

Concomitant Medication(s) relevant to the event (exclude those used to treat event)

Concomitant drug(s) and dates (YYYY-MMM-DD) of administration.
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Reporter information

Investigator information

Name:	Name:
Address:	Address:
Phone:	Phone:
Profession:	Profession:
Signature & Date	Signature & Date

Fill in this form and mail or fax it within xx hours to sponsor:

Secure mail:
Nicholas.carlson.01@regionh.dk

Fax.no:
+45 3545 2240 / +45 3545 2672

Sponsors date and signature for receiving this report:

Date

Signature

PART 2: (To be filled in by sponsor)

Causality Assessment by Sponsor:

Result of causality evaluation:

- Not related to study drug (Unlikely/doubtful) → (If judged related by investigator go to box below)
- Related to study drug (Possible/Probable/Definite) → (Go to box below)

Expectedness Assessment by Sponsor (only relevant if SAE is related to study drug):

Result of expectedness evaluation:

- Expected (due to relevant reference document)
- Unexpected → (Go to box below)

Summary:

Category of event:

- SUSAR (SAE is both related and unexpected)
- SAR (SAE is related but not unexpected)
- SAE (SAE is not related)

Notify relevant authorities according to protocol

Sponsors comments (including information regarding unblinding):

Sponsors date and signature:

Date

Signature