Department for
Science, Innovation
& Technology

Life Sciences Innovative Manufacturing Fund

Scheme guidance

May 2023

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Scheme Overview

The Department for Science Innovation and Technology (DSIT) is reopening the **Life Sciences Innovative Manufacturing Fund (LSIMF)** to support businesses investing in manufacturing projects in the UK.

Over its lifetime, this £60m fund will provide capital grants for investments in the manufacture of human medicines (drug substance and drug product), medical diagnostics and MedTech products.

This could include manufacturing investments in:

- Curative and therapeutic treatments for both population-level and rare diseases (e.g. cell, gene, and nucleic acid therapies)
- Earlier and better detection and diagnosis of disease (e.g. 'breathalysers' for the early detection of cancer or wearable continuous glucose monitors), or
- Smarter pacemakers, tricorders and robotic surgical devices

This list is not intended to be exhaustive.

The scheme has already funded a number of projects. The fund is reopening for a period of one month to allocate the remainder of the £60m.

Scheme Objectives

DSIT aims to build a portfolio across high-quality projects, with Ministers making the final decision on which projects will receive funding.

Applicants will be assessed and prioritised for funding based on their alignment to the fund's objectives:

1. Creating **economic opportunity** through investments that will make a substantial contribution to Gross Value Added and provide high-wage, high-skilled jobs;
2. **Deploying cutting-edge innovations** (at either pilot or commercial scale) which may be embedded in the product itself or within the manufacturing process;
3. Increasing **health resilience** in the UK through increased domestic capacity, or by providing flexible capabilities that have the ability to be re-deployed in a future health emergency;
4. **Minimising impact on the environment** which could include becoming more sustainable through the reduction or use of alternative input resources (e.g. energy, solvents, water, carbon), the minimising of waste or supporting the Government's Net Zero agenda.

Fund Criteria

Manufacturers may apply for the fund if they meet the mandatory criteria below. These criteria will be tested throughout the application and appraisal process to ensure eligibility.

1. Company Type

You must be:

- A UK registered company.
- A wholly private sector business.
- Proposing a project that is a single company investment (as opposed to forming a partnership between companies or other types of organisations).
- A product developer, contract / development manufacturing organisation, or a generics manufacturer.

2. Project Type

Your project can be for the upgrade, expansion or establishment of new manufacturing facilities and is likely to include both building infrastructure (e.g., air handling, the building), buying land and manufacturing equipment.

Your project must:

- Be located in the UK.
- Be a manufacturing project – this could be manufacturing product for clinical trials or for commercial sale.
- Require a specific amount of grant funding to progress. For example, without the specific amount of grant funding you are requesting:
  - The project would not go ahead. In some cases, this might be because other projects have had to take priority over this one;
  - The project would go ahead overseas;
  - The project would be of a smaller size; or
  - The project would be significantly delayed (3 years or more).
- **Not** be publicly announced or planning to announce.

We particularly welcome applications that include the adoption of innovative technologies such as:

- Flexible manufacturing enabling product switching
- Scalable manufacturing
- Novel manufacturing processes
- Technologies that will minimise your impact on the environment
- Continuous manufacturing
- Digital twins, which harness the power of data analytics and modelling to optimise manufacturing processes

This list is not intended to be exhaustive.

3. Sectorial Scope

We will only accept applicants whose projects are to manufacture:

- **Human Medicines** (this includes both the manufacture of Active Pharmaceutical Ingredients (API) / drug substance and finished product / drug product). The fund is open to applications across the breadth of types of MHRA licenced medicines for human use.
- **Medical Diagnostics** – for both disease identification and monitoring in human health.
- **MedTech** – all types of medical devices related to human health.

We particularly welcome applications in the following areas:

- **Complex medicines** such as advanced therapies and nucleic acid therapies, non-biological complex medicines and medicines that require complex delivery mechanisms.
- **Innovative medical technologies** such as nanomedicine applications in imaging, sensing, diagnosis, and delivery through medical devices, 5G enabled devices, smarter pacemakers and 3D printed devices.
- **Diagnostics** such as 'breathalysers' for the early detection of inflammatory and infectious diseases and 'lab on a chip'

This list is not intended to be exhaustive.

We will not accept applications that propose to manufacture:

- Veterinary medicine;
- Herbal medicines;
- Nutritional supplements or vitamins;
- Input materials; or
- Consumables or Equipment suppliers (e.g. vials or syringes).

4. Project Costs and Grant

Project costs

The **minimum total project cost**[1] **for this phase of the fund is £20m**.[2]

You can submit more than one application (to this fund or across other government funds), but they must be distinct investments with separate costs.

[1] Total project costs are capital costs plus wider project costs e.g., R&D costs

[2] We reserve the right to approve projects whose total project costs fall below £20m during the due diligence process

If you are receiving additional public funding for your project, you must explain how much funding you are receiving, which public body is providing the funding and what the funding is for. If you are receiving funding already for this project, this will impact your project value for money assessment.

We also cannot link LSIMF grant funding to other government procurements contracts.

Eligible and ineligible project costs

Although we ask for your total project cost to ensure your overall project meets the minimum threshold, this is a capital grants fund so we can only provide grant funding on your capital costs (tangible assets that can be capitalised using UK Generally Accepted Accounting Practice (UK GAAP)).

All other costs such as those associated with R&D or staff training are ineligible for grant funding, but it is important you tell us about these as they will be considered as part of the economic analysis.

We cannot provide any funding to support overseas projects or to cover costs that weren't for the applicant to bear (i.e., costs that another company within your group will bear). If your project includes internally generated costs, we can only count the actual cost the business incurred.

Note: Any eligible expenditure incurred after the date you have submitted your Application Form (Stage Four of the process below) can be counted towards your total capital costs. **However, until your grant offer letter is signed this spend is entirely at your own risk. We cannot fund any costs incurred before the date you submit your Application Form.**

Calculating your grant request

While your grant request **must** be calculated from the amount of grant funding you can evidence that you need, historically our intervention rate (percentage of grant to your capital costs) to ensure value for money for the taxpayer is 10-20%.

In your application you will be asked to set out your spend profile per financial year and for us this runs from April to March. Whilst your overall spend profile may be for a substantially longer period you will only be able to claim grant for the financial years of 2023-2024 and 2024-2025. Your final grant claim must be submitted by March 2025.

5. Regulatory Requirements

Medicines Manufacturers

You must hold or intend to apply for either a:

- Good Manufacturing Practice (GMP) Human Medicines licence; or
- Investigational Medicinal Products Directive (IMP) licence.

These must be issued by the MHRA. https://www.gov.uk/guidance/apply-for-manufacturer-or-wholesaler-of-medicines-licences

During the appraisal of your application, you may be required to explain where you are in the process of obtaining one of these licences. If this is unclear, we may not be able to proceed in assessing your application.

If you have stated that you will be applying for a site licence from the MHRA and your application is successful, we will seek evidence of this as part of the monitoring process (Stage Eight of the process below), which will start once your grant offer letter is signed.

Medical Diagnostics and MedTech Device Manufacturers

Your device must either meet the requirements of the Medical Devices Regulations 2002 (as amended), including safety and performance, or be in process of meeting the requirements. Standards, both horizontal and product specific, can be used to demonstrate compliance. The list of designated standards can be found here.

If it is unclear how your device will meet these standards, we may not be able to proceed, and your application will be unsuccessful. If your application is successful, we may seek evidence to demonstrate compliance during our monitoring process.

6. Subsidy Control

The LSIMF will provide funding in line with the UK's obligations and commitments to Subsidy Control. Further information about the UK Subsidy Control requirements can be found within the EU-UK Trade and Cooperation agreement.

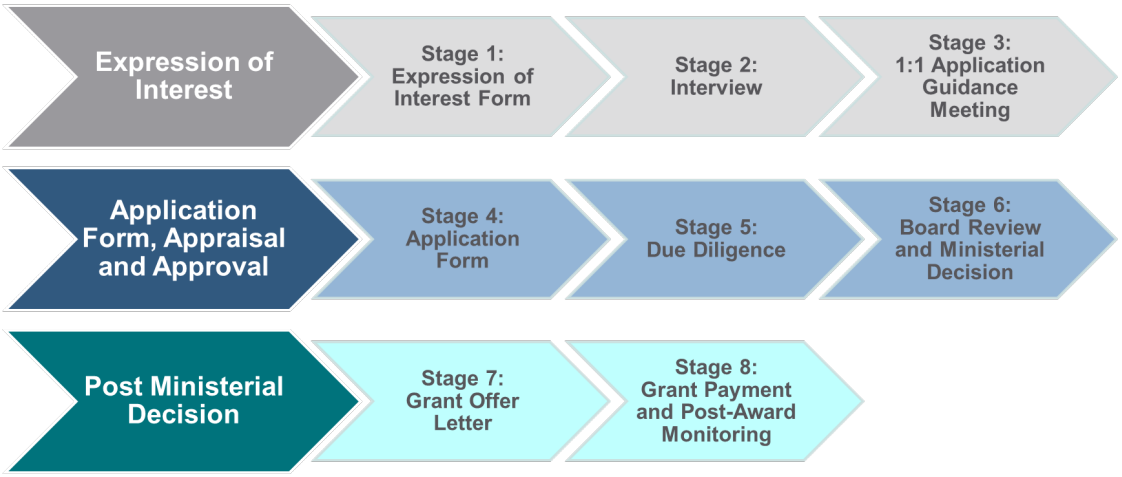
If you are an applicant receiving subsidy (grant) in respect of activities that will affect trade of goods and electricity between Northern Ireland and the EU then Article 10 of the Protocol on Ireland/Northern Ireland in the EU Withdrawal Agreement will apply, and aid will need to comply with EU State aid rules. This will be of primary application in Northern Ireland.

In certain very limited circumstances, the European Commission State aid rules may also apply if you are an organisation located in England, Wales, or Scotland and conduct activities that affect the trade of goods and electricity between Northern Ireland and the EU. For further information, please see the Department for Business and Trade (DBT) technical guidance .

If your application is successful, recovery of funds would be required in the event of non-compliance with subsidy control requirements.

All grant awards will be made under Section 7 or 8 of the Industrial Development Act 1982 https://www.legislation.gov.uk/ukpga/1982/52/contents.

Formal Appraisal Process



Stage 1: Expression of Interest form

We will use an Expression of Interest (EOI) form to identify projects that have a strong fit with the fund's objectives of increasing health resilience, deploying cutting-edge innovations and minimising the impact on the environment (see Scheme Objectives for full details). We will ask questions on the objective 'Creating economic opportunity' in the Application Form.

The EOI form will cover the following three areas:

1. Company details
2. Eligibility
3. Project details and benefits

Once your Expression of Interest Form has been submitted, DSIT will appoint a Case Officer who will act as a point of contact for you throughout the process.

Applicants that demonstrate eligibility and alignment with the fund's objectives will be invited for a 30-minute interview. Those that are not eligible or show no alignment with our objectives will be informed that they are unsuccessful.

Stage 2: Interview with Expert Panel

At the interview you will be asked to give a five-minute presentation summarising your investment to the Expert Panel. The remaining 25 minutes are allocated to the Panel to ask you questions and to assess your project's alignment with the fund's objectives.

The Panel will score each project according to our scoring matrix. Applicants with a strong alignment to the fund's strategic objectives will be invited to submit an Application Form, all other bids will be notified they are unsuccessful.

Your interview will take place on MS Teams. If you have any technical difficulties regarding access to MS Teams, please contact LSIMF@officeforlifesciences.gov.uk

You will be asked to nominate three people who will present your project to the Panel. You must provide your nominations before the deadline stated in the invitation email.

If you are successful at this stage, you will be invited to complete our Application Form.

Stage 3: 1-2-1 Application Guidance Meeting

If you are successful at Stage Two, you will be invited for a call to discuss what information you will need to complete the Application Form and outline the way the Due Diligence process will work.

Stage 4: Application Form

After the meeting we will send you a link to our online Application Form and this must be submitted by the deadline agreed in your 1-2-1 Application Guidance meeting.

You must complete all questions in the Application Form; an incomplete form cannot be submitted. Please ensure that you have responded to all questions in full to avoid delays in submitting your Application Form.

Stage 5: Due Diligence

The Due Diligence stage consists of an economic, financial, project delivery, risk analysis and subsidy control assessment of your application. Within these assessments we will consider the evidence to support the funding and need for the grant, the expected outcomes, and the deliverability of the project. We will also assess (amongst other things) factors such as value for money and additionality, in line with Green Book guidance. The result of these assessments will culminate into a Due Diligence report.

The Green Book guidance is aimed at public servants and sets out an approach of appraising policies, programmes, and projects. There is no requirement for you to ensure compliance with the Green Book, but as this guidance document's principles will be used to assess all bids to the fund, it may be a useful point of reference.

During the Due Diligence stage, your Case Officer may request further details about your application. It is essential that these requests are responded to within the time specified (as set out by the Case Officer). Failure to do so may result in your application being rejected.

Requests for further information may cover a range of topics and may include a request to supply executive decision-making documents supporting the proposed project (for example, demonstrating the approval of authorised individuals to apply to the fund).

During the Due Diligence stage, your grant request may be lowered to ensure it is compliant with the Green Book, Managing Public Money or state aid rules.

Stage 6: Board Review and Ministerial Decision

Once Due Diligence is complete, the LSIMF Programme Board will review your Due Diligence report to decide if your application should be recommended to Ministers or rejected.

If your grant request is over £5m the statutory body Industrial Development Advisory Board (IDAB) may also be required to provide Minister's financial and commercial advice. We may require a meeting with you to discuss any additional information that IDAB require while you are undergoing Due Diligence, but there is no further action for you at this stage.

You will be notified without delay if the Programme Board decides your application is unsuccessful.

Ministers will make the final decision on awarding the grant, taking account of the strength of your application's alignment to the fund's objectives, any concerns raised at Due Diligence, the recommendation from the Programme Board and any advice from IDAB.

Stage 7: Grant Offer Letter

If your application is successful, DSIT will set out the terms of the grant in a grant offer letter. The letter will include details such as the amount of grant offered and the profiling of the grant across the years. The amount of grant offered will be non-negotiable.

An example of a grant offer letter can be found on the landing page, please note that the terms in your specific grant offer letter may differ.

Once you have received your grant offer letter, you must confirm within 10 working days (or such other time as DSIT reasonably requires) whether you will accept the terms and conditions of the grant offer and proceed with the project. Failure to do so could result in the offer being retracted by DSIT.

For companies within a Group, we will require either a Parental Undertaking Guarantee from your ultimate parent company or a guarantee from a bank with an investment grade credit rating. This is compulsory and must be provided. Failure to do so will result in the grant not being issued.

Stage 8: Grant Payment and Post-Award Monitoring

A Monitoring Officer will be appointed to you for the duration of your project to ensure value for money and deliverability. The Monitoring Officer will explain the monitoring requirements, which will be in line with the Managing Public Money guidance.

The grant will be paid in arrears on receipt of a completed claim form and supporting evidence, such as invoices and bank statements, to demonstrate that the amount you have submitted in your claim form has left your bank account. You can submit more than one claim form throughout the life of your project.

Grant recipients will typically need to complete and provide monitoring reports on a quarterly basis (or more regularly where the Grant Funding Agreement sets this out). All relevant information will be provided in the grant offer letter.

You may be contacted at various stages for evaluation purposes to help inform the design and development of future schemes.

Expected timings of the formal appraisal process

Assessment	**Timings**
EOI and interview	No longer than one month from the end of the month that you submitted your EOI form in.
Due diligence	Approximately 10 weeks dependent on your ability to respond promptly to clarification questions and provide complete information.
Board and Ministerial approval	Likely to take four to six weeks

We will keep you informed of the outcome of each stage in a timely manner. If you have any concerns over your progress, please contact LSIMF@officeforlifesciences.gov.uk

Applicant Support

We have tried to include answers to most of the questions you will have in this scheme guidance. Please review these carefully but if you do have any unanswered questions, you can send them to us at LSIMF@officeforlifesciences.gov.uk with the subject heading: LSIMF Application Clarification [Project title].

If the answer to your question might be useful to other applicants (or potential Applicants), we may use a non-identifiable version of your question and answer to create a FAQ document that we will publish on the landing page.