BUILDING TOMORROW'S HEALTH CARE FOR GENETIC DISORDERS & BEYOND

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Genetic Disorders - Economic Burden of €887B[1]

- 350M people with 10,000 genetic disorders[2][3]
- Approved treatment for 500[2][3] of diseases

Challenge

- Accurate + Fast + Affordable diagnosis towards precision treatments or clinical trials
- Early diagnosis could save €500K per patient[4]

Solution - Companion Diagnostics (€30B market)

- Conventional techniques[5] (inaccurate)
- Next Generation Seq. (complex & expensive)
- gMendel®'s novel combination of genomics & AI

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(1) The US National Economic Study on Rare Diseases by EveryLife Foundation (Sept 2021); Worldwide estimate: €2-3 Trillion
(2) Nguengang Wakap, *et al*. Estimating cumulative point prevalence of rare diseases: analysis of Orphanet database. Eur. J Hum Genet 28, 165 (2020)
(3) https://www.statnews.com/2023/02/07/2022-was-a-breakthrough-year-for-understanding-rare-diseases-2023-needs-to-be-better/
(4) The Cost of Delayed Diagnosis in Rare Disease by EveryLife Foundation (Sept 2023), https://everylifefoundation.org/delayed-diagnosis-study/
(5) Mass spectrometry, Karyotyping/FISH, chromosomal microarrays, Sanger seq., CGH arrays, MLPA- & PCR-based techniques

Market & Competition – Companion Diagnostics

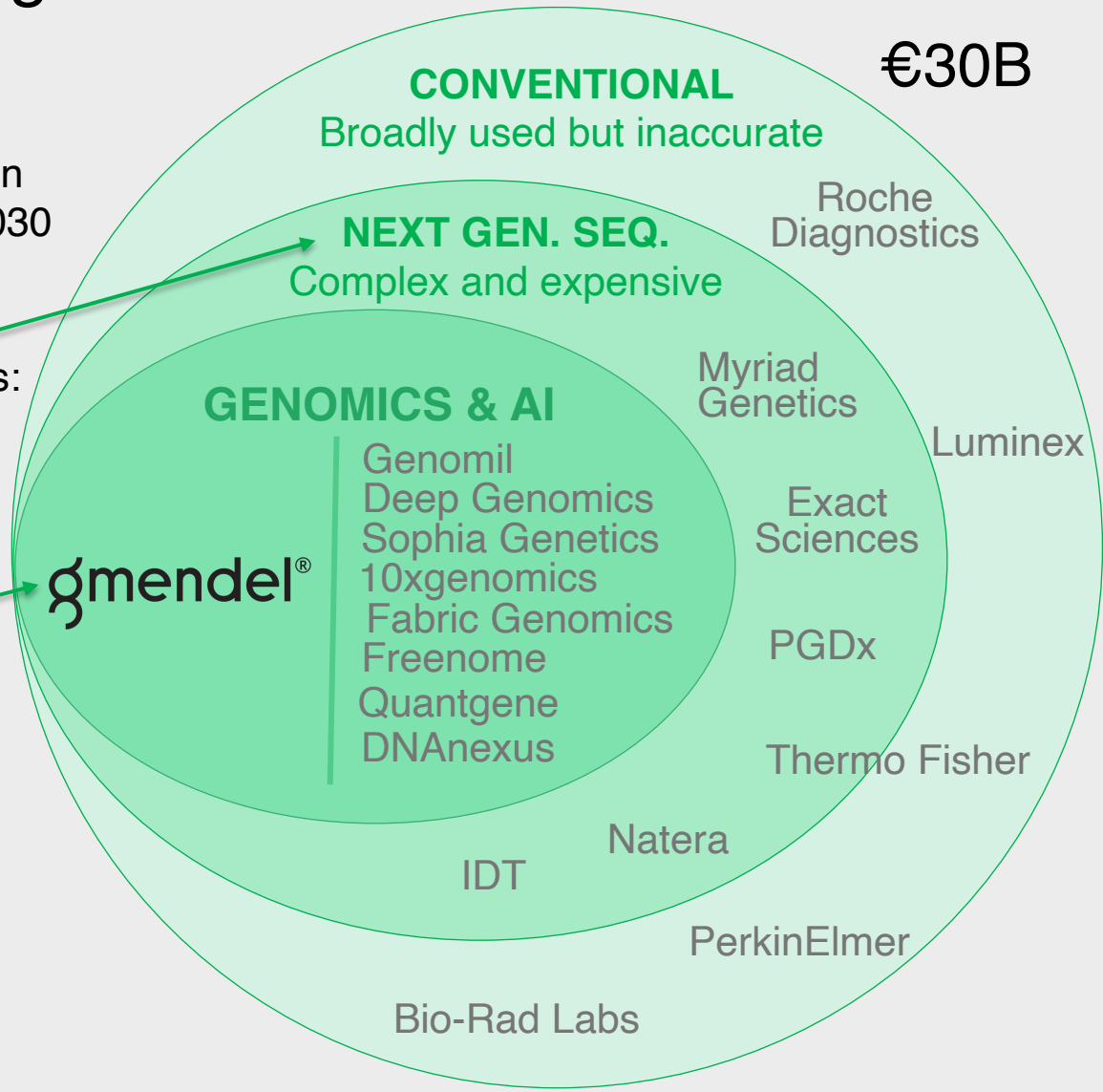
The market of CDx for identifying patients for clinical trials & eligible patients towards precision treatments is €30B[(1)]; projected to double by 2030

Current NGS methods are categorized as Lab Developed Tests (LDTs), which have drawbacks:

- Limited scalability
- Require expert analysis
- Inconsistent results

gMendel® unique advantages:

- End-to-end solution
- Automation
- Real time
- Accuracy
- Single test for broad spectrum of diseases



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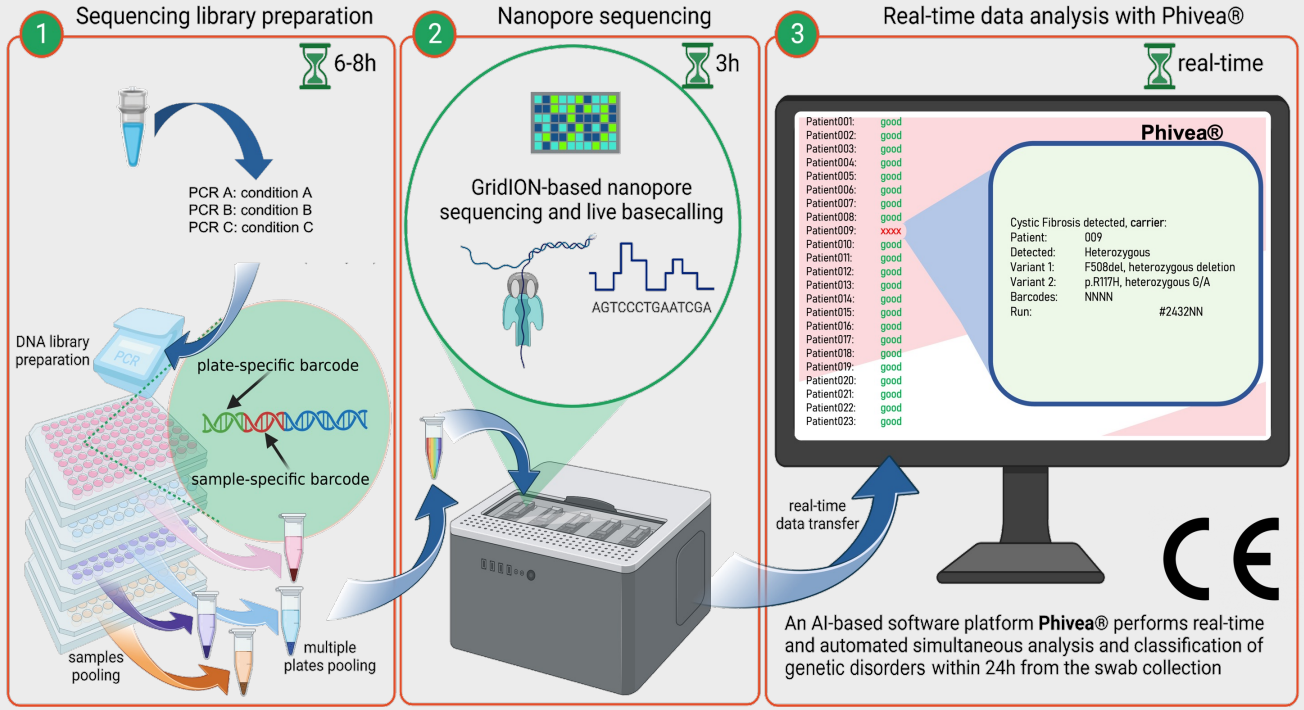
(1) https://www.statista.com/statistics/1295812/rare-disease-diagnostics-market-size-worldwide/ and various other reports

