www.abcsg.at
Austrian Breast & Colorectal Cancer Study Group

Annual Report

Austrian Breast & Colorectal Cancer Study Group 2022

„SCIENCE FROM THE HEART OF EUROPE“

ABCSG
AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

„SCIENCE
FROM THE HEART
OF EUROPE"

ABCSG
AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

Table of Contents

Introduction and Key Facts

„SCIENCE
FROM THE HEART
OF EUROPE"

ABCSG
AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

Reviewing 2022 in clinical research – ABCSG activities in Austria and globally

After a few challenging years of clinical research being heavily impacted by the COVID-19 pandemic, meetings being held virtually, and patients and caregivers having to adapt to virtual/remote tools of medicine and communication, the **Austrian Breast and Colorectal Cancer Study Group** can look back at an exciting 2022 with insightful study results as well as new projects in the set-up phase that will guide our scientific work, and hopefully address important research and clinical questions in clinical trials over the next few years.

In addition to previously reported advantages of adding denosumab to aromatase inhibitor therapy in the **ABCSG 18 trial to mitigate adverse effects in bone health and improve disease-free survival outcomes, the final long-term analysis also supported this result** (publication in NEJM Evidence 2022, oral presentation at ASCO 2022, further sub-analysis published in ESMO Open 2022). Also, sub-analyses of the **ABCSG 42 / PALLAS study – which is following patients in 21 countries until 2028 – were presented in high-ranking journals and at major oncology conferences** (ASCO 2022, JCO 2022, Lancet Oncology 2022). Also, the ABCSG 50 / BRCA-P study – the first prevention study to investigate "preventive" denosumab treatment as an alternative to mastectomy for BRCA1 mutation carriers – was launched in further countries under the leadership of ABCSG Vice-President Christian Singer together with Judy Garber (Dana-Farber Cancer Institute), and under the operational coordination of the ABCSG trial office in Vienna. The **ABCSG 52 / ATHENE trial, investigating neoadjuvant atezolizumab in a phase II setting, was very successful** on many levels: in contrast to many projects being negatively impacted by the pandemic, this study recruited in time, and database lock and analysis of results were both achieved in due time with the first public presentation of primary endpoint results being eagerly awaited in 2023. ABCSG-affiliated investigators successfully published research results in 9 different high-ranking medical journals. Exemplifying pars-pro-toto, and representing the group efforts, **also in 2022 ABCSG president Michael Gnant ranked – already for the third time – among the global 1% of "Highly Cited Researchers"** (source: *Clarivate statistics*). Furthermore Michael Gnant was awarded the **Umberto Veronesi Prize** on the occasion of the Vienna Surgical Week. This prestigious award in memory of the distinguished Italian oncologist Umberto Veronesi is conferred once a year where a renowned surgical leader is awarded and invited to deliver a dedicated lecture.

Besides these successes in academic clinical research, the ABCSG further invested in digitalisation, interactive events and "life-long learning" initiatives that bring newest research results to caregivers, along with expert panel discussions. On-site events in Vienna, recorded e-learnings, but also live online events (e.g. focusing on CDK4/6 inhibitors) were launched successfully for an interested audience from many different countries. Together with various task forces (e.g. **"Future Now"** comprising the next generation of leaders in clinical research), we are also producing new educational and interactive formats and content such as podcasts for the greater public community. Since the ABCSG continuously monitors the activity level of its task forces' work to ensure that the next generation increasingly takes over operational responsibility within the network, there were again some changes within the ABCSG leadership during the past year, notably **Lukas Weiss took over the lead of ABCSG´s Colorectal Cancer Executive Committee**, and is dedicated to develop new study ideas in this second major tumor entity of our study group to supplement the large breast cancer program. Last, but certainly not least, our portfolio in the areas of translational research and machine-learning / AI-assisted approaches is steadily increasing and focuses on genetic, proteomic as well as imaging tools that are developed, tested and/or validated in ABCSG study cohorts and bio-samples with the "abcsg. research" program led by **Martin Filipits**.

Given the exciting current treatment landscape with fast-paced discoveries and new insights that emerge in the fields of biomarker-guided therapies, ADCs, oral SERDs and other agents that have yet to be better understood and fully integrated into clinical practice, **we are eager to initiate and sponsor new clinical studies in 2023 as well as contribute to large phase III studies,** again leaving a strong academic footprint in global collaborations with academic and industry partners for the benefit of cancer patients.

In this ABCSG Annual Report 2022 you will receive an overview of our study projects and associated activities that are carried out with strong dedication, expertise and a great team spirit. We hope you enjoy reading it!

Sincerely,
Michael Gnant, Marija Balic, Richard Greil,
Christian Singer and Christian Marth
ABCSG president and vice-presidents,
on behalf of the whole ABCSG team

„SCIENCE FROM THE HEART OF EUROPE"

„SCIENCE FROM THE HEART OF EUROPE"

ABCSG Key Facts 2022

effective date 31 Dec 2022

Subsidiary GmbH

Year of foundation: 2015

Ownership:
99 % Association, 1 % Persons

Commercial Managing Director:
Mag. Hannes Fohler

Scientific Managing Director:
Prof. Dr. Michael Gnant

Current purpose: legal entity international registration study PALLAS

Research Service 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

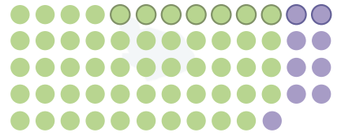
Association

Year of foundation: 1984

9 Board members
11 Members Executive Committee
44 Members General Assembly

Tax status: non-profit

Employees (Head Count)



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

13.9 years ...

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

176

Total Publications ABCSG (peer reviewed)

Publications 2022 (peer reviewed)	10

Number of ...

... all ongoing breast cancer studies in 2022	18
... all ongoing colorectal studies in 2022	1
... all ongoing pancreas studies in 2022	1

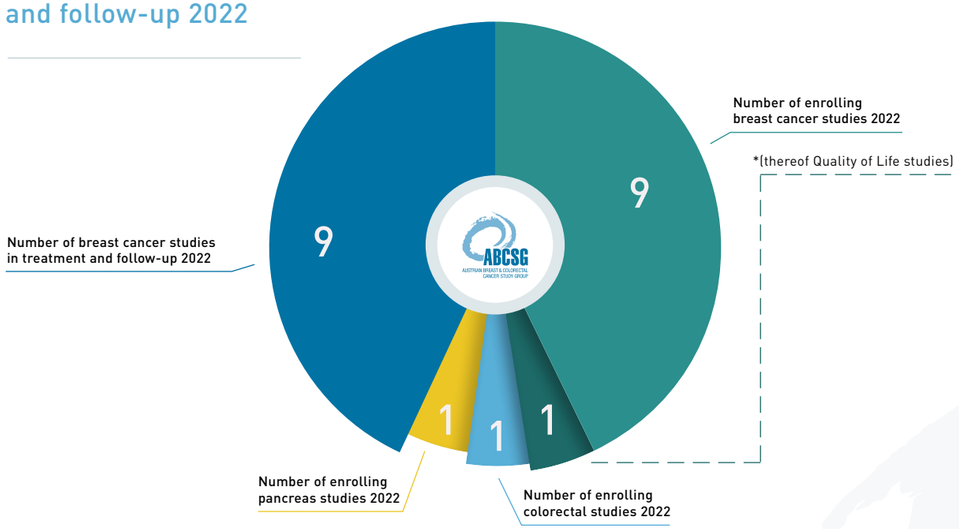
Number of all patients ever enrolled

28.959

Number of ...

