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An Implementation Roadmap to Accelerate Academic Clinical Cancer Research in Portugal: A Multistakeholder Perspective

Um Roteiro para Acelerar a Investigação Clínica Académica em Oncologia em Portugal: Uma Perspectiva Multistakeholder

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INTRODUCTION

Cancer care has progressed remarkably in recent years with the approval of innovative therapies, primarily developed through industry-led clinical trials to support regulatory decisions. While these advancements have significantly improved treatment standards, newly approved medicines often have evidence gaps, particularly regarding real-world effectiveness, optimal treatment sequences, treatment combinations, and de-escalation strategies.[1] Additionally, the rising incidence and prevalence of cancer, along with the substantial cost of new treatments, challenge the financial sustainability of healthcare systems.[2]

Academic clinical research in oncology constitutes a fundamental link between scientific discovery and clinical practice, addressing knowledge gaps by prioritizing clinically and patient-relevant questions. It fosters the generation of actionable evidence to inform practice, potentially improving resource allocation and benefiting patients. Achieving a balanced integration of commercial and non-commercial research is essential for advancing cancer care.[1]

Despite increasing recognition of investigator-led studies, academic research in Portugal has experienced limited growth. Over the past decade, academic trials have consistently accounted for less than 10% of all approved clinical trials,[3] compared to 20% - 45% in other European Union member states.[4] As oncology comprises approximately one-third of all approved trials annually in Portugal,[3] there is a significant opportunity to strengthen academic research in this field, potentially leading to high-impact clinical, economic, and societal gains.

The existing literature has identified several barriers to academic research in Portugal, including limited financial investment, inadequate technical support, and insufficient protected time for research.[5,6] Nevertheless, there is still no systematic identification of barriers and facilitators specific to oncology, particularly in research on solid tumors. This gap highlights the need for a collaborative, multistakeholder

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approach and a comprehensive roadmap that targets clinical, organizational, and policy levels to accelerate academic cancer research in Portugal. Implementation science, which bridges the gap between knowledge and practice, may be instrumental in systematically mapping challenges and guiding structured actions to foster progress.[7]

At the 2024 National Congress of the Portuguese Society of Oncology, a multistakeholder session was convened with two main objectives: 1) to systematically identify barriers and facilitators to advancing academic clinical cancer research in Portugal, from a multilevel and multisectoral perspective, 2) to propose strategies, while fostering national collaboration. An iterative, implementation science-based approach was employed to develop a roadmap [Fig.1 and Appendix 1 (Appendix 1: https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/23479/15855)]. This article presents the outcomes of this collaborative initiative, outlining concrete actions for relevant national actors.

Section 1: Barriers and facilitators to advance academic clinical cancer research in Portugal

Barriers and facilitators were categorized following the constructs of the 'Tailored Implementation for Chronic Diseases' (TICD) checklist,[8] which comprises social, political, and legal factors; organizational change capacity; incentives and resources; professional interactions; patient factors; practice/clinical trials factors; and individual health professional factors (Appendix 2: https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/23479/15856).

Among social, political, and legal factors, key barriers identified included the insufficient prioritization of academic trials, the lack of funding opportunities, and lengthy assessment timelines from national regulatory agencies. In contrast, the existence of a national healthcare system with broad population coverage was seen as a major enabler.

Regarding incentives and resources, the lack of dedicated research time and insufficient technical support were perceived as the main barriers. Concerning professional interactions, limited engagement within the Portuguese network and with international counterparts was considered a significant barrier.

At the patient level, limited engagement and restricted access to information were perceived as key barriers. At the health professional level, a major barrier was the lack of recognition of the value of academic research, insufficient recognition of scientific achievements (such as publications), and insufficient experience and guidance. As key enablers, training and guidance by regulatory agencies were highlighted. At practice/clinical trial level, narrow eligibility criteria and the requirement for large sample sizes were emphasized as relevant barriers.

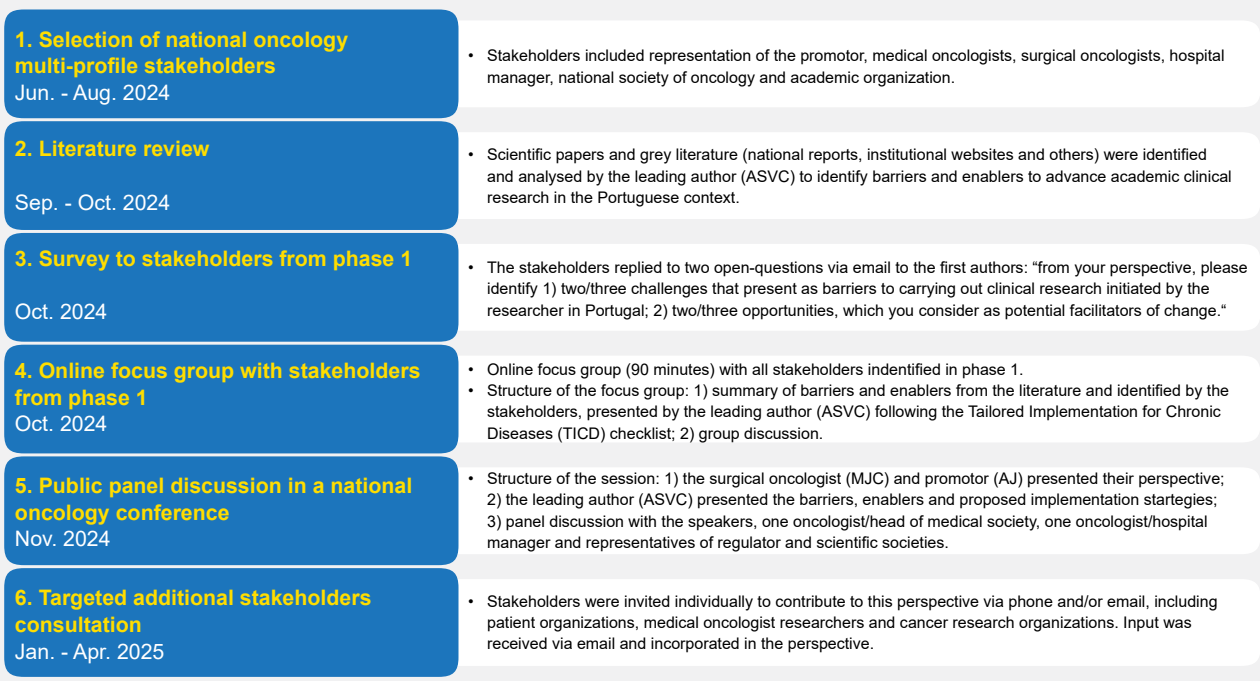

Figure 1 – Phases of the collaborative development of an implementation roadmap to accelerate academic clinical cancer research in Portugal

Section 2: A collaboratively developed implementation roadmap

Drawing on the barriers and enablers identified, the multistakeholder group developed a roadmap towards implementation (Table 1). Stakeholders responsible for action were categorized according to the three health system levels – policy, organizational and clinical –, thus answering the question "who should do what?".

Table 1 – Proposed implementation strategies by key actors at the Portuguese cancer care ecosystem (part 1 of 2)

Governmental bodies: Ministries of Health, Finances, Economy, Science, Education and Innovation	
Political commitment and leadership	- Secure multisectoral governmental commitment to prioritise and fund structured cancer clinical research, recognising its short-, medium-, and long-term economic benefits, e.g. leveraging the recently created National Innovation Agency ("Agência Nacional da Inovação"), considering the development of targeted national strategies to foster academic clinical research in the cancer field. - Integrate cancer clinical research as a core component of oncology practice, with national-level investment to embed clinical trials into routine care. - Promote legislation to encourage private donations to research through fiscal incentives and tax benefits.
Legislation	- Promote the creation of clinical trial support units in reference centres to assist researchers from trial planning to completion, including grant application support. - Enhance career attractiveness and stability for professionals in research through fair financial compensation and growth opportunities to support long-term retention. - Promote the recruitment of clinician-scientists with dedicated time for cancer research. - Promote the concentration of research expertise in selected centres, ensuring patient access through integrated cancer care and research networks. - Ensure the streamlined and consistent application of current and future legislation and regulations, preventing unnecessary bureaucratic burden.
Funding	- Invest in national and international funding for cancer clinical trials focusing on patient-centred research and pragmatic designs, through the appropriate funding agencies for this domain and fostering the generation of high-quality real-world data. - Invest in cancer clinical research by providing dedicated funding to clinical research centres, ensuring financial autonomy for research units separate from direct care delivery. - Establish mechanisms to provide organizations with technical research support. - Foster collaboration between governmental bodies and private sector to leverage funding, resources, and expertise for cancer clinical research initiatives.
Advisory, regulatory and funding agencies with a role in research	
Prioritise necessary changes, communication, and influence	- Promote funding opportunities for cancer clinical research. - Develop strategic partnerships with foundations, academic institutions, and non-governmental organizations to increase funding for academic cancer research. - Invest in national funding to improve compensation for research sites and patients. - Ensure the streamlined and consistent application of regulations, while preventing unnecessary bureaucratic burden. - Develop and monitor indicators related to the number of academic-led clinical trials. - Encourage and guide organizations in monitoring the percentage of cancer patients with access to clinical trials at national, regional, and local levels.
Domain knowledge, awareness, skills	- Encourage the integration of clinical trials into standard cancer care by raising awareness and developing dedicated cancer guidelines. - Promote the simplification of bureaucratic processes to enhance the efficiency of clinical trial assessments. - Develop standardised submission documents, such as protocol and informed consent templates, to streamline preparatory steps and assessment. - Support organizations in building technical cancer research teams and providing logistical support for large projects, including consortia and public-private partnerships. - Establish mechanisms to ensure researchers have seamless access to information and the opportunity to clarify inquiries regarding clinical trial development.
Portuguese Medical Association and Medical Colleges of cancer-related specialties	
Training, regulation and support	- Encourage the training of medical oncologists and cancer-related specialists in clinical research by ensuring that dedicated research training periods are preserved and monitored. - Consider establishing protocols with national and international organizations with capacity to offer research training and internships.

Table 1 – Proposed implementation strategies by key actors at the Portuguese cancer care ecosystem (part 2 of 2)

Medical and scientific societies related to cancer, including the Portuguese Society of Oncology	
Awareness and skills of professionals and availability of resources	- Ensure the regular update of a web platform centralising all cancer clinical trials in Portugal, notably the recently launched platform 'Portugal Clinical Studies'. - Raise awareness among cancer-related healthcare professionals about the importance of regularly consulting available platforms to determine if their patients are eligible to participate in clinical trials. - Develop training programs focused on clinical cancer research. - Contribute to the establishment of national networks for cancer-related healthcare professionals, potentially linked with international networks, to foster collaboration and research.
Hospital Management Boards, Clinical Directors and Heads of Oncology Departments	
Attitudes, awareness and skills of health professionals	- Develop and support initiatives to enhance awareness of the potential of academic research, notably highlighting the importance of embedding clinical trials into standard cancer care, instead of considering them as a last resource for patients. Initiatives should also include training programs and forums for discussion between clinicians and translational researchers. - Invest in well-resourced clinical trial support units, prioritising expertise in cancer clinical research, to provide targeted guidance and assistance with funding acquisition. - Acknowledge and promote the value of participating in international cancer research networks.
Communication, influence and referral processes	- Prioritise academic cancer research, by ensuring expedited contract resolution and facilitating financial approval of in-clinical trial standard of care procedures. - Establish partnerships with universities capable of supporting research activities, including statistical advice, project initiation, and management. - Establish and develop intra- and inter-organisational networks. - Develop strategic partnerships with foundations and academic institutions to enhance funding availability for academic cancer research. - Establish patient advisory boards to better identify unmet needs. - Monitor the proportion of cancer patients, by cancer type, with access to clinical trials throughout their care pathway, and benchmark with other cancer centres and registries.
Patients and patient representatives	
Patient needs, beliefs and knowledge	- Collaborate with clinical trials support units to ensure patient involvement from the outset of projects. - Contribute to setting research priorities by identifying unmet patient needs and patient-relevant outcomes. - Contribute to study design, synopses, informed consent, and patient information documentation. - Participate in trial steering committees to provide patient perspectives on trial conduct. - Invest in dissemination strategies and educational materials to raise awareness and literacy on clinical trials among the general population and cancer patients.
Healthcare professionals involved in cancer care	
Attitudes, awareness and skills	- Acknowledge the value of academic cancer research. - Develop and support initiatives to enhance knowledge and awareness, such as training sessions. - Develop educational materials for the population, in collaboration with patients. - Contribute to enhancing cancer patients' health literacy regarding clinical trial participation.
Communication and influence	- Contribute to the establishment of national collaborative networks for cancer patient referrals. - Actively engage in international collaborative networks. - Create coalitions of multi-level cancer stakeholders to discuss and formulate long-term proposals for increasing knowledge and awareness. -Persuade decision-makers to prioritise cancer clinical research, highlighting its role in advancing standard care, prioritising patient well-being, and implementing cost-effective interventions.

At the policy level, multisectoral prioritization and investment in academic cancer research are critical to strengthening both short- and long-term resilience in cancer care, improving patient outcomes, and ensuring the sustainability of the healthcare system. Notably, academic research should be recognized and regulated as part of standard clinical cancer practice, supported by well-resourced "clinical trial support units" with expertise in trial design and biostatistics, potentially centralized and connected through coordinated cancer care and research networks. Advisory, regulatory, and funding agencies play a vital role in raising awareness, providing resources, and supporting healthcare professionals in operationalizing academic cancer trials.

