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Austrian Breast & Colorectal Cancer Study Group

Annual Report

Austrian Breast & Colorectal Cancer Study Group 2023

„SCIENCE FROM THE HEART OF EUROPE“

ABCSG
AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

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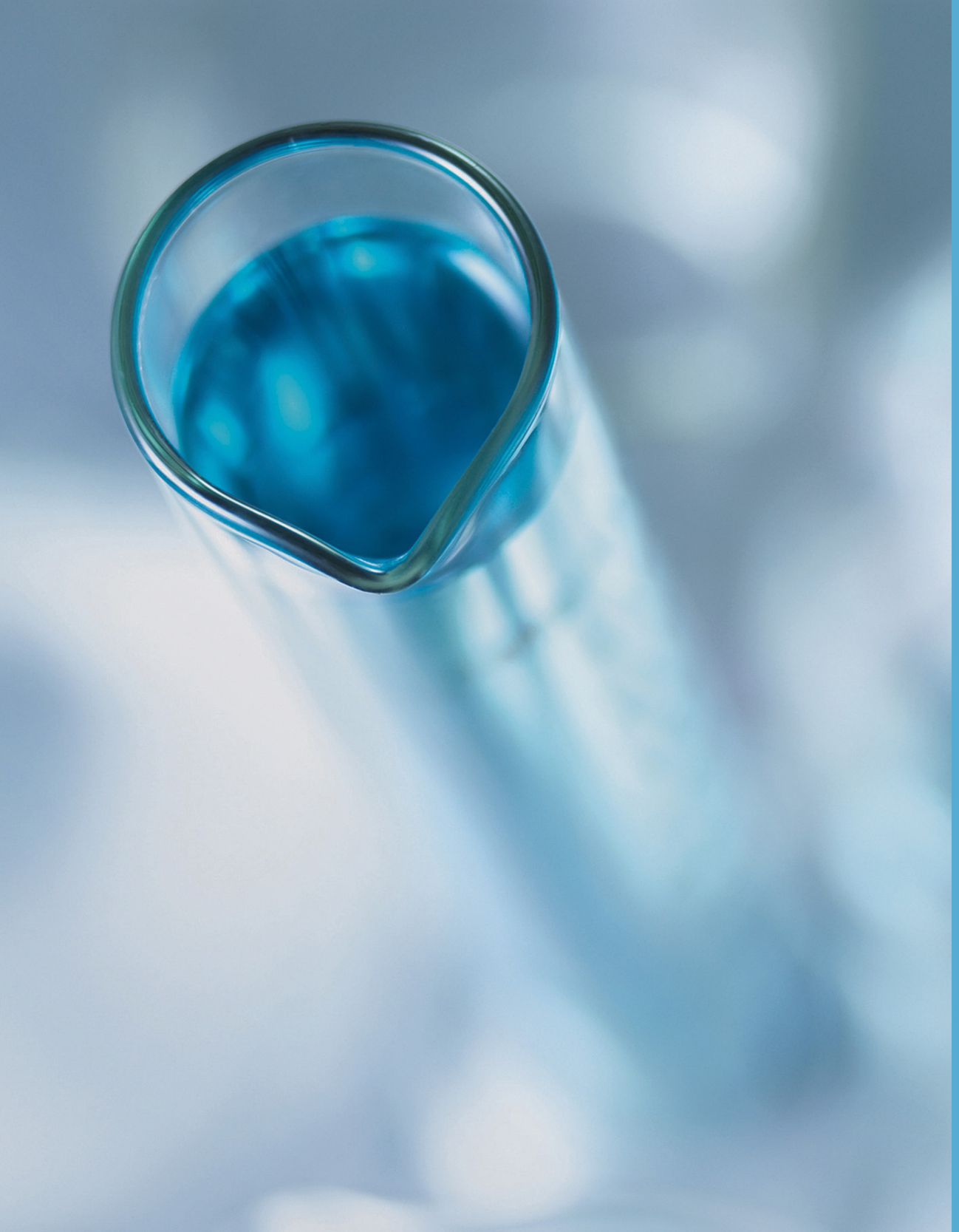

Introduction and Key Facts

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ABCSG Activities in Austria and Worldwide – Looking Back at 2023 in Clinical Research

2023 has been a year of even more geopolitical and global economic tension, including violent conflicts and high inflationary pressures that are also affecting research and clinical care to certain extents. Despite these challenges, the research efforts of ABCSG – together with many partners around the globe – continue to provide new scientific knowledge for the benefit of breast cancer patients in Austria and worldwide.

In the past year, our expertise has been acknowledged through oral and poster presentations at the most important breast cancer conferences and through numerous scientific publications. Particular highlights were the presentation of the positive results of ABCSG 52 / ATHENE by Prof. Gabriel Rinnerthaler and the ABCSG 22 Registry presentation on the associated quality of life survey by Prof. Vesna Bjelic-Radisic at ESMO Breast, presentations on ABCSG 42 / PALLAS as ASCO virtual plenary (Stage IIA subgroup analysis by Prof. Angela DeMichele), at SABCS (Genomic subtypes based on RNA sequencing by Dr. Daniel Stover), and the PALLAS publication (Influence of BMI on therapy-related adverse events, dose reductions and study discontinuations) by Prof. Georg Pfeiler, which was prominently placed in the Journal of Clinical Oncology. Two PALLAS poster presentations at SABCS and the successful collaboration with the young Canadian researcher Dr. Ana-Alicia Beltran-Bless, which led to the publication of ABCSG 12 data (Treatment regimen and bone health) in the European Journal of Cancer, should also be mentioned. The final results of the ABCSG 18 zoledronic sub-study were presented as posters by Prof. Georg Pfeiler at SABCS and ASBMR and the full manuscript is awaited in 2024. By participating in international academic projects, ABCSG is helping to answer other important questions, as evidenced by its co-authorship of several publications in the past year (including e.g. ABCSG 48 / POSITIVE and ABCSG 53 / TAXIS).

We also had a very successful operational year: enrollment in ABCSG 45 and ABCSG 56 / SASCIA was completed, and the ABCSG 55N / AMBHER, ABCSG 12 follow-up project with Cepheid and ABCSG 60 / CAMBRIA-1 studies were successfully activated. The set-up phase of ABCSG 62 / CAMBRIA-2 required a lot of efforts and dedication, and that study was launched globally in Q4 2023. In this context, the ABCSG coordinates a network of 8 academic study groups in 8 countries as the "lead cooperative group" (COOP) and will also be responsible for validating the data collection and analysis from an academic perspective. In addition to the introduction of technical innovations in our trial office (e.g. new CTMS, eTMF, QMS software) and the execution of numerous exciting translational projects (e.g. Artera, ProCan), we will expand our study portfolio in 2024 with the launch of ABCSG 61 / TEODOR, ABCSG 63 / ERIKA and ABCSG 65 / DEFINITIVE. We are also working intensively on new topics and research areas within our Colorectal Task Force (e.g. TNT Rectal Cancer Registry) as well as newly designed study protocol in breast cancer with agents such as antibody-drug-conjugates (ADCs)

To ensure the future of breast and colorectal cancer research within the ABCSG, we have developed and negotiated a new model of collaboration ("hybrid" resp. "transparency" model) between industry and academic partners based on sustainable management that will allow us to remain optimistic about the future of academic clinical trial conduct, ensuring high quality data and independent validation of results as well as a strong scientific and patient recruitment contribution from the academic network.

In addition to conducting clinical trials and publishing the results, the ABCSG organizes several annual educational events, both online and on-site, on a national and international level. The aim of these efforts is to share the latest research findings and their implementation into clinical practice with breast cancer specialists as well as referring physicians and young medical professionals and to facilitate interdisciplinary scientific discourse.

We not only fulfill our educational mission towards the next generation with interdisciplinary training events, but also through the activities of our task force "Future Now", an association of young talents within the ABCSG. In addition, we regularly appoint young scientists as Leading Co-Investigators in our translational research projects.

As in the past, the ABCSG Annual Report provides you with an overview of our trial projects and related activities, which are carried out with great dedication, expertise, and team spirit.

We hope you enjoy reading it!

Sincerely,
Michael Gnant, Marija Balic, Richard Greil,
Christian Singer and Christian Marth
President and Vice Presidents, on behalf of
ABCSG

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ABCSG Key Facts 2023

effective date 31 Dec 2023

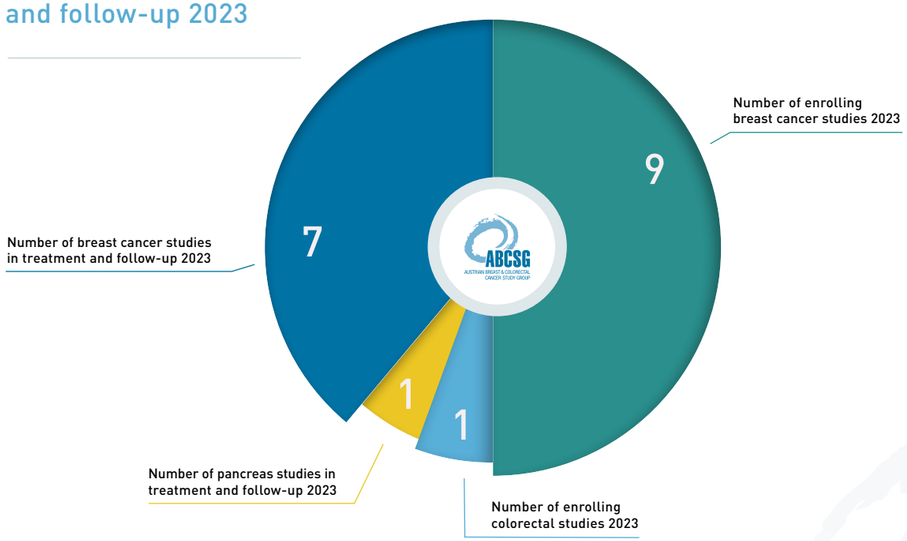
Number of all patients ever enrolled

29.289

Number of ...

... translational projects 2023	3
... enrolling studies 2023	10
... studies in treatment phase and follow-up 2023	8

Clinical studies in enrollment, treatment and follow-up 2023



Number of ...

... all ongoing breast cancer studies in 2023	16
... all ongoing colorectal studies in 2023	1
... all ongoing pancreas studies in 2023	1

187

Total Publications ABCSG (peer reviewed)

Publications 2023 (peer reviewed)	11

Austrian Breast and Colorectal Cancer Study Group (Association)

Year of foundation: 1984

9 Board members
12 Members Executive Committee
33 Members General Assembly

Tax status: non-profit

ABCSG GmbH

Year of foundation: 2015

Ownership:
99 % Association, 1 % Persons

Commercial Managing Director:
Mag. Hannes Fohler

Scientific Managing Director:
Prof. Dr. Michael Gnant

Current purpose: legal entity for international registration study PALLAS

Research Services GmbH

Year of foundation: 2022

Ownership:
99 % Association, 1 % Persons

Commercial Managing Director:
Mag. Hannes Fohler

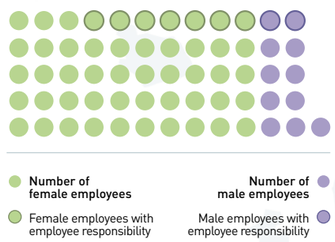
Scientific Managing Director:
Prof. Dr. Michael Gnant

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

14.9 years ...

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

Employees (Head Count)



Structure, Aims, Visions and International Network

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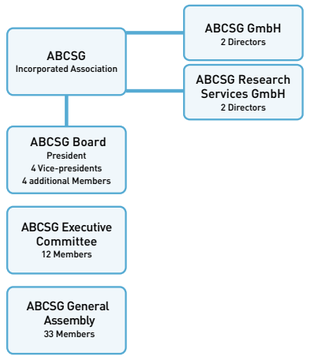
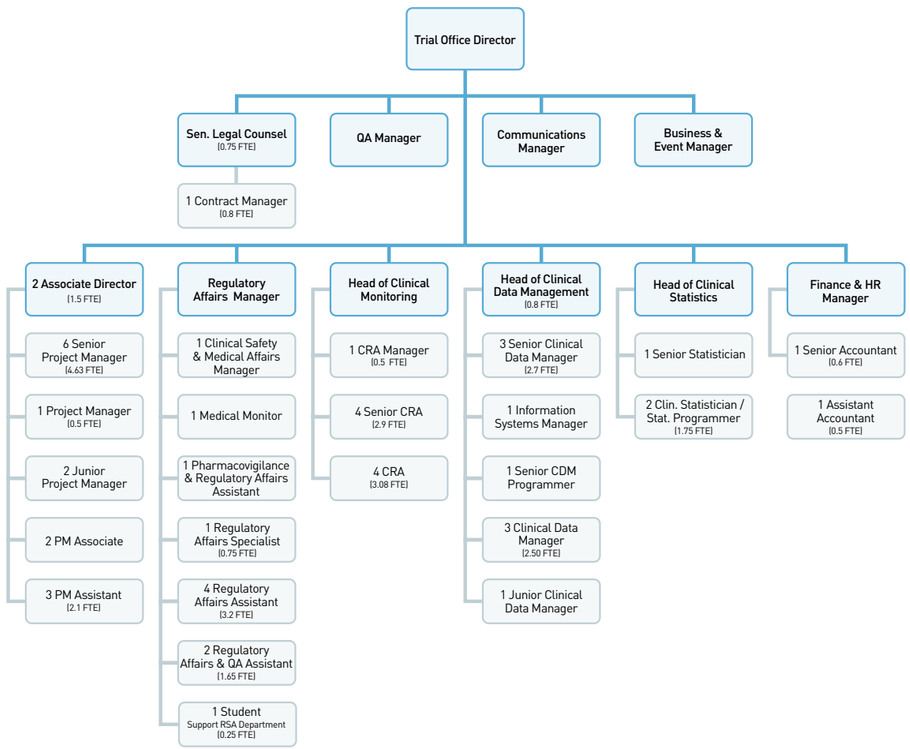
ABCSG Structure



ABCSG Trial Office

60 Employees (50.23 FTE)
1 Student (0.25 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 and, where necessary, 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, due to the high medical need, studies on pancreatic cancer were launched since 2013. 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. The name Austrian Breast & Colorectal Cancer Study Group (ABCSG) is in use as the organization name but since 2015 and 2022, respectively, there are also two subsidiary entities available for dedicated projects. Their main purpose is 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

Overall, the **ABCSG is part of a network of (breast) cancer study groups** encompassing more than 70 countries on all continents. The ABCSG is involved in BIG (Breast International Group) sponsored studies as well as studies of several partner organizations in and outside of Europe, but also directly acts as a legal sponsor of international studies where these partner organizations participate.

However, the ABCSG also collaborates with other organizations beyond this network: a particular example is the **transatlantic academic collaboration** with Alliance Foundation Trials (AFT) in the context of the phase III PALLAS trial. While AFT has the legal responsibility for this collaborative study project in the USA, ABCSG acts as legal sponsor in 20 countries and coordinates about 250 study sites. The ABCSG is supported by many academic and commercial partners in this largest study to date, with the coordination of these multiple stakeholders being the responsibility of the professional team at the trial office headquarters. 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 BRCA-P (for *BRCA* mutation carriers) where ABCSG coordinates this multinational, double-blinded study in 7 countries.

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 fairly new collaboration model on the horizon of the clinical trial landscape could be successfully launched in 2023 in the format of a **transparency model**, where a new **hybrid of working together between pharmaceutical industry and CROs with the involvement of academic study groups** such as ABCSG 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 8 countries who are responsible for about a third of enrolled patients in that study which was launched in Q4 2023.

Furthermore, in **translational projects of the ABCSG**, there have been intensive collaborations with international partners, including the Centre for Cancer Prevention of the Wolfson Institute of Preventive Medicine at Queen Mary University of London, biotech companies such as Nanostring, Agendia, Cepheid, Myriad, OncoMark, ProCan and Artera 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.

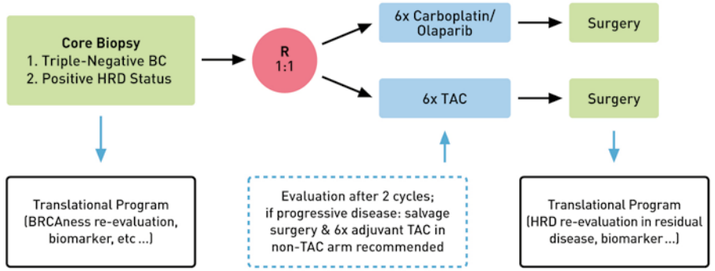
ABCSG 45

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**

Design:



Description and status:

ABCSG 45 is an open, randomized phase II study, aiming to enroll 90 patients with early triple-negative breast cancer and homologous recombination deficiency (HRD) in their tumor tissue. The patients are 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 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 is 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. 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 has been open for recruitment of additional 70 patients from June 2021 to December 2023. The final 90th patient was enrolled on December 13th, 2023 and recruitment closed.

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. A total of 20 ABCSG 45 patients is eligible to participate in this substudy, which will be ongoing in 2024.

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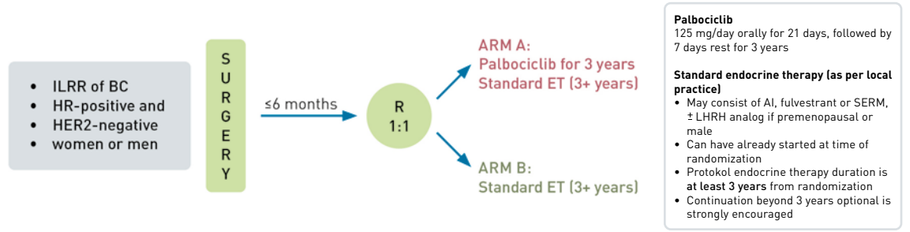
ABCSG 49 / POLAR

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: **Marija Balic** (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 hormone-receptor positive (HR+) / human epidermal growth factor receptor 2 (HER2)-negative 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-positive/ HER2-negative breast cancer, there is interest in whether the benefits of CDK4/6 inhibition may translate into the adjuvant setting which is the purpose of the POLAR trial.

The trial is sponsored by ETOP IBCSG Partners Foundation and started with "First Patient In" in Switzerland in August 2019. Globally, a total of 51 sites are participating in countries such as Italy, Spain, Switzerland, Hungary, France as well as four sites in Austria. In order to enroll 400 patients worldwide, the recruitment phase will last until December 2024. As of December 2023, a total of 322 patients were enrolled into the POLAR Trial, reaching 80 % of the targeted accrual goal. In Austria, all four sites are active and 15 patients were randomized so far.

