20 years of extracting the best in breast cancer treatments
Together we make a real difference in patients’ lives, both today and in the future.
Dear reader,

It is with pride that I have taken on the role of BIG’s new Chair, following in the footsteps of BIG’s co-Founder and previous Chair, Professor Martine Piccart, who dedicated over twenty years to BIG and who will continue to play an important role as President of BIG against breast cancer.

In 2019, BIG celebrated its 20th anniversary. For over twenty years, BIG and its global network of academic research groups have been working together to find better treatments and cures for breast cancer.

The featured article of this report, “BIG and two decades of breast cancer research: extracting the best in breast cancer treatments”, by science writer Jenny Bryan, sheds light on breast cancer de-escalation therapies. By tailoring treatments more precisely to individual patient needs, the hope is to safely reduce the amount of treatment some patients receive, without affecting their recovery or increasing the risk of recurrence.

The featured article of this report, “BIG and two decades of breast cancer research: extracting the best in breast cancer treatments”, by science writer Jenny Bryan, sheds light on breast cancer de-escalation therapies. By tailoring treatments more precisely to individual patient needs, the hope is to safely reduce the amount of treatment some patients receive, without affecting their recovery or increasing the risk of recurrence.

De-escalation trials such as BIG Radio Tuning (scientific name: EXPERT) want to find out if, by removing some elements of treatment, the side effects patients experience can be reduced or avoided without compromising outcomes.

In 2019, BIG celebrated its 20th anniversary. For over twenty years, BIG and its global network of academic research groups have been working together to find better treatments and cures for breast cancer.

The featured article of this report, “BIG and two decades of breast cancer research: extracting the best in breast cancer treatments”, by science writer Jenny Bryan, sheds light on breast cancer de-escalation therapies. By tailoring treatments more precisely to individual patient needs, the hope is to safely reduce the amount of treatment some patients receive, without affecting their recovery or increasing the risk of recurrence.

De-escalation trials such as BIG Radio Tuning (scientific name: EXPERT) want to find out if, by removing some elements of treatment, the side effects patients experience can be reduced or avoided without compromising outcomes.

In 2019, BIG celebrated its 20th anniversary. For over twenty years, BIG and its global network of academic research groups have been working together to find better treatments and cures for breast cancer.

The featured article of this report, “BIG and two decades of breast cancer research: extracting the best in breast cancer treatments”, by science writer Jenny Bryan, shedding light on breast cancer de-escalation therapies. By tailoring treatments more precisely to individual patient needs, the hope is to safely reduce the amount of treatment some patients receive, without affecting their recovery or increasing the risk of recurrence.

De-escalation trials such as BIG Radio Tuning (scientific name: EXPERT) want to find out if, by removing some elements of treatment, the side effects patients experience can be reduced or avoided without compromising outcomes.

In 2019, BIG celebrated its 20th anniversary. For over twenty years, BIG and its global network of academic research groups have been working together to find better treatments and cures for breast cancer.

The featured article of this report, “BIG and two decades of breast cancer research: extracting the best in breast cancer treatments”, by science writer Jenny Bryan, sheds light on breast cancer de-escalation therapies. By tailoring treatments more precisely to individual patient needs, the hope is to safely reduce the amount of treatment some patients receive, without affecting their recovery or increasing the risk of recurrence.

De-escalation trials such as BIG Radio Tuning (scientific name: EXPERT) want to find out if, by removing some elements of treatment, the side effects patients experience can be reduced or avoided without compromising outcomes.

In 2019, BIG celebrated its 20th anniversary. For over twenty years, BIG and its global network of academic research groups have been working together to find better treatments and cures for breast cancer.

The featured article of this report, “BIG and two decades of breast cancer research: extracting the best in breast cancer treatments”, by science writer Jenny Bryan, sheds light on breast cancer de-escalation therapies. By tailoring treatments more precisely to individual patient needs, the hope is to safely reduce the amount of treatment some patients receive, without affecting their recovery or increasing the risk of recurrence.

De-escalation trials such as BIG Radio Tuning (scientific name: EXPERT) want to find out if, by removing some elements of treatment, the side effects patients experience can be reduced or avoided without compromising outcomes.

In 2019, BIG celebrated its 20th anniversary. For over twenty years, BIG and its global network of academic research groups have been working together to find better treatments and cures for breast cancer.

The featured article of this report, “BIG and two decades of breast cancer research: extracting the best in breast cancer treatments”, by science writer Jenny Bryan, sheds light on breast cancer de-escalation therapies. By tailoring treatments more precisely to individual patient needs, the hope is to safely reduce the amount of treatment some patients receive, without affecting their recovery or increasing the risk of recurrence.

De-escalation trials such as BIG Radio Tuning (scientific name: EXPERT) want to find out if, by removing some elements of treatment, the side effects patients experience can be reduced or avoided without compromising outcomes.

In 2019, BIG celebrated its 20th anniversary. For over twenty years, BIG and its global network of academic research groups have been working together to find better treatments and cures for breast cancer.

The featured article of this report, “BIG and two decades of breast cancer research: extracting the best in breast cancer treatments”, by science writer Jenny Bryan, sheds light on breast cancer de-escalation therapies. By tailoring treatments more precisely to individual patient needs, the hope is to safely reduce the amount of treatment some patients receive, without affecting their recovery or increasing the risk of recurrence.

De-escalation trials such as BIG Radio Tuning (scientific name: EXPERT) want to find out if, by removing some elements of treatment, the side effects patients experience can be reduced or avoided without compromising outcomes.

In 2019, BIG celebrated its 20th anniversary. For over twenty years, BIG and its global network of academic research groups have been working together to find better treatments and cures for breast cancer.

The featured article of this report, “BIG and two decades of breast cancer research: extracting the best in breast cancer treatments”, by science writer Jenny Bryan, sheds light on breast cancer de-escalation therapies. By tailoring treatments more precisely to individual patient needs, the hope is to safely reduce the amount of treatment some patients receive, without affecting their recovery or increasing the risk of recurrence.

De-escalation trials such as BIG Radio Tuning (scientific name: EXPERT) want to find out if, by removing some elements of treatment, the side effects patients experience can be reduced or avoided without compromising outcomes.

In 2019, BIG celebrated its 20th anniversary. For over twenty years, BIG and its global network of academic research groups have been working together to find better treatments and cures for breast cancer.

The featured article of this report, “BIG and two decades of breast cancer research: extracting the best in breast cancer treatments”, by science writer Jenny Bryan, sheds light on breast cancer de-escalation therapies. By tailoring treatments more precisely to individual patient needs, the hope is to safely reduce the amount of treatment some patients receive, without affecting their recovery or increasing the risk of recurrence.

De-escalation trials such as BIG Radio Tuning (scientific name: EXPERT) want to find out if, by removing some elements of treatment, the side effects patients experience can be reduced or avoided without compromising outcomes.
For over 20 years, BIG’s global network of academic research groups have been working together to find better treatments and cures for breast cancer.

The Breast International Group (BIG) is an international not-for-profit organisation that represents the largest global network of academic research groups dedicated to finding cures for breast cancer.

In 1999, BIG was founded with the aim to address fragmentation in European breast cancer research. Research groups from other parts of the world rapidly expressed interest in joining BIG and, two decades later, BIG represents 57 like-minded research groups from around the world and reaches across approximately 70 countries on 6 continents.

Through its network of groups, BIG connects several thousand specialised hospitals, research centres and world-class breast cancer experts who collaborate in pioneering breast cancer research. BIG also works closely with the US National Cancer Institute and the North American Breast Cancer Group, to act as a strong integrating force in the field of breast cancer research.

BIG’s mission is to facilitate and accelerate breast cancer research at an international level. We are proud to be both global and local, helping breast cancer patients from all over the world.

Thanks to this global collaboration, BIG enrols large numbers of patients from around the world into clinical trials quickly, which, in turn, leads to faster results.

BIG’s research is supported in part by its philanthropy unit, known as BIG against breast cancer. This denomination is used to interact with the general public and donors.

www.BIGagainstbreastcancer.org
BIG AND TWO DECADES OF BREAST CANCER RESEARCH: EXTRACTING THE BEST IN BREAST CANCER TREATMENTS

BREAST CANCER DE-ESCALATION TRIALS: CAN SOME PATIENTS HAVE LESS TREATMENT WITHOUT AFFECTING RECOVERY?

By science writer Jenny Bryan

For two decades BIG has collaborated with breast cancer researchers around the world to carry out ground-breaking clinical trials and define the best in breast cancer treatment. Already, BIG trials have contributed to major changes in breast cancer care – improving outcomes and tailoring treatment more precisely to individual patient needs. Now, BIG is once again at the forefront of research – conducting de-escalation trials aimed at reducing the amount of treatment some patients receive and seeking patient perspectives about the risks and benefits of such studies.

"BIG can bring together the global expertise and perform the large, collaborative de-escalation trials that are needed. We want to find out if, by removing or changing some elements of treatment, we can reduce the side effects patients experience without compromising outcomes," says BIG Chair, Professor David Cameron.

"De-escalation trials of medical therapies are now starting, but we have a huge responsibility to ensure that we have well defined, consistent methodology. We must always remember that we are dealing with curative treatments for breast cancer and if we de-escalate in the wrong patients, we risk unnecessary relapse," says Piccart.

Cameron agrees: “There is a clear desire to identify people who do not need some aspects of treatment, but we must tread cautiously. De-escalation needs to be done in clinical trials so that patients are assured that any change from standard therapy has been agreed by ethics and other experts, a data monitoring committee is watching emerging results and correct safeguards are in place.”

BIG DE-ESCALATION TRIALS

In the MINDACT drug de-escalation trial carried out by the European Organisation for Research and Treatment of Cancer (EORTC) in close collaboration with BIG, researchers showed that approximately half of high-risk patients with early stage breast cancer could avoid chemotherapy and its likely side effects if a sophisticated tumour genetics test (MammaPrint®) showed their cancer was unlikely to recur. The study, published in 2016 in the New England Journal of Medicine1, is one of a series of completed and ongoing trials investigating how drug therapy may be more effectively tailored to patient needs.

“MINDACT was a step in the direction of drug de-escalation because it used a novel diagnostic test to show that some patients who might previously have been given chemotherapy did not in fact need it. It showed that we are moving towards using the biological characteristics of a tumour to help safely exclude the need for a treatment which has previously been thought necessary,” says Cameron.
In the EXPERT trial, BIG, together with Breast Cancer Trials Australia & New Zealand (BCT-ANZ), is now investigating whether some patients with low risk early breast cancer may not need radiotherapy after breast conserving surgery. As in MINDACT, a genomic test on breast tumours is being used to determine risk of recurrence. In patients at low risk of recurrence, the combination of standard radiotherapy and hormone treatment is being compared with hormone treatment alone.

Professor Boon Chua
Principal Investigator of the EXPERT trial and BIG Executive Board Member,
explains that, over the last 20 years, the increasing use of shorter radiotherapy courses and partial breast irradiation in some cases have helped make treatment less toxic and more convenient for patients.

“We now need to get better at tailoring radiotherapy after surgery to an individual patient’s risk of recurrence. Advances in molecular profiling of breast cancer have the potential to help us do this more accurately, and this is a rapidly evolving area of research,” she says.

She is particularly delighted that, as an investigator-led trial, EXPERT will include multiple centres that may not have an opportunity to participate in other breast cancer trials.

“It is very exciting that BIG is including a large cross-section of member groups and supporting them in conducting clinical trials such as EXPERT. The question of how to safely select patients for radiotherapy de-escalation is important for all clinicians and patients, especially as a time when many countries have limited resources,” says Chua.

While MINDACT and EXPERT base de-escalation decisions on tests of tumour biology, in DECRESCENDO, a BIG study in development, clinicians will identify patients with hormone receptor negative, HER2-positive breast cancer suitable for drug de-escalation on the basis of their response to pre-surgical (neoadjuvant) treatment. Those who have a complete response to neoadjuvant therapy will have reduced treatment after surgery compared to those who still have signs of cancer.

With planned recruitment of over 1,000 patients, involving investigators in many countries, DECRESCENDO is likely to have a greater impact than could be expected with smaller, national studies.

“As so many doctors will have experience of the DECRESCENDO protocol, if treatment de-escalation is successful in patients who achieve a complete response to neoadjuvant therapy, this could change clinical practice on a large scale,” says Piccart.

BIG is committed to engaging with patients with experience of breast cancer to understand how they feel about treatment de-escalation so that trial protocols take account of their priorities and concerns. In 2019, BIG and their counterpart the North American Breast Cancer Group (NABCG) held two patient workshops where participants considered what increased risk of recurrence they would be willing to accept for reduced side effects in a de-escalation trial.

Participants said they would accept an increase in risk of recurrence of up to 3% in a de-escalation trial. The more severe and long lasting the possible side effects of treatment, the greater the acceptable increased risk of recurrence.

“It was clear that if the risk of toxicity was low, such as with trastuzumab, patients were not prepared to accept a risk of recurrence, but if the risk of toxicity was high, for example with an anthracycline that can have long-term side effects on the heart, a 3% increased risk of recurrence was more acceptable,” recalls Piccart.

“From the surveys and from our experience of de-escalation studies to date, patients need to know that the de-escalation approach is designed in a way that they may experience only a very minimal loss of treatment efficacy,” says Cameron. “We need to engage patients to find out what loss of efficacy they will accept, and we also need to know what improvement in toxicity they would consider worthwhile.”

Diagnosed with breast cancer in 2008 when she was 26, Španić feels she was fortunate that her consultant offered her a less demanding protocol that only became part of guidelines some years later.

“It’s always a balance – weighing up side effects against risk of recurrence, but we are starting to see more de-escalation data to help with these decisions, and it is important that patients are given the right information,” says Španić.

At the BIG-NABCG patient workshops, participants supported the use of videos and patient-friendly visual aids to convey information about de-escalation risk. They particularly liked the idea of a nurse or volunteer sitting in consultations with them and being available to answer questions afterwards.

“GETTING THE PATIENT PERSPECTIVE”

Tanja Španić, President of Europa Donna Slovenia and a participant at one of the workshops, has been faced with such decisions.

“All patients struggle with side effects when we are undergoing treatment, but if we then have late side effects after several years, that perhaps we weren’t even aware of, it can have a huge effect on quality of life,” she says.
THE WAY FORWARD

With acceptable differences in outcomes always likely to be small, large numbers of patients will need to be recruited for de-escalation studies in order to get robust results.

“Individual groups or countries may struggle to carry out definitive studies because they don’t have access to the number of patients who are needed for these studies. By building international collaborations and accessing different expertise, BIG can enable studies to be carried out that might not otherwise be done,” says Cameron.

Piccart agrees the need for multinational studies: “For the results of de-escalation trials to be seen as important enough to change clinical practice, they need to speak to clinicians in many different countries. It may not always be possible to do global studies because of regulatory differences, but we can lead the way from a European perspective and, where possible, extend to other regions.”

As treatment de-escalation moves from clinical trials to clinical practice, Chua points to the need for a multidisciplinary approach and good communication between clinicians: “If surgeons, radiation oncologists and medical oncologists are all de-escalating their therapies, we need to think very carefully about the overall effects on patients. We need to ensure that patients receive the right treatment that will give them the best chance of successful tumour control with minimal possible toxicity, in the safest possible way. We need to move forward together with a good understanding of what each of us is trying to achieve.”

Reference

BREAST CANCER INCIDENCE

According to the latest figures (source: Globocan 2018), by end of 2018, approximately 2.1 million people, including twenty-one thousand men (1%), were estimated to be diagnosed with breast cancer. With no fewer than 627,000 deaths (72 deaths/hour) worldwide, it is the cancer that causes the most deaths in absolute terms.

Breast cancer incidence rates are the highest in Australia/New Zealand, Northern Europe (UK, Sweden, Finland and Denmark), Western Europe (Belgium, The Netherlands, France), Southern Europe (Italy) and Northern America. In women, these rates far exceed those for other cancers in both developed and developing countries, making it the most commonly diagnosed cancer in women: 24.2 %, or about 1 in 4 of all new cancer cases in women worldwide. It is also the leading cause of cancer death in women (15%), and the 5th leading cause of death (6.6%) of all cancer deaths worldwide, for both women and men.

Fortunately, mortality rates are falling thanks to the research conducted to date. Women diagnosed with breast cancer 20 years ago had very few treatment options and a low survival rate. But today, patients have access to more individualised treatments.

Many BIG trials now focus on groups of patients having tumours with specific genetic aberrations. The objective is to develop increasingly personalised and precise cancer treatments. BIG trials also anticipate the future, collecting biospecimens for subsequent research to help us better understand tumour biology and learn why some patients respond well to therapies while others do not. This will ultimately help doctors and their patients make better treatment decisions.
BIG’S PHILANTHROPIC COMMUNITY

The BIG network is like a two-sided coin: one side represents the scientific and academic community, consisting of 57 BIG member research groups from all over the world; the other side represents the philanthropic community, comprising ambassadors, foundations, companies and individual donors. They all share the same vision: improve breast cancer treatments and, ultimately, find cures for all the specific types of the disease affecting both women and men.

BIG is an internationally recognised not-for-profit organisation that was founded in 1999. After twenty years, we can proudly say that much of BIG’s research is landmark, introducing particularly innovative designs, contributing to significant breakthroughs, or paving the way towards more personalised treatment of breast cancer.

BIG’s dedicated philanthropy unit - BIG against breast cancer - conducts vital fundraising to help finance academic clinical trials and research programmes that have no commercial interest but are crucial for patients with breast cancer. These collaborative efforts have led to practice-changing achievements in the field of breast cancer care.

The funds raised provide the means for BIG’s member groups (made up of breast cancer experts across the globe), and their affiliated hospitals, to finance their efforts and patients’ participation in one or more BIG studies.

On the following pages, you will read more about BIG’s philanthropic community and the different fundraising activities that took place in 2019.

HOPE IS THE THING WITH FEATHERS
THAT PERCHES IN THE SOUL,
AND SINGS THE TUNE
WITHOUT THE WORDS,
AND NEVER STOPS AT ALL

From ‘Hope is the thing with feathers’ by Emily Dickinson
ACADEMIC TRIALS
YOU CAN SUPPORT

THANKS TO ITS UNIQUE POSITION IN THE FIELD
OF BREAST CANCER RESEARCH, BIG RESEARCHERS
DEVELOP ACADEMIC CLINICAL TRIALS WITHOUT
COMMERCIAL INTEREST, BUT CRUCIAL TO
PATIENTS. THESE TRIALS ARE FINANCED IN-PART
THROUGH BIG’S PHILANTHROPIC COMMUNITY.

Among the key academic studies requiring support
within the BIG network are BIG Metastatic Breast
Cancer GPS (scientific name: AURORA), BIG Time
for Baby (scientific name: POSITIVE) and BIG
Radio Tuning (scientific name: EXPERT). All three
are ongoing and funding is still required, either to enrol
the number of patients needed or to continue with
follow-up, both essential to generate robust results and
to answer important questions.

BIG METASTATIC BREAST CANCER GPS
(SCIENTIFIC NAME: AURORA)

When a breast cancer develops metastases, it
means that the disease will spread to other organs
and parts of the body. This advanced form of
the disease, responsible for 90% of breast cancer
deaths, is more difficult to treat and remains
incurable.

Like a navigation device tracing the route to be
followed, the BIG Metastatic Breast Cancer
GPS, an ambitious research programme run by
BIG in collaboration with Institut Jules Bordet’s
Clinical Trials Support Unit and Frontier Science
Scotland, aims to map the path taken by cancer
cells by analysing their abnormalities in a wide
range of genes and at different timepoints during
the evolution of the disease. If we can anticipate
the paths taken, we will be able to block (with
highly targeted drugs) and therefore slow down
the metastatic process. If we know how to block
the progression of cancer cells, we will be able to
delay the process and possibly stop it completely.

This academic research programme, launched
in 2014, involves more than 60 hospital in
12 European countries and will enrol 1,000
patients. It aims to understand why breast cancer
spreads and why some patients respond poorly
to standard treatment while others respond very
well. Through the findings, we aim to develop
better treatments in the future and potentially
offer cures one day to patients with this still
incurable disease. By end of December 2019,
already 860 of the 1,000 needed patients are
participating.

In May 2019, the results based on the analysis of data
collected from the first 381 patients were presented
at the annual ESMO Breast Cancer Congress. BIG’s
researchers identified genetic abnormalities present in
excess in metastases that may be correlated with the
spread of cancer and increased resistance to standard
treatments. In addition, researchers estimate that in
almost 50% of cases, the genetic abnormalities identified
could provide treating oncologists with additional useful
information (for example, patients could be considered
for clinical trials testing new drugs targeting specific
molecular alterations).

Patients participating in BIG Metastatic Breast Cancer
GPS have clearly understood its importance. They
are enthusiastic about taking part in the study and
are contributing generously by providing samples and
accepting to be monitored regularly for up to 10 years.

Over its lifetime, this research programme will collect
some 30,000 blood and tumour samples and generate
thousands of clinical and genetic data to improve our
understanding of metastatic breast cancer.
BIG TIME FOR BABY
(SCIENTIFIC NAME: POSITIVE)

About 15% of patients with breast cancer are diagnosed during their reproductive years. This study will evaluate the safety of interrupting endocrine therapy for young women with hormone-sensitive breast cancer who wish to become pregnant, as well as the pregnancy outcomes.

By 31 December 2019, the BIG Time for Baby study, run by the International Breast Cancer Study Group (IBCSG) under the BIG umbrella, met its target accrual, enrolling 518 patients from 203 hospitals from 20 countries around the world.

BIG Time for Baby represents a unique opportunity to allow young women who have had breast cancer to plan and try to become pregnant without waiting many years after completing their endocrine treatment.

The study expects to provide an answer to the question of whether women can interrupt their endocrine treatment to try to have a baby, without increasing the risk of cancer recurrence.

The study has recruited pre-menopausal women, aged 42 years and younger, with ER+ early breast cancer who have received endocrine therapy for 18 to 30 months and who wish to interrupt endocrine therapy to become pregnant.

During the study, they take a three-month break in treatment before attempting pregnancy and stop treatment for up to two years to allow time for conception, delivery and breastfeeding (or potential failure to conceive). Endocrine therapy then restarts and continues for the duration of treatment. Women will be followed up for 10 years after enrolment.

As of 31 December 2019, 125 healthy babies had already been born.

BIG RADIO TUNING
(SCIENTIFIC NAME: EXPERT)

The societal impact of this academic study on breast cancer could be substantial. The results of this study could influence how 2 in 5 women with breast cancer are treated.

If the BIG Radio Tuning study proves that certain patients do not need radiation therapy, many women affected by this disease may be spared its potential side effects and healthcare systems could also make significant savings.

The aim of BIG Radio Tuning, run by Breast Cancer Trials Australia & New Zealand (BCT-ANZ) together with BIG, is to better analyse the risk profile of tumours in order to identify which women could safely avoid radiation therapy in the future. In this study, patients whose tumours qualify as “low-risk” (according to a 50-gene test) will then receive either hormone treatment, or hormone treatment combined with radiation therapy. The study hopes to show that both groups do well and that, therefore, patients with “low-risk” tumours may safely be spared radiation therapy in the future.

In 2019, 29 hospitals were already actively involved out of the 90 hospitals that will participate in the study. By end of December 2019, 260 out of a total of 1,170 patients had already been included.

In the treatment of breast cancer, after surgically removing the tumour, radiation therapy is administered to patients with the goal of limiting the risk of the cancer recurring. Like adjusting your radio to find the right frequency, the BIG Radio Tuning study aims to better define the tumour’s risk profile in order to personalise the intensity of the radiation therapy, even going as far as to avoid it altogether.

The prospect of safely de-escalating radiation therapy is of great interest to many patients, who will appreciate not having to be subjected to a treatment that will not benefit them significantly if their tumours are low-risk, while ensuring that patients at greater risk of relapse do receive treatment of an appropriate intensity.

