The Veterinary Biologics Industry Response to Emerging Disease

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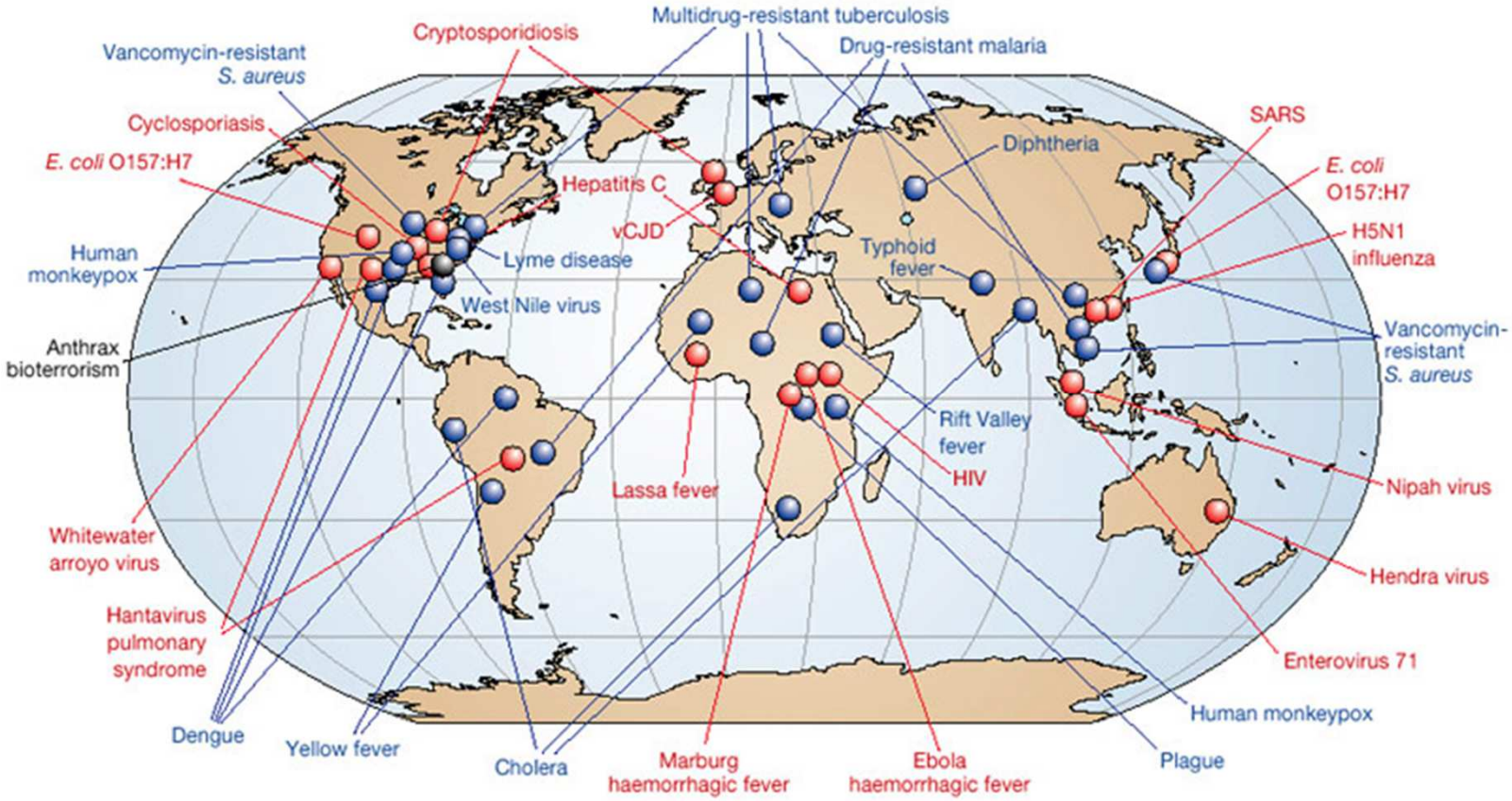
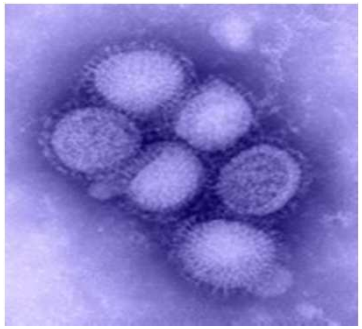
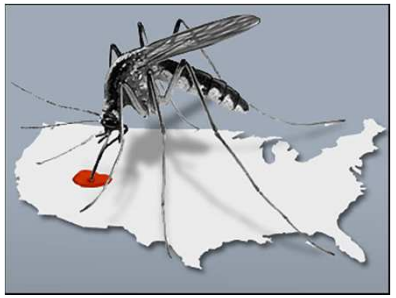
Industry Dilemma - Where to begin?



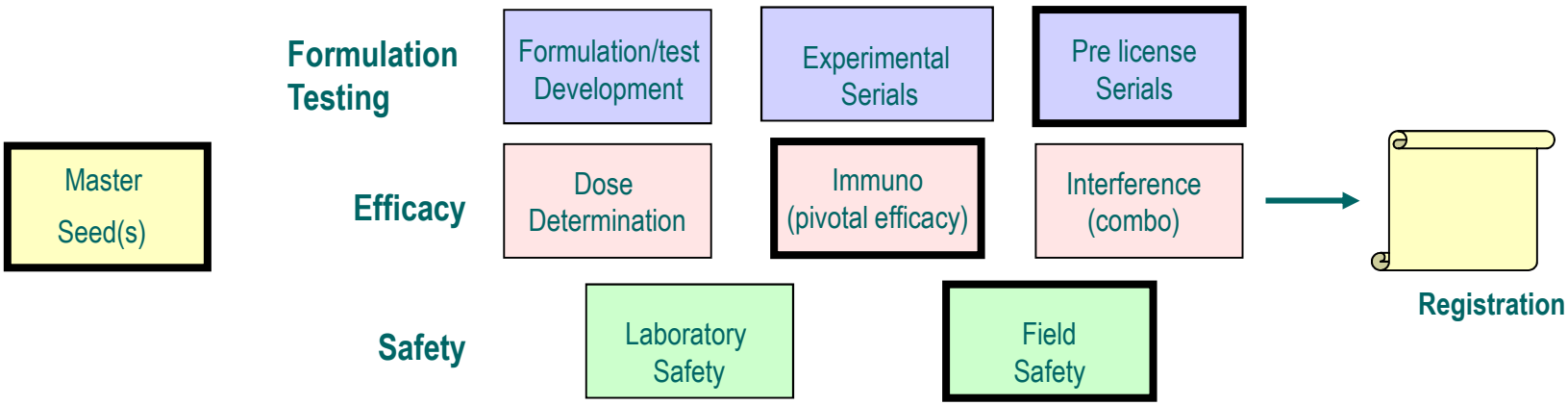
“Emerging” Scenario Considerations

- What is “Emerging”
  - Geographic Expansion – *West Nile, Rift Valley Fever, FMD*
  - Strain variance, re-assortant – *c-H3N8, a-H5N1, pH1N1 Influenza*
  - New entity (identified or “emerged”) – *CPV, PRRS, PCV*
- Species Consideration
  - Livestock
  - Companion Animal
  - Zoonotic potential
- Regulatory Considerations
  - Fast track approach availability
  - Regional control strategies
  - Stockpile plans
- Other Factors
  - Availability of technology
  - Intellectual property, Freedom to Operate
  - Severity, potential economic impact
  - Rate of spread

