Oncode Clinical Proof of Concept programme

Terms and conditions

Project ID:

Oncode Investigator:

Home Institution:

Co-applicant(s):

Project title:

Budget approved: €

Duration of project:

Expected Start date project
(no later than 6 months after approval letter):

Expected end date project:

Date:

- Your expression of interest has been reviewed by the Clinical Advisory Board (CAB) and the Research Management Committee. The full proposal, drafted with the support of Oncode's dedicated business developer and the OEDES (Oncode Exploratory Development Expert Support) team, was reviewed offline by the Clinical Advisory board, the RMC and Valorization team. If applicable, the rebuttal will be reviewed by the chair of the CAB and OEDES. The funding decision has been adjudicated by the Managing Board based on the advice of the CAB and OEDES. This document provides an overview of the specific terms and conditions relevant for the project including reporting, financing and communication requirements.
- The granted project will be supported by Oncode on topics such as future funding and business opportunities, IP, regulatory topics and/or further clinical development when necessary.

Oncode endorses the WHO joint statement of public disclosure of results from clinical trials and is committed to execute the clinical proof of concept programme following these guidelines: '*Prospective registration and timely public disclosure of results from all clinical trials is of critical scientific and ethical importance. Furthermore, timely results disclosure*

reduces waste in research, increases value and efficiency in use of funds and reduces reporting bias, which should lead to better decision-making in health'. Oncode expects the researchers to adhere to these guidelines and Oncode will include this in the monitoring of the project.

Project requirements

1. Pre-study documentation and preparation

1.1. Before recruitment of the first study subject and before the 30% pre-finance will be transferred by Oncode, the following needs to be approved by Oncode and executed:

- Start date project: we expect you to start *no later than 6 months* after the letter of approval. In the event that the project will not meet this deadline, the Oncode Investigator will timely inform Oncode, no later than 1 month before the initial start date. As a consequence, Oncode can decide to put project funding on hold or withdraw the project funding.
- Budget breakdown per year, according to the template provided by Oncode.

1.2. Documents which needs to be ready together with the first bi-annual report (progress report):

- Data Management Plan, according to the ZonMw template available at DMPonline (https://dmponline.dcc.ac.uk/) to support the working according to FAIR principles and approved by the data steward of your home institution.
  For directions towards the support offered by the Oncode partner institutes, visit Research data management support at *Oncode Institute - Open Science and FAIR Data*.
- Data Governance Plan or a strategy towards the development of such a plan, describing the strategies and policies for sharing data and samples, including plans for data usage agreements (independent) review panels, if applicable, and making these access policies transparent via a (publicly available) sample and data catalogue.
- Brief summary about the project for the Oncode website, template will be provided.

1.3. In case the project includes a clinical study, the following documents and actions need to be executed and information needs to be provided to Oncode:

- Study protocol approved by the home institution referring to relevant SOPs and protocols of home institution (only for information).
- Electronic study case report form (eCRF), preferably central, if a multicentre study.
- Broad informed consent form in which the study object agrees to provide access to the data research within the home institute, Oncode and where possible the academic community.
- Register the trial in a publicly available, free to access, searchable clinical trial registry complying with WHO's international agreed standards (who.int/ictrp), preferably in clinicaltrials.gov or clinicaltrialsregister.eu.

2. Finance

- Funding by Oncode is granted based on the project budget approved by Oncode (the project funding includes VAT).
- The project budget is checked and signed for approval by the responsible financial controller of the home institution or department from the Oncode Investigator and by the financial controller of the department of the clinical PI. The head of the department from the Oncode Investigator also agrees to the budget by signing the terms and conditions.
- Upon approval of the project, Oncode will notify the Oncode Investigator in writing with respect to the advance funding schedule. As a default, Oncode will make an advance payment of 30% at the start of the project, but this may be adjusted in the event the project gives cause to do so. 10% of the funding will be set aside and paid after the approval of the final report by Oncode, including all the project requirements, and the submission of the summary in the trial registry.
- Oncode will continue to pay the advance funding on the basis of receipt and approval of the progress reports. In the event that the progress is not sufficient, the advance funding may be temporarily or permanently stopped. The advance funding schedule may be adjusted in the event that the progress report gives cause to do so.
- Invoices can be sent to *admin@oncode.nl with a copy to Marlinde Smit (marlinde.smit@oncode.nl)*. Please refer to 'clinical PoC programme **P20xx-00xx**' clearly.
- The Oncode Investigator must submit any budget changes exceeding 10% or €40,000 of the original budget in advance and must substantiate the reason for the change in question. The changes to the budget amounts will be effective only after they have been approved by Oncode.
- The Oncode Investigator must submit a financial final report within 13 weeks after the date on which the project ends. Oncode will provide guidelines in advance in which it will indicate the manner in which the finances must be accounted for. In the financial accounts the Oncode Investigator must give Oncode sufficient insight to enable Oncode to form a sound opinion with respect to the budget and the realisation. Significant differences between the budget and the realisation must be explained. In the final financial report the actual costs must be compared with the cost items that were included in the budget that Oncode approved. The total amount paid by Oncode will be adjusted to the final approved financial report. The grantees will be required to refund any overpayments to Oncode.
- If the Oncode Investigator and their team moves institutions, as a general rule, the Oncode funding will move with them. Nevertheless, Oncode may determine that the Oncode funding should remain at Partner Institution either on its own account or at Partner Institution's or Oncode Investigator's request. Such a decision will be set out in writing and communicated to both the Oncode Investigator and Partner Institution. Oncode may take such decision (without limitation): (i) if the Oncode Investigator moves out of the Netherlands, or (ii) if the Oncode Investigator moves to an institution that is not an Oncode Partner Institution.