Radiation therapy has common side-effects such as fatigue, skin burns, breast tenderness, swelling and scarring, which may cause adverse aesthetic effects. Uncommonly radiation therapy may cause complications of the heart and lung, and radiation-related cancer. For low-risk patients, these side-effects could be effectively avoided in the future if the BIG Radio Tuning study demonstrates what it believes to be possible.
IN 2019, BIG CELEBRATED ITS 20TH ANNIVERSARY

Throughout the year, BIG’s philanthropy unit, BIG against breast cancer, organised a series of fundraising events. The aim was to strengthen BIG’s existing and new relationships by connecting and reconnecting, and to raise funds for academic breast cancer research.

20 KM THROUGH BRUSSELS’ ANNUAL RUN
19 May

A BIG against breast cancer team of 150 enthusiasts participated in Brussels’ 20 km run, a popular annual race through the city of Brussels – each kilometre marking a year of BIG’s commitment to finding better treatments and a cure for breast cancer.

Employees from BIG Headquarters also participated in the 20 km race – as runners, volunteers helping with the logistics of the event, or supporters cheering along the route for colleagues and friends of the BIG against breast cancer team. Some created their own fundraising page on the MoveforBIG platform.

Thanks to the participants, supporters and generous sponsors (AG Insurance, AtlasGo, Baobab Collection, Buy Way, Delen Private Bank, Delvaux, Le Soir, The National Lottery, Nuxe Belgium, Ozalys & Urgo), we raised more than € 20,000, which was directly invested into the BIG Metastatic Breast Cancer GPS study (scientific name: AURORA). This international research programme will collect some 30,000 blood and tumour samples and generate thousands of clinical and genetic data to improve our understanding of metastatic breast cancer. This will, we hope, help us soon find a way to block the progression of this disease or, even better, find a cure for it.
OFFICIAL CELEBRATION OF 20 YEARS OF BIG, IN THE PRESENCE OF HER MAJESTY THE QUEEN OF THE BELGIANS

17 September

Conference “The evolution of breast cancer treatment: past, present and future”, followed by a reception

On 17 September 2019, BIG organised a conference and invited international and national breast cancer experts and supporters to talk about the evolution of breast cancer treatment in the past, the present and the future.

This academic session, in the presence of BIG’s Honorary President, Her Majesty the Queen of the Belgians, was followed by a reception. Over 150 participants attended the event held at the Palais des Académies in Brussels.

Speakers included Professor David Cameron (Chair of BIG), Professor Martine Piccart (Immediate Past Chair and Co-Founder of BIG), Doctor Alberto Costa (CEO European School of Oncology), Princess Amaury de Merode (President of BIG’s Committee of Ambassadors) and Ms Betty Baligant (a breast cancer survivor).

Each scientific speaker addressed the treatment of breast cancer with a lens towards the past, present or future. The underlying message of the conference was how far we have come in twenty years to improve breast cancer treatments. Women faced with the disease now have a better chance of survival and receive more personalised treatments, which are less toxic, more targeted and less invasive. Future treatment options were also discussed, such as immunotherapy, which aims to activate the immune system to destroy breast cancer cells. De-escalating therapies (whenever possible for patients who can be shown to be at low risk of relapse) is also at the forefront of BIG’s research interests.

This seventh edition of BIG’s annual gala dinner was organised under the theme of “The Roaring Twenties”, a perfect way to celebrate two decades of hope and progress in breast cancer research.

The funds raised during the annual gala dinner will be invested in the BIG Metastatic Breast Cancer GPS study (scientific name: AURORA).

Over 600 attendees joined this event and participated in an auction full of exclusive and unusual prizes donated by BIG’s partners and individual benefactors.

On 24 October, BIG held the second edition of its “PINK is the new black” dinner and dance party, in the presence of Professor Martine Piccart.

Delphine Remy, a young woman who was diagnosed with breast cancer in June 2019, was invited to take the floor and gave a moving speech about her life as a breast cancer patient (see also page 25 of this report).

All the proceeds from this event went towards the BIG Metastatic Breast Cancer GPS study (scientific name: AURORA).

The concert, which took place at the BOZAR in Brussels, featured iconic music by Carl Orff, Leonard Bernstein and Igor Stravinsky, three leading 20th century composers. The Brussels Choral Society was accompanied by the Brussels Orchestral Ensemble and soloists Julie Gebhart (soprano), Michael Adair (baritone), Teun Michiels (tenor) and Julia O’Connor (soprano). Eric Delson was the conductor.

Programme: Carl Orff – Carmina Burana
Leonard Bernstein – Chichester Psalms
Igor Stravinsky – Symphony of Psalms

BIG was a beneficiary of this cultural event and invited companies and individuals to attend.
HOW YOU CAN MAKE A DIFFERENCE

Every act of support contributes to BIG's research, crucial for finding cures for breast cancer. Giving is also contagious; help us spread the word.

- Join our community and stay in touch with news from the philanthropy unit.
- Introduce BIG to your professional network.
- Donate for any occasion. Think BIG for a birthday, Mother's Day, anniversary or make a gift in memory of a loved one, or to commemorate a family member or friend who has battled breast cancer. You can do this by making a transfer to our bank account or with the MoveforBIG platform.
- Attend an event.
- Give in-kind (e.g. artwork from your own collection or an exquisite experience) for an auction to benefit BIG.
- Create a Facebook birthday fundraiser @BIGagainstbreastcancer

Thank you to our supporters who “thought BIG” in 2019 and asked their loved ones to donate for their special occasion.

FOR MORE INFORMATION ON HOW YOU CAN SUPPORT BIG, CONTACT PHILANTHROPY@BIGAGAINSTBC.ORG

FOLLOW US ON
- @BIGagainstbreastcancer
- @BIGagainstBC
- BIG against breast cancer

LAUNCH OF THE moveforBIG FUNDRAISING PLATFORM

In June 2019, BIG launched moveforBIG.org, a user-friendly electronic fundraising platform that encourages and allows BIG’s supporters to create their own fundraising initiatives. A personal fundraising page gives extra hope and support to many women - and men - who are confronted with breast cancer.

Visitors can create their own events, ranging from sports challenges to baby showers, birthday parties, memorials, corporate events, and others. Friends and family are generously invited to make donations to BIG, which will go directly to the funding of breast cancer research.

In just six months, the moveforBIG platform had already proved to be a success, raising almost €50,000 for breast cancer research.
One of BIG’s courageous and admirable supporters is Delphine Remy, a young woman who was diagnosed with breast cancer in June 2019.

At BIG’s “PINK is the new black” dinner and dance party in October 2019, Delphine was invited to take the floor. Her testimony was touching and encouraging. She spoke about her experience, how she copes with the disease, her hopes for the future, her gratitude for the progress that has been made in breast cancer research, and for the unstoppable ambition of scientists and academics to find a cure. She highlighted that it was thanks to the results of an innovative gene test, analysing the likelihood of her experiencing a breast cancer recurrence, that her doctors were able to safely adapt and personalise her chemotherapy treatment, reducing its side effects and improving Delphine’s quality of life.

The disease hasn’t stopped her from believing in a cure and she is determined to do all it takes to get better and resume her normal life. Driven by this strong wish, and with a lot of perseverance and positive attitude, she created her own blog (https://cancer-je-gere.blog/), has been setting-up actions to raise funds for breast cancer research and to raise further awareness about the importance of academic research. Because research saves lives. She knows.

Asking her what inspired her, Delphine explains:

“As the chemo sessions became less severe, I gradually found my energy back and felt a strong need to move mountains and do something for the breast cancer community. Even if this is only a tiny drop in the big ocean, remember Mother Theresa’s wise words ‘We ourselves feel that what we are doing is just a drop in the ocean. But the ocean would be less because of that missing drop’. So, let’s all join forces to advance breast cancer research and let’s create a giant tsunami to make things happen!’

Delphine has created her own fundraising page on the moveforBIG platform. The funds raised will be invested into the BIG Metastatic Breast Cancer GPS study (scientific name: AURORA).

Before her departure, Mathilde launched a fundraising campaign and created her own fundraising page on the moveforBIG platform. In total, she raised €10,000, to be invested in BIG’s academic breast cancer research.

Mathilde, who overcame breast cancer, says:

“This was something that I needed to do. Just to prove to myself and to all other breast cancer patients, that there is life after breast cancer. I could not have done this without the support and encouragements of my friends and family. We need one another, and we make each other stronger. Just like the path to Compostela brings all pilgrims together, the path to a cure for breast cancer brings us together”.

Soutenez le programme GPS destiné à comprendre pourquoi un cancer du sein métastase!
A FEW HIGHLIGHTS OF OUR CORPORATE COLLABORATIONS IN 2019

SAINTE-ANNE
Château Sainte-Anne honoured us by choosing BIG against breast cancer as the beneficiary of its 2019 charity work. It was an eventful year, marked for example by a conference with Professor Martine Piccart to raise awareness about the impact of research, a sports day, and culminating in a Christmas dinner and raffle.

FROM SHADOW TO LIGHT
14 November
On 14 November, BIG against breast cancer organised an emotional dinner experience entitled “From Shadow to Light” in the superb setting of Hôtel de la Poste, in Brussels. The gourmet dinner was punctuated with magnificent artistic performances, gently illustrating the journey of a woman diagnosed with breast cancer. Throughout the evening, guests were taken on a voyage, travelling from the shadow into the light, with an awakening of all five senses.

BIG against breast cancer is very thankful for its corporate partners BEST agency, Hilton Brussels Grand Place, Nuxe Belgium, Pfizer, Roche and Tamarind Foods, which contributed to the success of this special event.

CORPORATE PARTNERS

A BIG Thank You to 2019 Event Sponsors and Partners:
Alexandre Laurent photographe • Autoworld Brussels • Barco • Beldiamond • Bouvy • Bozar Brussels • Brussels Choral Society • C12- Galerie Horta • Caméléon Comptoir Privé • Caspian Tradition • Challenge MC • Champagne de Castellane • Château de Bioul • Chocolatier Elisabeth • Claris Clinic • Comme Chez Soi • Compagnie du Zoute • Compagnie des Jardins • Criteres • Danaïs • Delvaux • Duvel • Editions Albin Michel • Editions Assuline • Estée Lauder • Genko • Grant Taylor • Guerlain • Interparking • Isabelle Arpin • James Reilly • JML • JNL • La Chapelière • Leonidas • L’Eventail • Luxeaviation • Michael Lewis-Anderson • Mitchell’s • Musica Mundi • NA Productions • Nuxe Belgique • Odile Jacob • Orenzo • Panda Gin • Piano’s Maenès • Paris Match • Qilak • Ralph Lauren • Rolex • Rothschild & Co Wealth Management Belgium • Sharing Box • Shows on the Road • Sotheby’s Realty • Taschen • Traiteur Lefevere • Traiteur Leonard • Thienpoint Wine • Tiger Lily • Vélu Vins

BIG IMPACT – HOW YOUR COMPANY CAN MAKE A DIFFERENCE

Supporting BIG is supporting researchers who work hard to find cures for patients with breast cancer all over the world!

During the last four years, BIG has expanded the number and types of excellent collaborations with the corporate world, and we are very proud to be able to count on the loyalty of our partners.

Be involved, be creative …

With different packages, your company can support breast cancer research; for example:

CSR PATRONAGE PACKAGES
Having your company associated with a leading international organisation in breast cancer research can only be positive. Such a partnership helps refine your corporate identity and your Corporate Social Responsibility (CSR) commitments.

This package entails a long-term, stable engagement between your company and BIG, through a donation or a global partnership.

MY-EMPLOYEES-COUNT PACKAGES
With such a high incidence rate, breast cancer greatly impacts employees and their family members confronted with the disease, and ultimately business life.

You can choose among various attractive packages, including information sessions, sports activities (MoveforBIG.org), corporate events, sponsoring private concerts, gala evenings, among others.

PINK MARKETING PACKAGES
What about taking the opportunity to engage your customers through your brand? Simply allocate a percentage of your total turnover, or a percentage of the sales of a specific product or service, to breast cancer research.

It’s the opportunity to communicate your support for a cause that touches many women and men in our communities.

