Diabyuda
Deck for DEEP TECH

Pamplona, 27 October 2025

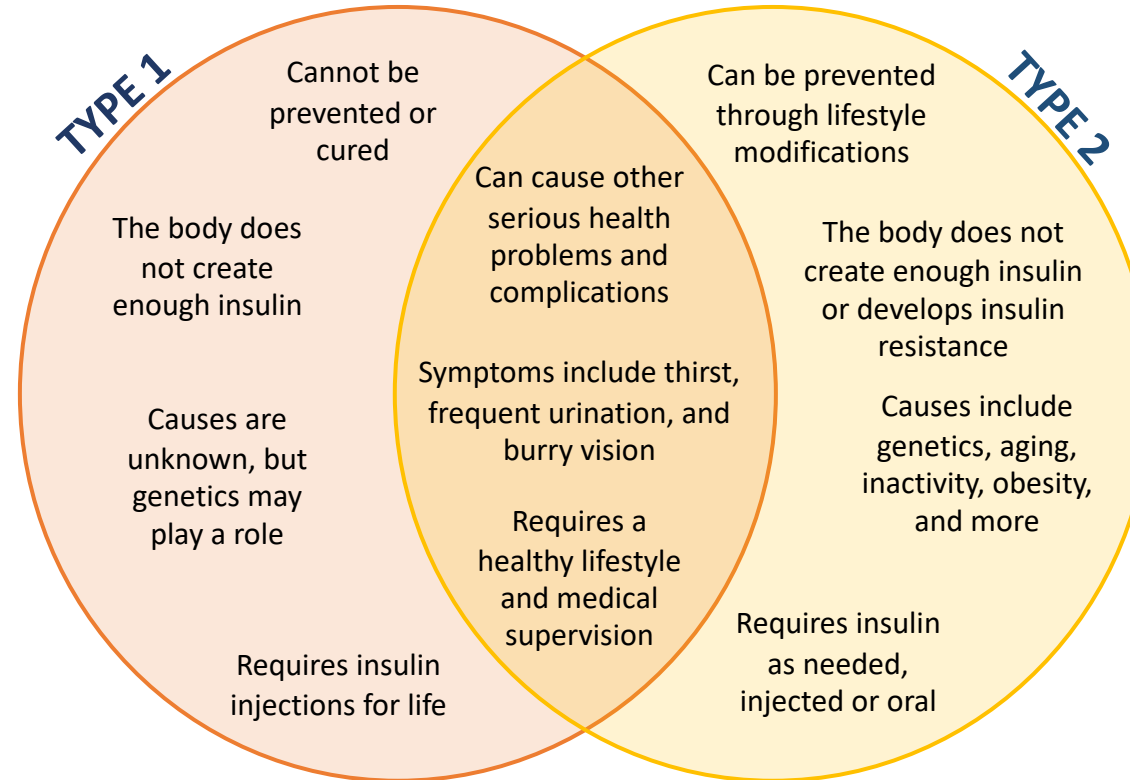Diabyuda

diabyuda

NAVARRABIOMED
CENTRO DE INVESTIGACIÓN BIOMÉDICA

Diabetes is the most common endocrine disorder

Diabetes is a **chronic**, **metabolic disease** characterized by **elevated levels of blood glucose** (or blood sugar), which leads over time to serious damage to the heart, blood vessels, eyes, kidneys and nerves.

TYPE 1 DIABETES (T1D)

Formerly known as insulin-dependent diabetes, is a type of diabetes that predominantly develops in children or young adults before the age of 40 years. It accounts for 5-10% of all diabetes cases and occurs as a result of the autoimmune destruction of pancreatic beta cells, responsible for producing insulin.
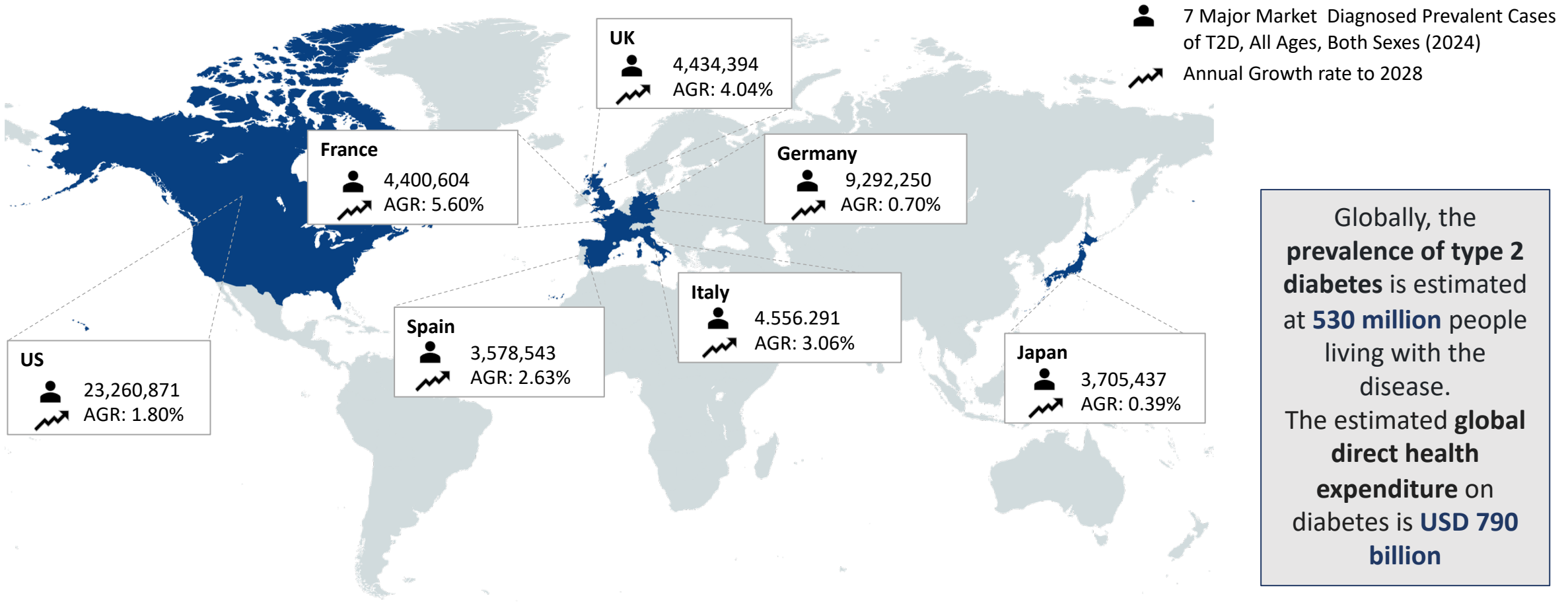
TYPE 1

Cannot be prevented or cured

The body does not create enough insulin

Causes are unknown, but genetics may play a role

Requires insulin injections for life

Can cause other serious health problems and complications

Symptoms include thirst, frequent urination, and burry vision

Requires a healthy lifestyle and medical supervision

TYPE 2

Can be prevented through lifestyle modifications

The body does not create enough insulin or develops insulin resistance

Causes include genetics, aging, inactivity, obesity, and more

Requires insulin as needed, injected or oral

TYPE 2 DIABETES (T2D)

The most common and usually in adults. It is a chronic disorder of glucose equilibrium that results from the body's inability to make use of available insulin along with relative insulin deficiency. It accounts for 90-95% of all diabetes cases and a leading cause of blindness, end-stage renal failure, non-traumatic limb amputations and cardiovascular morbidity and mortality in the working-age population.

In particular, the global burden of type 2 diabetes is increasing worldwide, being a clear unmet medical need.

Prevalence and Incidence of Type 2 Diabetes

7 Major Market Diagnosed Prevalent Cases of T2D, All Ages, Both Sexes (2024)

Annual Growth rate to 2028

UK
4,434,394
AGR: 4.04%

France
4,400,604
AGR: 5.60%

Germany
9,292,250
AGR: 0.70%

Spain
3,578,543
AGR: 2.63%

Italy
4.556.291
AGR: 3.06%

Japan
3,705,437
AGR: 0.39%

US
23,260,871
AGR: 1.80%

Globally, the **prevalence of type 2 diabetes** is estimated at **530 million** people living with the disease.
The estimated **global direct health expenditure** on diabetes is **USD 790 billion**

Sources:
Global Data – T2D: Epidemiology Forecast to 2028

Unmet need: New clinical support tool to deliver personalized treatment for T2D

Over 50% of T2D patients remain poorly controlled, facing increased risks of serious complications (cardiovascular disease, kidney failure, and vision loss).

Primary care physicians are **overburdened** (10 minutes per patient) and often **lack accessible tools to integrate the latest scientific evidence** with each patient's specific needs.

Traditional care models are fragmented, with treatment protocols scattered across multiple specialties, leading to **gaps in comprehensive care**.

Clinical guidelines are frequently updated across disciplines like endocrinology, cardiology, and nephrology, making it **difficult for clinicians to stay current in real-time practice**.

New strategies are needed to bridge these gaps by offering an advanced clinical decision support system (CDSS) tailored specifically for T2D and its associated diseases.

Clear unmet need

There is a clear unmet need for a **unified clinical support tool** that enables **primary care physicians** to deliver **personalized**, **evidence-based treatment** for T2D.

Diabyuda: CDSS in pharmacological decision-making in the management of T2D

There is a **critical gap** in type 2 diabetes (**T2D**) **management**: the **integration** of **personalized**, **multidisciplinary care** across the patient journey to **improve treatment adherence** and **reduce complication.**

An advanced **Clinical Decision Support System** (CDSS) tailored specifically for T2D and its associated diseases.

The group of Joaquin de Carlos is developing a **CDSS** leverages **real-world data** and **clinical guidelines** to generate **personalized**, **evidence-based recommendations** for professionals in real time.

→ Diabyuda is designed to provide contextual recommendations within electronic health records.

→ It integrates the **latest evidence-based clinical guidelines** into a streamlined platform that provides **real-time**, **patient-specific recommendations**.

→ It **automatically adjusts** for factors such as **renal function** and **drug-drug interactions**, ensuring **safer** and **more accurate treatment** while reducing the cognitive burden on healthcare professionals.

→ DIABYUDA **reduces time burdens** and **enhancing efficiency**.

Enables **healthcare professionals to provide high-quality**, comprehensive care that responds to the **unique complexities of each patient with T2D**.

Diabyuda: features and value proposition

Diabyuda includes:

Patient: Personalized therapy guidance, providing customized drug recommendations, adjusting for specific factors such as age, comorbidities, prior treatments. Generating reports and **lifestyle recommendations**

Healthcare professionals: Supports therapeutic decision-making, particularly in complex polypharmacy scenarios, improving **dosing accuracy and patient safety**. Saving time.

Healthcare system: Optimizes resource allocation, saving money.

Diabyuda offers the potential for substantial **cost savings** by **reducing adverse events**, **optimising treatment**, and **minimising unnecessary interventions**. By bridging the clinical and technological domains, **Diabyuda aligns with healthcare's digital transformation** goals and offers a **scalable**, **patient-centric approach** to managing complex chronic diseases such as T2D.

Main points to consider

1 For Diabyuda IP protection, is based on a combination of strategies including:

- **Trademark Registration:** it is recommended to register a trademark for the **Diabyuda name** and **logo** in key markets, including Europe and the USA, to ensure legal protection of the brand identity in case the team wishes to retain and use it for future marketing purposes.
- **Trade secrets:** for the protection of **algorithms** and **software.**
- **Copyrights protection:** to ensure the **authorship of code.**

2 Diabyuda initial IP protection focus is **Europe**, with planned expansion to the high-prevalence diabetes regions, **America** and **Asia**.

3 Diabyuda team has conducted a **preliminary FTO analysis** to identify any existing patents that could pose a risk to their method's commercialization. A more **comprehensive FTO** will later be carried out by a **patent agency** to confirm that Diabyuda's intellectual property does not infringe on existing patents, ensuring their ability to operate freely within the intended markets.

⚠ **Strong Intellectual Property is required to obtain the interest of investors.**

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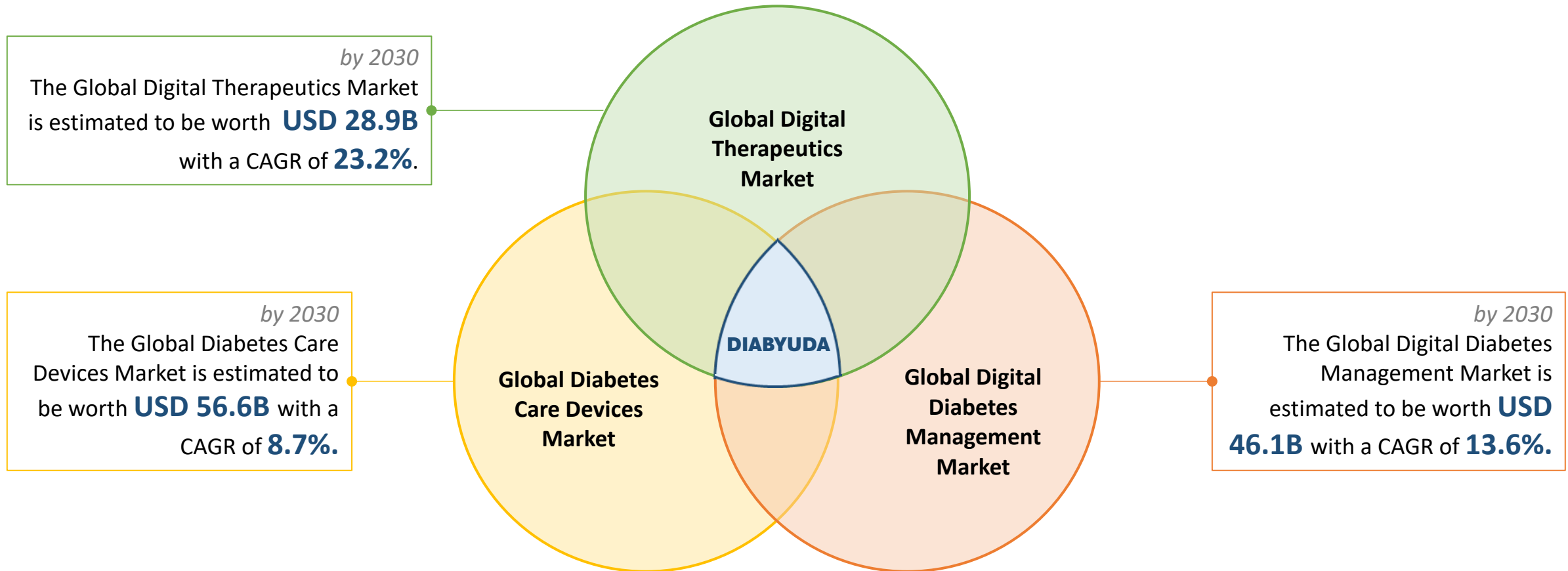
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Diabyuda Market Analysis Overview

GENESIS Biomed has analyzed the following markets where **Diabyuda** can be positioned. All of them are expected to grow in the forecast period with a **compound annual growth rate (CAGR)** value of approximately **between 8 and 24%**.

by 2030

The Global Digital Therapeutics Market is estimated to be worth **USD 28.9B** with a CAGR of **23.2%**.

by 2030

The Global Diabetes Care Devices Market is estimated to be worth **USD 56.6B** with a CAGR of **8.7%**.

by 2030

The Global Digital Diabetes Management Market is estimated to be worth **USD 46.1B** with a CAGR of **13.6%**.

Global Digital Therapeutics Market

Global Diabetes Care Devices Market

Global Digital Diabetes Management Market

DIABYUDA

Competitors Analysis methodology

In order to identify the **main competitors** of DIABYUDA, two different approaches have been made:

1 Competitors previously identified

In this section, previously identified competitors have been included and complemented with additional information.

2 New competitors

In this section, new competitors have been sought by following three different complementary methodologies:

2.1 Analysis of the companies found in the Market Analysis

2.2 Analysis of the companies found in GlobalData

A) Products search criteria
- Indication: Diabetes
- Key words: Clinical decision support system, Diabetes digital health interventions, Mobile health interventions in diabetes, Diabetes self-management.
- Development stage: Marketed or Under Development.
- Exclusion criteria: inactive products have not been considered in this analysis.

2.3 Analysis of the companies found by Organic search

Search criteria
- Software for the management of diabetes.

Competitors Previously Identified (1/2)

- While the following competitors were highlighted by DIABYUDA, they differ significantly in format and approach, and are therefore not the most directly comparable products.

Product	Company	Headquarters	Regulatory	Application(s)	Description
Cecelia Health	Cecelia Health	USA	Not considered Medical Device	Mobile App	**Cecelia Health** is a virtual specialty clinic for people with chronic conditions, delivering virtual care designed with a human element **to improve adherence and health outcomes.** The main services are: Virtual specialty clinic, Medication adherence, Remote patient monitoring, Clinical support & Education and Data analytics. Diabetes is one of the main focused disease of the app, but it can be used for other chronic conditions. This app can be download in Google Play and App Store.
Dario Health	Dario	USA	For the Glucose Monitoring System: FDA as Class II CE Mark	Mobile App	**DarioHealth** offers a mobile app that integrates with connected devices such as glucose meters and blood pressure monitors. This app allows users to monitor health metrics such as **blood glucose levels, blood pressure, weight and physical activity in real time**. It also provides personalized alerts, trend analysis and the ability to share data with healthcare professionals. If dangerously low glucose levels are detected, the app can automatically send text messages with GPS location to emergency contacts. This app can be download in Google Play and App Store.
Noom	Noom	USA	Not considered Medical Device	Mobile App	**Noom's Diabetes Prevention Program** is intended to reduce risk of **type 2 diabetes** through improving eating habits, physical activity, stress management, emotional eating, sleep hygiene, and other areas that may affect health. Noom's psychological approach identifies the patient's subconscious thoughts and triggers, building a personalized action plan that allows the patient to form healthy habits quickly.

Competitors Previously Identified (2/2)

Product	Company	Headquarters	Regulatory	Application(s)	Description
SendoDiabetes*	Sendo Health	Spain	Not considered Medical Device	Mobile App	**Sendo Diabetes** is a diabetes coach with a powerful algorithm and **Artificial Intelligence** that **programmes personalized diabetes diet and physical activity plans for patients with diabetes.** Based on their profiles and self-assessments, the algorithm in this diabetes app designs the physical activity and diabetes diet that best suits each patient. This app can be download in Google Play.
SocialDiabetes	Social Diabetes	Spain	FDA CE Mark as Class I	Mobile App	The **SocialDiabetes** app is a Digital Solution For Diabetes Management that allows patients to sync their blood glucose data from their glucometer to the phone and add additional information such as **food intake and exercise in real time**. Patient data is accessible by healthcare provider teams who track patient progress and can make evidence-based treatment decisions. This app can be download in Google Play and App Store.
dAIbetes	-		Under development	-	The federated dAIbetes technology will **harmonise existing data of ca. 800,000 type 2 diabetes patients** of 6 cohorts distributed across the globe, and **learn prognostic virtual twin models**. This federated virtual twin technology will enable **personalised disease management and act as a blueprint for other complex diseases**. The project aim to validate their technology starting in Q12026 with at least **3,600 patients**. • **dAIbetes partners**: Semmelweis Egyetem (Hungary), Karolinska University Hospital (Sweeden), Region Stockholm (Sweeden), Università Degli Studi Della Campania Luigi Vanvitelli (Italy), Università Degli Studi Di Roma La Sapienza (Italy), Research Institute AG & Co KG (Austria), SBA Research gGmbH (Austria), Medizinische Universität Wien (Austria), Gnome Design SRL (Romania), Brigham and Women's Hospital (USA), Joslin Diabetes Center (USA), Universität Hamburg (Germany), Friedrich-Alexander-Universität Erlangen-Nürnberg (Germany) and tp21 GmbH (Germany). • Coordinator: **Universität Hamburg (Germany)**. • Project budget: **9.4M€** (Horizon Europe and Semmelweis University received funding from the Hungarian National Research, Development and Innovation Fund). • Project duration: **January 1st 2024 – December 31st 2028**.

*The company website has not been linked because it is currently inactive.

Main competitor

- The following competitor stands out as the most comparable to DIABYUDA due to its integrated approach to managing the primary condition alongside comorbidities.

Product	Company	Headquarters	Regulatory	Application(s)	Description
Avo	Avo	USA	Not considered Medical Device	Software Platform	**Avo** is a **clinical decision support platform** (web and app based) that transforms complex medical guidelines into interactive tools. Accessible via mobile apps, web browsers, and EHR integrations, it delivers evidence-based recommendations at the point of care. Clinicians can customize content to align with institutional protocols. The platform enhances efficiency, reduces burnout, and improves patient outcomes. Avo partners with leading medical societies to ensure up-to-date clinical content. Through a strategic partnership with the American Association of Clinical Endocrinology (AACE), Avo has integrated AACE's latest clinical practice guidelines, covering obesity, osteoporosis, **type 2 diabetes**, NAFLD, and diabetes technology, directly into its platform. These updated guidelines are embedded into customizable workflows that align with institutional protocols. Once AACE clinical guidelines reach the clinician, their practical operation is focused on guiding medical decision-making. The clinician uses the guidelines as a roadmap for the diagnosis, treatment and follow-up of endocrine diseases. These recommendations allow more informed decisions to be made in line with the latest evidence, especially in complex clinical situations. The guidelines are designed to be adapted to each patient according to the clinical status, comorbidities, patient preferences and available resources. As they are regularly updated, they help to incorporate new scientific advances into daily practice. Their app can be download in Google Play and App Store.

Conclusions of the Competitors Analysis

The competitor's analysis has been based according to their technology. In total, **23 marketed competitors** and **4 under development competitors** have been found in the market through GlobalData and organic search, that offer a Diabetes digital health solution.
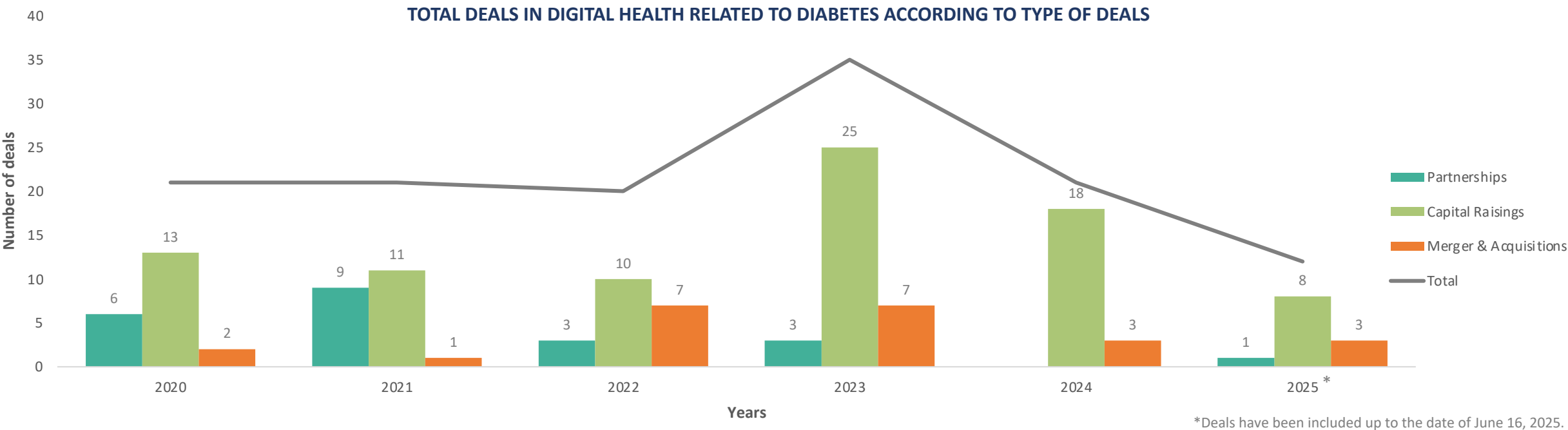
Main conclusions of the **MARKETED** competitors:

- Most of the competitors that have been found are diabetes patient management apps.
- **7 out of 23** are based on Artificial Intelligence, the same as **DIABYUDA's** solution.
- Most of the companies are based in the United States (13), few are located in Europe (5), and especially in Spain (2), and the rest are based in Canada (1), Brazil (1), Israel (2) and Taiwan (1).
  - Spanish applications should also be considered relevant due to their geographic implementation, such as: **Sendo Health and SocialDiabetes**.
- Most software platforms are associated with a device that is considered medical device and requires approval from regulatory agencies, but the software is not considered as such.
- In general, most apps/software can be implemented for both type 1 and type 2 diabetes and are even used for the monitorization of chronic diseases.
- It is also important to highlight that most of the products are found in both **Google Play** and **App Store**, which are the two main marketplaces for these apps.
- **Avo** represents the product that most closely resembles **DIABYUDA**, despite not being limited to diabetes. It also integrates content and support for other diseases through a broader set of clinical guides. Despite this, it does not include risk assessment, monitoring or patient engagement information.

Regarding the products **UNDER DEVELOPMENT**, the management of type 1 and type 2 diabetes is among the most pressing challenges faced by hospitals, and these products aim to provide the most effective solutions available. However, most of them focus on disease **management rather than directly addressing treatment.**

- Of the 4 products identified 2 are being developed in Spain, 1 in USA and 1 is a European Project lead by the Universität Hamburg.
- The European project aim to create a virtual twin technology to enable personalised disease. It is expected to be completed by the end of 2028.

The DIABYUDA's platform is the only Clinical Decision Support System that focuses on type 2 diabetes and includes personalized patient guidance, risk assessment and monitoring and lifestyle recommendations.

Global Deals Analysis

TOTAL DEALS IN DIGITAL HEALTH RELATED TO DIABETES ACCORDING TO TYPE OF DEALS

*Deals have been included up to the date of June 16, 2025.

- Between 2020 and 2025, a **total of 130 deals** were identified. With 35 deals, **2023** stands out as the **most dynamic year**, driven particularly by a peak in capital raisings (25) and a high number of mergers and acquisitions (7), suggesting a strong investment environment.

- **Capital raisings** are the **most predominant** type of deal. These agreements **dominate the landscape**, reflecting a significant increase in investment and funding for the development of digital health products related to diabetes, as companies seek to strengthen their market position.

- **Between 2020 and 2021, partnerships represented a substantial portion of the activity**, highlighting a clear trend toward collaboration and joint development in digital health. However, beginning in 2022, the number of partnerships declined significantly, while mergers and acquisitions became more prominent, suggesting a **strategic shift toward consolidation and corporate restructuring**.

- All **grants have been excluded** from the analysis. Despite this, without any data limitations, a total of **7,016 grants** related to digital health in diabetes have been identified.

Regulatory classification according to MDR – Assumptions and proposed classification

DIABYUDA Software classification

Rule 11 was introduced into the MDR and is intended to address the risks related to the information provided by an active device, such as MDSW. Rule 11, in particular, describes and categorizes the significance of the information provided by the active device to the healthcare decision (patient management) in combination with the healthcare situation (patient condition).

DIABYUDA would be classified as a **Class IIa** MD according to Rule 11

ACCORDING TO THE PRODUCT'S TECHNOLOGY

Rule 11

Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

— death or an irreversible deterioration of a person's state of health, in which case it is in class III; or

— a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.

— Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb. All other software is classified as class I.
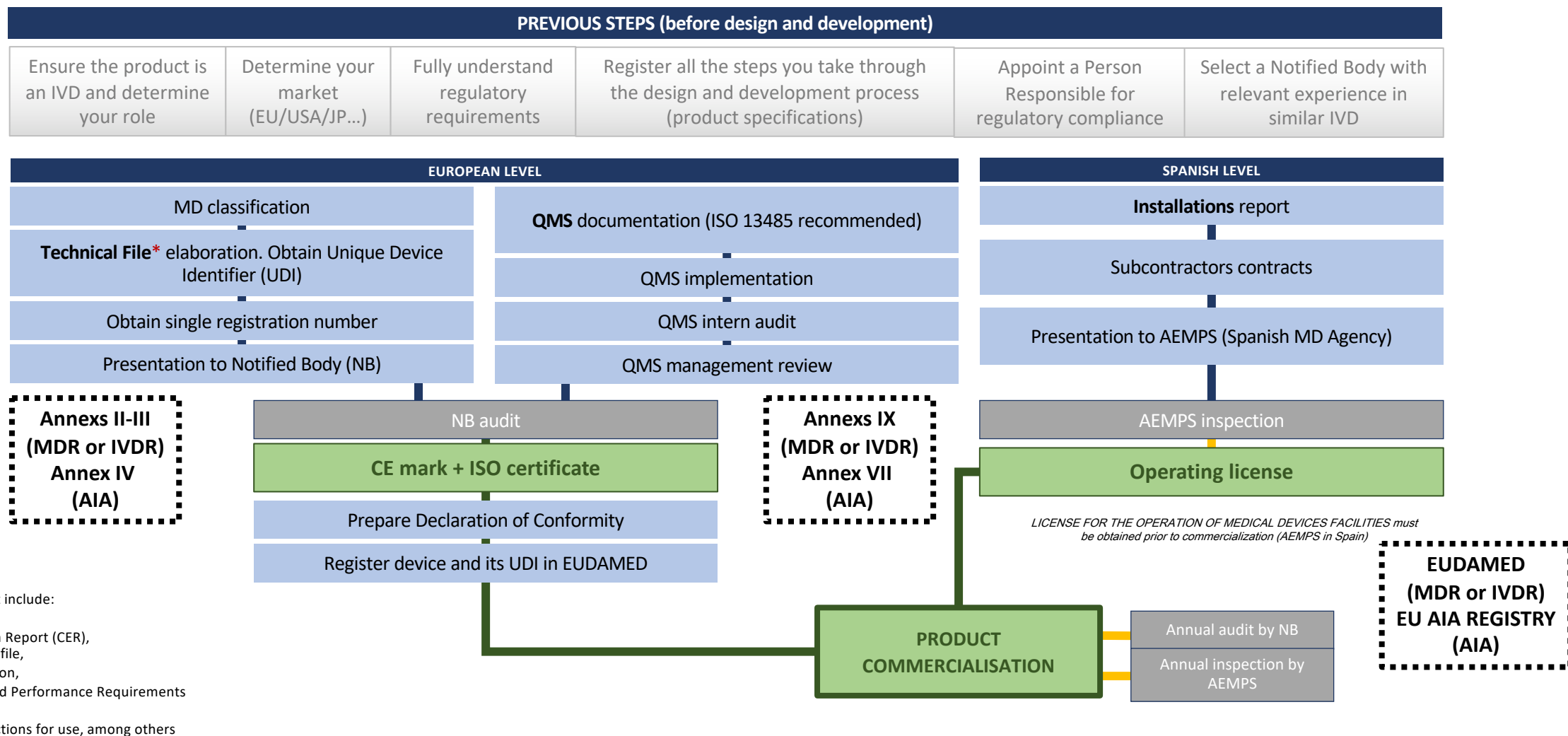
Class IIa

