

TAP Trial Termination

CSL Behring has made the difficult decision to end the Trauma and Prothrombin Complex Concentrate (TAP) Trial of Kcentra® (BE1116_3006), for trauma patients with major bleeding. The trial began in early 2023 and was originally scheduled to last until 2026.

As the TAP trial progressed, it became clear that the trial would take several years longer than originally planned, and results would not be available in a reasonable amount of time. It is possible that the study results may not have been relevant in several years because of changes in trauma care. Importantly, the decision to stop the trial was not due to any safety or quality concerns. Several reasons would have caused the trial to take longer than expected:

- While over 90 hospitals committed to participate, this was fewer than were needed to complete the study in a reasonable period of time.
- Hospitals were not enrolling as many participants as anticipated.
- Some participants who were enrolled in the study never received the study drug either because of logistical reasons, or because their condition changed. Because these patients would not have been affected by the study drug, these patients would not help in determining whether treating with the study drug helps trauma patients.

By the time the trial ended it had already enrolled just under 1,400 patients, making it one of the largest studies of trauma patients ever completed. The TAP study team will analyze the information collected, including a safety analysis and make the results public when available. The study results will be available on <http://www.ClinicalTrials.gov>, and will be published in a peer-reviewed medical journal. The summary of the study results will be available at www.trialssummaries.com when the final study results are completed.

If you obtained an Op-out bracelet indicating you did not wish to be enrolled in this clinical trial, you no longer need to wear the bracelet.

We would like to extend our sincere gratitude to each community that agreed to conduct this important trial, which will hopefully contribute to advancing trauma care for years to come. Special thanks are owed to the participants and families who took part in the TAP trial.