Wound Market Consulting
The International Wound Care Industry Specialists

Market Insights: (Intelligent) Clinical Development in Advanced Wound Care

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With more than 22 years of experience in translational medicine, specialising in wound healing, tissue repair and inflammatory disease, she maintains a thorough knowledge of the wound cascade and the global competitor landscape.

So, you're developing a wound care product? Super. Wound healing is a real and growing problem, particularly in our ageing global society. Truly effective wound care products are a panacea. What motivates you? Your genuine interest in wound healing? Or, your great product/ technology looking for an indication?

I was approached recently by a Company with, I agreed, a very interesting compound, that they proposed to develop for other indications, but might look at wound healing as a "low-hanging fruit". An "easy win". Let me tell you, this it is not. The wound care market is already crowded, the advanced wound care market is not uncomplicated; the evidence base is scant, but evidence now, is needed. To break into this space requires commitment.

The "one-size-fits-all" product:

I regularly review clinical protocols for wound care. Most recently, I was pitched a relatively simple technology, proposing clinical utility for burns, trauma, surgical site wounds, chronic wounds (including diabetic foot ulcers, venous leg ulcers and pressure ulcers) and rare disease wound indications; basically every type of wound in the book. I was unconvinced. To me, this screams inexperience, and "hedging" that the product will influence *something* in the wound cascade. But what? A product that stimulates healing in chronic wounds, is unlikely, used in the same way (at what timepoint in the healing process?) to be beneficial to acute wounds, where closure is less of a problem than scarring.

This brings us to MOA (mode-of-action):

Know what your product does, and "how" it will fill the clinical unmet need. Know what you *need* to demonstrate (to prove efficacy? to satisfy the regulatory bodies? to satisfy marketing claims? To support your USP?). Is it complete closure, or stimulation of healing? What are your "nice to haves"? All those 30 biomarkers? Be mindful of your budget, and timeline. Remember, it's *always* about the regulatory. Marketing claims which don't align with regulatory requirements, and the evidence you submit to support, should not be claimed at all.

The development pathway:

Simplicity is key (read para above). Decide on your end goal and stay on the simplest path. If you are unsure of your best development path, take advice early. This can be decided on regulatory status, which you need to know (drug/ device/ class?). Design the Protocol for your 1st trial to inform that of your efficacy trial. Keep the protocol focussed, and as concise as you can. Follow this rule. Think carefully about your patient group; will anyone *actually read* a 42 page PIS (yes, I've seen one!), or even beyond page 4? Over-complicating (clinical procedure and paperwork burden) *will* affect recruitment.

Every wants a "Rock-star":

KOLs (Key opinion leaders) are the "rock-stars" of the clinical world. Everybody wants them running their trial. Every clinician is *not* a rock-star. Neither do they need to be. Your goal is to conduct your trial, with timely recruitment, and on budget. The best clinician for your trial may be the one who tells you honestly that they cannot fulfil, they already have too many commitments/competing interests. Research carefully, do your background, engage help – it is out there.

In summary, endeavour to truly understand your indication, the underlying physiological processes and the competitor market. Alternatively, focus on what you yourself do best, and engage with someone who does.