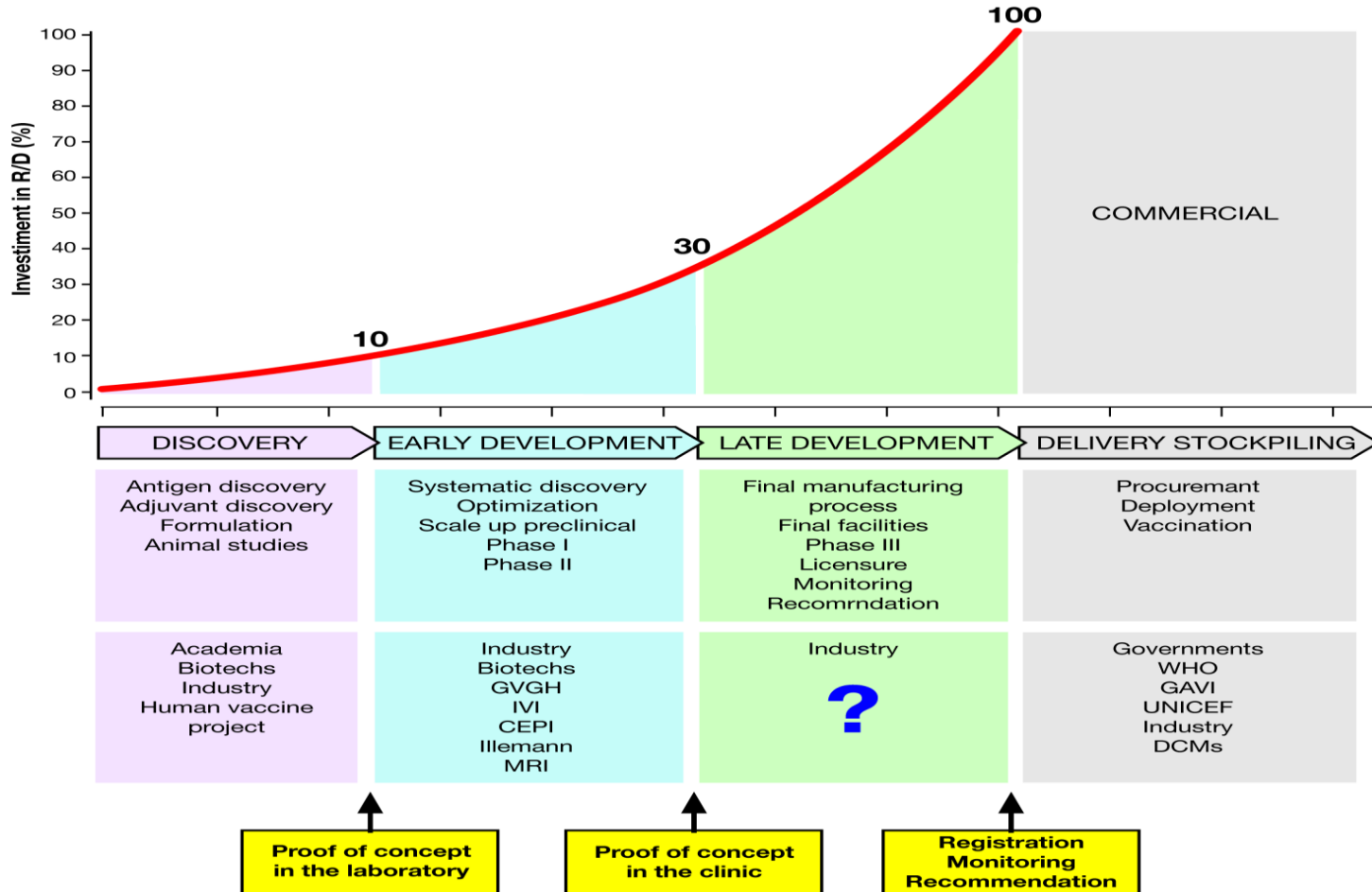
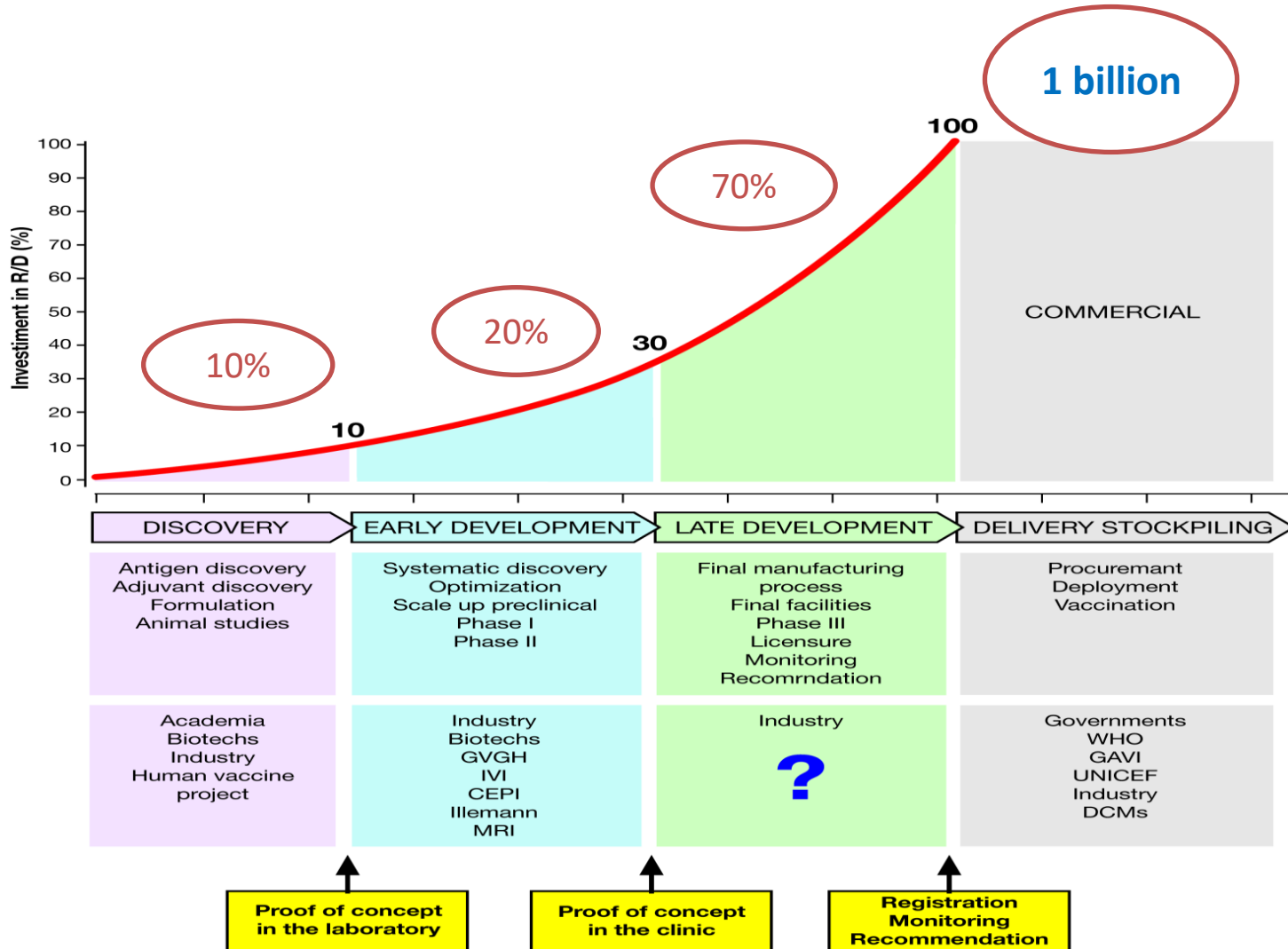


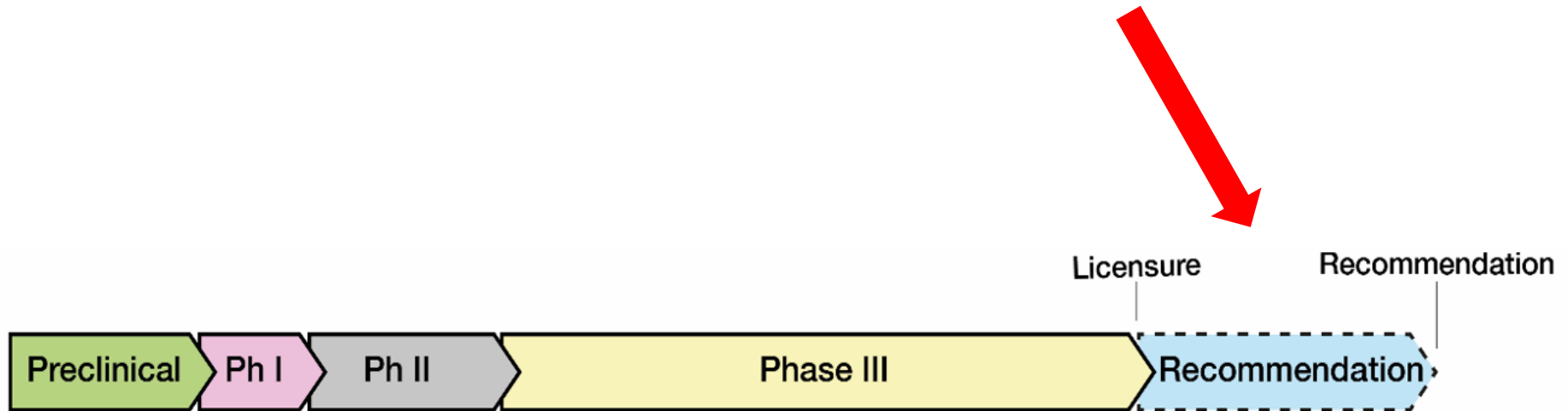
Vaccine development



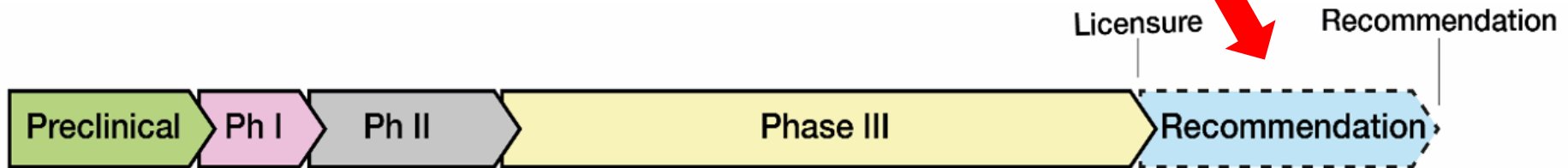
Cost of vaccine development



Recommendations are made after Phase III and approval by regulatory agencies

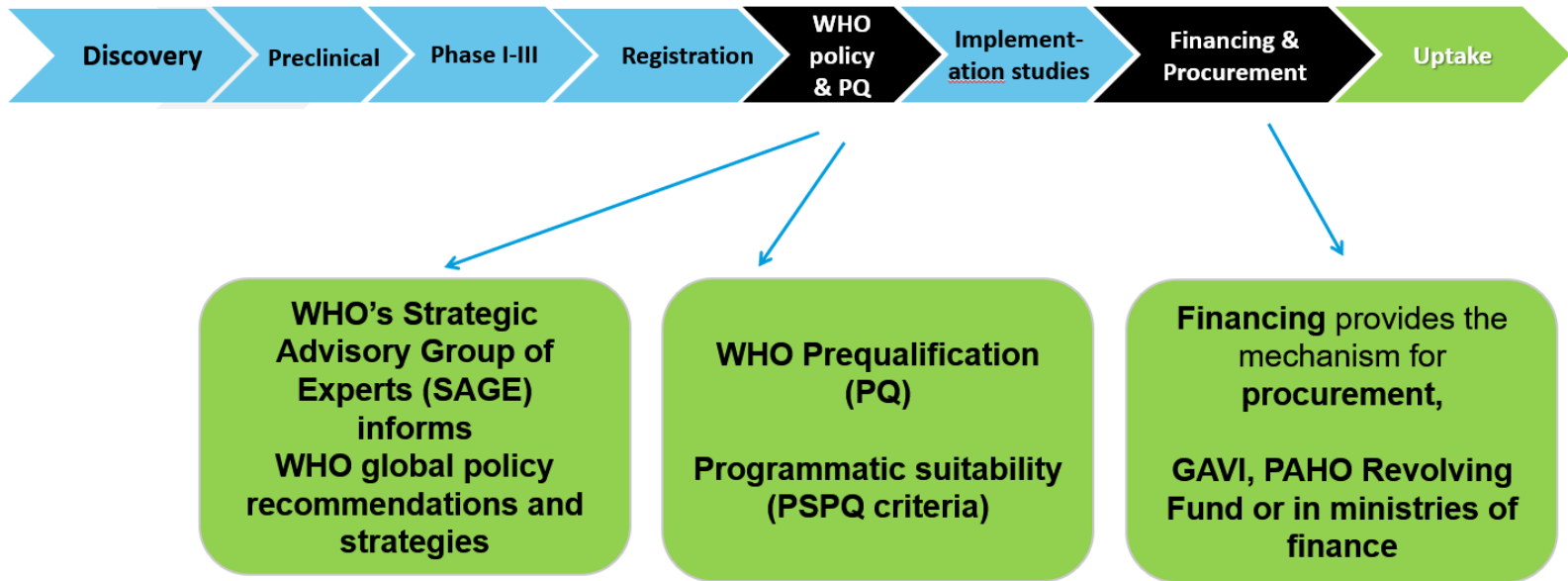


Recommendations are made after Phase III and approval by regulatory agencies

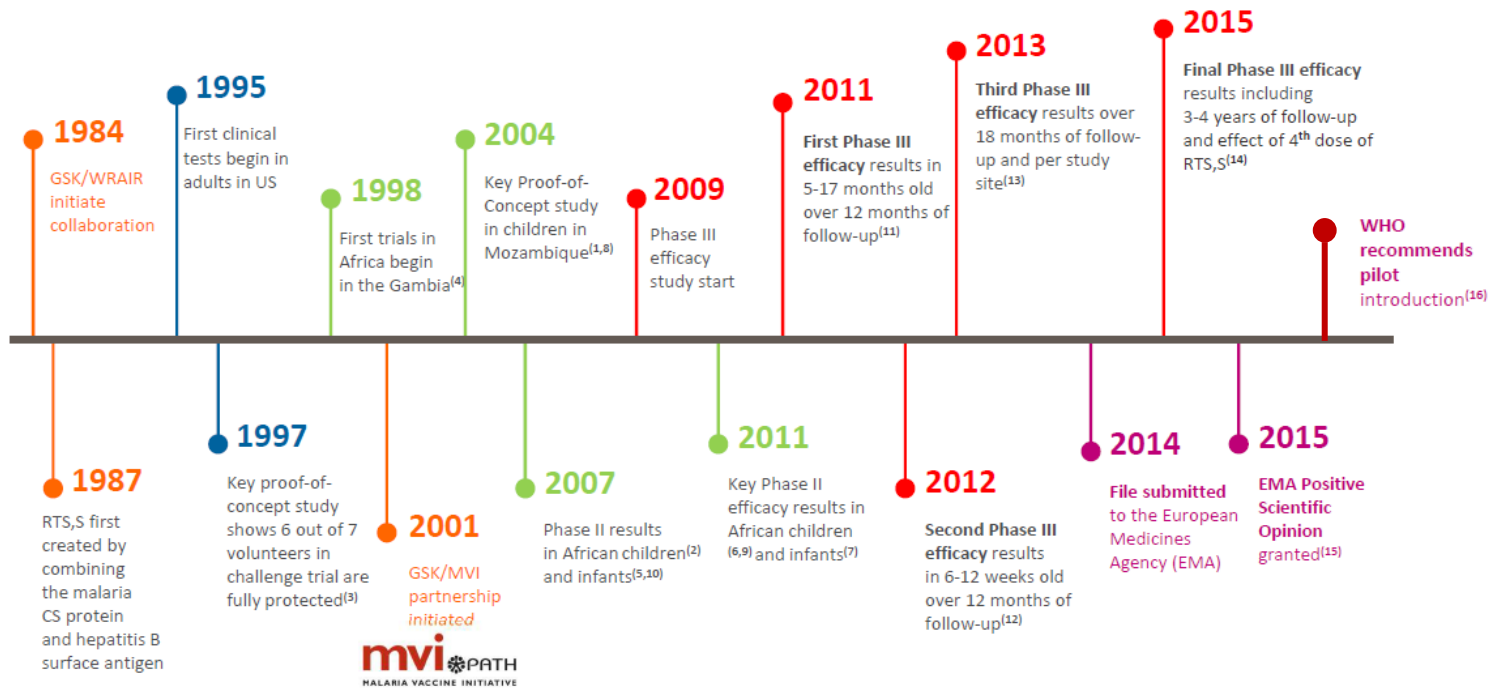


If recommending bodies are asking for additional evidence about safety, efficacy, schedule etc additional studies will be necessary, with additional investments and delays in delivering lifesaving vaccines to the people that need them

Additional steps for vaccine uptake in LMICs



Case Study: RTS,S/AS01_E (Mosquirix[®]): 30+ years in development



(1) Alonso P et al. Lancet 2004; (2) Aponte J et al. Lancet 2007; (3) Stoute J et al. NEJM 1997; (4) Doherty J et al. AJTMH 1999; (5) Bejon P et al. NEJM 2008; (6) Olotu A et al. Lancet ID 2011; (7) Asante KP et al. Lancet ID 2011; (8) Sacarlal J et al. JID 2009; (9) Agnandji ST et al. JID 2010; (10) Abdulla S et al. NEJM 2008; (11) RTS,S Clinical Trials Partnership. NEJM 2011; (12) RTS,S Clinical Trials Partnership. NEJM 2012; (13) RTS,S Clinical Trials Partnership, PLoS Med 2014; (14) RTS,S Clinical Trials Partnership, Lancet 2015; (15) www.ema.europa.eu; (16) www.who.int/immunization/research/development/malaria_vaccine_ga/en/

