



# The International Annual Conference on AI in Health

Health **2024**

11-12 November 2024 | Basel, Switzerland

*Abstract Book*



**Revolutionizing Healthcare with AI: Integrating Multi-modal Data for Personalized Medicine**

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Background - Artificial Intelligence (AI) has the potential to transform healthcare by aiding physicians in diagnosing illnesses, creating tailored treatment plans for patients, and generating new hypotheses about the biological mechanisms behind the clinical manifestations of complex diseases. Additionally, AI can utilize molecular data to inform individuals about their disease risks and offer personalized health strategies for better prevention.

Objectives/Methods - The swift progress in life sciences and medical technologies has resulted in the production of vast amounts of diverse data, including omics profiling data, (bio)images, clinical health records, and digital signals through the monitoring of vital parameters. To make the most of this extensive information, we use advanced embedding and deep learning techniques to integrate multi-modal data for predictive outcome tasks such as patients' drug responses and disease severity classification. Moreover, we improve the explainability and interpretability of our predictions by developing biologically-informed models that incorporate pre-existing knowledge in the form of pathways.

Results/Conclusions - This presentation will showcase applications of these newly developed innovative methods in tackling various challenges within cancer research and personalized health.

### **A Novel Foundation Model for Estimating Brain MRI Health**

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#### Background

AI has advanced significantly in neuroscience but lacks models for rapid, comprehensive brain health assessments. The brain age gap, the difference between chronological and predicted brain age, may serve as a biomarker and proxy for healthy ageing, making it a promising measure for brain health evaluation.

#### Objectives

This project aims to create the first foundational AI model for neuroscience, offering a precise and comprehensive brain health assessment. It focuses on utilizing synthetic neuroimaging data and real-world MRI datasets to estimate brain age, track changes in brain structure, and assess the effects of life behaviours.

#### Methods

To address the lack of clinical data, we generated a large synthetic MRI dataset (100,000 volumes) using generative AI. The fine-tuned model on the UK Biobank dataset (~56,000 MRI volumes) is then deployed on several novel tasks: it can act as a brain health estimator to test life-behavior factors, map patient health trajectories over time, and identify changes in the brain's anatomical structures and their links to cognitive changes.

#### Results

The model achieved state-of-the-art accuracy in estimating brain age on the synthetic dataset. Initial findings indicate significant increases in brain age gaps between the healthy population and patients with dementia symptoms, head injury, Parkinson's disease, and multiple sclerosis. In addition, we see an increased brain age gap in those who are currently smoking versus non-smoking controls, demonstrating lifestyle effects on brain health. We are further validating the method on a traumatic brain injuries cohort (~21,000 MRI volumes), testing the association between a history of TBI and a broad range of general and mental health outcomes across the lifespan.

#### Conclusions

This innovative model offers the first comprehensive foundation for brain health assessment, capable of differentiating between various brain dysfunctions. It has significant potential for clinical and research applications, advancing personalized brain health evaluation and monitoring.

AI Diagnostics: Clinical Decision Support

**Enhancing Tuberculosis Screening through Context-specific Quality Assurance in Computer-Aided Detection Implementation in Myanmar**

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Background

Computer-aided detection (CAD) technology can enhance chest X-ray (CXR) interpretation for TB screening by improving efficiencies in case detection and standardizing X-ray interpretation, crucial in low-resource setting like Myanmar. In PATH's TB REACH Wave 7 project, using Qure.ai's CAD technology, a threshold score (TS) of 0.5 demonstrated high accuracy as a clinical decision support tool among Myanmar private health facilities. The USAID-funded HIV/TB Agency, Information and Services Activity integrated this CAD system in diverse settings across Myanmar to improve TB screening outcomes.

Objective

This exercise aims to evaluate the appropriateness of CAD TS in diverse demographic and epidemiological contexts within Myanmar by implementing context-specific quality assurance (QA) measures. The goal is to optimize effectiveness of TB screening, particularly in regions with limited access to molecular diagnostic tools.

Method

A blinded comparative analysis was conducted between qXR CAD-generated results and binary interpretation by a panel of local expert CXR readers specializing in TB. The representative sample size of 549 was calculated based on parameters from a previous PATH project to ensure sufficient statistical power and its sample size applied to each setting.

Results

Between July 2023 and June 2024, data was collected from all settings, including conflict-affected, remote, and peri-urban areas. The agreement rate, Kappa, and area under the curve (AUC) for CAD system compared to panel's interpretation observed was: conflict-affected areas (89.43%, 0.66, 0.79 (95% CI: 0.75-0.83) , n=596); remote areas (86.91%, 0.51, 0.71 (95% CI: 0.67-0.75, n=596); and peri-urban areas (88.46%, 0.70, 0.84 (95% CI: 0.80-0.88), n=598).

Conclusion

The findings suggest that qXR with current TS is a robust diagnostic support tool across diverse settings in Myanmar, showing strong agreement rates, moderate to substantial Kappa values, and reliable AUC performance. However, a few variations across contexts highlight the need for calibrating CAD settings to improve TB screening accuracy.

AI Diagnostics: Clinical Decision Support

**From Pixels To Diagnosis: AI-based Detection Of Oral Cancer Using Clinical Photos**

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Background

Oral cancer is the 8th most common cancer in men in the US. Despite numerous advancements in understanding its biology, the mean five-year survival rate is still very poor at about 50%, with lower rates when the disease is detected at later stages. Therefore, early detection of oral cancer is crucial because the prognosis is significantly better when diagnosed in its initial stages.

Objective

To develop an algorithm and an AI-powered tool for the early detection of oral cancer.

Methods

We studied a cohort of 1,470 patients and examined various deep-learning methods for the early detection of oral cancer cases; We investigated the use of clinical photographic images taken by common smartphones for the automated detection of cases that may require urgent biopsy.

Results

Our results demonstrate the efficacy of these methods, providing a comprehensive understanding of the patient's condition. When evaluated on holdout data, the model predicting oral cancer achieved an AUC of 0.96 (CI: 0.91, 0.98), sensitivity of 0.91, and specificity of 0.81. When data is stratified based on lesion location, we find that our models can provide enhanced accuracy (AUC 1.00) in differentiating specific groups of patients.

