Funding Guidance for

MedTech Accelerator:

Rapid Regulatory Support fund

cpi

Version 1.0 03/10/24

This document is intended to give guidance to applicants regarding the process, governance arrangements and funding rules for the MedTech Accelerator: Rapid Regulatory Support fund.

You should read and understand this document before you submit your application.

If you are successful, these rules along with the Grant Offer Letter and the Terms and Conditions will govern the contract between you and CPI, who is delivering this UK Government funded MedTech Accelerator on behalf of the Office of Life Sciences.

Contents

Grant funding process

The MedTech Accelerator: Rapid Regulatory Support fund involves a competitive process to apply for grant funding to support with the costs of external regulatory affairs provider. Companies working in MedTech can use this regulatory support to help gain regulatory approval to place their product on the market, or to retain or expand regulatory approval so their product may remain on the market.

Submit your application here: https://forms.office.com/e/iyqc4EL4HQ

The **application assessment process** involves three steps:

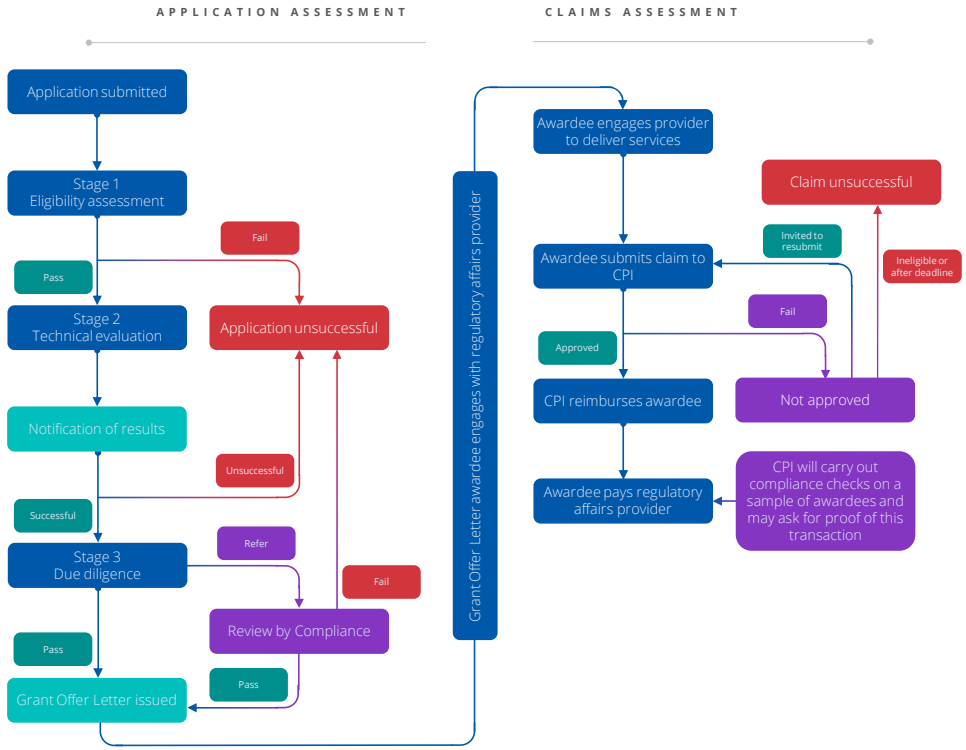
- Eligibility assessment – a pass/fail check of eligibility for participation
- Technical evaluation – each application will be scored by three independent reviewers
- Due diligence – a pass/fail check of the applicant and their nominated regulatory affairs provider. We reserve the right to stipulate additional conditions upon the funding to mitigate any risks identified during the due diligence checks.
- We will also contact you to verify bank details for future fund transfer

If an application passes the checks and is one of the highest scorers, then CPI will issue a Grant Offer Letter. This will enable the successful applicant (the awardee) to commence work with the regulatory affairs provider.

The **claims assessment process** involves submitting:

- Correctly completed claim form and subsidy control declaration
- An invoice from the agreed regulatory affairs provider as evidence

The grant funding process is illustrated on the page opposite.



