MuSIC
Mitochondrial DAMPs as mechanistic biomarkers in Crohn's disease

STUDY ID: ☐☐☐☐-☐☐☐ Subject Initials: ☐☐☐

MUSIC Baseline Visit

VISIT DATE

Visit Date: *(DD-MM-YYYY)* ☐☐-☐☐-☐☐☐☐

ELIGIBILITY REVIEW
INCLUSION CRITERIA

Yes	No		***All inclusion criteria must be answered YES for the patient to participate in the study***
☐	☐	1.	Patient is aged 16 years old or over
☐	☐	2.	Patient has a diagnosis of IBD (CD or UC)
☐	☐	3.	All patients must have active IBD at the time of screening: Active IBD symptoms by referring clinician's judgement in addition to one of the below criteria (within 6 weeks of screening): • FC level of >100ug/g • Blood CRP >5mg/l • Endoscopic, radiological or histological evidence of active IBD
☐	☐	4.	All IBD patients with disease involvement that is amenable for endoscopic assessment of mucosal healing. This includes: • CD patients with previous ileal or colonic surgical resection • CD patients with perianal disease where ileo-colonoscopy or sigmoidoscopy are not contraindicated • CD patients with ileal involvement only where endoscopic disease activity can be recorded
Yes	**No**		***For the patient to be eligible, ONE of the following criteria must be answered YES***
☐	☐	5.	All IBD patients will require a recent ileo-colonoscopy or flexible sigmoidoscopy within 6 weeks of recruitment that has: • Clear documentation of endoscopic disease activity and extent (SES-CD and Rutgeert's score for CD; Mayo Score or UCEIS for UC) • Photographs of endoscopic mucosal IBD disease activity • If there is not a recent ileo-colonoscopy or flexible sigmoidoscopy, the participant will be asked to undergo an ileo-colonoscopy or flexible sigmoidoscopy at baseline.
☐	☐	6.	If patients have undergone an ileo-colonoscopy or flexible sigmoidoscopy within 6 weeks but with an endoscopic report that is insufficient in endoscopic disease activity data as per (5), potential participant can still be considered providing there is: • Supporting objective evidence of IBD disease activity (FC, CRP) within 2 weeks of index ileo-colonoscopy or flexible sigmoidoscopy.

ELIGIBILITY REVIEW
EXCLUSION CRITERIA

Yes	No		***All exclusion criteria must be answered NO for the patient to participate in the study***
☐	☐	1.	IBD patients with severe/fulminant disease at screening: • Subjects with colitis fulfilling the Truelove and Witts' criteria (stool frequency >6/24 hours with **all** of the features of fever >38C, pulse rate >100 beats per minute, blood haemoglobin <105 g/l, albumin <30g/l) • Subjects displaying evidence of toxic megacolon (transverse colon diameter >6m on plain abdominal X-ray with accompanying full radiological report). Note – abdominal X-ray will be carried out if clinically indicated by referring clinician

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			• Evidence of significant bowel obstruction, abdominal sepsis, abscess formation and fistula formation (bowel or perianal) as documented by referring clinician that is supported by clinical, radiological and blood laboratory investigations
☐	☐	2.	Referring clinician's judgement where surgical intervention (colectomy or resection) is deemed likely within 3 months of screening
☐	☐	3.	Evidence of intestinal dyplasia or malignancy (histologic, endoscopic or radiologic)
☐	☐	4.	UC patients with limited involvement of the rectum (<15cm – proctitis)
☐	☐	5.	UC patients who have had a colectomy (total and subtotal)
☐	☐	6.	UC patients with an ileo-anal pouch
☐	☐	7.	IBD (UC, CD or IBD-U) with an intestinal stoma
☐	☐	8.	Patients where ileo-colonoscopy or flexible sigmoidoscopy are contra-indicated (e.g. significant co-morbidities e.g. cardiovascular, respiratory, cancer, renal failure; and pregnancy)
☐	☐	9.	Participants where there are limitations to language communication where there is a potential issue where information sheet cannot be reliably understood and/or the subject cannot provide full informed consent

INFORMED CONSENT

Has PIS been provided to patient at least 6 hours (inpatient) or 24 hours (outpatient) prior to consent? ☐ Yes ☐ No

Date of consent *(DD-MM-YYY)*: ☐☐-☐☐-☐☐☐☐

Initials of person taking consent: ☐☐☐ **Other patient study ID:** _____

Consent form version: _____ **PIS Version:** _____

PATIENT DETAILS

Patient Email: _____ ☐ N/A

Patient Tel no.: _____

CHI No. ☐☐☐☐☐☐☐☐☐☐ **Gender:** ☐ Male ☐ Female

Date of Birth: *(DD-MM-YYYY)* ☐☐-☐☐-☐☐☐☐

DIAGNOSIS

Diagnosis: ☐ Crohn's disease ☐ Ulcerative colitis ☐ IBDU **Notes:** _____

Date of diagnosis: *(DD-MM-YYY)* ☐☐-☐☐-☐☐☐☐

*Date of first pathology if possible; otherwise to the best of your knowledge. If only month/year available record as 01-mm-yyyy, if only year is available record as 01-01-yyyy

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CLINICAL ASSESSMENT

Height: ☐☐☐cm **Weight:** ☐☐☐.☐kg

Current smoking status: ☐ Yes ☐ No ☐ Ex -smoker **If ex-smoker, when did they stop?** _____

Current active IBD symptoms: ☐ Yes ☐ No

Description of symptoms:	

Physician's Global Assessment: ☐ Remission ☐ Mildly active ☐ Moderately active ☐ Severely active

Comments:

CLINICAL ASSESSMENT – CROHN'S DISEASE

HBI – circle relevant options below

Total = sums of items on table + number of liquid stool/day
<5 remission, 5-7 mild, 8-16 moderate, >16 severe

	1	2	3	4	5
Wellbeing	Very well	Slightly below par	Poor	Very Poor	Terrible
Abdo pain	None	Mild	Moderate	Severe	
Abdo mass	None	Mild	Moderate	Severe	
Arthralgia	No	Yes			
Uveitis	No	Yes			
Erythema nodosum	No	Yes			
Pyoderma gangrenosum	No	Yes			
Anal fissure	No	Yes			
New fistula	No	Yes			
Abscess	No	Yes			

No. of liquid stools a day: _____ **Total HBI score =** _____

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CLINICAL ASSESSMENT – ULCERATIVE COLITIS
SCCAI – circle relevant options below

	0	1	2	3	4
Wellbeing	Very well	Slightly below par	Poor	Very Poor	Terrible
Bowel frequency (day)	1-3	4-6	7-9	>9	
Bowel frequency (night)	0	1-3	4-6		
Urgency of defecation	None	Hurry	Immediately	Incontinence	
Blood in stool	None	Trace	Occasionally frank	Usually frank	
Erythema nodosum	No	Yes			
Pyoderma gangrenosum	No	Yes			
Arthralgia	No	Yes			
Uveitis	No	Yes			
				Total SCCAI score = _____	

CLINICAL ASSESSMENT
PARTIAL MAYO SCORE – circle relevant options below

	0	1	2	3
Stool frequency	Normal	1-2x/day – above normal	3-4x/day above normal	>4x/day above normal
Rectal bleeding	None	Visible in <50% of stools	Visible in >50% of stools	Frank blood
Physician assessment	Normal	Mild	Moderate	Severe

Total Partial Mayo score = _____ (0-9) <2 remission, 2-4 mild, 5-7 moderate, >7 severe

LIFETIME EIMs

Any previous/Lifetime EIMs (including inactive) *the above scores only record active EIMs at point of visit

EIMs (tick all that apply):	**Yes**	**No**
Arthralgia/arthritis	☐	☐
Ankylosing Spondylitis	☐	☐
Erythema Nodosum	☐	☐
Pyoderma Gangrenosum	☐	☐
Uveitis	☐	☐
Episcleritis/scleritis	☐	☐
Other	☐	☐ Please specify: _____

