



**CALL FOR EXPRESSION OF INTEREST  
FOR EXPERT PANELS ON MEDICAL DEVICES AND IN VITRO DIAGNOSTIC  
MEDICAL DEVICES  
804/PP/GRO/CODEL/20**

**ANNEX I - Application form**

**WARNING:**

This is a text version of the online application form for the call for expression of interest for the European Commission expert panels on medical devices and *in vitro* diagnostic medical devices. An application will be deemed admissible only if it is submitted via the **online** Application Form (EUSurvey) before the deadline indicated in the call.

**Introduction:**

The Commission is calling for expressions of interest to draw up a list of candidates that are eligible and apt in regard to their expertise in relevant clinical or other scientific technical areas. A key role for selected experts will be to provide an independent opinion on high-risk devices to notified bodies before such devices are certified for EU market access. The experts will also be involved in other tasks such as contributing to the development of common specifications for clinical evaluation of device categories, guidance documents or standards.

Interested individuals are invited to submit their application using the below application form. As the working language of the expert panels is English, all applications must be completed in English.

An application will be deemed admissible only if it is sent through this application form, within the deadline and including the following documents:

- A curriculum vitae (CV) in electronic format (preferably pdf), not exceeding four pages.
- A copy of your national ID or passport as proof of citizenship.
- A declaration of interests ('DOI') using the standard DOI form attached to this call. The form can also be downloaded under background documents. Individuals applying to be appointed as members of the expert panels must disclose therein any circumstances that could give rise to a conflict of interest. Submission of a duly completed DOI form is necessary in order to be eligible to be appointed in a personal capacity. Additional supporting documents may be requested at a later stage.

## **1. Personal information**

### 1.1 Contact Information

Title:

Surname:

First name(s):

Date of birth: DD/MM/YYYY

Nationality:

Address:

Postal Code:

Town:

Country:

Daytime (office) phone number:

Mobile telephone number:

E-mail address:

Alternative E-mail address:

## 1.2 Professional experience

Please list here your last 5 work experiences starting with the most recent.

Occupation or position held:

Dates (from/to): MM/YYYY to MM/YYYY

Main activities and responsibilities:

Name and address of employer:

Type of sector:

- Academia
- Research & Development
- Hospital or Clinical sector
- Medical Device Industry
- Pharmaceutical Industry
- Private sector
- Consultancy
- Notified Body
- National Competent Authority
- Governmental
- Public Administration
- International Organisation
- Non-profit organisation
- Other

## **2. Eligibility criteria**

Please confirm that you meet all of the below eligibility requirements:

- ⊗ I am a citizen of an EU Member State, EFTA Member State or Turkey;
- ⊗ I have a university degree in a relevant medical, scientific or technical field at graduate level;
- ⊗ I have at least 10 years of relevant professional experience in areas related to the subject of the call (clinical, medical diagnostics, non-clinical/technical or regulatory);
- ⊗ I have good knowledge of the English language allowing active participation in the deliberations and writing reports in English<sup>1</sup>;

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<sup>1</sup> As a guide, 'Ability to work in English' corresponds to level B2 or above, as set out in the Council of Europe reference document for the European Language Portfolio ('Common European Framework of Reference: Learning, Teaching, and Assessment'). For more information please refer to <http://euopass.cedefop.europa.eu/en/resources/european-language-levels-cefr>

### **3. Educational background**

#### 3.1 Graduate Studies

Please indicate your graduate-level university degree in a medical, scientific or technical field relevant for this call:

- Medicine (go to 3.1.2 and 3.1.3)
- Dentistry (go to 3.1.2 and 3.1.3)
- Pharmacy (go to 3.1.3)
- Nursing or Midwifery (go to 3.1.3)
  
- Biology (go to 3.1.3)
- Biochemistry (go to 3.1.3)
- Chemistry (go to 3.1.3)
- Engineering (go to 3.1.3)
- Mathematics or Statistics (go to 3.1.3)
- Physics (go to 3.1.3)
- IT, bioinformatics (go to 3.1.3)
  
- Others

### 3.2 Medical Specialities

If applicable, please indicate your medical speciality relevant for this call<sup>2</sup>:

