



TID ECOSYSTEM BACKGROUND AND CONCEPTUAL FRAMEWORK

Index

Introduction to Type 1 Diabetes (T1D) Digital Registry.....	1
Key Principles.....	2
The Conceptual Framework of T1D	3
T1D Digital Registry.....	6
Sandbox Model	7
T1D Analytical Dashboard	8
T1D Patient Dashboard	10
T1D Mobile Application	11
T1D Conversational AI Chatbot	12
Integration with External Devices.....	13
Stock management.....	15



Introduction to Type 1 Diabetes (T1D) Digital Registry

Type 1 diabetes (T1D) is a lifelong autoimmune condition that impairs the body's ability to produce insulin, leading to excess glucose that, if untreated, causes severe health complications and premature death. It is one of the most common chronic childhood illnesses, with an estimated 8.75 million people living with T1D globally in 2022, including 1.52 million children under the age of 20. The only long-term treatment is multiple daily insulin injections, as there is currently no prevention or cure.

In low-resource settings, children with T1D are often misdiagnosed or lack access to essential healthcare services, contributing to poor health outcomes. To address this, a public-private partnership was established in 2009 to provide comprehensive care for children and young people with T1D in low- and middle-income countries. This partnership includes free life-saving medicines and supplies for people up to 25 years old.

A critical challenge in supporting this initiative has been the lack of standardized, high-quality patient data collection over time.

Such data is crucial for improving health outcomes, monitoring individuals with T1D, optimizing treatment protocols, and driving research innovations in diabetes care.

To address this, Dure Technologies partnered with Novo Nordisk to develop a global T1D e-registry, leveraging Dure's experience in implementing digital health systems in low- and middle-income countries. This registry aims to improve data quality and reporting, ultimately enhancing the healthcare experience and quality of life for children and young people with T1D.

Key Principles



OPEN-SOURCE POLICY: The platform is built on open-source technologies already supported by the country.



INTEROPERABLE: The T1D platform is interoperable with other data ecosystem in the country (eg: DHIS2)



PLATFORM OWNERSHIP: Since the platform is built on open-source technology stack, the complete ownership lies with the country



DATA OWNERSHIP: The Ministry of Health is the primary owner of the data and will have access to any health data collected irrespective of platform or partners.



LOCAL CAPACITY BUILDING: The platform can be managed by existing technical resources within the countries



HOSTING AND DEPLOYMENT: The platform is hosted in MOH recommended servers within the country



COMPLIANCE: T1D platform is fully compliant with data security and privacy policies of the country.



CONFIGURABILITY: The KOLs can themselves manage the platform leveraging the configuration set-up



CO-CREATION: Any digital health system should be developed through a consultative and co-creation involving all key stakeholders.



*1:

