40 FORTY YEARS ABCSG

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Austrian Breast & Colorectal Cancer Study Group

Annual Report

Austrian Breast & Colorectal Cancer Study Group 2024

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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 2024

While the global economic challenges of recent years have slightly eased after the pandemic, the world remains in a fragile state, with economic and political tensions and marked volatility affecting various sectors. Despite these challenges, the ABCSG has maintained a safe and stable working and research environment through proactive policies and negotiations, ensuring a solid foundation for continued scientific discovery. **This has been our approach for 40 years, and in 2024 we have continued on this path, celebrating four decades of success and stability.**

2024 was once again marked by our strong global scientific presence, with **numerous presentations and publications** that both reflect our achievements and lay the foundation for future international collaborations. **ABCSG 34** played a leading role, for example, at EBCC-14 in Milan with the poster presentation *"PD-L1 and IRF1 expression is associated with improved therapy response in the prospective randomized neoadjuvant ABCSG 34 trial"* by Ulrike Heber, at ASCO in Chicago with *"Addition of the MUC-1 vaccine Tecemotide to Neoadjuvant Systemic Therapy Improves Survival of Patients with Early Breast Cancer: Results from the Prospective Randomized ABCSG 34 Trial"* by Christian Singer, leading to numerous press reports and television coverage, and *"Association of ctDNA in patients with long-term outcome of breast cancer patients undergoing neoadjuvant treatment in the randomized ABCSG 34 clinical trial"* by Daniel Egle, further at SABCS in San Antonio with *"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"* by Ulrike Heber. These well-received (substudy) results of a trial with its immunotherapy already long completed, showed that **persistence and academic interest** in gaining long-term follow-up data of (neo)adjuvant studies can lead to remarkable observations in the interest of generating new knowledge.

The long-standing scientific importance of the **ABCSG 42 / PALLAS** trial was demonstrated again at ASCO 2024 with the poster presentations *"Analysis of the sensitivity to endocrine therapy (SET) assay in the PALLAS adjuvant trial of palbociclib in HR+/HER2- breast cancer (ABCSG-42/AFT-05/BIG-14-13)"* by Otto Metzger and *"Outcomes in Stage IIA vs. Stage IIB/III in the PALLAS Trial"* by Angela DeMichele.

Our translational collaboration with Cepheid was presented at SABCS with *"The Xpert® Breast Cancer Insight assay predicts distant recurrence and overall survival in estrogen receptor-positive, HER2-negative early breast cancer: A validation study in ABCSG Trial 8"* by Martin Filipits.

ABCSG researchers have also made **important methodological contributions**, such as *"Clinical applications of next-generation sequencing-based ctDNA analyses in breast cancer: defining treatment targets and dynamic changes during disease progression"*, *Eva Valentina Klocker et al.* in Molecular Oncology, *"Is the CTS5 a helpful decision-making tool in the extended adjuvant therapy setting?"*, Kerstin Wimmer et al. in Breast Cancer Research and Treatment, *"Explained variation and degrees of necessity and of sufficiency for competing risks survival data"*, Andreas Gleiss et al. in Biometrical Journal, *"Standardized Definitions for Efficacy End Points for Adjuvant Trials – The Updated STEEP Criteria"*, Dominik Hlauschek et al. in JAMA, and *"The future of clinical trials – goals, ideas, and discussion"*, Michael Gnant et al. in the Magazine of European Medical Oncology. Kindly refer to Chapter 7 "Publications and Presentations" for details of all publications and presentations of 2024.

From an **operational perspective**, the year was marked by the successful and timely transition of several ABCSG protocols (ABCSG 42 / PALLAS, ABCSG 45 and ABCSG 52 / ATHENE) to the EU Clinical Trials Regulation platform CTIS and the excellent start of the two CAMBRIA studies (ABCSG 60 and 62). With impressive recruitment figures in both studies, we stand out as a small country in a global comparison, and with ABCSG 62 we have further strengthened international collaboration and leadership, along with specific expertise in data management and statistics. This demonstrates the value and effectiveness of the *"Transparency Model"* which is applied for the CAMBRIA-2 study that involves industry partners and academic study groups, as our contributions and "data oversight" are intended to further improve the quality of study data. ABCSG protocols 61 / TEODOR, ABCSG 63 / ERIKA and ABCSG 64 / neoGRACE will be launched along with the global study collaboration ABCSG 65 / DEFINITIVE in 2025.

In addition to advancing clinical research through trials and publications, the ABCSG is committed to fostering **continuous learning** within the breast cancer community. Each year we organize a variety of **educational events**, both in-person and online, both nationally and internationally. These initiatives are designed to share the latest research developments with breast cancer specialists, as well as referring physicians and new medical professionals, while encouraging interdisciplinary exchange and collaboration. A major highlight of our events in 2024 was the emphasis on nurturing the next generation of scientists. Dedicated sessions at our annual meeting gave young investigators the opportunity to present our recruiting studies. Our educational efforts have been well received, as evidenced by the **record attendance** at our 2024 events. These included 151 participants at the Post-SABCS in January, 122 at the Interdisciplinary Mamma Discourse in October, 230 at the 33rd Annual Meeting in Saalfelden in November, and 116 participants from 15 countries at our online webinar on CDK4/6 inhibitors.

As in previous years, the ABCSG Annual Report provides an overview of our research projects and activities – driven by commitment, excellence, and teamwork. We hope you find it enlightening!

Sincerely,

Michael Gnant,
on behalf of the ABCSG

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ABCSG Key Facts 2024

effective date 31 Dec 2024

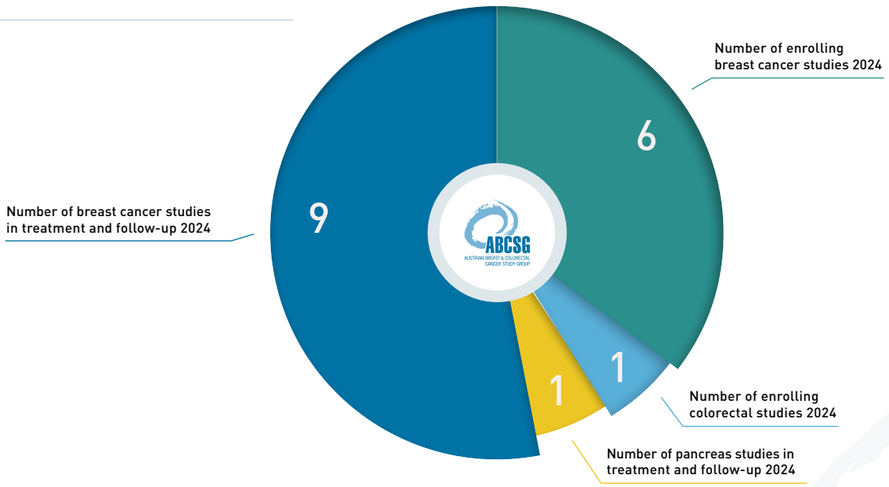
Number of all patients ever enrolled

29.653

Number of ...

... translational projects 2024	3
... enrolling studies 2024	7
... studies in treatment phase and follow-up 2024	10

Clinical studies in enrollment, treatment and follow-up 2024



Number of ...

... all ongoing breast cancer studies in 2024	15
... all ongoing colorectal studies in 2024	1
... all ongoing pancreas studies in 2023	1

204

Total Publications ABCSG (peer reviewed)

Publications 2024 (peer reviewed)	17

Austrian Breast and Colorectal Cancer Study Group (Association)

Year of foundation: 1984

9 Board members
12 Members Executive Committee
36 Members General Assembly

Tax status: non-profit

Subsidiary 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

Research Services GmbH

Year of foundation: 2022

Ownership:
99 % Association, 1 % Persons

Commercial Managing Director:
Mag. Hannes Fohler

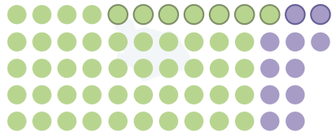
Scientific Managing Director:
Prof. Dr. Michael Gnant

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

15.4 years ...

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

Employees (Head Count)



Structure, Aims, Visions and International Network

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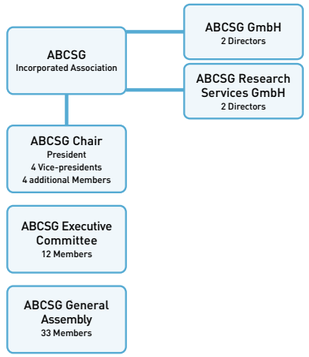
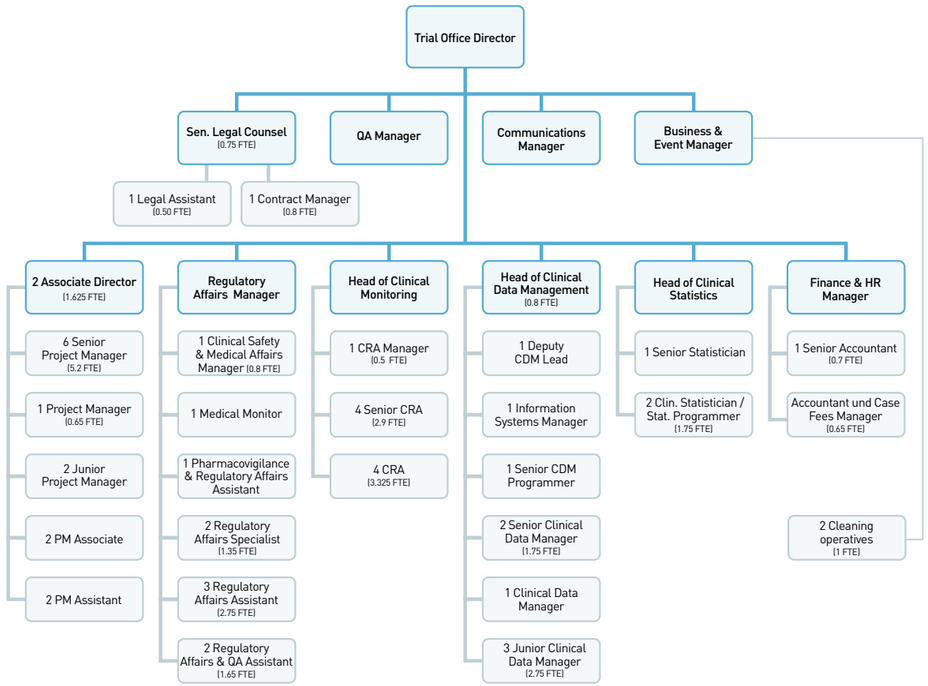
ABCSG Structure



