

# MITRE / FLUX NOTES **TOXICITIES v14.7**

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## I MARKING “DONE” IN POC



Dr. Jraker299 referred ms. Debra24 Hernandez98Aj due to pain in left breast. Dr. Jraker299 is ms. Debra24 Hernandez98Aj's primary care physician for 12 years.

Summary

Checkboxes: 240 grey, 100% opacity

State 0: unfilled

State 1: Requirements are satisfied. Checkmark appears: 221 grey, weight 1.5

State 2: User clicks box, or there are no more choices to make. Box collapses to summary line. Checkmark: 170 grey, weight 2.

In this example:

action 1: select T1 and N2, Staging becomes "satisfied", State 1.

action 2: click staging box -> State 2.

action 3: click #ER "Negative" -> State 2

action 4: click #PR box -> State 2. This is equivalent to ignoring.

Progress  
10 April 2018

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Close



☒ > #Staging Tumor size T1 Node size N2 Metastasis No data  
Metastasis

☐ > #Disease status Status No data Reason No data Reference date No data As of date No data  
Status

☐ > #toxicity Adverse event Nausea Grade No data Attribution No data  
Grade

☐ > #HER2 Receptor No data  
Receptor

☐ > #ER Receptor No data  
Receptor

☐ > #PR Receptor No data  
Receptor

☐ > #enrollment Clinical trial No data  
Clinical trial



Dr. Jraker299 referred ms. Debra24 Hernandez98Aj due to pain in left breast. Dr. Jraker299 is ms. Debra24 Hernandez98Aj's primary care physician for 12 years.

### Summary

Ms. Debra24 Hernandez98Aj is a 51-year-old menopausal non hispanic or latino woman with invasive ductal carcinoma of the breast, diagnosed on 13 January 2012. Her most recent status, recorded on 15 May 2017, is of worsening, disease progression based on pathology, imaging, and symptoms.

She underwent a lumpectomy. She underwent a sentinel lymph node biopsy on 20 September 2012 which revealed infiltrating poorly differentiated ductal carcinoma, stage IV, estrogen receptor 0, etc.

diagnostic mammogram on 4 October 2013 revealed a 2 cm mass in the right breast at 7 o'clock and an

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> #Staging

Tumor size T0 Node size N2 Metastasis No data

> #Disease status

Status No data Reason No data Reference date No data As of date No data

Status

Complete  
response

Complete  
resection

Responding

Stable

Progressing

Inevaluable

> #toxicity

Adverse event Nausea Grade No data Attribution No data

Grade

Grade 1

Grade 2

Grade 3

Grade 4

> #HER2

Receptor No data

Receptor

Positive

Negative



> #ER

Receptor Negative



> #PR

Receptor No data

> #enrollment

Clinical trial No data

Clinical trial

PATINA

PALLAS

title

## 2 SEARCHING FOR ADVERSE EVENTS





Summary

Timeline

Medication

Dr. Jraker299 referred ms. Debra24 Hernandez98Aj due to pain in left breast. Dr. Jraker299 is ms. Debra24 Hernandez98Aj's primary care physician for 12 years.

## Summary



Ms. Debra24 Hernandez98Aj is a 51-year-old menopausal non hispanic or latino woman with [invasive ductal carcinoma of the breast](#), diagnosed on [13 January 2012](#). Her most recent status, recorded on [15 May 2017](#), is of [worsening](#), disease progression based on pathology, imaging, and

Initially, the Adverse event selector is populated with the 4 or 5 most common adverse events.

The user taps "Show More" if the desired one is missing.

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> #Staging

Tumor size [T1](#) Node size [N2](#) Metastasis [No data](#)

Metastasis

M0

M1



> #Disease status

Status [No data](#) Reason [No data](#) Reference date [No data](#) As of date [No data](#)

Status

Complete  
response

Complete  
resection

Responding

Stable

Progressing

Inevaluable



> #toxicity

Adverse event [No data](#) Grade [No data](#) Attribution [No data](#)

Adverse event

Nausea

Febrile  
Neutropenia

Fatigue

Anemia

Show More



> #HER2

Receptor [No data](#)

Receptor

Positive

Negative



> #ER

Receptor [No data](#)

Receptor

Positive

Negative



> #PR

Receptor [No data](#)

Receptor

Positive

Negative



> #enrollment

Clinical trial [No data](#)



Dr. Jraker299 referred ms. Debra24 Hernandez98Aj due to pain in left breast. Dr. Jraker299 is ms. Debra24 Hernandez98Aj's primary care physician for 12 years.

Summary

Ms. Debra24 Hernandez98Aj is a 51-year-old menopausal non hispanic or latino woman with invasive ductal carcinoma of the breast, diagnosed on 13 January 2012. Her most recent status, recorded on 15 May 2017, is of worsening, disease progression based on pathology, imaging, and

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> #Staging

Tumor size T1 Node size N2 Metastasis No data

Metastasis

M0

M1



> #Disease status

Status No data Reason No data Reference date No data As of date No data

Status

Complete response

Complete resection

Responding

Stable

Progressing

Inevaluable



> #toxicity

Adverse event No data Grade No data Attribution No data

Adverse event

Nausea

Febrile  
Neutropenia

Fatigue

Anemia

Diarrhea

Generalized  
Muscle Fatigue

Weight Loss

Insomnia

search for other

Prev 1-8 of 720 Next



> #HER2

Receptor No data

Receptor

Positive

Negative



> #ER

Receptor No data

Receptor

Positive

Negative



> #PR

Receptor No data

Receptor

Positive

Negative

The cell expands, exposing a second row of options, a search bar, and a tool to navigate the options.





Dr. Jraker299 referred ms. Debra24 Hernandez98Aj due to pain in left breast. Dr. Jraker299 is ms. Debra24 Hernandez98Aj's primary care physician for 12 years.

Summary

Ms. Debra24 Hernandez98Aj is a 51-year-old menopausal non hispanic or latino woman with invasive ductal carcinoma of the breast, diagnosed on 13 January 2012. Her most recent status, recorded on 15 May 2017, is of worsening, disease progression based on pathology, imaging, and

Progress  
10 April 2018

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Close



#Staging

Tumor size T1 Node size N2 Metastasis No data

Metastasis

M0

M1



#Disease status

Status No data Reason No data Reference date No data As of date No data

Status

Complete response

Complete resection

Responding

Stable

Progressing

Inevaluable



#toxicity

Adverse event No data Grade No data Attribution No data

Adverse event

Generalized Muscle Weakness

Fatigue

Anemia (hemolysis)

Motor Neuropathy

weak

Prev 1-4 of 4 Next



#HER2

Receptor No data

Receptor

Positive

Negative



#ER

Receptor No data

Receptor

Positive

Negative



#PR

Receptor No data

Receptor

Positive

Negative



#enrollment

Clinical trial No data



### 3 CAPTURING ENUMERATED ELEMENTS



Summary

Timeline

Medication

Dr. Jraker299 referred ms. Debra24 Hernandez98Aj due to pain in left breast. Dr. Jraker299 is ms. Debra24 Hernandez98Aj's primary care physician for 12 years.

## Summary



Ms. Debra24 Hernandez98Aj is a 51-year-old menopausal non hispanic or latino woman with invasive ductal carcinoma of the breast, diagnosed on 13 January 2012. Her most recent status, recorded on 15 May 2017, is of worsening, disease progression based on pathology, imaging, and

Toxicities, medications, and other enumerated elements must have a way to capture multiple instances from a single template entry.

Initially, there is no data captured for a toxicity. There are no tools for adding or removing them.

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Close



> #Staging

Tumor size T1 Node size N2 Metastasis No data

Metastasis

M0

M1



> #Disease status

Status No data Reason No data Reference date No data As of date No data

Status

Complete response

Complete resection

Responding

Stable

Progressing

Inevaluable



> #toxicity

Adverse event No data Grade No data Attribution No data

Adverse event

Nausea

Febrile  
Neutropenia

Fatigue

Anemia

Show More



> #HER2

Receptor No data

Receptor

Positive

Negative



> #ER

Receptor No data

Receptor

Positive

Negative



> #PR

Receptor No data

Receptor

Positive

Negative



> #enrollment

Clinical trial No data



Dr. Jraker299 referred ms. Debra24 Hernandez98Aj due to pain in left breast. Dr. Jraker299 is ms. Debra24 Hernandez98Aj's primary care physician for 12 years.

## Summary



Ms. Debra24 Hernandez98Aj is a 51-year-old menopausal non hispanic or latino woman with invasive ductal carcinoma of the breast, diagnosed on 13 January 2012. Her most recent status, recorded on 15 May 2017, is of worsening, disease progression based on pathology, imaging, and

The user has captured one field for #toxicity. The options to clear this element and to add another adverse event appear.

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Close



### > #Staging

Tumor size T1 Node size N2 Metastasis No data

Metastasis

M0

M1



### > #Disease status

Status No data Reason No data Reference date No data As of date No data

Status

Complete response

Complete resection

Responding

Stable

Progressing

Inevaluable



### > #toxicity

Adverse event Nausea Grade No data Attribution No data

Delete toxicity

Grade

Grade 1

Grade 2

Grade 3

Grade 4

+ Add toxicity



### > #HER2

Receptor No data

Receptor

Positive

Negative



### > #ER

Receptor No data

Receptor

Positive

Negative



### > #PR

Receptor No data

Receptor

Positive

Negative





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## Summary



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The user has tapped "Add adverse event". An new unfilled row under #toxicity appears. Clearing an unstarted toxicity will remove the row.

Progress  
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Close



### > #Staging

Tumor size T1 Node size N2 Metastasis No data

Metastasis

M0

M1



### > #Disease status

Status No data Reason No data Reference date No data As of date No data

Status

Complete response

Complete resection

Responding

Stable

Progressing

Inevaluable



### > #toxicity

Adverse event Nausea Grade No data Attribution No data

Delete toxicity

Grade

Grade 1

Grade 2

Grade 3

Grade 4

Adverse event No data Grade No data Attribution No data

Delete toxicity

Adverse event

Nausea

Febrile Neutropenia

Fatigue

Anemia

Show More



### > #HER2

Receptor No data

Receptor

Positive

Negative



### > #ER

Receptor No data

Receptor

Positive

Negative



### > #PR

Receptor No data





Dr. Jraker299 referred ms. Debra24 Hernandez98Aj due to pain in left breast. Dr. Jraker299 is ms. Debra24 Hernandez98Aj's primary care physician for 12 years.

Summary

Ms. Debra24 Hernandez98Aj is a 51-year-old menopausal non hispanic or latino woman with invasive ductal carcinoma of the breast, diagnosed on 13 January 2012. Her most recent status, recorded on 15 May 2017, is of worsening, disease progression based on pathology, imaging, and

The user has captured data for the second adverse event.

Progress  
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Close



> #Staging

Tumor size T1 Node size N2 Metastasis No data

Metastasis

M0

M1



> #Disease status

Status No data Reason No data Reference date No data As of date No data

Status

Complete response

Complete resection

Responding

Stable

Progressing

Inevaluable



> #toxicity

Adverse event Nausea Grade Grade 2 Attribution No data

Delete toxicity

Attribution

Treatment

Disease

Unknown

Unrelated

Adverse event Fatigue Grade Grade 3 Attribution No data

Delete toxicity

Attribution

Treatment

Disease

Unknown

Unrelated

Add toxicity



> #HER2

Receptor No data

Receptor

Positive

Negative



> #ER

Receptor No data

Receptor

Positive

Negative



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Progress  
10 April 2018

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Close



### > #Staging

Tumor size T1 Node size N2 Metastasis No data

Metastasis

M0

M1



### > #Disease status

Status No data Reason No data Reference date No data As of date No data

Status

Complete  
response

Complete  
resection

Responding

Stable

Progressing

Inevaluable



### > #toxicity

Adverse event Nausea Grade Grade 2 Attribution No data

Adverse event Fatigue Grade Grade 3 Attribution No data



### > #HER2

Receptor No data

Receptor

Positive

Negative



### > #ER

Receptor No data

Receptor

Positive

Negative

The user check the "all done" box. The two toxicities collapse into two rows. The controls to add/remove are gone. To edit toxicities, the user can uncheck the box, or tap on one of the fields.

## 4 DEFINING GRADES





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## Summary



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The meanings of the specific grades is very specific, but not obvious. We understand that clinicians often will not capture a grade with a toxicity. Providing the meaning of the Grades in-line will encourage the clinician to attribute an accurate grade.

This interaction can be applied to anything that warrants "details" during selection.

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Close



> #Staging Tumor size T1 Node size N2 Metastasis No data

Metastasis

> #Disease status Status No data Reason No data Reference date No data As of date No data

Status

> #toxicity Adverse event Nausea Grade No data Attribution No data [Delete toxicity](#)

Grade

[Show details](#)

[Add toxicity](#)

> #HER2 Receptor No data

Receptor

> #ER Receptor No data

Receptor

> #PR Receptor No data

Receptor





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## Summary



Ms. Debra24 Hernandez98Aj is a 51-year-old menopausal non hispanic or latino woman with invasive ductal carcinoma of the breast, diagnosed on 13 January 2012. Her most recent status, recorded on 15 May 2017, is of worsening, disease progression based on pathology, imaging, and

The user taps "Show details", and an expanded menu appears. Each option is listed with a sentence description customized to the specific Adverse event selected. The Grade details are shown for this user until they tap "Hide details".

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Close



### > #Staging

Tumor size T1 Node size N2 Metastasis No data

Metastasis

M0

M1



### > #Disease status

Status No data Reason No data Reference date No data As of date No data

Status

Complete response

Complete resection

Responding

Stable

Progressing

Inevaluable



### > #toxicity

Adverse event Nausea Grade No data Attribution No data

Delete toxicity

Grade

Hide details

Grade 1

Loss of appetite without alteration in eating habits

Grade 2

Oral intake decreased without significant weight loss, dehydration or malnutrition

Grade 3

Inadequate oral caloric or fluid intake; IV fluids, tube feedings

Grade 4

Life-threatening consequences

Add toxicity



### > #HER2

Receptor No data

Receptor

Positive

Negative



### > #ER

Receptor No data

Receptor

Positive

Negative

## 5 SPECIFYING DETAILED REASONS



Dr. Jraker299 referred ms. Debra24 Hernandez98Aj due to pain in left breast. Dr. Jraker299 is ms. Debra24 Hernandez98Aj's primary care physician for 12 years.

## Summary



Ms. Debra24 Hernandez98Aj is a 51-year-old menopausal non hispanic or latino woman with invasive ductal carcinoma of the breast, diagnosed on 13 January 2012. Her most recent status, recorded on 15 May 2017, is

The user selects "Treatment" and is presented with a menu to further specify.

Note: From the current SHR spec, it appears that our "Attribution" is the "Cause Category".

"AdverseEventAttribution" specifies a particular substance or action and, there can be many. These appear to be no formal relationship between the "Cause Category" and these AdverseEventAttributions

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Close



> #Staging Tumor size T1 Node size N2 Metastasis No data

Metastasis

> #Disease status Status No data Reason No data Reference date No data As of date No data

Status

> #toxicity Adverse event Nausea Grade Grade 3 Attribution No data ✗ Delete toxicity

Attribution

unspecified treatment

medications

Lisinopril

ibuprofen

hydrocortisone

PAClitaxel

> procedures

> #HER2 Receptor No data

Receptor

> #ER Receptor No data

Receptor

> #PR Receptor No data

Receptor

+ Add toxicity





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The summary bar and the buttons both change to reflect the various attributions captured.

When the treatment button is pressed again, previous selections appear at the top of the dropdown menu and can be removed via the "x" interaction.

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10 April 2018

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Close



Metastasis

M0

M1

> #Disease status Status No data Reason No data Reference date No data As of date No data

Status

Complete response

Complete resection

Responding

Stable

Progressing

Inevaluable

> #toxicity

Adverse event

Nausea

Grade Grade 3

Attribution Treatment + Disease

Delete toxicity

Attribution

Treatment

Disease

Unknown

Unrelated

Adverse event

Insomnia

Grade Grade 3

Attribution Treatment (2)

Delete toxicity

Attribution

Treatment (2)

Disease

Unknown

Unrelated

Adverse event

Fatigue

Grade Grade 3

Attribution Treatment (Lisinopril)

Delete toxicity

Attribution

Treatment

Disease

Unknown

Unrelated

Lisinopril

unspecified treatment

medications

ibuprofen

hydrocortisone

PAClitaxel

procedures

> #HER2

Receptor No data

Receptor

Add toxicity