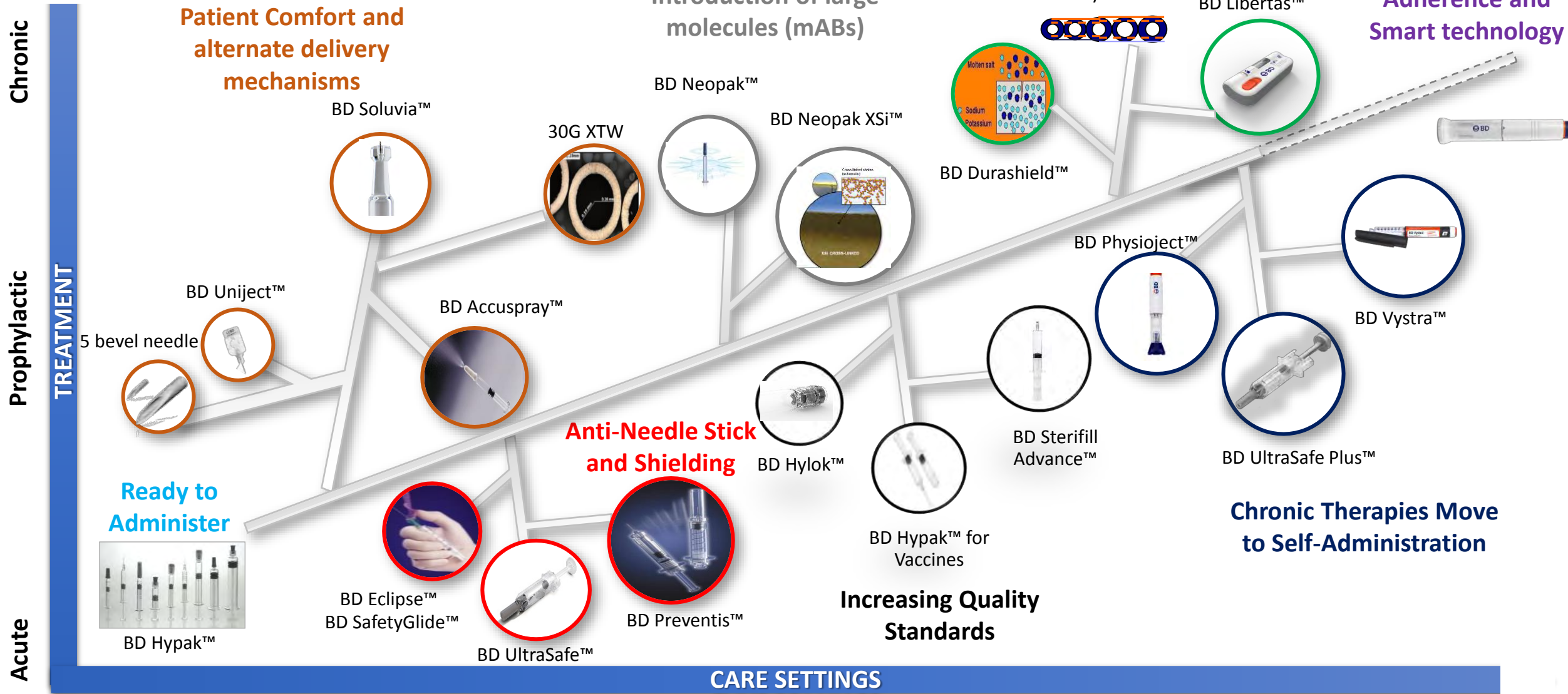


3 Months from Concept to Demo: Mobile Device Case Study

key tech.®



Innovation at BD – Focus on key market trends and customer unmet needs, leads to new product development



Hospital

CARE SETTINGS

Alternate Care

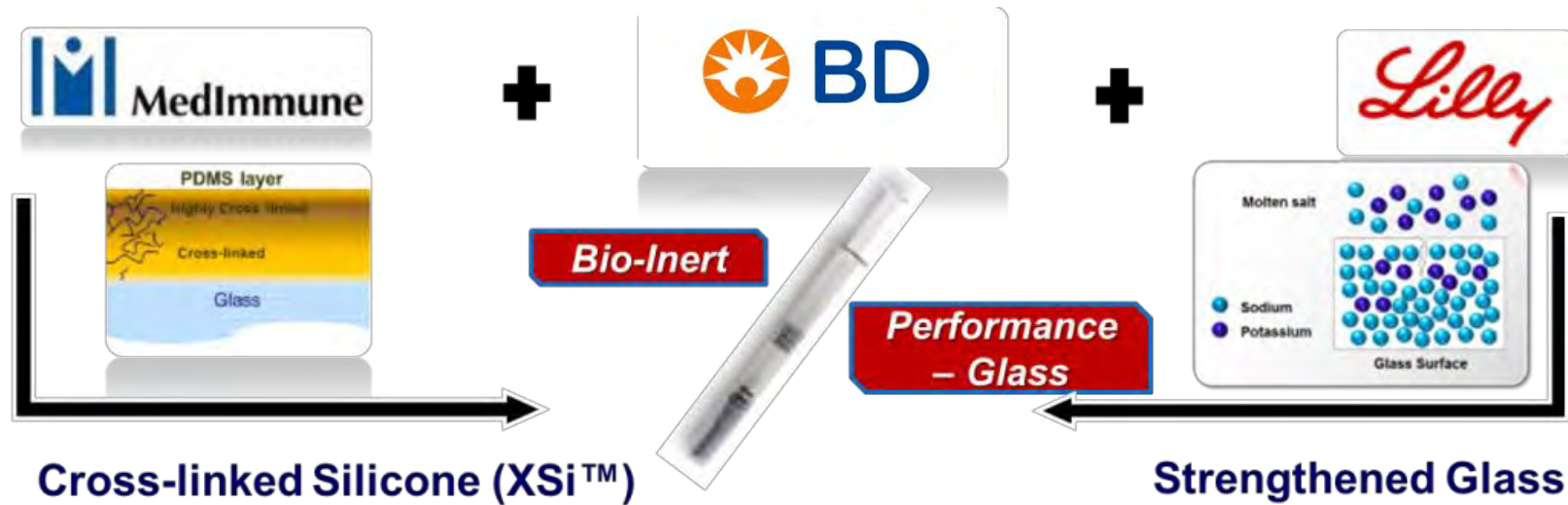
Home



Drug Delivery PARTNERSHIP

- Tapping into potential opportunities resulting from trends and unmet needs
- Whether innovating in the area of programs, technologies, or business models, partnerships can be an important path to enable success
- Adapting principles from the lean start-up approach to increase speed, and lower risk, in innovation

BD has collaborated to develop new technology . . .