ABCSG Trial Office

62 Employees (54.24 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 the 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 the 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) of the ABCSG 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 – also Association for the Prevention and Therapy of Malignant Diseases – 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 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. For example, ABCSG is involved in the BIG (Breast International Group) network, encompassing more than 70 members across all continents, where we participate in BIG sponsored studies as well as studies of several partner organizations in and outside of Europe, but also directly act as a legal sponsor of international studies where these study groups and academic organizations in turn participate as our partners.

After having gained valuable experience in trans-atlantic and global partnerships on the adjuvant ABCSG 42 / PALLAS trial (where ABCSG acts as legal trial sponsor in 20 countries, along 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.

In addition to smaller and larger academic studies, ABCSG also participates in relevant research questions in industry-initiated studies and coordinates these in Austria. 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).

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 enrolment and care. ABCSG is coordinating study groups in 9 countries who are responsible for about a third of enrolled patients in that study which is set to complete the randomization phase in 2026.

In translational research, there have been close collaborations with international partners, including biotech companies such as Nanostring, Agendia, Cepheid, Myriad, OncoMark, ProCan, Artera and Ataraxis 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 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.

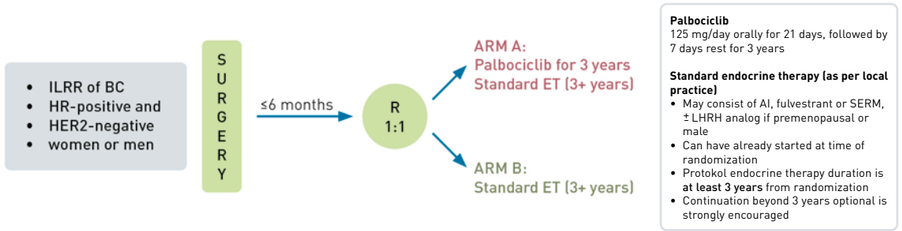
ABCSG 49 / POLAR

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:	Sample size:	Sponsor:
08/2019 (global) **11/2020** (national)	**400**	**ETOP IBCSG Partners Foundation**

Design:



Description and status:

ABCSG 49 / POLAR is an unblinded, multi-center, randomized phase III trial, examining adjuvant palbociclib combined with endocrine therapy versus endocrine therapy alone, for patients with HR+/ HER2- resected isolated locoregional recurrence of breast cancer. It is commonly known 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 is available serving as a basis for 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+/HER2- 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 45 sites are participating in countries such as Italy, Spain, Switzerland, Hungary, France as well as three sites in Austria. In order to enroll 400 patients worldwide, the recruitment phase lasted until December 2024, with 19 patients coming from Austrian sites.

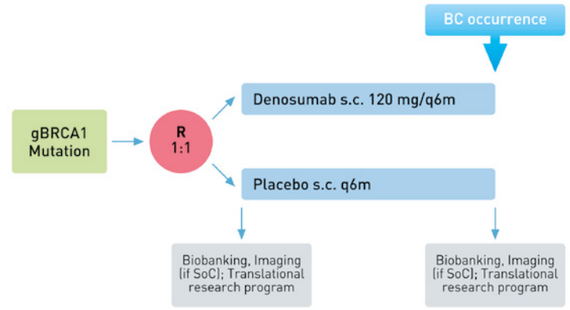
ABCSG 50 / BRCA-P

A randomized, double-blind, placebo-controlled, multi-center 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:	Sample size:	Sponsor (Austria):
07/2019 (global and national)	**2.918**	**ABCSG**

Design:



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-Dec-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, as well as cooperation with local sponsors.

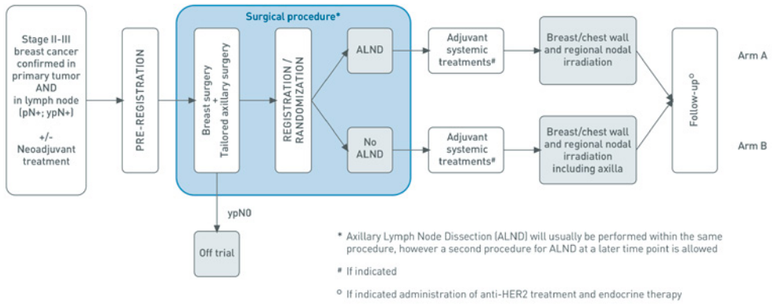
ABCSG 53 / TAXIS

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)	**1.500**	**Universitätsspital Basel (USB)**

Design:



Description and status:

ABCSG 53 / TAXIS investigates the hypothesis that ALND (axillary lymph node dissection) is no longer necessary for confirmed lymph node involvement in the initial diagnosis of breast cancer. That is, in the case of extensive regional lymph node irradiation in clinically lymph node-positive patients in the adjuvant setting or incomplete response of the affected lymph nodes in the neoadjuvant setting. For 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. The TAXIS study examines TAS (tailored axillary surgery), a tailor-made procedure in which the tumor-affected lymph nodes are removed. The main objective of the TAXIS study is to show that TAS and axillary radiotherapy are not inferior to ALND in terms of disease-free survival (DFS) with lymph node involvement in terms of effective systemic therapy and extensive regional lymph node irradiation. Until the end of 2024, a total of 146 Austrian patients were included and 1.284 patients were randomized in 13 countries globally. Recruitment is projected to be open until end of 2025.

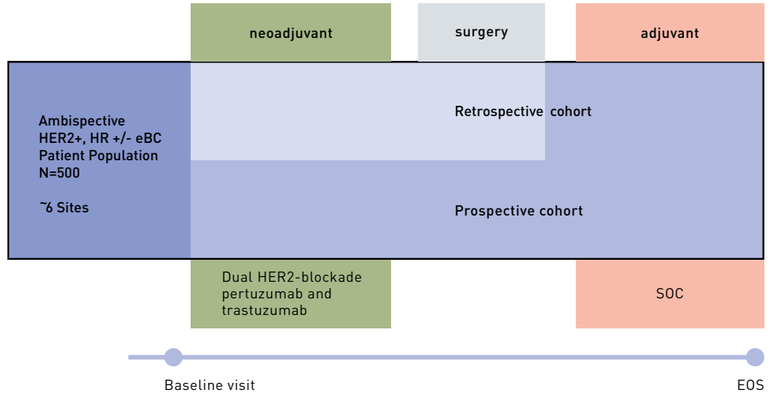
ABCSG 55N / AMBHER

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)

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 2024, 344 patients had been registered for the study at 8 sites throughout Austria.

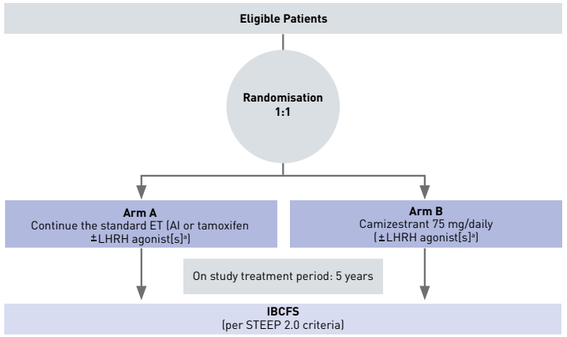
ABCSG 60 / CAMBRIA-1

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+/HER2- 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.

With a recruitment period of approximately 40 months, projections are estimating the end of global recruitment in June 2025. 14 sites are actively recruiting in Austria, with an overall outstanding enrollment performance of 110 randomized patients by end of 2024. Global enrollment remains competitive, so we encourage active ABCSG sites to continue their commendable recruitment efforts!

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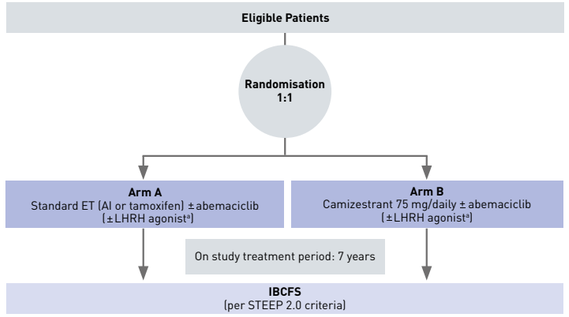
ABCSG 62 / CAMBRIA-2

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+/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

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+/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. 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.

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Studies open for Enrollment

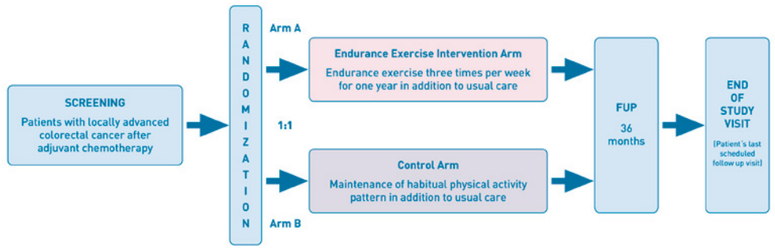
ABCSG C08 / EXERCISE II

Randomized trial of endurance exercise following adjuvant chemotherapy for colorectal cancer

Coordinating Investigator: **Gudrun Piringer** (Linz)

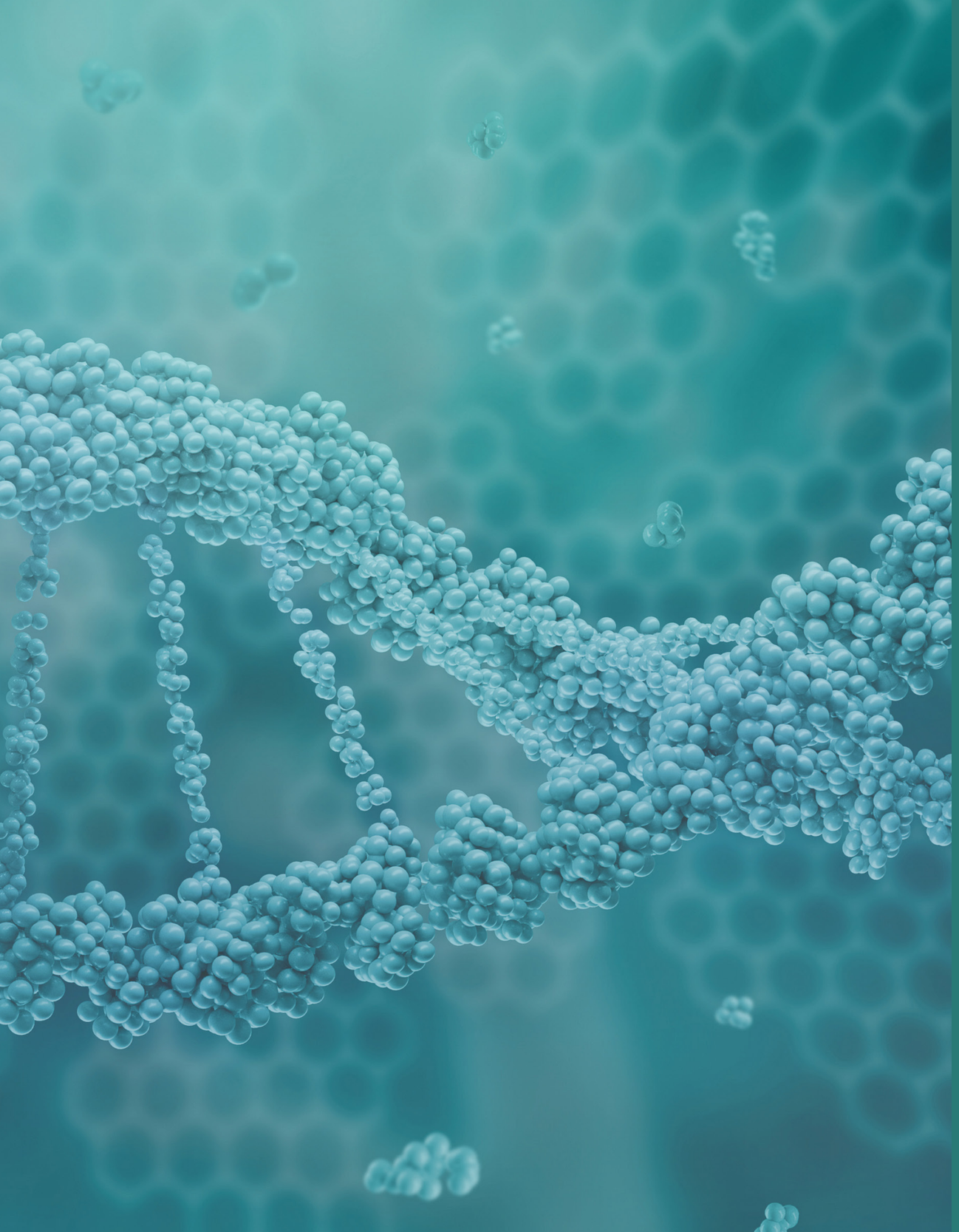
Start of study:	Sample size:	Sponsor:
11/2018 (national)	100	ABCSG

Design:



Description and status:

The ABCSG C08 / EXERCISE II study is a randomized, two-arm, multicenter trial to investigate the efficacy of endurance exercise following adjuvant chemotherapy in patients with colorectal cancer. Patients participate in a study aiming to reduce relapse rates and improve the quality of life by an increase of their physical activity. Participants within the training group receive individually supervised training based on regularly performed ergometries. They are encouraged to complete the endurance training three times a week for an intended period of 12 months. After a slow build-up phase during the first months, the time required for training is estimated with three hours per week. In addition to the usual follow-up care after a colorectal cancer treatment, a variety of other parameters such as increased physical performance, quality of life, metabolic parameters or molecular markers are assessed in the course of the study. By the end of 2024, when enrollment was closed, a total of 91 patients had been included at 8 Austrian sites.



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 36 / PENELOPE[B] / ETERNITY

Phase III trial to evaluate palbociclib (PD-0332991), a cyclin kinase 4/6 inhibitor, in patients with hormone receptor positive, HER2-negative primary breast cancer and a high risk of relapse following neoadjuvant chemotherapy

ETERNITY: Registry for long-term follow-up of safety and efficacy parameters of GBG study participants

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

Start of study: **11/2013** (global) **/ 07/2015** (national)

Sample size: **1.250**

Sponsor: **GBG**

Description and status:

PENELOPE[B] is an international phase III trial evaluating the effect of palbociclib combined with endocrine therapy on invasive disease-free survival (iDFS) in patients with HR+/HER2- primary breast cancer and high relapse risk after neoadjuvant chemotherapy. The global enrollment goal was achieved by the end of 2017. Worldwide, 1.694 screenings were performed, followed by randomization of 1.250 patients. 19 sites were activated in this study in Austria and 25 patients were enrolled. Final analysis on the primary endpoint was completed in early autumn 2020 and revealed that the trial did not meet the primary endpoint of improved iDFS. The results were presented at the San Antonio Breast Cancer Symposium (SABCS) Virtual Meeting 2020.

Beyond the end of the PENELOPE[B] study, the long-term follow-up was conducted via the ETERNITY registry (GBG 107, Registry for long term follow-up of safety and efficacy parameters of GBG study participants). In Austria, the registration phase began in spring 2022, with 7 sites being activated. Despite a positive IDMC recommendation in November 2023 to continue the project, the sponsor decided in early 2024 to terminate it prematurely due to insufficient follow-up compliance. The database was closed on April 12, 2024, with 11 Austrian registered patients.

ABCSG 39 / APHINITY

A randomized multicenter, double-blind, placebo-controlled comparison of chemo-therapy 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: **4.800**

Sponsor: **Roche**

Description and status:

The APHINITY trial included patients with newly diagnosed primary invasive, HER2+ breast cancer in order to compare invasive disease-free survival (IDFS) of patients randomized to receive chemotherapy plus one year of trastuzumab plus placebo, or chemotherapy plus one year of trastuzumab plus pertuzumab.

Study recruitment was completed globally and in Austria, a total of 52 patients could be included in the APHINITY study at 11 sites. The follow-up phase ended in November 2024, followed by data cleaning and study close out preparations, which will take place in 2025.

In 2024, the results of the 3rd interim analysis on Overall Survival (OS) were published in the Journal of Clinical Oncology (Loibl et al., DOI: https://doi.org/10.1200/JCO.23.02505). Results of 80-gene signature subtyping were reported in JCO Precision Oncology (Krop et al., DOI: https://doi.org/10.1200/PO.22.00667) and a poster on the effect of ER- and HER2-expression on therapy benefit was presented at the San Antonio Breast Cancer Symposium (De Azambuja et al., DOI: 10.1158/1538-7445.SABCS23-PS09-04).

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 May 28th, 2019. According to the current study protocol, the study will last until 2028. 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 enrolled up until the end of recruitment.

The results of the analysis of the primary endpoint (Invasive Disease-Fee Survival, IDFS) were published on June 3rd, 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. In 2024, the transition to the EU platform in accordance with the Clinical Trial Regulation (CTR) has been successfully completed. Data cleaning and patient retention efforts will remain the main challenges in the upcoming year.

Studies in Treatment Phase and Follow-up

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:	Sample size:	Sponsor:
09/2015 (global) **10/2015** (national)	**5.600**	**ABCSG** (20 countries) **AFT** (US)

Description and status:

The adjuvant early breast cancer study ABCSG 42 / PALLAS (AFT-05 / BIG14-03) 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 legal sponsor in cooperation with the BIG network, for all 20 non-US countries involved. Recruitment was closed in late 2018, enrolling over 5.700 patients worldwide. The analysis of the scheduled 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 current follow-up phase is conducted as per protocol until 2028 and biosample collection during follow-up for the translational research program Trans-PALLAS remains ongoing until 7- and 10-years post-randomization, respectively. 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 of the study is the main aim of the current study phase. 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.