PREFERENTIAL PARTNER
As a sponsor of one of our philanthropic activities, by providing financial support (covering part of our communications, venue, or catering costs) or by giving in-kind, your company can become a preferential partner

BE CREATIVE …
IF YOU HAVE AN IDEA, A SUGGESTION …
OUR PHILANTHROPY TEAM IS LISTENING TO YOU!
Together we can find actions to support breast cancer research
Philanthropy@BIGagainstbreastcancer.org

"When communities, companies and individuals with BIG hearts unite for the same cause, something beautiful happens. Together, we can make a BIG difference in the lives of breast cancer patients and their loved ones."

26

27
BIG’s mission is to facilitate and accelerate breast cancer research at the international level. Together we will find a cure for breast cancer through global research and collaboration.

BIG is the largest global network of breast cancer research groups and their affiliated experts. Their work benefits patients locally.

We have been recognised for over 20 years to generate credible scientific results and safeguard patients’ interests.

Our research changes practice in the treatment of women and men with breast cancer. We have a real impact on patients’ lives.
Each year, BIG receives support from Belgian and international foundations. We are thankful for these donations that help finance BIG studies and advance breast cancer research. In 2019, the following foundations provided their support:

BCRF
The Breast Cancer Research Foundation® (BCRF) is a not-for-profit organisation committed to achieving prevention and a cure for breast cancer. The BCRF provides financial support for clinical and translational cancer research projects worldwide, to fuel advances in tumour biology, genetics, prevention, treatment, metastasis and survivorship. It is one of the highest-rated breast cancer organisations in the US.

A loyal partner of BIG, BCRF has, over many years, provided generous funding to support the BIG Metastatic Breast Cancer GPS programme (scientific name: AURORA), as well as many other projects.

www.bcrf.org

BELGIAN NATIONAL LOTTERY
The Belgian National Lottery encourages responsible participation to solidify its commitment towards society. Thanks to their players, the Belgian National Lottery was able in 2019 to reinvest more than € 185 million in a host of civil society projects and associations that have humanitarian, social, athletic, cultural, and scientific objectives. The Belgian National Lottery is so much more than just games. Since 2018, BIG has been receiving support for the BIG Radio Tuning study (scientific name: EXPERT).

www.loterie-nationale.be
www.nationale-loterij.be

FONDS BAILLET-LATOUR
For the third consecutive year, BIG was blessed with the support of the Baillet-Latour Fund, specifically for the BIG Time for Baby study (scientific name: POSITIVE). This charitable trust was created to encourage, promote and foster human excellence in Belgium, with a diligent but open approach to social development. Over the years, and through the allocation of grants, prizes and scholarships, the organisation has increased its scope of action focusing on four pillars: health, culture, education and sports. All the projects and initiatives supported in each field have a Belgian dimension and international vocation.

www.fondsbailletlatour.com

FONATION CANCER, LUXEMBOURG
The foundation’s objective is to raise awareness about cancer prevention and the fight against cancer, as well as to encourage all sort of initiatives, scientific research and information campaigns that contribute more generally to fighting cancer.

For several years now, Fondation Cancer, Luxembourg has been a strong supporter of BIG’s research, providing funds to support the BIG Metastatic Breast Cancer GPS programme (scientific name: AURORA).

www.cancer.lu

FONATION KIABI
The KIABI foundation, a longstanding supporter of BIG, is a corporate foundation that endorses projects to which employees are committed, alongside associations. It promotes cooperation in the areas of health, education, employment and well-being. “The foundation is a marvellous medium for combining and mobilising our actions together. It gives us real opportunities, and everyone has their role to play in getting involved in an action or in being associated with a project”, says Olivier Ballegnien, Manager of the KIABI Foundation.

www.fondationkiabi.com

FONATION NIF
The NIF Foundation supports initiatives that increase the well-being of all men and women, irrespective of their age, origin, nationality, philosophical and religious views. It seeks to address needs that are felt in the social fabric in areas where public institutions are unable, not yet able or can no longer intervene. It contributes financially, in accord with its raison d’être and within its means, to humanitarian projects that are in-line with its mission statement. A generous supporter of many years, the NIF Foundation currently contributes to the BIG Metastatic Breast Cancer GPS programme (scientific name: AURORA).

www.fondation-nif.com

FONDATION CANCER, LUXEMBOURG
The foundation’s objective is to raise awareness about cancer prevention and the fight against cancer, as well as to encourage all sort of initiatives, scientific research and information campaigns that contribute more generally to fighting cancer.

For several years now, Fondation Cancer, Luxembourg has been a strong supporter of BIG’s research, providing funds to support the BIG Metastatic Breast Cancer GPS programme (scientific name: AURORA).

www.cancer.lu

FONATION KIABI
The KIABI foundation, a longstanding supporter of BIG, is a corporate foundation that endorses projects to which employees are committed, alongside associations. It promotes cooperation in the areas of health, education, employment and well-being. “The foundation is a marvellous medium for combining and mobilising our actions together. It gives us real opportunities, and everyone has their role to play in getting involved in an action or in being associated with a project”, says Olivier Ballegnien, Manager of the KIABI Foundation.

www.fondationkiabi.com

FONATION NIF
The NIF Foundation supports initiatives that increase the well-being of all men and women, irrespective of their age, origin, nationality, philosophical and religious views. It seeks to address needs that are felt in the social fabric in areas where public institutions are unable, not yet able or can no longer intervene. It contributes financially, in accord with its raison d’être and within its means, to humanitarian projects that are in-line with its mission statement. A generous supporter of many years, the NIF Foundation currently contributes to the BIG Metastatic Breast Cancer GPS programme (scientific name: AURORA).

www.fondation-nif.com
BIG NETWORK: TWENTY YEARS OF INTERNATIONAL COLLABORATION TO MOVE RESEARCH FORWARD

BIG designs and conducts its own research through its 57 members groups worldwide and their extended network of hospitals and breast cancer experts. In 2019, it reached across approximately 70 countries on 6 continents. Together, BIG members represent the largest global network dedicated to breast cancer research. Each BIG group plays a crucial role in today's research. Their expertise, collaborative spirit, dedication and hard work are essential to improving the lives of patients confronted with breast cancer.
BIG AND 20 YEARS OF BREAST CANCER RESEARCH

“Patients’ needs are at the heart of our activities. Genetic research in recent decades has shown us that breast cancer is not a single disease, but many different subtypes. Each patient is different, requiring a unique treatment approach.”

How it all started
In the mid-1990s, the organisation was little more than an idea generated by two oncologists who had set their hearts on increasing the chances of finding a cure for breast cancer. At the time, breast cancer research in Europe was extremely fragmented, with many academic groups working on similar trials in isolation rather than collaborating. Professor Martine Piccart and Professor Aron Goldhirsch shared a different vision for the future, one where international teams could discuss the results of their latest research, share ideas for new clinical trials and conduct them together. In 1996 they created the Breast International Group (BIG), which became a legal entity in 1999.

Today, over 30 clinical trials and several research programmes are being run or are under development under the BIG umbrella. Since 1999, more than 95,000 patients have participated in BIG’s clinical trials. BIG’s ambition is to see the next generation of patients affected by the disease:

- Over the years, BIG has developed and successfully run numerous large, phase 3 clinical trials involving thousands of international investigators and institutions.
- Many BIG studies have been practice-changing, for example putting aromatase inhibitors on the map (BIG 1-97, BIG 2-97 & BIG 1-98), changing how we treat young women with breast cancer (SOFT), leading to a major breakthrough in treating HER2-positive breast cancer (HERA), helping physicians evaluate which women with early breast cancer could be spared chemotherapy after surgery (MINDACT) or answering important questions about the adjuvant treatment of women with early HER2-positive breast cancer and confirming that trastuzumab in combination with chemotherapy should remain the standard treatment (ALTTO & NeoALTTO).
- Our aim is to find the right treatment for every patient. That’s why BIG’s trials introduce particularly innovative designs, contributing to significant breakthroughs, or paving the way towards more personalised treatment of the disease.

BIG achievements
Since the creation of the not-for-profit in 1999, more than 50 trials have been run under the BIG umbrella, including several landmark trials that have had a real impact on breast cancer treatments and the lives of patients affected by the disease:

- Over the years, BIG has developed and successfully run numerous large, phase 3 clinical trials involving thousands of international investigators and institutions.
- Many BIG studies have been practice-changing, for example putting aromatase inhibitors on the map (BIG 1-97, BIG 2-97 & BIG 1-98), changing how we treat young women with breast cancer (SOFT), leading to a major breakthrough in treating HER2-positive breast cancer (HERA), helping physicians evaluate which women with early breast cancer could be spared chemotherapy after surgery (MINDACT) or answering important questions about the adjuvant treatment of women with early HER2-positive breast cancer and confirming that trastuzumab in combination with chemotherapy should remain the standard treatment (ALTTO & NeoALTTO).
- Our aim is to find the right treatment for every patient. That’s why BIG’s trials introduce particularly innovative designs, contributing to significant breakthroughs, or paving the way towards more personalised treatment of the disease.

BIG AND THE NORTH AMERICAN BREAST CANCER GROUP

A long-term international collaboration
For fifteen years, BIG has been collaborating closely with the North American Breast Cancer Group (NABCG) – a network of major US and Canadian-based research groups, supported by the US National Cancer Institute (NCI).

BIG and NABCG have been meeting annually since 2005 with the aim of identifying difficult aspects of breast cancer research, focusing on research areas not supported by the pharmaceutical industry, and collaborating to resolve common problems.

This long standing, academically-driven collaboration is supported by the generous help of the Breast Cancer Research Foundation®.

The 2019 BIG-NABCG annual meeting (Chicago, USA)
Like every year in May, the BIG-NABCG meeting took place days prior to the annual meeting of the American Society of Clinical Oncology (ASCO), which is held in Chicago, USA.

This year, about 60 world-class cancer researchers and breast cancer patients brainstormed on the topic of “de-escalating systemic adjuvant therapy for breast cancer”, tackling two main challenges: how to develop clinical trials that will, in the future, help doctors better identify which patients will really benefit from adjuvant treatment and which can safely be spared; and how to better involve patients in the design of these de-escalation trials.

Listening to patients’ perspectives - BIG’s Patient Workshops
In preparation for this important BIG-NABCG annual meeting, two patient workshops were organised in April, one in New York, USA, and one at BIG Headquarters in Brussels, Belgium.
About 20 patient advocates, men and women, were invited to talk about their own experiences as cancer patients and express their thoughts about de-escalation clinical trials. Among the questions asked were: What is the level of cancer recurrence risk that patients would be willing to accept in a de-escalation trial? How is the balance between risks and benefits communicated to them? And which factors influence their decision to participate in a clinical trial?

At the end of each workshop, patients responded to a survey probing the factors considered in deciding to participate in clinical trials testing a de-escalation strategy. Four patients were invited to attend the annual meeting in Chicago to share the workshop conclusions.

Several topics were discussed at the annual BIG-NABCG meeting, including the psychological aspects of treatment de-escalation, the statistical design of such trials, the rationale behind reduction of loco-regional and other adjuvant chemo or endocrine therapies, and what type of biomarkers can be used as tools to facilitate de-escalation trials.

The patient perspective is undoubtedly essential in the development and design of new de-escalation trials. Both BIG and NABCG will work together to increasingly involve patients directly in future projects.
Following BIG’s General Assembly of 2 June 2019 in Chicago, BIG appointed Professor David Cameron as new Chair.

Professor Martine Piccart, Co-Founder of BIG, is serving as Immediate Past Chair and President of BIG against breast cancer, the philanthropy unit of BIG.

“"The role of chair is perhaps less of that of the 'leader' but more of the helmsman steering a ship who is totally dependent on his fellow crew members - Executive Board members, headquarters staff and of course all the member groups.”

Professor David Cameron, BIG Chair

On Friday 27 September 2019, during the opening ceremony of the ESMO conference, Doctor Angelo Di Leo was honoured with the ESMO Lifetime Achievement Award.

This award is given to acknowledge outstanding lifetime achievements in oncology and to recognise research by individuals, that demonstrate commitment to clinical cancer research and education.

With a career spanning over three decades, Dr Di Leo has been dedicated to the treatment and research of breast cancer. He has coordinated several international, pivotal phase III trials in new adjuvant therapiesties, and has been deeply involved in the evaluation of molecular markers with potential predictivie value for breast cancer. He also developed the medical oncology department at the Hospital of Prato, Istituto Toscane Tumori, Italy, transforming it into a leading national centre for the treatment of cancer.

