

# BIG

RESEARCH  
IN FOCUS

November 2023 - issue n°19

## FIGHTING BREAST CANCER AROUND THE GLOBE

*Overcoming the challenges  
of funding academic  
breast cancer research*



Co-funded by  
the European Union



Breast International Group

# COLOPHON

## **BIG Executive Board**

Philippe Bedard, MD  
Judith Bliss, MSc  
Etienne Brain, MD, PhD  
David Cameron, BIG Chair, MD  
Eva Carrasco, MD  
Boon Chua, MD, PhD  
Giuseppe Curigliano, 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  
Gustavo Werutsky, MD, PhD

## **Managing editors**

Carolyn Straehle  
Valerie Van der Veecken  
Katrien Van Impe

## **Design**

www.kalman.be  
Photos © Shutterstock

## **Print**

VCP Graphics BV  
IZ 'Blauwe Toren'  
Hoge Hul, 49  
8000 Brugge  
Belgium

BIG Research in Focus is published by Breast International Group (BIG)-aisbl. The opinions or conclusions stated or implied in the articles herein are those of the authors and do not necessarily reflect those of the publisher.

BIG Headquarters' contact address:  
Breast International Group (BIG)-aisbl  
Rue de Bretagne 20 Bretagnestraat  
1200 Brussels  
Belgium  
Tel: +32 2 486 16 00  
VAT: BE 0468 176 240  
E-mail: info@BIGagainstbc.org  
www.BIGagainstbreastcancer.org



THE BREAST INTERNATIONAL GROUP  
IS PROUD TO ADHERE TO THE CODE  
OF ETHICS OF THE VEF-AERF



Co-funded by the European Union under an operating grant from the European Union's EU4Health programme under grant agreement No 101124555. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the European Health and Digital Executive Agency (HaDEA). Neither the European Union nor the granting authority can be held responsible for them.

# CONTENTS

1	NOTE FROM THE EDITORS
2	BIG RESEARCH: OVERCOMING THE CHALLENGES OF FUNDING ACADEMIC BREAST CANCER RESEARCH
12	BIG NETWORK
22	BIG CLINICAL TRIALS AND ACTIVITIES
40	BIG STUDIES - OVERVIEW
44	BIG MEMBER GROUPS



# NOTE FROM THE EDITORS

Pink October and the global Breast Cancer Awareness Month have drawn to a close. This special time of the year unites us in the fight against breast cancer, fostering awareness and support on a global scale. It serves as a reminder that research saves lives, offering hope. Yet we cannot overlook the ongoing challenges in funding academic breast cancer research. Together, we can make a difference and continue the quest for early detection, improved treatments, and ultimately a world without breast cancer.

The featured article in this edition of our *BIG Research in Focus* highlights the theme **“Overcoming the challenges of funding academic breast cancer research”**. Securing funding for academic breast cancer research has become increasingly daunting. The growing complexities and costs associated with clinical trials, the limited budgets of funding bodies, the lingering effects of the Covid-19 pandemic, and the economic consequences of global crises, present challenges to international research organisations like BIG. The BIG Headquarters' (HQ) communications team would like to thank **Drs Carlos Barrios, David Cameron, Vassilis Golfinopoulos, Theodora Goulioti, Larry Norton, and Ines Vaz-Luis**, who kindly accepted to be interviewed on this topic by medical journalist Jenny Bryan. She explored how leading cancer research groups and funders are addressing these fundraising challenges and gathered their insights and advice for colleagues seeking research grants. *See from [page 2](#).*

The section **“BIG Network”** includes updates on the BIG Executive Board and BIG members, as well as an overview of Pink October activities carried out by BIG HQ. *See from [page 12](#).*

**BIG against breast cancer, BIG's dedicated philanthropic unit, designed and launched BIG's new Pink October 2023 awareness and fundraising campaign entitled “I miss you”**. Through the campaign, we aim to increase awareness about the importance of global academic breast cancer research and the constant need for funding and support. Throughout the month of October, the campaign gained significant visibility, not only in the media but also through various activities and fundraising events that BIG HQ organised. For an overview, *see from [page 14](#).*

For the fifth consecutive year and as part of the campaign, BIG and the EORTC have once again joined forces in co-hosting their annual webinar. Given the growing hurdles in securing funding, the theme of the webinar also centred on **“Overcoming the challenges of funding academic breast cancer research”**. For the programme, key speakers, and key messages of the webinar, *see from [page 17](#).*

The section **“BIG Clinical Trials and Activities”** features an update article on the launch of the second phase of the AURORA research programme, provides an overview of recently published manuscripts related to BIG trials, and presents highlights from GBCC 2023 and ASCO 2023. *See from [page 22](#).*

It also showcases research and related activities by BIG member groups around the world. See *“Other Trials and Activities by BIG Member Groups”*, from [page 28](#).

Finally, you will find the tables with the **“Overview of the Current Studies Run within the BIG Network”**, from [page 40](#).

In closing, we extend our warm appreciation for your continued support and collaboration. As we reflect on the achievements of the BIG network and the ongoing endeavours of the BIG community, we also look forward to 2024, which holds special significance as it marks BIG's 25th anniversary. More details on this milestone will follow soon.

Enjoy the reading!

*Together, we will cure breast cancer*

*BIG's Editorial Team*

## *Fighting breast cancer around the globe*

# OVERCOMING THE CHALLENGES OF FUNDING ACADEMIC BREAST CANCER RESEARCH



Obtaining funding for academic breast cancer research has never been more challenging. The growing complexity and expense of trials, the limited budgets of funding bodies, and the lingering effects of the Covid-19 pandemic, as well as the economic consequences of global crises, are some of the issues facing international research organisations such as BIG. Medical journalist, Jenny Bryan, asked leading cancer research groups and funders how they are addressing the challenges of raising money for research and what is their advice to colleagues seeking grants.

A recently published analysis of public and philanthropic investment in cancer research identified 66,388 awards worth a total of about US\$24.5 billion made between 2016 and 2020.<sup>1</sup> Breast cancer received the largest share of investment, with 7,146 awards valued at \$2.7 billion (11.2% of total investment). However, across all cancers, investment fell year on year with the largest drop from 2019-2020 when there was a 45% decrease – possibly linked to the Covid-19 pandemic and/or fewer charitable donations or a worsening of the overall downward trend.

BIG CEO, Dr. Theodora Goulioti, is in no doubt about the increased difficulty of securing funding for BIG studies in recent years.

*“Since the Covid-19 pandemic in 2020, our philanthropy unit, BIG against breast cancer, has seen quite a difference. Covid seems to have been just the beginning of a whole series*

*of circumstances – war in Ukraine as well as in other parts of the world, inflation, earthquakes, countless climate change and human tragedies to name just a few – that render fundraising quite challenging,” she says.*

Dr. Vassilis Golfinopoulos, Headquarters Director of the European Organisation for Research and Treatment of Cancer (EORTC) agrees:

*“Cancer research is a very crowded place to raise money, and breast cancer has both strengths and weaknesses in competing for funding. It is very common, so almost everyone knows someone who has been affected and may therefore consider donating to research. However, because breast cancer is so common, there are many breast cancer charities competing for grants, sponsorship, and donations,” he points out.*

Add to this the inexorable rise in costs of conducting research, and it’s no surprise that getting funding has become so difficult.

*“In the past, practice-changing trials were much easier and less expensive to carry out than they are today. We can’t reduce all our costs, but we do need to simplify and decentralise our trials and make the process of data capture easier and therefore cheaper while maintaining the quality of research,” says BIG Chair, Professor David Cameron.*



For Professor Larry Norton, Founding Scientific Director of the Breast Cancer Research Fund (BCRF), the world's largest private funder of breast cancer research, unrestricted philanthropic support is essential for supporting innovation, collegiality, and cooperation between breast cancer researchers.

*“After decades of significant expansion, the level of philanthropic support is now pretty flat. However, we are in a period of massive growth in innovation and creative opportunity, so we need an urgent expansion in philanthropic support,” says Norton. “Good ideas and people rise, and they will rise faster and in greater volume if we can use philanthropic support imaginatively in early-stage research, before moving on to government grants for later stages and then industry sponsorship for product development.”*

## WHERE DOES FUNDING COME FROM?

Commercial funding plays a valuable part in supporting some academic research as well as trials of new drugs. However, as Cameron explains, the goals of pharmaceutical companies may differ from those of academic researchers, so commercial funding may not be an option for some research.

*“Studies funded by pharmaceutical companies tend to focus on new drugs while academic researchers may want to look at older agents with potentially unrecognised efficacy or at radiotherapy or other non-drug treatments. In addition, commercial partners may be reluctant to sponsor academic trials if investigators want to be involved in developing protocols and holding and analysing trial data – a standard requirement for research organisations such as BIG. In all our research, we need to ensure we are addressing questions that matter to patients and are relevant to clinicians worldwide,” he says.*

With the exception of the USA, France, and the UK, few national governments offer an independent funding stream for academic clinical research. Dr. Inez Vaz-Luis, from the Institut Gustav Roussy, Paris, France, a

member of Unicancer Breast Group (UCBG), France, and a member of BIG's Executive Board, explains that several funding mechanisms are available, including multinational initiatives (e.g., the EU Commission) and national funding, such as by the US and French governments through the National Institutes of Health (NIH) and the French National Research Agency (Agence Nationale de la Recherche or ANR), respectively. In the UK, the National Institute for Health and Care Research is the British government's major funder of clinical, public health, social care, and translational research. In addition to these regional and national funding sources, there are also charitable and philanthropic organisation, foundations, and institutional funders of academic research.

Vaz-Luis recalls that, at the start of her career, she benefited from charitable, philanthropic, and governmental funding in her native Portugal that gave her flexibility to learn how to do research and put her in a good position to receive a career development award to go to the USA.

*“In the USA, I was fortunate to have mentors who involved me in applications for large research grants, and I then received a further career development award through which I moved to France and started my independent research career,” she says. “In France I have been able to apply for funding through different French institutional and other mechanisms for grants of different sizes, and this success has given me a platform to apply for large European grants.”*

## RISING COSTS AND FUNDING SHORTFALLS

A large international breast cancer clinical trial can now cost tens of millions of euros, owing to the complexity of today's high tech, big data approach to research that requires use of expensive equipment and collection of more samples and images than was previously the case. Goulinopoulos explains that centralised trial administration brings salaries and overheads, participating hospitals need to be paid for the extra work of trial participation, and suppliers have to be paid for services such as drug procurement and distribution, tumour sample collection, shipment, analysis, and storage.

*“Hospitals where research is carried out used not to charge for some infrastructure costs but, as their budgets are now so much tighter and the equipment so much more expensive, they cannot be so generous. They have to scrutinise all the costs very carefully, and they assess protocols for academic studies in much the same way as those funded by pharmaceutical companies, so the administrative burden and costs have also increased,” he says.*

Some costs, such as developing a trial protocol and building a database, are fixed, irrespective of the size of the study. In contrast, the costs per patient in a study are variable depending on factors such as how often they are seen, what tests are needed, how they are monitored and followed up, and how results are recorded.

Difficulties can arise because research grants are agreed and fixed but service costs, for example for transporting and analysing samples, may increase during a trial, especially if it continues for several years. This has been a particular problem in the last few years as prices have risen much faster than previously, particularly for transport services.

*“We plan for price increases during a study and most funders understand that this is necessary – they live in the real world! We are also very vigilant about costs and, if additional research is suggested during a study, we look very closely at whether it is worth the extra money. Sometimes we can go back to funders, and they may be able to increase what they are giving, especially if the research is going well. However, we do sometimes end up having to subsidise some aspects of research,” says Goulioti.*

In general, research organisations such as BIG and EORTC are building relationships with large funders that can provide a major share of trial costs, and they hope only to need a few additional funders for top-up grants.

*“When BIG and EORTC together ran the MINDACT trial, we received €7 million partial support from the European Commission, but the total cost was about €47 million, meaning that all the rest of the funding had to be pieced together through a great many grants. This*

*represents a tremendous effort in terms of grant writing and reporting, in addition to the complex work needed just to run the study,” points out Goulioti.*

Funders may also expect more for their investment than they used to, not only in terms of update reports but also publicity surrounding their contribution. A logo on a research protocol and a mention on publications is no longer sufficient and there is an expectation for events and strong social media coverage – all of which add to the costs of trials.

## A DIGITAL SOLUTION?

Digitally enabled research is increasingly being proposed to reduce the costs of breast cancer trials and make them less time consuming and more attractive to investigators and patients.<sup>2</sup> Fewer in-person visits to obtain patient consent, carry out interventions, collect data and perform follow ups have been suggested. Telehealth consultations, and home-based treatments, remote monitoring and data collection could all help to reduce the need for in-person visits, with all their associated costs for care providers and patients. Similarly, fragmented longitudinal, often paper-based patient-reported outcomes could be replaced by continuous electronic reporting. Laboratory tests and imaging could be decentralised to local facilities, so patients have to travel shorter distances. This also has the potential to increase the diversity of patients in trials by taking studies to older patients and those of different socioeconomic and ethnic backgrounds.

In France, the French government gave €11 million through the ANR to invest in WeShare – a patient-centric digital infrastructure to provide cancer researchers with technical tools for quantitative and qualitative data collection and to facilitate interventional research and study management initially focused on quality of life and social and human sciences. WeShare also plans to build a public standardised data repository of patient reported outcomes, clinical, behavioural, and socioeconomic data that will allow large-scale ancillary or secondary cancer studies to be conducted. Finally, it aims to create researcher-patient communities, a culture of patient engagement, and co-creation of clinical projects of diverse and equal reach.

*“I believe that streamlining digitally enabled patient-centric research from beginning to end of all study processes would bring a world with less costly research and make it easier to do large, multinational, practice-changing, pragmatic research,” says Vaz-Luis who is Scientific Coordinator of WeShare.*

## IS THE BEST RESEARCH GETTING FUNDED?

Major cancer research organisations and funders have tried and tested methods for ensuring that the best research gets funded. BIG does not raise funds for which individual researchers can apply on a competitive basis. Instead, all BIG studies are developed and run within the BIG network, together with BIG member groups. This means that proposals for a potential BIG study are first reviewed by BIG’s Executive Board.

*“They want to be sure that the study really requires the network (as opposed to an individual group), that it aims to address an unmet need, that it can answer questions that can have a real impact on patients’ lives, and that it can potentially change practice,” says Goulioti.*

She explains that if a project gets the green light, it will be discussed during BIG’s Scientific Meetings and further improved and developed within the network, with the leadership and model of collaboration for each study decided on a case-by-case basis. As most BIG studies involve drug treatment, the ‘first stop’ is to seek partnership with a pharmaceutical company, whether to provide the study drug(s) and funding only (in the form of a grant), or as a study in which the company is sponsor. Pharma-sponsored studies are always run according to BIG’s principles of research conduct.

Studies developed under the BIG umbrella that do not involve drug treatment need to seek other funding paths, such as grants from private foundations or the EU, or fundraising with the help of BIG against breast cancer. Recent examples include academic research such as BIG’s AURORA programme on metastatic breast cancer, the EXPERT study of adjuvant radiotherapy in luminal-A early breast cancer, and the POSITIVE study of endocrine therapy interruption for women with breast cancer to try to become pregnant.

At the EORTC, there is extensive independent peer review of studies proposed to the organisation, mainly by experts outside Europe.

*“As we have limited opportunities for trials because of rising costs, we have had to raise the bar and are looking for fewer but better studies requiring funding. No more than half of academic trials that come to us are taken forward. Some trials that would previously have been accepted are now no longer accepted, but we cannot do everything,” says Golfopoulos.*

The BCRF takes a somewhat different approach, using a model based on that of arts organisations to identify research worthy of funding, explains Norton. An expert panel looks at the field, sees where the gaps are, approaches researchers who are making or have the potential to make the greatest advances, and asks them to submit proposals for annual funding decisions.

*“We don’t just support the project, we support the people doing the project. The project can be modified depending where the science and creativity of the researchers is going. Whether they are established researchers or just starting out, we encourage innovation and, as a result, we’ve attracted many of the best minds in the world, not just in the United States,” says Norton.*

There is still a high degree of accountability, with reports required from all grant holders annually and with long-term grant holders reviewed for their impact every five years.

*“We encourage researchers to work collectively – it’s not a gladiatorial contest. We give them freedom to be creative and security to continue their work,” adds Norton.*

## ADDRESSING THE FUNDING GAP IN LMICS

Establishing a track record in research is a key step towards accessing major funding and, as Professor Carlos Barrios, President, Latin American Cooperative Oncology Group (LACOG) and former member of BIG’s Executive Board, explains, it is a severe challenge for researchers in low- and middle-income countries (LMICs) where basic healthcare provision takes priority over research.

*“There is a lack of awareness of the importance of research, especially academic research, both in government and in society, because of other priorities for funding and organisation, and there is often a lack of infrastructure that makes it difficult to compete for funding,” he says.*



Barrios advises that the first step in addressing such problems is to review the local situation, identify specific barriers to change and agree creative solutions. Having undertaken this type of exercise, LACOG (founded in 2009) was able to identify opportunities for research development and now has more than 400 investigator members carrying out clinical and translational cancer research in 194 institutions in 16 Latin America countries.

*“We have been able to establish cooperation to stimulate and engage with investigators to participate in research, particularly academic research. The results have had an impact on society in the region and are helping to build credibility and a track record in research that can be used to support future applications for funding,” says Barrios.*

Alongside evolving research collaborations, LACOG is seeing sustained improvements in infrastructure across the region, and in public and government awareness that cancer is a critical issue that needs research support. An important study on breast cancer epidemiology in Brazil ([Amazona<sup>3</sup>](#)) and, more recently, a similar study across the whole region ([LATINABreast](#)) have underlined the importance of local academic research.

*“We identified the need to generate this information because of the lack of epidemiological data in the region. We then engaged with collaborators in a number of institutions, developed the basis for the Amazona and LATINABreast studies and went in search of funding. As we had done the groundwork and were asking the right questions, we were able to get government, philanthropic, and industry funding,” says Barrios.*

In Brazil, breast cancer researchers have benefitted from funding from PRONON, a government programme through which a proportion of taxes paid by some of Brazil’s largest companies can be spent on important academic cancer and other medical research. In 2021, Projeto Cura (CURA), a non-government organisation which has been very successful in raising awareness about the importance of cancer research and fundraising for studies, successfully achieved funding through PRONON for the [NeoSamba](#) trial. This study is evaluating neoadjuvant sequencing of anthracyclines and taxanes for locally advanced HER2-negative breast cancer. Another study on duration of adjuvant anti-HER2 therapy has recently been submitted and hopefully will be funded in the same way.



*“While the question of trastuzumab duration has been addressed in many other trials, it remains controversial, and we hope to be more definitive with our results. If we show that treatment can be of shorter duration in selected patients, this will save money for the government and reinforce the value of funding research,” explains Barrios.*

PRONON was due to end in 2023 but, thanks to the successful lobbying of Projeto Cura, the programme will continue, with further opportunities to fund breast cancer research in Brazil.

## COULD PAYERS FUND ACADEMIC RESEARCH?

Wherever breast cancer researchers are working, there are never enough funding options for academic studies, so could healthcare providers be a previously unrecognised potential source of investment? asks Cameron.

*“Healthcare providers need to understand that research isn’t just something to do for profit, it’s also something from which they can benefit. If they enable research, they can not only improve outcomes for their patients – less toxicity and better cure rates – they may also save money by reducing the amount of treatment patients need,” he suggests.*

*Golfinopoulos agrees: “National healthcare providers have started to understand that they need to be more active and not just wait for evidence. For example, if they pay for a treatment de-escalation trial, they will save money as a result of reduced drug costs during the trial. It is more difficult for healthcare providers to do these sorts of studies in smaller countries, but they are starting to group together to make it possible.”*

*“We need all partners – researchers, regulators, hospitals and funders – to sit down together and work out how to make things easier and cheaper without impacting the quality of research,” Cameron concludes.*

## TOP TIPS FOR GETTING RESEARCH FUNDING

- > “Be innovative, imaginative, and creative, work incredibly hard, and make sure your work gets known. There are plenty of opportunities to present or publish research, but to stand out from the crowd, your research needs to show you’re moving in a new direction while staying close enough to what’s accepted in the field so that people don’t think you’re a crackpot!” *Professor Larry Norton*
- > “Get good advice about the design of your study, think about who it is most relevant to in terms of potential funders, and don’t give up! Be sure to involve patients in your research and get their insights. The patient voice can be incredibly powerful and can take your ideas outside the academic sphere.” *Professor David Cameron*
- > “Epidemiological studies are a good place to start for breast cancer researchers in LMICs because they aren’t as expensive as clinical trials, and they provide much needed relevant data than may be different from that collected in Europe and North America. They also help researchers raise their profile and build credibility.” *Professor Carlos Barrios*
- > “Focus on what really needs to be funded. Sit down with colleagues in your department and choose four or five projects to apply for funding. Don’t submit a large number and end up competing with yourselves!” *Dr. Vassilis Golfinopoulos*
- > “Check with your own institution and for opportunities within your own country. Organisations such as BCRF and Komen for the Cure also offer research funding to individuals. It’s much more complicated to get funding for very large international research undertakings such as the studies run under the BIG umbrella, which inevitably involve many groups and hospitals across multiple countries and cost millions if not 10s of millions of euros.” *Dr. Theodora Goulioti*
- > “Start small by applying for charitable or philanthropic funding in your own country, and then learn how to apply for larger grants from bigger organisations. Ideally, find mentors who can help with your grant applications, so you can build a track record of research. But be prepared to be told ‘no’, and then try again!” *Dr. Ines Vaz-Luis*

>> See also key points of BIG-EORTC webinar on the same theme “Overcoming challenges of funding academic breast cancer research”, [page 19](#)

## REFERENCES:

1. McIntosh SA, Alam F, Adams L, et al. Global funding for cancer research between 2016 and 2020: a content analysis of public and philanthropic investments. *Lancet Oncol*. 2023 Jun;24(6):636-645. doi: [10.1016/S1470-2045\(23\)00182-1](https://doi.org/10.1016/S1470-2045(23)00182-1)
2. Franzoi MA, Gillanders E, Vaz-Luis I. Unlocking digitally enabled research in oncology: the time is now. *ESMO Open*. 2023 Oct;8(5):101633. doi: [10.1016/j.esmoop.2023.101633](https://doi.org/10.1016/j.esmoop.2023.101633)
3. Liedke PER, Finkelstein DM, and Szymonifka J, et al. Outcomes of breast cancer in Brazil related to Health Care Coverage: a retrospective cohort study. *Cancer Epidemiol Biomarkers Prev* 2014;23 126–133. doi: [10.1158/1055-9965.EPI-13-0693](https://doi.org/10.1158/1055-9965.EPI-13-0693)

## MEET THE EXPERTS



**Carlos Barrios, MD**

Past member of BIG's Executive Board

Professor, Department of Medicine,  
PUCRS School of Medicine  
Director, Hospital do Câncer Mãe  
de Deus, Porto Alegre  
Director, Centre for Research in  
Oncology, São Lucas Hospital  
Co-founder and President, Latin  
American Cooperative Oncology  
Group (LACOG)  
Brazil



**David Cameron, MD**

Chair of BIG  
Professor of Oncology at  
Edinburgh University  
Edinburgh, UK



**Vassilis Golfopoulos, MD**

Director, EORTC Headquarters  
Brussels, Belgium



**Theodora Goulioti, MD**

CEO, BIG Headquarters  
Brussels, Belgium



**Larry Norton, MD**

Founder and Scientific Director,  
Breast Cancer Research  
Foundation (BCRF)  
Senior Vice President, Office of  
the President  
Medical Director, Evelyn H.  
Lauder Breast Center  
Norna S. Sarofim Chair in  
Clinical Oncology  
Memorial Sloan Kettering  
Cancer Center  
New York, USA



**Ines Vaz-Luis, MD**

Member of BIG's Executive Board  
Member of UCBG (Unicancer  
Breast Group, France)  
Medical oncologist and patient-  
oriented clinical researcher  
Breast Cancer Survivorship  
Research Group, Institut  
Gustave Roussy  
Paris, France

# BCRF: BIG'S LIFETIME SUPPORTER



The Breast International Group (BIG) is extremely grateful for the long-standing and generous support of the Breast Cancer Research Foundation (BCRF)<sup>®</sup>, which has facilitated BIG's practice-changing research in breast cancer for almost 20 years.

Founded in 1993 by Evelyn H. Lauder, BCRF is the largest private funder of breast cancer research—and metastatic breast cancer research—worldwide.

Investing in the best minds in science—from those investigating prevention, diagnosis, treatment, survivorship, and metastasis—and fostering cross-disciplinary collaboration, BCRF's approach accelerates the entire field and moves us closer to the answers we urgently need to put an end to breast cancer.

A long-standing partner of BIG, BCRF has over the years generously provided approximately 23 million Euros in funding to support BIG's academic research. Currently, BCRF is the main funder of BIG's large **AURORA research programme** dedicated to metastatic breast cancer.

## TOGETHER TO ADVANCE BREAST CANCER RESEARCH

BCRF has been supporting the **BIG-NCTN collaboration** since 2005, which has shown to be crucial in the global fight against breast cancer.

BIG and the NCI National Clinical Trials Network (NCTN) – the latter being a network of major US and Canadian-based research groups supported by the US National Cancer Institute (NCI) – meet annually, gathering about 60 world-class researchers and involving breast cancer advocates to tackle unresolved issues of the disease.

Together they identify difficult and unresolved aspects of breast cancer treatment and care, focus on research areas not supported by the pharmaceutical industry, and collaborate to set up large international research programmes that **always put patients' needs first**.

This collaboration was initiated by Martine Piccart and William Wood, co-Chairs of the first meetings, in partnership with Larry Norton (BCRF) and JoAnne Zujewski (NCI).

Among the main achievements that have already resulted from this collaboration, in addition to AURORA, are the **POSITIVE study**, investigating the safety of pausing endocrine therapy for breast cancer to try to conceive; the **International Male Breast Cancer Programme**, helping us better understand this rare disease and how we could treat men more optimally in the future; and the **DECRESCENDO trial** (with a US counterpart, COMPASS HER2-pCR), aiming to de-escalate adjuvant chemotherapy in HER2-positive breast cancer.

[Learn more at BCRF.org.](https://www.bcrf.org)



*Introducing***THE RENEWED BIG EXECUTIVE BOARD**

Following the bi-annual elections held in June 2023, we're pleased to introduce our renewed Executive Board (EB). They are the dynamic leadership behind BIG, responsible for driving BIG's scientific and overall strategy.

BIG's EB serves as the governing body of the organisation, reporting to the General Assembly of all member groups. Its primary responsibilities include proposing, shaping, and reviewing BIG's strategies and related objectives, as well as ensuring the association's long-term sustainability.

Today, the EB comprises 15 individuals selected from BIG's member groups, representing a broad spectrum of areas of cancer expertise, including medical oncology, radiation oncology, medical statistics / clinical trials methodology, and translational research. This diverse composition allows us to address the unique needs and perspectives of different regions across the world.

BIG's EB plays a critical role in ensuring that all clinical trials and programmes conducted under the BIG umbrella adhere to BIG's mission and research principles. These aim to eliminate bias from the research process, protect academic freedom, and maintain integrity vis-à-vis patients, whether we are collaborating with pharmaceutical partners or working independently. Of particular importance is BIG's commitment to prioritising research that otherwise would not be possible and cannot be done by a single research group alone.

Within this framework, BIG conducts research to advance treatments that make a real difference to women and men with breast cancer.



*Thank you and good luck, Carlos!*

---

## PROFESSOR CARLOS BARRIOS STEPS DOWN FROM THE BIG EXECUTIVE BOARD



With deep gratitude for his significant contributions, it is with a heavy heart that we announce the departure of Professor Carlos Barrios from the BIG Executive Board (BIG EB). His unwavering dedication and invaluable insights have played a vital role in the growth and success of the BIG network, leaving a lasting impact on global breast cancer research, particularly in Brazil and the broader Latin American region.

Professor Barrios has been an active, valued member of BIG since 2012, when his group LACOG joined the network. In 2014 he hosted a retreat of all the Latin American groups involved in BIG together with representatives from the BIG EB and BIG HQ. The aim was to discuss shared challenges, including how to raise awareness about the importance of academic breast cancer research and the need to fund it, as well as how to better address the interests and needs of groups in this region of the world in BIG's global research agenda. This meeting led to a training programme the following year, co-hosted by the EORTC and BIG HQ, for four promising young research leaders in Latin America.

In 2018 Professor Barrios was elected to BIG's EB, and although he has stepped down from this role, he remains deeply committed to his clinical work and sharing his experience, both in Latin America and internationally.

In this edition of *BIG Research in Focus*, Professor Carlos Barrios has lent his expertise to the featured article "**Overcoming the challenges of funding academic breast cancer research**". For his insights, please [see from page 2](#).

We extend our best wishes to Professor Carlos Barrios in his future endeavours and our heartfelt gratitude for the significant role he has played (and will continue to play) in advancing breast cancer research and care.



## FRONTIER SCIENCE SCOTLAND (FSS)



We extend a warm welcome to Frontier Science Scotland (FSS), the newest member of BIG's global network of academic research groups. Their addition, effective from June 2023, brings the total number of BIG member groups to 59.

FSS has maintained a strong, over 20-year partnership with BIG and its network members. This collaboration, starting with the HERA study, highlights their commitment to long-term relationships.

As a not-for-profit contract research organisation (CRO), FSS specialises in designing, running and analysing the results of clinical trials. Their expertise encompasses data management, biostatistics, and quality services, with a focus on improving patient well-being. Based in the Highlands of Scotland, their influence extends worldwide.

For more information on FSS and their activities, see also [page 31](#).

[www.frontierscience.co.uk](http://www.frontierscience.co.uk)



### *ASCO 2023 Annual Meeting - 3 June 2023*

---

## PROFESSOR HANS WILDIERS, RECIPIENT OF THE B.J. KENNEDY GERIATRIC ONCOLOGY AWARD

**We extend our warmest congratulations to Professor Hans Wildiers, a highly-respected and valued member of the BIG network, on receiving the B.J. Kennedy Geriatric Oncology Award at the ASCO 2023 Annual Meeting. With this well-deserved recognition, Professor Wildiers follows in the footsteps of Professor Etienne Brain, who received this prestigious award last year.**

Established in 2007 in honour of the late B.J. Kennedy, MD, the award acknowledges the exceptional contributions of an ASCO member in the fields of research, diagnosis, and treatment of cancer in elderly patients. It also recognises their efforts in promoting awareness and understanding of geriatric oncology among young clinicians and researchers.

