

Micro & Nano Bio Solutions

a ” must have” to solve user’s unmet needs in a *Mega* disease: Diabetes

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Global Head Drug Delivery & Monitoring
Sanofi Diabetes

The Problem: Type1 and Type2 Diabetes

TYPE1 diabetes is usually diagnosed in children and young adults, and was previously known as juvenile diabetes. Only 5% of people with diabetes have this form of the disease.

In type 1 diabetes, the body does not produce insulin. Insulin is a hormone that is needed to convert sugar, starches and other food into energy needed for daily life. With the help of insulin therapy and other treatments, even young children can learn to manage their condition and live long, healthy lives

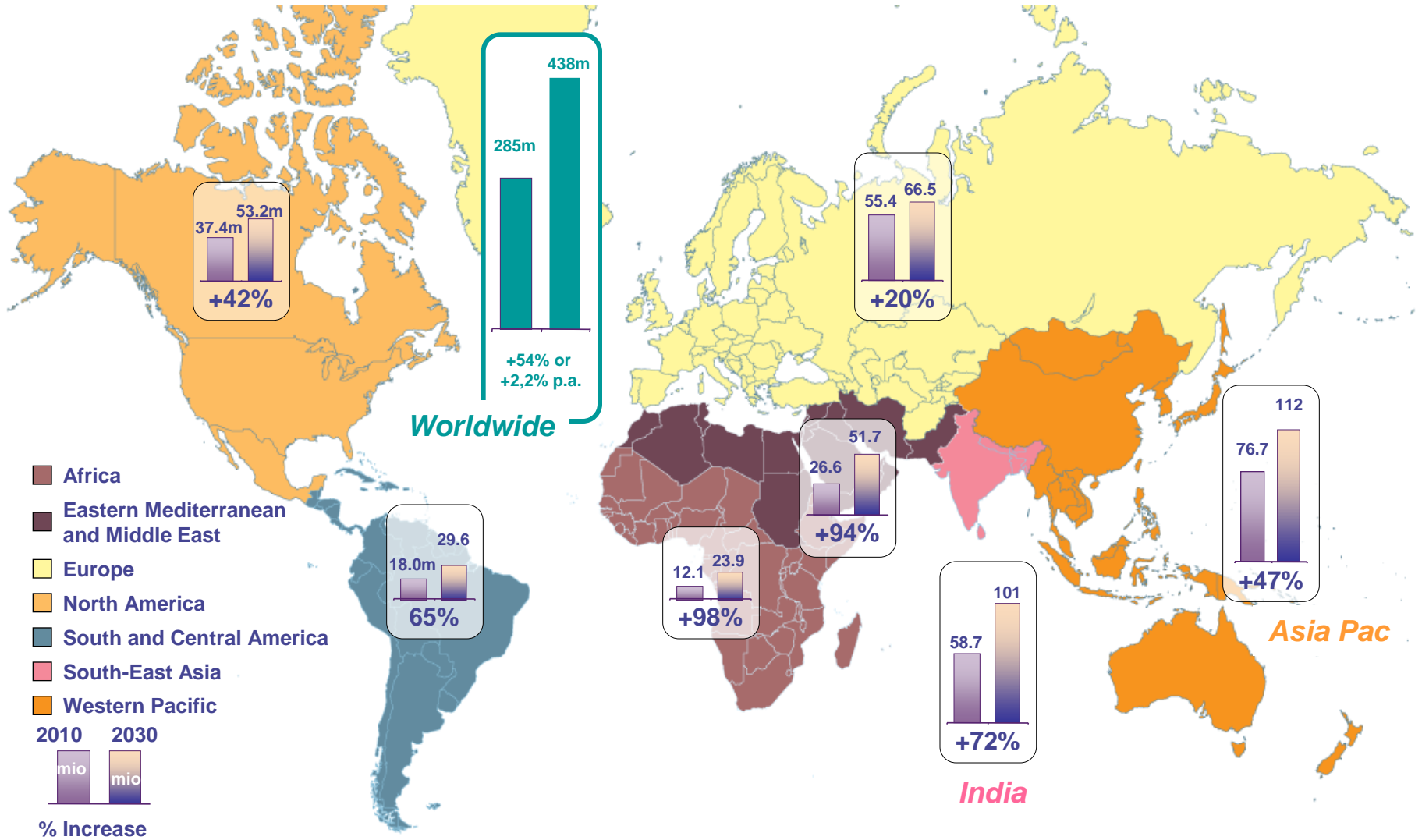


TYPE2 Diabetes is a problem with your body that causes blood glucose (sugar) levels to rise higher than normal. This is also called hyperglycemia. Type 2 diabetes is the most common form of diabetes.

If you have type 2 diabetes your body does not use insulin properly. This is called insulin resistance. At first, your pancreas makes extra insulin to make up for it. But, over time it isn't able to keep up and can't make enough insulin to keep your blood glucose at normal levels.

