

Adverse Event Reporting System (AERS)

AERS is an application developed to allow clinical research staff to collect adverse event, AE, information from patients using Common Terminology Criteria for Adverse Events, version 4, CTCAE v4, event definitions. Research staff can review ongoing AEs, review previously resolved AEs, and enter new AEs for a patient.

Accessing AERS

AERS is accessible from the Clinical Trial Management System, CTMS, dashboard or through a link in EPIC. When accessing AERS through the CTMS dashboard, research staff must search for the specific study in which the patient is enrolled, then search for the patient. When accessing AERS through EPIC, staff will be taken directly to the patient's AE record.

CTMS Dashboard

1. To search for a research study, go to the **IRB Number** or the **Study Title** search box, enter the appropriate information, and click **[Search Study]**.
Note: The most recent studies that you have searched for are listed in the Study Protocols List.
2. Select the study in which the patient is currently enrolled by clicking the IRB Number in the Study Protocols list.

The screenshot shows the AERS web application interface. At the top, there is a header with the AERS logo and the University of Arkansas for Medical Sciences (UAMS) logo. Below the header, there is a search section with two input fields: 'IRB Number' and 'Study Title'. A 'Search' button is located to the right of the 'Study Title' field. Below the search fields, there is a table titled 'Study Protocols'. The table has three columns: 'IRB Number', 'Study Title', and 'Patient's Modified Adverse Event'. The first row of the table shows '90029' in the IRB Number column and 'Study for Clinic in Adverse System' in the Study Title column. The second row shows '90049' in the IRB Number column and 'A Multicenter Treatment Protocol for Expanded Access Use of Zoledronic Acid (ZOMETA) in Subjects with Unresectable Stage III or Stage IV Metastatic' in the Study Title column. Below the table, there is a footer section with 'User Name: [blank]', 'Copyright © 2002-2011 University of Arkansas for Medical Sciences', and 'UAMS Research Portal'.

3. Once you are in a research study, search for patients by typing in the patient medical record number or patient name into either the **MRN** or **Patient Name** search

box and click **[Search AE]**.

Note: The most recent patients you have edited or searched for are listed in the Patient List.

4. Click **Add New AE Patient** if this is the first time you are entering AE data for a patient or click on the Patient MRN to navigate to the adverse event collection screen.

The screenshot displays the AERS (Adverse Event Reporting System) interface. At the top, the 'AERS' logo is prominent, followed by 'ADVERSE EVENT REPORTING SYSTEM'. To the right, the 'UAMS' logo and 'UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES' are visible. Below the header, there are search fields for 'MRN', 'Patient Name', and 'Study Title'. A 'Patient List' table is visible with columns for 'Patient MRN', 'Patient First Name', and 'Patient Last Name'. Two yellow callouts labeled 'Step 1' and 'Step 2' point to the 'MRN' and 'Patient Name' fields respectively. The footer contains copyright information and a 'UAMS Research Form' link.

EPIC

1. When in the patient's chart, type **.aers** into the form to initiate the jump from EPIC to AERS.

Adverse Events


Once inside a patient's AE record, there are seven tabs: New AEs, Resolved AEs, No AEs, Medical History, LAB AEs, Abnormal Lab Non-AE, and Ongoing AEs:

- **New AEs** tab allows research staff to create new AEs. This is the default tab when entering a patient's AE record and there are no existing records on AERS.
- **Resolved AEs** tab allows review of all AEs that have been reported and resolved.
- **No AEs** tab allows research staff to report that there are no AEs. This function is not available if there are any current, ongoing AEs.
- **Medical History** tab allows review of ongoing medical history AEs.
- **LAB AEs** tab allows review of all Lab based AEs that pushed by CALAEGS. Those out of range with empty grade AEs would not be sent to EPIC.
- **Abnormal Lab Non-AE** tab allows review of all Lab based AEs that have been

graded as No Grade:Non AE, abnormal lab result. This tab would not be sent to EPIC and will be moved to LAB AEs tab if the grade is changed to normal grades.

- **Ongoing AEs** tab allows research staff to review all AEs currently ongoing and not resolved. This is the default tab when entering a patients AE record.


Note: The number on each tab indicates the number of AEs on the tab. The reminding redbox shows the tab needs to be viewed before hitting the submit button on the ongoing Tab.



