



TFS SPAIN, MEDICAL WRITING UNIT

- The Medical Writing Unit is qualified and experienced to support compiling, organizing, writing, editing and producing a wide range of medical or scientific documentation required to support product development efforts. The documentation provided by our medical writers is clearly written and compliant with all ICH guidelines and regulatory requirements.
- The Medical Writing Unit is able to support national, regional and international clinical trials and non-interventional studies.
- The Medical Writers at TFS have many years of experience in clinical research and in writing medical documents for large European, Asian and US pharmaceutical firms as well as small biotech and medical device companies.
- Our writers have long experience in the field and are only dedicated to medical writing with a strong track-record in the main therapeutic areas and medical device.

OUTSOURCING MEDICAL WRITING SERVICES OF CLINICAL RESEARCH ORGANIZATIONS TO TFS MEDICAL WRITING UNIT, BARCELONA

Output deliverables of Medical Writing Services from January to June 2010 are presented

INTRODUCTION

- The writing of medical texts by professionals allows distributing scientific research findings with clarity and rigor.
- The outsourcing of medical writing services by the Pharmaceutical and Biotech industries to the specialized departments of Clinical Research Organizations (CROs) has increased progressively in recent years.

MATERIAL AND METHODS

- From the global projects database of the TFS Medical Writing Unit, Spain (Barcelona) the medical writing services has been analyzed during the first half of 2010.
- It has been identified the client or sponsor, type of investigation, specific documents or services and therapeutic area. A descriptive analysis of data was performed.

RESULTS

• From January 1 to June 30, the TFS Medical Writing Unit, Barcelona has participated in the writing of a total of 248 documents for 20 different clients. Figure 1 show the distribution by monthly of total medical writing services developed on this period.

• A total of 17 therapeutic areas were identified, being the most frequently requested Oncology, Transplantation (TX) and Cardiovascular disease (Figure 3).

Figure 1: Monthly distribution of services during the first half of 2010

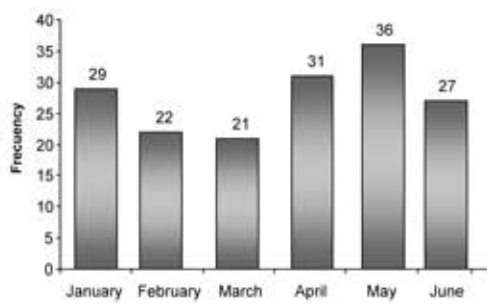
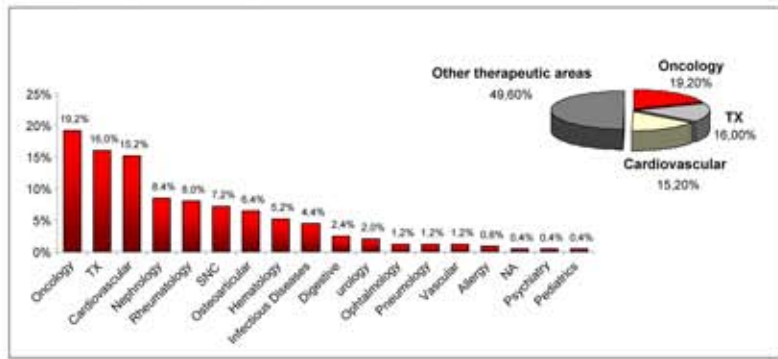


Figure 3: Therapeutic areas experience



• More than half of the documents developed corresponded to Communication to Congresses (51.6%) with abstracts, posters, oral presentations, followed by the production of Protocols and Final reports of studies (21.3%) and the writing manuscripts or management for publication (18.2%) (Figure 2).

• Regarding the design of clinical research, the number of non-interventional (observational) studies carried out was superior to clinical trials (Figure 4).

Figure 2: Distribution of different services

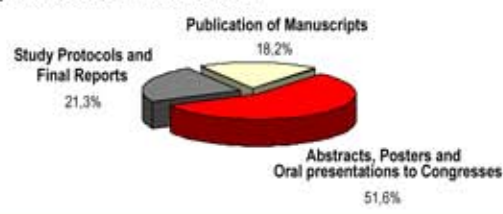
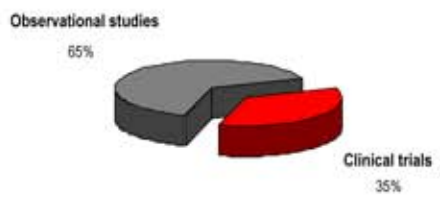


Figure 4: Summary of clinical studies



CONCLUSIONS

The results of our company revealed that the outsourcing needs of medical writing services by the industry have basically focused on:

- Communications to congresses
- Study Protocols and Clinical Study Reports
- Manuscripts writing and management

Oncology, Transplantation and Cardiovascular disease were identified as the main therapeutic areas of research with the predominance of observational studies versus clinical trials.