## ABSTRACT FORM ECAT SYMPOSIUM 8 – 9 NOVEMBER 2018

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### Title:

**Future perspective in quality assurance**

### Abstract:

The appearance of the extended half-life Factor VIII and IX products for the treatment of haemophilia patients is a challenge for both laboratory diagnostics and quality assurance programmes.

Traditional external quality assessment in haemostasis is, due to the lack of a reference system, based on the concept of consensus values. This concept is, with the current state-of-the-art, fit-for-purpose to assess the quality of testing for native patient samples.

However, when patients are treated with a drug, the most important question for a laboratory is whether they are able to measure accurately the drug level in the patient sample. Here specific external quality assessment surveys are required.

It has been demonstrated that the measured level of extended half-life Factor VIII and IX products may strongly depend on the type of assay and/or reagent used. Therefore the concept of consensus values here is not the most appropriate approach. An alternative approach will be discussed.

The set-up of external quality assessment is always retrospective assessment of the accuracy of measurement. However, when laboratories introduce a new or modified method for the monitoring of extended half-life Factor VIII and IX products, they want to know after finalising their validation procedure and before introducing the method in clinical practice whether the drug can be measured accurately. The ECAT has now developed, together with a pharma company, so-called evaluation sets which can be used by laboratories on demand to establish their accuracy of measurement. This new concept will be discussed.