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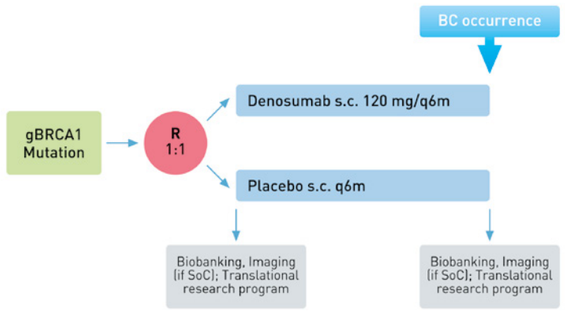
ABCSG 50 / BRCA-P

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

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.

A total of 2.918 healthy women with a *BRCA1* germline mutation shall be randomized worldwide. Next to Austria, also Australia, Germany, Israel, Spain, the UK, and the US are involved in this trial. All countries are actively enrolling in the trial and a total of 257 women had been recruited so far, out of which 64 participants were included at Austrian sites. Additional sites are selected for participation in various countries such as Spain, Israel and UK to increase patient recruitment, which is behind projection so far.

The primary analysis is planned once 167 primary endpoint events occur, the primary endpoint is defined as the occurrence of breast cancer. 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.

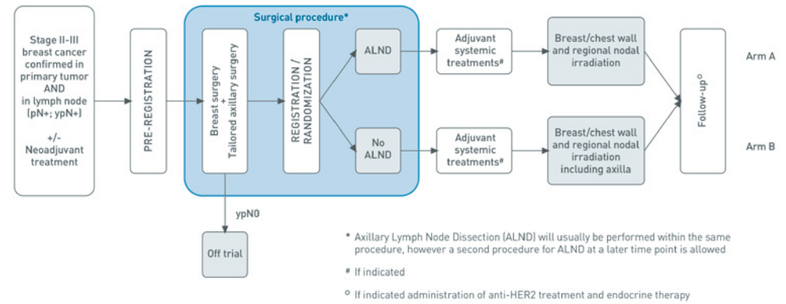
ABCSG 53 / TAXIS

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 2023, a total of 99 Austrian patients were included and 914 globally. Recruitment is projected to be open until end of 2025.

In 2023, the results of pre-defined endpoints, assessed while recruitment is ongoing, were published in the various scientific journals, such as Breast Cancer Research and Treatment (Tausch et al., DOI: 10.1007/s10549-023-06999-9), Journal of American Medical Association (Weber et al., DOI: 10.1001/jamasurg.2023.2840), Annals of Surgical Oncology (Weber et al., DOI: 10.1245/s10434-023-14404-4), and in The Breast (Heidinger et al., DOI: 10.1016/j.breast.2023.03.005).

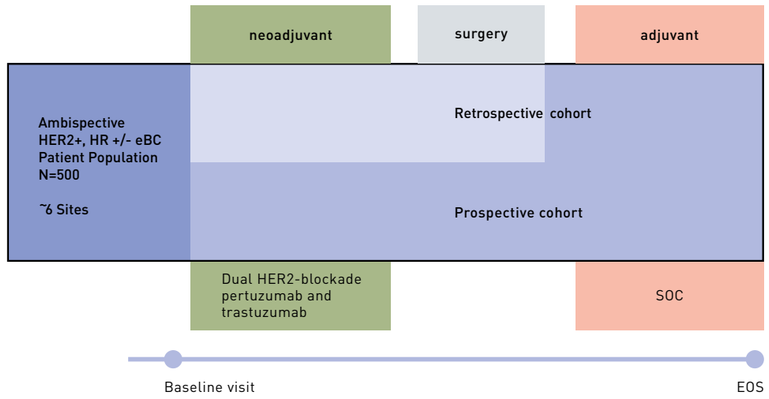
ABCSG 55N / AMBHER

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 2023, 166 patients had been registered for the study at seven sites throughout Austria.

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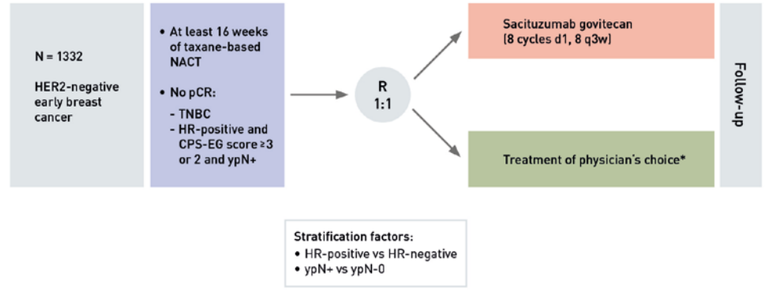
ABCSG 56 / SASCIA

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:	Sample size:	Sponsor:
12/2020 (global) **09/2022** (national)	**1.332**	**GBG**

Design:



* **Capecitabine** (8 cycles) or **platinum-based chemotherapy** (8 cycles) or **observation/endocrine therapy**. **Pembrolizumab** in patients with TNBC who received pembrolizumab as neoadjuvant therapy is allowed as monotherapy in the TPC arm.
Background therapy: in patients with HR-positive breast cancer, endocrine-based therapy will be administered according to local guidelines.

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.

According to the approved protocol v2.0, the global enrollment target is 1.332 patients with end of recruitment planned for Q1 2024. In Austria, 14 out of 15 planned sites were activated for study recruitment (unfortunately with a delay in activation), whereof 13 sites were still active at the end of 2023. On December 1st, 2023, screening was stopped globally and 34 patients were randomized in Austria, with the last patient enrolled on November 30th, 2023. As of December 27th, 2023, the global enrollment target had already been exceeded with 1.359 randomized patients.

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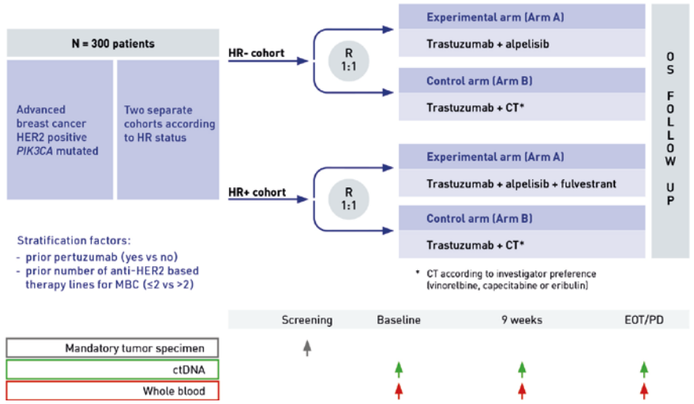
ABCSG 57 / ALPHABET

A randomized phase III trial of trastuzumab + ALpelisib +/- fulvestrant versus trastuzumab + chemotherapy in patients with PIK3CA mutated previously treated HER2-positive Advanced BrEasTcancer

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

Start of study:	Sample size:	Sponsor:
10/2021 (global) **09/2022** (national)	**252**	**GEICAM**

Design:



CT: chemotherapy,
ctDNA: circulating tumor deoxyribonucleic acid,
EOT: end of treatment,
HER2: human epidermal growth factor receptor 2,
HR: hormone receptor,
MBC: metastatic breast cancer,
OS: overall survival,
PD: progressive disease,
PIK3CA: phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha gene,
R: randomization.

Description and status:

The ALPHABET trial evaluates the efficacy and safety of the PI3K inhibitor alpelisib, given to patients with HER2-positive breast cancer and a *PIK3CA* mutation. *PIK3CA* mutations can be linked to cancer growth and might lead to resistance to anti-HER2 therapy. The patient cohort consists of advanced or relapsed HER2-positive breast cancer patients, who had been pre-treated with trastuzumab and have a *PIK3CA* mutation determined. The HR status defines the patient cohort, whereof HR- patients randomized to arm A receive trastuzumab and alpelisib or trastuzumab and chemotherapy in arm B. HR+ patients receive a combination therapy of trastuzumab, alpelisib and fulvestrant in arm A or trastuzumab and trastuzumab and chemotherapy in arm B.

The study accrual target is 252 patients, 120 in the HR-cohort and 132 in the HR+ cohort with an initially estimated recruitment period of 38 months. In December 2023, the study leadership together with the funding partner Novartis and in consultation with the Independent Data Monitoring Committee, has communicated halting the accrual and prematurely terminating the ALPHABET study. Challenges in accrual and site activation, low incidence of the targeted population and the rapidly evolving treatment landscape, as well as ethical considerations to enroll patients in a study that is unlikely to reach relevant conclusions of scientific questions and financial aspects were drawing factors to ultimately decide to discontinue the trial.

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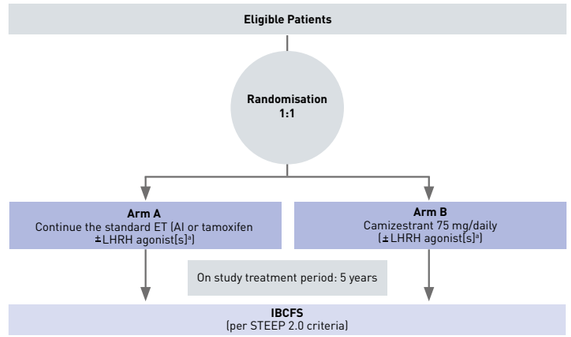
ABCSG 60 / CAMBRIA-1

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+/HER-2 negative early breast cancer patients with an intermediate to high risk of recurrence. Patients must have completed definitive locoregional therapy and at least 2 years of standard endocrine therapy without disease recurrence at time of enrollment and at least another 5 years of standard endocrine therapy treatment must be foreseen. The primary endpoint of CAMBRIA-1 is to demonstrate superiority of extended therapy with camizestrant as compared to standard endocrine therapy by assessment of invasive breast cancer-free survival (IBCFS). Patients will 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.

The recruitment period is envisioned to be 40 months, closing recruitment in Austria in August 2025. The first patient in Austria was randomized on September 25th, 2023 by the team at the Pyhrn-Eisenwurzen Klinikum Steyr under the supervision of PI Dr. Dieter Rossmann. 11 of 14 Austrian sites were activated by the end of 2023, with a total of 30 randomized patients. Enrollment at Austrian sites has significantly exceeded any projections within the first four months of the enrollment phase.

SCIENCE FROM THE HEART OF EUROPE | ABCSG | CAMBRIA-1

Studies open for Enrollment

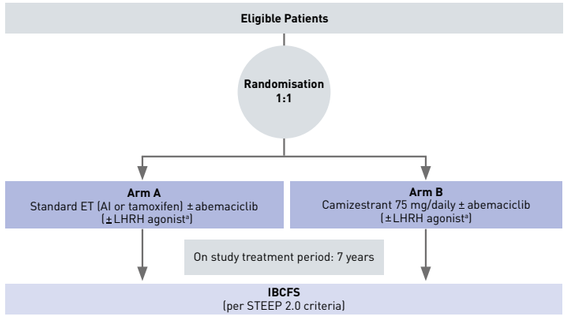
ABCSG 62 / CAMBRIA-2

A phase III, open-label, randomized study to assess the efficacy and safety of Camizestrant (AZD9833, a next generation, oral selective estrogen receptor degrader) versus standard endocrine therapy (aromatase inhibitor or Tamoxifen) as adjuvant treatment for patients with ER+/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 will 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.

Patients will be followed-up for a total period of 14 years after randomization, whereas the recruitment period is estimated for 3,5 years. It is planned to conduct the trial in 700 sites worldwide in more than 40 countries under the coordination of AstraZeneca, Fortrea and ABCSG. 9 countries were selected to be part of the ABCSG network of academic cooperative study groups: Austria, Australia, France, Germany, Ireland, New Zealand, Spain, Switzerland and partly the US. In Austria, 16 sites will participate in the trial. The first patient was already enrolled in October 2023 in Canada and first sites within the ABCSG network are planned to get activated in March / April 2024 with an expected FPI shortly thereafter.

SCIENCE FROM THE HEART OF EUROPE™ · ABCSG · CAMBRIA-2

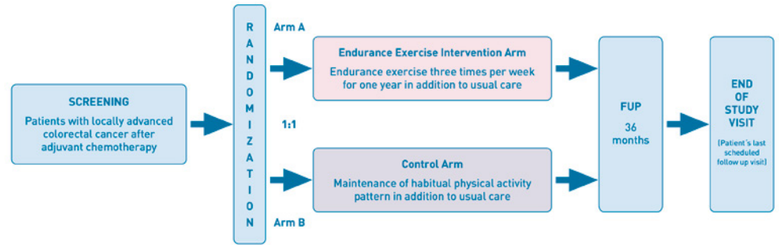
ABCSG C08 / EXERCISE II

Randomized trial of endurance exercise following adjuvant chemotherapy for colorectal cancer

Coordinating Investigator: **Josef Thaler** (Wels-Grieskirchen) with transition to **Gudrun Piringer** (Linz) at the end of the year

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

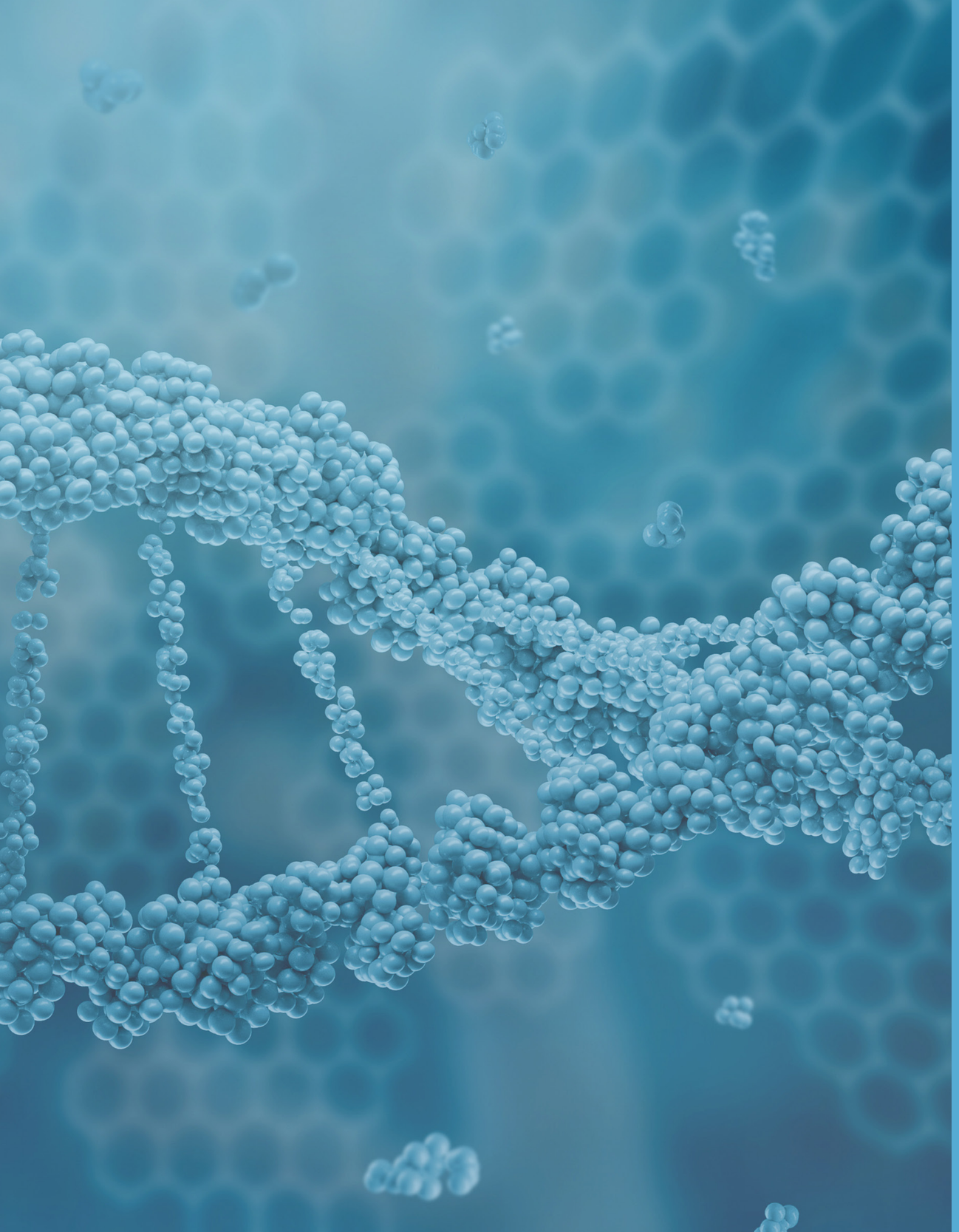
Design:



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 have the opportunity to participate in a study aiming to reduce relapse rates and improve the quality of life by an increase of their physical activity. Patients 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 2023, a total of 79 patients had been included at 8 activated Austrian sites.

SCIENCE FROM THE HEART OF EUROPE™ · ABCSG · ABCSG-C08 EXERCISE



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:	Sample size:	Sponsor:
11/2013 (global) **07/2015** (national)	**1.250**	**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 hormone receptor (HR)-positive / human epidermal growth factor receptor 2 (HER2)-negative 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.

Following the recommendation of the trial´s Independent Data Monitoring Committee (IDMC), the long term-follow up will continue beyond the end of the PENELOPE^{B} study. Moreover, translational research projects and subgroup analyses will be carried out. In Austria, the long-term follow-up continues within the ETERNITY registry (GBG 107, Registry for long term follow-up of safety and efficacy parameters of GBG study participants). After regulatory approval had been received in the spring of 2022, the study registration phase was initiated in Austria. 7 of the 8 initially planned Austrian sites were released for patient registration. At these 7 sites, 10 out of 15 patients potentially available could already be registered. According to the IDMC recommendation, dated November 28th 2023, the project will continue as planned.

ABCSG 39 / APHINITY

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

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

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

Sample size: **4.800**

Sponsor: **Roche**

Description and status:

The APHINITY trial included patients with newly diagnosed primary invasive, HER2-positive 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 is closed globally and in Austria, a total of 52 patients could be included in the APHINITY study at 11 sites. The trial is currently in the follow-up phase. The results of the 3rd interim analysis on Overall Survival (OS) were presented at the Annual Meeting of the "European Society of Medical Oncology"(ESMO) in a virtual plenary session in July 2022. Results of the cardiac safety analysis were published in February 2023 in ESMO Open (Azambuja et al, DOI: 10.1016/j.esmoop.2022.100772)

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 study project, exploring the efficacy and safety of study medication 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 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. Olaparib is now approved by the US FDA for adjuvant treatment of patients with *BRCA*-mutated HER2-negative high risk early breast cancer who have already been treated with chemotherapy either before or after surgery. In 2024, the transition to the EU platform in accordance with the Clinical Trial Regulation (CTR), a database lock for an additional interim analysis as well as patient retention will be the main challenges.

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. This result led the Independent Data Monitoring Committee (IDMC) to recommending to prematurely end the treatment phase of PALLAS. Upon the subsequent Steering Committee (SC) decision, all remaining active PALLAS patients were moved to the follow-up phase of the trial in June 2020.

The follow-up phase is conducted as per protocol until 2028 and biosample collection during follow-up for the translational research program Trans-PALLAS was even extended with the last implemented protocol amendment to collect additional blood samples 7- and 10-years post-randomization, respectively. The event size pre-defined to trigger the final analysis was reached in late 2020, with 469 documented invasive Disease-Free Survival (iDFS) events. That analysis dataset was presented prominently in an oral presentation at SABCS 2021 and in a parallel publication released by the Journal of Clinical Oncology. Additionally, the date of awareness for the pre-defined, event-driven stage IIA update analysis was reached in late 2021 and that data set was subsequently presented at the virtual ASCO monthly plenary session in October 2022. Keeping as many PALLAS patients in the extensive, ongoing follow-up phase of the study is a main aim of the current study phase. This will continue to ensure patient safety through close long-term monitoring and is continuously generating a valuable data resource that 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, are well under way. RNA sequencing of all available baseline tumor samples is completed, and the generated data resource will be made available for future scientific projects. First analysis within the extensive RNA sequencing data set were presented at SABCS 2023.

More deep and extensive analyses and insights from this data set are expected throughout the upcoming years. Additionally, 18 exploratory clinical or translational research proposals were endorsed by the PALLAS steering committee after being submitted through the first PALLAS harmonized, international research call for proposals. These projects are conducted in close collaboration between the researchers and both sponsors. First projects were already addressed and completed, with results presented also at the SABCS 2023. The remaining projects will keep all global teams engaged with this cohort and related research questions for many more years to come.

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: **5.505**

Sponsor: **University of Rostock**

Description and status:

This prospective surgical study headed by the University of Rostock investigates 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 in 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. The primary endpoint is invasive disease-free survival (IDFS) after breast-conserving surgery. A total of 158 patients were randomized at Austrian sites, 132 of these in Salzburg who took part in both randomization steps. Patients are currently in follow-up and the final analysis is planned for the end of 2024.

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. Four ABCSG sites, namely centers in Graz, Salzburg, Vienna, and Innsbruck are participating in this trial. 518 patients were enrolled, thereof seven in Austria.

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: 10.1056/NEJMoa2212856.). The trial is already 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.

Studies in Treatment Phase and Follow-up

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: 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 by two participating Austrian trial sites.

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**

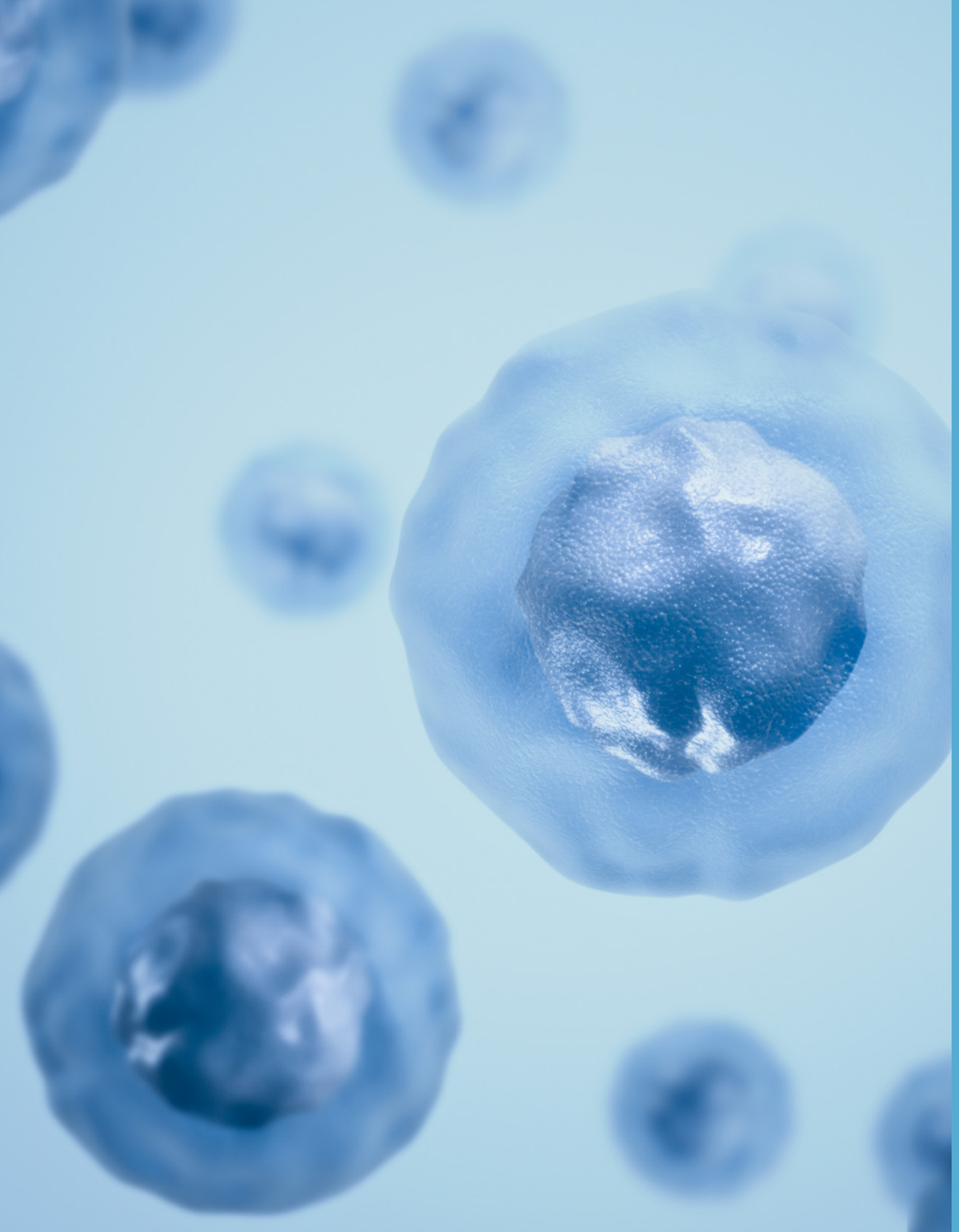
Sponsor: **ABCSG**

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 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. Patient treatment and study follow-up is continued as planned per study protocol.

Studies in Treatment Phase and Follow-up



Translational Projects and upcoming Studies

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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 and is planned to be validated in various ABCSG cohorts as well.

Work is continuing in a number of Cepheid work packages in parallel: for the Trax&Vields-05 project (ABCSG-34 cohort), clinical follow-up data was collected from former ABCSG-34 trial patients. This data is used to validate a prognostic breast cancer signature and for further explorative analysis of the STRAT4 test. All laboratory work on available tumor samples stored from this cohort in the ABCSG biobank and statistical analysis have been completed, including the analysis using the extended clinical follow-up data. A scientific publication describing this work is expected in 2024.

Ongoing progress was also made in the TraX-&Vields-02 work package (ABCSG-8): after receiving full approval, the laboratory work commenced and statistical analyses will be performed to validate the STRAT4 and Breast Cancer Insight tests.

Additionally, efforts were started to commence a new sub-project (TraX&Vields-08) in the ABCSG-6 cohort, to also validate the prognostic breast cancer Insight signature here.

In the work packages concerning the ABCSG-12 cohort, the protocol for validating the STRAT4 test and prognostic signature is finalized and approved by local authorities. Former ABCSG-12 sites are involved in collecting clinical follow-up data of ABCSG-12 patients and in centralizing tumor samples of these patients in the ABCSG central research facility in Vienna. The year 2023 focused on site initiations and activations of participating sites. Per end of 2023, 11 sites were activated to start contacting and re-consenting former ABCSG-12 patients, for whom archived tumor material is still available to be centralized.

The **ABCSG TR ProCan** collaboration is an analysis of protein expression to develop a proteomic signature of distant recurrence in hormone receptor-positive (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, are being facilitated for this project. The results of all analyses are being evaluated and a publication is planned for 2024.

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 of ABCSG-6 and ABCSG-8 cohort biosamples are planned to be used as training cohort, with ABCSG-12 cohort planned to serve as validation cohorts for the signature. In 2023, the ethics approval was received and work on the training cohort was initiated.

Outlook and planned Studies 2024

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.

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 study is currently in the final set-up phase with first patients planned to be enrolled in 2024.

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

In addition to clinical trials and the publication of their results, the ABCSG made a concerted effort to expand medical education through online and on-site trainings, as well as to increase our presence on social media platforms to raise awareness of clinical cancer research. We offered a total of 11 CME-accredited formats, focusing on the latest advances in cancer diagnosis and treatment.

We were very pleased and grateful to meet our colleagues from all over Austria at our on-site events, where we were able to exchange ideas and forge new collaborations face-to-face. However, the successful virtual formats with broad international participation introduced by the ABCSG during the COVID-19 pandemic have been retained due to strong demand and will be further developed and expanded in 2024.

The following are examples of ABCSG-developed formats and collaborative educational events. These efforts are designed to provide knowledge, expertise, and active scientific discourse to target audiences in Austria and beyond.