Numerous exploratory clinical and translational research proposals were endorsed by the PALLAS steering committee after being submitted through the first study-wide research call for proposals. Some of the approved projects are completed and have been published successfully in the meantime. The study leadership and sponsor are planning to open a second call for research proposals in 2025 to allow the submission of additional project proposals from within the international PALLAS community.

ABCSG 43 / INSEMA

Comparison of axillary sentinel lymph node biopsy versus no axillary surgery in patients with stage I and II invasive breast cancer and breast-conserving surgery: a randomized prospective surgical trial

Coordinating Investigator: **Michael Knauer** (St. Gallen)

Start of study: **09/2015** (global) **/ 03/2016** (national)

Sample size: **5.502**

Sponsor: **University of Rostock**

Description and status:

This prospective surgical study headed by the University of Rostock investigated whether a sentinel lymph node biopsy (SLNB) could be refrained from if the axilla is clinically and sonographically normal. The first randomization step ("Rando 1") was carried out only in Germany and at one Austrian trial site (Salzburg) and divided the patients into the arms „no SLNB" or „SLNB" in a 1:4 ratio. In the second randomization step ("Rando 2"), in which all additional Austrian ABCSG sites participated, those patients who had received an SLNB and had a maximum of one to three macro-metastases in the sentinel lymph nodes, were randomized either into an axillary dissection (ALND) arm or waiver on the same. Patients with four or more affected sentinel lymph nodes were completely operated on via ALND. A total of 158 patients were randomized at Austrian sites, 132 of these in Salzburg who took part in both randomization steps. The 5-year follow-up was completed in 2024, and primary study results were published in the New England Journal of Medicine (DOI: https://www.nejm.org/doi/full/10.1056/NEJMoa2412063). The study concluded that omitting axillary sentinel lymph node surgery was not inferior to SLN surgery in clinically node-negative patients with early breast cancer having upfront breast-conserving therapy.

„SCIENCE FROM THE HEART OF EUROPE"

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) in their tumor tissue. The patients 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 main study consists of 2 sub-phases: in dose-finding phase 1, the maximum tolerated olaparib dose was assessed in 20 patients at 6 sites and the identified olaparib dose was then administered in phase 2, with an additional 70 patients at 9 sites. The primary endpoint of ABCSG 45 is the central evaluation of the residual cancer burden (RCB) after surgery (following neoadjuvant treatment) to compare the efficiency of 6 cycles of olaparib / carboplatin with 6 cycles of TAC. Furthermore, the pathological complete remission (pCR) is assessed and the quality of life outcomes of participants are recorded using EORTC questionnaires. The dose-finding phase 1 was completed with 20 patients by the end of 2020 and the identified optimal olaparib dose was then used in study phase 2, which was open for recruitment of additional 70 patients from June 2021 to December 2023. In 2024, the last patient visit took place in June, subsequently data documentation and read-out were completed until end of 2024. The primary data results will be presented and published in 2025.

In Q1/2023, an optional substudy was implemented, which gives patients – who complete main study treatment – the option to continue with adjuvant intake of daily olaparib for one year. This substudy design was based on the promising OlympiA study results published in 2022 (Geyer et al., Ann. Oncol.), which showed an extension of overall survival after one year of adjuvant olaparib treatment. 8 patients were included in the substudy between March 2023 and July 2024, the treatment phase will be ongoing until approximately July 2026.

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 study is led by the International Breast Cancer Study Group (ETOP IBCSG Partners Foundation) with a total of 20 countries involved, such as the US, Canada, the Netherlands, Ireland, Greece and Austria, among others. 518 patients were enrolled, thereof seven in Austria at the four 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., 2023 N Engl J Med 2023;388:1645-1656. DOI: https://www.nejm.org/doi/full/10.1056/NEJMoa2212856). The trial was closed for enrollment and 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.

ABCSG 51 / AURORA

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

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

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., DOI: 10.1158/1538-7445.SABCS23-PS17-04).

Studies in Treatment Phase and Follow-up

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 – SASCIA

Coordinating Investigator: **Marija Balic** (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 postneoadjuvant study evaluating Sacituzumab 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 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 January 26, 2024. In total, 1.391 patients were enrolled globally, including 34 patients at 12 sites in Austria. In mid-2024, the study was successfully transferred to CTIS in accordance with the EU Clinical Trial Regulation (CTR). By the end of 2024, efforts were focused on the completion of the database as part of the preparations for the iDFS interim analysis. As a next step, data cleaning will be a crucial phase in early 2025 to ensure high data quality. The iDFS interim analysis, originally planned for Q3 2025, will take place earlier as the required number of events is being reached sooner than expected.

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ABCSG P02

A prospective randomized phase II trial of FOLFIRINOX alone versus FOLFIRINOX followed by radiochemotherapy in patients with locally advanced, primarily inoperable pancreatic cancer

Coordinating Investigators: **Carmen Döller** (Krems), **Gerald Prager** (Vienna), **Martin Schindl** (Vienna)

Start of study: **05/2017** (national)

Sample size: **112**

Sponsor: **ABCSG**

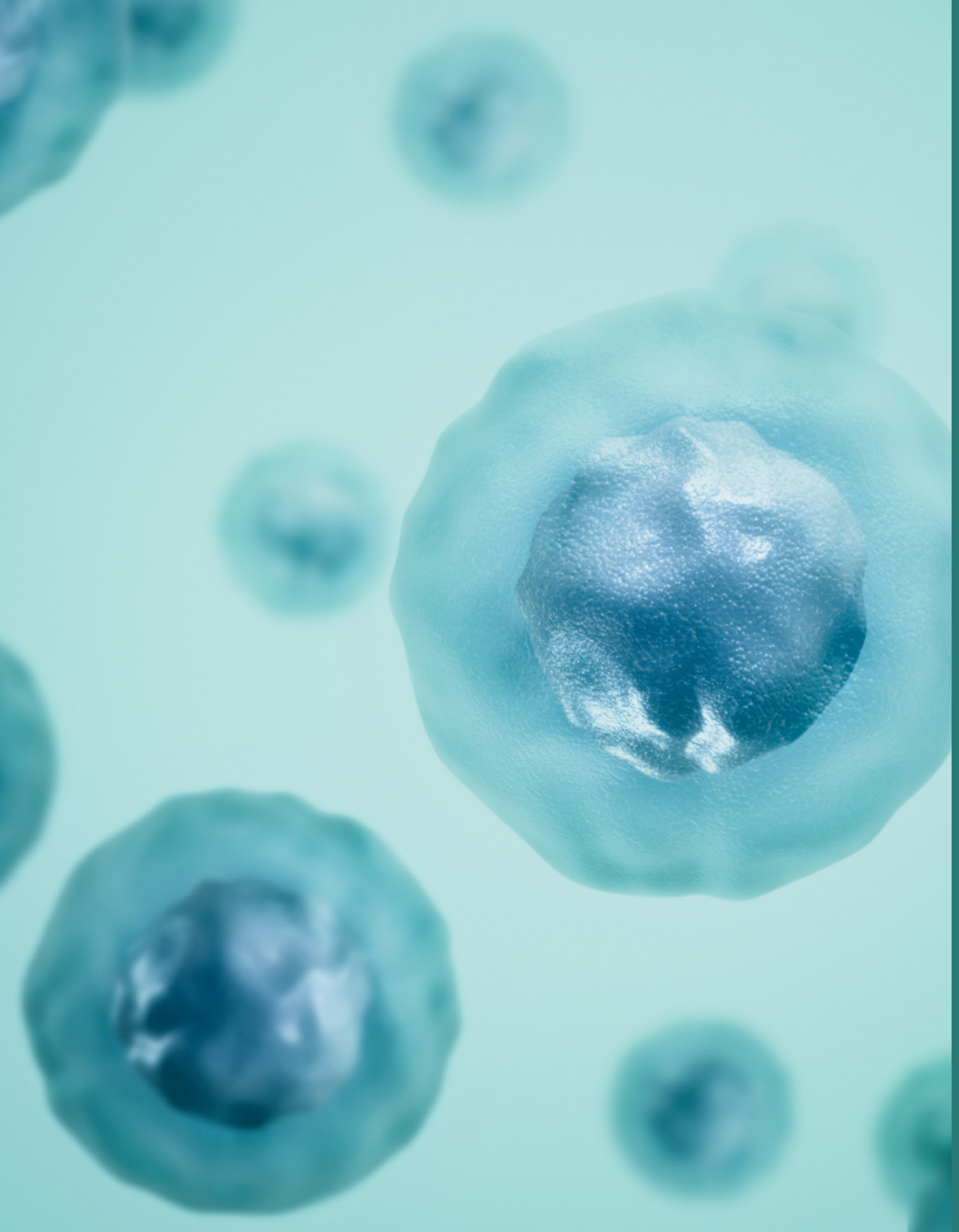
Description and status:

ABCSG P02 is the second pancreatic cancer related project initiated and conducted by ABCSG. Patients with locally advanced, primarily irresectable (irresectable and borderline irresectable) pancreatic cancer were enrolled into this Austrian-wide, academic research project. Primarily, this study was designed to demonstrate that within this patient collective, a neoadjuvant chemotherapy followed by concurrent radiochemotherapy is superior to neoadjuvant chemotherapy alone in terms of R0-resectability.

