EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

<Date of submission>

Submission of comments on 'Draft Qualification Opinion of MCP-Mod as an efficient statistical methodology for model-based design and analysis of Phase II dose finding studies under model uncertainty ' (EMA/CHMP/SAWP/592378/2013)

Comments from:

Name of organisation or individual
IDEAL (Integrated DEsign and AnaLysis of small population group trials) FP7 Consortium (**European Union Seventh Framework Programme under grant agreement n° 602552)**

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).

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	We welcome this statement. Dose finding is one of the most difficult steps in drug development and the note provides a realistic assessment of the value of one flexible and useful approach to dose finding (the MCP Mod approach). It would be helpful to future potential users of this approach if the agency could state whether it would be prepared to consider the use of doses in subsequent stages of development that were identified by this method although not actually studied in Phase II. For example if the method suggested that the optimal dose would be one between two of the doses actually studied.	

2. Specific comments on text

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

Please add more rows if needed.