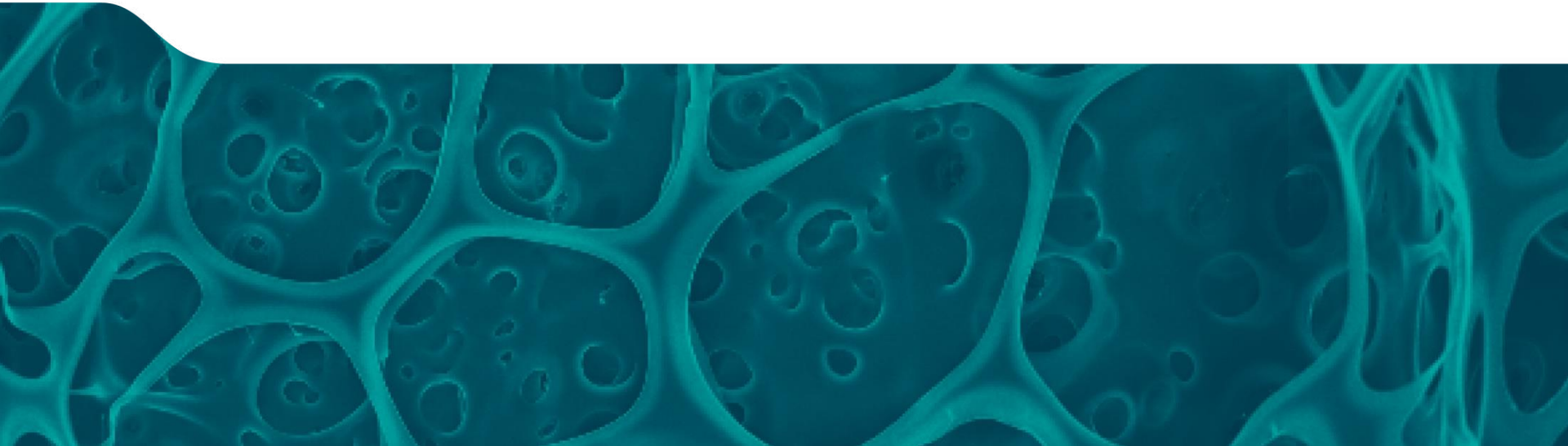
Webinar:
SFI-Pfizer Biotherapeutics Innovation Award Programme 2016



Partnership Team

- **SFI**
  - Dr Siobhan Roche (SFI Partnerships Manager)
  - Dr Avril Monahan (Scientific Programme Manager)
  - Ms Caroline Coleman (Administration Manager)
  - Dr Anne Costello (SFI Fellow)

- **Pfizer**
  - Dr Orla Cunningham (Director of Global Biotherapeutics Technology Group)
  - Mr Olivier Drap (Associate Director of R&D Business Development)
  - Mr Stephen Murnaghan (Sr European Patent Attorney)
  - US staff at the Centers for Therapeutic Innovation

Agenda

- Partnership model
- Pfizer Global Biotherapeutics Technologies Group
- Call for Proposals

PARTNERSHIP MODEL

SFI Partnerships

- **Agenda 2020**
  - To be the exemplar in building partnerships that fund excellent science and drive it out into the market and society

- **Innovation 2020**
  - Increase collaboration between firms and the public research system
  - Ensure the mobility of researchers between academia and industry

SFI-Pfizer Biotherapeutics Innovation Award Programme

Structure of SFI-Pfizer Partnership

- **Joint SFI-Pfizer call for proposals**
  - Joint design of programme
  - SFI administrative lead
  - Pfizer input to project selection

- **Joint award oversight**

Objectives

- 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

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

Pfizer Areas of Interest

- Immunology & Inflammation
- Oncology
- Neuroscience
- Cardiovascular and Metabolic Diseases
- Rare Diseases

See Section 2 of call document for further details

Research Collaboration

- **Pfizer GBT**
  - Protein drug discovery platforms and expertise
- **Academic Team**
  - Novel biological target or pathway of interest
- **Collaboration**
  - Development of biotherapeutic by Pfizer
  - Preclinical testing in cell-based and in vivo models by academic team

Validation of a potential drug candidate that can advance into clinical testing

Collaborative Research Agreement

- **Programme Participation Agreement (PPA)**
- **Specifies terms and conditions of research collaboration**
  - Intellectual property, confidentiality, award oversight etc.
- **Template PPA pre-agreed including management of IP**
- **Principles for management of IP agreed**

Intellectual Property

- **Background IP (BIP)**
  - Ownership retained by partner that introduces BIP
  - Non-exclusive, royalty free license for research purposes

- **Foreground IP (FIP)**
  - Pfizer will own all compound FIP and any FIP developed solely by Pfizer that does not incorporate the RB BIP
  - RB will own all other FIP

Option Rights

- **Research Body will grant to Pfizer**
  - Exclusive option to obtain an exclusive, royalty-bearing license to RB FIP for commercial purposes
  - Include a non-exclusive license to RB BIP
- **Option period**
  - Execution date of PPA to 6 months following submission of final report to Pfizer

By submitting an application to the programme, the applicant and RB acknowledge these terms and agree to enter into an appropriate PPA if funded

PFIZER GLOBAL BIOTHERAPEUTICS TECHNOLOGIES GROUP

GBT Dublin Group

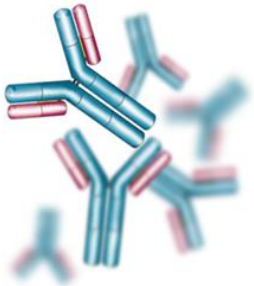
GBT GC Business Park, Dublin

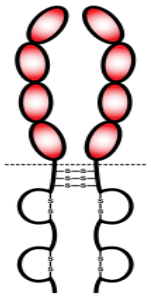
GBT, Kendall Square, MA

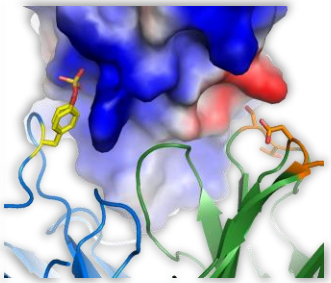
CTI, Boston, San Francisco & San Diego

GBT Dublin at SFI-Pfizer BIAP Awardee Announcement
TBSI, April 2016

GBT: An ecosystem for biologics discovery







Antibody Engineers

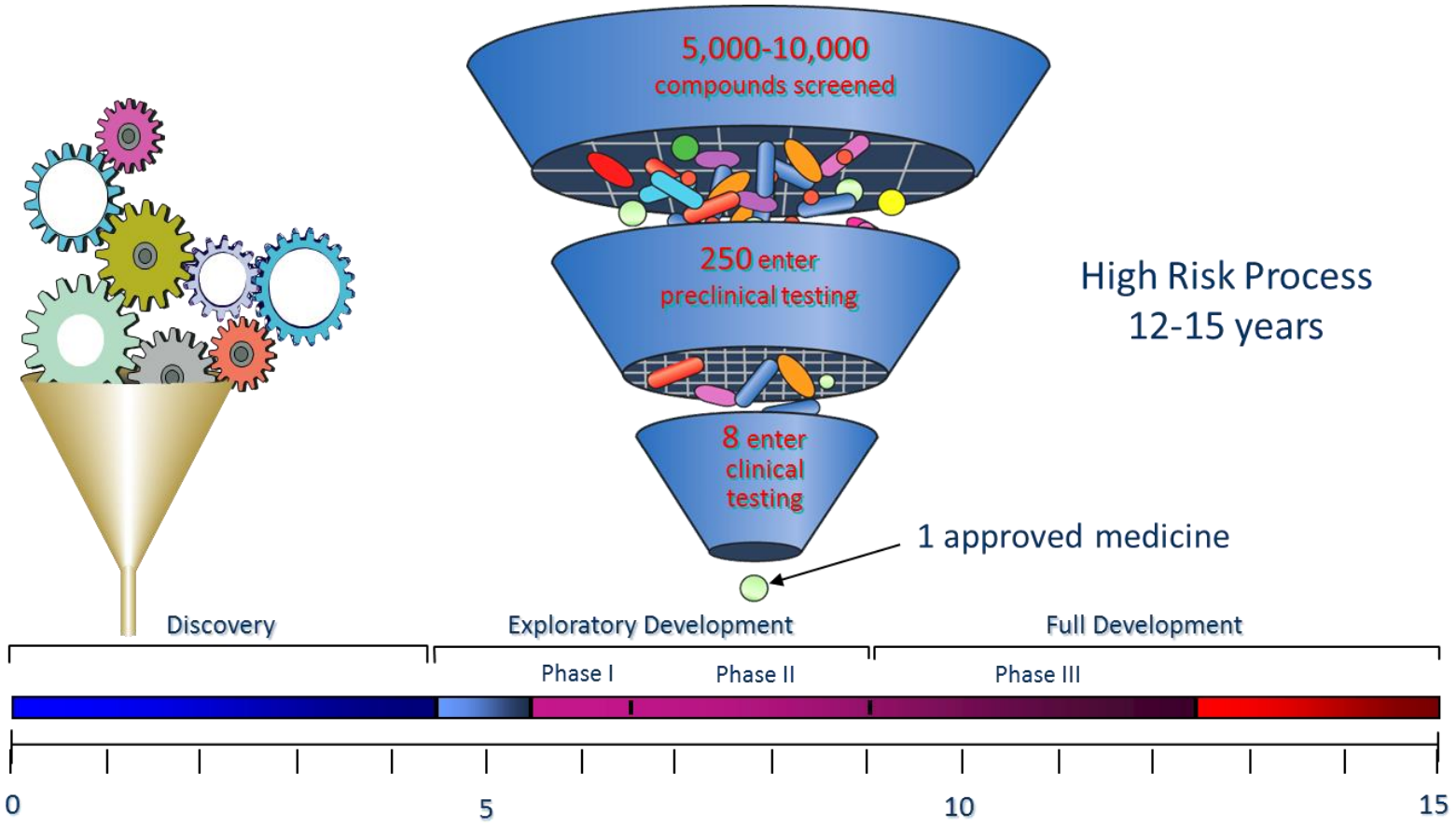
- *In vitro* lead generation: Phage Display library design, generation and screening
- *In vivo* lead generation: Rodent hybridoma, B-cell selection, Avian mAbs, human antibodies
- Format conversion, affinity, stability and selectivity maturation
- Humanization
- PK Engineering
- Bi-functional engineering