In his Award Lecture titled “Looking Back and Moving Forward”, Professor Wildiers highlighted the significant progress made in the field of geriatric oncology and emphasised the continued efforts needed to improve the quality of care for older individuals facing cancer.

In an insightful interview, published in *ASCO Connection* (7 April 2023), Professor Wildiers shares his perspectives on the field of geriatric oncology, discussing his initial fascination with the subject, tracing its evolution over the years, and shedding light on the unanswered research questions that continue to drive his work. The interview provides valuable insights into the intersection of geriatrics and oncology and highlights Professor Wildiers' expertise in the field:

[Breast Oncologist Professor Wildiers Works at the Intersection of Geriatrics and Oncology | ASCO Connection](#)

Professor Wildiers is a medical oncologist dedicated to breast cancer research. He has been a valuable member of the Department of Medical Oncology at the University Hospital Leuven, Belgium, since 2004. Since 2015, he has played a key role as the coordinator of the Leuven Multidisciplinary Breast Center. Professor Wildiers has been instrumental in leading numerous academic studies in the fields of breast cancer and geriatric oncology, and his contributions are reflected in over 350 peer-reviewed publications. He has demonstrated long-standing commitment to the field by serving on the Board of the International Society of Geriatric Oncology (SIOG) for many years, including a term as the organisation's president from 2018 to 2020. From 2009 to 2015, he chaired the Cancer in the Elderly Task Force of the European Organisation for Research and Treatment of Cancer (EORTC).

Other source: [Special Awards | ASCO Annual Meeting](#)

See also the themed article “**The unmet needs of older patients with breast cancer**”, published in **BIG Research in Focus 17** (Oct 2022), which features interviews with Professors Wildiers and Brain, among other experts from the BIG network:

[big-research-in-focus-unmet-needs-of-older-people.pdf](http://big-research-in-focus-unmet-needs-of-older-people.pdf)  
([bigagainstbreastcancer.org](http://bigagainstbreastcancer.org))



## BIG RECEIVES EU GRANT – THE BIG-SCOPE PROJECT

BIG, a leading EU-based (Belgian) health NGO, was founded in 1999 with the mission to unite academic breast cancer research groups worldwide. It aims to address fragmentation in European breast cancer research by promoting global collaboration. BIG now consists of a network of 59 research groups from all over the world, including 26 of the 27 EU Member States, all dedicated to reducing unnecessary duplication of efforts, sharing data, and advancing breast cancer treatment.

BIG’s network of academic research groups and breast cancer experts have built a strong reputation of innovative, practise-changing, patient-oriented research during its almost 25 years of existence and is recognised as a world leader in this field. BIG’s groundbreaking studies have significantly influenced clinical practice and patient well-being.

**However, despite this success, many aspects of BIG’s work remain underfunded. To address these challenges, and in the frame of the EU4Health Programme 2021-2027\*, BIG successfully applied for a grant.**

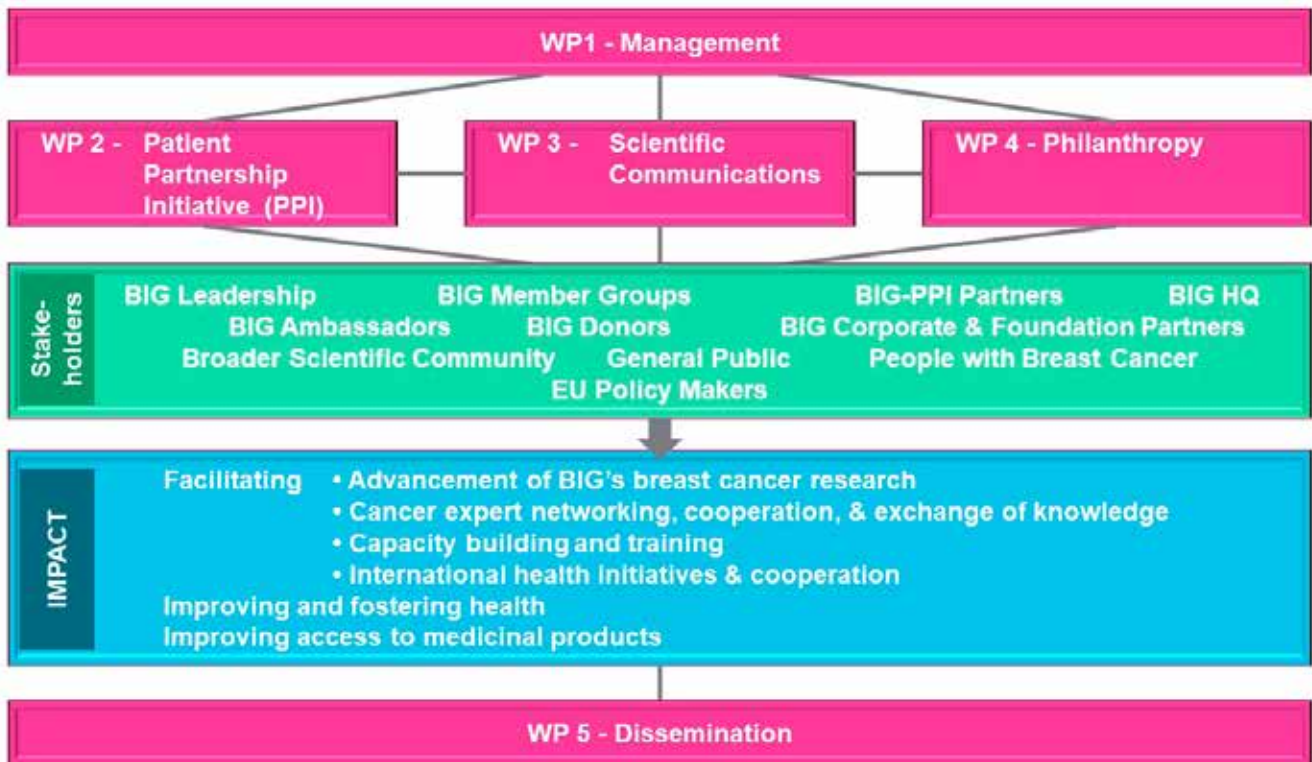
Extending beyond its clinical trials and research programmes, BIG has already a demonstrated strong track record in the kinds of activities that are necessary to implement the EU’s broader policy objectives, namely awareness raising on various health aspects,

communication and dissemination, capacity building and training (in particular with BIG’s patient partners), and expert collaboration and networking.

**The EU4H-2023-OG** operating grant greatly enhances BIG’s capacity to continue with such work, contributing both to its long-term sustainability as a leader in independent academic breast cancer research in Europe and beyond, and directly to the EU4Health Work Programme general objectives (“improving & fostering health”, “improving access to medicinal products”) and specific objectives (“cancer”, “international health initiatives & cooperation”, “enhancement of availability or medicinal products”).

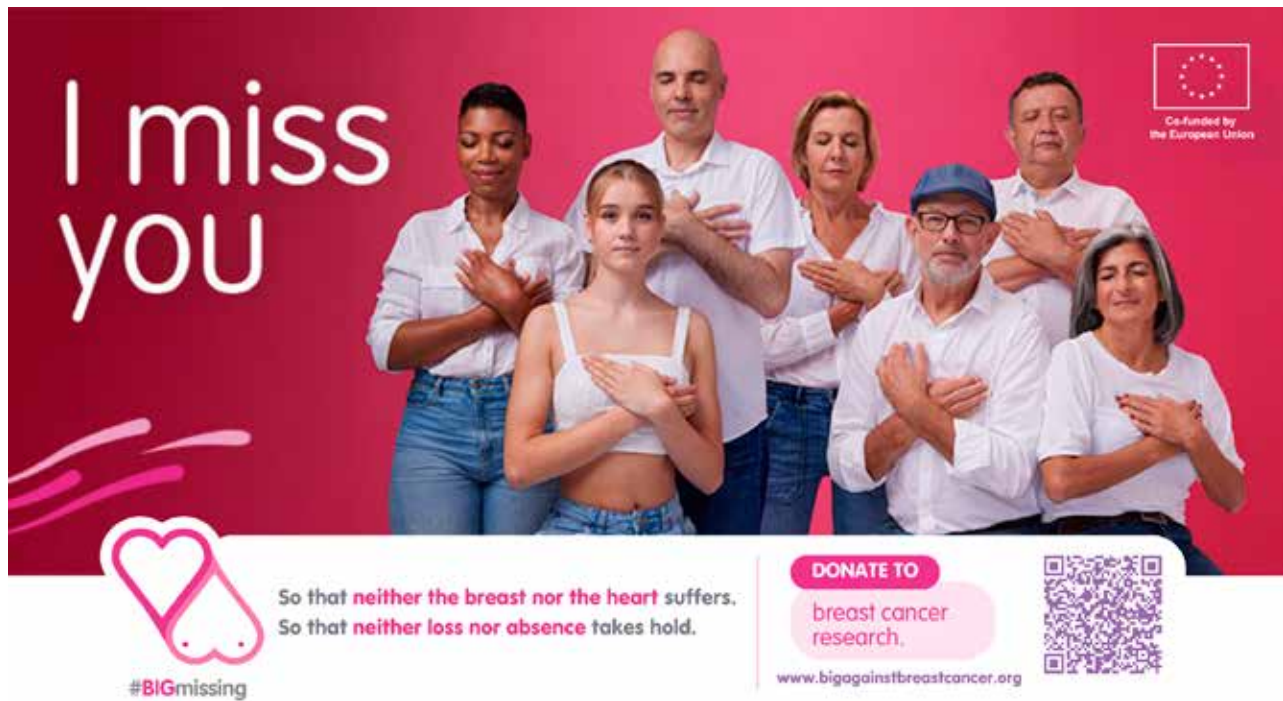
**The BIG-SCOPE project**, comprising 5 work packages and running from February through December 2023, aims to ensure the smooth operation of BIG’s activities in 2023, enhance patient involvement in guiding research, improve communication within the breast cancer community, and implement a philanthropic strategy to fund academic studies and related endeavours. With the BIG-SCOPE project, BIG will receive up to 1 million euro in co-funding from the EU.

*\*EU4Health, with a budget of €5.3 billion, is the fourth and largest of the EU health programmes since their launch in 2003.*



## BIG Pink October 2023 campaign

# “I MISS YOU”



The philanthropy and communications teams at BIG’s headquarters in Belgium have launched their new **Pink October 2023 campaign** entitled **“I miss you”**.

Through the campaign, **BIG aims to increase awareness about the importance of global academic breast cancer research and the constant need for funding and support.**



The campaign, for which BIG created this elegant and minimalistic logo, is centred around 7 portraits of women and men with different stories and testimonials. The casting reflects a diverse population. A touching gesture of hands placed on the breast and heart symbolises the core message of the **“I miss you”** campaign and the associated emotions of loss, empathy, and hope.

For some, it symbolises the pain in their **hearts** that comes with the **absence** of a loved one. For others, it represents the grieving of a former life or the **loss** of a **breast**, a profound symbol of femininity and motherhood.

However, **“I miss you”** is not just a poignant reflection; it is also a message of **hope**. It’s like a postcard sent to a dear friend you are looking forward to seeing again. It embodies the aspiration to rediscover a stronger version of oneself after enduring multiple treatments.

The campaign’s primary goal is to increase BIG’s visibility and brand recognition, raise further awareness about the critical importance of funding breast cancer research and, ultimately, attract new donors and corporate partners. The funds we raise will support fully academic studies under the BIG umbrella, such as AURORA, EXPERT, and POSITIVE.

Throughout the month of October, the **“I miss you”** campaign gained significant visibility, not only in the media but also through various activities and fundraising events that BIG HQ organised. Campaign boards decorated the streets and shopping centres of Brussels and Antwerp, including visibility on public transport.



19 September 2023

# PRESS CONFERENCE AND OFFICIAL LAUNCH OF THE "I MISS YOU" CAMPAIGN

Speakers: *Professor Martine Piccart and Professor Hans Wildiers*



Martine Piccart

Professor Piccart is co-founder of BIG, President of *BIG against breast cancer* and Senior Advisor to BIG. She is also professor of oncology at the Université Libre de Bruxelles and Scientific Director at the Jules Bordet Institute in Brussels.

Professor Wildiers is a medical oncologist dedicated to breast cancer research, Professor at the Faculty of Medicine of the Katholieke Universiteit Leuven and a Member of the EORTC Breast Cancer Group. He plays a key role in leading academic studies in the fields of breast cancer and geriatric oncology.



Hans Wildiers

Professors Piccart and Wildiers shared their expertise in breast cancer research, focusing on men and young women. The BIG-EORTC Male Breast Cancer Programme and the OlympiA study were presented.

The powerful testimonials from Kris (a male breast cancer survivor who was diagnosed with the BRCA mutation), and Juliette (a young woman who's in remission of breast cancer) emphasised our cause and need for funding.

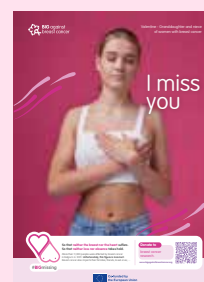
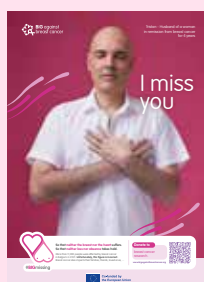
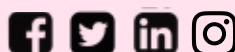


## COMMUNICATION MATERIALS

For this campaign, BIG HQ developed press material, video testimonials, campaign boards and social media content. All communication materials can be accessed via BIG's website and the campaign's landing page:

<https://bigagainstbreastcancer.koalect.com/en-GB/pink-october-i-miss-you>

Social media where you can find, like, comment, reshare our content:



## ANNUAL BIG-EORTC PINK OCTOBER WEBINAR



One of the highlights of BIG's Pink October campaign 2023 was the annual **Pink October BIG-EORTC webinar**.

For the fifth consecutive year, and on the occasion of the International Breast Cancer Awareness Month, the European Organisation for Research and Treatment of Cancer – Breast Cancer Group (EORTC BCG) and the Breast International Group (BIG), organised their Pink October webinar.

This year's theme, **“Overcoming the Challenges of Funding Academic Breast Cancer Research”**, was designed for anyone interested in understanding how breast cancer research is financed and the related challenges.

It's crucial to recognise that research not only saves lives but is also extremely expensive. Obtaining necessary funding has become progressively challenging and poses a significant obstacle for academic organisations conducting research. At EORTC and BIG, we are committed to intensifying efforts to raise funds to facilitate international breast cancer studies without commercial interest. This funding is critical and covers the A to Z of running a study – from setting it up to enrolling the number of patients needed and ensuring adequate follow-up. All of these are essential for generating robust data and results, and for addressing important questions that matter to persons facing the disease.

The theme “Overcoming the challenges of funding academic breast cancer research” highlighted various aspects, including the drivers of clinical trial costs, hurdles in securing funding, and the need for significant change in this regard. The webinar offered insights from different stakeholders and explored potential solutions.

Based on their expertise and understanding of this topic, we had invited the following key speakers from the BIG and EORTC networks:

### **David Cameron, MD, PhD**

*BIG Chair*

*Professor of Oncology at Edinburgh University, UK*

Works at the National Health Service (NHS) Lothian's cancer centre treating breast cancer patients. He is the joint lead for the Edinburgh Experimental Cancer Medicine Centre. He also holds a part-time deputy director role in the Scottish Government-funded Innovative Health Care Delivery Programme (IHDP). This programme aims to improve access to and the use of routine cancer patient data within NHS Scotland.



“Breast cancer is the most frequently diagnosed cancer in women, representing 1 in 4 cancer cases diagnosed in women globally. Although it is a rare disease in men, accounting for around 1% of new breast cancer cases diagnosed each year, incidence amongst men has increased over time. Research is a lifesaver, but it comes at an increasing cost. Securing funding is now more challenging than ever for academic organisations conducting critical research. This funding is crucial as it allows organisations like BIG and the EORTC to address, without commercial interest, those questions that matter to those who have to confront this disease.”

### **Theodora Goulioti, MD**

*BIG Headquarters CEO, Brussels, Belgium*

In partnership with the BIG Executive Board, is responsible for overseeing the successful execution of BIG's strategy as a research association, in particular

from the day-to-day management perspective. Leads the BIG HQ team, consisting of about 45 passionate and committed people who work on behalf of BIG's Executive Board and BIG's General Assembly. *BIG against breast cancer*, BIG's dedicated philanthropy unit within BIG HQ, conducts vital fundraising to support BIG's clinical trials and research programmes without commercial interest.



“Each year, ± 2.3 million people worldwide are diagnosed with breast cancer. Belgium has the highest incidence, with 11,319 women and 113 men diagnosed in 2021. In our quest for breast cancer research funding, it's vital to get the BIGger picture of the fundraising landscape, including historical and current funding resources. Today, post-Covid, amid challenges like rising inflation and global conflicts, fundraisers tirelessly strive to secure even a fraction of the substantial funding required for non-commercial academic studies. With increasing demands for resources across important social causes, the EORTC and BIG (and its philanthropy unit *BIG against breast cancer*) are even more committed to their mission: securing necessary funding and make a meaningful impact on the lives of millions of breast cancer patients and their families.”

### **Vassilis Golfopoulos, MD, PhD**

*EORTC Headquarters Director, Brussels, Belgium*

Oversees the performance and sustainability of the clinical research infrastructure of EORTC. He advises and carries out the scientific and operational strategy of the organisation by leading the scientific, operational, and project management activities of EORTC Headquarters.



“Since 2020, breast cancer has become the most commonly diagnosed type of cancer overall, surpassing the incidence of lung cancer. As we delve into the world of cancer research and funding challenges, it's essential to understand why research costs are so high. These are influenced by various factors even beyond the cost of any drugs, such as ensuring

regulatory compliance, being in step with privacy legislation, shipment and storage of biological samples, among many other aspects. Obtaining necessary funding has become progressively challenging and poses a significant obstacle for academic organisations conducting international research, such as BIG and the EORTC. There's a clear need for urgent change in this regard. By understanding the cost drivers and the significant challenges we face, we can pave the way for more effective strategies in funding and conducting academic breast cancer research.”

### **Ines Vaz-Luis, MD, PhD**

*Member of BIG's Executive Board*

*Member of UCBG (Unicancer Breast Group, France)*

*Medical oncologist and patient-oriented clinical researcher  
Institut Gustave Roussy, Paris, France*

Leads an innovative research group focusing on survivorship in both clinical practice and research. Her research and group are fully and independently financed by public, private, and philanthropic entities.



“Over the course of their lifetime, about 1 in 8 women and 1 in 800 men will be diagnosed with breast cancer. As a medical oncologist and patient-oriented clinical researcher, I have the privilege of leading an innovative French research group that focuses on breast cancer survivorship. Over the years, we've successfully navigated various funding models, obtaining financial support from public, private, and philanthropic sources. Drawing inspiration from the French example, I believe there are ideas and solutions that can be applied more broadly to secure crucial resources, and to fuel the vital work of the almost 60 academic groups and affiliated breast cancer experts and researchers within the BIG and EORTC networks. Together, we can make a profound impact on the lives of countless individuals affected by this disease.”

>> In case you weren't able to attend this event, a full replay of the Pink October BIG-EORTC webinar is now available [here](#).

>> See also themed article on "Overcoming the challenges of funding academic breast cancer research", [page 2-10](#)



## KEY MESSAGES OF THE WEBINAR

**Academic breast cancer research looks for answers to questions about the causes, diagnosis and treatment of breast cancer that are most important for patients, irrespective of business or commercial considerations.**

- 1 Getting funding for academic breast cancer research is more challenging than ever before because:
  - > Studies are more complex and expensive to run than they used to be
  - > Breast cancer researchers must compete for funding with research into many other diseases, including Covid-19
  - > The global financial crisis, wars and recent natural disasters mean there is less money for medical research
  - > Some people think that breast cancer is 'solved' – but it isn't ... yet
- 2 Academic breast cancer research is funded mainly by multinational initiatives (e.g. the European Commission), national governments (e.g., USA, France, UK), philanthropic organisations (e.g. Breast Cancer Research Fund), and charities, foundations, and individual institutions
- 3 Funding is needed for a wide range of research expenses including hospital infrastructure, offices, salaries and administration, as well as supplies of medicines, equipment, and services (e.g., tumour sample collection, transport, storage, and analysis)
- 4 Research grants are fixed, but costs often increase during a trial, and this makes budgeting very difficult
- 5 Research organisations such as BIG and EORTC are actively trying to limit costs while maintaining research quality. Future avenues include:
  - > Simplifying and decentralising clinical trials so there are fewer overheads and less administration
  - > Introducing more telehealth/online consultations – reducing the need for clinics
  - > Enabling tests and scans to be done at local hospitals, not just at larger centres
  - > Helping more patients to have trial treatment and monitor their health at home
  - > Using digital tools to collect and process data and reduce time-consuming paper-based reporting and analysis
- 6 These changes will make it easier and more convenient for patients to take part in clinical trials, and make studies more inclusive – bringing research opportunities to patients wherever they live and irrespective of their age, general health, socioeconomic or ethnic background
- 7 Achieving funding for academic breast cancer research is not only about reducing costs, it is also about designing the best possible studies and convincing funding partners of the value of investment. It means being innovative and creative, relevant, and rigorous. It means involving patients and benefiting from their insights. It means working incredibly hard and establishing a strong track record of performing high quality research. It means being prepared for rejection – and always ready to try again!

**TWO NEW EBCC-14 AWARDS (€5000 EACH)**

**Multidisciplinary Team Award**

**Young Investigator Innovation Award**

**SUBMIT YOUR ABSTRACT**

**15 November 2023**

---



[www.eortc.org/ebcc](http://www.eortc.org/ebcc)

**20 - 22 March 2024**

**Milan, Italy**





## New Awards At EBCC-14

Together with the EBC Council, we have worked very hard to provide participants with the opportunity to have their work recognised by the Breast Cancer Community, by offering prestigious awards to participants and their team.

### The European Breast Cancer Council Multidisciplinary Team Award (EBCC MTEA)

#### What is it?

A new prestigious award for a multidisciplinary team conducting impactful research related to breast cancer.

#### Why?

The European Breast Cancer Conference prides itself on offering state-of-the-art education, but this year we also want to provide a forum for original research to be presented.

EBCC-14 aims to attract high quality original multidisciplinary research in breast cancer. The main topic of EBCC-14 will be research and innovation in the multidisciplinary management of breast cancer. For this reason, we are launching the prestigious EBCC MTEA.

#### Who is eligible?

Multidisciplinary teams that submit an original research abstract to EBCC-14 in the fields of medical oncology, surgical oncology, radiotherapy, medical imaging, survivorship, translational and basic research, and healthcare research related to breast cancer not previously published or presented in another conference. The work needs to be multidisciplinary.

#### What does EBCC MTEA provide?

The multidisciplinary team award recipients will receive 5,000 EUR, free travel arrangements, accommodation, registration to the conference and an invitation to the faculty dinner for 3 people.

#### How do I apply?

To apply, you will first need to [submit an abstract](#). Please note on the application that you wish to be considered for this award.

Deadline for Abstract Submission is **15 November 2023**.

#### What is the EBCC MTEA selection procedure?

The **EBCC scientific committee** that has reviewed all the abstracts submitted to EBCC will provide to the **EBCC MTEA selection committee** a list of the top submitted abstracts that involve multidisciplinary work. The **EBCC MTEA selection committee** will further select among the top abstracts based on the criteria of excellence, innovation and impact for the patient and the society. Then, the committee will invite the multidisciplinary team of the selected abstract to submit a 2-page outline of the importance of the present work and the next steps the team plans to take. Only one multidisciplinary team will be selected to receive this award.

### The European Breast Cancer Council Young Investigator Innovation Award (EBCC YIIA)

#### What is it?

A new prestigious award in medical oncology, surgical oncology, radiotherapy, medical imaging, survivorship, translational and basic research, and healthcare research related to breast cancer.

#### Why?

On top of providing a state-of-the-art educational programme, EBCC-14 aims to attract high-quality original research in the areas of medical oncology, surgical oncology, radiotherapy, medical imaging, survivorship, translational and basic research, and health care research related to breast cancer. The main topic of the conference is 'research and innovation in the multidisciplinary management of breast cancer'.

#### Who is eligible?

Early and mid-career investigators up to 45 years of age that submit an original research abstract to EBCC-14 in the fields of medical oncology, surgical oncology, radiotherapy, medical imaging, survivorship, translational and basic research, and healthcare research related to breast cancer not previously published or presented in another conference.

#### What does EBCC YIIA provide?

The winner of the EBCC YIIA award will receive 5'000 EUR, free travel arrangements, accommodation, registration to the conference and an invitation to the faculty dinner.

#### How do I apply?

To apply, you will first need to [submit an abstract](#). Please note on the application that you wish to be considered for this award.

Deadline for Abstract Submission is **15 November 2023**.

#### What is the EBCC YIIA selection procedure?

The **EBCC scientific committee** that has reviewed all the abstracts submitted to EBCC will provide to the **EBCC YIIA selection committee** a list of the top submitted abstracts. The **EBCC YIIA selection committee** will further select among the top abstracts based on the criteria of excellence, innovation and impact for the patient and the society. Then, the committee will invite the author of the selected abstract to submit a 5-page CV and a 2-page outline of the importance of the present work and the next steps she/he plans to take. Only one candidate will be retained to receive this award.

#1

# BIG TRIAL UPDATES



## AURORA 2.0

### A New Chapter in Metastatic Breast Cancer Research

Speeding up the pace towards unravelling the mysteries of metastatic breast cancer, the Breast International Group has announced the launch of AURORA 2.0, the extension phase of its AURORA study. This new phase will focus on triple-negative breast cancer (TNBC), invasive lobular carcinoma (ILC), and patients experiencing late relapses. Notably, the intention is to include 252 patients, who will be followed-up for up to 5 years. Combining the data from this group of patients with the data from patients already included in AURORA will allow more in-depth investigation of these challenging breast cancer types.

#### Global Collaboration

Like the first phase of the study, AURORA 2.0 is a testament to international collaboration, uniting 17 hospitals from seven BIG research groups spanning eight different European countries. The study team is finalising documentation for site activation and the resumption of patient recruitment, with the first patient expected to be included by the end of the last quarter of 2023.

#### Data Sharing for Progress

In a commitment to transparency and shared knowledge, clinical and molecular data from the AURORA study's inaugural manuscript, published in *Cancer Discovery* in 2021\* and featuring insights from 381 patients, has been made accessible to researchers who wish to reproduce these analyses or conduct original research. A dedicated website (<https://aurora.bigagainstbreastcancer.org/>) has been established to facilitate access to this invaluable dataset, as well as to enable researchers to submit research proposals. These proposals are carefully reviewed and approved by a scientific committee to ensure adequacy of the request, prior to agreeing on the legal framework necessary for data sharing. As of the present writing, 8 new research proposals have been approved and one has already

led to a research manuscript, currently under internal review. Work is ongoing to share the dataset from the full cohort of included patients.

With the generous support of the [Breast Cancer Research Foundation](#) (BCRF), BIG and the NCI National Clinical Trials Network (NCTN) – the latter a network of major US and Canadian-based research groups supported by the US National Cancer Institute (NCI) – have been meeting annually and in topic-specific working groups since 2005. AURORA (and its extension) evolved in this context, and North American colleagues have been conducting similar work (AURORA-US). This cross-Atlantic collaboration will extend into the future, resulting in the sharing of additional data that promise to provide deeper insights into metastatic breast cancer.

#### Paving the Way for Breakthroughs

BIG's Core Data Analysis Committee for AURORA, comprising a diverse team of bio-informaticians and clinical experts, has been segmented into nine topic-specific working groups, each dedicated to various research areas. 2023 has already marked several exciting developments, with different publications such as:

- Caballero C, Irrthum A, Goulioti T, et al. International research to address the challenges of metastatic breast cancer: the AURORA Program (BIG 14-01), *npj breast cancer*. 2023;9(1):1-5. doi:[10.1038/s41523-023-00548-9](https://doi.org/10.1038/s41523-023-00548-9)
- Hilbers F, Venet D, Agostinnetto E, et al. Characterization of the immune microenvironment in matched primary and metastatic breast cancer lesions from the AURORA study: BIG 14-01, *Journal of Clinical Oncology*. 2023;41(16\_suppl):1009-1009. doi:[10.1200/JCO.2023.41.16\\_suppl.1009](https://doi.org/10.1200/JCO.2023.41.16_suppl.1009)
- Agostinnetto E, Sotiriou C, Ignatiadis M, et al. Clinico-molecular characteristics associated with outcomes in breast cancer patients treated with CDK4/6 inhibitors: Results from the AURORA

Molecular Screening Initiative, *Journal of Clinical Oncology*. 2023;41(16):1019-1019. doi:[10.1200/JCO.2023.41.16\\_suppl.1019](https://doi.org/10.1200/JCO.2023.41.16_suppl.1019)

Additionally, the second main manuscript for AURORA is being elaborated, which aims to incorporate data from the entire cohort of patients, totaling 1,156 individuals. Its publication is anticipated in 2024.

### **A Beacon of Hope**

With these promising strides, the AURORA study remains at the forefront of metastatic breast cancer

research, offering hope to patients and researchers worldwide. The collaboration between multiple countries, research groups, and clinical experts underscores the power of collective efforts in the relentless search for better understanding, better treatments, and ultimately cures against breast cancer. AURORA 2.0 marks a pivotal chapter in this ongoing quest, bringing us closer to the day when we can conquer this devastating disease and save countless lives.



# RECENT PUBLICATIONS ON BIG TRIALS

## AURORA (BIG 14-01)

> Agostinetti E, Sotiriou C, Ignatiadis M, et al. Clinico-molecular characteristics associated with outcomes in breast cancer patients treated with CDK4/6 inhibitors: Results from the AURORA Molecular Screening Initiative, *Journal of Clinical Oncology*. 2023;41(16\_suppl):1019-1019. doi:[10.1200/JCO.2023.41.16\\_suppl.1019](https://doi.org/10.1200/JCO.2023.41.16_suppl.1019)

> Caballero C, Irrthum A, Goulioti T, et al. International research to address the challenges of metastatic breast cancer: the AURORA Program (BIG 14-01), *npj breast cancer*. 2023;9(1):1-5. doi:[10.1038/s41523-023-00548-9](https://doi.org/10.1038/s41523-023-00548-9)

> Hilbers F, Venet D, Agostinetti E, et al. Characterization of the immune microenvironment in matched primary and metastatic breast cancer lesions from the AURORA study: BIG 14-01, *Journal of Clinical Oncology*. 2023;41(16\_suppl):1009-1009. doi:[10.1200/JCO.2023.41.16\\_suppl.1009](https://doi.org/10.1200/JCO.2023.41.16_suppl.1009)

## DECRESCENDO (BIG 19-02)

> Debieu V, Adam V, Coart E, et al. DECRESCENDO: de-escalating chemotherapy in HER2-positive, estrogen receptor-negative, node-negative early breast cancer, *Future Oncology*, 2023;19(24):1655-1667. doi:[10.2217/fon-2022-1282](https://doi.org/10.2217/fon-2022-1282)

## NeoALTTO (BIG 1-06)

> Lambertini M, Ceppi M, Anderson RA, et al. Impact of Anti-HER2 Therapy Alone and With Weekly Paclitaxel on the Ovarian Reserve of Young Women With HER2-Positive Breast Cancer, *Journal of the National Comprehensive Cancer Network*. 2023;21(1):33-41.e16. doi:[10.6004/jnccn.2022.7065](https://doi.org/10.6004/jnccn.2022.7065)



> Singer CF, König F, Kacarovsky-Strobl S, et al. Association of HER2/CEP17 ratio with pCR after HER2-directed neoadjuvant treatments in the phase III NeoALTTO trial, *Journal of Clinical Oncology*. 2023;41(16\_suppl):600-600. doi:[10.1200/JCO.2023.41.16\\_suppl.600](https://doi.org/10.1200/JCO.2023.41.16_suppl.600)

## OlympiA (BIG 6-13)

> Yamauchi H, Toi M, Takayama S, et al. Adjuvant olaparib in the subset of patients from Japan with BRCA1- or BRCA2-mutated high-risk early breast cancer from the phase 3 OlympiA trial, *Breast Cancer*. Published online April 1, 2023. doi:[10.1007/s12282-023-01451-8](https://doi.org/10.1007/s12282-023-01451-8)

## PALLAS (BIG 14-03)

> Pfeiler G, Hlauschek D, Mayer EL, et al. Impact of BMI in Patients With Early Hormone Receptor-Positive Breast Cancer Receiving Endocrine Therapy With or Without Palbociclib in the PALLAS Trial, *Journal of Clinical Oncology*. Published online August 9, 2023. doi:[10.1200/JCO.23.00126](https://doi.org/10.1200/JCO.23.00126)

## SOFT (BIG 2-02)

> Luen SJ, Viale G, Nik-Zainal S, et al. Genomic characterisation of hormone receptor-positive breast cancer arising in very young women, *Annals of Oncology*. 2023;0(0). doi:[10.1016/j.annonc.2023.01.009](https://doi.org/10.1016/j.annonc.2023.01.009)

# 2

# BIG AT CONFERENCES



## GLOBAL BREAST CANCER CONFERENCE (SEOUL, KOREA) FROM 27 -29 APRIL 2023

Exciting news from GBCC2023! BIG proudly participated in the Asian Breast Cancer Network's panel discussion. The session, "Beyond Borders," emphasised the power of international collaborations and overcoming practical obstacles in breast cancer research.



©GBCC

## 2023 ASCO ANNUAL MEETING

## ASCO 2023 ANNUAL MEETING (CHICAGO, IL, USA) FROM 2 TO 6 JUNE 2023

### AURORA (BIG 1-14)

["Characterisation of the immune microenvironment in matched primary and metastatic breast cancer lesions from the AURORA study: BIG 14-01"](#).

The multi-omics characterisation of the immune landscape of metastatic breast cancer in the AURORA programme brings novel insights that could help understand the mechanisms behind tumour immune response and immunotherapy failure. This analysis was presented in the Dr. Bernard Fisher Memorial Annual Clinical Science Symposium: Harnessing the Breast Cancer Immune Response.



Presentation at the Dr. Bernard Fisher Memorial Annual Clinical Science Symposium, by Florentine Hilbers: Immune WG Abstract (1009) entitled *Characterization of the immune microenvironment in matched primary and metastatic breast cancer lesions from the AURORA study: BIG 14-01*.

“Clinico-molecular characteristics associated with outcomes in breast cancer patients treated with CDK4/6 inhibitors: Results from the AURORA Molecular Screening Initiative”.

Awarded with a Merit Award, this poster presented the analysis of data from 339 AURORA patients treated with CDK4/6 inhibitors (CDK4/6i) in combination with endocrine therapy as their first-line treatment. The researchers sequenced the DNA from both the primary and metastatic tumour lesions and the germline DNA, analysing a total of 411 cancer-related genes.

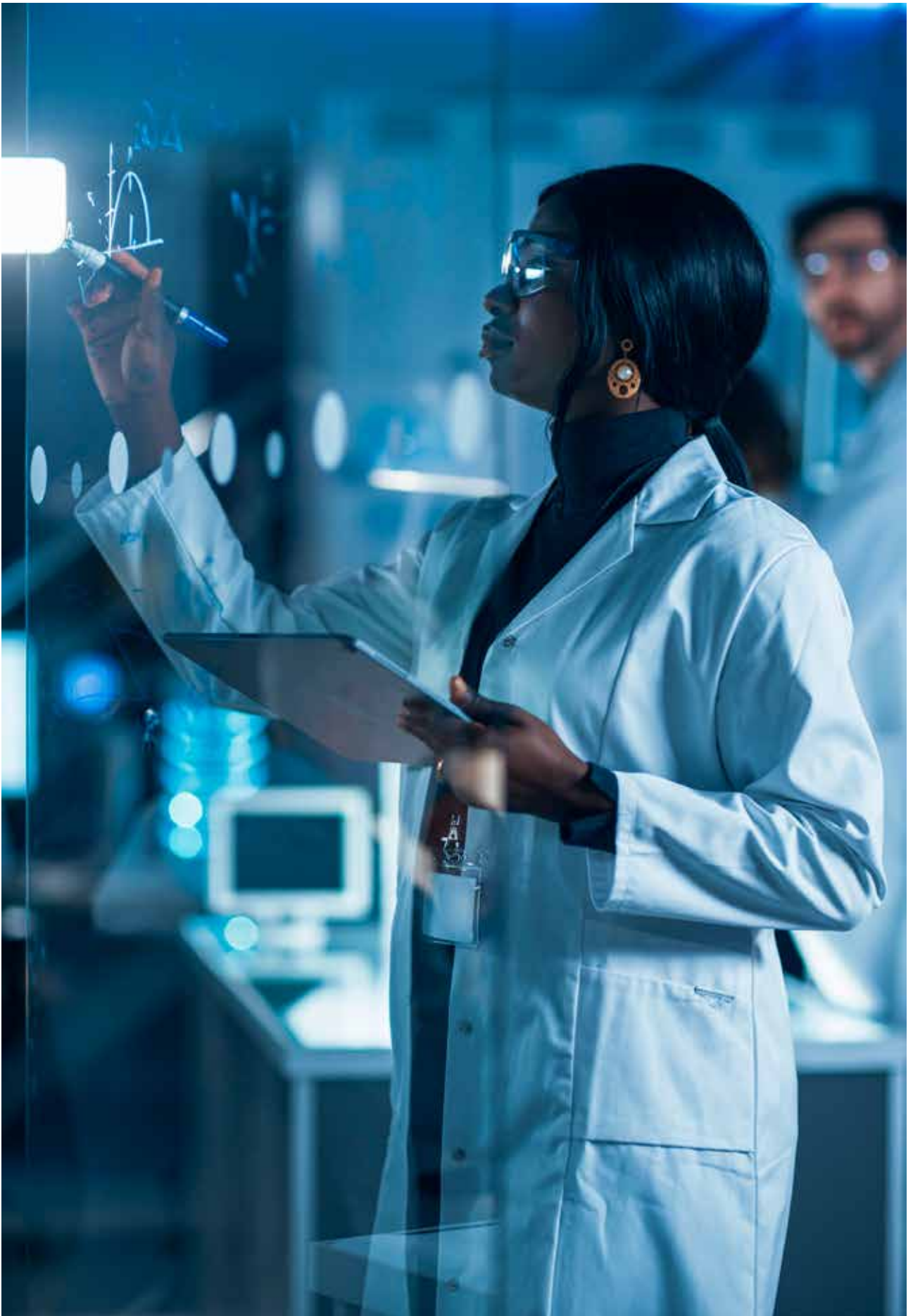


## NeoALTTO (BIG 1-06)

The NeoALTTO study focused on comparing the efficacy of neoadjuvant lapatinib plus paclitaxel, versus trastuzumab plus paclitaxel, versus concomitant lapatinib and trastuzumab plus paclitaxel given as neoadjuvant treatment in HER2/ErbB2 over-expressing and/or amplified primary breast cancer. A NeoALTTO-related translational research project was presented as a poster: [“Association of HER2/CEP17 ratio with pCR after HER2-directed neoadjuvant treatments in the phase III NeoALTTO trial”](#). The authors found that analysing the pre-treatment HER2/CEP17 ratio using FISH (Fluorescence In Situ Hybridisation) in breast cancer patients treated with HER2-based neo-adjuvant therapy can predict pathological complete response (pCR), but not event-free survival (EFS). This research provides valuable insights into treatment response prediction in breast cancer patients.

## SOFT (BIG 2-02)

The PAM50 ROR (Risk of Recurrence) score, as evaluated in the SOFT trial, serves as a prognostic indicator for premenopausal patients with hormone receptor-positive (HR+), HER2-negative early-stage breast cancer. However, it is not predictive of the benefits of ovarian function suppression (OFS) treatment. Notably, a majority of premenopausal women with lymph node involvement (N+) showed high-risk ROR scores, and among the very young patients, there was a prevalence of more aggressive disease biology. This information highlights the significance of ROR scoring in assessing prognosis and the potential differences in disease characteristics among specific patient groups. These findings were described in an oral presentation: [“Evaluation of PAM50 intrinsic subtypes and risk of recurrence \(ROR\) scores in premenopausal women with early-stage HR+ breast cancer: A secondary analysis of the SOFT trial”](#).



# 3

# OTHER TRIALS AND ACTIVITIES BY BIG MEMBER GROUPS

## ABCSG

### AUSTRIAN BREAST AND COLORECTAL CANCER STUDY GROUP

#### ABCSG 52 / ATHENE trial - successful recruitment during COVID-19 pandemic and very promising trial results

In the open-label, two-arm, randomised, single-stage phase II study **ABCSG 52 / ATHENE**, a neoadjuvant **chemotherapy de-escalation immunotherapy escalation** regimen with trastuzumab, pertuzumab, atezolizumab and epirubicin was investigated. Patients with previously untreated HER2-positive early breast cancer were randomised 1:1 to two 3-weekly cycles of a chemotherapy-free induction phase (part 1) with trastuzumab and pertuzumab (TP) plus atezolizumab (TP+A) or TP alone. Afterwards, all patients received 4 cycles of TP+A in combination with epirubicin (part 2). The primary endpoint was pathological complete response (pCR) in the overall study population. Based on clinical data from the NeoSphere trial and statistical and medical expert opinion, a pCR rate of  $\geq 40\%$  was considered as a positive trial result.

**Patients were recruited as projected** between 3 July 2020 (first enrolment) and 30 May 2022 (last patient last visit) in 9 Austrian trial centres. **No important protocol deviation occurred due to COVID-19.** At least one non-important protocol deviation due to the pandemic occurred in 3 patients. These deviations were related to surgery visits only, due to time-window deviation.

Primary endpoint results were presented by Professor Gabriel Rinnerthaler at the best abstract session at ESMO Breast 2023. Overall, 58 patients were randomised to TP-A (n=29) or TP (n=29). Median age was 57 (range 33-82), 16 patients (27.6%) had hormone-receptor (HR)-negative and 42 (72.4%) had HR-positive tumours. 45 patients (77.6%) had stage  $\leq$  IIA and 13 (22.4%)  $\geq$  IIB. In 35 patients a pCR was observed (60.3%; 95%CI 47.5% to

71.9%), 19 (65.5%) in the TP-A group and 16 (55.2%) in TP group ( $\Delta$  10.3%; 95%CI -14.7% to 35.4%). Treatment emergent adverse events (AEs) grade  $\geq 3$  were reported in 17 patients (29.3%), 9 in TP-A group and (31.0%) and 8 (27.6%) in TP group. In PD-L1-negative patients, pCR rate was 69.2% (N=18/26; 95%CI 50.0% to 83.5%) compared to 55.2% (N=16/29; 95% CI 37.5% to 71.6%) in PD-L1-positive patients. No AEs of special interest (immune-related AEs, cardiac disorders grade  $\geq 2$ , or infusion-related reactions) grade  $\geq 3$  were detected.

The authors concluded that for HER2-positive EBC, a neoadjuvant chemotherapy de-escalation immunotherapy regimen with trastuzumab, pertuzumab, atezolizumab, and epirubicin is highly effective and safe and merits further investigation. The highest benefit was shown in PD-L1-negative patients.

At the San Antonio Breast Cancer Conference 2023, a secondary analysis regarding pCR according to early metabolic remission in an interim FDG-PET scan and to tumour infiltrating lymphocytes will be presented.

The successful recruitment and conduct of this trial during the pandemic demonstrates that good clinical research is possible even under difficult conditions. This is possible thanks to a well-organised trial structure, intrinsically motivated investigators, and the participation of patients who are aware of the importance of clinical trials.



*Contribution by Professor Gabriel Rinnerthaler, 3rd Medical Department, University Hospital Salzburg, Austria. Member of the ABCSG General Assembly. ●*



## EORTC BCG EUROPEAN ORGANISATION FOR RESEARCH AND TREATMENT OF CANCER – BREAST CANCER GROUP

The EORTC Breast Cancer Group (BCG) is a group of the most important academic hospitals in Europe aiming to develop new standards of care for breast cancer patients through innovation. Our research focus is the evaluation of innovative treatments and multidisciplinary approaches to increase survival and improve the quality of life of all breast cancer patients.

### Events:

- > **28-29 September 2023: The BCG Autumn retreat and group meeting dedicated to Locoregional therapy.**
- > **15-21 June 2024: 24th Workshop on Methods in Clinical Cancer Research (MCCR)**, Sint Michielgestel, the Netherlands. Applications for this workshop will open from December 2023 to February 2024. More information is available on the EBCC website: <https://www.eortc.org/event/24th-workshop-on-methods-in-clinical-cancer-research-mccr/>
- > **20-22 March 2024 - EBCC-14**, Milan, Italy. More information is available on the EBCC website: [Home - EBCC 14 \(eortc.org\)](#). Abstract submission deadline: 15 November 2023.

### Recent publications:

- > Bartels S, Donker M, Poncet C, et al. Radiotherapy or Surgery of the Axilla after a Positive Sentinel Node in Breast Cancer: 10 year Results of the Randomised Controlled EORTC 10981-22023 AMAROS Trial. *Journal of Clinical Oncology*, 2023;41 (12):2159-2165. doi: [10.1200/JCO.22.01565](https://doi.org/10.1200/JCO.22.01565)
- > Schröder C, van Leeuwen-Stok E, Cardoso F, et al. Quality of life (QoL) in male breast cancer (BC): Prospective study of the International Male BC Program (EORTC10085/TBCRC029/BIG2-07/NABCG). *The Oncologist*, Volume 28, Issue 10, October 2023, Pages e877-e883. Doi: [10.1093/oncolo/oyad152](https://doi.org/10.1093/oncolo/oyad152)
- > Pasquier D, Bidaut L, Oprea-Lager DE, et al. Designing clinical trials based on modern imaging and metastasis-directed treatments in patients with oligometastatic breast cancer: a consensus

recommendation from the EORTC Imaging and Breast Cancer Groups. *The Lancet Oncology*, August, 2023. Doi: [10.1016/S1470-2045\(23\)00286-3](https://doi.org/10.1016/S1470-2045(23)00286-3)

- > EORTC BCG has contributed to several recent meta-analyses through data sharing of clinical data:
  - Early Breast Cancer Trialists' Collaborative Group (EBCTCG). Anthracycline-containing and taxane-containing chemotherapy for early-stage operable breast cancer: a patient-level meta-analysis of 100 000 women from 86 randomised trials. *Lancet*. 2023 Apr 15;401(10384):1277-1292. doi: [10.1016/S0140-6736\(23\)00285-4](https://doi.org/10.1016/S0140-6736(23)00285-4)
  - CTNeoBC Project. Re-Evaluation of Pathologic Complete Response as a Surrogate for Event-Free and Overall Survival in Human Epidermal Growth Factor Receptor 2-Positive, Early Breast Cancer Treated With Neoadjuvant Therapy Including Anti-Human Epidermal Growth Factor Receptor 2 Therapy. *J Clin Oncol*. 2023 Jun 1;41(16):2988-2997. doi: [10.1200/JCO.22.02363](https://doi.org/10.1200/JCO.22.02363).
  - CTNeoBC Project Pathologic Complete Response and Individual Patient Prognosis After Neoadjuvant Chemotherapy Plus Anti-Human Epidermal Growth Factor Receptor 2 Therapy of Human Epidermal Growth Factor Receptor 2-Positive Early Breast Cancer. *J Clin Oncol*. 2023 Jun 1;41(16):2998-3008. doi: [10.1200/JCO.22.02241](https://doi.org/10.1200/JCO.22.02241). Epub 2023 Apr 19.

### Main studies in development:

**EORTC-1984-BCG (BIG 6-13): Neoadjuvant Olaparib and Durvalumab for patients with BRCA-associated Triple Negative Breast Cancer (NOBLE):** Study coordinator: Etienne Brain. Young study coordinator: Anne-Sophie Hamy Petit.

This is a multicentre randomised phase II clinical trial to evaluate the efficacy of olaparib alone or olaparib and durvalumab as neoadjuvant treatment in patients with triple negative breast and cancer and carrying a tBRCA mutation or HRD+ profile based on methylation. This trial will be conducted in collaboration with different groups within the BIG network. The recruitment is expected to start soon. A Trial in Progress poster will be presented at ESMO 2023.

### **EORTC-2129-BCG TREAT ctDNA (BIG 1-12): Elacestrant for ctDNA-positive ER+/HER2- BC:**

Study coordinator: Michail Ignatiadis; Study Co-coordinators: Emmanouil Saloustros and Wolfgang Janni.

This phase III study aims to evaluate whether elacestrant can delay occurrence of distant metastasis or death when compared to current adjuvant endocrine therapy in patients with ER+/HER2- breast cancer and with late ctDNA-relapse, treated with adjuvant endocrine therapy. Patients will be randomised after a positive ctDNA test during the screening period and after confirmation by imaging of the absence of distant metastasis or locoregional recurrence.

This trial will be conducted in collaboration with different groups, including from within the BIG network. The study is under evaluation by health authorities and ethics committees.

#### **Active studies, recruiting:**

##### **RP-1828 (IMMUcan)**

IMMUcan is a downstream project of the SPECTA platform. The goal is to generate broad molecular (WES and RNAseq) and cellular profiling data (multiplex IF and IHC) of the tumour and its microenvironment from cancer patients integrated with clinical data, to understand how the immune system and tumours interact, and the impact of current therapeutic interventions. A molecular report with all clinically targetable molecular alterations will be returned to clinicians. Three cohorts of adult patients with breast cancer treated with standard of care have been opened for recruitment:

- > **Cohort 1:** patients with confirmed locally advanced or metastatic triple negative breast cancer (TNBC), naïve of treatment (in metastatic settings), to be treated with immune checkpoints inhibitor (1st line or 2nd line in patients resistant to platinum) or immune checkpoint inhibitor - chemo.
- > **Cohort 2:** patients with confirmed diagnosis of localised TNBC (stage I to III), to be treated with neo-adjuvant chemotherapy, enrolled prior to neo-adjuvant chemotherapy.
- > **Cohort 3:** patients with confirmed diagnostic of localised HER2+ (stage I to III) breast cancer, to be treated with neo-adjuvant chemotherapy, enrolled prior to neo-adjuvant chemotherapy.

Recruitment started in May, 2019. As of 6 September 2023, 1,055 patients had been enrolled in IMMUcan, including 554 patients with breast cancer). Collaboration with the Institute Jules Bordet's Synergy trial is currently ongoing for the analysis of materials from 84 patients with mTNBC. End of recruitment is expected in August 2024.

##### **EORTC-1811 (E<sup>2</sup>-RADIatE)**

The EORTC-ESTRO radiotherapy registry/platform was launched on 25 June 2019. This multi-cohort platform aims to collect real-world data of cancer patients treated with radiotherapy. This platform includes two cohorts:

###### **> RP-1822 OligoCare cohort**

This observational cohort evaluates radical radiotherapy for oligometastatic lung, breast, prostate or colorectal cancer patients. As of 6 September 2023, 2,245 patients were enrolled in 55 sites in 11 countries, including 318 (14%) patients with oligometastases from their breast cancer.

###### **> RP-2011 ReCare cohort**

The objective of this cohort is to evaluate patients treated with high-dose Re-irradiation. The first site was authorised on 15 June 2023. As of 6 September 2023, 5 sites (out of a selected total of 26) had been authorised for recruitment and 12 patients were enrolled. ●

## FSS FRONTIER SCIENCE SCOTLAND

### About Us

At Frontier Science Scotland (FSS), we are delighted to have recently become BIG's 59th member. We've been working with BIG since becoming involved with the HERA trial in 2002, and we are looking forward to plenty of future collaboration within the BIG network.

We're a team of 30+ committed individuals united in our goal of working on projects that lead to public benefit, and we have worldwide customers in industry, academia, and health services. Our experts in our specialist areas of data management, biostatistics and quality are committed and highly experienced.

We're based in the Highlands of Scotland and enjoy an affiliation with Frontier Science organisations in the United States and Greece. Some of the projects we've worked on over the years include APHINITY, ALTO, HERA, ALEXANDRA and OlympiA.

Like BIG and all its partners, FSS pride ourselves on our educational mission to share and inform the public about all research findings, specifically those which have significant health benefit. In the last six months, we have contributed to two important conferences, Society for Clinical Trials in Baltimore, USA, and Royal Statistical Society in Harrogate, UK.

### **Society for Clinical Trials 44th Annual Meeting (21-24 May 2023), Baltimore**

We presented a session focused on the extensive and bespoke data review processes that led to outstanding and practice-changing results in the OlympiA trial.

FSS was commissioned to manage the data for the Rest of World (RofW), create a consolidated database to merge RofW and United States (US) data, generate CDISC-compliant analysis files and conduct the statistical analysis.

The ability of our team to be flexible and accommodate many changes during the study was one of the contributing factors to its success, as well as the bespoke and robust data review process we developed. Collaboration, excellent communication, and stringent data quality procedures ensured the data across the two distinct data capture systems were consistent and high quality.



At database lock, 99.98% of lab issues and 99.99% of data queries were resolved and anything remaining was risk-assessed by the wider study team as having minimal or no impact on the consolidated database. The study was inspected by the FDA and the PMDA, who found zero data management issues.

### **Royal Statistical Society (RSS) International Conference 2023 (4-7 September 2023)**

Marion Procter and Faye Samy, two FSS statisticians, recently presented a poster sharing the results of a simulation study on the impact of an increase in late patient dropout in a long-term study.

Marion and Faye ran the simulation in the context of an adjuvant breast cancer study in which the (definitive) event-driven analysis of overall survival is several years after the study treatment ends. Dropout rates can increase at a late stage in such trials if patients feel the study results will not change clinical practice. This can then influence the clinical cut-off date (CCOD).

The simulation found that late patient dropout would increase the length of follow-up. Though the delay indicated in the clinical cut-off date was small in relation to the length of the simulation study (over eight years post-randomisation), it highlights the potential impact a late increase in patient dropout has on the CCOD.

*For further information, please visit:*

[www.frontierscience.co.uk](http://www.frontierscience.co.uk) ●

## GEICAM SPANISH BREAST CANCER GROUP

### Tucatinib in combination with trastuzumab and vinorelbine in HER2 metastatic Breast Cancer: TrasTUCAN\_GEICAM/2020-08 study.

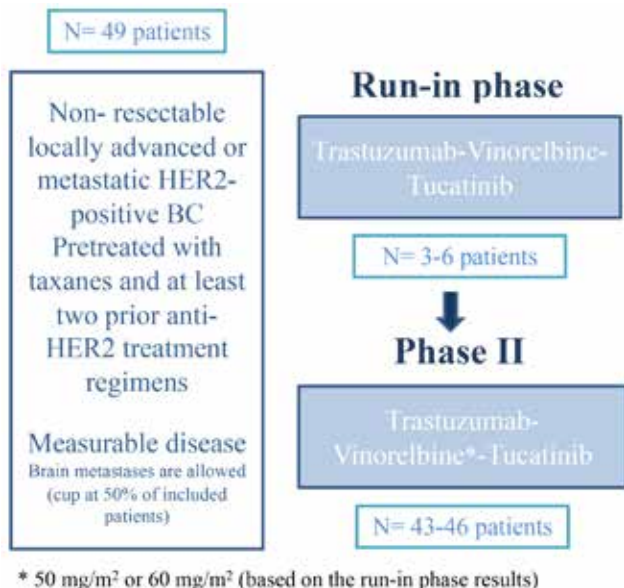
Single arm phase II study of the efficacy and safety of the combination of Trastuzumab plus TUCAtinib plus viNorelbine in patients with HER2-positive non-resectable locally advanced or metastatic breast cancer. (NCT05583110).

The objective of this study is to test the combination of tucatinib plus trastuzumab plus vinorelbine in patients with advanced HER2-positive breast cancer previously treated with taxanes, and at least two prior anti-HER2 treatment regimens. The intent of this phase II trial is to determine if the combination of tucatinib + trastuzumab + vinorelbine is safe and active enough to be used as an alternative option in these patients.

As of this writing, GEICAM was initiating the recruitment phase of this study with the participation of 18 sites across Spain that are expected to include 49 patients (figure 1).

For study information, see [link](#).

Figure 1: TRASTUCAN GEICAM/2020-08 study design



### GEICAM activities in the Oncological Physical Exercise research area: EVAL-ACTIVA study and publication in *Nutrients*

**EVAL-ACTIVA: Validation of the physical activity questionnaires (IPAQ-LF and GSLTPAQ) with accelerometer, as a gold standard test, in breast cancer (BC) patients.**

In this study we want to compare the physical activity (PA) data obtained through the most used self-administered questionnaires in clinical trials: IPAQ (International Physical Activity Questionnaire) and Godin Leisure-Time Exercise Questionnaire (GSLTPAQ), with the objective measurement obtained from the Actigraph® accelerometer. This is a prospective observational study including some different breast cancer cohorts based on disease stage: i.e.: early breast cancer (BC) on neo/adjuvant treatment, early BC during follow-up period, advanced BC, and a specific cohort of male BC patients. We expect to validate the self-administered questionnaires as a reliable tool to measure PA in BC patients. This will enable the use of this cost-effective and practical tool in clinical trials to develop specific training programs for the different stages of BC to improve patient's quality of life (figure 2).

### Publication in *Nutrients*

GEICAM, in collaboration with Universidad Politécnica de Madrid (UPM), recently published a systematic review of the effects of exercise interventions combined with diet and/or dietary supplement interventions on anthropometry, body composition, metabolic biomarkers, physical function, healthy lifestyles, quality of life, psychosocial variables, and fatigue for women with breast cancer.

For study information, see [link](#).

Publication:

Pérez-Bilbao T, Alonso-Dueñas M, Peinado AB, et al. Effects of Combined Interventions of Exercise and Diet or Exercise and Supplementation on Breast Cancer Patients: A Systematic Review. *Nutrients*. 2023 Feb 17;15(4):1013. PMID: 36839371; PMCID: [PMC9964362](#). doi: [10.3390/nu15041013](#).

### ALPHABET (GEICAM/2017-01) VIDEO: encouraging patient's recruitment

GEICAM in collaboration with ETOP IBCSG Partners Foundation, former IBCSG (International Breast Cancer Study Group) and BIG is leading this study, which is a randomised phase III trial of trastuzumab + alpelisib +/- fulvestrant versus trastuzumab + chemotherapy in patients with PIK3CA mutated previously treated HER2+ advanced breast cancer (NCT05063786).

The recruitment is ongoing, and we launched a website and video to encourage patient recruitment: <https://alphabetstudy.com/>. Please feel free to share this information with your followers on social media.

For study information, see [link](#). ●

Figure 2: EVAL-ACTIVA study design

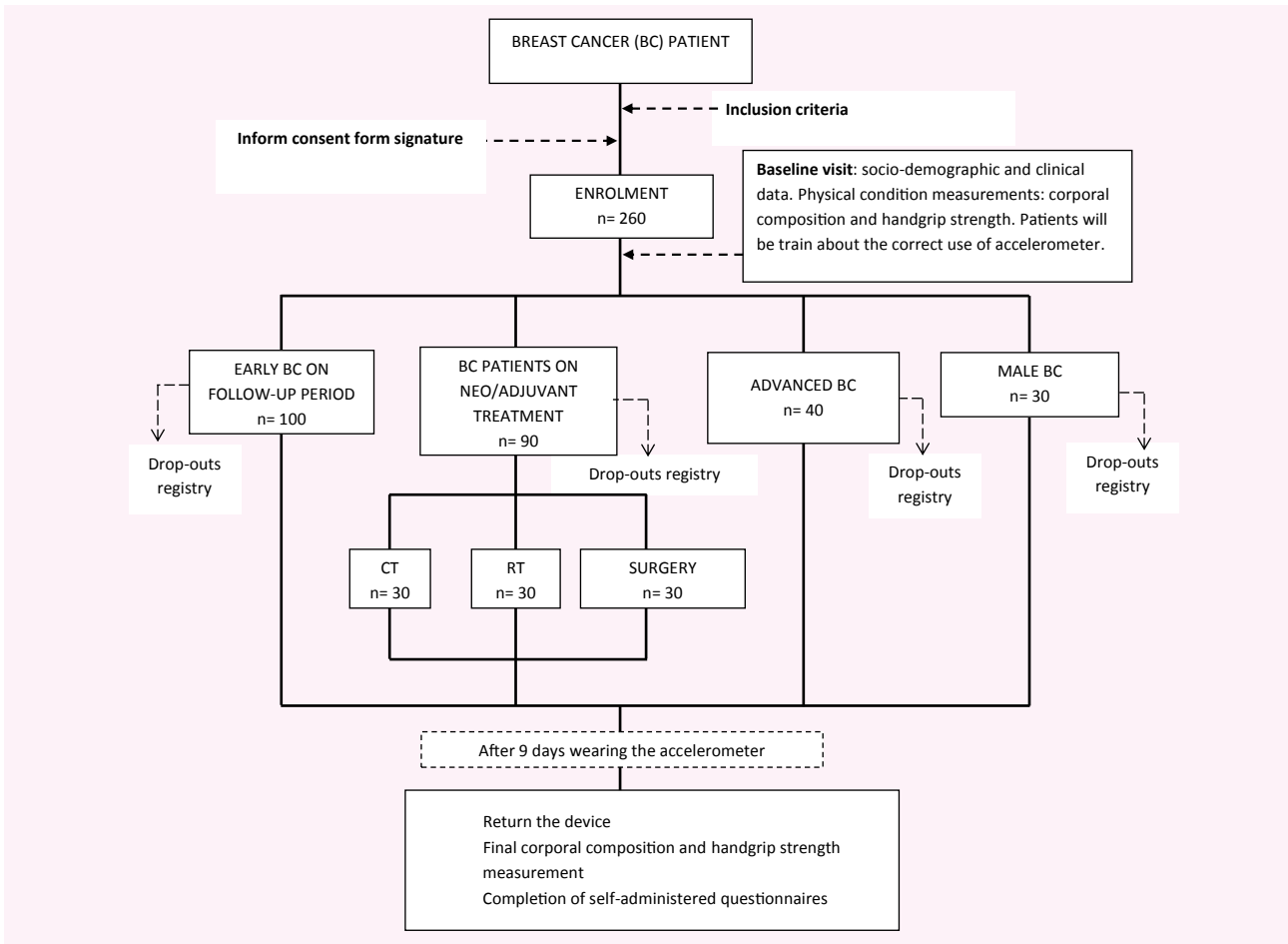
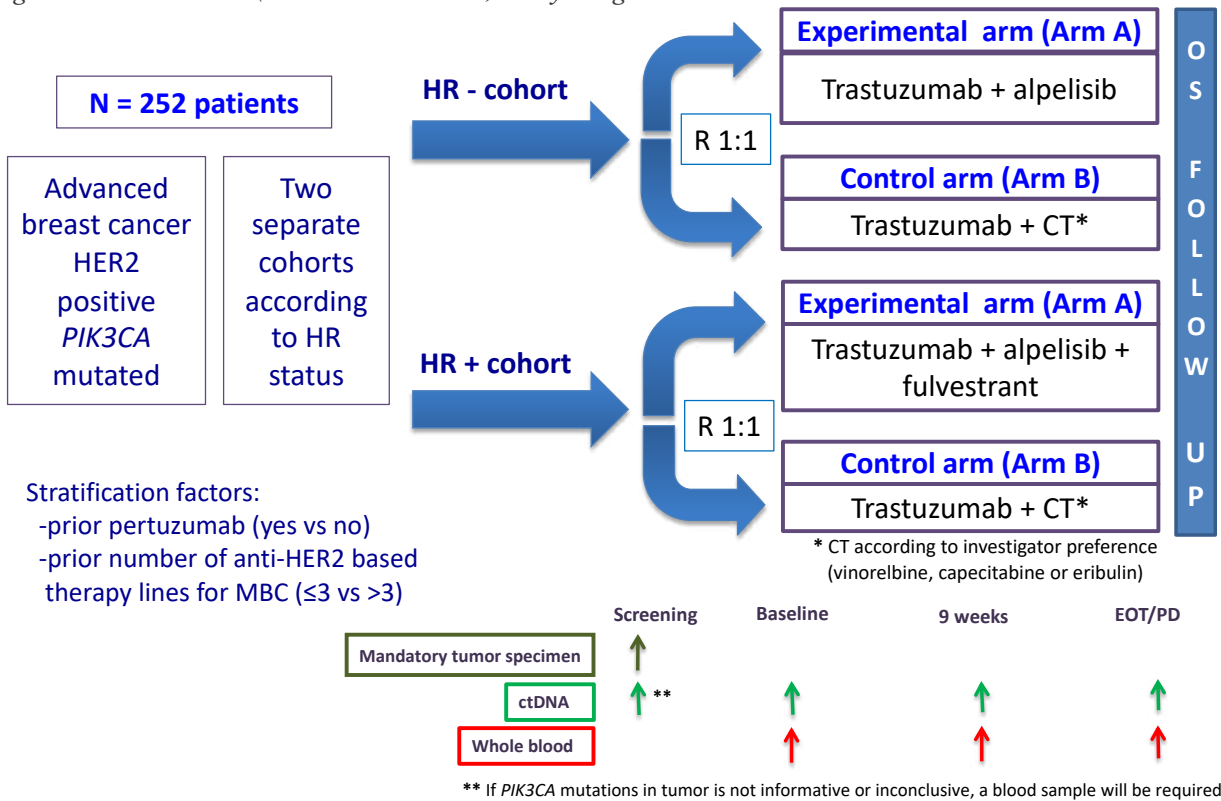


Figure 3: ALPHABET (GEICAM/2017-01) study design



## JBCRG JAPANESE BREAST CANCER RESEARCH GROUP

### Ongoing clinical trials and publications

The **Japanese Breast Cancer Research Group (JBCRG)** is running the following clinical trials:

- **JBCRG-ABCD project:** the Advanced Breast Cancer Database (ABCD) project.
- **JBCRG-C08 (ATTRIBUTE):** ATezolizumab in patients with TRIPle-negative Breast cancer, mUlticenter observational study for Treatment safety and Efficacy.
- **JBCRG-C07-A1 (REIWA2):** an exploratory study,
  - a) using gene expression analysis to assess the predictability of resistance to hormone therapy and chemotherapy sensitivity in luminal breast cancer patients who have a treatment history of CDK4/6 inhibition, and
  - b) investigating patients with luminal or triple negative breast cancer showing FGF•FGFR mutation/ amplification detected using FoundationOne® comprehensive gene expression analysis.
- **JBCRG-M08 (AMBER):** innovation of the 1st line strategy optimised as abemaciclib with endocrine therapy based on the ESR1 mutation of ctDNA for HR-positive HER2-negative advanced metastatic breast cancer patients (JBCRG-M08) – a multi-institutional phase II trial.
- **JBCRG-C09 (OPTIMAL):** Olaparib treatment in metastatic/advanced breast cancer patients using real world data in Japan (OPTIMAL study).

### Presentations at congresses

#### 1) ESMO Breast Cancer 2023 (11-13 May 2023): JBCRG-20

Mini Oral Presentation by Dr. Kenichi Inoue: Long-term outcomes of neoadjuvant trastuzumab emtansine + pertuzumab (T-DM1+P) and docetaxel + carboplatin + trastuzumab + pertuzumab (TCbHP) for HER2-positive primary breast cancer: JBCRG20 study (Neo-peaks).



#### 2) ASCO 2023 (6-10 June 2023): JBCRG-M05

Poster Discussion Presentation by Dr. Yutaka Yamamoto: Pertuzumab retreatment in patients with HER2-positive locally advanced/ metastatic breast cancer: Overall survival results of a phase III randomized trial (JBCRG-M05: PRECIOUS).



### Recent publications

#### 1) JBCRG-M07 in *Breast Cancer Research and Treatment*, 2023

Kenichi Watanabe, Naoki Niikura, et al. Fulvestrant plus palbociclib in advanced or metastatic hormone receptor-positive/ human epidermal growth factor receptor 2-negative breast cancer after fulvestrant monotherapy: Japan Breast Cancer Research Group-M07 (FUTURE trial) *Breast Cancer Research and Treatment*. 2023 Mar; 199: 253–263. <https://doi.org/10.1007/s10549-023-06911-5>

#### 2) OlympiA in *Breast Cancer*, 2023

Hideko Yamauchi, Masakazu Toi, et al. Adjuvant olaparib in the subset of patients from Japan with BRCA1- or BRCA2-mutated high-risk early breast cancer from the phase 3 OlympiA trial. *Breast Cancer*, 2023 April; 30, 596-605. <https://doi.org/10.1007/s12282-023-01451-8>

#### 3) JBCRG-C06 in *Cancer Medicine*, 2023

Misato Masuyama, Norikazu Masuda, et al. Fulvestrant with or without anti-HER2 therapy in patients in a postmenopausal hormonal state and with ER-positive HER2-positive advanced or metastatic breast cancer: a subgroup analysis of data from the Safari study (JBCRG-C06). *Cancer Medicine*. 2023; 00:1–13. <http://doi:10.1002/cam4.6390>.

### Participation in global trials

JBCRG is involved in the following studies run under the BIG umbrella: **ALEXANDRA/IMPpassion030 (BIG 16-05)**, **OlympiA (BIG 6-13)**, **POSITIVE (BIG 8-13)**, **Penelope-B (BIG 1-13)** and **PALLAS (BIG 14-03)**. For details about the trial leadership, please refer to the overview of BIG trials on [page 40-43](#).

## Longstanding partner ELC Japan GK supports JBCRG

With the aim to improve cancer care and raise further awareness about breast cancer and clinical trials, ELC Japan GK (a subsidiary of Estée Lauder Companies, Inc.) has been providing continuous support to JBCRG's initiatives since 2015 through donations.

JBCRG has been collaborating as a medical advisor for their annual fundraising Breast Cancer Campaign. This year, Dr. Atsuko Kitano from St. Luke's International Hospital was a featured speaker at the event on 26 October in Marunouchi, Tokyo, delivering a brief lecture and engaging in discussions to raise awareness about the importance of breast cancer research.



## LACOG LATIN AMERICAN COOPERATIVE ONCOLOGY GROUP

### The Brazilian Breast Cancer Conference 2023 – LACOG- GBECAM and Best of SABCS® Brazil

On 31 March and 1 April, the Brazilian Breast Cancer Conference 2023 - LACOG-GBECAM - Best of SABCS was held at the Intercontinental Hotel in São Paulo. Experts from all over Brazil gathered to present and discuss the main studies from the oral sessions of the San Antonio Breast Cancer Symposium 2022, as well as topics such as screening and genetic risk in breast cancer, hot topics in surgery and pregnancy, ductal carcinoma in situ, and luminal tumours, among others.

The scientific programme, presented by 47 national and international lecturers, was attended by 325 in-person participants, and virtually by more than 600 individuals from various states.



## LACOG at ESMO Breast 2023 Annual Conference

LACOG President Dr. Carlos Barrios and Executive Director Dr. Gustavo Werutsky were invited to participate in the ESMO Breast 2023 Annual Conference. The event took place between 11 and 13 May, in Berlin, Germany. The 2023 edition welcomed 4,000 participants from 115 countries, and more than 270 studies were presented during the Congress.

Dr. Werutsky, a member of the ESMO Breast 2023 Scientific Committee, presented two lectures, one in the Proffered Paper session on the new safety and quality of life data from the DESTINY-Breast 04 and 02 studies, and another in the “Optimal sequencing in advanced luminal breast cancer” session, where he spoke about the recent progress in treating luminal metastatic breast cancer with CDK 4/6 inhibitors.

Dr. Barrios was the author and presenter of the late-breaking abstract “LBA1 - Final analysis of the placebo-controlled randomised phase 3 IMpassion031 trial evaluating neoadjuvant atezolizumab (atezo) plus chemotherapy (CT) followed by open-label adjuvant atezo in patients (pts) with early stage triple-negative breast cancer (eTNBC)”.



## LATAM Cancer Connection Webinar – Breast Module

On 24 May, the webinar LATAM Cancer Connection – Breast Module was held. The online event is a partnership between LACOG and MSD and aims to bring technical knowledge to clinical practice in oncology throughout Latin America. The programme featured renowned international speakers from Brazil, Argentina, Colombia, Mexico, and the United States, and involved participation of oncologists from all over Latin America.



### **LACOG Scientific Meeting at ASCO 2023**

The LACOG Scientific Meeting was held on 2 June at the ASCO Annual Meeting 2023. The meeting took place at the Hyatt Regency Chicago Hotel and was attended by approximately 60 members of the group from Latin America. During the meeting, ongoing LACOG studies were presented, and new research projects for the next year were discussed.

### **BIG Executive Board - Bi-annual Elections**

The LACOG Executive Director, Dr. Werutsky, was elected to the BIG Executive Board (EB) during BIG's bi-annual elections. Through his participation in the BIG EB, it will be possible to promote new studies focused on breast cancer in Latin America, in addition to strengthening the relationship between investigators from the region and broader BIG network.

### **LACOG 0221 - BRAVE Study - Recruitment Completed**

The LACOG 0221 - BRAVE - "Real-World Data on First-line Treatment of Hormone Receptor-positive, HER2-negative, Metastatic Breast Cancer in Brazil" study successfully completed its recruitment. LACOG appreciates all the efforts of the 15 research sites in Brazil, which included 308 patients in this study.

### **Recent Publication**

The article "[Moderately hypofractionated post-operative radiation therapy for breast cancer: Preferences amongst radiation oncologists from countries in Latin America and the Caribbean](#)" was published in the *Report of Practical Oncology and Radiotherapy (2023)* by LACOG Radiation Group Vice-Chair Dr. Gustavo Nader Marta and other authors.

According to Dr. Nader Marta, the survey conclusions pointed out that even though moderately hypofractionated post-operative radiation therapy for breast cancer is considered a new standard of care for the vast majority of patients, its unrestricted application in clinical practice across Latin America and the Caribbean remains limited. ●





## Overview of the

# CURRENT STUDIES RUN WITHIN THE BIG NETWORK

### Open trials / research programmes

Study name	BIG number	Short description	Principal Investigator(s)	Trial model & partners
<b>ALPHABET</b>	BIG 18-04	A randomised phase III trial of trastuzumab + Alpelisib +/- fulvestrant vs. trastuzumab + chemotherapy in patients with PIK3CA mutated previously treated HER2+ Advanced BrEaST cancer	A. Pérez-Fidalgo C. Criscitiello P. Bedard	Co-lead trial (Co)-Leading partners: GEICAM (sponsor) / ETOP IBCSG Partners Foundation and BIG HQ Pharma partner: Novartis Funding: Novartis
<b>AURORA (Metastatic Breast Cancer GPS)</b>	BIG 14-01	The AURORA programme: aiming to understand the molecular aberrations in metastatic breast cancer - NCT02102165	P. Affimos M. Benelli A. Guerrero Zotano	BIG-sponsored programme (Co)-Leading partners: BIG (sponsor) / IJB-CTSU / FSS 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), 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.
<b>Breast Cancer in Pregnancy</b>	BIG 2-03	Prospective registry of women treated for breast cancer while pregnant - NCT00196833	S. Loibl G. von Minckwitz	Supporter trial (Co)-Leading partner: GBG (sponsor) Pharma partner: N/A Funding: GBG, Deutsches Konsortium für Translationale Krebsforschung
<b>DIANER GEICAM</b>	BIG 18-03	A Randomized Phase II Study to Evaluate the Incidence of Discontinuities due to Diarrhoea at 3 Cycles in patients with Early-stage HER2-positive (HER2+), Hormone Receptor-positive (HR+) Breast Cancer treated with Neratinib plus Loperamide prophylaxis versus Neratinib with Initial Dose Escalation plus PRN Loperamide prophylaxis versus Neratinib plus Loperamide plus Colesevelam prophylaxis - NCT05252988	M. Martin M. Gil	Supporter trial (Co)-Leading partner: GEICAM Pharma partner: Puma Biotechnology
<b>EXPERT (BIG Radio Tuning)</b>	BIG 16-02	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 - NCT02889874	B. Chua G. Gruber	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
<b>POLAR</b>	BIG 18-02	Palbociclib for HR+ isolated local or regional recurrence of breast cancer - NCT03820830	E. Munzone S. Aebi	Supporter trial Coordinating group: ETOP IBCSG Partners Foundation (sponsor) Pharma partner: Pfizer Funding: Pfizer
<b>RIBOLARIS</b>	BIG 21-02	Neoadjuvant and Adjuvant Ribociclib and ET for Clinically High-risk ER+ and HER2- Breast Cancer	A. Prat P. Cottu J. Gavilá T. de La Motte Rouge	Supporter trial Coordinating group: SOLTI (sponsor) Pharma partner: Novartis Pharma AG Funding: Novartis Pharma AG

## Follow-up or post-study activities, recently closed studies

Study name	BIG number	Short description	Principal Investigator(s)	Trial model & partners
<b>ALEXANDRA / IMpassion 030</b>	BIG 16-05	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	M. Ignatiadis H. McArthur S. Saji	Lead trial (Co)-Leading partners: BIG HQ / IJB-CTSU / FSTRF and AFT Pharma partner: Roche/Genentech (sponsor) Funding: Roche / Genentech
<b>ALTO</b>	BIG 2-06	Adjuvant Lapatinib and/or Trastuzumab Treatment Optimisation: sequence and combination for patients with HER2/ ErbB2 positive primary breast cancer - NCT00490139	M. Piccart A. Moreno-Aspitia	Lead trial (Co)-Leading partners: BIG HQ / IJB-CTSU / FSTRF / Alliance (former NCCTG, sponsor for the US) Pharma partner: Novartis (global sponsor for all countries with the exception of US) Funding: GSK (past) / Novartis
<b>AMEERA-6</b>	BIG 20-01	Amcenestrant in patients with HR+, HER2-negative/positive breast cancer who experienced toxicities with aromatase inhibitors - NCT05128773	D. Cameron E. Brain O. Metzger	Co-lead trial (Co)-Leading partners: EORTC / AFT / BIG HQ Pharma partner: Sanofi (sponsor) Funding: Sanofi
<b>APHINITY</b>	BIG 4-11	Comparison of single-versus-dual anti-HER2 therapy (trastuzumab, pertuzumab) for patients with HER2-positive primary breast cancer - NCT01358877	M. Piccart S. Loibl J. Bines	Lead trial (Co)-Leading partners: BIG HQ / IJB-CTSU / FSTRF Pharma partner: Roche (sponsor) Funding: Roche
<b>APPALACHES</b>	BIG 18-01	A Phase II study of Adjuvant PALbociclib as an Alternative to CHemotherapy in Elderly patients with high-risk ER+/HER2- early breast cancer - NCT03609047	H. Wildiers E. Brain K. Punie	Supporter trial Coordinating group: EORTC (sponsor) Pharma partner: Pfizer Funding: Pfizer
<b>BRAVO</b>	BIG 5-13	Niraparib for patients with HER2-negative, germline BRCA mutation-positive, locally advanced or metastatic breast cancer - NCT01905592	N. Turner J. Balmaña D. Cameron J. Erban	Co-lead trial (Co)-Leading partners: EORTC / BIG HQ Pharma partner: Tesaro (sponsor) Funding: Tesaro
<b>DCIS</b>	BIG 3-07	Radiation doses and fractionation schedules for women with DCIS - NCT00470236	B. Chua	Supporter trial (Co)-Leading partner: TROG (sponsor) Pharma partner: N/A Funding: National Health & Medical Research Council Project Grant, Susan G. Komen
<b>DECRESCENDO</b>	BIG 19-02	De-escalation of adjuvant chemotherapy in HER2-positive, HR-negative breast cancer - NCT04675827	M. Piccart G. Zoppoli	Co-lead trial (Co)-Leading partners: IJB-CTSU (sponsor) and BIG HQ Pharma partner: Roche Funding: Roche (grant)
<b>Exceptional Responders</b>	BIG 16-04	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	A. Irrthum (coordinator)	BIG-sponsored programme (Co)-Leading partner: BIG HQ Pharma partner: N/A Funding: Breast Cancer Research Foundation
<b>FINESSE</b>	BIG 2-13	Oral lucitanib for patients with FGFR1 ER+ metastatic breast cancer - NCT02053636	F. André J. Cortés	Lead trial (Co)-Leading partners: BIG HQ / IJB-CTSU / FSS Pharma partner: Servier (sponsor) Funding: Servier
<b>IBIS-II</b>	BIG 5-02	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	J. Cuzick	Supporter trial (Co)-Leading partner: IBIS Pharma partner: AstraZeneca Sponsor: Queen Mary University of London Funding: Cancer Research UK, Queen Mary University of London

<b>INTERNATIONAL MALE BREAST CANCER PROGRAMME</b>	BIG 2-07	Registration and biologic characterisation programme of breast cancer in men - NCT01101425	F. Cardoso S. Giordano	Supporter programme (Co)-Leading partners: EORTC (sponsor) / NABCG NCTN / TBCRC (US) Pharma partner: N/A Funding: Breast Cancer Research Foundation
<b>LORELEI</b>	BIG 3-13	Neoadjuvant letrozole plus taselisib versus letrozole plus placebo in postmenopausal women with ER+, HER2-negative, early-stage breast cancer - NCT02273973	C. Saura E. de Azambuja	Co-lead trial (Co)-Leading partners: ABCSG, SOLTI and BIG HQ Pharma partner: Genentech (sponsor) Funding: Genentech
<b>MA.32 Metformin</b>	BIG 5-11	Effect of metformin on recurrence and survival in early stage breast cancer - NCT01101438	P. J. Goodwin	Supporter trial (Co)-Leading partner: 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.
<b>MINDACT</b>	BIG 3-04	Can addition of 70-gene signature to common clinical-pathological criteria safely spare patients with 0 to 3 node positive breast cancer from adjuvant chemotherapy? - NCT00433589	E. Rutgers F. Cardoso M. Piccart	Co-lead trial (Co)-Leading partners: EORTC (sponsor) / BIG HQ Commercial partners: Roche, Sanofi, Novartis and Agendia Funding: European Commission, Roche, Sanofi and Novartis grants, BCRF, Susan G. Komen for the Cure, Cancer Research UK, EORTC Charitable Trust, numerous national cancer societies and many other charitable grants*
<b>NEO-ALTO</b>	BIG 1-06	Comparison of dual HER2 inhibition (lapatinib, trastuzumab) plus chemotherapy before surgery versus single HER2-targeted therapy - NCT00553358	S. Di Cosimo J. Huober	Co-lead trial (Co)-Leading partners: IJB-CTSU / FSS / SOLTI / BIG HQ Pharma partner: Novartis (global sponsor for all countries with the exception of US, where Alliance is the sponsor) Funding: GSK (past) / Novartis
<b>OLYMPIA</b>	BIG 6-13	Olaparib vs. placebo for patients with BRCA-mutated, high-risk HER2-negative breast cancer, having completed local treatment and (neoadjuvant chemotherapy - NCT02032823	A. Tutt D. Cameron B. Kaufman J. Garber C. Geyer	Lead trial (Co)-Leading partners: NRG Oncology (sponsor in US), BIG HQ and FSTRF Pharma partner: AstraZeneca (global sponsor for all countries excluding the US) and Merck (co-developer of the drug) Funding: AstraZeneca
<b>PALLAS</b>	BIG 14-03	PALbociclib CoLLaborative Adjuvant Study: palbociclib with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy alone for HR+ / HER2-negative early breast cancer - NCT02513394	E. Mayer M. Gnant A. DeMichele	Co-Lead trial (Co)-Leading partners: ABCSG, Alliance for Clinical Trials in Oncology Foundation (sponsors for Rest of the World and the US respectively) and BIG HQ Pharma partner: Pfizer Funding: Pfizer grant
<b>PENELOPE-B</b>	BIG 1-13	Post-neoadjuvant palbociclib for patients with HR+, HER2-normal primary breast cancer with high relapse risk after neoadjuvant chemotherapy - NCT01864746	S. Loibl	Supporter trial (Co)-Leading partner: GBG (sponsor) Pharma partner: Pfizer Funding: Pfizer grant
<b>POSITIVE (BIG time for Baby)</b>	BIG 8-13	Endocrine therapy interruption to enable conception for young women with ER+ breast cancer - NCT02308085	O. Pagani	Supporter trial (Co)-Leading partner: ETOP IBCSG Partners Foundation (sponsor) Pharma partner: N/A Funding: ETOP IBCSG Partners Foundation, Fonds Baillet-Latour, BIG HQ, national and local funding bodies, individual donors

\* full information available on the BIG website.

**Legend:** AFT: Alliance Foundation Trials, LLC; BCRF: Breast Cancer Research Foundation; FSS: Frontier Science Scotland, LTD; FSTRF: Frontier Science and Technology Research Foundation, Inc; N/A: not applicable; NCTN: National Clinical Trials Network; NCCTG: North Central Cancer Treatment Group; NCI: US National Cancer Institute; SCTBG: Scottish Cancer Trials Breast Group; TBCRC: Translational Breast Cancer Research Consortium

<b>PYTHIA</b>	BIG 14-04	Palbociclib plus fulvestrant for pretreated patients with ER+/HER2- metastatic breast cancer - NCT02536742	L. Malorni	Co-lead trial (Co)-Leading partners: ETOP IBCSG Partners Foundation (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.
<b>SNAP</b>	BIG 2-12	Schedules of nab-Paclitaxel: evaluation of different schedules of nab-paclitaxel for metastatic breast cancer - NCT01746225	A. Gennari G. Jerusalem	Supporter trial (Co)-Leading partner: ETOP IBCSG Partners Foundation (sponsor) Pharma partner: Celgene Funding: Celgene grant
<b>SOFT</b>	BIG 2-02	Evaluation of ovarian suppression and of exemestane as adjuvant therapy for premenopausal women with endocrine responsive breast cancer - NCT00066690	P. Francis G. Fleming	Supporter trial (Co)-Leading partner: ETOP IBCSG Partners Foundation (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.
<b>SOLE</b>	BIG 1-07	A phase III trial evaluating the role of continuous letrozole versus intermittent letrozole following 4 to 6 years of prior adjuvant endocrine therapy for postmenopausal women with hormone-receptor positive, node positive early stage breast cancer (SOLE - Study Of Letrozole Extension) - NCT00553410	M. Colleoni P. Karlsson S. Aebi J. Chirgwin	Supporter trial Coordinating group: ETOP IBCSG Partners Foundation Sponsor: ETOP IBCSG Partners Foundation Pharma partner: Novartis Funding: Novartis
<b>SUPREMO</b>	BIG 2-04	Selective Use of Postoperative Radiotherapy After Mastectomy: adjuvant chest wall irradiation for 'intermediate risk' breast cancer following mastectomy - NCT00966888	I. Kunkler P. Canney	Supporter trial (Co)-Leading partner: SCTBG Sponsor: UK Medical Research Council Pharma partner: N/A Funding: UK Medical Research Council, EORTC, Cancer Australia, William and Elizabeth Davies Charitable Trust, Peter Chan Jee Yat Foundation, Yeung Ying Yin and May Yeung Foundation.
<b>TEXT</b>	BIG 3-02	Tamoxifen and Exemestane Trial: evaluation of exemestane plus GnRH analogue for premenopausal women with endocrine responsive breast cancer - NCT00066703	O. Pagani B. Walley	Supporter trial (Co)-Leading partner: ETOP IBCSG Partners Foundation (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.
<b>TREAT-CTC</b>	BIG 1-12	TRastuzumab in HER2-negative Early breast cancer as Adjuvant Treatment for Circulating Tumor Cells (CTC) - NCT01548677	M. Ignatiadis M. Piccart J.-Y. Pierga B. Rack C. Soliriou	Supporter trial (Co)-Leading partners: EORTC BCG, SUCCESS, UNICANCER Sponsor: EORTC Pharma partner: Roche, Janssen Diagnostics Funding: Roche educational grant/ medication; Janssen test kits
<b>ULTIMATE</b>	BIG 16-01	Immunotherapy combined with standard endocrine therapy as neoadjuvant treatment for women with ER+/HER2-negative breast cancer - NCT02997995	F. André A. Prat	Co-lead trial (Co)-Leading partners: UNICANCER and BIG HQ Pharma partner: AstraZeneca Funding: AstraZeneca grant

NB: This table does not include the studies in development and all closed trials. For more information, please visit: [www.BIGagainstbreastcancer.org](http://www.BIGagainstbreastcancer.org).

# ABOUT BIG

## THE BIG NETWORK: GLOBAL RESEARCH COLLABORATION TO CURE BREAST CANCER

***For almost 25 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, two decades later, BIG represents about 60 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 and the North American Breast Cancer Group, to act as a strong integrating force in the field of breast cancer research. 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, and to raise funds for BIG's purely academic breast cancer trials and research programmes.

[www.bigagainstbreastcancer.org](http://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** Shaikat 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

**ABCBSG** Austrian Breast & Colorectal Cancer Study Group

**AGO-B** Arbeitsgemeinschaft Gynäkologische Onkologie Breast Study Group

**BOOG** Borstkanker Onderzoek Groep

**CEEORG** Central and East European Oncology Group

**CT-IRE** Cancer Trials Ireland

**DBC** 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)

**FBCG** Finnish Breast Cancer Group

**FSS** Frontier Science Scotland

**GCSG** Georgian Cancer Study Group

**GEICAM** Spanish Breast Cancer Group

**GIM** Gruppo Italiano Mammella

**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 Clínicos 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



A graphic featuring a blue heart with the text "SUPPORT BIG" inside, surrounded by radiating lines. Below the heart is a blue outline of a hand holding the heart.

# TODAY'S RESEARCH FOR TOMORROW'S CURES

**IBAN BE08 0689 0916 0213**  
(communication: BIG RESEARCH)

**OR DONATE ONLINE:**  
[www.BIGagainstbreastcancer.org/donate](http://www.BIGagainstbreastcancer.org/donate)



**BIG**  
Breast International Group

**BIG**  
RESEARCH  
IN FOCUS

The magazine that keeps you up to date with trending topics in the world of breast cancer and BIG member groups' academic research.

A FREE bi-annual digital or print copy?

**SIMPLY SCAN THE QR CODE WITH YOUR  
SMARTPHONE OR TYPE IN THE LINK**

[HTTPS://BIGAGAINSTBREASTCANCER.ORG/  
BIG-RESEARCH-IN-FOCUS/](https://bigagainstbreastcancer.org/big-research-in-focus/) TO BE DIRECTED  
TO THE SIGN-UP FORM.



**SUBSCRIBE  
NOW**

for your FREE copy  
of 'BIG Research  
in Focus'



[www.bigagainstbreastcancer.org](http://www.bigagainstbreastcancer.org)