

F R O S T & S U L L I V A N

FROST & SULLIVAN BEST PRACTICES AWARD

PROSTATE CANCER DIAGNOSTIC IMAGING - GLOBAL

Technology Innovation 2019

EXACT+ IMAGING

FROST & SULLIVAN

2019

BEST  
PRACTICES  
AWARD

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## Background and Company Performance

### *Industry Challenges*

#### **Conventional Transrectal Ultrasound (TRUS) is Insufficient to Image Prostate Cancer**

Although conventional TRUS is a standard of care for imaging prostate cancer, it is not able to visualize the majority of prostate cancers and has a high false negative biopsy rate. Currently, the clinical standard for TRUS varies in the range of 6 to 9 megahertz (MHz). At these frequencies, it is difficult to visualise the architecture of the prostate - such as normal and abnormal ductal patterns, zonal anatomy, small foci of disease, micro-calcifications, and many cystic lesions. It is generally accepted in clinical urology that systemic TRUS biopsies have a high rate of false negatives, meaning that approximately 30% of men with benign or normal biopsy results may actually have missed prostate cancer. These men require repeated biopsy until the cancer is found, which adds unnecessary pain, infectious complications, and risks the cancer spreading before it is discovered.

#### **Complex Workflows, Operator Expertise, and Lower Reimbursement Restrict Multiparametric MRI (mpMRI) for Diagnosis of Prostate Cancer**

During active surveillance or when conventional TRUS biopsy results are negative though the prostate-specific antigen (PSA) level is elevated, an mpMRI is performed. Frost & Sullivan notes that an mpMRI has clear advantages over conventional TRUS in visualisation of whole prostate and provides details on the penetration of cancer throughout the prostate and in the bone. However, Frost & Sullivan analysis confirms that there are associated disadvantages which outweigh the full potential of mpMRI in daily clinical practice.

First, mpMRI has a complex workflow and is limited in relation to the operator's expertise. The operator has to be well-versed in both performing mpMRI and interpreting the Prostate Imaging Reporting and Data System results. Second, mpMRI incurs significant capital and operational costs and involves extended patient waiting time for an available MRI. Lastly, mpMRI has a lower rate of reimbursement (in the United States and Europe), yet is advised in cases with multiple negative prostate biopsies and persistent elevated PSA levels. Further, it is time consuming and difficult to biopsy within the MRI, requiring biopsy targets to be transferred to TRUS in a second separate procedure which may introduce error.

## *Technology Attributes and Future Business Value*

### **Micro-Ultrasound for Targeted Real-Time Prostate Biopsies**

Prostate cancer is one of the most common cancers in men and is responsible for the third and fourth highest cancer-related deaths in The United States and Europe, respectively. In response, early diagnosis (beginning age 40 years) and active surveillance are being increasingly prescribed by clinicians. Traditionally, a positive PSA test leads to a systemic TRUS. However, conventional TRUS has limitations in delineating the accuracy of malignancy in either hypo- or hyper-echoic lesions. Moreover, conventional TRUS is not efficient at visualising the critical architecture in prostate cancer and has an approximate 42% false negative rate.

To this end, Frost & Sullivan recognizes how Exact Imaging's ExactVu™, the world's first 29 MHz micro-ultrasound, has revolutionised the TRUS space with significant improvement in the resolution, down to 70 microns, and ability to visualise the full depth of most prostates - in comparison to the competition, which offers a resolution more than 3-times lower. With the ability to visualise anatomy and tissue texture, ExactVu™ micro-ultrasound helps in the identification of zone margins, small calcified lesions, prior biopsy needle tracks, and subtle deviations in prostate margins. Frost & Sullivan notes that the ability of ExactVu™ micro-ultrasound to resolve anatomical details down to 70 microns marks a true transformational change in the effectiveness of TRUS-guided biopsies.

### **Micro-Ultrasound for Targeted Real-Time Biopsies: A Novel Approach Compared to Conventional TRUS**

ExactVu™ supports both conventional and high-resolution transducers, which operate at a frequency in between 2 and 29 MHz. While the conventional transducers may be used for abdominal and general urological imaging, the high-resolution transducer, operating at 29 MHz, provides excellent spatial resolution of prostate architecture for visualisation of prostate cancer. At 29 MHz, ExactVu™ has the ability to completely visualise most of the prostate, with a depth up to 50 mm. This provides a 300% improvement in resolution both in the axial and lateral planes (when compared to conventional TRUS).

In a recent study, Exact Imaging's micro-ultrasound demonstrated 73% and 9.5% improvement in sensitivity and specificity over conventional TRUS. Moreover, it identified more high-grade lesions. While the competition proposed the fusion of ultrasound and mpMRI for optimal prostate cancer diagnosis, ExactVu™ has provided information for clinically significant prostate cancer on par with mpMRI, which confirms the diagnostic power of ExactVu™ micro-ultrasound.

### **High Resolution Micro-Ultrasound Imaging for Diverse Clinical Applications**

ExactVu™ provides urologists with the most practical solution for diagnostic imaging, operating at a frequency in between 2 and 29 MHz. This allows for abdominal imaging,

including kidney and bladder, and large prostate procedures. The implication of high resolution micro-ultrasound imaging is not limited to prostate TRUS and can be scaled to other clinically relevant applications. Frost & Sullivan feels that ExactVu's™ potential to expand to other clinical specialties for high-resolution transducers is tied to its disruptive role in accurately visualising normal anatomy and distinguishing it from abnormal anatomy. This will further enhance the experience of oncologists in detecting malignancies.

In bladder cancer, MRI is a standard of care for preoperative staging. However, MRI is capital intensive, may be contraindicated for patients with deteriorated renal function, and may still require cystoscopy and trans-urethral resection. ExactVu™ delivers a high-resolution micro-ultrasound as an excellent alternative that accurately delineates the normal anatomy of the bladder wall from the bladder tumours and discriminates non-muscle invasive bladder cancer from muscle-invasive bladder with a strong pathological correlation.

Application diversity also comes from the potential for high resolution micro-ultrasound guided focused laser ablation (FLA). Exact Imaging's ExactVu platform may offer a superior solution for image-guided FLA for the urology market by eliminating the need for MRI guidance during the procedure, making treatment faster, more accurate, and more cost effective. Exact Imaging's micro-ultrasound real-time imaging and biopsy guidance will dramatically increase the clinician's ability to target diseased tissue and receive superior guidance during the procedure to ultimately monitor the FLA treatment.

### **Exact Imaging's Innovation in Targeted Prostate Biopsies – Key Criteria to Boost Customer Acquisition**

Current market participants in the urology ultrasound space have an inclination towards providing MRI-TRUS fusion imaging as the best-in-class approach to prostate cancer imaging and guided biopsies. However, a major segment of end users (i.e., many healthcare facilities) do not have access to an MRI, or contend with long waiting periods. These restraints - along with the capital-intensive nature of MRI – the requirement for highly experienced personnel for fusion imaging, and the contraindications for selected patient populations make MRI-TRUS fusion imaging an unattractive choice.

Conversely, ultrasound is a bed-side procedure and requires minimal capital investment and hands-on experience. ExactVu™ micro-ultrasound TRUS offers a unique value proposition (UVP) that encompasses four aspects:

1. Expedited and highly accurate real-time targeted biopsies, without the need for MRI-TRUS fusion
2. Short time frame needed to familiarize oneself with ExactVu™ micro-ultrasound TRUS to achieve accurate real-time targeted biopsies

3. Reduced use of mpMRI and patient referrals for re-biopsy
4. Enhanced architectural visualisations of prostate gland using the PRI-MUS™ protocol, allowing a higher detection rate through targeted biopsies

Different healthcare facilities have diverse capacities and capabilities in the urology ultrasound space. With its UVP, Exact Imaging is set to attract a diverse customer base, due to its ease of use, accessible bedside biopsy for prostate, and enhancement of the urologist's experience for targeted biopsies. Finally, given the many benefits and foreseeing the attractive total cost of ownership of micro-ultrasound, the current customer base is expected to grow by several fold in next 2 years.

**Exact Imaging's Brand Equity in the Urological Market** Exact Imaging has demonstrated strong financial metrics, with healthy financing support from global financial institutions and government agencies alike. In 2017, the company secured financial support of around USD 32 million for commercializing its flagship ExactVu™ micro-ultrasound. Exact Imaging has also secured key commercial partnerships for expanding its addressable market and to boost sales. One key partnership is with UroGPO, the prominent urology-specific GPO in North America. With this partnership, Exact Imaging is keen to leverage UroGPO's 550+ member urology practices across the United States. As part of the partnership, UroGPO members will have preferential pricing and service packages for ExactVu™. Another key commercial partnership is with Southern California's largest urology practice, Skyline Urology. Some of the key academic customers who have published their results using the ExactVu system include Ordensklinikum Linz (Austria), Urología Clínica (Spain), Humanitas Clinical and Research Center (Italy), Polyclinique de Reims Bezannes (France), Urology of Virginia (USA), Riverside Research (USA), Cleveland Clinic (USA), University of Toronto (Canada), and Princess Margaret Cancer Centre (Canada). As Exact Imaging closes its financial books for 2018, it generated about USD 5 million for commercializing its flagship ExactVu™ micro-ultrasound. Exact Imaging aims to excel the revenue growth metrics by crossing net worth of USD 50 million by 2021. In the next 5 years, the company also envisions to boost its sales by exceeding 1,000 installed micro-ultrasound systems in the NA and EU markets.

## Conclusion

Conventional TRUS, using current clinical standard-of-care conventional ultrasound systems operate with frequencies between 6 and 9 MHz, which lacks the ability to fully visualize and differentiate anatomical abnormalities and suspicious prostatic tissue. As such, prostate biopsies guided by these conventional ultrasound systems are “blind” and have a high (30 – 40%) false negative biopsy rate. Another option for prostate biopsies is multiparametric MRI, which provides strong visualization of the prostatic anatomy but suffers from high cost, complex workflow, dependence on a Radiologist and access to an MRI, is costly for the patient and payer and has high variability between sites and between operators.

Exact Imaging’s micro-ultrasound-based system, ExactVu™, operates at 29 MHz, providing a 300% improvement in visualisation over conventional urological ultrasound systems, and has the ability to completely visualise anatomical details down to 70 microns. Alongside these superior features, Frost & Sullivan independent analysis concludes that the technical and financial independence from MRI for healthcare providers enhances the overall USP of Exact Imaging’s flagship ExactVu™ micro-ultrasound system.

For its strong overall performance and significant potential to become the standard of care in prostate cancer targeted biopsies, Exact Imaging has earned the 2019 Frost & Sullivan Technology Innovation Award.

## Significance of Technology Innovation

Ultimately, growth in any organization depends on finding new ways to excite the market and maintaining a long-term commitment to innovation. At its core, technology innovation, or any other type of innovation, can only be sustained with leadership in 3 key areas: understanding demand, nurturing the brand, and differentiating from the competition.



## Understanding Technology Innovation

Technology innovation begins with a spark of creativity that is systematically pursued, developed, and commercialized. This spark can result from a successful partnership, a productive in-house innovation group, or a bright-minded individual. Regardless of the source, the success of any new technology is ultimately determined by its innovativeness and its impact on the business as a whole.



## Key Benchmarking Criteria

For the Technology Innovation Award, Frost & Sullivan analysts independently evaluated 2 key factors—Technology Attributes and Future Business Value—according to the criteria identified below.

### Technology Attributes

- Criterion 1: Industry Impact
- Criterion 2: Product Impact
- Criterion 3: Scalability
- Criterion 4: Visionary Innovation
- Criterion 5: Application Diversity

### Future Business Value

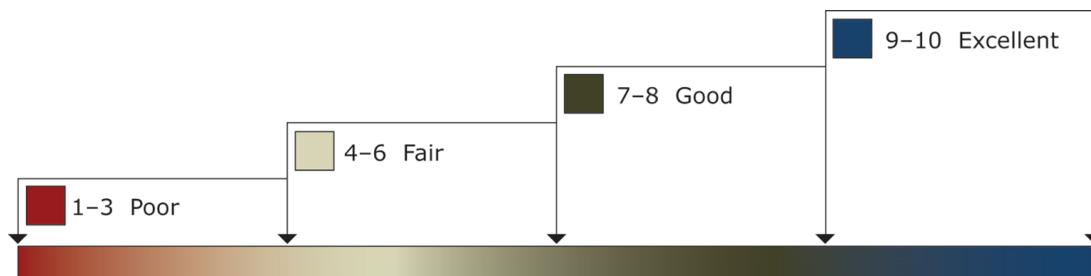
- Criterion 1: Financial Performance
- Criterion 2: Customer Acquisition
- Criterion 3: Technology Licensing
- Criterion 4: Brand Loyalty
- Criterion 5: Human Capital

## Best Practices Award Analysis for Exact Imaging

### 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 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 considers Technology Attributes and Future Business Value (i.e., the overarching categories for all 10 benchmarking criteria; the definitions for each criterion 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 has chosen to refer to the other key participants as Competitor 2 and Competitor 3.

<i>Measurement of 1-10 (1 = poor; 10 = excellent)</i>			
<b>Technology Innovation</b>	Technology Attributes	Future Business Value	Average Rating
<b>Exact Imaging</b>	<b>9.0</b>	<b>9.0</b>	<b>9.0</b>
Competitor 2	9.0	8.0	8.5
Competitor 3	8.5	8.5	8.5

### *Technology Attributes*

#### **Criterion 1: Industry Impact**

Requirement: Technology enables the pursuit of groundbreaking ideas, contributing to the betterment of the entire industry.

#### **Criterion 2: Product Impact**

Requirement: Specific technology helps enhance features and functionalities of the entire product line for the company.

#### **Criterion 3: Scalability**

Requirement: Technology is scalable, enabling new generations of products over time, with increasing levels of quality and functionality.

#### **Criterion 4: Visionary Innovation**

Requirement: Specific new technology represents true innovation based on a deep understanding of future needs and applications.

#### **Criterion 5: Application Diversity**

Requirement: New technology serves multiple products, multiple applications, and multiple user environments.

### *Future Business Value*

#### **Criterion 1: Financial Performance**

Requirement: Potential is high for strong financial performance in terms of revenue, operating margins, and other relevant financial metrics.

#### **Criterion 2: Customer Acquisition**

Requirement: Specific technology enables acquisition of new customers, even as it enhances value to current customers.

#### **Criterion 3: Technology Licensing**

Requirement: New technology displays great potential to be licensed across many verticals and applications, thereby driving incremental revenue streams.

**Criterion 4: Brand Loyalty**

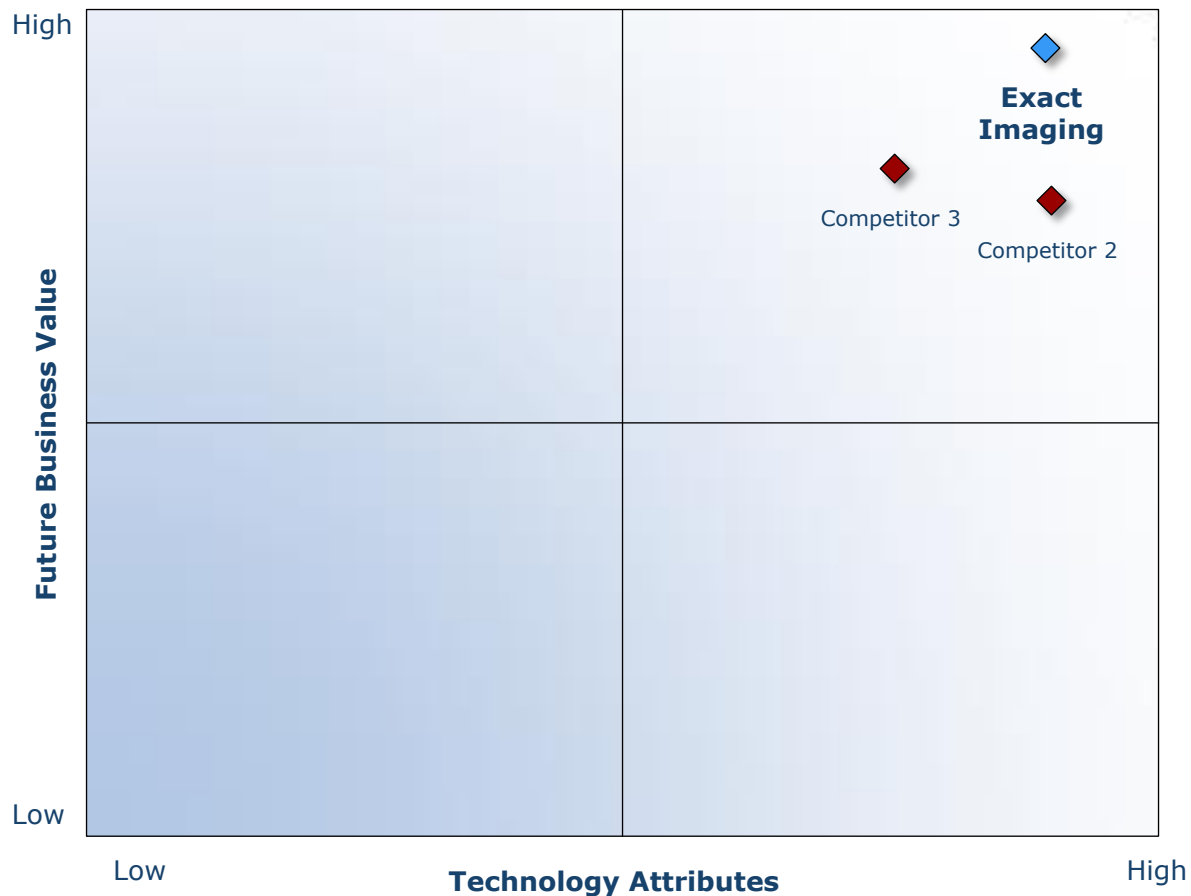
Requirement: New technology enhances the company’s brand, creating and/or nurturing brand loyalty.

