SCIENCE FOUNDATION IRELAND

SFI-Pfizer Biotherapeutics Innovation Award Programme 2016

Call for Submission of Proposals

KEY DATES

Call announcement:	5 July 2016
Deadline for pre-proposal submission:	15 September 2016, 13.00 Dublin Local Time
Deadline for full proposal submission:	20 January 2017, 13.00 Dublin Local Time

SFI TERMS OF REFERENCE

While every effort has been made to ensure the accuracy and reliability of this document, it is provided for information purposes only and as a guide to expected developments. It is not intended, and should not be relied upon, as any form of warranty, representation, undertaking, contractual, or other commitment binding in law upon Science Foundation Ireland, the Government of Ireland, Pfizer Inc., Pfizer Pharmaceuticals Ireland or any of their respective affiliates, servants or agents. SFI Terms and Conditions of Research Grants and Pfizer's Programme Participation Agreement shall govern the administration of SFI grants and awards to the exclusion of this and any other oral, written, or recorded statement.

All full proposal submissions in response to this Call for Submission of Proposals will be treated in confidence and no confidential information contained therein will be communicated to any third party without the written permission of the applicant except insofar as is specifically required for the consideration and evaluation of the proposal or as may be required under law, including the Industrial Development (Science Foundation Ireland) Act, 2003, the Industrial Development (Science Foundation Ireland) (Amendment) Act 2013 and the Freedom of Information Acts 1997 and 2003.

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1 Introduction

The remit of SFI is to promote, develop and assist the carrying out of oriented basic and applied research in strategic areas of scientific endeavour that concern the future development and competitiveness of industry and enterprise in the State. As outlined in SFI's Strategic Plan, Agenda 2020, the Foundation is committed to continuing its focus on funding excellent science that will deliver strongly on impact, thus realising significant benefits for the Irish economy and Irish society. Forming partnerships with key stakeholders is a major goal to ensuring excellent science is driven into the market and society. Furthermore, Ireland's five-year strategy on research and development, science and technology, Innovation 2020[1], sets out the roadmap for continuing progress towards the goal of making Ireland a Global Innovation Leader, with key actions focused on driving increased collaboration between the enterprise sector and public research system.

Pfizer employs approximately 3,200 people at six sites in Ireland across manufacturing, shared services, Research and Development (R&D), treasury and commercial operations. Pfizer has invested $7 billion in operations in Ireland since opening the first site in 1969. Many of Pfizer's leading medicines are manufactured for global export from Irish sites. The Global Biotherapeutics Technology group at Grange Castle was established in 2006 and is part of a world-leading protein drug discovery unit within Pfizer Worldwide R&D. Pfizer focuses R&D on core areas where they are best positioned to bring unique, needed therapies to patients. Key to this approach is collaborating in new and dynamic ways with other innovators across the health landscape including academic scientists, patient foundations, governments and other biopharmaceutical companies.

Arising from the strong focus of both Pfizer and SFI on adopting collaborative approaches with the goal of translating scientific discoveries into new medicines, the SFI-Pfizer Biotherapeutics Innovation Award Programme (BIAP) was established. The programme represents a unique opportunity for leading academic investigators with novel biological targets or pathways to collaborate with Pfizer scientists. Under the terms of the collaboration, successful applicants will gain access to Pfizer's drug discovery technologies and expertise in addition to accessing appropriate tools and molecules. The collaboration provides an opportunity for academic teams to work in close collaboration with Pfizer scientists by forming joint research teams and working towards common goals. A number of outstanding collaborative projects dedicated to the translation of basic biomedical research into potential new therapies have been supported to date.

BIAP 2016 will provide an opportunity for support of a new cohort of joint projects with Pfizer scientists. The purpose of each collaborative project will be to identify potential biopharmaceutical candidates (therapeutic and/or preventative) directed at novel disease targets or pathways of interest that are suitable to modulation by a biologic or protein-drug conjugate. Pfizer scientists will work with academic teams to blend the research expertise of academics in target biology with Pfizer's developmental expertise and resources with the goal of creating a potential drug candidate that can advance into clinical testing and potentially bring truly differentiated medicines to patients in need. In this way, this partnership has potential for delivering significant economic and societal impact.

The specific **objectives** of the SFI-Pfizer Biotherapeutics Innovation Award Programme are to:

- Create new collaborations between Pfizer and academics through an open innovation model that deploys Pfizer's world-leading biotherapeutic R&D resources to identify potential new therapeutics
- Deliver significant economic and societal impact through acceleration of the progress of research and drug development with the potential to make beneficial new medicines to treat diseases of high unmet medical need
- Support enhanced training of researchers in areas of importance to industry

[1] Innovation 2020, Published 2015

- Maximise the state investment in research through leveraging of non-exchequer funding

2 Pfizer Areas of Interest

Proposals are sought for research projects that aim to develop protein biotherapeutic drug candidates directed against novel biological targets or pathways in the Immunology and Inflammation, Oncology, Neuroscience, Cardiovascular and Metabolic, and Rare disease indications, as outlined in the examples below. This list is not exhaustive however, and influential pathways in similar diseases of high unmet medical need aligned to one of the five areas of focus below will also be considered.

Immunology and Inflammation

- Inflammation-related tissue remodelling
- Rheumatoid Arthritis (RA)
- Systemic Lupus Erythematosus (SLE)
- Inflammatory Bowel Disease (IBD)
- Non-alcoholic Steatohepatitis (NASH)
- Atopic Dermatitis

Specific areas of interest include:

- Cytokines and their signalling pathways
- Adaptive immunity, lymphocyte biology including Th17 lymphocytes
- Regulatory cells and tolerance induction
- Innate immune suppressors
- Oxidative stress modulators
- Anti-fibrotics

Oncology

- Lung, colorectal, breast, ovarian, renal, and haematological cancers
- Cancers prevalent in Asia (e.g., gastric cancer, hepatocellular carcinoma)
- Targets and technologies that enable mAb, ADC, Immunotherapy (e.g. checkpoint inhibitors) and T-cell retargeting approaches
- Immuno-oncology
    - Novel Targets for Overcoming Tumour-induced Immune Resistance
    - Targets that promote immune response whether alone or in combination with checkpoint inhibitors
    - Targets that provide Innate immune support/activation
    - Targets that reduce immune suppression
    - Directed tumour killing via immune- based mechanisms
- Oncogenic signalling mechanisms, tumorigenesis
- Tumour metabolism and epigenetics
- Precision medicine approaches

Neuroscience

- Neurodegenerative Diseases
    - Alzheimer's Disease including strategic partnerships on Pfizer assets
    - Parkinson's Disease
- Functional domains relevant across multiple nervous system diseases such as Cognition, Anxiety, and Motivation/Apathy
- Neuroinflammation
    - Chronic neuroinflammation mechanisms with impact on AD or PD neurodegeneration
- Huntington's Disease
- Multiple Sclerosis – Remyelination approaches targeting Chronic Progressive disease only
- Cerebrovascular disease
- Conformational antibodies that have cross reactivity to all "amyloids" (e.g., tau, Aß, huntingtin, δ-synuclein

Cardiovascular and Metabolic Diseases

- Cardiovascular Disease and Heart Failure
    - Improving cardiac performance via myocardial protection, repair or improved myocardial perfusion and energetics
    - Primary and secondary prevention of cardiovascular events in high-risk patients
- Non-alcoholic fatty liver disease (NAFLD) and Non-alcoholic steatohepatitis (NASH)
- Obesity and Eating Disorders
- Diabetes. hyperinsulinemia and hyperglycemia
- Brain signals that regulate energy homeostasis and metabolism

Rare Disease

- Haematology
    - Haemophilia
        - Extended half-life of coagulation factors
        - Oral anti-haemophilic agents
    - Other rare hematologic (non-malignant) indications
        - Sickle cell disease
        - Haemaglobinopathies and beta-Thalassemia
        - Haemostasis
- Neuromuscular diseases
    - Duchenne/Becker muscular dystrophy
    - Friedreich's ataxia (FA)
    - Amyotrophic lateral sclerosis (ALS)
    - Spinal Muscular Atrophy (SMA)
- Pulmonary diseases

- Cystic Fibrosis
- Pulmonary arterial hypertension and idiopathic pulmonary fibrosis

Example therapeutic modalities for use in the indications above:

- Human/humanized monoclonal antibodies
- Antibody drug conjugates
- Bispecific antibodies for engaging multiple targets or multiple epitopes on single targets
- Oligoclonal antibody combinations for engaging multiple targets or multiple epitopes on single targets
- T-cell retargeting biologics for directed tumour killing via immune mechanisms
- Native proteins, peptide or receptor Fc-fusions, half-life extension conjugates (e.g. PEGylation)

3 Programme Details

3.1 Definition of Applicant

The applicant must meet the eligibility criteria set forth in greater detail in Section 3.2 below.

Successful applicants will be responsible for the scientific and technical direction of the research programme and the submission of reports to SFI and Pfizer. The applicant and his or her employer (hereafter referred to as the Research Body) have primary fiduciary responsibility and accountability for carrying out the research within the funding limits awarded and in accordance with the terms and conditions of SFI and the terms and conditions of the collaborative research agreement (hereafter referred to as the Programme Participation Agreement or PPA) between the relevant Research Body and Pfizer. The applicant will serve as the primary point of contact for SFI on the award, during the review process, and if successful, during the course of the award. The applicant will be recognised as an SFI Principal Investigator.

In exceptional circumstances, a co-applicant may be required within an application. An example would be an instance where a biomedical researcher is developing a biotherapeutic in close collaboration with a chemist, or the key biology has been co-discovered with another Irish research group and their material and intellectual involvement in the project is essential.

A co-applicant must have a well-defined, critical and continuing role in the proposed investigation. For the purposes of **eligibility, reviewing** and **monitoring**, a co-applicant applying for funding under this funding programme will receive equal evaluation to the applicant and will hold equal accountability for the delivery of the proposed research objectives. In this documentation, the terms and conditions for 'applicant' and 'co-applicant' are interchangeable.

Collaborators are not permitted roles within this programme. Pfizer scientists will serve as the official collaborators.

3.2 Eligibility Criteria of Applicant and Co-Applicant

The applicant and co-applicant must be:

- **A Member** of the academic staff of an eligible Research Body (permanent or with a contract that covers the period of the grant) or
- **A Contract Researcher** with a contract that covers the period of the grant, who is recognised by the Research Body as an independent investigator and will have an independent office and research space at the host Research Body for which he/she will be fully responsible for at least the duration of the SFI grant**.**

Furthermore, the applicant and co-applicant must

- hold a **PhD or equivalent[2] for at least 5 years** by the proposal deadline. The official date of a PhD is defined as the year that the degree was conferred, i.e., the year printed on the official PhD certificate. The number of years is determined by calendar year. Therefore, only individuals with an official date of 2011 or prior are eligible to apply to the 2016 call.
- have demonstrated **research independence** through securing at least one independent, competitively reviewed research grant as a lead investigator or as co-investigator. See FAQs for further details.

The applicant, and co-applicant if applicable, is expected to have the capability and authority to mentor and supervise postdoctoral researchers and team members.

Research Body submission confirms that the applicant meets these criteria and is either a member of the academic staff, or awaiting appointment as defined above.

Applicants fulfilling the eligibility criteria above may submit a maximum of 3 pre-proposal applications to BIAP 2016.

Applicants currently under review for other SFI programmes and current SFI award holders are eligible to apply to this call once all other eligibility criteria are met with the exception that applicants who are currently in receipt of more than one BIAP award are not permitted to apply to the 2016 Call.

Where, in the opinion of SFI, an applicant fails to meet the eligibility criteria outlined above, the application will be deemed ineligible and will not be accepted for review.

3.3 Eligibility of Research Body

The Research Body is the body responsible for the overall financial and administrative co-ordination of research programmes supported by research grants from SFI. Host Research Bodies must be situated in the Republic of Ireland to be eligible for funding. The grant will be administered by the Research Body of the applicant (i.e., host Research Body). A list of Eligible Research Bodies is available on the SFI website.

3.4 Funding

SFI will fund up to a maximum award size of €400,000 direct costs over a duration of 36 months. The award will support a contribution to the salary of a postdoctoral researcher hired specifically to carry out the research programme, in addition to materials and consumables and travel costs directly related to the research programme. For targets at a more advanced stage of development, a shorter duration of 24 months may be more appropriate. In such cases, a pro-rated award size of €266,000 direct costs over a duration of 24 months will apply.

[2] Please see the SFI website for further details on equivalence - http://www.sfi.ie/funding/grant-policies/sfi-policy-on-phd-equivalence.html.

Funding will support an experienced post-doctoral researcher to perform preclinical studies including

- The establishment of 'drug-discovery ready' biochemical assays
- Cell based assays and animal models
- Efficacy and preliminary safety studies in appropriate animal models
- The coordination and analysis of lead candidate pK properties in appropriate models

Additionally, Pfizer will provide a team of protein drug discovery researchers, from its Global Biotherapeutics Technologies (GBT) group, including certain researchers based at its BioTx R&D, GBT facility at Grange Castle. The Pfizer team will collaborate closely with the successful applicants and Research Body, but will be primarily responsible for drug moiety discovery and development activities, including: target protein production and characterization, binding assay optimization, biotherapeutic drug discovery selection and screening, lead expression, biophysical characterization, potency/stability optimization, candidate definition and collaboration with other internal Pfizer groups necessary for advancement of the funded research project.

3.5 Overheads

In addition to the direct costs, SFI will make an indirect or overhead ***contribution*** to the host Research Body, which is reflected as a percentage (currently 30%) of the direct costs (excluding equipment) of the SFI contribution to the research project. Overheads are payable as a contribution *to the Research Body* for the indirect costs of hosting SFI-funded research programmes and are intended to enable the Research Body to develop internationally competitive research infrastructure and support services.

3.6 Intellectual Property Management

The general principles by which intellectual property rights (IP) related to the collaborative research programme will be managed are summarized below, but will be set forth in greater detail in a Programme Participation Agreement (PPA), to be executed between Pfizer and the host Research Body. The PPA will specify the terms and conditions of the research collaboration, including the management of IP. By submitting an application to this funding Call, the applicant and host Research Body acknowledge the below IP principles and agree to enter into an appropriate PPA prior to commencement of the relevant research programme.

Background IP: Ownership of all background IP, including compound IP and target IP, that is not generated in the performance of the research collaboration will be retained by the partner that introduces the background IP to the research collaboration. However, each partner must agree to grant to the other partner a non-exclusive, royalty-free license to such background IP for the purposes of carrying out the approved research programme.

Foreground IP: Pfizer shall own (i) all IP related to compounds proprietary to Pfizer and compounds isolated or discovered in the performance of the collaborative research programme and (ii) all IP invented or developed solely by or on behalf of Pfizer during the performance of the research programme that does not incorporate the host Research Body's background IP. The host Research Body will assign any rights, title and interest to all such IP to Pfizer. The host Research Body will own all other foreground IP developed during the term of the collaborative research agreement and Pfizer will assign any rights, title and interest to such IP to the host Research Body.

Option Rights: The host Research Body will grant to Pfizer an exclusive option to obtain an exclusive royalty-bearing license to the host Research Body foreground IP for commercial purposes. This commercial license agreement would also include a non-exclusive license to the host Research Body

background IP. The option period will commence as of the execution date of the PPA and will expire 6 months following the submission of the final report to Pfizer.

3.7 Application Preparation

BIAP 2016 is comprised of a two stage application process. Stage 1 requires submission of a non-confidential pre-proposal application. Successful applicants will be invited by email to submit a full proposal application at Stage 2. Full proposal applications will be prepared in collaboration with Pfizer scientists.

Pre- and full proposals must be submitted by an authorised representative of the Research Body to SFI by email (partnerships@sfi.ie) as a single Adobe PDF (including scanned cover sheet) using the templates provided, before the call deadline (See Section 5 for dates). Proposals must comply with all of the guidelines below, "SFI Terms and Conditions of Research Grants", and the "SFI Grant Budget Policy". Each application must be accompanied by a standard cover sheet (see template in Appendix I) signed by the applicant and the appropriate signatory from the host Research Body. The submission of an application to SFI shall be construed as consent by the applicant and the Research Body to participate in the peer review process and to abide by the terms and conditions of funding. SFI reserves the right to return applications without review where the application does not meet the eligibility criteria.

General Guidelines

- All text must be provided in Times New Roman font or similar, with minimum font size of 11, and at least single-line spacing as well as a minimum margin size of 2.54cm.
- Applications should be prepared using the templates provided by SFI (where required), located at the end of this call document.
- The number of pages or words must not exceed the specifications for any given section. Applications that do not comply with these guidelines will be deemed ineligible and will be returned without review.
- Appendices or other unsolicited documentation are not permitted. Applications that include such unsolicited documentation will be returned without review.
- The currency to be used is the euro (€), in whole integer amounts e.g. €1,000.

Applications not adhering to these guidelines or with incomplete content will be deemed ineligible and will not be accepted for review, regardless of the date of submission. It is the responsibility of the applicant to ensure that eligible proposals are received by SFI. In order to safeguard against ineligibility, applicants are reminded to adhere rigorously to the proposal checklist included in Appendix VII.

3.8 Proposal Review Procedure and Criteria

Pre-Proposal Evaluation

Pre-proposals are not confidential and must not contain any confidential information of the Research Body. All pre-proposals that are accepted for review will be evaluated by a panel of Pfizer scientists (Pfizer Panel) from the core therapeutic areas based on the following criteria:

Research Programme and Impact

- Relevance of the proposed research to the desired disease indications

- Strength of the preliminary data and hypothesis supporting validation of the target or pathway, including the association to human disease
- Feasibility of the proposed research project - potential to access and engage the target with a biotherapeutic molecule
- Feasibility of target modulation by a protein therapeutic
- Quality of the scientific assets (including potential lead candidate drugs)
- Clear path forward to proof-of-mechanism studies in animal models with relevance to human disease
- Competitive landscape of the target and pathway in the pre-clinical and clinical space

Applicant

- Quality, significance and relevance of the recent research record of the applicant

The Pfizer Panel will meet with SFI to discuss the pre-proposals with the goal of identifying those applicants that should progress to the full proposal stage. The recommendations of the Pfizer Panel will be submitted to SFI Executive Committee and Pfizer for approval. Decisions resulting from the pre-proposal evaluation will be provided to the applicant, including the Pfizer Panel reviews.

Full Proposal Evaluation

Full proposals will undergo a scientific peer review and panel review, as outlined below. Full proposals may contain confidential information. Confidentiality will be managed in accordance with the provisions outlined in Section 4.2.

Scientific Peer Review

Full proposals will be sent for postal review. For each proposal under evaluation, SFI will solicit a minimum of three written reviews (i.e., postal review) from international topic experts who will appraise the quality of the applicant team and proposed research programme based on the following review criteria:

- *Quality, significance, and relevance of the recent research record of the proposed investigator(s), taking into account the career stage of the applicant(s), performance on recent awards, and the applicant's (and co-applicant's) record of securing relevant funding over the previous ten years*
- *Quality, significance, and relevance of the proposed research, including the potential to lead to the discovery of a novel biotherapeutic and advance knowledge and understanding within its own field or across different fields*

Panel Review

Appraisals submitted by the postal reviewers will be considered by a panel consisting of members with expertise in research translation and research commercialisation and Pfizer scientists, which will be convened to identify the most highly competitive applications for funding. Panel members will have the responsibility for assessing both the scientific merit of each application, as informed by the scientific peer reviews, and the potential impact of the proposed research. The Panel will be tasked with identifying fundable proposals and will rank full proposals in order of priority for funding.

During the Panel review, the following review criteria will be applied

- *Quality, significance, and relevance of the recent research record of the proposed investigator(s), taking into account the career stage of the applicant(s), performance on recent awards, and the applicant's (and co-applicant's) record of securing relevant funding over the previous ten years*

- *Quality, significance, and relevance of the proposed research, including the potential to lead to the discovery of a novel biotherapeutic and advance knowledge and understanding within its own field or across different fields*
- *Quality, significance, and relevance of the proposed research's potential contribution to demonstrably support and underpin enterprise competitiveness and societal development in Ireland*

SFI reserves the right to carry out pre-award site visits by international peers where required. Pre-award site visits, conducted by SFI staff, to examine infrastructure will also be a possibility, where appropriate. Performance of applicants on previous SFI grants, as determined through site visits and/or annual reports, will be taken into consideration in the decision-making process. The final funding decisions are at the sole and exclusive discretion of SFI and Pfizer.

Decisions resulting from the evaluation will be provided to the applicant, including the postal and panel reviews following the conclusion of the SFI review process.

The identity of the experts who conduct both the pre- and full proposal evaluations shall remain confidential and shall not be disclosed to the applicants.

SFI is solely resonsible for coordinating with all reviewers. While SFI will coordinate the execution of non-disclosure agreements with members of the IRP receiving confidential full proposals, neither SFI nor Pfizer shall be liable for the release of information concerning proposals to third parties by those members of the IRP involved in the merit review process.

SFI reserves the right to modify the review process. Applicants and Research Bodies will be notified of any relevant modification to the review procedure.

4 Proposal Application

Both pre-proposal and full proposal applications must contain a **Cover Sheet**. A scanned version of the cover sheet is acceptable. The following information must be included in the cover sheet.

- **Proposal Title (up to 30 words):** The proposal title must be non-confidential and should clearly convey the nature of the work programme to be undertaken, in up to 30 words.
- **Pfizer Areas of Interest:** Applicants must specify which Pfizer area of interest the proposed research aligns. See Section 2 of this call document for details.
- **Justification:** Applicants are required to complete a brief statement (max. 250 words) justifying that the application is within SFI's legal remit. The statement must describe how the proposed research is oriented basic or applied research which promotes or assists the development and competitiveness of industry, enterprise and employment in Ireland. For further information on SFI's legal remit please see the website**.**

Applicants must also provide the following information on the cover sheet:

- Name of Applicant
- Name of Research Body (Only one host Research Body may be listed)
- Total requested SFI Budget, direct costs only (€). At pre-proposal stage, an indicative budget is acceptable. This may be modified at the full proposal stage.
- A comment box is available for a representative from the Technology Transfer Office (TTO) to show that they are aware of the proposed BIAP 2016 application and any relevant intellectual property discussions and approve of the IP requirements for this call. Any existing industrial collaborations connected to the proposed research project must also be declared.
- Signatures

The Cover Sheet must be signed and stamped by the applicant, and official representatives of the Research body and the TTO.

The TTO must state within the comment box that the Research Body will abide by the principles for IP management, as stated in Section 3.6, if the application is approved for funding.

Proposals without all necessary approval signatures will be deemed ineligible and returned without review.

It should be noted that institutional submission of an application encompasses approval of an application and agreement to SFI Terms and Conditions of Research Grants. Submission must only be made by an authorised institutional representative. In particular, the institution is verifying:

- Eligibility of the applicant and co-applicant (if relevant)
- That the applicants are, or will be upon receipt of the grant, recognised as employees of the Research Body for the duration of the grant.
- That the requested budget including salaries/stipends, equipment, travel and consumables are in line with accepted institutional guidelines
- The availability of infrastructure within the institution as outlined by the applicant in the research proposal
- That the proposed research programme has not been funded by other sources
- That relevant ethical approval has been or will be sought and must be granted prior to the award commencing
- That the relevant licences will be in place at the time of award
- The Research Body is agreeing to the IP requirements if the award is funded

Submission of an application encompasses agreement to SFI Terms and Conditions of Research Grants.

4.1 Pre-Proposal Application

Pre-proposals are not confidential and should not contain any confidential information of the Research Body.

Cover sheet

A signed cover sheet must be included in the pre-proposal application (see Appendix I for template).

Technical Summary (max. 250 words)

This should be a succinct and accurate summary of the proposed work programme when separated from the application. It should provide a technical expert with a clear explanation of the proposed work programme.

Applicant CV (max. 2 pages)

Applicants and co-applicants **must** use the Applicant Pre-proposal CV Template provided in Appendix II.

Scientific Rationale, Background and Impact (max. 1000 words or 2 pages with graphics)

This section must contain:

- A brief description of the target/pathway and link to human disease and disease mechanism(s). What is/are the unmet medical need(s) this target/pathway could address? Is this pathway targetable by a biotherapeutic?
- An initial review of the competitive landscape to assess novelty of the target and pathway in the pre-clinical & clinical space. Are there other treatments available? Please describe why this is different (greater efficacy/ safety etc.) and the expected impact for patients if the approach is successful.
- Key evidence available to support the hypothesis above (i.e., human genetic, human tissue, preclinical proof-of-mechanism/concept models).

Proposed Biotherapeutic Drug Candidate Modality (max. 200 words)

Please describe any available potential biotherapeutic molecule(s) the applicant has generated against the target and its mechanism of action. If available, please describe the characteristics of said molecule (affinity, humanisation, PK etc.). Please be sure to communicate this information within the limits of any IP constraints. If unavailable, please indicate the characteristics of the preferred biotherapeutic agent.

Proposed Biological Proof-of-Mechanism Readout (in vitro* model *or in vivo* models*) (max. 200 words)

Provide a brief description of *in vitro* and/or *in vivo* models which will be employed to demonstrate proof-of-mechanism.

Research Plan and Reagents Needed (max. 500 words)

Provide a brief description of the research plan to be carried out (objectives, specific aims) leading to demonstration of proof-of-mechanism. Please list the available reagents and assays to support the research plan. Alternatively, please describe reagents and assays that may need to be developed and any gaps in the plan (and how Pfizer scientists may contribute, i.e. complete mechanistic studies *in vitro*, develop cellular assays, discover biomarkers, etc.).

4.2 Full Proposal Application

Applicants successful during the pre-proposal review process will be invited to submit a full-proposal. Full-proposals must contain a completed cover sheet (see Appendix I) which includes the appropriate signatures.

Full proposals may contain confidential information of the Research Body. Prior to disclosure of any such confidential information to Pfizer, Pfizer will coordinate the process for execution of a non-disclosure agreement between the Research Body and any personnel of Pfizer receiving such confidential information. SFI will be solely responsible for providing full proposals to the reviewers

mentioned in Section 3.8 above, and will coordinate the process for execution of non-disclosure agreements with any third parties receiving confidential information of the Research Body.

Cover Sheet

A signed cover sheet must be included in the full proposal application (see Appendix I).

Keywords (max. 15 words)

Please list the keywords/phrases from the research discipline or sub-discipline that best describe the research proposed in the application.

Technical Summary (max. 250 words)

This should be a non-confidential, succinct and accurate technical summary of the proposed work programme when separated from the application. It should provide a technical expert with a clear explanation of the proposed work programme.

Lay Abstract (max. 100 words)

This should be a non-confidential, succinct and accurate summary of the proposed work programme in lay, non-technical language when separated from the application. It should provide a lay-person (i.e. non-technical person) with a clear explanation of the proposed work programme.

Applicant CV (max. 7 pages)

Applicants and co-applicants **must** use the Applicant Full Proposal CV Template provided in Appendix III.

Research description (max. 10 pages) and References (max. 5 pages)

Applicants are requested to **provide sufficient detail** for peer reviewers to comment on the quality of the proposed ideas. It should be noted that a lack of appropriate and sufficient detail within the research programme is a recurring issue raised by reviewers.

The proposal content must be structured under the headings:

i. **Objectives Summary:** State the overall goals of the project, intended pre-clinical proof-of-mechanism studies, expected outcome and the potential benefit to patients.

ii. **Scientific and Clinical Rationale:** This section must include

- A description of the therapeutic target
- Tissue expression and function of the target
- Details of the mechanistic, genetic and/or pharmacological link to human disease(s)
- Details of the molecular pathway, its novelty, the *in vitro* and *in vivo* target biology and current validation status

iii. **Proposed modality:** Based on the pre-clinical study and end points articulated above, describe the desired characteristics of the potential drug molecule (e.g. antagonist, binding selectivity and affinity, functional properties and potency etc.). Please see examples in the table below.

Biologic form	Examples: Agonistic or antagonistic human or humanized IgG (non-cytotoxic) Antibody drug conjugate with cytotoxic or disease-modifying payload Bispecific, bivalent or monovalent antibody Receptor-Fc fusion (a.k.a. ligand 'Trap' e.g. Enbrel) Soluble protein factor (e.g. replacement factor) PEGylated protein pharmaceutical
Affinity	• K_D low enough to ensure adequate biological activity. • For mAbs, a K_D < 1 nM towards target is preferred pending PK modeling. For receptor-ligand targets, affinity to a receptor target should be at least equivalent to affinity of receptor to cognate ligand. • Binding to cynomolgus monkey ortholog required, mouse cross-reactivity desirable. For mAb, K_D towards cynomolgus monkey ortholog within 5-fold of human target. For ADC, K_D towards cynomolgus monkey ortholog within 2-fold of human target.
Potency	To be defined on a case-by-case basis. Define biologic activity with an IC_{50} or EC_{50} value (target dependent) for a specific cell-based assay.
Selectivity	Greater than 100x selectivity to relevant human target against closest human homologues (by primary sequence, structure or function) of intended target
Pharmacokinetics	To be defined on a case-by-case basis. Intended dosing frequency needs to be defined and proposed half-life needs to support dosing schedule.
Safety profile	For non-antibody-drug conjugates: No adverse effects observed in toxicity studies and safety pharmacology studies in appropriate animal models at a 10-fold higher exposure following dose conversion based on body surface area than the estimated pharmacologically active dose in humans. For antibody-drug conjugates: To be defined based on feedback from GBT
Efficacy	To be defined on a case-by-case basis.

iv. **Research Plan and Reagents Needed:** Propose a path or testing scheme (primary and secondary screening assays, selectivity assays, functional assays, *in vitro*, *ex vivo*, pharmacology model etc.) to identify the desired biotherapeutic candidate drug, relevant target species for PK and toxicology studies, path to understand drug exposure and biological response (PK/PD/biomarker) in translatable models and manufacturing activities. Research plan should provide timelines, go/no-go decision points and potential accelerators to reach goals. **The plan should extend to Candidate Selection stage and focus on key decision points and key data required to drive decisions.**

v. **Pre-Clinical Design to Achieve Meaningful Proof-of-Mechanism:** Describe in detail an *in vitro* discovery, characterization and pre-clinical research plan towards demonstration of a positive clinical proof-of-mechanism (relevant biological readout), in animal models. Outline a study in which the candidate drug will be tested to demonstrate a relevant biological readout that is indicative of modulation of target biology and disease mechanism. Define criteria (molecular signatures, protein biomarker changes etc.) by which the mechanistic hypothesis will be monitored and tested. If those factors are not already clear, describe a clear path to identify such criteria in the near term, to enable the pre-clinical study. Applicants are

requested to review the Guidance on Ethical and Scientific Issues in Appendix VI and to provide the requested information on study design.

vi. **Existing Assets/Technologies:** In addition, please include any physical assets such as assays, drug candidates, or other assets, that can be brought to the project by Pfizer or the applicant. Please provide a list of required reagents and assets. Also describe which reagent or asset is available, and which will need to be developed, such as:

- DNA, antibodies, cell lines, primary human cells, functional assays, and screen systems
- Mechanism biomarkers, disease biomarkers, and clinical sample assets
- Analytical methods (quantitative analysis of biomarkers and active agent (e.g. mAb))
- Reagents needed to develop and execute bioanalytical methods in support of *in vitro* and *in vivo* pre-clinical pharmacology models

vii. **Understanding of Risk and Mitigation:** Please identify risks for the project and plans to mitigate, or assess risk (these activities could be built into the research plan below). It is important to address risks and provide potential mitigation from several key perspectives:

- Confidence in the Biology/Mechanism and Clinical Relevance
- Safety and Tolerability
- Pharmacokinetic/Pharmacodynamic input –include desired profile, characteristic, modelling etc.

viii. **Key Activities and Personnel:** Identify key activities and key scientific personnel needed to execute the described project.

Appropriate references and citations for the research project must be provided (max. 5 pages).

The application should also include the following sections:

Impact Statement (max. 2 pages)

For BIAP 2016, scientific excellence is both necessary and paramount but is not sufficient; applications must also demonstrate potential impact by clearly articulating the opportunity for the research programme to generate a potential new therapeutic in collaboration with Pfizer that may lead to new treatments in one of the diseases of interest outlined in Section 2.

Applicants are required to prepare an impact statement (2 page limit) as part of the full proposal application. The statement should be as specific as possible and provide information that external reviewers will find helpful in assessing the potential impact of the proposed research activity. It should be written primarily in lay, non-technical language. Appropriate plans, milestones and deliverables associated with the potential impact may also be indicated. Potential economic and societal impacts should be addressed by answering the following overarching questions:

- **What are the benefits of this collaboration with Pfizer?**
- **How will the academic partner and Research Body benefit from this research?**
- **What are the potential benefits of this collaboration to the Irish economy and Irish society?**
- **Who are other potential beneficiaries?**
- **What is the expected impact on patients if the proposed project is successful?**
- **Over what timeframe might the benefits from the research be realised?**

Applicants are encouraged to consider SFI's Strategic Plan Agenda 2020 and Partnering with Pfizer Worldwide R&D before writing their impact statement.

In critically appraising various possible impacts, the following points should also be considered:

- What is the potential outcome of the project, including the unmet medical need that may be addressed if the research is successful and a new drug molecule is developed?
- If targeting a disease indication with successful drugs already on the market, how is the proposed approach differentiated and/or superior?
- What is the patient population that will be addressed and the severity of the disease? Is there a specific group of patients not already served adequately by current therapies?
- What is the proposed project's potential impact on the R&D activities and product pipeline of Pfizer?
- How will Pfizer enable increased impact? What supports can Pfizer provide?
- What is the activity's potential impact on the Irish economy, competitiveness and development?
- What is the proposed project's potential impact on the education, training and career of Ireland's students and research team members?
- How will the potential impacts of your research best be realised?
- How do you propose the impact of your research could be measured?
- What is the project's potential impact on society and the quality of life of Ireland's citizens?
- Are there potential beneficiaries within the private sector, public sector, third level sector or any others (e.g. professional or practitioner groups, charities or patient groups)?

Please see consult the SFI Website for additional guidance on preparing an impact statement.

Intellectual Property Management (max. 1 page)

Applicants should include as much detail as possible on the relevant IP landscape surrounding the research in question, including the biological target, which should detail any background IP that will be introduced to the project.

Infrastructure, facilities, services and space to be provided by Research Body (max. 1 page)

Describe the infrastructure, facilities and space to be provided by the Research Body. This should include details of the office, laboratory, computing, animal or other facilities as necessary, where the research will be done, including all of the equipment that will be available, but excluding equipment requested in this application.

Proposed Budget

Applicants are requested to complete a detailed budget breakdown of the planned expenditure on the BIAP 2016 award. Budgets should be prepared on a notional basis (i.e. Year 1, Year 2, Year 3) as opposed to a calendar year basis (2017, 2018, 2019), covering a period of 36 months. Please note that the **Budget Tables** for completion by the applicant are located in Appendix IV.

The costs eligible for grant support under the BIAP 2016 are those costs which can, uniquely and unambiguously, be identified with the proposed research project. SFI will support costs associated with the preclincial studies, as described in Section 3.4. Applicants must provide details of all relevant costs, including staff (i.e., post-doctoral fellow), equipment, materials, and travel. Ensure that the final total provided includes all direct costs requested from SFI. All awards are made directly to the applicant's Research Body. Please also refer to the SFI Grant Terms & Conditions and also the SFI Grant Budget Policy (version July 2016).

General overheads, currently 30% of 'modified' total SFI direct costs, should not be included in the requested budget.

Budget Justification (max. 2 pages)

The applicant should justify the postdoctoral researcher's role in the research project. Please include the postdoctoral researcher salary scale (as per SFI Team Member Budget Scale, Version July 2016). Clear and explicit justification is required for any request for an experienced post-doctoral researcher, i.e., one who will be appointed higher than Level 2A, Point 1 of the SFI Team Member Budget Scale. Additionally, strong justification and a clear staffing plan is required where salary support for more than one team member is requested.

Justification should also be provided for requested equipment, consumables and travel, and the requested duration of funding. Only eligible Research Bodies will be entitled to receive direct funding through the award.

If funding is sought for overseas services, this should be clearly justified and the rationale for not carrying out this activity in Ireland must be explained.

5 Summary Programme Timeline

Call announcement	5 July 2016
Webinar information event	19 July 2016, 15:00-16:00 Dublin local time
Pre-proposal deadline	15 September 2016, 13:00 Dublin local time
Pre-proposal panel meeting	November 2016
Applicants invited to submit full proposal	November 2016
Full proposal deadline	20 January 2017, 13:00 Dublin local time
Full proposal funding decision announced	April 2017

While we will make every attempt to adhere to the timetable and deadlines outlined above, SFI retains the right to modify the timetable, if necessary, for operational reasons. In such an eventuality, SFI will advise all applicant groups in the evaluation process at that stage as soon as possible.

6 SFI Resubmission Policy

Applications to any call that are based primarily on unsuccessful submissions (following peer review) to any SFI programme must demonstrate that the review comments resulting from the initial application have been taken into account in the preparation of the new submission. SFI will not review resubmissions that have not clearly taken into account the major comments or concerns resulting from the prior review and these proposals will be withdrawn without review. Please see SFI Policy on Resubmission of Grant Applications[3] for further information. Applicants to an SFI call for proposals must declare whether a new submission relates to a previously submitted application to any SFI scheme. If the application is a resubmission, a statement referencing the previous application and explaining the differences must be provided and making reference to reviewer comments where relevant. Please email this statement to partnerships@sfi.ie prior to the deadline. This statement will

[3] http://www.sfi.ie/funding/grant-policies/sfi-policy-on-resubmission.html

assist SFI Scientific Staff in the assessment of eligibility of a revised application and will not be shared with reviewers.

7 Research Integrity

SFI places high importance on ensuring research integrity and endorses the National Policy Statement on Ensuring Research Integrity in Ireland. All applicants and institutions are expected to abide by the aforementioned Irish Policy on Research Integrity and European Code of Conduct for Research Integrity. SFI plans to audit compliance by award holders and relevant research bodies with the principles laid down in these guidelines that are relevant to the agency's activities and the awards it makes.

8 Ethical Issues

All investigators and research bodies must ensure that, before the research commences and during the full award period, all the necessary ethical, legal and regulatory requirements in order to conduct the research are met, and all the necessary licences and approvals have been obtained. All research bodies are responsible for ensuring that a safe working environment is provided for all individuals associated with a research project.

All applicants submitting a full proposal are required to complete the Ethical Issues Table provided within Appendix V and include this as part of the grant submission. Those applicants proposing research that involves animal and/or human subjects must also provide the information requested in Appendix VI within the description of their proposed research and methodology.

SFI will require evidence that relevant ethical and regulatory approval has been granted for studies involving human or animal subjects prior to an award commencing. In exceptional cases where such research may not commence until a late stage of an award, SFI may permit submission of ethical and regulatory approvals following the award start date but prior to commencement of the research involving animal and/or human subjects.

9 Non-Compliance

Proposals not in compliance with any details specified in this document or in the SFI Terms and Conditions of Research Grants will not be eligible for a grant and will be **returned without review**.

10 Confidentiality

Science Foundation Ireland takes all reasonable steps to ensure that information provided in the application form is treated as confidential, subject to submission to the members of its committees and merit review and to any obligations under law.

Pre-proposals are not confidential and must not contain any confidential information of the Research Body.

Confidentiality of full proposals will be managed in accordance with the provisions outlined in Section 4.2.

11 Conflict of Interest

Conflict of interest rules are applied rigorously and apply to both reviewers and applicants.

Reviewers engaged by SFI are required to adhere to SFI's conflict of interest policy and immediately declare to SFI where a conflict of interest exists or arises so that an alternative reviewer may be appointed. International peer reviewers will not provide comments or scores on any application on which they have a conflict of interest.

Reviewers must adhere to high standards of integrity during the peer review process. They must not compromise the intellectual property integrity of the application and may not appropriate and use as their own, or disclose to any third party, ideas, concepts or data contained in the applications they review.

