Adverse Event (AE) Capture Form Guidance - Ascott Nurses FINAL

0:01
Welcome to the adverse event reporting form guidance during this training we hope to do a knowledge refresher to revisit the basics and a reminder of where the reference materials available to you are.

0:18
Help improve guidance and accuracy by showing you the importance of accurate.

0:23
A reporting and clarification on fields in the AER form IE what to enter and some tips and tricks to help you remember the best case examples and completed a forms that you can refer to.

0:42
Ascot is an important customer facing extension of our team and a critical part of the Takeda system for a reporting.

0:50
The data you collect and provide to Takeda helps us with new insights and better care, providing unique perspectives and guiding Takeda's management of their products.

0:59
Crucial for safety compliance so that we ensure to regulatory adherence and comprehensive documentation.

1:06
Detailed documentation captures all relevant information for proper assessment and management.

1:13
The work that you do bridges the gap between HCPS, patients and pharmacovigilance teams to collect valuable insights on our products.

1:22
You also help to cater, identify and document adverse events related to programmed medications and ensure accurate and timely reporting to the pharmacovigilance department.

1:32
You make sure that Takeda maintains compliance with regulatory requirements and reported standards.

1:38
Without you, Takeda cannot continue to ensure patient safety and ensure the success of our pharmacovigilance efforts locally and globally.

1:47
This slide is a reminder of some of the resources you can use for filling out the AER form.

1:53
The Brain Shark training slides are a great resource as they list out the definitions for adverse events and timelines of when to report.

2:01
The link you would have used to complete your training is a live link and could be accessed at any point in time should you need to refer back to it.

2:08
You also have access to your Ascot IQ via Patient Services SOP and additionally there are great guidance pages within the AER form itself which you can refer to.

2:18
Whilst all scenarios are not covered, it covers the basics very well.

2:22
If your questions are still not answered after referring to these documents, you can always reach out to your colleagues internally or even ask GPSCA&Z.

2:31
We're happy to help guide.

2:34
The key thing to remember is if you're in doubt, refer and if you're unsure, ask.

2:42
In this slide, we will show you where your reports go and how they can impact patient safety.

2:47
As you can see, Takeda receives adverse event reports from various sources such as clinical studies, scientific articles from the public and through patient support programmes like Qtivia Pathway.

2:58
When received at Takeda, our adverse event intake team triages the reports.

3:03
Where applicable, they are sent to the corresponding departments, such as Product Quality complaints or Millinfo, where there is a component that relates to their function.

3:12
Occasionally, the adverse Event Intake team may have followed questions around a submitted case to ensure that they are accurate before being sent to the Global Safety database where all reports are stored.

3:25
In some instances, these reports are shared with health authorities or other companies, depending on the regulations or agreements in place at the time.

3:33
It is important to note that there are usually tight timelines associated to these tasks.

3:40
Any information you report plays a part in patient safety.

3:43
This data is real world data that would not necessarily be available to Takeda, such as pregnancy, breastfeed, and off label use.

3:52
Data that's reported is used to determine if an update is to be made to a product label, such as warning of contraindications or maybe a new warning of precautions so that HTPS and patients are fully aware of the potential risks.

4:08
On this slide we're going to show some examples of errors leading to inaccurate reports in the impact that it has.

4:14
In the first instance, an interviewer patient's age is incorrectly recorded as 8 instead of 18 years old.

4:21
The impact of this is that the adverse event would be captured as a paediatric patient instead of an adult patient and this incorrectly changes the patient's demographic and also the case type to change to off label use due to the event.

4:34
In the second example, the indication is captured incorrectly.

4:38
Capturing the incorrect indication can lead to inaccurate data on how Entyvio is actually being used, impacting not just safety but other functions within the Takayla system.

4:50
Finally, a patient on an Entyvio experiences new onset joint pain and swelling after several infusions.

4:57
However, it is reported in the adverse event that it's just a flare up of the underlying disease.

5:03

All AES should be reported as admitting the event of joint pain and swelling may lessen the completeness of the report.

5:10
If more than one event is reported, please be sure to add each event to each box within the adverse event form.

5:19
Using the last example on the previous slide, we're now going to show you three different versions of the form.

5:27
In this example, the form has been filled out incorrectly, so you can see the reporters assume that joint pain and swelling were indicative of the flare up of the disease.

5:37
The reporter's exact word in should have been used where possible, and this can be indicated by with quotation marks to distinguish it from the text written by the individual.

5:48
In the improved form, you can see that the reporter's exact word in verbatim has been reported as indicated by the quotation marks in the narrative.

5:59
Additionally, the date of the report has been currently captured as separate to the event onset date as the event onset date was not provided by the reporter, therefore captured as unknown.

6:13
And here is the recommended adverse event report form.

6:17
As you can see, the reporter's exact wording has again been reported.

6:22
The date of report and onset date has been captured correctly, but this time the narrative outlines that no further details were provided by the reporter.

6:32
This communicates to the adverse event intake team that no further actions are pending and no more information is available.

6:43
To reiterate, collecting accurate and complete information benefits our patients to cater able to ensure that we have correct reports and can make informed decisions about our products.

6:53

Inaccurate information can lead to incorrect conclusions on Decatur's products, potentially impacting patient safety.

7:00
If we help to minimise the questions, we can help improve compliance.

7:04
Inconsistent information will create queries from the adverse event intake team, which can be avoided with right first time information.

7:11
If you're on time, we're on time.

7:14
And lastly, help save time.

7:17
Fewer errors because no one's perfect means lower volumes of emails.

7:21
There'll be a reduction in Kappas and less time spent on investigating queries from the Adverse Event Intake team.

7:28
Provide guidance.

7:29
Improve accuracy.

7:32
Day zero is defined as the date that any Takeda employee or employee working on behalf of Takeda in this instance Ascot slash IQVIA are notified of an adverse event, special situation report or product complaint.

7:45
And this is the clock start date.

7:48
Some examples of clock start dates.

7:50
Day zeros can be the date that you talk to a HTP or consumer, maybe you talk to a friend.

7:56
The date you review a website, The date that you're aware of an adverse event at a conference.

8:01
The date importantly, that the email reaches your inbox, the date that the fax was received and the date that the post was received.

8:12
On this slide, we're going to cover the importance of Day 0.

8:15
Takeda's regulatory clock starts with day zero.

8:18
It is the starting point for the safety data exchange of information to partners and or health authorities.

8:25
Reporting the wrong day zero may lead to delays in investigating and addressing the adverse event.

8:32
It helps to ensure timely and accurate reporting of safety information.

8:36
Reporting the incorrect a zero can affect the report submission, compliance and resulting deviations or kappas.

8:46
Repeated late cases to health authorities or partners may result in an inspection.

8:53
Reporting the correct date will minimise the inconvenience of investigating the adverse event intake teams, queries and requests and allows you to avoid writing up campus.

9:05
Below is an impact example of where the day zero was incorrectly reported as the 8th of Feb 2023 instead of 8th of Feb 2024 and this case would appear to have been reported late.

9:19
The impact would be a late report to the health authority with the time then being spent by Ascot, the A intake team and Global correcting the submission if it's later identified as just a typo.

9:31
Repeated instances of these scenarios may again trigger a health authority inspection.

9:37
Accurate reporting of the indication helps ensure patient safety and complies with the regulatory reporting requirements.

9:43
Remember, capture the indication as reported as verbatim.

9:48
If multiple indications are provided, ensure the indication is reported for the current adverse event and not per previous medical history.

9:56
Remember to consider the patient's medical history.

9:59
Consider the patient's conditions, their medications.

10:02
Ask yourself is this indication expected or seems out of place?

10:06
Also consider the drug indication.

10:08
Identify the specific condition for which the drug was prescribed.

10:12
Report the indication in the indication field within the AER form document.

10:17
Again, source verbatim in the narrative for any additional information related to the AE, especially if off label use is used.

10:25
What should you do if a reported indication does not correlate with the previous report or scenes out of place?

10:31
The discrepancy found should be checked for accuracy by ensuring it's not a misunderstanding or documentation error.

10:39
Be sure to check with the history of the patient, including medication or get it right.

10:49
No follow up right on this slide, we'll look at event details.

10:55
Inaccurately captured event details will lead to queries from Global and the adverse event intake team.

11:02
In rare instances, health authorities may request a cater to investigate and provide additional information where an adverse event is of concern.

11:11
Short timelines are associated with these requests, so it's important that we get the information right first time For out of window reports, this occurs when the Entyvio dose is given ±3 days from the scheduled on label dosing schedule.

11:27
The start date of the out of window is the day the out of window dose is given, not to the date of the previous infusion.

11:36
A fatal outcome does not indicate that the event is stopped.

11:39
It is not the event stop date.

11:41
The date of death is captured separately.

11:45
When an adverse event is reported as being resolved, this means the event is stopped.

11:50
If provided, report this date as the event stop date.

11:54
If it has not been provided, it should be a trigger to go back and clarify or request the information provided.

12:01
It is also important not to make assumption based on what you think has been reported.

12:06
Always report verbatim and again utilising the quote masks within the narrative.

12:11
This can be communicated to health authorities so that they can be clear on the information that dictator has received and subsequently reported.

12:20
On this slide, we're going to go through a scenario where a patient has received Entyvio 2 days out of window points to consider.

12:31
Product details are limited and a partial product start date was reported.

12:36
Additionally, the reporter's exact wording should be used where possible.

12:40
You can indicate this as mentioned before with quotation marked within the narrative.

12:48
With regards to the event details, the event was reported as two days out of window.

12:52
The dose was due on the 16th of February and to be captured in the narrative.

12:58
The out of window events, start dates and stop dates is the recent dose given IE 21st of Feb.

13:10
Here we're going to talk about product details.

13:13
Capturing the correct product dates and details is crucial for regulatory adherence and helps Decatur making formal decisions to ensure patient safety.

13:22
Errors in reporting product details and associated dates can lead to incorrect assessments of cases.

13:28
Remember, if there is a change in the formulation dose, product start date or stop date, including the batch lot number, this will need to be specified within the adverse event form.

13:39
The start and stop date of an adverse event is where is separate to that of the product except to where explicitly noted.

13:46
A fatal outcome does not mean that the product was stopped because of an adverse event, and the date of death does not equal the product stop date.

13:53
Unless absolutely specified by the reporter.

13:57
The action taken refers to the steps or measures implemented in response to the reported adverse event.

14:03
We can't assume that the fatal outcome means the product was discontinued as a result.

14:08
To ensure accurate reporting, always provide as much relevant information as possible, don't make assumptions, and always report verbatim.

14:19
If I'm sure.

14:20
Always seek feedback or assistance from HCPS or colleagues if and when needed, and indicate any discrepancies, missing or unknown information within the narrative.

14:32
Check the spelling, accuracy and consistency of the product details.

14:37
Again, don't assume report verbatim.

14:40
If you do identify a discrepancy and you're aware of that discrepancy, be sure to put that in the narrative to avoid questions.

14:49
Here we have a scenario where a patient reports I had started entyvio on the 20th of Jan and on the second of Jan I experienced headaches.

14:57
This can be interpreted that the patient's headache had started before the patient started entyvio.

15:03
It may be assumed that the patient mixed up the start date of Entyvio and the start date of the event.

15:09
It may also be assumed that the patient made a typo in reporting the dates.

15:14
What will happen next?

15:16
A few days later, the Adverse Event Intake team will send you an email regarding clarification requests of the products and events start dates.

15:24

You will need to go back and investigate and you'll need to reach out to the patient and or colleague to review their medical history to confirm.

15:31
You'll also need to reply to the Adverse Event Intakes team with the clarification.

15:38
If unclear, query.

15:39
The best course of action is to ask the patient to clarify, review their medical history and confirm whether what they had reported was accurate reflection of the event.

15:49
Once confirmed, document the interaction and report the correct dates.

15:54
If you've been unable to contact the patient immediately, you can reply to Adverse Intake as such avoiding convenience of having to investigate the report after receiving a request from the Adverse Event Intake team.

16:10
On this slide, we're going to go through a scenario where a patient was on Entyvio 4 and changed to Entyvio Subcut after experiencing headaches whilst on the IV infusion.

16:21
Points to consider for this case are that the product details are limited.

16:25
The product stop date of the Entyvio 4 was not mentioned.

16:29
When it comes to capturing the product details, either this IV or the subcut formulation could be captured within the form.

16:38
In the form on the screen that you see now, the IV formulation has been captured and the narrative updated accordingly.

16:47
The preferred approach is to detail the product details with the latest relevant formulation for which the adverse event occurred.

16:57
As you can see highlighted in yellow, the sub cut solution for injection formulation was entered in relation to the adverse event.

17:06
The narrative has been updated accordingly and applicable details regarding the IV start and previous dose were not available has been captured in the narrative.

17:19
Here we have some tips on reported details and serious criteria.