... translational projects 2022	2
... enrolling studies 2022 thereof Quality of Life studies*	11 1
... studies in treatment phase and follow-up 2022	9

Clinical studies in recruitment, treatment and follow-up 2022

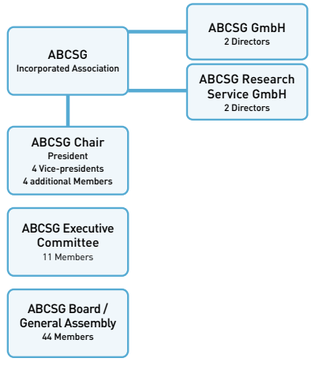


Structure, Aims, Visions and International Network

„SCIENCE
FROM THE HEART
OF EUROPE"

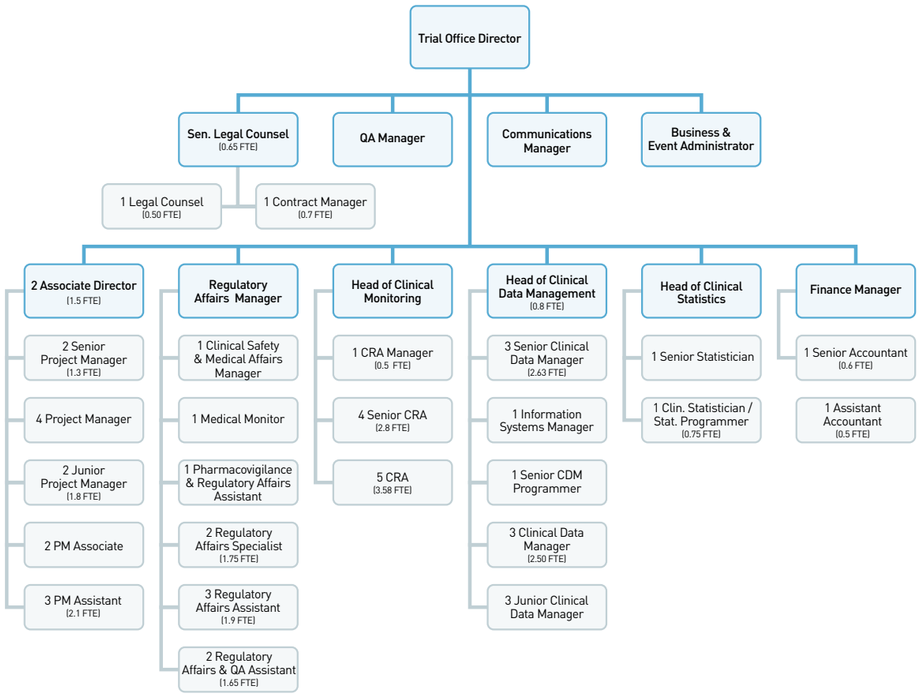
ABCSG
AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

ABCSG Structure



ABCSG Trial Office

62 Employees (51.51 FTE)



The ABCSG – Tasks, Goals and Structure

The 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 and conducted by the ABCSG nationally but also 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 therapy. Of great importance for the affected patients is a constant improvement 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. The ABCSG has set itself the goal of achieving continuous improvements in these areas through its studies and projects.

Multidisciplinary approaches are key to the worldwide success of the ABCSG and have contributed significantly to improving the chances of cure and patient survival. Surgeons, oncologists, gynaecologists, radiotherapists, pathologists, radiologists and, if necessary, physicians from other disciplines or basic researchers join forces to find new answers to important diagnostic and therapeutic questions about various cancers.

Since many years, studies on **breast and colorectal cancer** have been the focus of the ABCSG. Due to the high medical need, the ABCSG has also been conducting studies on **pancreatic cancer** since 2013. In order to bundle activities and to generate additional synergies, there are also smaller working groups ("task forces") in various specialized and organizational areas. Several projects and associated task forces are currently in the planning phase.

The clinical trials and translational research projects are very transparent and are monitored at every stage by responsible ethics committees, the relevant authorities and a highly professional as well as dedicated operational ABCSG team. The execution of clinical trials is furthermore associated with a substantial logistical effort. In the ABCSG trial office in Vienna, highly qualified staff members are involved in the design and organization of the studies and, last but not least, in the analysis and publication of the resulting data.

The trial office is headed by the Managing Director and comprises the departments Clinical Data Management, Regulatory Affairs with Clinical Safety and Medical Affairs, Medical Monitoring, Project Management, Clinical Statistics, as well as a Legal Department, Quality Assurance, Business and Event Management, Finance and Controlling as well as Public Relations. Clinical Monitors / CRAs of the ABCSG, located throughout Austria, are responsible for the protocol-compliant study management and 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. Since 2015, there is also a non-profit subsidiary GmbH. Its main purpose is to serve as the legal entity for the extensive international pivotal study PALLAS. With ABCSG Research Services GmbH, another subsidiary was added to our portfolio in November 2022 in order to intensify our cooperation with industry partners.

„SCIENCE
FROM THE HEART
OF EUROPE"

ABCSG
AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

International Network

The ABCSG is part of a network of breast cancer study groups encompassing 65 countries and 6 continents. These include the Spanish study groups GEICAM and SOLTI, the International Breast Cancer Study Group (IBCSG) and the German Breast Group (GBG), among many others. The ABCSG is involved in BIG sponsored studies (Breast International Group) as well as studies of the named partner organizations and also directly acts as a legal sponsor of international studies in which organizations of the BIG network 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, the 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.

In addition to smaller and larger academic studies, the ABCSG also participates in relevant research questions in industry-initiated studies and coordinates these in Austria. Due to the large number of conducted studies, the ABCSG has so far been able to generate and collect an enormous amount of clinical and scientifically relevant data. This opens up new opportunities for collaborations with renowned academic institutions abroad for retrospective meta-analyses, translational research as well as the development 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).

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 within the scientific community that has been the basis of ABCSG's success and constant development for almost 40 years.

Studies open for Enrollment

„SCIENCE
FROM THE HEART
OF EUROPE"

ABCSG
AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

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.

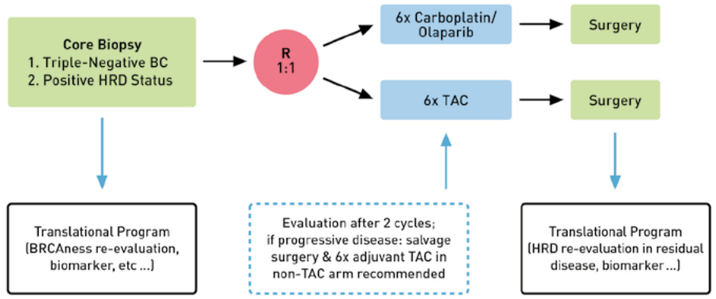
ABCSG 45

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 is currently used in study phase 2, which opened for recruitment of additional 70 patients in June 2021 at 9 sites. Enrollment is currently planned until end of 2023 and a total of 43 patients had already been included into study phase 2 by end of 2022.

