CASE STUDY
Probiotics

Study description
Multicenter, open-label, parallel-groups, randomized and controlled study vs X to evaluate the efficacy and the tolerability of x in treating patients suffering from acute diarrhoea.
Post-marketing study

Study objective
The sponsor wanted to assess the clinical efficacy of a probiotics after administration per os in subjects suffering from acute diarrhea.
The primary end point was the disappearance of the symtomatology (period expresses in days) during treatment phase in comparison with the group treated with the confronting drug.
The sponsor also aimed to assess the possible onset of correlated symptoms or of relapses during the follow-up period.
The tolerability of the product was evaluated through the number of unwanted effects occurred during the treatment period and/or during the follow-up period.

Patient population
200 patients of both genres, aged > 18 with acute diarrhea.

Investigatonial drug
Probiotic

Treatment period
10 days – after the treatment period a 1 week follow-up period

Primary Efficacy parameter
The reduction of the mean rate of the period of the diarrhoea in at least 20% of the group of subjects treated with the probiotic under study vs the group of subjects treated with the confronting product was considered a therapeutic success.
Whereas the tolerability of the treatment was assessed after 10p days of treatment and at the end of the follow-up period and was expresses by patients by means of a diary.

Participating countries
Italy

Sintesi Research Services
Project Management, Regulatory, Sites coordination, Monitoring activities, Investigators and CRA Meetings, data management and final clinical report.

Key challenges
Since the study proved of high interest because of the product, of various activities, of the involvement of General Practitioners and the local sanitary districts Sintesi Research planned a detailed survey questionnaire to evaluate the experience of the General Practitioners in the clinical trials, to assess the facilities qualification and the potential case study.
Because of the very common pathology a deep and exact evaluation of the potential subjects was performed.
Because of the seasonal nature of the study the Sponsor wanted a fast start.
From a regulatory point of view the study need to receive approvals not only from Local Ethics Committee and Competent Authority bur also from the Sanitary District Board. This third step could delayed sites initiation.
Sanitary District Pharmacy was involved in the allocation and in the preparation of the study drug kits. The sponsor wanted to implement a remote monitoring system: e-CRF was designed, all monitoring forms and reports were entered in a study specific program.

Keys of project success

To maximize patients recruitment Sintesi Research performed a very exact country and sites evaluation and selected highly skilled and motivated investigators.
Before starting the study Sintesi Research and the Medical Direction of the Sponsor met the coordinating Investigator to ensure the feasibility of the study with General Practitioners. Sintesi Research organized a local investigators with the participation of the CRAs and the Sponsor to ensure the understanding and the commitment to the study. A workshop on the E-crf held by a trained team was planned in order to familiarize the investigators with the completion of the CRFs.
The electronic management of the monitoring activities enabled a timely and a high quality data delivery to speed up the data management procedures.
The Sponsor met Sintesi Research proposal consisting in a free drug supply for the sites that reached the target.

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