

Operationalizing {gsm} with {grail}

Risk Signal Triage for Central Monitoring

PHUSE 2026

2026-03-16

Agenda

1. Background
2. Intro to {grail}
3. {grail} Process
4. Action Management
5. Reporting Layer
6. Conclusion



Background

{gsm} Overview

- {gsm} (Good Statistical Monitoring) is a qualified set of R packages that provides a GxP framework for central monitoring in clinical trials.
- Designed to support a variety of business processes, from manually executed RBQM reporting to enterprise-wide monitoring platforms.
- 10+ packages, 50+ releases, deployed across 20+ clinical studies.

{gsm} Business Process - Analytics

- View Studies in Portfolio
- View Reports for a Study
- View Site Trends in a Report
- View Participant Trends in Deep Dive App

{gsm} Business Process - Analytics

View Studies in Portfolio

Studies

ID ↓ ▼	Name ▼	Report Status ▼	Study Status ▼	Site Activation	Enrollment	FPFV
uat-S0003 →	OAK-11	active	Active	7 / 100 (7%)	21 / 500 (4.2%)	2012-01-05
uat-S0004 →	OAK-37	active	Active	3 / 50 (6%)	10 / 250 (4%)	2012-01-12
uat-S0005 →	GROOVE-64	active	Active	2 / 50 (4%)	11 / 250 (4.4%)	2012-01-15
uat-S0006 →	GROOVE-66	active	Active	19 / 110 (17.3%)	92 / 546 (16.8%)	2012-01-04
uat-S0007 →	TREE-75	active	Active	6 / 10 (60%)	16 / 20 (80%)	2012-01-18

View all studies →

{gsm} Business Process - Analytics

View Reports for a Study

uat-S0004 OAK-37

active

Study Characteristics

Therapeutic Area	Inflammation
Indication	Cardiovascular Health
Product	Product Name 3
Phase	P3
Status	Active
Site Activation	3 / 50 (6%)
Enrollment	10 / 250 (4%)
FPFV	2012-01-12
LPFV	2012-12-21
LPLV	2013-03-26

Resources

Study-specific

[ClinOps Dashboard](#)

Central Monitoring Tools

Country-Level Key Risk Indicator Report

Jan 31, 2012

Site-Level Key Risk Indicator Report

A report summarizing key risk indicators at the site level

QTL Report

Jan 31, 2012

Deep Dive App

Launch

Endpoint Monitoring

Progression-Free Survival Report

Jan 31, 2012

{gsm} Business Process - Analytics

View Site Trends in a Report

Set Up

Report

Study Status

Study Overview

Results

Adverse Event Rate

Serious Adverse Event Rate

Non-Important Protocol Deviation Rate

Important Protocol Deviation Rate

Grade 3+ Lab Abnormality Rate

Study Discontinuation Rate

Treatment Discontinuation Rate

Query Rate

Delayed Query Resolution Rate

Delayed Data Entry Rate

Data Change Rate

Screen Failure Rate

PK Collection Compliance Rate

Inclusion/Exclusion Violation Rate

Metric Details

Study Overview

58 Red KRIs81 Amber KRIs

Summary Charts

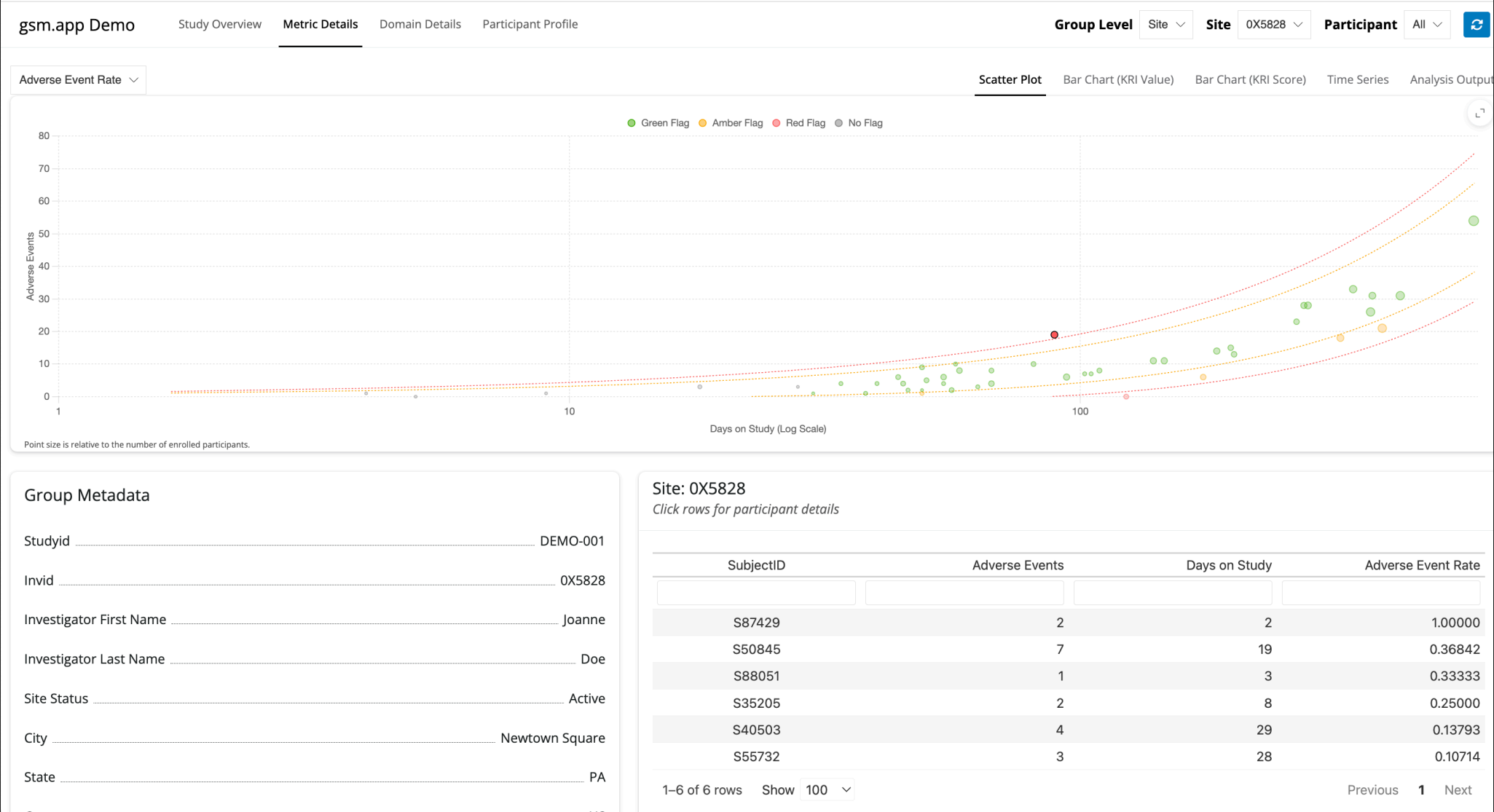
Site Overview

Site Subset: 1+ red flag