AERS

ADVERSE EVENT REPORTING SYSTEM

[CTCAE 4](#) | [CTCAE 3](#) | [HOME](#) | [LOGOUT](#) | [PROJECTS](#) | [CHANGES](#)



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Patient Identifier: 00000789539
Patient Name: ABBIE UAMSTEST

Related IRB: 110396 - (IRB#110396) Vaccination of High Risk Breast Cancer Patients

New AEs

Resolved AEs

No AEs

Medical History [1]

LAB AEs [1]

Abnormal Lab Non-AE [0]

Ongoing AEs [4]

AE ID: 40051 Created by chawndia on 2012-08-22 14:16:40 1

Reporting a New Adverse Event

1) Type **.aers** to go from EPIC to AERS.

2) Click on the **New AEs** tab in AERS.

3) Select the dictation tag number that was inserted into the form in EPIC

Note: The Tag dropdown will only show the last three visiting dates of this patient. If no select options show, please enter the tag number on the textbox.

Tag Number: [10000007615398] US ABDOMEN COMPLETE (2015-06-16 11:00:00 at US)

Enrolling Provider: [10000007615398] US ABDOMEN COMPLETE (2015-06-16 11:00:00 at US)

[10000008087435] RETURN GYN (2015-06-24 15:15:00 at FCPOB) For Provider: SAMANTHA MCKELVEY

(LastName, FirstName)

4) The Enrolling provider name will be prefilled if exist. If you wish to change to other provider, enter the enrolling provider's last name and first name on the textbox, a suggestion list of providers will showed. Please select the name of provider on the list to properly retrieve correct provider information. This will be the physician that is treating the patient.

Enrolling Provider: hutchi

(LastName, FirstName)

001181 [Hutchins Laura]

005595 [Hutchins David]

5) Enter the onset date of the adverse event by selecting a date from the popup calendar

Onset Date: 2015-07-01

Select Affected System: [4] July [2015]

Medical History Event?

Is it a Serious AE?

Event

Is it a Solicited AE?

SU	MO	TU	WE	TH	FR	SA
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

6) Select the affected system from the **Select Affected System** dropdown menu. This selection is based on the CTCAE version associated with the related IRB of this Patient.

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Patient Identifier: 00000
Patient Name: ABBIE UAI
Related IRB: 110396 - (I)

New AEs | Resolved AEs | Ongoing AEs [4]

Tag Number:
Enrolling Provider:
Onset Date:
Select Affected System: Select Affected System

Medical History Event? ☐ Yes ☒ No
Is it a Serious AE? ☐ Yes ☒ No
Event ☐ Expected ☒ Unexpected

Select Affected System:
[CTCAE4] Blood and lymphatic system disorders
[CTCAE4] Cardiac disorders
[CTCAE4] Congenital, familial and genetic disorders
[CTCAE4] Ear and labyrinth disorders
[CTCAE4] Endocrine disorders
[CTCAE4] Eye disorders
[CTCAE4] Gastrointestinal disorders
[CTCAE4] General disorders and administration site conditions
[CTCAE4] Hepatobiliary disorders
[CTCAE4] Immune system disorders
[CTCAE4] Infections and infestations
[CTCAE4] Injury, poisoning and procedural complications
[CTCAE4] Investigations
[CTCAE4] Metabolism and nutrition disorders
[CTCAE4] Musculoskeletal and connective tissue disorders
[CTCAE4] Neoplasms benign, malignant and unspecified (incl cysts and polyps)
[CTCAE4] Nervous system disorders
[CTCAE4] Pregnancy, puerperium and perinatal conditions
[CTCAE4] Psychiatric disorders

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<< Go Back

- 7) Select the category of the selected affected system from the **Search By** dropdown menu.

(Lastname, Firstname)

Onset Date: 2015-07-01

Select Affected System: [CTCAE4] Eye disorders

Search By: Select Category

Medical History Event? Select Category

Is it a Serious AE? Symptoms

Event ☐ Expected ☒ Unexpected

Is it a Solicited AE? ☐ Yes ☒ No

Is it related to a study? ☐ Yes ☒ No

Diagnosis

Symptoms

- 8) Select the adverse event from the **Select Adverse Event** dropdown menu. Mouse hover will show description of this Adverse Event. If you see an event is grayed out, it means it already exist on this patient. Please check on other tabs for the review.

