

101191967 - GREG

Testing, improving, and co-creating Guidance and Tools for Real World Evidence Generation and Use for Decision-Making in Europe

WP7 – Engagement of Patients and Patient Communities

D7.I PAG Detailed Composition

Lead contributor	EUPATI, 10, Maria Duterte & Finn McCartney
Other contributors	UOXF, 2, Annika Jödicke NOVO, 17, Konstantinos Chatzidimitriou & Hongye Ren SARD, 18, Carole Ehrhardt MDT, 34, Despina Voulgaraki & Kati Pulkkinen EDW, 36, Annabell Merklin & Rachele Busca PFIZER, 40, Sally Dews
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Document History

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V0.1	03/09/2025	First draft
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Definitions

Participants of the GREG Consortium are referred to herein according to the following codes:

1. Erasmus Universitair Medisch Centrum Rotterdam (EMC)
2. The Chancellor, Masters and Scholars of The University of Oxford (UOXF)
3. SYNAPSE Research Management Partners SL (SYNAPSE)
4. National Institute for Health and Care Excellence (NICE)
5. GETREAL Institute (GetReal)
6. Societe Europeenne De Cardiologie (ESC)
 - 6.1. Region Uppsala (REGION UPPSALA)
7. Erasmus Universiteit Rotterdam (EUR)
8. Stichting European Health Data and Evidence Network (EHDEN-F)
9. Stichting Eupati Foundation (EUPATI)
10. Instituto Aragonés De Ciencias De La Salud (IACS)
11. University Of Galway (GALWAY)
12. The Hyve BV (THE HYVE)
13. University Of Dundee (UNIVDUN)
14. Universidade De Aveiro (UAVR)
15. Direktoratet for medisinske Produkter (NOMA)
16. Novo Nordisk A/S (NOVO)
17. Sanofi-Aventis Recherche & Developpement (SARD)
18. Bayer Aktiengesellschaft (BAYER)
19. Edwards Lifesciences Belgium BV (EW)
20. Medtronic Bakken Research Center B.V. (MDT)
21. Mölnlycke Health Care AB (MHC)
22. Institut De Recherches Internationales Servier (IRIS)
23. Pfizer Inc (PFIZER INC)
24. W. L. Gore & Associati S.R.L. (GORE S.R.L.)
 - 24.1. W. L. Gore et Associés S.A.R.L. (Gore S.A.R.L.)
 - 24.2. W. L. Gore & Associates BV (GORE BV)
25. Bristol-Myers Squibb Company Corp (BMS)
26. Boehringer Ingelheim International GmbH (BII GMBH)
27. Janssen Cilag SA (JCSPAIN)
28. GlaxoSmithKline Research & Development Limited (GSK)
29. AMGEN (AMGEN)
30. Sanofi US Services Inc. (Sanofi US Inc)
31. Sanofi-Aventis gulf F.Z.E. (SANOFI Gulf)
32. Sanofi Winthrop Industrie (SWI)
33. Sanofi Pasteur SA (Sanofi P SA)
34. Aventis Pharma Limited (Sanofi Pharma)
35. Sanofi Pasteur Limited Canada (Sanofi P L)
36. Edwards Lifesciences Sarl (EW SARL)
37. Edwards Lifesciences LLC (EW LLC)
38. Pfizer Hellas S.A. (Pfizer Hellas)
39. Pfizer AB (Pfizer AB)
40. Janssen Research & Development, LLC (JRDLLC)

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41. Medical Device Business Services Inc (MDBSI)
42. Edwards Lifesciences SRL (EW SRL)
43. Edwards Lifesciences SL (EW SL)
44. Edwards Lifesciences SAS (EW SAS)
45. Edwards Lifesciences GmbH (EW GMBH)
46. Medtronic, Inc. (MDT Inc)
47. Medtronic France (MDT FR)
48. Medtronic Italia S.p.A. (MDT IT)
49. Medtronic Ltd (MDT LTD)
50. Pfizer R&D UK Limited (PFIZER R&D UK)
51. Pfizer Limited (PFIZER LTD)
52. Actelion Pharmaceuticals Ltd (ACTELION)
53. Medical Devices & Diagnostics Global Services, LLC (MDDGB)

Grant Agreement (GA)	The agreement signed between the beneficiaries and the IHI for the undertaking of the GREG project (101191967)
Project	The sum of all activities carried out in the framework of the Grant Agreement.
Consortium	The GREG consortium, comprising the above-mentioned legal entities hereby referred as Participants of the GREG consortium.
Consortium Agreement (CA)	Agreement concluded amongst GREG beneficiaries for the implementation of the Grant Agreement (GA). Such an agreement shall not affect the parties' obligations to the Community and/or to one another arising from the GA.