A firm believer in the value of independent academic research and international collaboration, Dr Di Leo has been active in the Breast International Group since the beginning and is a member of BIG’s Executive Board.

The aim of this session was to raise awareness about breast cancer, highlight the importance of global breast cancer research, demonstrate the progress that has been made, and illustrate the promising future that new technologies could offer in treating, and hopefully curing, breast cancer.

During the session, participants - who were a mix of breast cancer patients, advocates, family members, students, researchers and breast cancer specialists - were also invited to ask the speakers any questions they had, allowing for a true learning and sharing experience.
The Vienna Breast Surgery Day (VBSD) is organised the day prior to the conference and brings together renowned experts in the field of breast cancer therapy with an emphasis on surgical/local therapy interventions.

The fourth Vienna Breast Surgery Day, entitled “From Eminence to Evidence”, took place on 19 March 2019. It was organised by the Austrian Breast & Colorectal Cancer Study Group (ABCSG), together with its breast surgery expert Professor Florian Fitzal of the Medical University of Vienna. The organisers welcomed 180 participants from over 28 countries to discuss latest achievements in breast cancer surgery. “95% of all patients with breast cancer undergo surgical treatment. This therapy is still one of the most effective modalities in improving overall survival. International meetings like the VBSD help to spread international experts’ knowledge about evidence-based methods regarding modern breast conservation and reconstructive techniques,” says Professor Fitzal.

At every VBSD, a Lifetime Achievement Award is given to an international breast expert with an outstanding curriculum at this particular event. In 2019, Professor Alberto Costa, from the European School of Oncology in Milan, was honoured for his efforts in education and support of young researchers and scientists. Participants’ feedback was very positive and we are looking forward to the next meeting in 2021.

The bi-annual St. Gallen International Breast Cancer Conference in Vienna (Austria) is one of the most important conferences in our field worldwide. In addition to highest level updates from all research and clinical fields of early breast cancer, the Consensus Panel, composed of many of the most distinguished global thought leaders, defines the current state of the art.

BCT-ANZ
Breast Cancer Trials Australia & New Zealand (BCT-ANZ) is the largest, independent, oncology clinical trials research group in Australia and New Zealand. Founded in 1978 by researchers that includes Professor John Forbes AM and Professor Alan Coates AM, BCT-ANZ conducts a clinical trials research programme for the treatment and prevention of breast cancer.

Our research involves multicentre national and international clinical trials and brings together almost 800 researchers in over 100 institutions in Australia and New Zealand. Almost 16,000 women have participated in our clinical trials over the last 40 years.

The BCT-ANZ research programme encompasses approximately 85 clinical trials in various stages of recruitment, follow-up, analysis and publication and BCT-ANZ has contributed to approximately 1,170 publications.

Research Programme
In 2019, BCT-ANZ had eight clinical trials open to recruitment:

• **BRCA-P** – a world-first clinical trial that aims to determine the preventive effect of denosumab on breast cancer in women carrying a BRCA1 germline mutation.

• **CHARIOT** – aims to evaluate whether the addition of two immunotherapy drugs (ipilimumab and nivolumab) to standard treatment can improve the survival of women and men with high risk triple-negative breast cancer.

• **DIamOND** – is investigating the addition of two immune monoclonal antibodies (durvalumab and tremelimumab) to trastuzumab for patients who have metastatic HER2 positive breast cancer.

• **EXPERT (BIG 16-02)** – is investigating whether a genomic test of breast cancer tissue can be used to identify women with early breast cancer, who can safely avoid radiation therapy after breast cancer surgery and the potential side effects of this treatment.

• **Olympia (BIG 6-13)** (recruitment closed in 2019) – is investigating whether taking olaparib tablets twice a day for 12 months can reduce the risk of breast cancer coming back after all standard anticancer treatments have been completed, for patients with HER2 negative breast cancer with an inherited BRCA1 or BRCA2 mutation.

• **PATINA** – aims to investigate if people with metastatic breast cancer could benefit from the addition of palbociclib, when given in combination with anti-HER2 therapy (trastuzumab and pertuzumab) and endocrine therapy.

• **POSONC** – is investigating axillary (armpit) treatment in women with early stage breast cancer who have metastases in one of two sentinel nodes and whether it may be possible for some women to avoid removal of all axillary nodes or radiotherapy to the armpit and the potential side effects.

• **PROSPECT** (closed in 2019) – uses breast magnetic resonance imaging (MRI) in combination with a review of pathological features of the breast tumour to identify women who might safely avoid radiotherapy because their risk of local recurrence is very low.

New Board Directors
In 2019, BCT-ANZ welcomed two new board directors – Mr Luke Bugden and Ms Fiona McPhee. Mr Bugden is a partner of professional services firm Pricewaterhouse Coopers (PwC). Ms McPhee is a fundraising and marketing specialist providing coaching, consulting and training to fundraisers and not-for-profit leaders.
As a leading cooperative study group in the field of breast cancer in Germany, the German Breast Group (GBG) currently manages over 40 clinical trials across all major therapeutic areas: prevention, surgical palliative, adjuvant and neoadjuvant, which the group is best known for.

GBG consistently delivers high-quality results contributing to improving breast cancer treatment and patients’ quality of life. Being supported by broad translational research programmes, GBG-led clinical trials also allow for analysis of biomaterial in academic co-operations worldwide.

In 2019, the group attended the main scientific congresses to present study results as well as several pooled analyses and various high-impact translational research projects. Here is just a brief peek at a few of their activities during the past year.

At ASCO, GBG presented the results of the GeparOCTO, a study for which germline mutation analysis of BRCA1/2 and 16 further breast cancer predisposition genes were investigated in 914 patients. The germline BRCA1/2 mutation prevalence was 17.6% in triple negative breast cancer (TNBC), 14.1% in HER2+/HR- and 1.4% in HER2+ breast cancer. Overall, patients with germline BRCA1/2 mutations achieved higher pathological complete response (pCR) rates compared to patients with germline BRCA1/2 wildtype mutations, with more pronounced effects in the PM(Cb) arm of the GeparOcto study.

An investigation that raised a lot of interest in the breast cancer community following an oral presentation at the ESMO Breast Cancer Congress was the retrospective pooled analysis based on the GBG meta-database that aimed to identify factors predicting relapse despite a pCR. A total of 2,188 patients with pCR from five major neoadjuvant trials were included. It could be shown that, despite favourable prognosis following a pCR, still around 15% of patients had a relapse and 10% a distant relapse after 5 years. Interestingly, initial tumour load (tumour size and nodal status) and histological tumour type remained prognostic factors of long-term outcome even when a pCR was achieved and thus could be helpful for further treatment decisions following surgery.

A big success at ESMO was the research project on the impact of chemotherapy-induced ovarian failure on long-term outcomes in young women with early breast cancer, for which Jenny Furlanetto, a medical advisor and researcher at GBG, received a Merit Award. In this pooled analysis of four GBG neo/adjuvant trials, patients with chemotherapy-induced ovarian failure after anthracycline/taxane-based chemotherapy showed better disease-free survival (DFS), especially women with hormone-receptor positive tumours or younger than 30 years. The improvement in DFS translates into a survival advantage in patients with hormone receptor-positive early breast cancer.

Finally, at SABCS in December 2019, GBG presented the results of a meta-analysis including 12 prospective randomised trials with a total of 15,457 patients. The question investigated was the use of capcitabine in early breast cancer as neoadjuvant or adjuvant therapy. While capcitabine did not improve DFS, when administered in addition to systemic treatment, an improvement in DFS could be observed. Overall survival (OS) was improved by capcitabine treatment in the cohort of all patients and when in addition to systemic treatment. Regarding biological subtypes, only patients with triple-negative breast cancer (TNBC) benefitted from treatment with capcitabine overall and in addition to systemic therapy in terms of both survival endpoints. All effects were small and the largest one was observed for OS in patients with TNBC who received capcitabine in addition (HR 0.78, 95%CI [0.66, 0.92]). There was no evidence supporting predictive value of capcitabine-specific adverse events for DFS.

Ongoing trials and future research

Currently, a number of GBG trials with focus on immune-checkpoint and innovative targeted therapies, as well as registries, are ongoing in the neoadjuvant, adjuvant and palliative settings. Among them SASCIA (recruitment start in summer 2020), GeparDouze (recruiting), and the randomised phase II ALEXANDRA/Impassion030 (GBG 98 / BIG 16-05) study. The latter evaluates the efficacy, safety and pharmacokinetic profile of atezolizumab in combination with standard anthracycline/taxane-based adjuvant chemotherapy versus chemotherapy alone in early triple-negative breast cancer patients.

In metastatic breast cancer, several trials of CDK4/6 inhibitors are also recruiting (i.e. AMICA, PADMA).

In the future, GBG will continue to develop clinical trials and translational research programmes to investigate new therapeutic agents for breast cancer.

References:
1. van Mackelenbergh M, Seither S, Markus V, et al. Effect of capcitabine as part of neo-/adjuvant chemotherapy. A meta-analysis of individual patient data from 12 randomized trials including 25,657 patients. SABCS 2019
The same as our wish to conquer breast cancer, we also wish for all lives across the globe to be protected from natural disasters, which can occur anywhere.

Activities

JBCRG received donations from several companies involved in the Breast Cancer Awareness Campaign run by ELC Japan K.K. (Estee Lauder Companies), JBCRG staff visited some events and helped to raise funds for the #TimeToEndBreastCancer campaign. JBCRG's representative director Dr Shinji Ohno, MD, PhD, was invited as a guest speaker at the JBCRG's annual meeting (December 2019). JBCRG introduced its history and structure, and had a warm discussion about the different medical structures and future visions of the respective countries. Together with its supporters, JBCRG will continue to work towards a world free of breast cancer.

JBCRG's annual meeting

JBCRG's 10th Educational Meeting from 12 October 2019 had to be postponed due to the terrible typhoon HAGIBIS, which caused a lot of damage to eastern Japan. The rescheduled date became 15 February 2020. The JBCRG's 10th Educational Meeting from 12 October 2019 had to be postponed due to the terrible typhoon HAGIBIS, which caused a lot of damage to eastern Japan. The rescheduled date became 15 February 2020. The theme was "Revolution of diagnosis and treatment for breast cancer through artificial intelligence and precision medicine", and around 100 investigators attended.

JBCRG received donations from several companies involved in the Breast Cancer Awareness Campaign run by ELC Japan K.K. (Estee Lauder Companies), JBCRG staff visited some events and helped to raise funds for the #TimeToEndBreastCancer campaign.

JBCRG's representative director Dr Shinji Ohno, MD, PhD, was invited as a guest speaker at the breast cancer seminar of a private company, which is promoting Breast Cancer awareness.

The Latin American Cooperative Oncology Group (LACOG) is the largest multinational cooperative group in Latin America, exclusively dedicated to clinical and translational research in cancer. To date the group has more than 400 investigator members from 194 institutions from 16 countries. Dr Carlos Barnios, LACOG Executive Director, is also member of the BIG's Executive Board.

During SABCS 2019, LACOG Breast Group members from Brazil, Mexico and Peru organised a meeting to discuss ongoing and new breast cancer studies.

LACOG and studies

LACOG is currently participating in the following studies that are run under the BIG umbrella: PALLAS (BIG 14-03), ALEXANDRA/Impassion030 (BIG 16-05) and LORELEI (BIG 3-13). These studies are open in Brazil and Mexico.

In 2019, LACOG published the results of the AMAZONA observational study, as well as the first results of the AMAZONA III prospective registry. Both studies are lead by GBECAM (Grupo Brasileiro de Estudos em Cancer de Mama), in collaboration with LACOG. Data from these studies showed a low rate of breast cancer screening, high proportion of young patients as well as high rate of locally advanced stage in the public health system in Brazil. In addition, Dr Alessandra Borba presented at SABCS 2019 an analysis which identified that 37% of new cases of breast cancer have criteria to BRCA test that is not widely provided in the country. AMAZONA studies highlight the importance of generating real world data in developing countries to better understand the patients' needs. At SABCS 2019, Dr Tomas Reinert presented a poster showing that ESR1 mutations are not a mechanism of primary resistance to aromatase inhibitors in ER-positive breast cancer treated with neoadjuvant endocrine therapy.