Conclusions

These results underscore the potential of leveraging clinical photographic images for the timely and accurate detection of oral cancer, with a particular emphasis on specific anatomical locations.

Based on our research and algorithm, we created Oralyze, a smartphone-based technology for self and accurate detection of oral cancer.

### **Development of a Clinical Decision Support Model for Early Diagnosis and Prognosis of Septic Shock**

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#### Background:

Sepsis is a life-threatening condition caused by a systemic response to infection. If not treated promptly, it can lead to high mortality rates, with septic shock mortality reaching 50%. Early detection systems are crucial to improving patient outcomes, especially for hospital-acquired sepsis.

#### Objectives:

This study aims to develop a predictive model using complete blood count (CBC) test results and vital signs for early diagnosis of septic shock and predicting high-risk symptoms in septic shock patients.

#### Methods:

Data were collected from Severance Hospital, South Korea. The dataset includes 29,472 patients diagnosed with acute infections, with anonymized data from 5,484 septic shock patients. The data consists of CBC results, vital signs, nursing information, medication records, and diagnostic codes. Machine learning and deep learning models were used, considering variables like gender, age, CBC results, and vital signs recorded up to 24 hours and five days before the onset of septic shock. The model underwent cross-validation and hyperparameter tuning for optimization.

#### Results:

The developed model monitored patients starting five days before the onset of septic shock and predicted the risk within the subsequent 24 hours, achieving an accuracy of 0.75, sensitivity of 0.75, specificity of 0.77 and an AUC score of 0.832. Additionally, the model identified nine potential high-risk symptoms, including pulmonary edema and systemic inflammatory response syndrome, based on their frequency and severity, and predicted their occurrence. The model predicting these nine high-risk symptoms achieved an average accuracy of 0.92 and an AUC score of 0.94.

#### Conclusion:

Unlike prior studies focusing on electronic health records and complex clinical parameters, this model uses widely accessible CBC results and vital signs, making it practical for diverse healthcare settings, including resource-limited environments. The model shows significant potential for early diagnosis and prognosis of septic shock, enabling timely interventions to improve patient outcomes.

### **Enhanced Survival Prediction in Early-stage Lung Cancer Treated with Stereotactic Body Radiotherapy Using Synthetic Data**

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**Background:** Stereotactic Body Radiotherapy (SBRT) is effective in treating inoperable early-stage non-small cell lung cancer (NSCLC), but the risk of local and regional recurrence remains a concern. There is no well-established clinical model for predicting locoregional recurrence-free survival (LRFS), with limited sample sizes and unbalanced outcomes posing challenges.

**Objectives:** This study hypothesizes that augmenting real radiomic features with synthetically generated data can improve the predictive accuracy of LRFS in early-stage NSCLC patients treated with SBRT.

**Methods:** A training set comprising 126 patients from Institution-1 and a test set of 66 patients from Institution-2 were established. In total 107 radiomic features (RFs) per subject were extracted. A benchmark model was constructed using the original dataset and a random survival forest (RFS) model. For synthetic data generation, we tested the effect of augmentation in two ways. First, four distinct synthetic generators (Gaussian Copula, Tabular Variational Autoencoder, Conditional Tabular GAN, and Copula GAN) were trained on training set and generated synthetic datasets of different sizes (100, 300, 500, and 1000 samples) were then generated and added to the original data. Feature selection on these 16 datasets was conducted using two methods (Lasso, Elastic Net). Alternatively, we performed feature selection on the real dataset first then trained the same four types of generator on the dimensionally-reduced data. We applied these datasets to develop 64 RFS and evaluated it by the concordance index (C-index).

**Results:** The benchmark model achieved a C-index of 0.61. The optimal C-index for the application of the four different synthetic generators are as follows: 0.66 (Gaussian Copula, Lasso pre-synthetic, 1000 samples), 0.70 (Tabular Variational Autoencoder, Lasso post-synthetic, 300 samples), 0.64 (Conditional Tabular GAN, elastic pre-synthetic, 300 samples), 0.71 (Copula GAN, elastic post-synthetic, 1000 samples).

**Conclusion:** Synthetic data notably improved the predictive performance of LRFS in early-stage NSCLC patients treated with SBRT.

**Labelling segmentation-based ROI using transformers**

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**Background**

Rapid technological developments in non-invasive clinical imaging have led to increased volume of imaging and increased clinician workload. Deep Learning segmentation algorithms are essential and crucial for organ and tumour delineation, a key step in planning medical interventions. Automatically identifying and labelling segmented regions with descriptive captions reduces doctors' workload, enhancing diagnostics and improving patient care.

**Objectives**

The objective is to have a fully automated and fully-agnostic model to label pre-annotated images to a universal naming convention, irrespective of the original name. We propose a transformer-based image captioning method to generate accurate labels by identifying segmented region in a medical image.

**Methods**

OPC (Oropharyngeal Cancer) Radiomics dataset from the Cancer Imaging Archive, consisting of 600 CT volumes of patients with primary oropharyngeal squamous cell carcinoma was used. Each CT slice was treated as a separate data point, with human-expert segmentations of the region of interest (ROI) overlaid on the image, obscuring the human label. The model was trained to generate ROI labels (Gross Tumour Volume (GTV), Larynx, Left and Right Eye, Left and Right Parotid) based on image intensity and shape. We employed a Full Transformer Network for Image Captioning, using an Adam optimizer with a learning rate of  $1e-4$  for 30 epochs. Both the encoder and decoder have 6 layers with 8 attention heads, trained on NVIDIA Tesla-V100 GPU.

**Results**

Model achieved 99% accuracy and F1 score of 0.996 by effectively detecting and captioning the ROI. It had 0.2% false positives in identifying GTV as Larynx and Parotid, and 0.08% false negatives in detecting Larynx and Parotid instead of GTV.

**Conclusion**

The experiment demonstrated high accuracy in organ captioning, with minimal errors. The model proves reliable for annotating segmented region in a medical image, thus aiding syntactic and semantic interoperable labels.



