Catalyst Grant Additional Conditions

This document should be read in conjunction with Breast Cancer Now's standard grant terms and conditions.

1. Introduction

1.1 These grant conditions (**Catalyst Grant additional conditions**) are relevant to Applicants for and holders of Catalyst Grants made as part of BCN Research Ltd's Catalyst Grant Research Funding Scheme which is supported by Pfizer.

1.2 As the trading subsidiary of Breast Cancer Now, BCN Research Ltd expects and requires the Grant Holder and the Host Institution to also comply with **BCN Research Ltd Grant Conditions** (to the extent varied by these Catalyst Grant additional conditions) a copy of which is enclosed with the Grant Award Letter, and it's **Funding Policies**. Breast Cancer Now's Funding Policies are available on the Breast Cancer Now's website (www.breastcancernow.org). These Catalyst Grant additional conditions, the Grant Award Letter and Breast Cancer Now's Grant Conditions and Funding Policies set out the terms and conditions on which the Grant is made by BCCT to the Host Institution and Grant Holder.

2. Interpretation

2.1 In these Catalyst Grant additional conditions the following words shall bear the meanings given to them below. All other defined terms shall have the meaning given to them in Breast Cancer Now's Grant Conditions.

BCN Research Ltd	means BCN Research Ltd, a company incorporated in England (number 05047652) whose registered office is at Breast Cancer Now, 42-47 Minories, London, EC3N 1DY;
IIR	means each and every *Investigator Initiated Research agreement* to be entered into between Pfizer, the Grant Holder and the Host Institution, covering the conduct and sponsorship of a study involving clinical trials; as well as supply and use of any study drug.
MTA/CTA	means each and every *Materials Transfer Agreement or Commercial Transfer Agreement* to be entered into between Pfizer, the Grant Holder and the Host Institution, relating to the supply and use of any Study Drug or Research Drug by Pfizer;
Pfizer	means Pfizer Inc, with offices at 235 E. 42nd Street, New York, NY 10017;
Research Drug	means a research drug to be provided by Pfizer to the Grant Holder and the Host Institution pursuant to an MTA/CTA;

Research Funding Scheme	means the Catalyst Grant Research funding scheme established by BCN Research Ltd to support development, initiation, administration, and completion of a research program which shall include solicitation and review of proposals for preclinical and clinical studies, development and review of protocols, conduct and monitoring of the approved studies, and evaluation of study findings, as related to preclinical and clinical breast cancer treatments, involving Study Drugs and Research Drugs;
Research Grant Agreement	means the agreement between BCN Research Ltd and Pfizer dated 22 December 2015 relating to the Research Funding Scheme; and
Study Drug	means a study drug to be provided by Pfizer to the Grant Holder and the Host Institution pursuant to an IIR or MTA/CTA.

2.2 References to Breast Cancer Now in Breast Cancer Now's Grant Conditions and Funding Policies shall for the purpose of the Grant made under this Grant agreement be construed as references to BCN Research Ltd.

2.3 In the event of any inconsistency between these Catalyst Grant additional conditions and Breast Cancer Now's Grant Conditions, these Catalyst Grant additional conditions shall prevail to the extent of any inconsistency.

3. Responsiblities in Research Practice

3.1 The Host Institution shall ensure that the Research:

3.1.1 either (and as notified by BCN Research Ltd in the Grant Award Letter):

(a) involves preclinical or translational studies investigating the mechanisms of action of Study Drugs, or Research Drugs either alone or in combinations with other drugs or treatments or

(b) incorporates key elements of translational research into trials to investigate mechanisms of action; biochemical, cellular, molecular and genetic endpoints; predictive and prognostic markers; and underlying biological effects of the Study Drugs or Research Drugs (whether alone or in combinations with other drugs or treatments), and

3.1.2 is conducted in Europe.

3.2 It is the Host Institution's responsibility to ensure that it and all other parties, including collaborators, supervisors and staff employed in relation to the Research:

3.2.1 undertake the data management, statistical analysis and quality assurance process associated with the Research as governed by Good Clinical or Laboratory Practice, as applicable;

3.2.2 ensure that arrangements for the management and monitoring of clinical trials meet the standards laid out in Good Laboratory Practice in respect of Research Drugs; and

3.2.3 ensure that arrangements for the management and monitoring of clinical trials meet the standards laid out in Good Clinical Practice in respect of Study Drugs.

3.3 The Host Institution taking the administrative lead in respect of the Grant must be based in Europe.

3.4 The Host Institution undertakes to BCN Research Ltd that:

3.4.1 any Research must have obtained appropriate ethical approval in advance of the Research being conducted;

3.4.2 the Research must be conducted in accordance with all applicable laws and regulations in the jurisdiction where the Research is conducted; and

3.4.3 the Research will not include the use of any Research Drug for use in humans.

3.5 If the Principal Investigator or researchers undertaking the Research become aware during the conduct of the Research of any of the following information or circumstances relating to the Study Drug or Research Drug, the Host Institution undertakes to promptly notify BCN Research Ltd and Pfizer (even if complete information is not yet available) of:

3.5.1 an imposition by an applicable competent regulatory authority in any area of the world in which the Study Drug or Research Drug is marketed of any prohibition or restriction of the Study Drug's or Research Drug's use; and

3.5.2 any new information that in the opinion of a reasonably alert and informed researcher might influence the evaluation of the risks and benefits of the Study Drug or Research Drug. This could include both positive and negative results from clinical trials or other studies in relation to all indications and populations, whether or not use of the Study Drug or Research Drug in that indication or population is approved under the relevant marketing authorization.

