Survey on expert panels

Aim and context of the survey

This survey is targeted at Member States, industry, notified bodies and other stakeholders and aims at retrieving information and views relevant for the establishment and running of **expert panels** (MDR* Article 106).

The survey draws on a scoping paper produced by JRC in consultation with DG GROW, which provides more detailed information on some aspects of the survey (areas of competence relevant for defining a landscape of expert panels, selection criteria, roles, practical steps towards their establishment, detailed workflows, estimates of their workload etc.).

This survey has been designed to collect information from relevant parties and to gauge their opinions, views and preferences, in view of the establishment of expert panels in agreement with the provisions of the MDR and IVDR:

- According to MDR* Article 106(1) the Commission shall make provisions for the designation of expert panels for the assessment of the clinical evaluation of certain high risk medical devices (MDR* Article 54(1)) and to provide views on the performance evaluation of certain in vitro diagnostics (IVDR** Article 48(6)). Recipient of the panels' advice in this regard are notified bodies.
- Expert panels shall also provide advice to the Medical Device Coordination Group (MDCG), the Commission and Member States as outlined in MDR* Article 106(11) and IVDR** Article 50(3),

- Additionally, expert panels shall advice manufacturers if they wish consultation prior to clinical evaluation and/or investigation (MDR* Article 61(2)).

- Expert panels may have a variety of tasks (MDR Article 106(10), depending on the requisite needs, e.g. contribution to guidance and common specifications, to develop and review clinical and performance evaluation guidance in relation to conformity assessment, to contribute to the development of standards, and to contribute to the identification of concerns and emerging issues on safety/performance of devices.

- Expert panels shall consist of advisors appointed by the Commission on basis of their up-to-date clinical, scientific or technical expertise and the Commission shall determine the number of members of each panel in accordance with the requisite needs (MDR* Article 106(3)).

- The Commission may recover the cost of their advice by fees that are payable by manufacturers and notified bodies (MDR* Article 106(13)) and the fee structure needs to be set in a transparent manner (MDR*Article 106(14)).

*) MDR = Medical Device Regulation (EU) 2017/745

**) IVDR = In vitro Diagnostics Medical Device Regulation (EU) 2017/746

You are kindly requested to complete this survey as far as possible for you. If you cannot answer certain questions please leave them blank and continue with the next one.

Please reply by 24 August 2018

Organisation's name and address

Legal name of organisation

TEDDY - EUROPEAN NETWORK OF EXCELLENCE FOR PAEDIATRIC CLINICAL RESEARCH

Address

via Luigi Porta 14

Country

Italy

Functional email

scientificsecretariat@teddynetwork.net

Section 1: Specialisation of expert panel

QUESTION 1: The table below lists clinical specialisations and technical competences that may be of relevance for the CECP (Clinical Evaluation Consultation Procedure) and PECP (Performance Evaluation Consultation Procedure, i.e. expert panel views on performance evaluation of class D in vitro diagnostics) procedures as well as other needs (Article 106). Could you please prioritise these specialisations/competences on a scale from 1 (low priority) to 10 (high priority) and provide your reasoning where appropriate.

Clinical areas (CECP)

	Priority	Your reasoning
1 - Skeletomuscular & Orthopaedics (Orthopaedic and rehabilitation devices)		
2 - Circulatory system & Cardiology (including vascular and lymphatic system)		
3 - Central & peripheral nervous system		
4 - Ear, nose, throat (otorhinolaryngology)		
5 - Ophthalmology		
6 - Dentistry		
7 - Endocrinology & diabetes		
8 - Obstetrics & gynaecology		
9 - Gastroenterology / Urology / Nephrology		
10 - General & plastic surgery		
11 - General Hospital & wound care		

IVDs (PECP)

	Priority	Your reasoning
12 - Blood grouping & Tissue typing		
13 - Infectious agent testing		

Technologies & horizontal issues

	Priority	Your reasoning
14 - Software, apps, artificial intelligence & cybersecurity, robotics		
15 - Bioinformatics		
16 - Innovative technologies (e.g. new design, materials, production processes, clinical procedures)		

Areas that should be added in your opinion

	Name	Reason
17	Paediatrics	There are specific issues about the science, usability, and research of devices and in vitro diagnostics in neonates, children and young people. Science: Many conditions are unique to neonates, children and young people. Illnesses present differently in these age groups. The natural history of many illnesses differs between age-groups. Usability: the size of individuals varies 100-fold between neonates and adolescents (from 500g to 50kg). The size of users has marked effects on relevance and practicability of devices and in vitro diagnostics. For example, the maximum allowable size of blood samples in neonates may be 100 microliter and this requires the development of specific technologies. Research. Neonates, children and young people cannot give consent and may have extra vulnerabilities compared to other populations. Furthermore, as mentioned above, methodological issues should be also considered possibly affecting research and use in clinical practice of devices. Experience accumulated in medicines for children sector, with reference to alternative study design, reduction of experimental population, choice of adequate outcomes/endpoints and timepoints, etc could be of help in guiding studies' conduct and evaluation process. This requires specific expertise in the design and conduct of

		studies. Experience with medicines demonstrates that evaluation of science, usability and research requires specific paediatric expertise. Experienced assessors with limited paediatric knowledge can make poor decisions about medicines used in children.
18		
19		

QUESTION 1b: Please make proposals for a possible expert panel landscape in the table bel
priority) to 10 (high priority) and the expected workload of each suggested panel.

	Name	Priority level
1	Paediatrics	1
2		
3		
4		
5		
6		
7		
8		

QUESTION 1c: Do you have any further comments or suggestions?

Neonates, children and young people are not “small adults”. For this reason, we need specialists in paediatrics with documented expertise in paediatric research methodology and evaluation procedures, clinical studies and healthcare processes.
A special attention should be also draw to children affected by chronic diseases and disabilities, including genetic and rare diseases, with extra vulnerabilities and possibly increased need of devices. For these subjects, paediatric experts should be also addressed.

Section 2: Assessment of workload of expert panels in relation to routine regulatory procedures

In order to assess the number of experts with a certain profile as well as in order to gauge possible budgetary requirements for expert reimbursement, robust information is required on **the number of dossiers that need to be processed as a matter of routine regulatory procedures in the context of expert panel advice to notified bodies concerning the clinical and performance evaluation of high risk devices.** For this purpose we would like to ask you kindly to provide us with data and/or estimates concerning the number of dossiers for the last two years (2017 and 2016) which would – under MDR and IVDR – qualify for the

- **Clinical Evaluation Consultation Procedures (CECP)** for implantable medical devices of class III and class IIb devices intented to administer and/or remove medicinal products, body liquids or other substances from the body (as requested by MDR Article 54; Annex VIII, Rule 12; Annex IX Section 5.1).
- **The process for "views on performance evaluation" (PECP)** for IVD class D devices which are subject to a first certification and for which no Common Specifications do exist and (IVDR Article 48).

QUESTION 2a: Information on the number of dossiers qualifying for the clinical evaluation consultation procedure according to MDR Article 54.

Please insert figures or ranges in the following table. If you have proposed additional areas of expertise to be covered in Question 1a, please use the corresponding lines below.

Please take into account that two of the three derogation/exemption provisions will likely not be applicable at the initial phases of implementation. These are MDR 54(2)(a) relating to renewal of MDR certificates and MDR 54(2)(c) relating to availability of Common specifications.

Clinical areas (CECP) - Suggested areas of clinical / technical specialty

	Number of dossiers i
1 - Skeletomuscular & Orthopaedics (Orthopaedic and rehabilitation devices)	
2 - Circulatory system & Cardiology (including vascular and lymphatic system)	
3 - Central & peripheral nervous system	
4 - Ear, nose, throat (otorhinolaryngology)	
5 - Ophthalmology	
6 - Dentistry	
7 - Endocrinology & diabetes	
8 - Obstetrics & gynaecology	
9 - Gastroenterology / Urology / Nephrology	
10 - General & plastic surgery	
11 - General hospital & wound care	

Areas that should be added in your opinion

	Name	Reason
A	Paediatrics	
B		
C		
D		
E		

QUESTION 2b: Could you please provide an estimate on the percentage of the clinical evaluation consultation procedures that will be concluded by the expert panels with the supply of a scientific opinion?

Due to the lack of previous experience, a precise estimation is not possible. However, considering that the use of medical devices is going to increase, we could estimate a percentage of 30% of procedures including a paediatric interest.

QUESTION 2c: Could you please provide your views to which extent the availability of Common Specifications may reduce the number of dossiers that have to be processed through the CECP involving expert panels. Will this affect all clinical areas in the same way? What should be priority areas for the development of Common Specifications?

Common Specifications could be generally recommended. A survey investigating the current status of medical devices use in the paediatric population could be planned in order to identify needs and priorities.

QUESTION 2d: Information on the number of dossiers qualifying for the PECP according to IVDR Article 48.

Could you please provide an estimate (number or range) for the number of IVD medical devices that would have been qualified for the performance evaluation consultation procedure based on your data for 2016 and 2017?

Please insert figures or ranges in the following table. If you have proposed additional areas in Question 1, use the corresponding lines below. We are aware of the difficulty to provide such data, but they will provide at least an indication of the possible workload.

In the case of in vitro diagnostic medical devices the existing Common Technical Specification (CTS), applicable under IVDD, might become available as Common Specifications (CS), applicable under IVDR, in time to reduce the workload for the concerned expert panels.

IVDs ('PECP') - Suggested areas of clinical / technical specialty

	Number of dossiers in 2016 Without CS	Number of dossiers in 2016 With CS	Number of dossiers in 2017 Without CS	Number of dossiers in 2017 With CS
12 - Blood grouping & Tissue typing				
13 - Infectious agent testing				

Areas that should be added in your opinion

	Name	Reason
F		
G		
H		
I		
J		

Section 3: Working days per expert per year

Typically, experts, especially clinicians, will be active in their profession and hence have limited capacity to contribute to expert panel work. For experts that are employed there may be further contractual constraints with regard to additional work to be taken up by the expert.

QUESTION 3: How many days per year are experts expected to be available for expert panel tasks?

- ○ Up to 20 days per year
  (This corresponds to about 10% of the annual work time of an expert, when considering their current professional activities, holidays and other obligations such as participation in conferences)
- ◉ 20 to 30 days per year, striving for keeping an average of 24 days (two per month)
- ○ More than 30 days per year

Do you have any comments or suggestion?

With regards to paediatrics as well as to other specialities, as this is a new process, the competent authorities should plan a set of training activities both at national and at EU level.

Section 4: Size of expert panels

A preliminary estimate of the workload related with the CECP indicates that for certain fields such as orthopaedic and cardiology up to 40 experts might be required to distribute the workload, assuming that an individual expert cannot spend much more than 2 full working days per month. An expert panel of such size is difficult to manage and it may take more time than available to reach consensus. This may also require that the chairperson shares his work with one or more vice-chairpersons if the panel has to deal with several procedures simultaneously. An alternative could be to establish several smaller panels which can be handled following the same rules and procedures, e.g. splitting cardiological devices into electronic devices (pacemakers and defibrillators) and heart valves/stents and others.

QUESTION 4a: Which of the following options do you prefer?

The availability of experts will limit the number of procedures that can be processed per year by a single panel with a certain number of members. There are several mitigation strategies conceivable.

- (●) More than one panel for the same clinical specialty (dealing with different types of products though).
- ( ) One larger panel that allows distributing work to more members
- ( ) None of these.

Could you provide your reasoning and possibly indicate other options:

All specialties need a subpanel that deals with neonates, children and young people, as well as in paediatric research methodology and evaluation procedures, clinical studies and healthcare processes.

QUESTION 4b: What would you, generally, consider the adequate size of a single expert panel?

- ( ) 9 experts
- ( ) 11 experts
- ( ) 15 experts
- ( ) Other number

Please provide your reasoning:

Section 5: Conflicts of interest

QUESTION 5a: Do you consider one of the following situations as constituting a possible conflict of interest for a member of an expert panel? Please provide your reasoning.

1 - Acting currently as coordinator of a clinical trial/investigation sponsored by industry (manufacturer or competitor) for the same or a similar type of device?

(●) Yes ( ) No

Comments:

2 - Acting currently as coordinator of a clinical trial/investigation sponsored by industry for a different type of device?

○ Yes ◉ No

Comments:

3 - Acting in the past as coordinator of a clinical trial sponsored by industry?

○ Yes ◉ No

Comments:

What would be adequate waiting periods regarding past involvements as coordinator?

4 - Involvement in a clinical trial sponsored by industry without decision making power in the trial?

◉ Yes ○ No

Comments:

5 - Working occasionally* as a consultant for industry? (*occasionally shall mean not at present and not for only one company)?

○ Yes ◉ No

Comments:

6 - Holding patents on medical device technology / procedures with or without commercial valorisation as of yet?

◉ Yes ○ No

Comments:

QUESTION 5b: Do you see other situations that could constitute a conflict of interest? How could they be controlled or managed? Do you have further comments or suggestions?

The expert is involved in a clinical trial sponsored by industry with a decision making power in the trial. Conflicts of interest may be controlled/managed as EMA is used to do.

QUESTION 5c: Do you agree or not agree with the following measures to manage a possible conflict of interest?

	Agree	Do not agree
1 - An expert should not get access to dossiers if he has a link* to the sponsor of the trial.	◉	○
2 - If an expert has a link* to a certain company he should not get access to dossiers of trials sponsored by a competitor.	◉	○
3 - The number of CECP/PECP procedures for which a single expert is executing the task of rapporteur or co-rapporteur per year should be limited.	○	◉

* Links could include for example holding common patents, ongoing involvement in clinical trials/investigations with decisional power concerning the same or similar type of devices, or involvement in such trials in the past.

Do you have any comments or suggestion?

