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Multi-stakeholder Platform Advisory Group (MSP Advisory Group) mandate and rules of procedure

1. Introduction

The Multi-stakeholder Platform Advisory Group (MSP Advisory Group) forms part of the ACT EU multi-stakeholder platform (ACT EU MSP), which aims to provide regulators and stakeholders with a platform to exchange views on clinical trials. The MSP brings the views from stakeholders into the ACT EU initiative through the work of the MSP Advisory Group, the organisation of ACT EU multi-stakeholder events and stakeholder consultations.

This document outlines the MSP Advisory Group's mandate and rules of procedures.

2. Mandate and objectives

The MSP Advisory Group brings together key stakeholder groups who are directly impacted by clinical trial-related activities in the EU. It offers these groups the opportunity to meet with ACT EU's regulatory partners and ethics committees representatives on a regular basis in order to increase collaboration and build mutual trust and contribute to improving the EU clinical trials landscape.

Topics for discussions at the MSP Advisory Group encompass all aspects of clinical trials, including design, conduct, statistical analysis, proposals for revision of regulation(s), transparency of data and patient engagement.

By ensuring a balanced representation of views and interests from all stakeholders, the MSP Advisory Group provides insight into the perspectives and needs of the different stakeholder groups and allows stakeholders to provide strategic and operational advice regarding ACT EU.

The MSP Advisory group composition, mandate and rules of procedures are subject to revision every 3 years.

3. MSP Advisory Group

3.1. Composition

The MSP Advisory Group is formed mainly by nominated permanent stakeholder representatives (and their alternates) with the possibility to include *ad hoc* representatives based on the topics of discussion (see Annex 3). This allows the participation of other non-permanent stakeholder organisations, international bodies, health technology assessment (HTA) bodies and payers, where relevant.

Each stakeholder organisation nominates one MSP Advisory Group permanent representative in addition to an alternate representative, who shall replace the permanent representative when the latter is unable to attend MSP Advisory Group meetings.

It is recommended that each appointed representative (permanent and ad hoc) participates to the meetings on behalf of one organisation only.

The MSP Advisory Group composition is adopted by the ACT EU Steering Group, while the mandate and rules of procedures are revised and agreed by the Advisory Group itself.

The MSP Advisory Group has two chairpersons (hereafter referred to as the regulatory co-chair and the stakeholder co-chair), one representing the ACT EU regulatory partners (regulatory co-chair) and the other representing the stakeholder groups (stakeholder co-chair).

The MSP Advisory Group also includes participation from the ACT EU regulatory partners (EC/HMA/EMA) with relevant ACT EU priority action representatives joining the discussions as needed. This promotes dialogue between regulators and stakeholders, while maintaining strong links to the relevant ACT EU initiatives. The inclusion of ACT EU regulatory partners also enhances the exchange of information between the MSP Advisory Group and other European regulatory clinical trial expert groups such as the Clinical Trials Coordination Group (CTCG) or the European Commission Clinical Trials Expert Group (CTEG) and Clinical Trials Coordination and Advisory Group (CTAG).

Additionally, the MSP Advisory Group includes two ethics committee representatives therefore acknowledging the important complementary initiatives taking place between ACT EU and ethics bodies.

The Advisory Group has a secretariat that provides operational support.

3.1.1. Roles and responsibilities

Participation in the MSP Advisory Group activities requires commitment from the representatives to actively participate in the group's work. Each stakeholder organisation contributes to the MSP Advisory Group's work by:

- providing the ACT EU Steering Group with their views and strategic advice on the ACT EU multi-annual workplan;
- identifying stakeholder needs, concerns, challenges and priorities, and communicating these to the ACT EU regulatory partners;

- advising ACT EU regulatory partners on stakeholder engagement and communication;
- reviewing and agreeing on the mandate, workplan and any governance-related documents of the advisory group;
- keeping their respective stakeholder group informed of the output from ACT EU MSP initiatives and overall ACT EU activities.

The discussions within the MSP Advisory Group are of a non-confidential nature and do not refer to any ongoing medicine specific evaluations, however each non-commercial representative shall complete a public declaration of interests and be included in the Agency's Experts database for transparency purposes.

Participation of non-commercial representatives are reimbursed in line with EMA's delegates reimbursement policies[1].

If the appointed stakeholder organisation is not represented at three consecutive meetings (either physically or remotely), the ACT EU Steering Group may consider a replacement from another organisation.

3.1.2. Selection of stakeholders

Representatives of the MSP Advisory Group stakeholder organisations are selected via a public call for expression of interest. The following representations are included:

1. Patients/consumers: 5 selected from relevant organisations, including PCWP[2];
2. Healthcare professionals: 4 selected from relevant organisations, including HCPWP[3];
3. Pharmaceutical industry EU trade organisations: 4 selected from relevant organisations;
4. Non-commercial European clinical data and translational research organisations and networks: 4 selected from relevant organisations;
5. Research funders: 4 selected from relevant organisations.

Additional extension to other stakeholder groups shall be considered based on the experience gathered during the first mandate of the group.

For additional information on how MSP Advisory Group stakeholders representatives are appointed please refer to Annex 2.

3.1.3. Replacement of stakeholder representatives

If there is need to replace a stakeholder representative, the MSP Advisory Group secretariat should be informed as soon as possible. The secretariat then establishes whether a suitable candidate can be selected from the list of previous nominations. If no suitable candidate can be identified, a new call for nominations is considered.

[1] Rules for reimbursement of expenses for delegates attending meetings
[2] Patients and Consumers' Working Party
[3] Healthcare Professionals' Working Party

The ACT EU Steering Group is informed in writing by the MSP Advisory Group secretariat of any changes to the MSP Advisory Group composition; if no objections are received within a given timeframe, the new representative is considered appointed.

3.1.4. Ethics committees, ACT EU regulatory partners and *ad hoc* expert representation

Two ethics committee representatives are directly appointed by the Clinical Trials Coordination Group (CTCG) Ethics Advisory subgroup.

The ACT EU regulatory partners, represented by priority action co-leads and coordinators, actively participate in the meetings, highlighting areas of activity where stakeholder advice is needed. This establishes a link between the MSP Advisory Group and each priority action.

Ad hoc experts are directly appointed by the relevant group and involved in MSP Advisory group meetings as per the process outlined in Annex 3.

3.2. Co-chairs and selection procedure

The MSP Advisory Group has two chairpersons, known as the regulatory co-chair and the stakeholder co-chair, who are selected for a term of at least 2 years and are responsible for ensuring the advisory group runs efficiently.

- The regulatory co-chair is a rotating position held in turn by one of the three founding organisations (EMA, HMA, EC) and is directly appointed by the ACT EU Steering Group as a representative of the ACT EU initiative.
- The stakeholder co-chair shall be selected from the non-commercial advisory group permanent and alternate representatives following a call for candidates as per procedure outlined in 3.2.1. and after agreement by the ACT EU Steering Group who considers the criteria outlined in Annex 4.

The co-chairs play a fundamental role in driving discussions and promoting balanced dialogue among MSP Advisory Group representatives and regulatory partners. In cooperation with the MSP Advisory Group secretariat, the co-chairs:

- run the MSP Advisory Group meetings;
- plan the MSP Advisory Group's work, based on the ACT EU multi-annual workplan;
- steer the discussion to achieve collaboration and consensus on issues and proposals discussed and ensure that all participants views are reflected in the meeting highlights;
- report to the ACT EU Steering Group.

One co-chair shall deputise for the other co-chair if they are unable to chair part or all of a meeting. On such occasions the MSP Advisory Group secretariat shall be informed as soon as possible.