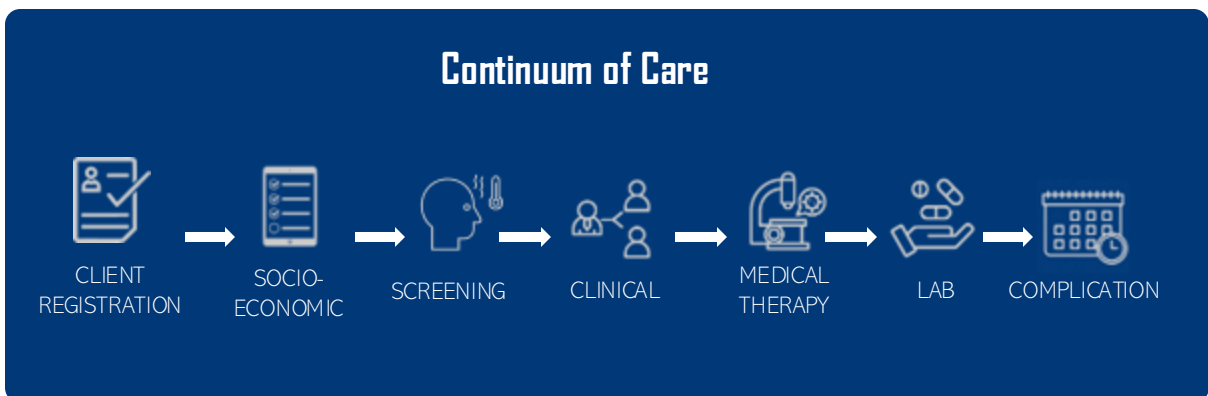
The Conceptual Framework of T1D

The T1D Digital Framework is designed to transform the care journey for individuals living with Type 1 diabetes by ensuring they are supported at every step through a continuum of care. By integrating patient data collection, clinical management, and multilevel monitoring, the framework creates a unified digital system that improves both patient outcomes and national healthcare capabilities.

Leveraging tools such as web and smartphone applications, cloud-based hosting, and seamless integration with national health systems, this digital framework ensures that every T1D patient receives continuous, high-quality care. Furthermore, the framework ensures that patient data is not just confined to individual care but also contributes to broader public health outcomes, driving more informed decision-making and improving T1D management at the country level.

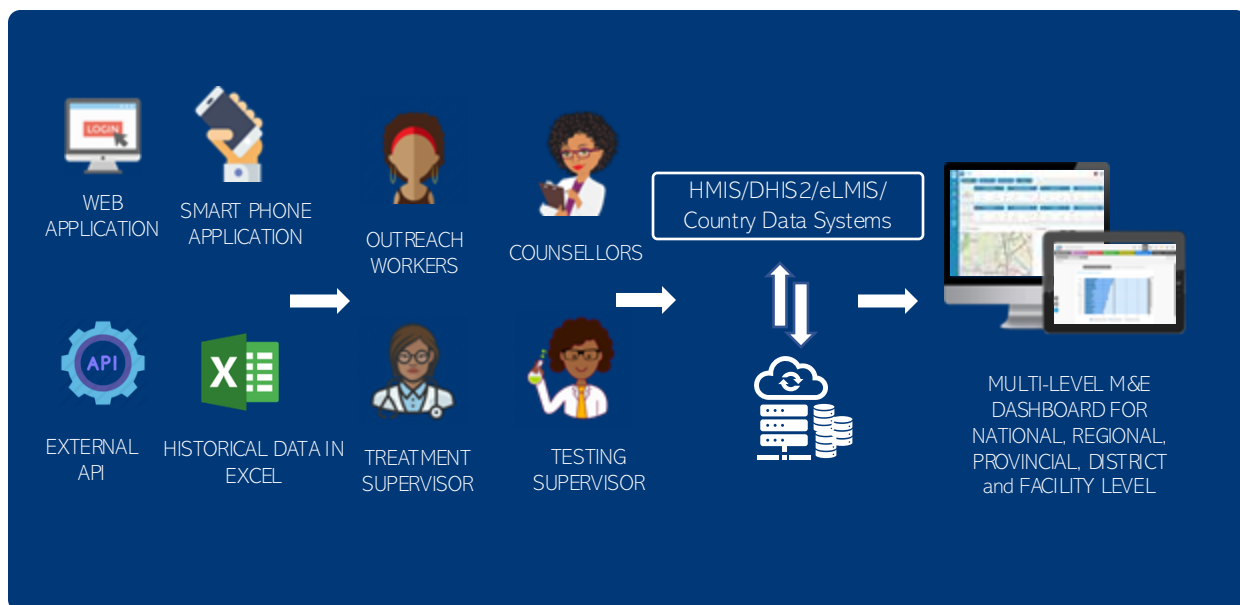
Through this framework, each patient's care journey starts with client registration, followed by a comprehensive socio-economic assessment, and screening for complications or comorbidities. This data informs the clinical management process, allowing for personalized care plans and treatment protocols that include medical therapy, especially insulin management.

