

ALL

Compliance with ~~FDA~~ Safety Reporting Requirements: A NIAID Approach

April 10, 2013

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SAIC-Frederick, Inc.

Topics

- Safety Reporting Requirements
- NIAID Intramural Safety Office
- Regulatory Branch Portfolio
- Safety Office Services and Initiatives

1. Safety Reporting Requirements

Safety Reporting Requirements





International Conference on Harmonisation (ICH)

■ Categories

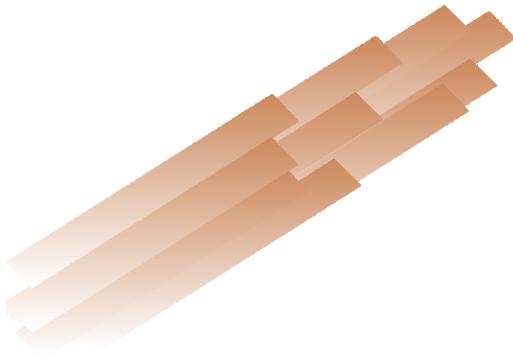
- (Q) Quality
- **(E) Efficacy**
- (S) Safety
- (M) Multidisciplinary

■ Efficacy

- E1-E2F (Clinical Safety)
- **E2A (Expedited Safety Reporting)**
- E3 (Clinical Study Reports)
- **E6 (Good Clinical Practice)**

Guidance for Industry

E6 Good Clinical Practice: Consolidated Guidance



ICH
April 1996

INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL
REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN
USE

ICH HARMONISED TRIPARTITE GUIDELINE

CLINICAL SAFETY DATA MANAGEMENT:
DEFINITIONS AND STANDARDS FOR
EXPEDITED REPORTING
E2A

Current *Step 4* version
dated 27 October 1994

Department of Health & Human Services (DHHS)

- FDA
- Office of Human Research Protections (OHRP)
- NIH

FDA

- Studies conducted Title 21 CFR
 - 21 CFR 312: Drugs, biologics
 - 21 CFR 812: Devices
 - 21 CFR 11: Electronic records/signatures
 - 21 CFR 50: Protection of human subjects
 - 21 CFR 56: IRB

- Guidance documents

Guidance for Industry and Investigators

Safety Reporting Requirements for INDs and BA/BE Studies

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

December 2012
Drug Safety

Office of Human Research Protections (OHRP)

- 45 CFR 46 (“Common Rule”)
- Unanticipated Problems (UP) reporting
 - UPs are reported to OHRP per 45 CFR 46
 - At NIH, UPs are reported to OHRP by Office of Human Subjects Research Protections
 - UP Guidance on the OHRP website

NIH Institute & Center (IC)

- Office of Biotechnology Activities /Institutional Biosafety Committees
- NIH OHSRP SOPs
- IC and IRB specific requirements
- NIH Policy and Guidance for data and safety monitoring 1998/2000
- NIH Clinical Research Guideline (2007), Standards (2009)

Guidelines for the

CONDUCT OF RESEARCH

in the

Intramural Research

Program at NIH

National Institutes of Health
Office of the Director

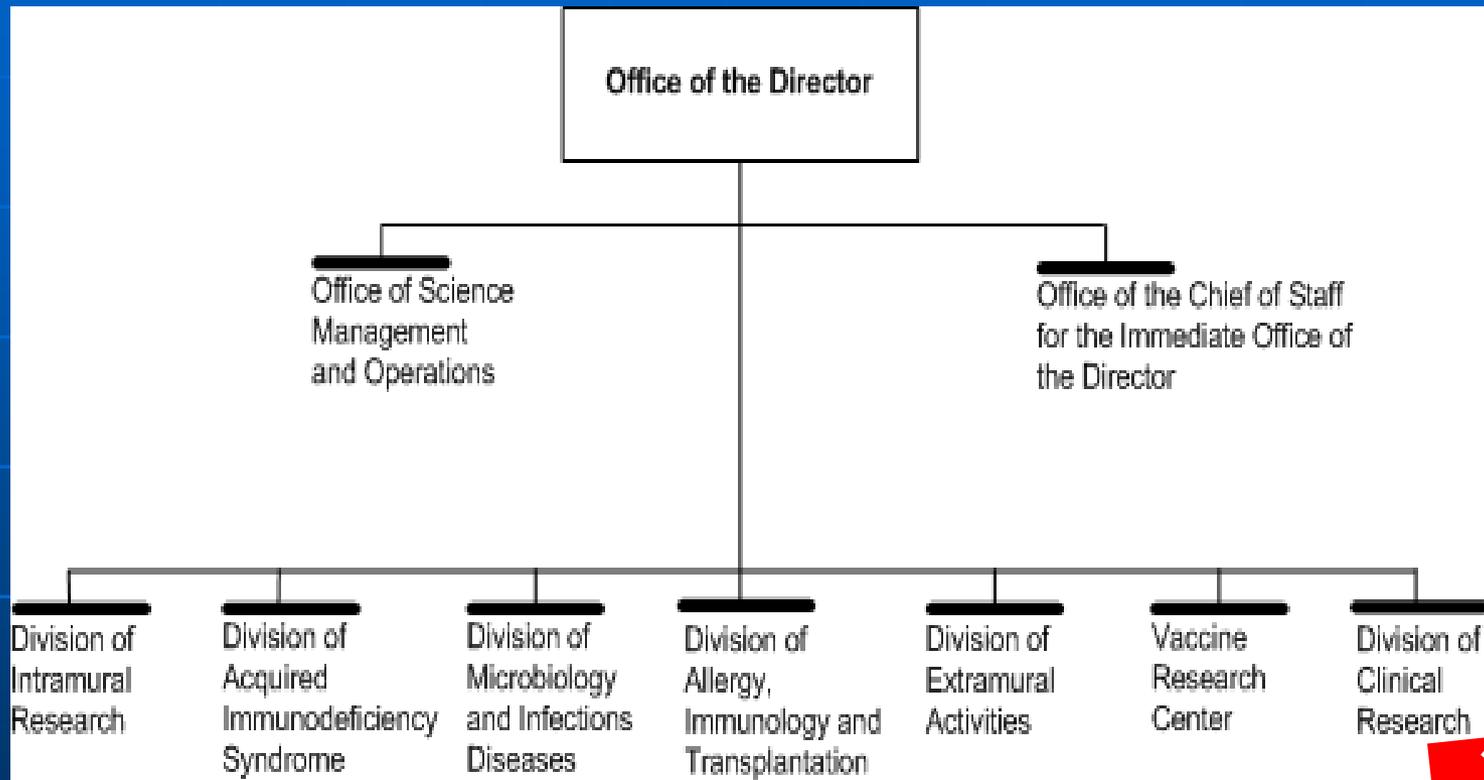


Standards for
CLINICAL
RESEARCH
WITHIN
THE NIH
INTRAMURAL
RESEARCH
PROGRAM

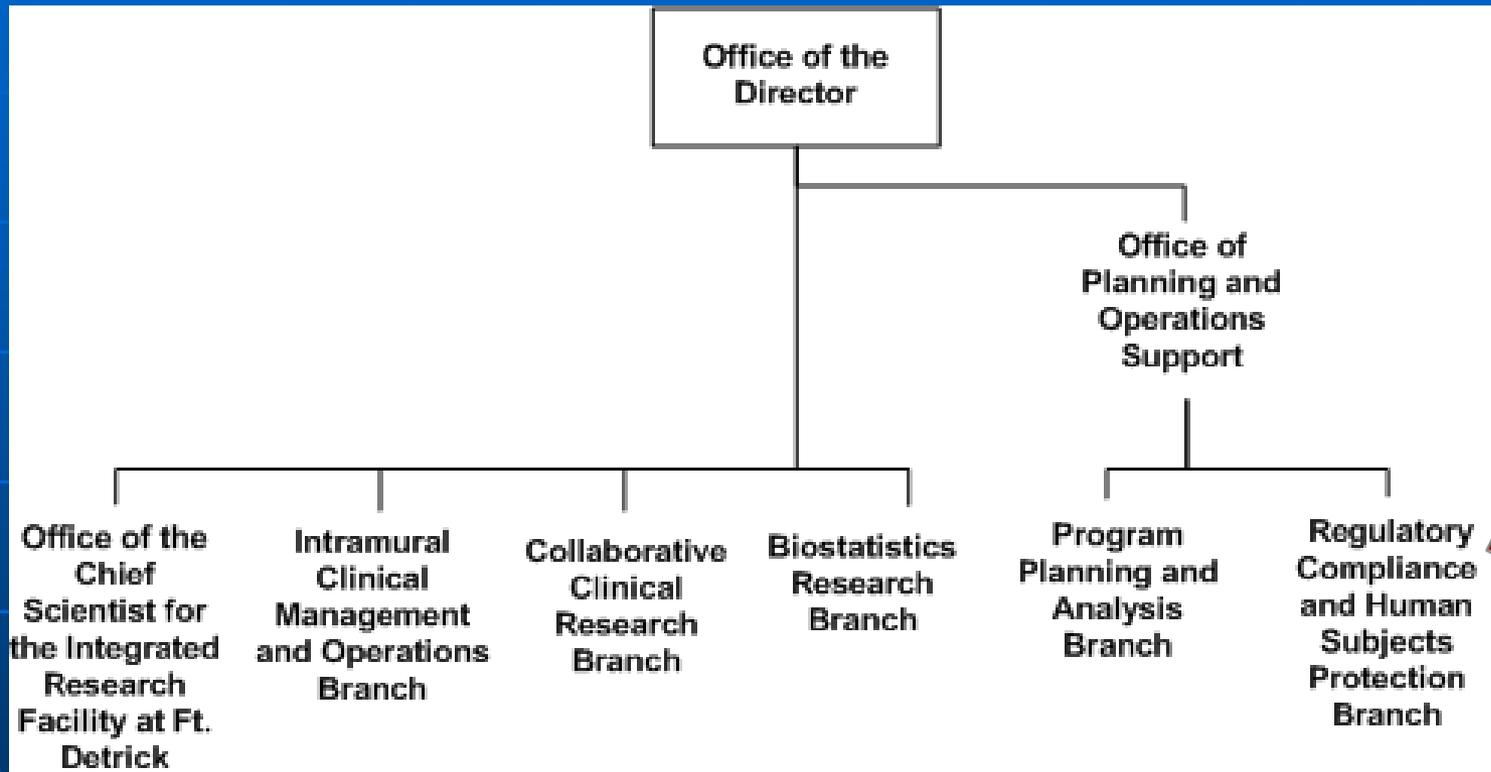
National Institutes of Health

2. NIAID Intramural Safety Office

NIAID



Division of Clinical Research



Regulatory Compliance and Human Subjects Protection Program

Regulatory Affairs

- Overall guidance of regulatory compliance with IND components for phase I-III clinical trials
- Preparation, submission, and maintenance of INDs and DMFs
- Regulatory review of clinical protocols, informed consent, and other clinical documents
- Liaison for regulatory issues with the FDA, Sponsor, OHRP, and other regulatory bodies

Clinical Trials Management

- Study start-up
- Study documents including design, preparation, submission, distribution and tracking
- Development of guidelines
- Investigator meetings and site initiation
- Site monitoring and close-out visits (GCP/ICH/NIH/OHRP Compliance)
- Site training
- Preparation for FDA and drug-sponsored audits

Project / Program Management

- Procurement management to oversee establishment and execution of subcontracts (clinical/hospital sites, correlative studies, laboratory services, consultants, CROs)
- Liaison with support teams (clinical, regulatory, safety, protocol teams)
- Document control
- Informatics support
- Logistical support (conference planning, travel, purchasing and shipping)
- Quality Assurance / Compliance

Clinical Teams

- Protocol Nurses (Study Coordinators)
- Case Managers / Research Nurses
- Patient Care Coordinators
- Physicians / Physician Assistants
- Nurse Practitioners
- Pharmacists

Pharmacovigilance

- Medical Monitoring
- Establishment and management of DSMB
- Safety Surveillance – adverse event review, SAE reporting and follow-up

Protocol Development / Protocol Navigation

- Medical and scientific writing
- Technical writing, editing and formatting of clinical/scientific materials
- Drafting of scientific papers
- Quality control evaluation of regulatory documents to ensure consistency and accuracy

3. NIAID Intramural Portfolio

Diseases

■ Infectious Diseases

- Influenza
- Dengue
- Malaria
- TB
- Hepatitis
- Parainfluenza
- Lyme disease

■ Inflammatory

- Hypereosinophila
- Chronic granulomatous disease

■ Immunodeficiency

- Acquired: HIV
- Congenital: XSCID

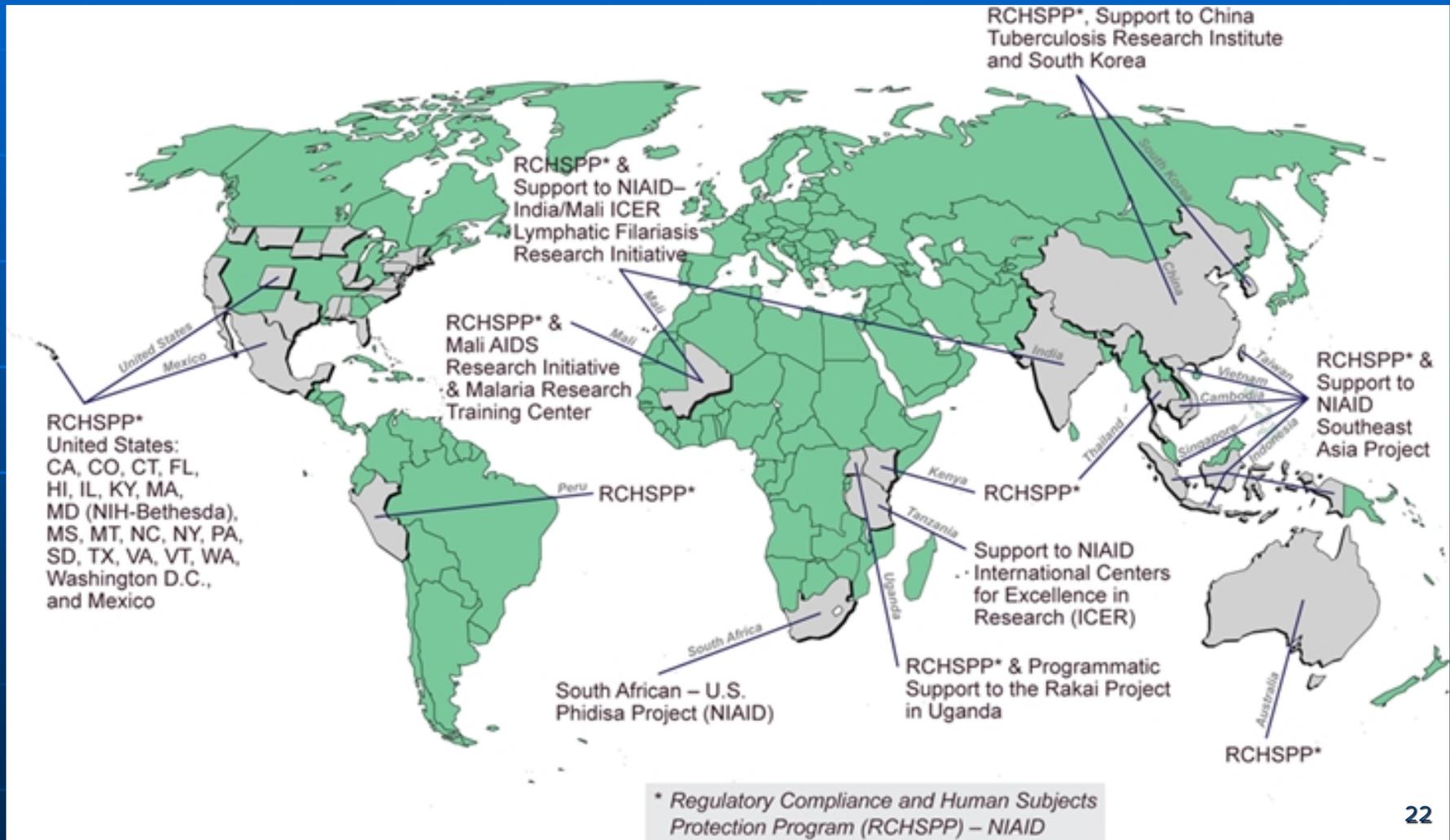
Products

- Biologics
 - Vaccines
 - Immune plasma / immunoglobulin
 - Monoclonal antibodies
- Drugs
- Gene therapy
- Allogeneic transplant
- Diagnostic tests
- Abscess ablative device

NIAID Active Protocols FY2012

| Protocol Types | IDE | IND | Non-IND | Total |
|-----------------|----------|-----------|------------|------------|
| Natural History | 0 | 2 | 87 | 89 |
| PK/PD | 0 | 0 | 1 | 1 |
| Phase 0 | 0 | 3 | 0 | 3 |
| Phase I | 2 | 44 | 13 | 59 |
| Phase II | 0 | 15 | 6 | 21 |
| Phase I - II | 0 | 1 | 1 | 2 |
| Phase III | 0 | 0 | 3 | 3 |
| Phase IV | 0 | 2 | 4 | 6 |
| Screening | 0 | 0 | 3 | 3 |
| TBD/Combination | 0 | 1 | 4 | 5 |
| Total | 2 | 68 | 122 | 192 |

Regulatory Branch Sponsored Research Studies

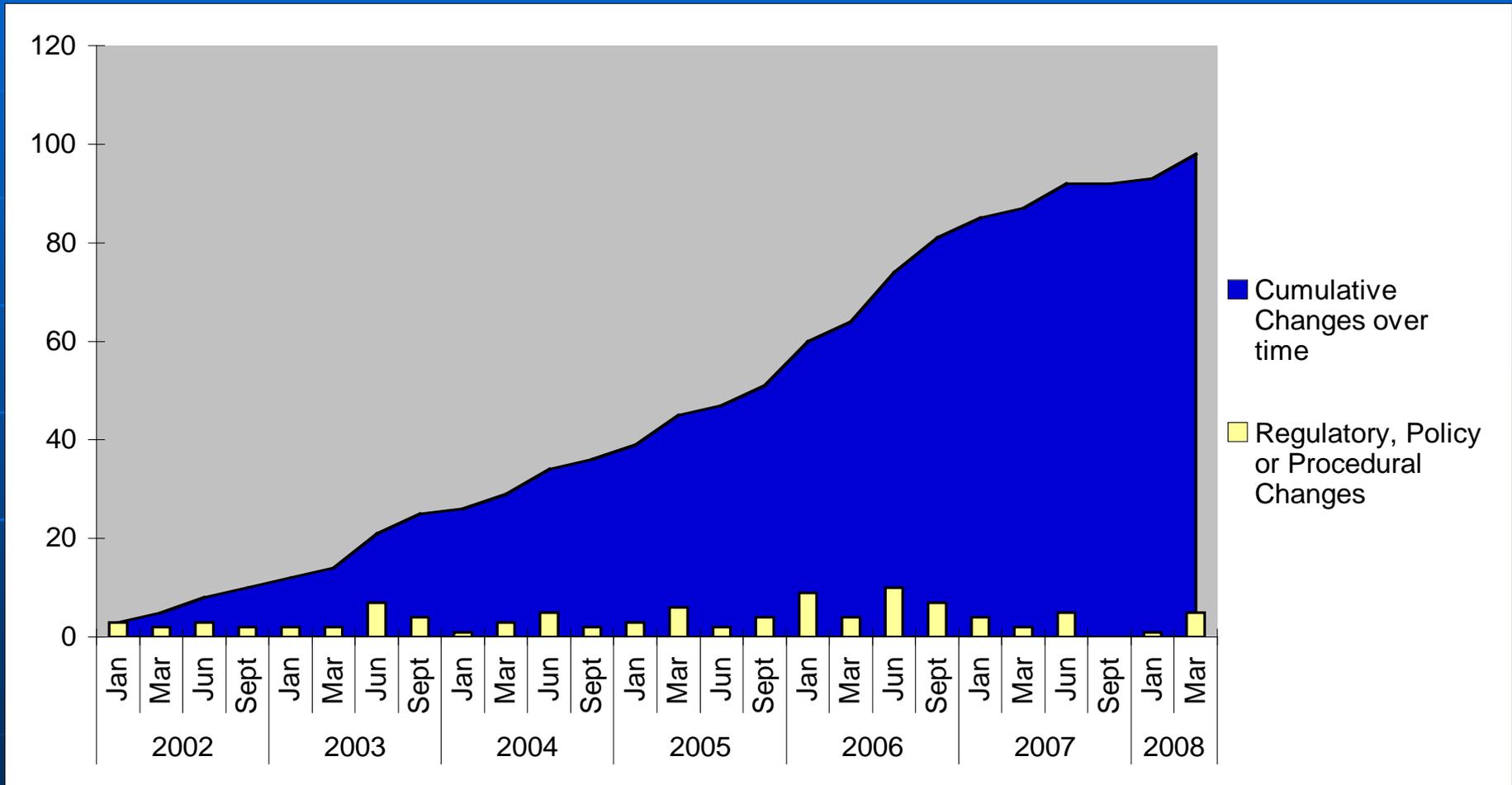


4. Safety Office Services and Initiatives

Document Review for Safety Compliance

- Review of protocol documents pre-IRB submission for:
 - Regulatory compliance
 - Subject safety
 - Data integrity
- Assuring appropriate adverse event monitoring language is included in all protocols
- Safety section template for IND protocols

Changes to the NIAID Protocol Template over Time



Standardized Protocol Safety Section Template

- Standard Safety Office protocol section on NIAID web portal
- Implemented in Sept. 2011, revised at least annually
- Standardized halting rules, safety definitions, reporting criteria
- Compliant with DHSS, NIH, FDA, NIAID IRB, OHRP and OHSRP SOP 17 (Data and Safety Monitoring)

Sample Protocol Safety Sections Template

(For INDs Held by RCHSPB)

FINAL # 6.9 02Aug11

***(Note: only include applicable sections of template)**

Note: The term "subject" is throughout the safety section. Please consider if this is consistent with previous sections of the protocol.

1 ASSESSMENT OF SAFETY

1.1 DOCUMENTING, RECORDING, AND REPORTING ADVERSE EVENTS

At each contact with the subject, information regarding adverse events will be elicited by appropriate questioning and examinations and will be:

- immediately documented in the subject's medical record/source document,
- recorded on the Adverse Event Case Report Form (AE CRF) or electronic database, and
- reported as outlined below (e.g., IND Sponsor, IRB, FDA)

1.2 DEFINITIONS

Adverse Event (AE)

An adverse event is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (e.g., abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the research.

Adverse Reaction (AR)

An adverse event that is caused by an investigational agent (drug or biologic).

Suspected Adverse Reaction (SAR)

An adverse event for which there is a reasonable possibility that the investigational agent caused the adverse event. 'Reasonable possibility' means that there is evidence to suggest a causal relationship between the drug and the adverse event. A suspected

IRB Stipulations Review Project

- Since 2010, all NIAID IRB stips for protocols reviewed by Regulatory Branch are categorized and reviewed
- Database by protocol section (N=2300+)
- Monthly team discussion
- Annual review of protocol safety template for changes
- Reduction in number of safety section stips in first year by 58%

Summary of 21 CFR 312.32 Changes

- Codifies FDA's expectations for timely review, evaluation, and submission of important and useful safety information
- More fully defines responsibilities of sponsors and investigators (specifically submission of serious and unexpected suspected adverse reactions)
- Implements internationally harmonized definitions and reporting standards
- Clarifies confusing terminology in existing regulations
- Improves the utility of premarket safety reports, thereby enhancing human subject protection

(information from FDA DIA presentation Nov. 17, 2010)

Safety Review and Communications Plan (SRCPP)

- An SRCPP plan is drafted for IND protocol where the Reg Branch holds the IND
 - A communication tool between Sponsor and PI to establish safety review responsibilities
- SRCPP defines all details on safety oversight for a study
 - conduct of safety review, frequency of assessments
- Sponsor Medical Monitor assigned to every IND/IDE protocol
- Verification and documentation – audit ready

Safety Review and Communications Plan Template



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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MSC 1632
Bethesda, MD 20892-1632
Phone: (301) 451-3432
Fax: (301) 451-5398

Safety Review and Communications Plan Regulatory Compliance and Human Subjects Protection Branch

1 Safety Review and Communications Plan

Protocol Title:

Principal Investigator (PI): [name]

Protocol Number: [protocol number]

IND # [IND ID#]

Sponsor/Medical Monitor (SMM): [name]

Data management system: [insert_name/description_of_data_management-system]

1.1 Overview

In April, 2011, the Code of Federal Regulation Title 21, section 312 was revised to expand and clarify the responsibilities of an IND Sponsor for overseeing safety aspects of clinical research trials. As a consequence of the revised regulations, a Safety Review Communications Plan (SRCP) has been developed. The SRCP is an internal communications document between the Principal Investigator and the IND Sponsor Clinical Safety Office (CSO), which delineates the safety oversight responsibilities of the PI, the CSO, and other stakeholders.

The purpose of this SRCP is to identify all safety related responsibilities and communications pathways are contained in a single document. This ensures that these responsibilities are being conducted in a timely and thorough manner to protect research participants and comply with regulatory reporting requirements. Since this is an internal communications document, this SRCP is not intended to be part of the protocol as required by an IRB, sponsor or any institution or agency.

1.2 Periodic Safety Surveillance Assessments

The Sponsor Clinical Safety Office [and PI when applicable if both the CSO and PI agree to do reviews together] will conduct periodic safety surveillance assessments as follows:

[Insert table or description of interval data format and individuals involved in the assessment]

(Note: The interval may vary depending on enrollment numbers, frequency of study drug administration, or frequency of adverse events. Include +/- windows in the schedule to account for acceptable delays in generating data for the reviews)

SRCP Verification Form

Appendix A: Verification of Safety Review per SRCP

Appendix A
REGULATORY COMPLIANCE AND HUMAN SUBJECTS PROTECTION PROGRAM
RCHSPP CLINICAL SAFETY OFFICE
TELEPHONE # (301) 846-3301
FAX # (301) 846-6224
email: RCHSPSafety@mail.nih.gov

SRCP Verification of Safety Review

Instructions-this completed form should be placed in the site Regulatory Binder

Protocol Title: Review Date:

Check all that apply:

- No safety concerns noted. Continue current protocol plan
- Subject safety concern identified (note concern and action taken)
- Temporary discontinuation of all enrollments/vaccinations (note reason)
- Protocol closed to accrual (note reason)

This is the periodic safety surveillance assessment for which SRCP timepoint?

Additional comments and notations:

Signature of Sponsor Medical Monitor or designee

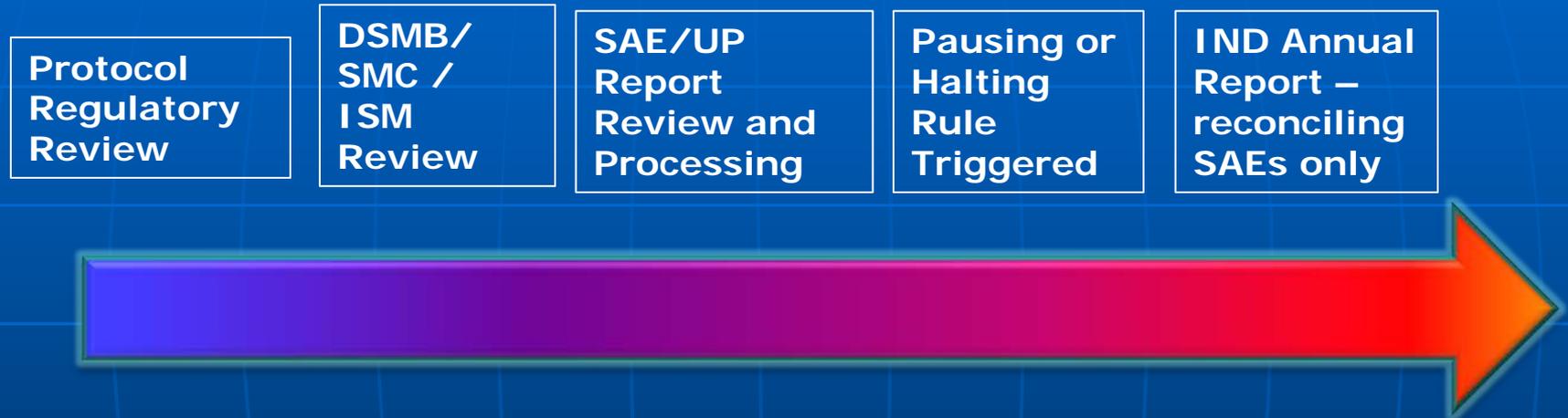
Date

Print name

SRCP-TORO Assessment of Risk Plan (STARS Plan)

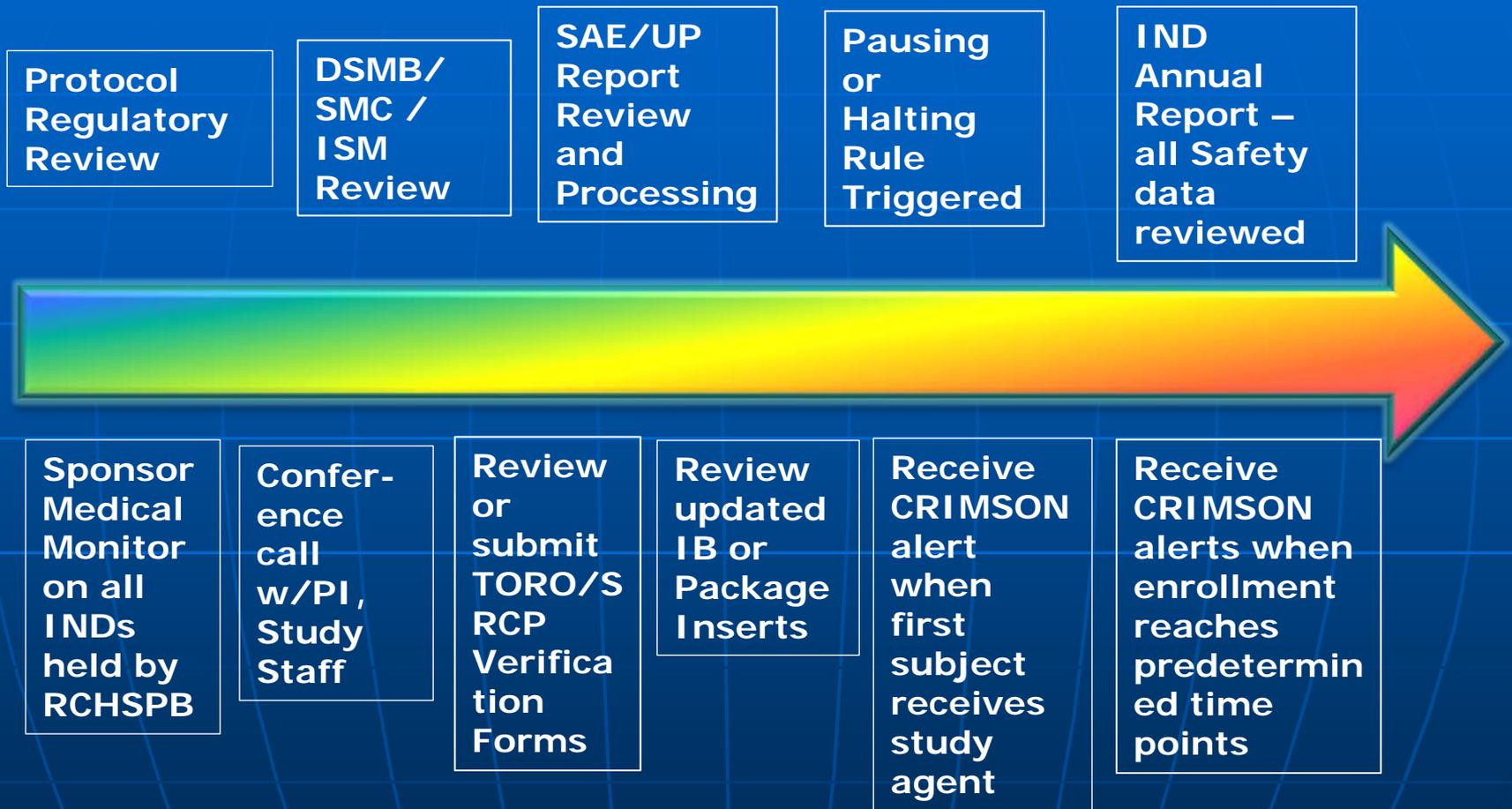
- Developed objective risk assessment criteria based on FDA risk based monitoring guidance
- Criteria and relative risk to the Branch will determine the type of safety oversight to be implemented

Safety Office Role Pre Sept. 2011



5 Safety Office opportunities to obtain safety related information

Safety Office Role Post Sept 2011



11 Safety Office opportunities to obtain safety related information

Safety Oversight Committees

- Data and Safety Monitoring Board
 - ~ 25 active protocols monitored
 - In 2012, 47 reviews conducted
- Safety Monitoring Committees
 - 2 protocols and 5 reviews in 2012
- Independent Safety Monitors
 - 2 protocols and 14 reviews in 2012

Standardized Data Tables

- CRIMSON – NIAID research database
- DSMB tables
 - Enrollment
 - Severity
 - Causality
 - AE Line listing
 - SAE
 - Reactogenicity/vaccine studies
- Repurposed for other safety reviews



RCHSPB Web Pages

- RCHSPB Home
- Protocol Development
- Investigational New Drug (IND) Management
- Data and Safety Monitoring Board (DSMB)**
- Clinical Trials Management (CTM)
- Safety Office (SAE and UP Reporting)
- Training

SharePoint Resources

Calendar

Division of Clinical Research > Regulatory Compliance

NIAID Intramural Data and Safety Monitoring Board

Clinical Research Oversight Manager for DSMB: Kelly Cahill 301-451-2438
Executive Secretary to the NIAID DSMB: Nancy April 301-846-5301

It is NIH policy that data and safety monitoring of a clinical trial is to be commensurate with the risks posed to study participants and research be responsible for oversight of data and safety monitoring, ensuring that monitoring systems are in place, that the quality of monitoring activities.

Attachments:
DSMB Policy

DSMB Member Roster

List of Standardized DSMB Data Tables

- [Table A Enrollment Summary V2.0 11Sept2012 FINAL](#)
- [Table B Freq of AEs by Cohort and Severity V2.0 11Sept2012 FINAL](#)
- [Table C Freq of AE by Cohort and Causality V2.0 11Sept2012 FINAL](#)
- [Table D Line Listing of AEs by Cohort and Subject V2.0 11Sept2012 FINAL](#)

DSMB Member Roster

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- [Table C Freq of AE by Cohort and Causality V2.0 11Sept2012 FINAL](#)
- [Table D Line Listing of AEs by Cohort and Subject V2.0 11Sept2012 FINAL](#)
- [Table E Line Listing of SAEs by Cohort and Subject V2.0 11Sept2012 FINAL](#)
- [Table F Frequency of Reactogenicity AEs by Cohort and Severity \(VACCINE STUDIES ONLY\) V2.0 11Sept2012 FINAL](#)

- ICH GCP
- Medical Administrative Series Policy
- NIAID Web site
- FDA Summaries/ Presentations

All Site Content



| Verbatim Term | Total # AEs (N=86) | Cohort 1 (N=56) Related | Cohort 1 (N=56) Not Related | Cohort 1 (N=56) Not Entered | Cohort 2 (N=30) Related | Cohort 2 (N=30) Not Related | Cohort 2 (N=30) Not Entered |
|---|--------------------|-------------------------|-----------------------------|-----------------------------|-------------------------|-----------------------------|-----------------------------|
| Headache | 72 (40) 46.6% | 33 (19) 33.9% | 19 (14) 25.0% | 0 (0) 0.0% | 9 (7) 23.3% | 11 (8) 26.6% | 0 (0) 0.0% |
| Fatigue | 34 (21) 24.4% | 10 (6) 10.7% | 10 (8) 14.2% | 0 (0) 0.0% | 7 (5) 16.6% | 7 (6) 20.0% | 0 (0) 0.0% |
| Erythema | 31 (28) 32.5% | 6 (6) 10.7% | 16 (15) 26.7% | 0 (0) 0.0% | 5 (5) 16.6% | 4 (4) 13.3% | 0 (0) 0.0% |
| Rash, Dengue vaccine-like | 31 (31) 36.0% | 22 (22) 39.2% | 0 (0) 0.0% | 0 (0) 0.0% | 9 (9) 30.0% | 0 (0) 0.0% | 0 (0) 0.0% |
| Decreased hemoglobin | 27 (11) 12.7% | 2 (1) 1.7% | 23 (8) 14.2% | 0 (0) 0.0% | 1 (1) 3.3% | 1 (1) 3.3% | 0 (0) 0.0% |
| Upper respiratory infection | 27 (24) 27.9% | 0 (0) 0.0% | 20 (18) 32.1% | 0 (0) 0.0% | 0 (0) 0.0% | 6 (5) 16.6% | 1 (1) 3.3% |
| Lymphadenopathy cervical | 25 (22) 25.5% | 12 (11) 19.6% | 7 (7) 12.5% | 0 (0) 0.0% | 2 (2) 6.6% | 4 (4) 13.3% | 0 (0) 0.0% |
| Nausea | 21 (16) 18.6% | 2 (1) 1.7% | 12 (10) 17.8% | 0 (0) 0.0% | 4 (3) 10.0% | 3 (3) 10.0% | 0 (0) 0.0% |
| Myalgia | 15 (10) 11.6% | 7 (5) 8.9% | 6 (4) 7.1% | 0 (0) 0.0% | 2 (2) 6.6% | 0 (0) 0.0% | 0 (0) 0.0% |
| Bruising | 9 (9) 10.4% | 0 (0) 0.0% | 9 (8) 16.0% | 0 (0) 0.0% | 0 (0) 0.0% | 0 (0) 0.0% | 0 (0) 0.0% |
| Prolonged partial thromboplastin time (PTT) | 8 (4) 4.6% | 1 (1) 1.7% | 7 (4) 7.1% | 0 (0) 0.0% | 0 (0) 0.0% | 0 (0) 0.0% | 0 (0) 0.0% |
| Erythema at injection site | 7 (6) 6.9% | 6 (5) 8.9% | 0 (0) 0.0% | 0 (0) 0.0% | 1 (1) 3.3% | 0 (0) 0.0% | 0 (0) 0.0% |
| Photophobia | 6 (5) 5.8% | 2 (2) 3.5% | 1 (1) 1.7% | 0 (0) 0.0% | 1 (1) 3.3% | 2 (2) 6.6% | 0 (0) 0.0% |
| Prolonged prothrombin time (PT) | 6 (5) 5.8% | 1 (1) 1.7% | 2 (2) 3.5% | 0 (0) 0.0% | 0 (0) 0.0% | 3 (2) 6.6% | 0 (0) 0.0% |
| Rash, not Dengue vaccine-like | 6 (6) 6.9% | 0 (0) 0.0% | 6 (6) 10.7% | 0 (0) 0.0% | 0 (0) 0.0% | 0 (0) 0.0% | 0 (0) 0.0% |
| Retro-orbital pain | 6 (6) 6.8% | 3 (3) 5.3% | 0 (0) 0.0% | 0 (0) 0.0% | 3 (2) 6.6% | 0 (0) 0.0% | 0 (0) 0.0% |
| Sore throat | 6 (6) 6.9% | 3 (3) 5.3% | 1 (1) 1.7% | 0 (0) 0.0% | 2 (2) 6.6% | 0 (0) 0.0% | 0 (0) 0.0% |
| Thrombocytopenia | 6 (1) 1.1% | 1 (1) 1.7% | 5 (1) 1.7% | 0 (0) 0.0% | 0 (0) 0.0% | 0 (0) 0.0% | 0 (0) 0.0% |
| Toothache | 6 (6) 6.9% | 0 (0) 0.0% | 6 (6) 10.7% | 0 (0) 0.0% | 0 (0) 0.0% | 0 (0) 0.0% | 0 (0) 0.0% |
| Arthralgia | 5 (4) 4.6% | 2 (2) 3.5% | 3 (2) 3.5% | 0 (0) 0.0% | 0 (0) 0.0% | 0 (0) 0.0% | 0 (0) 0.0% |
| Elevated ALT(SGPT) | 5 (4) 4.6% | 5 (4) 7.1% | 0 (0) 0.0% | 0 (0) 0.0% | 0 (0) 0.0% | 0 (0) 0.0% | 0 (0) 0.0% |
| Induration (skin and subcutaneous tissue) at injection site | 4 (4) 4.6% | 3 (3) 5.3% | 0 (0) 0.0% | 0 (0) 0.0% | 1 (1) 3.3% | 0 (0) 0.0% | 0 (0) 0.0% |
| Neutropenia | 4 (4) 4.6% | 2 (2) 3.5% | 1 (1) 1.7% | 0 (0) 0.0% | 1 (1) 3.3% | 0 (0) 0.0% | 0 (0) 0.0% |
| Dizziness | 3 (3) 3.4% | 0 (0) 0.0% | 2 (2) 3.5% | 0 (0) 0.0% | 0 (0) 0.0% | 1 (1) 3.3% | 0 (0) 0.0% |

Expedited Safety Reporting

- Investigator to Sponsor:
 - Serious adverse event/unanticipated problems form
- Sponsor to FDA:
 - Regulatory Branch customized template for IND Safety Reports

SAE/UP Report Form



**National Institute of Allergy and Infectious Diseases Institutional Review Board
Regulatory Compliance and Human Subjects Protection Program**

Combined Serious Adverse Event (SAE) and Unanticipated Problem (UP) Report Form
Attention: This form cannot be edited after saving. Additional form instructions are attached after page 3

Protocol Number: _____ IND or IDE Number: _____

Protocol Title: _____

Principal Investigator: _____

Office Telephone: _____

Report Status: _____

Adverse Event Term: _____

Enter the sign, symptom or diagnoses term entered in the research data base that was the primary cause of the SAE outcome being reported on this form.

Onset Date of AE: _____ Date of SAE: _____ Site Awareness Date: _____

Subject Study #: _____ Subject Age: _____ Gender: Male Female

Disease Under Study: _____ or Healthy Subject Site where subject is enrolled: _____

| Reason for Reporting (select appropriate reason(s) or N/A) | | Relationship of SAE to Research: | Have similar adverse events occurred on this protocol? |
|---|---|---|--|
| <input type="checkbox"/> Unanticipated Problem <i>(must meet all 3 criteria below)</i> <input type="checkbox"/> N/A 1. Unexpected 2. Related to research <i>Possibly (may be related)</i> <i>Probably (likely related)</i> <i>Definitely (clearly related)</i> 3. Increases risk of harm to subject or others or is an SAE <i>*Report all UPs to NIAID IRB and all UPs that are AEs to the IND Sponsor/RCHSPB</i> | <input type="checkbox"/> Serious Adverse Event <i>(Indicate an outcome below)</i> <input type="checkbox"/> N/A <input type="checkbox"/> Death <input type="checkbox"/> Life-threatening event <input type="checkbox"/> Hospitalization <input type="checkbox"/> Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions <input type="checkbox"/> Congenital anomaly or birth defect <input type="checkbox"/> Medically important <i>*Report SAEs that are possibly, probably, or definitely related to research, regardless of expectedness, to NIAID IRB. Report all SAEs regardless of relationship or expectedness to the IND Sponsor/RCHSPB.</i> | <input type="checkbox"/> Possibly <input type="checkbox"/> Unlikely <input type="checkbox"/> Probably <input type="checkbox"/> Unrelated <input type="checkbox"/> Definitely | <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes," how many? _____ <i>Please describe further on a separate attached document.</i> |
| <input type="checkbox"/> Protocol Specified Event <input type="checkbox"/> N/A <i>If defined in the protocol only. Refer to the protocol for reporting requirements</i> | | Expectedness of SAE to Research: <input type="checkbox"/> Expected <input type="checkbox"/> Unexpected If any steps are planned as a result of the AE reported above, provide documentation to the IRB for review and approval. (Select appropriate action below) <input type="checkbox"/> No action required <input type="checkbox"/> Amend consent (Amendment Request Form required) <input type="checkbox"/> Amend protocol (Amendment Request Form required) <input type="checkbox"/> Inform existing subjects <input type="checkbox"/> Terminate or suspend protocol <input type="checkbox"/> Other; Describe on a separate attached document | |
| <input type="checkbox"/> Unanticipated Adverse Device Effect (UADE) <input type="checkbox"/> N/A <i>*Report UP to NIAID IRB and IDE Sponsor/RCHSPB</i> | | In addition to the IRB, this event is being reported to: <input type="checkbox"/> FDA (Investigator held IND) <input type="checkbox"/> IND or IDE Safety Office <input type="checkbox"/> Office of Biotechnology Activities (when appropriate) <input type="checkbox"/> Institutional Biosafety Committee (when appropriate) <input type="checkbox"/> Other: _____ <input type="checkbox"/> None of the above are applicable. | |

Signature of Investigator/ Designee: _____ Date: _____

Medical Advisory Investigator's Signature (MAI) (if applicable): _____ Date: _____

Page 1

Safety Office Review Functions

- Investigator brochures amendments
- Package inserts changes
- FDA IND annual reports
- Final study reports
- Monitoring visit reports
- Case report forms

Training

- Guides
 - UP Guide
 - TORO/SRCP Q&A
 - DSMB Data Tables guidance
- Presentations – 33 conducted
- Computer based training
- DSMB on-line training modules

DSMB Training

URL: <https://dsmblearningcenter.niaid.nih.gov>

Data Safety Monitoring Board (DSMB) Training

[End Course](#)
[Web Resources](#)
[Help/Feedback](#)

Identifying DSMB Purpose and Objectives

Module 1

[◀ Back](#) [Next ▶](#)

> 1: Purpose/Objectives

[Purpose of DSMBs](#)
[History of DSMBs](#)
[DSMBs Recommended](#)
[DSMB Role](#)
[Conflicts of Interest](#)
[Module 1: Test](#)

2: Organization/Responsibilities

3: Statistical Topics

[Print Courses](#)
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Module 1: Identifying DSMB Purpose and Objectives

Introduction

At the conclusion of the **Identifying DSMB Purpose and Objectives** module, the participant will be able to:

- Explain the overall purpose of a data safety monitoring board (DSMB).
- Describe the history of DSMBs in government and pharmaceutical sponsored clinical trials.
- Recognize the various types of clinical trials for which the establishment of a DSMB is recommended.
- Describe the scope of a DSMB's authority and its obligations to a trial's sponsors and research participants.
- Explain the importance of having DSMB participants avoid any conflicts of interest.
- Understand the National Institutes of Health's and National Institute of Allergy and Infectious Diseases' policy with respect to DSMBs.

SUMMARY

- Standardized protocol safety language
- Sponsor medical monitor assigned to all IND/IDE protocols
- SRCP - delineates all safety responsibilities
- Pre-IRB protocol regulatory review

SUMMARY (con't)

- Management of DSMB, SMC, and ISMs
- Standardized CRIMSON data tables
- Standardized SAE/UP report form
- Multifaceted review process
- Comprehensive training program

Clinical Safety Office Contact Information

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cahillke@niaid.nih.gov
- Barry Eigel, MD, CPI
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eigelb@mail.nih.gov
- SAIC-Frederick, Inc. - RCHSPP - CSO
5705 Industry Lane, Suite J
Frederick MD 21702
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Acknowledgements

- H. Clifford Lane, MD
- Jerry Pierson, RPh, PhD
- Beth Baseler, MS
- Molly Buehn, MS
- Scott Garrand, MS
- Angel Gonzalez
- Shelly Simpson, MS
- Nikki Cline
- Terry Mainprize, PhD
- Marc Teitelbaum, MD
- Karen Sweeney, RN
- Nancy Aprill, RN
- Debbie Hissey
- Laurie Lambert
- Giwan Jiri
- The CRIMSON Team

