

**CANCER
GRAND
CHALLENGES**



Cancer Grand Challenges

Commercialisation Policy

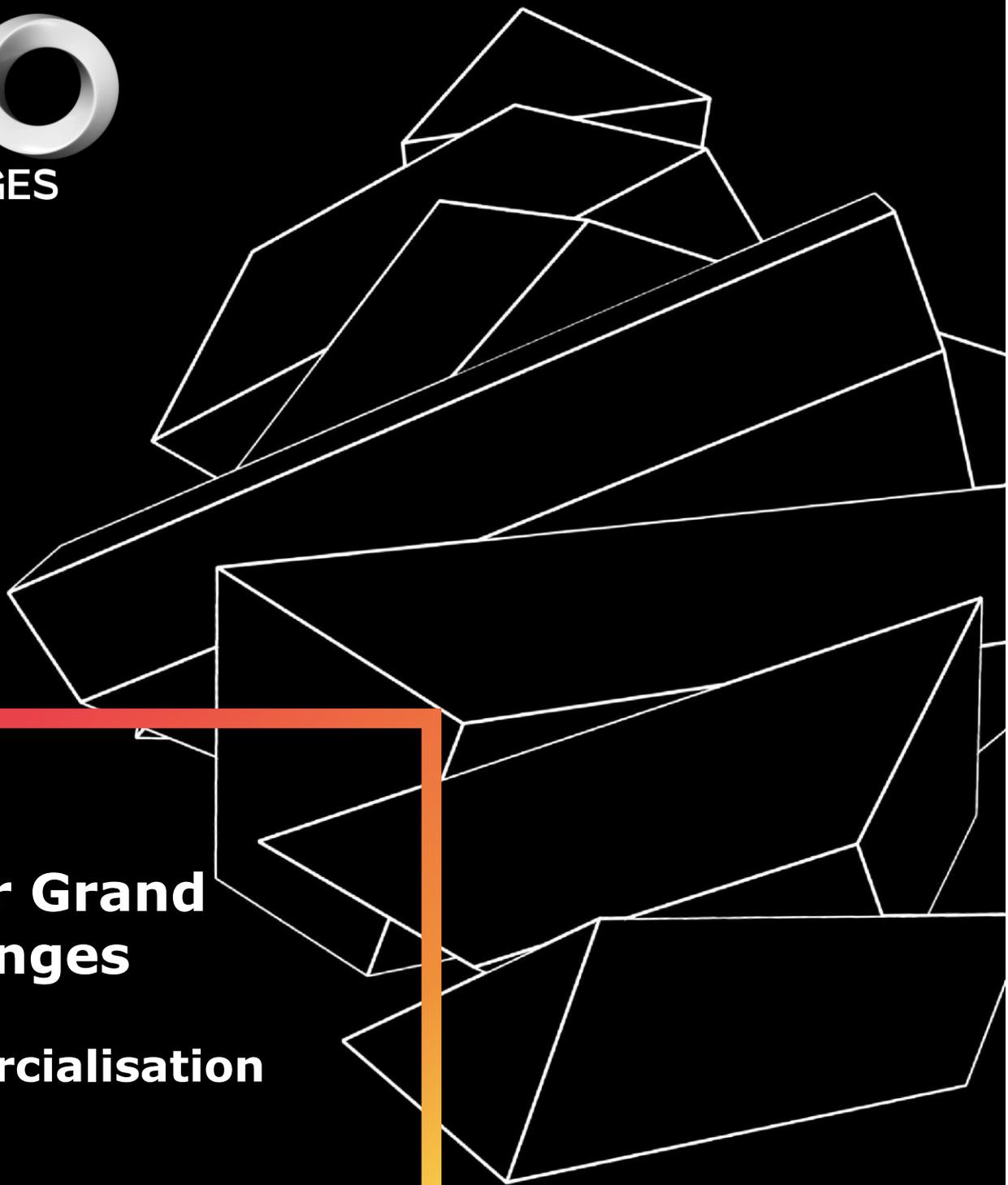




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Part A: Purpose of the Policy

The principal purpose of Cancer Grand Challenges is to co-fund transformative cancer-focused 'team' science within the Remit at scale to maximise impact. Each Host Institution (HI) acknowledges the importance of working together in a collaborative spirit and promoting the sharing of Results by institutions participating in Cancer Grand Challenges in a manner that endeavours to deliver benefits to patients, support cancer research, advance public health, and enhance the general public good. Accordingly, it is important that Results capable of being translated through commercialisation to benefit cancer patients are not fragmented and remain capable of being commercialised in an efficient, coordinated fashion. The provisions of this Policy are intended to advance these objectives.