3. Progress documentation

- Internal use: Brief bi-annually updates to monitor the progress, deviations of the study and next step(s) to secure follow up. Approval of this report by Oncode is a prerequisite to continue the advance funding schedule. Oncode will provide a template. If there are important changes or deviations of the project between the scheduled bi-annually updates, please inform the programme manager of the CPoC programme; *marlinde.smit@oncodeinstitute.nl*
- External use: Annual progress report as part of the annual monitoring process of Oncode including a summary of the project, status updates and (if applicable) results. This contribution may be (partially) included in Oncode's annual report for funders and external stakeholders.

4. Closure documentation

- Within 13 weeks after the end of the project, the Oncode Investigator submits a substantive and a financial final report including a dissemination plan, unless otherwise agreed.
- A summary of the study including results and conclusions needs to be submitted by the Oncode Investigator to the study entry in the trial registry trial registry https://clinicaltrials.gov/ or https://www.clinicaltrialsregister.eu/ . Approval of the final report and completion of submission of the summary in the trial registry will release the remaining 10% of funding.

5. Communication

- Summary of the project for a general public.
  Oncode will prepare, together with the applying Oncode Investigator, a summary of the project's aim which will be aligned with the Oncode Investigator.
- At the end of the project, the project summary will be complemented with the results and, if applicable, future follow-up.
- If there is communication about the study with third parties, Oncode wants to be informed and involved as quickly as possible.

6. Follow up steps and studies

Based on the results of the study, Oncode expects that follow-up will be done. Please contact your dedicated business developer from Oncode for this and inform Oncode about the next steps.

7. Dissemination and Open Science

Register the trial in a publicly available, free to access, searchable clinical trial registry complying with WHO's international agreed standards (who.int/ictrp), preferably in clinicaltrials.gov or clinicaltrialsregister.eu. The trial ID or registry identifier code/number should be included in all publications about the clinical trial to allow linking of publications with the clinical trial registry site records.

- Study results must be made accessible to the public through open access publication as quickly as possible after the project ends but at least within 12 months after the project ends (WHO defines this as '*the last visit of the last subject for collection of data on the primary outcome*'). Click here for our Open Access Publishing Policy.
- Oncode highly encourages project applicants to make study data available after the project ends, as much as possible according to the FAIR principles including a clear description of the access policy. This data also counts as Oncode Investigator output.

Relevant section Affiliation Agreement: article 15, 19 and 13.5

In the event of any inconsistencies between these terms and conditions and the Affiliation Agreement, the Affiliation Agreement will take precedence.

Definitions

Affiliation Agreement:	The affiliation agreement between Oncode and a Partner Institution
Oncode Investigator:	Principal investigators employed by and/or holding a clinical or academic appointment at a Partner Institution, and (i) who are designated as an "Oncode Investigator" by the Managing Board (upon recommendation of the Research Management Committee) in accordance with the appointment procedure agreed upon with the Partner Institutions; (ii) which appointment was approved by the relevant Partner Institution; and (iii) who signed the Template Oncode Investigator Acknowledgement Form. A list of Oncode Investigators is included in Appendix C to the Affiliation Agreement.
Partner Institution:	A university medical center, university or research institute which is party to an Affiliation Agreement with Oncode

Agreed and signed:

By:	By:
Title: Oncode Investigator Date:	Title: Head of the department Date: