



## **EFCC Science Committee**

### ***Postanalytical External Quality Assessment (WG-PEQAS)***

Committee and WG Chair: Prof. Sverre Sandberg, Norway

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EFCC has established a Working Group on Postanalytical External Quality Assessment under its Science Committee. The background, rationale and terms of reference of the working group are listed below.

#### **Background and rationale**

To be able to use laboratory tests in a rational way, it is important that there is knowledge to secure that the pre-analytical, analytical and post-analytical phases of the laboratory processes are carried out in an evidence-based manner. So far most efforts have been focused on the analytical phase whereas less attention has been paid to the pre- and postanalytical phases. This is typically seen in quality assessment/assurance where a lot of programs exist for the assessment of the analytical performance of laboratories whereas few are addressing the pre- or postanalytical phases.

After laboratory results are produced, there is little evidence on how test results are interpreted and used to improve patient care, and whether the actions of physicians comply with existing guideline recommendations. Several pilot projects with clinical case histories have been carried out to see how physicians in different countries handle patients in situations where laboratory tests are of great importance in decisions about patient management.

#### **Terms of reference:**

To develop post-analytical quality assurance programs for European countries\*

#### **Deliverables (2010-12):**

1. To set up a proposal for a European scheme for clinical post-analytical quality assessment of laboratory tests.
2. First survey on prothrombin time monitoring of oral anticoagulant therapy will be carried out in 2010.

\* The programs will be discussed and developed in cooperation with The European Committee for External Quality Assurance Programmes in Laboratory Medicine (EQALM).

**EFCC Science Committee, Chair: Prof. Sverre Sandberg**  
**Test Evaluation Working Group (WG-TE),**  
*Chair: Prof. Andrea Rita Horvath, Hungary*  
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EFCC has established a Working Group on Test Evaluation under its Science Committee. The background, rationale and terms of reference of the working group are listed below.

### **Background and rationale**

Clinical utilization and reimbursement for laboratory tests should move from a cost-based towards a value- and evidence-based approach. Laboratory tests have clinical value only if they provide benefit to patients at acceptable costs. Translational research aims to decrease the gap between the identification of new biomarkers and proving that these are clinically effective and improve patient-centred, organizational or economic outcomes. Nevertheless, new laboratory tests are often released to market with little evidence supporting their value or impact in clinical practice. Since resources are finite, evidence-based decisions about the use of diagnostic interventions should depend on well-designed and conducted test evaluation studies and technology appraisals.

After initial discovery of new biomarkers, careful consideration should be given to its purpose, the context and the clinical pathway for its application, the population and healthcare setting in which the test is intended to be used, and its potential consequences in clinical practice. No new test should be subjected to tedious evaluation if the test is unlikely to result in improved clinical actions or measurable outcomes. Test evaluation should be carried out with carefully planned study designs appropriate for the questions addressed at each stage of development. The below steps are proposed when investigating the value of testing: Phase I: Basic research into the association of disease with the new biomarker; Phase II: Clinical research into the validity of tests; Phase III: Clinical research into the application/utility of tests; Phase IV: Impact of testing in practice

The evidence-based methodology of these steps is not widely understood and there are now a number of published examples on the common pitfalls and potential biases in test evaluation studies that may lead to inappropriate medical decisions and threaten patient safety. Therefore the European Commission and IVD regulatory bodies have also acknowledged that a more responsive and proportionate risk assessment during pre-market approval of new tests is needed, which involves the review of the evidence for the clinical effectiveness and impact of new biomarkers.

### **Terms of reference:**

1. To develop guidance documents or protocols for the appropriate evaluation of the clinical effectiveness and impact of new laboratory tests.
2. To develop practical toolboxes which support the design and conduct of clinical research trials for the above purposes.
3. Education and training of researchers via pilot biomarker studies on how to design test evaluation studies.
4. Collaboration with epidemiologists, industry and regulatory authorities in setting standards for clinical evaluation of new biomarkers.

### **Deliverables:**

- General guidance on the process of test evaluation studies and on the best study design for the clinical evaluation of new tests at various stages of the test development process.
- Standards for test evaluation studies depending on the purpose or intended clinical application of the new test (i.e. diagnosis, screening, monitoring, risk assessment, prognosis)
- Minimum reporting and acceptance criteria that can be used by regulatory or approvals bodies (e.g. FDA, CE marking) assessing the clinical value of new biomarkers
- Training materials and courses on diagnostic trial design and how to conduct high quality diagnostic studies.
- Representation of EFCC's above interests and influencing the revision of the EU IVD Directive at EC level accordingly. (This will be carried out in collaboration with EFCC's delegates to the EC Exploratory Process on Medical Devices and with EFCC's WG-IVD)

## EFCC Quality Management Committee

### IVD Working Group (WG-IVD)

Committee and WG chair: Dr. Jean-Claude Libeer, Belgium

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EFCC has established a Working Group on IVDs under its Quality Management Committee. The terms of reference and the short and long-term goals of the working group are listed below.

