**Project Design Phase-II**

**Solution Requirements (Functional & Non-functional)**

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| --- | --- |
| Date |  |
| Team ID | LTVIP2025TMID54121 |
| Project Name | Revolutionizing Liver Care |
| Maximum Marks | 4 Marks |

**Functional Requirements:**

Following are the functional requirements of the proposed solution

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| **Module** | **Functional Requirements** |
| **Data Ingestion** | • Accept structured inputs: demographics, labs (e.g. bilirubin, albumin, platelets, INR), fibrosis scores (FIB-4, APRI, MELD‑Plus) [pubmed.ncbi.nlm.nih.gov+4arxiv.org+4arxiv.org+4](https://arxiv.org/abs/2302.08427?utm_source=chatgpt.com)[pmc.ncbi.nlm.nih.gov+3en.wikipedia.org+3pubmed.ncbi.nlm.nih.gov+3](https://en.wikipedia.org/wiki/MELD-Plus?utm_source=chatgpt.com). <br>• Accept imaging (DICOM: US/CT/MRI/elastography). <br>• Support digitized histology WSIs (if available). <br>• Optional: integrate omics (metabolomics, microbiome) . |
| **Preprocessing & Feature Engineering** | • Clean tabular data: normalization, missing-value handling.  • Segment liver tissue in images using CNNs (e.g., U-Net) and extract radiomic features . <br>• Extract histological markers (fibrosis regions, ballooning). <br>• Select key omics features via ML (e.g., LASSO). | |
| **Modeling & Explainability** | • Train supervised models: Random Forest, Light, XGBoost, Neural Networks, SVM, logistic regression [mdpi.com+7jmai.amegroups.org+7mdpi.com+7](https://jmai.amegroups.org/article/view/9521/html?utm_source=chatgpt.com). <br>• Hybrid architectures combining imaging + structured data (e.g., Dense Net + blood tests with voting classifier, 92.5% accuracy) [arxiv.org+1mdpi.com+1](https://arxiv.org/abs/2504.19755?utm_source=chatgpt.com). <br>• Include interpretability tools (SHAP/LIME, Grad‑CAM). | |
| **Training, Validation & Evaluation** | • Use data splits: train/validation/test + external cohorts.  • Metrics: AUROC, accuracy, sensitivity, specificity; segmentation uses Dice coefficient . <br>• Apply k‑fold cross‑validation. <br>• Compare against traditional scores (FIB‑4, APRI, MELD‑Plus) [translational-medicine.biomedcentral.com+10jmai.amegroups.org+10pubmed.ncbi.nlm.nih.gov+10](https://jmai.amegroups.org/article/view/9521/html?utm_source=chatgpt.com). <br>• Use calibration, decision‑curve analyses. | |
| **Deployment & Integration** | • Provide REST APIs for image segmentation and risk scoring.  • Web UI dashboard: data upload, viewing explanations, PDF reporting.  • EHR/EMR integration for flagging at-risk patients.  • Deploy on GPU-enabled cloud or local servers. |
| **Monitoring & Maintenance** | • Monitor real‑world performance (drift, FP/FN rates).  • Retrain with new histology/outcomes.  • Versioning and audit logs.  • Regulatory compliance: GDPR/HIPAA, ISO 13485. |
| **Security, Ethics & Governance** | • Encrypted data at rest and in transit; RBAC.  • Fairness validation across demographics.  • Clinician-in-the-loop: human overrides.  • Regulatory readiness: FDA/EMA documentation. |
| **Future Enhancements** | • Integrate real-time monitoring (wearables, sensors) using time‑series AI [pubmed.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/39837961/?utm_source=chatgpt.com). <br>• Build multimodal early-warning systems with dynamic predictions . |

**Non-functional Requirements:**

Following are the non-functional requirements of the proposed solution

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| **NFR Category** | **Requirement** | **Rationale / Measurable Criteria** |
| **Performance & Responsiveness** | • Risk prediction must return results within **<500 ms** for real-time use.<br>• Batch processing can run **overnight**, handling ≥10K records. | Ensures usable response times for clinicians; meets expectations for both real-time triage and bulk reporting. [sciencedirect.com+8slideshare.net+8pmc.ncbi.nlm.nih.gov+8](https://www.slideshare.net/slideshow/document-effective-heart-disease-prediction-using-hybrid-machine-learning-techniques-docx/276004175?utm_source=chatgpt.com) |
| **Scalability & Capacity** | • Support **horizontal scaling** to handle increased users/data. • Efficient use of CPU/GPU: ≤70% utilization per node. | Prepares the system for growth in workload across sites and higher data volumes. |
| **Reliability & Availability** | • ≥ 99.5% uptime SLA. • Aim for MTBF ≥ 30 days; MTTR ≤ 1 hour. • Graceful degradation during partial failures. | Ensures high system availability critical in healthcare settings. |
| **Data Integrity & Quality** | • Validate all inputs: no more than 1% missing or invalid lab values. • Maintain **audit trail** of data lineage. | Guarantees trusted predictions and regulatory compliance via traceability. |
| **Robustness & Model Resilience** | • Maintain ≥ 90% baseline accuracy under moderate noise/adversarial scenarios. • Monitor for concept drift; retrain if AUC drops >5%. | Prevents silent degradation and ensures reliable performance over time. |
| **Reproducibility & Repeatability** | • Same training config and seed yields AUC variation ≤ 0.01. • Predicting identical inputs produces ≤1% variation. | Critical for clinical trust and regulatory auditability. |
| **Explainability & Transparency** | • Provide SHAP/LIME for tabular data; Grad-CAM for imaging. • Document model structure, assumptions, error rates, uncertainty. | Meets clinicians' need to understand and trust AI decisions. |
| **Security & Privacy** | • Full encryption (TLS + AES-256). • Role-based access control. • Data anonymization; GDPR/HIPAA compliance. • Federated learning support. | Essential to protect sensitive patient data and enable multi-institutional collaboration. |
| **Usability & Accessibility** | • Response interface conforming to WCAG 2.1 AA. • ≤ 3 clicks to generate a report; UI task time ≤ 2 minutes. | Ensures accessibility and efficiency for end users. |
| **Maintainability & Extensibility** | • Modular architecture (API-based). • Code coverage ≥ 80%, CI/CD pipeline. • Retraining pipelines for new data. | Promotes long-term adaptability and easier software updates. |
| **Auditability & Logging** | • Log all model runs, data changes, user actions. • Retain logs for ≥ 7 years. | Provides traceability and supports compliance with medical device regulations. |
| **Portability & Interoperability** | • Compatible with Windows, Linux; containerized (Docker/K8s). • FHIR and DICOM support. | Ensures integration with diverse clinical infrastructures. |
| **Testability & Validation** | • Automated tests for edge cases and drift detection. • Validate fairness across demographics. | Ensures consistent efficacy and identifies performance disparities. |