Sustainable Medicines Manufacturing Innovation Programme – Information Webinar FAQs

Key Dates:

- **EOI:**
  - Open date: 14th August 2024
  - Close date: 16th October 2024
  - Project start date: 1st December 2024
- **CRD:**
  - Open date: 30th August 2024
  - Close date: 16th October 2024
  - Project start date: 1st February 2025
- **Grand Challenge:**
  - Open date: June 2025

All dates are subject to change until the competition brief has been published on IFS. Please note that some details regarding the Grand Challenge competition are still being finalised. Information will be released as soon as possible.

Application Questions:

International Partners

The EOI and CRD competitions are only open to UK-based companies. International organisations will not be eligible to apply and will not receive funding.

Qt: Can international affiliates of UK companies support a Grand Challenge?
Ans: To be determined. This will be communicated at the earliest opportunity.

Qt: Most of our CDMOs are outside of the UK. Can a consortium be formed by NHS, a UK pharma, and a CMO outside the UK?
Ans: International partners are not eligible to apply for the EOI and CRD competitions. It has not been decided if international partners will be eligible to apply for the Grand Challenge. This will be communicated at the earliest opportunity.

Qt: If the company is headquartered in Europe but has entities in the UK, can they be considered?
Ans: The UK entity can be considered for funding only if it is registered in the UK with a Companies House number. Work must be carried out in the UK to be eligible to claim the grant.

Qt: Do the CDMOs need to be UK-based?
Ans: For the EOI and CRD competition, CDMOs need to be UK-based and must have a Companies House number. International partners are not eligible for these competitions. Eligibility for the Grand Challenge will be communicated later.

EOI and Grand Challenge Consortium:

Qt: Would the consortium need to be in a final shape with respect to the companies taking part at the EOI stage?
Ans: At the EOI phase, you may apply as a single applicant or collaboration but are not required to have a fully formed consortia. Full Grand Challenge projects will require at least three organisations from across the supply chain (where appropriate).

Qt: Can you still be a consortia participant for grand challenge funding if you do not submit an expression of interest?
Ans: Yes, as long as you join a consortium which received EOI funding and partake in the Grand Challenge.

Qt: If an organisation is not in the EOI (either named in an application or having applied), can it be included in a consortium at a later date?
Ans: Yes, you may still be a partner for the Grand Challenge as long as you join a consortium which received EOI funding.

Qt: Should EOI be submitted by the technology provider or the end user?
Ans: Anyone can submit the EOI if they adhere to the rules/eligibility criteria of the competition.

Qt: Is there a minimum number of organisations that need to be involved in the consortia?
Ans: Full Grand Challenge applications will require at least three organisations from across the supply chain (where appropriate).

Qt: Can the grand challenge scheme be led by an SME?
Ans: Yes, if the SME can demonstrate the experience and capacity to lead and manage such a large project.

Qt: Will MFA rules apply for EOI phase only? Or both phases for the Grand challenge scheme?
Ans: MFA rules only apply to the EOI phase.

Qt: Can an organisation lead the EOI without receiving funding due to MFA rules?
Ans: No, leads must be grant claiming.

Qt: Will the process consider linking applications which can then form consortia?
Ans: This has not yet been determined. We will communicate this with successful EOI applicants at the earliest opportunity.

Qt: If a full GC proposal is deemed to be too ambitious, will there be a discussion to reduce the scope/funding request?
Ans: This has not yet been determined. We will communicate this with successful EOI applicants at the earliest opportunity.

Eligibility:

Qt: Do projects need to be led by industry as the main partner rather than an SME or charity as the lead?
Ans: No, there is no requirement for industry to lead as long as the rules/eligibility criteria of the competition are adhered to.

Qt: Can SMEs apply for the collaborative R&D grant if they are enlisting universities and UK research organisations as contractors?
Ans: If a suitable collaboration is in place, UK research organisations and universities can be brought in as subcontractors with proper justification. However, they are encouraged to come in as partners from the start if possible.

Qt: Are there restrictions on who can lead on a collaborative R&D application?
Ans: Academia cannot lead any application (EOI, CRD, or Grand Challenge) but can be included as a partner.

Qt: Could an SME be part of an EOI and a Collaborative R&D proposal?
Ans: Yes.

Qt: Can collaboration be Start-Up and academia?
Ans: For the CR&D competition, yes.

Qt: Can projects in the CR&D strand be led by a large company?
Ans: Yes.

Subcontractors:

Subcontractors for the expression of interest (EOI) phase are not allowed but will be considered for the Grand Challenge and CR&D competitions.

Qt: Is there a limit to subcontractors involved in the projects?
Ans: No, however subcontractors must be UK-based. International subcontractors may only be considered under exceptional circumstances with justification submitted to IUK for approval.

Qt: Can subcontractors (UK-based) be included and are there any restrictions on what

can be covered?
Ans: Subcontractors for the EOI phase are not allowed but will be considered for the Grand Challenge and CR&D competitions. There are no restrictions on scope activities if they are relevant to the project and in line with the competition scope.

