## Functional Capability or Tool Name

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| ***Adopt* caBIG™ Tool**  **caAERS** | For caAERS, CCCWFU instantiated a pilot project within it Research CCOP. This pilot uses caAERS to create SAE forms (mainly ADEERS) on Research Base patients enrolled locally at WFUBMC.  Having proven caAERS functionality for SAE reporting and system stability, WFU is now exploring expansion of this pilot along the following parameters in the Research Base   1. The use of caAERS to record all AE’s (routine AE CRF’s) 2. The use of caAERS for affiliate site data.   In addition, since the caAERS ADEERS link has been established, WFU would like to leverage its experience with caAERS to use caAERS in its ADEERS reporting. As a participant in many cooperative group trials once caAERS can handle non final submissions, this would be a natural progression.  Finally, and most significantly, because WFU is participating in C3PR and is a leader in CTRP work, WFU would like to integrate its caAERS use with C3PR, (to add patients), CTRP (to instantiate trials) and possibly lab viewer.  Data sharing remains an open question. Although WFU was the first to share CTMS data on caGRID using a de-identified instance of caAERS, there is concern that a systematic method of deidentification is needed to make this an ongoing practice.  . |
| *Adapt* Local Infrastructure to caBIG™ Compatibility | Currently the local CTMS is a legacy SQL 2000 server. Normalization to standard data vocabularies and models began prior to caBIG adoption activities and will continue, guided by gap analysis during import activities. More substantial work has begun to adopt CTMS workflow to standard models. Both of these activities will be crucial during initial adoption of caAERS. |

### End-User Community caAERS

The initial users of caAERS in the early pilot phase were CCCWFU Research Base, which conducts NCI approved symptom control trials, and thus offered usage testing to DCP. Users were primarily nurses (Cissy Yates- (Rhonda Kimball, Protocol Specialist, Ashley Parker, Data coordinator) and protocol managers (Cissy Yates, Robin Rohsdal RN) As we move towards routine AE templates, CRA’s Ashley Parker and Rhonda Kimbal will become the most frequent users. These users will collate events from around the country at affiliate sites for entry into caAERS. Also of significant importance will be the biostatisticians who will use the export of the final data for analysis. Expansion into ADEERS will bring non research base Nurses such as Michelle Harmon and Robin Harrellson on board. These nurses would use the envisioned hosted mode of caAERS Local PI’s on research trials may receive reports but are not expected to log into the system directly.

### Deployment Goal

The initial deployment goal will be to expand Research Base use of caAERS to routine AE events (for all patients) on a single trial. Secondary goals would be the use of C3PR and CTRP as source data services for patient registrations and protocol instantiation via the caBIG integrated suite. The timeline of these goals are dependent on the instantiation of new trials and system capabilities respectively, but we believe we could have initial pilot expansion under way in spring of 2011. The expansion beyond research base to ADEERS reporting via a hosted mode of caAERS for cooperative group trials is entirely dependent on development of the hosted mode and non final SAE submission capability but could be as soon as fall of 2010

### Component Name Metrics

The specific metrics for these goals will be as follows:

1. Instantiation of a new trial to be used for all AE recording.
2. The registration of patients in C3PR automatically appearing in caAERS
3. The instantiation of a protocol using CTRP data services.
4. Submission of ADEERS reports via the caAERS hosted mode.

### Internal Deployment Support Resources

The internal resource for the caAERS deployment already exist. A virtual server is already running caAERS version 2.09 and informatics staff and Research Base are familiar with its use.

### External Deployment Support Resources

External resources needed for adoption of this tool will be support from developers, which is expected as part of WFU’s contracted adoption activities.

### Integration Plans

Initial integration may affect workflows by forcing evaluation of rules and determination for actual necessity of current reporting patterns. While the current pilot has identified instances of over reporting, use of caAERS for routine AE’s may reveal under reporting instances.

#### Modifications to Selected Software

No modifications of the software are expected.

#### Legacy Data Upload

No legacy data uploads are planned for this pilot expansion.

#### Changes to Processes and Responsibilities

No changes in processes are envisioned at this time. Zhiqiang Cheng will assume the responsibility of administrating the caAERS application.

#### Documentation and Training Activities

Because WFU was the primary author or existing caAERS documentation, and participation in adoption activities will afford Research Base staff opportunity to work directly with developers, WFU will have ample training resources to train Research Base staff on the use of caAERS.

#### Testing, Validation, and Verification

This section should describe how the testing, validation, and verification activities required by the Center will be carried out in support of the selected adopted/adapted component. Cross reference activities to the roles that will accomplish them and the associated timelines.

### Data Sharing Plans

This section should outline the data sharing plan for the tool: describe the data that will be shared, including its source and the type of data in detail; the technical means by which it will be shared; the community with whom it will be shared; and the process for securing the necessary Center approvals for sharing the data. This data rolls up to Section 5.6. This section includes the following four distinct sub-sections that clearly outline the Center’s data sharing plans.

#### What Data Will Be Shared?

#### How Will the Data Be Shared?

#### With Whom Will the Data Be Shared?

#### What Is the Timeline for Making the Data Available?