

A photograph of an operating room with a surgical table covered in blue drapes, overhead surgical lights, and various medical equipment. The image is slightly faded to serve as a background for the text.

# PAROLA *Insights*

## How to find an unmet need in the medical device industry and considerations for pursuing it

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### Introduction

In this article we will cover practical, learned-by-doing aspects of bringing a medical device to market. We will begin with the important topic of ways to find an unmet need and early considerations once you have found one. We will progress from there to tips on working brainstorming sessions, how to prioritize and assess leading concepts, and useful guidance on product development. We will then delve more specifically into intellectual property considerations including provisional patent applications, assessing patentability, and understanding your freedom to operate.

This article is aimed towards individuals, startups, and early stage companies with little to no experience in this endeavor, however it is also applicable to anyone looking to, perhaps, do things a different way, learn something new, or consider different perspectives.

## Finding an unmet need

Research. There is no way around it, research is required to truly understand the market in which you seek to uncover unmet needs. There are many sources of information that can be drawn from to develop such an understanding of your market of interest that do not cost money per se, but they do require your time and diligence. It is important to note that at the heart of any accurate needs assessment are observations and hypotheses driven by facts and as much quantitative data as possible. This doesn't mean ignoring your intuition, as the ability to "read between the lines" and extract the unsaid are important as well, but they should instead help guide your fact-finding mission rather than serve as the final say.

Now, where to start? The following are free resources that are a great place to begin your journey, and they do not require any initial intimate knowledge of your market of interest nor contacts within it.



### Sources for identifying unmet needs

Source	What to gain
<b>Web search</b>	High-level intel on your market of interest, including trends, latest developments, pain points, etc.
<b>Free market trend reports</b>	High-to-low level details on your market of interest, who is investing, market size, major players, trends, etc.
<b>Blogs and Q&amp;A sites</b>	Information on aspects of your market of interest from the doctors, surgeons, companies, and influencers themselves.  <b>Tip:</b> There's perhaps no better place to quickly hone in on the pain points (and therefore, potential unmet needs) within your market of interest other than talking with these individuals directly.
<b>Curated news sites</b>	News of your market of interest in quick, easily digestible segments. Lookout for recurring themes, latest trends, and who (doctors, industry partners, etc.) is giving their opinion.  <b>Tip:</b> Make this easy on yourself by signing up for e-mail notifications to receive the latest news directly in your inbox.
<b>Professional social media platforms</b>	Latest news and updates from the major players, groups, and organizations within your market of interest.  <b>Tip:</b> Follow parties of interest to receive the latest updates directly in your feed.
<b>Professional associations</b>	An understanding of the major organizations within your market of interest, what their short- and long-term goals are, who leads them, and what topics they cover during their professional meetings.  <b>Tip:</b> Look past to present within their meeting agendas to gain an understanding of which topics have grown in popularity/importance. Furthermore, look into who is on the podium within their events, particularly those that participate in roundtable discussions, and who appear to be the early adopters within the field. Follow all individuals of interest and try to determine what they are doing and why.
<b>Surgical and/or procedural videos</b>	A deeper understanding of the devices and methods employed by the medical professionals in your market of interest.  <b>Tip:</b> Watch for variations between professionals, pain points, and aspects that are particularly complicated, difficult, lengthy, or require special skill/experience; all can lead to potential unmet needs.
<b>Indications and contraindications of current devices and/or procedures</b>	An understanding of the range of disease states and variables that are specifically included and excluded in solutions currently available. Additionally, they can serve as a great source of criteria for design inputs and the eventual indications and contraindications of your own products/procedures. Contraindications in particular can lead to the discovery of niche unmet needs and market opportunities.

### After the unmet need is identified

Upon identifying a potential unmet need, it is advisable to further assess the market to ensure you have a viable opportunity to address it. It is now a great time to start building a business plan using a simple, yet powerful, tool such as a business model canvas. Importantly, this exercise can quickly help you identify your customers, with whom you will need to open lines of communication to truly bring a useful solution to market. Keep in mind that doctors alone may not be your only customer; when broadening your view, you may find that the patients (or other end users of your medical device), the clinical treatment team as a whole (including nurses, technicians, physician assistants, admin staff, etc.), and the facilities where procedures take place (hospitals, ambulatory surgery centers, private clinics, etc.) are all potential customers as well. With your customers identified, performing additional research through ethnography, voice of the customer, and mapping your customer journey can all help you refine/challenge your understanding of the unmet need you have identified, clearly define the “problem” to be solved, and lead you on your way to solutions. Understanding your customers cannot be stressed enough.

When in the early stages of building your business plan, refining your identified unmet need, and brainstorming/testing solutions, it is important not to lose sight of the big picture. Further considerations and food for thought include an assessment of the following:

- Your market: where has it been, what is the current state, and where is it likely to go? First, there may be no point in investing in solutions to an unmet need that relates to a technology that may soon become obsolete or surpassed (unless speed to market is within your capabilities). Second, understanding your total addressable market (e.g., based on the number of patients it could treat and the growth rate of the market for similar devices) will allow you to quickly determine if there is a viable market opportunity.
- Themes: what has gone well, what has not gone well, and why?
- Risk vs reward, and the doctors’ oath of first do no harm.
- Your value proposition: return to it regularly for each customer segment so as not to get off track (or, conversely, to at least understand how any changes along the way affect this parameter).
- Does your solution add or reduce complexity, and at what tradeoff(s)?

- Are your customers willing to pay for your solution (no matter what it can provide, and even if it appears to you to be a “no brainer”)? What does reimbursement (the amount insurance will pay to doctors and facilities) look like and how does it compare to the potential cost/pricing of your solution? Understanding this all early will save you valuable time and resources, and help you pivot quickly when a particular pathway is not financially feasible.
- Customer location/demographics/resources: the needs of one customer may not be applicable to all, so research broadly to ensure you are not making assumptions of the market as a whole or missing potential opportunities. Understand differences in your market such as rural vs metropolitan, small clinic vs large hospital, low vs high resources, ease of access, insurance/Medicare reimbursement, etc.

While still in the early stages of your journey, there are additional resources that can help you gain yet a further understanding of your market and playing field. These include:

Source	What to gain
<b>Annual reports and financial institution reports</b>	Market intelligence, supporting financial information and other quantitative data for your business plan. Note that publicly traded companies, non-profits, and government entities in the US must all report their financials (and some geographies abroad even require private companies to do the same).
<b>Centers for Medicare and Medicaid Services (CMS) data</b>	Quantitative utilization and payment data based on a current procedural terminology (CPT) code of interest. This data can be extremely useful if you can find a relevant CPT code that your unmet need solution would fall under; by searching this code in these databases (which are compiled per year for years past), you can uncover who performed the procedure, the number of procedures they performed, the type of facility the procedure was performed in, and how much they were reimbursed by Medicare. Extracting this data to your market as a whole will depend on the specifics of your market and the ratio of private health insurance vs Medicare procedures performed.
<b>Third party market research</b>	Additional insights, at a cost. There are multiple options here, spanning paid access to syndicated reports, paid-for customized reports on your specific market of interest, to dedicated third party market research endeavors. This type of research is useful because it can allow for a greater understanding of your unmet need of focus through discussions with potential customers directly, as well as provide the opportunity to test reactions to solutions if you have them. Before enlisting the services of a third-party market research firm, ensure you have built a business plan, understand your customers, and finally, go in educated. You can do this research yourself/in-house, however be informed as to the legal and ethical obligations before pursuing. A note on qualitative vs quantitative research - be as quantitative as you can, even if sample sizes are small, to allow for comparisons between different solutions/ideas/concepts.
<b>Pubmed</b>	Knowledge of universities with focus and/or individual investigators leading the charge in your technology area of interest. This information can be used to understand where your market may be heading, identify key opinion leaders, as well as lead you to potential licensing opportunities through associated university technology transfer offices.
<b>Patent research</b>	Knowledge of what has been thought of so far to address your unmet need of focus, what has recently emerged as potential solutions, and identification of the main players. A patent search can also lead to potential licensing opportunities, as well as serve as a starting point for further innovation. This type of research is typically performed by a third party at a cost, so ensure this activity aligns with your business plan before proceeding.
<b>Key opinion leaders (KOLs)</b>	Intimate knowledge of your market and unmet need of focus, typically utilized on a consulting basis. All your research to this point should have helped you to identify potential KOLs, and note that CMS utilization data can be a great resource here as well (i.e., sorting the number of services provided in descending order to generate a list of the providers that have performed the most of a given procedure). Another way to identify potential KOLs is by searching Open Payments data. Regardless of how identified, ideally you'll want to enlist KOLs that represent the diversity of your market - think hospitals vs ASCs vs clinics, metropolitan vs rural, patient populations seen, doctor inclination for procedures (e.g., surgical vs medicinal, devices vs surgical procedures, etc.). Be mindful that different KOLs may be best suited for different stages of your process - idea generation vs pre-clinical testing vs clinical testing. Importantly, choose KOLs that will challenge your ideas, which after all is the whole point.

### More on patent research

Due to the business implications and influence intellectual property (IP) can have on even the smallest and earliest of ventures, it is important to build your business plan with an IP strategy in mind. At the early time point of identifying an unmet need, building your understanding of it, and determining ways to address it via devices, combination products, procedures and/or services brought to market, you may ask yourself what you should even be doing regarding this topic. As touched on above, patent research is a place to start. There are arguments for and against performing your own patent research or enlisting the help of a third party, as highlighted below:

#### Why not to search?

- Consumes resources, such as your time, effort, and (if not done in-house) money.
- Can distract you from your focus of developing solutions to the identified unmet need.
- Can lead to a false sense of security, if not done well.

#### Why to search?

- If resources allow, a third-party patent search can allow you to retain focus on addressing the unmet need you have identified while an actionable patent landscape report is developed in parallel.
- Provides an unconventional way to learn about your technology area of interest. Patent applications must be enabled, meaning a person of ordinary skill in the art must be able to make and use the claimed invention without undue experimentation; hence they can serve as a great tool to improve your understanding of your subject matter of interest.
- Provides knowledge of what has been thought of so far to address your unmet need of focus, as well as (if performed on a regular basis) what emerges as potential solutions.
- With an understanding of what has already been done, patents and patent applications can serve as a launching point for further innovation. For example, information gleaned from them can influence your product development and rapid prototyping endeavors.

- Allows for competitive analysis, such as who owns what IP, the value of that IP, and the latest trends in the market.
- Can lead to licensing opportunities and/or shortcutting of the product development cycle.
- Informs your decision of whether or not to pursue IP rights of your own for solutions you develop to the identified unmet need, or worst case, abandon your pursuit altogether.
- Provides intel on prior art and allows you to focus on what is unique and novel about your solutions to the unmet need of interest. In particular, this intel can improve the quality of any patent applications you pursue.

### Brainstorming/idea generation

Armed now with a thorough knowledge of your market, your customers, and the criteria relevant to your identified unmet need, it is time to brainstorm solutions. We recommend the following approach:

- Have a problem statement.
- Have clear design inputs which are based on needs and not wants (this cannot be stressed enough).
- Create a plan with clear ground rules, define expectations, and set criteria for evaluating the generated ideas. As part of this, educate yourself and your team on intellectual property and have an invention disclosure system in place to address (at minimum) confidentiality, assignment of rights, and inventorship. Through this you can develop a culture mindful of intellectual property; and to help, consider incentivising your team by providing a monetary award for any ideas that lead to a provisional patent filing.
- Choose a facilitator that will be able to provide guidance and encourage all participants - make it known that there are no bad ideas. Also have a dedicated scribe.
- It is important to have a diverse group of participants with no preconceived notions. To prevent tunnel vision and/or latching on to one or a few ideas alone, it can be beneficial for each team member to brainstorm individually before sharing thoughts with the group at large.
- Expect two sessions: the first to generate ideas, the second to further develop upon leading ideas.

Between the first and second brainstorming sessions is a great time to perform further research on the top ranked ideas from the group. Both patent and competitor research are valuable here, and will allow you to uncover what has been done before (so as to avoid the same), what is successful on the market (so you can uncover the “why” and potentially further build upon/ refine), and what may be obstacles in your path.

### **Building out your concepts and assessing feasibility**

With top ideas chosen and preliminarily vetted, further viability and prioritization can be assessed by:

- Prototyping and testing first principles. Do not rely on thought experiments alone.
- Discussing concepts early and often with a diverse set of KOLs, who will likely have different perspectives than you and each other.
- Determining what adds the most value to the customer.
- Analyzing all the risks associated with the product – business, financial, regulatory, and IP. Return to your business model canvas, revisit previously mentioned considerations and further understand:
  - How much initial investment is required to move the product through to development?
  - How will you market the product?
  - What is the expected cost of the device to the end-user and what can the market bear? What are the possible COGs and what would be an allowable margin?
  - How does the product fit into your overall business strategy?
  - What is the regulatory pathway for product approval? What classification? What is the intended use? What is the indication of use? Answering these questions is critical so that you are not surprised by FDA regulatory requirements.
    - Class I or Class II - with or without exemption? If exempt, a 510(k) approval is not required.

- Class III – requires a Premarket approval (PMA) or a 510(k) depending on whether the device is a pre-amendments device. Investors may be very reluctant to support a company having to go through a PMA due to the time and money involved with clinical studies before FDA clearance.
- Will a usability study be required?

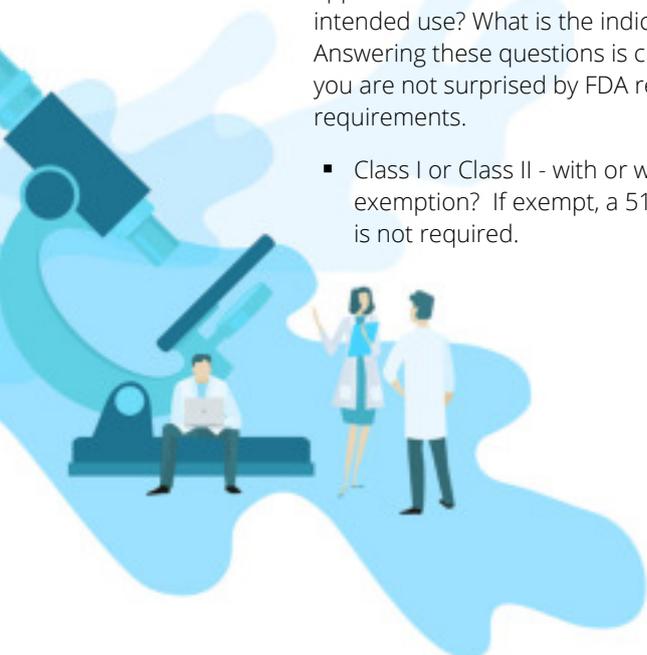
Altogether, this information will allow you to fail fast and pivot quickly to the most promising avenues.

### **Product development and your quality management system**

As you work to determine unmet needs and brainstorm ideas, you must also consider and develop the backbone of your company's quality management system (QMS) using ISO 13485 and FDA 21 CFR Part 820. QMS is a system of procedures and processes covering all aspects of design, process and production control, change management, corrective and preventative action, management responsibility, and resource and product surveillance. The complexity of the QMS will depend on the classification of device that your company will be manufacturing. What is critical to remember is that the internal procedures and documents should be something that your company can actually follow. Any audit findings will be based on how well you follow the procedures you have created for your company.

With feasibility completed and a product design chosen, activities moving forward need to follow the Design Control Requirements within ISO 13485 and CFR 820.30. Generally speaking, they have similar steps:

1. Planning
2. Input/Output (traceability matrix that matches the input requirements and how each were met)
3. Review (design, FMECA, etc.)
4. V&V (validation and verification)
5. Design Transfer
6. Change Control
7. Design History Folder



Due to possible time constraints and resources available, creating a Product Development Process and proceeding with internal development may not be feasible, especially at the beginning of product development. You may consider having an outside team/company take charge of part or all of this process. Each route has its pros and cons, and they can also be combined for efficiency:

	<b>Internal Development</b>	<b>External Development</b>
<b>Pros</b>	Less costly. Can focus effort on developing QMS and other parts of the company.	Can be easier to control, milestone based.
<b>Cons</b>	Will need time to develop your own product development procedures and templates for drawings, reports, DHF, etc.	More expensive. Product development procedures will already be in place.

During the development phase, be ready to pivot and change direction as needed as challenges arise and remember it is always cheaper to cancel a project than launch an unsuccessful product.

### Briefly on non-disclosure agreements (NDAs)

At some point you will have to enter into confidential discussions with KOLs, consultants, contractors, suppliers, other companies, etc. Before doing so, it is in your best interest to ensure an NDA is in place that covers at minimum a definition of the confidential information being disclosed, the disclosing party/parties, how this confidential information will be handled, the term, and the governing jurisdiction. Overall, it is best to avoid disclosing confidential information unless you have to, and it is just as important not to let someone else disclose confidential information to you unless they need to. Do not assume you must have an NDA in place to have external conversations, just be aware of the "line" and ensure the party you are communicating with knows as well (in fact, it is best to address this directly by asking the other party not to disclose confidential information).

### Patent applications, patentability and freedom to operate

Returning to the matter of intellectual property, provisional patent applications on viable concepts should be filed as early as possible to obtain a priority date, but understand that without quality content and disclosure, you may not be able to rely on your provisional application for the very priority date you seek. For this reason, it is recommended as a goal to file a provisional patent application as if it is going to be a utility patent application, complete with claims.

At what point in this process then do you perform a patentability search? As part of your overall research to this point, you may have turned to patent research specifically to gain a better understanding of your playing field and, as recommended, used this information to help determine which potential avenues to pursue; however, a dedicated prior art search is helpful specifically come time to file for patents. A patentability search can be performed before or after your provisional patent application filing, but it is certainly recommended before a PCT or utility patent filings in geographies of interest. As mentioned, a patentability search should improve the quality of any patent applications you file by allowing you to distinguish between the prior art and what is unique and novel in your application, and hence allow you to draft better patent claims.

Now, the ability to obtain a patent does not necessarily give you the freedom to market and sell your product. Others may already have patent claims (either granted or pending) that the product you intend to bring to market may infringe upon. This is where a freedom to operate (FTO) search, otherwise known as a clearance or infringement search, comes into play. There are two “flavors” here, a FTO search alone, and a FTO search with legal opinion; the former can be as inexpensive as a patentability search, while the latter could run in the tens of thousands of dollars. The option you elect will depend on the details of your business and any investor requirements. By the very nature of this type of activity, you will have to have defined the details of your product as intended for market, so a FTO search will naturally be an activity performed once you are beyond brainstorming and into product development.

**IN SUMMARY**, identifying an unmet need is the first step in the pursuit of bringing a new medical device to market. We hope this practical guide aids you in your journey.

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## ABOUT THE AUTHORS

**Dominic Filice**, PhD is a Patent Agent at Parola Analytics, Inc. He has a doctorate in bioengineering and specializes in research and development (R&D) as well as patent preparation, prosecution, and research in the sciences. His areas of focus include medical devices, biomedical engineering, biotechnology, and the broader life and physical sciences.

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## ABOUT US

Our mission is fueled by our passion: **transform data into intelligence.**

We are a team of patent and technical analysts, data scientists, researchers and consultants with backgrounds in various fields such as Electrical Communications and Engineering, Computer Science, Physics, Chemistry, Material Science and Biochemistry. Our expertise in these fields has made us a trusted partner in delivering business-critical insights to decision-makers worldwide.

Driven by our passion for innovation, our team help you get ahead of the curve by unlocking actionable intelligence. Our flagship products **ParolaNOW** and **ParolaCUSTOM** provide data-driven patent landscape analysis. With our expertise in various fields, we also provide a suite of other patent research services that will help your organization formulate the best strategic business decisions.

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