

CLEAR™

Common Language Evaluation and Reconciliation



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Facilitator

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The average time to execute a clinical trial agreement (CTA) between sponsors, contract research organizations (CROs) and sites takes more than 13 weeks globally and over 10 weeks in North America. Sadly, these statistics have actually gotten worse since 2010, doubling in length.¹

The impact on clinical outcomes can be illustrated by focusing on melanoma as a case example. Melanoma accounts for only about 1% of all skin cancer cases, but the vast majority of skin cancer deaths.² It is the third most common cancer among women ages 20-39 and the second most common cancer in men ages 20-39.³ Each year over 10,000 lives are lost from melanoma in the United States, more than one hundred and ninety-four per week.⁴ The impacts of all of these weeks lost to execute the CTA quickly add up in lives lost. Add up the impact among all therapeutic areas, all countries and all patients and the reality is beyond sobering. Commitment to move the needle for CTA execution from 13 weeks to even seven weeks brings a life-saving product to market six weeks earlier, and potentially saves 1,164 patients suffering from melanoma, and this just in the United States. The worldwide implications are astonishing.

This reality was brought home to the clinical trial community through the story of T.J. Sharpe. Diagnosed with Stage IV melanoma in August 2012 at the age of 37, with a wife and two young children at home, he found hope in a clinical trial. However, that hope dimmed when the start of the clinical trial was delayed for six weeks due to a CTA not being executed. T.J. Sharpe eventually found his clinical trial, continues to participate in research, and has survived melanoma for more than four years. TJ has moved countless clinical research audiences with his story. You can view his video on the SCRS website at <http://myscrs.org/tjs-story>.

Across the industry, organizations have identified CTA language component negotiations as a significant and frequent bottleneck for clinical trial initiation. Sites, sponsors, and CROs alike are all concerned that CTA negotiations stifle clinical trial research efficiency around the globe and ultimately negatively impact the process of bringing clinical medicines to the patients who need them.

While some industry groups have tried to tackle this problem, none to date has succeeded in crafting a viable solution that has substantial support from the relevant stakeholder groups. Recognizing this ongoing challenge, SCRS spearheaded the development of the Common Language Evaluation and Reconciliation (CLEAR) initiative. CLEAR has gathered the critical mass of industry stakeholders necessary to finally make progress on the problem of CTA delays.

The purpose of CLEAR is to streamline contract negotiations and thereby accelerate site initiations, leading to increased recruitment timeliness and reduced study start-up costs. Improving productivity by reducing cycle times and accelerating clinical research will allow industry to get new treatments in development to patients faster without sacrificing quality. This initiative benefits all the stakeholders within industry—sponsors, CROs and sites—but most importantly patients.

To obtain a copy of this paper, go to MySCRS.org and click on "News & Press" and follow the link to White Papers.

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The CLEAR initiative charter was developed through SCRS with the support of TransCelerate BioPharma, Inc. (TransCelerate) and the Association for Clinical Research Organizations (ACRO). The working group includes members from sites, sponsors and CRO stakeholders. Members of this team of subject matter experts were invited to participate regardless of whether they were members of TransCelerate or ACRO. They have worked diligently over the past two years, communicated often, and met frequently to develop mutually acceptable model CTA clauses for clinical research in Phase II to III clinical trials with initially a North American focus. The most common clauses that created the delay were validated via an SCRS survey in 2015 and were agreed upon by the working group as the ones which the CLEAR working group would focus. Emphasis on “the clauses that matter” was the mantra of the working group to help ensure CLEAR provided industry a launching pad to help dramatically expedite the contract process.

The working group identified the five leading principles to apply to the CLEAR clauses:

- Key perspective is that of the patient
- Focus on the absolute must-have language
- Negotiation on principles, not positions
- A level of compromise is required by all parties
- The current CTA negotiation model is not sustainable

After much serious consideration, the working group determined the best course of action was not to build a model CTA, but rather to address the five key CTA clauses that cause the most contention during negotiations: Indemnification, Intellectual Property, Publication, Subject Injury, and Confidentiality.

CLEAR Clauses

***Indemnification
Publication
Confidentiality***

***Intellectual Property
Subject Injury***

The CLEAR clauses are proposed solutions for sites, sponsors, and CROs to adopt to expedite contract negotiations. It is recognized that adopting CLEAR will dramatically reduce the unnecessary time spent negotiating contracts. It is further recognized that adopting standardization of the CLEAR clauses will improve efficiency - using the time and effort spent in clinical research to bring life-saving treatments to market rather than re-negotiating the same clauses over and over.

The CLEAR project will continue to evolve as the industry evolves. The working group will continue to evaluate and modify the CLEAR language through a sustainability process. This process will ensure that CLEAR remains relevant and valuable to the future of clinical trial research for North America. The working group will also evaluate other countries for how they may benefit from the CLEAR initiative.

As an industry seeded in appropriate deep regulatory and legal process it is easy to lose site of the patients waiting for us to get it right. However, as TJ reminds us “to you it’s a document, to me it’s my life.” As an industry we owe it to all the TJs to get this right and we believe the adoption of CLEAR is a clear first critical step in the right direction.

Definitions

“Agreement” means this agreement comprising its clauses, schedules and any appendices attached to it.

“Applicable Law” means all of the statutes, regulations, rules and guidelines, including without limitation, Regulatory Authority rules and guidelines relating to the conduct of the Clinical Trial, ICH GCP, and federal and state (replace with “provincial” in Canada) privacy legislation and data protection laws that apply to the conduct of the Clinical Trial by the Institution, the Principal Investigator and Sponsor.

“Intellectual Property” means patents, trademarks, trade names, trade secrets, service marks, domain name copyrights, moral rights, rights in and to databases (including rights to prevent the extraction or reutilization of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including applications for registration of any of them. Intellectual Property includes all and any technical and other information which is not in the public domain (other than as a result of a breach of confidence), including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, materials, substances, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, clinical data, manufacturing data and information contained in submissions to regulatory authorities, whether or not protected by Intellectual Property Rights or any applications for such rights.

“Effective Date” means the date of the last Party to sign this Agreement.

“Principal Investigator” means the person who will take primary responsibility for the conduct of the Study at the Trial Site or any other person as may be agreed from time to time between the Parties as a replacement.

“Protocol” means the clinical protocol entitled “XXX” as may be modified from time to time by the Sponsor and approved by the Institutional review board and applicable regulatory authorities.

“Institution” means any public, private, entity or agency or medical facility where clinical investigations are conducted.

“Sponsor” means a legal entity which takes responsibility for the initiation, management and financing of the Study.

“Study” means the clinical trial investigation that is to be performed in accordance with this Agreement and the Protocol for purposes of gathering information about the compound identified in the Protocol

“Study Data” means data, results, information, documents, discoveries, inventions, processes and methods (whether patentable or not) resulting from or developed by Principal Investigator and/or the Institution, its employees and/or collaborators in the performance of the Study; but excluding all subject medical records.

“Study Drug” means the investigational medicinal product or control material as defined in the Protocol.

“Study Personnel” – includes, but not limited to, sub-investigators and any researchers, scientists, technicians, and other individuals employed by the Institution or any subcontractors, agents, consultants or Affiliates of the Institution, engaged in any aspect of the Study.

“Study Subject” means a person recruited to participate in the Study.

“Trial Site” means any premises approved by the Institution and the Sponsor in which the Study will be conducted.

Indemnification

(a) Sponsor shall indemnify, defend, and hold harmless Institution, the Study Personnel and the Principal Investigator (collectively, the "Indemnitees") from and against any and all liabilities, damages, losses, claims, and expenses, including court costs and reasonable attorneys' fees ("Losses") resulting from or arising out of any third-party claims, actions or proceedings arising out of (i) personal injury to or death of any Study subject enrolled in the Study, which injury or death is caused by (a) the Study Drug used in accordance with the Protocol and this Agreement, or (b) the performance of any procedure required by the Protocol (that would not occur but for the participation in the Study) or Sponsor's written instructions; (ii) Sponsor's use or publication of Study Data; or (iii) Sponsor's and Sponsor's employees', contractors' and agents' negligent acts, omissions or willful misconduct related to the Study or Sponsor's obligations under this Agreement, in each case to the extent that such Losses do not arise out of any Indemnitee's (A) failure to comply with this Agreement, the Protocol, any written instructions of Sponsor concerning the Study, or any Applicable Law, or (B) negligence or willful misconduct.

Notwithstanding the above, medically necessary deviations from the Protocol for reasons of Study Subject safety shall not nullify Sponsor's indemnification obligations, as long as such deviations are consistent with prevailing standards of medical care.

(b) Indemnification Procedures. An Indemnitee claiming a right of indemnification or defense under this Agreement shall provide Sponsor with prompt written notice of any such claim (including a copy thereof) served upon it, and shall cooperate fully with Sponsor and its legal representatives in the investigation of any matter regarding the subject of indemnification, at Sponsor's expense; provided, however, that failure by an Indemnitee to provide prompt notice shall not relieve Sponsor of its obligations hereunder except to the extent that Sponsor is prejudiced by such failure. Sponsor shall have the right to exercise sole control over the defense and settlement of any such complaint or claims for which indemnification or defense is sought, including the sole right to select defense counsel and to direct the defense or settlement of any such claim or suit; provided, that Sponsor shall not enter into any non-monetary settlement or admit fault or liability on behalf of any Indemnitee without the prior written consent of such Indemnitee, which consent shall not be unreasonably withheld, conditioned or delayed. An Indemnitee shall have the right to select and to obtain representation by separate legal counsel at the Indemnitee's sole expense.

(c) Survival: This Section shall survive termination or expiration of the Agreement.

Intellectual Property

(a) Pre-existing Intellectual Property. Ownership of inventions, discoveries, works of authorship, processes, procedures and other developments existing as of the Effective Date, and all patents, copyrights, trade secret rights and other intellectual property rights therein (collectively, "Pre-existing Intellectual Property"), is not affected by this Agreement, and no party shall have any claims to or rights in any Pre-existing Intellectual Property of the other party, except as may be otherwise expressly provided in a separate written agreement between the parties.

(b) All Intellectual Property arising from and relating to the Study, the Study Drug (including but not limited to its formulation and use alone or in combination with other drugs) or the Protocol (collectively "Sponsor Intellectual Property") shall vest exclusively in the Sponsor.

For clarity, Sponsor Intellectual Property excludes any clinical procedures or other processes or procedures relating in general to the conduct of clinical trials and improvements thereto that are the procedures of the Institution.

(c) Disclosure and Assignment. Principal Investigator and Institution shall, and shall ensure that their Study Personnel, disclose all Sponsor Intellectual Property promptly and fully to Sponsor in writing, and Principal Investigator and Institution hereby assign, and shall ensure that their Study Personnel assign to Sponsor all of its rights, title and interest in and to all Sponsor Intellectual Property, including all patents, copyrights and other intellectual property rights contained therein, (but excluding patient medical records), and all rights of action and claims for damages and benefits arising due to past and present infringement of said rights.

The Principal Investigator and Institution shall cooperate and assist Sponsor, at Sponsor's expense, by executing and ensuring that their Study Personnel execute, all documents reasonably necessary for Sponsor to secure and maintain Sponsor's ownership rights in the Sponsor Intellectual Property.

(d) License. Sponsor hereby grants to Institution a perpetual, non-exclusive, non-transferable, paid-up license, without right to sublicense, to use the Study Data, subject to the obligations set forth in Section (Confidentiality), for its own internal research and educational purposes (all of which must be non-commercial purposes), and for publications, presentations and public disclosures in accordance with Section (Publication Rights).

(e) Patent Prosecution. Institution and Principal Investigator shall reasonably cooperate, at Sponsor's request and expense, with Sponsor's preparation, filing, prosecution, and maintenance of all patent applications and patents for Sponsor Intellectual Property.

(f) Survival. This Section shall survive termination or expiration of this Agreement.

Publication Rights

(a) Publication and Disclosure. Institution and Principal Investigator shall have the right to publish or present the results of Institution's and Principal Investigator's activities conducted under this Agreement, including Study Data, only in accordance with the requirements of this Section, and provided such publication does not constitute a violation of Section (Confidentiality). Institution and Principal Investigator agree to submit any proposed publication, abstract or presentation, whether in any written, electronic, oral or audio-visual, related to the Study (each, a "Publication") to Sponsor for review at least forty-five (45) days prior to submitting any such proposed Publication to a publisher or proceeding with such proposed presentation. Within forty-five (45) days of such receipt, Sponsor shall advise Institution and/or Principal Investigator, as the case may be, in writing of any information contained therein that is Confidential Information or that may be required for protection of Sponsor's Intellectual Property. Sponsor shall have the right to require Institution and/or Principal Investigator, as applicable, to remove specifically identified Confidential Information and/or to delay the proposed Publication for an additional seventy-five (75) days to enable Sponsor to seek protection of Sponsor's Intellectual Property.

(b) Multi-Center Publications. If the Study is a multi-center study, Institution and Principal Investigator agree that they shall not, without the Sponsor's prior written consent, publish, present or otherwise disclose any results of or information pertaining to Institution's and Principal Investigator's activities conducted under this Agreement until a multicenter publication is published; provided, however, that if a multi-center publication is not published within eighteen (18) months after completion of the Study and database lock at all research sites or any earlier termination or abandonment of the Study, Institution and Principal Investigator shall have the right to publish and present the results of Institution's and Principal Investigator's activities conducted under this Agreement, including Study Data, in accordance with the provisions of this Section.

(c) For all Publications relating to the Study or including any Study Data, each of Sponsor, Institution and Principal Investigator agrees to comply with all ethical standards concerning publications and authorship as established by the International Committee of Medical Journal Editors ("ICMJE") (found at <http://www.icmje.org>).

(d) Registry and Reporting. Sponsor will register the Study with a public clinical trials registry in accordance with Applicable Law and will report the results of the Study publicly when and to the extent required by Applicable Law.

(e) Survival. This Section shall survive termination or expiration of the Agreement.

Confidentiality

(a) Definition. “Confidential Information” means the confidential and proprietary information of Sponsor and includes without limitation: (i) all information disclosed by or on behalf of Sponsor to Institution, Principal Investigator or Study Personnel, including without limitation, the Study Drug, technical information relating to the Study Drug, all Preexisting Intellectual Property of Sponsor, Sponsor’s Intellectual Property and the Protocol; and (ii) Study enrollment information, information pertaining to the status of the Study, communications to and from regulatory authorities, information relating to the regulatory status of the Study Drug, and Study Data. Confidential Information shall not include information that: (i) can be shown by documentation to have been public knowledge prior to or after disclosure by Sponsor, other than through wrongful acts or omissions attributable to Principal Investigator, Institution or Study Personnel; (ii) can be shown by documentation to have been in the possession of Principal Investigator, Institution or Study Personnel prior to disclosure by Sponsor, from sources other than Sponsor without restriction as to use or confidentiality; or (iii) can be shown by documentation to have been independently developed by Principal Investigator, Institution or Study Personnel.

(b) Obligations. Institution, Principal Investigator and Study Personnel shall not: (i) use Confidential Information for any purpose other than the performance of the Study, aggregate and de-identified (as to Sponsor or Study) metric reporting to third parties and for internal training and quality assurance purposes; or (ii) disclose Confidential Information to any third party, except as permitted by this Section and by Section (Publication Rights), or as may be required by law or by a regulatory authority or as authorized in writing by the disclosing party. To protect Confidential Information, Institution and the Principal Investigator agree to: (i) limit dissemination of Confidential Information to only those personnel having a “need to know”; (ii) advise all personnel who receive Confidential Information of the confidential nature of such information; and (iii) protect Confidential Information from disclosure.

Nothing herein shall limit the right of Institution and Principal Investigator to disclose Study Data as permitted by Section (Publication Rights) or as may be required during the informed consent process.

(c) Compelled Disclosure. In the event that Institution or Principal Investigator receives notice from a third party seeking to compel disclosure of any Confidential Information, the notice recipient shall provide Sponsor with notice as promptly as possible so that Sponsor may seek a protective order or other appropriate remedy, unless prohibited by Applicable Law. In the event that such protective order or other remedy is not obtained, the notice recipient shall furnish only that portion of the Confidential Information which is legally required to be disclosed, and shall request confidential treatment for such Confidential Information.

(d) Return or Destruction. Upon termination of this Agreement or upon any earlier written request by Sponsor at any time, Institution and Principal Investigator shall return to Sponsor, or destroy, at Sponsor’s option and expense, all Confidential Information other than as may be permitted by Section (Publication Rights), except that Institution and the Principal Investigator may retain one copy of such Confidential Information in a secure location for archival purposes and ongoing compliance under the Agreement, and thereafter make no use of the Confidential Information whatsoever. Any Confidential Information retained in computer backups shall be maintained in accordance with this Agreement.

(e) Survival. This Section shall survive termination or expiration of this Agreement for seven (7) Years.

Study Subject Injury

If a Study Subject suffers an adverse reaction, illness, or injury that was caused by the Study Drug or any procedure performed in accordance with the Protocol (one that would not have been performed but for their participation in the Study), or as the result of any actions taken at the written instruction of Sponsor, Sponsor shall pay for the reasonable and necessary costs of medical diagnosis and treatment of such injuries. Notwithstanding the foregoing, Sponsor shall not be liable for expenses that arise as a result of (i) negligence or willful misconduct on the party of the Principal Investigator, Institution or Study Personnel, or (ii) the natural progression of an underlying or pre-existing condition or events, unless exacerbated by participation in the Study.

Co-Chairs



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¹ KMR Group. Site Contracts from Weeks to Months: Results from KMR Group's Site Contracts Study. Biospace.com. 24 August 2016. Accessed from: <http://www.biospace.com/News/site-contracts-from-weeks-to-months-results-from/430240>

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³ Lotze MT, Dallal RM, Kirkwood JM, Flickinger JC. Cutaneous Melanoma. In DeVita VT, Rosenberg SA, Hellman S, eds. Principles and Practice of Oncology, 6th ed. Philadelphia, PA: Lippincott; 2001. Cited by: Aim At Melanoma Foundation. Accessed from: <https://www.aimatmelanoma.org/about-melanoma/melanoma-stats-facts-and-figures/>

⁴ American Cancer Society. "Cancer Facts and Figures 2016". Atlanta: American Cancer Society; 2016. Cited by: Aim At Melanoma Foundation. Accessed from: <https://www.aimatmelanoma.org/about-melanoma/melanoma-stats-facts-and-figures/>

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