

Supplementary Data B: Trial characteristics of the included 70 RCTs

S. No.	Drug for I	Ind.	Age (years)	Trial	Dose of I mg/day	No. in I arm	Active C	No. in C arm	Dose of C mg/day	No. in PLB arm	Study R duration (weeks)	Coding dictionary used	Trial phase	Any psycho active or sedative medications permitted	Excluded patients with suicidal risk
1.	duloxetine	MDD	18-65	HMAQa	20 to 60	70	FLX	33	20	70	8	COSTART	2	Y	Y
2.	duloxetine	MDD	18 to 65	HMAQb	20 to 60	82	FLX	37	20	75	8	Not stated	2	Y	Y
3.	duloxetine	MDD	at least 18	HMAYa	40 or 60	188 40: 95 60: 93	PAR	86	20	93	8	Not stated	3	Y	Y
				HMAYa EXT/CONT*	40 or 60	145 40: 70 60: 75	PAR	70	20	58	26	Not stated	3	Y	Y
4.	duloxetine	MDD	at least 18	HMAyb (Acute)	40 or 60	196 40: 93 60: 103	PAR	97	20	99	8	Not stated	3	Y	Y
				HMAyb EXT/CONT*	40 or 60	152 40: 71 60: 81	PAR	70	20	71	26	Not stated	3	Y	Y
5.	duloxetine	MDD	at least 18	HMBHa	60	123	None	NA	NA	122	9	Not stated	3	Y	Y
6.	duloxetine	MDD	at least 18	HMBHb	60	128	None	NA	NA	139	9	Not stated	3	Y	Y
7.	duloxetine	MDD	at least 18	HMBC	60	533	None	NA	NA	None	12	MedDRA	3	Y	Y
				HMBC EXT/CONT*	60	136	None	NA	NA	142	26	MedDRA	3	Y	Y
8.	duloxetine	MDD	at least 18	HMATa	20 or 40	175 20: 91 40: 84	PAR	89	20	90	8	Not stated	3	Y	Y
9.	duloxetine	MDD	at least 18	HMATb	20 or 40	177 20: 86 40: 91	PAR	87	20	89	8	Not stated	3	Y	Y
10.	duloxetine	MDD	18 to 72	HMAH	20 or 30	89	None	NA	NA	88	10	Not stated	2	Y	Y
				HMAH EXT	20 or 30	23	None	NA	NA	23	44	Not stated	2	Y	Y

S. No.	Drug for I	Ind.	Age (years)	Trial	Dose of I mg/day	No. in I arm	Active C	No. in C arm	Dose of C mg/day	No. in PLB arm	Study R duration (weeks)	Coding dictionary used	Trial phase	Any psycho active or sedative medications permitted	Excluded patients with suicidal risk
				/CONT*											
11.	duloxetine	MDD	at least 18	HMAI	5, 10 or 20	390 5: 130 10: 129 20: 131	CLO	132	150	126	8	Not stated	2	Y	Y
				HMAI EXT/CONT*	5, 10 or 20	185 5: 57 10: 71 20: 57	CLO	64	150	59	44	Not stated	2	Y	Y
12.	duloxetine	MDD with short REM latency	18 to 72	HMAG	20	53	None	NA	NA	52	12	Not stated	2	Y	Y
13.	duloxetine	SUI for Women	at least 18	SBAT	80	247	None	NA	NA	247	12	MedDRA	3	N	N
14.	duloxetine	SUI for Women	18 to 65	SAAW	20, 40, or 80	415 20: 138 40: 137 80: 140	None	NA	NA	138	12	MedDRA	2	N	N
15.	duloxetine	SUI or mixed for Women	18 to 80	SAAB	20, 30, and 40	221 20: 75 30: 69 30/40: 77	None	NA	NA	67	6	Not stated	2	N	N
16.	duloxetine	SUI or mixed for Women	at least 18	SBAX	80	227	None	NA	NA	231	12	MedDRA	3	N	N
17.	duloxetine	SUI or mixed for Women	at least 18	SBAV	80	344	None	NA	NA	339	12	MedDRA	3	N	N
18.	duloxetine	SUI for Women electing surgery for severe pure	≥18 and ≤75	SBAM	80 to 120	55	None	NA	NA	54	8	MedDRA	2	N	N

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		GSI													
19.	duloxetine	SUI, urge, or mixed	30 to 80	SAAA	20	55	None	NA	NA	37	3	Not stated	2	N	N
20.	duloxetine	SUI with Urinary Urgency and PDO	18 to 85	SAAH	30 or 40	16	None	NA	NA	16	1	COSTART	2	N	N
21.	duloxetine	BPH in Men	40 to 85	SAAI	30 or 40	47	None	NA	NA	44	4	COSTART	2	N	N
22.	duloxetine	FM with or without MDD	at least 18	HMBOa	60	104 37 with MDD and 67 with No MDD	None	NA	NA	103 42 MD and 61 no MD	12	Not stated	2	Y	Y
23.	duloxetine	DPNP	at least 18	HMAW	60BI D ¹ 60Q D ² 20Q D	342 60 ¹ : 113 60 ² : 114 20: 115	None	NA	NA	115	12	Not stated	2	Y	N
24.	fluoxetine	MDD	8 to <18 (8 to <13 children 13<18 adolescents)	X065	20**	48	None	NA	NA	48	8	COSTART	3	N	N
25.	fluoxetine	MDD	8 to <18 (8 to <13 children 13<18 adolescents)	HCJE	20 to 60	109	None	NA	NA	110	9	Not stated	3	Y	Y
				HCJE EXT/	20 to 60	FLX/	FLX/ PLB	20	NA	PLB/ PLB	42	Not stated	3	Y	Y

S. No.	Drug for I	Ind.	Age (years)	Trial	Dose of I mg/day	No. in I arm	Active C	No. in C arm	Dose of C mg/day	No. in PLB arm	Study R duration (weeks)	Coding dictionary used	Trial phase	Any psycho active or sedative medications permitted	Excluded patients with suicidal risk
				CONT*		FLX 20				40					
26.	fluoxetine	OCD	7 to <18 (7 to <13 children 13<18 adolescents)	HCIJW	20 to 60	71	None	NA	NA	32	13	COSTART	3	Y	Y
27.	paroxetine	MDD	12 to 18 (18+11 months)	329	20 to 40	93	IMI	95	50 to 300	87	8	ADECS	Not stated	N	Y
28.	paroxetine	MDD	13 to 18 (18+11 months)	377	20 to 40	187	None	NA	NA	99	12	ADECS	Not stated	N	Y
29.	paroxetine	MDD	7 to 17	701	10 to 50	104	None	NA	NA	102	8	ADECS	Not stated	N	Y
30.	paroxetine	PTSD	at least 18	627	20 to 50	160	None	NA	NA	162	12	ADECS	Not stated	Y	Y
31.	paroxetine	PTSD	at least 18	648	20 to 50	151	None	NA	NA	156	12	ADECS	Not stated	Y	Y
32.	paroxetine	PTSD	at least 18	651	20 or 40	365 20: 183 40: 182	None	NA	NA	186	12	ADECS	Not stated	Y	Y
33.	paroxetine	SAD/SP	8 to 17	676	10 to 50	165	None	NA	NA	157	16	ADECS	Not stated	N	Y
34.	paroxetine	OCD	7 to 17	704	10 to 50	100	None	NA	NA	107	10	ADECS	Not stated	N	Y
35.	sertraline	MDD in hospitals	18 to 65	050-101	50,100, 200 or 400	96 50: 26 100: 24 200: 23 400: 23	None	NA	NA	26	4	Not stated	Not stated	Y	U
36.	sertraline	MDD	18 to 65	050-103	50, 100	278 50: 95	None	NA	NA	91	6	Not stated	2/3	Y	U

