Communication of Clinical Trial Results with Participants: Beyond Publication

Researched and Written by: Andrew Milroy[1]

Edited by: Gordon B. Robinson , B.A.Sc. (Eng), Ph.D[2].

Today in the minds of the public and certainly with potential Clinical Trial Participants, there exists a great deal of suspicion and a lack of positive attitudes towards such Trials. While awareness campaigns may improve public perception, there still are many areas for considerable improvement throughout the Trial's life-cycle.

Purpose of the Paper

To examine Clinical Trial Researchers' attitudes towards Participants and specifically, towards the current, common-UHN practice of communicating Trial Results solely through Publication.

Background

Any Trial Participant is an investment on the part of the entire research community. Once recruited, many aspects of attitudes towards and how Participants are treated go a long way towards maximum retention. Throughout and at the finish-point of a Study, where the Participant feels they were a valued member of the research team, will go considerably further towards creating a positive attitude towards Trials in the minds of the public.

Discussion

Participants want the opportunity to be informed of their Trial's results which was explained in a recent paper[3]. This publication reviewed the current environment regarding the communication of Clinical Trial results with Participants. It cited, as a best-practice, the Center for Information and Study on Clinical Research Participation ("CISCRP") Program for sharing such results in lay language , similar to that in Informed Consent Forms ("ÏCF") . It concludes with a statement that any organization should develop industry- leading policies relating to repeated communication with Trial Participants. Not only is there an ethical foundation for the practice of communicating Clinical Trial results to Participants, it also has wide-spread support among "Stakeholders" of the Clinical Research enterprise.

Recently[4], it was shown that the Chairs of Canadian REB-s overwhelmingly supported sharing results with Participants. Not only the Chairs favour sharing, studies show that a high-percentage of Participants want to be advised of a Trials results[5] A study in late 2013 surveyed more than 5,600 Study Participants and discovered that learning of the results was one of the foremost reasons for participating[5]. Another study[4] showed the percentage of those wanting

to receive the results at 90 % Further, Principal Investigators themselves have been shown to be highly supportive of this sharing.

Despite wide-spread support from other "Stakeholders", the majority of Participants never receive results[4] In another Study, about 90% reported that they never learned the results from Investigators, Staff, the Institution or the Sponsors[3] . Some of the numbers:

- Only 5 out of 150 Institutions surveyed had any formal mechanism for returning Research Results to Participants
- Only 6 out of 180 Leukemia Clinical Trials indicated that Participants could receive Study Results
- Only 9 out of 22 Canadian REB-s surveyed had policies addressing communication of results or required Investigators to address the issue themselves..

Eighteen Studies provide sufficient data on the overwhelming desire by Participants to receive, in layman's language, their Study Results[4]. Thus, there is clear evidence that improvements in how Clinical Trials should be run, but unfortunately, Participant preferences are seldom considered when developing policy and what seems like a simple process as it is not in the cultural framework of Trial operations[6]. One Cancer Study reported that 86% of the Participants were not even offered the chance to receive the results at all[7] while another[3] showed less than 5% received results.

Often the practice of sharing Clinical Trial results, if at all, is done through publications and posting information to clinicaltrial.gov or similar on-line platforms. Further, when shared the results remain in technical language which is not in keeping with the guiding principles for Informed Consents. Such on-line platforms are meant for a different audience than Participants. It defies logic and common sense that Trial results are not offered in lay-language !! In fact, Kenneth Getz, the co-founder of CISCRP stated that such practices fail to satisfy the critical obligation to communicate results with Participants[3].

Clearly Participants want to receive their Clinical Trial results and more research on this issue in not needed. Attention must be given to efficiently share results in lay-language with Participants. Doing so would provide Participants with a much-needed sense of appreciation and help considerably to build increasing trust in the Clinical Trial enterprise.

An opportunity currently exists to build stronger ties with Participants through intelligent results-sharing, before it is mandated. In March of 2014,, The European Parliament voted overwhelmingly in favour of regulations that all Clinical Trial results be accompanied with a lay-language summary. Such programs are increasingly being implemented on a voluntary basis by Sponsors to honour and thank Participants[5] .

> Within 5 years, pharmaceutical and biotech companies will routinely provide Clinical Trial results to study volunteers in response to regulatory mandate, public pressure and desire to strengthen relationships with those volunteers.

Although it is reasonable to believe that lay-summaries will be required, some postulate that there are barriers, which could include[4] , although some of these possibilities have been negated. In fact Miller[4] found that negative consequences were not a deterrent to a vast majority of Participants in one Study.

Communication Practices

Any barriers can be overcome and there are examples of successful programs that shared results with Participants. One example is the MA.17 Trial[5] which tested whether extended adjuvant therapy with the aromatase inhibitor *'letrozole'* after *'tamoxifen'* reduced the risk of breast cancer reoccurrence. When, mid-way through the Trial, that *'letrozole'* improved disease-free survival, the Trial was halted and the Coordinator sent-out an e-mail to akk Study Sites 3 days before any public announcement and each Participant was immediately offered open-label to *'letropzole'* with such greatly improved communications improving the attitudes of Participants.

Another example of exemplary communications with Trial Participants Is through the work of 'CISCRP' which began in 2010 when they started a program of communicating in lay-language, Trial results to Participants and have stated that they can … "easily, feasibly and affordably establish as a standard practice within organizations and industry-wide" [3], CISCRP-lead studies showed that what a majority of Participants wanted was a small recognition and information of when the results would be available understandably to them. Further assessment indicates that such a practice is feasible and generally easy to perform.

Currently, CISCRP is assisting more than 12 companies in support of their post-Trial communication initiatives[3] and although it was slow to begin, they have seen a doubling in each of the past 2 years of Sponsors joining, bringing to about 24 .

Such a communication imitative positively impacts volunteer recruitment, retention and long-term trust in the Clinical Research Trials by recognizing the Participant as a fellow "Stakeholder" in the process showing signs of respect for the risks assumed and the commitments' made by the Participant[3] .

Opportunities for Relationships

Substantial missed opportunities of building trust and establishing relationships with Study Participants are encountered when they do not receive appropriate communication. Only lay-summaries shared with Participants, rather than the current usual practice of publication, should be considered as a means of meeting ethical obligations.

With Participants and Investigative sites amongst others, all asking for Study Results and growing support from Sponsors to providing lay-summaries, there needs to be greater demand in the form of institutional policies mandating that results be shared with Participants in a form that they can understand. In addition, this policy when applied during a Trial, can yield positive

results. Furthermore, in keeping with ethical standards, the plan for communication should be discussed both in the ICF and in Protocols.

Policies that increase the level of importance placed on communicating Trial Results and their subsequent enactment shows respect for the collaborative relationship between Investigators and Participants and would enhance trustworthiness of Research and Researchers.

Conclusion

The 3-R's …. In order to maintain or increase the number of Recruited and Retained, Clinical Trial Participants, UHN must improve the level of Respect in which such Participants are viewed.

UHN should consider development of a country-leading, communication policy where Clinical Trial Participants are communicated with both in periodic appreciation and then, with understandable verbiage of lay-language summaries of the Trial Results.

Further, this policy would be concomitant with that of Consent Forms which mandates language at a 6^{th}- 8^{th}- grade education level.

Such an action on the part of UHN would be another example of how it is leading in Research Ethics compliance.

Bibliography

1) Andrew Milroy, former Member of the UHN, Oncology-REB ('12-'14), now employed as the HRPP & CQA Manager at Merita CQA in Montreal

2) Gordon B. Robinson, B.A.Sc. (Eng), Ph.D. is a Member of the UHN Oncology-REB ('07 - present) and a Member of the Federal, Tri-Agency Panel on Research Ethics (PRE)

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