

Trial adoption request for collaboration form

CHIEF INVESTIGATOR		
Surname	First Name	Initials
Address		
Town/City	County	Postcode
Phone No.	Email Address	
Current Employer		
Honorary Contracts		
GCP Training	No Yes	Date of GCP Training
Have you previously acted as CI?	No Yes	Please indicate number/type of studies:

STUDY DETAILS		
Title		
Acronym		
Name of Sponsor(s)		
Has the study been discussed with the Sponsor?		No Yes
If 'yes' please provide details	Date	Meeting held with:
Has the study been discussed with Manchester CTU?		No Yes
If 'yes' please provide details	Date	Meeting held with:

STUDY TYPE – Please complete the relevant section

Is the study a Clinical Trial of an Investigational Medicinal Product (CTIMP)?	No	Yes	Don't know
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Clinical Trial of an Investigational Medicinal Product

Name of IMP(s)

Is the IMP licensed for this disease indication?

No Yes

Is the IMP provided by a company/funder?

No Yes

Name of company

Will the IMP provider provide labelling, QP release and distribution of the IMP?

No Yes

Details and/or comments

Clinical Trial of a Medical Device

Is the medical device licensed for this disease indication?

No Yes

Is the medical device CE marked?

No Yes

Is the medical device provided by company/funder?

No Yes

Name of company

Other Clinical Trial or Clinical Investigation

Screening and Prevention

Complex Intervention

Surgery

Diagnostic Test Evaluation

Radiotherapy

Psychological and Behavioural

Human Tissue (Sample and Data)

Questionnaires Only

Qualitative Study

Other

Please specify:

Translational work

Will the study involve any translational work?

No Yes

Please state which labs will be used:

Please state what samples will be analysed:

PHASE / TYPE		
I	II	III
Translational	Pilot	Feasibility
Open Label	Blinded	Randomised
Cluster Randomised	Placebo Controlled	Observational
Single Centre	Multicentre	Other
Please Specify:		

STUDY SYNOPSIS
Background/Brief Summary of Evidence
Aims
Methods

PICOS (Participant, Intervention, Control and Study/Statistical design)

P – Participant group(s)	
I – Intervention(s)	
C – Control	
O – Outcome and follow up period	
S – Study/Statistical design (eg RCT)	

TRIAL DEVELOPMENT AND SAMPLE SIZE CALCULATIONS

An estimate of your primary study outcome measure for the control group (eg response rate expected without the new intervention)	
The clinical significant difference you would want to observe between groups for the study to be convincing (eg be worthwhile for funders and patients, change practice)	
Please provide sources/justification for these estimates from pilot work/literature	
Proposed sample size	

RECRUITMENT	
Anticipated number of UK sites	
Anticipated number of European sites	
Number and names of sites already identified as willing to participate	
Age range of participants	
Please describe your recruitment plan and how do you arrived at this recruitment rate/figures? Please provide sources/justification for these estimates from pilot work/literature	
What are the plans to address potential recruitment issues? (eg opening of additional/ international sites)	
Have you made contact with a research network or national specialty group(s)?	No Yes
Does the trial intend to recruit any vulnerable participants? (eg elderly, those with mental capacity issues, prisoners)	No Yes
Are there likely to be any recruitment issues? (eg where the participant will be recruited, who will recruit the participant)	No Yes
Please specify:	

ESTIMATED STUDY TIMELINES	
Estimated total trial duration in months (First participant first visit – Last participant last visit)	
Estimated study set-up duration in months	
Estimated recruitment duration in months	
Estimated follow-up duration in months	
Estimated duration of the intervention per participant in months	

Planned trial duration per participant in months	
Estimated close-out (analysis and study report duration) in months	
Estimated start of set-up date	
Estimated recruitment start date	
Estimated end of follow up	

INDUSTRY INVOLVEMENT

Is this study part of industry collaboration?	No	Yes	Comments
Will the results of this study be used for marketing authorisation or CE marking?	No	Yes	Comments

RESEARCH DESIGN SERVICE

Has the study design been discussed with the RDS?	No	Yes
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HEALTH ECONOMICS INPUT *(Please note that the CTU cannot provide this and if the input of health economics is required please inform the CTU).*

Does the study require Health Economics input?	No	Yes	
Has a Health Economist already been consulted?	No	Yes	Please provide contact details:

NIHR/CRN CLINICAL STUDIES GROUP SUPPORT

Has the study been discussed/approved or due to be discussed at the relevant CSG?	No	Yes
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PATIENT AND PUBLIC INVOLVEMENT

Is PPI planned?	No	Yes
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Please specify:

MANCHESTER CTU SUPPORT REQUESTED

Methodology support	No	Yes
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Trial coordination	No	Yes
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Central data management	No	Yes
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Randomisation service	No	Yes
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Statistical support	No	Yes	Please clarify if not required:
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Study Monitoring (consent, data, SDV, ISF etc)	No	Yes
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Other (please specify)		
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FINANCE

Is funding already in place?	No	Yes	Funding amount and funder
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Will this study proposal be subject of a grant funding application?	No	Yes	Grant application submission deadline
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Grant funding body (eg NIHR, CRUK MRC etc)		
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Funding stream (eg RfPB, EME etc)		
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Details of competition call (eg themed, commissioned, open)		
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Type of application? Full, Outline, EOI	
Deadline for submission	
Proposed (target) submission date	
Expected date when outcome known	
Expected date of start of award	
Estimated potential grant total (if known)	
Has this study been discussed with your Research Support Manager?	No Yes