



INNOGENETICS
BIOTECHNOLOGY FOR HEALTHCARE

Therapeutic vaccines: introduction

Guy Buyens, MD, Chief Therapeutics Officer



Therapeutic vaccines

Introduction

Guy Buyens, Chief Therapeutics Officer

The science behind therapeutic vaccination

Lydie Meheus, Director of Therapeutic R&D

Therapeutic vaccine programs

- ◆ Hepatitis C and Hepatitis B

Geert Maertens, Program Manager

- ◆ HPV and cervix carcinoma

Hilde De Winter, Medical Director

- ◆ Tolerance and auto-immune diseases

Ann Union, Project Leader



Therapeutics vision

- › **Become a major player in the therapeutic vaccines industry**
- › **With a focus on infectious diseases**
- › **And in the short term a significant opportunity in HCV**



**What did we already accomplish to become
a player in therapeutic vaccines?**



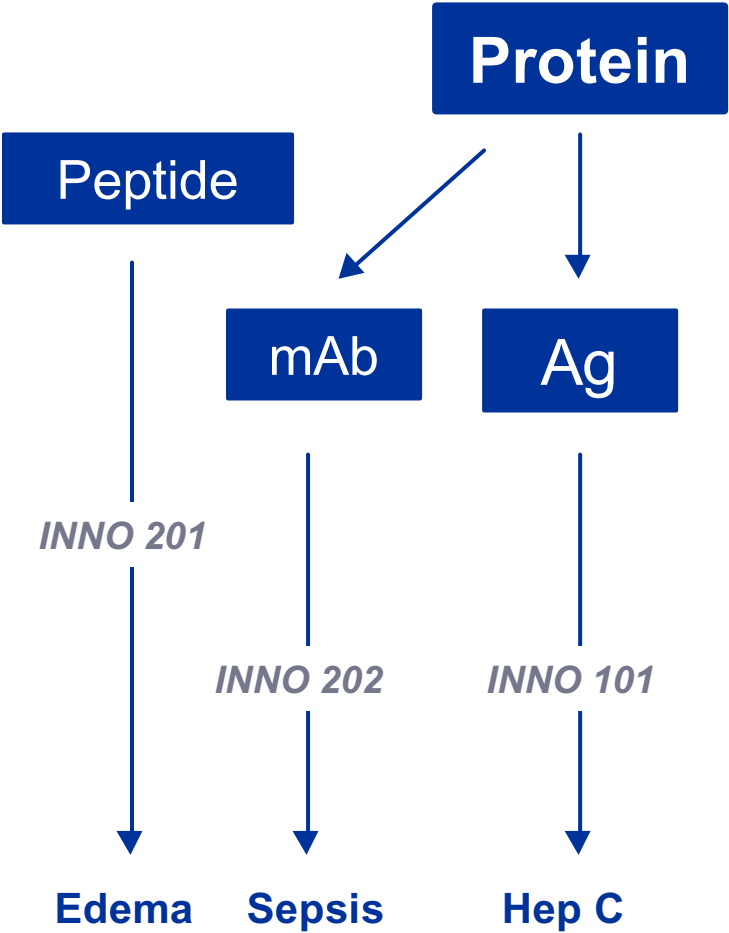
Therapeutic vaccines

Focus



Therapeutic vaccines

Focus



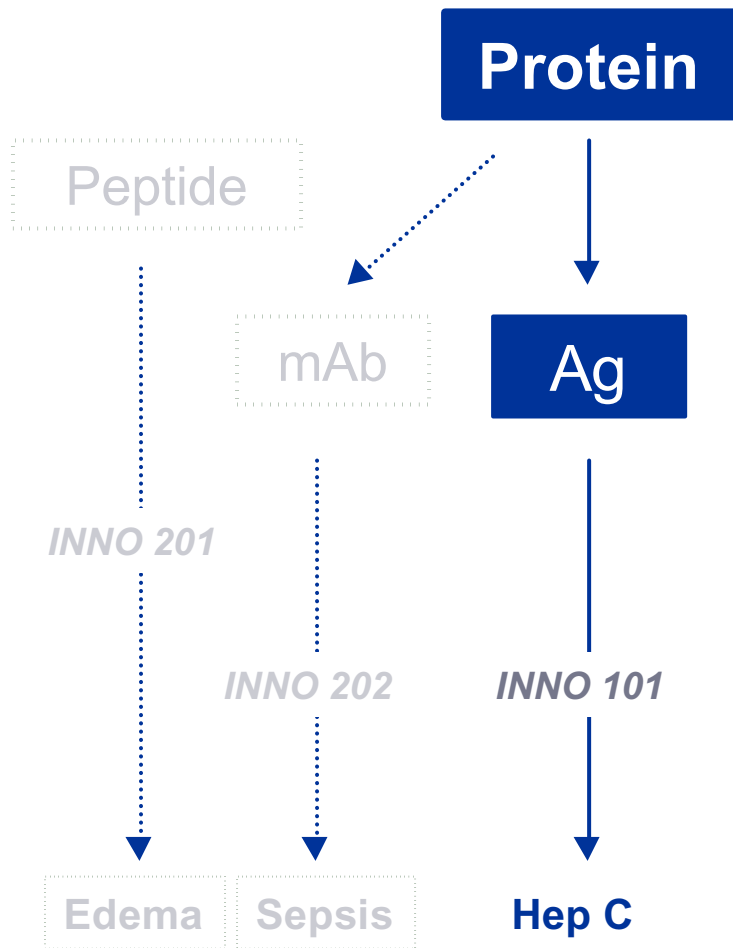
2003

Therapeutic programs in diverse fields



Therapeutic vaccines

Focus



2003

Therapeutic programs in diverse fields

Need to bring non-therapeutic vaccine programs to the stage that we can partner

And

Focus on HCV therapeutic vaccine



Therapeutic vaccines

Prepare the organisation

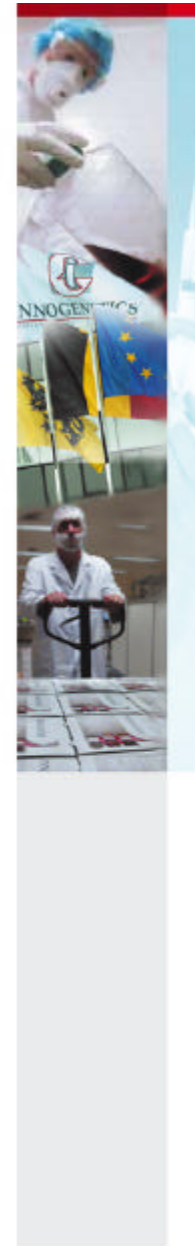


Therapeutic vaccines

Prepare the organisation

In 2003: already a lot of strengths

- ◆ Immunology, Virology, Molecular Biology
- ◆ Protein technology
- ◆ Disease expertise also through Diagnostic activities
- ◆ Hepatitis network and HepC Clinical phase II program
- ◆ Bio-manufacturing