Protein Engineers

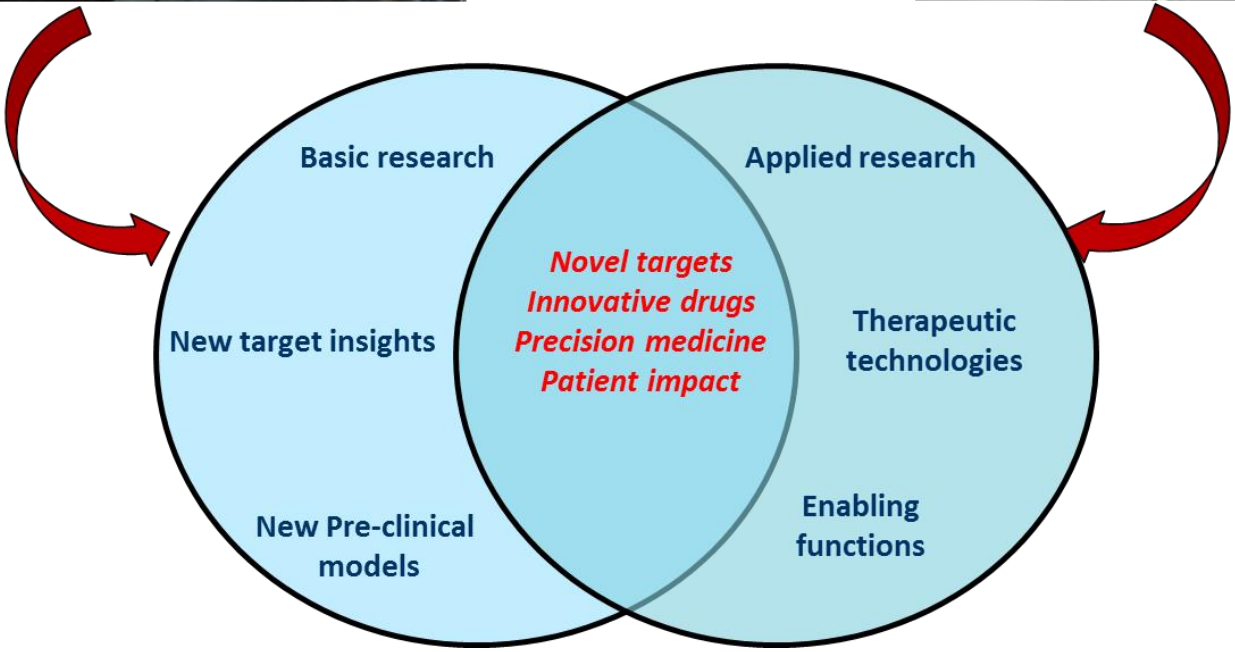
- Protein engineering to improve potency, attributes, PK
- Protein modifications (e.g., PEGylation)

- Biophysics and Bioanalytics
- X-ray crystallography
- Molecular modeling
- Non-GMP bulk production

The challenge:
Drug discovery attrition rates remain high



Increasingly, biomedical research institutes & industry share common objectives



But, Past Partnering Efforts have Met with Mixed Results……

- Large institutional grants – generally low ROI
- Licenses and sponsored research agreements, not direct collaboration
- Academia has great biology, but less experience with the drug development process
- Collision of priorities
  - Pharma desire to control product development, intellectual property
  - Natural desire of academics to explore activities of pharma compounds outside the project goals

Today: Genuine Collaboration

VISION

Accelerate the Translation of Academic Innovative Discoveries into Potential Candidate Molecules

STRATEGY

Leverage Innovative Pfizer GBT Group in Dublin

Joint Teams for Rapid Discovery and Optimisation of Candidates

Leveraging Complimentary Expertise

APPROACH

Biotech-like Approach

Close Collaboration with Scientific Partners

Goal Alignment!

CALL FOR PROPOSALS

Application Process

- **Non-Confidential Pre-proposal**
  - Maximum of 3 pre-proposals per applicant
  - Pre-proposal deadline – 13:00, 15th September 2016
  - Pfizer Panel review

- **Invitation to submit full proposal**
  - Full proposal deadline – 13,00, 20th January 2017
  - Full proposal prepared in collaboration with Pfizer scientists
  - International peer review
  - Panel review

- **Call will be managed outside of Sesame**
  - partnerships@sfi.ie

Eligibility of Applicant

- PhD or equivalent for at least 5 years
- Member of academic staff/ contract researcher
- Eligible Irish Research Body
- Secured at least one independent, competitively reviewed research grant as lead or co-investigator

Funding

SFI

- **Maximum award size €400,000 over 3 years**
  - Includes salary for a Postdoctoral Researcher, consumables, equipment & travel
- **€266,000 over 2 years for targets at more advanced stage of development**

Pfizer

- **Drug development activities**
  - Target protein production & characterisation
  - Binding assay optimisation
  - Biotherapeutic drug discovery selection & screening
  - Potency/stability optimisation0

Confidentiality

- Pre-proposals must only contain non-confidential information
- Ensure title and abstract also non-confidential
- Full proposals may contain confidential information
- NDA between Pfizer and Research Body – process coordinated by Pfizer
- Confidentiality agreement in place with all international experts reviewing on behalf of SFI
- TTO must sign off on pre- and full-proposals

TTO Sign Off

- Confirm awareness of application
- Ensure appropriate discussions on intellectual property (IP) have taken place
- Acknowledgement of the IP ownership terms
- Declaration of any existing industrial collaborations in relation to the proposed research

Non-Confidential Pre-Proposal

- **Signed Cover Sheet**
- **Technical Summary (max. 250 words)**
- **Applicant CV (max. 2 pages, SFI template)**
- **Scientific Rationale, Background & Impact (max. 1000 words or 2 pages with graphics)**
  - A brief description of the target/pathway and link to human disease and disease mechanism(s)
  - What is/are the unmet medical need(s)?
  - 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
  - Describe how the proposed approach is different and the expected impact for patients if the approach is successful
  - Key evidence available to support the hypothesis.

Pre-Proposal

- **Biotherapeutic Drug Candidate Modality (max. 200 words)**
  - Describe biotherapeutic molecules generated against target, mechanism-of-action, molecule characteristics

    OR
  - Characteristics of preferred biotherapeutic agent

- **Proposed Proof-of-Mechanism Readout (max. 200 words)**
  - In vitro & in vivo models

- **Research Plan & Reagents (max. 500 words)**
  - Provide a brief description of the research plan to be carried out leading to demonstration of proof-of-mechanism.
  - List the available reagents and assays to support the research plan.
  - Alternatively, describe reagents and assays that may need to be developed and any gaps in the plan
  - Outline how Pfizer scientists may contribute (i.e. complete mechanistic studies *in vitro*, develop cellular assays, discover biomarkers, etc.)

