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Austrian Breast & Colorectal Cancer Study Group

Annual Report

Austrian Breast & Colorectal Cancer Study Group 2021

„SCIENCE FROM THE HEART OF EUROPE“

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Introduction and Key Facts

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ABCSG in 2021: a year of remarkable achievements under challenging circumstances

All of us were forced to learn that clinical trials can be prone to failures and challenges – particularly during the past year 2021, COVID-19's lasting impact on clinical trial conduct continued to test our resilience and engagement, and all of us personally. Given these circumstances, the **Austrian Breast and Colorectal Cancer Study Group (ABCSG)** is especially grateful for some remarkable **clinical research achievements** in 2021:

The **ABCSG-16 / S.A.L.S.A** study, with its significant practice-changing results published in the *New England Journal of Medicine* in July 2021, answered a relevant clinical question, thus clarifying a standard treatment duration for most postmenopausal patients with hormone receptor-positive breast cancer. Furthermore, the huge **ABCSG-42 / PALLAS** data treasure trove started to pave the way for many new sub-projects with translational research and correlative science focus to be conducted, even though the final endpoint analysis presented at **SABCS 2021** by **ABCSG president Michael Gnant** turned out to be negative: the addition of palbociclib to endocrine therapy did not provide benefit in terms of improving invasive disease-free survival in the adjuvant setting.

Since the pandemic has been devastatingly disruptive for a lot of trials, especially with regard to patient recruitment, the **ABCSG-52 / ATHENE** study, investigating neoadjuvant atezolizumab, is also noteworthy. This particular study completed its recruitment phase at a great pace, with the first patient randomised in Salzburg in July 2020 and enrolment completed in late 2021 – as planned!

Overall, in 2021 ABCSG-affiliated investigators successfully published research results in **15 high-ranking medical journals**. Exemplifying *pars-pro-toto*, Michael Gnant ranked – already for the second time in 2021 – among the global 1% of "Highly Cited Researchers" (source: *Clarivate statistics*).

Besides the success in academic clinical research, the ABCSG established and promoted its digitalisation initiative, **ABCSG goes digital**. The objective was to disseminate widely the ABCSG's many breast cancer training programmes and educational formats such as e-learnings, science news and podcast series. Given that in 2021 these ABCSG events once more had to take place exclusively in digital spheres, the ABCSG network responded well to the virtual content being offered, which has accelerated ever since. The innovative format **ABCSG in touch goes digital**, which gives younger physicians, residents and researchers a platform (summarised as the **Task Force *FutureNow***), was launched in March 2021. This cross-generational knowledge transfer and networking event was also appealing to medical and academic junior talents and resulted in another meeting taking place in November 2021. Finally, an important highlight of the ABCSG year was the **30th anniversary of the ABCSG Annual Meeting**, held virtually.

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 also some changes within the ABCSG leadership during the past year. **Daniel Egle** of the Medical University Innsbruck was elected to the ABCSG board, and **Christian Singer** became ABCSG's newest vice president. ABCSG's founding president **Raimund Jakesz** was awarded the very first ABCSG honorary membership.

"For 2022 I am confident that we all will try our best to build on the successes of 2021. Most importantly, we have already laid the solid foundation for the various upcoming ABCSG trial launches in 2022. We will also continue to improve our educational services for caregivers and patients, constantly aiming to perfect our operational capability, scientific excellence and global interdisciplinary collaboration", says Professor Gnant.

In the following ABCSG Annual Report 2021 you will receive an overview of our study projects and associated activities which could be excellently implemented – even in these challenging times – due to our strong cohesion and team spirit.

We hope you enjoy reading it!

Sincerely,

ABCSG president and vice-presidents,
Michael Gnant, Marija Balic, Richard Greil,
Christian Singer and Christian Marth

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ABCSG Key Facts 2021

effective date 31.12.21

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

Tax status: non-profit

Association

Year of foundation: 1984

9 Board members
10 Members Executive Committee
44 Members General Assembly

Tax status: non-profit

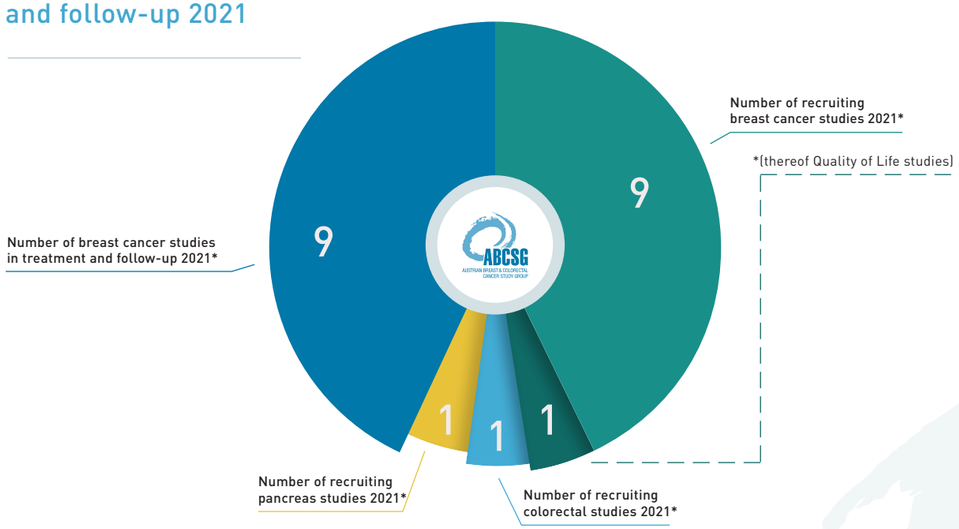
Number of all patients ever recruited

28.884

Number of ...

... translational projects 2021	2
... enrolling studies 2021*	11
... studies in treatment phase and follow-up 2021	9

Clinical studies in recruitment, treatment and follow-up 2021



Number of ...

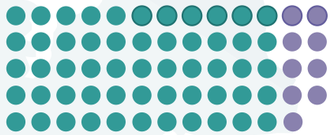
... all ongoing breast cancer studies in 2021	18
... all ongoing colorectal studies in 2021	1
... all ongoing pancreas studies in 2021	1
... all ongoing liver metastasis studies in 2021	0

166

Total Publications ABCSG (peer reviewed)

Publications 2021 (peer reviewed)	15

Employees* (Head Count)



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

*including working students

12.9 years ...

