

## Implementing an Audit Trail within a Clinical Reporting Tool

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### ABSTRACT

This paper is a follow-up to "Overview of a Browser-Based Clinical Report Generation Tool," presented at PharmaSUG 2003. Improved control over the reporting environment was stated as one of the next steps, with the planned addition of a Move to Production facility and accompanying system audit trail. The discussion in this paper will focus on the implementation of the system audit trail.

An audit trail is a useful tool for management to record and review the activities of staff responsible for development and maintenance within a Clinical Reporting Environment. A system audit trail is a vital component in a system intended to satisfy 21 CFR Part 11 and other regulatory requirements.

DataCeutics has developed a system audit trail for the DataCeutics' Report Portal™ (DRP), to further establish the DRP as a comprehensive Clinical Reporting Tool, suitable for use on clinical projects intended for submission. The system audit trail, like the DRP, was developed using the SAS system, SAS/IntrNet application, HTML, and JavaScript.

This paper is an overview of the system audit trail component of the DRP application, focusing on the technical and functional design and compliance with 21 CFR Part 11.

### INTRODUCTION

The objectives of a Clinical Reporting Tool are to increase reporting efficiency and quality while saving time, reducing costs and maintaining regulatory compliance. This is achieved through the introduction of automation and an environment where good programming practices are enforced. DataCeutics, Inc. has developed The Clinical Reporting Solution™ (CRS) to address these objectives. The CRS is comprised of the DataCeutics Report Portal™ (DRP) front-end user interface, a back-end report generator and customized report templates. The audit trail and Move to Production facility discussed in this paper are part of the DRP component.

The design and implementation of a Clinical Reporting Tool, the DataCeutics Report Portal (DRP), was discussed in the paper "Overview of a Browser-Based Clinical Report Generation Tool," presented at PharmaSUG 2003. The DRP met the objectives of automating clinical report generation, providing a server-based application requiring only a web browser on the client, and helping to enforce a 21 CFR Part 11 compliant programming environment. One of the next steps for the DRP was to implement an automated Move to Production facility, along with an accompanying system audit trail.

The inclusion of a reliable, easy-to-follow audit trail is considered one indication of good internal control in a system. In the Pharmaceutical Industry, audit trails are most often associated with the collection, cleaning, and management of clinical data. All major Clinical Database Management Systems (CDBMS) include an audit trail. Less mature in the industry, however, is an audit trail to track activities within a clinical reporting environment. The audit trail presented here is a component of the DRP, tracking development and maintenance activities within the reporting environment.

The DRP is a browser-based thin-client application for automating and controlling the production of SAS Clinical Reports. In the DRP, programs are created in the development environment and then promoted to production. The audit trail is defined as an electronic record of the development, promotion, execution and deletion of stored SAS program files. This paper will review the requirements of the DRP audit trail and Move to Production facility and demonstrate the functionality within the DRP that contributes to the audit trail.

### PROBLEM ADDRESSED

The DRP facilitates enforcement of a 21 CFR Part 11 compliant SAS programming environment by allowing for creation and management of programs and output in a validated environment, with separate development and production areas. As programs are updated, previous versions and associated metadata (e.g. titles and footnotes) are archived. These archived programs and metadata can later be viewed or retrieved. Without a system audit trail, it is difficult to know who created, deleted or promoted programs. The ability to control the environment is compromised, if users are able to carry out these activities within the reporting environment without a record, even if the users are authorized to perform these functions.

## **BENEFITS**

Through the implementation of a system audit trail, internal control is established, allowing a traceable history of all of the significant events surrounding the development, maintenance, and promotion to production of programs that are vital to the submission of clinical data. A system audit trail can be beneficial in meeting the following objectives:

- Regulatory Compliance – by recording time-sequenced development and maintenance activities by user ID, the audit trail provides the documentation required to ensure that the system is being maintained with suitable control.
- Management Control – through the same components that satisfy regulatory compliance, management is able to review the activities of staff to ensure that clinical report development is occurring according to project goals and standard operating procedures and that production programs are protected against unexpected changes after validation has occurred.

## **AUDIT TRAIL COMPONENTS**

Some considerations for implementing a system audit trail are storage and retrieval, security, integrity and extendibility.

The design of the DRP audit trail is an attempt to address these considerations both directly and indirectly, with explicit features meeting these needs or a design that will allow for their future implementation as DRP requirements and functionality are expanded.

