Building a Clinical Research Hub in Portugal: The GIMM CARE Model

Policy Brief

Version 1.0 January 2026

GIMM CARE

Funded by the European Union

GIMM Gulbenkian Institute for Molecular Medicine

Executive Summary

Portugal's healthcare and scientific ecosystem is poised to strengthen its position as a regional leader in clinical and translational research. The GIMM CARE initiative proposes a scalable, multi-centric operating model that connects hospitals, universities, and industry partners to foster innovation, accelerate clinical trials, and improve patient access to cutting-edge therapies. This *policy brief* outlines the strategic context, operational framework and implementation roadmap necessary to establish GIMM CARE Clinical Research Hub as a national and international reference model for clinical research management.

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DOI: 10.5281/zenodo.18352446

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1. Background and Rationale

As described in the 2025 working policy paper *"The Health Ecosystem, Value Creation, and the Impact on the Economy"* presented by Fórum Saúde XXI[1], healthcare in Portugal transcends a traditional role of providing clinical care, positioned as a strategic system for sustainable development, social cohesion, and economic value. The contribution of clinical research to this system is evident, translating scientific innovation into practice, filling evidence gaps and enabling timely prioritization of resources. Nationally, clinical research – both commercial and academic - remains a key underexploited economic and scientific opportunity. Despite possessing world-class hospitals, academic capacity and willing champions[2], the country is lacking in mechanisms to promote clinical research and underperforms relative to peers in the

[1] O Ecossistema da Saúde, a Criação de Valor e o Impacto na Economia. (2025) Fórum Saúde XXI https://forumsaudexxi.pt/wp-content/uploads/2025/10/MKTV_FSXXI_Working-Policy-Paper_16-09-2025.pdf

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number and volume of clinical trials[3][4]. Closing this gap could yield substantial socioeconomic returns, combining revenue, cost-savings, clinical skills, and staff satisfaction[5].

2. Global Context and Opportunities for Portugal

Clinical trials operations globally are facing a paradigm shift characterized by increased trial complexity, longer enrollment times, and a concentration of recruitment sites in limited geographies. Europe's comparative lag in agility and trial registration growth compared to regions such as East Asia[6] and the Americas underscores the need for new operating models that combine simplified regulatory processes, rapid ethics approvals efficiency, scale, and integrated digital infrastructures[7][8].

Portugal's opportunity lies in aligning policy, infrastructure, and human resources to attract and retain global trials while advancing its own public health priorities. With a heterogenous population and the appropriate scale, Portugal holds unique potential as a "lab for the world", creating solutions that can be tested in Portugal and applied globally. Our own investigations, plus key insights from recent projects led by the Portuguese Association for the Pharmaceutical Industry (Apifarma)[9], the Agency for Clinical Research and Biomedical Innovation (AICIB)[10], and the Policy Group of the National Cancer Hub[11] indicate that strategic improvements are required across three key dimensions: (1) Quality — ensuring GCP-compliant facilities and standard operating procedures; (2) Agility — accelerating approval and contracting mechanisms; including, but not limited to, integrated information systems (digital transformation); (3) Investment — securing sustainable funding and human resource management. These pillars are essential to develop a competitive, innovation-driven research ecosystem.

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[3] Borges-Carneiro, F., Torre Souto, M., Silva, I., Leão Moreira, P., Ferraz de Oliveira, P., Lopes, D. J., Figueira, L., Reina-Couto, M., Cunha-Miranda, L., Ponces Bento, D., & Magro, F. (2024). Clinical Trials in Portugal: Past and Future. Position Paper from the Colleges of Clinical Pharmacology and Pharmaceutical Medicine. *Acta Médica Portuguesa, 37*(9), 585–588. https://doi.org/10.20344/amp.21371

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[5] European Federation of Pharmaceutical Industries and Associations, & IQVIA. (2024). Assessing the clinical trial ecosystem in Europe: Final report (October 2024). EFPIA. URL: https://www.efpia.eu/media/oipkatpg/efpia-ct-report-embargoed-221024-final.pdf

[6] World Health Organization: Number of clinical trials by year, country, WHO region and income group (1999-2024). https://www.who.int/observatories/global-observatory-on-health-research-and-development/monitoring/number-of-clinical-trials-by-year-country-who-region-and-income-group

[7] European Federation of Pharmaceutical Industries and Associations, & IQVIA. (2024). Assessing the clinical trial ecosystem in Europe: Final report (October 2024). EFPIA. URL: https://www.efpia.eu/media/oipkatpg/efpia-ct-report-embargoed-221024-final.pdf