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

Structure, Aims, Visions and International Network

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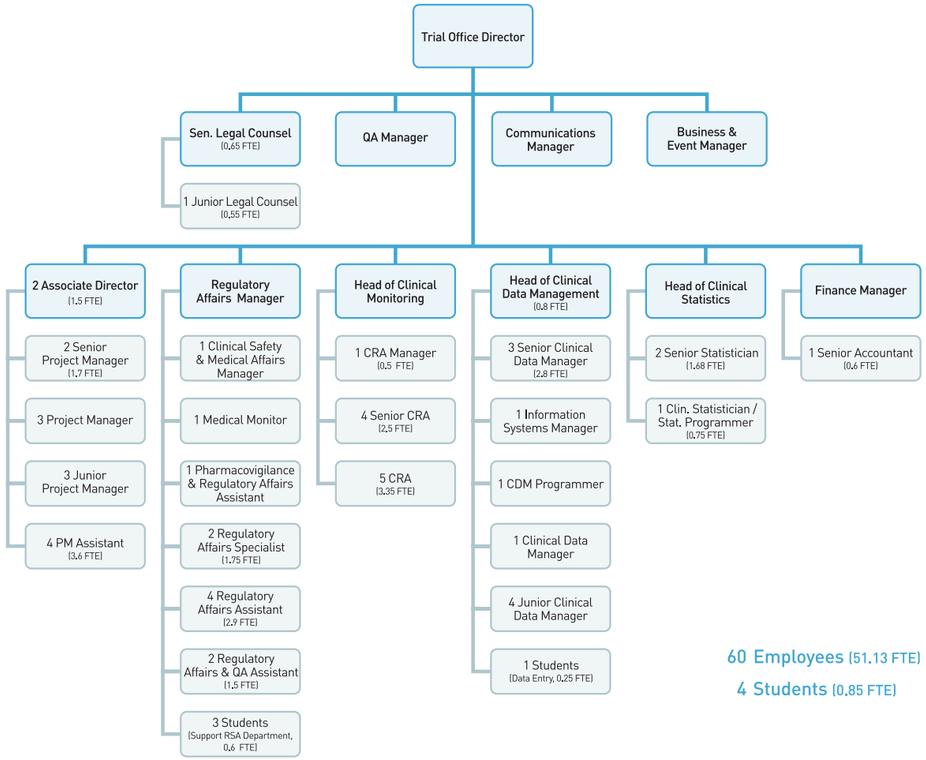
ABCSG Trial Office



60 Employees (51.13 FTE)
4 Students (0.85 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 has 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. Currently, there are several projects and associated task forces in concrete planning stages.

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 as well as 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.

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International Network

The ABCSG is part of the Breast International Group (BIG) network, the largest international association dedicated to breast cancer research and control. Overall, the ABCSG is part of a network of breast cancer study groups encompassing 65 countries and 6 continents. These include the Spanish study groups Investigación en Cáncer de Mama (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 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 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). 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 and OncoMark, and 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 almost 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 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:	Sample size:	Sponsor:
07/2019 (national)	**600**	**ABCSG**

Description and status:

The ABCSG 22R-QoL is a survey among breast cancer patients who have received hormone therapy to treat their breast cancer and whose data have already been recorded in the ABCSG patient register 22R. While in 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 is 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 are issued and analyzed. The department of Gynecology at the Medical University of Graz was activated as the leading center. Completed questionnaires of 600 patients are planned within 36 months. Eleven sites throughout Austria, who had recruited most of the participants for the 22R patient register, agreed to join the survey. Since the study start in July 2019, a total of 450 questionnaires were issued to patients at 11 sites. Despite temporary difficulties in accessibility of the sites due to the COVID-19 outbreak, the willingness of patients to take part in the survey remains high, making an important contribution to gaining new knowledge in medical research regarding quality of life after cancer therapy.

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Studies open for Enrollment

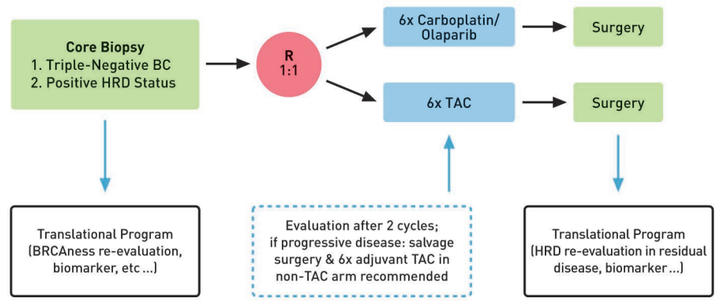
ABCSG 45

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 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 subphases: in dose-finding phase 1, the maximum tolerated olaparib dose is assessed in 20 patients at 6 sites and the identified olaparib dose is then administered in phase 2, with an additional 70 p in 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) and the quality of life of the patients 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 2022 and a total of 15 patients have already been included into study phase 2 by end of 2021.

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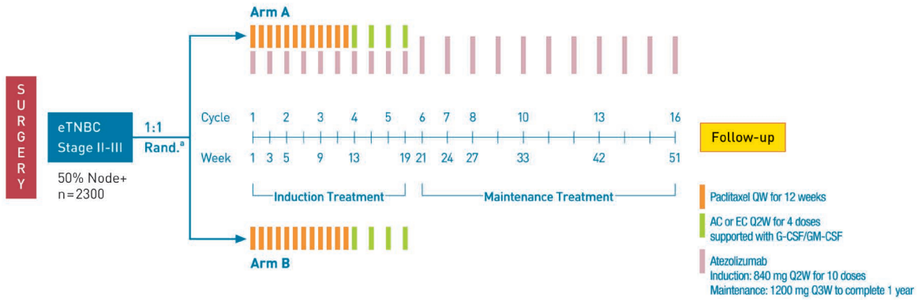
ABCSG 47 / IMpassion030 / ALEXANDRA

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 efficiency of adjuvant treatment with 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 2021 and 2.072 patients have been randomized so far. In Austria, all 9 planned sites were activated in 2021, and 10 patients have been included by the end of 2021.

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Studies open for Enrollment

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:
11/2020 (national) **08/2019** (global)	**50**	**IBCSG**

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 the International Breast Cancer Study Group (IBCSG) and started with the "First Patient In" milestone at a site in Switzerland in August 2019. Globally, a total of approx. 50 sites are planned to participate 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. In Austria, all 4 sites are already active and a total of 8 patients have been enrolled so far.

