

Data Safety Monitoring Board

The Data Safety Monitoring Board (DSMB) was appointed by UCL (the sponsor of the EVERREST clinical trial) and had their first meeting in September 2013. They are responsible for overseeing patient safety and the conduct of the clinical trial. They will consider the clinical trial protocol in detail, decide how they might respond to hypothetical situations, develop and agree a charter governing their remit and conduct, and agree the stopping rules for the trial. The DSMB will also agree a list of safety issues and unexpected serious adverse events that will be used to review the phase I/IIa trial once it is underway. If a serious concern with the safety of the patients in the trial arises, the DSMB may recommend early termination of the study.

Chair: Zarko Alfirovic, Professor of Fetal and Maternal Medicine, Centre for Women's Health Research, University of Liverpool, Liverpool Women's Hospital, Liverpool UK (with experience in clinical trials, fetal medicine, fetal therapy, maternal medicine, obstetrics, and systematic reviews)

Yves Ville, Professor and Chairman of the Department of Obstetrics and Fetal Medicine at Necker-Enfants-Malades Hospital, Paris Descartes University, Paris, France (with experience in fetal medicine, fetal therapy and clinical trials)

Adrian Thrasher, Professor of Paediatric Immunology, Institute of Child Health, Consultant in Paediatric Immunology, Great Ormond Street Hospital London, Director of Gene Therapy Programme ICH/GOSH, London, UK (with experience in paediatric immunology, clinical trials and gene therapy)

Andy Baker, British Heart Foundation Professor of Translational Cardiovascular Sciences, Institute of Cardiovascular and Medical Sciences, University of Glasgow, Scotland (with experience in pharmacology, toxicology, gene therapy, clinical trials, and cardiovascular disease)

Marc Sapoval, Professor of Clinical Radiology and Chair of the Cardiovascular Radiology Department, Hôpital Européen Georges-Pompidou, Paris, France (with experience in interventional radiology and clinical trials)

Umberto Simeoni, Professor of Neonatology, Aix-Marseille University and Department of Neonatology, AP-HM University Hospital, Marseille, France (with experience in neonatology, clinical trials, developmental origins of adult diseases, perinatal nephrology, and perinatal bioethics)