Clinical Studies Sweden Forum South

Clinical Trial Registration and Reporting

Current work at Region Skåne

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Disclaimer:

- I present an objective view based on my affiliation at Clinical Studies Sweden - Forum South.

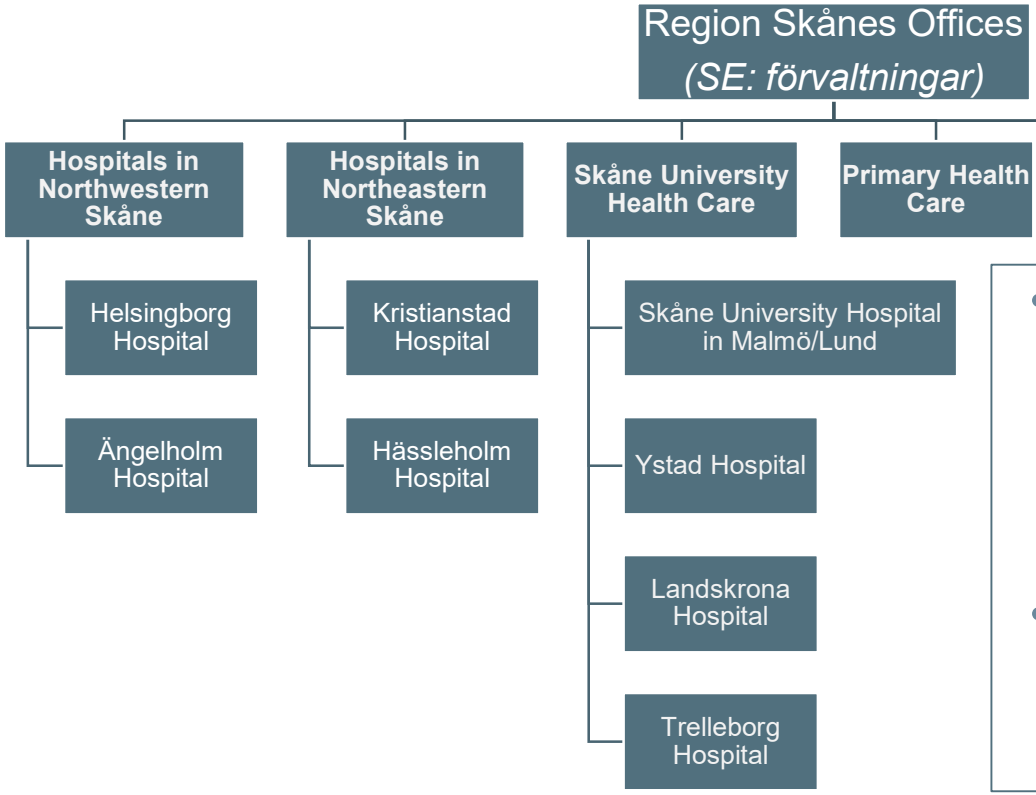
Kliniska Studier Sverige Forum Söder

Stödjer klinisk forskning i Södra sjukvårdsregionen

How do Forum South come in contact with trial registration and reporting

- Trial registration och reporting is executed by the sponsor-investigator or the responsible researcher.
- Requirements is part of our educational packages.
- Contracted monitoring unit (GCP-requirement): Trial registration is checked at start-up; Trial reporting is informed of at close-out.
- Administrates the account ‘Region Skane’ on ClinicalTrials.gov: guidance documents and hands-on support.

Region Skåne - simplified organisation



- Applications for clinical trial authorisations are signed at department - level within hospital.
- No single entry-point for trial/research registration and reporting

Clinical trials with Region Skåne as Sponsor

Studies subject to authorisation from the Swedish Medical Products Agency *(clinical trials - drugs and medical devices)*

- Handling of this research is part of a larger review within Region Skåne
  - ✓due to the upcoming new database CTIS for drug trials (prel. going live 31 January 2022)
  - ✓due to the upcoming new database Eudamed (functional earliest in may 2022
- However, this may only partly solve the already missing trial-reporting

Clinical research with Region Skåne as Research Principle *(SE: Ansvarig forskningshuvudman)*

Medical research subject to authorisation from the Swedish Ethical Review Authority only.

- Observational, non-interventional, registry-based, epidemiological research
- Establishing a process for approving submissions for Ethical Review by the “Research Principle” is ongoing.

How can we centralise trial registration and reporting - an opportunity

- Within Region Skåne there is one single entry-point for all research.
  - ✓Application for access to personal data from Region Skåne's information system and paper records for health and medical care to be used for research purposes. "the KVB*- application"
  - ✓A digital platform for application is coming soon.
- However, this may only partly solve the already missing trial-reporting

*SE: Samråd KVB (kvalitetsregister, vårddatabaser och beredning)

Different records – different names

(Numbers are a rough estimate and not quality controlled)

Sponsor name	Trials on EUCTR (due date expired)	Trials on Clinicaltrials.gov (due date expired)	Trials on ISRCTN (due date expired)
Region Skåne (Region Skane)	19 (4)	212 (144) *Only 5 results reported*	2 (1)
Skåne University Hospital	29 (6)	3 (3)	3 (2)
➢ Lund University Hospital	13 (4)	4 (3)	
➢ Malmö University Hospital	2 (1)	4 (2)	2 (2)
Regional Hospital / Nordic/Scandinavian trial groups / "Other adverse Names"	8+	3 (3)	3 (3)
Lund University	12 (4)	19 (10)	4 (4)
Malmö University	2 (0)	4 (2)	0

What do Forum South think about data transparency

- When I was asked to speak today, one of the questions posed was ”What can Lund University learn from you?

- The question is rather what can we learn from each other, what can we do together to create a structure for the researchers within our research community.