PORTEC-4
SAE instruction

The SAE reporting procedure is the same for both study arms.

SAE definitions

An SAE is defined as: any untoward medical occurrence or effect that at any dose:

- is life-threatening or fatal;
- requires or prolongs hospitalisation;
- results in persistent or significant disability or incapacity;
- is a congenital anomaly or birth defect;
- is considered an important medical event*.

* Important medical events are those which may not be immediately life-threatening, but are clearly of major clinical significance. They may jeopardise the patient, and may require intervention to prevent one of the other serious outcomes.

Reporting procedure for Serious adverse events

Information about SAEs that occur within 28 days after last day of protocol treatment is collected and recorded on the Serious Adverse Event Report Form. The local investigator will determine if the events are related to the study treatment (i.e. unrelated, unlikely, possible, probable, definitely and not assessable). The SAE form should be completed in the English language and should be send within 24 hours from moment of first knowledge.

The SAE Form should be send by email within 24 hours after the initial observation of the event to the **IKNL Clinical research department; e-mail: trialbureau@iknl.nl**

For questions or remarks please email or phone +31 (0)88-2346500. The IKNL clinical research department is responsible for reporting the SAE to the authorities. All SAEs will be reported in the annual safety report.

Follow up & final

A follow-up report is expected within two weeks after the initial report, and the final report should be submitted within two weeks after the stop date. The follow up and final report should be updated versions of the initial report.

All forms should be dated and signed by the responsible investigator or one of his/her staff members*

*please note that any staff member completing or signing the SAE form should be noted on the delegation log.

Please complete this form in case of a serious adverse event and mail at lease the first page within 24 hours to: IKNL Trialbureau. E-Mail: trialbureau@iknl.nl

Hospital trial code |__|__| (01)

Patient trial number |__|__|__| (02)

Type of SAE report (1=new SAE report, 2=additional information after previous SAE report) |__| (03)

Contact physician, hospital and phone number:

REPORT ON OCCURRENCE AND THERAPY OF SERIOUS ADVERSE EVENT

Date onset SAE: (dd/mm/yyyy) ..... |__|__|.|__|__|.|__|__|__|__| (03)

Moment of SAE onset: 1 = before start of brachytherapy or EBRT*, 2= during or within 3 weeks after brachytherapy or EBRT, 3 = during observation or follow-up ..... |__| (04)

Treatment arm: 1 = standard adjuvant treatment, 2 = molecular profile based treatment..... |__| (05)

Treatment according to protocol: 0 = no*, 1 = yes: ..... |__| (06)
* specify: .....

Action regarding protocol treatment: 0 = no, 1 = delayed, 2 = discontinued, 3 = other*
* specify: ..... |__| (07)

SAE category: ..... |__| (08)
1 = death
2 = life threatening
3 = (prolongation of) hospitalization
4 = severe/permanent disability
5 = other, specify; .....

Causality from protocol treatment: ..... |__| (09)
0 = unrelated
1 = unlikely
2 = possible
3 = probable
4 = definite
5 = not evaluable, specify: .....

Outcome of SAE: ..... |__| (10)
0 = resolved
1 = ongoing, recovering
2 = ongoing, recovery uncertain
3 = permanent disability
4 = deteriorating
5 = death

If resolved, date SAE resolved: (dd/mm/yyyy) .... |__|__|.|__|__|.|__|__|__|__| (11)

If death, date of death: (dd/mm/yyyy) ..... |__|__|.|__|__|.|__|__|__|__| (12)

cause of death: .....

CTC grade of SAE (***please also send in Form 5)***: ..... |__| (13)

.....

Date: ..... *Name and signature:* .....

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Hospital trial code |__|__| (01)

Patient trial number |__|__|__| (02)

Type of SAE report (1=new SAE report, 2=additional information after previous SAE report) |__| (03)

Contact physician, hospital and phone number:

Description of situation, treatment and other relevant information (such as relevant medical history and additional comments):

If not all items can be filled out at initial report, please fax additional information within 10 days

Date: ..... *Name and signature: …….*