

# eCRF completion guidelines

## PORTEC-4a trial



Central datamanager: Karen Verhoeven-Adema, 088-2346125, [k.verhoeven@iknl.nl](mailto:k.verhoeven@iknl.nl)

### 1. General information

eCRF system: TRIAS (website: <https://trias.onconet.nl>)

Instructions how to use TRIAS are available in TRIAS.

Go to Help -> User documents and select the instruction manual (handleiding lokaal datamanager) or FAQ document (Trias\_FAQ\_voor lokaal datamanager).

### 2. Access to eCRF

Account requests should be sent to the central datamanager of this trial, either directly or by sending an e-mail to [trialbureau@iknl.nl](mailto:trialbureau@iknl.nl).

Accounts are personal and should not be shared with others.

### 3. Electronic Case Report Forms (eCRFs)

The following eCRFs are available for this trial:

#### **Baseline:**

Randomization checklist

Baseline

PA review (entry by CDM, access to this eCRF is limited to view only)

Toxicity

#### **Treatment:**

Treatment

Toxicity

End of Treatment

#### **Follow Up:**

Follow Up

Toxicity

Recurrence

Instructions how to complete these eCRFs are provided in the eCRF.

### 4. Queries

Queries will be attached to the eCRF in TRIAS. See also instruction manual of TRIAS.

### 5. Randomisation form (paper)

To randomise a patient the local investigator/treating physician should complete the randomisation form and randomise the patient either by emailing/telephoning the IKNL Trialbureau secretaries ([trialbureau@iknl.nl](mailto:trialbureau@iknl.nl) or 088-2346000) or directly on the ALEA online Website.

### 6. Serious Adverse Events (SAE) form (paper)

SAE's should be reported within 24 hours of becoming aware of the event by the local investigator/treating physician according to the instructions provided on the form and this SAE form should be updated when new information becomes available.

SAE forms need to be filled out and signed by the responsible physician, and sent to

[trialbureau@iknl.nl](mailto:trialbureau@iknl.nl).

If you notice an SAE which has not been reported, please notify your responsible physician to do so, and alert the Central Datamanager that you have done so.

Central Datamanagement will enter the SAE forms in TRIAS, the local datamanager will be able to view the information. Please check if these data are consistent with your own, regular, entries.

**Please note:** Definition of SAE is provided in the protocol, chapter 7: Safety reporting.

### 7. Quality of life (paper)

If patients participate in QoL study, they complete the QoL form at baseline, after completion of treatment, 6 months, 12 months, 18 months, 24 months, 3 years, 5 years, 7 years and 10 years after randomisation.