Fostering Oncology Research by Charities in Europe – FORCE

FORCE
CONSORTIUM

"Quality of life–integrated approaches to improve treatment of rare and/or hard-to-treat cancers through pragmatic clinical trials"

Call text

Submission deadlines:

Pre-proposals: 21 September 2026, 2pm CET

Full proposals: Early 2027

Electronic proposal submission system: https://appelsaprojets.fondation-arc.org/

For further information, please visit https://force4cancer.eu/

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1.Background

Rare and/or hard-to-treat cancers comprise a heterogeneous group of malignancies characterised by low incidence, biological complexity, limited therapeutic options, or persistent resistance to available treatments. In Europe, rare cancers are commonly defined as malignancies with an incidence of fewer than six cases per 100,000 persons per year, a threshold established by the RARECARE initiative to reflect the epidemiological and organisational challenges associated with low-frequency diseases[1]. Although individually uncommon, rare cancers collectively account for more than one in five cancer diagnoses in Europe, underscoring their substantial public health burden[2]. However, rarity alone does not capture the full spectrum of unmet need. Within European cancer policy frameworks, hard-to-treat cancers generally refer to malignancies for which current standards of care remain insufficient to achieve durable disease control. This may result from poor survival outcomes, including low long-term survival such as 5-year overall survival rates often below 50%, limited survival in advanced disease, or persistent disease progression despite treatment. They may also be characterised by situations where available therapies are associated with a substantial burden due to toxicity, long-term effects, or major impacts on quality of life. More broadly, cancers with aggressive biology, high clinical complexity, therapeutic resistance, or persistent unmet therapeutic needs may also fall within this category. Together, these populations represent a major and underserved area of oncology requiring adapted research strategies.

These diseases expose a fundamental weakness in the current architecture of clinical research. They are precisely where therapeutic uncertainty is greatest, yet traditional randomised trials are least capable of delivering timely, generalisable evidence. As highlighted by several landmark analyses, rarity is not merely a matter of incidence: it reflects fragmented expertise, biological complexity, and the persistent absence of robust comparative data. In such settings, conventional trial paradigms often fail to keep pace with clinical reality, leaving patients and clinicians to navigate decisions based on limited evidence, extrapolation, or local practice[3].

This challenge is particularly acute in paediatric oncology, where most malignancies are rare by definition and frequently hard to treat due to limited therapeutic innovation, small patient populations, and high relapse rates. Adolescents and young adults face similar constraints, with survival improvements lagging behind those observed in other age groups[4]. Across oncology, patients with rare and/or hard-to-treat cancers therefore face poorer outcomes, substantial uncertainty regarding treatment options, and a marked impact on quality of life. Even when several therapeutic strategies are used in routine practice, decisions often rely on retrospective series, small single-arm studies, or extrapolation from more common cancers rather than comparative evidence[5].

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[1] *Casali PG, Trama A. Rationale of the rare cancer list: a consensus paper from the Joint Action on Rare Cancers (JARC) of the European Union. ESMO Open. 2020*

[2] *Elmadani M et al. Global burden of rare cancers: insights from GLOBOCAN 2022 estimates. Cancers (Basel). 2025;17(10):1721.*

[3] *Boyd N, Dancey JE, Gilks CB, Huntsman DG. Rare cancers: a sea of opportunity. Lancet Oncol. 2016*

[4] *Ferrari A, Stark D, Peccatori FA, et al. Adolescents and young adults (AYA) with cancer: a position paper from the AYA Working Group of the European Society for Medical Oncology (ESMO) and the European Society for Paediatric Oncology (SIOPE). Ann Oncol. 2021*

[5] *Gatta G, Capocaccia R, Botta L, et al. Burden and centralised treatment in Europe of rare tumours: results of RARECAREnet—a population-based study. Lancet Oncol. 2017*

These persistent evidence gaps have driven growing interest in **pragmatic clinical trials**, which evaluate interventions under routine clinical conditions rather than in highly controlled experimental settings. Pragmatic trials sit on a continuum with explanatory trials, aiming to maximise the applicability of findings to clinical practice while preserving methodological rigor. Whereas explanatory trials prioritize internal validity through strict eligibility criteria, protocol-driven interventions, and intensive monitoring, pragmatic trials are designed to reflect the heterogeneity of real-world patient populations and decision-making contexts. They typically employ broader inclusion criteria, more flexible treatment delivery, simplified procedures, and outcomes that are directly relevant to patients, clinicians, and healthcare systems[6].

This approach is particularly valuable where multiple therapeutic options are already used in clinical practice, but uncertainty remains regarding comparative effectiveness, optimal sequencing, tolerability, and implementation across healthcare systems. Pragmatic designs are especially relevant in rare and hard-to-treat cancers, where conventional randomized trials are constrained by small, geographically dispersed populations and rapidly evolving therapeutic landscapes. By embedding research within routine care pathways, they facilitate recruitment, reduce operational complexity, and generate evidence that is directly interpretable and applicable in practice. They also improve the inclusion of patient groups often under-represented in traditional trials, including older adults, patients with comorbidities, and those treated outside academic centres, thereby strengthening the external validity and equity of evidence generation[7].

Beyond evaluating the effectiveness and safety of therapeutic interventions, pragmatic trials are uniquely suited to address a range of clinically important questions that remain underexplored in conventional explanatory research. They can help define appropriate dose intensity and treatment duration in routine care, for example by assessing whether reduced-dose regimens or shorter treatment courses preserve clinical benefit while limiting toxicity. They can also clarify how therapies should be sequenced or combined within increasingly complex treatment pathways, such as determining the optimal order of targeted therapies, immunotherapies, and local interventions[8]. In addition, they are well suited to evaluating de-escalation strategies, including treatment discontinuation, omission of selected modalities, or less intensive follow-up approaches, when these may reduce treatment burden without compromising outcomes[9]. Pragmatic trials can further assess supportive care interventions and organisational aspects of care, such as multidisciplinary management pathways or alternative delivery models, which may influence patient outcomes and healthcare resource utilisation but are rarely examined in traditional trial settings[10]. These questions are particularly relevant in

[6] *Ford I, Norrie J. Pragmatic trials. N Engl J Med. 2016*

[7] *Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2 tool: designing trials that are fit for purpose. BMJ. 2015*

[8] *Glasmacher A, Garralda E, Gwaltney C, Rupalla K, Li C, Weber H. Dose optimization in cancer drug development: Review and outcome of a multi-stakeholder workshop. Eur J Cancer. 2025*

[9] *Remon J, Bortolot M, Bironzo P, et al. De-Escalation Strategies With Immune Checkpoint Blockers in Non–Small Cell Lung Cancer: Do We Already Have Enough Evidence? J Clin Oncol. 2025*

[10] *Selby P, Popescu R, Lawler M, Butcher H, Costa A. The value and future developments of multidisciplinary team cancer care. ASCO Educational Book. 2019*

rare and/or hard-to-treat cancers, where uncertainty often concerns not only which intervention to use, but also how, when, and in whom it should be delivered[11].

Their successful implementation depends on robust data infrastructures, **including population-based cancer registries, and effective data-sharing mechanisms**. Because individual institutions often manage very small numbers of patients, no single centre can generate sufficiently powered evidence in isolation. Consequently, the aggregation and harmonisation of data across national and European cancer registries, clinical networks, and real-world datasets are essential to enable meaningful analyses, support feasibility, and improve external validity. Initiatives such as the European Cancer Patient Digital Centre (ECPDC) and the UNCAN programme illustrate the growing importance of coordinated European infrastructures for integrating data sources and strengthening collaborative research in rare and hard-to-treat cancers[12,13]. European population-based cancer registries illustrate the value of such collaborative infrastructures in overcoming fragmentation and strengthening evidence generation in rare cancers[14].

As essential as data infrastructure, pragmatic clinical trials require inclusive and **patient-centered research** frameworks. Given the limited number of patients and the heterogeneity of disease presentations, research priorities cannot be defined solely from traditional academic or regulatory perspectives. Meaningful engagement of patients, carers, and patient organizations is therefore essential to ensure that research questions address unmet needs and that outcomes reflect what matters most in real-world clinical decision-making. This participatory approach is closely aligned with pragmatic trial principles, which aim to generate evidence embedded within routine care pathways and responsive to clinical complexity[15].

Within this framework, **patient-reported outcomes (PROs**) are central endpoints. Among the outcomes that may be assessed through PROs measures, health-related **quality of life (QoL)** is of particular importance. Their integration extends evidence generation beyond traditional efficacy measures to capture functional impact, symptom burden, and overall well-being in real-world settings[16] .

Accordingly, QoL should be systematically incorporated alongside survival or tumour control. Despite growing recognition, PROs remain inconsistently implemented across oncology trials and are often limited by insufficient methodological robustness when treated as exploratory outcomes. Robust PRO evaluation requires prespecified, hypothesis-driven endpoints and appropriate analytical frameworks to ensure interpretability alongside clinical outcomes. In pragmatic trials, PROs are essential to contextualize efficacy by capturing toxicity, functional impact, and treatment burden.

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[11] *Borges FC, van der Graaf WTA, Saesen R, Aebi S, Amariutei AE, Bekelman JE, et al. Defining the role of pragmatic clinical trials in cancer clinical research: outcomes of a collaborative workshop hosted by the European Organisation for Research and Treatment of Cancer. Lancet Oncology. 2025*

[12] *Boutros M et al. UNCAN.eu: Toward a European Federated Cancer Research Data Hub. Cancer Discov. 2024*

[13] *European Commission: Directorate-General for Research and Innovation, An operational concept for a European Cancer Patient Digital Centre – EU missions – Cancer, Publications Office of the European Union, 2024*

[14] *Topham JT et al. Data sharing in cancer research: perceived risks and the consequences of not sharing. Lancet Oncol. 2024.*

[15] *Zambrano Lucio M et al. Scoping review protocol of person- and patient-centred outcomes in cancer clinical trials: definitions and methodologies. BMJ Open. 2025*

[16] *Shakhnenko I et al. Incorporating patients' input in the development and validation of patient-reported outcome measures in oncology: a scoping review. Health Qual Life Outcomes. 2026*

The validity of PRO data depends on the use of validated, responsive instruments and their relevance to diverse populations and care settings. PROMs should capture the multidimensional patient experience, including physical, emotional, social, and functional domains, and be informed by patient input to ensure relevance and acceptability[17].

As the field moves toward broader integration of PROs into clinical guidelines and health technology assessment, greater standardization is required in their design, collection, and interpretation, alongside predefined strategies to manage missing data and ensure robustness in real-world settings[18].

Sustainable funding remains an important enabler of pragmatic clinical trials in rare and/or hard-to-treat cancers, particularly when research questions focus on treatment optimization, comparative effectiveness, supportive care, and QoL rather than the development of novel proprietary agents. In these settings, charitable organisations and patient advocacy groups can play a key role in supporting academically led studies addressing areas of high unmet need.

Despite these advances, the implementation of pragmatic clinical trials in rare and/or hard-to-treat cancers remains highly heterogeneous across key dimensions, including study design, data infrastructure, funding, patient engagement, outcome selection, and analytical approaches. This persistent variability reflects fragmentation across clinical, methodological, and data ecosystems and continues to limit comparability, scalability, and the translation of evidence into clinical practice and policy.

2.Aim of the call

In this context, the first FORCE call for projects aims to support **international pragmatic clinical trials designed to optimize diagnostic and therapeutic strategies for patients with rare and/or hard-to-treat cancers, while strengthening the integration of robust, decision-relevant evidence generation across heterogeneous clinical settings**. Particular emphasis is placed on the systematic incorporation of **quality of life** as a central component of trial evaluation.

