

## **EQALM Haematology WG**

### **Outline proposal for new work item - DRAFT**

#### **TITLE**

The provision of External Quality Assessment Schemes (EQAS) for the diagnostic tests associated with rare anaemias in Europe

#### **AIMS AND OBJECTIVES**

1. To survey EQA providers within European Union member states to determine the provision of EQAS for rare and congenital anaemias.
2. To discuss with EQA providers the use of reference methods for haematological parameters within EQAS and how IVDD companies use reference methods in the calibration and development of instruments and kits.
3. To work in collaboration with the European Network for Rare and Congenital Anaemias (ENERCA) to produce a collated catalogue of relevant EQAS.
4. To present the outcome of the survey at the EQALM annual meeting, 2011.

#### **BACKGROUND**

The ENERCA project ([www.enerca.org](http://www.enerca.org)) has operated for nearly 10 years, as 3 work projects, with the support of the European Parliament. The aims of the project are to improve the provision of care for individuals with rare and congenital anaemias, including the haemoglobinopathies, thalassaemia syndromes, red cell enzymopathies, red cell membrane disorders, erythropoietic disorders, metabolic disorders of iron and acquired haemolytic disease. For many of these conditions, the number of patients in any one member state is very small with only a few laboratories providing diagnostic testing. In these cases, the development of pan-European EQA may be the only means by which standardisation of methods and results can be achieved.

#### **METHOD**

ENERCA has established a list of core laboratory tests that are used in the diagnosis of rare and congenital anaemias. This project will survey EQAS providers within Europe and members of EQALM to identify the EQAS provision for tests that are included in this core list. EQAS providers will also be asked to provide details of the EQAS, such as the nature of the survey material, the performance criteria, the region covered etc. In addition, the survey will determine whether the EQAS provider is willing or able to accept participants from other member states or regions, and whether they are willing to work with other EQAS providers to establish pan-European services. The use of higher order reference methods, where available, to determine target values in EQA and to calibrate IVDDs will also be examined as part of the survey.

The results of this survey will be used to collate a catalogue of available EQAS within Europe, in collaboration with the ENERCA project. This catalogue will be an information resource for providers of diagnostic testing for rare anaemias in Europe and will identify the most important areas for EQA collaboration and development.

#### **TIMESCALE**

This survey will be undertaken in the early part of 2011, and the report will be available for initial consultation and comment in June 2011. The work item will be reported at the EQALM 2011 meeting.

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**On behalf of the EQALM Haematology WG**

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