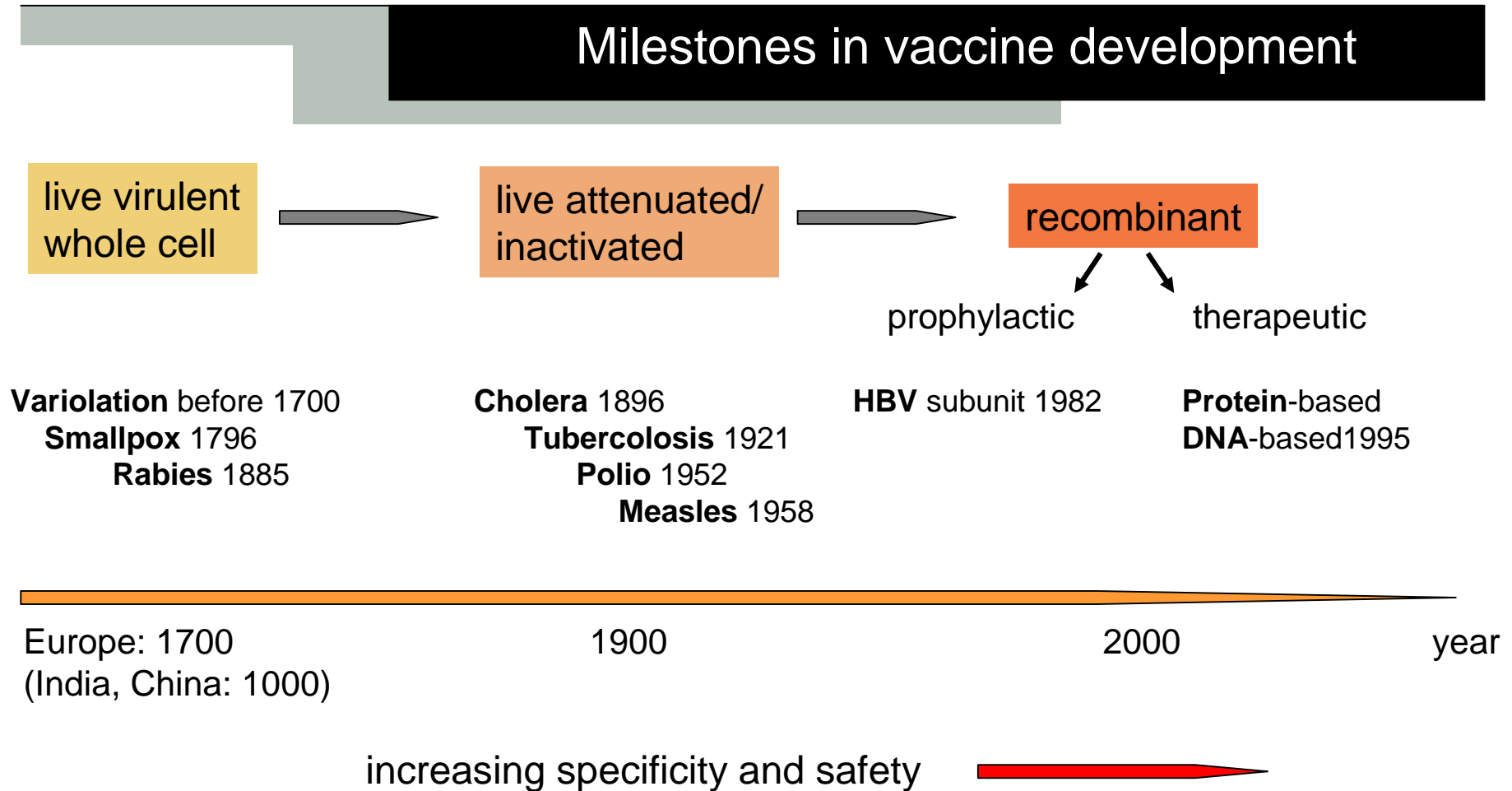


Vaccination against
CHRONIC DISEASES
a novel therapeutic modality

The History of Vaccines



Vaccination

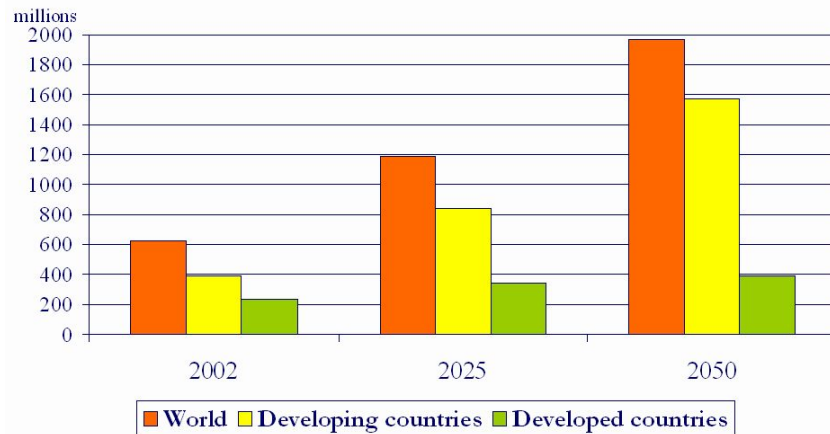
Elimination of the Risk for Infection



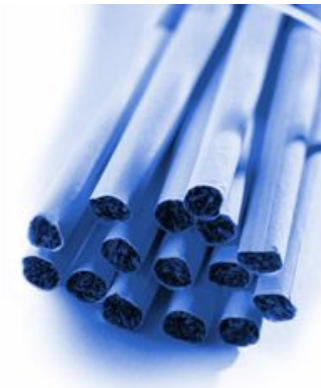
Risk Factors in the 21st Century

Growing Burden of Ageing Societies

Number of people aged 60 and over



Source: UN, 2002



Risk Factors in the 21st Century

The Treatment of Risk Factors

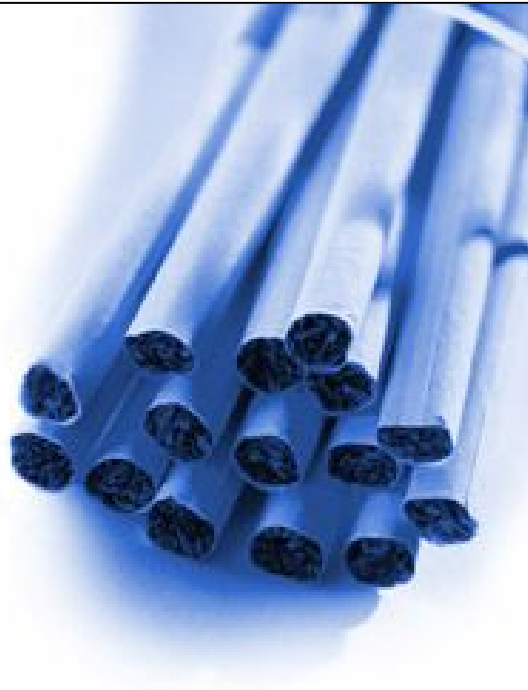
Drugs treating risk factors have to be:

- **Convenient, to maximize**
- **Compliance**

à Vaccines are convenient since they have a long-lasting effect

CYT002-NicQb

A Novel Vaccine for
Nicotine Addiction



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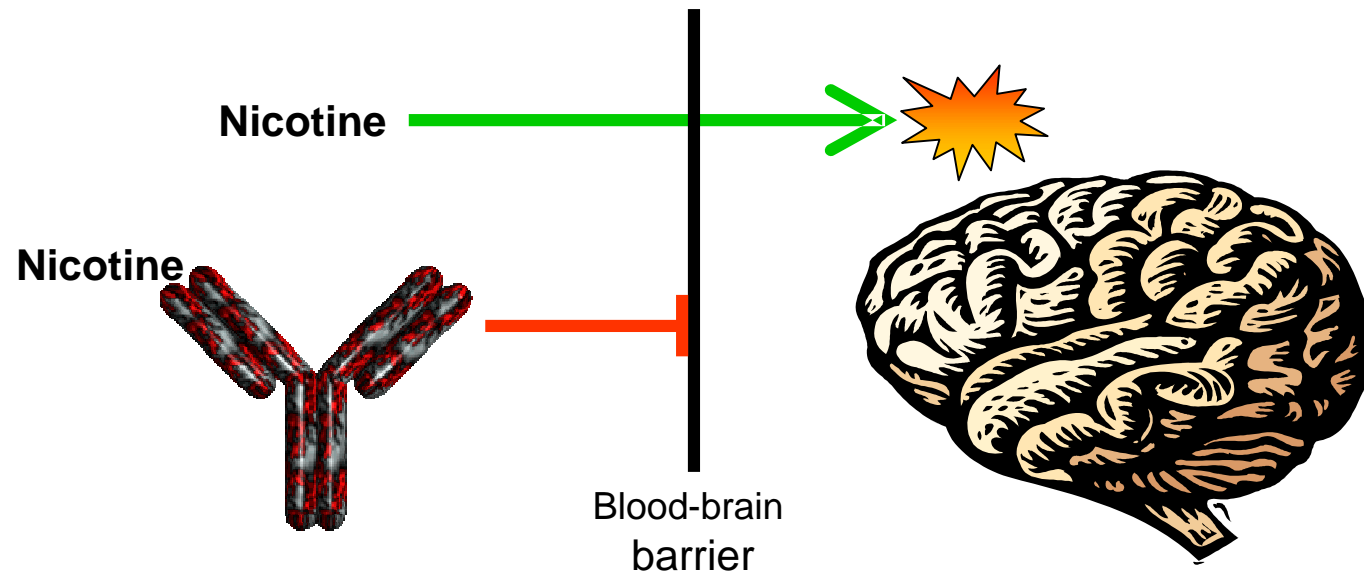
Smoking

Facts

- According to the WHO, 1.3 billion people smoke
- With 5 million tobacco-related deaths per year, tobacco use is the leading cause of preventable death in the world today
- On average smokers lose more than 10 life years
- 75% of smokers in the U.S. report that they want to quit smoking
- Less than 5% of those who try quitting are able to stay tobacco-free for 3 to 12 months (Surgeon's General Report, USA, 2004)

Rationale for Vaccine Approach

Postulated Mechanism of Action



Antibodies reduce the amount and rate of nicotine entering the brain

○ interrupt reinforcing effect (reward)

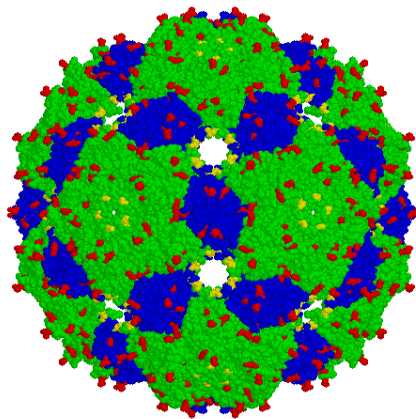
○ prevent relapse in case of single slips after successful quit attempt

Vaccine Design

Give Nicotine the „Look of a Virus“

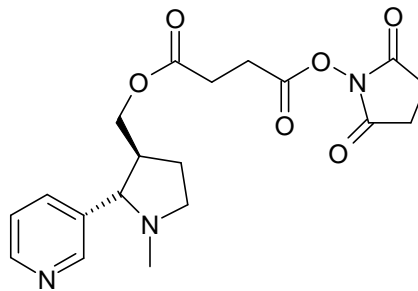
Nicotine is coupled to the surface of a virus-like particle (Qb)...

...which renders it highly immunogenic

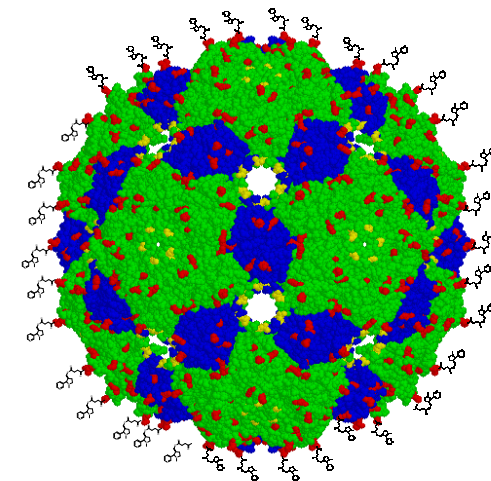


VLP Qb

+



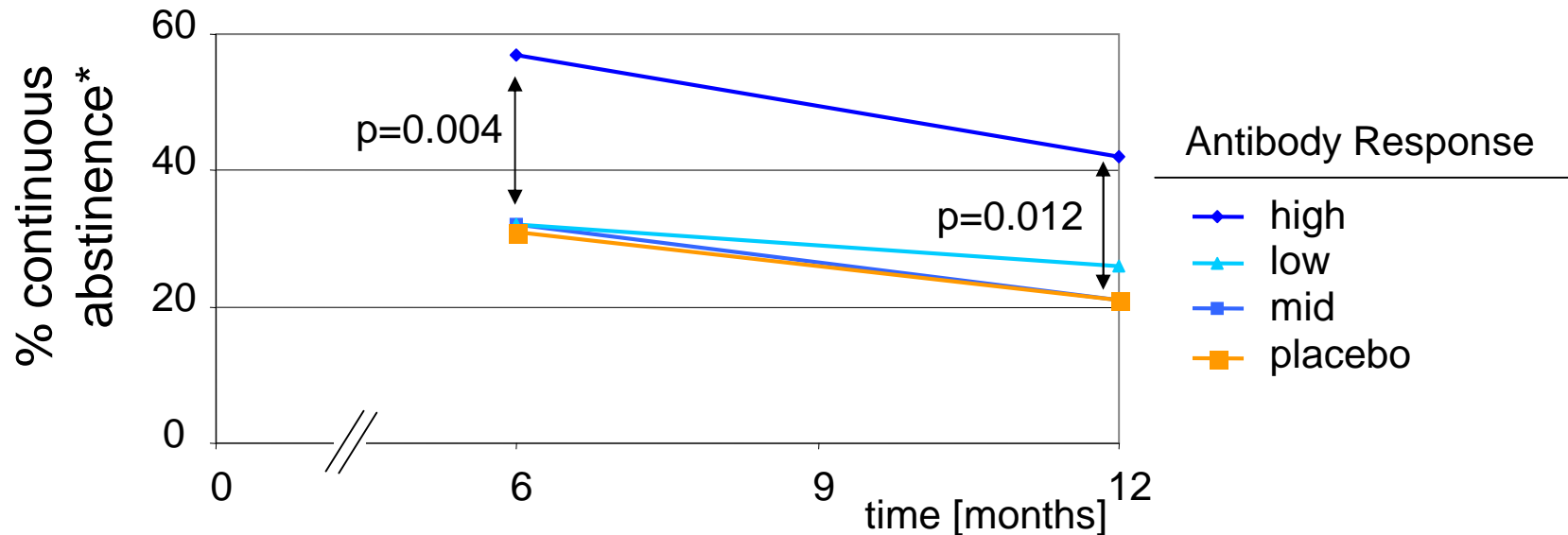
Nicotine derivative



CYT002-NicQb

Phase II Results

Continuous Abstinence from Smoking (PP)