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PAST MEDICAL/SURGICAL HISTORY

Primary Sclerosing Cholangitis?: ☐ Yes ☐ No **Date of diagnosis:** ☐☐-☐☐-☐☐☐☐

Appendix removed?: ☐ Yes ☐ No **If yes, age removed:** _____

Tonsils removed?: ☐ Yes ☐ No **If yes, age removed:** _____

Medical History	Start date (date of diagnosis)	End date

Previous IBD Surgical History	Date of Procedure	Comments

FAMILY HISTORY

No. of biological brothers: _____ **No. of biological sisters:** _____

No. of biological daughters: _____ **No. of biological sons:** _____

Does the patient have a family history of IBD?: ☐ Yes ☐ No ☐ Unclear

If yes, relationship: _____ **Age at diagnosis:** _____

Diagnosis: _____

If yes, relationship: _____ **Age at diagnosis:** _____

Diagnosis: _____

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MEDICATION DATA COLLECTION

PREVIOUS IBD MEDICATIONS

Please tick all IBD medications previously taken by the patient:

Medication	Start Date	Stop Date*	Reason for discontinuation if available
☐ **5-ASA**			☐ Primary non-response ☐ Secondary loss of response ☐ Definite immunogenicity ☐ Adverse effect ☐ Other _____(e.g. planned withdrawal)
☐ **Azathioprine**			☐ Primary non-response ☐ Secondary loss of response ☐ Definite immunogenicity ☐ Adverse effect ☐ Other _____
☐ **Mercaptopurine**			☐ Primary non-response ☐ Secondary loss of response ☐ Definite immunogenicity ☐ Adverse effect ☐ Other _____
☐ **Methotrexate**			☐ Primary non-response ☐ Secondary loss of response ☐ Definite immunogenicity ☐ Adverse effect ☐ Other _____
☐ **Infliximab**			☐ Primary non-response ☐ Secondary loss of response ☐ Definite immunogenicity ☐ Adverse effect ☐ Other _____
☐ **Adalimumab**			☐ Primary non-response ☐ Secondary loss of response ☐ Definite immunogenicity ☐ Adverse effect ☐ Other _____
☐ **Vedolizumab**			☐ Primary non-response ☐ Secondary loss of response ☐ Definite immunogenicity ☐ Adverse effect ☐ Other _____
☐ **Ustekinumab**			☐ Primary non-response ☐ Secondary loss of response ☐ Definite immunogenicity ☐ Adverse effect ☐ Other _____

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☐ **Golimumab**			☐ Primary non-response ☐ Secondary loss of response ☐ Definite immunogenicity ☐ Adverse effect ☐ Other _____
☐ **Tofacitinib**			☐ Primary non-response ☐ Secondary loss of response ☐ Definite immunogenicity ☐ Adverse effect ☐ Other _____
Other _____			☐ Primary non-response ☐ Secondary loss of response ☐ Definite immunogenicity ☐ Adverse effect ☐ Other _____
Approximate dates acceptable, if continues on therapy write ongoing in date of final withdrawal *date of final withdrawal if patient has been on drug intermittently			

CURRENT IBD MEDICATIONS

Name	Dose	Frequency	Start/stop date	Brand name if avail

CURRENT NON-IBD MEDICATIONS

Name	Dose	Frequency	Start/stop date	Brand name if avail

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SAMPLE COLLECTION

Blood samples

Were blood samples collected?	☐ Yes	☐ No	*If yes, please record date and time collected below*
Serum 4.9ml (NHS)	☐ Yes	☐ No	**Destination:** _____
EDTA 2.7ml (NHS)	☐ Yes	☐ No	**Destination:** _____
EDTA 9ml #1	☐ Yes	☐ No	**Destination:** _____
EDTA 9ml #2	☐ Yes	☐ No	**Destination:** _____
PaxGene ccfDNA	☐ Yes	☐ No	**Destination:** _____
PaxGene RNA	☐ Yes	☐ No	**Destination:** _____

