

Overview of Respiratory Network sites – What are our capabilities?

Unit: Lungemedicinsk Forsknings Afdeling

Hospital: Århus Universitetshospital

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Staff and Training			
	YES	#(number)	NO
Experienced study nurses at site	x	3	
GCP trained nurses	x	3	
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	3	
Personnel trained and experienced in quit-smoking counseling	x	3	

Clinical Trial Experience			
	YES	#(number)	NO
Phase 1 (# past 5 years)			x
Phase 2 (# past 5 years)	x	5	
Phase 3 (# past 5 years)	x	15	
Phase 4 (# past 5 years)	x	15	
Experience with infusion in trials (# past 5 years)	x	1	

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		Spirothrae vitalograf	
Masterscope	X			
Flowscreen	X			
Threadmill exercise test VO _{2max}		X		
Bike exercise test VO _{2max}	X		Ergoselect/Ergoline	.
6MWT	X			
Incremental and Endurance shuttle walk test	X			
X-ray	X			
HRCT scanning	X			
Body box/ plethysmography	X		Elite Platinum	
Diffusion capacity test - DLCO	X		Medgrafic	
ECG	X			
FENO	X			
Alveolar NO	X			
Nasal NO		X		
Skin prick test	X			
Methacholine test/histamine test	X		Spira Elektra 2 Dossimeter	
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 IMP	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		X	
with temp monitoring	X			
Freezer – 20 degrees	X		X	
with temp monitoring				
Freezer – 80 degrees	X		X	
with temp monitoring		X		
Local lab for blood sample analysis	X		X	

Local lab certification	X		X	
IATA certification for handling dry ice shipment	X			
Experience in collaboration with external/central labs	X		X	
Induced sputum, analysis	(x)		X	
Centrifuge	X		X	
Cooling centrifuge	X		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: