

Expedited Reporting via DAERS

Lauren Miller

DAIDS Regulatory Support Center (RSC) Safety Office

FSTRF DMC Workshop Safety Training
Johannesburg, South Africa
11 November 2015



National Institute of
Allergy and
Infectious Diseases



Objectives

At the end of this session, participants should be able to demonstrate an understanding of:

- The NIAID Clinical Research Management System (DAIDS)
- The purpose and use of DAIDS Adverse Experience Reporting System (DAERS)
- How to use the DAERS through a case demonstration

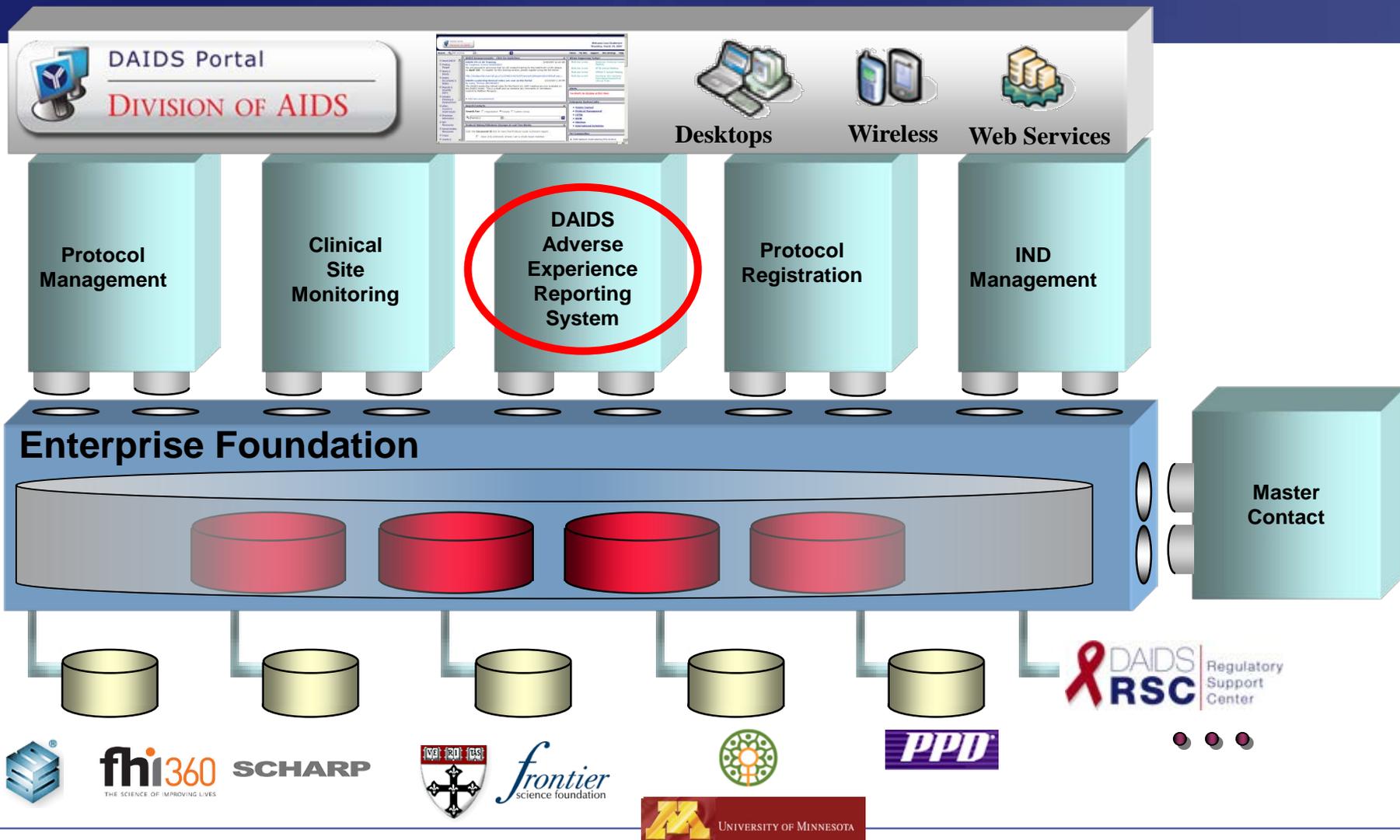
NIAID CRMS (DAIDS)

What is the NIAID CRMS (DAIDS)?

- **The NIAID Clinical Management System (NIAID CRMS)...**
 - NIAID CRMS houses information for several NIAID divisions, such as DAIDS
 - The DAIDS component has multiple modules for different business areas
 - Enhances clinical research by supporting scientific, administrative, and regulatory processes



NIAID CRMS (DAIDS) Components



DAIDS Adverse Experience Reporting System (DAERS)

DAERS: Overview

DAERS: **D**AIDS **A**dverse **E**xperience **R**eporting **S**ystem

- One module of many in the NIAID CRMS (DAIDS)
- A secure, confidential, web-based system through which sites are required to submit expedited reports to DAIDS
- All EAEs and supporting information must be submitted using DAERS, unless the system is unavailable for technical reasons
- DAERS Integration Group meets as needed to address technical issues and system changes
 - Updates to the system occur approximately every 6 months

DAERS: Use

- **Sites:** Create and submit EAEs; respond to queries
- **DAIDS RSC Safety Office:** Triage and processes EAEs; queries sites and receives responses; analyzes safety data
- **DAIDS Medical Officers:** Perform safety assessments and reviews; conduct safety monitoring

Case Study and DAERS Demonstration

**CASE STUDY HANDOUT
TO BE REVIEWED FOR
5 MINUTES**

Case Study: Intrauterine Fetal Demise

- **5 Jun 2015:** 31 year old, HIV infected Black female enrolled in 1077BF (PROMISE)
- **17 Jun 2015:** Subject was ~ 20 weeks pregnant and presented to the clinic with grade 2 lower abdominal pain and vaginal bleeding
 - BP: 142/72 mmHg, Pulse: 140 bpm, T: 35.9°C, and Hgb: 9.5 g/dL
 - Ultrasound confirmed no fetal heartbeat and no liquor
 - Subject was hospitalized for further management
 - Later on the same day, the subject's fetus was expelled; the placenta and membranes were noted as healthy and complete

Reporter and Site Information

- **Site Awareness Date: The date the site first became aware of the adverse event occurring at a reportable level**
 - Date adverse event (AE) occurred
 - **16 Jun 2015**
 - Date serious adverse event (SAE) occurred
 - **17 Jun 2015**
 - Date site aware event occurred at a reportable level
 - **17 Jun 2015**

Case Study: Intrauterine Fetal Demise

**Timeline for Submission: Must submit within 3
'reporting days' of site awareness**

June 2015

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17 Site Awareness	18	19 Report Due (11: 59 PM Local Time)	20
21	22	23	24	25	26	27
28	29	30				



Primary Adverse Event

- **Seriousness Criteria:**

- Select appropriate ICH-SAE criteria
- More than one criteria can be selected
 - **Requires inpatient hospitalization or prolongation of existing hospitalization**

- **Primary Adverse Event:**

- **Intrauterine fetal demise**

- **Severity Grade:**

- **Grade 3 (Severe)**

Primary Adverse Event

- **Onset Date:** The date the primary adverse event first occurred at the level requiring expedited reporting
 - **17 Jun 2015**
- **Did this AE result in Fetal Loss?:**
 - **Yes**
- **Date of Fetal Loss:**
 - **17 Jun 2015**
- **Country of AE Origin:** The country where the event occurred; may not necessarily be where the site is located
 - **South Africa**



Primary Adverse Event

- **Status Code at Most Recent Observation:** The status code of the subject at the most recent observation
 - **Recovering/Resolving**
- **Status Date: Date of the most recent observation of the subject**
 - Date must be on or after the site awareness date
 - Date of most recent observation for subject status can be on or after the site is aware of the occurrence of the event
 - **17 Jun 2015**

Case Narrative

- **Provide information on reported Primary AE**
- **Describe:**
 - Clinical course
 - Therapeutic measures
 - Outcome
 - Relevant past medical history
 - Concomitant medication(s)
 - Alternative etiologies
 - Any contributing factors
 - Other relevant information

Case Study: Intrauterine Fetal Demise

Study
Product
1

- **Lopinavir/Ritonavir**

Study
Product
2

- **Lamivudine/Zidovudine**



Study Product

- **Not a free text field**
 - **Choose study product from drop down menu of smart text field**
 - Study Product 1: **Lopinavir/Ritonavir**
 - Study Product 2: **Lamivudine/Zidovudine**
 - **Relationship of Study Product 1 to Primary AE:**
 - **Related**
 - **Study Product 1 Dose and Unit of Measurement:**
 - **200/50 mg**
-

Study Product

- Exposure to and duration of use of study product is important information to assess the case
- Ensure accuracy of information
- If unsure, please indicate that the date is estimated
- Date of First Dose:
 - 5 Jun 2015
- Date of Last Dose: The date the subject took the last dose prior to the onset of the adverse event
 - 16 Jun 2015

Study Product

- **Action Taken: Enter the study physician's action taken with the study product after awareness of the SAE**
 - **Continued without change**
- **Action Date: Date has to be on or after the site awareness date, i.e., study physician can take action with the study product only after the site is aware the AE has occurred at a reportable level**
 - **17 Jun 2015**
 - If action taken is "Course Completed or Subject Off Study Agent at AE Onset," action date can be left blank

ConMeds and Other Events

- **Concomitant Medications:**
 - **Folic Acid**
 - **Ferrous Sulfate**
 - **Amoxicillin**

- **Other Events: List other clinically significant signs and symptoms that more fully describe the nature, severity, and/or complications of the Primary AE**
 - **Abdominal Pain (grade 2)**
 - **Vaginal Bleeding (grade 2)**

Laboratory and Diagnostic Tests

- **Laboratory Tests:**
 - Hemoglobin
 - Creatinine
- **Diagnostic Tests:**
 - Abdominal Ultrasonography

Submission

- **Reporter:** Completes and sends the report for final review
- **Submitter:** Reviews and submits the report to DAIDS
- **E-mail notification of EAE report submission sent to site staff and other key stakeholders**
 - A submission confirmation is generated by the system indicating that the report was successfully submitted
- **If a confirmation is not received, the site is responsible for following up with the DAIDS RSC Safety Office**

Case Study: Intrauterine Fetal Demise

UPDATE

Case Study Update Information

- **Status Code at Most Recent Observation:**
 - **Recovered/Resolved**
- **Status Date: Date of the most recent observation of the subject**
 - **22 Jun 2015**
- **Case Narrative:**
 - **18 Jun 2015: discharged from hospital**
 - **22 Jun 2015: evaluated in study clinic**
- **Additional Information:**
 - **Upload discharge summary**

Submission of Update

- **Completion Check to put the EAE Report in “Ready for Final Review Status”**
- **Click “View PDF Report” to verify your edits have been made**
 - **Update status code and status date**
 - **Update case narrative**
 - **Additional Information**
- **Submitter will review the report and submit through DAERS**

Teaching Points

- **Provide relevant information with adequate details to allow for assessment of the case by sponsor and regulatory authority**
 - Distinguish symptom/sign/condition/diagnosis
 - Provide rationale for relationship assessment
 - Provide severity grade, units, and normal ranges where applicable
 - If information is unavailable to the site, note what information is pending or being sought and will be provided when available

Teaching Points

- **Use best judgment as medically qualified person**
- **Continue to follow case until resolution or stable**
- **Additional information received at site should be reviewed for:**
 - Impact on initial assessment
 - Is it clinically associated with the primary AE in initial submission or is it another primary AE?
 - If another primary AE, does it meet reporting criteria?

Teaching Points

- **Use Google Chrome or Internet Explorer (Version 11)**
- **Ensure Compatibility View settings is turned off**
- **Study products are listed by generic name the same way as they are listed in the Protocol Management module**
- **Documents uploaded in the *Additional Information* section must be less than 5MB in file size**
- **Do not include patient identifiers**

How to Report to DAIDS

Reports must be submitted via DAERS:

- **DAERS via web:** <https://ncrms.niaid.nih.gov>
- **For emergency use only:**
 - FAX: +1-301-897-1710
or 1-800-275-7619 (USA only)
 - E-mail: DAIDSRSCSafetyOffice@tech-res.com
 - If e-mailing, scan or fax signature page

Accessing DAERS

- **CRS Leader or CRS Coordinator requests access using the Site Enrollment Module in DAERS**
 - Provide the user's name, contact information (e-mail, phone, and fax) and DAERS role (i.e., “reporter” or “submitter”) for each protocol
 - **User must complete the on-line DAERS training (i.e., DAERS – New User Introductory Webinar) on the DAIDS Learning Portal at <https://www.daidslearningportal.com/>**
 - **User must send the training certificate to NIAID CRMS Support at CRMSSupport@niaid.nih.gov**
-

Accessing DAERS

- **“Submitters” must:**

- Mail a signed, original, hard copy study physician Attestation and Agreement for Electronic Signatures form (see <http://rsc.tech-res.com/safetyandpharmacovigilance/expeditedreportingdaers.aspx>) to the DAIDS RSC Safety Office, and
- Be study physicians listed on either the FDA 1572 form or DAIDS Investigator of Record Agreement (IoRA) form (*Note: These documents must be submitted to the DAIDS Protocol Registration Office at the DAIDS RSC during protocol registration*)

Where to Get Help

Help is just an e-mail or a phone call away!

■ Content-related questions...

- DAIDS RSC Safety Office
 - E-mail: DAIDSRSCSafetyOffice@tech-res.com
 - Telephone: 1 (301) 897-1709 or 1 (800) 537-9979
 - Business Hours: Monday through Friday, 8 AM to 5 PM EST

■ Technical questions...

- NIAID CRMS Support
 - E-mail: CRMSsupport@niaid.nih.gov
 - Telephone: 1 (240) 778-2517
 - Business Hours: Monday through Friday, 8: 30 AM to 5:30 PM EST
-

Questions?

