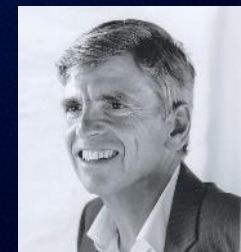


# The IFCC committee on EQA and Proficiency Testing (IFCC C-PT) Major Objectives and **New Projects**

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Chair IFCC Committee on proficiency testing (C-PT),  
Greek Proficiency Testing Scheme for Clinical Laboratories  
(ESEAP)



# IFCC Committee on Proficiency Testing

## Introduction

The role of Proficiency Testing schemes (or External Quality Assurance programs) is of primordial importance:

- to the analytical quality,
- to the standardization of the methods and
- to the harmonization of the results,

**but there is a lack of interest from the commercial providers of such schemes**

- for the more **new** and **complex** tests and
- for the **very old and simple** measurands that involve a **new calibration curve**, because of the very subtle problems induced at the interpretation of the statistical results of their, already well-established and running, schemes.

# IFCC Committee on Proficiency Testing Objectives

- The C-PT is a **multidisciplinary effort** in the analysis and the exploration of the Proficiency Testing issues. Our **aims** are:
  - To facilitate the **introduction of international proficiency testing schemes** for **uncommon but clinically important measurands** (analytes).
  - To use the information to **select measurands** (analytes) that may be suitable for **method harmonization** as a means to improving patient outcomes.

## Main project of the C-PT

- Is the **creation of an online database - web application** accessible via web browsers and via specific applications for the major mobile platforms.
- The roots of this database will be the **analytes** (tests, measurands) that will be filed with all possible synonyms ("official" from the C-NPU) as also as the **methods** (assays, instruments, reagents etc.) also with all possible synonyms.
- Another part of the DB, maintained with the cooperation of the C-AQ, will be the **EQA-PT providers section** containing all their contact information, their programs with the analytes, frequencies, type of statistics, commutability of control materials, their accreditation or certification status etc.
- All **register users** can **add any term in the database**, although the application will propose similar ones if there are already filed, searching all synonyms.
- Finally, they can "**vote**" **expressing their desire for the introduction of a PT** for this analyte.

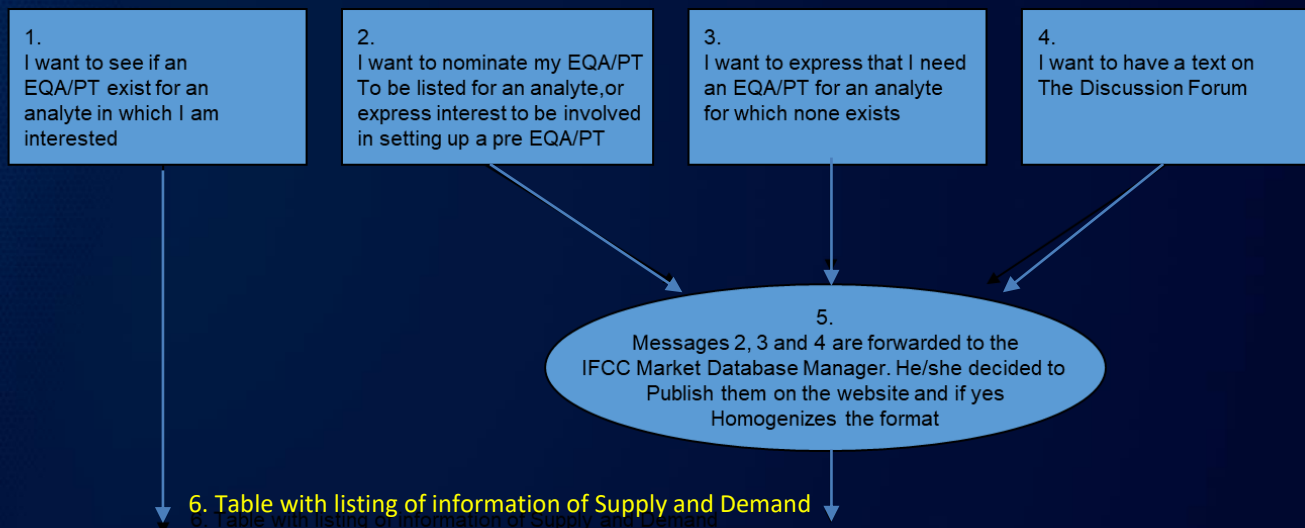


# Online Database or Web Application

Developed as **web application**, as **opposed to classic website** provides:

