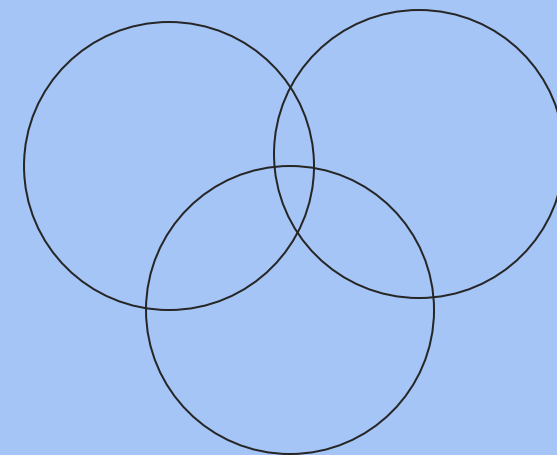




Staying Out of the Ditch

How Governance Can Provide Your Team with Guardrails

Presenter:

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Agenda

Overview

- 1 The High Stakes of QC
- 2 Common Pains for Clinical Programmers
- 3 Vision and Principles for Next-Gen QC
- 4 Real-World Application: Integrated QC
- 5 How Domino Helps SCE Leaders Strengthen Governance

The High Stakes of QC

Real-World Risks and Consequences

Patient safety and
data integrity

Regulatory
scrutiny

Financial and
reputational risks



**Robust QC tracking and governance
frameworks are essential**

Real-World Governance Lessons



Improper post-hoc analysis changes

- FDA issued a complete response letter (CRL)
- Voted against approval

Dosing error and deleted records

- FDA issued a CRL and warning letter
- Reputation damage

Hidden tab with undisclosed data

- Investor confidence plummeted
- Stock suffered billion-dollar market cap decline

Common QC Tracking Challenges

Do these sound familiar?

Disjointed Processes

QC tracking is in a separate environment and software from where development takes place



**Time Consuming |
Costly Mistakes**

Lack of Audit Trails

Excel spreadsheets are shared ad-hoc, not tracked, not audited, and not collaborative



**Compliance |
Reproducibility Risks**

Policy Visibility Issues

Difficult for individuals to keep track of their policies, where, and how they are being adhered to



**Hard to Track |
Harder to Visualize**

Impact: Late-stage errors, cost overruns, compliance risks

Key Drivers for Transformation

Changes must be made now...

**Stricter
Regulations**

**Larger, More
Complex Trials**

**Faster
Insights**

**Competitive
Advantages**

Vision and Principles for Next-Gen QC

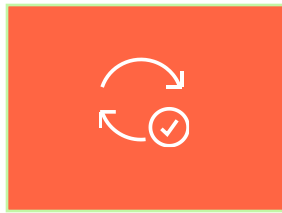
Remove friction, reduce errors, empower everyone

