Supplementary file 8 - Roles and responsibilities

Daily management team (including the Principal investigator (PI))

Conduct of DanAF

Preparation of protocol and revisions

Design of Redcap database

Organising steering committee meetings

Conceive manuscripts of results for review by the steering committee

In charge of supervising start-up of sites

Budget administration and contractual issues with individual centres

Organisation of central serum sample collection

Design of randomisation

Securing that the GDPR is complied with (by interaction with the Regional data controller)

Site investigators

Joshua Buron Feinberg (Holbaek University Hospital), Axel Brandes (Odense University Hospital), Ulrik Dixen (Hvidovre University Hospital) and Ole Dyg Pedersen (Region of Zealand University Hospital - Roskilde)

Responsible for the proper conduct at respective sites.

In charge of reporting Serious adverse events (SAE) including Suspected unexpected serious adverse reactions (SUSAR) to PI in a timely manner as well as reporting serious adverse events for annual review by the regional ethics committee.

Steering committee (SC)

All authors of the protocol will be invited to be part of the steering committee.

Agreement of final protocolReviewing progress of study and if necessary agreeing changes to the protocol.

In charge of reviewing proper conduct of the trial according to GCP, Helsinki-declaration and ethics review demands.

Providing advice to lead investigators and personnel.

Review of analyses provided by the blinded statistician

Review of manuscript prepared by daily management team

Assistance with international review

Data manager

Maintenance of trial IT system and data entry (OPEN).

Data verification (OPEN in collaboration with PI)

Providing data to the DSMC

Providing data to the blinded statistician

Outcome adjudication committee

Responsible for adjudicating serious adverse events.

Data safety monitoring committee

Responsible for the safety of trial participants and the continuous scientific merit for the trial. Will report findings to the SC.

Blinded statistician

Prepare analysis for the steering committee to review

Regional data controller (independent from trial)

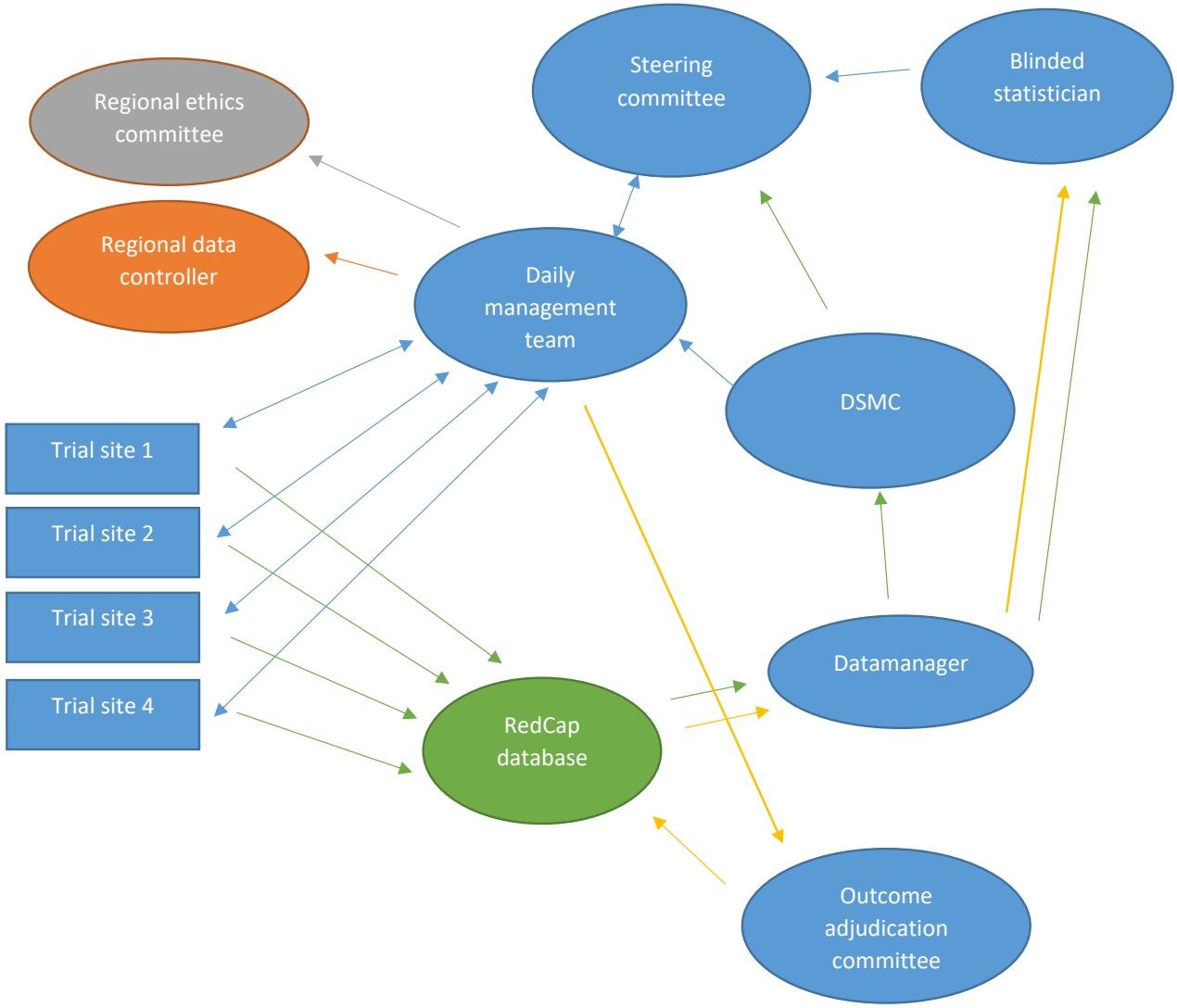
Data controller for the study hence must keep record of the type of data kept, data processor agreements and any other requirements needed to comply with GDPR

Regional ethics committee (independent from trial)

Approve the trial by review of protocol, written participant material, informed consent forms, etc.

Monitor trial through reports of SAE and SUSAR reported to them by the daily management team as well as the yearly report submitted by the PI.

Figure outlying the organisation



Grey arrow: Serious adverse events including SUSAR. Orange arrow: Information necessary to follow GDPR. Green arrow: Data. Yellow arrow: data for adjudication/adjudicated data.

Blue bubbles: Part of the trial organization. Green bubble: database. Orange/grey bubble: External regulatory body.