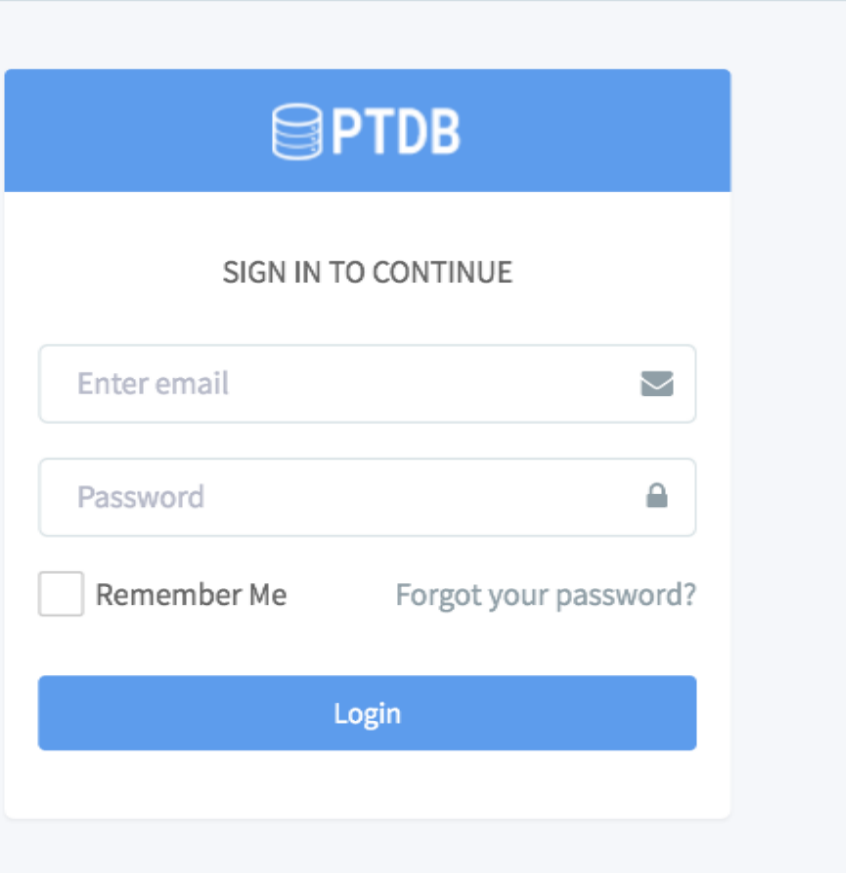
- **Capabilities:**
  - **Optimized** for smartphones, tablets and desktop
  - **Responsive**
  - **Adapts** to the **screen size**
  - **Modern** and **fast**
  - Mobile app ready
- **Features:**
  - Left pane navigation
  - Public area
  - Admin area (**login required**)
  - Switch languages

# Flowchart of the Online Database Web Application



| Analyte    | Supply (pre) EQA/PT       |   | Demand EQA/PT           |                         |                    |                              | Forum    |
|------------|---------------------------|---|-------------------------|-------------------------|--------------------|------------------------------|----------|
|            | I have an EQA/PT in Place | I'm interested to be involved in pre EQA/PT | I'm a laboratory        | I'm an EQA/PT organiser | I'm a Manufacturer | I'm none of these categories |          |
| X in Serum | INSTAND - DE              | UKNEQAS - UK                                | Hospital X Beijing - CN | RCPA AU                 | Roche - DE         | Government - GR              | FDA - US |


Login Page: <http://ptdb.ifcc.org>




The image shows a login page for PTDB. At the top, there is a blue header with the PTDB logo (a database icon) and the text "PTDB". Below the header, the text "SIGN IN TO CONTINUE" is centered. There are two input fields: "Enter email" with an envelope icon and "Password" with a lock icon. Below the password field, there is a checkbox for "Remember Me" and a link for "Forgot your password?". At the bottom, there is a blue "Login" button.