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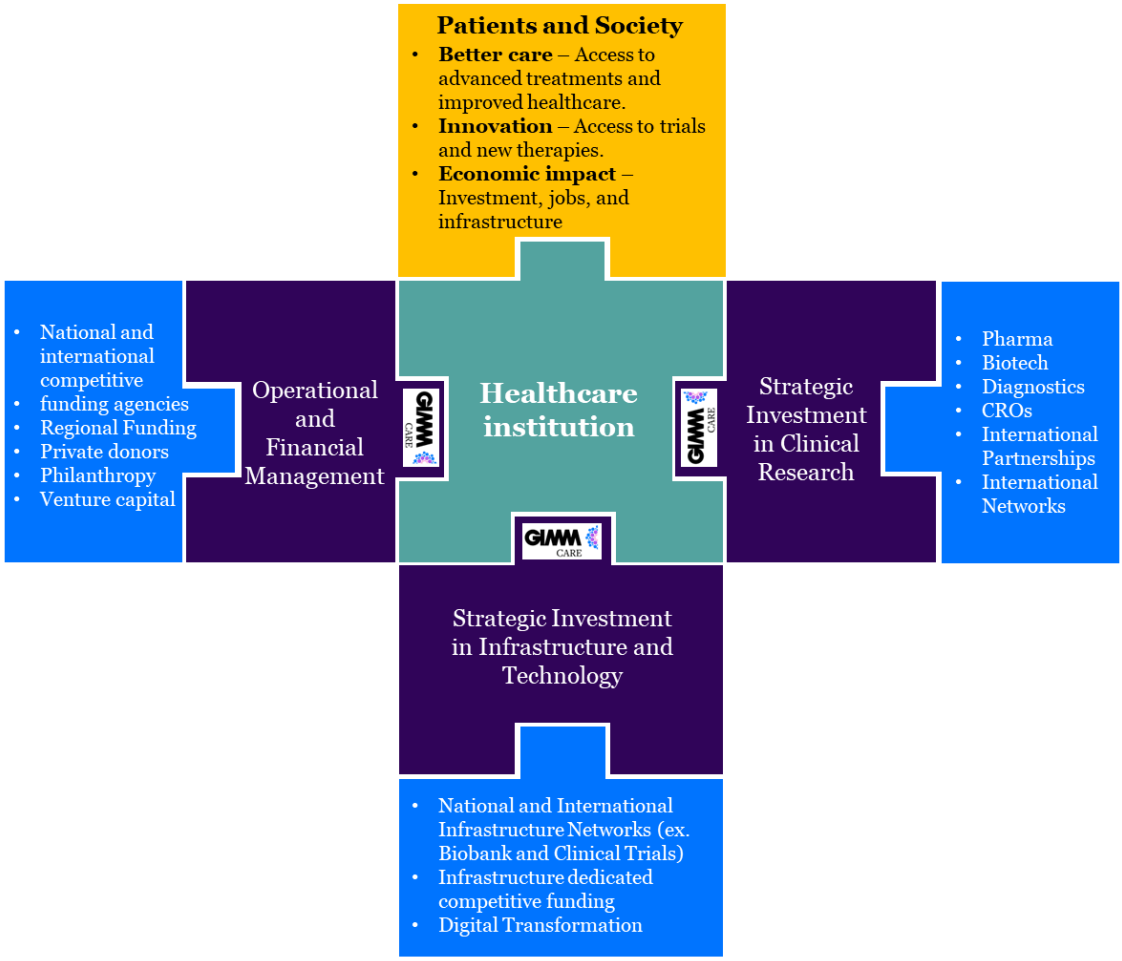
[11] A Investigação Clínica e a Inovação Biomédica em cancro em Portugal Posição conjunta dos elementos do Policy Group do National Cancer Hub; URL: https://aicib.pt/wp-content/uploads/2023/05/Posicao-conjunta_Cancro.pdf

3. The GIMM CARE Model

GIMM CARE seeks to operationalize a **multi-centric clinical research hub** anchored within public and private health institutions and supported by the scientific excellence of the Gulbenkian Institute for Molecular Medicine (GIMM)[12]. The model integrates healthcare, academia, regional authorities, and industry partners within a collaborative governance structure designed for agility and scalability.

Its operating philosophy follows a **'Lego® model'** (Figure 1) - attaching a complementary structure to existing health units, while preserving institutional autonomy. This modular approach strengthens performance across key domains: diversified funding, strategic investment in clinical research, digital transformation, and robust operational management, securing long-term sustainability for both organizations by aligning resources, expertise, and growth opportunities.



[12] Gulbenkian Institute for Molecular Medicine (GIMM). https://gimm.pt/

Figure 1. The GIMM CARE "Lego® model". Attaching a complementary structure to the central healthcare institution preserves each organization's independence while enhancing performance in key areas: diversified funding, strategic clinical research, advanced infrastructure and technology and strong operational management. CRO = Contract Research Organization.

The model's initial investment focus is 4-fold, providing the foundations for capacity building and sustainable growth: **People and Management** (recruitment, retention, professionalized management spanning the operations-coordination spectrum); **Training** (via an open platform for healthcare professionals, promoting investigator-led trials); **Infrastructure** (strengthening logistical and technological capabilities with modern facilities dependent on identified gaps; and **Synergies** (collaboration with state-of-the-art scientific platforms). This approach ensures that Portugal's scientific excellence translates into clinical innovation, benefiting patients, professionals, and the national health system alike.

4. Governance and Implementation

GIMM CARE Hubs will adopt a consortium structure inspired by academic clinical centers (*centros académicos clínicos, CACs*). Governance will be ensured by a small executive board — comprising representatives from the GIMM Foundation, University partners, and the host hospital/healthcare institution— supported by a Scientific Council for oversight and quality assurance. This streamlined model allows rapid decision-making while ensuring compliance with ethical and legal frameworks.

The implementation roadmap includes three key stages: (1) **Memorandum of Understanding** and capability assessment; (2) **Contract** signing and project kick-off; and (3) **International benchmarking visits** to reference centers such as the German Cancer Research Centre[13] (Gustave Roussy (Paris)[14], Rigshospitalet (Copenhagen)[15], MD Anderson (Texas)[16], the Victorian Comprehensive Cancer Center (Melbourne)[17] and the Vall D'Hebron Research Institute (Barcelona), a major "Prime site" with positive trends in trial delivery[18]. These exchanges will guide the refinement of operational procedures and foster long-term international partnerships. Throughout implementation, strategic

[13] German Cancer Research Center https://www.dkfz.de/
[14] Gustave Roussy https://www.gustaveroussy.fr/en/institute
[15] Rigshospitalet https://www.rigshospitalet.dk/
[16] MD Anderson https://www.mdanderson.org/
[17] Victorian Comprehensive Cancer Center Melbourne https://vcccalliance.org.au/
[18] Vall d'Hebron https://vhir.vallhebron.com/en/clinical-trials

alignment is essential between the actions needed and the **best-suited agent** from the consortium to execute each action.

Considering the broader picture, it will also be important to design a **"ready to scale" operation** and consequently ensure the efficient use of resources and investment. In the mid-term, both centralized and decentralized/local investments will be necessary in three key areas: (1) dedicated specialized staff; (2) regulatory compliance; and (3) data management, with the level and ownership of investment in each area determined on a consortium-by-consortium basis, together with a commitment to harmonization and a common quality threshold. Future directions should be towards a **connected, decentralized investment model** so that multiple sites can scale together, strengthening clinical research through robust design, funding, recruitment, and compliance, while creating a multi-centric hub that expands capacity, drives efficiency, and ensures high-quality outcomes.

5. Long-Term Vision and Actionable Recommendations

The GIMM CARE vision extends toward establishing a national network of interconnected research hubs across mainland Portugal, Madeira, and the Azores. This unified system would harmonize processes, strengthen compliance, and leverage population diversity to generate robust clinical evidence. Such a framework would position Portugal as a global partner in both industry-sponsored and investigator-initiated trials. To realize this vision, and in line with several recommendations from the 2024 Draghi report towards closing the innovation gap[19], **named stakeholders should**:

a) Establish a Dedicated Competitive Funding Stream for Clinical Research Capacity

Action: Prioritize a **Clinical Research Capacity Fund** offering multi-year competitive grants for research infrastructure, governance modernization, and network integration, making use of evaluation matrices tailored to clinical research (i.e. not equal to those used to assess fundamental research which is not directly comparable).

Lead Agents: Agência de Investigação e Inovação (AI²); Ministry of Science, Technology and Higher Education; Ministry of Health; Regional Governments; Philanthropists.

Outcome: Increased attractiveness of the EU for conducting research; stable and predictable funding pipeline enabling institutions to invest in human capital and digital systems for clinical research; reduced

[19] European Commission: European Political Strategy Centre, *The future of European competitiveness. Part A, A competitiveness strategy for Europe*, Publications Office of the European Union, 2025, https://data.europa.eu/doi/10.2872/9356120

reliance on EU Widening funding for capacity-building (Portugal is foreseen to part of its access to this funding stream post-2023, which has been instrumental for expanding R&I institutions capacity).

b) Enable Public–Private Partnership (PPP) Frameworks for Research Hubs

Action: Adopt PPP legal models (similar to EIT Health and IPCEI - Important Projects of Common European Interest - frameworks) allowing private-sector co-creation, co-funding and shared management of clinical research hubs.

