

**Adverse Events (AEs) Logs,  
Concomitant Medications (CON-MEDs) Logs  
and Medical History Logs  
on eRecord**

**DLV-GEN-WI-014**

## Relates to SOP:

- [DLV-GEN-SOP-003 Paperlite: Recording and Auditing Research Activity in eRecord](#)
- [NJRO-REG-SOP-007 "Recording, managing and reporting Adverse Events for Clinical Trials of Investigational Medicinal Products and trials of Advanced Therapy Medicinal Products"](#)

## Introduction

This working instruction will enable use of eRecord PowerChart for recording, viewing and modifying Adverse Event Log entries (AEs), Concomitant Medication Log entries (CON-MEDs) and Medical History Log entries.

The contents of this working instruction are:

1. [Preliminary steps](#)
2. [Adding a new log entry](#)
3. [Reviewing an existing log entry – to view history and modifications](#)
4. [Modifying an existing log entry](#)
5. [A note on timestamps](#)
6. [Using a PowerChart "Tear Off" to have two PowerChart windows open simultaneously](#)
7. [Appendix – Log Entry Forms](#)

## 1 Preliminary steps

1. Log in to eRecord and open PowerChart
2. Select the correct patient and the correct encounter  
See DLV-GEN-WI-013 section 2 (Switching to a Research Encounter) for instructions on how to do this.
3. Open the Research view from the left-hand menu (near the bottom of the menu)

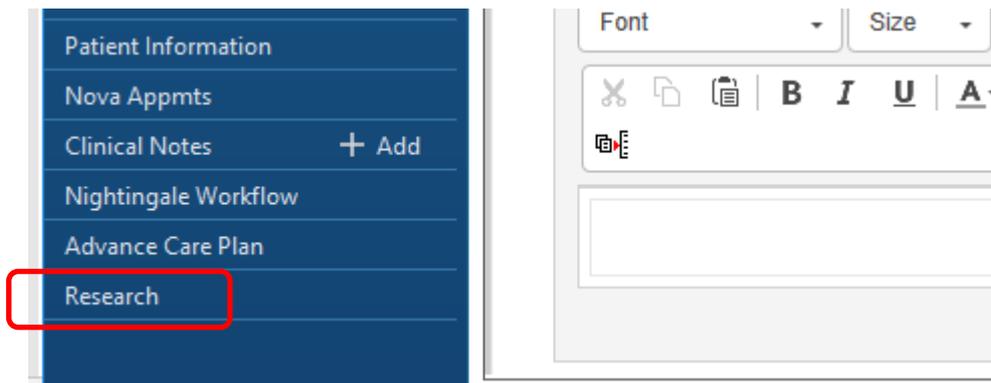


Figure 1 - Research button

4. The Research view loads, showing sections about research forms including sections for:
  - Adverse Events Log
  - CON-MEDs Log
  - Medical History Log
  - Completed/Modified Powerforms
  - Documents Viewing

a. If this patient has no research form entries, the sections will be empty:

