

Working instruction	13 – CSR/Publication QC form
Version	2 – 05.03.19
Please improve on the form as you feel fit Remove this box when preparing form for use With publications, the Sponsor should review the publication ahead of being published. However, the Sponsor is not an expert in each medical field. Therefore, find out from the CI/PI who reviews the publication e.g. does the journal send the draft publication to an independent expert reviewer and if so, adapt this form to document what happens.	

Clinical Study Report/**Publication** Quality Control Form

Brief study title:	R&D ref no:
Principal Investigator:	Hospital address:
Document title:	
Document version number and date:	
Name of author(s):	

R&D QA staff

R&D review <i>(please add/delete rows as applicable)</i>	Checked	Changes required/comments <i>(give headings and page numbers where applicable)</i>
Has the CSR/ publication been sent in PDF format?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Do the header and footer appear on every page?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	
Are the header and footer correct on every page?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	
Are page numbers sequential and present on every page?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Are there any typographical or grammatical errors?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Do the font type and size remain the same in the main body of the text <i>(this excludes tables, figures and attachments)</i> .	Yes <input type="checkbox"/> No <input type="checkbox"/>	

Reviewer to complete:

Print name:		
Signature:		Date of review:
Role:		

Statistician

Statistical review	Checked	Changes required/comments <i>(give headings and page numbers where applicable)</i>
Is the statistical analysis consistent with the Stats Analysis Plan/stats section in the protocol?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
If a cross-over trial, have the period and carry over effects been analysed?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	
Has the stats analysis been carried out correctly?	Yes <input type="checkbox"/> No <input type="checkbox"/>	

Please list your findings in the comments column.		
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Reviewer to complete:

Print name:		
Signature:		Date of review:
Role:		

R&D Director

Methodology and design review	Checked	Changes required/comments <i>(give headings and page numbers where applicable)</i>
Does the methodology and design in the CSR correspond to that in the protocol?	Yes <input type="checkbox"/> No <input type="checkbox"/>	

Reviewer to complete:

Print name:		
Signature:		Date of review:
Role:		

Author to complete:

I confirm that all changes requested by the Sponsor have been made.

Print name:		
Signature:		Date:
Role:		

Sponsor sign off:

I confirm that all changes requested have been addressed by the author.

Print name:		
Signature:		Date:
Role:		