This year LACOG started the LATINA study (LACOG 0615) which is the biggest prospective breast cancer registry ever done in Latin America that will open in 35 sites within 11 countries. “The LATINA study will provide for the first time detailed information on socioeconomic, clinical and pathological outcomes of breast cancer in Latin America. This study may identify gaps for optimal therapy in our continent”, said Dr Gustavo Werutsky, LACOG’s Chair and study PI.

Educational Events

In March, LACOG organised, in collaboration with GBECAM, the annual Brazilian Breast Cancer Conference and the official "Best of SABCS in Brazil", which in 2019 was attended by over 400 breast cancer specialists from around the country.

Every year in May, LACOG organises the licensed “Best of ASCO Brazil”. In 2019, around 700 participants attended. LACOG's annual meeting occurs the day before the event, and its aim is to discuss ongoing studies in different tumour types. A dedicated meeting involving national groups from Argentina (GAICO), Chile (GOCCHI), Peru (GECOPERU) and Mexico (INCAN) took place.

Patient advocacy collaboration

It is part of LACOG’s strategy to improve clinical trials awareness in Latin America. LACOG and Proyecto CURA supported a dedicated session for cancer clinical research during the event “Todos Juntos Contra o Cancer (TJCC 2019)” in São Paulo, Brazil. The benefits of cancer research were highlighted, as well as the importance of patients and society engagement to improve access to clinical trials.

2019 was a successful year for LACOG. The group has been growing rapidly and motivating investigators in Latin America to contribute to breast cancer research globally. “BIG has been a key partner in this process and we expect to further strengthen our collaboration within the BIG network”, said Dr Gustavo Werutsky.

LACOG is currently participating in the following studies that are run under the BIG umbrella: PALLAS (BIG 14-03), ALEXANDRA/Impassion030 (BIG 16-05) and LORELEI (BIG 3-13). These studies are open in Brazil and Mexico.

In 2019, LACOG published the results of the AMAZONA observational study, as well as the first results of the AMAZONA III prospective registry. Both studies are lead by GBECAM (Grupo Brasileiro de Estudos em Cancer de Mama), in collaboration with LACOG. Data from these studies showed a low rate of breast cancer screening, high proportion of young patients as well as high rate of locally advanced stage in the public health system in Brazil. In addition, Dr Alessandra Borba presented at SABCS 2019 an analysis which identified that 37% of new cases of breast cancer have criteria to BRCA test that is not widely provided in the country. AMAZONA studies highlight the importance of generating real world data in developing countries to better understand the patients' needs. At SABCS 2019, Dr Tomas Reinert presented a poster showing that ESR1 mutations are not a mechanism of primary resistance to aromatase inhibitors in ER-positive breast cancer treated with neoadjuvant endocrine therapy.

This year LACOG started the LATINA study (LACOG 0615) which is the biggest prospective breast cancer registry ever done in Latin America that will open in 35 sites within 11 countries. “The LATINA study will provide for the first time detailed information on socioeconomic, clinical and pathological outcomes of breast cancer in Latin America. This study may identify gaps for optimal therapy in our continent”, said Dr Gustavo Werutsky, LACOG’s Chair and study PI.

Educational Events

In March, LACOG organised, in collaboration with GBECAM, the annual Brazilian Breast Cancer Conference and the official “Best of SABCS in Brazil”, which in 2019 was attended by over 400 breast cancer specialists from around the country.

Every year in May, LACOG organises the licensed “Best of ASCO Brazil”. In 2019, around 700 participants attended. LACOG’s annual meeting occurs the day before the event, and its aim is to discuss ongoing studies in different tumour types. A dedicated meeting involving national groups from Argentina (GAICO), Chile (GOCCHI), Peru (GECOPERU) and Mexico (INCAN) took place.

Patient advocacy collaboration

It is part of LACOG’s strategy to improve clinical trials awareness in Latin America. LACOG and Proyecto CURA supported a dedicated session for cancer clinical research during the event “Todos Juntos Contra o Cancer (TJCC 2019)” in São Paulo, Brazil. The benefits of cancer research were highlighted, as well as the importance of patients and society engagement to improve access to clinical trials.

2019 was a successful year for LACOG. The group has been growing rapidly and motivating investigators in Latin America to contribute to breast cancer research globally. “BIG has been a key partner in this process and we expect to further strengthen our collaboration within the BIG network”, said Dr Gustavo Werutsky.
CURA PROJECT: Ready for Christmas event

The important Christmas Show for the CURA Project was hosted on 13 December 2019, in Miami, Florida (USA)

The Ready For Christmas event, organised by LACOG, took place in partnership with the Journey Through Brazilian Experience event, a cultural activity of the Consulate General of Brazil in Miami. It included performances by the great Venezuelan singer-songwriter Marger, accompanied by Puerto Rican pianist and conductor José Negroni and his jazz band, which has been nominated three times for the Latin Grammy.

The show was organised to benefit “Projeto CURA”, a cultural activity of the Consulate General of Brazil in Miami. It included performances by the great Venezuelan singer-songwriter Marger, accompanied by Puerto Rican pianist and conductor José Negroni and his jazz band, which has been nominated three times for the Latin Grammy.

The event was attended by an audience of 250 people, representing several Latin American and Caribbean countries (Venezuelans, Colombians, Mexicans, Peruvians, Argentines, Brazilians, Cubans, Puerto Ricans, among others). Also present was Dr Orlando Silva, medical oncologist in Miami and Scientific Director of “Projeto CURA”, as well as Dr Luí Fernando Correia, MD, journalist and CURA Ambassador.

The important Christmas Show for the CURA Project was hosted on 13 December 2019, in Miami, Florida (USA)

The Ready For Christmas event, organised by LACOG, took place in partnership with the Journey Through Brazilian Experience event, a cultural activity of the Consulate General of Brazil in Miami. It included performances by the great Venezuelan singer-songwriter Marger, accompanied by Puerto Rican pianist and conductor José Negroni and his jazz band, which has been nominated three times for the Latin Grammy.

The show was organised to benefit “Projeto CURA”, a cultural activity of the Consulate General of Brazil in Miami. It included performances by the great Venezuelan singer-songwriter Marger, accompanied by Puerto Rican pianist and conductor José Negroni and his jazz band, which has been nominated three times for the Latin Grammy.

The event was attended by an audience of 250 people, representing several Latin American and Caribbean countries (Venezuelans, Colombians, Mexicans, Peruvians, Argentines, Brazilians, Cubans, Puerto Ricans, among others). Also present was Dr Orlando Silva, medical oncologist in Miami and scientific director of CURA, as well as Dr Luí Fernando Correia, MD, journalist and CURA Ambassador.

SOLTI

The POSITIVE study (IBSCG 48-14 / BIG 8-13 - public name: BIG Time for Baby): pregnancy after breast cancer

Today it is not unusual for young women to be diagnosed with breast cancer, though frequently they can be treated successfully and cured; at the same time, the age of motherhood is increasingly delayed. The combination of these two trends makes answering the question about whether it is safe to interrupt hormonal treatment after breast cancer diagnosis in order to try to conceive a child extremely important.

Patricia Villagraa, Scientific Director of the SOLTI Breast Cancer Research Group (SOLTI), says: “As an academic research group, and part of BIG, we promote some trials aimed at answering medical needs that may not be at the focus of the pharmaceutical industry for various reasons. An example of this is the POSITIVE trial, which fits the group’s commitment to giving breast cancer patients the best quality of life. Moreover, this study is a unique opportunity to collect definitive and prospective data about the pregnancy outcomes and safety of interrupting endocrine therapy in young women who desire to have a baby, information that we currently do not have.”

The commitment of SOLTI to the POSITIVE study has been strong from the very beginning: with the participation of 10 sites throughout Spain and one in Portugal, and with a total of 63 patients recruited, SOLTI is a top performer.

The trial closed to recruitment recently and the results are eagerly awaited. “From SOLTI, we are proud to be part of this unique and academic trial that will have a huge impact on reproductive decisions of women who have had breast in the future.” highlights Dr Cristina Saura, member of the SOLTI Board of Directors. SOLTI Coordinator for the POSITIVE Trial and Principal Investigator of the trial at Vall d’Hebron University Hospital and Vall d’Hebron Institute of Oncology (VHIO).

Each patient with breast cancer has her own story to tell, but in the case of cured patients who want to take on the challenge of becoming mothers after the disease and to help to build the evidence needed for women in their situation in the future, being included in the POSITIVE trial makes their story even more valuable.

CURA PROJECT: Ready for Christmas event

The important Christmas Show for the CURA Project was hosted on 13 December 2019, in Miami, Florida (USA)

The Ready For Christmas event, organised by LACOG, took place in partnership with the Journey Through Brazilian Experience event, a cultural activity of the Consulate General of Brazil in Miami. It included performances by the great Venezuelan singer-songwriter Marger, accompanied by Puerto Rican pianist and conductor José Negroni and his jazz band, which has been nominated three times for the Latin Grammy.

The show was organised to benefit “Projeto CURA”, a cultural activity of the Consulate General of Brazil in Miami. It included performances by the great Venezuelan singer-songwriter Marger, accompanied by Puerto Rican pianist and conductor José Negroni and his jazz band, which has been nominated three times for the Latin Grammy.

The event was attended by an audience of 250 people, representing several Latin American and Caribbean countries (Venezuelans, Colombians, Mexicans, Peruvians, Argentines, Brazilians, Cubans, Puerto Ricans, among others). Also present was Dr Orlando Silva, medical oncologist in Miami and Scientific Director of “Projeto CURA”, as well as Dr Luí Fernando Correia, MD, journalist and CURA Ambassador.

This is Emma’s case. Dr Cristina Saura’s patient who participated in the POSITIVE trial and who is now Paula’s mother. She shares her experience as follows:

When were you diagnosed with breast cancer? What were your plans at that time?

I was 36 years old when they confirmed what I didn’t want to hear. At that time, there was the excitement of the beginning of a relationship as it had been five months since I met Xavi, my current partner and father of my daughter. In addition, there was the desire of becoming a mother, though I realised that 36 years was already quite an advanced age for pregnancy. On the other hand, I also wanted to keep growing in my professional career.

How did you discover the POSITIVE study?

It was my oncologist, at Hospital de Sant Pau in Barcelona, Dr Agustí Barnadas, who first told me about the existence of this study. He invited me to participate in it and I did not hesitate at all. To me, anything that I could do to contribute to research and increase the knowledge about breast cancer in order to improve treatments was crucial. I wanted to help other women that were in the same situation as me.

How do you look at motherhood now?

To me, motherhood is a gift of life, the best gift I could ever ask for. I also look at it with great enthusiasm and emotion: every time I see Paula I think “We still have many moments to live together”, and this makes me so happy.

To me, motherhood is a gift of life, the best gift I could ever ask for. I also look at it with great enthusiasm and emotion: every time I see Paula I think “We still have many moments to live together”, and this makes me so happy.

How do you look at motherhood now?

To me, motherhood is a gift of life, the best gift I could ever ask for. I also look at it with great enthusiasm and emotion: every time I see Paula I think “We still have many moments to live together”, and this makes me so happy.

What would you say to any young woman suffering from breast cancer and wishing to become a mother?

I would say that nothing is impossible, that you never have to lose hope and that, sometimes, the psychological factor may play a role against you. After overcoming cancer, it is important to relax and go for it. And, above all, I would recommend participating in trials and studies like POSITIVE. I am sure that they will help other women, just as other women have already helped many of us.
TROG Cancer Research celebrates 30 years of global progress against cancer

Over three decades, the Trans-Tasman Radiation Oncology Group (TROG Cancer Research) has facilitated over 100 clinical trials that have involved more than 14,500 cancer patients and helped improve the outcome and quality of life for thousands more cancer patients globally.

Over that time, the prognosis of cancer patients has improved considerably: in the 1980s, the cancer survival rate was less than 50%. Today, for some cancers, the survival rate is as high as 90%.

Providing hope to people with all cancers through one treatment – radiation therapy – TROG Cancer Research has become one of the largest clinical trial groups in Australia and New Zealand working with hospitals, universities, cancer centres and the wider community.

