

FROST & SULLIVAN

# **U.S. Market Assessment for iKnee** *Actionable Customer Insights to Guide iOI to Market Success*

**Proposal Prepared for PFD Capital/iOI**

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October 11<sup>th</sup>, 2021

# Cover Letter

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October 11<sup>th</sup>, 2021

Dear Eric,

We value the opportunity to respond to your request for a proposal to gather insights from U.S. surgeons and patients to assess the disruptive market potential for your company's iKnee system.

Our proposal includes our understanding of your current requirements, our recommended approach to address your objectives, the expected results and the required investment. As it is critically important that we have the same expectations for the project as PFD Capital-iOI, we would appreciate any feedback and suggestions that will allow us to refine our proposal.

Our mutual goal is to assure the greatest possible success for PFD Capital-iOI as you proceed with your strategic growth plans. We are convinced this project, as proposed herein, will significantly enhance the effectiveness of your plans and thereby justify your investment in our services.

We very much look forward to discussing our approach with you.

Sincerely,

**Charlie Whelan**

Vice President of Consulting, Transformational Health, Americas  
Frost & Sullivan

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# Frost & Sullivan's Approach



# Project Overview

- iOI corporation, a part of the PFD family of companies, has been created to develop and commercialize the iKnee which is a biocompatible polymer implant designed to be inserted into the joint space of the knee to protect and pad the surfaces of bones in the joint. The hope is that the treatment will be a faster, less invasive and less costly alternative to total knee arthroplasty, and that it could also be used for other treatments associated with cartilage repair in the joint. The iKnee procedure would be a valuable addition to a surgeon's portfolio of approaches for managing a patient's knee pain filling a gap between arthroscopy and intra-articular injections and a complete knee replacement.
- More than one million primary total knee arthroplasties (TKA) are expected to be completed by the end of 2020. A significant portion of these patients as well as others with less advanced knee degeneration are likely candidates for the iKnee procedure.
- iOI is in the early stage of clinical trials for the iKnee product. During this clinical evaluation phase, iOI wishes to gather more insight into the perceived value of the iOI and the size of the addressable market through conversations with prospective implanting surgeons as well as prospective patients. These insights will be used for internal planning purposes, but will also be presented in a final document suitable for presenting to prospective investors and partners.
- The United States is the single largest market for knee surgery in terms of revenue potential, so this research will be focused on orthopedic surgeons and patients in this country.
- Frost & Sullivan is in an ideal position to support iOI on this project because of its extensive expertise in assessing new medical technologies, including those in the orthopedic sector. The company's team of medtech subject matter experts combined with consultants focused on deploying and analyzing qualitative and quantitative research make it an idea partner for this important engagement.

## Benefits of iKnee vs. Total Knee

	Total knees	>>vs.>>	iKnee
<i>Surgical duration:</i>	2 - 4 hours		~ 1 hour
<i>Joint sparing:</i>	No		Yes
<i>Revision surgery:</i>	Difficult		Easy
<i>Procedure cost:</i>	\$45k - \$50k		\$15k - \$20k
<i>Recovery time:</i>	1 - 2 months		2 - 3 days
<i>Pain reduction:</i>	50% - 75%		80% - 100%
<i>Components:</i>	3 metal/plastic PE		1 polymer PU
<i>Bone and cartilage:</i>	Ablated		Preserved/Restored
<i>Anesthesia type:</i>	General or spinal		Local or epidural
<i>Minimally Invasive:</i>	No		Yes

# Project Objectives

Over the course of multiple phases of the engagement, Frost & Sullivan will explore the following questions and others:

Objective	Surgeons	Patients
<b>Respondent Background</b>	<ul style="list-style-type: none"> <li>Demographics; Practice Setting; Geography; Case Mix</li> <li>Surgical volumes for 2020 broken by type of patient, severity, patient journey</li> <li>Attitudes toward different surgical intervention (aggressive vs. conservative, etc.)</li> </ul>	<ul style="list-style-type: none"> <li>Patient journey (timeline)</li> <li>Current treatment methods used for knee pain</li> <li>Knee pain impact on function and quality of life; desire for alternatives</li> </ul>
<b>Needs Assessment/ Gap Analysis (Unprompted)</b>	<ul style="list-style-type: none"> <li>Perceived needs for less invasive treatment alternatives; Satisfaction with current approaches in terms of outcomes, economics, throughput, etc.</li> <li>Current bottlenecks to providing better care for knee pain</li> <li>Surgeon perspective on patient experience</li> </ul>	<ul style="list-style-type: none"> <li>Satisfaction with past/current treatment methods. Desire for alternatives.</li> </ul>
<b>Feedback on Product</b>	<ul style="list-style-type: none"> <li>Perceived iKnee advantages/ disadvantages (responding to prepared iKnee description)</li> <li>Expected adoption rate under different “evidence scenarios”</li> </ul>	<ul style="list-style-type: none"> <li>Perceived feedback on value of iKnee surgery vs. TKA surgery expressed as benefits to patient, e.g. pain, procedure time, recovery time, risk, ability to revise, etc.</li> <li>Patient adoption of iKnee compared to other interventions at varying degrees of knee pain/ function</li> </ul>
<b>Economics/ Reimbursement</b>	<ul style="list-style-type: none"> <li>Influence of TKA reimbursement on treatment pathway; Do surgeons view iKnee as cannibalizing TKA or just delaying?</li> <li>How would surgeon adoption be impacted by different billing codes allowed? Does iKnee align with bundled payment approaches?</li> <li>What would facilities and payors think about iKnee?</li> </ul>	<ul style="list-style-type: none"> <li>Current insurance status</li> <li>Out-of-pocket payment for knee pain interventions</li> <li>Feedback on iKnee out-of-pocket expense compared to TKA</li> <li>Degree to which patients might select facilities and surgeons specifically for offering iKnee</li> </ul>
<b>Competitive Strategies</b>	<ul style="list-style-type: none"> <li>Feedback on similar/ alternative treatments</li> <li>Surgeon preference for direct support from iOI vs. partner</li> <li>Optimal marketing/ positioning strategy for iKnee</li> </ul>	<ul style="list-style-type: none"> <li>Preference of competing approaches vs. iKnee</li> <li>Optimal marketing/ positioning strategy for iKnee</li> </ul>

