

EACVI Clinical Study/Registry proposal form

Of note: the blue sentences in the right column are there to guide you in completing this form. Please delete them when submitting your proposal.

TITLE			
ACRONYM			
PROPONENT			
PROMOTOR	EACVI		
STUDY			
PARTICIPANTS			
ESTIMATED BUDGET			
Funding	Already agreed YES	NO	
	If NO, please specify whether you require	VEC	NO
	EACVI advice in fundraising (industry)	YES	NO
	Or in application to FII Research Calls	VFS	NO
PROPOSAL VERSION	Or in application to EU Research Calls V 1.0	YES	NO
PROPOSAL VERSION	V 1.0		NO
PROPOSAL VERSION FULL PROTOCOL		NO NO	NO
	V 1.0 Already available YES		NO
	V 1.0 Already available YES If YES, please enclose in appendix		NO NO
	V 1.0 Already available YES If YES, please enclose in appendix If NO, please specify whether you require	NO	
FULL PROTOCOL	V 1.0 Already available YES If YES, please enclose in appendix If NO, please specify whether you require	NO	
FULL PROTOCOL BACKGROUND,	V 1.0 Already available YES If YES, please enclose in appendix If NO, please specify whether you require	NO	
FULL PROTOCOL BACKGROUND, RATIONALE AND	V 1.0 Already available YES If YES, please enclose in appendix If NO, please specify whether you require	NO	
FULL PROTOCOL BACKGROUND, RATIONALE AND HYPOTHESIS	V 1.0 Already available YES If YES, please enclose in appendix If NO, please specify whether you require	NO	
FULL PROTOCOL BACKGROUND, RATIONALE AND HYPOTHESIS PRIMARY OBJECTIVE SECONDARY OBJECTIVES (≤ 3)	V 1.0 Already available YES If YES, please enclose in appendix If NO, please specify whether you require	NO	
FULL PROTOCOL BACKGROUND, RATIONALE AND HYPOTHESIS PRIMARY OBJECTIVE SECONDARY	V 1.0 Already available YES If YES, please enclose in appendix If NO, please specify whether you require	NO	
FULL PROTOCOL BACKGROUND, RATIONALE AND HYPOTHESIS PRIMARY OBJECTIVE SECONDARY OBJECTIVES (≤ 3)	V 1.0 Already available YES If YES, please enclose in appendix If NO, please specify whether you require	NO	
FULL PROTOCOL BACKGROUND, RATIONALE AND HYPOTHESIS PRIMARY OBJECTIVE SECONDARY OBJECTIVES (≤ 3) ENDPOINT (S)	V 1.0 Already available YES If YES, please enclose in appendix If NO, please specify whether you require	NO	

STUDY/REGISTRY	Design	Registry		
DESIGN AND	2 001811	Observational Study		
METHODS		Interventional Non Randomiz	zed Trial	
		Interventional Randomized T		
		interventional Kandonnized 1	1141	
DESCRIPTION OF THE				
STUDY POPULATION				
INCLUSION CRITERIA	Patients eligible	e for inclusion in this study have	ve to fulfill	all of the fol-
	lowing criteria:			
	_	ormed Consent		
EXCLUSION	Patients fulfilling	ng any of the following criteria	are not eli	gible for inclu-
CRITERIA	sion in this stud	y:		
I rem on pompymy y	A1 1 1	NEC N		
LIST OF POTENTIAL	Already agreed	YES No	U	
PARTCIPATING CENTRES AND				
COUNTRIES				
COUNTRIES				
	If NO, please sp	pecify whether you require		
	EACVI advice		YES	NO
FOLLOW-UP				
CARDIOVASCULAR	Tranethora	ncic echocardiography (TTF)		
IMAGING INVOLVED	Transthoracic echocardiography (TTE) Transoesophageal echocardiography (TEE)			
INTEGRATE IN COLUMN	TD.	1 1 1 1 1 1 7		

STATISTICAL METHODOLOGY AND SAMPLE SIZE CALCULATION	Cardiovascular magnetic resonance (CMR) Cardiac computed tomography (CT) Nuclear imaging Invasive imaging Others (if so, provide details please):	
NUMBER OF PATIENTS / CENTERS / YEARS, MONTH, WEEK VARIABLES TO BE		
COLLECTED MISSING DATA MANAGEMENT		
ETHICS APPROVAL STARTING DATE STUDY DURATION	Estimate of timing for Ethics approval Estimate of study starting date Estimate of study closing date	
STUDY OPERATIONAL DETAILS	Please specify whether you require: EACVI advice in data management YES N	ΙO
	Please specify whether you require: EACVI advice in statistical analysis YES N	0
CHALLENGES (RISKS) AND PLANS		

AUTHORSHIP				
KEYWORDS				
NCT NUMBER				
(CLINICAL.GOV)				
PUBLICATION				
POLICY				
	Please specify whether you require			
	EACVI advice in manuscript revision	YES	NO	

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APPENDIX (Estimated Budget)

TITLE	
ACRONYM	
PROPONENT	
PROMOTOR	EACVI
STUDY PARTICIPANTS	
STUDY PARTICIPANTS	
ESTIMATED BUD	 GET
TOTAL ESTIMATED BUDGET (€)	
TOTAL ESTIMATED BUDGET (C)	
TOTAL ESTIMATED COSTS	DDE A L'DOWN
	DREARDOWN
PERSONNEL COSTS (€)	
SUBCONTRACTING COSTS (€)	
. ,	
Travel & subsistence purchase costs (€)	
EQUIDATIVE DUDGUAGE COGEG (C)	
EQUIPMENT PURCHASE COSTS (€)	
OTHER GOODS/WORKS/SERVICES PURCHASE COSTS (€)	
INTERNALLY INVOICED GOODS/SERVICES COSTS (€)	
Indirect costs (€)	
INDIRECT COSTS (C)	
TOTAL ELIGIBLE COSTS (€)	
ALREADY AGREED FINANCIAL	CONTRIBUTIONS
TOTAL ESTIMATED FINANCIAL CONTRIBUTIONS	
INSTITUTION/COMPANY	
Financial contribution (\mathfrak{C})	
INSTITUTION/COMPANY	
FINANCIAL CONTRIBUTION (€)	