WHO recommended pilot implementation of RTS,S/AS01 in young African children

RTS,S/AS01 appears safe and well tolerated

Significant VE seen at all time points

Efficacy wanes, but over several years

Clear benefit of 4th dose



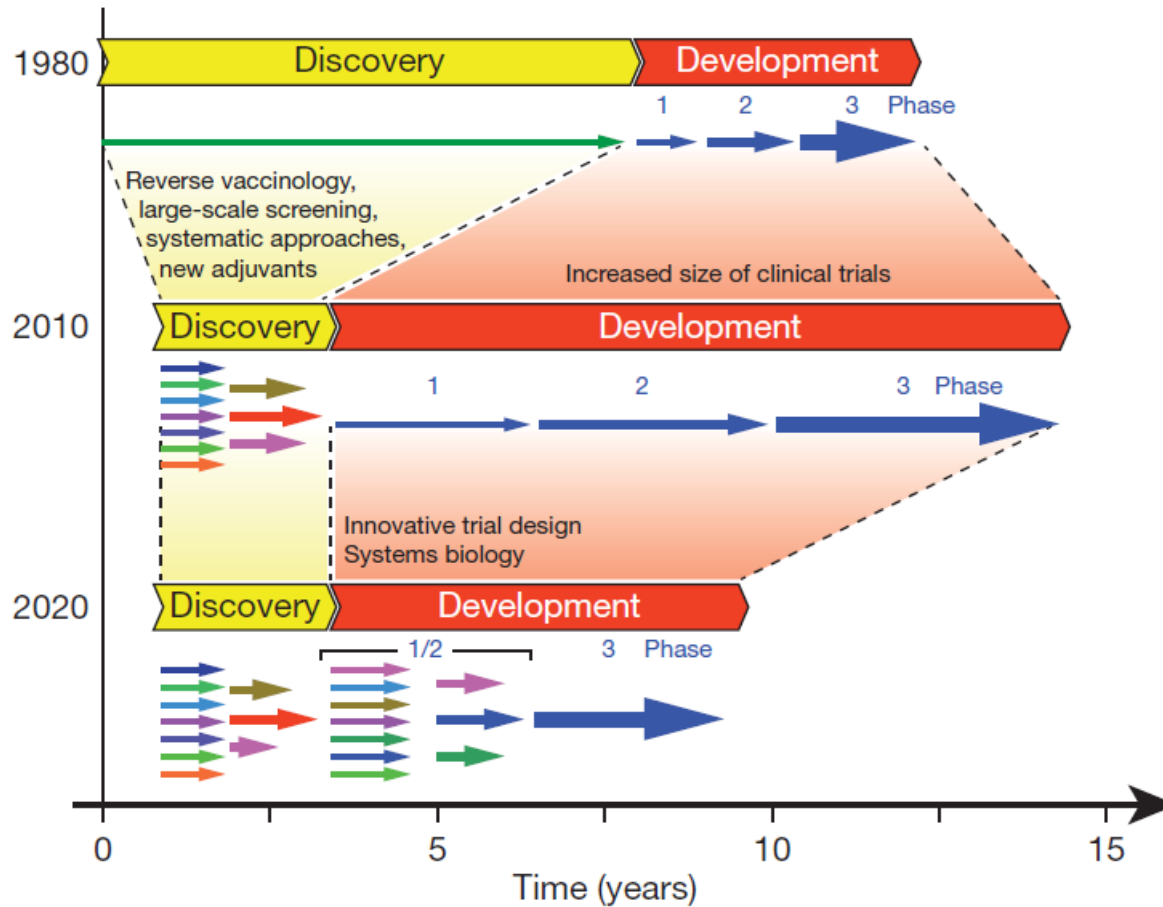
EMA Positive Opinion
for indication of RTS,S/AS01
in children aged 6 weeks to 17 months

WHO recommends implementation in young children via large scale pilot projects (January 2016)

