Dutch Kidney Foundation
Call for Pre-proposals

DKF-Health~Holland Public-Private Project Grant

Information Sheet 30 January 2018

Disclaimer
The execution of a DKF Call for proposals, selection of pre-proposals for full application and positive DKF grant award decisions are conditional on DKF revenues and budgetary means. DKF explicitly reserves the right to cancel an initiated Call for proposals, to suspend a running procedure or to lower a grant amount in relation to earlier statements.

This Call for pre-proposals is an initiative of the section Care & Innovation (C&I) of the Dutch Kidney Foundation (DKF) in collaboration with Health~Holland (Top Sector Life Sciences & Health). The advisory board for this call is the International Scientific Advisory Board (ISAB). The C&I Program Committee (PC) is responsible for awarding decisions, Health~Holland will evaluate compliance with the PPP-Allowance regulation.

1. Grant
The total available budget for this call is €1,300,000, consisting of €500,000 DKF contribution and €800,000 contribution by the ministry of Economic Affairs and Climate, through PPP-Allowance that was granted to the Top Sector Life Sciences & Health for the stimulation of Public-Private Partnerships. As a consequence, specific rules apply for proposals submitted in this call. Please read the guidelines carefully and contact us in case you have any questions. With the funds available two Public Private Projects can be funded.

2. Aim
Kidney disease related research in the Netherlands is among the top countries in the world in terms of scientific output and ratings. The purpose of this call is to initiate new collaborations in the kidney disease domain between leading scientists, upcoming talents, patients, care-professionals and private enterprises. These collaborations help to exploit the available scientific excellence in developing specific solutions and tangible products that impact the lives of (future) kidney patients or prevent kidney damage and disease. These collaborations will increase innovation and economic activity in the Netherlands thereby contributing to the aims of Health~Holland.

3. Scope
The project proposals must meet at least the following criteria:
- Public-Private Projects must be new projects that have not been initiated before approval by DKF.
- There is no restriction in research phase, but all projects must be targeted at developing and/or validating specified solutions for improved prevention, diagnosis, treatment and/or care of kidney disease, improving well-being and quality of life of (future) kidney patients.
- Project duration is maximum 4 years
- Projects must ultimately start before September 2019 and end before September 2023
- Projects should be a collaborative effort of a consortium consisting of at least one Dutch public knowledge institute and at least one private enterprise.
- Co-funding by private enterprises of at least 25% of the total budget is required. If a large company is involved (>250 staff headcount and > €50M annual turnover), at least 2/3rd of its contribution should be in cash. See chapter 8., the Budget Sheet and the Application Form for more details.
- To ensure full commitment, all participating private enterprises must make a minimum cash contribution depending on the size of the company: SME (<250 staff headcount and < €50M annual turnover) €3000, Large companies (>250 staff headcount and > €50M annual turnover) €10,000.
- There is a complementary and effective collaboration (see chapter 12.) and the participants in the consortium will jointly bear the costs and risks of realizing the project.
- The proposal and budget are in accordance with the rules and regulations of the PPP-Allowance.
- All consortia must at least involve end-users, consisting of future development partners, (care) professionals and kidney patients, to ensure optimal alignment of the development and the envisaged end-product. Involvement can be as participant or as advisors to the consortium. The intended end-user involvement needs to be indicated in the pre-proposal. The involvement needs to be formalized at the full-application.

Specific aspects to consider in comparison to regular DKF-Consortia:
- Public-Private collaboration, offers great opportunities, but also brings complexities in the specific agreements that need to be drafted and signed. Please make sure all participants are aware of the rules and regulations regarding the agreements that need to be signed, as well as publication and Intellectual Property rights (IPR) and transfer thereof.
- The PPP-Allowance used to partially fund this call brings specific requirements regarding ultimate start and end dates, financial reporting and agreements that need to be in place before the start of the project. These are comparable to other funding instruments of the Ministry of Economic Affairs and Climate, but more stringent than the requirements of regular DKF calls.

4. Deadline
The deadline for this call for pre-proposals is Thursday 15 March 2018, 24:00h (digital version only). The deadline for full applications is expected at 1 September 2018.

