

CLL Immune Challenges Task Force

Terms of Reference

V8

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1. Project overview

In May 2023, CLLAN, in partnership with AstraZeneca, worked with global experts and advocates to develop and launch a White Paper titled “[Compromised: Uncovering the immune-related challenges facing people with chronic lymphocytic leukaemia](#)”. The foundational report outlines specific recommendations to address the unmet need of immune challenges (IC) experienced by people living with CLL, looking at how to improve quality of life and reduce mortality by fostering more informed, proactive, and person-centred care.

In 2025, CLLAN established a new community-led initiative – the CLL IC Task Force – that will translate these findings and recommendations into tangible improvements for people living with CLL. The mission of this new initiative is to drive policy change and create new resources that directly address immune challenges faced by CLL patients to improve outcomes, quality of life and autonomy for people living with CLL.

After significant community consultation via workshops, prioritization survey and consultation calls across 2024 and 2025, the following core workstreams are to be taken forward by the CLL IC Task Force:

- **Workstream 1:** support people living with immune challenges
- **Workstream 2:** ensure the clinical community recognises the impact of immune challenges

2. Project governance

The CLL IC Task Force will be an alliance of members including patient advocacy groups, clinicians, policy- and decision-makers and providers from around the world. CLLAN will be the executive body of the Task Force. As such, the CLLAN Steering Committee will have oversight of the Task Force. Steering Committee members will join its membership.

The CLL IC Task Force will be made up of a multidisciplinary, multistakeholder Operational Committee and two Working Groups, supported by the Secretariat (Figure 1). The number of Working Groups will reflect the number of workstreams in each mandate. For 2025 and 2026, there will be two workstreams: an advocacy stream focused on supporting people living with immune challenges and another, focused on ensuring the clinical community recognises the impact of immune challenges. Members in any of the groups will receive the following benefits:

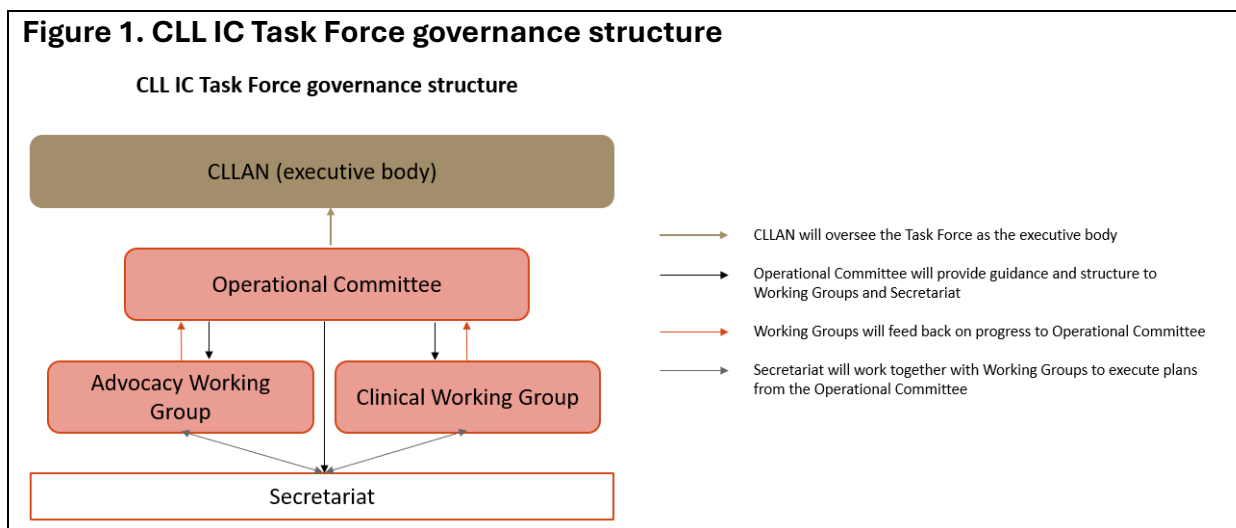
- The opportunity to collaborate with a network of experts in CLL to share best practices and learn from other experts in the field.
- A right to vote along with other members to determine community consensus.

- Name listed as a co-author (Working Group) or contributor (Operational Committee) on core externally facing deliverables.
- The opportunity to display your organisation’s logo and name on core externally facing deliverables.
- The ability to freely disseminate all externally facing deliverables and highlight your involvement in the initiative.

The Task Force is supported by industry partners, who provide financial support for the Task Force’s activities and act as members of the Working Groups and also Operational Committee dependent on their level of funding. The Task Force is currently supported by grants from AstraZeneca (major industry partner), Takeda (major industry partner) and Johnson & Johnson (minor industry partner). Please see section 2.4 for more information on the role of industry partners. As new industry partners come on board, these Terms of Reference will be updated.

All members of the Task Force are asked to ensure they reflect key principles of objectivity; multidisciplinary perspectives, consensus and equality of voice; and transparency set out in section 5. All stakeholders have valuable knowledge and insights to provide and will therefore have an equal voice in all groups and across the entire programme of work. The Secretariat will ensure that no single group holds undue influence or authority over the direction, decisions or outcomes of the Task Force.

Figure 1. CLL IC Task Force governance structure



2.1. CLLAN

Role: Act as the chair and executive body for the CLL IC Task Force during the first mandate (2025-2027).

As CLLAN is the executive body of the Task Force in the first mandate (2025-2027), the CLLAN Steering Committee will:

- Establish the structure and agree the membership of the Task Force.
- Sign-off the Task Force’s Terms of Reference.
- Oversee all aspects of the Task Force. CLLAN Steering Committee members will sit across the Task Force’s Working Groups and Operational Committee. For the avoidance of doubt, this includes:
 - a. Acting as Chair of virtual meetings of the Operational Committee during the first mandate.¹
 - b. Reviewing and providing feedback on draft content developed by the Secretariat in advance of distribution to members.
 - c. Leading and safeguarding all operational and financial activities for the CLL IC Task Force and ensure the execution of all activities chosen via member consensus.
- Maintain oversight, including:
 - a. Approving funding for activities recommended by the community.
 - b. Signing-off on all final deliverables.
 - c. Publishing all deliverables on the CLLAN website.
- Receive reimbursement of costs for activities associated with leading the CLL IC Task Force, disseminating as appropriate.

As the executive body of the Task Force, CLLAN Steering Committee will also:

- Retain the IP of all deliverables stemming from the Task Force in the first mandate.
- Be able to decide to continue this role in the second mandate or handover to another appropriate executive body.

After an initial two-year term, the CLLAN Steering Committee and the Operational Committee will review the governance structure. If it is jointly decided, elections could be held for the Operational Committee and Working Group chairs. CLLAN will continue its role as formal convening body for the Task Force.

¹ Formal elections would occur for the chair of the second mandate of the Task Force.

2.2. Operational Committee

Role: Act as a senior guiding force and advisory council for the CLL IC Task Force, shaping and guiding all initiatives and making strategic decisions about the direction and priorities of the Task Force.

The Operational Committee will comprise of 14 highly active members, including those who sit on the CLLAN Steering Committee, and one representative of each major industry partner. Participation is by invitation from the CLLAN Steering Committee who will ensure the composition of the group is representative of all stakeholders with an interest in CLL and immune challenges. All members of the Operational Committee will:

- Join two virtual meetings across 2025 and 2026 with other members to discuss actions and activities to:
 - Approve projects taken forward by the Working Groups (2025).
 - Review progress towards the overarching aims of the CLL IC Task Force and discuss activities for the next mandate (2027+).
- Provide written feedback and scrutiny on deliverables stemming from the Working Groups at key milestones to ensure that they represent an objective, multidisciplinary consensus.
- Agree to the key principles and ways of working as outlined in these Terms of Reference.
- Actively contribute to all discussions.
- Have one vote and equal rights as other members when decisions need to be made, and consensus found.
- Endorse and widely disseminate core externally facing deliverables and give consent for their involvement to be published (including on the CLLAN Task Force website, which will recognise their contributions to the development of deliverables).
- Be able to leave the CLL IC Task Force by notifying the Secretariat in writing.

For the avoidance of doubt, industry partners who qualify as major funders will participate in the Operational Committee and have the same roles and responsibilities as all other members within the Operational Committee. They will be invited to contribute to discussions and activities, however, they will not, at any time, outnumber or outweigh the representation of advocates and clinicians on the Operational Committee. The Secretariat will ensure that representatives from industry partners do not hold a majority, nor exert disproportionate influence over decisions or recommendations, and reserve the right to expand the group should there be risk of an imbalance.

All resources created by the CLL IC Task Force will be independent, free from formal legal or medical review by industry partners.

Industry representatives shall have to strictly comply to the public rules in terms of conflict of interest.

2.3. Working Groups

Role: Work together to drive specific workstreams and co-develop deliverables with support from the Secretariat.

For the 2025-2026 mandate, there will be two workstreams: an advocacy workstream, supporting people living with immune challenges, and a clinical workstream, ensuring the community recognises the impact of immune challenges.

There will be one Working Group to lead each workstream. Each Working Group will comprise of up to 20 active members invited to participate for their knowledge, skills and expertise as they relate to the chosen workstream alongside one representative of each major and minor industry partner. Industry partners will have the same roles and responsibilities as all other members within the Working Groups.

Participation in the Working Group is by invitation from the CLLAN Steering Committee who will ensure the composition of the group is balanced with regard to expertise, global perspectives and skills. All members of each Working Group will:

- Join three virtual meetings across 2025 and 2026 at key workstream milestones to:
 - Agree upon and lead specific activities within the workstream, feeding back progress to the Working Group and Operational Committee as appropriate.
 - Provide in-depth comments on materials (e.g. drafts and pre-final outputs) to ensure all deliverables reflect a multidisciplinary and evidence-based consensus and accurately represent the perspectives and experiences of the group.
- Actively contribute to all discussions – in meetings and during review processes.
- Agree to the key principles and ways of working as outlined in these Terms of Reference.
- Have one vote and equal rights as other members when decisions need to be made, and consensus found.
- Endorse and widely disseminate their final workstream-specific, externally facing deliverables and give consent for their involvement to be published in the public domain.
- Be able to leave the CLL IC Task Force by notifying the Secretariat in writing.

For the avoidance of doubt, major and minor industry partners have the same roles and responsibilities as all other members within the Working Groups. They will be invited to

contribute to discussions and activities, however, they will not, at any time, outnumber or outweigh the representation of advocates and clinicians on the Working Groups. The Secretariat will ensure that representatives from industry partners do not hold a majority, nor exert disproportionate influence over decisions or recommendations, and reserve the right to expand the group should there be risk of an imbalance.

All resources created by the CLL IC Task Force will be independent, free from formal legal or medical review by industry partners.

Industry representatives shall have to strictly comply to the public rules in terms of conflict of interest.

2.4. Industry partners

Role: Provide financial support to the CLL IC Task Force and all activities led by members and be a full member of the Task Force.

One individual from each funding organisation will be invited to join as members of the CLL IC Task Force. The minimum funding commitment is 10,000 EUR per year, with:

- Major industry partner defined as partners that provide over 45,000 EUR per year.
- Minor industry partner defined as partners that provide between 10,000-44,999 EUR per year.

Major industry partners are invited to have one representative be a full member of the Operational Committee and each Working Group. Minor industry partners are invited to have one representative be a full member of the Working Groups only. However, it is not mandatory for industry partners to join the Operational Committee (major industry partners) and Working Groups (major and minor industry partners) or provide input.

Despite these different benefits, all outputs and deliverables from the CLL IC Task Force are considered to be co-funded by all industry partners. Partners will be listed in funding disclaimers on all documents in order of funding levels within their tiers. Partners may change their tier each year dependent on the level of funding they wish to provide.

In addition to the roles and responsibilities of the groups related to their sponsorship level, all industry partners will have the opportunity to:

- Provide written feedback on selected outputs. Partners may wish to consult relevant colleagues – such as those from Medical Affairs, Patient Advocacy, or Communications – when preparing feedback, to provide additional skillsets and insights to enhance specific deliverables. The final feedback shared with the Secretariat should be presented in a single, consolidated response. For the avoidance of doubt:

- Any additional informal reviewers will also be asked to adhere to these Terms of Reference.
- Only one vote will be given to each industry partner, regardless of how many colleagues were consulted.
- No industry partner will receive reimbursement for participation in the group.
- No deliverables will be required to have a formal legal and medical review.
- Have their organisation's logo alongside the logos of the other members.
- Have their organisation's name included in a funding declaration on final deliverables.

2.5. Secretariat

Role: Provide overall management and coordination for the CLL IC Task Force, working in close collaboration with CLLAN, the Operational Committee and Working Groups.

The Secretariat will work to achieve the project aims, and will be responsible for:

- Organising and coordinating CLL IC Task Force activities. This includes leading all stakeholder engagements; organising, diarising, managing and facilitating all group meetings including the development of pre-reads, agendas, slide decks, minutes and follow-up; leading all research and engagement activities on behalf of the members; collating feedback and revising drafts of written documents as required.
- Leading all project management activities. This includes all work planning, administration and liaison with CLLAN, CLL IC Task Force group members and industry partners.
- Developing deliverables. Support Working Groups to develop specific outputs and deliverables under their guidance as required.
- Supporting dissemination activities. This includes developing and executing dissemination plans for written deliverables in collaboration with CLLAN, CLL IC Task Force group members and industry partners.
- Upholding these Terms of Reference. Ensuring transparency, objectivity, balance and high ethical standards across all activities; responsible for ensuring all documents include funding disclaimers.
- Regularly report to the CLLAN Steering Committee.

MHP Group will be providing the Secretariat function to the CLL IC Task Force in the first mandate.

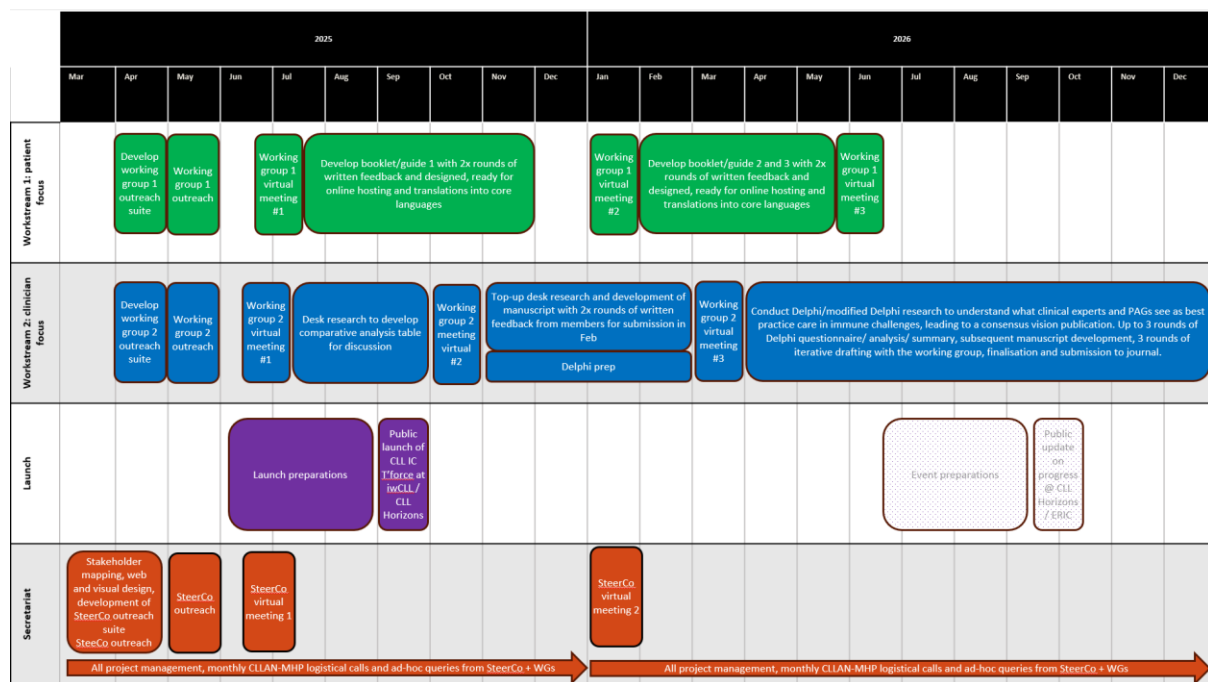
3. Project funding

The CLL IC Task Force is currently funded by AstraZeneca (major industry partner), Takeda (major industry partner) and Johnson & Johnson (minor industry partner). To ensure transparency, all industry partners are listed on all external facing deliverables in alphabetical order within their tiers of funding.

CLLAN is engaged in an ongoing process of outreach and discussion with other potential industry partners to obtain additional support. As new industry partners are brought into the project in the future, these Terms of Reference will continue to be updated.

4. Workplan for the first mandate

The below diagram outlines the core activities across each workstream for the first mandate which occurs across 2025 and 2026.



5. Key principles and ways of working

All members of the CLL IC Task Force, industry partners, and the Secretariat will work in a way that demonstrates:

- **Objectivity:** All outputs will be based on a balanced review of the available evidence. They will be strictly non-promotional. Editorial control and review of deliverables will lie with members, with the Secretariat acting as chief editor.

- **Multidisciplinary perspectives, consensus and equality of voice:** Each member has one vote and an equal voice in all consensus-building and will share all decision-making. All outputs from the project will aim to accurately represent a consensus among all members, brokered by the Secretariat. All final outputs will be freely available in the public domain and the intellectual property is jointly owned by all members of the CLL IC Task Force.
- **Transparency:** All outputs will have a clear declaration naming AstraZeneca, Takeda and Johnson & Johnson, as well as any subsequent industry partners, as partners and declaring terms of engagement with members. Industry partners must act in accordance with these Terms of Reference and the requirements of ethical codes including The European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Conduct, The Prescription Medicines Code of Practice Authority (PMCPA) Code of Practice, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practice, as well as other national or regional codes not listed.

Please note, that by agreeing to participate in meetings of the Operational Committee and Working Groups, participants consent to having the meetings recorded for internal reference only. These recordings will be made solely for the purpose of notetaking and accuracy, they will be stored securely by MHP Group, but not be shared with CLLAN, partners, or any other external organisations.

6. Contact

Should you have any questions, please do not hesitate to reach out to the following:

<p>Peter Haggert Steering Committee Member and Chair peter.haggert@ccladvocates.net</p>	<p>Riddhi Thakrar Account Director, MHP Group cllictaskforce@mhpgroup.com</p>
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