Breast cancer research

CHANGE

renewal and hope

ANNUAL REPORT

2021

BIG
Breast International Group
“Having flown the earth for 300 million years, the dragonfly symbolises transformation and our ability to overcome times of hardship. It carries the wisdom of change.”
Dear reader,

For BIG’s Annual Report 2021, we have chosen the theme change, illustrated by the metaphor of the dragonfly, which has been hovering the world for more than 300 million years and which, in many parts of the world, symbolises transformation, renewal and change. And with change, comes hope.

2021 was a year full of changes. First and foremost, through BIG’s global breast cancer research in 2021, we increased our knowledge about breast cancer (e.g., AURORA) as well as about both old (e.g., MA.32) and new treatments (e.g., OlympiA). We are hopeful and confident that we will continue to deliver practice-changing results in the future, with several new BIG studies launched and with advancements and completion of important ones. Each such step helps to transform the way breast cancer is treated, bringing ever more personalised treatments – and hope – to women and men suffering from the disease. The section “BIG Research” provides an update on some key BIG trials, their status and promising results.

For the BIG network, these changes were not only organisational – with newly elected members of BIG’s Executive Board and two research groups joining the network —, but also physical – with the move of BIG Headquarters’ offices from the centre of Brussels (Belgium) to the surroundings of the capital. Our offices are now located in Kraainem, one of Brussels’ municipalities. More information on the role of BIG’s EB and on BIG’s vision, mission and strategy statements can be found in the section “BIG Network”.

BIG against breast cancer, BIG’s dedicated philanthropy unit within BIG HQ, conducts vital fundraising to support BIG’s clinical trials and research programmes that have no commercial interest but are crucial for breast cancer patients. The funds raised – through the generosity of foundations, companies, ambassadors, and other individuals – contribute to the work of BIG member groups and their affiliated hospitals and help support patient participation in a study.

Due to the Covid-19 pandemic and related public health measures, planned events had to be cancelled and we had to re-invent how to reach BIG’s community of supporters, as described in the section “BIG Philanthropy”. A special mention and thanks goes to the many personal fundraising initiatives launched by individuals via our MoveforBIG platform.

In name of everyone at BIG, I would like to extend our sincere gratitude and appreciation to all member groups, partners, faithful ambassadors and donors for their support and collaborative spirit to help advance breast cancer research and change the face of it. I also want to honour the commitment from BIG Headquarters and the different teams that work relentlessly to make this possible. And, just as importantly, we wish to thank and honour the thousands of patients who participate in our trials and work with us to develop tomorrow’s cures.

Enjoy the reading.

Professor David Cameron
BIG Chair

Together, we can change the face of breast cancer
Dear reader,

The year 2021 marked yet another period full of challenges, changes and achievements, which nonetheless give us excellent prospects for the future: We signed the main study agreement with Sanofi for AMEERA-6, a major registration study being co-led in collaboration with the EORTC and AFT; the Breast Cancer Research Foundation approved the extension of AURORA, to enable the resumption of recruitment, focused on specific subtypes of metastatic breast cancer; and discussions on ideas for new studies continued throughout the year.

We also published the first AURORA manuscript in Cancer Discovery, followed by the positive and very promising OlympiA results in the New England Journal of Medicine, as well as numerous other publications and presentations for many BIG studies. We moved BIG Headquarters to a new location, and our IT systems remained fully operational in the hybrid office and tele-working context. And there are so many other achievements from each team, both within BIG Headquarters and across the network, that I could not possibly mention them all without writing a book!

At the beginning of 2021, we had hoped to return to normal, a return to “freedom”, away from COVID-19 restrictions. But we had to change our plans, with COVID continuing to affect our operations. Virtual congresses, virtual scientific meetings, virtual working meetings, virtual fundraising,… (hence the critical value of IT to keep us functioning!) and cancellation of face-to-face meetings and philanthropic events. The pandemic proved to be much more persistent than we had hoped for, and so we adapted. This required constant resilience, agility, creativity and motivation from us all.

Behind all this “virtual” there are real people: us. In 2021 life continued with the good and the bad in our private sphere. We should acknowledge that the pandemic weighed heavily on us. Some of us experienced COVID more than once, and we all know people who suffered directly or indirectly as our health care systems were forced to delay regular care and, in some cases, came close to collapse.

The good news is that throughout the course of 2021, through continuous research and experience, we gained improved insights, and we learned step-by-step how to live within our changed environment. We now have valuable prophylactics at our disposal in the form of vaccines, as well as recently licensed treatment tools that may offer better outcomes in case of serious COVID disease. And, thanks to all the work of BIG Headquarters’ Human Resources team, our new office was prepared to safely accommodate BIG staff with all the necessary measures implemented for working “in person” again.

So, I wish to extend a warm-hearted thanks to all BIG HQ staff, our many BIG network colleagues around the world, and the women and men who participate in our studies: by working tirelessly, we are able to master with courage and agility the challenges we face; by working tirelessly, we will continue to develop our knowledge about breast cancer, develop better treatments, and give hope to the many millions affected by this disease.

Warmest regards,

Theodora Goulioti, MD
BIG CEO

Together, we are stronger to change the lives of breast cancer patients and their families

1 European Organisation for the Research and Treatment of Cancer; Alliance Foundation Trials.
BEHIND ALL THIS ‘VIRTUAL’ THERE ARE REAL PEOPLE: US
1 IN 8 WOMEN and 1 IN 800 MEN will be diagnosed with breast cancer over the course of their lifetime.

2.3 MILLION PEOPLE were diagnosed with breast cancer in 2020.

± 100 000 PATIENTS have participated in BIG trials, thus helping to develop better breast cancer treatments.

> 30 patient-centred clinical trials and research programmes are run under the BIG umbrella at any one time.

> 10 000 breast cancer specialists within the BIG network.

± 50 000 breast cancer specialists within the BIG network.

78 PEOPLE / HOUR die from breast cancer.

> 50 academic research groups make up the largest international network dedicated solely to breast cancer research.

PATIENTS ARE AT THE HEART OF BIG’S RESEARCH. The goal is to offer the best possible treatments to each patient.

1 IN 8 WOMEN and 1 IN 800 MEN will be diagnosed with breast cancer over the course of their lifetime.

1 IN 8 WOMEN and 1 IN 800 MEN will be diagnosed with breast cancer over the course of their lifetime.
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, more than two decades later, BIG represents over 50 like-minded research groups from around the world and reaches across more than 70 countries on 6 continents.

Through its network of groups, BIG connects thousands of hospitals and world-class breast cancer experts who collaborate in pioneering breast cancer research. BIG also works closely with the US National Cancer Institute (NCI) and the National Clinical Trials Network (NCTN), so that together they act as a strong integrating force in the breast cancer research arena.

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 enrolls 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

“Together we will cure breast cancer”
RESEARCH CHANGES THE LIVES OF PATIENTS AND THEIR LOVED ONES

While research has made huge strides in recent decades to improve and significantly extend the lives of patients with breast cancer, mainly in early stage, the disease still represents the most commonly diagnosed cancer in the world, even surpassing lung cancer. Breast cancer is the most common cancer in women, and the leading cause of cancer death in women (1 in 6)\(^1\).

**BIG’s research aims to change the lives of men and women affected by breast cancer.** While some studies are conducted to better understand the development of the disease and others to test new promising drugs or treatment strategies, the ultimate goal is always to provide better and more personalised treatments and, hopefully one day, offer cures to each individual patient affected by breast cancer.

**2021 was a year of hard work to launch new studies and advance with or complete important ones, all of which will one day bring change in the way breast cancer is treated.**
PROMISING RESULTS

OLYMPIA:
A NEW TREATMENT FOR WOMEN WITH HEREDITARY BREAST CANCER

In June 2021, the important results of the BIG OlympiA study were published in the *New England Journal of Medicine* 2. This clinical trial, led by BIG and involving over 1,800 patients from 23 countries around the globe, is an academic and industry partnership investigating a possible personalised treatment for women with hereditary breast cancer.

The most common cause of hereditary breast cancer is an inherited mutation in the *BRCA1* or *BRCA2* genes, which also may cause the disease to develop at a significantly earlier age than usual. An estimated 2.3 million people were diagnosed with breast cancer worldwide in 20203, and *BRCA1* and *BRCA2* mutations are found in approximately 5% of breast cancer patients4. While we have made great progress in the early treatment of this type of cancer, most patients are concerned about the risk of the cancer coming back. Finding better and more targeted approaches for adjuvant treatments, i.e., given after surgery, will help keep cancer and the fear of recurrence away.

The results of the OlympiA Phase III trial showed that giving the drug olaparib (*Lynparza*) for one year to patients who had completed surgery (with or without radiotherapy) and received standard chemotherapy either before or after surgery, reduced the risk of cancer returning after treatment by 42%.

While writing this text, the findings of OlympiA led to olaparib being approved by the U.S. Food and Drug Administration as a new treatment for patients in the U.S. with hereditary BRCA mutations and high-risk, early-stage breast cancer. The treatment is expected to be approved in other regions of the world soon.

“THESE RESULTS REINFORCE HOW COLLABORATIVE CANCER RESEARCH DEEPENS OUR UNDERSTANDING OF TREATING FAMILIAL CANCERS AND SHOWS THE VALUE OF TESTING FOR THESE MUTATIONS IN PATIENTS WITH EARLY BREAST CANCER.”

PROFESSOR ANDREW TUTT, CO-PRINCIPAL INVESTIGATOR OF THE OLYMPIA STUDY AND PROFESSOR OF ONCOLOGY AT THE INSTITUTE OF CANCER RESEARCH, LONDON, AND KING’S COLLEGE LONDON

OlympiA is a global collaborative trial coordinated by the Breast International Group (BIG) worldwide, in partnership with NRG Oncology, the US National Cancer Institute (NCI), Frontier Science & Technology Research Foundation (FSTRF), AstraZeneca and MSD. The trial is sponsored by NRG Oncology in the US and by AstraZeneca outside the US.

21 BIG member groups are participating in the study.

References:

1Globocan 2020


“THE IN-DEPTH ANALYSES OF METASTATIC BREAST CANCER SAMPLES IN AURORA SHOULD EMPOWER RESEARCH TOWARDS A COMPREHENSIVE UNDERSTANDING OF THE DISEASE AND THE DEVELOPMENT OF BETTER AND MORE APPROPRIATE TREATMENT STRATEGIES.”

DR PHILIPPE AFTIMOS, CO-PRINCIPAL INVESTIGATOR OF THE AURORA RESEARCH PROGRAMME AND CLINICAL TRIALS DEVELOPMENT LEADER AT THE INSTITUT JULES BORDET IN BRUSSELS, BELGIUM

AURORA:
BETTER UNDERSTANDING METASTATIC BREAST CANCER TO IMPROVE TREATMENTS

According to recent estimations, about 30% of patients with breast cancer will eventually develop metastases in other parts of the body. This advanced form of the disease is responsible for the great majority of breast cancer deaths. Metastatic breast cancer is more difficult to treat and currently remains essentially incurable, and whilst some individuals live much longer than others with the disease, we do not understand why.

The current treatment options are usually based on the clinical-pathological characteristics of the primary tumour (where the cancer began) rather than on the characteristics of the tumour once it has spread.

AURORA (public name: BIG Metastatic Breast Cancer GPS) was launched by BIG in 2014 as a large European research programme totally devoted to metastatic breast cancer and taking place in 12 countries.

Recruitment of the first 1,000 patients in the study concluded in August 2020 and the initial results for the first 381 patients included were published in Cancer Discovery in June 2021. The first findings are encouraging and will hopefully lead to major changes in the way patients with metastatic breast cancer will be treated in the future.

10 BIG member groups and 1 independent site are participating in the study.

By analysing the genetic profiles of tumours, AURORA is laying the groundwork for answering key questions in metastatic breast cancer, such as: How do tumour cells spread to other organs? Is this due to the genetic profile of the primary tumour or to genetic changes that occur over time? How do mechanisms of treatment resistance develop?

This is why AURORA consists in collecting and analysing primary and metastatic tumour material, as well as serial blood samples, collected from each patient, as well as long-term follow-up (up to 10 years) to monitor the disease evolution over time.

The findings of AURORA will enable us to develop new treatment strategies leading to prolonged disease control and better quality of life for people affected by metastatic breast cancer. The huge amount of collected information will also enable new hypotheses to be generated for future research.

With the generous support of the Breast Cancer Research Foundation (BCRF), an extension of the study starting in 2022 will focus on specific subtypes of metastatic breast cancer, namely triple-negative, invasive lobular and patients with late relapses (at least 10 years after their primary breast cancer diagnosis).

AURORA is made possible in part by generous grants from the BCRF as the main funder, Fondation Cancer (Luxembourg), Pfizer grant for non-drug research, Fondation contre le Cancer (Belgium), National Lottery (Belgium), NIF Foundation, Rhone Trust, Barrie and Dena Webb, Candriam, Fondation Futur 21, Sogerim, Think Pink Belgium (SMART Fund), Cognizant Foundation, Eurofins Foundation and many individual donors. AURORA has also been supported by the Fund Friends of BIG, managed by the King Baudouin Foundation.

References:
NEW BIG STUDIES LAUNCHED

DECRESCENDO: LESS INTENSIVE CHEMOTHERAPY FOR PATIENTS WITH HER2-POSITIVE BREAST CANCER

HER2-positive breast cancer is an aggressive form of the disease that accounts for about 15-20% of all breast cancer cases. Patients with early HER2-positive disease usually receive a combination of multiple chemotherapy drugs and surgery, combined with an anti-HER2 treatment, and continue with the latter for up to one year after surgery. While results are encouraging, with more than 90% of the patients alive and free of cancer recurrence after five years, the combination of chemotherapy and HER2 blockade can cause burdensome side effects—such as hair loss, nausea, vomiting, fatigue or even cardiac toxicity—most of which can be attributed to chemotherapy.

In 2021 BIG and the Institut Jules Bordet joined efforts to set up the DECRESCENDO trial. This large international study will assess whether it is possible to give a less intensive chemotherapy treatment, and reduce related side effects, without increasing the risk of cancer recurrence for patients with HER2-positive, hormone receptor-negative early breast cancer. As we are writing these lines (March 2022), the study has already recruited 4 patients.

DECRESCENDO is an academia-led study sponsored by the Institut Jules Bordet and conducted by its Clinical Trials Support Unit (IJB-CTSU, Brussels, Belgium), in collaboration with the Breast International Group (BIG). The study will enrol over 1,000 patients from about 164 hospitals in 12 countries worldwide.

12 BIG member groups are taking part in the study.

References:

EXPERT: COULD SOME PATIENTS AVOID RADIOTHERAPY AFTER SURGERY?

After Australia, New Zealand and Taiwan, the EXPERT study (public name: BIG Radio Tuning) was finally launched in Europe and Latin America in July 2021, with Spain being the first country to start recruiting patients, followed by Switzerland, Argentina and Chile. In total, this trial will run in 8 countries around the globe and enrol 1,170 patients.

In EXPERT, researchers use a genetic test (PAM 50-based Prosigna® Assay) to characterise the biological profile of tumours and evaluate their potential aggressiveness. The idea is that these tests, used in combination with the standard clinic-pathological observations, could help doctors identify those patients with low-risk early breast cancer who could safely avoid radiation therapy after breast cancer surgery.

The results of EXPERT could influence how 2 in 5 women with breast cancer are treated in the future. If the 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.

While writing this text (March 2022), 542 patients have already been randomised in the EXPERT trial.

This study is coordinated and sponsored by the Breast Cancer Trials – Australia & New Zealand (BCT-ANZ) in collaboration with the Breast International Group (BIG) Headquarters.

It is funded by Breast Cancer Trials – Australia & New Zealand (BCT-ANZ) (sponsor) and the National Health and Medical Research Council of Australia, National Lottery (Belgium), plus funds raised by the BIG Headquarters’ philanthropy team.

5 BIG member groups are participating in the study, in addition to BCT-ANZ.
BIG’s de-escalation studies, such as DECRESCENDO and EXPERT, contribute to breast cancer treatments being tailored more precisely to individual patient needs. These trials test the possibility to safely reduce the amount and/or the duration of some breast cancer treatments – or avoid them entirely – without increasing the risk of the cancer coming back or affecting a patient’s quality of life. The prospect of safely de-escalating breast cancer treatment is of great interest to patients, who can receive an optimal therapy with fewer side effects that is better tailored to their individual condition. Likewise, reducing the incidence of severe side effects also benefits healthcare systems, thanks to the optimised allocation of resources and reduced use of the facilities for unnecessary emergencies.

“EACH PATIENT DESERVES THE BEST POSSIBLE TREATMENT. BIG’S DE-ESCALATION RESEARCH AIMS TO OFFER MORE PERSONALISED CANCER CARE TO EVERY WOMAN AND MAN AFFECTED BY BREAST CANCER”

PROFESSOR GABRIELE ZOPPOLI, CO-PRINCIPAL INVESTIGATOR OF THE EXPERT STUDY, ASSISTANT MEDICAL DIRECTOR AT THE INTERNAL MEDICINE AND ONCOLOGY UNIT, ASSISTANT PROFESSOR AT THE OSPEDALE POLICLINICO SAN MARTINO AND UNIVERSITÀ DEGLI STUDI DI GENOVA, MEMBER OF THE BOARD OF DIRECTORS OF THE GRUPPO ONCOLOGICO ITALIANO DI RICERCA CLINICA (GOIRC) GENOVA, ITALY

ALPHABET: FINDING NEW STRATEGIES TO OVERCOME TREATMENT RESISTANCE

Treatment resistance is a common problem in patients with advanced HER2-positive breast cancer, and it can lead to the cancer coming back or continuing to grow. In some tumours for example, the PIK3CA gene, which contains the information needed to produce the PI3K protein, is abnormal (or mutated) and linked to cancer growth. Previous research suggests that mutations in the PIK3CA gene might lead to resistance to anti-HER2 therapy.

The ALPHABET trial was launched in July 2021 and aims to test a new treatment strategy to overcome this resistance by combining the anti-HER2 therapy with alpelisib, a drug that blocks the PI3K protein and is known as a “PI3K inhibitor”. This new treatment will be tested in patients with advanced HER2-positive breast cancer that is also positive for a PIK3CA mutation.

ALPHABET is an international study that will enrol about 300 patients in approximately 110 hospitals from 6 European countries. It is being run and sponsored by GEICAM (the Spanish Breast Cancer Group) in collaboration with IBCSG (the International Breast Cancer Study Group) and the Breast International Group (BIG).

ALPHABET is made possible by a research grant and provision of the study drug (alpelisib) by Novartis.

As we are writing these lines (March 2022), the study has already recruited 6 patients.

5 BIG member groups are participating in the study, in addition to GEICAM.
AMEERA-6: OFFERING PATIENTS BETTER TREATMENT OPTIONS

2021 marked the launch of a new and important academia-pharma partnership, the AMEERA-6 trial.

This adjuvant Phase III study, which will enrol 3,738 patients from 650 hospitals and cancer centres in about 29 countries, will evaluate the safety and efficacy of Sanofi’s investigational drug amcenestrant in patients with oestrogen receptor-positive (ER+) early breast cancer who have prematurely discontinued the standard aromatase inhibitor therapy due to treatment related side effects, and have high risk of disease recurrence.

Adjuvant therapy is given after surgery with or without radiotherapy to help prevent and delay the progression of the disease into a more advanced and incurable form. However, current adjuvant therapies, like aromatase inhibitors, can have side effects for patients, which may cause them to discontinue the medication prematurely. As a result, many of these patients experience disease recurrence. Amcenestrant may be a potential option for women in this setting.

Amcenestrant is an oral selective oestrogen receptor degrader (SERD). This is a type of drug that binds and degrades the oestrogen receptor (ER), thereby inhibiting the ER signalling pathway, which is responsible for the proliferation of breast cancer cells sensitive to oestrogens.

The purpose of this study is to compare the efficacy of amcenestrant versus tamoxifen and assess tolerance in patients with hormone receptor-positive (HR+) breast cancer who have prematurely ended their adjuvant aromatase inhibitor therapy due to side effects.

If the hypothesis of AMEERA-6 is confirmed, it would give doctors additional treatment options to help prevent patients with early breast cancer from developing advanced, incurable disease and this would represent a significant treatment advance.

The AMEERA-6 trial is a partnership coordinated by BIG Headquarters in collaboration with the European Organisation for Research and Treatment of Cancer (EORTC) and Alliance Foundation Trials (AFT). Sanofi is the pharmaceutical partner and sponsor of the study, providing funding and study drugs.

The AMEERA-6 study randomised its first patient on 17 March 2022.

18 BIG member groups are participating in this trial, which will involve 3,738 patients from 650 sites in about 29 countries.

“TOGETHER WITH OUR RESEARCH PARTNERS, BIG CONDUCTS LANDMARK, PRACTICE-CHANGING TRIALS THAT CAN HAVE A SIGNIFICANT IMPACT ON THE LIVES OF WOMEN WITH BREAST CANCER.”

PROFESSOR DAVID CAMERON, CHAIR OF THE BIG EXECUTIVE BOARD, PROFESSOR OF ONCOLOGY AND CLINICAL DIRECTOR AT THE CANCER RESEARCH UK EDINBURGH CENTRE, EDINBURGH, UK
BIG PICTURE OF BIG AGAINST BREAST CANCER

- ± 3 000 community members
- 10 grants from foundations
- ± 5 500 followers on Facebook and Instagram
- 21 influential ambassadors
- ± 221 000 people reached via Facebook and Instagram
- 22 Facebook Fundraisers by you, our community

94.2% of all funds BIG received in 2021, including from BIG AGAINST BREAST CANCER’s philanthropic activity, were spent directly on BIG’S research.

Thank you for keeping in touch with us this year!
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 help BIG’s member groups (made up of breast cancer experts across the globe), their affiliated hospitals, and research staff at BIG Headquarters to finance their efforts and patients’ participation in one or more BIG studies.
BIG ACADEMIC STUDIES NEEDING SUPPORT

THANKS TO BIG’S UNIQUE POSITION IN THE FIELD OF BREAST CANCER RESEARCH, ACADEMIC STUDIES WITHOUT COMMERCIAL INTEREST ARE DEVELOPED BY BIG RESEARCHERS AND CAN BE FINANCED IN-PART THROUGH OUR PHILANTHROPIC COMMUNITY.

Funding is still required for three studies, either to enrol the number of patients needed or to continue with follow-up, both essential to generate robust data and results and to answer important questions!

BIG METASTATIC BREAST CANCER GPS (SCIENTIFIC NAME: AURORA)

Around one in every eight women will develop breast cancer in their lifetime, and the figure for men is about one in every 800 (source: Globocan Report, Dec. 2020). A percentage of them will be affected by an advanced form of the disease – metastatic breast cancer. This form of the disease is treatable but remains incurable. Metastatic breast cancer still represents the leading cause of death among people with this disease.

The BIG Metastatic Breast Cancer GPS is an innovative, international research programme that aims to understand why breast cancer spreads by mapping the routes that cancer cells take to invade other organs as well as understand why some patients respond poorly to standard treatment while others respond very well.

Launched in 2014, the BIG Metastatic Breast Cancer GPS involves more than 60 hospitals in 11 European countries. In June 2021, analyses of data from the first 381 patients revealed important molecular and clinical features that shed more light on the evolution of metastasis in breast cancer. So far, the study has included over 1,158 patients, and an ambitious plan to recruit additional patients with specific breast cancer types that are particularly difficult to treat, such as triple negative disease, is now underway.

AURORA is made possible in part by generous grants from the Breast Cancer Research Foundation (BCRF) as the main funder, Fondation Cancer (Luxembourg), Pfizer grant for non-drug research, Fondation contre le Cancer (Belgium), National Lottery (Belgium), NIF Foundation, Rhone Trust, Barrie and Dena Webb, Candriam, Fondation Futur 21, Sogerim, Think Pink Belgium (SMART Fund), Cognizant Foundation, Eurofins Foundation and many individual donors. AURORA has also been supported by the Fund Friends of BIG, managed by the King Baudouin Foundation.

“UNDERSTANDING WHY SOME BREAST CANCERS RECUR AND SPREAD WHILE OTHERS ARE CURED IS PARAMOUNT TO DEVELOPING TREATMENT STRATEGIES THAT WILL BOOST RECOVERY RATES. AURORA AIMS TO ADDRESS THIS GOAL THROUGH AN ADVANCED MOLECULAR ANALYSIS OF A SAMPLE TAKEN FROM THE BREAST TUMOUR AND A SAMPLE TAKEN FROM ANOTHER ORGAN. WE HOPE THAT THIS INTERNATIONAL STUDY WILL BE A MAJOR CONTRIBUTION IN THE FIGHT AGAINST THIS DISEASE.”

DR PHILIPPE AFTIMOS, CO-PRINCIPAL INVESTIGATOR OF THE AURORA PROGRAMME AND CLINICAL TRIALS DEVELOPMENT LEADER AT THE JULES BORDET INSTITUTE IN BRUSSELS, BELGIUM.
BIG TIME FOR BABY (SCIENTIFIC NAME: POSITIVE)

About 15% of patients with breast cancer are diagnosed during their reproductive years.

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. 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.

518 women are participating in the study, which includes questionnaires designed to help us learn about their concerns and psychological well-being. As of September 2021, 307 healthy babies were born within the context of the BIG Time for Baby study.

BIG RADIO TUNING (SCIENTIFIC NAME: EXPERT)

Which women could be spared radiotherapy following breast conserving surgery? Generally, after surgically removing the tumour, radiation therapy is administered to patients to limit the risk of relapse. However, not all patients benefit from this therapy, and some may be “overtreated” as a result.

Like adjusting your radio to find the right frequency, the BIG Radio Tuning study aims to personalise radiation therapy to each individual patient, even going as far as to avoid it altogether. To do this, a test of 50 genes is used to identify “low risk” patients, who then receive either a combination of standard radiotherapy and endocrine treatment, or endocrine treatment alone. The hope is to show that many women with low-risk breast cancer do well without the added radiotherapy.

The societal impact of this academic study could be substantial, influencing how 2 in 5 women with breast cancer are treated in the future.

The BIG Radio Tuning study follows other efforts by BIG to optimise treatment to individual tumour characteristics and to avoid overtreatment, such as the MINDACT study, which demonstrated that as many as 46% of patients who definitely would have received chemotherapy in the past, could safely avoid it.