Unless otherwise defined in this Policy, capitalised terms used in this Policy will have the same meaning they do in the CGC Award Agreement ("CGC Award Agreement").

Part B: Sharing Materials, Data and Background

1 Materials

1.1 Transfer

Each HI acknowledges that certain materials may need to be transferred within the Funded Team to perform Cancer Grand Challenges ("Materials"). In this Policy, a HI that provides Material ("Provided Material") to another HI for Cancer Grand Challenges is the "Provider", and the receiving Funded Team is the "Recipient". Clauses 1.2 and 1.3 below will govern the transfer of Material, and the relevant Provider and Recipient shall enter into a separate material transfer agreement that contains terms consistent with clauses 1.2 and 1.3 and the other terms of this Policy [and the relevant sections of the CGC Award Agreement and the Cancer Grand Challenges Award Management and Funding Policy Guide ("Guide")].

1.2 Ownership

As between the Parties and subject to the relevant clauses of this Policy and CGC Award Agreement, Provided Material will be and remain the property of the Provider. The Recipient (a) acknowledges that a Provider of Provided Materials of human origin may be the custodian, rather than the owner, of that Provided Material and (b) will only use that Provided Materials within the scope of consent provided by the person from whom that Provided Materials originates. As between the Provider and the Recipient, the Provider is expected to bear the delivery, insurance and other costs incurred in shipping Provided Material to the Recipient. Funded Teams make Provided Materials available on an "as is" basis, namely without any responsibility on the part of the Provider for the quality and fitness for the purpose for which the Material is provided.

1.3 Use of materials

Unless agreed with the Provider and documented in a separate agreement, the Recipient will only use Provided Material for Cancer Grand Challenges and for no other purpose, and will ensure no one at the Recipient other than Researchers has access to Provided Material. The Recipient will keep Provided Material at the laboratory in which the Recipient's Researchers work in a secure environment protected against damage, loss and misuse, and will handle, store and use Provided Material properly and safely. The Recipient may not modify, disassemble or re-engineer Provided Material, determine its structure or composition through other means or make it available to any person other than as permitted by the Provider.



2 Data sharing

2.1 The Award Management and Funding Policy Guide details the requirements for data sharing as part of Cancer Grand Challenges. Please see section 3.3.2.

3 Background IP: Ownership and Use

3.1 Ownership

Background IP introduced to Cancer Grand Challenges by a HI will remain the property or under the control of that HI (unless the HI is a party to a TTA, in which case the ownership arrangements set out in that TTA will apply as described in below in clauses 5.3 and 8.1.2). Nothing in this Policy or the CGC Award Agreement gives or grants any right to Background IP of another Party other than as expressly described in this Policy and CGC Award Agreement. Each HI's Background IP in existence at the date that it executed the CGC Award Agreement is included in the Schedule attached to CGC Award Agreement together with a description of any third party rights that might affect the grant of rights to Cancer Research UK under clause 6.1.3 (and the HI will keep CRUK apprised of any third party right that may arise or come to its attention between the date of execution of the CGC Award Agreement and the Start Date that might affect the grant of rights to Cancer Research UK under clause 6.1.3).

3.2 Right to use

Each HI gives the other HIs a fully paid-up, non-transferable, non-sublicensable and nonexclusive right to use its Background IP to perform Cancer Grand Challenges in the manner anticipated by Cancer Grand Challenges research activities, and for no other purpose other than under clause 6. The right given in this clause is personal. It may be sub-licensed to subcontractors in accordance with the relevant clauses of CGC Award Agreement.

