

BUSINESS PLAN: SMARTPRESCRIPTION AI

Chapter 1: Executive Summary & Strategic Vision

1.1 Mission and Vision

SmartPrescription was created with the mission of eliminating inappropriate empirical prescribing in antibiotic therapy, transforming clinical decision-making into a precision-based process supported by Artificial Intelligence and Advanced Genomics. The company's vision is to become the standard Clinical Decision Support System (CDSS) platform for European hospitals and telemedicine networks, supporting doctors in the fight against Antimicrobial Resistance (AMR) and preserving the effectiveness of medicines for future generations.

1.2 Value Proposition

SmartPrescription analyzes patient parameters, clinical and blood history, local microbiology, and pathogen genomic data in real time. Within seconds, it provides doctors with:

1. The antibiotic with the highest probability of therapeutic success.
2. Personalized dosage and treatment duration.
3. A risk score for inducing further resistance, in compliance with WHO AWaRe / PNCAR guidelines.

1.3 Financial Requirements and Milestones

To complete MVP development, conduct concordance studies, and obtain certification as Software as a Medical Device (SaMD) under EU MDR 2017/745, the company requires a **Seed Round of €200,000–€270,000**.

- **Months 0–6 (Phase 1 – MVP):** €39,000–€58,000 for the development of the genomic AI pipeline, initial cloud architecture, and legal/regulatory consulting.
- **Months 6–18 (Phase 2 – Pilot & Certification):** €127,000–€215,000 for model fine-tuning, integration with hospital systems (EHR), a clinical concordance trial, and CE MDR certification.

Chapter 2: Problem and Target Market Analysis

2.1 The Global AMR Emergency

According to World Health Organization (WHO GLASS 2025) reports, bacteria-drug combinations with increased resistance have grown by **40% in recent years**. Today, 1 in 6 bacterial infections worldwide is already resistant to conventional antibiotics. Without corrective action, by 2050 AMR will become one of the leading causes of death globally, compromising surgery, oncology, and organ transplantation.

2.2 The Clinical Bottleneck: Empirical Prescribing

In hospital and emergency-room settings, therapeutic decisions must be made within the first hours after patient admission. However, traditional antibiogram results require **24 to 72 hours**. As a result, doctors are forced to make an **empirical prescription** guided by:

- Personal experience and cognitive biases (fear of therapeutic failure).
- Lack of immediate visibility into resistance data for the individual department/hospital.
- Consequently, excessive use of broad-spectrum or second-/third-line antibiotics, which increases selective pressure on resistant strains.

2.3 Target Market Definition (TAM, SAM, SOM)

- **TAM (Total Addressable Market):** The global market for Clinical Decision Support Systems (CDSS) and healthcare software solutions, estimated at over \$8 billion by 2026.
- **SAM (Serviceable Addressable Market):** The market for CDSS solutions focused on infection management and antimicrobial stewardship in public/private hospitals and clinics in Europe (~€1.2 billion).

- **SOM (Serviceable Obtainable Market):** Italian National Health Service (SSN) hospitals, starting with high-complexity facilities (IRCCS and hospital organizations in Lombardy and Northern Italy), with an initial target of **50–80 facilities during the first 3 years**.

Chapter 3: Product, AI Architecture and Genomic Innovation

3.1 Product Workflow and Clinical Integration

SmartPrescription integrates as a Clinical Decision Support System (CDSS), operating through three sequential phases designed to have a low impact on physicians' workload:

1. **Data Ingestion:** The system collects patient clinical information (age, weight, symptoms, vital signs, renal/hepatic function, medication history, and blood tests) directly through API integration with the Electronic Health Record (EHR/LIS).
2. **Algorithmic Processing (AI Analysis Engine):** The inference engine cross-references patient data with local epidemiological databases, regional resistance trends (e.g., facility databases and regional centers of excellence), and the global WHO GLASS database.
3. **Prescription Recommendation:** The platform generates a ranking of suitable antibiotic molecules with an estimate of therapeutic success probability, optimized dosage, treatment duration, and further resistance risk index, in accordance with WHO AWaRe guidelines.

3.2 Supervised Predictive Model

The primary prescription module uses supervised Machine Learning algorithms (XGBoost and classified neural networks) trained on anonymized medical records and hospital microbiology reports.