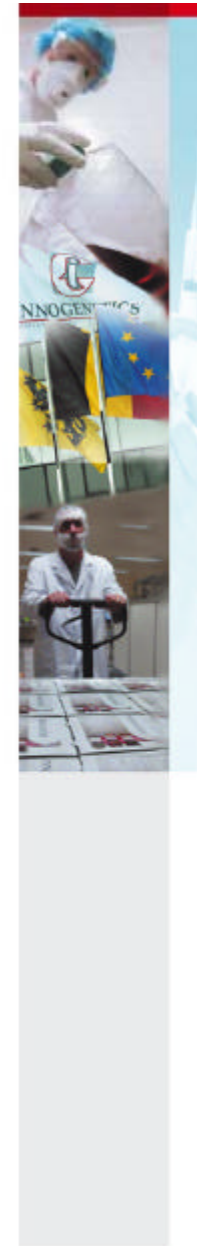
Therapeutic vaccines

Prepare the organisation

In 2003: already a lot of strengths

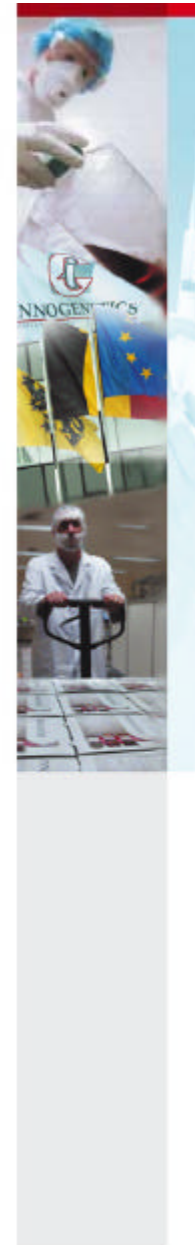
- ◆ Immunology, Virology, Molecular Biology
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Building on these strengths we enhanced our organisation and made a solid Research & Development assembly line



Therapeutic vaccines

Build an R&D assembly line



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Therapeutic vaccines

Build an R&D assembly line

Vaccine
Design



Classical design and lead optimization (e.g. protein engineering)

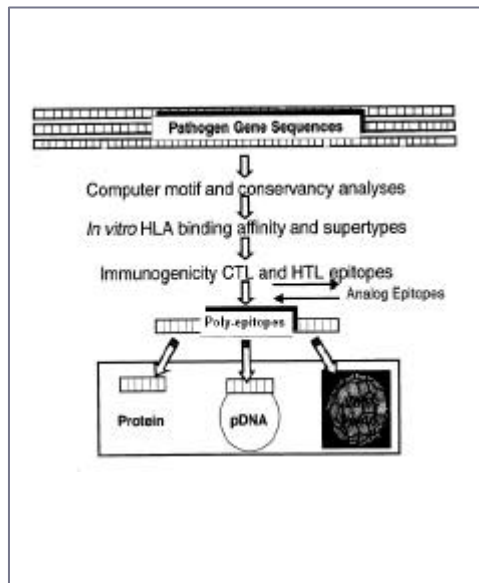
Poly-epitope vaccines: prediction models

- Use of data bases
- Computer prediction
- Collaborations (e.g. Algonomics)



Therapeutic vaccines

Build an R&D assembly line



Generation of research product

- Peptides, proteins, DNA
 - Purification and characterisation
 - Binding assays
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- Production of minigene constructs
 - Efficient process to move from several minigene candidates towards a vaccine candidate