General:

Qt: Is there an expectation that the competition will award grants over the duration of the 4-year window?
Ans: While there are no plans to conduct additional EOI or Grand Challenge competitions beyond those announced, we may consider running further Grand Challenge competitions in the future.

Qt: What is the definition of an organisation for the purposes of this?
Ans: For more information on company sizes, please refer to the Company accounts guidance.

Qt: Is there a minimum age for startups seeking to apply for this funding?
Ans: No, as long as it is a UK-based company, and the project is within scope.

Qt: How many projects do you expect to fund per scheme?
Ans: Roughly 10 for the EOI, 15 for the CRD, and 5 for the Grand Challenge.

Qt: Will funding meet part of the costs towards regulatory approval?
Ans: We will have to direct this to our finance department as this is likely to be decided on a case by case basis.

Qt: Does it mean the project would accept the budget for regulatory, or does it mean regulatory expertise needs to be obtained before the project application?
Ans: Regulatory costs can be covered as part of the funding.

Qt: How will LPMs/Innovate UK gather ESG outcomes from each project?
Ans: Innovate UK's Impact Metric Framework will be utilised.

Number of Applications:

Qt: Are you able to expand on the maximum number of projects you can lead/be involved in at both EOI and GC stages?
Ans: For the EOI phase, an eligible organisation can lead on more than one application and can be included as a collaborator in any number of applications. For the CR&D phase, an eligible organisation can lead on no more than two applications and can be included as a collaborator in any number of applications. This has not yet been determined for the Grand Challenge Phase. Further details will be provided in due course.

Scope:

Qt: Is AI technology for sustainable medicine manufacturing within the scope?
Ans: Yes, if it demonstrates a clear benefit within the 3 pillars.

Qt: Are emissions restricted to greenhouse gases or do they include aquatic emissions?
Ans: All emissions associated with medicines manufacturing are within scope.

Qt: Are the manufacture of medical devices in scope?
Ans: Medical devices are not within scope, though combination products (defined as a device pre-filled with a medicine, e.g., an inhaler or pre-filled syringe) are in scope.

Qt: Are there benchmarks for resource efficiency and other sustainability metrics?
Ans: All projects should aim to align with industry standards. Data sharing between organisations will be encouraged.

Qt: Can you elaborate on Green Chemistry?
Ans: Please refer to the slides for examples provided.

Qt: Is this only for human medicine, not the production of medical/surgical devices?
Ans: Non-human medicines are out of scope for these competitions.

Qt: Is product development (e.g., discovery, formulation, pre-clinical, and clinical) included within manufacturing?
Ans: Medicines discovery projects are out of scope, but formulation development and clinical manufacturing projects are within scope if they demonstrate a sustainability benefit.

Qt: Is there potential in fractionation to understand the active components and move to the manufacture of a pharmaceutical active from sustainable agricultural biomass?
Ans: Only human medicines are in scope, and the benefit of sustainability within medicines manufacturing must be demonstrated.

Qt: Are herbal medicines included?
Ans: Herbal medicines are not in scope.

Qt: Are processes for the synthesis of pharmaceutical intermediates/precursors considered for R&D projects?
Ans: Yes, if the project demonstrates a sustainability benefit.

Qt: How far downstream does "the whole supply chain" extend?
Ans: The main focus should be on manufacturing innovation enabling more sustainable medicines manufacturing, including supply to and dispensing from hospital or community pharmacy.

Qt: Would projects where the end user is also the technology developer be supported?
Ans: Yes, as long as the project is technically within scope.

Finding Collaborators:
Please contact colleagues at Business Connect for support in finding a partner. While we have links to many organisations, we cannot guarantee this, so applicants should also independently reach out to potential collaboration partners.

- **Owen Burbidge:** owen.burbidge@iuk.ktn-uk.org
- **Roya Esa-Dabestani:** roya.esat-dabestani@iuk.ktn-uk.org

Collaboration Document:
Given the number of questions regarding finding partners/collaborations at the information webinar, we have created an online collaboration document. This will enable you to input your information regarding your collaboration needs and offerings. It will be released with the EOI competition and periodically updated. You are then free to engage with those companies you are interested in collaborating with.

- Create your collaboration profile

Networking Events:
We are running several face-to-face networking events across the country, as well as an online networking event for those who can't attend in person. These events will give you further opportunities to network, find a partner, ask questions related to the application process, and meet the IUK team. Please note that there are limited spaces for face-to-face events; however, anyone is welcome to attend the online event.

- **Face-to-Face Events:**
  Due to venue capacity, we have limited the number of face-to-face events that you can attend to one per organisation. We reserve the right to cancel places if more than one person from each company has registered.
- **Online Event:**
  The online event on 11th September is open to all and has no restrictions on numbers. We encourage attendance at this event.

We hope to involve members of the Medicines and Healthcare products Regulation Agency (MHRA) and other parties who can support critical enablers (regulation, measurements, standards, and data) in our online networking event.

- Register for these events

Feel free to reach out if you have any further questions or need additional support.