

A woman with red lips and blonde hair is shown from the chest up, wearing a grey V-neck shirt. She is holding a red apple in her left hand and a chocolate muffin in her right hand. The background is white. A semi-transparent grey banner is overlaid on the right side of the image, containing the text 'CALIPSO Project' and 'an innovative approach to insulin therapy management'.

CALIPSO Project

an innovative approach to insulin therapy management

- **Preface**

- Our project

- Preliminary business plan

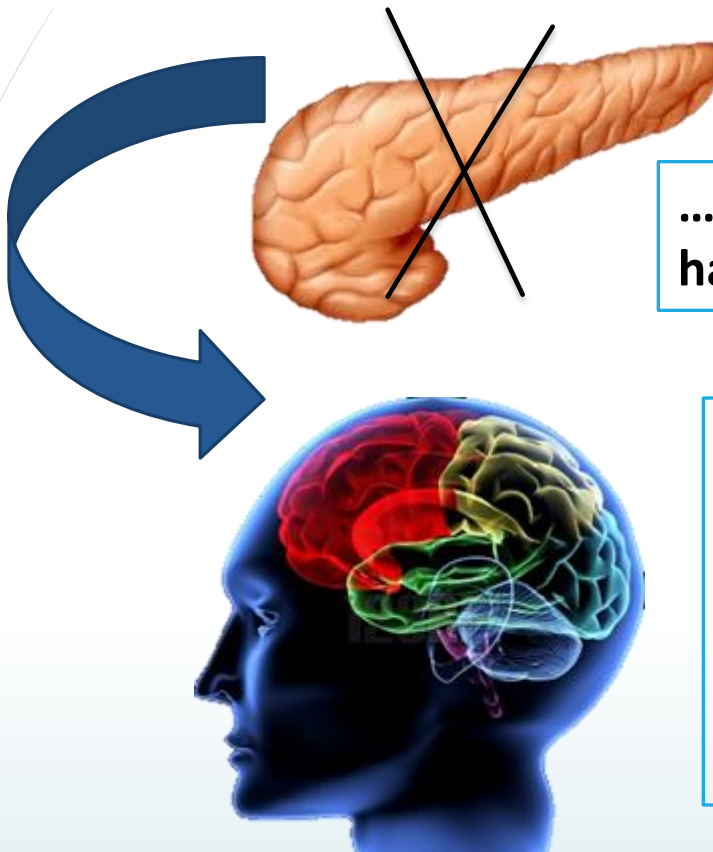
- Project Team

Why it should be so hard for diabetics to manage their own insulin therapy?



**We absolutely
need an
innovative idea**

When beta-cells fail...



...necessarily the mind of the patient has to replace them.

"Transplantation of pancreatic beta-cells in the brain of the patient"

This is essentially the therapeutic education of diabetic.

But control of his own diabetes with insulin is a cumbersome and danger process

**Always remember:
this device is a weapon!**

**Not only
Therapeutic**

**But also
potentially lethal!**





Eureka!

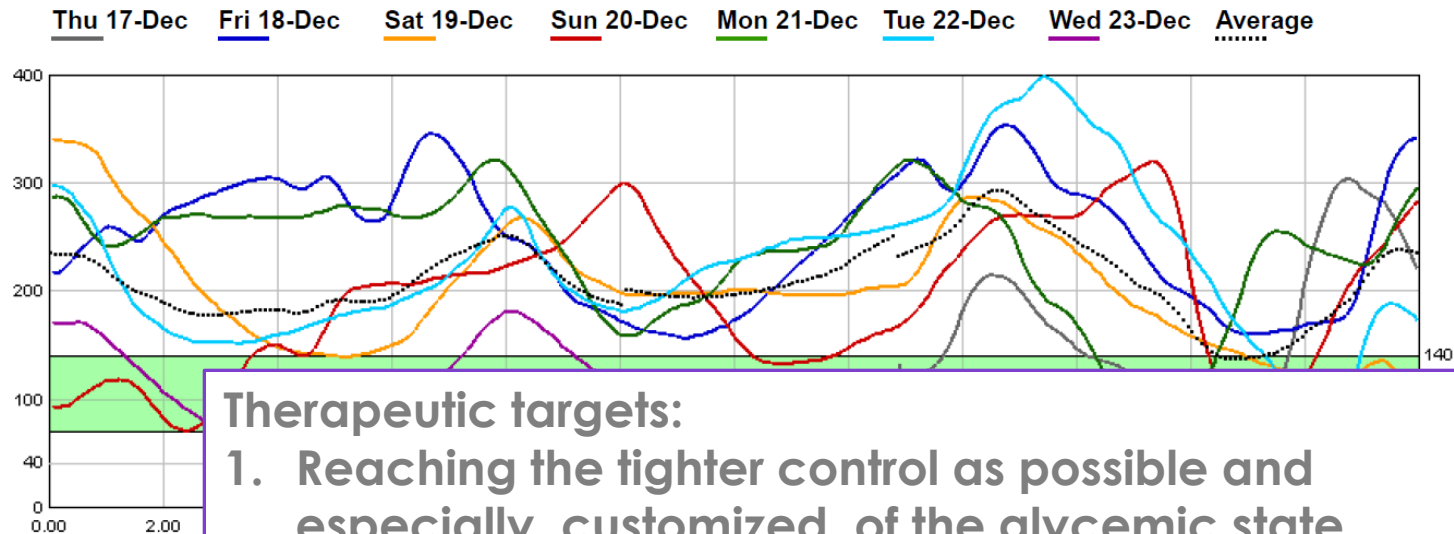
Today we can give a
response to this unmet
need thanks to...

CALIPSO PROJECT

Telehealth project for
insulin-treated diabetics
via web and app on
smartphone

The therapeutic target is hard to reach...

Sensor Data (mg/dL)



Therapeutic targets:

1. Reaching the tighter control as possible and especially, customized, of the glycemic state
2. avoiding hypoglycemic crisis, particularly severe ones

Toxicity of diabetic disease:

- CHRONIC HYPERGLYCEMIA AND HIGH VARIABILITY → micro- and macrovascular complications
- HYPOGLYCEMIA: → Acute complications, especially in T2DM with comorbidities

Evidence: DCCT/EDIC study

Tight glycemic control

achieved with intensive glucose lowering treatment reduces the risk of long-term complications of diabetes

but

it is counter-balanced by an increased incidence of **hypoglycemia**.

"DCCT paradox":
the best glycated hemoglobins
can be reached only by increasing
frequency of hypoglycemia

Evidence: ACCORD study

The NEW ENGLAND JOURNAL *of* MEDICINE

ESTABLISHED IN 1812

JUNE 12, 2008

VOL. 358 NO. 24

Effects of Intensive Glucose Lowering in Type 2 Diabetes

The use of intensive therapy with insulin to target normal glycated hemoglobin levels increased mortality and did not significantly reduce major cardiovascular events

Moreover in 2010 it was published by **Kelly** a meta-analysis of intervention studies performed on type 2 diabetes:
NNT (Number Needed to Treat) to prevent one cardiovascular event varies between 60 and 110 while the NNH (Number Needed to Harm) for hypoglycemia is about 25.



HYPOS-1 (an Italian study)

ECONOMIC IMPACT OF HYPOGLICEMIA

in type 1 diabetes: hypoglycemia causes more hospital admissions (ER) and lost working days.

whereas

in type 2 diabetes hypoglycemia is associated with longer hospital stay and caregivers' involvement.



Technologies for diabetics

In order to address these challenges for a long time the manufacturers of pharmaceuticals and medical devices, have sought solutions of two types:

- Technologies for insulin administration
- Technologies for glycemic control



Technologies for insulin administration

1. Pens
2. Increasingly performing insulins (very long-acting and flat profile basals; ultra-rapid insulins)
3. CSII
4. Others

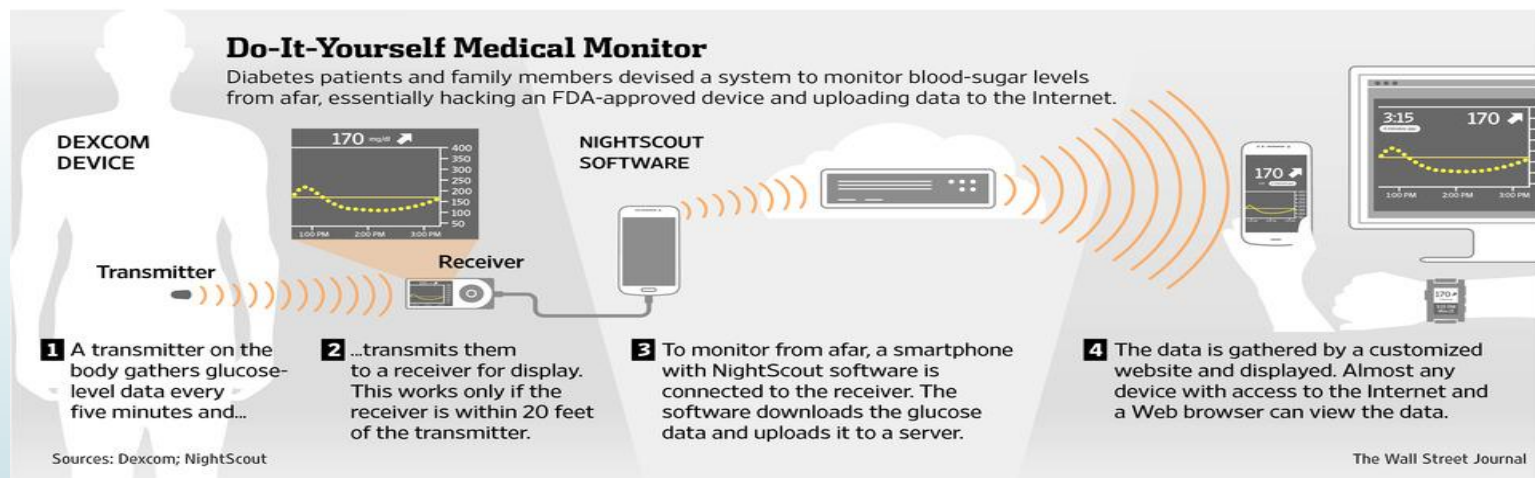
Warning: “FINANCIAL SUSTAINABILITY”

