Regulation PH clinical cases 2026

1. Objectives

MSD – Merck, Sharp & Dohme has developed a continuing medical education project – PH clinical cases, aimed at collecting, selecting, and discussing PH clinical cases among medical societies in different international countries.

This project aims to encourage the clinical discussion and networking of theoretical and practical knowledge, enabling multidisciplinary discussion in these fields with a view to improving patient care.

Countries involved in this MSD project, include:

Baltics – Estonia, Latvia and Lithuania

PACE – Portugal, Czech Republic, Slovakia, Hungary, Romania

SEE – Bulgaria, Croatia, Serbia, Slovenia

2. The project:

PH Clinical cases (group 1 to 5 WHO PH groups) should be submitted via a digital platform available at phclinicalcases.com where all information regarding the project can be found.

PH clinical cases will culminate in a virtual event, to be held in November 2026 within "School of PH webinar", where the selected and highest-scoring clinical cases will be presented and discussed with an independent scientific committee.

This independent scientific committee will be responsible for voting on these clinical cases, based on specific pre-determined criteria (section 3.3), and discussing on the aforementioned virtual scientific meeting with the presenters of the selected oral presentations, where winning oral presentation will also be elected.

This committee will be composed of international PH experts, recognized in their countries, and internationally, for their extensive dedication to this field.

At the end of the project, eligible approved submitted clinical cases will be published in a digital PDF "PH clinical cases compendium 2026" to be shared with all participants and medical communities that scientifically endorsed this initiative.

3. Clinical cases elegibility criteria for submission:

    - should be **on label PH clinical cases** from any WHO group, considered relevant from a scientific perspective, worth discussing among the medical community and that will benefit from this multidisciplinary discussion and leverage clinical experience exchange and learnings.
    - Authors should consider originality, rarity, or diagnostic/therapeutic challenge, and whether the submission adds value for clinicians who deal with these conditions daily, thereby contributing to improved patient care and knowledge in these fields.

3.1. Submission of Clinical cases

3.1.1 Access and Confidentiality Website access is restricted to healthcare professionals. Registration is done through phclinicalcases.com, and the personal data provided are the responsibility of the healthcare professional, who must ensure their truthfulness, accuracy, timelines, and authenticity. Users are also responsible for maintaining the confidentiality of the personal data created for registration and submission on the website, including secure internet browsing conditions.

3.1.2 Submission Applications must be submitted via the phclinicalcases.com, in strict compliance with the following rules:

Registration:

- The author must start by registering his personal HCP (healthcare professional) data to be validated and approved to proceed with submission
    - Include the first and last name of first author, hospital role, Local HCP ID and affiliated institution (public or private);
    - The corresponding author must be indicated, along with their contact details (email address and mobile phone number);
    - Teams may include different healthcare professionals involved in the work, but at least one physician, who must necessarily be the first author. Physicians may be residents or specialists, regardless of specialty;
    - Co-authors may be included if contributed for the clinical case evaluation and discussion (submissions may include a maximum of 5 authors), however they must express their consent to the first author with their names being included, and must validate submitted content;

- Each first author may submit only one Case Report (as main author);
- Scientific committee should not be co-authors in any clinical cases;
- After 1st author data registration (upon validation to proceed with application), the application is automatically filled with 1st author inserted data.

Application:

At the time of submission, the author must choose the most appropriate category among PH clinical cases:

- WHO group 1 PAH; WHO Group 2 PH (left heart disease); WHO Group 3 PH (lung disease); WHO group 4 PH (CTEPH); WHO group 5

If the work spans more than one category, the author should select the one considered most representative for the case in question.

a) Title in English (not exceeding 150 characters including spaces)

b) Abstract of the Case Report in English (brief case description not exceeding 500 words/2500 characters), divided into:

- Introduction;
- Description;
- Discussion;
- Conclusions;
- Keywords: one to five

c) References (optional)

d) Powerpoint (PPT) file with clinical case details (up to 6 slides) – attached in PDF format:

- PPT file template should be downloaded from the platform
- A maximum of 6 slides (including title) should be prepared and submitted;
- The structure of the slides should respect the structure defined in the template;
- The PPT must be converted to PDF before submission in the platform to avoid unformatting issues
- **PDF must not exceed 25MB**

e) optional video upload (<50MB)

- It is possible to upload a video file up to a maximum of 50 MB

f) Images and personal data protection:

- Under no circumstances may the data included in the submission of Case Report allow patient identification. It is the sole responsibility of the participating clinician(s) to conceal patients' personal data and any physical features that may lead to their identification, and to obtain the necessary authorization/informed consent from the patient for the processing of their personal data, ensuring to MSD that this has been done as set out below. Confirmation of compliance will be made in the case submission form by checking the validation box stating: "I hereby formally declare that I comply with personal data protection obligations and have obtained the necessary authorizations required for its processing."
- The copyrights of submitted scientific works will be held by the authors or their employers or institutions (in accordance with the authors' respective contractual terms).
- Authors must agree with following declarations to proceed before submission:

- I hereby declare that I have read and accept the document "PH Clinical Cases 2026 Regulations".

- I formally declare that I comply with my obligations regarding the protection of personal data and that I have obtained all the necessary authorizations for their respective processing;

- I declare that, where applicable, I have obtained the consent of the healthcare provider with whom I carry out my professional activity (as an employee or in a similar capacity), and that I have obtained authorization for the use of the information (including any evidence) to which I had access in the course of such activity, for the purpose of using it in the submission of the clinical case;

- I acknowledge that it is the sole responsibility of the participating clinician(s) to conceal patients' personal data or any physical characteristics that could enable their identification, as well as to obtain the necessary authorization/informed consent from the patient for the processing of their personal data, ensuring MSD that this has been duly carried out;

- I declare that I have read and accept the terms set out in the privacy notice associated with this initiative (section 5). Should the information submitted relate to third parties, I am responsible for informing those individuals about the applicable privacy requirements;

- I authorize that any images and/or videos captured by MSD (or by communication partners) may be shared, in whole or in part, through MSD's various communication channels (project website, social media, newsletters, among others), provided that this use falls within the scope of PH Clinical Cases activities.

3.2. Submission deadlines and notification of selected applications:

The submission period for clinical cases runs from April 2026 to 30th June 2026.

The author submitting a clinical case will have to fill in a digital form with personal HCP data to be validated before being allowed to proceed with the clinical case submission.

When receiving the confirmation of registration, submissions must be made by completing the dedicated digital form available on the official platform phclinicalcases.com, including an abstract and a PPT file (converted to PDF), with clinical case details. A video may be uploaded if considered relevant clinically to evaluate the case.

Voting on the Clinical cases by the scientific committee will take place until 30th August, 2026.

Within 15 days after final voting results, MSD will contact the authors selected by the Scientific Committee for Oral Communication, to take place at the scientific virtual meeting happening in November 2026 (date TBD).

All authors of selected Clinical cases must submit their Presentation (for Oral Communication) on the website where they submitted their application (phclinicalcases.com) according to an established deadline that will be communicated in the same email received to communicate their selection for oral presentation.

3.3. Evaluation and selection criteria will be the exclusive responsibility of the independent Scientific Committee who will be blinded and score the clinical cases submitted in the platform. Highest score cases will be presented orally at the scientific virtual meeting to be held in November.

The selection of the best work to receive an Honorable Mention will be announced at the end of the meeting.

While evaluating the works, the following criteria will be considered and weighed: a) Relevance; b) Originality; c) Scientific rigor; d) Impact on the medical community's knowledge and on patient care; e) Clinical reasoning.

Each criterion will be scored on a scale from 0–10.