5. Who can apply?
Public-private partnerships containing Dutch knowledge institutes can apply. A proposal for a DKF-Health~Holland Public-Private Project Grant is submitted by the project's Principal Investigator (PI). The PI is the first responsible for management and execution of the Public-Private Project. The PI is affiliated to either a Dutch knowledge institute or a private enterprise located in The Netherlands. The PI is either a researcher with a strong track record in kidney disease related research, or the primary responsible person for the development at the private enterprise. However, only the activities at the Dutch knowledge institutes can be funded (see chapter 8.).

If the PI is affiliated to a private enterprise, this company has to present evidence of ensured financial stability during for the full duration of the project. This evidence has to be submitted at the full proposal stage. This can be done by presenting annual reports or investment agreements. The same accounts if DKF questions the ability to deliver the support committed by the participating companies.

Since high potential to achieve impact on kidney disease lies in technological innovation, Dutch technical universities are also invited to submit or collaborate in proposals.

We are well aware of the innovative potential that is vested in the young scientists in the field. Therefore, we also specifically invite ambitious young investigators to act as PI and submit a proposal. In that case the required experience to successfully lead a public-private collaboration has to be embedded in the project team and project advisors.

Exchange of employees between participants is encouraged to further strengthen the synergy within the Public-Private consortium.

6. Priorities & Assessment
The Public-Private Projects fit in with ‘Nierziekte de baas’, the joint Dutch renal strategic agenda for research and innovation (developed by DKF, Nierpatiënten Vereniging Nederland and Nederlandse Federatie voor Nefrologie), the Health~Holland Knowledge and Innovation Agenda 2018-2021 Grow~Motion and the Nationale WetenschapsAgenda. Proposals are assessed on relevance and quality using the assessment criteria as listed below.

**DKF-Health~Holland Public-Private Project Relevance Criteria**

**Innovative Potential**
- Is the project innovative, does it advance knowledge and insight of current renal physiology, research, clinical practice, patient care or prevention? Does the project utilize theoretical concepts, approaches or methodologies, instrumentation, devices or interventions that are novel to the field or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, devices or interventions proposed?
Significance for CKD Patients and Prevention

- Does the project address, directly or indirectly, progress in understanding, diagnosis and treatment of CKD and the prevention of kidney damage and disease, from early kidney damage and renal disease to transplantation and chronic transplant dysfunction? This includes all types and topics in renal research.

Scientific Significance

- Does the project address an important problem or a critical barrier to progress to a next step in the development towards (clinical) application? If the aims of the project are achieved, will scientific knowledge and/or technical capability be improved? Will successful completion of the project change the concepts, methods and/or technologies that drive this field?

Clinical Significance

- Does the project address an important problem or a critical barrier to progress in the clinical renal field? Is the topic original, timely and relevant in the clinical perspective? If the aims of the project are achieved, will clinical practice and/or prevention be improved? Will successful completion of the project change the treatments, services and/or preventative interventions that drive this field?

Linking Basic and Applied Research with a Clinical Perspective

- Does the proposal connect basic and/or applied research in an inherently necessary and meaningful way in view of the expected clinical outcome? Are there realistic and important prospects for clinical applications and/or medical developments? Is the expected time scale of this within short or medium term (five or ten years after beginning the proposed research)?

Quality of the Individual Groups and Environment

- What is the past performance of the individual research groups and their track record with collaborative initiatives? Are the principal investigator and the participants well suited to the project, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Coherence

- Is the research program well-focused and structured? Is the division into project areas and individual work packages convincing? Do the individual work packages clearly fit in with the overall goals? Is each participant’s expertise essential in the proposed research program? What is the potential for cooperation between the individual work packages and participants? Are productive collaborations in place? Are synergies to be expected? How adequate is the consortium’s self-monitoring and control based on the proposal? Are management and administration handled appropriately? Is the contribution of the participants well-balanced and suitable to the aims of the project?

International Positioning of the Consortium

- How is the proposed consortium positioned internationally? What are its prospects in international competition? What is the international visibility? What relationships exist to thematically related institutions or larger projects, including those at other locations?

Broad Value for Money

- Are the proposed efforts and expenditures proportional to the expected outcome and benefits in a broad sense?

**DKF-Health~Holland Public-Private Project Quality Criteria**

Problem Definition, Hypothesis and Aims

- Is problem, (hypothesis and) aims well described? Do (hypothesis and) aims build on a firm theoretical and/or empirical basis? Are the strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? If successful, will the project be
of added value to the existing knowledge base and/or practice of care? Can the anticipated results be tested and/or quantified?