The system further ensures routine lab testing to monitor critical health indicators like blood glucose and HbA1c levels. Additionally, the framework enables complication monitoring, allowing healthcare providers to manage potential long-term complications like retinopathy or cardiovascular issues. By seamlessly integrating every step of care into a centralized, patient-centric system, the T1D Digital Framework enhances not only the quality of care but also the broader ecosystem of healthcare by linking patients, providers, and national health systems.



*1:

The Conceptual Framework of T1D



Digital Framework Supporting Continuum of Care:

Web Application: The web app allows healthcare professionals to access patient data, review treatment plans, and input updates, providing real-time access to patient information.

Smartphone Application: A smartphone app enables outreach workers, patients, and caregivers to interact with the system on the go. This mobile platform can be used for scheduling appointments, receiving medication reminders, or entering glucose readings.

External API: The system allows integration with external APIs, enabling interoperability,

with other health information systems ensuring seamless data exchange, driving better management of Type 1 Diabetes at a country level.

This framework not only improves the way T1D care is managed but also enhances patient outcomes by utilizing technology to provide real-time data, patient-centric care, and comprehensive health system integration.

Historical Data in Excel: The framework also supports the migration of historical patient data in Excel format, ensuring that any previously recorded data from paper or legacy systems is preserved and utilized in patient care management.

Key Personnel in the System:

Outreach Workers: They play a critical role in connecting patients in rural or underserved areas to the digital platform, ensuring that they receive care, medication, and education on diabetes management.

T13. Counsellors: They provide support for patients, helping them navigate the emotional and psychological challenges.

Treatment Supervisor: ensures that patients are following their prescribed treatment plans, especially when it comes to insulin therapy and lifestyle adjustments.

Testing Supervisor: Oversees the lab work and ensures that patients are undergoing the necessary tests at regular intervals.

Data Integration and Monitoring:

Integration with National Systems
The system integrates with national health systems like HMS (Health Management System), DHIS2, or eLMIS. This allows for the seamless sharing of data between the T1D registry and larger national health databases, which is essential for country-wide monitoring and reporting.

Multilevel Monitoring and Evaluation Dashboard:

A multilevel M&E (Monitoring & Evaluation) dashboard is used for tracking health outcomes at different levels – national, regional, provincial, district, and facility level. This dashboard provides real-time data on patient outcomes, treatment adherence, and service delivery, helping governments and health organizations to make informed decisions about resource allocation and health interventions.

Cloud-Based Hosting:

The system utilizes cloud-based servers for data storage and hosting, ensuring data security, privacy, and scalability. Cloud hosting allows for continuous upgrades, ease of access for stakeholders, and efficient management of large volumes of patient data.

Comprehensive Data Element Creation:

Support the creation of all data element types within DHIS, offering flexibility in data collection through various input formats like checkboxes, radio buttons, and more.

T1D Digital Registry

The global CDIC ecosystem is an integrated system to address the data collection, analysis, engagement and operational aspects of T1D patient's care journey. The major aspect of this is Global T1D registry based on the Core, Core+, Core++, and Core+++ variables with a data flow based on the clinic operations. This global T1D registry is developed with key best practices suggested and validated by Novo Nordisk and Harvard University. Below are some key developments on the registry.

The goal was to develop an E-registry for T1D patients for country adaptation with a hybrid approach of extending it to EMR wherever applicable and required by the countries. The initial assessment and secondary research the global T1D registry version 1.1 was released. With the initial assessment in country like Cameroon,

Ethiopia, and Malaysia, developed the framework further and subsequent changes were implemented in next 3 version of the registry including various operational flows of the T1D facilities. This was presented the World Health Assembly 2024 in Geneva to the Wave 1 country KOLs.

Post the assessment and feedback sessions from the countries at WHA, the registry was presented to Harvard research team, our team further adapted the global registry version 1.4. which included the rules and validation of the data variables. Later to this a few final revisions were made with respect to improve the user experience and data quality. Currently, the most advanced version (1.6) of the Global T1D registry is released in the production environment validated by Novo Nordisk and Harvard team jointly.



Sandbox Model

T1D has now incorporated the Sandbox model. This model provides a system which allows countries to adapt T1D system in accordance with their specific health landscape and indicators. This enables tailoring and contextualizing the solution to country specific needs.

Program Creation & Management
Easily create and manage public health programs within DHIS using customizable registration forms with various data elements like checkboxes, radio buttons, text fields, and dropdowns. This flexibility ensures programs are tailored to specific needs.

Stage and Sub-Stage Management
Organize program stages and sub-stages effortlessly, adding or rearranging data elements for a structured data collection process. Comprehensive support for creating data elements in multiple formats ensures versatility in capturing information.

Conditional Logic & Rules
Apply conditional visibility rules to data elements, showing or hiding fields based on specific criteria, and toggle elements between mandatory or optional with ease, adapting quickly to program requirements.

Multi-Language Support

Advanced translation tools allow for language selection and translation across platforms, ensuring a consistent experience for users on mobile apps, web apps, and dashboards. Each platform's translations can be managed individually for precision.

Advanced Search Management

Customize search parameters to allow quick and efficient retrieval of patient data, based on selected data elements, improving data access and analysis.

Automatic User Management

Automate user creation post-program publishing to streamline onboarding and deployment, ensuring timely and efficient access for all stakeholders.

Preview & Facility Management

Preview the program layout on both web and mobile apps before publishing, ensuring all elements function as expected. Efficiently manage associated facilities, ensuring smooth organization and oversight of public health programs. This comprehensive feature set streamlines DHIS program management, enabling flexible, efficient, and impactful public health initiatives.

T1D Analytical Dashboard

The Type 1 Diabetes Program Dashboard is a sophisticated tool designed to monitor and manage key health indicators for patients with Type 1 Diabetes within a single facility. It centralizes vital data, facilitating informed decision-making based on clinically and operationally significant parameters. Key features are as follows:

Operational Indicators

Total Patients Registered Till Now: Displays the total count of patients registered up to the current date, offering a cumulative overview.

Yearly, Monthly, Weekly Registrations: Provides insights into patient registration trends

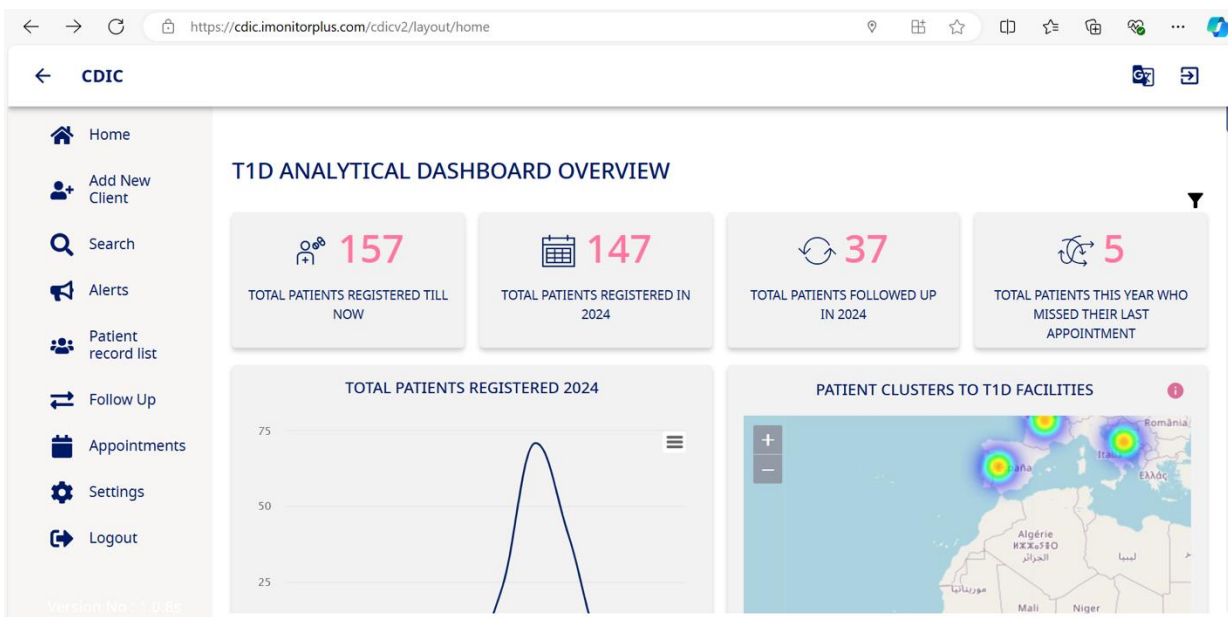
over different time periods (year, month, week), helping to identify patterns in patient intake.

Follow-Up Tracking: Monitors the total count of patients who have had follow-up visits within the current year.

Missed Appointments: Highlights patients who missed their appointments, aiding in proactive patient management.

Geographical Distribution: A map-based feature showing patient distribution by location, essential for regional analysis.

Age & Gender Distribution: Visualizes the distribution of patients by age (bar chart) and gender (pie chart), providing demographic insights.



Global Filter: A global filter allows users to filter all dashboard data by yearly, monthly, and custom date ranges, facilitating the analysis of trends over specific periods.

Pulse: A line chart or bar chart showing the distribution of pulse rates among patients from routine visits.

Insulin Distribution: A bar chart or line chart illustrating the distribution of insulin doses among patients, providing insights into insulin usage patterns.

Complications & Risk Factors:

Risk Factors & Complications: Tree maps categorize patients by various risk factors and complications, such as mental health disorders, neuropathy, and more.

Hyperglycemic & Hypoglycemic Incidences: Heatmaps track the occurrences of hyperglycemic and hypoglycemic symptoms, offering a visual representation of these critical conditions.

Risk Factors: A tree map displaying various identified risk factors among patients, including mental health disorders, celiac disease, thyroid disorders, smoking, and other risks.

Benefits

- **Centralized Patient Data:** The dashboard consolidates essential clinical and operational data in one place, streamlining patient management.
- **Real-Time Insights:** Visual indicators and charts provide instant insights into patient health trends and program effectiveness.
- **Scalable & Customizable:** The system is designed to be scalable, with customizable features that adapt to the specific needs of different facilities.
- **This dashboard is an essential tool for healthcare providers, enabling them to deliver high-quality care to patients with Type 1 Diabetes through data-driven decision-making.**



T1D Patient Dashboard

The Patient Dashboard is a critical feature of the Type 1 Diabetes Program Dashboard, designed to provide healthcare providers with a comprehensive, real-time view of patient health data.

This tool consolidates essential patient information, including medical history, lab values, appointments, and alerts, into a single, user-friendly interface. The Patient Dashboard is engineered to support informed decision-making, timely interventions, and efficient patient management, thereby enhancing the quality of care delivered to individuals with Type 1 Diabetes.

