Agreement of Terms (AoT) for Open Data Access Collections

A document that formalises agreement between Data Owners and Data Consumers, for open access to data, based on a specified data-scope, a specified data user-base and the limitations and terms associated to data-use.

The table below should be used for document control purposes:

Document Control	
Document type	*Agreement of Terms for Open Data Access Collection*
Description of application	*N/A is a template*
Author	*Jamie MacPherson, Ben Barnard*
Version Number	*0.1*
Creation Date	*22-Sep-2025*

The table below should be used for record of review and approval of application of the document:

Review and approval	
Reviewed by	*Renee Iacona, Jorge Reis-Filho, Peder Blomgren*
Approved by	*Data Office Lead: Peder Blomgren* *Data Owners / Delegate Data Owners: Renee Iacona* *Data User Lead: Jorge Reis-Filho*
Approval Completion Date	*<insert date>*
Effective Date	*<insert date*

Table of Contents

1. Document context, purpose and key definitions

In this section, we provide the required context to support review and approval for an AoT for a new (or updated) Open Data Access Collection. This section remains the same for any AoT, so is not subject to review as part of AoT approval.

1.1. Document purpose - Agreement of Terms (AoT) for Open Data Access Collections

An *Agreement of Terms (AoT)* is used to formalise open access to data in AstraZeneca R&D. Such instances of open access are referred to as *Open Data Access Collections*. Agreement of Terms for *Open Data Access Collections* are based on three key defining criteria of access:

(i) ***Data scope*** – a definition of the data that that will be made openly accessible.
(ii) ***User scope*** – a definition of the data consumer.
(iii) ***Terms and conditions of use*** – an agreed set of usage types that are supported by the agreement

Using these three definitions in combination, the AoT essentially defines who (or what) can openly access what data, for what supported purpose. The outcome of creating *Open Access Collections* is that these users can freely use the data (so long as they remain within the supported purpose), to avoid unnecessary and time-consuming approvals for each project they conduct and support data use and scientific innovation at speed and scale.

Therefore, this document is organised to support the definition and review of those three criteria.

1.2. AoT Accountable roles

Key accountable roles are required for AoT approval, all of whom should review the details of the three defining criteria – data scope, user score and terms and conditions of use.

- **Data Owner or Delegate Data Owner** – Data Owners (as defined by AstraZeneca R&D's Data Accountability Framework) are accountable for data, including how that data is used and any risks associated. Data Owners typically utilise the actions of Delegate Data Owners to actively wield that accountability. For the AoT, their accountability is wielded by reviewing and approving how their data will be used.
- **Data Consumer Lead** – Data Consumer Leads are accountable for work done by their staff, work commissioned via projects they run and through AI or IT systems within their ownership. For the AoT, Data Consumer Leads are required to review the agreement, to ensure that the access they will gain will provide the desired business benefit and approve that they agree to use the data within the bounds of the agreement.
- **R&D Data Office Lead** – The Data Office creates and owns the AoT and facilitates processes of open access setup and maintenance. They are required to approve the AoT to both assert that the AoT is within bounds of R&D's broader data access policies, and as agreement to commit to initiation of delivery and maintenance of the Open Access Collection.

1.3. Open Data Access Collections Process

For context, we provide a high-level view of the end-to-end process for setting up an Open Data Access Collection, where definition and approval of the AoT document are key activities (highlighted).

Description of process steps	
(a) Update Data Strategy	Strategic planning that determines how R&D intends to benefit from using data, outlining opportunities, risks and gaps. The R&D Data Office will either lead or engage with R&D groups to understand how Open Data Access Collections may be used to drive benefit, as part of such plans.
(b) Agreement of Principle (AiP)	A step used to seek clear sponsorship and endorsement from the three accountable parties – Data Owners or Delegates, Data Consumer Leads and R&D Data Office Leads – to progress to development of an AoT.
(c) Agreement of Terms (AoT)	Development of the details of the AoT, specifying clear data scope, user scope and terms and conditions of use, that when agreed is approved by the three accountable roles – Data Owners or Delegates, Data Consumer Leads and R&D Data Office Leads).
(d) Implement Open Access Collection	The technical setup plus necessary change management (e.g., communication and training) of the Open Access Collection based on the details within an approved AoT. **When this step is complete, users of the data gain open access.**

(e) Manage Open Access Collection	The act of managing active Open Data Access Collections to ensure that they remain within our policies, continue to provide business benefit and do not incur unwanted data risks. During this phase in the Open Access Collection lifecycle, changes may be identified and the AoT may be amended, re-approved and technical changes to access can follow.

