Volume II, Issue 1, April 2014

NEWSLETTER

In this Issue:

IRB Company Survey Report 2013: Survey results indicate 98% of our clients are satisfied with their interactions with the IRBco Staff.

A survey was developed and conducted by an independent contractor for the IRB Company to measure and rate the satisfaction of IRB Company clients. An invitation was sent to all of the Company's clients with individual login information to Survey Monkey for data collection (n=56).

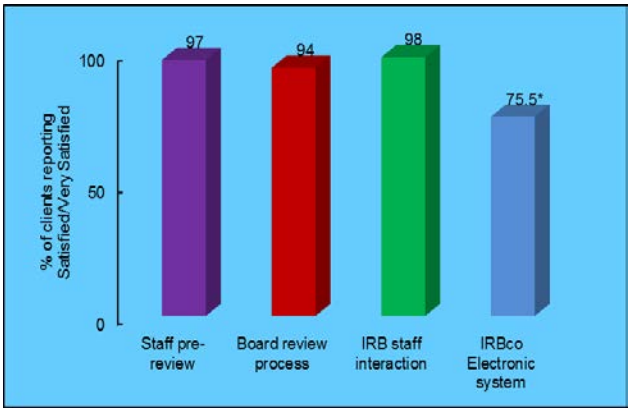

Fig. 1 Client satisfaction with IRBco

Data from 25 clients were collected by the deadline. All responses were confidential and the IRB Company only received an aggregate result in this report.

97% of the clients were found to be satisfied with the Staff pre-review process at IRBco. The questions in this section pertained to the quality of pre-review, the length of time for pre-review and feedback from the staff.

94% of the clients found the board review process to be highly qualitative and useful. Of note, 96% and 100% of the clients found the turn-around time to be satisfying for full board reviewed studies and expedited studies, respectively.

The clients were extremely pleased and satisfied with their interactions with the staff. 75.5% of the clients were satisfied with the IRBco electronic system.

*The system has been revised since the survey and IRBco will also be moving to a new electronic system called IRB Manager on April 21, to make it easier for our clients to submit their application. IRBco staff will be contacting our clients regarding training. At IRBco, we strive to achieve 100% satisfaction rate by constant quality evaluations and through clients' valuable feedback. ■

FDA Issues Memo: Good Review Practice MAPP – Obligation to consider breadth of patient populations and discourage unnecessary exclusions of patients in trials at EOP2.

In December 2013, a memo was issued by Robert Temple, Deputy Center Director for Clinical Science to update the Good Review Practice MAPP.

The intent of this memo was to describe the FDA's obligation to consider breadth of patient population in trials at EOP2 and other meetings which would ensure that the drug would be tested in a population which is more representative of the people who will use the drug if approved.

IRBco is happy to find that our existing operating policies and procedures are in line with the recommendations made in this memo.■

The Phases of Human Clinical Trials

Clinical trials are conducted to collect data regarding the safety and efficacy of a new drug or device. Clinical trials involving a new drug are commonly classified into four phases. Drug development is normally processed through all four phases over many years.

Phase I trials are the first time the drug or the device is being used in humans. These trials are done to test safety and tolerability. The pharmacokinetics (how a drug is absorbed, metabolized and

The Phases of Human Clinical Trials continued…

eliminated by the body) of a drug are also tested during this phase. These trials can also investigate the side effects that occur as dosage levels are increased. Phase I trials are usually conducted at a clinical research site that allows for observation by full-time staff. This phase can take several months to complete.

Phase II trials are designed to test the efficacy of the drug or device. Genetic testing commonly occurs during this phase when there is evidence of variation metabolic rate. Phase II trials are usually randomized, include a control group that receives a placebo or the standard of care, and are blinded so that the investigator can provide the sponsor and the FDA with comparative information about safety and effectiveness. This phase can take several months to two years to complete. Some trials combine Phase I and Phase II testing test both efficacy and toxicity.

Phase III trials are designed to further test the effectiveness of the drug or device, the range of possible adverse reactions and compare the new treatment with other treatments already available. These trials are usually randomized multicenter trials and are sometimes called the "pre-marketing phase" because it actually measures consumer response to the drug. The regulatory process for FDA approval is usually started while phase III trials are still in process, but once a Phase III trial is complete, a pharmaceutical company can request FDA approval for marketing.

Phase IV trails are designed to detect any rare or long-term adverse effects over a much larger population and longer time period than what was possible in any of the previous phases. Phase IV trials can sometimes result in a drug or device being taken off the market or restrictions of use could be placed on the product depending on the findings. ■

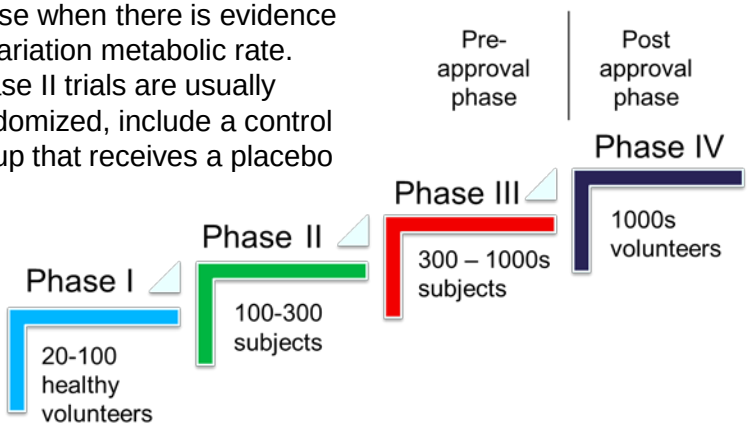

Fig. 2 The multiple phases of clinical trials

IRBco. Receives Full AAHRPP Reaccreditation

IRBco. is pleased to announce that it has received full reaccreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

AAHRPP promotes high-quality research through an accreditation process that helps organizations worldwide strengthen their human research protection programs (HRPPs).

As an independent, non-profit accrediting body, AAHRPP uses a voluntary, peer-driven, educational model to ensure that HRPPs meet rigorous standards for quality and protection. To earn accreditation, organizations must provide tangible evidence—through policies, procedures, and practices—of their commitment to scientifically and ethically sound research and to continuous improvement. For more information, visit http://www.aahrpp.org. ■

Contact IRBco.

Interested in learning more about IRBco? Our team is ready to answer your inquires regarding your organization's specific IRB needs.

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