

AstraZeneca Clinical Trial Transparency

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AstraZeneca's policy on **Clinical Trial Transparency** is aligned with US and EU regulatory and legal requirements, European Medical Association Policy and EFPIA/PhRMA joint principles for responsible clinical data sharing.

Individual Patient-Level Data

Sharing Assessment
De-identified data plus data specification
(available on request, subject to approval)

Patient Engagement

Thank-you note
Ongoing study updates
Lay Language Summary

Clinical Trial Posting

Public Registrations
Clinical Study Protocol
Clinical Result Summary
Clinical Study Report

Redacted Documents

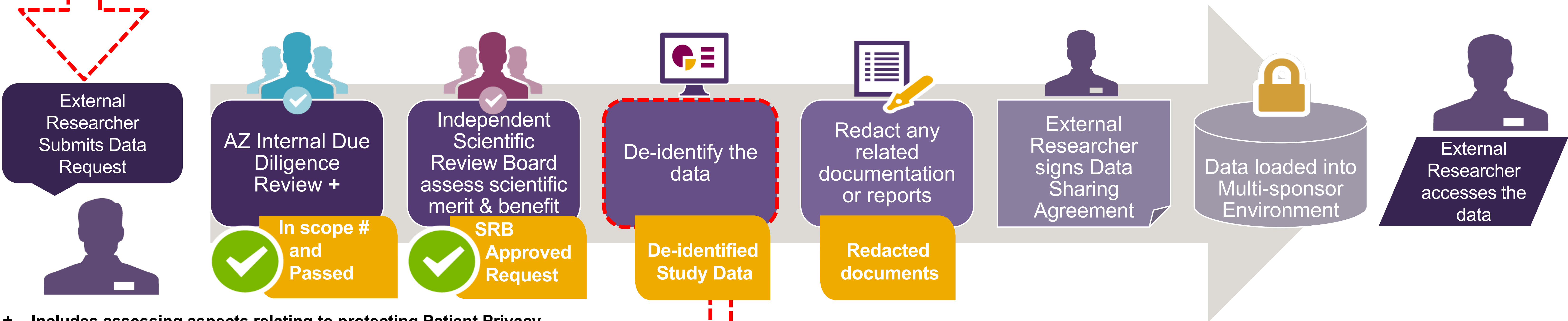
Clinical Overview
Clinical Study Report
Clinical Study Protocol
Sample Case Report Form
Statistical Analysis Plan
Clinical Summary

Information** will be made available on:

- AstraZenecaClinicaltrials.com
- ClinicalTrialsRegister.eu
- ClinicalTrials.gov

** For AZ Sponsored Phase 1 – 4 interventional studies

External Sharing of Individual Patient-Level Data



+ Includes assessing aspects relating to protecting Patient Privacy

In scope studies for Scientific Review Board (SRB) review:

- AZ sponsored interventional Phase 1–4 study
- Submitted to US/EU/Japan Health Authorities & process complete for approved indications
- First Subject In since 2009
- Other studies will be considered for external sharing on a case by case basis

De-identification of data to be shared externally goes above and beyond the complete set of US HIPAA Regulations

The following data will be de-identified:

- Subject ID replaced with random number / removed
 - Including any related variable
- Centre replaced with random number / removed
- Remove geographical locations smaller than a state
- Remove all patient related dates whilst preserving study timings
- Remove all verbatim text
- Replace individual ages with 5 year age bands

Assess further data protection risks and consider appropriate actions as needed:

- Consider deletion of a small random proportion of information records
- Ensure the company, products and studies are not identifiable
- Consider aggregating/removing individual data which is extreme or unique

An example of how the rules may be applied for a study...

STUDYID	SUBJID	CENTRE	PATIENT	COUNTRY	RFSTDTC	RFENDTC		TERM_XL	BRTHTDC	AGE	AGEU	SEX	RACE	ETHNIC	ARMCD
D1234C00001	E0001001	1	102	GBR	2010-12-15T12:55	2011-02-02T13:00		Other; patient left country	02/02/1952	57	YEARS	M	WHITE	HISPANIC OR LATINO	A01
Assign new random ID values				Remove date/time variables		Add in study day variable RFENDY	Remove verbatim text	Remove birth date variables	Replace with age band variable AGE_B	Remove variable (as only one patient with this value)					
D1234C00001	E5002002	5002	41	GBR	<DELETE>	<DELETE>	50	Other	<DELETE>	55-59	YEARS	M	WHITE	<DELETE>	A01

References: Global Standard for Clinical Trial Transparency; Global Standard for Sharing Individual Patient Level Data; Functional Standard for data Privacy Related to Clinical Information Sharing and Use; Functional Standard for Clinical Information Sharing