



Helping a Medical Device Manufacturer Maintain Its Right-to-Sell

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Exactech, a mid-sized medical device manufacturer, approached us with an unusual problem that, if left unaddressed, would prevent them from continuing sales of their orthopaedic prostheses in one of their larger markets. Ultimately, Exactech tasked our team with identifying meaningful differences between the most recent annual reports from the UK National Joint Registry (NJR) and the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) because an expert opinion from an independent third-party was required to refute any claims.

Approach

Importantly, the UK NJR highlighted unfavorable revision rates of Exactech's Optetrak Primary System (PS) and Rotating Bearing Knee (RBK) System which were not confirmed by the AOANJRR data and results. Considering both countries have similar enough populations and surgical implant statistics, our team focused on highlighting the meaningful differences between the two registries' methodologies and the subsequent calculated revision rates.

While we had access to the UK NJR's raw data, for replicability purposes, the team was not provided access to the AOANJRR's raw data, which is why we had to focus on differences between methodologies / data selection and exclusion procedures.

Thankfully, Exactech was also able to provide our team with internally-collected data from the Exactech knee database that we then used to run a Kaplan-Meier survival analysis to corroborate our methodological findings.

Contact Us

To find out more about how our strategy team can assist you with unpacking and solving your most pressing problems, contact us today.

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Recommendations

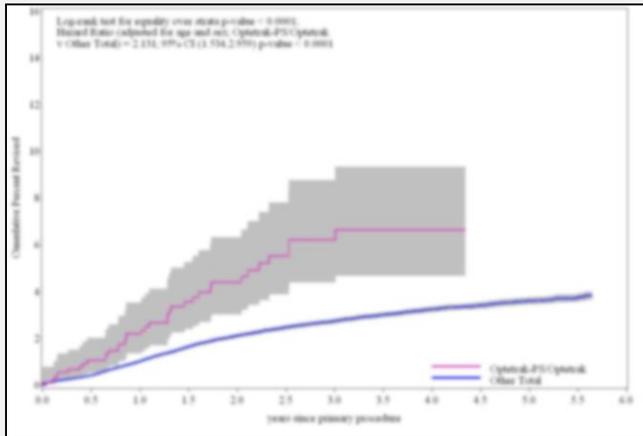
Once we received all materials, our team conducted an in-depth review of the two methodologies behind the UK NJR and AOANJRR annual reports. Importantly, we then worked with the client to determine that while overall revision rates were of interest to all parties, we also needed to calculate the revision rate per 100 observed component years since this would allow us to smooth out some of the data inconsistencies across the multiple datasets.

Results

Immediately, our team identified several key inconsistencies between how the UK NJR calculated its revision rates compared to the AOANJRR, primarily with the sample sizes used in the calculations. While the UK's results were not wrong in any statistical way, the degree certainty derived from the selective approach used was misrepresentative of the overall revision rate.

To support this point, our team's calculation of the Kaplan-Meier estimator highlighted a significantly lower revision rate than the UK report, especially concerning revisions per 100 observed component years, which placed Exactech on par with competitors.

Ultimately, Exactech used our findings to successfully rebut the safety claims against their products and continue selling.



The continued value that Exactech derives from continuing operations in Australia has paid for this project multiple times over, yet the greatest value likely stems from preventing any negative ripple effect that would have arisen from having to exit the market entirely.

About Statistics Solutions

Statistics Solutions is a consulting firm headquartered in Clearwater, FL. It specializes in experimental study design and execution, with core competencies in quantitative and qualitative data collection methods, as well as data analysis, interpretation, and presentation. Its team of professionals primarily works with executives to solve key business issues related to market positioning and strategy.

If you would like to learn more, feel free to visit our website (address provided below) before emailing or calling Hugo St. John III to begin understanding how we can help you achieve your goals with better-than-expected results.