**AI for Metastatic Lung Nodules Characterization in Sarcoma: Scope of Peri-Tumoral Radiomics in CT imaging**

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**Background**

Early detection of lung metastasis is crucial for treatment planning improving outcome and overall survival[. CT-image analysis using radiomics reported promising results in early detection of lung tumors[4].

**Objectives**

Epigenic changes are observed in the peri-tumoral regions during disease progression, this study aims to assess if peri-tumoral radiomics play any relevant role in diagnosing pulmonary metastasis in patients with sarcoma.

**Methods**

Data-preparation: Thoracic-3D-CT scans of 28 patients (n=26;Male:Female=21:7;Age= $21.2 \pm 5.8$  years) with bone and soft tissue sarcomas were analysed retrospectively under institute review broad approved protocol. A total of n=253 nodules were identified with clinical correlation (malignant:144;benign:109) by an expert radiologist. An in-house built semi-automated 3D adaptive region-growing based lung nodule segmentation tool was used to delineate lung nodules and peri-tumoral regions (Figure1.a-d).

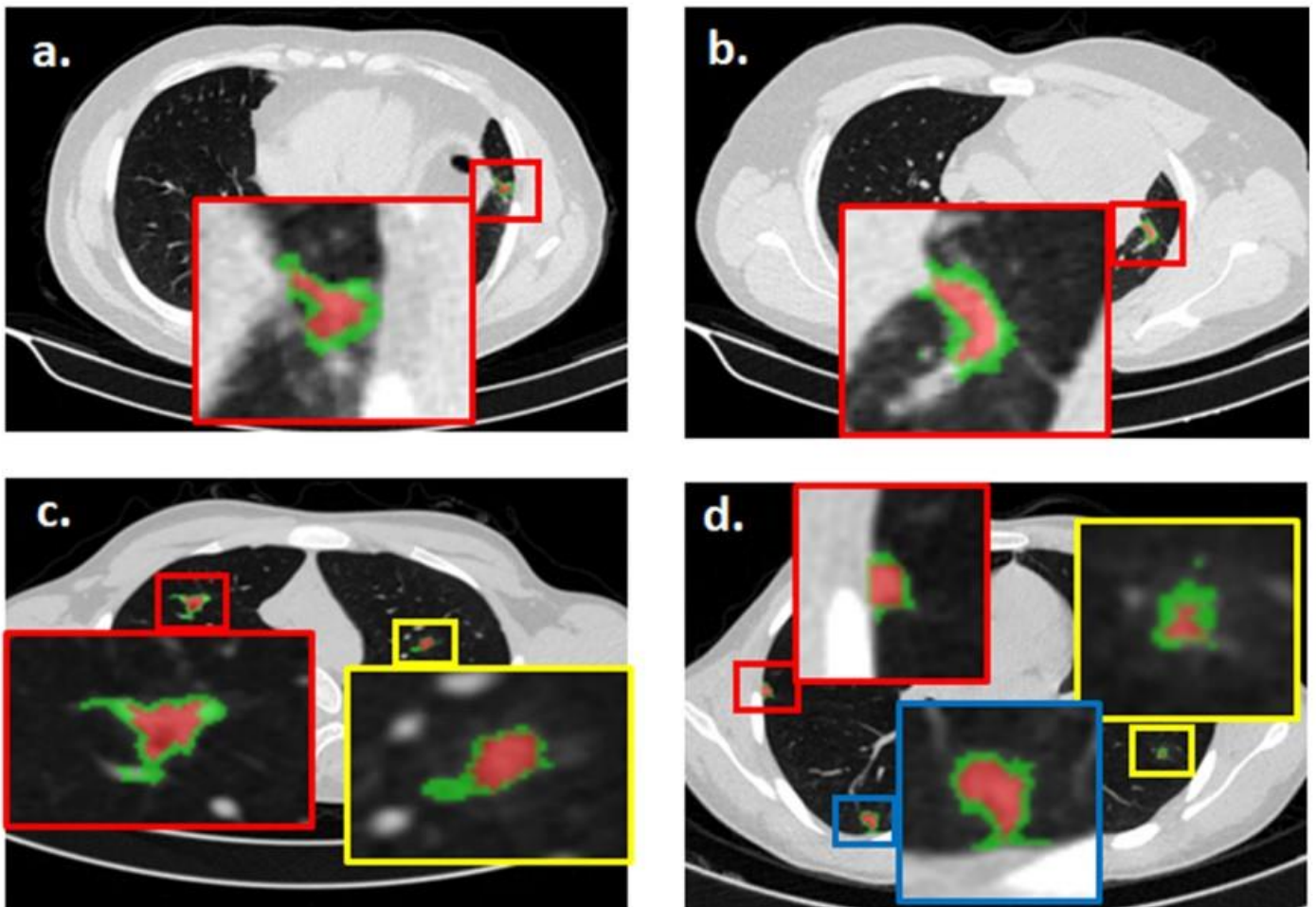
Radiomics and Machine learning models: A total of 108 radiomics features were extracted in 3D intra-tumoral and peri-tumoral regions separately using PyRadiomics v3.1.0. Recursive-Feature-Elimination with Cross-Validation was applied for relevant features selection for intra-tumoral, peri-tumoral and combined radiomics models separately. Five classification models 1) Logistic Regression(LR), 2) Linear Discriminant Analysis(LDA), 3) Histogram Gradient Boosting(HGB), 4) Random Forest(RF), and 5) Extra Trees(ET) were trained for classifying metastatic and benign nodules using 5-fold cross validation. Classification accuracy, area under the receiver operating characteristics curve(AUROC), sensitivity and specificity were evaluated.