Study start and "First Patient In" occurred on March 23rd, 2017 at the study site "Ordensklinikum Linz – Elisabethinen". Due to insufficient patient recruitment within the planned enrollment period, the ABCSG P02 Investigator's and ABCSG Board decided in May 2022 to close study recruitment early. A total of 83 out of the 112 planned patients were enrolled into the study. "Last Patient Last Visit" took place on October 14th 2024, and the study database was closed in November 2024. The study analysis has been completed, and preparations for a corresponding publication are currently underway.

„SCIENCE FROM THE HEART OF EUROPE" ABCSG

Studies in Treatment Phase and Follow-up



Translational Projects and upcoming Studies

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AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

Translational Studies and 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&Vields project in collaboration with Cepheid** is one of ABCSG's largest endeavors, as it includes work packages for multiple former ABCSG trial patient cohorts. The main aim of all work packages is twofold: the Cepheid GeneXpert Breast Cancer STRAT4 is a novel test to reliably, reproducibly, and quantitatively test common tumor markers using their mRNA expression levels. This test is to be validated in a number of ABCSG trial patient cohorts and has already achieved CE-certification in some countries. Secondly, a prognostic breast cancer signature to predict the recurrence risk of early breast cancer patients is to be developed and validated. In 2020, a new predictive breast cancer signature (Xpert Insight) has come into focus but strategic business decisions within Cepheid have led to discontinuing the commercial development of the Xpert Insight signature in the meantime. Despite this, ABCSG and Cepheid will continue their collaborative efforts to complete ongoing work packages:

The Trax&Vields-05 project (ABCSG-34 cohort), including the collection of clinical follow-up data and sample analysis, was completed in 2023. A scientific publication describing this work is expected to be published in 2025.

The planned laboratory work to complete the TraX-&Vields-02 work package (ABCSG-8) was finalized in 2024 to validate the STRAT4 and Breast Cancer Insight tests. The scientific manuscript of the STRAT4 analysis was submitted, expecting its publication in 2025.

Additionally, a new sub-project (TraX&Vields-08) in the ABCSG-6 cohort to validate the prognostic breast cancer Insight signature was completed. Despite the decision by Cepheid to discontinue commercial development of the signature, the signature showed promising results in this validation cohort.

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 2024, 16 sites were actively contacting and reconsenting former ABCSG-12 patients, for whom archived tumor material is still available to be centralized. Documented data and samples were available for 372 patients at that time. The efforts of all sites remain ongoing, with the common target to provide clinical follow-up data and archival tumor samples for as many ABCSG-12 patients as possible.

The **ABCSG TR ProCan** collaboration is an analysis of protein expression to develop a proteomic signature of distant recurrence in HR+ 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 2025.

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 are used for model optimization and digitized HE-slides and clinical data of ABCSG-8 are planned to be 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 – is planned to be locked in 2025 and results are planned to be published thereafter.

Outlook and planned Studies 2025

ABCSG 61 / TEODOR
In the prospective, randomized, controlled, open label multicenter phase II study TEODOR (Neoadjuvant TrEatment Optimization driven by ctDNA and endOcrine Responsiveness), early and locally advanced breast cancer patients will be randomized according to their baseline ctDNA status and endocrine responsiveness, to either receive chemo- or endocrine therapy. TEODOR will be a national trial with approx. 15 sites planned in Austria. Study submission to the Ethics Committee is planned for Q1/2025 and study start estimated for Q2 2025.

ABCSG 63 / ERIKA
ABCSG 63 / ERIKA is designed as an open-label, two-arm, randomized, phase II study of elacestrant plus ribociclib vs. AI (and GnRH agonist in pre-/perimenopausal women and men) plus ribociclib as neoadjuvant therapy for endocrine-responsive, HER2 negative early breast cancer. The ERIKA trial will be conducted in Austria and Germany with approximately 18 trial sites participating to randomize a total of 120 patients. The CTIS submission of the study was done in early December 2024 and clinical trial authorization and subsequent study start are estimated for Q2 2025.

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 endocrine non-responsive ER+/HER2-negative early breast cancer. The study is sponsored by ABCSG and aims to enroll 80 patients across 8 sites in Austria. After the contract with the pharmaceutical partner Gilead was finalized in December 2024, protocol development will start in early 2025.

ABCSG 65 / DEFINITIVE
DEFINITIVE (Diagnostic HER2DX-guided treatment For patIeNts wIth early-sTage HER2-positIVE breast cancer) is an international phase III trial, sponsored by the Spanish Fundació de Recerca Clínic Barcelona-Institut d'Investigacions Biomèdiques August Pi I Sunyer, which will be funded by the European Union's Horizon Europe research and innovation program. In DEFINITIVE, 7 countries will participate to enroll 304 HER2-positve early breast cancer patients, who will be treated according to their HER2DX score. The trial aims to investigate the use of the HER2DX assay (REVEAL genomics) as genomic diagnostic tool to tailor neoadjuvant and adjuvant treatment.

Further internal study concepts are in different stages of development and negotiation with partners and those include breast cancer and colorectal cancer trials as well as translational research projects to be launched in the upcoming months and years.

ABCSG Events and Activities

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ABCSG Events and Activities

„SCIENCE FROM THE HEART OF EUROPE"

In addition to conducting clinical trials and publishing their results, ABCSG is committed to advancing medical education across Austria and beyond. In 2024, we offered a total of 8 CME-accredited programs, featuring the latest advancements in cancer diagnosis and treatment.

We were thrilled to meet colleagues from across Austria at our on-site events, where face-to-face interactions fostered valuable exchanges of ideas and collaborations. Equally significant, our webinars and virtual educational formats have become a powerful international platform, attracting participants from across the globe. This broad international reach highlights ABCSG's role as a leader in disseminating cutting-edge knowledge in cancer research and care.

The following pages showcase examples of ABCSG-developed formats and collaborative initiatives, designed to provide medical professionals in Austria and worldwide with expert insights, practical knowledge, and opportunities for active scientific exchange.

On-site Events & Activities

11. POST-SABCS

11th Post-SABCS (Vienna)

For the 11th time, the ABCSG brought the latest study data from the "San Antonio Breast Cancer Symposium – SABCS" to Austria in a compact format in proven cooperation with Universimed – with more participants than ever before! A total of 151 interested attendees joined, a new record which we are very pleased about.

ABCSG President Prof. Michael Gnant, who chaired a general session in Texas last December, led the Friday afternoon session with expertise, wit, and a critical eye. Our rapporteurs presented numerous new scientific findings, analyzing them from multiple perspectives. After the update presentations, our renowned interdisciplinary panel discussed the meaningful integration of these findings into clinical practice for the benefit of our patients.

Sciences & Cases (Pörtschach)

The popular continuing education format "Breast Cancer: Science and Cases", which had to be interrupted for several years due to the pandemic, finally took place live again on May 23 at the picturesque setting of Lake Wörthersee under the scientific direction of Dr. Gregor Huber.

A total of 41 participants from the fields of oncology, surgery, radiology, radiotherapy and general medicine attended. We were especially pleased with the large number of young physicians who braved the rainy weather to come to Pörtschach.

Upon registration, participants were divided into four small interdisciplinary groups. Following the presentation of four clinical cases by our ABCSG experts, the groups discussed the issues of the case and made a joint treatment decision. The results of the group work were then presented and discussed in the plenary session moderated by ABCSG President, Prof. Michael Gnant. Finally, our speakers presented the current state-of-the-art treatment decision and justified it based on the latest scientific data.

science into practice 2.0

Science into Practice (Vienna)

The colorectal cancer education format "Science into Practice" of the ABCSG Colorectal Branch, which could not take place live for several years due to the pandemic, welcomed nearly 50 participants on June 17 at the House of Engineers in Vienna.

The event chaired by Assoc. Prof. Dr. Lukas Weiss focused on the interdisciplinary scientific exchange of all disciplines involved in the research and treatment of rectal cancer at a high academic level, the presentation of current data and therapeutic developments in the individual disciplines with four keynote lectures on quite controversial topics, followed by a critical panel discussion that was lively and exciting.

The evening began with a presentation on MRI-based (re-)staging as a basis for treatment decisions, followed by a discussion on imaging interpretation. New neoadjuvant treatment concepts with radiotherapy and chemotherapy, their impact on response and relapse risk, and the role of immunotherapy for microsatellite unstable tumors were explored. After a short break, the focus shifted to the "watch and wait" strategy and salvage surgery for local recurrence.

breast cancer science and cases

ABCSG in touch (Innsbruck)

The innovative breast cancer training format for young physicians, led by Dr. Stephanie Kacerovsky-Strobl, took place for the first time in Innsbruck on June 25. Despite strong competition due to the decisive European Championship soccer match between Austria and the Netherlands, we were able to welcome 42 young doctors to an exciting event on the topic of breast cancer and pregnancy.

Two case studies served as the basis for practical presentations from all participating disciplines.

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Our experts spoke about genetic testing and the consequences of BRCA-mutations, presented radiologic alternatives during pregnancy and lactation, and explained changes in pathology. Systemic therapy options and (im)possible chemotherapy regimens, as well as local therapy options and reconstructive plastic surgery techniques, were clearly illustrated with clinical examples. After each lecture, our participants used the online voting tool Slido to confirm what they had heard in an interactive quiz.

A final panel discussion, moderated by Prof. Günther Steger, rounded off the educational evening.