NEW PFS TECHNOLOGY:
Cross-Linked Silicone Coating Reduces Sub-visible Particles and Improves Compatibility with Biologics

Sebastien Jouffray, Program Manager
 R&D, BD Medical Pharmaceutical Systems

Mariana N. Dimitrova, Principal Scientist, Ph.D.
 Formulation Sciences Department, MedImmune

The Continuing Evolution and Opportunities for Glass Performance

Justin Wright, Ph.D.
 BD Medical - Pharmaceutical Systems


Ronald Iacocca, Ph.D.
 Eli Lilly and Company

Lilly **BD**

The Universe of Pre-filled Syringes and Injection Devices
 October 10-12, 2012 | Red Rock Resort and Spa | Las Vegas, Nevada

BD has collaborated to pilot new ideas and define solutions . . .

FEATURE



Prefilled Syringe Vaccine Doses

An Emerging Option in the Retail-Based Clinic Setting

Eileen Myers, MPH and Sarah Rosenberg, JD

Prefilled Syringe Use Offers Advantages That Can Help Pharmacists Improve Quality of Care

Overview
The use of manufacturer-filled syringes (PFSs) for vaccine doses offers many advantages to providers who are looking to better operational efficiency, minimize risk, and improve patient safety in the clinical administration of vaccines. The growing recognition of the advantages of PFSs has resulted in a major shift in the marketplace away from the use of multidose vials (MDVs) for all vaccine types, but most significantly, influenza. The percentage of flu vac-

...cine packaged in prefilled syringes more than doubled, from about 21% during the 2006-2007 flu season to approximately 48% during the 2012-2013 season.¹ While PFSs have been widely adopted in the broader market, retail-based clinics (RBCs) have lagged behind. Unlike other clinical settings, RBCs have storage constraints that may need to be overcome to allow the wholesale stocking of PFSs compared with MDVs, which have a much smaller footprint.

About PFSs
It is essential to understand how PFS doses differ from vaccines packaged in MDVs. PFS doses offer a means for vaccine delivery that supports RBCs' ability to:

- Reduce or eliminate vaccine waste.
- PFS packaging can help ensure doses purchased are administered. PFSs remove the variation inherent in drawing from an MDV, where the yield obtained may be fewer than 10 doses per vial.²
- Increase administrative consistency. Some clinicians are more adept than others at drawing from vials in terms of time and dose yield per vial, resulting in variation across an organization. By removing the need to draw at all, prefills allow for consistency in administration across all locations and clinicians.
- Improves efficiency. Because prefills do not need to be drawn up, the amount of time required to prepare is decreased. Studies support that when PFSs are compared with MDVs, prefills save between 37 and 43 seconds per dose in preparation time.



Directions in Pharmacy** March 2015 www.PharmacyTimes.com 15

Pilot Study Results

Operationalizing the Use of Prefilled Syringes in a Convenient Care Setting

CCA Board Meeting 2013

Eileen Myers
Sarah Rosenberg
Brian Lynch

The Little Clinic Study (Pilot #2): 2012-2013 Influenza Vaccination Campaign

Meet with TLC to discuss Pilot #2

Multi-party collaboration: official project kick-off

Interviews with key stakeholders

Clinician surveys distributed and returned




Develop white paper for publication

Refine project scope; develop preliminary plan

Official Pilot Kick-off Event in Nashville

Time motion studies conducted

Interviews with key stakeholders


Collaboration Partners






Summary

- The pilot study demonstrated . . .
 - Supply chain solutions - storage, inventory management, ordering, invoicing - can help operationalize PFS in cold chain limited point-of-use environments
 - Confirmation of PFS clinical excellence benefits
 - Both hard and soft value needs to be considered





8. Please complete the sentence: The process of switching to using PREFILLED DOSES . . .

Ready 50% of respondents identified switching to prefilled needles and syringes as a benefit.



9. Please complete the sentence: Now that we have switched to using prefilled doses, I expect next season will run . . .

Discontinuing MDVs, before that point because we'll run more efficiently by using prefilled syringes.

BD has collaborated with external organizations to help educate and drive change . . .

American Academy of Pediatrics

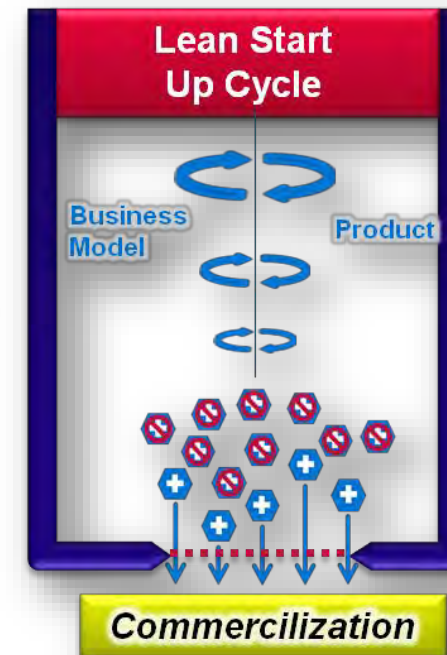
BD Sponsored AAP's Vaccine Storage & Handling Best Practices Exhibit at their 2015 Annual Conference



How do we innovate for the evolving ecosystem and leverage best practices from other industries to develop solutions?



How do we decrease cycle times for fast moving markets where solutions require unique and novel technologies and/or business models?



1. *Business-hypothesis-driven experimentation*
2. *Rapid and iterative product releases*
3. *“Validated Learning”*

Mobile Immunization Case Study: Market Trends & Unmet Needs

Unmet Needs

Questions / Unmet Needs Across the 5 P's

- Public Health – How can vaccine coverage/uptake be improved?
- Providers
 - Can device technology help enable new business models to deliver care differently?
 - Cold chain constraints
 - Cold chain integrity
- Pharma – balancing needs of stakeholders; finding a differentiation vector
- Payers – It's all about the outcomes
- Patients – Quality affordable convenient healthcare