Technologies for glycemic control

1. Glucometers
2. Abbott's FreeStyle Libre
3. The sensors with or without the CSII

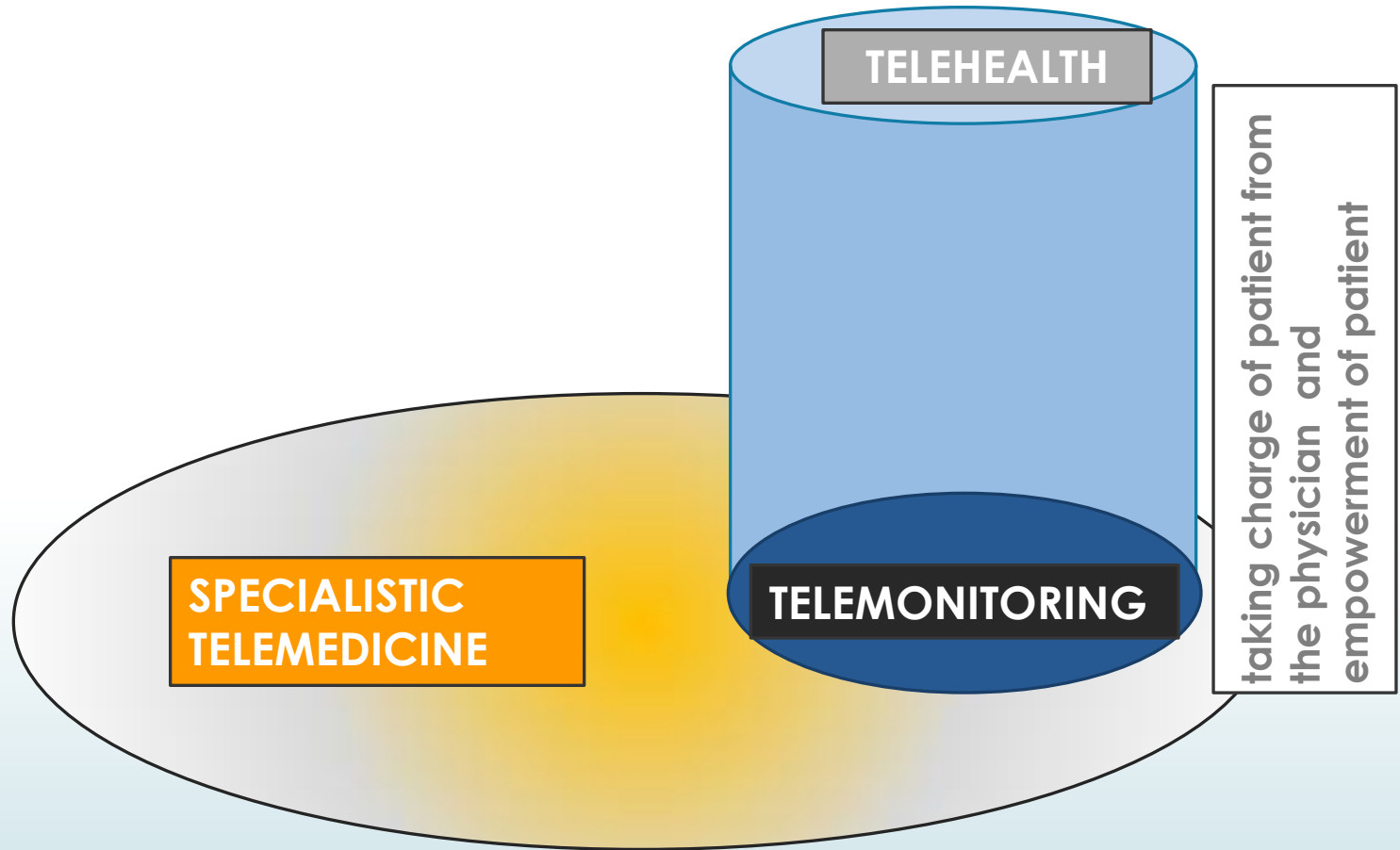
The control systems from remote via cloud

- Nightscout (associated with the DexCom sensor)
- Others system of glucose telemonitoring



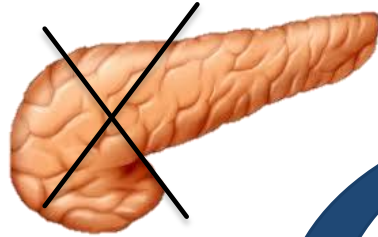
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Why a telehealth project?