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List of abbreviations

Abbreviation	Definition
PAG	Patient Advisory Group
WP	Work Package
RWE	Real-World Evidence
RWD	Real-World Data
IHI JU	Innovative Health Initiative Joint Undertaking
GA	Grant Agreement
KPIs	Key Performance Indicators

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Executive Summary

To ensure that the patient perspective is fully integrated into the activities, processes, and outcomes of the GREG project, a Patient Advisory Group (PAG) will be established and coordinated under Work Package 7 (Engagement of Patients and Patient Communications), as part of Task 7.1: *Patient Advisory Group (PAG) establishment and coordination (M1-M60)*.

This deliverable (D7.1) provides a detailed description of the roles and responsibilities of PAG members and outlines the planned mechanisms for feedback and engagement plans.

The foreseen **composition** of the PAG is described, and a comprehensive **selection** criterion for PAG members is presented, comprising patients¹, caregivers and the broader patient community from across Europe, covering multiple disease areas.

The **roles and responsibilities** of PAG members are summarised as follows:

- Providing insights and guidance in several key tasks throughout the project's lifetime.
- Liaising with members of the consortium in several Work Packages (WPs) to ensure continuous patient involvement and consultation.
- Contributing to the co-design and dissemination of the e-learning course and lay summaries under T7.4, ensuring materials remain accessible and patient-relevant.
- Supporting the monitoring of the implementation of Patient Involvement Key Performance Indicators (KPIs) in collaboration with T7.2, ensuring ongoing alignment with the project objectives.

The rules of engagement are defined for clear and transparent functioning of the PAG and their interaction with the Consortium members and the different WPs.

¹ The term "patient" is used throughout this text in a broad sense, encompassing not only individual patients, and patient experts, but also family members, caregivers, patient organization representatives, citizens, and consumers.

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I Introduction

This deliverable (D7.1) documents the roles and responsibilities of the Patient Advisory Group (PAG) members and outlines the planned feedback and engagement process. It provides a description of the foreseen composition of the PAG, the comprehensive selection criteria for its members, and the rules of engagement for the PAG and its interaction with the GREG consortium.

WP7 is the central point for patient involvement within GREG, and the PAG (defined in T7.1) is a key element in this approach. However, several tasks within WP7 are interconnected and enhance patient involvement in the project.

The work of the PAG is coordinated by the task lead of T7.1. The task lead will have a key role in the PAG recruitment & onboarding process, while all T7.1 members will be active contributors and provide input throughout.

The PAG plays a pivotal role in bridging scientific evidence and real-world experience. Within GREG, the PAG supports the integration of Real-World Data (RWD) and Real-World Evidence (RWE) into project outputs, ensuring patient-relevant data informs research design, evidence generation, and dissemination activities.

2 Engagement of Patients and Patient Communities in GREG

'The value of patient involvement² in medicines [and health products] research and development is increasingly recognised by all stakeholders. Unfortunately, limited formal documentation of patient involvement activities hampers the sharing of experience and learnings, preventing timely and systematic implementation. Patient involvement often lacks structure and consistency in approach and happens too late.

Involving patients in research can hugely benefit the medicines [and health products] development process: by bringing in their priorities and perspectives, patients can contribute to developing better treatments for them and others. Greater patient involvement in R&D will boost the efficacy and safety of new treatments and increase public support for medical research. To enable this, it is essential that patients have thorough knowledge of the processes and methods by which medicines [and health products] are developed and brought to the market to understand where and how they can make a meaningful impact.' (Extracts from EUPATI 'Patient Engagement Roadmap³', 2017)

As described in its project plan, the GREG consortium is committed to ensuring that patient involvement is well integrated and documented throughout the project's lifetime.