Market Trends

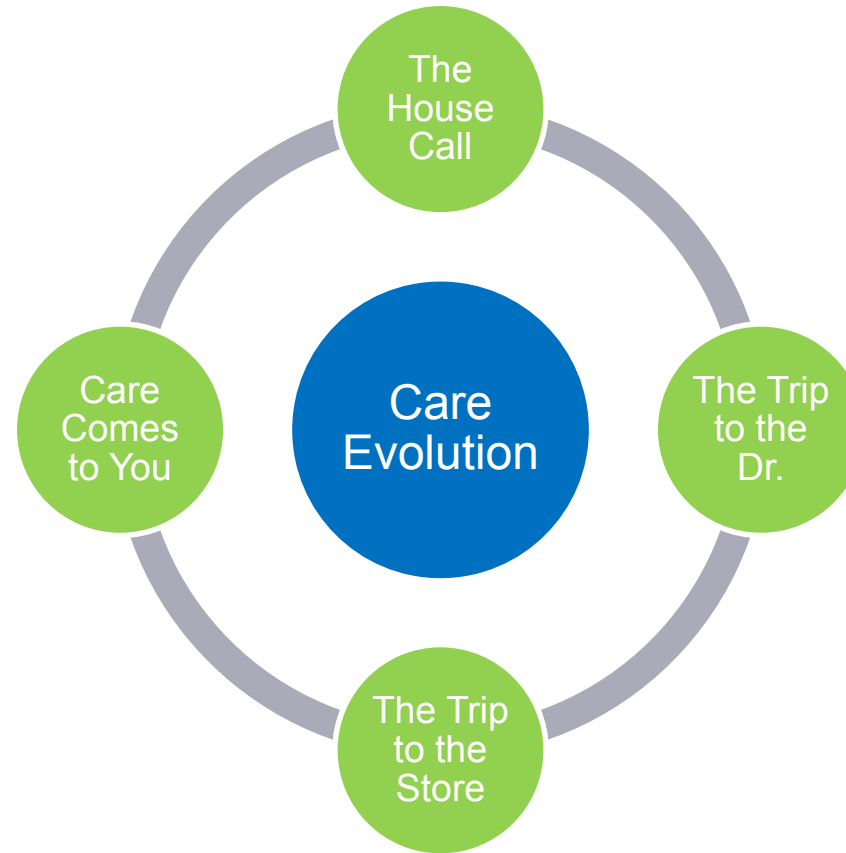
Market/Customer Trends

- *Retailization of Immunization . . .and care in general*
- Care moving closer to the patient
- Healthcare “when I want it, where I want it”
- Consumers & technology
- Decentralized healthcare

Immunization's Role in the Emerging Retail Care Space

- Vaccination - many times the first client engagement
 - *the most common retail clinic services billed - flu shot, vaccine administration and strep test**

A Look Ahead (or Back to the Future)



Mobile Immunization Case Study: Trends & Unmet Needs Lead to New Opportunities . . .

Outsmart the Flu with UberHEALTH

The collage includes a blue graphic with medical icons (band-aids, stethoscope, syringe, ambulance, plus signs), a photo of a man in an UberHEALTH t-shirt, a presentation slide titled "UberHEALTH National Adult and Influenza Immunization Summit" with logos for CDC, MIT, and Health, and three bar charts showing survey results.

Chart 1: Did you receive?

Response	Count
No	200

Chart 2: How likely were you to receive this year?

Response	Count
Definitely Likely	150

Chart 3: Would you use UberHEALTH again in the future?

Response	Count
Definitely Likely	390
Somewhat Likely	70
Definitely Not	20

Case Study: From unmet needs and market trends, features and benefits were identified for our hypothesized solution and provided to our technical partner

Hypothesize Solutions

Feature	Benefit
Smart, Universal Injector	<ul style="list-style-type: none"> • 100% data reporting to cloud • Automatic link to EMR • Data available for patient tracking, outcomes determinations • Predictive vaccine production
BD Hypak™ Tub	<ul style="list-style-type: none"> • Minimal changes to fill/finish for pharma
High density packaging	<ul style="list-style-type: none"> • Minimize cold storage space requirements
Lock & technology (syringe to injector)	<ul style="list-style-type: none"> • Limit medication errors (5 rights)
Prefilled syringes	<ul style="list-style-type: none"> • Ready, easy to use format for HCP

BD – Franklin Lakes, NJ



BD – Research Triangle Park, NC

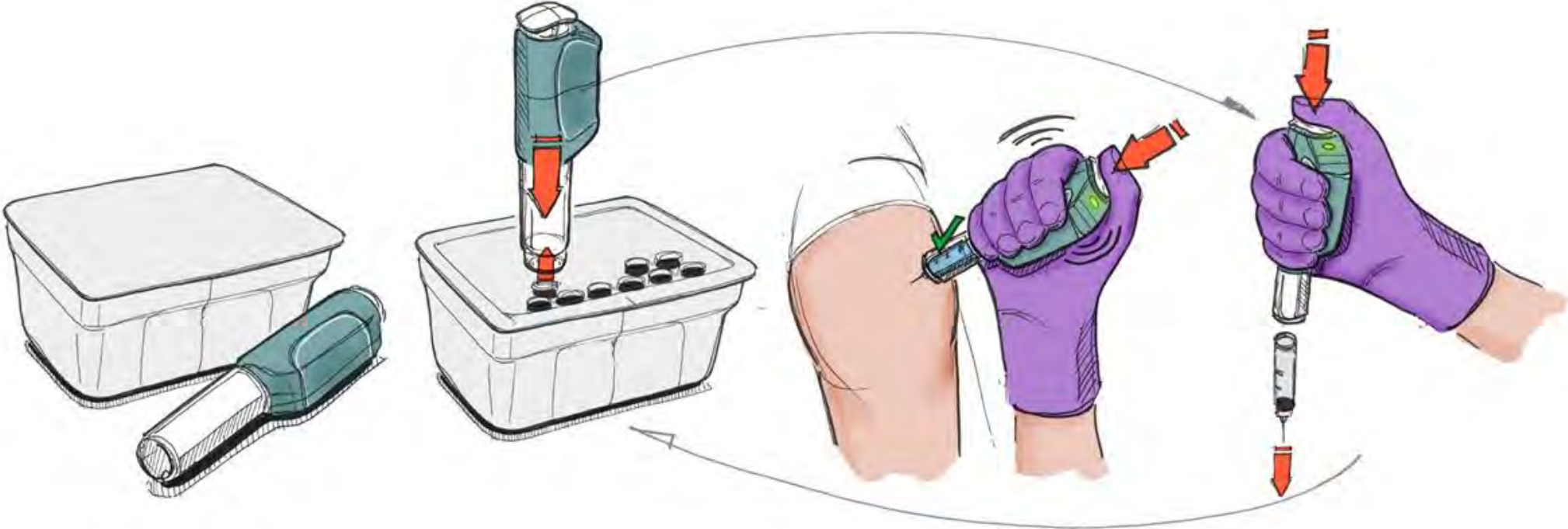


BD – Pont de Claix, France



External Partners;
To bring this to life quickly, we partnered with KeyTech – who had a team they could dedicate to this project, the next day!

Mobile Drug Delivery Concept

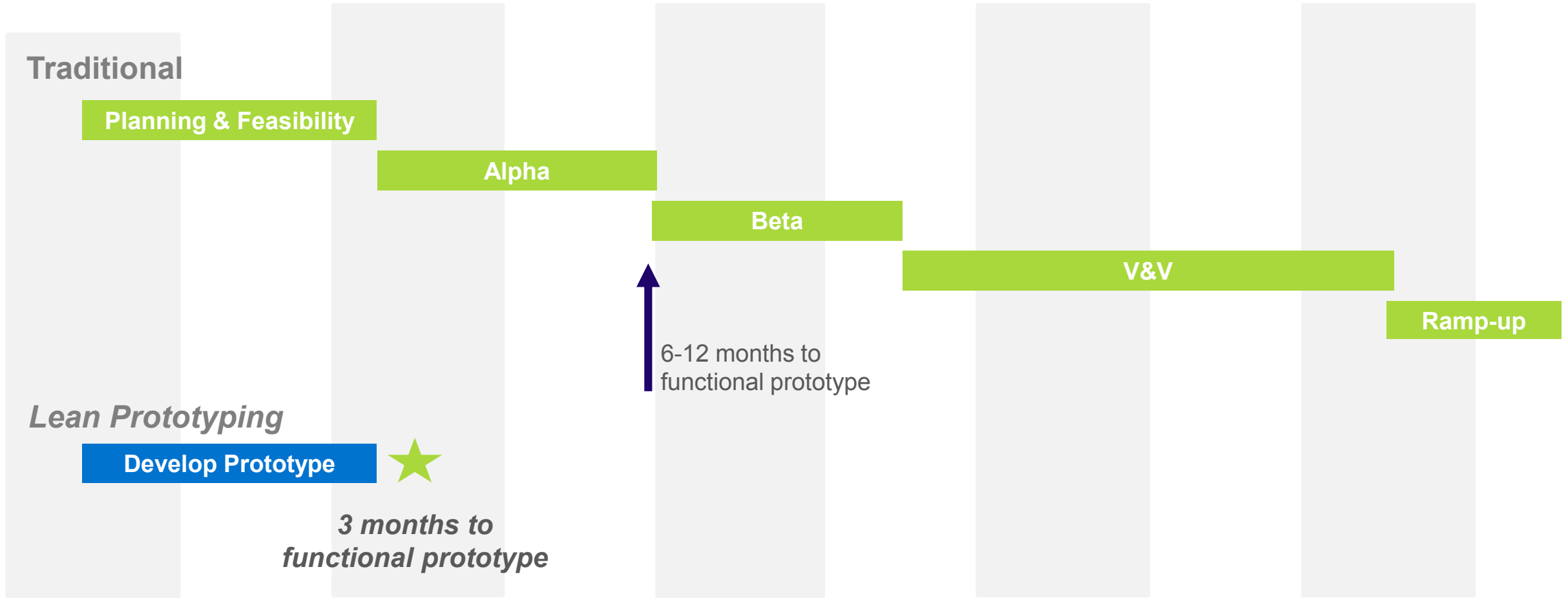


Note: This product could be subject to regulatory approval

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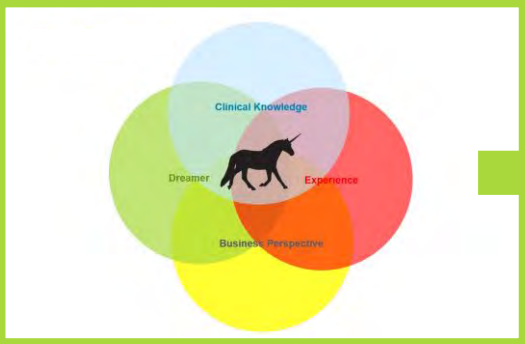
Traditional vs. Lean



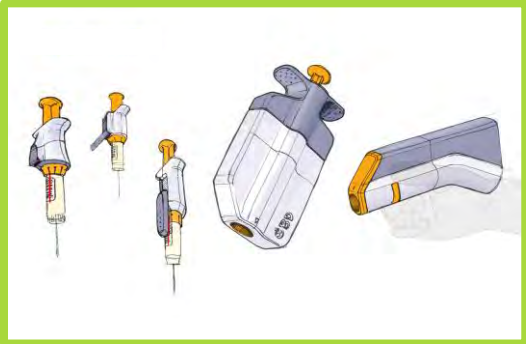
**Prototype development timeline determined on a case-by-case basis and may be longer than three months.*

Lean Prototyping Process

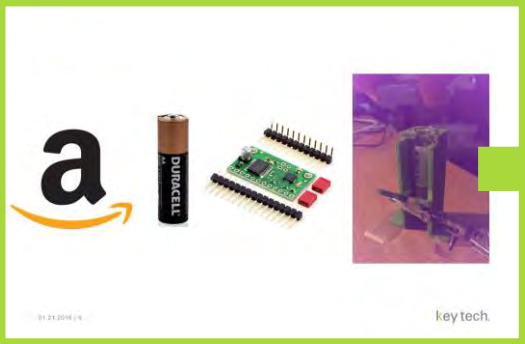
Define User Inputs



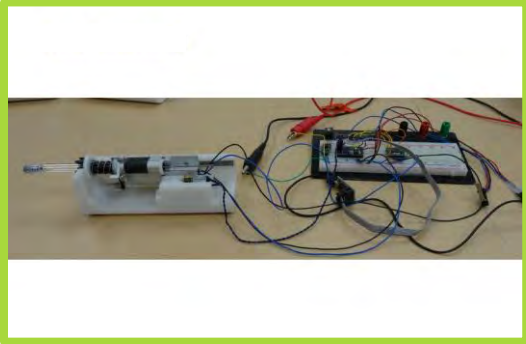
Evaluate Form



Be a Maker



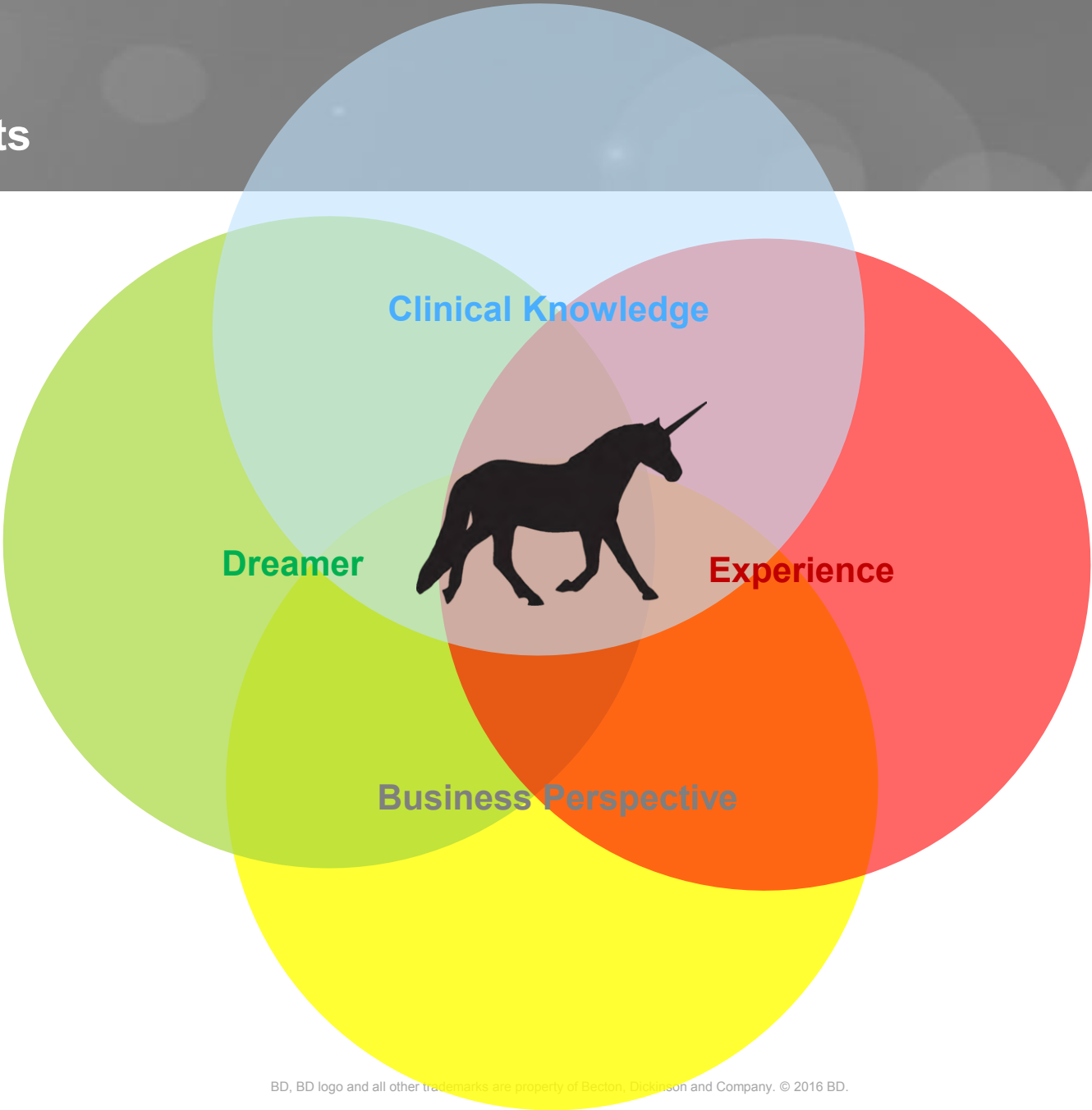
Prove Functionality



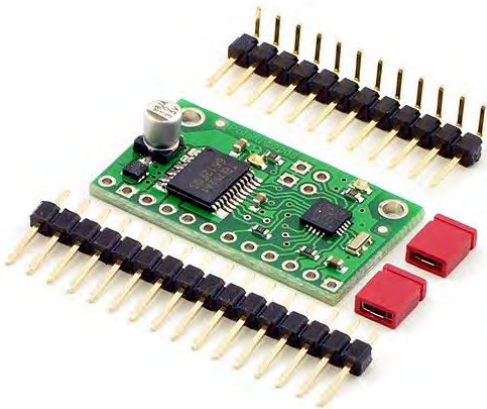
Integrate



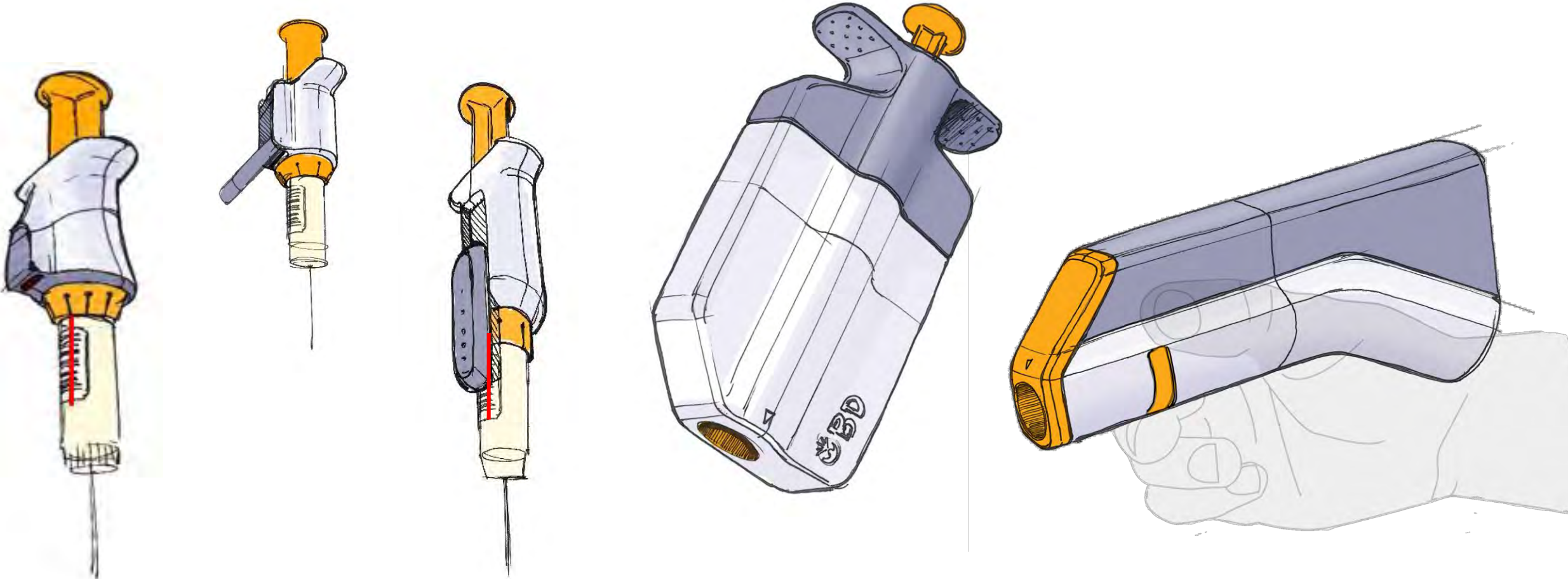
Define User Inputs