Group	Enrolled	Red Flags	Amber Flags	Risk Score	AE	SAE	PD	IPD	LB	SDSC	TDSC	QRY	OQRY	ODAT	CDAT	SF	PK	IE
0X213 (Smith)	10	2	2	34	⬇️	✅	✅	✅	✅	—	⬆️	✅	✅	✅	⬆️	✅	—	⬆️
0X4535 (Doe)	7	2	1	9	✅	⬇️	✅	✅	✅	—	—	✅	✅	⬆️	✅	✅	—	⬆️
0X759 (Smith)	5	2	0	25	✅	✅	✅	✅	✅	⬆️	—	✅	✅	✅	✅	✅	—	⬆️
0X3601 (Doe)	5	1	3	15	⬇️	⬇️	⬇️	✅	—	—	—	✅	✅	—	✅	✅	—	⬆️
0X9360 (Smith)	10	1	2	25	✅	✅	✅	✅	✅	⬆️	⬆️	✅	✅	✅	✅	✅	—	⬆️
0X4338 (Doe)	4	1	2	21	✅	⬇️	✅	⬆️	✅	—	—	✅	✅	✅	✅	✅	✅	⬆️
0X2005 (Deer)	5	1	2	16	⬇️	⬇️	✅	✅	✅	—	—	✅	✅	✅	✅	✅	—	⬆️
0X4264 (Deer)	9	1	2	16	⬇️	⬇️	✅	✅	✅	—	—	✅	✅	✅	✅	✅	—	⬆️
0X7514 (Deer)	5	1	2	9	⬆️	⬆️	✅	✅	✅	—	—	✅	✅	✅	✅	✅	—	⬆️
0X9346 (Doe)	9	1	2	16	⬇️	⬇️	✅	✅	✅	—	—	✅	✅	✅	✅	✅	—	⬆️
0X4323 (Smith)	14	1	1	8	✅	⬇️	✅	✅	✅	✅	—	✅	✅	✅	✅	✅	—	⬆️
0X8799 (Doe)	10	1	1	9	✅	✅	✅	✅	✅	—	—	✅	✅	✅	⬆️	✅	✅	⬆️
0X1750 (Smith)	6	1	1	16	⬇️	✅	✅	✅	✅	—	—	✅	✅	✅	✅	✅	—	⬆️
0X187 (Smith)	6	1	1	16	⬇️	✅	✅	✅	✅	—	—	✅	✅	✅	✅	✅	—	⬆️
0X1881 (Doe)	5	1	1	12	✅	✅	⬆️	✅	✅	—	—	✅	✅	✅	✅	✅	—	⬆️
0X2532 (Doe)	6	1	1	16	✅	✅	✅	⬆️	✅	—	—	✅	✅	✅	✅	✅	—	⬆️