Onset Date: 2015-07-01

Select Affected System: [CTCAE4] Eye disorders

Search By: Symptoms

Adverse Event: Select Adverse Event

Medical History Event? Select Adverse Event

Is it a Serious AE? Blurred vision

Event Eye pain

Is it a Solicited AE? Flashing lights

Is it related to a study? Floaters

Night blindness

Watery eyes

Dry eye.
A disorder characterized by dryness of the cornea and conjunctiva..

- 9) If the adverse event is a medical history event, click on **Yes** next to “**Medical History Event?**”.

Note: This AE will be moved to Medical History Tab after done grading.

Medical History Event? ☒ Yes ☐ No

10) If the adverse event is a serious AE, click on **Yes** next to “**Is a Serious AE?**”.

Is it a Serious AE? ☒ Yes ☐ No

11) If the adverse event is expected, click on **Expected** next to “**Event**”.

Event ☒ Expected ☐ Unexpected

12) If the adverse event is a solicited AE, click on **Yes** next to “**Is a Solicited AE?**”.

Is it a Solicited AE? ☒ Yes ☐ No

13) If the adverse event is related to a study, click on **Yes** next to “**Related to a study?**”.

Note: The default option is “No” and if the adverse event is not related to the study, you will skip to Step 22.

Is it related to a study? ☒ Yes ☐ No

14) Click on one of the Study Relatedness options: **Unlikely**, **Possible**, **Probably**, or **Definite** and click Save.

Study Relatedness ☐ Unlikely ☒ Possible ☐ Probably ☐ Definite

15) If the adverse event is related to the study therapy, click on **Yes** next to “**Related to a study therapy?**”.

Note: The default option is “No” and if the adverse event is not related to the study therapy, you may skip to Step 22.

Related to a study therapy? ☒ Yes ☐ No

16) If the adverse event is related to a study drug, click on **Yes** next to “**Related to drugs?**”

Related Drug: ☒ Yes ☐ No

17) Select the study drug that the adverse event is related from the drug list and click Save. Click **Add Drug** if there is more drugs related.

Note: A drug list will only show when there has related drug on the study.

Related Drug: [Save](#)

Related Device:

Related to others?

18) If the adverse event is related to a study device, click on **Yes** next to “**Related to Device?**”

Related Device: ☒ Yes ☐ No

19) Select the study device that the adverse event is related from the device list and click Save. Click **Add Device**

Note: A device list will only show when there has related device on the study.

Related Device: ☒ Yes ☐ No

Related Device: [Add Device](#)

20) If the adverse event is related to the study in some other way, such as a procedural reaction, click on **Yes** next to “**Related to Others?**”

Related to others? ☒ Yes ☐ No

21) Enter the description or name on the textbox next to **Related Others** and Click **Save**. Click **Add Others** if there is more others related.

Related Others: [Delete](#)

[Add Others](#)

22) Click **Go Survey** to navigate to the Adverse Event grading page.

[Go Survey](#)

- 23) Select the grade of the adverse event by clicking on the button next to the corresponding grade, and enter any comments related to the adverse event that you feel are necessary.
- 24) Click on Submit to commit the adverse event or **<< Previous** to return to the adverse event selection page.
- 25) Once you have submitted the adverse event, it will appear under the **Ongoing AEs** tab.

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Patient Identifier: 00000789539
Patient Name: ASBIE UANTEST

Related IRB: 110396 - (IRB#110396) Vaccination of High Risk Breast Cancer Patients

Tag Number: 10000007815398
Enrolling Provider: Hutchins, Laura (LastName, FirstName)
Onset Date: 2015-07-01
Select Affected System: [CTCAE4] Eye disorders
Search By: Symptoms
Adverse Event: Dry eye
Medical History Event: ☒ Yes ☐ No
Is it a Serious AE? ☒ Yes ☐ No
Event: ☒ Expected ☐ Unexpected
Is it a Solicited AE? ☒ Yes ☐ No
Is it related to a study? ☒ Yes ☐ No
Study Relatedness: ☐ Unlikely ☒ Possible ☐ Probable ☐ Definite
Related to a study therapy? ☒ Yes ☐ No
Related Drug: ☒ Yes ☐ No
Related Drug: [IRB:110396] P105-PA0RE [Save](#)
Related Device: ☐ Yes ☒ No
Related to others: ☒ Yes ☐ No
Related Others: procedural reaction [Delete](#)
[Add Others](#)
[Go Survey](#)

User Name: chenwanchi Preferences
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UAMS Research Portal

CTCAE4 Eye Disorders

0% ☐ 100%

Eye disorders

***Dry eye**
A disorder characterized by dryness of the cornea and conjunctiva.

Choose one of the following answers

☒ Grade 1: Asymptomatic; clinical or diagnostic observations only; mild symptoms relieved by lubricants
☐ Grade 2: Symptomatic; multiple agents indicated; limiting instrumental ADL
☐ Grade 3: Decrease in visual acuity (<20/40); limiting self care ADL

Please enter your comment here:

[<< Previous](#) [Submit](#)

Reviewing and Updating Ongoing AEs

The default tab in AERS is **Ongoing AEs**, allowing for quick review and update of all ongoing adverse events. All adverse events that have not been resolved previously are displayed in the **Medical History/Lab/Abnormal Lab Non-AE/Ongoing AEs** tabs. Adverse events in those tabs can be updated as **ongoing without grade change**, **ongoing with grade change**, or **resolved**.

Change onset fields on AE

All fields on the AE is editable if it has not been sent to EPIC yet. Simply click on the pencil icon next the fields you would like to change and click on the save icon after the change made.

Patient Identifier: 00000789539
Patient Name: ABBIE UAMSTEST
<< Go Back

Related IRB: 110396 - (IRB#110396) Vaccination of High Risk Breast Cancer Patients

AE ID: 2337 [Onset Created by chenwanchi on 2015-07-28 15:55:37]

Enrolling Provider: Hutchins,David (LastName, FirstName)
Description: Dry eye
A disorder characterized by dryness of the cornea and conjunctiva.

Comments: Testing

Is it a Medical History? ☒ Yes ☐ No
Is it a Solicited AE? ☒ Yes ☐ No
Is it Related to Study? ☒ Yes ☐ No
Related to a study therapy? ☒ Yes ☐ No

Is it a Serious AE? ☒ Yes ☐ No
Event ☒ Expected ☐ Unexpected
Study Relatedness ☒ Unlikely ☐ Possible ☐ Probably ☐ Definite

Related Drug: P105-PADRE [Delete](#)
[Add More]

Related Device: [Add More]

Related Others: procedural reaction [Delete](#)
[Add More]

Onset Date: 2015-07-01
Onset Grade: Grade 1: Asymptomatic; clinical or diagnostic observations only; mild symptoms relieved by lubricants

Change Status: ☒ Ongoing ☐ Resolved

[Submit To EPIC/OC](#) [Delete AE](#)

Delete AE

AE can be deleted if it has not been sent to EPIC yet. Just click on Delete button.

Change Status: ☒ Ongoing ☐ Resolved

[Submit To EPIC/OC](#) [Delete AE](#)

Ongoing Without Grade Change

1. Select the **Ongoing** radio button to the right of **Change Status** in the AE that you wish to update. A redbox indicates this AE needs assessment.

AE ID: 1981 [Onset Created by chenwanchi on 2013-04-04 16:30:18]

Enrolling Provider: Hutchins, Laura (LastName, FirstName)

Description: Back pain
A disorder characterized by marked discomfort sensation in the back region.

Comments:

Is it a Medical History? ☐ Yes ☒ No

Is it a Solicited AE? ☐ Yes ☒ No

Is it Related to Study? ☐ Yes ☒ No

Related to a study therapy? ☐ Yes ☒ No

Onset Date: 2013-04-04

Onset Grade: Grade 1: Mild pain

Change Status: ☒ Ongoing ☐ Resolved

Ongoing Status: Click on the contents to edit if the ongoing has not been sent to

Date	Grade	Comment	Assessment Date	Admin
2013-11-11	Grade 1: Mild pain	1112	2013-11-12 15:13:50	Wanchi Chen Epic Sent OC Failed

Show All Ongoing

2. Click **No** on the **Grade Changed?** Box.

Grade Changed?

