

Overview of Respiratory Network sites – What are our capabilities?

Unit: Department of Respiratory Medicine,

Hospital: Odense University Hospital

Date: 13th of June, 2014

Person providing responses:

Ingrid Louise Titlestad, Consultant, Ph.D., Ass. Prof.

Staff and Training			
	YES	#(number)	NO
Experienced study nurses at site	X	4	
GCP trained nurses	X	4	
Experienced sub-investigators at site	X	4	
GCP-trained investigators	X	3	
Availability of additional resources in case of e.g. need for unblinded personnel	X	2	
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	6	
Phase 3 (# past 5 years)	X	> 15	
Phase 4 (# past 5 years)	X	5	
Experience with infusion in trials (# past 5 years)	X	5	

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		X	
Bike exercise test VO _{2max}	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	X
Diffusion capacity test - DLCO	X		X	X
ECG	X		X	
FENO	X		X	
Alveolar NO				
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	X		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		
Possibility of archiving of study material for 15 years	x	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			
IATA certification for handling dry ice shipment	X		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: