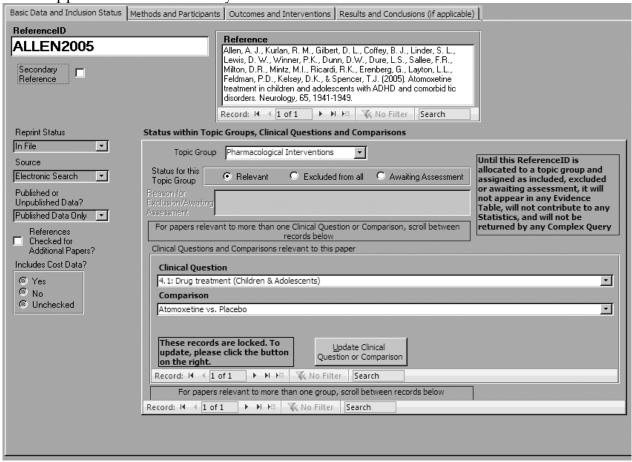
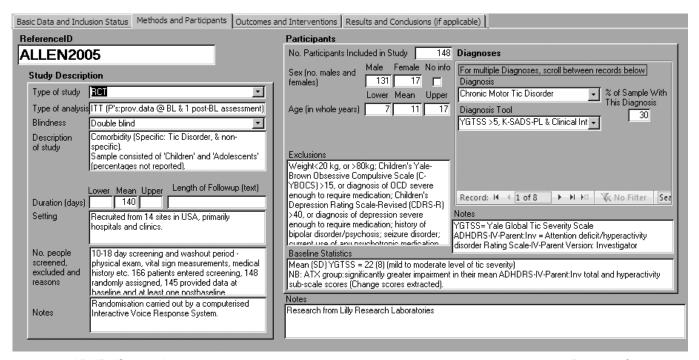
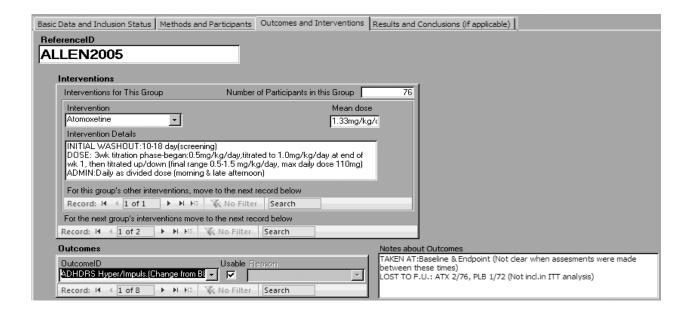
# 1 Appendices

Appendix 9: Clinical study information database	2
Appendix 10: Quality checklists for diagnostic studies, clinical studies	
	1

Appendix 1: Clinical study information database







# Appendix 2: Quality checklists for diagnostic studies, clinical studies and reviews

The methodological quality of each study was evaluated using dimensions adapted from SIGN (SIGN, 2001). SIGN originally adapted its quality criteria from checklists developed in Australia (Liddel et al., 1996). Both groups reportedly undertook extensive development and validation procedures when creating their quality criteria. For information about how to use these checklists please see (*The Guidelines Manual*<sup>1</sup>).

Quality Checklist for a Systematic Review or Meta-Analysis				
Study I	D:			
Guideli	ne topic:	topic: Key question no:		
Checkli	ist completed by:			
SECTIO	ON 1: INTERNAL VALIDITY			
In a we	ll-conducted systematic review:	In this study this cr	riterion is:	
		(Circle one option for each question)		
1.1	The study addresses an	Well covered	Not addressed	
	appropriate and clearly	Adequately	Not reported	
	focused question.	addressed	Not applicable	
		Poorly addressed		
1.2	A description of the	Well covered	Not addressed	
	methodology used is included.		Not reported	
		addressed	Not applicable	
		Poorly addressed		
1.3	The literature search is	Well covered	Not addressed	
	sufficiently rigorous to identify	Adequately	Not reported	
	all the relevant studies.	addressed	Not applicable	
		Poorly addressed		
1.4	Study quality is assessed and	Well covered	Not addressed	
	taken into account.	Adequately	Not reported	
		addressed	Not applicable	
		Poorly addressed		
1.5	There are enough similarities	Well covered	Not addressed	
	between the studies selected to	Adequately	Not reported	
	make combining them	addressed	Not applicable	
	reasonable.	Poorly addressed		
SECTIO	SECTION 2: OVERALL ASSESSMENT OF THE STUDY			

<sup>&</sup>lt;sup>1</sup> Available from: www.nice.org.uk ADHD (September 2008)

2.1	How well was the study done	
	to minimise bias? <i>Code</i> ++, + <i>or</i>	
	-	

Qual	ity Checklist for an RCT		
Study	ID:		
Guid	eline topic:	Key question no:	
Chec	klist completed by:		
SECT	TION 1: INTERNAL VALIDITY		
In a v	vell-conducted RCT study:	In this study this	criterion is:
		(Circle one option	for each
		question)	
1.1	The study addresses an	Well covered	Not addressed
	appropriate and clearly focused	Adequately	Not reported
	question.	addressed	Not applicable
		Poorly addressed	
1.2	The assignment of subjects to	Well covered	Not addressed
	treatment groups is randomised.	Adequately	Not reported
		addressed	Not applicable
		Poorly addressed	
1.3	An adequate concealment method	Well covered	Not addressed
	is used.	Adequately	Not reported
		addressed	Not applicable
		Poorly addressed	
1.4	Subjects and investigators are kept	Well covered	Not addressed
	'blind' about treatment allocation.	Adequately	Not reported
		addressed	Not applicable
		Poorly addressed	
1.5	The treatment and control groups	Well covered	Not addressed
	are similar at the start of the trial.	Adequately	Not reported
		addressed	Not applicable
		Poorly addressed	
1.6	The only difference between	Well covered	Not addressed
	groups is the treatment under	Adequately	Not reported
	investigation.	addressed	Not applicable
		Poorly addressed	
1.7	All relevant outcomes are	Well covered	Not addressed
	measured in a standard, valid and	Adequately	Not reported
	reliable way.	addressed	Not applicable
		Poorly addressed	

1.8	What percentage of the		
	individuals or clusters recruited		
	into each treatment arm of the		
	study dropped out before the		
	study was completed?		
1.9	All the subjects are analysed in the	Well covered	Not addressed
	groups to which they were	Adequately	Not reported
	randomly allocated (often referred	addressed	Not applicable
	to as intention-to-treat analysis).	Poorly addressed	
1.10	Where the study is carried out at	Well covered	Not addressed
	more than one site, results are	Adequately	Not reported
	comparable for all sites.	addressed	Not applicable
	_	Poorly addressed	
SECTI	ON 2: OVERALL ASSESSMENT	OF THE STUDY	
2.1	How well was the study done to		
	minimise bias?		
	Code ++, + or -		

Qual	lity Checklist for a Cohort Study*		
Stud	y ID:	Relevant questions:	
		_	
Guid	leline topic:		
Chec	klist completed by:		
SEC	ΓΙΟΝ 1: INTERNAL VALIDITY		
		In this study the sui	itarian ia
III a	well conducted cohort study:	In this study the cri	
		(Circle one option for	or each
		question)	
1.1	The study addresses an appropriate	Well covered	Not addressed
	and clearly focused question.	Adequately	Not reported
		addressed	Not applicable
		Poorly addressed	11
SELE	ECTION OF SUBJECTS		
1.2	The two groups being studied are	Well covered	Not addressed
	selected from source populations that	Adequately	Not reported
	are comparable in all respects other	addressed	Not applicable
	than the factor under investigation.	Poorly addressed	

1.3	The study indicates how many of the	Well covered	Not addressed
	people asked to take part did so, in	Adequately	Not reported
	each of the groups being studied.	addressed	Not applicable
		Poorly addressed	11
1.4	The likelihood that some eligible	Well covered	Not addressed
	subjects might have the outcome at	Adequately	Not reported
	the time of enrolment is assessed and	addressed	Not applicable
	taken into account in the analysis.	Poorly addressed	11
1.5	What percentage of individuals or		
	clusters recruited into each arm of the		
	study dropped out before the study		
	was completed?		
	•		
1.6	Comparison is made between full	Well covered	Not addressed
	participants and those lost to follow-	Adequately	Not reported
	up, by exposure status.	addressed	Not applicable
		Poorly addressed	
ASSI	ESSMENT		
1.7	The outcomes are clearly defined.	Well covered	Not addressed
		Adequately	Not reported
		addressed	Not applicable
		Poorly addressed	
1.8	The assessment of outcome is made	Well covered	Not addressed
	blind to exposure status.	Adequately	Not reported
		addressed	Not applicable
		Poorly addressed	
1.9	Where blinding was not possible,	Well covered	Not addressed
	there is some recognition that	Adequately	Not reported
	knowledge of exposure status could	addressed	Not applicable
	have influenced the assessment of	Poorly addressed	
	outcome.		
1.10	The measure of assessment of	Well covered	Not addressed
	exposure is reliable.	Adequately	Not reported
		addressed	Not applicable
		Poorly addressed	
1.11	Evidence from other sources is used	Well covered	Not addressed
	to demonstrate that the method of	Adequately	Not reported
	outcome assessment is valid and	addressed	Not applicable
	reliable.	Poorly addressed	•

1.12	Exposure level or prognostic factor is	Well covered	Not addressed
	assessed more than once.	Adequately	Not reported
		addressed	Not applicable
		Poorly addressed	
CON	IFOUNDING		
1.13	The main potential confounders are	Well covered	Not addressed
	identified and taken into account in	Adequately	Not reported
	the design and analysis.	addressed	Not applicable
		Poorly addressed	
STA	ΓΙSTICAL ANALYSIS		
1.14	Have confidence intervals been provide	led?	
SEC	ΓΙΟΝ 2: OVERALL ASSESSMENT O	F THE STUDY	
2.1	How well was the study done to minimum	mise the	
	risk of bias or confounding, and to est	ablish a	
	causal relationship between exposure	and	
	effect?		
	Code ++, + or -		

\*A cohort study can be defined as a retrospective or prospective follow-up study. Groups of individuals are defined on the basis of the presence or absence of exposure to a suspected risk factor or intervention. This checklist is not appropriate for assessing uncontrolled studies (for example, a case series where there is no comparison [control] group of patients).

Quali	ty Checklist for an RCT		
Study I	TD .		
Guidel	ine topic	Key question no:	
Checkl	ist completed by:		
SECTI	ON 1: INTERNAL VALIDITY		
In a well conducted diagnostic study:		In this study the criterion is: (Circle one	
		option for each ques	tion)
1.1	The nature of the test being studied is	Well covered	Not addressed
clearly specified.	clearly specified.	Adequately	Not reported
		addressed	Not applicable
		Poorly addressed	

1.2	The test is compared with an appropriate gold standard.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.3	Where no gold standard exists, a validated reference standard is used as a comparator.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.4	Patients for testing are selected wither as a consecutive series or randomly, from a clearly defined study population.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.5	The test and gold standard are measured independently (blind) of each other.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.6	The test and gold standard are applied as close together in time as possible.	Well covered Adequately addressed Poorly addressed	Not addressed  Not reported  Not applicable
1.7	Results are reported for all patients that are entered into the study.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
ASSE	SSMENT		
1.8	A pre-diagnosis is made and reported.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
	TION 2: OVERALL ASSESSMENT OF THE ST	TUDY	
2.1	How reliable are the conclusions of this study?  Code ++, + or -		
2.2	Is the spectrum of patients assessed in this study comparable with the patient group targeted by this guideline in terms of the proportion with the disease, or the proportion with severe versus mild disease?		