PORTEC-3 Newsletter no 11 10 November 2016

FINAL ANALYSIS WILL BE DONE IN APRIL 2017 !

At the October 2016 Data and Safety Monitoring Board meeting, a progress report with event projection was discussed:

- **Median follow-up was 53.3 months**, which confirms that in March-April 2017, the median FU will be 5 years
- It was decided **not to do the second interim analysis** specified in the protocol (as this would have no consequences and not doing the second interim analysis reduces alpha-spending).
- It was decided to endorse the proposal to **move from an event-based analysis to a time-based analysis** and do the final analysis in April 2017, at a median follow-up of 5 years and additional FU after inclusion of the last patient of 42 months
- A **protocol amendment to the statistical paragraph** was suggested and sent to Central Ethics to include the analysis of the co-primary endpoint failure-free survival and detail alpha-partitioning with omission of the second interim analysis.
- See attached: Letter from DSMB to TMG and protocol amendment.

TIMELINES FOR UPDATE OF EVENTS AND FOLLOW-UP

- Most important: a **request to all groups and all investigators to ensure for all patients a follow-up date in 2016**, as this makes all of the difference for the quality of the final analysis of the trial.
- **What we need**
  - *A follow-up date in 2016 for each trial participant*
  - *Full information on events, cause of deaths, and on vital status of patients with events within last 6 months*
  - *Information from GPs and/or other hospitals for those patients not in active follow-up at the initial trial site*
  - ***Due date Jan 31, 2017***

- Data entry, data checks, final queries will be done during February 2017, for database checks and preparation for statistical analysis in March and writing of a late breaking abstract for ASCO 2017

PORTEC-3 Investigator's meeting during GCIG 2016

A PORTEC-3 Investigator's update meeting was held during GCIG in Lisbon on Friday, 28 October 2016. See attached presentation.

PORTEC-3 publications

- First PORTEC-3 publication on toxicity and quality of life – de Boer et al, Lancet Oncology 2016 Aug;17(8):1114-26 (sent previously)
- ANZGOG/TROG side study on Australian QA Benchmarking: Jameson et al, Journal of Medical Imaging and Radiation Oncology 60 (2016), 554-559 (see attached)
- ANZGOG side study on patient preferences – Blinman et al, British Journal of Cancer, 2016 online (see attached)

Results of pathology review in the PORTEC-3 trial

Stephanie de Boer has spent a month in London to analyse UK pathology review along with the Dutch pathology review, to provide results of pathology review for the two largest groups (together 329 pts in the trial), both with 2 pathologists doing all the reviews. A total of 1124 pathology reports (original/review) were evaluated. Overall, 102 patients (8.3%) were not eligible for the PORTEC-3 trial after pathology review. A poster has been presented at IGCS in Liston and a manuscript is in preparation.

Radiotherapy QA

The analysis of radiotherapy QA is well underway, although some plans are still pending, and these investigators have been contacted. Planning is to complete uploading of plans in December 2016, for analysis by TROG early 2017. Aims are to have a short paragraph on QA in the paper on the final analysis of the PORTEC-3 trial, and have a full paper on QA (to be written by the TROG/ANZGOG investigators) thereafter.

PORTEC-3 biobank and TransPORTEC consortium

Thanks to many efforts done by trial coordinators, PIs, pathologists and scientists from the participating groups, the PORTEC-3 biobank has almost been completed, and will overall comprise of about 63% of the tissues of the patients who have participated in the trial, or 74% of those groups who have participated in the translational research.

While creating the central PORTEC-3 biobank, preliminary studies have been done on a high-risk pilot set, which have shown that these joint projects were feasible and highly successful with 3 papers published, 1 accepted and 3 in preparation. With these and ongoing preliminary studies grant applications for a joint umbrella project with different work packages will be prepared.