3.3 Consistency

No HI will make any Contribution, or introduce any Background IP to Cancer Grand Challenges, that is subject to terms or third-party rights that would prevent it being used in Cancer Grand Challenges and/or prevent the grant of rights under clause 6.

Part C: Maximising outcomes; public and patient benefit

4 Publications

4.1 The Award Management and Funding Policy Guide details the requirements for publishing as part of Cancer Grand Challenges. Please see section 3.3.1.

5 Results – ownership, use and licenses

5.1 Purpose

The principal purpose of Cancer Grand Challenges is described above in Part A. Each HI acknowledges the importance of working together in a collaborative, rather than proprietary, spirit and sharing outputs from Cancer Grand Challenges in a manner that benefits patients, supports cancer research efforts and is performed for the general public good. Accordingly, it is important that Results capable of being translated through commercialisation to benefit



cancer patients are not fragmented and remain capable of being commercialised in a coordinated fashion. The provisions of this clause 5 are intended to support this objective.

5.2 Ownership

As between the HIs, and subject to the provisions of clause 7, Results will be owned by the inventing or originating HIs, and if any Result is invented or originates from more than one HI, it will be owned in equal and undivided shares by those HIs. For HIs that are party to a TTA, the terms of that TTA will apply as described in clauses 5.3 and 8.1.2 to the ownership and use of Results that HI invents or originates. Except as expressly stated in this clause 5.2, section 7 or an applicable TTA, no HI will be required to assign or convey ownership of any of its interest in or to any Results to any other Party. To the extent necessary to comply with this clause 5.2, section 7 or an applicable TTA, each HI shall do such acts and things as are reasonably necessary to: (a) assign or convey ownership of its interest in Results and Intellectual Property Rights into equal and undivided shares as required by this clause 5.2 and; (b) to ensure that Results and Intellectual Property Rights generated by any Researchers are owned by their employing HI.

5.3 TTAs

For each HI that is a party to a TTA, the terms of that TTA will apply to Results invented or originating from that HI on the basis that those Results are considered to be funded by Cancer Research UK and Cancer Grand Challenges is research activity to which the TTA applies.

5.4 Reserved rights and use

Each HI grants (i) a fully paid-up and non-exclusive right to each other HI to use all Results to perform Cancer Grand Challenges; (ii) a fully paid-up and non-exclusive right to each For-Profit HI (and their respective affiliates) to use Results in its own internal research but not for the purpose of commercialising any product or service. For the avoidance of doubt, this grant does not include the right to use Results in the development, including but not limited to seeking regulatory authorisation, or sale of any product or development or provision of any service, and (iii) a fully paid-up, perpetual, irrevocable, sublicensable and non-exclusive right to each non-profit HI to use all Results and Intellectual Property Rights in or relating thereto for Academic Research, including for purposes of publication as contemplated by 3.3 in the CGC Award Management and Funding Policy Guide.

5.5 Government funding

To the extent that Background IP or Results were developed using U.S. Government funding, other than the funding provided through Cancer Grand Challenges, the U.S. Government has certain rights in said Background IP or Results under 35 U.S.C. §§ 200-212 and applicable regulations. As provided in the CGC Award Agreement, each HI grants to the U.S. Government a non-exclusive, non-transferable, irrevocable, paid-up licence to practice or have practised any Invention conceived using U.S. Government funding, throughout the world by or on behalf of the U.S. Government.

6 Results – Further development

6.1 The main outputs of Cancer Grand Challenges are expected to be Know How suitable for publication and wider dissemination in the cancer research community. HIs acknowledge that it is important to Cancer Research UK and NCI that the outputs of Cancer Grand Challenges are developed in the manner that will best deliver cancer patient benefit and wider public good, and are not exploited by different HIs in a manner that is divergent or contrary to Cancer Research UK's and NCI's strategic goals. To achieve this, Cancer Research UK expects, to the extent reasonably achievable, to exploit commercially the Results through its wholly owned subsidiary, CRT, as contemplated by clause 6.1.5(b). In connection with those objectives, if Intellectual Property Rights arise from the performance of Cancer Grand Challenges



- 6.1.1** Subject to its right to receive a share of revenue pursuant to clause 8.1 and subject to clauses 6.1.2 - 6.1.5 (inclusive) and the risk allocation provisions under CGC Award Agreement, and effective as of the date of disclosure by the HI or the Start Date (whichever comes first), each HI that is not a party to a TTA grants to CRT an exclusive option and right to take a license that is worldwide, perpetual and irrevocable (unless CRT expressly refuses to enter into a share of revenue pursuant to clause 8.1), that is exclusive in respect of Results that are the subject to a patent or copyright or rights to tangible property and, if requested by CRT, and subject to clause 6.1.2, non-exclusive in respect of all other Results and any Background IP to the extent necessary to use the Results ("**CRT Licence**"), with the right to sub-license, under that HI's rights, title and interest therein for any and all purposes and, subject to any third party rights at the Start Date (or, in the case of a new HI, the Join Date). Such option shall be exercisable by CRT providing written notice to the HI and the HI and CRT shall promptly and in good faith agree the terms of the CRT Licence which shall reflect the provisions of clauses 6, 7 and 8 and shall not require the payment by CRT of any further consideration (but for the avoidance of doubt shall provide for the HI to receive a share of net revenue as contemplated by section 8). For the avoidance of doubt, TTAs will be used to ensure that CRT can lead the commercial exploitation of Results and Intellectual Property Rights in accordance with their terms but shall not prejudice the rights of NCI or restrict the grant of rights by a HI pursuant to clause 6.1.3.
- 6.1.2** CRT may at any time request that any Results that are proposed to be or have been licensed non-exclusively as part of a CRT Licence, subject to any obligations owed to third parties, should be licensed exclusively and the relevant HI shall cooperate by acting reasonably and in good faith in responding to and negotiating with CRT in respect of any such request. The license granted under this clause 6.1.2 is subject to the rights of each Party under clauses 5.4 and 5.5.
- 6.1.3** To the extent that Results arise from any research funded by the US Federal Government, nothing shall prevent a HI from granting licenses to the US Federal Government in accordance with any rights reserved by law pursuant to 35 USC §§ 200-212 and 37 CFR § 401 et seq and applicable Government implementing Regulations;
- 6.1.4** Cancer Research UK encourages ideas and proposals from Funded Teams and the wider cancer research community on approaches to use Results to benefit cancer patients and for the wider public good. In respect of each Funded Team, a single committee ("**Commercialisation Committee**") shall be established promptly following the first identification of an Invention comprised in any Results with representation for (a) the HI that employs the Team Lead; (b) each HI that created the Results to which the Invention relates; (c) Cancer Research UK and CRT; and (d) NCI. As and when any later Invention comprised in the Results of the Funded Team is disclosed, the representation of the Commercialisation Committee shall be extended to include any additional HI whose Researchers created the Results to which such later Invention relates. Such Commercialisation Committee will meet periodically to discuss and advise on the potential uses and applications for the relevant Results, and opportunities to further develop the relevant Intellectual Property Rights. The Parties will establish the committee and agree its terms of reference as soon as is practicable. The Cancer Grand Challenges Management Group and any Commercialisation Committee that are formed pursuant to this clause 6.1.4 shall actively liaise to proactively drive the use of Results to advance cancer science and for the benefit of patients and to enable the Cancer Grand Challenges Management Group to seek and identify opportunities for patenting or otherwise securing Intellectual Property Rights protection for Results.

