

World Vaccine Congress
Barcelona
10-12 October 2017



 **Enesi**
Pharma

Immunity for Life

Who we are



- Enesi Pharma is a clinical stage pharmaceutical company developing a range of injectable solid dose, drug-device combination products
- Enabled by our proprietary Implavax™ formulation and device technologies, data suggests that these products have the potential to transform the performance and delivery of vaccines and therapeutics, making a material impact on global healthcare
- Significant potential benefits for patients, care givers, health-care professionals and payers

ImplaVax™ vaccine platform

Combination of unique formulation and device technology



Actuator

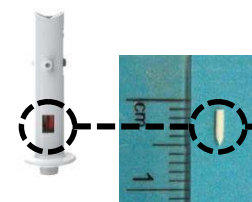
- spring loaded
- charged by pressure on patient's skin
- automatic trigger with audible click
- re-useable up to 1,000 times, if required

Cassette

- contains unit dose solid implant
- single use, disposable
- viewing window confirms delivery
- eliminates cross-contamination

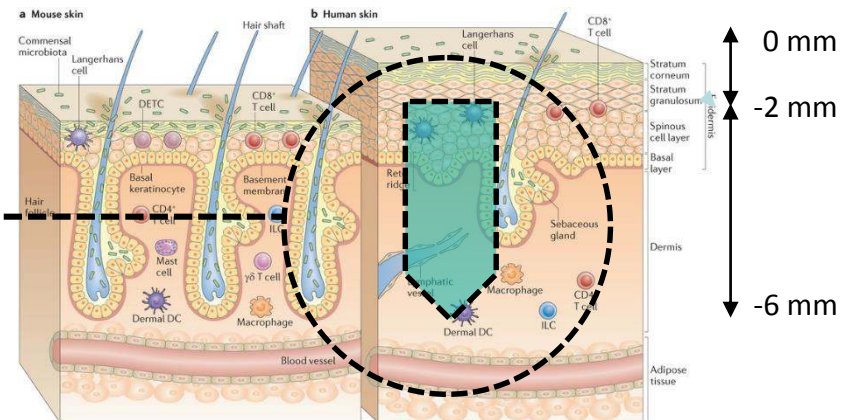
Optional Cassette Cap

- disposable
- stores cassette
- aids handling



Universal Vaccine Implant (UVI)

- unit solid dose
- needle free, syringe free
- stored safely inside cassette until delivery
- eliminates need for point-of care reconstitution with diluent
- eliminates needle-stick-injury and sharps disposal challenge
- unit dose delivery assured – each time every time
- enhanced stability
- reduces / eliminates cold chain



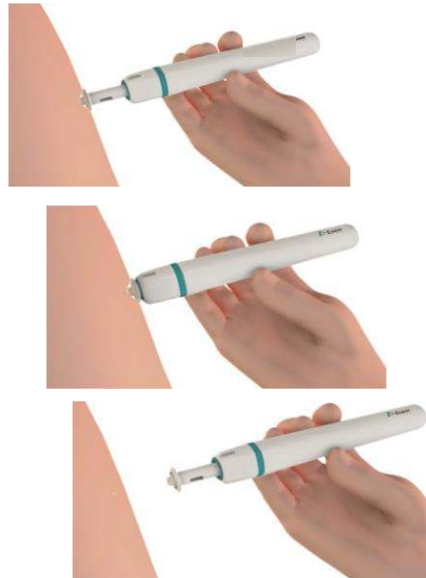
Nature Reviews | Immunology

Intuitive, easy, and quick to use

- Only 4 steps
- Administration achieved in approx 20 seconds per patient



1. Open pouch
2. Load cassette



3. Administer drug



4. Remove & dispose of cassette

ImplaVax™ achievements to date



- Unique Solid Dose Universal Vaccine Implants (UVI)
 - enhanced immunogenicity response demonstrated on multiple vaccines
 - more rapid onset of immune response
 - dose sparing demonstrated
 - potential to achieve threshold immunity from a single dose
 - excellent extended stability profiles shown
 - eliminate need for diluents and point of care reconstitution
- Proprietary Unit Dose Device
 - single or repeat use operation as required
 - utilised in multiple clinical trials¹ to date
- Strong patient preference for novel device
 - additional Human Factor study underway
- Robust IP position with protection through 2036

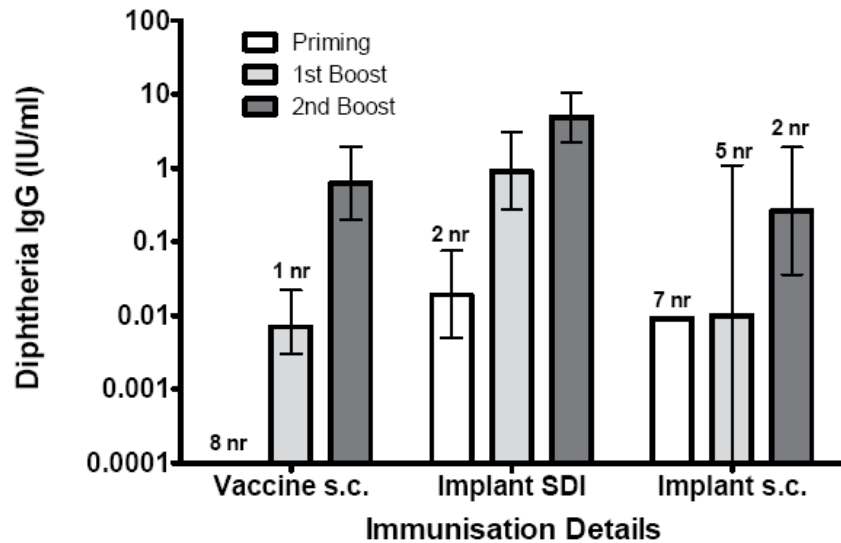
¹ Fentanyl, Octreotide x 2, Sumatriptan

Solid Implants improve immune response #1

Diphtheria - Guinea Pig Immunogenicity Study

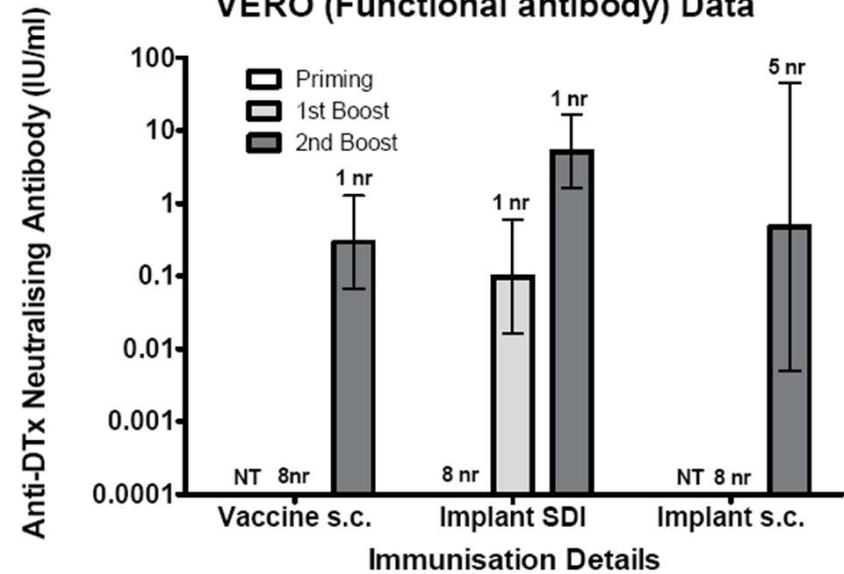


Diphtheria Vaccine 0.4 IU/dose
ELISA (Total antibody) Data



nr = non-responder (below LOD)

Diphtheria Vaccine 0.4 IU/dose
VERO (Functional antibody) Data



NT = not tested
nr = non-responder (below LOD)

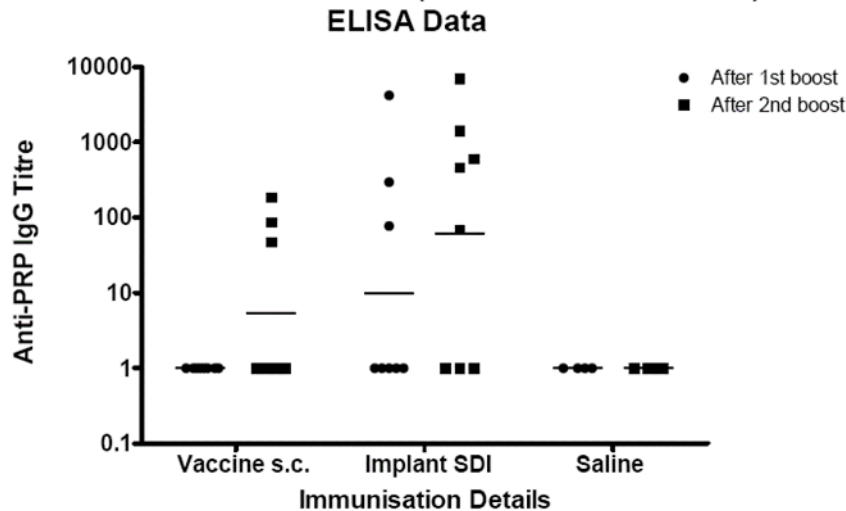
- Enesi implant better than standard vaccine delivered by needle and syringe
- Reconstituted solid dose formulation control is comparable to standard vaccine
- Suggests solid dose implant may have its own beneficial effect

Solid Implants improve immune response #2

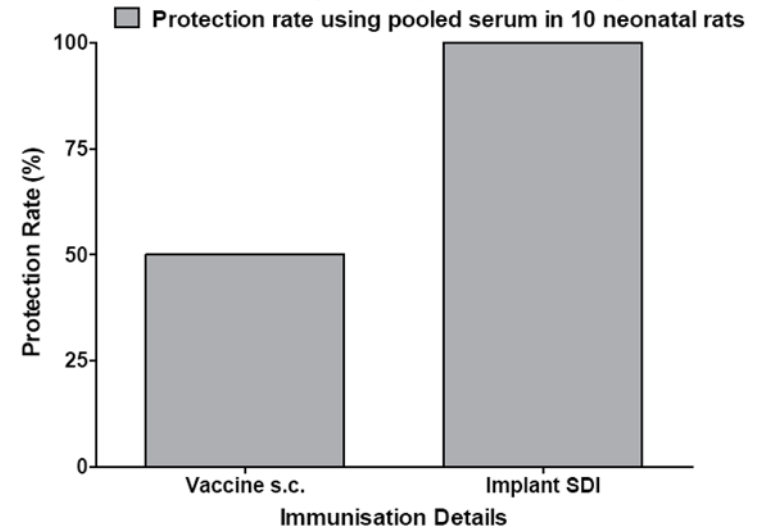
HIB - Guinea Pig Immunogenicity Studies; Rat Challenge



HIB VACCINE PRP Titres (after 1st and 2nd boost)



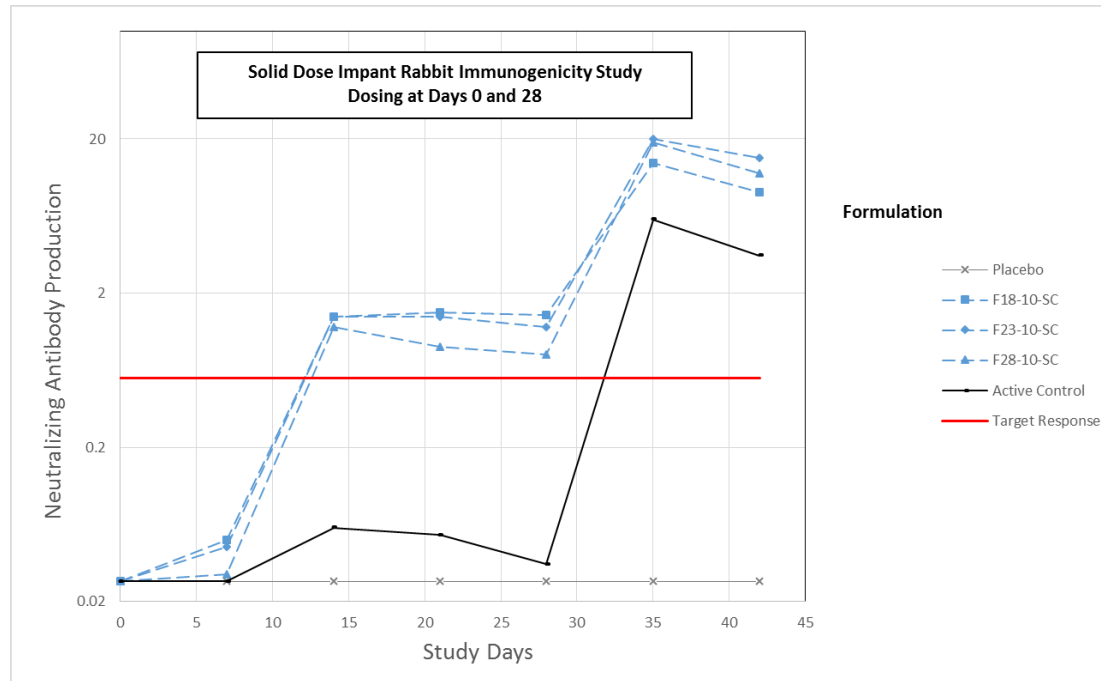
Hib Challenge Data (after 2nd boost)



- Enesi implant better than standard vaccine delivered by needle and syringe
- Immune response from 1st boost dose better than standard post 2nd boost
- 100% protection rate achieved

Solid Implants improve immune response #3

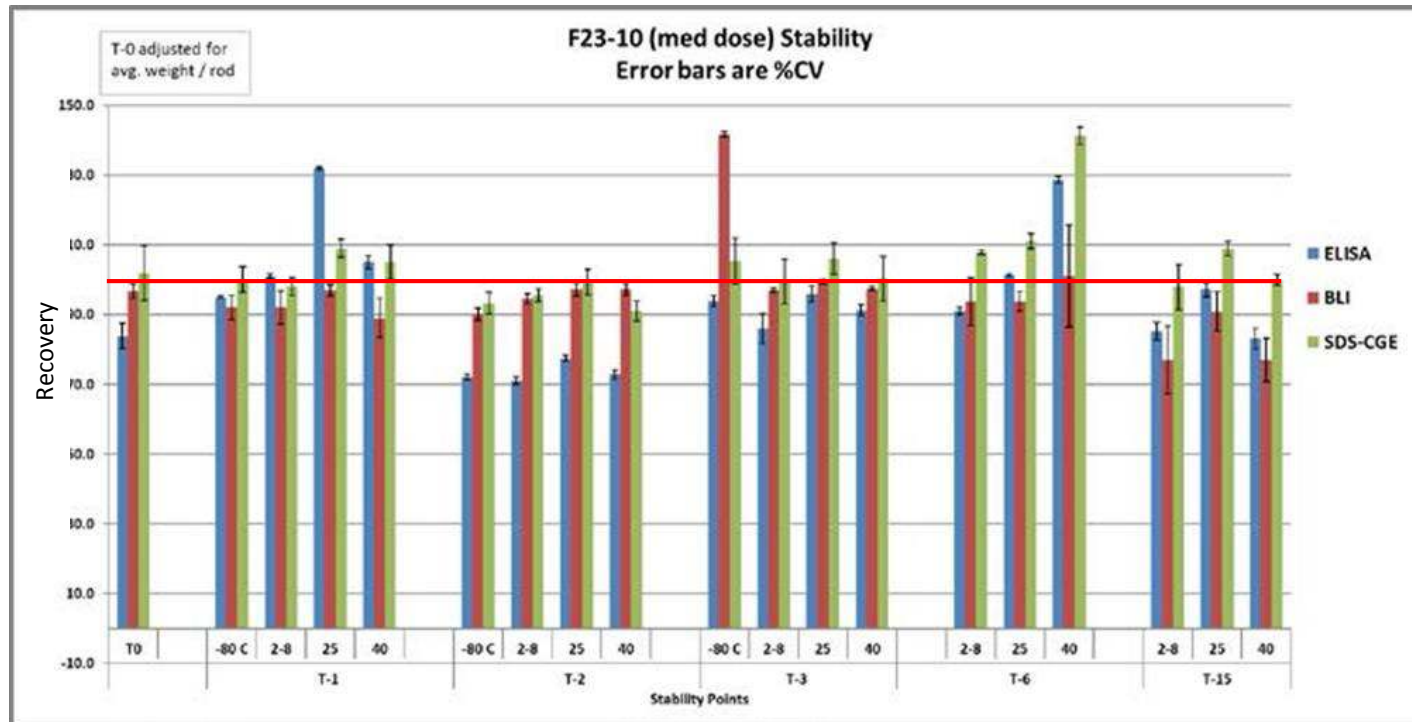
Rabbit Immunogenicity Studies



- Multiple Enesi formulations tested at various antigen loadings; SC delivery, no adjuvant
- Significantly higher antibody levels observed for Enesi formulations, compared to placebo and commercially available standard¹ used as active control
- Suggests antibody levels with a single dose of Enesi formulations are sufficient to achieve target response level, transforming dosing regimen

Solid implants enhance stability

Potency and mechanical performance maintained



- Antigen formulated into solid dose implant
- 3 different test methods confirm retained potency of antigen
- Exemplar stability with potency retained after 15 months storage at 40°C, 75% RH

Strong patient preference for Enesi device

As compared to needle and syringe¹



Which of the two injections did you prefer?



"As opposed to injection it was far better"

"The speed of it. It's delivered in an instant"

"It would be handy & no needles to dispose of"

"Faster & easier didn't bleed"

"Painless"

"No big sharp needle poking in me"

Is the Enesi system better than an injection with a needle and syringe?



¹ Octreotide Human factor study

ImplaVax™ vaccine platform

Transformational potential with universal application



- Enhanced immune response for solid dose vaccines demonstrated
- Dose sparing evidenced suggesting possibility of immunity from a single dose
- Guaranteed unit dose delivery
- Removes need for diluents and point-of-care reconstitution
- Eliminates needle-stick injury and cross contamination
- Removes disposal challenges of hazardous vials, syringes or needles
- Eliminates cold chain challenge via improved thermal stability
- Fast and simple to use in both one-off and repeat use regimens
- Clear patient preference

Enesi is now applying ImplaVax™ to high value vaccine and vector targets as part of its integrated product development strategy

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