Seamless Code & Data Integration



Built into
SAS/R/Python
workflows

Automated Event/Trigger System



Every commit
initiates
QC tasks

Embedded Governance & Risk Management



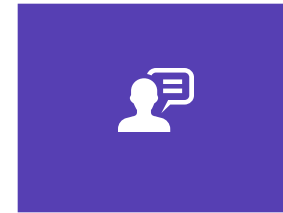
Policies enforced
in real-time

Comprehensive Audit Trail



Full traceability of
code, data and
environment

AI Agents & Workflows



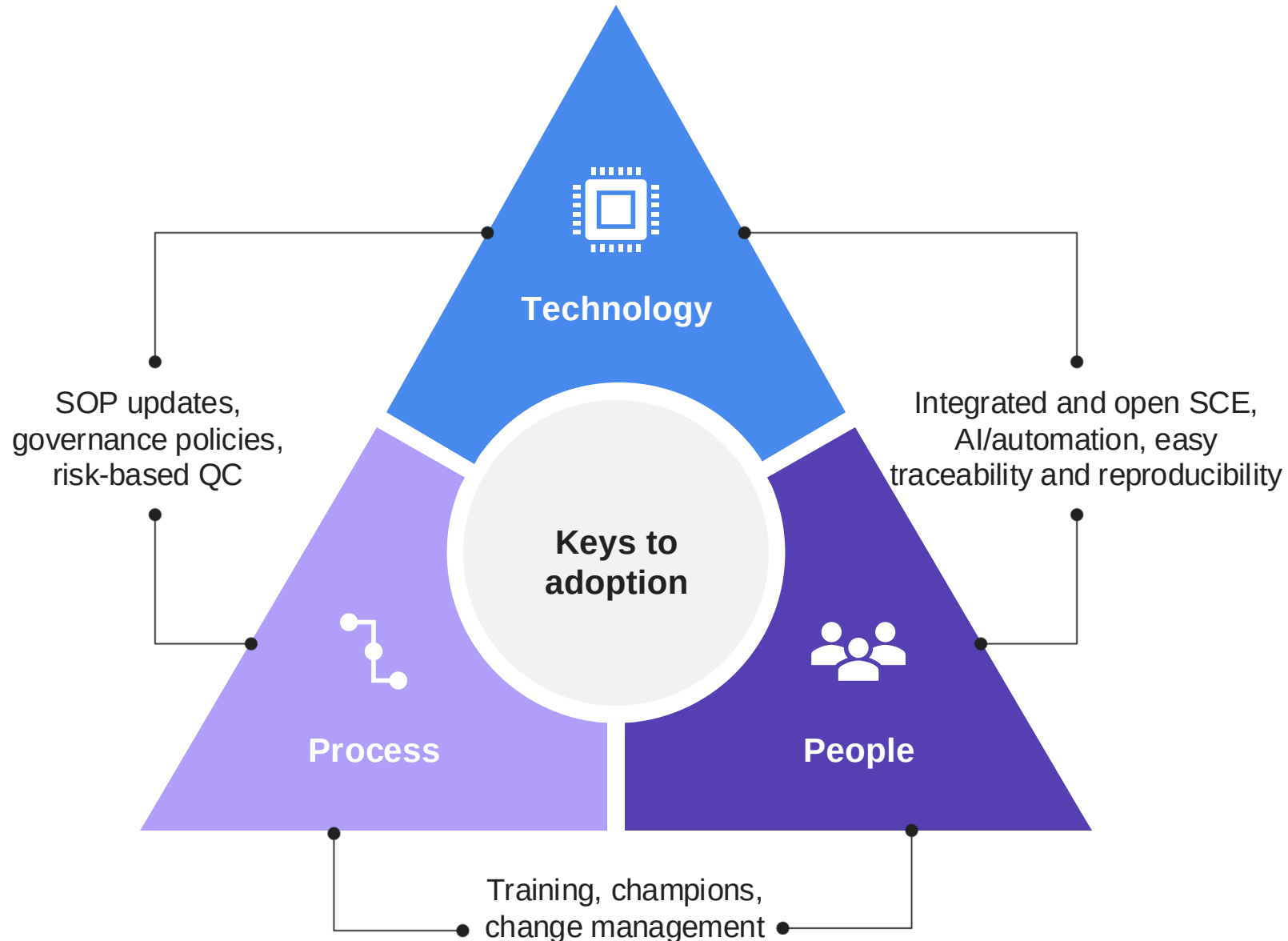
Proactive checks
for anomalies or
compliance gaps

