



**Wolfgang Höffer, PhD**  
 Managing Director  
 whoeffe@analyze-realize.com

**analyze & realize GmbH**  
 Waldseeweg 6  
 13467 Berlin, Germany

Tel. +49 30 4000 8100  
 Fax +49 30 4000 8400

www.analyze-realize.com



**Gordana Bothe, PhD**  
 Head of  
 Scientific Affairs  
 gbothe@analyze-realize.com

BVMA member since 2005  
 Audits passed in 2005, 2007,  
 2010 and 2013



## HISTORY AND MISSION

analyze & realize GmbH is a leading full service CRO and consulting firm focusing on natural products and phytomedicines ("The Natural Products Experts"). Services include clinical trials phase II-IV and strategic, scientific and regulatory consultancy. More than 35 experts with diverse backgrounds provide vast experience and expertise in the development of medicinal products, dietary supplements, functional foods, PARNUT products and medical devices.



## HIGHLIGHTS

analyze & realize GmbH was founded in 2000 merging Background Consultancy GmbH (established in 1992) and Phytopharm GmbH.

As an audited CRO we have conducted over 300 studies in various therapeutic areas including pediatric studies. We perform studies in our own study center with well-trained physicians and study nurses, a large network of GPs and specialists and in strategic alliance with the Charité Hospital, Berlin and the DIfE.

We have published several books, including ***PDR-Physician's Desk Reference for Herbal Medicines, Die grüne Apotheke and Alternativ Heilen.***

## SERVICES

### Full service contract research organisation

- ▷ Concept, design, planning, conduct and reporting of interventional (Phases II – IV) and non-interventional studies, clinical investigations with medical devices, nutritional studies, pilot studies
- ▷ Medical writing, submission to EC/CA, PI identification, site and subject recruitment, project management, trial logistics, monitoring, data management, biostatistics, study report, documentation management (TMF, ISF) etc.
- ▷ Publications in peer-reviewed journals

**Professional study center** with a large subject database, also available as study site for 3rd party CROs

### Nutritional Business Consulting

- ▷ Product development for functional ingredients, functional foods, dietary supplements as well as PARNUTs, safety assessments, expert statements
- ▷ Clarification of Novel Food status, compilation of Novel Food dossier

### Health Claim support - EFSA claims

- ▷ Set up and conduct of clinical trials to substantiate proprietary claims
- ▷ Compiling and submitting convincing scientific dossiers for health claim application

### Drug and medical device regulatory affairs

- ▷ Regulatory affairs for herbal drugs & medical devices, product development, safety & quality assessment, scientific consulting, medical writing, CTD etc.

### In vitro studies

- ▷ Examination of mode of action & marketing studies