RQMIS Inc.
Highlight

RQMIS Helps US Manufacturer Design/Conduct Retrospective Clinical Study on Device used to Treat Pancreatic Cancer

Customer:
- US Based Medical Device Manufacturer

Industry:
- Class II (US) and IIb (EU) Active Medical Device

Project Timeline:
- 6 months to design study protocol and CRFs, gain IRB clearance, negotiate contracts and collect/analyze data.
- 1 month to publish Clinical Report.

Customer Objectives:
- Independently collect objective, clinical experience with a FDA cleared device using a prospective clinical study protocol and case report forms.
- Gain IRB approval and comply with HIPAA at all sites
- Utilize DSMB for review of all safety data
- Utilize Independent Radiographic Analysis

Background:

Client was interested in determining how surgeons were using their 510(k) cleared medical device with respect to soft tissue ablation. Surgeons were chosing to use the product for soft tissue tumor ablation in the pancreas. Although clinical study was collecting/analyzing retrospective clinical data, Client wanted to utilize propective study protocol, case report forms, gain IRB approval and comply with HIPAA regulations. The potential for using this clinical dataset in future FDA submissions was a potential.

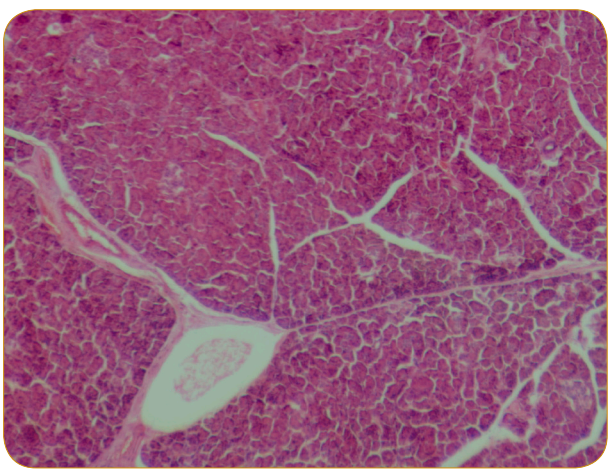
RQMIS Approach:

A project team consisting of a Senior Clinical Consultant, Senior Regulatory Consultant and Clinical Monitor was formed. RQMIS interviewed and trained three surgical oncologists to become members of the study's Data Safety Monitoring Board (DSMB). We also retained an independent radiologist to critically review MRI/CT imaging.

Once the protocol and study related documentation was designed and placed under document control, RQMIS assisted two well respected clinical sites in preparing IRB submissions. In addition, RQMIS negotiated contracts with these clinical sites. Both IRBs granted approval within 45 days of submission.

RQMIS collected patient demographics, baseline and all followup visit blood chemistry, imaging, adverse events and clinical scores/outcomes on 21 patients with Stage III Pancreatic Cancer. Data collection, coding adverse events per MedDRA and database freeze occurred within 30 days of initiating data collection. Both the independent radiologist and the DSMB reviewed the relevant source data within 30 days of database freeze. All of the reviews were included within the data package for statistical analysis. Statistical analysis and the clinical report was drafted/finalized within 30 days of DSMB review.

Since RQMIS consultants had previously designed, implemented and managed over 20 phase II and III clinical studies in the US and EU the knowledge was available to execute this project in an efficient and effecitve manner. We utilized our network of Field Monitors to effectively manage data collection to expedite the process as well.



Challenges And Issues:

- Executing a retrospective study has numerous challenges including determining data that is available for collection, quality of radiographic imaging, etc. However, the primary objective of this study was to determine the safety of use of the subject active medical device with a secondary objective of determining patient outcomes.
- There was a clear objective from all parties involved that the data should be collected by an independent third party (RQMIS), analyzed by an independent group of oncological surgeons (DSMB)/radiologist to provide an independent evaluation of patient outcomes when this technology was used.

Benefits/ Results:

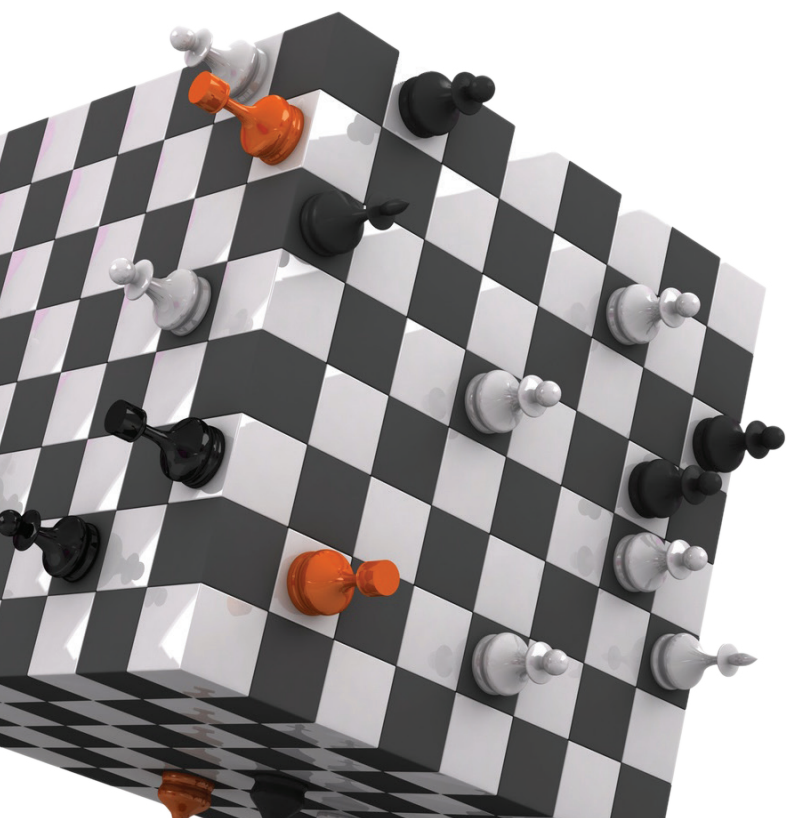
The client received an independent analysis of the safety profile of their medical device. The clinical report demonstrated that the use of their device was safe and could support the initiation of a phase II prospective clinical study in this patient population. All of this work was completed within a six - seven month timeframe.

About Us:

RQMIS, Inc. is a solutions-driven provider of therapeutically focused, comprehensive, regulatory consultation to the global medical device and the combination product industry. The regulatory consultancy is focused in three principal areas, regulatory strategy/submissions, clinical study design/management and quality systems design/compliance. We are headquartered just outside of Boston, MA.

RQMIS was established in 1996 with the specific intent to provide medical device/biotechnology manufacturers with strategic guidance on how to effectively navigate the FDA and EU regulations specific to medical devices and combination products. Sr. management has worked both at the Office of Device Evaluation/CDRH/FDA and in the field for FDA.

For further information about RQMIS, Inc., please visit www.rqmis.com or call 978-358-7307.



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