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ABSTRACT BOOK

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Poster Board #01

The Problems in Teaching Investigators and Site Staff to Work in Randomized Clinical Trials

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Introduction

Professional working in the Randomized Clinical Trials (RCTs) requires site staff training. Physicians don't have specific competencies to participate in RCTs in routine practice, even having high medical qualification. The investigator meetings can't resolve all the education issues. Training programs for physicians working in RCTs are necessary.

Purpose of the study

To structure the investigator education in order to make it an independent site stuff unit.

Materials and methods

The Clinical Trials Center (CTC) has been working for 10 years headed by Elena Vishneva, PhD, MScD. The CTC has participated in 41 RCTs, often getting leading positions in patient enrolment in Russia.

Results

The training program has been developed in the CTC. Traditionally, at the first stage, the education starts with the GCP learning. At the second stage, Principal Investigator (PI) teaches Investigators the general principles of work. Before RCT initiation, PI requests to renew theoretical knowledge about the disease, traditional approaches of treatment and the study drug and the results of previous RCTs. The beginning Investigators run the test according to protocol and procedures for visits. At the third stage, young Investigators are supervised by a curator, participate in pre-screenings and get gradually involved in all activities. Especially, working with eCRF has significance as an indicator of site work. After graduating the education, young Investigators start working under the guidance of another curator for another clinical trial. Running the trainings is obligatory for each member of experienced Investigators team. Generally, the Investigator training takes at least 12 months to ensure his ability to participate in various clinical trials within his specialty.

Conclusions

The laborious process of the beginning Investigators' training to become professional is compensated by his conscious attitude to this serious work, what generally ensures the required quality of RCTs.

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Poster Board #02

Patients Adherence to Clinical Trials at the Russian Clinical Center

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Introduction

Inclusion of a sufficient quantity of patients and the correct intake of study drug is necessary to obtain a statistical result of the clinical trial. We clarified the main factors motivating patients to participate in clinical trials.

The aim

Define the main factors of patients' motivation to participate in clinical trials.

Materials and methods

The work of the Center of Clinical Trials under the guidance of the Doctor of Medical Science Vishneva Elena has been analyzed for 10 years. The Center of Clinical Trials had participated in 41 randomized clinical trials. The total number of patients included in the study was 1070, 918 of them were randomized, 152 patients were excluded from the study at the screening stage. None of the patients have refused to participate in the research of all time.

To clarify the motivation of patients was developed a questionnaire. Each question of 10 was evaluated on a 5-point scale where: 1 is not important at all, 5 is very important. 328 patients took part in the questionnaire.

Results

The main factor of patients' motivation was the possibility of observation by the main investigator (58% indicated 5 points, 32% - 4 points) and qualitative free laboratory diagnostics (5 points - 48%, 4 points - 46%). For 79% of respondents it is important to be able to communicate with an investigator at any time. Part of the patients (43% - 5 points and 21% - 4 points) considers the basic therapy for the disease important. However, the opportunity to participate in clinical trials the results of which are important for the medicine's development wasn't a principal factor.

Conclusions

For patients participating in RCTs in Russia it is important to have an opportunity to be observed with a qualified specialist, free communication with a doctor and laboratory diagnostics.

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Poster Board #03

Patients' Retention in Randomized Clinical Trials

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Introduction

To obtain reliable results in randomized clinical trials it is important not only to have a sufficient statistical sample of participants but also to complete all patients with a clinical trial protocol. Research physicians always make great efforts to achieve high retention results in RCTs.

The aim

To suggest the methods of promoting patients to stay in RCTs.

Materials and methods

The methods of patient retention in the Center of Clinical Trials under the leadership of Elena Vishneva were analyzed. The Center participated in 41 RCTs, totaling 1,070 patients, 918 of whom were randomized. The areas of researches are: cardiovascular diseases - 653 patients, diabetes mellitus - 195 patients, COPD - 71 patients, asthma - 144 patients, rheumatologic diseases - 7 patients. For 10 years informed consent was withdrawn - 0, lost for observation - 0. 9 patients stopped taking the study drug and agreed to further observation in the study. The total number of patients participated in 2 RCTS was 234 and in 3 or more RCTs - 449.

Results

The opportunities provided by the doctors of the research team which are not directly related to the study protocol and the study drug were the most important for the patients. There are a doctor-researcher's consultation at any time; availability of telephone communication; counseling family members on health issues; participation in the social life of patients. It was effective too to collect the contact information from close familiar patients to prevent a loss of contact.

Conclusions

In the retention of patients in the study the key link is the researcher`s personal desire to expand the range of his activities. The patient in this way figure out the investigator's interest not only in conducting the RCTs protocol for a specific disease but also the possibility of obtaining a full consultation of a specialist for himself and his relatives.

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Poster Board #04

Medical Infrared Thermography, Outside-the-Box Thinking in Clinical Trials Endpoints Selection

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One of the main struggles faced when developing a clinical study protocol is the choice of endpoints best suited to evaluate a study hypothesis. Ideally, the chosen endpoint would be clinically relevant, objective, sensitive and easily quantifiable. Whenever these conditions are not simultaneously met, the study design inherently becomes complicated in order to maintain a low impact level for confounding factors (sample size increases, control arms are added, composite endpoints are considered etc.).

The time has come to use modern-days technology solutions to reduce sample size requirements in efficacy studies with primary endpoints historically derived from subjective symptom scores or acquired in a manner that may be subject to bias. With that in mind, what might connect an efficacy study conducted on a locally acting/locally applied nasal decongestive with one conducted on a molecule intended for treatment of inflammatory rheumatoid arthritis and a TDDS adhesion performance study? The common denominator is merely temperature distribution within a defined body region, and the technique used for the assessment is medical infrared thermography (MIT). MIT is non-invasive, non-radiating, and can be used to detect and locate thermal abnormalities, characterized either by an increase (hyperthermia caused by inflammation or injury-related blood-flow variations) or a decrease (hypothermic pattern due to degenerations such as reduced muscular activity and poor perfusion) in skin surface temperature. Also, by temperature mapping the surface of a TDDS we can objectively pinpoint areas associated with detachment from skin and compute the information to obtain adhesion percentages.

The data presented demonstrate that temperature variance assessed through MIT is a relevant, sensitive, objective and (when validated) reliably quantifiable endpoint that can be successfully used for evaluating adhesion performance of TDDSs and for assessing treatment efficacy in knee inflammation, nasal congestion, diabetic neuropathy, Raynaud syndrome, inflammatory rheumatoid arthritis and other pathologic conditions.

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Poster Board #05

Risk Management Focus of Nestlé Clinical Studies in Nutrition

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Background

The ICH GCP guidelines are the gold standard rules in clinical studies in nutrition. In context of ICH E6 addendum, risk management is an essential and integral part of clinical trial management.

Objective

Risk management activities is part of quality management which should be documented and communicated by sponsor to all involved and affected by such activities to facilitate risk review and continuous improvement during study execution. Nestlé developed a robust process to identify, mitigate and report the risks specific to nutritional clinical studies.

Methods

The areas of assessment for risk identification should include both system level (e.g. SOPs, computerized systems, personnel) and clinical trial level (e.g. trial design, informed consent process).

The risks identified may be prioritized in terms of criticality to allow focus of mitigation and defining the best operational model. The identified critical points should be considered for risk management during all study stages.

Results

The main risks identified are related to the investigational products. Blinding of products is often at risk due to differences in appearance, smell, taste, volume and/or packaging as well as logistics and delivery (e.g. importation). To mitigate these risks, a suitable planning and production processes are closely monitored.

Furthermore, regulations for nutritional clinical trials are not always standardized. The lack of harmonization of regulatory requirements (e.g. Asia) and ever-changing and unpredictable policy and rules (e.g. China, India) may impact the trial quality, timelines and budget. To mitigate the risks, a complete regulatory and risk assessment (e.g. Custom clearance, biological samples exportation) should be performed prior to start. The selection of local CROs, brokers in contact with competent bodies and a well-documented submission dossier are also essential.

Conclusion

The risks analysis and lessons learned (effectiveness of mitigation implemented) throughout the lifespan of the study are key to ensure knowledge management for successful nutritional studies.

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Poster Board #06

Knowledge and Attitude to Clinical Trials: A Cross-Sectional Pilot Survey of Medical and Non-Medical Students in Poland

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Background

The public awareness of the benefits of clinical trials (CTs) in Poland is low. Opinions on the subject matter are influenced by public media and focus mainly on communicating negative examples and misinterpretations thus creating biased picture impacting recruitment.

Objective

To determine the current state of knowledge and attitude to clinical trials of medical and non-medical students in Poland.

Methods

We conducted an anonymous 23-item survey among 382 randomly selected students of two leading Polish universities: Medical University of Warsaw (MUW), representing medical students (n=194, 50,8%) and Lazarski University (UL), representing non-medical students (n=188, 49,2%). Four areas of CTs were analyzed: knowledge, opinions, preferences and expectations.

Results

Overall attitude to CTs were reported on 0-10 points Likert scale (0 - markedly negative and 10 - definitely positive) and were as follows: MUW/UL total average: 8,24 vs. 6,75 (diff. 1,49, p=0,0001) of which MUW female/male 8.27 vs. 8.18 (p=0,6649) and UL female/male 6.98 vs. 6.35 (p=0,0059).

The overall attitude to CTs was significantly correlated with the year of study on MUW (R=0,20, p=0,0041), while there was no statistical significantly correlation on UL group (p=0,0825) by Spearman`s correlations.

The overall attitude to CTs was significantly correlated with the age on MUW (R=0,22, p=0,0019) and UL group (R=0,25, p=0,0005) by Spearman`s correlations.

73% of all students complaint on insufficient amount of information of CTs and 83,8% expect to hear more.

Conclusions

There was a statistically significant difference in the assessment of clinical trials by medical and non-medical students. It’s disturbing to see the growth of the negative opinions along with the increase in the study year

among non-medical students which should be a rationale for CTs awareness campaign. Both groups of students are open for educational messages.