Calipso Project OBJECTIVES

BETA-CELLS



The mind decides, it
does no more
calculations!

"Beta-cells
transplantation
on the web
portal and on the
patient
smartphone"



Who Calipso takes care of...

All insulin-treated diabetics

especially

- with glycometabolic imbalance ($A1c >9$)
- not eligible for insulin pump therapy or patients who reject it

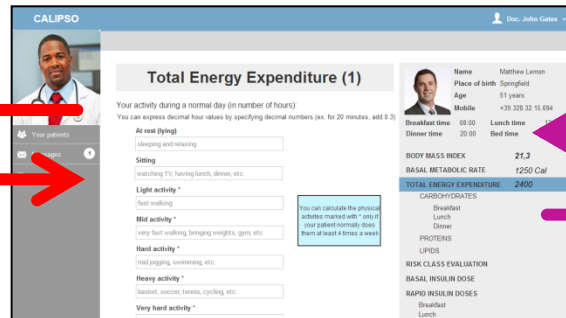
Actors and technological means

PATIENT INTERFACE



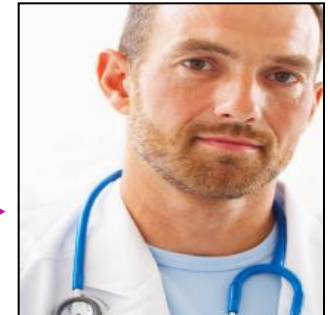
- Sign up to the platform
- Makes glucose self-monitoring
- Follows the suggested insulin boluses and the others advise
- Interacts with his doctor through messaging and video conferencing
- Learn the educational contents

CALIPSO PLATFORM



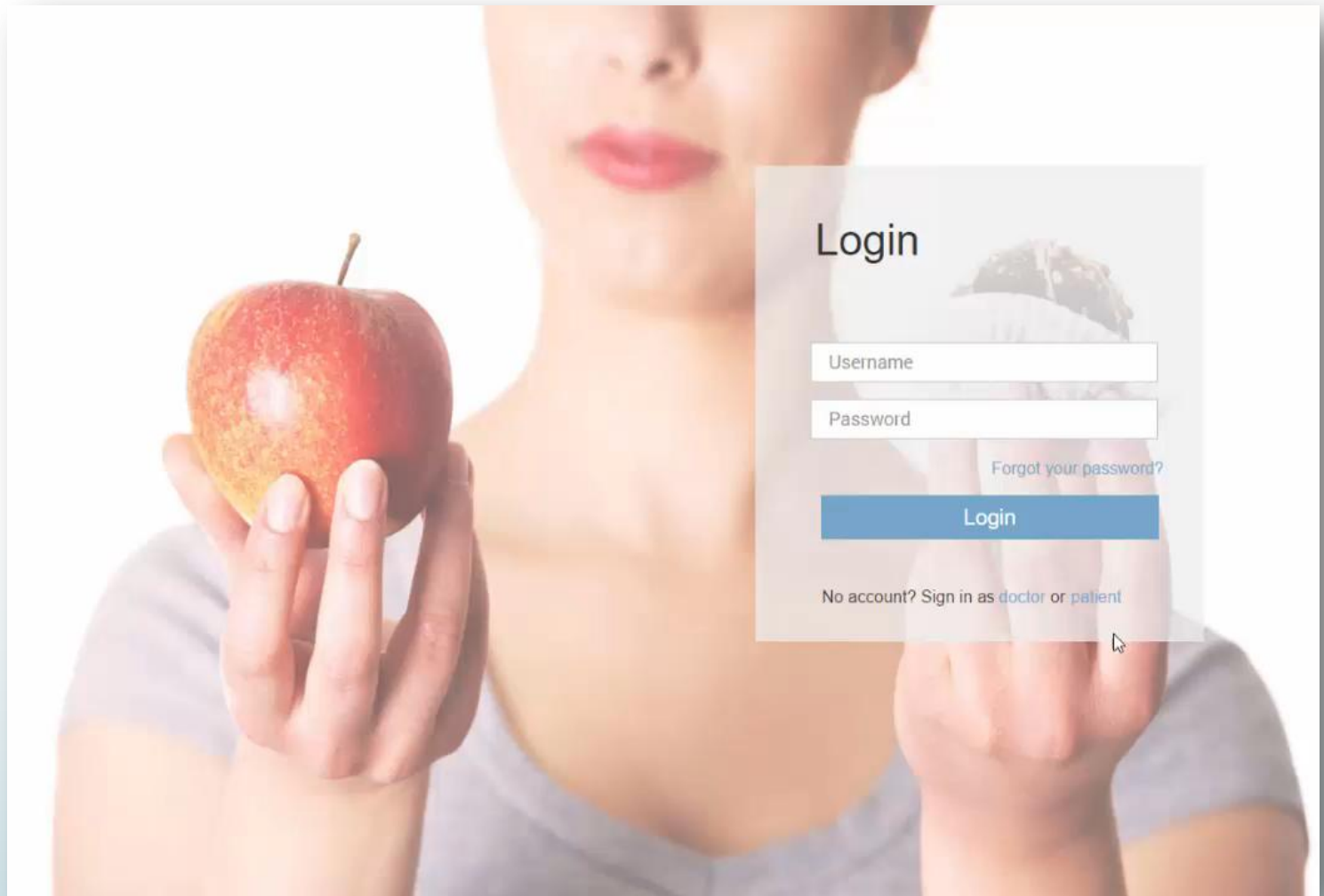
- Processes the patient data
- Compiles statistics
- Suggests insulin boluses
- Compiles a daily logbook
- Teaches carb counting
- Supports training and disease management

