AR-CRIS
Comprehensive Research Informatics Suite

Angie Smith, MS, CCRP, PMP
Director of IT Research Systems
UAMS IT Research
Overview of AR-CRIS

- Arkansas Comprehensive Research Informatics Suite (AR-CRIS)
  - Group of web-based applications integrated together to facilitate study management, data collection, data submission, data analyzing, auditing and reporting
  - Highly flexible
  - Provides full spectrum of services for clinical researchers
Overview of AR-CRIS

- Clinical Trial Management System (CTMS)
  - Participant registration and tracking
  - Electronic data capture
  - Regulatory submission tracking
  - Study activity tracking
  - Adverse event reporting
  - Specimen inventory management
  - Reporting
  - Others
Access to AR-CRIS

- Access AR-CRIS at cris.uams.edu
- Once access is granted, requested application(s) show on your AR-CRIS dashboard
Access to AR-CRIS

- Go to My Sites to switch between training and production applications
Overview of Applications

- **RPRS: Research Participant Registration System**
  - Hosts participants’ demographics, study registrations, consents, progress status (epoch or phase)
  - Registration record can be sent to other AR-CRIS components and EPIC

- **ET: Event Tracker**
  - Captures supplementary study related data
  - Tracks regulatory submissions, study level services, delegation logs
  - Tracks pre-study build process
Overview of Applications

- Electronic Data Capture Systems
  - REDCap
  - LimeSurvey
    - Enables users to quickly deliver questionnaires to respondents & collect responses
    - An offline version developed so users can collect data at rural areas without internet
  - OpenClinica (21 CFR Part 11 Compliant)
Overview of Applications

- **AR-PSC: Patient Study Calendar**
  - Track/manage subject’s research visits and activities based on study calendar template
  - CLARA study budget matrix can be imported into PSC

- **caTissue**
  - Specimen inventory management system
  - Includes tracking, annotation, transaction, etc. of specimen
Overview of Applications

- **AR-AERS: Adverse Event Reporting System**
  - Allows collections of adverse events for research participants using Common Terminology Criteria for Adverse Events (CTCAE) versions 3-5 event definitions (other data sources can be added easily)
  - EPIC lab results are automatically graded and Lab AEs can be automatically created and/or resolved
  - Assessed AEs can be pushed to EPIC and OC

- **Others** (TrialSearch, caTies, PSS, Reports, etc.)
**RPRS**

- **Research Participant Registration System**

- Required for all clinical research studies
RPRS

Study Summary
### Study Registrations

**Study title:** PSC Test Study 100  
**Primary identifier:** 56789 (UAMS-TRI)  
**Study status:** Open  
**Coordinating center:** UAMS-TRI  
**Principal investigator:** Richardson, Robin (UAMS-TRI)

#### Registrations

<table>
<thead>
<tr>
<th>Subject name</th>
<th>Subject primary identifier</th>
<th>Gender</th>
<th>Race</th>
<th>Site</th>
<th>Registration status</th>
<th>Current Epoch</th>
<th>Enrollment date</th>
<th>Registration identifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rose Bush</td>
<td>67891</td>
<td>F</td>
<td>Unk.</td>
<td>UAMS-TRI</td>
<td>Off-Study</td>
<td>Screening</td>
<td>08/23/2016</td>
<td></td>
</tr>
<tr>
<td>Daisy Flowers</td>
<td>1234567892222</td>
<td>F</td>
<td>Unk.</td>
<td>UAMS-TRI</td>
<td>Enrolled</td>
<td>Screening</td>
<td>08/23/2016</td>
<td></td>
</tr>
<tr>
<td>Daffodil Spring</td>
<td>65789</td>
<td>F</td>
<td>NR</td>
<td>UAMS-TRI</td>
<td>Enrolled</td>
<td>Treatment</td>
<td>08/23/2016</td>
<td></td>
</tr>
</tbody>
</table>
RPRS

Participant Overview

Study Registrations

Subject

- First name: Candy
- Last name: Cane
- Gender: Female
- Primary identifier: CC_0004

Birth date: Not specified
- Ethnicity: Hispanic or Latino
- Race(s): Unknown

Study

- Study title: Test Study X
- Primary identifier: testx123
- Status: Open
- Phase: Pilot
- Randomized by RPRS: No
- Stratified by RPRS: No
- Study version: Original version
- Version date: 05/23/2016

Study Site

- Name: UAMS-TRI County
- Address:
- Status: Active
- NCI institution code: AR006-CLRI
- IRB approval date: 05/20/2016
- Start date: 05/23/2016
# Participant Overview

## Epoch History

<table>
<thead>
<tr>
<th>Epoch Name</th>
<th>Type</th>
<th>Enrolling</th>
<th>Status</th>
<th>Arm</th>
<th>Start Date</th>
<th>Off Date</th>
<th>Off Reason(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening Epoch</td>
<td>Screening</td>
<td>No</td>
<td>Off Epoch</td>
<td></td>
<td>09/13/2017</td>
<td>09/13/2017</td>
<td></td>
</tr>
<tr>
<td>Treatment Epoch</td>
<td>Treatment</td>
<td>Yes</td>
<td>Registered</td>
<td>Arm A</td>
<td>09/13/2017</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Current Epoch & Arm

- **Name**: Treatment Epoch
- **Type**: Treatment
- **Arm**: Arm A
- **Epoch is enrolling**: Yes
- **Epoch status**: Registered
RPRS

Participant Overview

Study Registrations

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First name: Candy
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Epic Research Alert
Dataflow between EPIC and AR-CRIS

AR–Comprehensive Research Informatics Suite (AR–CRIS) Tools

**EPIC**: UAMS Electronic Medical Record System

**CLARA**: Clinical Research Administration

**RPRS**: Research Participant Registration System

**AERS**: Adverse Event Reporting System

**TIMS**: Tissue Inventory Management System (caTissue)

**F1**: Foundation One
EventTracker (ET)

- Regulatory submissions tracking
EventTracker (ET)

- Regulatory submissions tracking
Electronic Data Capture Apps

- REDCap
# Electronic Data Capture Apps

- REDCap

[Image of REDCap interface showing Baseline Data and options to add fields and matrices of fields for Baseline Measurements, Date of baseline visit, Date blood was drawn, and Serum Albumin (g/dL).]

- [Baseline Data]
  - Add Field
  - Add Matrix of Fields

- [Baseline Measurements]
  - Add Field
  - Add Matrix of Fields

- [Date of baseline visit]
  - Add Field
  - Add Matrix of Fields

- [Date blood was drawn]
  - Add Field
  - Add Matrix of Fields

- [Serum Albumin (g/dL)]
Electronic Data Capture Apps

- REDCap

![Image of REDCap Baseline Data form]

**Current instrument:** Baseline Data

*NOTE:* Please be aware that branching logic and calculated fields will not function on this page. They only work on the survey pages and data entry forms.

**Baseline Measurements**

- **Date of baseline visit**
- **Was blood drawn?**
  - Yes
  - No
- **Date blood was drawn**
- **Serum Albumin (g/dL)**
- **Serum Prealbumin (mg/dL)**
- **Creatinine (mg/dL)**
- **Normalized Protein Catabolic Rate (g/kg/d)**
- **Cholesterol (mg/dL)**
- **Transferrin (mg/dL)**
- **Kt/V**
- **Dry weight (kilograms)**
Electronic Data Capture Apps

- LimeSurvey

Diet, Exercise, and Sleep Habits of Adults with Attention Deficit Disorder (ADD)

Exercise Habits

- In the past month, have you exercised at least twice per week?
  Choose one of the following answers
  - Yes
  - No

What types of exercises do you most often do?
Check any that apply

- Walking
- Running, jogging
- Weight/strength training
- Stretching
- Yoga
- Other: 

Sleep Habits

- Do you regularly take medication(s) to help you sleep? If you answer Yes, please list the medication(s) in the text box. If you answer No, you may either leave the field blank or explain why you choose not to take sleep medication. Choose one of the following answers
  - Yes
  - No

Please enter your comment here:

- On a scale of 1–5, with 1 being poor and 5 being excellent, please rate the following regarding your sleep experience in the last month.

<table>
<thead>
<tr>
<th>Ease of falling asleep</th>
<th>1 (poor)</th>
<th>2 (fair)</th>
<th>3 (okay)</th>
<th>4 (good)</th>
<th>5 (excellent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ease of staying asleep</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality of sleep</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amount of sleep</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Electronic Data Capture Apps

- OpenClinica
- CFR 21 Part 11 Compliant
Patient Study Calendar
Patient Study Calendar

2015-06-09 133529 / Screening / Screening / Screening (54 activities, 9 completed, 3 dropped)
- 01 Other (EMR) (1 activities)
  - History Taking / X
- C.T. SCAN (1 activities)
  - 74177 - CT ABDOMEN and PELVIS W/CONTRAST / C / $120 / cpt74177
- C.T. SCAN/BODY (1 activities)
  - 71260 - CT THORAX W/DYE / C / cpt71260
- C.T. SCAN/HEAD (2 activities)
  - 70460 - CT HEAD/BRAIN W/DYE / C / cpt70460
  - 70491 - CT SOFT TISSUE NECK W/DYE / C / cpt70491
- CLINIC (6 activities)
  - 99214 - OFFICE/OUTPATIENT VISIT EST / C / cpt99214
  - Physical Examination (PE) / X
  - Pulse / X
  - Respiratory Rate / X
  - Temperature / X
  - Weight / X
- ECG/EKG (1 activities)
  - 93005 - ELECTROCARDIOGRAM TRACING / CNMS / cpt93005

2015-07-08 133529 / Screening / Screening / visit 2 (1 activities)
- C.T. SCAN/BODY (1 activities)
  - 71260 - CT THORAX W/DYE / C
AR-AERS

Adverse Event Reporting System

AR-AERS Instance: Staging

[Image of AR-AERS interface]

- Affected System: [CTCAE] Cardiac Disorders
- AE Category: All, Symptoms, Diagnosis, Others
- Adverse Event: [Diagnosis] Acute coronary syndrome
- Description: A disorder characterized by signs and symptoms related to acute ischemia of the myocardium secondary to coronary artery disease. The clinical presentation covers a spectrum of heart diseases from unstable angina to myocardial infarction.
- Onset Date: 2017-09-07
- Assessment Date: 2017-09-07
- Onset Grade: Grade 3: Symptomatic, unstable angina and/or acute myocardial infarction, cardiac enzymes abnormal, hemodynamically stable
- Comments:
- Baseline? Baseline: Yes
- Lab AE? Yes
- Serious AE? Yes
- Expected AE? Yes
- Action Taken: -- select an action --
- Clinical Significant? Yes
S1320, "A Randomized, Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib (NSC-763/60) and Trametinib (NSC-76393) in BRAFV600E/K Mutant Melanoma."

This protocol is: Open; Open for enrollment, NOT published internally

Approved by the IRB on 04/14/2015

The purpose of this study is to compare any good and bad effects of receiving the drugs dabrafenib and trametinib continuously to receiving dabrafenib and trametinib with a break in treatment. Dabrafenib and trametinib are similar to vemurafenib and have ...

Contact Neitrisha Harris at for more details. More about IRB #203655...

SWOG 0931, EVEREST: Everolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study

This protocol is: Open; Closed for enrollment, Published internally

Approved by the IRB on 07/05/2011

The purpose of this study is to see whether treatment with everolimus after surgery for kidney cancer will increase the
Application Connections

Epic
  Adverse Events
AR-AERS
LimeSurvey
CLARA
User Permissions
RPRS
MRN
Patient’s Study Status
User Permissions & Participant Info
User Permissions
ET
User Permissions
REDCap
Participant Info
OpenClinica
User Permissions
AR-PSC
Participant Info
User Permissions
Access to AR-CRIS

- CRIS.uams.edu
- “Access Request”
Access to AR-CRIS

- If “User Request” form is required:
  - Log in to AR-CRIS or request an account
  - Complete form

  Do you have an AR-CRIS account or a UAMS employee login?
  
  (Students will request an AR-CRIS account the first time they request access.)

  Yes, Login   No, Request AR-CRIS Account
Access to AR-CRIS

Access Request Form

To submit an access request please, fill out the form below and press "Submit Request." You must select a minimum of one instance and at least provide the information listed with an asterisk (*) under the "Personal information" section. Some of this can be looked up by filling in fields with the [ ] indicator.

Note: Some applications do not require an access request to be submitted (i.e., TrialSearch or RedCap). Please check the application before submitting an access request if you are uncertain. With these applications, UAMS users, faculty, staff, and students can log in to the site with their domain name/password.

<table>
<thead>
<tr>
<th>Application</th>
<th>Instances</th>
</tr>
</thead>
<tbody>
<tr>
<td>AERS</td>
<td>☐ Training ☐ Production</td>
</tr>
<tr>
<td>caTissue</td>
<td>☐ TMI ☐ Tissue Procurement ☐ ACH</td>
</tr>
<tr>
<td>CRIS Dashboard</td>
<td>☑ Check my dashboard assignments</td>
</tr>
<tr>
<td>CRIS Reports</td>
<td>☐ TRI ☐ Other ☐ CCTRA</td>
</tr>
<tr>
<td>Event Tracker</td>
<td>☐ Training ☐ Production</td>
</tr>
</tbody>
</table>
Access to AR-CRIS

- Access Request Form

- Personal information
  - First name: Robin
  - Last name: Richardson
  - Username: RichardsonRobinF
  - Email Address: RFRichardson@uams.edu
  - Supervisor's Email Address:
    - TCWalls@uams.edu
  - Associated Organization: INFO Development Systems

- Requesting access to
  (Study IRBs for OpenClinica, RPRS, or caTissue)

- Notes
  - Unlisted application? Mention it here.
Getting Help with AR-CRIS

- User guides and tutorial videos
Getting Help with AR-CRIS

- User guides and tutorial videos
Getting Help with AR-CRIS

- User Support
Questions?