

Trial Nation

Clinical Trials Denmark

CENTER FOR RESPIRATORY MEDICINE
A network of Danish lung clinics

Your clinical research partner within the
respiratory field

Trial Nation Respiratory Center

The Center is a network of Danish lung clinics that specializes in sponsor initiated clinical research with medicinal products across all respiratory diseases. The Center facilitates clinical trials requiring participants diagnosed in a specialized clinical setting with trained staff, harmonized clinical assessments and specialized diagnostic methods.

Professor Charlotte Suppli Ulrik is the Medical Lead for Trial Nation Respiratory Center.

The Center was established in 2015. 37 trials have been initiated in Trial Nation sites since. Trial Nation offers one point of contact to the network. The Center has been involved, with one or more departments, in all relevant commercial respiratory clinical trials in Denmark from 2015 until 2019.¹

Trial Nation Respiratory Clinics

The Center has six clinics at its core – their capabilities regarding clinical trials are summarized below. The clinics are committed, under the Trial Nation Center, to develop and maintain Denmark as a preferred site for respiratory clinical research. Trial Nation also maintain The Danish Respiratory Network which constitute a broader structure of an additional 12 clinical sites covering all

respiratory research departments in Denmark.

The respiratory clinics constituting the Trial Nation Respiratory Center collaborate on:

- Fast centrally coordinated feasibility process
- Clinical training and certification of staff

DANISH UNIVERSITY CLINICS IN TRIAL NATION RESPIRATORY MEDICINE	REGION	CONTACT
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1. Information on trials from 2015 to 2018 (both included) retrieved via GlobalData in June 2019. Paediatric trials are carried out on Paediatric depts. Cystic fibrosis trials are carried out on depts. for Infectious diseases. Both are thus not counted here.

- Harmonization initiatives at annual network meetings
- Solidarity regarding the delivery of the estimated national recruitment commitment
- An optional centrally negotiation of fee

The main interest of the Trial Nation Respiratory Center is to facilitate clinical trials based on pharmacological interventions. We maintain lasting positive relationships with industry representatives to ensure that infrastructural advancements developed in one trial can be applied in the next.



Patients

The clinics can recruit patients for clinical trials within all respiratory disease areas.

Respiratory Research Unit (Catchment area)	Patients at site					Trial Phase capabilities				Facilities in addition to FENO, Body-box, DLCO, Spirometry, Sputum cell count, bronchoscopy, BAL, Histology, VOMax, nasal endoscopy, ECG, CT, MRI, PET, X-ray, and DEXA.					
	Asthma	COPD	Allergy	ILD	Bronchiectasis	I (Incl FiH)	II	III	IV	Bronchial challenge	Alveolar NO	MBW	Oscillometry	EVH	Asthma running tests
Bispebjerg University Hospital (1,835,000)	+	+	+			I	II	III	IV	+	+	+			
Hvidovre University Hospital (1,835,000)	+	+	+		+	I	II	III	IV	+	+				
Næstved Hospital (836,000)	+	+	+				II	III	IV	+	+		+		
Odense University Hospital (1,223,000)	+	+		+	+	I	II	III	IV		+				
Aalborg University Hospital (589,000)	+	+			+		II	III	IV	+	+		+		
Aarhus University Hospital (1,320,000)	+	+		+	+		II	III	IV	+			+	+	+

Patients: COPD: Chronic Obstructive Pulmonary Disease, ILD: Interstitial Lung Disease. **Facilities:** FENO: Fractional Exhaled Nitric Oxide test. DLCO: Diffusion capacity of the Lungs for Carbon monOxide. BAL: Bronchoalveolar Lavage. VOMax: Maximum rate of oxygen consumption. ECG: Electrocardiography. CT: Computed Tomography. MRI: Magnetic Resonance Imaging. PET: Positron Emission Tomography. DEXA: Dual-energy X-ray absorptiometry. MBW: Multiple breath washout. EVH: Eucapnic Voluntary Hyperventilation test.

Diagnostic Criteria and Clinical outcome measures in clinical practice

DIAGNOSTIC CRITERIA USED IN CLINICAL PRACTICE	
Diagnosis	Diagnostic criteria
COPD	Global Initiative for Chronic Obstructive Lung Disease (GOLD) COPD Report: 2019 update ¹
Asthma	GINAs severe asthma guideline ² Nordic consensus statement on the systematic assessment and management of possible severe asthma in adults ³
Allergic rhinitis	Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines 2016-revision ⁴
Bronchiectasis	European Respiratory Society guidelines for the management of adult bronchiectasis ⁵ British Thoracic Society guidelines for bronchiectasis in adults ⁶
IPF	Diagnosis of Idiopathic Pulmonary Fibrosis. An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline ⁷
Sarcoidosis	ATS/ERS/WASOG statement on sarcoidosis. American Thoracic Society/European Respiratory Society/World Association of Sarcoidosis and other Granulomatous Disorders ⁸
Chronic rhinosinusitis with nasal polyps	Chronic Rhinosinusitis with Nasal Polyps ⁹

CLINICAL OUTCOME MEASURES USED IN CLINICAL PRACTICE	
COPD	Medical Research Council (MRC) dyspnoea scale ¹⁰
COPD / Asthma / IPF	Sct. George Respiratory Questionnaire ¹¹
Asthma	Asthma Control Questionnaire (ACQ) ¹²
Asthma	Asthma Control Test (ACT) ¹³
Chronic Rhinosinusitis	Sino-Nasal Outcome Test (SNOT) ¹⁴
Respiratory function	Fosters talk test ¹⁵
Bronchiectasis	Bronchiectasis Severity Index (BSI) ¹⁶ Multidimensional approach to non-cystic fibrosis bronchiectasis: the FACED score ¹⁷
ILD	The King's Brief Interstitial Lung Disease (KBILD) questionnaire: an updated minimal clinically important difference ¹⁸

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References

1. GOLD. Global Strategy for the diagnosis, management and prevention of Chronic Obstructive Pulmonary Disease: 2019 update. [Online] June 2019. goldcopd.org.
2. GINA. [Online] July 2019. <https://ginasthma.org/wp-content/uploads/2018/04/wms-GINA-2018-report-V1.3-002.pdf>.
3. Porsbjerg, Celeste, et al. Nordic consensus statement on the systematic assessment and management of possible severe asthma in adults. *Eur Clin Respir J*. March, 2018, Vol. 5, 1.
4. Brożek, Jan L., et al. Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines-2016 revision. *J Allergy Clin Immunol*. Oct, 2017, Vol. 140, 4.
5. Polverino, Eva, et al. European Respiratory Society guidelines for the management of adult bronchiectasis. *European Respiratory Journal*. 50, 2017.
6. Hill, Adam T., et al. British Thoracic Society Guideline for bronchiectasis in adults. *Thorax*. 74, 2019, Vol. Issue Suppl 1.
7. Raghu, Ganesh. Diagnosis of Idiopathic Pulmonary Fibrosis. An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline. *Am J Respir Crit Care Med*. 198, 2018, Vol. 5.
8. Hunninghake, Gary M., et al. ATS/ERS/WASOG statement on sarcoidosis. American Thoracic Society/ European Respiratory Society/World Association of Sarcoidosis and other Granulomatous Disorders. *Sarcoidosis Vasc Diffuse Lung Dis*. 16, 1999, Vol. 2.
9. Stevens, W. Whitney, Schleimer, P. Robert and Kern, C. Robert. Chronic Rhinosinusitis with Nasal Polyps. *The Journal of Allergy and Clinical Immunology: In Practice*. 4, 2016, Vol. 4.
10. Stenton, Chris. The MRC breathlessness scale. *Occupational Medicine*. 58, 2008, Vol. 3.
11. Jones, W. Paul, Quirk, H. Sarah and Barley, E. Marshall. Sct. George Respiratory Questionnaire. *Respiratory Medicine*. 5, 1991, Vol. 2.
12. Juniper, F. Elizabeth, et al. Development and validation of a questionnaire to measure asthma control. *Eur Respir J*. 14, 1999, Vol. 4.
13. Nathan, A. Robert, et al. Development of the asthma control test: a survey for assessing asthma control. *J Allergy Clin Immunol*. 113, 2004, Vol. 1.
14. Lange, Bibi, et al. The Sino-Nasal Outcome Test 22 validated. *Dan Med Bul*. 58, 2011, Vol. 2.
15. Foster, Carl, et al. The talk test as a marker of exercise training intensity. *J Cardiopulm Rehabil Prev*. 28, 2008, Vol. 1.
16. Chalmers, D. James, et al. The Bronchiectasis Severity Index. An International Derivation and Validation Study. *Am J Respir Crit Care Med*. 189, 2015, Vol. 5.
17. Martínez-García, Miguel Á., et al. Multidimensional approach to non-cystic fibrosis bronchiectasis: the FACED score. *European Respiratory Journal*. 43, 2014.
18. Denmark, Statistics. <https://www.dst.dk/en>. [Online] Januar 2019. <https://www.statistikbanken.dk/BY1>.

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