SFI recognises that applicants may have a prior relationship with an industry collaborator engaged in an application for funding to SFI, which may be perceived as a conflict of interest. Where a potential conflict of interest exists, SFI requires that it is disclosed by the Applicant to the Foundation and Research Body, and that it is managed by the Research Body in accordance with the principles and mandates laid out in the National Intellectual Property Guidelines.

12 Progress Reporting Requirements

SFI has stringent requirements for the reporting on awards that it makes. Individuals who hold the primary responsibility for reporting and who fail to comply with reporting requirements, run the risk of having their grant payments suspended and their eligibility to apply for funding in forthcoming SFI calls affected. Reporting is inclusive of annual reporting, completion of the annual stocktake of SFI Research Outputs (formerly referred to as the SFI Census) and the completion of a Researcher Snapshot.

The SFI Grants and Awards Management System, SESAME, is the primary conduit for annual reporting. SFI-Pfizer BIAP awardees will be requested to submit their annual report by 31st January every year to report on activity during the previous calendar year (January – December). The Standard Report template which is available on SESAME must be used. An additional final report must be submitted (also using the Standard Report template) within 3 months of the expiration date of the award. In addition to the annual report, awardees are also obliged to keep their SESAME Research Profile updated, as the annual stocktake of SFI Research Outputs is drawn directly from the data entered into the Research Profile; this must also be updated and completed by 31st January every year. SFI reporting procedures are detailed here, and webinars describing the entry of data into the Research Profile are available here.

The annual report is used to monitor progress of the individual awards against the overall objectives of the SFI-Pfizer BIAP and the Key Performance Indicators (KPIs) set out in SFI's Strategic Plan, Agenda 2020. The main sections to the Standard Report template and their relevance to the SFI-Pfizer BIAP objectives and Agenda 2020 KPIs are described below and are also explained in the guidance notes provided with the reporting template.

The award recipient will be required to update their Researcher Profile for several years after completion of the award and so inform an evaluation of the success of the collaboration in question.

Team Members

A key objective of the SFI-Pfizer BIAP is to "support enhanced training of researchers in areas of importance to industry". In addition to tracking the profiles of team members working under the SFI-Pfizer BIAP awards, SFI is interested in monitoring the movement of team members into industry. In this section of the report information on where team members are employed once they leave the award can be entered. This is important as SFI have set a key target in relation to SFI trainees moving into industry; "By 2020, 50% of SFI trainees will be moving to industry as a first destination".

Scientific Information

In this section of the report, awardees are asked to report on scientific progress made over the year both in scientific and layman terms and to provide details on any deviations from the original work programme. There is also the opportunity to add any updates to the SFI Researcher Snapshot which is made available to external agencies and companies and is available on the SFI website.

Academic Outputs

Awardees are asked to report on all refereed journal and conference publications and international presentations directly supported by the grant. This support must be acknowledged in all publications as "This work was supported by a research grant from Science Foundation Ireland (SFI) under the SFI-Pfizer BIAP 2016, grant number 16/BIAP/####". If the research is also funded by other bodies, for example as a result of future successful grant applications to Horizon 2020, publications must acknowledge "This work was supported in part by a research grant from Science Foundation Ireland (SFI) under the SFI-Pfizer BIAP 2016, grant number 16/BIAP/####".

Strategic Impact

A key objective of the SFI-Pfizer BIAP is to "deliver significant economic and societal impact through acceleration of the progress of research and drug development with the potential to make beneficial new medicines to treat diseases of high unmet medical need". In the Strategic Impact section of the report, awardees are provided with a list of 10 Impacts and are asked to prioritise at least five relevant options from the ten provided. At least one option must be selected but awardees are encouraged to rank up to 5 options, starting with the number 1 (being the most relevant). Awardees are then asked to provide more details justifying the options chosen. This will help SFI to quantify the types of impacts coming from the SFI-Pfizer BIAP 2016.

1. The research conducted through my award has enabled me to leverage international funding through industry/collaborative research.
2. The research conducted through my award has resulted in the start or expansion of a company which has resulted in the creation of high value jobs.
3. The research conducted through my award has attracted developing and nurturing businesses, through for example, the licensing of technologies.
4. The research conducted through my award has attracted international scientists and talentedpeople.
5. The research conducted through my award has resulted in a new policy being implemented and/or an improvement to the delivery of a public service.
6. The research conducted through my award has enhanced the quality of life and health of Irish citizens.

7. The research conducted through my award has developed the country's international reputation.
8. The research conducted through my award has resulted in the creation of employment through the production of a highly educated and relevant workforce in demand by industry and academia.
9. The research conducted through my award has impacted in other areas not reflected in the choices provided, for example by enhancing the creative output of Irish citizens.
10. The research conducted through my award has not yet realised any significant impact.

Knowledge Transfer and Commercialisation Activities

Awardees are asked to input details on Invention disclosures filed, patents files granted or exploited, licensing agreements signed, industry collaborations, ICT standards and spin out companies created. Gathering of this information will enable SFI to report against the following KPI, "By 2020, the proportion of invention disclosures, patents, licenses, and spin outs recorded by Enterprise Ireland that are linked to SFI research, will be doubled"

Funding Diversification

SFI expects that awardees will obtain research funding from as wide a range of sources as possible. In the annual report awardees are asked to report on the funding opportunities that they have pursued and won.

The Irish government has a target of securing €1.25bn in research funding over the next six years under Horizon 2020. SFI's Strategic Plan, Agenda 2020, sets a number of KPIs for Ireland to lead and take part in Horizon 2020 and ERC. These KPIs are reflected in the following objective of Pfizer BIAP 2016 call: To maximise the state investment in research through leveraging of non-exchequer funding.

13 Further information

Please see the FAQs at the following link for further information: http://www.sfi.ie/funding/funding-calls/open-calls/sfi-pfizer-biotherapeutics-innovation-award-programme-2016.html

For all additional queries please contact: partnerships@sfi.ie

Appendix I Cover Sheet

For Official Use Only	
PROGRAMME NAME **SFI-Pfizer Biotherapeutics Innovation Award Programme**	PFIZER AREA OF INTEREST
TITLE OF PROPOSAL (up to 30 words) *The title should not contain confidential details, given that the titles of funded proposals are published by SFI and Pfizer.*	
FULL NAME OF APPLICANT	RESEARCH BODY
TOTAL REQUESTED BUDGET (DIRECT COSTS, €)	REQUESTED STARTING DATE
PROPOSED DURATION	

Signatures below confirm acceptance and agreement with the SFI Terms and Conditions of Research Grants, and that the institution ensures the applicant meets eligibility requirements, and that the project is in full agreement with all legal and regulatory matters governing research in Ireland, and no aspect of this project is already being funded from another source and all details provided are correct.	
INSTITUTIONAL SIGNATORY AUTHORITY. Name: Position: Email: Signed: Date:	TECHNOLOGY TRANSFER OFFICE Name: Position: Email: Signed: Date:
Comment from TTO Director/Officer	

Applicant Contact Details and Signatures

Signatures above and below confirm acceptance and agreement with the SFI grants and awards Terms and Conditions, and that the institution ensures the applicant meets eligibility requirements, and that the project is in full agreement with all legal and regulatory matters governing research in Ireland, and no aspect of this project is already being funded from another source and all details provided are correct.

Applicant Contact Details

Applicant

Title	
Name	
Department	
Research Body	
Address	
Telephone	
Email	
Signature	

Co-Applicant (if relevant)

Title	
Name	
Department	
Research Body	
Address	
Telephone	
Email	
Signature	

Pfizer Area of Interest

Applicants must specify which Pfizer area of interest (Section 2) the proposed research aligns.

SFI Remit Justification (max. 250 words)

Applicants are required to complete a brief statement justifying that the application is within SFI's legal remit. The statement must describe how the proposed research is oriented basic or applied research which promotes or assists the development and competitiveness of industry, enterprise and employment in Ireland. For further information on SFI's legal remit please see the website.

Appendix II Pre-Proposal CV Template

Maximum of 2 pages.

Section 1: Required Details (Max. 1 page)

- **Name and Contact Details**
- **Career Profile (Education and Employment)**

  Include details of any adjunct positions held and include year of Ph.D.

- **Details of Most Relevant Research Funding as Lead/Co-Applicant**

  This section should only include funding, current and expired, obtained as an Independent PI.