Work Plan
- Is the work plan well described? Is the work plan complete, coherent and consistent? Are the proposed methods, techniques and analyses adequate to meet the proposed objectives? Does the work plan properly address the proposed aims?

Patient Inclusion
- Are the plans for the recruitment and retention of subjects adequate? Are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes, as well as the inclusion of elderly people and of children, adequate and justified in terms of the scientific goals and research strategy proposed? Is the collaboration with the patient group adequate? Are the patient group and the strategy for patient inclusion well described? Is the approach of the patient group adequate? Is the inclusion strategy feasible? Are patient risks and efforts acceptable? If METC (Ethical Review Board) permission is necessary, is the timeline of the procedure realistic?

Animal Models
- Are the proposed models essential for addressing the project's problem and hypothesis? Are the proposed models suitable for the proposed aims in the context of available models? Are the proposed models well described? Are the proposed models adequately representative for human physiology and disease in relation to the project's topic? Are the proposed procedures well described? Is the motivation for animal use appropriate? If DEC (Animal Review Board) permission is necessary, is the timeline of the procedure realistic?

Approach & Feasibility
- Are organization and management set up adequately? Are necessary collaborative arrangements in place? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Is there a sound funding plan? With regard to the co-funding, is it clear what is (will be) agreed with the co-funder(s) about reporting, financial accountability and communication? Are there no conflicts between the grant requirements of the Dutch Kidney Foundation, Health~Holland and awarded co-funding? Will the strategy establish feasibility and will particularly risky aspects be managed? Are potential problems and obstacles, alternative strategies, and benchmarks for success presented? Is the proposed time line realistic?

7. Conditions
Grant conditions are non-negotiable. To prevent unwanted surprises during the writing of the full proposal or drafting the consortium agreement, make sure that all participants are aware of the conditions related to this grant. This prevents situations like companies not willing to comply with the conditions regarding intellectual property. Therefore, specifically share the conditions for the Agreements, Data Sharing and IPR (see 7.5.) at the pre-proposal stage, so that everyone is aware of what they are getting themselves into.

The following conditions apply to this call:
- PPP-Allowance regulation (Regeling van de Minister van Economische Zaken van 11 juli 2014, nr. WJZ / 13125043, houdende vaststelling van nationale subsidie-instrumenten op het terrein van Economische Zaken (Regeling nationale EZ-subsidies)), with special attention to chapter 3.
- The DKF Grant Conditions (Subsidievoorwaarden 1 januari 2017) apply, in addition the following special conditions apply (numbers 7.1-6).

7.1. Collaboration
- Public-Private Project consortia consist of at least one Dutch public knowledge institute and at least one private enterprise.
- Existing and new collaborations can submit in this call, but the projects must be new and not have started before approval by DKF.
- DKF requires all Public-Private Project consortia whose proposal is accepted for full application to start a collaboration with the Dutch Kidney Patient Association (Nierpatiëntenvereniging Nederland) aiming to involve patients in the writing phase of the project.
DKF provides support for the organization of consortium review meetings and symposia in order to strengthen internal cohesion and collaboration, to improve consortium impact and to promote dissemination, communication and publicity of consortium results. More information on consortium meetings and support from DKF can be found in the separate Infosheet Consortium Meetings.

- All Public-Private Project consortia have to at least involve end-users, consisting of for example future development partners, nephrology experts and kidney patients, to ensure optimal alignment of the development and the envisaged end-product. Involvement can be as participant or as advisors to the consortium. The intended end-user involvement needs to be indicated in the pre-proposal. The involvement needs to be formalized at the full-application.

7.2. Participation

- The PI is affiliated to either a Dutch knowledge institute or a Dutch private enterprise.
- The majority of the research funded by the DKF contribution and the PPP-Allowance, should be performed in the Netherlands.
- The participation of research teams based at an institute outside the Netherlands ('foreign teams') is encouraged under the following conditions:
  - The foreign team brings specific expertise that cannot be found in the Netherlands;
  - The grant budget of foreign teams is calculated in accordance with the Health~Holland cost systematics (See Chapter 8.1.). At most 33 percent of the total requested budget can be allocated to foreign teams.
- All participating private enterprises should have an active contribution to the aims of the project and provide co-funding (see chapter 8).
- The country of residence of participating private enterprises is of no concern, however if applicable long distance collaboration and international regulatory differences need to be addressed in the proposal.
- In case the PI is primarily affiliated to a private enterprise, this enterprise needs to reside in the Netherlands.
- The expertise of each participant is indispensable to realize the research program goals.