# Why Partner with Frost & Sullivan?



- ✓ **Global Healthcare Consulting company with over 60 years experience and a strong track record in helping clients define their future value propositions**
  - *Frost & Sullivan is an international consulting and business intelligence firm focused on Growth. Our clients regularly use our services to define how best to address their customers' current and future needs. We have a wealth of value proposition development experience we can leverage as best practice for this project*
  - *Multidisciplinary team of consultants in the United States dedicated to iOI's project success*
  
- ✓ **Highly experienced teams dedicated to Healthcare, Consulting and Customer Research who deliver on complex, global projects**
  - *Frost & Sullivan has dedicated specialists in Healthcare markets, business consulting and in Customer Research. Our Customer Research team is made up of over 60 professionals globally with on average over 15 years experience*
  
- ✓ **Successful project track record with other medtech clients to assess market potential**
  - *Extensive experience working with start-up medtech companies across many fields to assess the disruptive potential of their technology, size their addressable market and communicate that to executives, partners, investors and other stakeholders.*
  - *Significant experience conducting research with clinicians and modelling market opportunities for surgical technology companies based on disease epidemiology and care pathways.*
  
- ✓ **Existing knowledge in orthopedic surgery**
  - *Frost & Sullivan has been tracking trends in the orthopedic surgery marketplace in its syndicated research and consulting work for years. In recent years, we've completed whitepapers looking at the ROI for robotics in orthopaedic surgery, assessed the penetration of biologics and new implants into various surgical procedures and sized the market potential for the ENTIRE orthopedic sector in Brazil and Mexico for a major player.*



# Project Methodology and Deliverables



## Project Kickoff

- Internal iOI interviews
- Develop discussion guide, inc. iKnee description and evidence scenarios

## P1: In-Depth Surgeon Interviews

- Completion of 10 1-hour, telephone interviews with U.S. orthopedic surgeons: ~50% reconstructive surgeons, ~50% sports medicine surgeons
- Surgeons will be asked to review corporate video in link below prior to call
- Consolidate findings in PowerPoint presentation and feed into Web survey design

## P2: Surgeon Web Survey

- Develop, program, field and analyze a 20-25 min Web survey of 50 U.S. orthopedic surgeons with >30 performing TKA and >30 performing meniscectomy.

## P3: Patient Web Survey

- Develop, program, field and analyze a 15-20 min Web survey of 500 U.S. adults representative of iKnee patients
  - ~200 ALREADY received TKA
  - ~150 Severe Knee Pain (TKA likely in <1 year, been told they need TKA soon)
  - ~150 Moderate Knee Pain (TKA likely in <3 years, receiving advanced treatments, e.g. arthroscopy, injections, etc.)

## P2/P3: Deliverables

- Findings from both survey will be presented in a single PowerPoint presentation combined with P1 surgeon insights
- Deliverables will also include a simple Excel model showing size of addressable U.S. market based on different customer segmentation, adoption and pricing scenarios for iKnee



## P4: Whitepaper

- Frost & Sullivan will produce a ~6 page, fully-designed, static summary whitepaper consolidating relevant findings from all three project phases focusing on the unique and disruptive qualities of the iKnee as well as Frost & Sullivan's estimated market size for the product
- No additional lead generation, public relations or digital media support is included

## iOrthopedics iKnee Overview Video

<https://vimeo.com/610154984/45261265a0>



# Expected Deliverables

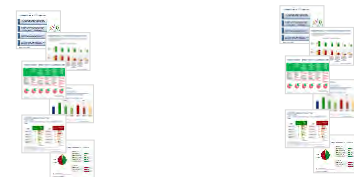
Frost & Sullivan will provide four deliverables for this project.

## Final P1/P2/P3 Deliverable Sample Table of Contents

1. Research Methodology/ Respondent Profiles
  2. Executive Summary
  3. Needs Assessment/ Gap Analysis
    - a. (Factors of IMPORTANCE for Knee Pain Solutions vs. Satisfaction With Current Solutions on Those Factors)
  4. Feedback on Product
  5. Economics/ Reimbursement
  6. Competitive Strategies
  7. iKnee U.S. Addressable Market
  8. Strategic Recommendations
- All deliverables provided in English.
  - No interview transcripts provided. Raw Web survey data provided. No competitive interviews included.
  - No other countries, products or respondent customer segments included.

## Example PPT Deliverable

(P1 Interview Summaries; P2/3 Analysis)



## Example Excel Deliverables (Addressable U.S. iKnee Market Model)

A sample Excel spreadsheet is displayed, showing a complex table with multiple columns and rows of data. The data appears to be organized into sections, possibly representing different market segments or time periods. The spreadsheet includes various numerical values and some text labels.

## Example Whitepaper (P4 Summary)



# Project Organization

**Key principle: Seamless integration between PFD Capital-iOI and Frost & Sullivan is required to maximize project impact**

Project Team Organization		Shared Responsibilities
<b>Steering Committee</b>		
<b><u>PFD Capital-iOI</u></b> Eric Hansen Board Members	<b><u>Frost &amp; Sullivan</u></b> E. Sujith	<ul style="list-style-type: none"> <li>▪ Provide supervision for the engagement</li> <li>▪ Approve initiatives</li> <li>▪ Eliminate roadblocks, facilitate client organization buy-in</li> <li>▪ Make decisions for engagement progress</li> </ul>
<b>Project Lead</b>		
<b><u>PFD Capital-iOI</u></b> Eric Hansen	<b><u>Frost &amp; Sullivan</u></b> Charlie Whelan	<ul style="list-style-type: none"> <li>▪ Key PFD Capital-iOI point of contact</li> <li>▪ Supervise creation of deliverables</li> <li>▪ Monitor progress against plan</li> <li>▪ Review weekly status</li> </ul>
<b>Project Team</b>		
<b><u>PFD Capital-iOI</u></b> TBD	<b><u>Frost &amp; Sullivan</u></b> Patrick Riley Sascha Vetter	<ul style="list-style-type: none"> <li>▪ Manage day-to-day tasks</li> <li>▪ Provide deep industry expertise</li> <li>▪ Identify and collect data</li> <li>▪ Conduct primary interviews</li> <li>▪ Create and confirm hypotheses</li> <li>▪ Analyze, model, and develop results</li> <li>▪ Produce deliverables and recommendations</li> </ul>

