

# Adverse Event

study\_unique\_id

\_\_\_\_\_

adverse\_event\_number

\_\_\_\_\_

sae\_cardiac\_experience\_onset\_date

\_\_\_\_\_

sae\_cardiac\_experience\_onset\_time

\_\_\_\_\_

sae\_cardiac\_experience\_resolve\_date

\_\_\_\_\_

sae\_cardiac\_experience\_resolve\_time

\_\_\_\_\_

sae\_cardiac\_experience\_due\_to\_hypothermia

- ☐ false  
☐ not likely  
☐ possibly  
☐ probably  
(SAEAttributable)

sae\_cardiac\_experience\_action\_taken

- ☐ no change  
☐ hypothermia discontinued  
(SAEAction)

sae\_cardiac\_experience\_outcome

- ☐ completely resolved  
☐ resolved with sequelae  
☐ patient died  
☐ not resolved  
(SAEOutcome)

sae\_cardiac\_experience\_comment

\_\_\_\_\_

sae\_metabolic\_acidosis\_onset\_date

\_\_\_\_\_

sae\_metabolic\_acidosis\_onset\_time

\_\_\_\_\_

sae\_metabolic\_acidosis\_resolve\_date

\_\_\_\_\_

sae\_metabolic\_acidosis\_resolve\_time

\_\_\_\_\_

sae_metabolic_acidosis_due_to_hypothermia	<input type="radio"/> false <input type="radio"/> not likely <input type="radio"/> possibly <input type="radio"/> probably (SAEAttributable)
sae_metabolic_acidosis_action_taken	<input type="radio"/> no change <input type="radio"/> hypothermia discontinued (SAEAction)
sae_metabolic_acidosis_outcome	<input type="radio"/> completely resolved <input type="radio"/> resolved with sequelae <input type="radio"/> patient died <input type="radio"/> not resolved (SAEOutcome)
sae_metabolic_acidosis_comment	_____
sae_thrombosis_experience_onset_date	_____
sae_thrombosis_experience_onset_time	_____
sae_thrombosis_experience_resolve_date	_____
sae_thrombosis_experience_resolve_time	_____
sae_thrombosis_experience_due_to_hypothermia	<input type="radio"/> false <input type="radio"/> not likely <input type="radio"/> possibly <input type="radio"/> probably (SAEAttributable)
sae_thrombosis_experience_action_taken	<input type="radio"/> no change <input type="radio"/> hypothermia discontinued (SAEAction)
sae_thrombosis_experience_outcome	<input type="radio"/> completely resolved <input type="radio"/> resolved with sequelae <input type="radio"/> patient died <input type="radio"/> not resolved (SAEOutcome)
sae_thrombosis_experience_comment	_____
sae_bleeding_experience_onset_date	_____
sae_bleeding_experience_onset_time	_____

---

sae\_bleeding\_experience\_resolve\_date

---

---

sae\_bleeding\_experience\_resolve\_time

---

---

sae\_bleeding\_experience\_due\_to\_hypothermia

☐ false  
☐ not likely  
☐ possibly  
☐ probably  
(SAEAttributable)

---

---

sae\_bleeding\_experience\_action\_taken

☐ no change  
☐ hypothermia discontinued  
(SAEAction)

---

---

sae\_bleeding\_experience\_outcome

☐ completely resolved  
☐ resolved with sequelae  
☐ patient died  
☐ not resolved  
(SAEOutcome)

---

---

sae\_bleeding\_experience\_comment

---

---

sae\_alteration\_skin\_integrity

☐ false  
☐ erythema  
☐ sclerema  
☐ cyanosis  
☐ subcutaneous fat necrosis  
☐ true  
(SAEAlterationSkinIntegrity)

---

---

sae\_alteration\_skin\_integrity\_onset\_date

---

---

sae\_alteration\_skin\_integrity\_resolve\_date

---

---

sae\_alteration\_skin\_integrity\_due\_to\_hypothermia

☐ false  
☐ not likely  
☐ possibly  
☐ probably  
(SAEAttributable)

---

---

sae\_alteration\_skin\_integrity\_action\_taken

☐ no change  
☐ hypothermia discontinued  
(SAEAction)

---

---

sae\_alteration\_skin\_integrity\_outcome

☐ completely resolved  
☐ resolved with sequelae  
☐ patient died  
☐ not resolved  
(SAEOutcome)

---

---

sae\_alteration\_skin\_integrity\_comment

---

---

sae\_death\_date

---

---

sae\_death\_time

---

---

sae\_death\_due\_to\_hypothermia

- ☐ false  
☐ not likely  
☐ possibly  
☐ probably  
(SAEAttributable)

---

sae\_death\_action\_taken

- ☐ no change  
☐ hypothermia discontinued  
(SAEAction)

---

sae\_death\_outcome

- ☐ completely resolved  
☐ resolved with sequelae  
☐ patient died  
☐ not resolved  
(SAEOutcome)

---

sae\_death\_comment

---

---

sae\_other

---

---

sae\_other\_onset\_date

---

---

sae\_other\_onset\_time

---

---

sae\_other\_resolve\_date

---

---

sae\_other\_resolve\_time

---

---

sae\_other\_due\_to\_hypothermia

- ☐ false  
☐ not likely  
☐ possibly  
☐ probably  
(SAEAttributable)

---

sae\_other\_action\_taken

- ☐ no change  
☐ hypothermia discontinued  
(SAEAction)

---

sae\_other\_outcome

- ☐ completely resolved  
☐ resolved with sequelae  
☐ patient died  
☐ not resolved  
(SAEOutcome)

sae\_other\_comment

---