WP7 (Patients, carers, and citizen engagement) focuses on engaging and involving patients, carers, and the broader public in the chosen research questions and use cases of the project. These groups will be involved in the design of GREG-EU research use cases and studies to maximise the patient impact of our learnings and, in turn, the resulting guidance and tools.

The work of WP7 is divided into five different tasks:

- Task 7.1.: Patient Advisory Group
- Task 7.2.: Consortium Training on Patient Involvement in RWE/RWD

² The terms patient involvement and patient engagement are used throughout this document. They are sometimes used interchangeably. For the purpose of this document, no specific definition was provided as this will be part of Task 7.2.

³ <https://toolbox.eupati.eu/resources-guidance/patient-engagement-roadmap/>

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- Task 7.3: Target Audience Mapping, Needs assessment, and State of the Art Review (for training of patients and citizens)
- Task 7.4.: Co-Creation of E-Learning Courses on RWE & RWD for patients and citizens (including lay summaries of use cases)
- Task 7.5.: Summary of GREG outputs for patients

While the PAG is established by T7.1, the quality and success criteria (Key Performance Indicator setting) for involving patients in this project will be established and conducted within T7.2.: Consortium Training on Patient Involvement (M1-M14). This in-person training provides an opportunity for all consortium partners to define a shared understanding of meaningful patient involvement throughout the project and agree on key definitions in this area. The focus of this in-person training will be focused on patient involvement, as it relates to this project, with an overall introduction to standards and best practices (e.g. principles of patient engagement, quality criteria in patient engagement, defining the endpoints and concrete implementation of patient engagement activities), and a library of practical exercises.

The methodology for patient involvement will build on the patient engagement training expertise of EUPATI and the consortium partners. It will be further guided by a framework co-created through an initial consultation call and survey with the consortium to identify their needs.

One of the aims of the in-person consortium training will be to set specific project objectives to assess its patient-centric approach (KPIs setting). This will allow the PAG to follow the project's approach throughout its run and maintain checks and balances to ensure a patient-centric approach.

3 Patient Advisory Group (PAG)

As defined in T7.1, the PAG will be established and composed of patient experts (EUPATI Fellows), patient organisation representatives, carers, and relevant groups and communities. Establishment of the PAG will be coordinated by T7.1 members, with the task lead leading. The consortium will be asked to reach out to their respective patient and carer communities to ensure that a diverse group of members are identified. Section 4: PAG Member Selection Criteria and Section 5: PAG Recruitment and Onboarding outline how this process will be conducted.

T7.1. Members have put forward the following recommendations when selecting the PAG:

- The PAG must represent different perspectives – patients, patient experts, carers, patient organisation representatives, etc – and other disease areas, ideally linked to GREG use cases.
- The PAG members should receive adequate, relevant, and tailored onboarding for their roles and have access to the required information about the GREG project, its partners, and objectives. Members should also be provided with introductory information about Real-World Data and Real-World Evidence.
- The ideal size of the PAG is 10 members. This number can change, and additional members can be added depending on the needs of the project workload. The initial 10 will ensure that each WP has a dedicated PAG member as its primary contact point for the group. Depending on the PAG's annual work plan and budgetary resources, this number may be revisited.
- The **roles and the responsibilities** of PAG members are summarised as follows:

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- Providing the patient perspective to ensure that the patient voice is integrated throughout the project.
 - Advising on project design and implementation by reviewing and commenting on the materials and activities to ensure they are relevant, understandable, and patient-centred.
 - Liaising with members of the consortium from several WPs to ensure continuous patient involvement and consultation (see current groupings below).
 - Contributing with specific input for WP7, and specifically for T7.4.: Co-authoring an e-learning course on the topic of Real-World Data and Real-World Evidence and lay summaries of selected use cases.
- The PAG members should interact with the following WP groupings:
 - Work package 1
 - Work packages 2 & 3
 - Work packages 4 & 5
 - Work package 6
 - Work package 8
 - The PAG members' involvement with the other WPs should always be intentional, well-defined, well-coordinated and properly documented (see Rules of Procedure, Rule 6-8).

The envisioned Governance structure is shown in **Figure 1**.

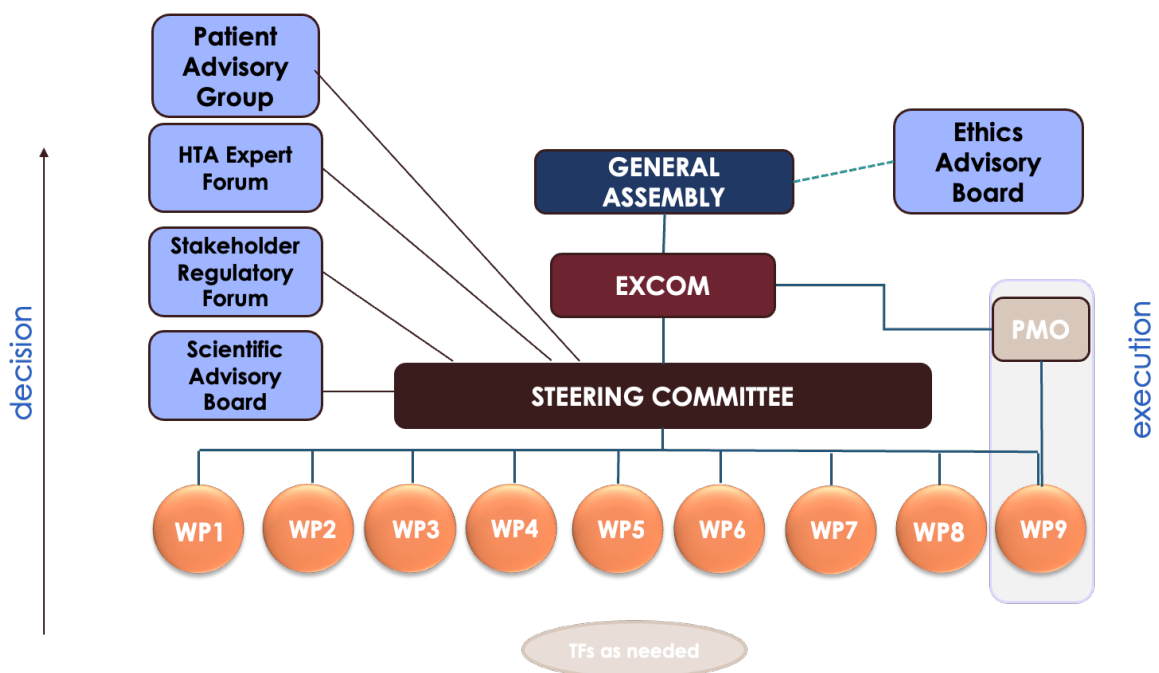


Figure 1 Envisioned Governance Structure in GREG

The PAG will play a key role in GREG's governance. As illustrated in the figure above, they will work across the GREG project and will influence the steering committee. The members of the PAG will be assigned to a WP/WP grouping to ensure that the patient voice is embedded and utilised throughout the project.

Remuneration Policy: PAG members will receive honoraria for their time and expertise in accordance with EUPATI and IHI JU guidelines. Compensation will reflect workload and responsibilities, including preparation, meeting

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attendance, and follow-up contributions. Travel and subsistence will be reimbursed in accordance with the consortium's financial policy.

4 PAG Member Selection Criteria

The selection criteria for membership of the PAG will be made based on the following criteria:

1) Lived experience

The GREG PAG members will ideally have the lived experience of a patient, family member or a caregiver or a certain disease or condition and identify as patients, patient experts, carers, and/or patient organisation representatives.

2) Time commitment

Each member of the PAG is expected to contribute to the project as defined in an annual PAG workplan (also reflected in individual agreements). The PAG workplan will be set at the beginning of every calendar year. The PAG is expected to meet on a bi-monthly basis, with the workload and time commitment to be agreed upon after being confirmed as a PAG member. Some in-person meetings, including travel, may occur during the project lifespan.

3) Interest and/or experience in co-authorship of educational materials

As part of the GREG project, PAG members will be invited to co-author an e-learning course on the topic of RWE/RWD, create lay summaries of the project guidelines and use cases, and contribute to the project's website.

4) Interest and /or experience in medicines and health products research and development (R&D)

While not a requirement, PAG members' interest and experience in medicines and health products R&D can facilitate their involvement in the work.

