From research to beta testing a diabetes e-health solution – some thoughts

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Outline

• Dianovator – introduction
• The solution
• From research to beta release – timeline
• Preamble – from research to company
• Pre-commercial Phase – from foundation to beta release
About me & background to the idea

• Fredrik Ståhl
• CEO & Founder
• Malmöit
• Type 1 diabetes (2002)
About Dianovator AB

- Founded in 2017
- Spinoff from research at Lund University. PhD thesis *Towards Defence in Depth in Diabetes Self Glucose Management* (Fredrik Ståhl, 2015)
- Office in Malmö (Stortorget 13b)
- 7 FTE engagement
The Global Diabetes Challenge

• **425 Million** persons with diabetes (half undiagnosed)

• **30%** use insulin (U.S.)

• **50%** do not reach the recommended HbA1c levels (>80% in type 1)

• **850 Billion USD or 12% of total world healthcare expenditure**

Sources:
The Patient: Current practise weaknesses

- **Short-term**
  - Low glucose: Coma, Death
  - High glucose: Tiredness, ketoacidosis

- **Long-term**
  - Heart and cardiovascular complications
  - Neurological complications
  - Kidney disease
  - Gangrene, Blindness, etc.

- **Quality of life**
  - Anxiety
  - Constant reminder and needs to be considered
The Clinician: Current practise weaknesses

- Poor overview of patients
- HbA1c (long term average) does not reflect dynamic effects
- Current tools for glycemic evaluation are arbitrary and time-consuming
- Shortage of HC personnel and increased workload.
Diact – More stable blood glucose

- Increase time in range
- Medical Device (Class 1 & Class 2a)
- SaaS Business Model
- Patent pending
Diact Ecosystem

Diact
Cloud Computing

Upload data
Patients upload data from their devices

Personal device
- with patient's data

Diact Pro
Clinician/patient meeting
- Assess
- Adjust
- Communicate

Patient
- Attaining a more even blood glucose level
Timeline

Preamble

2002: Diagnosed with type 1 diabetes
2003: MSc Thesis
2006-2013: DIAdvisor Project
2013: Section K Johnson Grant (100,000 EUR)
2013: Vinovo Vinnfuture
2014: SWELife Grant (330,000 EUR)
2015-10: PCT application
2015-12: PhD Thesis

Pre-Commercial Stage

2017-04: Dianovator AB founded
2017-08: First round of financing done (6 MSEK)
2018-04: National patents filed
2018-08: Seal of EIT Health grant
2018-10: Beta Release
ISO13485 SOPs in place
Ongoing Clinical Evaluation
Preamble

From research to company

- Financing
- Patent
- Early prototype
Financing – Early Soft Money

What Dianovator did

• Personal Means
• Private Funds (Sten K Johnson)
• LUIS – Vinnova VINN Verifiering
• ALMI Innovationscheck
• SWELife/Vinnova Grant

Findings

• Don’t give up!
• Use the fact that you’re connected to a university (hospital)
• Lots of funds out there – google!
Patent Filing

What Dianovator did

• Filed a PCT application with help from LUIS and patent attorney.

Findings

• Filing cost is cheap – writing is expensive
• Take care when writing – limited possibilities to change!
Early Prototype

What Dianovator did

• Early prototype with independent developer at fixed price.
• Very basic backend – focus on frontend functionality.

Findings

• Focus – MVP, MVP, MVP!
• Early validation, also commercial wise – be ready to pivot!
Pre-commercial Phase

From foundation to beta testing

- Basics
- Financing
- CE
- Development work
Founding – basics

What Dianovator did

• Formed a new aktiebolag
• Hired an independent chairman

Findings

• Aktiebolag – learn the basics of accounting and applicable laws
• Course in board of directors work, e.g. Styrelseakademin (certificate)
Funding

What Dianovator did

• Equity offer
  • Connect Skåne ‘Språngbräda’
  • Personal contacts
  • Deal: 6 MSEK

• Soft Money
  • Horizon 2020 – SME Instrument Phase 1: Seal of Excellence
  • EIT Health – 50 000 EUR

Findings

• Get connected!
• Train you pitch – a lot!
• Take help from a lawyer and senior business advisor when writing/negotiating the shareholders’ agreement
• Take help from expert if pursuing Horizon 2020/SME
CE Mark

What Dianovator is doing

• Hooked up with a regulatory expert.
• Carefully analyzed classification and definition of intended use.
• Standard Operating Procedures (ISO13485) in place, mostly by expert consultant.

Findings

• Takes more time than you might think - Start early!
• You need an expert.
• If in class 2a or above, reach out to a NB early on.
Development work

What Dianovator is doing

• Work agile.
• Rigorous requirement – test framework.
• Dedicated DevOps resource – keep environment under absolute control.
• Most in-house to build and keep knowledge-base.

Findings

• The regulatory dimension adds a lot of work early, but the rigid control brings clarity and speed later on.
Thank you!

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