Phivea®: End-to-end Solution for Detection of Genetic Disorders & Beyond



Phivea® Performance Evaluation(1):

- **Better:** sensitivity 99% *vs.* 63%
  Unclassified reads 6% vs. 24%
- **Faster:** 1520 *vs.* 138 reads/sec
  Dual approach to achieving scalability & precision
- **More affordable:** € *vs.* €€€€€
  10x more samples in one flow cell

Novel combination of genomics & AI - easy to implement(2)

(1) The performance evaluation filed with the Danish Medicines Agency, Pharmacovigilance & Medical Devices (DKMA) resulted in successful CE marking. This demonstrates enhanced performance, accelerated results, and outstanding cost-effectiveness.
(2) The novel integration of genomics & AI delivers a fully automated solution, transcending the need for bioinformatician's intervention and has a potential to revolutionize genetic analysis.

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Highly Skilled, Diverse Team & Strong Ecosystem

Team

Consists of 6 full-time & 14 part-time employees working out of 6 countries covering science, tech dev, QA/RA & BD

Executive Management

CEO: Dr. Chris Kyriakidis, PhD in Bio-chemistry, MSc in Physics, MBA. Ran a €130M business & founded 2 start-ups; Lived in 9 countries & done business in 70 countries in pharma & MedTech for 25 years (Novo Nordisk, ALK, GN) *

CTO: Zoran Velkoski, MSc in Embedded Systems, MBA. 30 years' experience as entrepreneur (2 successful Exits), brought to market 150 products for companies within emerging tech, IoT & AI *

CSO: Dr. Carmen Garrido Navas, PhD in genetics with extensive research experience (20 field publications & 15 research projects, supervising PhD students & teaching at the Univ. of Granada)

CAIO: Prof. Gjorgji Madjarov, PhD, in-depth understanding of advanced AI/ML methodologies & state-of-the-art algorithms (professor at Ss. Cyril & Methodius University, Skopje)

* Invested

Company domicile: DK

Collaborations: Coriell Institute for Medical Research, USA; UMass Chan Medical School, USA; Univ. of Copenhagen, DK; National Centre for Scientific Research "Demokritos", GR; Univ. of Ss. Cyril & Methodius in MK

Alliances: Netcetera AG (Software Development CO, CH); GenXone S.A. (DNA Seq. Lab, PL); Star Global (QA/RA); Oxford Nanopore Tech (Biotech Co, UK), Agilent Technologies (US)

Networks: NORD (N. American Org. RDs); ASHG (American Soc. H. Genetics); ESHG (European Soc. H. Genetics); ISNS (Intern. Soc. Neonatal Scr.)

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Recent Traction

ISO Q1 2022

CE Q2 2022

Grants & LOIs for pilots

REGION Rigshospitalet

AARHUS UNIVERSITY

Pilot Agreements

UMass Chan MEDICAL SCHOOL

COMMONWEALTH OF MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH

BIOTECH

Pilot agreement

Distribution Agreement

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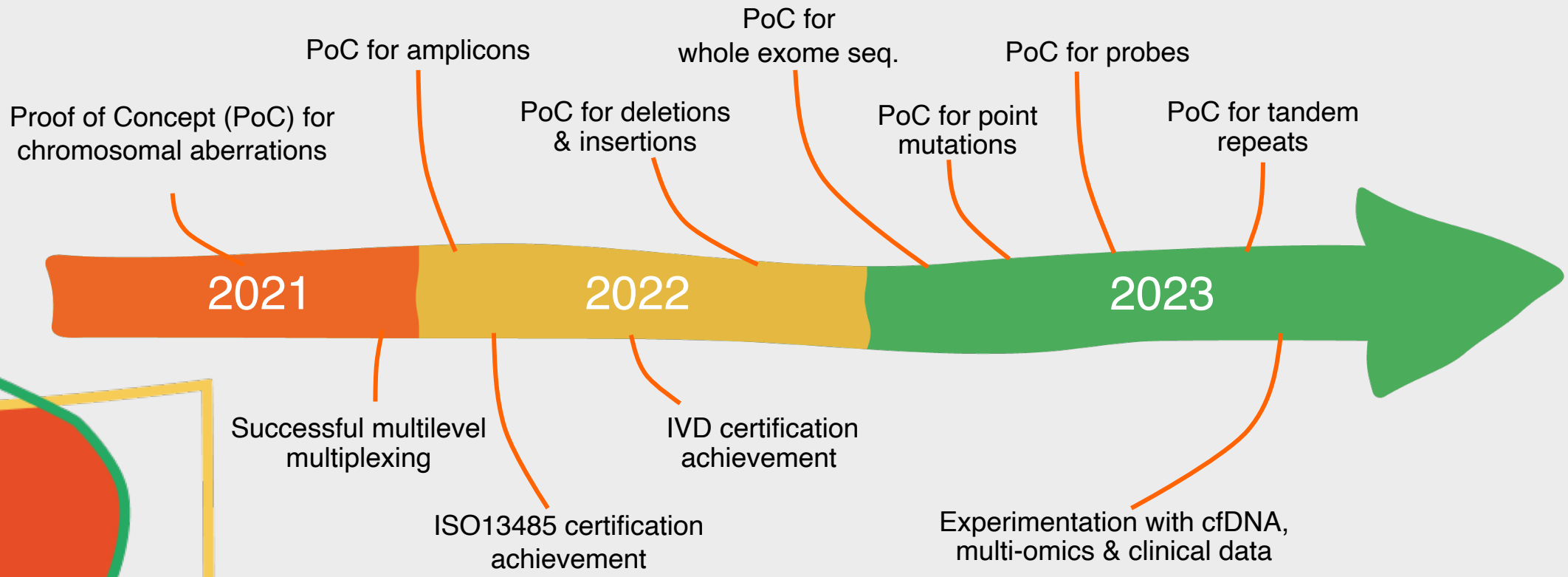
Key research & technology milestones to date



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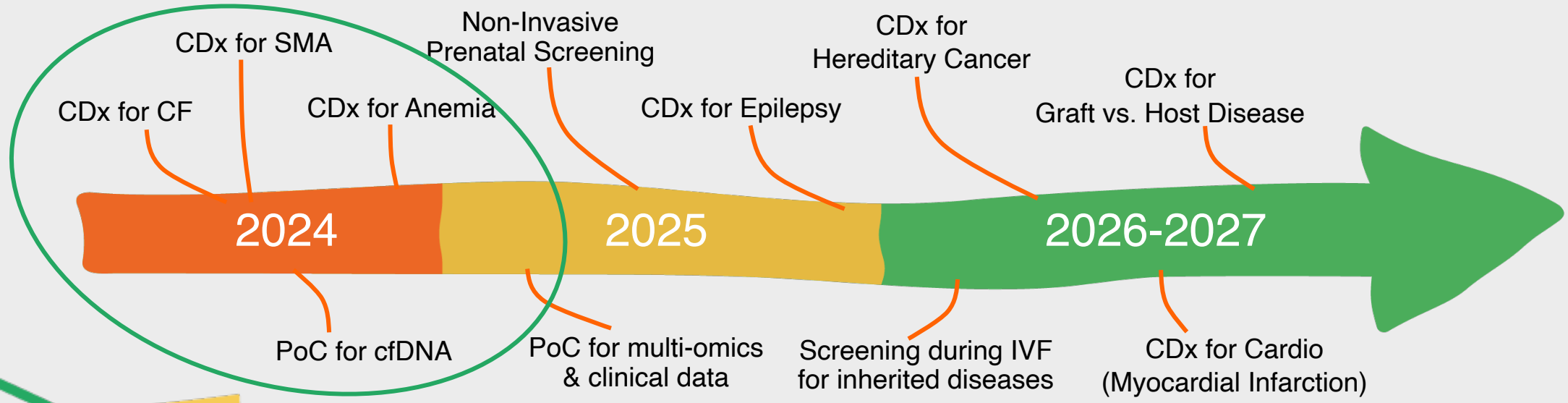
Roadmap



Investment focus:

- Commercialisation of 3 CDx (Companion Diagnostics)
- Supplement to approved grants

