

Plain Language Summary (PLS) of a Clinical Trial



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Document Identity & Purpose

- **Document Type:** Plain Language Summary (PLS) of Clinical Trial Results
- **Intended Audience:** Adolescents with Type 2 Diabetes and their Caregivers
- **Context of Use:** Mandatory Public Disclosure under the European Union Clinical Trials Regulation (EU CTR 536/2014), Article 37
- **Industry Importance:** Regulatory bodies globally, led by the European Medicines Agency (EMA), now mandate that sponsors provide a summary of clinical trial results in lay language within one year of study completion. This creates a high-volume demand for medical writers who can masterfully bridge the gap between complex clinical data and patient-centric, low-literacy communication.

Portfolio Header & Positioning Statement

Positioning Statement: This portfolio sample demonstrates MedLexis's operational capability to navigate stringent European regulatory mandates.

By translating high-level, technical Phase III clinical data into an empathetic, 6th-grade-level public disclosure document, MedLexis delivers regulatory compliance without compromising scientific precision.

Trial Reference Metadata

- **Official Trial Name:** Efficacy and Safety of GLP-1 Analog MX-17 in Adolescents with Type 2 Diabetes
- **Protocol ID:** MLX-GLP1-2024-T2D-PED
- **Sponsor:** MedLexis Pharmaceuticals (Simulated)
- **Date Completed:** September 2025 (Simulated)

MedLexis Brand Standards & Editorial Compliance

This document strictly adheres to the MedLexis Editorial Guidelines:

- **No Clinical Advice:** Information is presented for disclosure purposes only; no therapeutic recommendations are made.
- **Simulated Compound Rule:** The therapeutic agent evaluated, **GLP-1 Analog MX-17**, along with its associated clinical data ranges, is explicitly labeled as simulated for

demonstration purposes to prevent regulatory misrepresentation.

Lay Summary

1. Introduction: Why This Summary Matters

We want to thank all the young people and their families who took part in this important study. Your participation helps doctors find better ways to care for teenagers with diabetes around the world.

This summary explains the main results of the trial in an easy-to-understand way. We are sharing this information so that everyone—especially those who participated—can know what we learned. Sharing these results is required by law in the European Union (EU) to ensure medical research is open, transparent, and helpful to the public.

2. General Information: What Was This Study Asking?

- **The Problem We Are Trying to Solve:** Type 2 Diabetes (T2D) is a health condition in which the body has trouble using glucose for energy. This causes sugar to build up, making blood sugar levels too high. T2D is becoming more common in adolescents. Doctors urgently need new and better treatments to help young people manage their blood sugar effectively and stay healthy long-term.
- **The Main Goal of the Study:** The main goal of this study was to see if an investigational medicine, named MX-17, was safe and effective at lowering blood sugar levels in adolescents with Type 2 Diabetes. Blood sugar control was tracked using a standard medical number called HbA1c.

3. The Study Medicine: What Was Tested?

The medicine tested in this study is called **GLP-1 Analog MX-17**. (Note: The data for this compound are simulated for demonstration purposes).

- **How MX-17 Works:** MX-17 belongs to a group of medicines called GLP-1 receptor agonists. Think of it as a natural signal booster. It tells the body to release the right amount of its own insulin exactly when food is eaten. This safely moves sugar out of the blood and into cells where it can be used for energy.
- **How It Was Given:** Participants received MX-17 as a simple injection under the skin (subcutaneous) once a week.

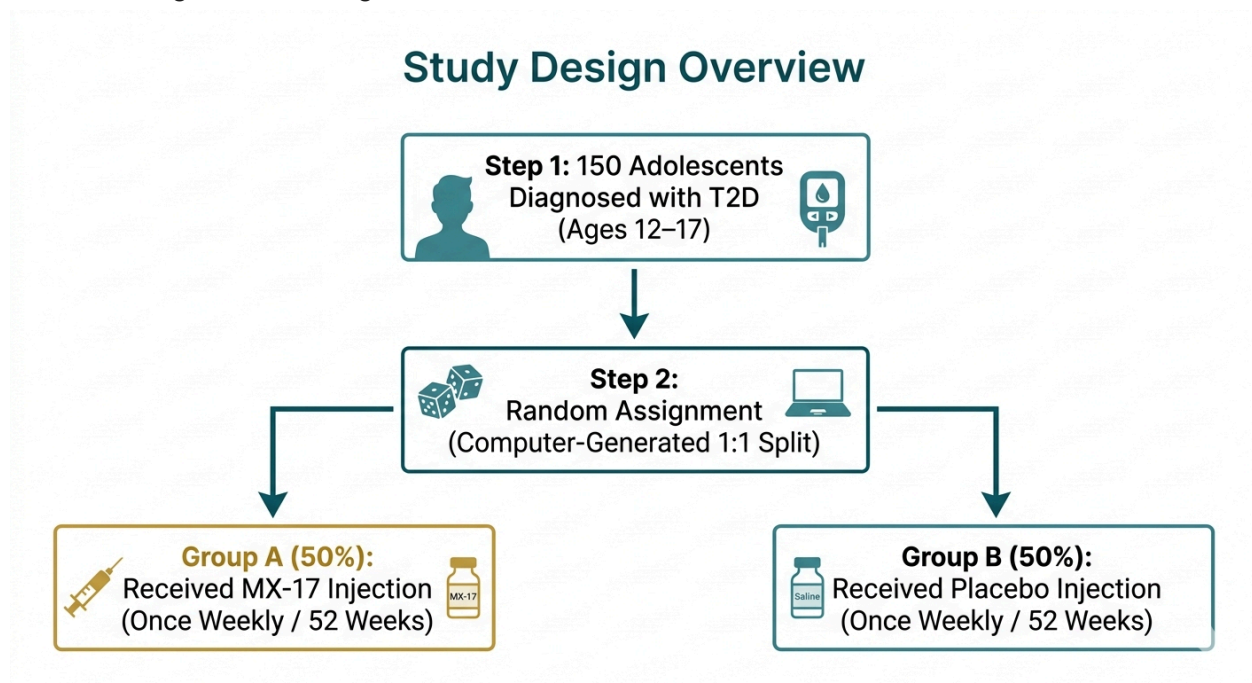
4. Study Design: Who Took Part and How Was It Done?

- **Age Range:** Adolescents aged 12 to 17 years old.

- **Total Participants:** 150 young people across clinics in the USA and Europe.
- **Duration:** Each participant stayed in the study and took their assigned medicine for 52 weeks (about 1 year).

To make sure the results were completely fair and accurate, this trial used a **Randomized, Double-Blind, Placebo-Controlled** method:

- **Randomized:** A computer randomly decided if a participant received the active medicine (MX-17) or a placebo. This ensures fairness, like flipping a coin. Half (50%) received MX-17 and half (50%) received the placebo.
- **Placebo:** A placeholder injection that looks exactly like the study medicine but contains no active ingredients. This shows us what happens without the medicine.
- **Double-Blind:** Neither the participants, their families, nor the study doctors knew who was getting the active MX-17 or the placebo. This prevents personal expectations or feelings from altering clinical observations.



5. Efficacy Results: What Were the Main Results?

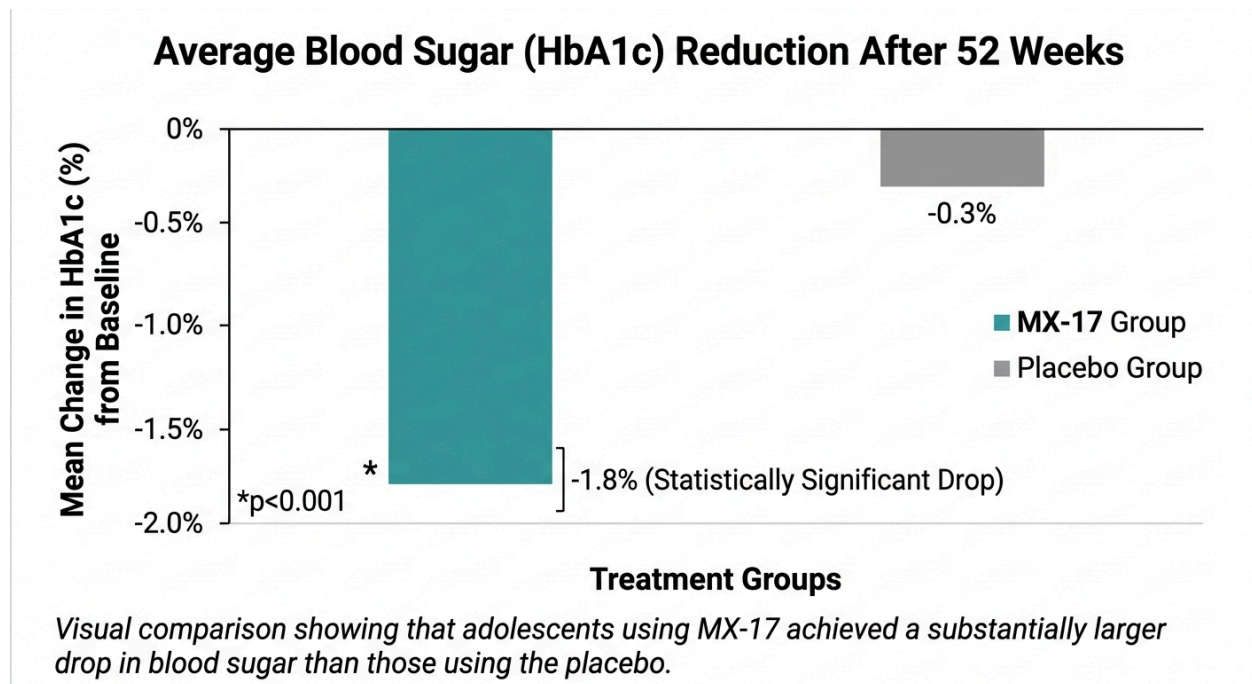
After 52 weeks (1 year) of treatment, researchers measured the change in the average blood sugar number (HbA1c) from the start of the study.

