Accelerating RTOR In Oncology: The AIM Model For Agile Trial Operations

HPR11

Jigar Prajapati*, Vatsal Chhaya, Shaurya Deep Bajwa, Kapil Khambholja
Catalyst Clinical Research, Wilmington, NC, USA

Presented at ISPOR Europe 2025: November 9-12, 2025; Glasgow, Scotland

INTRODUCTION

- The FDA's Real-Time Oncology Review (RTOR) pathway accelerates oncology drug review by enabling early data submission and iterative regulatory engagement
- Realizing RTOR benefits requires early data readiness, streamlined operations, and proactive cross-functional coordination.
- Small to mid-sized biotechs often lack the integrated workflows and regulatory infrastructure needed for RTOR alignment.
- CRO partnerships frequently fall short might not always be adequate due to siloed processes and absence of RTOR-focused operational frameworks.
- This reveals a critical industry gap demanding scalable, fit-for-purpose solutions that enable RTOR readiness for emerging oncology sponsors.

RTOR PROCESS

Request Submission
Application submits RTOR request with top-line efficacy/safety data

FDA Decision
Acceptance decision within 20 business days

Planning Meeting
Optional teleconference to finalize submission timeline

Staggered Submissions
Up to 3 pre-submission +1 final submission

Review Clock Starts
Upon receipt of final component

OBJECTIVE

To develop a conceptual model focusing on automation capabilities to enhance the existing RTOR workflow.

METHODS

Problem Identification
Mapped key RTOR workflow challenges

↓

Literature Review
to understand existing RTOR workflows

↓

Stakeholder Consultation
to capture real-world RTOR barriers
(Structured interviews and workshops mapped process gaps and prioritized automation opportunities.)

↓

Model Design Thinking
to brainstorm possible options for agile regulatory solutions.

↓

Model Final Conceptualization (AIM Framework)

From Insight to Impact:
Agile RTOR Framework Design

Clinical Operations

Regulatory Affairs

Digital Innovation Teams

Medical Writing SMEs

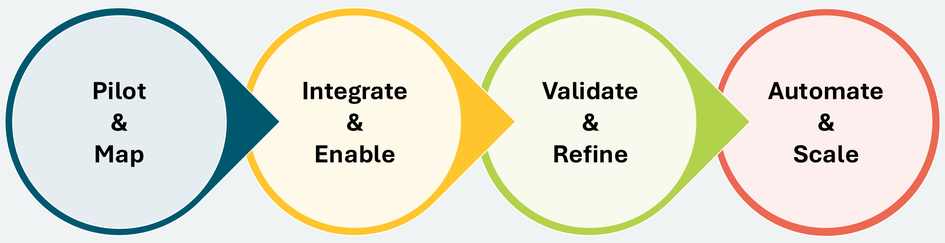
RESULTS AND DISCUSSION

Literature Review Findings

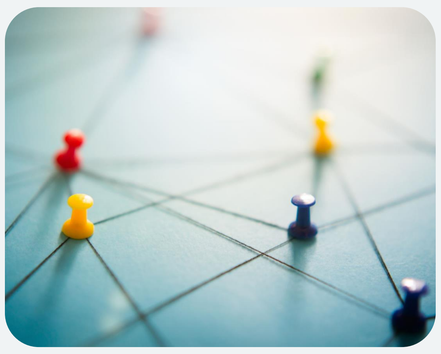
- Gaps Identified in current RTOR workflows
  - Fragmented Data Systems
  - Manual Document Workflows
  - Underused Automation Tools
  - Integration Barriers

Stakeholder Consultation

- Key Findings
  - Fragmented systems, misaligned timelines, and manual processes hinder digital integration and submission readiness.



- RTOR workflows with initial registry–federated linkage.
- AI/ML-driven data extraction and NLP automation.
- HITL feedback and regulatory alignment.
- Workflows with dashboards and wider data integration.



Automate

- **RTOR Context**: Facilitates early submission of top-line efficacy and safety data post-database lock, SDTM/ADaM datasets, and structured documents (e.g., SAP, DMC charters)
- **Digital Leverage**: Automate data curation · Auto-QC pipelines · NLP-driven document generation

Integrate

- **RTOR Context**: Supports modular pre-submissions across clinical, statistical, and regulatory domains
- **Oncology Relevance**: Aligns clinical ops and regulatory teams for synchronized delivery of labeling, PK/PD analyses, and supportive toxicology data

Monitor

- **RTOR Context**: Ensures timely tracking of trial milestones—database lock, pre-submission status, and final component readiness
- **Oncology Relevance**: Tracks database lock, top-line data availability, and pre-submissions

STRENGTHS AND LIMITATIONS

Strengths:

- Insight-backed: Developed through cross-functional stakeholder inputs and real-world process mapping.
- Replicable: Structured framework adaptable across oncology trial settings and functions.
- Scalable: Designed for phased expansion with modular AI/ML integration.

Limitations:

- Conceptual framework; real-time validation pending
- One size may not fit all: Applicability may vary across stakeholders and oncology trial types
- Need for extensive training due to HITL approach

CONCLUSION AND RECOMMENDATIONS

- AIM model conceptually addresses fragmented RTOR workflows through AI-enabled automation and integration.
- Proposed automation framework may accelerate data readiness and modular submissions.
- Hypothetical cross-functional integration framework aims to enhance synchronized clinical–regulatory alignment.
- Model feasibility may be limited by data standardization and interoperability challenges.
- Future validation and alignment with FDA and WHO Responsible AI guidance are recommended.

REFERENCES

1. FDA guidance RTOR (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/real-time-oncology-review-rtor)
2. https://friendsofcancerresearch.org/publication/2018-annual-meeting-panel-3-real-time-oncology-review-and-the-assessment-aid/
3. Artificial Intelligence and Machine Learning Innovations to Improve Design and Representativeness in Oncology Clinical Trials | American Society of Clinical Oncology Educational Book

CONTACT INFORMATION

Shaurya Deep Bajwa
Sr. Medical Writer - RWE Analyst II
Catalyst Clinical Research
Email: Shaurya.Bajwa@catalystcr.com
www.CatalystCR.com

SCAN HERE
TO LEARN MORE