

SafeBoosC-IIIv Newsletter

Dear Investigators,

This is the SafeBoosC-IIIv newsletter, which we will send out regularly and publish on the website (safeboosc.eu) to keep you continuously updated. We will send the newsletter to all Principal Investigators and National Coordinators. Please let us know if you would like to add an email address to the list.

We are pleased to inform you we have received interest from countries across six continents. We are currently in contact with more than 50 centres.

Central status

We submitted the protocol to the Danish Research Ethics Committee and expect to receive approval in November 2024. We are currently working on the final central steps, and we expect to be ready for randomisation to begin in January 2025. We are continuously updating the website (safeboosc.eu) with standard operating procedures, Steering Committee meeting minutes, and other relevant information.

Principal Investigator status

Before each centre can start randomisation, the following steps need to be taken:

- Obtain local ethics approval
- Sign the collaboration agreement
- Report the blinding procedure to caroline.kamp@ctu.dk
- Organise and complete initiation monitoring visit based on ICH-GCP principles (information will be sent to centres in November)
- Complete delegation log (information will be sent to centres in November)

We have contacted all centres with information about each step. Please see the attached list of progress for all centres.

Please do not hesitate to reach out to us if you have any questions or updates (e.g. ethics approval etc.).

Thank you and best wishes,
Caroline, Johanne and Janus