

# OUR GUIDING PRINCIPLES

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## Commercial Data Partnerships



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# INTRODUCTION

Cancer Research UK (CRUK) is the world's leading independent cancer charity dedicated to saving lives through research, influence and information. CRUK's vision is to bring about a world where everybody can lead longer, better lives, free from the fear of cancer.

Cancer Research Horizons (CRH) is the innovation engine of CRUK and is responsible for the commercialisation of the outputs of CRUK-funded research. CRH have a proven track record of translating discoveries made by CRUK researchers into new prevention measures, tests and treatments that have a tangible impact for people affected by cancer, working closely with our strong network of partners.

Over the past 5 to 10 years advances in data science have helped us gain insights into cancer biology, prevention, detection and therapies and will increasingly lay the foundations for improvements in patient outcomes in the future. But we need to do more to capitalise on new technologies and uses of data.

Through CRUK's extensive research portfolio, we have been responsible for the generation of large amounts of Patient Derived Data (defined in the Glossary below) that could be leveraged to drive patient benefit. We believe that, due to their unique skill set, resources and experience taking products to market, collaborating with commercial organisations is an important part of unlocking the maximum impact of this Patient Derived Data, and CRH want to enable this through establishing Commercial Data Partnerships. However, we recognise the sensitivities involved in the sharing of Patient Derived Data, and are committed to maintaining trust, transparency and accountability when establishing data partnerships. We are taking extra steps to ensure that we maintain the trust of the public and people affected by cancer, and protect the interests of the patients and academics involved in generating valuable data.

# GLOSSARY

The landscape of data partnerships is continually evolving with different organisations defining common concepts in different ways. To ensure clarity when reading and interpreting this document, we apply the following definitions:

Academic Research	Publishable research conducted at an academic not-for-profit institution, including that sponsored by or in collaboration with a 3rd party commercial entity as long as the 3rd party commercial entity is granted no commercial rights to the research results
Anonymise	To render Personal Data in such a way that the individual is not or no longer identifiable (and “Anonymised” shall be construed accordingly)
Commercial Data Partnership	Collaborations, licences and other forms of formal partnerships with a commercial entity that relate specifically to Patient Derived Data in which the commercial entity acquires rights or access to the underlying Patient Derived Data. For clarity this does not include Academic Research
Pseudonymised	Personal Data which has been processed in such a way that it can no longer be attributed to an individual without the use of additional information, where such information is kept separately and subject to technical and organisational protective measures
Patient Derived Data	Data about a patient generated through clinical trials or research projects performed outside of standard clinical practice. This may include Raw Clinical Data where it is linked to data generated in a research project to provide clinical context or where the Raw Clinical Data has been built on through curation, annotation or linkage as part of a research project.
Personal Data	Data relating to an identified or identifiable individual, as defined in the UK Data Protection Act 2018
Raw Clinical Data	Data about a patient collected as part of standard clinical practice (for example, data held in patient electronic health records) and which has not been processed beyond what is needed to enable or perform standard clinical practice
Trusted Research Environment (TRE)	A computing environment that holds data, and enables remote access to approved researchers to use it for research, in a secure and controlled way

# PURPOSE

This document sets out the principles that CRH will adopt when establishing Commercial Data Partnerships to unlock the impact of Patient Derived Data generated in CRUK's research network. These principles have been developed through extensive consultation across the public and private sectors and, importantly, with people affected by cancer. These principles will be reviewed in consultation with patients at least annually, and then updated as necessary, to ensure that they are up to date and reflect the evolving landscape.

## SCOPE

### ***If you're an institution who is part of CRUK's research network interested in CRH's approaches to data governance:***

This document sets out the principles that CRH will use when it has the necessary rights to lead on the commercialisation of Patient Derived Data. In some situations, CRH will not be the leading party and any commercialisation will occur via our academic partners, who will each operate their own principles in this space. We expect this guidance document to evolve regularly and with time as custom, law and practice develops in this space.

### ***If you're a commercial researcher interested in establishing a Commercial Data Partnership with CRH:***

CRUK are a research funding organisation, not a hospital group and therefore **CRH does not have access to Raw Clinical Data outside of the context of providing clinical context or annotation to data generated in research.** Therefore, the Commercial Data Partnerships referred to in this document do not generally include the transfer of or access to Raw Clinical Data independent of research data.

### ***If you're a member of the public or a person affected by cancer:***

CRH will only enter into Commercial Data Partnerships to the extent it has the necessary patient consent and ethical approvals in place for the Patient Derived Data to enable the Commercial Data Partnership envisioned. We will shortly be publishing more information about how we involve patients and the public in our data strategy and in particular in review of data partnerships.

## OUR PRINCIPLES

### 1. Transparency & Accountability

- 1.1. CRH will only enter into a Commercial Data Partnership and enable access to Patient Derived Data for a defined purpose, which must include the prevention, screening, diagnosis, treatment or monitoring of cancer and related diseases. Any use of the Patient Derived Data beyond this approved purpose shall be explicitly prohibited.
- 1.2. CRUK is funded by public donations and therefore public transparency is integral to CRH's activity. As a result, CRH will require a plain English summary to be made available for public scrutiny, consisting of non-confidential information relating to the aims and objectives of each Commercial Data Partnership we enter into.
- 1.3. CRH will involve patients in the decision-making process when entering into Commercial Data Partnerships and prospective partners shall provide sufficient information to allow a comprehensive review to be performed, including a detailed overview of the intended use of the data.
- 1.4. Upon completion of a Commercial Data Partnership involving the direct transfer of Patient Derived Data, the commercial partner will permanently delete the Patient Derived Data it holds. If the commercial partner wishes to conduct further research using the dataset it must request renewed access to the Patient Derived Data for the new purpose. In certain circumstances the partner may request the retention of a single static copy of the Patient Derived Data if it is required for compliance with laws and regulations.
- 1.5. The commercial partner will keep CRH informed about the progress of the project and provide suitably detailed progress/outcome reports so that CRUK can effectively manage and inform its internal business processes.
- 1.6. CRH will share non-confidential, plain English summaries of progress/outcome reports with patient involvement groups to inform further partnering activity and the evolution of policies and principles in line with our public & patient involvement process.
- 1.7. The commercial partner's use of the Patient Derived Data shall be transparent and auditable, and CRH will seek to obtain the right to audit to ensure that the principles of the partnership and this document are being maintained.

