

## Grant Recipient Terms and Conditions for the Health Technology Regulatory and Innovation Programme

- A. These terms and conditions (including the Schedules) apply to **Health Technology Regulatory and Innovation Funding (“Funding”)** offered to grant recipients under the Health Technology Regulatory and Innovation Programme (“**Programme**”). In these terms “**we**” and “**us**” refers to Centre for Process Innovation Limited (“**CPI**”) and “**you**” and “**your**” refers to the SME applying for the grant.
- B. By submitting an application, you agree to these terms and conditions which have been made available to you on commencement of your application and are also available from the Programme website which can be found at <https://www.uk-cpi.com/healthtech-regulatory-support>.

### Definitions

In these terms and conditions, we use various terms which are shown in this definitions section. Where these definitions are used, they will have the meanings set out below:

“**Data Protection Legislation**” means all applicable data protection and privacy legislation in force from time to time in the UK including the UK General Data Protection Regulation (UK GDPR); the Data Protection Act 2018 (DPA 2018) (and regulations made thereunder) and the Privacy and Electronic Communications Regulations 2003 (SI 2003/2426) as amended and all other legislation and regulatory requirements in force from time to time which apply to a party relating to the use of personal data (including, without limitation, the privacy of electronic communications).

“**Group**” means any undertaking which is your subsidiary undertaking or parent undertaking or a subsidiary undertaking of your parent undertaking, as defined in section 1162 of the Companies Act 2006.

“**Regulatory Provider**” means the company providing regulatory support to you as the grant recipient, which includes the activities listed on the Programme’s website including but not limited to mock audits, clinical guidance pertaining to regulatory affairs, guidance of technical file development and notified body costs.

“**SME**” means a Micro, Small and Medium Enterprise based on staff headcount and either of turnover or balance sheet total under *SME definition | Internal Market, Industry, Entrepreneurship and SMEs (europa.eu)* namely;

| Company category | Staff headcount | Turnover | or | Balance Sheet Total |
|------------------|-----------------|----------|----|---------------------|
| Medium-sized     | < 250           | ≤ €50m   |    | ≤ €43m              |
| Small            | < 50            | ≤ €10m   |    | ≤ €10m              |
| Micro            | < 10            | ≤ €2m    |    | ≤ €2m               |

These ceilings apply to the figures for individual firms only. A firm that is part of a larger group may need to include staff headcount/turnover/balance sheet data from that group too.

## 1. Eligibility for the Programme

- 1.1. The Funding supports SMEs who are currently selling or are developing products in the medical technology, health technology and diagnostics (including in-vitro diagnostics) space (“**Health Technology Industry**”) to get regulatory advice and support. This is currently especially pertinent as the UK and the EU have seen changes to medical device and in vitro diagnostic device regulations which will affect UK industry. This Programme seeks to offer support to the UK Health Technology Industry to mitigate these changes. For the avoidance of doubt, we include medical technology, diagnostics/in-vitro diagnostics and software as a medical device as eligible.
- 1.2. The Programme is open for applications between 9am on 14<sup>th</sup> February 2022 and midday on 31<sup>st</sup> May 2022. For you to be eligible to qualify for Funding and be paid that Funding you must fulfil the following criteria both at the point of application for Funding and also, if you are successful, when that Funding is paid to you:
  - 1.2.1. Applications must be from a UK Companies House registered SME company which is developing or currently producing and selling Health Technologies 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 Regulation (EU) 2017/745 (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745>) or Regulation (EU) 2017/746 (<https://eur-lex.europa.eu/eli/reg/2017/746/oj>).
  - 1.2.2. When you apply for Funding you must provide details to us of the Regulatory Provider you intend to spend your Funding with if you are successful. If that Regulatory Provider is not UK based, you will need to explain to us why you intend to use them. We suggest that you provide details of your Regulatory Provider to us before you issue a purchase order to them so that we can check their eligibility for this Programme. For their advice to be eligible for this Programme your Regulatory Provider must:
    - 1.2.2.1. be a corporate or other legal entity, registered with Companies House, which has been trading for 3 years or more (if the entity has not been trading for 3 years references are required);
    - 1.2.2.2. have and provide evidence on our request of delivering services such as those listed in the Regulatory Provider section of our website;
    - 1.2.2.3. have the ability to deliver at least one £30,000 project in accordance with the agreed specification for this Programme by 5pm on 19<sup>th</sup> August 2022.  
You will need to tell us and gain our approval if you wish to change your Regulatory Provider during the Programme.
  - 1.2.3. Any Funding you receive must not cause you or your Group to exceed the Special Drawing Rights limits under UK subsidy control rules which are detailed in paragraph 3 below.
  - 1.2.4. You must be prepared to support our promotion of the Programme, including providing information for a case study and taking part in any Programme evaluation surveys.

