

Issue 1
Dec 2025

ACESO Trial

Upadacitinib Co-therapy with Corticosteroids in Early Acute Severe Ulcerative Colitis
(A Phase III randomised placebo controlled double blinded trial)



This monthly newsletter will provide you with the current study status, updates, tips and other useful information.

WELCOME & WELL DONE

A warm welcome to all our newly activated sites, and a big well done to everyone for the fantastic start to recruitment.

Thank you to Wolverhampton and Leeds for beginning with such an impressive recruitment pace — an excellent start!

Congratulations to Chelsea, St Mark's, Bristol, and Maidstone for recruiting your very first participants. Thank you all for your continued dedication — we look forward to seeing the momentum grow!



RECRUITMENT UPDATE

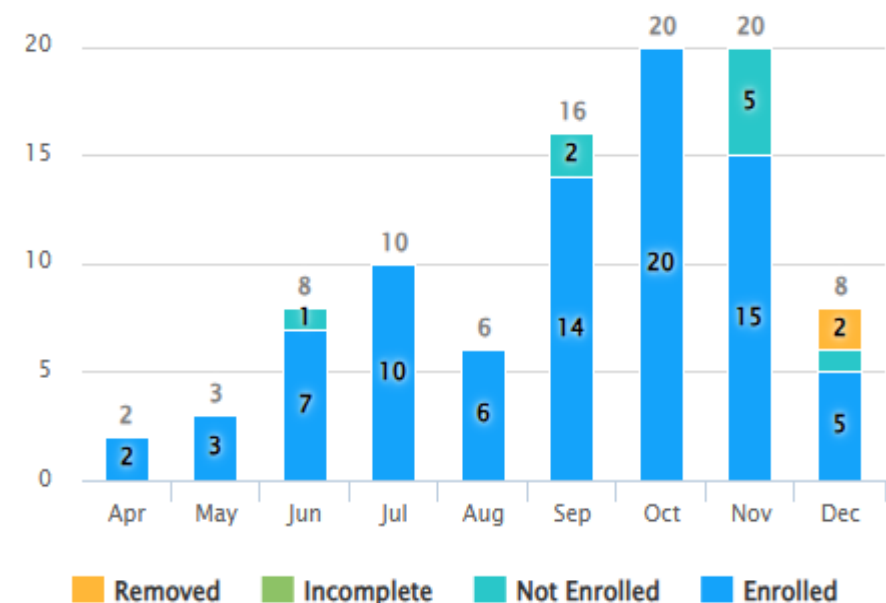
We are delighted to share that, as of 8 December, a total of **28 sites** are open and **83 participants** have been recruited into the study.

To stay on track with our milestones:

- ♦ We need to recruit two participants per month from every site to reach 150 by May 2026 (interim internal pilot analysis).
- ♦ Following this, we aim to reach 300 participants by May 2027.

If there is anything we can do to support recruitment at your site, please let us know.

Your continued efforts are greatly appreciated.



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INFORM REMINDERS

Please note the timelines below, as these are currently **not being met at all sites**. Your support in improving compliance is greatly appreciated.

• Data Entry into the eCRF

Data from baseline to the end of the in-patient stay should be entered **daily**, preferably **within 24 hours**.

• Responding to Data Queries

All data queries should be answered **within 7 days** of being issued.

• Review the eCRF Guidelines

Please remember to review the **eCRF User Guidelines** before starting data entry,



TIPS AND BEST PRACTICE

Important Reminder: Emergency Unblinding

We had an emergency unblinding error occur recently, so we would like to remind all teams of the correct process.

Patients who are not responding to treatment by Day 3 should not be unblinded on Sealed Envelope to select rescue therapies.

Please follow the correct workflow:

- **Complete the Day 3 CRF**
- **Complete the Clinical Response CRF**
- **RCC will then guide you through the appropriate sub-studies**

Please contact HHTU and chief investigator on phone **07787227885** or **07453240514** in all circumstances considering unblinding for rescue therapy for non-response.

Moving to a sub study video link

YouTube: https://youtu.be/iFS5gXi_2fw

HHTU Box: <https://hhtu.box.com/s/5i1n9jv3pqj7rms6xwi9zs4g4e26c2v9>

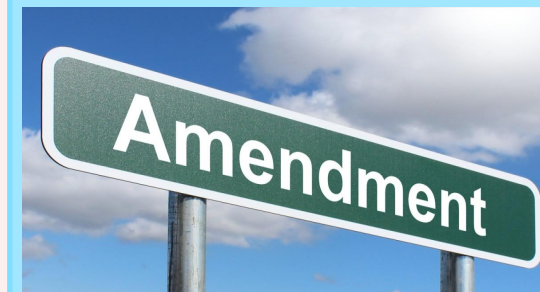
Thank you for helping us maintain protocol compliance.



KEY STUDY DOCUMENTS

SA002 NEW this month!

- ✓ Protocol V1.3 14.AUG.2025
- ✓ PIS V1.3 30.OCT.2025
- ✓ Decisional Regret Scale questionnaire V1.1 10.OCT.2025
- ✓ CRFs
- ✓ Creep sheets
- ✓ Lab Manual V1.1
- ✓ Pharmacy Manual V1.1
- ✓ Decisional Regret Scale questionnaire V1.1 10.OCT.2025



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SITE LEADERBOARD



Site	PI Name	Site Opening	Total recruitment	Recruitment in last 2 months
ACE-01 Hull	Prof. Shaji Sebastian	April	22	6
ACE-02 Cambridge	Dr Tim Raine	May	10	4
ACE-03 St Georges	Dr Sailish Honap	May	8	1
ACE-18 Wolverhampton	Dr Philip Harvey	September	5	5
ACE-14 Leeds	Dr Christian Selinger	October	4	4
ACE-09 Kings	Dr Alexandra Kent	August	4	2
ACE-05 Barts	Dr Gareth Parkes	July	4	3
ACE-08 Kettering	Dr Ajay Verma	May	3	0
ACE-04 Glasgow: GRI	Prof. Daniel Gaya	June	3	2
ACE-11 Oxford	Dr Alissa Walsh	August	3	2
ACE-15 Manchester	Prof. Jimmy Limdi	August	2	2
ACE-20 Chelsea	Dr Alice Moore	October	2	2
ACE-10 Devon	Dr Jonathan Digby-Bell	May	2	1
ACE-23 Imperial	Dr James Alexander	November	2	2
ACE-06 Lothian	Dr Shahida Din	July	2	1
ACE-16 Newcastle	Dr Andrew King	September	2	2
ACE-22 Somerset	Dr Emma Wesley	September	2	2
ACE-13 Glasgow QEUH	Prof. Daniel Gaya	July	1	1
ACE-21 St Marks	Dr R Misra	October	1	1
ACE-27 Bristol	Dr Susanna Meade	October	1	1
ACE-28 Maidstone	Dr Paul Blaker	October	1	1
ACE-12 Shrewsbury	Dr Jeffery Butterworth	November	0	0
ACE-07 Guys	Ray Shuvra	October	0	0
ACE-24 Southampton	Prof. Fraser Cummings	November	0	0
ACE-25 Cardiff	Dr Dharmaraj Durai	December	0	0
ACE-26 Belfast	Dr Patrick Allen	November	0	0
ACE-29 Homerton	Dr Nishani Jayasooriya	November	0	0
ACE-30 Antrim	Dr Kok Diong	December	0	0