If no, reason not collected: _____

Date Collected: *(DD-MM-YYYY)* ☐☐-☐☐-☐☐☐☐ **Time Collected:** *(24 Hour Clock)* ☐☐:☐☐

Stool samples

Was a stool sample provided?	☐ Yes	☐ No	*If yes, please record date and time collected below*
Faecal calprotectin	☐ Yes	☐ No	**Destination:** _____
qFIT	☐ Yes	☐ No	**Destination:** _____
OmniGut	☐ Yes	☐ No	**Destination:** _____
Standard stool container	☐ Yes	☐ No	**Destination:** _____

If no, reason not collected: ☐ Unable to produce ☐ Other: _____

Date Collected: *(DD-MM-YYYY)* ☐☐-☐☐-☐☐☐☐ **Time Collected:** *(24 Hour Clock)* ☐☐:☐☐

Saliva Sample

Was a saliva sample collected? ☐ Yes ☐ No *If yes, please record date and time collected below*

If no, reason not collected: _____ **Destination:** _____

Date Collected: *(DD-MM-YYYY)* ☐☐-☐☐-☐☐☐☐ **Time Collected:** *(24 Hour Clock)* ☐☐:☐☐

REMINDERS

Has patient completed CUCQ32 questionnaire?	☐ Yes	☐ No
Has the patient been provided with sample kits to take home?	☐ Yes	☐ No
Has a follow up visit been arranged?	☐ Yes	☐ No
Have the patient's medical records been updated following this visit?	☐ Yes	☐ No
Has the GP letter been sent?	☐ Yes	☐ No

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POST-VISIT DATA COLLECTION

DATE COMPLETED (if different to visit date)

Visit Date: *(DD-MM-YYYY)* ☐☐-☐☐-☐☐☐☐ ☐ N/A

BASELINE ENDOSCOPY

Has the patient had an endoscopy within the 6 weeks prior to consent? ☐ Yes ☐ No

If no, note scheduled endoscopy date and record details below when available: ☐☐-☐☐-☐☐☐☐

Date of endoscopy: ☐☐-☐☐-☐☐☐☐

Endoscopy type: ☐ Ileo-colonoscopy ☐ Flexible sigmoidoscopy ☐ Other, specify: _____

Endoscopy result:	

	Tick box if available	Score
Mayo score:	☐	
UCEIS total score:	☐	
SCS-CD Score – Ileum:	☐	
SCS-CD Score – Caecum:	☐	
SCS-CD Score – Transverse colon:	☐	
SCS-CD Score – Left colon:	☐	
SCS-CD Score – Rectum:	☐	
SCS-CD Total Score:	☐	

HISTOLOGY (within the last 12 months)

Has the patient had any histology investigations within the last 12 months? ☐ Yes ☐ No

If yes, date of investigation: ☐☐-☐☐-☐☐☐☐

Histology report:	

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RADIOLOGY (within the last 12 months)

Has the patient had any relevant radiology investigations within the last 12 months? ☐ Yes ☐ No

If yes, date of investigation: ☐☐-☐☐-☐☐☐☐

Radiology type: ☐ CT-abdomen pelvis ☐ MRI small bowel ☐ MRI pelvis

Other, specify: _____

Radiology result:

MONTREAL CLASSIFICATION

Date of Montreal Classification: *(DD-MM-YYY)* ☐☐-☐☐-☐☐☐☐

Crohn's Disease		Ulcerative Colitis	
Location	☐ L1 ileal ☐ L2 colonic ☐ L3 ileocolonic ☐ +/- L4 upper GI disease	**Extent**	☐ E1 Proctitis only ☐ E2 Left-sided UC (distal UC) ☐ E3 Extensive UC (pancolitis)
Behaviour	☐ B1 non-stricturing, non-penetrating ☐ B2 stricturing ☐ B3 penetrating ☐ +/- P perianal disease	**Severity**	☐ S0 Remission ☐ S1 Mild UC ☐ S2 Moderate UC ☐ S3 Severe UC