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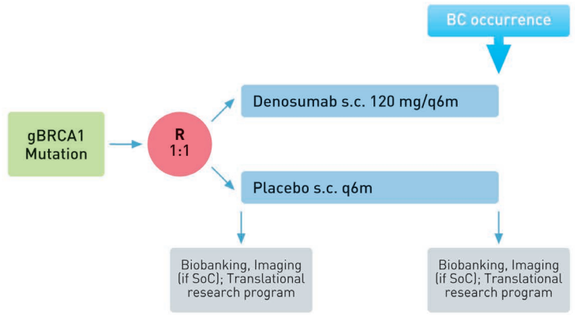
ABCSG 50 / BRCA-P

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 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 will be randomized worldwide. Next to Austria, also Australia, Germany, Israel, Spain, the UK, and the US are involved in this trial. In Austria, all 5 sites are already active. Currently Austrian, Australian, Spanish and Israeli sites are enrolling in the trial and a total of 116 women have been recruited so far, out of which 55 participants were included in Austrian sites. Great progress is expected for the next months, as the remaining countries, namely Germany, the UK and the US will start with their recruitment. The primary analysis is planned once 167 primary endpoint events occur, whereat 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.

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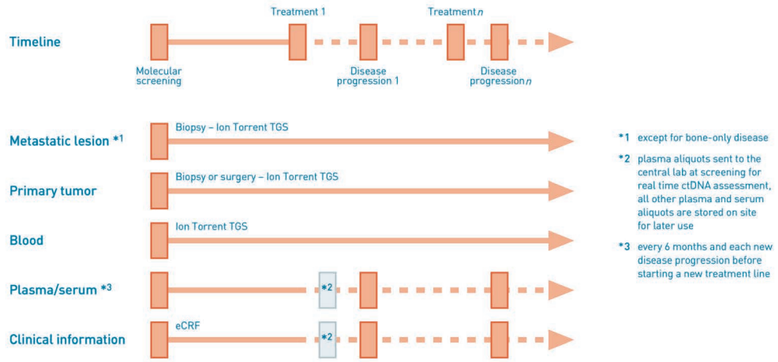
ABCSG 51 / AURORA

Aiming to Understand the Molecular Aberrations in Metastatic Breast Cancer: The AURORA Program

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

Start of study:	Sample size:	Sponsor:
09/2014 (global) **12/2018** (national)	**2.000** (revised in August 2020)	**Breast International Group** (BIG)

Design:



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 help of genomic and transcriptomic data. The first AURORA manuscript was published in June 2021 [Aftimos et al., Cancer Discovery (2021)]. Enrollment of new participants in the AURORA program is currently on hold as per sponsor communication. Until the end of 2021, 1.160 patients were included globally, out of which 18 patients have been recruited in the participating Austrian trial sites.

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AURORA
Metastatic Breast Cancer – molecular aberrations

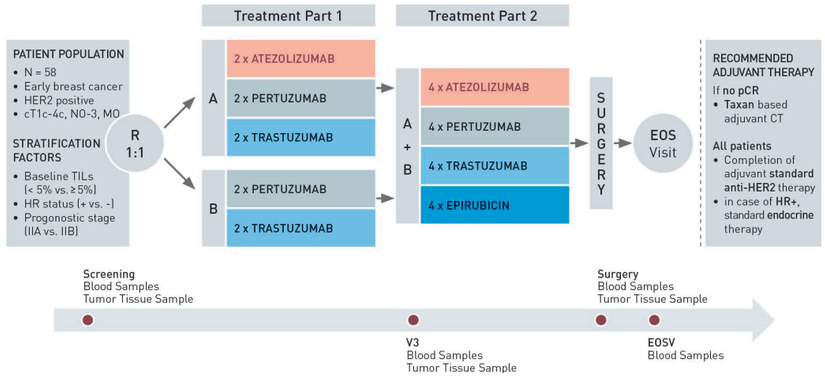
ABCSG 52 / ATHENE

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:	Sample size:	Sponsor:
07/2020 (national)	**58**	**ABCSG**

Design:



Description and status:

ABCSG 52 / ATHENE study is investigating the efficacy and safety of neoadjuvant immunochemotherapy regimen consisting of atezolizumab, trastuzumab, pertuzumab and epirubicin in human epidermal growth factor receptor 2 (HER2)-positive early breast cancer patients in regards to pathologic complete response (pCR). Furthermore, this study project includes a comprehensive translational research program with accordingly defined study endpoint. This academic Austrian-wide research project is conducted in 9 study sites. On July 3rd, 2020, the first patient was randomized into the study at the trial site in Salzburg under the PI-ship of ABCSG vice president Richard Greil. Due to the strong performance of the Austrian trial sites despite the challenges of the COVID-19 pandemic, the 58th patient could be enrolled beginning December 2021 at the top recruiting site in Innsbruck under PI Daniel Egle and study enrolment was closed. Currently, biosample collection as well as study treatment is still ongoing and "Last Patient Last Visit" is estimated to occur mid-2022.

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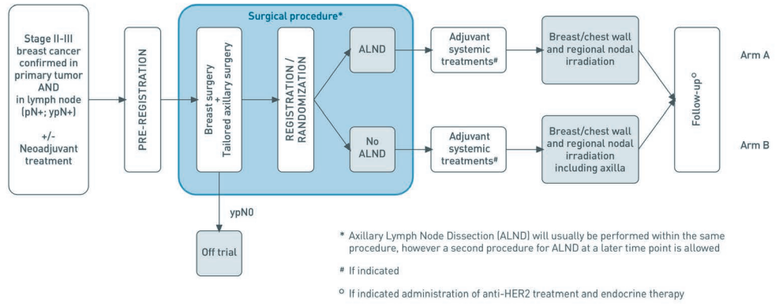
ABCSG 53 / TAXIS

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**	**USB (previously SAKK)**

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 in 2021 and re-opened the first Swiss site in May 2021, followed by Hungary in November 2021. Germany, Lithuania and Austria have still been working on re-starting recruitment by the end of 2021. In total, 458 patients could be included in TAXIS until 31st Dec 2021, 30 out of these in Austria.

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Studies open for Enrollment

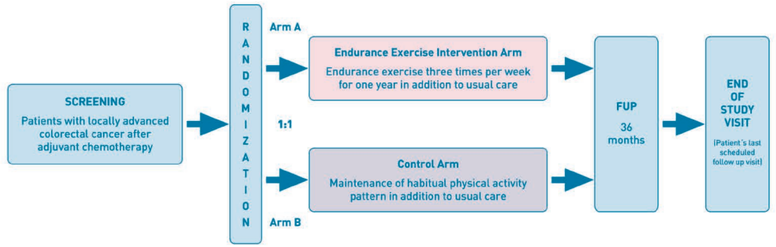
ABCSG C08 / EXERCISE II

Randomized Trial of Endurance Exercise following adjuvant Chemotherapy for Colorectal Cancer

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

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

Design:



Description and status:

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 building 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. Due to insufficient patient recruitment, enrollment will not be extended beyond 100 patients (i.e. "feasibility phase"), so the analysis will be performed based on this patient cohort of the feasibility phase. By the end of 2021, a total of 40 patients have been included at 7 out of 8 activated Austrian sites.

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

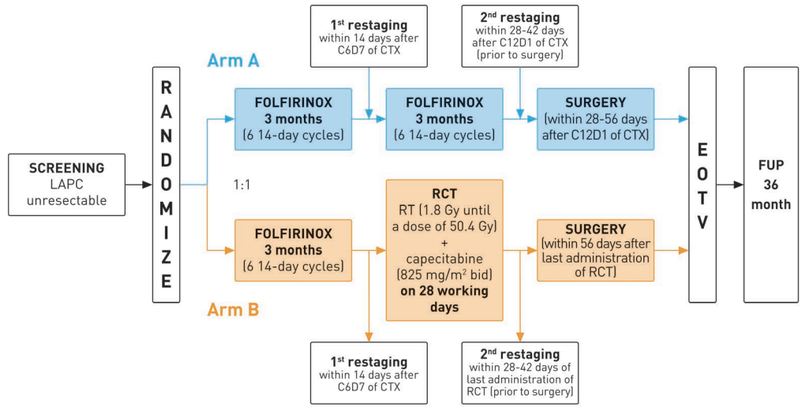
ABCSG P02

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:	Sample size:	Sponsor:
05/2017 (national)	**112**	**ABCSG**

Design:



Description and status:

ABCSG P02 is the second pancreas-related project organized by ABCSG. Patients with locally advanced, primarily irresectable (irresectable and borderline irresectable) pancreatic cancer are enrolled into this Austrian-wide, academic research project. Primarily this study was designed to demonstrate, that within this patient collective a neoadjvuvant 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". According to the current study protocol, 112 patients are planned to be randomized into the study and up until end of 2021 83 patients have been recruited. All of the seven participating trial sites have already randomized study patients. This academic project sponsored by ABCSG offers the opportunity to answer important questions for a patient cohort, that is currently presented with a limited number of possibilities for study participation.

SCIENCE FROM THE HEART OF EUROPE™ ABCSG

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 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 study:
12/2006 (main study/global and national)
02/2020 (zoledronic acid substudy, 18 ZA / in a national patient subset)

Sample size:
3.400 (main study)

Sponsor:
Amgen

Description and status:

ABCSG 18 is 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 post-menopausal 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 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). Willing and eligible patients who 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 receive 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 continues for a total of 18 months after day 1. After day 1, the patients are evaluated every 6 months. During the 1 year enrollment phase starting in February 2020, 50 patients eligible for the ZA substudy were randomized at selected ABCSG 18 centers. The results of this subset analysis are eagerly awaited.

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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 of the 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 2017 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 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 didn't alter the quality of life, however reported health status and physical functioning were predictors for the survival of the patients.

ABCSG 36 / PENELOPE[B]

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

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

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

Sample size: **1.250**

Sponsor: **GBG**

Description and status:

PENELOPE[B] is an international phase III trial evaluating the effect of palbociclib combined with endocrine therapy on invasive disease-free survival (IDFS) in patients with 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 recently 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 study. Moreover, translational research projects and subgroup analyses will be carried out. In Austria the long term follow up will continue within the ETERNITY register (GBG 107, Registry for long term follow-up of safety and efficacy parameters of GBG study participants).

ABCSG 39 / APHINITY

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

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

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

Sample size: **4.800**

Sponsor: **Roche**

Description and status:

The APHINITY trial included patients with newly di-agnosed primary invasive, human epidermal growth factor receptor 2 (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 recruit-ment has already been 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, which was originally planned to end in Q3 2023 but will be extended by 5 years, until Q4 2028. The extension is due to a request by the European Medicines Agency (EMA), to ensure that the definitive analysis of the study's objective overall survival (OS) is met. The results of the 2nd interim analysis on OS and IDFS were published in the Journal of Clinical Oncology in February 2021 (Piccart et. al, 2021). A poster on APHINITY was presented at the Annual Meeting of the American Society of Clinical Oncology (ASCO).

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 human epidermal growth factor receptor 2 (HER2)-negative high-risk breast cancer patients with germline BRCA 1 / 2 mutations. The primary objective is to assess the effect of adjuvant treatment with olaparib on Invasive Disease-Free Survival (IDFS). This AstraZeneca sponsored trial reached 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 (IDFS) were published on June 3rd, 2021 in the New England Journal of Medicine. The study has met the pre-specified criteria for superiority for the primary endpoint and no safety signals of concern were noted. On December 15th, 2021, data base lock of the Overall Survival (OS) interim analysis was announced by the study sponsor and results thereof are currently still pending.

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 industrial 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, with sites 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. 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 and Trans-PALLAS biosample collection during follow-up was even extended with the last implemented protocol amendment to collect additional blood samples 7- and 10-years post-randomization, respectively. The dataset and analysis of the second interim analysis resulted in the first successful publication of PALLAS trial data, which was accepted for publication in Lancet Oncology. The event size pre-defined to trigger the final analysis was reached on November 20th, 2020, with 469 documented invasive Disease-Free Survival (IDFS) events. Data cleaning and analysis was completed in May 2021. This final 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 on December 2nd, 2021. Data cleaning is currently ongoing and the completion of the analysis is targeted for end of May 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 longterm 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, have already commenced. RNA sequencing of all available baseline tumor samples is targeted to be completed within the first half of 2022, generating an immense genomic dataset, potentially useful to address a multitude of scientific objectives. Additionally, the first harmonized, international research call for translational project proposals was announced in the second half of 2021 to all PALLAS investigators. All received proposals are being reviewed by the responsible study committees and endorsed proposals will be conducted in close collaboration of both sponsors and the investigators. The Trans-PALLAS program is promising to keep the world-wide PALLAS teams engaged with this cohort for many years to come. The ABCSG would like to express gratitude towards the entire PALLAS study team, all global partners and study sites as well as supporters for their ongoing hard work and dedication.

