GNL Site Dossier (Structural Sample)

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STRUCTURAL SAMPLE, NOT THE FULL DOSSIER

This document is a redacted sample of a Via Negativa Health launch dossier, published as an example of the kind of governance and evidence dossier Via Negativa produces for its consultancy clients. It is not a complete record and must not be relied on as one.

What you can see. Roughly the first half is shown in full: the framing, document control, methodology, company and regulatory context, positioning, and language-standards sections. These show the structure, depth, and house standard of the work.

What is withheld. The critical and proprietary sections are blanked with a clear "[REDACTED, AVAILABLE UNDER NDA]" panel: algorithm internals and parameters, evidence-base specifics, validation data, governance internals, data-handling detail, commercial terms, and tier and pricing figures. Tier and pricing material is also subject to a pending content correction and is withheld for that reason as well.

The full dossier is available under a non-disclosure agreement. Via Negativa Health produces comparable dossiers, to this structure and depth, as a standard consultancy deliverable for clients bringing a product, tool, or platform to market.

Via Negativa Health is a trading name of GNL Ltd. Enquiries: john@theglucoseneverlies.com

THE GLUCOSE NEVER LIES®

GNL Site Dossier

GNL Explorer Suite + Platform: Legal, Regulatory, Evidence, Compliance, Operating Model, Governance Record

Build date 10 May 2026 (internal version v11.0, supersedes v10.3 with the algorithm appendix removed and folded into the Grace Dossier Section 15; date-named filename per the locked dossier convention 10 May 2026; the standalone "Compliance & Governance Dossier" naming is retired in favour of "GNL Site Dossier")

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Tagline: Keep GNL Grace Free for T1D

[Line redacted in the public sample: contains tier, pricing, commercial, or cohort-evidence figures withheld pending the current content fix and the NDA gate.]

The Glucose Never Lies Ltd Company No. 16733595 VAT Registration No. GB 516 3272 08 (effective 01 April 2026, Flat Rate Scheme 12%) 36 Lea Green Lane, Wythall, Birmingham, B47 6HE, United Kingdom https://theglucoseneverlies.com UK Trademark: UK00004267795 | Classes 41, 44 Second Trademark (accepted for publication): UK00004360249 | Classes 41, 42 Registered 3 October 2025

DOCUMENT CONTROL

Version	Date	Author	Summary
[Line redacted in the public sample: contains tier, pricing, commercial, or cohort-evidence figures withheld pending the current content fix and the NDA gate.]			

| 1.0 | 28 Mar 2026 | John Pemberton / Claude Code | Initial build | | 2.0 | 28 Mar 2026 | John Pemberton / Claude Code | IOB correction, Pemberton & Uday 2026, evidence cross-matrix | | 3.0 | 28 Mar 2026 | John Pemberton / Claude Code | Full comprehensive build, 10 sections, 7 appendices, all compliance profiles | | 4.0 | 30 Mar 2026 | John Pemberton / Claude Code | Language alignment: "Exercise IOB Calculator" →

"Exercise IOB Explorer" throughout; output field renames applied (estimated_carb_range, estimated_change, projected_glucose); mandatory uncertainty statement added to all single-value carb outputs; §5.3 and §5.4 updated with new forbidden/required language rows; Appendix E audit figures updated to reflect 30 March site-wide alignment (28 pages, 34 fixes); DKA escalation row added to §9.5 compliance checklist | | 5.0 | 30 Mar 2026 | John Pemberton / Claude Code | Alcohol and T1D Explorer (page 12753, v1.1.0) added to all compliance sections: explorer suite updated from five to six tools throughout; §10.1-10.3 evidence base updated; Appendix B extended with 10 alcohol references [37]-[46]; Appendix C6 (Alcohol Explorer evidence map) added; Appendix D6 (Alcohol Explorer compliance checklist) added; Appendix E updated to include Alcohol Explorer audit | | 5.1 | 30 Mar 2026 | John Pemberton / Claude Code | GDPR framework updated for registration system launch: §7 completely revised, registered user accounts added to §7.2; §7.1 review date updated; §7.3 corrected; §7.4 retention periods updated; §7.5 security updated (Brevo, email verification); §7.8 processor table updated (Mailerlite removed, Mailchimp and Brevo added). Privacy Policy (page 12810) and Terms and Conditions (page 12811) created and published live. | | 6.0 | 31 Mar 2026 | John Pemberton / Claude Code | Governance update: §6.3 equity structure updated to confirmed board (John 40%, Phil 20%, Anj 20%, Othmar 10%, Dessi 10%), Dessi and Othmar now non-executive Scientific Advisers with equity; §6.2 Phil profile updated from five to six explorers. §9 heading corrected from "five" to "six explorers". Company number verified as 16733595 against Companies House (live T&Cs and Privacy Policy were corrected from wrong number). Appendix B extended with CGM standardisation reference [47]. | | 7.0 | 31 Mar 2026 | John Pemberton / Claude Code | Correction factor rules updated across all 5 responsiveness levels: Level 5: 90→80 (1600→1400 mg/dL); Level 4: 95→85 (1700→1500); Level 3: 100→90 (1800→1600); Level 2: 105→100 (1900→1800); Level 1: 110 unchanged (2000 unchanged). Summary range now 80-110/TDD (1400-2000 mg/dL). All CF references updated throughout document and appendices. Document certification updated to v7.0 | 31 March 2026. | | 7.1 | 31 Mar 2026 | John Pemberton / Claude Code | **Trademark correction:** UK00004267795 is Classes 41, 44 only (NOT 42), confirmed from registration certificate. Class 42 row removed from §1.3. Renewal date corrected from "September 2026" to "22 September 2035". Second trademark UK00004360249 formally added as §1.3a with full application details, class descriptions, and IPO series issue status. §1.6 IP Action Plan updated with UK00004360249 status and third trademark filing. Appendix G timeline updated with trademark filing and IPO correspondence dates. Footer updated with both marks. | | 7.2 | 31 Mar 2026 | John Pemberton / Claude Code | **Trademark acceptance:** UK00004360249 accepted for publication by IPO (Anna McIlroy, Trade Marks Registry, 31 March 2026). Marks 3 & 4 removed as agreed, series of 2 confirmed. Application proceeds to Trade Marks Journal publication. 2-month opposition period starts on publication date (extendable to 3 months if challenge received). §1.3a status updated. §1.6 IP Action Plan status updated. Appendix G timeline and pending actions updated. Document certification and footer updated. | | 7.3 | 5 Apr 2026 | John Pemberton / Claude Code | **Algorithm accuracy audit and structural additions.** (1) CF mg/dL values corrected in §A5 body table: 1,440/1,530/1,620/1,800/1,980 to 1,400/1,500/1,600/1,800/2,000 (matching API and appendix). (2) CGM trend multiplier range corrected from x0.7-x1.4 to x0.70-x1.30 in Appendix C1. (3) MDI mixed bolus reduction corrected from 33% to 35% in §9.3 and C5 (matching API). (4) IOB model documentation corrected: §A1 now documents three distinct models (Activity/IOB Calculator, Hypo Prevention triangular, Exercise Planner sigmoidal) instead of claiming a single uniform model. (5) §A7 added: Alcohol and T1D Explorer full algorithm documentation (27 drinks, risk bands, basal/bolus reduction rules, post-drinking glucose table, AID strategies). (6) §1.1a added: Via Negativa Health Ltd (Co. 17137000) registered 5 April 2026 as subsidiary brand. (7) Double-check instructions updated to v7.3. | | 7.3.2 | 15 Apr 2026 | John Pemberton / Claude Code | **IOB sigmoidal rising-branch clamp (safety hotfix).** User-reported defect: a 35 kg user with a 4 U bolus 1 h prior returned 5.0 U active insulin on the Activity Explorer, exceeding the administered dose, a physical impossibility. Root cause: the pre-peak (rising) branch of the unified sigmoidal `remainingFraction()`

formula in §A1a was not bounded at 1.0 and returned fractions up to 1.52 across all dose sizes. Not a paediatric edge case: adult 80 kg / 12 U at 1 h also returned 15.4 U (128% of dose). A secondary defect was also confirmed: a discontinuity of approximately −0.57 in fraction at `hours = peak`, where the rising branch terminates near 1.20 and the falling branch begins near 0.63. Remediation: server-side clamp `max(0, min(1, s))` applied to the rising branch of ActivityAndExerciseEngine.php, ExercisePlanningCalculator.php, and ExerciseCarbohydrateCalculator.php in the Laravel API (phillhayes/gnl commit e8062ec, deployed to api.theglucoseneverlies.com on [date-of-deploy]). §A1a pseudocode updated to reflect the clamp. The discontinuity at peak is a known remaining limitation and will be addressed by a subsequent formula redesign (proposed replacement: monotonic power-law residual). Evidence grade for the clamp itself: **A** (enforces a physical invariant, remaining fraction cannot exceed 1.0). | | 7.3.1 | 5 Apr 2026 | John Pemberton / Claude Code | **IOB model unification.** The power-law (onset-plateau-decay) remaining fraction model previously used by the Activity Explorer and IOB Calculator has been retired. All remaining-fraction IOB calculations now use the unified sigmoidal pharmacokinetic model across all three exercise tools (Activity Explorer, IOB Calculator, Exercise Planner). §A1 reduced from three sub-models (A1a/A1b/A1c) to two: A1a (unified sigmoidal remaining fraction model) and A1b (triangular activity model for Hypo Tab 2 only). Evidence maps C1 and C2 updated. §9.1 and §9.2 algorithm decision tables updated. | *[Line redacted in the public sample: contains tier, pricing, commercial, or cohort-evidence figures withheld pending the current content fix and the NDA gate.]*

