Science and research are integral elements of anthroposophic medicine. These however are not confined to scientific methods and criteria, but – as in the case of treatment – go a step further. The principal aim of anthroposophic medical research is to gain an understanding of the human being as an entity, and not to study individual physical reactions. One of the fundamental tasks of anthroposophic medicine is to overcome the arbitrary division of medicine into countless subsets, each with their own distinct foundations and terminology, which can sometimes lead to interdisciplinary conflicts and often lead to adverse therapeutic interactions. The anthroposophic guiding principle is to create a shared interdisciplinary picture of the human being – in such a way as to be clear and understandable for everyone. Anthroposophic medicine’s main concern is the encounter between individuals with the aim of restoring or maintaining the health of the individual.

It is concerned with – recognising the reality – daily medical practice. This places the patient in the centre of the process and encourages the patients involvement, participation and ownership of the process. In view of this basic principle, anthroposophic medicines do not follow a mechanical concept with the aim either of replacing certain substances in the body or of suppressing overactive processes. Instead they aim to influence those processes that are off-balance so that their natural equilibrium is restored.

Anthroposophic medicine and therapy are therefore based on the ability of the human organism to regulate itself. Self-regulation means the ability to restore physical and mental imbalance, overcome crises, and turn every situation to good account. The internal and external capacity for self-regulation varies from person to person. It is therefore impossible to make the ability to self-regulate a prerequisite for all. Self-regulation reveals itself in strengths and weaknesses, which vary from individual to individual, and through personal reactions to accepted forms of treatment. What is good for one patient may be detrimental to another. Anthroposophic research must therefore aim to take not only the typical and general, but also the individual into account in its methodology.
Several recent examples have shown that research is a vital part of anthroposophic medicine:

• The AMOS study (see page 12) has proved conclusively that anthroposophic treatments are both effective and economical.

• Staff at the Herdecke hospital discovered that, when used in elocution therapy, speaking in hexameters – familiar from Homer’s Odyssey – has a positive effect on the co-ordination of heartbeat and breathing.

• International studies reveal that children who are treated anthroposophically (acceptance of childhood diseases, fewer immunisations, half as many antibiotics and fever-reducing remedies, bio-dynamic nutrition), suffer significantly fewer allergies.

• A four-year study into adults with chronic polyarthritis is currently nearing completion. It compares the anthroposophic approach to treatment with basic conventional treatment, which doesn’t always have the desired effect and is often accompanied by severe side effects.

• For many years now numerous studies (preclinical and clinical) have been conducted into the use of mistletoe as a cure for cancer (see page 10).

• Two conferences, attended by leading representatives of the German medical profession, on the human being and clinical research in complementary medicine are scheduled for 2004.

The differences between anthroposophic and conventional research

Conventional medical research focuses on experimental clinical trials that are subject to strict disqualification criteria. The prospective, randomised, controlled, double-blind study, during which, if possible, the method under examination is preferably compared with a placebo or standard form of treatment, is generally regarded as the “gold standard” for proving the efficacy of new medicines and treatments.

Prospective studies with a future orientation only include patients who fulfil certain criteria (e.g. same age, same stage of illness, no secondary ailments). Retrospective studies on the other hand use sources such as patient data and questionnaires to investigate treatment results achieved to date. Randomised means that test persons are divided at random into two groups – the one group receives the medicine or treatment under investigation, the other a placebo or standard form of treatment. The aim is to eliminate the “doctor drug”, thereby preventing trial results from being affected. Controlled means they include an element of comparison – with a standard form of treatment or placebo (placebo-controlled). Double-blind means neither doctor nor patient knows who is receiving the medicine or treatment under investigation. This is to prevent the doctor’s own convictions from influencing the objective assessment of results. All studies depend on precisely recorded data. During the consultation, the doctor determines whether a patient meets the study criteria. In conclusion the doctor explains the aims of the study, what measures are planned, and then requests the patient’s approval (left). Before enrolment into the study a physical examination is carried out (right).
having a suggestive influence on the efficacy of the medicine or procedure under examination. In addition it is important to rule out the possibility of the patient’s attitude producing a misleading result. If patients know it is a medicine or a placebo they are receiving, their attitude to the treatment will be affected.