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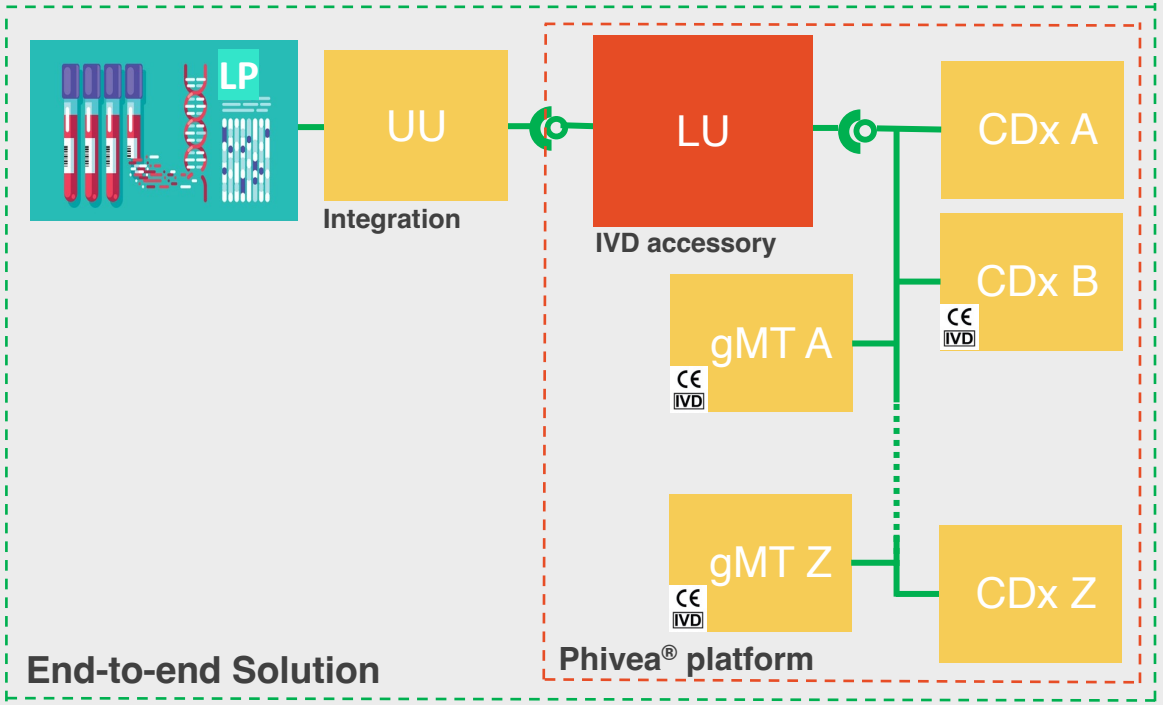
Roadmap Architecture



Modules

LP	Library Preparation and Sequencing
UU	Uploader Unit – Automatic uploading of Fast5 & Fastq files
LU	Laboratorian Unit - Configuration, preprocessing, status, control, UI application, reporting, authentication, authorization, audit, etc.
CDx	Companion Diagnostic Unit can contain one or more Genetic Disorders
gMT A	gMendel®Test unit – first to come is NIPT. Unit configuration is specific to a state HCS, market, region, customer etc.

Phivea® platform is a cloud-based software that provides in vitro diagnostic (IVD) medical device software as a service.

Companion Diagnostic as a Service (CDxaaS) is a cloud-based software distribution model, where the software is provided as a service on demand (rather than treated as a product).

From CDxaaS point of view and gMendel® as an IVD manufacturer, the following standards are relevant:

- ISO 13485 Quality Management System
- ISO/IEC 27018 Information technology — Security techniques
- ISO/IEC 29100 Information technology — Security techniques — Privacy framework
- IEC 62304 Medical device software — Software life cycle processes

