

Non-Confidential - Expression of Interest Form Guidance Notes

These are guidance notes for investigators before completing your Expression of Interest (EOI) form to provide the relevant details summarising your EOI.

Criteria for Inclusion	
Background	Strong scientific and clinical rationale
	Relevant preclinical data and/or proposals for associated preclinical work to support the combination
	Lack of overlapping toxicity
	Minimal or no existing trial data and no ongoing/competing trials
	Outside of the main research areas prosecuted by the pharma company or other investigator lead trials
Development Strategy	Patient population is accessible
	Sponsorship and operational management confirmed (<i>preferred</i>)
	CTU capacity
	Developability of proposal is considered
	Capability to open study within 12 months of NAC
CSG Support	CSG/sub-group support prior to workshop (<i>preferred</i>)
ECMC Support	ECMC lead supports the proposal

Combinations Alliance Requirements	
Phase Ib/Ila	Primary endpoint: Safety, tolerability, PK of combo
	Secondary endpoint: Non-statistically powered efficacy (preferably biomarkers)
Dose escalation	2-4 cohorts
	3-6 pts/cohort
Dose expansion	Randomised combo versus Standard of Care (SoC)
	~10 pts/arm
Combination	Essential, e.g., radiotherapy, SoC, novel:novel
Sites	ECMC
Funding Committee	NAC

Note on Delivery:

The success of these Alliances is dependent on the timely EOI development and clinical trial delivery. We highly recommend that the intended Sponsor and Clinical Trial Unit (CTU) that would support the proposed study is involved as early as possible to achieve the following delivery timelines.

Expected delivery:	Funding Committee approval - IRAS submission:	8 months
	IRAS approval - 1st centre open:	4 months
	First centre open - first patient randomisation:	4 weeks

Note on Confidentiality:

Only non-confidential information should be included in the EOI proposal. If confidential data exists that would strengthen the rationale or other aspects of the proposal, the author can/should emphasise that a statement is supported by confidential information the author is able to share, but only under a Confidential Disclosure Agreement (CDA). If the company finds the non-confidential EOI proposal sufficiently intriguing, execution of a CDA so that information can be considered will be discussed.