IVD: Clinical Performance Study Plan for FoundationOne®CDx Used as a Clinical Trial Assay in Clinical Trial D7080C00001 (ALAFOSS-01)

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The objective of this CPS is to establish the clinical performance of F1CDx as a companion diagnostic (CDx) for AZD0022 in patients with NSCLC, CRC, or PDAC with a KRASG12D mutation. This CPSP will be executed in combination with the clinical trial...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON57424

Source
ToetsingOnline

Brief title
ALAFOSS-01 IVD

Condition

- Other condition

Synonym
KRAS change, KRASG12D mutation

Health condition

pancreatic ductal adenocarcinoma (PDAC), colorectal cancer (CRC), non-small cell lung cancer (NSCLC)

Research involving
Human

Sponsors and support

Primary sponsor: Astra Zeneca
Source(s) of monetary or material Support: AstraZeneca

Intervention

Keyword: colorectal cancer (CRC), KRASG12D mutation, non-small cell lung cancer (NSCLC), pancreatic ductal adenocarcinoma (PDAC)

Outcome measures

Primary outcome

The primary endpoint of the clinical trial D0780C00001 (ALAFOSS-01) is to investigate the safety and tolerability, determine the MTD and/or OBD of AZD0022 as monotherapy and in combination with anti-cancer agents in participants with advanced tumours harbouring a KRASG12D mutation, as well as to estimate the anti-tumour activity of AZD0022 as a monotherapy and in combination with other anti-cancer agents. The same efficacy endpoint(s) will be used to establish the clinical performance of F1CDx as a CDx for AZD0022 in patients with NSCLC, CRC, or PDAC with a KRASG12D mutation who are most likely to benefit from AZD0022 as monotherapy or in combination with other anti-cancer agents. Data from this study may be used to support CDx approval from health authorities to demonstrate the device is safe and effective for its intended use.

The primary endpoint of the assessment of safety and tolerability, and the MTD and/or OBD is to determine the incidence and severity of AEs/SAEs, incidence of

DLTs (Dose escalation), clinically significant changes in vital signs, laboratory parameters, and ECG results, and discontinuation of AZD0022 due to toxicity.

Efficacy endpoints of anti-tumour activity of AZD0022 as a monotherapy and in combination with other anti-cancer agents are defined as Radiological response evaluated according to RECIST v1.1 (ORR, CR rate, DoR, DCR, DRR, TTR, PFS, and change in tumour size) and OS.

Secondary outcome

N/A

Study description

Background summary

In clinical trial D7080C00001 (ALAFOSS-01), AZD0022, a novel KRASG12D inhibitor, will be administered as monotherapy and in combination with other anti-cancer agents in patients with tumours harbouring a KRASG12D mutation. A validated test is needed as a companion diagnostic (CDx) to identify patients with NSCLC, CRC, or PDAC with a KRASG12D mutation who are most likely to respond to AZD0022.

Study objective

The objective of this CPS is to establish the clinical performance of F1CDx as a companion diagnostic (CDx) for AZD0022 in patients with NSCLC, CRC, or PDAC with a KRASG12D mutation. This CPSP will be executed in combination with the clinical trial D7080C00001 (ALAFOSS-01). Data from this study may be used to support CDx approval from health authorities to demonstrate the product is safe and effective for its intended use.

Study design

This is a clinical performance study (CPS) of F1CDx used as a clinical trial assay (CTA) in the clinical trial D7080C00001 (ALAFOSS-01). FFPE tissues will

be shipped to the testing site where they will be screened for KRASG12D mutation status to identify patients who may benefit from treatment with AZD0022. This CPS is an interventional clinical performance study as defined in point (46) of Article 2 of the IVDR, i.e., the test results may influence patient management decisions and/or may be used to guide treatment.

Intervention

Blood sample will be collected during the pre-screening period. If not present: tumor biopsy is collected as well.

Study burden and risks

A blood sample is taken during the pre-screening testing period and a new biopsy may have to be taken if no or not enough tissue is available. Collection of blood and tissue biopsy samples is considered part of standard clinical practice.

Contacts

Public
Astra Zeneca

Prinses Beatrixlaan 582
Den Haag 2595BM
NL
Scientific
Astra Zeneca

Prinses Beatrixlaan 582
Den Haag 2595BM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Sample Inclusion Criteria:
For the IVD study, this will include tumour tissue sent as part of the main clinical trial that meets the central laboratory tissue sample quality requirements.
All of the following requirements must be met for the sample to pass the Foundation Medicine pathology review for processing with the F1CDx:
• Primary Specimen ID and Subject ID accompanying sample
• FFPE specimens, including tumour resections and core needle biopsies.
• Archival FFPE tumour samples from the most recently collected tumour tissue sample, derived from the primary or recurrent cancer site.
• Optimal tissue volume of at least 0.6 mm3 or absolute minimum tissue volume of 0.2 mm3
• Final percent tumour nuclei of at least 20% (optimally 30% or greater)
• Sufficient cellularity - determined by Foundation Medicine, Inc. pathologist discretion.
• 10 x 4 micron sections on positively charged slides, minimum of 3 consecutive slides

Exclusion criteria

Sample Exclusion Criteria:
• Fine-needle aspirates (FNA) and effusion cytology samples/other sample types agreed with study team are NOT accepted.
• Sample is fixed in anything other than 10% NBF (e.g. Bouins, B5, Holland*s, zinc buffered formalin).
• Samples baked above 37 degrees Celsius.
• Blocks larger than 30 x 25 mm cannot be processed.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	22-04-2025
Enrollment:	60
Type:	Anticipated

Medical products/devices used

Generic name:	F1LCDx assay
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	10-04-2025
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL88312.000.24