7.3. Research

- There is no restriction in research phase, but all projects have to be targeted at developing and/or validating specified solutions for improved prevention, diagnosis, treatment and/or care of kidney disease, improving well-being and quality of life of (future) kidney patients.
- The Public-private Project has well-defined goals.
- Project duration is maximum 4 years.
- A Public-Private Project consists of at least three work packages. A work package is a conceptually relatively independent set of activities which is directed toward reaching the goal of the Public-Private Project. Work packages are tightly interconnected in the overall organization of the project.

7.4. Translational perspective

- A Public-Private Project aims at connecting research and (medical) need at stimulating translational research and application of research results.
- A Public-Private Project strives for physician researchers and end-users as direct participants in carrying out the research or as advisors to the project.
- A Public-Private Project is aimed at application of the research results in clinical practice within seven years after the formal start of the project.

7.5. Agreements, Data Sharing and IPR

- After a Public-Private Project Grant has been awarded, the participants must sign a Consortium Agreement between themselves. Templates for the Consortium Agreement are provided by DKF.
- Public-Private Project participants must comply with the DKF Data Sharing Policy and FAIR data principles. Participants must strive for rapid and wide availability without restrictions of research data resulting from research funded by the Public-Private Project Grant. Data availability may be delayed as a consequence of procedures for protection of intellectual property rights (IPR). A Data Sharing Plan is part of the Consortium Agreement.
- IPR protection is handled using ownership follows inventorship principles.
- Transfer of ownership of IPR has to take place according to market conditions and must be in
compliance with the EU Framework for State aid for research and development and innovation and the PPP-Allowance regulation.

- Opportunities and plans for IPR protection resulting from the Public-Private Project research must be reported to DKF.
- IPR management must be conducted in collaboration with DKF and the IPR departments of the participating research institutes.
- DKF will not develop an IPR portfolio.
- DKF aims at maximizing the return to renal research from the revenues from IPR protection.
- DKF may challenge planned IPR protection or patent usage that it considers to be inhibiting or restraining scientific endeavour, renal research or advances in renal patient care.
- Data and IPR management plans must be specified in the full grant application.
- Consortium participants must timely report to DKF any results that are of value for the communication of results of DKF projects: e.g. forthcoming publication in a prominent scientific journal, forthcoming publication of research results that have a high impact on patient care, etc.

7.6. Publications

- DKF encourages research groups to implement and follow the ARRIVE (Animal Research: Reporting of In Vivo Experiments) guidelines in the design and reporting of animal research to increase its reproducibility and quality.
- DKF supports and encourages Open Access publishing, preferably via the Gold Route which makes the final version of an article freely and permanently accessible for everyone, immediately after publication. More information can be found on openaccess.nl.

8. Budget requirements

The amount of PPP-Allowance that can be used to fund a specific activity depends on the research type of that activity. Health~Holland distinguishes 3 research types (see also chapter 12.):

- **Fundamental research** means experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts, without any direct commercial application or use in view.
- **Industrial research** means the planned research or critical investigation aimed at the acquisition of new knowledge and skills for developing new products, processes or services or for bringing about a significant improvement in existing products, processes or services.
- **Experimental development** means acquiring, combining, shaping and using existing scientific, technological, business and other relevant knowledge and skills with the aim of developing new or improved products, processes or services.

Activities not belonging to these research types cannot be part of the project. In case of doubt which research type applies, we refer to the [Frascati manual](#) of the OECD, specifically chapter 2.

The following maximum PPP-Allowance funding percentages apply to the research types.

<table>
<thead>
<tr>
<th>Research type</th>
<th>% PPP- Allowance</th>
<th>% funding by DKF and participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fundamental research</td>
<td>75%</td>
<td>25%</td>
</tr>
<tr>
<td>Industrial Research</td>
<td>50%</td>
<td>50%</td>
</tr>
<tr>
<td>Experimental development</td>
<td>25%</td>
<td>75%</td>
</tr>
</tbody>
</table>

The research phase of each individual work package (WP) must be indicated in the proposal and in the budget sheet. A work package (WP) must fall within 1 research type. If a WP to your opinion contains several research phases, this WP needs to be divided into separate WPs for each research type.

