

Management of Acute Severe Ulcerative Colitis (MASC)

ESCP 2019 SNAPSHOT AUDIT – Frequently Asked Questions

Is it too late to get involved in MASC? - no, it's not too late!

The MASC start-up window has been extended until 1st July 2019. Once you have your local approvals in place you can start screening for patients on or before 1st July 2019 to join the audit.

How can I take part in this study?

All hospitals medically or surgically treating patients with ASUC are able to take part in MASC. Teams can have up to 8 people and must include a Consultant-level surgeon <u>and</u> a Consultant-level gastroenterologist. One of the Consultant-level investigators will be the official local 'lead' of the study. In each team, at least one team member will need to be a member of the <u>ESCP</u>. Teams will be required to let us know that they have local approval to participate in the audit.

You can sign up your team to take part in MASC <u>here</u>. Or copy this link into your browser <u>https://is.gd/mascteams.</u>

Your centre will also need to sign the MASC data sharing agreement. You can contact the MASC audit team to request a copy – escp@contacts.bham.ac.uk.

What approvals do we need?

Please follow the correct local process in your centre to gain approval to participate in the study. This will vary from country to country, see below for additional information on Ethics and Data Sharing Agreements.

Applying for Ethics

Different centres have different rules about ethics. In the UK MASC is regarded as an audit so no ethics are required. If you need to see the ethics approval from another site taking part in MASC please email us to let us know (escp@contacts.bham.ac.uk).

Is a Data Sharing Agreement needed to take part in MASC?

Yes, we request that each centre signs the generic MASC Data Sharing Agreement (DSA). Contact us to receive a personalised agreement for local signature. Please note we cannot use a DSA from a collaborating institution, as we are required to use the University of Birmingham DSA (who host the REDCap system used by the MASC project), and we cannot accept any amendments to the DSA.

MASC in the UK

Participating centres in the UK can register this study as an audit with their trust.

PTO



My team registered online but I have not received my REDCap login

Once you have registered your team we will aim to get your REDCap passwords to you about a week later, or sooner if we can, as long as there are no queries.

Two points to remember -

- **Approval**: we can only issue passwords to teams that have confirmed they have local approvals in place. If you've signed up your team before that remember to drop us an email to let us know when you have approval, escp@contacts.bham.ac.uk.
- **Email addresses**: you will need to supply us with an 'institutional' email address to receive a REDCap login. So a hospital or university email address is required, we cannot use private email accounts, e.g. gmail, hotmail etc. The email address should also be one allocated to an individual and not a shared mailbox.

Do we have to have uploaded at least one patient to REDCap by 1st July 2019?

No. The date you start the MASC audit should be on or before 1st July 2019. Start to screen for patients from your start date. We understand that you might not have an eligible patient on that day.

How long should we continue to screen for patients after starting the audit?

You should screen patients for a *minimum* of six consecutive months.

Can we audit for longer than six months?

Yes! If your team has the capacity to continue the audit for longer than six months please do, just remember that the last day to enter new patients is 1st January 2020.

How long should patients be followed up for?

Each patient should be followed up for 90 days.

What is the last day to include new patients?

The 1st of January 2020 is the last day for including new patients into MASC.

Patient selection – we have a patient that responded well to medical management, should they still be included in MASC?

Yes, definitely. If a patient is admitted with ASUC (or the UC becomes acute during hospitalization) then they should be included in the MASC audit, including those patients that respond well to medical treatment. As long as they are 16 years or older, and don't have infectious or ischemic colitis if there is no previous diagnosis of UC. MASC is not just about those that don't respond to medical management, as we are aiming to capture the pathway for all ASUC patients. See the Protocol for a full list of inclusion and exclusion criteria.

My REDCap login does not work / I have forgotten my login details

Email escp@contacts.bham.ac.uk and we will reset your password for you.

Who should I contact with any questions about MASC or REDCap?

Please email the MASC/REDCap team at <u>escp@contacts.bham.ac.uk</u>, we will help if we can or redirect your question to one of the MASC Committee members.