DOCTOR INTERFACE



- Sign up to the platform
- Sets the parameters required by the expert system
- Supports the patient for therapy adjustments
- Interacts with his patients through messaging and video conferencing

Calipso-Physician interface



Calipso-Patient interface

The screenshot displays the Calipso patient interface. On the left, a sidebar contains a doctor's profile picture and navigation links: "Your patients", "Messages", and "Lugnet". The main area shows a patient information form for Mario Rossi. The form includes fields for Name, Sex, Place of birth, Date of birth, Place of residence, and a table for meal times. A QR code labeled "PATIENT CODE" with the code "G27A13H" is also visible.

Breakfast time	Lunch time	Dinner time	Bedtime
07 : 45	13 : 00	19 : 00	23 : 00

Mario Rossi lives in Rome. He has a Type 2 diabete, with medium risk factor and 30 as Insuline Sensivity value.

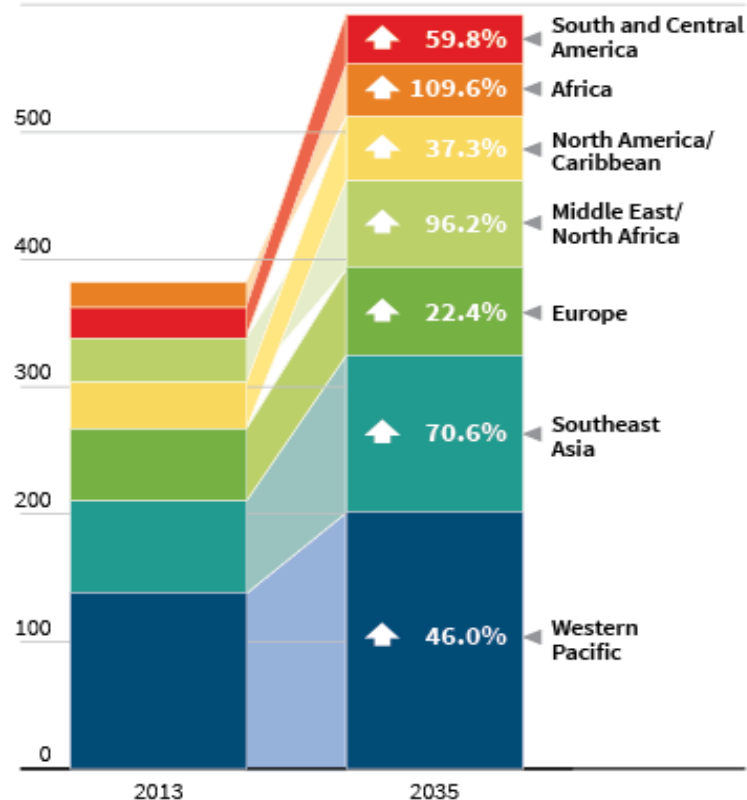
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Global Digital Snapshot