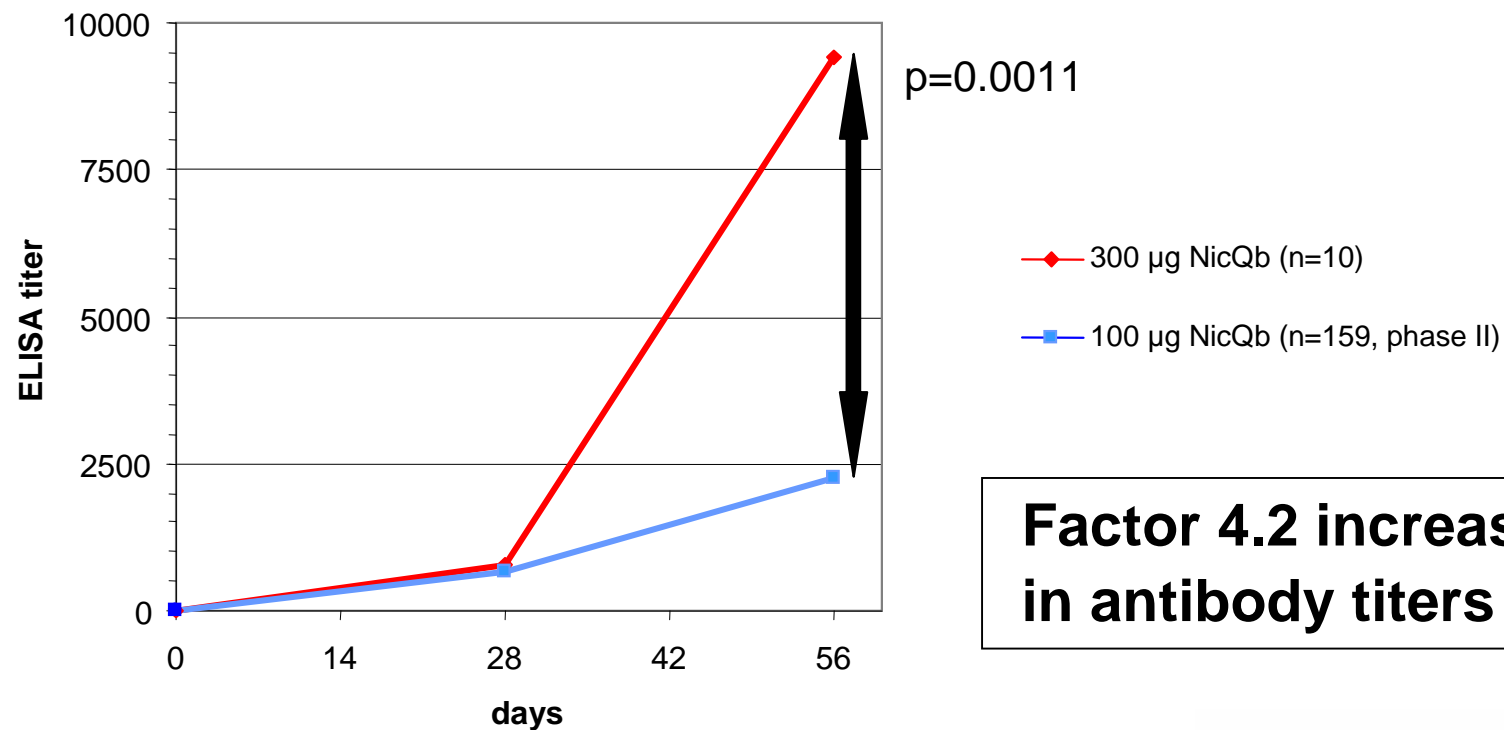


	6 month	12 month
CYT002-NicQb		
high responder	57% (30 / 53)	42% (22 / 53)
medium responder	32% (17 / 53)	21% (11 / 53)
low responder	32% (17 / 53)	26% (14 / 53)
Placebo	31% (25 / 80)	21% (17 / 80)

NicQb Dose Optimization

300 μ g Dose Surpasses Antibody Target

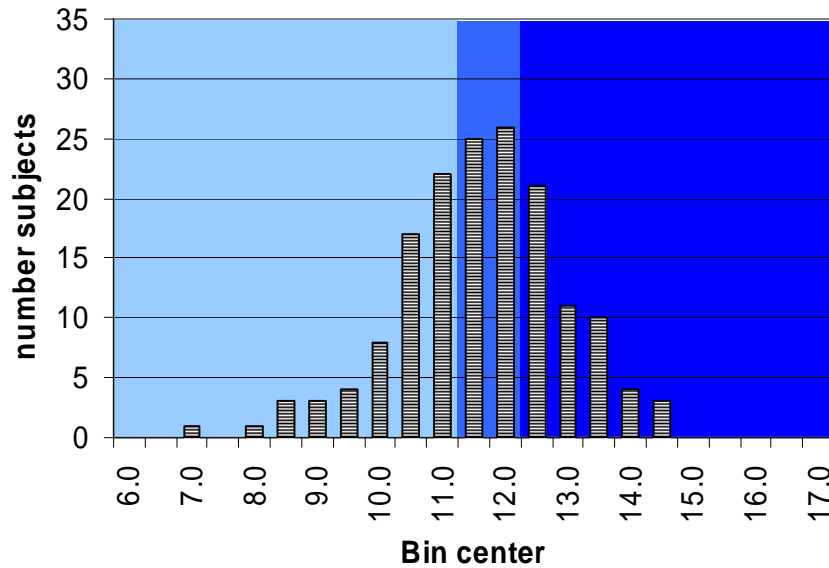
Effect of dose on anti-nicotine IgG titers (GMT)