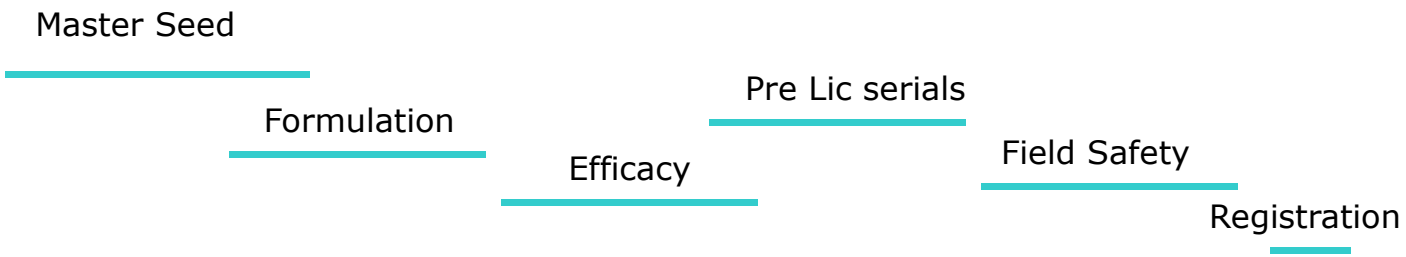




Animal Health Biological Pathway and Timeline



Timeline



2-5 Years

Timeline not to scale

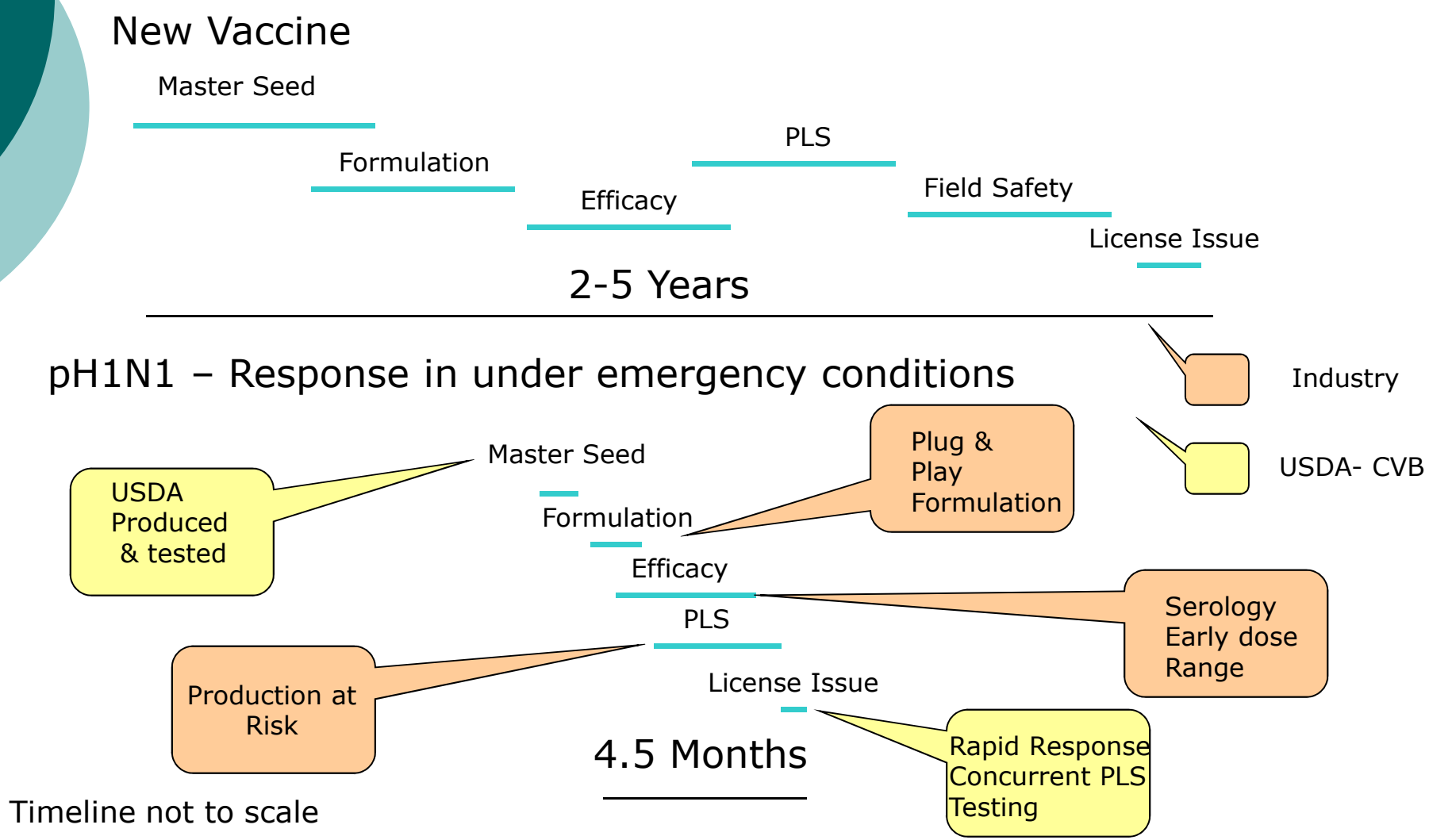
Scenario 1: Pandemic H1N1

- What is "Emerging"
  - Re-assortant – pH1N1 Influenza √
- Species Consideration
  - Livestock (swine)/Zoonotic √
- Regulatory Considerations
  - USDA Master Seed and Conditional license option √
- Other Factors
  - Availability of technology, Pfizer's Influenza platform √
  - Intellectual property, Freedom to Operate √
  - Severity, potential economic impact √
  - Rate of spread √

pH1N1 Timeline

- April 2009: Novel influenza A (H1N1) Isolated in Mexico and the United States Rapid Spread of Virus in Humans Throughout the World
