Streamlining the process - from mCTA to pragmatic contracts

Desired Outcomes

It has long been known that Canada has the opportunity to improve the contract process for clinical trials. It is proposed that a pragmatic, online contracting tool be developed that will help reduce the amount of time spent on the negotiation of clinical trial agreements and improve clinical trial start-up times in Canada. The tool will allow the capability to choose clauses by Province and potentially Institution which will already be agreed upon in principle by key clinical trials stakeholders in Canada.

Background and Current Status

Clinical trial contract negotiations can take as much as 9 months to a year to complete. There are two separate but related and converging efforts going on in Canada and internationally to reduce negotiation times for clinical trials.

1. **mCTA** – The model Clinical Trials Agreement was originally negotiated by members of Rx&D and HealthCareCAN through the resources of CIHR and using the "CAHO principles" or contract best practices. The mCTA was pilot tested between October 1, 2011 and March 31, 2012 revealing significant content and process challenges. To assist in addressing these, it was agreed that HealthCareCAN would begin by working with all of their members, and FQRS, CTO, BCCRIN, SKPOR, Alberta Innovates, NS, NB, and NFLD to offer a working draft of "common consensus mCTA elements" + "province specific requirements/elements". This was based on the BCCRIN adaptation and FQRS adaptation of the mCTA. An Ontario based lawyer reconciled what is common and what is "necessarily province specific" and this was further discussed by sites across the country. Proposed common elements and province specific requirements as well as preferences were offered back to Rx&D members for review. Rx&D is in the process of reviewing the province specific requirements and preferences to sort through the jurisdictional specific requirements.

2. **TransCelerate CLEAR (Common Language Evaluation and Reconciliation) Initiative** – At the same time as the mCTA is in progress, an industry membership driven organization is conducting a North American initiative to identify text that could reduce negotiation times for the five of the most contentious clauses including Subject Injury, Indemnification, Intellectual Property, Publication and Confidentiality. Text has been agreed on for Subject Injury and Indemnification language is also almost complete. There is a significant representation of Rx&D members at the TransCelerate table.

In the proposed next steps, both of these initiatives will be integrated to move Canada toward a more structured contracting process which incorporates the realities of differing provincial legislation.

Proposed Action Plan Moving Forward

It is proposed that representatives of TransCelerate, Rx&D, HealthCare*CAN*, N2, the provincial bodies, and the Canadian Clinical Trials Coordinating Centre (CCTCC) work together to advance the potential of a common contract in the following manner:

1. The model clinical trials agreement will be reconceptualised into two groups of clauses: (1) clauses that are currently on the TransCelerate agenda (contentious clauses) and (2) clauses that are not currently on the TransCelerate agenda (non-contentious clauses).

2. For the contentious clauses on the TransCelerate CLEAR initiative agenda, a Canadian contingent composed of representatives from Rx&D, Healthcare*CAN*, N2, and provincial bodies will work in parallel to the CLEAR project. Feedback from the Canadian contingent will be brought back to the table for CLEAR consideration and inclusion to ensure the developed language will work in Canada. This will ensure a Canadian site perspective is offered efficiently in the development of the text for the contentious clauses previously identified. The Canadian contingent will meet face-to-face at least twice between now and December as well as communicate via email and electronic meetings as required ensuring the development of the TransCelerate clauses are acceptable in Canada.

3. For the remainder of the clauses in the mCTA, Rx&D members will review the comments and preferences expressed by the provincial bodies and sites and will come back with an offer for consideration by the sites. Where there is acceptability, these clauses will be entered into the online contracting tool. Jurisdictional differences will be accounted for with a "drop down option".

4. A web tool developer will be engaged by CCTCC to begin the process of designing the tool and incorporating provincial differences and TransCelerate clauses as they are produced. The idea will be to offer maximum standardization where it is realistic and flexibility where it is needed. The online nature of the tool will allow for ease of use and the capability to update as required.

5. A communications and education strategy will be developed for Rx&D member companies and Healthcare*CAN* members which will include a change in name for the new tool - moving away from a model clinical trial agreement, and closer to a pragmatic online contract tool.

6. Evaluation criteria will be developed to measure the reduction of negotiation times upon implementation of the new tool.

7. A pilot phase of the tool will be ready for launch in December 2015 and will be housed with the CCTCC.

8. In parallel, it was proposed a separate team be formed to begin work on exploring a Fair Market Pricing and budget component for the tool which could be added as a second phase, post launch. Composition and objectives of this team will be discussed with CCTCC and partners for further development with the objective of further reducing negotiation times in the contracting process.

A summary of the above plan was proposed to the CCTCC Executive Committee on June 11th with full support.