YES NO CANCEL

3. A new ongoing record will showed on the table of ongoing status. The ongoing date will be the assessment date and the grade and comment will be the same as the lastest onset/ongoing assessment.

ADVERSE EVENT REPORTING SYSTEM

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Patient Identifier: 00000789539

Patient Name: ABBIE UAMSTEST

Related IRB: 110396 - (IRB# 110396) Vaccination of High Risk Breast Cancer Patients

AE ID: 1981 [Onset Created by chenwanchi on 2013-04-04 16:30:18]

Enrolling Provider: Hutchins, Laura (LastName, FirstName)

Description: Back pain
A disorder characterized by marked discomfort sensation in the back region.

Comments:

Is it a Medical History? ☐ Yes ☒ No

Is it a Solicited AE? ☐ Yes ☒ No

Is it Related to Study? ☐ Yes ☒ No

Related to a study therapy? ☐ Yes ☒ No

Onset Date: 2013-04-04

Onset Grade: Grade 1: Mild pain

Change Status: ☐ Ongoing ☒ Resolved

Ongoing Status: Click on the contents to edit if the ongoing has not been sent to

Date	Grade	Comment	Assessment Date	Admin
2015-07-28	Grade 1: Mild pain	1112	2015-07-28 16:09:51	chenwanchi Delete

Show All Ongoing

Submit To EPIC/OC

AE ID: 1998 [Onset Created by chenwanchi on 2013-08-23 14:16:40]

- If you would like to change the ongoing date, click on the column of the Date you wish to change, a calendar will pop up. Select a date and then click “YES” on another pop up confirm window.

A disorder characterized by marked discomfort sensation in the back region.

Comments:

Is it a Medical History? ☐ Yes ☐ No

Is it a Solicited? ☐ Yes ☐ No

Is it Related to a Study? ☐ Yes ☐ No

Related to a study therapy? ☐ Yes ☐ No

Onset Date:

Onset Grade:

Change Status: ☐ Ongoing ☐ Resolved

Submit To EPIC/OC

Ongoing Status: ☐ Ongoing ☐ Resolved

Click on the contents to edit if the ongoing has not been sent to EPIC/OC

Date	Grade	Comment	Assessment Date	Admin
2015-07-28	Grade 1: Mild pain	1112	2015-07-28 16:09:51	Delete



AE ID:

Enrolling Provider:

Description:

13-08-23 14:16:40

the amount of hemoglobin in 100 ml of blood. Signs and symptoms of anemia may include pale skin, shortness of breath, palpitations of the heart, soft systolic murmurs, lethargy,

- If you would like to change comment of ongoing AE, click on the comment you wish to change. The background color of comment will become white and a save  and a cancel  icons will show. Enter your comment and click on save icon to make changes

Change Status: ☐ Ongoing ☐ Resolved

Submit To EPIC/OC

Ongoing Status: ☐ Ongoing ☐ Resolved

Click on the contents to edit if the ongoing has not been sent to EPIC/OC

Date	Grade	Comment	Assessment Date	Admin
2015-07-28	Grade 1: Mild pain	1112	2015-07-28 16:09:51	Delete

Show All Ongoing

- If there is more than one ongoing records on this AE, you will see a show all ongoing link under the ongoing table. Click on it to view more ongoing records if need.

Onset Date:

Onset Grade:

Change Status: ☐ Ongoing ☐ Resolved

Submit To EPIC/OC

Ongoing Status: ☐ Ongoing ☐ Resolved

Click on the contents to edit if the ongoing has not been sent to EPIC/OC

Date	Grade	Comment	Assessment Date	Admin
2015-07-28	Grade 1: Mild pain	1112	2015-07-28 16:09:51	Delete

Show All Ongoing

- If the ongoing has not been sent to EPIC, you will see a delete link at Admin column. Click on it to delete the ongoing record

Onset Date:

Onset Grade:

Change Status: ☐ Ongoing ☐ Resolved

Submit To EPIC/OC

Ongoing Status: ☐ Ongoing ☐ Resolved

Click on the contents to edit if the ongoing has not been sent to EPIC/OC

Date	Grade	Comment	Assessment Date	Admin
2015-07-28	Grade 1: Mild pain	1112	2015-07-28 16:09:51	Delete

Show All Ongoing

Ongoing With Grade Change

1. Select the **Ongoing** radio button to the right of **Change Status** in the AE that you wish to update.

AE ID: 1981 [Onset Created by chenwanchi on 2013-04-04 16:30:18]

Enrolling Provider: Hutchins, Laura (LastName, FirstName)

Description: Back pain
A disorder characterized by marked discomfort sensation in the back region.