At the organizational level, hospital managers, clinical directors and cancer unit heads should strengthen engagement in intra- and inter-organizational networks, as well

as in international collaborative counterparts. Another key strategy is the development and sustained implementation of initiatives to enhance professionals' knowledge and awareness. In addition, a more proactive and efficient approach to trial set-up at the organizational level, along with sound resource allocation decisions, should be actively encouraged.

At the clinical level, patient involvement, either through advocates or organizations, should be strengthened. Patient representatives should be highly engaged in all research stages to raise awareness, promote interest and participation, and ensure patient-centered cancer research. Health professionals involved in cancer care should value academic research as a tool to improve care and outcomes, while contributing to peer and patient education efforts.

CONCLUSION

The optimal use of newly emerged cancer treatments is often poorly documented, leaving clinically relevant questions unanswered. This challenges the financial sustainability of healthcare systems and hinders progress towards more patient-centered cancer care. These questions are often not of commercial interest, thus unlikely to be answered by the commercial sector. In this context, it is incumbent on society to develop solutions to optimize cancer management and treatment. This article includes the perspectives of patient representatives, clinicians, hospital managers, medical and scientific societies, and public health specialists, using an implementation science lens. We showcase the challenges to overcome, the facilitators to leverage, and propose a roadmap to accelerate academic cancer research in Portugal. While we aimed to be inclusive, we were unable to gather input from all relevant stakeholders. Given the critical importance of collaboration, it is imperative to continue strengthening awareness among national stakeholders involved in cancer care regulation and delivery.

We conclude that independent clinical cancer research must be prioritized at policy, organizational and clinical levels in Portugal, to bridge the evidence-gap in pre- and post-approval settings focused on patient needs. This should be underpinned by increased, consistent and predictable public financial investment to ensure embedding of clinical trials into routine cancer care, stronger national and international multistakeholder collaboration, enhanced patient involvement, and greater training and technical support for healthcare professionals. Despite initial investment, patient-centered research may prove cost-saving in the medium to long term. Good practices from other European countries could serve as inspiration for these efforts,[9] adapted to the national context. Furthermore, efforts to increase patients' and society's health literacy regarding cancer clinical trials are crucial. Portuguese cancer-related patient organizations are willing to be more frequently engaged in various steps of research and development efforts and are also particularly motivated to ensure that cancer research is better aligned with patients' needs.[10]

Improving public investment, awareness among healthcare professionals and patients, collaboration with patient organizations, and access to cancer clinical trials are critical levers to enhance the competitiveness of the Portuguese national health system. While not emphasized in the stakeholder discussions, factors such as improvements in health data infrastructure for secondary use and the strategic use of artificial intelligence tools have the potential to drive innovation in clinical trials and enhance overall health system performance. Recent initiatives, such as the integration of artificial intelligence in the recently launched "Portugal Clinical Studies" platform represent promising steps in this direction. These combined efforts may yield measurable health and economic benefits for the Portuguese society.

PREVIOUS AWARDS AND PRESENTATIONS

This work has not been fully presented or published elsewhere. Portions of its content were shared at the 2024 Portuguese Society of Oncology's Congress (session: "Clinical research in Portugal: challenges and opportunities"), providing a foundation for multistakeholder input that shaped this final manuscript.

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AUTHOR CONTRIBUTIONS

ASVC, FCB, JLPC: Conceptualization; visualization; writing – original draft; writing – review & editing.

MJC, JO, SC, LC, IF, DG, MG, TM, SR, MS, CS, NS: Validation; writing – review & editing.

JPS, AJ: Conceptualization; visualization; validation; writing – review & editing.

All authors approved the final version to be published.

CONFLICTS OF INTEREST

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JO serves on the Board of the Organisation of European Cancer Institutes.

JPS has received consulting fees from INFARMED I.P.; received honoraria from the Association of Integrative Medicine (AIM).

IF serves on the Board of the National Program for Oncological Diseases; received consulting fees from INFARMED I.P.

TM has received honoraria from Illumina and is on boards for the National Cancer Hub Portugal and ePAG ERN GENTURIS.

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NS serves on the boards of the Portuguese Association for Cancer Research (AICIB) and the P5 Clinical Digital Center; is Chief Medical Officer for Pathena; formerly served on the board of 2CA – Centro Clínico Académico de Braga.

All other authors have no conflicts of interest to declare.

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