DAIDS Safety Information Types

Safety information is only distributed through a DAIDS-approved distribution list which includes CRS Leaders, CTU or Grant PIs, CRS and CTU Coordinators, and Investigators of Record (IoR) at applicable sites, as well as the DAIDS Medical Officers (MO) and relevant Operations Centers. Recipients can use their internal email system functions to auto-forward DAIDS RSC Safety Information Center (RIC) communications to others at their site. Please see the DAIDS RIC FAQs for more information at https://rsc.niaid.nih.gov/about-us/rsc-safety-information-center-faqs

Package Insert

Description: Information prepared by the manufacturer about an approved drug. It contains information on the indications and use of the drug, including contraindications, warnings, cautions, common adverse reactions, dosing and administration of the drug.
Distribution Method: The package insert is posted on the DAIDS RSC website, and an e-mail notification is sent via the DAIDS-approved distribution list to sites that are using the approved drug in an active protocol. Notifications of updates to package inserts previously posted on the website are also sent to all applicable sites and include a comparison document.

Investigator's Brochure

Description: Information prepared by the manufacturer about a study agent under clinical development, either not yet approved by the FDA or being investigated for other use. The Investigator's Brochure (IB) contains confidential and proprietary information, which is restricted to DAIDS employees, contractors and grantees pursuant to a Confidential Disclosure Agreement (CDA) or Clinical Trial Agreement (CTA) during the distribution process.
Distribution Method: An e-mail notification is sent via the DAIDS-approved distribution list to sites that are using the study agent in an active protocol. The CRS Leaders and CRS Coordinators at the sites using the study agent can access the IB electronically via the NIAID Clinical Research Management System (NCRMS) after acknowledging the Receipt Confirmation. CRS Leaders and CRS Coordinators can also receive IBs electronically upon request.

IND Safety Report or MedWatch Report

Description: A Safety Report is written by DAIDS and submitted to the FDA, notifying the agency that a serious adverse event (SAE) meeting reporting criteria has occurred on a study sponsored and/or supported by DAIDS. For studies conducted under an IND, IND Safety Reports are submitted as an amendment to the IND at the FDA. For studies that are not under an IND, a voluntary MedWatch report is sent to the FDA via MedWatch (the FDA Safety Information and Adverse Event Reporting Program; http://www.fda.gov/Safety/MedWatch/default.htm).

Distribution Method: An e-mail notification containing a PDF copy of the report submitted to the FDA is sent via the DAIDS-approved distribution list to sites registered to active protocols using the study agent in the report.

Safety Memo

Description: When a safety report is prepared and submitted to the FDA by a pharmaceutical company on a reportable event in a company sponsored study, DAIDS receives the safety report from company collaborators according to a CTA. DAIDS reviews the safety report and drafts a safety memo which accompanies the safety report and distributes both to sites that are using the study agent.

Distribution Method: An e-mail notification containing a PDF copy of the report provided by the pharmaceutical company is sent via the DAIDS-approved distribution list to sites registered to active protocols using the study agent in the report.

Safety Alert

Description: Safety information that DAIDS has determined to be of sufficient concern to warrant expedited distribution to sites. The information may be publically available, such as an FDA e-mail alert, or be a confidential communication from DAIDS and/or the manufacturer or pharmaceutical company collaborator.

Distribution Method: An e-mail notification containing a PDF copy of the original material and/or official memo from DAIDS is sent via the DAIDS-approved distribution list to sites registered to active protocols using the study agent in the alert.

Safety Notice

Description: Publically available safety information that DAIDS has determined to be of sufficient concern to warrant distribution to sites but which does not need to be distributed in an expedited timeframe. Examples of a Safety Notice include Dear Healthcare Professional letters or other FDA e-mail communications.

Distribution Method: An e-mail notification containing a PDF copy of the original material and/or official memo from DAIDS is sent via the DAIDS-approved distribution list to sites registered to active protocols using the study agent in the notice.

DSMB Memo

Description: A memo from the DAIDS Biostatistics Research Branch (BRB) containing the decision of the DSMB following a review of a specific protocol. The DSMB's decision is summarized in the memo.

Distribution Method: An e-mail notification containing a PDF copy of memo is sent via the DAIDS-approved distribution list to sites registered to the specific protocol.

Monthly Comprehensive Safety Distribution Report

Description: A monthly report listing all safety information types that were distributed to sites by the DAIDS RSC Safety Information Center (RIC) during the previous twelve (12) month period.

Distribution Method: An e-mail notification containing a cover memo and Excel spreadsheet is sent via the DAIDS-approved distribution list to all sites registered to active protocols.