Should one of the co-chairs resign, the other co-chair shall take the chair until the ACT EU Steering Group has made a new appointment. Appointment of a new co-chair shall only be for the remainder of the current mandate.

3.2.1. Stakeholder co-chair selection procedure

1. A call for candidates is launched at least 3 weeks prior to the ACT EU Steering Group meeting where the selection is to take place.
2. All candidates express their interest by writing to the MSP Advisory Group secretariat before a predefined deadline, submitting a brief resume that outlines their background, experience and motivation in support of their candidature.
3. Candidatures received in accordance with the criteria outlined in Annex 4 are discussed by the ACT EU Steering Group and a decision is made on the most suitable candidate. The outcome of the decision is then communicated in writing to the selected candidate. All other candidates are also informed in writing of the outcome of the selection procedure before it is communicated to the MSP Advisory Group.
4. After appointment of the co-chair, the organisation to which the new co-chair is affiliated shall nominate a new representative to replace the co-chair as a representative in the advisory group.

3.3. MSP Advisory Group secretariat

The MSP Advisory Group secretariat supports the organisational aspects of the MSP Advisory Group by:

- organising the meetings including the drafting and maintaining of the workplan and operational documents;
- drafting of the agenda in cooperation with the ACT EU regulatory and ethics committee representatives and MSP Advisory Group co-chairs, ensuring stakeholder's requests, views and concerns are reflected in the agenda;
- drafting and disseminating meeting minutes and reporting the advice and views provided by the MSP Advisory Group to the ACT EU Steering Group;
- drafting and publishing meeting highlights on ACT EU website;
- managing the MSP Advisory Group composition and related declarations of interest;
- managing the stakeholders' selection process;
- maintaining links between the MSP Advisory group and other stakeholder groups.

4. Operations of the MSP Advisory Group

4.1. MSP Advisory Group meetings

4.1.1. Meeting frequency

The advisory group meets at least twice a year in hybrid or virtual plenary meetings. Additional *ad hoc* meetings or written consultations can take place when needed. The meetings are held in English.

Physical meetings are held at the premises of the European Medicines Agency in Amsterdam, the Netherlands. The meeting dates are proposed annually by the MSP Advisory Group secretariat and agreed with the co-chairs, in consultation with the MSP Advisory Group permanent representatives.

Upon request from a stakeholder organisation whose representative or alternate may otherwise not be able to travel to EMA, remote participation may be accommodated.

When a permanent representative of the MSP Advisory Group is unable to participate in a meeting, part of a meeting, or a specific discussion topic, they must inform both the secretariat and the nominated alternate in advance. Such declarations shall be recorded in the minutes of the meeting in question.

4.1.2. Creation of agendas, minutes and highlights

It is responsibility of the MSP Advisory Group secretariat to initiate the drafting of the agenda in line with the ACT EU multi-annual workplan.

Ethics committees, ACT EU regulatory partners together with MSP Advisory Group representatives may propose topics for consideration by the group. Topics must be submitted at least 6 weeks before the scheduled date of the next meeting. Topics must remain within the remit of the MSP Advisory Group mandate and should be linked to the ACT EU multi-annual workplan. The topics discussed are not subject to confidentiality.

The draft agenda for each meeting, and any relevant supporting document, are be circulated by the MSP Advisory Group secretariat, in consultation with the co-chairs, ideally 4 weeks before the meeting to the MSP Advisory group representatives and to the ACT EU Steering group for awareness.

Draft meetings minutes, including arising action points, are drafted by the MSP Advisory Group secretariat and circulated to MSP Advisory Group representatives with a given period for comments. Minutes are then shared with the ACT EU Steering Group before publication of the relevant highlights.

Agendas and meeting highlights are published on the ACT EU website together with other meeting-related documents (e.g., presentations).

4.2. MSP Advisory Group feedback

Upon request of ACT EU regulatory partners, the MSP Advisory Group discusses the relevant topics in agenda and provides the advice reflecting stakeholders perspectives.