# Terms and Conditions/ Letter of Agreement



# Detailed Activities Schedule for Invoicing

Phase		1	2	3	4
Week	Dates	Surgeon Interviews	Surgeon Survey	Consumer Survey	Whitepaper
1	10/17-10/23	Project Kickoff; Internal iOI Interviews; Discussion Guide Development; Recruitment; Project Management			
2	10/24-10/30				
3	10/31-11/6				
4	11/7-11/13				
5	11/14-11/20	Interviews; Incentives; Analysis; Project Management	Develop and Program Survey; Project Management	Develop and Program Survey; Project Management	
6	11/21-11/27				
7	11/28-12/4				
8	12/5-12/11		Recruitment; Fieldwork	Recruitment; Fieldwork	
9	12/12-12/18				
10	12/19-12/25				
11	12/26-1/1				
12	1/2 – 1/8		Incentives; Survey Analysis	Incentives; Survey Analysis	Internal iOI Interviews; Whitepaper Outline
13	1/9-1/15				
14	1/16-1/22				
15	1/23-1/29				Data Review; Whitepaper Writing; Paper Design

# Professional Fees, Activities and Invoicing Schedule

Phase		1	2	3	4	-
Week	Invoice Dates	Surgeon Interviews	Surgeon Survey	Consumer Survey	Whitepaper	Total
1	Project Initiation	\$12,616				\$12,616
2						
3						
4						
5	End of November	\$12,616	\$12,111	\$7,065		\$31,792
6						
7						
8	Mid-December		\$30,278	\$17,662		\$47,940
9						
10						
11						
12	Early January		\$18,167	\$10,597	\$3,028	\$31,792
13						
14						
15	End of January				\$12,111	\$12,111
<b>Total</b>		<b>\$25,231</b>	<b>\$60,556</b>	<b>\$35,324</b>	<b>\$15,139</b>	<b>\$136,250</b>

# Terms and Conditions

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**PFD Capital-iOI** is hereafter referred to as the “the Client.”

1. Upon Project kickoff, Frost & Sullivan will begin invoicing based on scheduled provided in previous slide. All invoices will be due upon receipt. All honoraria and recruitment costs are included, but all travel and other out-of-pocket costs related to the project will be billed separately at cost. Unpaid invoices may be subject to a 1.5 percent late fee per month past due.
2. Any change in the scope or content of work from that stated in the project scope will be reflected in a change of work order, agreed upon by both the Client and Frost & Sullivan. The revised scope may reflect additional billing as required and may result in a revised invoice or be reflected in a time and expenses billing. This additional work will begin only when the change order signed by the Client is received by Frost & Sullivan.
3. The stated project fee includes the delivery to the Client at the project’s completion of electronic copies of the research deliverables for this project in either PowerPoint, Word, Excel or PDF formats.
4. This project is done on a proprietary basis for the Client. As such the Client will have ownership of the final product developed for this project. This will not be shared with other organizations. Frost & Sullivan retains the right to use market related knowledge from this project as part of its ongoing research, with the exception of confidential materials that provide or relate to Client information, customized metrics and strategic recommendations developed specifically for the Client in the context of this project.
5. Written deliverables may be reproduced in printed and electronic format for distribution within the Client organization. We request that any materials, either in part or in whole, from our work that is used in public domain communications (e.g. press releases) be reviewed and approved by Frost & Sullivan prior to their publication. This is to assure that any data or conclusions are presented in the proper context, to avoid any misunderstanding by the reader or audience, and to ensure the accuracy of the data.

# Terms and Conditions (continued)

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6. The Client and subsidiaries will not actively solicit to employ any Frost & Sullivan employee connected to this project for a period of 12 months following project completion. Should such an event occur, The Client agrees to damages of two times the person's annualized salary, due and payable immediately to Frost & Sullivan.
7. Frost & Sullivan will always strive to provide first-rate work. However, there is no representation of certainty, express or implied, by Frost & Sullivan, except in the case of demonstrable negligence on the part of Frost & Sullivan. This is because the markets we study have varying degrees of fragmentation. The Client acknowledges this and accepts this point. The Client waives any claim to actual, consequential, or punitive damages against Frost & Sullivan based on their reliance on Frost & Sullivan's work, except in the case of demonstrable negligence on the part of Frost & Sullivan.
8. Some data may be considered proprietary or sensitive by companies and/or individuals to be interviewed or surveyed, and they may be unwilling to divulge any given piece of information or data to Frost & Sullivan. All research and analysis will therefore be executed on a "best efforts" basis.
9. The Client shall have 20 business days following the final presentation of the project results to request clarifications or submit questions that are reasonable and within the original scope of the project. Additional work beyond the scope of the project or the 20 business days will be billed on a time and expenses basis.
10. The Client may terminate this agreement provided there is a reasonable basis and that an agreement is signed in writing by both parties. Work on the engagement will cease on the day that the request to terminate is received by Frost & Sullivan. The Client agrees to pay Frost & Sullivan
  1. a pro rata fee for tasks accomplished, plus related direct expenses incurred prior to termination
  2. a cancellation penalty of 10% of the full contract value,
  3. any costs Frost & Sullivan has incurred and/or any non-refundable portion of committed costs incurred prior to Frost & Sullivan receiving the engagement termination request.Termination charges will be invoiced to the Client and must be paid in full immediately.

# Terms and Conditions (continued)

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11. Frost & Sullivan shall not be liable for delays or failures in performing its obligations resulting from any cause beyond Frost & Sullivan's reasonable control. In the event of any material delay, Frost & Sullivan will notify the Client and specify the revised schedules as soon as practicable.
12. Both parties must agree upon any change, extension or reduction in the scope of the project in writing. The revised scope will be reflected via either a revised letter of engagement or a time and expenses billing, which will reflect additional billing as required to complete additional work.
13. The Client may request Frost & Sullivan to make additional presentations of results of this project beyond what has been specified in the project scope. Frost & Sullivan will bill the Client on a time and expenses basis, including preparation, presentation and travel costs and time.
14. All of our material is by default written in English, unless it has been specifically agreed in the context of the project definition that our material would be written in another common language. In case the Client wishes to have our material translated in an additional language all translation costs will be charged to the Client.
15. The California law is the governing law in case of any dispute related to this agreement. California law will also apply in case of any arbitration in a Court of Arbitration.
16. Frost & Sullivan will provide the Deliverables as outlined in the Project Objectives portion of this document



# Project Acceptance Certificate

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We hereby state that we have acquainted ourselves with, fully agree to, and accept the contents of Frost & Sullivan's proposal, "U.S. Market Assessment for iKnee" dated October 11<sup>th</sup>, 2021 and the contents of the "Terms and Conditions" sections. By signing this Acceptance Certificate, we enter into a Contract with Frost & Sullivan, comprising of this document, the mentioned proposal and the mentioned Terms & Conditions.

Please sign this page, scan, and return (via e-mail attachment) to Charlie Whelan's attention. We will commence work at that time. After we have received the authorization to proceed, we will schedule a conference call with our consulting team to officially launch the project. We look forward to working with PFD Capital-iOI.

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Signature of Authorized PFD Capital-iOI Representative

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Signature of Frost & Sullivan Representative

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Print Name

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Print Name

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Title

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Title

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Date

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Date

# Appendix Case Studies



# Forecasting Market Opportunity for New LAA Devices



## The Client: Global Leader in Medical Devices Manufacturing

### The Challenge

Client was evaluating opportunities for LAA occlusion devices in Atrial Fibrillation patients whose conditions render them at risk for formation of blood clots that could lead to stroke or other life threatening embolic event. As this new treatment is still under clinical evaluation for effectiveness, projections for the market opportunity vary greatly.

### Project Objectives

Client sought to engage Frost & Sullivan in analysis to properly gauge upside, downside, and likely forecast scenarios. Points of analysis included **assessment of addressable patient opportunity**, **current treatment paradigm** and approaches for stroke prevention, existing patient **referral pathways**, as well as validation of **facility capacity** for adoption and **integration** of LAA occlusion treatments into **current workflow**.



## Our Approach and Work

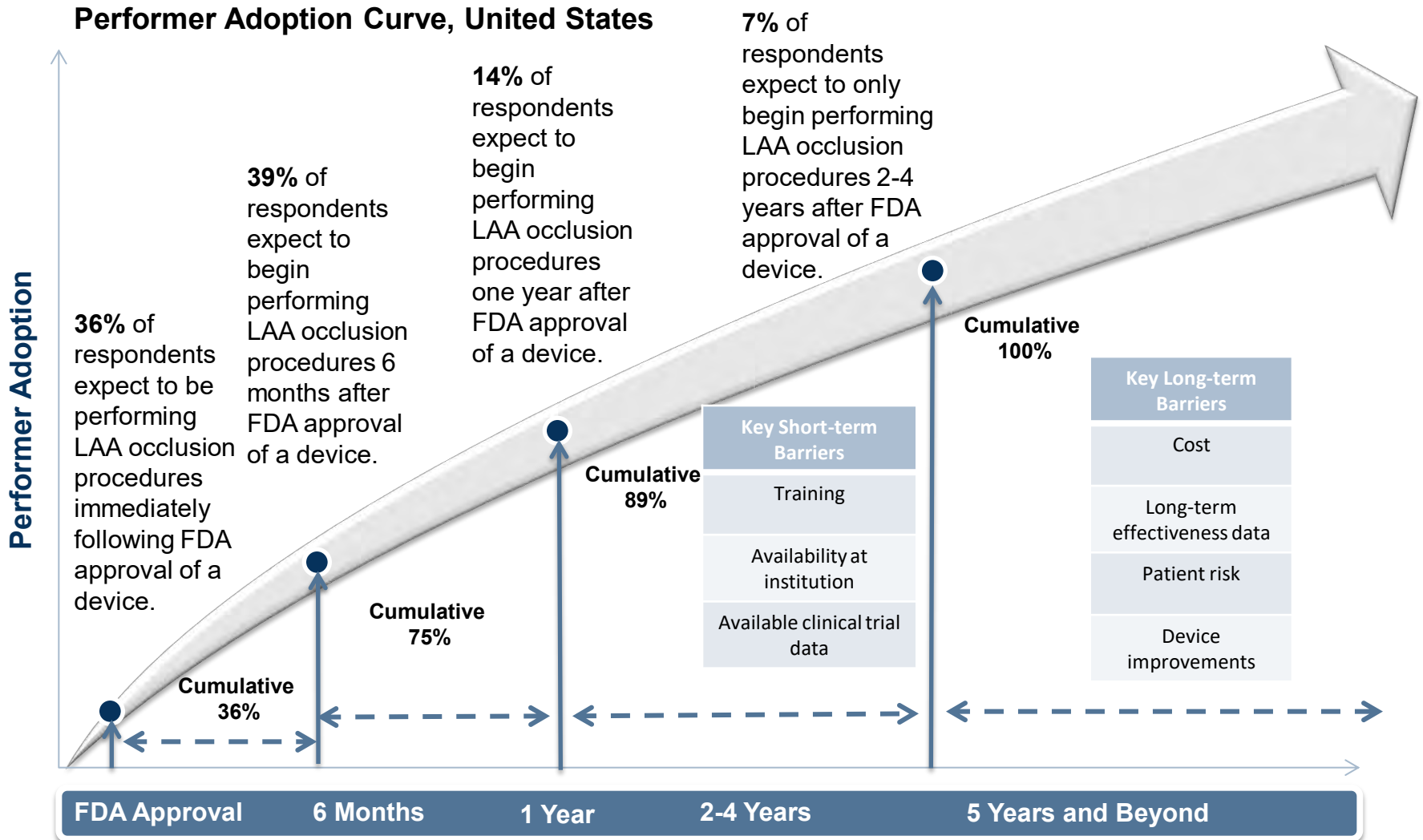
- Frost & Sullivan is looking to leverage its cross regional customer analysis team to capture current perceptions and influencers impacting adoption and utilization of LAA occluders.
- **Key Regions of Analysis:** United States, Western Europe
- **Key Specialty Types:** Electrophysiologists, Cardiac Surgeons, Interventional Cardiologists