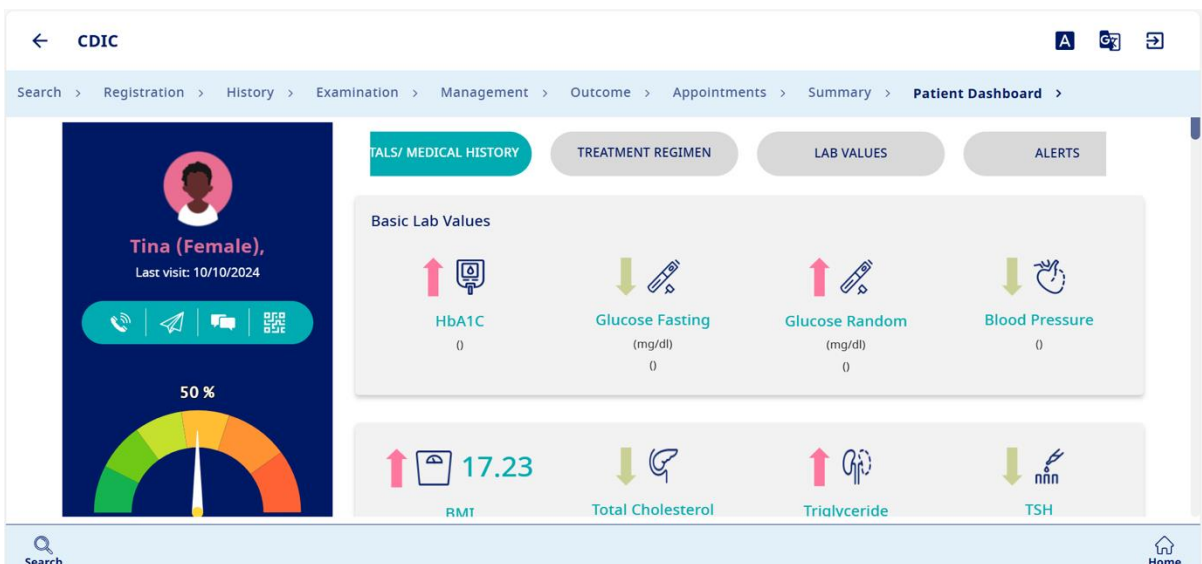
Key Features of Patient Dashboard

Patient Demographics and Socioeconomic Information

Essential Patient Information: Name, age, gender, address, and contact information are readily accessible, ensuring that providers have immediate access to basic patient details.

Socioeconomic Data: Information such as insurance status, education level, and household income is presented to provide context around the patient's social and economic circumstances. This data helps tailor care plans to the patient's needs.

Geospatial Visualization: The patient's location is mapped, showing proximity to the nearest healthcare facility. This feature aids in planning interventions and understanding logistical challenges.



T1D Mobile Application

During the course of their day to day lives, the patients must monitor their glucose levels at predetermined intervals (as instructed by their physician) and monitor their calorie intake to ensure optimum T1D case management. They may also have a lot of questions that they'd like to clarify with scientific resources and may need help scheduling their appointments, reminders for blood glucose level monitoring and alerts for upcoming appointments or investigations.

With the goal of providing assistance T1D management on the patient's end, the mobile application has been developed specifically for the patients and parents of children suffering from T1D who are enrolled in the CDIC registry. The following features of the application enable the patient to:

Previous Investigations: Securely access lab test and other relevant data from the registry for reference as required.

Compliance to Treatment Protocol: Recording of essential activities like glucose monitoring, calorie intake etc.

Appointment scheduling: Conveniently book your appointment with your preferred healthcare provider and reschedule easily in case something comes up

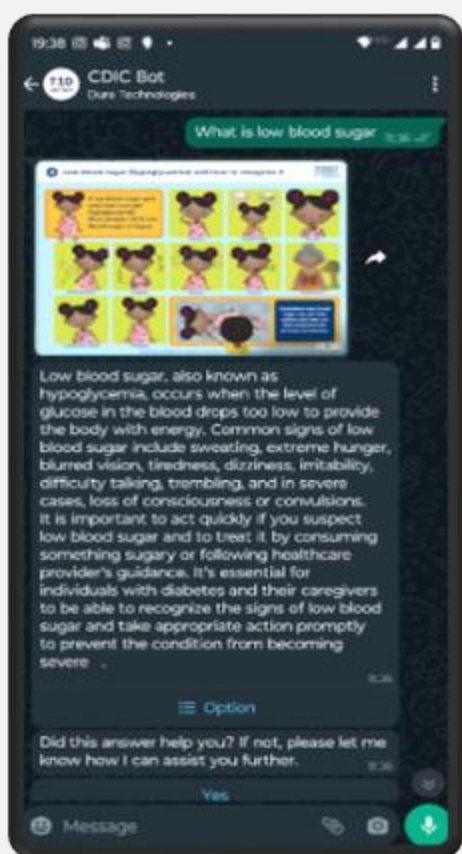
Reminders, Alerts: Notify the patient of pending lab tests, missed appointments and glucose monitoring times

With these features, the patient can easily access up-to-date, evidence-based healthcare information and also seek adequate services to ensure effective case management. The application is available for download across mobile phones and tablets via apk on android and Testflight for iOS devices. To access the application, the patient will login with their details as enrolled in the e-Registry with their healthcare provider thus enabling seamless integration and sharing of data securely across the two entities.



T1D Conversational AI Chatbot

The chatbot solution is integrated with WhatsApp, allowing T1D patients to interact with the chatbot using their WhatsApp accounts. designed for providing 24*7 helpdesk and support for T1D patients and care givers that works on both App and WhatsApp. Following are the use cases of the Conversation AI Chatbot developed for T1D patients.



Personalized Diabetes Management: Personalized advice based on patient's blood glucose levels, diet, physical activity, and medication regimen

Blood Glucose Monitoring: Remind patients to check their blood glucose levels and log readings. Suggest actionable advice in case of hyperglycemia or hypoglycemia

Nutritional Guidance: Offer nutritional advice, suggest meal plans, and even provide recipes tailored to the patient's dietary needs, preferences, and glycemic goals

Medication and Insulin Management: Remind them to take their medication, track their medication adherence. With caregiver approval, adjust insulin dosage based on self reported metrics

Lifestyle and Behavioral Coaching: Encourage and support lifestyle modifications essential for diabetes management, such as increasing physical activity, quitting smoking, and reducing stress

Integration with External Devices:

Objectives

Validate Real-time Data Transmission: Ensure that the IoT-enabled device can transmit test results to the centralized server instantly.

Test System Stability and Reliability: Assess the performance of the system under repeated and prolonged usage.

Evaluate Ease of Use: Confirm that the IoT connector can be used without requiring special training for the end users.

Verify Data Integrity: Ensure that the transmitted data is accurate and securely stored.

Ensure reusability: Ensure that the printer serial port of device can be reused for data transmission using the IoT connector.

Process

1. Setup and Configuration:

Installed the IoT connectors on a HbA1c blood testing machine.

Configured the device to connect to the centralized server via a secure communication protocol (HTTPS).

2. Initial Testing:

Conducted initial tests to verify the connectivity and data transmission capabilities.

Simulated patient tests to generate sample data for transmission.

3. Multiple Submissions:

Performed repeated submissions of test results from the device to assess system stability.

Monitored the system for any potential issues or data transmission failures.

4. Prolonged Usage Testing:

Operated the system continuously over an extended period to evaluate long-term performance and reliability.

Ensured that the system maintained consistent performance without degradation.

5. Ease of Use Assessment:

Simulated the usage of IoT-enabled devices as end users without additional training.

Collected feedback on the usability and simplicity of the IoT connector.

Outcomes

1. Successful Real-time Data Transmission:

The IoT-enabled HbA1c device successfully transmitted test results to the centralized server instantly upon completion of each test.

The data was accurately received and stored in the patient registry system without any loss or corruption.

2. System Stability and Reliability:

The system demonstrated high reliability, handling multiple submissions from the device seamlessly.

There were no instances of data loss or transmission failures, indicating robust system performance.

Prolonged usage testing confirmed that the system remained stable and responsive over extended periods of operation.

3. User-friendly Operation:

The IoT connector was easy to install and use, functioning as a simple plug-in device.

There was no reported difficulties in using the IoT-enabled devices, affirming that no special training was required. The transition to using the IoT connectors was smooth, with user

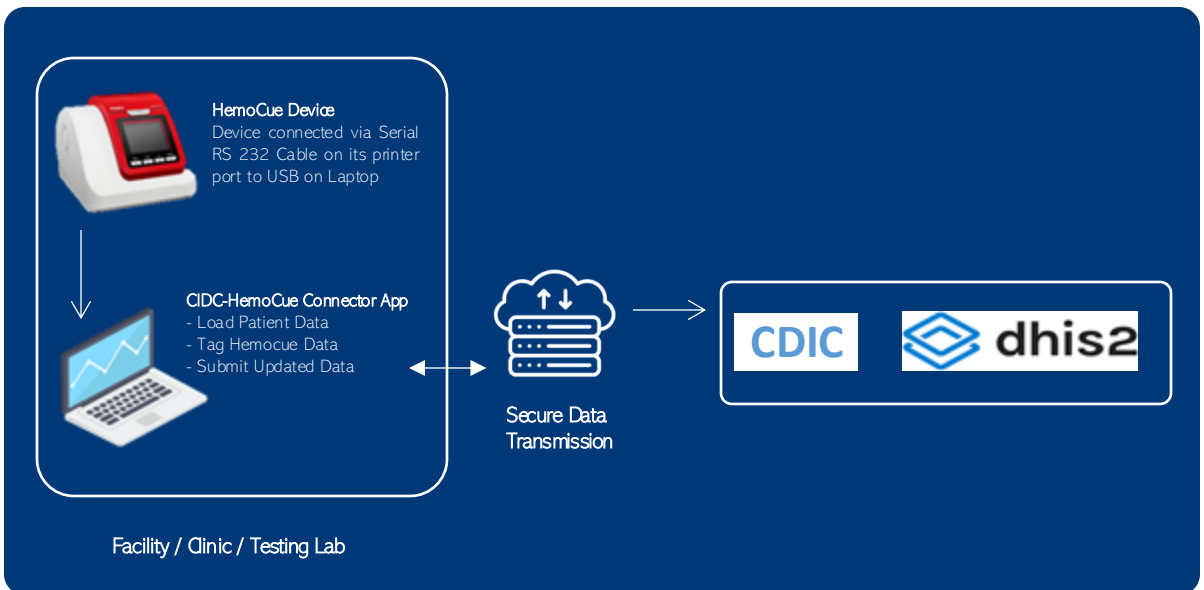
able to integrate the new functionality into their routine operations effortlessly.

4. Data Integrity and Security:

Advanced encryption protocols ensured that the transmitted data was secure and compliant with healthcare data protection regulations.

The integrity of the data was maintained throughout the transmission and storage processes, providing accurate and reliable information for patient management.

HemoCue Device Integration with HMIS



Stock management

Stock management is amongst the most crucial of hospital management activities as it directly impacts the availability of essential medication like insulin which is critical for the care of patients affected by T1D. Within the field of stock management, it is essential to note that aspects like cold chain must be maintained at all points throughout the transport of the insulin vials lest they lose their efficacy and become unusable. To enable the inventory management requirements of the facilities participating in the CDIC T1D e-registry, a stock management module was created which will enable the administrator to manage their inventory.

While designing the application, the team drew on their experiences from the on-site visits to the facilities across participating countries.

By observing their workflows and daily processes at the facilities, the team was able to determine the best features for this module of the application and isolated the functions outlined below.

Monthly Inventory Management: Input of stock for the month with Stock in and Stock Out against each line item

Inventory Levels Overview: Auto update of stock balance based on stock consumption

Threshold Alerts: To maintain optimum stock for each item, the system will alert the admin when the threshold for an item is reached.

Data Analytics and Visualization: Dashboard provides a preview of the stock levels and consumption and can be filtered across time period/ item/ expiry etc. which can be further leveraged to forecast supply and demand once sufficient data is available





T1D Ecosystem Background And Conceptual Framework