



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

DLV-GEN-WI-014

AEs, CON-MEDs and Medical History Logs on eRecord - v2

DLV-GEN-WI-014

Page 1 of 18





Relates to SOP:

- DLV-GEN-SOP-003 Paperlite: Recording and Auditing Research Activity in eRecord
- <u>NJRO-REG-SOP-007</u> "Recording, managing and reporting Adverse Events for <u>Clinical Trials of Investigational Medicinal Products and trials of Advanced</u> <u>Therapy Medicinal Products</u>"

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. <u>Reviewing an existing log entry to view history and modifications</u>
- 4. Modifying an existing log entry
- 5. <u>A note on timestamps</u>
- 6. <u>Using a PowerChart "Tear Off" to have two PowerChart windows open</u> <u>simultaneously</u>
- 7. <u>Appendix Log Entry Forms</u>

AEs, CON-MEDs and Medical History Logs on eRecord - v2

DLV-GEN-WI-014

Page 2 of 18





1 Preliminary steps

The Newcastle upon Tyne Hospitals NHS Foundation Trust

- 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)

Patient Information	Font	• Size •
Nova Appmts	X 6 🛱	B <u>I</u> <u>U</u> <u>A</u> -
Clinical Notes + Add	© · E	
Nightingale Workflow		
Advance Care Plan		
Research		
_		

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

AEs, CON-MEDs and Medical History Logs on eRecord - v2

DLV-GEN-WI-014

Page 3 of 18







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

P ZZZTESTING, FREIDA - 91682375	Opened by Edney, Martin				×
Task Edit View Patient Re	cord Links Navigation Help				
🗄 🚰 Home 🖃 Message Centre 🎬 A	Ambulatory Organiser 🌇 CareCompass	🌃 Clinical Ward Summary 🍍 🕅 🎞	ear Off 📲 Exit 💵 Medication A	Administration <u>R</u> Depart	iAware 🕺 Capacity Management 🧰 Collections Inquiry
ZZZTESTING, FREIDA 🛛 🗵					$\leftarrow \text{ List } \rightarrow \widehat{} \mbox{ Recent } \checkmark \mbox{ MRN } \qquad \bigcirc \checkmark$
ZZZTESTING. FREIDA DOB:04/Apr/15 Age:8 years	MRN:91682375 NHS: Gender:Female	** Allergies Not Recorded **	Weight: Fin#:11466373	TEP: Resus:	Loc:FHDUMMY Outpatient Referral FIN: 11466373 EDD:
Menu Ŧ	< 🔿 🔻 🏫 Research				🏹 Full screen 🛛 🖶 Print 🏼 🆅 1 minutes ago
Results Review	🗚 📄 📄 📄 🔍 🔍 100%	4			
Echo	Research X	+			🖬 0 👗 No Severity 🍡 😑
Requests/Care Plans					
Document Store	Ŧ	Adverse Events Log			+ V All Visits Last 5 years
Document Creation	Adverse Events Log	No Results Found			
Document Viewing + Add	CON-MEDs Log	No Results Found			
Ad-Hoc Forms	Medical History Log				
Diagram Store	Document Viewing (0)	CON-MEDS LOg			All VISIUS Last 5 years 9
Diagnosis & Problems	Completed/Modified	No Results Found			
Patient Work List	Powerforms (0)				
Nova Appmts		Medical History Log			+ V All Visits Last 5 years
Great North Care Record					
Research		No Results Found			
		Document Viewing (0)			+ All Visits Last 1 years Last 3 years V G
		No Results Found	Display: Facility defined view	Change Filter	st 50 Notes My Notes Only Group by Encounter
Patient Management conversations					N1PRD EDNEYM 31 January 2024 17:17 GMT

