Statement on the procedures adopted for ensuring data protection/confidentiality/privacy including duration of storage of personal data in the framework of the FENICE Trial - Fluid Challenges in Intensive Care.

Brussels, January 13, 2013

I hereby confirm that all patient data collected for the FENICE trial will be anonymised and stored in a secure database. An electronic CRF will be used, with access protected through password linked to IP address. Database will be stored securely and accessed only through IP protected access by the principal investigator and study statistician. The study statistician will be Mr Hassane Njimi (Brussels).

All procedures comply with the EU Directive on data protection 95/46/EC. All data recorded and collected cannot be linked to the subject who supplied it. The patient is assigned a unique identifier number that will be used to identify the data. The patient’s identity is kept locally, in the centre where the patient was included, under responsibility of the local investigator, together with an identification number and a copy of the data in order to answer to answer queries during the process of database cleaning. Once the database is cleaned, the local investigator will destroy the material that links a patient’s identity to the identifier number.

In this trial, at least 783 patients should be included to detect a 5% absolute difference in the incidence of use of functional hemodynamic tests versus standard tests, with a p value of 0.05 and a power of 80%. This number was rounded up to 1000 to account for missing values and higher number of patients will also allow exploratory subgroups analysis. To achieve this number, at least 100 centres should take part in the study, as each centre will be allowed to include a maximum of 20 patients. At this stage, more than 200 centres worldwide have committed to include patients.

Sincerely,

Pr Dr Daniel DE BACKER, Principal Investigator