- **History of Mentoring and Supervision**

  Include numbers of current and completed MSc and PhD students, directly under your supervision, as well as details of previous and current post-doctoral staff.

- **Innovation/Commercialisation Activity (e.g., relevant industry collaborations, invention disclosures, patents, spin-outs)**

  Distinguish between patents applied and under review versus patents granted

- **Other Information as Appropriate**

  Include details of key achievements including measures of esteem, invited presentations, principal scientific activities and responsibilities, as well as a statement demonstrating the applicant's accomplishments as an independent investigator.

Section 2: Selected Publications (Max. 1 page)

List most recent, relevant publications using the full reference, including title, for each publication.

Highlight with an asterisk each of your senior author publications (as per the eligibility criteria).

Please underline your name in each publication listed.

Appendix III Full Proposal CV Template

Maximum of 7 pages: Section 1 (max. 2 pages) + Section 2 (max. 3 pages) + Section 3 (max. 2 page)

Section 1 – Required Details (max. 2 pages)

- **Name and Contact Details**
- **Career Profile (Education and Employment)**

  Include details of any adjunct positions held and include year of Ph.D.

- **Details of Most Relevant Research Funding as Lead/Co-Applicant**

  This section should only include funding, current and expired, obtained as an independent PI.

- **History of Mentoring and Supervision**

  Include numbers of current and completed MSc and PhD students, directly under your supervision, as well as details of previous and current post-doctoral staff.

- **Innovation/Commercialisation Activity (e.g., relevant industry collaborations, invention disclosures, patents, spin-outs)**

  Distinguish between patents applied and under review versus patents granted

- **Other Information as Appropriate**

  Include details of key achievements including measures of esteem, invited presentations, principal scientific activities and responsibilities, as well as a statement demonstrating the applicant's accomplishments as an independent investigator.

Section 2 – Publication Listing (max. 3 pages)

Full List of Publications (or up to maximum space allowed)

Fill in the table including the total number of publications and categorize that number according to the additional categories below.

Total Publications: #	Senior Author Publications: #				
Journal Articles: #	Reviews: #	Book Chapters: #	Books: #	Conference associated publications[4]: #	Other: #

Please underline your name in each publication listed.

[4] Classified into peer reviewed conference papers and edited conference proceedings where appropriate as per discipline

Section 3 – Research Funding History (max. 2 pages)

List of research funding (include expired, current and pending) within the last 5 years using the table below. This should include competitive research funding received from funding agencies (international & national), charities, industry, etc.

For current and pending grants, any overlap with the proposed research project under consideration must be indicated.

For collaborative grants where you are not the sole grant-holder, state your role (PI, co-PI or collaborator), the total value of the award (€) and the specific amount of the award (€) allocated in your name. For example, if you participate in a multi-partner project, you must identify that portion of the overall award funding (e.g., €1million) that is specifically allocated to you (e.g., €200k).

For current grants, applicants must indicate their percentage time commitment to these other projects, as a function of 100% of their total working time.

The portion of research funding that you claim in your name in this document must be an accurate and a fair reflection of your responsibility in the projects listed and will be verifiable as such. SFI may conduct audits to verify such claims and reserves the right to reject proposals where the above principle of proportionality is not observed.

Awarding Agency & Grant #	**Role: PI/ co-PI/ collaborator**	**Current/ Expired/ Pending**	**Total Award (€)**	**Amount Allocated to Applicant (€)**	**% Time Commitment**	**Start Date**	**End Date**

Appendix IV Full Proposal Budget Template

Applicants are requested to complete a detailed budget breakdown of the planned expenditure on the BIAP 2016 award. Budgets should be prepared on a notional basis (i.e. Year 1, Year 2, Year 3) as opposed to a calendar year basis (2017, 2018, 2019 etc.), covering a period of 36 months.

Category	Year 1	Year 2	Year 3	Total
Staff				
Equipment				
Materials				
Travel				
TOTALS				

SFI Funded Staff	Year 1	Year 2	Year 3	Total
Total				

+*Inclusive of PRSI & Pension, indicate exact level for each post

Equipment	Year 1	Year 2	Year 3	Total
Total				

SFI Funded Materials	Year 1	Year 2	Year 3	Total
Total				

Travel	Year 1	Year 2	Year 3	Total
Total				

Appendix V Ethical Issues Table

Applicants are also required to complete the Ethical Issues Table below following review of the Guidance on Ethical and Scientific Issues in Appendix VI.

Table 1

Section	Ethics Issues Table	
Use of Animals in Research		
1	Does your research involve the use of animals?	Yes □ No □
2	Please confirm that Ethical approval will be obtained for the study prior to commencement of any research	Yes □ No □
Human Participants / Material / Data		
3	Does your research involve human participants, human biological material, or identifiable/potentially identifiable data?	Yes □ No □ If No, please review entire checklist but do not complete Sections 4-21. If Yes, complete all remaining sections.
4	Please confirm that Ethical approval will be obtained for the study prior to commencement of any research	Yes □ No □
Human Embryos/Foetuses		
5	Please confirm that your research does not involve Human Embryonic Stem Cells (hESCs)?	Yes □ No □
Humans		
6	Does your research involve human participants?	Yes □ No □
7	Are they vulnerable individuals or groups, patients or persons unable to give informed consent (including children/minors)?	Yes □ No □
8	In the course of your research programme, do you propose to use Clinical Research Facility/Centre (CRF/C) facilities?	Yes □ No □
9	Is a formal sponsor required for the research programme?	Yes □ No □
10	Does your research involve physical interventions on the study participants?	Yes □ No □
11	Does your research involve a clinical trial or investigation?	Yes □ No □

12	Is the clinical trial or investigation covered by the EU Clinical Trials Directive?	Yes □ No □
13	If yes, please confirm that HPRA approval will be obtained prior to study commencement.	Yes □ No □
14	Please confirm that an independent Trial Steering Committee (TSC) will be established.	Yes □ No □
15	Please confirm that the trial or investigation will be registered in a publicly available, free to access, searchable clinical trial or investigation registry	Yes □ No □
16	Please confirm that the requisite insurance cover will be sought for the clinical trial or investigation and evidence of cover submitted to SFI prior to trial initiation.	Yes □ No □
17	Does this clinical trial or investigation involve activities outside of the Republic of Ireland or partnerships with international collaborators?	Yes □ No □
	Human cells/Tissues	
18	Does your research involve human cells or tissues?	Yes □ No □
19	Does your application include an element of biobanking?	Yes □ No □
	Personal Data	
20	Does your research involve personal data collection and/or processing?	Yes □ No □
21	If any potentially commercially exploitable results may be based upon tissues or samples derived from human participants, please confirm that there has been appropriate informed consent for such use.	Yes □ No □

Appendix VI Guidance on Ethical and Scientific Issues

Animal Studies

Where animals are to be used in research projects, applicants must comply with the SFI Use of Animals in Research Policy[5] and the Health Products Regulatory Authority's (HPRA)[6] position on the use of animals in research. SFI will only support research using animals that is fully compliant with the requirements of the HPRA, has been independently peer reviewed and where consideration has been given to the use of alternative approaches not involving the use of live animals and addressing the principles of the 3R's (replacement, reduction, refinement).

Additional external sources of guidance include the HPRA and ARRIVE[7] (Animal Research: Reporting In Vivo Experiments) guidelines produced by the UK National Centre for the Replacement, Refinement & Reduction of Animals in Research (NC3Rs).

In order to allow for the appropriate evaluation of the scientific merit of applications for funding involving animal use, applicants submitting full proposals must provide the information outlined in Table 2 below *within the description of their proposed research and methodology*. In addition, all applicants are required to complete the Ethical Issues Table (Appendix V) which must be included in the grant application submitted to SFI.

Table 2[8] – Information required for research involving the use of animals

Information	Details to be provided in the main body of your Grant Proposal
Ethical Statement	Indicate the nature of the ethical review permissions, relevant licences and national or institutional guidelines for the care and use of animals that cover the research. **SFI will require evidence that relevant ethical and regulatory approval has been granted prior to the award commencing.**
Study Design	For each experiment, give brief details of the study design including: a) The number of experimental and control groups. b) Any steps taken to minimise the effects of subjective bias when allocating animals to treatment (e.g. randomisation procedure) and when assessing results (e.g. blinding). c) The experimental unit (e.g. a single animal, group or cage of animals). d) The number of times each animal will be measured.
Experimental animals	a) Provide details of the animals used, including species, strain, sex, developmental stage and weight. Include a sound scientific reason for these choices.

