THE MODEL OF GOOD CLINICAL PRACTICE IN APPLIED RESEARCH IN COMPLEMENTARY ALTERNATIVE MEDICINE.

UPDATE ABOUT GUNA'S CLINICAL RESEARCH PROJECT.

Research in homeopathy according to the International Guidelines for Good Clinical Practice is not easy: on the one hand, personalized homeopathic treatments, on the other hand the need for a standardized approach to therapy. In 2009 Guna S.p.a. started a Clinical Project, the first project of Applied Research in Complementary Alternative Medicine (CAM) in accordance with the International Standards of ethics and scientific quality.

The products studied are homotoxicological drugs, but, above all, of Physiological Regulating Medicine, namely, some of the normal biological molecules which can be found in the body, such as cytokines, hormones, neuropeptides in homeopathic dilutions.

The *messenger molecules* in homeopathic dilution have shown to be capable of speaking a biological language through a possible interaction with specific cellular receptors according to *informational* mechanisms.

Guna S.p.a. Clinical Research Unit has been created mainly aiming at organizing, recording, coordinating, monitoring and carrying out clinical trials sponsored by the Internal Scientific Committee, according to GCP standards. For each study the development of the protocol has been entrusted to " specialists", university professors or researchers, documenting all the steps and monitoring them in all their phases.

An original idea was to take advantage of the computer network that gathers medical graduates from A.I.O.T. (Italian Association of Medical Homotoxicology) to launch the Clinical Research project and select the protocol managers as well as the active investigators.

For each study, an electronic CRF (data form) has been created; a Handbook for users has been provided to all investigators and an Investigator brochure has been realized to describe the pharmacological characteristics of the experimental product, with reference to International Literature.

Furthermore, the Clinical Research Unit has edited any necessary forms and documentation and the list of blindness randomization and managed the organization of different batches of preparations (*verum* and placebo for the *trial)*.

Currently, 9 of the studies of the Clinical Research project have already finished or almost finished and 3 other studies are in progress, concerning the activity of herbal products and dietary supplements.