3.3 Genomic Innovation: CNN ID & Genomic Transformers

While traditional CDSS solutions assess only the presence or absence of individual isolated resistance genes, SmartPrescription analyzes the complex structure of the bacterial genome:

- **Convolutional Neural Networks (CNN ID):** Convolutional neural networks designed to directly scan pathogen nucleotide sequences and extract resistance patterns.
- **Genomic Transformers:** Architectures based on self-attention mechanisms capable of analyzing sequence order, single-nucleotide polymorphisms (SNPs), and multigene interactions to estimate the resistant phenotype directly from the genotype, drastically shortening culture waiting times.

Chapter 4: Regulatory Strategy, GDPR Compliance and Intellectual Property

4.1 MDR Classification and Certification (EU 2017/745)

SmartPrescription falls within the definition of **Software as a Medical Device (SaMD)**.

Regulatory Pathway:

- **Presumed classification: Class IIa** (under Rule 11 of Annex VIII of EU Regulation 2017/745 – software intended to provide information used to make decisions for diagnostic or therapeutic purposes).
- **ISO Accreditation Plan:** Implementation of an ISO 13485 Quality Management System and ISO 14971 standard for medical-device risk management.
- **Clinical Evaluation and Concordance:** Planning of a retrospective and prospective clinical concordance study (comparison between AI recommendations and decisions made by infectious-disease stewardship committees), required for the preparation of the Clinical Evaluation Report (CER) for CE marking.

4.2 Data Protection & Privacy (EU GDPR 2016/679)

The protection of sensitive health data (Article 9 GDPR) is ensured through a *Privacy by Design* architecture:

- **Pseudonymization at source:** Patient clinical data are pseudonymized locally before being transferred to the AI engine.
- **Certified Cloud Infrastructure:** Deployment of the platform on data centers located within the EU and certified under ISO/IEC 27001, ISO/IEC 27017, and ISO/IEC 27018.

4.3 Intellectual Property (IP) Strategy

- **Platform and Algorithms:** Registration of the source code and protection of proprietary know-how related to the training of Genomic Transformers applied to phenotypic prediction.
- **Registered Trademarks:** Registration of the *SmartPrescription* trademark at European level (EUIPO).

Chapter 5: Go-To-Market (GTM) Strategy and Business Model

5.1 Phased Commercialization Strategy (Phased GTM)

Entering the healthcare sector requires reducing decision-making and operational friction within hospitals. The strategy is divided into three main phases:

1. Phase 1 — Validation & Pilot (Months 0–18):

- Establish research agreements and pilot projects with 2–3 leading IRCCS/university hospitals in Lombardy.
- Use the platform in *shadowing* mode (the software processes data in parallel without affecting official prescribing) to validate predictive accuracy against real antibiograms.

2. Phase 2 — EHR/LIS Channel Partnerships (Months 18–36):

- Integration via standard APIs (HL7 / FHIR) with the main providers of Electronic Health Record (EHR) and Laboratory Information Systems (LIS) software operating within the SSN.
- Co-selling model: EHR vendors distribute SmartPrescription as an additional AI module, accelerating adoption without the need to build a large direct sales force.

3. Phase 3 — National and European Scale-Up (Months 36+):

- Participation in regional public tenders (e.g., ARIA in Lombardy) to provide CDSS systems supporting AMR prevention plans (PNCAR).
- Expansion into European markets with strong antimicrobial-stewardship focus (Nordics, DACH) and telemedicine platforms.

5.2 Revenue Model (B2B SaaS)

SmartPrescription adopts a recurring B2B Software-as-a-Service (SaaS) model:

- **Annual Enterprise License:** Recurring annual subscription fee calculated according to hospital size or number of active beds (e.g., high-risk departments such as Intensive Care, Infectious Diseases, and Emergency Departments).
- **Integration & Setup Fee:** One-time fee for the initial cloud infrastructure configuration and API integration with the local medical record.
- **Public Health Intelligence Dashboard:** License for aggregated and anonymized epidemiological data for regional or national public-health surveillance authorities.

Chapter 6: Economic Value Proposition and Hospital ROI Calculation

To obtain approval from hospital management, the technical proposal must demonstrate an economic return on investment (ROI) in addition to clinical value.

6.1 Hospital Cost-Saving Drivers

1. Reduction in Length of Stay (LOS):

- Inappropriate empirical therapy prolongs hospitalization while awaiting microbiological results or changing the antibiotic following therapeutic failure.

- b. The average cost of a hospital bed in Italy ranges from **€500 to €1,500 per day** (up to more than €2,500/day in Intensive Care).

2. Optimization of Pharmaceutical Spending:

- a. Reduction in unjustified use of broad-spectrum and reserve antibiotics (high-cost molecules) when effective lower-cost first-line options are available, in compliance with WHO AWaRe.

3. Prevention of Healthcare-Associated Infections (HAIs):

- a. Reduction in the transmission of multidrug-resistant strains within hospital departments, lowering additional isolation and sanitation costs.

6.2 Estimated ROI Model (Average Hospital Facility – 400 Beds)

Clinical / Economic Parameter	Estimated Value Without SmartPrescription	Estimated Value With SmartPrescription	Estimated Annual Savings
Inappropriate Empirical Prescribing Rate	~25%–30%	<10%	Reduction in clinical risk
Unnecessary Length of Stay (LOS)	~1,200 days/year linked to empirical treatment failures	20% reduction (- 240 days)	€168,000 (calculated at €700/day)
Reserve Antibiotic Spending	€250,000/year	15% reduction	€37,500
Total Estimated Savings per Facility Annual	—	—	~€205,500/year
SmartPrescription SaaS License Cost	—	—	~€35,000/year
Gross ROI for the Hospital	—	—	~5.8x investment

Chapter 7: Financial Model & 3–5 Year Projections

7.1 Unit Economics & Pricing Model

- **Average Annual Recurring Revenue (ARR) per Hospital: €35,000/year** per average facility (400 beds).
- **Setup & Integration Fee (One-time): €10,000** for cloud configuration and HL7/FHIR API integration with the hospital's EHR.
- **Cost of Goods Sold (COGS):** ~15% of revenue (GPU cloud infrastructure on ISO/IEC 27001-certified servers and first-level technical support).
- **Gross Margin: ~85%**, characteristic of scalable B2B SaaS MedTech solutions.

7.2 Financial Projections (5-Year P&L)

Financial Item	Year 1 (Seed / R&D)	Year 2 (Pilot & CE)	Year 3 (Go-To-Market)	Year 4 (Scale-Up IT)	Year 5 (Scale-Up EU)
Active Customer Hospitals	0 (2 pilot)	3 (paying)	15 hospitals	45 hospitals	110 hospitals

SaaS Revenue (ARR)	€0	€105,000	€525,000	€1,575,000	€3,850,000
Setup / Integration Revenue	€0	€30,000	€150,000	€300,000	€500,000
TOTAL REVENUE	€0	€135,000	€675,000	€1,875,000	€4,350,000
Operating Costs (COGS)	€12,000	€25,000	€95,000	€260,000	€580,000
GROSS MARGIN	-€12,000	€110,000	€580,000	€1,615,000	€3,770,000
R&D and Personnel Costs	€120,000	€160,000	€280,000	€550,000	€1,100,000
Regulatory & Legal Expenses	€40,000	€60,000	€30,000	€50,000	€80,000
Sales, Marketing & GTM	€10,000	€35,000	€120,000	€320,000	€750,000
EBITDA (Operating Profit)	-€182,000	-€145,000	+€150,000	+€695,000	+€1,840,000
EBITDA Margin %	N/A	N/A	22.2%	37.0%	42.2%

7.3 Break-Even Analysis & Runway

- **Break-Even Point:** Reached in **Month 30 (mid-Year 3)** with approximately 12–15 active customer hospitals.
- **Seed Capital Runway:** 18 months guaranteed by the initial €200k–€270k investment round.

Chapter 8: Seed Round Details & Fund Allocation (€200k–€270k)

The requested amount will cover the two development phases required to move from the current prototype to a certified, market-ready product:

SEED CAPITAL ALLOCATION (€200k–€270k)

- **Phase 1 (Months 0–6) — Prototype / MVP (€39,000–€58,000):**
 - Genomic AI & Genomics Pipeline Development (Transformers/CNN ID): €25,000–€35,000
 - UI/UX & Clinical Dashboard: €4,000–€6,000
 - Cloud Infrastructure & GPU Compute: €2,000–€4,000
 - MDR / GDPR Legal Preparation: €5,000–€8,000
 - Data Preparation & Initial Validation: €3,000–€5,000
- **Phase 2 (Months 6–18) — Hospital Pilot & CE Certification (€127,000–€215,000):**
 - Genomic AI Model Fine-Tuning: €50,000–€80,000
 - Clinical Dashboard Integrated with Hospital Workflows: €10,000–€15,000
 - Cloud Scaling & GPU Compute: €12,000–€20,000
 - MDR Certification Pathway (SaMD Class IIa/IIb): €35,000–€60,000
 - Clinical Concordance Trial & Hospital Validation: €20,000–€40,000