World diabetes cases expected to jump 55 percent by 2035

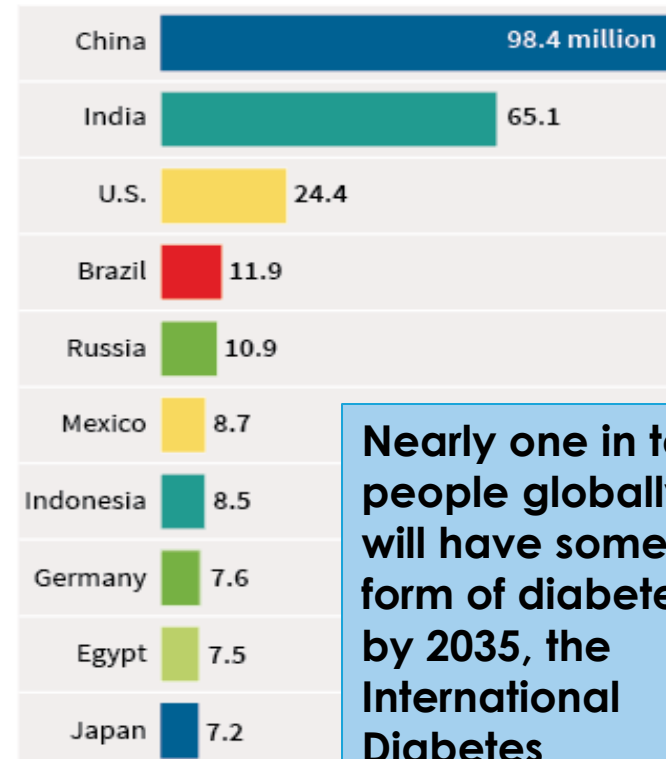
Current and projected cases of diabetes by region
600 million



Source: International Diabetes Federation

S. Culp, 12/11/2013

Top 10 countries by number of people with diabetes in 2013, ages 20 to 79

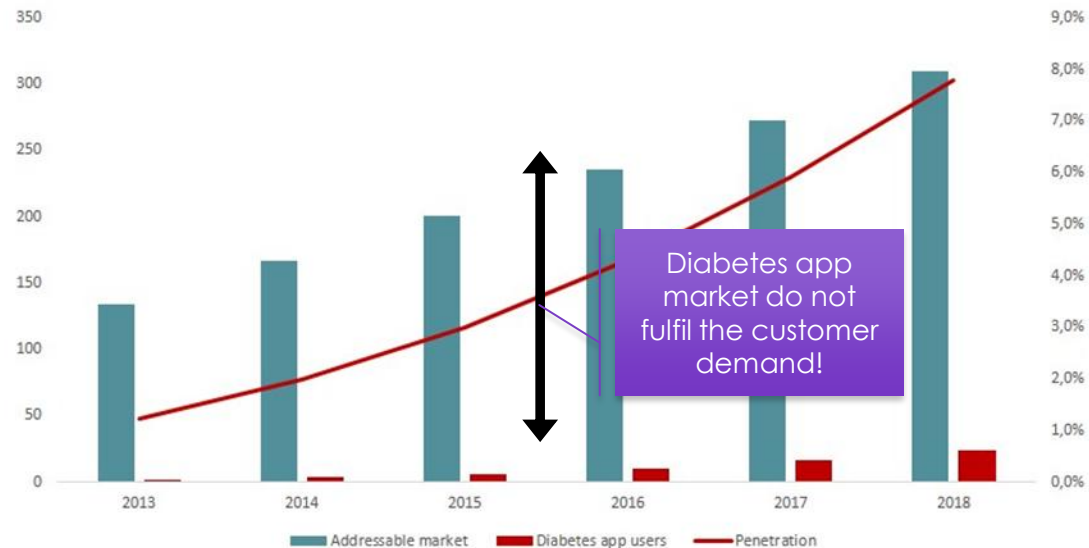


Nearly one in ten people globally will have some form of diabetes by 2035, the International Diabetes Federation predicts in a new report.

Market analysis

Diabetes apps will be used by 7,8% of diabetics that have a capable device in 2018