NIFA®

23rd NIFA (Vienna)

NIFA (Neue Impulse in Fortbildung und Ausbildung), AstraZeneca's largest stand-alone breast cancer meeting organized each year in collaboration with the ABCSG, brought together breast cancer experts and healthcare professionals from all over Austria for its 23rd edition on October 4 and 5. As usual, the scientific program was developed in cooperation with the ABCSG and provided an update on the latest developments in breast cancer.

Scientific presentations of relevant data on local and systemic therapy were followed by a recap of this year's NIFA workouts.

As an annual highlight, this year's event once again featured Oxford-style debates with 4 up-and-coming young female physicians.

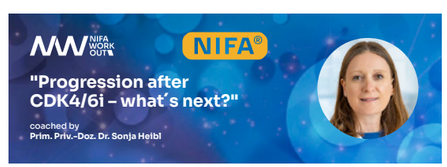
The grand finale of the event was the "Duel of the Giants". The topic of their discussion was only announced shortly before the start, after the audience had voted on Friday from three possible topics.

NIFA Workout 3.1: Rise of ADCs: Present and Future

The first NIFA Workout of 2024, chaired by Prof. Birgit Grünberger, focused on the "Rise of ADCs: Present and Future". The session featured recorded lectures as well as an expert round table discussing key aspects such as the clinical routine use of ADCs, resistance mechanisms and sequencing, as well as ILD detection and management from a pulmonary and radiological perspective. The on-demand videos provide in-depth insights into the evolving role of antibody-drug conjugates in oncology.

NIFA Workout 3.2: Progression After CDK4/6 Inhibitors – What's Next?

The second NIFA Workout of 2024, led by Dr. Sonja Heibl, focused on post-progression therapeutic strategies with CDK4/6 inhibitors in the treatment of HR-positive, HER2-negative metastatic breast cancer. Three expert lectures provide in-depth insights into critical aspects such as biomarker testing, maximizing endocrine therapy options in clinical practice, and subsequent treatment pathways. A high-level roundtable discussion further explores these key topics and provides a deeper understanding of the challenges and opportunities in managing this patient population.



18th Interdisciplinary Mamma Discourse (Vienna)

On October 9, the 18th Interdisciplinary Mamma Discourse took place at the Palais Berg in Vienna. Together with the Austrian Society of Senology, we were able to welcome a record number of 122 participants this year.

Guided by the motto "Revolutionizing Breast Cancer Care", ABCSG President Prof. Michael Gnant and Prof. Michael Fuchsjäger, President of the Austrian Society of Senology, led the highly topical program in their usual entertaining and confident dual conference style.

One of the world's most distinguished radiology experts, Christiane Kuhl from the University Hospital of Aachen – the undisputed "superstar" of breast imaging – kicked things off with a brilliant keynote lecture on "The Present and Future of Breast MRI".

The presentations that followed, provided a solid foundation for the two panel discussions that critically examined the future of breast cancer research. The discussions not only promoted a practical exchange between the ABCSG experts and the interested audience but also facilitated a debate on developments in breast cancer research.

ABCSG Annual Meeting (Saalfelden)

„SCIENCE FROM THE HEART OF EUROPE"

The 33rd Annual Meeting of the ABCSG was held at the Hotel Gut Brandlhof in Saalfelden on November 8–9, and was again a remarkable success. Under the leadership of Congress President Prof. Michael Gnant, the event provided an important platform for interdisciplinary exchange and presentation of significant advances in breast cancer research, colorectal cancer therapy, and translational science.

With over 230 attendees, the meeting highlighted breakthroughs in adjuvant therapies, new approaches to metastatic breast cancer, and innovative colorectal surgery techniques integrating technologies such as fluorescence angiography and artificial intelligence.

A strong emphasis was placed on translational research, bridging laboratory discoveries to clinical practice and fostering collaboration between senior scientists and early-career researchers. Special sessions allowed young investigators to present their work, while interactive discussions fostered knowledge transfer and inspired future partnerships.

Beyond the presentations, attendees had ample opportunity to network and socialize in a collaborative and engaging atmosphere.

EXPERTS ON TOUR®

Experts on Tour (Graz)

On November 20, the ABCSG continued its commitment to advancing breast cancer research and education in the periphery with the "Experts on Tour®" event in Graz. With 54 participants, engaging lectures, and a dynamic interdisciplinary panel discussion, the event was a resounding success.

The scientific program, led by Assoc. Prof. Gabriel Rinnerthaler and moderated by ABCSG President Prof. Michael Gnant, covered cutting-edge topics in breast cancer research, including advances in clinical trials, treatment strategies for luminal and triple-negative breast cancer, and challenges in toxicity management.

A special highlight was the interactive and interdisciplinary case discussion on axillary management. Experts from radiology, radiation therapy, surgery, and gynecology presented and discussed different perspectives, emphasizing the importance of collaboration to improve patient outcomes.

Online Education Formats

New in 2024: Surgery News by ABCSG Expert Prof. Florian Fitzal

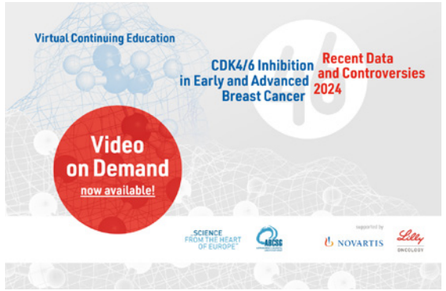
We are pleased to introduce our newest video format, "Surgery News"! Tailored specifically for our network of surgeons, plastic surgeons, allied health professionals, and investigators, this format provides clear and accessible video summaries of key scientific findings in breast cancer surgery, reconstructive surgery, and local therapies from the major international breast cancer meetings.

The inaugural edition focused on surgical highlights from SABCS 2024 - San Antonio Breast Cancer Symposium.

Science News by ABCSG-Expert Prof. Günther Steger

The Science News format offers our network of researchers a concise video summary of key highlights from the most significant breast cancer congresses. These video recaps are distributed to our members via the ABCSG newsletter and are also available for download on our website shortly after the events.

In 2024, ABCSG Science News covered the European Breast Cancer Conference (EBCC), ESMO Breast, ASCO, ESMO, and SABCS, and the format continues to be very popular, with over 3,000 views.



„SCIENCE FROM THE HEART OF EUROPE"

ABCSG AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

Webinar CDK4/6 Inhibitors

The virtual educational event "CDK4/6 Inhibition in Early and Advanced Breast Cancer - Recent Data and Controversies 2024" sponsored by Novartis and Eli Lilly took place on October 30.

A total of 116 participants from 15 countries joined the webinar, which was moderated by ABCSG President Prof. Michael Gnant.

Part 1 focused on CDK4/6 inhibitors in metastatic hormone receptor positive breast cancer, while part 2 focused on the latest data on the adjuvant use of CDK4/6 inhibitors.

The event concluded with a panel discussion on recent controversies and clinical implications. All speakers, joined by additional discussants, engaged in a dynamic discussion.

ABCSG PODCAST "Medicine in Context" Nutrition in cancer: study situation, prevention, myths and controversies, practical nutrition tips

Sarah Falkner, MSc, nutritionist and member of the Nutrition and Oncology Working Group of the Austrian Association of Nutritionists, and Dr. Laura Weidinger from the University Clinic for Gynecology and Obstetrics in Vienna, moderated by ABCSG President Prof. Michael Gnant, review the latest research and discuss prevention, side effect management, and food interactions during cancer therapy.

The podcast topics are further supplemented by the view on nutrition myths compared to current data and practical nutrition tips.

ABCSG PODCAST "Medicine in Context" Inspiring Careers in Senology: Spotlight on the Future

The latest episode of the podcast "Medicine in Context," created by the ABCSG Task Force "Future Now" explores career paths in senology with Prof. Alexandra Resch. The discussion covers the evolution of radiology and radiation therapy, the growing importance of interdisciplinarity in oncology, and ways to inspire young physicians to enter the field.

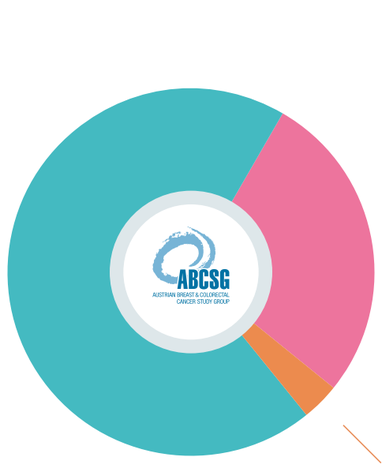
Listeners gain valuable insights into modern breast cancer diagnosis and therapy, as well as the challenges and opportunities shaping the future of senology.

Visitor Statistics 01. Jan. – 31. Dec. 2024

Visitors 81.085
Pageviews 175.806

Websites and Social Media

abcsg.org
Visitors 56.064
Pageviews 127.483



brustkrebsexperten.at
Visitors 22.166
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studynurses.at
Visitors 2.855
Pageviews 7.134

www.abcsg.org

offers an overview of all ongoing ABCSG trials for healthcare professionals, regular news and updates, event announcements and registration, as well as all our scientific publications.

www.brustkrebsexperten.at

provides comprehensive information on breast cancer and ongoing trials for patients, including contact details of respective healthcare professionals.

www.studynurses.at

serves as a dedicated platform for study nurses and study coordinators, offering opportunities for professional networking.

ABCSG's presence on social media platforms such as LinkedIn, X, and Instagram continues to grow, with a targeted approach to specific audiences remaining a key focus in 2025.