The Scientific Committee will not see the identification of the authors or their institution(s). Voting will be anonymous and impartial. If there is a possibility that the committee recognizes works from their own institution or specialty service, the committee will have to abstain from voting, and the average score from the remaining members will be used.

The authors of the five highest-scoring scientific works, as determined by the Scientific Committee, will be notified by MSD and asked to prepare an Oral Communication to be delivered at the final scientific virtual meeting.

The oral communication may be longer than the PPT file submitted in the platform, and participants will receive further guidance when receiving the communication that they were selected.

On the day of the meeting and after clinical cases discussion with our independent committee, there will be a final analysis and voting for each work, and the presentation with the highest score will be announced – Winner Honorable Mention.

All the cases that were eligible and submitted to the contest will be aggregated in a final "clinical case compendium" in PDF format.

4. Scientific Committee:

Members of the Scientific Committee may mentor some of the submitted scientific works, but cannot be included as co-authors, and will abstain from voting on these cases.

Scientific members from some of the participating countries, will be selected by MSD medical department based on their partnership, willingness to collaborate and expertise in PH. Not all countries will be able to have scientific members representatives in the committee, but on the virtual meeting to be held in November, all participants from different countries will be able to contribute and enrich the discussion and experience sharing.

5. Personal Data Protection

- During PH clinical cases, personal data of participants may be collected and stored, namely:
  ((1) Name, (2) Email, (3) Mobile Phone, (4) Local HCP ID, (5) Place of work, (6) Country (with a dropdown: Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Portugal, Romania, Serbia, Slovakia, Slovenia), (7) Profession and (8) Specialty.
- Personal data will be collected and processed by a Third Party –Performance Sales Lda, contracted by MSD Portugal (msd.portugal.dpo@msd.com, Merck Sharp & Dohme, Lda. Quinta da Fonte,Edifício Vasco da Gama, Porto Salvo 2770-192 Paço de Arcos) for this purpose, to process the data on behalf of and under the responsibility of MSD, in compliance with the rules and principles established by the General Data Protection Regulation
  (GDPR), Regulation (EU) 2016/679 of April 27.
- You have the right to formally complain to the official data-protection regulator "authority" if you believe your personal data has been handled unlawfully or unfairly.

- Providing personal data is necessary and required for processing the entire evaluation workflow and determining those selected, namely to allow for contacting participants throughout the project. Participants acknowledge and accept that collecting their contact details is necessary for the operation of the PH clinical cases project.
- Participants also agree that the data collected may be used for quality control related to the selection and assessment of the submitted scientific work.
- Participants may withdraw their consent at any time, without affecting the lawfulness of data processing carried out prior to the withdrawal.
- The name of the Lead Author, the Institution, and the remaining authors may be disclosed by MSD in dissemination activities on its websites or to the third party contracted by MSD for the development of the clinical case compendium.
- The personal data collected from participants will be stored in an electronic file for 365 days from the date of the final event.
- MSD guarantees participants the security and confidentiality of personal data processing and, under the GDPR, guarantees the right to information, access, rectification, or erasure, as well as the right to data portability, where feasible, and the right to restrict or object to processing.
- To exercise the rights mentioned above, participants can consult MSD's Privacy Policy PRIVACY STATEMENT - MSD Privacy
- MSD does not transfer personal data to third parties, except where necessary for participation in the contest or to comply with legal obligations to which MSD is subject. Any transfer of data to third parties will be carried out in accordance with the GDPR and within the limits of the established processing purposes.
- Participants' personal data may be made available for determining civil and criminal liability upon request by the competent authority, under applicable law.
- Participation and application to PH clinical cases presuppose reading all items of these regulations and imply agreement with and acceptance of all their terms and conditions.

6. Notification of Relevant Safety Information

The current regulatory framework requires us to identify and report adverse events and other safety-relevant information associated with MSD products. Examples of other reportable information include product quality complaints, the use of medicines for unapproved therapeutic indications, or the use of MSD medicines during pregnancy (non-exhaustive list).

If the scientific work you submit for participation in the PH clinical cases project includes any reportable information, it will be recorded in accordance with MSD's pharmacovigilance procedures and transmitted to regulatory authorities according to applicable legislation. You may also be contacted to obtain follow-up information regarding the case presented.

For spontaneous reporting of pharmacovigilance cases, use the following contacts and the AE form annex to this regulation and present on the website:

Estonia	dpoc.estonia@msd.com
Latvia	dpoc_latvia@msd.com
Lithuania	dpoc_lithuania@msd.com
Portugal	dpoc_portugal@msd.com
Czech Republic	dpoc_czechslovak@msd.com
Slovakia	dpoc_czechslovak@msd.com
Hungary	dpoc.hungary@msd.com
Romania	dpoc.romania@msd.com
Bulgaria	dpocbulgaria@msd.com
Croatia	dpoc.croatia@msd.com
Serbia	dpoc.serbia@msd.com
Slovenia	dpoc.slovenia@msd.com

7. Other notes

Selected candidates commit to presenting the work at the meeting or, if that is not possible, to being represented by one of the remaining co-authors (the order of the submitted authors should be followed). If none of the authors is able to present, the opportunity for Oral Communication will pass to the next highest-scoring submission.

These regulations may be amended without prior notice to participants in the project, provided such amendment does not affect substantive aspects.

8. Contacts For additional information, please contact:

Project owner: joana.duarte@msd.com

Technical support: **support.phclinicalcases@wyperformance.com**

Annex 1:

AE form

General Guidance for completing Adverse Event and Product Quality Complaint Form

- **Complete all sections** that apply
- **Dates** should be entered as DD-MMM-YYYY. If the exact dates are unknown, provide the best estimate. Partial dates are acceptable.
- **Date Received:** Earliest date initial and/or follow up adverse event information is received by company employee or person/agent acting on the company's behalf. For Non-Interventional Studies (NIS), where there is both an Investigator and Supplier, this field should be completed by the Supplier if the Supplier is managing AE/PQC reporting from the Investigator to MSD.
- **Patient/Reporter Details:** Name or initials
    - Anonymized: Patient/reporter details need to be withheld for privacy
    - Unknown: Patient/reporter details are not known
- **Age:** Enter patient's age at onset of event and age unit (days, weeks, months, years), e.g. 24 weeks
- **Age Group:** Enter patient's age group at time of event if Date of Birth or Age is not available
    - Foetus (Prior to birth)
    - Neonate (1 day - 28 days)
    - Infant (>28 days - <24 months)
    - Child (2 years - <12 years)
    - Adolescent (12 years - <18 years)
    - Adult (18 years - <65 years)
    - Elderly (65 years and older)
- **Product:** Trade/brand name (preferred) Generic Name (acceptable)
- **Action Taken:** Dose (decreased, increased, interrupted, or not changed), Withdrawn, Unknown, NA
- **Lot/Batch/Serial#/ Model#/Catalog#/UDI#:** provide all numbers exactly as they appear on the device or device labeling (including spaces, hyphens, etc.) or pharmaceutical product (lot/batch), as applicable.
- **Seriousness:** Adverse event resulted in:
    - **Hospitalization:** prolonged hospital stay, or an emergency room visit results in hospital admission
    - **Life-threatening:** Substantial risk of dying or continued product use may have resulted in death
    - **Death:** Death (include the date, cause of death, if known)
    - **Disability:** significant, persistent, or permanent impairment or diminished quality of life
    - **Medically Significant:** could have jeopardized the patient or required medical or surgical intervention (treatment) to prevent serious outcome
    - **Congenital Anomaly/Birth Defects:** Outcome in a child from exposure to a medical product prior to conception or during pregnancy
    - **Required Intervention related to a device or device component:** Medical or surgical intervention was necessary to preclude permanent impairment of a body function or permanent damage to a body structure (provide details in the narrative)
- **Narrative:** Summary of all relevant medical information (clinical course, treatment) office visit notes, hospital discharge summary (if applicable)

