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HIGHLIGHTS – VIDEO

Predictive
ACADEMY

Performance and AI Validation Studies of the AccuChek SmartGuide CGM: A novel monitoring device with glucose prediction

Dr. Ana María Gómez

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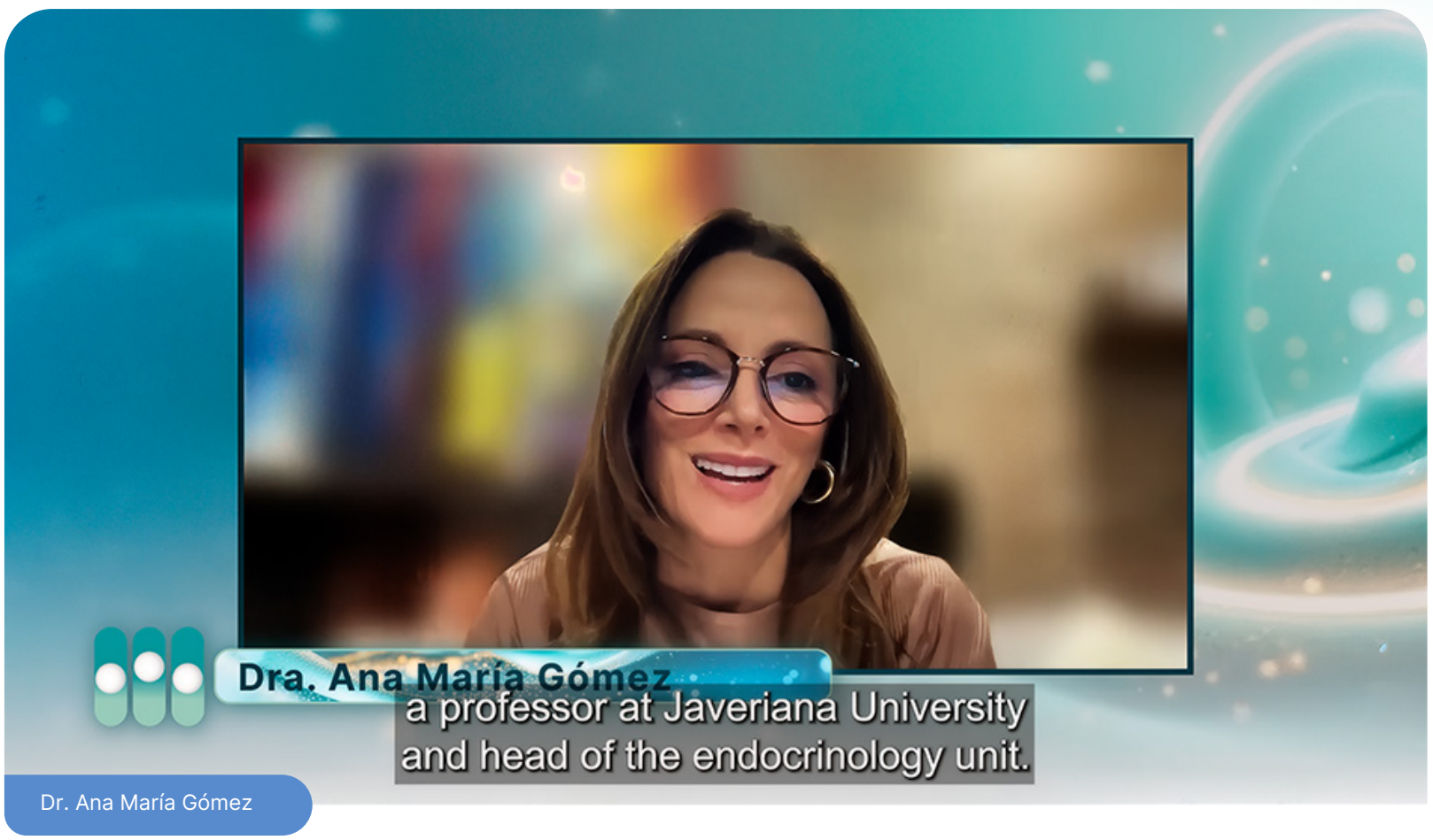

Dr. Ana María Gómez

On February 9, 2026, the recording of the video "Performance and AI Validation Studies of the AccuChek SmartGuide CGM: A novel monitoring device with glucose prediction" was conducted, presented by Dr. Ana María Gómez.