5) Diversity and inclusion

The composition of the PAG aims to ensure diversity and inclusion across gender, geography, disease areas, and expertise domains. The group will include members with experience in medicines, medical devices, regulatory processes, and HTA to ensure well-rounded representation of patient perspectives.

5 PAG Recruitment and Onboarding

The T7.I lead will launch a recruitment campaign for the PAG upon finalisation of this deliverable. Information about the recruitment of PAG members will be circulated among EUPATI Fellows (patient experts), patient organisations in partnership with EUPATI and its European networks (e.g., the European Patients' Forum), and all consortium members. The timeline in **Table I** sets out the steps T7.I members will take to recruit the PAG. See **Annex I** and **Annex II** for more details on the application form and declaration of interest form.

Table I Timeline for PAG Applications

Task	Description	Start Date & End Date
Applications Open for GREG PAG Membership	Once D7.I has been submitted, the recruitment process for PAG members shall commence. The T7.I lead will inform the GREG consortium to disseminate the	1 st November 2025 - 31 st March 2026*

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Task	Description	Start Date & End Date
	application form and relevant links/documents to their respective communities.	
Selection Process of PAG Members	Applications will be coordinated and conducted by WP7 leads. Once a shortlist of candidates has been created, T7.1 task contributors will be involved to make the final selection (see Rule 3 of the Rules of Procedure for more details).	1 st November - no later than 31 st March 2026*
Interview of Applicants	Interviews (if required) will take place on a rolling basis to familiarise applicants with the project and set clear expectations of their role.	22 nd November - 31 st March 2026*
PAG Members confirmed	Once the PAG members have been selected and confirmed by T7.1 members, the application process will close, and preparations for the 1 st PAG meeting will begin.	31 st May 2026*
1 st PAG Meeting	In accordance with rules 2-5 of the procedural rules, the 1 st PAG meeting will take place, and the PAG Chair shall also be elected.	No later than 60 <u>calendar</u> days after PAG members have been confirmed

*The dates provided above are the latest date the task in question is expected to be completed by. These steps will likely be completed ahead of schedule.

Following the establishment of the PAG, an onboarding process will be initiated no later than 60 calendar days after this date. The T7.1 lead will begin this process and serve as the first point of contact for GREG members regarding queries for PAG involvement. The onboarding process (set out in rule 7 of the Rules of Procedure) will familiarise the PAG with the goals of the GREG project, who is involved, and set expectations for the PAG and GREG members.

All personal data collected during the PAG application and selection process will be processed in accordance with the EU General Data Protection Regulation (GDPR, Regulation 2016/679). Applicants will provide explicit consent for the use of their personal data for evaluation and contact purposes only.

6 Work Package Engagement & Feedback

As defined in section 3, each relevant WP will be assigned PAG Members (set out in rule 7 of the Rules of Procedure) following the discussion in the first PAG meeting. The allocation of PAG members will take into account experience, motivation, time commitment, and budgetary resources. The assigned PAG members will be responsible for sharing their respective WP's updates and requests for patient involvement in each task.

7 Rules of Procedure

Once PAG members have been approved, all parties will adhere to the following rules. These rules will form part of the agreement between the PAG member and the T7.1 lead, acting on behalf of the GREG Consortium.

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GREG **Patient Advisory Group (PAG)**

Rules of Procedure

Rule 1

The Patient Advisory Group

1. The Patient Advisory Group (hereafter “the PAG”) shall perform the functions defined in T7.1 of the Description of Action for the project titled “*Testing, Improving, and Co-Creating Guidance and Tools for Real-World Evidence Generation in Europe and Use for Decision-Making in Europe*” (GREG), project number 101191967, financed under the call HORIZON-JU-IHI-2024-06-02-two-stage.
2. The PAG will provide advice and contribute the patient perspective (patient involvement) to the Consortium, as well as offer input to the project’s guidelines and outputs.
3. The PAG is an external advisory group and is not a member of the GREG Consortium. PAG members do not have delegated authority to act on behalf of the Consortium, the project or its partners.

Rule 2

Constituent meeting of the PAG

1. The PAG shall meet within 60 calendar days of the first official communication sent out to its Members.
2. At its constituent meeting, the PAG shall be provisionally chaired by a member of the T7.1 lead. At the constituent meeting, the PAG shall elect a Chair-in-Office from among its membership. No other business shall be transacted while a member is provisionally in the chair by virtue of this paragraph. To support the PAG chair, a co-chair from the T7.1 lead will also be appointed.
3. The PAG shall adopt its annual calendar of meetings at its constituent meeting.

Rule 3

Initial Members

1. The initial members of the PAG are shortlisted by T7.1 leads and voted on by T7.1 contributors.
2. A simple majority of T7.1 contributors will confirm the entire PAG membership.
3. In the event of disagreements, T7.1 contributors will meet to discuss and agree on a new PAG.

Rule 4

Mandate

1. The mandate of a PAG member is renewable every calendar year, ending on 31st December.
2. Members of the PAG will be asked two months before the end date whether they wish to renew or end their membership.

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3. In the event of a PAG member not renewing their membership, a new member will be, in consultation with the PAG and T7.I contributors, recruited to fill a vacant seat.
4. In the extraordinary event of a vacant PAG seat due to unforeseen extraordinary circumstances, a new member will be, in consultation with the PAG and selection panel, recruited to fill a vacant seat.
5. In the event of the end of the mandate or resignation of one of its members, the PAG shall continue to fully exercise its functions until a new member is appointed by the task lead, in collaboration with T7.I contributors.
6. Membership of the PAG can be terminated by the member with one month's notice, by mutual agreement, or immediately by the T7.I lead on grounds of misconduct, failure to fulfil their obligations, or unprofessional behaviour.

Rule 5

Chair

1. The Chair of the PAG shall be elected at the first PAG meeting of a given calendar year in consultation with all PAG Members.
2. The Chair and co-chair will ensure that meetings of the PAG are organised on a bi-monthly basis.
3. In the event of the end of the mandate or resignation of the Chair, the co-chair will assume the role until a new Chair is elected within an agreed-upon timeframe.

Rule 6

Meetings of the PAG

1. The PAG shall aim to meet at least six times per calendar year.
2. Extraordinary meetings of the PAG may be called by the Chair or by a majority of the PAG's permanent members.
3. Any information, views exchanged, or documents assessed during the PAG that are not in the public domain shall be treated as confidential.
4. In the event of disagreements among PAG members, a vote will be held, with a simple majority determining the direction of the PAG.

Rule 7

Requests for guidance from Members

1. The PAG shall, within 60 calendar days of receipt of each request, reply to all requests from Consortium Members for guidance on implementing meaningful patient engagement.
2. The PAG may request supplementary information from the Consortium Member. If the Member requesting guidance does not clarify their request within 15 calendar days, the guidance shall be provided based on the available information.
3. Each Work Package will, in addition to the co-chair, designate a PAG member as its main point of contact for this group.
4. The designated PAG member will be invited to the regular WP meetings and be responsible for liaising with the other PAG members when/if required.

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5. The PAG member will report the content of the WP meeting in question at the next PAG meeting.

Rule 8

Patient Involvement monitoring

1. The PAG shall proactively monitor the implementation of measures related to patient involvement within the project GREG.
2. These measures will be co-created and agreed upon by the PAG & GREG consortium during the in-person consortium training, which will take place by month 14 of the Project (31st July 2026 at the latest).
3. These measures will be monitored and reported in deliverable D7.2 'Report on PAG involvement in the project'.
4. The PAG will co-develop Key Performance Indicators (KPIs) for Patient Involvement during the GREG Consortium Training (T7.2). These KPIs will serve as measurable indicators for assessing the quality, inclusiveness, and impact of PI activities throughout the project lifecycle.

Rule 9

Outside expertise

1. Advice received from outside experts shall be treated in complete confidentiality.
2. The PAG may consult external patient or expert representatives when specific domain knowledge is required. Such consultations will follow the same confidentiality and conflict-of-interest procedures as formal PAG activities.

Rule 10

Annual Report

1. The PAG shall adopt its annual report one month before the GREG General Assembly Meeting.
2. This report shall be co-written by the PAG chair and co-chair and presented to the GREG consortium.
3. In this report, it shall be recorded how the PAG has been involved in the GREG project and highlight recommendations for the following reporting year.

