



## INVESTOR / ANALYST SITE TOUR

11<sup>th</sup> March 2016  
LIVERPOOL

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## INTRODUCTION

Gordon Naylor, President



# The global burden of seasonal influenza remains high

Each year, influenza related illness:

- Attacks **5%–10%** of adults and 20-30% of children globally<sup>1</sup>
- Causes **3 million – 5 million** cases of severe illness<sup>1</sup>
- Causes up to **500,000** deaths annually<sup>1</sup>
- **All** countries are affected
- Significant economic costs: Medical care and lost labour in the US alone costs up to **USD \$17bn** annually



## Northern hemisphere

Influenza peak:  
November–March

## Tropics

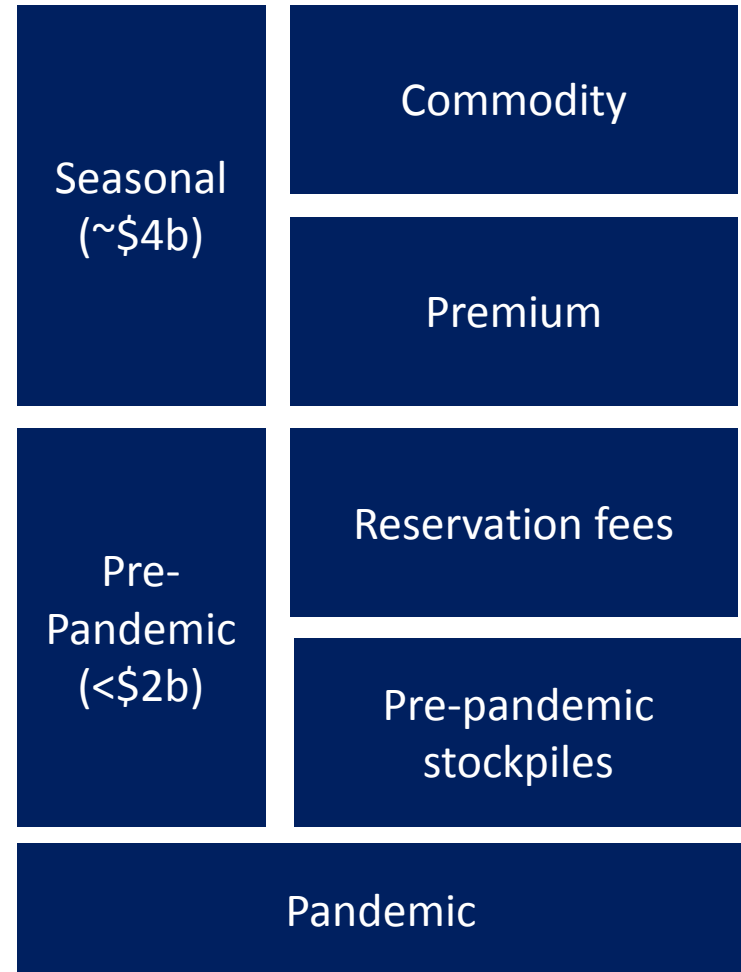
Year-round activity

## Southern hemisphere

Influenza peak:  
April–September

# Industry Overview

- ~\$6b global market including pre-pandemic
- Seasonal market growing at low single-digits pa
- Distinct but related segments, with different competitive and growth characteristics



# Seqirus Today

## GLOBAL

- Influenza

## AUSTRALIA/NZ

- In-licensing
- Contract logistics
- Immunohaematology
- Products of national significance:  
Q-fever vaccine and anti-venoms

CSL™

CORPORATE FUNCTION

OPERATIONAL BUSINESSES

CSL R&D

**CSL Behring**  
Biotherapies for Life™

**Seqirus™**  
A CSL Company

**CSL Plasma**  
Good for You. Great for Life.



# Seqirus Manufacturing Sites & Commercial presence

□ ~1900 employees

□ Capacity Northern Hemisphere ~130mds\*(projected QIV)

*\*Assumption is QIV, ~34 weeks of NH campaign (@ 7 day / week operation)*

## Highlights

World's no. 2 influenza vaccine provider in sales with operations in more than 20 countries.

### State-of-the art manufacturing

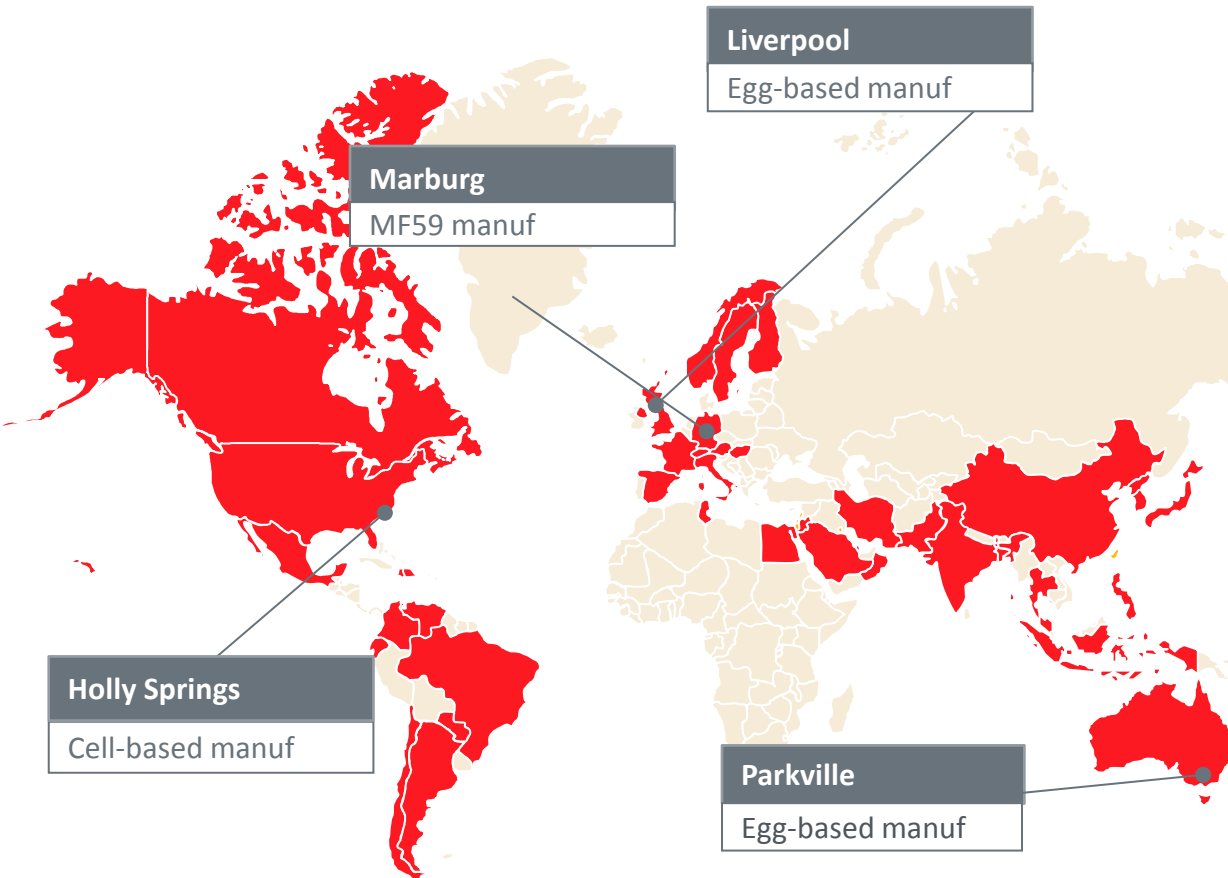
**Liverpool:** Manufacture of egg-based influenza vaccine

**Holly Springs:** Largest cell culture derived flu vaccine facility in the world, incl MF59 (adjuvant) production & pre-filled syringe capacity

**Marburg:** MF59 production

**Parkville:** Manufacturing of egg-based influenza vaccine

World's only manufacturer of Q-Fever vaccine, and a manufacturer of antivenoms for human use since the 1930s.





# Leadership Team



**President**  
**GORDON NAYLOR**



**SVP Commercial  
Operations**  
**BRENT  
MACGREGOR**



**SVP Business  
Services**  
**KEN LIM**



**SVP Operations**  
**STEVE MARLOW**



**VP Human  
Resources**  
**TANYA KENNEDY**



**SVP R&D**  
**RUSSELL BASSER**



**VP Quality**  
**VAS MAVROGENIS**



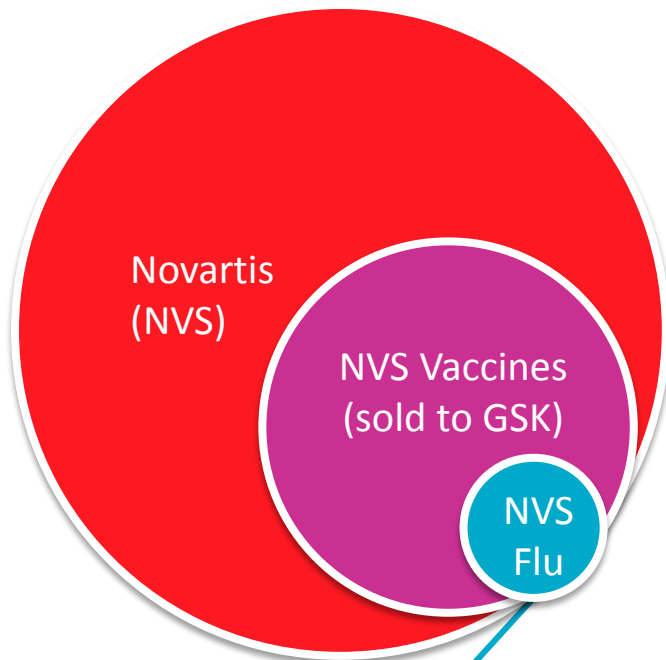
**VP Finance**  
**HELEN GEARING**



**Global Head Legal**  
**JOHN MINARDO**



# Integration & Turnaround Update



## Included:

- Most manufacturing assets, commercial footprint & people

## Not included:

- IT systems & infrastructure

- Acquisition was a carve out from a carve out
- Integration progressing well:
  - Transaction closed on 31 July 2015
  - Combined leadership team and organisation re-design
  - New global headquarters in Maidenhead, UK
- Major project underway to establish IT platform, including greenfield SAP

# Success Plan

Complete integration

Improved focus /  
efficiency

Step down in R&D

Launch new products

Innovation

- Remaining elements of organisational design
- IT
- COGS, speed to market, quality, customers, Government
- Reduction in spend as complete clinical development programs
- Bring pipeline to market
- Shift to differentiated products
- Enhanced profitability facilitates margin expansion while funding innovation

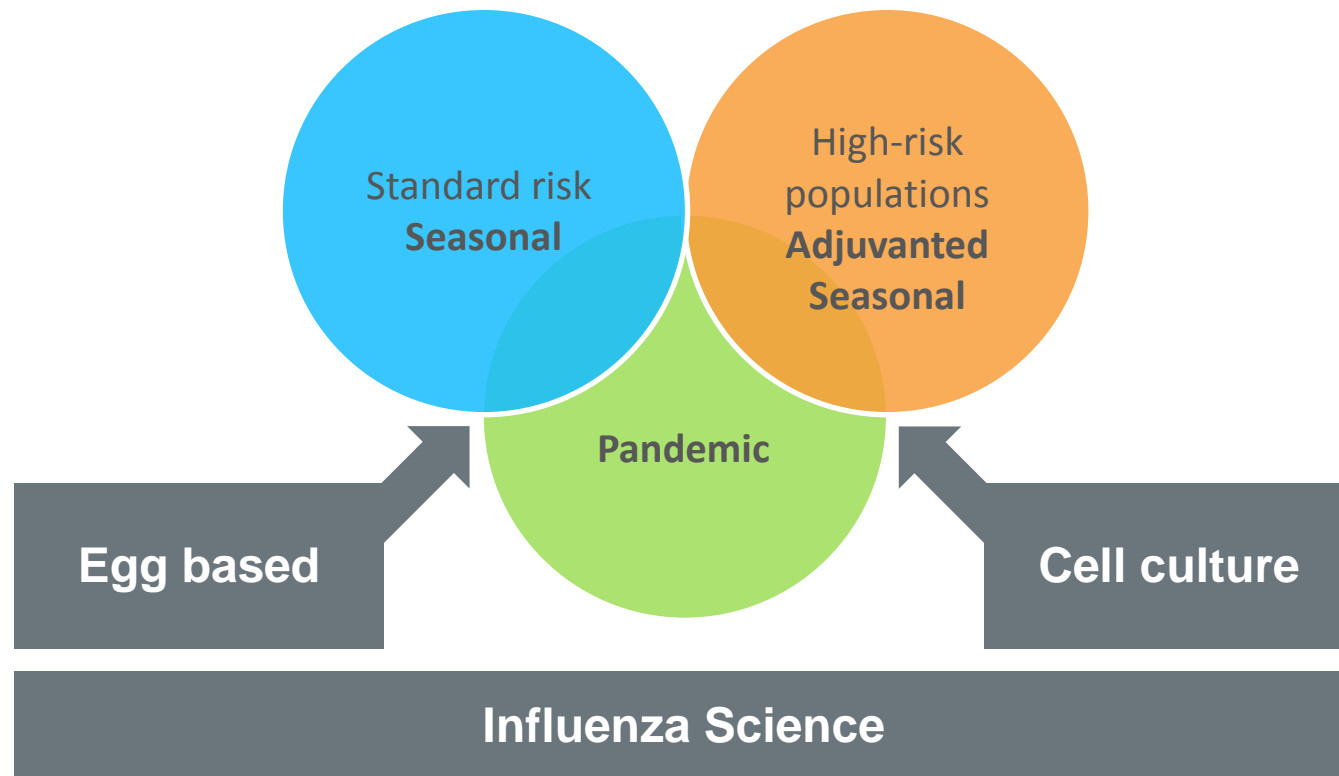


## SEQIRUS RESEARCH & DEVELOPMENT

Russell Basser, SVP R&D



# Seqirus Influenza Vaccine Platform



# The difference between epidemic vs pandemic influenza

## ANTIGENIC DRIFT

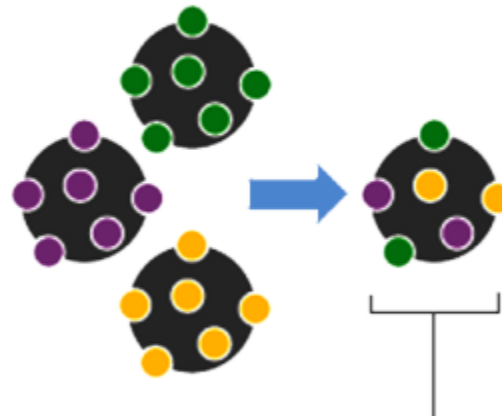


Small mutations

*Epidemic*  
(yearly)

*May vary season to season*  
*SH vs NH*

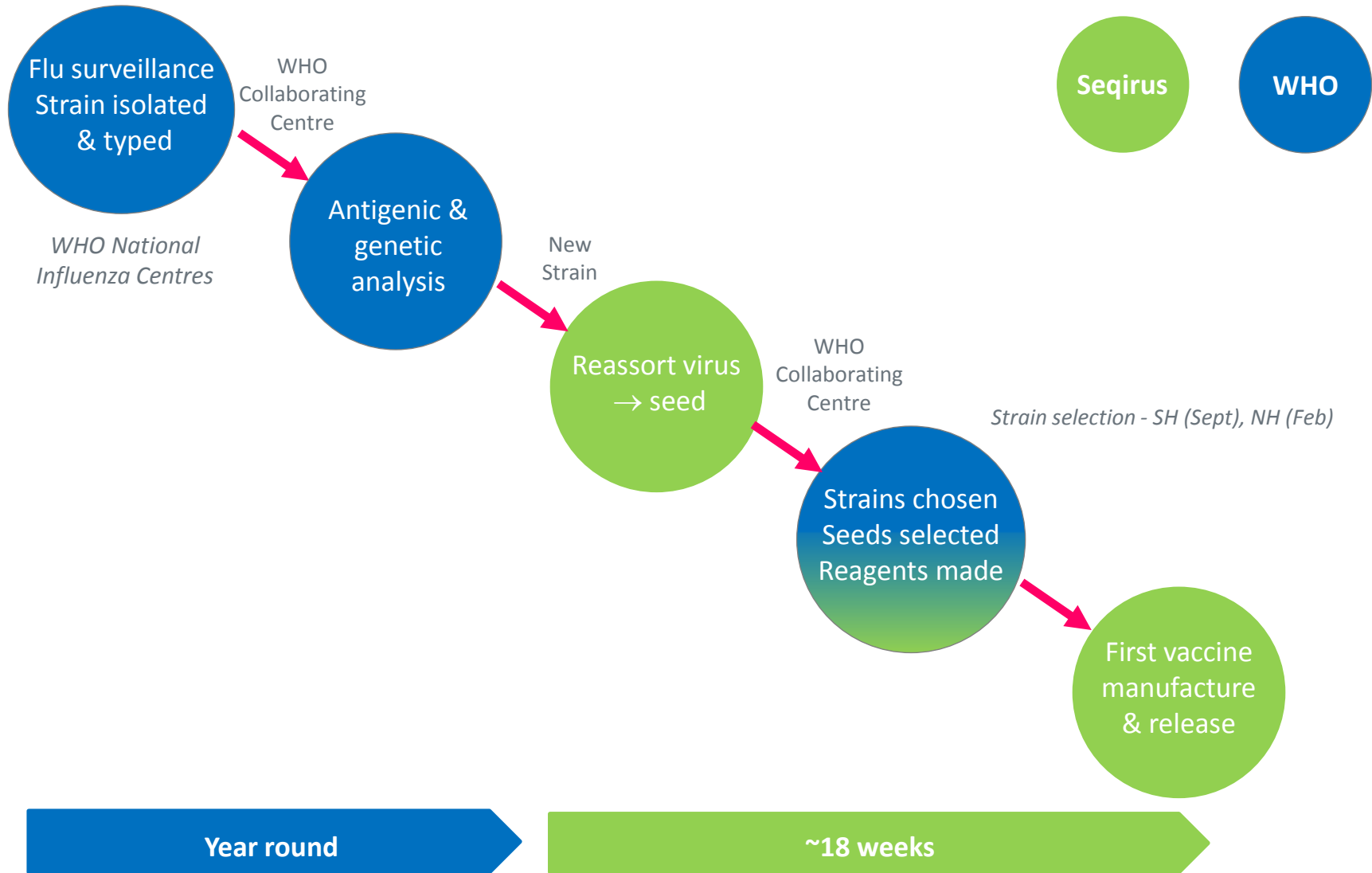
## ANTIGENIC SHIFT



New strain

*Pandemic*  
(occasionally)

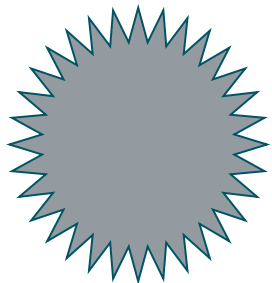
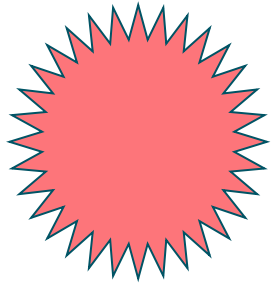
# Identification and preparation of seasonal influenza vaccine strains (1)



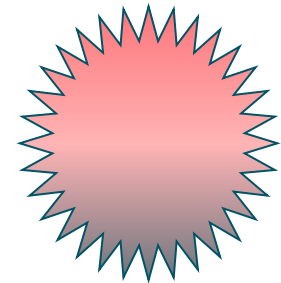
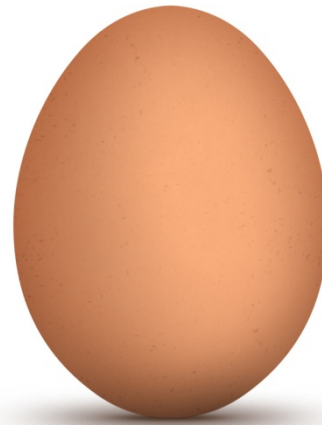
# Identification and preparation of seasonal influenza vaccine strains (2)

## *Adaptation of virus for growth in eggs (reassortment)*

Seasonal strain



High growth donor strain



Selection based on

- seasonal HA and NA
- high growth properties



# The difference between Trivalent (TIV) & Quadrivalent (QIV) Influenza Vaccine

**Trivalent vaccine** = two A strains + “dominant” B strain

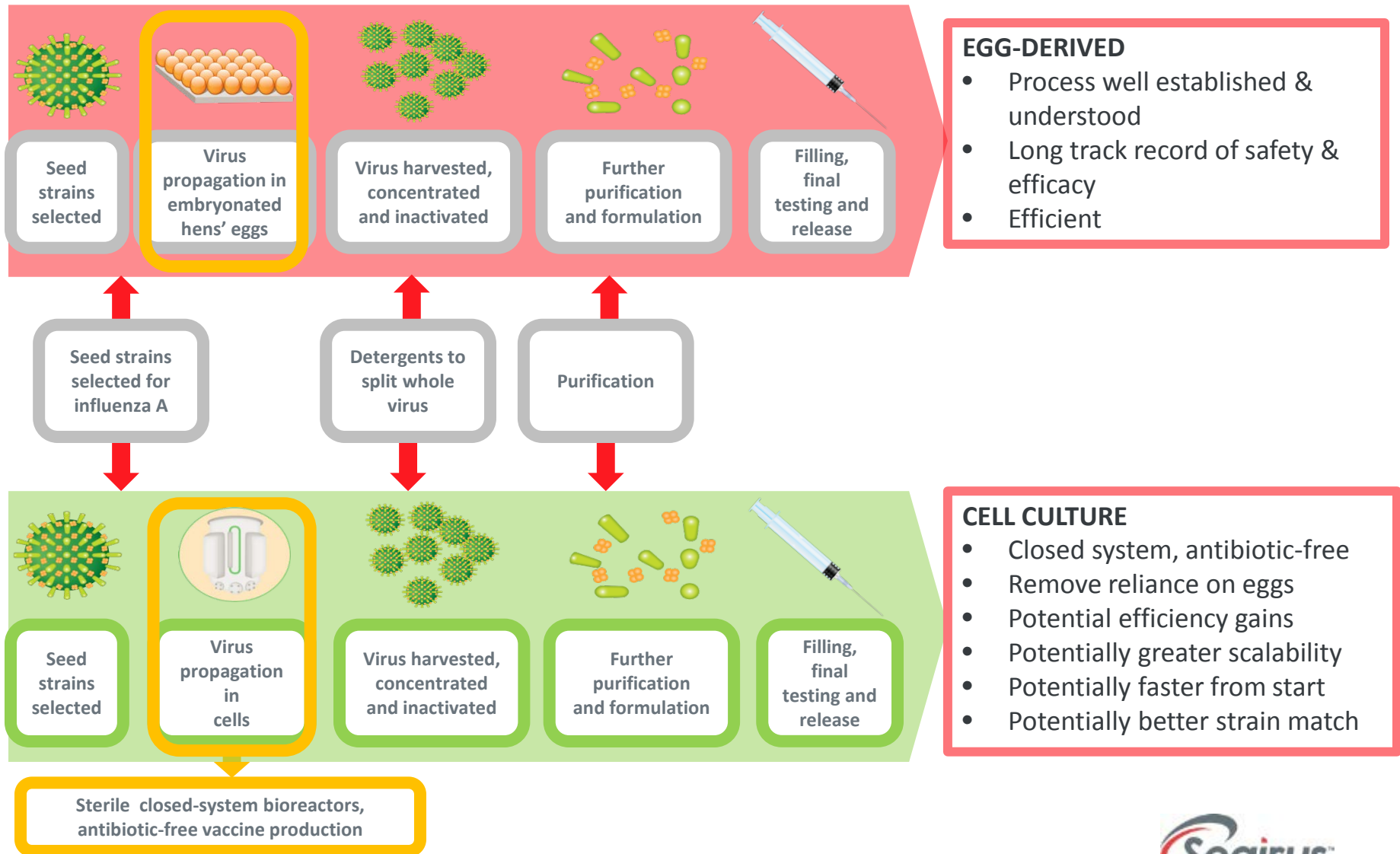
**Quadrivalent vaccine** = two A strains + two B strains

## WHO Influenza Collaborating Centres

- select strains for vaccine twice per year – SH (Sept), NH (Feb)
- determine likely dominant B strains

Type A influenza	Type B influenza
2 circulating strains (H1N1, H3N2)	2 circulating strains (B/Victoria, B/Yamagata)
One maybe dominant	One tends to be dominant
Can cause significant clinical disease	Tends to cause milder disease
Infects humans, other species (birds, pigs, etc)	Limited to humans

# Egg vs cell culture manufacturing of influenza vaccine



# Benefits of MF59 Adjuvant in seasonal and pandemic influenza vaccines

FLUAD™	MF59	
Improved efficacy	Antigen Sparing	Cross-reactivity
Pediatrics - efficacy 86% vs 43% non-adj. <sup>1</sup> Elderly - ↓ hospitalization by 25% <sup>2</sup>	Especially pandemic vaccine	Improved breadth of immune response
Extensive Safety Data		
<ul style="list-style-type: none"> <li>Fluad™ licensed in 30 countries (1st approved Italy 1997)</li> <li>&gt;100 million doses of MF59 adjuvanted vaccines distributed <ul style="list-style-type: none"> <li>76 million seasonal Fluad™ (elderly)</li> <li>~25 million H1N1 pandemic (incl pregnant women / young children)</li> </ul> </li> <li>Data in ~120,000 subjects from clinical studies</li> </ul>		

1. Vesikari et al, *N Engl J Med*. 2011;365:1406-16.

2. Iob et al, *Epidemiol Infect*. 2005;133:687-693; Mannino et al, *Am J Epidemiol*. 2012;176:527-53; Van Buynder et al, *Vaccine* 2013;31:6122-8.

# Key R&D Influenza Vaccine Programs



TIV

4+ under review in US

Currently **approved for 18+ yrs in US**  
Paediatric (4+yrs) under review  
[Link to QIV program](#)

Cell culture QIV

Under review in US

Target 4+ years



TIV

Approved

Long standing approval in EU  
Approved 6M-2 yrs, 65+ yrs Canada  
Approved 65+ yrs US 2015

Adjuvanted QIV

Phase III completed

Age 6M to ≤6yrs – filing Q1 2017

Phase III

Age ≥65yrs – pivotal study to commence 2016



QIV

Under review in US & AUS

Age ≥18yrs

QIV

Phase III completed

Age ≥ 5yrs – 18yrs



QIV

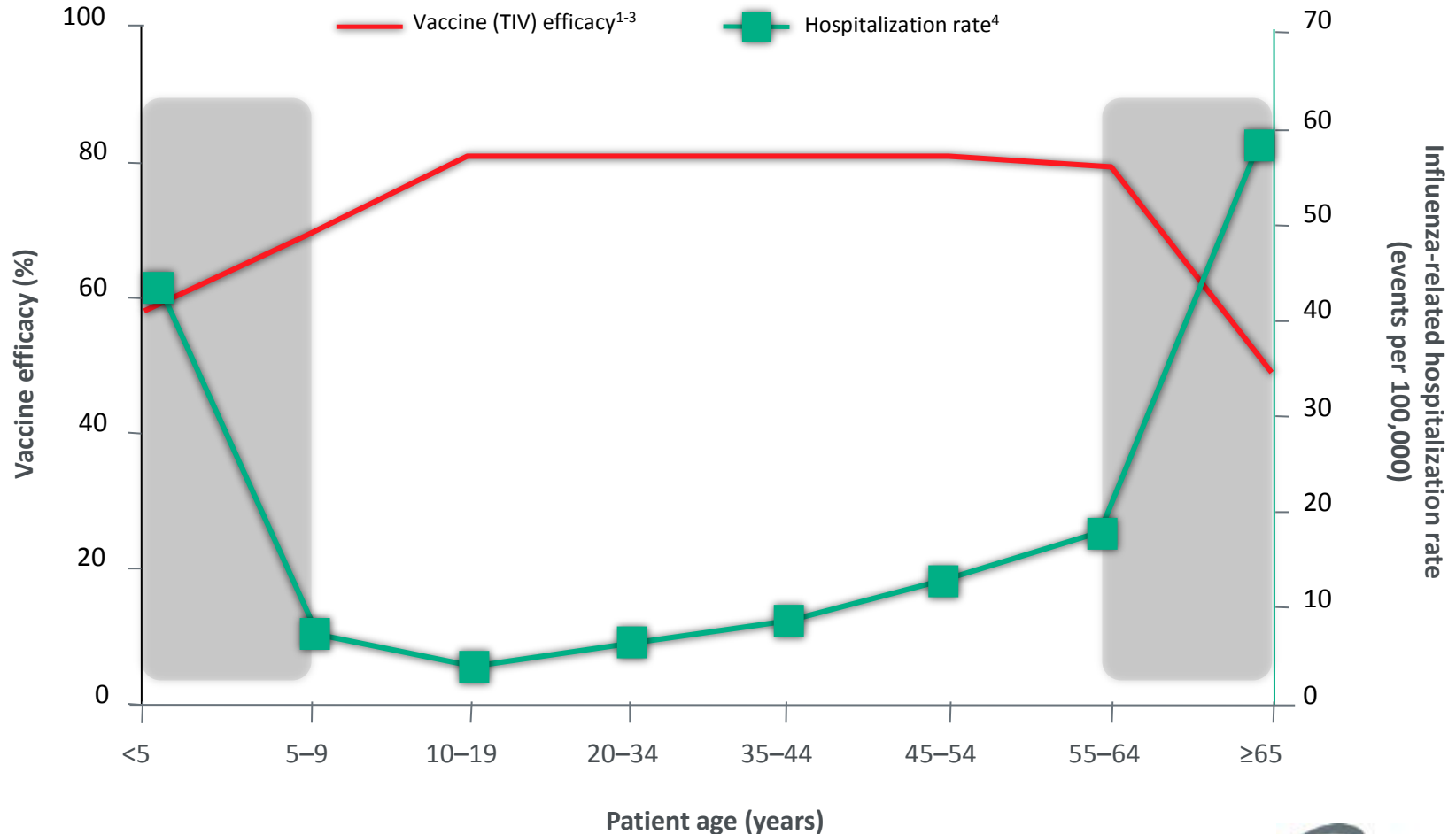
Phase III

Age ≥ 6mo - <5yrs – pivotal study to commence 2016

# Why Adjuvanted Vaccines

## Targeting age groups at high risk

Age-related hospitalizations and TIV efficacy rates



# Future directions for influenza vaccine innovation

## *Alternate routes of delivery*

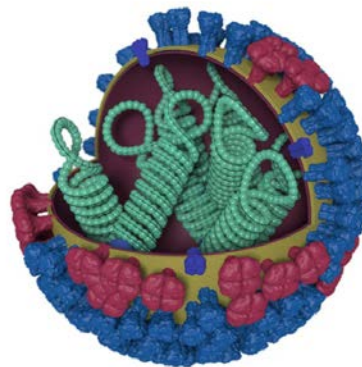


## *Novel sources of antigens*



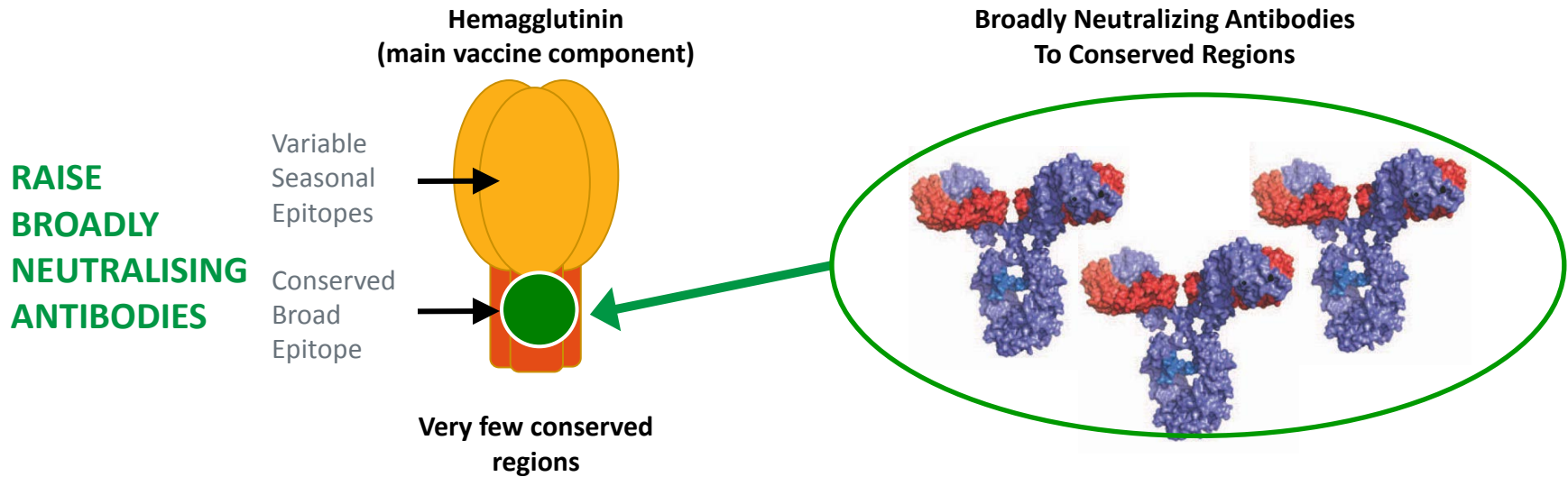
## *Universal vaccine*

AN INFLUENZA VIRUS

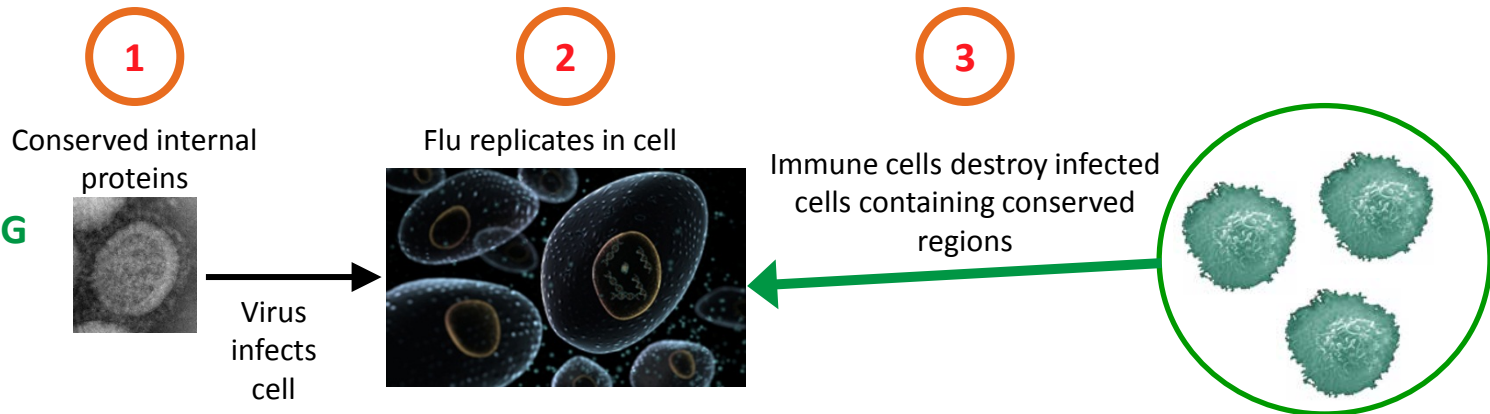


# Universal flu vaccine - target conserved parts of virus

*Goal to find 'Achilles heel/s' present in all flu viruses*



**RAISE BROADLY NEUTRALISING IMMUNE CELLS**







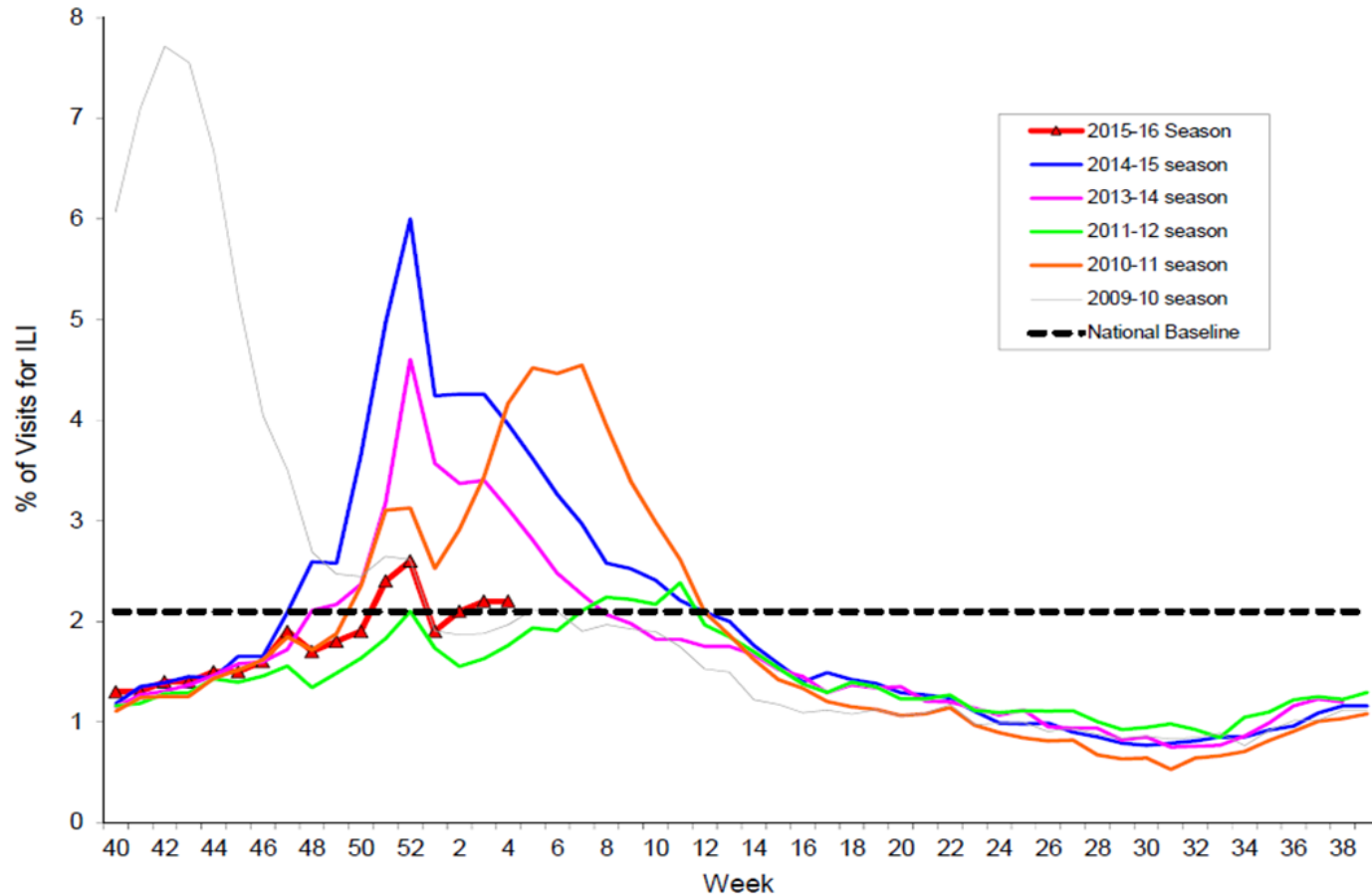
## SEQIRUS COMMERCIAL

Brent MacGregor, SVP Commercial  
Operations



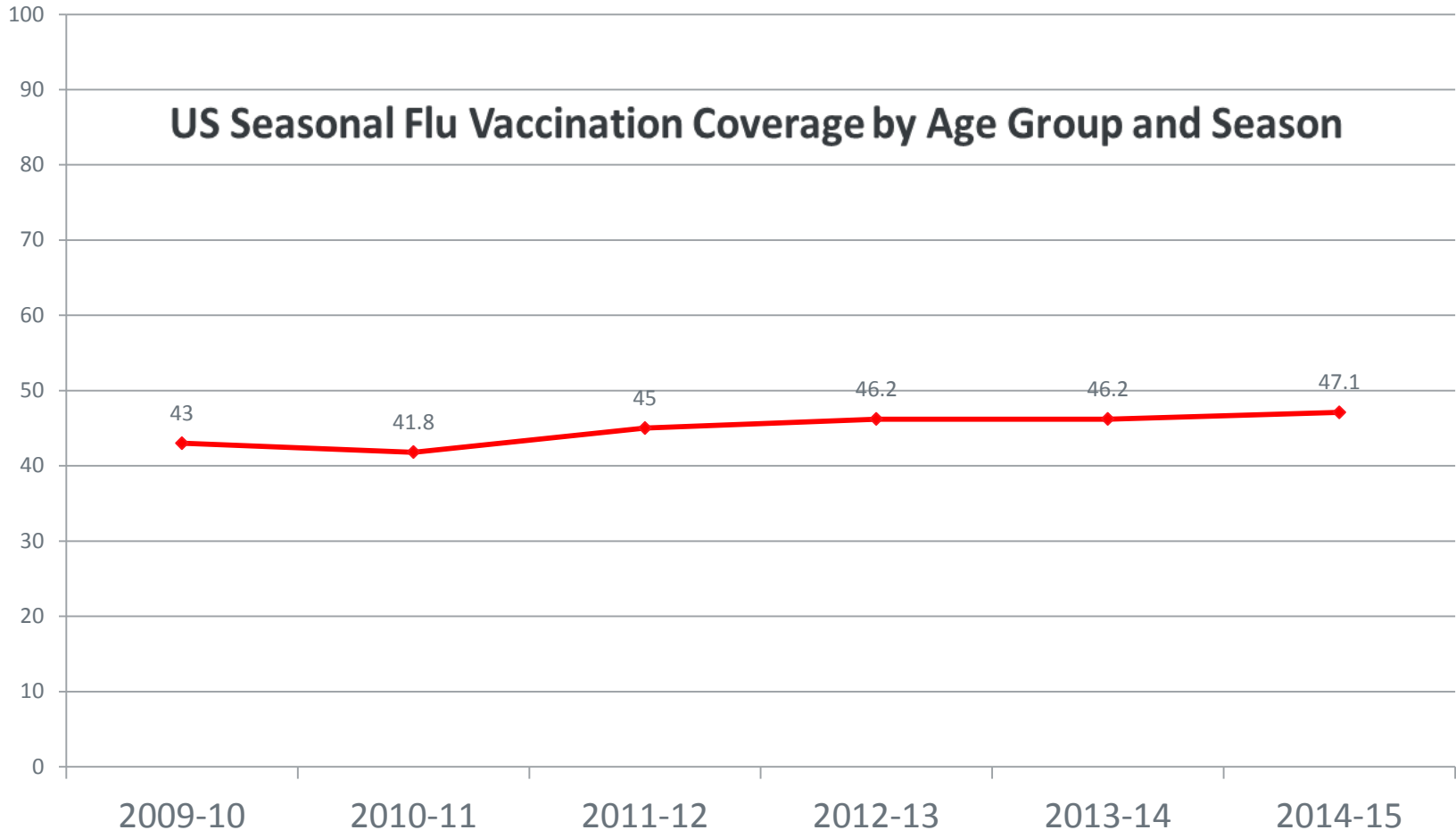
# Influenza causes significant hospitalizations each year

Percentage of Visits for Influenza-like Illness (ILI) Reported by the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), Weekly National Summary, 2015-2016 and Selected Previous Seasons










In the US there has been modest growth of vaccination rates despite 2010 universal recommendation








Source: National Immunization Survey-Flu (NIS-Flu) and Behavioral Risk Factor Surveillance System (BRFSS), <http://www.cdc.gov/flu/fluview/coverage-1415estimates.htm>. Accessed November 19, 2015.

# Our commercial focus for the coming years will be around five key drivers of growth

1		Launch Fluad 65+ in the US market in the elderly segment first, followed by the pediatric segment
2		Maintain our TIV offer in the near-term while launching our QIV offer
3		Grow our RapiVab business as a convenient intravenous offer in the hospital-setting emergency department
4		Focus our efforts on our key markets in the near-term: US, Europe, Australia
5		Optimise our pandemic and pre-pandemic enterprise to reinforce our reputation as a partner-of-choice in pandemic preparedness

## Seqirus provides a differentiated portfolio of vaccines and treatment for influenza that we will continue to improve

Brand	Age Indication Today	Planned Future Age Indication	Target Offer
	65+ years	6 mths-6 years 65+years	QIV
	18+ years	4+ years	QIV
	18+ years	6mths+	QIV
	18+ years	5+ years	I.V.
<b>Influenza Virus Vaccine Fluvirin®</b>	4+ years	4+ years	TIV
	6mths+	6mths+	TIV



Our product strategy: adjuvanted QIV product in Pediatric and Elderly and egg or cell-based QIV for the general population



6m - 6y

Fluad  
Pediatric  
(aQIV)



65y+

Fluad  
(aQIV)