By end of December 2021, 500 out of a total of 1,170 patients had already been included.
OUR AMBASSADORS

COMMITTEE OF AMBASSADORS

Each with a stake in the fight against breast cancer, the individuals making up the Committee of Ambassadors provide precious support to the work of the BIG against breast cancer philanthropy team. Through their networks of contacts, participation in events, search for new donors and partners, creative ideas and generosity, they contribute to progress in BIG’s research.

STRATEGIC COMMITTEE

Chaired by Princess Nathalie de Merode, the members of the Strategic Committee are Patsy Israël, Mathy Kandiyoti, Nathalie Misson, and Jessica Parser.

“As time goes by, as an ambassador, you become increasingly aware of the exceptional impact of BIG’s work on the world around us. The progress made in recent years has been extraordinary, bringing so much hope in the face of what remains one of the most devastating cancers. I am very proud and happy to be able to make a modest contribution to BIG.”

Nathalie de Merode

“RESEARCH CANNOT WAIT. BIG’S RESEARCH REMAINS VITAL BECAUSE OF THE HOPE IT BRINGS AND THE LIVES IT SAVES.”

Patsy Israël

“I am so honoured to be part of the BIG Ambassadors’ Committee. We need to support research and facilitate collaboration between medical experts around the world. This is the only way to eradicate disease and give life a chance”

Patsy Israel

“It is with conviction that I adhere to this organisation. It’s hard not to be concerned by this evil that affects so many women. This kind of initiative really gives hope to recover, and the assurance of not feeling lonely in front of adversity. It is so important to feel supported and understood. In fact, this is a real part of the therapy. I consider BIG as truly essential.”

Mathy Kandiyoti
"A couple of years ago, the sky was falling down on my head: breast cancer. I was going to leave my loved ones forever. Thanks to Martine Piccart, her team, and the administered treatments, today I can say that ‘I survived’. Armed with this experience, I’m convinced that bringing experts together to work on international trials – just the way BIG does – is the key to finding a cure for breast cancer."

Nathalie Misson

“The year 2021 was a challenging time for everyone as the entire world focused on Covid-19 and its devastating consequences. But it’s essential not to forget the continuing importance of BIG’s research programmes and studies and the enormous positive impact they have had – and continue to have – in saving lives. I am proud to be part of the group of Ambassadors whose role is to keep BIG against breast cancer in the public’s mind.”

Jessica Parser

Extended Committee of Ambassadors in 2021

RAISING AWARENESS OF METASTATIC BREAST CANCER

Every year, to mark international Breast Cancer Awareness Month, the Breast International Group carries out a campaign to sensitize the general public on a specific topic concerning the disease.

Despite the enormous progress already made in early-stage breast cancer, metastatic breast cancer is still an incurable disease that affects many patients. And while some patients live longer than others, we still do not understand why. This is why we decided to centre the 2021 Pink October campaign around metastatic breast cancer.

Inspired by Denis Korrman’s Legend of the Hummingbird, the Breast International Group, supported by BIG against breast cancer, chose this formidable little creature to represent its work dedicated to curing breast cancer.

One day, in a forest somewhere, an enormous fire was raging. All the animals were terrified, running around in circles, screaming, crying and helplessly watching the impending disaster.

But amid all this, over and over, the tiniest little hummingbird was flying from a small pond collecting drops of water in its beak and dropping them on the fire.

The other animals watched the little creature incredulously and asked it, “But why are you doing this? Your little drops of water won’t stop the fire.”

To which the hummingbird replied, “Could be, but I’m going to do my bit. This act of heroism and selflessness inspired the other animals, who in their turn started picking up droplets of water and putting them on the fire.

Eventually, with the dedication, perseverance and teamwork of the animals, the fire was extinguished.

Much like the animals of the forest, BIG’s researchers around the world, and their patients, work tirelessly together each day, each contributing their piece to advance research more rapidly. These efforts contribute to improving and saving the lives of women and men affected by the disease.

On Wednesday 29 September, Dr Martine Piccart, Joëlle Thils (a 52-year old Belgian woman living with metastatic breast cancer), and artist Roseline D’Oreye spoke to the press about the BIG campaign.

Joëlle Thils graciously picked up the role of Ambassador for not only this campaign but for BIG against breast cancer as well. Throughout the month of October, she gave a face to the millions of people living with metastatic breast cancer by sharing her poignant story of living with this disease. This was done through an interview published in the press release announcing the campaign and touching video clips that were shared on BIG’s social media. Joëlle, who’s a sportswoman and ultrarunner, compared her cancer to an ultramarathon that requires endurance, strength and never giving up. She explained her everyday battle ranging from regular check-ups, the scars and traumas of the various treatments and operations she has had, to the worry that she may not live to see her grandchildren.

Despite the heavy burden for her and her family, Joëlle shared a message of strength and commitment to enjoying life with her family and friends.

Roseline d’Oreye joined forces with BIG to create a unique hummingbird design for a silk ribbon, pocket square and scarf to support BIG’s research.

Thanks to this digital and press campaign we were able to raise awareness about metastatic breast cancer and the urgent need for research.
PINK OCTOBER & BIG-EORTC WEBINARS: TWO INTERACTIVE EVENTS

During Pink October or the International Breast Cancer Awareness Month, BIG united forces with the European Organisation for Research and Treatment of Cancer (EORTC) to raise further awareness of breast cancer and the importance of international research. The successful collaboration resulted in two interesting and educational webinars, one addressed to the general public and the other one to all breast cancer experts.

The first webinar “I Have Metastatic Breast Cancer: what is my future?” took place on October 13. This day also marks Metastatic Breast Cancer Awareness Day, so what better time than to draw attention to this advanced form of the disease, for which there still is no cure.

Speakers included breast cancer experts from the BIG and EORTC networks – Dr Fatima Cardoso (Portugal), Dr Philippe Aftimos (Belgium) and Dr Frederieke van Duijnhoven (The Netherlands) – who were joined by Eva Schumacher-Wulf (Germany). Eva is a breast cancer advocate and the editor-in-chief of the breast cancer magazine Mamma Mia.

110 participants joined us for a one-hour webinar filled with interesting questions and valuable insights.

The webinar started with Dr Cardoso giving facts and figures about advanced breast cancer, highlighting the current challenges and the need to offer better treatments to the patients affected by the disease. It was followed by the testimonial of Eva, who explained what it actually means for her to live with metastatic breast cancer. Then Drs Aftimos and van Duijnhoven gave a summary of the research that is being conducted by EORTC and BIG.

You could not attend? Watch the recording here: www.youtube.com/watch?v=hksOEg0BGME

On October 26, during the last days of Pink October, EORTC and BIG organised a second webinar entitled “Early Breast Cancer: new strategies to optimise adjuvant endocrine treatment” and addressed to all healthcare professionals interested in breast cancer research and treatment.

Dr Michail Ignatiadis (Belgium) began the webinar with a brief introduction, followed by an interesting presentation on new RNA-based approaches in HR+/HER2-negative breast cancer by Dr Aleix Prat (Spain). After that, Dr Etienne Brain (France) took over with his presentation “Extended adjuvant endocrine treatment: how long and in whom?”. The webinar ended with an interactive Q&A session between our key speakers and the 55 attendees.

Rewatch the expert webinar here: www.youtube.com/watch?v=kWX229eO5RE
OUR PHILANTHROPY EVENTS

2021 – a year of continued renewal

Although the impact of the Covid-19 pandemic still weighed heavily on all our lives throughout 2021, the BIG against breast cancer team took the exceptional circumstances as an opportunity for change and growth. Time was taken to create new events, re-invent existing ones, and welcome two new team members.

BIG against breast cancer is extremely grateful to its community for their continued support and loyalty during this period of unprecedented change. Their involvement and dedication to the cause was deeply felt by their enthusiasm for the events organised throughout the year:

ENRIQUE GRANADOS, L’ARTISTE RETROUVÉ*

Saturday 12 June was an important day for BIG against breast cancer, marking the first in-person philanthropic event organised in over a year. On this day, in collaboration with the Cultural Centre of Uccle, we organised the “Enrique Granados, l’Artiste retrouvé” musical show, which featured the soprano Julie Gebhart, daughter of Professor Martine Piccart, Valeria Becerra and Pablo Matías Becerra.

The influx of enthusiastic people showed that even after a difficult period, solidarity and motivation are still highly valued by the BIG against breast cancer community. In total, €1,380 were raised to support BIG’s academic studies.

*A production of the Queen Elisabeth Music Chapel with Valeria Becerra, Pablo Matías Becerra and Julie Gebhart.

BIG TOUR RALLY

On Sunday 22 August, over 40 cars and their 100 passengers attended the first edition of the BIG Tour Rally. With roadbooks in hand to guide their way, attendees got into their cars and hit the road to take on the BIG Tour Rally. Along the way the participants encountered, in the middle of the idyllic region of Waterloo, various mind-bending questions and fun challenges to complete. The only way for our participants to overcome these obstacles was to work together and, we have to say, everyone put their best foot…. or tire, forward!

A first edition filled with positive energy, warmth, and enthusiasm was able to raise €9,285.

“When we least expect it, life sets us a challenge to test our courage and willingness to change; at such a moment, there is no point in pretending that nothing has happened or in saying that we are not yet ready. The challenge will not wait. Life does not look back.”

PAULO COELHO, AUTHOR
20KM BRUSSELS

On 12 September, a **BIG against breast cancer** team of close to 100 enthusiasts participated in Brussels’ 20 km run, a popular annual race through the city of Brussels.

Employees from BIG Headquarters also participated – as runners, volunteers helping with the logistics of the event, or supporters cheering along the route for colleagues and friends. Some created their own fundraising page on the [MoveforBIG](#) platform. Thanks to the participants, supporters and generous sponsors, we were able to raise over €9,000 for the BIG Metastatic Breast Cancer GPS programme.

PINK IS THE NEW BLACK EVENING

On 28 October, more than 250 people dressed in their very finest, with a touch of pink, joined the dinner and dance party to benefit **BIG against breast cancer**. Thanks to the dedication of the organising committee, the support of our partners and the generosity of the participants, we raised €91,200, which is an amount equal to the participation of 31 patients for one year in the AURORA research programme, also known as the “BIG Metastatic Breast Cancer GPS”.

**BIG against breast cancer** is very thankful for its corporate partners, which contributed to the success of this special event.
ART IS BIG

During the whole month of December, the gallery Art’is Big, located in Waterloo, Belgium, chose to support breast cancer research by donating a percentage of the sales of their art pieces, which amounted to €2,225.

In 2020, in the midst of the worldwide Covid-19 pandemic, Marianne Goffard decided to open an art gallery for one month, with the idea of offering artists a place to exhibit their work in a pop-up.

One year later, Art’is Big had grown to be more than a temporary space and has become a place where artists, writers and charities meet.

Thank you to the artists who chose to support BIG: Valérie Alter, Senses of nature by Ben & Kof, Marianne Goffard, Graine d’Elles, Philippine, Henry de Frahan, Iain Mackenzie, Les Toup’Art.

---

EXPOSITION “VOYAGE”

Décembre 2021

Du mardi au samedi - Dimanche 12 & 19 décembre
(En dehors des heures d’ouvertures Marianne Goffard 0471 92 26 00)

What Galerie

Chaussée de Bruxelles 233 à 1410 Waterloo
Suivez-nous sur Instagram Art.is.Big

Auteure Fatoumata Faty Sidibé
Séances de dédicaces le jeudi 2 de 15h à 17h.

Les Artistes soutiennent l’Association BIG - Breast International Group
Vos dons sur le compte BE............................
While Covid-19 impacted us in a way that the total amount raised from events – €122,816 – was modest in 2021, all of these moments were important: they brought many of BIG’s supporters together again and gave us the opportunity to remind the public of the importance of breast cancer research.

In addition to the funds raised in this way, we received contributions through donations (€2,816,568) and multiple personal fundraisers (€60,548).

You too can contribute to saving lives!

Why support BIG?

By doing so, you help the millions of patients around the world and thousands of researchers who – thanks to your support and donations – work tirelessly to develop new treatments and therapies that improve the quality of life of women and men with breast cancer.

Your donations represent hope – your donations represent LIFE!

Please let us know if you wish to support all research conducted under the BIG umbrella, or if you would prefer to focus on one particular study.

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.

How you can make a difference:

> **Make a one-time donation**

Can you make a difference as an individual? Research budgets seem huge. And people often wonder if their support makes a real difference. Of course it does! If everyone gives just a little bit, as in the Legend of the Hummingbird, tremendous progress can be achieved!

*Together, we will find cures for breast cancer*

> **Make a recurring donation**

Join our community of monthly donors giving hope to the millions of women and men whose lives are impacted by breast cancer.

No gift is too small!

From choosing to donate the equivalent of just one coffee a month, or perhaps the equivalent of one take-out dinner, these precious monthly gifts help us advance BIG’s academic research.

Remember, all donations made from a Belgian account equal to or above €40 are subject to a 45% tax deduction.

If you donate from another country and want to know if this donation can be tax deductible, please contact us at philanthropy@bigagainstbc.org!

*Alone we go faster, together we go further!*

> **Legacy giving**

Make a lasting gift.

By planning a future legacy donation to BIG you help ensure that our research will continue and bring us ever closer to accomplishing our mission of finding cures for breast cancer.

In choosing to make a legacy donation, you are giving a gift of hope that will impact the lives of millions of women and men around the globe suffering from breast cancer, both now and long into the future.

MoveForBIG

Every cent counts, every action counts. By creating your own fundraiser, you are not only creating unforgettable memories, but you are also giving hope to the millions of women and men impacted by breast cancer.
Launching your own fundraiser is easy, and anything goes. No idea is too crazy, or impossible.

