Peer Review 2

Description

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1. ***INTRODUCTION***

Studies by clinicians and theoretical scientists concerning the bioresonance procedure of Regumed Regulative Medizintechnik GmbH were submitted to us so that we might appraise their scientific evidence.

The numerous studies explaining the bioresonance procedure are not to be considered here. Rather, as a biometrician/biostatistician with 40 years of experience in the field of clinical research for about 140 pharmaceutical firms and university institutes, I want to consider whether there is indication for the efficacy of the bioresonance therapy in the sense of evidence-based medicine .

With this in mind, I would first like to explain the concept of scientific evidence. In literature there are different representations of a gradation of evidence to be found. On the following pages an eight-step scheme is reproduced, which is applied within the scope of the guidelines for cardio-pulmonal reanimation. It was published in "Circulation 2000, 102" and it is presently often used in English speaking areas.

This degree of evidence scheme, however, should never be used rigidly: level 1 or level 2 studies have the highest degree of scientific evidence, such high levels, however, are not necessary in every case. These kinds of studies (level 1 or level 2) — together with large numbers of patients — make sense with the usual morbidity and mortality studies, but there are cases in which an observational study of patients with level 4 or 5 is conclusive. For example, in oncology such studies have been used for 40 years and are still being used even today as a first pilot study in man (so-called Gehan-Design or

Simon-Design).

These studies make sense when it is known how the course (e.g. the reaction rate) will be without therapy or with hitherto usual therapy. A therapy scheme for multiple sclerosis can, for example, only be investigated within the framework of a randomized double-blinded study because of large spontaneous fluctuations in the course of disease. Also an allergy study with a symptom suppressing preparation today is usually performed according to level I. However, when it is a question of the assertion of a cure or a great improvement with an already well-know rate of spontaneous improvement, then an observational study with level 4 or even 5 may be used to support arguments in favour of a certain alternative treatment.

THE DEGREE OF VALIDITY OF SCIENTIFIC STATEMENTS

Level 1 	Statistically significant randomized controlled studies or meta-analyses with statistically significant results	Meta-analyses of many randomized controlled studies with homogeneous and statistically significant therapy effects or with heterogeneous results, which, however, together are statistically significant.
Level 2 	Statistically not significant randomized controlled studies or meta-analyses; statistically not significant meta-analyses from inconsistent randomized controlled studies	Meta-analyses of many randomized controlled studies with consistent therapy effects in the individual studies, which, however, are not statistically significant; Meta-analyses of many randomized controlled studies with heterogeneous and statistically not significant therapy effects
Level 3 	Prospective, controlled, but not randomized cohort studies	Prospective studies with a cohort of patients which is not randomized with regard to the intervention. The investigators usually try to establish a simultaneously treated group or a comparison group.
Level 4 	Historical, not randomized cohorts or case-control-studies	Historically not randomized cohort studies; retrospective studies or observational studies; the investigators try to provide a control group or comparison group.
Level 5 	Observational studies	Studies in which patients are included sequentially either prospectively or retrospectively and the effect of an intervention is observed; no control group
Level 6 	Experimental studies with animals and mechanistic model studies	Experimental studies with animals and mechanistic model studies
Level 7 	Reasonable extrapolation of existing data; quasi-experimental design	Reasonable extrapolation with quasi-experimental design or with existing data that was collected for other purposes
Level 8 	Rational conviction (generally accepted); historical acceptance as a standard practice	The practice agrees with the general feeling and has seeming validity. Traditionally accepted as standard practice before the requirements for scientifically confirmed recommendations (EBM): no new scientifically confirmed information to support a change; no indication of a negative effect

Classifying of the „Level of Evidence" by American Heart Association (AHA) Modified by: W.F. Dick: Evidence based emergency medicine. Anaesthesist 1998; 47: 957 and Circulation 2000; 102: I-4

2. ***PEER REVIEWS' REMARKS ON THE STUDIES UNDER CONSIDERATION***

In the following individual indications are discussed with studies or other informative materials being available.