S. No.	Drug for I	Ind.	Age (years)	Trial	Dose of I mg/day	No. in I arm	Active C	No. in C arm	Dose of C mg/day	No. in PLB arm	Study R duration (weeks)	Coding dictionary used	Trial phase	Any psycho active or sedative medications permitted	Excluded patients with suicidal risk
					or 200	100: 92 200: 91									
37.	sertraline	MDD	18 to 65	050-104	50, 100, or 200	149	AMY	149	50, 100, or 150	150	8	Not stated	2/3	Y	N
38.	sertraline	MDD	18 to 65	050-310	50, 100, 200 or 400	151 50: 39 100: 36 200: 38 400: 38	None	NA	NA	37	4	Not stated	Not stated	Y	U
39.	sertraline	MDD or bipolar depression	18 to 70	050-334	50 to 200	129	None	NA	NA	129	6	Not stated	Not stated	N	Y
40.	sertraline	MDD	18 to 60	86CE21-0238	50, 100, 200 or 400	159	None	NA	NA	40	8	Not stated	Not stated	Y	Y
41.	sertraline	MDD	60 and above	86CE21-0247	50 to 200	43	DES	45	25 to150	42	8	Not stated	Not stated	Y	Y
42.	sertraline	MDD	6 to 17	A0501001	25 to 200	97	None	NA	NA	91	10	WHO-ART	3	Y	Y
43.	sertraline	MDD	6 to 17	A0501017	25 to 200	92	None	NA	NA	96	10	WHO-ART	3	Y	Y
44.	sertraline	PTSD	18 or older	93CE21-0640	25 to 200	100	None	NA	NA	108	12	WHO-ART	3	Y	Y
45.	sertraline	PTSD	18 or older	93CE21-0641	25 to 200	86	None	NA	NA	83	12	WHO-ART	3	Y	Y
46.	sertraline	PTSD	at least 18	95CE21-0671	25 to 200	94	None	NA	NA	93	12	WHO-ART	3	Y	Y
47.	sertraline	PTSD	at least 18	96CE21-0682	25 to 200	96	None	NA	NA	97	12	WHO-ART	3	Y	Y

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48.	sertraline	GSP	at least 18	R-0601	25 to 200	211	None	NA	NA	204	12	WHO-ART	3	Y	Y
49.	sertraline	SP	18 to 60	STL-NY-94-004	50 to 200	135	None	NA	NA	69	20	Not stated	3	N	Y
50.	sertraline	OCD	16 to 75	050-336	50 to 200	76	None	NA	NA	78	12	Not stated	Not stated	N	N
51.	sertraline	OCD	18 or older	86CE21-0237 & 86CE21-248	50 to 200	44	None	NA	NA	43	8	WHO-ART	Not stated	Y	U
52.															
53.	sertraline	OCD	18 or older	88CE21-0371 & 88CE21-0372	50, 100 or 200	241 371:102 372: 139	None	NA	NA	84 371: 38 372: 46	12	WHO-ART	Not stated	Y	U
54.															
				88CE21-0371 & 88CE21-0372 EXT/CONT*	50, 100 or 200	96 371: 40 372: 56 50: 33 100: 25 200: 38	None	NA	NA	22 371: 9 372: 13	48	WHO-ART	Not stated	Y	U
55.	sertraline	OCD	18 or older	91CE21-0546	50 to 200	86	None	NA	NA	82	12	WHO-ART	Not stated	Y	U
56.	sertraline	OCD	6 to 17	90CE21-0498	25, 50 or 200	94	None	NA	NA	95	12	WHO-ART	Not stated	N	N
57.	sertraline	PD	18 or older	90CE21-0514	50, 100 or 200	119	None	NA	NA	38	12	WHO-ART		Y	N
58.	sertraline	PD	18 or older	90CE21-0529	50, 100 or 200	132	None	NA	NA	45	12	WHO-ART	Not stated	Y	N

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59.	sertraline	PD	18 or older	93CE21-0629	25 to 200	85	None	NA	NA	88	10	WHO-ART	Not stated	Y	Y
60.	sertraline	PD	18 or older	93CE21-0630	25 to 200	88	None	NA	NA	90	10	WHO-ART	Not stated	Y	Y
61.	sertraline	PD	18 or older	93CE21-0646	25 to 100	103	None	NA	NA	99	10	WHO-ART	Not stated	Y	Y
62.	sertraline	NIDDM	18 to 70	050-113	50 to 200	181	None	NA	NA	175	54	Not stated	Not stated	N	U
63.	venlafaxine	MDD	18 or older	600A-:302-US, CA/302	75 to 200	72	TRA	77	150 to 400 avg.: 294 to 300	76	6	Not stated	3	Y	Y
				600A-:302-US, CA/302 EXT/CONT*	75 to 200	37	TRA	30	150 to 400 avg.: 294 to 300	29	67.6	Not stated	3	Y	Y
64.	venlafaxine	MDD	18 or legal age of consent or older	0600A1-372-US	200, 300 or 375	157	FLX	158	40, 60 or 80	152	6	COSTART	3	Y	Y
65.	venlafaxine	MDD	18 to 65	0600A-203-US	25, 75, or 125	266	None	NA	NA	92	6	Not stated	2	Y	U
					25 mg 89 75 mg 89 125mg 88										
66.	venlafaxine	MDD	18 or legal age of consent	600A-303-US	75 to 225	83	IMI	82	75 to 225 avg.: 177	82	6	Not stated	3	Y	Y

S. No.	Drug for I	Ind.	Age (years)	Trial	Dose of I mg/d ay	No. in I arm	Active C	No. in C arm	Dose of C mg/day	No. in PLB arm	Study R duration (weeks)	Coding dictionary used	Trial phase	Any psycho active or sedative medications permitted	Excluded patients with suicidal risk
			or older						to185						
				600A-303-US EXT/CONT*	75 to 225	33	IMI	35	75 to 225	33	51.5	Not stated	3	Y	Y
67.	venlafaxine	MDD	18 to 65	600A-313-US	25, 75 or 200	238 25: 80 75: 76 200: 82	None	NA	NA	80	6	Not stated	3	Y	Y
68.	venlafaxine extended release	MDD	18 or legal age of consent or older	0600B-209-US	75 to 225	100	None	NA	NA	104	8	Not stated	3	Y	Y
69.	venlafaxine extended release	MDD	18 or legal age of consent or older	0600B-367-EU	75 or 150	167 75: 85 150: 82	PAR	82	20	83	8	Not stated	3	Y	Y
70.	venlafaxine extended release	MDD	18 or legal age of consent or older	0600B 1-384-US/EU/CA	150 to 375	180	IMI	187	50 to 200	68	6	Not stated	3	Y	Y

Y: yes; N: no; U: unclear- no list of inclusion and exclusion criteria only summary information and no access to protocol for confirmation.
I: intervention; C: comparator; PLB: placebo

BID: twice daily; QD: once daily

AMY: amitriptyline; CLO: clomipramine; DES: desipramine; IMI: imipramine; TRA: trazodone; V

BPH: Irritative Symptoms of Benign Prostatic Hyperplasia; diabetic peripheral neuropathic pain; FM: Fibromyalgia; GSI: genuine stress incontinence; GSP: generalized social phobia; MDD: major depressive disorder; NIDDM: patients with non-insulin-dependent diabetes mellitus for obesity; OCD: obsessive compulsive disorder; PD: panic disorder; DPNP: Painful Diabetic Neuropathy; PDO: Proven Detrusor Overactivity; PTSD: posttraumatic stress disorder; REM: short rapid eye movement ; SAD: social anxiety disorder; SP: social phobia; SUI: stress urinary incontinence

ADECS: Adverse Drug Experience; COSTART: Coding System Coding Symbols for a Thesaurus of Adverse Reaction Terms; MedDRA: Medical Dictionary for Regulatory Activities; WHO-ART: World Health Organization Adverse Drug Reaction Terminology

**denotes extension phase or continuation (EXT/ CONT) of trial;*

**** notes that patients unable to tolerate fluoxetine could dose every other day instead of daily dosing in trial X065**