UNIVERSITÄT BERN

Safety reporting in clinical trials with drugs

CTU Lecture 08.11.2017

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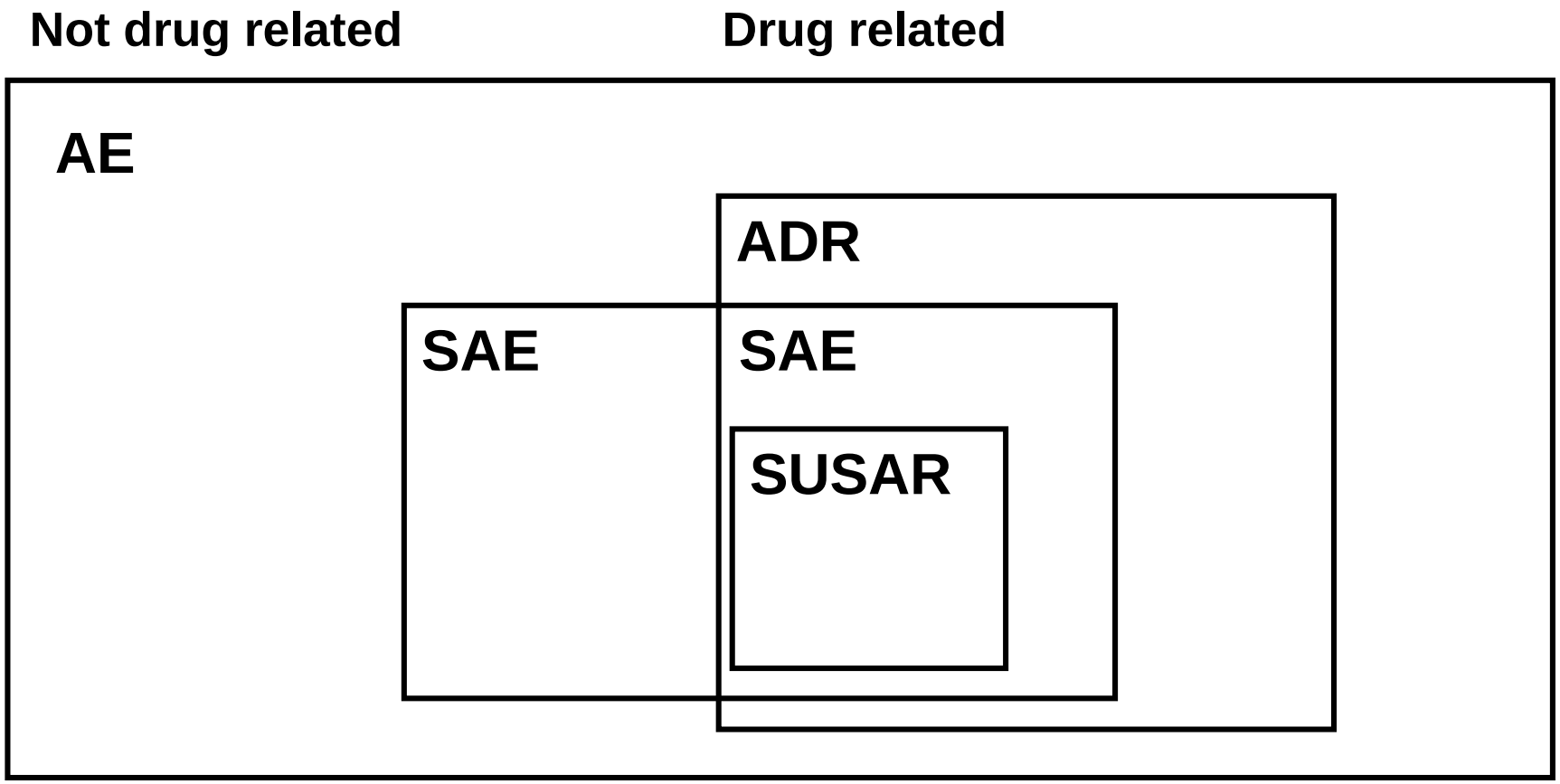
Agenda

- Presentation/Promotion SOP
  - Overview on events
  - Overview on SOP: process and procedures of safety reporting
  - Highlights and examples of the safety reporting core procedures: detection, assessment, documentation, reporting
- Q & A, Discussion

Limitations:

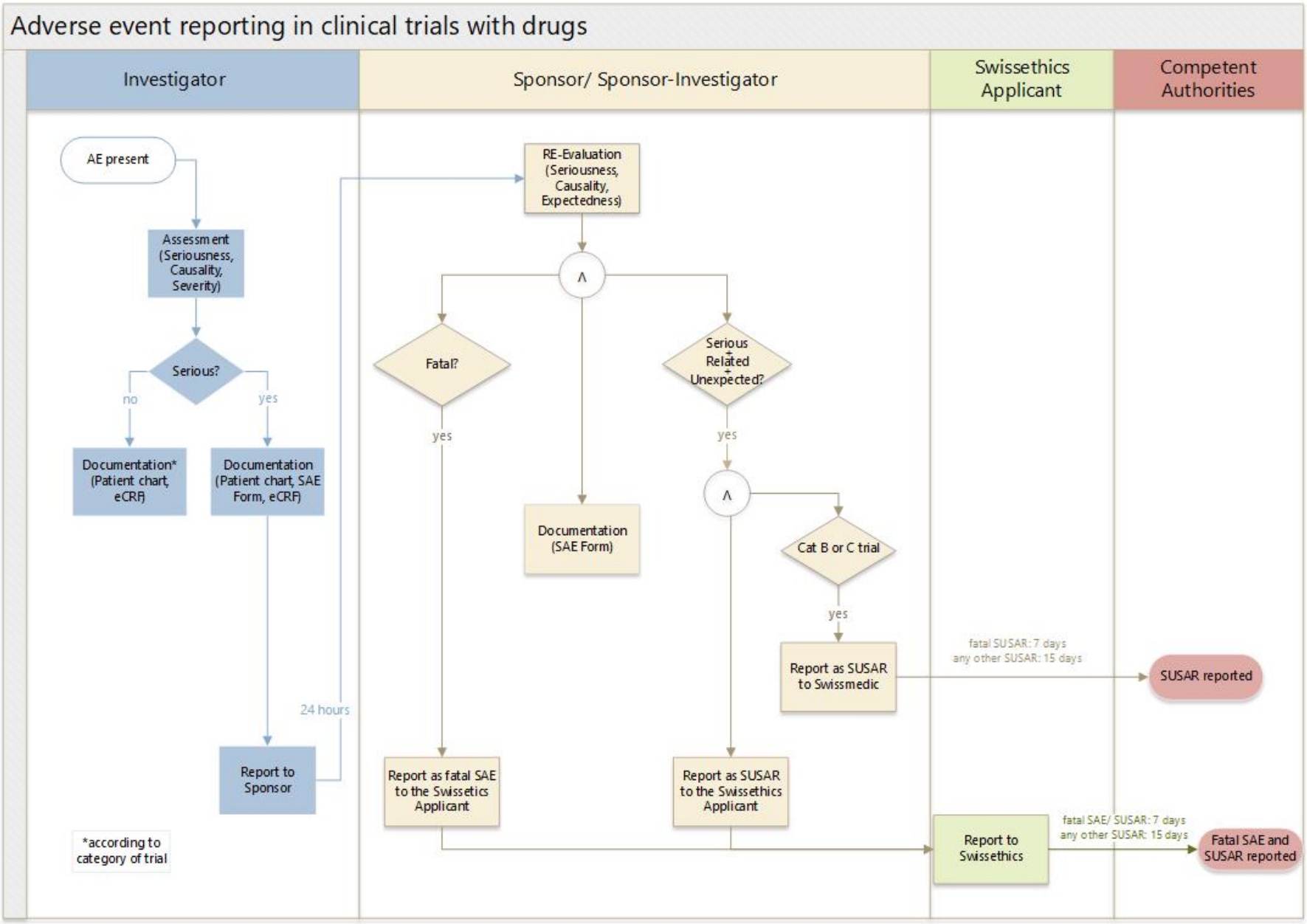
- No in-depth definitions
- Not a step by step instruction
- Limited to IMP trials

Overview on «events»