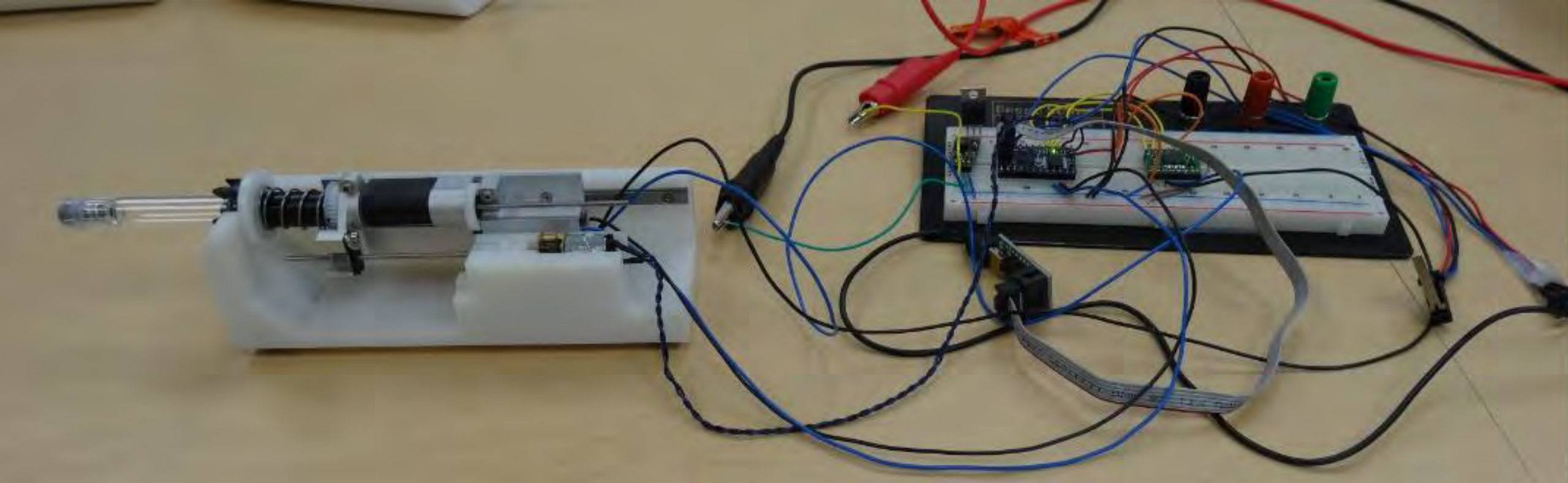
Be a Maker



Evaluate Form



Prove Functionality

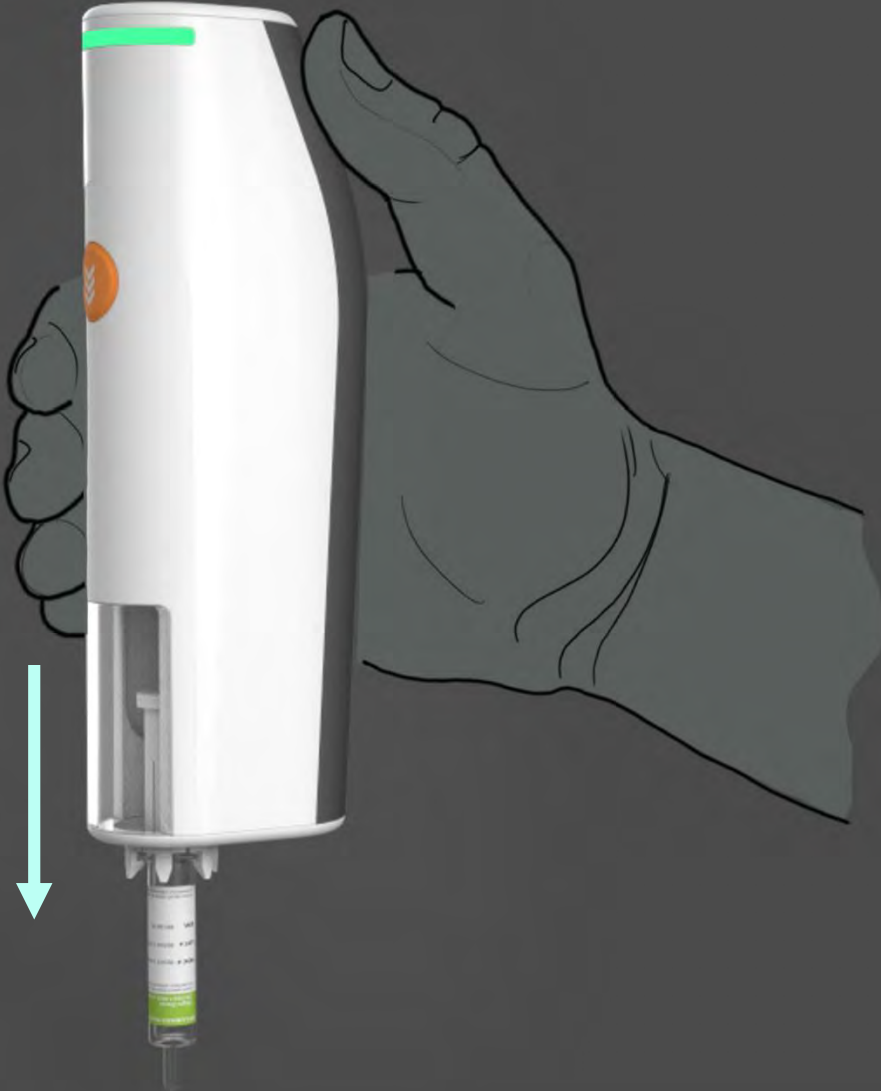


Integrate

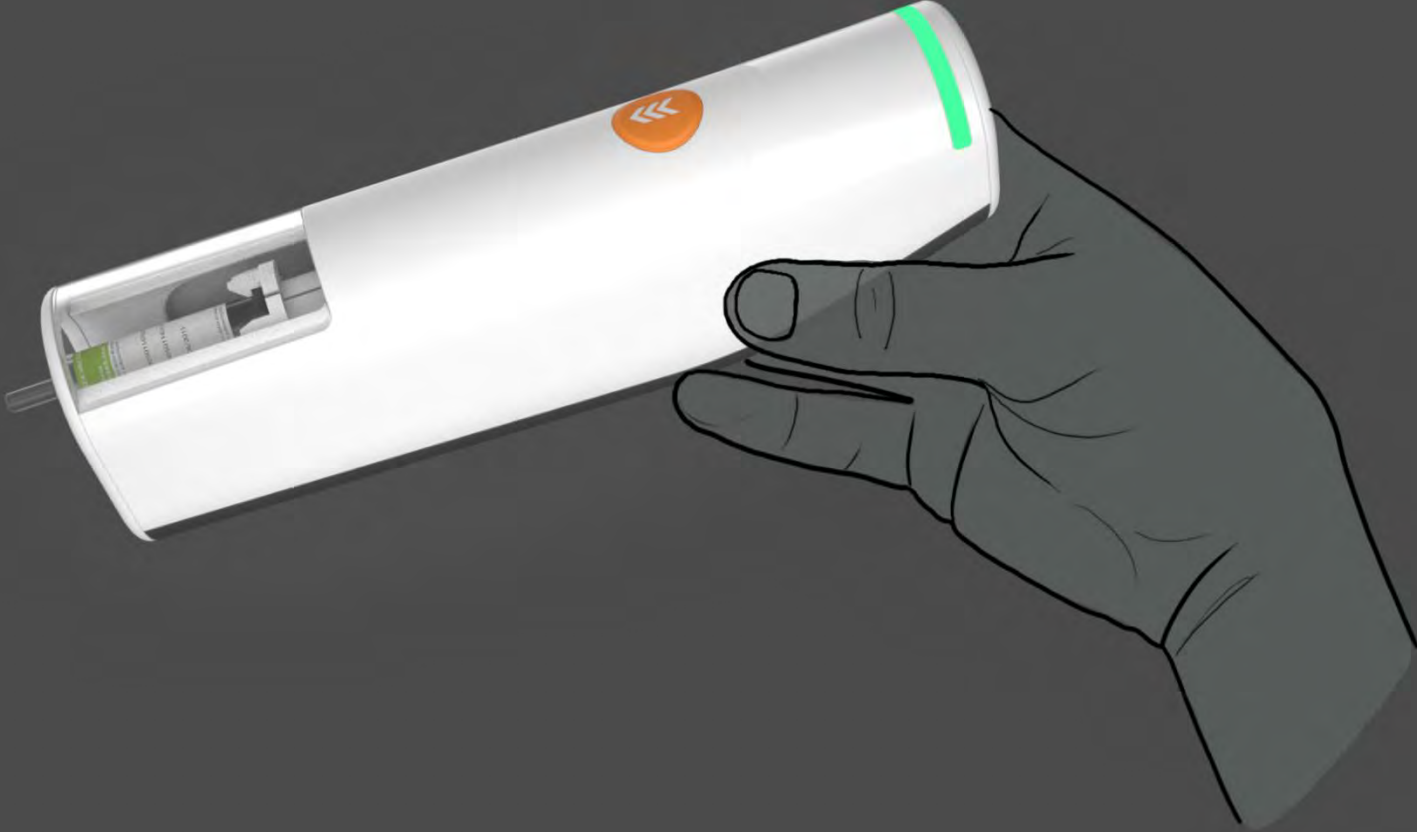


Functional Prototype

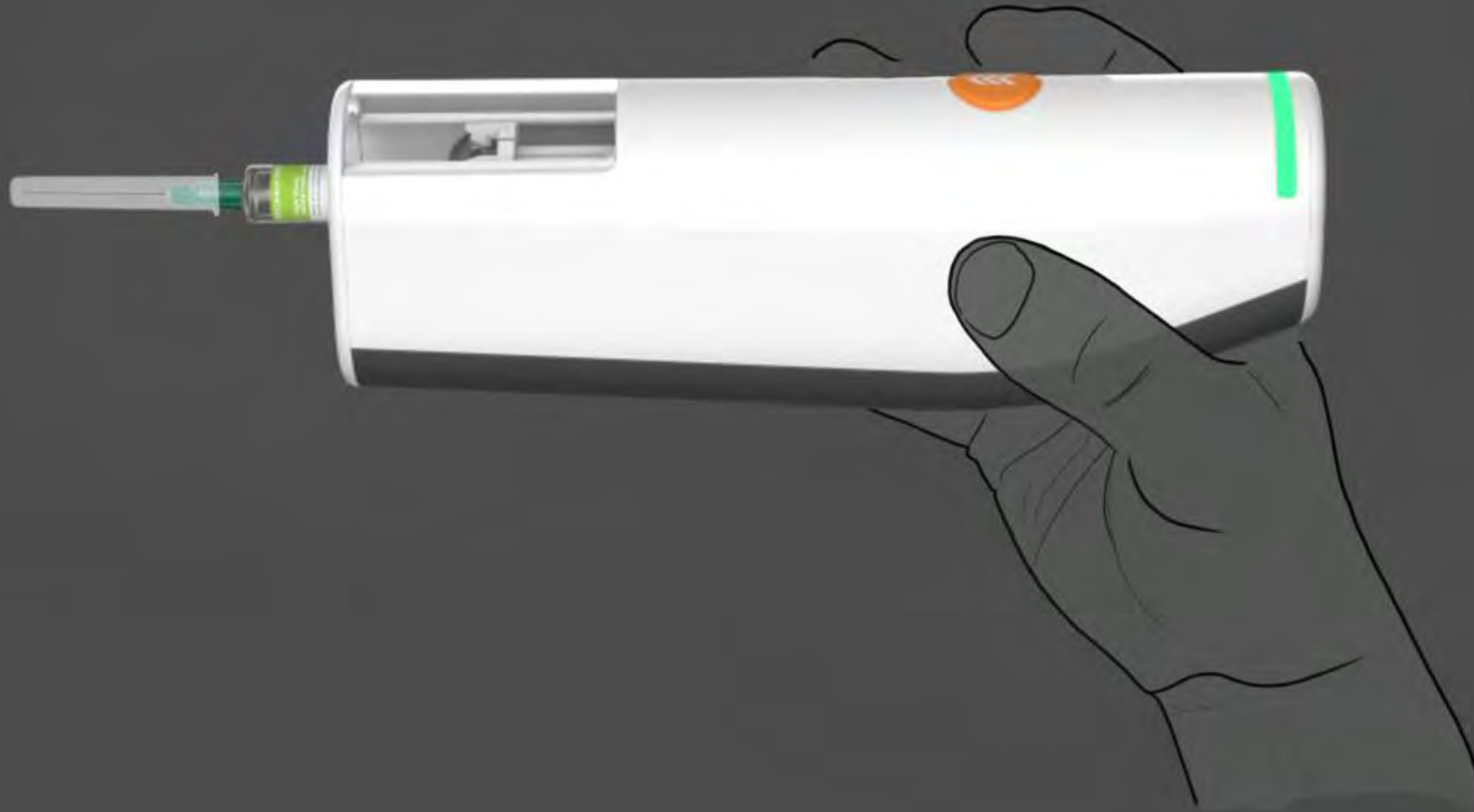
Load Syringe



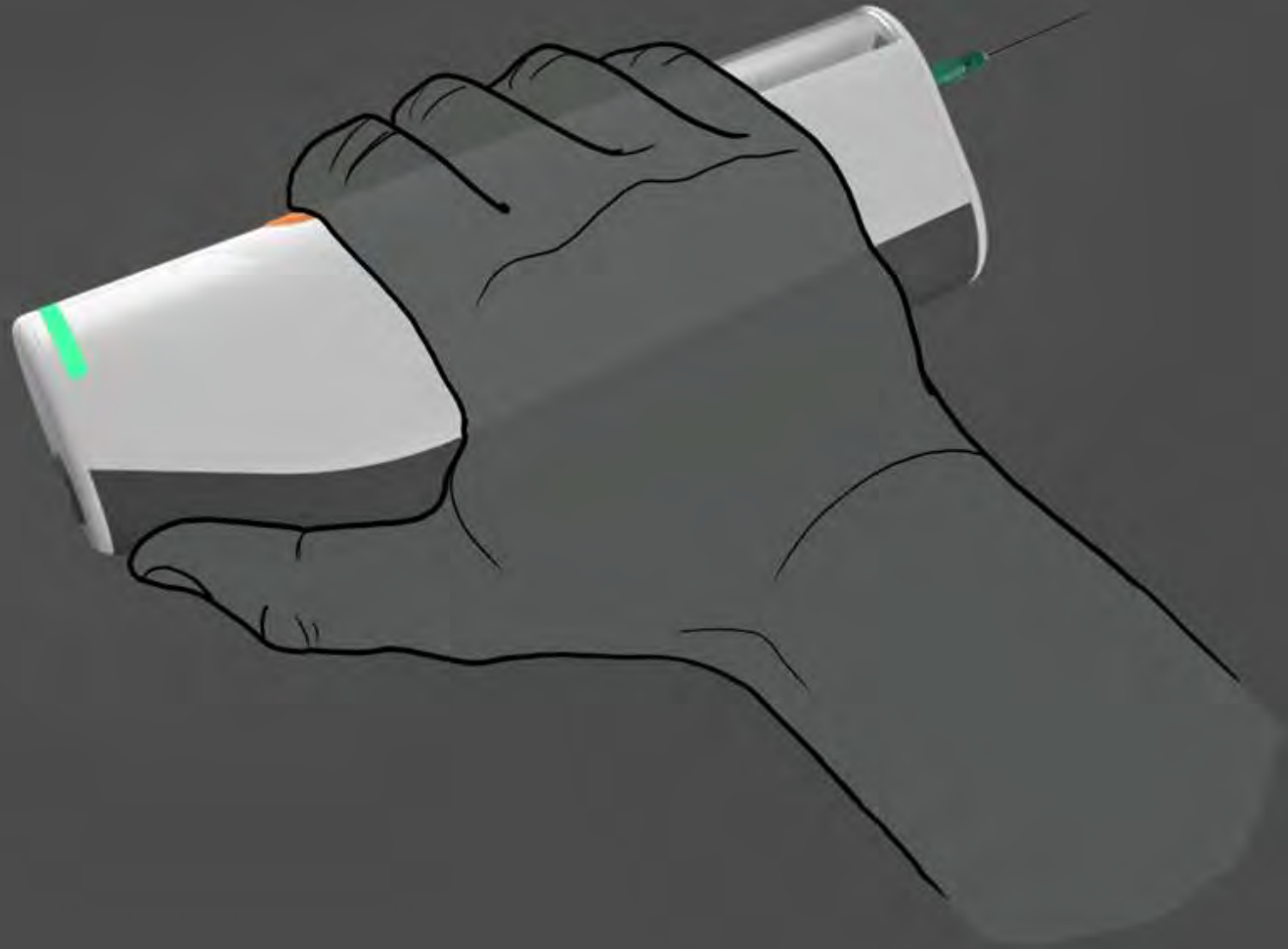
Present to Patient



Attach Needle



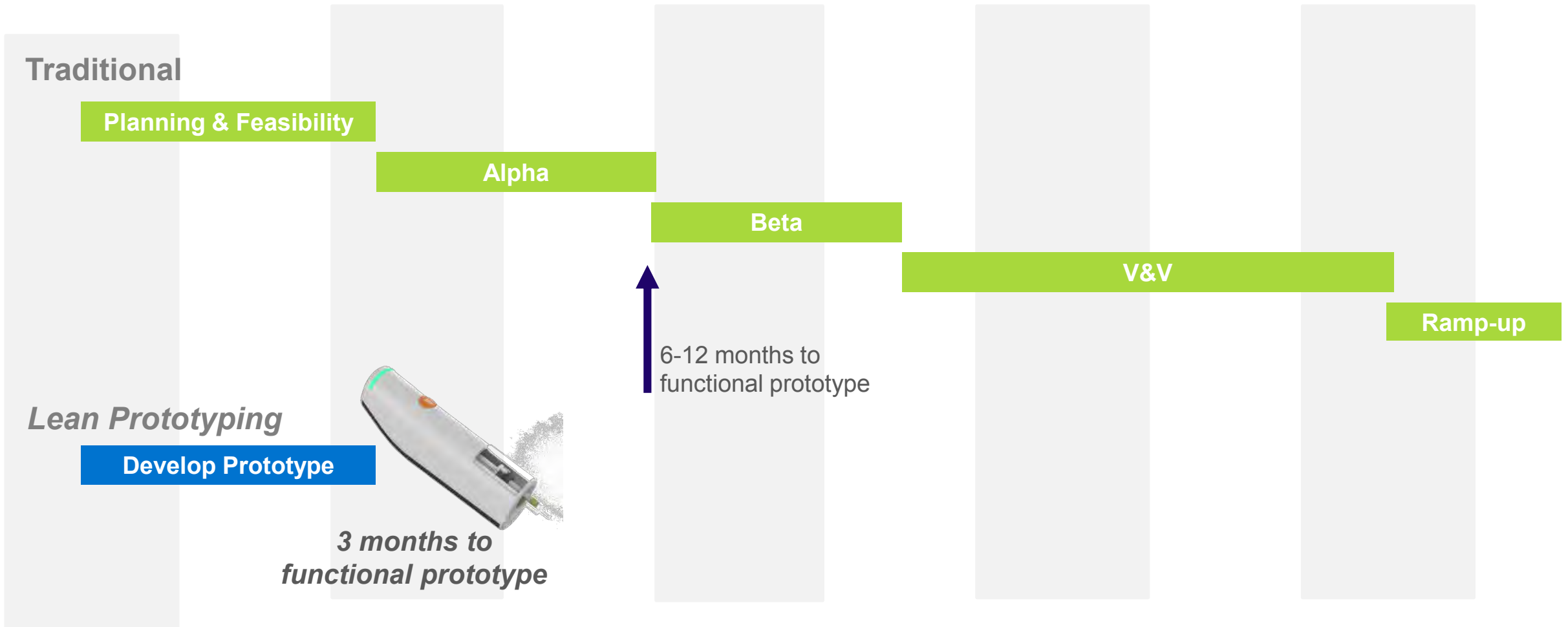
Administer



Eject Syringe



Traditional vs. Lean

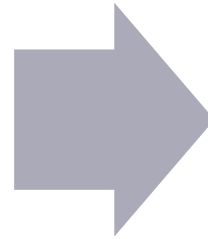


Final Thoughts . . .

Lean Principles: At Work in the Front-End and Back-End of Innovation

Key process inputs:

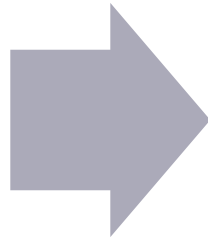
Broad and deep market sensing
Understand unmet needs across multiple
enterprise stakeholders



Critical to assess the potential for disruptive
healthcare delivery technology and/or
business models

Lean innovation principles:

Co-innovation
Early engagement with key
stakeholders and partners
Identify super-users (unicorns)
Develop the minimum viable prototype



Critical to accelerate innovation and
reduce risk