

Overview of Respiratory Network sites – What are our capabilities?

Unit: Medicinsk afdeling, lungemedicinsk afsnit

Hospital:

Regionshospitalet Viborg og Regionshospitalet Skive

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Person providing responses: Michael Skov Jensen

Staff and Training			
	YES	#(number)	NO
Experienced study nurses at site	X	1	
GCP trained nurses	X	1	
Experienced sub-investigators at site		2	
GCP-trained investigators		3	
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)			x
Phase 2 (# past 5 years)			x
Phase 3 (# past 5 years)	x	4	
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		x	
Masterscope				
Flowscreen				
Threadmill exercise test VO _{2max}				
Bike exercise test VO _{2max}	x		x	
6MWT	x		x	
Incremental and Endurance shuttle walk test	x		x	
X-ray	x		x	
HRCT scanning	x		x	
Body box/ plethysmography	x		x	
Diffusion capacity test - DLCO	x		x	
ECG	x		x	
FENO				
Alveolar NO	x		x	
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)				
Eucapnic hyperventilation test				
CO measurement	x		x	
Induced sputum, Easyneb				
Nasal lavage/ nasal irrigation				

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				
Freezer – 20 degrees		x		x
with temp monitoring				
Freezer – 80 degrees		x		x
with temp monitoring				
Local lab for blood sample analysis	x			
Local lab certification				
IATA certification for handling dry ice shipment				

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			
Log pad			
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: