

PROACTIVE DIABETES MANAGEMENT



Background

We hypothesized that simplifying the sharing of glucose data via a customized wireless device would provide efficiencies in the case management process. Prerequisites for success of this proactive protocol would focus on removing latency and data errors from the reporting process. The “Six Pillars” of Proactive Diabetes Management were defined as:

- Remove PC/Internet tech savvy requirements for the patients
- Provide a simple tool w/ minimal training and maintenance
- Automate SMBG collection
- Improve Data Integrity through telemetry
- Deliver Peer Group Analytics
- Simplify two-way Communications across the team

Methods

Trial Demographics:

- 10 patient families with Type 1 diabetes
- Mean age was 10.7 years

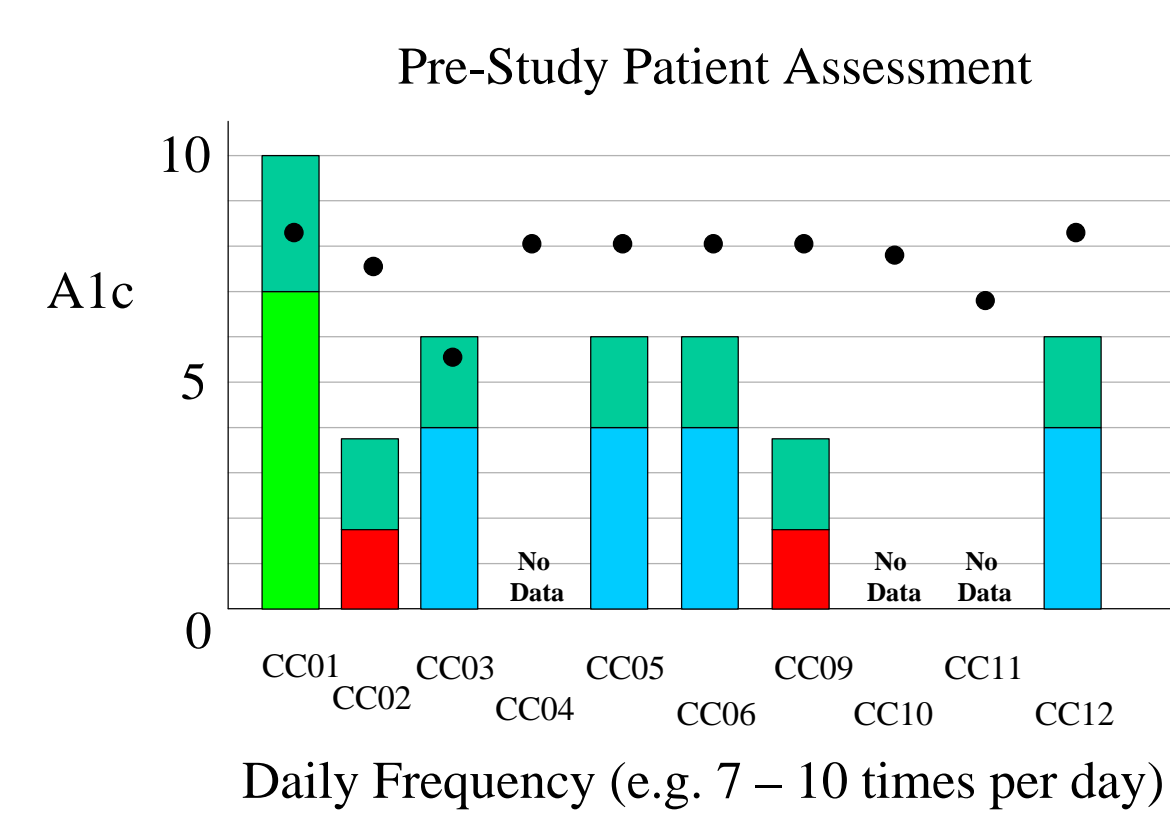


Chart #1 above is based on survey data and the patient record. Lots of questions remain.

Tools Issued:

- Each family was issued a modified two-way wireless pager
- A specialized glucose meter polling application and
- A custom cable for connecting the pager to the meter
- A second pager for e-mail communication.

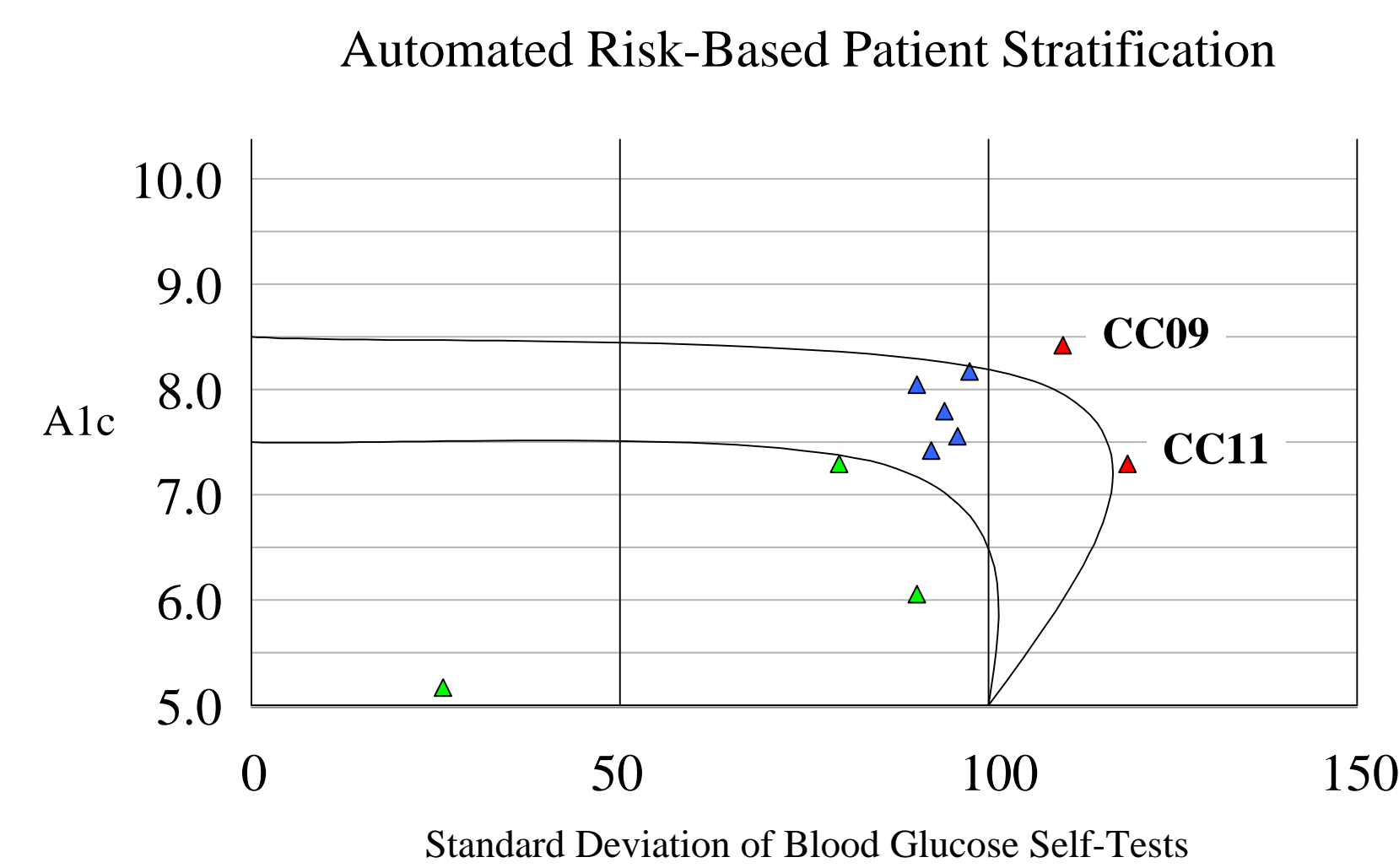
Collection and Review Procedure:

1. Following a blood sugar test as normal, **the patient pressed a button on the device** to transmit BG data to a secure website where it was added to the patient record.
2. Based on the patient profile, test confirmations were sent to members of the team as defined within the IRB. This pager alert mechanism was also selectively employed by the medical team during chronic episodes for the various patient participants.
3. Specialized analytics were deployed for the 3-month study to take advantage of the real-time system characteristics. Occasionally, the medical team would send recommendations to the family via email based on their unprompted review of the data. This could be simple advice or sometimes request to call the office.

Methods (cont'd)

Analysis and Feedback Procedure:

