

## Overview of Respiratory Network sites – What are our capabilities?

### Unit:

Allergi- og Lungeklinikken Helsingør, Sct. Olai Gade 39,1, 3000 Helsingør,  
ved praktiserende speciallæger  
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**Date:** 8-11-2015

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<b>Staff and Training</b>			
	YES	#(number)	NO
Experienced study nurses at site	+	2	
GCP trained nurses	+	2	
Experienced sub-investigators at site	+	3	
GCP-trained investigators	+	3	
Availability of additional resources in case of e.g. need for unblinded personnel	+		
Personnel trained and experienced in quit-smoking counseling	+	1	

<b>Clinical Trial Experience</b>			
	YES	#(number)	NO
Phase 1 (# past 5 years)			x
Phase 2 (# past 5 years)			x
Phase 3 (# past 5 years)	x	5	
Phase 4 (# past 5 years)	x	2	
Experience with infusion in trials (# past 5 years)			X (no, but from more than 5 years ago)

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.	+		Medical Electronic Construction (MEC) Belgium	
Masterscope		+		
Flowscreen		+		
Threadmill exercise test VO <sub>2max</sub>				+
Bike exercise test VO <sub>2max</sub>				+
6MWT	+			
Incremental and Endurance shuttle walk test				
X-ray		+	Can refer	+
HRCT scanning		+	Can refer	+
Body box/ plethysmography	+		MEC	
Diffusion capacity test - DLCO	+		MEC	
ECG	+			
FENO	+		Aerocrine NIOX MINO og NIOX VERO	
Alveolar NO	+			
Nasal NO	+			
Skin prick test	+			
Methacholine test/histamine test	+			
Mannitol test	+			
Exercise-asthma test	+			
Bronchoscopy		+		+
FOT (Forced Oscillation Test)		+		+
Eucapnic hyperventilation test	+			
CO measurement	+			
Induced sputum, Easyneb	+			
Nasal lavage/ nasal irrigation	+			

<b>Facility</b>		
	YES	NO
Separate and locked room for IMP	+	
Possibility for temperature monitoring of IMP	+	
Room for Monitor	+	

<b>Other Procedures</b>		
	YES	NO
Availability of written SOP procedure for study procedures (e.g. informed consent)	+	
Possibility of 24 h visits	+	
Possibility of 24h PK sampling	+	
Establishment of databases	+	
Establishment of biobanks		+
Satellite sites		+
Possibility of archiving of study material for 15 years		+

<b>Laboratory</b>				
	YES	NO	Site has equipment at site	Site can insource other department/ local lab to perform
Refrigerator	+			
with temp monitoring	+			
Freezer – 20 degrees		+		
with temp monitoring				
Freezer – 80 degrees		+		
with temp monitoring				
Local lab for blood sample analysis	+			
Local lab certification	+			
IATA certification for handling dry ice shipment		+		
Experience in collaboration with external/central labs	+			
Induced sputum, analysis		+		+
Centrifuge	+			
Cooling centrifuge		+		

Data Recording			
	YES	NO	Comment
Experience in use of e-CRF	+		
Experience in use of e-diaries e.g	+		
AM3		+	
Log pad	+		
Experience in use of MoveMonitor		+	

IT			
	YES	NO	Comment
Availability of back up plan in case of crash	+		
Own computers, high speed internet	+		
Internal firewalls			
Wireless internet connection	+		
Electronic medical record system	+		
Electronic medical record system – <b>certified</b> (need of passwords, CRA only access to certain patients etc)	+		

**Other Comments:**

Our main interest in the clinic and where we have many patients are:  
Allergic as well as non-allergic asthma (including difficult to treat asthma), allergic rhinitis,  
diagnostic of dyspnea and cough, allergic sting reactions and urticaria.  
Studies concerning these diseases/problems are properly those, where we could be  
interested in participating.

We also do see diagnosed KOL-patients as well as other lung patients, and as we do not  
have a static clinic, studies with these patients might be interesting in the future.

More information of the clinic can be found at [www.allergia.dk](http://www.allergia.dk)

We are active in DALFUMAT (Danske referenceværdier for lungefunktion) so our  
Bobybox/diffusion/spirometry equipment and our performance of doing these tests are  
thereby certified. One of our doctors has taken ERSs European Spirometry Driving  
License (ESDL) and another doctor and a nurse have taken the similar English education.

The Clinic has a long tradition of doing clinical as well as other kind of research.

As we are a clinic “Site can insource other department/ local lab to perform” means that we  
will outsource to another site.