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INITIATIVE & INSIGHT

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Investigator initiated trial (IIT) service for institutions

The Investigator Initiated Trial Service offering provides comprehensive oversight and management of all clinical supply activities. We recognize that more investigators are conducting this type of collaborative research to explore investigational drugs for new indications, patient populations, dosage regimens, or in combination with other treatments. Setting up the clinical supply chain for these trials can present complexities when taking into account regulatory requirements and other considerations such as label and packaging design, label text translations, global distribution and resupply requests.

The Investigator Initiated Trial Service enables you to achieve your research objectives without having to worry about setting up and executing a clinical supply chain. We allocate IIT team members to meet your needs. This support includes:

- **Supply chain planning services during protocol development:**
  Guidance and assistance to investigators as you evaluate the most effective clinical supply chain. From packaging and label design, to questions about customs or transportation across geographies, to initial and ongoing forecasting of supply requirements, we will provide support in answering any of your questions. We will help you to design the optimal efficient clinical supply chain to meet the unique requirements of your study.
- **Enhanced communication and a main point of contact for all sites:**
  We have team members committed solely to managing these trials. Investigator site personnel will have a main point of contact, a Clinical Supply Chain Manager, who has complete oversight of each individual trials' performance from protocol development to study close-out.

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

- **English master text and translations:**
  Regulatory requirements around label text and design can be daunting. Our experienced team will manage your label design and translations for you.
- **Labelling product:**
  Many pharmaceutical companies will not label product for IITs, leaving this responsibility with the IIT Sponsor. Our team provides assistance with labeling the material throughout your study as well as managing expiry dates and resupplies.
- **Transportation management and trade compliance for multi-country studies:**
  Moving material across countries or geographies is challenging. Our experienced staff will manage these logistics for you if you need to move drug outside of your region or country.
- **Shipment coordination:**
  Your Clinical Supply Chain Manager will help you track shipments and coordinate with you optimal times for shipment deliveries to ensure that you and your teams are prepared and on-hand to receive the material.
- **Web-order system or interactive response technology (IRT) setup assistance:**
  Our online system will enable you to order supplies and resupplies. 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.
- **Supply chain tracking and visibility:**
  A variety of forecasting tools, study dashboards and communication templates were specifically designed to ensure that up-to-date information on trial status is always available. These tools can be customized to fit your needs.

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, out team is committed to supporting investigators conducting critical clinical research. By reducing complexities and providing proactive support for all of your clinical supply chain needs, the Investigator Initiated Trial Service enables you and your staff to focus on the research at hand.

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