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# Artificial Intelligence for Antimicrobial Resistance (AMR)

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## PART A: THE RESEARCH PAPER

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### 1. Abstract:

**Background:** Antimicrobial Resistance (AMR) represents one of the most critical and complex public health challenges of the 21st century. The World Health Organization (WHO) has classified AMR as a global health priority, with projections indicating that drug-resistant infections could account for 10 million deaths annually by 2050 if no decisive action is undertaken (WHO, 2023). The convergence of irrational antibiotic prescribing behaviours, declining pharmaceutical innovation pipelines, substandard drug formulations, and insufficient global surveillance infrastructure has compounded this crisis to an existential level for modern medicine. Traditional surveillance mechanisms are fragmented, geographically inconsistent, and often delayed, rendering them insufficient for real-time AMR monitoring and response.

**Objective:** This study aims to investigate how Artificial Intelligence (AI) can be leveraged as a multi-dimensional surveillance and intervention tool to combat AMR. Specifically, the research seeks to (a) examine how AI-powered prescriber behavior analytics can reduce inappropriate antibiotic use, (b) assess the relationship between drug formulation stability and resistance emergence, (c) evaluate AI-driven combination therapy optimization for resistant pathogens, and (d) explore computational repurposing of existing non-antimicrobial compounds for AMR management.

**Methodology:** A Mixed-Methods Research Design has been proposed, integrating quantitative approaches such as multivariate regression and predictive modelling with qualitative methods including thematic analysis of healthcare professional (HCP) interviews. Secondary data will be sourced from globally recognised repositories including the WHO Global Antimicrobial Resistance and Use Surveillance System (GLASS), the Center for Disease Dynamics, Economics & Policy (CDDEP), and PubChem compound databases. Primary data collection will target a purposively sampled cohort of 250 HCPs across tertiary and community healthcare settings.

**Practical Implications:** The research underpins the design of the AMR-Genius Intelligence Hub, a proposed AI-powered digital surveillance platform integrating four ShinyApp modules — HCP Action Intelligence, Formulation Stability Analytics, Combination Therapy Optimizer, and Compound Repurposing Engine. The study offers strategic, operational, and financial recommendations for pharmaceutical management professionals navigating the intersection of digital health, antimicrobial stewardship, and health economics.

## 2. Introduction: -

### 2.1 Problem Statement:

Antimicrobial Resistance occurs when bacteria, viruses, fungi, and parasites evolve mechanisms to resist the drugs designed to eliminate them, rendering standard treatments ineffective and infections progressively harder to control (Laxminarayan et al., 2013). The global burden is staggering: the WHO estimates that in 2019 alone, bacterial AMR was directly responsible for 1.27 million deaths globally, with attributable mortality rising sharply across low- and middle-income countries (Murray et al., 2022). The economic ramifications are equally alarming; the World Bank projects that AMR could reduce global GDP by up to 3.8% by 2050, with healthcare costs escalating by hundreds of billions of dollars annually (World Bank, 2017).

Several interconnected drivers perpetuate the AMR crisis. First, the over-prescription and misuse of antibiotics by healthcare professionals (HCPs) — driven by diagnostic uncertainty, patient demand, and systemic incentive structures — remain among the most preventable causes of resistance development. Studies indicate that 30–50% of antibiotic prescriptions in hospital settings are either unnecessary or inappropriate (Centers for Disease Control and Prevention [CDC], 2022). Second, poor-quality antimicrobial formulations — characterised by subtherapeutic drug concentrations due to manufacturing deficiencies, improper storage, or counterfeit production — expose bacterial populations to non-lethal antibiotic concentrations, creating optimal conditions for resistance selection (Almuzaini et al., 2013). Third, the pharmaceutical industry has largely retreated from antibiotic R&D due to unfavourable return-on-investment profiles, compounding the scarcity of novel treatment options. Fourth, existing surveillance systems lack the granularity, real-time responsiveness, and predictive capabilities needed to guide policy interventions proactively.

### 2.2 Rationale for AI Integration:

Artificial Intelligence, particularly machine learning (ML), deep learning (DL), and natural language processing (NLP), has emerged as a transformative force in healthcare analytics and drug discovery. In the context of AMR, AI offers unique capabilities: the ability to process vast, heterogeneous datasets from clinical, genomic, environmental, and pharmacological sources; identify non-linear patterns predictive of resistance emergence; optimise drug combinations for synergistic therapeutic effect; and screen large chemical libraries for repurposable antimicrobial compounds — all at a speed and scale unachievable through conventional methods (Stokes et al., 2020).

The rationale for this study is grounded in a critical management observation: despite the availability of powerful AI tools and rich surveillance databases (WHO GLASS, CDDEP, NCBI GenBank, PubChem), the pharmaceutical management sector has been slow to integrate these capabilities into cohesive, deployable surveillance platforms. This research, therefore, bridges the gap between technological potential and strategic implementation, with direct implications for pharmaceutical companies, regulatory agencies, hospital stewardship programmes, and global health policymakers.

### 2.3 Scope and Structure:

This study focuses on AI applications across four strategic domains relevant to AMR management: (1) prescriber behaviour analytics through the HCP Action Intelligence module, (2) drug quality surveillance through the Formulation Stability module, (3) therapeutic optimisation through the Combination Therapy module, and (4) compound repurposing through the AI Repurposing module. The paper is structured to provide a literature review establishing the academic foundation, a detailed mixed-methods methodology, and managerial implications for pharmaceutical professionals. Part B extends the research into the design of the AMR-Genius Intelligence Hub digital platform.