General population

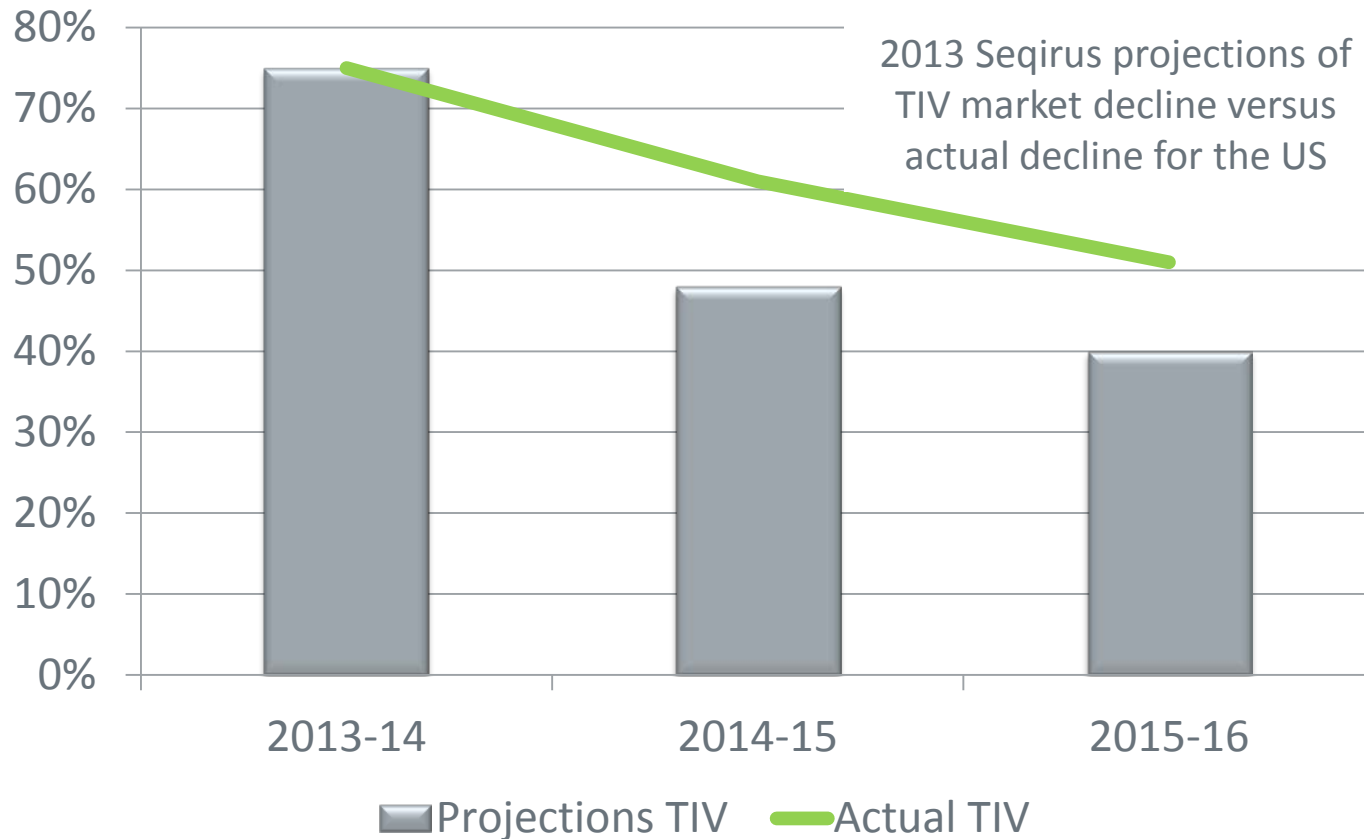
Afluria QIV  
*Flucelvax*  
QIV

Expected greater efficacy in vulnerable populations compared to non-adjuvanted influenza vaccines

Flexibility of manufacturing platforms in US and Australia



While the US and European markets are transitioning to QIV, this transition has taken longer than originally expected

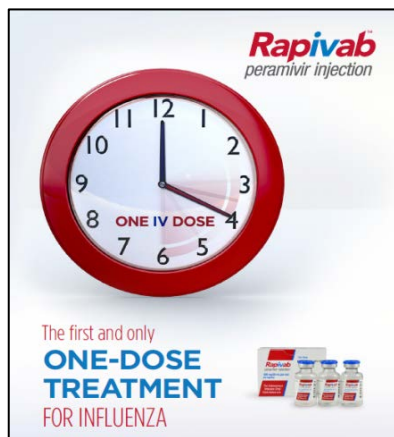


- Seqirus volume market share stable in 2015/16
















# Rapivab™ (peramivir injection) is an effective complement to our Flu vaccines portfolio



- Approved in the US Dec 2014
- Niche indication for the treatment of acute uncomplicated influenza in patients 18 years and older who have been symptomatic for no more than 48 hrs
- Single, rapid IV administration
- Stable at room temp. for 5 years

## Treatment of adults patients with influenza

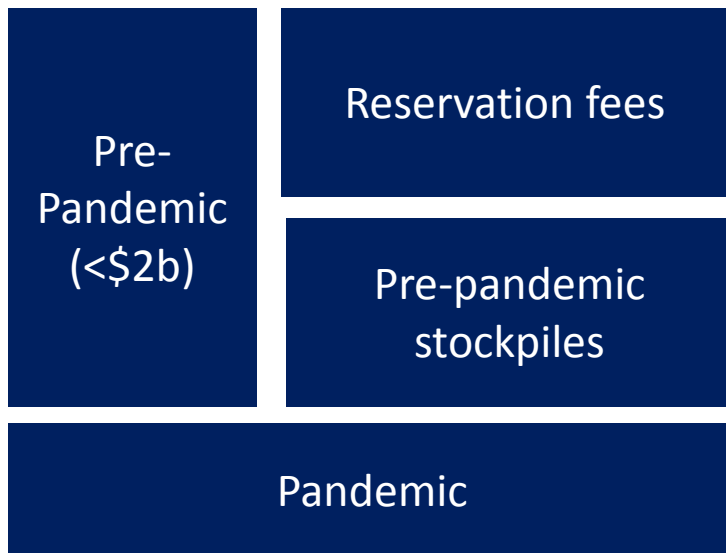
	Day 1		Day 2		Day 3		Day 4		Day 5	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
<b>Tamiflu</b> (75mg twice daily)										
<b>Rapivab</b> (600mg IV)			<i>No further injections required</i>							

~20% of patients prescribed a course of oral multi-dose antiviral adhere to only 2 of the 5 days <sup>1-4</sup>



# In pandemic preparedness, Seqirus is a leading global player with a strong track record

## Leading pandemic assets and capabilities













**Production capabilities** with global manufacturing network with different technologies. Holly Springs specifically designed for rapid scale-up of production in a pandemic situation

**Strong worldwide reputation and track record** built through fast response and significant value capture in the 2009 flu pandemic and, more recently, in the H7N9 threat

**Unique product offering** due to MF59 adjuvant, enhances efficacy and production efficiency, which maximizes population coverage and has made us a preferred pandemic supplier to governments

**Key government contracts around the world**

# In Australia and NZ, Seqirus augments its core flu vaccine with a comprehensive In-Licensed Vaccine & Pharmaceutical Portfolio

Vaccine Partners	Products	Pharma Partners	Products
	Gardasil, RotaTeq, Varivax, Vaqta, Pneumovax23, Zostavax, MMRII, H-B-VaxII	Pain  	Palexia Tramal Caldolor Versatis
	Rabipur Menjugate Jespect	Antibiotics  	Fuicidin BenPen Burinex
	Vivotif Oral Dukoral	CNS 	Tetrabenazine
 STATENS SERUM INSTITUT	ADT Booster	Allergy therapeutics 	Grazax Mitizax Jext

## IN SUMMARY

Gordon Naylor

# On track to meet our growth targets over the next few years

- Integration is going well
- Fluad will drive a material increase in defensible value in our primary market
- Migration to QIV in key markets will increase value per dose across much of the sales volume
- Deep operational and scientific capabilities will deliver a nimble, efficient supply chain
- Rapivab is a useful complementary product
- The proven cell culture platform provides strategic optionality
- We see interesting potential Innovation pathways for the future



Holly Springs



Liverpool



Parkville