1. Peer Group Review



2. Individual Patient Glucose Analysis

3. Individual Logs

4. Email or Telephone Consultation

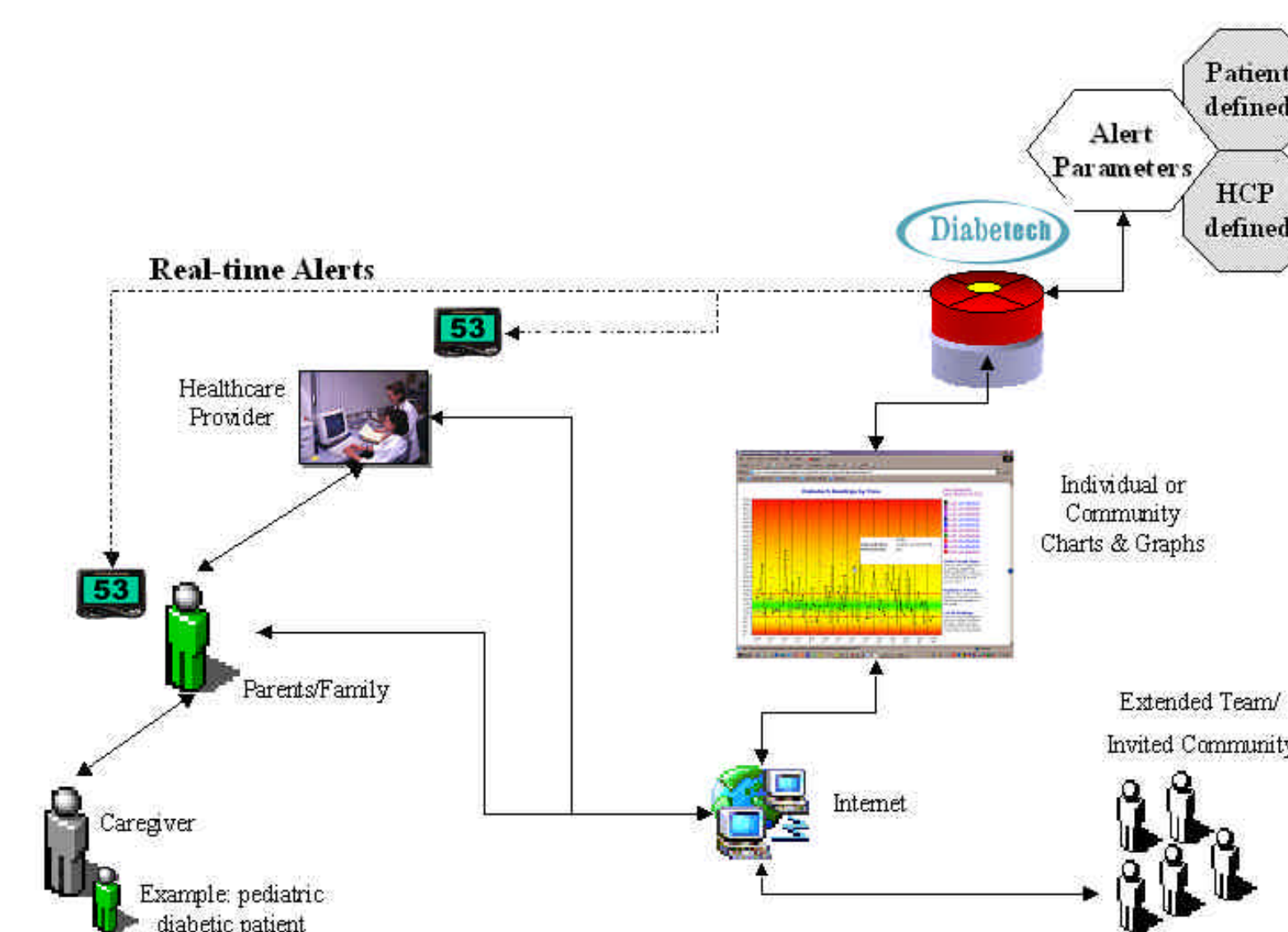
5. In-office visits as appropriate

Results

Prevent Hospital Stays: DKA Patient Case Study

The most striking use of the system occurred when a 15 yr. old male study participant entered the Emergency Room with rapid onset of DKA due most likely to pump site failure. The typical steps were taken to stabilize the patient's glucose level, flushing of ketones, etc... What was different this time was having the option to Remotely Monitor the patient in real-time after he was stabilized. Therefore, the decision was made to release the patient instead of admitting him to the hospital:

- The patient promised to self-test every 2 hours;
- The family went home;
- The physician monitored compliance and BGs remotely over his pager via real-time alerts.



The practical application of Proactive Diabetes Management is extremely cost-effective and simply a better way to manage through chronic events for all concerned.

Educational Opportunities

The medical team enjoyed many efficiencies especially in the area of diabetes education. The trial system provided a much-enhanced platform from which to deliver insightful self-test glucose analysis training. In addition, patient families expressed a high degree of satisfaction related to proactive medical advice.

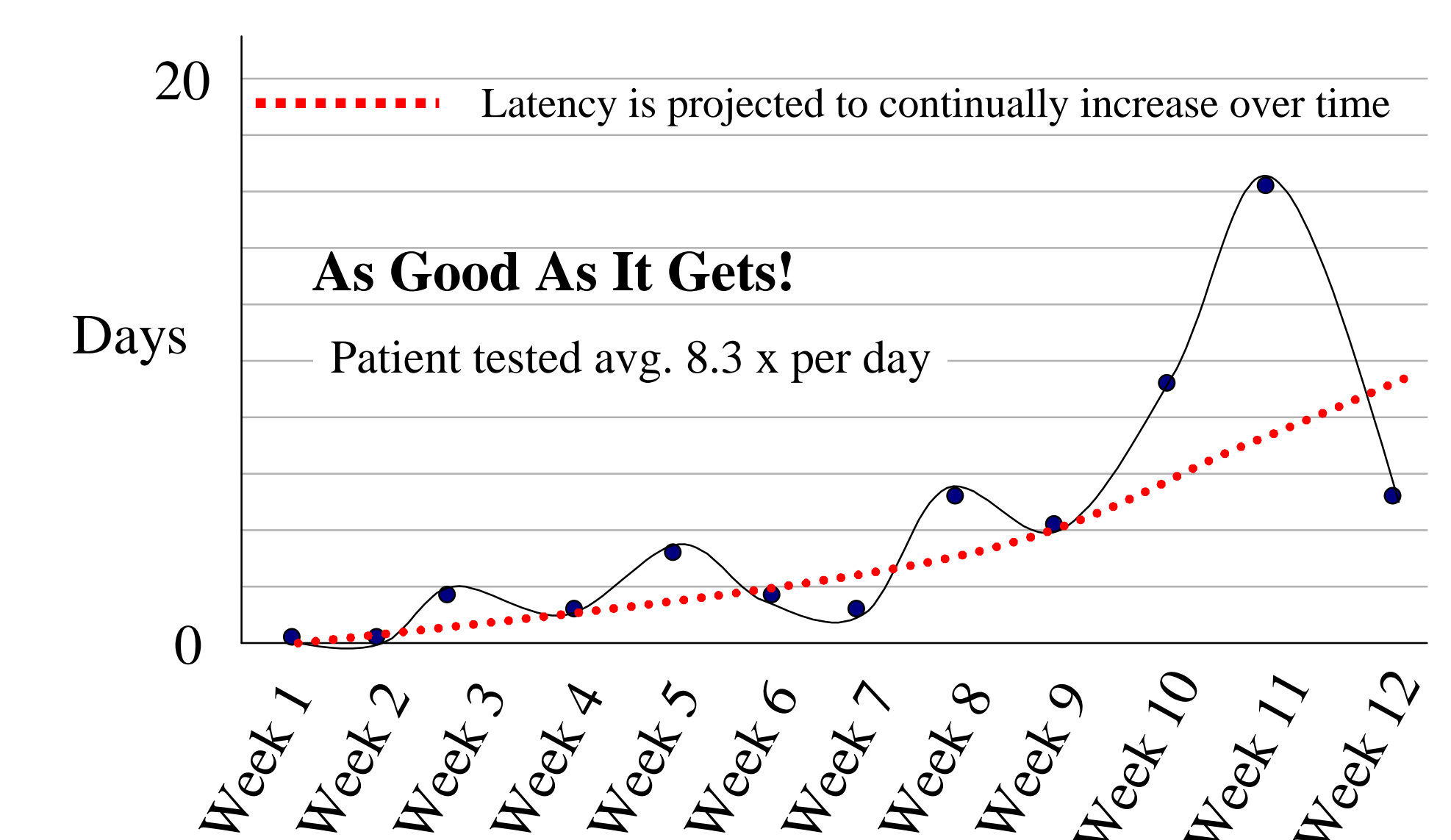
Conclusions

It is possible to achieve superior outcomes through simplifying the sharing of diabetes data. Specific events witnessed during the study suggest that a remote monitoring system for tracking disease state and compliance does contribute to an overall reduction in healthcare expenditures.

Keeping in mind the Six Pillars, liberating the blood glucose data from the meter so that it can be accessed by the extended team is the key. Otherwise, people forget, they don't have time, etc..., the data becomes unreliable, and the need for coordination prevents proactive review and intervention.

And, just because you have a frequent tester doesn't mean they will manually transmit to the degree required for Proactive Management (see below).

Typical Observed Days Between Transmission



You will notice a change in the upward trend at weeks 6 and 7. This was due to intensive management for modifying the basal profile. Otherwise, the upward trend in latency between transmissions would have surely continued to increase.

Another factor weighing in on the behavior of the study group is known as the “Hawthorne Effect” (thank you Rick Mendosa). Simply stated, when you are watched, you do better. Even though transmission latency increased over time, we observed increased test frequency by several families.

Total and complete automation of the relevant patient data collection and its transmission is essential if long-term Proactive Diabetes Management is to ever become widely adopted.

On the other hand, a diabetes management team armed with the patient's data can make remarkable progress toward shared goals including in some cases, preventing hospitalization.

The next-generation of this wireless diabetes technology has been commercialized and has incorporated total automation as its design cornerstone. A randomized follow-on peer reviewed clinical trial is in the planning stage and is expected to begin early in 2004.

Trial Sponsor

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