**Results**

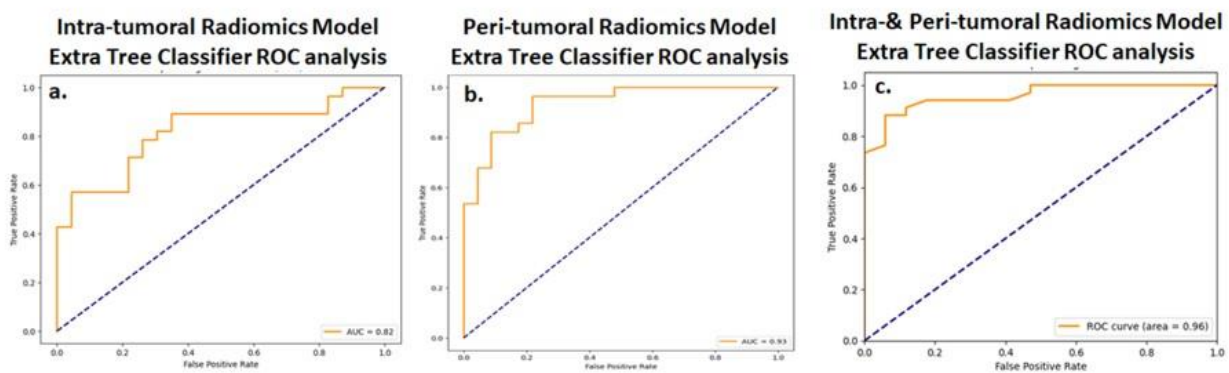
Extra Trees classifier showed the highest classification accuracy among all classification models showing AUC=0.82;0.93;0.94 for intra-tumoral, peri-tumoral, combined radiomics models respectively (Figure2.a-c). Individual peri-tumoral radiomics models produced superior AUC=0.82-0.93 than individual intra-tumoral radiomics models (AUC=0.76-0.82); while combined radiomics models produced comparative better AUC=0.87-0.94 than both (Table1). Shape-based and histogram features were effective for distinguishing between metastatic and benign lung nodules.

**Conclusion**

Experimental results showed that peri-tumoral radiomics can capture epigenetic changes surrounding the core lung nodules during disease progression and can play an important role in diagnosing metastatic lung nodules.



**Figure 1:** a, b, c, and d) Intra-tumoral segmentation mask (red overlay) and peri-tumoral segmentation mask (green overlay) for lung nodules presented in CT image slices. Nodules with peri-tumoral regions are enlarged in the insets.



**Figure 2:** Receiver operating characteristics (ROC) curve analysis for Extra Tree classifier for classifying metastatic lung nodules from benign nodules using a) Intra-tumoral radiomics, b) Peri-tumoral radiomics and c) Intra-tumoral and peri-tumoral radiomics in combination.

**Table 1:** Selected optimal features in intra-tumoral, peri-tumoral and combination of both and corresponding classification accuracy for diagnosing metastatic lung nodules.

	Selected optimal features	Classification model	Accuracy (%)	Sensitivity (%)	Specificity (%)	AUC
Classification using intra-tumoral radiomics	Total = 12 Shape:2; Histogram:8; GLCM:1; GLDM:1	LR	76	86	65	0.76
		LDA	80	89	70	0.79
		HGB	75	93	52	0.80
		RF	78	89	65	0.81
		ET	76	89	61	0.82
Classification using peri-tumoral radiomics	Total = 16 Shape:3; Histogram:8; GLCM:1; GLSZM:2; NGTDM:2	LR	82	78	86	0.85
		LDA	78	70	86	0.82
		HGB	82	83	82	0.92
		RF	84	87	82	0.91
		ET	84	87	82	0.93
Classification using combination of intra-tumoral and peri-tumoral radiomics	Total = 18 Intra-tumoral features: 7 (Shape:2; Histogram:5) Peri-tumoral features 11 (Shape:1; Histogram:7; GLSZM:1; NGTDM:2)	LR	80	70	89	0.87
		LDA	82	86	78	0.89
		HGB	84	93	74	0.93
		RF	84	89	78	0.90
		ET	84	96	79	0.94

AI Diagnostics: Clinical Decision Support

### **Survival Prediction with Artificial Intelligence in Critically-ill ICU Patients for Optimized Triage and Resource Planning**

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#### **Background**

Critical care units handle patients with life-threatening conditions requiring intensive monitoring and treatment. In a resource limited setting with low physician-patient ratio, providing consistent care becomes challenging. A survival prediction model could improve prognosis evaluation, resource allocation, and triaging.

#### **Objectives**

This study aims to develop a data driven artificial intelligence classification model to predict patient outcome based on the clinical parameters.

#### **Methods**

A total of 660 mechanically ventilated patients (n=660, M:F=365:295, Age:44.45±19.36) from three ICUs at AIIMS, Delhi were retrospectively included after institutional ethics approval. A feature set of 100 parameters per patient were collected. Two Ensemble classification models, Model-1 using features selected by Shapley Additive explanations (SHAP) and Gentle-Boost-Ensemble and Model-2 using general clinical parameters i.e. vitals, demographic and routine blood test parameters and Decision-Tree-Ensemble were tested for predicting survival. For SHAP, top features representing 90% of whole data were selected. Both the models were trained using 10-fold cross-validation, with 70% of data for training and 30% of data reserved for testing. Test accuracy, sensitivity, specificity, positive-predictive-value (PPV), negative-predictive-value (NPV), Area under the receiver-operating-characteristics-curve (AUROC) were measures for the prediction models.

#### **Results**

Using SHAP, top 39 features were chosen for Model-1 giving a test accuracy of 78.7% and AUROC of 0.8556. Top 3 features came out to be SOFA score with 27.4% importance level, followed by Albumin/Creatinine ratio and Duration of Illness before ICU admission. Model-2 comprising of 39 general clinical parameters gave a test accuracy of 74.6% and AUROC of 0.8422.

#### **Conclusion**

The automated method for prognosis prediction can help clinician triage the patients early and enable optimized allocation of resources. The study also highlights the importance of general clinical parameters and SOFA score that are used by clinicians as first assessment tools for patients.

