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Austrian Breast & Colorectal Cancer Study Group

Annual Report

Austrian Breast & Colorectal Cancer Study Group 2025

„SCIENCE FROM THE HEART OF EUROPE“

ABCSG
AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

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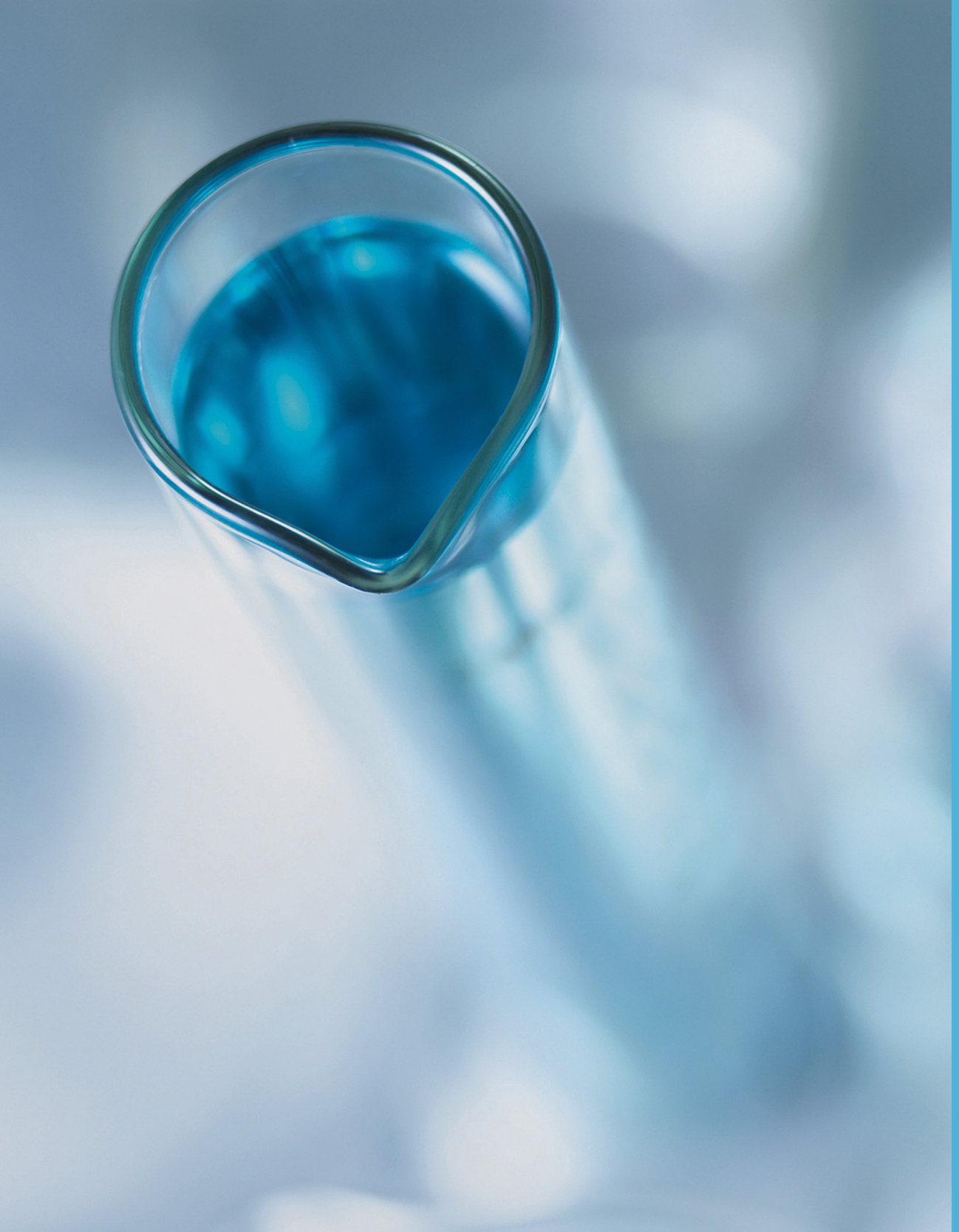

Introduction and Key Facts

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ABCSG Activities - A Review of Clinical and Translational Cancer Research in 2025

In general, the year 2025 unfolded in a global environment marked by increasing uncertainty in many dimensions. International scientific collaboration has become more challenging, and long-standing frameworks can no longer be taken for granted. In this context, it is especially gratifying to reflect on a year in which the Austrian Breast and Colorectal Cancer Study Group was able to build on its strengths and further consolidate its position as a reliable, successful, and independent academic research organization.

From a scientific output perspective, 2025 remarkably was the most substantial and productive year in the history of the ABCSG. With 30 peer-reviewed full publications, our work achieved broad international recognition in top journals. Among many important contributions, the publication of the ABCSG 52 / ATHENE trial, *"Neoadjuvant atezolizumab in combination with dual HER2 blockade plus epirubicin in women with early HER2-positive breast cancer"* (Rinnerthaler et al.) in Nature Cancer stands out as a particular milestone. Additionally, multiple high-quality publications based among others on ABCSG 42 / PALLAS and ABCSG 34 further emphasized the long-term scientific value of our academically driven clinical trials and their translational follow-up.

Our research was also prominently represented at major international conferences. At the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, ABCSG Vice President Christian Singer presented a rapid oral talk on the ABCSG 45 trial, which compares neoadjuvant olaparib/carboplatin with standard TAC chemotherapy in patients with HRD-positive triple-negative breast cancer, highlighting ABCSG's contributions to precision medicine for this challenging subtype. At the San Antonio Breast Cancer Symposium (SABCS), ABCSG contributions included three oral and eight poster presentations, covering both clinical and translational research across multiple trials, including ABCSG 42 / PALLAS, Trans-PALLAS projects, ABCSG 8, ABCSG 18, and ABCSG 34, further underscoring the group's visibility in high-impact scientific forums.

A central focus of 2025 was the further expansion of our clinical trial portfolio with four new and innovative breast cancer studies being launched: ABCSG 61 / TEODOR and ABCSG 63 / ERIKA, both of which were developed by ABCSG, as well as ABCSG 65 / DEFINITIVE and the non-interventional study ABCSG 67N / CAROLEEN where ABCSG participates in international collaborations. With a total of 47 site initiations and over 100 patients enrolled within a short period, all studies started extremely well. These achievements reflect an exceptionally high level of engagement, coordination and efficiency across all ABCSG teams and sites. Meanwhile, the ongoing management and coordination of an academic network in large international trials such as ABCSG 42 / PALLAS, ABCSG 50 / BRCA-P and ABCSG 62 / CAMBRIA-2 remained resource-intensive and demanding, further highlighting the operational strength and experience of our organization.

Education and knowledge exchange continue to be core elements of the ABCSG mission. As the host and cooperating partner of the St. Gallen International Breast Cancer Conference (SGBCC), we are proud to contribute to making Vienna a hub for cutting-edge research and clinical consensus every two years. Our established educational formats, such as Post-SABCS, Daten – Fakten: Konsequenzen?, Science and Cases, Experts on Tour, the Interdisciplinary Mamma Discourse, abcsg in touch for young physicians organized by the Task Force "Future Now", and the Annual Group Meeting in Saalfelden, reached a broad national audience. At the international level, the online CDK4/6 inhibitor webinar attracted over 100 participants from 12 countries, demonstrating ABCSG's ability to bring together two competing pharmaceutical companies for an independent academic project.

From an organizational perspective, 2025 was also a year of internal renewal. During the Annual Meeting, the ABCSG Board was elected for the next 3 years, our Executive Committee was expanded, and an Advisory Board was established. The Advisory Board consists of experienced members, while new and emerging young clinical researchers were integrated into ABCSG's Board and Executive Committee. I am deeply honored to have been re-elected as president of the ABCSG and remain profoundly grateful for the trust placed in me over the past 20 years. This anniversary is not an individual achievement, but rather the result of sustained teamwork, collegiality, and a shared commitment to independent academic research. I am thankful to all colleagues, collaborators, and partners who continue to shape the ABCSG with their expertise, integrity, and enthusiasm.

As in previous years, this Annual Report provides an overview of our activities, achievements, and ongoing projects. I hope it conveys not only the breadth of our work, but also the spirit of collaboration and responsibility that drives ABCSG forward.

Sincerely,

Michael Gnant,
on behalf of the ABCSG

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ABCSG Key Facts 2025

effective date 31 Dec 2025

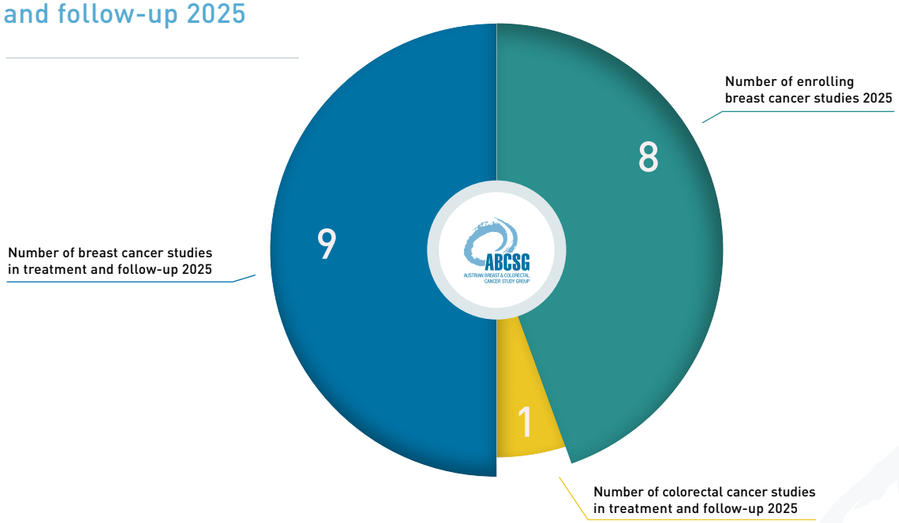
Number of all patients ever enrolled

29.858

Number of ...

... translational projects 2025	4
... enrolling studies 2025	8
... studies in treatment phase and follow-up 2025	10

Clinical studies in enrollment, treatment and follow-up 2025



Number of ...

... all ongoing breast cancer studies in 2025	17
... all ongoing colorectal cancer studies in 2025	1

Austrian Breast and Colorectal Cancer Study Group (Association)

Year of foundation: 1984

10 Board members
12 Members Executive Committee
42 Members General Assembly
5 Members Advisory Board

Tax status: non-profit

ABCSG GmbH

Year of foundation: 2015

Ownership:
99 % Association, 1 % Persons

Commercial Managing Director:
Mag. Hannes Fohler

Scientific Managing Director:
Prof. Dr. Michael Gnant

Current purpose: legal entity for international registration study PALLAS

Tax status: non-profit

ABCSG Research Services GmbH

Year of foundation: 2022

Ownership:
99 % Association, 1 % Persons

Commercial Managing Director:
Mag. Hannes Fohler

Scientific Managing Director:
Prof. Dr. Michael Gnant

Current purpose: legal entity for conduct of international industry sponsored trials

234

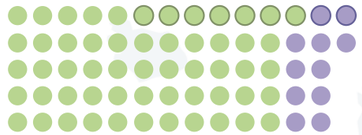
Total Publications ABCSG (peer reviewed)

Publications 2025 (peer reviewed)	30

16.4 years ...

... is the average employment duration of the ABCSG management team

Employees (Head Count)



Number of female employees
Female employees with employee responsibility
Number of male employees
Male employees with employee responsibility

Headcounts include all active employment contracts as of 31 December 2025, including parental leave.

Structure, Aims, Visions and International Network

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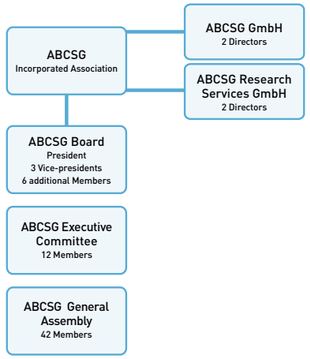
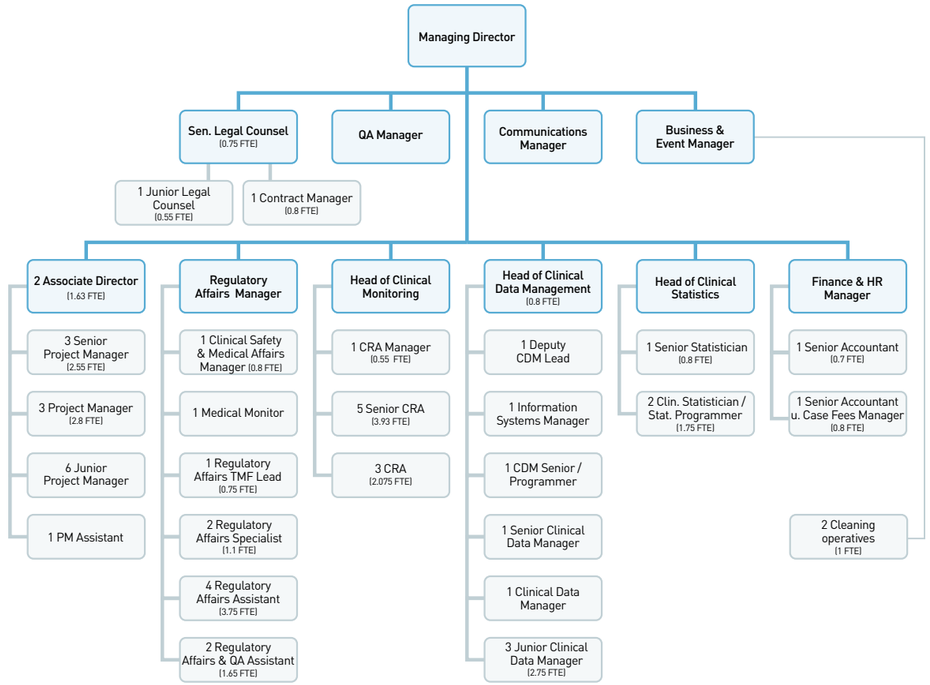
ABCSG Structure



ABCSG Trial Office

62 active Employees (52.94 FTE)



The ABCSG – Tasks, Goals and Structure

ABCSG (Austrian Breast & Colorectal Cancer Study Group) is Austria's largest academic research organization in the field of clinical studies. Clinical studies in breast, colorectal and pancreatic cancer as well as scientific and translational research projects are planned, conducted and analyzed by ABCSG nationally, but also strongly embedded in an international network.

The primary goals are to standardize diagnostics, therapy, and follow-up treatment throughout Austria, but also internationally, and to provide patients with the best possible, newest cancer therapy and care. **Of great importance for the affected patients is a constant advancement of the diagnostic, prognostic but also predictive possibilities, coupled with the latest treatment options, in order to maintain a high quality of life in the long term.** ABCSG has set itself the goal of achieving continuous improvements in these areas through its studies and projects, as well **as dissemination of research results into the wider public and investing in education of investigators.**

Multidisciplinary approaches are key to the worldwide success of ABCSG and has contributed significantly to improving the chances of cure and patient survival. Surgeons, oncologists, gynaecologists, radiotherapists, pathologists, radiologists as well as physicians from other disciplines or basic researchers, such as molecular biologists and bioinformaticians, join forces to find new answers to important diagnostic and therapeutic questions about various cancer entities.

Since many years, studies on breast and colorectal cancer have been the focus of ABCSG. In order to bundle activities and to generate additional synergies, there are also smaller working groups ("task forces") in various specialized areas. The oversight committee for all scientific decisions is the ABCSG Board, comprising of experts and clinicians from these entities, and furthermore supported by the Executive Committee that also welcomes a younger generation of researchers and key opinion leaders that contribute to the development of new clinical studies and research projects.

The clinical trials and translational research projects are conducted in a very transparent manner and are monitored at every stage by ethics committees, a responsible Data Monitoring Committee (DMC), assigned health authorities and a highly professional as well as dedicated operational ABCSG team.

In the ABCSG trial office in Vienna, highly qualified staff members are involved in the design and organization of the studies as well as ultimately in the data generation and analysis of the resulting data for publication. The trial office is headed by the Managing Director and comprises the departments Clinical Data Management, Regulatory Affairs with Clinical Safety and Medical Affairs as well as Medical Monitoring, Project Management, Clinical Statistics, as well as a Legal Department and further units dedicated to Quality Assurance, Business and Event Management, Finance and Controlling as well as Public Relations / Communications. Clinical Monitors (CRAs) are located throughout Austria and responsible for the protocol-compliant study oversight at sites and via remote monitoring tools as well as the important verification of the collected study data at the participating study sites.

The ABCSG was founded in 1984 and is non-profit oriented. Since 2015 and 2022, respectively, there are also two subsidiary entities available for dedicated projects with the main purpose to serve as the legal entity for the international registration trial PALLAS (ABCSG GmbH) where ABCSG acts as legal sponsor in 20 countries, and other large global trials in cooperation with industry partners (ABCSG Research Services GmbH).

International Network

While many study protocols and research projects are executed in Austria (only), with a well-established network of trial sites, the ABCSG is also part of a large, international network of academic study groups.

After having gained valuable experience in transatlantic and global partnerships on the adjuvant ABCSG 42 / PALLAS trial (where ABCSG acts as legal trial sponsor in 20 countries, along with AFT for the USA), another international collaboration with groups such as AFT (USA), BCT (Australia and New Zealand) and European partners, is the first phase III breast cancer prevention trial ABCSG 50 / BRCA-P (for *BRCA1* mutation carriers) where ABCSG coordinates this multinational, double-blinded study in 7 countries, from study systems to drug supply, and is responsible for data management and statistical analysis as well.

Due to the large number of studies, the ABCSG has been able to generate an enormous treasure of data and this also opens up opportunities for collaboration with renowned academic institutions abroad in the context of retrospective meta-analyses and translational research questions as well as developments of applications or diagnostic tools. For example, data from large ABCSG studies are an essential component of collaborative high-level publications of the Early Breast Cancer Trialists' Collaborative Group (EBCTCG).

In addition to smaller and larger academic studies, ABCSG also participates in relevant research questions in industry-initiated studies and coordinates these in Austria. A new hybrid model of working together between pharmaceutical industry and CROs with the involvement of academic study groups such as ABCSG was successfully established in the format of the "transparency model" which materialized in large global studies such as the CAMBRIA-2 trial. This collaboration combines many advantages of all involved stakeholders by ensuring the highest possible data quality standards and independent validation of results, while making use of the excellent network of specialized breast cancer study groups and their affiliated network sites that can significantly contribute to patient enrollment and care. ABCSG is coordinating study groups in nine countries that are responsible for about a third of the patients enrolled in the study which is set to complete the randomization phase.

In translational research, there have been close collaborations with international partners, including biotech companies such as Nanostring, Agendia, Cepheid, Myriad, OncoMark, ProCan, Artera, Ataraxis and Spotlight Medical, as well as new collaborations and approaches are continuously added to the global translational research portfolio.

The focus is always on the value of the proposed scientific questions and the potential benefit for patients, preferably implemented within independent academic structures. It is precisely this balanced mix of various collaborative models and a close interaction in the scientific community that has been the basis of ABCSG's success and constant development for more than 40 years.

Studies open for Enrollment

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Scientific terms and definitions used in the study titles and descriptions are based on the official study protocols and may therefore vary between the respective texts.

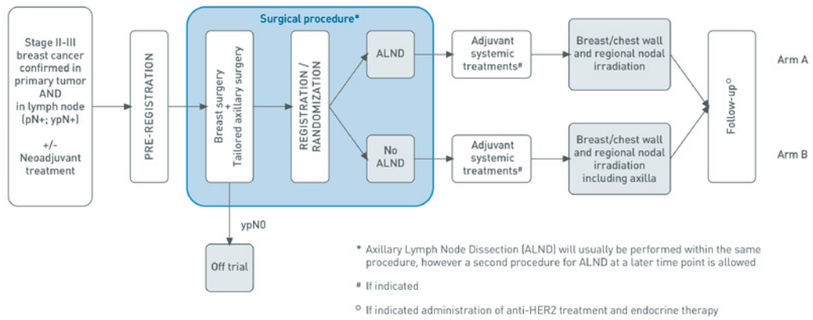
ABCSG 53 / TAXIS

Tailored axillary surgery with or without axillary lymph node dissection followed by radiotherapy in patients with clinically node-positive breast cancer (TAXIS): a multicenter randomized phase III trial

Coordinating Investigator: **Daniel Egle** (Innsbruck)

Start of study:	Sample size:	Sponsor:
08/2018 (global) **12/2019** (national)	**1.587**	**Universitätsspital Basel (USB)**

Design:



Description and status:

ABCSG 53 / TAXIS investigates the hypothesis that Tailored Axillary Surgery (TAS), together with radiotherapy, is non-inferior to Axillary Lymph Node Dissection (ALND) in terms of disease-free survival of breast cancer patients with confirmed lymph node involvement at first diagnosis. In many patients who undergo ALND, the number of lymph nodes removed exceeds the number of cancerous ones. Removal of several unaffected lymph nodes increases morbidity (e.g., in the form of lymphedema, impaired shoulder mobility) without having an oncological advantage. TAXIS participants undergo TAS, which is the removal of the sentinel lymph nodes and palpably suspicious nodes, before being intraoperatively randomized to receive either ALND or axillary radiotherapy in the setting of extended regional nodal irradiation.

Recruitment in the TAXIS trial started in 2018 and lasted until the end of 2025. In total, 187 participants were randomized in Austria and more than 1.580 in 13 countries globally. The trial is now in the follow up phase, which lasts 10 years after the last participant was randomized.

In 2025, Knauer et al. published their findings from a pre-specified TAXIS sub-study on genomic recurrence risk, measured in primary tissue and lymph node metastases (https://www.sciencedirect.com/science/article/pii/S0959804925003673).

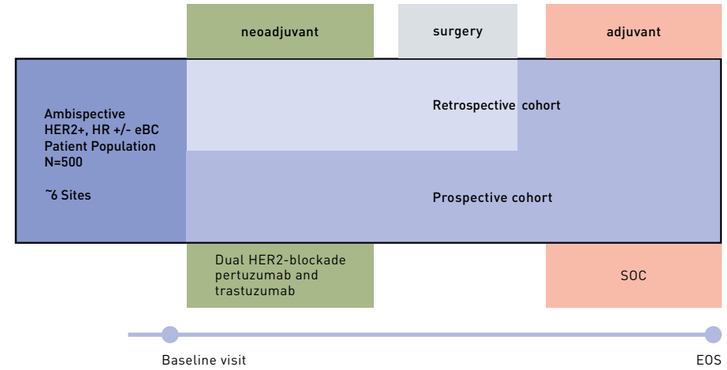
ABCSG 55N / AMBHER

Description of patients with HER2-positive breast cancer undergoing neoadjuvant treatment and development of a dynamic composite risk score to predict the risk of distant recurrence

Coordinating Investigator: **Marija Balic** (Graz /Pittsburgh)

Start of study:	Sample size:	Sponsor:
03/2023 (national)	**500**	**ABCSG**

Design:



Description and status:

ABCSG 55N / AMBHER is a non-interventional, single-arm, multicenter study with an ambispective study design where patients either belong to the retrospective or prospective cohort. Data are collected from patients with HER2-positive early breast cancer who have received neoadjuvant therapy with a dual HER2 blockade of pertuzumab and trastuzumab.

Subsequently, a dynamic prediction model will be developed to estimate the risk of distant recurrence. This should help to identify those patients who will benefit most from adjuvant pertuzumab therapy, thereby enabling a further step towards precision medicine. In addition, the study serves to investigate the cardiac safety of pertuzumab and trastuzumab in combination with standard chemotherapy in the neoadjuvant setting in this patient population. By the end of 2025, 448 patients had been registered to the study at 8 sites throughout Austria.

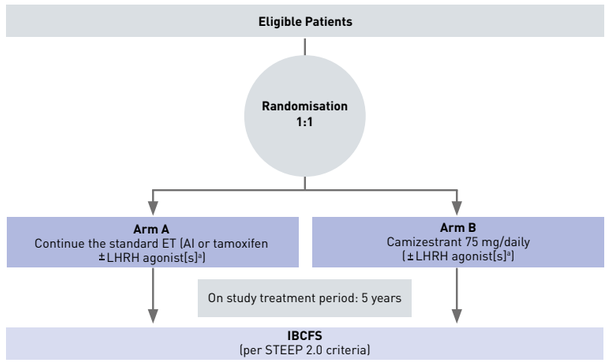
ABCSG 60 / CAMBRIA-1

A phase III, open-label, randomized study to assess the efficacy and safety of extended therapy with Camizestrant versus standard endocrine therapy in patients with ER+/HER2- early breast cancer and an intermediate or high risk of recurrence who have completed at least 2 years of standard adjuvant endocrine-based therapy without disease recurrence

Coordinating Investigator: **Daniel Egle** (Innsbruck)

Start of study:	Sample size:	Sponsor:
04/2023 (global) **08/2023** (national)	**4.300**	**AstraZeneca**

Design:



Description and status:

The ABCSG 60 / CAMBRIA-1 trial is an open, randomized phase III study, evaluating the efficacy and safety of camizestrant in comparison to standard endocrine therapy in HR-positive/HER2-negative early breast cancer patients with an intermediate to high risk of recurrence. Patients must have completed definitive locoregional therapy and at least 2 years of standard endocrine therapy without disease recurrence at time of enrollment and at least another 5 years of standard endocrine therapy treatment must be foreseen. The primary endpoint of CAMBRIA-1 is to demonstrate superiority of extended therapy with camizestrant as compared to standard endocrine therapy by assessment of invasive breast cancer-free survival (IBCFS). Patients receive 75 mg camizestrant daily or continue their standard endocrine therapy for 5 years. Subsequently, patients will be followed-up for a total of approximately 10 years after randomization.

Thanks to outstanding global enrollment, the actual recruitment phase was considerably shorter than originally projected. The last CAMBRIA-1 patient in Austria was included on 13 May 2025. During the enrollment phase, 133 patients were successfully recruited at 14 Austrian sites. The treatment and follow-up phases of CAMBRIA-1 will focus on patient retention while consistently treating, caring for, and monitoring patients until the study's completion in 2035.

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ABCSG 61 / TEODOR

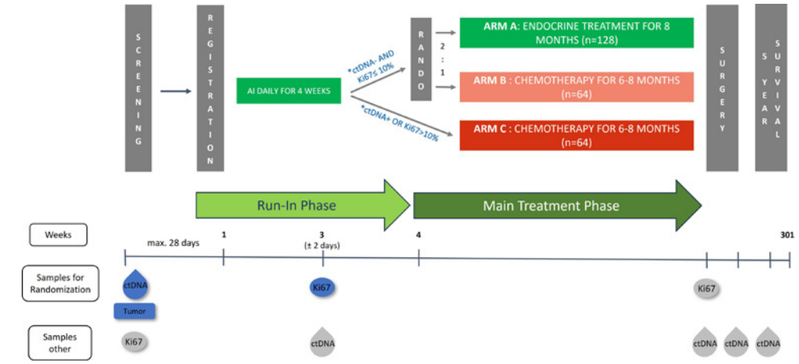
Neoadjuvant Treatment Optimization driven by ctDNA and endocrine Responsiveness

A prospective, randomized, controlled, open-label multicenter phase II study investigating neoadjuvant endocrine therapy versus chemotherapy in HR-positive/HER2-negative, ctDNA-negative and endocrine responsive early and locally advanced breast cancer

Coordinating Investigator: **Daniel Egle** (Innsbruck), **Michael Gnant** (Vienna)

Start of study:	Sample size:	Sponsor:
08/2025	**256**	**ABCSG**

Design:



Description and status:

The TEODOR trial aims to test the hypothesis that the efficacy of neoadjuvant endocrine treatment is at least comparable to the efficacy of neoadjuvant chemotherapy in 192 randomized endocrine responsive, early and locally advanced HR-positive/HER2-negative breast cancer patients, without detectable circulating tumor DNA (ctDNA).
Prior to treatment start, the ctDNA-status of trial participants is assessed with the Signatera™-test. Endocrine response is measured through Ki-67-values in the participants' tumor biopsy after 3 weeks of aromatase inhibitor therapy (AI). If no ctDNA is detected in the blood sample and the Ki-67-value is ≤ 10% (=endocrine responsive), the participant is randomized 2:1 to either receive 8 months of endocrine treatment in arm A, or 6-8 months of chemotherapy in arm B. Study participants with a Ki-67-value > 10% after 3 weeks of AI, or with a positive ctDNA-status prior to treatment, are enrolled in an observatory third arm C to receive chemotherapy. All study treatment is administered as per standard of care.
As primary study endpoint, the modified preoperative endocrine prognostic index (PEPI) score at the time of surgery is evaluated locally. After surgery, long-term study outcome is monitored in a 5-year follow up phase. Further study objectives are quality of life, surgical questions and ctDNA-kinetics.
The first patient was registered in the TEODOR trial in August 2025 at one of 13 participating sites in Austria. Until 31 December 2025, 38 patients were registered.

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Studies open for Enrollment

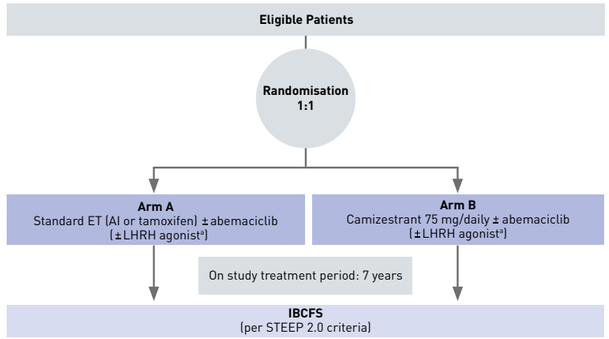
ABCSG 62 / CAMBRIA-2

A phase III, open-label, randomized study to assess the efficacy and safety of Camizestrant (AZD9833, a next generation, oral selective estrogen receptor degrader) versus standard endocrine therapy (aromatase inhibitor or Tamoxifen) as adjuvant treatment for patients with ER-positive/HER2- negative early breast cancer and an intermediate-high or high risk of recurrence who have completed definitive locoregional treatment and have no evidence of disease

Coordinating Investigator: **Daniel Egle** (Innsbruck)

Start of study:	Sample size:	Sponsor:
10/2023 (global) **04/2024** (national)	**5.500**	**AstraZeneca**

Design:



[a] Pre- and peri-menopausal women receiving SoC treatment with AI or tamoxifen (Arm A) or camizestrant (Arm B) must receive an LHRH agonist. In men (where medically applicable), an LHRH agonist is mandatory with AI (Arm A) or camizestrant (Arm B).

Description and status:

The phase III global open label trial ABCSG 62 / CAMBRIA-2, sponsored by AstraZeneca, is assessing the efficacy and safety of camizestrant (+/- abemaciclib) versus standard endocrine therapy (+/- abemaciclib) as adjuvant treatment for patients with ER-positive/HER2-negative early breast cancer and an intermediate- high or high risk of recurrence, who have completed definitive locoregional treatment and have no evidence of disease. The CAMBRIA-2 trial is aiming to demonstrate superiority of camizestrant with or without abemaciclib as compared to standard endocrine therapy (ET) with or without abemaciclib by assessment of invasive breast cancer-free survival (IBCFS) as its primary objective. Patients receive 75 mg camizestrant daily, or standard endocrine therapy, for a period of 7 years. A subset of patients – as clinically indicated – will also receive abemaciclib for the first 2 years of treatment, although this proportion is capped at max. 30% of the study population.

Given the continuously strong enrollment, projections are estimating the end of global participant recruitment ahead of time by June 2026. 15 sites are actively recruiting in Austria, with 96 randomized patients by end of 2025.

SCIENCE FROM THE HEART OF EUROPE | ABCSG | CAMBRIA-2

ABCSG 63 / ERIKA

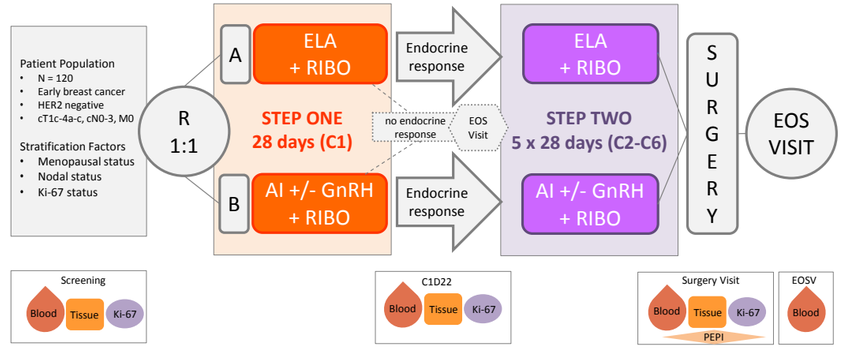
Elacestrant and Ribociclib in Ki67-tested endocrine responsive breast cancer:

An open-label, two-arm, randomized, phase II study of elacestrant plus ribociclib vs. AI (plus GnRH agonist in pre-/perimenopausal women and men) plus ribociclib as neoadjuvant therapy for endocrine-responsive HER2-negative early breast cancer

Coordinating Investigators: **Christian Singer** (Vienna), **Michael Gnant** (Vienna)

Start of study:	Sample size:	Sponsor:
09/2025 (national and global)	**120**	**ABCSG**

Design:



Description and status:

ABCSG 63 / ERIKA is an open-label, two-arm, randomized, phase II study of elacestrant plus ribociclib vs. AI (plus GnRH agonist in pre-/perimenopausal women and men) plus ribociclib as neoadjuvant therapy for endocrine-responsive HER2-negative early breast cancer.

Patients are randomized 1:1 to receive either 28 days of 400 mg elacestrant dihydrochloride plus 400 mg ribociclib in arm A, or 28 days of AI (and GnRH agonist in pre-/perimenopausal women and men) plus 400 mg ribociclib in arm B, to identify endocrine-responsive tumors. Tumors which exhibit a Ki-67 of ≤ 10 % at the C1D22 visit, as determined by local pathologist, will be considered "endocrine responsive" and these patients will continue to receive treatment – dependent on the initial randomization – for further 5 x 28 days.

The primary endpoint is defined as the proportion of modified PEPI (Preoperative Endocrine Prognostic Index) score of 0 at the time of surgery. The study is sponsored by ABCSG and conducted at trial sites in Austria and Germany, in a cooperation with the WSG (Westdeutsche Studiengruppe) in Germany. A total of 120 patients are planned to be enrolled by September 2026.

The first patient was enrolled on 11 September 2025 in Graz. Recruitment is proceeding well, with a total of 39 patients enrolled by the end of 2025.

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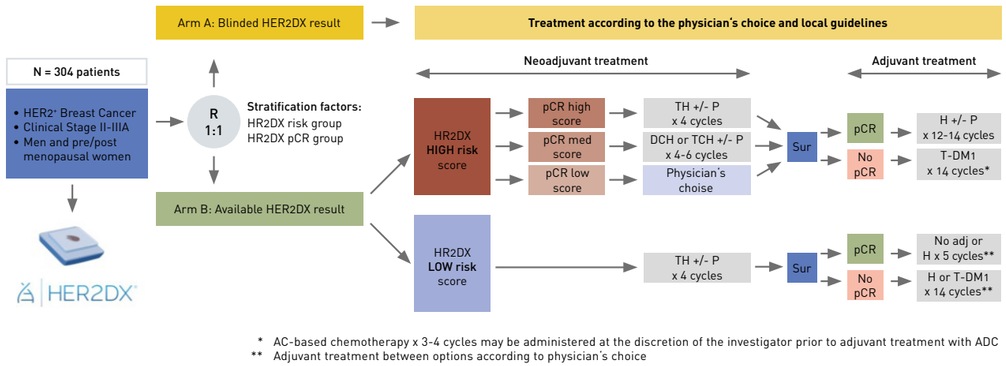
ABCSG 65 / DEFINITIVE

Diagnostic HER2DX-guided treatment For patIeNts wIth early-stage HER2-posiTIVE breast cancer: An international, multicenter, prospective, two-arm, randomized, open-label phase III study designed to demonstrate that personalized treatment decisions in HER2-positive early-stage breast cancer using the HER2DX® diagnostic test improve quality of life without compromising outcomes and survival rates

Coordinating Investigator: **Simon Gampenrieder** (Salzburg)

Start of study:	Sample size:	Sponsor:
11/2024 (global) **10/2025** (national)	**304**	**FRCB-IDIBAPS**

Design:



* AC-based chemotherapy x 3-4 cycles may be administered at the discretion of the investigator prior to adjuvant treatment with ADC
** Adjuvant treatment between options according to physician´s choice

Description and status:

DEFINITIVE is a clinical performance evaluation study of an IVD (in vitro diagnostic) assay, investigating whether the HER2DX® diagnostic test enables more precise and personalized treatment of patients with early HER2-positive breast cancer. The test development incorporated artificial intelligence and uses both biological and clinical information about the tumor. The aim of the study is to investigate whether personalized therapy based on HER2DX® can improve patients' health-related quality of life while maintaining safety and efficacy and without negatively impacting survival. Randomized patients will either receive treatment which is recommended by the HER2DX® test result, or treatment by investigator´s choice.

The first patient in Austria was enrolled on 9 October 2025. DEFINITIVE aims to include at least 304 patients with early HER2-positive breast cancer in seven countries. Austria is participating with a total of nine trial sites and by the end of 2025, Austria included seven out of 123 patients globally.

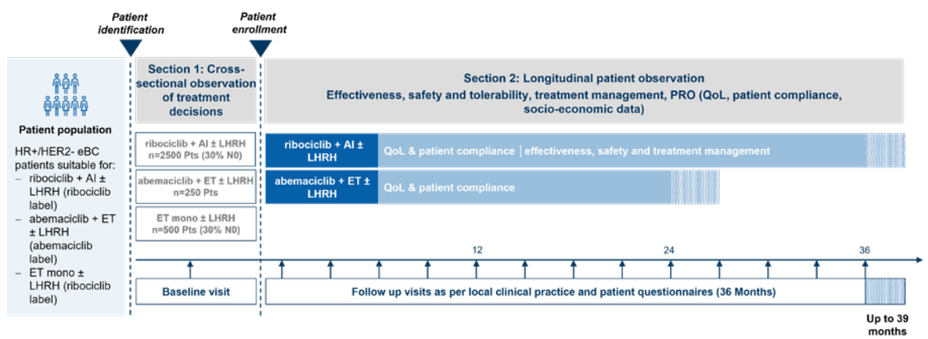
ABCSG 67N / CAROLEEN

A non-interventional study for ribociclib in combination with an aromatase inhibitor for adjuvant treatment in patients with HR-positive/HER2-negative early breast cancer at high risk of recurrence to evaluate real-world effectiveness, safety profile, patient compliance and quality of life

Coordinating Investigator: **Christian Singer** (Vienna)

Start of study:	Sample size:	Sponsor:
Q1/2025 (global) **Q4/2025** (national)	**3.250**	**Novartis**

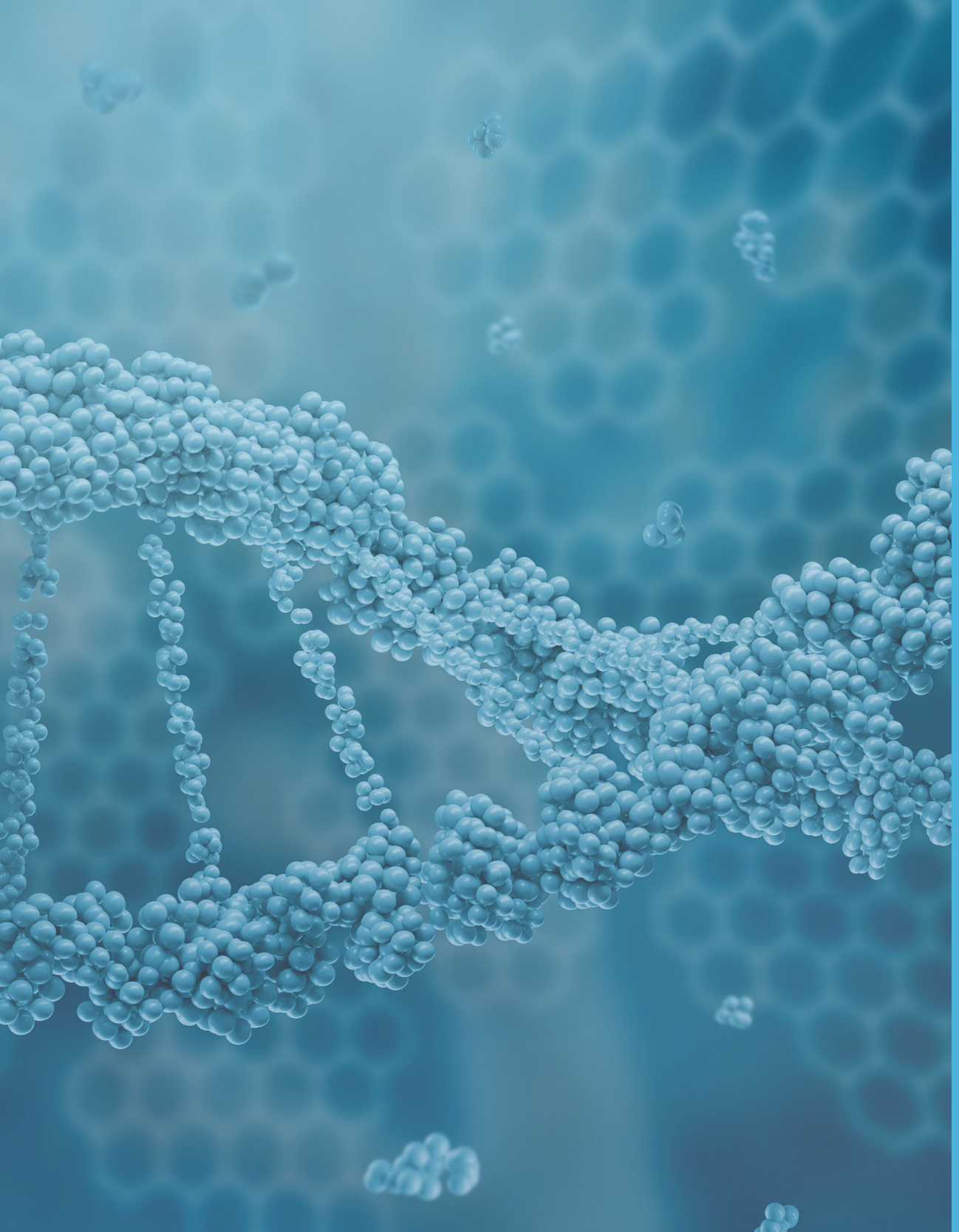
Design:



Description and status:

ABCSG 67N / CAROLEEN is a non-interventional study of various treatment regimen, including ribociclib in combination with an aromatase inhibitor (AI) for adjuvant treatment in patients with HR-positive/HER2-negative early breast cancer (eBC) at high risk of recurrence. The aim is to evaluate real-world effectiveness, safety profile, patient compliance and quality of life. Three cohorts are being observed: ribociclib in combination with an AI (2.500 patients), endocrine monotherapy (500 patients) and abemaciclib in combination with endocrine therapy (250 patients). The primary protocol objective is to evaluate iDFS (invasive disease-free survival) for adjuvant therapy with ribociclib + AI ± LHRH (luteinizing hormone-releasing hormone) in patients with HR-positive/HER2-negative eBC at 36 months.

The first patient in Austria was enrolled on 22 October 2025 in Vienna. Recruitment is proceeding well, with a total of 18 patients enrolled by the end of 2025.



Studies in Treatment Phase and Follow-up

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Scientific terms and definitions used in the study titles and descriptions are based on the official study protocols and may therefore vary between the respective texts.

ABCSG 39 / APHINITY

A randomized multicenter, double-blind, placebo-controlled comparison of chemotherapy plus trastuzumab plus placebo versus chemotherapy plus trastuzumab plus pertuzumab as adjuvant therapy in patients with operable HER2-positive primary breast cancer

Coordinating Investigator: **Günther Steger** (Vienna)

Start of study: **10/2011** (global) **/ 05/2012** (national)

Sample size: **4.804**

Sponsor: **Roche**

Description and status:

The phase III APHINITY trial (Adjuvant Pertuzumab and Herceptin IN Initial TherapY in Breast Cancer) globally enrolled 4.804 participants with newly diagnosed primary invasive, HER2-positive breast cancer to evaluate the efficacy and safety of adjuvant pertuzumab plus trastuzumab and chemotherapy compared to adjuvant trastuzumab and chemotherapy. The primary endpoint is invasive disease-free survival, secondary endpoints include cardiac and overalls safety, overall survival and quality of life.

Study recruitment was completed in 2014, a total of 52 patients were included at 11 Austrian sites. The follow-up phase ended in November 2024 and in 2025 all APHINITY sites were closed globally.