- Accident and emergency medicine
- Allergology / Clinical and experimental immunology
- Anaesthesiology
- Cardiology
- Clinical neurophysiology
- Communicable (Infectious) diseases
- Dentistry
- Dermatology
- Diabetes
- Endocrinology
- Gastroenterology
- General (Internal) Medicine
- Genetics
- Geriatrics
- Haematology
- Laboratory medicine
- Maxillofacial surgery
- Medical oncology
- Nephrology
- Neurology
- Obstetrics & Gynaecology
- Ophthalmology
- Orthopaedics & Traumatology
- Otorhinolaryngology
- Paediatrics
- Palliative care
- Pathological Anatomy
- Pharmacology
- Physical Medicine and Rehabilitation
- Psychiatry
- Public health medicine
- Radiation Oncology and Radiotherapy
- Radiology
- Respiratory medicine / Pulmonology
- Rheumatology
- Surgery

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<sup>2</sup> Based on Directive 2005/36/EC

- ⊗ Urology
- ⊗ Venereology

### 3.3 Post-graduate studies

Please indicate if you hold a university degree at post-graduate level in a relevant medical, scientific or technical field relevant for this call:

- MSc \_\_\_\_\_
- PhD \_\_\_\_\_



#### **4. Professional experience**

##### **4.1 Relevant medical fields**

Please indicate your professional experience by answering each of the below questions and if applicable, selecting the most appropriate competence(s). Multiple replies are possible. This section is intended to categorise your experience in addition to any medical speciality or post-graduate studies indicated above and is open to all types of relevant professions.

##### **1. Do you have experience in accident and emergency medicine?**

- YES
- NO

##### **2. Do you have experience in Allergology or Clinical and experimental immunology?**

- YES
- NO

##### **3. Do you have experience in Anaesthesiology?**

- YES
- NO

If applicable, select the most appropriate competence(s) in Anesthesiology:

- Critical Care Medicine
- Neurocritical Care
- Pain Medicine

##### **4. Do you have experience in Laboratory medicine?**

- YES
- NO

If applicable, select the most appropriate competence(s) in Laboratory Medicine:

- Blood transfusion
- Clinical chemistry
- Clinical microbiology
- Haematology
- Immunology
- Metabolic diseases
- Point of care testing (POCT)
- Pathogen detection (qualitative)
- Pathogen detection (quantitative)
- Virology

##### **5. Do you have experience in Haematology?**

- YES
- NO

If applicable, select the most appropriate competence(s) in Haematology:

- Clinical haematology
- Laboratory haematology

**6. Do you have experience in Cardiology?**

- YES
- NO

If applicable, select the most appropriate competence(s) in Cardiology:

- Cardiac electrophysiology
- Cardiovascular Imaging
- Interventional cardiology
- Heart failure and devices

**7. Do you have experience in Communicable (Infectious) diseases?**

- YES
- NO

If applicable, select the most appropriate competence(s) in Communicable (Infectious) diseases:

- Blood transfusion
- Transplantation medicine
- Tropical medicine
- Travel medicine
- Pathogen detection for blood donations, cells and tissues, organ transplantation, e.g. HIV 1/2, Hepatitis B, Hepatitis C, Hepatitis D, HTLV I/II, CMV, EBV, Treponema pallidum, Hepatitis A, Hepatitis E, West Nile, Dengue virus, Chikungunya, Zika
- Virus infection patient management, e.g. HIV 1/2, Hepatitis B, Hepatitis C, CMV, EBV
- Respiratory diseases, e.g. Influenza virus, SARS CoV, MERS CoV
- Haemorrhagic fevers and other BSL4 viruses, e.g. Ebola, Marburg, Lassa, Smallpox, CCHF
- Parasites with relevance for transplantations, e.g. Plasmodium spp., Trypanosoma cruzi, Toxoplasma gondii
- Infectious molecules, e.g. prions

**8. Do you have experience in Public health medicine?**

- YES
- NO

If applicable, select the most appropriate competence(s) in Public Health Medicine:

- Clinical epidemiology
- Public Health Management and Policy
- Health Economics and Outcomes Research