Generally the advice provided is not considered a formal recommendation or position as such, however, in the case that this is requested by the EMA, HMA and/or EC, the MSP Advisory Group shall seek to reach a conclusion by consensus.

The quorum required for the adoption of a recommendation(s) or position(s), shall be reached when two thirds of the total MSP Advisory Group permanent representatives are present (physically or remotely). If, however, consensus cannot be reached and (a) representative(s) object(s) or diverge(s), this should be noted in the minutes.

5. Transparency and dissemination of information

MSP Advisory Group agendas and meeting highlights are published on the ACT EU website.

Each MSP Advisory Group representative is also expected to gather and disseminate relevant information, input and output to the other members of the represented organisation. Additional communication tools may be considered as needed.

6. Annexes

For details on the MSP Advisory Group's composition, selection procedure and other operational documents, refer to the below listed annexes.

Annex 1: MSP Advisory Group stakeholders composition

List of MSP Advisory Group permanent representative organisations

Stakeholder group	Organisation name
Patients/Consumers	Cancer Patients Europe
Patients/Consumers	European Patients' Forum (EPF)
Patients/Consumers	Rare Diseases Europe (Eurordis)
Patients/Consumers	European AIDS Treatment Group (EATG)
Patients/Consumers	European Young Person's Advisory Groups Network (eYPAGnet)
Healthcare professionals	European Society of Oncology Pharmacy (ESOP)
Healthcare professionals	European Society of Cardiology (ESC)
Healthcare professionals	European Academy of Neurology (EAN)
Healthcare professionals	European Haematology Association (EHA)
Academia	European infrastructure for translational medicine (EATRIS)
Academia	European Organisation for Research and Treatment of Cancer (EORTC)
Academia	European Clinical Research Infrastructure Network (ECRIN)
Academia	European Network of Excellence for Paediatric Research (TEDDY)
Industry EU trades	Association of Clinical Research Organizations (ACRO)
Industry EU trades	European Federation of Pharmaceutical Industries and Associations (EFPIA)
Industry EU trades	EuropaBio
Industry EU trades	European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
Research funders	Innovative Health Initiative Joint Undertaking (IHI JU)
Research funders	Dutch Cancer Society (KWF)

List of MSP Advisory Group ad hoc representative organisations

Stakeholder group	Organisation name
Patients/Consumers	World Patients Alliance
Patients/Consumers	Europa Uomo
Patients/Consumers	Parkinson's Europe
Patients/Consumers	StopDuchenne Poland Foundation/Fundacja StopDuchenne
Healthcare professionals	Drug Development (Phase 1) Programme & Clinical Trial Center, A. Gemelli Hospital
Healthcare professionals	International League Against Epilepsy
Healthcare professionals	KKS Network, KKSN/ KKS-Netzwerk e. V.
Healthcare professionals	European Association of Nuclear Medicine (EANM)
Healthcare professionals	University Medical Center Utrecht (UMC Utrecht)
Healthcare professionals	Cancer Drug Development Forum (CDDF)
Healthcare professionals	Polish Society of Child Neurologist/ Medical University of Silesia in Katowice
Healthcare professionals	European Society of Paediatric Oncology (SIOP-E)
Healthcare professionals	French Federation for Cancer Control (UNICANCER)
Academia	European Cardiovascular Research Institute (ECRI)
Academia	CoLAB TRIALS
Academia	European Forum Good Clinical Practice (EFGCP)
Academia	Paediatric Rheumatology International Trials Organisation (PRINTO)
Industry EU trades	European Federation of Statisticians in the Pharmaceutical Industry (EFSPI)
Industry EU trades	European CRO Federation (EUCROF)
Industry EU trades	Vaccines Europe

Stakeholder group	Organisation name
Industry EU trades	European Industrial Pharmacists Group (EIPG)
Industry EU trades	Medtech & Pharma Platform (MPP)

Annex 2: Process for selection of MSP Advisory Group stakeholders composition (permanent and *ad hoc* representatives)

Launch of public call for expression of interest

The public call for expression of interest is managed through the EU Survey tool and published on the ACT EU website, in addition to targeted mailings to all relevant groups. The MSP Advisory Group inbox (msp-agsecretariat@ema.europa.eu) is provided as a contact point.