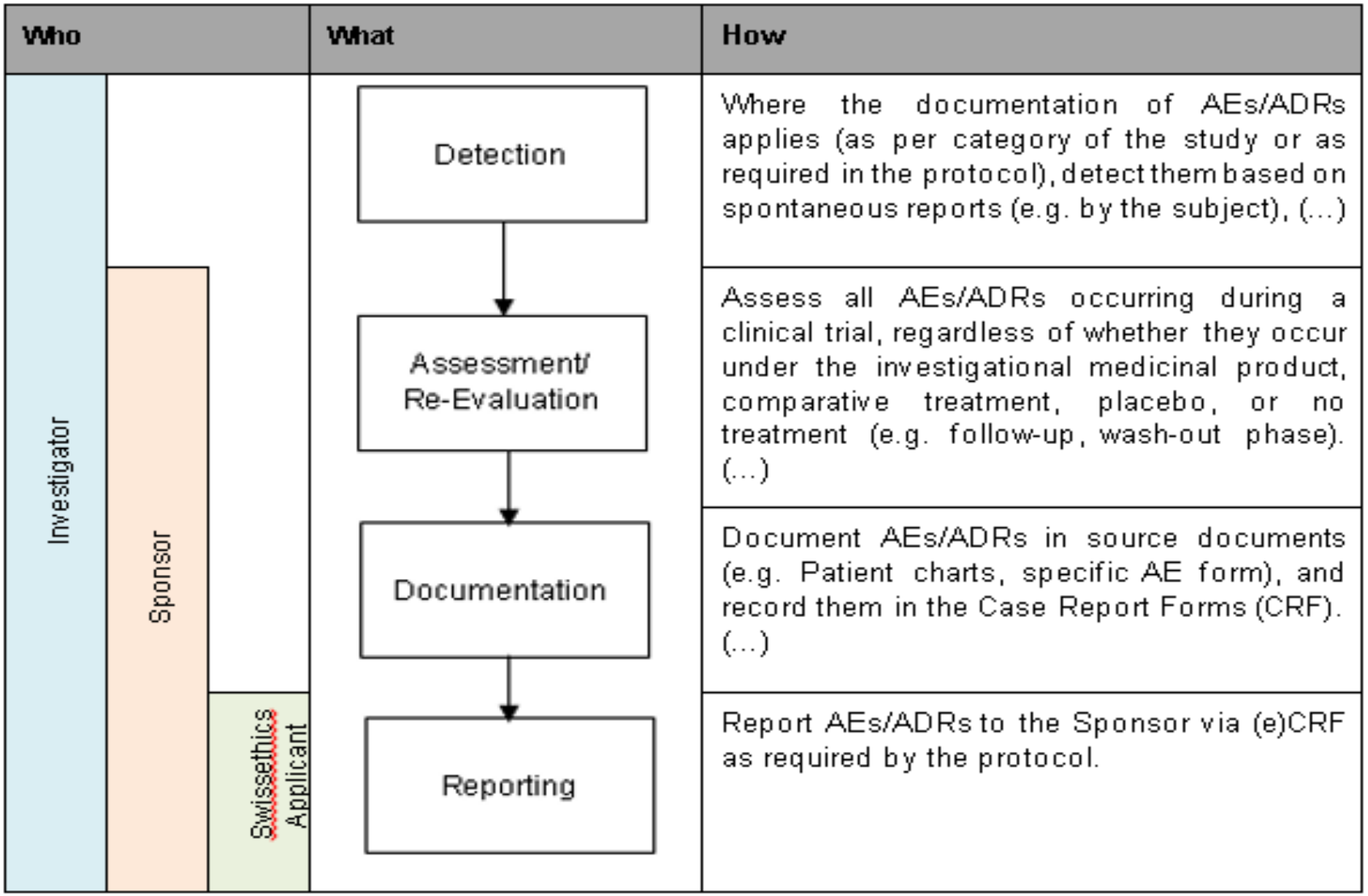


A=Adverse; E=Event; D= Drug R=Reaction;
S=Serious/Suspected; U=Unexpected

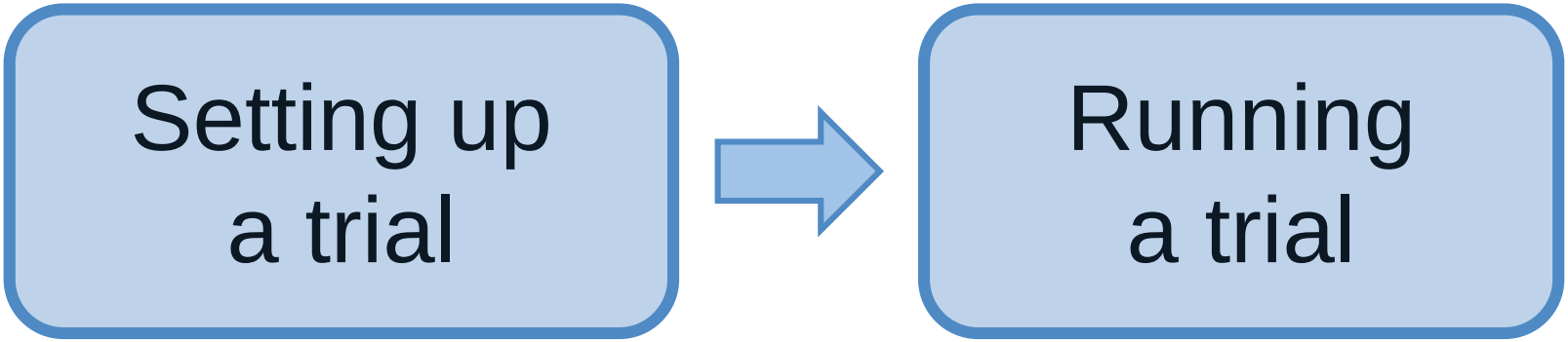
Overview on the process



Overview of procedures



Who, What, How… and When?