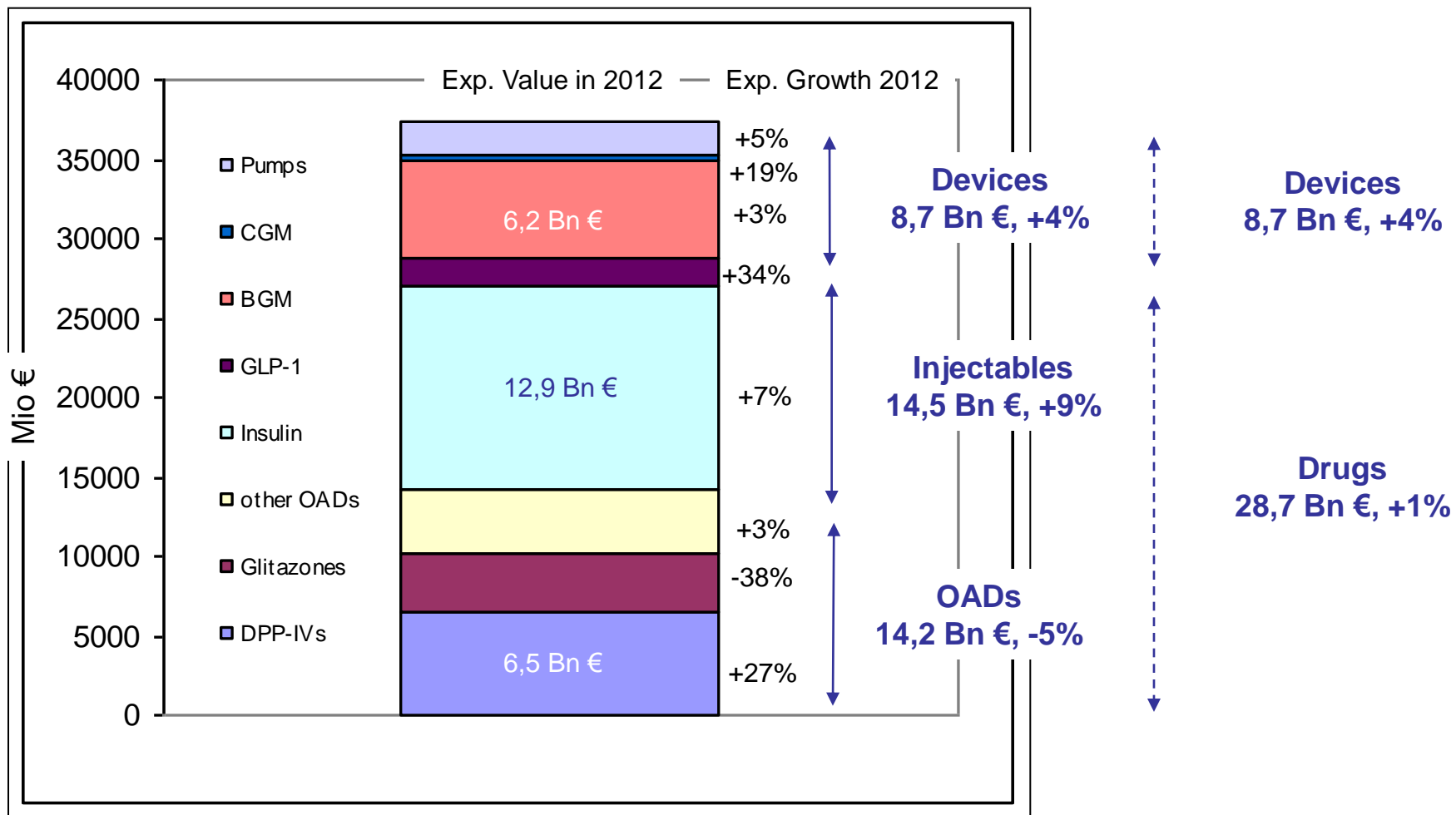
Source: ADA

The worldwide Diabetes Epidemic continues to rise



Source: IDF Diabetes Atlas. <http://www.diabetesatlas.org> | 3

The worldwide Diabetes Market in Value: 37 B € in 2012



Note: negative growth in OAD segment a one-time effect due to TZD generification in 2012

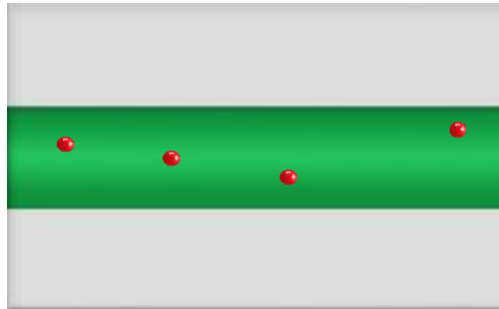
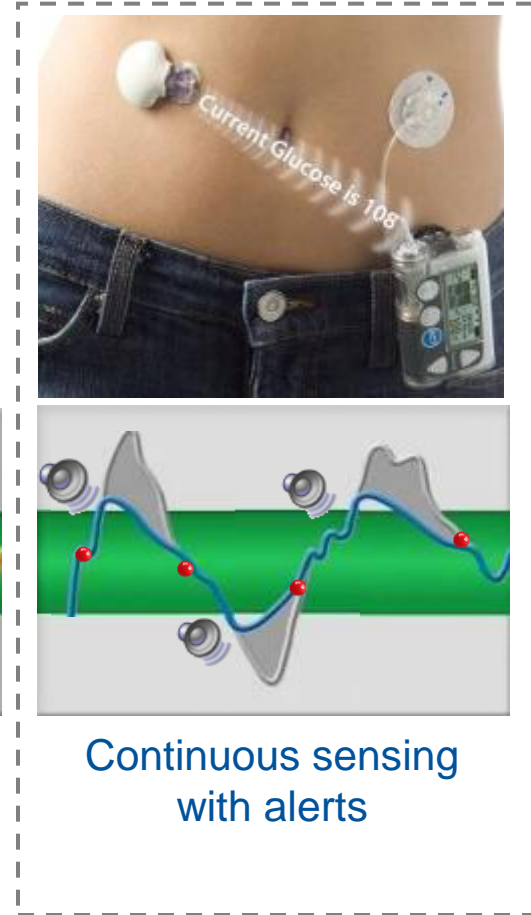
Sources: Decision Resources, Evaluate Pharma, Simon-Kucher, IMS