In May 2025, updated results of the final analysis were published by S. Loibl *et al.* (https://www.esmoopen.com/article/S2059-7029(25)00981-0/fulltext), which showed statistically improved overall survival for patients in the pertuzumab arm after 11,3 years of median follow up period.

ABCSG 41 / OLYMPIA

A randomized, double-blind, parallel group, placebo-controlled multi-centre phase III study to assess the efficacy and safety of olaparib vs placebo as adjuvant treatment in patients with germline *BRCA 1/2* mutations and high risk HER2-negative breast cancer who have completed definitive local treatment and neoadjuvant or adjuvant chemotherapy

Coordinating Investigator: **Christian Singer** (Vienna)

Start of study: **03/2017** (global) **/ 01/2015** (national)

Sample size: **1.800**

Sponsor: **AstraZeneca**

Description and status:

This international clinical study, exploring the efficacy and safety of olaparib, recruited HER2-negative high-risk breast cancer patients with germline *BRCA1/2* mutations. This AstraZeneca sponsored trial reached its global end of recruitment on 28 May 2019. According to the current study protocol, the study will last until appr. Q3 2029. Globally, a total of 1.836 patients were randomized. The initially planned recruitment target of the participating Austrian trial sites was 47 patients and due to the excellent recruitment activity, a total of 53 Austrian patients could be included until the end of enrollment.

The results of the analysis of the primary endpoint (Invasive Disease-Fee Survival, IDFS) were published on 3 June 2021 in the New England Journal of Medicine. The study met the pre-specified criteria for superiority for the primary endpoint and no safety signals of concern were noted. In March 2022, the study sponsor announced the results of the second interim analysis of overall survival (OS), which showed that one year of adjuvant olaparib, relative to placebo, led to statistically significant and clinically meaningful improvement of OS. Data cleaning and patient retention efforts will remain the main challenges in the upcoming year.

ABCSG 42 / PALLAS

PALbociclib CoLlaborative Adjuvant Study: A randomized phase III trial of palbociclib with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy alone for hormone receptor positive (HR+) / human epidermal growth factor receptor 2 (HER2)-negative early breast cancer

Coordinating Investigator: **Michael Gnant** (Vienna)

Start of study:
09/2015 (global)
10/2015 (national)

Sample size:
5.600

Sponsor:
ABCSG (20 countries)
AFT (USA)

Description and status:

The adjuvant early breast cancer study ABCSG 42 / PALLAS is ABCSG's largest trial and a successful cooperation between academic and industry partners. The trial is conducted in 21 countries and ABCSG acts as the legal sponsor for all 20 non-US countries involved. Recruitment was closed in late 2018, enrolling over 5.700 patients worldwide. The second interim analysis of PALLAS showed that the addition of palbociclib to standard endocrine therapy was unlikely to provide benefit to patients (published in Lancet Oncology: Mayer E et al., 2021, DOI: https://doi.org/10.1016/S1470-2045(20)30642-2). Importantly, however, no safety concerns were raised by this analysis.

The event-driven pre-defined trigger for the final analysis was reached in late 2020, with 469 documented invasive Disease-Free Survival (iDFS) events. That analysis was presented prominently in an oral presentation at SABCS 2021 and in a parallel publication in the Journal of Clinical Oncology. Subsequently, the date of awareness for the pre-defined, event-driven stage IIA update analysis was reached in late 2021 and that data set was prominently presented at the virtual ASCO monthly plenary session in October 2022.

Retaining as many active PALLAS patients as possible in the extensive, ongoing follow-up phase until 2028 is the main aim of the current study phase, as well as collecting the 7- and 10-year post-randomization blood samples and recurrence samples in accordance with the protocol. Keeping patients on study ensures patient safety through close long-term disease monitoring and continuously generates valuable data resources, which will be used to address questions aimed at understanding and developing treatment of early breast cancer in the future. The first Trans-PALLAS projects, as part of the ambitious translational program associated with the PALLAS trial, have been completed successfully. For example, RNA sequencing of all available baseline tumor samples is completed, and the generated data is made available for future scientific projects. State-of-the-art ctDNA analyses are underway, as well as DNA sequencing approaches of available biosamples. These projects, once complete, will generate unique data resources available for future analyses. First results of the ctDNA project together with Natera, Inc. were presented at SABCS 2025.

Numerous exploratory clinical and translational research proposals from all over the world were submitted between 2021 and 2025 and endorsed by the PALLAS steering committee. At SABCS 2025, six PALLAS associated posters and rapid oral presentations were included. Furthermore, Mayer et al. published 5-year overall survival data in 2025 in Annals of Oncology (DOI: https://doi.org/10.1016/j.annonc.2025.10.003)

Studies in Treatment Phase and Follow-up

ABCSG 45

A prospective, open, randomized, phase II study of carboplatin / olaparib in the pre-operative treatment of patients with triple-negative primary breast cancer which exhibit the features of positive homologous recombination deficiency (HRD) status

Coordinating Investigator: **Christian Singer** (Vienna)

Start of study:	Sample size:	Sponsor:
11/2019 (national)	**90**	**ABCSG**

Description and status:

ABCSG 45 is an open, randomized phase II study including 90 patients with early triple-negative breast cancer and homologous recombination deficiency (HRD), measured in the tumor tissue prior to treatment start. The participants were randomized 1:1 to either receive neoadjuvant treatment with the PARP inhibitor olaparib, in combination with carboplatin, or a neoadjuvant taxane- / anthracycline-based chemotherapy (TAC), consisting of doxorubicin or epirubicin, docetaxel and cyclophosphamide.

The maximum tolerated olaparib dose, in combination with carboplatin, was identified in an initial dose-finding phase with 20 participants, the first one was enrolled in November 2019. The identified olaparib dose was then administered in the second study phase, where further 70 participants were randomized. In total, 90 study participants were enrolled at 9 Austrian sites until December 2023. The primary study endpoint is the central evaluation of residual cancer burden (RCB) at surgery, to compare the efficacy of 6 cycles of olaparib / carboplatin with 6 cycles of TAC. Pathological complete remission (pCR) is assessed as a secondary endpoint, as well as quality of life, using EORTC questionnaires. The primary study results were presented in an oral rapid presentation at the ASCO conference in May 2025 by Christian Singer (https://ascopubs.org/doi/10.1200/JCO.2025.43.16_suppl.510).

In March 2023, enrollment into an optional sub-study was implemented for participants who had completed the ABCSG 45 main study treatment. In this sub-study, patients received adjuvant olaparib daily for one year. This design was based on the OlympiA study results (Geyer et al., Ann. Oncol., 2022, DOI: https://doi.org/10.1016/j.annonc.2022.09.159), which showed the benefits of one year of adjuvant olaparib treatment. Eight patients participated in the sub-study, the last patient visit took place in September 2025 and further results will be published.

ABCSG 48 / POSITIVE

A study evaluating the pregnancy outcomes and safety of interrupting endocrine therapy for young women with endocrine responsive breast cancer who desire pregnancy (POSITIVE)

Coordinating Investigator: **Vesna Bjelic-Radisic** (Graz/Wuppertal)

Start of study: **12/2014** (global) **/ 04/2018** (national)

Sample size: **500**

Sponsor: **ETOP IBCSG Partners Foundation**

Description and status:

For the first time in a clinical trial setting (and in Austria), it is being examined whether an interruption of endocrine breast cancer therapy is possible, without disadvantages for the patient in order to pursue the wish to become pregnant. The POSITIVE study is led by ETOP IBCSG Partners Foundation with a total of 20 countries involved. Enrollment was completed with 518 patients, seven thereof in Austria at the three participating trial sites.

First results show that the rates of breast cancer recurrence were similar to women who did not interrupt their treatment. With a total of 368 women having at least one pregnancy and 365 babies born (six in Austria), the rates of conception and childbirth were similar to or higher than rates in the general population (Partridge et al., N Engl J Med 2023;388:1645-1656. DOI: 10.1056/NEJMoa2212856). The trial long-term follow-up is planned to confirm long-term safety. Data collected in the trial are of high relevance to all physicians, as they are often confronted with the patients' wish to become pregnant, yet without any evidence-based information for that setting being available so far. In 2025, two publications related to the POSITIVE trial were released. One study, by Peccatori et al. (J Clin Oncol 2025;43(24):2712-2719, https://doi.org/10.1200/JCO-24-02697), demonstrated the feasibility of breastfeeding after breast cancer treatment. Another, by Demeestere et al. (Breast 2025;83:104547, https://doi.org/10.1016/j.breast.2025.104547), focused on a predefined secondary endpoint, assessing the risk of low ovarian reserve and premature ovarian insufficiency by hormone assessment.

ABCSG 49 / POLAR

A phase III open-label, multicenter, randomized trial of adjuvant palbociclib in combination with endocrine therapy versus endocrine therapy alone for patients with hormone receptor positive / HER2-negative resected isolated locoregional recurrence of breast cancer

Coordinating Investigator
Austria: **Gabriel Rinnerthaler** (Graz)

Start of study: **08/2019** (global) **/ 11/2020** (national)

Sample size: **400**

Sponsor: **ETOP IBCSG Partners Foundation**

Description and status:

ABCSG 49 / POLAR is an open, multicenter, randomized phase III trial, examining adjuvant palbociclib combined with endocrine therapy, versus endocrine therapy alone, for patients with HR-positive/HER2-negative resected isolated locoregional recurrence of breast cancer. It is well-established that adjuvant chemotherapy and endocrine therapy can reduce the recurrence of breast cancer in patients with primary breast cancer. However, so far only limited data are available to guide recommendations on the systemic treatment of locoregional recurrence. In view of the documented activity and safety of palbociclib in the first-line treatment of metastatic HR-positive/HER2-negative breast cancer, there is interest in whether the benefits of CDK4/6 inhibition may translate into the adjuvant setting which is the purpose of the POLAR trial.

The trial is sponsored by ETOP IBCSG Partners Foundation and started with "First Patient In" in Switzerland in August 2019. Globally, a total of 51 sites are participating in countries such as Italy, Spain, Switzerland, Hungary, France as well as three sites in Austria. The recruitment phase of the POLAR trial lasted until December 2024 with 405 patients enrolled globally and a total of 22 patients enrolled in Austria.

Studies in Treatment Phase and Follow-up

ABCSG 50 / BRCA-P

A randomized, double-blind, placebo-controlled, multicenter international phase III study to determine the preventive effect of Denosumab on breast cancer in women carrying a *BRCA1* germline mutation

Coordinating Investigator: **Christian Singer** (Vienna)

Start of study: **07/2019** (global and national)

Sample size: **364**

Sponsor: **ABCSG**

Description and status:

The prevention study ABCSG 50 / BRCA-P – which started in July 2019 at the Medical University of Vienna – examines whether the preventive administration of denosumab, a drug currently used and approved to treat osteoporosis, reduces the risk to develop breast cancer. In the experimental arm A, participants receive a subcutaneous injection of 120 mg denosumab every 6 months for a total of 5 years, in the control arm B, women receive a placebo at the same frequency and for the same period of time.

Next to Austria, also Australia, Germany, Israel, Spain, the UK, and the US are involved in this trial. A total of 364 women were randomized into the study until the end of the enrollment phase on 31 December 2024, out of which 65 participants were included at Austrian sites.

The primary endpoint is defined as the occurrence of breast cancer, with other endpoints and research questions, including breast density and bone health, being investigated further as part of a comprehensive translational research program. ABCSG is leading this study globally and is responsible for international coordination, including the management of trial-related systems such as central data management and statistical analyses, study drug management, as well as cooperation with local sponsors.

ABCSG 51 / AURORA

Aiming to understand the molecular aberrations in metastatic breast cancer: The AURORA program

Coordinating Investigator: **Marija Balic** (Graz /Pittsburgh)

Start of study: **09/2014** (global) **/ 12/2018** (national)

Sample size: **2.000**

Sponsor: **BIG**

Description and status:

The ABCSG 51 / AURORA program is dedicated to researching the molecular characteristics of locally recurrent / advanced and metastatic breast cancer not amenable to treatment with curative intent. For this purpose, the tumor and blood samples of participants are assessed for tumor heterogeneity, clonal evolution and transcriptional changes using high-throughput sequencing technologies (NGS). In addition, biomarkers of response and resistance to systemic therapies are evaluated with the help of genomic and transcriptomic data. The first AURORA manuscript was published in June 2021 (Aftimos et al., Cancer Discovery (2021), DOI: https://doi.org/10.1158/2159-8290.CD-20-1647). Recruitment of new participants was closed in February 2021. Until the end of recruitment, 1.160 patients were included globally, of which 18 patients were recruited by two participating Austrian trial sites.

In 2024, a poster was presented at the San Antonio Breast Cancer Symposium on metastatic tumor alterations under anti-cancer therapy (Guerrero-Zotano et al., https://doi.org/10.1158/1538-7445.SABCS23-PS17-04).

ABCSG 56 / SASCIA

Phase III postneoadjuvant study evaluating sacituzumab govitecan, an Antibody Drug Conjugate in primary HER2-negative breast cancer patients with high relapse risk after standard neoadjuvant treatment

Coordinating Investigator: **Christoph Suppan** (Graz)

Start of study: **12/2020** (global) **/ 09/2022** (national)

Sample size: **1.332**

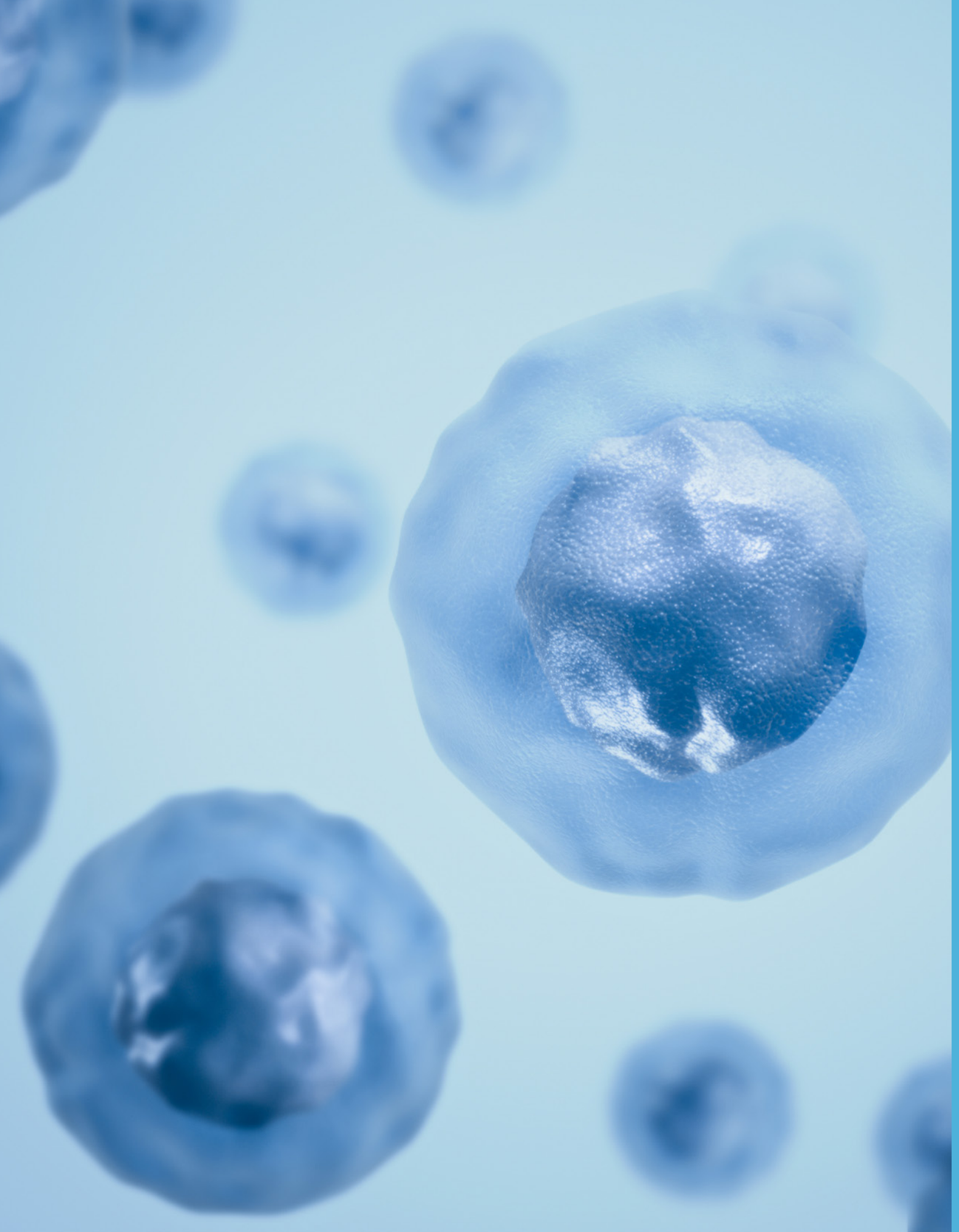
Sponsor: **GBG**

Description and status:

The ABCSG 56 / SASCIA trial is an open, randomized phase III post-neoadjuvant study evaluating sacitu-zumab govitecan in primary HER2-negative breast cancer patients with high relapse risk after standard neoadjuvant treatment. Patients are randomized 1:1 to receive either sacituzumab govitecan or a treatment of physician's choice. The primary study objective is to compare invasive disease-free survival (iDFS) between the treatment arms.

Recruitment was closed in early 2024 as planned, with LPI on 26 January 2024. In total, 1.391 patients were enrolled globally, including 34 patients at 12 sites in Austria. The iDFS interim analysis, originally planned for Q3 2025, was moved to Q1 2025 due to the high number of documented events. In accordance with the IDMC's recommendation, the study continued as planned per protocol. The final iDFS analysis and the OS interim analysis are scheduled for Q1 2027.

Studies in Treatment Phase and Follow-up



Translational Projects and upcoming Studies

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Translational Research Projects

Translational research (TR) studies, which aim at developing, testing, and validating new biomarkers, tumor signatures or assays, are increasingly gaining significance within modern oncology. These studies are often the basis for novel diagnostic tools and thereby for targeted and personalized therapies, which are becoming more common in clinical trials and daily clinical practice. ABCSG is involved in – and operationally conducts – numerous translational research projects and collaborations as the extensive collection of biosamples and data from former ABCSG trials is a valuable resource for such projects.

The **TraX&Yields collaboration with Cepheid** to validate tumor marker assays is one of ABCSG's largest endeavors, as it includes work packages for multiple former ABCSG trial patient cohorts.

The Trax&Vields-05 project (ABCSG 34 cohort), including the collection of clinical follow-up data and sample analysis, was completed in 2023. The scientific publication describing this work was published in *The Breast* in 2025 https://doi.org/10.1016/j.breast.2025.104633

The TraX-&Vields-02 work package (ABCSG 8 cohort) aiming to validate the STRAT4 and Breast Cancer Insight tests was also completed. Additionally, the lab work and analysis of the sub-project (TraX&Vields-07) in the ABCSG 6 cohort, validating the prognostic breast cancer Insight signature, was completed.

In the work package concerning the ABCSG 12 cohort, the collection of clinical follow-up data and sample centralization remains ongoing with the aim to generate a comprehensive extended follow-up database and archival tumor sample collection in the ABCSG central research facility in Vienna. Per end of 2025, 20 sites were actively contacting and reconsenting former ABCSG 12 study patients, for whom archived tumor material is still available to be centralized. Documented data and samples were available for more than 500 patients at that time.

The **ABCSG TR ProCan** collaboration is an analysis of protein expression to develop a proteomic signature of distant recurrence in HR-positive early breast cancer. The Children's Medical Research Institute (CMRI) in Sydney Australia, is the trial sponsor who approached ABCSG to support this interesting endeavor. HE-stained tumor tissue slides from the ABCSG 6 trial cohort, and afterwards also the ABCSG 8 trial patients, were facilitated for this project. The results of all analyses have been evaluated, with some subprojects emerging from the main question as well, so results will be published in 2026.

ABCSG TR Artera is a digital imaging project in cooperation with the US based company Artera to develop a breast cancer signature, based on HE-stained tumor tissue slides, via artificial intelligence methods that integrate machine learning algorithms. Digitized HE-slides and clinical data of ABCSG 6 were used for model optimization and digitized HE-slides and clinical data of ABCSG 8 were used for model validation. The final model – which additionally to the ABCSG trial cohorts includes WSG's ADAPT and PlanB as well as NSABP B14, B20, B34 and B42 study data – was locked in 2025 and initial results were presented in ASCO 2025 as well as SABCS 2025. Full manuscripts are expected to be published soon.

ABCSG TR Ataraxis is a digital imaging project in cooperation with the US based company Ataraxis AI to validate a prognostic and predictive foundation model-based AI test in breast cancer. Digitized HE-slides and clinical data of ABCSG 6 and ABCSG 8 are planned to be used. The full EC approval for this IVDR project has been granted in June 2025 and analyses are under way.

Outlook and planned Studies 2026

Among several international clinical trials, ABCSG-initiated and academically sponsored studies as well as translational research collaborations, the following are planned to launch in 2026.

Interventional Breast Cancer Studies

ABCSG 64 / neoGRACE
ABCSG 64 / neoGrace is an open-label, two-arm, randomized phase II study evaluating sacituzumab govitecan vs. standard of care as neoadjuvant therapy for patients with ER-positive/HER2-negative early breast cancer. Whereas ABCSG 61 / TEODOR and ABCSG 63 / ERIKA target patients from that breast cancer cohort that are endocrine responsive (measured by Ki-67 after neoadjuvant induction treatment), ABCSG 64 / neoGRACE will include those patients who are not considered endocrine responsive after that initial therapy. Those with a Ki-67 value above the defined threshold will be randomized to either receive sacituzumab govitecan or standard of care and the neoadjuvant therapy of approximately 24 weeks will be followed by surgery. It is furthermore planned to include prospective follow-up data collection along with longitudinal biosampling to assess relevant research questions in this cohort. The study is sponsored by ABCSG and aims to enroll 80 patients across 8 sites in Austria.

ABCSG 66 / ADAPTela
ABCSG 66 / ADAPTela is a WSG-sponsored, adjuvant, open-label, interventional Phase III clinical trial for a high-risk HR-positive/HER2-negative early breast cancer patient population, comparing elacestrant with standard of care endocrine treatment (both arms with or without ribociclib). The genomic *Oncotype DX®* test is used to determine a specific genomic profile of patients, making it a personalized therapeutic approach to predict treatment benefits in HR-positive/HER2-negative early breast cancer.

The trial will include patients from Spain, Germany and Austria, with 1.520 planned participants in total, an enrollment period of 30 months and a treatment time of 5-7 years. Study start is expected for Q1 2026.

Translational Research

AI-collaboration with Spotlight Medical
This upcoming collaboration focuses on the validation of an AI-based prognostic assay by Spotlight Medical S.A.S in ER-positive/HER2-negative breast cancer. To this aim, H&E sections from patients enrolled in the ABCSG 8 study will be digitized and the AI-based assay predicts risk of distant recurrence, to classify patients into three risk groups (low/intermediate/high) by integrating baseline clinical data and image-derived features.

Rectal Cancer

ABCSG R07 Rectal Cancer Non-Interventional Study
ABCSG R07 is a non-interventional study for participants with locally advanced adenocarcinoma of the rectum, treated with total neoadjuvant therapy (TNT) or dMMR/MSI-H disease.

This study is sponsored by ABCSG and aims to enroll 600 participants (300 retrospective, 300 prospective) across 6 sites in Austria to evaluate disease response to standard therapies, inform about available modern treatment standards and guide further research in the TNT setting.

ABCSG Events and Activities

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ABCSG Events and Activities

In addition to conducting clinical trials and publishing scientific results, the ABCSG places a strong emphasis on medical education in Austria and around the world. In 2025, we organized nine continuing medical education (CME)-accredited educational programs that addressed current developments and emerging concepts in cancer diagnostics and treatment.

Once again, our in-person events provided an important forum for direct exchange, bringing colleagues from across Austria together to discuss clinical practice, research, and future perspectives. Meanwhile, ABCSG's digital and hybrid formats further established them as an international hub for medical professionals, enabling participation from around the world.

This growing national and international engagement highlights ABCSG's commitment to providing high-quality medical education and knowledge in the field of oncology. The following pages present selected educational formats and collaborative initiatives led by ABCSG.

On-site Events & Activities

12. POST-SABCS

12th Post-SABCS (Vienna)

On January 10th, 2025, ABCSG once again presented and discussed the latest study results from the San Antonio Breast Cancer Symposium (SABCS) for an audience in Austria. The 12th Post-SABCS attracted 170 participants, marking another increase in attendance and underlining the continued relevance of this established educational format.

The program provided a structured and practice-oriented overview of the most recent data in breast cancer research and care. The lectures included advances in systemic therapies, surgery, radiotherapy, pathology, and imaging, as well as the growing role of digital tools and artificial intelligence in oncology. A new interactive element further enhanced audience engagement: for each lecture, participants were invited to respond to pre-specified questions via live polling, enabling immediate feedback and supporting focused discussion and knowledge exchange. Each topic area concluded with an interdisciplinary expert panel, in which the presented data were critically discussed and placed into clinical context.

SGBCC 2025

19th St. Gallen International Breast Cancer Conference (Vienna)

From March 12th-15th, 2025, the 19th St. Gallen International Breast Cancer Conference (SGBCC 2025) once again attracted approximately 3,200 participants from over 100 countries to Vienna, making it a key international meeting point for early breast cancer research. As cooperating partner and host, ABCSG contributed to the conference's scientific success, confirming Austria's established role as a global hub for breast cancer expertise.

As in previous years, a defining element of the conference was the St. Gallen Consensus Session on the final day, which is often referred to as the "largest tumor board in the world." More than 80 international panelists, including experts from Austria and the ABCSG network, participated in the consensus voting. The 2025 panel was notable for its high proportion of newly appointed members and, for the first time, a female majority, reflecting ongoing progress in diversity and international collaboration. The results of the consensus process were subsequently condensed by the St. Gallen Scientific Committee and published as the 2025 St. Gallen International Breast Cancer Consensus Statement in Annals of Oncology (DOI: 10.1016/j.annonc.2025.09.007), providing globally relevant guidance for clinical decision-making in early breast cancer.

Post St. Gallen "Data – Facts: Consequences?" (Vienna)

Traditionally held around two weeks after the St. Gallen International Breast Cancer Conference, the ABCSG symposium "Daten – Fakten: Konsequenzen?" took place in Vienna on March 29th, 2025. Under Günther Steger's scientific leadership, the meeting provided a structured review of the St. Gallen Consensus results and attracted a record-breaking 95 participants.

Our expert rapporteurs presented the outcomes of the consensus voting and placed them in their respective clinical and scientific contexts. The key disciplines included pathology, molecular biology, surgery, radiotherapy, and systemic treatment approaches. The symposium concluded with an interdisciplinary discussion that focused on the practical consequences of the consensus recommendations.

DATEN-FAKTEN: KONSEQUENZEN?

Breast Cancer: Science and Cases (Pörtschach)

The educational format, "Breast Cancer: Science and Cases", was held on May 22nd, 2025, once again in Pörtschach, following the positive experience at this location the previous year. Gregor Huber led the scientific program, and Michael Gnant, the president of ABCSG, co-moderated the meeting.

A total of 45 participants from medical oncology, surgery, radiotherapy, and general practice took part in this highly interactive, interdisciplinary format. Working in small, cross-institutional groups, participants discussed five real-life clinical cases, aiming to reach a joint treatment decision. The subsequent presentation of group conclusions in the plenary session enabled in-depth discussion and comparison with the therapies ultimately implemented in clinical practice.

abcsg in touch (Graz)

On June 23rd, 2025, the educational program "abcsg in touch" was held for the first time in Graz. Led by Stephanie Kacerovsky-Strobl, head of the ABCSG Task Force "Future Now," the event offered early-career medical professionals an interactive, practice-oriented forum to discuss current issues related to germline mutations.

Participants engaged with two complex clinical cases and used live polling to facilitate real-time discussion. The case presentations focused on diagnostic approaches, the implications of genetic testing for therapy decisions and family planning, and management strategies for hereditary breast cancer. This included considerations for systemic treatment in neoadjuvant, adjuvant, and metastatic settings.

An expert panel provided further critical analysis of the cases and their practical implications.

19th Interdisciplinary Mamma Discourse (Vienna)

Traditionally held at the beginning of Breast Cancer Awareness Month and in collaboration with the Austrian Society for Senology, the 19th Interdisciplinary Mamma Diskurs took place on October 1st, 2025, at Palais Berg in Vienna. The program began with an off-topic geopolitical keynote address by Brigadier (Ret.) Professor Walter Feichtinger, followed by medical sessions led by ABCSG President Michael Gnant and Günther Steger.

The first medical block focused on surgical strategies, including the timing of autologous breast reconstruction in relation to radiotherapy, and featured critical discussions of treatment options spanning breast-conserving therapy, mastectomy, reconstruction, and radiotherapy.

The second block addressed systemic therapy and covered new options in neoadjuvant treatment, the potential use of CDK4/6 inhibitors in luminal breast cancer, strategies for escalation and de-escalation in triple-negative disease, and emerging endocrine therapies. Panel discussions encouraged interdisciplinary dialogue and critical reflection on the clinical implications of the presented data.

24th NIFA – New Impulses in Education and Training (Vienna)

From October 10th–11th, 2025, the 24th edition of NIFA conference, organized by AstraZeneca in collaboration with ABCSG, convened a record 139 participants from across Austria to discuss the latest developments in breast cancer diagnosis and treatment. The scientific program included nine lectures, five interdisciplinary discussion rounds, and interactive case presentations, offerings participants practical, evidence-based knowledge.

Friday evening was traditionally dedicated to off-topic themes. The evening began with a keynote by Andreas Jäger on "Facts Instead of Fake News: Climate Change as an Opportunity?" followed by a special session, "Women in Focus," which highlighted the role of women in medicine and science.

