

Overview of Respiratory Network sites – What are our capabilities?

Unit:

Hospital: Vendsyssel

Date: 13 Aug-2014

Person providing responses: Bente Grønlund

Staff and Training			
	YES	#(number)	NO
Experienced study nurses at site	x	1	
GCP trained nurses			x
Experienced sub-investigators at site		1	
GCP-trained investigators			x
Availability of additional resources in case of e.g. need for unblinded personnel			
Personnel trained and experienced in quit-smoking counseling	x	4	

Clinical Trial Experience			
	YES	#(number)	NO
Phase 1 (# past 5 years)			x
Phase 2 (# past 5 years)			x
Phase 3 (# past 5 years)			x
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		x	
Flowscreen				
Threadmill exercise test VO _{2max}		x		
Bike exercise test VO _{2max}		x		
6MWT	x		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
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		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		

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				
with temp monitoring	x		x	
Freezer – 20 degrees		x		
with temp monitoring				
Freezer – 80 degrees		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		?		
Induced sputum, analysis		x		
Centrifuge	x			x
Cooling centrifuge		?		

Data Recording			
	YES	NO	Comment
Experience in use of e-CRF		x	Not for quite a while
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		?	
Own computers, high speed internet		?	
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:

Re temperature monitoring: Our medicine room is manually monitored of staff (no automated monitoring), whereas refrigerator has an automated sensor with alarm.

Re IMP storage Manual control of room by staff. In case a locked room would be needed we would acquire such

Re lab certifications: No details available at the moment