

**Nomination of the Contract Research Organisation Klifovet AG, represented by Dr. Klaus Hellmann, for the Best Supporting Role Award**

**What has been this organisation's most significant achievement during the year?**

September 2005: Completion, statistical analysis and reporting of a field study under extreme time pressure in response to questions by EMEA/CVMP on a clinical indication for a newly submitted veterinary product. The high quality of the work of Klifovet AG led to acceptance of the indication.

**Give details of what this organisation has accomplished this year in terms of:**

**Range of services provided to the animal health industry**

Klifovet AG offers a truly complete range of services for veterinary drug development including medical writing, dossier compilation and regulatory advice/ support for the various European submission procedures. The website gives an excellent overview of the services provided. Most outstanding is the Links Menu providing an extensive list of Animal Health (AH) Agencies, AH Organisations, Laboratories, Libraries and Veterinary Faculties. This shows that one main **objective of Klifovet is service rather than acquisition of contract work**, only.

Klifovet can conduct **clinical studies in numerous countries** including Germany, France, Belgium, The Netherlands, UK, Italy, Sweden, Denmark, Portugal, Spain, Switzerland, Austria, Hungary and Poland. This offers the animal health industry a comprehensive choice of European countries, important both for national registrations and being representative of the EU area for centralised registrations.

**Consistently meeting project deadlines or exceeding expectations of timelines**

As mentioned above, Klifovet perfectly met the tight timelines for the field study in response to authority questions. On a more recent project, Klifovet managed to complete a field study two months in advance of the agreed timeline so that a follow-on project can be started earlier than expected, which is very important considering seasonal occurrence of the disease investigated. Hence, **totally saved time may amount to more than half a year**.

**Consistently meeting or exceeding quality standards of work**

Klifovet consistently provides **fully GCP compliant study protocols, statistical analyses and final study reports of high quality**. Of particular benefit is the excellent monitoring of the clinical studies including follow-up of deviations. Thus, departures are detected regularly and close to their occurrence so that appropriate actions can be taken such as inclusion of additional cases. As a consequence, there are no bad surprises at the stage of writing the report as experienced with some other CROs.

### Design and introduction of new service aimed at the animal health industry, addressing an unmet need

Klifovet is currently establishing an **electronic data entry system for clinical studies** which could contribute to shortening of the duration of studies and even further improve the quality of the entered data.

Klifovet has recently extended their **service of applications for authorisation** of clinical studies – that previously comprised Germany, France, Belgium, Denmark, Slovakia, and UK – to Hungary, Portugal, Slovenia and Sweden. Management of the often complicated and time consuming trial applications is a valuable service to the industry.

### Consistently providing value for money

A recent comparison of Klifovet with other large (multinational) CROs revealed that Klifovet **prices are competitive**. Considering the excellent quality of work provided by Klifovet, the company offers very good value for money. This was the case over the time period considered for this award as well as consistently from 2001 until today.

### Demonstrating a proactive approach in delivering services to the industry/or other stakeholder groups

Regulatory authorities increasingly require MIC data on veterinary bacterial pathogens, mostly from domestic isolates. In cooperation with external partners, Klifovet has proactively established a **collection of veterinary pathogens** comprising many important organisms. The collection is available to the industry and can be of high value in defending claims for antimicrobial products. End of 2005, the collection has been extended by *Mycoplasma bovis* that is difficult to isolate in the field and in early 2006 by *Haemophilus parasuis*.

Klifovet consistently provides **regulatory advice** during development projects. Once they become aware of possible changes of guideline requirements, sponsors are contacted immediately so that the new requirements can be taken into account for ongoing or future studies.

**Excellent monitoring** and close follow-up of clinical studies enables Klifovet to proactively avoid problems, e.g. by timely amendments, rather than reacting to deviations. Another example is inclusion of additional investigators should the inclusion rate be lower than expected in order to **keep the agreed timelines**.

### **Conclusion**

We are **very satisfied** with the support offered by Klifovet during various clinical projects.

A Customer