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:

Nine ABCSG centers were active in this prospective surgical study headed by the University of Rostock. The study 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 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 other ABCSG centers in Austria also participated in, those patients who had received an SLNB and had a maximum of one to three macrometastases 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 centers, 132 of them in Salzburg who took part in both randomization steps. Patients are currently in follow-up and the final analysis is planned for 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: **IBCSG**

Description and status:

For the first time 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 (IBCSG) 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. Of note, the POSITIVE study already counted over 350 pregnancies and over 300 babies were born in the course of study participation. Data collected in the trial are of high relevance to all physicians, as they are often confronted with the patients' wish to become pregnant without any evidence-based information being available for that setting. The trial is already closed for enrollment, pregnant patients and patients who have already given birth are currently pausing treatment before resuming with endocrine therapy. The primary analysis is planned once 1600 patient years of follow-up in the database are reached, which is expected for the Q1 2022 with the primary analysis data being available end of 2022. First publications e.g., regarding patient characteristics are already available (Partridge et al. 2021).

Translational Projects and upcoming Studies

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Translational Studies and Projects

Translational 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 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 is currently being collected from former ABCSG-34 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 has been completed already 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 also made in the TraX&Vields-01 work package (ABCSG-6 cohort): all laboratory work and analysis regarding the concordance data for the STRAT4 test have been concluded successfully and results were successfully published in Clinical Cancer Research in 2021.

Also, the work packages concerning ABCSG-8 and ABCSG-12 cohorts are progressing: the protocol for validating the STRAT4 test and prognostic signature within the ABCSG-8 cohort has been finalized and laboratory analyses are targeted to commence at the beginning of 2022. The protocol for centralizing samples and documenting clinical follow-up data of former ABCSG-12 patients is currently being finalized aiming to allow initiating sites for the documentation of follow-up data in the first half of 2022. Laboratory analysis of centralized ABCSG-12 samples to validate the STRAT4 test and prognostic signature are then planned subsequently.

Another exciting translational project was conducted in cooperation with OncoMark. This project includes biosamples and data available in the ABCSG-8 cohort to validate the OncoMasTR Test. The OncoMasTR Test is a novel, prognostic breast cancer signature to predict the recurrence risk of early breast cancer patients. It uses a combination of analysis of mRNA expression of tumor markers and clinical data and is ultimately developed to be a supportive diagnostic tool for treating clinicians. The reliable estimation of recurrence risk of a patient can be extremely helpful in choosing the most promising therapy for a patient, and thereby increasing a patient's quality of life significantly. The successful validation in this cohort was published in ESMO open in 2021.

A new translational cooperation has been initiated with Daiichi Sankyo aiming at defining expression levels of HER3 over time in the ABCSG-34 cohort. The protocol was finalized and submitted to the respective ethics committee in 2021, aiming to conduct the laboratory work in the first half of 2022. Depending on the outcome of this translational project, a prospective clinical study investigating targeted HER3 therapies may follow.

Outlook and planned studies 2022

Ongoing challenges in relation to the COVID-19 pandemic have also partly impacted study starts, leading to delays in some projects. However, the landscape of clinical research will still receive new contributions by ABCSG and affiliated sites in the year 2022 and a few anticipated study starts are summarized below.

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.

In addition, global collaborations in large clinical trials will be further strengthened in 2022. An international clinical trial, which is currently in the set-up phase, is ABCSG 56 / SASCIA, sponsored by the academic study group GBG. This phase III, post-neoadjuvant study will be evaluating sacituzumab govitecan, an antibody drug conjugate, in primary HER2-negative breast cancer patients with high relapse risk after standard neoadjuvant treatment. 1200 patients will be included in presumably eight countries. In Austria it is planned to activate 15 sites.

The phase III trial ABCSG 57 / ALPHABET within the BIG network under the sponsorship of the Spanish GEICAM study group investigates trastuzumab + alpelisib +/- fulvestrant versus trastuzumab + chemotherapy and will include 300 patients with previously treated HER2-positive advanced breast cancer, harboring PIK3CA mutations. The primary aim of this trial is to determine whether the PIK3CA inhibitor alpelisib + trastuzumab improve efficacy, as measured by progression-free survival (PFS).

Another new class of anti-cancer agents will be investigated in the ABCSG 59 / AMEERA-6 study which is sponsored by Sanofi and will be conducted within the BIG network with several Austrian sites. Amcenestrant, a type of oral selective estrogen receptor degrader (SERD), will be compared to tamoxifen in terms of efficacy and safety in HR-positive early breast cancer patients who have discontinued adjuvant AI therapy due to treatment-related toxicity. This large global phase III study will enroll 3738 participants.

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 2021, the ABCSG offered a total of nine DFP-approved, digital educational formats on various topics related to state-of-the-art breast cancer diagnosis and therapy. Due to the ongoing challenges of the COVID-19 pandemic, all educational formats in 2021 were implemented solely digitally and can be accessed for the most part without time constraints via ABCSG members area on the ABCSG website abcsg.org. In addition to the training and continuing education of investigators, the focus was also on the continuing education of study personnel. Here, digital channels were used for the dissemination of information as well as conventional training courses were implemented virtually. The digital presence of the ABCSG on social media and websites, as well as traditional press relations, are the cornerstones of ABCSG communication strategy and will be further enhanced in the future.

8. Post-SABCS

About one month after the San Antonio Breast Cancer Symposium, the most important data from the significant breast cancer conference are summarized by ABCSG rapporteurs at the annual Post-SABCS educational event. On the 15th of January 2021, the ABCSG, together with the publishing house Universimed, hosted this popular educational event for the eighth time in form of a virtual webinar. The virtual event, led by ABCSG President Michael Gnant, had an attendance record of 264. Presentations as well as the panel discussion can be accessed via ABCSG members area on the ABCSG website abcsg.org.

ABCSG in touch goes digital

The innovative educational format ABCSG in touch goes digital, which gives younger physicians, residents and researchers a platform (summarised as the Task Force *FutureNow*), was launched in March 2021. This cross-generational knowledge transfer and networking event was also very appealing to medical and academic junior talents and resulted in another virtual meeting taking place in November 2021. ABCSG in touch (goes digital) will be continued in 2022.