8 Updating PAG membership & terms of reference

Membership of the PAG will be reviewed and renewed every calendar year by all parties concerned, in accordance with Rule 4 of the procedural rules.

The terms of reference or Procedural rules can be amended following a request of the PAG or concerned GREG partner. These changes will be subject to the approval of T7.1 members and the PAG.

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9 Conclusion

The PAG will provide the vital patient voice on how this diverse stakeholder community understands and can contribute to Real-World Evidence and Real-World Data studies in the lifecycle of medicines research and development. Through a comprehensive application process, a diverse group of patients and representatives will be recruited to ensure meaningful and inclusive patient involvement in the GREG project.

The structures and procedures established in the deliverable will form the foundation for future outputs, including D7.2 (Report on PAG involvement in project) and D7.3 (Consortium training workshop). These will ensure continuity between the foundation of the PAG, the capacity-building activities and the mechanisms for monitoring and evaluating patient involvement throughout the project's duration.

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Annexes

Annex I Application Process

The Work Package 7 (WP7) task lead will coordinate the application process leads, with Task 7.1 members involved in the final selection of the Patient Advisory Group (PAG). The recruitment process will formally begin after the submission of this deliverable (31st October 2025).

Applicants will be invited to complete an online form containing the following questions:

- 1) Full name
- 2) Email address
- 3) Place of Residence
- 4) Nationality
- 5) Are you currently affiliated with a patient organisation, an EUPATI National Platform, or any similar organisation?
- 6) Do you have previous experience in patient-centred activities (e.g., advisory boards, conferences, etc)?
- 7) Have you previously participated in patient activities? If yes, please specify whether this is at the local, national, regional, or global level.
- 8) Have you been involved in patient education or training initiatives?
- 9) Do you have experience presenting or speaking at public forums or meetings (e.g., conferences, webinars, or patient workshops)?
- 10) Why are you interested in joining the GREG Patient Advisory Group? (Please explain in 500 words or less, your reasoning)
- 11) What experience can you bring to the GREG PAG? (Please explain in 500 words or less, referring to any experience you may have in Health Technology Assessment (HTA), Real-World Evidence/Real-World Data (RWE/RWD), or related areas).
- 12) Please provide any additional information you wish to share to support your application (maximum 500 words).
- 13) Please upload a current Curriculum Vitae (CV) in PDF format. This document should include any relevant declarations of interests.

These questions are designed to allow applicants to highlight their experience in patient involvement and their motivation for joining the GREG PAG. Applications will be evaluated according to predefined selection criteria, including the diversity of backgrounds, the relevance of experience, and demonstrated commitment to patient engagement principles.

The Task 7.1 contributors, in accordance with Rule 4 of the Rules of Procedure, will determine the final 10-member PAG. Once successful applicants have been notified, the first PAG meeting will take place no later than 60 calendar days after the final member has accepted their role.

All personal data collected during the application process will be handled in compliance with the EU General Data Protection Regulation (GDPR – Regulation 2016/679). Applicants will provide informed consent for their data to be used solely for recruitment, evaluation, and communication purposes.

Applicants will also be asked to submit a Declaration of Interests.

	D7.1 PAG Detailed Composition		
	WP7 - Engagement of Patients and Patient Communities	Version: v4.0	
	Author(s): Maria Dutarte and Finn McCartney (EUPATI)	Security: PU	18/22

Note: Mentioning a conflict of interest does not automatically exclude the applicant from consideration. Instead, declared interests will be reviewed to ensure transparency and appropriate management. Applicants are encouraged to disclose any potential conflicts openly, as the aim is to ensure balanced participation and accountability rather than exclusion.

Applicants will be informed of the selection results via email and will receive onboarding materials and the PAG Rules of Procedure upon appointment.

	D7.1 PAG Detailed Composition		
	WP7 - Engagement of Patients and Patient Communities	Version: v4.0	
	Author(s): Maria Dutarte and Finn McCartney (EUPATI)	Security: PU	19/22

Annex II Declaration of Interests (DoI) Template Form

This Declaration of Interests (DoI) form is to be completed by all members of the Patient Advisory Group (PAG) and any external experts who participate in GREG-related activities. The purpose of this form is to ensure transparency and integrity in all project-related work. Please complete all sections and return the signed form to the WP7.1 coordination team.

Section 1 – Personal Information

- 1) Full Name:
- 2) Email Address:
- 3) Affiliation / Organisation:
- 4) Country of Residence:
- 5) Date of Submission:
- 6) Role in the GREG Project (if selected)
 - ☐ PAG Member
 - ☐ Trainer
 - ☐ Consultant
 - ☐ Other

Section 2 – Declaration of Interests

Please disclose any current or past interests (financial or non-financial) that could be perceived as influencing your work with the GREG consortium. Having an interest does not necessarily preclude participation.

Examples include (but are not limited to): employment, consultancy, advisory roles, ownership of shares, research funding, honoraria, or participation in advocacy groups.

Type of Interest	Organisation / Entity	Description of Relationship	Current / Past (Specify Dates)
Example: Consultancy	ABC Biotech Ltd.	Served as a patient representative in advisory board meetings.	Jan 2022 – Dec 2023

Add additional rows if necessary.

Section 3 – Declaration Statement and Signature

I hereby declare that the information provided in this Declaration of Interests form is complete and accurate to the best of my knowledge. I understand that the purpose of this declaration is to ensure transparency and integrity in the work of the GREG Patient Advisory Group (PAG). I agree to inform the WP7.1 coordination team immediately should any changes occur that may alter the information provided above.

	D7.1 PAG Detailed Composition		
	WP7 - Engagement of Patients and Patient Communities	Version: v4.0	
	Author(s): Maria Dutarte and Finn McCartney (EUPATI)	Security: PU	20/22

Note: Mentioning that one has a conflict of interest does not mean that one cannot be selected. All declarations will be reviewed in accordance with GREG's transparency and ethical standards.

Name:

Signature:

Date:

	D7.1 PAG Detailed Composition		
	WP7 - Engagement of Patients and Patient Communities	Version: v4.0	
	Author(s): Maria Dutarte and Finn McCartney (EUPATI)	Security: PU	21/22

Annex III PAG Application Timeline

Task	Description	Start Date	End Date	Responsible
Preparation and Submission of D7.1	Finalisation, internal review, and submission of Deliverable D7.1, which serves as the foundation for the PAG application process.	01 Sep 2025	31 Oct 2025	T7.1 Lead
Applications Open for GREG PAG Membership	Once D7.1 has been submitted, the recruitment process_for PAG members shall commence. WP7 leads will inform the GREG consortium to disseminate the application form and relevant links/documents to their respective communities.	01 Nov 2025	31 Mar 2026*	T7.1 Lead/ Consortium Partners
Selection Process of PAG Members	Applications will be coordinated and conducted by WP7 leads. Once a shortlist of candidates has been created, T7.1 task partners will be involved to make the final selection (see Rule 3 of the Rules of Procedure for more details).	01 Nov 2025	31 Mar 2026*	T7.1 Lead & Task 7.1 Contributors
Interview of Applicants	Interviews (if required) will take place on a rolling basis to familiarise applicants with the project and clarify expectations for their role.	22 Nov 2025	31 Mar 2026*	T7.1 Task Lead
Notification of Selected Members	Selected candidates will be formally notified by email and invited to confirm their participation. Unsuccessful applicants will also be informed in a timely and transparent manner.	01 Apr 2026	15 Apr 2026*	T7.1 Lead
PAG Members Confirmed	Once members have been selected and confirmed by Task 7.1, the application process will close, and	16 Apr 2026	31 May 2026*	T7.1 Lead

	D7.1 PAG Detailed Composition		
	WP7 - Engagement of Patients and Patient Communities	Version: v4.0	
	Author(s): Maria Dutarte and Finn McCartney (EUPATI)	Security: PU	22/22

	preparations for the first PAG meeting will begin.			
First PAG Meeting	In accordance with Rules 2–5 of the Rules of Procedure, the first PAG meeting will take place, and the PAG Chair will be elected.	01 June 2026	31 July 2026* No later than 60 days after members have been confirmed	T7.1 Lead

* Indicative timeline. Dates may be adjusted following the formal submission of Deliverable D7.1 and coordination with T7.1 contributors.