On Saturday, the focus was on scientific updates, covering local and systemic therapies, as well as recaps of the NIFA Workouts 4.1 (Spring Awakening of Endocrine Therapy) and 4.2 (High Season of ADCs). The event concluded with Oxford-style debates, a highlight in which six participants engaged in lively discussion of controversial oncology topics, including a showdown of previous winners.

34th ABCSG Annual Meeting (Saalfelden)

The 34th Annual Meeting of the ABCSG took place from November 7th–8th, 2025, in Saalfelden under the moderation of ABCSG President Michael Gnant. Gabriel Rinnerthaler, head of the program planning committee, guided the scientific content, which attracted around 240 participants to Saalfelden.

Sessions covered local therapy, systemic treatment, radiotherapy, and translational research, with discussions leading to practical recommendations. A panel on de-escalation in the interdisciplinary setting highlighted the balance between over- and undertreatment, while tumor board case presentations illustrated the integration of research findings into clinical practice. Other sessions focused on study conduct, including patient retention, follow-up, and the integration of laboratory and translational research, emphasizing the importance of long-term data and sample collection. Special attention was also given to communication in clinical care, including interactions between physicians, study nurses, and patients.

The meeting concluded with a summary of key takeaways, reinforcing interdisciplinary collaboration and inspiring future projects within the ABCSG network.

EXPERTS ON TOUR®

Experts on Tour® 2025 (Wiener Neustadt)

On November 20th, 2025, ABCSG continued its commitment to advancing breast cancer education with the "Experts on Tour®" event in Wiener Neustadt. The program was held under the scientific leadership of Birgit Grünberger and co-moderated by ABCSG President Michael Gnant.

The well-attended audience engaged in a dense, interdisciplinary scientific program and practice-oriented agenda, with experts presenting the role of breast health centers, molecular characterization in breast cancer, de-escalation strategies in the perioperative setting, axillary management, medication interactions, and the contribution of the breast care nurse to patient care.

The evening concluded with an interactive panel discussion supported by live polling to engage the audience and a summary of the event's key takeaways.

Online Education Formats

Science News by ABCSG-Expert Günther Steger

With the Science News format, ABCSG provides its research network with compact video summaries of the most significant findings from the major international (breast) cancer congresses. The concise recaps are shared with our members through the ABCSG newsletter and made available for download on the ABCSG website shortly after each conference.

In 2025, Science News covered key insights from SGBCC, ESMO Breast, ASCO, ESMO and SABCS. The format continues to be well-received with over 3,000 views per year, reflecting strong interest in timely, practice-relevant scientific updates.

Surgery News by ABCSG-Expert Florian Fitzal

Since its launch in 2024, the Surgery News video format has quickly become a well-established component of ABCSG's online educational portfolio. Designed for surgeons, plastic surgeons, allied health professionals, and clinical investigators, Surgery News offers concise, accessible summaries of key scientific developments in breast cancer surgery, reconstructive procedures, and local therapies from major international conferences.

In 2025, two editions of Surgery News were released, focusing on surgical highlights from SGBCC and SABCS. The strong response and high viewership numbers, with over 1,000 clicks in 2025, underscore the relevance and value of this targeted format for keeping up with advances in breast cancer surgery.

Webinar: CDK4/6 Inhibition in Early and Advanced Breast Cancer

On October 29th, 2025, ABCSG hosted an international webinar on CDK4/6 inhibition in early and advanced breast cancer, moderated by ABCSG President Michael Gnant. The online educational event attracted more than 100 participants from 12 countries.

Part 1 focused on the use of CDK4/6 inhibitors in metastatic hormone receptor-positive breast cancer and featured two debate-style presentations, addressing the question of whether or not CDK4/6 inhibitors should remain the backbone of treatment for as long as possible.

Part 2 centered on the adjuvant use of CDK4/6 inhibitors and the latest clinical trial data, including updates from the NATALEE and monarchE trials.

The webinar concluded with a panel discussion on updated evidence, ongoing controversies, and clinical implications for everyday practice. ABCSG is proud that this independent academic project was supported by two competing industry partners in this particular field, Lilly and Novartis, highlighting a shared commitment to advancing breast cancer care.

NIFA Workout 4.1

Endocrine Therapy in HR+/HER2- Breast Cancer – For Whom, How Long, and in Which Combinations?

The first NIFA Workout of 2025, organized by AstraZeneca with ABCSG support and coached by Gabriel Rinnerthaler, focused on key clinical questions in endocrine therapy for HR-positive/HER2-negative breast cancer.

The program covered key topics, including the mechanisms of endocrine resistance, the clinical implications of axillary de-escalation, and combination strategies and sequencing in metastatic disease. Three expert lectures were followed by a roundtable discussion. All content was made available as on-demand videos for flexible access by healthcare professionals.

NIFA Workout 4.2

Antibody–Drug Conjugates (ADCs) – Current Trends and Future Directions

The second NIFA Workout of 2025, organized by AstraZeneca with ABCSG support and coached by Maximilian Marhold, focused on antibody-drug conjugates (ADCs) in the treatment of metastatic breast cancer.

The program covered important topics, such as treatment algorithms for ADCs, key clinical and nursing considerations for patients undergoing ADC therapy, and updates on HER2 testing. Three expert lectures were followed by a roundtable discussion. All content was made available as on-demand videos for flexible access by healthcare professionals.

ABCSG Websites and Digital Presence

The ABCSG website, **www.abcsg.org**, continues to serve as the central information hub for healthcare professionals, providing an overview of all ongoing ABCSG trials, scientific publications, news and updates, as well as event announcements and online registration for our educational activities.

In 2025, the website was further enhanced by the introduction of the new section **"Clinical Opinions"** developed under the scientific leadership of Gabriel Rinnerthaler. This expert-driven format addresses the growing need for guidance in areas where clinical evidence is rapidly evolving and formally published consensus guidelines may lag behind, offering well-founded perspectives on practice-relevant and sometimes controversial topics. The first article covers the omission of sentinel node biopsy in breast cancer care.

The patient information platform **brustkrebsexperten.at** was completely redesigned and relaunched in 2025. Now titled "Information for Cancer Patients," it is fully integrated into the ABCSG website and accessible via www.abcsg.org, as well as directly at **https://www.abcsg.org/fuer-patientinnen-und-patienten/**. The platform provides evidence-based information for cancer patients, including an overview of our ongoing clinical trials, helpful questions to support medical consultations, patient guides and brochures available for order, as well as a glossary explaining frequently used medical terms in lay language.

The website **http://www.studynurses.at**, which is dedicated to study nurses and coordinators, has been expanded to include the Forum Breast Care Nurses. This addition is intended to further promote professional networking and future activities within these important groups.

ABCSG Websites

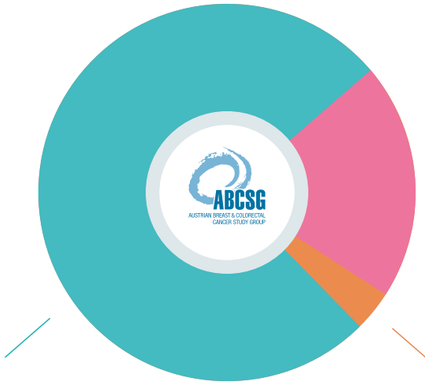
Visitor Statistics 01. Jan. – 31. Dec. 2025

Visitors 77.108
Pageviews 173.713

brustkrebsexperten.at*
Visitors 15.809
Pageviews 28.184

*Fully integrated into the ABCSG website and accessible via **www.abcsg.org**. Now titled *"Information for Cancer Patients"*

abcsg.org
Visitors 58.801
Pageviews 140.090



studynurses.at
Visitors 2.498
Pageviews 5.439

„SCIENCE FROM THE HEART OF EUROPE"

Public Relations and Press

2025 was an exceptionally successful year for the ABCSG, marking the most extensive scientific output in the Group's history. With 30 scientific publications, ABCSG research achieved remarkable visibility in leading international journals. Among these, the ABCSG 52 / ATHENE study "Neoadjuvant atezolizumab in combination with dual HER2 blockade plus epirubicin in women with early HER2-positive breast cancer" (Rinnerthaler et al.), published in Nature Cancer, stands out as a particular milestone.

In addition to peer-reviewed journals, ABCSG's work received outstanding coverage in popular science and medical media, with a total of 99 contributions in 2025. JATROS Hämatologie & Onkologie reported extensively on ABCSG's post-SABCS educational event, while krebs:hilfe! magazine provided a comprehensive summary on St. Gallen 2025 under the headline "Science with Impact", including an interview with ABCSG President Michael Gnant, followed by coverage of the Interdisciplinary Mamma Discourse.

Since its inception, ABCSG has been very pleased to contribute to Dialog Darm, including the article by Lukas Weiss on "Aspirin® in PIK3CA-mutated colorectal cancer", reflecting the importance of providing patients with accessible, high-quality information.

In addition, ABCSG President Michael Gnant published a leading editorial entitled "The future of surgical research" in the British Journal of Surgery (Oxford University Press, June 2025), contributing to the international discussion on the direction of academic surgical research. ABCSG research was also featured in the BIG Research in Focus newsletter (April 2025), highlighting the development of AI-based prognostic tests for breast cancer led by the ABCSG.

High-impact scientific publications, media presence, and targeted communication formats facilitated the transfer of clinically relevant cancer research to the medical community and the wider public.

Trial Office Activities

Clinical Monitors Meeting

From May 6th–8th, 2025, ABCSG's Clinical Monitoring Department convened for its annual meeting in Nussdorf am Attersee. Together with ABCSG's Managing Director, Associate Directors, and the Head of Clinical Data Management, the team reviewed the status of ongoing and planned clinical trials, discussed cross-departmental topics, and addressed current and future challenges in clinical research monitoring. The meeting concluded with a team-building "Team Trophy" activity, combining light physical challenges and quiz elements, which fostered collaboration and strengthened team spirit across departments.

Company Outing 2025

In response to numerous requests from team members, the ABCSG company outing 2025 took place in Vienna at the Filmquartier, a venue combining a touch of Hollywood flair with an urban green oasis, featuring a historic brick building and a leafy inner courtyard.

The day began with a relaxed breakfast, followed by an engaging lecture on fire safety and fire extinguishing, including a hands-on practical exercise that provided valuable insights into emergency preparedness. Afterwards, the team enjoyed a barbecue lunch, creating space for nice chats across departments. The afternoon was dedicated to the team-building activity "Crescendo – Teambuilding with Violins". Guided by professional instructors, we learned the basics of violin playing and even rehearsed the Danube Waltz. While the musical results were more enthusiastic than perfect, the experience proved highly entertaining and strengthened team spirit through shared creativity and humor.

Cancer Research Run 2025 – Together We Go Further

On October 4th, 2025, a highly motivated ABCSG team participated in the 19th Cancer Research Run organized by the Medical University of Vienna.

Under beautiful autumn weather, our runners completed lap after lap in support of a shared goal: advancing cancer research.

In addition, despite wintry temperatures, ABCSG was represented at the Vienna City Marathon with three relay teams, and our enthusiastic runners took part in the Vienna Night Run once again.

The dedication and team spirit of our trial office team exemplify ABCSG's commitment to making research visible to society, not only in clinical trials, but also beyond them. Together, we strive for more knowledge, progress, and hope.

ABCSG Team Meeting & Holiday Celebration 2025

The 2025 ABCSG Team Meeting and Holiday Celebration was held at the Cobenzl, a venue known for its panoramic views of Vienna.

As is customary, the afternoon was dedicated to an internal working meeting with all departments. The program began with a report from the Managing Director Hannes Fohler reviewing the past year, followed by study updates presented by the project managers, providing a focused and informative exchange across teams. The session concluded with the annual IT security training.

Long-standing ABCSG colleagues were traditionally honored by ABCSG President Michael Gnant, followed by a festive dinner and a cheerful end to the evening with music and dancing.

"Driven by Many. United by Purpose."

„SCIENCE FROM THE HEART OF EUROPE"
ABCSG AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

Publications 2025 and Study Overview

„SCIENCE FROM THE HEART OF EUROPE"

ABCSG
AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

Publications 2025

HER2/CEP17 ratio is associated with pCR after HER2-directed neoadjuvant treatment in the phase III NeoALTTO trial

Singer CF, Koenig F, Kacerovsky-Strobl S, Danzinger S, Brunner C, Suppan C, Deutschmann C, Balic M, Greil R, Egle D, de Azambuja E, Di Cosimo S, Choudhury A, Gnant M

The Breast – published on 22 December 2025

40P Use of an artificial intelligence model to predict Ki67 from H&E-stained whole slides images in breast cancer

Kates-Harbeck D, Filipits M, Kreipe HH, Hlauschek D, Christgen M, Rinnerthaler G, Gluz O, Gampenrieder S, Mahner S, Haider K, Hulla W, Kates R, Zhang J, Piehler A, Pinckaers H, Smit G, Griffin J, Harbeck N, Gnant M

ESMO Real World Data and Digital Oncology – published November 2025

40P An artificial intelligence model predicts Ki67 from H&E-stained whole slide images in breast cancer

Kates Harbeck D, Filipits M, Hlauschek D, Rinnerthaler R, Gampenrieder SP, Haider K, Hulla WH, Kates RE, Kreipe H, Christgen M, Gluz O, Mahner S, Zhang J, Pinckaers H, Smit G, Piehler A, Griffin JR, Harbeck N, Gnant MI

ESMO Real World Data and Digital Oncology – published November 2025

ESR1, PGR, ERBB2, and MKi67 mRNA expression in diagnostic core biopsies from breast cancer patients of the ABCSG Trial 34

Kacerovsky-Strobl S, Deutschmann C, Hlauschek D, Bago-Horvath Z, Singer CF, Bartsch R, Greil R, Sotlar K, Rinnerthaler G, Petru E, Lax SF, Egle D, Pichler A, Bodó K, Petzer AL, Moinfar F, Weidler J, Bates M, Dubsky P, Gnant M, Filipits M.

