

PACE FAQs

General

What is PACE, is it just about grant funding?

PACE is a collaboration between three leaders in the UK's health innovation and research community. The £30m initiative harnesses the expertise of the partner organisations to not only grant fund projects but also to offer advice and mentorship and to provide access to a collaborative network of potential project partners to enable the best chance of project success - de-risked and investment-ready assets for potential downstream funding (by, e.g. CARB-X, corporate and venture investment and other later stage funding and support mechanisms).

What is the PACE Catalyser?

The Catalyser is part of PACE's commitment to strengthening the AMR research ecosystem by providing support to applicants that are selected to submit Full Applications following the EOI stage. The support provided will be aimed at helping development of Full Applications and, as part of this, shaping projects with maximum potential to deliver de-risked and investment-ready assets for onward development.

What is the PACE Academy?

The Academy is part of PACE's commitment to providing support as well as funding to PACE portfolio projects. The content of the academy will be tailored to the cohort of funded projects but is expected to connect innovators with a variety of stakeholders and experts, who will provide tailored support and guidance to help teams progress their assets. For example, this could include support with scientific study design, regulatory strategy or introductions to downstream funders or investors.

What is the role of the PACE R&D Advisor?

PACE R&D Advisors will actively engage with you and your project team throughout the lifecycle of the project (including helping develop the full application). Support will be tailored to individual project needs (defined at the full application stage). Support may include signposting and making connections across the PACE delivery partner network and beyond as needed; mentorship and advice including but not limited to drug/diagnostic discovery, disease area insight, experimental work package design and support to engage 3rd party delivery partners as needed (e.g. development of a statement of works and acting as the point of contact); facilitating scientific advisory boards and public and patient engagement panels. PACE R&D Advisors will not make funding decisions about your project, but they will be involved in reporting on project progress to the PACE joint programme management board.

What is the PACE Delivery Partner Network, how do I access it and do I have to use it?

PACE has brought together a <u>network of delivery partners</u> to enable all aspects of outsourced project work across the PACE-funded project portfolio. PACE recognises that not all applicants will have the internal resources and pre-existing relationships required for end-to-end project delivery and, for that reason, wants to be able to facilitate connections and collaborations. Recipients of PACE Project Awards will retain the right to choose whom they work with to deliver their project, including where the Recipient has established relationships with their own delivery partners. PACE R&D Advisors will work closely with Recipients of funding to identify where access to a PACE delivery partner is in the best interests of the project.

How does my organisation become a PACE delivery partner?

To find out more and apply to join the delivery partner network, please visit the <u>DPN webpage</u>.



Can PACE provide access to any other wider enabling capabilities?

As part of PACE support, we are tackling barriers to AMR therapeutic and diagnostic development by connecting global innovators with UK national capabilities to help shape and drive projects forward. One such cross-cutting collaboration established is with the UK Health Security Agency (UKHSA) to enable early evaluation of in vitro antimicrobial activity across the PACE therapeutic portfolio. We are continually assessing the AMR ecosystem to identify additional capabilities that can strengthen delivery of our portfolio of projects and address common gaps within data packages. To find out more about enabling technologies and capabilities, please visit the <u>Partnerships</u> page.

Do you anticipate future funding calls?

We expect further funding calls aligned with our aim to bring together the sector to help innovators with earlystage antimicrobial and diagnostic projects move forward with greater speed and confidence, accelerating the delivery of new innovations to tackle AMR. The exact nature and timings will be determined.

Scope of the 2024 Diagnostic Innovations Funding Round

Why are we prioritising diagnostics solutions for UTI, LRTI and BSI/Sepsis, rather than other indications?

These are some of the indications representing the highest burden of AMR for which we have identified a particular unmet need for diagnostics and for which PACE is also supporting the development of novel antimicrobials.

What pathogens are in scope?

The primary focus should be on the intended use, i.e. the medical scenarios your test is being developed for. We are looking to support projects aiming to develop rapid diagnostics for UTI, LRTI and BSI/ sepsis – and we will be prioritising proposals that address the key pathogens associated with those indications specifically in relation to antimicrobial resistance, as exemplified in recent publications in the Lancet:

<u>https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)02185-7/fulltext</u> and <u>https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02724-0/fulltext</u>. For all diagnostic proposals but particularly for those that focus on one or a few pathogens only, the positioning, intended use setting and potential for clinical impact should be considered and explained clearly.

What do we mean when we say tests requiring central lab infrastructure are out of scope?

Tests that require samples to be sent offsite to a central laboratory for testing are out of scope. For this funding round we are focussing on point-of-care and near-patient solutions (i.e. tests conducted <u>on site</u> with minimal processing/ training, close to where patient care/ treatment is provided) for healthcare levels 1 and 2/3, which were identified as areas of greatest unmet need and greatest potential for impact for improved diagnostics. As infrastructure available at different healthcare levels may vary by geography, appropriate justification for the intended setting and how the test would improve on current practices should be provided.

What are the different Technology Readiness Levels (TRL) and which levels are PACE looking to fund in?

Please see the website and funding launch webinar slides for a description of TRLs. We are looking to fund projects at the earlier stages of diagnostic development, namely from TRL3 to TRL5; from proof of concept/ technical feasibility into early prototype stages, including field studies for generating data in a relevant environment. We will consider late-stage TRL2 projects with particularly strong rationale and supporting data. We are not looking for projects from TRL6 (clinical studies) onwards. This was described in detail in the call launch webinar, a recording of which can be accessed <u>here</u>. Note that this relates to the project plan activities fundable by PACE, so applicants with a later-stage technology can seek funding for earlier-stage activities to address gaps when repositioning or expanding the application of their technology.



What do you mean by "data on real samples is required" for TRL 4-5?

At TRL4-5 we expect data collected on human samples; preferably collected for the precise use-case/indication, or suitable archived samples that can serve the same purpose (i.e., are representative of the types of samples expected to be collected from the patient and tested by the diagnostic that is under development).

Can I have some guidance to determine which stage my project is at? Does my project stage influence the level of funding I am eligible for?

You can refer to our webinar slide-deck, available <u>here</u>, where we provide guidance on project stages, which can also help inform work packages to be included in your project plan. We appreciate that determination of project stage may not always be clear cut, and it is used in this instance for guidance and benchmarking. As guidance, we allocate budgets of around £300K for earlier stage projects (up to and including TRL3), and up to £1M for later-stage projects (TRL4-5), however, the requested budget should be appropriate to the work plan and will be agreed with PACE advisors during the full project stage.

Can PACE funding be used to further define strategic positioning and translational plans for my project?

PACE funding can be used for translational activities appropriate for the development stage of the project. For example, funding could be allocated for advice to refine TPPs and intended use, such as advice on clinical and competitive positioning or surveys to understand user needs, however, funding cannot be used for regulatory submission and associated clinical studies.

Can you provide more detail about the test characteristics you are looking for in the scope of this call?

Further details about the test characteristics for each indication (UTI, LRTI and BSI/Sepsis) can be found <u>here</u>. Please note that these are ideal test characteristics to help guide you. Proposals for products that do not meet all the criteria will still be considered.

What do we mean by different healthcare settings?

The definitions we are using of the different healthcare levels can be found <u>here</u>, alongside the ideal test characteristics. We appreciate that these definitions are a simplified view and that healthcare systems vary significantly between different geographies. If you feel your target setting is not represented in these definitions, choose the nearest appropriate one and provide an explanation within your application form.

Are diagnostics working on blood culture (rather than blood sample) acceptable?

For BSI/sepsis, we are looking for diagnostics that can either work straight from blood samples or involve reduced sample processing and culture times to deliver AST results within the timespan of a hospital shift (<8hrs). More details can be found in our <u>ideal test characteristics</u>.

What do you mean by novel tests vs improvement on existing technologies? Would a new diagnostic to be used alongside existing tests be in scope? Would evaluating the utility of a marketed test in a new setting be eligible?

The focus of this funding call is on diagnostic innovation, therefore pure repositioning of existing technologies in new contexts without technical innovation to meet the new setting needs or intended use would not be in scope. However, modifying existing diagnostics for example to improve accuracy or for use in low resource settings (removal of cold chain, power source requirements etc) would be in scope. Likewise, diagnostics that fit alongside other tests in the existing care pathway are in scope. The development of additional validated markers on existing cartridges for existing diagnostic platforms, on the other hand, would likely be out of scope. Please reach out using the <u>enquiry form</u> on the funding page if you have questions regarding the eligibility of your proposal.



What do you mean by "standalone" in the out-of-scope criteria? E.g. would sample collection methods be in scope?

We do not fund projects that solely focus on the development of sample collection or processing methods, biomarker identification, AI models, and others as outlined in the <u>scope criteria</u>. Such activities may however be included as part of the proposed diagnostics development work plan.

How accurate should the Cost of Goods Sold (COGS) estimate be for a diagnostic prototype?

The Cost of Goods Sold (COGS) estimate should be the best estimate provided by the manufacturer of the product. The cost of labour, materials and manufacturing overheads, and the scale of the manufacturing batch used to estimate the cost per unit, should be detailed where available.

Our project is not in scope. Is there anything PACE might be able to support with?

We would always welcome <u>enquiries</u> and may be able to help or advise. Please sign up to <u>PACE news</u> to stay engaged with us.

Eligibility

I'm not based in the UK, can I apply for funding?

Yes, these are global funding calls therefore, you can apply, subject to the eligibility criteria provided on the <u>funding pages</u>.

Are academics eligible to apply?

We welcome applications from academics and SMEs meeting the funding call's eligibility criteria.

How do you define SMEs?

A breakdown of the different organisation sizes is in the below table:

Qualifying Criteria	Small Enterprises	Medium- Sized Enterprises	Large – Sized Enterprises
Turnover	Not more than £10.2 million	Not more than £36 million	Above £36 million
Balance Sheet Total	Not more than £5.1 million	Not more than £18 million	Above £18 million
Number of Employees	Not more than 50	Not more than 250	<u>Above 250</u>

Can a consortium apply?

Yes, but a lead applicant would need to be listed on the application from an eligible SME, academic or organisation. Co-applicants will be subject to the same standard PACE T&Cs as the lead applicant.

What level of experience should a principal investigator have to be considered eligible?

A Principal investigator would typically be a research active member of staff (incl. Postdoctoral researchers) who can demonstrate: experience in the successful management and delivery of (ideally translational) research projects; experience in leading collaborative research projects; and relevant technical expertise.

Can investigators/ applicants be on multiple applications?

Yes, if the projects are distinct and unrelated.



Do I need to have the capabilities, tools and facilities to deliver the project in house?

No. However, applicants will need to articulate a clear plan as to what capability, tools or facilities will be accessed to deliver the proposed research plan, either through collaboration with project partners or by outsourcing defined parts of the research plan to Contract Research Organisations (CROs). Any gaps or areas applicants would like support on can be outlined in the respective section in the Eol. Applicants that are invited to submit a Full Application to PACE following expressions of interest will have the opportunity to take part in a Catalyser which will include the opportunity for PACE to facilitate connections with the PACE delivery partner network. Value for money must be demonstrated for outsourced CRO work.

Application Process

Where can I see an overview of the application process?

On the <u>funding pages</u> for each funding round, you can find a graphic depicting the stages and timescales of the application process.

Where is the link to the application portal to apply for funding?

When a funding call is live, you can access the application portal on the relevant funding page for that call.

Can I add references into my application?

We strongly encourage that key data or material to support the application should be included and references (PMIDs) provided throughout.

Will the PACE team offer support to applicants for the Expression of Interest stage?

The funding round launch webinar and supporting slides (found <u>here</u>) provide an overview of PACE, a detailed description of the call scope and application process. During an open funding call, you can complete an enquiry form on the relevant <u>funding page</u> so we can answer your questions. For general enquiries, you can reach out to us via our <u>Contact Us page</u>.