| 7.5 | 9 Apr 2026 | John Pemberton / Claude Code | **Population-average framing enforcement, site-wide.** "Personalised plan" and equivalent language identified as a clinical safety issue: these phrases imply individual prediction, which all GNL outputs explicitly disclaim. §5.3 Forbidden Language table updated with new row. §5.4 Required Language table updated with required alternatives. Six live pages updated: page-12166 (Explorers hub, 2 instances), page-12518 (Exercise Planner explorer), page-12694 (Exercise Planner explainer), page-12753 (Alcohol Explorer), page-12682 (Registration). Grace system prompts (all three scripts) updated with hard ban and mandatory framing. "Phil Hayes" corrected to "Phillip Hayes" in §6.2 summary. Claude double-check instructions updated to v7.5. | *[Line redacted in the public sample: contains tier, pricing, commercial, or cohort-evidence figures withheld pending the current content fix and the NDA gate.]*

| 8.1 | 13 Apr 2026 | John Pemberton / Claude Code | **Grace widget interactive selectors.** (1) §6.7 Grace updated: widget now embeds interactive priority selectors for CGM (10 criteria, 7 devices incl. FSL2/FSL3 Plus scored separately) and AID (8 criteria, 4 systems) directly in chat. Same scoring matrices as wiki concepts (cgm-selection.md, aid-selection.md). FIFO multi-select (max 3), client-side scoring, top 2 results with gradient bars and guide page links. (2) Topic chip buttons added: bullet-point lists containing known device/system/topic names auto-upgrade to clickable chips with FIFO selection. (3) Wiki concept page `grace-widget-ui.md` added documenting UI patterns, styling spec, consistency rules, and IP protection. (4) Styling uses GNL blue system (#006CFF) consistent with standalone CGM selector on /cgm-guide/. | *[Line redacted in the public sample: contains tier, pricing, commercial, or cohort-evidence figures withheld pending the current content fix and the NDA gate.]*

| 8.8 | 1 May 2026 (evening) | John Pemberton / Claude Code | **Hyper Treatment Explorer v2.0.0 consolidated; high-ketones 20% TDD rebuild; Hypo Treatment Explorer rename.** (1) **New explorer slug** `hyper-treatment-explorer` shipped as the canonical hyper home, separating hyper logic from the legacy Hypo & Hyper Treatment Explorer. Four-pathway routing on glucose + ketone band: under-0.6 standard correction `(glucose - 6.5) / (90 / TDD)` Grade D; 0.6-1.4 light ketones `0.05 U/kg` Grade B (ISPAD 2024 Ch14) with 10% TDD cross-check Grade D (DAFNE/BERTIE adult education programmes); 1.5-2.9 moderate-to-high ketones `min(0.20 * TDD, 0.15 * weight_kg)` Grade D; over-3.0 NULL escalate to emergency care Grade A. Backend:

`app/Domain/Explorers/HyperTreatment/HyperTreatmentCalculator.php` with constants `MODERATE_KETONES_PCT_TDD = 0.10`, `HIGH_KETONES_PCT_TDD = 0.20`, `SAFETY_CAP_UKG = 0.15`. (2) **High-ketones (1.5-2.9) clinical false-negative fixed.** The previous build returned no dose for high-ketones, which contradicted DAFNE / BERTIE adult-education-programme practice (10-20% TDD rule) and ADA 2026 sick-day guidance backbone. Independent Grace review (internal Opus 4.7 sub-agent with full wiki file access, never the live API per the 20 Apr 2026 hard rule) confirmed 20% TDD with a 0.15 U/kg weight-based safety cap is correct population-average framing, evidence grade D (honestly labelled GNL synthesis on a Grade A/B evidence base). Cross-matrix and worked example: `min(0.20 * 50, 0.15 * 80) = min(10, 12) = 10 U`; high-TDD case `min(0.20 * 100, 0.15 * 80) = min(20, 12) = 12 U` (cap binds). Cap-binding triggers an additional framing notice. (3) **Hypo Treatment Explorer rename.** The legacy `hypo-and-hyperglycaemia-explorer` (page 12121, API v3.0.0) is renamed user-facing to "Hypo Treatment Explorer". Slug stays for back-compat; Tab 1 (hypo) is the primary surface; Tab 2 (legacy hyper) remains alive on the slug during the transition. New consolidated Hyper Treatment Explorer is the canonical hyper home going forward. (4) **Flutter app changes** (gnl-app commit `286c689`): hub Management category split into separate "Hypo" (red `0xFFEF4444`) and "Hyper" (amber `0xFFC97A00`) categories; new `_ExplorerHubItem.live` row added for `hyper-treatment-explorer`; `_hyperBasisLabel` updated for the new `'percent-of-tdd'` enum; result figure block wrapped in `_MiniPanel` for white-on-blue compliance per §3.4; cross-check %TDD line suppressed when `correction_basis == 'percent-of-tdd'` (would be redundant); form intro paragraph rewritten to describe four-pathway routing including 20% TDD. Forge api deploy `9f74bb8`, app deploy `286c689`. (5) **Test coverage:** `tests/Feature/HyperTreatmentExplorerTest.php` rewritten; `test_high_ketones_pathway_now_returns_20_pct_tdd` replaces the old "no dose" test; new `test_high_ketones_safety_cap_at_0_15_per_kg_for_high_tdd` (TDD 100 / weight 80 returns 12 U cap-binding case). All Hyper Treatment Explorer feature tests passing. (6) **Algorithm Appendix updated.** `docs/GNL_DOSSIER_APPENDIX_ALGORITHMS.md` bumped v2.5 → v2.6 with new §A8 documenting the four pathways, evidence grades, safety cap reasoning, correction-dose framing rules, action chain, and decision cross-matrix. (7) **Section 9 platform deployment table** above split into separate rows for Hypo Treatment Explorer (legacy slug, page 12121, API v3.0.0) and Hyper Treatment Explorer (new slug, API v2.0.0). (8) **Population-average framing preserved.** `correction_basis: 'percent-of-tdd'` framings carry the population-average qualifier on the units figure; cap-binding triggers an extra framing notice; no language implies individual prediction. (9) Claude double-check instructions updated to v8.8. | *[Line redacted in the public sample: contains tier, pricing, commercial, or cohort-evidence figures withheld pending the current content fix and the NDA gate.]*

| 9.1 | 2 May 2026 (afternoon) | John Pemberton / Claude Code | **Four coordinated Laravel + Flutter pushes through the day, all live-verified post-deploy.** (1) **Row 2 + algorithm-strength sweep** (merge `888803a` Laravel; AlcoholAndT1DCalculator residue swept; AidAlgorithmCalculator already at "algorithm strength" + §1 framing block in `assumptions[]` + new "heuristic 20% / clinical-team conversation" sentence on every system; CanonicalIobRiskScale gains `iobBandsArray()` + `deviceIobCaveat()` static helpers; Activity + 30-min Carb + Planner all return aligned `iobLevel` / `iobBands` / `iobCaveat` on the same payload). (2) **Row 5 sub-task 1, Exercise Planner bolus-input rebuild + cross-tool wording sweep** (Laravel merge `8c4e402` + Flutter merge `67cf19a`). Slider replaced with `_BolusRowsEditor` titled "Boluses in previous 8 hours" matching Activity + 30-min Carb. Result-card metric label "Insulin exposure" → "IOB level" on both Planner and 30-min. ExercisePlanningCalculator `safetyMessage()` body strings rewritten to anchor on "from boluses in the previous 8 hours" instead of "high level of insulin exposure for exercise"; `copyText()` "Exposure:" label renamed to "IOB level:"; ActivityAndExerciseExplorer description rewritten to drop "active rapid-acting insulin exposure" wording. **Row 20, Grace tier collapse to {grace, max}** (Laravel merge `6225bdd` + follow-up fix `efc0733`; Forge deploy `68662375`).

`users.grace_tier` collapsed from `{anon, basic, free, pro, pro_plus, max}` to `{grace, max}` per CLAUDE.md tier-model lock. Migration `2026_05_02_000001_collapse_grace_tier_to_grace_and_max` ran on the api box: existing legacy values mapped forward to `grace`; `grace_usage_policies` upserted with `grace` (15/day, 2,000 max output tokens, 1 PDF/session, 30-day history) and `max` (35/day, 8,000 tokens, extended thinking, file uploads); legacy policy rows deactivated for audit. `doctrine/dbal` blocker dodged by replacing `Schema::table()->change()` with a User model `$attributes = ['grace_tier' => 'grace']` default. Resolver, Stripe webhook, Grace controller, and prompt-path map all flipped to emit only `{grace, max}`; new `grace.md` is a copy of the old `pro.md` per "Grace inherits the Pro feature set." Test sweep across 7 files (~21 assertions). Live verify: `GET /api/grace/entitlement` returns `tier:'grace', limit:15, prompt_profile:'grace.md'`. (3) **Row 5 sub-task 2 + audit row 4, Exercise Planner result-card visual redesign + meal-timing fields** (Laravel merge `914fa0f` + Flutter merge `348ea1e`; Forge deploy `68668757`). ExercisePlanningCalculator gains four new private helpers (`mealTiming()`, `insulinPlan()`, `afterTable()`, `plainSummary()`) and modifies `overnight()` to always return non-null with an `applicable: bool` flag. Response shape additions: `plainSummary` (composed lead-paragraph), `mealTiming.{before,during,after}` (AID/HIIT-aware variants), `insulinPlan.{descriptive, preMealReductionPct, postMealReductionPct}`, `afterTable.{snackG, recheckMin, message, isAID, regLabel}`. Flutter `_buildPlanningSections()` rewritten end-to-end: 1) "Your plan" plain-summary card leads, prominent on navy; 2) safety notice (danger/warning) above all sections so alerts read first; 3) Before/During/After/Overnight sections with `mealTiming` lead-strings + facts + tables; 4) IOB strip + bar + IOB caveat at the bottom as a secondary surface. Existing widgets reused; calculator math identical. (4) **AID Optimiser manufacturer-recommended starting configs** (Laravel merge `37463f1` + Flutter merge `fc7c888`; Forge deploy `68669717`). New `result.manufacturerStarting` object on every AID Optimiser response. 780G per-band targets sourced verbatim from the Cohen letter (28 Apr 2026): adult-default 100 mg/dL, paediatric (7-14) 110 mg/dL, preschool (2-6) 120 mg/dL; AIT 2 h fixed across bands. CamAPS / Control-IQ + Mobi / Op5 surface a single same-config-all-bands placeholder per John "any age gets the same settings for the others for now but can be adapted over time" (2 May 2026). Infants are refused upstream; the helper returns a refusal stub for that band. Five new private helpers (one dispatcher + four per-system variants) carry the wording locks. Flutter renders a `_ManufacturerStartingCard` below the existing paediatric-floor notice; title-bar suffix " (placeholder)" on the three non-780G systems. **Housekeeping sweep** (no audit doc, paperwork-only): six audit-revealed-already-done rows closed in one pass (carb-source vocab, carb-sources lookup smoke, schema/DTO drift generator, Flutter LegalLinks contrast, AID Optimiser care-team disclaimer in `assumptions`, email-URL deep-link via auth-4a). Two rows tightened rather than closed: therapy-enum row narrowed to "unify AID Optimiser short codes with Hypo/Hyper full slugs" (kebab consistent across all four explorers); Stripe Pro narrowed to manual dashboard click. **Net for the afternoon (P0/P1):** P0 all closed; P1 dropped from 16 (morning start) to 7. Action list at `rendered/TECHNICAL_JOBS.html` rev 7.14 (local-only, gitignored). All four pushes carry written audit docs at `docs/phil-audits/2026-05-02-*.md` per the audit-before-push hard rule (locked 1 May 2026). Phil sign-off post-hoc; CI gated each Laravel deploy via `.github/workflows/backend-ci-deploy.yml`. Claude double-check instructions updated to v9.1. | | 9.0 | 1 May 2026 (evening) | John Pemberton / Claude Code | **Age Banding Canon shipped across the platform.** New SECTION 11 (Age Banding Canon) added, sitting between SECTION 10 Evidence Base Overview and APPENDIX A. Six-band runtime scheme locked at `gnl-grace/wiki/policies/age-banding-canon.md`: `infant` (<2 yr), `preschool` (2-6), `paediatric` (7-14), `adolescent` (15-17), `adult` (18-64), `older-adult` (65+), plus `unknown`. Two-representation rule: profile DOB drives screening reminders + cohort analytics; the runtime band is selected per session and is what each explorer's algorithm and Grace's voice route on. **"Weight is king"** narrowing (1 May 2026 evening, John

clarification): carb-per-kg and insulin-per-kg calculations stay weight-driven across every band; age-band routes only AID Optimiser specifics (per-system manufacturer paediatric target floors per the Cohen letter), Alcohol 18+ refusal, framing strings + `result.meta.guidelineAnchor` on Hypo and Hyper, and safety refusal gates. **Per-explorer routing.** AID Optimiser v1.1.0 (Phase 1, commit `8137e3d` per audit `2026-05-01-age-banding-aid-optimiser.md`): Cohen-locked 780G floors, op5 paediatric 6.1 mmol/L, Tandem fixed 6.1 across bands, CamAPS no flooring; m780g/op5/mobi refuse infant ("from age 2"), ciq refuses infant + preschool ("from age 6"), CamAPS approved from age 1. Hypo Treatment Explorer v1.1.0 (commit `576ad65` per audit `2026-05-01-age-banding-hypo-treatment.md`): removed the cross-explorer `min(weight, 60)` cap from `treatmentGrams` and `preventionCarbs` (the cap belongs to Exercise Planning §A4 only); added infant refusal; added `result.meta` with band-resolved + guideline-anchor; CarbAbsorption::clampToWindow at 15 g (absorption-physiology ceiling) preserved. Hyper Treatment Explorer v2.1.0 (commit `bd5e3ae` per audit `2026-05-01-age-banding-hyper-treatment.md`): U/kg + %TDD math IDENTICAL across bands (verified live: 40 TDD / 50 kg paediatric vs adult both return 7.5 units); paediatric framing routes through ISPAD Ch13 paediatric sick-day, adult retains DAFNE / BERTIE adult-education on the Grade A ISPAD Ch13 + ADA 2026 sick-day backbone; explicit-unknown + ketones >= 1.5 refused (null/omitted falls through to adult-default for back-compat). Grace dynamic system prompt (commit `f34d69b` per audit `2026-05-01-age-banding-grace-system-prompt.md`): added `age_band` to `GraceQueryData`, `toContext()` propagation, new `ageBandInstruction()` helper injects band-specific block naming the primary guideline anchor + voice rule + 6 banned strings ("now that they're", "now you should", "change to", "set the target to", "adjust the X to", "on their birthday"). **Phase 3 wiki side**: new policy `gnl-grace/wiki/policies/audience-tagging.md` describes the `audience` metadata convention (`all` / `paediatric` / `adult` / `older-adult` / `hcp-only`); three concept pages tagged on the locking day (alcohol-and-t1d → adult, driving-and-t1d → adolescent,adult,older-adult, pregnancy-and-aid → adult). **Phase 3 regression layer**: new static scanner `gnl-grace/test_age_band_banned_strings.py` asserts no banned phrase or "DAPHNE" misspelling appears in the wiki or Laravel `app/Domain/` ; passes clean across both repos. **No pre-fill from profile** (1 May 2026 evening, John repeat correction): no explorer input field is pre-filled from profile DOB, weight, TDD, or any other profile attribute; the user picks every value at the start of every session; GNL is educational and population-average, not personalised. Memory: `feedback_no_prefill_from_profile.md` . Policy §2.2 corrected. **DAFNE spelling sweep**: UK structured-education programme is DAFNE (not "DAPHNE"); recurring misspelling swept across 11 files (Laravel + Flutter + dossier + policy + CLAUDE.md). Memory: `feedback_dafne_not_daphne.md` . **Internal Grace Opus 4.7 reviews on file**: AID APPROVE, Hypo APPROVE, Hyper REJECT-fix-APPROVE, Grace prompt APPROVE. **John override #2** logged in `to-do/OUTSTANDING-ACTIONS.md` ("if all green we go to (c)"); Phil sign-off post-hoc. Companion algorithm appendix bumped v2.6 → v2.7 with new §A12 documenting the full canon. Grace dossier bumped v6.9 → v7.0 with new §13 documenting age-aware voice. Claude double-check instructions updated to v9.0. | | 8.2 | 16 Apr 2026 | John Pemberton / Claude Code | **Hypo & Hyper Explorer 2-tab restructure + IOB model cleanup.** (1) Hypo & Hyper Treatment Explorer collapsed from 3 tabs to 2. Tab 1 (Hypo prevention and treatment) now handles both treatment and prevention via continuous glucose slider 2.0 to under 6.0 mmol/L with banded carbohydrate recommendations (treatment band below 4.0, prevention band 4.0 to under 6.0), weight-scaled and arrow-modified. Tab 2 (former Tab 3 Highs + Ketones) renumbered without logic change; still driven by TDD, glucose, duration, ketone level, AID system. (2) Former Tab 2 (Hypo Prevention with insulin-dose inputs) retired, functionality migrated to the Carbs for 30 Minutes Exercise (Exercise IOB) explorer, eliminating the duplicate-insulin-entry issue across tools. (3) §A1 IOB model documentation corrected: the triangular activity model (§A1b) has been retired as documentation drift, audit confirmed this model never existed in the production Laravel code. §A1 now documents a single sigmoidal pharmacokinetic model (§A1a only), used consistently across all three exercise tools. (4) Tab

enum at the Laravel API updated from `['1','2','3']` to `['1','2']`; insulin-dose payload removed from Tab 1; ketone_level input type on Tab 2 now a string band (e.g. `'1.5–2.9'`) rather than a numeric value. (5) §C3 evidence map and §D3 compliance checklist updated to reflect the 2-tab structure. (6) Shipped files: `pages/page-12121-explorer.html` (tab button removed, hhxTab2 panel removed, Tab 1 slider replaces band selector), `pages/gnl-hypo-explorer.js` (v4.0.0, 546 lines, Tab 2 code removed, Tab 3 payload `tab:"3"` → `tab:"2"`), `gnl-grace/wiki/concepts/hypoglycaemia.md` (2-tab reflect), `gnl-grace/CHANGE_LEDGER.md` new row. (7) Grace wiki `evidence-grades/insulin-iob-evidence.md` already aligned with sigmoidal-only framing (updated 16 Apr 2026 independently). (8) Claude double-check instructions updated to v8.2. (9) Filename renamed `GNL_COMPLIANCE_DOSSIER_v8.0.md` → `GNL_COMPLIANCE_DOSSIER_v8.2.md`. |

Next scheduled review: on addition of any new explorer, or within 12 months of this date.

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CLAUDE DOUBLE-CHECK INSTRUCTIONS

> This dossier is version 10.3. When reviewing this document, check every instance below and confirm each is correct before signing off.

Naming check, confirm ALL of these are correct throughout

- [ ] "Carbs for 30 Minutes Exercise (Exercise IOB)", never "Exercise IOB Calculator" (except the API endpoint slug which retains the technical name)
- [ ] "explorers", never "calculators" anywhere in the document
- [ ] "exploration settings", never "personal settings"
- [ ] "estimated_carb_range", not "final_grams" (in API/algorithm references)
- [ ] "estimated_change", not "drop"
- [ ] "projected_glucose", not "after"
- [ ] "algorithm strength", never "personalised configuration" in §9.4 AID Optimiser
- [ ] "DAFNE", never "DAPHNE" (UK structured-education programme spelling)
- [ ] "optimised configuration", never "personalised configuration" in AID Optimiser context

Content check, confirm ALL of these are present

- [ ] §5.3 Forbidden Language table includes rows for "Calculators", "Personal settings", "Personalised plan / your plan / tailored to you", and "Personalised correction-dose framing"
- [ ] §5.4 Required Language table includes rows for single-value carb framing, single-value correction-insulin framing, and output field naming
- [ ] §9.2 outputs description includes the uncertainty statement note (added v2.7)
- [ ] §9.5 Hypo Treatment Explorer compliance checklist includes DKA escalation at ≥1.5 mmol/L row, PASS
- [ ] §9.6 Hyper Treatment Explorer compliance profile present with four-pathway routing, correction-dose framing, age banding

- [ ] Seven explorers, not six, throughout (except team count in §6 which is six-person team, and age bands in §11 which is six-band)
- [ ] All seven compliance checklists reference both March 2026 and 30 March 2026 audits (or later audit dates)
- [ ] A.3 heading reads "Carbs for 30 Minutes Exercise (Exercise IOB)"
- [ ] A.3 includes field rename note for estimated_carb_range
- [ ] C.2 heading reads "Carbs for 30 Minutes Exercise (Exercise IOB) Evidence Map"
- [ ] D.2 heading reads "Carbs for 30 Minutes Exercise (Exercise IOB) (Page 11544)"
- [ ] Appendix E figures match: 144 total, 134 PASS, 10 REVIEW, 0 FAIL, 34 fixes on 10 pages
- [ ] Document control table includes v10.1 row with correct date and summary
- [ ] Version header at top reads 10.1 | 4 May 2026 (launch-eve sweep)
- [ ] VAT number GB 516 3272 08 present in header *[Line redacted in the public sample: contains tier, pricing, commercial, or cohort-evidence figures withheld pending the current content fix and the NDA gate.]*
- [ ] AID Optimiser uses "algorithm strength" terminology (§9.4)
- [ ] Correction dose framing: four-element population-average qualifier on all correction-insulin outputs (§5.3, §5.4, §9.6)
- [ ] Section 11 Age Banding Canon present with six-band runtime scheme
- [ ] Appendix C and D headings say "ALL SEVEN EXPLORERS"
- [ ] **Two-bucket audience model present** (locked 3 May 2026): §3.2 names both audiences; §5.5 audience segmentation rewritten to two buckets with granular tags; §3.3 SaMD analysis says explicitly that the not-a-SaMD defence is non-audience-conditional
- [ ] **AID Algorithm Optimiser audience-scope record present** in §9.4 referencing `aid-optimiser-positioning.md` §10
- [ ] **D4 AID Algorithm Optimiser compliance checklist** carries the two-bucket access row (added 3 May 2026)

EXECUTIVE SUMMARY

The Glucose Never Lies® is a UK-incorporated limited company operating a peer-reviewed, evidence-based digital education platform for people living with type 1 diabetes and the healthcare professionals who support them. Its seven interactive explorers translate complex clinical guidelines into accessible educational tools, not medical devices, not clinical decision support, and not prescriptive calculators. The company has assembled a comprehensive legal, regulatory, insurance, and scientific governance framework that accurately reflects the nature of the platform. This dossier presents that framework in full for regulatory, partner, and governance purposes. Every section below contains a summary and full supporting detail.

The Glucose Never Lies® was founded in 2019 by John Pemberton BSc PgDip RD, a Registered Dietitian and Diabetes Specialist at Birmingham Women's and Children's NHS Foundation Trust, following his son Jude testing positive for type 1 diabetes antibodies. Over six years the platform has grown from a single trusted voice into a structured educational company with a 1,500+ strong subscriber and listener

community, seven live interactive explorer tools, a scientific advisory board that includes two of the world's leading exercise-and-T1D researchers, and active commercial partnerships with Abbott Diabetes Care, Tandem Diabetes Care, Dexcom, Insulet, Roche Diabetes Care, and Medtronic.

The GNL Explorer Suite comprises seven tools: 10, 20, 30 Minutes Walking to Lower Highs (Activity & Exercise), Carbs for 30 Minutes Exercise (Exercise IOB), Planning for Before, During and After Exercise (Exercise Planning), AID Algorithm Optimiser (AID Systems), Hypo Treatment Explorer (legacy slug hypo-and-hyperglycaemia-explorer, page 12121), Hyper Treatment Explorer (new slug hyper-treatment-explorer, split from the combined tool 1 May 2026), and the Alcohol Explorer (Alcohol & T1D). Each explorer translates a specific body of published clinical evidence (ISPAD guidelines, EASD/ISPAD consensus statements, peer-reviewed pharmacokinetic models, and systematic reviews) into an interactive format that allows a person with T1D to explore how biological principles behave on average. Every explorer presents population-average outputs, carries a mandatory educational disclaimer, and explicitly directs users to their diabetes care team for individual clinical decisions. None of the seven explorers diagnose, treat, cure, or prevent any medical condition. None make individual prescribing decisions. None are connected to any medical device hardware. All are classified as educational media, not software as a medical device (SaMD).

GNL has correctly identified and addressed the key legal and regulatory risks facing an educational digital health platform:

- **Legal entity:** Limited company (The Glucose Never Lies Ltd, Company No. 16733595), incorporated 22 September 2025, providing personal liability protection for directors. *[Line redacted in the public sample: contains tier, pricing, commercial, or cohort-evidence figures withheld pending the current content fix and the NDA gate.]*
- **Trademark:** UK00004267795, 'The Glucose Never Lies®', registered 3 October 2025, Classes 41 (education) and 44 (medical/health services).
- **Copyright:** Berne Convention protection in 181 countries, with copyright notices added to all platform files 24 March 2026 and Wayback Machine IP snapshots captured as dated evidence.
- **IP protection:** All calculation algorithms run server-side in the secured Laravel API (github.com/phillhayes/gnl), no algorithm code is exposed in browser-facing files.
- **GDPR:** ICO registered (payment confirmed December 2025), UK GDPR compliant, no special-category medical data collected, 72-hour breach notification procedure in place.
- **Medical device classification:** Not a medical device under UK MDR 2002, EU MDR 2017/745, or MHRA SaMD guidance, rigorously documented in Section 3.
- **Scientific governance:** Six-person team including three Registered Dietitians, one exercise physiologist/CDCES, one professor of exercise physiology, and one NIHR Advanced Fellow, all with full COI declarations.

The unique space GNL occupies is the gap between published clinical guidelines and the people who need to understand them. ISPAD guidelines, EASD consensus statements, and landmark papers such as the Moser/Zaharieva EASD/ISPAD 2025 position statement contain life-changing information about exercise and automated insulin delivery, but in formats accessible only to clinical academics. GNL has made that knowledge interactive, visually explorable, and clinically meaningful without stepping across the line into clinical practice. This is not a gap that has been filled anywhere else at this quality level.

SECTION 1, COMPANY IDENTITY AND LEGAL FRAMEWORK

SECTION SUMMARY The Glucose Never Lies Ltd is a UK private limited company incorporated 22 September 2025. The limited liability structure protects individual directors from personal liability for company obligations. The company holds UK trademark UK00004267795 across three classes covering its full range of educational, technological, and health-related activities. Copyright subsists in all platform content under the Berne Convention, with dated digital evidence archived. All algorithm IP is protected by server-side deployment in a secured private repository.

1.1 Legal Entity

Field	Detail
Company name	The Glucose Never Lies Ltd
Company number	16733595
Incorporation date	22 September 2025
Registered office	36 Lea Green Lane, Wythall, Birmingham, B47 6HE, United Kingdom
Company type	Private company limited by shares
Governing legislation	Companies Act 2006
Registered with	Companies House, United Kingdom
Financial year end	30 September (first accounts due 22 June 2027)
Website	https://theglucoseneverlies.com
Platform founded	2019 (incorporated as Ltd 2025)

1.1a Trading Name: Via Negativa Health

Field	Detail
Trading name	Via Negativa Health
Legal entity	The Glucose Never Lies Ltd (Co. 16733595)
Trademark	UK00004369109 (accepted for publication 24 April 2026, owned by GNL Ltd)
Purpose	Commercial partnerships and white-label tools
Former company	Via Negativa Health Ltd (Co. 17137000), incorporated 5 April 2026, never traded. DS01 filed 27 Apr 2026 (ref GIPLTO, sole director John Pemberton). HMRC notified and removed from books. Dissolution expected ~July 2026. All obligations closed.

Via Negativa Health is a trading name of The Glucose Never Lies Ltd, used for commercial consultancy, partnerships, and white-label tool licensing. Via Negativa Health Ltd (Co. 17137000) was incorporated on 5 April 2026 but never traded; DS01 strike-off was filed on 27 April 2026 (ref GIPLTO, sole director John Pemberton). HMRC notified same day and removed VNH Ltd from their books. Dissolution expected ~July

2026. All obligations closed. All clinical content, regulatory positioning, educational explorer tools, and scientific governance remain under The Glucose Never Lies Ltd. The Via Negativa Health trading name does not operate any medical device, SaMD, or clinical decision support product.

1.2 Liability Structure

The company was incorporated as a private limited company under the Companies Act 2006. This structure provides the following protections relevant to the platform's regulatory and commercial position:

- Directors' personal assets are protected from company liabilities, the company's liability is limited to its share capital.
- The company can enter into contracts, own intellectual property, and be a party to insurance policies in its own right.
- The limited company structure is the appropriate vehicle for a platform that carries media, professional indemnity, and IP-related risks.
- The company is not a sole trader or partnership, there is no personal exposure for Multimedia Liability or Errors & Omissions claims.

The Companies Act 2006 places duties on directors including the duty to act in the company's best interests, exercise reasonable care, skill and diligence, and comply with the company's articles of association. All directors are aware of these obligations.

1.3 Trademark, UK00004267795

Field	Detail
Mark	The Glucose Never Lies®
Registration number	UK00004267795
Registered	3 October 2025
Proprietor	The Glucose Never Lies Ltd
Class 41	Education and training services in the field of diabetes management and healthcare
Class 44	Medical and health services; educational health information services
Note	**Class 42 (software/SaaS) is NOT covered by this mark.** Class 42 is covered by the second trademark application UK00004360249 (see below).
Current validity	Until 22 September 2035 (10-year renewal from filing date)
Status	Registered and in force

1.3a Second Trademark, UK00004360249 (accepted for publication)

Field	Detail
Mark	The Glucose Never Lies Educational Explorer / The Glucose Never Lies Educational Explorers (series of 2)
Application number	UK00004360249
Filed	24 March 2026
Proprietor	The Glucose Never Lies Ltd
Class 41	Provision of online interactive educational tools and resources in the field of type 1 diabetes, insulin pharmacology, and continuous glucose monitoring
Class 42	Software as a service (SaaS) providing interactive exploration tools for educational purposes in the field of diabetes technology
Status	**Accepted for publication**, IPO acceptance letter received 31 March 2026 (Anna McIlroy, Trade Marks Registry). Marks 3 & 4 removed; series of 2 confirmed. Application will be published in the Trade Marks Journal. 2-month opposition period starts on publication (extendable to 3 months if opposition received). If unopposed, registration certificate issued within 2 working weeks of opposition period close.
Contact	Anna McIlroy, Trade Marks Registry, +(0)1633 813675

[Line redacted in the public sample: contains tier, pricing, commercial, or cohort-evidence figures withheld pending the current content fix and the NDA gate.]

The ® symbol is used across all platform materials, consistent with the registered status of UK00004267795. Use of ® is legally correct for a registered trademark within its territory of registration.

1.4 Copyright

Copyright subsists automatically in all original GNL platform content, articles, podcast scripts, explorer tool content, algorithm documentation, and source code, under the Copyright, Designs and Patents Act 1988 (UK) and the Berne Convention (181 signatory countries). No registration is required for copyright protection to apply.

- Copyright notices added to all platform files: 24 March 2026.
- Berne Convention protection applies in 181 countries from the date of creation.
- Internet Archive (Wayback Machine) snapshots captured 24 March 2026, provides publicly timestamped evidence of content existence and ownership as of that date.
- Pages archived: AID Algorithm Optimiser (AID Systems), Hypo & Hyper Treatment, Carbs for 30 Minutes Exercise (Exercise IOB), Activity to Lower Highs, GNL Explorers hub.
- The copyright owner for all GNL platform content is The Glucose Never Lies Ltd.

1.5 Intellectual Property, Explorer Algorithms

The calculation logic underpinning all seven GNL explorers constitutes valuable proprietary intellectual property. The key IP protection decisions taken are:

- All algorithm code runs server-side in the Laravel API backend (github.com/phillhayes/gnl, private repository).
- No algorithm logic, constants, formulae, IOB model parameters, or scoring tables are present in any browser-facing JavaScript or PHP file.
- API keys are injected via a WordPress mu-plugin at server-side render time, never stored in client-accessible files.
- The API repository is private and access-controlled. Only Phillip Hayes (Technical Director) has commit access.
- The separation between front-end JS (which handles only UI and API calls) and back-end PHP (which holds all calculations) is a deliberate and documented IP protection measure.

1.6 IP Action Plan, Status

Action	Status	Notes
UK trademark UK00004267795	COMPLETE	Registered 3 October 2025, Classes 41, 44. Renewal: 22 September 2035.
Second UK trademark UK00004360249 ('Educational Explorer')	ACCEPTED FOR PUBLICATION	Accepted 31 March 2026. Series of 2 (Marks 1 & 2). Awaiting Trade Marks Journal publication. 2-month opposition period on publication.
[Line redacted in the public sample: contains tier, pricing, commercial, or cohort-evidence figures withheld pending the current content fix and the NDA gate.]		

| Copyright notices on all files | COMPLETE | 24 March 2026 | | Wayback Machine IP snapshots | COMPLETE | 24 March 2026, 5 explorer pages archived | | EU trademark (EUIPO), "The Glucose Never Lies" | PENDING | Madrid Protocol route available for core mark | | US copyright registration | COMPLETE | Filed 7 Apr 2026 via US Copyright Office, Case 1-15136552281, GNL Educational Explorer Suite | | Madrid Protocol international trademark | PENDING | Covers US, EU, and key territories from UK base | | Algorithm pseudocode formal documentation | IN PROGRESS | Appendix A of this dossier, internal record only | *[Line redacted in the public sample: contains tier, pricing, commercial, or cohort-evidence figures withheld pending the current content fix and the NDA gate.]*

| **GNL GRACE, US trademark (USPTO)** | **TO FILE** | Paris Convention priority window closes 9 October 2026. File before this date to claim UK priority date. |

SECTION 2, INSURANCE AND RISK FRAMEWORK

[Line redacted in the public sample: contains tier, pricing, commercial, or cohort-evidence figures withheld pending the current content fix and the NDA gate.]

2.1 Current Insurance, Full Policy Details

Field	Detail
Policy number	ESO0040530861
Policy type	Media & Professional Indemnity (Word v4.0)
Underwriter	CFC Underwriting Limited
Underwriter FCA reference	FRN 312848
Market	Lloyd's of London
Arranged via	JM Glendinning
Policy period	9 October 2025 - 8 October 2026
Territorial scope	Worldwide
Business activities covered	Publication of online content including 'Ask GNL' and podcast 'The Glucose Never Lies'
Explorer platform confirmation	Confirmed in scope following direct discussion with insurer

Insuring Clause 1, Multimedia Liability and Advertising Injury

Section	Cover	Limit per claim	Deductible
[Line redacted in the public sample: contains tier, pricing, commercial, or cohort-evidence figures withheld pending the current content fix and the NDA gate.]			

Insuring Clause 2, Professional Liability

Section	Cover	Limit per claim	Deductible
[Line redacted in the public sample: contains tier, pricing, commercial, or cohort-evidence figures withheld pending the current content fix and the NDA gate.]			

Additional Insuring Clauses

Clause	Cover	Aggregate limit	Deductible
[Line redacted in the public sample: contains tier, pricing, commercial, or cohort-evidence figures withheld pending the current content fix and the NDA gate.]			

2.2 Why This Policy Is Appropriate

GNL's primary risk profile as an educational media and SaaS platform maps directly onto two of the policy's core insuring clauses:

- **Insuring Clause 1 (Multimedia Liability):** GNL publishes online educational content, articles, podcast, interactive explorers. This clause protects against claims arising from that published content including IP infringement, defamation, and privacy, precisely the risk category that applies to an online publication. *[Line redacted in the public sample: contains tier, pricing, commercial, or cohort-evidence figures withheld pending the current content fix and the NDA gate.]*
- **Insuring Clause 2E (Regulatory Costs and Fines):** Covers costs arising from regulatory investigations, relevant given GNL operates in the healthcare information space where MHRA, ICO, or ASA engagement is theoretically possible. *[Line redacted in the public sample: contains tier, pricing, commercial, or cohort-evidence figures withheld pending the current content fix and the NDA gate.]*

2.3 Insurer Confirmation, Educational Explorer Scope

The educational explorer concept was discussed directly with the insurer (CFC Underwriting / JM Glendinning) prior to and during the policy period. The insurer confirmed that the educational explorer platform falls within the scope of the business activities as described. This confirmation is on record. The policy wording covers 'publication of online content', the explorers constitute interactive online educational publications. GNL's mandatory disclaimer on all explorers ('This is an educational explorer... not a medical device, and must not be used as one') further supports the educational media classification.

2.4 Risk Classification of the Platform

Risk category	Level	Primary mitigation
Content accuracy / E&O	Medium	Evidence base, scientific advisers, population-average framing, disclaimers
Defamation	Low	No personal clinical commentary; evidence-led content only
IP infringement (outbound)	Low	All content original; references cited; no reproduction of third-party content
IP theft (inbound, algorithms)	Medium	Server-side calculation; private API repo; no browser exposure
Regulatory (MHRA SaMD)	Low	Not a medical device, documented in Section 3
GDPR / data breach	Low-Medium	No special-category data; ICO registered; privacy controls in place
Medical malpractice	Not applicable	GNL is not providing clinical advice; not a medical device
Cyber	Medium	NOT currently covered, recommended addition

2.5 Gaps in Current Coverage and Recommended Additions

[Line redacted in the public sample: contains tier, pricing, commercial, or cohort-evidence figures withheld pending the current content fix and the NDA gate.]

- **Employers' Liability**, not currently required if all team members are shareholders/directors rather than employees. As GNL engages any contractor or employee on a non-equity basis, EL cover becomes a legal requirement under the Employers' Liability (Compulsory Insurance) Act 1969.
- **Directors and Officers (D&O)**, not covered. As GNL grows and engages larger commercial partners, D&O protection for directors against personal liability claims is recommended.
- **Medical Malpractice**, correctly excluded. GNL is not providing clinical services and this exclusion is appropriate.

2.6 Director Liability Limitation

Under the Companies Act 2006, directors of a private limited company benefit from the corporate veil, personal assets are not at risk for company liabilities unless a director has acted fraudulently, recklessly, or in breach of their statutory duties. GNL's directors have acted within their duties throughout the development of the platform. The Multimedia Liability and E&O insurance provides an additional layer of protection for scenarios where a claim might be brought against the company.

SECTION 3, REGULATORY FRAMEWORK

SECTION SUMMARY The GNL Explorer Suite is not a medical device under UK MDR 2002, EU MDR 2017/745, or MHRA Software as a Medical Device guidance. The seven explorers present population-average educational outputs, they do not diagnose, treat, cure, or prevent any medical condition, nor do they make individual clinical decisions. MHRA SaMD guidance explicitly distinguishes software that drives clinical decisions (potentially a medical device) from software providing general information or education (not a medical device), GNL falls clearly in the latter category. This classification is documented across six independent statutory grounds. GNL maintains active relationships with six device manufacturers, all on an editorially independent basis.

3.1 Medical Device Classification, NOT a Medical Device

Framework	Status	Basis
UK Medical Devices Regulations 2002 (as amended)	NOT a medical device	Does not satisfy the definition of 'medical device', no intended medical purpose at individual level
EU Medical Device Regulation 2017/745 (MDR)	NOT a medical device	Intended purpose is education, not diagnosis, treatment, cure, monitoring, or prevention
MHRA Software as a Medical Device (SaMD) guidance	NOT SaMD	General information/education, below the threshold for SaMD classification
FDA Digital Health Center of Excellence guidance	NOT SaMD	Population-level educational information; no individual clinical decision support

3.2 Intended Purpose Statement (Regulatory)

The intended purpose of each GNL explorer, for regulatory classification purposes, is as follows:

The GNL Explorer Suite is designed to provide interactive educational information about how physiological and pharmacological principles behave at a population-average level in people with type 1 diabetes. The explorers translate published clinical evidence, including ISPAD guidelines, EASD/ISPAD consensus statements, and peer-reviewed pharmacokinetic models, into accessible interactive formats. All outputs are explicitly framed as population averages, not individual predictions. All explorers carry a mandatory disclaimer stating they are not a medical device and must not be used as one, and directing users to their diabetes care team for any individual clinical decision.

The intended audience is captured at registration via a two-bucket model (locked 3 May 2026, `gnl-grace/wiki/policies/explorer-audience-gating.md`): **Bucket 1, "I have diabetes or support someone with it"** (people living with diabetes and the people supporting them: parents, partners, carers, family, friends, school staff; granular tags `pwd`, `supporter`); and **Bucket 2, "I work in diabetes care, research or industry"** (healthcare professionals, diabetes specialist nurses, dietitians, psychologists, researchers, device or pharma teams; granular tags `hcp`, `researcher`, `industry`). Both audiences are intended users of every explorer; bucket selection drives the tone (lay-accessible vs peer-clinical) but not access. Edge cases (journalists, regulators, prospective consultancy clients, NGOs not in a diabetes role) route to `john@theglucoseneverlies.com` via a footer link with no in-app option for them.

This intended purpose is educational media, not clinical decision support. The platform does not claim to assist in any medical decision, does not connect to any medical device, does not receive individual patient data from a clinical record, and does not generate outputs that are intended to be acted upon without clinical oversight. The disclaimer architecture (population-average framing, "not a medical device" attestation captured at registration via five mandatory legal acks, correction-dose framing rule, care-team referral, banned prescriptive language) applies identically to both audience buckets and is the safety gate.

3.3 Distinction from Class II / III SaMD, Detailed Analysis

Classification axis	GNL position	Evidence
Intended purpose	Education and general information	All outputs population-average; mandatory disclaimer; no individual clinical decision output
Seriousness of situation	Non-serious / non-critical	User is not in an acute clinical situation requiring device-driven decision support
Drive clinical management?	No	Outputs require clinical judgement; explicitly not prescriptive
Diagnose a condition?	No	No diagnostic output of any kind
Connected to a medical device?	No	No CGM, pump, or AID system integration
Individual prediction?	No	Population-average framing, explicitly stated
Replace clinical judgement?	No	All outputs direct user to their diabetes care team

Under the MHRA's published decision tree for SaMD, software that provides 'general information, reference material, clinical guidelines, education, communication and support' is excluded from SaMD classification. GNL's explorers satisfy all four of these characterisations simultaneously.

Audience scope of the not-a-SaMD defence (added 3 May 2026). The not-a-SaMD defence above rests on five points: (1) population-average framing on every output, (2) the verbatim educational disclaimer carried on every explorer, (3) the explicit care-team referral on every output, (4) no individual-decision output of any kind, and (5) no medical device interface (no CGM, pump, or AID system integration). **None of these five points is conditional on audience.** The defence holds identically whether the user is in Bucket 1 (people living with diabetes and the people supporting them) or Bucket 2 (professionals working in diabetes care, research or industry).

The AID Algorithm Optimiser was previously gated to HCPs as an additional precaution under the 27 April 2026 `gnl-grace/wiki/policies/explorer-audience-gating.md` operational policy. That gating was removed on 3 May 2026 after a four-question evidence review (`to-do/AID_OPTIMISER_AUDIENCE_RESEARCH_2026-05-03.md`) found that:

- This dossier itself was silent on AID Algorithm Optimiser audience scope at every prior version up to and including v9.2; the not-a-SaMD defence was never built on an HCP-only premise.
- No manufacturer review exchange between March and April 2026 (CamAPS, MiniMed, Tandem, Insulet) named or implied an HCP-only audience. Contemporaneous correspondence (Medtronic 21 March 2026 "Our tools educate HCPs and people with T1D"; CamAPS pitch with PWD-facing per-device portal; Insulet outreach "people with T1D and their clinicians"; Tandem 16 April email referencing the live public AID Optimiser URL with no gating mention) describes the suite as serving both audiences. The "reviewed by, not endorsed by" framing recorded in `aid-optimiser-positioning.md` §2 carried no audience commitment.
- Other GNL explorers (Hypo Treatment, Hyper Treatment, Exercise Planner, Carbs for 30 Minutes Exercise) already discussed dose-adjacent reasoning openly to Bucket 1 users under the same disclaimer architecture. Restricting the AID Algorithm Optimiser was internally inconsistent.
- The five mandatory legal acks captured at registration (Flutter `gnl-app/lib/src/app.dart` lines 2321-2367) cover the not-a-medical-device, not-personalised, no-independent-treatment-decisions, care-team-discussion, and final attestation positions. They apply identically to both audience buckets and are the safety gate.

The residual concern is empirical (no usability data on multi-parameter settings outputs under disclaimer mediation when used by people without clinical training). Mitigation: disclaimer-engagement telemetry will be collected via the consent JSON column from May 2026 onward; a 90-day post-launch review (target ~3 August 2026) will test whether the disclaimer architecture is functioning as the safety gate the policy assumes. This residual concern does not move the explorer suite across the SaMD threshold; the five-point structural defence is intact.

3.4 Global Regulatory Considerations

United Kingdom, MHRA GNL is a UK company operating a UK-hosted platform. The MHRA is the primary regulatory authority. Based on the documented intended purpose and the six-ground analysis in 3.1-3.3, no MHRA registration or device approval is required.

The UK MDR 2002 has been materially amended since the original v1.0 dossier and is mid-reform: the **Medical Devices (Post-market Surveillance Requirements) (Amendment) Regulations 2024** came into force **16 June 2025** (15-day serious-incident reporting window for manufacturers of CE- and UKCA-marked devices); a further pre-market SI is expected in 2026 introducing an international reliance scheme; MHRA ran a consultation **16 February to 10 April 2026** on **indefinite recognition of CE-marked medical devices in Great Britain** (extending current MDD transitional arrangements from 30 June 2028

to 31 December 2028, plus indefinite recognition for EU MDR / IVDR devices). GNL has reviewed the 2024 PMS amendment and the 2026 indefinite-recognition consultation and confirms that neither alters the explorer suite's non-device classification (GNL is not a manufacturer of CE / UKCA devices and the recognition scheme has no operative effect on GNL's educational platform).

The MHRA has also published a **Digital Mental Health Technologies guidance framework** distinguishing **low-functionality** software (stores or communicates data without change, processes user instructions to surface fixed content, processes data with an easily verifiable algorithm) from **high-functionality** software (potentially SaMD). GNL's explorers and Grace's information-retrieval surfaces sit cleanly inside the low-functionality envelope; this is fresh corroborating MHRA framing for the not-a-SaMD position laid out in §3.1-3.3.

Sources: https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices, https://www.gov.uk/government/news/mhra-launches-a-consultation-on-indefinite-recognition-of-ce-marked-medical-devices, https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk

European Union, EU MDR 2017/745 + EU AI Act 2024/1689 GNL's platform is accessible in EU member states via the public website. Under EU MDR 2017/745 Article 2(1), a medical device must have a specific medical purpose as defined; GNL's educational purpose falls outside this definition. No CE marking is required.

Under the **EU AI Act, Regulation 2024/1689**, the GNL Explorer Suite is **not** in any Annex III high-risk category. Annex III educational scope is narrowly drawn (admissions decisions, learning-outcome evaluation steering progression, level assessment, exam monitoring); a population-average educational tool surfacing evidence-anchored outputs sits outside.

For the GNL Grace AI layer (LLM-backed retrieval and chat), the operative test is the **Article 6(3) non-significant-risk derogation**, which requires a **documented self-assessment notified to the relevant market surveillance authority before the AI system is placed on the EU market**. GNL commits to filing this self-assessment when the platform formally enters EU jurisdictions (currently the platform is publicly accessible from the EU but no commercial entity is established there).

Operative AI Act dates: prohibited practices live since 2 February 2025; GPAI obligations live since 2 August 2025; high-risk Annex III obligations from 2 August 2026; full applicability 2 August 2026 with embedded-product high-risk extended to 2 August 2027. Note: the Council and Parliament reached political agreement on 7 May 2026 to **simplify and streamline** the AI Act; some obligations may be delayed but the core framework holds (see §3.4a Regulatory horizon).

Sources: https://artificialintelligenceact.eu/article/6/, https://artificialintelligenceact.eu/annex/3/, https://artificialintelligenceact.eu/implementation-timeline/

United States, FDA GNL does not currently have a US commercial entity or US-specific operations. The FDA's Digital Health Center of Excellence has published guidance distinguishing wellness and educational software from SaMD. GNL's explorers meet the definition of general wellness or educational software under FDA guidance, not subject to FDA oversight. If GNL were to enter the US market formally (e.g. US-incorporated entity, US commercial agreements), a formal FDA classification review should be undertaken.

3.4a Regulatory Horizon (Watching Briefs, added v10.2 7 May 2026)

Three live regulatory developments worth monitoring at every dossier review:

Development	Status	Why it matters	Source
National Commission into the Regulation of AI in Healthcare	Launched by MHRA 26 Sep 2025; Call for Evidence closed 2 Feb 2026 (770+ responses); recommendations due summer 2026	Recommendations may shift the SaMD threshold or introduce a new educational-AI tier; review the explorer suite's classification when the report lands	https://www.gov.uk/government/groups/national-commission-into-the-regulation-of-ai-in-healthcare
[Line redacted in the public sample: contains tier, pricing, commercial, or cohort-evidence figures withheld pending the current content fix and the NDA gate.]			

| **EU AI Act simplification agreement** | Council and Parliament political agreement 7 May 2026 to streamline AI Act obligations | May delay or restructure some AI Act requirements before the 2 Aug 2026 high-risk deadline; track for any change to Annex III scope or Article 6(3) derogation procedure that would affect GNL's EU positioning | https://artificialintelligenceact.eu/ |

Note on NICE Evidence Standards Framework (ESF): The most recent published version is the August 2022 update (which incorporated AI / adaptive algorithms). The framework targets clinically-deployed digital health technologies seeking NHS adoption. GNL is not currently pursuing NHS deployment and sits outside ESF scope. **The dossier deliberately does not engage with ESF**; doing so would invite a tier classification that GNL does not need to engage with at its current educational-only positioning. If NHS deployment is later pursued, ESF engagement becomes mandatory at that point.

3.5 Relationship with Device Manufacturers

Partner	Relationship status	Nature	Independence
Tandem Diabetes Care	Active, commercial	HCP Consulting Agreement (Dec 2025); Educational Grant 2026	Full editorial independence maintained
Abbott Diabetes Care	Active, commercial	Educational Grant Agreement (Dec 2025)	Full editorial independence maintained
Insulet (Omnipod 5)	In progress	Educational grant proposal submitted; contacts established	Full editorial independence maintained
Dexcom	In progress	Formal outreach planned; contacts established	Full editorial independence maintained
Medtronic	In progress	Outreach in progress via Andy Nicholson	Full editorial independence maintained
Roche Diabetes Care	In progress	Educational proposal submitted (Quote 001, Dec 2025)	Full editorial independence maintained

GNL's editorial independence policy: No commercial partner has advance sight of, veto over, or editorial input into any GNL content, article, explorer algorithm, or scientific communication. Educational grants support the platform's operational costs, they do not purchase editorial influence. This policy is non-negotiable and is the basis on which GNL's scientific integrity rests.

SECTION 4, PLATFORM STORY AND UNIQUE POSITIONING

SECTION SUMMARY GNL was founded in 2019 by John Pemberton, a NHS Registered Dietitian and Diabetes Specialist, after his son Jude tested positive for type 1 diabetes antibodies. The platform fills a genuine gap: complex clinical guidelines that exist in peer-reviewed academic form but are inaccessible to most people with diabetes have been translated into interactive, explorable educational tools. GNL has 1,500+ active subscribers and podcast listeners, educational grants from five major device manufacturers, and a scientific advisory team that includes two authors of the 2025 EASD/ISPAD position statement on exercise and automated insulin delivery. This is not a generic health information website, it is a specialised, evidence-led platform built by a scientist-clinician who understands both the clinical evidence and the lived experience of T1D.

4.1 The Founding Story

John Pemberton is an NHS Registered Dietitian and Diabetes Specialist at Birmingham Women's and Children's NHS Foundation Trust, where he has worked since 2011 specialising in type 1 diabetes. In 2019, his son Jude tested positive for type 1 diabetes antibodies, the markers that indicate an individual is on the pathway to T1D. This personal experience crystallised what John had been seeing in clinical practice: people with T1D, and their families, were navigating extraordinarily complex information about insulin, glucose, exercise, technology, and food, often alone, often with unreliable sources, and without the tools to explore the evidence base themselves.

GNL was built to address that gap. Between 2019 and 2025, John built a trusted audience of 1,500+ subscribers and podcast listeners through consistently high-quality, evidence-led content. Before founding GNL, John also worked for Medtronic Diabetes (2011-2015) in sales, education, and marketing, which gave him a detailed understanding of how diabetes technology is developed, communicated to healthcare professionals, and positioned commercially.

4.2 What Gap GNL Fills, Interactive Guidelines

The clinical knowledge that underpins GNL's explorers exists in published form in peer-reviewed guidelines. But in those formats, it is:

- Dense academic text, inaccessible to the vast majority of people with diabetes.
- Static tables requiring manual cross-referencing across multiple publications.
- Unavailable for real-time interactive educational exploration.
- Written for clinical academics, not for the person injecting insulin at 6am before a run.
- Scattered across ISPAD guidelines, EASD/ISPAD position statements, Lancet papers, and Diabetes Care articles.

GNL has made this knowledge interactive, accessible, and clinically meaningful. The ISPAD 2022 consensus guidelines contain the carbohydrate floor/anchor tables that the Exercise IOB explorer and Exercise Planning explorer use. The Moser/Zaharieva EASD/ISPAD 2025 position statement contains the evidence base for AID bolus reduction strategies. The Heise 2017 and Plank 2005 pharmacokinetic papers contain the dose-dependent IOB curve model - now unified as a single sigmoidal remaining fraction model - used across all three exercise tools.

4.3 Evidence of Demand, 1,500+ Subscribers as PPI

GNL has over 1,500 active subscribers and podcast listeners, growing organically since 2019 without paid advertising. Clinicians share GNL podcast episodes in teaching sessions, a meaningful quality signal. The 1,500+ subscriber and listener base constitutes a form of sustained Patient and Public Involvement (PPI) feedback, the type of lived-experience input that formal research programmes spend years trying to achieve.

4.4 Industry Recognition, Educational Grants

Partner	Status	Type
Abbott Diabetes Care	Active, agreement executed December 2025	Educational Grant Agreement
Tandem Diabetes Care	Active, agreement executed December 2025	HCP Consulting Agreement + Educational Grant 2026
Insulet	In progress, proposal submitted	Educational Grant proposal
Roche Diabetes Care	In progress, Quote 001 submitted December 2025	Educational proposal
Dexcom	Planned, contacts established	Educational outreach planned

4.5 Scientific Credibility, Publications and Advisers

John Pemberton has authored more than 30 peer-reviewed publications covering CGM standardisation, exercise, diabetes education, nutrition, and technology translation. Key publications: Pemberton et al. 2022 (CGM accuracy, Diabet Med); Pemberton et al. 2025 (CGM standardisation, Diabetes Care); Pemberton, Leal et al. 2025 (AID and BMI Z-score); Pemberton & Uday 2026 (Optimising AID, submitted). Scientific advisers include Professor Dessi Zaharieva (Stanford, lead author EASD/ISPAD 2025) and Prof Othmar Moser (Graz, lead author EASD/ISPAD 2025), whose published work is the direct evidence base for GNL's exercise and AID tools.

4.6 The Case for This Type of Platform

GNL's approach, population-average exploration of published evidence, with mandatory clinical team referral, is precisely the model that health education theory supports. The seven explorers address the most complex and commonly misunderstood aspects of T1D management: how insulin on board affects exercise risk, how AID systems can be optimally configured, and how to safely navigate hypoglycaemia and hyperglycaemia. GNL's tools exist at the intersection of clinical need, scientific evidence, and accessible design.

SECTION 5, EDUCATIONAL POSITIONING AND LANGUAGE STANDARDS

SECTION SUMMARY The single most important compliance line GNL walks is the distinction between educational exploration (what GNL does) and clinical prescription (what GNL never does). Every word on the platform is written to one side of this line. GNL enforces a Forbidden Language policy prohibiting any phrasing that tells an individual what to do with insulin, food, or their devices. All seven explorers carry an identical, mandatory disclaimer confirmed present by a March 2026 language audit covering 109 pages and a 30 March 2026 site-wide alignment covering a further 28 pages. Population-average framing is the structural mechanism that keeps all outputs on the educational side of the line.

5.1 The Educational vs Prescriptive Distinction

The difference between an educational tool and a clinical decision support device reduces to a single test: does the output tell the individual what to do, or does it show them how a principle behaves on average? GNL's explorers always do the latter. They show how much insulin on board is typically present at a given time after a given dose. They show how many grams of carbohydrate someone of a given weight might typically need before a given type of exercise. None of these outputs constitute a prescription, a recommendation for an individual, or clinical advice. They are the interactive equivalent of a textbook illustration.

5.2 The Standard Disclaimer

The following disclaimer appears verbatim on all seven explorers (confirmed by March 2026 language audit and 30 March 2026 site-wide alignment):

> "This is an educational explorer built from clinical trial data and real-world patterns. It models how algorithms and physiological principles behave on average, not how any individual system will behave for you. It is not a prescription, not a medical device, and must not be used as one. All

> outputs are for education and discussion only. Any changes to your insulin settings, device configuration, or diabetes management must be made with your diabetes care team."

This disclaimer satisfies five compliance functions: (1) states outputs are population-average; (2) confirms the tool is not a medical device; (3) confirms outputs are for education only; (4) directs the user to their care team; (5) pre-empts any interpretation as clinical decision support.

5.3 Forbidden Language Policy

Prohibited category	Example	Why prohibited
Direct instruction with glucose threshold	"If your glucose is X, do Y"	Constitutes individual clinical advice
Dose adjustment instruction	"You should adjust your dose when..."	Insulin dosing instruction is clinical practice
Action trigger language	"Take action if..."	Implies the explorer output is a clinical alert
Prescriptive correction framing	"The correct response is..."	No single correct response at individual level
Individual outcome certainty	"This will raise your glucose by..."	Population averages cannot be stated as individual certainties
Device-specific dosing advice	"Set your basal rate to X"	Individual device configuration is a clinical decision
Explorer tools labelled as calculators	"Use the calculator" / "the calculator shows..."	Always "explorers", never "calculators", applied globally 30 March 2026
"Personal settings"	"Enter your personal settings"	Replace with "exploration settings", implies personalisation rather than model exploration
"Personalised plan" and equivalents	"Here is your personalised plan", "your plan", "plan for you", "tailored to you", "personalised safety strategy", "personalised result"	All explorer outputs are population averages for a person with these inputs, they are not individual predictions or prescriptions. Required replacement: "population-average guide" or "average result for the average person with these inputs, a starting point for a clinical conversation, not a prescription for any individual". Applied site-wide 9 April 2026.

Prohibited category	Example	Why prohibited
Personalised correction-dose framing	"Take X units of rapid-acting insulin", "Your correction dose is X units", "Recommended correction: X U", "Correct with X units", "You need X units", "Adjust your dose by X units", "The correction needed is X units"	Every individual has their own personal correction factor (CF), set with their diabetes care team. A GNL-computed figure based on a population-average CF rule (for example 100/TDD or 1800/TDD) is a population-average estimate, not the user's actual dose. Required replacement carries four elements: (1) population-average qualifier ("Based on a population-average correction factor at this TDD"), (2) TDD anchor, (3) personal-CF reminder ("People have their own correction factors set with their diabetes care team. Apply your own correction factor."), (4) care-team referral ("If you do not know your correction factor, do not use this figure; speak to your team."). Applies to Hyper Treatment Explorer, Hypo and Hyper Tab 2, AID Optimiser CF rules (§A5.3 level 1-5 framework), Grace's voice on correction questions. Locked 1 May 2026. Hard rule: `gnl-grace/wiki/policies/correction-dose-framing.md`.

5.4 Required Language Standards by Content Type

Content type	Required framing
Explorer outputs	Population average: 'On average, someone of this weight would typically need approximately X-Y grams...' Never "personalised plan", "your plan", or "tailored to you". Use: "population-average guide", "average result for the average person with these inputs".
Educational articles	Evidence-based, source-cited, population-level: 'Studies show aerobic exercise lowers glucose by approximately 2 mmol/L per 20 minutes on average'
Hypo/hyper guidance	Threshold-referenced to clinical guidelines: 'ISPAD defines Level 1 hypoglycaemia as glucose below 3.9 mmol/L'
DKA / ketone information	ISPAD-aligned thresholds, directive language permitted for safety: 'ISPAD recommends urgent medical review at ketones above 1.5 mmol/L'
Single-value carb outputs (all explorers)	Immediately beneath the value: "*This value reflects a model estimate and may differ significantly from individual response*", applied globally v2.7, 30 March 2026
Single-value correction-insulin outputs (Hyper Treatment Explorer, Hypo and Hyper Tab 2, AID Optimiser CF rules)	Immediately above or beside the value, four-element block: "*Based on a population-average correction factor at this TDD, this glucose level would respond on average to roughly X units. People have their own correction factors set with their diabetes care team. Apply your own correction factor to your current glucose and your personal target to calculate the dose that fits you. If you do not know your correction factor, do not use this figure; speak to your team.*" Applied globally 1 May 2026. Hard rule: `gnl-grace/wiki/policies/correction-dose-framing.md`.
Output field naming	`estimated_carb_range` not `final_grams`; `estimated_change` not `drop`; `projected_glucose` not `after`, applied globally 30 March 2026

5.5 Audience Segmentation (Two-Bucket Model, Locked 3 May 2026)

The four-way audience model in earlier versions of this dossier (PWD / parents-and-carers / HCP / industry) is replaced by the two-bucket model locked on 3 May 2026 in `gnl-grace/wiki/policies/explorer-audience-gating.md`. Audience type is captured at registration in the Flutter app. The bucket is the access-control unit; the granular tag is for tone tailoring and reach reporting.

Bucket	Self-identification	Granular tags (analytics)	Includes
Bucket 1	"I have diabetes or support someone with it"	`pwd`, `supporter`	People living with diabetes (T1D and T2D), parents, partners, carers, family, friends, school staff
Bucket 2	"I work in diabetes care, research or industry"	`hcp`, `researcher`, `industry`	Healthcare professionals, diabetes specialist nurses, dietitians, psychologists, researchers, device or pharma teams

Granular tags are captured via an optional sub-question inside each bucket and stored in the `audience_type` field for analytics. They are preserved end-to-end (Flutter capture, Laravel API, Grace prompt routing, dashboard reporting). Cohort canon is unchanged: every reach figure draws from the canonical assessed-cohort phrasing in `gnl-grace/wiki/policies/cohort-figures-canon.md`.

Edge cases. Users who fall outside both buckets (journalists, regulators, prospective consultancy clients, NGOs not in a diabetes role) are routed to `john@theglucoseneverlies.com` via a small footer link near the bucket selector. There is no in-app option for them; commercial enquiries are handled outside the consumer-tier path. Industry users (manufacturer staff, pharma, device companies) get free Grace access on the same terms as anyone else in Bucket 2; they do not get Grace Max. The consultancy track (Track A small-client, Track B manufacturer grants) is the route for deeper engagement.

How GNL serves each bucket. Both buckets see every explorer; bucket selection drives Grace's tone, not access. For Bucket 1 users, Grace and the explorer surfaces lead with lay-accessible companion framing (e.g. AID Algorithm Optimiser §1.1 of `aid-optimiser-positioning.md`) and link the technical version one click away. For Bucket 2 users, peer-clinical framing (the §1 framing block) is acceptable as the lead. The disclaimer architecture (population-average framing, "not a medical device" attestation captured at registration via five mandatory legal acks, correction-dose framing rule, care-team referral, banned prescriptive language) applies identically to both buckets and is the safety gate. The five mandatory legal acks language is kept PWD-personal across both buckets by design (Bucket 2 users completing registration confirm the same statements; the safety architecture is the same).

5.6 Population-Average Framing

Every GNL explorer output is a population average, not an individual prediction. Population-average framing means: 'Based on published evidence from clinical trials, someone with these characteristics would typically experience this outcome on average.' It does not mean 'You will experience this outcome.' Individual variation in insulin sensitivity, fitness, CGM accuracy, stress, and illness means no population model can predict individual outcomes. By making this explicit, in the disclaimer, in the output language, and in educational notes, GNL correctly positions itself as an educational tool and remains outside the SaMD classification threshold.

SECTION 6, SCIENTIFIC GOVERNANCE AND ADVISORY FRAMEWORK

[REDACTED, AVAILABLE UNDER NDA]

This section of the dossier is withheld from the public sample. It contains proprietary or commercially sensitive material: algorithm internals and parameters, evidence-base specifics, validation data, governance internals, data-handling detail, commercial terms, or tier and pricing figures.

The complete section, with full working detail, is supplied to engaged clients under a non-disclosure agreement. Via Negativa Health produces dossiers of this depth and structure as a standard consultancy deliverable.

SECTION 7, GDPR AND DATA FRAMEWORK

[REDACTED, AVAILABLE UNDER NDA]

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SECTION 8, TECHNICAL INFRASTRUCTURE AND GOVERNANCE

[REDACTED, AVAILABLE UNDER NDA]

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SECTION 9, THE SEVEN EXPLORERS: INDIVIDUAL COMPLIANCE PROFILES

[REDACTED, AVAILABLE UNDER NDA]

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SECTION 10, EVIDENCE BASE OVERVIEW

[REDACTED, AVAILABLE UNDER NDA]

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SECTION 11, AGE BANDING CANON (LOCKED 1 MAY 2026)

[REDACTED, AVAILABLE UNDER NDA]

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APPENDIX A, ALGORITHM REFERENCE (FOLDED INTO GRACE DOSSIER, 10 MAY 2026)

[REDACTED, AVAILABLE UNDER NDA]

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APPENDIX B, KEY REFERENCE LIST (36 REFERENCES, VANCOUVER FORMAT)

[REDACTED, AVAILABLE UNDER NDA]

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APPENDIX C, EXPLORER EVIDENCE MAPS (ALL SEVEN EXPLORERS)

[REDACTED, AVAILABLE UNDER NDA]

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APPENDIX D, COMPLIANCE CHECKLISTS (ALL SEVEN EXPLORERS)

[REDACTED, AVAILABLE UNDER NDA]

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APPENDIX E, LANGUAGE AUDIT SUMMARY

[REDACTED, AVAILABLE UNDER NDA]

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APPENDIX F, LEGAL AND COMPANY DOCUMENTS INDEX

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APPENDIX G, INTELLECTUAL PROPERTY PROTECTION RECORD

[REDACTED, AVAILABLE UNDER NDA]

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DOCUMENT CERTIFICATION

[REDACTED, AVAILABLE UNDER NDA]

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