2.1 Indication: Therapy of Allergies

Study 1

Author: Schumacher, Peter

Publications

1. Biophysikalische Therapie von Allergien, in: Handbuch zu den nattirlichen Heilweisen and besonderen Therapieeinrichtungen, Hrsg. von O. Ausserer, Reihe ZDN, Alfred & Sohne, Meran 1992, S. 139-144

(English translation: Biopyhsical therapy of allergies, in Handbook on naturopathy and special therapeutic devices, published by 0. Ausserer, series ZDN, Alfred & Sohne, Meran 1992, pages 139-144)

2. Biophysikalische Therapie der Allergien: erweiterte Bioresonanztherapie, Sonntag-Verlag, Stuttgart 1994

(English translation: Biophysical therapy of allergies: extended bioresonance therapy, Sonntag-Verlag, Stuttgart 1994)

3. Biophysikalische Therapie, Brtlgemann Institut, Gauting 1991, Forschungsbericht

(English translation: Biophysical therapy, Brtigemann Institut, Gauting 1991, research report)

Design: One-group cohort study

Degree of Evidence: 4/5

Treatment: Allergy extinguishing therapy with inverse oscillation of the allergen (BICOM® Program 999), with allergen-abstention in the extinguishing phase

Patients investigated

Patients with a demonstrated allergy, confirmed with reaction to a provocation test or by abstention to allergen. Patient cohort: all patients who were treated for 6 months; sample size N: 204 treated cases in 164 patients. Results are ascertained through postal queries with questionnaires. Applying test diagnostics with the BICOM® device resulted in one or more allergies or intolerances for a variety of items such as e.g. wheat, cow milk, preservative, azo dye, cacao, and geese feathers. As stated previously, all patients already had the clinical symptoms of an allergy such as, for example, rash, coughing, bronchial-spasms (in this study, however, no pollen allergy). At 6 months after treatment, adult patients (or the patients in case of children) judged the success of the treatment on the following

estimation scale:

1. The allergy is extinguished, i.e. since end of therapy the patient has tolerated the allergen without any reaction whatever.
2. The allergy improved, i.e. the presence of the allergy can still be perceived, but it is gradually considerably less pronounced.
3. The allergy continues unchanged.
4. After being initially extinguished the allergy returned.
5. Not evaluable, because in the meantime there has been no contact with the allergen.

The percentages of the treatment results:

1: 83 %; 2: 11 %; 3+4: 4.5 %; 5: 1.5%

Biometrical/medical evaluation of the results

For this indication a spontaneous cure is very seldom, healings with therapeutic measures are unknown. It is therefore true that a cure (here referred to as an extinguishing) of the allergy with a quota of 83% is quite convincing (15% healings would already have been clinically meaningful).

A cohort study with a control in time is here persuasive — as opposed to other allergy studies with symptom relieving preparations. The successful healings cannot be attributed to a selection phenomena because of the high response rate. It also is not possible to attribute the results to spontaneous healing or originally incorrect diagnoses. Within the

framework of evidenced based medicine the efficacy of the BICOM® therapy has become very convincing.

Study 2

Allergy (Asthma)

Yang Jinzhi and Zhang Li

Research Center of the Child’s Hospital for Prevention and Treatment of Asthma of the City Jinan in the Province Shandong

Research report: Presented in an authorized translation.

Design: Prospective, controlled, not randomized study with two groups

Degree of Evidence: 3

Treatments:

1. BICOM treatment, 213 patients
2. Conventional treatment in accordance with the international guidelines with corticoids and anti-allergies, N = 87 patients

The results after treatment and after 6 months of observation were classified as:

1. Visibly effective (Free of symptoms)
2. Effective (some reduction of symptoms)
3. Improvement
4. Without effect

The results are displayed in the following table:

Tab. 1

Groups	Categories				Valid No.
	Visibly Effective	Improvement	Effective	Without Effect	
BICOM (N = 210)	92 43.2%	67 31.4%	23 10.8%	28 13.1%	210
Medication (N =87)	37 42.5%	17 19.5%	12 13.8%	21 24.1%	87

Exact P = 0.0492; Kolmogorov-Smirnov Test

It is clear that the BICOM® treatment was not only equally as good as but, indeed, superior to the conventional treatment. As we were able to determine through recalculations this superiority was even statistically significant (P = 0.049); Kolmogorov-Smirnov Test). When the table is considered more into detail it is possible to see that both groups are very similar regarding complete freedom from symptoms, but that the BICOM group is superior by a large margin in the categories “improvement” and “without effect”.

Particularly noteworthy is the fact that the BICOM treatment is practically free of side effects, which is by no means true of the medication therapy with corticoids and antiallergics.

Evaluation:

The conventional medication treatment is — at least in treating symptoms — very effective. It is therefore astonishing that the BICOM treatment achieves the same or even greater efficacy. The study design had a high degree of evidence (level 3) so that the results should be interpreted as a demonstration of efficacy.

Study 3

Allergy (all kinds)

Yuan Ze, Huang Jioh, Wang Haiyan and Yu Chunyan Department of Paediatrics of Xian, Central

Hospital, Xi’an

Publikation
Research report in English
Original Publication (Chinese) in: Maternal and Child Health Care of China (2004)

Design: One-group cohort study with observations at different points in time

Degree of Evidence: 4/5

Study

From June 2002 to January 2004 a total of 154 allergy patients, who had already undergone conventional treatment on several occasions, were treated with BICOM. Diagnoses were dermatitis, rhinitis, allergic conjunctivitis, and asthma. Immediately before and during the BICOM treatment, there was no anti-allergic concurrent medication.

The results were documented on the following estimation scale:

1. Healing (no symptoms in 6 months)
2. Much improved
3. Improved
4. No effect

After the treatment 120 of 154 patients (= 78%) were completely cured (free of symptoms for 6 months). There were no adverse effects.

Evaluation of the Study

The study with degree of evidence 4/5 provides here a sufficient demonstration of efficacy because a spontaneous remission in this indication is scarcely to be expected and the effect with this high rate of success cannot be explained through the placebo effect. As far as the different diagnostic groups are powered with enough patients, these groups can also be compared regarding healing. There is not much difference between the rates of improvement: 73% and 85%. At issue here are diagnoses that by conventional medical therapy can only be controlled to some degree using long-term treatments that have many side effects (e.g. corticoids): eczema, urticaria, dermatitis, neurodermitis, allergic rhinitis, asthma.

Study 4

Allergy (different diagnoses)

Autoren Ze, Y. and Haiyan, W.

Pediatrics of the Central Hospital of the Xi’an City, China Clinical results with the BICOM 2000 bioresonance device

Lecture, 45 International Congress for BICOM Users, April 29, 2005 to May 1, 2005, Fulda, printed in the Congress report RTI-Volume 29, April 2005

Design: Cohort study with observations at different points in time

Degree of Evidence: 4/5

The report describes the treatment of 1639 patients in the Central Hospital of Xi'an from June 2003 until December 2004. It describes patients with different diagnoses for allergy, all of whom were previously treated with the usual medications, but with almost no success.

The different types of allergy each were treated with BICOM, but obviously each type differently, with a series of standard programs by now distinguished from one another by numbers. In some cases a single treatment was enough, in others, e.g. in allergic rhinitis, 10 to 20 treatments were necessary. The patients were observed for 6 months after therapy, and the results were judged in accordance with the following scale:

1. Cure: allergic symptoms disappear completely. No recurrence of symptoms within 6 months after end of therapy.
2. Clearly effective: Allergic symptoms disappear completely, but return with milder
3. Effective: Allergic symptoms obviously improve, but there are relapses.
4. Not effective: No reduction of the allergic symptoms

In the following the table is reproduced from the original in abbreviated form. We cite the diagnosis, the number of cures/the total number of patients, as well as the percentage of cases with cures:

Eczema	176/188	93.6 %
Urticaria	266/353	75.4 %
Contact-Dermatitis	137/158	86.7 %
Neurodermatitis	30/55	54.5 %
Sweating	160/183	87.4 %
Allergic Rhinitis	140/165	84.8 %
Asthma	155/187	82.9 %
Spastic Muscle Tremor	120/146	82.2 %
Allergic Conjunctivitis	66/80	82.5 o/
Neurourethritis	1031125	82.4 %

The percentages of patients who were free of symptoms for 6 months are generally over 80%. Exceptions here are urticaria with 75,4 % and neurodermatitis with only 54,5 %; on the other hand,

eczema with 93.86% responds very well to the therapy. Considering percentages only, allergic rhinitis (pollinosis) responds well to the therapy (84.4%), but the pollen allergen are more difficult and more tedious to treat, as can be seen in the text.

Biometric Appraisal

The trial is a cohort study with a large number of patients (N=1639), all with allergies having very different diagnoses and origins who were previously treated with different medications but little success. At least for the six symptom-free months after the BICOM therapy the patients were cured (for the seasonal pollinoses it is surely necessary to observe patients for more than one year to obtain a meaningful definition of “cure”). Nothing is reported concerning adverse effects from BICOM treatments. It is to be assumed that after the test the category “cured” means that patients in this category — for at least 6 months — did not need further medication therapy. Spontaneous healing, placebo effect, and similar effects cannot explain the percentage of patients who experienced healing in this field of allergy. The demonstration of efficacy in this observational cohort study is self-evident. As a consequence of the large sample size the resulting percentages are very accurate statistical estimates and are subject to only a small random variation.

Study 5
Autor: Hennecke, J., Aachen

2 Publications

1. Energetische Allergietherapie-Moglichkeiten and Erfahrungen mit der BICOM®-Bioreso-nanztherapie, Arztezeitschrift fur Naturheilverfahren 35 (1994) 427-432

(English translation: Energetic Allergy Therapy Possibilities and Experiences with the BICOM® Bioresonance Therapy, Doctors’ Journal for Naturopathy 35 (1994) 427-432)

2. Zwei Jahre Erfahrungen mit der Allergie-Therapie ohne Karenz — Auswertung einer statistischen Studie, praktische Konsequenzen, Kolloquium des Internationalen Medizini–schen Arbeitskreises BICOM Therapie vom 1. bis 3. Oktober 1993 in Fulda.

(English translation: Two Years Experience with the Allergy Therapy without Abstention — Evaluation of a Statistical Study, Practical Consequences, Colloquium of the International Medical Working Group BICOM Therapy from October 1st to 3rd, 1993 in Fulda.)

Design: Patients treated from June 1991 until June 1993. One group cohort study.

Queries sent through the post regarding the success of the treatment. Evaluation of the first 200 returned questionnaires of the 248 questionnaires that were originally dispatched (personal message); quota: 80.6%. Patients with allergies and a long prior allergological history with a variety of treatments.

Degree of Evidence: 4/5

Treatment:

At first diagnosis of all allergens with the BICOM-device (central allergens, e.g. milk, wheat;

symptom provoking allergens, e.g. house dust, pollen; allergic exposition, e.g. vaccinations, pesticides, heavy metal).

Then the breakup of energy blockage through acupuncture with the introduction of the allergy information through modulation by H + Di-switching (program 530) without allergy elimination. Only one session, if failure of the one therapy session – additional breakup of energetic blockages (geopathology, scar interference fields, psychic blockages)

Patients Investigated: Patients with allergy related skin disorders (neurodermitis, eczema), pruritus, allergic conjunctivitis, allergic intestinal disorders, allergic respiratory system disorders, pollen allergies

Results: Results for 200 patients are obtained using postal queries with modified questionnaires from the study by Dr. Schumacher.

The therapy results over all groups were (distributed as percentages into classes determined by the estimation scale):

Complaint free:	50,4	%
Improved:	34,1	%
Not improved:	15,5	%

Adverse effects were observed only in very few instances and none of these were serious (tiredness, initial worsening).

Appraisal: 80.6% of the questionnaires from the postal queries were returned. This indicates that the results could be somewhat over optimistic because, for example, patients prefer to report positive results. Despite a possible distortion of the results, it can be assumed that a substantial number of the patients are free of complaints. This number is surely not to be explained away with placebo effects or erroneous diagnoses, so that it is possible to speak of the efficacy of the treatment having been demonstrated.

3.1 Indication: Damage to Liver Cells

Autors: Machowinski, R. and Gerlach, I.

Publication

Prospektive, randomisierte Studie zur Uberprufung der Behandlungserfolge mit patienteneigenen Schwingungen (BICOM) bei Leberzellschadigungen. Vortrag anlasslich des Symposiums in Fulda am 16.04.1996

(English translation: Prospective, randomised study to investigate the treatment successes with patient caused oscillations (BICOM) in liver cell damage. Lecture at the symposium in Fulda on April 16th, 1996)

Design

Prospective, randomised, 2-arm parallel group study, 2 x 14 patients

Degree of Evidence: Level 1

Diagnosis: Damage to liver cells

Excluded: Cirrhosis, acute hepatitis, autoimmune disease, alcohol abuse, chemotherapy Included: At least two of three liver enzymes with above normal values: ALAT; ASAT, gamma-GT, all chronic liver cell damages that have been recognized for at least one year.

Patient population: Twelve patients with positive hepatitis serology, 2 patients with severe, unclear infections in their patient histories, 2 patients with cholelithiasis, 2 patients state after with pancreatitis.

Treatment:

BICOM treatment:

1. Improvement of the energetic condition with the program No. 102
2. Therapy with program “Lymph chronic degenerative”
3. Program “Intestinal treatment”

Results

The liver enzymes were the primary variable for appraising success.

It is interesting that the median value of the enzymes in the control group scarcely change: They remain largely pathological in the individual patient. In the group with the BICOM verum treatment it is possible to see a considerable improvement in the median value. The individual values for most patients become normal. The differences between the groups are substantial and statistically significant.

Appraisal

The study shows not only a significant difference to the reference group, but the effects are also quite substantial and medically relevant.

The design of the study with degree of evidence no. 1 makes it possible to conclude that there is a statistically demonstrated and quite substantial efficacy for this indication.

4.1 Indication: stress syndrome in top athletes Papa, B. J. and Barovie

Teaching Hospital, Maribor, Slovenia Department Medical Rehabilitation

Report on the use of the **BICOM** resonance therapy in top athletes with excessive demand and stress syndrome.

Research report (without date)

Design

Two groups of athletes, not randomized, with treatment (12 patients in each group):

1. Therapy with ultrasound, 5 times weekly, for 5-10 minutes, additional cryo therapy, electrotherapy
2. BICOM device, Version 4, with program 630 [CH + Di, 114 Hz, wobble, amplification H = 2,5, Di = 26, time 5 min. (later after the test 8-12 minutes)]

Degree of Evidence: Level 2

Major criterion for efficacy VAS pain scale [Scores: 0-10]

Duration of the Therapy

Reference group: 144 days with 120 therapies altogether Test group: 104 days with 48 therapies altogether

Results:

In the reference group the mean value of the pain scores improved from 5.25 at the beginning to 2.6 at the end: in the BICOM group the mean value changed from 5.41 to 0.61. The difference is medically relevant (about 2.0 units on the scale [0-10] are generally interpreted as very relevant) and statistically significant ($P<0.05$). The considerably shorter treatment time in the test group is also interesting. The study investigators considered the BICOM procedure to be very effective for the stress syndrome of the top athletes and reported no adverse events related to the treatment.

Biometrie Appraisal

On the 8- point scale for degree of evidence the study design is at level 3 and thus the study should provide powerful evidence. In this sense efficacy is demonstrated statistically significant. Efficacy is considerable with **respect to therapy** duration, as well as with respect to the pain score (about two units **difference on the 10** point scale; the majority of patients on the BICOM group practically **free of complaints:** 10 patients **with** score 0 or 1.0).

4.2 Other relevant studies

There are some preclinical studies which show statistically significant and relevant effects. They show effects which by themselves already show the causality of efficacy or direct effects. Some of the studies are listed here.

