



Early dialogue – essential for better trials



Annual Meeting Amsterdam 2023

Bernhard Sandner (www.netstap.de)

AGENDA

- Compact Network Overview
- Stakeholders in Clinical Trials
- Communication & Early dialogue
- What mainly happens
- Conclusion & Vision

NETSTAP -since 2018 Member Enpr-EMA (Cat. I)



Network of Pediatricians for Clinical Studies in the Ambulant Pediatrics

www.netstap.de

Members / Sites

- Actual ca. 100 Pediatricians in private practices or some outpatient clinics throughout Germany (est. 2001)
- General confidential from single site → NETSTAP
- Direct communication with help by protected own Intranet



Publications (finalized 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 (2010) 65 (Suppl. 92):174-175

Design and recruitment for the GAP trial, 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*

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

Publications (finalized 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.*

Standardized quality (SQ) house dust mite sublingual immunotherapy tablet (ALK) reduces inhaled corticosteroid use while maintaining asthma control: A randomized, double-blind, placebo-controlled trial *J Allergy Clin Immunol (2014); 134:568-575*

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 *J Nutr Sci (2016); 5, e42:1-13*

Side effects during subcutaneous immunotherapy (SCIT) in children with allergic diseases. *Pediatr Allergy Immunol (2018) ; 29:267-274*

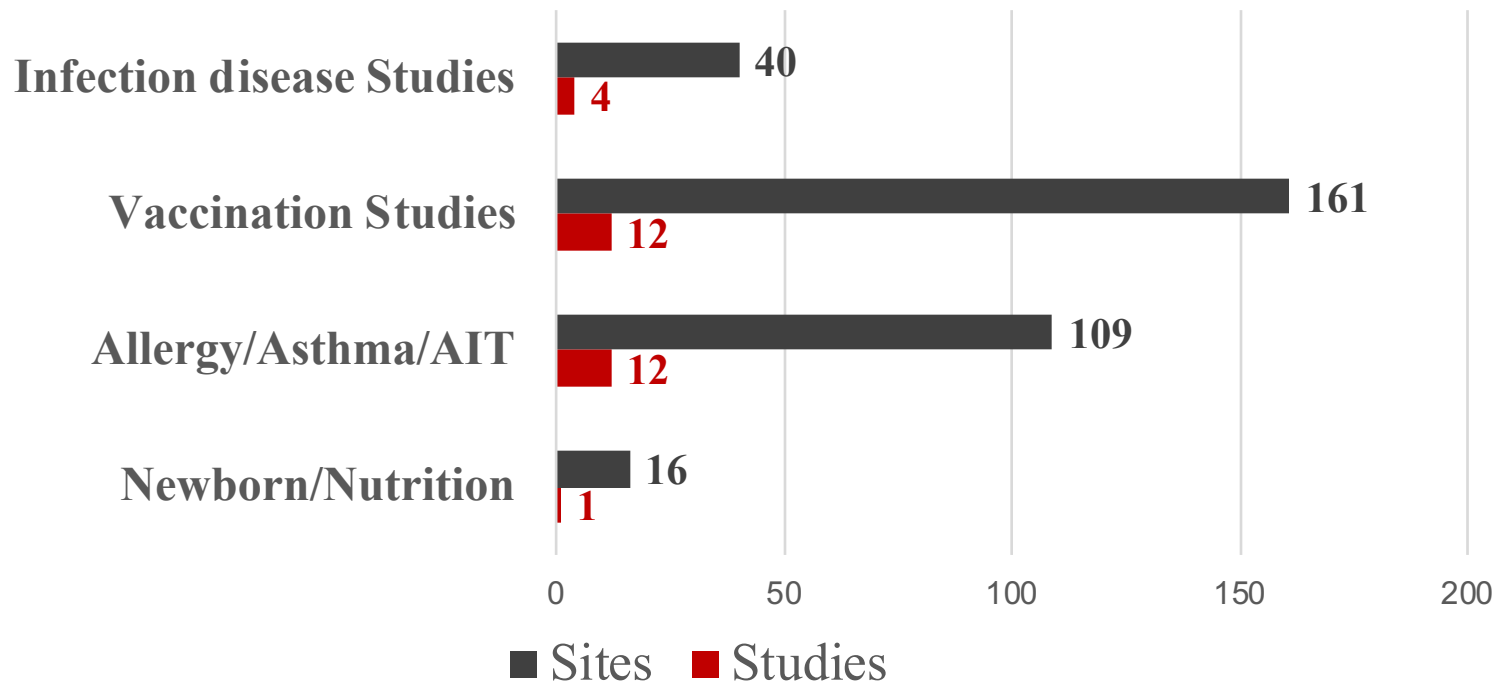
MenQuadfi Pooled Naive toddlers Poster [ECCMID 2022 4April2022](#)

