

### Edoxaban pilot study

In Spring 2018 a pilot study was performed on the laboratory testing of the direct Xa inhibitor Edoxaban. The meaning of this pilot study was to make an inventory of the current practice of testing for Edoxaban.

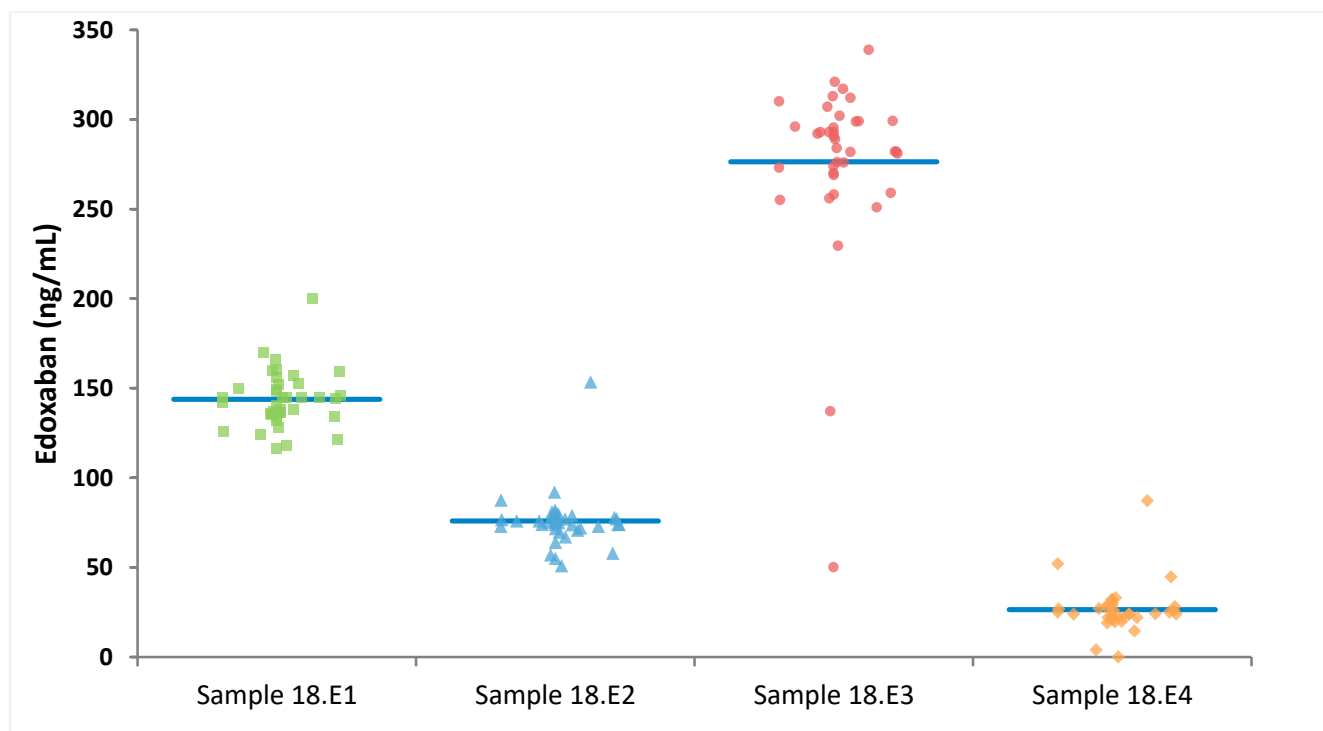
In total 57 different laboratories had indicated their interest in this pilot study. Thirty-eight laboratories returned results.

The samples used in this pilot study were normal citrated pooled plasma spiked with different levels of Edoxaban in the range between approximately 25 and 300 ng/mL.

The table below shows the overall statistical evaluation of the results.

Sample	Description	Mean (mg/mL)	SD (ng/mL)	Range (ng/mL)	Inter-laboratory CV (%)
Sample 18.E1	Approx. 150 ng/mL Edoxaban	143.0	14.0	116.0 – 200.0	9.8
Sample 18.E2	Approx. 75 ng/mL Edoxaban	74.9	5.7	51.0 – 153.6	7.6
Sample 18.E3	Approx. 285 ng/mL Edoxaban	284.6	24.3	50.0 – 288.9	8.5
Sample 18.E4	Approx. 25 ng ng/mL Edoxaban	25.0	5.4	0.0 – 87.3	21.6

The figure below shows the distribution of the results per sample irrespective of which method was used by the participants.



In general the between-laboratory variation observed in this pilot study is comparable with those observed for Rivaroxaban and Apixaban in the regular ECAT surveys. Only the low Edoxaban sample showed a relatively high between-laboratory variation. For Rivaroxaban and Apixaban such a low sample was never distributed in the regular surveys.

In 2019 ECAT will include also Edoxaban in their regular survey programme. This means that we offer our participants an external quality assessment programme for the direct anti-Xa inhibitors Rivaroxaban, Apixaban and Edoxaban as well as for the direct anti-IIa inhibitors Argatroban and Dabigatran.