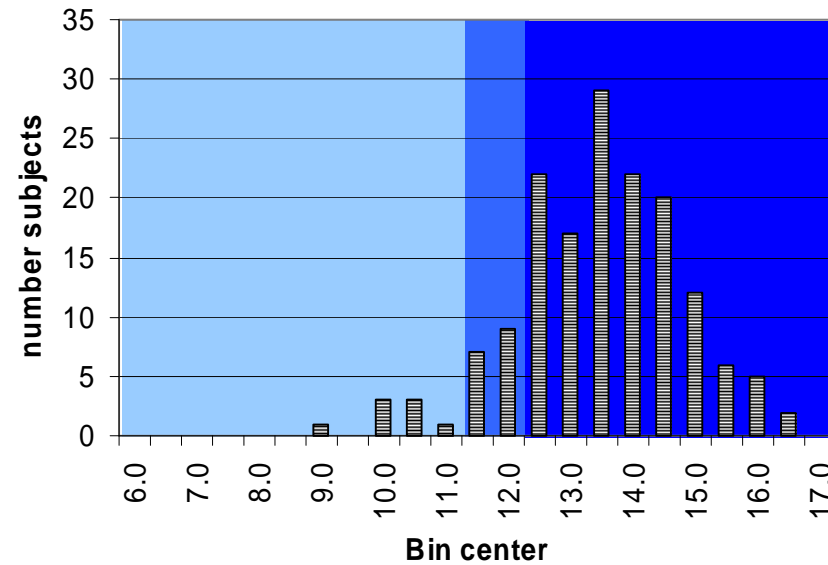
NicQb Dose Optimization

87% of Vaccinated Individuals Calculated to Reach Target Titers

Histogram of AUC46; n=159



Histogram of AUC46 (titer * 4.2; n=159)



Low Medium High
33% 33% 33%

% subjects

Low Medium High
5% 8% 87%

CYT005-AllQbG10

A Novel Vaccine for Allergy
and Asthma



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Allergic Diseases

A Large Unmet Medical Need

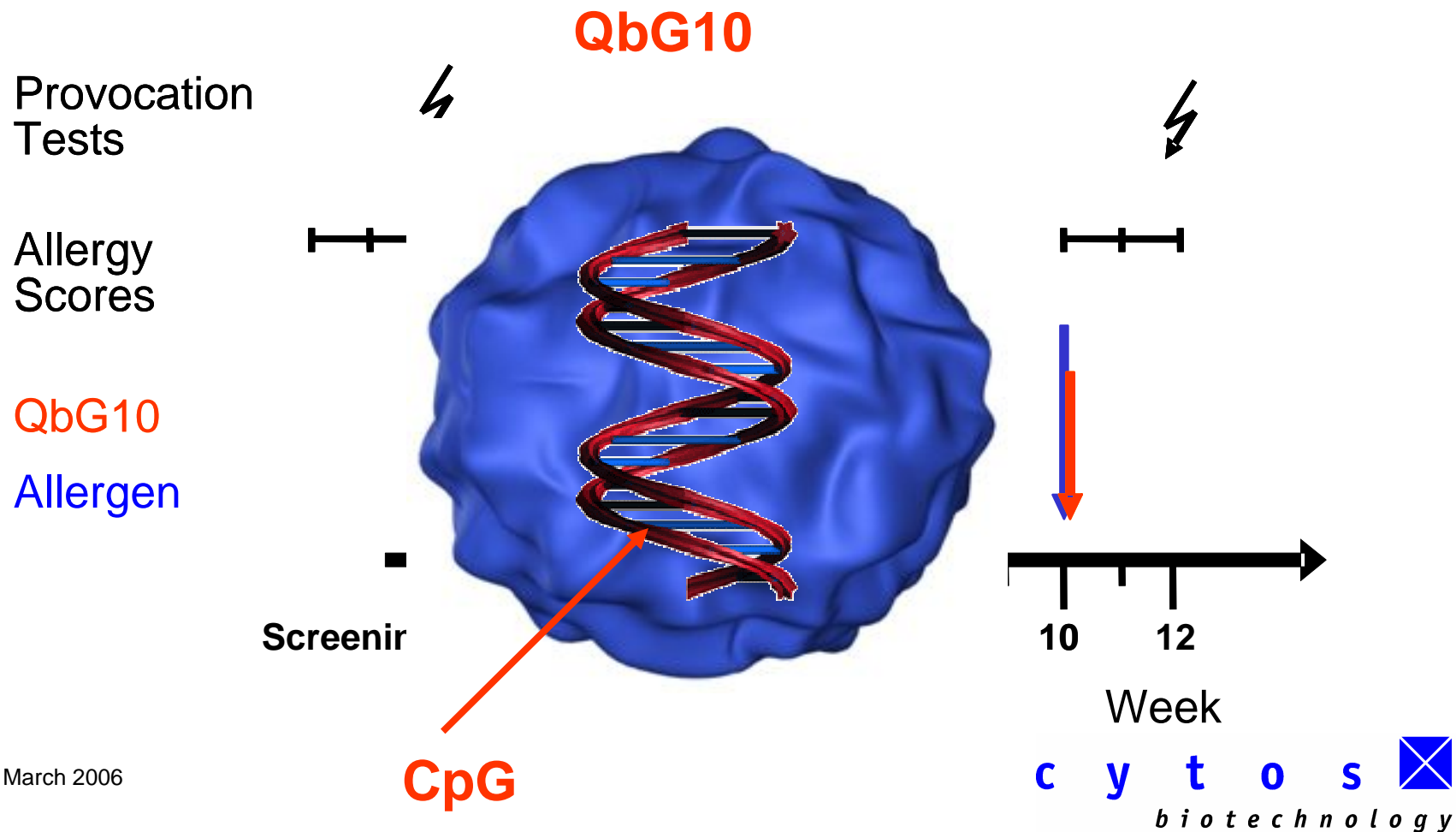
According to WHO more than 20% of the world population suffers from allergic diseases; up to 30% of these sufferers develop asthma