Global penetration of diabetes app users within the target group

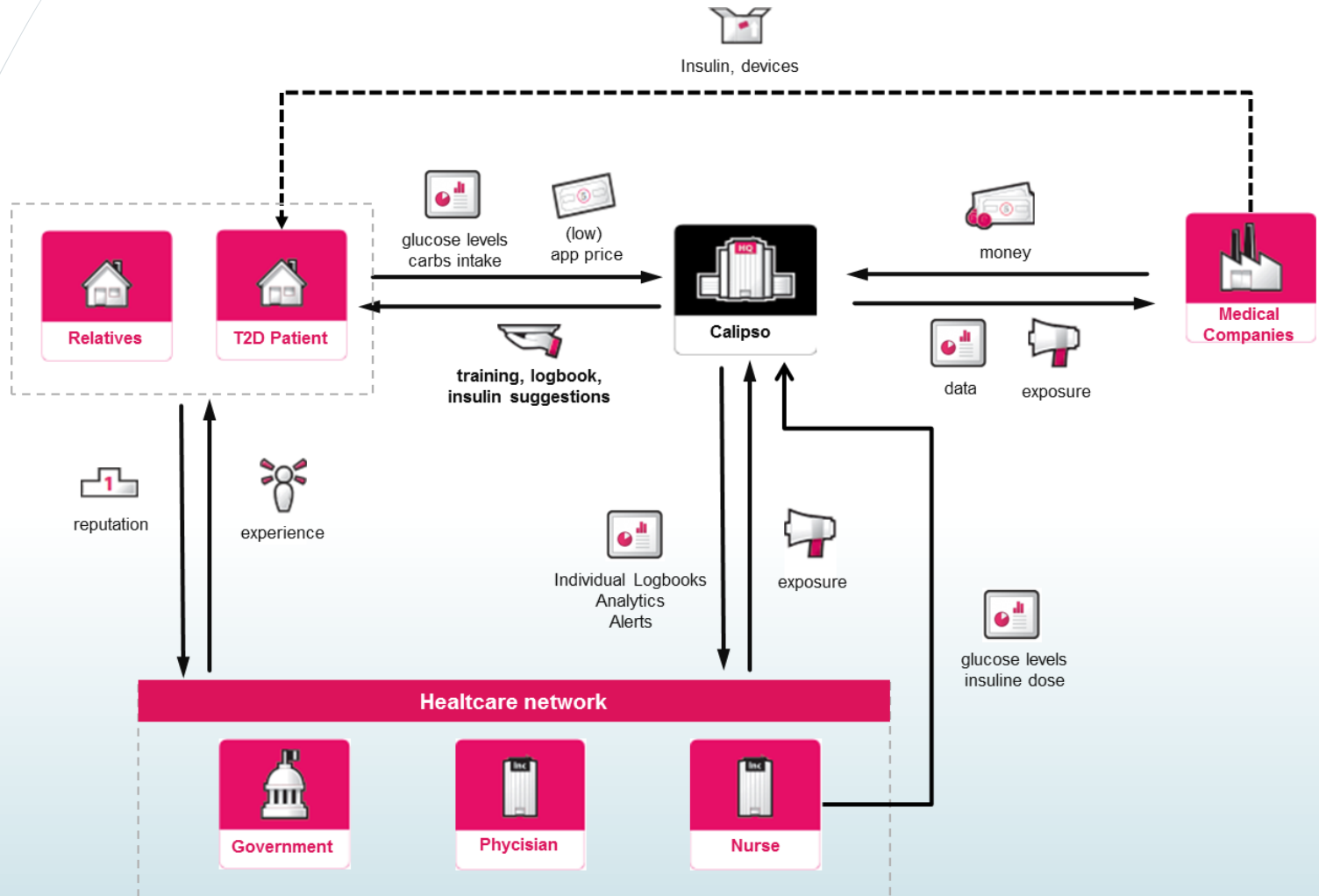


Comment: The chart is based on the results of the „Diabetes App Market Report 2014“. Addressable market includes people with diabetes (20-79y) that have a smartphone or tablet.

Source: IDF Diabetes Atlas, 6th edition, research2guidance, 2014
www.research2guidance.com

Only **1.2 percent** of diabetics that have a mobile device globally (1.6 million people) currently use a diabetes app to manage their health condition

Business Model Blocks



Business Model Canvas

Key Partners



Who are our Key Partners? Who are our key suppliers?
Which Key Resources are we acquiring from partners? Which
Key Activities do partners perform?

Pharmaceutical and bio-medical companies

- Insulin producers
- CGM suppliers
- Pens and pumps
- Biosensors and new sensing devices producers

They produces items required A therapy protocol can be set-up that includes:

- Calipso app
- smart sensors / CGM for initial continuous monitoring
- Insulin, pens and glucometers supply for day-by-day therapy

They provides an initial funding and advertise the protocol on Physicians network.

In-app purchases and advertising allows a quick ROI.

Academies and Hospitals

Provides scientific validation for the protocol

Key Activities



What Key Activities do our Value Propositions require? Our
Distribution Channels? Customer Relationships?
Revenue streams?

- App development
- Scientific Validation of the protocol that enlightens long term HbA1c reduction
- Medical protocol definition
- Training and advertising

Key Resources



What Key Resources do our Value Propositions require? Our
Distribution Channels? Customer Relationships?
Revenue Streams?

- Initial funding for app development
- Promotion to physician network
- Academic sponsorship for validation

Value Propositions



What value do we deliver to the customer?
Which one of our customer's problems are we helping to solve?
What bundles of products and services are we offering to each Customer Segment?
Which customer needs are we satisfying?

Diabete management app for patient and family network

- Adaptive insulin calculator, based on predictive algorithm
- Glycemic and CHO intake logbook
- Family and Nurses monitoring and collaboration on therapy
- User friendly interface
- Training through gamification
- Reminders
- Support community

Diabete management app for healthcare network

- Physician monitoring and therapy setup
- Nurses for therapy logging and information sharing

Customer Relationships



What type of relationship does each of our Customer Segments expect us to establish and maintain with them?
Which ones have we established?
How are they integrated with the rest of our business model?
How costly are they?

For patients and family:

- Gamification
- Social Communities
- Sponsored by physicians

For Healthcare operators:

- Sponsored by key partners

Channels



Through which Channels do our Customer Segments want to be reached?
How are we reaching them now? How are our Channels integrated? Which ones work best?
Which ones are most cost-efficient?
How are we integrating them with customer routines?

