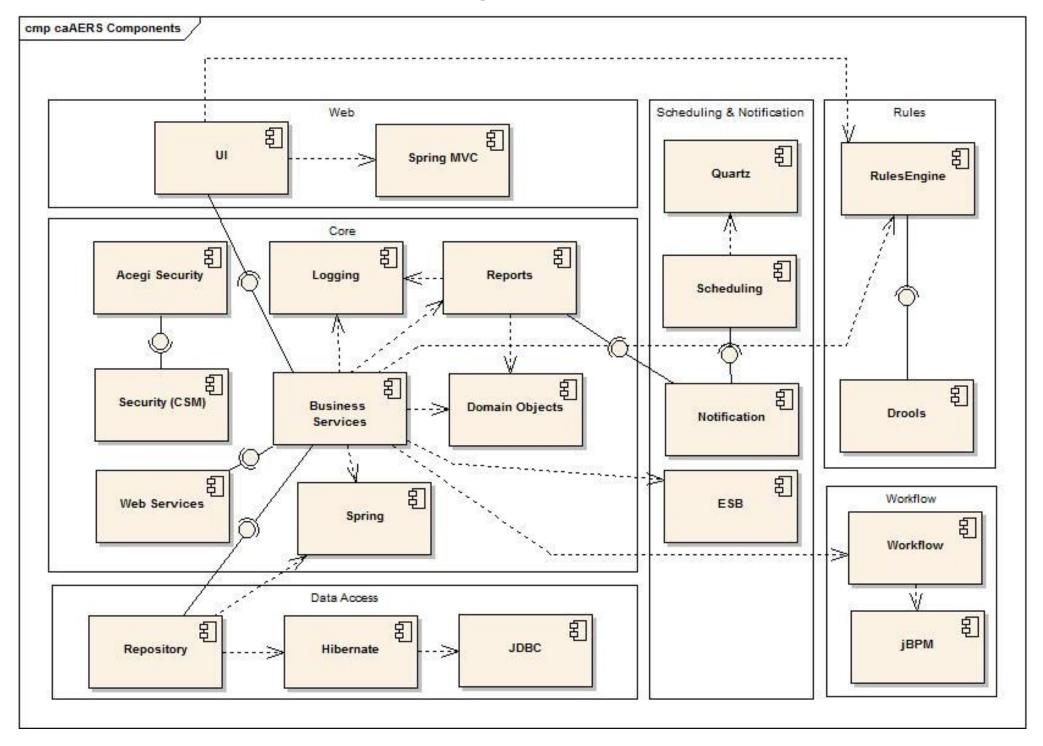
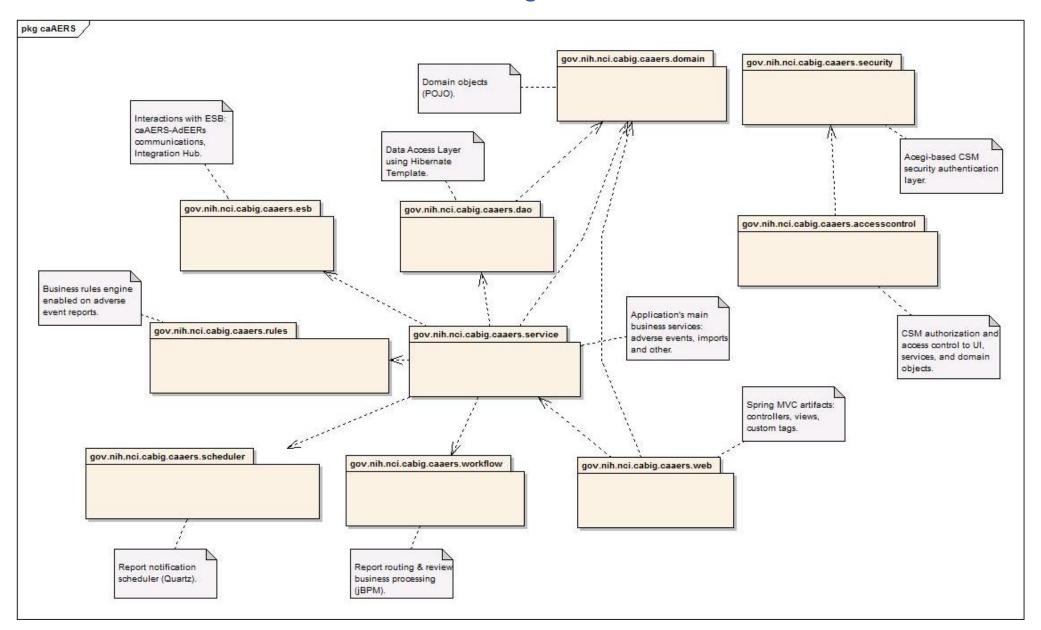


