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CLINICAL COUNTS CONSIDERABLY

Clinical & Regulatory impact investment decisions.

In this, our second installment from Emerging MedTech, we explore how clin/reg strategies help with investor dialogues, messaging and prod development. All intel gleaned from one panel conversation led by a mix of investors, former FDA representatives, leading CROs and consultants. This group collectively cited the importance of early clinical & regulatory planning. Why? Two reasons, time and ROI.

1. Time impacts ROI. Milestone advancement always takes longer than you think it might
2. ROI is time-contingent

This panel's message **reinforced our earlier observation** around conference themes: increasing complexity requires new thought processes and unlocking innovation starts with reverse-engineering from the outcome you wish to create back to the technology you plan to innovate.

THE NET OUTCOME:

You cannot deliver real change to patient lives without a solid understanding of the entire pathway to get there. A solid, thought-through Clin/Reg Strategy is a critical part of the overall business strategy for medical technology companies. Investors and strategics want to see this early and upfront in your presentations.

META ANALYSIS (NEW DATA!):

Whether seeking a 510 (k), Denovo or PMA, how much can you rely on the FDA website to shape your expectations around time and costs. Physician, former FDA rep and @NAMSA Strategy Consultant @Adam Saltman performed a 'meta analysis' of the last 300 FDA approvals in these categories to gauge the reality:

PATHWAY	DEFINED	FDA SAYS	ANALYSIS SHOWS
510 (k)	Your device is based on a predicate ('it's like that, but different').	90 days to approval $5,000 for smaller companies up to $1 million	120+ on average Well above $5,000
Denovo	No predicate to compare to. You must develop enough compelling evidence to prove the merits of moving forward	120 days $30,000	Most took 1 year North of $100,000
PMA	High risk devices; most difficult pathway. All about developing your evidence	180 days $500,000*	2 years on average $1 million plus

**First time submission can get a 'pass' and submit for free*

The delta between the FDA website and reality is due to:

1. The FDA likes to change the rules – no surprise there!
2. There are always holds, questions, deferrals, meetings and more information is desired and required.

SHAPING YOUR INVESTOR APPROACH:

Deepen your bench strength early and be prepared to adapt to changing regulatory conditions. Demonstrate that you know and understand the clin/reg landscape as you present to investors. This creates confidence and credibility that you 'did the homework." And it works across all levels: your team, your sites, your partners.

ASK YOURSELF:

When reverse-engineering from the outcome, start with asking yourself "where is the value?" Value can be created at different junctures:

DEFINED	FDA SAYS	ANALYSIS SHOWS
Is this a new clinical area? Are we 'creating the market?'	Creating a novel device is cost-heavy along the entire pathway	Can open market for tens of millions
Is this disruptive to the status quo?	Lower threshold upfront, but harder on the back end.	Cost heavy to create adoption – persuading physicians, clinicians to switch
Are we a better/more improved version of something that exists? (better mousetrap premise)	Me-too innovation is not bad!	Lift is heavier here to gain market share from incumbents

Early stage investor conversations often center around clinical needs and clinical data helps gain buy-in.

THAT "PLATFORM" THING:

If your innovation may be scalable across multiple indications, the FDA prefers a 'land & expand' strategy over attempting to secure multiple approvals at once.

The advice was: go with a primary indication– focus on a singular beachhead then rollout a timed plan for future indications.

The FDA prefers to see evidence supporting the exploration into other indications.

For potential platform opportunities, investors want to see the associated clinical and regulatory strategies to support the expansion. They need this level of detail to have confidence. Confidences stems from demonstrating high-level clarity around end points, patient numbers – all clinical parameters (even if rough estimates).

Investors want to know the roadmap as the FDA pre-subs open up. Feel free to do multiple pre-subs, buddy up with your FDA representatives and engage them early. Get your questions answered and those answers will inform both your clinical and regulatory strategy. (note: some investors will not engage in a dialogue until you have FDA feedback).

MOST IMPORTANTLY:

New indications are gravy – not steak. That 'beachhead' indication must sustain the company. New indications, new markets are meant to scale and grow but investors see them as potential distractions unless you demonstrate singular focus on a primary indication first.

HOW INVESTORS DEFINE CLINICAL STRATEGY:

Investors on the panel said: Clinical strategy is more than getting through regulatory.	FDA wants to ensure your device is "safe and effective".	CMS needs proof it is reasonable and necessary.	Clinicians need easy adoption options and compelling reasons to switch.

Demonstrate to your investors that your clinical plan can help clear these hurdles. They are inter-reliant and supportive of one another.

That should be the through-line of your strategy story.

PCRG is here to help at every stage – and like regulatory bodies, the earlier we engage with you, the more we can help. **Contact us today!**