Open Access Collection (OAC) Agreement – Oncology Closed Collection

This document defines the Open Access Collection (OAC) for Oncology Closed Studies; it does not grant access to the data collection (this is contained in the Agreement of Terms) but instead defines the criteria that specify the scope of the Open Access Collection.

The table below should be used for document control purposes:

Document Control	
Document type	*Open Access Collection (OAC) Agreement*
Description of application	*Oncology Closed Collection*
Author	*Henry Constable, Ben Barnard, Jamie MacPherson*
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The table below should be used for record of review and approval of application of the document:

Review and approval		**Approved (date)**
Delegate Data Owners:	• *Renee Iacona, VP, Oncology Biometrics and COO Oncology R&D*	*24.11.2025*
R&D Data Office Lead:	• *Peder Blomgren, VP R&D Data Office*	*24.11.2025*
	Effective Date:	*24.11.2025*

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1. Introduction

1.1. Context and Purpose

An **Open Access Collection** refers to a specified scope of strictly confidential data that data consumers can potentially be allowed to openly access under the *Role-based Open Access Model*. This document only supports the specification of an **Open Access Collection**, it does not approve any access to those data. The activity captured in this document supports the process step highlighted below. More information both about this process and the role that Open Access Collections play in this data access model can be found in the 'Role-based Open Access Model – Guidance' document.

2. Definition

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

2.1. Open Access Collection – Overview

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

High level Information about the Open Access Collection	
Collection Identifier	OAC - 002
Collection name	Oncology Closed Collection
Description and key notes	A collection of closed, AZ sponsored, Oncology AZ interventional studies (and all corresponding datasets), for primary use (ie: full, non-subsetted data) across ONCOLOGY – further details below: Included: • AZ closed interventional studies, reaching DBL > 6mo ago Excluded: • AZ closed interventional studies that have achieved a DBL < 6mo ago • Ongoing AZ interventional studies that have not yet achieved a final DBL • Other study types (eg: Non-AZ Sponsored studies, Non-interventional studies, etc) This Open Access Collection is designed to hold data that can be shared to Oncology users across ONCOLOGY TA – however by exception Delegate Data Owners may flag and exclude studies from the collection, under the recommendation of GPTs, in the case of business sensitivity restrictions. Responsible data & AI use is still in place – whereby R&D Data Office will ensure necessary checks are considered prior to any data sharing (eg: Drug Product Rights, Cross Border Data Transfer Limitations) – through established access processes.

2.2. Data Scope Criteria

Here we specify the criteria of the data scope that will be made accessible in this **Open Access Collection**. First, we specify data scope according to the clinical study status:

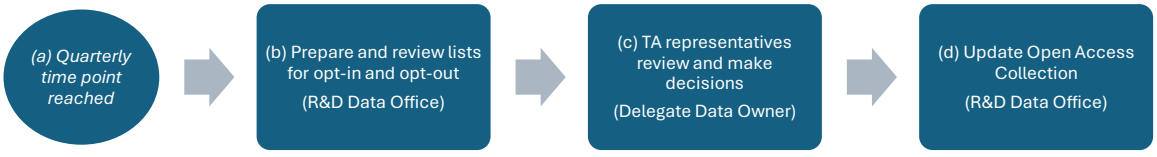
Criteria	Data scope	Classification	Notes / Rationale
TA = ONCOLOGY	Oncology AZ interventional studies across ONCOLOGY (corresponding TA descriptions = Oncology [ONC], Immuno-oncology [IMMUONC])	Included	Delegate Data Owner approval for Oncology Open Access Collection – covering studies across ONCOLOGY TA.
Status = Closed	AZ interventional studies that are classified as Closed Studies (ie: have achieved a final DBL that was >6 months ago)	Included	Studies that are fully closed > 6 months post DBL have a lower level of sharing constraints than ongoing studies
Scope = Primary Use (Full Patient Data)	Full patient population (and corresponding data) captured in the trial will be included in the Open Access Collection	Included	Since the scope of the collection is to cover Primary Use intents – full patient populations are required

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

High level category	Low level category	Inclusion Criteria
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

(Optional Step – if opt-in / opt-out active approval required)

Third, we specify the regular process through which opt-in / opt-out decisions on datasets will be achieved. *(If an accelerated exclusion / business sensitivity risk is identified outside of this regular cadence – ie: by a GPT – then Delegate Data Owners must be informed, so that Delegate Data Owners can provide a mandate to the R&D Data Office to action)*



Description of process steps		Accountability & Responsibility
(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.	Data Office is A&R
(b) Prepare and review lists for opt-in and opt-out	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.	Data Office is A&R
(c) Take opt-in and opt-out decisions (Delegate Data Owner)	A meeting will be scheduled and include the following parties: • Biometrics representative as a Data Steward • Biometrics Head – Delegate Data Owner • R&D Data Office During this meeting, or as direct follow-up, decisions for opt-in and opt-out will be taken.	Data Office will be responsible to hold the meeting and the Delegate Data Owner will be responsible for decision-making.
(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.	Data Office is A&R

2.3. Data Use Boundaries

Here we specify base data use boundaries that must be considered for any use of the data within this Open Access Collection. These base boundaries will apply in any downstream access agreement.

The table below specifies types of data-use and whether that type of use is permitted.

High level category	Low level category	Use permitted for this collection?
Primary Use under IMI-guided study protocol language *(allowing use of full scope of patient data in the corresponding studies)* (See AZ position statement on primary use for more details)	R&D activities supporting AZ drug development	Yes
	Data use by AZ and third parties operating under AZ direction only	Yes
	Examples include, but are not limited to: • Conduct this trial and comply with regulatory obligations • Develop the drug/investigational product • Get permission to introduce and keep the drug on market • Monitor drug safety • Drug reimbursement activities • Related research activities necessary for drug development	Yes

	• Understand how the study drug and similar drugs work in the body • Better understand the studied disease and associated health problems • Develop diagnostics tests • Learn from past studies to plan new studies • Improve scientific analysis methods • Publish research results in scientific journals or use them for educational purposes (following existing SOPs) • AI analytics (excluding AI development and training)	
Secondary Use - Beyond IMI-guided study protocol language for primary use	Future use scientific health-related research, within country limitations and subject to patient approval	**No**
	Data use by AZ or external partners under contract	**No**
	Examples include, but are not limited to: • *AI development/training* • *External data sharing* • *Commercial use*	**No**

Top-Line Approval

Delegate Data Owner

Renee Iacona

Oncology - Closed Studies Collection

10 November 2025

SO WHAT – CHANGE / IMPACT

Oncology target users are given continuous open access to available closed studies, to be used in ctDNA priorities and future priority pieces of work requiring this data

USERS	DATA	USAGE	ROLLOUT	TIMELINE
ODSAI: Data Scientists, Data Engineers, Bioinformaticians, Computational Pathologists, Data Analysts **Early / Late Onc Dev:** Research Scientists **Oncology Biometrics:** Statisticians, Statistical Programmers	AZ-sponsored ONC studies, DBL >6 months Ongoing studies identified as PTAP Full primary data and modalities HGR approved China data*	Primary Use No Secondary Use (AI Dev, external sharing) Publication: Internal allowed; standard PSO for external Domino / SCP analysis env.	Data Office to work with Althena steerco (Justin Johnson, etc) to further co-shape and define specifics of rollout	Initial release in Q4 2025 – to drive impact across immediate ctDNA priority & upcoming future priority projects

**data existing outside of China has already gone through HGR checks*

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