NETSTAP-Studies

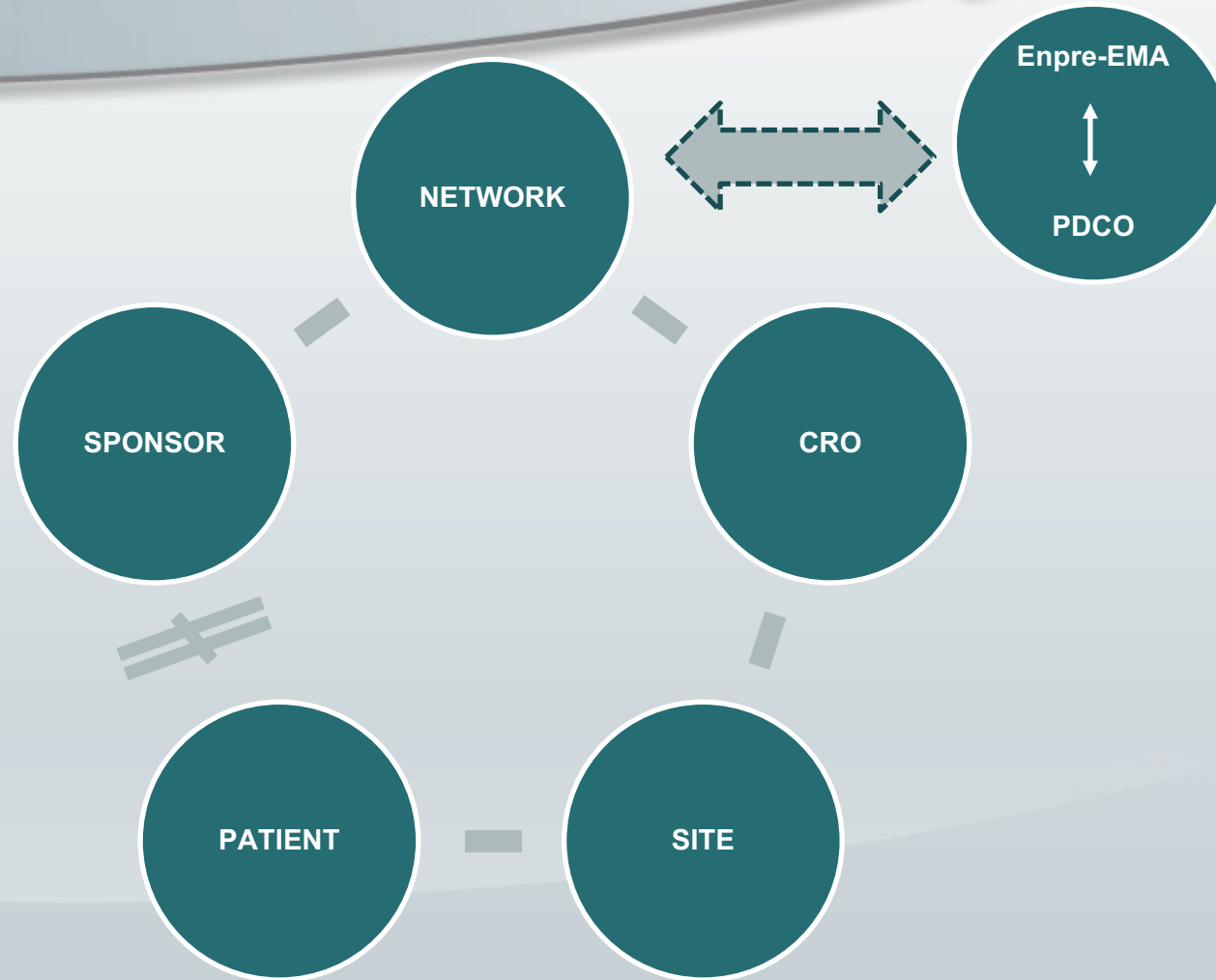
Studies between 2001 and 2022

n=29 / involved sites n=326

Number of studies & sites 2001-2022



Stakeholders for Clinical Trials



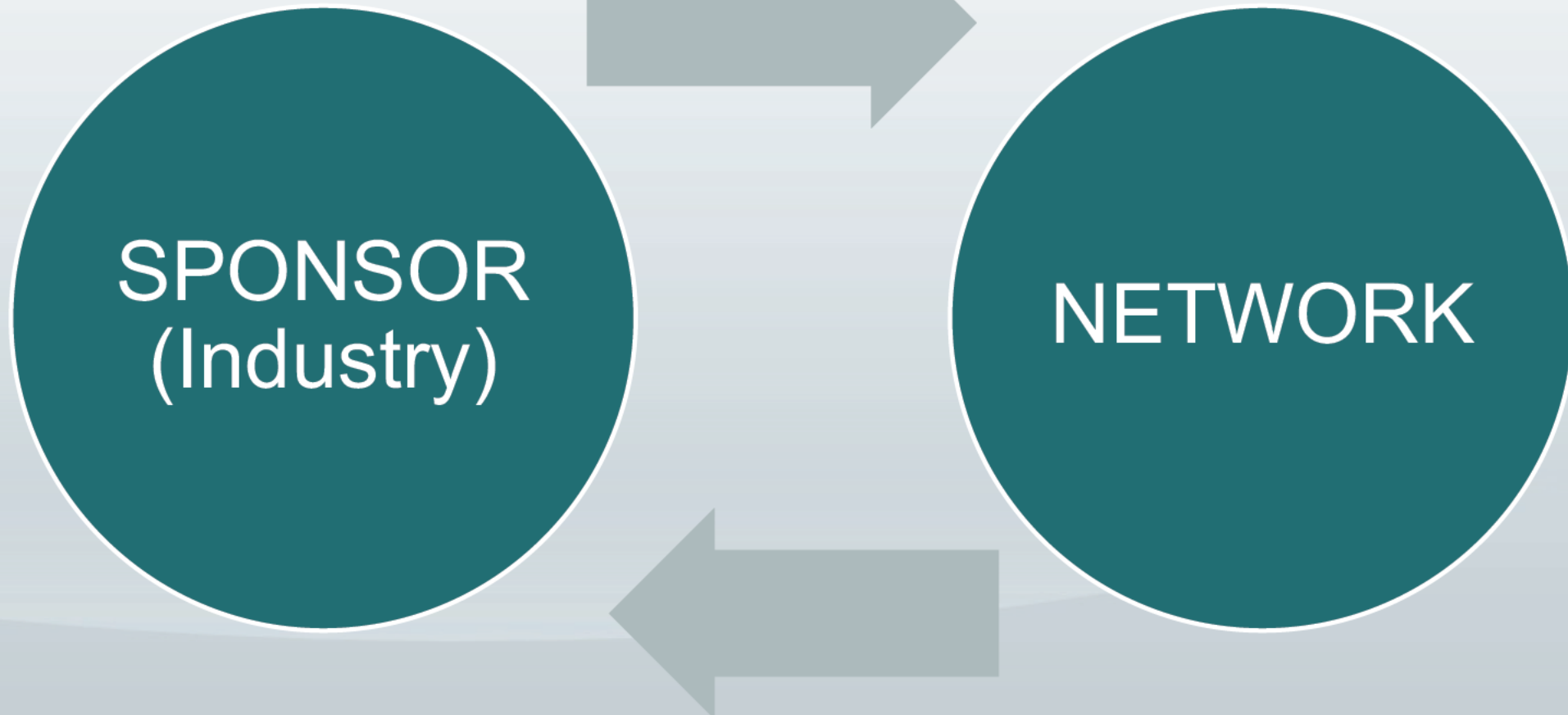
COMMUNICATION

IN PARALLEL WAYS



Source:
<https://www.krone.at/> 6989 #fb
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COMMUNICATION & Early dialogue

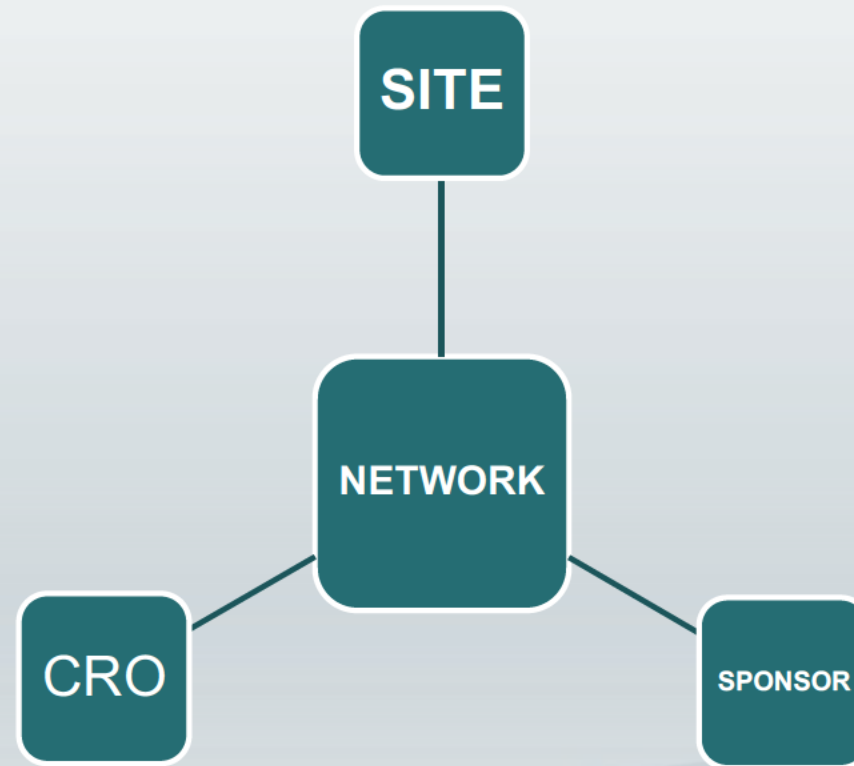


- Better trial conditions in childhood
(evidence based medicine)
- Pediatric-conform Studies and Designs
(because there are taken more often designs from adult trials!)



Consideration with Sponsor and support
→ Essential: „early dialogue“ - e.g.
in order avoiding expensive amendments

COMMUNICATION



COMMUNICATION



Source
<http://www.faz.net/aktuell/finanzen/meine-finanzen/geldausgeben/faehrt-mein-zug-morgen-13551154/bahngleise-in-frankfurt-13551247.html>

EARLY DIALOGUE → RESULTS



WHAT HAPPENS in the main

CRO → Single SITE (calling for feasibility)

SITE (if organized) → Network (more by chance)

After recommending maybe CRO

will contact the network (not without any order from SPONSOR)

WHAT HAPPENS in the main



There is simply existing
NO „Early Dialogue“

...So we can see a lot of
-not necessary- roundabout ways...

WHAT HAPPENS

- CRO and Network (sometimes after a long period) agree upon a letter of intent with the aim of near and valid feasibility from the sites
- Preliminary taken place detailed consideration inside the network board regarding sensefull study-conducting and specifically practical aspects
- May be in mind a suboptimal design of the study and one or another pitfall which could`nt be eliminated (design!)

WHAT HAPPENS

Nevertheless : maybe 8 or 10 sites from the network will be accepted/elected by the CRO/Sponsor and can be involved in the upcoming clinical trial

WHAT HAPPENS

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graph TD; RISKS --> A[Not practice-relevant Study-Design]; RISKS --> B[Pitfalls]; RISKS --> C[Expensive Amendments];
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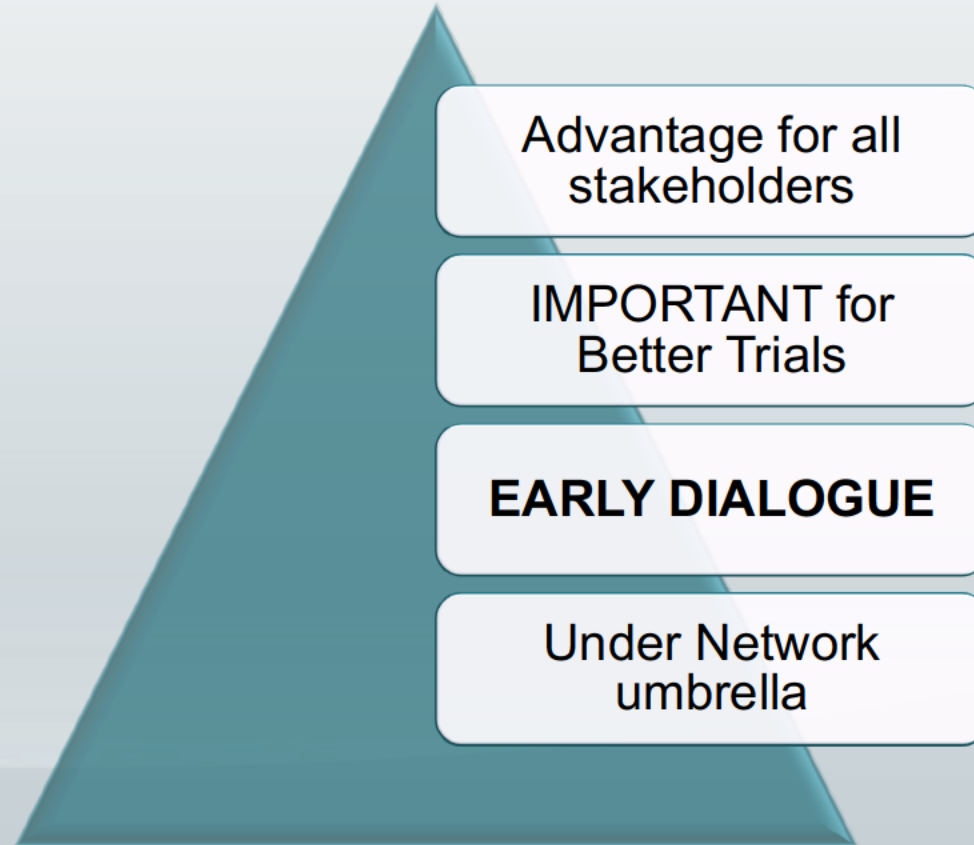
RISKS

Not practice-relevant
Study-Design

Pitfalls

Expensive
Amendments

CONCLUSION



CONCLUSION & VISION

From our network`s experience

Awariness to need many sites in paediatric trials

But bureaucratism is more and more one inhibitor

CONCLUSION & VISION

As an INVESTIGATOR

You should have joy for solid documentation



BUREAUCRACY according to GCP(ICH)



BUT what can we do in order to minimize BUREAUCRATISM ?

THANK YOU !



Source
<https://www.eurordis.org/en/content/paediatric-committee-pdco>

→ COMMENTS ? - QUESTIONS ?