

# Putting people with diabetes at the center



#### Vision and mission

Vision statement:

Fun despite diabetes. Diabetics will be able to handle their diabetes simply and effectively.

Mission statement:

We enable patients with diabetes to avoid mistakes in there daily diabetes therapy.



## Why a smart pen?

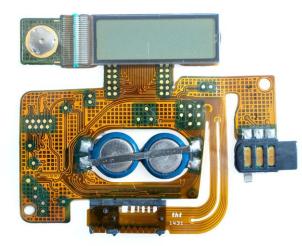
- The smart pen is not changing the mechanic or accuracy of a reusable mechanical pen.
- It makes the pen smart by enabling patients with diabetes to avoid mistakes in there daily usage of a Insulin pen.
- The smart pen records the amount of Insulin released from the pen and transmits the data to the complementing smartphone app.
- The smart pen will create transparency about when and how much Insulin was injected in the past.
- The smart pen is monitoring the temperature of the Insulin inside (cold chain monitoring)
- The pen can be located by leveraging the location functionality of location service of iOS or Android.
- Individual design, plain white or Swarovski design, what is your style?
- Complementing diafyt software to alert patients if necessary and if used to deliver data for diafyt guide AI algorithm.





## Unlike other Insulin pens in the market ..

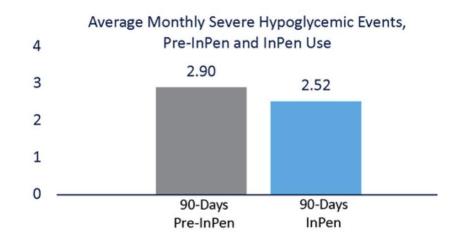
- The diafyt smartpen recognizes the user's handling,
- warns the patient and corrects errors with the help of
- high-tech electronics and artificial intelligence.



- BLE 5.2 (new wireless technology)
- digital sensors (very accurate)
- ultra low power design (over 1 year battery life)
- Apple FindMy technology build in (never lose your pen)
- Al in AWS, open source API

#### Results

#### Potential cost savings of using diafyt Smart pen



**13%** decrease in sensor-detected severe hypoglycemic events in the 90 days after initiating Smartpen use

The anticipated cost reduction per user per month with Smartpen = \$237

The expected annual savings per user would be = \$2176

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A parallel clinical trial would demonstrate <sup>**© diafyt**</sup> medical relevance and safety.

- Clinical Trail Partner: Univ.-Prof. Dr. med. Knut Mai, Clinic of Endocrinology, Diabetes and Nutrition, Clinical Research Unit, Charité, Berlin
- Endpoints
  - Safety & performance
- Timeframe
  - Start in 12 Months



## Goto market startegy

The idea is to license the smart pen to insulin pen manufactures.

#### Reasons patients would use the diafyt sensor

- In order to address mistakes using insulin pens, a smart pen is the key to get closer to the possibilities of an insulin pump driven therapy.
- Improvement in therapy in combination with diafyt guide AI software for Insulin dosage calculation and the overall future diafyt diabetic product and service portfolio.
- Individual design



## diafyt MedTech

- started 2016
- Founding team: 3, team as of today 13
- Partners: TU-Dresden, Charite Berlin, Univ. Hospital Dresden, Texas Instruments, DLR
- Finance: SAB (ESF, EFRE), ZIM (BMWI), priv. Investor
- Patents: granted 1, applied 1, word mark granted "diafyt", cooperation with patent office of TU Dresden
- Company: GmbH, registered med tech company in EU
- Admissions: CE MDD Klasse 1, MDR Klasse 2b



## Founding Team



#### Markus Oehme, Development

PhD in Mathematics, Member of MENSA, Graduate from Universität Jena, Germany

#### Thomas Wuttke, CEO, Diabetic

Engineering degree and 4 years law school, founder of diafyt MedTech and pg40 Consulting Group in Germany and USA

#### **Rene Richter**, Hardware Design

PhD in Electronics, Inventor of 30+ patents for insulin drug delivery devices in collaboration with Sanofi

Matthias Badack, Advisor Business Development Knut Mai, Medical Advisor: PhD and Professor at Charité Total team size in 2021: 13



## Challenges

- Tight time line to achieve milestone prototype
- Bio compatibility needs to be assured before clinical trial
- Address early involvement of patient in realization of use cases and usability research
- Identify interface between pen mechanics and design to enable individual design or at least variants
- Licensing product to pen manufacturer
- Patent research regarding Bluetooth connectivity

#### Being smart is not enough anymore

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## Thank you very much

The ultimate goal, the diafyt diabetes universe.