Figure 2 - Research view with no log entries

AEs, CON-MEDs and Medical History Logs on eRecord - v2

DLV-GEN-WI-014

Page 4 of 18



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

Task Edit View Patient Record Links Navigation Help										
🔐 Home 😂 Task List 📓 Ambulatory Organiser 🖃 Message Centre 🖕 Short Patient List 📓 Discharge Summary 📓 Ward Dashboard 📓 Draft Documents 📜 🗮 Tear Off 📲 Exit 📓 Calculator 🦉 AdHoc 🎟 Medication Administration										
ZZZTESTING, VALIDATION	×							← List →	🕆 Recent 👻 MRN	Q -
ZZZTESTING. VALIDATION DOB:01/Jan/01 Age:23 years	MRN:91836773 NHS: Gender:Male	** Allergies I	Not Recorded **	Weight: Fin#:138	59 Kg(M) 15/01/2 57888	24 TEP: Resu	s:For CPR 26/05	 /2023	.oc:RV17; B01; 02 npatient [01/Au EDD:	2 g/2023 14:25:00 B
Menu Ŧ	< > - AHP Workflow	v						- 	screen 📑 Print	t 🧳 2 minutes ago
AHP Workflow										
Critical Care Workflow										
Results Review	Research X Diete	ics ×	Occupational Th	er × Physic	therapy \times	Psychology	× +	ji o ini o	A. No Severity	♥ 4 =-
Assessments/Fluid Balance	Ŧ	Adverse Ever	nts Log					+ ~	All Visits Las	t 5 years 💪 🔨
Patient Task List	Adverse Events Log		02 AUC 2022	21 10 2022			04 100 2022			02.1111.2022
eObservations	CON-MEDs Log		10:11	12:05	11:34	09:44	13:19	10:40	09:51	15:32
eObservation Variations	Medical History Log	- Adverse Event	s Research Log							
Drug Chart	Documents Viewing (50)									
Drug Summary	Completed/Modified	AE Trial Name	Trial test2	GB66661	GB66661	GB66661	GB66661	testing∆	Testing	Testing testin
Allergies & Sensitivities	Powerforms (1)	AE R&D Number	R&D 12334	234GLOW	234GLOW	234GLOW	234GLOW	3456	1234	1546
Requests/Care Plans + Add										
Document Store		AE Patient Tri	134	23445	23	023ATTTT	23ATTTT	345	123	152
Document Creation						14.4			alt a but	
Medical Photography Images		AE Adverse Ev	Headache	Pain	TSGa	astret	Headache	Arthiritis in Wri	Shin Splintsa	Headache
Great North Care Record		AE Serious Ad	No	No	No	Yes	Yes	No	No	No
Document Viewing + Add										
Ad-Hoc Forms		AE Adverse Ev	No	No	No	Yes	No	Yes	No	No
Patient Summary		AE Madically A	No	No	No	Voc	No	No	No	No
Diagram Store		AE MEDICALLY A	140	140	NO	165	NO	NO	NO	NO
Diagram Creation		AE Severity Gr	Mild	3	1	fewewf	Mild	2	Mild	3
Disersaria & Decklares										
Diagnosis & Problems		AE Start Date	31 JUL 2023	27 JUN 2023	18 JUL 2023	31 JUL 2023	03 JUL 20234	08 MAY 2023	26 JUN 2023	30 JUN 2023
Histories		AE Is End Dat	No	No	No	No	Yes∆	No	No	Yes
Patient Work List										
Advanced Growth Chart		AE End Date					04 JUL 2023			30 JUN 2023
Patient Information			0	AU/	On and in a			Onester	Onestine	
Nova Appmts		AE Comments	Ungoing	INK	Ungoing			Ungoing	Ungoing	-
Clinical Notes + Add		AE Event Relat	No	Maybe	fds	refgreg	No	Maybe	No	No
Nightingale Workflow										
Advance Care Plan		AE Other Actio	None	None	sdf	argreqg	Medication	Monitoring	None	None
								N1BLD	EDNEYM 31 Janua	ry 2024 17:25 GMT

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

AEs, CON-MEDs and Medical History Logs on eRecord - v2

DLV-GEN-WI-014

Page 5 of 18





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

Adverse Events Log	1		 +	~ ~	All V	isits	Last 5 years	(J
No Results Found		2	 A	Adverse	e Events	Log		

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.

