diaTribe

TIME COALITION IN RANGE

July 14, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, DC 20201
Submitted via Regulations.gov

RE: Request for Information (RFI); Ensuring Lawful Regulation and Unleashing Innovation to Make America Healthy Again [AHRQ-2025-0001]

Dear Secretary Kennedy:

On behalf of the Time in Range Coalition (TIRC), thank you for the opportunity to "help HHS identify any opportunities to produce cost savings, increase efficiency, and stoke health and economic innovation through deregulation" through the "Ensuring Lawful Regulation and Unleashing Innovation to Make American Healthy Again" request for information (RFI) issued on May 14, 2025 [AHRQ-2025-0001]. The TIRC respectfully urges your attention to removing an impediment to innovation in diabetes treatment by directing the Food and Drug Administration (FDA) to finalize a deregulatory draft guidance document, "Diabetes Mellitus: Efficacy Endpoints for Clinical Trials Investigating Antidiabetic Drugs and Biological Products: Draft Guidance," [FDA-2023-D-0625] that, when implemented, will increase the efficiency of diabetes drug development.

Background

Spearheaded by The diaTribe Foundation, the TIRC is a diverse group of global diabetes stakeholders, including nonprofit organizations, professional societies, industry, and patient advocates working to drive awareness and adoption of time in range (TIR). Reliable measurement of TIR, which is the percentage of time a person spends within a target glucose range and includes times above range (TAR) and times below range (TBR), is now possible through advancements in continuous glucose monitoring (CGM). As you noted during your June 24, 2025 testimony before the House Energy and Commerce Committee, this technology empowers individuals living with diabetes to be aware of their glucose levels every one to few minutes, such that they can make real-time adjustments to their diet, activity, and medication dosing to improve health outcomes.[1,2] Studies have shown that as one's TIR increases, health complications from the disease–and associated healthcare costs—decrease.[3–13]

More than 11% of the U.S. population has diabetes – a staggering 38.4 million people.[14] Over the past decade, FDA approvals of safe and effective drugs and devices have transformed diabetes care. People with diabetes now have access to therapies and devices that not only improve glucose levels, but also support weight management, reduce hypoglycemia, and prevent some of the costly complications associated with diabetes, including cardiovascular and renal disease. Furthermore, advances in the accuracy and ease of use of CGM technology has increased the acceptability by clinicians and people with diabetes who are increasingly reliant on CGM metrics like TIR for the daily diabetes management. A growing body of evidence shows that TIR has added value in clinical, research, and regulatory settings

beyond the currently accepted gold standard of hemoglobin A1c (A1c).[15–18]

The Importance of FDA Guidance in Minimizing Regulatory Burden & Maximizing Innovation

FDA plays a critical role in facilitating innovation and improving the efficiency of the drug development process through the issuance of guidance for industry, which provides important clarity, consistency, and transparency to sponsors about the necessary testing and criteria to facilitate progress toward approval of new medical products. Well-crafted guidance reduces regulatory burdens on drug sponsors, ensures that the value of the patients' participation in clinical trials is optimized, and speeds new therapies to individuals living with chronic and rare diseases, thus improving health care outcomes. In particular, "Diabetes Mellitus: Efficacy Endpoints for Clinical Trials Investigating Antidiabetic Drugs and Biological Products: Draft Guidance," [FDA-2023-D-0625] is critical for delineating the FDA's perspectives on efficacy endpoints for diabetes drugs, including the use of CGM-based metrics.

We encourage the incorporation of detailed recommendations for CGM-based metrics such as TIR, TAR, and TBR to establish clear expectations for trial designs. By ensuring consistency in the application of these measures, the guidance can significantly spur innovation in diabetes treatment and ensure that clinical trials deliver meaningful information on the efficacy of new therapies. We respectfully ask that FDA be directed to finalize that much-needed guidance prior to the end of calendar year 2025.

Conclusion

We look forward to partnering with HHS and FDA to ensure evidence-based, common-sense regulatory approaches are brought to bear to expand and advance initiatives that will improve the lives of people with diabetes. Thank you for prioritizing efforts to increase the efficiency of the diabetes drug development process.