Supported projects are expected to:

- Evaluate interventions already established in clinical practice, including approved or repurposed medicines, radiotherapy and surgery.
- Address practical questions not resolved by traditional regulatory trials, such as dose optimization, treatment duration, sequencing or combination strategies, de-escalation approaches, streamlined care pathways, patient stratification, or reduction of treatment burden while maintaining clinical outcomes.
- Be designed according to principles of pragmatism, including:
  - broad and representative eligibility criteria,
  - recruitment in usual care settings,
  - delivery of the intervention under real-world clinical conditions,

[17] *Paravathaneni M et al. 15 years of patient-reported outcomes in clinical trials leading to GU cancer drug approvals: a systematic review on the quality of data reporting and analysis. eClinicalMedicine. 2024*

[18] *Deverka PA et al. A new framework for patient engagement in cancer clinical trials cooperative group studies. J Natl Cancer Inst. 2018*

  - minimal additional burden for patients and clinicians,
  - use of routine care data when appropriate.
- Integrate patient-centred endpoints, including prespecified and methodologically robust PROs assessing health-related QoL, symptoms, functioning, and treatment burden.
- Demonstrate active patient involvement throughout the research process, including identifying unmet needs, assessing the relevance and importance of the research question for patients, informing trial design, evaluating and minimizing the burden of study participation, contributing to trial conduct, participating in the interpretation of study findings, and contributing to dissemination activities.
- Provide a clear implementation plan outlining how the trial results could be rapidly adopted within European healthcare systems and inform clinical practice, guidelines, and policy.

3. Application requirements & guidelines

A single joint application must be submitted by the Project Leader on behalf of all participating research teams (see Submission procedure).

3.1 Application requirements

APPLICATION REQUIREMENTS	
Study sponsor	The clinical study must be designed, initiated, conducted, and sponsored under the full responsibility of **a non-industrial, non-profit sponsor**, irrespective of its legal status (organised under public or private law). **Trials sponsored by industry are not eligible.**
International research collaboration	Proposals must describe a **multicentre, collaborative clinical trial that is internationally conducted**, led by a Project Leader in one of the funding countries and involving partners from **at least two other funding countries: France, Spain, Belgium, the Netherlands, Sweden, Poland, Latvia, Ireland and Italy.** The need of transnational clinical research collaboration must be clearly justified. Active and meaningful collaboration between partners from the funding countries is strongly encouraged, in particular where it clearly enhances the added value and alignment with the objectives of the trial. In accordance with national funding regulations, consortium partners must be established in one of the funding countries and belong to one of the following categories: • Academic research groups, including universities or other higher education or research institutions; and/or • Clinical or public health research groups, including hospitals, public health institutions, healthcare settings, or health organisations (organised under public or private law).

APPLICATION REQUIREMENTS	
External inclusion centres	To enhance the overall quality, impact, and efficiency of patient recruitment, **collaboration particularly among partners from the funding countries is strongly encouraged**. In case there is a clear need, applicants may request additional funding for external inclusion centers located outside the funding countries. However, this funding is subjected to further availability of dedicated budget for these centres. Following requirements must be taken into account: • The external inclusion centres are located within geographical Europe. • Requested funding for external inclusion centres cannot exceed 20% of the total requested budget.

Cancer type	Rare and/or hard-to-treat cancers defined as:
	
	Rare cancers: the cancer type must be rare, defined as having an annual incidence (number of initial diagnoses) of fewer than 6 cases per 100,000 individuals in the European region, based on the most recent and reliable epidemiological data or registry sources. This classification is based solely on the cancer type itself and is independent of the stage at initial diagnosis. Rare cancer in both adult and paediatric populations is accepted.
	
	Hard-to-treat cancers: To be considered hard-to-treat, the targeted cancer type must be justified as meeting at least one of the following population-level criteria, supported by appropriate epidemiological and/or clinical evidence:
	• **Low survival outcomes** characterized by:
	  ○ Low 5-year overall survival
	  ○ Very limited median survival in advanced or metastatic disease
	• **High treatment-related burden** in which currently available treatments are associated with substantial toxicity and/or long-term side effects that:
	  ○ Limit the availability to deliver effective therapy in a significant proportion of patients and/or
	  ○ Lead to major and persistent impairment in patient QoL and/or patient-reported outcomes
	
	Proposals may address **any invasive stage of cancer in any age group.**
	
	Rare and/or hard-to-treat subgroups within more common cancer types are also eligible, taking into account the definitions above and if the intervention under investigation necessitates a specific approach tailored to the subgroup.
	
	The submission of trials specifically designed for, or explicitly incorporating **the paediatric patient population,** is encouraged.

Research type	**Interventional prospective pragmatic clinical trials** that are close to real-world patient impact, which may be achieved among other approaches, through implementation in clinical practice, regulatory approval, and/or changes to treatment guidelines.

APPLICATION REQUIREMENTS	
	Under no circumstances will funding be made available for early-phase developmental or translational research activities, as the aim of this call is to accelerate clinical research towards implementation in clinical practice. Trials may incorporate validated biomarkers (e.g. genetic or molecular markers) for patient identification or stratification, provided that the primary endpoint is clinically meaningful and not biomarker validation.
Pragmatism	Trials must have **a clearly defined pragmatic intent**. The use of the **PRECIS-2 framework*** is encouraged as a guiding and illustrative tool; however, full adherence to all its criteria is not strictly required: proposals should incorporate pragmatic elements where appropriate to maximize relevance and facilitate timely uptake into routine care and must reflect in particular: • multicentre conduct in **usual care settings**, • **broad eligibility criteria:** the study patient population must be representative for the real-world patient population of the disease. • intervention performed as delivered and designed for **implementation into real-world clinical practice**, • **minimal additional burden** for patients and clinicians. While practical constraints may limit the extent to which pragmatism can be achieved across all aspects of the design, applicants are expected to ensure that key design choices consistently prioritize real-world relevance. The inclusion of only isolated pragmatic features within an otherwise explanatory design will not be sufficient to meet this requirement. **Loudon, K., Treweek, S., Sullivan, F., Donnan, P., Thorpe, K. E., & Zwarenstein, M. (2015). The PRECIS 2 tool: Designing trials that are fit for purpose. BMJ, 350, h214*
Intervention type	Cancer-related diagnostic and treatment interventions, **already used in routine clinical practice in Europe** are eligible, including approved, guideline-recommended or off-label options and interventions with the potential for repurposing. Diagnostic interventions are only eligible where their use is expected to directly impact patient outcomes or QoL, for example by informing subsequent treatment decisions within the same study. In such cases, the eligible intervention under evaluation is the combined strategy (diagnostic intervention plus consequent treatment pathway). The interventions can be **both pharmacological as well as non-pharmacological** like radiation therapy, surgical procedures and lifestyle interventions, amongst others. Where pharmacological interventions are included, applicants are encouraged, where applicable, to design clinical trials in line with the principles of low-intervention clinical trials as defined in the EU Clinical Trials Regulation (EU CTR).

APPLICATION REQUIREMENTS	
Patient-centred outcomes & endpoints	Trials must address **unmet patient needs**, co-defined by patients and researchers. **A clearly defined and well-substantiated evidence gap** must be demonstrated. This can include gaps in evidence to inform treatment decision-making, limitations in the strength or absence of clinical guideline recommendations, or the lack of structured prioritisation among available treatment options. Proposed studies should generate outcomes that are both relevant to patients and meaningful for decision making in routine clinical practice. The selection of a (core set of) outcomes must be focused and well justified to ensure feasibility and interpretability, with priority given to outcomes of highest clinical and patient relevance, and designed to generate evidence that is meaningful for decision-making in routine clinical practice. QoL must be systemically integrated as a core outcome, ensuring the patient perspective is valued alongside traditional clinical endpoints such as survival. Proposals must include prespecified, hypothesis-driven **patient-reported outcome (PRO) endpoints** as primary, co-primary, or secondary outcomes, not exploratory. PRO endpoints should be analysed alongside clinical endpoints to assess the overall net clinical benefit of the intervention. Proposals must clearly demonstrate that QoL and other PRO data meet decision-grade standards, appropriate for informing clinical guidelines, health technology assessment (HTA), shared decision-making, market access, reimbursement and pricing decisions. Both validated clinically relevant endpoints and validated surrogate endpoints are acceptable.
Patient Involvement	Active and meaningful patient involvement is mandatory throughout the entire project lifecycle. Applicants must provide a **Patient Involvement Plan** that clearly outlines when and how patients have been, and will be, involved at each stage of the trial, including design, conduct, monitoring, interpretation of results, and dissemination. Proposals that lack a credible, well-structured, and adequately resourced patient involvement plan may be considered non-compliant. Applicants are required to adhere to the **Guidelines for Patient Involvement.** Trial proposals must include **patients and/or carers with lived experience**, represented by clearly identified patient organisations, groups, or individual representatives who are formally included as partners in the consortium and whose roles are explicitly described in the proposal.

Go-to-patient/clinical implementation strategy	The proposal must include **a credible and proportionate plan for future implementation within national healthcare systems**, taking into account relevant regulatory and assessment pathways (e.g. EMA, HTA processes), where applicable. Applicants should outline how positive trial results could support adoption into routine clinical practice, including across relevant European settings, demonstrating general awareness of regulatory, reimbursement, and implementation considerations. Proposals should demonstrate how the consortium is positioned to facilitate or contribute to implementation efforts, for example through relevant expertise, networks or stakeholder engagement, in the case that the trial demonstrate effectiveness, including meaningful benefits in patient-reported outcomes (PROs).

3.2 Application guidelines

APPLICATION GUIDELINES	
Timing and trial duration	The call aims to support trials that can **inform and influence clinical practice in a timely manner**. While flexibility is retained to accommodate endpoints requiring longer follow-up, applicants are expected to prioritize **efficient trial conduct and early impact**, and to justify any prolonged study duration. In any case, the proposed trials shall meet the following deadlines: • Trials must be initiated (first site activation) within 12 months after award decision. • Recruitment duration should not exceed three years, ensuring efficiency. Exceptions are permissible for specific patient populations, such as ultra-rare cancers, when appropriately justified. • The final primary endpoint must be analysed within a maximum of 10 years after trial initiation, with shorter timelines strongly encouraged where feasible.
Project management	Applicants must demonstrate that the project will be supported by a management structure with sufficient expertise to coordinate and deliver an international clinical trial. This should include strong experience in international trial management and regulatory interactions with Ethics Committees and Competent Authorities (EC/CA). The involvement of an internationally experienced project manager is strongly encouraged. Given the complexity of multinational pragmatic trials, particularly with respect to the design, conduct, and analysis of patient-reported outcomes, applicants should demonstrate access to an experienced and competent clinical trials unit, ensuring adequate methodological, operational, and data management expertise.
Public/Private collaborations	**Public/Private collaborations** are accepted if needed for the execution of the project, and as long as co-funding as well as appropriate agreements on intellectual property and fair pricing are in place. • Commercial parties cannot be a Project Leader or National Coordinator and may only be involved if collaborating with Academic or

APPLICATION GUIDELINES	

	Clinical/public health research groups. Applicants must provide a clear description of the role and responsibilities of each commercial partner involved in the project.
	• Commercial parties are only accepted if it is needed for the core execution of the clinical trial and are required to provide in-kind contribution to the project. This contribution should be of an extent appropriate for the type and size of the project. In case of financial contribution by the commercial party, a justification is required explaining the nature of the contribution, and why the remaining budget cannot be foreseen by the commercial party and why non-profit funding would be needed to execute the project.
	• Commercial parties cannot receive funding from this call.
	• Intellectual Property (IP): the background owned by any applicant will remain the sole property of the applicant (or his/her affiliated research structure (i.e. institutes, research centres and investigators). In addition, all data and results that are generated during the project remain the property of the applicants or his/her affiliated research structure (i.e. institutes, research centres and investigators) for the duration of the project. Projects with IP of study results exclusively owned by commercial parties are not eligible for this call.
	• Commercial parties are requested to express their commitment and guarantee their maximal and reasonable efforts to accommodate further implementation in clinical practice. Clear agreements between industry partners and researchers should be in place prior to the trial, assuring independent research and publishing, and no restrictive access to results.
	• Applicants must provide evidence of engagement and alignment with all relevant commercial partners whose products, technologies, devices or related intellectual property are required for the proposed clinical trial.
	  ○ As part of the preproposal, a letter of intent or other documentation demonstrating the commercial partner's willingness and capacity to support the study, including provision of investigational products where applicable, is requested.
	  ○ As part of the full proposal application, applicants should submit copies of executed agreements and supply commitments. This requirement needs to ensure that the proposed trial can be initiated without significant delays arising from unresolved negotiations or uncertainties regarding access to required products or materials.
	• Recognising that formal contractual commitments may not always be feasible at the application stage, applicants are encouraged to provide the strongest possible evidence of partner engagement and anticipated support. The level of supporting documentation provided will be considered during evaluation as an indicator of project readiness and feasibility.
	• Where formal agreements are not yet in place, applicants selected for funding are required to provide such commitments within six months from the date of award decision. Failure to do so may affect release of funding or even withdrawal of funding.

APPLICATION GUIDELINES	
Co-funding	Applicants must provide clear and transparent information on any dependencies on co-funding. This should include the status of such co-funding (i.e. whether it has been secured, still under application, or will potentially be applied for), as well as a substantiated assessment of the feasibility of the proposed trial in the absence of this co-funding.
Trial design	Proposals must use a **pragmatic, prospective clinical trial design** aimed at evaluating effectiveness in real-world settings and enabling rapid integration into routine clinical practice across diverse European healthcare systems. Eligible designs include, but are not limited to, • Randomised trials (including seamless phase II/III trials and registry-based randomized trials; • Innovative or adaptive designs, such as adaptive pragmatic platforms, MAMS (multi-arm multi-stage) or SMART (Sequential multiple assignment randomized trials); • Approaches that enhance patient inclusion; • Designs leveraging existing patient registries; • Cluster randomisation may be used if appropriately justified; • Approaches that build on or extend existing clinical trial infrastructures, for example by adding new treatment arms or comparisons within ongoing or established studies, when scientifically justified. At the time of full proposal submission, applicants are required to upload the most advanced available version of the clinical protocol.
Patient-reported outcome measures (PROMs)	• Only reliable, responsive and preferably validated patient-reported outcome measures (PROMs) may be employed within the proposed study. Any use of non-validated PROMs must be clearly and adequately justified. • The selection of PROMs must be justified based on scientific validity, reliability, cross-country applicability, and feasibility for integration into routine clinical workflows. • PROM selection must reflect, as closely as possible, the lived experience of patients, capturing the impact of interventions on physical, emotional, social, and functional well-being. • Protocols must include a prospective strategy for handling missing PRO and QoL data, including defining what constitutes "missing", documenting reasons for missingness, using appropriate statistical methods and implement strategies to minimize the occurrence of missing data. • Applicants are encouraged to adopt a modular measurement strategy combining a core multidimensional questionnaire (e.g., EORTC QLQ-C30, EQ-5D, FACT-G) with disease-specific or treatment-specific modules to enable precise capture of relevant symptoms and functional domains. • If an economic evaluation is planned, it is strongly recommended to include a preference-based instrument that allows utility estimation (e.g., EQ-5D).

APPLICATION GUIDELINES	
Dissemination plan	A plan to disseminate project data and results is required. Projects must actively contribute to reproducible science and have a plan to disseminate their data and results, addressing the following elements: • Registration of the clinical trial in a relevant, publicly accessible and regulated trial registry prior to initiation; • Timely dissemination of results through scientific publications and, where appropriate, public databases; • Use of patient-focused communication channels. Results need to be communicated in an accessible, relevant and understandable manner for patients, consistent with the requirement for patient involvement across all stages of the trial; • A data sharing approach aligned with FAIR (Findable, Accessible, Interoperable, Reusable) principles, where feasible, and in accordance with the sponsor's data sharing policy; • A commitment to make data available to the academic community for legitimate scientific and public health purposes, subject to applicable data protection, confidentiality, and ethical requirements; • Publication of results in open-access journals.

4.Glossary

CALL STEERING COMMITTEE – The CSC is composed of representative(s) from each funding organisation participating in the FORCE Joint Call 2027. The CSC supervises the preparation and implementation of the call and take all decisions concerning the call. Members of the CSC are not allowed to submit proposals to this call.

JOINT CALL SECRETARIAT - The JCS, with the help of the CSC, is responsible for the day-to-day management of the FORCE Joint Call and is the primary contact for any subject matter on call procedures. The JCS for the FORCE Joint Call 2027 is hosted by the Fondation ARC pour la recherche sur le cancer (force@fondation-arc.org).

NATIONAL COORDINATORS – National Coordinators must be located in France, Spain, Belgium, the Netherlands, Sweden, Poland, Latvia, Ireland or Italy. Only one National Coordinator is to be nominated per country. Each National Coordinator is responsible for the research and financial activities at his/her national level.

PATIENT ADVISORY COMMITTEE - The PAC is a panel of (former) patients, relatives or caregivers in charge of the evaluation of submitted pre- and full proposals. Their evaluation is based on the evaluation criteria described in this document. Reviewers are not allowed to submit or participate in proposals within this call and must sign declarations on conflict of interest and confidentiality.

PROJECT LEADER – The Project Leaders must be located in France, Spain, Belgium, the Netherlands, Sweden, Poland, Latvia, Ireland or Italy. The Project Leader is the international project coordinator, in charge of submitting the application on behalf of the whole research consortium. He/she will be the main contact point for the project submission and follow-up, as he/she oversees all activities related to the project. He/she may be responsible for research

and financial activities related to the external inclusion centres, in addition to the activities at his/her national level.

SCIENTIFIC EVALUATION COMMITTEE - The SEC is a panel of internationally recognised scientific experts in charge of the evaluation of submitted pre- and full proposals. Their evaluation is based on the evaluation criteria described in this document. External reviewers will also evaluate full proposals, based on their expertise in the type of tumour or intervention, to assist SEC members in their own evaluation. Implementation advisory bodies (including regulatory agencies, HTA bodies, health policy, payers, and other implementation experts) may also provide nonbinding input during the evaluation of the full proposals, where feasible. Reviewers are not allowed to submit or participate in proposals within this call and must sign declarations on conflict of interest and confidentiality.

5.Budget guidelines

The budget for the single joint application submitted by the Project Leader must follow the FORCE Budget Guidelines.

Where applicable, national-specific rules and conditions apply only to the respective participating research teams. Applicants are strongly encouraged to contact their respective national contact person for further clarification about national-specific rules and conditions. Additional justification or details on the national budgets might be asked by the funding organisations after pre-proposal or full proposal selection.

5.1 Total budget

The estimated total budget for the FORCE first call is approximately **13 million EUR**, provided by 11 funding organisations of the FORCE consortium.

No maximum budget per trial is defined. The requested budget should be determined by the scientific and medical needs of the proposed trial and must be clearly justified. **The FORCE consortium aims to fund around three to four clinical trials through the first FORCE Call.**

Applicants need to plan their budget in line with the strategic priorities of the call. As all participating funding organisations are charitable foundations, **applicants are expected to propose a cost-conscious budget** and **ensure that all requested costs are necessary, proportionate, and clearly justified in relation to the patient needs, study design, and scientific objectives of the requested funding.**

5.2 Eligible beneficiary institutions

The host institution (legal entity) is the official recipient of FORCE funding and will be the contracting party. Project Leaders and National Coordinators must be affiliated with an eligible institution and have the authority and capacity to ensure appropriate conduct of the study (if needed differentiate between requirements on international and national level)

Funding may be granted to the following types of institutions:

- Public research institutions
- Non-profit organisations

- Hospitals or other healthcare providers (organised under public, private or non-profit law)
- Cooperative research groups: As a general principle, cooperative groups may participate in FORCE-funded projects either as beneficiaries or as collaborators. Following exceptions apply:
  - Cooperative research groups in Spain are not eligible as direct beneficiaries and therefore cannot act as Project Leaders or National Coordinators. They may, however, participate as collaborators. Funding is then allocated to an eligible host institution (e.g. hospital or research institution), which enters into the funding agreement and collaborates with the cooperative group.
  - For cooperative groups in the Netherlands, the national budget guidelines of KWF apply. (See section 5.5).

Eligible institutions should be localized within the funding countries. For participating sites from other countries located in geographical Europe ('external inclusion centres') budget can be requested under certain conditions (please see 5.3 Eligible cost categories and principles for further details).

5.3 Eligible cost categories and principles

Costs are considered eligible if they:

- are necessary to answer the research question, and
- would not have been incurred in the absence of the trial.

All costs must be reasonable, proportionate to the planned work, and in line with national standards.

Personnel costs

Staffing costs must be clearly justified and proportionate to the study design, scale, and duration. Eligible staffing costs may include permanent and non-permanent personnel, provided that

- funding is linked to additional workload generated by the trial, and
- costs reflect national salary standards and remain reasonable. Funding cannot be used to cover routine clinical duties.

National-specific eligibility rules for personnel costs in France, Belgium and Spain:

- **France:** Personnel costs for staff with permanent status are not eligible for funding. This includes both civil servants and staff employed on permanent or open-ended contracts.
- **Belgium:** Personnel costs for medical staff with a permanent position (senior medical staff) are not eligible for funding.
- **Spain:** Personnel costs for medical staff with a permanent position (e.g. senior medical staff) are not eligible for funding, and the personnel costs cannot exceed 45% of the total Spanish budget.

Operational costs, travel expenses and other costs

Eligible operational costs, travel expenses and other costs include study related costs, such as:

- **Operational costs:** project design and set-up, ethical and regulatory review, monitoring, safety-related costs, data management, statistics, reporting and publication, patient involvement, IMP/Intervention handling (if applicable), travel to inclusion centres, site costs and project management costs for activities not implied in previously listed categories and conducted by the International Project Lead.
  Where project tasks are carried out by external organisations, the associated costs must be budgeted as service provider costs (not personnel costs), and must be clearly justified. The use of external service providers should be limited to activities that cannot reasonably be performed within the applicant institutions.
- **Travel expenses:** Travel costs must be necessary for project coordination and implementation and clearly justified in the budget.
- **Patient costs:** For costs related to the recruitment of patients at each site, applicants are requested to structure the budget, as far as possible, using:
  - **a start-up fee**: covering costs required to initiate the clinical trial at a site, and/or
  - **a fee per patient**: covering costs related to the treatment and follow-up of a patient within the study.
  - Both the start-up fee and the per-patient fee may cover personnel and operational costs associated with the external inclusion centre. These costs must be clearly specified and justified through a detailed cost breakdown of the services included in the fees.
  - The requested budget should be presented as an amount per site and/or inclusion centre, calculated on the basis of the start-up fee, per-patient fee and the site-specific enrolment target (i.e. the estimated number of patients to be enrolled per site, as defined in the Clinical Trial Agreement).
- **External Inclusion Centres** refer to participating sites located **outside the funding countries**, and may be included to enhance recruitment, representativeness, or feasibility of the trial. The provision of funding for external inclusion centres is contingent upon the availability of a dedicated budget and is subject to the following conditions:
  - External inclusion centres must be located **within geographical Europe.**
  - The total budget allocated to external inclusion centres must not exceed **20% of the total requested project budget**.
  - This 20% threshold applies at the **project level** and includes all costs related to these centres.
  - The budget should be based on:
    - a start-up fee: covering costs required to initiate the clinical trial at a site, and/or
    - a fee per patient (covering costs related to the treatment and follow-up of a patient within the study).
  - Both the start-up fee and the per-patient fee may cover personnel and operational costs associated with the external inclusion centre. These costs must be clearly specified and justified through a detailed cost breakdown of the services included in the fees.

- The requested budget should be presented as an amount per site and/or inclusion centre, calculated on the basis of the start-up fee, per-patient fee and the site-specific enrolment target (i.e. the estimated number of patients to be enrolled per site, as defined in the Clinical Trial Agreement).

All such costs must be clearly linked to the conduct of the trial and justified in the budget**.**

Non-eligible costs

As a general principle, costs related to the **direct purchase and manufacturing of medicines or medical devices** as interventions are not eligible, but intervention-related research costs may be eligible, if they are well justified.