PTDB

SIGN IN TO CONTINUE

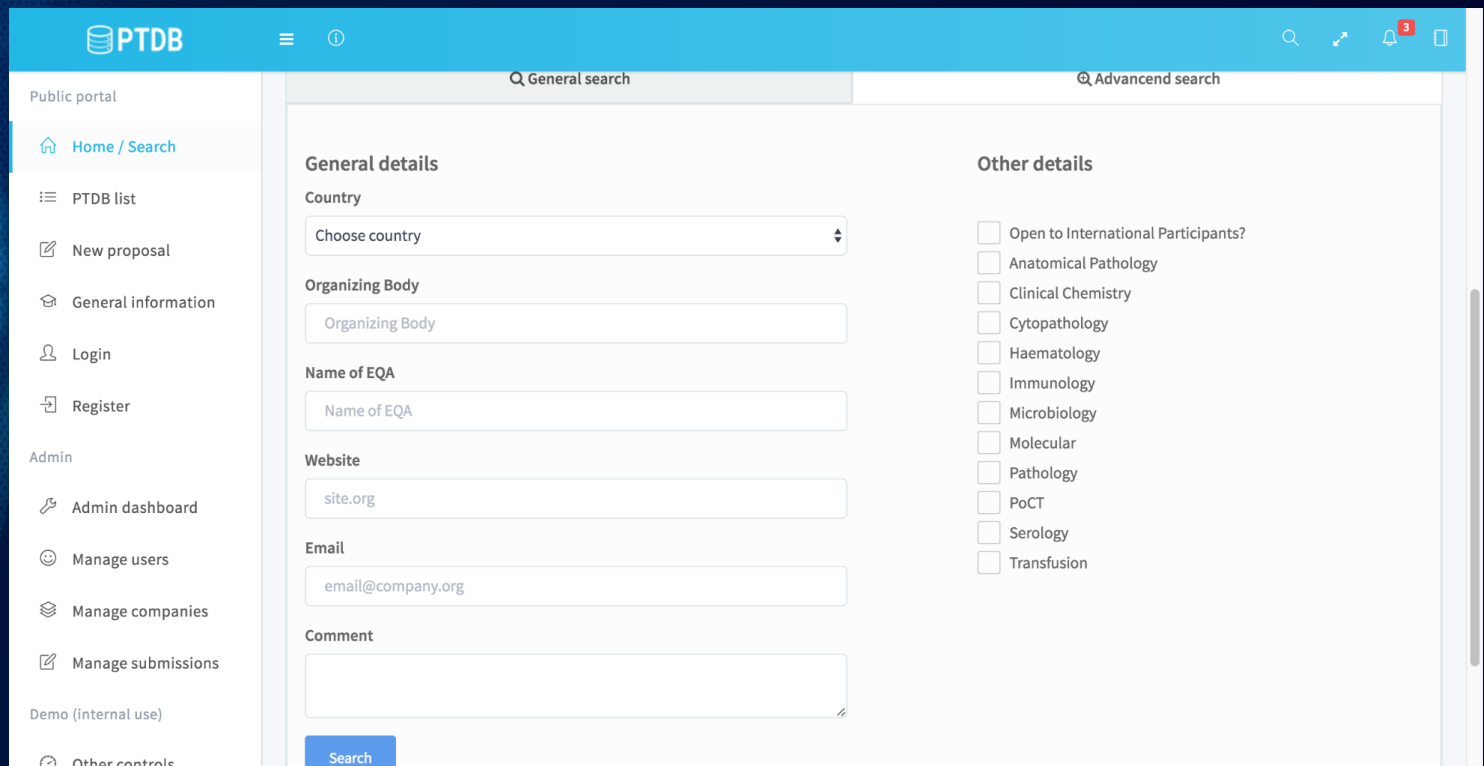
Enter email 

Password 

Remember Me [Forgot your password?](#)

Login

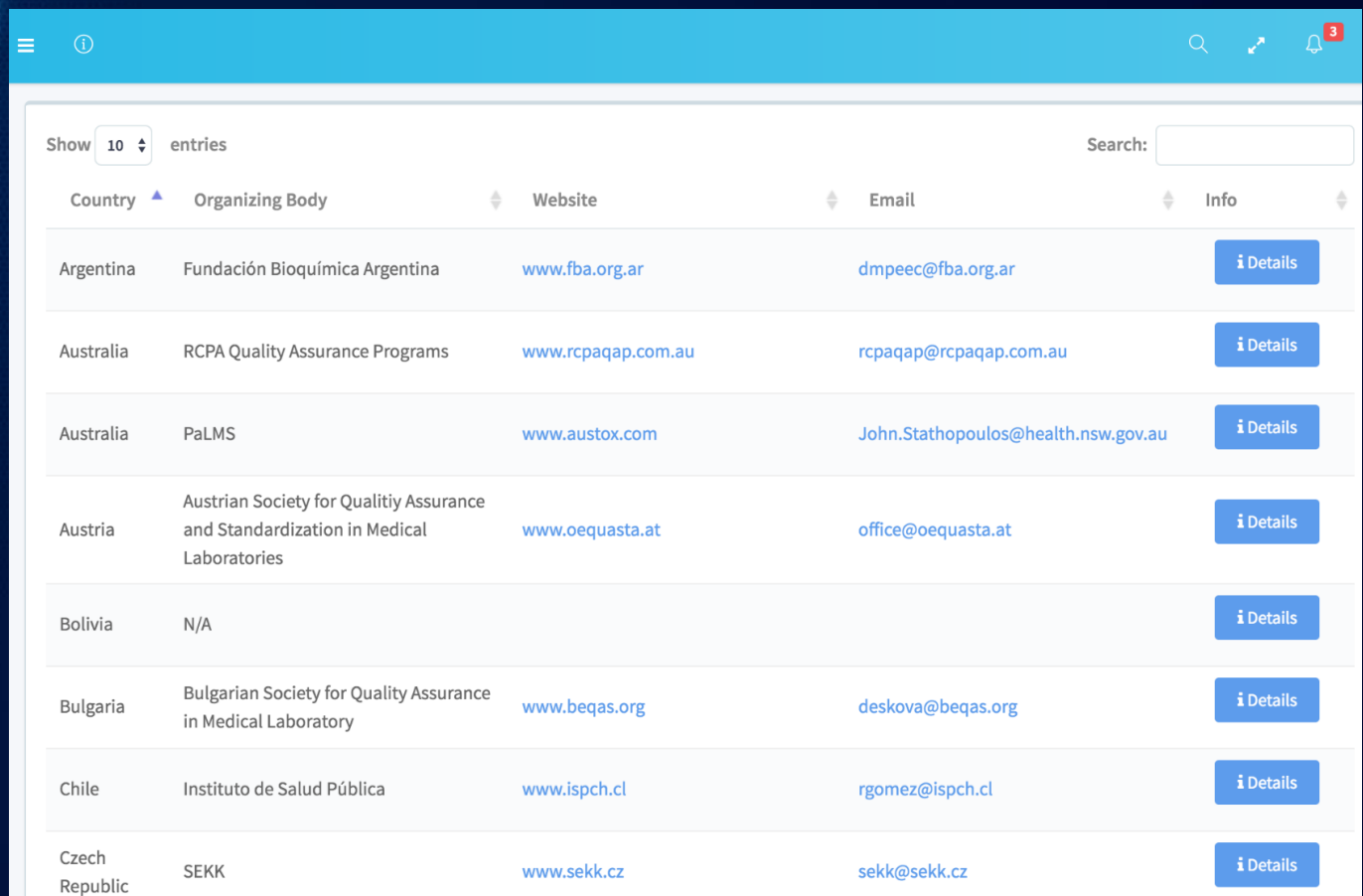
# Search for a PT provider - EQA organizer



The screenshot shows the PTDB (Public Testing Database) website interface. The top navigation bar is blue and contains the PTDB logo, a menu icon, a search icon, and a notification bell with a red '3' badge. Below the navigation bar, there are two tabs: 'General search' (selected) and 'Advanced search'. The main content area is divided into two columns: 'General details' and 'Other details'. The 'General details' column contains several input fields: 'Country' (a dropdown menu with 'Choose country' selected), 'Organizing Body' (a text input field), 'Name of EQA' (a text input field), 'Website' (a text input field with 'site.org' entered), 'Email' (a text input field with 'email@company.org' entered), and 'Comment' (a text area). The 'Other details' column contains a list of checkboxes for various laboratory specialties: 'Open to International Participants?', 'Anatomical Pathology', 'Clinical Chemistry', 'Cytopathology', 'Haematology', 'Immunology', 'Microbiology', 'Molecular', 'Pathology', 'PoCT', 'Serology', and 'Transfusion'. A blue 'Search' button is located at the bottom of the 'General details' column. On the left side of the page, there is a sidebar menu with the following items: 'Home / Search', 'PTDB list', 'New proposal', 'General information', 'Login', 'Register', 'Admin dashboard', 'Manage users', 'Manage companies', 'Manage submissions', 'Demo (internal use)', and 'Other controls'.