The Breast – published on 30 October 2025

Palbociclib with adjuvant endocrine therapy in early breast cancer: 5-year follow-up analysis of the global multicenter, open-label, randomized phase III PALLAS trial (ABCSG-42/AFT-05/PrE0109/BIG-14-13)

Mayer EL, Hlauschek D, Gnant M, O'Brien PJ, Bellet-Ezquerra M, Goetz MP, Ruiz-Borrego M, Chan A, Clifton K, Egle D, Lake D, Cabrera P, Mamounas T, Pristauz-Telsnigg G, Dayao Z, Gil Gil M, Cameron D, Traina T, Morris PG, Sabanathan D, Rinnerthaler G, Meisel J, Prat A, Wolff AC, Tseng LM, Isaacs C, Singer CF, Rubovszky G, Foukakis T, Jassem J, Winer EP, Vetter M, Federmann J, Metzger O, Schurmans C, Gauthier E, Lu DR, Fesl C, Dueck A, DeMichele A

ESMO Annals of Oncology– published on 17 October 2025

A core outcome set for locoregional treatment reporting in neoadjuvant systemic breast cancer treatment trials

Potter S, Avery K, Ahmed R, De Boniface J, Chatterjee S, Dodwell D, Dubsky P, Federmann JJ, Finestone S, Gnant M, Hlauschek D, Iwata H, MJiang MY, Kaidar-Person O, Lee HB, Mackenzie M, Meyn A, Poortmans P, Poulakaki F, Richardson A, Sepulveda K, Spillane A, Thompson A, Werutsky G, Wittmann P, Wright JL, Zdenkowski N, Cowan K, McIntosh S

BMJ – published on 17 October 2025

Surgical outcome parameters in breast cancer: A survey comparing oncoplastic and non-oncoplastic surgeons as well as certified with non-certified breast health centers

Wimmer K, Gordon K, Emmanuel K, Steger G, Gnant M, Weber WP, Fitzal F

Breast Care Published online: 3 October 2025

Prevalence and prognosis of patients with breast cancer eligible for adjuvant abemaciclib or ribociclib: a nationwide population-based study

Liu X, Binicy B, Acs B, Eriksson Bergman L, Loibl S, Gnant M, Untch M, Valachis A, Bergh J, Hartman J, Foukakis T, Matikas A

The Lancet - Region Health Europe – published on 29. September 2025

New perspectives in the management of triple-negative breast cancer

Bartsch R, Bago-Horvath Z, Egle D, Gampenrieder SP, Grünberger B, Heibl S, Marhold M, Preuss C, Rinnerthaler G, Strasser-Weippl K, Suppan C, Singer CF, Gnant M

Breast Care – published on 15 August 2025

Extending the duration of endocrine treatment for early breast cancer: patient-level meta-analysis of 12 randomised trials of aromatase inhibitors in 22 031 postmenopausal women already treated with at least 5 years of endocrine therapy

Early Breast Cancer Trialists' Collaborative Group

Lancet - published on 09 August 2025

Hormonal factors predictive of fertility in patients with breast cancer interrupting adjuvant endocrine therapy to attempt pregnancy in POSITIVE trial

Demeestere I, Niman SM, Partridge AH, Diego DS, Kammler R, Ruggeri M, Colleoni M, Shimizu C, Saura C, Gelmon KA, Saetersdal AB, Kroep JR, Mailliez A, Amant F, Ruız-Borrego M, Lee JE, Kataoka A, Walshe JM, Takei J, Borstnar S, Borges VF, Saunders C, SusnjarS, Bjelic-Radisic V, Cardoso F, Meisel JL, Kawwass JF, Spanic T, El-Abed S, Piccart M, Korde LA, Goldhirsch A, Gelber RD, Pagani O, Azim HA Jr., Peccatori FA, for the International Breast Cancer Study Group and the POSITIVE Trial Collaborators

The Breast - published online on 26 July 2025

Genomic profiling of primary tumor and lymph node metastasis in patients with clinically node-positive breast cancer: Prospective cohort study within TAXIS (OPBC-03, SAKK 23/16, IBCSG 57-18, ABCSG-53, GBG 101)

Knauer M, Egle D, Hayoz S, Sávolt A, Tausch C, Bucher S, Simonson C, Ratler R, Heil J, Bekes I, Bjelic-Radisic V, Audeh W, Lam GT, Menicucci A, Muenst S, Ostapenko V, Kurzeder C, Heidinger M, Weber WP

European Journal of Cancer - published on 25 July 2025

Breastfeeding After Hormone Receptor–Positive Breast Cancer: Results From the POSITIVE Trial

Peccatori FA, Niman SM, Partridge AH, Ruggeri M, Colleoni M, Saura C, Shimizu C, Satersdal AB, Kroep JR, Gelmon K, Amant F, Mailliez A, Moore HCF, Ruiz-Borrego M, Walshe JM, Borges VF, Gombos A, Kataoka A, Rousset-Jablonski C, Borstnar S, Takei J, Lee JE, Saunders C, Bjelic-Radisic V, Susnjar S, Cardoso F, Klar NJ, Ferreiro T, El-Abed S, Piccart M, Korde LA, Goldhirsch A, Gelber RD, Pagani O, Azim HA Jr, for the International Breast Cancer Study Group and the POSITIVE Trial Collaborators

J Clin Oncol - published 9. July 2025

The impact of analysis methodology details on invasive breast cancer-free survival in randomized clinical trials

Hlauschek D, Fesl C, Gnant M

ESMO Open - published on 07 July 2025

Abstract P2-01-24: Immune activation of tumor cells and microenvironment as assessed by PD-L1 expression and interferon gamma signaling predict long term disease-free and overall survival: Results of the prospective randomized neoadjuvant ABCSG 34 trial

Heber U, Hlauschek H, Singer CF, Egle D, Greil R, Helfgott R, Huber G, Müller-Holzner E, Hauser-Kronberger C, Rudas M, Pfeiler G, Bartsch R, Lax S, Filipits M, Rinnerthaler G, Gnant M, Bago-Horvath Z

Clinical Cancer Research, published on 13 June 2025

Abstract PS3-03: Vaccination with MUC-1-targeting tecemotide improves Survival of patients receiving neo-adjuvant chemotherapy for early breast cancer: Results from the Prospective Randomized ABCSG 34 Trial

Singer CF, Hlauschek D, Pfeiler G, Egle D, Bartsch R, Suppan C, Pichler A, Petru E, Greil R, Rudas M, Seifert M, Huber G, Petzer A, Fitzal F, Bago-Horvath Z, Filipits M, Soelkner L, Fesl C, Gnant M

Clinical Cancer Research, published on 13 June 2025

Abstract P2-03-30: Association of ctDNA in patients with long-term outcome of breast cancer patients undergoing neoadjuvant treatment in the randomized ABCSG 34 clinical trial

Egle D, Hlauschek D, Gampenrieder S, Rinnerthaler G, Singer CF, Pfeiler G, Bartsch R, Huber G, Pichler A, Petru E, Bago-Horvath Z, Kermanidis A, Fesl C, Graf R, Weber S, Dandachi N, Filipits M, Gnant M, Heitzer E, Balic M

Clinical Cancer Research, published on 13 June 2025

Abstract P4-01-26: The Xpert® Breast Cancer Insight test predicts distant recurrence and overall survival in estrogen receptor-positive, HER2-negative early breast cancer: A validation study in ABCSG Trial 8

Filipits M, Gruber V, Singer CF, Fitzal F, Bago-Horvath Z, Greil R, Balic M, Regitnig P, Toro-Bauer N, Hulla W, Egle D, Lizarraga D, Baker A, Kaldate R, Satva M, Weidler J, Bates M, Campbell S, Hlauschek D, Dubsky P, Gnant M

Clinical Cancer Research, published on 13 June 2025

The future of surgical research

Gnant M

British Journal of Surgery, published on 06 June 2025

Quality-of-life and symptom severity in the PALLAS randomized trial of palbociclib with adjuvant endocrine therapy in early breast cancer (AFT-05, ABCSG-42, BIG-14-03, PrE0109)

Naughton MJ, Zahrieh DM, Gnant M, Zdenkowski N, Lemieux J, Mao JJ, Bjelic-Radisic V, Shinn E, Balic M, Thomssen C, Meisel JL, Ruiz GM, Loibl S, Isaacs C, Cameron D, Henao-Carrasco FM, Goetz MP, Singer CF, Werutsky G, Rugo HS, Vetter M, Tseng LM, Miller K, Fitzal F, Gil Gil JM, Park H, Linderholm B, Bajetta E, Dayao Z, Prat A, Ehrhardt K, Metzger O, Arahmani A, Law EH, Partridge AH, Carey LA, Zoroufy A, Dueck AC, O'Brien P, Hlauschek D, DeMichele A, Mayer EL

ESMO Open - published on 04 June 2025

St. Gallen/Vienna 2025 Summary of Key messages on therapy in Early Breast Cancer from the 2025 St. Gallen International Breast Cancer Conference (SGBCC)

Ditsch N, Gnant M, Thomssen C, Harbeck N

Breast Care - published on 03 May 2025

Impact of adding palbociclib on treatment adherence to ongoing adjuvant endocrine treatment in the global randomized PALLAS randomized trial in patients with early breast cancer

Shinn E, Zahrieh D, DeMichele A, Zdenkowski N, Lemieux J, Mao J, Bjelic-Radisic V, Naughton MJ, Pfeiler G, Gelmon K, Balko JM, Egle D, Zoppoli G, Traina T, Jimenez MM, Novoa SA, Haddad T, Chan A, Ring A, Wolff A, Symmans WF, Ponce Lorenzo J, Sabanathan D, Burstein HJ, Nowecki ZI, Pristauz-Telsnigg G, Brufsky A, Bellet-Ezquerra M, Foukakis T, Novik Y, Rubovszky G, Singer CF, Muehlbacher K, Filho OM, Goulioti T, Law E, Partridge AH, Carey LA, Zoroufy A, Hlauschek D, Fesl C, Mayer EL, Gnant M

Breast Cancer Research - published on 27 March 2025

Augmenting Insufficiently Accruing Oncology Clinical Trials Using Generative Models: Validation Study

El-Kababji S, Mitsakakis N, Jonker E, Beltran-Bless AA, Pond G, Vandermeer L, Radhakrishnan D, Mosquera L, Paterson A, Shepherd L, Chen B, Barlow W, Gralow J, Savard MF, Fesl C, Hlauschek D, Balic M, Rinnerthaler G, Greil R, Gnant M, Clemons M, El Emam K

Journal of Medical Internet Research - published on 05 March 2025

CAMBRIA-1 & CAMBRIA-2 phase III trials: camizestrant versus standard endocrine therapy in ER+/HER2- early breast cancer

Hamilton EP, Loibl S, Bachelot T, Gnant M, Niikura N, Park YH, Tolaney SM, Pistilli B, Rastogi P, Saini KS, Gioni I, Johnston S, Nunes R, Quintana A, Stuart M, Syta E, Walding A, Klinowska T, Mayer IA

Future Oncology - published on 27 February 2025

Validation of the CTS5 in four prospective, multicenter, randomized ABCSG trials

Wimmer K, Hlauschek D, Balic M, Pfeiler G, Greil R, Singer CF, Halper S, Steger G, Suppan C, Gampenrieder SP, Helfgott R, Egle D, Filipits M, Jakesz R, Sölkner L, Fesl C, Gnant M, Fitzal F; Austrian Breast & Colorectal Cancer Study Group

The Breast - published on 19 February 2025

Outcomes in stage IIA versus stage IIB/III in the PALLAS trial [ABCSG-42/AFT-05/PrE0109/BIG-14-13])

DeMichele A, Dueck AC, Hlauschek D, Martin M, Burstein H, Pfeiler G, Zdenkowski N, Wolff A, Bellet-Ezquerra M, Winer E, Balic M, Miller K, Colleoni M, Lake D, Rubovsky G, Cameron D, Balko J, Singer CF, Nowecki Z, Iwata H, Wolmark N, Parraga KA, Rugo H, Steger GG, Traina T, Werutsky G, Czajkowska D, Metzger O, El-Abed S, Theall KP, Lu RD, O'Brien P, Fesl C, Mayer E, Gnant M

Breast Cancer Research - published on 23 January 2025

Efficacy and Safety of CDK4/6 Inhibitors: A Focus on HR+/HER2- Early Breast Cancer

Klocker EV, Egle D, Bartsch R, Rinnerthaler G, Gnant M

Drugs - published on 17 January 2025

Neoadjuvant atezolizumab in combination with dual HER2 blockade plus epirubicin in women with early HER2-positive breast cancer: the randomized phase 2 ABCSG-52/ ATHENE trial

Rinnerthaler G, Egle D, Bartsch R, Schmitt CA, Petzer A, Balic M, Petru E, Denison U, Singer CF, Bjelic-Radisic V, Gampenrieder SP, Knauer M, Sotlar K, Brunner C, Posch F, Hlauschek D, Sölkner L, Bago Horvath Z, Filipits M, Gili M, Ritter M, Wieser V, Albertini C, Zaborsky N, Weiss L, Marhold M, Schneeweiss B, Pusch R, Gnant M, Greil R

nature cancer - published 16 January 2025

HER2 and HER3 expression during neoadjuvant treatment of HER2-negative early breast cancer: potential for biomarker-driven sequencing of T-DXd and HER3-DXd

Singer CF, Jahn SW, Hlauschek D, Heber UM, Mang-Manger C, Egle D, Balic M, Pichler A, Pfeiler G, Kacerovsky-Strobl S, Suppan C, Ritter M, Petru E, Greil R, Bago-Horvath Z, Deutschmann C, Steger GG, Seifert M, Fitzal F, Bartsch R, Santhanagopal A, Machacek-Link J, Sellami D, Schwarz M, Fesl C, Sölkner L, Esker S, Filipits M, Gnant M; Austrian Breast and Colorectal Cancer Study Group

Cancer Communication - published on 06 January 2025

Drug-drug interactions between palbociclib and proton pump inhibitors in early breast cancer: an exploratory analysis of PALLAS (ABCSG-42/AFT-05/BIG-14-13/PrE0109)

Agostinetto E, Pfeiler G, Hlauschek D, Mayer EL, Lambertini M, de Azambuja E, Bellet-Ezquerra M, Meisel JL, Rubovszky G, Zdenkowski N, Novik Y, Ruiz-Borrego M, Gelmon KA, Mamounas EP, Iwata H, Lu DR, Soelkner L, Fesl C, Gnant M, DeMichele A

ESMO Open - published on 03 January 2025

CONFERENCE ORAL PRESENTATIONS 2025

Development of a Multi-Modal Artificial Intelligence (MMAI) Model for Predicting Distant Metastasis in HR+ Early-Stage Invasive Breast Cancer

Presentation by Geyer Jr. C
Kates-Harbeck D, Rastogi P, Kates R, Filipits M, Hlauschek D, Fesl C, Christgen M, Nitz U, Kuemmel S, Graeser M, Christgen H, Gluz O, Freeman T, Anderson S, Pinckaers H, Piehler A, Zwerink W, Zhang J, Joun S, Ross J, Chao C, Griffin J, Kreipe H, Gnant M, Wolmark N, Harbeck N

San Antonio Breast Cancer Symposium 2025, December 2025

Evaluation of a digital pathology based multimodal artificial intelligence (MMAI) model for prognosis and prediction of chemotherapy benefit in node-negative, hormone receptor-positive breast cancer patients: analysis of the NSABP B-20 trial

Presentation by Geyer Jr. C
Filipits M, Harbeck N, Zhang J, Rastogi P, Piehler A, Freeman T, Balic M, Zwerink W, Kreipe H, Hlauschek D, Anderson S, Chao C, Griffin J, Kates-Harbeck D, Gnant M, Wolmark N

San Antonio Breast Cancer Symposium 2025, December 2025

Adjuvant Palbociclib for ER+ Breast Cancer (PALLAS Trial (ABCSG-42/AFT-05/PrE0109/BIG-14-13): Post-Recurrence Treatment and Overall Survival at 7 Years

Presentation by DeMichele A
Dueck A, Gnant M, Hlauschek D, Martin M, Wolff A, Rubovsky G, Henao F, Hahn O, Chan A , Brufsky A, Morris P, Burstein H, Huber G, Anderson D, Garcia-Estevez L, Pfeiler G, Rugo H, Zdenkowski N, Gampenrieder S, Wolmark N, Sabanathan D, Miller K, Cameron D, Winer E, Brunner C, Liu F, O'Brien P, Fesl C, Mayer EL

San Antonio Breast Cancer Symposium 2025, December 2025

Tumor-informed circulating tumor DNA (ctDNA) analysis to assess molecular residual disease (MRD) for prognosis in the PALLAS trial (AFT-05; ABCSG-42)

Presentation by Parsons HA
Ballman K, Heitzer E, Watson M, Balic M, Hlauschek D, Renner D, Kalashnikova E, Steger G, Balko JM, Novik Y, Martin M, Rodriguez AA, Dayao Z, Chan A, Nili Gal-Yam E, Liu MC, Isaacs C, Los M, Gil Gil M, Felder B, Denkert C, Fasching PA, Liu F, O'Donnell T, Mayer EL, Gnant M, Symmans WF, DeMichele A

San Antonio Breast Cancer Symposium 2025, December 2025

Trial in Progress - BRCA-P: can denosumab prevent breast cancer in BRCA1 mutation carriers?

