

SFI-PFIZER BIOTHERAPEUTICS INNOVATION AWARD PROGRAMME (BIAP) 2016 FAQs

Remit

Q1a To qualify for BIAP 2016, at what stage does the research need to be?

The minimum requirement is that there must be some clear preliminary data (e.g., early genetic/proteomic/cell biology data) that strongly implicates a drug target in a specific disease. Fully realised targets with developed intellectual property (IP) are also acceptable.

Q1b Are Pfizer only interested in novel targets and pathways?

Novel targets and novel associated biology are preferred, but applications will be considered where a known target has been linked to new biology or a novel insight suggests utility for that target in a newly-defined disease scenario. Influential pathways in diseases of high unmet medical need will be considered once they are aligned with one of Pfizer's five areas of focus as follows: Immunology and Inflammation; Oncology; Neuroscience; Cardiovascular and metabolic Diseases and Rare Disease.

Q1c Is a reference to a publication implicating a target/pathway with a disease enough supporting evidence for an application?

The minimum requirement is that there must be some clear preliminary data from the applicant's research that strongly implicates a drug target in a specific disease.

Q1d Will small molecules be considered in this programme?

Small molecules will only be considered for BIAP 2016 if there is a strong rationale for a protein-drug conjugate form such as antibody drug conjugates, etc. Small molecule approaches and assets that are stand-alone could be submitted at the pre-proposal stage, but if it is deemed that the molecule is unsuitable for conjugation with a protein the proposal will be eliminated from the BIAP evaluation process.

Q1e Are Pfizer interested in non-protein therapeutics?

Non-protein approaches may be submitted at the pre-proposal stage, but only if they are suitable for protein bioconjugate delivery, as outlined in Q1d. If it is deemed that the molecule is unsuitable for an active collaboration in the near term, the proposal will be eliminated from the BIAP evaluation process. Stand-alone small molecule and nucleic acid-based approaches are not within scope. If you have a non-protein approach which you are unsure is suitable for the programme, please contact partnerships@sfi.ie to discuss.

Q1f Are novel vaccine targets for unmet bacterial infections being considered under this call?

Such proposals are not appropriate for this call.

Q1g Is there less priority given to pathways and disease areas not listed with the areas of interest listed by Pfizer?

If an investigator wishes to propose a compelling target that is at an advanced stage of validation but addresses a biological pathway or disease not included within the list in Section 2 (Pfizer Areas of Interest) of the Call Document, such proposals will have equal priority to other submitted proposals so long as they address a disease indication of significant unmet medical need that is aligned to one of the five areas of focus.

Q1h Are *in vivo* models essential for this programme?

Preliminary data using *in vivo* models is not essential for submission of a pre-proposal. The applicant must however include a plan for proof of mechanism studies in appropriate *in vivo* models, within the 3-year term of the program. The applicant must be able to access the appropriate models.

Eligibility

Q2a Can I include a co-applicant and/or collaborator on my application?

Collaborators are not permitted roles within this programme. Pfizer scientists will serve as the official collaborators. However, in certain circumstances, there may be need for a co-applicant to be included 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.

Q2b What information do you want to see in the pre-proposal non-confidential technical summary?

This should be a succinct and accurate technical summary of the proposed work programme. It should provide a technical expert with a clear explanation of the proposed work programme. It is not explicitly necessary to name potential drug targets of the work if unpublished and undisclosed, with institutional IP being currently generated. See Q3a for further detail.

Q2c Can the co-applicant be a postdoc who will also draw his salary from the project?

Post-doctoral Fellows are not eligible to serve as a co-applicant. Applicants and co-applicants 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.

Salaries for applicants and co-applicants are not permitted.

Q2d Do prior and ongoing collaborations with other pharma partners exclude people from applying?

This depends on the nature of the agreement with the other party. Applicants should declare any legal relationship with other Pharma companies up-front that relates to the target and/or research plan proposed. This declaration must be included within the TTO Comment Box within the proposal cover sheet.

Q2e What is an eligible Research Body?

The list of Eligible Research Bodies is available on the [SFI website](#). Only researchers in SFI [Eligible Research Bodies](#) can receive funding from the BIAP 2016. Researchers based outside of Ireland are NOT eligible to receive funding through this programme.

Q2f Is there a minimum number of senior-author publications an applicant must have to be eligible for BIAP 2016?

There is no limit on the number of senior-author publications an applicant must have when applying to BIAP 2016.

Q2g I am currently under review for another SFI programme. Am I eligible to apply?

Yes. Applicants currently under review in other SFI programmes are eligible to apply to this call provided all other eligibility criteria are met.

Q2h Can current SFI grant holders apply to the Programme?

Yes. Current SFI grant holders are eligible to apply to this call once all other eligibility criteria are met with the exception that investigators who are currently in receipt of more than one BIAP award are not permitted to apply to the 2016 call.

Q2i I have never previously been funded by an SFI award. Am I eligible to apply?

Yes. Applicants who have never before held an SFI award are eligible to apply to this call provided all other eligibility criteria are met.

Q2j I am employed by a Research Body in Northern Ireland, am I eligible to apply?

No, applicants must be based in an eligible Research Body in the Republic of Ireland.

Q2k How many applications can an individual make to the Programme?

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

Q2l What qualifies as an independent research grant?

The lead applicant (and, where relevant, co-applicant/s) is (are) required to have

demonstrated research independence through securing at least one independent research grant as lead investigator or as co-investigator. The grant must have been competitively awarded and internationally peer reviewed. Eligible research grants would be expected to support at least one full-time equivalent, excluding the applicant(s), and include research team costs (e.g. materials and consumables). This excludes smaller awards such as travel grants, equipment grants, post-graduate fellowships, post-doctoral fellowships, and awards of short duration (12 months or less). Laboratory fit-out / setup funding, awards from the applicant's institution, and awards that have not been subject to external international peer review are also excluded. Applicants may be required to provide evidence to support the validity of an award upon request. If you are uncertain regarding the eligibility of funding you have received, please contact SFI at partnerships@sfi.ie.

Q2m Is a retired member of academic staff, who meets all the other eligibility criteria, eligible to apply to BIAP 2016 if the Research Body can make the necessary commitments regarding infrastructure requirements and independent status of the individual?

The Emeritus/Retired Eligibility Policy for SFI Programmes can be found at this link - <http://www.sfi.ie/funding/grant-policies/emeritusretired-eligibility-policy.html>

Q2n I am a post-doctoral researcher on a contract; can I apply to the BIAP 2016 and request my own salary?

No. Lead PI/co-PI salary is not an eligible cost. Furthermore, to be eligible to apply to this programme, a contract researcher must be recognised by the host Research Body as an independent investigator as defined in Section 3.2 of the call document. Further details about SFI's Grant Budget Policy are available [here](#). The budget policy will be updated in July 2016 – BIAP 2016 applicants who are invited to submit a full proposal should refer to the July 2016 version when completing their requested budget.

Intellectual Property

Q3a At the pre-proposal stage, how do I avoid disclosing my novel target name but yet convey that the target will be appealing to Pfizer/SFI?

If the target name is obvious from the description of data or the publication history of the applicant, then it is not essential to blind that. Only key, unpublished, IP-supporting data need be blinded to protect undisclosed material.

Q3b If I already have a compound developed against the biological target of interest, do the IP terms outlined in Section 3.6 of the call document still apply?

If an academic is bringing a compound into the collaboration as background IP, separate terms for management of IP will be negotiated with Pfizer.

Application

Q4a Is a detailed budget required in the pre-proposal application?

A detailed budget breakdown is not required in the pre-proposal application. However, applicants are required to provide an indicative total requested budget within the cover sheet. The total budget amount requested (direct costs) may be modified at the full proposal stage.

Q4b Can references be included in the pre-proposal application?

It is permitted to provide references in your pre-proposal although it is not anticipated that a large number of references would be required at the pre-proposal stage. It is not necessary to embed the references in the text. Inclusion within an appendix is acceptable.

Other

Q5a Will feedback be given on pre-proposals?

Written feedback will be provided to applicants at the conclusion of the pre-proposal evaluation.

Q5b Does my research require ethical approval?

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 of the call document 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.