

Overview of Respiratory Network sites – What are our capabilities?

Unit: Lungemedicinsk forskningsafdeling

Hospital: Aalborg Universitetshospital

Date:16.06.14

Person providing responses: Kirsten Frederiksen

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

Clinical Trial Experience			
	YES	#(number)	NO
Phase 1 (# past 5 years)			X
Phase 2 (# past 5 years)	X	1	
Phase 3 (# past 5 years)	x	10	
Phase 4 (# past 5 years)			x
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	x			
Flowscreen	?			
Threadmill exercise test VO _{2max}		X		
Bike exercise test VO _{2max}		X		
6MWT	x			
Incremental and Endurance shuttle walk test		X		
X-ray				X
HRCT scanning				X
Body box/ plethysmography	x			X
Diffusion capacity test - DLCO	x			X
ECG	x		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 IMP yes	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		x	
Freezer – 20 degrees	x		x	
with temp monitoring	x		x	
Freezer – 80 degrees	x		x	
with temp monitoring	x		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			
Induced sputum, analysis		x		
Centrifuge	x		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: