

# Identify competitor trials including patient segments of interest

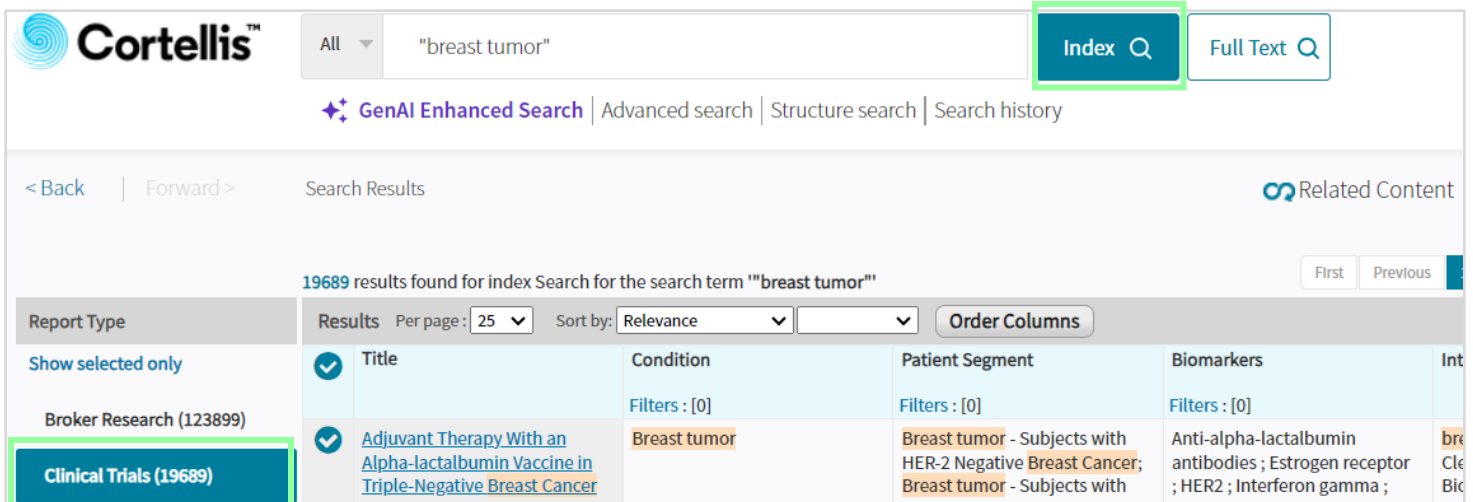
This guide will help you benchmark competitor clinical trials focused on a specific patient population to evaluate their endpoints, biomarkers and outcomes to potentially redesign your next studies and increase the chances of success.

Cortellis editors gather insights from clinical trial registries, conferences, press releases and other sources to help you access that information all in one place. They also index clinical trials by condition, target, sponsor, patient segments and many other fields -available in filters- allowing you to quickly understand competitor trials details.

Cortellis Clinical Trials Intelligence provides you with patient segments including gene mutations in comparative tables and charts for easy visualization.

**Example:** Find clinical trials studying breast cancer in patients with AKT mutations. Are results available? Which endpoints have been included? Have these endpoints been met?

1. Quick search 'Breast tumor' and select 'Clinical Trials' on the left menu under Report Type.



The screenshot shows the Cortellis Clinical Trials Intelligence interface. At the top, there is a search bar with the text "breast tumor" and a green box highlighting the "Index" button. Below the search bar, there are links for "GenAI Enhanced Search", "Advanced search", "Structure search", and "Search history". The main content area shows "19689 results found for index Search for the search term 'breast tumor'". On the left, there is a "Report Type" menu with "Broker Research (123899)" and "Clinical Trials (19689)" options, with "Clinical Trials" highlighted in a green box. The main table displays search results with columns for Title, Condition, Patient Segment, Biomarkers, and Int. The first result is "Adjuvant Therapy With an Alpha-lactalbumin Vaccine in Triple-Negative Breast Cancer" under the condition "Breast tumor".

Report Type	Results	Per page:	Sort by:	Order Columns
Broker Research (123899)	✓ Title	25	Relevance	
Clinical Trials (19689)	✓ Adjuvant Therapy With an Alpha-lactalbumin Vaccine in Triple-Negative Breast Cancer		Filters : [0]	Filters : [0]
			Breast tumor	Breast tumor - Subjects with HER-2 Negative Breast Cancer; Breast tumor - Subjects with
				Anti-alpha-lactalbumin antibodies ; Estrogen receptor ; HER2 ; Interferon gamma ;

2. Apply filters to narrow down results by:
  - a. Condition: breast tumor. Please use hierarchical filters to automatically include subcategories.

SHOW ALL FILTERS

☐ Non-Hierarchical List
 ☒ Hierarchical List

Condition

Patient Segment

Biomarkers

Biomarker Type

Biomarker Role

Endocrine disease (15230)

Adrenal disease (28)

Breast disease (14520)

Breast tumor (14477)

Inflammatory breast cancer (32)

Male breast neoplasm (14)

Metastatic breast cancer (5898)

Phyllodes tumor (2)

- b. Patient segment: AKT

SHOW ALL FILTERS

☐ Non-Hierarchical List
 ☒ Hierarchical List

Condition

**Patient Segment**

Biomarkers

Biomarker Type

Biomarker Role

Drug Pipeline Interventions

Drug Pipeline Highest Development Status

Site Name

Contact Name

Sponsors/Collaborators

Sponsor Field of Activity

Breast tumor (9957)

BRCA Mutation Positive Breast Cancer Subjects (241)

Breast Cancer Subjects with Bone Metastasis (187)

Others (910)

Subjects at Risk of Developing Invasive Breast Cancer (776)

Subjects by disease severity (3)

Subjects with Adenocarcinoma of the Breast (302)

Subjects with Advanced/Metastatic Breast Cancer/Stage IV Breast Cancer (5092)

Subjects with Early Stage Breast Cancer (1705)

Subjects with gene variants (1649)

ABL2\_HUMAN\_Mutation (1)

ACVR1B\_HUMAN\_Mutation (1)

AKT1\_HUMAN\_Mutation (10)

AKT1\_HUMAN\_rs121434592(A) (1)

AKT2\_HUMAN\_Mutation (2)

AKT3\_HUMAN\_Mutation (2)

- A comparative results table allows you to evaluate biomarkers, primary endpoint completion dates, recruitment status and more (please scroll to the right to see more). Click on the title of a trial of interest to read more details.

Title	Patient Segment	All Endpoints	Primary Endpoint Completion Date	Trial Arms Descriptions	Biomarkers
	Filters : [22] Clear	Filters : [0]	Filters : [0]		Filters : [0]
<a href="#">Safety, Tolerability and Potential Anti-cancer Activity of Increasing Doses of AZD-5363 in Different Treatment Schedules</a>	Breast tumor - Subjects with Advanced/Metastatic Breast Cancer/Stage IV Breast Cancer; Breast tumor - Subjects with Treatment Resistant Disease; Breast tumor - Subjects with gene variants - AKT1_HUMAN_Mutation;	Breast tumor - Assessment of Laboratory/Diagnostic Measures; Breast tumor - Assessment of Mortality/Death Rates; Breast tumor - Assessment of Organ Function; Breast tumor - Assessment of	26-Apr-2019 (Actual)	Oral AZD5363 twice daily, 4 days on treatment, 3 days off treatment to cessation of therapy combined with background therapy of fulvestrant at its licensed dose of 500mg intramuscularly on days 1,15,29 and once	Cell-free DNA ; Estrogen receptor ; GSK3-beta interaction protein ; Glucose ; HER2 ; Hemoglobin A, glycosylated ; Insulin ; Left ventricular ejection fraction ; Phosphatidylinositol 3-Kinase ; Phosphatidylinositol-3,4,5-
<a href="#">Phase I, Dose-Escalation Study With an Allosteric AKT 1/2 Inhibitor in Patients</a>	Breast tumor - Subjects with Advanced/Metastatic Breast Cancer/Stage IV Breast Cancer; Breast tumor - Subjects with Unresectable Tumor; Breast tumor - Subjects with gene variants - AKT1_HUMAN_rs121434592(A)	Breast tumor - Assessment of Pharmacokinetic/Pharmacodynamic Parameters; Breast tumor - Assessment of Response Rates (RR); Breast tumor - Assessment of adverse events; Solid tumor - Assessment of	31-Jul-2016 (Actual)		Alanine transaminase ; Alkaline phosphatase ; Aspartate aminotransferase ; Gamma-glutamyltranspeptidase 1 ; RAC-alpha serine/threonine-protein kinase

- The Protocols & Results tab provides details of trial arms, results and adverse events (if any).

Safety, Tolerability and Potential Anti-cancer Activity of Increasing Doses of AZD-5363 in Different Treatment Schedules

Snapshot

Highlight☐ Search Terms & Synonyms

< Previous

Next >

Protocol & Results

PROTOCOL & RESULTS

AIMS & SCOPE

■ Aims & Scope

■ Protocol Description

■ Trial Arms

■ Regimens

■ Results

■ Adverse Events

The aim of this study was to investigate the safety and tolerability of [AZD-5363](#) , in patients with advanced cancer and to identify a dose and schedule that can be used in the future. This study was also to investigate how the body handles AZD-5363 (ie, how quickly the body absorbs and removes the drug). This study would also investigated anti-tumor activity of AZD-5363 in patients with advanced/metastatic breast, gynecological cancers or other solid cancers bearing either AKT1 or PIK3CA or PTEN mutation [ [1878528](#) ].

PROTOCOL DESCRIPTION TEXT

The study would consist of four arms: Arm 1: patients would receive part A and B schedule 1, continuous dosing. Part A: ascending doses of AZD-5363 administered orally, every day to define the maximum tolerated dose. Part B: dose expansion phase, at the defined maximum tolerated dose or recommended dose from part A.

Arm 2: parts A, B, C and D schedule 2, intermittent dosing. Part A: ascending doses of AZD-5363 would be administered orally, twice-daily, on a 7-day repeating regimen (4 days on, 3 days off and 2 days on, 5 days off), to define the maximum tolerated dose. Part B: dose expansion phase, at the defined maximum tolerated dose or recommended dose from part A (4 days on, 3 days off and 2 days on, 5 days off). Part C and D: AZD-5363 orally, twice-daily on an intermittent regimen (4 days on, 3 days off).

Scroll down to read results and identify adverse events found in this trial.

ADVERSE EVENTS TEXT	
In August 2020, results from patients with AKT1 E17K-mutant, ER-positive metastatic breast cancer were published. Combination therapy was found to be more tolerable than monotherapy and the most frequent grade ≥ 3 adverse events were: rash (9 versus 20%), hyperglycemia (5 versus 30%) and diarrhea (5 versus 10%) [ <a href="#">2295491</a> ].	
Adverse Event Details	
<a href="#">Expand all</a>	
capivasertib (4)	

5. The Subjects & Measurements tab provides eligibility criteria, biomarkers and patient segmentation as well as primary and secondary endpoints included in this trial.

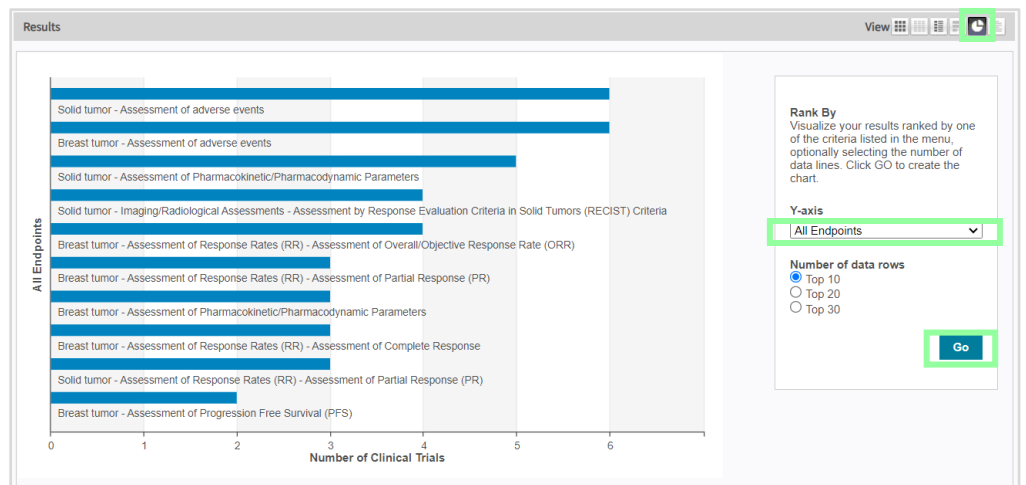
Safety, Tolerability and Potential Anti-cancer Activity of Increasing Doses of AZD-5363 in Different Treatment Schedules

Snapshot	Highlight <input type="checkbox"/> Search Terms & Synonyms	< Previous	Next >
Protocol & Results	SUBJECTS & MEASUREMENTS		
Subjects & Measurements	ELIGIBILITY CRITERIA		
<ul style="list-style-type: none"> <li>Eligibility Criteria</li> <li>Outcome Measures</li> <li>Patient Segmentation</li> <li>Biomarkers</li> </ul>	Inclusion Criteria Text	<ul style="list-style-type: none"> <li>Aged at least <math>\geq</math> 18 years with World Health Organization (WHO) performance status of 0 to 1 -Parts A, B: the presence of a solid, malignant tumor, excluding lymphoma, that is resistance to standard therapies or for which no standard therapies exist -ER+/HER2+ breast, ovarian, cervical, endometrial cancer, or other solid cancers, resistance to standard therapies with a PIK3CA gene mutation (part C), AKT1 gene mutation (part D) or a dysregulatory aberration on the PIK/AKT pathway (part D), advanced or metastatic ER+ positive breast cancer that has an AKT1 gene mutation (part E) or advanced or metastatic ER+ positive breast cancer that has a PTEN gene mutation (part F) -The presence of at least one lesion that can be accurately assessed at baseline by CT, MRI or plain X-ray and is suitable for repeated assessment. Estimated life expectancy of <math>&gt;</math> 12 weeks -Estimated life expectancy of <math>&gt;</math> 12 weeks</li> </ul>	
	Inclusion Criteria Index	<ul style="list-style-type: none"> <li>Breast tumor</li> </ul>	

Scroll down to identify biomarkers included. Further information on biomarkers can be found in Cortellis Drug Discovery Intelligence, depending on your company's subscription.

BIOMARKERS			
Name		Role	Type
HER2	<a href="#">View in CDDI</a>	Disease marker	Genomic; Proteomic
Estrogen receptor	<a href="#">View in CDDI</a>	Disease marker;Therapeutic effect marker	Genomic; Proteomic
Phosphatidylinositol-3,4,5-trisphosphate 3-phosphatase and dual-specificity protein phosphatase PTEN	<a href="#">View in CDDI</a>	Disease marker;Therapeutic effect marker	Genomic; Proteomic

6. Back in the results page, you can change views at the top right to display a bar chart and visualize the top 10 endpoints included in these trials. Click on any of the bars to display the relevant trials as a table.



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