Respectfully,

Jim Carroll
CEO, The diaTribe Foundation

Julie K. Heverly
Vice President, Time in Range Coalition and Patient Advocacy, The diaTribe Foundation

---

References

1. Martens TW, Willis HJ, Bergenstal RM, Kruger DF, Karslioglu-French E, Steenkamp DW. A Randomized Controlled Trial Using Continuous Glucose Monitoring to Guide Food Choices and Diabetes Self-Care

in People with Type 2 Diabetes not Taking Insulin. *Diabetes Technol Ther*. Published online January 6, 2025. doi:10.1089/dia.2024.0579

2. Willis HJ, Henderson MSG, Zibley LJ, JaKa MM. "Now I can see it works!" Perspectives on Using a Nutrition-Focused Approach When Initiating Continuous Glucose Monitoring in People with Type 2 Diabetes: Qualitative Interview Study. *JMIR Diabetes*. 2025;10(1):e67636. doi:10.2196/67636

3. American Diabetes Association Professional Practice Committee. 7. Diabetes Technology: Standards of Care in Diabetes—2025. *Diabetes Care*. 2024;48(Supplement_1):S146-S166. doi:10.2337/dc25-S007

4. Beck RW. The Association of Time in Range and Diabetic Complications: The Evidence Is Strong. *Diabetes Technol Ther*. 2023;25(6):375-377. doi:10.1089/dia.2023.0141

5. De Meulemeester J, Charleer S, Visser MM, De Block C, Mathieu C, Gillard P. The association of chronic complications with time in tight range and time in range in people with type 1 diabetes: a retrospective cross-sectional real-world study. *Diabetologia*. Published online May 24, 2024. doi:10.1007/s00125-024-06171-y

6. Shah VN, Kanapka LG, Akturk HK, et al. Time in Range Is Associated with Incident Diabetic Retinopathy in Adults with Type 1 Diabetes: A Longitudinal Study. *Diabetes Technol Ther*. 2024;26(4):246-251. doi:10.1089/dia.2023.0486

7. Raj R, Mishra R, Jha N, Joshi V, Correa R, Kern PA. Time in range, as measured by continuous glucose monitor, as a predictor of microvascular complications in type 2 diabetes: a systematic review. *BMJ Open Diabetes Res Care*. 2022;10(1):e002573. doi:10.1136/bmjdrc-2021-002573

8. Yapanis M, James S, Craig ME, O'Neal D, Ekinci EI. Complications of Diabetes and Metrics of Glycemic Management Derived From Continuous Glucose Monitoring. *J Clin Endocrinol Metab*. 2022;107(6):e2221-e2236. doi:10.1210/clinem/dgac034

9. Feig DS, Donovan LE, Corcoy R, et al. Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial. *Lancet Lond Engl*. 2017;390(10110):2347-2359. doi:10.1016/S0140-6736(17)32400-5

10. Kovatchev BP, Lobo B, Fabris C, et al. The Virtual DCCT: Adding Continuous Glucose Monitoring to a Landmark Clinical Trial for Prediction of Microvascular Complications. *Diabetes Technol Ther*. 2025;27(3):209-216. doi:10.1089/dia.2024.0404

11. Lu J, Wang C, Shen Y, et al. Time in Range in Relation to All-Cause and Cardiovascular Mortality in Patients With Type 2 Diabetes: A Prospective Cohort Study. *Diabetes Care*. 2021;44(2):549-555. doi:10.2337/dc20-1862

12. Alkhuzam K, Li P, Abuloha S, et al. Long-term health benefit and economic return of time in range (TIR) improvement in individuals with type 2 diabetes. *Diabetes Obes Metab*. 2025;27(3):1564-1571. doi:10.1111/dom.16168

13. Sanusi AA, Xue Y, McIlwraith C, et al. Association of Continuous Glucose Monitoring Metrics With Pregnancy Outcomes in Patients With Preexisting Diabetes. *Diabetes Care*. Published online October 2, 2023:dc230636. doi:10.2337/dc23-0636

14. CDC. National Diabetes Statistics Report. Diabetes. June 6, 2024. Accessed July 16, 2024. https://www.cdc.gov/diabetes/php/data-research/index.html

15. Battelino T, Alexander CM, Amiel SA, et al. Continuous glucose monitoring and metrics for clinical trials: an international consensus statement. *Lancet Diabetes Endocrinol*. 2023;11(1):42-57. doi:10.1016/S2213-8587(22)00319-9

16. Bevan A, Ellis G, Eskandarian M, Garrisi D. The Application of Continuous Glucose Monitoring Endpoints in Clinical Research: Analysis of Trends and Review of Challenges. *J Diabetes Sci Technol*. Published online November 28, 2024:19322968241301800. doi:10.1177/19322968241301800

17. De Block C, Cheng AYY, Christensen TB, Patted URH, Ginovker A. Healthcare Professionals' Knowledge of and Attitudes Towards the Use of Time in Range in Diabetes Management: Online Survey Across Seven Countries. *Diabetes Ther*. 2023;14(8):1399-1413. doi:10.1007/s13300-023-01429-x

18. Battelino T, Danne T, Bergenstal RM, et al. Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range. *Diabetes Care*. 2019;42(8):1593-1603. doi:10.2337/dci19-0028