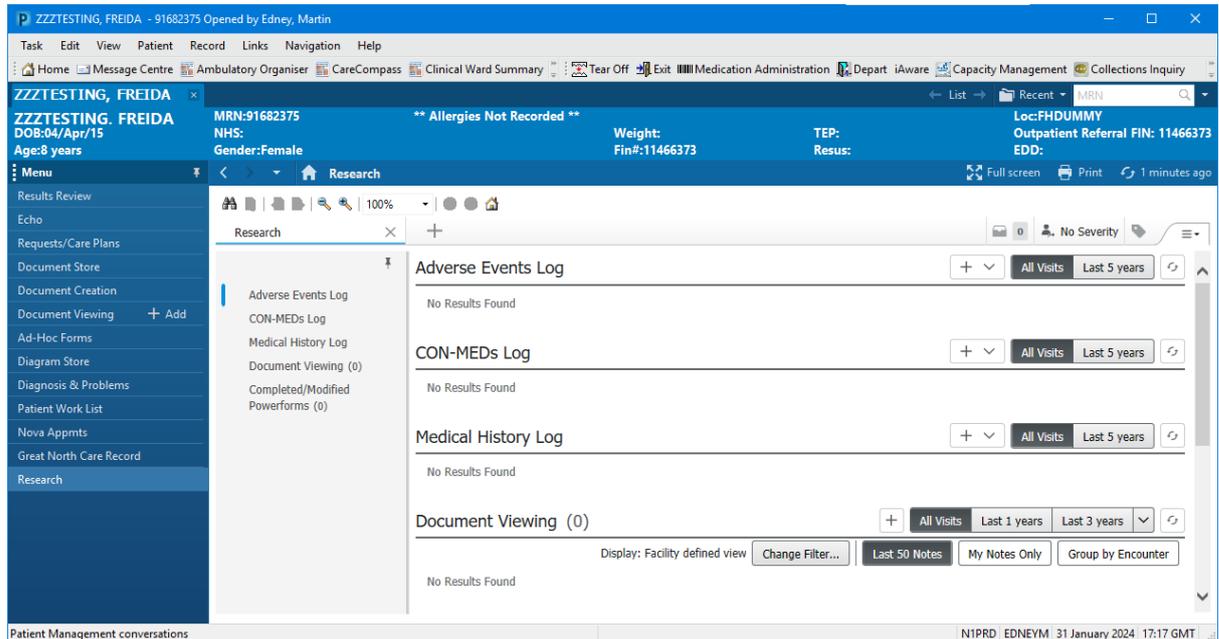


Figure 2 - Research view with no log entries

b. If this patient has research log entries, they will be shown on the View

	03 AUG 2023 10:11	31 JUL 2023 12:05	11:34	09:44	04 JUL 2023 13:19	10:40	09:51	03 JUL 2023 15:32
AE Trial Name	Trial test2	GB66661	GB66661	GB66661	GB66661	testing	Testing	Testing testin
AE R&D Number	R&D 12334	234GLOW	234GLOW	234GLOW	234GLOW	3456	1234	1546
AE Patient Tri...	134	23445	23	023ATTTT	23ATTTT	345	123	152
AE Adverse Ev...	Headache	Pain	fsda	dsfref	Headache	Arthritis in wri...	Shin Splints	Headache
AE Serious Ad...	No	No	No	Yes	Yes	No	No	No
AE Adverse Ev...	No	No	No	Yes	No	Yes	No	No
AE Medically A...	No	No	No	Yes	No	No	No	No
AE Severity Gr...	Mild	3	1	fewewf	Mild	2	Mild	3
AE Start Date	31 JUL 2023	27 JUN 2023	18 JUL 2023	31 JUL 2023	03 JUL 2023	08 MAY 2023	26 JUN 2023	30 JUN 2023
AE Is End Dat...	No	No	No	No	Yes	No	No	Yes
AE End Date	--	--	--	--	04 JUL 2023	--	--	30 JUN 2023
AE Comments...	Ongoing	NK	Ongoing	--	--	Ongoing	Ongoing	--
AE Event Relat...	No	Maybe	fds	refreg	No	Maybe	No	No
AE Other Actio...	None	None	sdf	argreg	Medication	Monitoring	None	None

Figure 3 - Research view with log entries

c. Use the Navigator to navigate between the sections on the View

Figure 4 - Navigator on the Research view

## 2 Adding a new log entry (“Adverse Events Log” section, “CON-MEDs Log” section and “Medical History Log” section)

1. Select the + button in the relevant section (i.e., in the “Adverse Events Log” section to add an Adverse Events Log entry, in the “CON-MEDs Log” section to add a CON-MEDs Log entry, or in the “Medical History Log” section to add a Medical History Log entry).
2. Select the log’s name in the drop down