- 1.2.5. Your company must be based within the UK. Companies that have most of their activities outside of the UK but have a company registered in the UK for functions such as regional sales, are excluded from receiving Funding.
  - 1.2.6. You must have told us whether you are registered for VAT.
- 1.3. We reserve the right to determine in our absolute discretion whether you and your Regulatory Provider are eligible for Funding both at the point of your application and also, assuming you are successful, when you claim that Funding. We also reserve the right to withdraw your registration from the Programme if, for any reason we identify that you and / or your Regulatory Provider is ineligible. If this happens your ongoing claim may not be paid as a result. We therefore urge you to carefully check your eligibility on an ongoing basis. If you have any questions please ask us.

## **2. Funding**

- 2.1. The total funding available for the Programme is £6,390,000 however this may change. This funding is being awarded under Article 3.2(3) of the Trade and Cooperation Agreement between the European Union and the United Kingdom.
- 2.2. Funding available for each grant recipient is up to £30,000.
- 2.3. We reserve the right to adopt a portfolio approach across the competition. We do this to ensure that there is a diversity of sectoral applications for the Funding.
- 2.4. We reserve the right to stop issuing Funding at any time.
- 2.5. Funding must be used with a Regulatory Provider you have notified to us in your application for Funding or subsequently had approved by the Programme team.
- 2.6. We reserve the right to carry out checks on both applicants and Regulatory Providers and to pursue funds released through any fraudulent activity, including with respect to eligibility.
- 2.7. Our decisions in relation to the Programme including but not limited to eligibility of applicants, eligibility of Regulatory Providers and decisions whether to award Funding / the amount of any Funding awarded are final. We will not enter into correspondence relating to our decisions.

## **3. Subsidy Control**

- 3.1. As the Programme is publicly funded, the Subsidy Control regime under the Trade Cooperation Agreement applies to the Programme. The Subsidy Control regime allows for companies (including their Group) to obtain small amounts of financial assistance outside of the Subsidy Control regime (SAFE). SAFE allows the receipt of a subsidy of 325,000 Special Drawing Rights (approx. £335,000) per SME or Group over any period of three fiscal years, including the current year. Innovate UK provide a

useful description of this here <https://www.ukri.org/councils/innovate-uk/guidance-for-applicants/general-guidance/funding-rules/>.

You are advised to read the section entitled “*Special Drawing Rights (“SDRs”) and EU de minimis awards*”.

- 3.2. As you / your Group cannot receive more than 325,000 Special Drawing Rights over a period of three fiscal years, including the current year, you must declare to us whether funding you receive through this Programme would cause you or your Group to exceed the Special Drawing Rights limit. You will be ineligible for any funding under SAFE which exceeds the Special Drawing Rights limit. The obligation to declare is ongoing throughout the Programme and you must immediately notify us if you or your Group’s entitlement to funding changes in any way.
- 3.3. In the event you become ineligible at any point during the Programme, we will have the immediate right to cancel, suspend or withdraw your participation in the Programme and you will be required to immediately repay the Funding paid to you.

#### **4. Your responsibilities**

- 4.1. You are responsible for checking that you meet and continue to meet the eligibility requirements for the Programme.
- 4.2. You will be asked to self-certify to us that you meet the eligibility criteria in paragraph 1.2 above.
- 4.3. You are responsible for providing to us, as soon as is practicable, all the information reasonably requested by us concerning your application to the Programme, including any additional information that we may consider necessary for the purposes of processing your Funding, deciding on your award amount, considering your or your Regulatory Provider’s eligibility or in relation to the operation of the Programme. If you do not respond to any reasonable request for information within 14 days, we may decide to decline your application or, where relevant, withdraw our offer to you of Funding.
- 4.4. We are unable to provide details of Regulatory Providers. You should undertake your own research and due diligence checks to satisfy yourself of the standing and suitability of any Regulatory Provider you plan to use and propose to us.
- 4.5. You agree to provide reasonable information and assistance to support our promotion of the Programme, including providing information for a case study and taking part in any Programme evaluation surveys.
- 4.6. Any Funding awarded by us to you must be used no later than 31<sup>st</sup> August 2022. This date may be subject to change which would be publicised on our website if relevant. If the Regulatory Provider is not able to deliver the relevant services and you cannot

use the Funding with another Regulatory Provider we have approved by this date, then the Funding will expire and the Funding will be no longer be available to you.

4.7. You may only participate in the Programme and benefit from Funding up to the limit of the Funding awarded to you. You must pay any additional costs of the advice you receive from your Regulatory Provider yourself.

4.8. Your Funding award must be continue to be valid at the point of redemption and the Regulatory Provider whose services you are claiming in respect of must match the details you have provided to us and we have approved (either in your application or, subsequently). Payment will be made only on the basis of a complete and valid claim which meets all requirements. Missing, incomplete or unclear information may delay processing and may result in your claim being rejected.

Once your Regulatory Provider has provided the agreed services to you, they will invoice you. You must provide the Regulatory Provider's valid invoice to us in order to redeem your Funding. Remember that we need your valid invoice no later than 31<sup>st</sup> August 2022. Once we have your valid invoice we will pay you the eligible costs of the support you have received up to the level of your Funding award within approximately 4 weeks following our receipt of a valid invoice. You must use these funds to pay for the support you have received and for no other purpose.