- June 2009: Cases of Novel Influenza A (H1N1) reported in over 70 Countries. World Health Organization elevates the Worldwide Pandemic Alert Level to Phase 6
- June 2009 USDA VS Memorandum No. 09-10: Availability of H1N1 Influenza Virus
- Aug, 2009: Pfizer Receipt of USDA Master Seeds
- December 2009 – Conditional USDA license issued and product made available
- September 2010: Full USDA license issued

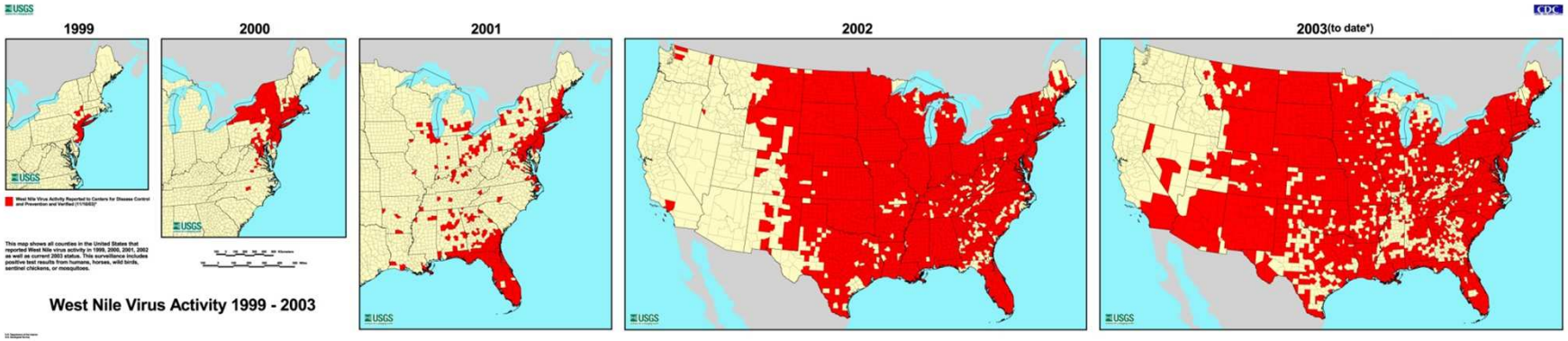
Impact on timelines – pH1N1



Rift Valley Fever

- Mosquito vectored viral disease – Africa
  - US mosquitoes are compatible vectors – similar to West Nile
  - Predominantly in cattle, sheep, and goats
- Epidemics occur when vertebrates that develop high viremia are present
  - Arthropod, direct and aerosol transmission from blood documented
  - Established epidemics in new territory: Egypt, Saudi, Yemen
- Potential for intentional spread

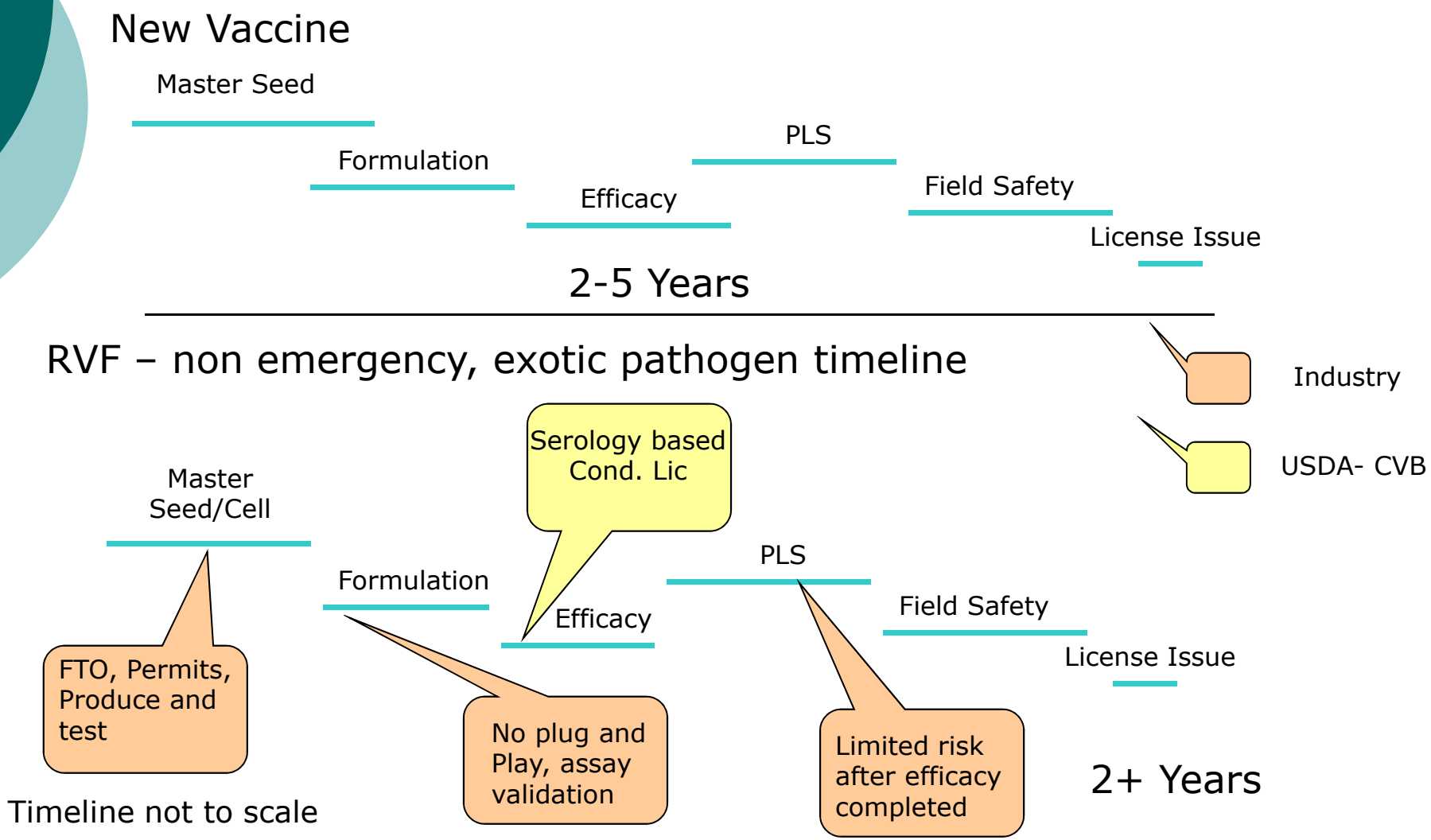
West Nile Example



Scenario 2: Rift Valley Fever

- What is "Emerging"
  - Geographic Expansion – Rift Valley Fever
- Species Consideration
  - Livestock (cattle/sheep)/Zoonotic √
- Regulatory Considerations
  - Pathway defined
  - US Conditional license option √
  - Stockpile potential
- Other Factors
  - Technology is available√
  - Freedom to Operate √
  - Severity, potential economic impact √
  - Rate of spread
- Missing
  - Drivers to accelerate a risk based or high technology program

Impact on timelines – RVF



Key Learning's

- Industry will use a risk based development process driven by public perception, actual need and financial considerations
- “Plug and Play” production and testing systems are critical to rapid response
- Open and frequent dialog with regulatory agency coupled with agreed on development plans are critical for a rapid response
- Pfizer and USDA have demonstrated the industry can respond rapidly in an emergency situation
- Rapid response requires an appropriate risk analysis based approach by both industry and government