- **MX-17 Group:** The average blood sugar number **dropped by 1.8%**. In diabetes care, this is a large, highly important drop that helps protect young people from long-term

health complications.

- **Placebo Group:** The average blood sugar number **dropped by only 0.3%**.

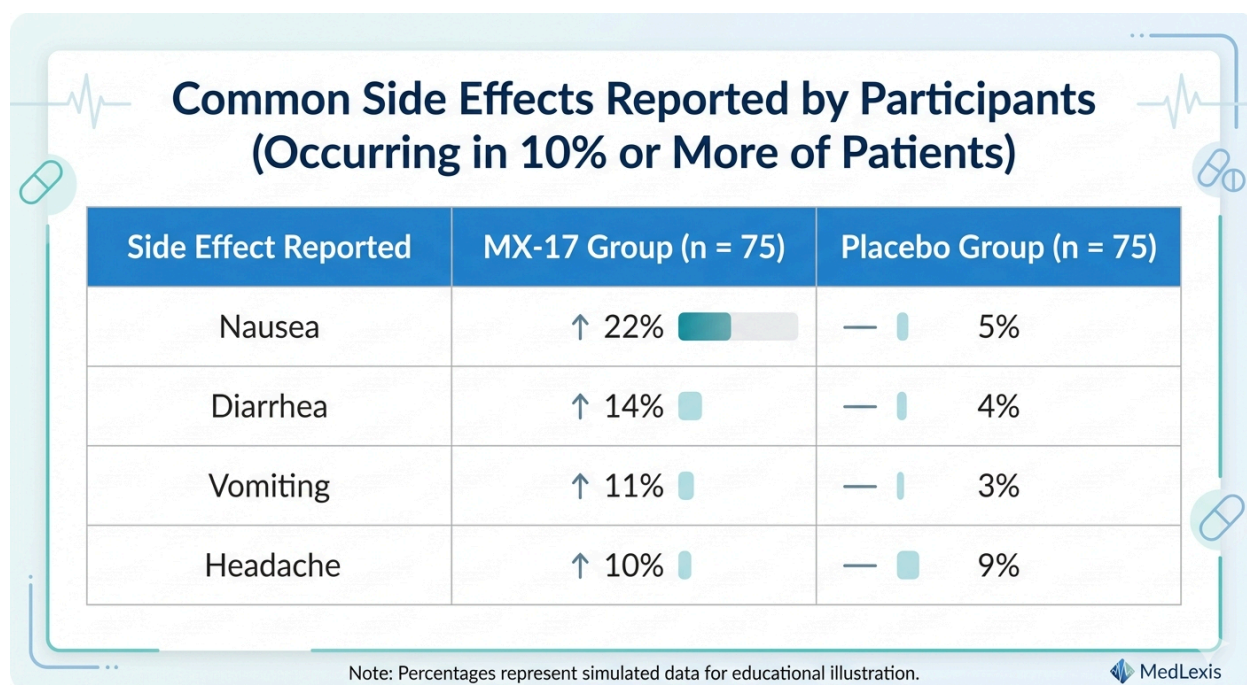
The data show that MX-17 lowered blood sugar significantly better than the placebo injection.



6. Safety Profile: What Were the Side Effects?

All medicines can have side effects. Doctors closely tracked all health events during the 52 weeks. Most side effects observed in this study were mild, temporary, and easily managed.

- **Most Common Side Effects:** The most frequent side effects occurred in the digestive system:
 - Nausea (feeling sick to your stomach)
 - Vomiting
 - Diarrhea
- **Timing:** These digestive issues usually happened during the first few weeks of the study when the dose of the medicine was being increased. For most teenagers, these feelings went away on their own after a short time.
- **Serious Side Effects:** Severe side effects that required hospital care were very rare. They occurred at equal rates in both the MX-17 group and the placebo group, meaning they were generally not caused by the medicine itself.



7. Study Limitations: What This Study Cannot Tell Us

Every clinical trial has limits. It is important to know what questions this study could not answer:

- **Age Limits:** This trial only looked at teenagers aged 12 to 17. We do not know how well or how safely MX-17 works for younger children or older adults.
- **Time Limits:** The study lasted exactly 52 weeks. Because of this, we do not yet know the long-term safety or efficacy of taking MX-17 for many years. More studies will be needed to track long-term health outcomes.

8. Conclusion: What Do These Results Mean?

This study successfully showed that the investigational medicine MX-17 is highly effective at lowering blood sugar levels in adolescents with Type 2 Diabetes. It also demonstrated a manageable safety profile, with mild stomach side effects being the primary issue.

Medical experts and regulatory agencies will use these results to decide if MX-17 can be safely approved for public use as a new prescription option for teenagers.

Glossary of Terms

- **HbA1c (Hemoglobin A1c):** A simple blood test that measures your average blood sugar levels over the past 2 to 3 months. It gives doctors a long-term picture of diabetes control

rather than a single daily snapshot.

- **Insulin:** A natural hormone made by your body's pancreas that acts like a key, letting sugar leave the blood and enter your cells to give you energy.
- **Placebo:** A dummy treatment (like a sugar pill or an injection containing only saltwater) that looks identical to the real medicine but contains no active drug. It helps ensure trial results are fair and objective.
- **Randomized:** A process where a computer uses pure chance—like flipping a coin—to assign a participant to either the medicine group or the placebo group, removing human bias.
- **Double-Blind:** A strict clinical trial setup where neither the teenagers, their families, nor the treating physicians know which injection is being given until the entire study is finished.

Where to Learn More

Full clinical and technical details of this study are maintained transparently for public inspection. You can view the expanded clinical registry on the **European Union Clinical Trials Information System (CTIS)** database:

- **Search Identifier:** Protocol ID MLX-GLP1-2024-T2D-PED
- **Search Term:** "GLP-1 Analog MX-17"
- **Sponsor Inquiry Office:** MedLexis Pharmaceuticals (Simulated Public Relations Desk)

References

1. European Union Clinical Trials Regulation (EU CTR) No 536/2014, Article 37(4) regarding the submission of summaries of clinical trial results for laypersons.
2. European Medicines Agency (EMA). *Good Lay Summary Practices (GLSP)*. Recommendations of the Expert Group on Clinical Trials for the implementation of Regulation (EU) No 536/2014.
3. American Diabetes Association (ADA). Standards of Care in Diabetes—2026. *Children and Adolescents: Standards of Medical Care in Diabetes*. Diabetes Care 2026;49(Suppl.

MedLexis Strategic Value Statement

- **Real-World Application:** This document functions as a direct response to the EU CTR 536/2014 mandate, which penalizes non-compliance for trial sponsors operating within the European marketplace. Lay summaries are now an unavoidable operational line-item for pharma companies.
- **MedLexis Service Delivery Method:** MedLexis fulfills this specialized need by deploying a dual-expert editorial workflow. A credentialed medical writer establishes scientific accuracy using the technical Clinical Study Report (CSR). Then, a health communication specialist adjusts the syntax using readability indices (e.g., Flesch-Kincaid) to ensure compliance with the 6th-grade readability ceiling without stripping the clinical value of the trial results.
- **High-Value Agency Capability:** This sample demonstrates that MedLexis offers an end-to-end medical writing package. By organizing explicit layout rules and brackets for graphic designers (e.g., data visualizations, flowcharts), we streamline production pipelines for medical affairs and regulatory teams, positioning MedLexis as a premium, system-driven agency.

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