**9. Do you have experience in Dentistry?**

- YES
- NO

If applicable, select the most appropriate competence(s) in Dentistry:

- Implantology
- Oral pathology
- Oral surgery
- Orthodontics
- Periodontology
- Prosthetic dentistry
- Restorative dentistry

**10. Do you have experience in Dermatology?**

- YES
- NO

**11. Do you have experience in Venereology?**

- YES
- NO

**12. Do you have experience in Radiology?**

- YES
- NO

If applicable, select the most appropriate competence(s) in Radiology:

- Computed tomography (CT)
- Diagnostic radiology
- Interventional radiology
- Magnetic resonance imaging (MRI)
- Nuclear medicine
- Nuclear medicine including positron emission tomography (PET)
- Ultrasound
- X-ray radiography

**13. Do you have experience in Diabetes?**

- YES
- NO

If applicable, select the most appropriate competence(s) in Diabetes:

- Diabetes other
- Gestational diabetes
- Paediatric diabetes
- Type 1 diabetes
- Type 2 diabetes

**14. Do you have experience in Endocrinology?**

- YES
- NO

If applicable, select the most appropriate competence(s) in Endocrinology:

- General endocrinology
- Reproductive endocrinology

**15. Do you have experience in Gastroenterology?**

- YES
- NO

If applicable, select the most appropriate competence(s) in Gastroenterology:

- Biliopancreatic disease
- Digestive endoscopy
- Early digestive preneoplastic and neoplastic lesions
- Gastrointestinal neuroendocrine tumors
- Inflammatory bowel diseases
- Liver diseases
- Neurogastroenterology / motility disorders
- Nutrition
- Proctology

**16. Do you have experience in General (Internal) Medicine or Pathological Anatomy?**

- YES
- NO

If applicable, select the most appropriate competence(s) in General (Internal) Medicine or Pathological Anatomy:

- Bone and soft tissue pathology
- Breast pathology
- Clinical autopsy pathology
- Cytopathology
- Dermatopathology
- Digestive pathology
- Electron microscopy
- Endocrine pathology
- Forensic pathology
- Gynecological pathology
- Head and neck pathology
- Hematopathology
- Molecular pathology
- Nephropathology
- Neuropathology
- Oral and maxillofacial pathology
- Pulmonary pathology
- Surgical pathology
- Uropathology

**17. Do you have experience in a surgical discipline relevant for this call?**

- ⊗ YES
- ⊗ NO

If applicable, select the most appropriate competence(s) in Surgery:

- ⊗ **Cardiovascular surgery**
- ⊗ Cardiac surgery
- ⊗ Congenital cardiac surgery
- ⊗ Thoracic surgery
- ⊗ Vascular surgery
- ⊗ **Gastrointestinal surgery**
- ⊗ Bariatric surgery
- ⊗ Digestive surgery
- ⊗ Colorectal surgery
- ⊗ Biliopancreatic surgery
- ⊗ Hepatic surgery
- ⊗ Transplant surgery
- ⊗ Endocrine surgery
- ⊗ **Orthopaedic surgery**
- ⊗ Arthroplastic surgery
- ⊗ Hands surgery
- ⊗ Elbow surgery
- ⊗ Shoulder surgery
- ⊗ Hip surgery
- ⊗ Knee surgery
- ⊗ Ankle / foot surgery
- ⊗ **Otorhinolaryngological surgery**
- ⊗ Lateral skull base surgery
- ⊗ Facial plastic surgery & anterior skull base surgery
- ⊗ Head & neck surgery
- ⊗ Neurological surgery
- ⊗ Complex Spine Surgery
- ⊗ Functional Neurosurgery incl. Restorative Neurosurgery
- ⊗ Stereotactic Neurosurgery
- ⊗ Neurosurgical Oncology
- ⊗ Neurointerventional surgery
- ⊗ Stereotactic Radiosurgery
- ⊗ **Other surgeries**
- ⊗ Paediatric surgery
- ⊗ Maxillofacial surgery
- ⊗ Kidney surgery
- ⊗ Robotic surgery
- ⊗ Plastic, reconstructive and aesthetic Surgery
- ⊗ Plastic Surgery within the head and neck
- ⊗ Urological surgery
- ⊗ Uroncologic surgery

