

**TRANSBIG Traineeship Programme**  
**Call for applications 2010 – Description of available positions**

**Description of available position number 1**

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| <b>Name of the host institute</b>   |
| Institute Jules Bordet, Translational Research Unit   |
| <b>Location of the traineeship</b>  |
| Boulevard de Waterloo 121, Bruxelles 1000, Belgium  |
| <b>Title of the project</b>   |
| Application of genomics to clinical breast cancer research.   |
| <b>Aim of the project</b>   |
| Projects will involve depending on duration of fellow but can include: <ol style="list-style-type: none"> <li>1. Analysis of immune response using gene expression profiling and how it relates to prognosis and prediction of therapy.</li> <li>2. Analysis of stroma tissue using gene expression profiling and how it relates to prognosis and prediction of therapy.</li> <li>3. Analysis of the Her2 amplicon and its relationship to biology, prognosis and prediction of response to anti-HER2 therapies.</li> <li>4. Epigenetics and patterns of DNA alterations in breast cancer- its relationship to biology, breast cancer subtypes and clinical outcome.</li> </ol> |
| <b>Fellowship duration</b>  |
| One or two years starting Sept/Oct 2010.  |
| <b>Ideal candidate</b>  |
| Foreign or local physician who has been recently board-certified in medical oncology, highly motivated to conduct research projects in the field of breast cancer.<br>Or scientist highly motivated to have more exposure to clinical application of basic science.<br>Good knowledge of written / spoken English.<br>Some knowledge of French an advantage.<br>Interested in breast cancer research, integrating translational, microarray based and molecular biology with clinical medicine.   |
| <b>Role of the trainee</b>  |
| The trainee will learn basics of microarray analysis and application to a clinical problem<br>Laboratory skills relating to microarray research.<br>Skills in validation of results and learning experimental procedures relating to in vitro validation of biological hypotheses generated from results.<br>Possibilities of “translation back to the clinic”- clinical trial design, translational sub-studies of adjuvant or neoadjuvant trials.   |
| <b>Traineeship supervision</b>  |
| Dr Christos Sotiriou, MD, PhD - overall Head of the TRU, will oversee project.<br>Dr Sherene Loi, MD, PhD – oversight of the bioinformatics and clinical application components.<br>Dr Christine Desmedt, PhD – oversight of the lab part.  |

**Description of available position number 2**

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| <b>Name of the host institute</b> |
| BIG / TRANSBIG Headquarters       |

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| <b>Location of the traineeship</b>  |
| c/o Institut Jules Bordet, Blvd de Waterloo 121, 7 <sup>th</sup> fl., 1000 Brussels, Belgium  |
| <b>Title of the project</b>   |
| Clinical and translational research in the setting of multinational and multi-centric networks. The BIG and TRANSBIG networks and its major projects (e.g. the MINDACT trial).  |
| <b>Aim of the project</b>   |
| The aim is to acquaint the trainee with translational research and to help him/her understand how multinational and multi-centric networks work together.   |
| <b>Fellowship duration</b>  |
| 1 year, starting in October 2010.   |
| <b>Ideal candidate</b>  |
| Foreign physician who has been recently board-certified in medical oncology, highly motivated to run research projects in the field of breast cancer.<br>Perfect knowledge of written / spoken English / some knowledge of French (optional).<br>Preliminary experience in the area of cancer research. |
| <b>Role of the trainee</b>  |
| The trainee will be involved in:<br>- coordination of international prospective trials in breast cancer;<br>- grant writing and reporting;<br>- translational research projects;<br>- writing of abstracts, manuscripts and book chapters;<br>- cutting-edge laboratory work (optional).                |
| <b>Traineeship supervision</b>  |
| Direct supervision: Fatima Cardoso (on a daily basis) and Carolyn Straehle (for any BIG related projects).<br>Tutor: Martine Piccart (on a 2-weekly basis)  |

### Description of available position number 3

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| <b>Name of the host institute</b>   |
| European Organisation for Research and Treatment of Cancer  |
| <b>Location of the traineeship</b>  |
| 83 avenue E. Mounier, Brussels, Belgium   |
| <b>Title of the project</b>   |
| MINDACT Trial Quality Assurance and Quality Control Program.  |
| <b>Aim of the project</b>   |
| Due to changing regulatory environment after the implementation of the Clinical Trials Directive, the EORTC and the TRANSBIG-MINDACT Executive Committee would like to ensure that we are in a position to demonstrate the high and homogeneous level of quality of the trial. The EORTC Quality Assurance Unit did a risk-assessment for the trial and proposed a global Quality Assurance and Quality Control Plan (QA & QC Plan) with a similar format to Quality Assurance Programs used in US Intergroup Studies. The MINDACT QA & QC Plan encompasses the usual EORTC extensive central monitoring checks, data quality checks and data timeliness for all sites participating in MINDACT trial. The QA & QC Plan also details the audit plan for the study.<br><br>MINDACT is an 'avant-garde' trial with a central translational research component/question. Logistics are challenging for the sites, and require a very good interaction between the different departments (medical oncology, surgery, pathology) to allow it to run smoothly in each center. |

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| The trainee's role would be to evaluate and provide input on this process.  |
| <b>Fellowship duration</b>  |
| 1 year, starting 2 <sup>nd</sup> Semester 2010.   |
| <b>Ideal candidate</b>  |
| The ideal candidate must: <ul style="list-style-type: none"> <li>• Have a medical degree</li> <li>• Preferably have some clinical research background (specific courses and/or practical experience)</li> <li>• Be fluent in English</li> <li>• Be computer literate</li> <li>• Be able to work in an international environment</li> <li>• Have excellent communication skills</li> <li>• Have team spirit</li> <li>• Be under 35 years of age.</li> </ul>  |
| <b>Role of the trainee</b>  |
| <ol style="list-style-type: none"> <li>1. Review of the trial logistics and feasibility with the sites.</li> <li>2. Review of recruitment process: % screening and enrolled subjects, patients risk profile, randomizations. Screening failures and ineligibility: overview the reasons and feedback for improved recruitment.</li> <li>3. Analysis of non-compliance to all steps of the trial: timelines, randomization arms, treatments required.</li> <li>4. Translational Research: overview of the biological material collection and the quality of the blood and tumor samples, sample handling.</li> <li>5. Actively participate in the Medical Review implementation and process for this trial.</li> <li>6. Actively participate in answering medical queries to the sites related to the trial, when required.</li> <li>7. Actively elaborate queries to the investigators related to the SAEs reported at the Pharmacovigilance Unit (EORTC Headquarters), when required.</li> <li>8. To contribute to the yearly IDMC reports for this trial.</li> <li>9. Actively participate in all internal meetings regarding this trial.</li> <li>10. The opportunity to participate in internal educative sessions for the EORTC staff, as to external educative meetings.</li> </ol> |
| <b>Traineeship supervision</b>  |
| The trainee will be supervised by: <ul style="list-style-type: none"> <li>• Internal Data Center Supervisor, Lissandra Dal Lago, Clinical Research Physician of the EORTC Breast Cancer Group.</li> <li>• Head of the Medical Department of EORTC Data Centre, Jocelyne Flament.</li> <li>• Coordinator EORTC Data Center FellowShip Programme: Denis Lacombe.</li> </ul>   |
| <b>Additional information</b>   |
| Trainee will benefit from <ul style="list-style-type: none"> <li>• A thorough induction plan to the EORTC functioning</li> <li>• A complete training on clinical trials methodology</li> <li>• A specific and regular follow-up of work progress and deliverables</li> <li>• At the end of the fellowship the trainee will have had the opportunity to be involved in the organisation and running of a state-of-the-art international clinico genomic trial.</li> </ul>  |

#### Description of available position number 4

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| <b>Name of the host institute</b> |
| Institut Gustave Roussy           |

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| <b>Location of the traineeship</b>  |
| 39 rue c Desmoulins, 94805 villejuif, France  |
| <b>Title of the project</b>   |
| Identification of mediating resistance to trastuzumab.  |
| <b>Aim of the project</b>   |
| <p>This project will aim at identifying molecular events that mediate resistance to trastuzumab. This is a two step project. In the first part of the project, we will compare genomic profiling, hot spot mutations and phosphokinome before and after trastuzumab exposure. In order to address this question, we have identified 50 patients for which we have tumour biopsy before trastuzumab and when disease progressed after trastuzumab. Candidate events will be validated in a series of 50 samples treated with neoadjuvant trastuzumab and for which we have pre- and post-trastuzumab biopsies.</p> <p>From this analysis, we will identify candidate pathway that will be validated using siRNA. This step of functional validation will be done in collaboration with C. Swanton, the Royal Marsden Hospital, London, UK.</p> <p>Once validated by extinction, the molecular pathway will be targeted in vitro and in mice models by drugs. This part of the project is not included in the grant period.</p> |
| <b>Fellowship duration</b>  |
| 1 year, starting 2 <sup>nd</sup> Semester 2010.   |
| <b>Ideal candidate</b>  |
| The ideal candidate will be a pathologist well trained in the handling of tumour samples and molecular analyses. He/she will be trained on site for functional experiments (siRNA etc.). The pathologist should be highly motivated in pursuing an academic career in translational research.   |
| <b>Role of the trainee</b>  |
| The trainee will supervise the project and will perform all the experiments except genomic profiling.   |
| <b>Traineeship supervision</b>  |
| <p>Fabrice Andre will supervise the trainee and the project.</p> <p>Fabrice Andre is Director of the Biomarker Unit INSERM U981 at Institut Gustave Roussy. The trainee will also be supervised by a pathologist (Dr Mathieu) and a post-doctoral fellow (Virginie Quidville). One weekly meeting (Friday morning) usually takes place for this kind of supervision</p>   |

#### **Description of available position number 5**

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| <b>Name of the host institute</b>  |
| University Hospital Cologne / Breast Center; West German Study Group.  |
| <p>The Breast Center at the University of Cologne is one of the largest academic breast centers in Germany. Due to the particular medical education system in Germany one of the unique features is that the care for breast cancer patients is within the hands of the treating physicians, i.e. gynaecologists. Thus, if interested, the successful candidates will be able to participate in all aspects of breast cancer care from diagnosis to surgery and systemic therapy within the same department. Moreover, the breast center is the academic headquarter of the West German Study Group, a study group with a focus on large adjuvant chemotherapy trials. From the most recent trials (e.g. EC-DOC; AM01), TMAs are available which can now be used for marker evaluation raising questions about predictive markers for taxane treatment, chemo-resistance etc.</p> <p>Cologne is one of the 10 Comprehensive Cancer centers in Germany with an active ongoing scientific program in all aspects of molecular and clinical oncology.</p> |

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| <a href="http://cms.uk-koeln.de/brustzentrum/content/index_ger.html">http://cms.uk-koeln.de/brustzentrum/content/index_ger.html</a><br><a href="http://www.wsg-online.com/wsg/default.aspx">http://www.wsg-online.com/wsg/default.aspx</a>  |
| <b>Location of the traineeship</b>  |
| Cologne / Moenchengladbach  |
| <b>Title of the project</b>   |
| Evaluation of novel prognostic and predictive markers in randomized breast cancer trials.   |
| <b>Aim of the project</b>   |
| <p>The position will consist of two parts with more or less equal time required:</p> <p>The first part of this position will focus on the establishment and coordination of clinical trials at the breast centre of the University of Cologne. With more than 500 primary breast cancers per year this centre plays an important role in development and establishment of new therapeutic approaches. In addition, Prof. Dr. N. Harbeck and her team are highly interested in conducting phase II trials with novel agents and translational research projects. The trainee will be directly involved in conducting clinical trials at the university hospital Cologne. One trial he/she will be responsible for is the MINDACT trial.</p> <p>The second part of the trainee programme will be arranged in collaboration with the West German Study Group (WSG) since Prof. Harbeck is the scientific co-chair of the WSG. The WSG cooperates with other German and European study groups as well as with about 150 recruiting trial sites in Germany and is closely working together with the Breast Center of the University of Cologne and the Breast Center Niederrhein/Mönchengladbach. The major task of the trainee within the WSG should be the further development of the tumour bank from randomized WSG trials. He/she will mainly be responsible for evaluation of drug resistance markers in differentially treated breast cancer patients who received adjuvant chemotherapy.</p> |
| <b>Fellowship duration</b>  |
| 1 year, starting 2 <sup>nd</sup> Semester 2010.   |
| <b>Ideal candidate</b>  |
| <p>A young foreign physician who has recent experience in medical oncology (particularly breast oncology), breast surgery or breast pathology. He/she should be highly motivated in conducting translational research projects in breast cancer and to take care of study patients. First experience in management of clinical studies and basic skills in biology of breast cancer are anticipated.</p> <p>Experience in the development and maintenance of databases will be advantageous.</p>  |
| <b>Role of the trainee</b>  |
| <p>Part one: During the trainee phase at the Breast Center of the University of Cologne the following activities are anticipated:</p> <ul style="list-style-type: none"> <li>• Analysis and improvement of critical issues of preoperative management of patients who are suitable for the MINDACT trial and development of general pathways according to the German clinical standards to be presented to other German (and European) study sites to accelerate recruitment and improve data quality.</li> <li>• Coordination of collection of tumour and blood samples of MINDACT patients.</li> <li>• Coordination of necessary regulatory processes.</li> <li>• Care for study patients.</li> <li>• Presentation of the MINDACT trial at cooperating trial sites to improve recruitment in the region.</li> <li>• Participation in diagnosis and surgery of study patients (optional).</li> </ul> <p>Part two: Within the study group (WSG):</p>  |

- Collection of tumour samples, establishment and management of the necessary logistics.
- Development and database maintenance.
- Cooperation with local and central pathologists.
- Histological and immunohistochemical examination of tumour type, grading and classical prognostic markers.
- Construction of tissue micro arrays.
- Analysis of immunohistochemical expression of YB-1 protein and other markers in the TMA's (about 3000 samples).

#### **Traineeship supervision**

Prof. Dr. N. Harbeck, Head of the Breast Center at the University Hospital of Cologne, will be responsible for supervision, together with Prof. U. Nitz, the Clinical Co-Chair of the WSG. The cooperative team meeting of the WSG and Department's staff takes place bi-weekly. During this meeting the trainee will present interim results of his/her work.

#### **Additional information**

Status and contacts: Trainees will be regarded as scientific staff members of the University Hospital with all rights. Trainees will find a large educational portfolio of lectures etc. on site since the Cologne Cancer Center (CIO) is highly active in research, clinical work, and education.

Logistics: The university hospital is a campus with all faculties on site. The hospital itself is located in the center of Cologne with good access to public transportation and about a 10 min tram ride to the main station, Rhine river, and Cathedral. The hospital is also located next to Cologne University which is one of the largest universities in Germany. The WSG - located in Moenchengladbach - can easily be reached by train.