

Trial Nation

Clinical Trials Denmark

A network of Danish research sites in
respiratory medicine

Your clinical research partner within the respira-
tory field

Trial Nation Center for Respiratory

The Center is a network of Danish respiratory research units specializing 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 2016. Trial Nation offers one point of contact to the network. The Center has been involved, with one or more departments, in 99 relevant commercial respiratory clinical trials in Denmark from 2015 until 2020.1

The center also collaborates with the Danish Lung Association to increase the level of knowledge and communication about clinical trials.

Trial Nation Respiratory Clinics

The Center has six sites at its core – their capabilities regarding clinical trials are summarized below. The sites in the Trial Nation Center are committed to developing and maintaining Denmark as a preferred country for respiratory clinical research. The center also collaborates with The Danish Respiratory Network, which constitutes a broader structure of an additional 12 clinical sites covering all respiratory sites in Denmark.

The respiratory research sites constituting the Trial Nation Respiratory Center collaborates on:

- Fast centrally coordinated feasibility process
- Training and certification of staff
- Harmonization initiatives at annual net- work meetings
- Solidarity regarding the delivery of the estimated national recruitment commitment
- Central negotiation of fees



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2. Respiratory Research Unit, Dept. of Respiratory Medicine, Odense University Hospital
3. Respiratory Research Unit, Dept. of Respiratory Medicine, Næstved University Hospital
4. Respiratory Research Unit, Dept. of Respiratory Medicine, Copenhagen University Hospital-Bispebjerg
5. Respiratory Research Unit, Dept. of Respiratory Medicine, Copenhagen University Hospital-Hvidovre
6. Respiratory Research Unit, Dept. of Respiratory Medicine, Aalborg University Hospital

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

Patients

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

	Patients at site					Trial Phase capabilities				Facilities <i>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.</i>					
	Asthma	COPD	Allergy	ILD	Bronchiectasis	I (incl FH)	II	III	IV	Bronchial challenge	Alveolar NO	MBW	Oscillometry	EVH	Asthma running tests
<i>Respiratory Research Unit (Catchment area)</i>															
<i>Hvidovre University Hospital (1,835,000)</i>	+	+	+		+	I	II	III	IV	+	+	+	+		+
<i>Bispebjerg University Hospital (1,835,000)</i>	+	+	+			I	II	III	IV	+	+	+	+	+	
<i>Næstved Hospital (836,000)</i>	+	+	+				II	III	IV	+	+		+		
<i>Odense University Hospital (1,223,000)</i>	+	+		+	+	I	II	III	IV	+	+	+	+		+
<i>Aalborg University Hospital (589,000)</i>	+	+	+		+		II	III	IV	+	+		+		
<i>Aarhus University Hospital (1,320,000)</i>	+	+	+	+	+	I	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	
<i>Diagnosis</i>	<i>Diagnostic criteria</i>
COPD	Global Initiative for Chronic Obstructive Lung Disease (GOLD) COPD Report 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 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: 2021 update. [Online] goldcopd.org
2. GINA. [Online] <https://ginasthma.org>
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. Broek, Jan L., et al. Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines. *J Allergy Clin Immunol*. Oct, 2017, Vol. 140, 4. Jean Bousquet et al., Next-generation Rhinitis and its Impact on Asthma (ARIA) guidelines for allergic rhinitis based on Grading of Recommendations Assessment, Development and Evaluation (GRADE) and real-world evidence - *Journal of Allergy and Clinical Immunology*, Jan 2020
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.

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