- Female pelvic reconstructive surgery
- Sexual / gender surgery
- Breast surgery
- Surgery - wound healing

**18. Do you have experience in Geriatrics?**

- YES
- NO

**19. Do you have experience in Genetics?**

- YES
- NO

If applicable, select the most appropriate competence(s) in Genetics:

- Cancer genetics
- Cardiogenetics
- Development genetics
- Immunogenetics
- Neurogenetics
- Ophthalmogenetics
- Acquired/cancer genetics
- Biochemical genetics
- Constitutional genetics

**20. Do you have experience in Medical oncology?**

- YES
- NO

**21. Do you have experience in Nephrology?**

- YES
- NO

If applicable, select the most appropriate competence(s) in Nephrology:

- Hemodialysis
- Hemofiltration & Hemodiafiltration
- Peritoneal Dialysis (e.g. CAPD & APD)
- Plasmapheresis & apheresis techniques in general
- Immunoabsorption

**22. Do you have experience in Neurology?**

- YES
- NO

If applicable, select the most appropriate competence(s) in Neurology:

- Autonomic nervous system disorders
- Clinical neurophysiology

- Epilepsy
- Headache
- Neuro-critical care
- Neuro-rehabilitation
- Pain panels
- Sleep-wake disorders
- Stroke

**23. Do you have experience in Clinical neurophysiology?**

- YES
- NO

If applicable, select the most appropriate competence(s) in Clinical neurophysiology:

- Ageing and dementia
- Autonomic nervous system and its disorders
- Deep brain stimulation (DBS)
- Epilepsy
- Intraoperative neuromonitoring (IOM)
- Motor control and movement disorders
- Motor neuron disorders
- Neuromuscular disorders/Peripheral neuropathies
- Pain and small fibre neuropathy assessment
- Psychophysiology/cognition
- Sleep/Sleep disorders and disorders of consciousness
- Therapeutic non-invasive brain stimulation (NIBS)
- Visual system

**24. Do you have experience in Obstetrics & Gynaecology?**

- YES
- NO

If applicable, select the most appropriate competence(s) in Obstetrics & Gynaecology:

- Gynaecology Oncology
- Maternal- foetal medicine
- Reproductive Medicine
- Urogynaecology

**25. Do you have experience in Ophthalmology?**

- YES
- NO

If applicable, select the most appropriate competence(s) in Ophthalmology:

- Cataract and refractive surgery
- Cornea
- Glaucoma
- Medical retina

- Oculo-plastics and orbita
- Strabismus
- Vitreo retinal surgery

**26. Do you have experience in Orthopaedics & Traumatology?**

- YES
- NO

If applicable, select the most appropriate competence(s) in Orthopaedics & Traumatology:

- Orthopedic Degenerative Diseases
- Robotics
- Sports Medicine
- Traumatology / Accidents

**27. Do you have experience in Otorhinolaryngology?**

- YES
- NO

If applicable, select the most appropriate competence(s) in Otorhinolaryngology:

- Audiological Science
- Audiology
- Auditory Implantation Otology
- Laryngology
- Neuro-Otology
- Otology
- Rhinology

**28. Do you have experience in a medical field relevant for this call in combination with Paediatrics?**

- YES
- NO

If applicable, select the most appropriate competence(s) in Paediatrics:

- Adolescent medicine
- Neonatal-perinatal medicine
- Paediatric cardiology / GUCH
- Paediatric critical care medicine
- Paediatric emergency medicine
- Paediatric endocrinology
- Paediatric gastroenterology
- Paediatric hematology-oncology
- Paediatric hospital medicine
- Paediatric infectious diseases
- Paediatric rheumatology
- Paediatric transplant hepatology
- Paediatric orthopaedics



- Paediatric dentistry
- Paediatric pathology
- Paediatric neurosurgery
- Paediatric rehabilitation medicine
- Paediatric otorhinolaryngology
- Paediatric respiratory diseases

**29. Do you have experience in palliative care?**

- YES
- NO

**30. Do you have experience in pharmacology?**

- YES
- NO

**31. Do you have experience in physical medicine & rehabilitation?**

- YES
- NO

If applicable, select the most appropriate competence(s) in physical medicine & rehabilitation:

- Brain injury medicine
- Neuromuscular medicine
- Pain medicine
- Spinal cord injury medicine

**32. Do you have experience in psychiatry?**

- YES
- NO

If applicable, select the most appropriate competence(s) in psychiatry:

- Addiction Psychiatry
- Affective / mood disorders
- Child and Adolescent Psychiatry
- Computational psychiatry
- Digital medicine (psychiatry)
- Forensic Psychiatry
- Geriatric Psychiatry
- Obsessive compulsive disorder (OCD)
- Psychiatric genomics
- Psychosis

**33. Do you have experience in radiation oncology & radiotherapy?**

- YES
- NO

**34. Do you have experience in respiratory medicine or pulmonology?**

- YES
- NO

If applicable, select the most appropriate competence(s) in respiratory medicine or pulmonology:

- Airway diseases
- Interstitial Lung Diseases (ILD)
- Occupational & environmental diseases
- Pleural diseases
- Public health & prevention of respiratory disease
- Pulmonary vascular diseases
- Respiratory Critical Care
- Respiratory Infections
- Respiratory physiology
- Sleep and breathing disorders
- Thoracic oncology

**35. Do you have experience in rheumatology?**

- YES
- NO

**36. Do you have experience in urology?**

- YES
- NO

If applicable, select the most appropriate competence(s) in urology:

- Urogynecology / Functional Urology
- Endourology

#### 4.2 Other scientific, technical and/or clinical areas relevant to the call

Please indicate your professional experience in other scientific, technical and/or clinical areas relevant to the call, i.e. with relevance for medical or *in vitro* diagnostic devices.

- Analytical instrumentation (e.g. mass-spectrometry, NMR, etc)
- Artificial intelligence
- Biocompatibility
- (Bio)electronics / electromagnetic compatibility
- Bioinformatics
- Biomaterial – Materials science
- Biomechanics
- Biomedical engineering / Clinical engineering
- Biomedical optics
- Bionics
- (Bio)statistics
- Biotechnology (e.g. genetic engineering, gene sequencing, etc.)
- Clinical pharmacy
- Clinical trials methodology
- Computational biology
- Cybersecurity
- Digital medicine
- Epidemiology
- Fluid mechanics
- Human factors / Patient Involvement
- Intensive Care Medicine
- Medical / Health informatics
- Medical device software
- Medical device sterilization and disinfection
- Medical ethics
- Midwifery
- Nanotechnology
- Neural engineering
- Nursing
- Omics
- Optometry
- Quality assurance
- Radiation protection
- Regenerative medicine
- Rehabilitation engineering
- Robotics
- Standardization (contribution to development of common specifications & standards)
- Tissue engineering
- Toxicology

#### 4.3 Ongoing experience in medical, scientific or technical areas relevant to the call

Applicants are requested to describe their ongoing expertise in areas relevant for this call, i.e. with relevance for medical or *in vitro* diagnostic medical devices. Please describe the nature of your work, the field of activity, your specific role(s) and responsibilities in the specified areas.

## **5. Device-specific and other expertise**

### 5.1 Device-specific expertise

Please list your ongoing practical experience with the use of medical devices or *in vitro* diagnostic medical devices (IVDs), clinical investigation with medical devices or performance evaluations of IVDs, Research and Development of medical devices or IVDs, and reporting or analysis of medical device problems or failures. Please list top 3 devices or groups of devices and years of experience.

