PL05 Clinical trials in the safety and efficacy evaluation of phytopharmaceuticals – A scientific challenge

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The presentation provides an overview on recent clinical results on safety and efficacy of a number of phytopharmaceuticals.
A set of around 100 clinical study publications of the last 5 years is critically highlighted. Key drugs evaluated include cone flower (*Echinacea* sp.), horse chestnut (*Aesculus hyppocastanum*), willow bark (*Salix* sp.), ginkgo (*Ginkgo biloba*) and Saint John's wort (*Hypericum perforatum*).
Like any other drug, efficacy of phytopharmaceuticals has to be shown in controlled, double-blind clinical studies performed according to GCP (1). Whilst most of the rather formal requests related to GCP could be fulfilled in a fairly easy way, the real challenge lies in the clinical and pharmacological methodology, which very often does not address the particular profile of the phytopharmaceutical drugs under evaluation. Hence, a number of analysed studies in this presentation - especially those of the "early days" of clinical research in this field - fails to show efficacy.
At the same time single case reports and analogies have often been used to question safety of phytopharmaceuticals (2). In the light of lack of proven efficacy the risk/benefit ratio was then considered to be negative.
Recent data on cone flower and horse chestnut are presented as examples showing the above mentioned methodological difficulties but also solutions in proving efficacy of phytotherapeuticals.
As a matter of fact, the number of clinical trials conducted according to GCP with relevant positive information concerning efficacy has increased.

References: 1. ICH Guidelines, ICH Topic E6, Note for Guidance on Good Clinical Practice, Sept. 1997. **2.** Schönhöfer, P. and Schulte-Sasse H. (1989) Dtsch. med. Wschr. 114: 1804-1806.

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Dr. Bruno Gianetti was born in Lyon (France) in 1952. After his studies in chemistry, he did his Doctoral Thesis in the University of Bonn under the title: “New antibiotic acting agents from basidiomycetes” (1977-1981). In 1981 he became PhD in Organic Chemistry and Pharmacology. Registered as a physician (1983), he also did a Doctoral Thesis in medicine (University of Bonn) under the title: "Characterisation of CEA and NCA by monoclonal anti-CEA antibodies in combination with Gel-Permeation-Chromatography" (1983-1985).
He has occupied different positions in several companies, such as Madaus AG (Cologne, Germany), Immuno AG (Vienna, Austria), Coopers & Lybrand (Basle, Switzerland), CRM GmbH (Rheinbach, Germany), α Care GmbH (Celle, Germany), VTS Denmark, CRMB GmbH (Rheinbach, Germany), Verigen Inc. (USA), VTSI AG (Leverkusen, Germany), He has 40 scientific papers published in several journals and 8 patents.