Molecular Diagnostics ExpertAPPLICATION FORM

## Please complete the following form and send email to the IFCC office (paola.bramati@ifcc.org) by **February 12, 2016.**

## For additional details or clarification, email Professor Debs Payne at the following: Debs\_Payne@yahoo.com

1. INVESTIGATORS

|  |
| --- |
| Principle Applicant |
| Title | Surname, First name |
|  |  |
| Email address: |  |
| Telephone number (including country code) |  |
| MDC Area of Interest(see page 2 for list) |  |
| Co-Applicants and 2°(Name of Secondary Contact at Your Organization) |
|  | Title | Surname, First name and Email |
| i) |  |  |
| ii) |  |  |
| iii) |  |  |
| 2° |  |  |

2° The secondary contact should be available if the IFCC cannot reach the primary contact

2. INSTITUTION DETAILS

###### (a) Name & full address of Institutions (s)

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| If this is a multi-centre application, please identify all institutions (example, pathology department and genetic department) involved (such as for Co‑Applicants i), ii), and iii)). |

3. Details of the Principle Applicant

Correspondence relating to this application will be sent to the Principle Applicant

|  |  |  |  |
| --- | --- | --- | --- |
| (i) | Title | Given Name | Surname |
|  |  |  |
| (ii) | Current Appointment: |  |
| (iii) | Institution:  |  |
| Department:  |  |
| Postal Address:  |  |
| Courier Address:(if different to postal address) |  |
| Telephone:  |  | Facsimile: |  |
| Email: |  |
|  | Alternate Email\*: |  |

**\*An alternate email is necessary if the principle contact cannot be reached using the first email**

4. Levels of Participation

This section is for information only

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| **Participation as an** ***IFCC MDC Expert Laboratory*** |
| **Objective:** to act as a point of reference within a special area of interest within the general membership and member societies of IFCC.These laboratories will be recognized as an IFCC MDC Expert Laboratory. Laboratories may participate or show leadership in one or more of the following areas within a special area of interest, such as:* Offer expert advice on the conduct and interpretation of molecular diagnostic tests.
* Act as a point of reference for analysis of difficult samples.
* Assay optimization.
* Provision of reference samples or sample exchange for alternate assessment
* Provision of sequence data to better characterize disease loci.
* Offer Expertise on genotype/phenotype correlations.
* Participate in development of reference methods.
* Participate in evaluation of new methodologies.
* Participate in the organization of Workshops, Training Courses
* Participate in translational research
* Support translation of guidance documents into different non English languages
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| **5. MDC Area of Interest** |
|  | **Examples** | **Specific Area** |
| Single-Gene Disorders | Hemochromatosis, Fragile X, Cystic Fibrosis, Factor V Leiden |  |
| Multi-Gene Disorders | Dyslipidemias |  |
| Oncology | Solid Organ: Breast, colon, lungs, prognostic testing, therapeutic response |  |
|  | Hematological: Bcr-Abl quantitative PCR, B and T cell clonality, etc. |  |
| Pharmacogenetics | CYP2D6, TPMT |  |
| Inherited Errors of metabolism | glycogen storage disease, phenylketonuria, porphyria, Lesch-Nyhan syndrome |  |
| Infectious Diseases | Sexually transmitted diseases, Respiratory, Meningitis/Encephalitis, Hepatitis, Gastrointestinal Diseases, tropical diseases, Drug resistance, pediatric diseases |  |
| Circulating cell free DNA, Circulating Tumor Cells | Noninvasive prenatal testing, prognostic testing, therapeutic response |  |
| Bioinformatics and Laboratory information systems | Massively parallel sequencing data analysis, patient management algorithms, instrument interfacing |  |
| Education | User education i.e. website, health care provider (example, nurse and doctor education), Laboratory and workflow design |  |
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| Other(s) (specify): |

6. Laboratory Details

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| **6.a Accreditation Status**  |

