Category: Emerging Technology – Work in Progress

Modernizing Regulatory Strategy for Next-Generation Oncology Technologies

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1. Background

Oncology research is rapidly incorporating In-vitro diagnostics (IVDs), AI-driven platforms, software, and digital health technologies. These new technologies often don't fit neatly into traditional drug or device categories, which creates challenges in determining Food and Drug Association (FDA) jurisdiction and investigational requirements for investigational new drug (IND) and Investigational Device Exemptions (IDEs). As oversight evolves, institutions risk delays in study activation, misaligned regulatory strategies, and unexpected FDA feedback. Traditional, reactive compliance approaches are no longer sufficient to address the evolving regulatory landscape. To address this, the Investigational new drug office (INDO) at MSKCC has implemented a proactive regulatory review and strategy process that supports investigators from early development through FDA submission readiness.

2. Goals

- Flag emerging technology studies early in protocol development
- Standardize regulatory pathway assessments and FDA jurisdiction decisions
- Partner with principal investigators (PIs) and internal stakeholders to align development strategies with FDA expectations
- Support the progression of innovative technologies toward FDA authorization by reducing regulatory uncertainty and preventing downstream delay

3. Solutions and Methods

- **Continuing Education and Regulatory Intelligence**: The team engages in ongoing training and active monitoring of FDA guidance, enforcement trends, and policy updates to stay aligned with the evolving regulatory landscape
- **Early Identification of Technology:** Standardized intake criteria flag novel technology studies early, enabling timely regulatory assessment
- **Regulatory Pathway Assessment:** INDO performs structured reviews to determine FDA jurisdiction, investigational requirements, and appropriate development pathways
- **PI and Stakeholder Collaboration**: We work closely with PIs and key stakeholders to clarify regulatory requirements, identify data or documentation gaps, and align study design with FDA expectations, including quality considerations and long-term milestones
- **Proactive FDA Engagement**: When appropriate, INDO leads preparation and submission of materials (e.g., Pre-IND or IDE meetings) to obtain early FDA feedback and reduce regulatory risk
- **Systems Integration and Tracking:** Regulatory milestones and documentation are tracked within institutional systems to support consistency, transparency, and submission readiness throughout the project lifecycle

4. Outcomes

Our office now engages earlier in the protocol lifecycle to strengthen consistency and uphold regulatory standards across the MSK-sponsored IND/IDE portfolio. Emerging technology studies are identified during protocol development, enabling timely FDA pathway decisions and clearer regulatory alignment. Structured collaboration with PIs and stakeholders has improved submission quality and reduced

revisions. Strategic use of pre-submission meeting and programs has limited unexpected FDA feedback and enhanced institutional readiness. Overall, this proactive approach improves regulatory alignment, supports compliance, and helps innovative technologies advance more efficiently toward approval.

5. Lessons Learned and Next Steps

Early, formalized regulatory engagement is critical for technologies without clear precedents. Early institutional identification reduces ambiguity and ensures consistent oversight. Working directly with primary stakeholders accelerates adoption and regulatory maturity. Proactive FDA engagement through pre-submission meetings helps de-risk development. Looking ahead, we plan to expand guidance for AI enabled tools, refine processes as FDA policies evolve, and enhance real-time tracking of regulatory milestones to support scalable innovation across the research enterprise.