Adverse Event and Product Quality Complaint Form

CASE DETAILS

Date Received: DD/MMM/YYYY

Country of Incidence:

Program/Study ID#: WMS 885

Program/Study Name: PH Clinical Cases

SENDER DETAILS (Applicable Business Partner (BP), Investigator, Vendor, Supplier)

Name/Initials:

Email Address:

BP/Vendor Name or ID#: N/A

PATIENT DETAILS (complete in accordance with local privacy laws)

Name/Initials: ☐ Anonymized ☐ Unknown

DOB: DD/MMM/YYYY

Age:

Age Group:

Address:

Sex: ☐ Male ☐ Female ☐ Unknown

Pregnant: ☐ Yes ☐ No ☐ NA

Patient/Subject ID#:

Site # (if applicable):

If yes, date of last menstrual period: DD/MMM/YYYY

REPORTER DETAILS (complete in accordance with local privacy laws)

Name/Initial: ☐ Anonymized ☐ Unknown

Email:

Phone:

Address:

Fax:

☐ Physician
☐ Consumer
☐ Lawyer
☐ Pharmacist
☐ Other Health Prof

Is the Reporter/HCP willing to be contacted? ☐ Yes ☐ No ☐ Unknown

PRODUCT(S) DETAILS

(To add more fields, click fields below and look for the blue + icon on the right)

Product Name Suspect (S) Concomitant (C)	***Formulation Dose/Frequency***	***Indication***	***Start Date***	***Stop Date***	***Action Taken***	***Lot/Batch/Serial#/ Model#/Catalog#/ UDI#***
			DD/MMM/YYYY	DD/MMM/YYYY		
			DD/MMM/YYYY	DD/MMM/YYYY		

ADVERSE EVENT/PRODUCT QUALITY COMPLAINTS

(To add more fields, click fields below and look for the blue + icon on the right)

Event:

Onset Date: DD/MMM/YYYY

Stop Date: DD/MMM/YYYY

Outcome:
☐ Fatal ☐ Not recovered
☐ Recovered ☐ Recovering
☐ Sequelae ☐ Unknown

Was the event considered Serious? ☐ Yes ☐ No ☐ Unknown

If yes, select all that apply (see cover page for details):

☐ Hospitalization ☐ Life Threatening ☐ Death ☐ Disability ☐ Medically Significant ☐ Congenital Anomaly
☐ Required Intervention (Device/Device Component) (*provide details in narrative*) ☐ Other (*provide details in narrative*)

Was the Adverse Event(s) related to the product? ☐ Yes ☐ No ☐ Unknown

☐ **This is a non-interventional study/program with no HCP assessment of seriousness or causality (*for internal use only*)**

Is this a Product Quality Complaint?

☐ Yes

☐ No

Is the product available for return, if requested?

☐ Yes (*provide contact details)*

☐ No (*specify reason if known*)

MEDICAL DEVICES ONLY

Date Implanted: DD/MMM/YYYY ☐ Initial Use ☐ Repeated Use

Date Explanted: DD/MMM/YYYY **Operator of Device:** ☐ HCP ☐ Patient/Lay User ☐ Other

DESCRIPTION OF ADVERSE EVENT(S) AND/OR PRODUCT QUALITY COMPLAINT

Information not captured in the fields (other products taken by the patient, current medical conditions, relevant medical history, laboratory tests etc.)

COMPLETE BELOW SECTION IF APPLICABLE (internal use only)

Form Completed By:	***Date Completed:***	***QC Check Completed By:***	***QC Check Date:***
DD/MMM/YYYY	DD/MMM/YYYY	DD/MMM/YYYY	DD/MMM/YYYY