Life Cycle of Lab-based Quantitative AE
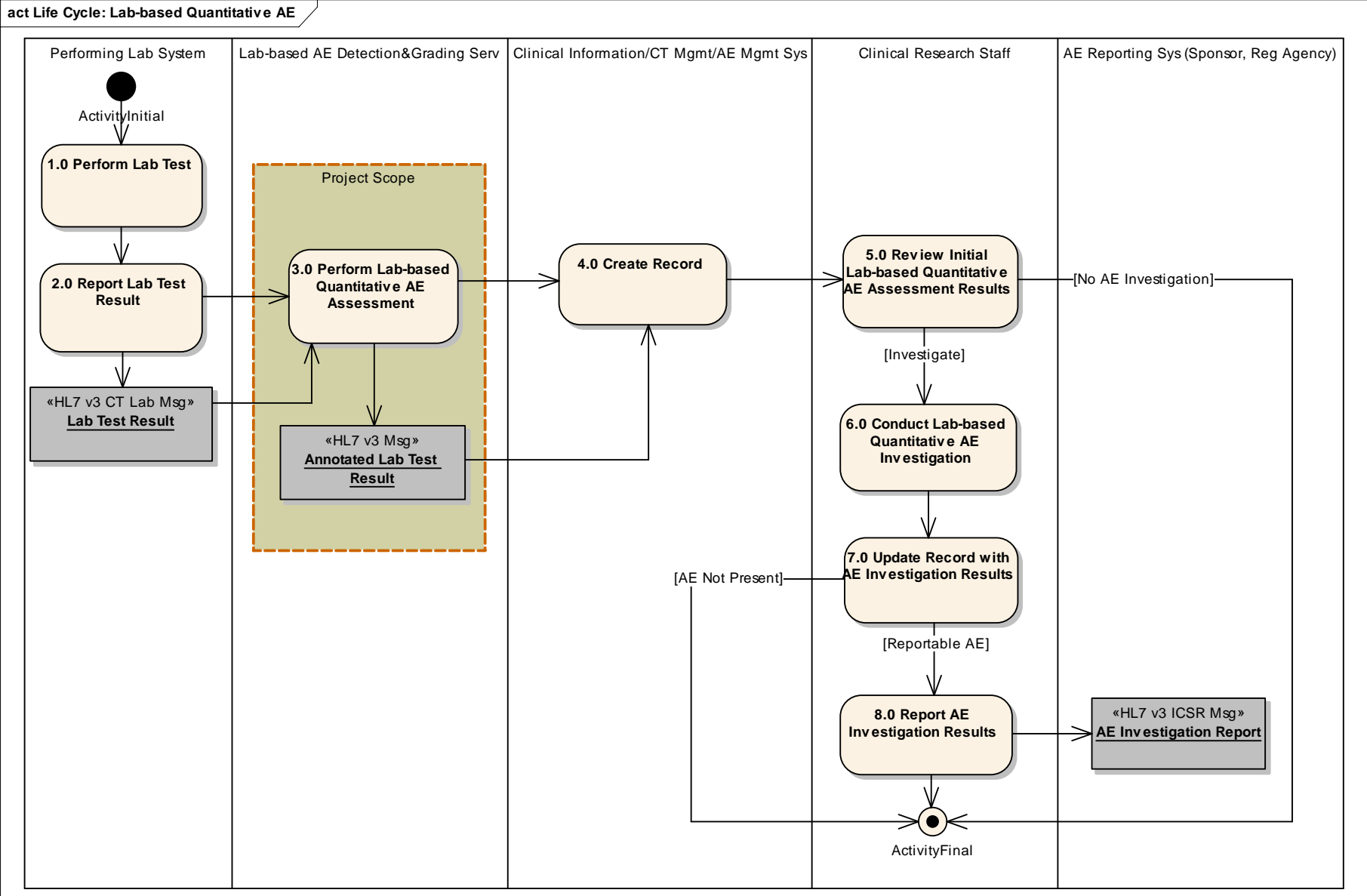
act Life Cycle: Lab-based Quantitative AE

Figure 1: Life Cycle: Lab-based Quantitative AE

1.0 Perform Lab Test

Type: *public* **Activity**
Package: Life Cycle of Lab-based Quantitative AE

A laboratory facility within the local clinical research environment conducts an analysis of a patient specimen, as directed in the order request.

2.0 Report Lab Test Result

Type: *public* **Activity**
Package: Life Cycle of Lab-based Quantitative AE

This activity represents the process by which the performing laboratory facility issues the outcome of the analysis that was performed on the patient specimen.

Lab Test Result

Type: *public «HL7 v3 CT Lab Msg»* **Object**
Package: Life Cycle of Lab-based Quantitative AE

This message contains the laboratory test result data, including such items as patient ID, specimen accession #, specimen collection date/time, laboratory test name, test result value, test reference interval, test result unit of measure.

3.0 Perform Lab-based Quantitative AE Assessment

Type: *public* **Activity**
Package: Life Cycle of Lab-based Quantitative AE

This activity represents the automated process of evaluating a lab test result that is subject to quantitative adverse event assessment using a specified grading scale.

An automated lab-based AE detection and grading service evaluates lab test result data, and:
a.) Detects and assesses/grades the level of severity of the AE represented by the lab test result; OR
b.) Determines that the test result is within normal limits and that the corresponding lab-based AE for which the assessment is performed is Not Present; OR
c.) Determines that lab data required for a quantitative AE assessment is/are missing or invalid, and an exception/error note is returned

Annotated Lab Test Result

Type: *public «HL7 v3 Msg»* **Object**
Package: Life Cycle of Lab-based Quantitative AE

This message contains the original laboratory test result data as provided in the incoming Lab Test Result message, as well as the results of the initial quantitative lab-based AE assessment, which consists of:
a.) The AE Category, AE Term(s), AE grade(s), additional comments about the grade(s) and/or assessment when applicable, OR
b.) An exception/error describing the reason(s) a lab-based quantitative AE assessment could not be performed for a lab test result.

4.0 Create Record

Type:　　　　*public* **Activity**
Package:　　　Life Cycle of Lab-based Quantitative AE

This activity represents the process of creating a new record for the laboratory test result data and the results of the initial lab-based quantitative AE assessment.

The local clinical research site is responsible for determining the appropriate repository/system for consuming the Annotated Lab Test Result HL7 v3 message.

5.0 Review Initial Lab-based Quantitative AE Assessment Results

Type:　　　　*public* **Activity**
Package:　　　Life Cycle of Lab-based Quantitative AE

This activity represents the manual process by which the local clinical research staff reviews the laboratory test result data and its corresponding initial quantitative AE assessment to identify those that require an AE investigation.

A lab test result assessed to be within normal limits may not require or be associated with an AE investigation.

6.0 Conduct Lab-based Quantitative AE Investigation

Type:　　　　*public* **Activity**
Package:　　　Life Cycle of Lab-based Quantitative AE

This activity represents the manual process by which local clinical research staff gathers information about the patient's condition and assesses for qualitative factors in order to determine, in part, the final grade for a quantitatively indeterminate grade, and/or the reporting requirements as dictated by such entities as the protocol sponsor, the oversight committee, and/or the regulatory agency.

7.0 Update Record with AE Investigation Results

Type:　　　　*public* **Activity**
Package:　　　Life Cycle of Lab-based Quantitative AE

This activity represents the manual process by which local clinical research staff updates the record containing the raw laboratory test result data and its initial quantitative AE assessment results, to reflect the findings of the AE investigation.

8.0 Report AE Investigation Results

Type:　　　　*public* **Activity**
Package:　　　Life Cycle of Lab-based Quantitative AE

This activity represents the process by which the local clinical research staff submits a report for an investigated AE as required by such entities as the protocol sponsor, the oversight committee, and/or the regulatory agency.

AE Investigation Report

Type:　　　　*public «HL7 v3 ICSR Msg»* **Object**
Package:　　　Life Cycle of Lab-based Quantitative AE

This object represents the output of the activity Report AE Investigation Results. The report contains information that describes and provides supporting evidence for an AE experienced by a particular patient.