

Press Release
May 12, 2022

May 20 = International Clinical Trials Day
THEME 2022: “RECRUITMENT IN CLINICAL TRIALS”

The BIG network:
Recruiting patients globally for faster progress against breast cancer

On May 20, which marks International Clinical Trials Day, the Breast International Group (BIG) wishes to shine some light on the importance of recruitment in clinical trials and how global research and collaboration can save lives.

Thanks to its global network of breast cancer research groups, BIG can quickly enrol 1000s of patients from around the world into large clinical trials, leading to faster and stronger results and benefits for patients and healthcare systems.

So far, about 100,000 patients have participated in BIG trials and contributed to making progress against the disease.

Working together means making progress more rapidly

We know that breast cancer has multiple subtypes and that each of them requires a different treatment approach. If we want to obtain reliable results when we test a new treatment, we need to make sure that the clinical trial has enrolled enough patients with the same breast cancer subtype. To do that, research today cannot be limited to one hospital or even one country.

Global research and collaboration are therefore essential. Thanks to its network of over 50 academic breast cancer research groups and their extended network of hospitals, BIG reaches over 10,000 breast cancer experts based in approximately 70 countries on 6 continents. Together, these experts design and run clinical trials that will enrol patients from many different countries. This increases the possibility of recruiting a large number of patients with the same specific subtype of breast cancer more rapidly and getting reliable and statistically robust results.

BIG trials, global collaboration and successful recruitment: OlympiA, PALLAS and DCIS

Three recent BIG clinical trials illustrate how international collaboration leads to rapid recruitment and faster and stronger results. Benefitting patients and healthcare systems worldwide.

OlympiA, a partnership between BIG, Frontier Science & Technology Research Foundation, NRG Oncology, and AstraZeneca, opened in 23 countries, making it possible to recruit, in 49 months, 1,800 patients with a specific subtype of hereditary breast cancer (BRCA mutation). The trial’s first results, published in *The New England Journal of Medicine*¹, are highly encouraging: olaparib (*Lynparza*) given for one year to patients with BRCA-mutated HER2-negative high-risk early breast cancer who completed surgery (with or without radiotherapy) and received standard chemotherapy either before or after surgery **reduced the risk of cancer returning after treatment by 42%**. In the US, the OlympiA results have already led to FDA (Food and Drug Administration) approval of olaparib to treat this type of uncommon cancer. Approval in other countries is expected soon.

¹ Tutt ANJ, Garber JE, Kaufman C et al. Adjuvant Olaparib for Patients with BRCA1- or BRCA2-Mutated Breast Cancer. *N Engl J Med*. 2021 Jun 24;384(25):2394-2405. doi: 10.1056/NEJMoa2105215. Epub 2021 Jun 3.

“OlympiA needed an organisation with the networks and coordinating experience of BIG to bring together the partners and all the researchers required to identify a pool of patients with inherited mutations in the BRCA1/2 genes that was large enough to find the numbers of patients needed for the study”, says BIG Chair David Cameron, who is also OlympiA co-principal investigator, and Professor of Oncology at Edinburgh University, UK.

PALLAS, a partnership between BIG, the Austrian Breast and Colorectal Cancer Study Group (ABCSCG), Alliance Foundation Trials and Pfizer, recruited 5,796 patients in 21 countries in just 3 years. Despite the unexpected negative study results, **PALLAS is another example of the importance and benefits of global collaboration** between academia and industry when running a huge pivotal clinical trial. Further studies will enable us to continue researching the effects of palbociclib in the treatment of patients with hormone receptor-positive (HR+), HER2-negative early breast cancer.

“Recruiting almost 6,000 patients in 21 countries in three years is an achievement that speaks for itself. For sure, we had hoped for another adjuvant breakthrough for patients with luminal breast cancer when we started this huge enterprise. However, it is science, not religion - we learn at least as much from “negative” trial results as we do from outrightly “positive” trials,” says Professor Michael Gnant, co-Principal Investigator of the study and President of ABCSCG.

DCIS, a partnership between BIG and Trans-Tasman Radiation Oncology Group (TROG) Cancer Research (Australia/New Zealand), **accomplished recruitment of 1,608 patients from 11 countries two years earlier than projected** and demonstrated the importance of tailoring radiation treatment of patients with DCIS (ductal carcinoma in situ) according to their risks of recurrence to avoid over- or undertreatment. It showed that, after breast conserving surgery, higher radiation doses to the part of the breast where the DCIS was found, in addition to radiotherapy of the whole breast, significantly reduced its risk of returning in patients with higher-risk DCIS. Compared to 5 weeks of whole breast radiotherapy, the study also showed that the shorter, more convenient 3 weeks of radiotherapy did not increase recurrence.

“Thanks to the strong support and powerful momentum of our global team of BIG researchers to conduct this large-scale global academic study without commercial sponsorship, we were able to complete recruitment of participants a full two years ahead of schedule. This outstanding achievement shows that research on DCIS is a high priority for many patients and researchers to deliver the high-level evidence necessary and improve patient outcomes.” says Professor Boon Chua, M.D., PhD, Principal Investigator of the DCIS study, Director of Cancer and Haematology Services at UNSW (University of New South Wales) and Prince of Wales Hospital, Sydney, Australia.

International research and collaboration are essential to ensuring fast recruitment to clinical trials and rapid progress against breast cancer.

Together we will cure breast cancer

Breast cancer – facts and figures

Today, breast cancer represents around 1 in 4 cancers diagnosed among women globally. About 1 in 8 women will be diagnosed with breast cancer over the course of her lifetime. Because of its high prevalence in low- and middle-income countries, female breast cancer has now become the most commonly diagnosed cancer, even surpassing lung cancer. For men, the lifetime risk of developing breast cancer is about 1 in 800. It has been estimated that by the end of 2020, approximately 2.3 million people, amongst whom about 1% were men, would have been diagnosed with breast cancer across the globe.

Female breast cancer incidence rates are the highest in Australia/New Zealand (about 95%), Western Europe (about 90%), Northern America (about 90%), Northern Europe (about 86%) and Southern Europe (about 80%). These rates far exceed those for other cancers in both developed and developing countries, making it the most commonly diagnosed cancer in women: about one quarter of all new cancer cases worldwide. It is also the leading cause of cancer death in women (1 in 6), and the fifth-leading cause of cancer mortality worldwide with an estimated 685,000 deaths per year (*Source: Globocan Report, Dec. 2020*).

About the Breast International Group (BIG)

The Breast International Group (BIG) is an international not-for-profit organisation for academic breast cancer research groups from around the world, based in Brussels, Belgium.

Global collaboration is crucial to make significant advances in breast cancer research, reduce unnecessary duplication of effort, share data, contribute to the faster development of better treatments, and increase the likelihood of cures for patients. Therefore, BIG facilitates breast cancer research at international level, by stimulating cooperation between its members and other academic networks, and collaborating with, but working independently from, the pharmaceutical industry.

In 1999, BIG was founded by Dr Martine Piccart and Dr Aron Goldhirsch with the aim to address fragmentation in European breast cancer research. Research groups from other parts of the world rapidly expressed interest in joining BIG and, more than two decades later, BIG represents a network of over 50 like-minded research groups from around the world. These entities are tied to several thousand specialised hospitals, research centres and world-class breast cancer experts across approximately 70 countries on 6 continents. More than 30 clinical trials are run or are under development under the BIG umbrella at any one time. BIG also works closely with the US National Cancer Institute (NCI) and the National Clinical Trials Network (NCTN), so that together they act as a strong integrating force in the breast cancer research arena.

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.

For more information, visit www.BIGagainstbreastcancer.org



@BIGagainstbreastcancer



@BIGagainstBC



BIG against breast cancer

Note to editors (not for publication):

For further information on BIG, and/or for interview requests, please contact:

BIG's communications team: Valerie Van der Veecken / Oriana Spagnolo / Gia Questiaux

Communications@BIGagainstbc.org