This creates an artificial environment that bears little relation to the reality of treatment practised on a daily basis by doctors and hospitals. Such studies merely capture a single, strictly defined facet of treatment — under unnatural circumstances. Nevertheless, medicines or treatments that do well in prospective, randomised, placebo-controlled studies are regarded as effective for all patients even though we know for certain that this is not the case in practice.

Individuality, with all its physical and functional peculiarities, cannot therefore be ruled out. For this reason even the large-scale multi-centric mega studies are often unable to guarantee the efficacy of a procedure 100 percent, and certainly cannot guarantee no possibility of adverse drug or therapy interactions.

Research must be realistic
Anthroposophic researchers and leading scientists such as the clinical pharmacologist Georges Fülgraff have characterised the problem thus: “It entails replacing reality with models; the more complex reality is, the simpler the models are, until conversely, the only part of reality that is perceived is that which occurs in the model. In this way, we no longer acquire medical experience: treatment is based on models and not on reality.”

If science wishes to maintain links with reality, it must take the physiological, psychological and social dimensions into account. The more a study is able to reflect what really takes place in the hospital ward or practice, the more scientific it is.

Anthroposophic doctors and researchers do not dismiss prospective, randomised, controlled studies completely. They simply do not regard such trials as absolute proof of efficacy, but rather as a strictly limited opportunity to prove a particular effect under prescribed, extremely restricted circumstances.

Moreover, it is a fact that, only a small proportion of conventional medicines have been tested according to this "gold standard".
Evidence-based versus cognition-based medicine

The “artificial” cause and effect model of prospective, randomised, controlled studies, upon which most of the guidelines issued by medical associations concerning the treatment of particular diseases are based, represents the zenith of evidence-based medicine (or EBM).

This perception focuses solely on the external evidence, which per se calls into question the possibility of individualised findings: every investigative effort must be formalised, objectified, and de-humanised.

Evidence implies that a claim is convincingly supported by data and findings, but also most people understand, that the term evidence implies something manifest, which depends on the existence of an immediately recognisable context, and which therefore requires no further evidence or data: “The blindingly obvious”.

Evidence in this sense also enjoys a high status among anthroposophic researchers: they attach considerable importance to individually and subjectively substantiated findings. Meanwhile anthroposophic researchers have proposed a complementary form of clinical research methodology, which offers a solution to the dilemma of randomised controlled studies and their artificial design. This “cognition-based medicine” is based on personal, individual findings. Its methodological basis is the clearly understandable and reasoned decisions of doctors in the treatment of individual cases. Ideally this should mean it is possible to assess the efficacy of a treatment using recognised phenomena and the spectrum of results obtained.

This presupposes considerable treatment experience on the part of the doctor, from which may be derived a probability of expectation.

Furthermore the doctor needs to possess precise knowledge of the available treatment tools (medicines, remedies, treatment procedures) as well as a comprehensive appreciation of the human organism, taking into account both the inter-connectedness of organs and any mental or spiritual influences. As far as the patient is concerned, success depends on the extent the individual is prepared to engage in the treatment and actively participate in the healing process.

Research to date

Approximately 400 studies on anthroposophic medicines and treatment procedures have been conducted over the last 20 to 30 years. Many of these projects took the form of individual case studies. These studies often produced statistically relevant results in favour of anthroposophic treatment methods, which were also confirmed in the clinical experience of anthroposophic doctors.

Research into the use of anthroposophic mistletoe therapy in the treatment of cancer
patients occupies a special place and these days preparations containing mistletoe extract are among the most frequently prescribed medicines overall in the field of oncology (in German speaking countries) by both anthroposophic doctors, and conventional therapists (doctors, naturopaths) as well.

Countless preclinical research studies using mistletoe extracts exist, not to mention more than 60 clinical studies on the practical application of the five different anthroposophic mistletoe preparations (AbnobaViscum®, Helixor®, Iscador®, Isocarin®, Isorel®).

The studies’ findings have proved predominantly positive. Treatment with mistletoe brings improved quality of life, and may lengthen patients’ cancer-free survival time, or even their survival time as a whole.

These studies do not comply with the methodological standards set by conventional medicine because:

• It has proven to be very difficult to get patients to volunteer not to have a treatment which has such a track record of success especially in life threatening situations.
• It has proven impossible to get anthroposophic doctors to take part in decisions not to give a medicine which they consider to be effective and safe and to participate in a process which contradicts their moral and ethical professionalism.
• The subcutaneous administration of mistletoe preparations is also incompatible with double blind trials. The skin around the site of injection often becomes inflamed, is itchy and shows a tendency to harden. No known placebo is capable of creating the same effect.

Recently, in 2004 two new epidemiological cohort studies have been conducted, using data compiled retrospectively on patients who have been undergoing mistletoe treatment. This group is compared with a control cohort of patients treated with conventional therapy only.

Such comparative epidemiological cohort studies can be used to support the efficacy and safety of existing and established medicines (“well-established use”) in the European Union without asking the patient to take an unacceptable “risk” or the doctor to make an unethical decision.

Vor über 80 Jahren wurde die Mistel als Heilpflanze in die Krebstherapie eingeführt. Heute gehört sie zu den meistverordneten Arzneimitteln in der Onkologie.

Mistletoe preparations target the immune system. For instance the number and behaviour of the different blood cells may change – an effect verified by microscopic examination.

Both doctor and patient are immediately able to recognise who has been given the medicine and who the placebo. It is therefore impossible to create blind conditions.

Mistletoe extract as a medicinal herb for treating cancer was introduced by Rudolf Steiner over eighty years ago. These days it is one of the most widely prescribed medicines in oncology.
New research areas
One specific example of a study conducted according to the criteria of cognition-based medicine is the Anthroposophic Medicine Outcomes Study, AMOS for short.

The aim of this three year, GCP (good clinical practice) study was the evaluation of the benefit, necessity, and cost effectiveness of anthroposophic treatments (eurythmy therapy, artistic treatment forms, rhythmic massage and anthroposophic medicines) in cases of chronic illnesses (asthma, sinus infections, anxiety syndrome, headaches, backache, neck tension). 141 anthroposophic practices and outpatient clinics throughout Germany, together with 898 patients aged from 1 to 75 took part; using standardised methods, doctors and patients were survey-ed separately 3, 6, 12, 18 and 24 months fol-lowing the beginning of treatment.

The experienced reactions and symp-toms of the patients were recorded, as were the findings and objective criteria of the doctor, with which he/she justified the treat-ment. The results reveal that symptoms and health-related quality of life in the chronically ill undergo a clear and lasting improvement when treated anthroposophically, while total treatment costs are reduced at the same time.

This example clearly demonstrates that if properly documented and evaluated using standardised methods, it is possible to prove efficacy with reference to individual cases by comparing the treatment with the case history of the illness or the patient in an untreated condition. In such instances, the doctor/patient relationship, the therapeutic knowledge of the doctor, the opinion of the patient, and his/her active co-operation are all vital.

The study thus becomes an accurate reflection of practice conditions that can be assessed using standardised criteria. In addition this allows patient results to be collated in cohorts, which may then be evalu-ated statistically, leading to further possible findings.

Using specific exercises tailored to each, therapeutic eurythmy harmonises, strengthens, and restores the rhythm of all bodily functions.
The future of anthroposophic research

A crucial and groundbreaking example of modern anthroposophic research is the "Evaluation of Anthroposophic Medicines" (EvAMed) project in Germany. The aims of this research project are:

- to create an infrastructure that allows the flexible, swift and economic scientific documentation and evaluation of anthroposophic medicines
- to gather data on the indication-based prescription and application of anthroposophic medicines in medical practices and hospitals, and to obtain the first data for selected anthroposophic medicines with the aim of achieving EU safety certificates by 2005
- to establish a broad platform for joint oncological clinical research within anthroposophic medicine through the Oncology Network (an association of various anthroposophic and conventional oncological practices and hospitals)
- to bring together a circle of experts, made up of practising and clinical doctors with an anthroposophic orientation, with the aim of creating anthroposophic treatment evaluation sheets that deal specifically with illnesses and medicines
- to establish a department of clinical research in co-operation with other institutions.
- to analyse and re-work existing study models and contents, for a more disease-related evaluation of anthroposophic medicines in future
- to collate initial data on the proof of efficacy of (a few selected) anthroposophic medicines according to European Union guidelines (by 2005).

This project has already begun and is to be expanded at a national and international level over the coming years. It is being funded by charitable institutions.

EvAMed provides the necessary data on those areas already subjected to methodological processing, thereby creating the basis for subsequent, even more comprehensive research projects into the benefits and efficacy of anthroposophic medicines in medical practices and hospitals.