

# MINDACT

## Principles for Publication and Presentation Applicable to the MINDACT study

version 2.0



v2.0

# Content

1. Introduction .....	2
2. Principles.....	2

## 1. Introduction

This document is based on the EORTC – BIG – AGENDIA Agreement, the MINDACT Protocol, the EORTC Disclosure of Results and Publication Policy and the Breast International Group (BIG) Guidelines for Publications and Presentations (Including Abstracts and Posters). It concerns the dissemination of results based on “MINDACT STUDY DATA AND MATERIAL” that include clinical data, molecular data, and/or biological material collected during MINDACT study.

For the purpose of these guidelines, “publications” shall be understood as being manuscripts, abstracts or posters. “Presentations” shall be understood to include the content of the presentation and the slides designed for this purpose

## 2. Principles

Any publication / presentation related to MINDACT STUDY DATA AND MATERIAL must comply with the EORTC « Disclosure of Results and Publication Policy » (POL009). Please refer to the EORTC internet website for an updated version of this policy.

In addition,

1. Without any exception, all publications / presentations of results related to the MINDACT STUDY DATA AND MATERIAL must be submitted to the MINDACT Executive and Steering Committees, EORTC and BIG Headquarters for review prior to their submission to a journal, a congress or any presentation. All publications / presentations reporting on MINDACT STUDY DATA AND MATERIAL must be reviewed and approved by :
  - a. The EORTC Statistician and Clinical Research physician in charge of the study, and, for research involving biological material and/or molecular data also the Head of the EORTC Translational Research Unit.
  - b. The BIG Scientific Advisor
  - c. The MINDACT Executive and Steering Committees

The following maximum delays are envisaged for the review of the publications / presentations:

- a. Abstracts, posters, presentations: a maximum of 15 calendar days
  - b. Full-length articles: a maximum of 5 weeks
2. In addition to the **acknowledgements** determined by the EORTC’s POL009,
    - a. **EORTC and BIG**

EORTC and BIG and their respective trial numbers must be visible in the publication's header of publications of all publications / presentations relating to MINDACT clinical trial data:

“EORTC 10041/BIG 3-04”

If this is not possible because of the journal's publication policy, BIG and EORTC should appear at the end of the authors' list. In this case, it is recommended to finish the list of authors by mentioning “on behalf of the MINDACT Investigators, EORTC Breast Cancer Group and the Breast International Group”.

**b. Company(ies) supporting the study**

All publications / presentation must acknowledge <sup>1</sup> the companies that contributed to the MINDACT study : Novartis, Roche, Sanofi-Aventis and Agendia.

**c. Other sources of funding**

All publications and presentations must acknowledge the support received from the following bodies:

- The European Commission's 6<sup>th</sup> Framework Programme
- Breast Cancer Research Foundation
- National Cancer Institute (NCI)
- EBCC-Breast Cancer Working Group – asbl/vzw
- Jacqueline Seroussi Memorial Foundation
- Prix Mois du Cancer du Sein (2004 award)
- Susan G. Komen for the Cure
- Fondation Belge Contre le Cancer / Stichting tegen Kanker (Belgian Cancer Foundation)
- KWF Kankerbestrijding (Dutch Cancer Society)
- Association « Le cancer du sein, parlons-en! »
- Deutsche Krebshilfe
- The Grant Simpson Trust and Cancer Research UK
- Brussels Breast Cancer Walk-Run & the American Women's Club of Brussels
- Novartis
- F. Hoffman La Roche
- Sonofi-Aventis
- Agendia
- Eli Lilly
- Veridex LLC
- NIF Trust
- EORTC Cancer Research Fund

In the publications the following acknowledgment text should be used:

*This trial has received grants from the European Commission Framework Programme VI (FP6-LSHC-CT-2004-503426), the Breast Cancer Research Foundation, Novartis, F. Hoffman La Roche, Sanofi-Aventis, the National Cancer*

---

<sup>1</sup> « This study was supported in part by grants from... »

*Institute (NCI), the EBCC-Breast Cancer Working Group (BCWG grant for the MINDACT biobank), the Jacqueline Seroussi Memorial Foundation (2006 JSMF award), Prix Mois du Cancer du Sein (2004 award), Susan G. Komen for the Cure (SG05-0922-02), Fondation Belge Contre le Cancer (SCIE 2005-27), Dutch Cancer Society (KWF), Association Le Cancer du Sein, Parlons-en!, Deutsche Krebshilfe, the Grant Simpson Trust and Cancer Research UK. This trial was also supported by the EORTC Cancer Research Fund. Whole genome analysis was provided in kind by Agendia.*

*We are grateful to all women participating in this study; all the investigators, surgeons, pathologists, and research nurses; the National Coordinating Centers/BIG Groups (BOOG, GOIRC, NCRI-BCG, SOLTI, UNICANCER, WSG); World Courier; the pharma companies Novartis, Roche, and Sanofi- Aventis; and Agendia.*

3. In addition to the **authorship rules** determined by the EORTC's POL009,
  1. **Authorships of the main publications / presentations** are allocated according to the tables in **Annex 1** (for internal use only) which can be reviewed and updated as the need arises by the MINDACT Executive and Steering Committees
    - The other high recruiters and members of the Executive Committee could do important national presentations on any of the 3 questions of the trial.
  2. **Authorships of other publications / presentations**

For research proposals approved by the MINDACT Executive and Steering Committees, not related to the MINDACT protocol but involving MINDACT STUDY DATA AND MATERIAL, the person who took the lead in conducting the ancillary study or research project is the first author of the publication. Co-authors include EORTC Headquarters' staff who contributed to the analysis and publication (if any). Other co-authors are selected amongst the other scientific contributors to the research project. In addition, investigators who contributed patient and data to the study might be added as co-authors. The list of co-authors must be approved by MINDACT Executive and Steering Committees.

If the authorship list does NOT contain any EORTC Headquarters' neither any member of the MINDACT Steering Committee AND if it was NOT agreed upfront that the publication would be "on behalf of EORTC" or as "EORTC research", the EORTC and MINDACT Steering Committee must be acknowledged for sharing the data for the research and the publication/presentation must contain the following disclosure "The contents of this publication and methods used are solely the responsibility of the authors and do not necessarily represent the official views of the EORTC or MINDACT SC".