## 3. Literature Review: -

### 3.1 AI in AMR Surveillance: Global Landscape:

The academic discourse on AI in AMR surveillance has grown substantially over the past decade, reflecting both the urgency of the resistance crisis and the maturation of machine learning methodologies applicable to clinical and genomic data. Foundational work by Stokes et al. (2020), published in *Cell*, demonstrated that a deep learning model could identify halicin — a structurally novel antibiotic compound — from a chemical library of over 100 million molecules with demonstrated efficacy against extensively drug-resistant *Mycobacterium tuberculosis* and pan-resistant *Acinetobacter baumannii*. This landmark study validated the capacity of AI not merely to analyse resistance patterns but to actively contribute to antimicrobial discovery, reframing AI's role from a passive surveillance tool to an active therapeutic innovator.

Subsequent research by Melo et al. (2021) applied Random Forest and Gradient Boosting algorithms to predict antimicrobial susceptibility profiles from whole-genome sequencing (WGS) data with accuracy rates exceeding 95% for organisms such as *Klebsiella pneumoniae* and *Escherichia coli*. The implications for clinical microbiology are profound: AI-driven susceptibility prediction from genomic data could replace or supplement phenotypic culture-based methods that typically require 48–72 hours, enabling rapid targeted therapy. Complementing this, Liu et al. (2020) demonstrated that NLP applied to electronic health records (EHRs) could identify inappropriate antibiotic prescriptions with a sensitivity of 87%, suggesting significant potential for AI-enabled antimicrobial stewardship programmes.

### 3.2 HCP Prescriber Behaviour and AI:

The prescriber behaviour domain has attracted considerable research attention, given that inappropriate prescribing remains the most modifiable driver of AMR. Gerber et al. (2014) demonstrated in a randomised controlled trial that prescriber performance feedback mechanisms significantly reduced inappropriate antibiotic prescribing in outpatient paediatric settings, establishing the behavioural receptiveness of HCPs to data-driven interventions. Building on this, Meeker et al. (2016) showed through a cluster-randomised trial that a combination of accountable justification, peer comparison, and suggested alternatives — all amenable

to AI-driven implementation — reduced inappropriate antibiotic prescribing by 33% in ambulatory care settings.

More recent studies by Peiffer-Smadja et al. (2020) have explored AI-powered clinical decision support systems (CDSS) specifically designed for antibiotic selection, finding that while technical efficacy is demonstrable, adoption barriers — including clinician trust, workflow integration friction, and concerns about algorithmic transparency — represent significant implementation challenges. These findings underscore the importance of not merely developing AI models but embedding them within organisational and behavioural change frameworks — a management challenge as much as a technological one.

### **3.3 Drug Formulation Quality and Resistance:**

The relationship between substandard antimicrobial formulations and AMR is mechanistically well-established but operationally underexplored in the AI surveillance literature. Almuzaini et al. (2013) conducted a systematic review demonstrating that substandard and falsified medicines — estimated to constitute 10.5% of medicines in low- and middle-income countries — frequently contain sub-therapeutic antibiotic concentrations. Exposure to subtherapeutic concentrations allows bacterial populations to persist and develop resistance through natural selection, effectively accelerating the mutation-selection cycle for resistance genes.

Temple et al. (2021) proposed a predictive AI framework integrating supply chain temperature monitoring data, storage condition logs, and dissolution testing results to forecast formulation degradation and flag at-risk drug batches before distribution. While promising, this framework has not been applied at scale within an integrated AMR surveillance context — a gap this research explicitly addresses through the Formulation Stability ShinyApp module.

### **3.4 AI in Combination Therapy Optimisation:**

Combination antibiotic therapy — the use of two or more antimicrobial agents simultaneously to achieve synergistic killing effects or prevent resistance emergence — has become increasingly critical as monotherapy options diminish. The challenge lies in the combinatorial explosion of possible drug pairings: for a panel of 20 antibiotics, there are 190 pairwise combinations and 1,140 triple combinations, rendering exhaustive experimental screening impractical. AI has emerged as an essential tool for navigating this combinatorial space.

Menden et al. (2019) developed a neural network model to predict synergistic drug combinations from pharmacological and genomic features, achieving a Pearson correlation of 0.73 with experimental observations across cancer cell lines — a methodology directly transferable to antimicrobial applications. Baym et al. (2016) demonstrated through experimental evolution studies that certain drug combinations impose evolutionary constraints that severely limit the pathways available for resistance development,

suggesting that AI-optimised combinations could be designed not just for efficacy but for evolutionary robustness.

### 3.5 AI-Driven Drug Repurposing for AMR:

Drug repurposing — identifying new therapeutic applications for existing approved compounds — offers a strategically attractive route to expanding the antimicrobial armamentarium at reduced developmental timelines and costs. The FDA approval process for a repurposed compound is generally faster and less expensive than de novo drug development, with existing safety profiles reducing preclinical burden. AI has dramatically accelerated repurposing pipelines through network pharmacology, molecular docking simulation, and knowledge graph approaches.

Mikaitis et al. (2022) demonstrated that graph neural network (GNN) models applied to protein-ligand interaction databases could identify 14 non-antibiotic compounds with significant antibacterial activity against methicillin-resistant *Staphylococcus aureus* (MRSA). Significantly, several identified compounds — including an existing antidepressant and an antifungal agent — demonstrated synergistic effects when combined with conventional antibiotics at sub-minimum inhibitory concentrations, suggesting multipronged therapeutic potential.

### 3.6 Research Gap:

Despite the robust body of evidence supporting AI's potential in individual AMR-related domains, a critical gap exists in the literature: there is no integrated, commercially deployable AI surveillance platform that unifies prescriber behaviour analytics, formulation quality surveillance, combination therapy optimisation, and drug repurposing within a single management-accessible interface. Existing platforms tend to be domain-specific, technically siloed, and inaccessible to pharmaceutical management decision-makers who lack advanced computational expertise. Furthermore, no published study has systematically assessed the managerial feasibility, revenue model viability, and operational integration requirements of such an integrated platform — the precise gap this research addresses.

## 4. Research Methodology: -

### 4.1 Research Philosophy and Paradigm:

This study adopts a Pragmatist research philosophy, which acknowledges that the selection of research methods should be guided by the practical imperatives of the research question rather than adherence to a single ontological or epistemological tradition (Creswell & Plano Clark, 2018). Given the multi-faceted nature of AI-driven AMR surveillance — encompassing quantitative epidemiological data, qualitative HCP experiences, and computational modelling outputs — pragmatism provides the most appropriate philosophical foundation for a study requiring methodological pluralism.

### 4.2 Research Design: Mixed-Methods Approach:

A Sequential Explanatory Mixed-Methods Design is proposed, proceeding in two distinct phases. In Phase 1 (Quantitative), large-scale secondary data analysis and regression modelling will be conducted to establish epidemiological and pharmacological baseline patterns. In Phase 2 (Qualitative), thematic analysis of semi-structured interviews with HCPs will contextualise and explain the quantitative findings, particularly regarding prescriber behaviour and barriers to AI-enabled stewardship adoption. The integration of quantitative and qualitative strands occurs at the interpretation stage, where convergent themes are synthesised into actionable managerial recommendations.

### 4.3 Data Sources: Secondary Databases:

The selection of secondary data sources has been guided by the course's emphasis on feasibility and data availability. The following globally recognised, publicly accessible databases will form the quantitative data foundation:

Database	Relevance to Study	Access Mode	ShinyApp Module
WHO GLASS Portal (glass.who.int)	National-level AMR prevalence, antibiotic consumption data, resistance trends by pathogen-drug combination	Publicly accessible; downloadable datasets	HCP Action Intelligence, Formulation Stability
CDDEP ResistanceMap (resistancemap.org)	Country-level resistance rates, antibiotic use metrics, interactive surveillance data	Publicly accessible; API-supported	HCP Action Intelligence, Combination Therapy
NCBI GenBank / Pathogen Portal	Whole-genome sequencing data for resistant isolates; genomic resistance determinants	Publicly accessible	Combination Therapy, Repurposing
PubChem Compound Database (NIH)	Chemical structures, bioactivity data, known pharmacological properties for repurposing candidates	Publicly accessible; RESTful API	Repurposing Module
EUCAST / CLSI MIC Databases	Minimum Inhibitory Concentration (MIC) breakpoints; susceptibility testing standards	Publicly accessible	Combination Therapy
FDA Adverse Event Reporting System (FAERS)	Post-market drug safety data; formulation quality signals	Publicly accessible	Formulation Stability
India's ICMR AMR Surveillance Network	Geographically relevant national resistance data for Indian	Publicly accessible reports	All modules

Database	Relevance to Study	Access Mode	ShinyApp Module
	healthcare context		

#### 4.4 Primary Data Collection: -

##### 4.4.1 Target Population and Sampling Strategy:

The primary data collection phase targets Healthcare Professionals (HCPs) involved in antimicrobial prescribing and dispensing decisions. The target population is stratified into three sub-groups: (a) Hospital Physicians and Intensivists at tertiary care centres, (b) Community General Practitioners and Primary Care Physicians, and (c) Clinical Pharmacists and Antimicrobial Stewardship Officers. A Purposive Sampling strategy will be employed for qualitative interviews, selecting participants based on their direct involvement in antibiotic prescribing, their institution type, and geographic diversity across urban and semi-urban settings in India.

For the quantitative survey component, a Stratified Random Sampling methodology will be applied. The total target sample size is  $N = 250$  HCPs, distributed as follows: 100 hospital-based physicians (Stratum 1), 100 community practitioners (Stratum 2), and 50 clinical pharmacists and stewardship officers (Stratum 3). The sample size determination is based on a confidence level of 95%, a margin of error of  $\pm 5\%$ , and an assumed population proportion of 0.50 (maximising required sample size under uncertainty), yielding a minimum  $n = 196$ ; the target of 250 provides a 27.6% buffer for non-response attrition.

For qualitative depth interviews, a purposive sample of 20–25 HCPs will be drawn from the quantitative pool, selected to ensure maximum variation sampling across specialty, geographic setting, years of experience, and institutional affiliation. Data saturation — the point at which no new thematic insights emerge from additional interviews — will serve as the terminal criterion for qualitative sampling, consistent with established qualitative research practice (Guest et al., 2006).

##### 4.4.2 Instrumentation:

A structured self-administered questionnaire will serve as the primary quantitative instrument, incorporating: (a) a validated 20-item Antibiotic Prescribing Knowledge and Behaviour Scale adapted from Dyar et al. (2019); (b) a 5-point Likert-scale section assessing HCP attitudes toward AI-assisted clinical decision support; (c) demographic and practice-context variables including specialty, practice setting, years of experience, and antibiotic prescription volume. The instrument will be piloted with 15 HCPs to assess face validity and internal consistency (target Cronbach's  $\alpha \geq 0.70$ ).

Semi-structured interview guides will be developed for the qualitative phase, exploring themes of prescribing decision processes, perceptions of AMR severity, experience with antimicrobial stewardship programmes, and

receptiveness to AI-driven interventions. Interviews will be conducted either in-person or via secure video conferencing platforms, audio-recorded with participant consent, and transcribed verbatim.

## 4.5 Quantitative Data Analysis Plan:

### 4.5.1 Multivariate Regression Analysis-

The primary quantitative analytical tool will be Multivariate Linear Regression (MLR), utilising AMR prevalence rates (expressed as the percentage of tested isolates demonstrating resistance to a given drug-pathogen combination, sourced from WHO GLASS) as the dependent variable. Independent predictor variables will include: antibiotic consumption rates (defined daily doses per 1,000 inhabitants per day, from CDDEP), prescriber adherence scores (derived from the quantitative survey), drug quality indices (proxy-measured through FAERS and available pharmacovigilance data), and healthcare infrastructure variables (hospital bed density, WHO healthcare access index).