# Search Results



Search Results

Show 10 entries

Search:

| Country        | Organizing Body  | Website  | Email  | Info                      |
|----------------|--|--|--|---------------------------|
| Argentina      | Fundación Bioquímica Argentina   | <a href="http://www.fba.org.ar">www.fba.org.ar</a>         | <a href="mailto:dmpeec@fba.org.ar">dmpeec@fba.org.ar</a>                                     | <a href="#">i Details</a> |
| Australia      | RCPA Quality Assurance Programs  | <a href="http://www.rcpaqap.com.au">www.rcpaqap.com.au</a> | <a href="mailto:rcpaqap@rcpaqap.com.au">rcpaqap@rcpaqap.com.au</a>                           | <a href="#">i Details</a> |
| Australia      | PaLMS  | <a href="http://www.austox.com">www.austox.com</a>         | <a href="mailto:John.Stathopoulos@health.nsw.gov.au">John.Stathopoulos@health.nsw.gov.au</a> | <a href="#">i Details</a> |
| Austria        | Austrian Society for Quality Assurance and Standardization in Medical Laboratories | <a href="http://www.oequasta.at">www.oequasta.at</a>       | <a href="mailto:office@oequasta.at">office@oequasta.at</a>                                   | <a href="#">i Details</a> |
| Bolivia        | N/A  |  |  | <a href="#">i Details</a> |
| Bulgaria       | Bulgarian Society for Quality Assurance in Medical Laboratory                      | <a href="http://www.beqas.org">www.beqas.org</a>           | <a href="mailto:deskova@beqas.org">deskova@beqas.org</a>                                     | <a href="#">i Details</a> |
| Chile          | Instituto de Salud Pública   | <a href="http://www.ispch.cl">www.ispch.cl</a>             | <a href="mailto:rgomez@ispch.cl">rgomez@ispch.cl</a>   | <a href="#">i Details</a> |
| Czech Republic | SEKK   | <a href="http://www.sekk.cz">www.sekk.cz</a>               | <a href="mailto:sekk@sekk.cz">sekk@sekk.cz</a>   | <a href="#">i Details</a> |

# Details of Search Results

The screenshot shows a search results interface with a modal window displaying details for the Austrian Society for Quality Assurance and Standardization in Medical Laboratories. The modal window contains the following information:

| Austrian Society for Quality Assurance and Standardization in Medical Laboratories                    |  |
|---|--|
| Full details about Austrian Society for Quality Assurance and Standardization in Medical Laboratories |  |
| <b>Country</b>  | Austria  |
| <b>Organising Body</b>  | Austrian Society for Quality Assurance and Standardization in Medical Laboratories |
| <b>Name of EQA</b>  | OEQUASTA   |
| <b>Website</b>  | <a href="#">Go to</a>  |
| <b>Email</b>  | <a href="#">Email</a>  |
| <b>Open?</b>  | Yes  |
| <b>Anatomical Pathology</b>   | No   |
| <b>Clinical Chemistry</b>   | Yes  |
| <b>Cytopathology</b>  | No   |
| <b>Haematology</b>  | Yes  |
| <b>Immunology</b>   | Yes  |
| <b>Microbiology</b>   | No   |
| <b>Molecular Pathology</b>  |  |

The background shows a search results table with columns for Country and Organising Body. The table lists several organizations from various countries, including Argentina, Australia, Austria, Bolivia, Bulgaria, and Chile. Each row has a 'Details' button next to it.

# Proficiency Testing (PT) schemes - External Quality Assurance (EQA) programs in Molecular Tests

- We organized an EQA program for the Cobas EGFR v2 mutation test in ctDNA of plasma in Greece for Liquid Biopsy samples.
- Launched under the auspices of the Laboratory of Circulating Tumor Cell Analysis (ACCT Laboratory) of the University of Athens by the Greek Proficiency Testing Scheme for Clinical Laboratories, (ESEAP - [www.eseap.gr](http://www.eseap.gr)).
- This preliminary program was based on the distribution of 10 plasma samples (synthetic reference materials produced by Horizon Discovery, Cambridge, United Kingdom) to eight laboratories in Greece.
- Six of eight laboratories are accredited according to ISO 15189 for the EGFR mutation testing in tissues using methods such as COBAS, Vienna labs hybridization, DNA sequencing, and new generation sequencing (NGS).
- Moreover, three of them use human plasma as a sample matrix.