TROG Cancer Research’s CEO, Susan Goode, said it was hard to believe that 30 years has passed since the organisation was founded in 1989.

Susan acknowledged the unwavering support of the medical and Australian/New Zealand community as a significant contributor to the organisation’s success.

“We’ve come a long way since our humble beginnings in 1989, when members of seven radiation therapy centres across Australia and New Zealand formed a clinical trial group to advance the study of cancers that could be treated with radiation therapy,” Susan said.

“Today we have medical professionals approaching us from around the world with new ideas on how to use radiation therapy to improve quality of life and treatment of a specific cancer disease. One in two cancer patients could benefit from radiation therapy, so the research we conduct is vital.”

“By collaborating and bringing to life these concepts in a managed environment, we’ve been able to achieve great advancements in cancer patient care and outcomes that have changed the way patients are treated worldwide.”

TROG Cancer Research trials have been run in more than 200 hospitals and cancer centres in urban hubs and regionally around the world, including Australia, New Zealand, United Kingdom, Asia, Canada, Europe and South America.

While over 30 years of technological advancement in radiation therapy and a better understanding of tumour biology have improved the efficacy of radiation therapy resulting in improved quality of life and treatment options, Susan said there is still more work to be done.

“Although our clinical trials have facilitated great advancements in the way that different cancers are treated and have improved the quality of life for patients, there’s still much to be done to continue to increase cure rates, minimise side effects and improve the patient experience,” Susan said.

“Radiation therapy remains an important curative treatment option; however, ongoing research is still needed to ensure we can progress the ways we use this advanced technology to outsmart the many strains of the disease and also enable patients to maintain their quality of life both during and after treatment.”

TROG Cancer Research has facilitated over 100 cancer research trials over 30 years to enable researchers and healthcare professionals to better understand cancer and discover more effective ways of managing and treating it.
## Overview of the clinical studies run within the BIG network in 2019

**Open, recruiting patients**

<table>
<thead>
<tr>
<th>Study name</th>
<th>BIG number</th>
<th>Short description</th>
<th>Principal investigators</th>
<th>Trial model &amp; partners</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALEXANDRIA / Impassion 030</td>
<td>BIG 16-05</td>
<td>A randomised phase II trial comparing palbociclib alone or in combination with standard chemotherapy vs. chemotherapy alone as adjuvant treatment in patients with operable TNBC - NCT03489776</td>
<td>M. Ignatiadis H. McKeough</td>
<td>Lead trial (IC); Co-Leading partners: BIG HQ / UB-CTSU (BEAST) / FSTRF and AFT; Pharma partner: Roche/Gentech (sponsor); Funding: Roche / Genentech</td>
</tr>
<tr>
<td>APPALACHES</td>
<td>BIG 18-01</td>
<td>A Phase II study of Adjuvant Palbociclib or an Alternative to Chemotherapy in Elderly patients with high-risk ER+ /HER2- early breast cancer - NCT03609047</td>
<td>H. Wildiers E. Brain K. Punie</td>
<td>Supporter trial (coordinator: EORTC (sponsor); Pharma partner: Pfizer; Funding: Pfizer)</td>
</tr>
<tr>
<td>AURORA (Metastatic Breast Cancer GPS)</td>
<td>BIG 14-01</td>
<td>The AURORA programme: aiming to understand the molecular aberrations in metastatic breast cancer - NCT02102165</td>
<td>P. Allmers M. Olivara</td>
<td>BIG-sponsored programme (IC); Co-Leading partners: BIG HQ (sponsor) / UB-CTSU / FSTRF; Pharma partner: N/A; Funding: Breast Cancer Research Foundation, Fondation Cancer Luxembourg, IBBT, the National Lottery Belgium, Mr and Mrs Banse and Den Hertogh; individual donors</td>
</tr>
<tr>
<td>Breast Cancer in Pregnancy</td>
<td>BIG 2-03</td>
<td>Prospective registry of women treated for breast cancer while pregnant - NCT01096353</td>
<td>S. Loibl G. van Mindenwijk</td>
<td>Supporter trial (IC); Co-Leading partners: GBG (sponsor); Pharma partner: N/A; Funding: GBG, Deutsches Konsortium für Translationale Krebsforschung</td>
</tr>
<tr>
<td>Exceptional Responders</td>
<td>BIG 16-04</td>
<td>A global hunt for exceptional responders in the BIG network: aiming to identify breast cancer patients with a truly remarkable clinical response to anticancer treatments, and to characterise their tumours molecularly</td>
<td>A. Ithmm (coordinator)</td>
<td>BIG-sponsored programme (IC); Co-Leading partners: BIG HQ; Pharma partner: N/A; Funding: Breast Cancer Research Foundation</td>
</tr>
<tr>
<td>EXPERT</td>
<td>BIG 16-02</td>
<td>A randomised phase II trial of adjuvant radiation therapy vs observation after breast conserving surgery for patients with molecularly characterised low-risk luminal A or early breast cancer - NCT02889874</td>
<td>B. Chua</td>
<td>Co-lead trial (IC); Co-Leading partners: BCT-ANZ (sponsor) and BIG HQ; Pharma partner: N/A; Funding: BCT-ANZ, the National Health and Medical Research Council, Australia and the National Lottery Belgium and BIG HQ; Funding initiatives</td>
</tr>
<tr>
<td>POLAR</td>
<td>BIG 18-02</td>
<td>Palbociclib for HR+ isolated local or regional recurrence of breast cancer - NCT03820830</td>
<td>E. Munzone S. Aebi</td>
<td>Supporter trial (Co-coordinating group: BCGC (sponsor); Pharma partner: Pfizer)</td>
</tr>
<tr>
<td>POSITIVE (BIG time for Baby)</td>
<td>BIG 8-13</td>
<td>Endocrine therapy interruption to enable conception for young women with ER+ breast cancer - NCT02308085</td>
<td>O. Pagani</td>
<td>Supporter trial (IC); Co-Leading partners: BCGC (sponsor); Pharma partner: Pfizer; Funding: BCGC, Fonds Baillot-Latour, national and local funding bodies, individual donors</td>
</tr>
<tr>
<td>Follow-up or post-study activities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study name</th>
<th>BIG number</th>
<th>Short description</th>
<th>Principal investigators</th>
<th>Trial model &amp; partners</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALTTO</td>
<td>BIG 2-06</td>
<td>Adjuvant Lapatinib and or Trastuzumab Treatment Optimisation: sequence and combination for patients with HER2/ ErbB2 positive primary breast cancer - NCT00491039</td>
<td>M. Piccart A. Marianna-Apikov</td>
<td>Lead trial (IC); Co-Leading partners: BIG HQ / UB-CTSU (BEAST) / FSTRF and AFT; Pharma partner: Novartis (global sponsor) headlines in the US; Funding: Novartis; Pharma partner: Pfizer (sponsor) and Roche (sponsor)</td>
</tr>
<tr>
<td>APHINITY</td>
<td>BIG 4-11</td>
<td>Comparison of single-versus-dual anti-HER2 therapy (trastuzumab, pertuzumab) for patients with HER2 positive primary breast cancer - NCT0358877</td>
<td>M. Piccart S. Lobl J. Bines</td>
<td>Lead trial (IC); Co-Leading partners: BIG HQ / UB-CTSU (BEAST) / FSTRF; Pharma partner: Roche (sponsor); Funding: Roche</td>
</tr>
<tr>
<td>AZURE</td>
<td>BIG 1-04</td>
<td>Does Adjuvant Zoledronic acid reduce Recurrence in patients with high-risk, locally advanced breast cancer? - NCT00702020</td>
<td>R. Coleman</td>
<td>Supporter trial (IC); Co-Leading partners: NCI; Pharma partner: Novartis; Sponsor: University of Sheffield; Funding: Cancer Research UK, Experimental Cancer Medicine Centre (ECMC), National Institute for Health Research Cancer Research Network (CIERN), Novartis and Inbiration</td>
</tr>
<tr>
<td>BRAVO</td>
<td>BIG 5-13</td>
<td>Niraparib for patients with HER2-negative, germline BRCA mutation-positive, locally advanced or metastatic breast cancer - NCT01905592</td>
<td>N. Yumar J. Balmaña D. Cameron J. Ehrlich</td>
<td>Co-lead trial (IC); Co-Leading partners: EORTC / BIG HQ; Pharma partner: Tesaro (sponsor); Funding: Tesaro</td>
</tr>
<tr>
<td>DCIS</td>
<td>BIG 3-07</td>
<td>Radiation doses and fractionation schedules for women with DCIS - NCT04702326</td>
<td>B. Chua</td>
<td>Supporter trial (IC); Co-Leading partners: TRIG (sponsor); Pharma partner: N/A; Funding: National Health and Medical Research Council, Susan G. Komen for the Cure, Breast Cancer Now, Ovarius, and Dutch Cancer Society</td>
</tr>
<tr>
<td>FINESE</td>
<td>BIG 2-13</td>
<td>Oral lactulose for patients with FGFR1 ER+ metastatic breast cancer - NCT02053636</td>
<td>F. André J. Carles</td>
<td>Lead trial (IC); Co-Leading partners: BIG HQ / BEAST / FSTRF; Pharma partner: Sanofi (sponsor); Funding: Sanofi</td>
</tr>
<tr>
<td>BIG-5</td>
<td>BIG 5-02</td>
<td>Prevention study of anastrazole for postmenopausal women at increased risk of breast cancer; and of effects of tamoxifen vs. anastrazole in postmenopausal women with DCIS - NCT00072462</td>
<td>J. C Rustick</td>
<td>Supporter trial (IC); Co-Leading partners: ABCSG, SOLTI and BIG HQ; Pharma partner: N/A; Funding: Breast Cancer Research Foundation</td>
</tr>
<tr>
<td>INTER VII</td>
<td>BIG 7-07</td>
<td>Registration and biologic characterisation programme of breast cancer in men - NCT01011425</td>
<td>F. Cardoso S. Giordano</td>
<td>Supporter programme (IC); Co-Leading partners: EORTC / NACRT; Pharma partner: N/A; Funding: Breast Cancer Research Foundation</td>
</tr>
<tr>
<td>LORELI</td>
<td>BIG 3-13</td>
<td>Neoadjuvant letrozole plus tamoxifen versus letrozole plus placebo in postmenopausal breast cancer patients with ER+ / HER2-negative, early-stage breast cancer - NCT02273973</td>
<td>C. Soures E. de Azambuja</td>
<td>Co-lead trial (IC); Co-Leading partners: ABCSG, SOLTI and BIG HQ; Pharma partner: Genentech (sponsor); Funding: Genentech</td>
</tr>
</tbody>
</table>
### MINDACT

BIG 3-04: Can addition of 70-gene signature to common clinical-pathological criteria safely spare patients with 0 to 3 node positive breast cancer from adjuvant chemotherapy? - NCT00433589

E. Rutgers
M. Piccart
Co-lead trial
EORTC (sponsor) / BIG HQ
Pharma partner: Roche, Sanofi, Novartis, and Novartis grants, Breast Cancer Research Foundation, Susan G. Komen for the Cure, Cancer Research UK, EORTC, Charitable Trust, numerous national cancer societies and many other charitable grants

### NEO-AIITTO

BIG 1-07: A phase III trial evaluating the role of continuous letrozole versus intermittent letrozole following 4 to 6 years of prior adjuvant endocrine therapy for postmenopausal women with hormone-receptor positive, node positive early stage breast cancer (SOLE - Study Of letrozole Extension) - NCT00533492

G. von Minckwitz
Supporter trial
Lettrozole
Pharma partner: AstraZeneca (sponsor in Rest of the World), Roche, Sanofi, Novartis

### OLYMPIA

BIG 6-13: Olaparib vs. placebo for patients with BRCA-mutated, high-risk HER2-negative breast cancer, having completed local treatment and neoadjuvant chemotherapy - NCT0033823

M. Piccart
Co-lead trial
EORTC (sponsor) / BIG HQ
Pharma partner: Novartis global sponsor for all countries with the exception of US, where Alliance is the sponsor

### PALLAS

BIG 18-03: Palbociclib Collaborative Adjuvant Study (palmcis): palbociclib with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy alone for HR+ / HER2-negative early breast cancer - NCT0213394