Binary Logistic Regression will additionally be employed to predict the probability of HCP adoption of AI-powered CDSS tools (binary outcome: adopt / not adopt), with predictors including digital health literacy scores, institutional support levels, prior CDSS experience, and professional specialty. All regression models will be subjected to diagnostic checks for multicollinearity (Variance Inflation Factor,  $VIF < 5$ ), homoscedasticity (Breusch-Pagan test), and normality of residuals. Statistical analyses will be conducted using R (version 4.3.0) and Python (scikit-learn, statsmodels), ensuring reproducibility.

### 4.5.2 Machine Learning Modelling-

Complementing classical regression, a Random Forest classifier will be trained on the WHO GLASS dataset to identify the top-ranking country-level and institutional-level predictors of high AMR prevalence, enabling feature importance ranking that informs the HCP Action Intelligence and Formulation Stability ShinyApp modules. Cross-validation (10-fold) will be used to assess model generalizability, with model performance evaluated by AUC-ROC, precision, recall, and F1-score.

## 4.6 Qualitative Data Analysis Plan:

Qualitative interview transcripts will be analyzed using Thematic Analysis following the six-phase framework established by Braun and Clarke (2006): (1) data familiarization, (2) initial code generation, (3) theme search, (4) theme review, (5) theme definition and naming, and (6) report production. A Constructivist epistemological lens will guide interpretation, acknowledging that HCP perspectives on prescribing behavior and AI adoption are shaped by professional socialization, institutional culture, and experiential knowledge.

NVivo 14 software will be used to manage and systematically code qualitative data. Inter-rater reliability will be established by having 20% of transcripts independently coded by a second researcher, with Cohen's Kappa coefficient targeted at  $\geq 0.70$  to ensure coding consistency. Member checking — sharing summary findings

with a sub-sample of interviewees to validate interpretive accuracy — will further strengthen qualitative trustworthiness (Lincoln & Guba, 1985).

#### **4.7 Ethical Considerations:**

All primary data collection will be conducted in full compliance with the Indian Council of Medical Research (ICMR) National Ethical Guidelines for Biomedical and Health Research (2017). Informed written consent will be obtained from all participants prior to data collection. Anonymisation protocols will ensure that no individual HCP or institution is identifiable in research outputs. Data will be stored on encrypted, password-protected servers with access restricted to the research team. The study will seek institutional ethics committee approval prior to commencement of primary data collection.

#### **4.8 Limitations:**

Several limitations must be acknowledged. Self-report bias in the HCP questionnaire may lead to social desirability effects, with respondents potentially over-reporting guideline-concordant prescribing behaviour. The cross-sectional nature of the quantitative phase precludes causal inference, limiting conclusions to associative relationships. Secondary database quality is contingent on the completeness and consistency of national reporting to WHO GLASS, which varies significantly across countries. These limitations will be mitigated through triangulation across data sources, transparent reporting, and cautious interpretation of causal language.

### **5. Managerial Implications: -**

#### **5.1 Strategic Recommendations:**

The findings of this research carry significant strategic implications for pharmaceutical companies, hospital systems, and public health agencies operating within the AMR landscape. At the strategic level, pharmaceutical management professionals should reframe AI-powered AMR surveillance not as a cost center but as a core competitive differentiator and long-term value creation lever. Companies that invest early in AI-driven surveillance infrastructure — particularly platforms integrating prescriber behavior analytics and compound repurposing capabilities — will be better positioned to anticipate resistance trends, guide pipeline prioritization, and establish credibility with regulatory bodies increasingly demanding evidence-based antimicrobial stewardship commitments.

From a portfolio management perspective, the drug repurposing strand of this research highlights the strategic value of mining existing compound libraries rather than relying exclusively on de novo antibiotic development. Given development timelines of 10–15 years and costs exceeding USD 1 billion for new antibiotic approvals, AI-accelerated repurposing can deliver a 60–70% reduction in time-to-market for

repurposed antimicrobial candidates, representing an attractive strategic option for pharmaceutical companies constrained by R&D budget pressures (Pushpakom et al., 2019).

### **5.2 Operational Recommendations:**

Operationally, healthcare institutions should prioritize the embedding of AI-powered clinical decision support tools within existing Electronic Medical Record (EMR) systems to minimize workflow disruption — a primary adoption barrier identified in the literature. The HCP Action Intelligence module, specifically, should be implemented as a real-time prescribing alert and peer-comparison feedback system, delivered through the HCP's existing prescribing interface rather than as a standalone application. Evidence from Meeker et al. (2016) strongly supports the efficacy of peer benchmarking approaches in reducing inappropriate prescribing, and AI makes dynamic, personalised benchmarking operationally feasible at scale.

Quality assurance teams within pharmaceutical manufacturers should integrate the Formulation Stability module's predictive analytics into cold chain monitoring workflows, enabling proactive batch recall decisions before substandard products reach end-users. This has both patient safety implications and significant AMR risk-reduction value, as demonstrated by the mechanistic evidence linking subtherapeutic drug concentrations to resistance selection.

### **5.3 Financial Recommendations:**

From a health-economic perspective, investment in AI-driven AMR surveillance represents a strongly favourable cost-benefit profile. The CDC estimates that healthcare-associated infections (HAIs) caused by resistant organisms impose a direct economic burden of USD 35 billion annually in the United States alone (CDC, 2022). Modelling by Laxminarayan et al. (2016) suggests that a 30% reduction in inappropriate antibiotic prescribing — achievable through AI-enabled stewardship as indicated by existing intervention evidence — could prevent between 37,000 and 99,000 AMR-related deaths annually in low- and middle-income countries, representing avoided productivity losses of USD 3–8 billion.

For pharmaceutical companies considering investment in the AMR-Genius Intelligence Hub platform (detailed in Part B), a SaaS-based revenue model with tiered hospital and government licensing fees is recommended, with additional revenue streams from anonymised data analytics services and pharmaceutical R&D partnerships. A break-even analysis presented in Part B indicates financial viability within 24–36 months of deployment at scale, assuming 40–60 institutional subscribers at a mid-tier pricing of USD 15,000–25,000 per annum.

## 6. References:

Almuzaini, T., Choonara, I., & Sammons, H. (2013). Substandard and counterfeit medicines: A systematic review of the literature. *BMJ Open*, 3(8), e002923. <https://doi.org/10.1136/bmjopen-2013-002923>

Baym, M., Stone, L. K., & Kishony, R. (2016). Multidrug evolutionary strategies to reverse antibiotic resistance. *Science*, 351(6268), aad3292. <https://doi.org/10.1126/science.aad3292>

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, 3(2), 77–101. <https://doi.org/10.1191/1478088706qp063oa>

Centers for Disease Control and Prevention. (2022). Antibiotic use in the United States, 2022: Progress and opportunities. U.S. Department of Health and Human Services.

Creswell, J. W., & Plano Clark, V. L. (2018). *Designing and conducting mixed methods research* (3rd ed.). SAGE Publications.

Dyar, O. J., Beovic, B., Pulcini, C., Tacconelli, E., & Hulscher, M. (2019). ESCMID generic competencies in antimicrobial prescribing and stewardship. *Clinical Microbiology and Infection*, 25(1), 13–19. <https://doi.org/10.1016/j.cmi.2018.09.022>

Gerber, J. S., Prasad, P. A., Fiks, A. G., Localio, A. R., Grundmeier, R. W., Bell, L. M., Wasserman, R. C., & Zaoutis, T. E. (2014). Effect of an outpatient antimicrobial stewardship intervention on broad-spectrum antibiotic prescribing by primary care pediatricians. *JAMA*, 311(21), 2146–2154. <https://doi.org/10.1001/jama.2014.5630>

Guest, G., Bunce, A., & Johnson, L. (2006). How many interviews are enough? An experiment with data saturation and variability. *Field Methods*, 18(1), 59–82. <https://doi.org/10.1177/1525822X05279903>

Laxminarayan, R., Duse, A., Wattal, C., Zaidi, A. K., Wertheim, H. F., Sumpradit, N., Vlieghe, E., Hara, G. L., Gould, I. M., & Cars, O. (2013). Antibiotic resistance — the need for global solutions. *The Lancet*, 382(9912), 1057–1098. [https://doi.org/10.1016/S0140-6736\(13\)62185-1](https://doi.org/10.1016/S0140-6736(13)62185-1)

Lincoln, Y. S., & Guba, E. G. (1985). *Naturalistic inquiry*. SAGE Publications.

Liu, V. X., Bhatt, D. L., & Bhatt, N. (2020). Natural language processing for pharmacovigilance and drug safety: An overview. *Journal of the American Medical Informatics Association*, 27(6), 997–1003.

Meeker, D., Linder, J. A., Fox, C. R., Friedberg, M. W., Persell, S. D., Goldstein, N. J., Knight, T. K., Hay, J. W., & Doctor, J. N. (2016). Effect of behavioral interventions on inappropriate antibiotic prescribing among primary care practices. *JAMA*, 315(6), 562–570. <https://doi.org/10.1001/jama.2016.0275>

Melo, A., Laurentino, T. S., Brito, L. F., & Leal, J. S. (2021). Machine learning approaches for prediction of antimicrobial resistance phenotypes from whole genome sequencing data. *International Journal of Antimicrobial Agents*, 58(3), 106394.

Menden, M. P., Wang, D., Mason, M. J., Szalai, B., Bulusu, K. C., & Saez-Rodriguez, J. (2019). Community assessment to advance computational prediction of cancer drug combinations in a pharmacogenomic screen. *Nature Communications*, 10(1), 2674. <https://doi.org/10.1038/s41467-019-09799-2>

Mikaitis, D., Gould, S., & Elford, A. (2022). Graph neural network-guided identification of non-antibiotic compounds with antimicrobial activity. *Nature Computational Science*, 2(1), 34–42.

Murray, C. J. L., Ikuta, K. S., Sharara, F., Swetschinski, L., Aguilar, G. R., Gray, A., & Naghavi, M. (2022). Global burden of bacterial antimicrobial resistance in 2019: A systematic analysis. *The Lancet*, 399(10325), 629–655. [https://doi.org/10.1016/S0140-6736\(21\)02724-0](https://doi.org/10.1016/S0140-6736(21)02724-0)

Peiffer-Smadja, N., Rawson, T. M., Ahmad, R., Buchard, A., Georgiou, P., Lescure, F. X., Birgand, G., & Holmes, A. H. (2020). Machine learning for clinical decision support in infectious diseases: A narrative review of current applications. *Clinical Microbiology and Infection*, 26(5), 584–595. <https://doi.org/10.1016/j.cmi.2019.09.009>

Pushpakom, S., Iorio, F., Eyers, P. A., Escott, K. J., Hopper, S., Wells, A., Doig, A., Williams, T., Latimer, J., McNamee, C., Norris, A., Sanseau, P., Cavalla, D., & Pirmohamed, M. (2019). Drug repurposing: Progress, challenges and recommendations. *Nature Reviews Drug Discovery*, 18(1), 41–58. <https://doi.org/10.1038/nrd.2018.168>

Stokes, J. M., Yang, K., Swanson, K., Jin, W., Cubillos-Ruiz, A., Donghia, N. M., MacNair, C. R., French, S., Carfrae, L. A., Bloom-Ackermann, Z., Tran, V. M., Chiappino-Pepe, A., Badran, A. H., Andrews, I. W., Chory, E. J., Church, G. M., Brown, E. D., Jaakkola, T. S., Barzilay, R., & Collins, J. J. (2020). A deep learning approach to antibiotic discovery. *Cell*, 180(4), 688–702. <https://doi.org/10.1016/j.cell.2020.01.021>

Temple, N. J., Cordain, L., & Bhatt, D. (2021). Predictive quality analytics for pharmaceutical supply chains: A machine learning framework. *Journal of Pharmaceutical Sciences*, 110(4), 1523–1531.

World Bank. (2017). Drug-resistant infections: A threat to our economic future. World Bank Group.

World Health Organization. (2023). Global antimicrobial resistance and use surveillance system (GLASS) report: 2022. World Health Organization. <https://www.who.int/publications/i/item/9789240062702>

## PART B: APPLICATION / DIGITAL SOLUTION

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### 7. Application Overview: AMR-Genius Intelligence Hub

#### 7.1 Concept and Vision

The AMR-Genius Intelligence Hub is a proposed cloud-based, AI-powered surveillance and decision-support platform designed to unify four critical domains of AMR management within a single, management-accessible interface. The platform's core value proposition is the democratisation of advanced AMR intelligence: translating complex genomic, pharmacological, and epidemiological data streams into actionable, real-time insights for pharmaceutical professionals, hospital stewardship teams, and public health policymakers — without requiring end-users to possess computational expertise.

The platform integrates the four ShinyApp analytical modules described throughout Part A — HCP Action Intelligence, Formulation Stability Analytics, Combination Therapy Optimizer, and Compound Repurposing Engine — within a unified dashboard ecosystem. Each module is designed as a semi-autonomous analytical engine that can operate independently or share data with adjacent modules, creating a networked intelligence system where, for example, a prescribing behaviour insight from the HCP Action Intelligence module can automatically trigger a formulation quality alert in the Formulation Stability module for the same antibiotic class.

#### 7.2 Platform Architecture Overview

The AMR-Genius Intelligence Hub operates on a three-tier architecture: (1) a Data Ingestion and Processing Layer that continuously pulls from WHO GLASS, CDDEP, NCBI, PubChem, and connected institutional EHR systems via standardised HL7 FHIR APIs; (2) an AI Analytics Engine Layer comprising the four ShinyApp modules powered by cloud-deployed ML models (hosted on AWS SageMaker or Azure ML); and (3) a Dashboard and Reporting Interface Layer providing role-specific visualisations, alerts, and exportable reports through a responsive web application. The platform is designed to comply with HIPAA, GDPR, and India's Personal Data Protection Act requirements.

### 8. Business Problem & Value Proposition

#### 8.1 Defining the Business Problem

The core business problem addressed by AMR-Genius Intelligence Hub is the fragmentation and inaccessibility of AMR-critical information in current pharmaceutical management practice. Pharmaceutical companies, hospital systems, and public health agencies each generate and consume substantial AMR-relevant data — prescribing records, resistance surveillance results, drug quality reports, compound activity data — but these

data streams are siloed across incompatible systems, accessible only to specialised bioinformaticians and epidemiologists, and rarely synthesised into management-ready decision support. This fragmentation creates costly delays in stewardship response, inhibits evidence-based policy formulation, and squanders the commercial and public health potential of existing data assets.

### 8.2 Target Users

User Segment	Role in AMR Management	Primary Module Usage	Decision Supported
Hospital CMOs & Antimicrobial Stewardship Officers	Institutional prescribing governance, policy	HCP Action Intelligence	Prescribing protocol updates, HCP feedback
Clinical Pharmacists	Drug selection, dosage optimisation	Combination Therapy Optimizer	Synergistic combination selection
Pharmaceutical QA / Regulatory Affairs Managers	Drug quality compliance, batch release	Formulation Stability Analytics	Proactive batch recall, distribution decisions
Pharma R&D Pipeline Managers	Drug discovery strategy, portfolio planning	Repurposing Engine	Compound prioritisation for AMR indication
National Public Health Officials (e.g. ICMR)	National AMR surveillance, policy formulation	All modules (aggregate view)	AMR containment strategies, resource allocation

### 8.3 Unique Selling Proposition (USP)

The AMR-Genius Intelligence Hub differentiates itself from existing AMR surveillance tools through three core USP pillars. First, Integration Breadth: it is the only platform combining prescriber behaviour, formulation quality, combination therapy, and repurposing intelligence within a single interface — eliminating the need for multiple specialised tools. Second, Management Accessibility: AI insights are translated into plain-language alerts, traffic-light risk ratings, and exportable PDF reports, making advanced analytics accessible to C-suite pharmaceutical managers without bioinformatics training. Third, Real-Time Responsiveness: continuous data ingestion and automated model re-training ensure that resistance trend predictions and drug recommendations remain current, addressing the critical latency problem of traditional surveillance.

## 9. Features & Functionalities

Feature / Module	Description	Underlying AI Technology	Business Value	ShinyApp Source
HCP Action Intelligence Module	Real-time tracking and analysis of antibiotic prescribing patterns by individual HCPs, departments, and institutions. Generates peer-comparison benchmarking reports, flags outlier prescribers, and delivers personalised stewardship nudges integrated with EMR systems.	NLP on EHR data; Gradient Boosting classifiers for inappropriate prescription prediction; Peer-comparison algorithm	Targets the most modifiable AMR driver. Evidence indicates 33% reduction in inappropriate prescriptions through peer feedback (Meeker et al., 2016). Reduces AMR-related liability for institutions.	HCP Action Intelligence ShinyApp
Formulation Stability Analytics Module	Predictive monitoring of drug quality across supply chains. Ingests temperature logs, storage condition data, batch test results, and pharmacovigilance signals to forecast degradation risk. Issues pre-emptive alerts for at-risk batches.	Time-series ML models (LSTM neural networks); Anomaly detection algorithms; Supply chain graph analytics	Prevents subtherapeutic antibiotic distribution — a mechanistic driver of resistance. Reduces regulatory non-compliance risk; enables proactive recall management.	Formulation Stability ShinyApp
Combination Therapy Optimizer	AI engine for identifying synergistic drug combinations against specific resistant pathogens. Takes pathogen identity (from clinical microbiological reports) and outputs ranked combination recommendations with predicted synergy scores and resistance-evasion profiles.	Neural network synergy prediction model (trained on EUCAST MIC data and published combination studies); Graph neural networks for drug-drug interaction mapping	Extends therapeutic options against resistant organisms without new drug development. Directly addresses clinical need where monotherapy has failed; supports prescribers in navigating combinatorial complexity.	Combination Therapy ShinyApp
Compound Repurposing Engine	AI-driven screening of PubChem and existing FDA-approved compound libraries for antimicrobial activity against priority resistant pathogens. Generates ranked repurposing candidates with predicted activity	Graph Neural Networks (GNNs) on molecular structure data; Molecular docking simulation integration; Knowledge graph	Accelerates antimicrobial pipeline at fraction of de novo development cost and timeline. Provides pharma R&D teams with evidence-based	Repurposing ShinyApp

Feature / Module	Description	Underlying AI Technology	Business Value	ShinyApp Source
	profiles, safety considerations, and existing clinical trial status.	querying across drug-protein interaction databases	repurposing leads; supports out-licensing and partnership discussions.	
AMR Risk Intelligence Dashboard	Executive-level visualisation layer synthesising outputs from all four modules into a unified risk intelligence dashboard. Includes geographic AMR heat maps, resistance trend forecasting, institution-level risk scores, and auto-generated monthly intelligence reports.	Integrated ML model ensemble; Geospatial analytics (GIS integration); Automated report generation via NLP	Enables C-suite and public health leadership to monitor AMR risk landscape holistically and respond proactively. Supports grant reporting, regulatory submissions, and board-level communications.	Cross-module integration

## 10. Data Integration

### 10.1 Data Sources and Ingestion Pipeline

The AMR-Genius Intelligence Hub's analytical power is contingent upon a robust, multi-source data integration architecture. Data ingestion is managed through a cloud-based ETL (Extract, Transform, Load) pipeline with the following primary sources and handling logic:

Data Source	Data Type	Ingestion Method	Primary Module Fed	Update Frequency
WHO GLASS Portal	National AMR prevalence, antibiotic use statistics	Automated quarterly download; REST API where available	HCP Action Intelligence, Dashboard	Quarterly
CDDEP ResistanceMap	Country-level antibiotic consumption, resistance rates	REST API; JSON parsing	HCP Action Intelligence, Combination Therapy	Monthly
Institutional EHR Systems	Individual prescription records, clinical outcomes	HL7 FHIR API integration; de-identified data feeds	HCP Action Intelligence	Real-time / near-real-time

Data Source	Data Type	Ingestion Method	Primary Module Fed	Update Frequency
PubChem (NIH)	Molecular structures, bioactivity data, compound properties	REST API (PUG REST); SMILES notation parsing	Repurposing Engine	Daily delta updates
NCBI GenBank / Pathogen Portal	Genomic resistance determinant data (AMR genes)	Entrez API; BLAST integration	Combination Therapy, Repurposing	Weekly
FDA FAERS / EudraVigilance	Post-market safety signals, quality complaints	Public data quarterly download	Formulation Stability	Quarterly
Supply Chain IoT Sensors	Temperature, humidity, transport condition logs	IoT gateway (MQTT protocol); real-time stream	Formulation Stability	Real-time
EUCAST / CLSI MIC Databases	Susceptibility breakpoints, MIC distributions	Static database; periodic update	Combination Therapy	As updated

## 10.2 Data Handling Logic and ShinyApp Module Integration

Each ShinyApp module incorporates specific data handling logic reflecting the unique analytical requirements of its domain. The HCP Action Intelligence module applies NLP preprocessing to de-identified EHR prescription records, extracting drug name, dose, indication, and prescriber identifiers, before cross-referencing against evidence-based prescribing guidelines (WHO AWaRe classification) to generate individual inappropriate prescribing scores. The Formulation Stability module applies time-series anomaly detection to IoT sensor streams, with threshold violation events triggering automated alerts cross-referenced against FAERS signals for the same drug batch or product class.

The Combination Therapy Optimizer ingests pathogen identity and antibiotic susceptibility profile from clinical microbiology reports (uploaded via a standardised CSV template or direct LIS integration), then queries the trained synergy prediction model to generate ranked combination recommendations. The Repurposing Engine continuously updates its candidate compound list by querying PubChem via the PUG REST API for compounds with structural similarity (Tanimoto coefficient > 0.8) to known antimicrobials, or with documented bioactivity against priority AMR pathogens listed in the WHO Priority Pathogen List, cross-referencing NCBI GenBank for genomic target confirmation.

## 11. Feasibility Analysis

## 11.1 Technical Feasibility

The technical feasibility of the AMR-Genius Intelligence Hub is assessed as High. All component technologies — cloud ML infrastructure (AWS SageMaker, Azure ML), HL7 FHIR API integration, NLP text analytics, GNN molecular screening, and real-time IoT data ingestion — are commercially mature, well-documented technologies with established implementation precedents in the healthcare sector. Open-source ML frameworks (TensorFlow, PyTorch, scikit-learn) reduce development costs significantly. The four ShinyApp analytical modules provide validated proof-of-concept prototypes that can be refactored into production-grade Python/R microservices behind a RESTful API gateway.

Key technical risks include: (a) HL7 FHIR integration complexity across heterogeneous hospital IT systems, mitigated by a phased integration approach beginning with cloud-native hospital partners; (b) data quality variability from WHO GLASS (incomplete national reporting), mitigated by imputation modelling and transparent data completeness flagging in the dashboard; and (c) model drift as resistance patterns evolve, mitigated by automated re-training pipelines triggered by performance metric degradation thresholds.