- Date of online publication **September 29, 2018**
- URL: <https://doi.org/10.1515/cclm-2018-0676>

## Letter to the Editor

Aliki Ntzifa, Christos Kroupis<sup>a</sup>, Alexander Haliassos<sup>b</sup> and Evi Lianidou<sup>c,\*</sup>

# A pilot plasma-ctDNA ring trial for the Cobas<sup>®</sup> EGFR Mutation Test in clinical diagnostic laboratories

<https://doi.org/10.1515/cclm-2018-0676>

Received June 27, 2018; accepted August 20, 2018

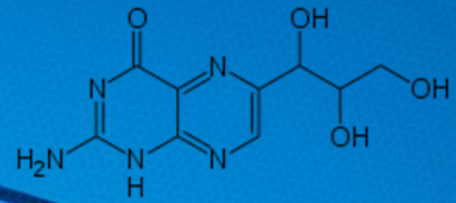
**Keywords:** circulating tumor DNA; epidermal growth factor receptor (*EGFR*) mutations; external quality assessment (EQA); liquid biopsy; non-small cell lung carcinoma (NSCLC).

To the Editor,

Liquid biopsy based mainly on the analysis of circulating tumor cells (CTCs) and circulating tumor DNA (ctDNA)

accredited according to ISO17043 standard or in inter-laboratory comparisons that are in substantial agreement with [4].

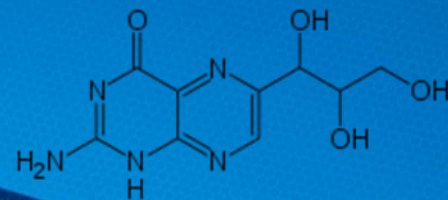
Epidermal growth factor receptor (*EGFR*) mutation testing is an established critical parameter in non-small cell lung carcinoma (NSCLC) tissues for therapeutic decisions according to the new era of personalized medicine. Nowadays, tissue genotyping for *EGFR* mutations has been well incorporated in clinical practice as a gold standard for therapeutic decisions and for early detection of recurrences or selection of tyrosine kinase inhibitors (TKI). However, major limitations emerge quite often: limited



# IFCC Committee on Proficiency Testing

## New Programs (I) Neopterin in CSF validation

- **Target Molecule**
- **Neopterin** is a **pteridin** implicated in the **cell immune stimulation**.
- Neopterin or *D-erythro*-Neopterin
- The *L-Threo*-Neopterin is called **Monapterin**.
- Empirical Formula (Hill Notation):  $C_9H_{11}N_5O_4$
- Molecular Weight: 253.21
- CAS Number: [2009-64-5](#)
- Human pteridins is a **family of about 10 members**: Biopterin, Neopterin and its isomer Monapterin, Lumazine, 6-OH biopterin, Xanthopterin, Pteric Acid...



## IFCC Committee on Proficiency Testing New Programs (I) Neopterin in CSF validation

- The neopterin controls prepared by a member of C-PT are very stable even at ambient temperature!
- We decided to distribute, tentatively before the end of 2019, a set of 8 vials (4 duplicates at clinically significant concentrations) to 15-20 laboratories around the world to measure during the next four months, using all available methods, as a pilot scheme. This program can be implemented easily because of the control samples stability.
- Using the results we will compare the measuring assays and afterwards we will forward them to the ICHLR (acronym for the International Consortium for Harmonization of Clinical Laboratory Results) to initiate the harmonization of measuring methods.

# IFCC Committee on Proficiency Testing

## New Programs (II) –EQA providers cooperation

- During the **last two months**, we started discussions with EQA-PT providers of neighboring countries.
- The C-PT proposes and supports **the collaboration of EQA providers** through the ***simultaneous use of common control materials***, tailor made from accredited IVD manufacturer(s), and the ***anonymized exchange of laboratory results***, including ***methods and instruments***.
- This is a ***win-win situation*** that can greatly help participating EQA-PT providers giving them ***the possibility to use much bigger “peer groups”*** to calculate their target values, thus ***improving their accuracy*** and the ***quality of produced performance evaluations*** for the participating laboratories.
- We will ***try to implement this collaboration*** from the 2020 distributions.



# Thank you for your attention!!!



**Balkan Clinical Laboratory  
Federation Meeting**


**BCLF 2019**

**XXVII. XXX.**

**National Congress of the  
Turkish Biochemical Society**

**TBS 2019**

 **OCTOBER 27-31, 2019**

 **PAPILLON ZEUGMA CONVENTION CENTRE, BELEK ANTALYA - TURKEY**

**EFLM**  
EUROPEAN FEDERATION OF CLINICAL CHEMISTRY  
AND LABORATORY MEDICINE

  
International Federation  
of Clinical Chemistry  
and Laboratory Medicine

## IFCC Committee on proficiency testing (C-PT)

<https://www.ifcc.org/ifcc-education-division/emd-committees/c-pt>

