Scilife

Deep dives:
Tackle OOS with Scilife's Events solution like a pro

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Housekeeping

Today's session will be recorded

Use Zoom Chat if you have technical difficulties

Drop your question at the Zoom Q&A

Recording will be sent to you

Resources in the Academy (Product certifications)

Certifications

Product video Events

Administrator certification: Events Tool

Product video Events

Regular user certification: Events tool

Product video Events

Manager certification: Events Tool

Product video Events

Read-Only certification: Events tool

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01

Introduction to OOS, OOT, OOE

Guidelines

Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

May 2022

Pharmaceutical Quality/Manufacturing Standards
Current Good Manufacturing Practice (CGMP)

Revision 1

Medicines & Healthcare products Regulatory Agency

MHRA

Out of Specification & Out of Trend Investigations

October 2017

OOS vs OOT vs OOE

Out-of-Specification (OOS) **Result**

All test results that **fall outside the specifications or acceptance criteri**a established in drug applications, drug master files (DMFs), official compendia, or by the manufacturer.

The term also applies to all in-process laboratory tests (IPCs) that are outside of established specifications.

OOS vs OOT vs OOE

Out of Trend (OOT) **Result**

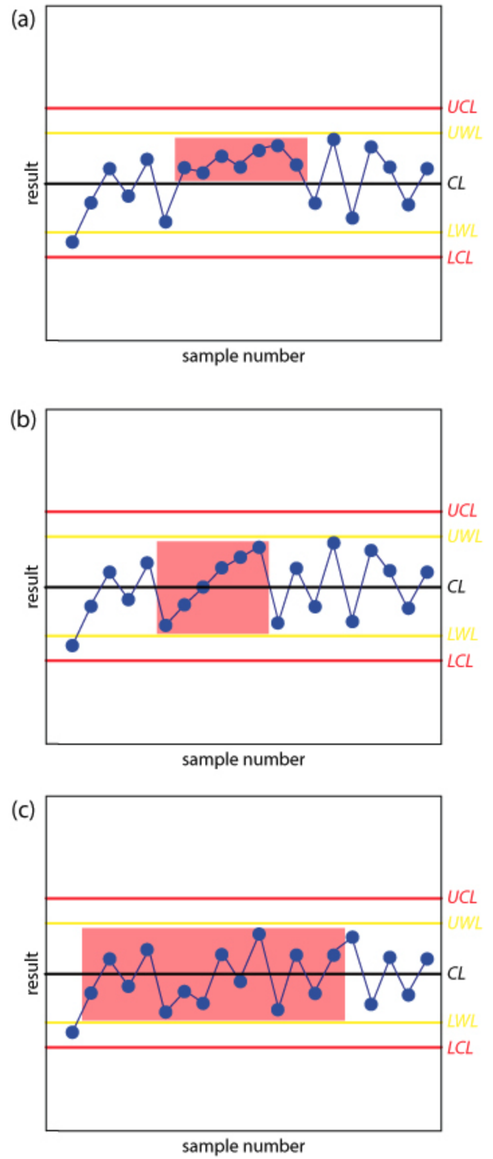
A test result that does not follow the expected trend, either in comparison with other batches or with respect to previous results collected during:

- a stability study
- starting materials and in-process samples
- Semi-finished or final products

The result is not necessarily OOS but **does not look like a typical data point**.

Should be considered for environmental trend analysis such as for viable and non viable data (action limit or warning limit trends)

UNDER CONSIDERATION



OOS vs OOT vs OOE

Out of Expectation (OOE) **Result**

- Atypical / Aberrant / Anomalous Result
- Test results that are still within specification but are unexpected, questionable, irregular, deviant or abnormal.
- Examples:
  - Chromatograms that show unexpected peaks
  - Unexpected results for stability test point
  - Etc.

Important to note that OOE...

It's important to note that ...

- Unlike an OOS result, which fails to meet predetermined acceptance criteria, or an OOT result, which doesn't follow an expected data pattern, an OOE (atypical result) *does* meet the specified limits but raises concerns due to its unusual nature.
- OOE results often trigger investigations, similar to OOS and OOT results, to understand the underlying cause.

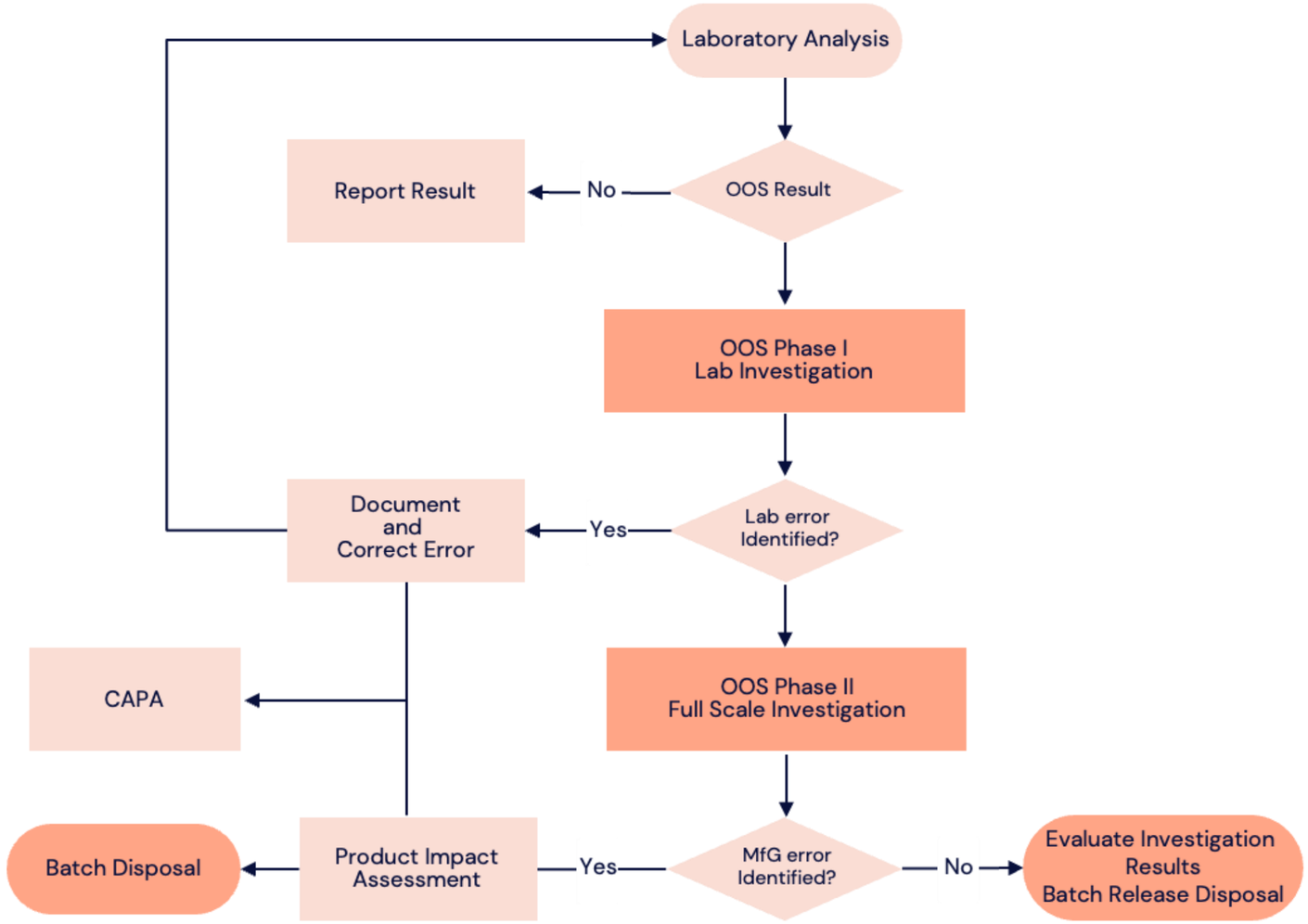
02

OOS PROCESS

INVESTIGATION PROCESS

1. **Phase 1:** Initial lab investigation
2. **Phase 2:** Full scale investigation
3. **Phase 3:** Concluding phase (Batch disposition and CAPAs)

OOS process


Laboratory Analysis
OOS Result
No
Report Result
OOS Phase I
Lab Investigation
Lab error
Identified?
Yes
Document
and
Correct Error
CAPA
OOS Phase II
Full Scale Investigation
MfG error
Identified?
No
Evaluate Investigation
Results
Batch Release Disposal
Product Impact
Assessment
Yes
Batch Disposal

Phase I (Lab investigation)

-Initial assessment lab's data
-Aberration of lab process?

