Reliable Trial Monitoring for Personalized Clinical Development Insights

Durable Workflow Orchestration + Generative AI for Proactive Trial Monitoring

Anisha Suri, Niki Pavlopoulou, Bashar Ammari, John Austin, Finian O'Neill

Development - Clinical Data Science - AI Research Center – PHUSE 2026

INTRODUCTION

- Clinical development teams depend on continuous surveillance of external trials to track protocol amendments, enrolment milestones, study status changes, endpoint revisions, and competitive landscape shifts
- Growing trial volume across therapeutic areas makes manual monitoring untenable, causing information overload and delayed awareness of impactful changes
- To address this challenge, we developed an External Trial Intelligence Alert System that combines Temporal's durable workflow orchestration with generative AI to transform raw trial updates into personalized, actionable intelligence
- The platform continuously monitors external clinical trial data sources (example, ClinicalTrials.gov), detects meaningful changes across studies of interest, and automatically generates concise summaries tailored to the needs of different stakeholders - Clinical Development, Biostatistics, Regulatory Affairs, Medical Affairs

DATA SOURCES

The tool currently uses data from ClinicalTrials.gov and intends to combine **diverse approved exclusive + public external data sources** such as Citeline

BUSINESS PROBLEM

Amendments are implemented in 260 days on average, with sites operating under different protocol versions for ~215 days*

$ Delayed awareness compounds downstream costs: mis-scoped SAPs, stale competitive positioning, and missed regulatory windows

RESULTS - TRIAL MONITORING WORKFLOW

Trial data via API

User input options at setup for Clinical Development Persona

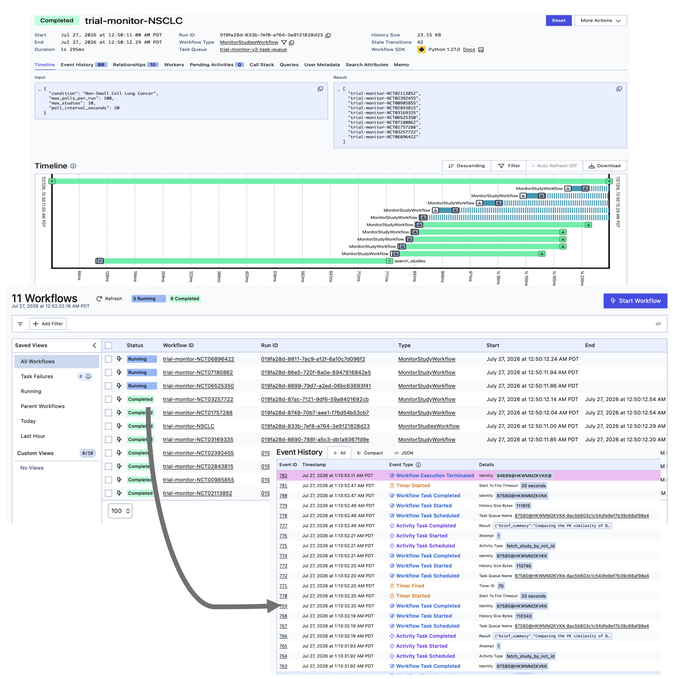
```
{
  "user_id": "clinical_dev_nsclc"

  "therapeutic_areas": [
    "Oncology"
  ],

  "indications": [
    "Non-Small Cell Lung Cancer"
  ],

  "phases": [
    "Phase 2",
    "Phase 3"
  ],

  "mechanisms": [
    "PD-1",
    "PD-L1",
    "TIGIT"
  ],

  "competitors": [
    "Merck",
    "BMS",
    "AstraZeneca"
  ],

  "alert_preferences": {
    "protocol_amendments": true,
    "endpoint_changes": true,
    "recruitment_updates": true,
    "status_changes": true,
    "biomarker_updates": true
  }
}
```

Non-Small Cell Lung Cancer 10 trials being fetched

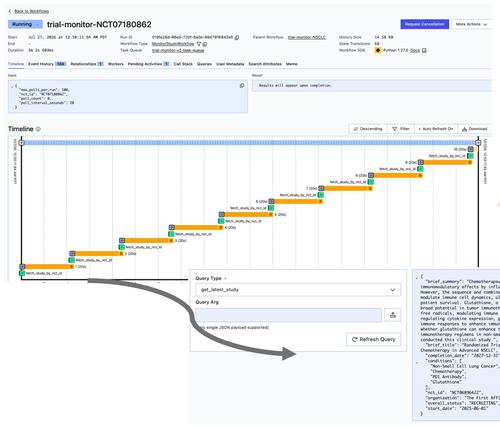
```
(trialmonitor) (base) asuri1@HKWMM2KVKK trialmonitor % uv run hello/trial_monitor_V2.py st
  --condition "Non-Small Cell Lung Cancer" \
  --max-studies 10 \
  --poll-interval-seconds 20 \
  --workflow-id "trial-monitor-NSCLC"
Started child workflows:
 - trial-monitor-NCT02113852
 - trial-monitor-NCT02392455
 - trial-monitor-NCT00985855
 - trial-monitor-NCT02843815
 - trial-monitor-NCT03169335
 - trial-monitor-NCT06525350
 - trial-monitor-NCT07180862
 - trial-monitor-NCT01757288
 - trial-monitor-NCT03257722
 - trial-monitor-NCT06896422
```

Temporal durable trial workflows

Parent workflow triggers 10 Child workflows for trials in progress – ongoing recruitments, planned



Custom Change Detection and Tracking



20s

Configurable poll interval per trial

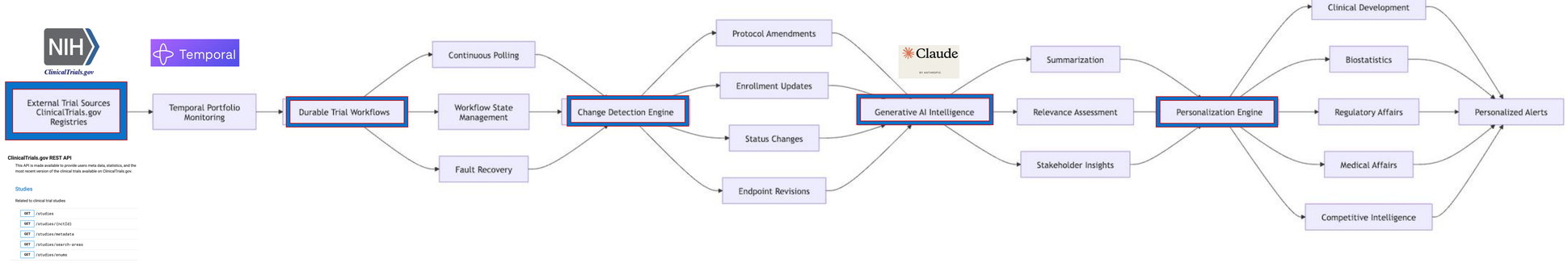
Personalized Alerts via GenAI

Change Classification

LLMs identify clinically relevant edits: amendments, endpoint changes, design modifications, and recruitment updates.

```
{
  "recipient_role": "Clinical Development",

  "alert_priority": "HIGH",

  "trial": "NCT06896422",

  "summary": "The trial expanded enrollment from 120 to 200 patients, completed
recruitment, replaced ORR with PFS as the primary endpoint, and added PD-L1
subgroup analyses. Collectively these changes suggest increased investment in the
program and a stronger focus on demonstrating durable clinical benefit.",

  "relevance": "NSCLC / Immuno-Oncology",

  "recommended_action": "Review for potential competitive implications against
internal NSCLC immunotherapy programs."
}
```

METHODS - ARCHITECTURE OVERVIEW AND DURABLE WORKFLOW



ClinicalTrials.gov REST API

This API is made available to provide users meta data, statistics, and the most recent version of the clinical trials available on ClinicalTrials.gov.

Studies

Related to clinical trial studies

GET /studies
GET /studies/{nctId}
GET /studies/metadata
GET /studies/search-areas
GET /studies/enums

DISCUSSION

- Durable workflow orchestration and generative AI can be combined to shift external trial monitoring from passive surveillance to proactive intelligence generation.
- By delivering personalized summaries and targeted alerts, the platform can help teams stay informed of relevant developments across the rapidly evolving clinical trial landscape supporting faster and more informed decision-making.

IMPLEMENTATION STACK

- Temporal Cloud for workflow orchestration, event history, and horizontal scaling
- Python worker pool executing ClinicalTrials.gov fetch activities and change diffing
- LLM inference layer (Claude) for change classification and per-role narrative generation
- Middleware topic bus (Kafka-style) for subscriber fan-out and delivery-channel routing

*Source: Getz K, Smith Z, Botto E, Murphy E, Dauchy A. New Benchmarks on Protocol Amendment Practices, Trends and their Impact on Clinical Trial Performance. *Ther Innov Regul Sci*. 2024
(A study by Tufts Center for the Study of Drug Development, USA)

CONTACT INFORMATION

Talk Data to Me!
anisha.suri1@gilead.com