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.
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.
• 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)*

<table>
<thead>
<tr>
<th>Sponsor name</th>
<th>Trials on EUCTR (due date expired)</th>
<th>Trials on Clinicaltrials.gov (due date expired)</th>
<th>Trials on ISRCTN (due date expired)</th>
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<tbody>
<tr>
<td>Region Skåne (Region Skane)</td>
<td>19 (4)</td>
<td>212 (144)</td>
<td>2 (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Only 5 results reported</td>
<td></td>
</tr>
<tr>
<td>Skåne University Hospital</td>
<td>29 (6)</td>
<td>3 (3)</td>
<td>3 (2)</td>
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<td>Malmö University Hospital</td>
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<td>2 (2)</td>
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<td>Regional Hospital / Nordic/Scandinavian trial</td>
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<td>Malmö University</td>
<td>2 (0)</td>
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</tr>
</tbody>
</table>
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.