The Challenge

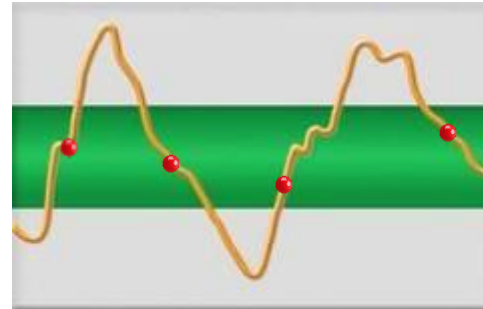


Glucose Monitoring

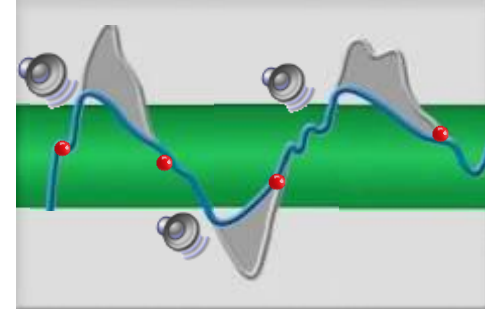
Source: Sanofi / Medtronic



Finger stick testing
with meter/strip

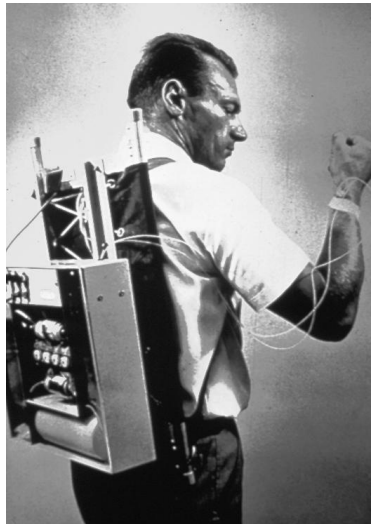


Continuous
sensing



Continuous sensing
with alerts

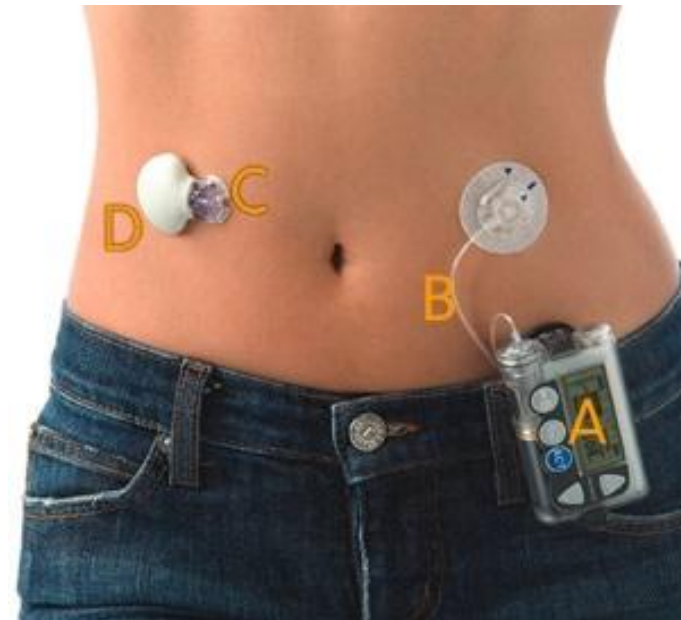
Technology must improve clinical outcomes and convenience



1977



2010

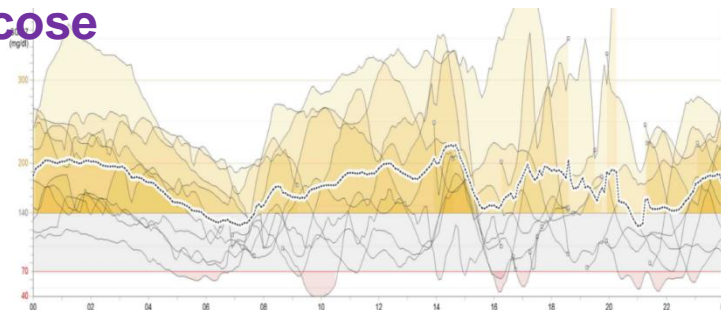


Is Data management Easy and Meaningful ?

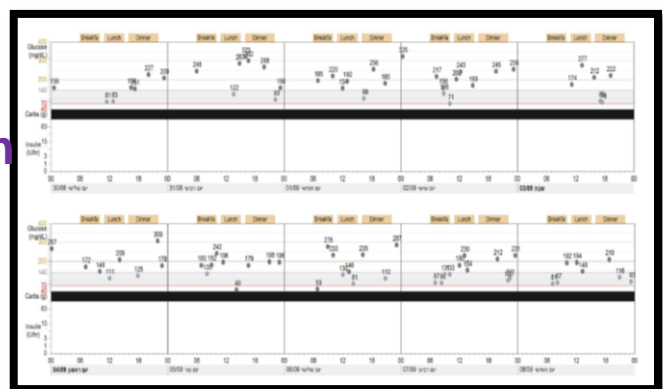
Meals

	00	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	
Dienstag 17.01.2012								103	108			225	272	248	129							175	195	
Mittwoch 18.01.2012								110	115			105	107									129		
Donnerstag 19.01.2012								85				243		225								187		
Freitag 20.01.2012								181				15		40							350	331	237	
Samstag 21.01.2012												114			216	352	401						81	218
Sonntag 22.01.2012												71		10		5,50	2,30					20		