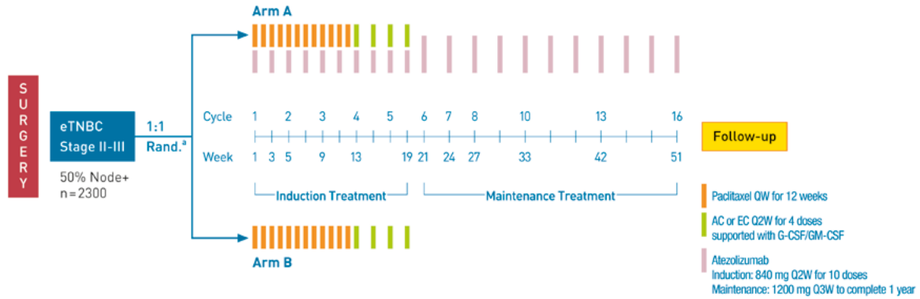
ABCSG 47 / IMpassion030 / ALEXANDRA

A Phase III, multicenter, randomized, open-label study comparing atezolizumab (Anti PD-L1 Antibody) in combination with adjuvant anthracycline/taxane-based chemotherapy versus chemotherapy alone in patients with operable triple-negative breast cancer

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

Start of study:	Sample size:	Sponsor:
08/2018 (global) **11/2019** (national)	**2.300**	**Roche**

Design:



Notes: The study population will be enriched for patients with node-positive disease such that the final population will contain no more than 50% of node-negative patients. Node-negative patients with tumors ≤ 2 cm in size are not eligible to participate in this study. G-CSF/pegylated G-CSF/GM-CSF will be used with each dose of AC/EC. In the induction period, 1 cycle = 4 weeks; in the maintenance period, 1 cycle = 3 weeks.

a) Randomization should occur no more than 8 weeks after definite surgery, and study drug administration should begin within 1 week after randomization but no sooner than 2 weeks after surgery.

Description and status:

ABCSG 47 / IMpassion030 / ALEXANDRA is an open, randomized phase III trial to evaluate the efficacy of adjuvant treatment with the PD-L1 antibody atezolizumab in patients with early triple negative breast cancer (TNBC). Immunotherapy is administered in combination with chemotherapies paclitaxel, doxorubicin or epirubicin and cyclophosphamide. The primary endpoint is invasive disease-free survival (iDFS) of patients who received atezolizumab plus T-AC / EC compared to T-AC / EC alone. iDFS of the subpopulation with a positive PD-L1 tumor status and questionnaires on the quality of life of the patients are secondary endpoints. Globally, 365 sites in 30 countries had been activated by the end of 2022 and 2.199 patients were randomized so far. In Austria, all 9 planned sites were activated in 2021, and 10 patients had been included by the end of 2022. In November 2022, recruitment was put on hold due to a request from the study's Independent Data Monitoring Committee.

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 is participating in countries such as Italy, Spain, Switzerland, Hungary, France as well as four sites in Austria. The recruitment phase will last approx. 3.5 years, in order to enroll 400 patients worldwide. As of December 2022, a total of 224 patients were enrolled into the POLAR Trial, reaching more than 50 % of the targeted accrual goal. In Austria, all 4 sites are already active and a total of 9 out of 50 planned patients had been randomized so far.

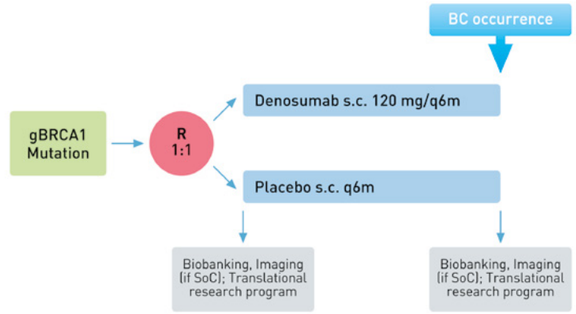
ABCSG 50 / BRCA-P

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 started in July 2019 at the Medical University of Vienna, led by Christian Singer. ABCSG 50 / BRCA-P 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. In Austria, 4 sites remain active, currently Austrian, Australian, Spanish and Israeli sites are enrolling in the trial and a total of 161 women had been recruited so far, out of which 59 participants were included at Austrian sites. The first sites in UK and US could be activated, regulatory approval is awaited in Germany and in Spain and Israel, additional sites are selected for participation 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.

Studies open for Enrollment

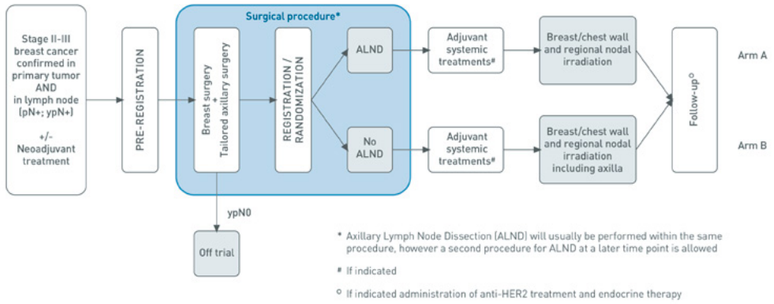
ABCSG 53 / TAXIS

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: **Florian Fitzal** (Vienna)

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. As of November 2020, recruitment was put on hold due to a change in the study sponsor. University Hospital Basel (USB) took over as new sponsor from SAKK in 2021 and Austrian sites re-opened for recruitment in Q1/2022. Until the end of 2022, a total of 49 Austrian patients were included and 644 globally.

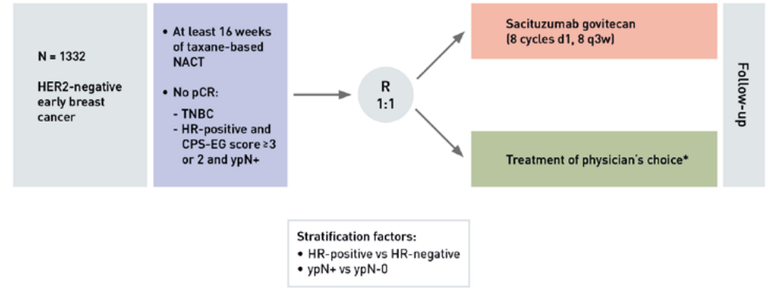
ABCSG 56 / SASCIA

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 sacitizumab govitecan or treatment of physician's choice. The primary study objective is to compare invasive disease-free survival (iDFS) between the treatment arms. The study target enrollment per approved protocol v2.0 is 1332 patients and end of recruitment is targeted for Q1 2024. Until the end of November 2022, 685 patients had been randomized globally. On September 6th, 2022, the first Austrian patient was randomized into the study at the trial site at Klinikum Vöcklabruck under the supervision of PI Ferdinand Haslbauer. 15 sites are planned to be activated for study recruitment in Austria, whereof 12 sites were active as of end of 2022 and a total of 6 patients out of 50 planned patients had been randomized at the Austrian trial sites so far.

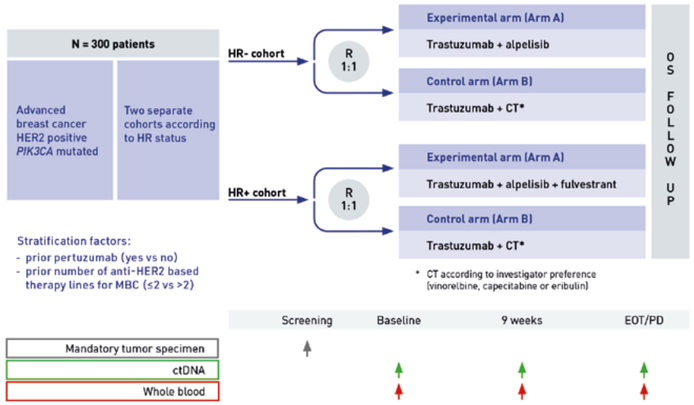
ABCSG 57 / ALPHABET

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)	**300**	**GEICAM** in collab. with ETOP IBCSG Partners Foundation and BIG

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 PIK2CA 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 300 patients, 144 in the HR- cohort and 156 in the HR+ cohort and the estimated recruitment period is 38 months (38 months for HR- and 32 months for HR+) until Q1 2025. The screening assessment is rather extensive and consequently, a high screen failure rate is observed with globally 113 screen failures and 15 randomized patients observed until the end of 2022. Spain, France, Italy, Switzerland, the Netherlands and Austria will participate in this study with a total of 110 sites. In Austria, 10 sites are planned to randomize approximately 30 patients and 4 sites were activated.