2. Agreement of Terms (AoT) for the Open Data Access Collection

In this section, we outline the details that define the newly proposed or updated Open Data Access Collection. This is where details of the proposed data scope, user scope and terms and conditions of use of data are specified and should therefore be subject to review by the Data Owner or Delegate Data Owner, Data Consumer Lead and R&D Data Office Lead.

2.1. Open Access Collection Summary

Here, the high-level details of the Open Data Access Collection are provided, plus key accountable role names.

High level Information about the Open Access Collection	
Collection Identifier	OaC-2.00
Open Access Collection name	Oncology R&D AZ Sponsored Closed, Primary-use Clinical Study Collection
Description and key notes	A collection of AZ sponsored Oncology clinical study datasets, designed for primary use (i.e., full, non-subsetted data), from closed clinical studies.
Data Owner / Delegate Data Owner(s) required to review and approve	Rene Iacona – VP Oncology Biometrics
Data Consumer Lead(s) required to review and approve	Jorge Reis-Filho – VP Oncology Data Science & AI Rene Iacona – VP Oncology Biometrics
Data Office Lead required to review and approve	Peder Blomgren – VP Head of Data Office

2.2. Data Scope

Here we specify the details of the data scope that will be made accessible in the Open Access Collection. The following notes apply:

- Data Scope is defined using multiple criteria that map data to Open Access Collections.
- Data Scope can utilise *inclusions* i.e., data that is included within the Open Access Collection, and *exclusions*, i.e., data that is omitted from the Open Access Collection.
- For each inclusion criteria there is a mechanism to manage the inclusions that can be one of the following:
    - **Included:** Included by default automatically
    - **Included, opt-out:** Included by default, but with an active review process to allow for opt-out
    - **Included, opt-in:** Included only when an active review process has chosen to opt-in
- Where a study meets multiple criteria, the more strict of the two inclusion mechanisms will be chosen.

First, we specify data scope according to the scope of 'project':

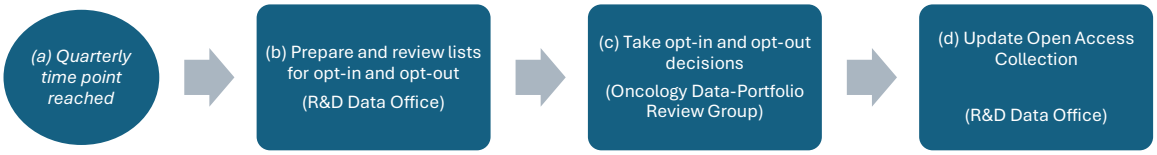
Criteria ID	Data scope	Included or excluded? Opt in/out (optional)	Notes / additional rationale
OaC-2.00-C1	Oncology R&D's clinical study datasets (full primary) from closed (historical) clinical studies that have achieved DBL across all arms, but the latest DBL was >6 months ago.	Included	Studies can be removed if required but there is not an active process to review due to reduced business sensitivity of closed studies
OaC-2.00-C2	Oncology R&D's clinical study datasets (full primary) from ongoing studies that have stopped active recruitment across the entire study but remain in follow-up or monitoring phases and have achieved a DBL for reporting or analysis across all arms, but the latest DBL was >6 months ago.	Included	Studies can be removed if required but there is not an active process to review due to reduced business sensitivity, as these studies can be considered as closed for reuse purposes.

The list of studies that this would map to (correct as of 17-Sep-2025) can be found in the appendix for this document

Second, we specify data scope according to more technical categories of are included:

High level category	Low level category	Included or excluded? Opt in/out (optional)
Study and patient data	Individual patient level data from clinical studies	Included
	Study metadata	Included
Data modalities	Electronic clinical report form (eCRF)	Included
	Digital devices data	Included
	Medical imaging	Included
	Molecular and 'omic' data	Included
Data formats	DICOM images	Included
	SDTM	Included
	FASTQ	Included
	CSV	Included
	Other file types	Included
'Geographies'	Data held outside China not requiring HGR approval	Included

Third, we specify the process through which opt-in, or opt-out on data is achieved.



Description of process steps	
(a) Quarterly time-point reached	A quarterly cadence for review of opt-in and opt-out will be introduced. This will allow the processing of opt-in and opt-outs.
(b) Prepare and review lists for opt-in and opt-out (R&D Data Office)	Quarterly, the R&D Data Office will prepare a list of data that will be included in the Open Access Collection, identifying candidate data for opt-in and opt-out decisions. This can be to prompt a decision *ahead of time*, e.g., when a DBL is pending, a decision could be taken ahead of time whether the data can be shared when that DBL is achieved, or, to prompt a decision that is currently required. The R&D Data Office will send this out for review prior to the meeting below.
(c) Take opt-in and opt-out decisions (Oncology Data-Portfolio Review Group)	A meeting will be scheduled and include the following parties: • GPPM • Biometrics representative • R&D Data Office During this meeting, or as direct follow-up, decisions for opt-in and opt-out will be taken.
(d) Update Open Access Collection	The Open Access Collection data scope will be updated to reflect the decisions on opt-in and opt-out, thus affecting what users are able to access.

2.3. User Scope

Here we specify the details of the user scope who will be able to freely utilise all data in the Open Data Access Collection. User scope can be identified by the combinations of one or more mechanisms:

- By job role, ideally mapped to AstraZeneca's job catalogue
- By line management chain

The table below specifies the users that can use data within the Open Data Access Collection.

User scope – by department	**User scope – by role type**	**Notes / additional rationale**
Report to the Oncology Data Science & AI group.	Must be of the following role-types: • Data Scientist • Data Engineer • Bioinformatician • Computational Pathologist • Data Analyst	
Report to the Early & Late Oncology Development groups.	Must be of the following role-types: • Research Scientist	
Report to the Oncology Biometrics group	Must be one of the following role-types: • Programmer • Statistician	

2.4. Terms and Conditions of Use

Here we specify the terms and conditions of use, which may be required to limit the uses of uses to those which are permissible from legal, ethical or business sensitivity standpoints.

The table below specifies types of use in high-level and specific terms, stating whether they are permitted

High level category	**Low level category**	**Use permitted under this agreement?**
Primary use under IMI-guided study protocol language for primary use	Understand how the study drug and similar drugs work in the body	Yes
	Better understand the studied disease and associated health problems	Yes
	Develop diagnostic tests for the disease	Yes
	Learn from past studies to plan new studies	Yes
	Improve scientific analysis methods	Yes
Publication	Ability to publish results internally as 'company restricted' finding	Yes
	Ability to publish results externally	**Standard PSO process applies**
Beyond IMI-guided study protocol language for primary use	AI research, AI model training	**No**
	Software development and testing	**No**
External sharing	Sharing with an external 3rd party or collaborator	**Standard External Sharing process applies**

Appendix

Studies included in Collection – CTDNA Priority Studies

The below list of studies are those which have been identified as being candidates for inclusion in the collection defined above. This table shows the inclusion criteria that each have met in order to be candidates for inclusion. For those where the proposed process is to "opt-out" of inclusion, they column "Include in Collection?" has been set to "Yes". For anything that was set to "opt-in" the value is marked as requiring review.

For reviewers: Please update the "Include in Collection?" column to reflect the final list of studies included in the collection.

Codes C1-C2 refer to the criteria for inclusion from section 2.2, but are criteria are repeated here for ease of review:

- **C1** - Oncology R&D's clinical study datasets (full primary) from closed (historical) clinical studies that have achieved DBL across all arms, but the latest DBL was >6 months ago.
- **C2** - Oncology R&D's clinical study datasets (full primary) from ongoing studies that have stopped active recruitment across the entire study but remain in follow-up or monitoring phases and have achieved a DBL for reporting or analysis across all arms, but the latest DBL was >6 months ago.

PRODUCT AND STUDY INFO			GENERAL RESTRICTIONS		CRITERIA FOR INCLUSION		BUSINESS PRIORITY	
Study code	**Acronym[1]**	**AZ product name**	**Data Location[2]**	**Legal Restrictions[3]**	**C1**	**C2**	**CTDNA Priority**	**Include in Collection?**
D4190C00010	*Not Documented*	Imfinzi	Yes	No	Yes	No	Yes	Yes
D4190C00021	*Not Documented*	Imfinzi	Yes	No	Yes	No	Yes	Yes
D5330C00014	*Not Documented*	ceralasertib	Yes	No	Yes	No	Yes	Yes
D6070C00005	*Not Documented*	oleclumab	Yes	No	Yes	No	Yes	Yes
D791PC00001	*Not Documented*	Iressa	No	No	Yes	No	Yes	Yes
D7980C00006	*Not Documented*	volrustomig	Yes	No	Yes	No	Yes	Yes
D8360C00001	*Not Documented*	AZD4785	Yes	No	Yes	No	Yes	Yes
D4191C00003	ATLANTIC	Imfinzi	Yes	No	Yes	No	Yes	Yes