#### **Components**

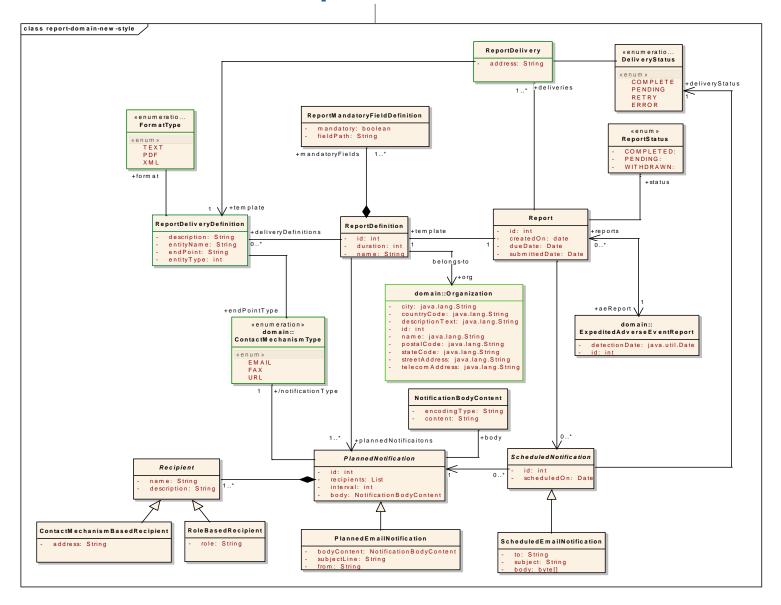


### **Packages**

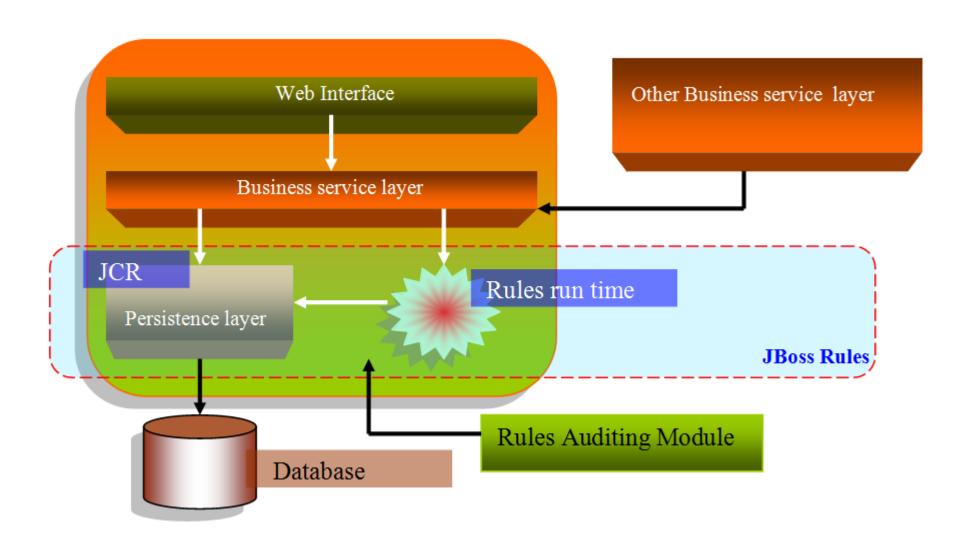


#### **Adverse Events Domain** +adverseEvent AdverseEvent attributionToStudy: int 0. comments: string endDate: java.util.Date eventApproximateTime: TimeValue eventLocation: string expected: boolean grade: Grade adverseEvents ort ExpeditedAdverseEventReport gradedDate: java.util.Date hospitalization: boolean id: int timeCreated: java.sql.Timestamp postSubmissionUpdatedDate: java.util.Date reported: boolean signature: java.lang.String startDate: java.util.Date +aeReport verbatim: java.lang.String +adverseEvents / 0. +reportingPeriod +reportingPeriod 1 AdverseEventReportingPeriod oydeNumber: int dataEntryStatus: String description: java.lang.String description: String name: java.lang.String endDate: java.util.Date isBaseline: boolean +epochs/\ 0. name: String startDate: java.util.Date +observations / 0. Study descriptionText: java.lang.String id: int loadStatus: LoadStatus +study longTitleText: java.lang.String multilnstitutionIndicator: boolean phaseCode: StudyPhaseCode precisText: java.lang.String reportFormats[]: ReportFormatType +treatmentAssignments \ shortTitleText: java.lang.String **TreatmentAssignment** status: java.lang.String treatmentAssignment verbatimFirst: boolean code: java.lang.String comments: java.lang.String description: java.lang.String doseLevelOrder: java.lang.Integer StudyParticipantAssignment StudyParticipantPreExistingCondition assignmen+preConditions baselinePerformance: java.lang.String other: java.lang.String firstCourseDate: java.util.Date 0 id: int startDate: java.util.Date +precondition +priorTherapies /\0. +assignment PreExistingCondition id: int meddraHighLevelGroupTerm: java.lang.String +medications meddraLowLevelTerm: java.lang.String meddraLowLevelTermCode: java.lang.String StudyParticipantConcomitantMedication text: java.lang.String agentName: java.lang.String endDate: java.util.Date +assignment \ startDate: java.util.Date stillTakingMedication: boolean StudyParticipantPriorTherapy PriorTherapy +priorTherapy endDate: java.util.Date other: java.lang.String meddraCode: java.lang.String startDate: java.util.Date meddraTerm: java.lang.String text: java.lang.String StudyParticipantPriorTherapyAgent +agents +diseaseHistory 0 StudyParticipantDiseaseHistory diagnosisDate: java.util.Date otherPrimaryDisease: int otherPrimaryDiseaseSite: java.lang.String

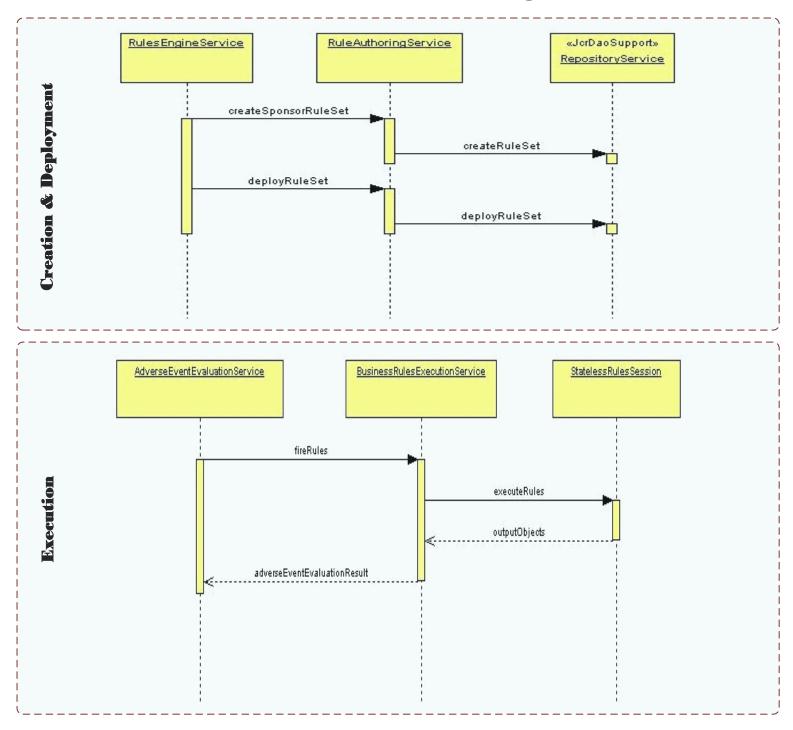
#### **Reports Domain**



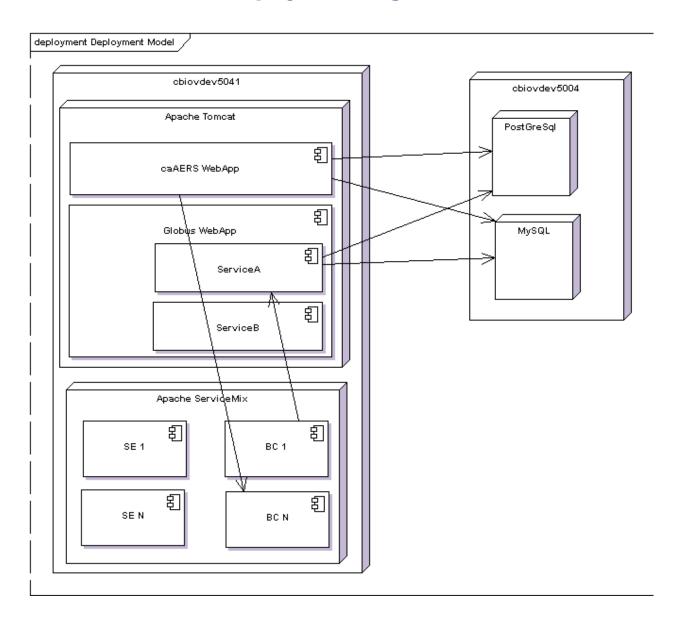
### **Business Rules Architecture**



### **Business Rules Processing**



# **Deployment Diagram**



# **Requirement/Solution Matrix**

Requirement	Motivation & Challenges	Solution	Technolo	Reasoning
Portability & Platform-Independence  Portability	Run reliably on all major platforms and databases	Platform- independent language & ORM	Java/Hibe rnate	<ul> <li>Proved platform- independence</li> <li>Portability across databases with little</li> </ul>
Adverse Event Reporting Business Rules  Module 1d	<ul> <li>Very adaptive to changes in business.</li> <li>Rapid provisioning.</li> <li>Domain-specific authoring of rules.</li> <li>Decoupled from Java source code</li> </ul>	framework Rules Engine	Drools	or no changes.  Spring integration Open-source Strong financial backing Large community
Report Routing & Review  Module 5	<ul> <li>Very adaptive to individual organization's needs for report review process.</li> <li>Platform-independent authoring</li> <li>Decoupled from Java source code</li> </ul>	Workflow Engine	јВРМ	<ul> <li>Integration with Spring Hibernate, databases</li> <li>Open-source</li> <li>Strong financial backing</li> <li>Large community</li> <li>Multiple process definition languages</li> </ul>
Adverse Event Capture & Reporting  Module 1a	<ul> <li>Run notifications on a given schedule</li> <li>Reliability (schedule survives server restarts and crashes)</li> <li>Flexible way of describing the schedule</li> </ul>	Scheduling Engine	Quartz	<ul> <li>Lightweight</li> <li>Integration with Spring and Hibernate</li> <li>Supports CRON syntax</li> <li>Uses database to persist jobs</li> </ul>
External Agency Reporting  Module 4	<ul> <li>Conformance to reporting requirements of external agencies in a scalable manner.</li> <li>Decoupling from external systems' interfaces</li> </ul>	Enterprise Service Bus	Apache ServiceMi x / iHub	<ul> <li>Consistency: used already by the Suite Applications</li> <li>Standardization (JBI)</li> <li>Open-source</li> </ul>
User Interface  GUI Specification	UI should be pretty, responsive, and easy to use UI must create an impression of a desktoplike application and avoid unnecessary page refreshes UI must work across browsers	Web 2.0	AJAX, YUI, Prototype, Scriptacul ous	<ul> <li>Cross-browser         JavaScript support</li> <li>Rich widget         collection</li> <li>Strong backing</li> <li>Open-source</li> <li>Large community</li> </ul>