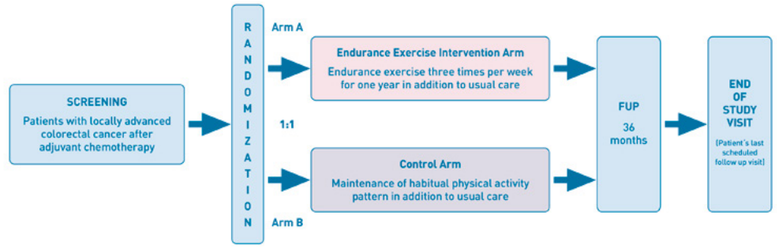
ABCSG C08 / EXERCISE II

Randomized trial of endurance exercise following adjuvant chemotherapy for colorectal cancer

Coordinating Investigator: **Josef Thaler** (Wels-Grieskirchen)

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 2022, a total of 58 patients had been included at 8 activated Austrian sites.

Studies in Treatment Phase and Follow-up

„SCIENCE
FROM THE HEART
OF EUROPE"

ABCSG
AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

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 22R-QoL

A survey conducted on the quality of life of breast cancer patients registered in ABCSG 22R

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

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

Sample size: **600**

Sponsor: **ABCSG**

Description and status:

The ABCSG 22R-QoL is a survey among breast cancer patients who had received hormone therapy to treat their breast cancer and whose data had already been recorded in the ABCSG patient registry "ABCSG 22R". While in the registry study 22R, the registration of premenopausal patients with hormone-sensitive breast cancer under existing therapy with Nolvadex® and Zoladex® was carried out and corresponding data were collected, the aim of the survey was to investigate long-term quality of life (QoL) outcome including sexual health and fertility concerns in breast cancer survivors. A total of 7 questionnaires on the topics of QoL, sexual health, body perception, as well as specific questionnaires on fertility concerns and QoL after menopause were issued and analyzed. The department of Gynecology at the Medical University of Graz was activated as the leading center. Completed questionnaires of 600 patients were planned to be collected within 36 months. Eleven sites throughout Austria, who had recruited most of the participants for the 22R patient registry agreed to join the survey. Between the survey start in July 2019 until its end on 15 July 2023, a total of 469 questionnaires are issued to patients at 11 sites. Results of the survey will be published and presented at conferences in 2023.

ABCSG 25 / PANTHER

A randomized phase III study comparing biweekly and tailored epirubicin + cyclophosphamide followed by biweekly tailored docetaxel (dtEC→dtT) (A-arm) versus three weekly epirubicin + cyclophosphamide, 5-fluorouracil followed by docetaxel (FEC→T) (B-arm) in lymph node positive or high-risk lymph node negative breast cancer patients – a continuation of the feasibility part of the SBG 2004-1 study

Coordinating Investigator: **Richard Greil** (Salzburg)

Start of study: **02/2007** (global) **/ 10/2007** (national)

Sample size: **2.000**

Sponsor: **ABCSG** (Co-Sponsor) **and SBG**

Description and status:

This controlled, randomized, adjuvant phase III study examines the effects of a dose-dense chemotherapy tailored to the individual breast cancer patient compared with standard chemotherapy. In the course of the tailored chemotherapy, affected women received the active ingredients epirubicin and cyclophosphamide (dtEC) at the beginning of therapy and were then treated with the active ingredient docetaxel (dtT) after a three-week break. The individually assessed dose was based on changes in blood count triggered by the therapy. This therapy impact on the blood count varies between patients. The control group was treated with standard chemotherapy starting with fluorouracil, epirubicin und cyclophosphamide (FEC), after a three-week break resuming with docetaxel (T) without any adjustments based on the laboratory values. This project is conducted as a collaboration between the Scandinavian Breast Group (SBG) and the ABCSG and is currently in the follow-up phase. Austrian, Swedish, and German sites are involved with 2.017 enrolled patients in total. In Austria, 465 patients at 16 sites could be enrolled in this study. First results show no significant difference in the 5-year overall and disease-free survival between the two arms. However, with the individually tailored therapy, a significantly better event-free survival could be observed compared to the control group. Results were already presented at international breast cancer conferences, such as ASCO 2016, ESMO 2017, and were also successfully published (Foukakis T et al, JAMA 2016). Scientific translational subprojects are currently being planned.

ABCSG 28 / POSYTIVE

Primary Operation in SYnchronous meTastasized InVasivE breast cancer, a multicenter prospective randomized study to evaluate the use of local therapy

Coordinating Investigator: **Florian Fitzal** (Vienna)

Start of study: **11/2010** (national)

Sample size: **254**

Sponsor: **ABCSG**

Description and status:

The purpose of the POSYTIVE study is to follow the disease progression of patients suffering from metastasized breast cancer where the main tumor is removed by surgery. The control arm of the randomized trial consists of patients where such breast surgery is only carried out on demand, e.g., bleeding or infections have occurred. A total of 90 patients were randomized at 14 centers throughout Austria. The recruitment was stopped prematurely on November 6th, 2015, whereupon all patients transitioned into the 5-year follow-up phase which ended in October 2020. The results of the study could not demonstrate a benefit for patients within the surgery arm in terms of survival, instead the data indicated a trend towards the opposite. These findings were published in 2018 by Florian Fitzal in the journal Annals of Surgery. Another publication by Vesna Bjelic-Radisic on the quality of life of the study participants was published in June 2020 in the British Journal of Cancer. The surveys revealed that the surgery did not alter the quality of life, however reported health status and physical functioning were predictors for the survival of the patients.

ABCSG 36 / PENELOPE^{B} / ETERNITY

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

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

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

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

Sample size: **1.250**

Sponsor: **GBG**

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. Overall, in this study in Austria, 19 sites were activated, 42 screenings were performed, 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 register (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. 6 of the 8 participating Austrian centers are already released for patient registration. Austria registered the first patients worldwide and until the end of 2022, a total of 2 patients had been registered in Austria.

Studies in Treatment Phase and Follow-up

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.

ABCSG 41 / OLYMPIA

A randomised, 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 1836 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.

ABCSG 42 / PALLAS

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

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

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

Sample size:
5.600

Sponsor:
ABCSG (20 countries)
AFT (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 the expected benefit to patients (published in Lancet Oncology: Mayer E et al., 2021). 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 being 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. 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 will be conducted in close collaboration between the researchers and both sponsors and will keep all global teams engaged with this cohort and related research questions for many more years to come.

Studies in Treatment Phase and Follow-up

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. The trial is already closed for enrollment, and to date, about three thirds of study participants have resumed with endocrine therapy. Long-term follow-up is planned to confirm long-term safety.
Data collected in the trial are of high relevance to all physicians, as they are often confronted with the patients' wish to become pregnant, yet without any evidence-based information for that setting being available so far.

ABCSG 51 / AURORA

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

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

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

Sample size: **2.000**

Sponsor: **BIG**

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)]. Recruitment of new participants was closed in February 2021. Until the end of 2022, 1.160 patients had been included globally, out of which 18 patients were recruited in the participating Austrian trial sites.

ABCSG 52 / ATHENE

An open-label, two-arm, randomized, single-stage phase II study of ATezolizumab in combination with dual HER2 blockade plus epirubicin as NEoadjuvant therapy for HER2-positive early breast cancer

Coordinating Investigators: **Richard Greil** (Salzburg), **Michael Gnant** (Vienna)

Start of study: **07/2020** (national)

Sample size: **58**

Sponsor: **ABCSG**

The ABCSG 52 / ATHENE study is investigating the efficacy and safety of a neoadjuvant immunochemotherapy regimen consisting of atezolizumab, trastuzumab, pertuzumab and epirubicin in HER2-positive early breast cancer patients in regards to pathologic complete response (pCR). Furthermore, this study project includes a comprehensive translational research program with a corresponding study endpoint. This academic Austrian-wide research project was conducted at 9 study sites. On July 3rd, 2020, the first patient was randomized into the study at the trial site in Salzburg under the supervision of ABCSG vice president Richard Greil. Due to the strong performance of the Austrian trial sites despite being launched in the midst of and accompanied by the challenges of the COVID-19 pandemic, the last patient could be enrolled in the beginning of December 2021 at the top recruiting site in Innsbruck under PI Daniel Egle and study enrollment was closed accordingly in time. The database lock occurred in August 2022 and study results are presented at ESMO Breast 2023.

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. It was decided that patient treatment and study follow-up will continue as planned per study protocol.

„SCIENCE FROM THE HEART OF EUROPE"

ABCSG 18 AND ZOLEDRONIC ACID SUBSTUDY

A randomized, double-blind, placebo-controlled, multi-center phase 3 study to determine the treatment effect of denosumab in subjects with non-metastatic breast cancer receiving aromatase inhibitor therapy

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

Start of main study/ABCSG 18: **12/2006** (global a. national)

Start of substudy/18 ZA: **02/2020** (in a national patient subset)

Sample size: **3.400** (main study), **50** (substudy)

Sponsor: **Amgen**

Description and status:

The ABCSG 18 trial was a placebo-controlled, double-blind, multi-center phase III study that included 3.425 patients with hormone receptor-positive breast cancer. The standard of care treatment for postmenopausal women with this type of breast cancer are aromatase inhibitors (AI), but these have a negative effect on bone density and significantly increase the risk of osteoporosis. The monoclonal antibody denosumab was therefore used in addition to anti-hormonal therapy in one of the two study arms. As previously reported for the study results, denosumab reduced the incidence of clinical bone fractures by 50 % and generally improved bone health with no additional side effects. However, cessation of denosumab therapy is associated with a decrease in bone mass and a suggestive increase in vertebral body fractures. Bisphosphonate treatment (with e.g., zoledronic acid) after discontinuing denosumab could prevent these fractures, especially in patients who were not previously exposed to bisphosphonates and who are at high risk of fractures. To test this hypothesis, substudy 18 ZA was developed as an additional part of the protocol. The zoledronic acid (ZA) substudy evaluates the effects of a single intravenous administration of ZA on bone mineral density, fracture incidence (clinical and morphometric), and bone turnover markers (CTX and osteocalcin). Fifty willing and eligible patients who had participated in the open label phase (OLP) of the main study and received OLP denosumab could choose to participate in the ZA substudy. Depending on the randomization group, they received either a single dose of ZA (therapy arm) or are treated according to the current standard of care for this patient population (control arm). Follow-up continued for a total of 18 months and the patients are evaluated every 6 months. On 26 July 2022, the last patient went "End of study" and collected blood samples of all 50 patients are analyzed at the Medical University of Graz. Results of bone turnover markers and bone mineral density are eagerly awaited and will be presented in 2023.

Studies in Treatment Phase and Follow-up

Translational Projects and upcoming Studies

„SCIENCE
FROM THE HEART
OF EUROPE"

ABCSG
AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

Translational Studies and Projects

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

The **TraX&Vields** project in collaboration with Cepheid is one of ABCSG's largest endeavors, as it includes work packages for multiple former ABCSG trial patient cohorts. The main aim of all work packages is twofold: the Cepheid *GeneXpert Breast Cancer STRAT4* is a novel test to reliably, reproducibly, and quantitatively test common tumor markers using their mRNA expression levels. This test is to be validated in a number of ABCSG trial patient cohorts and has already achieved CE-certification in some countries. Secondly, a prognostic breast cancer signature to predict the recurrence risk of early breast cancer patients is to be developed and validated. In 2020, a new predictive breast cancer signature *(Xpert Insight)* has come into focus and is planned to be validated in various ABCSG cohorts as well.

Work is continuing on 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 will be 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 was completed and the validation of *STRAT4* concordance data is already complete as well. Data analysis using the extended clinical follow-up data will be the final step in this cohort.

Great progress was made in the TraX&Vields-02 work package (ABCSG-8): after receiving full approval, the laboratory work was started in summer 2022. We hope to progress this sub-project further in 2023 to produce the first validation results of the novel breast cancer signature. In the work packages concerning the ABCSG-12 cohort the protocol for validating the *STRAT4* test and prognostic signature is finalized and submitted to local authorities. Upon approval, former ABCSG-12 sites will be 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. Laboratory analysis of centralized ABCSG-12 samples to validate the *STRAT4* test and prognostic signature are then planned subsequently. We are targeting to activate all involved sites in 2023 and would like to express our appreciation of their support during set-up and conduct of this sub-project.

A translational cooperation with **Daiichi Sankyo** was aiming at defining expression levels of HER3 over time in the ABCSG-34 cohort. All laboratory analyses and statistical work were completed in 2022, with a scientific manuscript being prepared. The work done in this translational project may provide the basis for a prospective clinical study investigating targeted HER3 therapies in the future.

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 approach. Samples and HE-stained slides from the ABCSG-6 trial cohort, and afterwards also the ABCSG-8 trial patients, are being facilitated for this project. The analysis of the ABCSG-6 samples is currently under way.

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 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 further ABCSG trial populations planned to serve as validation cohorts for the signature. The study protocol will be submitted to the local authorities in 2023 to launch the project soon.

Outlook and planned Studies 2023

ABCSG 55N / AMBHER
The single-arm, two cohort, multicenter non-interventional study (NIS) **ABCSG 55N / AMBHER** will collect data of patients with HER2-positive early breast cancer treated with pertuzumab and trastuzumab in Austria. This ABCSG sponsored study with the support of Roche is aiming at the development of a dynamic composite risk score to predict the risk of distant recurrence. For this purpose, it is planned to retrospectively as well as prospectively include a total of 500 patients treated with dual HER2-blockade in the neoadjuvant setting at various Austrian sites. The study is currently in the initiation phase and patient data collection will start in 2023.

ABCSG 60 / CAMBRIA
Phase III global trial **ABCSG 60 / CAMBRIA** sponsored by AstraZeneca assessing the efficacy and safety of the extended therapy with camizestrant versus standard endocrine therapy in patients with ER+/HER2- early breast cancer (expected sites appr. 658 global, 11 AT, planned patients appr. 4300 global, 75 AT).

ABCSG 61 / TEODOR
In the prospective, randomized, controlled, open-label multicenter phase II TEODOR study (Neoadjuvant **T**r**E**atment **O**ptimization driven by ct**D**NA and end**O**crine **R**esponsiveness), 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. The study is currently in set up phase and the first sites are planned to open for recruitment up in 2024.

ABCSG 62 / Cambria-2
Phase III global open label trial ABCSG 62 / Cambria-2 sponsored by AstraZeneca is assessing the efficacy and safety of camizestrant versus standard endocrine therapy 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. This trial will be managed by ABCSG in 9 countries (Austria, Australia, France, Germany, Ireland, New Zealand, Spain, Switzerland and the US). ABCSG will act as academic network umbrella. The study will be conducted in approximately 700 sites in more than 40 countries, where it is planned to enroll 5.500 patients.

ABCSG 63 / Elacastrant/Ribociclib study
ABCSG 63 is designed as an open-label, two-arm, randomized, two-step, 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. ABCSG 63 is planned to be conducted in two countries (Austria and an additional country) with approximately 18 trial sites participating to randomize a total of 120 patients. The study is currently in the set-up phase with first patients planned to be enrolled in the first quarter of 2024.

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

„SCIENCE FROM THE HEART OF EUROPE"

ABCSG
AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

„SCIENCE FROM THE HEART OF EUROPE"

ABCSG Events and Activities

In 2022, the ABCSG was not only engaged in clinical research and publication of results but also in expanding on medical education and (online as well as onsite) trainings, social media outreach and increasing awareness for clinical research and breast cancer, more specifically. We offered 7 continuing medical education-accredited formats on specific topics related to state-of-the-art breast cancer diagnosis and therapy.

After being strongly impacted in that field by the COVID-19 pandemic, on-site training courses and educational events could finally take place again in the last year. Nevertheless, the successful virtual ABCSG-formats were maintained in 2022 due to high demand and will continue to be rolled out and expanded in 2023.

The digital presence of the ABCSG on our social media channels LinkedIn, Twitter and Instagram has been intensified in line with specific target groups and will continue to be the focus of our communication efforts in 2023. ABCSG's traditional press work left a notable footprint in numerous clippings and publications and will be further enhanced in the future.

The examples described below provide an overview of ABCSG-developed formats and collaborative medical training events that aim at providing knowledge, expertise and active scientific discourse to target audiences in Austria and abroad.

Science News

The Science News format gives our network of investigators the opportunity to listen to the highlights of the most important congresses in the field of breast cancer, but also GI cancer, as a compact video summary sent out to our members via newsletter and also made available shortly after the event for download on the ABCSG website.
In 2022, the ABCSG Science News offered a video résumé of the Annual Meetings ESMO Breast, ASCO, ESMO, EBCC and SABCS and was greatly followed with over 2.000 views.
The ESMO wrap-up also featured a live video panel discussion with the three renowned experts Univ. Prof. Dr. Günther Steger, Assoc. Prof. Priv.-Doz. Dr. Marija Balic and Assoc. Prof. Priv.-Doz. Dr. Rupert Bartsch.

Post-SABCS

On January 14th the ABCSG, together with the publishing house Universimed, hosted the popular Post-SABCS educational event for the 9th time. In accordance with tradition, approximately one month after the most important congress on breast cancer, the key data from the San Antonio Breast Cancer Symposium were summarized by ABCSG experts from all over Austria.
After an interruption and being held as an online event due to the COVID-19 pandemic in past years, the Post-SABCS took again place as an onsite format with approximately 70 interested participants.
Besides the presentation of current study data, an interdisciplinary panel was dedicated to engaging with the audience to discuss the integration of these data in clinical practice.

The Changing Treatment Landscape of CDK 4/6 Inhibitors: Moving From Late To Early Stages

On May 9th 2022, the breast cancer education webinar „The Changing Treatment Landscape of CDK 4/6 Inhibitors: Moving From Late To Early Stages" took place for the second time online, with an international audience following the English presentations and discussions. In this joint event with Novartis, both ABCSG and Novartis global experts discussed the drastically changing treatment landscape of CDK4/6 inhibitors in different stages of breast cancer.
Hot topics such as overall survival data and their significance for clinical routine and therapeutic decision-making, the profiling of intrinsic subtypes and the role of selectivity were contents of the webinar as well as the analysis of the efficacy of preclinical studies, prospective research directions and co-targeting therapy strategies to overcome CDK4/6 inhibitor resistance through SERDs.

16th Interdisciplinary Mamma Discourse

After two virtual formats in 2020 and 2021, the 16th Interdisciplinary Mamma Discourse was again held as face-to-face event in cooperation with the Austrian Society for Senology at Palais Berg in Vienna on October, 5th with almost 80 participants in attendance at this educational evening. ABCSG President Univ.-Prof. Dr. Michael Gnant and Senology President Univ.-Prof. Dr. Günther Steger led through the educational evening consisting of three overview lectures on highly relevant topics in breast cancer therapy, followed by Case Report Tumor Board discussions that provided very practical insights in challenges and possibilities for clinical routine.

NIFA-Workout 1.1 and NIFA-Symposium

From October 14th-15th, the 21st edition of an event series called NIFA finally took place again as a face-to-face format in Vienna. More than 90 Austrian breast cancer experts came together to learn and discuss the most important news and future „hot topics" on breast cancer. Together with medical experts from AstraZeneca, the participants were again offered a varied program with focus on scientific and controversial discussions on different therapeutic approaches and study data. This year's program was complemented by special guest Prof. Konrad Paul Liessmann, who gave a gripping lecture on the topic „People, do you want to live "forever"? Medical innovation between youth cult and fear of old age" by introducing a philosopher´s perspective.
The new digital format „NIFA Workout" was successfully launched in July 2022 with three on-demand videos by top experts on the topic „Trends for the future - how is the landscape of eBC evolving?" followed by a panel discussion on September, 5th.

31th Annual Meeting of the ABCSG

From November 4th to 5th, the 31st Annual Meeting of the ABCSG finally took place again at Gut Brandlhof in Saalfelden after having been held in the virtual space due to the pandemic in 2020 and 2021. About 200 participants gathered to attend the interesting lectures and study updates in the various entities (including breast, colorectal and pancreatic cancers) and to exchange scientific and clinical ideas within the dedicated ABCSG network. In addition to discussing established trials or global standard of care-changing successes and resulting ABCSG sub-studies, the diverse Saalfelden 2022 program also proved that the ABCSG continued to advance clinical research on a national and international level in 2022 with the presentation of a variety of new studies in the pipeline.

Webinar „Brainstorming – Together against Brain Metastases in mBC"

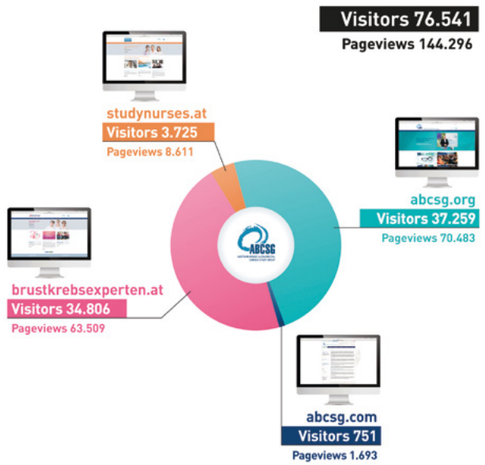
On November 23rd the virtual education event on the interdisciplinary topic „Brainstorming - together against brain metastases in mBC" was held for the first time in cooperation with Seagen. About one third of patients with metastatic breast cancer (mBC) develop brain metastases during the course of the disease despite systemic therapy. In cerebral metastasis, there are different, complementary therapeutic approaches in neurosurgery, radiosurgery, radiation oncology as well as drug therapy. Interdisciplinary discourse is thus an important asset.
In the interdisciplinary webinar, which was attended by 90 online participants, recent findings, key questions and therapy options were presented and discussed in a practical manner with top-class experts in order to achieve the best possible therapeutic success for affected patients.