17:24
Capturing the correct reported details as seriousness criteria matters for patient safety, regulatory adherence and making informed decisions.

17:32
Errors can lead to an accurate reports being sent to the health authorities.

17:36
Remember, if hospitalisation is not reported to be the course of action due to any event, it is not considered the outcome of the event.

17:44
Incorrectly capturing the reporter such as occupation details IE consumer versus HTP may lead to a misinterpretation of clinical context.

17:53
When unclear information is given, ask questions.

17:56
If it can't be provided, do not make assumptions.

17:59
And remember, report to DECADA as verbatim.

18:03
Document your efforts for clarification.

18:06
Avoid having to investigate with the AE intake team.

18:11
On this slide, we're going to touch upon data privacy.

18:15
Adverse event reports contain sensitive information about the patient's health and well being, but protecting the privacy of this data is essential to maintain trust in the reporting system and to comply with local regulations.

18:28

Data privacy and adverse event reports safeguards personal information and prevents unauthorised access.

18:35
It also maintains confidentiality and ensuring the integrity and liability of the reporting process.

18:42
Personal identifiable information, here abbreviated as PII, such as full name initials, can be retained.

18:50
Addresses, phone numbers, and any other details that could directly identify individuals should be redacted before sending to the AE intake team to protect privacy.

19:01
Always be sure to verify the accuracy of the recipient email address before sending adverse events.

19:06
To prevent potential data privacy breaches, always ensure redactions are made of all personal identifiable information, including within the attachments, before sending these reports to the Adverse Event intake team and having to avoid writing up Kappas.

19:27
Fast is fine, but accuracy is everything.

19:31
Reporting product quality complaints as like an AE, it is important to capture as much information as possible.

19:41
Describe what has occurred.

19:43
What is the product quality issue?

19:45
Was this a faulty product?

19:47
A lack of effect?

19:48
An incorrect label?

19:49
Include when it occurred and how it was reported to you.

19:53
Was the product used or was a defect found prior to use?

19:57
If it was used, submit the AE.

20:01
Did the patient miss a dose as a result of the product quality complaint again?

20:07
If yes, submit the AE.

20:11
Report the product details.

20:13
Provide as much information as possible.

20:17
Product description and batch lot number of the products should be provided.

20:21
In the instance where a lot number is not available, please include this in the report with a reason why IE product in the shaft container.

20:30
Expiry dates and number of units impacted should also be provided.

20:35
Where possible, provide photographic evidence.

20:40
Another important factor is the availability of the product for return.

20:44
Details of availability for product return should include details of the supplying pharmacy and confirmation of a sample pickup address.

20:56
Loss, lack of effect reports Adverse event only reports those.

21:01
Escalation within product information guidelines is not considered a PQC.

21:06
Cessation of treatment after review by a HDP i.e.

21:11
after the initial dose in week 12 to 14 is not considered a PQC unless there is an allegation of product quality failure.

21:20
Here we have an example product quality complaint report form.

21:24
As you can see, the individual has completed the product description as well as the description of the event.

21:31
The individuals also pointed out that the patient did not miss a dose as a result.

21:38
The individual has noted that the pen is available for return and that photographs were attached to the email.

21:50
Tips and tricks Tips and tricks Accurate reporting is the foundation of ensuring patient safety.

22:00
Always be sure to review the event details and go through the AAU description to ensure it's clear.

22:05
Make sure that the date makes sense and the times are accurate.

22:08
Cross check with patient medical history where applicable to avoid making any assumptions.

22:14
Use clear and concise language when filling out the AER form and provide sufficient detail, noting all actions taken to confirm discrepancies.

22:22
Be sure to seek clarification for any discrepancies and document the results.

22:28
Finally, check the final form before submitting.

22:31
Double checking prevents errors and supports patient safety.

22:34
The accuracy will save you time and effort in the long run.

22:38
You don't have to deal with the follow up questions from an A a intake team.

22:41
Remember, precision takes time.

22:44
Remember, before sending to Decatur, do a sense check.

22:48
Are you confident the information entity is accurate?

22:51
If it doesn't make sense to you, it won't make sense to someone else.

22:54
Do it self QC.

22:56
Go over the information entered and check that it matches what was reported.

23:00
Once you're happy and have confirmed it's correct, hit that button and send away.

23:05
Remember, good things take time.

23:08
Better things take a little bit longer.