6.1.5 Development activities:



- (a) Before it grants any rights under clause 6.1.1 to a third party for any purpose other than Academic Research, CRT shall provide to the Commercialisation Committee and each HI that created the relevant Results a commercialisation and development plan that (i) identifies Results and Intellectual Property Rights capable of commercial exploitation; and (ii) describes development and commercialisation activities proposed to be performed in respect of those Results by CRT, and the timescales in which they are expected to be performed. CRT shall consider, in good faith, all comments that it receives from the Commercialisation Committee, before it grants the relevant rights, in relation to the development plan and the arrangements proposed with that third party.
- (b) Subject to clause 6.1.5 (a), CRT will use reasonable efforts to commercialise Results and/or Intellectual Property Rights in accordance with the development plan referred in clause 6.1.5(a). In the event that CRT has failed within three (3) years of the End Date specified in CGC Award Agreement for the funding of Cancer Grand Challenges to enter into a license or other commercialisation arrangement with a commercial third party (including any company formed for the purpose) to exploit commercially the Results ("**Commercialisation Agreement**"), then any HI(s) that has (or have) generated Results and/or Intellectual Property Rights that have been included within the Results and/or Intellectual Property Rights which CRT has been commercialising ("**Interested Parties**") shall discuss with CRT in good faith the development plan and commercial activity conducted to date and agree whether the exclusive right of CRT to commercialise such Results and/or Intellectual Property Rights should be extended for an agreed further period. If the Interested Parties, acting reasonably and in the best interest of expediently developing products or services for cancer patients, agree that CRT no longer represents the most appropriate route forward for the commercialisation of such Results and/or Intellectual Property Rights, the Interested Parties may nominate between themselves a single HI that wishes to lead commercial exploitation and such HI may enter into good faith negotiations with Cancer Research UK and CRT to allow such HI to assume responsibility for commercialisation of the Results. For the avoidance of doubt such HI shall be subject to the obligation to share net revenue (including with CRT) in accordance with section 8 and compliance with clause 6.1.5(c);
- (c) In the event that the Commercialisation Agreement entered into by CRT grants a license to a commercial third party in only the field of cancer research and development, CRT shall consider in good faith any request from a HI that it should be permitted to develop and exploit Results in other fields. Any HI assuming responsibility for commercialisation pursuant to this clause 6.1.5(c) will be bound by obligations materially identical to the commercialisation obligations of CRT within this Policy and CGC Award Agreement. Any Commercialisation Agreement concluded by CRT or one or more HI shall:
 - (i) reserve rights consistent with clauses 5.4 and 5.5;
 - (ii) (if applicable) reserve rights required by law pursuant to 35 USC §§ 200-212 and 37 CFR § 401 et seq, in favour of US-based HIs and the Government;
 - (iii) exclude all warranties by any HI, Cancer Research UK, CRT, or NCI including the exclusion of any warranties relating to the validity, enforceability and non-infringement of Rights;
 - (iv) include an indemnity from the commercial third party in favour of each HI in terms materially similar to the following: "[third party] will indemnify,



hold harmless, and defend each HI, Cancer Research UK, CRT, and NCI and their respective officers, employees, and agents and the inventors of any Rights and their employers against any and all claims, suits, losses, damages, costs, fees, and expenses resulting from, or arising out of, exercise of the rights granted by the Commercialisation Agreement. This indemnification includes, but will not be limited to, any product liability.”;

- (v) include an obligation by the third party to obtain customary commercial general and product liability insurance;
- (vi) for Commercialisation Agreements granting exclusive rights under any Results, an obligation for the third party to pursue commercially reasonable and diligent efforts to commercialize the Results;
- (vii) customary provisions acknowledging that there are no implied licenses granted to such third party to use any other intellectual property belonging to the Parties, other than the relevant Results and Rights;
- (viii) restrictions on such third party’s use of the names of the Parties;
- (ix) grant to the commercial third party the right to defend and enforce any exclusively licensed Rights (to which the HIs hereby consent); and
- (x) the inclusion of the following specific commitments by the commercial partner (a) to prioritise within a particular territory the achievement of regulatory authorisation for any products developed using the Intellectual Property Rights, CRT shall use all reasonable efforts to ensure that equivalent obligations apply to the United States; and (b) to sell therapeutic products developed using the Intellectual Property Rights at an affordable price in the UK, the commercial partner shall be required to use all reasonable efforts to ensure that such products are made available at an affordable price in the United States (on terms no less favourable than the pricing terms applicable to the UK but taking into account the different reimbursement models that apply in the United Kingdom and the United States). Cancer Research UK or CRT will use reasonable efforts to negotiate reimbursement of any patent costs incurred by a HI to the extent that they relate to Rights comprised in Results that are the subject matter of any Commercialisation Agreement.

6.16 If Cancer Research UK and NCI together did not provide the majority of the total funding for the research that resulted in Results and/or Intellectual Property Rights (taking into account the relative contributions of the inventors of the Results), then CRT will endeavour to negotiate with the other third party or parties which provided the majority funding to agree on the appropriate leading party and route for commercial exploitation (taking into account the particular respective expertise of Cancer Research UK, CRT and any third parties), and the division of any revenues accruing from such Results.

7 Patent protection – notification, ownership, management, responsibilities

7.1 Aim

It is important to Cancer Research UK and NCI that outputs from Cancer Grand Challenges are made available in a manner that supports further research efforts, and that patents are only filed in respect of discoveries made during Cancer Grand Challenges where Cancer Research UK and NCI believe it is both appropriate and in the best interests of delivering cancer patient benefit. In some situations, it may be appropriate to protect certain Results to help deliver



cancer patient benefit and safeguard the future availability or development of promising discoveries.

7.2 Discoveries and Inventorship

Inventorship of Inventions from HIs shall be determined in accordance with applicable laws, and ownership shall follow inventorship, subject to applicable institution policies.

7.3 Disclosure

Each HI shall take appropriate steps to cause all its Researchers to fully disclose any and all Inventions to the appropriate organizational office that manages such disclosures for that institution which shall report such matters to CRUK, CRT and to the Commercialisation Committee.

7.4 Patent Filing; Prosecution and Licensing Responsibility

Each Funded Team will promptly provide to Cancer Grand Challenges Management Group and the Commercialisation Committee details of any Result that is or may be protectable as a patent or other Intellectual Property Right. Cancer Grand Challenges Management Group will keep a register of Results notified. The responsibility for protecting any Intellectual Property Rights shall reside with the HI at which the Invention is conceived provided that:

7.4.1 in the event that such HI elects not to protect any Intellectual Property Rights, reasonably prior (and in any event not less than sixty (60) days) to the expiry of any applicable time bar for protection, the HI(s) shall permit CRT to seek protection;

7.4.2 such HI shall consider any input provided by the Commercialisation Committee prior to commercialisation.

7.4.3 In relation to any Intellectual Property Rights (including any patents) where the inventors consist of personnel from more than one HI, each application for a registered Intellectual Property Right, and all resulting Rights, will be owned in equal and undivided shares by each HI that employs an inventor of the relevant Results and, unless otherwise agreed, would be managed by CRT and the prosecution and maintenance of such Rights shall be at CRT's discretion and all costs incurred in relation thereto shall be paid by CRT.

7.4.4 If CRT declines or ceases to prosecute any such Intellectual Property Rights which are owned by more than one HI, then the relevant HIs shall, through a HI nominated by them, enter into good faith discussions to decide amongst themselves which of the HIs (if any) shall assume prosecution of the Intellectual Property Rights in question. CRT shall be permitted at its discretion to decline or cease to prosecute any Intellectual Property Rights provided that it takes reasonable steps to give at least 30 days' notice to the nominated HI before any applicable time bar for filing or prosecution arises.

8 Revenue share

8.1 Sharing fairly

Cancer Research UK is required to make sure that Results do not result in any private gain that is more than incidental to the charitable goals of Cancer Research UK and Cancer Grand Challenges, and that the Results are applied for public benefit. It is also important each HI's contribution to Cancer Grand Challenges is recognised appropriately.

8.1.1 If CRT or a HI enters into any arrangement with a third party under which it receives revenue from any exploitation of Results, Invention or Intellectual Property Rights, it will share with each HI that contributed to the Results and Cancer Research UK a fair and reasonable portion of the net revenue as further described in clause 8.1.2 below.

8.1.2 The portions of net revenue to be shared between the respective contributing HIs and Cancer Research UK will be discussed in good faith between the relevant HIs and CRT



and agreed, in writing, based on a range of factors including, among others, that HI's contribution compared to the contributions of other HIs to the package of Results, Inventions and Intellectual Property Rights for which the revenue is received and also any applicable TTAs with the latter taking priority as between CRT and any HIs entitled to a revenue share that has an extant TTA with CRT. Nothing in any TTA limits the rights granted to each HI under clause 5.4.