WHO prequalification
Filing with National Regulatory Authorities

Suggestions for the future

Vaccine Vision in 2011

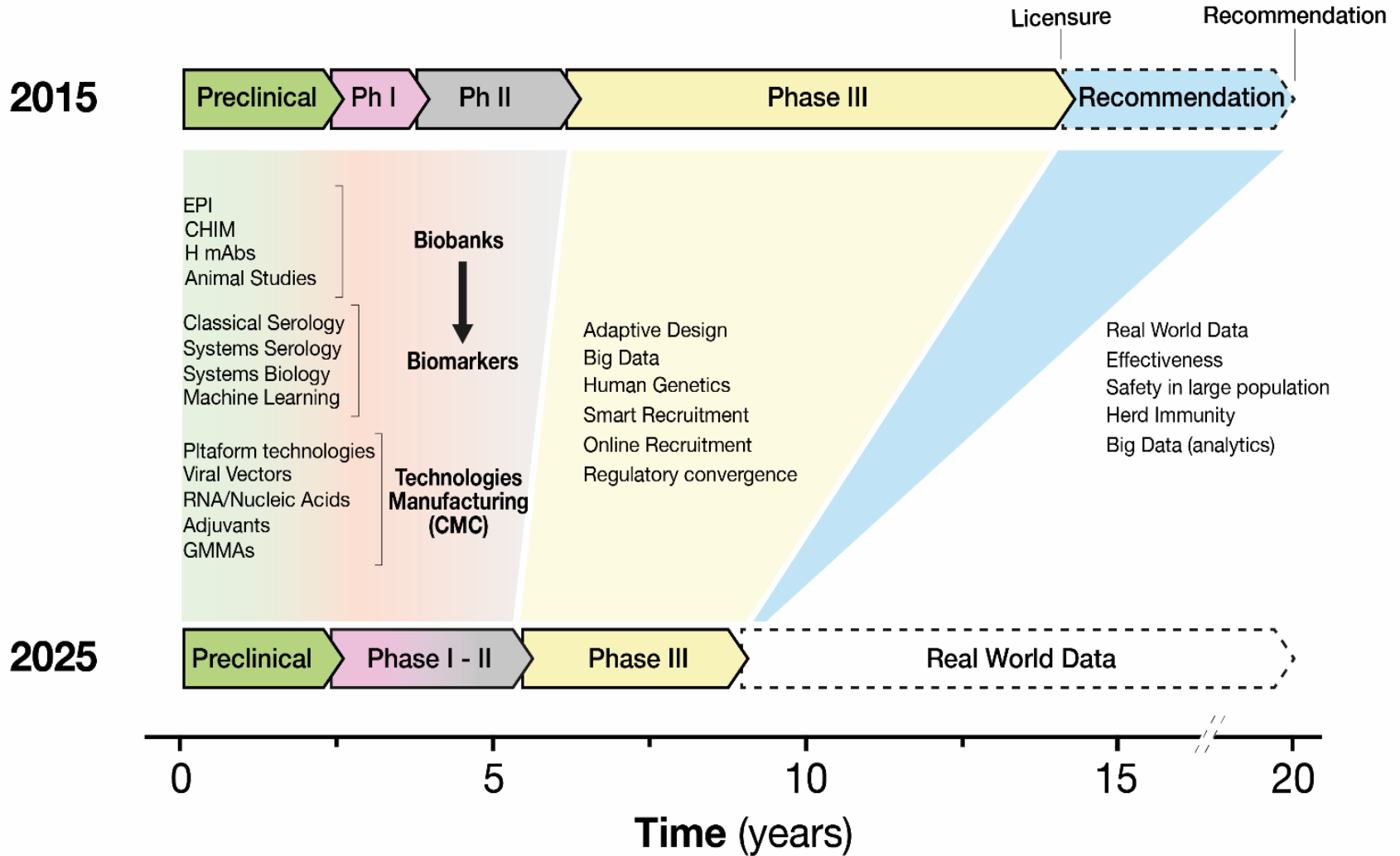


Rino Rappuoli¹ & Alan Aderem²

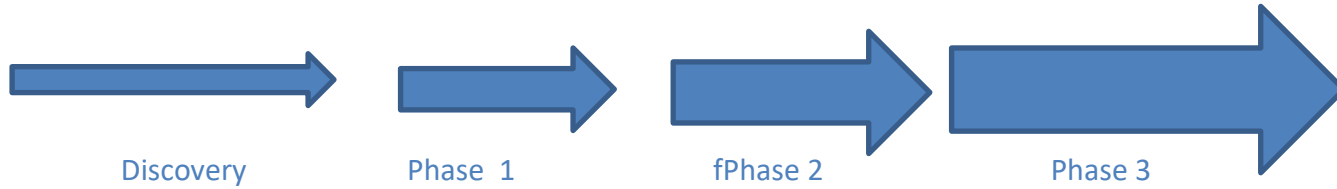
Transforming vaccine development is possible



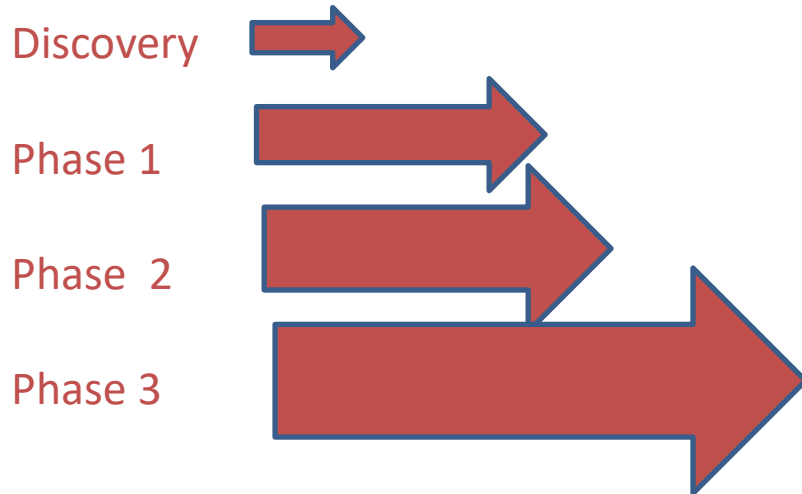
Palio meeting July 1st 2019



Vaccine development has been transformed

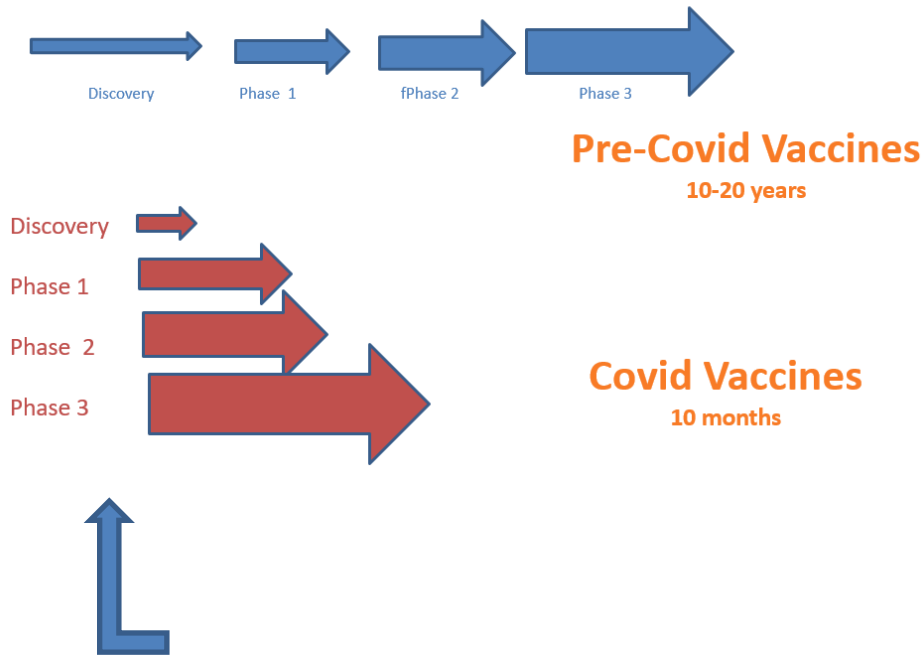


Pre-Covid Vaccines
10-20 years



Covid Vaccines
10 months

Vaccine development has been transformed



In the post-Covid era it is absolutely necessary to receive guidance from recommending bodies at the very beginning of the project

- **Clear, aligned R&D, policy, regulatory and financing processes**
- **Priorities, accountability and risks need to be shared and better coordinated**