## 2. Data Security & Management

- 2.1. CRH will only enable access to Patient Derived Data which has been Pseudonymised or Anonymised, and in all cases will ensure that its partner has adhered to all relevant regulations and ethical approvals before CRH will enable access to Pseudonymised or Anonymised Patient Derived Data
- 2.2. Where the Patient Derived Data is Anonymised, CRH will enable access to this Patient Derived Data through either:
  - 2.2.1. Direct transfer:
    - 2.2.1.1. CRH will work with the data owner or custodian to ensure that it is shared through a secure medium; and
    - 2.2.1.2. CRH will require the recipient commercial partner to ensure that, once the data is transferred, it is kept in a secure environment and protected from damage or loss.
  - 2.2.2. Use of a Trusted Research Environment (TRE).
- 2.3. Where the Patient Derived Data is classified as Personal Data, it is CRH's preference to enable access to the Patient Derived Data using a TRE.
  - 2.3.1. Where the use of a TRE is not possible, CRH will consider direct transfer of the Patient Derived Data if we believe there is the potential for significant patient benefit to arise from the Commercial Data Partnerships.
  - 2.3.2. Where direct transfer is elected, CRH will work with the research institution that generated the Patient Derived Data and require the commercial partner receiving the Patient Derived Data to securely store and manage the data and adhere to all relevant regulations including UK GDPR and the Data Protection Act 2018, even if the data is transferred outside of the UK.
- 2.4. CRH will require the commercial partner to limit access to the Patient Derived Data to employees whose access is reasonably necessary for the performance of the project.
- 2.5. CRH will require the commercial partner provide details of its experience in data security (including formal standards and assessments, where relevant) and maintain security of the data. In the case of a breach of security, the partner will be required to inform CRUK promptly and take reasonable steps to remedy such breach.

2.6. CRH will require the commercial partner to make no efforts to identify individuals that are the subject of the Patient Derived Data.

2.7. CRH will require the commercial partner not to further sub-license the Patient Derived Data to a 3<sup>rd</sup> party without CRH's consent.



### 3. Protecting Academic Research

- 3.1. The originating research institutes, researchers and/or NHS Trusts and their collaborators shall, at all times, retain the rights to continue to use the Patient Derived Data in Academic Research, including sharing with academic collaborators and for the delivery of patient care and can continue to publish the outputs of their research.
- 3.2. CRH will consult the lead PI who generated the data in the decision-making process when entering into Commercial Data Partnerships and prospective commercial partners shall provide sufficient information to allow a comprehensive review to be performed by CRH, including a detailed overview of the intended use of the Patient Derived Data.
- 3.3. The ownership of the IP rights in the Patient Derived Data will remain with CRH and/or the originating institution(s) as per established technology transfer agreements.
- 3.4. CRH recognises that it can add value both to researchers and commercial partners for Commercial Data Partnerships to involve collaboration with the originating researchers(s), and so will seek to enable this wherever possible and practical.
- 3.5. Publication of any outputs of the use of Patient Derived Data should correctly recognise the contribution of CRH, CRUK, involved institutions and the originating researchers.
- 3.6. For Anonymised Patient Derived Data, the commercial partner shall, at no times, publish or make available on an unsecured source/server or public repository, the licensed data, without approval from CRH and the originating researchers and only if accompanied by an appropriate data access statement, process or agreement. The commercial partner will not publish Patient Derived Data that constitutes Personal Data.

## 4. Fair Partnership

- 4.1 Commercial Data Partnerships should be on mutually beneficial and fair financial terms, this may include different mechanisms such as: cost sharing (development and maintenance), cost recovery, access fees, annual fees, revenue shares, milestones and royalties. CRH will share any net revenue generated from Commercial Data Partnerships with the research organisations and NHS sites/hospital organisations that it contracted with to contribute to the generation and collection of data. Any net revenue that CRUK retains from these partnerships will be reinvested in funding further cancer research.
- 4.2 CRH are aware that the use of the Patient Derived Data may be different for each partnership. CRH will endeavour to work with the commercial partners to adopt business models and financials that are tailored for each particular partner and partnership, and that correctly balance the needs to maximise the impact of the Patient Derived Data whilst respecting commercial considerations.
- 4.3 CRH's preference is for the licensing of research data to be non-exclusive, but we recognise that in some situations, where there is the potential for significant patient benefit and/or added value to the quality or scope of the Patient Derived Data, time-limited or field-restricted exclusivity would be considered.
- 4.4 Where granted, exclusivity would not prevent academics from continuing to use the Patient Derived Data for Academic Research and will not extend to Raw Clinical Data in the database.
- 4.5 In some circumstances where the partner generates enriching data that improves the utility of the Patient Derived Data and has broad applicability, CRH may request that such additional enriching data is provided back to CRH so that it can be made available for other academic and commercial users.