing lung cancer in 2020 for the first time. It is responsible for almost 30% of all cancers in women and current trends show its increasing incidence. Neoadjuvant chemotherapy (NAC) has shown promise in reducing mortality for advanced cases, but the therapy is associated with a high rate of over-treatment, as well as with significant side effects for the patients. For predicting NAC respondents and improving patient selection, artificial intelligence (AI) approaches based on radiomics have shown promising preclinical evidence, but existing studies have mostly focused on evaluating model accuracy, all-too often in homogeneous populations.

RadioVal is the first multi-centre, multi-continental and multi-faceted clinical validation of radiomics driven estimation of NAC response in breast cancer. The project builds on the repositories, tools and results of five EU-funded projects from the AI for Health Imaging (AI4HI) Network, including a large multi-centre cancer imaging dataset on NAC treatment in breast cancer.

To test applicability as well as transferability, the validation will take place in eight clinical centres from three high-income EU countries (Sweden, Austria, Spain), two emerging EU countries (Poland, Croatia), and three countries from South America (Argentina), North Africa (Egypt) and Eurasia (Turkey). RadioVal will develop a comprehensive and standardised methodological framework for multi-faceted radiomics evaluation. Furthermore, the project will introduce new tools to enable transparent and continuous evaluation and monitoring of the radiomics tools over time. The RadioVal study will be implemented through a multi-stakeholder approach, taking into account clinical and healthcare needs, as well as socio-ethical and regulatory requirements from day one.

Learn More About Our Work Plan

View The RadioVal Consortium



Our Vision

We will evaluate multiple dimensions of performance, including accuracy, robustness, fairness, usability, confidence and productivity.

Manage consent

The first half of the project is dedicated to a dialogue with clinicians, patients, AI developers and ethicolegal experts to design the evaluation study and understand the exact needs of all stakeholders. During the second half, we will perform the evaluation study on real-world data from eight hospitals all over the world.

We want to involve a multidisciplinary group of stakeholders and understand that it's very important that clinicians, patients and developers understand the project, and that they are involved in it.

Ultimately, we want to establish AI tools that provide insights into the decision-making (explainability), how certain or uncertain they are (uncertainty) and provide traceability tools to track AI performance through time.

RadioVal is a research project, but it focuses on research very close to clinical practice.

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We noticed a lot of AI tools were of very good quality with interesting results, but not sufficiently translated into clinical practice because there was a lack of evidence they could be trusted in the real world

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Karim Lekadir

Coordination <u>Team</u>



Karim Lekadir

Dr. Karim Lekadir is a Senior/Tenure Track Researcher at the University of Barcelona and coordinator of RadioVal. He holds a Master's Degree in Computer Science from the University of Montpellier II (France) and a PhD in Medical Image Computing from Imperial College London (UK).



Oliver Diaz

Dr. Oliver Diaz is an Assistant Professor at UB and the co-coordinator of RadioVal. He holds a Ph.D. in Medical Imaging/Physics from the Centre for Vision, Speech, and Signal Processing at the University of Surrey (UK).



Anais Emelie

Anais Emelie is the Project Manager of RadioVal. She holds a Master's degree in Applied Bioengineering from the University of Washington.

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Increasing prospects of radiomics artificial intelligence in breast cancer treatment planning

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RadioVal Work Packages

Aims and specific objectives

RadioVal develops a validated AI-based decision-making support system, increasing clinicians' and patients' trust in artificial intelligence tools by implementing the first international, clinical validation study of radiomics-based prediction of neoadjuvant chemotherapy (NAC) treatment response from breast MRI. This reduces overtreatment in patients undergoing chemotherapy and reduce costs of breast cancer care. To test applicability as well as transferability, the validation will take place in eight clinical centres from three high-income EU countries (Sweden, Austria, Spain), two emerging EU countries (Poland, Croatia), and three countries from South America (Argentina), North Africa (Egypt) and Eurasia (Turkey).

Objective 1: Implement the very first international, multi-faceted clinical validation study for radiomicsbased prediction of response to neoadjuvant therapy in multiple developed and developing countries.

• Objective 2: Introduce a holistic, standardised methodological framework for multi-faceted and trustworthy evaluation of radiomics AI, taking into account multiple technical, clinical as well as ethical criteria.

Objective 3: Implement a multi-stakeholder, inclusive approach to improve awareness, acceptance and promotion of radiomics AI in future breast cancer care.

Objective 4: Develop the very first traceability tool for radiomics AI, which will enable transparent monitoring and continuous evaluation of radiomics tools during their lifetime.

Work Package description

WP1: Multi-stakeholder engagement and social innovation

- Develop a social innovation framework to compile multi-stakeholder requirements and pathways for enhancing radiomics evaluation and implementation in breast cancer.
- Develop a radiomics information and communication package that will be leveraged during social innovation and radiomics evaluation by RadioVal's multi-disciplinary stakeholders.
- Leverage the social innovation framework to define multi-disciplinary requirements and pathways in the following specific areas:
 clinical, patient and healthcare,
 - socio-ethical,
 - legal and regulatory.

WP2: Multi-faceted evaluation framework, resources and guidelines

- Identify criteria and metrics for multi-faceted evaluation of radiomics AI, in breast cancer in particular.
- Define stages, timelines and procedures for radiomics evaluation, incl. in-silico and external validations.
- Establish an open-access reference dataset for comparative evaluation and community benchmarking of radiomics AI in the field of breast NAC.
- Introduce a cost-effectiveness analysis approach that will model the specificities of radiomics AI tools.
- Develop and disseminate new guidelines for the reporting of radiomics evaluation studies.

WP3: Tools for continuous evaluation, monitoring and traceability

- Develop the radiomics passport for standardised description and traceability of radiomics models.
- Implement methods for both image and segmentation automated quality controls.
- Develop methods for automated failure detection, especially out-of-distribution abnormal deviations.
- Implement human-in-the-loop mechanisms to enable a degree of human oversight and to integrate clinical feedback to radiomics
 Al over the model's lifetime.
- Integrate all these methods into a ready-to-deploy radiomics traceability suite.

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WP4: Preliminary evaluation and tool calibration

- Perform a preliminary evaluation of ; the very first toolbox for radiomics monitoring and continuous evaluation.
- Evaluate mitigation measures and suitable strategies to enhance the radiomics fairness, robustness, usability and explainability for treatment assessment in breast cancer.
- Integrate the radiomics tools and AI optimisation methods into a functional Clinical Decision Support System (CDSS) that will be ready for clinical deployment and validation.
- Produce the second version of the information and communication package integrating new information and guidelines on the tool's clinical usability, as well as on radiomics fairness, robustness and explainability.

WP5: Multi-centre clinical evaluation study

- Implement an international study for in-depth, multi-faceted evaluation of the radiomics tools for treatment planning in breast cancer.
- Evaluate and analyse in particular the robustness, fairness, usability, explainability, traceability and scalability of the radiomics models.
- Compare the results between internal and external sites, as well as across international countries.
- Gather feedback and report the results of the study according to the reporting guidelines.

WP6: Impact evaluation and maximisation

- Perform an in-depth cost-effectiveness analysis of the radiomics tool for breast cancer treatment and care.
- Evaluate impact of the introduction of radiomics based treatment planning in breast cancer practice.
- Evaluate the socio-ethical implications of the introduction of the radiomics tool in the real world.
- Establish pathways for regulatory certification of radiomics AI tools for clinical translation.
- Deliver the final version of the RadioPack information package by integrating clinical feedback.
- Examine possible exploitation routes and sustainability plans to maximise impact beyond the project.

WP7: Project management and outreach

- Manage the timely implementation of the research activities, administrative and financial tasks based on the frequently updated Data Management Plan (DMP).
- Continuously disseminate and communicate the project and its results to clinical, research and industrial stakeholders, as well as to the wider public.
- Organise scientific workshops and other outreach events throughout the duration of the project.
- Create synergies with other initiatives in the field of radiomics, AI and/or breast cancer.

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Our Consortium



The RadioVal consortium is a highly experienced and ambitious consortium with a unique blend of assets and expertise uniquely suited to achieve the ambitious objective of a first multi-faceted international validation study in the field of radiomics.

The RadioVal consortium is, first of all, an alliance of 5 European projects (EuCanImage, CHAIMELEON, INCISIVE, TCIA and PRIMAGE) represented by their coordinators, as well as by additional members of these projects. These partners cover a lot of the expertise needed in this project, such as breast cancer care, big data in cancer imaging and FAIR data management, radiomics AI, machine learning in breast cancer, in-silico validation, and dissemination and communication in biomedical imaging.

To complete the consortium, 6 additional clinical centres join to form a highly diverse international clinical network, covering Southern, Northern, Central-Western and Eastern Europe, South America, Eurasia and North Africa.

Furthermore, the consortium is reinforced by NHG, a European expert on value-based care, cost-effectiveness analysis and regulatory aspects, especially for emerging digital services.

Last but not least, SHINE 2Europe completes the consortium as a major European expert in social innovation and participatory democracy.

The participation of Hacettepe University, the Alexander Fleming Institute and Ain Shams University, as representatives of low-to-middle income countries from Eurasia, North Africa and Asia, will demonstrate radiomics scalability and transferability like never before. This promotes diversity and inclusion in AI for healthcare, in particular for women's health, and inspires best practices to ensure future AI solutions can benefit all the human population well beyond high-income countries.



Spain	Greece	
University of Barcelona (project coordinator)	FORTH	
Quibim	Italy	
University Hospital La Fe	Maggioli	Manage consent
Argentina	Netherlands	
Alexander Fleming Institute	Maastricht University	
Austria	Poland	
Medical University of Vienna	Medical University Gdansk	
European Institute for Biomedical Imaging Research	Portugal	
Croatia	Shine 2Europe	
University of Zagreb	Sweden	
Egypt	Karolinska Institute	
Ain Shams University	Turkey	
Finland	Hacettepe University	

Nordic Healthcare Group

Click on each partner to found our more about their role in RadioVal and their expertise.

The RadioVal consortium comprises a wealth of expert leaders and established scholars.

Philippe Lambin (Maastricht University) is the inventor of the radiomics concept in 2012, an Advanced ERC grant winner and a highly cited author (>47,000 in Google Scholar).

Pascal Baltzer is a member of the Executive Board of the European Society of Breast Imaging (EUSOBI), Editor-in-Chief of the European Journal of Radiology and co-author of the EUSOBI recommendations for women's information in breast MRI.

D. Fotiadis (FORTH) is a pioneer in in silico trials and a highly cited scholar in the field (>18,000 citations).

Karim Lekadir (University of Barcelona) is the coordinator of the EuCanImage project, General Chair of the 27th MICCAI Conference (Medical Image Computing & Medical Image Computing) and Director of the DA TAETHICS Summer School: "Big Data, Big Implications: The Ethics of Artificial Intelligence in Biomedicine".

Fredrik Strand (Karolinska Institute) is the principal investigator of MammoAI, a Swedish study aiming to improve breast cancer screening by applying deep learning to mammographic images, as well as the Cohort of Screen-Aged Women, a multi-million breast image dataset and population-based screening cohort in breast cancer.

Angel Alberich is co-founder of Quibim, one of the most active European SMEs in the field of cancer image analytics and radiomics, and a Young-Innovator-Under-35 from Massachusetts Institute of Technology.

Carina Dantas (SHINE 2Europe) has more than 20 years' experience working in health and social care. She is Vice-President of the European Covenant on Demographic Change and Member of the Standing Committee of Policy and Advocacy in the International Health Literacy Association.

Other members such as D. Meyers (Alexander Fleming Institute), current President of the Argentinian Society of Radiology, Boris Brkljacic (University of Zagreb), past President of the European Society of Radiology, and W. Tantawy (Alexander Fleming Institute), Board Member of the Egyptian Society of Radiology and Nuclear Medicine, further illustrate the experience and leadership that is consistently available in all sites to successfully drive the proposed validation study.

RadioVal as access to the most advanced infrastructures that will help implement the project efficiently and successfully.

For example, the University of Barcelona has full access to a MareNostrum Supercomputer (Main cluster with 3,456 48-core nodes and 11.15 Pflops of performance, and the CTE-Power cluster with 52 20-core and 512 GB RAM).

QUIBIM has developed Precision®, an interoperable cloud platform for high-throughput data analytics in medical imaging, which is ISO13485

certified and holds CE mark.

Maastricht University manages three well-established web-portals in the field of cancer radiomics (radiomics.world and predictcancer.org, which will be leveraged for dissemination and communication activities.

FORTH has its own private cloud infrastructure with an aggregate of 128 CPU cores and 1 TB of RAM.

The University Hospital La Fe has a dedicated MRI Research Unit for clinical trials and clinical research projects with patients, including modern 3T MR scanners (Philips Achieva TX, multi-transmission). The Medical University of Gdanks has two different breast MRI scanning systems (Magnetom Aera by Siemens and Achieva TX by Philips) and the Medical University of Vienna has two types of Siemens MRI systems, Prisma with multi-sequence interventional capability and Avanto for performing MRI-guided biopsies.

Our international clinical partners have access to a range of MRI scanners with dedicated breast coils (1.5T Signa General Electric and 1.5T Ingenia by Philips), which will enable to validate the tool's robustness and scalability under different imaging equipment and conditions.

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The University of Barcelona (UB) is one of the oldest universities in Spain and the largest university in Catalonia. It has over 60,000 students and 5,000 researchers, as well as 340 graduate and 48 doctorate programs in 16 faculties (including mathematics, informatics, medicine and biology). UB is particularly interested in fostering international relations and, for many years, has managed an average of 150 European projects per year. This project will be carried out by the research team of the Artificial Intelligence in Medicine Laboratory of the University (BCN-AIM), which is an essential part of the Department of Mathematics and Computer Science. The research team has an established track record in coordination and participation in national, European and international projects on data science and AI (such as EuCanImage, euCanSHare, EarlyCause, LONGITOOLS, DataTools4Heart).

UB In RadioVal

The University of Barcelona (UB) is the Project Coordinator of RadioVal, while also leads the preliminary evaluation and calibration of the tool in WP4 and contributes to the elaboration of a multifaceted evaluation framework in WP2. UB also participates to the design and implementation of the tools for continuous evaluation, monitoring and traceability within WP3.

Dr. Karim Lekadir

Dr. Karim Lekadir is a Senior/Tenure Track Researcher at the University of Barcelona and coordinator of RadioVal. He holds a Master's Degree in Computer Science from the University of Montpellier II (France) and a PhD in Medical Image Computing from Imperial College London (UK). He was also previously a Visiting Scholar at Stanford University (USA). He was the recipient of a Marie-Curie research fellowship awarded by the European Commission and a Juan de la Cierva postdoctoral fellowship funded by the Spanish Ministry of Science and Innovation. He participated in several EU-funded projects in the field of medical imaging and computational biomedicine. His software, developed during his PhD studies for cardiac functional quantication, has been CE marked and commercialised by CMR tools, and is now used in more than 250 clinical centres worldwide.

His current research focuses on the development of data science and machine learning approaches for the analysis of large-scale biomedical data, including medical images, radiomics and non-imaging data. He is currently coordinating the H2020 euCanSHare, EuCanImage, the Horizon Europe DataTools4Heart, in addition to RadioVal and he is WP Leader in LONGITOOLS. He recently was granted the ERC Consolidator Grant to work on AIMIX, to develop inclusive Articial Intelligence for accessible medical imaging across resource-limited settings.



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Dr. Oliver Diaz

Dr. Oliver Diaz is an Assistant Professor at UB and the co-coordinator of RadioVal. He holds a Ph.D. in Medical Imaging/Physics from the Centre for Vision, Speech, and Signal Processing at the University of Surrey (UK). With the support of Cancer Research UK, he developed breast image simulation tools currently used to support Virtual Clinical Trials in the UK (OPTIMAM). He is also a visiting academic researcher at the University of Surrey (UK) and the Institute for Research and Innovation Parc Taulí (Spain). Currently he is member of several EU and American working groups such as EFOMP Working Group on Artificial Intelligence; AAPM/EFOMP task group No. 282; and EFOMP Working Group on Digital Breast Tomosynthesis quality control. Dr. Diaz has over 10 years of international research experience and was awarded with a prestigious EU Marie Slodowska-Curie Postdoctoral Fellowship in 2015. He has participated in 10 medical imaging research projects funded by the EU (ASSURE, SCARtool as PI), UK (OPTIMAM 1 & 2) and the Spanish government (SMARTER, ICEBERG). His scientific production includes over 50 scientific publications among high-impact JCR journals (12) and conferences, receiving 315 citations . His h-index is 9 (source: Google Scholar).

Anais Emelie

Anais Emelie is the Project Manager of RadioVal. She holds a Master's degree in Applied Bioengineering from the University of Washington. Additionally to being a Project Manager for the BCN-AIM group at the University of Barcelona and for RadioVal, she also manages EuCanImage, a Horizon 2020 project which seeks to build a secure, large-scale European cancer imaging platform that will advance the application of artificial intelligence (AI) in oncology. She is also part of the organising committee for MICCAI 2024.





Smriti Joshi

Smriti Joshi, first-year doctoral student at University of Barcelona and AI lead of RadioVal, received master's degree with distinction in Image Processing and Computer Vision, jointly coordinated by the Autonomous University of Madrid (Spain), University of Bordeaux (France), and Pázmány Péter Catholic University (Hungary), funded with Erasmus Mundus scholarship. She wrote her Master Thesis at the Visual Computing Group at Harvard University (USA). Before this, she received an Integrated Master's degree in Physics from Birla Institute of Technology and Science, Pilani (India) with the master thesis written at the "Laboratoire de Recherche Xlim" (CNRS 7252) (France). Her current research focuses on developing fair and robust methods for breast cancer treatment planning using machine learning and deep learning-based methods. Her past research themes include domain adaptation and segmentation for biomedical

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Get in touch

If you have questions about the project or would like to receive more in-depth information, don't hesitate to get in touch with us!

You can contact us through our Twitter and LinkedIn pages, or send us an email at radioval@eibir.org.

During office hours you cal also call +43-1-533-4064-323 to get in touch with our communication and dissemination manager.

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