Glucose

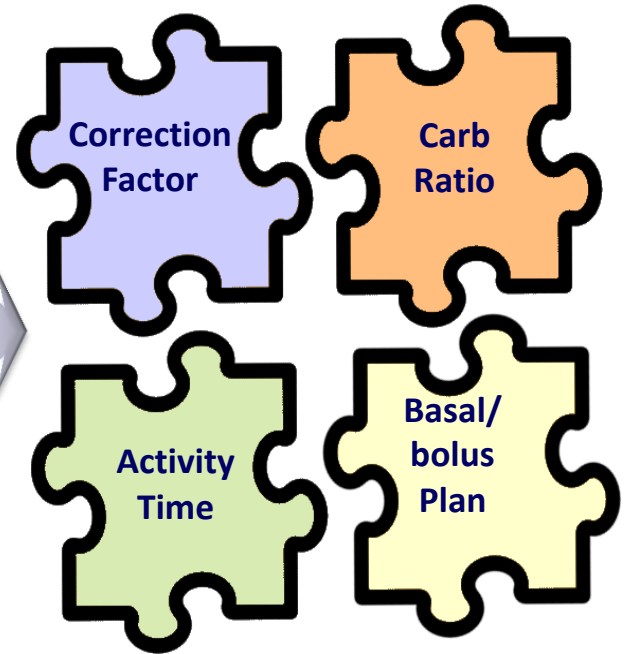


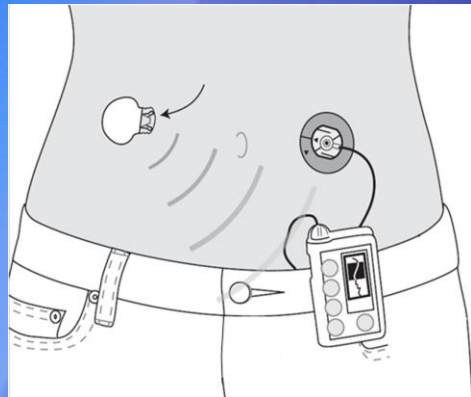
Insulin



Towards effective Personalized Medicine

Algorithm Analysis





Advanced Disease Management through Integrated Solutions

Patch Pump with prefilled insulin
integrated double probe CGM sensor (Enzymatic + Optical)
Cardio & Exercise sensors



connection to Server

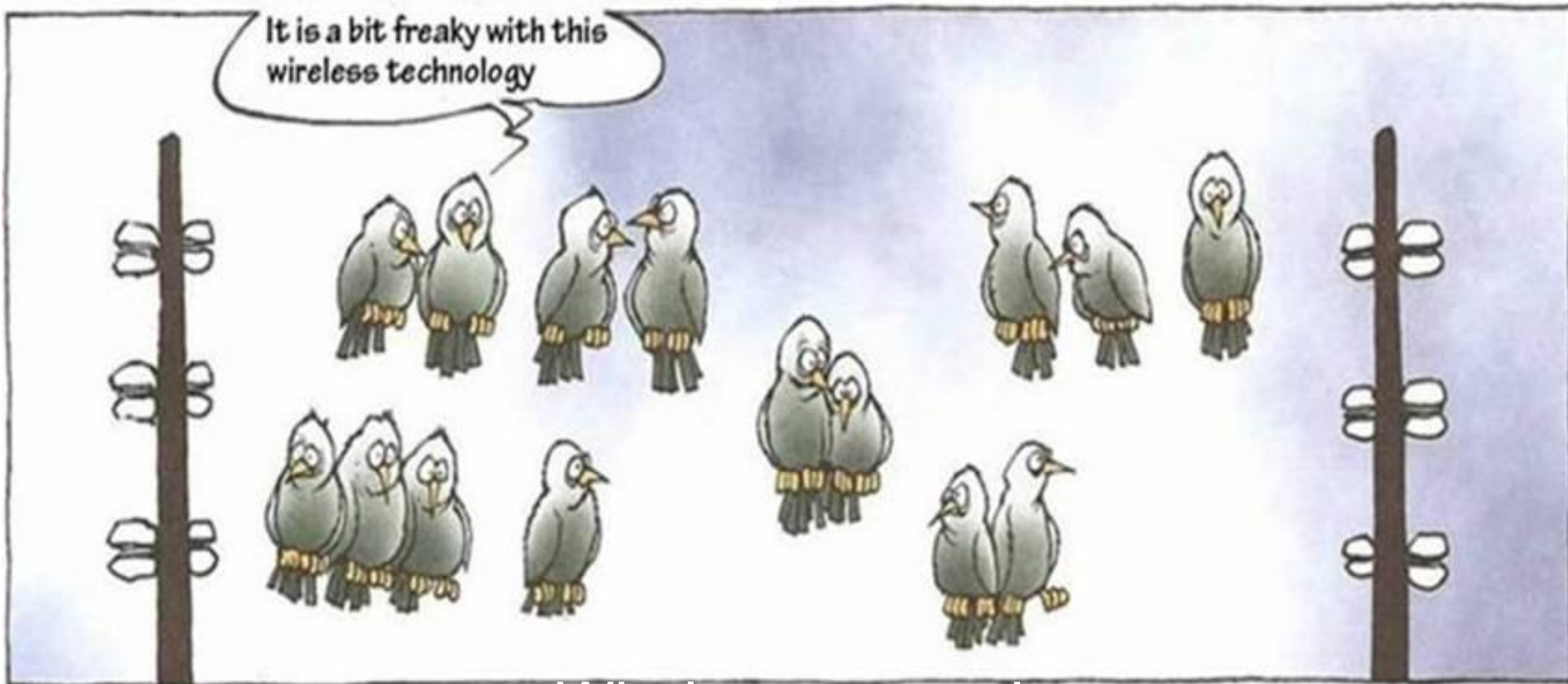
→ Data Mgt. - Monitoring + Coaching -
Tele-Medicine

New DRUGS

- Concentrated
- Thermo-stable
- ...



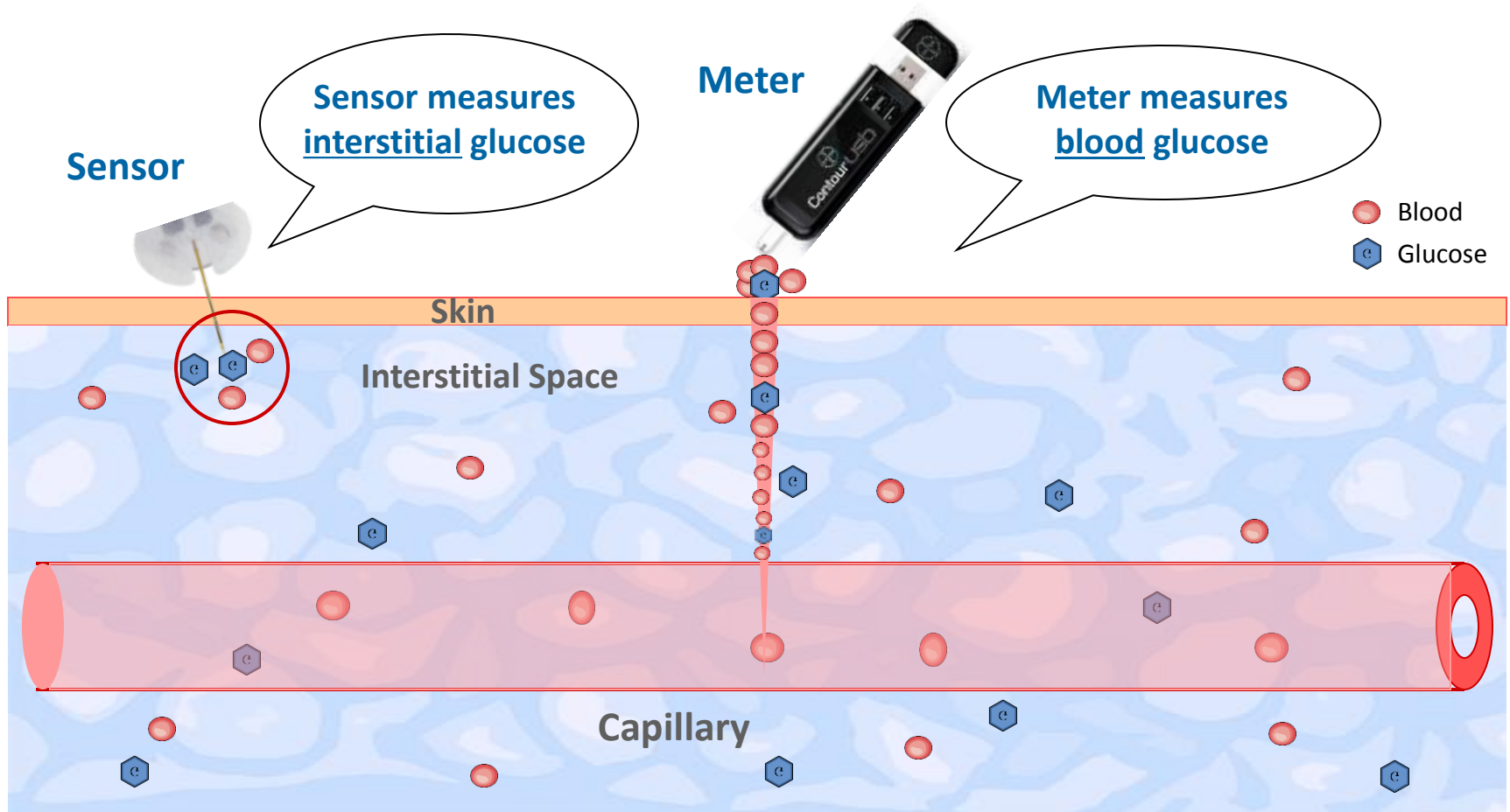
Wireless is not yet approved by Regulatory bodies



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Monitoring

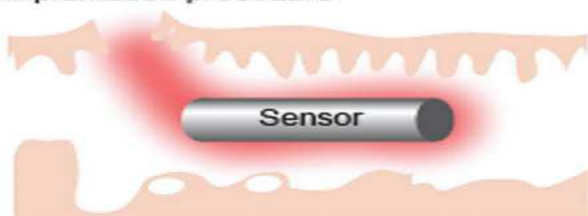
BGM versus CGM Sensors and Meters Measure in Different Places



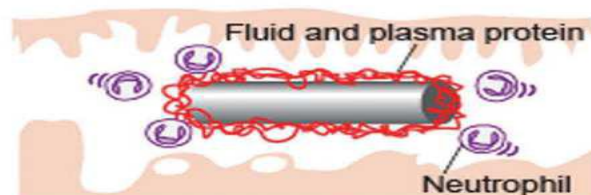
CGMs are “calibrated” with meter readings to calculate CGM values

Implantable CGMs raise a variety of issues like body response, implantation site, sensor drift, calibration and response time

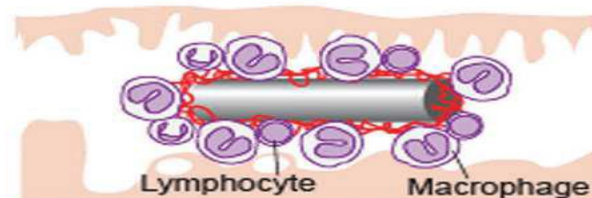
Initial damage from implantation procedure



