Rheumatology Patient Improvement Fund For Ireland

Application Form

This application will only be considered if at least one of the applicants is a member of the Irish Society for Rheumatology and proposes a study site located in the Republic of Ireland

DATE OF APPLICATION SUBMISSION:		
CONTACT INFORMATION		
	Primary Investigator	**Co-Applicant**
Name (First, Last):		
Title:		
Institution:		
Department/Address:		
Telephone:		
Email:		
Signature:		
Sponsor – Legal Sponsor **Name:** **Email:** **Signature:**		
This form MUST be completed by the Primary Investigator.		

Study Design and Information	
Location(s):	**Number of Sites:**
	Institution Name and Address:
Study Title (max. 50 words):	
Describe the overall study plan (max. 2000 words). ***If references are included, they will not count toward the word limit.***	
Identify the study endpoints (max. 300 words).	
Specify details of treatment/intervention which will be used in this study. ***Prescriptions, therapy, devices, equipment, solutions, products needed to conduct study*** **(max. 500 words):**	
What patient need will this study address? (max. 300 words)	
Does the study require a Clinical Trial Application (CTA), and/or any other similar regulatory application? ☐ Yes ☐ No	

1 Supported by UCB through an educational grant UCB has no editorial control on the contents

If other, please specify and explain:		
How will the results of this study be disseminated? **Ireland (max. 250 words):** **Elsewhere (max. 250 words):**		
STUDY TIME ESTIMATION/DATES		
Study dates	Start: End:	
Study Duration		
IRB or Ethics Approval Required ?	☐ Yes ☐ No (explain):	Date of approval:
Internal or patient reviews required ?	☐ Yes (identify): ☐ No	Date of approval:
STUDY PARTICIPANTS		
Study population, including pathology and disease state (max. 250 words):		
Inclusion Criteria:	**Exclusion Criteria:**	
Duration of patient exposure:		
Total number of subjects to be enrolled, including controls, if applicable:		
Detail the composition of groups needed for the study:		
Will there be any patient/study participant input? If yes, please explain (max. 300 words).		
BUDGET INFORMATION (EURO)		
Detailed explanation (max. 250 words):		
Investigator and applicant		
Nurse/ Research assistant:		
Other personnel (please specify):		
Equipment and supplies		
Travel and publications		
Other expenses – please specify		
Total		
PLEASE PROVIDE THE TOTAL BUDGET REQUESTED		

Adverse Event Reporting **For clinical research including interventional and non-interventional studies**
• Primary Investigator is responsible for reporting AEs to the Ethics committee, relevant regulatory authority and to the manufacturing company of the drug, biologic or device. • All SAEs/significant safety concerns must be sent to the relevant authorities as above within 24 hours [include non-serious AEs for non-interventional studies if they are collected per protocol].
How will adverse events be reported – please explain (max 250 words):

Submission Checklist

☐ Complete, signed and dated RPIF application form

☐ Any other supporting evidence as is applicable

Application Submission

Send your completed application form and any attachment(s)
via email to the ISR email address: info@isr.ie by 16 August 2019