## Outcome and Business Impact

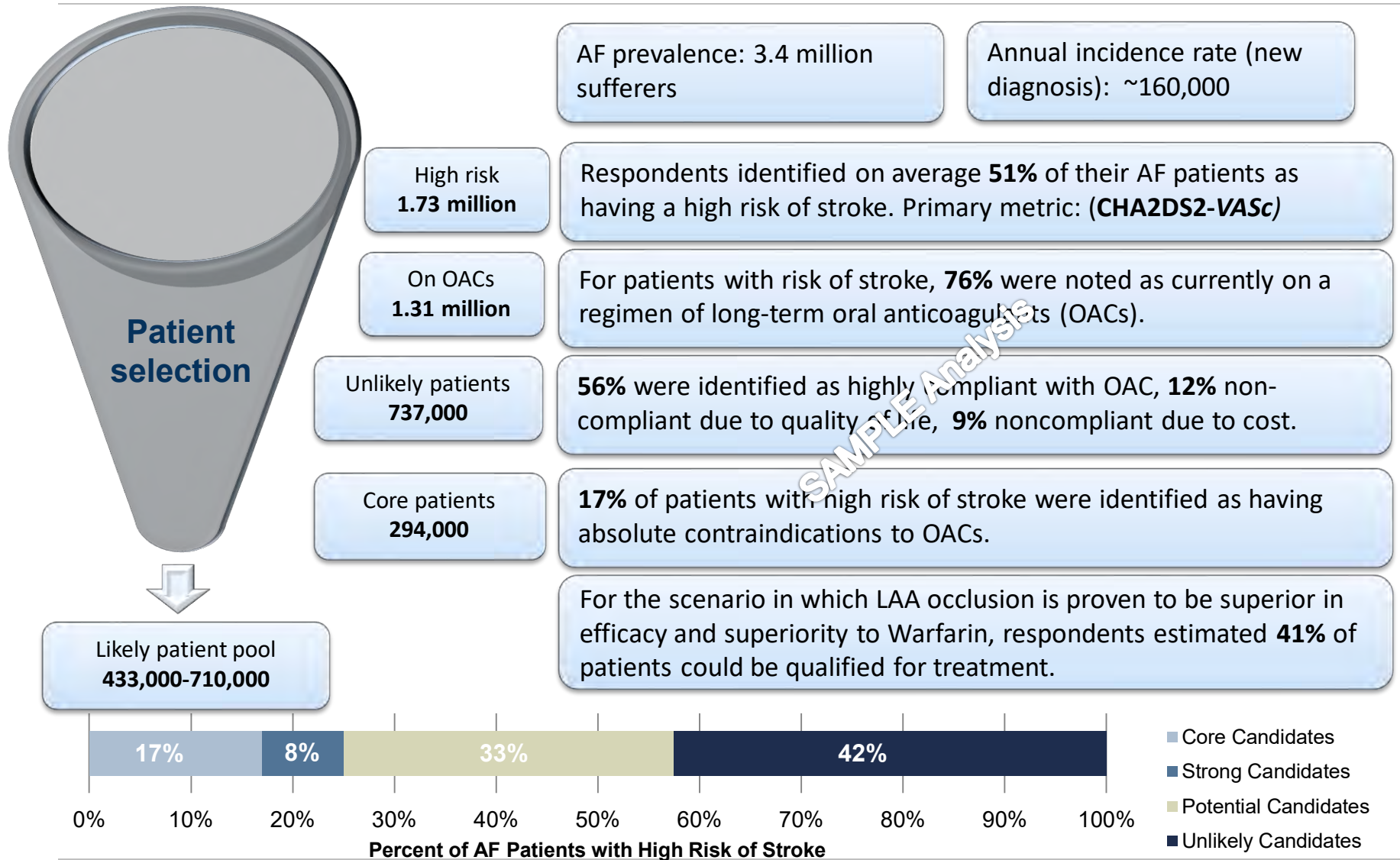
The client was able to build a scenario model to project treatment growth for LAA occlusion therapy factoring AF prevalence data against the various down-selection factors identified by respondents in the adoption of this novel treatment. As analysis showed significant interest from the potential performing clinical community, client was able to validate the market opportunity with its board and gain funding approval to move forward with the next stage of product development.

# Sample- U.S. Market Adoption Model



Source: Frost & Sullivan

# Sample- U.S. Addressable Patient Population



# Market Assessment for Overactive Bladder Therapies

## The Client: Leading Global Medical Device Manufacturer Interested in Pelvic Health



### The Challenge

- Following a major investment in a company focused on treating overactive bladder (OAB), the client wishes to size the market for clinical treatments for OAB in selected European and Asian countries.
- The company also wished to learn more about the commercial sales structure of competitors in the field.
- Finally, the client wished to better understand the composition of the physician population performing sacral nerve stimulator (SNS) implantation surgeries for OAB.

### Project Objectives

- Size market for medications, Botox, PTNS, and SNS in nine European and APAC countries
- Describe clinical pathway and selection criteria for OAB patients receiving these treatments
- Profile the commercial structure for companies selling these products in these regions



### Our Approach and Work

- Frost & Sullivan conducted interviews with surgeons performing SNS surgeries for OAB in each country. In addition, distributors and manufacturers of products in the space were also interviewed. These insights were combined with extensive secondary research conducted in native language to map out treatment pathways for OAB in each of the nine countries. A highly-detailed forecast model was also developed showing disease epidemiology, treatment adoption, unit sales and revenue generation for the four target interventions.



### Outcome and Business Impact

Going into the project, the client had a detailed understanding of the potential for OAB treatments in the United States, but no comparable data for the world's other developed medical technology markets. These research insights allowed the client to have better clarity on the stage of maturity of the market in each nation, its current and future revenue potential, and therefore what the full value of its investment stake in the new venture was worth.

# Assessment of the U.S./ European Advanced Surgical Energy Market



**The Client: A leading global medical technology company**

## The Challenge

A leading medical device manufacturer needed to refine its internal forecast models with more detailed insights into how advanced surgical energy devices were used in the United States and major European countries across five specialties. In addition, the company was seeking to better understand attitudes related to robotic surgery, new technologies and pricing pressures on the instruments. The client needed validate on energy penetration for specific surgeries, detailed on the kind of energy used, make/model of device used and detailed insights into surgical tasks the energy instrument is used on.

## Our Strategic Approach and Work



Frost & Sullivan developed and deployed a quantitative Web survey to 210 operating room managers across the six countries. The consulting team also interviewed 60 surgeons (2 per specialty X 5 specialties X 6 countries) to gather qualitative insights into surgical energy use, preferences and technique. Frost & Sullivan also conducted competitive and secondary research to support the customer research. The insights were compiled into a detailed presentation delivered during regular meetings and a final teleconference.

## Outcome and Business Impact



Frost & Sullivan delivered the project on time and on budget to a large client team matrixed across specialties and geographies. The data was integrated into the client's forecasts providing a new level of detail and insight that had never existed before. Frost & Sullivan's recommendations identified numerous specialties, geographies and surgical tasks presenting opportunities for market and product development.

# Assessment of the Global Colorectal Surgery Market



## The Client: A leading global medical technology company

### The Challenge

Medtronic sought to develop a comprehensive understanding of the current colorectal surgery market in major countries outside the United States. The focus was on understanding major drivers and restraints behind clinical practices, technology adoption, unmet needs and economic pressures. A secondary goal was to assess novel product concepts Medtronic was developing for the market.

### Our Strategic Approach and Work



Frost & Sullivan focused its efforts on 11 target countries: France, Germany, UK, Netherlands, Turkey, Kingdom of Saudi Arabia, South Africa, China, India, Japan, and Brazil. Consultants interviewed surveyed 76 senior colorectal surgeons across the countries. The team also designed, deployed and analyzed a Web survey administered to 297 colorectal surgeons across the countries. Extensive secondary research was also conducted by the consultants.

### Outcome and Business Impact



Frost & Sullivan developed a comprehensive analysis of the market for Medtronic allowing it to understand which concepts were the most attractive in each country and the best way to position each. The insights the team gathered also allowed Medtronic to evaluate the scope of the market opportunity in each country for the new products in development.



# New Product Concept Testing for Surgical Tissue Sealants



## The Client: A Fast-Growing, Mid-Sized Manufacturer of Portable Medical Imaging and Diagnostic Technologies

### The Challenge

One of the world's leading companies in the application of transgenic technology for the production of human proteins for therapeutic use. The Client intends to first launch a fibrin sealant onto the EU market. In order to optimize strategic decision making and to add value into the development of the fibrin product, F&S were asked to conduct a pre-market entry analysis to provide a reliable and unbiased assessment of the market potential for fibrin sealants in Germany, France, Italy and Spain.

### Project Objectives

- To evaluate opportunities in Europe and consequently assess the market potential for fibrin sealants using:
- Market size
- Market potential in relation to selected surgical procedures
- Competitive structure
- End-user analysis (usage patterns, motivational factors for usage/non usage, key requirements, switching criteria)
- Product concept testing (level of acceptance, migration path, usability)



### Our Approach and Work

This research process gathered knowledge from end-users (consultant surgeons) and key market competitors via in-depth interviews.

### Outcome and Business Impact

The extensive research and analysis provided the company with:  Competitive Environment, acquiring market share

- Fibrin Sealant Applications
- Usage Trends, Product Preferences, Switching
- Pricing Strategy
- Products in Development
- Strategic Market and Geographic Attractiveness Recommendations
- Strategic Recommendations for realizing market potential
- Solution / Outcome



# European Surgeons' Impressions of a Novel Joint Implant for Treating Arthritis



## The Client: Innovative US company selling a unique implant device

### The Challenge

Our client developed and produces a joint implant with a novel mechanism for alleviating the progression and symptoms of arthritis in a specific joint. Because of the novel design of the device, the client faced hurdles in gaining acceptance by orthopedic surgeons. To optimize its initial marketing in Europe, our client needed to know which practice types and patient populations would be most interested in using the device.

### Project Objectives

Frost & Sullivan, as an independent expert researcher, would obtain open and frank responses to questions about surgeons' practices and their initial reactions to the client's device. We would collect and deliver information on surgeons' specialties, patient demographics and degree of arthritis progression, methods used in diagnosis and treatment of arthritis of the specific joint, patient referral patterns, and surgeons' impressions of the client's device.



### Our Approach and Work

Frost & Sullivan conducted in-depth discussions with orthopedic surgeons in three western European countries deemed to be the most promising initial markets. We collected information from them on their practices and attitudes toward the client's device, and analyzed the data to identify correlating factors that would indicate potential adoption of the device by surgeons, or that would disfavor adoption.



### Outcome and Business Impact

Our work allowed the client to develop a marketing plan that optimized positioning the benefits of the device and reduce the hurdles to acceptance. Additionally the client was able to identify specific types of orthopedic surgery practices that would constitute the optimal target market. We also identified country-specific nuances in physicians' attitudes towards the device. With this information our client was able to refine its messaging and launch the device to gain the highest initial acceptance. This was critical to ensure that the device received favorable first impressions, which would have long term effects on future sales.

# Assessing Customer Behaviors in the Purchase and Use of Video Laryngoscopes



## The Client: A Fast-Growing, Mid-Sized Manufacturer of Portable Medical Imaging and Diagnostic Technologies

### The Challenge

Frost & Sullivan's client was a fast-growing manufacturer of measurement and visualization technologies for the medical field. The company's lead product line was focused on video laryngoscopes (VLs), a market the company effectively created at its founding. In recent years, the client had witnessed an increasing uptake in the adoption of VL in the United States suggesting a growing opportunity for the company's technology; however, much of this information was anecdotal and qualitative. In order to develop a stronger growth strategy for penetration the VL market, the client requested that Frost & Sullivan conduct a detailed, quantitative assessment of the industry powered by primary research with customers in a number of key market segments.

### Project Objectives

- The objectives of the project were to:
- Profile trends in airway management and use of VL
- Estimate purchasing and installed base of VLs
- Produce a market forecast for VL
- Conduct a detailed make/model competitive assessment
- Identify the most important VL attributes and motivations for purchase
- Assess major VL brands



### Our Approach and Work

Frost & Sullivan administered a detailed, 20-minute Web survey to 95 hospital OR managers, 95 hospital ED managers and 50 ambulatory surgery center nurse managers. In addition, Frost & Sullivan conducted a detailed historical competitive pricing assessment of the VL market powered by a third-party database of hospital purchasing data. Frost & Sullivan consultants analyzed the data, developed strategic recommendations and presented them in the context of a multidisciplinary workshop with executive management.



