

# Developmental status of different therapeutics, vaccines plus antivirals and resistance

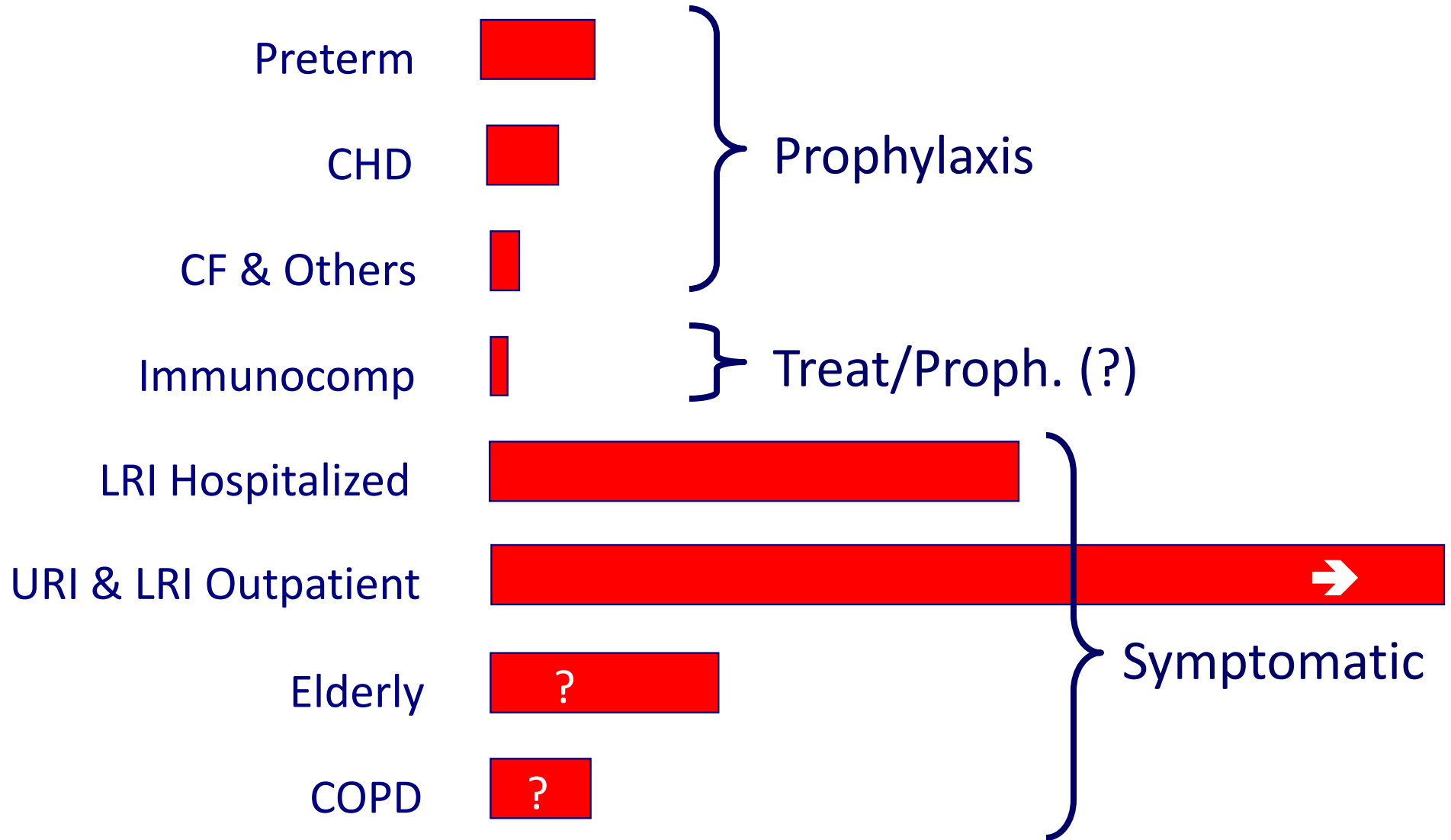
Octavio Ramilo



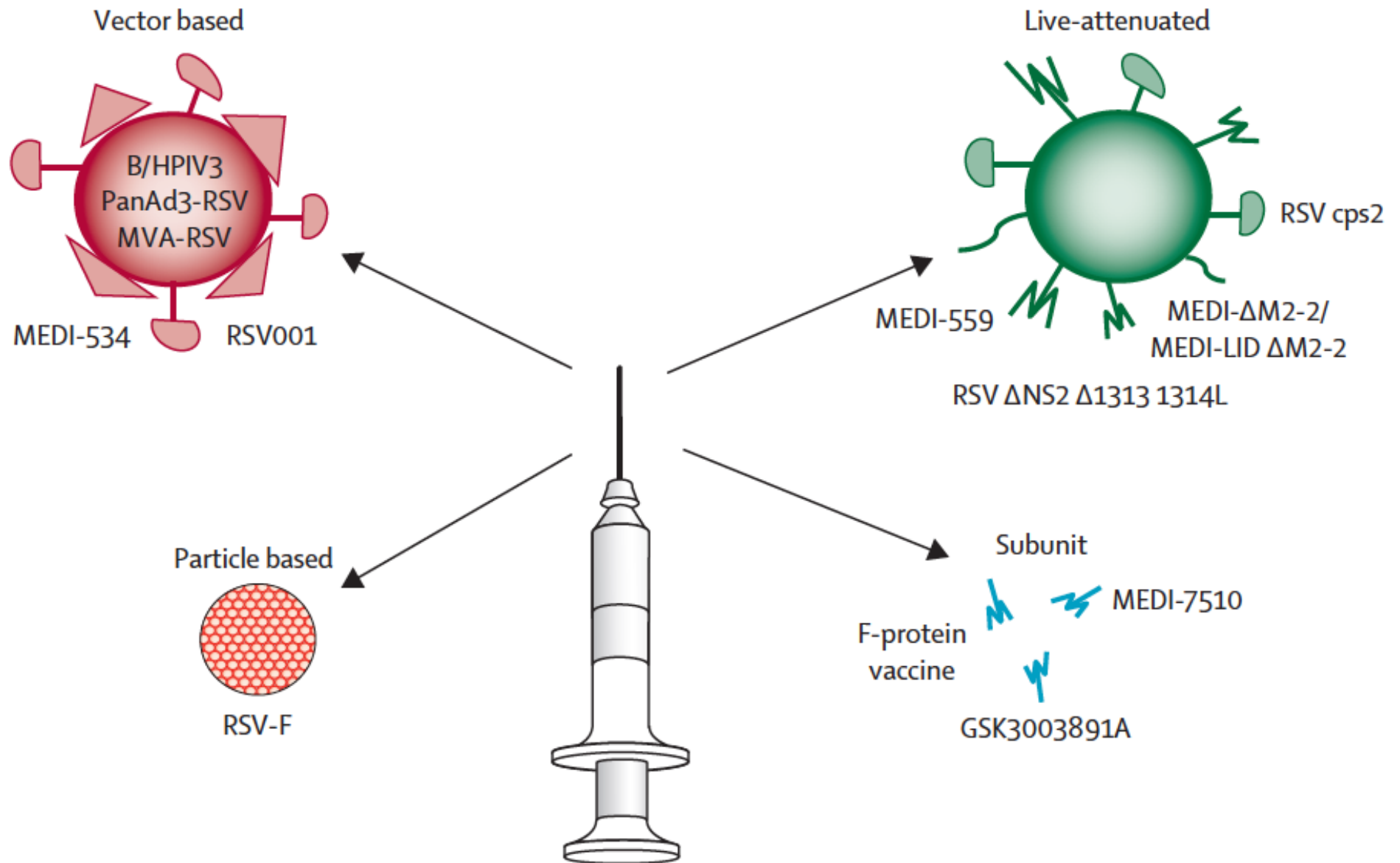
# Interventions for RSV Infection

- Populations affected by RSV infection
- Therapeutic and preventive strategies
- Considerations for treatment
- Considerations for immunization
- Implications for study design

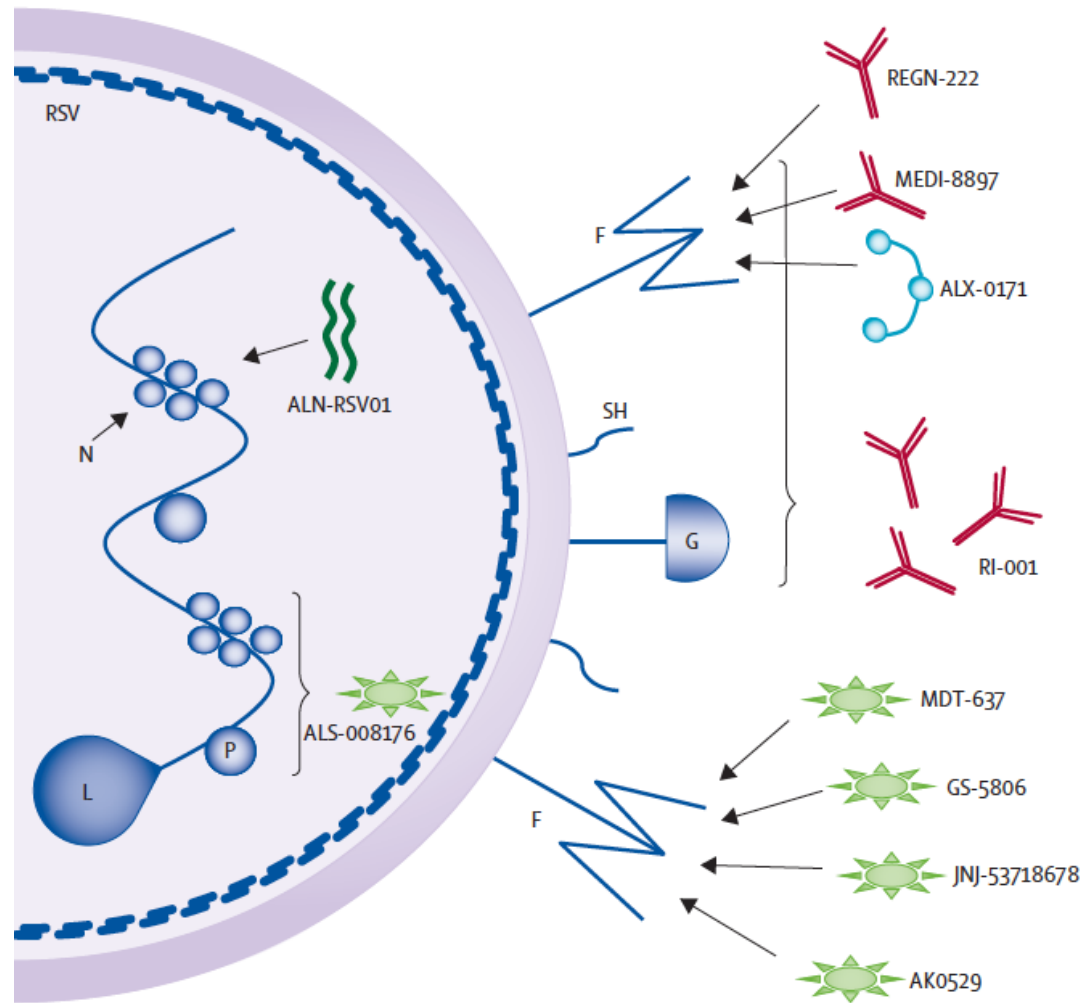
# Target populations for therapy for RSV infection (2010)



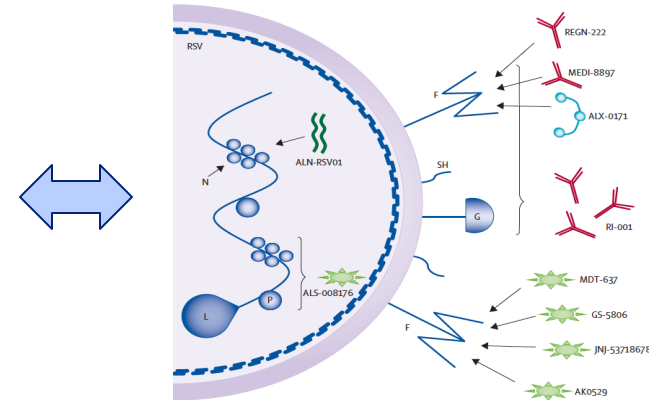
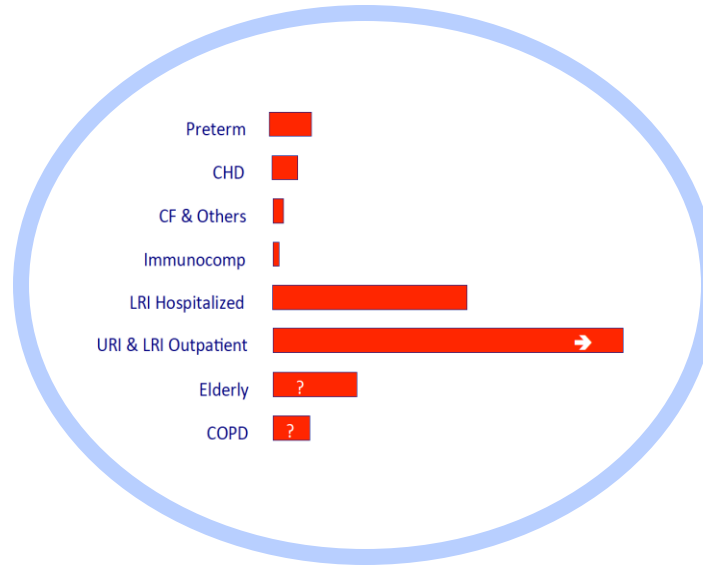
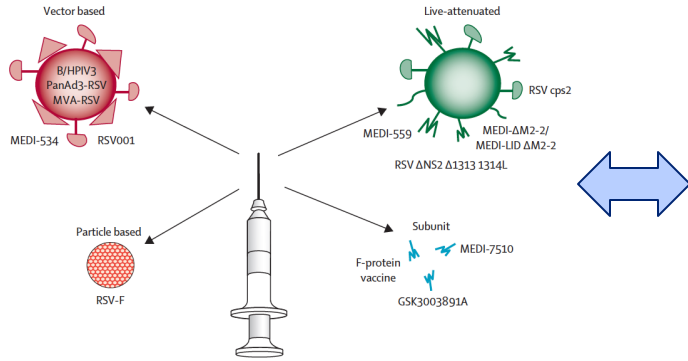
# Vaccines in development



# Antivirals and Mabs in development



# Targeting different patient populations with best antivirals and vaccines



# Selecting target population(s) for treatment

- Who?

- Infants: healthy vs chronic conditions
- Elderly
- Immunocompromised individuals

- When?

- Early: outpatients
- Severe disease: inpatients

- How?

- Route: oral, intravenous, inhaled
- Single agent, combination therapy

- How we decide?

- Clinical endpoints and laboratory markers
- Flexibility, learning as we advance

# Lessons of antiviral therapy: ART for HIV

## ■ Who?

- adults, children, infants, pregnant women
- adolescents, older individuals

## ■ When?

- early infected, advanced patients
- all HIV infected individuals

## ■ How?

- monotherapy, dual therapy
- combination therapy

## ■ How we decide?

- clinical endpoints
- virologic, immunologic markers
- analysis, reassessing as we advance



# Selecting target population(s) for vaccination & prevention

- Who?

- Infants: newborns, 2 mo, > 6 mo
- Elderly
- Pregnant women

- How?

- Live attenuated, vector-based
- Recombinant proteins, subunit, particle
- Passive: mAbs

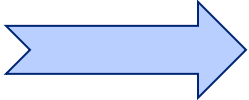
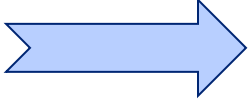
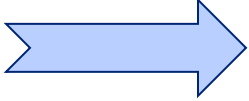
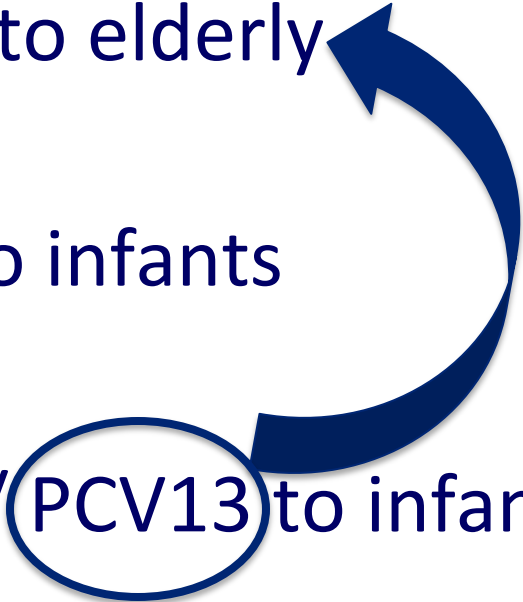
- Where?

- Developed and developing countries
- Established and new research networks

- How we decide?

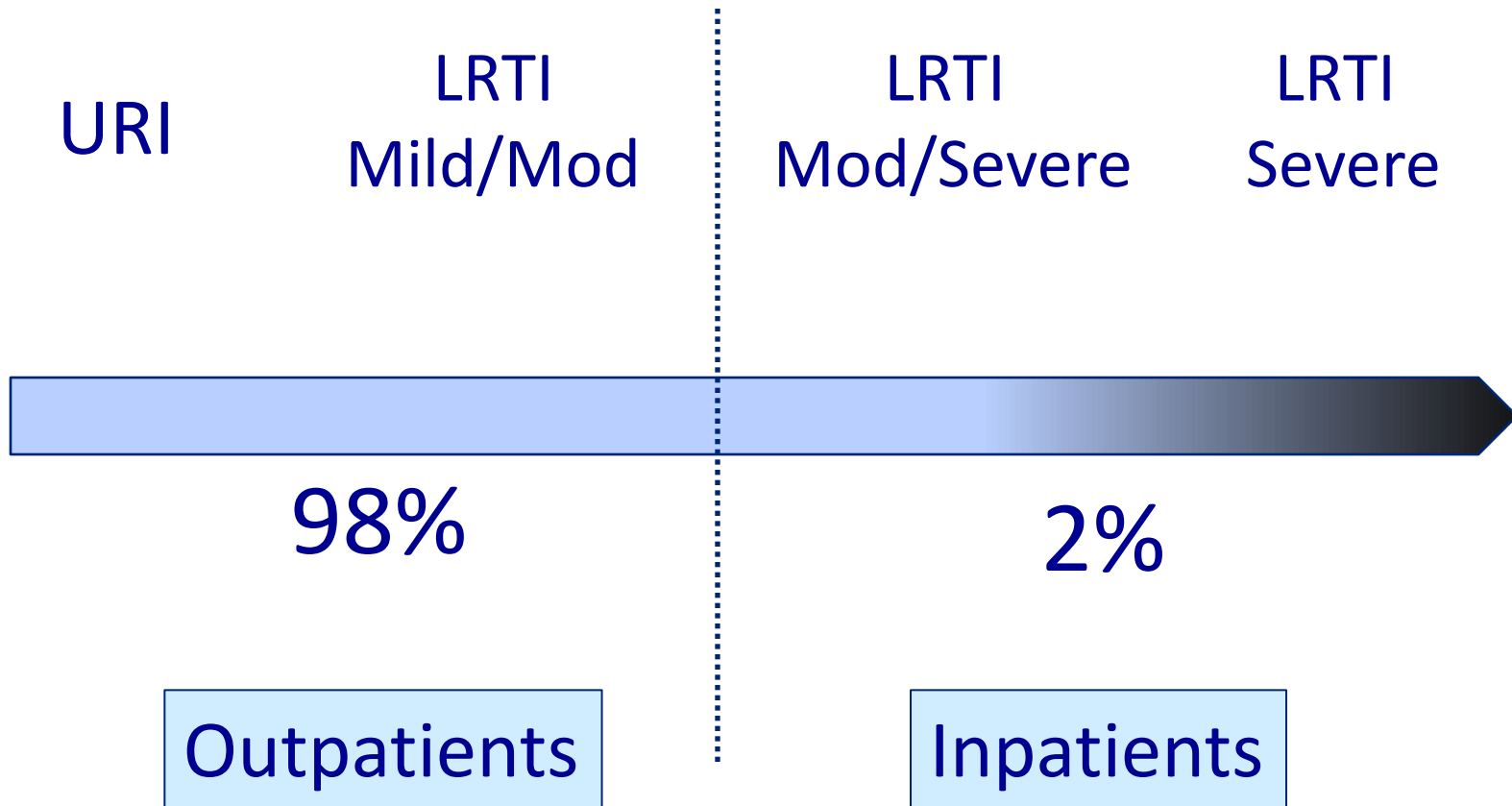
- Clinical endpoints and laboratory markers
- Adapted by patient groups
- Adapted to healthcare systems

# Lessons vaccine development: Pneumococcus

- Initial:  PPV23 to elderly
  - 2nd:  PCV7 to infants
  - 3rd:  PCV10/**PCV13** to infants
- 

# RSV clinical disease

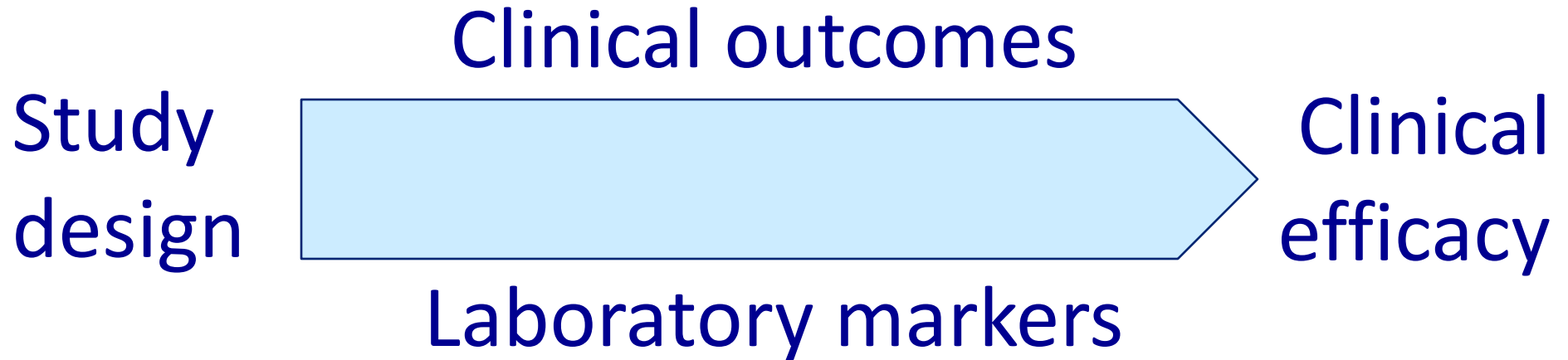
# Variability in clinical presentation of RSV infections



# How do we explain the variability in clinical presentations?



# Implications for study design



# Defining and adapting clinical endpoints

## Challenges

- Intervention type: prevention vs treatment
- Infants vs elderly vs immunocompromised
- Inpatients vs outpatients
- Developed vs developing countries

## Opportunities

- Identify common endpoints
- Acute and long-term outcomes

# Selecting laboratory markers

## *Virologic markers*

- Viral loads
- Viral genotypes (Viral sequences)
- Viral resistance

## *Immune markers*

- Antibody titers: PreF, PostF, G; neutralizing Abs
- T cell responses
- Transcriptome



# Proposed clinical pathway

Phase 1 → Phase 2 → Phase 3 → Outcome

Phase 1 → Phase 2 → Phase 3 → Approval

# Questions