Table 1: Selected features for prediction Model-1 and Model-2.	
Selected Features (Model-1)	COUNT (39)
Demographic	2
Vitals	5
Blood	18
Ventilatory	5
Composite/Ratios	6
Others	3
Selected Features (Model-2)	COUNT (39)
Demographic	3
Vitals	8
Blood (Blood gas, CBC, LFT, KFT)	28

Table 2: Test accuracy for Model-1 and Model-2 for predicting outcome (survival or mortality) in patients.						
Prediction Model	Accuracy (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	AUC (%)
Model-1 (Gentle-Boost Ensemble)	78.70	81.20	76.20	76.50	81.10	85.56
Model-2 (Decision-Tree Ensemble)	74.60	82.30	67.30	70.50	80.00	84.22

## AI Diagnostics: Clinical Decision Support

**Prognosis Prediction in Stroke Rehabilitation using Machine Learning and Explainable AI Modelling**

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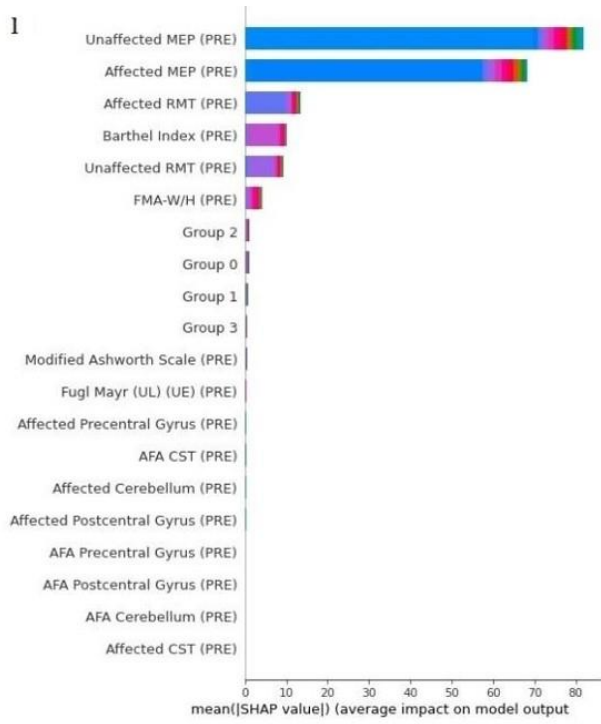
**Background:** Machine learning has been used extensively in medical data analytics predictive modelling; scope of AI based multi-dimensional stroke data-analytics for rehabilitation is not widely explored.

**Objectives:** We hypothesized that in rehabilitative-training, pretherapy-parameters hold prognostication value to predict the post-therapy-parameters and subsequently insights to patient motor-function recovery. Also, if diffusion-MR imaging has any additive role in AI-model optimization.

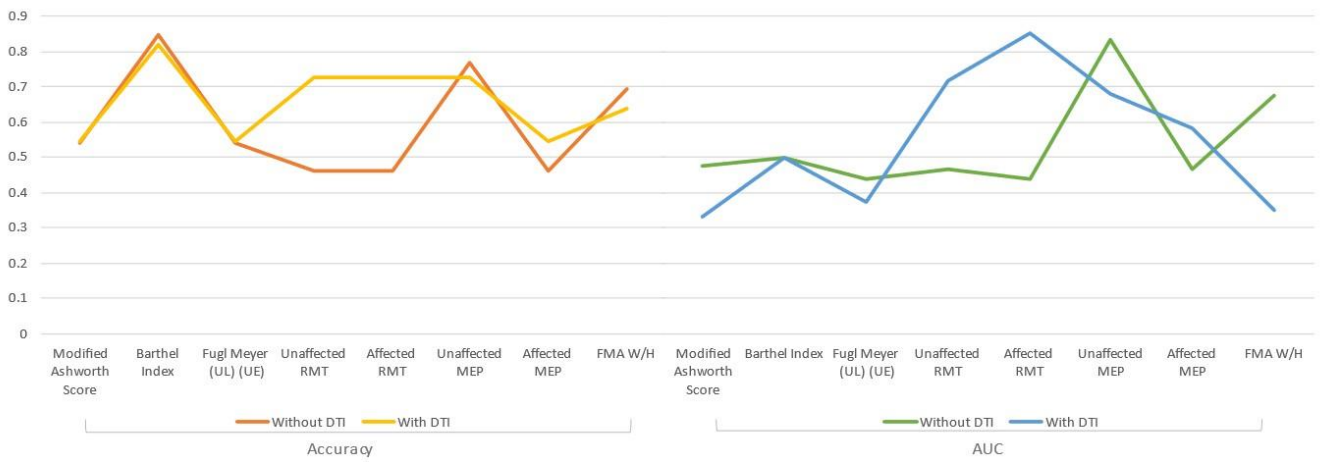
**Methods:** Cohort of 64 patients (n=64) was retrospectively studied, grouped based on the therapeutic-intervention received, under three domains: Diffusion Tensor Imaging (DTI), Clinical-Assessment Scales (Modified-Ashworth-Scale, Fugl-Meyer-Assessment-scale, FMA-Wrist/Hand) and Neurophysiological-data (Resting Motor-Threshold and Motor-Evoked-Potential of ipsilesional-hemisphere) using Transcranial-Magnetic-Brain-Stimulation for both Pre-and-Post-rehabilitative-therapy. Cohort was further split into, with (n=64) and without DTI-data (n=52). Data was processed with Python3, including outlier-detection, missing-value interpolation, and one-hot encoding of categorical-data. Correlation-analysis and Prediction-Power Scores were used to identify linear and non-linear dependencies within the data. Neural-Network-based Multi-Input-Multi-Output (MIMO) regression model was trained to predict post-therapy outcomes using only pre-therapy parameters, iterating over various clinically relevant feature subsets to find the optimal combination. Neural-Network (NN) Model architecture: Number-of-hidden-layers=1, Number-of-neurons-in-hidden-layer=40, Test-Train-Split=20%, Kernel-Initializer=Uniform, Activation-Function=ReLU, Optimizer=Adam. SHAP (Shapley-Additive-exPlanations) was used. A binary-based response-variable categorized: Responder and Non-Responder, as therapeutic-outcome.