Lead Agents: Ministry of Science, Technology and Higher Education; Ministry of Economy; AICIB; Associação Portuguesa da Indústria Farmacêutica (APIFARMA); Pharma Industry; Research Institutes.

Outcome: More responsive management structures capable of executing high-quality, industry-relevant studies.

c) Streamline Ethics and Contract Approval Across the Network

Action: Reduce administrative burden and increase flexibility with regards to Ethics Committee contracting, reporting requirements and management, not excluding the introduction of basic remuneration for this essential and time-consuming work. Provide improved digital support tools.

Lead Agents: Ministry of Health; Directorate-General of Health; National Ethics Committee for Clinical Research (CEIC); INFARMED; Serviços Partilhados do Ministério da Saúde (SPMS).

Outcome: Shorter trial activation timelines, greater attractiveness for global sponsors.

d) Invest in Workforce Development and Professional Training

Action: Support timely accreditation of innovative, flexible and non-traditional Clinical Research Training Programs, co-developed by research institutes, universities and CROs, offering certified modules for investigators, study coordinators, and data managers. Open new calls to hire, educate, train and structure support human taskforce developing clinical research.

Lead Agents: Ministry of Science, Technology and Higher Education; Agência de Avaliação e Acreditação do Ensino Superior (A3ES); Professional associations; Hospitals; Research institutes.

Outcome: Expanded pool of skilled professionals and improved retention in the clinical research workforce; professionalized management of clinical research activity.

e) Protect Research Time for Clinician-Scientists

Action: Build on European level benchmarking efforts[20][21], national position papers[22] and emergent career-stage specific schemes[23], facilitate the incorporation of protected time for research time and performance incentives into employment frameworks funded through national and/or EU public instruments.

Lead Agents: Administração Central do Sistema de Saúde (ACSS); Ministry of Health; Directorate-General of Health; ULS; Hospitals; Research Institutes.

Outcome: Increased participation in clinical research activities; Improved retention of clinicians.

f) Accelerate Digital Health Integration and Stakeholder Access

Action: Deploy national digital solutions for patient recruitment, e-consent, and real-time monitoring, integrated with existing SPMS systems and compliant with EU AI and data protection regulations, including the European Health Data Space Regulation (EHDS)[24]. Develop shared academia–industry Infrastructure and data platforms, governed by public interest consortia ensuring FAIR data standards.

Lead Agents: SPMS; Agência para a Modernização Administrativa (AMA); DG CONNECT; Research Institutes and Universities; Industry associations (e.g., APIFARMA).

Outcome: Higher patient engagement; simple stratification to detect cross-stakeholder opportunities; efficiency in trial management; data transparency; seamless collaboration between academia and industry, accelerating translation of clinical research into innovation.

g) Systematically Showcase Portugal's Clinical Research Capabilities Globally

Action: Proactively collect data and success stories from key institutions conducting clinical research and create a coordinated outreach initiative showcasing the national network's capabilities to pharmaceutical headquarters and CROs.

Lead Agents: AICIB; Agência para o Investimento e Comércio Externo de Portugal (AICEP); APIFARMA; Research institutes; embassies and trade missions: Philanthropists.

Outcome: Enhanced international visibility and foreign investment attraction in the Portuguese research ecosystem.

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[20] European Commission: Directorate-General for Research and Innovation, *ERA monitoring 2024 – ERA scoreboard 2024 – Executive summary*, Publications Office of the European Union, 2025, https://data.europa.eu/doi/10.2777/9077105

[21] European Commission: Directorate-General for Research and Innovation, *Knowledge ecosystem – Defining a European competence framework for R&I talents*, Publications Office of the European Union, 2022, https://data.europa.eu/doi/10.2777/1117

[22] Investigator-Led Clinical Research in Portugal: Problem Identification and Proposals for Improvement Acta Med Port 2023 May;36(5):305-308 ▪ https://doi.org/10.20344/amp.19333.

[23] Faculdade de Medicina, Universidade de Lisboa.

[24] Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847. ELI: http://data.europa.eu/eli/reg/2025/327/oj

With strategic alignment and sustained investment, GIMM CARE Clinical Research Hubs can become a cornerstone of Portugal's expanding innovation ecosystem - connecting science, healthcare, and industry to deliver measurable impact for patients and society.

Acknowledgments

GIMM-CARE is funded by the European Union under grant agreement No. 101060102. CARE is co-funded by the Portuguese Government, the National Foundation for Science and Technology (FCT), ARICA – Investimentos, Participações e Gestão, Jerónimo Martins, the Gulbenkian Institute for Molecular Medicine and CAML - Lisbon Academic Medical Centre.

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Funded by the European Union