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Safety surveillance

Work package 4
Task leader „Safety“: R. Pilger

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Content

- Safety Surveillance
- Assessment and reporting of safety events
- Roles of investigator and sponsor/safety desk
- Summary

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MACE

Major Adverse Cardiovascular Event:

- **Nonfatal myocardial infarction**
- **Nonfatal stroke**
- **Cardiovascular death**

- Relevant safety event and primary endpoint!
- MACE rate: identification of safety risks during study conduct?

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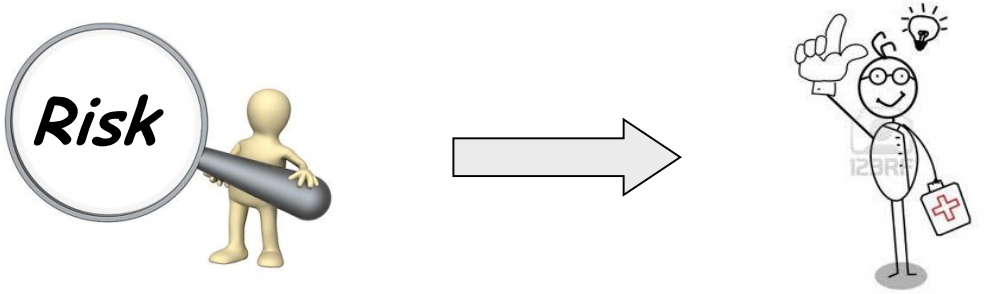
Safety surveillance

- Documentation, collection and assessment of safety information ➔ corrective and preventive actions



- Implementation of system for collection safety information
- Assessment of information is the responsibility of sponsor and investigator

➔ ***Risk for patients by study intervention/design?***
➔ ***Need of (corrective and preventive) actions?***

DISCHARGE: Investigator‘s responsibilities

- Documentation of all safety events
- Assessment of events
  - » Seriousness
  - » MACE
  - » Causal relationship to
    - – underlying disease
    - – interventional procedure
    - – other
- Reporting (via fax) within 24 h after becoming aware to KKS Charité (in behalf of the sponsor); Format: SAE form
- Follow up until stable condition
- If applicable (required by single national regulation) : reporting of fatal and life-threteaning events to EC (see approval/favourable opinion of local EC

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Definition:AE

- **<u>Adverse Event (AE):</u>** Any untoward medical occurrence in a patient or clinical investigation subject ... and which does not necessarily have a causal relationship with this treatment.

➔ ***Definition of exeptional rules and special events of interest!***

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Definition SAE

- **<u>Serious Adverse Event (SAE):</u>** Any untoward medical occurrence at any reason, that
  - results in death,
  - is life-threatening,
  - requires inpatient hospitalization or prolongation of existing hospitalization,
  - results in persistent or significant disability/incapacity,

  or
  - is a congenital anomaly/birth defect

- **MACE is an SAE!**

Events of special interest (serious and non serious)

- **Examples (expected events after CTA/ICA):**
  - » **Bleeding or bruising at the site of the incision**
  - » **Infection at the incision site**
  - » **Mild to moderate allergic reaction or a serious life-threatening allergic reaction to the contrast dye**
  - » **Heart attack**
  - » **Stroke**
  - » **Blood vessel damage (requiring further surgery)**
  - » **Death**
  - » **Thrombosis**

