Reviewer's report

**Title:** Transaortic transcatheter aortic valve implantation - rationale and design of the first multicenter, multinational prospective registry (ROUTE)

**Version:** 1  
**Date:** 29 September 2014

**Reviewer:** Stefan Stortecky

**Reviewer's report:**

The present manuscript provides detailed information on the rationale and the design of the multinational, multicenter ROUTE registry, investigating clinical outcomes after transaortic transcatheter aortic valve interventions (TAo). The ROUTE registry and its protocol is original and will provide important information on the safety and efficacy of the transaortic access route with the Edwards Sapien bioprosthesis. The manuscript is well written and the methodology is described in detail. I still have the following remaining comments:

1. Throughout the manuscript, the authors describe the use of the Edwards Sapien THV prosthesis for the treatment of TAo patients. As the Edwards Sapien THV refers to the first generation Edwards Sapien device, the authors might wish to provide detailed information on the device itself – are the operators also allowed to use the Sapien XT or the Sapien 3 prosthesis within this registry?

2. It might be of interest to add the European centers with the local PI as supplemental information.

3. As indicated in the methods section, the investigators decided to choose a follow-up period from day 23 to day 37 after TAVI for the 30-day follow-up assessment. Follow-up assessment for the peri-procedural endpoint at 30 days should not be assessed prior to 30 days, but can have an assessment range until 45 days after the procedure.

4. Please indicated, whether events and event severity are self-reported or will undergo independent event adjudication according to the updated VARC endpoint definitions. As the authors are also interested in investigating all other VARC endpoints as secondary endpoint, independent event adjudication could increase the scientific value of this registry.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests.