Oncology IITs – custom made and handcrafted

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In the healthcare space, clinical trials are probably among the most sophisticated and complex activities and despite all the advances made possible by the IT revolution and all its ramifications, a clinical trial (CT) ultimately remains a highly intellectual human endeavor. No matter what the marketing and PR departments of the CT outsourcing enterprises will promise, a CT cannot be shaped into a streamlined industrial process. Even more importantly, the process shouldn't be thought along those lines but rather as an expression of human culture in the anthropological sense. The acknowledgment of this reality and the fact that the process of a clinical trial has not changed fundamentally in the last decades for a great part shapes our business philosophy as an academically minded sponsor for investigator initiated trials. IITs span the whole spectrum of clinical development (Phase I to IV) and more often than not the lines are blurred. In the essence, each trial we conduct is a unique synthesis of the following ingredients: design and scientific objectives, coordinating investigator and academic collaborators, funding sources/ budgetary constraints, business partners and regulatory frame. Consequently, our response can only be a custom made solution.

The process typically starts by stripping down the trial to its core necessities followed by the setting of budgetary limits and completed by a gradual building around the center. For each

trial than a careful balancing is performed between the allocation of in-house capabilities and the acquisition of external expertise and services. Although package deals with CROs may have their merits, we usually prefer a pick-and-choose approach tailored towards the specific requirements of the prospective study. The more complex contract negotiation, which may be the consequence of such an approach are usually worth the time and effort because all involved parties develop a much deeper understanding of the trial at hand and expectations are clearly communicated resulting in less friction down the line. The end product is usually a lean no-frills trial without compromise in quality.

Tightly interwoven into the more technical aspects of the above mentioned trial operations is the matter of clinical trial team assembly and the assignment of roles. In a recent article that appeared in *Clinical Trials Arena* Alex O'Leary already weighed in on this subject and we would like to add on to this tremendously important aspect.

No clinical trial is going to organize itself. It is the hands of our staff that assembles the pieces, occasionally micro-manage the unmanageable and craft a trial that benefits patients and hopefully inspires discussion in the scientific community for years to come. Not unusually, in the beginning of a project more personnel is allocated to a trial than would normally be needed and we draw in expertise from other trial teams temporarily to speed up the start-up track. Only

over time a team will consolidate. Since every trial in our portfolio is to some extent unique, cross team communication is strongly encouraged to provide an excellent learning opportunity for everyone. Moreover, the fact that all our staff have more than marginal knowledge of each other's projects renders the problem of temporary replacement and sickness cover much more manageable.

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Our employees are thinking individuals who bring their wits, creativity and self-motivation to the table. We thank them by not calling them "human resources", by provision of a liberal work place, levelheaded performance metrics and incentives beyond a pecuniary recompense. In return our staff develops a strong sense of ownership of the projects they manage. The result is exceptional employee retention and continuity. So far staff continuity from project start to trial completion has been the norm not an exception. The price to pay for such a philosophy and the environment it creates is to limit our company to an organic growth trajectory.

IITs in oncology are run on a shoestring, yet seldomly we as a sponsor organization will declare a project impossible to implement. Since money as a problem-solver is a limited option, we try to overcome obstacles by intense communication and the establishment of networks. We seek to create a sense of mutual interest in all participants, define common goals and invest in relationships to build partners with commitment and dedication. For a research idea to coalesce into a successful clinical trial a great deal of flexibility and empathy are required. Naturally, we expect as much from our business partners.

By the time a clinical trial is completed our human imprint and that of all collaborators begins to fade. Reports are submitted, papers get published, treatment guidelines are changed and a trial will be reduced to a set of numbers, graphs and bare statistics, yet during the course of a study emphasis on the human element is the key to success.