Research based on the principle of "good clinical practice" *

From the work of the institute for oncological and immunological research

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The institute for oncological and immunological research in Berlin, which has a close working relationship with the Society, would like to give a brief overview of its work in this year's Society for Cancer Research report.

A major motivation behind the 1994 founding of our registered association, the society for oncology and immunological research, was the fact that from the mid-seventies onwards - resulting from a development starting in the US - new medicines laws came into effect in all European countries. Justifiably, these laws required scientifically transparent and testable proofs of the quality, therapeutic efficacy and lack of side effects of "unconventional" medicines such as homeopathic, anthroposophic and herbal remedies.

It is therefore the declared aim of our institute to carry out clinical studies with Iscador® for a wide variety of indications, according to internationally accepted guidelines, and thus contribute to building bridges between anthroposophical and mainstream, scientific medicine. A second emphasis of our work is to develop a cannabis remedy (Cannador®) for treating a series of complaints which often restrict the quality of life of cancer patients to a marked extent – such as lack of appetite, tumour pain, nausea, depressive moods and sleep disorders. We have also set ourselves the goal of expanding the range of our clinical research with innovative research approaches and study designs that are more appropriate to the special character of complementary medical methods.

"Clinical research" quality standard

We see a focus of our activity in the proper realisation of "controlled" clinical studies, as expected both by the registering authorities – e.g. for recognition of a new indication – and also by the scientific world in general. Randomisation (random assignment of a study patient to one of two or more treatment groups) and blinding (neither the study doctor nor patients know who has been assigned to which treatment group) are frequently questioned and criticised on ethical grounds. Alongside the knowledge gained through such studies, however, participation in them can also be experienced as a kind of sacrifice for future generations of patients, for whom our medicines are preserved in consequence. New developments and above all official authorisation of anthroposophical remedies really cannot be imagined without clinical studies run according to international guidelines.

Thus if, in the interests of further developing anthroposophical medicine, one acknowledges the place of randomised and, where necessary, placebo-controlled study designs - complementary to the "cognition-based

medicine" research approach – then it is important to carry out such studies to a high professional standard, in accordance with applicable guidelines, without any diminution of the required quality. Such under-performance might arise from a reluctance to follow requirements one dislikes any more than necessary; but a half-hearted "controlled" study is certainly more problematic both in scientific and in ethical terms.

Originally based on the *Helsinki declaration on acknowledgement of universal human rights,* similar though very variable guidelines have in recent years been developed in each country for carrying out clinical studies on patients. For the past ten years or so, the EU, the USA and Japan have implemented unified standards and thus made successful efforts to gradually adapt these guidelines to ensure the high quality of clinical research, and problem-free mutual acceptance of new medical knowledge. These guidelines are regarded as binding on relevant registration authorities for the authorisation of new medicines. Further recommendations, above all relating to administrative conduct of clinical studies, have been made by the different national medicines institutes. Although Switzerland is not a member of the EU, it closely aligned itself in 2000 with the above guidelines through revision of its medicines law.

These guidelines relate to all areas of clinical research, from initial planning of a study through selection of patient participants, fixing of research parameters and periods, data collection, data quality assurance and evaluation through to drafting of the clinical/biometric concluding report. Aspects to be emphasised are the close involvement of the ethics commission at the patient study location, and the close collaboration between statisticians and doctors from the first stage of planning onwards. Logistical and staffing preconditions are also needed for proper quality assurance through the use of validated EDP software, and through data managers who check data collection at the study centres so as to uncover and resolve any possible inconsistencies locally and as swiftly as possible.

In accordance with the aims of our registered association, we have set ourselves the task of developing a high quality standard in our own clinical research practice, and of using this set of tools to support and advise on other research initiatives in the field of complementary medicine.

Looking ahead

Through our work based on the principle of GCP (Good Clinical Practice) and internationally accepted scientific rules, we wish to contribute to full recognition of our "medicines from whole plant extracts" research work, both in the world of mainstream medicine and science, and also in the legislative sphere of health authority jurisdiction.

But alongside our chiefly pragmatic acknowledgement of conventional methods of clinical research, we have not lost sight of increasingly apparent

failings and limitations of the legislative parameters within which we must work. Patients increasingly object to the collective and ethical imposition of playing “roulette” with their health by taking part in randomised and double blind studies. Furthermore it is dubious whether the high logistical and financial cost of these studies always leads reliably to a valid, generally applicable clinical result. The inclusion and exclusion criteria formulated in a study plan often over-restrict the group of patient subjects in a study, so that one can hardly derive conclusions relevant to the full reality of all affected patients. These questions are therefore ones that continue to accompany us in our work, motivating us, in collaboration with other researchers, to seek innovative research methods and study designs that can offer a solution to this problem.