



BREAST INTERNATIONAL GROUP • BIG NEWSLETTER

Patient and Community Links in the Research Process

EUROPA DONNA— The European Breast Cancer Coalition

Deirdre O'Connell, Vice President EUROPA DONNA—The European Breast Cancer Coalition, Chair Europa Donna Ireland, The Irish Breast Cancer Campaign

EUROPA DONNA—The European Breast Cancer Coalition was founded in 1994 and works to raise public awareness of breast cancer and to mobilize the support of European women in pressing for improved breast cancer education, appropriate screening, optimal treatment and care, as well as increased resources for breast cancer research. Membership is open to all European countries (as defined by the World Health Organization) and currently stands at 37. Membership of the National Fora comprises patients, female health professionals, breast cancer-related organisations and institutions, and others wishing to identify with the fight against breast cancer.

As a result of a concept presented at the EUSOMA Congress in Paris in 1993 by Professor Umberto Veronesi, EUROPA DONNA was established as an educational programme of the European School of Oncology in Milan with the support of Dr. Alberto Costa. The first EUROPA DONNA Pan-European conference was held in Milan in 1994 under the guidance of founding President Gloria Freilich and a board of women representing various European countries. The organisation, now fully independent, is well established as Europe's breast cancer advocacy organisation and recognized as such by the institutions of the European Union (EU).

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Note From the Editors

In recent issues of the BIG Newsletter, we have highlighted several types of positive collaborations that have developed between academic research groups around the world and between industry and academia. What we hope to have conveyed is that a spirit of openness and collaboration is vital to all our research endeavours.

While the collaborative process is inevitably fraught with challenges, including occasional setbacks that send us back to the drawing board to reevaluate our positions and to come up with new and creative solutions, the benefits are many. This was recently highlighted by the presentations of the trastuzumab trials (to be featured in an upcoming newsletter) at ASCO 2005. As echoed by Deirdre O'Connell, Vice-President of EUROPA DONNA—The European Breast Cancer Coalition, "collaboration is not easy and poses challenges for all of us, but we all have the same aim, which is the development of ever more effective treatments for women with breast cancer."

Our lead article in this issue therefore focuses on the critical role played by patient advocates in the research process. In the European context, EUROPA DONNA provides such leadership, by acting as *the* link between patients, the scientific community, and political decision makers.

Similar broad collaborations are also in their early stages with regard to fundraising initiatives that involve BIG. The articles on the first Brussels Breast Cancer Walk Run and the Jean-Claude Heuson Fund highlight this, another new frontier in our efforts to generate awareness about breast cancer, the essential role of research, and the need to secure adequate funding to ensure that such progress continues.

We are certain that we are only at the beginning of realizing the potential of our collaborative partnerships and look forward to the many fruits these will bear.

Martine Piccart
Carolyn Straehle

Watch for upcoming issues on targeted therapy trials (trastuzumab), the EU Clinical Trials Directive, and trials for populations such as the elderly and the young.

Are there other topics you would like to see discussed in future BIG Newsletters?

Don't hesitate to contact us (big@bordet.be) with your ideas and feedback!

(continued from page 1)

The Ten Goals of EUROPA DONNA are as follows:

- To promote the dissemination and exchange of factual, up-to-date information on breast cancer throughout Europe
- To promote breast awareness
- To emphasize the need for appropriate screening and early detection
- To campaign for the provision of optimum treatment
- To ensure provision of quality supportive care throughout and after treatment
- To advocate appropriate training for health professionals
- To acknowledge good practice and promote its development
- To demand regular quality assessment of medical equipment
- To ensure that all women understand fully any proposed treatment options, including entry into clinical trials and their right to a second opinion
- To promote the advancement of breast cancer research

From its foundation EUROPA DONNA has maintained a close connection with scientists and clinicians in the field, initially through its relationship with EUSOMA and subsequently with EORTC, when all three groups worked together to create the European Breast Cancer Conferences, the first being held in Florence in 1998. This historic initiative involved an advocacy group as an equal partner in a scientific conference for the first time and the partnership has developed and strengthened over subsequent years and subsequent conferences, with EUROPA DONNA acting as co-chair.

This connection means that EUROPA DONNA has always been very conscious of the need to inform and educate women and decision makers at national and European levels as to the optimum conditions for the diagnosis and treatment of breast cancer, which is illustrated by the Ten Goals. Breast cancer mortality rates still vary immensely, not only between countries, but also between regions within countries and even between hospitals in the same region. The essential role played by standards and guidelines is very clear to us. EUROPA DONNA is also very conscious of the essential role played by research in improving treatments for women with breast cancer and works to inform women in this area. EUROPA DONNA has established an annual Advocacy Course (now funded by the European Commission) where delegates from member countries are briefed on current directions in breast cancer research and treatment by leading European physicians and researchers, and also receive communications training. EUROPA DONNA Pan-European Conferences also provide an opportunity to inform and educate our members, as does attendance at the European Breast Cancer Conferences. The result is that we are building a corps of informed advocates, mostly breast cancer survivors, who will campaign, along

with professionals, for the best possible breast cancer services for European women, including access to research.

