Experience of EMA innovation support from a university perspective

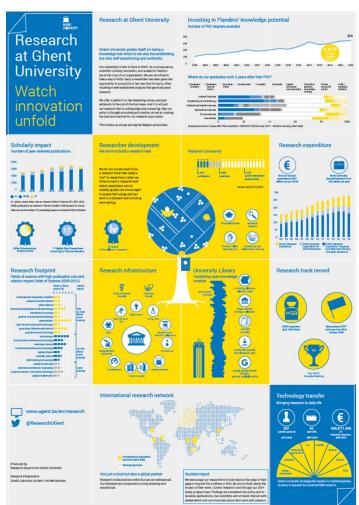
Sven Arnouts, PhD, RTTP Business Development Manager PROVAXS – Ghent University



ITF and EU Innovation Network for academics?

- early and informal dialogue
- to proactively identify scientific, legal and regulatory issues of emerging therapies, technologies and borderline products
- to be much earlier than when one would normally seek scientific advice
- provide guidance in the development process and road to market
- ensure EMA and NCA awareness and preparedness for assessment of the most recent developments in innovative medicine







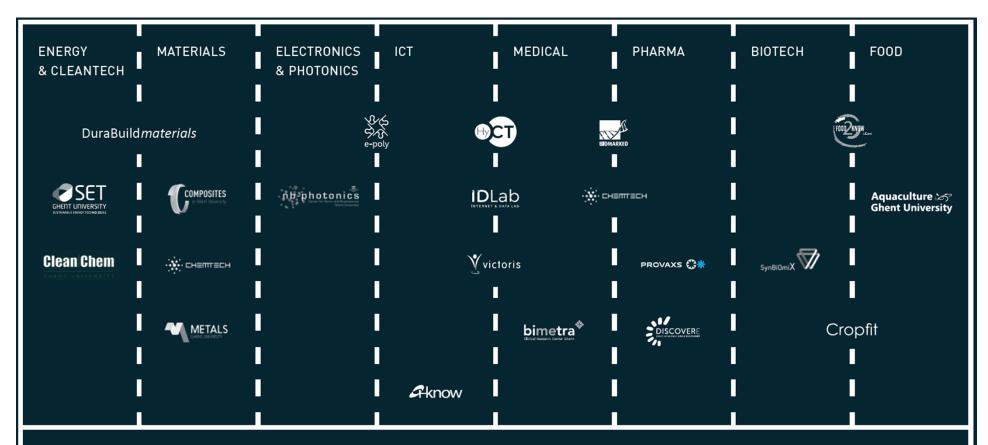




An entrepreneurial university

- stimulate transfer of technologies to industry and society
- deliver proof of concept
- be pro-active and build networks
- create partnerships to boost innovation





CENTRAL TECHNOLOGY TRANSFER OFFICE





Scope: immunity and infectious diseases in food producing animals

Facilitate collaboration and tech transfer to industry/society

Veterinary vaccines and other biologicals

Veterinary diagnostics

Feed additives (impact on immunity and health)





The INDUSTRIAL RESEARCH FUND provides PROOF OF CONCEPT funding to all AUGent researchers with **INNOVATIVE** projects

YOUR RESEARCH



CONCEPT

TECHNICAL PROOF OF CONCEPT

INDUSTRIAL PROOF OF CONCEPT



VALORISATION











CONCEPTT

STARTT









50.000 -100.000

















www.ugent.be/iof

iof@ugent.be









VALORISATION

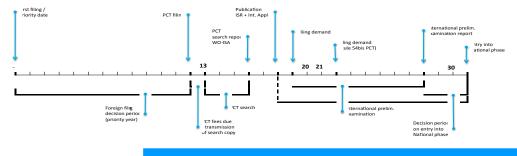








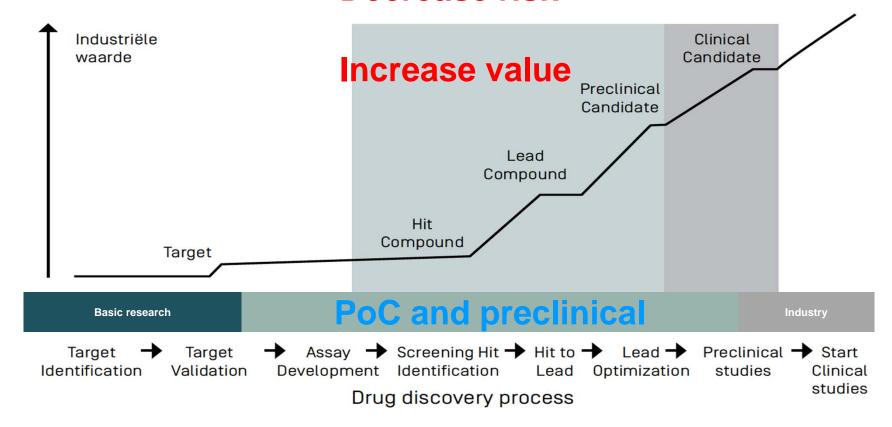
STARTT ADVANCED STEPSTONE



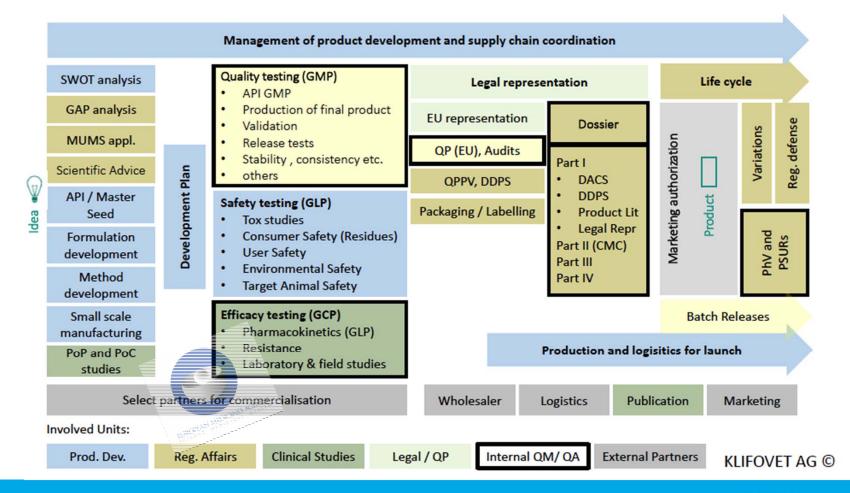
PARTNERING



Decrease risk











ITF meeting request

Product/technology	A novel vector for the development of oral vaccines for pigs. The novel vector shows good efficacy (protection) and safety (no adverse effects).
Topics to be discussed	
Scientific:	
Regulatory:	What are the legal and regulatory issues on the use of the vector for oral vaccination and which Agency procedures relate to this development? Do we need to consider specific guidelines in the design of experiments to deliver further proof of concept on efficacy and safety?
General:	We intend to perform additional experiments to deliver further proof of concept on efficacy (protection) and safety (adverse effects) of the vaccine vector at larger number of animals. Do we need to address other aspects of safety and efficacy that are critical for the use of the vector in commercial vaccines?





Topics discussed

- support from ITF and EMA to academia
 - the UGent model (first meeting)
 - from ITF to scientific advice
- regulatory issues on the use of the vector vaccine
 - presentation of the technology and proof of concept
 - guidelines and directives on use and registration of the vector



Good initiative!!





Evaluation

- ✓ early and informal dialogue (formal process)
- ✓ to proactively identify legal and regulatory issues: efficacy, persistence, maternal Abs, GMO, GMP to be much earlier than when one would normally seek scientific advice: universities are not eligible for reduced fee for scientific advice
- ✓ provide guidance in the development process and road to market: what can be done by the university and what by a start up/partner ensure EMA and NCA awareness: interaction between ITF and national innovation offices?
 - continuity in follow up meetings or meetings on other technologies?



ITF advice taken into consideration in application for follow up project

Titel Safe universal vector vaccine for oral vaccination in swine

Promotor Prof. dr. Hans Nauwynck

Financiering €90.000

Looptijd 18 maanden

Start- en einddatum 15/01/2018 – 15/07/2019 WBS-element IOFPRO2018000301

- safety & efficacy on a larger number of animals
- other applications: other antigens/diseases, sows









FLANDERS INNOVATION & ENTREPRENEURSHIP