Pre-Proposal Evaluation

- **Pre-Proposals Evaluated by Pfizer Scientists**

- **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

Full Proposal

Application Section	Max Limit
Signed Cover Sheet	SFI Template
Keywords	Max. 15 words
Non – Confidential Technical Summary & Lay Abstract	Technical Summary (max. 250 words) Lay Abstract (max. 100 words)
Applicant CV	Max. 7 pages (SFI template)
Research Description	Max. 10 pages (+ 5 page refs)
Impact Statement	Max. 2 pages
Budget & Justification	Budget template + 2 Page justification (new SFI Grant Budget Policy & salary scales)
IP Management	Max. 1 page
Host infrastructure etc.	Max. 1 page
Ethical Issues Table	SFI Template

Research Description

- **Objectives**
- **Scientific & clinical rationale**
  - Description of therapeutic target
  - Tissue expression & function
  - Link to human disease
  - Novelty of molecular pathway- in vitro & in vivo biology
  - Current validation status
- **Proposed modality**
  - Biologic form, Affinity, Potency, Selectivity, Pharmacokinetics, Safety, Efficacy

Research Description

- **Research plan & reagents needed**
  - Propose a path or testing scheme to identify desired biotherapeutic drug
  - Target species for PK & toxicology
  - Path to understand drug exposure and biological response in translatable models
  - Timelines, decision points & accelerators
- **Preclinical design to achieve PoM**
  - How will PoM be demonstrated? What are the readouts?
  - Applicants are requested to review the Guidance on Ethical and Scientific Issues in Appendix VI and to provide the requested information on study design.
- **Existing Assets & Technologies**
- **Risk & Mitigation**
- **Key Activities & Personnel**

Impact Statement

- **What are the benefits of this partnership with Pfizer?**
- **How will the academic partner and Research Body benefit?**
- **Who are other potential beneficiaries?**
- **What is the expected impact on patients?**
- **Over what timeframe might the benefits be realised?**
- **Supporting information**
  - http://www.sfi.ie/funding/sfi-research-impact/ - includes Impact webinar
  - SFI Agenda 2020
  - Partnering with Pfizer Worldwide R&D

Stage I Full Proposal Evaluation

Scientific Peer Review - Postal

- **Applicant**
  - 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

- **Research programme**
  - 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

Stage II Full Proposal Evaluation

Panel Review – International Reviewers + Pfizer Scientists

- **Applicant**
- **Research Programme**
- **Impact**
  - Quality, significance, and relevance of the proposed research's potential contribution to demonstrably support and underpin **enterprise competitiveness and societal development** in Ireland

Common Pitfalls in 2015

- Concerns over toxicity of the proposed biologic
- Failure to differentiate over what is offered by competitors
- Concerns over project feasibility
- Lack of convincing preliminary data
- Failure to identify a target
- Previous failed trials with the proposed biologic within Pfizer
- Insufficient recognition of the need for testing in pre-clinical animal models
- Applicant's lack of expertise in the area

Award Oversight

- **Joint Steering Committee**
- **Membership**
  - Pfizer, SFI, PI, University Representative
- **Overseeing and supervising the overall performance of the research project**
  - Review progress against objectives and milestones
  - Identify candidate compounds
  - Recommend project progression or termination
- **Annual reporting**

Key Dates

Activity	Date
Pre-proposal deadline	15th September 2016 (13:00, Dublin local time)
Pre-proposal evaluation outcome	November 2016
Full-proposal deadline	20th January 2017 (13:00, Dublin local time)
Full proposal panel meeting	March 2017
Full-proposal funding decision announced	April 2017
Project Initiation	From June 2017

Further Information

- FAQs & slides will be posted at this link: http://www.sfi.ie/funding/funding-calls/open-calls/sfi-pfizer-biotherapeutics-innovation-award-programme-2016.html

- Email partnerships@sfi.ie with additional queries

Science Foundation Ireland sfi For what's next

Pfizer

Thank You