Regulatory activities

The range of support required by companies seeking to gain regulatory approval and that offered by regulatory affairs providers is broad. The project team therefore does not want to be overly prescriptive in the types of support that are eligible, within the description of regulatory affairs.

Illustrative examples of the types of support you could request in your application include:

- Regulatory strategy
- Guidance on technical file development
- Clinical guidance for regulatory affairs
- Guidance on standards
- QMS
- Global registrations
- Guidance on UKCA, MDR, IVDR, FDA etc.
- Mock audits
- Remedial actions
- Advice on reimbursement models
- Notified body costs
- Regulatory training for staff

Eligibility

To be eligible for funding on this programme you must be an SME, registered in the UK, and developing or manufacturing a medical device or IVD product or service.

Definition of an SME

We will apply the SME definition as per Companies House accounts guidance. An extract is shown below, but full details are available on the UK government website at: https://www.gov.uk/government/publications/life-of-a-company-annual-requirements/life-of-a-company-part-1-accounts#medium-sized-company-accounts

A **micro-entity** must meet at least two of the following conditions:

- annual turnover must be not more than £632,000
- the balance sheet total must be not more than £316,000
- the average number of employees must be not more than 10

A **small company** must meet at least two of the following conditions:

- annual turnover must be not more than £10.2 million
- the balance sheet total must be not more than £5.1 million
- the average number of employees must be not more than 50

To be a **medium-sized** company, you must meet at least two of the following conditions:

- the annual turnover must be no more than £36 million
- the balance sheet total must be no more than £18 million
- the average number of employees must be no more than 250

Definition of UK based

Your company needs to be registered with Companies House in the UK

Applications will only be accepted from and will be awarded to a single legal entity. Only one application per company or company group is allowed.

Definition of MedTech

Applications must be from a company which is **developing** or currently **producing and selling** medical devices, software or IVD device as they are outlined in the:

- Medicines & Medical Devices Act 2021 (https://www.legislation.gov.uk/ukpga/2021/3/enacted)
- Or with EU CE Mark requirements set out in the Medical Devices Regulation (EU) 2017/745 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745) or In Vitro Diagnostic medical devices Regulation (EU) 2017/746 (https://eur-lex.europa.eu/eli/reg/2017/746/oj).

Selecting your regulatory affairs provider

You are responsible for identifying a regulatory affairs provider prior to applying. CPI does not hold a list of providers and is not permitted to make any recommendation of one to work with. You must conduct your own due diligence and whether the provider can carry out the work required for you.

Due diligence

CPI will carry out its own due diligence on your nominated provider to ensure they are a bona fide business, with the capability to provide regulatory support. However, CPI makes no representation or guarantee as to the quality of their services. It is your responsibility to ensure the provider is competent to provide the services you need and manage the work to ensure the services are delivered to your specification.

You should use a UK based regulatory affairs provider wherever possible, and if you nominate a non-UK based provider you must explain why it is not possible for you to use a UK-based provider in your application.

Conflict of interest

To prevent an unacceptable conflict of interest between applicant and regulatory affairs provider your nominated provider must not be linked to your business, examples include but are not limited to the following:

- sharing the same shareholders and/or directors and/or management team, or
- corporate shareholding linking the organisations, or
- personal relationship between representatives of the organisation

Conflict of interest between applicant company and regulatory affairs provider increases the risk of collusion between parties to defraud the grant funding scheme. We accept trading between associated companies is generally legitimate and sometimes commonplace, but your provider must be independent and not employed by your company.

As a precaution and part of our anti-fraud measures, CPI has decided it will not award funding where we determine there is a conflict of interest between applicant and provider. If time permits, applicants who have passed Stage 1 and Stage 2 but fail at the regulatory provider due diligence check in Stage 3 of the process will be invited to nominate another regulatory affairs provider.

Working with your provider

If you are successful in your application and issued with a Grant Offer Letter, you may commence the engagement with the regulatory affairs provider.

