

Method Health After Transfer

Post-transfer monitoring window · one method, one version, six periods after a controlled change

Representative figures. No employer, product, or vendor named.

FIRST-PASS ACCEPTANCE
96%
target 94%

INVALID / NON-REPORTABLE
2%
criterion 5%

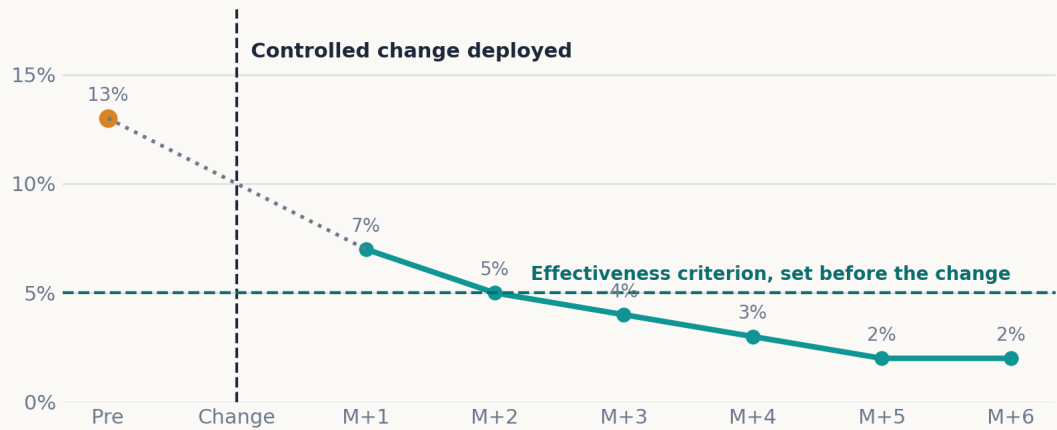
OPEN EXCEPTION CASES
2
both classified

DETECTION TO CLASSIFICATION
6 d
target 10 d

METADATA COMPLETENESS
100%
9 of 9 attributes

CAPA DURABLE AT 90 D
Yes
re-check at 180 d

RECOVERY AGAINST A CRITERION SET BEFORE THE CHANGE



OPEN AND CLOSED EXCEPTIONS, BY CLASSIFIED ROOT CAUSE

CLASSIFIED ROOT CAUSE	N	STATUS
Structural — endpoint gap	14	Closed
Analyst execution variance	4	Closed
Instrument configuration	3	Closed
Data-processing rule mismatch	2	Open
Upstream sample handling	1	Open

ESCALATION THRESHOLDS, AGREED IN ADVANCE

- Two consecutive periods above criterion opens a case.
- Same root-cause category twice forces a structural review.
- Any exception with no classification at 10 days escalates.

THE CUTS THAT TURNED A COMPLAINT INTO A DIAGNOSIS

By analyst group
No difference after queue time controlled
RULED OUT

By instrument
No difference across qualified units
RULED OUT

By product
Consistent across all products on the method
RULED OUT

By queue time
Failure rises sharply beyond the tested range
ROOT CAUSE

SIGNAL DEFINITION, AGREED BEFORE THE FIRST RELEASE RUN

WHAT COUNTS AS A SIGNAL
Non-reportable rate above criterion in any single period, or an upward trend across three consecutive periods.

THRESHOLD AND CRITERION
Criterion 5 percent, derived from the method acceptance criteria rather than from observed performance.

REVIEW CADENCE AND OWNER
Weekly through the monitoring window, then trended into periodic product review. Owner is a named role in QC.

EXIT CRITERIA
Six consecutive periods at or below criterion with no unclassified exception open. The method then leaves the window.