CDK4/6 Inhibitors: Nuance or Difference

On April 22, 2021 the virtual breast cancer education webinar "CDK4/6 Inhibitors: Nuance or Difference" took place for the very first time. In this joint event with Novartis, both ABCSG and Novartis Global experts discussed the biology of the CDK signalling pathway and its inhibitors, including preclinical and clinical data of all three investigated selective CDK4/6 inhibitors, and reported differences in their exact mechanism of action. It was also discussed how these drugs are being included in current international guidelines, how future directions for these agents might look like, and which new developments regarding (other) CDK inhibitors can be found in research pipelines. Nearly 130 participants from 25 countries followed the training course held in English on the drug group of CDK4/6 inhibitors. The on-demand videos are available in the ABCSG members area on the ABCSG website.

EXPERTS ON TOUR GOES DIGITAL®

Due to the pandemic the EXPERTS ON TOUR® educational series was also converted to a DFP-approved e-learning in 2020. Based on the virtual success, two more EXPERS ON TOUR goes digital e-learnings were launched in 2021. In July Christian Singer brought an update on the treatment in the adjuvant setting, Rupert Bartsch presented new treatment processes in HER2+ breast carcinoma from neoadjuvant setting to late therapy lines, and Marija Balic addressed the question if liquid biopsy is ready for prime time. The presentations were discussed in a virtual setting within the renowned ABCSG experts such as ABCSG President Michael Gnant, Daniel Egle and Kathrin Strasser-Weippl. The e-learning was accessed over 150 times by the end of 2021.

In December one more EXPERTS ON TOUR goes digital e-learning was produced, where Daniel Egle spoke about T-DXd as a new perspective in targeted

breast cancer therapy, Christoph Suppan presented the progress in HER2-low breast carcinoma and Verena Sagaster presented a case study with a new approved HER2 targeted therapy. In this e-learning Christine Brunner featured a special case study on the ABCSG 16 / S.A.L.S.A, which was a particular success to the ABCSG in 2021. The virtual discussion afterwards was again led by ABCSG President Michael Gnant – he joined the presenters in discussing their presentation content.

Both e-learnings are available in the ABCSG members area. A continuation of the EXPERTS ON TOUR® E-Learning series is planned.

15th Interdisciplinary Mamma Discourse

On the 20th of October 2021, the 15th Interdisciplinary Mamma Discourse hosted by the ABCSG in cooperation with the Austrian Society of Senology took again place virtually. Almost 150 people followed the two-hour program consisting of lectures and classic case reports as well as discussions on the scientific content presented. Following the educational session, the Mamma Discourse was uploaded as e-learning to ABCSG members area, an internal area on the ABCSG website that offers the opportunity to view mostly DFP-approved digital educational content, conveniently and on demand.

30th Annual Meeting of the ABCSG

The 30th Annual Meeting of the ABCSG again took place exclusively virtually during the week of November 2-7, 2021. During the Annual Meeting Week, it was possible to view the online lecture program on "ABCSG Study Specials & Educationals" without time constraints. On Friday the 5th of November 2021, the live webinar on "Spotlights & Discussions" took place. Selected ABCSG core topics from the most important breast, colorectal and pancreatic cancer studies were given a stage here. Nearly 320 participants attended the virtual live stream, which offered more than eight hours of information and updates.

Forum Study Nurses & Coordinators and Advanced Study & Care Program

In cooperation with the Forum Study Nurses & Coordinators, information specifically for this professional field is available on the website studynurses.at/studycoordinators.at. Furthermore, 3-day training courses for Study Nurses & Coordinators are offered every year and are well received. In 2021, these courses were conducted virtually. This year's **Advanced Study and Care Program** award was obtained by Andreas Ronge-Toloraya und Polina Toloraya for their project paper on "The Change of Clinical Trials", which was virtually announced during the 30th Annual Meeting of the ABCSG.

Science News

The Science News gives our network of Investigators the opportunity to view the highlights of the most important congresses in the field of breast cancer, but also GI cancer, as a compact video summary, time bound. ABCSG experts regularly summarize the most important results of the congresses; together with information slides, these are made available during or shortly after the event via the ABCSG website and mailings. In 2021, there were again video reports of the Annual Meetings ASCO, ESMO, EBCC, SABCS, ESMO BC and ASCO-GI.

Social Media

The ABCSG's digitization initiative, which received an additional boost in 2020 from the restrictions imposed by the COVID 19 pandemic, also has increasingly extended digital communication to social media. The ABCSG LinkedIn account (https://www.linkedin.com/company/abcsg) as well as the Twitter account (https://twitter.com/ABCSGVienna) have been increasingly used to disseminate exciting news about ABCSG publications, educational events or collaborations. Further expansion of these digital channels is planned in 2022.

Podcast series „Medicine in Context “

In the ABCSG podcast series "Medicine in Context", selected experts talk about the social aspects of medicine. The first three episodes of the new podcast series were recorded in 2020. In 2021 five more episodes on the topics of "Resilience In Daily Medical Routine" (Raimund Jakesz and Irene Thiel), "Patient Empowerment" (Michael Gnant and Barbara Prainsack), "Psycho-Oncology" (Georg Pfeiler and Theresia Rosner-Seifert), "Oncology Nursing" (Rupert Bartsch and Martina Spalt) and "Social Aspects of Medical Genetic Screenings" (Christian Singer and Ingrid Metzler were released). The podcast had been listened to over 500 times by the end of 2021, and the series will continue with new episodes in 2022.

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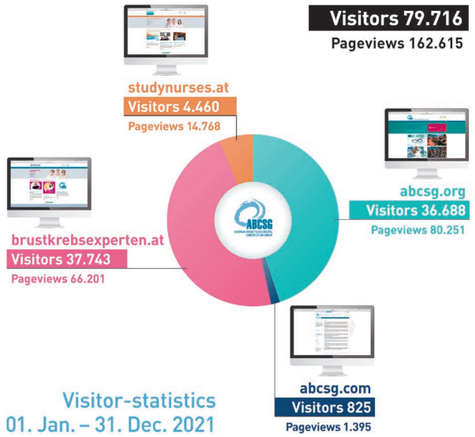

Websites and Patient portal

In addition to the websites abcsg.at and abcsg.com, which provide information on study-related content as well as on activities of the association in German and English, the website brustkrebs-experten.at, which is maintained by the ABCSG, has also been available for several years. This site provides low-threshold information on breast cancer and ongoing studies for patients. In addition, the site studynurses.at/studycoordinators.at is also co-maintained by the ABCSG. These existing ABCSG websites have been revised and modernized through the year, and this project is scheduled for completion in 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. In Austrian daily newspapers and relevant journals of medical publishers, nearly 90 articles appeared in 2021 in which the ABCSG was mentioned. Also, a press conference on the practice changing ABCSG-16 / S.A.L.S.A study results was held in July 2021. 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 enhanced in 2021.

