

# Innovative HealthTech - Revolutionary Addiction Therapy!

Starting with the classic tobacco cigarette.

# Relearning Non-Smoking – Step by Step!

- Over 1 billion people smoke traditional cigarettes.
- Around 60% want to cut down first.



World Health Organization

### **Pitch Deck**

### **Appendix**

- Why is the CiQuit system not bypassed?
- Why is the CiQuit system used?
- CiQuit and DiGA



For self-payers or reimbursement through health insurers as a DiGA!

### The societal challenge

# The global impact of tobacco use



- Worldwide, there are 1.3 billion tobacco consumers
- Tobacco kills over 7 million people every year
- Tobacco use causes millions of disabilities and long-term suffering
- Smokers' life expectancy is at least 10 years shorter than non-smokers
- The total global economic cost of smoking is estimated at around USD 1.4 trillion annually

The global challenge is powerfully illustrated in a short video (1 minute) by the Pan American Health Organization:

https://www.paho.org/en/campaigns/world-no-tobacco-day-2022 or on YouTube:

https://www.youtube.com/watch?v=d3RemnDHS9o&t=16s

# **Environmental destruction per year**

- 600 million trees
- 200,000 hectares of land
- 22 billion tons of water
- 84 million tons of climate-damaging CO<sub>2</sub><sup>3</sup>



An estimated

# 4.5 trillion

cigarette butts, containing more than 7,000 toxic chemicals, end up in the environment every year.<sup>4,5,6</sup>

- 1) Source: https://www.who.int/news-room/fact-sheets/detail/tobacco
- 2) Source: https://www.paho.org/en/topics/tobacco-control
- ) Source: https://www.paho.org/en/campaigns/world-no-tobacco-day-2022
- Source: https://www.nabu.de/natur-und-landschaft/aktionen-und-projekte/meere-ohne-plastik/29901.html
- 5) Source: https://www.euwid-recycling.de/news/wirtschaft/jaehrlich-werden-45-billionen-zigarettenstummel-weggeworfen-170522/
- Source: https://www.euwid-recycling.de/fileadmin/data/euwid\_recycling\_und\_entsorgung/news/images/Talking\_Trash\_EN.pdf



### Intention

# CiQuit - The world's mass-scale solution for smoke-free health

- Despite numerous support programs, most quit attempts fail because many smokers suffer from inability to abstain.
- Quitting immediately is overwhelming due to **inability to abstain**, most smokers never even attempt to quit.

### **CiQuit changes the paradigm:**

A mass-scale, affordable and practical companion that step by step restores ability to abstain - and opens the path to smoke-free living.

# **Our Vision**

CiQuit becomes what the seatbelt is for drivers: a global standard that saves millions of lives.







# CiQuit: From breakthrough technology to global standard



**Goals:** Reduce tobacco consumption worldwide, drastically reduce smoking rates, implement public health strategies.

### Governments

Goals: Relieve the burden on health systems, reduce costs due to tobacco-related diseases, and effectively implement prevention.

### **Foundations**

e.g.: Bloomberg Philanthropies

**Goals:** Promote tobacco control globally and promote innovation in the fight against the tobacco epidemic.

### **CiQuit Goals:**

Cooperation with WHO, governments and foundations

CiQuit addresses the common goals of WHO, governments and foundations:

### Reduce tobacco consumption worldwide.

Through the very cost-effective, everyday and highly scalable application, CiQuit offers for the first time a solution that reaches millions of smokers and thus has the potential to become the global standard for smoking cessation.

Example

# Bloomberg Philanthropies

### **Reducing Tobacco Use**

Today, one in ten deaths around the world is caused by tobacco use. Since 2005, Bloomberg Philanthropies has invested \$1.6 billion to fight tobacco use, working with a global network of partners to prevent tobacco-related illnesses and save lives.

Unless urgent action is taken, tobacco will continue to kill people every year. The scale of this human tragedy is preventable.

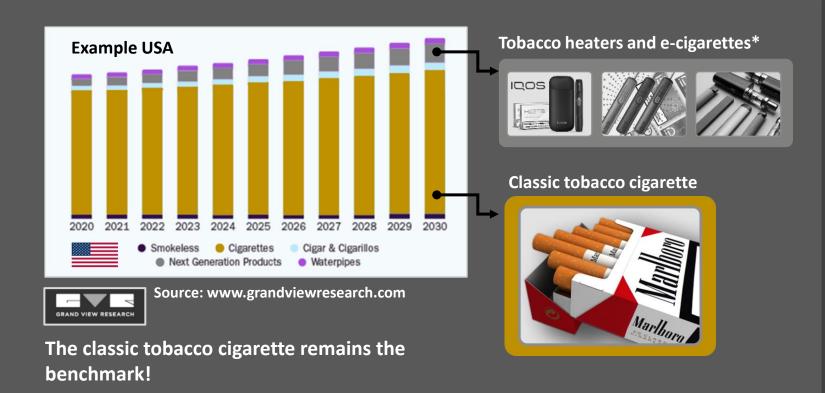
The tobacco industry is fighting to ensure the dangers of their product are concealed, but we are fighting back.

Source: https://www.bloomberg.org/publichealth/reducing-tobacco-use/



### **Market forecast**

# The market for tobacco products will grow to US\$ 1,050 billion by 2030





Of these, over

tobacco users

# 1 billion

smoke the classic tobacco cigarette



<sup>\*</sup>E-cigarettes and tobacco heaters are banned in many countries as they increase the attractiveness of smoking, especially for young people. Many governments, such as in India and Brazil, see them as a gateway to nicotine addiction and potential tobacco use.



# Around 60% of tobacco cigarette smokers do not find a suitable solution!



### The key question:

What dynamics can be observed in the consumption behaviour of smokers over the next year?

Continue to smoke the classic tobacco cigarette as before.

**≈** 30%

b) Quit completely or test e-cigarettes/tobacco heaters.











Example **Nicotine Replacement** Therapy

**Global Revenue** Forecast 2030

US\$ 3.7 billion



Relapse rate

≈ 90%

Reduce consumption or get out via reduction.1



The soft exit via reduction - enormous opportunity and mega potential.



# **Solution** for the masses

# Gentle reduction without withdrawal symptoms and restoration of the ability to abstinence!

### **Our two target groups**

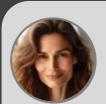


### 1. A gentle start to quitting



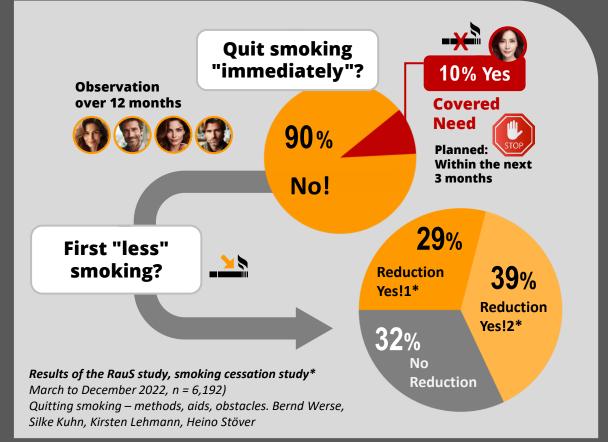
"First smoking less without it becoming stressful and then quitting completely without constant cravings would be exactly my thing."

### 2. Permanent reduction of tobacco cigarettes



"I smoke 20 cigarettes a day. 5 cigarettes a day (or only on certain occasions) without constant cravings would be fantastic."

# **CiQuit - The enormous gap in healthcare**



\*"First, daily smokers who have no motivation to quit smoking were asked whether they would like to reduce their consumption. Only 32% say that they do not want this. 39% state "Yes, I would like to reduce consumption at least somewhat (e.g. less cigarettes per day)" and 29% "Yes, I would like to significantly reduce consumption (e.g. no longer in everyday life, but only on special occasions)".

Quelle: https://www.unifrankfurt.de/138678087/Zigarette\_\_Werse 1.pdf

L U N A MEDICAL

<sup>1\* 29% =</sup> Only on selected occasions

<sup>&</sup>lt;sup>2\*</sup> 39% = Less cigarettes per day

### **Expanded Target Market**

# Patients with pre-existing conditions



Example: Smoker inability to abstain despite COPD treatment

Approximately 40% of those with COPD are current smokers!1

Inability to abstain

CiQuit supportive therapy for restoring the ability to abstain





- A significant proportion of patients with relevant pre-existing conditions (e.g. respiratory, cardiovascular or cancerous diseases) are **unable to abstain**.
- CiQuit
  Ideal therapy support for patients with pre-existing conditions who are unable to abstain:
  - Lower Barrier to Entry: No immediate, complete abstinence required.
  - Stronger Motivation: The existing motivation driven by their health condition is specifically supported by the CiQuit system.
  - Sustainable Success: Gradual restoration of the ability to abstain is often the only way to help this patient group remain smoke-free in the long term.

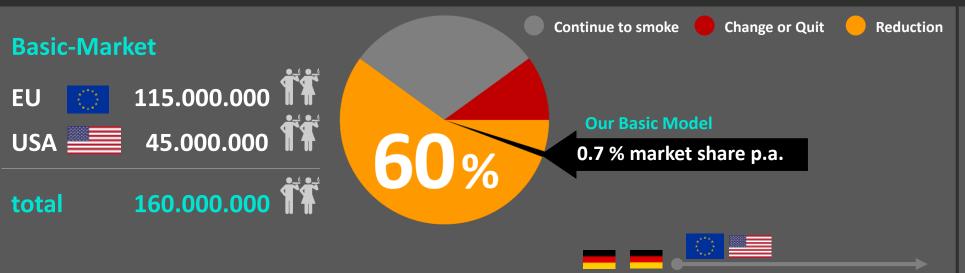
# The Power of Tobacco Addiction

- ≈ 40% of patients who have undergone laryngectomy attempt to continue smoking shortly afterwards."
- ≈ 50% of patients operated on for lung cancer resume smoking after surgery.<sup>2</sup>



### **Conservative revenue planning**

# €219 million in revenue with 101 million EBIDTA (year 5) – EU and US only and only 0.7% market share

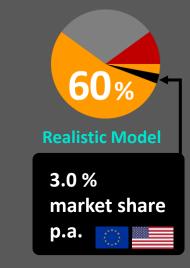




China\*293.000.000India74.000.000Indonesia77.000.000Japan18.000.000

\*https://tobaccoatlas.org/factsheets/china/

Users via	2026	2027	2028	2029	2030
Companies Corporate Health Management	700	1.800	34.500	82.900	114.500
Self-payers	3.000	17.000	54.000	250.000	900.000
Health insurance	0	5.000	20.800	59.000	153.000
in € million					
Revenue	0,5	5,4	34,4	83,4	219,3
Total costs	2,0	4,8	14,4	45,9	118,1
Marketing (proportion)	0,2	1,2	4,3	14,5	44,7
Hardware (proportion)	0,1	1,2	5,7	19,9	46,1
EBITDA	-1,5	0,5	20,0	37,5	101,1
Employees	5	7	10	22	56



2030
548.500
3.608.999
642.600
895,6
377,2
98,3
189,6
E10.2
518,3



### The product 1/2

# **CiQuit-Box = 24/7** companion: Unlearn smoking at the exact moment of craving!

**Reconditioning** = Body and mind unlearn smoking step by step!



- 1) Behavior control (Allowed Daily Limits: Slowly Falling): "Even the observation of one's own smoking behaviour leads to a significant reduction in smoking."

  Rainer Tölle, Gerhard Buchkremer, Cigarette smoking: epidemiology, psychology, pharmacology and therapy
- 2) Access Delay (The locked box delays the removal slowly increasing): The interruption of automated behaviour is one of the decisive factors. "

  Mag. Ilse Müller, Psychotherapist (behavioural therapy), Focus on nicotine addiction, among other things

### The product 2/2

# **CiQuit-App** = Al-driven training and coaching: Relearn not to smoke!



**Quit smoking goals**  1. Goal: Reduction of consumption Smoke less than 78 cigarettes per 2. Goal: At least 1 day smoke-free Choose your smoke-free day! O 3. Goal: At least 3 days smoke-free O 4. Goal: Quit smoking

for motivation and successful **learning** 

Goal 1 **Restoring the** ability to abstain

Goal 2 **Building motivation to** quit smoking

# Goal 3 Permanent abstinence without

- Cravings
- Withdrawal symptoms
- Smoking rituals

Coaching, positive experiences, and reinforcements provided by the CiQuit app help stabilize changes, foster positive emotions, and strengthen the motivation to quit smoking.

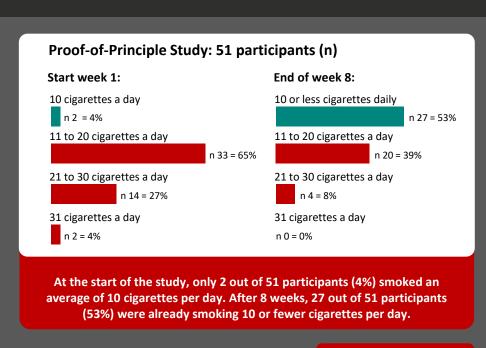
### Goal:

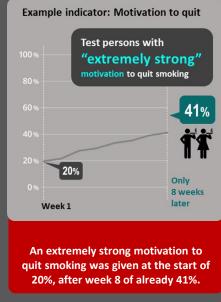
A smoke-free life – without cravings and without feeling like you're giving anything up!

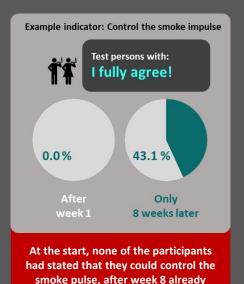


### **CiQuit – The Proof-of-Principle Study shows:**

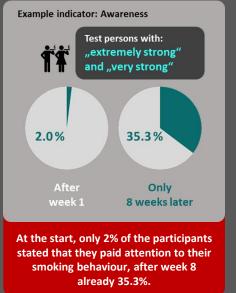
# Each indicator for achieving ability to abstain is improved after just 8 weeks!

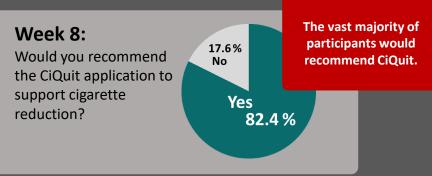






43.1%.







Average monthly cost of cigarettes at the start of the study around €230, after 8 weeks around €137



### The Patents – Status as of August 2025

# All countries with a high smoking rate and a high population are covered

### Method and device for restoring the ability to abstain



### Patents granted in over 30 countries:

### **European Union**

**Grant of a Unitary Patent:** 

Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Portugal, Sweden, Slovenia

### Direct grant:

Greece, United Kingdom, Poland, Spain, Turkey

- China, India, Indonesia, Vietnam, South Korea
- Brazil
- Eurasian Union

Russian Federation, Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Tajikistan, Turkmenistan

### Patents under review: USA, Japan, Thailand















# **Important!**



### **Effective patent** enforcement

- Health insurance funds are legally obliged to reimburse only the costs of medical devices that are lawfully placed on the market.
- Products that infringe existing patents do not meet this requirement.
- The financing of such products would not only constitute a violation of applicable laws and regulations, but would also undermine the integrity of the healthcare system.

Indonesia

Vietnam

South Korea

Brazil

**Eurasian Union** 

### **Summary**

# Problem / Solution from a medical point of view

# **Previous** treatment approach

Medication





to mitigate the effects of nicotine withdrawal

Psychological help



- AppsOnline courses

to overcome the effects of nicotine withdrawal

# **Problem** Quit smoking with inability to abstain





**Psychological** (mental) dependence +

Physical (bodily) dependence

### **Addiction Center**

Effects of nicotine withdrawal "Hungry nicotine receptors"

- · Craving = agonizing craving for addiction Irritability and restlessness
- Frustration and anger

- Concentration disorders
- Increased appetite and weight gain



High level of suffering

High relapse rates (despite assistance)

Next smoking cessation attempt is usually postponed for years

# **NEW**: Restoration of the ability to abstain!



# **Solution** Quit smoking with ability to abstain





Psychological (mental) dence + Pl s al (bodily) dependence

### **Addiction Center**

Effects of nicotine withdrawal "Hungry nicotine receptors"

Very much reduced.

At best, no longer available!



No or weak level of suffering

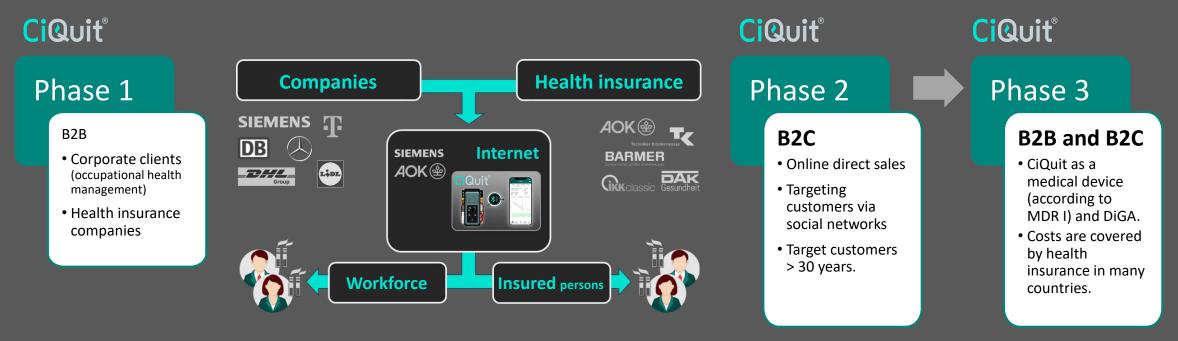
High success rates\*

In case of relapse: resume CiQuit.



### **Market entry phases**

# Initial market entry via cooperations = low marketing costs!



Cooperation with companies and health insurance companies keeps the initial marketing costs low.

Subscription model for self-payers without MDR I/DiGA certification 79 € one-off + 14.90 € per month 

Ø Planned term revenue: € 290

Price model for cost coverage by health insurance companies with MDR I/DiGA certification between € 300 and € 350 net (depending on the country)

Exemplary cooperation partners for global marketing:

**Pharma** 

MedTech

**Clinic chains** 



### Visibility in the target group as a growth driver

# When smokers meet, the box grabs attention – and starts the CiQuit conversation.

- The CiQuit Box immediately stands out within the target group every user is approached by other smokers: 'What is that? Where can I get it?'
- The benefit can be explained in seconds the app makes progress visible, boosts motivation, and clearly conveys the therapeutic approach.
- Visibility as a growth driver: The Box sparks curiosity, and the App convinces. CiQuit users thus open direct access to millions of smokers worldwide.















# Milestones and successes

### **Status Quo**

### Investment to date

### 1.5 million €

- Box development for medical device accessories
- App conceptualization to the medical device
- Software development app and backend
- Successful coordination with the BfArM
- Proof-of-principle study
- Test market self-payers Online sales

### From follow-up financing

### 6 months

### Finalization

- Software (app/backend)
- Regulatory MDR
- Web presence and online store
- Organizational structure
- Production of the first CiQuit boxes

### **Start marketing**

- Self-pay market
- Workplace health promotion
- Cooperation with health insurance companies
- International cooperation and sales

### 7 months

# 3 months

### Systematic data analysis

for provisional inclusion in the DiGA directory

# **BfArM**

**Examination** for provisional

inclusion in the DiGA directory

Bundesinstitut für Arzneimittel und Medizinprodukte The way into the **DiGA directory** 

### 1st BfArM consultation protocol on DiGA

- Box and app will be refunded
- Prerequisite:

Further development of the app into a medical device

### 2nd BfArM consultation protocol on DiGA

- App content is a medical device
- Medical endpoint "improvement in health status"
- Requirements of the study design with regard to consumption reduction

### 3rd BfArM consultation protocol on DiGA

Start marketing as

**DiGA** 

The BfArM supports the CiQuit approach of reduction in conjunction with building up motivation to try to stop smoking and avoiding a smoking cessation day that is set too early.



# **Highlights** and capital requirements

- Market gap 60%:
  - Unique solution between reduction and complete smoking cessation that existing methods do not cover.
- 1 billion smokers = high scalability:

CiQuit provides access to a global market of over 1 billion people.

• **Growing health awareness:**Ideal positioning within the trend toward a sustainable, healthy lifestyle.



For mass production around €10

Cost coverage by health insurance as a medical device according to MDR I and as a DiGA (digital health application)



The top five most common diseases that could currently be treated with a DiGA:

- Obesity/Overweight: ≈ 37 million
- Smoking: ≈ 23 million.
- Back and spine: ≈ 21 million
- Sleep disorders: ≈ 21 million.
- Diabetes: ≈ 7 million

Planned DiGA costs for these five diseases for all health insurance companies in Germany

450 million per year

# Capital requirement: € 1.5 Mio.

- Product finalization
- Market entry via companies and health insurance companies
- Inclusion in the DiGA directory





### Team, hardware partners and scientific support

# Let's make the world a healthier place – together!



Foundation June 2021

### Management



Andreas Unsicker
Business economist (FH)

- Company founder
- Network, marketing, patent development



Jürgen Röck Entrepreneur

- IT specialist
- Development of IT systems and IT team



Gregor Schommer Dipl.-Kfm.

- Specialist for hardware development
- 20 years in China

### **Cooperation partner**

**Engineering Hardware** 



https://www.insyslocks.com/de/ Hardware production



https://www.zollner.d e/branchen/healthcar e-lifesciences

### **LUNA medical GmbH: Primary areas of responsibility**

- Hardware conception / control
- Software conception / development /control
- Regulation
- Marketing
- Internationalization
- Product extension
- New product developments



### Universitätsklinikum Tübingen



Prof. Dr. med. Anil Batra Head of the Addiction Medicine and Addiction Research Section

Prof. Dr. Batra is currently leading the development of the S3 guideline "Screening, diagnosis and treatment of harmful and dependent tobacco use".

# Scientific support



Institut für Therapieforschung München



Dr. Eva Hoch, Dipl.-Psych. Scientific Director and Managing Director Research

S3 guideline development, intervention research (focus: cannabis and nicotine), health services research, clinical epidemiology.



### Thank you very much!

### **Further information and statements**





### Contact:

**Andreas Unsicker** Business economist (FH)



E-Mail: unsicker@luna-medical.de Mobile: + 49 (0) 172 533 42 92

### **Appendix**

- 1. Why is the CiQuit system not bypassed?
- 2. Why is the CiQuit system used?
- 3. CiQuit and DiGA

# **Convinced users stating:**

### Statements from the proof-of-principle study

"Very good thing, thanks to the control I was able to reduce my cigarette consumption from 18-20 to an average of 13 after just 8 weeks." Rainer W.

**"So I'm very enthusiastic,** I arrived on day 30 and I can only say one thing: simply great."

Astrid P.

**"The box made me realize** how often I had reached for a cigarette without thinking. Now, before every cigarette, I think about whether I really want it and how many I have left to achieve my own daily goal." Constanze K.

"It's simple to use. The box remembers your smoking behavior pretty quickly and I have to say that I smile every time the access time is increased. Habit becomes mindfulness!" Stefan F.

"I no longer light up a cigarette without thinking or reflecting. I can easily do without one or two. It makes you proud and, in retrospect, happy. I believe it is possible to become a real non-smoker. The brain adapts to it. Great invention!" Nils O.

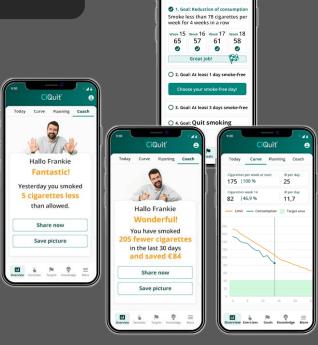


# **Appendix 1**

# Why is the CiQuit system not bypassed?

If a diet helps you lose 1 kilo per week
without hunger attacks, why deviate from
the plan and snack on the side?





# Second pack of cigarettes

- If there are no withdrawal symptoms and cravings, there is no reason to bypass the system.
- Continuous partial successes activate the reward system and keep you from risking the progress you have made.
- Safety measures ensure sustainable success in the event of excessive demands.

**CiQuit works** - simple, effective, suitable for everyday use!



### **Appendix 2**

# Why is the CiQuit system used?

### From wish to decision – the Rubicon model

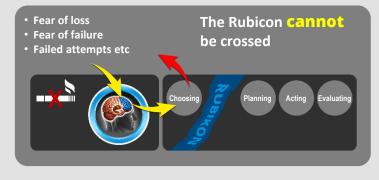
Support programs that require an abrupt quit.

**Quit smoking "immediately"!** 

Fear of losing something "precious"!

- Long decision-making process
- High persuasion effort

No, not now!



# CiQuit

First "less" smoking!

No fear of losing something "precious"!

- Fast decision-making process
- Low persuasion effort



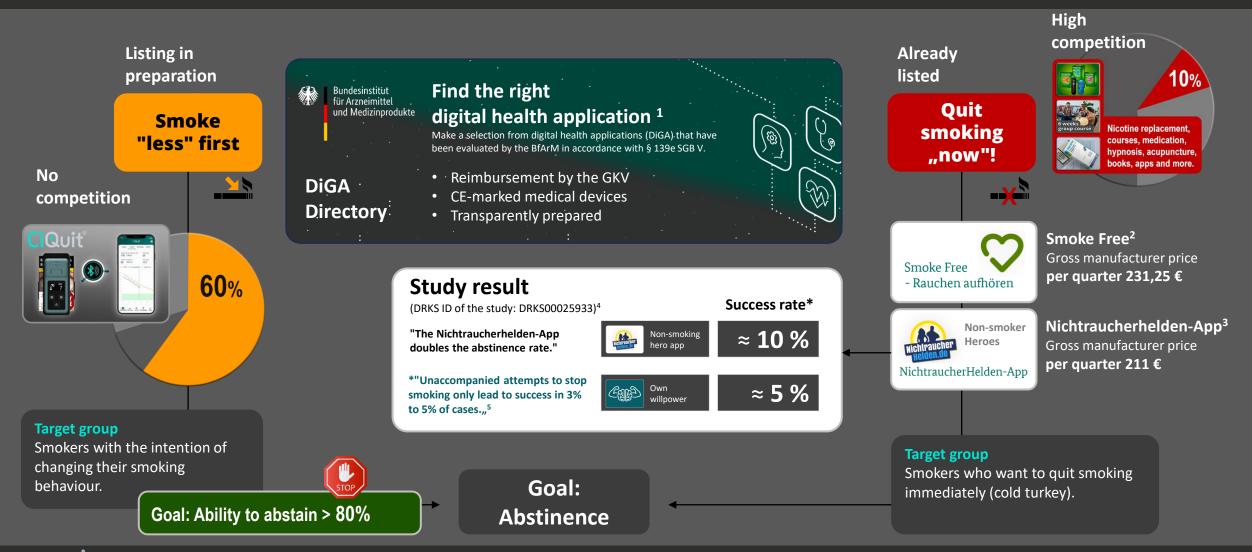
- CiQuit lowers the barrier to entry: first smoke less then become smoke-free.
- Crossing the Rubicon becomes easy:
   no high level of suffering, no fear of
   failure.'
- 'Maybe someday' turns into a clear 'Yes, I will!'
- Faster decision-making minimal persuasion – immediate, tangible benefits.



### **Appendix 3**



# CiQuit and DiGA e.g.: Reimbursement through health insurers as a DiGA





<sup>1)</sup> Source: https://diga.bfarm.de/de

<sup>2)</sup> Source: https://diga.bfarm.de/de/verzeichnis/01909/fachkreise

<sup>3)</sup> Source: https://diga.bfarm.de/de/verzeichnis/01085/fachkreise