21.12. UNEXPECTED SERIOUS ADVERSE EVENTS

SIOP - LGG 2003
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National Coordinating Center:

Surname, Prename Pat.-Nr. Hospital Pat.-Identity-Nr.
I_____I I_I_I_I_I I_I_I_I_I I__I I__I__I__I__I__I__I I_I__I__I__I__I
Date of birth

Unexpected, serious adverse events during treatment must be reported immediately to the national coordinating center, i. e. within the next working day, and followed up by the treating institution.

FAX-Number:

Reason for SAE-report:

- Therapy-related death (-> please fill out „Patient Status Report“ form 21.13.2. ❒ yes ❒ no
- Event, leading to a permanent, relevant handicap. ❒ yes ❒ no
- Life-threatening event ❒ yes ❒ no
- Unexpected, serious adverse, which cannotbe documented on the toxicity form ❒ yes ❒ no
- Grade 4 toxicity (renal, hepatic, cardiac, skin, nervous systems) symptoms ❒ yes ❒ no

Grading of SAE after NCI-CTC: ❒ 1 ❒ 2 ❒ 3 ❒ 4 ρ unknown /not assign to

Start or rather proof of SAE on I__I__I . I__I__I . I__I__I__I__I

During / after which element of therapy?

❒ Induction I ❒ Induction II ❒ Consolidation ❒ after end of therapy ❒ radiotherapy ❒ others_____

Please, describe the event and the adopted measures:
(kind, start, period of time, expression/severity, causality. Coherent symptoms and laboratory test results should be summed up to only one)

_____
_____
_____

Drugs at start of SAE:

	drug	dose/day	mode of application	day of therapy (from / to)	Relation between drug and SAE					
					none	impro-bable	possible	probable	sure	no decision, insufficient data
1.					❒	❒	❒	❒	❒	❒
2.					❒	❒	❒	❒	❒	❒
3.					❒	❒	❒	❒	❒	❒
4.					❒	❒	❒	❒	❒	❒
5.					❒	❒	❒	❒	❒	❒
6.					❒	❒	❒	❒	❒	❒

- Is there a relation between SAE and the drugs, which have been applicated before SAE? ❒ no ❒ yes,_____
- Have one or several drugs been discontinued? ❒ no ❒ yes, Nr._____
- Did the reaction wear off after stopping these? ❒ no ❒ yes, Nr._____
- Have one or several drugs been restarted? ❒ no ❒ yes, Nr._____
- Has the reaction reappeard after this drug’s restart? ❒no ❒ yes, Nr._____
- Have one or more drug dosages been changed? ❒ no ❒ yes, Nr._____

What do you assume to cause of the start of SAE?
❒ complication of tumor ❒ other, concommittant disease
❒ complicationen of therapy with SIOP-LGG 2004 protocol ❒ other, concommittant therapy
❒ other known or possible reasons; explaining:_____

Course
❒(still) continuing SAE ❒ recovery without sequelae ❒ recovery with sequelae
❒ dead following SAE ❒dead, no connection to SAE
Date of recovery or dead: I__I__I.I__I__I.I__I__I or ❒ not applicable (still continuing)
remarks:_____

date stamp/signature name in blockletter