AEs, CON-MEDs and Medical History Logs on eRecord - v2

DLV-GEN-WI-014

Page 6 of 18







P Adverse Events	s Log - ZZZTESTING, BECKY		– D X
🗸 🖬 🚫 🔌	೫ + + ■ 🖩 🗎		
rerformed on:	07/08/2023 🛉 🗸 1626 🖨 BST		By: Edney, Martin
Adverse Events L	ZZZTESTING, BECKY NHS: MRN: 91544135		Adverse Events Log Entry
	Trial Name		
	Test trial	•	
5	R&D Number		-
	RD1245	3	
	Patient Trial Number		
	134		
	Adverse Event		
	•		
	Serious Adverse Event? (If Yes, Rer	nember to submit an SAE form)	
	O Yes O No		
	Adverse Event of Special Interest?		
	O Yes O No	- /	
	Medically Attended Adverse Event		
	O Yes O No O	Not applicable	
	Severity Grade / CTCAE Grade (e.g	. Mild / Moderate / Severe or Grade	1/2/3/4/5
	Start Date		
	жи јак јака		
	Is the End Date Known?	End Date	Comments (i.e. Not Known, Ongoing)
	O Yes O No	ne jan janne	
	Is This Event Related To The Diseas	se Under Study?	
	Other Action Taken / Any interventi	on (e.g. None / Procedure / Interver	tion stopped / Medication / Surgery / Hospitalisation)
			~
	<		In Progress a

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.

AEs, CON-MEDs and Medical History Logs on eRecord - v2

DLV-GEN-WI-014

Page 7 of 18



- 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)

AEs, CON-MEDs and Medical History Logs on eRecord - v2

DLV-GEN-WI-014

Page 8 of 18





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).

ZZZTESTING, VALIDATION - 91836	773 Opened by Edney, Martin						- 🗆 X
Task Edit View Patient Reco	ord Links Navigation Help						
🗄 🚰 Home 🔉 Task List 🌃 Ambulator	ry Organiser 🖃 Message Centre 🛔 S	hort Patient List 🌃 Discharge	Summary 🌇 Ward Dashbo	ard 🌃 Draft Documents 🚆	🕴 🔀 Tear Off 🛛 🗐 Exit	🔝 Calculator 🛛 MdHoc	IIIIIMedication Administration
ZZZTESTING, VALIDATION						← List → 音	Recent - MRN Q -
ZZZTESTING. VALIDATION DOB:01/Jan/01 Age:23 years	MRN:91836773 NHS: Gender:Male	** Allergies Not Reco	orded ** Weight: Fin#:13	59 Kg(M) 15/01/24 357888	TEP: Resus:For CPR	Lo Inj 26/05/2023 ED	c:RV17; B01; 02 patient [01/Aug/2023 14:25:00 B D:
Menu Ŧ	< > 👻 🔒 AHP Workflo	w				🔀 Full s	creen 🗧 Print 🕢 2 minutes ago
AHP Workflow	AA						
Critical Care Workflow							No Counting D.
Results Review	Research X Diete		auonai Ther X Physi	ounerapy A Psy	chology A		
Assessments/Fluid Balance	¥	Documents Viewing	g (50)			+ All Visits Last 1	years 🛛 Last 3 years 🗸 🖓 🔨
Patient Task List	Adverse Events Log	Time of Service 🗸 🗸	Subject	Note Type	Author	Last Updated	Last Updated By
eObservations	CON-MEDs Log	 In Progress (0) 					
eObservation Variations	Medical History Log	 Completed (50) 					
Drug Chart	Completed/Modified						
Drug Summary	Powertorms (1)	03 AUG 2023 10:11	Adverse Events Log	Adverse Events Log 🛆	Edney, Martin	04 AUG 2023 14:56	Edney, Martin
Requests (Care Dians + Add	Documents viewing (50)	03 AUG 2023 10:11	eAE Adverse Event	eAE Adverse Event	Edney, Martin	03 AUG 2023 10:11	Edney, Martin
Document Store							
Document Creation		03 AUG 2023 10:11	eAE Adverse Event Spe	AE Adverse Event Spe	Edney, Martin	03 AUG 2023 10:11	Edney, Martin
Medical Photography Images		03 AUG 2023 10:11	eAE Comments End Da	eAE Comments End Da	Edney, Martin	03 AUG 2023 10:11	Edney, Martin
Great North Care Record							
Document Viewing + Add		03 AUG 2023 10:11	2 elated-Pro	eAE Event Related-Pro	Edney, Martin	03 AUG 2023 10:11	Edney, Martin
Ad-Hoc Forms		03 AUG 2023 10:11	PAE IS END Date Known?	eAE Is End Date Known?	Edney, Martin	03 AUG 2023 10:11	Edney, Martin
Patient Summary			\		2011077 1 101011		2010// 10101
Diagram Store		03 AUG 2023 10:11	eAE Medically Attended	eAE Medically Attended	Edney, Martin	03 AUG 2023 10:11	Edney, Martin
Diagram Creation		02 AUG 2022 10:11	oAE Other Action Taken	oAE Other Action Taken	Ednov Martin	02 AUG 2022 10:11	Ednov Martin
Clinical Notes		05 A00 2025 10.11	EAE Other Action Taken	EAE Other Action Taken	Eurey, Marun	03 A0G 2023 10.11	Euriey, Marun
Diagnosis & Problems		03 AUG 2023 10:11	eAE Outcome	eAE Outcome	Edney, Martin	03 AUG 2023 10:11	Edney, Martin
Histories		02 41/5 2022 10:11	ALC Defines Trial Number	ALC Delivery Total Number	Educe Martin	02 41/2 2022 10:11	Educe Martin
Patient Work List		05 AUG 2023 10:11	CAE Patient Thai NUMber	Patient Thai Number	coney, Martin	03 AUG 2023 10:11	Euney, Martin
Advanced Growth Chart		03 AUG 2023 10:11	eAE R&D Number	eAE R&D Number	Edney, Martin	03 AUG 2023 10:11	Edney, Martin
Patient Information				A			
Nova Appmts		03 AUG 2023 10:11	eAE Serious Advesrse E	eAE Serious Advesrse E	Edney, Martin	03 AUG 2023 10:11	Edney, Martin
Clinical Notes + Add		03 AUG 2023 10:11	eAE Severity Grade	eAE Severity Grade	Edney, Martin	03 AUG 2023 10:11	Edney, Martin
Nightingale Workflow				N .			
Advance Care Plan		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 🛆	Edney, Martin	04 AUG 2023 14:56	Edney, Martin
			n	1 0			

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

AEs, CON-MEDs and Medical History Logs on eRecord - v2

DLV-GEN-WI-014

Page 9 of 18





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

2ZZTESTING, VALIDATION - 91836	773 Opened by Edney, Martin				- 0	×
Task Edit View Patient Reco	ord Links Navigation Help					
🗄 🚰 Home 🔒 Task List 🎬 Ambulator	ry Organiser 🖃 Message Centre 🖕 Sł	nort Patient List 📓 Discharge	Summary 🌇 Ward Dashbo	ard 🌃 Draf	aft Documents 🖞 🖾 Tear Off 🚽 Exit 📋 Calculator 🏾 🎬 AdHoc 💵 Medication Administration	* +
ZZZTESTING, VALIDATION					← List → 🛅 Recent - MRN	Q, 👻
ZZZTESTING. VALIDATION DOB:01/Jan/01 Age:23 years	MRN:91836773 NHS: Gender:Male	** Allergies Not Rec	orded ** Weight: Fin#:134	59 Kg(M) 1 357888	15/01/24 TEP: Inpatient [01/Aug/2023 14:25: Resus:For CPR 26/05/2023 EDD:	00 B
Menu Ŧ	< 🔶 🝷 👘 AHP Workflor	w			💱 Full screen 🛛 🖶 Print 🥠 12 minu	tes ago
AHP Workflow	A 100%	• • • 4				
Critical Care Workflow	Research X Diete	tics × Occup	ational Ther × Physi	otherapy	X Psychology X + A 0 0 A. No Severity S	=-
Results Review				oundrop,		
Assessments/Fluid Balance	+	Documents Viewin	g (50)		Print View Document Enable Continuous Scrolling	\times
Patient Task List	Adverse Events Log	Time of Service ∨	Subject	Note Type	e Adverse Events Log	
eObservations	CON-MEDs Log	 In Progress (0) 			Adverse Events Log (Modified) Author; Contributor(s): Edney, Martin	
eObservation Variations	Medical History Log	 Completed (50) 			Last Updated: 04 AUG 2023 14:56 Last Updated By: Edney, Martin	
Drug Chart	Completed/Modified					
All summary	Documents Viewing (50)	03 AUG 2023 10:11	Adverse Events Log	Adverse Ev	Adverse Events Log Entered On: 03/Aug/2023 10:12 BST	
Requests (Care Dans + Add	Bocanicita Hennig (30)	03 AUG 2023 10:11	eAE Adverse Event	eAE Adver	Performed On: 03/Aug/2023 10:11 BST by Edney, Martin	
Document Store						
Document Creation		03 AUG 2023 10:11	eAE Adverse Event Spe	eAE Adver	ar	
Medical Photography Images		03 AUG 2023 10:11	eAE Comments End Da	eAF Comm	Adverse Events Log <i>eAE Trial Name</i> : Trial test2	
Great North Care Record		007100202020121		012 00111	Edney, Martin - 04/Aug/2023 14:56 I [[Trial test] - previously charted by Edney, Martin at 03/Aug/2023 10:11 BS	3ST
Document Viewing + Add		03 AUG 2023 10:11	eAE Event Related-Pro	eAE Event	t eAE R&D Number : R&D 12334 eAE Patient Trial Number : 134	
Ad-Hoc Forms		02 AUG 2022 10:11	eAE Is End Date Known?	oAE Is End	eAE Adverse Event : Headache	
Patient Summary		05 A06 2025 10.11	eac is the bate knowing	EAE IS EIIC	eAE Adverse Event Special Interest? : No	
Diagram Store		03 AUG 2023 10:11	eAE Medically Attended	eAE Medic	eAE Medically Attended Adverse Events?: No eAE Severity Grade: Mild	
Diagram Creation					eAE Start Date : 31/Jul/2023 BST eAE Is End Date Known? : No	
Clinical Notes		03 AUG 2023 10:11	eAE Other Action Taken	eAE Other	eAE Comments End Date not Known : Ongoing	
Diagnosis & Problems		03 AUG 2023 10:11	eAE Outcome	eAE Outco	eAE Other Action Taken : None	
Procedures and Diagnoses					eAE Outcome : Recovered/Resolved Edney, Martin - 03/Aug/2023 10:111	BST
Histories		03 AUG 2023 10:11	eAE Patient Trial Number	eAE Patien	en an	
Patient Work List		03 AUG 2023 10:11	eAE R&D Number	eAE R&D N		
Patient Information						
Nova Appmts		03 AUG 2023 10:11	eAE Serious Advesrse E	eAE Seriou	κ.	
Clinical Notes + Add		03 AUG 2023 10:11	eAE Severity Grade	eAE Severi	r	
Nightingale Workflow				2 12 00701		
Advance Care Plan		03 AUG 2023 10:11	eAE Start Date	eAE Start I	:1	
		03 AUG 2023 10:11	eAE Trial Name	eAE Trial N	r	
				1995		

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

AEs, CON-MEDs and Medical History Logs on eRecord - v2

DLV-GEN-WI-014

Page 10 of 18





4 Modifying an existing log entry ("Completed/Modified Powerforms" section)

 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.)

P ZZZTESTING, BECKY - 91544135	Opened by Edney, Martin						– 🗆 ×
<u>T</u> ask <u>E</u> dit <u>V</u> iew <u>P</u> atient <u>R</u> e	ecord <u>L</u> inks <u>N</u> avigation <u>H</u> elp						
🗄 Home 🖃 Message Centre 🎬 A	Ambulatory Organiser 🌇 CareCompass	👫 Clinical Ward Summary	🌇 Discharge Summary	🜇 Ward Dashboard 📓	Draft D	ocuments 🊆 👯 Tear Off 🗄	± Exit ⅢⅢ Medication Administration
ZZZTESTING, BECKY \times						← List -	Recent - MRN Q -
ZZZTESTING. BECKY DOB:01/Jan/50	MRN:91544135 NHS:	** No Known Allergies **Flags**	** Weight:60	Kg(M) 09/11/23	TEP	:	Loc:FH11 Outpatient [19/Jul/2023 08:44:1
Age:74 years	Gender:Female		Fin#:14020	0138	Res	us:For CPR 09/03/2023	EDD:
Menu Ŧ	< 🗦 🔻 🔒 Research					53	Full screen 🗧 Print ᡝ 16 minutes ago
Results Review	🗚 🗎 🖶 🖿 🔍 🔍 100%	4					
Echo	Research ×	+				4	🖬 🛛 端 No Severity 🗣 🛛 🚍 🗸
Requests/Care Plans	Т			(-)	-		
Document Store	- T	Completed/Modif	ed Powerforms	(3)	_	Modify	×
Document Creation	Adverse Events Log	Result/Form Name	Result		Auth	Adverse Events Lo	q
Ad-Hoc Forms	CON-MEDs Log	✓ Results (0)				Δ Modified	-
Diagram Store	Medical History Log	▼ Forms (3)			_	Contributor List	
Diagnosis & Problems	Powerforms (3)					Edney, Martin	
Patient Work List	Document Viewing (5)	Medical History Log En	try th (Verif	ied)	Orop	13 DEC 2023 14:27	
Nova Appmts		Adverse Events Log	th (Verif	ied)	Edne	Edney, Martin 24 OCT 2023 09:33	
Great North Care Record						Edney, Martin	
Research		Adverse Events Log∆	Modified		Edne	16 AUG 2023 09:24	
						Edney, Martin 16 AUG 2023 09:23	
		Document Viewin	g (5)				
			Display: Facilit	y defined view Change	e Filter		
		Time of Service 🗸	Subject	Note Type	Auth		
		▼ In Progress (0)					
		✓ Completed (5)					
		04 JAN 2024 15:15	Medical History Log	Medical History Log	Orop		
		24 NOV 2023 15:33	NextCove Study (R+	Research Note Δ	Jevoi		
		07 NOV 2023 12:06	Adverse Events Log	Adverse Events Log	Educ		
		07 NOV 2023 12:06	Adverse Events LOg	Auverse Events LOg	cune		
		22 SEP 2023 09:59	CON-MEDs Log	CON-MEDs Log Δ	Edne		
		16 AUG 2023 09:08	Adverse Events Log	Adverse Events Log Δ	Edne		
					_		
						N1PF	RD EDNEYM 01 February 2024 10:13 GMT



- 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

AEs, CON-MEDs and Medical History Logs on eRecord - v2

DLV-GEN-WI-014

Page 11 of 18





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

P Adverse Events Log - ZZZTESTING, BECKY	— D X
🗸 🖶 🛇 🥸 🚮 🛧 🔸 📾 🖾 🔛	
* formed on: 16/08/2023 • 0908 • BST	By: Edney, Martin
Alverse Event ZZZTESTING, BECKY NHS: MRN: 91544135	dverse Events Log Entry
Trial Name	
7 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)	
C Yes No	
Adverse Event of Special Interest?	
O Yes No	
Medically Attended Adverse Event?	
C Yes No C Not applicable	
Severity Grade / CTCAE Grade (e.g. Mild / Moderate / Severe or Grade 1 / 2 / 3 / 4 / 5	
Mid	
Start Date	
15/08/2023	
Is the End Date Known? End Date Commer	nts (i.e. Not Known, Ongoing)
● Yes O No 15/09/2023 + ✓	<u>ě</u>
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)

AEs, CON-MEDs and Medical History Logs on eRecord - v2

DLV-GEN-WI-014

Page 12 of 18





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.

 Recovered/Resolved with sequelae Not Recovered/Not Resolved 	
Authorisation (Doctor)	Authorisation Date

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,	when each log entry was created (i.e., when it was first opened)
CON-MEDs Log and	
Medical History Log	
Completed/Modified	when each log entry was most recently saved – usually a few minutes after
Powerforms	it was created, but will be later if the entry has been modified
Documents Viewing	both timestamps
	• "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)
	 "Last Updated" shows when each log entry was most recently saved
	(i.e., same as the "Completed/Modified Powerforms" section)

AEs, CON-MEDs and Medical History Logs on eRecord - v2

DLV-GEN-WI-014

Page 13 of 18



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.

а		
🗄 🚰 Home 🖃 essage Centre 🌃 Ar	nbulatory Organiser 🧰 Diary 🛔 Shor	t Patient List 🏢
Tear Off Exit 🔝 Calculator	🖞 AdHoc 🍰 PM Conversation 🝷 🧔 🤇	Collections Inqu
Remove the current view an	d re-create on desktop	
ZZZTESTING. BECKY	MRN:91544135	
DOB:01/Jan/50	NHS:	
Age:73 years	Gender:Female	
Menu ¥	< 🔿 🔻 🟫 Nurse Workf	low
Clinician Workflow	A 100%	
Nurse Workflow		
ALID Worldinu	Outpatient ×	Continuatio
AFF WORKNOW		1
Critical Care Workflow	+	Presentir
NICU Workflow	Presenting Complaints	Enter Chief

Figure 12 - PowerChart Tear Off

AEs, CON-MEDs and Medical History Logs on eRecord - v2

DLV-GEN-WI-014

Page 14 of 18



7 Appendix – Log Entry Forms

7.1 Adverse Events Log entry form

P Adverse Events L	og - ZZZTESTING, BECKY			
🗸 🖬 🚫 🖄 🗖	🛿 🛧 🕂 📾 🖾 🗎			
*Performed on: 16	5/08/2023 • 0908 • BST			
Adverse Events L	ZZZTESTING, BECKY NHS: MRN: 91544135		Adverse Even	ts Log Entry
	Trial Name			
	R&D Number			
	Patient Trial Number			
	Adverse Event			
	Serious Adverse Event? (If Yes, R	emember to submit an SAE f	orm)	
	O Yes O No			
	Adverse Event of Special Interest	?		
	O Yes O No			
	Medically Attended Adverse Ever	t?		
	O Yes O No C	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, Ong	joing)
	O Yes O No	**/**/****	v]
	Is This Event Related To The Dise	ase Under Study?		
	Other Action Taken / Any interver	ntion (e.g. None / Procedure /	Intervention stopped / Medication / Surgery /	Hospitalisation)

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

AEs, CON-MEDs and Medical History Logs on eRecord - v2

DLV-GEN-WI-014

Page 15 of 18





IMP Number	Relationship To IMP
	(Probable / Possible / Likely / Unlikely or Related / Unrelated)
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
Outcome	
Recovered/Resolved Fatz Recovering/Resolving Recovered/Resolved with sequelae Not Recovered/Not Resolved	al known
Authorisation (Doctor)	Authorisation Date

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

AEs, CON-MEDs and Medical History Logs on eRecord - v2

DLV-GEN-WI-014

Page 16 of 18





7.2 Concomitant Medication Log entry form

08/2023 🗣 🗸 1416 📮 B	ST	
ZZZTESTING, BECKY		CON-MEDs Log Entry
NHS: MRN: 91544135		
	7	
Define the New York		
Patient Irial Number	7	
Principal Investigator		
R&D Number		
Medication (Please use trade r	name)	
Indication		
Start Date known?	Start Date	Partial Start Date Or Unknown (e.g. 'NK/12/2021' or 'NK')
O Yes O No	xx pxx pxxxx 🔺 🗸	
	-	
End Date known?	End Date	Partial End Date Or Unknown (e.g. 'NK/12/2021' or 'NK')
O Yes O No	××/××/×××× 🔹 🗸	
Dose (including units)	-	
Frequency		
O OD (Once Daily) O SD (S	Six times a day) O Three times a week	
O TDS (Three times a day) O DN (A	At night) O Not known	
QDS (Four times a day) O MDU D (Five times a day) O PRN	(As directed) (When required)	
Route		
O Oral O Sub-cutane	ous O Intrapericardial O Transderr	nal
O IM (intramuscular) O Intramyocar	dial ONebulised ONot know	n
 Inhaled Intranasal IV (intravenous) Intraosseous 	 Rectal Sublingual 	
Is this a vaccine trial?		
O Yes O No		
Solicited Event?		
O Yes O No		
Doctor Authentication	Doctor Authentication	on Date
Booton Automation		51 5410
	1 mm / 1	

Figure 15 - CON-MEDs Log entry form

AEs, CON-MEDs and Medical History Logs on eRecord - v2

DLV-GEN-WI-014

Page 17 of 18





The Newcastle upon Tyne Hospitals NHS Foundation Trust

7.3 Medical History Log entry form

P Medical History Lo	ig Entry - ZZZTESTING, RESEARCH	- D >
🗸 🖬 🚫 🕅 🧖		
*Performed on: 20/03	3/2024 • 0908 • GMT	By: Edney, Mar
Medical History Log	ZZZTESTING, RESEARCH NHS: MRN: 91865198 Medical History Log Er	ntry
1	Trial Name	
F	Patient Trial Number	
	ledical Term / Procedure	
	Common Terminology Criteria for Adverse Events (CTCAE) Grade Others	
•	0 1 0 2 0 3 0 4 0 5 0 Others 0 N/A	
	Start Date Partial Start date or Unknown (e.g. 'NK/12/2021' Yes No	or 'NK')
E	End Date Known? End Date Partial End date or Unknown (e.g. 'NK/12/2021'	or 'NK')
[O Yes O No O Ongoing (™/>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>	
4	Any Intervention?	
	No Ves: Medication Ves: Surgery Ves: Hospitalisation V N/A	
(Comments	
	Autoriation Dete	
<		>
		In Progress

Figure 16 – Medical History Log entry form

AEs, CON-MEDs and Medical History Logs on eRecord - v2

DLV-GEN-WI-014

Page 18 of 18