- Indicated to patients as therapy by their physicians
- Requested to nurses by patient or his family

- Promoted to physicians through key partners network
- Training to physicians and nurses offered online by Calipso

Customer Segments



For whom are we creating value?
Who are our most important customers?

T2D Patients

Usual profile:

- > 45 years
- Low technological skills
- Low info on diabetes
- Low education profile

Family Network

- Relatives
- greater education level and technological skills

Healthcare operators

- Physicians
- Nurses
- Public Health Ministry

Cost Structure



What are the most important costs inherent in our business model? Which
Key Resources are most expensive?
Which Key Activities are most expensive?

- App development
- Academic support for scientific validation
- Marketing materials
- Training materials
- Business startup consultancy

Revenue Streams

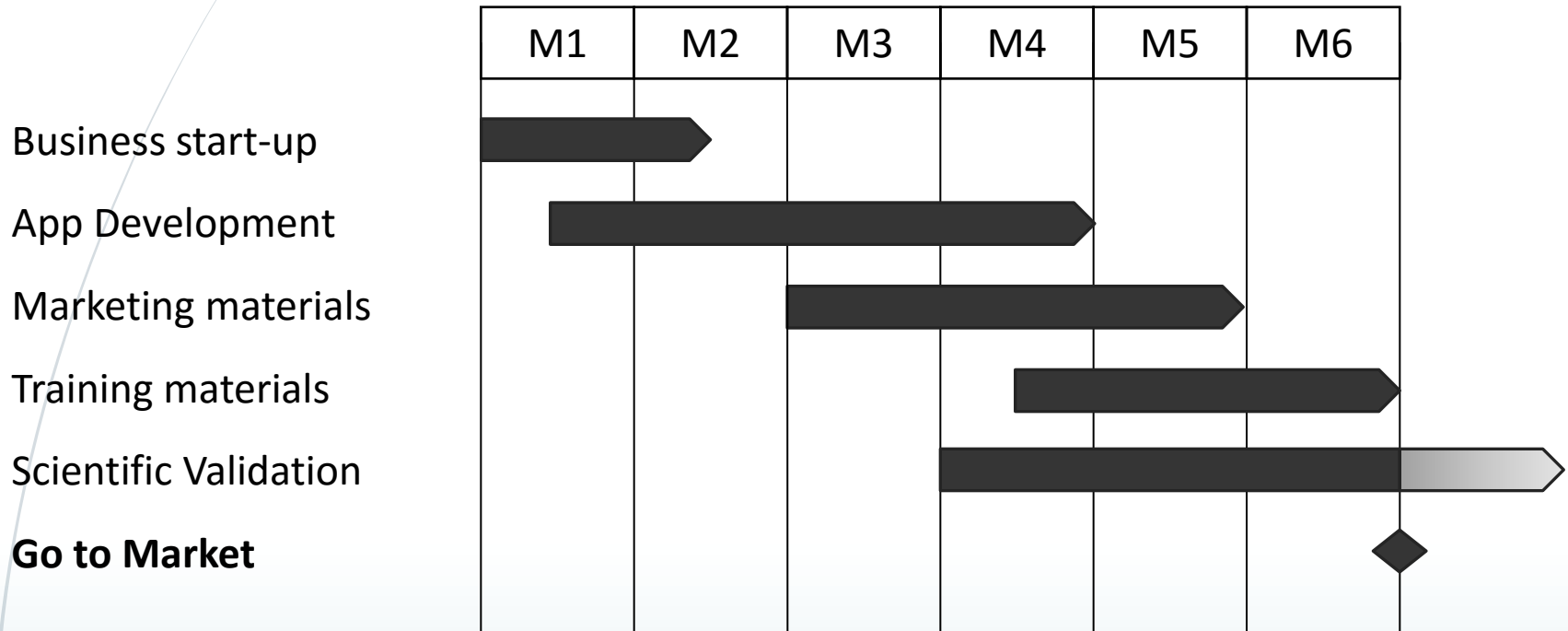


For what value are our customers really willing to pay? For what do they currently pay?
How are they currently paying? How would they prefer to pay?
How much does each Revenue Stream contribute to overall revenues?

- Initial founding from key pharmaceutical and bio-medical key partners

- App store revenues (huge patient market!)

High Level Time Plan



It's a challenging plan, but feasible with appropriate funding and key resources.

Challenging milestones represent the only way to hit the market at the right time!

Support needed!

We need:

- Initial funding
- Advertising on physicians network

We offer back:

- Brand advertising
- Company shares
- On long term, increasing numbers of T2D patients treated with insulin
- More safety and better results in diabetes treatment (ethical value!)

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«Calipso Project» Team



Michelangelo Menduni
Computer programmer
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Thanks for your attention!