



Building transformative software with generative AI: Potential and pitfalls

Marc G. Bellemare

How do business users find information today?

Commercial search engines

"Which team won the Stanley cup in 1990?"

Data aggregators

"Which team has won the most Stanley cups?"

Internal databases

"Which team do we think will win this year?"

Study Assessing the Efficacy and Safety of Treatment With Alpelisib Plus Fulvestrant Versus Placebo Plus Fulvestrant in Chinese Men and Postmenopausal Women With Advanced Breast Cancer

ClinicalTrials.gov ID ⓘ **NCT04544189**

Sponsor ⓘ Novartis Pharmaceuticals

Information provided by ⓘ Novartis (Novartis Pharmaceuticals) (Responsible Party)

Last Update Posted ⓘ 2024-03-15



+ Expand all content

— Collapse all content

Study Details

Researcher View

No Results Posted

Record History

On this page

Study Overview

Contacts and Locations

Participation Criteria

Study Plan

Collaborators and Investigators

Publications

Study Record Dates

More Information

Study Overview

Brief Summary

The primary objective is to evaluate whether treatment with alpelisib in combination with fulvestrant prolongs Progression Free Survival (PFS) compared to treatment with placebo in combination with fulvestrant.

The primary scientific question of interest is: what is the treatment effect based on PFS for alpelisib in combination with fulvestrant versus placebo in combination with fulvestrant in Chinese men and postmenopausal women with HR-positive, HER2-negative advanced breast cancer with a PIK3CA

[+ Show more](#)

Detailed Description

This is a Phase II, randomized, double-blind, placebo-controlled, multi-center study conducted in Chinese men and postmenopausal women with HR- positive, HER2-negative, PIK3CA mutant advanced breast cancer which progressed on or after AI treatment. The study also includes a single arm, open-label cohort (the PK cohort) to conduct pharmacokinetic analysis.

For the randomized cohort, in the randomized treatment phase, subjects will be randomized 1:1 to receive alpelisib or matching placebo plus fulvestrant.

[+ Show more](#)

Official Title

A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Resistant Positive HER2

"Which clinical trials have involved HER2-negative patients?"

Study Start (Actual) ⓘ

2021-01-20

Primary Completion (Estimated) ⓘ

2026-01-23

Study Completion (Estimated) ⓘ

2028-06-24

Enrollment (Actual) ⓘ

69

Study Type ⓘ

Interventional

Phase ⓘ

Phase 2

The mental menial labor of knowledge work

NCT Number	Study Title	Patient population is HER2 negative?
NCT04544189	Study Assessing the Efficacy and Safety of Treatment With Alpelisib Plus Fulvestrant Versus Placebo Plus Fulvestrant in Chinese Men and Postmenopausal Women With Advanced Breast Cancer	
NCT05230810	Clinical Trial of Alpelisib and Tucatinib in Patients With PIK3CA-Mutant HER2+ Metastatic Breast Cancer.	
NCT01872260	Study of LEE011, BYL719 and Letrozole in Advanced ER+ Breast Cancer	
NCT02276027	A Phase II, Open Label, Multiple Arm Study of AUY922, BYL719, INC280, LDK378 and MEK162 in Chinese Patients With Advanced Non-small Cell Lung Cancer	
NCT01719380	Study of LGX818 and Cetuximab or LGX818, BYL719, and Cetuximab in BRAF Mutant Metastatic Colorectal Cancer	
NCT05768139	First-in-Human Study of STX-478 as Monotherapy and in Combination With Other Antineoplastic Agents in Participants With Advanced Solid Tumors	

ACTIVE, NOT RECRUITING

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For the randomized cohort, in the randomized treatment phase, subjects will be randomized 1:1 to receive alpelisib or matching placebo plus fulvestrant.

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A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-

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Systematic reviews need more than a chat agent

- ❖ Hallucinations
- ❖ Lack of reference material
- ❖ Potentially outdated information
- ❖ Not comprehensive

Which clinical trials study HER2-negative patient populations?

HER2-negative breast cancer refers to breast cancer cells that do not have high levels of the human epidermal growth factor receptor 2 (HER2) protein. Since HER2 is not overexpressed in these cases, treatments targeting HER2 are generally not effective. Therefore, clinical trials studying HER2-negative patient populations typically focus on other aspects of breast cancer treatment, such as hormone receptor status (estrogen receptor-positive or progesterone receptor-positive) or other molecular targets.

Clinical trials for HER2-negative breast cancer may investigate various treatments including:

- 1. Hormone therapy: Trials evaluating different hormone therapies such as tamoxifen, aromatase inhibitors, or other drugs that target hormone receptors.*
- 2. Chemotherapy: Studies testing various chemotherapy regimens, combinations, and dosages.*
- 3. Immunotherapy: Trials assessing the effectiveness of immunotherapy agents, such as checkpoint inhibitors, in treating HER2-negative breast cancer.*
- 4. Targeted therapies: Researching new drugs or combinations of drugs that target specific molecular pathways involved in breast cancer growth and progression, such as CDK4/6 inhibitors or PI3K inhibitors.*
- 5. Radiation therapy: Investigating different radiation therapy techniques or schedules in combination with other treatments.*
- 6. Combination therapies: Trials combining different treatment modalities to improve outcomes, such as combining chemotherapy with targeted therapy or immunotherapy.*

To find specific clinical trials studying HER2-negative breast cancer patients, you can search databases like ClinicalTrials.gov or consult with a healthcare provider or oncologist who can provide information on available trials that may be suitable for your condition.

Generative AI for large-scale information queries

Concise

Easily interpreted and
manipulated

Comprehensive

Covering the entire dataset

Factual

Correct and verifiable

Retrieval-augmented generation (RAG)

Which clinical trials have involved HER2-negative patients?

Most relevant section?

ACTIVE, NOT RECRUITING

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For the randomized cohort, in the randomized treatment phase, subjects will be randomized 1:1 to receive alpelisib or matching placebo plus fulvestrant.

A total of approximately 120 subjects will be enrolled; randomization will be stratified by:

1. Lung and/or liver metastases (yes versus no)
2. Previous treatment with any CDK4/6 inhibitor (yes versus no) The total number of subjects pre-treated with any CDK4/6 inhibitor will be limited to 30% of the total number of subjects.

Approximately 15 subjects meeting the same inclusion/exclusion criteria as the randomized cohort will be enrolled into the PK cohort. Subjects in the PK cohort will receive alpelisib plus fulvestrant.

Subjects will continue to receive study treatment until disease progression as determined by investigator, unacceptable toxicity, or until discontinuation of study treatment due to any other reason.

[- Show less](#)

to LLM

The following text is part of the information pertaining to a clinical trial:

Detailed description: This is a Phase II, randomized, double-blind, [...]

According to this text, does this clinical trial involve HER2-negative patients? **Yes**

RAG is best suited for simple questions

- ❖ A single answer;
- ❖ From a single place;
- ❖ Within a group of similar documents;
- ❖ Requiring little language understanding.

How can we scale this up to handle 500,000 clinical trials all at once?

This is a “systems” problem

- ❖ Mixed data sources
- ❖ Mixed document types
- ❖ Cost/speed considerations
- ❖ High-recall requirements
- ❖ Data inconsistencies
- ❖ **User experience is key**

“Which clinical trials have involved HER2-negative patients?”



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NCT01872260	Study of LEE011, BYL719 and Letrozole in Advanced ER+ Breast Cancer	
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Literary license in LLMs

On what date did
this trial start?

March 29, 2021

On the 29th
of March (2021)

2021/29/03

A type system for LLMs

Machine code

```
C01E 8D F0      INHEX  BSR   INCH   GET A CHAR
C020 81 30      CMP A  #'0   ZERO
C022 2B 11      BMI   HEXERR NOT HEX
C024 81 39      CMP A  #'9   NINE
C026 2F 0A      BLE  HEXRTS  GOOD HEX
C028 81 41      CMP A  #'A
C02A 2B 09      BMI   HEXERR NOT HEX
C02C 81 46      CMP A  #'F
C02E 2E 05      BGT  HEXERR
C030 80 07      SUB A  #7    FIX A-F
C032 84 0F      HEXRTS AND A  #$0F  CONVERT ASCII TO DIGIT
C034 39
C035 7E C0 AF   HEXERR JMP   CTRL   RETURN TO CONTROL LOOP
```

Programming language

```
A = ["eggs", "bacon", "ham"]
sort_strings(A)
```

Free-form text

1. *Hormone therapy: Trials evaluating different hormone therapies such as tamoxifen, aromatase inhibitors, or other drugs that target hormone receptors.*
2. *Chemotherapy: Studies testing various chemotherapy regimens, combinations, and dosages.*
3. *Immunotherapy: Trials assessing the effectiveness of immunotherapy agents, such as checkpoint inhibitors, in treating HER2-negative breast cancer.*

Structured data

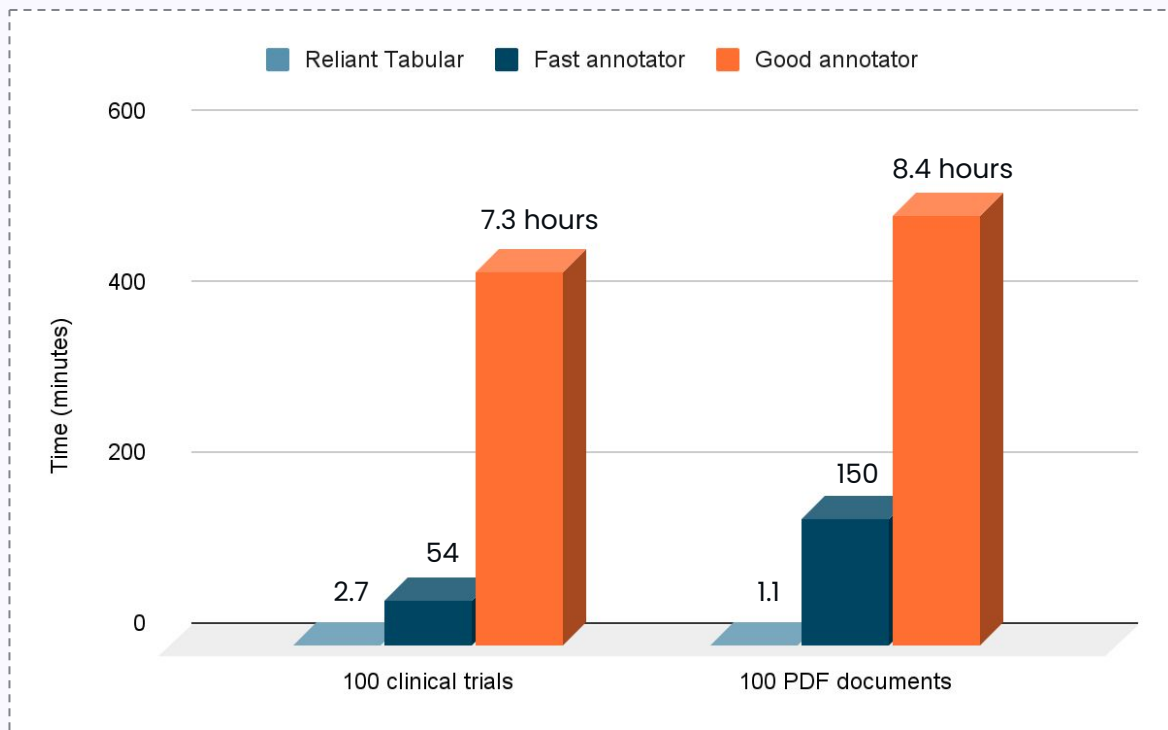
Therapy	Example
Hormone therapy	Aromatase inhibitors
Immunotherapy	Checkpoint inhibitors

Interrogative filtering

- ❖ Yes/no questions offer a filtering opportunity
- ❖ Can be tailored to different use cases
- ❖ Easily fine-tuned using reinforcement learning

NCT Number	Study Title	Patient population is HER2 negative?
NCT01719380	Study of LGX818 and Cetuximab or LGX818, BYL719, and Cetuximab in BRAF Mutant Metastatic Colorectal Cancer	N/A
NCT01923168	Study of Letrozole With or Without BYL719 or Buparlisib, for the Neoadjuvant Treatment of Postmenopausal Women	N/A
NCT05230810	Clinical Trial of Alpelisib and Tucatinib in Patients With PIK3CA-Mutant HER2+ Metastatic Breast Cancer.	No
NCT04544189	Study Assessing the Efficacy and Safety of Treatment With Alpelisib Plus Fulvestrant Versus Placebo Plus Fulvestrant in Chinese Men and Postmenopausal Women With Advanced Breast Cancer	Yes
NCT05768139	First-in-Human Study of STX-478 as Monotherapy and in Combination With Other Antineoplastic Agents in Participants With Advanced Solid Tumors	N/A
NCT03284957	Phase 1/2 Study of Amcenestrant (SAR439859) Single Agent and in Combination With Other Anti-cancer Therapies in Postmenopausal Women With Estrogen Receptor Positive Advanced Breast Cancer	Yes
NCT01872260	Study of LEE011, BYL719 and Letrozole in Advanced ER+ Breast Cancer	Yes
NCT02276027	A Phase II, Open Label, Multiple Arm Study of AUJ922, BYL719, INC280, LDK378 and MEK162 in Chinese Patients With Advanced Non-small Cell Lung Cancer	N/A
NCT03056755	Study Assessing the Efficacy and Safety of Alpelisib Plus Fulvestrant or Letrozole, Based on Prior Endocrine Therapy, in Patients With PIK3CA Mutant, HR+, HER2- Advanced Breast Cancer Who Have Progressed on or After Prior Treatments	Yes
NCT04762979	Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer	Yes
NCT02298595	Cetuximab, Cisplatin and BYL719 for HPV-Associated Oropharyngeal Squamous Cell Carcinoma	N/A
NCT05966584	A Study to Prevent Rash in People Starting Alpelisib for the Treatment of Breast Cancer	Yes
NCT04862143	Pilot Decentralized Clinical Trial in Men and Pre and Post-menopausal Women With Breast Cancer and a Specific Mutation (PIK3CA) Treated With Alpelisib in Combination With Fulvestrant	N/A
NCT05948943	Alpelisib in Pediatric and Adult Patients With Lymphatic Malformations Associated With a PIK3CA Mutation.	N/A
NCT04589650	Study Assessing the Efficacy, Safety and PK of Alpelisib (BYL719) in Pediatric and Adult Patients With PIK3CA-related Overgrowth Spectrum	N/A

Information, three orders of magnitude faster



Generative AI within a larger workflow

Hello, John!

Let's start a new project.

To start, select on of the predefined workflows.

Upload and search



Search and interrogate uploaded files (PDF, pptx, docx)

ClinicalTrials.gov



Search & import clinical trial data with bespoke filters from clinicaltrials.gov

Pubmed



PubMed is a free resource with millions of citations and abstracts of biomedical literature.

Trial - data join



Understand clinical development landscape by searching and analyzing connected databases (including published congress abstracts)

Ad Board & Expert Interviews



Analyze and extract insights from recorded audio content

HTA interrogation



Analyze HTA document to understand underlying clinical data and criteria for decision making

Business intelligence



Build and automate dashboards from public and commercial datasets

Epi analyzer



Analyze and extract insights from recorded audio content

Time series analysis



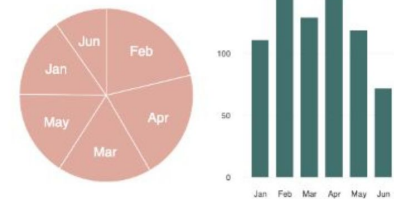
Analyze HTA document to understand underlying clinical data and criteria for decision making

Report Summary

The CRC Landscape Report provides a comprehensive overview of the current state of conservation, restoration, and connectivity efforts within the Chesapeake Riparian Corridor (CRC) region. Through detailed analysis of land use data, habitat trends, and conservation practices, the report highlights both the successes and challenges faced in protecting this critical ecosystem.

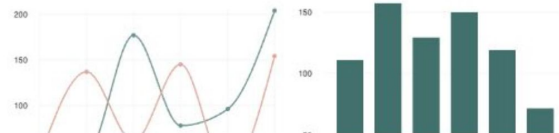
Analysis of CRC Landscape

Parameter	Value	Change
ROI	5%	+1%
Engagement	80%	-2%



Sales and Cost Analysis

Parameter	Value	Trend
Sales	\$1.2M	Upward
Cost	\$300K	Stable



Share

- John
Thanks for this.
- John
Does this analysis include CRC as well as BYD719?
- AI
Yes, the clinical trials underlying this analysis include both sources
- Sandra
Btw: you can filter for this, if you want - just remove BYD719 in the underlying source.
- John
Ah, awesome. Thx

Your message

Type your message here

Send message

Thank you