



CLASSICAL SWINE FEVER

LESSONS FROM A SUCCESSFUL COLLABORATION

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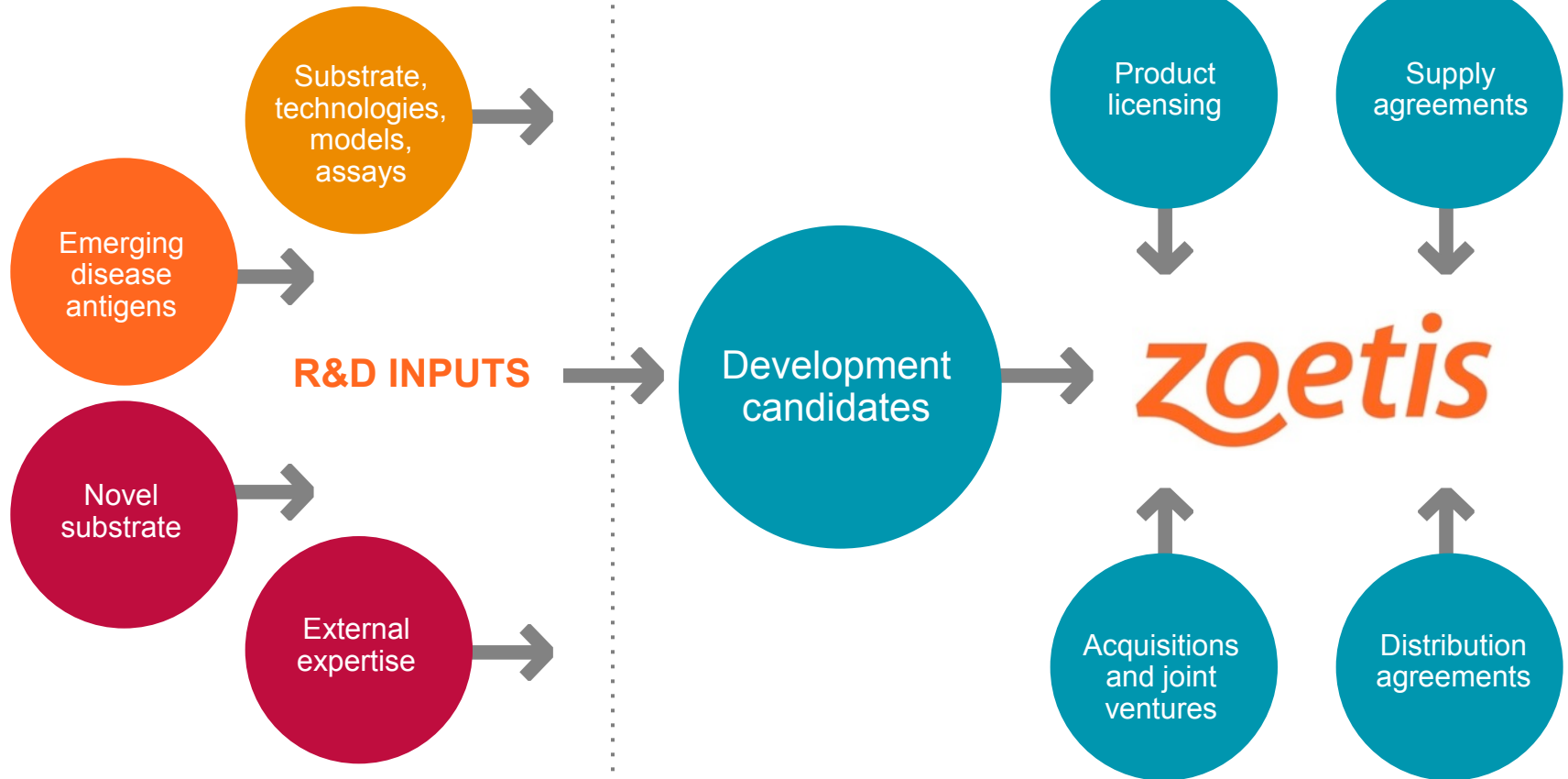
zoetis

Suvaxyn[®] CSF Marker

LEADERSHIP IN PRODUCT DEVELOPMENT OPEN INNOVATION PIPELINE

RESEARCH

DEVELOPMENT



- Research partnerships
- Emerging Infectious Disease Networks
- Co-funded consortia
- Business Development

LEADERSHIP IN PRODUCT DEVELOPMENT STRATEGIC PARTNERSHIPS

Our team is comprised of animal health, scientific and business experts who collaborate with external R&D partners and institutions. Together, we explore new market opportunities, technology and product acquisitions.

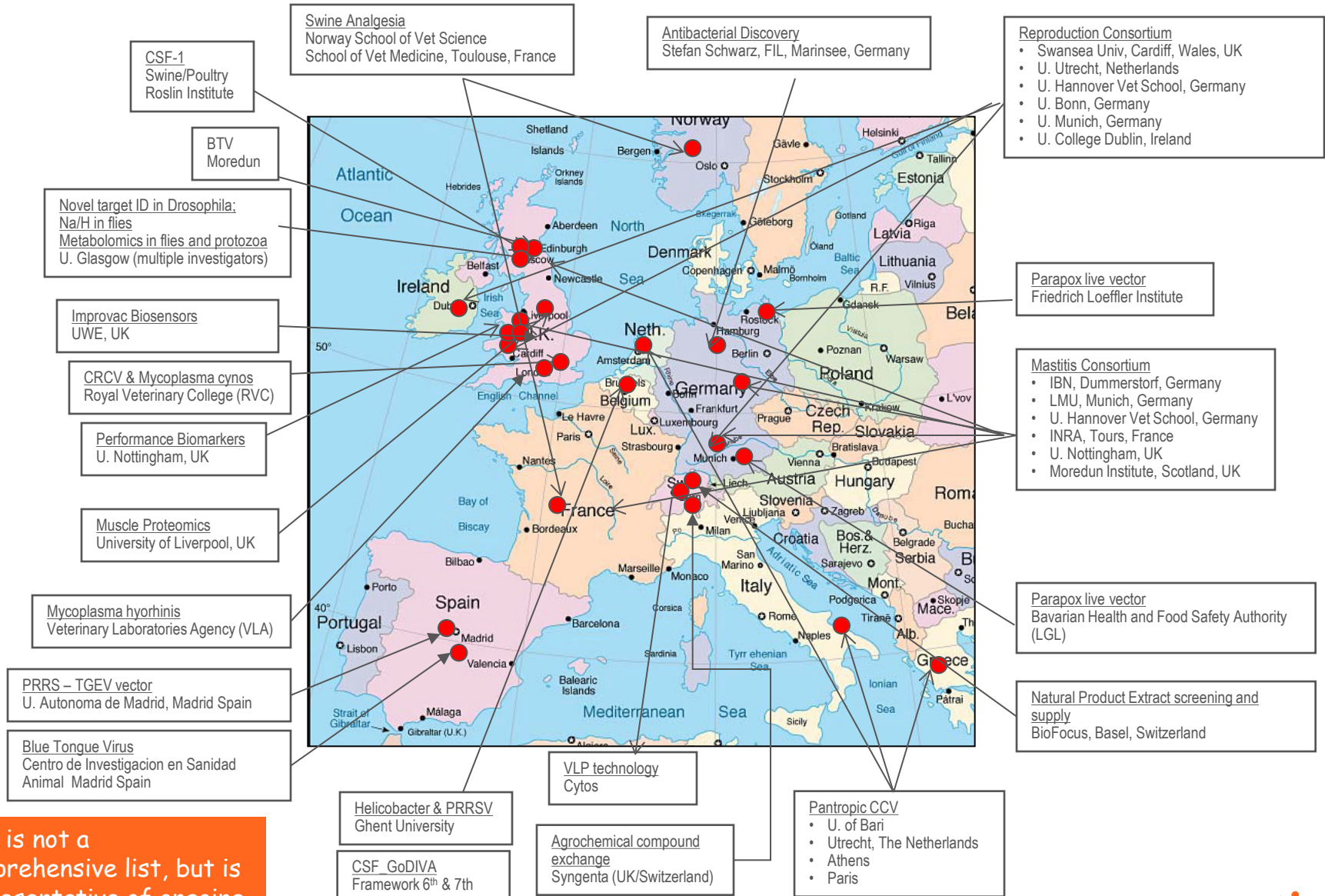
THREE KEY AREAS OF FOCUS

- Developing research collaborations and networks around the world
- New research models through participation in consortia with experts
- Identification and rapid response to emerging infectious diseases and collaborative food safety initiatives

GLOBAL ALLIANCE INITIATIVES



EU GLOBAL ALLIANCES COLLABORATORS



This is not a comprehensive list, but is representative of ongoing collaborations

AN EXAMPLE OF A STRATEGIC & SUCCESSFUL PARTNERSHIP

Classical Swine Fever



- **Classical swine fever (CSF)** is a highly contagious viral disease affecting pigs, which can lead to a tremendous socioeconomic impact.
- **Within the European Union (EU) and in other areas with significant pig production, the disease is controlled by strict, mandatory control measures without prophylactic vaccination.**
- However, emergency vaccination is usually foreseen and can be implemented in the case of a contingency. From a trade point of view, only marker vaccines are feasible (allow differentiation of infected from vaccinated animals).

Define and Align

Define the Problem to Solve

- Clearly define the objective as it relates to your participation
 - Especially true for large consortia
- Align with partners to avoid duplication and progress to the program goals
- Prevent dilution of resources to other areas of interest

“CSF_goDIVA” COLLABORATION



Partner 1	CODA-CERVA	Veterinary and Agrochemical Research Centre, Belgium
Partner 2	DTU-Vet	National Veterinary Institute, Denmark
Partner 3	ANSES	France
Partner 4	CAO-DVMP	Central Agricultural Office, Directorate of Veterinary Medicinal Products, Hungary
Partner 5	CVI	Stichting Dienst Landbouwkundig Onderzoek, The Netherlands
Partner 6	ZOETIS	Zoetis Manufacturing & Research Spain, S.L., Spain
Partner 7	FLI	Friedrich-Loeffler-Institut, Federal Research Institute for Animal Health, Germany
Partner 8	IZS-UM	Istituto Zooprofilattico Sperimentale Umbria e Marche, Italy
Partner 9	IVI	Eidgenössisches Volkswirtschaftsdepartement, Switzerland
Partner 10	ONCFS	Office National de la Chasse et de la Faune Sauvage, France
Partner 11	SCU	Bioengineering Research Center for Animal Disease Prevention and Control, China
Partner 12	SVA	Statens Veterinärmedicinska Anstalt, Sweden
Partner 13	TiHO	European Reference Laboratory for CSF, University of Veterinary Medicine Hannover, Germany
Partner 14	UCM	Universidad Complutense de Madrid, Spain
Partner 15	UFZ	Helmholtz Centre for Environmental Research, Germany
Partner 16	Spectos	Spectos GmbH, Germany
Partner 17	IZSA_M	Istituto Zooprofilattico Sperimentale dell’Abruzzo e del Molise “G Caporale”, Italy

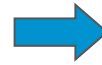
“CSF_goDIVA” COLLABORATION: THE GOAL OF THE PROJECT



**Wild Boar
(Reservoir for the virus)**



Infection



**Avoid images
similar to this one**



- Vaccination route:
Oral
- Presentation of the
vaccine: Baits



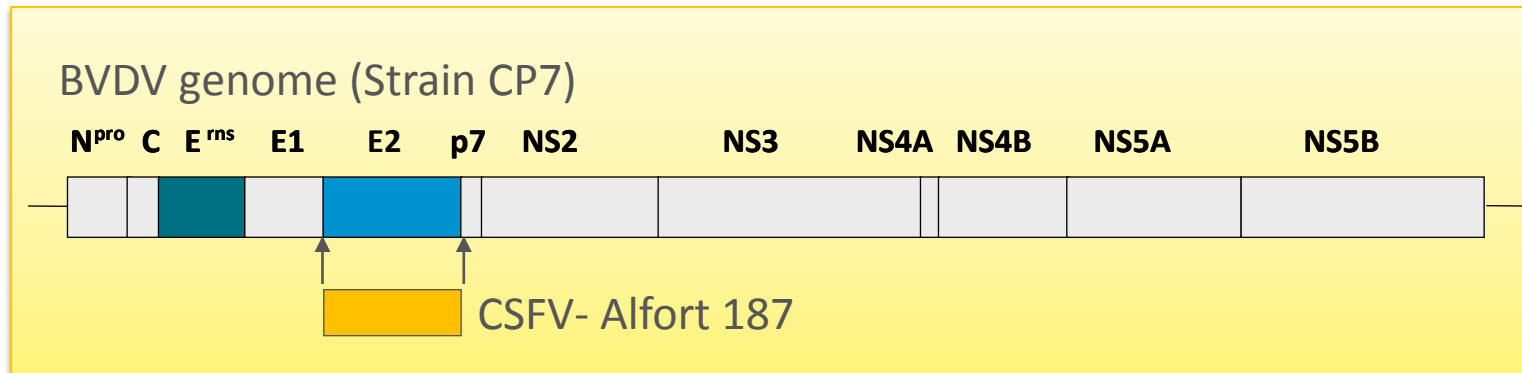
- Vaccination route:
Intramuscular
- Suvaxyn® CSF
Marker

“CSF_goDIVA” COLLABORATION

The DIVA Vaccine Candidate



- **Suvaxyn[®] CSF marker** is a recombinant vaccine that contains the CP7_E2alf virus which is a Bovine viral diarrhoea virus “CP7” backbone and carries the glycoprotein E2 of CSF virus (CSFV) strain “Alfort/187 (M. Beer et al., FLI)



- The marker concept is based on the differentiating antibodies directed against CSFV Erns

Status	Erns CSFV Ab	E2 CSFV Ab
Naive	Negative	Negative
Vaccinated	Negative	Positive
Infected	Positive	Positive

PROJECT MANAGEMENT

Effective Project Management

- Communication, communication, communication
- Identify inter-dependencies and critical path and facilitate when necessary to ensure timelines are met
- Priorities vary with partners - ensuring commitment and alignment is important for success

“CSF_goDIVA” COLLABORATION



- Within two collaborative research projects funded by the **6th and 7th EU Framework Programs**, a potent new live marker vaccine was developed, validated and finally licensed as **Suvaxyn[®] CSF Marker** through the European Medicines Agency in February 2015.
- **From the identification of a vaccine candidate to a product licensed and available in EU.**

RESULTS OF THE STRATEGIC PARTNERSHIP



- Suvaxyn® CSF Marker (Zoetis) is the first live CSF marker vaccine that received EU product license in Europe by the centralized authorization procedure.
- For the first time, an emergency vaccination scenario is feasible that would allow deviations from the trade restrictions for vaccinated animals.
- A vaccine that combines advantages of current live C-strain vaccines (fast protection) and DIVA technology.
- The vaccine strain was also tested as oral marker showing that a bait marker vaccine for wild boar is feasible.



HIGHLIGHTS OF A STRATEGIC & SUCCESSFUL PARTNERSHIP: A WIN - WIN SCENARIO

✓ What are the benefits for the pharmaceutical industry ?

- Opportunity to advance veterinary research through new technologies and innovation provided by the academic partners
- Access to Know-how, facilities, equipment access , etc.
- Minimize risks
- “Outsourcing”
- Sample access

✓ What are the benefits for the academic partners ?

- Future applicability of the projects
- Innovation + profitability
- Keep focus not only in research but also in development, diagnostics, animal welfare, etc.
- The industrial partner provides vaccine development expertise
- The industrial partner provides regulatory expertise

HIGHLIGHTS OF A STRATEGIC & SUCCESSFUL PARTNERSHIP: A WIN - WIN SCENARIO

Lessons learned on how to optimize collaboration between the industry and academic/research partners

- ✓ Work together with a common goal: e.g. focus the consortium into the development and registration of a new CSF marker vaccine in the market.
- ✓ Provide support to Academia with Industry expertise: e.g. regulatory support from the beginning with input in the study design ; Studies in compliance with the GLP's & GCP's; Concepts like equipment calibration; validation of analytical techniques, etc.
- ✓ Provide market analysis and market needs: e.g. develop a CSF vaccine not only for wild boar (oral route) also for domestic pigs (IM route) that is marker and avoid the stamping put in case of an outbreak.
- ✓ Regular meetings to define how to move forward the project together. Constant interaction between the industrial and academic partners to keep the focus, the needs of the market, the feasibility, etc. Having an experienced and effective Project Manager/Coordinator is key
- ✓ Mutual trust to share know-how, results and needs – e.g. Helps when only ONE industrial partner is in the consortium

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