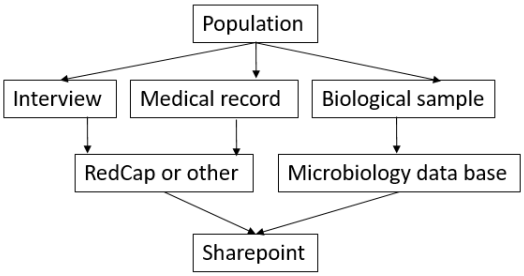
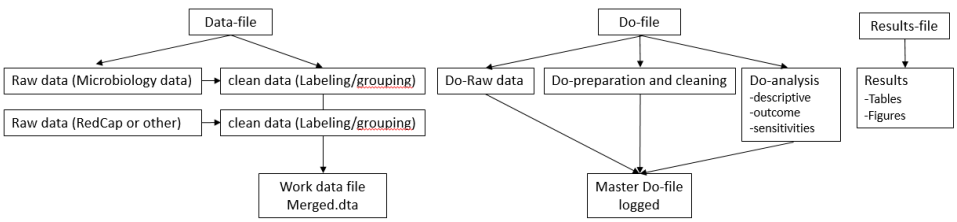
Data management plan checklist	
Table of content	1. Administrative Data 2. Data Collection and organization 3. Documentation and Metadata 4. Ethics and Legal Compliance 5. Storage and Backup 6. Long-term preservation 7. Data Availability 8. DMP-online
1. Administrative Data (kort afsnit da alle disse oplysninger skal stå i protokollen)	-Name of the persons involved in the project -Project Description: short introduction and clearly defined objectives -Method: Design, participants, sites and dates, guidelines followed (e.g. CONSORT, STROBE, and TRIPOD) -Related policies: Study permissions and approvals (registration numbers), founding, study owners, data protection/security policy from the institution, and data management policy. ***Henvis evt. til protokollen og SAP***
2. Data collection and organization	-Type and source of the data (questionnaire, interview, biological samples, extraction from medical record mv.) -Recommend a figure illustrating how data is to be combined e.g.  -Names of folders and files. Do-files should include detailed information on data process and management, including labelling and preparation for the analysis. Results files should match precisely the tables and figures applied in the papers. 

<table>
<tr><td></td><td>-Include a system describing the version of the documents and files e.g. Nameyyyymmdd (year, month, day)

-consider a quality assurance process (e.g. supervision, external data check)

Henvis her til terminologilisten og evt. til SAP.</td></tr>
<tr><td>3. Documentation and Metadata</td><td>-Interpretation of the data in the future, helping secondary users to understand and reuse it, including a codebook e.g. [henvis til terminology-listen]

(Clinical studies)
<table><tr><th>Variable</th><th>Code</th><th>Classification</th><th>Data source</th><th>Data measures</th><th>Time of measurement</th><th>consideration</th></tr><tr><td>gender</td><td>Journal_sex</td><td>Binary
1 male
2 female</td><td>-at patient interview
-extracted from the patient identification number</td><td></td><td>-At admission</td><td>-reason of why this variable is of interest</td></tr><tr><td>crp</td><td>Blod_crp</td><td>Continuous</td><td>-patient medical record</td><td>-Mg/L</td><td>-At baseline, 3 and 6 months from baseline</td><td>-predictor of pneumonia</td></tr></table>
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- Data control for; requirements of the values for categorical variables, intervals allowed for numerical variables, assumptions for dates/times, and the lengths of time intervals.

-[Clinical studies] Handling of missing data: description of the expected reasons for missing data, the expected type of missing (MCAR, MAR, MNAR), and how missing data in each relevant variable is handled (exclude observations, impute values, or apply other handling strategies). Henvis her evt. til SAP.

-Timeline for data collection and follow-ups (example below for a clinical study). Henvis her evt. til protokollen eller SAP.

Timeline for data collection of the INDEED study (Skjøt-Arkil H et al BMJ open 2021):</td></tr>
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<table>
<tr><td></td><td>
<table>
<tr><td></td><td colspan="11">STUDY PERIOD</td></tr>
<tr><td></td><td>RECRUITMENT</td><td>ALLOCATION</td><td colspan="8">POST-ALLOCATION</td><td colspan="2">CLOSE-OUT</td></tr>
<tr><td>TIMEPOINT
(h=hours, d=days)</td><td>-½h</td><td>0h</td><td><1h</td><td><4h</td><td><24h</td><td><48h</td><td><5d</td><td><7d</td><td><14d</td><td>30d</td><td>90d</td></tr>
<tr><td colspan="12">ENROLMENT</td></tr>
<tr><td>Eligibility screeen</td><td>x</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Informed consent</td><td>x</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Physician assessment</td><td>x</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Allocation</td><td></td><td>x</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="12">INTERVENTIONS – all tracks</td></tr>
<tr><td>Collection of blood sample</td><td></td><td></td><td>x</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>• PCT analysis</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>x</td><td></td><td></td></tr>
<tr><td>• suPAR analysis</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>x</td><td></td><td></td></tr>
<tr><td>Collection of urine sample</td><td></td><td></td><td></td><td>x</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>4. Ethics and Legal Compliance</td><td>-Detailed description of informed consent, pseudonymization, and management of sensitive data

-Data owner
Henvis evt. til protokollen</td></tr>
<tr><td>5. Storage and Backup</td><td>-Description of where the data and files are stored [link til hjemmesiden]
-[Clinical studies] Informed consent storage
-Plan to control access to keep the data secure and ensure that collaborators can access data securely
- Ensure safety in transferring the collected data into the main secured systems, and have a plan of who will administer the system</td></tr>
<tr><td>6. Long-term preservation</td><td>-Time the data (reports, biological samples) will be available
-Achievement of the data

Example for biological samples preservation of the INDEED study (Skjøt-Arkil H et al BMJ open 2021):
<table>
<tr><th></th><th>Blood for analysis of PCT and suPAR</th><th>Blood for research biobank</th></tr>
<tr><td>Collection</td><td>The blood will be collected in an EDTA plasma tube.</td><td>Biobank blood is only collected for patient in track A and includes one tube of EDTA plasma and one tube of LiHeparin plasma.</td></tr>
<tr><td>Storage</td><td>At two of the sites, the analysis will be performed within is tested within two hours from the collection of the blood sample. At the third site, samples will be stored locally in a -80 °C freezer.

The samples are pseudonymized with a code to protect the identity of the participants. All samples and code lists are stored safely and separately to prevent unauthorized access.</td><td>All samples will be stored locally in a -80 °C freezer. The samples are pseudonymized with a code to protect the identity of the participants. All samples and code lists are stored safely and separately to prevent unauthorized access.</td></tr>
<tr><td>Sample analysis</td><td>Serum procalcitonin (PCT)

Serum PCT concentration is quantified with an automated sandwich immunoassay "ECLIA" (Elecsys®, BRAHMS PCT-analyses) on Cobas e801. Calibration is performed after Cobas e pack has been registered in the instrument and is standardized to the BRAHMS PCT LIA assay. The correlation of Elecsys BRAHMS PCT analyses has been compared to BRAHMS PCT LIA and to BRAHMS PCT sensitive KRYPTOR with similar results of r=0.981 and r=0.988 respectively.</td><td>Molecular analysis for future use in ancillary studies will take place after all samples have been collected.</td></tr>
<tr><td>Evaluation</td><td>The results will be saved in a study database and not be visible for the physician in the medical journal.</td><td>The results will be saved in a study database.

The expiry date of the research biobank is expected to be October 2022. After expiry date, the remaining material in the research bank will be destroyed.</td></tr>
<tr><td>Location</td><td>Samples will be located at Bloodsamples, Biochemistry and Immunology, University Hospital of Southern Denmark, Aabenraa, Denmark</td><td>Samples will be located at:

- Bloodsamples, Biochemistry and Immunology, University Hospital of Southern Denmark, Aabenraa, Denmark</td></tr>
</table>

[Link til hjemmeside, når anbefalingerne er lagt ud]</td></tr>
</table>

7. Data Availability	-Due to Danish laws on personal data, data cannot be shared publicly: Data protection laws https://www.datatilsynet.dk/english/legislation -describe how to request the data and from whom -Consider at what level, the data can be shared and what kind of data (common projects or international collaboration) Example: Availability of data and material: "Due to Danish laws on personal data, data cannot be shared publicly. Please contact the corresponding author XXXX to request this data. The person responsible for the research was the principal investigator and corresponding author (XXXXX), and together with the Department of XXXX and the University Hospital of Southern Denmark own the data and have access to the final data set.
8. DMP- online register	https://dmponline.deic.dk/ Benefits: -More people can work on the document (e.g. supervisors) -DMP plan has the possibility of public sharing -The document can be adapted on an ongoing basis Limitations: -Not possible to attach figures and tables