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Appendix 1: RIAT Audit Record (RIATAR) [posted as supplied by author]

*A tool for documenting the transformation from regulatory documents to journal publication, based on the CONSORT 2010 checklist of information to include when reporting a randomised trial**

Section/Topic	Item No.	Checklist item	Reported on page No. of RIAT manuscript	Source section(s) of the Clinical Study Report (CSR): page No. and paragraph**	PDF page No. (for PDF files)***	Notes
Title and abstract						
	1a	Identification as a randomised trial in the title	p.1			
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	p.1	CSR Final Clinical Report Acute Phase; Report Synopsis, pages 13-21; Continuation Study, Final Clinical Report, Report Synopsis, pages 4 to 9.	CSR Final Clinical Report Acute Phase; Report Synopsis, pages 13-21; Continuation Study, Final Clinical Report, Report Synopsis, pages 4 to 9.	
Introduction				CSR Final Clinical Report Acute Phase; 1 Introduction, pages 22-23; Appendix A, Protocol, 1.0 INTRODUCTION, page 545-546; Continuation Study, Final Clinical Report, Introduction, page 17.	CSR Final Clinical Report Acute Phase, Same pages; Appendix A, Protocol, PDF pages 15-16; Continuation Study, Final Clinical Report, Introduction, page 17.	
Background and objectives	2a	Scientific background and explanation of rationale	p.2-3	CSR Final Clinical Report Acute Phase; 1 Introduction, page 22, paragraphs 1-2; Appendix A, Protocol, 1.0 INTRODUCTION, page 545, paragraphs 1-2;	CSR Final Clinical Report Acute Phase; 1 Introduction, page 22, paragraph 1-2; Appendix A, Protocol, 1.0 INTRODUCTION, page 15, paragraph 1-2;	
	2b	Specific objectives or hypotheses	p.2-3	CSR Final Clinical Report Acute Phase; Report Synopsis, Objectives, page 14, paragraphs 1 to 3; 2 Objectives, 2.1 Primary, page 24, paragraph 1; Objectives, 2.2 Secondary, page 24, paragraphs 2-4; Appendix A, Protocol,	CSR Final Clinical Report Acute Phase, Same pages; Appendix A, Protocol, SYNOPSIS, OBJECTIVES OF STUDY, page 10; 2.0	

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				SYNOPSIS, OBJECTIVES OF STUDY, page 540; 2.0 OBJECTIVES, 2.1 Primary, page 547 paragraph 1; 2.2 Secondary, page 547 paragraphs 2-4; Appendix A, Protocol, Appendices, APPENDIX G, CLINICAL MANAGEMENT FOR ADOLESCENT DEPRESSION, I. Purpose of Study, page 602; Continuation Study, Report Synopsis, Objectives, PDF page 1; Continuation Phase Final Clinical Report, 1 Introduction, page 17 paragraph 2; Continuation Phase Final Clinical Report, 2 Objectives, page 18;	OBJECTIVES, Primary, page17; Appendix A, Protocol Appendices PDF page 72; Continuation Study, Report Synopsis no page numbers in the document; Continuation Phase Final Clinical Report same pages;	
Methods						
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	p.9	CSR Final Clinical Report Acute Phase; Report Synopsis, Study Design, page 14, paragraph 4; 3 Methodology, 3.1 Study Design, page 25, paragraph 1; Figure 1 Study Design, page 26; 3.13.3 Method of Randomization, page 49 paragraph 4; Appendix A, Protocol, 3.0 STUDY PLAN, 3.1 Study Design, page 548 paragraph 1-3; Appendix A, Protocol, 5.0 CONDUCT OF STUDY, 5.2 Study Method, 5.2.2 Randomization, page 555; Continuation Study, Report Synopsis, Study Design, PDF page 1; Continuation Phase Final Clinical Report, 3 Methodology, 3.1 Overview, page 19-20;	CSR Final Clinical Report Acute Phase, Same pages; Appendix A Protocol, PDF page 18; Appendix A Protocol, 5.0 CONDUCT OF STUDY, 5.2 Study Method, 5.2.2 Randomization, page 25; Continuation Study, Report Synopsis no page numbers in the document;	
	3b	Important changes to methods after trial	p.4	CSR Final Clinical Report Acute Phase; Report Synopsis, Evaluation Criteria, page 15 paragraph 5; 3 Methodology, 3.1	CSR Final Clinical Report Acute Phase, Same pages; 3 Methodology, 3.1	

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		commencement (such as eligibility criteria), with reasons		Study Design,3.1.1 Protocol Amendments, Amendment 1 (approved 17 April, 1994), pages 26-27; Amendment 2 (approved 28 October 1996), pages 27-28; Amendment #1, page 536-537; Amendment #2, page 538-539;	Study Design,3.1.1 Protocol Amendments, Amendment 1 (approved 17 April, 1994), pages 26-27; Amendment 2 (approved 28 October 1996), pages 27-28; Appendix A, Protocol, PDF page 6-7; page 8-9;	
Participants	4a	Eligibility criteria for participants	p.3-4; Table 1	CSR Final Clinical Report Acute Phase; Report Synopsis, Study Population, page 14, paragraph 5; 3 Methodology, 3.1 Study Design, page 25, paragraph 1, page 26, Figure 1; 3.4 Eligibility Criteria, 3.4.1 Inclusion Criteria, page 30, paragraph 2; 3.4.2 Exclusion Criteria, pages 30, paragraph 3 to page 31; Appendix A, Protocol, 4.0 STUDY POPULATION, 4.2 Inclusion criteria, page 549 paragraph 2; 4.3 Exclusion Criteria, page 549 paragraph 2 to page 550; Continuation Study, Report Synopsis, Study Population, PDF page 2; Continuation Phase Final Clinical Report, 3.2 Inclusion Criteria: Continuation Phase, page 20 paragraph 1; 4 Study Population, 4.1 Entry into the Continuation Phase, page 24; 4.2 Reasons for Not Entering the Continuation Phase, page 25 to page 26 paragraph 1;	CSR Final Clinical Report Acute Phase, Same pages; Appendix A, Protocol, PDF page 19-20;	
	4b	Settings and locations where	p.4	CSR Final Clinical Report Acute Phase; Report Synopsis, Investigators and	Clinical Report Acute Phase, Same pages;	

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		the data were collected		Centers, page 13, paragraph 2; 3.2 Investigators, page 28, paragraph 3 to page 29;		
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	p.4	CSR Final Clinical Report Acute Phase; Report Synopsis, Treatment and Administration, page 15, paragraphs 1 to 3; 3.5 Treatments and Administration, 3.5.1 Study Medication, page 32; 3.5.2 Dosage and Administration, page 33 to page 35 paragraph 1; 3.5.4 Other Protocol-specified Therapy, page 35, paragraph 4; 3.6 Compliance with Study Medication, page 36; 3.7 Prior and Concomitant Medication, 3.7.1 Prior Medication, page 36, paragraph 2; 3.7.2 Concomitant Medication, page 36, paragraph 3-5; Appendix A, Protocol, 6.0 DRUG SUPPLIES AND PACKAGING, 6.1 Formulations, page 559; 6.2 Study Drug Administration, page 559; 6.4 Concomitant Medication, page 560 paragraph 1-2; 6.5 Packaging, page 560; 6.6 Labeling and Preparation, page 560; 6.7 Storage, page 560; 6.8 Drug Accountability, page 560; 6.9 Assessment of Compliance, page 561; Appendix A, Protocol Appendices, APPENDIX G, CLINICAL MANAGEMENT FOR ADOLESCENT DEPRESSION, pages 599 to 623; Continuation Study, Report Synopsis, Treatment and Administration, PDF page2; Continuation Phase Final Clinical Report, 3.3 Study Medication and	CSR Final Clinical Report Acute Phase, Same pages; Appendix A, Protocol, PDF page 29, 30-31; page 69-93; Continuation Study, Report Synopsis, Treatment and Administration, PDF page2; Continuation Phase Final Clinical Report, 3.3 Study Medication and Administration, page 20 paragraph 2 to page 21 paragraphs 1-2;	

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				Administration, page 20 paragraph 2 to page 21 paragraphs 1-2;		
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	p.4-9	CSR Final Clinical Report Acute Phase; Report Synopsis, Evaluation Criteria, Efficacy Parameters, Safety Parameters, Other Parameters, page 15, paragraphs 4-5, page 16, paragraphs 1-2; 3.9 Efficacy Assessments, pages 41-44; 3.9.1 Primary Efficacy Parameters, pages 43 paragraph 4 to page 44 paragraph 1; 3.9.2 Secondary Efficacy Parameters, page 44 paragraph 2; 3.10 Safety Assessments, 3.10.1 Adverse Experiences, page 44 paragraph 4 to page 45 paragraphs 1-2; 3.13.4 Planned Efficacy Evaluations, page 49, paragraph 5, Primary Efficacy Variables, page 49 paragraph 6 to page 50 paragraphs 1-6; Appendix A, Protocol, 9.0 DATA EVALUATION, 9.1 Criteria for Efficacy, 9.1.1 Primary efficacy variables, page 571 paragraph 1; 9.1.2 Secondary efficacy variables, page 571 paragraph 2; Appendix A, APPENDIX F, INSTRUMENTS, pages 597-598. Continuation Study, Report Synopsis, Evaluation Criteria, PDF page 2; Continuation Phase Final Clinical Report, 3.6 Planned Efficacy Evaluations, page 22 paragraphs 2-4;	CSR Final Clinical Report Acute Phase, Same pages; Appendix A, Protocol, PDF page 41, 67-68; Continuation Study, Report Synopsis, Evaluation Criteria, PDF page 2; Continuation Phase Final Clinical Report, 3.6 Planned Efficacy Evaluations, page 22 paragraphs 2-4;	
	6b	Any changes to trial outcomes after the trial	p.5	CSR Final Clinical Report Acute Phase; Report Synopsis, Evaluation Criteria, Efficacy Parameters, page 15, paragraph	Clinical Report Acute Phase, Same pages;	

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		commenced, with reasons		5;		
Sample size	7a	How sample size was determined	p.4,9	CSR Final Clinical Report Acute Phase; 3 Methodology, 3.1 Study Design,3.1.1 Protocol Amendments, Amendment 2 (approved 28 October 1996), pages 27-28; 3.13.2 Target Sample Size, page 49 paragraph 3; Appendix A, Protocol, Amendment #2 page 533, last line; Amendment #2, page 538-539; 9.2.2 Sample size determination, page 572 paragraphs 1-2;	Clinical Report Acute Phase, Same pages; Appendix A, Protocol, PDF pages 3, 8-9. 42;	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	4	CSR Final Clinical Report Acute Phase; 3 Methodology, 3.1 Study Design,3.1.1 Protocol Amendments, Amendment 2 (approved 28 October 1996), pages 27-28; 3.13.2 Target Sample Size, page 49 paragraph 3; 3.13.4 Planned Efficacy Evaluations, page 49; Appendix A, Protocol, Amendment #2, page 538-539;	Clinical Report Acute Phase, Same pages; Appendix A Protocol, PDF pages 8-9;	
Randomisation:						
Sequence generation	8a	Method used to generate the random allocation sequence	p.9	CSR Final Clinical Report Acute Phase; 3.13.3 Method of Randomization, page 49 paragraph 4; Appendix A, Protocol, 5.2.2 Randomization, Randomized Assignment of Subjects to Treatment, page 555 paragraph 2; Appendix A, Randomisation Code, page 1431 to 1434; Continuation Study, Final Clinical Report, 3.5 Method of Randomization, page 22.	CSR Final Clinical Report Acute Phase, Same pages; Appendix A, Protocol, PDF page 25; Appendix A, Protocol PDF pages 901-904; Continuation Study, Final Clinical Report, 3.5 Method of Randomization, page 22.	

Section/Topic	Item No.	Checklist item	Reported on page No. of RIAT manuscript	Source section(s) of the Clinical Study Report (CSR): page No. and paragraph**	PDF page No. (for PDF files)***	Notes
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	p.9	CSR Final Clinical Report Acute Phase; 3.13.3 Method of Randomization, page 49, paragraph 4; Continuation Study, Final Clinical Report, 3.5 Method of Randomization, page 22.	Clinical Report Acute Phase, Same pages; Continuation Study, Final Clinical Report, 3.5 Method of Randomization, page 22.	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	p.9	CSR Final Clinical Report Acute Phase; 3.13.3 Method of Randomization, page 49, paragraph 4; 3.5.3 Methods of Blinding, page 35, paragraph 2-3; Appendix A, Protocol, 5.2.2 Randomization, Randomized Assignment of Subjects to Treatment, page 555 paragraph 2; Blank Case Report Form (CRF), QUALIFICATION FOR ENTRY TO DOUBLE-BLIND PHASE, page 734; Continuation Study, Final Clinical Report, 3.5 Method of Randomization, page 22.	Clinical Report Acute Phase, Same pages; Appendix A, Protocol, 5.2.2 Randomization, Randomized Assignment of Subjects to Treatment, page 25 paragraph 2; Blank Case Report Form (CRF), QUALIFICATION FOR ENTRY TO DOUBLE-BLIND PHASE, page 204; Continuation Study, Final Clinical Report, 3.5 Method of Randomization, page 22.	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	p.9	CSR Final Clinical Report Acute Phase; 3.13.3 Method of Randomization, page 49, paragraph 4; Continuation Study, Final Clinical Report, 3.5 Method of Randomization, page 22.	Clinical Report Acute Phase, Same pages; Continuation Study, Final Clinical Report, 3.5 Method of Randomization, page 22.	
Blinding	11a	If done, who was blinded after assignment to	p.9	CSR Final Clinical Report Acute Phase; 3.1.1 Protocol Amendments, Amendment 1, page 27, paragraph 3; Amendment 2,	Clinical Report Acute Phase, Same pages;	

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		interventions (for example, participants, care providers, those assessing outcomes) and how		page 28, paragraph 2; 3.5.3 Methods of Blinding, page 35, paragraph 2-3; Final Clinical Report, Treatment and Administration, page 15, paragraph 3; Appendix A, Protocol, 5.2.3 Treatment Phase, Termination at end of acute study for non-responders, page 557, paragraph 5; 6.3 Blinding, page 559 paragraph 3;	PDF page Appendix A, pages 27, 29;	
	11b	If relevant, description of the similarity of interventions	p.9	CSR Final Clinical Report Acute Phase; Report Synopsis, Treatment and Administration, page 15, paragraphs 1 to 3; 3.5 Treatments and Administration, 3.5.1 Study Medication, page 32; 3.5.2 Dosage and Administration, page 33 to page 35 paragraph 1; 3.5.4 Other Protocol-specified Therapy, page 35, paragraph 4; 3.7 Prior and Concomitant Medication, 3.7.1 Prior Medication, page 36, paragraph 2; 3.7.2 Concomitant Medication, page 36, paragraph 3-5; Appendix A, Protocol, 6.4 Concomitant Medication, page 560 paragraph 1-2; Protocol Appendices, APPENDIX G, CLINICAL MANAGEMENT FOR ADOLESCENT DEPRESSION, pages 599 to 623;	CSR Final Clinical Report Acute Phase, Same pages; Appendix A, Protocol, PDF page 30; page 69-93;	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	p.10	CSR Final Clinical Report Acute Phase; Report Synopsis, Statistical Methods, page 16, paragraph 3; 3.13 Statistical Evaluation, page 48, paragraphs 6-7; 3.13.1 Comparison of Interest, page 49; 3.13.5 Methods of Analysis, page 50 paragraph 7-8 to page 51 paragraph 1-6;	CSR Final Clinical Report Acute Phase, Same pages; Appendix A, Protocol, PDF page 41; pages 42-43; page 43; pages 43-44; Statistical Report PDF pages 922-	

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				3.13.6 Populations/Data Sets to be Evaluated, page 51 paragraph 7 to page 54 paragraph 1-3; 5.1 Efficacy Evaluation, 5.1.1 Data Sets Analyzed, page 71 paragraph 1-2; 5.2.4 Sustained Response, page 78 paragraph 1; Appendix A, Protocol, 9.2 Statistical Methods, 9.2.1 Comparisons of interest, page 571 paragraph 3; Protocol, 9.3 Efficacy Analysis, 9.3.1 Intent to Treat Analysis, 9.3.2 Patients Valid For The Efficacy Analysis, page 572 paragraph 2 to page 573 paragraph 1; Protocol, 9.3.3 Statistical Methodology, page 573 paragraph 2-5; Protocol, 9.3.4 Test of Significance, page 573 paragraph 6 -7; Statistical Report, pages 1452-1453; Statistical Report, 2 Statistical Methodology, page 1454 to 1457; Details of statistical methods presented also in Statistical Report, 3 Summary of Statistical Results, page 1458-1479; Continuation Phase Final Clinical Report, 3.6.3 Statistical Analysis, page 23 paragraphs 2-3; 3.7 Planned Safety Evaluations, page 23 paragraph 3;	927; pages 928-949;	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	p.6-9 (methods for additional harms analysis)	CSR Final Clinical Report Acute Phase; page 15, paragraph 5; 3.1.1 Amendments, Amendment 2, page 27 paragraph 6 to page 28 paragraph 1; page 44, paragraph 3; 3.13.5 Methods of Analysis, page 50 paragraph 3; 5.1.1 Data Sets Analyzed, page 71 paragraph 1; 5.4 Efficacy Subgroup Analysis, page	Clinical Report Acute Phase, Same pages; Appendix A, PDF page 926;	

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				89 paragraph 1 to page 90 paragraph 1-2; Appendix A, Statistical Report, 2.5 Covariate Analyses, page 1456 paragraph 6;		
Results						
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	p.11, Figure 1	Final Clinical Report, Acute Phase, Report Synopsis, Patient Disposition and Key Demographic Data page 16 paragraph 4; Table Demographic and Clinical Characteristics at Entry page 17; Table Patient Disposition page 17; 4 Study Populations, 4.2 Patient Disposition, 4.2.1 Number and Distribution of Patients page 56 paragraph 2; Table 7, Number of Patients Who Were Randomized (R) to Each Treatment Group and Who Completed* (C) Acute Phase of Treatment at Each Center, page 57; 4.2.2 Number of Patients Present at Each Visit, page 57; Table 8, Number of Patients Remaining in the Study by Visit and Treatment Group, page 58; 4.7 Treatment Compliance and Titration, 4.7.1 Treatment Compliance, Table 18, Summary of Patient Compliance with Study Medication over the 8 Week Treatment Period (number (%) of patients), page 69; 4.7.2 Titration of Dose Table 19 Number of Patients at Dose Level by Treatment Group and Study Week, page 70; 5 Efficacy Results, 5.2 Efficacy Results, 5.2.1 Change from Baseline in Total HAM-D Score, Table 20	Same page numbers in the PDF of Final Clinical Report, Acute Phase, Final Clinical Report, Continuation Phase, and Appendix B;	

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				Baseline Mean (+/- SE) and Mean Change from Baseline (+/- SE) in Total HAM-D Score for OC Dataset at Each Treatment Week and the LOCF Dataset at Week 8, page 72; 5.2.2 Change from Baseline in HAM-D Subscales, Table 22 Baseline Mean (+/- SE) and Mean Change from Baseline (+/- SE) in Mood Item and Factors* of the HAMD for the Week 8 LOCF and OC Week 8 Datasets, page 74; 5.2.3 Responders and Remission Analysis, Table 23 Number (%) of Patients Who Responded* to Treatment for OC Dataset at Each Treatment Week and the LOCF Dataset at Week 8, page 76; Table 25 Number (%) of Patients in Remission* for OC Dataset at Each Treatment Week and the LOCF Dataset at Week 8, page 76; 5.2.5 CGI Improvement Scale, Table 28 Mean Improvement Score (+/- SE) on the CGI Scale for OC Dataset at Each Treatment Week and the LOCF Dataset at Week 8, page 80; Table 30 Number and Percent of Patients Having a CGI Score of "Very Much Improved" or "Much Improved" for OC Dataset at Each Treatment Week and the LOCF Dataset at Week 8, page 82; 5.2.6 K-SADS-L - Depression 9-Item Scale - Change from Baseline, Table 32 Baseline Mean (+/- SE) and Change from Baseline (+/- SE) in KSADS-L - Depression 9-Item Scale for OC Dataset at Each Treatment Week and the LOCF Dataset at Week 8, page		

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				84; 5.2.7 Change from Baseline in K-SADS-L Depressed Mood Item, Table 34 Baseline Mean (+/- SE) and Mean Change from Baseline (+/- SE) in Depressed Mood Item of the K-SADS-L Depression Scale for the Week 8 OC and Week 8 LOCF Datasets, page 86; 5.3 Functional, Self Perceptive and Behavioral Scales5.3.1 Autonomous Functioning Checklist, Table 36 Baseline Mean (+/- SE) and Mean Change from Baseline (+/- SE) in Total Score and Subscores on the Autonomous Functioning Checklist at Endpoint, page 87; 5.3.2 Self Perception Profile, Table 37 Baseline Mean (+/- SE) and Mean Change from Baseline (+/- SE) in Total Score on the Self Perception Profile for the Week 8 OC and Week 8 LOCF Datasets, page 88; 5.3.3 Sickness Impact Profile, Table 38 Baseline Mean (+/- SE) and Mean Change from Baseline (+/- SE) in Total Score and Subscores on the Sickness Impact Profile for the Week 8 OC and Week 8 LOCF Datasets, page 89; 5.4 Efficacy Subgroup Analysis, Table 39 Summary of Responders by Subgroup at Endpoint, page 90; 10 Data Source Tables: Study Population, Table 12.1 Summary of Patient Distribution by Investigator by Treatment (Intent-to-Treat Population), page 130; Table 12.2 Summary of Patients Remaining in the Study at Weekly Intervals (Intent-to-Treat		

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				Population), pages 131-132; 11 Data Source Tables: Efficacy Results, pages 189-221; Continuation Study, Final Clinical Report, Report Synopsis, Patient Disposition and Key Demographic Data, page 6; 4 Study Population4.1 Entry into the Continuation Phase, page 24, Figure 2 Disposition of Patients, page 25; Table 3 Number (%) of Randomized Patients Who Completed the Acute Phase But Did Not Participate in the Continuation Phase, by Reason (ITT Population), page 26; 4.3 Disposition of Patients in the Continuation Phase, page 26; 6 Efficacy Results, 6.3 Hamilton Depression Scale, Table 20 Baseline Mean (±SE) and Mean Change from Baseline at Each Visit–HAM-D Scale (ITT Population), page 58; 6.4 Clinical Global Impression of Improvement, Table 21 Distribution of Patients in Each Class of CGI Global Improvement at Week 32 LOCF Endpoint (Intent to Treat Population), page 59; Table 22 Mean (±SE) CGI Global Improvement at Each Visit (ITT Population), page 59; 9 Data Source Tables: Study Population, Table 12.2 Summary of Patients Remaining in the Study at Weekly Intervals(Intent to Treat Population), pages 66-67; 10 Data Source Tables: Efficacy, pages 88-112;		
	13b	For each group, losses and exclusions after	p.11; Figure 1	Final Clinical Report, Acute Phase, Report Synopsis, Patient Disposition and Key Demographic Data page 16	Same page numbers in the PDF of Final Clinical Report, Acute Phase,	

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		randomisation, together with reasons		paragraph 4; Table Patient Disposition, page 17; 4 Study Populations, 4.2 Patient Disposition, 4.2.1 Number and Distribution of Patients, page 56 paragraph 2; Table 7, page 57; Table 8, page 58; 4.2.3 Withdrawal Reasons, page 58; Table 9, Number (%) of Randomized Patients Who Completed or Were Withdrawn from the Study, by Reason for Withdrawal, page 59; page 59; Table 10, Number and Cumulative Percentage of Patients Withdrawn from the Study by Reason and by Week, page 60; 4.3 Protocol Violations, pages 60-62; 6.7 Withdrawals for Adverse Experiences, page 110; Table 49,Treatment-emergent Adverse Experiences, Regardless of Attribution, page 111-112; Table 50, Adverse Experiences Leading to Withdrawal Leading to Withdrawal (number (%) of patients), page 113-114; 10 Data Source Tables: Study Population, Table 12.3 Summary of Patient Withdrawals (Intent-to-Treat Population), pages 133-134; Table 12.4 Distribution of Patient Withdrawals by Reason and Week (Intent-to-Treat Population), pages 135-140; 12 Data Source Tables: Safety Results, Table 14.9.1 Summary of Adverse Experiences Leading to Withdrawal during Acute Phase by ADECS Body System and Preferred Term Non-gender Specific Adverse Experiences (Intent-to-Treat Population),	Final Clinical Report, Continuation Phase, and Appendix B;	

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				pages 308-309; Table 14.9.1a, Adverse Experiences Leading to Withdrawal Patient Narratives, pages 310-366; Table 14.9.3 Summary of Adverse Experiences Leading to Withdrawal during Acute Phase by ADECS Body System and Preferred Term Female Specific Adverse Experiences (Intent-to-Treat Population), page 367; Appendix B: Patient Data Listings of Demographic, Appendix B.1 Listing of Patient Terminations by Treatment Group and Patient Intent-to-Treat Population, pages 2-21; Continuation Study, Final Clinical Report, Report Synopsis, Patient Disposition and Key Demographic Data, page 6; 4 Study Population 4.1 Entry into the Continuation Phase, Figure 2 Disposition of Patients, page 25; 4.3 Disposition of Patients in the Continuation Phase, page 26; Table 4 Number (%) of Randomized Patients Who Completed or Were Withdrawn from the Study, by Reason for Withdrawal (ITT Population), page 27; 5 Safety Results, 5.5 Withdrawals for Adverse Events, pages 41-45; 9 Data Source Tables: Study Population, Table 12.3 Summary of Patient Withdrawals (Intent to Treat Population), pages 68-69; 12.4 Distribution of Patient Withdrawals by Reason and Week (Intent to Treat Population), pages 70-75; 10 Data Source Tables: Efficacy, Table 15.1 Number (%) of Patients Withdrawing for Lack of Efficacy (Continuation Phase)		

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				(Intent to Treat Population), page 87; 11 Data Source Tables: Safety, Table 16.9.1 Summary of Adverse Experiences Leading to Withdrawal during the Continuation Phase by ADECS Body System and Preferred Term-Non-gender Specific Adverse Experiences (Intent to Treat Population), page 192; Table 16.9.2 Summary of Adverse Experiences Leading to Withdrawal during the Continuation Phase by ADECS Body System and Preferred Term-Male Specific Adverse Experiences (Intent to Treat Population), page 193; Table 16.9.3 Summary of Adverse Experiences Leading to Withdrawal during the Continuation Phase by ADECS Body System and Preferred Term-Female Specific Adverse Experiences (Intent to Treat Population), page 194; Table 16.9.4 Narratives for Patients with Non-Serious Adverse Events Leading to Withdrawal, pages 195-210;		
Recruitment	14a	Dates defining the periods of recruitment and follow-up	p.3	Final Clinical Report, Acute Phase, Report Synopsis, Study Dates, page 13, paragraph 5; 3.2 Investigators, page 28 paragraph 4; 4 Study Populations, 4.1 Study Dates, page 56 paragraph 1; Continuation Study, Final Clinical Report, Report Synopsis, Study Dates, page 4, paragraph 2; 4 Study Population 4.1 Entry into the Continuation Phase, page 24, paragraph 2;	Same page numbers in the PDF of Final Clinical Report, Acute Phase and Final Clinical Report, Continuation Phase;	

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	14b	Why the trial ended or was stopped				
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Page 10-11; Table 2	Final Clinical Report, Acute Phase, Report Synopsis, Table Demographic and Clinical Characteristics at Entry, page 17; 4 Study Populations, 4.4 Demographic and Baseline Characteristics, 4.4.1 Demographic Characteristics, Table 13 Demographic Characteristics of Randomized Patients, page 63; 4.4.2 Baseline Characteristics, Table 14 Baseline Characteristics Regarding Major Depressive Disorder of All Randomized Patients, page 65; Table 15 Medical or Surgical Conditions Occurring in 3 or More of Patients in Any Treatment Group at Baseline (number (%) of patients), page 66; Table 16 Presenting Conditions Occurring in 3 or More of Patients in Any Treatment Group at Baseline (number (%) of patients), page 67; 4.6 Prior and Concomitant Medications, Table 17 Concomitant Medications Received by 5% or More of Patients in Any Treatment Group (number (%) of patients), page 68; 10 Data Source Tables: Study Population; Table 12.5.1 Summary of Demographic Data Intent-to-Treat Population, page 141-142; Table 12.5.2 Summary of Height and Weight at Screening/Baseline Intent-to-Treat Population, page 143; Table 12.6 Summary of Child Global	Same page numbers in the PDF of Final Clinical Report, Acute Phase and Final Clinical Report, Continuation Phase;	

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				(“However, the number of patients completing the additional six months of study medication in the continuation phase was small (18 in the paroxetine group and 13 each in the imipramine and placebo groups), which limits any conclusions that can be drawn regarding long-term efficacy.”); paragraph 2 (“Additionally, compliance in the continuation phase, defined as taking 80% to 120% of study medication over the course of the continuation phase, was less than ideal in all three treatment groups: 78.8% among paroxetine patients, 82.5% among imipramine patients and 72.7% among placebo patients. The small sample size along with poor compliance makes it difficult to draw meaningful conclusions about the results of the study.”); Safety:, page 62, paragraph 4 (“It is not unexpected for some adolescents to experience this degree of weight gain in an eight-month period.”); Efficacy:, page 63 paragraph 1 (“In this continuation phase of the study, patients were not re-randomized, which would be necessary in order to establish long-term efficacy.”), paragraph 3 (“Since the number of patients in each group was small, it is difficult to draw meaningful conclusions about any differences between the groups.”); 8 Conclusions, page 64 (“However, with such a small sample size, in the absence of pre- and post-dose body mass index data, the clinical relevance of such findings is difficult to establish in an actively growing		

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Protocol	24	Where the full trial protocol can be accessed, if	p.2, 26, 27 (references	SmithKline Beecham study 29060/329, Final Clinical Report Acute Phase,	Final Clinical Report Acute Phase, Appendix A, Protocol, from PDF page	

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		available	7 and 8)	Appendix A, Protocol, from page 531;	1;	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	p.26	SmithKline Beecham study 29060/329, Final Clinical Report Acute Phase, page 1; Supply of drugs: Final Clinical Report, Report Synopsis, Treatment and Administration, Test product, Reference therapies, page 15, paragraph 1-2; 3 Methodology, 3.5 Treatments and Administration,3.5 Treatments and Administration, 3.5.1 Study Medication, Table 2 Appearance, Formulation, Dosage Strengths, and Batch Numbers of Study Medication, page 32, paragraph 1; Role of funders: Final Clinical Report, 3.2 Investigators, page 28, paragraph 3-5 to page 29, paragraph 1; Role of funders:3 Methodology, 3.5 Treatments and Administration,3.5.3 Methods of Blinding, page 35, paragraph 3; Role of funders: 3.10 Safety Assessments, 3.10.1 Adverse Experiences, Serious Adverse Experiences, page 45 paragraph 2; 3.12 Data Quality Assurance, page 47 paragraph 5 to page 48 paragraph 1-5; Role of funders: Final Clinical Report Acute Phase, Appendix A, Protocol, Amendment #1 Approved: April17, 1994, Section 7.5.2, page 537; Amendment #2 Approved: October 28, 1996, Section 7.5.2, page 539, paragraph 5; 5.0 CONDUCT OF STUDY,5.1 Ethical Considerations, 5.1.1 Ethics Review Committee (ERC)/Institutional Review Board (IRB), page 551, paragraphs 3, 4; Appendix A, Protocol, 5.2.2 Randomization, page 555 paragraph 2; Final Clinical Report Acute	Same page numbers for PDF Final Clinical Report Acute Phase and Final Clinical Report, Continuation Phase; Final Clinical Report Acute Phase, Appendix A, Protocol, PDF pages 7, 9, 21; Appendix A, Protocol, PDF page 25; Final Clinical Report Acute Phase, Appendix A, Protocol, PDF page 26; Appendix A, Protocol, PDF pages 36, 37; Clinical Report Acute Phase, Appendix A, Protocol, PDF page 38; Clinical Report Acute Phase, Appendix A, Protocol, PDF page 38; Clinical Report Acute Phase, Appendix A, Protocol, PDF page 38; Appendix A, Protocol, PDF page 45; Final Clinical Report Acute Phase, Appendix A, Protocol, APPENDIX B, ADMINISTRATIVE MATTERS, II. PROTOCOL AMENDMENTS, PDF page 55; PDF pages 56-	

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				Phase, Appendix A, Protocol, 5.2.3 Treatment Phase, Assessments during study visits, Serum Levels, page 556 paragraph 3-4; 7.0 ADVERSE EXPERIENCES, 7.4 Following-up of Adverse Experiences, page 566; 7.5 Serious Adverse Experiences, 7.5.2 Reporting Serious Adverse Experiences, page 567; Final Clinical Report Acute Phase, Appendix A, Protocol, 7.6 Overdosage, page 568 paragraph 1; Final Clinical Report Acute Phase, Appendix A, Protocol, 7.7 Pregnancy, page 568 paragraph 4; Final Clinical Report Acute Phase, Appendix A, Protocol, 7.8 Breaking the Study Blind, page 568 paragraph 5; 10.0 ADMINISTRATIVE MATTERS, page 575; Final Clinical Report Acute Phase, Appendix A, Protocol, APPENDIX B, ADMINISTRATIVE MATTERS, II. PROTOCOL AMENDMENTS, page 585 paragraph 5; Final Clinical Report Acute Phase, Appendix A, Protocol, APPENDIX B, ADMINISTRATIVE MATTERS, III. SPONSOR'S TERMINATION OF STUDY, page 585 paragraph 7; Final Clinical Report Acute Phase, Appendix A, Protocol, APPENDIX B, ADMINISTRATIVE MATTERS, IV. CASE REPORT FORM INSTRUCTIONS, page 586 to page 587 paragraph 1-2; Final Clinical Report Acute Phase, Appendix A, Protocol, APPENDIX B, ADMINISTRATIVE MATTERS, V. MONITORING BY SMITHKLINE BEECHAM (i.e. the Sponsor), page 587	57; Final Clinical Report Acute Phase, Appendix A, Protocol, APPENDIX B, ADMINISTRATIVE MATTERS, MONITORING BY SMITHKLINE BEECHAM (i.e. the Sponsor), PDF page 57; PDF pages 57; pages 57-58; PDF pages 58-59; PDF page 905-916; PDF page 950-952;	

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				paragraph 3-4; VI. ARCHIVING OF DATA, page 587 paragraph 6-7; VII. AUDITS, page 587 paragraph 8 to page 588 paragraph 1-4; VIII. CONFIDENTIALITY AND PUBLICATION, page 588 paragraph 5-6 to page 589 paragraph 1-3; Certificates of Analysis, page 1435-1446; Audited Investigator Sites, page 1480-1482; SmithKline Beecham study 29060/329, Final Clinical Report, Addendum to Study Report Continuation Phase, page 1; 3.3 Study Medication and Administration, page 20; 3.5 Method of Randomization, page 22;		

*The aim of this audit tool is provide a permanent record of the parts of text, tables and figures of the source Clinical Study Report (CSR) selected for inclusion into the RIAT manuscript submitted for publication. This tool is based upon checklist items described in the CONSORT 2010 statement, which is a widely adopted standard for reporting randomised trials. RIAT authors should consult the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. Similar audit records can be created for other types of trials by adapting other CONSORT extensions, e.g. for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. See www.consort-statement.org for more details.

**Note that CSR Appendix A contains the study Protocol, which itself includes APPENDIX A to APPENDIX G. The CSR appendices are written here with lower case letters except for the first letter, which is upper case (Appendix A, Appendix B, etc.); the appendices of Appendix A are written with upper case letters entirely (ex. APPENDIX A, APPENDIX B, etc.).

***All CSR Final Clinical Report PDF page numbers are the same as the document page numbers.