IMPAACT Network Annual Meeting

Study Coordinators Meeting
13 June 2019
Washington DC

DAIDS Clinical Trials Insurance Requirements

Emily Brown
IMPAACT Operations Center

IMPAACT
International Maternal Pediatric
Adolescent AIDS Clinical Trials Network

Clinical Trials Insurance (CTI) Definition

Clinical trial liability insurance is a form of liability insurance that protects clinical trial sponsors, investigators, institutions and administrators from risks they assume when conducting clinical trials.

The coverages of a policy are tailored to the policyholder's specific needs (i.e. trial protocol, informed consent, site locations, in country regulatory requirements, local ethics committee requirements, etc.) and will vary in each instance.

The policy may include coverage against bodily injury or property damage that a drug, device, or treatment may cause, as well as liability coverage for any professional duties that an organization or its employees may have in the conduct of performing the clinical trials.

IMPAACT's current process for requesting to use grant funds for purchase of CTI

- P
p
- N
i
r
- S
r
I
r

Questions? Email Kim Enders and her team at
IMPAACT-Subs@jhmi.edu
for more information on requesting prior approval for purchase of CTI.

DAIDS Requirement for Clinical Trials Insurance, memorandum dated 10 August 2018

RE: DAIDS Requirement for Clinical Trials Insurance

Over the past months, the Division of AIDS (DAIDS) has undergone several regulatory inspections at both the site and sponsor level by the European Medicines Agency (EMA), the Food and Drug Administration (FDA), and national regulatory authorities.

As a clinical trial sponsor, DAIDS is ensuring that all clinical research sites (CRS), where required by country regulation or law, have secured clinical trials insurance (CTI) for every new and ongoing clinical trial sponsored by DAIDS to ensure compliance with the European Medicines Agency Committee for Proprietary Medicinal Products, Art 5.8 CPMP/ICH/135/95 and the Integrated Addendum to ICH (E6) (R1): Guideline for Good Clinical Practice E6 (R2) regarding Investigator/Institution insurance against trial related claims.

New DAIDS Sponsored Clinical Trials-Protocol Activation Requirement

Effective August 10, 2018 for new DAIDS sponsored clinical trials: The procurement and verification of CTI is now required as part of the Network study activation process. For large multi-site international trials, Networks are strongly encouraged to purchase a single policy to cover all participating CRSs in order to obtain standardized CTI coverage across sites and to off-set some of the CRS costs associated with individual CTI policies.

List of Countries Requiring Clinical Trials Insurance with DAIDS funded Clinical Research Sites

- Argentina
- Canada
- India*
- Indonesia
- Kenya*
- Malawi*
- Peru
- Philippines
- South Africa*
- Swaziland
- Switzerland
- Tanzania*
- Uganda*
- Ukraine
- Vietnam
- Zambia*
- Zimbabwe*

*Countries with IMPAACT sites

IMPAACT XXXX, [Full Study Title]
Site-Specific Study Activation Checklist

CRS XX: Site Name
(City, Country)
Updated by IMPAACT XXXX CTS as of DD MMM YYYY

Study Activation Requirement	Approval Date	Comments
Preparatory Activities		
Version X.0 protocol registration approval from the DAIDS RSC Protocol Registration Office		*To be confirmed by IMPAACT Ops*
Local Regulatory, Institutional, and National Regulatory Approvals		
Completion of study-specific delegation of duties log following the DAIDS Delegation of Duties Log Policy, Effective Date: 03/14/19		*Site IoR (or designee) to submit confirmation to IMPAACT Ops**
Completion of financial disclosure forms by all persons listed on the Form FDA 1572		*Site IoR (or designee) to submit confirmation to IMPAACT Ops**
Confirmation of clinical trial insurance per DAIDS memorandum "DAIDS Requirement for Clinical Trials Insurance" effected 10 August 2018		*Site IoR (or designee) to submit insurance certificate for review and approval by IMPAACT Ops*
Pharmacy Requirements		
DAIDS Pharmaceutical Affairs Branch approval of local pharmacy readiness		*To be confirmed by DAIDS Protocol Pharmacist*

DAIDS Clinical Trials Insurance Certificate Checklist

Date Submitted:	Site Name:	Site contact for CTI:
	Protocol #	Protocol Name:
	Trial Start Date:	Trial Completion Date:

	Item	Yes	No	Comment
1	Name of Insured to reflect the institution affiliated with the CRS			
2	Protocol Number, Title			
3	Site Locations or Territory (country)_			
4	Insurance Company Name			
5	Policy Number			
6	Policy Period*			
7	Number of Months automatically provided in the Extended Reporting Period			
8	Confirm Retroactive Coverage Date is same date as trial start date, or earlier			

Questions?

IMPAACT
International Maternal Pediatric
Adolescent AIDS Clinical Trials Network