On-site Events & Activities

Post-SABCS: 10th Anniversary

Together with our long-standing cooperation partner Universimed, we brought the latest news on current study data and scientific innovations in breast cancer from San Antonio to Austria in a compact format for the 10th time on January 13th. Every year, our ABCSG experts offer those who cannot attend the San Antonio Breast Cancer Symposium (SABCS) in person, the ideal opportunity to stay up to date in just one afternoon. This year, about 120 participants took part in the well-established event in Vienna. Prof. Michael Gnant, who attended the San Antonio Breast Cancer Symposium in Texas, chaired the Friday afternoon session, during which five rapporteurs summarized the latest content from the renowned international breast cancer congress. Following the presentations, the ABCSG's outstanding interdisciplinary panel of experts discussed the most interesting questions and sought to integrate the findings into clinical practice.

18th St. Gallen International Breast Cancer Conference

Primary Therapy of Early Breast Cancer – Evidence, Controversies, Consensus

Leading breast cancer experts and all major research groups, such as the ABCSG, involved in basic research, clinical research, and clinical care of breast cancer patients, presented their latest data to more than 3.000 participants from over 100 countries at the Austria Center in Vienna from March 15th–18th.

The results of the on-site voting and discussion by the panelists were then condensed by the St. Gallen Scientific Committee, and we are pleased to share their assessment of local and systemic therapies for women with early breast cancer, with a focus on evaluating multimodal treatment options. The consensus manuscript will help clinicians and patients worldwide make informed treatment decisions. Now available **online**

Post St. Gallen „Daten – Fakten: Konsequenzen?“

This year's "DATA - FACTS: CONSEQUENCES?" symposium, which was held on March 29th as a follow-up of the 18th St. Gallen International Breast Cancer Conference was once again held as a face-to-face event in Vienna under the scientific chairmanship of Prof. Dr. Günther Steger. About 70 participants attended this year's event.

17th Interdisciplinary Mamma Discourse

About 90 participants attended this year's 17th Interdisciplinary Breast Discourse on October 4th, hosted by ABCSG President Prof. Michael Gnant and Austrian Society for Senology President Prof. Günther Steger. The audience showed great interest in the three overview presentations on highly significant and future-oriented topics such as adjuvant therapy with CDK4/6 inhibitors, molecular subtyping in metastatic breast cancer with a focus on ctDNA and the new class of ADCs.

In the second part of the educational evening, two cases from clinical practice were presented and discussed by an interdisciplinary panel of renowned experts in the style of an interdisciplinary tumor board.

NIFA Oncology Symposium

103 participants – 12 scientific lectures – 5 interdisciplinary panels – 3 Oxford style debates – an exciting keynote lecture. That was this year's NIFA symposium on October 13th and 14th which is organized annually by AstraZeneca in collaboration with the ABCSG, and which once again attracted physicians and healthcare professionals from all over Austria to the Austrian capital. The 22nd edition provided many opportunities for breast cancer experts from various disciplines to exchange information on the latest trends in diagnostics and therapy, as well as to discuss future challenges.

32nd Annual Meeting of the ABCSG

From November 17th to 18th, the 32nd Annual Meeting of the ABCSG took place as an on-site event in Saalfelden, Austria.

Our annual scientific exchange once again provided the perfect opportunity to gain an overview of the numerous ABCSG study projects and the resulting state-of-the-art therapies for various oncological entities.

In addition, our educational mission to the next generation was again reflected in the meeting program, including presentations by the ABCSG-Task Force "Future Now".
As our study group was not only very active in the field of breast cancer in 2023, there were many updates and new therapeutic trends presented at the ABCSG Colorectal Cancer Branch sessions.

As always, there was plenty of time away from the lecture halls to network with peers in a relaxed atmosphere and forge promising new collaborations.

EXPERTS ON TOUR®

On November 22nd, the successful EXPERTS ON TOUR® training series was finally held again as a face-to-face event after the pandemic-related digital implementation and made a stop in Innsbruck under the chairmanship of Prof. Christian Marth.

Three lectures on pathology, surgery and modern breast cancer therapies opened the training event, followed by a clinical case where the audience voted on individual treatment options using a digital survey tool. Finally, there was the opportunity to question our expert panel and review the tumor board's treatment decisions in detail. This provided all participants with an interdisciplinary overview of current scientific research and its implementation in daily practice.

abcsg in touch

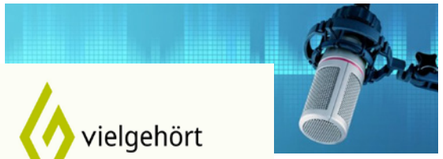
On December 14th, 42 participants attended "abcsg in touch", our newest training format for young physicians and scientists, which was held for the first time as an in-person event in Vienna.

Under the scientific direction of Dr. Kacerovsky-Strobl and the chairmanship of Prof. Günther Steger, four ABCSG experts presented exciting cases from clinical practice to an interested audience of junior doctors, who were able to vote on the selected treatment options using a digital survey tool. In the closing panel discussion, all open questions from the audience were discussed and – where possible – clarified.

abcsgintouch
medical lectures
case reports
discussions

Online Education Formats

Podcast Series "vielgehört" Oncology Congress Highlights Winter 2022: Update Breast Cancer

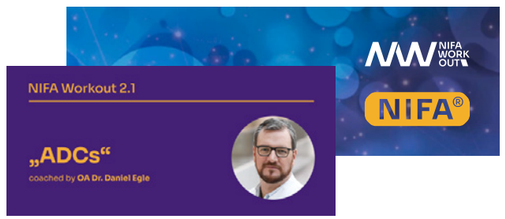


In the first episode of the series "Oncology Congress Highlights Winter 2022", host Christina Lechner and expert Prof. Michael Gnant discuss the breast cancer updates presented at SABCS, with a focus on the MonarchE study. Prof. Gnant reviews the latest results, discusses the improvement in invasive disease-free survival, and shares his practical experience. The use of Abemaciclib in the adjuvant setting is presented as well as its tolerability in the real world.

In the second episode of the series, the hosts Prof. Michael Gnant and Prof. Marija Balic talk about updates in breast cancer in the metastatic setting. They discuss the DESTINY trials and the implications of the results for clinical practice, as well as the CAPItello 291 and SERENA-2 trials on oral SERDs. Furthermore, they also analyze which patient populations are suitable for TROP-2-directed therapies and present alternatives in cases of resistance to endocrine therapies.

Science News

The Science News format gives our network of researchers the opportunity to hear the highlights of the most important breast cancer meetings in a compact video recap that is sent to our members via newsletter and also made available for download on the ABCSG website shortly after the event. In 2023, the ABCSG Science News provided video recaps of the St. Gallen International Breast Cancer Conference, ESMO Breast, ASCO, ESMO, and SABCS, and was well received with over 2.500 views.

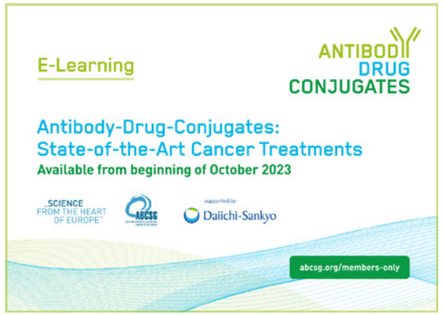


NIFA Workout 2.1 "ADCs of the next generation" coached by Dr. Daniel Egle

The focus of the NIFA Workout 2.1 **on-demand videos** is "Next Generation Antibody Drug Conjugates (ADCs)". Under the lead of coach Dr. Daniel Egle, an overview of HER2-directed ADCs and TROP2-directed ADCs is presented in two videos. The third video shares the patient perspective and is entitled "The Patient in Focus – How I Treat & Therapy Algorithms of Today".

NIFA Workout 2.2 "Dynamic Biomarkers" coached by Prof. Marija Balic

Part 2 of the online training course on breast cancer focuses on "Dynamic Biomarkers". Which biomarkers need to be tested when and why, how "liquid biopsy testing in practice" works, and how biomarkers will affect breast cancer diagnosis and treatment in clinical practice now and in the future are the topics of NIFA Workout 2.2. Under the chairmanship of Prof. Marija Balic, three outstanding experts present online lectures that you can follow **on-demand**.



E-Learning "Antibody-Drug-Conjugates: State-of-the-Art Cancer Treatments"

This on-demand educational format features three presentations followed by a panel discussion. Topics include advances with next-generation ADCs, successful management of adverse events, and current standards and future perspectives in HER2 therapy.

Webinar "Paradigm Shift: a changing CDK4/6 inhibitor treatment landscape"

The virtual educational event took place on September 14th with 87 participants from 13 countries. In this third webinar supported by Novartis, both the ABCSG and international breast cancer experts presented the latest data in the treatment of breast cancer patients as the treatment landscape with CDK4/6 inhibitors changes dramatically across the different stages of breast cancer, from metastatic to early breast cancer.

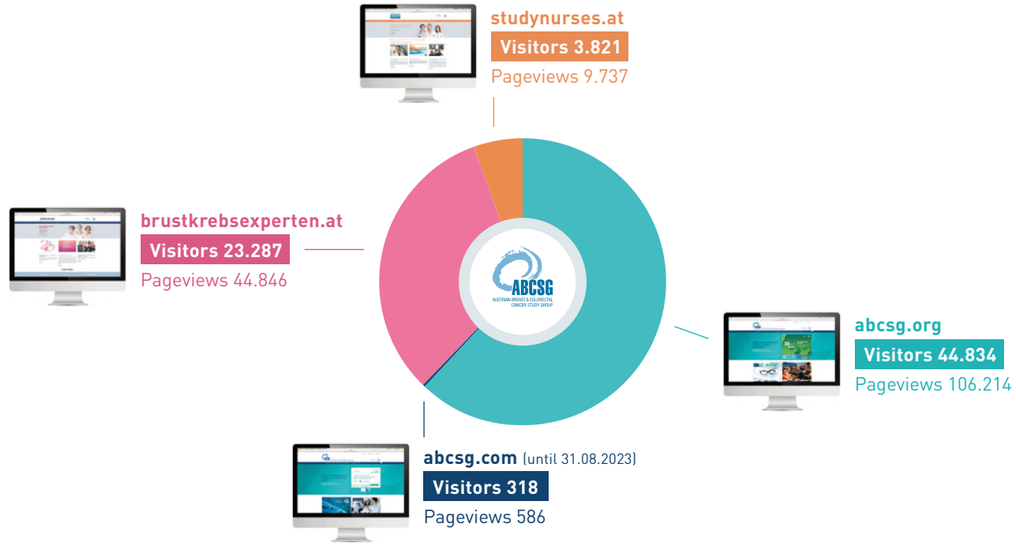
Webinar "CDK4/6 inhibition in early breast cancer – Recent data and controversies?"

The international webinar "CDK4/6 inhibition in early breast cancer - Recent data and controversies", co-sponsored by Eli Lilly and Novartis, took place virtually on November 8th with a total of 104 participants from 13 countries. The goal of the webinar was not only to learn about the clinical trial results, adjuvant treatment options with CDK4/6 inhibitors, and clinical implications for daily practice, but also to discuss the related controversies and current and future implications for early breast cancer patients and healthcare systems.

Websites and Social Media

Visitor Statistics
01. Jan. – 31. Dec. 2023

Visitors 72.260
Pageviews 161.023



www.abcsg.org

After a complete redesign and modernization of the www.abcsg.org-website in 2020 and 2021, the English-language website www.abcsg.com was completely migrated to www.abcsg.org in 2023.

www.brustkrebsexperten.at

Easily accessible information about breast cancer and ongoing trials for patients.

www.studynurses.at

The ABCSG forum for study nurses and study coordinators: A platform for continuing education and networking for clinical trial professionals.

ABCSG's digital presence on social media platforms such as LinkedIn, Twitter, and Instagram has been expanded and targeted to specific audiences. This strategic approach will remain a central focus of our communications efforts throughout 2024.

Public Relations and Press

The "JATROS Hämatologie und Onkologie" magazine

The "krebs:hilfe!" journal

Each year, the ABCSG's scientific endeavors and the dedication of its board and committee members receive remarkable media coverage.

ABCSG's traditional press outreach efforts again made a significant impact in 2023 with more than 60 appearances in popular science magazines and 11 scientific publications in prestigious journals such as The New England Journal of Medicine and The Lancet (Scientific publications see pages 56-59).

Our many years of successful cooperation with other study groups, such as the Breast International Group (BIG), as well as our collaboration with the most significant national and international specialist press and popular science magazines have again resulted in several prominent articles, such as an interview with Prof. Christian Singer about ABCSG 50 / BRCA-P trial in "JATROS Hämatologie und Onkologie", published by Universimed as part of Breast Cancer Awareness Month in October.

An article by Prof. Lukas Weiss on circulating tumor DNA, a topic on which the ABCSG is working intensively in various studies, was published in the newly founded magazine "Dialog Darm" of an Austrian colorectal cancer support group.

BIG's "Research in Focus" magazine published three articles with ABCSG background, one on liquid biopsies by Prof. Marija Balic and Prof. Ellen Heitzer, the other on the remarkable results of the ABCSG 52 / ATHENE study by Prof. Gabriel Rinnerthaler, as well as an in-depth interview with Prof. Michael Gnant.

Since more than two decades, the ABCSG is also co-publisher of the journal "krebs:hilfe!" in cooperation with the Austrian Cancer Aid. Prof. Michael Gnant's article "Unde venis? Quo vadis?" was printed in issue 6.2023 as part of the focus on "Clinical Cancer Research in Austria". In addition to the traditional print edition, the digital presence of krebs:hilfe! was expanded with the support of the ABCSG and now includes a digital magazine and newsletter.

BIG's "Research in Focus" magazine

The new"Dialog Darm" magazine

„SCIENCE FROM THE HEART OF EUROPE"

ABCSG AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

Trial Office Activities

Clinical Monitors Meeting

The team of our ABCSG Clinical Monitoring Department met on May 8th-10th for their annual reunion in the beautiful setting of the lake Grundlsee. The current status of all ongoing studies was presented and future projects, challenges and planned milestones were discussed and defined, together with the ABCSG Managing Director, Associate Directors and the Head of the Clinical Data Management. Enough time was scheduled to also resolve any outstanding questions on general study topics and future challenges in the practice of clinical research monitoring. In addition, a very nice teambuilding program was organized to support team spirit and solidarity within and across departments.

Teambuilding Event: Dragon Boat Race Together we are strong!

On August 3rd, the ABCSG went on its annual company excursion to the picturesque lake Stubenbergsee in Styria. Among others, the program included a dragon boat race. Paddling together and maintaining a synchronized, rhythmic motion was a great experience that strengthened our team's unity but also added quite a sense of competition and revealed our will to win. We had a lot of fun and the rainy weather showed once again that nothing can stop the ABCSG team.

Cancer Research Run 2023 – Together we finish – Cancer!

Once again this year, a highly motivated team from the ABCSG Trial Office participated in the 17th Cancer Research Run of the Medical University of Vienna on October 7th.

For a good cause, the common goal in the fight against cancer was not lost sight of in this charity event. Not only did the ABCSG runners have a great time on the course, but they also gave their all to contribute to the thousands of miles run each year.

We would like to thank our colleagues for their dedication and perseverance and hope that the ABCSG running group (this time with a record number of runners!) will continue to grow from year to year so that even more laps can be finished for cancer research next time.

Year End Recap Team Meeting

Our annual year end meeting provided a comprehensive overview of the company's performance in the past year and a preview of the upcoming challenges and opportunities. Our key financial figures were presented, and we received a refresher training on IT security and legal updates, particularly in the use of artificial intelligence, before covering study highlights and an outlook into upcoming clinical projects and IT system updates for 2024.

„SCIENCE FROM THE HEART OF EUROPE"

ABCSG AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

Publications 2023 and Study Overview

„SCIENCE FROM THE HEART OF EUROPE"

ABCSG
AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

Publications 2023

Differential immunomodulatory effects of epirubicin/cyclophosphamide and docetaxel in breast cancer patients

Wimmer K, Sachet M, Ramos C, Frantal S, Birnleitner H, Brostjan C, Exner R, Filipits M, Bago-Horvath Z, Rudas M, Bartsch R, Gnant M, Singer CF, Balic M, Egle D, Oehler R & Fitzal F

Journal of Experimental & Clinical Cancer Research volume 42, published on 14 November 2023

Emergence of immune-related adverse events correlates with pathological complete response in patients receiving pembrolizumab for early triple-negative breast cancer

Marhold M, Udovica S, Halstead A, Hirdler M, Ferner M, Wimmer K, Bago-Horvath Z, Exner R, Fitzal F, Strasser-Weippl K, Robinson T & Bartsch R

ONCOIMMUNOLOGY, published online on 13 November 2023

Patient-reported outcomes in high-risk HR+/HER2- early breast cancer patients treated with endocrine therapy with or without palbociclib within the randomized PENELOPEB study

García-Sáenz JA, Marmé F, Untch M, Bonnefoi H, Kim SB, Bear H, Mc Carthy N, Gelmon K, Martin M, Kelly CM, Reimer T, Toi M, Law E, Bhattacharyya H, Gnant M, Makris A, Seiler S, Burchardi N, Nekljudova V, Loibl S, Rugo HS

European Journal of Cancer, published on 05 November 2023

Impact of Imaging Guided Localization on Performance of Tailored Axillary Surgery in Patients with Clinically Node Positive Breast Cancer: Prospective Cohort Study Within TAXIS (OPBC 03, SAKK 23/16, IBCSG 57 18, ABCSG 53, GBG 101

Weber WP, Heidinger M, Hayoz S, Matrai Z, Tausch C, Henke G, Zwahlen DR, Gruber G, Zimmermann F, Montagna G, Andreozzi M, Goldschmid M, Schulz A, Mueller A, Ackerknecht M, Tampaki EC, Bjelic Radisic V, Kurzeder C, Sávolt A, Smanykó V, Hagen D, Müller DJ, Gnant M, Loibl S, Fitzal F, Markellou P, Bekes I, Egle D, Heil J, Knauer M.

Annals of Surgical Oncology, published on 30 October 2023

LM02 trial Perioperative treatment with panitumumab and FOLFIRI in patients with wild-type RAS, potentially resectable colorectal cancer liver metastases—a phase II study

Piringer G, Grienberger T, Thaler J et al.

Frontiers in Oncology, published on 09 August 2023

Impact of BMI in Patients With Early Hormone Receptor–Positive Breast Cancer Receiving Endocrine Therapy With or Without Palbociclib in the PALLAS Trial

Pfeiler G, Hlauschek D, Mayer EL et al

Journal of Clinical Oncology, published online on 09 August 2023

Association of Axillary Dissection With Systemic Therapy in Patients With Clinically Node-Positive Breast Cancer

Weber WP, Matrai Z, Hayoz S et al, von ABCSG Seite als Co Autoren vertreten sind Fitzal F, Gnant M, Egle D

JAMA Surg., published online on 19 July 2023

Trends in use of neoadjuvant systemic therapy in patients with clinically node positive breast cancer in Europe: prospective TAXIS study (OPBC 03, SAKK 23/16, IBCSG 57 18, ABCSG 53, GBG 101)

Tausch C, et al, ABCSG co-authors Fitzal F, Gnant M, Egle D, Hager C, Reisenberger K, Singer C

Breast Cancer Res Treat., published online 25 June 2023.

International research to address the challenges of metastatic breast cancer: the AURORA Program (BIG 14-01)

Caballero C, Irrthum A, Goulioti T, Cameron D, Norton L, Piccart M

NPJ Breast Cancer, published on 23 May 2023

Interrupting Endocrine Therapy to Attempt Pregnancy after Breast Cancer

Partridge AH, Niman SM, Ruggeri M, Peccatori FA, Azim HA Jr., Colleoni M, Saura C, Shimizu C, Sætersdal AB, Kroep JR, Mailliez A, Warner E, et al., for the International Breast Cancer Study Group, and the POSITIVE Trial Collaborators†

The New England Journal of Medicine, published on 04 May 2023

Anthracycline-containing and taxane-containing chemotherapy for early-stage operable breast cancer: a patient-level meta-analysis of 100 000 women from 86 randomised trials

Early Breast Cancer Trialists' Collaborative Group (EBCTCG)
Fesl C, Gnant M, Sölkner L, Steger G (Groups (lead investigators) contributing data)

Lancet, published on 15 April 2023

CONFERENCE ORAL PRESENTATIONS 2023

Adding atezolizumab to adjuvant chemotherapy for stage II and III triple-negative breast cancer is unlikely to improve efficacy: interim analysis of the ALEXANDRA/IMpassion030 phase 3 trial

Presentation by Ignatiadis M
Bailey A, McArthur H, Abed S, De Azambuja E, Metzger O, Chui SY, Dieterich M, Perretti T, Steger G, Jassem J, Lee SC, Higgins M, Zarba J, Schmidt M, Gomez H, Guerrero Zotano G, Moscetti L, Chiu J, Dufrane C, Honvault V, Altarcheh-Xifro R, Molinero L, Ellingson A, Munzone E, Ben-Baruch NE, Bajetta E, Ohno S, Im SA, Werutsky G, Gal-Yam EN, Gonzalez Farre X, Tseng LM, Jacot W, Gluz O, Shao Z, Shparyk Y, Sinielnikov I, Zimina A, Aleksander V, Shearer-Kang E, Winer E, Branco DM, Fielding S, Cameron D, Viale G, Saji S, Gelber R, Piccar M

San Antonio Breast Cancer Symposium 2023, December 2023

Protocol-defined biomarker analysis in the PALLAS adjuvant trial: genomic subtype derived from RNA sequencing of HR+/HER2- early breast cancer

Presentation by Stover D
Hlauschek D, Mayer EL, Symmans WF, Watson M, Barozzi I, Filipits M, Ballman K, Bellet-Ezquerra M, Balko J, Rubovszky G, Zdenkowski N, Brufsky A, Steger GG, Isaacs C, Loibl S, Henao F, Denkert C, Regan M, Liu Y, Fesl C, Dueck AC, DeMichele A, Gnant M, Metzger O

San Antonio Breast Cancer Symposium 2023, December 2023

Randomized Phase II Trial of neoadjuvant Atezolizumab in combination with dual HER2 blockade plus epirubicin in early HER2 positive Breast Cancer

Presentation by Rinnerthaler G
Egle D, Bartsch R, Schmitt C, Petzer A, Balic M, Petru E, Denison U, Singer CF, Bjelic-Radisic V, Gampenrieder SP, Knauer M, Posch F, Hlauschek D, Sölkner L, Bago-Horvath Z, Filipits M, Gili M, Gnant M, Greil R, (on behalf of the Austrian Breast and Colorectal Cancer Study Group (ABCSG)

ESMO 2023, October 2023

CONFERENCE POSTERS 2023

Pathological response according to early metabolic remission in an interim FDG-PET scan and to tumor infiltrating lymphocytes – A secondary analysis of the phase II trial ABCSG 52 / ATHENE investigating atezolizumab in early HER2+ BC

Poster by Rinnerthaler G
Egle D, Bartsch R, Schmitt C, Petzer A, Balic M, Petru E, Denison U, Singer CF, Bjelic-Radisic V, Gampenrieder SP, Knauer M, Sotlar K, Brunner C, Posch F, Hlauschek D, Solkner L, Bago-Horvath Z, Filipits M, Gili M, Gnant M, Greil R

San Antonio Breast Cancer Symposium 2023, December 2023

The impact of drug-drug interactions between palbociclib and proton pump inhibitors on clinical outcomes of patients with hormone receptor positive, HER2-negative, early breast cancer: an exploratory analysis of the PALLAS study

Poster by Agostinetto E & Pfeiler G
Hlauschek D, Mayer EL, Lambertini M, de Azambuja E, Bellet Ezquerra M, Lowe Meisel J, Rubovszky G, Zdenkowski N, Novik Y, Ruiz Borrego M, Gelmon K, Mamounas EP, Iwata H, Ray Lu D, Soelkner L, Fesl C, Gnant M, DeMichele A

San Antonio Breast Cancer Symposium 2023, December 2023

Clinical characterization, prognostic and predictive values of HER2-low in early breast cancer in the PALLAS trial

Poster by Nader-Marta G & Singer CF
Hlauschek D, DeMichele A, Tarantino P, Pfeiler G, Martin M, Balko JM, Nowecki Z, Balic M, Brufsky AM, Chan A, Morris PG, Haddad TC, Loibl S, Liu Y, Soelkner L, Fesl C, Mayer EL, Gnant M

San Antonio Breast Cancer Symposium 2023, December 2023

Racial and Ethnic Differences in Clinical Outcomes Among North American Patients With Hormone Receptor-positive, HER2-negative, Early-Stage Breast Cancer in the PALLAS Trial (AFT-05/ABCSG-42)

Poster by Kantor O & Fayanju OM
Dueck A, Gnant M, Burstein HJ, Goetz M, Isaacs C, Shepherd L, Hahn O, Miller K, Rugo H, Traina T, Dayao Z, Winer E, Wolff A, Wolmark N, Dongrui Lu R, O'Brien PJ, Scovil S, DeMichele A, Mayer EL

San Antonio Breast Cancer Symposium 2023, December 2023

Long-term patient-reported outcomes in premenopausal women with the hormone receptor-positive breast cancer from ABCSG 22 Registry

Poster by Bjelic-Radisic V
Egle D, Wette V, Melbinger-Zeinitzer E, Haslbauer F, Trapp E, Fitzal F, Greil R, Balic M, Pasterk C, Heck D, Bartsch R, Oberguggenberger A S, Sölkner L, Putz M, Gnant M

ESMO 2023, October 2023

Abstract P2-02-04: De-escalation of bone-targeted treatment: Does the number of 6-monthly adjuvant zoledronate infusions received affect treatment efficacy for early breast cancer? A sub-study of ABCSG-12

Poster by Beltran-Bless AA
Clemons M, Fesl C, Hlauschek D, Soelkner L, Pond G, Vandermeer L, Greil R, Balic M, Bjelic-Radisic V, Singer C F, Steger G, Helfgott R, Egle D, Gampenrieder S, Kacerovsky-Strobl S, Suppan C, Ritter M, Rinnerthaler G, Pfeiler G, Fohler H, Hilton J, Gnant M

Cancer Research 2023, published March 2023

Study Overview

Study	Sponsor	Title	Status
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	open for enrollment
ABCSG 49 / POLAR	IBCSG	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	SAKK	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 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	open for enrollment
ABCSG 57 / ALPHABET	GEICAM	A randomized phase III trial of trastuzumab + ALpelisib +/- fulvestrant versus trastuzumab + chemotherapy in patients with PIK3CA mutated previously treated HER2+ Advanced BrEasTcancer	open for enrollment
ABCSG 60 / CAMBRIA-1	AstraZeneca	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	open for enrollment
ABCSG 62 / CAMBRIA-2	AstraZeneca	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	open for enrollment
C 08 / 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
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

Study	Sponsor	Title	Status
ABCSG 39 / APHINITY	Roche	A randomized multicenter, double-blind, placebo-controlled comparison of chemotherapy plus trastuzumab plus placebo versus chemotherapy plus trastuzumab plus pertuzumab as adjuvant therapy in patients with operable HER2-positive primary breast cancer	treatment / follow-up
ABCSG 41 / OLYMPIA	AstraZeneca	A randomized, double-blind, parallel group, placebo-controlled multi-centre Phase III study to assess the efficacy and safety of olaparib vs placebo as adjuvant treatment in patients with germline BRCA 1/2 mutations and high risk HER2-negative breast cancer who have completed definitive local treatment and neoadjuvant or adjuvant chemotherapy	treatment / follow-up
ABCSG 42 / PALLAS	ABCSG (20 countries); AFT (USA)	PALbociclib CoLlaborative Adjuvant Study: A randomized phase III trial of Palbociclib with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy alone for hormone receptor positive (HR+) / human epidermal growth factor receptor 2 (HER2)-negative early breast cancer	treatment / follow-up
ABCSG 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 48 / POSITIVE	IBCSG	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 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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Cooperative Studygroup Mamma- & Colorectal Carcinom,
Austrian Breast & Colorectal Cancer Study Group (ABCSG)

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