

2. Pharmaceutical Development faces new challenges

Clinical research is becoming more and more complex and expensive. The average cost of developing one new drug doubled since 1980. This cost is estimated for \$ 500 million or, as reported in the recent Tufts University Study, for \$ 802 million¹. The average number of patients in clinical trials tripled since 1980. An analysis by CMR International, of 23 clinical dossiers submitted between February 1995 and April 1999 to the Regulatory Authorities in Europe, Japan, and the USA, found that dossiers contained on average 35 clinical trials, involving on average of more than 4000 subjects each. This exceeds by 3 times the average number of patients in clinical trials quoted by the FDA for HIV drugs. The European Commission pointed out in the explanatory memorandum attached to the project of the EU clinical trials directive that demonstration of efficacy and safety requires multi-centre clinical trials with up to 50-60 study centers involved in a single trial. These centers spread across more than one country making clinical development a substantial global process.

Tremendous political change in Central and Eastern Europe (CEE) allowed the inclusion of this region in the global process. It appeared quickly after that this region is an excellent contributor to the high-standard clinical studies conducted under US FDA IND. The number of clinical trials conducted in CEE increases and the advantages of this region, like fast patient recruitment, helps to shorten the development time of some key products.

One of the key issues in contemporary clinical research is the enormous complexity of the process. Clinical Project Managers must realize all consequences

¹ Washington Post, Dec. 1st, 2001

of such complexity. There is a basic, necessary, and justified level of complexity executed by the GCP guidelines and regulations of the appropriate authorities. If one's project complies with these guidelines it is complex enough and requires the handling of many documents. However, frequently enough one has to add on top of this system many other documents and data entry points resulting from lack of compatibility of different software employed by different project stakeholders or external vendors. Endless creativity of some managers brings additional "tools" that are a real burden for the CRAs causing double or even multiple entry of the same data into different systems or forms. Multiple progress reports and a variety of additional tracking "tools" are a real nightmare of inadequately prepared projects.

Then, if you add the international factor, by entering Central and Eastern Europe with different languages, different regulatory authorities, IRB/IEC, even different legal advisers in each study site (e.g. each hospital), the system may become unstable, if not built on a solid knowledge of the business and of the local clinical research environment.

There is only one remedy to this issue: keep things simple (sic!). From the very beginning of the project planning phase you should avoid all unnecessary forms, reports, so-called "CRA tools" and everything which requires additional human and financial resources. With every new "tool", sometimes strongly marketed and recommended by the CRO contracted by you, please check the real benefit of it versus an increase in complexity of the process. Do not hesitate to ask the question: "Can we live without it?" and if "yes," simply cut it out.