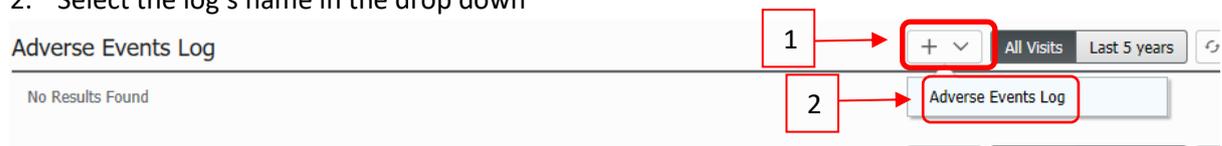
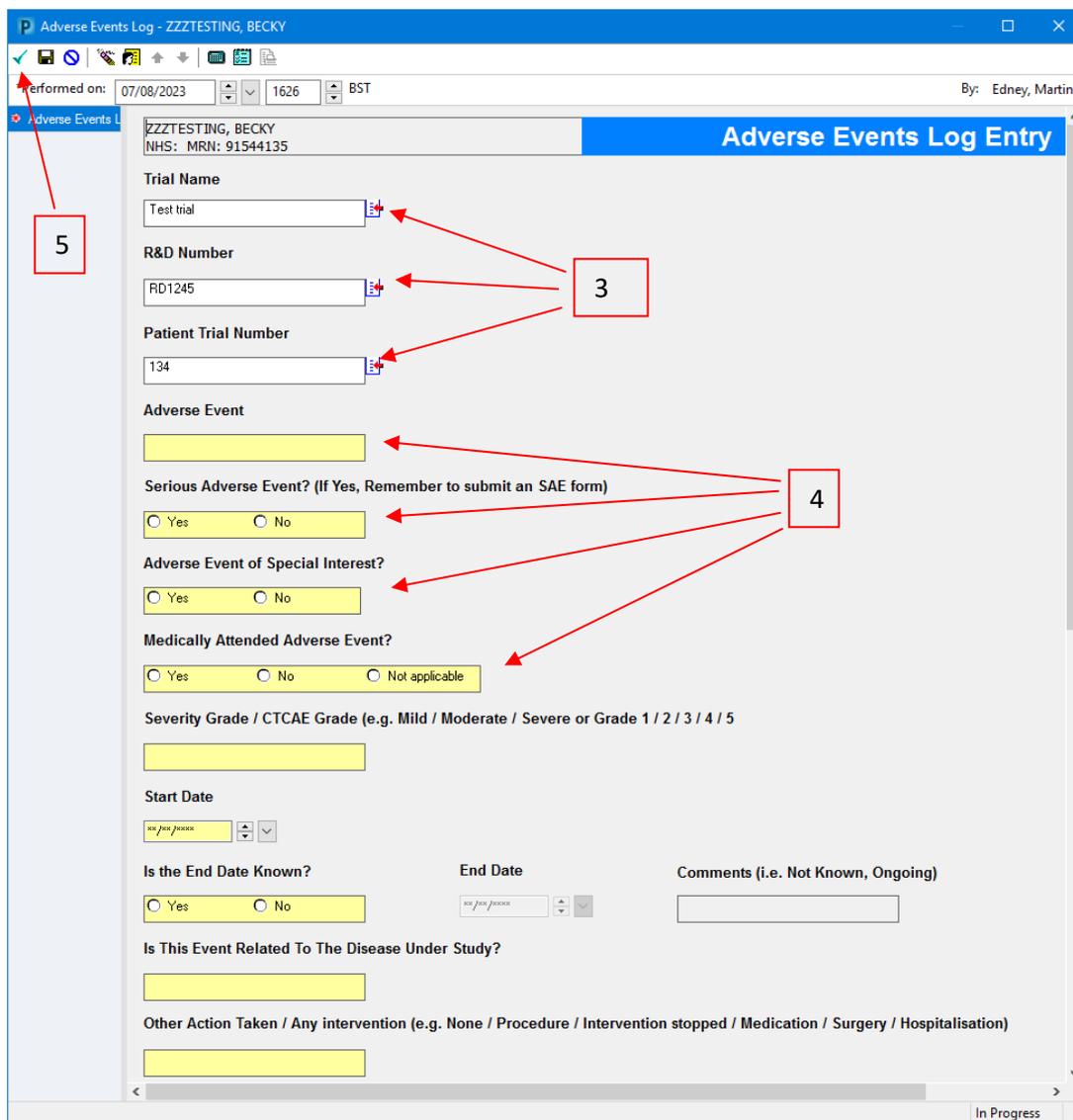


Figure 5 - adding a new log entry

The form for adding a new log entry of the type selected opens

3. Some fields will load the last value entered by the user, as indicated by this symbol . This is to make it easier to enter multiple log entries for the same participant on the same trial.



Adverse Events Log - ZZZTESTING, BECKY

Performed on: 07/08/2023 16:26 BST By: Edney, Martin

Adverse Events Log Entry

ZZZTESTING, BECKY  
NHS: MRN: 91544135

Trial Name  
Test trial

R&D Number  
RD1245

Patient Trial Number  
134

Adverse Event

Serious Adverse Event? (If Yes, Remember to submit an SAE form)  
 Yes  No

Adverse Event of Special Interest?  
 Yes  No

Medically Attended Adverse Event?  
 Yes  No  Not applicable

Severity Grade / CTCAE Grade (e.g. Mild / Moderate / Severe or Grade 1 / 2 / 3 / 4 / 5)

Start Date

Is the End Date Known? End Date Comments (i.e. Not Known, Ongoing)

Yes  No

Is This Event Related To The Disease Under Study?

Other Action Taken / Any intervention (e.g. None / Procedure / Intervention stopped / Medication / Surgery / Hospitalisation)

In Progress

Figure 6 - Adverse Events log entry form

4. Fill in the form. (The yellow highlight indicates mandatory fields).
5. When filling in the form, you must be guided by the trial protocol and the trial sponsor (for example, for the definition of Adverse Event of Special Interest).
6. If dates are not known or are estimates, set the "Is the date known" field to "No", and use the adjacent free text box ("Comments" or "Partial Start Date Or Unknown") to enter information about the date (e.g. "Not Known", "NK", "NK/12/2021", "15/12/2021 (estimate)"). The exact format to use may be trial specific, so you must be guided by the trial protocol or the trial sponsor.

7. The AEs log field “Other action taken” should specify the type of action taken as listed on the form (e.g. None / Procedure / Intervention stopped etc.) and brief details of the action (e.g. name of procedure). The field has a 255-character limit, so full details cannot be entered. Instead, where possible, cross-refer to a location in the patient record where further details can be found (e.g. by referring to a specific CON-MEDs log entry or to a specific research note).
8. Use the green tick to sign and save the form.  
(You should not use the “Save Form” icon as that results in the log entry being saved in an “In Progress” state for you to complete later, but the log entry is not properly signed off and completed and does not show in the “Adverse Events Log”, “CON-MEDs Log” or “Medical History Log” sections. There is also a risk that you will forget to sign off the log entry, and it will be lost)

### 3 Reviewing an existing log entry – to view history and modifications (“Documents Viewing” section)

1. Use the Navigator to go to the “Documents Viewing” section (see *Figure 4 - Navigator on the Research view, on page 5*).

The screenshot shows the 'Documents Viewing' section of the eRecord system. The table below represents the data visible in the screenshot:

Time of Service	Subject	Note Type	Author	Last Updated	Last Updated By
In Progress (0)					
Completed (50)					
03 AUG 2023 10:11	Adverse Events Log	Adverse Events Log <span style="color: blue;">▲</span>	Edney, Martin	04 AUG 2023 14:56	Edney, Martin
03 AUG 2023 10:11	eAE Adverse Event	eAE Adverse Event	Edney, Martin	03 AUG 2023 10:11	Edney, Martin
03 AUG 2023 10:11	eAE Adverse Event Spe...	eAE Adverse Event Spe...	Edney, Martin	03 AUG 2023 10:11	Edney, Martin
03 AUG 2023 10:11	eAE Comments End Da...	eAE Comments End Da...	Edney, Martin	03 AUG 2023 10:11	Edney, Martin
03 AUG 2023 10:11	2 eAE Event Related-Pro...	eAE Event Related-Pro...	Edney, Martin	03 AUG 2023 10:11	Edney, Martin
03 AUG 2023 10:11	eAE Is End Date Known?	eAE Is End Date Known?	Edney, Martin	03 AUG 2023 10:11	Edney, Martin
03 AUG 2023 10:11	eAE Medically Attended...	eAE Medically Attended...	Edney, Martin	03 AUG 2023 10:11	Edney, Martin
03 AUG 2023 10:11	eAE Other Action Taken	eAE Other Action Taken	Edney, Martin	03 AUG 2023 10:11	Edney, Martin
03 AUG 2023 10:11	eAE Outcome	eAE Outcome	Edney, Martin	03 AUG 2023 10:11	Edney, Martin
03 AUG 2023 10:11	eAE Patient Trial Number	eAE Patient Trial Number	Edney, Martin	03 AUG 2023 10:11	Edney, Martin
03 AUG 2023 10:11	eAE R&D Number	eAE R&D Number	Edney, Martin	03 AUG 2023 10:11	Edney, Martin
03 AUG 2023 10:11	eAE Serious Adverse E...	eAE Serious Adverse E...	Edney, Martin	03 AUG 2023 10:11	Edney, Martin
03 AUG 2023 10:11	eAE Severity Grade	eAE Severity Grade	Edney, Martin	03 AUG 2023 10:11	Edney, Martin
03 AUG 2023 10:11	eAE Start Date	eAE Start Date	Edney, Martin	03 AUG 2023 10:11	Edney, Martin
03 AUG 2023 10:11	eAE Trial Name	eAE Trial Name <span style="color: blue;">▲</span>	Edney, Martin	04 AUG 2023 14:56	Edney, Martin

Figure 7 - Documents Viewing section

2. A blue triangle against an entry shows that entry has been modified
3. Select the log entry to view

- A summary of the selected log entry is shown, highlighting the history, and details of any modifications

The screenshot displays the 'Documents Viewing' section of the eRecord system. The patient information at the top includes MRN: 91836773, DOB: 01/Jan/01, Age: 23 years, Gender: Male, Weight: 59 Kg(M), Fin#: 13857888, and TEP: Resus: For CPR 26/05/2023. The left-hand menu lists various document types such as Adverse Events Log, CON-MEDs Log, Medical History Log, etc. The main area shows a table of document entries with columns for Time of Service, Subject, and Note Type. A detailed view of a selected entry is shown on the right, including the text of the log and a list of modifications.

Time of Service	Subject	Note Type
03 AUG 2023 10:11	Adverse Events Log	Adverse E
03 AUG 2023 10:11	eAE Adverse Event	eAE Adver
03 AUG 2023 10:11	eAE Adverse Event Spe...	eAE Adver
03 AUG 2023 10:11	eAE Comments End Da...	eAE Comm
03 AUG 2023 10:11	eAE Event Related-Pro...	eAE Event
03 AUG 2023 10:11	eAE Is End Date Known?	eAE Is En
03 AUG 2023 10:11	eAE Medically Attended...	eAE Medic
03 AUG 2023 10:11	eAE Other Action Taken	eAE Other
03 AUG 2023 10:11	eAE Outcome	eAE Outco
03 AUG 2023 10:11	eAE Patient Trial Number	eAE Patien
03 AUG 2023 10:11	eAE R&D Number	eAE R&D N
03 AUG 2023 10:11	eAE Serious Adverses E...	eAE Seriou
03 AUG 2023 10:11	eAE Severity Grade	eAE Sever
03 AUG 2023 10:11	eAE Start Date	eAE Start
03 AUG 2023 10:11	eAE Trial Name	eAE Trial N

**Adverse Events Log**  
Adverse Events Log (Modified) Author; Contributor(s): Edney, Martin  
Last Updated: 04 AUG 2023 14:56 Last Updated By: Edney, Martin

**Adverse Events Log Entered On: 03/Aug/2023 10:12 BST**  
**Performed On: 03/Aug/2023 10:11 BST by Edney, Martin**

**Adverse Events Log**  
eAE Trial Name: Trial test2  
Edney, Martin - 04/Aug/2023 14:56 BST  
([Trial test] - previously charted by Edney, Martin at 03/Aug/2023 10:11 BST)  
eAE R&D Number: R&D 12334  
eAE Patient Trial Number: 134  
eAE Adverse Event: Headache  
eAE Serious Adverses Event?: No  
eAE Adverse Event Special Interest?: No  
eAE Medically Attended Adverse Events?: No  
eAE Severity Grade: Mild  
eAE Start Date: 31/Jul/2023 BST  
eAE Is End Date Known?: No  
eAE Comments End Date not Known?: Ongoing  
eAE Event Related-Progressive Disease?: No  
eAE Other Action Taken: None  
eAE Outcome: Recovered/Resolved  
Edney, Martin - 03/Aug/2023 10:11 BST

Figure 8 - Documents Viewing section – history, and details of any modifications

## 4 Modifying an existing log entry (“Completed/Modified Powerforms” section)

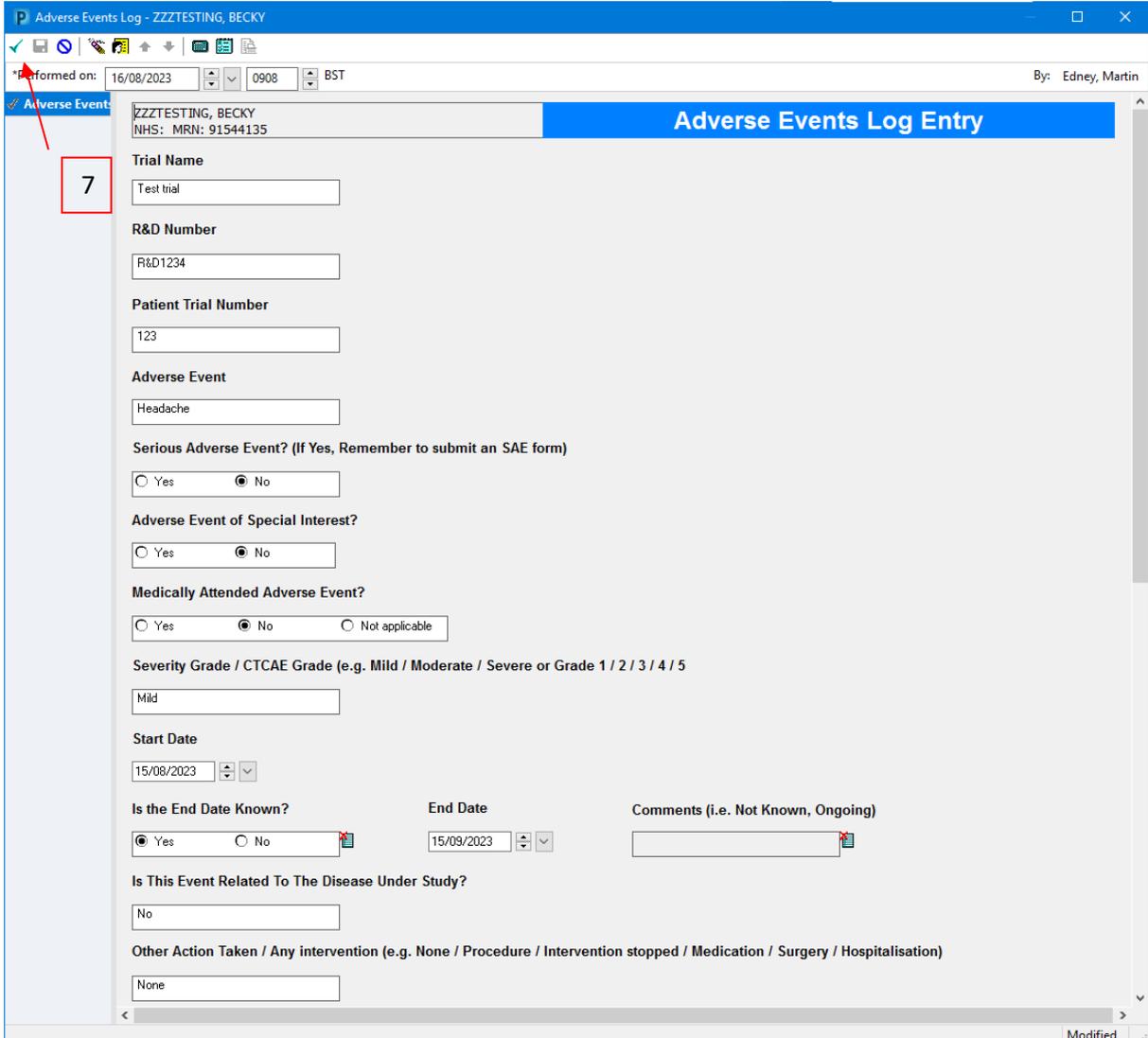
1. Use the Navigator to go to the “Completed/Modified Powerforms” section  
NB the “Completed/Modified Powerforms” section is encounter specific, i.e., it shows only the forms created using the selected encounter. Therefore, it may be necessary to switch encounter to find the specific form (see DLV-GEN-WI-013 section 2 (Switching to a Research Encounter) for instructions on how to switch encounter.)

The screenshot shows the eRecord interface for patient ZZZTESTING, BECKY. The patient header includes MRN:91544135, DOB:01/Jan/50, Age:74 years, and other clinical data. The sidebar menu on the left lists various document types, with 'Research' selected. The main content area displays a list of forms under 'Completed/Modified Powerforms (3)'. The list includes entries for 'Medical History Log Entry', 'Adverse Events Log', and another 'Adverse Events Log'. The 'Adverse Events Log' entry is highlighted with a blue triangle and a red box labeled '2'. A 'Modify' button is visible in the top right of the list, also highlighted with a red box labeled '4'. A right-hand sidebar shows details for the selected 'Adverse Events Log' entry, including a contributor list.

Figure 9 - Completed/Modified Powerforms section

2. A blue triangle against an entry shows that entry has been modified.
3. Select the log entry to modify
4. Select the Modify button in the right-hand sidebar

## 5. The Log Entry form loads with the data for the selected log entry



Adverse Events Log - ZZZTESTING, BECKY

\*Performed on: 16/08/2023 0908 BST By: Edney, Martin

Adverse Event

ZZZTESTING, BECKY  
NHS: MRN: 91544135

**Adverse Events Log Entry**

7

**Trial Name**  
Test trial

**R&D Number**  
R&D1234

**Patient Trial Number**  
123

**Adverse Event**  
Headache

**Serious Adverse Event? (If Yes, Remember to submit an SAE form)**  
 Yes  No

**Adverse Event of Special Interest?**  
 Yes  No

**Medically Attended Adverse Event?**  
 Yes  No  Not applicable

**Severity Grade / CTCAE Grade (e.g. Mild / Moderate / Severe or Grade 1 / 2 / 3 / 4 / 5)**  
Mild

**Start Date**  
15/08/2023

**Is the End Date Known?**  Yes  No **End Date** 15/09/2023 **Comments (i.e. Not Known, Ongoing)**

**Is This Event Related To The Disease Under Study?**  
No

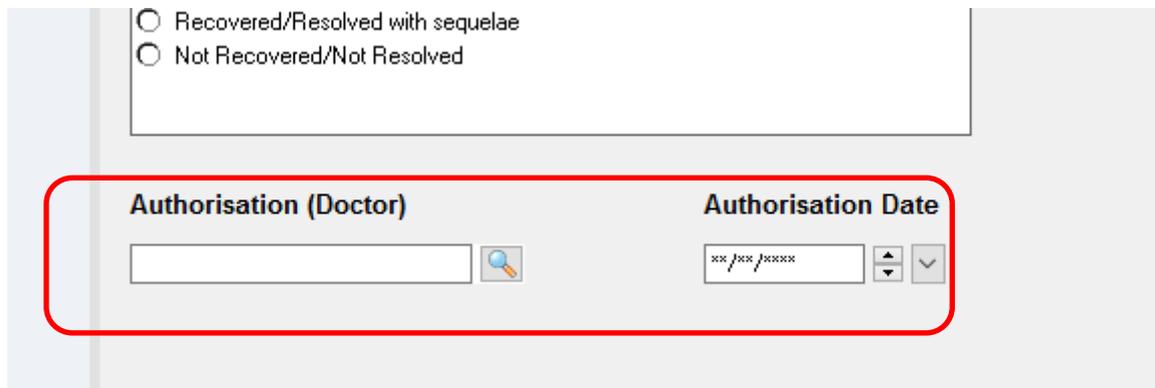
**Other Action Taken / Any intervention (e.g. None / Procedure / Intervention stopped / Medication / Surgery / Hospitalisation)**  
None

Modified

Figure 10 - Log Entry form to modify a log entry

6. Make the modifications needed
7. Use the green tick to sign and save the form (do not use the Save Form icon)

NB Doctors will have to use this option when authenticating / authorising log entries, by modifying the entry and filling in the Doctor Authentication / Authorisation fields at the bottom of the log entry form.



The screenshot shows a form with two radio buttons at the top: "Recovered/Resolved with sequelae" and "Not Recovered/Not Resolved". Below these, a red box highlights two fields: "Authorisation (Doctor)" which is a text input field with a magnifying glass icon, and "Authorisation Date" which is a date picker showing "xx/xx/xxxx".

Figure 11 - Adverse Events Log Entry form – Doctors' authorisation

## 5 A note on timestamps

The timestamps listed at the top of the “Adverse Events Log” section, the top of the “CON-MEDS Log” section and the top of the “Medical History Log” section show when each log entry was created (i.e., when it was first opened).

But in the “Completed/Modified Powerforms” section, the timestamp in the “Date/Time” column shows when each log entry was most recently saved – usually a few minutes after it was created.

The “Documents Viewing” section has columns that show both timestamps:

- “Time of Service” shows when each log entry was created (i.e., same as the “Adverse Events Log” and “CON-MEDs Log” sections)
- “Last Updated” shows when each log entry was most recently saved (i.e., same as the “Completed/Modified Powerforms” section)

Section	Timestamp shows...
Adverse Events Log, CON-MEDs Log and Medical History Log	when each log entry was created (i.e., when it was first opened)
Completed/Modified Powerforms	when each log entry was most recently saved – usually a few minutes after it was created, but will be later if the entry has been modified
Documents Viewing	both timestamps <ul style="list-style-type: none"> <li>• “Time of Service” shows when each log entry was created (i.e., same as the “Adverse Events Log”, “CON-MEDs Log” and “Medical History Log” sections)</li> <li>• “Last Updated” shows when each log entry was most recently saved (i.e., same as the “Completed/Modified Powerforms” section)</li> </ul>

## 6 Using a PowerChart “Tear Off” to have two PowerChart windows open simultaneously

To create an additional PowerChart window so you can view other parts of the patient’s record while completing logs, select “Tear Off” (a), and reconfigure your PowerChart windows to your preference.

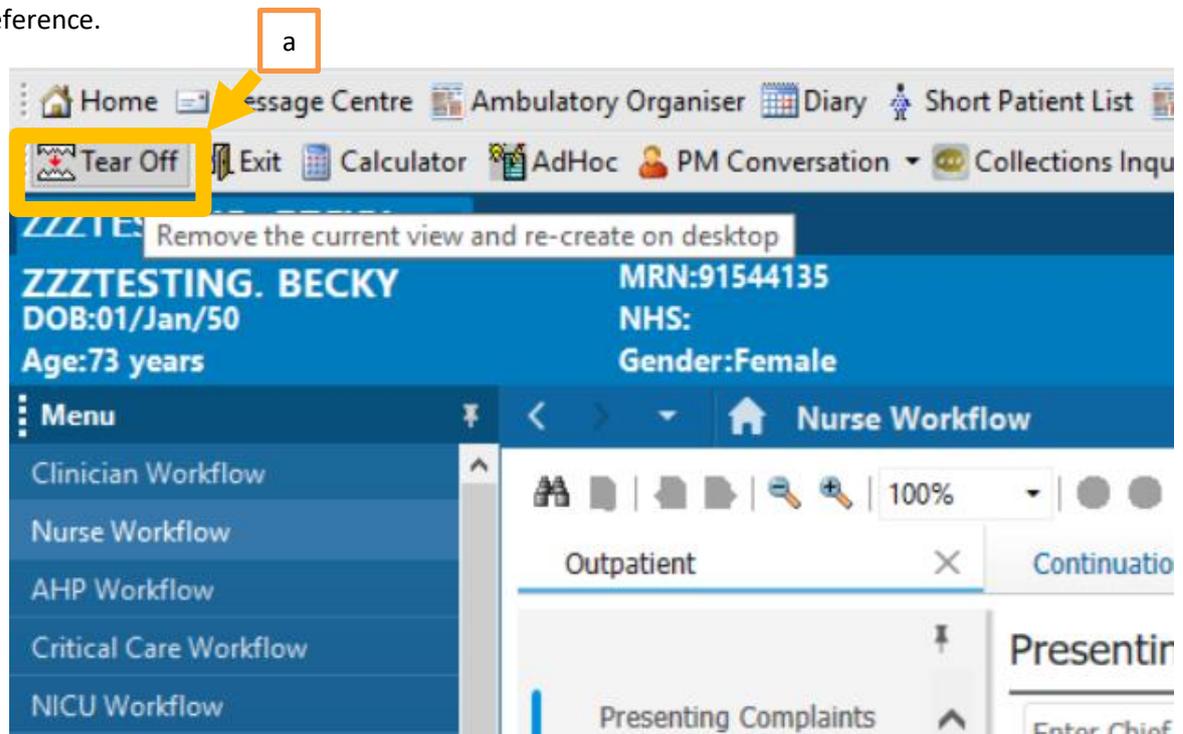


Figure 12 - PowerChart Tear Off

## 7 Appendix – Log Entry Forms

### 7.1 Adverse Events Log entry form

Adverse Events Log - ZZZTESTING, BECKY

\*Performed on: 16/08/2023 0908 BST

Adverse Events Log Entry

ZZZTESTING, BECKY  
 NHS: MRN: 91544135

**Trial Name**

**R&D Number**

**Patient Trial Number**

**Adverse Event**

**Serious Adverse Event? (If Yes, Remember to submit an SAE form)**  
 Yes  No

**Adverse Event of Special Interest?**  
 Yes  No

**Medically Attended Adverse Event?**  
 Yes  No  Not applicable

**Severity Grade / CTCAE Grade (e.g. Mild / Moderate / Severe or Grade 1 / 2 / 3 / 4 / 5)**

**Start Date**

**Is the End Date Known?**  Yes  No

**End Date**

**Comments (i.e. Not Known, Ongoing)**

**Is This Event Related To The Disease Under Study?**

**Other Action Taken / Any intervention (e.g. None / Procedure / Intervention stopped / Medication / Surgery / Hospitalisation)**

Figure 13 - Adverse Events Log entry form (top half)

**Relationship To Investigational Medicinal Product For Non-Vaccine Trial (With IMP Number)**

IMP Number	Relationship To IMP (Probable / Possible / Likely / Unlikely or Related / Unrelated)
1. <input type="text"/>	<input type="text"/>
2. <input type="text"/>	<input type="text"/>
3. <input type="text"/>	<input type="text"/>
4. <input type="text"/>	<input type="text"/>
5. <input type="text"/>	<input type="text"/>
6. <input type="text"/>	<input type="text"/>
7. <input type="text"/>	<input type="text"/>
8. <input type="text"/>	<input type="text"/>
9. <input type="text"/>	<input type="text"/>
10. <input type="text"/>	<input type="text"/>

**Outcome**

Recovered/Resolved       Fatal  
 Recovering/Resolving       Unknown  
 Recovered/Resolved with sequelae  
 Not Recovered/Not Resolved

**Authorisation (Doctor)**  

**Authorisation Date**

Figure 14 - Adverse Events Log entry form (bottom half)

## 7.2 Concomitant Medication Log entry form

The screenshot shows a web browser window with the title 'CON-MEDs Log - ZZZTESTING, BECKY'. The browser's address bar shows 'CON-MEDs log E'. The page content includes a header with the patient's name 'ZZZTESTING, BECKY' and NHS number 'MRN: 91544135'. The main form area is titled 'CON-MEDs Log Entry' and contains the following sections:

- Performed on:** 09/08/2023, 1416 BST. By: Edney, Martin
- Trial Name:** [Yellow input field]
- Patient Trial Number:** [Yellow input field]
- Principal Investigator:** [Yellow input field with search icon]
- R&D Number:** [Yellow input field]
- Medication (Please use trade name):** [Yellow input field]
- Indication:** [Yellow input field]
- Start Date known?:**  Yes  No. **Start Date:** [Date picker showing 'six Jan 2023']
- Partial Start Date Or Unknown (e.g. 'NK/12/2021' or 'NK'):** [Input field]
- End Date known?:**  Yes  No. **End Date:** [Date picker showing 'six Jan 2023']
- Partial End Date Or Unknown (e.g. 'NK/12/2021' or 'NK'):** [Input field]
- Dose (including units):** [Yellow input field]
- Frequency:**
  - OD (Once Daily)  SD (Six times a day)  Three times a week
  - BD (Twice Daily)  OM (In the morning)  Once only
  - TDS (Three times a day)  ON (At night)  Not known
  - QDS (Four times a day)  MDU (As directed)
  - FD (Five times a day)  PRN (When required)
- Route:**
  - Oral  Sub-cutaneous  Intrapericardial  Transdermal
  - Topical  Intraarterial  Intrathecal  Vaginal
  - IM (intramuscular)  Intramyocardial  Nebulised  Not known
  - Inhaled  Intranasal  Rectal
  - IV (intravenous)  Intraosseous  Sublingual
- Is this a vaccine trial?:**  Yes  No
- Solicited Event?:**  Yes  No
- Doctor Authentication:** [Input field with search icon]
- Doctor Authentication Date:** [Date picker showing 'six Jan 2023']

Figure 15 - CON-MEDs Log entry form

### 7.3 Medical History Log entry form

The screenshot shows a web browser window titled "Medical History Log Entry - ZZZTESTING, RESEARCH". The browser's address bar shows the URL "http://www.ncl.ac.uk/...". The page header includes the NHS logo and "The Newcastle upon Tyne Hospitals NHS Foundation Trust". The form itself is titled "Medical History Log Entry" and is for patient "ZZZTESTING, RESEARCH" with NHS MRN: 91865198. The form contains several sections:
 

- Trial Information:** Fields for Trial Name, R&D Number, Patient Trial Number, and Medical Term / Procedure.
- Adverse Events:** Radio buttons for Common Terminology Criteria for Adverse Events (CTCAE) Grade (1, 2, 3, 4, 5, Others, N/A) and an "Others" text box.
- Dates:** Fields for Start Date and End Date, each with a "Start Date Known?" or "End Date Known?" section containing radio buttons for Yes, No, and Ongoing. There are also fields for "Partial Start date or Unknown" and "Partial End date or Unknown".
- Intervention:** Radio buttons for "Any Intervention?" (No, Yes: Medication, Yes: Surgery, Yes: Hospitalisation, N/A).
- Comments:** A text area for "Comments".
- Authorisation:** Fields for "Doctors Authorisation" and "Authorisation Date".

 The browser's status bar at the bottom right shows "In Progress".

Figure 16 – Medical History Log entry form