CRA Insights: Life Sciences

CRA Charles River Associates

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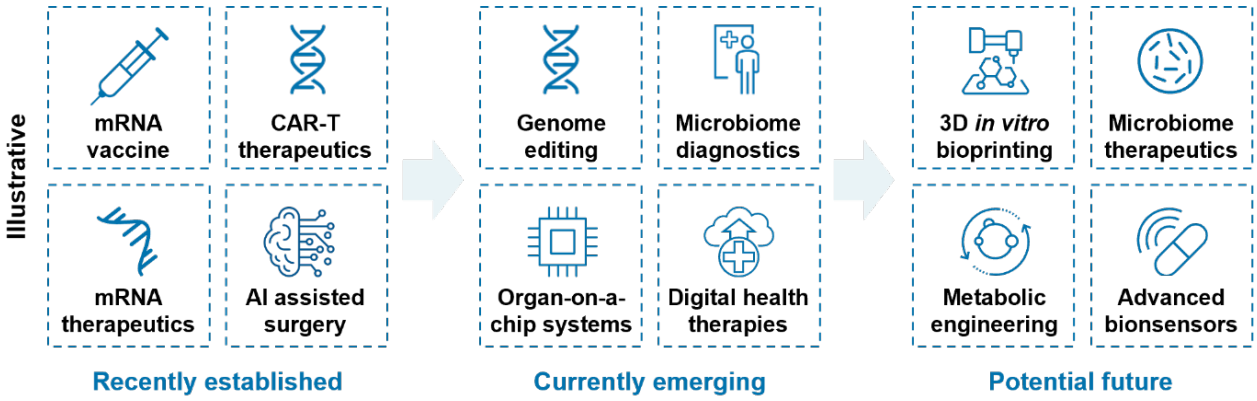
Unique barriers in development & launch of Disruptive Healthcare Products

We define Disruptive Products (DPs) as healthcare offerings highly differentiated from existing products with the potential to fundamentally alter the standard of care in their target markets – eg, microbiome therapeutics, organ-on-a-chip systems, or digital health platforms. As illustrated in Figure 1, some DPs – such as gene therapies and mRNA vaccines – are already playing a major role, while others are still moving toward market readiness.

Figure 1: Illustrative Disruptive Products



Source: CRA

Makers of DPs face unique challenges throughout development and commercialization, which are different than the challenges faced by manufacturers of traditional healthcare products. These barriers, illustrated in Figure 2, must be systematically identified and overcome by developers to ensure launch success.

Figure 2: Barriers to developing & launching Disruptive Products

Source: CRA

Developers advancing DPs are frequently faced with these barriers. Below, we provide five recent illustrative examples of DPs that CRA supported to overcome the barriers above.

CRA's Recent Support of Developers Advancing Disruptive Products:

Example #1 – Difficulties characterizing the commercial opportunity for a novel mRNA-based vaccine for a high-need disease

Recently, a manufacturer was developing a first of-its-kind mRNA vaccine. While high need was expected for the product, the public's likelihood to adopt varied significantly based on region and appetite for trialing a new vaccine. Complications abound given disparities in global adoption of the vaccine due to local vaccine hesitancies, evidence requirement differences, distribution abilities, and real-time vaccine supply needs.

To support effective vaccine rollout and launch planning strategy, CRA gauged the real-world level of expected demand for the mRNA vaccine. CRA first assessed commercial opportunity for the vaccine in each target country by leveraging a matrix with factors specific to the mRNA vaccine. Factors included a patient's potential to take advantage of a vaccine if available, manufacturing and distribution capabilities, reimbursement/payment potential, level of unmet need, and evidence required to convince a patient to be vaccinated.

With a clear sense for expected demand, CRA characterized commercial opportunity for the vaccine in each country, with process, timing, evidence required, and estimated demand, which utilized a tool calculating potential mRNA vaccine demand over time. This allowed the manufacturer to optimize education efforts, timing, manufacturing resources, pricing and focus for each country, and support rollout of the disruptive vaccine around the globe.

Example #2 - Need for strong comparative evidence and clinical/cost data for a microbiome-based diagnostic

Since emerging microbiome diagnostic technologies are far more accurate and convenient than existing tools, they offer the potential to change the standard of care in microbiome-disease diagnostics. With next-generation sequencing technology, clinicians can diagnose IBS and IBD before symptoms appear, allowing for earlier intervention, and providers can offer their patients more convenient at-home testing tools, potentially increasing population testing.

Recently, a developer of a novel microbiome-based diagnostic needed clinical utility evidence to support their product. The diagnostic offered mapping technology much more accurate than current inline microbiome-based diagnostics, but the developer sought a robust set of comparative data to convince gastroenterologists (GIs) of its reliability. Given that GIs historically had low understanding or willingness to try novel microbiome diagnostics, this evidence was crucial to the product launch.

