ACTA Accelerated Clinical Trial Agreement

ACTA Working Group In-Person Meeting
June 28, 2019 8:00 AM - 3:30 PM CT
SUMMARY

Meeting Agenda

Time	Topic	Facilitator (s)
8:00 – 8:15 am	Welcome & Introductions*	C. Lawrence/T. Edwards
8:15 – 10:15 am	Review of ACTA Updates	C. Lawrence
10:15 – 10:30 am	BREAK	
10:30 – 11:30 am	ACTA Updates cont'd. and Assigning Ownership of ACTA Family Documents • ACTA – CRO • ACTA Prime – CRO • ACTA Prime • ACDA • ACDA – CRO • Investigator Initiated ACTA • FDP-CTSA	N. Bruce
11:30 am – 12:30 pm	Working LUNCH* – International ACTA and General Data Protection Regulation (GDPR) Discussion	N. Bruce/L. Salberg
12:30 – 1:30 pm	ACTA Manuscript - Metrics	All
1:30 – 1:45 pm	BREAK*	
1:45 – 2:45 pm	Educational Materials and Marketing	All
2:45 - 3:25 pm	Open Discussion	All
3:25 – 3:30 pm	Review of Action Items	C. Lawrence
3:30 pm	ADJOURN	

1.) Review of ACTA Updates:
   a. The goal of the ACTA review is to "finalize" the draft of the document for distribution and review by the ACTA Large Working group (composed of representatives from all CTSA sites). The Large working group will be charged with identifying any "fatal flaws" with the revised ACTA.
   b. The group discussed adding language about remote monitoring but agreed to wait for a future iteration of the ACTA to assess prevalence/experience with the issue.
   c. Section 8: "Inventions, Discoveries and Patents" – edits were made to help support more Sponsor friendly language including providing better clarity as to which Inventions belong to the Sponsor.
      i. Sub-Section 8.2 – the following language was added "Institution represents and certifies that all Institution personnel, including Principal Investigator, performing the Protocol have assigned to or are obligated to assign to Institution (or appropriate technology transfer office, on behalf of Institution), all Inventions and intellectual property rights that are necessary to enable Institution to grant Sponsor all rights Institution purports to grant under this Agreement."
      ii. Sub-Section 8.4 – was edited to read "Institution shall have a right to use for its own internal noncommercial research, educational and patient care purposes, all Sponsor Inventions or Other Inventions licensed or assigned to Sponsor hereunder."

iii. The Annotated ACTA will need to include information stating the purpose of the ACTA is recommended for Phase II studies and beyond and more of a case by case basis for Phase I studies. Section 8 needs to be carefully reviewed for Phase I Studies.
iv. Need to make a defined term for Study Personnel – XX to send language.
v. A rationale for including Sub-Section 8.6 in the ACTA should be included – O. Doriocourt to send "savings clause" language.

d. Section 9: "Publications" – Sub-Section 9.3 – ". . .Sponsor agrees to provide such Institution access to the aggregate results pursuant to the Protocol from all Study sites." – the change was made to ensure Study PI's will get an opportunity to review the Study results in the absence of a publication.
   i. There is an outstanding question regarding how the concept of "aggregate results" compares to what is reported in CT.gov.
e. Section 11: "Indemnification and Limitation of Liability" – Sub-Section 11.3 is not amenable to several state institutions as some state entities may not indemnify. The group made additional changes to the language which need to be reviewed by state institutions.
f. Section 12: "Subject Injury" – Sponsor requested the modifier of 'medical' be added for further clarification: "If a Study subject suffers an adverse reaction, medical illness or injury which was directly caused by . . ."
g. Section 16: "Sponsor Equipment (if applicable)" – after lengthy discussion, the group agreed that the Equipment Section required an Exhibit (Exhibit B) as some healthcare systems require certain assurances about the equipment in the hospital and details for risk management that must be in the contract and the language within the contract is intentionally silent/vague.
h. Section 24: "Debarment" – there were concerns about using the term "Study personnel" because in industry, the staff is regularly changing. The group agree to compromise with "In the event that the Principal Investigator or any personnel reported on FDA Form 1572 or its equivalent, becomes debarred or disqualified during the term of this Agreement . . ." to cover changes to personnel and device studies.

