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Evolution of an Institution-Sponsored IND Program

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Background

The Institution-Sponsored IND (ISI) Program at Fred Hutchinson Cancer Center provides operational structure for the institution holding an IND instead of individual investigators, and ensures that ISIs are submitted, maintained, and overseen in accordance with FDA regulations. The Program is organizationally situated in the Clinical Research Support (CRS) office and has institutional oversight from a committee composed of physicians, senior institutional leadership, and compliance. The ISI portfolio includes the Cancer Consortium's highest risk and most complex INDs and supports all investigator-initiated studies involving manufacturing investigational product at Fred Hutch. Since the ISI Program's establishment in 2016, the volume and complexity of INDs and trials has increased by 300%, necessitating operational optimization to meet demand while ensuring efficiency, safety, and compliance.

Solutions and Methods

Safety Reporting
- Identify attribution to standard of care and/or study procedures; strengthen adjudication process to capture supportive information
- Create study-specific safety review sheets
- Implement bi-annual review of Investigator's Brochures

Multicenter Studies
- Leverage use of existing tools when practical
- Cross-collaboration with other comprehensive cancer centers for best practices

External Manufacturing
- Identify FDA-required elements for drug substance and drug product information
- Collaborate with industry experts to build Program expertise in product release requirements

Outcomes

Safety Reporting
- Significant reduction of incomplete forms, missed reporting, and study team consults; more robust assessment documentation
- Eliminated risk of late reporting per protocol-specific requirements; at-a-glance directives for reporting safety events
- Contemporaneous updates for expected risks

Multicenter Studies
- Development of tools for site selection and activation
- Creation of workflows for multicenter studies requiring in-house manufacturing and shipping to external sites
- Draft templates and tools, including batch records, SAE reporting forms, and protocol templates

External Manufacturing
- Enabled ability to support three projects with manufacturing outside of the United States
- Development of a facility audit process for both domestic and international needs
- Deepened expertise in requirements for drug substance and drug product information, as well as product release requirements for all stages of manufacturing

Goals

To implement and/or improve processes to:

- enhance safety evaluation and reporting
- support oversight of multicenter studies
- develop operational expertise to support ISIs requiring manufacturing external to Fred Hutch

Lessons Learned

- Process breakdowns provide the greatest opportunity to identify areas of improvement
- Simplification can be the most effective form of process improvement
- Cross-collaboration resulted in most significant outcomes

Future Direction

The Program's next set of goals include:

- expanding scope to support a larger IND portfolio
- establishing a centralized data and safety monitoring board (DSMB)
- exploring implementation of electronic Common Technical Document (eCTD) format
- continuing efforts to support multicenter studies