

Overview of Respiratory Network sites – What are our capabilities?

Unit: Pulmonary and infectious disease department

Hospital: Nordsjællands Hospital

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Person providing responses: Andrea Browatzki consultant

Staff and Training			
	YES	#(number)	NO
Experienced study nurses at site	X	5	
GCP trained nurses	X	5	
Experienced sub-investigators at site	X	4	
GCP-trained investigators	X	2	
Availability of additional resources in case of e.g. need for unblinded personnel	x		
Personnel trained and experienced in quit-smoking counseling	x	5	

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

Experience with Assessments/Procedures (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			
Masterscope				
Flowscreen				
Threadmill exercise test VO _{2max}		x		
Bike exercise test VO _{2max}	X			X
6MWT	x			
Incremental and Endurance shuttle walk test	x			
X-ray	x			
HRCT scanning	x			
Body box/ plethysmography	x			
Diffusion capacity test - DLCO	x			
ECG	x			
FENO	x			
Alveolar NO	x			
Nasal NO		x		
Skin prick test	x			
Methacholine test/histamine test		x		
Mannitol test	x			
Exercise-asthma test		x		
Bronchoscopy	x			
FOT (Forced Oscillation Test)		x		
Eucapnic hyperventilation test		x		
CO measurement	x			
Induced sputum, Easyneb		x		
Nasal lavage/ nasal irrigation		x		

Facility		
	YES	NO
Separate and locked room for IMP	x	

Possibility for temperature monitoring of IMPx	x	
Room for Monitor	x	

Other Procedures		
	YES	NO
Availability of written SOP procedure for study procedures (e.g. informed consent)	x	
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	

Laboratory				
	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		X	

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 – certified (need of passwords, CRA only access to certain patients etc)		X	

Other Comments: