Appendix 1. Table of content of an oseltamivir clinical study report, trial WV15799.

CLINICAL STUDY REPORT MODULES

This report consists of 5 modules.

Those not supplied in this submission are obtainable from the sponsor on request.

Appendix 2. Mapping and extraction tool for oseltamivir clinical study report (CSR) Module 2 elements to Cochrane Characteristics of Included Studies elements

Mapping Tamiflu CSR Module 2 elements to Cochrane Characteristics of Included Studies elements

Aim: To identify sections of the Clinical Study Reports (CSRs) Module 2 (defined as what Roche calls "Module 2") which may improve understanding of the content of the Cochrane included studies table (CIST).

Drug:	Oseltamivir (Tamiflu)
CSR for trial(s):	
Reviewer:	
Date(s) of extraction:	

Notes:

1. **Do not remove this notice**
2. **Do not merge cells in the tables (Merged cells wreak havoc in collating answers in a spreadsheet)**
3. **Do not copy-paste images from the CSR**

Trial Summary

Trial summary given in…	Trial summary
CSR	(*Short (2-3) sentence description of the trial as given in the CSR – most likely in the Synopsis section.*)
A159 (January 2012)	(*Copy and/or assemble this from the Characteristics of Included Studies table in the A159 review published in January 2012.*)
Your own words, after extracting M2	(*Write a new trial summary that is accurate based on your understanding of the trial after reading M2.*)

Risk of bias

Bias	A159 (Jan 2012) judgment	A159 (Jan 2012) support for judgment	Reviewer's judgment (post M2)	Support for judgment
Random sequence generation (selection bias)				
Allocation				

concealment (selection bias)				
Incomplete outcome data (attrition bias), symptoms				
Incomplete outcome data (attrition bias), complications of influenza				
Incomplete outcome data (attrition bias), safety data				
Selective reporting (reporting bias), other bias				
Other bias				
Blinding of participants and personnel (performance bias), all outcomes				
Blinding of outcome assessment (detection bias), all outcomes				

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22 **Trial timeline**

Serial	Timeline element	Date	Version (if a version name/number is given)	Page (PDF page no.) where item can be found
A	Patient enrollment dates			
B	Unblinding of the trial			
C	Protocol for which we have the full text (if we have multiple versions in full text, record all dates and versions)			
D	Protocol amendments (list all amendments with dates and their version stamp)			
E	Statistical Analysis Plan for which we have the full text (if we have multiple versions in full text, record all dates and versions)			

F	SAP amendments (list all amendments with dates and their version stamp)			
G	Patient consent form			
H	Randomization list			
I	Certificate of Analysis			

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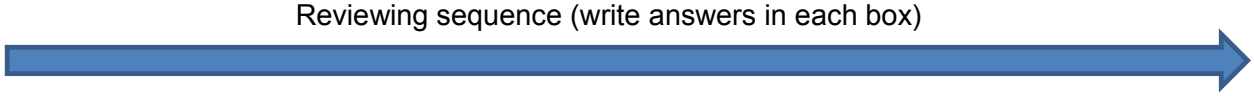
25 Reviewing sequence (write answers in each box)

26 

Serial	Cochrane Characteristics of Included Studies	Check these M2 elements with care:	Is M1 reporting consistent with M2? Yes – No – Unclear (choose one)	If the answer is no then record the difference
1	METHODS			
1a	○ Study Design	RPS		
1b	○ Location, number of centers	RPS LIESA		
1c	○ Duration of study	RPS		
2	PARTICIPANTS			
2a	○ Number screened	-	LEAVE BLANK UNLESS NEEDED	LEAVE BLANK UNLESS NEEDED
2b	○ Number randomized	-		
2c	○ Number completed	-		
2d	○ Number analysed	-		
2e	○ Male/Female ratio	-		
2f	○ Mean age	-		
2g	○ Baseline details	-		
2h	○ Inclusion criteria	RPS		
2i	○ Exclusion criteria	RPS		
2j	○ Definition of patient populations for analysis	RPS RAP		
3	INTERVENTIONS			

3a	○ Intervention	RPS CA RAP		
3b	○ Control	RPS CA RAP		
3c	○ Treatment period	RPS RAP FUC		
3d	○ Treatment duration	RPS RAP FUC		
3e	○ Follow up (in days)	RPS RAP FUC		
3f	○ Co-interventions	RPS RAP		
4	OUTCOMES			
4a	○ Primary outcome	RPS RAP CRF Note: ensure CRF can capture relevant info		
4b	○ Secondary outcomes	RPS RAP CRF Note: ensure CRF can capture relevant info		
5	NOTES			Make any other points you wish here
6	RISK OF BIAS			
6a	○ Random sequence generation (selection bias)	RPS RL		
6b	○ Allocation concealment (selection bias)	RPS		
6c	○ Incomplete outcome data (attrition bias)	RPS IC Note: IC may contain		

		details that suggest possible influence on retention or attrition		
6d	○ Selective reporting (reporting bias)	RPS IC LIESA Note: check if all contributors listed in core report are present in protocol and LIESA		
6e	○ Other bias	RPS		
6f	○ Blinding of participants and personnel (performanc e bias)	RPS CA Note: ensure CA supports description of placebo and active elsewhere in CSR	Are the intervention and control identical in all but the active principle?	
6g	○ Blinding of outcome assessment (detection bias)	RPS CA Note: ensure CA supports description of placebo and active elsewhere in CSR		

CA = Certificate of Analysis
CRF = Case Report Form(s)
FUC = Follow up cards/Diary cards
IC = Informed Consent and participant contract
LIESA = Lists of Investigators, IRB, EC and Site Addresses
RAP = Reporting Analysis Plan (Roche's term for the Statistical Analysis Plan (SAP))
RL = Randomisation List
RPS = Relevant Protocol Section (including latest amendments)

NOTE: Roche protocol amendments are designated with a suffix letter e.g. B, C, D. The latest version of the protocol is the one that should be followed in the trial which then assumes the suffix to denote the version followed e.g. WV 15799H.