- Storage and Retrieval – The audit trail is stored electronically. The DRP includes audit trail reports that can be viewed, printed and copied at any time. All users have access to the reports.
- Security – The DRP uses host-based authentication as provided by the SAS/Intrnet product. Only users with sufficient permission are able to access the DRP and audit trail. The DRP is intended to be used as a closed system with all users under control of the company.
- Integrity - The audit trail entries are permanently associated with a specific study and user ID. The audit trail cannot be disabled.
- Extendibility – For future requirements the DRP can easily capture new activities into the audit trail.

## **DESIGN OVERVIEW**

Developed using the SAS system, SAS/IntrNet, HTML and JavaScript, the DRP is a thin-client, server-based application. It acts as a user interface to the report generation software stored on the SAS server. The interface allows the user to generate SAS programs, select patient subsets, execute SAS programs, generate SAS output files, view SAS source files, view output files, view SAS log files and re-generate output. The interface also includes a Manage function where users and administrators can perform basic file management activities including file deletion and promotion of SAS programs from development to production.

The system supports two separate environments; a development environment and a production environment. The development environment is where users build and test the SAS report programs prior to moving the program into the production environment. The system maintains one audit trail for each environment and for each study. The audit trails are stored as SAS data sets. New audit trail records are appended to the data sets. There is no capability through the DRP interface to overwrite or modify entries once they are created.

## **DRP AUDIT TRAIL REQUIREMENTS**

The DRP Audit Trail was developed to meet the following requirements:

- All entries will record the date, time, user, file name and event description.
- Users must be able to view the audit trail in development and production.
- For user-initiated events, the user will be able to insert a comment into the audit trail.
- There will be one audit trail per clinical study.
- Previous versions of programs will be archived and available if needed.

The system will record the following events in the development environment:

- Creation of SAS programs
- Deletion of SAS programs

The system will record the following events in the Production environment:

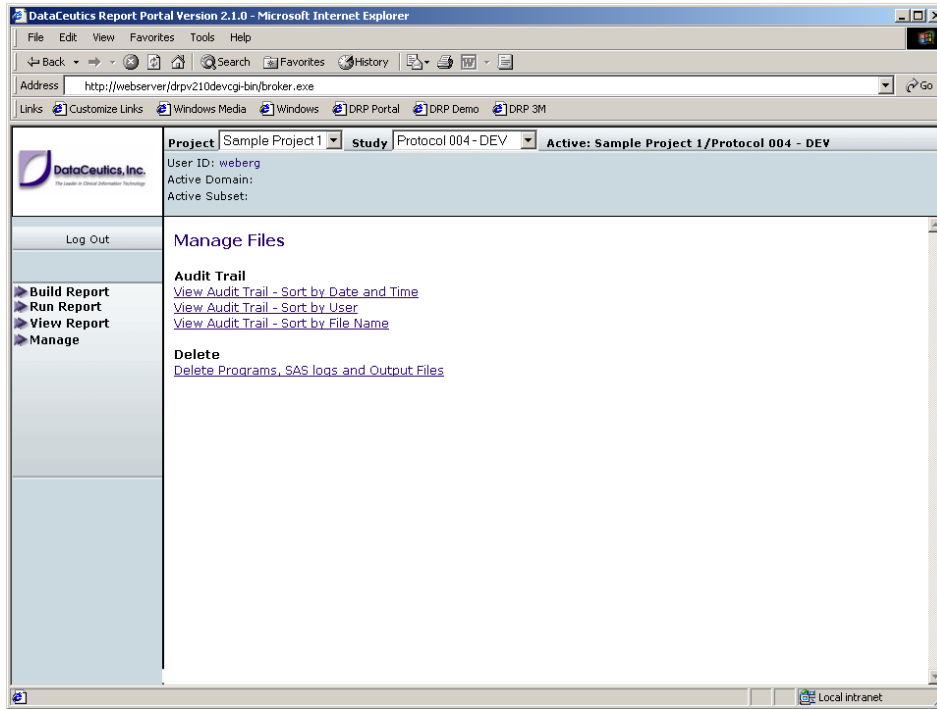
- Promotion of SAS programs to production
- Archival of SAS programs
- Deletion of SAS programs

## FUNCTIONAL OVERVIEW

The system requires users to login using a UNIX account, select a project and select a study within the project. The study selection box allows the user to work in a production or development mode. Once a study is selected, the user has access to the Build Report, Run Report, View Report and Manage functions.

## DEVELOPMENT AUDIT TRAIL

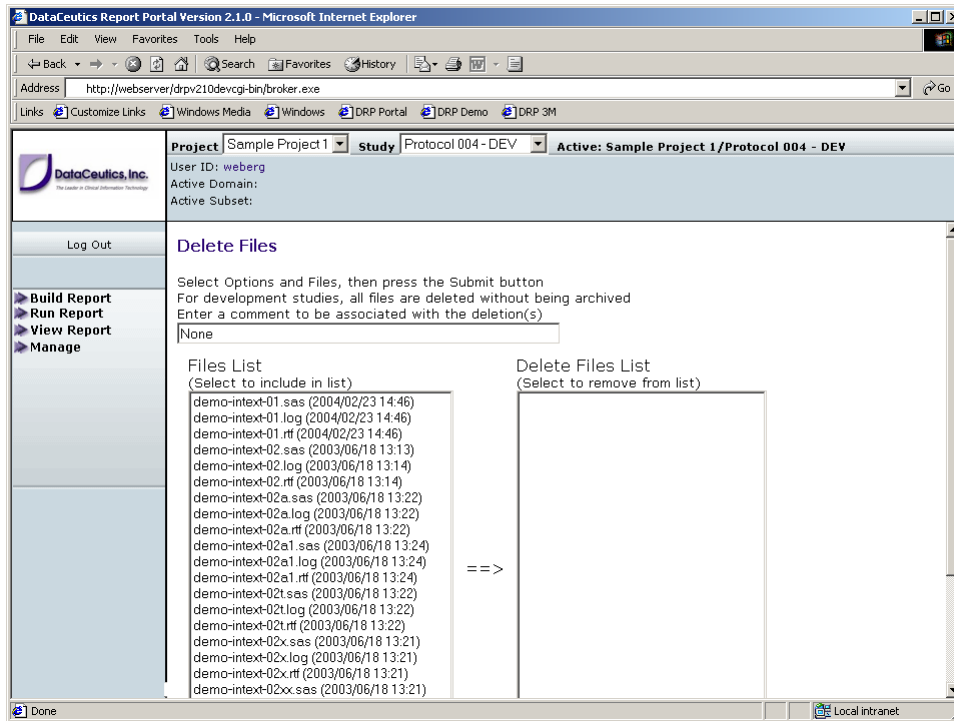
The following image shows the Manage Files interface as it appears in development. There are three reports available that show different views of the audit trail.



Selecting the first report link displays the audit trail sorted by Date and Time. The report shows the date, time, file name, user ID, system action and a user comment. The following screenshot shows a series of SAS programs created by user gilbertp. In development, programs can be saved as many times as needed, but each time a file is overwritten a new record is appended to the audit trail.

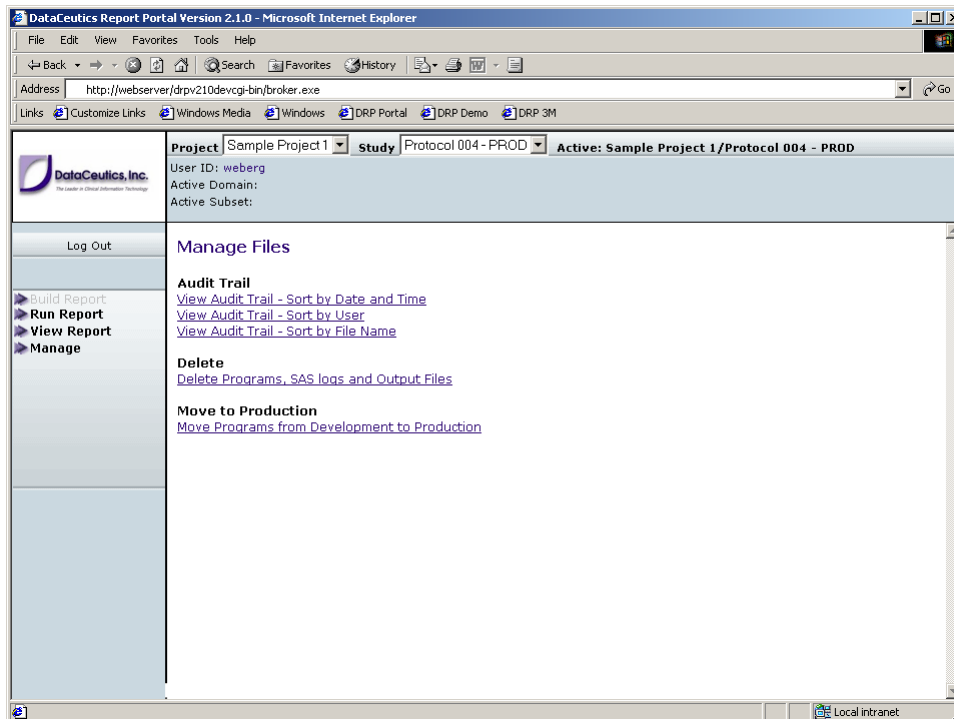
Obs.	ACTION_DATE	ACTION_TIME	FILE_NAME	USERID	ACTION	COMMENT
1	2003-06-18	11:20:27	demo_intext_01.sas	gilbertp	delete file	None
2	2003-06-18	11:42:24	demo-intext-01.sas	gilbertp	create file	None
3	2003-06-18	11:44:46	demo-intext-01.sas	gilbertp	delete file	None
4	2003-06-18	11:49:12	junk.sas	gilbertp	delete file	None
5	2003-06-18	12:02:25	demo-intext-01.sas	gilbertp	create file	None
6	2003-06-18	12:02:44	demo-intext-01.sas	gilbertp	create file	None
7	2003-06-18	12:40:23	demo-intext-02.sas	gilbertp	create file	None
8	2003-06-18	12:46:19	demo-intext-01.sas	tdev1	create file	None
9	2003-06-18	12:47:29	demo-intext-01.sas	tdev1	create file	None
10	2003-06-18	12:55:10	demo-intext-02.sas	gilbertp	create file	None
11	2003-06-18	12:56:20	demo-intext-02.sas	gilbertp	create file	None
12	2003-06-18	12:56:36	demo-intext-02.sas	gilbertp	create file	None
13	2003-06-18	12:57:17	demo-intext-02.sas	gilbertp	create file	None
14	2003-06-18	12:58:21	demo-intext-02.sas	gilbertp	create file	None
15	2003-06-18	13:01:27	demo-intext-02x.sas	gilbertp	create file	None
16	2003-06-18	13:01:43	demo-intext-02xxx.sas	gilbertp	create file	None
17	2003-06-18	13:02:07	demo-intext-02xxxx.sas	gilbertp	create file	None

Returning to the main Manage Files screen and choosing the Delete function, displays the Delete Files interface. In development, all users can select files to delete. Each time a file is deleted, the action is recorded in the audit trail. A comment field is available for users to provide additional information.



## PRODUCTION AUDIT TRAIL

The following image shows the Manage Files interface as it appears in production. In addition to the audit trail reports and delete function, a Move to Production function is available for promotion of SAS programs.

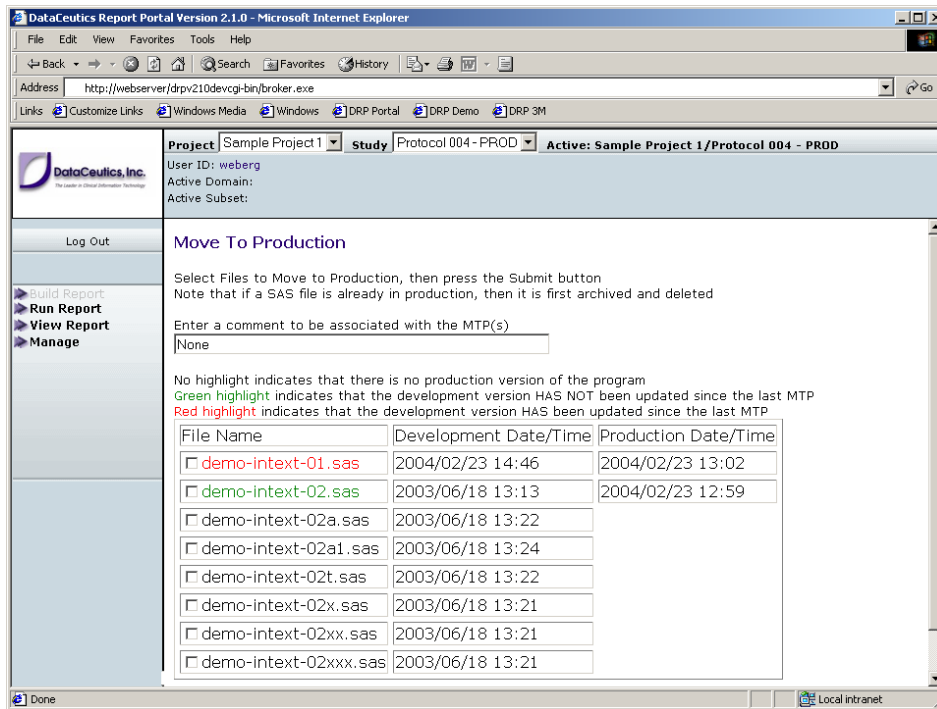


The Move to Production (MTP) interface is shown below. A table displays all programs that are available to move to

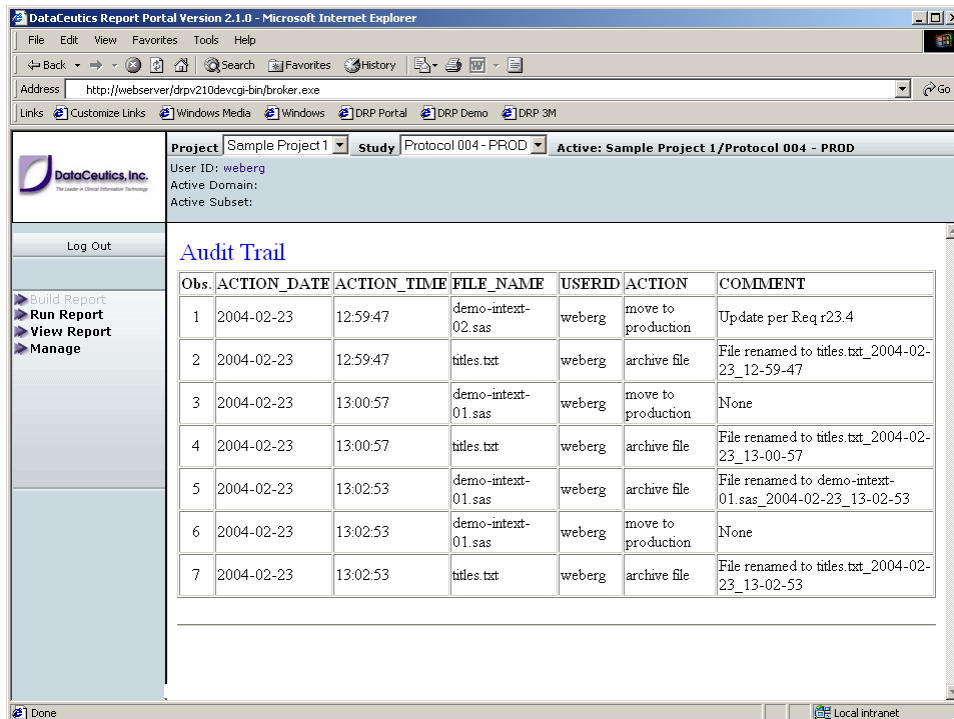
production. The table is color coded to indicate the status of the file.

- No highlight indicates that there is no production version of the program
- **Green** highlight indicates that the development version has NOT been updated since the last MTP
- **Red** highlight indicates that the development version HAS been updated since the last MTP

The user selects the files to move to production. If a file already exists in production, then it is archived with a date time stamp prior to being overwritten and two entries are placed in the audit trail. The first entry records the archival of the existing production version and the second entry records the move to production of the development version.



The screenshot below shows a view of the production audit trail.



The delete function has the same functionality in production as in development, but is only available if a user has the DRP-defined role of Project Manager.

When multiple files are selected for deletion or move to production, these files get individual entries in the audit trail, but are handled as a single batch and all receive the same date time stamp.

## CONCLUSION

The addition of an audit trail and Move to Production facility within the DRP facilitates enforcement of a 21 CFR Part 11 compliant SAS programming environment. Management control is enhanced by the system's ability to record and report user activity, including the creation, deletion, and promotion of SAS programs.

The design and functional overview demonstrated how the audit trail and Move to Production facility are integrated into the DRP. Audit trail events are automatically captured by the system and cannot be circumvented by a user. Read-only access to the audit trail information is provided through system audit trail reports.

## REFERENCES

“**Overview of a Browser-Based Clinical Report Generation Tool**”, by Greg Weber, Paul Gilbert and Teofil Boata, presented at PharmaSUG 2003, May 2003.

## Code of Federal Regulations, 21CFR11-- PART 11--ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

## CONTACT INFORMATION

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