

First-line Rituximab in Systemic lupus erythematosus Trial (FIRST)

Feasibility Form

Site details

NHS Trust	
List all participating hospitals within Trust	

Principal Investigator details

Name	
Position	
Email address	
Phone number	
Does the Principal Investigator have previous experience of conducting CTIMP randomised controlled trials as a recruiting site Principal Investigator? Yes ☐ No ☐	
Does the Principal Investigator have an in date GCP certificate*? Yes ☐ No ☐ <i>*Please note that all site team members working on the FIRST trial will need to provide a GCP certificate which includes the GCP E6(R3) update.</i>	
Does the Principal Investigator have a research CV which has been signed and dated within the past 3 years? Yes ☐ No ☐	

Research and Development (R&D) team details

Has the site R&D team been informed of your intention to be involved in the FIRST trial?

Yes ☐

No ☐

Name of key R&D contact	
Position	
Email address	
Phone number	

Contracts contact details (if different from R&D contact)

Name of key contract contact	
Position	
Email address	
Phone number	

Amendment/Modification notification contact

If your R&D team has a specific generic email address or named contact that must be informed of all amendments/modifications to ongoing trials, please complete the details here:

Name (if applicable)	
Email address	

Research team details

Name of lead research team contact	
Position	
Email address	
Phone number	

Does the research team have a generic email address(es) for use in trials?

Yes ☐ Please specify below

No ☐

Email Address	
Email Address	

Do you have a lead research nurse allocated to this trial? If so, please add their name and contact information here:

Name of lead research nurse contact	
Position	
Email address	
Phone number	

Pharmacy team details

Have the pharmacy team been informed of your intention to be involved in the FIRST trial?

Yes ☐

No ☐

Name of key pharmacy contact	
Position	
Email address	
Phone number	

Does the pharmacy team have a generic email address(es) for use in trials?

Yes ☐ Please specify below

No ☐

Email Address	
Email Address	

Other key team member details for site set up correspondence (if relevant for site (e.g. API))

Name of contact	
Position	
Email address	
Phone number	

Trial specific questions

How many patients aged 5 and above have been newly diagnosed with Systemic lupus erythematosus in the last year within your hospital/s? _____ patients
Are there any studies ongoing at your site that would be recruiting a similar group of patients that may impact recruitment to FIRST? Yes ☐ Please specify the trial's name: No ☐

How might potential participants be identified through the patient pathway for the trial (e.g. rheumatology, renal, dermatology as in/outpatients)?

Does the team have the facilities (e.g. computer or tablet) to complete electronic data entry into REDCap during a participant follow up?

Yes ☐

No ☐

Are treating consultants at site willing to support the trial (i.e. prescribe Rituximab as the initial treatment)?

Yes ☐

No ☐

Please specify if there are any factors that could significantly affect trial procedures (e.g. recruitment, conducting regular follow ups with participants, ensuring only the pharmacy team are unblinded to the treatment allocation)?

How did you hear about the FIRST trial?

Speaking to a colleague ☐

Through the Clinical Research Network ☐

Through social media ☐

Through the Research and Development Team ☐

Other ☐

Please record any other comments that would be useful for site set up:

Form completed by:

Date form was completed: