

2015 European Theranostics Product Leadership Award



FROST & SULLIVAN



50 Years of Growth, Innovation & Leadership

BEST PRACTICES RESEARCH



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Background and Company Performance Industry Challenges

The co-development of drugs and diagnostic tests is a complex process. The timelines for drug development and diagnostic test trials vary. The implementation of a diagnostic test at every phase of drug development becomes cumbersome for pharmaceutical companies, since they have to make many internal changes ranging from biomarker identification, validation, and technology platforms to labeling considerations. Frost & Sullivan recognizes that a pharmaceutical company has to be equipped with the right mix of resources in order to collaborate with a diagnostic company.

The role of physicians is critical in promoting companion diagnostic tests. Companion tests leave little choice for a physician to prescribe a drug of his or her choice, and physicians often doubt the ability of a companion test to prescribe the drug compared to their knowledge and experience. Therefore, removing this stigma and encouraging a new generation of physicians with a positive attitude towards theranostics will help to curtail this challenge.

Although the science behind theranostics is well understood, pharmaceutical companies are still late adopters because of the refinements that they will have to bring in order to change their approach from a blockbuster model to a more targeted, niche-market model. The blockbuster model caters to a broad population and predicts instant high return on investment, whereas segmentation of the market by theranostics results potentially means less profit for a drug.

Companies focusing on theranostics with already licensed drugs can play a key role in reaching out to larger pharmaceutical companies. The pharmaceutical companies must be aware of the importance of linking diagnostics to their drug development process. As pharmaceutical companies are less interested in forming their own diagnostic capabilities, they should look towards collaborating with existing IVD pioneers.

Product Family Attributes and Business Impact

Match to Needs

Theradiag's consistent focus is on the important market need to precisely determine the patient's response to a treatment. Theranostics solutions allow biotherapies for individualized treatment to be monitored. Autoimmune diseases and cancer are examples of crucial diseases with higher morbidity. Frost & Sullivan notes that this crucial market need has led to the repositioning of Theradiag's product family. The company strengthened its strategy to focus on theranostics separately by creating two business units: Theranostics and In-vitro Diagnostics. The Company's new focus on inhouse, highly innovative IVD and theranostics product have led to the company to bounce back to positive growth. One result of this strategy is the market's first full range of 10 CE-marked, innovative LISA TRACKER kits developed by Theradiag to monitor autoimmune diseases.



In addition, Theradiag is preparing the next generation of theranostics treatment through the development of a microRNA technological platform with applications for rectal cancer, HIV/AIDS and autoimmune diseases

Positioning

A unique feature of the LISA TRACKER kits is its facility to allow simultaneous dosage of two parameters: prescribed biologic, and the presence of antibodies directed against the medication (anti-drug neutralizing antibodies). This is achieved within three hours of reaction from a serum sample. Frost & Sullivan's analysis shows that the combination of these two parameters helps to anticipate, optimize, and better manage the patient's treatment, a unique feature that cannot be easily replicated by any competitor within three hours of reaction from a serum sample.

Financial Performance

Frost & Sullivan's analysis confirms that Theradiag has achieved exceptional growth in the sales of its theranostics products, reaching €1.4 million (\$1.7 million) in 2014. The company's high growth has been driven by strong sales of its LISA TRACKER products, leading to 3.6 times more sales in 2014 compared to the previous year. The company's strategic focus to stick to high-value theranostics products paid off, leading to international sales of 41% in 2014, compared to 32% the previous year.

Customer Acquisition

Theradiag is an expert partner for developing biological diagnosis and monitoring kit. As a fully integrated company, it possesses an organized, integrated expertise, from R&D to distribution. Frost & Sullivan's research reveals that unlike its competitors, Theradiag is one of the few companies with the potential to launch diagnostic solutions in less than 12 months. This integrated strength makes Theradiag a preferred partner for its customers in custom development and commercialization, leading to higher customer acquisition potential.

Growth Potential

Theradiag is constantly looking at growth opportunities, with new launches in 2014, product expansions, and progress in theranostics product development projects. In 2014, the company obtained the CE mark for its new test to monitor Avastin® (bevacizumab), in order to expand the LISA TRACKER product range to the oncology sector. In 2015, Theradiag CE-marked two other kits for Herceptin® (trastuzumab) and Stelara® (ustekinumab). The addition of these new tests increased the count to 10 kits in total for autoimmune diseases and cancer. With vast experience in the diagnostics industry, Frost & Sullivan anticipates that the company will further grow by targeting other autoimmune diseases treatments, for example in Crohn's disease. Theradiag is also expanding into developing predictive biomarkers in order to predict responses to chemo- and radiotherapy early, as well as to anticipate metastatic recurrences in rectal cancer. The company's development efforts to strengthen the brand show the company's growth potential in the theranostics market.



Human Capital

The company's culture and motto center on quality, reliability, timely service, and responsiveness, boosting the employees' morale to provide high-quality products and services. The company has been focusing on internal development as well as marketing a new theranostics product range through dedicated teams to serve clinicians and patients.

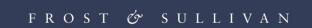
Best Practice Example:

Theradiag invests considerable human capital into different functionalities. The company has employed a team of more than 20 employees in R&D, manufacturing, and industrialization, as well as a hotline staffed by 2 technicians, an instrument application team, and 3 customer service engineers. Approved training is also provided for technicians and biologists, allowing them to quickly master newly developed technologies (e.g., Luminex®, ELISA, Dot). The company is also business certified by the LNE/G-MED (ISO 9001 and ISO 13485).

Conclusion

Few companies in the market, such as Theradiag, have been able to successfully maintain a dual profile as both a distributor as well as a biotech company. Frost & Sullivan's independent analysis clearly shows that Theradiag is the leader in theranostics and the first and only company to provide the market's largest range biotherapy monitoring kits for autoimmune diseases and cancer. Frost & Sullivan recognises that dedicated focus on theranostics and its continuous strategic repositioning of its business units has been instrumental for the company's success.

With its strong overall performance, Theradiag has earned Frost & Sullivan's 2015 Product Leadership Award.



Significance of Product Leadership

Ultimately, growth in any organization depends upon customers purchasing from your company, and then making the decision to return time and again. A comprehensive product line, filled with high-quality, value-driven options, is the key to building an engaged customer base. To achieve and maintain product excellence, an organization must strive to be best-in-class in three key areas: understanding demand, nurturing the brand, and differentiating from the competition.

· Acquire competitors' customers · Earn customer loyalty · Increase renewal rates · Foster strong corporate identity · Increase upsell rates · Improve brand recall · Build a reputation for value Inspire customers Increase market penetration · Build a reputation for creativity Product Leadership COMPETITIVE POSITIONING Stake out a unique market position Promise superior value to customers · Implement strategy successfully · Deliver on the promised value proposition · Balance price and value



Understanding Product Leadership

Demand forecasting, branding, and differentiation all play a critical role in finding growth opportunities for your product line. This three-fold focus, however, must be complemented by an equally rigorous focus on pursuing those opportunities to a best-in-class standard. Customer communications, customer feedback, pricing, and competitor actions must all be managed and monitored for ongoing success. If an organization can successfully parlay product excellence into positive business impact, increased market share will inevitably follow over time.

Key Benchmarking Criteria

For the Product Leadership Award, Frost & Sullivan analysts independently evaluated two key factors—Product Family Attributes and Business Impact—according to the criteria identified below.

Product Family Attributes

Criterion 1: Match to Needs

Criterion 2: Reliability and Quality Criterion 3: Product/Service Value

Criterion 4: Positioning Criterion 5: Design

Business Impact

Criterion 1: Financial Performance Criterion 2: Customer Acquisition Criterion 3: Operational Efficiency Criterion 4: Growth Potential

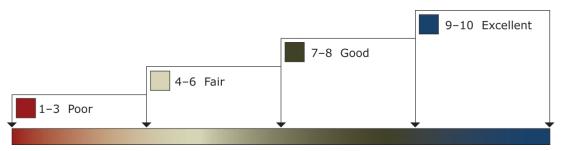
Criterion 5: Human Capital



Best Practice Award Analysis for Theradiag Decision Support Scorecard

To support its evaluation of best practices across multiple business performance categories, Frost & Sullivan employs a customized Decision Support Scorecard. This tool allows our research and consulting teams to objectively analyze performance, according to the key benchmarking criteria listed in the previous section, and to assign ratings on that basis. The tool follows a 10-point scale that allows for nuances in performance evaluation; ratings guidelines are illustrated below.

RATINGS GUIDELINES



The Decision Support Scorecard is organized by Product Family Attributes and Business Impact (i.e., the overarching categories for all 10 benchmarking criteria; the definitions for each criteria are provided beneath the scorecard). The research team confirms the veracity of this weighted scorecard through sensitivity analysis, which confirms that small changes to the ratings for a specific criterion do not lead to a significant change in the overall relative rankings of the companies.

The results of this analysis are shown below. To remain unbiased and to protect the interests of all organizations reviewed, Frost & Sullivan chose to refer to the other key players as Competitor 2 and Competitor 3.

DECISION SUPPORT SCORECARD FOR PRODUCT LEADERSHIP AWARD

Measurement of 1–10 (1 = poor; 10 = excellent)			
Product Leadership	Product Family Attributes	Business Impact	Average Rating
Theradiag	9	9	9
Competitor 2	7	7	7
Competitor 3	5	5	5



Product Family Attributes

Criterion 1: Match to Needs

Requirement: Customer needs directly influence and inspire the design and positioning of the product family

Criterion 2: Reliability and Quality

Requirement: Products consistently meet or exceed customer expectations for performance and length of service

Criterion 3: Product/Service Value

Requirement: Products or services offer the best value for the price, compared to similar offerings in the market

Criterion 4: Positioning

Requirement: Products or services unique, unmet need that competitors cannot easily replicate or replace

Criterion 5: Design

Requirement: The product features an innovative design, enhancing both visual appeal and ease of use

Business Impact

Criterion 1: Financial Performance

Requirement: Strong overall financial performance in terms of revenues, revenue growth, operating margin and other key financial metrics

Criterion 2: Customer Acquisition

Requirement: Product strength enables acquisition of new customers, even as it enhances retention of current customers

Criterion 3: Operational Efficiency

Requirement: Staff is able to perform assigned tasks productively, quickly, and to a high quality standard

Criterion 4: Growth Potential

Requirements: Product quality strengthens brand, reinforces customer loyalty and enhances growth potential

Criterion 5: Human Capital

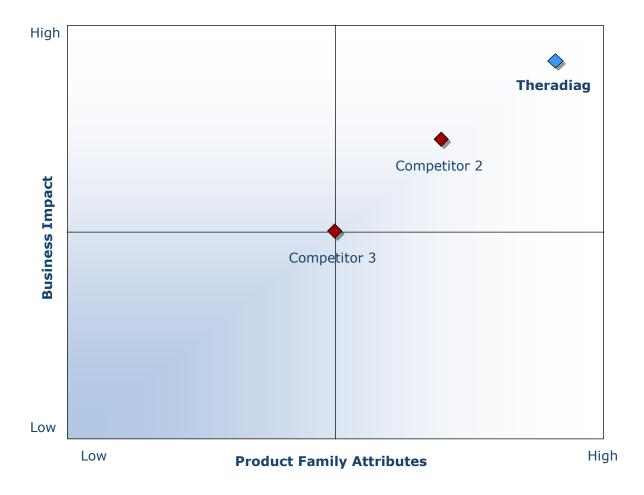
Requirement: Company culture is characterized by a strong commitment to product quality and customer impact, which in turn enhances employee morale and retention



Decision Support Matrix

Once all companies have been evaluated according to the Decision Support Scorecard, analysts can then position the candidates on the matrix shown below, enabling them to visualize which companies are truly breakthrough and which ones are not yet operating at best-in-class levels.

DECISION SUPPORT MATRIX: PRODUCT LEADERSHIP AWARD



The Intersection between 360-Degree Research and Best Practices Awards

Research Methodology

Frost & Sullivan's 360-degree research methodology represents the analytical rigor of our research process. It offers a 360-degree-view of industry challenges, trends, and issues by integrating all 7 of Frost & Sullivan's research methodologies. Too often, companies make important growth decisions based on a narrow understanding of their environment, leading to errors of both omission and commission. Successful growth strategies are founded on a thorough understanding of market, technical, economic, financial, customer, best practices, and demographic analyses. The integration of these research disciplines into the 360-degree research methodology provides an evaluation



platform for benchmarking industry players and for identifying those performing at best-in-class levels.

About Frost & Sullivan

Frost & Sullivan, the Growth Partnership Company, enables clients to accelerate growth and achieve best in class positions in growth, innovation and leadership. The company's Growth Partnership Service provides the CEO and the CEO's Growth Team with disciplined research and best practice models to drive the generation, evaluation and implementation of powerful growth strategies. Frost & Sullivan leverages more than 50 years of experience in partnering with Global 1000 companies, emerging businesses and the investment community from 40 offices on six continents. To join our Growth Partnership, please visit http://www.frost.com.