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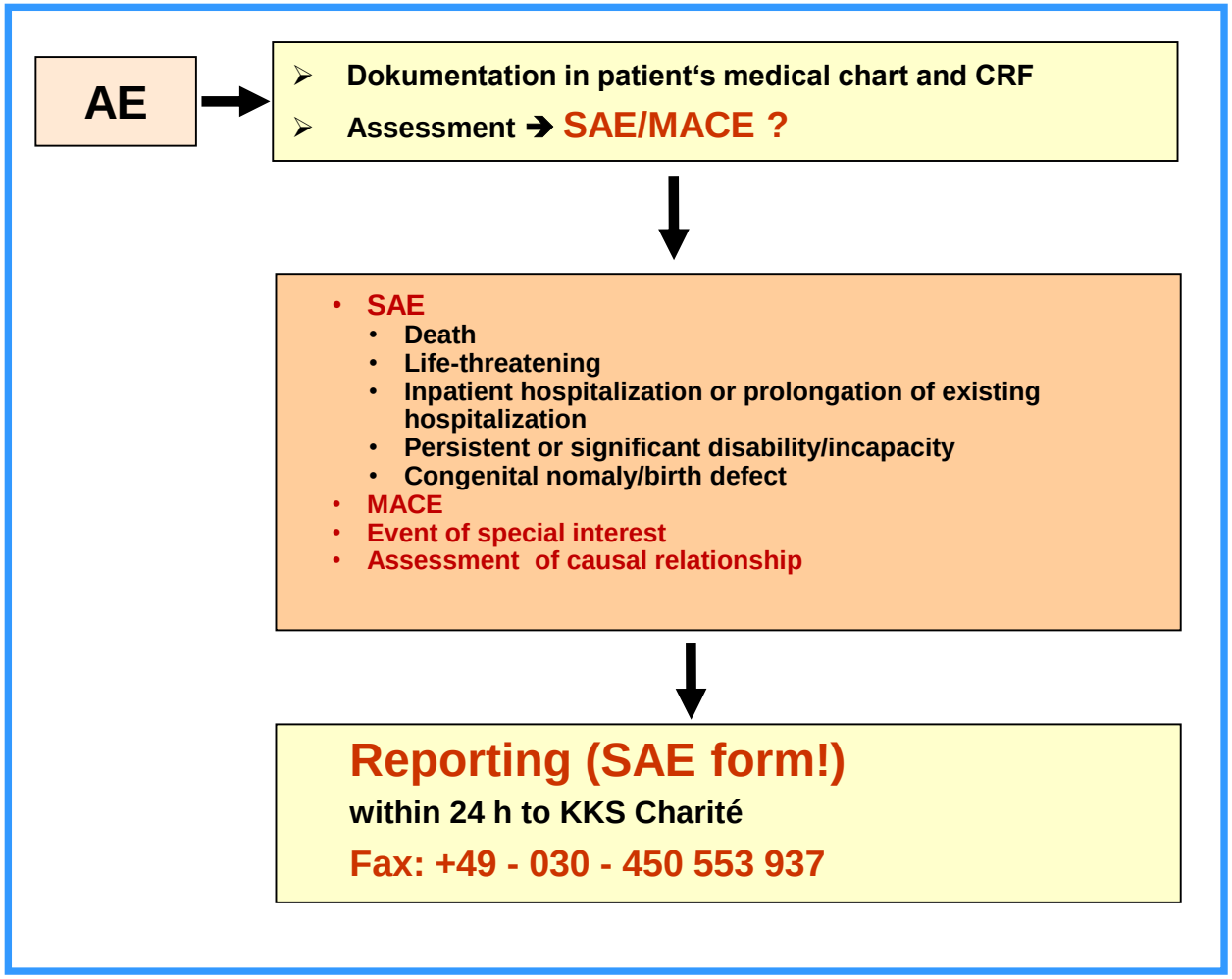
SAE Reporting by the investigator



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Sponsor‘s Safety Desk

- Coordination of all safety information: KKS Charité
- Documentation of all reported SAEs and safety issues
- Continuous assessment of SAEs regarding the impact on safety issues by the event committee (task of event committee)
- Suitable actions caused by safety issues

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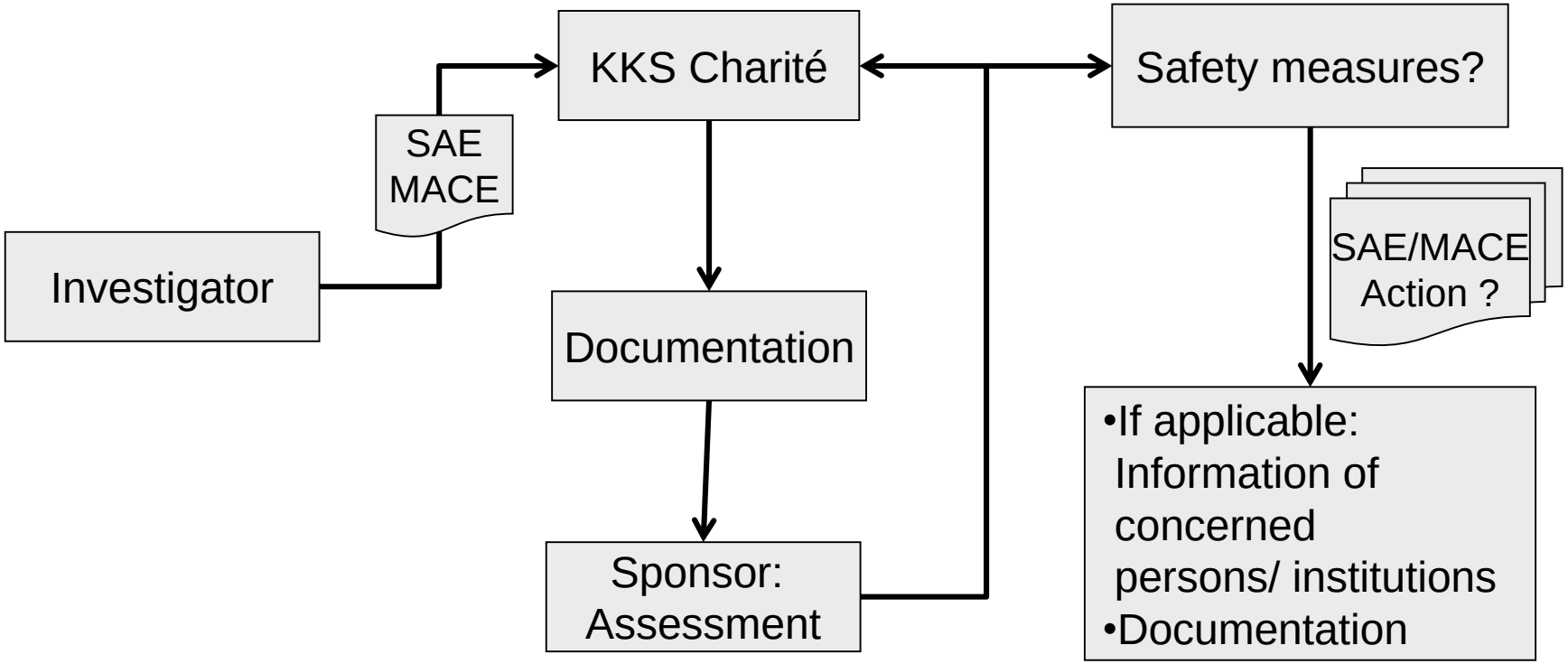
Information flow