D8151C00001	AZD0171	falbikitug	Yes	No	Yes	No	Yes	Yes
D6130C00001	AZD2811	defosbarasertib	Yes	No	Yes	No	Yes	Yes
D933LC00001	BEGONIA	Imfinzi	Yes	No	Yes	No	Yes	Yes
D9100C00001	CALLA	Imfinzi	Yes	No	Yes	No	Yes	Yes
D9108C00001	COAST	Imfinzi	Yes	No	Yes	No	Yes	Yes
D4193C00002	EAGLE	Imfinzi	No	No	Yes	No	Yes	Yes
D5161C00003	ELIOS	Tagrisso	Yes	No	Yes	No	Yes	Yes
D4193C00001	HAWK	Imfinzi	No	No	Yes	No	Yes	Yes
D419LC00001	KESTREL	Imfinzi	No	No	Yes	No	Yes	Yes
D419QC00007	LUMINANCE	Imfinzi	No	No	Yes	No	Yes	Yes
D0816L00003	LYN201	Lynparza	Yes	Requires Manual Check	Yes	No	Yes	Yes
D910LC00001	MERMAID-1	Imfinzi	Yes	No	Yes	No	Yes	Yes
D910MC00001	MERMAID-2	Imfinzi	Yes	No	Yes	No	Yes	Yes
D533AC00001	MONETTE	ceralasertib	Yes	No	Yes	No	Yes	Yes
D9108C00002	NEO-COAST	Imfinzi	No	No	Yes	No	Yes	Yes
D0816C00020	OPINION	Lynparza	Yes	Requires Manual Check	Yes	No	Yes	Yes
D933KC00001	PACIFIC2	Imfinzi	Yes	No	Yes	No	Yes	Yes
D419BR00008	Prevail	Imfinzi	No	No	Yes	No	Yes	Yes
D9820C00001	PRISM		Yes	No	Yes	No	Yes	Yes
D081DC00007	PROFOUND	Lynparza	Yes	Requires Manual Check	Yes	No	Yes	Yes
D8530C00001	SERENA-1	camizestrant	Yes	No	Yes	No	Yes	Yes
D8530C00002	Serena-2	camizestrant	Yes	No	Yes	No	Yes	Yes
D0816C00010	SOLO 3	Lynparza	Yes	Requires Manual Check	Yes	No	Yes	Yes
D081DC00008	UVA97934; Study8	Lynparza	Yes	Requires Manual Check	Yes	No	Yes	Yes
D4190C00010	PLANETTE	ceralasertib	Yes	No	Yes	No	Yes	Yes

D419NC00001		Imfinzi	No	Requires Manual Check	No	Yes	Yes	Yes
D5160C00003	AURA 3	Tagrisso	No	No	No	Yes	Yes	Yes
D5160C00002	AURA2	Tagrisso	No	No	No	Yes	Yes	Yes
D419QC00001	CASPIAN	Imfinzi	No	No	No	Yes	Yes	Yes
D5084C00009	CoC	Orpathys	No	Requires Manual Check	No	Yes	Yes	Yes
D910CC00001	COLUMBIA 1	Imfinzi	Yes	No	No	Yes	Yes	Yes
D419BC00001	DANUBE	Imfinzi	Yes	No	No	Yes	Yes	Yes
D967MC00001	DESTINY-PanTumor01	Enhertu	Yes	Requires Manual Check	No	Yes	Yes	Yes
D5160C00007	FLAURA	Tagrisso	Yes	No	No	Yes	Yes	Yes
D419AC00001	MYSTIC	Imfinzi	Yes	No	No	Yes	Yes	Yes
D419AC00003	NEPTUNE	Imfinzi	Yes	No	No	Yes	Yes	Yes
D0819C00003	OlympiAD	Lynparza	Yes	Requires Manual Check	No	Yes	Yes	Yes
D9102C00001	ORION	Imfinzi	Yes	Requires Manual Check	No	Yes	Yes	Yes
D081SC00001	PROpel	Lynparza	No	Requires Manual Check	No	Yes	Yes	Yes
D4190C00022	STUDY 22	Imfinzi	Yes	No	No	Yes	Yes	Yes
D5160C00006	TATTON	Tagrisso	Yes	Requires Manual Check	No	Yes	Yes	Yes
D6132C00001	TAZMAN	defosbarasertib	Yes	No	No	Yes	Yes	Yes
D9268C00001	TROPION-Breast01	Datroway	No	Requires Manual Check	No	Yes	Yes	Yes

[1.] Where "*Not Documented"* is listed as the value of the Study Name or Product this is due to the data not being present in AZCT.

[2.] Studies without locations cannot be provisioned, however if approval is granted it can be shared once the data has been located

[3.] Studies listed here as having a manual check may be excluded once checks have been completed depending on outcome.

Studies included in Collection – Other Studies

Due to the high priority nature of the CTDNA studies, other studies that would fall under the Criteria for this collection have not been collated at this time. These will be compiled at a later date.

CTDNA Priority	Study code	Acronym[1]	AZ product name	Data Location[2]	Legal Restrictions[3]	C1	C2	C4 [4]	C5 [4]	C6	Include in Collection?
…	…	…	…	…	…	…	…	…	…	…	…