### Outcome and Business Impact

The extensive research and analysis provided the company with:

- Insight into how two key competitors were encroaching on their market share, and what they should do about it
- Confirmation that a significant portion of the market was converting to single-use sheathes – a key insight for future product development
- Validation that the company's brand was the leader in the market, and possessed significant leverage for future market growth in the ED and other care settings

# Market Feasibility for an Implantable Textile Medical Device in US, Korea, and Taiwan



## The Client: A Chemical Company with an Innovative Synthetic Nerve Conduit

The Challenge	Project Objectives
<p>Our client had developed an innovative synthetic nerve conduit. The client wanted to evaluate the market feasibility for its new product in the U.S., Korea, and Taiwan.</p>	<ul style="list-style-type: none"><li>• To understand the physicians' perspective and regulatory environment for nerve regeneration devices in the U.S., Korea and Taiwan</li><li>• To estimate the market size and potential and evaluate the competition landscape for nerve regeneration devices</li><li>• To test the concept of its product and identify competitive advantage and recommend which market to focus on</li></ul>

## Our Approach and Work



We conducted extensive desk and primary research (including competitors, distributors, regulators, industry experts). We evaluated the market size, growth rate and profiled the competitors in detail. We also spoke with the key opinion leaders and prescribers to get their thoughts on the client's products and to identify if there was a market for this product and in which patient would this product be used. Based on our findings we recommended the client to avoid one particular market as the client's product would not have been able to differentiate itself in an highly competitive market; we also recommended our client to explore other markets further




## Outcome and Business Impact

Based on our recommendations, the client decided to not pursue one of the markets even though prior to the project the client was keen to enter that market. This saved the client substantial investments, which they are planning to divert to other markets.

# Patient Survey for GI Tract Syndrome

## The Client: Global pharmaceutical company with late stage trial drug

### The Challenge




A top multinational pharmaceutical manufacturer was in Phase III clinical trials for a new therapeutic approach to a GI tract syndrome. The drug was developed based on conventional wisdom that a certain percent of the U.S. population suffered from the particular syndrome. Yet, no rigorous research had been undertaken to identify the true prevalence in the general population.

### Project Objectives


The client's challenge was to determine the true prevalence of sufferers, to identify the target population for optimal product launch campaigns, and to develop a clearer understanding of patient symptoms, needs, and therapy path.

## Our Approach and Work



We proposed to undertake 3,000 randomized interviews with adults across the U.S. to determine the prevalence of the condition. The survey instrument was carefully designed by our consulting team to elicit data to qualify respondents for further in-depth interviewing. Once identified as a sufferer, the respondent was taken through a detailed step-by-step process to identify specific symptomatic issues and the chosen therapy path. In addition, we proposed a set of 20 focused interviews with diagnosed patients who had joined online sufferer support groups. The client was pleased with this approach because of the statistical significance of the data, which given the infinite population and the sample size, resulted in a confidence level of 95 percent and confidence interval of plus-or-minus 1.8 percent.

## Outcome and Business Impact



In just a few weeks, 3,012 interviews were completed. During this research, the client's analysts discovered that a very similar study of 5,000 U.S. households had been undertaken by the University of North Carolina which showed a prevalence rate nearly identical to ours. Our rigorous research methodology had now replaced an inflated "conventional wisdom" estimate with a number reflecting the true prevalence and helping to identify the target market for this drug.

# U.S. Market Opportunity Assessment for Transdermal Drug Delivery Technology



## The Client: An Innovative, Clinical Technology Incubator

### The Challenge

The client developed a new transdermal drug delivery patch capable of administering iron through a patient's skin. The client believed the technology held significant potential for patients with iron-deficiency anemia (IDA) since it could provide an alternative to oral iron therapy, which could reduce or eliminate GI side effects. The company sought to address a number of questions regarding the technology's market potential.

### Project Objectives

- Describe the addressable patient population for iron deficiency, current reasons for taking oral iron therapies, severity of iron deficiency, severity of side effects due to oral iron therapies, and compliance.
- Identify the needs and concerns of iron-deficient patients.
- Obtain the opinions, adoption rates, and willingness to pay regarding the iron patch technology product concept.

## Our Approach and Work



**Project 1 – U.S. Physician Survey:** Frost & Sullivan experts interviewed 12 U.S. primary care and ob/gyn physicians and conducted a Web-based survey of 150 physicians who treat patients with iron-deficiency anemia. Interviews were used to develop a profile of the target patient population, diagnostic procedures for IDA, treatment protocols, and feedback on the transdermal concept.

**Project 2 – U.S. Target Patient Survey:** A Web-based survey of 151 U.S. females between the ages of 18 and 54 who have taken iron pills in the past three years and experienced gastrointestinal side effects was conducted. Survey questions focused on IDA treatment methods, side-effect profiles, payment methods, drug delivery preferences, and feedback on the transdermal concept.

## Outcome and Business Impact



The client gained a better understanding of its target market, and determined the potential uptake of the iron patch technology. The results concluded that 82% of respondents were likely to adopt an iron patch instead of pills. The client received the following:

- Critical information on pricing and adoption of iron therapy to understand how to best position its product  
*Prior to the project, the client was planning a major push of the technology to healthcare insurers, but the project found that the majority of iron will be paid for out-of-pocket by patients in the near future. The insight suggested a major change in strategy to more heavily target patients directly.*
- A positive assessment of the technology, providing leverage to win future licensing partnerships

# Appendix

## Team Member Bios



# Charlie Whelan



**Charlie Whelan**  
*Vice President, Growth  
Consulting, Healthcare  
& Lifesciences*

**Frost & Sullivan**  
**North America**  
**San Antonio, Texas**

## Functional Expertise

- 20+ years of market research and analysis, as well as marketing communication and strategy consulting experience, having worked on more than 75 projects on a global scale. Particular expertise in:
  - New market and product development
  - Market modeling and trend forecasting
  - Marketing communications
  - Competitive intelligence
  - Business development, strategic partnering, M&A

## Industry Expertise

- Experience base covering broad range of healthcare sectors, including
  - Medical, surgical and patient monitor technologies
  - Healthcare information technology
  - Consumer healthcare and general healthcare system trends

## What I bring to the Team

- Analytical skills and ability to spot and communicate emerging trends
- Deep knowledge of trends in medical technology and U.S. healthcare system
- Global project management expertise
- Strong written and verbal communication skills

## Career Highlights

- Marketing communication, advertising, media and public relations experience
- Experience working on high-profile projects at Frost & Sullivan with industry executives from start-ups to leading companies, including:
  - Medical technology companies: Johnson & Johnson, PFD Capital-iOI, Philips, W.L. Gore
  - Providers: Mayo Clinic, Ascension Health
  - Others: Procter & Gamble, 3M, Sharp Electronics, Herman Miller

## Education

- BBA in Marketing and Business Journalism, Baylor University (Waco, Texas)
- MA, St. Mary's University (San Antonio, Texas)



# Patrick Riley



**Patrick E. Riley**  
*Principal Consultant,  
Growth Consulting,  
Healthcare & Lifesciences*

**Frost & Sullivan**  
**North America**  
**San Antonio, Texas**

## Functional Expertise

- 30 years of Healthcare industry expertise, which include Hospital Administration, Hospital Mergers & Acquisitions, Managed Care COO, Commercial and Medicare Advantage VP of Sales, Healthcare Marketing and Advertising, Healthcare Industry Qualitative and Quantitative Research, U.S. Army Medical Department, Senior Staff Officer for U.S. Army Surgeon General, Commander, Field Medical Hospital and Certified Healthcare Executive with American College of Healthcare Executives. Particular expertise in:
  - Healthcare Policy
  - Hospital Administration
  - Transformational Healthcare

## Industry Expertise

- Experience base covers military command of all medical assets in a combat theater, Hospital CEO, COO, Managed Care Director, VP of Marketing and Sales for National Medicare Advantage firm, COO of Healthcare Marketing and Advertising firm, and Installation Management Command (IMCOM) Global Director of Marketing and Interactive Solutions
  - Healthcare Advanced Medical Technology
  - Connected Health

## What I bring to the Team

- C-Suite leadership and experience across the healthcare industry continuum

## Career Highlights

- Extensive expertise in U.S. healthcare policy and transformational health regulations and legislation.
- C-Suite positions in several leading for profit U.S. hospital firms:
  - Vanguard Health System, Nashville, Tennessee
  - Valley Baptist Health System, Harlingen, Texas
  - Trinity-Mother Frances Health System, Tyler, Texas

## Education

- Master of Business Administration (MBA) from Baylor University, Waco, Texas, USA
- Master of Health Administration (MHA) from Baylor University, Waco, Texas, USA
- Master of Military Science from U.S. Army Command and General Staff College, Fort Leavenworth, Kansas, USA
- Bachelor of Science in Biology from State University of New York at Geneseo, Geneseo, New York, USA

# Daniel J. Colquhoun



Daniel J Colquhoun  
*Vice President, Customer  
Research*

Frost & Sullivan  
North America  
Toronto

## Functional Expertise

- Dan is a unique market research hybrid with a combination of extensive applied experience and executive management of research enterprises. With over 25 years of experience he has utilized all marketing research methodologies and analytical approaches to solve the simplest to the most complex business problem. If it could be distilled into just three broad areas, his expertise would be summarized as follows...
  - The design and execution of large scale multi-country research.
  - The application of advanced analytics and the presentation of quantitative data in highly accessible and powerful visuals.
  - A highly effective communicator of market research concepts, methodologies, and output.

## Industry Expertise

- Equally at ease with C-level and line of business personnel, Dan has conducted market research assignments numerous industries with a concentration in the following...
  - Consumer packaged goods
  - Automotive
  - Financial services
  - Information and communication tech
  - Healthcare
  - Energy

## What I bring to the Team

- Superbly disciplined team and project management skills
- Well developed survey instrument and experimental design expertise honed by literally decades of experience
- Practical application of advanced analytical techniques

## Career Highlights

- A broad base of experience with most of it on the market research supplier side in senior executive roles, but with just enough client side experience (ad agency but close enough) to understand how research is used in business decisions making within organizations. Past experience in order from most recent...
  - VP at Cossette Communications Group in Toronto, Canada
  - President of ACNielsen Customized Research in Canada
  - President of operating division of the Survey Research Group in Canada

## Education

- A Certified Market Research Professional (CMRP) with a degree in engineering from Ryerson University, Toronto.

# Sascha Vetter



**Sascha Vetter**  
*Director, NA Research  
Operations*

Frost & Sullivan  
North America  
Remote

## Functional Expertise

- 18 years of Project Management and Client Services experience, which includes particular expertise in:
  - Client services for Fortune 100 accounts with combined research budgets over 5M
  - Large-scale international data collection project management expertise
  - Extensive operational experience managing multi-site research call centers

## Industry Expertise

- Experience base covering a broad range of sectors, leveraging long-standing working relationships with leading industry participants' Senior Executives
  - Business to Business Research
    - Healthcare
    - Electronics
    - Telecommunications
    - Automotive & Transport
    - Energy

## What I bring to the Team

- Entrepreneurial approach when exploring all options to achieve client satisfaction
- Adept at creating custom solutions for clients and internal customers
- Excellent communication style to achieve large picture for decision makers/clients
- Detailed and thorough project management and quality control expertise
- Extensive supervisory, training and mentoring experience with distributed teams

## Career Highlights

- Extensive expertise in full service research with several leading firms:
  - Harris Interactive, Princeton, NJ
  - Cunningham Research, Ormand Beach, FL
  - Communications Center, Inc, Spokane, WA
- Owner/Proprietor for two small business ventures

# Romualdo Rodriguez



Romualdo Rodriguez

PhD

*Consulting Director*

*Customer Research*

Frost & Sullivan

Toronto, Canada

## Functional Expertise

Over 10 years of experience as a quantitative market research and marketing strategy consultant with expertise in:

- Brand equity research – consumer and B2B
- Customer satisfaction tracking research for global healthcare companies
- Advertising and message optimization
- Product features configuration and pricing optimization
- Market segmentation and positioning research
- Predictive modeling
- Advanced multivariate analysis
- Choice modeling using various methods (ACBC, CBC, MaxDiff, etc.)
- Marketing strategy formulation based on quantitative research insights

## Industry Expertise

Experience in quantitative market research for the following sectors and categories

- Global B2B research
- Research for power plants in the US and Europe
- Research on trends in medical devices in US and Europe
- Global research for healthcare (big pharma and medical devices)
- Global research for new technologies

## What I bring to the Team

- Ability to leverage experience with some of the most reputable brand names
- Ability to bridge business objectives and quantitative research objectives
- Ability to provide relevant marketing strategy framework and analytics framework.
- Ability to apply creativity and innovation to both research design and research presentation.
- Ability to derive and integrate key insights at a strategic level.

## Career Highlights

- Director, Advanced Analytics, Customer Research, Frost & Sullivan
- Strategist, Quantitative Research, In-Sync

## Education:

- Ph.D. in Business Administration (focus: Business Strategy)
- Master in Business Administration
- BSC Marketing Management
- AB Behavioral Science (minor: Sociology)

# We are looking forward to working with you!

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

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