[5] http://www.sfi.ie/funding/grant-policies/sfi-policy-on-the-use-of-animals-in-research.html
[6] https://www.hpra.ie/homepage/veterinary/scientific-animal-protection
[7] https://www.nc3rs.org.uk/arrive-guidelines
[8] *Table adapted from the NC3Rs ARRIVE Guidelines*

	b) Provide further relevant information such as the source of animals, international strain nomenclature, genetic modification status (e.g. knock-out or transgenic), genotype, health/immune status, drug or test naïve, previous procedures, etc.
Sample size	a) Specify the total number of animals used in each experiment, and the number of animals in each experimental group. b) Explain how the number of animals was arrived at. Provide details of any sample size calculation used. c) Indicate the number of independent replications of each experiment, if relevant
Experimental outcomes	Details regarding the experimental outcomes to be assessed.
Planned statistical analysis	An explanation of how the number of animals was arrived at, including power calculations, if appropriate, or other supporting information to demonstrate that the findings will be robust. A brief overview of the planned statistical analyses in relation to the choice of sample size, along with details of any statistical advice available.

Human Studies

For studies involving humans, ethical approval must be obtained from the relevant national or local ethics committee prior to the start of the project. SFI only permits early stage regulated clinical trials (Phase I or combined Phase I/II) and investigations to be undertaken under the scope of the following SFI programmes: SFI Research Centres, Spokes, and Strategic Partnerships in addition to SFI Research Professorship where the successful candidate will become a Co-Principal Investigator within an SFI Research Centre.[9] Clinical trials and investigations requiring approval by the Health Products Regulatory Authority (HPRA) will not be permitted through other SFI funding programmes, including BIAP 2016.

Funding requests for early stage research involving human volunteers and/or human samples that does not require regulatory approval are permitted under BIAP 2016. Where there is any doubt, applicants are advised to contact the HPRA prior to submission to ensure eligibility and are required to indicate in their application that the proposed study does not require HPRA approval.
Furthermore, in line with a current directive from its parent Government Department, research funded by SFI must not comprise any component of the following:

- Research intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer

[9] http://www.sfi.ie/funding/grant-policies/sfi-clinical-trial-and-clinical-investigation-policy.html

- Research using human embryonic stem cells or tissues.

In order to allow proper evaluation of the scientific merit of applications for funding, applicants who propose research involving human participants and/or biological material must provide the information requested in Table 3 below *within the description of their proposed research (full proposal only)*. In addition, all applicants are required to complete the Ethical Issues Table (Appendix V) which must be included in the grant application submitted to SFI.

Table 3 - Information required for research involving the use of human subjects

Information	Details to be provided in the main body of your Grant Proposal
Ethical Approval	Ethical approval is required for all research work funded by SFI that involves human participants or human material (including tissue). Applicants should state by whom and when the research programme will be reviewed and specify any other regulatory approvals that have been obtained, or will be sought. Applicants should allow sufficient time to obtain Ethical approval. **SFI will require evidence that relevant ethical and regulatory approval has been granted prior to the award commencing.**
Study Recruitment	Applicants are asked to provide specific details on study recruitment procedures including inclusion and exclusion criteria and informed consent procedures. These should include relevant, additional details for specific groups including children/minors, patients and vulnerable groups.
Clinical Research Infrastructure	Applicants are asked to provide specific details where they have access to, or plan to access, the support/services of a Clinical Research Facility/Centre (CRF/C) at study design and/or implementation phase. The following information must be provided: • Name and address of the CRF/C • Information on the nature and stage/s of the input/advice/collaboration/service • Rationale for the choice of facility/centre • Information on the costs of providing the service/input, setting out where this is provided in-kind, from additional funding or requested from the project budget Evidence of this support/service must be provided to SFI in the form of a letter from the Director of the facility at the time of application for funding.
Physical Interventions	Applicants are asked to address any potential risk and/or harm to the safety of the patients or human participants in the study, if relevant, and highlight any potential ethical concerns during this study and/or at follow-up stage, even if not part of this application and how you propose to deal with them.
Clinical Trials	SFI will only support trials that are fully compliant with the SFI Clinical Trial and Clinical Investigation Policy[10] and the requirements of the HPRA. For applications including clinical studies that fall within the scope of the EU

[10] http://www.sfi.ie/funding/grant-policies/sfi-clinical-trial-and-clinical-investigation-policy.html

	Clinical Trials Directive, approval from the HPRA is required. Necessary authorisations for trials involving medical devices differ depending on the device. Applicants are responsible for ensuring that all necessary approvals are in place and provided to SFI prior to study initiation. • **Sponsor:** Plans for appropriate sponsorship arrangements must be included in the application i.e. Letters of Support must be provided from sponsors or potential sponsors. Please note that SFI cannot act as sponsor. • **Steering Committee:** Applicants should provide details on the establishment and membership of an independent Trial Steering Committee. If any other type of independent monitor is to be implemented, please indicate and provide any relevant details. • **Study Registration:** Applicants are asked to outline plans for the registration of their trial or investigation on a publicly available, free to access, searchable clinical trial or investigation registry such as the International Standard Randomised Controlled Trial Register (ISRCTN) or ClinicalTrials.gov. • **Multi-Jurisdictional Studies:** Subject to pre-approval from SFI, applicants should provide relevant details in relation to clinical research activities outside of the Republic of Ireland or partnerships with international collaborators.
Human Cells/Tissues	Applicants are asked to provide details on the cells or tissues types, including the source of the material.
Biobanking	Applicants are asked to describe how they will comply with international best practice for biobanking components in this research programme[11][12][13][14], with particular regard to quality of sample collection, processing, annotation and storage, and describing data protection measures where appropriate. Please also reference relevant guidelines/standards you will use.
Protection of Personal Data	Compliance with legislation and EU rules on data protection is required. Applicants are asked to provide that appropriate safeguards will be put in place and provide examples e.g. details of their procedures for data collection, storage, protection, retention, transfer, destruction or re-use (including, collection methodology (digital recording, picture, etc.), methods of storage and exchange.

[11] http://www.oecd.org/science/biotech/44054609.pdf
[12] http://www.isber.org/?page=BPR
[13] http://www.molecularmedicineireland.ie/page/g/t/103
[14] http://biospecimens.cancer.gov/bestpractices/2011-NCIBestPractices.pdf

Appendix VII Proposal checklists

Pre-proposal Checklist

SECTION	DETAILS
Coversheet	The coversheet must include the following information: Applicant Name Research Body Proposal Title (max. 30 words) SFI Requested Budget (indicative budget at pre-proposal stage) Pfizer Area of Interest SFI Remit Justification (max. 250 words) TTO Comments Appropriate Signatures
Technical Summary	Max. 250 words
Applicant CV	Use template in Appendix II (max. 2 pages)
Scientific Rationale, Background & Impact	Max. 1000 words or 2 pages with graphics
Proposed Biotherapeutic Drug Candidate Modality	Max. 200 words
Proposed Biological Proof-of-Mechanism Readout	Max. 200 words
Research Plan & Reagents Needed	Max. 500 words

Full Proposal Checklist

SECTION	DETAILS
Coversheet	The coversheet must include the following information: Applicant Name Research Body Proposal Title (max. 30 words) SFI Requested Budget Pfizer Area of Interest SFI Remit Justification (max. 250 words) TTO Comments Appropriate Signatures
Keywords	Max. 15
Technical Summary	Max. 250 words
Lay Abstract	Max. 100 words
Applicant CV	Use template in Appendix III (max. 7 pages)
Research Description	Max. 10 pages
References	Max. 5 pages
Impact Statement	Max. 2 pages
Intellectual Property Management	Max. 1 page
Infrastructure, Facilities, Services & Space	Max. 1 page
Proposed Budget	Use template in Appendix IV
Budget Justification	Max. 2 pages
Ethical and Scientific Issues Table	Use template in Appendix V