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

RIAT Audit Record (RIATAR)

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	

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
				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	

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
		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;	

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
		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;	

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
				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;	

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
		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;	

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
		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-	

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
				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;	

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
				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;	

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
				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		

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
				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		

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
				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,	

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
		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;	

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
				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)		

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
				(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;	

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
	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;	

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
				Assessment Scale (Scores at Screening) Intent to Treat Population, page 144; Table 12.7 Summary of Kiddie-SADS-Lifetime Diagnostic Criteria at Screening Intent to Treat Population, page 145-150; Table 12.8 Summary of Personal History Intent-to-Treat Population, page 151-152; Table 12.9 Summary of Medical/Surgical History Intent-to-Treat Population, page 153-156; Table 12.10 Summary of Presenting Conditions Intent-to-Treat Population, page 157-160; Table 12.11 Summary of Prior Medications by WHO ATC Classification Intent-to-Treat Population, page 161-165; Table 12.14 Summary of Concomitant Medications by WHO ATC Classification Acute Phase Intent-to-Treat Population, page 167-172; Table 12.20 Summary of Duration of Current Episode (mo) Intent to Treat Population, page 176; Table 12.21 Summary of Number of Depressive Episodes Intent to Treat Population, page 177; Table 12.21 Summary of Number of Depressive Episodes Intent to Treat Population, page 178; Table 12.22 Summary of Age at Onset of First Episode (yr) Intent to Treat Population, page 179; Table 12.23 Summary of Melancholic/Endogenous Depression Intent to Treat Population, page 180; Table 12.24 Summary of Atypical Depression Intent to Treat Population, page 181; Table 12.25 Summary of Family History of Major Depression Intent		

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
				to Treat Population, page 182; Table 12.26 Summary of Any Concomitant Diagnosis Intent to Treat Population, page 183; Table 12.27 Summary of Anxiety Disorder Intent to Treat Population, page 184; Table 12.28 Summary of Externalizing Disorder Intent to Treat Population, page 185; Continuation Study, Final Clinical Report, 5.6 Vital Signs and Body Weight, 5.6.1 Mean Values and Changes in Value, Table 13 Vital Signs and Body Weight at Baseline and Endpoint (mean ± SD) (ITT Population), page 46; 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; 9 Data Source Tables: Study Population, Table 12.15 Summary of Concomitant Medications by WHO ATC Classification Continuation Phase Intent-to-Treat Population, page 76-79; 10 Data Source Tables: Efficacy, Table 15.3 Baseline Mean and Mean Change from Baseline at Monthly Intervals-HAMD Scale (Continuation Phase) (Intent to Treat Population), page 89; Table 15.4 Baseline Mean and Mean Change from Baseline at Monthly Intervals-K-SADS-L Depression 9-Item Scale (Continuation Phase) (Intent to Treat Population), page 90; Table 15.7 Baseline Mean and Mean Change from Baseline at Monthly Intervals-HAMD Anxiety Somatization		

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
				Scale (Continuation Phase) (Intent to Treat Population), page 93; Table 15.8 Baseline Mean and Mean Change from Baseline at Monthly Intervals-HAMD Sleep Scale (Continuation Phase) (Intent to Treat Population), page 94; Table 15.9 Baseline Mean and Mean Change from Baseline at Monthly Intervals-HAMD Cognitive Disturbance Scale (Continuation Phase) (Intent to Treat Population), page 95; Table 15.10 Baseline Mean and Mean Change from Baseline at Monthly Intervals-HAMD Retardation Scale (Continuation Phase) (Intent to Treat Population), page 96; Table 15.11 Baseline Mean and Mean Change from Baseline at Monthly Intervals-Self Perception Profile Scale (Continuation Phase) (Intent to Treat Population), page 97; Table 15.12 Baseline Mean and Mean Change from Baseline at Monthly Intervals-Autonomous Functioning Scale (Continuation Phase) (Intent to Treat Population), page 98; Table 15.13 Baseline Mean and Mean Change from Baseline at Monthly Intervals-Autonomous Functioning Scale: Self/Family Care Subscore (Continuation Phase) (Intent to Treat Population), page 99; Table 15.14 Baseline Mean and Mean Change from Baseline at Monthly Intervals-Autonomous Functioning Scale: Management Subscore (Continuation Phase) (Intent to Treat Population), page		

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
				100; Table 15.15 Baseline Mean and Mean Change from Baseline at Monthly Intervals-Autonomous Functioning Scale: Recreational Activity Subscore (Continuation Phase) (Intent to Treat Population), page 101; Table 15.16 Baseline Mean and Mean Change from Baseline at Monthly Intervals-Autonomous Functioning Scale: Social/Vocational Activities Subscore (Continuation Phase) (Intent to Treat Population), page 102; Table 15.17 Baseline Mean and Mean Change from Baseline at Monthly Intervals-Sickness Impact Profile Scale (Continuation Phase) (Intent to Treat Population), page 103; Table 15.18 Baseline Mean and Mean Change from Baseline at Monthly Intervals-SIP Scale: Present Health Subscore (Continuation Phase) (Intent to Treat Population), page 104; Table 15.19 Baseline Mean and Mean Change from Baseline at Monthly Intervals-SIP Scale: Present Quality of Life Subscore (Continuation Phase) (Intent to Treat Population), page 105; Table 15.20 Baseline Mean and Mean Change from Baseline at Monthly Intervals-SIP Scale: Sleep/Rest Subscore (Continuation Phase) (Intent to Treat Population), page 106; Table 15.21 Baseline Mean and Mean Change from Baseline at Monthly Intervals-SIP Scale: Home Maintenance Subscore (Continuation Phase) (Intent to Treat Population), page 107; Table 15.22		

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
				Baseline Mean and Mean Change from Baseline at Monthly Intervals-SIP Scale: Social Interaction Subscore (Continuation Phase) (Intent to Treat Population), page 108; Table 15.23 Baseline Mean and Mean Change from Baseline at Monthly Intervals-SIP Scale: Alertness Behavior Subscore (Continuation Phase) (Intent to Treat Population), page 109; Table 15.24 Baseline Mean and Mean Change from Baseline at Monthly Intervals-SIP Scale: Communication Subscore (Continuation Phase) (Intent to Treat Population), page 110; Table 15.25 Baseline Mean and Mean Change from Baseline at Monthly Intervals-SIP Scale: Recreational Pastimes Subscore (Continuation Phase) (Intent to Treat Population), page 111; Table 15.26 Baseline Mean and Mean Change from Baseline at Monthly Intervals-HAMD Depressed Mood Item (Continuation Phase) (Intent to Treat Population), page 112;		
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned	Page 11, Figure 1; page 12, table 3; page 13, Table 4; page 13, Table 5; page 14, Table 6;	Final Clinical Report, Acute Phase, Report Synopsis, Table Demographic and Clinical Characteristics at Entry page 17; Table Patient Disposition page 17; Table Mean Change from Baseline in HAM-D Total Score, Depression Item, K-SADS-L Depression Subgroup, K-SADS-L Depression Item, Mean CGI Score, and Percent of Patients Meeting Definition of Responder or Remission, page 19; 4.3	Same page numbers in the PDF of Final Clinical Report, Acute Phase and Final Clinical Report, Continuation Phase;	

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
		groups	page 15, Table 7; page 16-17, Table 9; page 17-19, Table 10; page 19-21, Table 11; page 21, Table 12; page 21-22, Table 13	Protocol Violations, 4.3.1 Protocol Violations Excluded from the Per-Protocol Population, page 60; Table 11 Numbers of Patients With Protocol Violations Leading to Exclusion From the Per-Protocol Analysis, page 61; 4.3.2 Protocol Deviations Included in the Per-Protocol Population, page 61-62; Table 12 Numbers of Patients With Protocol Deviations Included in the Per- Protocol Analysis, page 62; 5 Efficacy Results, 5.2 Efficacy Results, 5.2.3 Responders and Remission Analysis, Figure 4 Percent of Patients in LOCF and OC Datasets Achieving Responder and Remission Status, page 78; 10 Data Source Tables: Study Population, pages 130-185; 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 Population, page 131-132; Table 12.5.1 Summary of Demographic Data Intent-to-Treat Population, page 141; Table 12.8 Summary of Personal History Intent-to-Treat Population, page 151; Table 12.9 Summary of Medical/Surgical History Intent-to-Treat Population, page 153; Table 12.10 Summary of Presenting Conditions Intent-to-Treat Population, page 157; Table 12.11 Summary of Prior Medications by WHO ATC Classification Intent-to-Treat Population, page 161; Table 12.14 Summary of Concomitant		

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
				Medications by WHO ATC Classification Acute Phase Intent-to-Treat Population, page 167; Table 12.16 Summary of Patient Compliance Acute Phase Intent-to-Treat Population, page 173; Table 12.21 Summary of Number of Depressive Episodes Intent to Treat Population, page 177; Table 12.23 Summary of Melancholic/Endogenous Depression Intent to Treat Population, page 180; Table 12.24 Summary of Atypical Depression Intent to Treat Population, page 181; Table 12.25 Summary of Family History of Major Depression Intent to Treat Population, page 182; Table 12.27 Summary of Anxiety Disorder Intent to Treat Population, page 184; 11 Data Source Tables: Efficacy Results, pages 186-221; 12 Data Source Tables: Safety Results, pages 222-489. Continuation Study, Final Clinical Report, Report Synopsis, Patient Disposition and Key Demographic Data, Patient Disposition table, page 6; Safety Results, Adverse Events Occurring in ≥5% of Any Group and at Least 2X Placebo table, page 7; 4 Study Population, 4.3 Disposition of Patients in the Continuation Phase, Table 4 Number (%) of Randomized Patients Who Completed or Were Withdrawn from the Study, by Reason for Withdrawal (ITT Population), page 27; 4.4 Concomitant Medications, Table 5 Concomitant Medications by ATC		

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
				Classification Received by 10% or More of Patients in Any Treatment Group (number (%) of patients) (ITT Population), page 28; 5 Safety Results, 5.1 Extent of Exposure, Table 6 Exposure of Patients to Each Daily Dose of Study Medication and Duration of Exposure (number (%) of patients) (Continuation Phase) (ITT Population), page 31; 5.2 Adverse Events, Table 7 Number (%) of Patients with Treatment-emergent Adverse Events Most Frequently Reported (≥5% in Any Treatment Group), by Body System and Preferred Term (ITT Population), page 33; Table 8 Adverse Events Occurring in ≥5% of Either Paroxetine or Imipramine Patients and at Least 2X Placebo (ITT Population), page 34; Table 11 Treatment-emergent Adverse Events, Regardless of Attribution, Leading to Withdrawal (number (%) of patients (ITT Population), page 42; 5.6 Vital Signs and Body Weight, 5.6.1 Mean Values and Changes in Value, Table 13 Vital Signs and Body Weight at Baseline and Endpoint (mean ± SD) (ITT Population), page 46; Table 14 Number (%) of Patients with Vital Sign or Body Weight Values of Potential Clinical Concern at Any Time During the Continuation Phase (ITT Population), page 47; Table 15 Number of Patients with Laboratory Values Considered to Be of Clinical Concern (ITT Population), page 49; 5.8		

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
				Safety Results in the Continuation Phase Compared to the Acute Phase, Table 16 Adverse Events Occurring in ≥5% of Either Paroxetine or Imipramine Patients and at Least 2X Placebo in Either Phase of the Study or Both Phases Combined (ITT Population), page 52; Table 17 Number (%) of Patients with Serious Adverse Events in Each Phase of the Study and Both Phases Combined (ITT Population), page 54; 6 Efficacy Results, 6.1 Withdrawals Due to Lack of Efficacy, Table 18 Number (%) of Patients Withdrawing for Lack of Efficacy (Intent to Treat Population), page 55; Table 19 Summary of Relapse During the Continuation Phase for Patients Who Had a HAM-D ≤8 at End of Acute Phase (ITT Population), page 56; 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; 9 Data Source Tables: Study Population, pages 65-84; 10 Data Source Tables: Efficacy, pages 85-112; 11 Data Source Tables: Safety, pages 116-260.		
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its	p.11-12; Figure 2; page 12; Table 3; page 13, Tables 4	Final Clinical Report, Acute Phase, Report Synopsis, Efficacy Results, page 17 paragraph 2 to page 18 paragraph 1, paragraph 2; Table Mean Change from Baseline in HAM-D Total Score, Depression Item, K-SADS-L Depression	Same page numbers in the PDF of Final Clinical Report, Acute Phase and Final Clinical Report, Continuation Phase;	

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
		precision (such as 95% confidence interval)	and 5; page 14, table 6; page 15, table 7; page 16, Table 8; page 16-17, table 9; page 17-19, table 10	Subgroup, K-SADS-L Depression Item, Mean CGI Score, and Percent of Patients Meeting Definition of Responder or Remission, page 19; 5 Efficacy Results, 5.2 Efficacy Results, 5.2.1 Change from Baseline in Total HAM-D Score, page 71, Table 20 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; Table 21 Week 8 (OC and LOCF) Mean Treatment Differences (95% C.I.) in Total HAM-D Score, page 72; Figure 3 Mean Change from Baseline (SE) in Total HAM-D Score for the Week 8 LOCF and Week 8 OC Datasets, page 73; 5.2.2 Change from Baseline in HAM-D Subscales, page 73 paragraph 3 to page 74 paragraph 1, 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, page 75, paragraphs 2-3, 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 24 Week 8 (OC and LOCF) Mean Treatment Difference (95% C.I.) of Patients who Responded, page 76; Table 25 Number (%) of Patients in Remission* for OC Dataset at Each Treatment Week	Pages 929-938, 949 PDF, Appendix A, Statistical Report;	

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
				and the LOCF Dataset at Week 8, page 76; Table 26 Week 8 (OC and LOCF) Mean Treatment Difference (95% C.I.) of Patients in Remission, page 77; Figure 4 Percent of Patients in LOCF and OC Datasets Achieving Responder and Remission Status, page 78; 5.2.4 Sustained Response, page 78 paragraph 2, Table 27 Survival Analysis of Sustained Response During the Acute Phase, page 79; Figure 5 Kaplan Meier Survival Curves for Time to Sustained Response During Acute Phase, page 79; 5.2.5 CGI Improvement Scale, page 80 paragraph 2, 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 29 Week 8 (OC and LOCF) Mean Treatment Differences (95% C.I.) on the CGI Scale, page 80; page 81 paragraph 2, Figure 6 Mean CGI Score (SE) for Week 8 LOCF and Week 8 OC Datasets, page 81,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; Table 31 Week 8 (OC and LOCF) Mean Treatment Differences (95% C.I.) of Patients Having a CGI Score of "Very Much Improved" or "Much Improved", page 82; Figure 7 Percent of Patients Very Much Improved and Much Improved in CGI Global		

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
				Improvement at Endpoint, page 83; 5.2.6 K-SADS-L - Depression 9-Item Scale - Change from Baseline, page 83,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 84; Table 33 Week 8 (OC and LOCF) Mean Treatment Differences (95% C.I.) in KSADS- L Depression 9-Item Scale, page 84, Figure 8 Mean Change From Baseline (SE) in K-SADS-L - Depression 9-Item Scale For Week 8 LOCF and Week 8 OC Datasets, page 85; 5.2.7 Change from Baseline in K-SADS-L Depressed Mood Item, page 85 paragraph 2 to page 86 paragraph 1, 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; Table 35 Week 8 (OC and LOCF) Mean Treatment Differences (95% C.I.) in Depressed Mood Item, page 86; 5.3 Functional, Self Perceptive and Behavioral Scales 5.3.1 Autonomous Functioning Checklist, page 87 paragraph 2, 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, page 88 paragraph 1, Table 37 Baseline Mean		

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
				(+/- 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, page 88 paragraph 2, 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; 11 Data Source Tables: Efficacy Results, page 186-221; Final Clinical Report, Acute Phase, Appendix A, Statistical Report, 3 Summary of Statistical Results, page 1459-1468; Mean Change from Baseline in HAM-D Total Score, Depression Item, K-SADS-L Depression Subgroup, K-SADS-L Depression Item, Mean CGI Score, and Percent of Patients Meeting Definition of Responder or Remission, page 1479; Continuation Study, Final Clinical Report, Report Synopsis, Safety Results, page 7 paragraph 1 to page 8 paragraph 4, Adverse Events Occurring in ≥5% of Any Group and at Least 2X Placebo, page 7; Efficacy Results, page 8; 5 Safety Results, 5.2 Adverse Events, page 32 paragraph 1, Table 7 Number (%) of Patients with Treatment-emergent Adverse Events Most Frequently Reported (≥5% in Any Treatment Group), by Body System and Preferred Term (ITT Population), page 33; Table 8 Adverse Events Occurring in ≥5% of Either		

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
				Paroxetine or Imipramine Patients and at Least 2X Placebo (ITT Population) page 34; Table 9 Number (%) of Patients with the Five Most Frequently Reported Treatment-emergent Adverse Events by the Time of First Occurrence During the Continuation Phase (ITT Population) page 36; page 37 paragraphs 1-2; 5.3 Deaths page 37; 5.4 Serious Non-Fatal Adverse Events, page 38 paragraph 1 to page 39 paragraph 4; Table 10 Serious Non-Fatal Adverse Events (ITT Population), page 40; 5.5 Withdrawals for Adverse Events, page 41; Table 11 Treatment-emergent Adverse Events, Regardless of Attribution, Leading to Withdrawal (number (%) of patients (ITT Population), page 42; Table 12 Adverse Events Leading to Withdrawal in Continuation Phase (ITT Population), page 43; 5.6 Vital Signs and Body Weight 5.6.1 Mean Values and Changes in Value, page 45 paragraph 5, Table 13 Vital Signs and Body Weight at Baseline and Endpoint (mean ± SD) (ITT Population), page 46; 5.6.2 Patients with Vital Signs of Potential Clinical Concern, page 46 paragraph 1 to page 47 paragraph 1; Table 14 Number (%) of Patients with Vital Sign or Body Weight Values of Potential Clinical Concern at Any Time During the Continuation Phase (ITT Population), page 47; 5.7 Laboratory Tests, Table 15 Number of Patients with Laboratory Values Considered to Be of		

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
				Clinical Concern (ITT Population), page 49; 5.8 Safety Results in the Continuation Phase Compared to the Acute Phase, page 50 paragraph 5 to page 51 paragraph 2, Table 16 Adverse Events Occurring in ≥5% of Either Paroxetine or Imipramine Patients and at Least 2X Placebo in Either Phase of the Study or Both Phases Combined (ITT Population), page 52; 5.8.1 Serious Adverse Events in Both Phases Combined, page 53, Table 17 Number (%) of Patients with Serious Adverse Events in Each Phase of the Study and Both Phases Combined (ITT Population), page 54; 6 Efficacy Results, 6.1 Withdrawals Due to Lack of Efficacy, Table 18 Number (%) of Patients Withdrawing for Lack of Efficacy (Intent to Treat Population), page 55; 6.2 Analysis of Relapse, page 56 paragraph 2, Table 19 Summary of Relapse During the Continuation Phase for Patients Who Had a HAM-D ≤8 at End of Acute Phase (ITT Population) page 56; Figure 3 Kaplan Meier Survival Curves for Relapse During the Continuation Phase (ITT Population) page 57; page 57 paragraph 2; 6.3 Hamilton Depression Scale, page 58, 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, page 58 paragraph 3, Table 21 Distribution of		

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
				Patients in Each Class of CGI Global Improvement at Week 32 LOCF Endpoint (Intent to Treat Population) page 59; page 59 paragraph 2, Table 22 Mean (±SE) CGI Global Improvement at Each Visit (ITT Population) page 59; 6.5 Other Secondary Scales, page 59 paragraph 3 to page 60 paragraph 1; 10 Data Source Tables: Efficacy, pages 85-112; 11 Data Source Tables: Safety, pages 113-260;		
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Page 11-12, Figure 2, percent responding; page 12, table 3	Final Clinical Report, Acute Phase, Report Synopsis, Efficacy Results, page 18 paragraph 1, paragraph 2; Table Mean Change from Baseline in HAM-D Total Score, Depression Item, K-SADS-L Depression Subgroup, K-SADS-L Depression Item, Mean CGI Score, and Percent of Patients Meeting Definition of Responder or Remission, page 19; 5 Efficacy Results, 5.2 Efficacy Results, 5.2.3 Responders and Remission Analysis, page 75, paragraphs 2-3; 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 24 Week 8 (OC and LOCF) Mean Treatment Difference (95% C.I.) of Patients who Responded, 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; Table 26 Week 8 (OC and LOCF) Mean Treatment Difference (95% C.I.) of	Same page numbers in the PDF of Final Clinical Report, Acute Phase and Final Clinical Report, Continuation Phase; Appendix A, Statistical Report, PDF pages 934, 949;	

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
				Patients in Remission, page 77; Figure 4 Percent of Patients in LOCF and OC Datasets Achieving Responder and Remission Status, page 78; 5.2.4 Sustained Response, Table 27 Survival Analysis of Sustained Response During the Acute Phase, page 79; Figure 5 Kaplan Meier Survival Curves for Time to Sustained Response During Acute Phase, page 79; 5.2.5 CGI Improvement Scale, 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; Table 31 Week 8 (OC and LOCF) Mean Treatment Differences (95% C.I.) of Patients Having a CGI Score of "Very Much Improved" or "Much Improved", page 82; Figure 7 Percent of Patients Very Much Improved and Much Improved in CGI Global Improvement at Endpoint, page 83; 11 Data Source Tables: Efficacy Results, Table 13.3 Number (%) of Patients Responding to Treatment Acute Phase (Intent to Treat Population) page 193; Table 13.3.1 Number (%) of Patients Responding to Treatment Acute Phase (Per Protocol Population) page 194; Table 13.6 Number (%) of Patients Withdrawing for Lack of Efficacy Acute Phase (Intent to Treat Population) page 197; Table 13.11 Number (%) of Patients In Remission Acute Phase (Intent-to-Treat Population) page 203; Table 13.12		

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
				Number (%) of Patients With Sustained Response Acute Phase (Intent-to-Treat Population) page 204; Final Clinical Report, Acute Phase, Appendix A, Statistical Report, 3 Summary of Statistical Results, 3.4 Survival Analysis, Table 6 Survival Analysis of Sustained Response During the Acute Phase, page 1464; 3.7 Confidence Intervals for Efficacy Results at Week 8, Mean Change from Baseline in HAM-D Total Score, Depression Item, K-SADS-L Depression Subgroup, K-SADS-L Depression Item, Mean CGI Score, and Percent of Patients Meeting Definition of Responder or Remission, Week 8, ITT Population, page 1479; Continuation Study, Final Clinical Report, Report Synopsis, Safety Results, page 7 paragraph 1 to page 8 paragraph 4; Table regarding Adverse Events Occurring in ≥5% of Any Group and at Least 2X Placebo, page 7; Efficacy Results, page 8; 5 Safety Results, 5.2 Adverse Events, page 32 paragraph 1, Table 7 Number (%) of Patients with Treatment-emergent Adverse Events Most Frequently Reported (≥5% in Any Treatment Group), by Body System and Preferred Term (ITT Population), page 33; Table 8 Adverse Events Occurring in ≥5% of Either Paroxetine or Imipramine Patients and at Least 2X Placebo (ITT Population) page 34; Table 9 Number (%) of Patients with the Five Most		

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
				Frequently Reported Treatment-emergent Adverse Events by the Time of First Occurrence During the Continuation Phase (ITT Population) page 36; page 37 paragraphs 1-2; 5.3 Deaths, page 37; 5.4 Serious Non-Fatal Adverse Events, page 38 paragraph 1 to page 39 paragraph 4; Table 10 Serious Non-Fatal Adverse Events (ITT Population), page 40; 5.5 Withdrawals for Adverse Events, page 41; Table 11 Treatment-emergent Adverse Events, Regardless of Attribution, Leading to Withdrawal (number (%) of patients (ITT Population), page 42; 5.6.2 Patients with Vital Signs of Potential Clinical Concern, page 46 paragraph 1 to page 47 paragraph 1; Table 14 Number (%) of Patients with Vital Sign or Body Weight Values of Potential Clinical Concern at Any Time During the Continuation Phase (ITT Population), page 47; 5.7 Laboratory Tests, Table 15 Number of Patients with Laboratory Values Considered to Be of Clinical Concern (ITT Population), page 49; 5.8 Safety Results in the Continuation Phase Compared to the Acute Phase, page 50 paragraph 5 to page 51 paragraph 2; Table 16,Adverse Events Occurring in ≥5% of Either Paroxetine or Imipramine Patients and at Least 2X Placebo in Either Phase of the Study or Both Phases Combined (ITT Population), page 52; 5.8.1 Serious Adverse Events in Both Phases		

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
				Combined, page 53; Table 17, Number (%) of Patients with Serious Adverse Events in Each Phase of the Study and Both Phases Combined (ITT population), page 54; 6 Efficacy Results, 6.1 Withdrawals Due to Lack of Efficacy, Table 18, Number (%) of Patients Withdrawing for Lack of Efficacy (Intent to Treat Population), page 55; 6.2 Analysis of Relapse, page 56 paragraph 2; Table 19, Summary of Relapse During the Continuation Phase for Patients Who Had a HAM-D ≤8 at End of Acute Phase (ITT Population) page 56; Figure 3, Kaplan Meier Survival Curves for Relapse During the Continuation Phase (ITT Population) page 57; page 57 paragraph 2; 6.4 Clinical Global Impression of Improvement, page 58 paragraph 3; Table 21, Distribution of Patients in Each Class of CGI Global Improvement at Week 32 LOCF Endpoint (Intent to Treat Population) page 59; page 59 paragraph 2; Table 22, Mean (±SE) CGI Global Improvement at Each Visit (ITT Population) page 59; 10 Data Source Tables: Efficacy, Table 15.1,Number (%) of Patients Withdrawing for Lack of Efficacy (Continuation Phase) (Intent to Treat Population)pages 87; Table 15.2 Summary of Relapse During Continuation Phase for Patients Who Had HAMD </=8 at the End of Acute Phase (Intent to Treat Population), page		

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
				88; Table 15.6 Distribution of Patients in Each Class of CGI Global Improvement at Endpoint (Continuation Phase) (Intent to Treat Population), page 92; 11 Data Source Tables: Safety, pages 113-260;		
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Results of additional harms analysis, p.13, table 4, table 5; page 14, table 6; page 15, table 7; page 16, table 8; page 16-17, table 9; page 17-19, table 10; page 19-21, table 11; page 21, table 12; page 21-22, table 13	Final Clinical Report, Acute Phase, Report Synopsis, Safety Results, pages 19-20; Table regarding Adverse Events Occurring in ≥ 5% of Any Group and at Least 2X Placebo, page 20; Vital Signs:, page 20; Laboratory Tests, page 21; 5 Efficacy Results, 5.3 Functional, Self Perceptive and Behavioral Scales 5.3.1 Autonomous Functioning Checklist, page 87 paragraph 2; 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, page 88 paragraph 1, 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, page 88 paragraph 2, 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 page 89; 5.4 Efficacy Subgroup Analysis, page 90 paragraphs 3-4; Table 39, Summary of Responders by	Same page numbers in the PDF of Final Clinical Report, Acute Phase and Final Clinical Report, Continuation Phase; Clinical Report, Acute Phase, Appendix A, Statistical Report, PDF pages 928- 949.	

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
				Subgroup at Endpoint, page 90; Table 40 Summary of Covariate Analysis for Responders at Endpoint, page 91; 6 Safety Results 6.1 Extent of Exposure, page 92 paragraphs 2-3; Table 41, Exposure of Patients to Each Daily Dose of Study Drug (in mg) and Duration of Exposure, by Treatment Group (number (%) of patients) page93; 6.2 Adverse Experiences, pages 94-95; Table 42,Treatment-emergent Adverse Experiences Most Frequently Reported (by= or > 5% in Any Treatment Regimen), by Body System and Preferred Term(number (%) of patients), page 96; Analysis of Adverse Experiences by Age, page 97 paragraphs 2-3; Table 43, Number and Percent of Patients with Adverse Experiences by Age (by = or >5% in Any Group), by Body System, and Preferred Term (number (%) patients), pages 98-100; Male and Female - Specific Adverse Experiences, page 100; 6.2.1 Adverse Experiences by Severity, page 101 paragraphs 1-2; Table 44,Severe Treatment-emergent Adverse Experience and those Occurring in More Than One Patient in any Group (number (%) of patients), page 101; 6.2.2 Adverse Experiences by Time of First Occurrence, page 102 paragraph 2; Table 45, Number (%) of Patients of the Four Most Frequently Reported Treatment-emergent Adverse		

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
				Experiences by the Time of First Occurrence, page 103; 6.3 Dose Reductions for Adverse Experiences, page 104; Table 46,Treatment-emergent Adverse Experiences That Led to Dose Reductions, page 105; 6.4 Adverse Experiences Requiring Corrective Treatment, page 105 paragraph 1 to page 106 paragraph 2; Table 47,Adverse Experiences That Required Corrective Treatment (≥ 5%), Regardless of Attribution to Study Medication, page 106; 6.5 Deaths, page 106; 6.6 Serious Non-fatal Adverse Experiences, page 107 paragraph 2 to page 108 paragraph 3; Table 48 Serious Non-fatal Adverse Experiences page 109; 6.7 Withdrawals for Adverse Experiences, page 110; Table 49, Treatment-emergent Adverse Experiences, Regardless of Attribution, Leading to Withdrawal (number (%) of patients), pages 111-112; Table 50, Adverse Experiences Leading to Withdrawal, pages 113-114; 6.8 Vital Signs and Body Weight, page 114 paragraph 2 to page 115; Table 51,Vital Signs and Body Weight at Screening, Baseline and at Endpoint (mean +/- SD), page 116; Table 52 Number (%) of Patients with Vital Sign or Body Weight Values of Potential Clinical Concern at Any Time During Treatment, page 117; 6.9 Other Safety Data Serum Concentrations of Imipramine and Desipramine, page 117; Serum		

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
				Pregnancy Tests, page 118; 6.10 Laboratory Tests Change from Baseline in Laboratory Values at Endpoint, page 118; Laboratory Values of Potential Clinical Concern, pages 119-120; Table 53,Criteria for Flagging of Selected Laboratory Parameters, page 119; Table 54,Number of Patients with Laboratory Values Considered to Be of Clinical Concern, page 120; 10 Data Source Tables: Study Population, pages 128-185; 11 Data Source Tables: Efficacy Results, pages 186-221; Data Source Tables: Safety Results, pages 222-526; 13 Data Source Figures Figure 1 Kaplan Meier Survival Curves for Time to Sustained Response During Acute Phase Paroxetine - Protocol 329 Intent to Treat Population, page 528; Final Clinical Report, Acute Phase, Appendix A, Statistical Report,3 Summary of Statistical Results, 3.1 Efficacy Variables at Baseline, page 1458; 3.2 Change from Baseline Model Verification, page 1458; Table 2,Treatment-by-Investigator ANOVA P-values for Efficacy Parameters page 1459; 3.2.1 HAMD Total (17 items), page 1459; Table 3,ANOV A Table for HAMD Total Mean Change from Baseline at Endpoint, page 1460; Figure 1, Plot of Treatment-by-Investigator HAMD Total Mean Change from Baseline at Endpoint, page 1460; 3.2.2 K-SADS-L Depression Subscale page 1460; Table 4,ANOVA Table for K-		

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
				SADS-L Depression Subscale Mean Change from Baseline at Endpoint, page 1461; Figure 2, Plot of Treatment-by-Investigator K-SADS-L Depression Subscale Mean Change from Baseline at Endpoint, page 1461; 3.2.3 HAMD Retardation Subfactor page 1462; Table 5,ANOV A Table for HAMD Retardation Subfactor Mean Change from Baseline at Endpoint page 1462; Figure 3,Plot of Treatment-by-Investigator HAMD Retardation Subfactor Mean Change from Baseline at Endpoint, page 1463; 3.3 Percent Response Model Verification page 1463 paragraph 2; 3.4 Survival Analysis page 1464,Table 6 Survival Analysis of Sustained Response During the Acute Phase page 1464; Figure 4,Kaplan Meier Survival Curves for Time to Sustained Response During Acute Phase page 1465; 3.5 Per Protocol Analyses, 3.5.1 HAMD Total (17 items) page 1465; Table 7,ANOVA Table for HAMD Total Mean Change from Baseline at Endpoint Per Protocol Population page 1466; Figure 5,Plot of Treatment-by-Investigator HAMD Total Mean Change from Baseline at Endpoint Per Protocol Population page 1466; 3.5.2 K-SADS-L Depression Subscale pages 1466-1467; Table 8, ANOVA Table for K-SADS-L Depression Subscale Mean Change from Baseline at Endpoint Per Protocol Population page 1467; Figure 6 Plot of Treatment-by-Investigator K-		

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
				SADS-L Depression Subscale Mean Change from Baseline at Endpoint Per Protocol Population, page 1468; 3.6 Covariate Analyses,3.6.1 Percentage of Responders, pages 1468, 1469 paragraph 2; Table 13.28.1 Summary of Covariate Analysis for Percentage of Responders at Endpoint, page 1470; Table 13.28.2 Summary of Response at Endpoint by Covariate, page 1471; 3.6.2 HAMD Total page 1472 paragraph 2; Table 13.29.1 Summary of Covariate Analysis for HAMD Total at Endpoint, page 1473; Table 13.29.2 Summary of HAMD Total at Endpoint by Covariate, page 1474; 3.6.3 KSADS Total page 1475 paragraph 2; Table 13.30.1 Summary of Covariate Analysis for KSAD Total at Endpoint, page 1476; Table 13.30.2 Summary of KSAD Total at Endpoint by Covariate, page 1477; Mean Change from Baseline in HAM-D Total Score, Depression Item, K-SADS-L Depression Subgroup, K-SADS-L Depression Item, Mean CGI Score, and Percent of Patients Meeting Definition of Responder or Remission, page 1479;		
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT	p.13, table 4, table 5; page 14, table 6; page 15, table 7; page 16,	Final Clinical Report, Acute Phase, Report Synopsis, Safety Results, Adverse Experiences, page 19-20; Table Adverse Events Occurring in ≥ 5% of Any Group and at Least 2X Placebo, page 20, page 21 paragraph 1; 6.2 Adverse Experiences, page 94-95; Table 42	Same page numbers in the PDF of Final Clinical Report, Acute Phase and Final Clinical Report, Continuation Phase;	

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
		for harms)	table 8; page 16-17, table 9; page 17-19, table 10; page 19-21, table 11; page 21, table 12; page 21-22, table 13	Treatment-emergent Adverse Experiences Most Frequently Reported (by = or > 5% in Any Treatment Regimen), by Body System and Preferred Term (number (%) of patients), page 96; Analysis of Adverse Experiences by Age, page 97; Table 43, Number and Percent of Patients with Adverse Experiences by Age (by = or >5% in Any Group), by Body System, and Preferred Term (number (%) patients), page 98-100; Male and Female - Specific Adverse Experiences, page 100; 6.2.1 Adverse Experiences by Severity, page 101 paragraphs 1-2; Table 44 Severe Treatment-emergent Adverse Experience and those Occurring in More Than One Patient in any Group (number (%) of patients), page 101; 6.2.2 Adverse Experiences by Time of First Occurrence, page 102 paragraph 2; Table 45 Number (%) of Patients of the Four Most Frequently Reported Treatment-emergent Adverse Experiences by the Time of First Occurrence, page 103; 6.3 Dose Reductions for Adverse Experiences, page 104; Table 46 Treatment-emergent Adverse Experiences That Led to Dose Reductions, page 105; 6.4 Adverse Experiences Requiring Corrective Treatment, page 105-106; Table 47 Adverse Experiences That Required Corrective Treatment (≥ 5%), Regardless of Attribution to Study Medication, page		

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
				106; 6.5 Deaths, page 106; 6.6 Serious Non-fatal Adverse Experiences, page 106-108; Table 48 Serious Non-fatal Adverse Experiences, page 109; 6.7 Withdrawals for Adverse Experiences, page 110; Table 49 Treatment-emergent Adverse Experiences, Regardless of Attribution, Leading to Withdrawal (number (%) of patients), page 111-112; Table 50 Adverse Experiences Leading to Withdrawal, page 113-114; 6.8 Vital Signs and Body Weight, page 114 paragraph 2 to page 115; Table 51 Vital Signs and Body Weight at Screening, Baseline and at Endpoint (mean +/- SD), page 116; Table 52 Number (%) of Patients with Vital Sign or Body Weight Values of Potential Clinical Concern at Any Time During Treatment, page 117; 6.10 Laboratory Tests, Laboratory Values of Potential Clinical Concern, pages 118-120,Table 54 Number of Patients with Laboratory Values Considered to Be of Clinical Concern, page 120; Data Source Tables: Safety Results, Table 14.2.1 Summary of Treatment-Emergent Adverse Experiences during Acute Phase by ADECS Body System and Preferred Term Non-gender Specific Adverse Experiences Intent-to-Treat Population, page 226-229; Table 14.2.3 Summary of Treatment-Emergent Adverse Experiences during Acute Phase by ADECS Body System and Preferred		

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
				Term Female Specific Adverse Experiences Intent-to-Treat Population, page 230; Table 14.3.1 Summary of Treatment-Emergent Adverse Experiences by ADECS Body System and Preferred Term and by Maximum Intensity Acute Phase - Non-gender Specific Adverse Experiences Intent-to-Treat Population, page 231-239; Table 14.3.3 Summary of Treatment-Emergent Adverse Experiences by ADECS Body System and Preferred Term and by Maximum Intensity Acute Phase - Female Specific Adverse Experiences Intent-to-Treat Population, page 240-242; Table 14.4.1, Summary of Treatment-Emergent Adverse Experiences by Time of First Occurrence (Acute Phase) Non-gender Specific Adverse Experiences Intent-to-Treat Population, page 243-260; Table 14.4.3, Summary of Treatment-Emergent Adverse Experiences by Time of First Occurrence (Acute Phase)Female Specific Adverse Experiences Intent-to-Treat Population, page 261-266; Table 14.5.1 Summary of Treatment-Emergent Adverse Experiences Leading to Dose Reduction Regardless of Attribution by ADECS Body System and Preferred Term (Acute Phase) - Non-gender Specific Adverse Experiences Intent-to-Treat Population, page 267; Table 14.5.3 Summary of Treatment-Emergent Adverse Experiences Leading to Dose Reduction		

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
				Regardless of Attribution by ADECS Body System and Preferred Term (Acute Phase) - Female Specific Adverse Experiences Intent-to-Treat Population, page 268; Table 14.6.1 Summary of Treatment-Emergent Adverse Experiences Requiring Corrective Therapy Regardless of Attribution by ADECS Body System and Preferred Term (Acute Phase) - Non-gender Specific Adverse Experiences Intent-to-Treat Population, page 269-270; Table 14.6.3 Summary of Treatment-Emergent Adverse Experiences Requiring Corrective Therapy Regardless of Attribution by ADECS Body System and Preferred Term (Acute Phase) - Female Specific Adverse Experiences Intent-to-Treat Population, page 271; Table 14.8 Listing of Serious Adverse Experiences by Treatment Group and Patient Acute Phase Intent-to-Treat Population, page 272-275; Table 14.8a Serious Adverse Experiences Patient Narratives, page 276-307; 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, page 308-309; Table 14.9.1a Adverse Experiences Leading to Withdrawal Patient Narratives, page 310-366; Table 14.9.3, Summary of Adverse Experiences Leading to Withdrawal		

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
				during Acute Phase by ADECS Body System and Preferred Term Female Specific Adverse Experiences Intent-to-Treat Population, page 367; Table 14.10.1 Summary of Treatment-Emergent Adverse Experiences by Age Group (Acute Phase) Non-gender Specific Adverse Experiences Intent-to-Treat Population, page 368-376; Table 14.10.2 Summary of Treatment-Emergent Adverse Experiences by Age Group (Acute Phase) Male Specific Adverse Experiences Intent-to-Treat Population, page 377-379; Table 14.10.3 Summary of Treatment-Emergent Adverse Experiences by Age Group (Acute Phase)Female Specific Adverse Experiences Intent-to-Treat Population, page 380-382; Table 14.12 Summary of Clinically Significant Abnormal Vital Signs by Treatment Group Acute Phase Intent-to-Treat Population, page 392; Table 14.12a PATIENTS WITH ABNORMAL VITAL SIGNS OR BODY WEIGHT OFPOTENTIAL CLINICAL CONCERN DURING THE ACUTE PHASE, page 393-475; Table 14.14 Summary of Clinically Significant Abnormal Laboratory Values Acute Phase Intent-to-Treat Population, page 488-489; Table 14.14a Clinically Significant Abnormal Laboratory Values Patient Narratives, page 490-526; Continuation Study, Final Clinical Report, Report Synopsis, Safety Results, page 7		

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
				paragraph 1 to page 8 paragraph 4; Table, Adverse Events Occurring in ≥5% of Any Group and at Least 2X Placebo, page 7; 5 Safety Results, 5.2 Adverse Events, page 32; Table 7 Number (%) of Patients with Treatment-emergent Adverse Events Most Frequently Reported (≥5% in Any Treatment Group), by Body System and Preferred Term (ITT Population), page 33; Table 8 Adverse Events Occurring in ≥5% of Either Paroxetine or Imipramine Patients and at Least 2X Placebo (ITT Population) page 34; Table 9 Number (%) of Patients with the Five Most Frequently Reported Treatment-emergent Adverse Events by the Time of First Occurrence During the Continuation Phase (ITT Population) page 36; page 37 paragraphs 1-2; 5.3 Deaths page 37; 5.4 Serious Non-Fatal Adverse Events, page 38 paragraph 1 to page 39 paragraph 4; Table 10 Serious Non-Fatal Adverse Events (ITT Population), page 40; 5.5 Withdrawals for Adverse Events, page 41; Table 11 Treatment-emergent Adverse Events, Regardless of Attribution, Leading to Withdrawal (number (%) of patients (ITT Population), page 42; Table 12 Adverse Events Leading to Withdrawal in Continuation Phase (ITT Population), page 43; 5.6 Vital Signs and Body Weight 5.6.1 Mean Values and Changes in Value, page 45 paragraph 3-5; Table 13 Vital Signs and Body Weight at		

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
				Baseline and Endpoint (mean ± SD) (ITT Population), page 46; 5.6.2 Patients with Vital Signs of Potential Clinical Concern, page 46 paragraph 1 to page 47 paragraph 1; Table 14 Number (%) of Patients with Vital Sign or Body Weight Values of Potential Clinical Concern at Any Time During the Continuation Phase (ITT Population), page 47; 5.7 Laboratory Tests, Table 15 Number of Patients with Laboratory Values Considered to Be of Clinical Concern (ITT Population), page 49; 5.8 Safety Results in the Continuation Phase Compared to the Acute Phase, page 50 paragraph 4to page 51 paragraph 2; Table 16 Adverse Events Occurring in ≥5% of Either Paroxetine or Imipramine Patients and at Least 2X Placebo in Either Phase of the Study or Both Phases Combined (ITT Population), page 52; 5.8.1 Serious Adverse Events in Both Phases Combined, page 53, Table 17 Number (%) of Patients with Serious Adverse Events in Each Phase of the Study and Both Phases Combined (ITT Population), page 54; 11 Data Source Tables: Safety, 16.2.1 Summary of Treatment-Emergent Adverse Experiences during the Continuation Phase by ADECS Body System and Preferred Term-Non-gender Specific Adverse Experiences (Intent to Treat Population) pages 120-122; 16.2.2 Summary of Treatment-Emergent Adverse Experiences during the		

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
				Continuation Phase by ADECS Body System and Preferred Term-Male Specific Adverse Experiences (Intent to Treat Population) page 123; 16.2.3 Summary of Treatment-Emergent Adverse Experiences during the Continuation Phase by ADECS Body System and Preferred Term-Female Specific Adverse Experiences (Intent to Treat Population) page 124; 16.2.4 Summary of Treatment-Emergent Adverse Experiences during Both Phases Combined by ADECS Body System and Preferred Term (Intent to Treat Population) page 125-132; 16.3.1 Summary of Treatment-Emergent Adverse Experiences by ADECS Body System and Preferred Term and by Maximum Intensity-Non-gender Specific Adverse Experiences (Continuation Phase) (Intent to Treat Population) page 133-138; 16.3.2 Summary of Treatment-Emergent Adverse Experiences by ADECS Body System and Preferred Term and by Maximum Intensity -Male Specific Adverse Experiences (Continuation Phase) (Intent to Treat Population) page 139; 16.3.3 Summary of Treatment-Emergent Adverse Experiences by ADECS Body System and Preferred Term and by Maximum Intensity -Female Specific Adverse Experiences (Continuation Phase) (Intent to Treat Population) pages 140-142; 16.4.1 Summary of Treatment-Emergent		

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
				Adverse Experiences by Time of First Occurrence-Non-gender Specific Adverse Experiences (Continuation Phase) (Intent to Treat Population) pages 143-154; 16.4.2 Summary of Treatment-Emergent Adverse Experiences by Time of First Occurrence-Male Specific Adverse Experiences (Continuation Phase) (Intent to Treat Population) page 155; 16.4.3 Summary of Treatment-Emergent Adverse Experiences by Time of First Occurrence-Female Specific Adverse Experiences (Continuation Phase) (Intent to Treat Population) page 156-161; 16.5.1 Summary of Treatment-Emergent Adverse Experiences Leading to Dose Reduction Regardless of Attribution by ADECS Body System and Preferred Term-Non-gender Specific Adverse Experiences (Continuation Phase) (Intent to Treat Population) page 162; 16.5.2 Summary of Treatment-Emergent Adverse Experiences Leading to Dose Reduction Regardless of Attribution by ADECS Body System and Preferred Term-Male Specific Adverse Experiences (Continuation Phase) (Intent to Treat Population) page 163; 16.5.3 Summary of Treatment-Emergent Adverse Experiences Leading to Dose Reduction Regardless of Attribution by ADECS Body System and Preferred Term-Female Specific Adverse Experiences (Continuation Phase) (Intent to Treat Population) page 164; 16.6.1		

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
				Summary of Treatment-Emergent Adverse Experiences Requiring Corrective Therapy Regardless of Attribution by ADECS Body System and Preferred Term-Non-gender Specific Adverse Experiences (Continuation Phase) (Intent to Treat Population) pages 165-166; 16.6.2 Summary of Treatment-Emergent Adverse Experiences Requiring Corrective Therapy Regardless of Attribution by ADECS Body System and Preferred Term-Male Specific Adverse Experiences (Continuation Phase) (Intent to Treat Population) page 167; 16.6.3 Summary of Treatment-Emergent Adverse Experiences Requiring Corrective Therapy Regardless of Attribution by ADECS Body System and Preferred Term-Female Specific Adverse Experiences (Continuation Phase) (Intent to Treat Population) page 168; 16.7 Listing of Deaths by Treatment Group and Patient (Continuation Phase) (Intent to Treat Population) page 169; 16.8 Listing of Serious Adverse Experiences (Continuation Phase) (Intent to Treat Population) pages 170-172; Table 16.8.1 Narratives for Patients with Serious Non-Fatal Adverse Events pages 173-191; 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		

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
				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; Table 16.10.1 Summary of Treatment-Emergent Adverse Experiences by Age Group-Non-gender Specific Adverse Experiences (Continuation Phase) (Intent to Treat Population) pages 211-216; Table 16.10.2 Summary of Treatment-Emergent Adverse Experiences by Age Group-Male Specific Adverse Experiences (Continuation Phase) (Intent to Treat Population) pages 217-219; 16.10.3 Summary of Treatment-Emergent Adverse Experiences by Age Group-Female Specific Adverse Experiences (Continuation Phase) (Intent to Treat Population) pages 220-222; 16.12 Summary of Clinically Significant Abnormal Vital Signs by Treatment Group (Continuation Phase) (Intent to		

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
				Treat Population) page 232; Table 16.12.1 Narratives for Patients with Vital Signs of Potential Clinical Concern pages 233-246; Table 16.14 Summary of Clinically Significant Abnormal Laboratory Values (Continuation Phase) (Intent to Treat Population) pages 259-260; Table 16.14.1 Narratives for Patients with Laboratory Values of Potential Clinical Concern pages 261-262;		
Discussion				Final Clinical Report, Acute Phase, Report Synopsis, Statistical Methods page 16 paragraph 3 ("No comparisons were made between paroxetine and imipramine."); 3.13.1 Comparison of Interest page 49 paragraph 2 ("No comparisons were made between paroxetine and imipramine."); Continuation Study, Final Clinical Report, Report Synopsis, Efficacy Results, page 8 paragraph 6 ("The continuation phase of this study was not designed to analyze efficacy, as patients were not rerandomized at the end of the acute phase. In addition, only responders were to enter the continuation phase."); Conclusion page 9 paragraph 2 ("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 and maturing population such as this."); 7 Discussion, page 61 paragraph 1	Same page numbers in the PDF of Final Clinical Report, Acute Phase and Final Clinical Report, Continuation Phase;	

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
				(“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		

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
				and maturing population such as this.”);		
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	p.4; p. 6-7; p. 8, Box 1; p.22-23; p.23-25, Box 2; p. 25; p.25-26, Box 3			
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	p.23-25, Box 2; p.25-26, Box 3	Final Clinical Report, Acute Phase, Report Synopsis, Conclusions, page 21; 8 Conclusions, page 124; Continuation Study, Final Clinical Report, Report Synopsis, Conclusions, page 9; 8 Conclusions, page 64;	Same page numbers in the PDF of Final Clinical Report, Acute Phase and Final Clinical Report, Continuation Phase;	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	p.22-23; p. 25	Final Clinical Report, Acute Phase, Report Synopsis, Conclusions page 21 paragraph 2; 7 Discussion, page 121-123; 8 Conclusions, page 124; Continuation Study, Final Clinical Report, Report Synopsis, Conclusions, page 9; 7 Discussion, pages 61-63; 8 Conclusions, page 64;	Same page numbers in the PDF of Final Clinical Report, Acute Phase and Final Clinical Report, Continuation Phase;	
Other information						
Registration	23	Registration number and name of trial registry	p.26	SmithKline Beecham study 29060/329, Final Clinical Report Acute Phase, page 1; SmithKline Beecham study 29060/329, Final Clinical Report, Addendum to Study Report–Continuation Phase, page 1;	Final Clinical Report Acute Phase, page 1; Final Clinical Report, Continuation Phase, page 1;	
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	

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
		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-	

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
				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;	

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
				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.