Therapeutic vaccines

Build an R&D assembly line



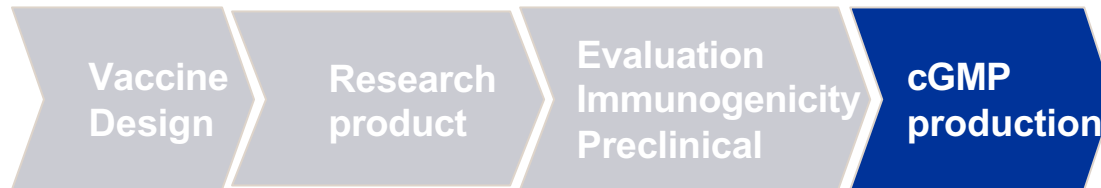
Tools for Immunogenicity testing

- ELISA
 - ELISPOT (γ -Interferon)
- Human recall testing
- Transgenic mice



Therapeutic vaccines

Build an R&D assembly line



Production of clinical grade material

- Capacity for phase III
- Authorisations of MoH and ISO certification

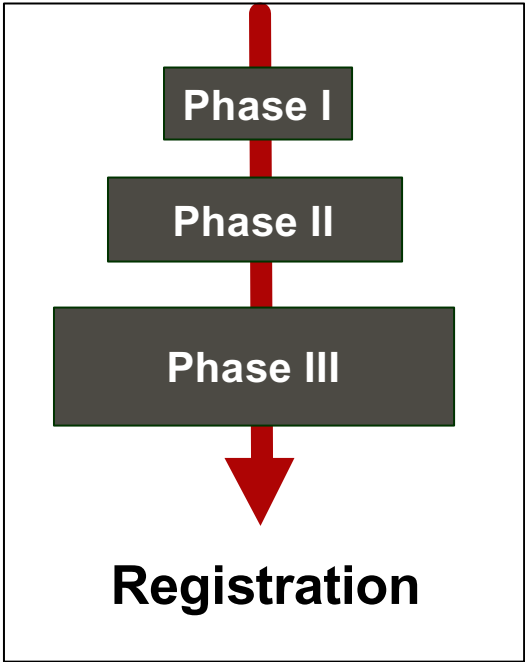
Increased efficiency

- Diverse protein expression systems
- “Smart” Contract Manufacturing
- DNA (Plasmid) production
- Outsourcing of non core activities



Therapeutic vaccines

Build an R&D assembly line



Efficient patient recruitment

From local to international trial management

- Clinical project management
- State of the art data management
- Ready to work under US IND

Optimal use of resources

- Use of CROs while still in charge

Regulatory strategy and drug development



Therapeutic vaccines

Build an R&D assembly line



Need to partner in phase III

High cost of phase III

Prepare the market

Commercial organization

= Important role for Business Development



Therapeutic vaccines

Build an R&D assembly line



Therapeutic vaccines

Strategic acquisition

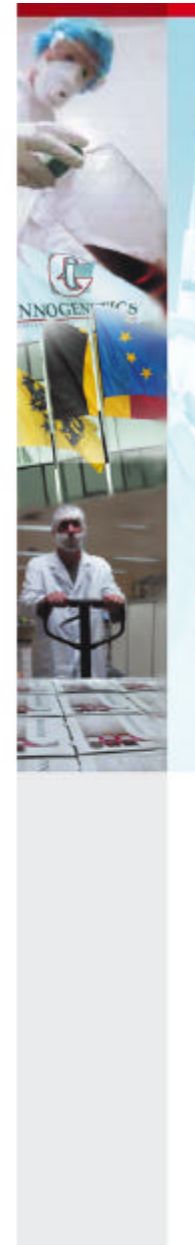


Therapeutic vaccines

Strategic acquisition

Criteria

- Therapeutic vaccines for Infectious Diseases
- Additional platforms to evaluate prime/boost
- Additional Clinical program
- Synergies in R&D



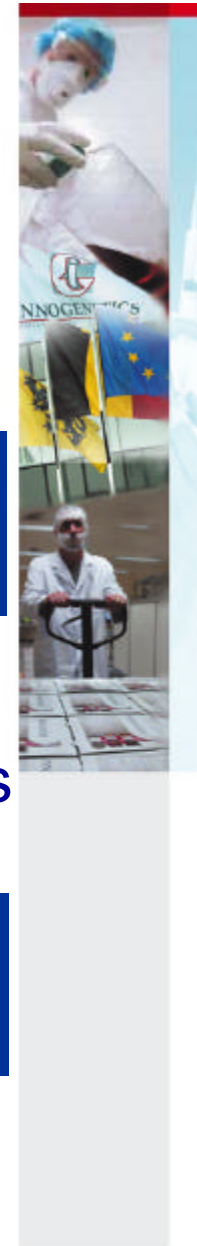
Therapeutic vaccines

Strategic acquisition

Criteria

Result

- Therapeutic vaccines for Infectious Diseases → Therapeutic vaccines for HBV, HPV & HCV
- Additional platforms to evaluate prime/boost → Poly-epitope CTL & HTL, plasmid DNA & viral vectors
- Additional Clinical program → Phase I Trial in HepB under US-IND
- Synergies in R&D → Epimmune (partner for poly-epitopes)



What do we have now?



Therapeutic vaccines

A therapeutic vaccine R&D assembly line



Therapeutic vaccines

A therapeutic vaccine R&D assembly line

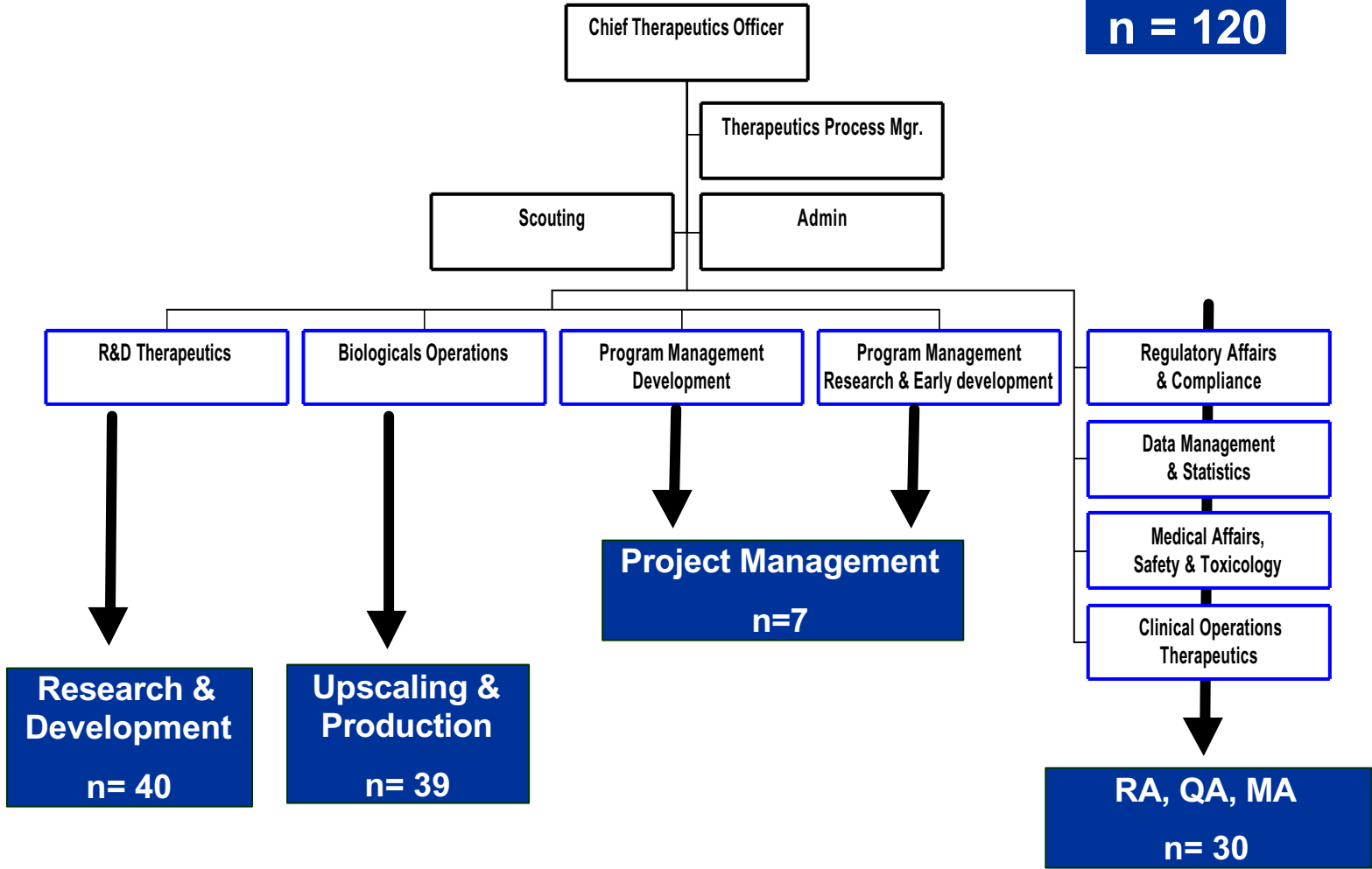


<p>Proteins</p> <p>CTL - HTL epitopes</p>	<p>Recombinant proteins</p> <p>New expression systems</p> <p>Plasmid DNA</p> <p>Viral vectors</p>	<p>Evaluation of Humoral and Cellular responses</p> <p>Access to transgenic mice</p>	<p>Recombinant proteins</p> <p>Plasmid DNA</p>	<p>Ongoing in Europe and USA</p>	<ul style="list-style-type: none"> • Hepatitis C • Hepatitis B • HPV
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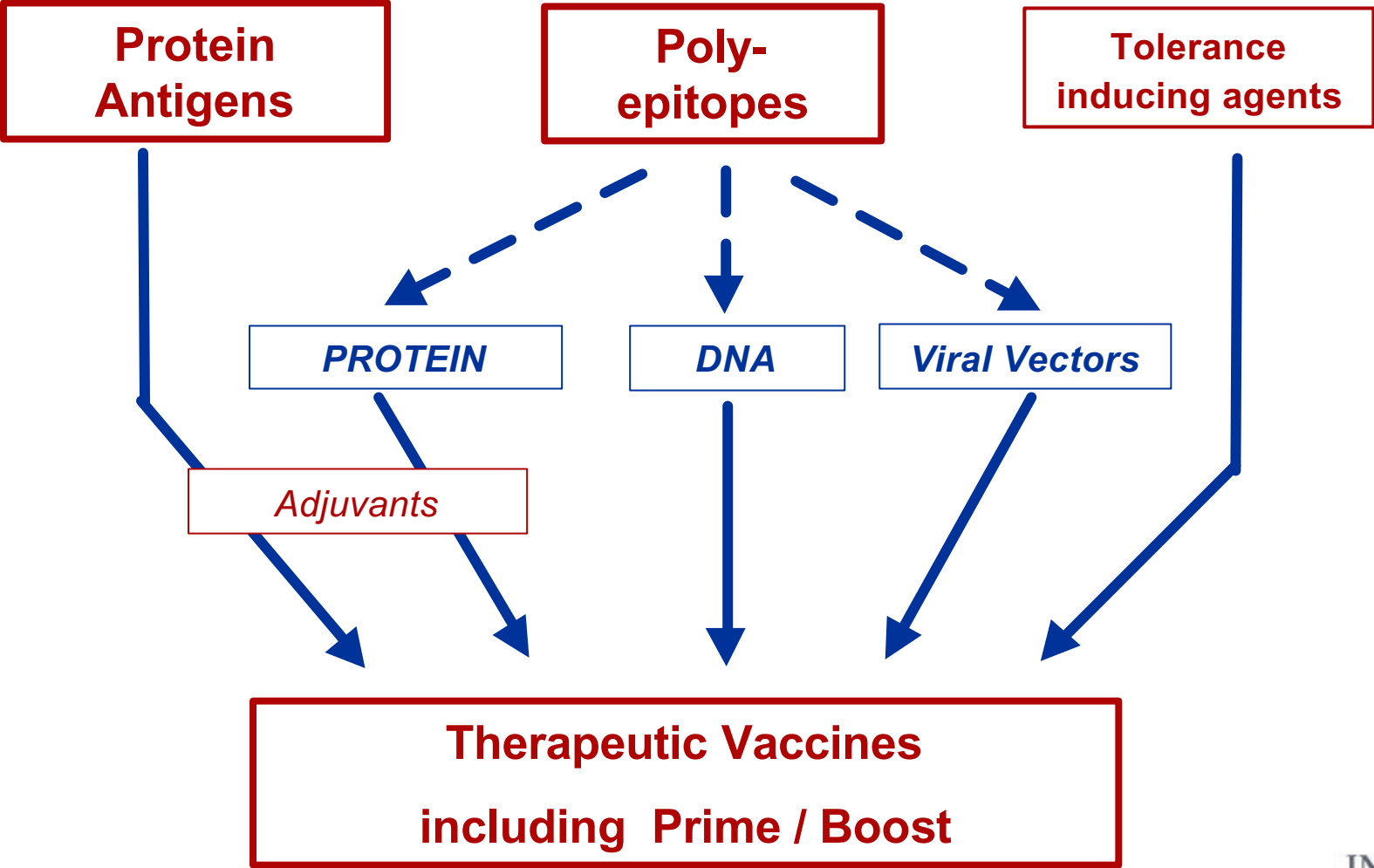
Therapeutic vaccines

A strong therapeutic organization



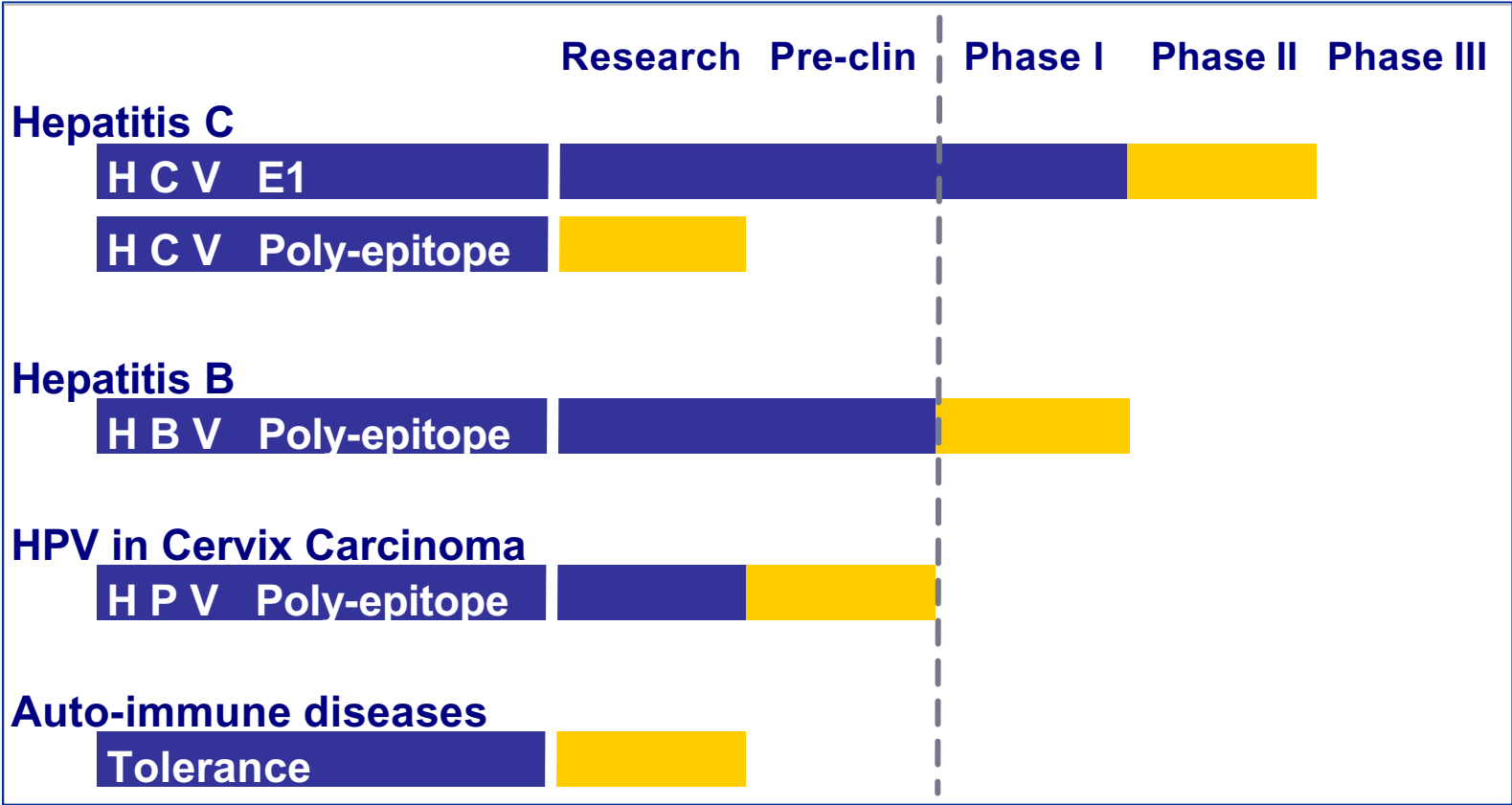
Therapeutic vaccines

The technology platforms to be successful



Therapeutic vaccines

A well balanced portfolio



■ completed ■ in progress

