

## **Listing of PORTEC-4a Protocol Amendments September 2016 (version 2.3, 09 September 2016)**

### **1. Administrative changes on front page:**

- new Trial Registries number for PORTEC-4a (Netherlands Trials registry and ISRCTN Registry)
- second clinical physicist for QA

### **2. Administrative changes in protocol text**

- Synopsis (p 4):
  - i. correction of inconsistencies with protocol text
  - ii. update of WHO pathology term serous (previous: papillary serous)
- Introduction (p 5): clarification about risk groups among stage II
- Update of published reference on page 11 (and accordingly in References, page 27)
- Patient selection (page 12):
  - i. correction of inconsistency in eligible stages
  - ii. update of classification of carcinosarcoma (no longer considered as uterine sarcoma)
- Pathology (pages 15-17):
  - i. correction and clarification of pilot phase and pathology review during the pilot phase (also corrected in Appendix A)
  - ii. update of pathology requirements (cornuae no longer in standard evaluation; 10% requirement for serous/clear cell now consistent with other sections)
  - iii. clarification of logistics of sending and returning slides and blocks
- Follow-up (page 17): correction and update of the followup visits and measurements, consistency with Appendix I and J
- Quality of life evaluation (pages 20-21): correction and update, consistency with Appendix I and J
- Participating centers (page 25 and ABR form): clarification that this is expected annual recruitment, while expected total recruitment numbers in the study have been corrected on ABR form
- Appendix I and J – some corrections for consistency with previous sections.

### **3. Amendment in statistical paragraph (page 21-23)**

- Clarification of international participation after the pilot phase
- Decision (agreement between NCRI UK Trial statistician and PORTEC statistician) to use annual confidential reports to DSMB with events and toxicity listing instead of an interim analysis, to ensure good overview for the DSMB without unnecessary alpha-spending.