

DDOTSTM 1997-2006 Navigator

Translating Technology to Improve Patient Outcomes, Enhance Quality, and Reduce Costs

Automatically Enter and Print Adverse Events

Log Adverse Events for the IRB and Print the Document

Logging Serious Adverse Events (SAE) and providing documents to Investigators can be troublesome and time consuming. CREDIT[©] provides a tool to dynamically load a single SAE, then populate multiple studies with an identical logging. Further, each event can be printed for presentation to the Investigator for review. If there are multiple IRBs involved, the event can even be logged for selected IRBs at the same time.

When SAEs are logged into CREDIT[©], each entry can have various actions. If the IRB requires that they review each and every event, the entry is logged as "Sent to IRB". SAEs can also be logged for review via "Full Board" or "Expedited".

CREDIT[©] captures the identifier for the SAE, the date, consent form changes and patient reconsent requirements. Event expectation, affiliation, Medwatch and Patient Identifier are also available for entry. Intensity, treatment and attribution are selectable. A memo box fills out the complete entry allowing for the description of the actual event.

The selection of parallel protocols for the entry is optional. The entry can be for the single study or for dozens of additional studies with the single entry. This feature saves valuable staff time by eliminating duplicate entry.

There are two options for saving the SAE entries. The event can simply be "Saved" or a one sheet document containing the entry can be generated immediately. The "Save and Print" feature allows that the SAE be formatted according to a template that can be edited. Once the template has imported the entry (about 2 seconds), the print command box pops up prompting for which printer to use. If the SAE was made for multiple protocols, each study will get the printed document. So, if there are 12 studies assigned to the SAE, there will be 12 documents created within seconds!

Serious Adverse Events Entry Page

Serious Adverse Events are logged into CREDIT[©] for processing to Investigator and/or IRB.

Unlimited SAEs Stored in CREDIT[©]

An unlimited number of Serious Adverse Events can be logged into CREDIT[©]. They can be sorted in a variety of ways as noted at the top of the above image.

Adverse Event Template with "Macros"

The screenshot shows a web browser window titled 'CREDIT - 2006 - Microsoft Internet Explorer'. The main content area is titled 'SERIOUS ADVERSE EVENT FORM'. The form contains several fields with macros (indicated by @ symbols) highlighted in red circles:

- Title of Study: @Prototitle @SPONSOR@National
- Study Number: @Local
- Principal Investigator: @IRBPIFirst01 @IRBPILast01.M.D.
- Site of AE: @AEAffiliated
- Is this study currently open to accrual? X @AEStatus
- Are there currently any participants at @HOSP @AEActiveTreatment
- 1. Intensity: @AEIntensity
- Date event occurred: @AEWordDate
- @AEMemo
- 2. Treatment Given: @AETreatment
- Description of treatment given: @AETreatmentDescription

At the bottom left, there are links for 'Back' and 'Back to IRB Central'.

Every institution can design their own Serious Adverse Event Template. The placement of the "Macros" (place-holders for data) can be anywhere on the document. The "Macros" get replaced with specific pieces of information based on the SAE entry.

Generate All SAE Documents for Meeting

The screenshot shows the 'Criteria for Creating Adverse Event Form' section of the CREDIT software. It includes the following elements:

- Meeting Date:** A dropdown menu showing '06/21/2006'.
- Protocols:** A list box containing the following protocol numbers: 0123, 0182, 0185, 0213, 0215, 0315, 0413. Below the list box are radio buttons for 'Selected Protocols' and 'All Protocols'.
- Select Type of Output:** Two radio buttons: 'Output to screen (for quick printing)' (selected) and 'Output to external Word Processor (for further editing)'.
- Buttons:** 'Return to Edit Letter' and 'Create Report'.

The Adverse Event Documents are generated specifically for a selected meeting. Optionally, specific protocols can be scanned for inclusion, or all studies are included in the inspection. The final output can be as a web page for instant printing, or it can be ported to Word for Windows.

DDOTS Navigator

DDOTS, Inc.
4571 Ellsworth Road
Ypsilanti, Michigan 48197
(734) 434-7734
e-Mail Address:
Navigator@ddots.com

The **DDOTS Navigator** is published to introduce news that has occurred in the ongoing development of **Cancer Research Environmental Data Information Tracking (CREDIT)**.

Since 1995 **CREDIT**® has been in constant growth. May of 2006, marked the 11th anniversary of this powerful system. Installed at sites across the country, **CREDIT**® is the leader in Collaborative Clinical Research Administration Software.

Email System Provides Contact Between Members

For those not familiar with a "Listserv", it is a list of members who want to be in contact with each other. The focus of the contact being questions and answers about how best to utilize the **CREDIT**® system.

Many users have found unique ways to implement specific modules to their benefit. Others, may not even have the module turned on and can benefit from hearing how another institution use it. As an example, one user may post an email to ask, "Does anyone use the Protocol Submission Log? If so, what submissions are you tracking?". All members will receive the email.

Upon receipt, those who are using that module may reply to detail the function and benefit they receive from logging submissions.

This new service is free to all **CREDIT**® installations. One more way **DDOTS, Inc.** provides the best service and support in the business.