

## Overview of safety reporting procedures to the **Ethics Committees** in Switzerland

Event and study type	Timeline	Responsible for reporting	Recipient of report	Document*
<b>SAE</b> for all studies with <b>drugs</b> (OClin, Art. 22) and <b>Not-LThP studies</b>  (related/ unrelated)	<i>Only if fatal</i> Immediately (max. 7 d)	Investigator  To lead EC: directly from sponsor accepted	Local EC local events**  Lead EC in CH All CH-events	SAE form
<b>Serious ADR</b> for all studies with <b>drugs</b> (OClin, Art. 23) and  <b>SAE Related to study procedure</b> <b>Not-LThP studies</b>	<i>If fatal or life threatening</i> Immediately (max. 7 d)	Investigator  To lead EC: directly from sponsor accepted	Local EC local events**  Lead EC in CH All CH-events	SAE form
<b>SAE Related to study procedure*</b> <b>Not-LThP studies</b>	If NOT fatal/life threatening  Within 15 d	Investigator  To lead EC: directly from sponsor accepted	Local EC local events**  Lead EC in CH all CH-events	SAE form
<b>SUSAR for all studies</b> (without MD-studies)  (OClin, Art. 23)	If fatal or life threatening  Immediately (max. 7 d)  If NOT fatal/life threatening  Within 15 days	Investigators  Unblinded reports directly from sponsor accepted***	Local EC local events**  Lead EC in CH all CH-events	SAE form
All other SAEs will be summed up in the annual safety update report, see below.				
<b>SAE</b> for Premarket clinical studies with <b>medical devices</b>  (OClin, Art. 20 and 24; MEDDEV 2.7/3 (Dez. 2010))	<i>Imminent risk of death, serious injury, or serious illness and that requires prompt remedial action for other patients/subjects, users or other</i>	Investigators  To lead EC: directly from sponsor accepted	Local EC Local events**  Lead EC in CH all CH-events	SAE form

Event and study type	Timeline	Responsible for reporting	Recipient of report	Document*
	Immediately (max. 2 d) Any other reportable event related to the medical device under investigation or due to study related procedures immediately (max 7 d)			
<b>SAE for postmarket clinical studies with medical devices</b>  (OClin, Art. 20, 24; MEDDEV 2.7/3 (Dez. 2010))	Any reportable event related to the medical device under investigation or due to study related procedures: immediately (max 7 d)	Investigators  To lead EC: directly from sponsor accepted	Local EC Local events**  Lead EC in CH all CH-events	SAE form
<b>Summary of safety events (as for Swissmedic)</b>	Annually	Investigator; Directly from Sponsor accepted	Local EC All events	Annual safety update report

#### Abbreviations:

EC = Independent Research Ethics Committee  
 LThP = Federal Law on Therapeutic Products (HMG/LPTh)  
 OClin = Ordinance on Clinical Trials of Therapeutic Products  
 MD = Medical Device  
 MEDDEV 2.7/3 (Dez. 2010): Guidelines on Medical Devices: Clinical Investigations: Serious Adverse Event Reporting under Directives 90/385/EEC and 93/42/EEC.

SAE = Serious Adverse Event;  
 Serious ADR = Serious Adverse Drug Reaction;  
 SUSAR = Suspected Unexpected Serious Adverse Reaction;  
 SAE *Related* = Relationship to study procedure could not be definitely excluded: relationship is certain/probably/possibly/unlikely/uncertain.

\* SAE-Form For Investigator driven studies (with sponsor-investigator) ask the Clinical Trial Units for SAE forms, for Industry-sponsored studies as usual.

\*\* Local events are those events which occur in the area of the EC responsibility.

\*\*\* If Investigator=sponsor (=sponsor-investigator), SUSAR could be sent either blinded or unblinded. If unblinded it has to be sent by an investigator independent site (CRO or pharmaceutical company).

AGEK

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