A3.27 Serious Adverse Event (SAE) Form

Must be entered onto eCRF within 24 hours (regulatory requirement)

1.	Seriousness *(Circle all that apply)*	Death	1
		Life-threatening	2
		Requires inpatient hospitalisation	3
		Prolongs current inpatient hospitalisation	4
		Results in persistent / significant disability / incapacity	5
		Consists of a congenital anomaly or birth defect	6
		Any episode of deliberate self harm	7
		Other: ______________________________	8

2.	Participant Information		
2a.	Sex	Male	0
		Female	1
2b.	Date of birth	☐☐ ☐☐ ☐☐☐☐ Day Month Year	
2c.	Ethnicity	White	1
		Mixed	2
		Asian	3
		Black	4
		Chinese	5
		Other	6

3a.	Event Onset	☐☐ ☐☐ ☐☐☐☐ : Day Month Year
3b.	Date Became Serious *(Only if different from event onset)*	☐☐ ☐☐ ☐☐☐☐ : Day Month Year

4.	Brief description of event – diagnosis or main symptom(s) only *(attach additional sheets if necessary)*

5.	Severity	Mild	1
		Moderate	2
		Severe	3

6.	Trial Medication (ie Placebo / Mirtazapine / Sertraline) for Depression in Dementia	
6a.	Start Date	☐☐ ☐☐ ☐☐☐☐ Day Month Year

6b.	Anticipated Stop Date	Day Month Year	
6c.	Dose at Event Onset	None	0
		Low	1
		Medium	2
		High	3
6d.	Date / Time of Last Dose *(prior to event becoming serious)*	Day Month Year :	
6e.	Trial medication administered in accordance with the protocol?	No	0
		Yes	1
		Unknown	88
6f.	Code broken as a result of this event	No	0
		Yes (Reason:_______________________________)	1

7a.	Action taken with trial medication	None	1
		Temporary Dose Reduction: Date of dose increase *(if applicable)*: Day Month Year	2
		Permanent Dose Reduction	3
		Temporary Discontinuation Date of reintroduction *(if applicable)*: Day Month Year	4
		Permanent Discontinuation	5
7b.	Use of corrective therapies for this event	No	0
		Yes (Specify:_______________________________)	1
7c.	Did the event reappear after reintroduction or dose increase?	No	0
		Yes	1
		Not applicable	77
		Unknown	88

8.	Outcome		
8a.	Death (Cause: ___________________________)	Day Month Year	1
8b	Ongoing (persistence)		2
8c.	Recovered with significant sequelae (Specify:___________________________)		3

		Day Month Year	
8d.	Recovered without significant sequelae	[ ][ ] [ ][ ] [ ][ ][ ][ ] Day Month Year	4
8e.	Unknown		88

9a.	Relationship to Study Medication	Definite	1
		Probable	2
		Possible	3
		Remote	4
		None	5
9b.	Relationship to Medical Conditions *(including Dementia and/or Depression)*	Definite	1
		Probable	2
		Possible	3
		Remote	4
		None	5

10.	Expected event (according to SmPC, protocol & medical history)	No	0
		Yes	1

11.	Additional Comments (if any)

12.	***Signature of Research Worker:*** ______________________ ***Date:*** __/__/_______