2.) Assigning Ownership of ACTA Family Documents:
   a. ACTA Prime – N. Bruce
   b. ACTA Prime – CRO – N. Bruce
   c. ACTA CRO – L. Salberg
   d. ACDA – J. Brown, P. Griffith, H. Ralston, and G. Vaughn
   e. ACDA – CRO - J. Brown, P. Griffith, H. Ralston, and G. Vaughn
   f. Investigator Initiated ACTA – C. Morales, S. Perry, G. Vaughn, T. Good, C. Carroll

3.) International ACTA and General Data Protection Regulation (GDPR)
   a. There is a draft template for the International ACTA that was created in 2017 but never finalized – the group agreed it is worthwhile to finalize development of the international template and to develop a flow chart to help guide users as to when GDPR might be applicable.
      i. Working group members:
         1. L. Salberg
         2. N. Bruce
         3. G. Vaughn/P. Seggebruch
         4. S. Sauder/Katie
         5. L. Haunert
         6. P. Griffith
         7. D. King
         8. O. Doriocourt
      ii. The group will meet every other week with the goal of having a final draft of the International ACTA and flow chart by end of October 2019.
   b. Working with Sponsors located in the EEA requires a consideration of GDPR.

i. There is a general debate as to when something is subject to GDPR – does GDPR apply if the data is collected in the United States? Does GDPR apply once the data is sent to/stored by a Company located in the EEA? Does it apply if the data is collected from someone with EU citizenship regardless of location of collection?
ii. The group could develop guidance for when GDPR should apply.

4.) ACTA Manuscript - Metrics
   a. The group should make a push to publish a paper on ACTA and the advantages of utilizing master contracts
      i. Data – review contracting office "vaults" to review contracts with various Sponsors and score/rate how close the various contracts came to the terms of the ACTA
      ii. Metrics collection is a challenge as various sites define T_0 and T_{FINAL} for contracts negotiations very differently
      iii. The general feeling is to collect when all documents are received to begin the process and when all the terms are negotiated (i.e. terms done but waiting on IRB or budget) – do all sites collect these data points?
         1. Median calendar days from date package received to date terms agreed upon
         2. If possible collect dates for these two milestones on ACTA vs general one off contracts vs master agreements
         3. Time period of data collection will be 1/1/2019 – 12/31/2019.
      iv. There was some interest in tracking the MACTA (modified ACTA) because many sites do not track MACTA use
      v. How does negotiation time vary between using the ACTA and using a Master Agreement (e.g. with Eli Lilly)?
      vi. Relevant paper on metrics from the CTSA.

5.) Educational Materials and Marketing
   a. Professional organizations to consider contacting for outreach and presentations
      i. DIA – Drug Information Association – National Meeting - June 2020 (Washington, DC)
      ii. CBI - Consider attending sessions of the Pharma compliance/regulatory series
      iii. AACI – Association of American Cancer Institutes – National Meeting – July 2019 (Chicago, IL)

ACTION ITEMS:

- C. Lawrence will update the ACTA for final review by the small working group and large working group - COMPLETE
- C. Lawrence will review and update the annotated ACTA (provided by L. Haunert) to clarify elements such as defining institution (e.g. non-profit, educational, etc) and an explanation of savings clause in 8.6.
- O. Doriocourt to send "savings clause" explanation - COMPLETE
- Need a definition for "Study Personnel".
- State institutions should review and/or propose edits to Sub-Section 11.3 – send edits to C. Lawrence.
- C. Lawrence to send out Doodle Poll to International ACTA Small Working Group – begin to schedule meetings in July.
- C. Lawrence to pull together a basic REDCap survey to capture data on contracting metrics from the CTSA sites.