MoveforBIG.org is a user-friendly online crowdfunding platform that allows you to launch your own campaigns to support BIG’s research.

Taking on a new personal sports challenge? Celebrating a birthday or an anniversary? You can create your own MoveforBIG.org page that you can easily share with your friends and family and encourage them to support this important cause.

A personal fundraising page gives extra hope and support to many women and men who are confronted with breast cancer.

Move For BIG – The 2021 Andalusian Challenge

Solidarity and motivation are highly valued by the BIG against breast cancer community.

An example of this motivation is taking on a 230 km desert footrace to raise precious funds for the AURORA study. In order to increase awareness about metastatic breast cancer as well as raise funds, BIG’s communications manager Valerie Van der Veeken initiated the “Al Andalus Ultimate Trail” fundraising challenge on the MoveforBIG platform and called it “AAUT TRAIL IN ANDALUSIA - Research is needed to prevent breast cancer from becoming a rucksack that you carry for the rest of your life”. Together with her friend Joëlle Thils, who had been diagnosed with metastatic breast cancer, they both participated in this tough, semi self-sufficient five-day footrace taking place in Andalusia and covering 230 km of difficult rocky terrain with lots of altimeters, temperatures around 40 °C during the day and dropping to 4 °C at night, and no comfort (sleeping in small tents, on thin mattresses). In total, Valerie and Joëlle raised about €2,500 for the AURORA study.

A ‘HOT’ booklet to support breast cancer research!

52 year old Hilde Dosogne, mother of four, bio-engineer and Regulatory Affairs Manager at the Ghent-based chemical company Christeyns, is an ultrarunner and TraKKs ambassador in her spare time. In October 2021, she participated at the Marathon des Sables, an iconic annual 250 km multi-day running race through the Sahara (Southern Morocco). The race was tougher than ever, with temperatures up to 57 °C! A hellish race that Hilde finished with flying colours and of which almost half of the participants did not make it to the finish line! Woman power!

It was such a special adventure that Hilde wrote a little book about it: "Highway to Hell – How I completed the 35th Marathon des Sables". Hilde has dedicated it to Joëlle and the many women, men and families affected by breast cancer. The proceeds of the booklet go directly to BIG’s breast cancer research, more specifically to support the AURORA study.

A heartfelt “BIG thank you” to Hilde!

We invite you to visit the MoveforBIG.org platform and see how other people are creatively raising funds for academic research.
BIG ACKNOWLEDGEMENTS

A SPECIAL THANK YOU TO OUR SUPPORTERS
WHO “THOUGHT BIG” IN 2021

Mr and Mrs Bernard Amory
Mrs Marianne Anciaux
Countess Amélie d’Archot Schoonhoven
Mrs Florine Asch
Countess Catherine d’Aspremont Lynden
Mrs Claire Begrimbabwe
Mrs Véronique Mouligneau - Barbier
Mr John-Alexander Bogaerts
Mr Eric Boschman
Mr and Mrs Patrice Bourg
Mr and Mrs Yves Carakéhian
Mr and Mrs Vladimir Cardon de Lichtbuer
Mrs Sylvia Chiche
Prince and Princess de Chimay et de Caraman
Mr and Mrs Eric Cleton
Mrs and Mr Alain Crefcoeur
Mrs Patricia Decraemer
Mr and Mrs Marc-Henri Decrop
Mr Bernard Depoorter
Mrs Helene Deslauriers
Mrs Nathalie Didden
Mr Yohann Dutilleul
Mrs and Mr Graham Edwards
Mr and Mrs David Fabri
Mr and Mrs Gilles de Fauconval
Mrs Jessica Parser and Mr François Gérard
Baron et Baroness Gillion Crowet
Mrs Vanessa Greindl
Mrs and Mr Laurent Hayem
Mrs Laure Hilbert
Mrs Anja Hoogstrate
Mrs Ariane Hourdeau
Baroneess Corinne Hubinont
Mr and Mrs Nissim Israël
Mrs Laurence Israelson
Mrs Pauline Janssen
Baroneess Jonet
Mr Michael Jones
Mr and Mrs Philippe Jungers
Mr and Mrs Erol Kandiyoti
Mrs Vanessa Kandiyoti
Mrs Diane de Lasteyries du Saillant
Mr Arnaud Lefebvre
Mrs and Mr Charles-Henri Léhideux
Mr Michael Lewis-Anderson
Countess de Limburg Strium
Mrs Theres Lindblad
Prince and Princess Michel de Ligne
Donna Matilde de ‘Medici di Toscana di Ottajano
Prince and Princess Amaury de Merode
Prince Aurèle de Merode
Prince Félix de Merode
Mr and Mrs François Amico
Mr and Mrs Thierry Misson
Count and Countess Philippe de Montmort
Mrs Jan Hein van de Mortel
Mrs Martine Nolet de Brauwere
Mr and Mrs Cedric Olbrechts
Mrs Roseline d’Oreye
H.E. Ambassador and Mrs Juan Prat Y Coll
Mrs Valentine Ralet
Mrs Delphine Remy
Mr Patrick Renson
Mr the European Commissioner and Mrs Didier Reynders
Mr Loïc Rigolet
Mr Damien Roman
Mr and Mrs Xavier Roland
Count and Countess Gerald de Roquemaurel
Mr and Mrs Frederic Van der Schueren
Mrs Severine Sommers
Mr and Mrs Thomas Spiller
Viscountess Sibylle de Spoelberch
Mr Daniel Thierry
Mrs Joëlle Thils
Mr Jacques Vanderulst
Mrs Michèle van Dessel
Mrs Natacha Vaxelaire
Baron and Baroness Raymond Vaxelaire
Baron and Baroness Marc de Villenfagne de Vogelsanck
Mr Gerald Watelet
Prince and Princess Cyril Wolkonsky
Mrs Gaëlle Woodbury
COMPANIES THAT CARE

Despite the continued difficulties that Covid-19 had on the global economic climate, in 2021 we were thankful to be able to continue to rely on the loyalty of our existing partners. We were also very grateful for the commitment and generosity of new partners for whom breast cancer research is essential.

Online sales during the pandemic saw a boom, and we benefited from a number of initiatives, such as the sale of bespoke earrings by Atelier Nomad.

TO ALL OUR PARTNERS, WE WOULD LIKE TO SAY A HEARTFELT “THANK YOU!”

You have helped us in our efforts by involving your staff in our activities, by inviting them to raise funds, or by asking your clients and partners to support breast cancer research. All of these efforts in turn help support the work of our research groups, enabling patients to participate in our studies and results to be achieved more quickly.

BAOBAB COLLECTION

The “Woman” and “Gentleman” candles were created by Corinne Bensahel, artistic director at Baobab Collection. Baobab Collection wishes to show its love for women and its commitment to a cause that concerns us all in one way or another: breast cancer research. The “Woman” and “Gentleman” candles will illuminate everyone’s conscience with their little flame, because without research we will not be able to overcome this disease that takes away our loved ones.
CANDRIAM

Candriam is a European multi-specialist asset manager, pioneer, and leader in sustainable investing with a broad and innovative range covering all asset classes. Sustainability and social impact are core to Candriam’s DNA. In late-2018, Candriam launched a strategy designed to contribute to the fight against cancer that invests in businesses around the world developing cancer treatment products and services (including diagnoses, tumour profiling, technology and treatments). In keeping with Candriam’s commitment to social impact and in order to support the fight against cancer, up to 10% of the yearly net management fees of the fund are earmarked for institutes working in cancer research and prevention and support for patients and their families. It is in this respect that the Candriam Institute for Sustainable Investment – Candriam’s philanthropic body – supports the high-quality research projects that BIG facilitates.

SOGERIM

A few years ago, Laurent Delgouffre, Managing Director of Sogerim, was confronted with the breast cancer of his then 35-year-old wife. He remembers his reaction on hearing the news: “The world was slipping out from under us, and we felt overwhelmed by the thought of a year’s worth of treatments ahead of us.” On the anniversary of the end of treatment, he wanted to partner with BIG to celebrate her recovery and to support research. “Our support for BIG is a mark of gratitude to the entire medical profession and all those fighting on behalf of patients.” Laurent Delgouffre.
How Your Company Can Make a Difference

There are many areas of research that hold great promise for patients but have no particular interest for commercial partners. It is possible that many patients could be cured or otherwise benefit from a “lighter” exposure to traditional cancer treatments, for example by reducing the duration of drugs or radiation.

These studies hold tremendous potential for patients and promise long-term gains for society, in all regions of the world. Our goal is to improve patient survival and quality of life, by finding the right treatment for every patient.

The money raised by BIG against breast cancer is directly invested into innovative academic research that makes a BIG difference for patients and their loved ones.

Every corporate partner helps drive this research through their support, having a direct impact on the lives of patients today and in the future.

Join our community of engaged corporate partners. Be part of today’s research, for tomorrow’s cures.

We are BIG against breast cancer
By becoming a partner with BIG against breast cancer not only is your organisation demonstrating that you are committed to bettering the lives of millions of people around the world, but you are also directly part of the solution.

There are many ways your company can support BIG and its research.

But we know that each organisation is unique, and therefore, deserves an adapted programme that reflects your values and meets your objectives!

Here are a few ways your company can get involved:

> Financial Corporate Sponsorship
Your company can choose to become a yearly sponsor or donate money to support a specific event or campaign that is aligned with your corporate identity.

> In-Kind Corporate Sponsorship
Support comes in many forms. An extremely helpful way your organisation could support us is by giving an in-kind donation related to an event, campaign, or BIG’s work in general. Examples of in-kind donations include graphic design services, goodies, raffle prizes, photography or translation services, and more.

> Media Corporate Sponsorship
Your company could lend a helping hand in giving more visibility to BIG against breast cancer by covering the cost of promoting philanthropic events and campaigns. This could include radio promotions, TV ads, or printed advertisements.

> Cause Marketing
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 impacts many women and men in our communities.

> Gift Matching Programme
Are you looking for a way to engage your employees in a good cause? By setting-up a gift-matching programme you encourage your employees to be involved in a cause close to their heart. A gift matching programme works by encouraging your employees to make a donation while the company pledges to match all donations.

> Corporate Fundraising Challenge
Directly involve your employees in a company-wide fundraising challenge via the MoveforBIG.org platform. Not only is this a great way to foster team spirit, but it is also a fun way to raise funds for BIG and help push forward research against breast cancer.

In exchange for your support, BIG against breast cancer ensures that your brand is given visibility alongside an internationally recognised not-for-profit dedicated to breast cancer research (via social media, event communication tools, interviews shared among our community via newsletter, and much more!). We will also ensure that your CSR objectives are met.
In 2021 the precious support of foundations made the difference that allowed us to continue to ensure progress in the BIG Metastatic Breast Cancer GPS (scientific name: AURORA) programme, BIG Time for Baby study (scientific name: POSITIVE), and BIG Radio Tuning trial (scientific name: EXPERT).

**BCRF**

*Granted €2,323,031 in 2021*

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](http://www.bcrf.org)

**FONDATION CANCER, LUXEMBOURG**

*Granted €102,600 in 2021*

The foundation's objective is to raise awareness about cancer prevention and the fight against cancer, as well as to encourage all sorts 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, contributing to the BIG Metastatic Breast Cancer GPS programme (scientific name: AURORA).

“Research is vital in oncology, it provides hope. I am regularly asked by patients in my consultations about whether there are any new advances and what drugs are coming onto the market. It is only by promoting research that we can move forward. This is one of the Foundation’s main aims. Supporting BIG against breast cancer (BIG) goes without saying.” Dr Carole Bauer, President of Fondation Cancer

[www.cancer.lu](http://www.cancer.lu)

**FONDS BAILLET LATOUR**

*Granted €100,000 in 2021*

For the fifth 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 five pillars: health, culture, education, environment, and sports. All the projects and initiatives supported in each field have a Belgian dimension.

[www.fondsbailettlatour.com](http://www.fondsbailettlatour.com)

**FONDATION NIF**

*Granted €18,900 in 2021*

Fondation NIF 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 Fondation NIF currently contributes to the BIG Metastatic Breast Cancer GPS programme (scientific name: AURORA).

[www.fondation-nif.com](http://www.fondation-nif.com)
Diversity is a key element in the successful core strategy of the Belgian National Lottery. We are aiming to reach a large and diverse audience through different channels in retail and online, offering a wide range of appealing draw and scratch games. We want our players to feel connected to the Good Causes we can support thanks to them. Because our players are very diverse, we choose to support a very large variety of causes in our society, going from culture over civil society projects to extensive scientific research.

The Belgian National Lottery provided funding for the BIG Radio Tuning study (scientific name: EXPERT) from 2018 to 2021 and renewed its commitment to BIG in 2021 to support the BIG Metastatic Breast Cancer GPS programme (scientific name: AURORA).

“BIG against breast cancer is one of those Good Causes which is dear to the hearts of many Belgians, including myself. The fact is that we all know someone in our surroundings that has been directly or indirectly affected by breast cancer or any other kind of cancer. It goes without saying that we will not hesitate to contribute to improving patient survival, quality of life and finding the most appropriate treatment for every patient. Thanks to all our players the Belgian National Lottery can offer much more than just games. Together we can make a difference.” – Jannie Haek, CEO of Belgian National Lottery

#muchmorethanjustgames #nationallottery #proudpartner

www.loterie-nationale.be
www.nationale-loterij.be
"Knowledge leads to empowerment, empowerment brings change and, with change, comes hope."

2021 was a year full of changes. First and foremost, through BIG’s global breast cancer research in 2021, we increased our knowledge about breast cancer (e.g., AURORA) as well as both old (e.g., MA.32) and new treatments (e.g., OlympiA). And we are confident to continue to deliver practice-changing results in the future with several new studies launched.

For the BIG network, these changes were not only organisational – with the newly elected members of BIG’s Executive Board (see further) –, but also physical – with the move of BIG Headquarters’ offices from the centre of Brussels (Belgium) to the surroundings of the capital. Our offices are now located in Kraainem, one of Brussels’ municipalities.
THE EUBREAST NETWORK (GERMANY/ITALY) JOINS BIG

At the virtual General Assembly of June 2021, the applications of two new academic cancer research groups were approved to join BIG, further enlarging the BIG network’s international reach.

We are pleased to welcome the European Breast Cancer Research Association of Surgical Trialists (EUBREAST) Network, which consists of the German association EUBREAST e.V. and its Italian counterpart EUBREAST ETS.

The European Breast Cancer Research Association of Surgical Trialists (EUBREAST) Network was founded by a group of European breast surgeons in 2018. The two not-for-profit EUBREAST associations in the network are chaired by Professor Dr Thorsten Kuehn (Germany) and Dr Oreste Gentilini (Italy).

EUBREAST promotes national and international research projects with the goal of developing less-invasive techniques for breast cancer surgery in order to improve affected patients’ quality of life. Several trials are currently underway, with more than 20 countries represented.

For further information: www.eubreast.com

“BIG AND EUBREAST SHARE THE SAME OBJECTIVE AND MISSION. WE ARE HAPPY AND HONOURED TO CONTRIBUTE TO THE BIG FAMILY WITH OUR FOCUS ON BREAST SURGICAL RESEARCH, AS THIS PARTNERSHIP WILL INCREASE AND IMPROVE INTERNATIONAL SCIENTIFIC COOPERATION, WHICH IS THE ULTIMATE GOAL OF BOTH ORGANISATIONS.”

PROFESSOR DR THORSTEN KUEHN AND DR ORESTE GENTILINI.

BIG represents over 50 like-minded research groups from around the world and reaches across more than 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 to design and conduct pioneering breast cancer research.

Each BIG group plays a crucial role. The combined expertise, collaborative spirit, dedication, and hard work are essential to improving the lives of patients confronted with breast cancer.
BIG’S HEADQUARTERS

The BIG Headquarters are located in Brussels, Belgium. The team is made up of about 40 dynamic, passionate and committed people who work on behalf of BIG’s Executive Board and BIG’s General Assembly. The latter consists of the voting representatives appointed by each BIG member group, and – together with the Executive Board – they move BIG’s research agenda forward.

The staff at BIG HQ represents a talented group of physicians, scientists, project managers, and jurists, as well as financial, HR, IT, administration, communications and fundraising specialists. They work in teams to develop and conduct clinical trials together with BIG’s member groups, industry and other partners, and raise funds for ambitious academic initiatives. They also manage all aspects of BIG as an international not-for-profit organisation under Belgian law.

Together, we are on track to find better treatments and ultimately a cure for breast cancer.
BIG’S EXECUTIVE BOARD RENEWED

On 11 June 2021, the newly elected Executive Board (EB) was presented to BIG’s General Assembly.

BIG is constantly striving to be at the fore of breast cancer research, adapting to new situations, further professionalising and enlarging its network of breast cancer experts. Let us not forget that we started quite small more than 20 years ago … and now we are (quite) BIG: the largest global network of academic research groups dedicated to finding cures for breast cancer.

The two co-founders of BIG, Martine Piccart and the late Aron Goldhirsch, made this possible. Global collaboration is key if we want to eradicate breast cancer.

BIG’s Executive Board represents the leadership of the organisation, reporting to the General Assembly of all member groups. It is primarily responsible for proposing, shaping, and reviewing BIG’s strategies and related objectives, and for ensuring the long-term viability of the association.

Today it consists of 14 individuals chosen from amongst its member groups, embodying a range of cancer expertise (medical oncology, radiation oncology, medical statistics / clinical trials methodology, and translational research) and covering different regions of the world.

As per BIG’s statutes, the General Assembly elected 4 individuals (Judith Bliss, Boon Chua, Sherene Loi, Shigehira Saji) from among the candidates, and the BIG EB appointed the remaining 4 (Barbro Linderholm, Seamus O’Reilly, Evangelia Razis, Ines Vaz-Luis) to join the EB members whose terms were continuing (Philippe Bedard, Etienne Brain, David Cameron, Eva Carrasco, Angelo di Leo, Ander Urruticoechea). Tragically, we were informed of Angelo di Leo’s death the day after the General Assembly; his term would have continued to 2023.

We wish to extend our sincere gratitude to the EB members whose terms ended in 2021 and who had devoted considerable time to BIG over the years, contributing to the organisation’s growth and progress. A BIG Thank You to Sibylle Loibl, Marco Colleoni, Shinji Ohno, and Aleix Prat.
BIG’s Leadership Authority

BIG as a network designs and conducts its own research. The role of the BIG Executive Board is critical to ensure that all clinical trials and programmes carried out under the BIG umbrella are run according to BIG’s mission and principles of research conduct and that they fall within BIG’s strategy.

These principles aim to eliminate bias from the research process, protect academic freedom, and maintain integrity vis-à-vis patients, both when working with the pharmaceutical partners or when working alone. Particularly important is that BIG commits to prioritising research that otherwise would not be possible and cannot be done by one research group alone. Within this framework, BIG conducts research to advance treatments that make a real difference to women and men with breast cancer.

Professor David Cameron, BIG Chair: “BIG recognises that the ‘global cancer problem’ has particularities in each region and country. I’m delighted by the composition of the new Executive Board – I’m confident that this talented, multi-national and multidisciplinary group of people will further develop the important advances already set into motion in recent years. In the years to come, the BIG network aims to continue to play an important role in international breast cancer research, allowing for the most efficient conduct of clinical trials and always keeping patients’ interests at the heart of its activities. Further collaboration with research groups in countries where research is scarcer and availability of innovative trials is rarer could be a significant step towards improving treatment and care for women and men with breast cancer, wherever they live.”

And he continues: “Finally, I would like to take this moment to make a special mention of Professor Angelo Di Leo (Head of the Sandro Pitigliani Medical Oncology Department at the Hospital of Prato, Italy) who tragically passed away on 12 June 2021. As a member of BIG since the beginning, and of BIG’s Executive Board since 2010, Professor Di Leo contributed to many of BIG’s major trials and research programmes. He also served as a key member of the Scientific and Executive Committee of the International Breast Cancer Study Group (IBCSG). Angelo was a true defender of academic research and international collaboration. He will be missed by all of us, his family and patients.”
BIG’s vision and mission statement

The Breast International Group (BIG) is an independent, international not-for-profit umbrella organisation for academic breast cancer research groups from around the world. We expect our members to share the principle of conducting breast cancer research that is scientifically independent and not motivated by personal profit, meaning that any surplus from BIG’s or its member groups’ research must be reinvested into breast cancer research. BIG’s vision is to cure breast cancer through global research and collaboration; its mission is to facilitate breast cancer research internationally.

BIG provides a forum for its member groups to:
- combine resources and expertise to conduct research to advance knowledge of the disease and to optimally serve patients
- establish clinical and translational research priorities
- reduce the unnecessary duplication of efforts
- obtain study results quickly
- collaborate with other scientific networks
- develop models of collaboration with the pharmaceutical and biotechnology industry that preserve scientific independence.

In 2021, the BIG Executive Board revised BIG’s vision and mission statement, and formulated its strategy, both endorsed by the General Assembly.

BIG’s strategy statement

We believe that it is possible to develop cures for breast cancer through global research and collaboration; our mission is therefore to facilitate and accelerate academic breast cancer research at an international level, and to do so by enabling groups to do more than their individual parts.

BIG commits to prioritising research that otherwise would not be possible and cannot be done by one research group alone by
- having a network of collaborative research groups and data centres, represented by their individual members, who are world-class experts in breast cancer research
- bringing together these individuals to discuss, prioritise and conduct clinical trials and research programmes that will help address the unmet related needs of individuals with breast cancer, without unnecessarily duplicating efforts
- appointing working groups and task forces to develop new research ideas that can only be done within a network such as BIG’s
- facilitating access to bio-samples and data collected in the context of BIG studies for the conduct of translational research, aiming to optimise individualised diagnosis and treatment
- providing a headquarters with trained and qualified staff who
  > work closely with BIG members to plan, develop, and run BIG studies and translational research
  > provide support in various forms, ranging from scientific input to legal advice, communications, fundraising, and the organisation of meetings and other events for BIG members and partners
- working according to specific research principles that will preserve academic freedom, even when partnering with commercial entities.

With this framework, the BIG network will thrive and conduct research to advance treatments that make a difference to women and men with breast cancer.
OUR MISSION

BiG’s mission is to facilitate and accelerate breast cancer research at the international level.

OUR VISION

Together we will find a cure for breast cancer through global research and collaboration.

TRUSTED

We have been recognised for over 20 years to generate credible scientific results and safeguard patients’ interests.
GLOBAL AND LOCAL
BIG is the largest global network of breast cancer research groups and their affiliated experts. Their work benefits patients locally.

IMPACTFUL
Our research changes practice in the treatment of women and men with breast cancer. We have a real impact on patients’ lives.
ABCSG

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

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

The ABCSG-16 / S.A.L.S.A study, with its significant practice-changing results published in the New England Journal of Medicine in July 2021, answered a relevant clinical question, thus clarifying a standard treatment duration for most postmenopausal patients with hormone receptor-positive breast cancer. Furthermore, the huge ABCSG-42 / PALLAS (BIG 14-03) data treasure trove started to pave the way for many new sub-projects with translational research and correlative science focus to be conducted, even though the final endpoint analysis presented at SABCS 2021 by ABCSG president Michael Gnant turned out to be negative: the addition of palbociclib to endocrine therapy did not provide benefit in terms of improving invasive disease-free survival in the adjuvant setting.

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

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

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

Since the ABCSG continuously monitors the activity level of its task forces’ work to ensure that the next generation increasingly takes over operational responsibility within the network, there were also some changes within the ABCSG leadership during the past year. Dr Daniel Egle (Medical University Innsbruck) was elected to the ABCSG board, and Dr Christian Singer (Medical University Vienna) became ABCSG’s newest vice president. ABCSG’s founding president Professor Raimund Jakesz (Medical University Vienna) became ABCSG’s new vice president. ABCSG’s founding president Professor Raimund Jakesz (Medical University Vienna) was awarded the very first ABCSG honorary membership.

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

References:
1 https://publons.com/researcher/3480820/michael-gnant/
2 Also featured on ABCSG’s website: https://www.abcsg.org/highly-cited-researcher-2021/

BCT-ANZ

Breast Cancer Trials – Australia New Zealand (BCT-ANZ) was founded in 1978 and conducts a multicentre national and international clinical trials research programme, which includes 820 members across 109 institutions.

In 2021, recruitment to clinical trials was impacted once again by Covid-19, and our staff had to work from home for a period of three months. However, in 2020, BCT-ANZ identified a range of areas where we could streamline processes and create new ways to engage our audiences, and this greatly helped our day-to-day business activities and trials management last year.

Professor Sunil Lakhani was elected to the position of Chair of the BCT-ANZ Board of Directors during the reporting period. He is the Executive Director of Research and Senior Staff Specialist at Pathology Queensland and Head of the Breast Group, Centre for Clinical Research, University of Queensland, Brisbane, Australia.

The Chair position was made vacant following the appointment of Professor Bruce Mann to the role of BCT-ANZ’s Director of Research and Chair of the Scientific Advisory Committee. Professor Mann was elected to the Board of Directors in 2015 and was Chair from 2017-2021. He is Director of the Breast Tumour Stream of the Victorian Comprehensive Cancer Centre, and works at Royal Melbourne, Royal Women’s Hospital and the Peter MacCallum Cancer Centre, Australia.

Professor Andrew Spillane was elected to the Board of Directors in 2021 and is a Professor of Surgical Oncology at The University of Sydney, Northern Clinical School, Sydney, Australia. He specialises in the surgical management of breast cancer and melanoma. Andrew is a senior VMO surgeon at the Mater North Sydney, Royal North Shore Hospital and North Shore Private Hospitals Sydney, Australia.

Meanwhile BCT-ANZ researcher Professor Sherene Loi was awarded the Frank Fenner Prize for Life Scientist of the Year, as part of the 2021 Prime Minister’s Prizes for Science.
The Prime Minister’s Prizes for Science are Australia’s most prestigious awards for outstanding achievements in scientific research, research-based innovation and excellence in science, mathematics or technology teaching.

Professor Loi was awarded the $50,000 Frank Fenner Prize for her work to translate scientific findings into innovative treatments that can improve the survival of breast cancer patients in Australia and around the world.

Professor Loi is the BCT-ANZ Study Chair of the DIAmOND and NeoN clinical trials, a Board Director and member of the Scientific Advisory Committee. She is the Head of the Translational Breast Cancer Laboratory at the Peter MacCallum Cancer Centre in Melbourne, Australia.

Clinical trial update: the EXPERT trial

Recruitment to the EXPERT clinical trial continued internationally.

This trial, coordinated by BCT-ANZ and its international collaborators – the Breast International Group (BIG) and the Spanish Oncology Trials Group (SOLT) – was open in Australia, New Zealand, Spain, Chile, Switzerland, Taiwan and Italy by late 2021. This is a great success for our team, especially after activation of the trial outside of Australia and New Zealand was delayed due to Covid-19.

In 2021, GEICAM (Spanish Breast Cancer Group) renewed and reoriented its board of directors and work groups towards a “generational replacement”, incorporating new and multidisciplinary professional profiles and thus responding to one of the strategic lines of the Group’s strategic plan until 2023. Professor Miguel Martin renewed his position as president of the group; Dr Ander Urruticoechea, Dr Ángel Guerrero and Dr José Ángel García Sáenz respectively became vice president, secretary and treasurer.

GEICAM also reinforced the role of its work groups to continue carrying out studies focused on the different breast cancer molecular subtypes. The Group’s current work groups are: luminal disease, HER2-positive disease and triple negative disease. In addition, there are two transversal working groups: TransGEICAM and Preventive Treatments, and Hereditary Cancer and Epidemiology.

Pathology and breast cancer: GEICAM-FSEAP collaboration agreement

The connection between pathologists and oncologists is gaining prominence as knowledge of molecular changes in cancer advances. This allows us to achieve more accurate diagnoses and more personalised and effective treatments.

For this reason, GEICAM signed in 2021 a collaboration agreement with the Spanish association of pathologists FSEAP (Fundación...
Sociedad Española de Anatomía Patológica), with the aims of encouraging a better understanding of issues related to pathology and breast cancer, working together in research activities, promoting precision medicine strategies, training professionals in a multidisciplinary way, and providing information to patients on the different phases of the healthcare process.

Hereditary breast cancer: GEICAM-AMOH collaboration agreement

In 2021, GEICAM also signed a collaboration agreement with AMOH, a Spanish association of hereditary breast and ovarian cancer patients. This collaboration will allow both entities to raise awareness on hereditary breast cancer, its research and early detection, as well as to start new clinical trials and projects on these subjects.

Breast Cancer development and alcohol consumption

In 2021, GEICAM investigators published an article on the relationship between alcohol consumption and breast cancer in the British Journal of Cancer (https://www.nature.com/articles/s41416-021-01492-w).

In this analysis, the investigators focused on evaluating four life trajectories of alcohol consumption – from adolescence to adulthood – to determine the potential influence of these distinctive trajectories throughout a woman’s life on the development of breast cancer. The main conclusions are the following:

• The greater the alcohol consumption accumulated throughout life, the greater the risk of breast cancer, especially in postmenopausal women
• Alcohol consumption during adolescence may particularly influence breast cancer risk

This manuscript represents a sub-analysis of the EpiGEICAM study. For this study, 1,017 women newly diagnosed with breast cancer were recruited between 2006 and 2011, by the oncology departments of 23 hospitals that are members of GEICAM Spanish Breast Cancer Group. This sample accounted for 78% of the Spanish population. Each breast cancer case was matched with a healthy control.

“Make history with your story” recruitment campaign: gestational breast cancer

Coinciding with the 2021 celebration of Mother’s Day (May 2), GEICAM launched the campaign “Make history with your story” (from the Spanish “Haz historia con tu historia”). It encourages women who had gestational breast cancer (diagnosed during pregnancy or up to one year after giving birth), as well as those who became pregnant after the disease, to participate in the EMBARCAM project, which is studying the relationship between breast cancer and pregnancy. Clinical information provided by women participating in this project will allow researchers to deepen their current knowledge on the subject. Visit the landing page of the campaign: https://hazhistoria.geicam.org/

World Breast Cancer Day: we can all contribute to scientific research

GEICAM’s 2021 campaign for World Breast Cancer Day (October 19) entitled #YoInvestigoTúInvestigas, underlined that everyone, regardless of their position, can contribute to scientific research. The Group developed this idea in a series of videos in which the protagonists challenge society and ask for support. Watch them here: https://yoinvestigotuinvestigas.geicam.org/
**JBCRG**

**BIG studies**

The Japan Breast Cancer Research Group (JBCRG) is participating in the following studies run under the BIG umbrella: AMEERA-6, POSITIVE, ALEXANDRA/IMpassion030, OlympiA, PENEOPE-B and PALLAS.

**Activities**

With the aim to improve cancer care and raise further awareness about breast cancer and clinical trials, JBCRG organises lectures for Japanese companies.

In 2021, Representative Director, Dr Norikazu Masuda, together with two members of the public relations committee, Dr Yasuyuki Kojima and Ms Naomi Sakurai, gave lectures during the in-house training of ELC Japan KK (a subsidiary of Estée Lauder Companies, Inc.), which continues to support JBCRG’s activities. Every year, ELC Japan KK runs the largest breast cancer awareness campaign in Japan and donates part of the earnings to our breast cancer research.

---

**IJB-CTSU**

The Institut Jules Bordet has moved!

The Institut Jules Bordet is a comprehensive cancer centre unique in Belgium with an international reputation. Its Clinical Trials Support Unit (IJB-CTSU) is fighting cancer through the design, set-up and conduct of innovative clinical trials that matter to patients.

In November 2021, the Institut Jules Bordet, a Brussels-based university hospital dedicated entirely to the fight against cancer, moved to a brand-new building on the Anderlecht campus. The new location, 90, rue Meylmeersch, is in the immediate proximity of the Erasmus Hospital and the Faculty of Medicine from the Free University of Brussels.

In the Old Bordet, the building area was around 35,000 m². The New Bordet now offers 80,000 m², thereby increasing by more than 50% its care capacity and its area dedicated to research. This extra space is devoted to the care, research and teaching mission in the field of oncology. In its new capacity, the Institut Jules Bordet proposes 250 conventional hospitalisation beds and 43 beds for day hospitalisation. The New Bordet also includes a Novel Treatments Unit (12 beds), entirely dedicated to the patients included in clinical trials.

The New Bordet is an effective comprehensive cancer centre where researchers will be able to exchange their ideas easily, design new projects in direct contact with the clinicians and share the same tools in an optimal way. The translational research laboratories are grouped together on the same floor (10,000 m²) and benefit from brand-new infrastructure equipped with the most advanced technologies. All the staff specifically devoted to research activities is located in the immediate vicinity of the medical staff, in the heart of the action.

In summary, the New Bordet has all the resources required to pursue its mission as a reference centre in the field of oncology, at both national and international levels. This new building is also a perfect place to encourage innovation, collaboration and excellence in Bordet teams and projects.
Organisation

Dr Norikazu Masuda, new Representative Director

Dr Norikazu Masuda, MD, PhD, Professor of the Department of Breast and Endocrine Surgery, Nagoya University School of Medicine (Nagoya, Japan) is JBCRG’s new Representative Director.

He shares his views on JBCRG HP and its strategy, vision and mission:

The Japan Breast Cancer Research Group (JBCRG) has contributed to the progress of healthcare for breast cancer patients nationally and internationally through its clinical research, which has been lauded for its remarkable achievements, including a response-guided treatment strategy for primary breast cancer using neoadjuvant therapy, new therapeutic strategies for advanced/recurrent breast cancer, and real-world evidence capturing the unmet needs of breast cancer patients. Moreover, as a member of the Breast International Group (BIG), the world’s largest international network of academic research groups for breast cancer, JBCRG has been active in collaborative research, cooperating with a number of international study groups, which aim to bring innovations to breast cancer care at a global perspective.

Based on our abundant experience in clinical and translational research, we will further promote work on new technologies and therapeutic approaches, which will give us valuable scientific insights to make breakthroughs in clinical outcomes.

Our mission is to develop the best treatment for every person suffering from breast cancer. Carrying on the footsteps of the great former Representative Directors, Dr Masakazu Toi and Dr Shinji Ohno, I feel the magnitude of the responsibility to meet the expectations toward JBCRG as it enters into its full maturity. I will dedicate myself to this role and exert my knowledge and experience to the fullest extent. I sincerely ask those who are concerned in our fight against breast cancer for your continuous support and cooperation in pursuing our challenges.

Dr Shigehira Saji, new member of the BIG Executive Board

Dr Shigehira Saji, MD, PhD, a Board Director of JBCRG and Professor of the Department of Medical Oncology, Fukushima Medical University (Fukushima, Japan), joined BIG’s Executive Board in 2021. JBCRG has been a member of the BIG network since 2006. Dr Saji is Dr Shinji Ohno’s successor. He is co-Principal Investigator of the international BIG study Impassion030/Alexandra.

Dr Saji hopes to contribute to the further progress of BIG and to enhance the collaboration between BIG and the Asian study groups in particular.

New directors

In 2021, JBCRG held elections for its board of directors: three members retired and the following three new members joined:

- Dr Takanori Ishida, Professor of the Department of Breast and Endocrine Surgical Oncology, Tohoku University Graduate school of Medicine (Miyagi, Japan),
- Dr Kenzo Shimazu, Professor of the Department of Breast and Endocrine Surgery, Osaka University Graduate school of Medicine (Osaka, Japan), and
- Dr Hiroko Bando, Department of Breast-Thyroid-Endocrine Surgery, Institute of Clinical Medicine, University of Tsukuba (Ibaraki, Japan).

JBCRG’s Educational and Annual Meeting

JBCRG’s 11th Educational Meeting took place on 11 February, by Zoom webinar meeting. The theme was “New normal breast cancer treatment brought about by liquid biopsy”.

On 23 November, JBCRG’s Annual Meeting also took place by Zoom. The topic of the lecture was “Outline of revisions to the 2021 Integration Guidelines and Guidance”. A Session “Reviews and discussions for thinking about new clinical trials” was also organised.

For both meetings, over 150 investigators attended. Due to Covid-19, it was a challenge for JBCRG staff to organise these on-line meetings. However, we are happy to see that the attendees who responded to our questionnaire indicated that the meetings had exciting themes and, at the same time, were easy to attend from home —, which was very comfortable.
The Brazilian Breast Cancer Conference 2021 – LACOG/GBECAM and Best of SABCS® Brazil

The Brazilian Breast Cancer Conference 2021 took place between 9 and 11 March 2021, alongside the official licensed event, Best of SABCS Brazil. This event was organised by the Latin American Cooperative Oncology Group (LACOG) and the Brazilian Group for Breast Cancer Studies (GBECAM), two Brazilian institutions that are dedicated to education and research on breast cancer.

The Brazilian Breast Cancer Conference 2021 event was held online. Experts from across Brazil and elsewhere came together to debate about the main developments in the diagnosis and treatment of breast cancer.

The conference involved 26 renowned national and international speakers, and 1,737 individuals from different states in Brazil attended virtually over the three days.

AMAZONA III presented at ASCO: the reality of breast cancer in elderly women in Brazil

A sub-analysis of the AMAZONA III study – “Sociodemographic and clinicopathologic features of elderly breast cancer patients in Brazil” – was selected for presentation during ASCO 2021. Conducted by the Brazilian Breast Cancer Study Group (GBECAM) in partnership with LACOG, the analysis sought to characterise and comprehend the profile of elderly women with breast cancer in Brazil.

This prospective cohort study, run from January 2016 to March 2018, included 2,950 women with recently diagnosed invasive breast cancer, sourced from 23 Brazilian centres. The sub-analysis presented at the annual ASCO congress only considered patients aged 65 years and older.

Using AMAZONA III data, investigators highlighted the importance of strategies to improve breast cancer tracing and provide educational programmes for the elderly population, to guarantee access to earlier diagnoses.

LATINA Breast study finished recruitment

LACOG 0615 - LATINA Breast – “A study to observe patient characteristics, treatment patterns and outcomes in patients with newly developed breast cancer in Latin America” – successfully completed its recruitment in August 2021. The study included 3,298 patients in 30 research sites across Brazil, Argentina, Uruguay, Chile, Peru, Colombia, Dominican Republic, Guatemala and Mexico.

LATINA Breast is a prospective, multicenter, analytical, non-interventional study of secondary data use. Its objectives are to:
- Prospectively describe patients’ characteristics and breast cancer subtypes at diagnosis in Latin America,
- Prospectively describe treatment patterns and outcomes in HER2 positive and other breast cancer subtypes in Latin America,
- Build an electronic platform/database to allow collection of epidemiological data on breast cancer patients in Latin America.

LATINA Breast study finished recruitment

LATINA Breast study finished recruitment

AMAZONA III presented at ASCO: the reality of breast cancer in elderly women in Brazil

AMAZONA III presented at ASCO: the reality of breast cancer in elderly women in Brazil

LATINA Breast study finished recruitment

LATINA Breast study finished recruitment

NEOSAMBA clinical trial approved for funding

On 18 November 2021, the Ministry of Health of Brazil approved the financial support for the LACOG 0419 - NEOSAMBA study. The funding request had been submitted in 2019 by Projeto Cura to PRONON - National Support Program for Oncological Care.

NEOSAMBA is a phase 3 randomised clinical trial evaluating treatment sequencing of neoadjuvant chemotherapy for HER2-negative breast cancer. The study will include almost 500 women in Brazil.
SOLTI trains promising young oncologists from across Spain in clinical trial design

The Clinical Trial Design in Oncology Workshop for Young Investigators organised by SOLTI aims to meet the training needs in clinical research – both theoretical and practical – of oncology residents and attending physicians.

SOLTI, a leading cooperative group in the field of clinical cancer research, organises this initiative for young oncologists from all over Spain to enhance their knowledge and active role in clinical research with the aim also of building bridges between them and the senior mentors taking part in the workshop.

The future of oncology is directly linked to clinical research. However, the eminently care-oriented approach that characterises the residency for young oncologists leaves little room for practical training in this field, specifically in the conceptualisation and design of clinical trials, which are the basic tools for the validation of new drugs and therapies in medicine. Aware of this need, SOLTI promotes this trial design workshop that seeks to introduce young doctors, both theoretically and practically, to the world of clinical trials, based on real problems and with the help of mentors with extensive experience in the field.

SOLTI is preparing the 9th edition of the project after the success of the last workshop, which took place in Madrid at the end of 2021 and was coordinated by Dr Maria Vidal (H. Clínic de Barcelona) and Dr Joaquín Gavilá (Instituto Valenciano de Oncología), both members of SOLTI’s Executive Board. Twenty professionals from across different areas of clinical research expertise participate. They include specialists in medical oncology, biostatistics, biomedicine, biochemistry or bioinformatics, among others.

During the oncology residency in hospitals, as Dr Gavilá points out, doctors have a first contact with clinical trials, but not from the beginning: “Residents can see the day-to-day running of the study once it has started in the hospital: from the first visit with each patient to the end, including all the follow-up. What they don’t get to see is how a trial is born – which is the most important thing for it to exist –; how we design it, how we do the sample calculation, how the protocols and synopses are written, and the different individuals involved in the whole process”.

Dr Maria Vidal adds: “Through this workshop, SOLTI helps participants to think and try to see how a study can be developed by simulating real practice, integrating the statistical part and, most importantly, starting from a real medical need. Seeing first-hand how a clinical study is developed is fundamental to give future doctors tools and to make them aware that any idea they might have can become a clinical study”.

Dr Rodrigo Sánchez, a young specialist in oncology at the Hospital 12 de Octubre in Madrid, concludes: “Initiatives such as this workshop are of great help since, at the moment, training in clinical research is a teaching need not equally covered across Spain, as it depends a lot on the type of hospital in which the residency is done. Also, because it is not part of routine clinical practice, participation in trials usually involves an extra administrative and bureaucratic burden for residents. Finally, although I think it is important for every young oncologist to be familiar with research, it usually depends on the doctor’s own motivation to do so”.
THE BIG NETWORK: GLOBAL RESEARCH COLLABORATION TO CURE BREAST CANCER

For over 20 years, BIG’s 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. Its mission is to facilitate and accelerate breast cancer research at an international level.

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, more than two decades later, BIG represents over 50 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 to design and conduct pioneering breast cancer research. Each BIG group plays a crucial role. The combined expertise, collaborative spirit, dedication and hard work are essential to improving the lives of patients confronted with breast cancer. BIG is thus global and local.

More than 30 clinical trials are run or are under development under the BIG umbrella at any one time. BIG also works closely with the US National Cancer Institute (NCI) and the National Clinical Trials Network (NCTN), so that together they act as a strong integrating force in the breast cancer research arena. 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, and to raise funds for BIG’s purely academic breast cancer trials and research programmes.

WWW.BIGAGAINSTBREASTCANCER.ORG

AFRICA
BGICS Breast Gynaecological International Cancer Society

ASIA
BDPCC Breast Disease Professional Committee of CMEA
BIEI Breast Intergroup of Eastern India
CTRG Cancer Therapeutics Research Group
HKBOG Hong Kong Breast Oncology Group
ICON ARO Indian Co-operative Oncology Network
IOSG Indian Oncology Study Group
JBCRG Japan Breast Cancer Research Group
KCSG Korean Cancer Study Group
SKMCH & RC Shaukat Khanum Memorial Cancer Hospital & Research Centre
TCOG Taiwan Cooperative Oncology Group
TSCO Thai Society of Clinical Oncology

AUSTRALASIA
BCT-ANZ Breast Cancer Trials Australia and New Zealand
TROG Trans-Tasman Radiation Oncology Group

EUROPE
ABCSG Austrian Breast & Colorectal Cancer Study Group
AGO-B Arbeitsgemeinschaft Gynäkologische Onkologie Breast Study Group
BOOG Borstkanker Onderzoek Groep
CCEEQ Central and East European Oncology Group
CT-IRE Cancer Trials Ireland
DBCQ Danish Breast Cancer Cooperative Group
EORTC BCG European Organisation for Research and Treatment of Cancer Breast Cancer Group
EUBREAST The European Breast Cancer Research Association of Surgical Trialists Network (EUBREAST e.V./Germany and EUBREAST ETS./Italy)
FBCQ Finnish Breast Cancer Group
GCQG Georgian Cancer Study Group
GEICAM Spanish Breast Cancer Group
GOIRC Gruppo Oncologico Italiano di Ricerca Clinica
HSBS Hellenic Society of Breast Surgeons
HeCOG Hellenic Cooperative Oncology Group
HORG Hellenic Oncology Research Group
IBCG Icelandic Breast Cancer Group
IBCSG International Breast Cancer Study Group
IBIS International Breast Cancer Intervention Studies
ICCG International Collaborative Cancer Group
ICR-CTSU Institute of Cancer Research - Clinical Trials & Statistics Unit
IJB-CTSU Institut Jules Bordet Clinical Trials Support Unit
ITMO Italian Trials in Medical Oncology
MICHELANGELO Fondazione Michelangelo
NBCG Norwegian Breast Cancer Group
NCRI-BCSG National Cancer Research Institute - Breast Cancer Clinical Studies Group
SABO Swedish Association of Breast Oncologists
SAKK Swiss Group for Clinical Cancer Research
SLO Société Luxembourgeoise
d’Oncologie
SOLTI Breast Cancer Research Group
SUCCESS Study Group
SweBCG Swedish Breast Cancer Group
UCBG Unicancer Breast Group
WSG Westdeutsche Studiengruppe

LATIN AMERICA
GAICO Grupo Argentino de Investigación Clínica en Oncología
GECO PERU Grupo de Estudios Clinicos Oncológicos Peruano
GOCCHI Chilean Cooperative Group for Oncologic Research
GOCUR Grupo Oncológico Cooperativo Uruguayo
LACOG Latin American Cooperative Oncology Group

MIDDLE EAST
IBG Israeli Breast Group
ICRC Iranian Cancer Research Center
SBCG Sheba Breast Collaborative Group

NORTH AMERICA
CCTG Canadian Cancer Trials Group

“TOGETHER, WE CAN WORK TO CHANGE THE WORLD.”
<table>
<thead>
<tr>
<th>Study name</th>
<th>BIG number</th>
<th>Short description</th>
<th>Principal Investigator(s)</th>
<th>Trial model &amp; partners</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALEXANDRA / IMpassion 030</td>
<td>BIG 16-05</td>
<td>A randomised phase III trial comparing atezolizumab (anti-PD-L1 inhibitor), given in combination with standard chemotherapy vs. chemotherapy alone as adjuvant treatment in patients with operable TNBC - NCT03498716</td>
<td>M. Ignatiadis, H. McArthur, S. Soji</td>
<td>Lead trial (Co)-Leading partners: BIG HQ / IJB-CTSU / FSTRF and AFT Pharma partner: Roche/Genentech (sponsor) Funding: Roche / Genentech</td>
</tr>
<tr>
<td>ALPHABET</td>
<td>BIG 18-04</td>
<td>A randomised phase III trial of trastuzumab + ALpelisib +/- fulvestrant vs. trastuzumab + chemotherapy in patients with PIK3CA mutated previously treated HER2+ Advanced BrEaSt cancer - NCT05063786</td>
<td>A. Pérez-Fidalgo, C. Criscitiello, P. Bedard</td>
<td>Co-lead trial (Co)-Leading partners: GEICAM (sponsor) / IBCSG and BIG HQ Pharma partner: Novartis Funding: Novartis</td>
</tr>
<tr>
<td>APPALACHES</td>
<td>BIG 18-01</td>
<td>A phase II study of Adjuvant PALbociclib as an Alternative to CChemotherapy in Elderly patients with high-risk ER+/HER2- early breast cancer - NCT03609047</td>
<td>H. Wildiers, E. Brain, K. Punie</td>
<td>Supporter trial Coordinating group: EORTC (sponsor) Pharma partner: 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. Altimos, M. Benelli, A. Guerrero, Zotoano</td>
<td>BIG-sponsored programme (Co)-Leading partners: BIG HQ (sponsor) / UB-CTSU / FB Pharma partner: N/A Funding: Breast Cancer Research Foundation® (BCRF) as the main funder, Fondation Cancer (Luxembourg), Pfizer grant for non-drug research, Fondation contre le Cancer (Belgium), National Lottery (Belgium), NF Foundation, Rhone Trust, Barnie and Dena Webb, Candriam, Fondation Futur 21, Sogerim, Think Pink Belgium (SMART Fund), Cognizant Foundation, Eurofins Foundation and many individual donors. AURORA has also been supported by the Fund Friends of BIG, managed by the King Baudouin Foundation.</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 - NCT00196833</td>
<td>S. Loibl, G. von Minckwitz</td>
<td>Supporter study Coordinating group: GBG (sponsor) Pharma partner: N/A Funding: GBG, Deutsches Konsortium für Translationale Krebsforschung</td>
</tr>
<tr>
<td>EXPERT (Big Radio Tuning)</td>
<td>BIG 16-02</td>
<td>A randomised phase III trial of adjuvant radiation therapy vs observation after breast conserving surgery for patients with molecularly characterised low-risk luminal A early breast cancer - NCT02289874</td>
<td>B. Chua, G. Gruber</td>
<td>Co-lead trial (Co-Leading partners: BCT-ANZ (sponsor) and BIG HQ Pharma partner: N/A Funding: BCT-ANZ, the National Health and Medical Research Council of Australia, National Lottery (Belgium) and BIG HQ fundraising 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. Aebe</td>
<td>Supporter trial Coordinating group: IBCSG (sponsor) Pharma partner: Pfizer</td>
</tr>
</tbody>
</table>
### Study name | BIG number | Short description | Principal Investigator(s) | Trial model & partners |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></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/ErB2 positive primary breast cancer - NCT00490139</td>
<td>M. Piccart, A. Moreno-Aspik</td>
<td>Lead trial (Co-Leading partners: BIG HQ / UB-CTS U / FSTRF / IRU / Alliance (former NCCTG, sponsor for the US)) Pharma partner: Novartis (global sponsor for all countries with the exception of US) Funding: GSK (past) / Novartis</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 - NCT01358877</td>
<td>M. Piccart, S. Loibl, J. Bines</td>
<td>Lead trial (Co-Leading partners: BIG HQ / UB-CTS U / FSTRF Pharma partner: Roche (sponsor) Funding: Roche</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. Turner, J. Balmaña, D. Cameron, J. Erban</td>
<td>Co-lead trial (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 - NCT00470236</td>
<td>B. Chua</td>
<td>Supporter trial Coordinating group: TROG (sponsor) Pharma partner: N/A Funding: National Health &amp; Medical Research Council Project Grant, Susan G. Komen</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. Irthum (coordinator)</td>
<td>BIG-sponsored programme (Co-Leading partner: BIG HQ Pharma partner: N/A Funding: Breast Cancer Research Foundation</td>
</tr>
<tr>
<td>FINESSE</td>
<td>BIG 2-13</td>
<td>Oral lucitanib for patients with FGFR1 ER+ metastatic breast cancer - NCT02053636</td>
<td>F. André, J. Cortès</td>
<td>Lead trial (Co-Leading partners: BIG HQ / UB-CTS U / FSTRF Pharma partner: Servier (sponsor) Funding: Servier</td>
</tr>
<tr>
<td>IBIS-II</td>
<td>BIG 5-02</td>
<td>Prevention study of anastrozole for postmenopausal women at increased risk of breast cancer, and of effects of tamoxifen vs. anastrozole in postmenopausal women with DCIS - NCT00072462</td>
<td>J. Cuzick</td>
<td>Supporter trial (Co-Leading partner: IBIS Pharma partner: AstraZeneca Sponsor: Queen Mary University of London Funding: Cancer Research UK, Queen Mary University of London</td>
</tr>
<tr>
<td>INTERNATIONAL MALE BREAST CANCER PROGRAMME</td>
<td>BIG 2-07</td>
<td>Registration and biologic characterisation programme of breast cancer in men - NCT01101425</td>
<td>F. Cardoso, S. Giordano</td>
<td>Supporter programme (Co-Leading partners: EORTC (sponsor) / NCTN (US)) Pharma partner: N/A Funding: Breast Cancer Research Foundation</td>
</tr>
<tr>
<td>LORELEI</td>
<td>BIG 3-13</td>
<td>Neoadjuvant letrozole plus taselisib versus letrozole plus placebo in postmenopausal women with ER+, HER2-negative, early-stage breast cancer - NCT02273973</td>
<td>C. Saura, E. de Azambuja</td>
<td>Co-lead trial (Co-Leading partners: ABCSG, SOLTI and BIG HQ Pharma partner: Genentech (sponsor) Funding: Genentech</td>
</tr>
<tr>
<td>MA.32 Metformin</td>
<td>BIG 5-11</td>
<td>Effect of metformin on recurrence and survival in early stage breast cancer - NCT0101438</td>
<td>P. J. Goodwin</td>
<td>Supporter trial Coordinating group: CCTG (sponsor) Pharma partner: Apotex Funding: NCI/NIH grants, Cancer Research UK, the Canadian Cancer Society, the Breast Cancer Research Foundation® (BCRF) and the Canadian Breast Cancer Foundation.</td>
</tr>
<tr>
<td>Study</td>
<td>BIG</td>
<td>Description</td>
<td>Lead Investigator</td>
<td>Collaborators</td>
</tr>
<tr>
<td>-------</td>
<td>-----</td>
<td>-------------</td>
<td>------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>MINDACT</td>
<td>BIG 3-04</td>
<td>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?</td>
<td>E. Rutgers, F. Cardoso, M. Piccart</td>
<td>Co-lead trial (Co-Leading partners: EORTC (sponsor) / BIG HQ) Commercial partners: Roche, Sanofi, Novartis and Agenda</td>
</tr>
<tr>
<td>NEO-ALITTO</td>
<td>BIG 1-06</td>
<td>Comparison of dual HER2 inhibition (lapatinib, trastuzumab) plus chemotherapy before surgery versus single HER2-targeted therapy</td>
<td>S. Di Cosimo, J. Huober</td>
<td>Co-lead trial (Co-Leading partners: UB-CTSU / FSS / SOlTI / BIG HQ) Pharma partner: Novartis (global sponsor for all countries with the exception of US, where Alliance is the sponsor)</td>
</tr>
<tr>
<td>OLYMPIA</td>
<td>BIG 6-13</td>
<td>Olaparib vs. placebo for patients with BRCA-mutated, high-risk HER2-negative breast cancer, having completed local treatment and neoadjuvant chemotherapy</td>
<td>A. Tutt, D. Cameron, B. Kaufman, J. Garber, C. Geyer</td>
<td>Lead trial (Co-Leading partners: NRG Oncology (sponsor in US), BIG HQ and FSTRF Pharma partner: AstraZeneca (sponsor in Rest of the World) and Merck) Funding: AstraZeneca</td>
</tr>
<tr>
<td>PALLAS</td>
<td>BIG 14-03</td>
<td>PALbociclib CoLlaborative Adjuvant Study: palbociclib with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy alone for HR+ / HER2-negative early breast cancer</td>
<td>E. Mayer, M. Grant, A. DeMichele</td>
<td>Co-Lead trial (Co-Leading partners: ABCSG (RoW), AFT (US) (sponsors) and BIG HQ Pharma partner: Pfizer) Funding: Pfizer grant</td>
</tr>
<tr>
<td>PENELope-B</td>
<td>BIG 1-13</td>
<td>Post-neoadjuvant palbociclib for patients with HR+, HER2-normal primary breast cancer with high relapse risk after neoadjuvant chemotherapy</td>
<td>G. von Minckwitz</td>
<td>Supporter trial Coordinating group: GBG (sponsor) Pharma partner: Pfizer Funding: Pfizer grant</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</td>
<td>O. Pagani</td>
<td>Supporter trial Coordinating group: IBCSG (sponsor) Pharma partner: N/A Funding: IBCSG, Fonds Boillet-Latour, national and local funding bodies, individual donors</td>
</tr>
<tr>
<td>PYTHIA</td>
<td>BIG 14-04</td>
<td>Palbociclib plus fulvestrant for pretreated patients with ER+/HER2- metastatic breast cancer</td>
<td>L. Malorni</td>
<td>Co-lead trial (Co-Leading partners: IBCSG (sponsor) and BIG HQ Pharma partner: Pfizer) Funding: Research grants and drugs from Pfizer and AstraZeneca. BIOVICA supplied support for sample handling and thymidine kinase assays.</td>
</tr>
<tr>
<td>SNAP</td>
<td>BIG 2-12</td>
<td>Schedules of nab-Paclitaxel: evaluation of different schedules of nab-paclitaxel for metastatic breast cancer</td>
<td>A. Gennari, G. Jerusalem</td>
<td>Supporter trial Coordinating group: IBCSG (sponsor) Pharma partner: Celgene Funding: Celgene grant</td>
</tr>
<tr>
<td>SOFT</td>
<td>BIG 2-02</td>
<td>Evaluation of ovarian suppression and of exemestane as adjuvant therapy for premenopausal women with endocrine responsive breast cancer</td>
<td>P. Francis, G. Fleming</td>
<td>Supporter trial Coordinating group: IBCSG (sponsor) Pharma partner: Pfizer Funding: Grants from BCRF, Cancer Research CH, Pfizer, Ipsen, Debiopharm, TerSera Therapeutics, US NCI, IBCSG and many participating collaborative academic groups, as well as various charities. Pfizer and Ipsen provided the drugs for these studies.</td>
</tr>
</tbody>
</table>
## Follow-up or post-study activities, recently closed studies

<table>
<thead>
<tr>
<th>Trial</th>
<th>Code</th>
<th>Description</th>
<th>Principal Investigators</th>
<th>Supporter Trial</th>
<th>Coordinating group</th>
<th>Sponsor</th>
<th>Pharma partner</th>
<th>Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOLE</td>
<td>BIG 1-07</td>
<td>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) - NCT00553410</td>
<td>M. Colleoni, P. Karlsson, S. Aebi, J. Chirgwin</td>
<td>Supporter trial</td>
<td>Coordinating group: IBCSG</td>
<td>Sponsor: IBCSG</td>
<td>Pharma partner: Novartis</td>
<td>Funding: Novartis</td>
</tr>
<tr>
<td>SUPREMO</td>
<td>BIG 2-04</td>
<td>Selective Use of Postoperative Radiotherapy After Mastectomy: adjuvant chest wall irradiation for ‘intermediate risk’ breast cancer following mastectomy - NCT00966888</td>
<td>I. Kunkler, P. Canney</td>
<td>Supporter trial</td>
<td>Coordinating group: SCTBG</td>
<td>Sponsor: UK Medical Research Council</td>
<td>Pharma partner: N/A</td>
<td>Funding: UK Medical Research Council, EORTC, Cancer Australia, William and Elizabeth Davies Charitable Trust, Peter Chan Jeo Yat Foundation, Yeung Ying Yin and May Yeung Foundation</td>
</tr>
<tr>
<td>TEXT</td>
<td>BIG 3-02</td>
<td>Tamoxifen and Exemestane Trial: evaluation of exemestane plus GnRH analogue for premenopausal women with endocrine responsive breast cancer - NCT00066703</td>
<td>O. Pagani, B. Walley</td>
<td>Supporter trial</td>
<td>Coordinating group: IBCSG (sponsor)</td>
<td>Sponsor: Pfizer</td>
<td>Pharma partner: Pfizer</td>
<td>Funding: Grants from BCRF, Cancer Research CH, Pfizer, Ipsen, Debiopharm, TerSera Therapeutics, US NCI, IBCSG and many participating collaborative academic groups, as well as various charities. Pfizer and Ipsen provided the drugs for these studies</td>
</tr>
<tr>
<td>TREAT-CTC</td>
<td>BIG 1-12</td>
<td>Trastuzumab in HER2-negative Early breast cancer as Adjuvant Treatment for Circulating Tumor Cells (CTC) - (“TREAT-CTC” Trial) - NCT01548677</td>
<td>M. Ignatiadis, M. Piccart, J.-Y. Pierga, B. Rack, C. Sotiriou</td>
<td>Supporter trial</td>
<td>(Co)-Leading partners: EORTC BCG, SUCCESS, UNICANCER</td>
<td>Sponsor: EORTC</td>
<td>Pharma partner: Roche, Janssen Diagnostics</td>
<td>Funding: Roche educational grant/medication, Janssen test kits</td>
</tr>
<tr>
<td>ULTIMATE</td>
<td>BIG 16-01</td>
<td>Immunotherapy combined with standard endocrine therapy as neoadjuvant treatment for women with ER+/HER2-negative breast cancer - NCT02997995</td>
<td>F. André, A. Prat</td>
<td>Co-lead trial</td>
<td>(Co)-Leading partners: French Breast Cancer Intergroup Unicancer (UCBG) (sponsor) and BIG HQ</td>
<td>Pharma partner: AstraZeneca</td>
<td>Funding: AstraZeneca grant</td>
<td></td>
</tr>
</tbody>
</table>

* full information available on the BIG website.
NB: This table does not include the trials in development and all closed trials. For more information, please visit: [www.BIGagainstbreastcancer.org](http://www.BIGagainstbreastcancer.org)
PEER-REVIEVED PAPERS PUBLISHED BY MEMBER GROUPS ABOUT THE BIG NETWORK AND ITS ACTIVITIES IN 2021


“BIG patients, researchers and supporters share the same goal: to eradicate breast cancer. Together, we achieve more.”
### BIG BALANCE SHEET

#### ASSETS

<table>
<thead>
<tr>
<th></th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fixed Assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intangible fixed assets</td>
<td>7,702</td>
<td>15,401</td>
</tr>
<tr>
<td>Tangible fixed assets</td>
<td>2,891,604</td>
<td>56,132</td>
</tr>
<tr>
<td>Financial fixed assets</td>
<td>162,949</td>
<td>146,668</td>
</tr>
<tr>
<td><strong>Total Fixed Assets</strong></td>
<td>3,062,255</td>
<td>218,201</td>
</tr>
<tr>
<td><strong>Current Assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Receivables up to one year</td>
<td>9,020,291</td>
<td>7,737,508</td>
</tr>
<tr>
<td>Current investments</td>
<td>64,436</td>
<td>1,544,366</td>
</tr>
<tr>
<td>Cash at bank</td>
<td>14,701,981</td>
<td>9,539,875</td>
</tr>
<tr>
<td>Deferred charges and accrued income</td>
<td>134,348</td>
<td>140,237</td>
</tr>
<tr>
<td><strong>Total Current Assets</strong></td>
<td>23,921,056</td>
<td>18,961,986</td>
</tr>
<tr>
<td><strong>TOTAL ASSETS</strong></td>
<td>26,983,311</td>
<td>19,180,186</td>
</tr>
</tbody>
</table>

#### LIABILITIES

<table>
<thead>
<tr>
<th></th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Equity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unrestricted net assets</td>
<td>229,148</td>
<td>460,408</td>
</tr>
<tr>
<td>Restricted net assets</td>
<td>4,679,698</td>
<td>4,552,180</td>
</tr>
<tr>
<td><strong>Total Equity</strong></td>
<td>4,908,846</td>
<td>5,012,588</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>22,073,953</td>
<td>14,077,598</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>Trade debts</td>
<td>21,696,622</td>
<td>13,563,231</td>
</tr>
<tr>
<td>Tax, remuneration and social security</td>
<td>377,330</td>
<td>514,367</td>
</tr>
<tr>
<td>Deferred charges and accrued income</td>
<td>512</td>
<td>90,000</td>
</tr>
<tr>
<td><strong>Total Debts</strong></td>
<td>22,074,465</td>
<td>14,167,598</td>
</tr>
<tr>
<td><strong>TOTAL LIABILITIES</strong></td>
<td>26,983,311</td>
<td>19,180,186</td>
</tr>
</tbody>
</table>
### INCOME & EXPENSES STATEMENT

<table>
<thead>
<tr>
<th>Operating Income &amp; Expenses</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turnover (research)</td>
<td>19,501,571</td>
<td>17,551,462</td>
</tr>
<tr>
<td>Other goods &amp; services</td>
<td>-15,739,499</td>
<td>-13,648,390</td>
</tr>
<tr>
<td><strong>Operating margin</strong></td>
<td><strong>3,762,072</strong></td>
<td><strong>3,903,072</strong></td>
</tr>
<tr>
<td>Remuneration, social security &amp; pension costs</td>
<td>-3,829,048</td>
<td>-3,870,787</td>
</tr>
<tr>
<td><strong>Operating result</strong></td>
<td><strong>-66,976</strong></td>
<td><strong>32,285</strong></td>
</tr>
<tr>
<td>Financial result</td>
<td>-25,102</td>
<td>-11,070</td>
</tr>
<tr>
<td>Extraordinary income (+)</td>
<td>6,674</td>
<td>459</td>
</tr>
<tr>
<td>Extraordinary expenses (-)</td>
<td>-18,339</td>
<td>-13,904</td>
</tr>
<tr>
<td><strong>Result for the financial year</strong></td>
<td><strong>-103,742</strong></td>
<td><strong>7,770</strong></td>
</tr>
</tbody>
</table>

*Between 2012 and 2021, BIG received over €151,864,914, 94.4% of which 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 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, MD
PHILIPPE BEDARD, MD
JUDITH BLISS, MSC
ETIENNE BRAIN, MD, PHD
DAVID CAMERON, BIG CHAIR, MD
EVA CARRASCO, MD
BOON CHUA, MD, PHD
BARBRO LINDERHOLM, MD, PHD
SHERENE LOI, MD, PHD
SEAMUS O’REILLY, MD, PHD
EVANGELIA RAZIS, MD, PHD
SHIGEHIRA SAJI, MD, PHD
ANDER URRUTICOECHEA, MD, PHD
INES VAZ-LUIS, MD, PHD
TOGETHER, we can change the world

SUPPORT BIG:
IBAN BE08 0689 0916 0213
(communication: AR 2021)

OR DONATE ONLINE:
www.BIGagainstbreastcancer.org/donate

#BIGAGAINSTBC
WWW.BIGAGAINSTBREASTCANCER.ORG

FOLLOW US ON
@BIGagainstbreastcancer  @BIGagainstBC  BIG against breast cancer