

## Overview of Respiratory Network sites – What are our capabilities?

**Unit: Region Midt**

**Hospital: Regionshospitalet Silkeborg**

**Date: 11-Maj-2015**

**Person providing responses: Kirsten Mørk Andersen**

<b>Staff and Training</b>			
	YES	#(number)	NO
Experienced study nurses at site	x	1	
GCP trained nurses	x	1	
Experienced sub-investigators at site	x	2	
GCP-trained investigators	x	3	
Availability of additional resources in case of e.g. need for unblinded personnel	x	2	
Personnel trained and experienced in quit-smoking counseling	x	1	

<b>Clinical Trial Experience</b>			
x	YES	#(number)	NO
Phase 1 (# past 5 years)			x
Phase 2 (# past 5 years)			x
Phase 3 (# past 5 years)	x	6	
Phase 4 (# past 5 years)			x
Experience with infusion in trials (# past 5 years)			x

<b>Experience with Assessments/Procedures</b> (tick all that apply)				
	YES	NO	Site has equipment at site	Site can insource other department/ local lab to perform
Spirometry testing (meeting ATS/ERS requirements) e.g.	x		x	x
Masterscope	x			
Flowscreen		x		
Threadmill exercise test VO <sub>2max</sub>		x		
Bike exercise test VO <sub>2max</sub>	x			
6MWT				
Incremental and Endurance shuttle walk test	x			x
X-ray	x		x	x
HRCT scanning	x		x	x
Body box/ plethysmography	x		x	
Diffusion capacity test - DLCO	x		x	x
ECG	x		x	
FENO	x			
Alveolar NO				
Nasal NO				
Skin prick test				
Methacholine test/histamine test				
Mannitol test				
Exercise-asthma test				
Bronchoscopy	x			x
FOT (Forced Oscillation Test)				
Eucapnic hyperventilation test				
CO measurement				
Induced sputum, Easyneb				
Nasal lavage/ nasal irrigation				

<b>Facility</b>		
	YES	NO
Separate and locked room for IMP	x	
Possibility for temperature	x	

monitoring of IMP		
Room for Monitor	x	

Other Procedures		
	YES	NO
Availability of written SOP procedure for study procedures (e.g. informed consent)		
Possibility of 24 h visits	x	
Possibility of 24h PK sampling	x	
Establishment of databases		
Establishment of biobanks		
Satellite sites		
Possibility of archiving of study material for 15 years	x	

Laboratory				
	YES	NO	Site has equipment at site	Site can insource other department/ local lab to perform
Refrigerator	x			
with temp monitoring				
Freezer – 20 degrees	x			
with temp monitoring				
Freezer – 80 degrees	x			
with temp monitoring				
Local lab for blood sample analysis	x			
Local lab certification	x			
IATA certification for handling dry ice shipment	x			
Experience in collaboration with external/central labs	x			
Induced sputum, analysis	x			
Centrifuge	x			

Cooling centrifuge				
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Data Recording			
	YES	NO	Comment
Experience in use of e-CRF	x		
Experience in use of e-diaries e.g	x		
AM3	x		
Log pad	x		
Experience in use of MoveMonitor		x	

IT			
	YES	NO	Comment
Availability of back up plan in case of crash			
Own computers, high speed internet	x		
Internal firewalls	x		
Wireless internet connection	x		
Electronic medical record system	x		
Electronic medical record system – <b>certified</b> (need of passwords, CRA only access to certain patients etc)	x		

**Other Comments: Most pulmonary disease relevant examinations can be conducted at this site, but is dependent of actual capacity at a given timepoint.**