Constructive Engagement Framework

Including Competition Law Guidelines

Revised May 2026 | Confidential

What this document is — and what it is not:

This framework establishes what partners commit to upon joining ALIGN-T1D, and the rules governing multi-sector engagement, competition law compliance, funding relationships, and conflict of interest conduct.

It does not replicate:

- the ALIGN-T1D Shared Governance Model, which defines governance bodies, decision rights, roles, and operational processes
- the ALIGN-T1D Meaningful Community Engagement Principles, which define standards and methods for community engagement

Where this document refers to governance structures or engagement standards, those governing instruments apply.

I. Purpose

ALIGN-T1D convenes representatives across industry, government, philanthropy, civil society, and people with lived experience to help close deadly gaps in care for type 1 diabetes (T1D) in low- and middle-income countries (LMICs). Global T1D prevalence is projected to more than double by 2040, with the steepest growth in LMICs, yet health systems remain unequipped to manage care at the scale required.

This multi-sector approach is essential to ALIGN-T1D's mission, but it carries inherent complexity. Bringing together industry, philanthropy, governments, and communities in the same governance spaces creates the conditions for conflicts of interest, competition law risk, and boundary violations if not actively managed.

This Constructive Engagement Framework (CEF) is the binding instrument that governs how partners engage with one another and with ALIGN-T1D. It establishes:

- the commitments all partners make upon joining
- the rules governing multi-sector engagement and competition law compliance
- the conflict of interest framework as it applies to partner conduct
- the funding model and donor relationship rules
- the process for dissemination, reporting, and framework management

This document is maintained as a standalone instrument because it serves functions beyond the Shared Governance Model — including partner onboarding, independent legal reference, and compliance documentation — and may be updated independently as legal requirements evolve.

Breakthrough T1D in-house counsel serves as legal counsel for ALIGN-T1D. Breakthrough T1D, in its role as the Secretariat, retains the discretion to engage outside legal counsel at its discretion.

In all cases of conflict or ambiguity, this document governs partner conduct; the Shared Governance Model governs governance processes.

> **Mission:** A world where all people living with type 1 diabetes have equitable access to T1D detection, diagnosis, treatment, education, and care, to live healthy, productive lives.
>
> **Vision:** Engage with governments and communities in low- and middle-income countries to sustainably enhance access for people living with T1D through integrated NCD approaches, and to optimize and mobilize funding towards government- and community-defined priorities.

II. Scope of Application

This framework applies to all ALIGN-T1D partners, including SSG and SAG members, Non-Member Observers, Secretariat staff and contractors, and implementing partners who conduct work in-country under ALIGN-T1D funding. Any individual or organization acting in a governance or representative capacity on behalf of ALIGN-T1D is subject to this framework from the point of onboarding.

ALIGN-T1D operates through three governance bodies — the Strategic Steering Group (SSG), Strategic Advisory Group (SAG), and Secretariat — and a Non-Member Observer designation. Full governance body descriptions, roles, decision rights, and operational processes are established in the Shared Governance Model. This section provides only the summary necessary to define the scope of partner commitments.

Body / Role	CEF Applies To
SSG	All member organizations and their designated representatives
SAG	All member organizations and their designated representatives
Secretariat	Breakthrough T1D staff and contractors acting in the Secretariat capacity
Non-Member Observers	Organizations and individuals attending in an observer capacity, for the scope of their participation
Implementing Partners	Organizations receiving ALIGN-T1D funding, via a written agreement with the Secretariat

Implementation phases and timeline are described in the Shared Governance Model.

III. Partner Commitments

ALIGN-T1D builds the following commitments into agreements with each partner. These commitments apply to all governance bodies, implementing partners, and Secretariat staff. They represent the foundational shared expectations for all who engage with ALIGN-T1D.

Positive Impact: Partnerships must be driven by genuine potential to advance ALIGN-T1D's mission and strategic goals. Every engagement will be evaluated on its ability to improve access to care for people living with T1D.

Compatibility and Alignment: A partner's mission, values, and operational culture must be compatible with those of ALIGN-T1D, including a commitment to empowering local governments and communities to define their own healthcare priorities. Partners are expected to make good faith efforts to align their resources with locally defined needs.

Accountability and Transparency: ALIGN-T1D designs for transparency regarding partner contributions, potential conflicts of interest, and outcomes through annual reporting and public notation of involved stakeholders. Public transparency supports internal accountability and ensures ALIGN-T1D is always working in the interest of the public good.

Integrity and Ethical Conduct: Partners are expected to uphold the highest ethical standards in all interactions (internally with one another and externally with governments, institutions, and communities).

Non-Exclusivity: Additional partners committed to ALIGN-T1D's mission, strategic goals, and ways of working are welcome to join. Participation is non-exclusive. Partners are free to engage in other initiatives that advance similar goals, provided they do not use ALIGN-T1D's confidential information, intellectual property, or brand to do so.

Partner Contributions: The provision of financial, in-kind, or subject-matter support does not entitle the contributing party to any improper benefits, advantages, or governance rights beyond those established in the Shared Governance Model. Financial contribution does not confer decision authority.

No Endorsement: Partnership with ALIGN-T1D does not constitute endorsement of a partner's products, services, or commercial strategies. Partners may not use ALIGN-T1D's brand, logo, or reputation without express written permission. All activities and tools supported by ALIGN-T1D — including education materials and demand forecasting — must remain agnostic of any partner's product or proprietary solution.

Confidentiality and Data Privacy: The ALIGN-T1D Secretariat will maintain the confidentiality of partner data shared with it and will only access, use, transmit, store, and dispose of it in accordance with a written agreement with the providing party. Personal data of patients and stakeholders will be de-identified and aggregated where possible and handled in accordance with applicable data privacy requirements.

Compliance with Applicable Laws: The Secretariat will conduct standardized vetting on all implementing partners and will enter into written agreements before disbursing funds. All partners are expected to maintain strict adherence to all applicable laws and regulations in their jurisdictions, including fair competition, anti-corruption, data privacy, and procurement requirements.

Donor Fund Restrictions and Stewardship: Funding partners may restrict contributions to specific activities, geographies, or program areas through written agreements. This is a standard and appropriate feature of philanthropic giving, consistent with the AFP Code of Ethical Standards and the GPA Code of Ethics.

A funding restriction defines the purpose of a gift. It does not create:

- rights to access proposal-level data, applicant identities, or review materials
- rights to influence, approve, or veto grantee selection or implementing partner decisions
- rights to direct in-country implementation, program design, or delivery approaches
- rights to contact or establish direct relationships with grantees outside Secretariat-managed processes
- special reporting obligations beyond appropriate stewardship

Donors with restricted funds receive stewardship reports prepared by the Secretariat describing how contributions were used in relation to their stated restriction. These reports do not include proposal-level or applicant-level data. Funding partners who seek to influence implementation decisions or grantee relationships beyond their defined governance role will be redirected to the Secretariat and, where necessary, to the conflict-of-interest process in Section IV.

IV. Conflict of Interest

This section establishes the conduct standards for conflict of interest management as they apply to partner engagement. The full COI framework — including governance body-specific provisions, structural conflict analysis, leadership composition commitments, and escalation procedures — is established in Section 10 of the Shared Governance Model. This section and Section 10 of the Shared Governance Model should be read together.

Commitment

All partners commit to identifying, disclosing, and managing conflicts of interest in accordance with this framework and the Shared Governance Model. A conflict of interest exists when an individual's or organization's personal, financial, or institutional interests could — or could reasonably appear to — influence their exercise of governance responsibilities. Actual and perceived conflicts are treated with equal seriousness.

Disclosure Requirements

All partners and Secretariat staff must:

- complete a conflict of interest disclosure at onboarding
- update their disclosure within 30 days whenever circumstances change, including when a prospective conflict emerges
- verbally declare any conflict at the start of any meeting where a potentially conflicted matter is on the agenda
- proactively disclose prospective conflicts — including anticipated grant eligibility — as soon as they are reasonably foreseeable

Operational Boundary Commitment

Partners commit to respecting the operational boundaries established in the Shared Governance Model. Attempts to influence decisions within the Secretariat's operational authority — including grantee selection, implementing partner relationships, in-country program design, and vendor decisions — are a violation of this framework and will be treated as a potential conflict of interest matter where the attempting party has a stake in the outcome.

Secretariat Transition Commitment

Where an organization serving as Secretariat identifies a conflict — including a prospective conflict arising from anticipated grant eligibility — it is obligated to disclose the conflict to the SSG Co-Chairs and ALIGN-T1D legal counsel immediately, develop a transition plan in consultation with SSG Co-Chairs and ALIGN-T1D legal counsel, and execute any transition in an orderly manner with sufficient notice to protect governance continuity. Abrupt or unplanned Secretariat transitions are inconsistent with the fiduciary responsibilities of the Secretariat role.

Escalation

Any member may confidentially report concerns about undisclosed or mismanaged conflicts to ALIGN-T1D legal counsel (Jesse Raben, jraben@breakthroughT1D.org, +1.212.859-7891). Concerns about Secretariat conflicts are reported directly to ALIGN-T1D legal counsel and SSG Co-Chairs. Consequences for undisclosed conflicts or repeated violations are established in the Shared Governance Model.

V. Operational Guidelines

Funding Model

- **Collective Funding:** ALIGN-T1D's strongly preferred funding method is for partners to contribute directly to the joint funding mechanism hosted by the Secretariat (Breakthrough T1D) for redistribution to selected implementing partners. Partners may restrict contributions to specific activities, geographies, or program areas in accordance with Section III.
- **Direct Giving:** Alternatively, partners may fund ALIGN-T1D-prioritized implementing partners directly. These contributions will be reported to the Secretariat for alignment, tracking, and record-keeping.
- **Management Fees:** Breakthrough T1D will not withhold a fee or percentage of donor dollars for fund management. The Secretariat is funded through a separate, dedicated funding channel.

Product Neutrality

All strategies, educational materials, and technical outputs created or funded by ALIGN-T1D are strictly independent of proprietary products and services. Where ALIGN-T1D engages in product demand forecasting, procurement, or supply, it does so in a way that respects the integrity of procurement systems, promotes fair and open competition, and safeguards independence and transparency. Procurement planning and forecasting support provided to implementing partners cannot favor any specific supplier or proprietary product.

Antitrust Compliance

To ensure a safe, non-competitive environment, ALIGN-T1D's competition law guidelines are reviewed verbally and in writing at the beginning of every governance meeting. ALIGN-T1D's legal counsel provides oversight and advice. Legal counsel attends key meetings to monitor discussions and intervene if interactions risk violating competition law or this framework. All meeting agendas are provided in advance, and attendees are required to proactively recuse themselves from any session or decision that presents a conflict of interest.

It is Breakthrough T1D's position that one of the purposes of the SSG is the free exchange of publicly available (e.g., not commercially sensitive) ideas among members to foster broader and better use of PROs across all T1D clinical studies and implementation partners. While we expect each Stakeholder to maintain the confidentiality of deliberations and the status of consensus work, the overall goal of the SSG is that members will share non-commercially sensitive ideas and that any such ideas shared may be freely used to improve the development of T1D products. For example, we hope that members will share their thoughts regarding important concepts that could be assessed during clinical trials, and these thoughts will inspire the other members, who will then be free to use these ideas in their own clinical work.

SSG members are asked to please bear this in mind when attending meetings. Participants may hear confidential information shared by others during governance activities, and such information may not be acted upon without the permission of the disclosing party. Any non-public or confidential information that a Stakeholder would not want freely usable by other members should not be shared during SSG meetings. Some examples of non-public, competitively sensitive information that should not be discussed include current or future pricing and discounts, bid amounts and terms, output or capacity levels, limits on sales levels or sales of certain products to certain regions, customers, key contract or sale terms, and strategic plans.

Competition Law Guidelines

✓ Do	☓ Do Not
Request a written agenda circulated in advance of each meeting	Exclude any firms that want to participate, even if they compete with an existing participant
Emphasize the pro-competitive purpose of ALIGN-T1D's work in meeting materials	Encourage or facilitate informal or private interactions among competitors outside of formal governance activities
Allow Breakthrough T1D counsel to review agendas before circulation	Discuss or exchange competitively sensitive information — including pricing, margins, costs, production levels, market shares, marketing or competitive strategies, customer-specific plans, trade secrets, R&D activities, capacity plans, or supplier and partner engagement plans
Limit discussions to written agenda topics	Discuss non-public competitively sensitive information related to areas where participants actually or potentially compete
Allow counsel to attend meetings and read an antitrust disclaimer at the opening of each meeting	Encourage or facilitate any agreement among competitors on the topics above
Limit agreements to only those reasonably necessary for developing a shared access strategy to improve T1D care in LMICs	Coordinate commercial behavior directly or indirectly among participants other than through normal bilateral negotiations
Ensure community consensus does not exclude any actual or potential competitor or limit new entrants' ability to compete	Take any steps that would create the appearance of improper activity
Steer discussions away from non-public competitively sensitive topics	Fail to report inappropriate conduct immediately to Breakthrough T1D counsel
Shut down or allow participants to "leave loudly" if a speaker persists on prohibited topics — and immediately report the incident to Breakthrough T1D counsel	Use information received in ALIGN-T1D activities for any commercial purpose outside the scope of those activities
Ensure accurate minutes are prepared and circulated to all attendees	Discuss legal advice or share written legal guidance — including these guidelines — with anyone other than Breakthrough T1D personnel and counsel
Keep copies of notes and materials circulated during meetings	Forget to seek guidance from ALIGN-T1D legal counsel when in doubt
Seek guidance from ALIGN-T1D legal counsel whenever in doubt	

If, after a meeting, you are concerned about a topic that was discussed, immediately contact ALIGN-T1D legal counsel:

Jesse Raben
Chief Legal & Risk Officer
Breakthrough T1D
jraben@breakthroughT1D.org
+1 .212.859.7891

Do not discuss the topic further with other participants.

VI. Framework Management

Dissemination and Onboarding

ALIGN-T1D disseminates this framework to all existing and incoming partners. All new members must acknowledge this framework and complete conflict of interest disclosures before their first governance participation. The Secretariat provides additional context, guidance, or training upon request.

Reporting and Counsel

Any member may confidentially consult with or report concerns regarding alignment with this framework to ALIGN-T1D's legal counsel. Counsel maintains a written process — reviewable by members upon request — for addressing and resolving concerns.

Framework Review

This framework is reviewed at the same cadence as the Shared Governance Model — formally at the 12-month mark and at the start of each subsequent phase. Amendments to partner commitments or governance rights require SSG approval via the Strategic Deliberation pathway. Updates to reflect changes in applicable law may be made by the Secretariat and ALIGN-T1D legal counsel without SSG deliberation.

Acknowledgements

ALIGN-T1D thanks and acknowledges the City Cancer Challenge, whose Constructive Engagement Framework provided inspiration for this document. ALIGN-T1D's stewardship and donor relations practices are guided by the AFP Code of Ethical Standards (Association of Fundraising Professionals) and the GPA Code of Ethics (Grant Professionals Association).