Comments:

Is it a Medical History? ☐ Yes ☒ No

Is it a Solicited AE? ☐ Yes ☒ No

Is it Related to Study? ☐ Yes ☒ No

Related to a study therapy? ☐ Yes ☒ No

Onset Date: 2013-04-04

Onset Grade: Grade 1: Mild pain

Change Status: ☒ Ongoing ☐ Resolved

Ongoing Status:

Date	Grade	Comment	Assessment Date	Admin
2013-11-11	Grade 1: Mild pain	1112	2013-11-12 15:13:50	Epic Sent OC Failed

Show All Ongoing

2. Click **Yes** on the **Grade Changed?** box.

3. Select the new grade in the **Ongoing AE Grade Change** window.

Anemia
A disorder characterized by an reduction in the amount of hemoglobin in 100 ml symptoms of anemia may include pallor of the skin and mucous membranes, sh palpitations of the heart, soft systolic murmurs, lethargy, and fatigability.

☐ Grade 1: Hemoglobin (Hgb) Less than LLN - 10.0 g/dL; Less than LLN - 6.2 mm

☐ Grade 2: Hgb <10.0 - 8.0 g/dL; <6.2 - 4.9 mmol/L; <100 - 80g/L

☐ Grade 3: Hgb <8.0 g/dL; <4.9 mmol/L; <80 g/L; transfusion indicated

☐ Grade 4: Life-threatening consequences; urgent intervention indicated

☐ Grade 5: Death

Comment: ffgdsd

Ongoing Date:

SAVE CANCEL

Note: Previous comments will be brought forward to the comment box in the grade change window. Change it if need.

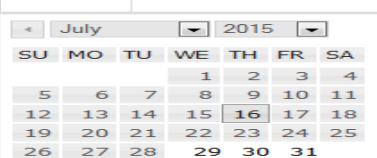
4. Select the **Ongoing Date**.

Ongoing AE Grade Change

Anemia
A disorder characterized by an reduction in the amount of hemoglobin in 100 ml of blood. Signs and symptoms of anemia may include pallor of the skin and mucous membranes, shortness of breath, palpitations of the heart, soft systolic murmurs, lethargy, and fatigability.

☒ Grade 1: Hemoglobin (Hgb) Less than LLN - 10.0 g/dL; Less than LLN - 6.2 mmol/L; Less than LLN
☐ Grade 2: Hgb <10.0 - 8.0 g/dL; <6.2 - 4.9 mmol/L; <100 - 80g/L
☐ Grade 3: Hgb <8.0 g/dL; <4.9 mmol/L; <80 g/L; transfusion indicated
☐ Grade 4: Life-threatening consequences; urgent intervention indicated
☐ Grade 5: Death

Comment: Here is a new changes

Ongoing Date: 

☐ Yes ☒ No
☒ Expected ☐ Unexpected
☐ Unlikely ☐ Possible ☐ Probably ☐ Definite

5. Click **Save** to save.

Ongoing AE Grade Change

Anemia
A disorder characterized by an reduction in the amount of hemoglobin in 100 ml of blood. Signs and symptoms of anemia may include pallor of the skin and mucous membranes, shortness of breath, palpitations of the heart, soft systolic murmurs, lethargy, and fatigability.

☒ Grade 1: Hemoglobin (Hgb) Less than LLN - 10.0 g/dL; Less than LLN - 6.2 mmol/L; Less than LLN
☐ Grade 2: Hgb <10.0 - 8.0 g/dL; <6.2 - 4.9 mmol/L; <100 - 80g/L
☐ Grade 3: Hgb <8.0 g/dL; <4.9 mmol/L; <80 g/L; transfusion indicated
☐ Grade 4: Life-threatening consequences; urgent intervention indicated
☐ Grade 5: Death

Comment: Here is a new changes

Ongoing Date: 2015-07-01

SAVE **CANCEL**

Resolved AE

1. Select the **Resolved** button to the right of **Change Status** in the AE that you wish to update. Related resolved fields will show up when it is selected.