Section 6: Professional profiles, qualifications and competences of experts

Experts for the expert panels shall be selected on the basis of their up-to-date clinical, scientific and technical expertise. This implies a multidisciplinary composition. Geographical distribution and gender balance will be other factors. The table below shows relevant professional backgrounds of experts. Please indicate your preferred representation of these backgrounds in %? You can add expertise you would like to see in the expert panels (+). Please note that some profiles might be shared between

several expert panels if they are available in the foreseen central list of advisors from which temporary appointments can be made to expert panels to deal with specific CECP or PECP procedures. You may indicate profiles for which this option is sufficient.

The experts on central list of advisors must fulfil the same high criteria as the experts appointed to the standing expert panels. Moreover, the central list of advisors must comprise experts with the same level of expertise in the same areas that are covered by the standing expert panels. In this way experts leaving a panel can be replaced by appointments from the central list avoiding the publication of a new call for experts. Additionally, the central list of advisors must cover a much broader range of expertise than that required for the panels in case that highly specialised knowledge will be requested e.g. in different medical disciplines, in engineering disciplines or concerning software and electromagnetic compatibility. To ensure equal quality standards, the experts that will be appointed to an expert panel and the experts that will be nominated for the central list of advisors have to be selected in the same call following the same criteria.

QUESTION 6a: Please indicate the preferred distribution of professional backgrounds

	Percentage of representation in panel on a permanent basis	Temporary assignment from central list of advisors is sufficient (Yes/No)	Your reasoning / comments
1 - Clinicians of various specialisations			
2 - Biomedical engineers			
3 - Biomaterials scientists			
4 - Life scientists			
5 - Statistician			
6 - Modelling experts (i.e. in silico methods)			
7 - Artificial intelligence, machine learning, deep learning, etc.			
8 - Robot technology			
9 - Biometrics			
10 - Software and programming			

Additional professional profiles you would like to see in the expert panels

	Name	Reason
11	Methodology of research	
12	Regulatory	
13		
14		
15		

QUESTION 6b: Areas of clinical speciality

The call for members of expert panels will likely refer to recognised professional qualifications in specialised medicine (medical specialty areas) and other regulated professions as laid down in the Directive 2005/36/EC of the European Parliament and of the Council 7 September 2005 on the recognition of professional qualifications amended by Directive 2013/55/EU of the European Parliament and the Council. (See https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32005L0036&from=EN, see especially Article 24-37 and Annex V).

Do you agree with using the Directive's terminology of specialities for the purposes of the call?

(●) Yes ( ) No

Your comments / suggestions:

Paediatrics needs to be added, taking account that different expertise is needed for neonates, children and young people.

Section 7: Selection criteria for members of expert panels

Experts shall be selected “on the basis of up-to-date clinical, scientific, or technical expertise in the field and with a geographical distribution that reflects the diversity of scientific and clinical approaches in the Union” (MDR 106(3)). The following table compiles several assessment criteria that could be used to evaluate these selection criteria in a transparent and verifiable way.

QUESTION 7: Could you please judge the suitability of the compiled criteria and assign a weight to them using “high”, “middle”, low”? If you consider a criteria as not adequate could you please provide your reasoning.

	high	middle	low	not adequate
1 - Number of years in the discipline the expert applies for	(●)	( )	( )	( )
2 - Scientific impact (e.g. number, quality and impact of publications)	(●)	( )	( )	( )

3 - Technological impact (No. of patents)	○	◉	○	○
4 - Experience in regulatory affairs	◉	○	○	○
5 - Experience in working in committees / organisation committees / expert groups	◉	○	○	○
6 - Experience as chairperson (management of groups to deliver high quality reports and keeping deadlines)	○	◉	○	○
7 - Experience in multicultural/international expert groups	○	◉	○	○
8 - Mastering of English language and communication skills	◉	○	○	○
9 - Experience in providing scientific advice	◉	○	○	○

If not adequate please provide your reasoning

Additional criteria you would like to add

	Criteria	Reason
10		
11		
12		
13		
14		

If you have further comments or would like to suggest a different approach:

If you have further comments or would like to suggest a different approach:

Section 8: Decision criteria of expert panels

Expert panels need to decide, under the supervision of the Commission, whether or not to provide a scientific opinion on a given clinical evaluation dossier in the context of the 'Clinical Evaluation Consultation Procedure' (e.g. MDR Annex IX, Section 5.1). To reach this decision, expert panels must take three criteria into account: (1) the novelty of the device or related clinical procedure and the clinical / health impact, (2) significant adverse change in the benefit-risk profile of a category or group of devices, (3) significant increased rate of serious incidents.

QUESTION 8: Please provide your views on the application of these criteria including how expert panels' access to relevant information could be facilitated, bearing in mind that the timeline for decision-making is only three weeks.

The regulatory agency should provide a continuous support and a remote access to documents.

Contact

JRC-MEDICAL-DEVICES@ec.europa.eu