Where you are registered for VAT our payment to you will not include the VAT charged on the invoice on the basis that you can reclaim this VAT in the ordinary course. If you are not registered for VAT our payment to you will be VAT inclusive.

Payment is conditional on you agreeing to support our promotion of the Programme, including providing information for a case study and taking part in any Programme evaluation surveys.

4.9. You must keep and maintain for a period of 7 years after your expenditure of the Funding, adequate and proper records and books of account recording any receipts and expenditure of monies paid by us and allow us to audit that information on request by us.

4.10. You must immediately inform us of any changes to the information submitted in your application. Changes will need to be reviewed by us to determine if they impact your eligibility for the Programme. Changes to your submitted information or failure to inform us of these changes could result in you being withdrawn from the Programme and any ongoing claims/monies not being paid to you as a result.

4.11. You must not do or omit to do anything which would cause us to breach the terms and conditions of the grant offer letter which applies to the Funding and the Programme. If you have any questions, please ask.

## **5. Liability**

5.1. We accept no liability for any work/services / advice undertaken by Regulatory Providers and/or advice given to you by the Regulatory Provider. It is your responsibility to choose

your Regulatory Provider and the responsibility of the Regulatory Provider selected to ensure that the advice and support given to you is correct.

- 5.2. We accept no liability, whether direct or indirect, for errors you may make in your application for a Funding or for any consequences which may arise from your participation in the Programme, including, but not limited to, liability for any damages or other costs arising from or associated with the Programme.
- 5.3. We accept no liability for incomplete, false or misleading information given by you. Where incomplete, false or misleading information is given to us by you, we reserve the right to either cancel your Funding or reclaim the Funding value from you in full. To the extent that our liability has not been excluded, our liability for any Losses will be limited to the value of the Funding issued to you.
- 5.4. In circumstances where you suffer loss or damage arising out of or in relation to these terms and conditions, we accept no liability and will not reimburse you for any losses.
- 5.5. You indemnify and hold harmless CPI with respect to all actions, claims, charges, demands, Losses and proceedings arising from or incurred by reason of your actions and/or omissions in relation to your participation in the Programme, the non-fulfilment of obligations by you under these terms and conditions, your obligations to third parties or your Regulatory Provider or their obligations to you.

Nothing in these terms and conditions shall limit any of our liability that cannot legally be limited.

For the purposes of this Clause “**Losses**” means all losses including (but not limited to) indirect and consequential loss, loss of profit, reputation and/or goodwill liabilities, damages, costs, expenses (including legal fees), disbursements, costs of investigation, litigation, settlement, judgment, interest and penalties whether arising in contract, tort (including negligence), breach of statutory duty, misrepresentation or otherwise and Loss will be interpreted accordingly.

## **6. Data Protection**

- 6.1. Where applicable, we and you agree to comply with all applicable Data Protection Legislation. Any personal data (of your employees, company representatives or otherwise) provided by you to us will be used in accordance with our privacy statement located at <https://www.uk-cpi.com/legal/privacy>
- 6.2. We may share your completed application and any questionnaires completed as part of the Programme with other entities working with us on this Programme as follows:

| <b>Entity</b>                                    | <b>Purpose of Sharing</b>  |
|--|--|
| Association of British HealthTech Industries Ltd | Compiling Programme Reports  |
| Cambridge Design Partnership Ltd                 | Contributing to Programme Reports  |
| Innovate UK (Programme Funder)                   | Fraud prevention and general reporting                                   |
| Subcontracted Technical Experts                  | Advising on delivery of the Programme and preparation of Project Reports |

6.3. You will comply with any additional data protection procedures notified by us and ensure that (a) you have provided such employees, company representatives or otherwise (as applicable) with our privacy statement; and (b) all fair processing notices have been given and/or, as applicable, consents are obtained to enable us to process the relevant data for the purpose of the Programme.

6.4. On our request you agree to comply with such additional provisions as we may reasonably determine to be necessary in order to enable us and you to comply with our respective obligations under applicable Data Protection Legislation.

## **7. General**

7.1. Participation in this Programme will constitute acceptance of these terms and conditions and you agree to be bound by these terms and conditions.

7.2. Funding is not transferable.

7.3. Subject to the provisions of Clause 2.4, we will not accept applications for Funding prior to 9am on 14<sup>th</sup> February 2022 or after midday on 31st May 2022.

7.4. You may top up the Funding from your own monies if the invoice from your Regulatory Provider exceeds your Funding.

7.5. No more than one Funding round can be claimed per legal entity or Group.

7.6. The Contracts (Rights of Third Parties) Act 1999 does not apply to these terms and conditions and no person other than you and us have any rights under it.

7.7. These terms and conditions and any dispute or claim arising out of or in connection with them or the Programme shall be governed by and in accordance with the law of England and Wales. The parties irrevocably agree that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with these terms and conditions and/or the Programme.

7.8. We reserve the right to discontinue or otherwise vary the terms and conditions of the Programme in any way upon reasonable notice without incurring any liability. You will be bound by the version of these terms and conditions that are in force on the date of your application. The current terms are available on request at any time.

7.9. We reserve the right to end the Programme at any time.