#### 1. Type of device

- ⊗ Medical device (go to 1.2 – 1.5)
- ⊗ *In vitro* diagnostic medical device (go to 1.6 – 1.7)

1.1 Description of devices: \_\_\_\_\_

1.2.a Years of hands-on experience with the use of this medical device

1.2.b Indicate your average number of cases/ year:

1.3 Years of experience with clinical investigations:

1.4 Years of experience in Research and Development of medical devices:

1.5.a Years of experience with reports or analysis of medical device problems or failures:

1.5.b Indicate the average number of cases/ year:

1.6 Years of hands-on experience with quality assurance/standardisation of IVDs:

1.7 Years of experience in Research and Development related to design and validation of IVDs and IVD related reference systems:

## 5.2 Other selection criteria

Applicants are requested to describe how they fulfil the selection criteria. Please describe how you fulfil the selection criteria for this call and if applicable the nature of your work, the field of activity, your specific role(s) and responsibilities in the specified areas.

1.) Scientific impact of relevance to high risk medical devices (e.g. 20 most relevant publications, number and impact factor of publications), chairmanship in professional societies, prizes and honours

2.) Experience in providing scientific advice and with analysing or reviewing complex information

3.) Experience in working in committees / organisation committees / expert groups

4.) Experience in a multi-disciplinary / international environment

5.) Experience as chairperson or coordinator (management of groups to deliver quality outputs and keeping deadlines)

6.) Experience in regulatory affairs of medical devices or *in vitro* diagnostic medical devices

7.) Experience in regulatory affairs of medicinal and/or combination products

## **6. Roles, tasks and availability**

Understanding the roles and tasks of the expert panels, as well as the required commitment I express the following availability or preference:

### a) Availability

- Up to 2 days per month
- Up to 3 days per month
- 3-5 days per month
- 6-10 days per month

### b) Roles

- I am available to act as a Chair or Vice-chair<sup>3</sup>

### c) Indicate which expert panel best fits your expertise<sup>4</sup>

- Orthopaedics, traumatology, rehabilitation, rheumatology
- Circulatory system
- Neurology
- Respiratory, anaesthesiology, intensive care
- Endocrinology and diabetes
- General and plastic surgery, Dentistry
- Obstetrics and gynaecology, including reproductive medicine
- Gastroenterology and hepatology, Nephrology and urology
- Ophthalmology
- In-vitro diagnostics (IVDs)
- I have horizontal expertise applicable to more than one panel

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<sup>3</sup> Candidates are informed that the estimated required monthly availability would be at least 3 days

<sup>4</sup> This preference will be used to group applications during the evaluation phase and cannot be understood as an application specifically for the chosen panel.

## **7. Acknowledgement of terms**

To complete the application, please tick the following statements:

- ⊗ If selected for appointment as advisor to an expert panel, I give consent for inclusion and publication of my name as expert panel member.
- ⊗ If selected, I will respect confidentiality and not divulge information acquired as a result of my work for the expert panels.
- ⊗ If selected, I will make a commitment to act independently and in the public interest.
- ⊗ If selected, I will participate in the activities of the expert panels on a regular basis. I will actively contribute to scientific discussions, examination of documents and drafting of opinions. I am available to attend physical meetings on invitation.
- ⊗ If selected, I am willing to act as rapporteur or co-rapporteur on a rotating basis with other expert panel members.
- ⊗ I am aware that I need to make complete declarations of any direct or indirect interests in the medical device industry that might be considered prejudicial to my independence and that this declaration will be made public (in accordance with MDR, Art. 106 (3) and Art 107). I am also aware that any financial interest or other interest that could affect my impartiality will exclude me from certain activities of the expert panels.
- ⊗ I am aware that a minimum availability of typically 2-3 working days per month is expected from expert panel members.
- ⊗ I am willing to work with electronic methods for the management and exchange of documents and also to attend meetings (by audio or video).
- ⊗ I declare that the information provided above is true and complete. I have carefully checked that the attached documents are correct.
- ⊗ In case my application is found both eligible and apt but did not lead to an appointment in one of the expert panels, I give consent for inclusion and publication of my name on the central list of available experts.

## **8. Submission and upload**

Each application shall include the following documents:

- A completed application form;
- A curriculum vitae (CV), not exceeding four pages. Applicants may use the European format (<https://europass.cedefop.europa.eu/en/documents/curriculum-vitae/templatesinstructions>);
- A copy of your national ID or passport as proof of citizenship;
- A declaration of interests ('DOI') form on the basis of the standard DOI form for expert groups attached to this call.