



## Netzwerk Kinder- und Jugendärzte für klinische Studien in der Ambulanten Pädiatrie

(network of pediatricians for clinical studies in ambulant treatment)

www.netstap.de

### board and office



#### **Board**:

- Prof. Dr. A. Bufe, Bochum
- Dr. R. Ebert, Tauberbischofsheim
- > Dr. F. Kaiser, Hamburg
- > Dr. R. Knecht, Bretten
- Dr. B. Sandner, Aschaffenburg
- R. Köllges, Mönchengladbach
- > Dr. C. Gronke, Ludwigsfelde

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### Vorstand und Geschäftsstelle





#### members



- about 100 pediatricians in surgeries or clinical ambulances in Germany.
- confidentiality agreement members → NETSTAP



### member profile



- GCP-ICH certified, study experience
- Specialists (>95% pediatricians)
- Specific features: allergological and pneumological diseases, vaccinations
- Trained personnel
- Constant quality management

# development of members 2002-2017







### aims and implementation



 Regular support of training for investigators and studynurses according to "Good Clinical Practice" (GCP-ICH)

→ since 2002 regular offer of certified GCP-ICH basic, progressive and refresher courses.

### aims and implementation



- Networking of members
- → protected intranet specially provided for NETSTAP members
- → special folder for each study (quality management)



### aims and implementation



- improving environment for clinical studies in child and adolescence population (evidence based medicine)
- promoting studies and study designs suitable for children

Support and consulting of Sponsor

#### current studies



- Study for sublingual immunotherapy 2018-2021
- Individual attendence on several trials (single NETSTAP-members) 2016-2019

# publication (completed studies)



- Efficacy of sublingual swallow immunotherapy in children with severe grass pollen allergic symptoms *Allergy (2004); 59: 498-504*
- Safety of specific sublingual immunotherapy with SQ standardized grass allergen tablets in children *Pediatric Allergy and Immunology (2007); 18:* 516-522
- Safety and efficacy in children of an SQ-standardised grass allergen tablet for sublingual immunotherapy *J Allergy Clin Immunol (2009); 123: 167-73*
- Clinical efficacy of the ALK house dust mite allergy immunotherapy tablet correlates with immunological endpoints *Allergy 65 (Suppl. 92):174-175*
- High-dose sublingual immunotherapy with single-dose aqueous grass pollen extract in children is effective and safe *J Allergy Clin Immunol.* 2012 Oct;130(4):886-93
- Design and recruitment for the GAP trail, investigating the preventive effect on asthma development of an SQ-standardized grass allergy immunotherapy tablet in children with grass pollen- induced allergic rhinoconjunctivitis *Clin Ther. 2011 Oct;33(10):1537-46*

# publication (completed studies)



- Immunogenicity and Tolerability of Recombinant Serogroup B Meningococcal Vaccine Administered With and Without Routine Infant Vaccinations According to Different Immunization Schedules JAMA 2012; 307:573-582
- Immunogenicity and safety of an investigational multicomponent, recombinant, meningococcal serogroup B vaccine (4CMenB) administered concomitantly with routine infant and child vaccinations: results of two randomised trials. *Lancet 2013; 12:61961-8.*
- Infant formula containing galacto-and fructo-oligosaccharides and Bifidobacterium breve M-16V supports adequate growth and tolerance in healthy infants in a randomised, controlled, double-blind, prospective, multicentre study (2016) J Nutr Sci; 5, e42:1-13
- Side effects during subcutaneous immunotherapy (SCIT) in children with allergic dieseases. (2018) Pediatr Allergy Immunol; 29:267-274