The strong connection with the scientific community also means that EUROPA DONNA is committed to communicating the views and needs of women to scientists and clinicians, and the European Breast Cancer Conferences provide a useful forum for such communication, as does our representation on a number of scientific and medical committees. Our involvement in BIG has led us to participation in committees of trials such as BIG 1-01/HERA and BIG 3-97/HABITS, and we have been following closely the development of translational research. Aware as we are of the importance of translational research, we are very pleased to sit on the Steering Committee, the Ethical Legal Committee, and the Spreading of Excellence Committee of TRANSBIG. TRANSBIG is in its early stages, but it is to be hoped that it will provide a model for the inclusion of patient advocate groups in the research process in Europe. It is an exciting development for patient advocates to be involved in a trial such as the BIG 1-01/HERA trial and to see results such as those announced at the American Society of Clinical Oncology annual meeting this past May. Every improvement in mortality and every improvement in quality of life is of vital importance to us.

Developments in biomedical research have improved prospects for treatment tailoring in the clinic, but also raise issues of concern to us. The use of biological materials, informed consent, patient confidentiality, and the consequences for patients and their families resulting from germline genetic testing are among the ethical issues that come with the new developments. EUROPA DONNA has facilitated discussion on these issues, both among its members and by communicating its concerns to the scientific community. As always, awareness of each other's points of view is the key to mutual collaboration.

It seems to me that an advocacy group such as EUROPA DONNA can play a useful role in bringing stakeholders together. At the European level and in some of our member states we have brought the research community together with politicians to inform the politicians of best standards in breast cancer services and of the need for support for research. Since we began lobbying at the European level we have stressed the need for greatly increased funding of independent research. The Breast Cancer Resolution presented to the European Parliament in June 2003 by Karin Jöns, MEP and President of Europa Donna Forum Germany, included the following section, paragraph 6, which

“Welcomes the allocation of EUR 400 million for cancer research in the sixth framework programme of research and calls on the Commission and the Member States to:

- a. ensure more effective coordination between national and European research,
- b. ensure that evidence-based medicine also constitutes the basis for breast cancer treatment in Europe,

- c. incorporate the positive findings of fundamental research into treatment as soon as possible and further strengthen clinical research, in particular the clinical trials coordinated by the European Organisation for Research and Treatment of Cancer (EORTC) and conducted in cancer centres and clinics across the EU,
- d. provide more funding than in the past for breast cancer research in order to:
 - step up the search for the causes of the disease and for forms of therapy,
 - improve prediction of the effect of treatment and certainty of outcomes,
 - further investigate the relationship between breast cancer and potential risk factors such as tobacco, diet, hormones and life-style (body weight, physical activity),
 - increase research into in-patient and out-patient treatment protocols, with a view to reducing the unnecessary burden on patients of clinical and medical treatment services, and
 - develop a method for the standardised risk assessment of women potentially in danger of developing a hereditary breast disease.”

The European Parliamentary Group on Breast Cancer (EPGBC), for which EUROPA DONNA provides the secretariat, brings experts in to advise it on various relevant aspects of breast cancer care and treatment.

At the European level EUROPA DONNA has become involved in the wider patient advocacy movement. We are founder members of the European Patients' Forum, whose organisations have a mutual interest in research. We very much welcome the foundation of the European Cancer Patient Coalition (ECPC) as a significant addition to the voice of the cancer patient in Europe. EUROPA DONNA is also a member of the EU Health Policy Forum set up by the European Commission's Health and Consumer Protection Directorate-General (DG SANCO), which provides another forum for our informed input and where we support professional groups calling for more research funds.

There is no doubt that there is a need for much greater public awareness of research and of clinical trials. Public knowledge of clinical trials is low and probably inaccurate.

EUROPA DONNA has published a booklet *Clinical Trials and Breast Cancer*, designed to give women diagnosed with breast cancer the information they need. The booklet is intended to be a public education piece for well women, so that they know something about trials before they must make a decision concerning participation. However, the occasion of a cancer diagnosis is a very difficult and challenging time for patients and the more informed the population at large is about clinical trials the more likely newly diagnosed patients are to agree to participate. Both patient groups and the research community need to collaborate to develop a better informed public. Including patient groups in the administration and conduct of research should result in more patient friendly procedures, and EUROPA DONNA is committed to involvement in this area. We are also, of course, very aware of the effects on independent research of the EU Directive on Clinical Trials (Directive 2001/20/EC) and continue to inform ourselves on this.

What is the future for collaboration in the field of breast cancer between patient groups and the scientific community? Collaboration has been established at the European level, largely as a result of the relationship begun at the foundation of EUROPA DONNA and continued through the European Breast Cancer Conferences. In our member countries there is much room for improvement. In some countries the role of the patient advocate on the Ethical Committees and other administrative committees of clinical trials is reasonably well established and accepted. In other countries this is not the case. EUROPA DONNA would like to see this situation change because we are convinced that patient advocates can play a very positive role on these bodies. We believe that training is vital for all members of these committees, including patient advocates. There is also the question of funding research areas that women themselves may feel are neglected, examples being psychosocial research and survivor studies.

Collaboration is not easy and poses challenges for all of us, but we all have the same aim, which is the development of ever more effective treatments for women with breast cancer. For its part, EUROPA DONNA will be working towards achieving the maximum benefit for present and future breast cancer patients by facilitating translational research resulting in better treatment outcomes, while ensuring that patient concerns are met satisfactorily.