The call lasts 6 weeks with extension if necessary and is addressed to all stakeholder groups: industry EU trade organisations, non-commercial European clinical data and translational research organisations and networks, patients/consumers organisations, healthcare professional organisations and research funders.

Review of nominations

Nominations are scored against the criteria outlined below and agreed on by the ACT EU Steering Group.

Criteria	Score (0: not met, 0.5: partially met, 1: met)	Remarks
Legitimacy: - Non-profit organisation established in EU/EEA with EU-wide representation/scope. - Or public or private higher education establishment with EU/EEA primary mission.	0: None of the criteria are met 0.5: between one and four of the criteria are met 1: all criteria are met	
Activities: specific interest in medicinal products with legitimate interest in the clinical trial area		
Representation: the organisation shall be representative of its members/affiliate and not represent individual entities.		
Accountability: statements and opinions of the organisation should reflect the views and opinions of its members. The organisation should ensure that the appropriate flow of information is in place to allow dialogue both ways: from and towards its members.		
Transparency: the organisation shall disclose to the EMA its sources of funding		

Criteria	Score (0: not met, 0.5: partially met, 1: met)	Remarks
both public and private by providing the name of the bodies and their individual financial contribution. Registration in **EU Transparency Registry** is also considered.		
Sectors/areas of involvement: – Pharmaceutical industry (indicate if Small Medium-sized Enterprises) – Medical devices industry – Biotechnology – Biosimilars/generic pharmaceuticals – Pharmacists – General practitioners – Nurses – Innovative therapeutic areas (indicate if oncology, unmet medical need, rare diseases) – Clinical research – Promotion of public health/healthcare standards – European research infrastructure – European research consortia funded under public research programmes – European learned/scientific	No sector provided: 0 Any sector provided: 1	Additional points may be given for specific topics requiring representation within the ACT EU advisory group (e.g., paediatrics, oncology, unmet medical needs, wide scope)

Criteria	Score (0: not met, 0.5: partially met, 1: met)	Remarks
societies, federations and networks – EU/EEA geographical representation		

Scores are then summed by organisation, and organisations ranked accordingly, taking into account any specific remark. The resulting list of permanent and *ad hoc* representatives are then agreed upon by the ACT EU Steering Group.

Inclusion of any additional stakeholder groups is considered as needed.

Annex 3: Process for involvement of *ad hoc* representatives

During the drafting of the MSP Advisory Group meeting agenda, each relevant priority action coordinator, in agreement with the relevant co-lead, is responsible for flagging the need to involve *ad hoc* representatives in the discussions.

The proposals are discussed with the co-chairs who can also provide additional input.

The secretariat follows up with the relevant *ad hoc* representatives identified during the nomination process. This is done 4 weeks in advance to allow *ad hoc* representatives to participate in the relevant meeting.

Annex 4: Criteria for screening the stakeholder co-chair candidates

Following a call for candidates as per the procedure outlined in 3.2.1 of the MSP Advisory Group mandate and rules of procedures, the stakeholder co-chair is selected from the non-commercial representatives of the advisory group and agreed upon by the ACT EU Steering Group. The following guiding criteria are used to review all candidates:

Criteria	Score (0: not met, 0.5: partially met, 1: met)	Remarks
Non-commercial organisation	0: None of the criteria are met 0.5: between one and three of the criteria are met 1: all criteria are met	
Capacity/availability to contribute		
Previous experience in chairing meetings with one or more stakeholder groups		
Experience in clinical trials, including involvement in relevant groups/platforms		