NB. Units can be certified, if required

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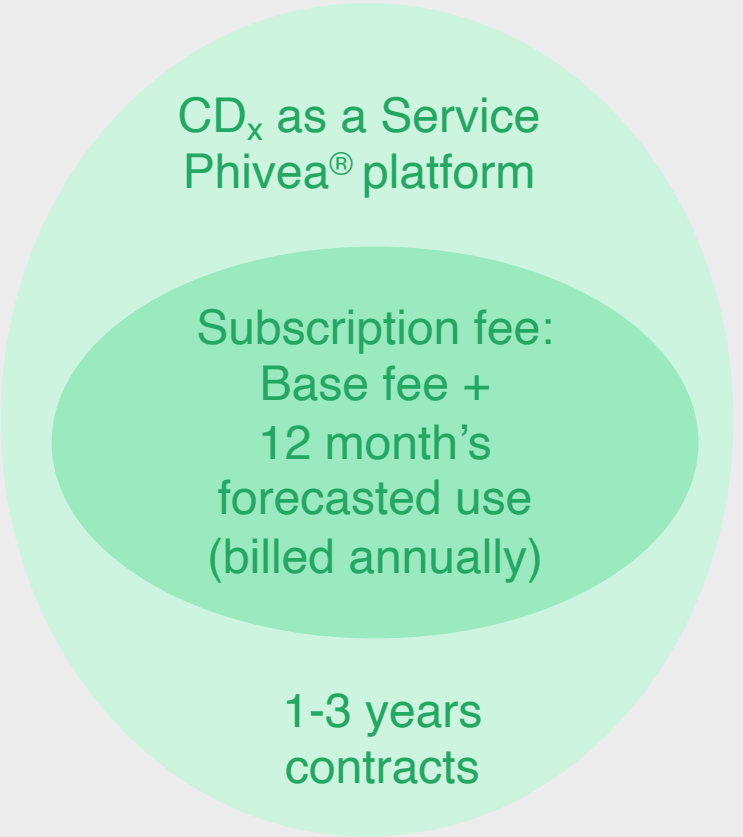
gMendel® to Generate Average Annual Revenue €2M per Customer

gMendel®'s CD_xaaS(1) Model Benefits:

- **No change to current health care protocols**
- **Single test for broad spectrum of diseases**
- **Subscription**: Customers(2) pay a subscription fee, which covers the base cost and an annual usage estimate.
- **Annual Billing**: Invoices sent annually based on predicted test volume, offering budget clarity.
- **Full Support**: Beyond software, provision of end-to-end support, including hardware, setup, maintenance, tech help, supplies, training, software updates.



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(1) CDxaaS: Companion Diagnostics as a Service for identifying patients for clinical trials & eligible patients towards precision treatments
(2) Customers: a) Biotech developing new treatment for Rare Diseases (US, EU, RoW); b) Hospitals (US, EU, RoW); c) Diagnostic labs (US, EU, RoW); d) NHS (EU, RoW) & state level department of health in the US; e) Managed Care (US)

IP is Well Protected

- Application No.: PCT/EP2023/064684
- Filing date: June 1st, 2023
- Title: A Computer Implemented Method For Identifying, If Present, A Preselected Genetic Disorder
- Freedom to operate (FTO) performed by Danish IP law firm Plougmann & Vingtoft (Feb- May 2022), followed by Patent Application No. 20220100462.
- Four additional patents under preparation

IP Roadmap

The novelty search ensured the FTO, and our IPR strategy will generate at least 4 new patent applications. There is no risk that other solutions in the market prevent the full implementation of the planned activities.

1. Prenatal screening technology for aneuploidies, insertions, deletions & point mutations .

2. Screening technology for detection of Graft versus Host Disease (GvHD)

3. Allogeneic bone marrow transplants, by identifying compatible matches to Major Histocompatibility Complex proteins.

4. Timely prediction of second myocardial infarction event by combining multi-omics, clinical data and AI

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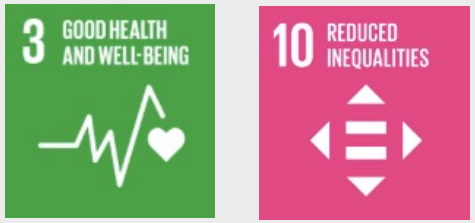
Our contribution to Sustainable Development Goals

WE CARE



- Contribute to better disease management for 350 M people with genetic disorders worldwide
- Increase life expectancy through accurate and timely diagnosis
- Reduce economic and social inequalities related to access to healthcare
- Advocate for health equity for all those living with rare diseases

WE INNOVATE

- Launch a reliable, safe, rapid & scalable technology for diagnosis of genetic disorders
- Outstand conventional sequencing tech at multiple levels, such as detection & sensitivity, complexity, cost & support environment
- Reduce healthcare costs for patients & national health systems

WE COLLABORATE

- Establish & scale up effective partnerships with stakeholders at all levels in the health community to maximise impact
- Maintain open innovation mindset, exchange knowledge & build on the experience, capacity & resourcing strategies of partnerships for progress in the field
- Support industry, states & societies to design & implement health strategies for equal access to diagnosis & treatment of genetic disorders

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Thank you!

WE CARE
WE INNOVATE
WE COLLABORATE

Building tomorrow's health care for genetic disorders & beyond.

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Contact us at: zoran@g-mendel.com