Can I save the Expression of Interest as a draft within the submission portal?

Yes, you can, once you have logged in using the Submittable link and filled in the applicant section.

Will feedback be provided on Expressions of Interest?

Yes, you will be informed as to whether your application has been successful soon after a decision has been made, and we will aim to provide brief summary feedback.

If my application is rejected, will I be eligible for future funding calls?

We want to support innovators and would encourage you to apply to other calls; resubmission of the same proposal without addressing feedback would likely be rejected.

Review and Award Process

Who will see my application?

Representatives from managing partners (MDC, IUK and LifeArc) will review your application at the Expression of Interest stage. All partners will abide by PACE confidentiality and <u>Conflict of Interest Policy</u> and procedures. In addition, we may share applications with scientific experts and patient representatives who will also abide by PACE confidentiality and Conflict of Interest Policy.



When will I hear if my application has been successful, and when might projects start?

Timelines for the whole application process can be found on the <u>funding page</u> for the call you are interested in. The exact start time of the project may vary depending on the nature of the project, applicant timelines and contracts being confirmed for all parties. We anticipate that projects will be required to be started within three months from receipt of Award Letters.

How detailed does the project plan and costings have to be at the Eol stage?

At this stage, we're looking for a high-level overview of project objectives and key deliverables, as well as an outline of the workstreams and associated milestones. Overall project budget and breakdown by milestones should be provided, however, we will work with successful applicants to refine these in the full application stage.

Funding

What is the nature of the funding? Is it 100% non-dilutive?

Project funding will be provided as a philanthropic grant. Funding will be non-dilutive, and investigators will own all arising IP generated as set out in our <u>T&Cs</u>.

Is there a maximum allowable budget?

Yes, Technical Feasibility Projects (late stage TRL2/TRL3) can request a budget of up to £300,000 UKGBP, with Product Development Project (TRL4-5) budgets limited to £1,000,000 UKGBP over a maximum two-year project.

What expenses are covered? Are salary costs eligible?

Awards shall cover 100% of the direct costs of the Recipient Project, provided such costs are Permitted Expenditure. Permitted Expenditure is expenditure which is reasonably incurred and properly evidenced and is directly related to and necessary for the delivery of the Project, in accordance with the Project Plan and Budget; complies with the Subsidy Law (in the case of a UK enterprise) and is not an expenditure on an Ineligible Cost. Examples of types of permitted expenditure include an appropriate %FTE of staff (Post Docs), plus consumables directly related to funded work, access to specialist equipment/reagents, and Contract Research Organisation work. Details on permitted expenditure can be found in the <u>T&Cs</u> with further post-award funding guidance also <u>available</u>.

Are University overheads eligible?

No, overheads are not a permitted cost. Only direct costs will be funded. PACE post award guidance which includes information on permitted costs is available <u>here</u>.

When and how are funds transferred to a company/academic after entry into the portfolio?

Payments will be made quarterly in arrears. Payments will be limited to the current active milestone working towards agreed associated success criteria.

Innovate-UK, part of UK Research and Innovation, an executive non-departmental public body, is a funder. What does this mean for me regarding my obligations under subsidy law?

If you are a UK Enterprise (as defined in the Subsidy Control Act 2022) and any part of the award sums provided to you are provided by UKRI-Innovate UK, this portion of the award is a subsidy and is provided under the <u>RDI</u> <u>Streamlined Route</u>. Recipients shall comply with the requirements of the Subsidy Control Act, the Streamlined Route, and any other applicable legislation.

Exploitation of Results and Intellectual Property

Who will own the IP generated in a funded project? Do I need to have patents in place before applying?

IP generated during the course of the Project will usually reside with the funded party(s). The contractual terms of any outsourced work should ensure that the contracting organisation will own arising IP generated under the contract. You should ensure that you have freedom to operate - i.e. you have access to or a reasonable plan to obtain access to the required background IP to commercialise the project outputs. We will review your translational plan and whether you have freedom to operate when we assess your application.