



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

<Date of submission>

Submission of comments on 'EMA Consultation: Points to consider on implications of Coronavirus disease (COVID-19) on methodological aspects of ongoing clinical trials' (EMA/158330/2020)

Comments from:

Name of organisation or individual

International Society for Clinical Biostatistics, ISCB

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).



1. General comments

Stakeholder number <i>(To be completed by the Agency)</i>	General comment (if any)	Outcome (if applicable) <i>(To be completed by the Agency)</i>
	<p>CJW comment: Line 62, line 91. Interpretability and any unforeseen changes to trial elements, missing data and intercurrent events.</p> <p>It would be helpful in the Points to Consider to refer explicitly to the trial estimand, as any action required due to a Covid-19 related change to the trial will differ depending on whether or not it impacts on the estimands of interest in the trial.</p>	

2. Specific comments on text

Line number(s) of the relevant text <i>(e.g. Lines 20-23)</i>	Stakeholder number <i>(To be completed by the Agency)</i>	Comment and rationale; proposed changes <i>(If changes to the wording are suggested, they should be highlighted using 'track changes')</i>	Outcome <i>(To be completed by the Agency)</i>
		Comment: Proposed change (if any):	
		Comment: Proposed change (if any):	
		Comment: Proposed change (if any):	

Please add more rows if needed.