ThermoFisher SCIENTIFIC

SOLVED WITH

INITIATIVE & INSIGHT

patheon

Investigator initiated trial (IIT) service for pharma companies

Our Investigator Initiated Trial service offering provides comprehensive oversight and management of all clinical supply activities. We recognize that conducting this type of collaborative research enables you to capture insightful data on the performance of your drug product across other therapeutic areas. Unfortunately, the internal resources required to support the clinical supply chains for these types of trials can be difficult to allocate.

The Investigator Initiated Trial Service enables you to achieve these strategic objectives while delivering unparalleled support to your critical investigator sites, without stretching your valuable internal resources too thin. You determine the level of involvement that you need, from a total "hands-off" approach to one that requires approval of certain key supply chain activities. The Investigator Initiated Trial team is committed to meet your needs. This support includes:

- **Supply chain planning services during protocol development:**
  We provide guidance and assistance to your IIT Review Committees as they review new IIT proposals and protocols. From simplified packaging and label design, to initial and ongoing forecasting of supply requirements, we will provide your team optimal support and input on the supply chain portion of the IIT protocols.
- **Enhanced communication and a main point of contact for pharmaceutical teams and sponsors (sites):**
  We have dedicated team members committed solely to managing these types of trials. You and the sites will have a main point of contact who has complete oversight of your IIT portfolio and individual trial performance.

OUR VALUE PROPOSITION

- Optimizes internal resources
- Augments trial management and oversight
- Enhances key investigator site relationships by facilitating communication channels
- Reduces burden to setup clinical supply chains
- Budget tracking and insight to optimize cost savings

- **Supply chain tracking and visibility:**
  A variety of forecasting tools, study dashboards and communication templates have been specifically designed to ensure that up-to-date information on trial status is always available. These tools can be customized to fit your needs.

- **Transportation management and trade compliance for multi-country studies:**
  Sites can lack expertise when it comes to moving material across countries or geographies. Our experienced team will manage the logistics for them if they need to ship material to sites outside of their region or country. Our IIT team will track shipments and provide pre-alert notifications so the sites are prepared when materials arrive.

- **English master text and translations:**
  We can provide regulatory insight when designing labels. Our experts provide guidance and assist with label design, English master text and translations.

- **Specific document approval with client specifications:**
  We understand that you might want a "hands off" approach when managing your IITs. We can approve the following documents with your specifications (Source Documents):

  - Pre-Batch Record Approval
  - Master Label Text Approval
  - LINKS Approval (variable text)
  - Packaging Campaign requests

  We can also monitor temperature excursions and provide 'Fit For Use' Determinations based on your given parameters.

- **Streamlined web-order system or interactive response technology (IRT) setup assistance:**
  We will use a streamlined web-order entry system for all sites to enable ordering supplies and resupplies in a consistent manner. If an IRT is required, we will assist you in evaluating the user specifications to ensure that it will satisfactorily meet your supply chain requirements.

MANAGEMENT THROUGHOUT IIT LIFECYCLE

IIT STUDY SETUP

- Strategic planning
- Initial supply forecasting
- Packaging and distribution
- Drug ordering process
- Kick-off meeting with sponsor

IIT EXECUTION

- Continuous monitoring (via dashboards, enrollment reports, and metrics)
- Management of forecasting, resupplies and expiry management

IIT CLOSE OUT

- Returns and destruction

Main point of contact for all parties involved (i.e., clinical supply teams, medical affairs teams, sponsors, and sub-sites)

From protocol development to study close out, our team is committed to supporting your Investigator Initiated Trials. By reducing complexities for both you and the investigator site, while ensuring your sites receive a premium service level, you and your sites can benefit from a seamless process and expend your efforts on conducting valuable clinical research.

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