

Overview of Respiratory Network sites – What are our capabilities?

Unit: Dep of Respiratory Medicine

Hospital: Næstved Hospital

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Person providing responses: Uffe Bodtger, MD PhD, Consultant, associate research professor

Staff and Training			
	YES	#(number)	NO
Experienced study nurses at site	X	1	
GCP trained nurses	X	1	
Experienced sub-investigators at site	X	2	
GCP-trained investigators	X	2	
Availability of additional resources in case of e.g. need for unblinded personnel	X	1	
Personnel trained and experienced in quit-smoking counseling	X	1	

Clinical Trial Experience			
	YES	#(number)	NO
Phase 1 (# past 5 years)			X
Phase 2 (# past 5 years)	X	2	
Phase 3 (# past 5 years)	X	4	
Phase 4 (# past 5 years)	X	2	
Experience with infusion in trials (# past 5 years)			(not yet but will start in August 2014)

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		X		
Threadmill exercise test VO _{2max}		X		
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	X		X	
Alveolar NO		X		
Nasal NO		X		
Skin prick test	X		X	
Methacholine test/histamine test	X		X	
Mannitol test	X		X	
Exercise-asthma test	X			
Bronchoscopy	X		X	
FOT (Forced Oscillation Test)		X		
Eucapnic hyperventilation test		X		
CO measurement		X		
Induced sputum, Easyneb		X		
Nasal lavage/ nasal irrigation	X		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		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			
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		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			Will be provided dependent on crash definition
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: