



The global offer for RVF Vaccines

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Existing RVF vaccines

Live attenuated

Smithburn

Clone-13

Inactivated

Smithburn

based on virulent strains

Human inactivated vaccine TSI-GSD 200

Drawbacks of current available vaccines

Inactivated vaccines:

Multiple doses needed, expensive to produce, lower efficacy, shorter onset of immunity, shorter duration of immunity

Live vaccines:

Smithburn; not safe for pregnant animals, teratogenic, reversion to virulence possible, viraemia, not environmentally safe

Clone 13: potential risk of reassortment, other?

If it is not the lack of vaccine candidates or research that lacks, what is then?

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Translation and follow through of vaccine candidates into development and implementation of efficient production systems is essential.

However with limited R&D budgets under pressure;

How to obtain sufficient return on investment?:

- Limited market size and purchase power in smaller markets affected by the disease.
- Enzootic and irregular outbreaks of the disease do provide often limited incentive for continuous vaccination

Ways in the decision process of vaccine projects: NPV calculation

NPV (Net present value) is an indicator of how much value adds a certain project to the firm.

NPV of a time series of cash flows, both incoming and outgoing, is defined as the sum of the present values of the individual cash flows of the same entity.

If	It means....	Then...
$NPV > 0$	The project would add value to the company	The project might be accepted
$NPV < 0$	The project would subtract value from the company	The project should be rejected
$NPV = 0$	The project would neither gain nor lose value for the company	We should be indifferent whether to approve or reject the project. Decision might be based on other criteria

Factors influencing NPV and project value

Technical risk of success

(e.g. inac versus vector based)

Regulatory aspects

(e.g. gmo versus natural strain)

Production aspects

(e.g. subunit versus replicon)

Cost of goods

(e.g. live versus inactivated)

Market attractiveness

(e.g. live versus inactivated)

Factors influencing NPV and project value

Parameter	Live attenuated	vector	Subunit or inactivated
safety	+	++	+++
Efficacy	+++	++	+
Production aspects	+++	++	+
COG	+++	++	+
Market attractiveness	+++	+++	+
Regulatory	+	++	+++
Environmental safety	+	++	+++

Which vaccine candidate to develop?

Needed in endemic situation:

- One shot vaccine
- Long duration of immunity (preferably live long)
- Short onset of immunity
- Safe also for pregnant animals
- Environmentally safe (no spread, no reversion, reassortment)
- Potential use in a range of species
- Cheap and easy to produce

Which vaccine candidate to develop?

Needed in disease free situation:

- Safe in all ages of animals
- Environmentally safe (no spread, no reversion, reassortment)
- Quick onset of immunity
- Efficacious
- DIVA

Which vaccine candidate to develop?

Needed in disease free situation:

- Safe in all ages of animals
 - Environmentally safe (no spread, no reversion, reassortment)
 - Potential use in a range of species
 - DIVA
 - Efficacious
-
- Can we afford to develop different vaccine candidates?

Incentives for commercial companies to invest in RVF vaccine development

- Create an equal level playing field
- Define specific requirements new vaccines should meet for safety, efficacy, quality criteria (OIE requirements?)
- Keep it simple;
- strictly limit the claims to defined needs
- Regulatory process
- Harmonization and necessary requirements
- External funding and support in research and development
- Governmental, Galvmed, BMGF, EU funding
- Create dependable markets
- Vaccine or antigen banks, funded control programs
- Public private partnerships in vaccine development
- The potential risk of RVF spread into EU and US
- Corporates social responsibility programs or corporate strategy

Conclusion

- RVF is a viral zoonosis and public health concern that can be controlled, best by controlling the disease in animals and preventing it from infecting humans
- It is technically feasible to produce good vaccines, candidate vaccines are available
- Challenge; limited incentive for the industrial entities with the technical know how to produce the vaccines
- Potential ways forward:
 - Agree on standards that need to be met by new vaccines
 - Provide incentives (research funding, market creation)

A close-up photograph of several brown cows, likely in a field. The cows are the central focus, with their heads and shoulders visible. The lighting is warm, suggesting a sunset or sunrise. The text '» THANK YOU' is overlaid in white, bold, sans-serif font across the middle of the image.

» THANK YOU