Role-Based Dashboards

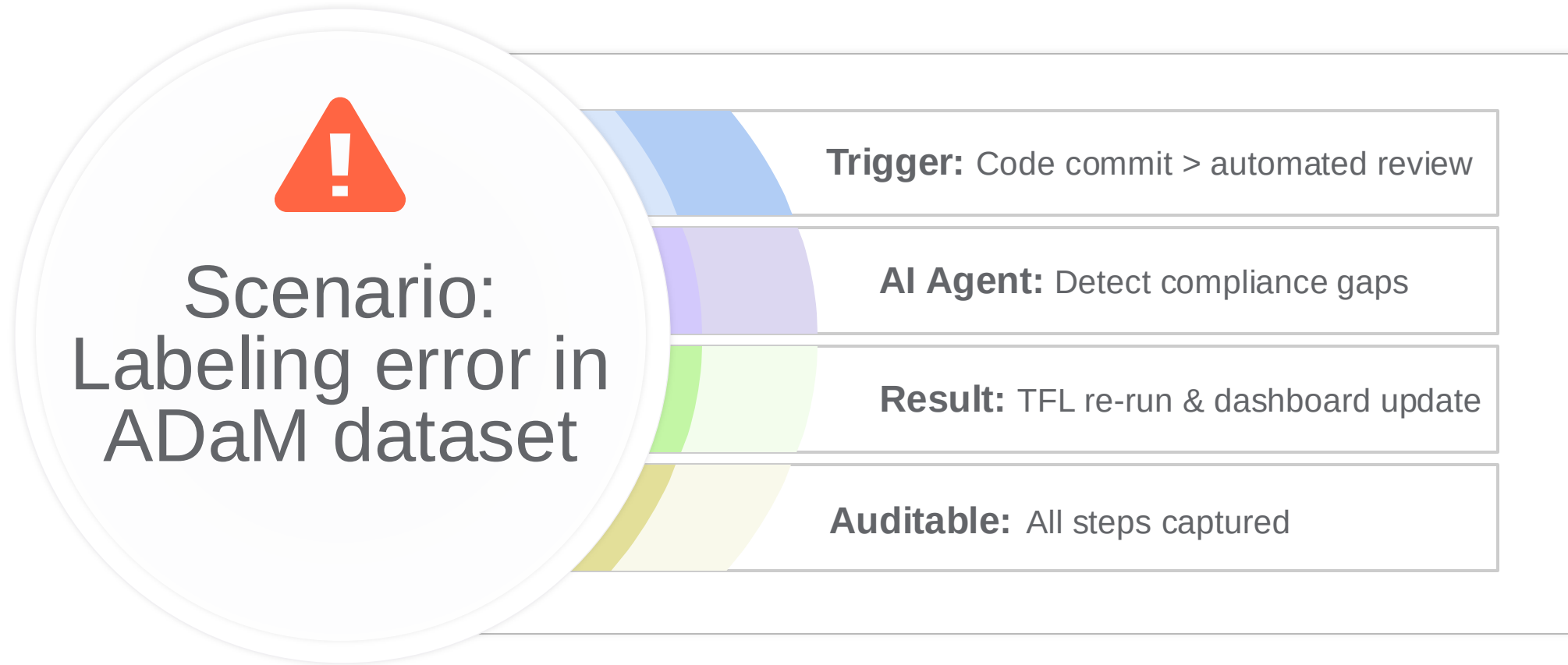


Predictive,
prescriptive KPIs

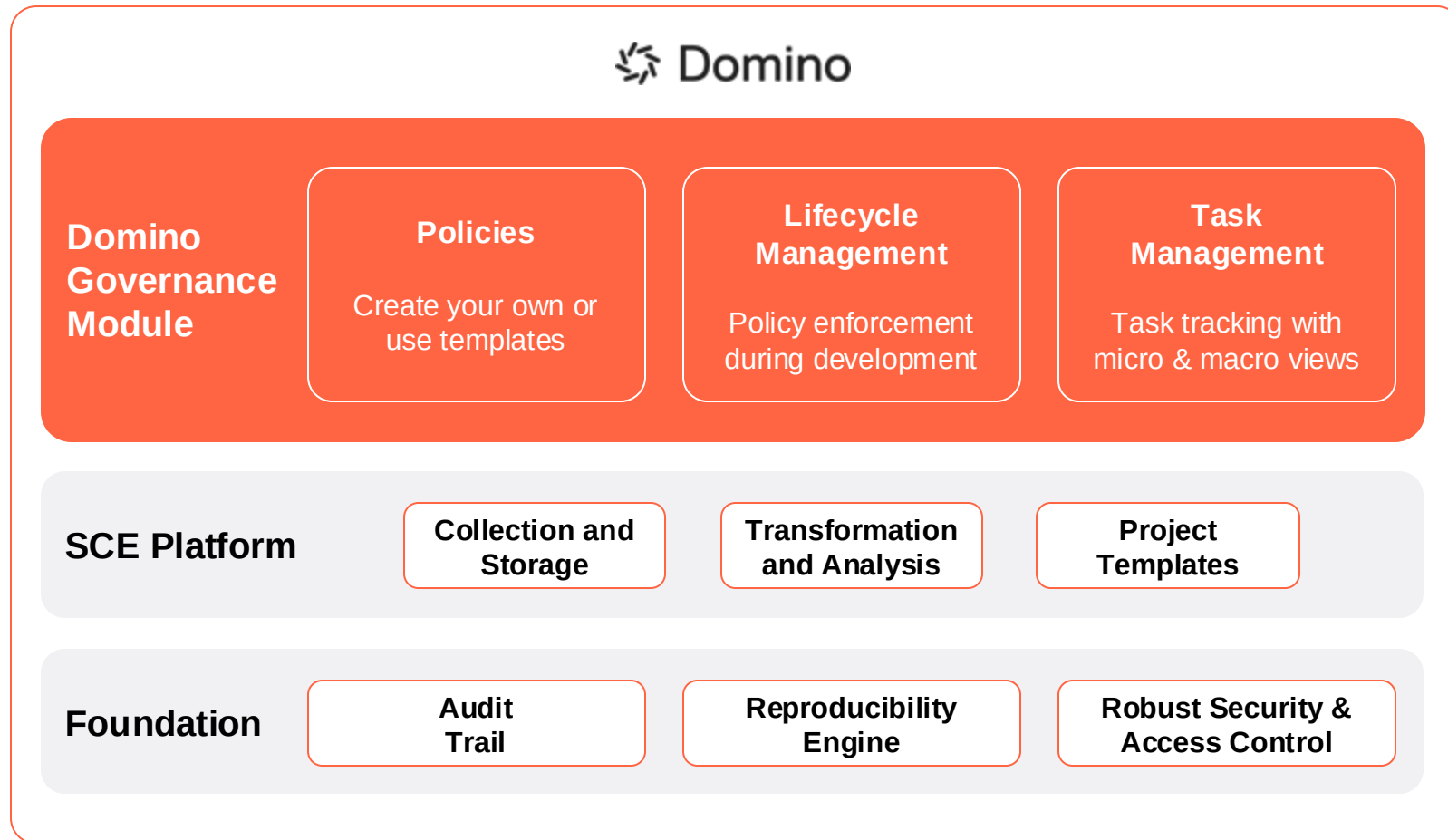
Keys to Adoption: People, Process, Technology



Real-World Example: Integrated QC



Domino's Foundation



- Multi-lingual (SAS, R, Python) SCE
- Reproducibility & Audit Trails
- Automated policy enforcement
- GxP and Non-GxP

How Domino Helps Strengthen Governance

For those running or overseeing an SCE



Key Takeaways



QC has high stakes



Failure has real consequences



Align people, processes, and technology for success



Domino has a governance foundation



QC is not a bolt-on; it's the backbone that ensures patient safety

Visit us at booth #XXXX

We're looking for design partners like you to help us build a QC solution that meets your needs