… and Why?

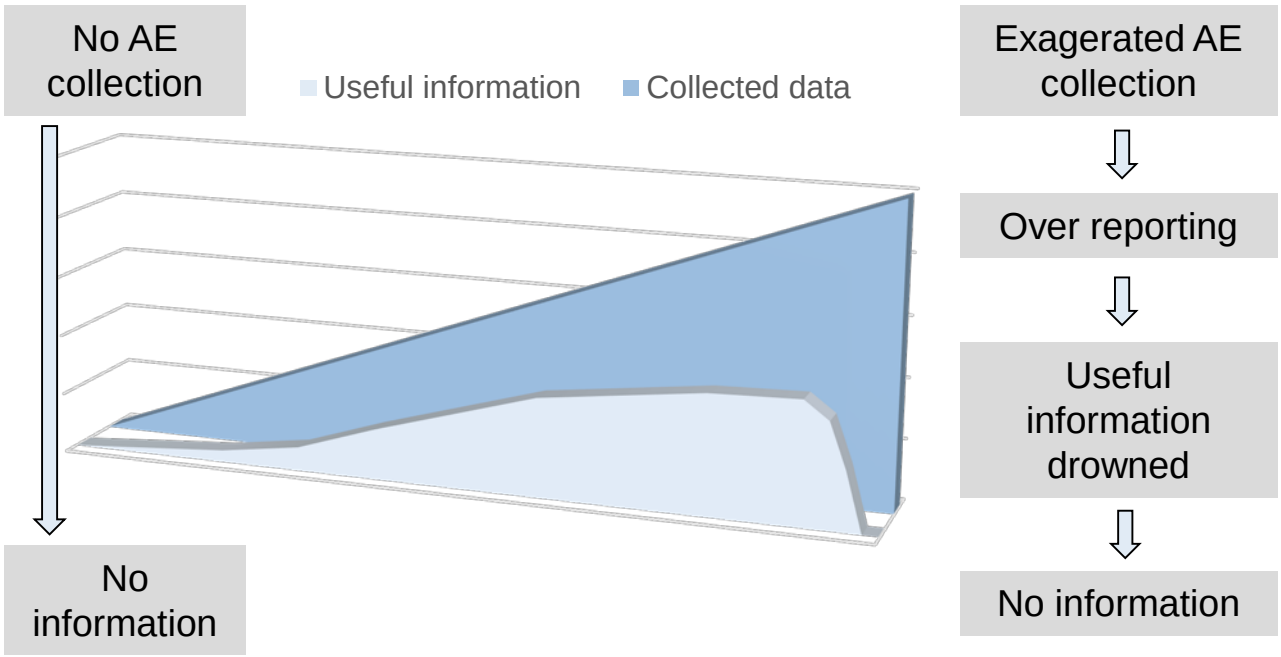
Patient safety and well-being

Who	What	
Investigator	Detection	
Sponsor	Assessment/ Re-Evaluation	
	Documentation	
SE-Applicant	Reporting	

AE/SAE detection – How?

Once you have the starting point
the process is quite straightforward

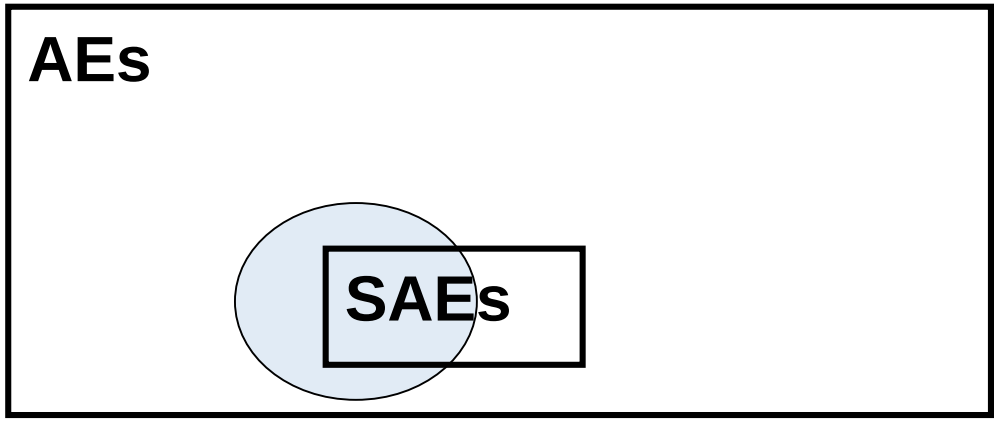
AE detection is how to get there…



Objective: Supervise known risks
Detect unknown risks

Danger: Information overload

Who	What	
Investigator	Detection	(ClinO, art.39, art.40) Category A: Only SAEs Category B: SAEs Requested by EC/RA According to protocol Category C: All AEs
Sponsor	Assessment/ Re-Evaluation	
	Documentation	
SE-Applicant	Reporting	(ClinO, art.40): Events which are not to be reported according to the protocol are exempted.



Who	What	
Investigator	Detection	Example 1: Heart surgery Solution: Exempt expected SAEs
Sponsor	Assessment/ Re-Evaluation	Example 2: Botox trial Solution: Define AE detection time window
	Documentation	Example 3: Ocular injection Solution: Only ophthalmic events
SE-Applicant	Reporting	**Warning!** Swissethics protocol template: "During the entire duration of the study, all adverse events (AE) and all serious adverse events (SAEs) are collected, fully investigated and documented in source documents and case report forms (CRF)."

Who	What	
Investigator / Sponsor / SE-Applicant	Detection	Event — Investigator Severity — Investigator Seriousness — Investigator + Sponsor Causality — Investigator + Sponsor Yes / No related, probably, possibly, unlikely, unrelated Other Related as a precaution ⇔ Missing a related event Expectedness — Sponsor Technical assessment IB / product information
	Assessment/ Re-Evaluation	
	Documentation	
	Reporting	

Who	What	
Investigator / Sponsor / SE-Applicant	Detection	Site documentation, 3 Levels: • Source documents • Forms • CRF } in line!
	Assessment/ Re-Evaluation	**Sponsor oversight** Responsible for ongoing safety evaluation and overview of the trial
	Documentation	• Listing of all AEs & SAEs • Review the situation Per AE category, per site, etc. Assess changes to risk benefit ratio Document! (Statement, sign and file) • Interval: Risk profile Frequency of reported events
	Reporting	

Who	What	
Investigator	Detection	Reporting…
Sponsor	Assessment/ Re-Evaluation	Patient safety and well-being **Ethics committee responsibility (ICH GCP):** Ensure the protection of the rights, safety and well-being of human subjects involved in a trial
	Documentation	**Swissmedic (home page):** We consistently and rigorously apply the requirement to ensure the safety of therapeutic products
SE-Applicant	**Reporting**	… to Ethics committees and Swissmedic

Who	What	
Investigator	Detection	Reporting… … to Ethics committees and Swissmedic **Swissmedic:** SUSARS safety and protective measures **Swissethics:** lethal SAEs SUSARS safety and protective measures And that's all! + once a year – Annual Safety Report YOU
Sponsor	Assessment/ Re-Evaluation	
	Documentation	
SE-Applicant	**Reporting**	

Questions & Answers

Discussion