1. Summarizing presentation of the in-vitro-modulation of the phagocytosis activity of human polymorphonuclear leukocyte through BICOM resonance therapy.

Authors:

Osadchaya, 0., Sakharov, **D.,** Lednyiczky, G. in: R. E. Kavetzky-Institut fur Experimentelle Pathologie,

Onkologie and Radiobiologie der Staatlichen Akademie der Wissenschaften der Ukraine sowie Hippocampus Forschungszentrum, Budapest, Ungarn.

(English translation: Kavetzky institute for experimental pathology, onkology and radiobiology of the National Academy of Science of Ukraine and Hippocampus research centre, Budapest, Hungary).

Content

The phagocytary activity of human leukocytes in the donor blood underwent a statistically significant modification through the BICOM treatment. In-vitro-study, controlled study.

Degree of Evidence: Level **1**

2. Investigations of the reconstruction of the immune systems of radioactively contaminated mice with BICOM resonance therapy.

Sakharov, D., Savtsova, Z. et al.

Location: as above

Content

The BICOM treatment of mice with weakened immune system status caused by radioactivity in Tschernobyl was statistically significant and medically relevant insofar as it could successfully bring the immune system status to a normal level. Animal experiment, controlled study.

Degree of Evidence: Level **1**

4.3. Indication: Diagnosis in the Clinic

Authors

Giannazo, E., Valenti, S., Puzzo, D.

Faculty of Physiology, Department of Biophysics at the University of Catania

Publication: Research report 2002

Users of electro-acupuncture according to Voll and of the BICOM therapy maintain that they can perform an allergy diagnosis by testing the acupuncture points on the hand and foot; this is disputed by sceptics.

Physicists and medical practitioners at the Department of Biophysics at the University of Catania performed a study to validate the BICOM diagnosis procedure by comparing the results with results of the standard procedure ‘Prick Test’. The results of the comparison were to be over those expected from a pure random result, indeed very much so, so that the BCOM test can be considered validated.

The authors have tested the 31 test persons for the allergy (positive/negative) with four

stimuli: mites, gramineen, oil tree, pellitory-of-the-wall (parietaria officinalis).

In the following we present our quantitative evaluation whereby we use the common measure of quality for all 124 (4 x 31) double determinations.

The sensitivity of BICOM is 0.84 (95 % CI: 0.72 — 0.92). The specificity is 0.66 (95 % CI: 0.53 — 0.78). These two variables define the correctly positive and correctly negative identified cases.

The Youden Index combines both measures and is exactly 0.5 (95 % CI: 0.34 to 0.64). (Boundary values 0 = rates; 1.0 = perfect test).

The BICOM test is this much better than guessing and of considerable usefulness in the medical field. (The 95 % confidence interval [CI] is the statistical uncertainty of the measurements; the width of the interval is clearly acceptable.)

Biometric Appraisal

The BICOM device as an objective procedure is **well** suited for performing allergy tests. Further investigations would be desirable in which the accuracy of the prick test as well as of the BICOM test are determined with a “gold standard” and discussed accordingly.

Degree of Evidence: Level 1

4.4 Summary appraisal of the research reports cited above

Summarizing it can be concluded:

1. Allergy Therapy

Using different therapy schemes, Schumacher and Hennecke convincingly demonstrate a large percentage of symptom-free patients. This is done in a cohort studies with a high degree of evidence for this indication. Three other studies from China are under consideration where the rates of improvement are similar for the patients under therapy: Among these three there are two cohort studies and a controlled but not randomized study. Efficacy is here demonstrated with a high degree of evidence.

2. Liver cells damage

The efficacy was demonstrated in a randomized study as statistically significant and relevant regarding liver enzyme improvement.

3. Stress syndrome of top athletes

The efficacy was demonstrated in a controlled, but not randomized study to be statistically significant and also medically relevant.

4. Other demonstrations of efficacy:

Ukranian and Hungarian scientists show in controlled studies

- Efficacy of BICOM treatment in leucocytes in an in-vitro experiment.
- Efficacy of BICOM treatment in mice with an immune status weakened by

5. Diagnostic in the Clinic

The Italian scientists Giannazo et al. (2002) have shown in a scientifically well founded study that the BICOM diagnosis method represents a valid procedure for diagnosing allergies measured against the standard prick test.

