# WEARABLE INJECTOR PLATFORM: THE CASE FOR EARLY PARTNERING

In this article, Jeannie Joughin, PhD, Vice-President, Corporate Development, Enable Injections, describes how significant factors and developments, in society, in science and in the industry, have converged leading to the rise of patient-centric healthcare, and with it self-administration, with the wearable injector now emerging at the cutting edge. She goes on to show that early clinical partnership with a platform wearable device company is beneficial across numerous criteria, and how suitability for early partnership through to commercial launch was a key design consideration for Enable's wearable technology.

Those with experience in the many areas of pharma that involve partnering, such as drug delivery, might have become numb to the calls for early partnering from would-be partners. However, whilst there is a lot of noise on this, it is important to be able to distinguish instances where the case for early partnership is in fact robust, evidence based and compelling. In this article we will make just such a case for early clinical partnership in the context of pharmaceutical product development involving the Enable wearable injector device platform.

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## A NEW ERA IN BIOLOGIC DRUG DEVELOPMENT

Before focusing on Enable's platform, it is useful to look at how we arrived at this point where patients, without special skills or professional training, are now able not only to receive valuable, highly advanced, complex and previously very difficult-to-deliver (sometimes impossible-to-deliver) biotherapeutics, but also to take these treatments home and administer them to themselves easily, hassle- and worry-free, and without disruption to their everyday lives.

In the 1990s, new science, in particular genomics, began bringing to light new means of treating and curing disease. The prospect of such innovative medicines spurred a period of intensive research into disease modifying therapies and treatments for chronic diseases that continues today.

It has been fruitful, giving us a new generation of effective biotech compounds such as monoclonal antibodies, multivalent vaccines and recombinant peptides. Yet today, developing innovative biotech compounds into marketed drugs is increasingly challenging in terms of the burden of cost, time, risk all arising from factors such as the tough regulatory environment and the sheer complexity of the task – the complex compounds, complex therapeutic mechanisms, and the increasing number of ever rarer diseases to be treated.

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Over the same period that the biotech industry has been born and grown, the wider world, including patient populations, has undergone huge change too. Patients have evolved, rapidly becoming more educated and aware, in part due to the internet. The healthcare sector has changed too – placing the patient at the centre of the value equation with an emphasis on value-based care and patient outcomes rather than just the treatment alone.

## PUTTING PATIENTS AT THE CENTER BENEFITS ALL

The marketplace has thus been transforming from a provider-dominated marketplace (pharma) to a consumer-centred system. On a simple level the consumer (the patient) can be seen to demand products that are more responsive and reflect their needs. But people are highly complicated and so the question then becomes, what are their needs?

Hope, control, freedom, independence, burden-free treatment, and treatment liberation are some of the things we might seek after being diagnosed with a serious, chronic disease. It is when considering these sorts of patient desires and demands that the value of self-administration becomes apparent - bringing biotech therapies out of the clinical setting and offering more of what the patient wants and needs.

Self-injection, and its ability to take quite advanced treatment out of the clinical setting, is favourable not least because in many circumstances it is ultimately more successful. Patient adherence benefits are clear, as are cost reduction benefits to the entire healthcare system. Shifting patients out of the clinical setting without compromising safety or efficacy frees up more resources to be used on those patients who absolutely need a clinical setting and the presence of healthcare professionals for drug administration (e.g. combination oncology therapies) and other treatments.

In response to these major changes that have taken place over the past few decades – the emergence of biotherapeutics, the associated cost, time, risk and complexity, the increasing focus on the patient, and in particular allowing them to self-administer at home – delivery solutions have begun to emerge that enable a new pharmaceutical product both to meet the patient's demands and desires from the outset and accommodate means to overcome the inherent obstacles that would otherwise ultimately affect the time, costs and risk involved in moving through clinical trial phases to commercial production.

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With hindsight, it is easy to see that the ever closer integration of devices and therapeutic candidates was inevitable. The key to success for pharmaceutical companies embarking on new development projects today is to integrate the device early in development.

Crucially the patient's role in clinical trials has also changed dramatically over time. In the past, human volunteers, in terms of their value to the trial, were almost just an organic substrate into which product candidates were infused and the physiological effects monitored and recorded. In contrast, the patient's role in clinical trials today is much more that of a whole person experiencing the treatment. The physiological data is gathered of course but patients are now reporting back on how the treatment experience felt, how it could be made easier, what they liked and disliked about it.

