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| **Secondary Data Request for the Translational Data Platform** |
| **Title** |  |
| **Scientific project summary** *Up to 500 words* |
| *Background, research objectives and proposed outcomes.* |
| **Translational potential of the project** Up to 300 words |
| *How is the use of these data going to help patient care?* |
| Which trial data cohorts are you interested in? |  |
| What data types are you interested in?  |  |
| What patient clinical information are you interested in? |  |
| Do you need additional data processing beyond what is in the data catalogue? (if yes please contact Andrew.blake@oncology.ox.ac.uk for details) |  |
| Do you need any training on how to access the data on cBioportal? (Please specify the level of training) |  |
| Start date of project: |  |
| End date of project: |  |
| Any other comment: |  |

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| All applicants must only sign after they have read understood and agreed with the Translational Data Platform terms of data use (below) |
| **Name** | **Department** | **Contribution to project** | **Date** | **Signature**  |
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# Translational Data Platform: Terms of Data Use

June 2024

## Purpose

This document is a set of guidelines for secondary data use and commercialisation of data managed by Oxford Cancer through the Translational Data Platform (TDP). The purpose of these guidelines is to maximise the impact of patients' data for cancer research whilst protecting the privacy and trust of patients and the interests of all those who have contributed to its creation, analysis and interpretation.

## The Translational Data Platform

The Translational Data Platform (TDP), developed by [Andrew Blake](https://www.oncology.ox.ac.uk/team/andrew-blake), enables Oxford researchers to capitalise on patient clinical data, imaging and molecular data generated from samples collected during clinical studies. The TDP is part of the [Oxford ECMC](https://www.ecmcnetwork.org.uk/oxford) and is key to its mission to integrate research science with early-phase clinical trials.

Data from clinical trials and observational studies includes single cell and bulk RNASeq expression data, NGS mutations, SNPs, copy number, methylation, proteomics, IHC scores and images, H&E images, MRI and other scans, clinical data, and outputs of machine learning image analysis algorithm models. The TDP combines these into a single, secure, user-friendly, multi-omic data platform: [cBioportal](https://www.cbioportal.org/) for specific studies. Patient-identifiable information is removed by our team to create a central point for rigorous analysis and interpretation.

### 2.1 The Translational Data Platform Ethos

The TDP exist to allow Oxford researchers to freely access this data and its mission is to integrate research science with early-phase clinical trials and help cancer researchers and clinicians conduct hypothesis-generating discovery research with the potential to translate into improvements in patient care.

## Scope

This policy covers researchers wishing to access the TDP database according to the following criteria:

1. Employees of Oxford University
2. Employees of any other academic or governmental institution
3. Employees of a commercial or industry-based research organisation.
4. Commercial members of academic consortia.

## Process for Providing Access

This process will ensure that data access is provided consistently and in line with TDP ethos and individual trial requirements:

1. Applicants must complete the TDP Data Access Request Form.
2. Submission will be reviewed by the TDP Data Access.
3. To be considered the request must show evidence of:
	1. Possible patient benefit or benefit to the Cancer research community;
	2. Suitability of the dataset to address the scientific questions;
	3. Conformity to the TDP ethos
4. If deemed successful the request will be forwarded to the specific study’s Data Access Committee (e.g. a trial specific management group).

*The TDP does not guarantee that requests deemed successful by the TDP Data Access Committee will grant access to the data.* The TDP will make every effort to make sure that the data stored are shared with the scientific community to maximise patient benefit.

## Data Access Policy

In order to support and widen the ongoing access to the TDP database, we have asked all our contributors to make the data submitted available to use by other researchers withing the University to answer scientific and clinical questions that could have positive impacts on patient care, including discovery research. As stewards of the data, the TDP Data Access Committee recognise that the legal and ethical gold standard to allow commercial use of the data is individual patient consent although it will be the responsibility of any specific study’s Data Access Committee to define the suitability of commercial use of the data.

Data can be made available for commercial access if:

1. The data is anonymised;
2. There is real potential to benefit future patients
3. The patients have consented or seeking additional informed consent might cause harm/distress or when the participants might have died.

## Confidentiality

Any organisation in receipt of data should make a clear commitment to keep the data secure and confidential and not to attempt reidentification. This commitment will be recorded within any data release agreement.

## Governance

1. The TDP Data Access Committee consists of individuals representing the different stakeholders: the TDP, Oxford Cancer and the Oxford ECMC, and oversees all applications.
2. The Data Access committee will aim to reach a consensus on each decision leading to an outcome of either approval or rejection.
3. If the committee cannot reach a consensus, then it will provide written feedback to the applicant and ask them to resubmit their data access request with further information.
4. Any conflicts of interest with a specific application by any member of the committee will be declared. If the conflict is deemed to be significant the member shall be excluded from the discussion of that application.

## Intellectual Property

1. The ownership of the data will remain with the authors of the specific study.
2. Any partner will use reasonable endeavours to progress any arising IP generated from the use of the data and keep the TDP, Oxford Cancer and the authors of the specific study reasonably informed of this development.
3. Secondary users will provide the TDP, Oxford Cancer and the authors of the specific study with appropriate academic research rights.

## Data Use and Management

If the use of the data is granted by the TDP Data Access Committee and the specific study Data Access Committee:

1. Applicants will be granted access to data for a particular research project only. Any further use of the data is subject to further approval by the access committee
2. The TDP will ensure that data is shared through a secure medium and once transferred, successful applicants will ensure that the data is kept in a secure environment and protected from damage, and loss and will limit access to the data to employees who are required for the performance of the project as described.
3. Successful applicants will take all steps required to maintain the security of the data and, in the case of a breach of security inform the TDP and the authors of the specific study immediately and take all steps to remedy such breach.
4. Successful applicants will keep the TDP access management group informed of any outputs from the work e.g., publications, conference posters/presentations, websites, public release statements, licensing of agents etc.
5. In all cases, successful applicants will comply with GDPR and any local data/ethics regulations of relevance.
6. Successful applicants will not sub-license or share the underlying data with a third party unless specifically named as part of the access application.

## Publications and Research rights

1. The academic leads of the original study and their collaborators shall retain the rights to continue to use existing data.
2. Publication of any outputs of the use of data should correctly recognise the contribution of the TDP and the originating researchers, including using their logos in presentations and acknowledgement when possible.

Suggested wording is summarised below but researchers seeking to publish should contact the TDP for specific authors and wording at the time of publication:

*“Data and/or research tools used in the preparation of this manuscript were obtained and analysed from the datasets available through the Translational Data Platform, part of the Oxford ECMC and run by Oxford Cancer. This manuscript reflects the views of the authors and may not reflect the opinions or views of the funder or of the individuals and entities submitting original data to the Translational Data Platform.”*

*“Funded by a grant from Cancer Research UK and the National Institute for Health and Care Research.”*

1. Each Party will make a reasonable effort to submit material intended for publication to the TDP and Oxford Cancer in writing not less than a month in advance of submission for publication.
2. The TDP strongly encourages that publications generated from its data will be made available through open-access payment journals.

##  Returning Data to the TDP

If the use of the data is granted it is expected that any additional data generated by their use would be returned to Oxford Cancer to be made available to the Oxford academic community. We request the data to be returned at the time of publication or 2 years after they have been obtained.