- 8.1.3** If the relevant HIs and CRT do not agree, within sixty (60) days after a request from either of them, the portion of relevant net revenue that HI will receive, then the relevant HI or CRT may request that the matter is discussed by the Cancer Grand Challenges Management Group or determined by an expert in accordance with the dispute resolution procedure as provided in CGC Award Agreement.



Glossary

Term	Definition
Academic Research	means academic teaching scientific or clinical research performed by or under the direction of a person in accordance with their respective charitable or academic status, whether alone or in collaboration with a third party and whether sponsored or funded by any third party (so long as the Results are not encumbered in favour of any commercial or 'for-profit' third party)
Background	The know-how, materials and rights that are not created or generated, or do not arise in the performance of, the Grand Challenges award and are introduced by a Host Institution to the Cancer Grand Challenges Team.
CGC Award Agreement	means an agreement that shall be entered into by CRUK, NCI and each organisation participating in Cancer Grand Challenges
CGC Management Group	has the meaning in section 2.3 of the Award Management and Funding Policy Guide
Commercialisation Agreement	has the meaning given in clause 6.1.5 (c)
Commercialisation Committee	has the meaning given in clause 6.1.4
CRT	means Cancer Research Technology Limited, the wholly owned subsidiary of CRUK that commercialises the results of CRUK-funded research
End Date	has the meaning as given in the CGC Award Management and Funding Policy Guide
Funded Team	means those HIs participating in Cancer Grand Challenges
Host Institution (HI)	has the meaning as given in the CGC Award Agreement
Intellectual Property (IP)	all copyrights and copyrightable subject matter, including any and all worldwide applications,



	registrations, renewals, and extensions thereof and all rights of reproduction and publication, rights to create derivative works and all of the rights incident to copyright ownership; all trade secrets, defined as any and all confidential information, technology, ideas, know-how, and proprietary processes and formulae; all inventions, designs, models, mask works, patents, and pending patent applications.
Invention	means any patentable or otherwise protectable invention or discovery that is conceived and reduced to practice in the performance of Cancer Grand Challenges during the term.
Know How	means information not in the public domain, including ideas, concepts, inventions, formulae, discoveries, data, specifications, procedures and protocols for experiments, studies and tests, results, laboratory records, information relating to methodologies, mathematical models, software programs, code and algorithms, and compilations even if individual components are in the public domain
Laws	means, with respect to a particular Party, all applicable laws (including common law and equity), rules, statutes, regulations (including guidelines of any relevant regulatory authority) in force from time to time that apply to such Party's activities under the Cancer Grand Challenges
Materials	materials, including (a) documents, models, prototypes, hardware, software, machinery, records of software and other electronic records; and (b) chemical or biological substance, including any organic or inorganic element or compound, nucleotide or nucleotide sequence including DNA or RNA sequences, gene, vector or construct including plasmids, phages, bacterial vectors, bacteriophages and viruses, host organisms including bacteria, fungi, algae, protozoa and hybridomas, eukaryotic or prokaryotic cell line or expression system or any development or strain or product of that cell line or expression system, protein including any peptide or amino acid sequence, enzyme, antibody or protein conferring targeting properties and any fragment of a protein or a peptide enzyme or antibody, drug or prodrug, assay or reagent, any other genetic or biological material or micro-organism
Parties	has the meaning as given in the CGC Award Agreement



Remit	means basic, translational and population cancer research, including discovery science through to clinical research, multi-disciplinary science (including biological and physical sciences, bioinformatics, scientific computing and artificial intelligence) which must be prosecuted by multi-national teams of research institutes (as assessed by the national domicile of the institutes). For the avoidance of doubt, in all cases the Remit shall be a focus on the understanding of and prevention, diagnosis and treatment of cancer.
Results	information not in the public domain, including ideas, concepts, formulae, data, specifications, procedures, processes and protocols for experiments, studies and tests, information relating to methodologies, mathematical models, and compilations even if individual components are in the public domain, in each case that are generated or developed in the performance of Cancer Grand Challenges, including inventions and materials.
Rights	has the meaning as given in the CGC Award Agreement
Start Date	has the meaning as given in the CGC Award Agreement
Team Lead	has the meaning as given in the CGC Award Management and Funding Policy Guide
TTA	has the meaning as given in the CGC Award Agreement

Version notes

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