

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

**Unit: Respiratory medicine**

**Hospital: Roskilde, Denmark**

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**Person providing responses: Christian Meyer**

<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	3	
GCP-trained investigators	x	4	
Availability of additional resources in case of e.g. need for unblinded personnel			x
Personnel trained and experienced in quit-smoking counseling	x	6	

<b>Clinical Trial Experience</b>			
	YES	#(number)	NO
Phase 1 (# past 5 years)			x
Phase 2 (# past 5 years)	x	1	
Phase 3 (# past 5 years)	x	Many	
Phase 4 (# past 5 years)	x	Many	
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	
Masterscope	X			
Flowscreen				
Threadmill exercise test VO <sub>2max</sub>	/			
Bike exercise test VO <sub>2max</sub>	X			Sister dept.
6MWT	X		X	
Incremental and Endurance shuttle walk test	X		X	
X-ray	X			
HRCT scanning	X			
Body box/ plethysmography	X		X	
Diffusion capacity test - DLCO	X		X	
ECG	X			
FENO	X		X	
Alveolar NO				
Nasal NO				
Skin prick test	X		X	
Methacholine test/histamine test	X		X	
Mannitol test	X		X	
Exercise-asthma test	X		X	
Bronchoscopy	x		x	
FOT (Forced Oscillation Test)		X		
Eucapnic hyperventilation test		X		
CO measurement				Did recently
Induced sputum, Easyneb		X		
Nasal lavage/ nasal irrigation		x		

<b>Facility</b>		
	YES	NO
Separate and locked room for IMP	X	
Possibility for temperature monitoring of IMP	x	
Room for Monitor	X	

<b>Other Procedures</b>		
	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	(x)	
Establishment of biobanks		X
Satellite sites		X
Possibility of archiving of study material for 15 years		x

<b>Laboratory</b>				
	YES	NO	Site has equipment at site	Site can insource other department/ local lab to perform
Refrigerator	X			
with temp monitoring	X			
Freezer – 20 degrees	X			
with temp monitoring	X			
Freezer – 80 degrees	X			
with temp monitoring	X			
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	X			

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			No knowledge

IT			
	YES	NO	Comment
Availability of back up plan in case of crash	X		
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	x	Access is only possible for the whole population

**Other Comments:**