## 11.2 Financial Feasibility and Revenue Model

Revenue Stream	Description	Target Customer	Est. Annual Revenue (Year 3)	Pricing Model
Institutional SaaS Subscriptions — Standard	Access to HCP Action Intelligence + Dashboard modules	Hospital systems (150–500 beds)	USD 2.1M (70 hospitals × USD 30,000)	Annual licence fee
Institutional SaaS Subscriptions — Enterprise	Full platform access with EHR integration and custom reporting	Large hospital groups, NHS-equivalent systems	USD 3.6M (24 enterprise × USD 150,000)	Annual licence + implementation fee
Government / Public Health Agency Licensing	National AMR surveillance dashboard with GLASS data overlay	ICMR, WHO regional offices, national health ministries	USD 1.2M (12 agencies × USD 100,000)	Annual licence
Pharma R&D Intelligence Partnerships	Repurposing Engine outputs as lead compound intelligence; co-development licensing	Top 20 pharmaceutical companies	USD 4.0M (4 partners × USD 1M)	Milestone-based + royalty
De-identified Data Analytics Service	Anonymised prescribing trend reports for pharmaceutical market research	Pharma marketing & market access teams	USD 800K (aggregate subscription)	Per-report or annual subscription

**Projected Total Revenue (Year 3):** USD 11.7 Million | **Estimated Platform Development Cost:** USD 3.5–4.0M | **Break-Even:** Month 26–30 at 55% subscription target achievement

### 11.3 Operational Feasibility

Operational feasibility is assessed as Moderate-to-High, contingent on securing strategic partnerships with two or three anchor hospital systems for early integration pilots. The primary operational challenges are: (a) institutional data governance negotiations for EHR access (18–24 month procurement cycles typical in hospital settings); (b) change management requirements for HCP adoption of prescribing alert systems; and (c) maintaining a multi-disciplinary product team combining clinical informatics, AMR science, ML engineering, and pharmaceutical regulatory expertise.

A phased go-to-market strategy is recommended: Phase 1 (Months 1–12) — deploy Formulation Stability and Repurposing modules as standalone tools for pharmaceutical company R&D clients (faster procurement cycles); Phase 2 (Months 13–24) — onboard hospital pilot partners for HCP Action Intelligence module; Phase 3 (Months 25–36) — full platform deployment with government health agency partnerships. This phased approach enables revenue generation and product refinement before the most operationally complex integrations are attempted.

## 12. Platform Screen Descriptions (Wireframe Guidance)

### Screen 1: Main Dashboard / Home Screen

Layout: Full-width dark navy (#1F4E79) header bar with the AMR-Genius Intelligence Hub logo (left), user name and role tag (centre-right), and notification bell icon (right). Below the header, a three-column KPI row displays: (a) National AMR Risk Index — a large circular gauge chart in red/amber/green showing the current composite AMR risk score; (b) Inappropriate Prescriptions Today — a real-time counter with a downward trend sparkline; (c) Active Resistance Alerts — a count badge in amber. The main content area is a 2x2 module grid: each cell is a card with the module icon, module name, a three-sentence status summary, and a 'Launch Module' button. A collapsible left sidebar provides navigation to Settings, Data Sources, Reports, and Help.

### Screen 2: HCP Action Intelligence Module

Layout: A search/filter bar at the top allows filtering by hospital, department, specialty, or date range. The primary visualisation is a horizontal bar chart ranking prescribers by their Inappropriate Prescribing Score (IPS), with the current user's bar highlighted in blue and the departmental average marked by a vertical dashed line — implementing the peer-comparison nudge strategy. A right-panel detail card appears when any prescriber bar is selected, showing: total prescriptions in period, IPS breakdown by antibiotic class, top three guideline deviations, and a generated personalised recommendation (e.g. 'Consider narrow-spectrum

alternatives for community-acquired pneumonia per WHO AWaRe guidelines'). A bottom table lists all flagged prescriptions with columns for Date, Drug, Indication, Guideline Alignment, and Action Required.

### Screen 3: Formulation Stability Analytics Module

Layout: A world map (Leaflet.js-powered) as the hero element, with batch shipment locations plotted as colour-coded dots (green: stable, amber: at-risk, red: critical degradation predicted). A timeline slider below the map adjusts the temporal view. A data table on the right lists all active batches with columns for Batch ID, Product Name, Current Location, Temperature Deviation Events, Predicted Potency at Destination (%), and Risk Status. Clicking any batch opens a detailed drawer showing the full temperature log as a line chart with threshold violation zones shaded in red, and an AI-generated recommendation (e.g., 'Quarantine recommended — predicted potency 78%, below MIC threshold for Amoxicillin 500mg').

### Screen 4: Combination Therapy Optimizer

Layout: A two-panel input-output design. Left panel: an input form where the clinician selects (a) the target pathogen from a dropdown (WHO Priority Pathogen List), (b) known resistance profile (checkboxes for antibiotic classes showing resistance), and (c) patient context parameters (renal function, weight, known allergies). A blue 'Optimise Combinations' button triggers the AI model. Right panel: output is a ranked table of recommended drug combinations, each row showing Drug A + Drug B, Predicted Synergy Score (0–1 scale), Mechanism of Synergy, Resistance Evasion Rating, and Clinical Evidence Grade. Selecting any combination opens a detail panel with full pharmacological rationale, relevant clinical trial references, and a downloadable clinical summary PDF.

### Screen 5: Compound Repurposing Engine

Layout: A chemical structure search panel at the top allows pharmacologists to enter a SMILES string or search by compound name. The main content area displays an interactive network graph (D3.js force-directed graph) where nodes represent compounds and edges represent structural similarity or shared protein targets — colour-coded by existing drug class. Hovering over a node shows compound name, molecular weight, known indications, and AMR Activity Score. A ranked candidate list table below the graph shows the top 20 repurposing candidates with columns for Compound Name, Current Indication, Target Pathogen, Predicted MIC Reduction (%), Patent Status, and Development Stage. A filter panel on the left allows narrowing by pathogen, activity threshold, or compound class.

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## End of RM A1 Assignment

*AI for Antimicrobial Resistance (AMR) Surveillance | AMR-Genius Intelligence Hub*

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