**Criterion 5: Human Capital**

Requirement: Customer impact is enhanced through the leverage of specific technology, translating into positive impact on employee morale and retention.

*Decision Support Matrix*

Once all companies have been evaluated according to the Decision Support Scorecard, analysts 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.



## Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

Frost & Sullivan analysts follow a 10-step process to evaluate Award candidates and assess their fit with select best practices criteria. The reputation and integrity of the Awards are based on close adherence to this process.

STEP	OBJECTIVE	KEY ACTIVITIES	OUTPUT
1 <b>Monitor, target, and screen</b>	Identify Award recipient candidates from around the world	<ul style="list-style-type: none"> <li>• Conduct in-depth industry research</li> <li>• Identify emerging industries</li> <li>• Scan multiple regions</li> </ul>	Pipeline of candidates that potentially meet all best practices criteria
2 <b>Perform 360-degree research</b>	Perform comprehensive, 360-degree research on all candidates in the pipeline	<ul style="list-style-type: none"> <li>• Interview thought leaders and industry practitioners</li> <li>• Assess candidates' fit with best practices criteria</li> <li>• Rank all candidates</li> </ul>	Matrix positioning of all candidates' performance relative to one another
3 <b>Invite thought leadership in best practices</b>	Perform in-depth examination of all candidates	<ul style="list-style-type: none"> <li>• Confirm best practices criteria</li> <li>• Examine eligibility of all candidates</li> <li>• Identify any information gaps</li> </ul>	Detailed profiles of all ranked candidates
4 <b>Initiate research director review</b>	Conduct an unbiased evaluation of all candidate profiles	<ul style="list-style-type: none"> <li>• Brainstorm ranking options</li> <li>• Invite multiple perspectives on candidates' performance</li> <li>• Update candidate profiles</li> </ul>	Final prioritization of all eligible candidates and companion best practices positioning paper
5 <b>Assemble panel of industry experts</b>	Present findings to an expert panel of industry thought leaders	<ul style="list-style-type: none"> <li>• Share findings</li> <li>• Strengthen cases for candidate eligibility</li> <li>• Prioritize candidates</li> </ul>	Refined list of prioritized Award candidates
6 <b>Conduct global industry review</b>	Build consensus on Award candidates' eligibility	<ul style="list-style-type: none"> <li>• Hold global team meeting to review all candidates</li> <li>• Pressure-test fit with criteria</li> <li>• Confirm inclusion of all eligible candidates</li> </ul>	Final list of eligible Award candidates, representing success stories worldwide
7 <b>Perform quality check</b>	Develop official Award consideration materials	<ul style="list-style-type: none"> <li>• Perform final performance benchmarking activities</li> <li>• Write nominations</li> <li>• Perform quality review</li> </ul>	High-quality, accurate, and creative presentation of nominees' successes
8 <b>Reconnect with panel of industry experts</b>	Finalize the selection of the best practices Award recipient	<ul style="list-style-type: none"> <li>• Review analysis with panel</li> <li>• Build consensus</li> <li>• Select recipient</li> </ul>	Decision on which company performs best against all best practices criteria
9 <b>Communicate recognition</b>	Inform Award recipient of recognition	<ul style="list-style-type: none"> <li>• Present Award to the CEO</li> <li>• Inspire the organization for continued success</li> <li>• Celebrate the recipient's performance</li> </ul>	Announcement of Award and plan for how recipient can use the Award to enhance the brand
10 <b>Take strategic action</b>	Upon licensing, company is able to share Award news with stakeholders and customers	<ul style="list-style-type: none"> <li>• Coordinate media outreach</li> <li>• Design a marketing plan</li> <li>• Assess Award's role in strategic planning</li> </ul>	Widespread awareness of recipient's Award status among investors, media personnel, and employees

## The Intersection between 360-Degree Research and Best Practices Awards

### Research Methodology

Frost & Sullivan's 360-degree research methodology represents the analytical rigor of the 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, resulting in 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 participants and for identifying those performing at best-in-class levels.



### About Frost & Sullivan

Frost & Sullivan, the Growth Partnership Company, helps clients 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-practices models to drive the generation, evaluation, and implementation of powerful growth strategies. Frost & Sullivan leverages nearly 60 years of experience in partnering with Global 1000 companies, emerging businesses, and the investment community from 45 offices on 6 continents. To join Frost & Sullivan's Growth Partnership, visit <http://www.frost.com>.