3.6 The Grant Holder and the Host Institution shall ensure that Pfizer's support is acknowledged in any publication or materials associated with a Grant, in such manner as reflects the objectives of the Catalyst Grant Research Funding Scheme (as shall be notified to the Grant Holder and the Host Institution by BCN Research Ltd).

4. Intellectual Property; MTA/CTA/IIRs with Pfizer

4.1 The Host Institution's use of any material provided by Pfizer (including the Research Drugs and Study Drugs), the disclosure of any results arising from the use of such material, and the exploitation of any intellectual property derived from Research using the materials so provided, will be governed by the applicable MTA/CTA or IIR made directly between the Grant Holder, the Host Institution and Pfizer.

4.2 The Host Institution acknowledges that BCN Research Ltd will not be a party to the IIR/MTA/CTA and will not be involved in any negotiations related thereto. BCN Research Ltd is not responsible for either the Host Institution's or Pfizer's conduct pursuant to an MTA/CTA or IIR.

4.3 BCN Research Ltd confirms that neither the Host Institution nor the Grant Holder require BCN Research Ltd's consent to enter into an MTA/CTA or IIR with Pfizer.

4.4 The Host Institution shall notify BCN Research Ltd if it knows or has reason to suspect that it's compliance with an MTA/CTA and / or IIR will put the Host Institution in breach of its obligations and duties owed to BCN Research Ltd (whether under these Catalyst Grant additional conditions and/or Breast Cancer Now's Grant Conditions and Funding Policies).

4.5 The terms of the relevant IIR or MTA/CTA between Pfizer, the Grant Holder and Host Institution as applicable, will govern the publication of results of any studies conducted as well as intellectual property rights arising from the use of the Study Drug provided thereunder.

5. Communication of the Research

5.1 The Host Institution and/or the Grant Holder must contact BCN Research Ltd before releasing any communications about either the Grant that has been awarded or the Research arising from the Grant and must comply with any communications protocol notified to it by BCN Research Ltd in relation to any public communications regarding the Grant or the Research arising from the Grant.

5.2 The Host Institution and the Grant Holder are free to identify Pfizer as providing a Study Drug or Research Drug, as applicable, in publications or in association with a listing of the Research in publicly available listings of ongoing clinical trials.

6. Breast Cancer Now

6.1 BCN Research Ltd reserves the right to assign or sub-contract its rights or obligations under this Grant agreement to Breast Cancer Now or another wholly-owned subsidiary of Breast Cancer Now.

6.2 The Grant Holder and Host Institution hereby give permission to BCN Research Ltd to share with Breast Cancer Now any materials or information it obtains from the Grant Holder and/or Host Institution pursuant to the Grant agreement and for Breast Cancer Now to be able to make use of such materials and information on the same basis as BCN Research Ltd.

7. Termination

7.1 In addition to BCN Research Ltd 's rights of termination pursuant to Breast Cancer Now's Grant Conditions, the Grant may be terminated by BCN Research Ltd immediately upon thirty days (30) written notice to the Host Institution, if BCN Research Ltd determines, in its sole but reasonable discretion, that continued performance of the applicable Research would violate legal or regulatory requirements, or breach scientific standards or pose a safety risk to personnel or study subjects, and no mitigation is possible.

7.2 BCN Research Ltd shall notify the Grant Holder and Host Institution as soon as reasonably possible in the event of termination of the Research Grant Agreement.

7.3 Without prejudice to any rights of termination contained in the IIR or MTA/CTA, the Grant Holder and Host Institution acknowledge and accept that in the event of termination of the Research Grant Agreement:

7.3.1 any Research shall continue to completion (subject always to condition 7.3.2 and save where this Grant agreement is terminated pursuant to condition 7.1 and/or Breast Cancer Now's Grant Conditions);

7.3.2 BCN Research Ltd shall notify the Grant Holder and the Host Institution where, as a result of termination of the Research Grant Agreement, its obligations in respect of the Grant become restricted, in which case BCN Research Ltd shall provide the Host Institution with any non-cancellable expenses of the Host Institution and/or Grant Holder relating to the Research, including future personnel costs applicable during the period of up to six (6) months following the date of termination of the Research Grant Agreement, so long as they were properly incurred and prospectively approved by BCN Research Ltd in the Research budget and only to the extent they cannot reasonably be mitigated. Subject thereto the Host Institution will refund to BCN Research Ltd any unused Grant that remains at the date of termination of the Research Grant Agreement and the Host Institution and the Grant Holder shall cease all work except as necessary for the orderly close out of the Research, for the fulfilment of regulatory requirements, or until such time no harm will occur to Research patients.

8. Confidentiality, Data Protection and Freedom of Information

8.1 If the Applicant and Applicant Institution desire to exchange confidential information relating to the Research, then the Applicant/Applicant Institution will enter into a mutually agreeable nondisclosure agreement.

8.2 In addition to the relevant terms of any IIR, the Host Institution will comply with such patient information confidentiality requirements and regulations that apply to the Research under the applicable laws of the jurisdiction(s) within which the Institution in question is conducting the Research, including (without limitation) the laws relating to the protection of personal data.

8.3 The Grant Holder and/or Host Institution shall conduct the Research in accordance with all applicable legal and regulatory requirements relating to patient confidentiality.

8.4 BCN Research Ltd acknowledges that the Host Institution may be or is subject to the Freedom of Information Act 2000 or equivalent legislation in the jurisdiction in which the Host Institution is established or operates, and is therefore subject to obligations to respond to requests for information received under such legislation.