8.1. Funding model

A Public Private Project Grant awards up to € 650,000 for a research period of up to 4 years. DKF applies the Health~Holland [cost systematics and budget form](#) to calculate grant budgets. Use the Budget Sheet to indicate the project costs and the individual in kind and in cash contributions by the participants. The PPP-Allowance and DKF contribution can only be used to cover costs of the public...
knowledge institutes in the Public-Private Project. Private enterprises have to account for their own costs.

The following minimal contributions are required.

- In all cases private enterprises have to account for at least 25% of total project costs.
- In case large companies have a major contribution and interest in the project, 2/3rd of their contribution needs to be in cash.
- At least 10% of the total project costs have to be contributed by the knowledge institutes in cash or in kind. This contribution is allowed to be 100% in kind.

The remaining costs of the activities at the knowledge institutes can be funded by DKF contribution.

To optimally exploit the budget available and to achieve maximum impact there is a minimum size requirement to the Public-Private Project of € 1 million. This results in the following build-up of contributions:

Total project size €1 million or more
- Subsidy €650,000
- DKF contribution €250,000
- PPP-Allowance €400,000
- Minimum contribution by private enterprise(s) € 250,000 (25%)
- Minimum contribution knowledge institute(s) € 100,000 (10%)

The budget sheet will indicate the percentage distribution of all commitments. Applicants are advised to play around with the contributions to come to the required minimum percentages.

With the funds available two Public Private Projects can be funded.

8.2. Criteria relating to in-kind co-funding

- For commitment of material resources, charge the cost price. Commercial rates are not accepted.
- For commitment of equipment, take previous depreciation and intensity of use into account.
- Commitment in the form of supplies of services are possible only if the service can be itemised as an identifiable new endeavour. The service should not already be available at the knowledge institute(s) realising the research. Research leaders may wish to claim services already supplied (such as a database or software) as in-kind co-funding. Acceptance is not automatic in such cases. Please contact DKF if such a case arises. Further consultations will take place to decide whether a specific value can be determined for this supply of services.

8.3. NOT permissible as co-funding

- Co-funding from direct or indirect (NWO, KNAW) government funding ('subsidiestapeling') is not allowed.
- The PPP-Allowance and DKF contribution cannot be used to buy or contract products or services among the participating organizations, to prevent improper mixing of funding and contributions
- Discounts on (commercial) rates for materials, equipment and/or services, for example do not count as co-funding.
- Costs relating to overheads and/or participation in a user or advisory committee cannot be regarded co-funding.

8.4. Letters of commitment (Only required with the full proposal!)

All participants must sign the pre-proposal before submission. Not fully-signed pre-proposals will not be considered eligible.

NB: If a pre-proposal is selected for full submission the consortium must supply letters of commitment of all participants with the full proposal. DKF advises research leaders to ensure that the co-funders pay particular attention to endorsing the importance of the proposal for their operations. The letter of commitment should satisfy the following requirements.

A. General requirements

- Letters of commitment must be printed on the letter paper of the participant.
- Letters of commitment are addressed to the research leader.
- Letters of commitment must be written in English.
• The address on the letter is correct.
• Letters of commitment must be signed by an authorised signatory.

B. Specific requirements
• Brief description of the participant and the core business (type of organization, size, which service, products).
• A statement that the participant is interested in and will commit itself to the research.
• An explanation as to why the answering of the research question is important to the company. How does this solution fit in their strategy?
• A brief explanation as to why this particular research group and research proposal are receiving support.
• What the company will contribute in concrete terms, what activities will be performed, what materials or what type of cash will be contributed (incl. capitalization in man-hours and euros) and why this fits in the research proposal/planning.
• Further specification of the in-kind support, both hours (number and/or tariff applied) and materials (numbers; cost price; tariff; percentage that can be attributed to the project, etc.).
• A statement that the participant provides the contribution described without additional conditions.

C. Declaration and signing by the co-funder
• The participant states that it has read the proposal and signs for this.
• The participant states that it will actively participate in the User Committee (UC) and signs for this.
• The participant states that it agrees to the Consortium Agreement and the ICA and signs for this. Letters of commitment are unconditional and do not contain any opt-out clauses.
• The amounts stated in the letters of commitment must correspond with the amounts stated in the budget presented.
• A copy or scan of the letter will suffice for the submission of a proposal.
• DKF will not approach persons or organizations who have signed letters of commitment to act as referees (code of conduct on conflicts of interest).

9. Application and Assessment Procedure
Since this is a novel call concept for DKF and considering the complexities involved with the PPP-Allowance, we invite all PI’s to contact us in case of any questions.