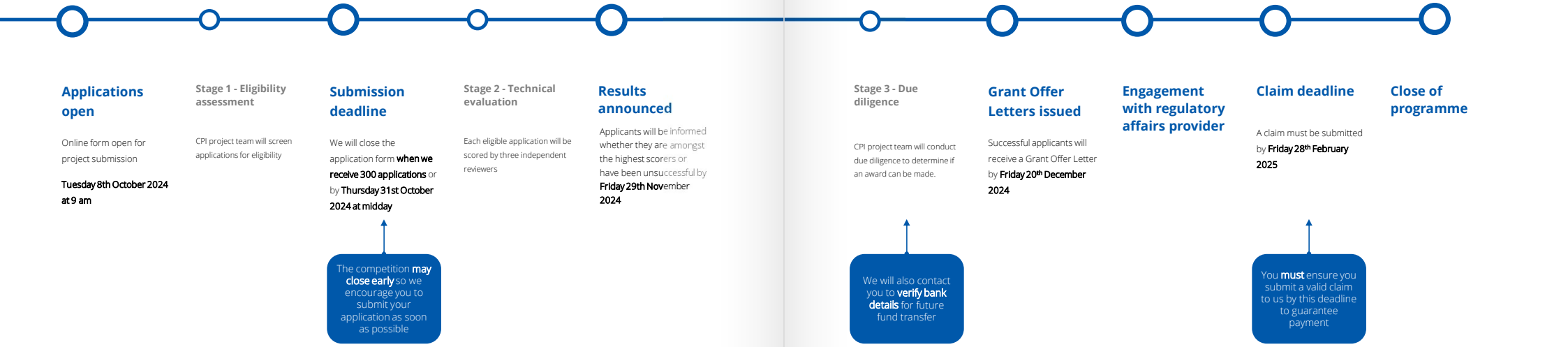
Work commenced before the date of the Grant Offer Letter, or any invoices dated prior to the Grant Offer Letter are not eligible for reimbursement.

You have discretion to agree contractual terms with your regulatory affairs provider, subject to the following stipulations:

- Your provider must send you a valid invoice or set of invoices for the work so that you can claim reimbursement from CPI. You can only make a claim for work that you have been invoiced for, irrespective of whether the services have been supplied in full at the date of making a claim.
- You must transfer payment to your provider within 30 days of receiving payment from CPI or when the invoice falls due, whichever is the sooner.

While we appreciate it would be preferable to pay the supplier when work is completed, for the purpose of fraud prevention we must ensure the funding is used as intended, and this is how we plan to do that.

Programme timeline



Due diligence

The purpose of CPI conducting due diligence is to ensure the responsible investment of public funding, and to minimise the risk of misuse. CPI will carry out due diligence on successful applicants and their nominated provider before issuing a Grant Offer Letter, to confirm identify, eligibility and identify any conflict of interests.

The following due diligence checks will be conducted on the applicant:

Companies House

- Verify identity of applicant as per application
- Review company status
- Look for winding up petitions or similar
- Look for conflict of interest with regulatory affairs provider

Credit check

We currently use Credit Safe but may use a different reputable provider.

- Verify that there are no outstanding CCJs or similar
- Review highlighted compliance alerts, such as director convictions
- Review indicative financial risks rating. Due consideration will be given where the credit risk is high, but the company is small or a start-up.

We will also contact you to verify bank details for future fund transfer

The following due diligence checks will be conducted on the regulatory affairs provider:

- Companies House check to verify the identity of the provider as per the application.
- Check the provider has sufficient capacity and capability to provide regulatory services. The provider will be required to complete a short questionnaire to ascertain this.
- If the provider is not UK based and we cannot verify their identity using Companies House, we will use an international credit check to verify the business exists. We will also review the justification provided by the applicant as to why a UK based provider cannot provide these services.
- If provider is not incorporated or has existed for less than three years, we may request references.

Using all the information gathered, we will check for a conflict of interest between the applicant and the nominated regulatory provider, as described on page 9.

When a risk is highlighted during due diligence it will be referred to our compliance team who may contact you for more information, and/or we may look to insert additional conditions to the offer of funding to mitigate the risk of awarding funding. Where a risk is highlighted that cannot be sufficiently mitigated, the application will be rejected.

Funding and subsidy control

This funding is awarded under the provision for Minimal Financial Assistance in the Subsidy Control Act 2022. You can find out more about the UK's Subsidy Control Regime here https://www.gov.uk/government/publications/subsidy-control-a-guide-for-beneficiaries/subsidy-control-a-guide-for-beneficiaries. We recommend you read section 7. Minimal Financial Assistance.

You will be required to declare the amount of funding you have received in the current and two previous fiscal years under the following schemes:

- De Minimis Aid in accordance with EU state aid regulations
- Small Amounts of Compatible Aid in accordance with Article 364.4 of the Trade and Cooperation Agreement between UK and EU [OJ L 149/10 [30 April 2021]
- Minimal Financial Assistance as defined under section 42(8) of the Subsidy Control Act 2022

The MFA provision states businesses can receive a maximum of £315,000 over three financial years.

We will use the information in your application to verify whether you have the capacity to receive the funding under MFA, we will issue a Subsidy Control Letter as part of the Grant Offer Letter, the declaration from this letter must be completed and returned before our payment can be issued to you.

CPI will publish the value of assistance provided to successful applicants on its website for a short period of time in accordance with provisions for transparency under the Subsidy Control Act

Value of grant funding

You are required to state the value of grant you are applying for in your application, up to a maximum of £30,000. The amount paid to you will be the value of the invoice submitted in your claim, or the awarded amount, whichever is less

Documentation retention

You must retain evidence to show the money received has been paid to the regulatory provider

Documentation relating to this grant funding programme must be retained for seven years from the date of payment

Claw back and unspent monies

CPI reserves the right to request full and prompt repayment of the funding if you breach the terms of the funding agreement or terms and conditions.

If, for any reason, you are unable to carry out the agreed activities with the regulatory affairs provider, or the cost of the services provided to you is lower than the funding you have received from CPI, you must return any unspent monies to CPI.

Claims process

CPI has designed this grant funding scheme to be as accessible as possible, particularly for small businesses who may have cashflow pressures.

Your claim must be submitted by 28th February 2025. Claims received later than this may not be paid.

To make a valid claim you must send an email to the Project Support Team with the following:

- A completed claim form, which will be issued to you along with the Grant Offer Letter
- Completed subsidy control declaration, which forms part of the Grant Offer Letter
- A valid invoice from your provider (see opposite page)

You must also have completed an industrial survey about challenges and opportunities in the UK MedTech industry, which will be sent to you separately.

CPI will endeavour to review your claim as quickly as practicable. We aim to pay claims within five weeks of the receipt of a valid claim. We will contact you by email to confirm that your claim has been accepted.

Submit a claim to:
medtech.accelerator@uk-cpi.com

Claim Deadline

8th February 2025

Eligible costs

Must be incurred with your approved regulatory affairs provider

Must be incurred after the project start date as defined in your Grant Offer Letter

Must be linked to the MedTech product or service described in your application

Must be for in scope activities relating to meeting regulatory obligations.

Ineligible costs

Your staff time and the normal costs of business

Costs for technical research and development

The purchase of equipment or software, including QMS software or regulatory guidance software

Costs incurred before the start date as defined in your Grant Funding Award

VAT, where you are VAT registered

Invoices

Your regulatory affairs provide must issue you with a valid invoice for the work for you to claim your funding from CPI. Please see guidance as to what constitutes a valid invoice here: https://www.gov.uk/invoicing-and-taking-payment-from-customers/invoices-what-they-must-include

If the provider is registered for VAT, this must be a valid VAT invoice.

We can only reimburse invoices from your approved provider, if any of the work was subcontracted, you must ensure the invoice is issued by your provider to you.

Payment to you

Upon receipt of a valid and verified claim, CPI will make a transfer of funds to you, the awardee. Funds can't be transferred directly to the regulatory affairs provider as they are not the recipient of this award, and you must have a valid UK business bank account to receive funds.

Invoices in currencies other than sterling will be converted to sterling using the Bank of England rate on the date of invoice and paid in sterling. We will not reimburse fees relating to transferring funds into a different currency.

During the initial application due diligence phase a member of our finance or compliance team may contact you be telephone to confirm your bank details as part of our fraud prevention procedure.

Paying your provider

The invoice(s) submitted with your claim do not need to have been paid. However, after receiving funds from CPI, you must pay the invoice(s) promptly, transferring the money to your regulatory affairs provider when the invoice falls due or within 30 days of CPI's payment to you, whichever is sooner.

While we appreciate it would be preferable to pay the provider when work is completed, for the purpose of fraud prevention we must ensure the funding is used appropriately, and this is how we plan to do that.

CPI will carry out compliance checks and may request proof of payment. We will require confirmation that a payment has been made from your bank account to your approved provider, such as a bank statement or extract from online banking.

CPI has no liability to regulatory affairs providers in the case of non-payment by the applicant company. However, CPI will take action to recover funding from applicants in cases where they have received funding from CPI but failed to make payment to their approved provider within 30 days.

Fraud prevention and detection

The funding for this programme comes from the public purse, and as such, CPI is committed to ensuring taxpayers receive best value for their investment. CPI is committed to preventing and detecting fraud on its publicly funded programmes, and ensuring money is spent appropriately.

We will do this through conducting proportionate due diligence and compliance checks throughout the programme.

At application stage, we will:

- Review the information submitted in your application and decide on a pass/fail basis whether the proposed activities and costs are within the scope of this funding
- Conduct due diligence upon the applicant and regulatory affairs provider, including a conflict of interest check between the parties.

When we receive a claim, we will:

- Check the funding has been used only for the purpose set out in your application and confirmed in the Grant Offer Letter. This includes checking that the invoice is valid and is from the agreed provider.
- Has not been used for a purpose not permitted, including, but not limited to normal business costs, staff costs or costs which would be ineligible as per this guidance.

When we make a payment to you, we will:

- Verify your bank details before making a payment to you. A member of our finance or compliance team may phone the person nominated in your application form to confirm the bank details submitted are correct and valid

To monitor ongoing compliance, we will:

- Conduct follow-up compliance checks to ensure that funding has been transferred to the regulatory affairs provider.

CPI is committed to ensuring taxpayers receive best value for their investment

Claw back and unspent monies

CPI reserves the right to request full and prompt repayment of the funding if you breach the terms of the funding agreement or the terms and conditions of the programme.

This includes but is not limited to:

- You receive the grant funding from CPI but hold on to it rather than transferring it to your nominated regulatory affairs provider.
- You spend the money in any way other than in payment of the submitted invoices

If, for any reason, you are unable to carry out the agreed activities with the regulatory affairs provider, or the cost of the services provided to you is lower than the funding you have received from CPI, you must return any unspent monies to CPI.

Variations

Written approval for any variation must be sought from CPI prior to making the variation. Variations we may consider include:

- A change of regulatory affairs provider
- A change of work scope

It is not possible to request an increase in the grant funding awarded to you, even if you requested less than the maximum amount and your regulatory costs are higher than anticipated.

Reducing the value of the grant awarded to you is not a variation that requires approval. In this case you would submit your claim with supporting invoice(s), and we would process the payment for this lower amount.

MedTech Accelerator: Rapid Regulatory Support fund

If you have any questions about this programme, please contact the Project Support Team at:

medtech.accelerator@uk-cpi.com

APPLICATION

- Application Form
- Terms and conditions

MORE INFORMATION

- **Competition Page**
  https://www.uk-cpi.com/medtech-accelerator-rapid-regulatory-support-marrs-programme
- **Further information**
  https://www.uk-cpi.com/rapid-regulatory-support