ACO/ARO/AIO-18.1.

Contact Information

Project Manager: **Martin Walker**

Tel: 069 / 7601 - 4571

E-Mail: Walker.Martin@ikf-khnw.de

PM-Assistenz: **Nejra Kosic**

Tel: 069 / 7601 - 4140

E-Mail: Kosic.Nejra@ikf-khnw.de

Monitor: **Vanessa Patronelli**

Tel: 069 / 7601 - 3692

E-Mail: Patronelli.Vanessa@ikf-khnw.de

Pharmacovigilance: **Fax: 069 / 7601 - 3655**

Safety Reporting: Adverse Events

- **All** Adverse Events occurring during study conduct must be
  - **noted** in the source data,
  - **reviewed** for causal relationship and
  - **reported** in the eCRF **in a timely manner**

- **All** Adverse Events must be reported from the time of first study treatment until EOT or 30 days after the last dose of study treatment

- This also applies to Medical History conditions (other than the study indication) that deteriorate during study conduct

- After end of treatment (>30 days after last dose of study treatment) only long term toxicity effects with a potential study relationship need to be reported

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Safety Reporting: Serious Adverse Events

- All **Serious Adverse Events** (Adverse Event fulfilling seriousness criteria)

  - must additionally be documented in **SAE section of eCRF**
  - must be reported to IKF **within 24 hours of awareness**

    - > save and print SAE Form
    - > signature by any investigator
    - > fax to pharmacovigilance FAX: **069 / 7601 - 3655**

- **All** Serious Adverse Events must be reported from the time of first study treatment until EOT or 30 days after the last dose of study treatment

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Documentation: eCRF

- Relevant data will be captured via **secuTrial based eCRF system**
- eCRF incl. helpdesk will be administrated by **IKF GmbH**
- **Accounts** will be provided after finalization of initiation process
- eCRF is accessible by any browser

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Initiation „visits“

- **Site initiation** will be performed by telephone (remote)

- Initiation calls will flexibly be conducted by PM, PMA or Monitor

- Initiation calls will take place as soon as
  - all regulatory necessary documents are available,
  - eCRF system is „live“ and
  - contracts are signed

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Monitoring visits

- **Monitoring visits of site** will be performed „on-site“
- Monitoring visits will usually be conducted by **Monitor**
- Monitoring visits will take place
  - as soon as the 2nd patient is enrolled
  - in risk based approach (depending on recruitment and data quality)
  - always in agreement with site and monitor