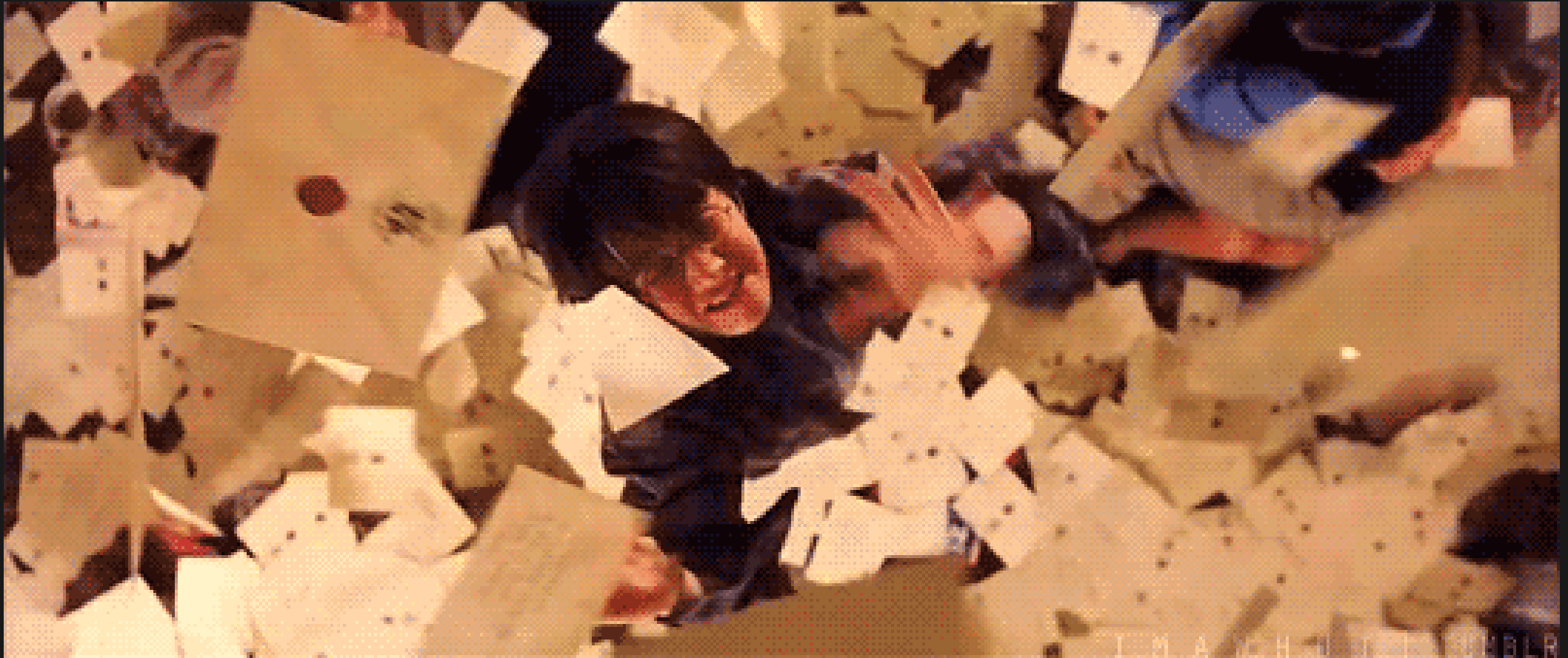
{gsm} Business Process - Analytics

View Participant Trends in Deep Dive App



{gsm} Business Process

And then what?



Intro to {grail}

Detection $\neq$ Action

- ICH E6(R2)/(R3), FDA, and EMA require **proactive risk detection**
- Central monitoring analytics can reliably **identify** potential risks
- But there is a persistent gap between **statistical detection** and **operational actioning**

❗ Flagging an anomaly is not the same as resolving it. CM teams need consistent business rules and workflows to convert risk signals into actionable, traceable tasks.

Scaling {gsm} to Portfolio-Level Risk Management

Early {gsm} deployments relied on analyst-driven spreadsheets to track and triage signals.



This became unsustainable as portfolio grew to 20+ studies.

Introducing {grail}

{gsm} Risk and Issue Listing

The {gsm} Risk And Issue Listing, or **{grail}**, is an R package that operationalizes **{gsm}** using reproducible workflows for risk signal triage and action management.

- Converts raw analytic flags → **action-ready risk signals**
- Enables **consistent and transparent** risk-based oversight
- Part of the broader open-source **{gsm}** framework



{grail} standardizes the post-analytics business process with *Consistent*, *Transparent*, and *Scalable* workflows.

{grail} Process

{gsm} Business Process - Analytics

1. View Studies in Portfolio
2. View Reports for a Study
3. View Site Trends in a Report
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{gsm} Business Process - Actions

5. **Create Risk Signals** — Create enhanced {grail} risk signals from {gsm} metrics.
6. **Action Risk Signals** — SME evaluates Risk Signals in dedicated Action Log (e.g. CTMS) for triage and follow-up.
7. **Monitor Trends** — Synchronize risk signal status with reporting layer for oversight and continuous improvement.

 Separates **analytics** from **actions** while keeping both tightly connected through structured metadata.

All workflows are YAML-defined via the {workr} engine — reproducible, configurable, and human-readable.

Full {gsm} Business Process

Analytics

1. View Studies in Portfolio
2. View Reports for a Study
3. View Site Trends in a Report
4. View Participant Trends in Deep Dive App

Actions

5. Create Risk Signals
6. Action Risk Signals
7. Monitor Trends

Overview

{grail} provides business logic that converts raw metrics into actionable risk signals by adding:

1. **Link Metadata** — study ID, snapshot date, metric labels, model info, report links, site/country descriptors
2. **Add Signal Context** — human-readable narrative
3. **Add Recommended Actions** — default recommended actions by metric & flag
4. **Identify Repeat Signals** — persistence across snapshots

 Output is one row per metric × group (e.g. site) × snapshot. Ready for SME Review!

Example

Metric

MetricID: Analysis_kri0001
GroupID: 123
Metric: 0.25
Score: 2.8
Flag: 2

Risk Signal

Metric_Label: "Adverse Event Rate"
Site_Name: "Regional Medical Center"
Country: "United States"
Priority: "High"
Action: "Review for data quality
issues or protocol
compliance"
State: "Awaiting Triage"



Metric = What was flagged

Risk Signal = What to do about it

Action Management

Risk Signals in the Action Log

Recently updated

Back to Work Items

2 of 13

↑

↓

RISK SIGNAL 10988

10988 2012-03-31 - SAE - UK

No one selected

0 Comments

Add Tag

Save

Follow

State

Awaiting Triage

Area

s0001\Triage

Reason

Moved to state Awaiting

Iteration

s0001

Updated by Federated_AWS_ADO_Integration: Aug 1, 2025

Details

2

0

Signal Description

Group Information

Related Work

Serious Adverse Event Rate is potentially low relative to other countries with 22 Serious Adverse Events identified in 825 Days on Study (Metric: 0.03).

Group Level

Country

Group ID

UK

Group Label

Group Status

Enrollment

25

Add link

Parent

10989 2012-03-31 Snapshot

Updated Aug 1... Awaiting ...

Related

10981 2012-02-29 - SAE - UK

Updated Aug 1... Awaiting ...

Recommended Action

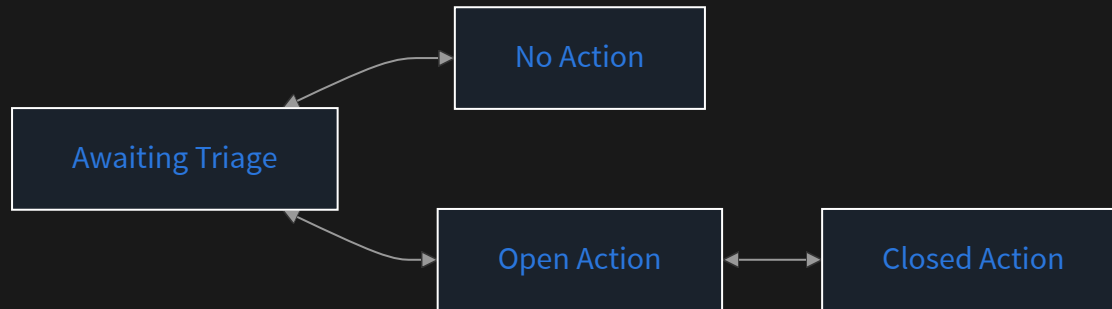
Click to add Recommended Action.

Action Taken

{grail}risk signals are exported to an action log (e.g. in Azure DevOps) for follow-up by study teams.

Action Workflow

First Triage, then Action if needed.



- All fields are editable by the SME during triage and follow-up
- Triage decisions and action details are tracked for traceability and reporting
- Threaded comments to capture rationale and discussion

Central Monitoring User Guide



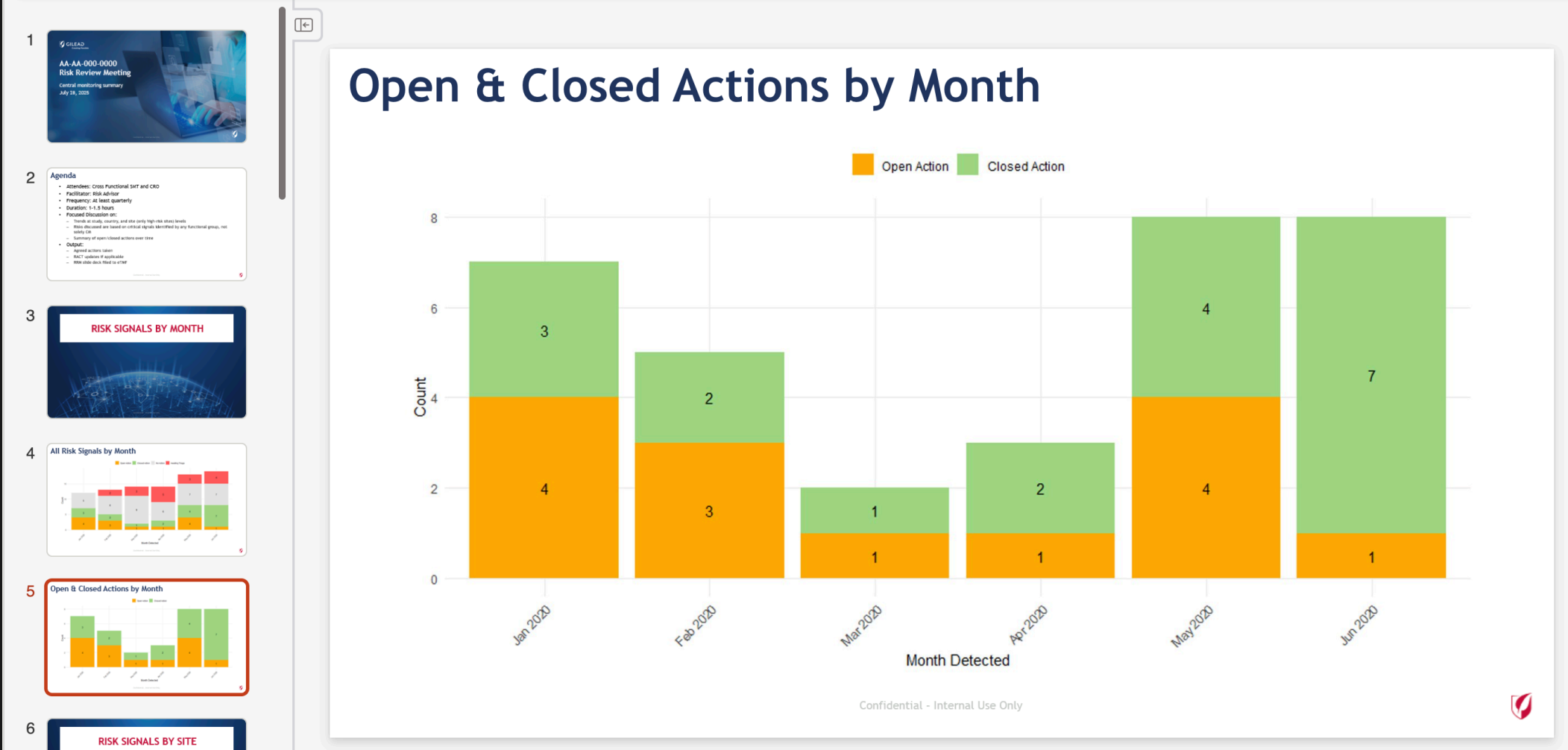
Metric-level guidance on triage decision-making and action management best practices.

Reporting Layer

Risk Signal Reporting Layer

- **Templated slide decks** for risk review meetings
 - Pre-populated with signal summaries, trends, action status
- **Templated Listings** for eTMF and CRO reporting
 - Rate of signal “actionability” by metric type
 - Portfolio-level view: action vs. noise
- **Analytics Dashboards** for continuous improvement
 - Triage timeliness metrics to surface bottlenecks
 - Signal persistence trends to identify chronic issues

Templated Slide Deck for Risk Review Meetings



Templated Listings

Standardized Excel reports for different operational needs:

Report	Purpose
AllRisksAndActionsReport	Complete listing for eTMF filing
OpenActionReport	Currently active risk signals
CROOpenActionReport	Active items assigned to CRO partners
ImportantDeviationsReport	QTL deviation capture
OngoingQTLReport	QTL status monitoring vs thresholds

Conclusion

`{grail}` and `{gsm}` provide an end-to-end RBQM workflow.

- Metrics → Risk Signals
- Flexible Action Management
- Tailored Reporting Layer