* + 1. **External Requirements**

**3.2.3.1 Regulatory**

* Data protection and privacy laws: The system must comply with Albanian data protection laws, including the General Data Protection Regulation (GDPR) and the Albanian Law on Personal Data Protection.
* Healthcare regulations: The system must comply with Albanian healthcare regulations, including regulations related to the storage and handling of medical records and patient information.
* Technical standards: The system must comply with relevant technical standards for electronic healthcare systems, including those related to data security and data interoperability.
* Accreditation: The system must meet the requirements of relevant accreditation bodies for healthcare systems in Albania, such as the Albanian National Accreditation Body.

**3.2.3.2 Ethical Requirements**

* Patient confidentiality: The system must maintain the confidentiality of patient information and only release it in accordance with patient consent or as required by law.
* Data security: The system must have appropriate security measures in place to protect patient data from unauthorized access, modification, or theft.
* Fairness and impartiality: The system must be impartial and not discriminate against patients based on race, religion, gender, age, or any other characteristic.
* Responsibility and accountability: The system must be responsible for ensuring that patient information is accurate, complete, and up-to-date, and must have processes in place for correcting errors and responding to patient inquiries.
* Transparency: The system must be transparent in its operations and decision-making processes, and must provide patients with information about their rights and responsibilities.
* Respect for patients: The system must respect patients' autonomy and dignity, and must ensure that patients are treated with compassion and understanding.
  + - 1. **Legislative Requirements**
* Healthcare laws: The system must comply with relevant Albanian healthcare laws and regulations, including laws related to patient privacy and data protection, healthcare services, and the storage and handling of medical records.
* Electronic commerce laws: The system must comply with relevant Albanian electronic commerce laws, including laws related to electronic signatures, data security, and consumer protection.
* Data protection laws: The system must comply with Albanian data protection laws, including the General Data Protection Regulation (GDPR) and the Albanian Law on Personal Data Protection.
* Contract law: The system must comply with relevant contract law in Albania, including laws related to the formation, performance, and termination of contracts.
* Consumer protection laws: The system must comply with relevant Albanian consumer protection laws, including laws related to the protection of consumer rights and interests.
* Intellectual property laws: The system must comply with relevant Albanian intellectual property laws, including laws related to copyrights, trademarks, and patents.