

Issue 2
JAN 2026

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.

THANK YOU & WELL DONE

Congratulations to all teams on the strong progress in recruitment, and thank you for your continued efforts over the winter break and the excellent recruitment achieved in January.



Special thanks to **Bristol, Wolverhampton & Imperial** for maintaining an impressive recruitment rate! Congratulations to **Guys, Belfast, Homerton, Cardiff and Shrewsbury** for recruiting your very first participants, marking an important milestone for each site. Thank you all for your continued

RECRUITMENT UPDATE

We are delighted to share that, as of 4th Feb, a total of **28 sites** are open and **127 participants** have been recruited into the study.

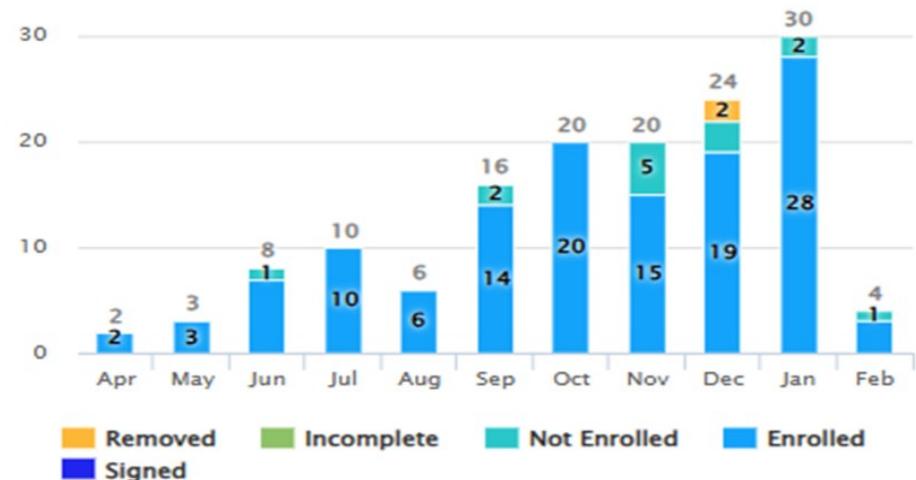
We look forward to seeing you at the site engagement meeting on Thursday, 12th February.

To stay on track with our milestones:

- ◆ We need 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

Thank you for consistently working with us to help reduce queries. The timelines below are not being consistently met across all sites, and we still need to work together to improve compliance.

• 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.

• Monitoring visits & monthly calls

Please ensure monitoring visits are arranged promptly in line with Sponsor requirements. This will help to reduce the number of queries.



KEY STUDY DOCUMENTS

SA002 was implemented on 19 January. Kindly ensure that the most recent version of the documents shared with you are used. Please check the updated eligibility criteria carefully.

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



TIPS AND BEST PRACTICE

Emergency Unblinding

No emergency unblinding errors have occurred recently; however, we would like to remind all teams of the correct procedure and thank you for your ongoing compliance.

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>

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ACESO Trial SITE LEADERBOARD



Site	PI Name	Site Opening	Total recruitment	Recruitment in last 2 months
ACE-01 Hull	Prof. Shaji Sebastian	April	26	6
ACE-02 Cambridge	Dr Tim Raine	May	11	2
ACE-18 Wolverhampton	Dr Philip Harvey	September	10	5
ACE-03 St Georges	Dr Sailish Honap	May	9	1
ACE-05 Barts	Dr Gareth Parkes	July	6	3
ACE-14 Leeds	Dr Christian Selinger	October	6	2
ACE-23 Imperial	Dr James Alexander	November	5	3
ACE-04 Glasgow: GRI	Prof. Daniel Gaya	June	5	2
ACE-11 Oxford	Dr Alissa Walsh	August	5	3
ACE-09 Kings	Dr Alexandra Kent	August	5	1
ACE-06 Lothian	Dr Shahida Din	July	4	2
ACE-15 Manchester	Prof. Jimmy Limdi	August	4	2
ACE-27 Bristol	Dr Susanna Meade	October	4	4
ACE-28 Maidstone	Dr Paul Blaker	October	3	2
ACE-22 Somerset	Dr Emma Wesley	September	3	1
ACE-16 Newcastle	Dr Andrew King	September	3	1
ACE-20 Chelsea	Dr Alice Moore	October	3	1
ACE-08 Kettering	Dr Ajay Verma	May	3	0
ACE-07 Guys	Dr Shuvra Ray	October	2	2
ACE-13 Glasgow QEUH	Dr John Paul Seenan	July	2	1
ACE-21 St Marks	Dr R Misra	October	2	1
ACE-10 Devon	Dr Jonathan Digby-Bell	May	2	0
ACE-26 Belfast (Ulster)	Dr Patrick Allen	November	1	1
ACE-29 Homerton	Dr Nishani Jayasooriya	November	1	1
ACE-25 Cardiff	Dr Dharmaraj Durai	December	1	1
ACE-12 Shrewsbury	Dr Jeffery Butterworth	November	1	1
ACE-24 Southampton	Prof. Fraser Cummings	November	0	0
ACE-30 Antrim	Dr Kok Diong	December	0	0