#### Terms of reference of WG-IVD

1. Interpretation and harmonization of the use of the EU IVD Directive in laboratory practice and during accreditation of laboratories in Europe.
2. Improvement of information given by IVD manufacturers to their customers (laboratories).
3. Guidance and recommendations for laboratories, vendors or distributors of IVD equipment and assessors on the requirements for the documentation (needed in the scope of accreditation) for the documentation of installation and preventive maintenance of equipment.
4. Guidelines for method validation/verification reports in different fields of laboratory medicine.
5. Influencing the EU regulatory frameworks related to IVDs.

#### Short-term goals:

*Re: ToR2. Improvement of information given by IVD manufacturers to their customers*

The WG wishes to contribute to an improvement of information given by the IVD manufacturers to laboratories and consumers, who purchase IVD instruments and devices, in order to enhance quality and safety of *in vitro* medical devices and analytical instruments used in clinical practice.

Directive 79/98/EC (annex I, essential requirements 8) defines the information to be supplied by the manufacturer. The WG critically evaluates the requirements and highlights those items that currently have shortcomings. The weaknesses identified will be addressed in more depth and suggestions will be made for modifications, in collaboration with EDMA. The WG will propose solutions to the problems identified in form of guideline recommendations which intend to improve the information given by IVD manufacturers.

*Re: ToR3. Recommendations for the documentation of installation and preventive maintenance of equipment.*

Directive 79/98/EC requires information to be supplied by the manufacturer on the traceability of the calibration of the device.

ISO 15189 audits often identified nonconformities in different countries pointing to the lack of *transparency* and *traceability* of installation reports and preventive maintenance reports of instruments. Certificates of calibrations and verifications are often lacking transparency (item 5.3.4 of ISO 15189). Moreover, measurement results (also those used for calibration of instruments) must be designed and performed so as to ensure that those are traceable to SI units or by reference to a natural constant (item 5.6.3 of ISO 15189).

In relation to the above, accreditation bodies currently assess compliance with these standards in variable ways in different European countries. For quality, comparability and transferability, a more harmonised approach is therefore needed all across Europe.

In collaboration with EDMA and UNAMEC, the WG will prepare concrete guidelines for:

- The deployment and installation of instruments in the laboratory of the customer: i.e. type and content of documents to be provided by manufacturers for the laboratory.
- Preventive maintenance: i.e. contract content, documentation of performed verifications, documentation of performed measurements in relation with the required specifications, proofs of traceability of used measurement equipment and types of certificates required.
- Policy for the delivery of batch release certificates by IVD reagent providers.

## Long term goals:

The WG-IVD plans the following activities:

*Re ToR4: Guidelines for method validation/verification reports in different fields of laboratory medicine*

### Validation reports

Elaboration of a general template that can be used for the presentation of a validation report according to ISO 15189 (in collaboration with the EA Health Care WG).

### Validation guidelines

In 2007, Rabenau *et al* published a guideline with specific recommendations for the verification and validation of diagnostic tests in clinical virology (*Journal of Clinical Virology* 40 (2007) 93-98). In this paper, a distinction was made in the requirements for validation/verification of manufacturer provided IVD kits or methods, modified methods or protocols, and in-house tests. This paper is often used now as a reference for auditors in this field.

The WG-IVD plans to set up similar guidelines for other laboratory fields, such as clinical chemistry, coagulation, cell counting, etc.

*Re ToR5: Influencing the EU regulatory frameworks related to IVDs.*

The European Commission (EC) has set up an Exploratory Process on the future challenges of the medical devices sector in 2009, which might have implications for the IVD industry and its users, i.e. medical laboratories, clinicians and their patients in Europe. EFCC, together with EDMA, have been invited by the EC to take part in these discussions and in the three key work stream groups of this exploratory process focusing on: (1) future challenges and opportunities for public health and medical technologies developments, (2) balance between patients' needs and financial sustainability, and (3) competitiveness and innovation of the medical devices industry. The aim of the discussions was to map the existing public health and industrial challenges in the sector and investigate possible topics of reflection at European level.

The WG is involved in these consultations and wishes to influence EU policy on this topic and to take part actively in the future revisions of the EU IVD Directive.

### ***Finance Committee***

Committee chair: Prof. Peter Schuff-Werner, Germany

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The Finance Committee is responsible for proper financial governance of EFCC, and for initiation and direction of fundraising activities and actions to support the work of EFCC.

The Finance Committee will deliver the following specific objectives of EFCC:

- Applying for scientific, educational and other grants to support the objectives of the Federation.

The Finance Committee will also support the Treasurer in his/her duties, specifically:

- financial management and administration of EFCC activities and administration of annual membership fees (with IFCC Office)
- preparation of annual budget plans and financial reports
- determining the reimbursement policies of EFCC
- supporting Committee and Working Group Chairs in financial matters and fundraising activities
- Liaising with companies and sponsors of EFCC activities
- Overseeing the annual audit of accounts