**Results:** Determining SHAP values, features MEP, RMT, FMA-W/H and Barthel-Index were observed to be most influential model-parameters, in this order respectively (Figure-1). In the process of model-training, including DTI, validation-error was 2.186 which increased with exclusion of DTI to 3.2081. Accuracy and ROC-AUC scores (Figure-2) for each parameter, a decrease in area under the curve values and median-accuracy was observed while excluding DTI.

**Conclusion:** DTI-data improves prediction-modelling, but predicting DTI-values alone is not satisfactory. Top-model-features were related to cortical-excitability, aligning their role in the binary-classification of responder and non-responders, and highlighting the importance of corticospinal-tract integrity and motor-cortex excitability. Proposed framework provides an agnostic-data driven-model to predict outcome using only pretherapy clinical-parameters and can gauge the rehabilitation-response, which might help achieve precision-rehabilitation.



**Figure 1** Showing the measure of influence of parameters on the NN MIMO regression model output.



**Figure 2** Showing the accuracy and ROC AUC scores binary classification of patients into responder non responders

## AI Diagnostics: Clinical Decision Support

**AI-Enhanced Emergency Severity Index for Comprehensive ED Triage**

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**Background:** Emergency Department (ED) triage systems, such as the Emergency Severity Index (ESI), are crucial for patient prioritization but have limitations in predicting outcomes and optimizing resource allocation. AI-enhanced triage systems offer potential improvements in accuracy, efficiency, and patient care.

**Objectives:** To develop an optimized AI-enhanced ESI score using the MIMIC-IV ED dataset, integrating patient history, real-time vital signs, model predictions, and traditional nurse-assigned ESI to create a more comprehensive, dynamic, and accurate triage tool.

**Methods:** We analyzed over 400,000 ED visits from the MIMIC-IV dataset. Using a customized autoML pipeline, we engineered features from triage variables, patient history, and temporal vital sign patterns. Multiple machine learning models, including XGBoost and MLPs, were trained to predict various outcomes. These predictions, along with the nurse-assigned ESI and real-time patient data, were then combined to create an optimized AI ESI score. Performance was evaluated using AUC, calibration metrics, and compared to traditional ESI scoring.

**Results:** Individual models demonstrated high performance in predicting key outcomes: hospitalization (AUC: 0.85), critical outcomes (ICU admission/mortality within 12 hours, AUC: 0.88), and ED reattendance (AUC: 0.75). These models, triage variables, and vital sign patterns were combined into a single AI-enhanced ESI score, which showed stronger correlation with critical outcomes compared to the nurse-assigned ESI. This combined score allowed for more precise patient ranking than the traditional 5-level ESI system, effectively refining the nurse-assigned ESI.

**Conclusion:** This AI-enhanced ESI system demonstrates significant improvements over traditional methods by integrating patient information with model predictions into a single, comprehensive, and dynamic triage score. It has the potential to optimize resource allocation, improve patient flow, and enhance overall patient care in EDs. Future work will focus on prospective validation, seamless integration into clinical workflows, and assessment of its impact on patient outcomes and ED efficiency.



AI Prospects: Digital Twins, Citizen Care, One Health

### **Conformity of AI Medical Device Software under the AI Act from a Notified Body`s Perspective**

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doc. RNDr. Jiří Tesař, Ph.D., General Director, Czech Metrology Institute, Czech Republic

The Artificial Intelligence Act (AIA), as part of the New Legislative Framework, is shaping the regulatory framework for AI systems across the European Union, including the medical device sector. Therefore this presentation will provide the attendees a comprehensive understanding of the intersection between AIA and MDR, practical guidance on compliance strategies, and insights into the evolving landscape of AI-regulated medical devices within the EU.

The presentation will analyze the scope of the AIA, distinguishing between AI systems that continue to learn post-market and those that used AI during the development phase of medical devices, and the risk classification of AI systems, as defined by the AIA, and its relation to MDR risk classification.

The critical discussion will focus on the key requirements imposed by the AIA on providers and deployers of AI systems and how to meet them, including the need for robust quality management systems, continuous risk management, post-market monitoring, and detailed technical documentation. We will also zoom into the overlap and complementarity between the AIA and Medical device Regulation requirements, focusing on areas such as QMS, risk management, clinical evaluation, data requirements or transparency.

Furthermore, the presentation will outline the expected pathways for providers to demonstrate documented compliance with AIA together with the crucial role of Notified Bodies in the conformity assessment process and how the conformity assessment will look like.

Finally, we will explore how the stakeholders — governments, providers, notified bodies - are prepared for the new AIA requirements and the potential impact on the EU medical device market, particularly for small and medium-sized enterprises (SMEs).

## Tattooing in the Age of AI: Developing an Intelligent Drug Interaction Database for Enhanced Safety

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**Introduction:** Around 15% of Europeans have tattoos or permanent make-up. Their application is often associated with numerous adverse events. Many of these complications are caused by medications used by clients during the procedure of permanent make-up or tattoo. Some medications can affect the healing process, increase the risk of bleeding or change the skin's reaction to the pigments used in permanent make-up and tattoos.

**Objectives:** The aim of the study was to create a comprehensive, automatically updated database of medications that are contraindicated or require special caution during the application of permanent make-up and tattoos.

**Methods:** Advanced machine learning techniques, including natural language processing algorithms and structured data analysis, were used to analyze and classify information from various sources, such as medical publications, pharmacological databases, and reports from cosmetic practices. An automatic data verification and validation system was developed by cross-comparing information from multiple sources and using statistical methods to assess the reliability of the collected data.

**Results:** The created AI system demonstrated high effectiveness in identifying potentially dangerous drugs during permanent makeup and tattoo procedures. A database containing over 300 active substances that may negatively affect the course and effects of these procedures was developed. The system allowed for categorization of drugs according to the level of risk and the time for which their use should be avoided before and after the procedure.

**Conclusions:** The use of artificial intelligence in creating and updating the database of contraindicated drugs for permanent makeup and tattoo significantly increases the safety of these procedures. The AI system demonstrated the ability to quickly process and analyze large amounts of data, enabling continuous updating of the knowledge base, which is crucial in the dynamically developing cosmetics industry. The developed tool provides valuable support to cosmetologists, tattoo artists and clients, helping them make informed decisions and minimize the risk of complications related to interactions of drugs and cosmetic procedures.

## Illuminating Drug Safety: AI-Powered Database for Phototoxicity Prediction

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**Background:** Phototoxicity occurs when a drug substance or its metabolite is photoactivated in the skin under the influence of UVA, UVB or visible light. As a result of this process, photoproducts or reactive oxygen species are formed, which can damage skin cells. Information on the phototoxicity of drugs is particularly important for patients using such drugs.

**Objectives:** The aim of the work was to: verify the possibilities of the process of automation and classification of phototoxic drugs by analyzing large pharmacological, clinical and molecular data. In addition, the possibility of developing mechanisms for continuous updating of the database based on the latest scientific reports, clinical reports and data from pharmacovigilance was determined.

**Methods:** Advanced machine learning techniques, including deep neural networks and natural language processing algorithms, were used to analyze and classify data from various sources, such as scientific publications, chemical structure databases, and clinical reports. An automatic data verification and validation system was developed by cross-comparing information from multiple sources and using statistical methods to assess the reliability and consistency of the collected data.

**Results:** The developed AI system achieved high efficiency in identifying drugs with phototoxic potential, significantly outperforming previous manual methods. A database containing over 500 active substances with significant photosensitizing potential was created.

**Conclusion:** The use of AI in creating and verifying phototoxic drug databases significantly increases the efficiency and accuracy of the process of identifying potentially dangerous substances, which can contribute to improving the safety of pharmacotherapy. The AI system demonstrated the ability to quickly process and analyze huge amounts of data, enabling continuous updating of the knowledge base on drug phototoxicity, which is crucial in the dynamically developing pharmaceutical environment. The developed tool constitutes a promising platform for further research into the mechanisms of phototoxicity and may provide valuable support to clinicians, scientists and regulatory authorities in making decisions regarding drug safety.

**Dynamic reporting of treatment related Symptoms via ePROs can reversely identify the Type of underlying Cancer**

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**Background:** Digital symptom reporting through cancer patients (ePRO) undergoing systemic treatment has demonstrated detection of symptoms, equivalent side effects regarding similar drugs, reduction of unplanned admissions, and machine learning (ML) may predict when patients will require emergency treatments. We examined whether dynamic reporting of treatment related symptoms via ePROs can reversely identify the type of underlying cancer.

**Methods:** 226 patients on treatment had self-reported on presence and severity (according to CTCAE) of more than 90 available symptoms via the medidux app (formerly consilium care). For a balanced analysis we used data from 25 patients treated for breast cancer, 19 for cancer of lung, 16 for colon, 12 for lymphoma and 7 for prostate cancer, respectively. Patients' symptoms over the entire study period were aggregated by counting the days on which a particular symptom was reported. Thus, each patient was represented by a vector of symptoms indicating how often the given symptom occurred. A human-interpretable ML logistic regression model was applied to predict the primary tumor of the patient from his/her respective symptom vector. All symptoms with positive coefficient above a certain threshold (0.1) were collected and then graphically displayed for association between symptoms and cancer type.

**Results:** The ML model was not able to recognize the prostate and blood-lymph patients in retrospect since their number was too small. Analysis for three remaining cancer types revealed a mean area under the curve (AUC) score of 0.72 (breast cancer AUC 0.74, CI: 0.62–0.85; gut cancer AUC 0.78, CI: 0.66–0.89; lung cancer AUC 0.63, CI: 0.50–0.77). Results indicate that ML performs “fair” and significantly better than random guessing (which would result in AUC = 0.5) for the reverse identification of the underlying cancer upon ePRO reporting from patients.

**Conclusion:** Cloud aggregation of patient reported symptoms and ML harbor the potential in identifying the type of cancer for which patients receive systemic treatment. Whether associations can be made from dynamic changes of reported symptoms, regarding the underlying cancer and adherence to oral medication shall be explored in prospective studies. Finally, ML and the anticipation of specific side effects might be a cost-effective tool in decentralized clinical trials and registries, enabling a more nuanced understanding of symptom associations with different cancer types.

## The Application Of Artificial Neural Networks And Design Of Experiment In The Development Of HPLC Method for Determination of Fluconazole – A Comparative Study

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### **Background:**

The analytical method development may be performed using the Design of Experiments (DoE) or Artificial Neural Network (ANN) approach. Both approaches allow for the analysis of the impact of each of the analyzed independent variables on the possible result. The application of DoE and ANN in developing the analytical procedure may comprise both the chromatographic separation and the recovery of the analyte from a matrix.

### **Objectives:**

The study's aim was to compare the ANN application in developing the HPLC method with the DoE approach.

### **Methods:**

The following parameters of chromatographic separation were optimized: retention time, tailing factor, peak height, and the sample pre-conditioning parameter, such as the recovery from a matrix. Central Composite Design (CCD) was applied to the optimization with DOE, and the multi-layer perceptron (MLP) was used in the case of ANN analysis. The statistical analysis was done using Statistica software.

### **Results:**

The acetonitrile concentration was the most significant factor influencing the retention time, tailing factor, and peak height. For recovery, the extracting agent's volume was the most significant factor. In most cases, the analysis conducted with both the DoE and ANN indicated similar factors in the similar order of their impact on the analyzed variable.

### **Conclusion:**

ANN is a promising tool in the optimization of the procedure of the chromatographic separation by HPLC as well as the sample pre-conditioning. The statistical analysis proved the validity of the model used to develop the analytical method. Due to this solution, reducing the use of resources spent on process development is possible.

**Diagnostics with immunoprofiling and federated learning****Jetlinda Krasniqi<sup>1</sup>**, Jan Kruta<sup>1</sup>, Laura Azzimonti<sup>2,3</sup>, Daniele Malpetti<sup>2</sup>, Enkelejda Miho<sup>1,3,4\*</sup><sup>1</sup> School of Life Sciences, University of Applied Sciences and Arts Northwestern Switzerland, Muttenz, Switzerland.<sup>2</sup> Dalle Molle Institute for Artificial Intelligence Studies (IDSIA USI-SUPSI), Switzerland.<sup>3</sup> Swiss Institute of Bioinformatics, Lausanne, Switzerland.<sup>4</sup> aiNET GmbH, Basel, Switzerland.Correspondence: [enkelejda.miho@fhnw.ch](mailto:enkelejda.miho@fhnw.ch)

Amyloid light-chain (AL) amyloidosis is a disorder characterized by the accumulation of misfolded light-chain proteins in organs, leading to severe organ dysfunction and failure. It occurs when unstable free light chains from bone marrow plasma cells infiltrate organs, manifesting as symptoms like heart failure, renal impairment, and neuropathy. Diagnosing AL amyloidosis is challenging due to its varied presentations, but technologies like high-throughput sequencing (HTS) and advances in machine learning (ML) are improving precision in diagnostics by detecting disease-specific immune patterns. However, the limited data from this rare disease and data-sharing restrictions across institutions can impede the application of these advanced diagnostics.

This study examines immune repertoire differences between AL amyloidosis patients and healthy controls, leveraging federated learning (FL) to address data-sharing constraints while preserving diagnostic utility. We analyzed mononuclear cell samples from bone marrow aspirates of seven AL amyloidosis patients and memory B cell samples from peripheral blood of seven healthy donors. Sequences were annotated, filtered, and then compared across cohorts. Local Models (LM) were independently trained at two simulated hospitals on filtered data encoded using the BLOSUM62 matrix. These models were then aggregated into a General Model (GM) via the FL platform Flotta5, which combined predictions without data exchange.

The Random Forest classifiers achieved 75% accuracy in classifying AL amyloidosis based on light-chain antibody repertoires, detecting patterns in patient sequences. While the local models showed higher accuracy on their specific datasets, the aggregated GM displayed better generalization across both datasets, indicating the advantage of multi-source data integration for robust predictions. This study demonstrates how federated learning can enhance diagnostic strategies for AL amyloidosis, especially with limited and restricted datasets.

**Benchmarking of Immunoinformatic Tools for Rare Diseases****Jan Kruta<sup>1</sup>, Mario Nuvolone<sup>2</sup>, Alice Nevone<sup>2</sup>, Enkelejda Miho<sup>1,3,4\*</sup>**<sup>1</sup> School of Life Sciences, University of Applied Sciences and Arts Northwestern Switzerland, Muttenz, Switzerland.<sup>2</sup> University of Pavia, Pavia, Italy.<sup>3</sup> Swiss Institute of Bioinformatics, Lausanne, Switzerland.<sup>4</sup> aiNET GmbH, Basel, Switzerland.Correspondence: [enkelejda.miho@fhnw.ch](mailto:enkelejda.miho@fhnw.ch)

Rare diseases present unique challenges in clinical diagnostics and monitoring due to their low prevalence and often severe impact on patients. A timely and precise diagnosis is critical. Next generation sequencing technologies can support precision diagnostics of amyloid light chain or primary amyloidosis (AL amyloidosis) by detecting and tracking the patient-specific immunoglobulin light chains causing AL amyloidosis. These sequences can be analyzed in the context of peripheral blood or bone marrow. Their identity and frequency provides insights on the diagnosis and minimal residual disease (MDR), the small number of cancer cells left in the body after treatment, thus informing personalized therapeutics. These immune biomarkers are essential for monitoring of disease and prediction of relapse.

A crucial step in the diagnostic process after sequencing of blood and bone marrow samples involves annotating and preprocessing raw next-generation sequences of immunoglobulin light chains. However, annotation and preprocessing of high-throughput sequencing data are not uniform across different immunoinformatics tools. These tools process data differently, leading to a variability in results. Harmonizing the output from various tools is a challenge that researchers and clinicians must address during preprocessing to ensure robustness and reproducibility of the analysis. Clinical applications related to precision diagnostics and monitoring of MDR in AL amyloidosis need to address the different output of the various immunoinformatics tools, benchmark these tools and quantify the impact of their different output on clinical insights. Our results show that (i) output differs in terms of a consistent top frequency clone detected from different immunoinformatic tools, (ii) differences in output evident in the overall VJ sequence and in the sequence region lengths, mainly frameworks 3 and complementary determining region 3 lengths (iii) the impact of the output differences across tools depends on the type of analysis performed for the detection and monitoring of the light chain clones, with highest impact on frequency-based analysis and lowest impact on sequence diversity architectures of entire immune repertoires and machine learning results from the detection of sequence patterns specific to AL-amyloidosis.

### **Dual Attention-Enhanced U-Net for Precise Wound Tissue Classification**

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#### Background:

Accurate wound tissue classification is essential for effective treatment and care management. Manual assessments by clinicians often introduce variability, leading to inconsistent treatment decisions. Deep learning (DL) models have emerged as an automated alternative, though many models struggle with classifying multiple tissue types accurately, especially in complex wound environments and across diverse skin tones.

#### Objectives:

The goal of this study is to develop a DL architecture that classifies wound tissue into four key categories: granulation, slough, necrosis, and epithelialization. By integrating VGG16 with U-Net and incorporating dual attention mechanisms, we aim to significantly improve classification accuracy and focus on critical wound regions.

#### Methods:

We designed a hybrid DL model that combines the feature extraction strengths of VGG16 with U-Net's powerful segmentation capabilities. Dual attention mechanisms were integrated to dynamically enhance the model's focus on relevant regions within wound images. The model was trained on a diverse dataset of 1,200 labeled wound images, covering six skin tones, and evaluated against state-of-the-art models using metrics such as the Dice coefficient and overall accuracy.

#### Results:

The proposed model demonstrated superior performance, achieving a Dice coefficient of 78% and an accuracy of 90% on the test set. The use of dual attention mechanisms greatly improved the model's ability to generalize across different skin tones, enhancing its classification accuracy across a diverse range of wound images.

#### Conclusion:

Our architecture, which integrates VGG16, U-Net, and dual attention mechanisms, offers a robust and accurate solution for wound tissue classification. The model's strong performance and ability to generalize across diverse wound types and skin tones make it a promising tool for clinical application, with the potential to improve wound care management and patient outcomes.