ISR reports

CASE STUDY:

Pancreatic Cancer Feasibility Planning & Patient Recruitment

A top 5 CRO wanted to ensure they could adequately recruit patients in a realistic timeline for a novel pancreatic cancer drug, and ISR's Investigator Forum was the perfect tool. In the 3-day moderated forum, the CRO and sponsor received feedback on recruitment, comparator products, competing trials, inclusion and exclusion criteria, test/ visit frequency, standard of care, and various other aspects of the protocol.

The Protocol and Feasibility Assist Forum with clinical investigators is a web-based bulletin board focus group that allows investigators from around the world to give and receive feedback on various aspects of a protocol. A sponsor or CRO can see results come in as instantly as they happen, while interacting with 20 to 30 geographically dispersed investigators.

OBJECTIVES AND RESULTS

DAY 1

Objective: Discuss the pancreatic cancer environment, competition, overall study design

RESULT:

- Generally positive feedback regarding study design
- Recommendations to separate locally advanced vs. metastatic tumors
- Identified shortcomings in the use of the comparator drug in multiple countries – could make the study a no-go

DAY 2

Objective: Gather feedback on inclusion/ exclusion criteria, patient recruitment, and retention

RESULT:

- Most restrictive inclusion criteria includes ECOG, blood chemistry, and pain
- Most restrictive exclusion criteria includes serum albumin levels, high CVD risk, and recent major surgery
- Uncovered more barriers to recruitment than retention

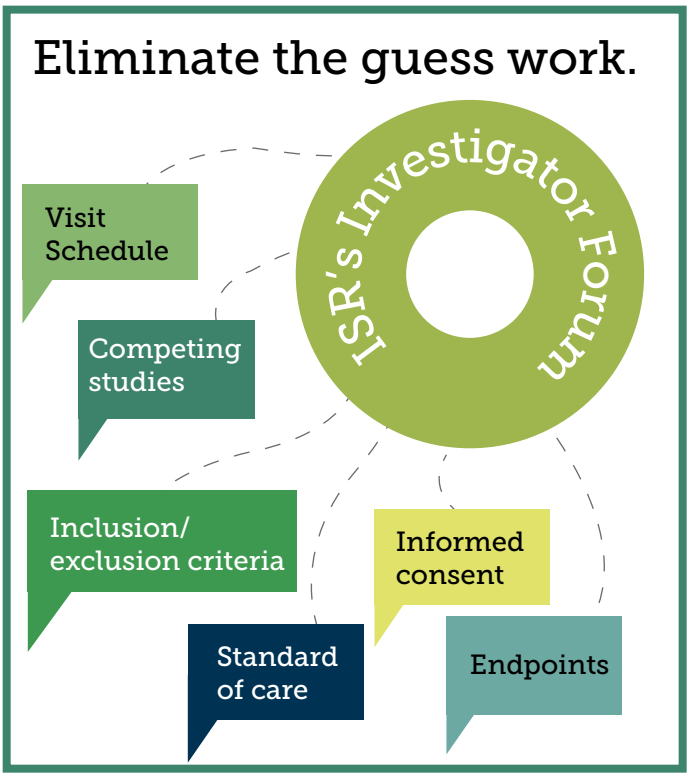
DAY 3

Objective: Assess aspects of analysis and measurement tools

RESULT:

- Participants agreed the timeframe before stopping for futility was acceptable
- Recommendation to extend toxicity recovery period from 14 to 21 days
- Recommendation to consider an 8-week CT/ MRI schedule over the proposed schedule

ISR's Investigator Forum is fast, actionable, reliable, and affordable. Save valuable time and money by avoiding in-person discussion groups and using our 3 day online model. Learn more by contacting an ISR research analyst at info@ISRreports.com.



THE RESULTS

Better patient recruitment timeline estimates

Eliminated several countries from feasibility and recruitment consideration based on the comparator product not being the standard of care.

Faster patient enrollment

More reasonable inclusion and exclusion criteria were developed.

Cost-effective and timely interactions with experts

Multi-country interactions with investigators, sponsor and CRO medics in a peer-to-peer environment. Recommendations delivered 6 weeks after project initiation.

FEEDBACK

"Product 1 is an appropriate comparator and reference drug. Prescription of Product 1 will have positive effects in patient recruitment."

– UKRAINIAN INVESTIGATOR

"My first feeling was not really good: locally advanced and metastatic pancreatic cancer are two different diseases - today, Product 1 is not the standard chemotherapy for metastatic pancreatic cancer in France"

– FRENCH INVESTIGATOR

"I would extend this [recovery] period to 21 days because 14 days may not be enough to recover from toxicity, especially after 4 or 6 cycles."

– RUSSIAN INVESTIGATOR

"Make a careful review of the inclusion-exclusion criteria. Please be advised that pancreatic cancer is a rapidly changing disease. Give the patient all the support you could give. Be patient. Always enrollment is slow at the beginning."

– FRENCH INVESTIGATOR

What are the key advantages of the Protocol and Feasibility Assist Forum with Clinical Investigators?

The investigator forum helps pharmaceutical companies and CROs generate moderator-controlled market research, collecting valuable suggestions regarding various aspects of a protocol. An online bulletin board focus group replaces the costly and time-consuming in-person discussion groups while providing clinical research teams with valuable direct feedback. ISR can also provide a comprehensive list of difficult-to-reach principal investigators from around the globe, avoiding time zone barriers by utilizing the non-real time format of the group. Participants can come and go as they please over the course of the 3-day forum, enabling flexibility for busy, time-challenged principal investigators.

What is the Protocol and Feasibility Assist Forum?

- 3-day moderated web-based bulletin board focus group
- Geographically dispersed PIs discuss various aspects of a protocol
- Format allows for interaction and follow-up questions
- Output presented in a comprehensive PowerPoint document and easily sorted Excel file with verbatim responses

What are the benefits?

- Ability to discuss risk mitigation and timeline feasibility
- Finds therapeutic expertise from PIs around the world
  - Your PI list
  - ISR's PI list
- Saves valuable time and money by avoiding in-person discussion groups
- Allows for discussion flexibility
- Provides clinical research teams with valuable feedback

For an online demonstration or for more information, please email us at Info@ISRreports.com or call (919)-301-0106