All previous studies and research work indicate that the BICOM procedure demonstrates not only statistically significant effects (demonstrable in the sense of statistics) but also effects that are medically relevant. These are to be interpreted as efficacy in the clinical context. Adverse effects, in particular those that are serious, are found in none of the studies.

The scientific evidence of the studies discussed here is not less than that of most studies performed at universities. There, a degree of evidence at level 1 with controlled double-blinded studies is not the rule. This measure of quality, level 1, is currently required only in the area of pharmaceutical research. It is furthermore true that the documents under consideration meet the requirements on clinical evaluation of medical products (see: R. Prestel, Anforderungen an die klinische Bewertung von „bekannten" Medizinprodukten aus der Sicht einer benannten Stelle, Medizintechnik 121 (2001) 9-13)

(English translation: Requirements on the clinical evaluation of „known" medical devices from the viewpoint of an authorised institute, Medizintechnik 121 (2001) 9-13)

Curriculum Vitae

Dr. **Volker W. Rahlfs, C. Stat. (RSS)**

Certificate „Biometrie in der Medizin", GMDS

Dr. Volker W. Rahliv was born in 1935, studied systematic musicology, psychology, phonetics, mathematics, physics, and philosophy in Hamburg from 1956 to 1965. He concluded his studies with a dissertation about themes of modern psychometry in musical perception for which the Department of Philosophy awarded him a Doctorate (cum laude). Thereafter he has been active in the fields qfpsy choinetry, biometry, and computer programming, first at the „Studio for Elektronic Music, Munich" with work in the field of acoustics as related to annoyance of noises. (Publication, ACUSTIC4 24, 1971).

In 1966 he founded the Institute for Data Analysis and Experimental Design (idv). During the ensur ing years more than 900 scientific studies in Germany and elsewhere have been supervised at idv. These studies have applications in all medical fields including pharmaceutical research, medical device research, as well as medical diagnostics and disease research. For 35 years he has conducted seminars for methodological questions in the biometrical research industry (approximately 400 seminars), consulted university institutes and industry on many occasions, written diverse biometrical expert reports, testified often as an expert in court and before pharmaceutical officials, and also acted as a so-

called Independent Statistician in large international studies with a Data Monitoring Committee. From 1979 until the present idv has been developing commercial PC programs for biomedical research (There are more than 140 idv program installations in the pharmaceutical industry and the academic area).

He has published more than 100 professional articles, among which 30 are methods-oriented, in peer-reviewed professional journals. The main themes of these publications are univariate and multivariate analysis (1971), multidimensional contingency table analysis (1973), meta analysis of studies (1973), pair comparison methods (1976), observational precision (1976), crossover for binary data (1978), crossover for quantitative data (1980), logrank tests (1983, 1986), non parametric procedures (1993, 1995, 1998), equivalence and non-inferiority studies (1996, 1998), alpha-adjusting because of multiplicity problems (1997).

He is holder of the certificate "Biometry in Medicine" from GMDS (1983) as well as being Chartered Statistician (C. Stat.), i, e. certified statistician of the Royal Statistical Society, UK (1993).

He is a member of the following professional societies: The German Society for Medical Informatics, Biometry, and Epidemiology (GMDS), the International Biometric Society, The American Statistical Association (ASA), The Royal Statistical Society (RSS), the International Society for Clinical Biostatistics (1SCB), the Society for Clinical Trials (SCT), The Drug Information Association (DIA), the German Society for Experimental and Clinical Pharmacology and Toxicology (DGP7), Society for Clinical Pharmacology and Therapy e. V. (GKPharm), German Society for Pharmaceutical Medicine (DGPharMed) the International Association for Statistical Computing (IASC) and numerous working groups dedicated to special statistical research.

Category

1. Scientific Studies

Tags

1. allergies
2. Clinical testing
3. liver cells

Date Created
2018/02/25
Author
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