Online services – study-related content and activities

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Publications 2021 and Study Overview

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ABCSG
AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

Publications 2021

Adjuvant Palbociclib for Early Breast Cancer: The PALLAS Trial Results (ABCSG-42/AFT-05/BIG-14-03)

Gnant M, Dueck AC, Frantal S, Martin M, Burstein H J, Greil R, Fox P, Wolff A C, Chan A, Winer E P, Pfeiler G, Miller K D, Colleoni M, Suga J M, Rubovsky G, Bliss JM, Mayer I A, Singer C F, Nowecki Z, Hahn O, Thomson J, Wolmark N, Amillano K, Rugo HS, Steger G G, Hernando Fernández de Aránguiz B, Haddad T C, Perelló A, Bellet M, Fohler H, Metzger Filho O, Jallitsch-Halper A, Solomon K, Schurmans C, Theall K P, Lu D R, Tenner K, Fesl C, DeMichele A, Mayer EL; PALLAS groups and investigators

Journal of Clinical Oncology, published online on December 7, 2021

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 online on December 3, 2021

Tailored axillary surgery in patients with clinically node-positive breast cancer: Pre-planned feasibility substudy of TAXIS (OPBC-03, SAKK 23/16, IBCSG 57-18, ABCSG-53, GBG 101)

Weber W P, Matrai Z, Hayoz S, Tausch C, Henke G, Zwahlen D R, Gruber G, Zimmermann F, Seiler S, Maddox C, Ruhstaller T, Muenst S, Ackerknecht M, Kuemmel S, Bjelic-Radisic V, Kurzeder C, Újhelyi M, Vrieling C, Satler R, Meyer I, Becciolini C, Bucher S, Simonson C, Fehr P M, Gabriel N, Maráz R, Sarlos D, Dedes K J, Leo C, Berclaz G, Dubsky P, Exner R, Fansa H, Hager C, Reisenberger K, Singer C F, Reitsamer R, Reinisch M, Winkler J, Lam G T, Fehr M K, Naydina T, Kohlik M, Clerc K, Ostapenko V, Fitzal F, Nussbaumer R, Maggi N, Schulz A, Markellou P, Lelièvre L, Egle D, Heil J, Knauer M

The Breast, published online on September 8, 2021

The OncoMasTR test predicts distant recurrence in estrogen receptor-positive, HER2-negative early-stage breast cancer: A validation study in ABCSG Trial 8

Filipits M, Rudas M, Kainz V, Singer C F, Fitzal F, Bago-Horvath Z, Greil R, Balic M, Regitnig P, Halper Sz, Hulla W, Egle D, Barron S, Loughman T, O'Leary D, Gallagher W M, Hlauschek D, Gnant M, Dubsky P

Clinical Cancer Research, published online on August 11, 2021

Continuous versus intermittent extended adjuvant letrozole for breast cancer: final results of randomized phase III SOLE (Study of Letrozole Extension) and SOLE Estrogen Substudy

Jerusalem G, Farah S, Courtois A, Chirgwin J, Aebi S, Karlsson P, Neven P, Hitre E, Graas M P, Simoncini E, Abdi E, Kamby C, Thompson A, Loibl S, Gavilá J, Kuroi K, Marth C, Müller B, O'Reilly S, Gombos A, Ruhstaller T, Burstein H J, Rabaglio M, Ruepp B, Ribi K, Viale G, Gelber R D, Coates A S, Loi S, Goldhirsch A, Regan M, Colleoni M, on behalf of the SOLE Investigators

Annals of Oncology, published online on August 10, 2021

ESR1, PGR, ERBB2, and MKi67 mRNA expression in postmenopausal women with hormone receptor-positive early breast cancer: results from ABCSG Trial 6

Filipits M, Rudas M, Singer C F, Fitzal F, Bago-Horvath Z, Greil R, Balic M, Lax S F, Halper S, Hulla W, Wu N C, Liu X, Weidler J, Bates M, Hlauschek D, Gnant M, Dubsky P

ESMO Open, published online on August 7, 2021

Who are the women who enrolled in the POSITIVE trial: A global study to support young hormone receptor positive breast cancer survivors desiring pregnancy

Partridge A, Niman S M, Ruggeri M, Peccatori F A, Azim Jr. H A, Colleoni M, Saura C, Shimizu C, Sætersdal A B, Kroep J R, Mailliez A, Warner E, Borges V, Amant F, Gombos A, Kataoka A, Rousset Jablonski C, Borstnar S, Takei J, Lee J E, Walshe J M, Borrego M R, Moore H , Saunders Ch, Cardoso F, Susnjar S, Bjelic-Radisic V, Smith K L, Piccart M, Korde L A, Goldhirsch A, Richard D. Gelber R D, Pagani O

The Breast, published online on August 3, 2021

Duration of Adjuvant Aromatase-Inhibitor Therapy in Postmenopausal Breast Cancer

Gnant M, Fitzal F, Rinnerthaler G, Steger G, Greil Ressler S, Balic M, Heck D, Jakesz R, Thaler J, Egle D, Manfreda D, Bjelic-Radisic V, Wieder U, Singer C F, Melbinger-Zeinitzer E, Haslbauer F, Sevelda P, Trapl H, Wette V, Wimmer K, Gampenrieder S, Bartsch R, Kacerovsky-Strobl St, Suppan C, Brunner C, Deutschmann C, Soelkner S, Fesl C, Greil R & Austrian Breast and Colorectal Cancer Study Group

The New England Journal of Medicine, published online on July 29, 2021

Genomic and transcriptomic analyses of breast cancer primaries and matched metastases in AURORA, the Breast International Group (BIG) molecular screening initiative