E. Mayer
M. Grant
A. DeMichele
Co-Lead trial
EORTC BCG, SUCCESS, EORTC BCTSU / FSS / SOLTI / EORTC Charitable Trust, numerous national cancer societies and many other charitable grants

### PENE-LOPE-B

BIG 1-13: Post-neoadjuvant palbociclib for patients with HR+, HER2-normal primary breast cancer with high risk of recurrence after neoadjuvant chemotherapy - NCT0164746

G. von Minckwitz
Supporter trial
Palbociclib
Pharma partner: Pfizer

### PYTHIA

BIG 14-04: Palbociclib plus fulvestrant for pretreated patients with ER+ / HER2- metastatic breast cancer - NCT0203674

I. Matamis
Co-Lead trial
EORTC BCG (sponsors) and BIG HQ
Pharma partner: Pfizer

### SNAP

BIG 2-12: Evaluation of different schedules of nab-paclitaxel for metastatic breast cancer - NCT00746225

A. Gennari
G. Jerusalem
Supporter trial
Nab-paclitaxel
Pharma partner: Celgene

### SOFT

BIG 2-02: Evaluation of ovarian suppression and all-arms vs adjuvant therapy for premenopausal women with endocrine responsive breast cancer - NCT00066990

P. Francis
G. Fleming
Supporter trial
EORTC BCG (sponsors) and BIG HQ
Pharma partner: Pfizer

**NB:** This table does not include the trials in development and the closed trials. For more information, please visit [www.BIGagainstbreastcancer.org.](http://www.BIGagainstbreastcancer.org)
Scientific papers published by member groups about BIG trials in 2019


## BIG BALANCE SHEET

### ASSETS

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fixed Assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intangible fixed assets</td>
<td>0</td>
<td>2,952</td>
</tr>
<tr>
<td>Tangible fixed assets</td>
<td>119,398</td>
<td>175,331</td>
</tr>
<tr>
<td>Financial fixed assets</td>
<td>140,637</td>
<td>137,769</td>
</tr>
<tr>
<td><strong>Total Fixed Assets</strong></td>
<td>260,035</td>
<td>316,052</td>
</tr>
<tr>
<td><strong>Current Assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Receivables up to one year</td>
<td>5,125,002</td>
<td>14,831,225</td>
</tr>
<tr>
<td>Current investments</td>
<td>3,144,370</td>
<td>64,336</td>
</tr>
<tr>
<td>Cash at bank</td>
<td>10,768,868</td>
<td>8,422,909</td>
</tr>
<tr>
<td>Deferred charges and accrued income</td>
<td>148,341</td>
<td>655,376</td>
</tr>
<tr>
<td><strong>Total Current Assets</strong></td>
<td>19,186,581</td>
<td>23,973,847</td>
</tr>
<tr>
<td><strong>TOTAL ASSETS</strong></td>
<td>19,446,616</td>
<td>24,289,899</td>
</tr>
</tbody>
</table>

### LIABILITIES

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Equity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unrestricted net assets</td>
<td>704,019</td>
<td>1,073,155</td>
</tr>
<tr>
<td>Restricted net assets</td>
<td>4,300,800</td>
<td>3,891,624</td>
</tr>
<tr>
<td><strong>Total Equity</strong></td>
<td>5,004,819</td>
<td>4,964,779</td>
</tr>
<tr>
<td><strong>Debts</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amounts payable after more than one year</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Amounts payable within one year</td>
<td>14,441,636</td>
<td>19,324,818</td>
</tr>
<tr>
<td>Current portion of amounts payable after more than one year falling due within one year</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>&gt; Trade debts</td>
<td>14,113,383</td>
<td>19,027,763</td>
</tr>
<tr>
<td>&gt; Tax, remuneration and social security</td>
<td>328,253</td>
<td>297,054</td>
</tr>
<tr>
<td>Deferred charges and accrued income</td>
<td>148,341</td>
<td>655,376</td>
</tr>
<tr>
<td><strong>Total Debts</strong></td>
<td>14,441,797</td>
<td>19,325,120</td>
</tr>
<tr>
<td><strong>TOTAL LIABILITIES</strong></td>
<td>19,446,616</td>
<td>24,289,899</td>
</tr>
</tbody>
</table>

### INCOME & EXPENSES STATEMENT

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Operating Income &amp; Expenses</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Turnover (research)</td>
<td>18,046,390</td>
<td>14,218,053</td>
</tr>
<tr>
<td>Other goods &amp; services</td>
<td>-14,820,796</td>
<td>-11,434,687</td>
</tr>
<tr>
<td><strong>Operating margin</strong></td>
<td>3,225,594</td>
<td>2,783,367</td>
</tr>
<tr>
<td>Remuneration, social security &amp; pension costs</td>
<td>-3,442,878</td>
<td>-2,952,007</td>
</tr>
<tr>
<td><strong>Operating result</strong></td>
<td>-217,284</td>
<td>-168,641</td>
</tr>
<tr>
<td>Financial result</td>
<td>238,607</td>
<td>170,314</td>
</tr>
<tr>
<td>Extraordinary income (+)</td>
<td>24,076</td>
<td>-39,016</td>
</tr>
<tr>
<td>Extraordinary expenses (-)</td>
<td>-5,359</td>
<td>-592</td>
</tr>
<tr>
<td><strong>Result for the financial year</strong></td>
<td>40,040</td>
<td>-37,935</td>
</tr>
</tbody>
</table>

Between 2012 and 2019, BIG received over € 115 000 000 * was spent directly on research conducted under the BIG umbrella, making a huge difference in the lives of women and men with breast cancer.
BIG ACHNOWLEDGEMENTS

A SPECIAL THANK YOU

Mr Daniel Abelow
Mrs Marie-Louise Albadia Jelgersma
Mr and Mrs Bernard Ameyot
Mrs Catherine Anspach
Mrs Véronique Barbier
Mrs Chantal Beineux-Gillion
Mr and Mrs Patrick Berko
Count and Countess Buyse
Mr and Mrs Patrick Callewaert
Mr and Mrs Yves Carakéhian
Mr and Mrs Cardon de Lichtbuer
Mr Michel Carlier
Mrs Marina Cartalis
Mr and Mrs Gilles Charpentier
Mrs Sylvia Chiche
Mr Didier Claes
Mr Eric Cleton
Count and Countess Arthur Cornet de Wys-Raart
Count and Countess Paul Cornet de Wys-Raart
Mr and Mrs Denis Dubois
Mrs Marie de Coco de Rameyen
Mr and Mrs Marc Desortz
Prince and Princess de Ligne
Prince and Princess Amaury de Merode
Princess Hélène de Merode
Prince and Princess de Chimay et de Caraman
Count and Countess Hervé de Liedekerke
Count and Countess Hadelin de Liedekerke Beaufort
Knight and Mrs Stéphane de Patoul
Mr and Mrs Alain De Pauw
Countess Fournier Laroque de Saint Côme
Knight Philippe de Sellettes
Mr and Mrs Alain de Sève
Mr and Mrs Jean-Marc Desolages
Mr Walter De Tooflor
Baron and Baronesse Marc de Villerfagnon de Voghsanck
Mr and Mrs Armand-François de Wasseige
Mrs Vinciane Morel de Wastgaver
Mr and Mrs Etienne de Woot de Janvier
Mr and Mrs Graham Edwards
Mr Philippe Feller
Mrs Jessica Parcer and Mr François Gérard
Mrs Evelyn Cruselier
Baron and Baroness Gillion Crowet
Mr Michael Goossens
Mrs Isabelle Hotimsky
Mrs Ariane Houardeau
Mr and Mrs Jean-Philippe Hubin
Mrs Lena Ismael
Mr and Mrs Nissim Israel
Mr and Mrs Erol Kendisoyi
Baroness Jansen
Mr Michael Jungers
Mr and Mrs Philippe Jungers
Mr and Mrs David Lebard
Mr Arnaud Lefèvre
Mr and Mrs Régine Haelgoetse
Mrs Meike Mars
Meerapfel Family
Mrs Alexandra Mikolajczak
Mr and Mrs Cedric Olibechn
Ambassadour and Mrs Juan Prat Y Coll
Mrs Bérangère Relecom
Mrs Michel Relecom
Mr and Mrs Didier Reylandt
Mr the European Comissioner and Mrs Didier Reyniers
Mr and Mrs Thomas Spiller
Mrs Ourly Scoul
Mr Daniel Thierry
Count and Countess t’Kint de Roodhe neke
Mr and Mrs Xavier Roland
Mr and Mrs Jean-Philippe Thierry
Mr and Mrs Frederic Van de Schouwer
Baron and Baroness Charles van de Straeten Waillier
Mr Emmanuel Van de Putte
Mr Frédéric Vanderoneoet
Mrs Micheline van Drongenbroek
Baron and Baronesse Raymond Vaxelaire
Mrs Virginie Vaxelaire
Mr Gerald Watier
Mr and Mrs Barrie and Dena Webb
LL.AA.SS. Prince and Princess Cyril Wolkonsky
Mr and Mrs Andy Wyckmans-Vaxelaire

BIG Executive Board

BIG’s EB represents the leadership and the main scientific and decision-making authority of the organisation. It aims to reflect the geographical extent of the network, as well as its multiculturalism and the broad range of expertise among its members, such as medical oncology, gynaecological oncology, surgical oncology, radiation oncology, medical statistics, clinical trials methodology, translational research and business.

The EB members develop BIG’s scientific strategy. With BIG headquarters, they implement decisions of the General Assembly and provide oversight of the organisation.

CARLOS BARRIOS, Medical Oncologist, Brazil
PHILIPPE BEDARD, Medical Oncologist, Canada
JUDITH BUSS, Medical Statistician & Trials Methodologist, United Kingdom
ETHRINE BIAN, Medical Oncologist, France
DAVID CAMERON, BIG Chair, Medical Oncologist, United Kingdom
EVA CARRASCO, Medical Oncologist, Spain
BOON CHUA, Radiation Oncologist, Australia
MARCO COLLEONI, Medical Oncologist, Italy
ANGELO DI LEG, Medical Oncologist, Italy
BARRITO LINDERHOLM, Medical Oncologist, Sweden
SIBYLLE LOBL, Gynaecologist, Germany
MARTINE McCART, BIG Co-founder & Immediate Past Chair, President of BIG against breast cancer, Medical Oncologist, Belgium
SHINJI OHNO, Surgical Oncologist, Japan
ALEX PRAT, Medical Oncologist, Spain
ANDER URRUTIA COBEA, BIG Treasurer, Medical Oncologist, Spain

Colophon

MANAGING EDITORS: MATHILDE JOORIS
JÖELLE LÉEMANS
GIA QUESTIAUX
ORIANA SPAGNOLO
CAROLYN STRAEHLE
VALÉRIE VAN DER VEEKEN

DESIGNED BY: VANDEN BROELE
PHOTOS @ SHUTTERSTOCK

THE OPINIONS OR CONCLUSIONS STATED OR IMPLIED IN THE ARTICLES HEREIN ARE THOSE OF THE AUTHORS AND DO NOT NECESSARILY REFLECT THOSE OF THE PUBLISHER.

BIG HEADQUARTERS’ CONTACT ADDRESS:
BREAST INTERNATIONAL GROUP (BIG)-AISBL
BLVD DE WATERLOO 76
1000 BRUSSELS, BELGIUM
TEL.: +32 2 486 16 00

VAT. BE 0468 176 240

E-MAIL: INFO@BIGAGAINSTBREASTCANCER.ORG
WWW.BIGAGAINSTBREASTCANCER.ORG

COPYRIGHT 2020
BREAST INTERNATIONAL GROUP
ALL RIGHTS RESERVED
TOGETHER, we have the opportunity to make a real difference in patients’ lives, both today and in the future.

SUPPORT BIG:
IBAN BE08 0689 0916 0213
(communication: AR 2019)

OR DONATE ONLINE:
www.BIGagainstbreastcancer.org/donate

#BIGAGAINSTBC
WWW.BIGAGAINSTBREASTCANCER.ORG

FOLLOW US ON
@BIGagainstbreastcancer @BIGagainstBC BIG against breast cancer