



Collaboration in regulatory science: the industry perspective

Paul Korte

Director Governmental and External Relations
Janssen Campus Netherlands
RSNN-EMA Workshop November 17, 2020

Leveraging the vibrant life sciences ecosystem

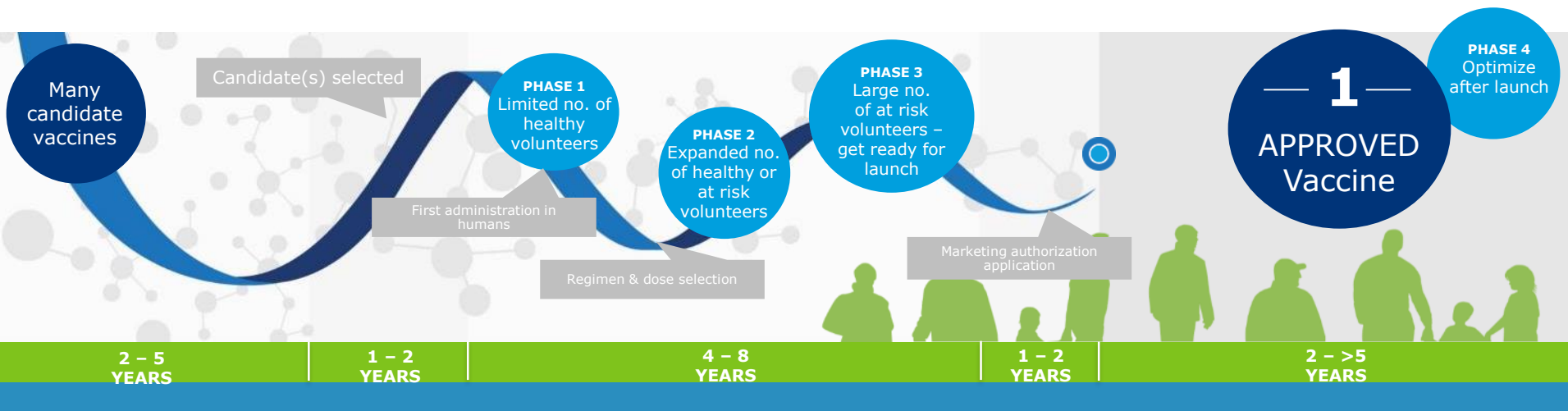
- Universities
- Pharmaceutical companies
- Academic Hospitals
- Research Centers
- Biotech Companies
- Bio incubators
- Science Parks

**In the
heart of
Europe**



Average Vaccine R&D Cycle

The timeframe of COVID-19 vaccine candidates is substantially accelerated in comparison to the typical vaccine development process.



PHARMACEUTICAL STRATEGY FOR EUROPE



Learning from
COVID-19,
towards a crisis-
resistant system



Ensuring
accessibility and
affordability of
medicines



Supporting
sustainable
innovation,
emerging science
and digitalisation



Reducing medicines
shortages and
securing strategic
autonomy

#EUPharmaStrategy



Regulatory Science: Collaboration

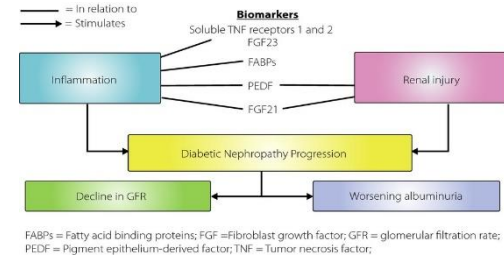


RSNN: Breeding ground

‘Label modification based on evidence deriving from investigator initiated trials.’



‘Precision Medicine for Chronic Diseases Using Biomarkers: Diabetic Nephropathy as a Case Study’



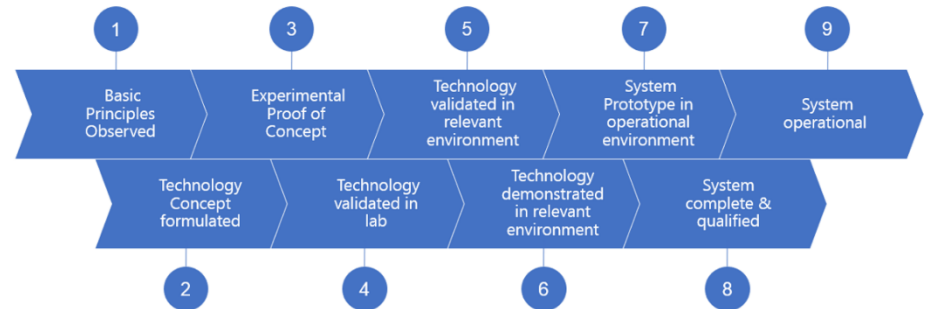
‘What’s in, What’s out, What’s relevant? – Towards a sensible label’



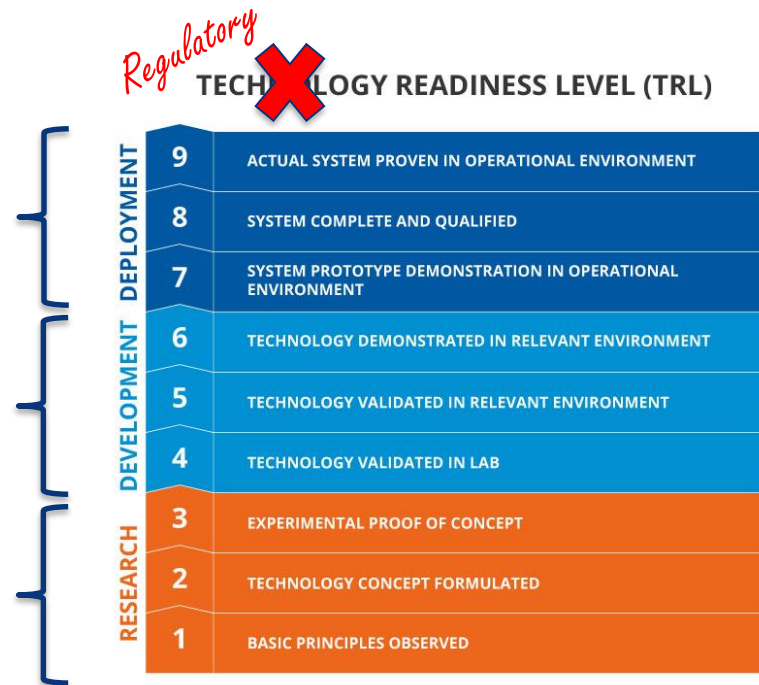
How to valorize regulatory science?

Innovation Chain – EU H2020 Technology Readiness Level

- Mission driven innovation
- Define end goals and work back
- Define “*Regulatory* Readiness Levels”



From collaboration to innovation to implementation

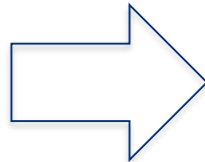


Regulatory Science Valorization at the core?



EMA Regulatory Science to 2025

Strategic reflection



THANK YOU



www.facebook.com/janssennederland



www.twitter.com/Janssen_Ned



www.linkedin.com/showcase/janssen-nederland/