Abstract by Martin FC
Muttiah C, Ballal H, Dow E, Campbell A, Friedlander M, Goodwin A, Harris M, Inglis PL, Kannourakis G, Moore K, Wilcken N, Wuttke M, Zdenkowski N, Lok SW, Brunet J, Evans GD, Hopkins JO, Howell S, Michaelson-Cohen R, Rhiem K, Schmutzler RK, Garber JE, Gnant M, Singer CF, Lindeman GJ,* for Breast Cancer Trials and the Austrian Breast & Colorectal Cancer Study Group

Kathleen Cunningham Foundation Consortium Meeting, July 2025

ABCSG 45: A prospective, open, randomized, phase II study of carboplatin/olaparib in the pre-operative treatment of patients with triple-negative primary breast cancer which exhibit the features of positive homologous recombination deficiency (HRD) status

Presentation by Singer CS
Hlauschek D, Egle D, Bago-Horvath Z, Pfeiler G, Christine Brunner, Peters-Engl C, Petru E, Daniel Reimer, Pusch R, Seifert M, Pichler P, Suppan C, Anette Reimer, Greil R, Tan Y, Bartsch R, Katharina Knoll, Kermanidis AS, Gnant M, on behalf of the Austrian Breast & Colorectal Cancer Study Group

American Society of Clinical Oncology 2025, May/June 2025

CONFERENCE POSTERS 2025

Relationship between physician-graded symptomatic adverse events and patient-reported quality of life (QOL): an analysis of the phase III PALLAS trial

Poster by Bjelic-Radisic V
Sölkner L, DeMichele A, Naughton M, Lemieux J, Zdendowski N, Ruiz M, Mao J, Shinn E, Singer C, Meisel J, Chan A, Iwata H, Mamounas T, Loibl S, Gauthier E, Amylou D, Hlauschek D, Mayer EL, Gnant M, on behalf of the PALLAS groups and investigators (ABCSG, AFT, BIG, PReCOG, GBG, NASBP)

European Society for Medical Oncology - Breast, May 2025

Prospective randomized Phase II Trial of FOLFIRINOX alone versus FOLFIRINOX followed by Chemo-radiation in Patients with Locally Advanced Pancreatic Cancer (ABCSG-P02)

Poster by Schindl M
Fuegger R, Laengle F, Romeder F, Schaberl-Moser R, Greil R, Djanani A, Schmid R, Widder J, Strobel O, Hlauschek D, Fesl C, Gili M, Döller C, Gnant M, Prager G

European-African Hepato-Pancreato-Biliary Association, June 2025

The improved long-term outcome of Denosumab-treated postmenopausal women with early luminal breast cancer is driven by patients with PR positive tumors

Poster by Singer CF
Hlauschek D, Egle D, Reiner A, Steger G, Huber G, Greil R, Rinnerthaler G, Fitzal F, Brunner C, Suppan C, Pfeiler G, Gampenrieder SP, Seifert M, Kacerovsky-Strobl S, Deutschmann C, Wimmer K, Balic M, Jakesz R, Fesl C, Fohler H, Gnant M

San Antonio Breast Cancer Symposium 2025, December 2025

Tumor Necrosis Factor-related Weak Inducer of Apoptosis (TWEAK) – A Potential Biomarker for Predicting Response and Long-Term Outcomes in Early Breast Cancer Patients

Poster by Wimmer K
Hlauschek D, Rauch A, Sachet M, Ramos C, Gerakopulos V, Pfeiler G, Brunner C, Pristauz-Telsnigg G, Rinnerthaler G, Pichler A, Fitzal F, Gampenrieder SP, Huber G, Seifert M, Egle D, Filipits M, Oehler R, Singer C, Gnant M

San Antonio Breast Cancer Symposium 2025, December 2025

Independent Validation of a Pathology-Based Multimodal Artificial Intelligence Biomarker for Predicting Risk of Distant Metastasis in Postmenopausal, Estrogen Receptor-Positive, Early-Stage Breast Cancer Patients: Analysis of the ABCSG Trial 8

Poster by Filipits M
Hlauschek D, Zhang J, Balic M, Kates R, Greil R, Fitzal F, Toro-Bauer N, Rinnerthaler G, Pinckaers H, Sotlar K, Bago-Horvath Z, Hulla W, Regitnig P, Piehler A, Geyer C, Kreipe H, Griffin J, Harbeck N, Wolmark N, Gnant M

San Antonio Breast Cancer Symposium 2025, December 2025

Prognostic and predictive role of RBsig and CCNE1/RB1 gene-expression signatures for patients with early breast cancer treated with endocrine therapy with or without palbociclib in the PALLAS trial (ABCSG-42, AFT-05, BIG 14-03)

Poster by Malorni L
Hlauschek D, Mayer EL, Benelli M, Biganzoli L, Migliaccio I, Kermanidis AS, Pfeiler G, Mamounas T, Brufsky A, Bellet-Ezquerra M, Clifton K, Rubovszky G, Foukakis T, Goetz M, Lee SC, Ruiz-Borrego M, Symmans F, Ballmann K, Liu F, Link J, Denkert C, DeMichele A*, Gnant M*, on behalf of the PALLAS groups and investigators (ABCSG, AFT, BIG, PrECOG, GBG, NSABP)

San Antonio Breast Cancer Symposium 2025, December 2025

Long-Term Prognostic and Predictive Value of Lobular Histology in the PALLAS Trial (ABCSG-42/AFT-05/PrE0109/BIG-14-13)

Poster by Nader-Marta G
Desmedt C, Hlauschek D, DeMichele A, Zoppoli G, Blondeaux E, de Azambuja E, Bellet-Ezquerra M, Metzger Filho O, Suga J, Pfeiler G, Goetz M, Ruiz-Borrego M, Loibl S, Meisel J, Ring A, Van Baelen K, Mamounas E, Zdenkowski N, Agostinetto E, Lambertini M, Gauthier E, Soelkner L, Dueck A, Gnant M*; Mayer E* on behalf of the PALLAS groups and investigators; *shared first/last authorship

San Antonio Breast Cancer Symposium 2025, December 2025

Exploratory analysis of palbociclib benefit in the PALLAS trial by SET(ER/PR) index and prior chemotherapy regimens (ABCSG-42/AFT-05)

Poster by Metzger O
O'Brien P*, Ballman K, Gnant M, Watson M, Chen E, Tran K, Hlauschek D, Martin M, Balko JM, Nowecki Z, O Hahn, Denkert C, Mayer EL, Curtis C, DeMichele, Feng Liu, Dueck AC, Symmans W * These authors contributed equally as co–first author

San Antonio Breast Cancer Symposium 2025, December 2025

Predictors of early discontinuation of adjuvant palbociclib in early HR+/ HER2- breast cancer: final analysis of the PALLAS (AFT-05; ABCSG-42) trial integrating patient-reported outcomes

Poster by Vetter MP
Wiencierz A, Gnant M, Hlauschek D, Kurzeder C, Grasic-Kuhar C, Zdenkowski N Shinn E, Suga J, Egle D, Meisel J, Antolin- Novoa D, Munzone E, Haddad T, Loibl S, Holynskyj A, Fesl C, Dueck A, DeMichele A, Mayer EL, on behalf of the PALLAS groups and investigators (ABCSG, AFT, BIG, PReCOG, GBG, NSABP)

San Antonio Breast Cancer Symposium 2025, December 2025

Study Overview

Study	Sponsor	Title	Status
ABCSG 53 / TAXIS	Universitätsspital Basel	Tailored axillary surgery with or without axillary lymph node dissection followed by radiotherapy in patients with clinically node-positive breast cancer (TAXIS): a multicenter randomized phase III trial	open for enrollment
ABCSG 55N / AMBHER	ABCSG	Development of a dynamic composite risk assessment tool for adjuvant HER2-targeted therapy indication in patients with HER2-positive breast cancer undergoing neoadjuvant treatment	open for enrollment
ABCSG 60 / CAMBRIA-1	AstraZeneca	A Phase III, Open-Label, Randomised Study to Assess the Efficacy and Safety of Switching to AZD9833 (a Next Generation, Oral SERD) vs Continuing Standard Endocrine Therapy (Aromatase Inhibitor or Tamoxifen) in patients with HR+/HER2- early breast cancer and a intermediate or high risk of recurrence who have completed definitive locoregional therapy and at least 2 years of adjuvant endocrine therapy without disease recurrence	open for enrollment
ABCSG 61 / TEODOR	ABCSG	A prospective, randomized, controlled, open-label multicenter phase II study investigating neoadjuvant endocrine therapy versus chemotherapy in HR-positive, HER2-negative, ctDNA-negative and endocrine responsive early and locally advanced breast cancer	open for enrollment
ABCSG 62 / CAMBRIA-2	AstraZeneca	A Phase III, Open-Label, Randomised Study to Assess the Efficacy and Safety of Camizestrant (AZD9833, a Next Generation, Oral Selective Estrogen Receptor Degrader) Versus Standard Endocrine Therapy (Aromatase Inhibitor or Tamoxifen) as Adjuvant Treatment for Patients with ER+/HER2- Early Breast Cancer and an Intermediate-High or High Risk of Recurrence Who Have Completed Definitive Locoregional Treatment and Have No Evidence of Disease	open for enrollment
ABCSG 63 / ERIKA	ABCSG	An open-label, two-arm, randomized, phase II study of elacestrant plus ribociclib vs. AI (plus GnRH agonist in pre-/perimenopausal women and men) plus ribociclib as neoadjuvant therapy for endocrine-responsive HER2-negative early breast cancer	open for enrollment
ABCSG 65 / DEFINITIVE	FRCB-IDIBAPS	An international, multicenter, prospective, two-arm, randomized, open-label phase III study designed to demonstrate that personalized treatment decisions in HER2-positive early-stage breast cancer using the HER2DX® diagnostic test improve quality of life without compromising outcomes and survival rates	open for enrollment
ABCSG 67N / CAROLEEN	Novartis	A non-interventional study for ribociclib in combination with an aromatase inhibitor for adjuvant treatment in patients with HR+/HER2- early breast cancer at high risk of recurrence to evaluate real-world effectiveness, safety profile, patient compliance and quality of life	open for enrollment
TraX&Vields	Cepheid	TraX&Vields: Training GeneXpert tools and validation in ABCSG biomarker cohorts	translational research project
ABCSG TR Procan	CMRI	Analysis of protein expression to develop a proteomic signature of distant recurrence in hormone receptor-positive (HR+) early breast cancer	translational research project
ABCSG TR Artera	Artera	Digital histopathology multi modal artificial intelligence to offer tailored prognostication and treatment selection for women with breast cancer	translational research project
ABCSG TR Ataraxis	Ataraxis AI	Digital imaging project to validate a prognostic and predictive foundation model-based AI test in breast cancer	translational research project

Study	Sponsor	Title	Status
ABCSG 39 / APHINITY	Roche	A randomized multicenter, double-blind, placebo-controlled comparison of chemotherapy plus trastuzumab plus placebo versus chemotherapy plus trastuzumab plus pertuzumab as adjuvant therapy in patients with operable HER2-positive primary breast cancer	treatment / follow-up
ABCSG 41 / OLYMPIA	AstraZeneca	A randomized, double-blind, parallel group, placebo-controlled multi-centre Phase III study to assess the efficacy and safety of olaparib vs placebo as adjuvant treatment in patients with germline BRCA 1/2 mutations and high risk HER2-negative breast cancer who have completed definitive local treatment and neoadjuvant or adjuvant chemotherapy	treatment / follow-up
ABCSG 42 / PALLAS	ABCSG (20 countries); AFT (USA)	PALbociclib CoLlaborative Adjuvant Study: A randomized phase III trial of Palbociclib with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy alone for hormone receptor positive (HR+) / human epidermal growth factor receptor 2 (HER2)-negative early breast cancer	treatment / follow-up
ABCSG 45	ABCSG	A prospective, open, randomized, phase II study of carboplatin/olaparib in the pre-operative treatment of patients with triple-negative primary breast cancer which exhibit the features of positive homologous recombination deficiency (HRD) status	treatment / follow-up
ABCSG 48 / POSITIVE	ETOP IBCSG Partners-Foundation	A study evaluating the pregnancy outcomes and safety of interrupting endocrine therapy for young women with endocrine responsive breast cancer who desire pregnancy (POSITIVE)	treatment / follow-up
ABCSG 49 / POLAR	ETOP IBCSG Partners-Foundation	A phase III open-label, multicenter, randomized trial of adjuvant palbociclib in combination with endocrine therapy versus endocrine therapy alone for patients with hormone receptor positive / HER2-negative resected isolated locoregional recurrence of breast cancer	treatment / follow-up
ABCSG 50 / BRCA-P	ABCSG (Austria, Germany), other national sponsors in Australia, Israel, Spain, UK, US	A randomized, double-blind, placebo-controlled, multi-center international phase 3 study to determine the preventive effect of Denosumab on breast cancer in women carrying a *BRCA1* germline mutation	treatment / follow-up
ABCSG 51 / AURORA	BIG	Aiming to understand the molecular aberrations in metastatic breast cancer: The AURORA Program	treatment / follow-up
ABCSG 56 / SASCIA	GBG	Phase III postneoadjuvant study evaluating Sacituzumab Govitecan, an Antibody Drug Conjugate in primary HER2-negative breast cancer patients with high relapse risk after standard neoadjuvant treatment	treatment / follow-up
C08 / EXERCISE II	ABCSG	Randomized trial of endurance exercise following adjuvant chemotherapy for colorectal cancer	treatment / follow-up

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ABCSG Trial Office
Nussdorfer Platz 8
1190 Vienna, Austria

T +43 1 408 92 30
F +43 1 409 09 90
E info@abcsg.at

www.abcsg.at
www.abcsg.com
www.abcsg.org

Editor:
Association for the Prevention and Therapy of Malignant Diseases
Cooperative Study Group for Breast and Colorectal Carcinoma
Austrian Breast & Colorectal Cancer Study Group (ABCSG)

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