To address this gap, CRA conducted research with a group of GI physicians to identify evidence that could encourage adoption of new technology. We then used these findings to develop a robust data generation plan, which included a patient chart study and key literature publications to provide the required clinical relevance.

Ultimately the microbiome diagnostic launched, backed by the key supporting evidence outlined in CRA's data generation plan. The product continues to build traction with GIs and is proving its clinical utility in the real world.

Example #3 - Difficult to communicate a compelling value proposition for a surgical robot

DPs are, by nature, quite different from existing therapies and tools. As a result, communicating value propositions for these products requires nuanced understanding of customer needs, behaviors, and practices, as well as a commitment to education.

A medical device manufacturer recently unveiled a surgical robot with the potential to become the standard of care for complex endoscopic lung procedures. The device allowed for enhanced control of endoscopic arms during the procedure, which would enable greater precision and higher volumes of procedures.

Despite positive publicity and clear benefits of the product, the manufacturer was struggling with hospitals and physicians hesitant to adopt an expensive and complicated piece of medical machinery. The high upfront cost combined with uncertainties around training, maintenance, and ongoing education, proved to be steep obstacles to adoption.

In many cases, the ultimate value proposition of DPs is clear, but potential customers are unsure how to maximize the potential benefits. To persuade hospitals and physicians of the

surgical device's value, CRA reframed the device's initial value proposition and highlighted how to incorporate it in existing workflows. By clarifying storage and maintenance issues, and creating training for optimal physician usage of the technology, CRA was crucial in helping potential customers optimize value from these expensive surgical robots.

Ultimately, large academic centers proved excellent potential customers and the manufacturer used CRA's recommended value positioning to sell into several hospital systems across the US.

Example #4 – Increased need for market development and awareness around digital health

Digital health data, when harnessed properly, offer substantial benefits to patient outcomes and experiences. Empowered with a wealth of information, physicians can make critical decisions earlier and more confidently to reduce unnecessary tests or procedures. This dual value proposition – to improve outcomes while minimizing costs – is relatively unique among cutting-edge pharma or healthcare technologies.

A recent pharma client was developing a smartphone application to help primary care physicians identify patients who could benefit from specific diagnostics. By collating and analyzing digital health data, the app accelerated diagnoses and treatments while streamlining ordering and operations for healthcare providers.

Despite clear benefits, the product faced a challenging rollout. Primary care physicians were largely unfamiliar with digital health, and outdated misconceptions that digital health solutions are ineffective fueled preconceived notions undermining the technology's potential. Launching the eHealth product therefore required an understanding of adoption drivers, existing notions of eHealth, and a nuanced perspective on educating the target physicians.

CRA first identified influential stakeholders in the target communities to understand prevailing attitudes and education levels. We then charted these groups on adoption pathways to focus on key adoption drivers for the client to drive in launch materials.

Our early conclusions highlighted two key barriers to launch: the separation between physicians' perceptions of the technology and evidence-backed reality, and the discrepancies between specialties regarding when to order and how to use the diagnostic. Each of these barriers required significant education to overcome. For successful rollout, the education and value messages required sensitivity, high levels of awareness, and messages tailored to specific market segments, which were integrated into a successful campaign targeting key stakeholders ahead of the product launch.

Example #5 – Need for a tailored go-to-market (GTM) strategy targeting influencers for a novel user interface (UI) technology

Raising awareness of new products and shaping emerging markets is critical to DPs' launch, but that is only half the battle. Selling products into these nascent markets is a vital second step and often requires creative GTM strategies.

A software developer recently created voice and gesture-recognition software offering myriad benefits to hospital surgery centers and intensive care units (ICUs). Using next-generation monitoring platforms, the voice and gesture-recognition software could reduce errors in

surgery, cut down surgery times, detect unmet needs in hospital workflows, and improve user experiences.

While next-generation UI technologies can offer benefits to hospitals and providers, many institutions are understandably hesitant to adopt these technologies in vital surgery centers. Therefore, the software developer needed a GTM strategy to accelerate product adoption and sales. CRA's GTM strategy building centered on two key efforts: finding customers willing to adopt an innovative technology, and identifying customers within this group to champion the product and drive sales. Though marketing and education campaigns are effective in established markets, DPs break new ground, so mainstream customers often look to trusted relationships, influencers, and real-world examples before making decisions. To shape the GTM strategy, CRA first applied advanced analytics to "fingerprint" US regions most likely to adopt the new technology. From there, we targeted certain large institutions to act as early adopters and KOLs, and champion the recognition software.

While novel UI technologies offer significant opportunities for hospitals and providers, selling new technology solutions presents significant challenges. CRA's customer analytics found potential customers and champions, but the software developer then needed launch materials to earn initial sales. CRA conducted a series of cross-functional working sessions to build buy-in for their new GTM model, and then provided function-level strategies and execution guidance to support the successful launch.

Conclusion

DPs face specific barriers throughout the development and launch process. To ensure a successful rollout, their makers must understand how to identify and effectively overcome these challenges for their product.

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