Dr. Ana María Gómez is a renowned specialist with extensive experience in the field:

- Internist Endocrinologist and Associate Professor at the Javeriana University in Bogotá - Colombia.
- Coordinator of the endocrinology postgraduate program and head of the endocrinology unit of the Internal Medicine department at San Ignacio University Hospital.
- Senior Researcher for the Ministry of Science, Technology, and Innovation of Colombia.

The intervention presents studies evaluating the accuracy, safety, and performance, as well as the validation of the Accu-Chek SmartGuide artificial intelligence algorithms within the context of continuous glucose monitoring.

This next-generation device integrates predictive models capable of anticipating glycemic dynamics, allowing for early identification of trends and potential hypoglycemic events.

Dr. Ana María Gómez introduces a multicenter open clinical trial designed to evaluate the accuracy, safety, and performance of a new continuous monitoring system in patients with type 1 and type 2 diabetes. The study included 48 individuals with type 1 diabetes (83%) and type 2 diabetes under treatment with multiple daily insulin doses, in whom three sensors were applied simultaneously per arm.

This approach allowed for the collection of more than 15,000 values over a 14-day follow-up period, providing a robust database for exhaustive precision and accuracy analyses in ambulatory and home settings. In the clinical setting, glucose excursions were introduced through the administration of insulin or additional carbohydrates, aiming to validate the device's response in extreme glycemic ranges. More than 8% of the values met levels below 80 mg/dL, and more than 5% were above 300 mg/dL.

This level of detail is essential to comply with international health regulations that require demonstrating specific accuracy at the extremes and not only in average or global values.

To evaluate these devices, regulatory entities demand strict compliance with three fundamental pillars: **statistical accuracy measured through the MARD, clinical safety validated via the Error Grid, and reliability within ranges through the 20/20 agreement standard.**[1-4]

The results confirm the system's high clinical fidelity, highlighting a MARD (mean absolute relative difference) of 9.2%, which is below 10%. This indicator is decisive, as it allows the device to be classified as "non-adjunctive," empowering both medical personnel and patients to make direct therapeutic decisions based exclusively on sensor data, eliminating the need for confirmation via capillary blood glucose monitoring.

The robustness of these findings is supported by compliance with the standard with a value of 90.5%, being highly accurate in hypoglycemia with an AR of 94.3%, and the consistency demonstrated by the simultaneous use of sensors, which guarantees the repeatability of the measurements.

Furthermore, the alignment of the data with Zones A and B of the Parkes Consensus provides the necessary safety to adopt medical behaviors with total confidence, minimizing the risk of errors in daily practice.[5-6]

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This analysis underscores that the accuracy obtained is vital for safe decision-making, especially in patients treated with insulin, where the exact detection of hypoglycemic events is critical to avoid serious complications.

The evaluation of clinical relevance of error demonstrated exceptional reliability of 99.8%, with the totality of the records located in zones A & B of the Cartesian plane. In addition to validating the device, it presents a solid safety profile; although 15 mild adverse events were reported at the insertion site, all were non-serious and resolved satisfactorily. User experience reinforces the system's value, with 88% of insertions rated as painless and 90% of participants describing the system as very easy to place and use. Aesthetic and functional acceptance was also high, with 81% liking the applicator design and 83% overall satisfaction with the CGM.

After validating these device accuracy criteria, the performance of the **Accu-Chek SmartGuide application's predictive models demonstrates an advanced capacity for proactive diabetes management.** Through the use of artificial intelligence and machine learning, the system offers three key functions: low glucose prediction at 30 minutes, a 2-hour glycemic horizon, and nocturnal hypoglycemia risk.

The 30-minute hypoglycemia alert uses current values and user trends, feeding on individual data recorded from the first day of use. On the other hand, the two-hour prediction evaluates continuous variables such as insulin boluses and carbohydrates collected over 14 days, while the nocturnal model analyzes up to 28 days of history to anticipate risks during rest.

These models have been validated through the "Predict" study and extensive cohorts of clinical and real-world studies, ensuring a reliable prognosis based on individual glycemic history, carbohydrate intake, and insulin on board. Validation confirms that the accuracy of the 2-hour prediction remains above 99% according to the Parkes Consensus, even in the absence of manual insulin and carbohydrate logs.
The predictive models for hypoglycemia detection at 30 minutes exhibit a sensitivity superior to 95% and a specificity superior to 94% in detecting hypoglycemia at 30 minutes, predicting approximately 16 minutes before the hypoglycemic event occurs, thus allowing the patient to take control of the situation, while the nocturnal prediction reaches an accuracy of 86%.[6]

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