

# Safety Reporting Procedure to the Swiss Research EC's

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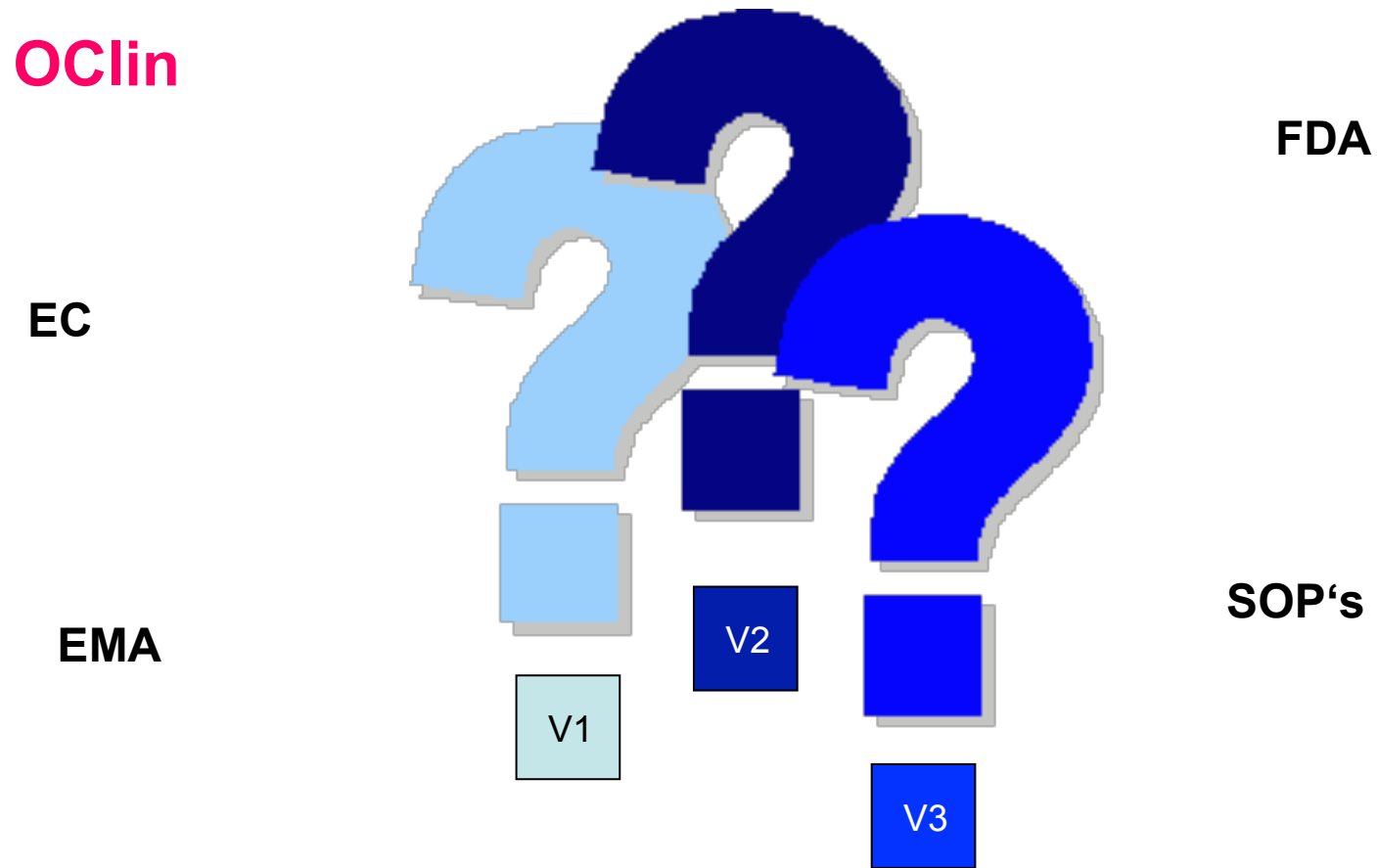
# Overview

1. Situation
2. Regulations
3. Basic Rules
4. Time lines for initial and follow-up reports
5. One center in Switzerland vs. multicenter
6. Forms
7. Annual Safety Report

# 1. Situation: EC's



# 1. Situation: Sponsors



## 2. Regulations

- OClin, Art. 20, 22, 23, 24.
- GCP, Art. 4.11.
- Clinical Safety Data management: **Definitions** and Standards für Expedited Reporting (ICH-E2A, 1994)
- MEDDEV 2.7/3, december 10 (EU Directives on Medical Devices)

### 3. Basic Rules → EC

- No single safety reports from abroad
- Safety reports only from the concerned *study*
- Safety reports from all concerned study *drugs*
- *Local safety reports to local EC*
- *All Swiss safety reports to lead EC*
- No AE's
- SAE's only if fatal
- Serious ADR only if fatal *or life threatening*
- *SUSAR in any case*
- EC's accept direct sending from sponsor
- Investigator=sponsor: Unblinding (optional) only from an investigator-independent site
- Annual Reports (not quarterly), as for Swissmedic

## 4. Time lines: Initial (without MD-studies)

If fatal or life threatening:

→ to EC: immediately,  $\leq 7$  days.

If NOT fatal or life threatening:

→ to EC:  $\leq 15$  days.

If immediate actions are necessary (OClin, Art. 20) :

1. Letter with actions taken immediately (study stop?)
2. Amendment as soon as possible

# 4. Time lines: Initial for MD-studies

## SAE **P**remarket:

If imminent risk of death, serious injury or illness that requires prompt remedial action for patients and others:

→ to EC: immediately,  $\leq 2$  days

Any other reportable event related to MD or study procedure:

→ to EC: immediately  $\leq 7$  days

## SAE **P**ostmarket:

Any reportable event related to MD or study procedure:

→ to EC: immediately  $\leq 7$  days

If immediate **actions** are necessary (OClin, Art. 20) :

1. Letter with actions taken immediately (study stop?) to EC
2. Amendment as soon as possible

## **4. Time lines: Follow-up**

All SAE's must be followed until resolution or until no further change is expected.

## 5. One center - multicenter study

1. Generally for all studies (local, international):  
Local safety reports to local EC
2. One center in CH or no lead EC in CH:  
Local safety reports to local EC.
3. Multicenter study with *lead EC* in CH:
  - Local safety reports to local EC, and:
  - *All CH-safety reports to lead EC by sponsor*

## 6. Forms

For trials with drugs:

CIOMS form or adequate forms/informations (s. [www.swissmedic.ch](http://www.swissmedic.ch) or website of CTU's)

For trials with medical devices:

MEDDEV-form, sponsor form

For other trials:

No mandatory form

# 7. Annual Safety Reports

See [www.swissmedic.ch](http://www.swissmedic.ch) (OClin, Art. 23):

1. *The safety report contains a precise, critical summary of the medicinal product's safety profile and new, relevant safety aspects and their effect on carrying out the clinical trial. A list in table form showing serious adverse drug reactions should also be appended, including detailed presentations of SUSAR from Switzerland and abroad.*
2. Separately: Status quo of the study sites in the area of the responsible EC (form see [www.swissethics.ch](http://www.swissethics.ch)) (pat. in study, drop-outs, completed etc.)

For EC's: List of the studies conducted at their centers

Thank you for your attention

