Health Economics in the Medical Device Space

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AdvaMed: The MedTech Conference is the leading gathering of medical technology professionals in North America. The conference brings together more than 1,000 companies and offers world class educational opportunities and networking. We highly recommend attendance for MedTec companies as it is an efficient way to meet investors and get up to date on the latest hot topics and issues in the industry.

For those of you who were not able to attend, the following is a summary of the topics relevant to startups. Next week, I will focus on investor insights gleaned from the conference.

Tips for Entering the US Market

Since it is a for profit system, the US market is more complex than most. First and foremost, you must figure out if and how you can get your technology reimbursed.

Health economics data is critical to adoption. Because of the multiple players, the value argument that works elsewhere may not work in the US.

A local presence is essential. The value of relationships cannot be underestimated. It's a relationship based economy. A good starting point is to engage with KOLs and move from there.

It will take some time to understand the market but an investment in market research will pay off. The research must focus on all stakeholders, the physician, consumer, system and payers.

There are many payers and many stakeholders. You need to have a value proposition for each one. The channels are defined and efficient but all the stakeholders are looking for a cut of the profits.

Don't' jump right into selling once you get your 510k, power test the economics with different healthcare systems, and test the selling technique. This is balancing act with investors as they will want you to start selling right away. Educate investors that you can't just launch following approvals. The decision making at Jefferson is different than at Kaiser but both will be lengthy. The cycle at a sole proprietor will be quick, a clinical specialist group will be somewhere in the middle.

A company should start small when getting the technology accepted. If the device works the first 5 times and not next 3, they won't question the tech, but if it does not work for the first 5 times, they will question it. There is no procedure that can't be bungled-you must have a team that teaches it well. Pre-screening patients early in the adoption curve is important.

It is not necessary to be the lowest cost product, but it is essential that the product adds value. Segment the market and enter the area where you have the highest value add. You must truly understand USP's of your product.

R&D spend is higher to enter the US market given the regulatory prerequisite.

You must move beyond the free trial concept quickly and determine if there is a paying market.

The experience with distributors is mixed. They do not understand your product as well as you do.

You can't google your way to wisdom. Build relationship with those that have done it before to see where the landmines are. Understand the business model and the exit strategy, it will determine the business strategy. Willingness to help in the US is high.

Focus on Health Economics

Not surprising, the pre-conference seminar targeted at startups focused on health economics. This has become the single most important topic in the medical device space.

The relative power of stakeholders has shifted. The decision makers are no longer the physicians, or the hospitals, payers are now the most important stakeholders.

Having efficacy and safety data is no longer sufficient for market acceptance. Economic data is now needed and is equally important as the first two. Your reimbursement story cannot be built without it.

There are no easy answers about how to measure the economic impact of a new technology. If you are eliminating whole steps in a surgical procedure, it is easy, but this rarely happens. Some of the measurements that are important to measure are fewer admissions rates and

fewer hospital visits. Think about what facts are going to be interesting to decision makers i.e. faster, deeper and measure it.

Payers prefer prospective data. You should start collecting health economics data early in your development program. Your clinical trials should be designed in such a way that they will generate data that will lead to reimbursement. The issue is that the various payers, such as Aetna and Kaiser don't all want the same things and it is not possible to go to all of them to ask what they want. US data is preferred but if you have quality evidence it will be accepted in all countries by all insurance companies.

There are many stakeholders who will require that value be demonstrated. A company must have a value proposition for each one. The argument for the administration, the physician and the patients will be different.

The importance of KOLs has diminished somewhat. Medical societies are now important decision makers and trump KOL's. They are responsible for making recommendations to hospitals and payers.

You must keep in mind that when your product saves money, someone will be negatively affected and they may make it difficult for your technology to get adopted.

Every hospital has a value committee but companies do not have a voice. A champion is needed. It is time consuming to get approval (9 months), but once it is approved by several different committees, others follow suit faster. On the other hand, the committee also forms a barrier to entry and protects your market. A company will not always know they are being assessed. A negative decision will need to be petitioned. Aetna does publish clinical policies and basis for decision on the net. Policies are reviewed annually and the schedule can be found on the web.

If you get a negative CMS national coverage decision, you lose any positive regional coverage decision. You must carefully consider whether or not you want a national decision.

Integrating the use of a device in an already busy day and making sure the practice gets paid is rising in importance, especially in some sub-specialty such as OB/GYN, ENT and orthopedics. This requires influencing the staff in surgical centers and physicians' offices.

Although the NIH in the UK is known to be tough, they do tell you what you need to get reimbursed. What makes it difficult to get paid: lack of long term evidence, lack of patient reported outcomes. I.e. is longer life a good thing after chemo? They also have guidance for treatment and diagnosis that are used around the world. www.nice.org.uk

Practical Advice on Health Economics

If you can, use an existing code, you may not need to generate much data. Having to generate a new code will require a very substantial amount of work.

Companies are starting to do Phase II studies incorporating the collection of health economics data because there is too much risk to go from feasibility to a large trial.

Access datasets that are owned by insurance companies and government. They are very insightful when it comes to understanding economics. CMS can track long term outcomes with real world data. NICE in the UK has great data that is accessible. It helps companies identify the early adaptors, assess patient flow etc.

NICE is also very interactive. You can pick up the phone and ask them if you have enough data to obtain reimbursement.

Keep in mind that physicians must "sell" procedure to patients. Companies who present a strong economic argument (deductibles and co-pay) for patients are more likely to get uptake of products.

If the product has the potential to be used by a very large number of patients, this may cause concern to payers who will be worried of the impact on their budget. It is best to focus the efforts on a smaller segment, one where the technology will have the biggest impact and the value proposition is very high. The market can then be grown from a position of strength. A good example of this is the use of drug eluting stents. If your product has limited application, let them know that because it will be cheaper for them and they are more likely to pay for it.

Companies are utilizing DTC (direct to consumer) to pull demand through. This also helps informs decision makers and clinicians that something new is available. You should however be cognizant of the fact that it can backfire. Companies should ensure the products are being used in the right populations in the early days to minimize any negative experiences. Using social media may make this difficult as it will bring in the wrong patients. Physicians can also be upset because they will need to screen too many patients that won't benefit from technology.

Are patients mainly CMS/Medicare? Or private insurance? CMS has a fundamental block and it is difficult to get newer more expensive technology reimbursed. Think of a cheaper version of the product for CMS vs private insurance. Or go to private insurance before seeking CMS reimbursement to prevent getting slotted with a low reimbursement level.

Think of different business models. For example, if your equipment is expensive, think of a way to lower the cost i.e. pay per patient instead of paying for the equipment. It can reduce time to market.