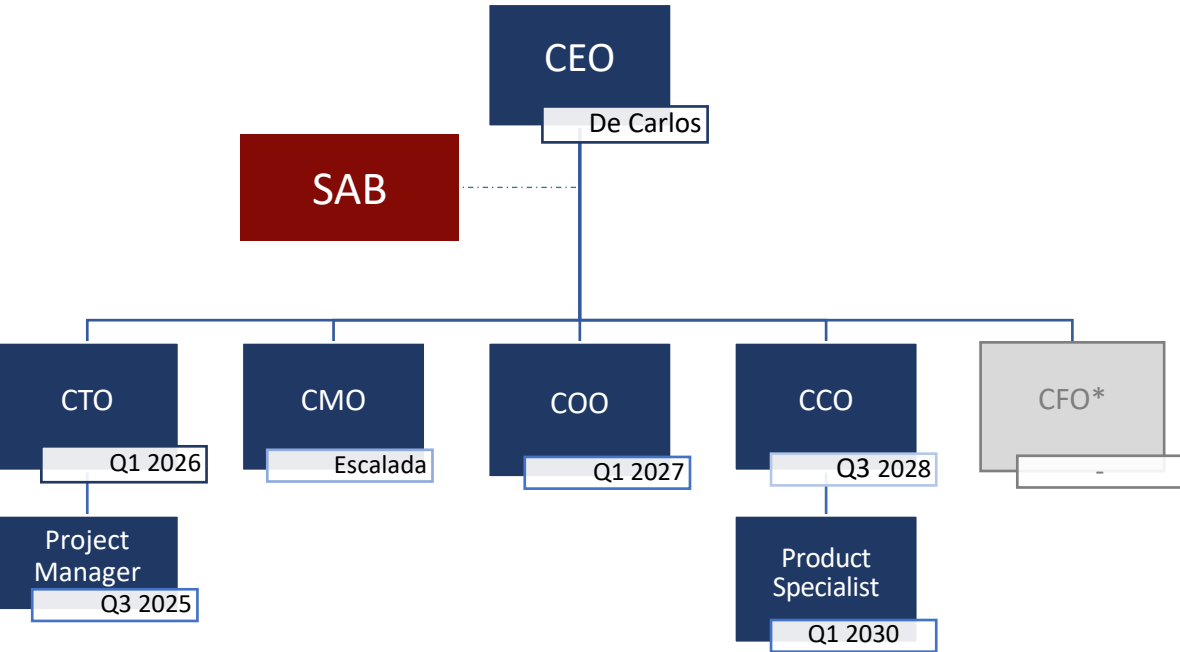*In the event of incorporating new functionalities, Diabyuda could be classified as **Class IIb**.*

advanced
ANALITYCAL CONSULTING SERVICES

How EU-AIA matches with current regulatory process Medical Devices

PREVIOUS STEPS (before design and development)					
Ensure the product is an IVD and determine your role	Determine your market (EU/USA/JP…)	Fully understand regulatory requirements	Register all the steps you take through the design and development process (product specifications)	Appoint a Person Responsible for regulatory compliance	Select a Notified Body with relevant experience in similar IVD

EUROPEAN LEVEL

MD classification

Technical File* elaboration. Obtain Unique Device Identifier (UDI)

Obtain single registration number

Presentation to Notified Body (NB)

QMS documentation (ISO 13485 recommended)

QMS implementation

QMS intern audit

QMS management review

SPANISH LEVEL

Installations report

Subcontractors contracts

Presentation to AEMPS (Spanish MD Agency)

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Annexs II-III
(MDR or IVDR)
Annex IV
(AIA)
```

NB audit

CE mark + ISO certificate

Prepare Declaration of Conformity

Register device and its UDI in EUDAMED

```
Annexs IX
(MDR or IVDR)
Annex VII
(AIA)
```

AEMPS inspection

Operating license

LICENSE FOR THE OPERATION OF MEDICAL DEVICES FACILITIES must be obtained prior to commercialization (AEMPS in Spain)

* **Technical File** must include:
- testing reports,
- Clinical Evaluation Report (CER),
- risk management file,
- processes validation,
- General Safety and Performance Requirements checklist,
- labelling & instructions for use, among others

PRODUCT COMMERCIALISATION

Annual audit by NB

Annual inspection by AEMPS

```
EUDAMED
(MDR or IVDR)
EU AIA REGISTRY
(AIA)
```

Organizational chart

CO-FOUNDERS

Dr. Joaquín de Carlos Artajo is a Medical Doctor at the Hospital Universitario de Navarra, specialized in **Endocrinology and Nutrition**. He combines clinical expertise with entrepreneurial experience participating in health forums, meetings and accelerators.

He has published a total of 17 scientific papers and book chapters.

Dr. Joaquín de Carlos Artajo

Dr. Francisco Javier Escalada San Martín is a leading endocrinologist and the **director of the Endocrinology and Nutrition department** at the Clínica Universitaria de Navarra. His clinical work is focused on **diabetes mellitus**, obesity, metabolic liver disease and gastroenteropancreatic endocrine tumours.

He has published a total of 76 scientific papers and has led multiple project and PhD thesis.

Dr. Francisco Javier Escalada San Martín

Sub-contracted rol

Monetization SaaS Model: most common pricing strategies used

SaaS (Software as a Service)

Revenue stream may come from

two mainly price strategies

Pay per Use

DIABYUDA

Potential Clients:
(NHS, RHS, Private Hospitals, Insurance Companies, etc)

€ set-up cost (registration)

€ non fixed monthly/annual fee

This modality will consist of a first payment which correspond to the registration to the online platform to enjoy the services. After registration to the platform, the company will pay on different modalities depending on each use purpose…

Subscription

DIABYUDA

Potential Clients:
(NHS, RHS, Private Hospitals, Insurance Companies, etc)

€ Annual or monthly fee

In this case, the client will pay a fixed **monthly fee/annual fee** that will include unlimited sessions for assessing and monitoring physical variables as well as software maintenance, updating and support in which the amount will be negotiated on the basis of expected turnover.

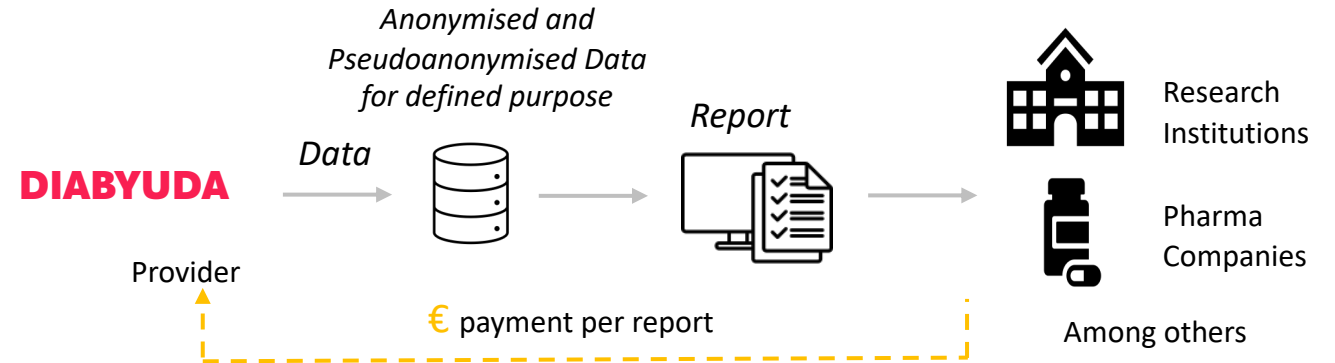# Monetization DaaS Model: most common pricing strategies used

Pay per report

DIABYUDA

Data

Anonymised and Pseudoanonymised Data for defined purpose

Report

Research Institutions

Pharma Companies

Provider

€ payment per report

Among others

DaaS (Data as a Service)

This Data could be monetised by two models

This modality will consist of contracting DIABYUDA by means of a **Pay Per Report**. Depending on the scope of the information required a report could be provided to the customer and negotiate Case-by-case basis.
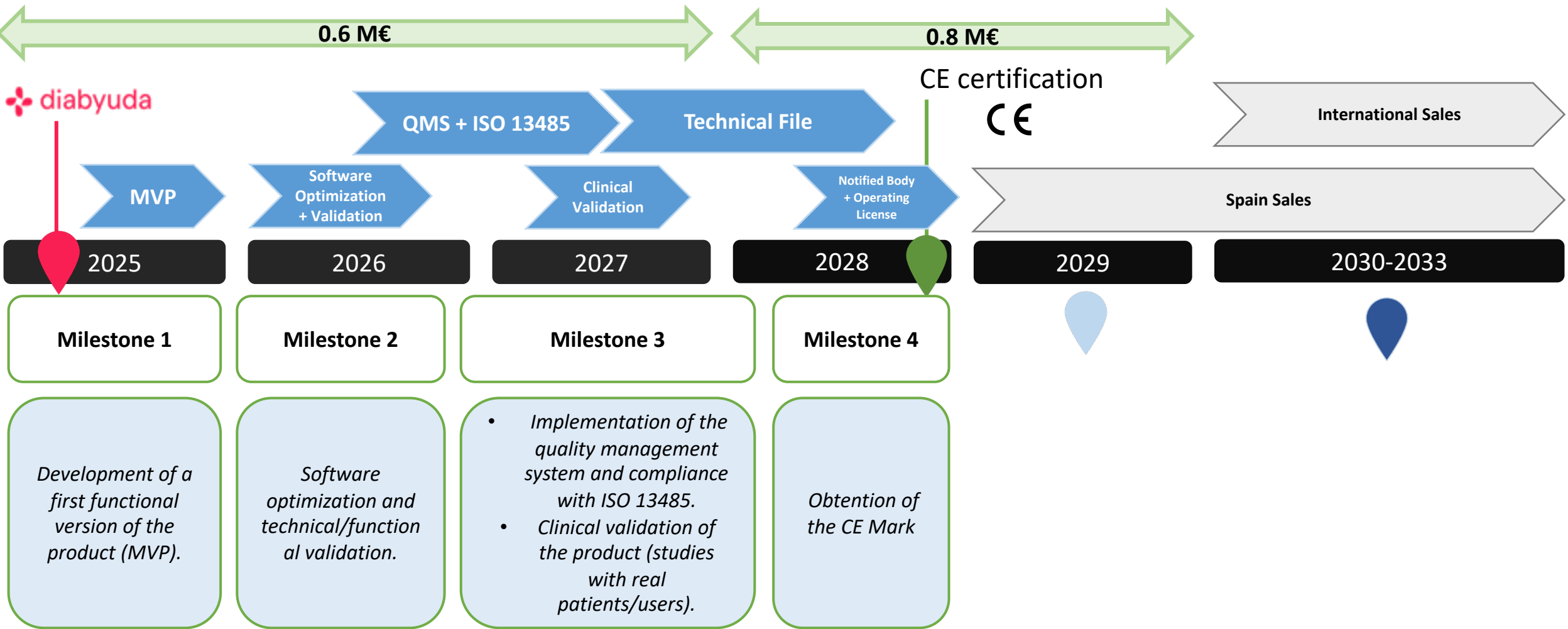
Pay per data

This model means big data collected, processed and transformed into prepared and usable data for consumption. This process include anonymisation and pseudoanonymisation, cleaning and structuration of the data. Normally monetisation is based on volume and type of data.

Cash Need and Fundraising

It has been envisioned to fund the company with two capital raisings, either public or private.

0.6 M€   **0.8 M€**

CE certification

QMS + ISO 13485 | Technical File

International Sales

MVP | Software Optimization + Validation | Clinical Validation | Notified Body + Operating License | Spain Sales

| 2025 | 2026 | 2027 | 2028 | 2029 | 2030-2033 |

| **Milestone 1** | **Milestone 2** | **Milestone 3** | **Milestone 4** |

| *Development of a first functional version of the product (MVP).* | *Software optimization and technical/functional validation.* | • *Implementation of the quality management system and compliance with ISO 13485.*
• *Clinical validation of the product (studies with real patients/users).* | *Obtention of the CE Mark* |

Diabyuda

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DIABYUDA has received funding and recognition from: