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Overview of safety reporting to the (Lead-) Ethics Committee and to Swissmedic

Reporting according to ClinO-MD (KlinV-Mep, OClin-Dim, OSRUm-Dmed) in clinical trials of medical devices

Category A clinical trials (post-market trials)

Event	ClinO-MD	Reporting by	Reporting to	Type	Timeframe
AEs, SAEs, DDs, health hazards that require measures	Art. 32	Investigator	Sponsor	mandatory	According to CIP
AEs, ADEs, DDs without SADE potential	Art. 32	Sponsor	(Lead-) EC* Swissmedic**	on request by the (Lead-) EC or by Swissmedic	-
SADE, DDs with SADE potential	Art. 33	Sponsor	(Lead-) EC* Swissmedic**	mandatory**	immediately
Safety and protective measures	Art. 34 and 36	Sponsor	(Lead-) EC* Swissmedic**	mandatory**	≤ 2 days, 24 hours in case of study interruption or premature study end
Annual Safety Report	Art. 35	Sponsor	(Lead-) EC	mandatory	annually

* Reporting to the (Lead-) Ethics Committee: Reporting is to be performed via the BASEC web portal using the Safety Form associated to the Project Form. The exact process is described in the FAQ 'safety notification' in the FAQ section in BASEC. Direct link to the FAQ here.
According to Article 10 ClinO-MD, the investigator may submit the application instead of the sponsor. In this case, the investigator assumes the sponsor's obligations under Articles 14 and 15 as well as the notification and reporting obligations vis-à-vis the competent ethics committee. Note: Article 10 does not apply to the notification and reporting obligations vis-à-vis Swissmedic.

** For reporting to Swissmedic please refer to section 7.1 of the Swissmedic information sheet BW600_00_015e_MB. Reporting to Swissmedic is mandatory only if materiovigilance reporting criteria are fulfilled. Further information can be found here.

Category C clinical trials (pre-market trials, incl. off-label use)

Event	ClinO-MD	Reporting by	Reporting to	Type	Timeframe
AEs, SAEs, DDs, health hazards that require measures	Art. 32	Investigator	Sponsor	mandatory	According to CIP but not later than 3 days***
AEs, ADEs, DDs without SADE potential	Art. 32	Sponsor	(Lead-) EC* Swissmedic**	on request by the (Lead-) EC or by Swissmedic	-
SADE, DDs with SADE potential	Art. 33	Sponsor	(Lead-) EC* Swissmedic**	mandatory	immediately***
Safety and protective measures	Art. 34, 36, 38	Sponsor	(Lead-) EC* Swissmedic**	mandatory	≤ 2 days, 24 hours in case of study interruption or premature study end
Annual Safety Report	Art. 35 and 38	Sponsor	(Lead-) EC* Swissmedic**	mandatory	annually

* Reporting to the (Lead-) Ethics Committee: Reporting is to be performed via the BASEC web portal using the Safety Form associated to the Project Form. The exact process is described in the FAQ 'safety notification' in the FAQ section in BASEC. Direct link to the FAQ here.
According to Article 10 ClinO-MD, the investigator may submit the application instead of the sponsor. In this case, the investigator assumes the sponsor's obligations under Articles 14 and 15 as well as the notification and reporting obligations vis-à-vis the competent ethics committee. Note: Article 10 does not apply to the notification and reporting obligations vis-à-vis Swissmedic.

** For reporting to Swissmedic please refer to section 7.2 of the Swissmedic information sheet BW600_00_015e_MB.

*** See European guidance document MDCG 2020-10/1. For SAEs and DDs, reporting deadlines to the sponsor normally vary between 24h to 3d, depending of stage of development and severity of possible consequences. Seven days are foreseen for the reporting of the sponsor to the (Lead-) EC and Swissmedic.

Abbreviations and definitions (alphabetical order)

ADE = Adverse Device Effect (ADE) (ISO14155)

Adverse event possibly, probably or causally related to the use of an investigational device or procedures.

Note: This includes any adverse event resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, operation, or any malfunction of the MD under investigation. It includes any event that is a result of a use error or intentional misuse, and it includes 'comparator' if the comparator is a medical device.

AE = Adverse Event (Art. 2(57) MDR)

Any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a clinical investigation, whether or not related to the investigational device.

Note: This includes events related to the MD under investigation or the comparator and to the procedures involved. For users or other persons this is restricted to events related to the MD.

CIP = Clinical Investigation Plan

DD = Device Deficiency (Art. 2(59) MDR).

Inadequacy of a medical device related to its identity, quality, durability, reliability, safety or performance, of an investigational device, including malfunction, user errors and inadequate information supplied by the manufacturer.

Note: The definition includes deficiencies related to the investigational MD or the comparator MD.

SADE = Adverse Device Effect (ADE) that has resulted in any of the consequences characteristic of a serious adverse event (ISO14155).

SAE = Serious Adverse Event (SAE) (Art. 2(58) MDR)

Any adverse event that led to any of the following:

(a) death,
(b) serious deterioration in the health of the subject that resulted in any of the following:
  (i) life-threatening illness or injury,
  (ii) permanent impairment of a body structure or a body function,
  (iii) hospitalisation or prolongation of patient hospitalisation,
  (iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
  (v) chronic disease,
(c) foetal distress, foetal death or a congenital physical or mental impairment or birth defect.

Note: planned hospitalization for pre-existing condition, or a procedure required by the CIP, without a serious deterioration of the health status of the subject, is not considered an SAE.