-Lab error/Instrument malfunction
-Initial checklist:
- Method
- Data
- Calculations
- Equipment
- Reagents/standards

-Analyst vs supervisor

-Hypothesis testing:
- Use test preparations
- Use same composite sample

Phase II (Full-scale investigation)

-Phase I investigation is inconclusive
-Aberration of manufacturing process?

-Manufacturing review & others
-Sampling review
-Additional lab testing
- Retesting
- Resampling

-Product impact assessment in other lots/products

Phase III (Conclusion and batch disposal)

-Results evaluation
-Root-cause

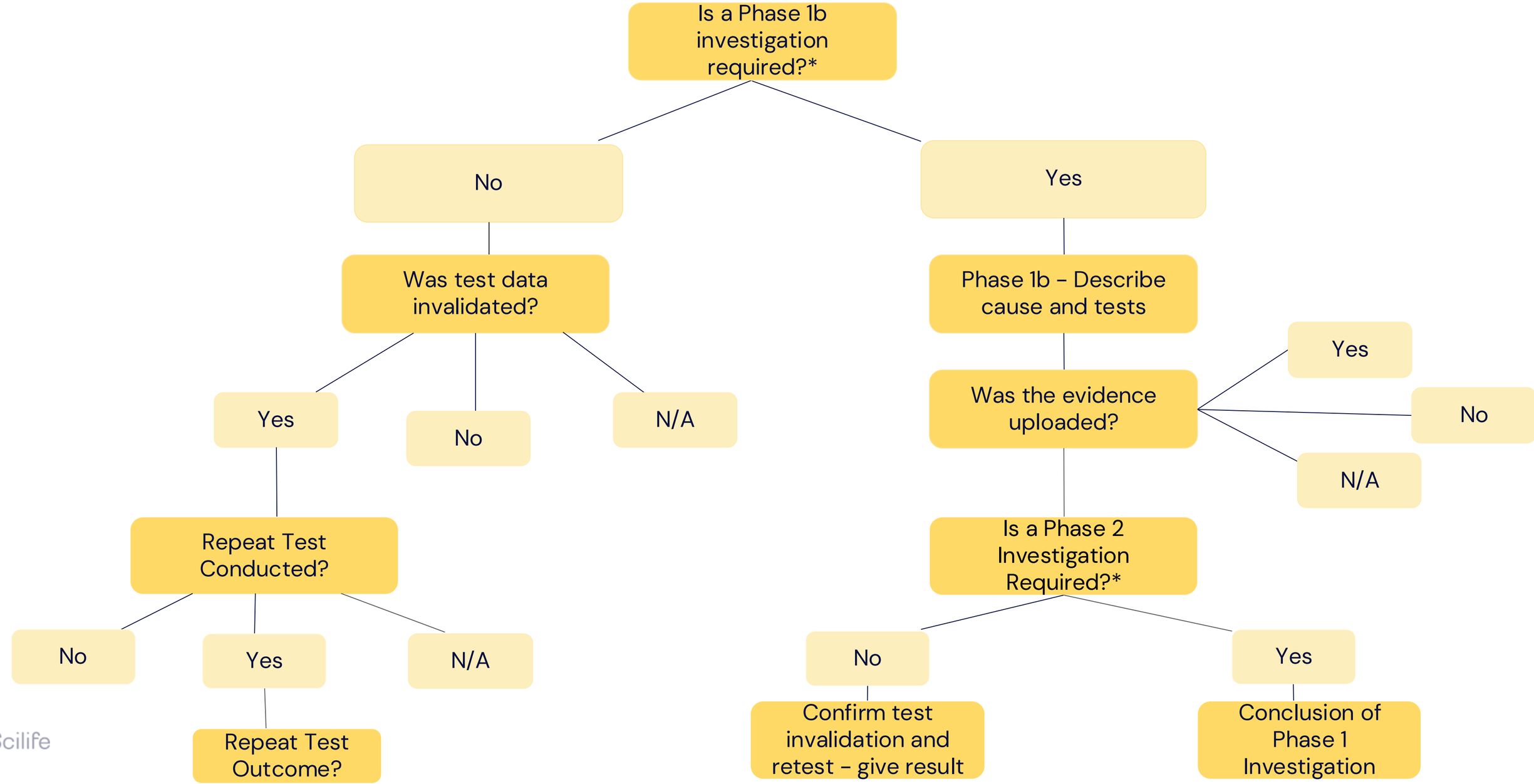
-Conclusive/Inconclusive

-Release decision

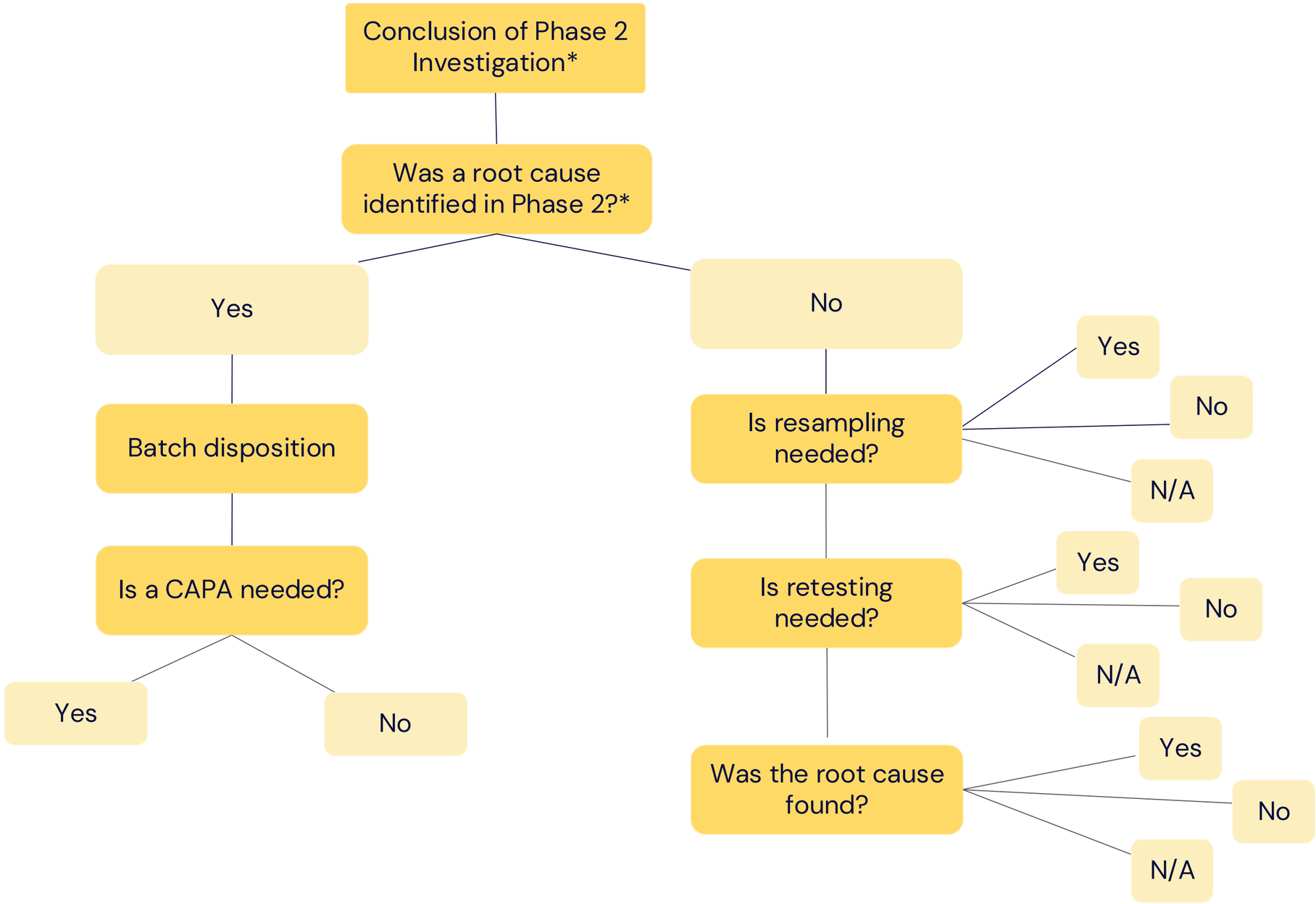
03

Demo OOS process with Events solution

Phase 1a & 1b Investigation



Phase 2 Investigation



Questions & Answers

Scilife

Thanks

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