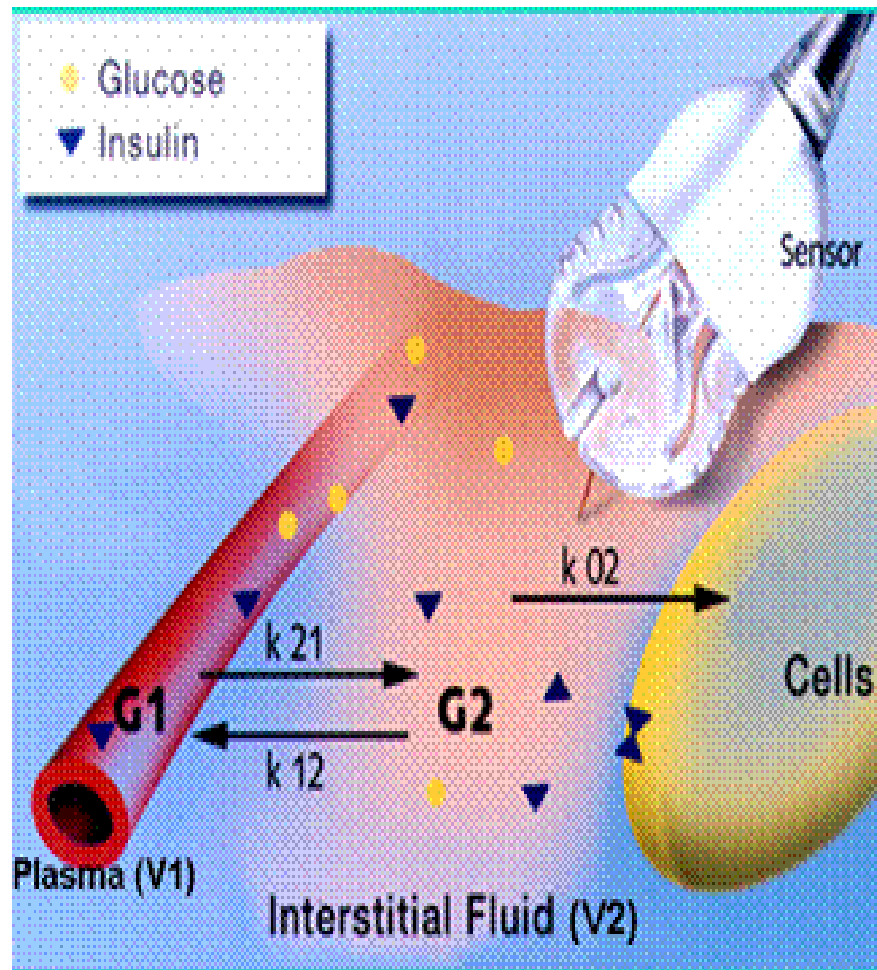
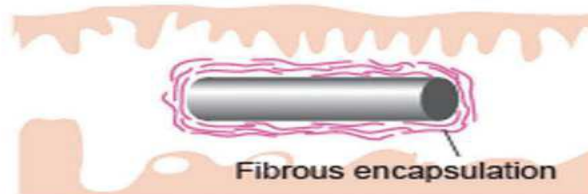
Protein adsorption



Cell interrogation/attack



Formation of fibrous encapsulation



Non-Invasive Monitoring



**There is no Non-Invasive Continuous Glucose Meter on the market at present...
... but this might change in the future**

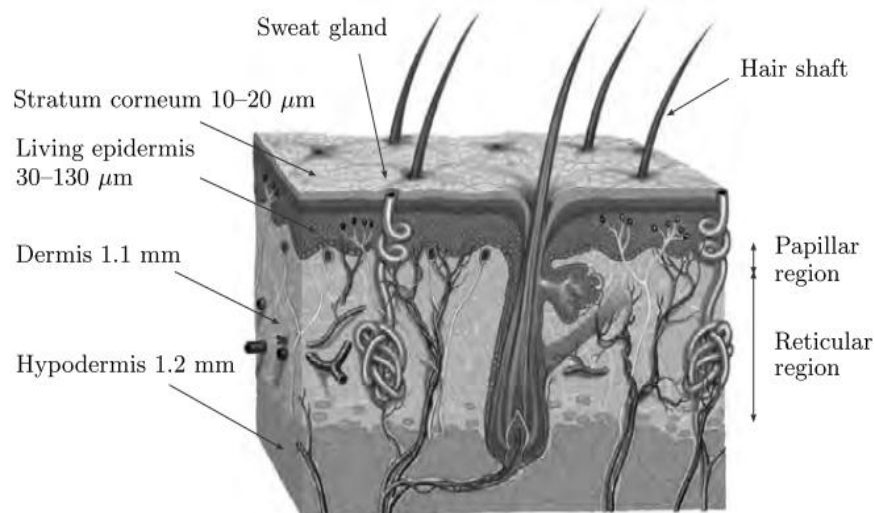
Infusion / Absorption

Example of Micro-Needles

**In vitro versus “real life”
Influence on Drugs PK / PD**

Micro-needle technology

Micro-needles ensure pain-free injection by passing only the stratum corneum; Different types could differ in their materials, manufacturing processes and designs



- Micro-needles penetrating the skin from 100-200 μm do not reach the nerve endings and are therefore painless upon application
 - Micro-needle has to withstand insertion force up to 10N
- Compromise between:
- Materials
 - Designs: tip, diameter, arrays, needles density...
- Depending on their types, can allow active or passive drug delivery

Differentiating factors:

- Materials: Glass, Metal, Polymer, Silicon, Sugar
- Manufacturing process
- Designs
- Types: Solid/Hollow/Biodegradable Micro-needle
- Micro-needle delivery devices

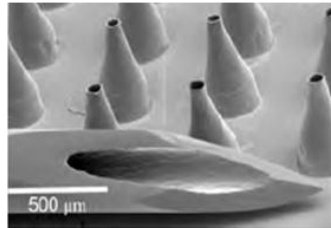
Micro-needle technology

Many types of materials such as metal, glass, polymer, sugar and silicon differentiate microneedle types from each other

- Metal (titanium, stainless steel, gold, nickel)

- Resistant
- Biocompatible
- Reduced choice

for designs

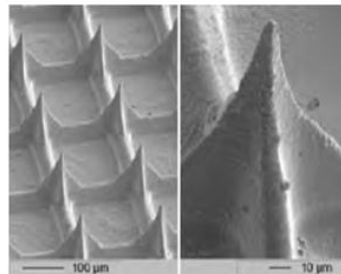


- Glass

- Reduced costs
- Biocompatible
- Needle breakage

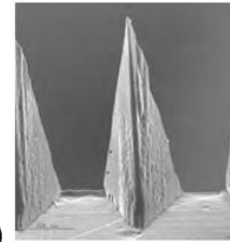
- Polymer

- Reduced costs
- Biocompatible
- Biodegradable
- Designs variety



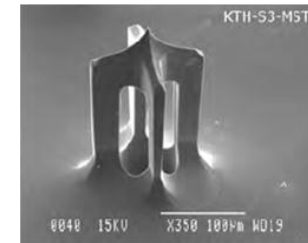
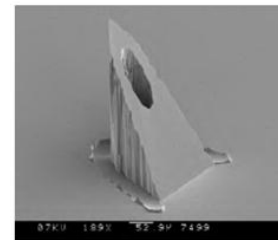
- Sugar

- Reduced costs
- Biocompatible
- Biodegradable
- Stability (moisture, air...)



- Silicon

- Designs variety (MEMS techniques)
- Needle breakage
- Expensive (clean-room processing)



- And combinations thereof...

Polymer core with metal coating to improve penetration force

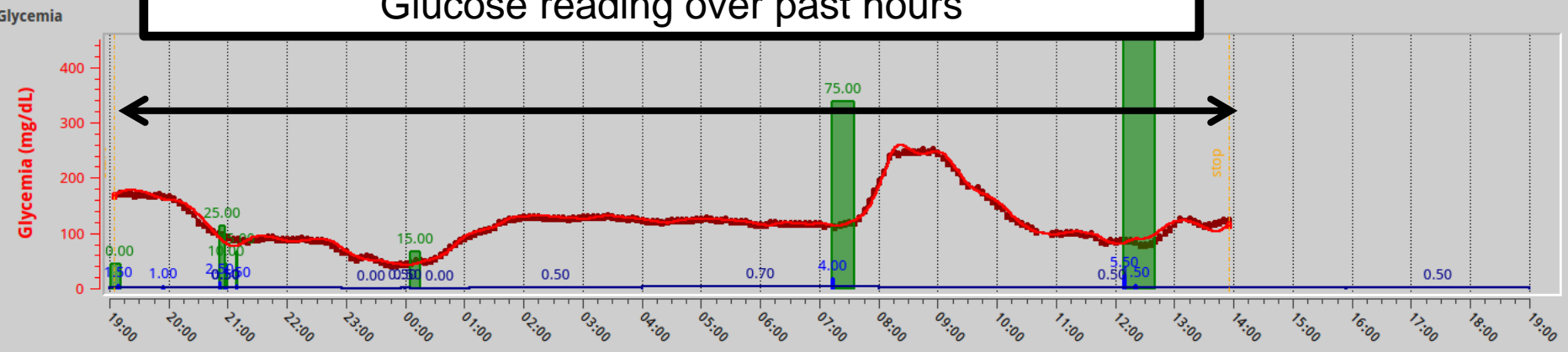
Signal Processing , Algorithm and Displaying



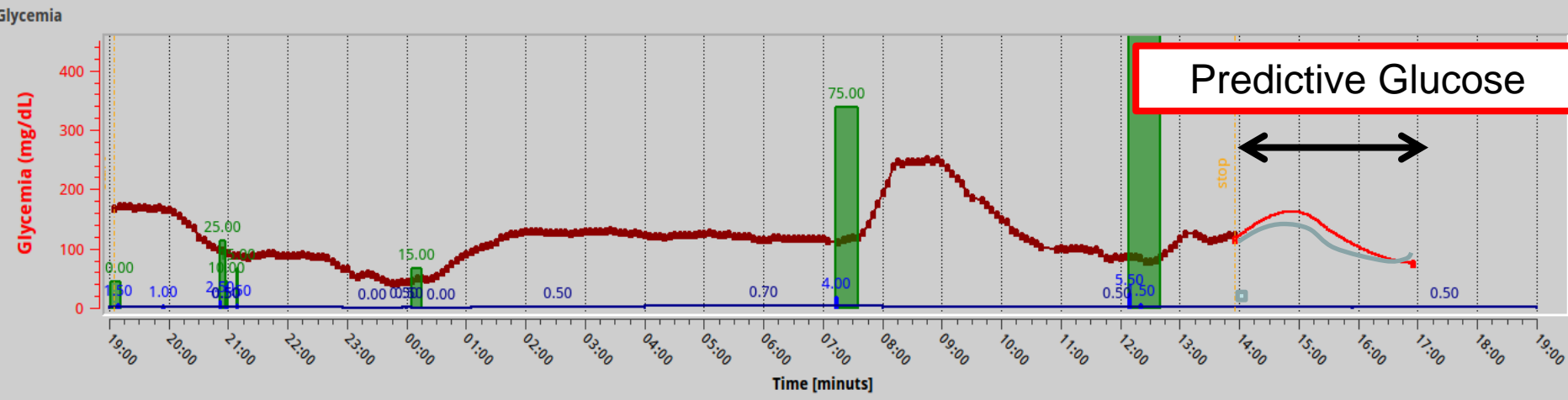
from 19:05 to 13:55

run estimation

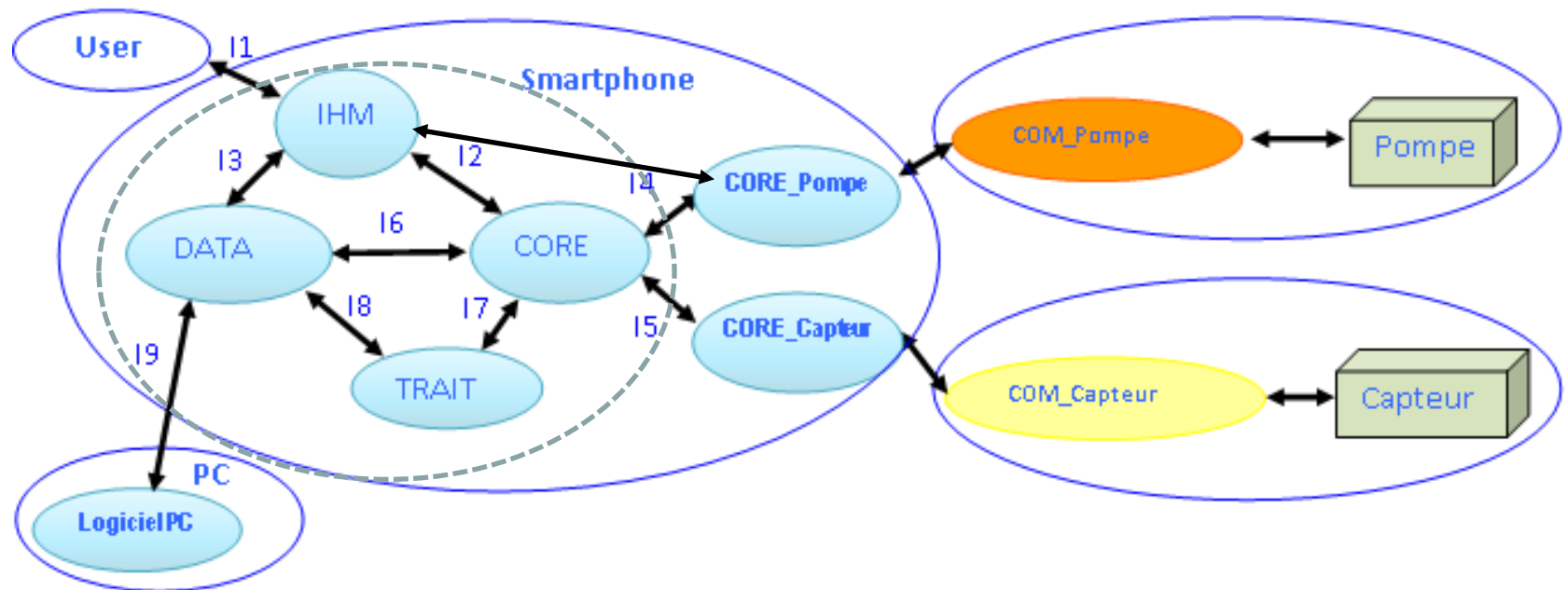
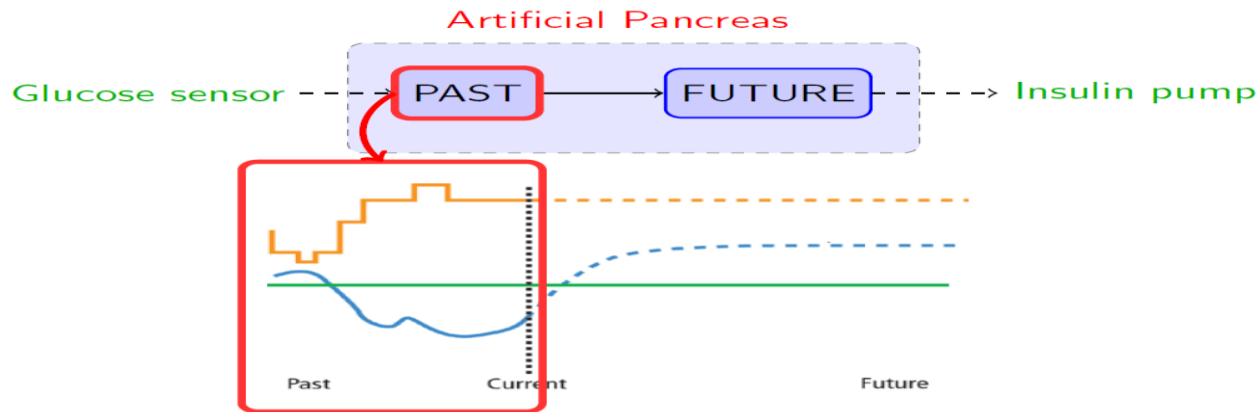
Glucose reading over past hours



Predictive Glucose



Why Regulatory Bodies are careful: Interfaces versus Safety



Why Regulatory Bodies are careful: Human factors



A woman is sleeping peacefully in a bed, her head resting on a white pillow. To her left, a laptop is open, displaying a dashboard with various charts and data points. A digital clock on the bedside table shows the time as 7:44. The scene is dimly lit, with a blue glow emanating from the laptop screen and the clock.

Placing Patients and HCP's at the center is CRITICAL

The right solution has to be

- ✓ Easy to use
- ✓ Meaningful and creating significant clinical outcomes
- ✓ At fair cost

Thank You