The DKF procedure is as follows:
• A Public-Private Project Grant round has a call for pre-proposals followed by full application upon invitation. Full application without pre-application is not admitted.
• Pre-proposals are assessed by DKF on complying with the conditions and the aims of the grant.
• The ISAB advises DKF on selecting pre-proposals for full application.
• DKF decides on selection of pre-proposals for full application. Pre-proposals are either accepted for full application or rejected.
• Public-Private project consortia whose pre-proposals are accepted for full application are required to involve patients in the writing phase of the full application via the Dutch Kidney Patient Association (Nierpatiënten Vereniging Nederland).
• Full proposals are reviewed by at least three international reviewers. DKF strives to avoid any form of conflicts of interest in appointing reviewers.
• Applicants have the opportunity to write a rebuttal.
• Individual ISAB members provide a summarizing assessment of each full proposal based on the reviews and the rebuttal.
• The ISAB discusses the applications in an ISAB meeting and provides a final advice with priority ranking to DKF.
• The grant award decision by DKF is expected in December 2018.
• Pre-proposals, full proposals and rebuttals are written in English. For all submissions, the most recent versions of the relevant DKF forms are used.

10. Monitoring and evaluation
Public-Private Projects are monitored by the ISAB and DKF by means of progress reports and review meetings. In consultation with the consortium, DKF schedules at least four review meetings throughout
the duration of the project as funded by DKF. A positive decision by DKF after the Midterm Review is explicitly required for continuation of the project. More information is provided in the Infosheet Consortium Meetings.

In addition Health~Holland requires yearly financial reporting and a final report accompanied by an auditor’s report. The relevant forms and auditor’s instructions will be distributed timely by DKF. Cost of the auditor’s report is non-fundable and will be borne by the organization the PI is affiliated to.

11. Information
More information can be found on our website. For questions about this Call please contact DKF program bureau, research@nierstichting.nl or phone +31(0)35 697 8011.

12. Important Definitions from the EU Framework for State aid for research and development and innovation

1.3.(h) ‘effective collaboration’ means collaboration between at least two independent parties to exchange knowledge or technology, or to achieve a common objective based on the division of labour where the parties jointly define the scope of the collaborative project, contribute to its implementation and share its risks, as well as its results. One or several parties may bear the full costs of the project and thus relieve other parties of its financial risks. Contract research and provision of research services are not considered forms of collaboration.

1.3.(j) ‘experimental development’ means acquiring, combining, shaping and using existing scientific, technological, business and other relevant knowledge and skills with the aim of developing new or improved products, processes or services. This may also include, for example, activities aiming at the conceptual definition, planning and documentation of new products, processes or services. Experimental development may comprise prototyping, demonstrating, piloting, testing and validation of new or improved products, processes or services in environments representative of real life operating conditions where the primary objective is to make further technical improvements on products, processes or services that are not substantially set. This may include the development of a commercially usable prototype or pilot which is necessarily the final commercial product and which is too expensive to produce for it to be used only for demonstration and validation purposes. Experimental development does not include routine or periodic changes made to existing products, production lines, manufacturing processes, services and other operations in progress, even if those changes may represent improvements;

1.3.(m) ‘fundamental research’ means experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts, without any direct commercial application or use in view;

1.3.(q) ‘industrial research’ means the planned research or critical investigation aimed at the acquisition of new knowledge and skills for developing new products, processes or services or for bringing about a significant improvement in existing products, processes or services. It comprises the creation of components parts of complex systems, and may include the construction of prototypes in a laboratory environment or in an environment with simulated interfaces to existing systems as well as of pilot lines, when necessary for the industrial research and notably for generic technology validation;

1.3.(ee) ‘research and knowledge dissemination organization’ or ‘research organization’ means an entity (such as universities or research institutes, technology transfer agencies, innovation intermediaries, research-oriented physical or virtual collaborative entities), irrespective of its legal status (organized under public or private law) or way of financing, whose primary goal is to independently conduct fundamental research, industrial research or experimental development or to widely disseminate the results of such activities by way of teaching, publication or knowledge transfer. Where such entity also pursues economic activities, the financing, the costs and the revenues of those economic activities must be accounted for separately. Undertakings that can exert a decisive influence upon such an entity, for example in the quality of shareholders or members, may not enjoy a preferential access to the results generated by it.