Three treatment options are available today

- Avoidance of the allergen
- Medication that targets the symptoms of the disease
- Desensitization

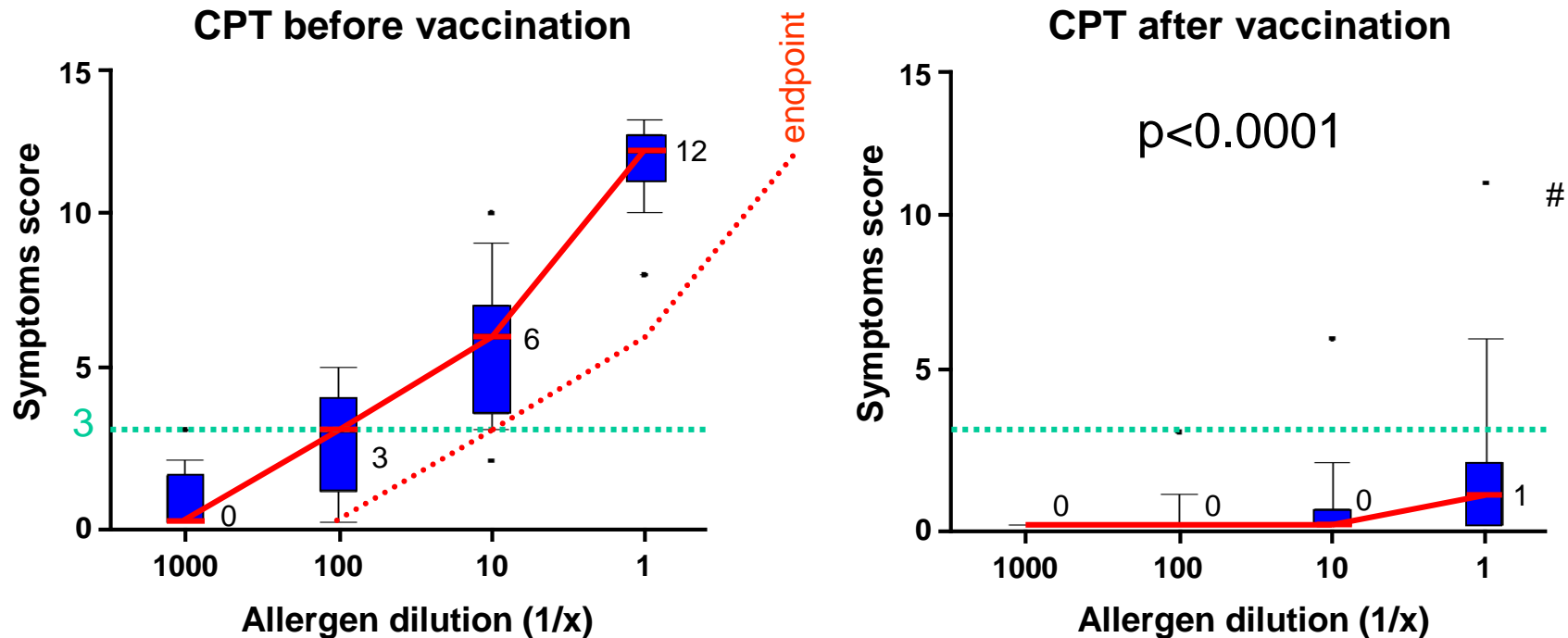
Phase IIa Design

Open Label Study in 20 Patients Suffering from Rhinoconjunctivitis and Asthma due to House Dust Mite Allergy



Phase IIa Results (1)

Primary Endpoint: Conjunctival Provocation Test (CPT)

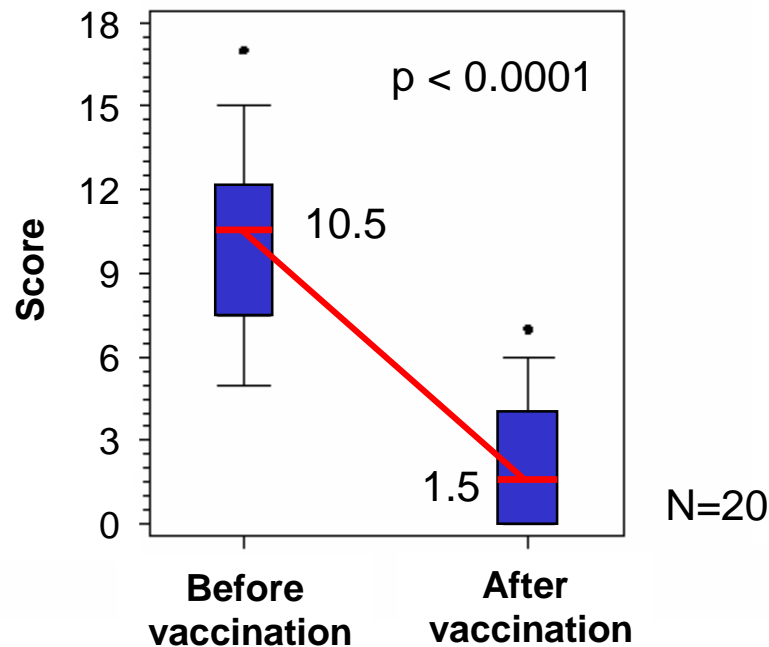


Assessed symptoms: conjunctival hyperemia, tearing, itching, burning, swelling of eyelids; each symptom could be absent (0 points), mild (1 p.), moderate (2 p.), or severe (3 p.)

Phase IIa Results (2)

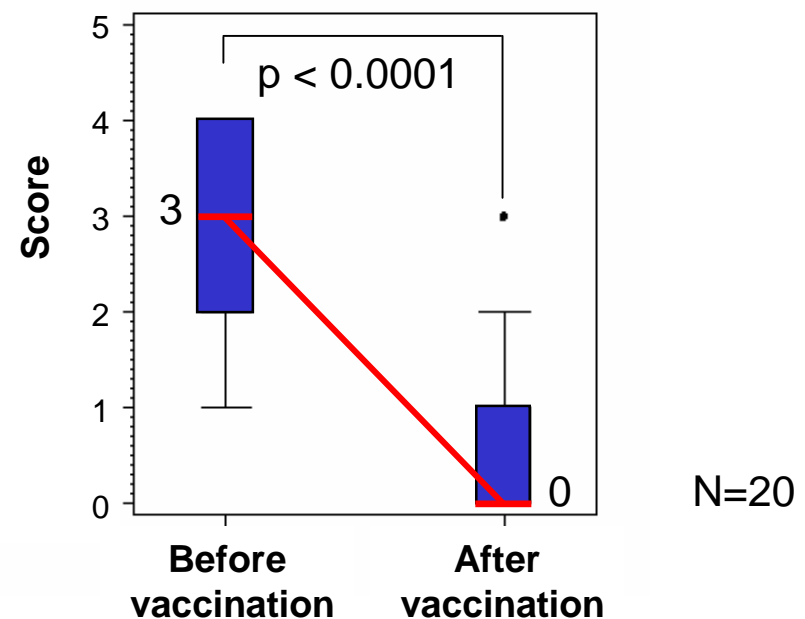
2nd Endpoint: Rhinitis in Daily Life

Rhinitis Symptoms in Daily Life



Assessed symptoms: Runny nose, clogged nose, periods of sneezing, itchy nose, itchy throat, itchy eyes, red eyes

Consequences of Rhinitis

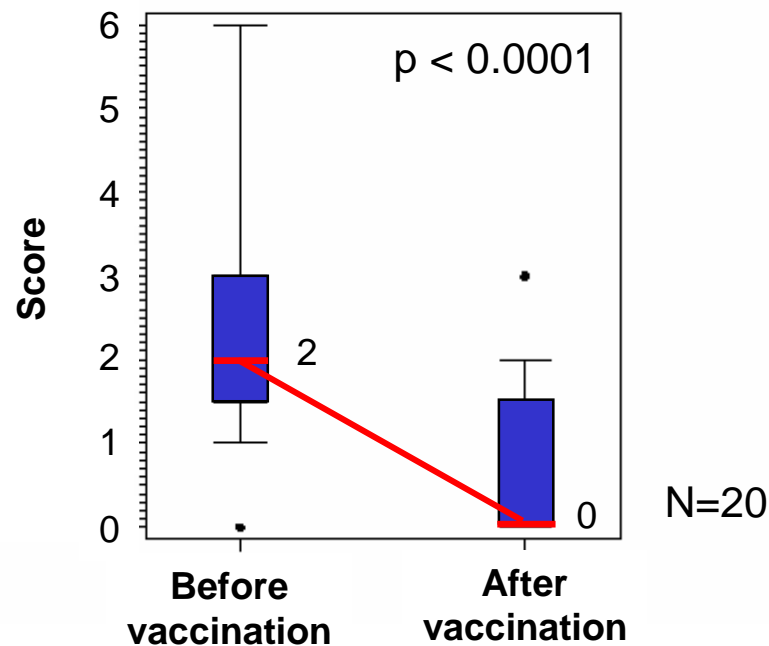


Assessed criteria: symptoms in daily life, sleeping disorders, restrictions during work or school, and during leisure time.

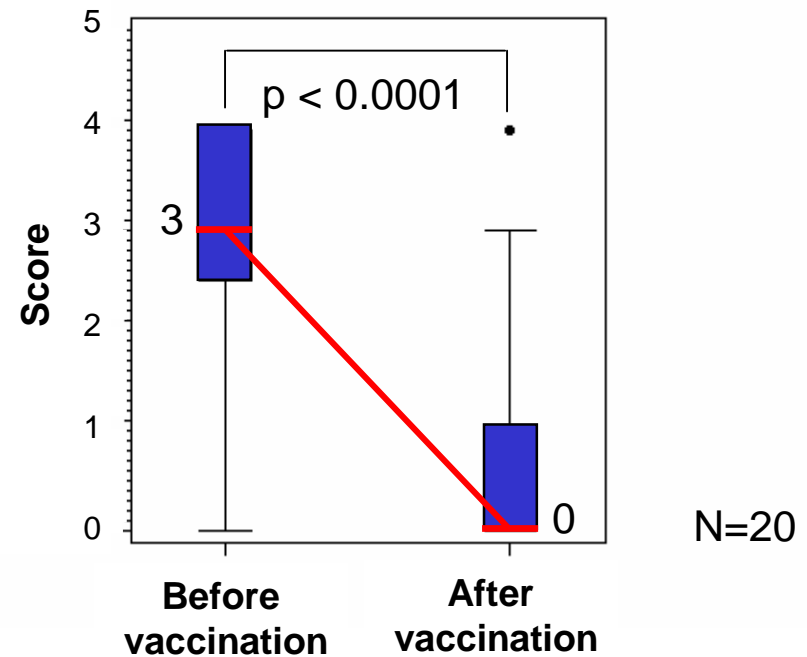
Phase IIa Results (3)

2nd Endpoint: Asthma in Daily Life

Asthma Symptoms In Daily Life



Consequences of Asthma



Assessed symptoms: Dry cough, and asthma bronchiale.

Assessed criteria: symptoms in daily life, sleeping disorders, restrictions during work or school, and during leisure time.

CYT009-GhrQb

A Novel Vaccine
for Obesity

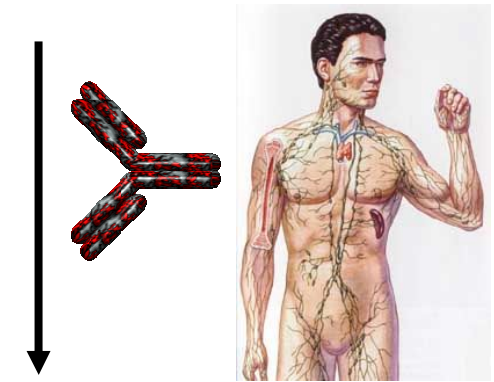
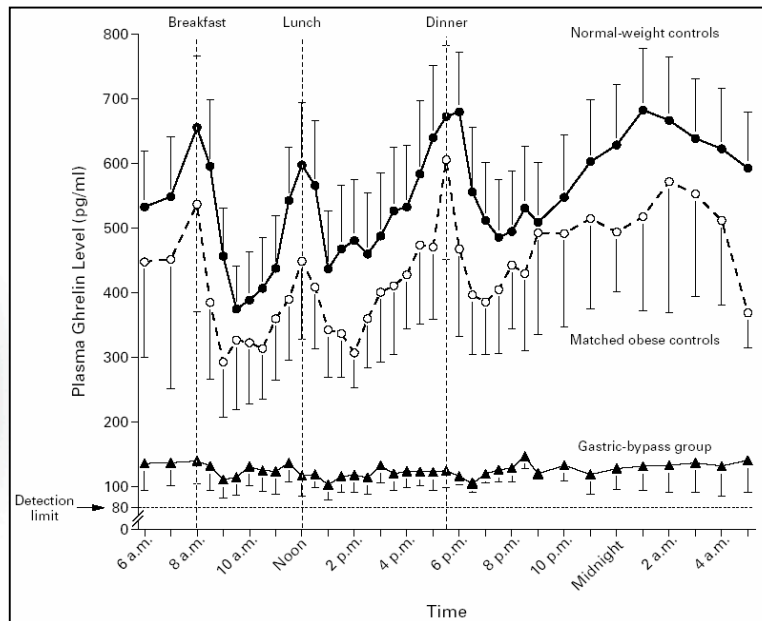
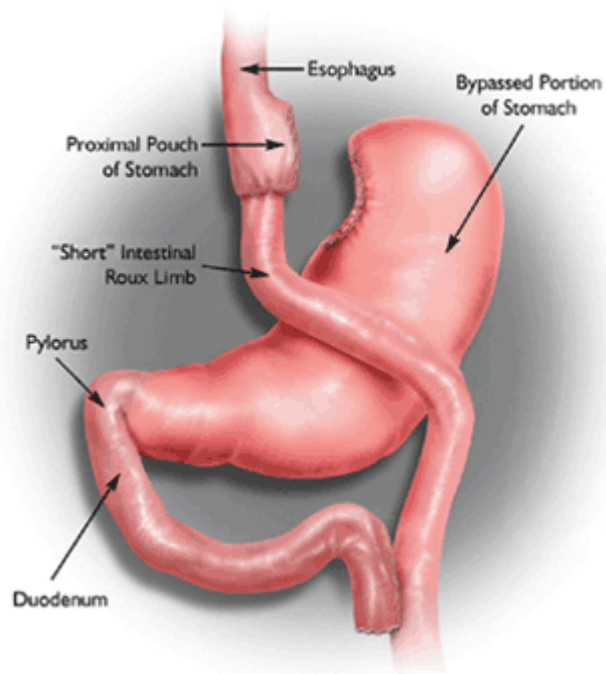


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CYT009-GhrQb

Modulate the Action of Ghrelin

Roux-en-Y Gastric Bypass



Clinical Phase I/IIa

Study Design

Indication	Obesity management (weight loss and maintenance)
Study design	Randomized, double-blind, placebo-controlled, 3 dose comparison multicenter study in 112 obese patients
Endpoints	Study period: 6 months plus monitoring 6 months Safety, tolerability, pharmacodynamic effects, and exploratory efficacy (weight loss)

CYT009-GhrQb

Summary Interim Clinical Observations

- CYT009-GhrQb was safe and well tolerated
- The number of responders corresponds with the expected number; all mounted an antibody response upon a single dose
- Antibody responses were reversible, an important safety feature
- A dose-response relationship (vaccine dose vs. induced antibody levels) is perceivable

Immunodrug™ Pipeline