Public Relations and Press

Each year, the ABCSG's scientific activities and the dedication of its Board and Committee members receive significant media attention. In 2024, the ABCSG's press and public relations efforts again had a significant impact, with more than 70 appearances in popular science magazines and 17 scientific publications in prestigious journals such as The New England Journal of Medicine and The Lancet. Among these, the article "The future of clinical trials – goals, ideas, and discussion" by Prof. Michael Gnant et al., published in memo – Magazine of European Medical Oncology (April 18, 2024, Volume 17, 1/2024), provided key insights into the evolving landscape of clinical trials and the future direction of cancer research.

We are also proud to highlight the important contribution of our young researcher Dr. Eva Valentina Klocker et al. Her article "Clinical applications of next-generation sequencing-based ctDNA analyses in breast cancer: defining treatment targets and dynamic changes during disease progression", published in Molecular Oncology (June 12, 2024), presents valuable scientific findings on personalized treatment strategies based on ctDNA analysis.

The ABCSG continued its collaboration with Dialog Darm with a contribution by Prof. Lukas Weiss, Head of the ABCSG Colorectal Cancer Executive Committee, on organ preservation in rectal cancer. The article explored innovative treatment strategies such as Total Neoadjuvant Therapy (TNT), which integrates a full-course of radiation and chemotherapy prior to potential surgery. This approach is gaining traction as studies suggest that it may allow a significant number of patients to avoid surgery altogether.

ABCSG's research was also featured prominently in BIG's Research in Focus magazine. Issue 20 (April 2024) covered the ABCSG 63 / ERIKA (Elacestrant and RIbociclib in Ki67-tested endocrine responsive breAst cancer) trial, which will begin recruitment in Q2 2025. Issue 21 (November 2024) focused on advances in personalized breast cancer treatment, highlighting both the ABCSG 61 / TEODOR (Neoadjuvant TrEatment Optimization driven by ctDNA and endOcrine Responsiveness) and ABCSG 63 / ERIKA trials.

A major media highlight this year was the widespread coverage of Prof. Christian Singer's poster presentation at ASCO. His presentation on the long-term exploratory analysis of ABCSG 34, entitled "Addition of the MUC-1 vaccine tecemotide to neoadjuvant systemic therapy for patients with early breast cancer: Survival results from the prospective randomized ABCSG 34 trial", attracted attention in both print and online media. The study's findings were also discussed in a television interview, further reinforcing the ABCSG's role as a leader in clinical research and innovation.

For more than two decades, the ABCSG has co-published the journal krebs:hilfe! in collaboration with the Austrian Cancer Aid. In 2024, ABCSG continued to support the journal's expansion into digital formats, including an online magazine and newsletter, to ensure broader access to oncology information.

Through strategic press relations and long-standing relationships with national and international media, the ABCSG continues to bring groundbreaking scientific discoveries to the forefront, ensuring that they reach both the medical community and the general public.

Trial Office Activities

Clinical Monitors Meeting

From July 2-4, ABCSG's Clinical Monitoring Department gathered for its annual meeting in Senftenberg. The agenda focused on reviewing the status of ongoing trials, discussing upcoming projects, and addressing future challenges in clinical research monitoring. Together with ABCSG's Managing Director, Associate Directors, and the Head of Clinical Data Management, key milestones were defined, and pending study-related questions were resolved. A highlight of this year's event was the team-building activity "Escape the Hotel," which fostered collaboration and strengthened team spirit across departments.

Company Outing 2024

On August 13, the ABCSG team gathered in the picturesque Pielach Valley for this year's company outing. The morning began with a choice of three activities: a high ropes course, curling or a hike through the "Dirndl" Nature Garden.

Afterwards, the whole team gathered for a delicious lunch at the Steinschalerhof. The afternoon brought even more fun at Steinschaler Dörfl with the "Almolympiade", a teambuilding event that encouraged friendly competition and strengthened our team spirit.

Despite the rain, which forced the Olympics to be moved indoors, all the teams showed great competitive spirit, enthusiasm and teamwork. The day ended with a cosy barbecue in the village square, where the team braved the weather to share some great moments together.

ABCSG Runs 2024 – Together for a good cause and health

In 2024, the ABCSG team participated in several running events, the highlight of which was the 18th Medical University of Vienna Cancer Research Run on October 5. This charity event focused on raising awareness and funds for cancer research, and our team was proud to contribute to this important cause.

In addition to the Cancer Research Run, we also participated in the Vienna Night Run and set a new record with four relay teams in the Vienna City Marathon, emphasizing the role of sport in promoting health and well-being.

We thank our dedicated colleagues and look forward to continuing this tradition with even more participation in the years to come.

ABCSG Team-Meeting & Year-End Celebration 2024

At this year's ABCSG Team Meeting, we welcomed our new colleagues and honoured long-standing employees, before reviewing key financial figures and diving into important updates on IT security and technical advances, including new systems and regulatory developments.

Highlights from our ongoing and recruiting studies provided an insight into current research progress, followed by an overview of our translational research collaborations. The event concluded with a preview of planned trials and future ABCSG initiatives.

After a productive afternoon of updates and interdepartmental sharing, the team gathered for roasted chestnuts and mulled wine before finishing the evening with a delicious dinner, music and dancing.

"Driven by Many. United by Purpose."

40 FORTY YEARS ABCSG „40 YEARS OF SUCCESS IN ADVANCING RESEARCH"

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

Publications 2024 and Study Overview

„SCIENCE
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OF EUROPE"

ABCSG
AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

Publications 2024

Evolving treatment paradigms after CDK4/6 inhibitors in advanced breast cancer Position paper on optimized sequencing

Gnant M, Balic M, Singer CF, Rinnerthaler G, Pfeiler G, Suppan S, Grünberger B, Strasser-Weippl K, Castagnaviz V, Heibl S, Bartsch R

memo – Magazine of European Medical Oncology, published on 20 December 2024

Axillary Surgery in Breast Cancer — Primary Results of the INSEMA Trial

Reimer T, Stachs A, Veselinovic K, Kuhn T, Heil J, Polata S, Marme F, Muller T, Hildebrandt G, Krug D, Ataseven B, Reitsamer R, Ruth S, Denkert C, Bekes I, Zahm DM, Thill M, Golatta M, Holtschmidt J, Knauer M, Nekljudova V, Loibl S, Gerber B

NEJM – The New England Journal of Medicine, published on 12 December 2024

Benefit from dose-dense adjuvant chemotherapy for breast cancer: subgroup analyses from the randomised phase 3 PANTHER trial

Matikas A, Papakonstantinou A, Loibl S, Steger G, Untch M, Johansson H, Tsiknakis N, Hellström M, Greil R, Möbus V, Gnant M, Bergh J, Foukakis Th

The Lancet (Regional Health Europe), published December 2024

Reductions in recurrence in women with early breast cancer entering clinical trials between 1990 and 2009: a pooled analysis of 155 746 women in 151 trials

Early Breast Cancer Trialists' Collaborative Group

The Lancet, published on 12 October 2024

Monocyte subsets in breast cancer patients under treatment with aromatase inhibitor and mucin-1 cancer vaccine

Knöbl V, Maier L, Grasl S, Kratzer C, Winkler F, Eder V, Hayden H, Amparo Sahagun Cortez M, Sachet M, Oehler R, Frantal S, Fesl C, Zehetner K, Pfeiler G, Bartsch R, Fitzal F, Singer CF, Filipits M, Gnant M, Brostjan C

Journal of Translational Medicine, published on 8 October 2024

Clinical characterization, prognostic, and predictive values of HER2-low in patients with early breast cancer in the PALLAS trial (ABCSG-42/AFT-05/BIG-14-13/PrE0109)

Nader-Marta G, Singer C, Hlauschek D, DeMichele A, Tarantino P, de Azambuja E, Pfeiler G, Martin M, Balko JM, Nowecki Z, Balic M, Brufsky AM, Chan A, Morris PG, Haddad T, Loibl S, Liu Y, Soelkner L, Fesl C, Mayer EL, Gnant M; PALLAS groups and investigators

Breast Cancer Research, published on 7 October 2024

Standardized Definitions for Efficacy End Points for Adjuvant Trials — The Updated STEEP Criteria

Hlauschek D, Fesl C, Gnant M

JAMA Oncology, published on 19 September 2024

mFOLFOX6 versus mFOLFOX6 + aflibercept as neoadjuvant treatment in MRI-defined T3-rectal cancer: a randomized phase-II-trial of the German Rectal Cancer Study Group (CAO/ARO/AIO 0214) and the ABCSG (R-06)

Hofheinz RD, Herrle F, Dechow T, von Weikersthal LF, Welslau M, Lettmaier S, Burkart C, Kubicka S, Kochen L, Merx K, Krause K, Ebert M, Rödel C, Fokas E, Ghadimi M, Reissfelder C, Gaiser T

ESMO, published online on 10 September 2024

Tailored Dose-Dense Versus Standard Adjuvant Chemotherapy for High-Risk Early Breast Cancer: End-of-Study Results of the Randomized PANTHER Trial

Matikas A, Möbus V, Greil R, Andersson A, Steger GG, Untch M, Fornander T, Malmström P, Schmatloch S, Johansson H, Hellström M, Brandberg Y, Gnant M, Loibl S, Foukakis T, Bergh J; SweBCG, ABCSG and GBG

Journal of Clinical Oncology, published on 17 July 2024

Clinical applications of next-generation sequencing-based ctDNA analyses in breast cancer: defining treatment targets and dynamic changes during disease progression

Klocker EV, Hasenleithner S, Bartsch R, Gampenrieder SP, Egle D, Singer CF, Rinnerthaler G, Hubalek M, Schmitz K, Bago-Horvath Z, Petzer A, Heibl S, Heitzer E, Balic M, Gnant M

Molecular Oncology, published on 12 June 2024

Palbociclib combined with endocrine treatment in hormone receptor-positive, HER2-negative breast cancer patients with high relapse risk after neoadjuvant chemotherapy: subgroup analyses of premenopausal patients in PENELOPE-B

Marmé F, Martin M, Untch M, Thode C, Bonnefoi H, Kim SB, Bear H, Mc Carthy N, Gelmon K, García-Sáenz JA, Kelly CM, Reimer T, Valota O, Toi M, Rugo HS, Gnant M, Makris A, Bassy M, Zhang Z, Furlanetto J, Nekljudova V, Loibl S

ESMO Open, published on 9 June 2024

Fertility Preservation and Assisted Reproduction in Patients With Breast Cancer Interrupting Adjuvant Endocrine Therapy to Attempt Pregnancy

Azim HA Jr, Niman SM, Partridge AH, Demeestere I, Ruggeri M; Colleoni M, Saura C, Shimizu C, Saetersdal AB, Kroep JR, Mailliez A; Warner E, Borges VF, Amant F, Gombos A, Kataoka A, Rousset-Jablonski C, Borstnar S, Takei J, Lee JE, Walshe JM, Ruiz-Borrego M, Moore H, Saunders C, Bjelic-Radisic V, Susnjar S, Cardoso F, Klar NJ, Spanic T, Ruddy K, Piccart M, Korde LA, Goldhirsch A, Gelber RD, Pagani O, Peccatori FA

Journal Clinical Oncology, published on 29 May 2024

Prediction of survival after neoadjuvant therapy in locally advanced rectal cancer – a retrospective analysis

Piringer G, Ponholzer F, Thaler J, Bachleitner-Hofmann T, Rumpold H, de Vries A, Weiss L, Greil R, Gnant M, Öfner D

Frontiers in oncology, published on 16 May 2024

The future of clinical trials — goals, ideas, and discussion

Gnant M, Gili M, Schwarz M, Fesl C, Hlauschek D, Jallitsch-Halper A, Fohler H

Memo, published on 18 April 2024

Explained variation and degrees of necessity and of sufficiency for competing risks survival data

Gleiss A, Gnant M, Schemper M

Biometrical Journal, published March 2024

Early breast cancer: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up

Loibl S, André F, Bachelot T, Barrios CH, Bergh J, Burstein HJ, Cardoso MJ, Carey LA, Dawood S, Del Mastro L, Denkert C, Fallenberg EM, Francis PA, Gamal-Eldin H, Gelmon K, Geyer CE, Gnant M, Guarneri V, Gupta S, Kim SB, Krug D, Martin M, Meattini I, Morrow M, Janni W, Paluch-Shimon S, Partridge A, Poortmans P, Pusztai L, Regan MM, Sparano J, Spanic T, Swain S, Tjulandin S, Toi M, Trapani D, Tutt A, Xu B, Curigliano G, Harbeck N

Annals of Oncology, published February 2024

Is the CTS5 a helpful decision-making tool in the extended adjuvant therapy setting?

Wimmer K, Hlauschek D, Balic M, Pfeiler G, 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, Greil R

Breast Cancer Research and Treatment, published on 25 January 2024 (correction May 2024)

CONFERENCE ORAL PRESENTATIONS 2024

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

Presentation by 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

San Antonio Breast Cancer Symposium 2024, December 2024

PD-L1 and IRF1 expression is associated with improved therapy response in the prospective randomized neoadjuvant ABCSG 34 trial

Presentation by Heber U
Hlauschek D, Singer C, Egle D, Greil R, Helfgott R, Müller-Holzner E, Hauser-Kronberger C, Rudas M, Pfeiler G, Fitzal F, Lax S, Filipits M, Gnant M, Bago-Horvath Z, ABCSG

European Breast Cancer Conference, March 2024

CONFERENCE POSTERS 2024

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

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

San Antonio Breast Cancer Symposium 2024, December 2024

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

Poster by Heber U
Hlauschek D, Singer C, Egle D, Greil R, HelfgottR, Huber G, Muller-Holzner E, Hauser-Kronberger C, Rudas M, Pfeiler G, Bartsch R, Lax S, Filipits M, Rinnerthaler G, Gnant M, Bago-Horvath Z

San Antonio Breast Cancer Symposium 2024, December 2024

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

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

San Antonio Breast Cancer Symposium 2024, December 2024

Adaptive subtyping reflects tumour heterogeneity of treatment response to neoadjuvant therapy in hormone receptor-positive HER2-negative early breast cancer – PENELOPE-B

Poster by Denkert C
Rachakonda S, Filipits M, Weber K, Marmé F, Untch M, Witkiewicz AK, Im SA, DeMichele A, Pehl A, Van't Veer L,Jank P, Schem C, Fasching P, Reimer T, Knudsen E, Liu Y, Rojo F, Turner N, Loibl S

ASCO 2024, June 2024

Estimating benefit from dose dense adjuvant chemotherapy for early breast cancer in the PANTHER randomized phase 3 trial.

Poster by Matikas A
Gnant M, Johannson H, Untch M, Tsiknakis N, Greil R, Loibl S, Foukakis T, Berg JCS

ASCO 2024, June 2024

Tailored axillary surgery with or without axillary lymph node dissection followed by radiotherapy in patients with clinically node-positive breast cancer (OPBC-03/SAKK 23/16/IBCSG 57-18/ABCSG-53/GBG-101-TAXIS)

Poster by Weber WP
Matrai Z, Hayoz S, Tausch C, Henke G, Zimmermann F, Montagna G, Fitzal F, Gnant M, Ruhstaller T, Muenst S, Mueller A, Lelièvre L, Heil J, Kurzeder C, Egle D, Sávolt A, Heidinger M, Knauer M
ASCO 2024, June 2024

Analysis of the sensitivity to endocrine therapy (SET) assay in the PALLAS adjuvant trial of palbociclib in HR+/HER2- breast cancer (ABCSG-42/AFT-05/BIG-14-13)

Poster by Metzger O
Ballman KV, Gnant M, Watson M, Chen E, Tran K, O'Brien P, Hlauschek D, Martin M, Balko JM, Nowecki Z, Hahn OM, Denkert C, Curtis C, Liu Y, Dueck AC, Fesl C, Mayer EL, DeMichele A, Fraser W
ASCO 2024, June 2024

Addition of the MUC-1 vaccine Tecemotide to Neoadjuvant Systemic Therapy Improves Survival of Patients with Early Breast Cancer: Results from the Prospective Randomized ABCSG 34 Trial

Poster by Singer CF
Hlauschek D, Pfeiler G, Egle D, Bartsch R, Suppan C, Pichler A, Petru E, Greil R, Rudas M, Seifert M, Petzer AL, Fitzal F, Bago-Horvath Z, Filipits M , Soelkner L, Fesl C, and Gnant M; on behalf ot the Austrian Breast & Colorectal Cancer Study Group
ASCO 2024, June 2024

10P – PIK3CA mutation and response to neoadjuvant taselisib and endocrine therapy – a biomarker study of the LORELEI trial

Poster by Fimereli D
Nuciforo P, De Azambuja E, Wilson T, Prat A, Filipits M, Pfeiler G, Aimi J,Metcalfe C, Stout TJ, El-abed S, Gnant M, Oliveira M, Vincent D, Rediti M, Rothe F, Saura C, Andre F, Sotiriou C
ESMO 2024, May 2024

Abstract PO4-27-07: A Phase 3, randomized, open-label study of upfront camizestrant vs standard endocrine therapy as adjuvant treatment for ER-positive/HER2-negative early breast cancer with intermediate-high or high risk of recurrence (CAMBRIA-2)

Loibl S, Park Y, Tolaney S, Gioni I, Johnston S, Klinowska T, Mayer I, Nunes R, Pistilli B, Stuart M, Quintana A, Walding A, Gnant M
Cancer Research 2024, published May 2024

Study Overview

Study	Sponsor	Title	Status
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	open for enrollment
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	open for enrollment
ABCSG 53 / TAXIS	Universitätsspital Basel (USB)	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 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
C08 / EXERCISE II	ABCSG	Randomized trial of endurance exercise following adjuvant chemotherapy for colorectal cancer	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

Study	Sponsor	Title	Status
ABCSG 36 / PENELOPE[B] ETERNITY	GBG	Phase III trial to evaluate palbociclib (PD-0332991), a cyclin kinase 4/6 inhibitor, in patients with hormone receptor positive, HER2-negativ primary breast cancer and a high risk of relapse following neoadjuvant chemotherapy **Eternity**: Registry for long-term follow-up of safety and efficacy parameters of GBG study participants	treatment / follow-up
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 43 / INSEMA	University of Rostock	Comparison of axillary sentinel lymph node biopsy versus no axillary surgery in patients with stage I and II invasive breast cancer and breast-conserving surgery: a randomized prospective surgical trial	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 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
ABCSG P02	ABCSG	A prospective randomized phase II trial of FOLFIRINOX alone versus FOLFIRINOX followed by radiochemotherapy in patients with locally advanced, primarily inoperable pancreatic cancer	treatment / follow-up

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„40 YEARS OF SUCCESS IN ADVANCING RESEARCH“

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40 FORTY YEARS ABCSG

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