



# Demonstrating Product Value Using Retrospective Claims Database Analysis

A leading global medical device manufacturer sought our services to conduct real world data analysis. The client had access to a large hospital-based all-payer database containing anonymized patient characteristics and health outcomes. The database also contained healthcare resource utilization and economic data from various hospitals in the US. Using statistical methodologies, clinical and economic outcomes were analyzed. Furthermore, health outcome predictors were used to evaluate the safety profile of the medical device.

## Background

In order to demonstrate the value of endoscopic surgical staplers, retrospective claims database analysis was conducted. Complications related to surgical staplers may include leakage from staple lines, bleeding, etc.<sup>1,2</sup> Anastomotic leakage following colorectal resection remains one of the most significant complications with relevant morbidity and mortality. There is evidence that a higher number of staples may affect the leak rate. However, the extent to which patient and surgery related variables impacted health outcomes was to be examined.

## Client Solution

A statistical model was built to establish the relationship between patient characteristics and health outcomes. Challenges included the volume and complexity of the dataset such as data imputation due to missing or invalid values, large number of variables to be analyzed, etc.

The steps in model building included:

- Descriptive and bivariate analyses
- Univariate and multivariate regression
- Model diagnostics and interpretation

This collaborative engagement enabled the client to support the safety and effectiveness of single vs multiple surgical staplers using real world evidence.

## Key Takeaways

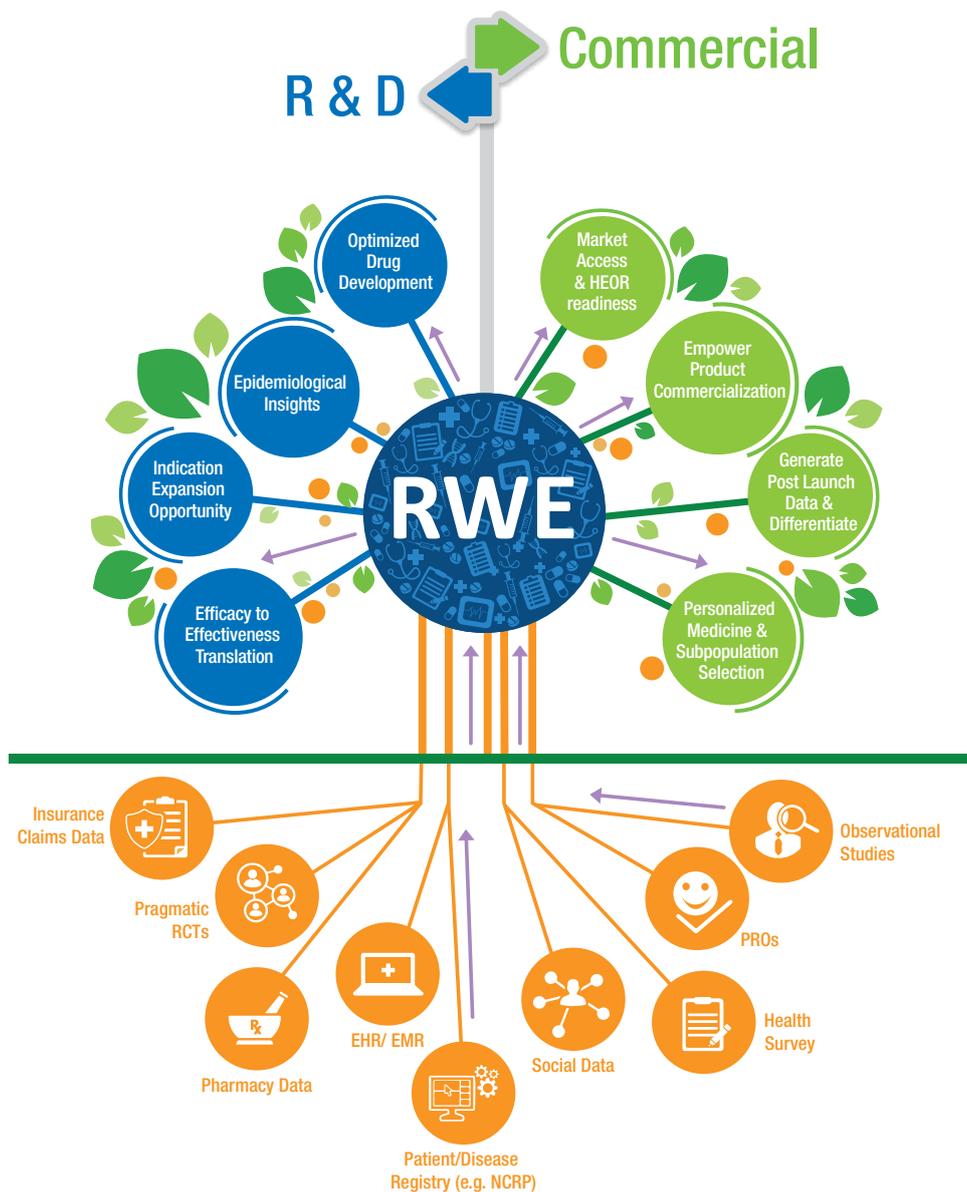
- RWE is playing a key role for organizations to demonstrate the value of their products
- Large raw datasets need to be processed and analyzed into meaningful and measurable outcomes of interest
- Retrospective analyses of claims databases is one of the many types of RWE being leveraged across the life sciences industry
- Specialized RWE expertise and resources are needed to undertake such studies

### References:

1. Gianfranco Silecchia and Angelo Iossa. Complications of staple line and anastomoses following laparoscopic bariatric surgery. *Ann Gastroenterol.* 2018 Jan-Feb; 31(1): 56–64.
2. Edward Chekan and Richard L. Whelan. Surgical stapling device–tissue interactions: what surgeons need to know to improve patient outcomes. *Med Devices (Auckl).* 2014; 7: 305–318.



## Sources and Uses of Real World Evidence (RWE)



### Sciformix Corporation

1500 West Park Drive, Suite 210  
Westborough, MA 01581. USA  
Phone : 1 (877) 576-5005  
Fax : 1 (508) 302-6520  
Email : bizteam@sciformix.com

[www.sciformix.com](http://www.sciformix.com)

US | EU | India | Philippines

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