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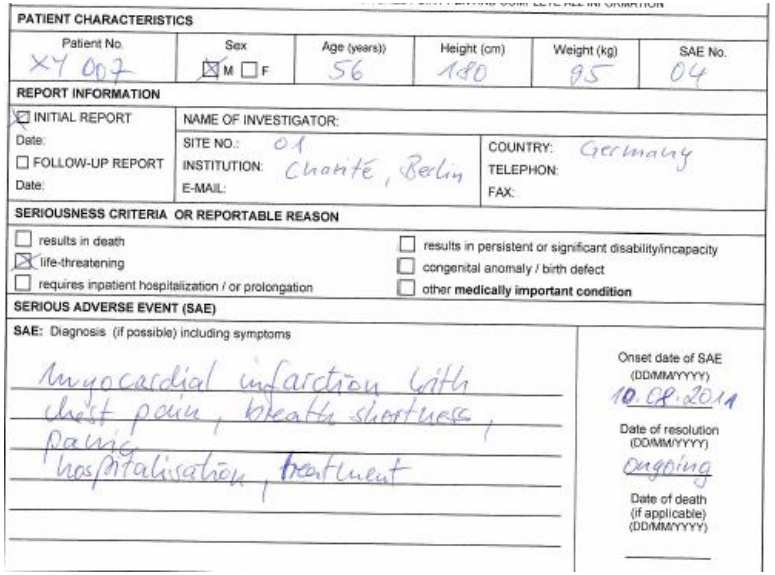
Usage of SecuTrail

- Overview on SAEs/events by data base
- Availability and usable for safety desk and (central) monitoring



PATIENT CHARACTERISTICS

Patient No.	Sex	Age (years))	Height (cm)	Weight (kg)	SAE No.
XY 007	☒ M ☐ F	56	180	95	04

REPORT INFORMATION

☒ INITIAL REPORT
Date:
☐ FOLLOW-UP REPORT
Date:

NAME OF INVESTIGATOR:
SITE NO.: 01
INSTITUTION: Charité, Berlin
E-MAIL:
COUNTRY: Germany
TELEPHON:
FAX:

SERIOUSNESS CRITERIA OR REPORTABLE REASON

- ☐ results in death
- ☒ life-threatening
- ☐ requires inpatient hospitalization / or prolongation
- ☐ results in persistent or significant disability/incapacity
- ☐ congenital anomaly / birth defect
- ☐ other **medically important condition**

SERIOUS ADVERSE EVENT (SAE)

SAE: Diagnosis (if possible) including symptoms

Myocardial infarction with chest pain, breath shortness, pains, hospitalisation, treatment

Onset date of SAE (DD/MM/YYYY): 10.08.2011

Date of resolution (DD/MM/YYYY): ongoing

Date of death (if applicable) (DD/MM/YYYY):

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Errors we want to avoid

- What has to reported, when and to whom?
- Information flow: how does the investigator get information on safety events?
- Verifying and monitoring of investigator‘s compliance?

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Summary

- Safety surveillance and suitable infrastructure is required by GCP (responsibility of the sponsor)
- Investigator is responsible for documentation, assessment and reporting of SAEs
- MACE is a SAE and primary endpoint ➔ attention ➔ reporting!
- Follow up of patients to receive information on adverse events
- Contact point: KKS Charité

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Thank you for your attention

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