CASE STUDY PRESENTED BY PREMIER RESEARCH

Is it Safe or Not? Ask a Panel of Independent Experts

When it comes to study data, not everything can be easily measured and reflected by numbers. In a recent trial of a new occluder device for transcatheter closure of secundum atrial septal defects, the primary efficacy endpoint of defect closure was easy to measure in millimeters of possible residual shunt. However, assessment of the safety of the device in terms of postoperative complications and device- or procedure-related adverse was more complex.

Enhancing the Validity and Integrity of Study Results

We recommended the use of a Clinical Endpoint Committee (CEC) to perform a safety assessment and to provide independent adjudication for endpoint analysis in a blinded and unbiased manner. We identified experts in the field, prepared the CEC Charter describing the adjudication process for the trial, and arranged all meetings. Our cross-functional team collaborated to collect, review, and anonymize all relevant safety reports, additional examination reports, and imaging to provide CEC members with the necessary information.

Independent endpoint adjudication can be critical to study success as it serves as a quality control check and can help to lower the risk of variation in important clinical trial outcome events for regulatory submission. In this case, the CEC members provided valuable insight on safety issues and rendered their opinions on whether such events were device- or procedure-related and whether they could be considered study endpoints.

Taking It One Step Further to Study Close

But, our work didn't end there. Our data management team entered the adjudicated results into a specifically designed CEC database and analysis of the results was presented at a subsequent Data Safety and Monitoring Board (DSMB) meeting. The DSMB recommended observing stopping rules and ending the trial with less subjects than projected due to proven non-inferiority of the device. The DSMB also concluded that the study data did not show any threat to patient safety, as supported by the adjudicated results of the CEC.

MEDICAL DEVICE

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Our sponsor was able to end the trial earlier than expected with less subjects than projected – saving time and money

Study Description:
Post CE mark trial of an occluder device for transcatheter closure of secundum atrial septal defects

Therapeutic Area:
Cardiovascular disease

Indication:
Secundum atrial septal defects

Services Provided:
Clinical Endpoint Committee (CEC) organization and management

Full service, including study set-up, data management, and management of Data Safety Monitoring Board (DSMB)

Outcome:
Independent endpoint adjudication by a CEC with adjudicated results presented to a DSMB, leading to successful early stoppage of the trial due to proven non-inferiority of the device and no evidence of threat to patient safety.

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