

SafeBoosC-IIIv Newsletter

Dear Investigators,

This is the first SafeBoosC-IIIv newsletter. We plan to send out a newsletter regularly and publish it 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 that 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 October 2024. We are currently working on web-based training similar to the training modules provided in SafeBoosC-III, and we expect the website to be ready in November 2024. We aim to complete all central steps to allow centres to begin randomisation in December 2024. We are continuously updating the website (safeboosc.eu) with standard operating procedures 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 October/November)
- Complete delegation log (information will be sent to centres in October/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.

Thank you and best wishes,
Caroline, Johanne and Janus