Bringing the device in at the early clinical stage provides an opportunity to engage associated patient populations early in product development. It improves the ability of the product to meet the patient needs and thus to align better with the reward for outcomes that governments and payers insist upon. It enables the pharma company to answer contextual questions regarding the patient sooner and therefore decrease cycle time for new product development

In this environment – with self-evident significant benefits to the product development process of these additional insights from the patient as a whole person experiencing the complete product, drug and device, the potential for greater product differentiation, better acceptance, and better uptake at the time of launch to achieve better outcomes – the case for including the drug delivery device from early in the clinical stage becomes ever stronger. Conversely, a pharma company leaving the inclusion of the delivery device as an afterthought, after the clinical trial stage, risks a huge missed opportunity, an inexcusable omission, and a substantial competitive disadvantage.

The patient is now at the centre of the value equation and the delivery device is now the element that, from the patient perspective, often defines the treatment experience more than any other. The drug itself will remain a most important factor, but inevitably it will represent a diminishing share of what comes together to deliver an overall outcome for the patient.

## FLEXIBLE DEVICE PLATFORM: A SUITABLE SOLUTION

Whilst early clinical-stage partnering and integration of a patient-centric device for self-administration is desirable, not all devices out there are necessary suited for clinical stage partnering. What then are the characteristics that describe a valuable and convenient delivery solution that is attractive for early partnership in the clinical environment?

Clearly, any solution must be affordable and flexible for pharma to accept at this stage of development. These are prerequisites, and point towards a technology platform. The platform approach embraces the fact that one size does not fit all and thus offers multiple "sizes" to a pharma partner (for example, the ability to use different types of standard drug container, or deliver a range of dose volumes) to accommodate various scenarios and patient populations.

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Modern drug development is risk heavy already and so pharma companies want the device solution to be a de-risking influence ideally, and definitely not a source of additional risk.

With a robust, versatile device platform integrated into the development process, if one drug candidate fails, the delivery device remains and is ready, both technically and in terms of budget spend, to take the next candidate forward. This allows the development project more "shots on goal" with drug candidates, increasing the chances (decreasing the cost and time) of finding the one that will be taken through full product development. Device flexibility, for example the capacity to deliver a large range of dose volumes up to very high volumes, increases the number of possible drug candidates and thus, again, increases "shots on goal" and de-risks the entire development program.

In addition, the solution should accommodate and utilise the existing infrastructure the pharma partner has already established to avoid risk, decrease costs and reduce timelines. The requirement for change should be minimal. A suitable device platform should avoid, and certainly not exacerbate, the challenges of filling complex compounds, and avoid the longer timelines, and increased risk and cost associated with bringing in a new container (e.g. testing). Utilising standard primary container closures minimises change, and the ability to use various forms (i.e. both syringes and vials, of the kind already used in clinic) adds the flexibility to accommodate a wide variety of drugs and user populations.

## TRANSITIONING FROM CLINIC TO MARKET

To be a viable proposition, a low risk clinical-stage drug delivery solution must also easily transition into a commercial solution. In the same way that both the delivery technology and the strategic partnership relating to it must be flexible and responsive for clinical trials, they must both be responsive to the needs of the commercial environment.

This goes beyond merely being suited to application in lifecycle management. Things change fast in the commercial environment. Market drivers change, concepts within biotech evolve. Patents expire and mature products are suddenly faced with new competition. Innovative delivery solutions that add value and convenience will prolong a branded drug's premium pricing and define its market share against competitive entrants with similar indications and patient profiles.

As pharma companies increasingly put patients at the centre of the value equation, and view them as their customers, with specific wants, needs and expectations, it becomes clear that the right delivery device platform offers many of the capabilities and features needed to accommodate current and future patient requirements, fulfilling the demand for better treatment outcomes, but going further, digging deeper. For example, patients are attracted to the idea of self-administration, and want greater convenience related to the services they are receiving, and the right device platform enables the pharma company to fulfil that customer desire completely. Likewise, the right device platform meets the patient-customer's wish for: comfortable drug administration (e.g. minimally invasive solutions); an administration means that allows them to control their chronic illnesses without compromising their daily activities; minimal anxiety and intimidation; and perhaps for a product that has an attractive appearance with environmentally responsible packaging.

Figure 1: Enable Injections' syringe transfer systems are favourable for variable fill volumes and provide the flexibility of accommodating any syringe or vial primary container.

Figure 2: Enable Injections' vial transfer systems will transfer entire or partial contents from the vial and can accommodate single or multiple vials.

Figure 3: Enable Injections' mixing systems can automatically or manually mix/reconstitute two vials of liquid or liquid/powder.

## ENABLE PLATFORM – OPTIMISED FOR CLINICAL-STAGE INTEGRATION

Enable Injections has long understood that the wearable injector would not be a mere afterthought in pharmaceutical product development. Whilst there are of course beneficial applications in lifecycle management later in development, the Enable wearable platform, and indeed the structure and culture of Enable Injections the company, is designed and built to fulfil their principle role – to play an integral part of pharma partners' overall development pipelines from the early clinical phase through to launch and beyond.

The Enable wearable injector is the core technology that can adapted to deliver a defined or variable dose, at a pre-determined flow rate, based on viscosity and patient comfort. Once the key attributes and the design are determined, the same injector may be used to deliver multiple clinical compounds. In early-phase clinical studies, when dose has yet to be determined, the injector may be filled with variable volumes using a syringe-transfer system (see Figure 1). Once the dosing regimen is established the same injector may be filled with the entire/partial contents of a vial (vial-transfer system, see Figure 2). If mixing is required – lyophilised product + diluent or two products in solution – the filling mechanism can transition to a simple, convenient means of pre-mixing and filling that same injector (see Figure 3).

Enable Injections actively encourages clinical collaborations with partners with a strong pipeline of products and/or additional lifecycle management – for example, new indications – since the platform technology offers the partner a fast-track to clinical trial. This form of collaboration provides a cost-effective, milestone-based means of supporting subsequent validation/verification for additional combination therapies in the partner's pipeline and mitigates development risk and cost for the pharma partner.

## SUMMARY

The last decade has seen remarkable breakthroughs in biotech, transformational changes in healthcare, and more broadly in society too. The patient is now at the heart of the pharmaceutical industry value equation, viewed as a person with feelings and desires and as a customer with demands and requirements.

A parenteral delivery device is required for the administration of the vast majority of new biologics, and this is increasingly integrated into the pharmaceutical product. The delivery system is often the aspect of the treatment that is most tangible to the patient and most able to meet their specific wants and needs. For drugs that require high volumes and longer delivery times, a wearable injector is a game changer, freeing patients from the healthcare setting and enabling them to take their medicine themselves, at home – self administration.

The value of the delivery device does not end there though. If the delivery system is brought in at the early clinical stage, the patients' feelings and opinions about the real treatment experience can be taken into account to improve the product at the right time, during development and not after launch when it is too late. Furthermore, the technical challenges complex biological molecules present can and do slow or halt product development. Utilising a delivery solution that accommodates variable dosing and can be readily switched to other pipeline products in the event of product failure significantly helps mitigate this risk.

Biotech/pharma companies are thus increasingly looking for a device partner whose business structure, culture and strategy is configured to work with them from the early clinical stage onwards, and which offers a technology platform that can accommodate a wide variety of drugs and user populations. We believe that Enable Injections the company, and the Enable on-body delivery platform, represent that partner.

In today's pharma industry, a delivery solution cannot just be "kept in mind" during clinical development. A drug delivery device platform must be brought in and implemented during clinical development as part of any optimised and streamlined biopharmaceutical development pipeline.

## ABOUT THE COMPANY

Enable Injections is a late-stage start-up company that has developed a disposable on-body injector to deliver high volume (up to 50 mL), high-viscosity drug/biological products to the subcutaneous tissue. The system utilises standard container closures (syringes or vials) and can automatically mix solutions or solubilise lyophilised product. It is designed to be simple to use and discreet promoting convenience and comfort for a preferred injection experience for the user. Enable's technology provides many differentiating advantages to both the user and bio-pharmaceutical company. Founded by medical device veterans the company has R&D, operations and manufacturing facilities in Cincinnati, OH, US. *For investigational use only.*

## ABOUT THE AUTHOR

**Jeannie Joughin**, PhD, Vice-President of Corporate Development at Enable Injections, is responsible for business development, strategic alliances, alliance management, marketing and clinical activities. She previously held various scientific positions including Senior Research Scientist, Post-Doctorate and Senior Post-Doctorate positions in Australia at The Alfred Hospital, The Walter & Eliza Hall Institute, as well as internationally in Austria (University Clinic, Innsbruck) and Switzerland (Ludwig Institute for Cancer Research, Lausanne).

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