MuSIC
Mitochondrial DAMPs as mechanistic biomarkers in Crohn's disease

STUDY ID: MID-☐☐-☐☐☐ 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 • 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

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☐	☐	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) 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 **Location:** ☐ Outpatient ☐ Inpatient

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

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

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

PATIENT DETAILS

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

CHI No. ☐☐☐☐☐☐☐☐☐☐

Patient Email: _____ ☐ N/A

Patient Tel no.: _____

DIAGNOSIS

Diagnosis: ☐ Crohn's disease ☐ Ulcerative colitis **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, how long since they last smoked? _____ ☐ Week(s) ☐ Month(s) ☐ Year(s)

Current active IBD symptoms: ☐ Yes ☐ No

Description of symptoms:	

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

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

	0	1	2	3	4
Wellbeing	Very well	Slightly below par	Poor	Very Poor	Terrible
Abdo pain	None	Mild	Moderate	Severe	
Abdo mass	Nil	Dubious	Definite	Definite and tenderness	
Arthralgia	No	Yes			
Uveitis	No	Yes			
Erythema nodosum	No	Yes			
Aphthous ulcers	No	Yes			
Pyoderma gangrenosum	No	Yes			
Anal fissure	No	Yes			
New fistula	No	Yes			
Abscess	No	Yes			
Liquid stools	No	Yes	**If 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)	0-3	4-6	7-9	>9	
Bowel frequency (night)	0	1-3	4-6		
Urgency of defecation	None	Hurry	Immediately (toilet nearby)	Incontinence	
Blood in stool	None	Trace	Occasionally frank (<50% of defecation)	Usually frank (>50% of defecation)	
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	1-2 more than normal	3-4 more than normal	≥5 more than 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

MONTREAL CLASSIFICATION

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

Crohn's Disease		Ulcerative Colitis	
Location	☐ L1 ileal ☐ L2 colonic ☐ L3 ileocolonic ☐ L4 isolated upper disease (concomitant upper gastrointestinal disease is present	**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 (concomitant perianal disease is present)	**Severity**	☐ No ☐ S0 Remission ☐ S1 Mild UC ☐ S2 Moderate UC ☐ S3 Severe UC

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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	☐	☐
None	☐	☐
Other	☐	☐ Please specify: _____

OTHER MEDICAL HISTORY

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

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

Primary Sclerosing Cholangitis?: ☐ Yes ☐ No

If yes, date of diagnosis: ☐☐-☐☐-☐☐☐☐

Body system codes

A – Cancer
B – Blood Pressure
C- Metabolic
D - Cardiovascular
E – Respiratory
F – Gastrointestinal
G – Genitourinary
H - Musculoskeletal
I – Dermatological
J – Neurological
K – Psychiatric
L - Endocrine
M – Haematological
N – Allergic/immunologic
O - Asthma
P – Other (specify)

Body system code	Medical history term	Start date (date of diagnosis)	End date

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PREVIOUS IBD SURGICAL HISTORY

Previous IBD Surgical History	Date of Procedure	Comments
☐ Colectomy (NOS) ☐ IBD resection (NOS) ☐ Ileocaecal resection ☐ Small bowel resection ☐ Perianal-fistula related ☐ Other IBD (specify) _____		
☐ Colectomy (NOS) ☐ IBD resection (NOS) ☐ Ileocaecal resection ☐ Small bowel resection ☐ Perianal-fistula related ☐ Other IBD (specify) _____		
☐ Colectomy (NOS) ☐ IBD resection (NOS) ☐ Ileocaecal resection ☐ Small bowel resection ☐ Perianal-fistula related ☐ Other IBD (specify) _____		

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 1:	_____	**Age at diagnosis:** _____	
Diagnosis:	☐ CD ☐ UC ☐ IBD ☐ Possible CD ☐ Possible UC ☐ Possible IBD ☐ Other _____		
If yes, relationship 2:	_____	**Age at diagnosis:** _____	
Diagnosis:	☐ CD ☐ UC ☐ IBD ☐ Possible CD ☐ Possible UC ☐ Possible IBD ☐ Other _____		
If yes, relationship 3:	_____	**Age at diagnosis:** _____	
Diagnosis:	☐ CD ☐ UC ☐ IBD ☐ Possible CD ☐ Possible UC ☐ Possible IBD ☐ Other _____		
If yes, relationship 4:	_____	**Age at diagnosis:** _____	
Diagnosis:	☐ CD ☐ UC ☐ IBD ☐ Possible CD ☐ Possible UC ☐ Possible IBD ☐ Other _____		
If yes, relationship 5:	_____	**Age at diagnosis:** _____	
Diagnosis:	☐ CD ☐ UC ☐ IBD ☐ Possible CD ☐ Possible UC ☐ Possible IBD ☐ Other _____		

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ENDOSCOPY (within the last 12 months)

This section should be used to record any endoscopies a patient has had performed clinically in the last 12 months, before their involvement in MUSIC. Baseline endoscopy data for MUSIC should be recorded directly on REDCap

Has the patient had an endoscopy (not including baseline within the last 12 months? ☐ Yes ☐ No

If yes, date of endoscopy: ☐☐-☐☐-☐☐☐☐

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

Endoscopy result:

	Tick box if available	Score
Extent total sore:	☐	
UCEIS total score:	☐	
Mayo 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:	☐	

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:

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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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 9/10ml #1	☐ Yes	☐ No	**Destination:** _____
EDTA 9/10ml #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:** _____

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)* ☐☐:☐☐

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Reason for stopping
R1: Primary non-response – did not respond to drug at all (specify below) R2: Secondary non-response – initially responded then lost response (specify below) R3: Treatment completed R4: Intolerance (specify below) R5: Adverse effect (specify below) R6: Confirmed immunogenicity R7: Other Specify: _____

Frequency of Use				
F1: Once per day	F2: Twice per day	F3: Three times per day	F4: Four times per day	F5: Once per week
F6: Fortnightly	F7: Monthly	F8: 6 weekly	F9: 8 weekly	F10: 3 monthly
F11: Pro re nata	F12: Alternate days	F13: Six times per day	F14: Five times per day	F15: Other_____

Drug brand			
B1:Adalimumab- Humira	B2: Adalimumab- Amgevita	B3: Adalimumab- Imraldi	B4:Golimumab- Simponi
B5: Infliximab- Remicade	B6: Infliximab- Inflectra	B7: Infliximab- Remsima	B8: Infliximab- Flixabi
B9: Mesalazine- Octasa	B10: Mesalazine- Asacol	B11:Mesalazine- Mezavant	B12: Mesalazine- Pentasa
B13: Mesalazine- Salofalk	B14: Other _____		

PREVIOUS IBD MEDICATIONS (LIFETIME EXPOSURE)

Please detail all IBD medications previously taken by the patient:

Medication 1		Dose	Frequency	Start date:	Stop date:	Reason for stopping:
Drug name	Brand					
A – 5-ASA B – Adalimumab C- Azathioprine D –Mercaptopurine E – Methotrexate F – Infliximab G - Ustekinumab H – Vedolizumab I – Golimumab J – Tofacitinib				□□-□□-□□□□	□□-□□-□□□□	

Medication 2		Dose	Frequency	Start date:	Stop date:	Reason for stopping:
Drug name	Brand					
A – 5-ASA B – Adalimumab C- Azathioprine D –Mercaptopurine E – Methotrexate F – Infliximab G - Ustekinumab H – Vedolizumab I – Golimumab J – Tofacitinib				□□-□□-□□□□	□□-□□-□□□□	

Medication 3		Dose	Frequency	Start date:	Stop date:	Reason for stopping:
Drug name	Brand					
A – 5-ASA				□□-□□-□□□□	□□-□□-□□□□	

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B – Adalimumab C- Azathioprine D –Mercaptopurine E – Methotrexate F – Infliximab G - Ustekinumab H – Vedolizumab I – Golimumab J – Tofacitinib						
Medication 4		**Dose**	**Frequency**	**Start date:**	**Stop date:**	**Reason for stopping:**
Drug name	**Brand**					
A – 5-ASA B – Adalimumab C- Azathioprine D –Mercaptopurine E – Methotrexate F – Infliximab G - Ustekinumab H – Vedolizumab I – Golimumab J – Tofacitinib				□□-□□-□□□□	□□-□□-□□□□	
Medication 5		**Dose**	**Frequency**	**Start date:**	**Stop date:**	**Reason for stopping:**
Drug name	**Brand**					
				□□-□□-□□□□	□□-□□-□□□□	
Medication 6		**Dose**	**Frequency**	**Start date:**	**Stop date:**	**Reason for stopping:**
Drug name	**Brand**					
				□□-□□-□□□□	□□-□□-□□□□	
Medication 7		**Dose**	**Frequency**	**Start date:**	**Stop date:**	**Reason for stopping:**
Drug name	**Brand**					
				□□-□□-□□□□	□□-□□-□□□□	
Medication 8		**Dose**	**Frequency**	**Start date:**	**Stop date:**	**Reason for stopping:**
Drug name	**Brand**					
				□□-□□-□□□□	□□-□□-□□□□	
Medication 9		**Dose**	**Frequency**	**Start date:**	**Stop date:**	**Reason for stopping:**
Drug name	**Brand**					
				□□-□□-□□□□	□□-□□-□□□□	
Medication 10		**Dose**	**Frequency**	**Start date:**	**Stop date:**	**Reason for stopping:**
Drug name	**Brand**					
				□□-□□-□□□□	□□-□□-□□□□	

