

## **Pandemic Preparedness and Response: Lessons Learned from H1N1**

# **H1N1 Vaccine Production: The Industry Perspective**

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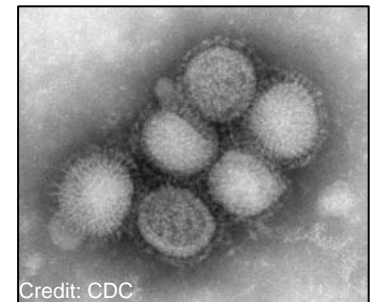
# Learning from the H1N1 pandemic

## ➤ Global collaboration led to most comprehensive response ever:

- Robust preparedness underpinned response: vaccine development, regulatory procedures & production capacity established before pandemic
- First vaccine approvals 3 months after pandemic declaration
- 3 months later >50 countries had initiated vaccination; significant vaccine supplies provided & industry responded to meet changing government needs
- Vaccine safety confirmed by extensive monitoring
- Global collaboration overcame technical challenges

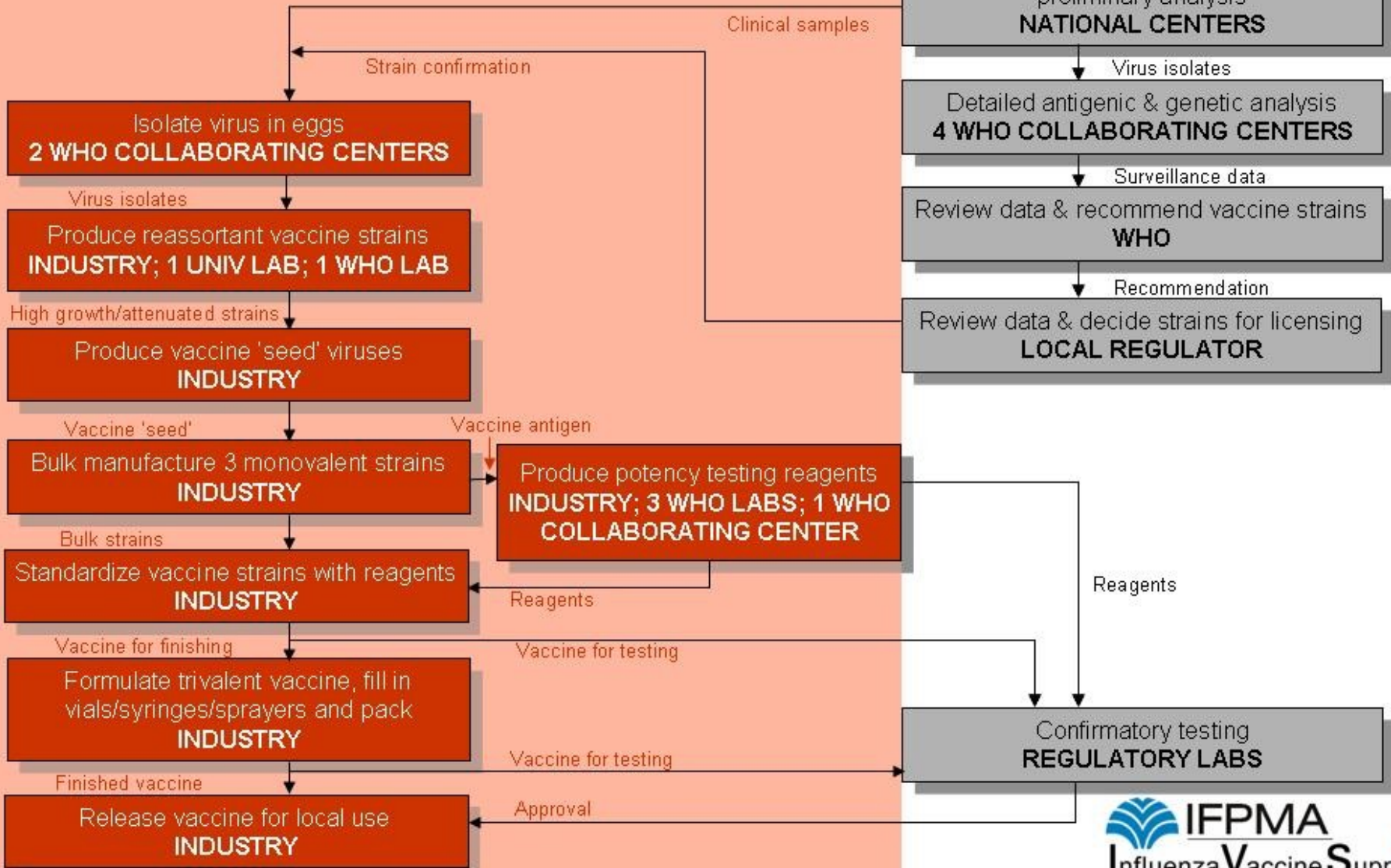
## ➤ Strengthening future preparedness:

- All stakeholders have a role to play
- Enhanced technical, regulatory, logistics & coupled with a reduction in bureaucratic processes could accelerate vaccine supply
- Information and communication is key
  - New approaches required to educate public and healthcare workers, to communicate risk/benefit, to drive vaccination and to counter mis-information



# WHO Network & standardized vaccine production

## VACCINE-RELATED ACTIVITIES ARE SUPPORTED FINANCIALLY & TECHNICALLY BY INDUSTRY



# WHO / IFPMA & Other Influenza Vaccine Manufacturers Technical Teleconferences



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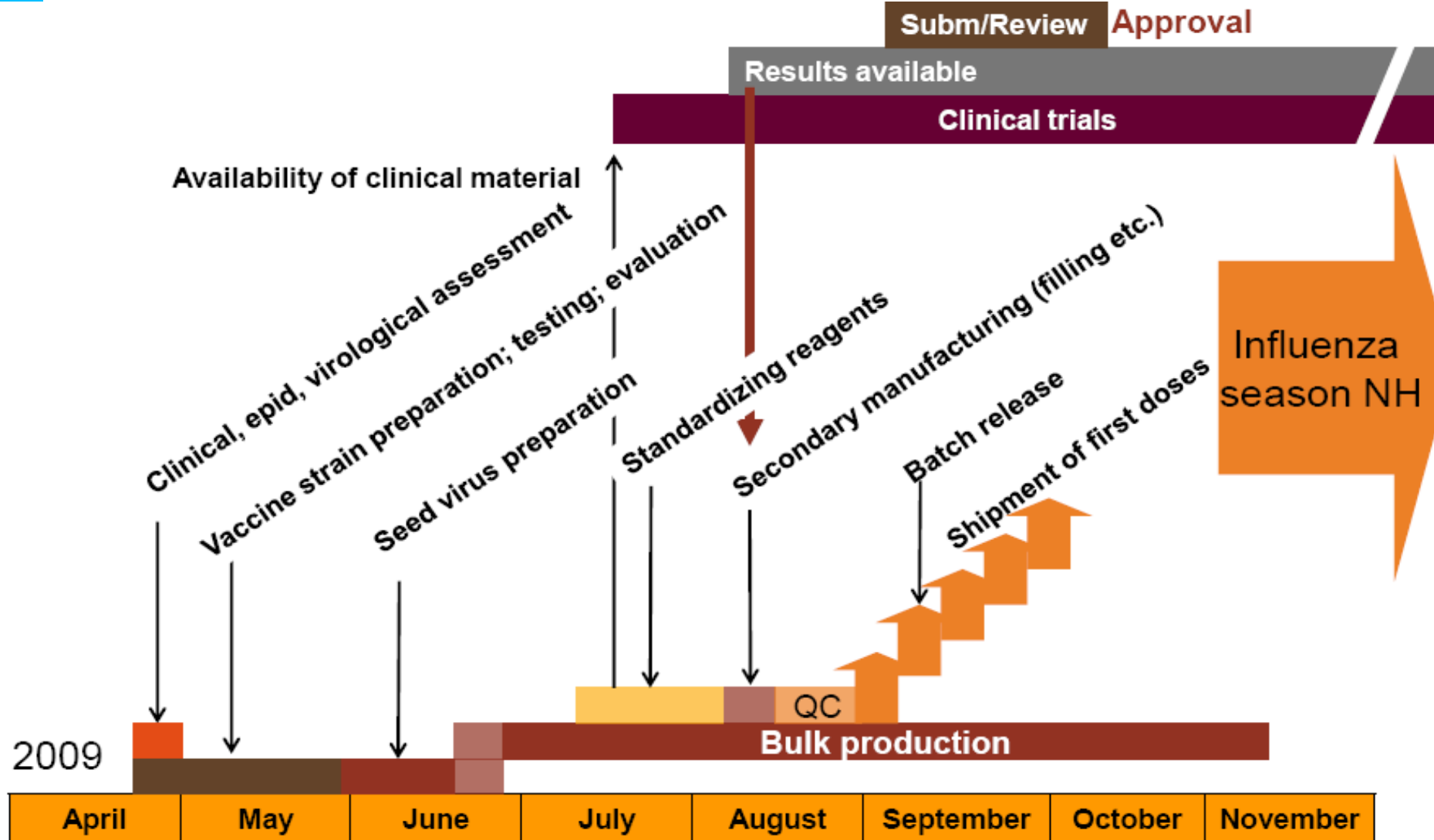
Starting in June 2009, weekly teleconferences on H1N1 were set up between WHO, ERLs, CCs, reassortant producers and manufacturers.

- Information on availability of all H1N1 influenza reassortant viruses
- Initial potential yield information.
- Information on biocontainment requirements and issues.
- Feedback from manufacturers on virus growth and yield characteristics.
- Consensus on which H1N1 reassortants to use for vaccine production.
- Timelines for SRD reagent production and availability.
- Advice on possible regulatory pathways.

# H1N1 Vaccine Production Timelines



International Federation of Pharmaceutical Manufacturers & Associations



# Building on H1N1: strengthening preparedness

# R&D Industry's role in preparedness



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## ➤ Sustaining appropriate production capacity:

- Expansion to 4.9 billion doses annual pandemic capacity (WHO estimate)
  - 3 billion doses for H1N1 due to reduced yield
  - 570 million doses produced based on actual demand
  - Sustainability - Further capacity expansion or technology transfer requires global growth in seasonal vaccine uptake

## ➤ Enhancing vaccine performance & production:

- Adjuvant, whole virion & cell culture technologies played a role against H1N1
- Long-term 'at-risk' investment requires supportive intellectual property system

## ➤ Supporting developing country supply:

- Donations (166m H1N1 doses pledged against 200m dose WHO target)
- Tiered-pricing approaches; reserved production capacity

## ➤ Supporting WHO Network:

- Technical assistance to enhance capabilities
- Industry support, including funding, for pandemic-vaccine related activities



## ➤ Technical enhancements to WHO Network:

- Production yields with initial H1N1 strains were 1/3 – 1/2 level of good seasonal strain: system to evaluate multiple strains could accelerate manufacture
- Reagent production proved challenging: adoption of additional standardization techniques could speed up vaccine supply

## ➤ Process efficiencies:

- Enhance pre-qualification process: currently follows national approval and site inspections required even if complete for seasonal vaccines or by competent local authority
- Establish advance supply agreements to reduce administrative delays

## ➤ Innovative financing mechanisms:

- Innovative financing supports many ambitious immunization programs
- 'Pandemic Influenza Fund' could support voluntary contributions to provide sustainable preparedness

## ➤ Accurately assessing pandemic vaccine demand:

- H1N1 shows demand is *not* a simple function of population; many factors play a role

## ➤ Establishing advance supply agreements:

- Largely not in place for H1N1: agreements assist planning & avoid intense time pressures

## ➤ Reducing regulatory duplication and bureaucracy:

- Mutual recognition of data & approvals avoids unnecessary duplication of clinical & lot release testing; reduction in bureaucracy would accelerate vaccine availability

## ➤ Supporting emergency response efforts:

- Many governments supported H1N1 vaccination in developing countries; international community contribution to preparedness enhances access to vaccines

## ➤ Developing vaccine deployment infrastructure:

- Building on existing capabilities (eg UNICEF) would assist supply in developing countries

## ➤ Supporting demand for seasonal influenza vaccines:

- Seasonal uptake offers health gains and supports pandemic vaccine production capacity

# In conclusion

# Global collaboration is essential for strong & sustainable preparedness



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All stakeholders have crucial and unique role to play

- Leverage H1N1 pandemic experience
- Growing manufacturing capacity through innovation and sustainable expansion
- Driving development of innovative technologies through a supportive IPR system
- Encouraging voluntary contributions from all stakeholders
- Establishing innovative financing to support long-term sustainability
- R&D Industry underlines support, including financial, for WHO Network's pandemic vaccine related work
- Virus-to-vaccine is only part of the complex story – must not forget the importance of getting vaccine into people