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|  | **Place an “X” against** **Yes or No** |
| Do you have accreditation status for performance of molecular diagnostic tests? |

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| --- | --- | --- |
| **Yes** |

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| **No** |

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| Type of accreditation (i.e. ISO 17025, ISO 15195..) | Type of Accreditation: |

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| **6.b Proficiency Testing** |

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|  | **Place an “X” against** **Yes or No** |
| Do you participate in any external quality assurance or proficiency testing schemes? |

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| **Yes** |

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| **No** |

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| Name of external quality assurance or proficiency testing schemes: | Scheme(s) name: |

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| **6.c Select the setting which best describes your group.** |

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|  | **Place an “X” next to your selection** |
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| Academic |  |
| Government/State Hospital Laboratory |  |
| Government/State Pathology Laboratory |  |
| Private Hospital Laboratory |  |
| Private Pathology Laboratory |  |
| Other (specify) |  |

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| **6.d Basic Infrastructure****And Sample Analysis** | Sample numbers and sample types.

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| Number of samples analysed |  |
| Number of samples per month |  |
| Sample types analysed |  |
| Blood |  |
| Other including buccal swab, saliva, tissue (please state the specific sample type) |  |
| Liquid based cytology |  |
| Microbiological media |  |

b) What technologies are currently being employed for by your laboratory in clinical practice? Rank the top three by placing a number by the method (example, real time quantitative PCR(1), Non PCR based amplifications (2) and gel electrophoresis (3))

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|  | **Place an “X” next to your selection** |
| DNA sequencing (Sanger) |  |
| Restriction enzyme analysis of PCR products |  |
| Real-Time PCR (Quantitative) |  |
| Real-Time PCR (Genotyping)  |  |
| DNA sequencing (massively parallel) |  |
| Gel electrophoresis |  |
| dHPLC |  |
| Non PCR based amplification methods (example, SDA, TMA, etc) |  |
| Southern Blotting |  |
| Circulating cancer cells |  |
| In house Bioinformatics |  |
| Circulating cell free DNA |  |
| Massively Parallel Sequencing (also known as NGS) |  |
| Mass Spectrometry |  |
| Linkage analysis using microsatellites or other markers. |  |
| DNA chip or microarray |  |
| Other Techniques |  |

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| **6.e Participation in national or international studies or societies or relevant projects.** | If applicable, cite areas of national and international collaboration in the area of interest (please limit to this one page highlighting areas of greatest importance and relevance). |
| **6.f Publications** | List if any, publications (max 10) you have in the area of interest, relevant to molecular diagnostics. |

***ADDENDUM.***

**The criteria for recognition of an IFCC MDC expert laboratory will be based on:**

* **Scientific excellence** (score up to 20) based on the data reported in the section **7.f: *Publications* (max 10)**
* **Availability of suitable Technological Infrastructures** (score up to 20) based on the data reported in the sections ***7.a: Accreditation status; 7.b: Proficiency Testing*** and ***7.d:Basic Infrastructure and Sample analysis***
* − **The potential capacity of dissemination** (score up to 10) based on ***geographical distribution*** (max 1 MDC per country for each Area of Interest) and on the data reported in the section **7.e:*Participation in National or international studies, or Societies***

The laboratories that will be selected to act as an IFCC MDC Expert Laboratory **must sign,** before acceptance, that their activities will be coordinated by the C-MD as follows:

These items can be directly performed by an IFCC MDC Expert Laboratory (however they should be recorded for reporting to the C-MD)

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* Offer expert advice on the conduct and interpretation of molecular diagnostic tests.
* Act as a point of reference for analysis of difficult samples.
* Offer Expertise on genotype/phenotype correlations.
* Submit case report annually

**ONLY** after a specific request from the C-MD such as:

* Assay optimization.
* Provision of reference samples.
* Provision of sequence data to better characterize disease loci.
* Participate in development of reference methods and/or materials.
* Participate in evaluation of new methodologies.
* Participate in the organization of Workshops, Training Courses