Overhead costs

No overhead costs are eligible for funding.

5.4 Involvement of commercial parties

FORCE funding cannot be granted to companies or organisations with commercial or for-profit interests.

Commercial parties may participate in FORCE submitted trials provided that they fulfil the requirements detailed in section 3.2 Application guidelines, under Public/Private collaborations.

5.5 National regulations and specific conditions

In addition to the national-specific rules and conditions outlined in the sections above (e.g. personnel costs), country-specific regulations and conditions apply as described below.

The Netherlands – KWF Kankerbestrijding:

- The KWF Funding Conditions 2025 and the KWF Accountants Protocol 2025 apply. These are available on the KWF website (see https://www.kwf.nl/en/forresearchers/downloads).
- Dutch applicants should contact KWF prior to submission if they have any questions regarding eligibility, budget requirements or funding conditions.
- Any proposed third-party agreements related to the funded project shall be subject to legal review and approval by KWF.

5.6 Budget management and monitoring

The International Project Leader is responsible for the consolidated project budget, overall financial planning, and budget monitoring at project level.

Funding will be provided by one or more of the participating funding organisations. Some organisations may fund research teams across national borders. The allocation of funding to individual beneficiaries will be determined after evaluation, based on proposal ranking, budget availability, and funder-specific eligibility rules.

Successful applicants will enter into a grant agreement governing the use of funds signed by the relevant funding organisations and beneficiaries

5.7 Duration of funding

The project duration corresponding to the funding period **cannot exceed 10 years**.

6.Funding commitment

The estimated total budget is approximately 13 million EUR, provided by the 11 cooperating funding organisations. Funding for multinational trials may be provided through cross-border funding mechanisms. The allocation of funding to individual research teams will depend on ranking of proposals, available budgets, and applicable funder-specific eligibility rules.

FUNDING ORGANISATION	COUNTRY	INDICATIVE CONTRIBUTION (EUR, MILLION)	NOTES
Anticancer Fund	BEL	0,1-0,25	May support cross-border funding under certain conditions
Breakthrough	IRL	0,117–0,3	May support cross-border funding under certain conditions
Fondation ARC	FRA	~2	Restricted to national beneficiaries
Fondazione AIRC per la ricerca sul Cancro	ITA	Up to 1,5	Restricted to national beneficiaries
Kom Op Tegen Kanker	BEL	~2	May support cross-border funding under certain conditions
KWF Dutch Cancer Society	NDL	~2	May support cross-border funding under certain conditions
Latvian Children's Oncology Foundation	LVA	~0.02	Restricted to national beneficiaries Focus on paediatric oncology
Scientific Foundation of the Spanish Association against Cancer FCAECC	ESP	Up to 1	Restricted to national beneficiaries
Swedish Cancer Society	SWE	Up to 2	May support cross-border funding under certain conditions
The Saving Kids with Cancer Foundation	POL	Up to 0,4	Restricted to national beneficiaries Focus on paediatric oncology
The Swedish Childhood Cancer Fund	SWE	Up to 1,8	May support cross-border funding under certain conditions Focus on paediatric oncology

7. Timeline of the call

Stage I – Pre-proposals	**Plan start**	**Plan end**
Application submission	29 June 2026	21 Sept 2026
Reviewing process	October 2026	November 2026
Results & Invitation to Stage II	Early December 2026	

Stage II – Full proposals	**Plan start**	**Plan end**
Application submission	Early December 2026	Early 2027
Reviewing process	February 2027	April 2027
Results	End of May 2027	

8. Submission procedure

This call is implemented through a **two-stage submission procedure**: the pre-proposal and full proposal stages. Both pre- and full proposals must be written in English and **submitted exclusively by the Project Leader through the electronic submission system of Fondation ARC** (https://appelsaprojets.fondation-arc.org/) no later than the deadlines of **21 September 2026, 2pm (CET)** for the pre-proposal, and **early 2027** for the full proposal (exact deadline will be communicated to the applicants after pre-proposals submission).

Please note that the electronic submission system will open on 7 July 2026 and that registration in the system is required prior to submitting your application. It is recommended to register as soon as possible.

In preparing the proposals, Project Leaders must follow the rules described in this Call Text. Any questions should be addressed to the Joint Call Secretariat (JCS):

Fondation ARC, France
E-mail: force@fondation-arc.org

Please note that only full proposals from Project Leaders who are explicitly invited by the JCS will be accepted.

At both the pre-proposal and full proposal stages, all Project Leaders and National Coordinators must sign a letter stating that all information submitted has been shared with and agreed upon by all of them (template provided on the electronic submission system).

In certain cases, individual national rules/funding conditions apply (see section 4. Budget guidelines). In such cases, questions should be addressed to the corresponding national contact persons.

9.Evaluation procedure

The evaluation process is based on transparency, equal treatment, independence, confidentiality, and documented decision-making.

There will be a two-stage evaluation procedure, based on the evaluation criteria indicated in sections 9.1 to 9.3:

- **Pre-proposal evaluation:** The scientific evaluation committee (SEC) and the patient advisory committee (PAC) members will independently assess the scientific and PAC parts of the proposals, respectively.
- **Full proposal evaluation:** The SEC members, the external reviewers, and the PAC will independently assess the full proposals. The committees will be clearly informed from the outset that no formal rebuttal phase will be foreseen, and they should take this into account when formulating their feedback on the full proposals.

9.1 Scientific evaluation criteria

Proposals are assessed according to the SEC and External reviewers' evaluation form. The scientific review focuses on the following criteria:

A. Scientific Quality

- Demonstrates strong scientific quality and clear relevance to the call objectives
- Is an investigator-initiated (non-commercial) clinical trial
- Targets rare and/or hard-to-treat cancers (with clear justification)
- Addresses patient-defined unmet needs and includes relevant endpoints
- Prioritises patient-centred outcomes, including QoL
- Uses an appropriate and robust trial design (including justified alternatives where relevant)
- Is supported by a clear scientific rationale
- The trial is expected to generate real-world evidence and reflect a pragmatic approach, including: multicentre conduct in routine care, a broad and representative population, interventions applicable in clinical practice, and minimal burden for patients and clinicians

B. Feasibility

- Presents a clear and realistic work plan and recruitment strategy, including a justified budget aligned
- Demonstrates an appropriate and complementary international consortium
- Shows that the intervention is feasible, safe and sustainable in routine practice
- Demonstrates the feasibility of any public-private collaboration
- Additional considerations include infrastructure, timelines, operational readiness and prior experience

C. Implementation Potential

- Provides a realistic plan for implementation in European healthcare systems
- Demonstrates potential to influence clinical practice
- Identifies and addresses key barriers to adoption (e.g. regulatory, HTA, access) where applicable
- Considers equity and access across countries and patient groups
- A full plan is not required at this stage, but a clear approach and next steps should be described

D. Patient Impact

- Targets clearly defined unmet patient needs
- Demonstrates potential to improve outcomes and QoL
- Includes meaningful patient-centred outcomes (e.g. PROs)
- Assesses benefit–burden balance for patients

9.2 PAC evaluation criteria for pre-proposals

The PAC members will assess whether the project pre-proposals are patient-centric and address a pressing need, from the perspective of the cancer patient or caregiver. The PAC evaluation for the pre-proposals will be done taking into account the following criteria:

A. Concrete patient needs

- The project addresses one or several concrete needs among patients that is/are clearly and comprehensively described.

B. Added relevance for the patients

- The proposed solution is adequate and provides added value for the patients in need.
- The solution must demonstrate patient-friendliness and potential impact on the life expectancy and/or QoL, including a realistic view on the feasibility and timing of the expected impact.
- The inclusion and exclusion criteria for the patient population in the study are appropriate from a patient perspective.

C. Patient burden and trial access

- Patient burden (physical, emotional, financial, etc) is monitored and addressed throughout the clinical trial and afterwards in the intended clinical implementation.
- The burden is minimised where possible, and the burden/benefit balance is appropriate.
- The trial access and accessibility, as for pragmatic trials, are feasible across real-life conditions.
- The side effect management plan (including expected short-term and long-term side effects and their follow-up).

D. Patient involvement/ co-creation

- The appropriate patient involvement throughout the entire project lifecycle (from the project's design, set-up and execution to the dissemination aspects).
- That patient associations are included as collaborative partners, providing a signed letter of intention or a letter of commitment.

9.3 PAC evaluation criteria for full proposals

As for the pre-proposals, patients will evaluate and score the PAC part of the full proposals. The PAC will evaluate how full proposals address these three criteria:

A. Added relevance for the patients

- The description of the current situation of the patients (e.g., incidence, diagnosis, treatment, etc), and the proposed solution relevant to the patients' needs.

- The potential impact of the project results on the patients, including expected timing of impact.
- The feasibility of the project is realistic.
- The inclusion and exclusion criteria for the patient population in the study are appropriate.

B. Patient burden and trial access

- Patient burden (physical, emotional, financial, etc) is monitored and addressed throughout the clinical trial and afterwards in the intended clinical implementation.
- The burden is minimised where possible, and the burden/benefit balance is appropriate.
- The trial access and accessibility, as for pragmatic trials, are feasible across real-life conditions.
- The side effect management plan (including expected short-term and long-term side effects and their follow-up).

C. Patient involvement/ co-creation

- The appropriate patient involvement throughout the entire project lifecycle (from the project's design, set-up and execution to the dissemination aspects).
- That patient associations are included as collaborative partners, providing a signed letter of intention or a letter of commitment.

10.Confidentiality of proposals

The proposals will be treated as confidential and will be used solely for the purposes of eligibility screening, evaluation, selection, and grant administration. Access to proposal materials will be limited to the call implementation bodies directly involved in the evaluation process, all of whom are required to maintain the confidentiality of the information received. Also, applications might be shared with other implementation advisory bodies (including regulatory agencies, HTA bodies, health policy, payers, and other implementation experts) during the review process. No proprietary, commercially sensitive, or otherwise confidential information contained in proposals will be disclosed to third parties without the applicant's prior consent, except where disclosure is required by applicable law.

Information about the proposed research (name of the Project Leader, title and abstract), if funded, might be published on public databases collecting data on national and international funding in cancer research in the full respect of the EU General Regulation 2016/679 on data protection.

11.Contact

11.1 Joint Call Secretariat

Fondation ARC, France

force@fondation-arc.org

https://force4cancer.eu/

11.2 National contact persons

Funding organisation	Country	Contact
Anticancer Fund	BEL	Rica Capistrano rica.capistrano@anticancerfund.org +32 2 268 48 16
Breakthrough Cancer Research	IRL	Frances Drummond frances@breakcancer.ie +353 21 422 6655
Fondation ARC	FRA	Corentin Louis force@fondation-arc.org +33 (0)1 45 59 58 46
Fondazione AIRC per la ricerca sul Cancro	ITA	Laura Galbiati laura.galbiati@airc.it +39 02 7797205
Kom Op Tegen Kanker	BEL	Inge Oudaert inge.oudaert@komoptegenkanker.be +32 (0)2 213 60 21
KWF Dutch Cancer Society	NDL	Jozefien de Groot jgroot@kwf.nl +31 (0)20 570 0423
Latvian Children's Oncology Foundation	LVA	Roberts Melbārdis Roberts.Melbardis@pmnet.lv
Scientific Foundation of the Spanish Association against Cancer FC AECC	ESP	Marina Reguero marina.reguero@aecc.es +34 913 98 59 00
Swedish Cancer Society	SWE	Annina Graan annina.graan@cancerfonden.se +46 76 814 74 03
The Saving Kids with Cancer Foundation	POL	Anna Król-Kołodziej anna.krol@naratunek.org +48 791241277
The Swedish Childhood Cancer Fund	SWE	Kerstin Sollerbrant kerstin.sollerbrant@barncancerfonden.se +46 70 525 58 62 Sonia Köllner sonia.kollner@barncancerfonden.se +46 70 437 90 07