Aftimos Ph, Mafalda O M, Irrthum A, Fumagalli D, Sotiriou Ch, Gal-Yam E N, Robson M E, Ndozeng J, Di Leo A, Ciruelos E M, de Azambuja E, Viale G, Scheepers E D, Curigliano G, Bliss J M, Reis-Filho J S, Colleoni M, Balic M, Cardoso F, Albanell J, Duhem C, Marreaud S, Romagnoli D, Rojas B, Gombos A, Wildiers H, Guerrero-Zotano A, Hall P, Bonetti A, Fs Larsson K, Degiorgis M, Khodaverdi S, Greil R, Sverrisdóttir A, Paoli M, Seyll E, Loibl S, Linderholm B, Zoppoli G, Davidson N E, Th Johannsson O, Bedard Ph L, Loi S, Knox S, Cameron D A, Harbeck N, Montoya M L, Brandão M, Vingiani A, Caballero C, Hilbers F S, Yates L R, Benelli M, Venet D, Piccart M J

Cancer Discovery, published online on June 28, 2021

Adjuvant Olaparib for Patients with BRCA1- or BRCA2-Mutated Breast Cancer

Tutt A, Garber J E, Kaufman B, Viale G, Fumagalli D, Rastogi P, Gelber R D, de Azambuja E, Fielding A, Balmaña J, Domchek S M, Gelmon K A, Hollingsworth S J, Korde L A, Linderholm B, Bandos H, Senkus E, Suga J M, Shao Z, Pippas AW, Nowecki Z, Huzarski T, Ganz PA, Lucas P C, Baker N, Loibl S, McConnell R, Piccart M, Schmutzler R, Steger G G, Costantino J P, Arahmani A, Wolmark N, McFadden E, Karantza V, Lakhani S R, Yothers G, Campbell C, Geyer C E Jr; OlympiA Clinical Trial Steering Committee and Investigators

The New England Journal of medicine, published online on June 3, 2021

Influence of Height on Risk and Outcome of Patients with Early Breast Cancer: A Pooled Analysis of 4,925 Patients from 5 Randomized Trials of the Austrian Breast and Colorectal Cancer Study Group (ABCSG)

Gampenrieder S P, Pircher M, Fesl C, Rinnerthaler G, Mlineritsch B, Greil-Ressler S, Steger G G, Sagaster V, Florian Fitzal F, Exner R, Devyatko Y, Balic M, Stöger H, Suppan C, Bauernhofer T, Singer C F, Pfeiler G, Seifert M, Helfgott R, Heck D, Rumpold H, Kwasny W, Wieder U, Gnant M, Greil R, Austrian Breast and Colorectal Cancer Study Group (ABCSG)

Breast Care, published online on May 21, 2021

PAM-50 predicts local recurrence after breast cancer surgery in postmenopausal patients with ER+/HER2- disease: results from 1204 patients in the randomized ABCSG-8 trial

Fitzal F, Filipits M, Fesl C, Rudas M, Greil R, Balic M, Moinfar F, Herz W, Dubsky P, Bartsch R, Ferree S, Schaper C, Gnant M, the Austrian Breast and Colorectal Cancer Study Group

British Journal of Surgery, published online on April 5, 2021

Conventional versus reverse sequence of neoadjuvant epirubicin/cyclophosphamide and docetaxel: sequencing results from ABCSG-34

Bartsch R, Singer C F, Pfeiler G, Hubalek M, Stoeger H, Pichler A, Petru E, Bjelic-Radisic V, Greil R, Rudas M, Muy-Kheng T M, Wette V, Petzer AL, Sevelda P, Egle D, Dubsky P C, Filipits M, Fitzal F, Exner R, Jakesz R, Balic M, Tinchon C, Bago-Horvath Z, Frantal S, Gnant M; Austrian Breast and Colorectal Cancer Study Group.

British Journal of Cancer, published online on March 24, 2021

Palbociclib with adjuvant endocrine therapy in early breast cancer (PALLAS): interim analysis of a multi-centre, open-label, randomised, phase 3 study

Mayer E L, Dueck AC, Martin M, Rubovszky G, Burstein H J, Bellet-Ezquerra M, Miller K D, Zdenkowski N, Winer E P, Pfeiler G, Goetz M, Ruiz-Borrego M, Anderson D, Nowecki Z, Loibl S, Moulder S, Ring A, Fitzal F, Traina T, Chan A, Rugo H S, Lemieux J, Henao F, Lyss A, Antolin Novoa S, Wolff AC, Vetter M, Egle D, Morris P G, Mamounas E P, Gil-Gil M J, Prat A, Fohler H, Metzger Filho O, Schwarz M, DuFrane C, Fumagalli D, Theall K P, Lu D R, Bartlett C H, Koehler M, Fesl C, DeMichele A, Gnant M

The Lancet Oncology, published online on January 15, 2021

A clinical validation study of MammaPrint in hormone receptor-positive breast cancer from the Austrian Breast and Colorectal Cancer Study Group 8 (ABCSG-8) biomarker cohort

Dubsky P, Van't Veer L, Gnant M, Rudas M, Bago-Horvath Z, Greil R, Lujinovic E, Buresch J, Rinnerthaler G, Hulla W, Moinfar F, Egle D, Herz W, Dreezen C, Frantal S, Filipits M.

ESMO Open, published online on December 31, 2020

Conference-Presentations 2021

Adjuvant palbociclib in HR+/HER2- early breast cancer: Final protocol-planned analysis results from 5,761 patients in the randomized phase III PALLAS trial

Presentation by Gnant M

San Antonio Breast Cancer Symposium 2021 (SABCS 2021, in person), December 2021

Immunomodulatory biomarkers in neoadjuvant chemotherapy of breast cancer and the impact of epirubicin and docetaxel on immune cells

Presentation by Wimmer K

62. Österreichischer Chirurgenkonkress (ÖCK 2021), June 2021

Study Overview

Study	Sponsor	Title	Status
ABCSG 18	Amgen	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	treatment / follow-up
ABCSG 18 ZA Substudy		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	open for enrollment
ABCSG 22R-QoL	ABCSG	A survey conducted on the quality of life of breast cancer patients registered in ABCSG 22R	open for enrollment
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.	treatment / follow-up
ABCSG 36 / PENELOPE[B]	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	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	open for enrollment
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	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 51 / AURORA	BIG	Aiming to Understand the Molecular Aberrations in Metastatic Breast Cancer: The AURORA Program	open for enrollment
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	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	enrollment on hold
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	open for enrollment
TraX&Yields	Cepheid	TraX&Yields: Training GeneXpert Tools and Validation in ABCSG Biomarker Cohorts	translational research project

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