AE ID: 1981 [Onset Created by chenwanchi on 2013-04-04 16:30:18]

Enrolling Provider: Hushins,Laura (LastName, FirstName)

Description: Back pain
A disorder characterized by marked discomfort sensation in the back region.

Comments:

Is it a Medical History? ☐ Yes ☒ No
 Is it a Solicited AE? ☐ Yes ☒ No
 Is it Related to Study? ☒ Yes ☐ No
 Related to a study therapy? ☐ Yes ☒ No

Onset Date: 2013-04-04
 Onset Grade: Grade 1: Mild pain

Change Status: ☐ Ongoing ☒ Resolved

End Date: **Resolved**

Resolved Comment:

Ongoing Status: Click on the contents to edit if the ongoing has not been sent to

Date	Grade	Comment	Assessment Date	Admin
2013-11-11	Grade 1: Mild pain	1112	Wanchi Chen	Epic Sent PC

2. Enter the **End Date** of the AE.

AE ID: 1981 [Onset Created by chenwanchi on 2013-04-04 16:30:18]

Enrolling Provider: Hutchins, Laura (LastName, FirstName)

Description: Back pain
A disorder characterized by marked discomfort sensation in the back region.

Comments:

Is it a Medical History? ☐ Yes ☒ No

Is it a Solicited AE? ☐ Yes ☒ No

Is it Related to Study? ☐ Yes ☒ No

Related to a study therapy? ☐ Yes ☒ No

Onset Date: 2013-04-04

Onset Grade: Grade 1: Mild pain

Change Status: ☐ Ongoing ☒ Resolved

End Date: 2015-07-28

Resolved Comment:

Ongoing Status: ☐ Ongoing ☒ Resolved

Click on the contents to edit if the ongoing has not been sent to

SU	MO	TU	WE	TH	FR	SA
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

Comment	Assessment Date	Admin
1112	2013-11-12 15:13:50	Wanchi Chen Epic Sent OC Failed

Show All Ongoing

3. Enter the **Resolved Comment** of the AE.

AE ID: 1981 [Onset Created by chenwanchi on 2013-04-04 16:30:18]

Enrolling Provider: Hutchins, Laura (LastName, FirstName)

Description: Back pain
A disorder characterized by marked discomfort sensation in the back region.

Comments:

Is it a Medical History? ☐ Yes ☒ No

Is it a Solicited AE? ☐ Yes ☒ No

Is it Related to Study? ☐ Yes ☒ No

Related to a study therapy? ☐ Yes ☒ No

Onset Date: 2013-04-04

Onset Grade: Grade 1: Mild pain

Change Status: ☐ Ongoing ☒ Resolved

End Date: 2015-07-28

Resolved Comment:

Ongoing Status: ☐ Ongoing ☒ Resolved

Click on the contents to edit if the ongoing has not been sent to

Date	Grade	Comment	Assessment Date	Admin
2013-11-11	Grade 1: Mild pain	1112	2013-11-12 15:13:50	Wanchi Chen Epic Sent OC Failed

Show All Ongoing

4. Click **Resolved**.

AE ID: 1981 [Onset Created by chenwanchi on 2013-04-04 16:30:18]

Enrolling Provider: Hutchins, Laura (LastName, FirstName)

Description: Back pain
A disorder characterized by marked discomfort sensation in the back region.

Comments:

Is it a Medical History? ☐ Yes ☒ No

Is it a Solicited AE? ☐ Yes ☒ No

Is it Related to Study? ☐ Yes ☒ No

Related to a study therapy? ☐ Yes ☒ No

Onset Date: 2013-04-04

Onset Grade: Grade 1: Mild pain

Change Status: ☐ Ongoing ☒ Resolved

End Date: 2015-07-28

Resolved Comment:

Ongoing Status: ☐ Ongoing ☒ Resolved

Click on the contents to edit if the ongoing has not been sent to

Date	Grade	Comment	Assessment Date	Admin
2013-11-11	Grade 1: Mild pain	1112	2013-11-12 15:13:50	Wanchi Chen Epic Sent OC Failed

Show All Ongoing

5. This AE will be moved to Resolved tab after it is sent to EPIC.