caAERS Release 2

WFU Continued Adoption Strategy

(Task 2.10)

DOCUMENT REVISION HISTORY

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| Version Number | Date | Description |
| 1.0 | 2/1/2008 | First Draft completed |
| 1.1 | 2/4/2008 | Incorporated edits from E. Mulaire |
| 1.12 | 2/4/2008 | Incorporated edits from BAH |

# Introduction

## Project Overview

The purpose of the caAERS project is to develop and deploy an adverse event reporting system that is nationally scalable with a robust architecture to meet the needs of the caBIG™ Community.

## Document Overview

## Wake Forest, as a primary adopter will be one of the first Cancer Centers to use the application for operational Adverse Event Reporting. This document details the strategy WFU will use to integrate caAERS during a pilot phase, scoping use to fit the limitations newly developed software into its CTMS operations.

## Project Participants and responsibilities

Wake Forest caBIG group consists of Robert Morrell, Steven Cheng and Kim Livengood, who have been closely involved with previous iteration testing. They will be responsible for installing, configuring caAERS at WFU, as well as training new users of the system

WFU CRM staff includes Cancer Center Principle Investigators, Clinical Research Management and Research Base staff that manage patients and events.

WFU security staff includes WFUBMC HIPAA officers, IT network security staff and general IT support staff.

# Strategy Assumptions

### This document assumes that two key objectives of the caBIG construction phase have been successfully achieved. These objectives include

1. A functioning, grid enabled version 1.0 of caAERS installed at WFU
2. A functioning link between the WFU instance of caAERS and CTEP (the ADEERS link).

The deadline for accomplishing these tasks is March 6th, 2008, however in the event of failure to reach these objectives; the strategies described in this document will proceed, albeit delayed.

# Constraints

WFU caAERS adoption is constrained by several limitations of the current iteration of the application and the grid environment in which it will operate.

1. caGRID security does not effectively support selective filtering of data (unpublished or HIPAA sensitive) contained in an application’s database.
2. The caAERS/ADEERS link only supports final reports.

The effects of these constraints are that

1. WFU is unable to shield sensitive data from the grid. This led WFU and the caAERS project team to propose a limited grid data exposure strategy during the construction phase. The caAERS grid data service was to be exposed not to all grid users but only to a select NCI staff who have authorization to see unpublished and HIPAA sensitive data on NCI supported trials.
2. Only studies sponsored by WFU can use the ADEERS link (because the sponsor does the final report).
3. The handling of other forms, including Medwatch fit in the WFU workflow has not been tested.

# Operational Sequence

1. Security validation: After successful completion of the construction phase, WFU will work with WFU IT security to assess the security of the grid node and the caAERS application server linked to it. A sign off on the security adequacy of the caAERS/Grid node configuration will be required before further implementation of caAERS can proceed. (Expected time required: one month)
2. Preparation of Research Base Trials: WFU caBIG team will import or enter active Research Base (locally sponsored, NCI approved trials) studies and their patients into the active grid node. The WFU caBIG team will train Research Base staff on caAERS use, and begin entering adverse events. For the medwatch forms, clarification will be sought on report construction, delivery methods, recipients and rules will be detailed. Dependent upon the state of grid node security filtering, some HIPAA constraints may be incorporated into data entry procedures. (Expected time required: two months)
3. Use of caAERS. CAERS will be used live for generation of SAE reporting for four 3 month intervals with review of results and application/grid infrastructure changes at the end of each period. Issues and problems will be reviewed, and potential expansions or contractions of scope of use will be considered. At the end of the 4 periods, a complete review of caAERS functionality and its context within the CTMS workspace will be performed and the decision will be made to proceed with adoption for all trials run at CCCWFU

# Notes

CCCWFU Research Base is primarily focused upon symptom control, and as such does not use ADEERS. Only one of its protocols (no longer recruiting) has the potential to generate a need for ADEERS reporting during the pilot period. Current trials also have at most a few Medwatch forms a month. Because Medwatch forms (sent to the FDA and the NCI, (the former perhaps unnecessarily)) are currently sent by mail, unless email delivery options can be arranged, the potential exists to operate caAERS off the grid as a Medwatch form generator, and export final, anonymized published data to the grid node version. This option may be preferable if the layering of grid security does not become available during the pilot phase.

The general low volume of Adverse Events, and flexible reporting methodologies provides CCCWFU with considerable flexibility in implementing caAERS, and should not engender great resistance to an untested and not fully mature application.