„SCIENCE FROM THE HEART OF EUROPE"

Websites and Patient Portal

In addition to the website abcsg.at that has been revised and modernized from scratch in 2020 and 2021 and the website abcsg.com which will receive a fresh-up in 2023 and which both provide information on study-related content as well as on activities of the association in German and English for medical professionals, the website brustkrebsexperten.at, which is also maintained by the ABCSG, provides low-threshold information on breast cancer and ongoing studies for patients. Furthermore, the site studynurses.at/studycoordinators.at is also co-maintained by the ABCSG.

Visitor-statistics
01. Jan. – 31. Dec. 2022



Public Relations and Press

Every year, the scientific work of the ABCSG, as well as the commitment of ABCSG board members and members, is followed by the media. Around 60 articles appeared in Austrian daily newspapers and relevant journals of medical publishers in 2022, in which the ABCSG was mentioned. In addition, the ABCSG itself has been the publisher of krebs:hilfe! – a professional journal – for over 20 years: the ABCSG is responsible for the content together with the Austrian Cancer Aid. In addition to the print edition, the digital presence of krebs:hilfe! in form of a digital magazine as well as a newsletter has been further enhanced in 2022.

Independent academic cancer research from Austria

„SCIENCE FROM THE HEART OF EUROPE"

Publications 2022 and Study Overview

„SCIENCE
FROM THE HEART
OF EUROPE"

ABCSG
AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

Publications 2022

Treatment Exposure and Discontinuation in the PALbociclib CoLlaborative Adjuvant Study of Palbociclib With Adjuvant Endocrine Therapy for Hormone Receptor-Positive/Human Epidermal Growth Factor Receptor 2-Negative Early Breast Cancer (PALLAS/AFT-05/ABCSG-42/BIG-14-03)

Mayer E L, Fesl C, Hlauschek D, Garcia-Estevez L, Burstein H J, Zdenkowski N, Wette V, Miller K D, Balic M, Mayer I A, Cameron D, Winer E P, Ponce Lorenzo J J, Lake D, Pristauz-Telsnigg G, Haddad T C, Shepherd L, Iwata H, Goetz M, Cardoso F, Traina TA, Sabanathan D, Breitenstein U, Ackerl K, Metzger Filho O, Zehetner K, Solomon K, El-Abed S, Theall K P, Lu D R, Dueck A, Gnant M, DeMichele A.

Journal of Clinical Oncology, published online on 07 January, 2022

Safety of adjuvant CDK4/6 inhibitors during the COVID-19 pandemic

Pfeiler G, DeMichele A, Amylou C. Dueck, Fesl Ch, Gnant M, Mayer E L

The Lancet Oncology, published on 02 February, 2022

Effect of concomitant statin treatment in postmenopausal patients with hormone receptor-positive early-stage breast cancer receiving adjuvant denosumab or placebo: a post hoc analysis of ABCSG-18.

Minichsdorfer C, Fuereder T, Leutner M, Singer CF, Kacerovsky-Strobl S, Egle D, Greil R, Balic M, Fitzal F, Pfeiler G, Frantal S, Bartsch R, Gnant M.

ESMO Open, published on 07 April, 2022

Persistence of ctDNA in Patients with Breast Cancer During Neoadjuvant Treatment Is a Significant Predictor of Poor Tumor Response

Zhou Q, Gampenrieder S P, Frantal S, Rinnerthaler G, Singer C F, Egle D, Pfeiler G, Bartsch R, Wette V, Pichler A, Petru E, Dubsky P C, Bago-Horvath Z, Fesl C, Rudas M, Ståhlberg A, Graf R, Weber S, Dandachi N, Filipits M, Gnant M, Balic M, Heitzer E

Clinical Cancer Research, published on 15 February, 2022

Independent validation of stromal uPA in ABCSG-08: Level 1b evidence for the prognostic value of uPA immunohistochemistry

Singer C F, Jahn S W, Rudas M, Bago-Horvath Z, Fitzal F, Abete L, Moinfar F, Gnant M, Filipits M; Austrian Breast and Colorectal Cancer Study Group (ABCSG).

The Breast, published on 19 May, 2022

Estrogen Receptor Alpha Gene Amplification Is an Independent Predictor of Long-Term Outcome in Postmenopausal Patients with Endocrine-Responsive Early Breast Cancer

Singer C F, Holst F, Steurer S, Burandt E C, Lax S F, Jakesz R, Rudas M, Stöger H, Greil R; ABCSG, Sauter G, Filipits M; ABCSG, Simon R, Gnant M; ABCSG.

Clinical Cancer Research, published on 15 September, 2022

Overall survival in the OlympiA phase III trial of adjuvant olaparib in patients with germline pathogenic variants in BRCA1/2 and high-risk, early breast cancer

Geyer CE Jr, Garber JE, Gelber RD, Yothers G, Taboada M, Ross L, Rastogi P, Cui K, Arahmani A, Aktan G, Armstrong AC, Arnedos M, Balmaña J, Bergh J, Bliss J, Delaloge S, Domchek SM, Eisen A, Elsafy F, Fein LE, Fielding A, Ford JM, Friedman S, Gelmon KA, Gianni L, Gnant M, Hollingsworth SJ, Im SA, Jager A, Jóhannsson ÓÞ, Lakhani SR, Janni W, Linderholm B, Liu TW, Loman N, Korde L, Loibl S, Lucas PC, Marmé F, Martinez de Dueñas E, McConnell R, Phillips KA, Piccart M, Rossi G, Schmutzler R, Senkus E, Shao Z, Sharma P, Singer CF, Španić T, Stickeler E, Toi M, Traina TA, Viale G, Zoppoli G, Park YH, Yerushalmi R, Yang H, Pang D, Jung KH, Mailliez A, Fan Z, Tennevet I, Zhang J, Nagy T, Sonke GS, Sun Q, Parton M, Colleoni MA, Schmidt M, Brufsky AM, Razaq W, Kaufman B, Cameron D, Campbell C, Tutt ANJ; OlympiA Clinical Trial Steering Committee and Investigators.

Annals of Oncology, published on 10 October, 2022

Cost-effectiveness of palbociclib in early breast cancer patients with a high risk of relapse: Results from the PENELOPE-B trial

Galactionova K, Loibl S, Salari P, Marmé F, Martin M, Untch M, Bonnefoi HR, Kim SB, Bear HD, McCarthy N, Gelmon KA, García-Sáenz JA, Kelly CM, Reimer T, Toi M, Rugo HS, Gnant M, Makris A, Burchardi N, Schwenkglenks M

Frontiers in oncology, published on 05 September, 2022

Long-Term Outcomes of Adjuvant Denosumab in Breast Cancer

Gnant M, Frantal S, Pfeiler G, Steger G, Egle D, Greil R, Fitzal F, Wette V, Balic M, Haslbauer F, Melbinger-Zeinitzer E, Bjelic-Radisic V, Artner-Matuschek S, Kainberger F, Ritter M, Rinnerthaler G, Sevelda P, Bergh J, Kacerovsky-Strobl S, Suppan C, Brunner C, Deutschmann C, Gampenrieder S, Fohler H, Jakesz R, Fesl C, Singer C, for the Austrian Breast & Colorectal Cancer Study Group

NEJM Evidence, published on 18 November, 2022

Does the number of 6-monthly adjuvant zoledronate infusions received affect treatment efficacy for early breast cancer? A sub-study of ABCSG-12

Beltran-Bless AA, Clemons MJ, Fesl C, Greil R, Pond GR, Balic M, Vandermeer L, Bjelic-Radisic V, Singer CF, Steger GG, Helfgott R, Egle D, Sölkner L, Gampenrieder SP, Kacerovsky-Strobl S, Suppan C, Ritter M, Rinnerthaler G, Pfeiler G, Fohler H, Hlauschek D, Hilton J, Gnant M

EJC European Journal of Cancer, published on 10 December, 2022

„SCIENCE
FROM THE HEART
OF EUROPE"

ABCSG
AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

Conference-Presentations 2022

Long-term outcomes of adjuvant denosumab in breast cancer: Fracture reduction and survival results from 3,425 patients in the randomised, double-blind, placebo-controlled ABCSG-18 trial

Presentation by Gnant M, Frantal S, Pfeiler G, Steger G G, Egle D, Greil R, Fitzal F, Wette V, Balic M, Haslbauer F, Melbinger-Zeinitzer E, Bjelic-Radisic V, Brunner C, Artner-Matuschek S, Rinnerthaler G, Wimmer K, Bergh J C S, Fesl C, Singer C F

American Society of Clinical Oncology 2022, June 2022

Conference-Posters 2022

A phase 3 study to determine the breast cancer risk reducing effect of denosumab in women carrying a germline BRCA1 mutation (BRCA-P Study)

Poster by Bhulani N, Wood M, Tsai J, Bedrosian I, Hopkins J O, Brunet J, Michaelson-Cohen R, Schmutzler R K, Evans G D, Gnant M, Fesl C, Mystek A, Lindeman G J, Singer C F, Garber J E

American Society of Clinical Oncology 2022, June 2022

Impact of body mass index on treatment and outcomes in patients with early hormone receptor-positive breast cancer receiving endocrine therapy with or without palbociclib in the PALLAS trial.

Poster by Pfeiler G, Hlauschek D, Mayer E L, Deutschmann C, Kacerovsky-Strobl S, Martin M, Meisel J L, Zdenkowski N, Loibl S, Balic M, Park H, Prat A, Isaacs C, Machacek-Link J, Schurmans C, Theall K P, Fesl C, Dueck A C, DeMichele A, Gnant M

American Society of Clinical Oncology 2022, June 2022

Focal ESR1 gene amplification is an independent prognostic marker in postmenopausal patients with endocrine-responsive early breast cancer

Poster by Singer C F, Holst F, Steurer S, Burandt E C, Lax S F, Jakes R, Rudas M, Stöger H, Greil R, Sauter G, Filipits M, Simon R, Gnant M, on behalf of the ABCSG

San Antonio Breast Cancer Symposium 2022, December 2022

Study Overview

Study	Sponsor	Title	Status
ABCSG 18 ZA Substudy	Amgen	Zoledronic Acid (ZA) substudy to evaluate the impact of a single intravenous (IV) ZA administration on bone mineral density, fracture incidence, and bone turnover markers	closed
ABCSG 22R-QoL	ABCSG	A survey conducted on the quality of life of breast cancer patients registered in ABCSG 22R	closed
ABCSG 25 / PANTHER	ABCSG (Co-Sponsor) and Scandinavian Breast Group (SBG)	A randomized phase III study comparing biweekly and tailored epirubicin + cyclophosphamide followed by biweekly tailored docetaxel (dtEC→dtT) (A-arm) versus three weekly epirubicin + cyclophosphamide, 5-fluorouracil followed by docetaxel (FEC→T) (B-arm) in lymph node positive or high-risk lymph node negative breast cancer patients – a continuation of the feasibility part of the SBG 2004-1 study	treatment / follow-up
ABCSG 28 / POSYTIVE	ABCSG	Primary Operation in SYnchronous meTastasized InVasivE breast cancer, a multicenter prospective randomized study to evaluate the use of local therapy.	closed
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-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	treatment / follow-up
ABCSG 39 / APHINITY	Roche	A randomized multicenter, double-blind, placebo-controlled comparison of chemotherapy plus trastuzumab plus placebo versus chemotherapy plus trastuzumab plus pertuzumab as adjuvant therapy in patients with operable HER2-positive primary breast cancer	treatment / follow-up
ABCSG 41 / OLYMPIA	AstraZeneca	A randomised, 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 (US)	PALbociclib CoLlaborative Adjuvant Study: A randomized phase III trial of Palbociclib with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy alone for hormone receptor positive (HR+) / human epidermal growth factor receptor 2 (HER2)-negative early breast cancer	treatment / follow-up
ABCSG 43 / INSEMA	University of Rostock	Comparison of axillary sentinel lymph node biopsy versus no axillary surgery in patients with stage I and II invasive breast cancer and breast-conserving surgery: a randomized prospective surgical trial	treatment / follow-up
ABCSG 45	ABCSG	A prospective, open, randomized, phase II study of carboplatin/olaparib in the pre-operative treatment of patients with triple-negative primary breast cancer which exhibit the features of positive homologous recombination deficiency (HRD) status	open for enrollment
ABCSG 47 / IMpassion030 / ALEXANDRA	Roche	A Phase III, multicenter, randomized, open-label study comparing Atezolizumab (Anti PD-L1 Antibody) in combination with adjuvant anthracycline/taxane-based chemotherapy versus chemotherapy alone in patients with operable triple-negative breast cancer	enrollment on hold
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 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	treatment / follow-up
ABCSG 50 / BRCA-P	ABCSG (Austria, Germany), other national sponsors in Australia, Israel, Spain, UK, US	A randomized, double-blind, placebo-controlled, multi-center international phase 3 study to determine the preventive effect of Denosumab on breast cancer in women carrying a BRCA1 germline mutation	open for enrollment
ABCSG 51 / AURORA	BIG	Aiming to understand the molecular aberrations in metastatic breast cancer: The AURORA Program	treatment / follow-up
ABCSG 52 / ATHENE	ABCSG	An open-label, two-arm, randomized, single-stage phase II study of ATezolizumab in combination with dual HER2 blockade plus epirubicin as NEoadjuvant therapy for HER2-positive early breast cancer	closed
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 registration
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-positive Advanced BrEasTcancer	open for enrollment
C 08 / Exercise II	ABCSG	Randomized trial of endurance exercise following adjuvant chemotherapy for colorectal cancer	open for enrollment
P 02	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
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

„SCIENCE FROM THE HEART OF EUROPE"

ABCSG AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

ABCSG Trial Office
Nussdorfer Platz 8
1190 Vienna, Austria

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

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

Editor:
Association for prevention and therapy of malignant diseases, Cooperative Studygroup Mamma- & Colorectal Carcinom, Austrian Breast & Colorectal Cancer Study Group (ABCSG)

„SCIENCE FROM THE HEART OF EUROPE"

ABCSG
AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP