Basic Extraction Information

Questions	Answer	Notes
1. Drug common name:		
2. Trial ID:		
➔ Now, fill in the drug and trial ID in the bottom-right corner the page.	E.g. "Tamiflu, WV15670"	
➔ Now, save this file under a new filename	Use the naming convention "*Drugname Trial ID - Extractor's initials - YYYYMMDD.docx"*, e.g. "Seroquel 015 - TJ - 20120311.docx"	
3. Report/CSR ID (if different from Trial ID):		
4. Extractor's name (Initials)		
5. Date of extraction		

Notes to extractor:

- Page numbers should be referred to by the format p.(page # as printed)/PDFp.(PDF page number, possibly indicating volume), e.g.
  - p.V-235/PDFp.945 = page "V-235", on PDF page 945
  - p.234/PDF(3)p.18 = page "234", on the 3rd PDF for this CSR, PDF page 18
- Most questions can be answered with a Y or N (indicating Yes or No) or a number (e.g. the number of PDF pages.
- Where specified as "Free form answer", the extractor may answer in his/her own words based on the extractor's reading of the CSR.

Item	Content	Notes
Overview questions 6. Does the CSR list a ISRCTN/NCT or equivalent registration number for this trial?		
7. List CSR number of authors		
8. List CSR authors & trialists (Copy names if available; "redacted" if redacted; "not listed" if not listed)		
9. Total length of CSR obtained, in PDF pages		
10. List CSR completion date		
11. Is the trial published?		
12. If Y give publication citation		
13. If Y give publication size (in pages)		
14. Who appears to be responsible for CSR? (Free form answer)		
Trial programme questions 15. How many trials appear to be in the trial programme?		
16. Does CSR indicate where this trial fits in the trial programme? (Free form answer)		
17. Does CSR say how much of the trial programme is published?		
18. How many trials are in possession of a ISRCTN/NCT or equivalent registration number?		
Basic elements of the Clinical Study Report		

19.	Does the CSR contain a **table of contents**?		
20.	If Y, is the **table of contents** listed as an Appendix?		
21.	If Y, is the **table of contents** accessible to us?		
22.	If Y, how long is the **table of contents** (in pages)?		
23.	Does the table of contents list a **title page**?		
24.	If Y, is the **title page** listed as an Appendix?		
25.	If Y, is the **title page** accessible to us?		
26.	If Y, how long is the **title page** (in pages)?		
27.	Does the table of contents list a **synopsis**?		
28.	If Y, is the **synopsis** listed as an Appendix?		
29.	If Y, is the **synopsis** accessible to us?		
30.	If Y, how long is the **synopsis** (in pages)?		
31.	Does the CSR contain a **list of abbreviations and definitions**?		
32.	If Y, is the **list of abbreviations and definitions** listed as an Appendix?		
33.	If Y, is the **list of abbreviations and definitions** accessible to us?		
34.	If Y, how long is the **list of abbreviations and definitions** (in pages)?		
35.	Does the CSR contain an **ethics section**?		
36.	If Y, is the **ethics section** listed as an Appendix?		
37.	If Y, is the **ethics section** accessible to us?		
38.	If Y, how long is the **ethics section** (in pages)?		
39.	Does the CSR contain a **investigators and study administrative structure**?		
40.	If Y, is the **investigators and study administrative structure** listed as an Appendix?		
41.	If Y, is the **investigators and study administrative structure** accessible to us?		
42.	If Y, how long is the **investigators and study administrative structure** (in pages)?		
43.	Does the CSR contain an **introduction**?		
44.	If Y, is the **introduction** listed as an Appendix?		
45.	If Y, is the **introduction** accessible to us?		
46.	If Y, how long is the **introduction** (in pages)?		
47.	Does the CSR contain a section on study objectives?		
48.	If Y, is the **section on study objectives** listed as an Appendix?		
49.	If Y, is the **section on study objectives** accessible to us?		
50.	If Y, how long is the **section on study objectives** (in pages)?		
51.	Does the CSR contain an **investigational plan** (from IHR 1995 E3, PDF p.13)?		
52.	If Y, is the **investigational plan** listed as an Appendix?		
53.	If Y, is the **investigational plan** accessible to us?		
54.	If Y, how long is the **investigational plan** (in pages)?		
55.	Does the CSR contain a section on **study patients**?		
56.	If Y, is the **study patients** listed as an Appendix?		
57.	If Y, is the **study patients** accessible to us?		
58.	If Y, how long is the **study patients** (in pages)?		

59.	If Y, does it include a list of protocol deviations?		
60.	Does the CSR contain a section on **efficacy evaluation**?		
61.	If Y, is the **efficacy evaluation** listed as an Appendix?		
62.	If Y, is the **efficacy evaluation** accessible to us?		
63.	If Y, how long is the **efficacy evaluation** (in pages)?		
64.	Does the CSR contain a section on **safety evaluation**?		
65.	If Y, is the **safety evaluation** listed as an Appendix?		
66.	If Y, is the **safety evaluation** accessible to us?		
67.	If Y, how long is the **safety evaluation** (in pages)?		
68.	Does the CSR contain a **discussion and overall conclusions** section?		
69.	If Y, is the **discussion and overall conclusions** listed as an Appendix?		
70.	If Y, is the discussion and overall conclusions accessible to us?		
71.	If Y, how long is the **discussion and overall conclusions** (in pages)?		
72.	Does the CSR contain a section on **tables, figures and graphs referred to but not included in the text**?		
73.	If Y, is the **tables, figures and graphs referred to but not included in the text** listed as an Appendix?		
74.	If Y, is the **tables, figures and graphs referred to but not included in the text** accessible to us?		
75.	If Y, how long is the **tables, figures and graphs referred to but not included in the text** (in pages)?		
76.	Does the CSR contain a **references** section?		
77.	If Y, is the **references** listed as an Appendix?		
78.	If Y, is the **references** accessible to us?		
79.	If Y, how long is the **references** (in pages)?		
Appendices related questions			
80.	Does the **table of contents** indicate that the CSR contains **appendices**?		
81.	If Y, does the **table of contents** list the **titles of the appendices**?		
82.	Does the CSR include the **study Protocol**?		
83.	If Y, is the **study Protocol** accessible to us?		
84.	If Y, how long is the **study Protocol** (in pages)?		
85.	Does the CSR contain a section on **Protocol amendments**?		
86.	If Y, is the section on **Protocol amendments** accessible to us?		
87.	If Y, how long is the section on **Protocol amendments** (in pages)?		
88.	Does the CSR contain a section on **Sample case report form (unique pages only)**?		
89.	If Y, is the section on **Sample case report form (unique pages only)** accessible to us?		
90.	If Y, how long is the section on **Sample case report form (unique pages only)** (in pages)?		
91.	Does the CSR contain a section on **List of IECs or IRBs (plus the name of the committee Chair if required by the**		

	regulatory authority) - Representative written information for patient and sample consent forms?		
92.	If Y, is the section on **List of IECs or IRBs (plus the name of the committee Chair if required by the regulatory authority) - Representative written information for patient and sample consent forms** accessible to us?		
93.	If Y, how long is the section on **List of IECs or IRBs (plus the name of the committee Chair if required by the regulatory authority) - Representative written information for patient and sample consent forms** (in pages)?		
94.	Does the CSR contain a section on **List and description of investigators and other important participants in the study, including brief (1 page) CVs or equivalent summaries of training and experience relevant to the performance of the clinical study**?		
95.	If Y, is the section on **List and description of investigators and other important participants in the study, including brief (1 page) CVs or equivalent summaries of training and experience relevant to the performance of the clinical study** accessible to us?		
96.	If Y, how long is the section on **List and description of investigators and other important participants in the study, including brief (1 page) CVs or equivalent summaries of training and experience relevant to the performance of the clinical study** (in pages)?		
97.	Does the CSR contain a section on **Signatures of principal or coordinating investigator(s) or sponsor's responsible medical officer, depending on the regulatory authority's requirement**?		
98.	If Y, is the section on **Signatures of principal or coordinating investigator(s) or sponsor's responsible medical officer, depending on the regulatory authority's requirement** accessible to us?		
99.	If Y, how long is the section on **Signatures of principal or coordinating investigator(s) or sponsor's responsible medical officer, depending on the regulatory authority's requirement** (in pages)?		
100.	Does the CSR contain a section on **Listing of patients receiving test drug(s)/investigational product(s) from specific batches, where more than one batch was used**?		
101.	If Y, is the section on **Listing of patients receiving test drug(s)/investigational product(s) from specific batches, where more than one batch was used** accessible to us?		
102.	If Y, how long is the section on **Listing of patients receiving test drug(s)/investigational product(s) from specific batches, where more than one batch was used** (in pages)?		
103.	Does the CSR contain a section on **Randomisation scheme and codes (patient identification and treatment assigned)**?		
104.	If Y, is the section on **Randomisation scheme and codes**		

	(patient identification and treatment assigned) accessible to us?		
105.	If Y, how long is the section on **Randomisation scheme and codes (patient identification and treatment assigned)** (in pages)?		
106.	Does the CSR contain a section on **Audit certificates (if available) (see Annex IVa and IVb of the guideline)**?		
107.	If Y, is the section on **Audit certificates (if available) (see Annex IVa and IVb of the guideline)** accessible to us?		
108.	If Y, how long is the section on **Audit certificates (if available) (see Annex IVa and IVb of the guideline)** (in pages)?		
109.	Does the CSR contain a section on **Documentation of statistical methods**?		
110.	If Y, is the section on **Documentation of statistical methods** accessible to us?		
111.	If Y, how long is the section on **Documentation of statistical methods** (in pages)?		
112.	If Y, is the **Documentation of statistical methods** dated?		
113.	If Y, what is the date of the **Documentation of statistical methods**?		
114.	Does the CSR contain a section on **Documentation of inter-laboratory standardisation methods and quality assurance procedures if used**?		
115.	If Y, is the section on **Documentation of inter-laboratory standardisation methods and quality assurance procedures if used** accessible to us?		
116.	If Y, how long is the section on **Documentation of inter-laboratory standardisation methods and quality assurance procedures if used** (in pages)?		
117.	Does the CSR contain a section on **Publications based on the study**?		
118.	If Y, is the section on **Publications based on the study** accessible to us?		
119.	If Y, how long is the section on **Publications based on the study** (in pages)?		
120.	Does the CSR contain a section on **Important publications referenced in the report**?		
121.	If Y, is the section on **Important publications referenced in the report** accessible to us?		
122.	If Y, how long is the section on **Important publications referenced in the report** (in pages)? Edfgyh+		
123.	Does the CSR contain a section on **Discontinued patients**?		
124.	If Y, is the section on **Discontinued patients** accessible to us?		
125.	If Y, how long is the section on **Discontinued patients** (in pages)?		
126.	Does the CSR contain a section on **Protocol deviations**?		
127.	If Y, is the section on **Protocol deviations** accessible to us?		
128.	If Y, how long is the section on **Protocol deviations** (in		

	pages)?		
129.	Does the CSR contain a section on **Patients excluded from the efficacy analysis**?		
130.	If Y, is the section on **Patients excluded from the efficacy analysis** accessible to us?		
131.	If Y, how long is the section on **Patients excluded from the efficacy analysis** (in pages)?		
132.	Does the CSR contain a section on **Demographic data**?		
133.	If Y, is the section on **Demographic data** accessible to us?		
134.	If Y, how long is the section on **Demographic data** (in pages)?		
135.	Does the CSR contain a section on **Compliance and/or drug concentration data (if available)**?		
136.	If Y, is the section on **Compliance and/or drug concentration data (if available)** accessible to us?		
137.	If Y, how long is the section on **Compliance and/or drug concentration data (if available)** (in pages)?		
138.	Does the CSR contain a section on **Individual efficacy response data**?		
139.	If Y, is the section on **Individual efficacy response data** accessible to us?		
140.	If Y, how long is the section on **Individual efficacy response data** (in pages)?		
141.	Does the CSR contain a section on Adverse event listings (each patient)?		
142.	If Y, is the section on **Adverse event listings (each patient)** accessible to us?		
143.	If Y, how long is the section on **Adverse event listings (each patient)** (in pages)?		
144.	Does the CSR contain a section on **Listing of individual laboratory measurements by patient, when required by regulatory authorities**?		
145.	If Y, is the section on **Listing of individual laboratory measurements by patient, when required by regulatory authorities** accessible to us?		
146.	If Y, how long is the section on **Listing of individual laboratory measurements by patient, when required by regulatory authorities** (in pages)?		
147.	Does the CSR contain a section on **Case Report Forms for deaths, other serious adverse events and withdrawals for AE**?		
148.	If Y, is the section on **Case Report Forms for deaths, other serious adverse events and withdrawals for AE** accessible to us?		
149.	If Y, how long is the section on **Case Report Forms for deaths, other serious adverse events and withdrawals for AE** (in pages)?		
150.	Does the CSR contain a section on **Other Case Report Forms** submitted?		
151.	If Y, is the section on **Other Case Report Forms submitted** accessible to us?		
152.	If Y, how long is the section on **Other Case Report Forms**		

	submitted (in pages)?		
153.	Does the CSR contain a section on **Individual patient data listings**?		
154.	If Y, is the section on **Individual patient data listings** accessible to us?		
155.	If Y, how long is the section on **Individual patient data listings** (in pages)?		