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IBD Medication Code			
A – 5-ASA **B** – Adalimumab **C**- Azathioprine **D** -Mercaptopurine **E** – Methotrexate	**F** – Infliximab **G** - Ustekinumab **H** – Vedolizumab **I** – Golimumab **J** – Tofacitinib	**K** – Steroid (enemas) **L** – Steroid (suppository) **M** – Mesalazine (enemas) **N** – Mesalazine (oral)	**O** - Mesalazine (suppository) **P** – Methylpresnidolone **Q** – Prednisolone (oral) **U** – Budesonide (oral)

Reason for stopping

R1: Primary non-response – did not respond to drug at all (specify below)
R2: Secondary non-response – initially responded then lost response (specify below)
R3: Treatment completed
R4: Intolerance (specify below)
R5: Adverse effect (specify below)
R6: Confirmed immunogenicity
R7: Other Specify: _____

Frequency of Use				
F1: Once per day	F2: Twice per day	F3: Three times per day	F4: Four times per day	F5: Once per week
F6: Fortnightly	F7: Monthly	F8: 6 weekly	F9: 8 weekly	F10: 3 monthly
F11: Pro re nata	F12: Alternate days	F13: Six times per day	F14: Five times per day	F15: Other_____

Drug brand			
B1:Adalimumab- Humira	B2: Adalimumab- Amgevita	B3: Adalimumab- Imraldi	B4:Golimumab- Simponi
B5: Infliximab- Remicade	B6: Infliximab- Inflectra	B7: Infliximab- Remsima	B8: Infliximab- Flixabi
B9: Mesalazine- Octasa	B10: Mesalazine- Asacol	B11:Mesalazine- Mezavant	B12: Mesalazine- Pentasa
B13: Mesalazine- Salofalk	B14: Other _____		

CURRENT IBD MEDICATIONS

Please detail all IBD medications currently taken by the patient:

Medication 1		Dose	Frequency	Start date:	Stop date:	Reason for stopping:
Drug name	**Brand**					
				☐☐-☐☐-☐☐☐☐	☐☐-☐☐-☐☐☐☐	
				Still taken? ☐ Yes ☐ No (In NO, Complete Stop date)		
Medication 2		**Dose**	**Frequency**	**Start date:**	**Stop date:**	**Reason for stopping:**
Drug name	**Brand**					
				☐☐-☐☐-☐☐☐☐	☐☐-☐☐-☐☐☐☐	
				Still taken? ☐ Yes ☐ No (In NO, Complete Stop date)		
Medication 3		**Dose**	**Frequency**	**Start date:**	**Stop date:**	**Reason for stopping:**
Drug name	**Brand**					
				☐☐-☐☐-☐☐☐☐	☐☐-☐☐-☐☐☐☐	
				Still taken? ☐ Yes ☐ No (In NO, Complete Stop date)		

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Medication4		Dose	Frequency	Start date:	Stop date:	Reason for stopping:
Drug name	Brand					
				□□-□□-□□□□	□□-□□-□□□□	
				Still taken? ☐ Yes ☐ No (In NO, Complete Stop date)		
Medication 5		**Dose**	**Frequency**	**Start date:**	**Stop date:**	**Reason for stopping:**
Drug name	**Brand**					
				□□-□□-□□□□	□□-□□-□□□□	
				Still taken? ☐ Yes ☐ No (In NO, Complete Stop date)		
Medication 6		**Dose**	**Frequency**	**Start date:**	**Stop date:**	**Reason for stopping:**
Drug name	**Brand**					
				□□-□□-□□□□	□□-□□-□□□□	
				Still taken? ☐ Yes ☐ No (In NO, Complete Stop date)		

Non-IBD Medication Code				
NonIBD1: Opiates	**NonIBD2:** Antibiotics	**NonIBD3:** PPI	**NonIBD4:** NSAIDS	**NonIBD5:** Other

CURRENT NON-IBD MEDICATIONS

Please detail all non-IBD medications currently taken by the patient:

Medication 1	Dose	Frequency	Start date:	Stop date:
			□□-□□-□□□□	□□-□□-□□□□
Medication 2	**Dose**	**Frequency**	**Start date:**	**Stop date:**
			□□-□□-□□□□	□□-□□-□□□□
Medication 3	**Dose**	**Frequency**	**Start date:**	**Stop date:**
			□□-□□-□□□□	□□-□□-□□□□
Medication 4	**Dose**	**Frequency**	**Start date:**	**Stop date:**
			□□-□□-□□□□	□□-□□-□□□□
Medication 5	**Dose**	**Frequency**	**Start date:**	**Stop date:**
			□□-□□-□□□□	□□-□□-□□□□

REMINDERS

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