

## Committee annual report

(all cells can be expanded as needed)

### Committee chair

Name of committee : Transplantation committee		
Chair : Yves Beguin	Since : 11-2007	Date of last election : 27-06-2011

### Committee members : name (E-mail)

Baron Frédéric ( <a href="mailto:F.Baron@ulg.ac.be">F.Baron@ulg.ac.be</a> ) Beguin Yves ( <a href="mailto:yves.beguin@chu.ulg.ac.be">yves.beguin@chu.ulg.ac.be</a> ) Berneman Zwi ( <a href="mailto:zwi.berneman@ua.ac.be">zwi.berneman@ua.ac.be</a> ) De Becker Ann ( <a href="mailto:Ann.DeBecker@uzbrussel.be">Ann.DeBecker@uzbrussel.be</a> ) Deeren Dries ( <a href="mailto:DDeeren@hhr.be">DDeeren@hhr.be</a> ) Graux Carlos ( <a href="mailto:carlos.graux@uclouvain.be">carlos.graux@uclouvain.be</a> ) Herman Julie ( <a href="mailto:julie.herman.bhs@gmail.com">julie.herman.bhs@gmail.com</a> ) Kerre Tessa ( <a href="mailto:Tessa.Kerre@UGent.be">Tessa.Kerre@UGent.be</a> ) Lewalle Philippe ( <a href="mailto:philippe.lewalle@bordet.be">philippe.lewalle@bordet.be</a> ) Lodewyck Tom ( <a href="mailto:Tom.Lodewyck@azbrugge.be">Tom.Lodewyck@azbrugge.be</a> ) Maertens Johan ( <a href="mailto:Johan.Maertens@uz.kuleuven.ac.be">Johan.Maertens@uz.kuleuven.ac.be</a> )	Noens Lucien ( <a href="mailto:lucien.noens@UGent.be">lucien.noens@UGent.be</a> ) Ory Aurélie ( <a href="mailto:aurelie.ory@chu.ulg.ac.be">aurelie.ory@chu.ulg.ac.be</a> ) Pierre Antoine ( <a href="mailto:pantoin1@ulb.ac.be">pantoin1@ulb.ac.be</a> ) Xavier Poiré ( <a href="mailto:xavier.poire@uclouvain.be">xavier.poire@uclouvain.be</a> ) Schots Rik ( <a href="mailto:rik.schots@az.vub.ac.be">rik.schots@az.vub.ac.be</a> ) Schoemans Hélène ( <a href="mailto:helene.schoemans@uzleuven.be">helene.schoemans@uzleuven.be</a> ) Selleslag Dominik ( <a href="mailto:dominik.selleslag@azbrugge.be">dominik.selleslag@azbrugge.be</a> ) Sophie Servais ( <a href="mailto:s.servais@chu.ulg.ac.be">s.servais@chu.ulg.ac.be</a> ) Straetmans Nicole ( <a href="mailto:nicole.straetmans@scarlet.be">nicole.straetmans@scarlet.be</a> ) Willems Evelyne ( <a href="mailto:E.Willems@chu.ulg.ac.be">E.Willems@chu.ulg.ac.be</a> ) Zachée Pierre ( <a href="mailto:pierre.zachee@zna.be">pierre.zachee@zna.be</a> ) Sebastian Wittnebel ( <a href="mailto:Sebastian.wittnebel@bordet.be">Sebastian.wittnebel@bordet.be</a> )
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### Activities in year 2015

Date	Activity
18-05-2015	Committee meeting
22-10-2015	Committee meeting
16-01-2016	Committee meeting
	<p><b>Main activities :</b></p> <ul style="list-style-type: none"> <li>- Preparation of reimbursement dossier for posttransplant vaccinations sent to INAMI/RIZIV in 10-2015</li> <li>- Preparation of reimbursement dossier for photopheresis to be sent to INAMI/RIZIV in 02-2016</li> <li>- Continuation of the Valcyte MNP</li> <li>- Preparation for and follow-up of GCP inspections of BHS trials performed by the FAGG at UZG and Roeselaere.</li> <li>- Analysis and publication of TC01 clinical trial results (Allogeneic hematopoietic cell transplantation with HLA-matched donors : a phase II randomized study comparing 2 nonmyeloablative conditionings) and of ancillary translational research on immune recovery.</li> <li>- Ongoing clinical trials             <ul style="list-style-type: none"> <li>• TC02 : Infusion of mesenchymal stem cells as treatment for steroid resistant grade II to IV acute GVHD or poor graft function: a multicenter phase II study (01-2008)</li> <li>• TC03 : Co-transplantation of mesenchymal stem cells and HLA-mismatched allogeneic hematopoietic cells after nonmyeloablative conditioning: a phase II randomized double-blind study (07-2010)</li> <li>• TC04 : A pilot study to assess the feasibility of unrelated umbilical cord blood transplantation with coinfusion of third-party mesenchymal stem cells after myeloablative or nonmyeloablative conditioning in adult patients with hematological malignancies (11-2010)</li> <li>• TC05 : Randomized double-blind study of mesenchymal stem cells (MSC) in patients undergoing matched unrelated allogeneic bone marrow or peripheral blood stem cell transplantation -A European multicentre study (08-2010)</li> <li>• TC07 : Allogeneic hematopoietic cell transplantation from HLA-matched donors after reduced-intensity conditioning: a phase II randomized study comparing 2 GVHD prophylaxis regimen (09-2011)</li> <li>• TC08 : Busulfan dosage in allogeneic stem cell transplant recipients receiving PO Busulfan containing conditioning regimens (07-2012)</li> <li>• TC09 : Wilms' tumor (WT1) antigen-targeted dendritic cell vaccination to prevent relapse in patients older than 65 years with acute myeloid leukemia: a multicenter randomized phase II trial (06-2013)</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>• <b>TC10</b> : Sequential administration of 5-azacytidine (AZA) and donor lymphocyte infusion (DLI) for patients with acute myelogenous leukemia (AML) and myelodysplastic syndrome (MDS) in relapse after allogeneic stem cell transplantation (12-2013)</li> <li>• <b>TC11</b> : A phase II study to assess the safety and the efficacy of extracorporeal photopheresis using the Theraflex ECPTM for patients with refractory chronic GVHD (09-2014)</li> </ul> <p>- <b>Activities of the Belgian Transplant Registry (BTR) in collaboration with the Cancer registry and EBMT</b></p> <ul style="list-style-type: none"> <li>* Descriptive analysis of transplant activity in Belgium 2007-2013; final report due in March 2016.</li> <li>* Outcome analyses on the 2007-2013 transplant activity in Belgium and evaluation of each individual transplant center; final report due in March 2016.</li> <li>* Evaluation of Belgium compliance with EBMT transplant indications on the 2007-2013 transplant activity in Belgium and evaluation of each individual transplant center; final report due in March 2016.</li> <li>* Retrospective analysis of secondary cancers after allogeneic hematopoietic stem cell transplantation ; project to be started in April 2016.</li> </ul>
<p><b>! Please provide minutes of all this year's committee meetings !</b></p>	

### **Publications in year 2015**

<ol style="list-style-type: none"> <li>1. Baron F, Zachée P, Maertens J, Kerre T, Ory A, Seidel L, Graux C, Lewalle P, Van Gelder M, Theunissen K, Willems E, Emonts M-P, Schots R, Beguin Y. Nonmyeloablative allogeneic hematopoietic cell transplantation following fludarabine plus 2 Gy TBI or ATG plus 8 Gy TLI: a phase II randomized study from the Belgian Hematological Society. J.Hematol.Oncol 8:4, 2015 (IF = 4.812)</li> <li>2. Hannon M, Beguin Y, Ehx G, Servais S, Seidel L, Graux C, Maertens J, Kerre T, Daulne C, De Bock M, Fillet M, Ory A, Willems E, Gothot A, Humblet-Baron S, Baron F. Immune recovery after allogeneic hematopoietic stem cell transplantation following Flu-TBI versus TLI-ATG conditioning. Clin.Cancer Res. 21:3131-3139, 2015 (IF = 8.722)</li> </ol>
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### **Plan (policy, activities with approximate dates...) for next year**

<ul style="list-style-type: none"> <li>- <b>Continuation of Valcyte MNP and efforts to re-initiate the Defibrotide MNP</b></li> <li>- <b>Continuation of ongoing clinical trials</b></li> <li>- <b>Preparation of 3 new clinical trials :</b> <ul style="list-style-type: none"> <li>* CMV specific T cell therapy for the treatment of relapsing or therapy refractory CMV infection after allogeneic stem cell transplantation with a CMV-positive donor</li> <li>* Prospective randomized trial comparing conditioning with fludarabin/busulfan vs fludarabin/melphalan in patients with high-risk hematological malignancies undergoing hematopoietic stem cell transplantation</li> <li>* A collaborative phase III trial with the HOVON, following on Hovon 116 trial "A Phase I/II feasibility study of the combination of panobinostat and decitabine prior to donor lymphocyte infusion in recipients of allogeneic stem cell transplantation with poor and very poor-risk AML"</li> </ul> </li> <li>- <b>Follow-up of GCP inspections of BHS trials performed by the FAGG at UZG and Roeselaere, and corrective actions.</b></li> <li>- <b>Participation to the scientific committee of annual congress of the Société Francophone de Greffe de Moelle et de Thérapie Cellulaire (SFGM-TC) in Liège on November 16-18, 2016.</b></li> <li>- <b>Interaction with the RIZIV/INAMI on:</b> <ul style="list-style-type: none"> <li>* reimbursement of posttransplant vaccinations</li> <li>* reimbursement of photopheresis</li> <li>* new HSCT nomenclature : transfer of Cancer Plan action 17 into new amounts for cellular products</li> </ul> </li> <li>- <b>Finalization and dissemination of final reports on</b> (1) descriptive analysis of transplant activity in Belgium 2007-2013, (2) Evaluation of Belgium compliance with EBMT transplant indications, (3) analyses of outcome on the 2007-2013 Belgian transplant activity.</li> <li>- <b>Analysis of TC02</b> clinical trial results (Infusion of mesenchymal stem cells as treatment for steroid resistant grade II to IV acute GVHD or poor graft function: a multicenter phase II study), cohorts 1 (AGVHD) and 2 (poor graft function) and publication of results. First abstract at BHS meeting 2016.</li> </ul>
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### **Comments / requests for the BHS board**

<p><b>Thank you for the support in the form of 2 x 0.5 FTE data manager to manage all the ongoing clinical trials !</b></p>
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