



Certification of Clinical Sites and CRF Working Groups

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Topics

- Certification of Clinical Sites
 - Certification in 3 Steps
- CRF Working Groups

Certification of Clinical Sites

- 3 Steps to Certify Clinical Site for Study
- 1. Attending Kick-off Meeting
- 2. Sending highest qualification of all CT readers to Charité (Adriane Napp@charite.de)
- 3. Participation in cardiac CT hands-on course in March
 - One CT reader per clinical site

CRF Working Groups

- Demographics
- Inclusion/ Exclusion criteria
- Physical Examination and vital signs
- Cardiac medical history
- Non-cardiac medical history
- Concomitant medication
- CT technique and reconstruction

CRF Working Groups

- CT or ICA procedure
- CT or ICA reading
- CT or ICA radiation (Geleijns)
- CT or ICA results and recommendations
- CT or ICA MACE, Events of Special Interest, Serious Adverse Events
- CT or CT management and treatment decisions
- ICA results and decisions

CRF Working Groups

- ICA IVUS
- ICA FFR
- ICA PCI
- Ischemia tests (ECG, stress echo,...)
- Follow-up: medical Status
- Follow-up: MACE
- Follow-up: Quality of Life

Summary

- Get certified – equivalence of level III
- Participate in CRF Working Groups