

**R&D for Avian / Pandemic Influenza Vaccines by IFPMA Influenza Vaccine Supply International Task Force (IVS ITF) members**  
(Updated 17 October 2006)

#	Company (Site Location)	Strain	Type	Culture	Adjuvant	Doses (µg)	Trials	Timing	Additional Information
1	Baxter (Czech Republic)	H5N1 Wild type (A/Vietnam/1203/2004)	Inactivated Whole virion	Cell Vero	Alum	3.7 / 7.5 / 15 / 30 / 45	Ph I&II* Adult**	Start: Jun 2006	* with NIID ** 18-45 year olds
2	Berna Biotech - Crucell Company (Switzerland)*	H9N2	Inactivated Whole virion	Egg	Alum	1.7 / 5 / 15 / 45***	Ph II	Start: 2006 End: Q4 2006	2 doses * with Leicester University ** Formulated with Virosomes as a carrier/adjuvant system *** Intramuscular **** Intradermal
			Inactivated Whole virion	Egg	None	5 / 15****			
			Virosome**	Egg	**	1.7 / 5 / 15 / 45***			
3	Biken (Japan)*	H5N1 (NIBRG-14)	Inactivated Whole virion	Egg	Alum	1.7 / 5 / 15	Ph I Adult**	Start: Mar 2006 End: Sep 2006	2 doses Intramuscular + subcutaneous Ph II & III Q3-4 2006 * with NIID ** 20-40 year olds
4	CSL Limited (Australia)	H5N1 (NIBRG-14)	Inactivated Split virus	Egg	AIPO <sub>4</sub>	7.5 / 15 (1 <sup>st</sup> set*) 30 / 45 (2 <sup>nd</sup> set**)	Ph II Adult***	1 <sup>st</sup> Start: Oct 05 1 <sup>st</sup> End: Feb 06 2 <sup>nd</sup> Start: Mar 06 2 <sup>nd</sup> End: Jun 07	* 1 <sup>st</sup> set results announced Feb 2006 ** 2 <sup>nd</sup> set testing in broader population *** 18-64 year olds for 2 <sup>nd</sup> set
5	CSL Limited (Australia)	H5N1 (NIBRG-14)	Inactivated Split virus	Egg	AIPO <sub>4</sub>	30 / 45	Ph II Child*	Start: 2006	* 6 months to 8 year olds
6	CSL Limited (Australia)	H5N1 (NIBRG-14)	Inactivated Split virus	Egg	AIPO <sub>4</sub>	30 / 45	Ph II Elderly*	Start: 2006	* > 65 year olds
7	Denka Seiken (Japan)*	H5N1 (NIBRG-14)	Inactivated Whole virion	Egg	Alum	1.7 / 5 / 15	Ph I Adult**	Start: Mar 2006 End: Jul 2006	* Intramuscular + subcutaneous Ph II & III Q3-4 2006 * with NIID ** 20-40 year olds

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	GSK Biologicals (Germany)	H2N2	Inactivated Whole virion	Egg	Alum	1.9 / 3.8 / 7.5 / 15	Ph I&II	Trials finished in 2005	Mock-up file submitted to EMA Dec. 2005
	GSK Biologicals (Germany)	H9N2	Inactivated Whole virion	Egg	Alum	1.9 / 3.8 / 7.5 / 15	Ph I&II	Trials finished in 2005	Mock-up files submitted to EMA Dec. 2005
8	GSK Biologicals (Canada & Germany)	H5N1	Inactivated Whole virion	Egg	Alum	3.8 / 7.5 / 15 / 30	Ph II Adult*	Start: Mar 2006	2 doses * 18-60 year olds
9	GSK Biologicals (Canada & Germany)	H5N1	Inactivated Split virus	Egg	yes*	3.8 / 7.5 / 15 / 30	Ph I&II Adult**	Start: Mar 2006	2 doses * Novel adjuvant ** 18-60 year olds
10	GSK Biologicals (Germany)	H5N1	Inactivated Split virus	Egg	yes*	15	Ph III Adult	Start: May 2006	2 doses * Novel adjuvant
11	Kaketsuken (Japan)*	H5N1 (NIBRG-14)	Inactivated Whole virion	Egg	Alum	1.7 / 5 / 15	Ph I Adult**	Start: Mar 2006 End: Jul 2006	Subcutaneous Ph II & III Q3-4 2006 * with NIID ** 20-40 year olds
12	Kitasato Institute (Japan)*	H5N1 (NIBRG-14)	Inactivated Whole virion	Egg	Alum	1.7 / 5 / 15	Ph I Adult**	Start: Mar 2006 End: Jul 2006	Intramuscular + subcutaneous Ph II & III Q3-4 2006 * with NIID ** 20-40 year olds
13	MedImmune (USA)*	H5N1 (A/Vietnam/1203 /2004)	Live attenuated	Egg	None	Intranasal	Ph I	Start: 2006	* CRADA with NIAID (Collaborative Research & Development Agreement)
14	MedImmune (USA)*	H5N1 (A/HongKong/49 2/1997)	Live attenuated	Egg	None	Intranasal	Ph I	Start: 2006	* CRADA with NIAID

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15	MedImmune (USA)*	H9N2	Live attenuated	Egg	None	Intranasal	Ph I	End: 2005 Expanded Ph I start in 2006	* CRADA with NIAID
16	MedImmune (USA)	H5N1	Live attenuated	Cell	None	Intranasal	Pre-clinical		
17	Merck & Co. Inc (USA)	M-2	Conserved Protein	Cell	None		Ph I	Start: 2006	
18	Nobilon International BV (Netherlands)	H5N1 (NIBRG-14)	Inactivated Whole virion	Cell	Alum	3.8 / 7.5 / 15 / 30	Ph I&II	Start: Q4 2006	
	Novartis Vaccines & Diagnostics (V&D) (Italy)	H5N3 (A/duck/Singapore/1997, NIB 40)	Inactivated Surface antigen	Egg	MF59	7.5 / 15 / 30	Ph I	Trials finished in 2000	<ul style="list-style-type: none"> <li>• <i>Lancet 2001 357: 1937-1943</i></li> <li>• <i>Vaccine 2003 21: 1687-1693</i></li> <li>• <i>JID 2005 191: 1210-1215</i></li> </ul>
	Novartis V&D (Italy)	H9N2 (G9/PR8)	Inactivated Surface antigen	Egg	MF59	3.75 / 7.5 / 15 / 30	Ph I&II* Adult**	Trials finished in 2005	2 doses Mock-up file submitted to EMEA Jan. 2006 * Trial conducted by NIAID ** 18-34 year olds
19	Novartis V&D (UK)	H5N1 (A/Vietnam/1203/2004)	Inactivated Surface antigen	Egg	None	7.5 / 15 / 30 / 45	Ph I&II* Adult**	Start: Mar 2006 End: Jul 2006	2 doses * Trial conducted by NIAID ** 18-64 year olds
					Alum	7.5 / 15 / 30			
					MF59	7.5 / 15			
20	Novartis V&D (Italy)	H5N1 (NIBRG-14)	Inactivated Surface antigen	Egg	MF59	7.5 / 15	Ph II* Adult-Elderly	Start: Mar 2006 End: Sep 2006	* Trial conducted by Novartis V&D
	Novartis V&D (Italy)	H5N3 (NIB 40) H3N2 (Panama) B/Guandong	Inactivated Surface antigen	Egg	LTK63	7.5*	Ph I	Trial finished in 2002	* Intranasal <i>J. Virol. 2006 10: 4962-4970</i>
					MF59	15			

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21	Novartis V&D (Italy)	H5N1	Inactivated Surface antigen	Egg	MF59	7.5 / 15	Ph II Adult*	Start: 2006	2 doses followed by a 6 month booster dose * 18-60 year olds
22	sanofi pasteur (France)	H5N1 (A/Vietnam/1194 /2004-NIBTG14)	Inactivated Split virus	Egg	Alum	7.5 / 15 / 30	Ph I* Adult*	End: 2005	2 doses * 18-40 year olds <i>Lancet 2006 367:1657-1664</i>
							Ph II Adult* Elderly**	Start: Q2 2006	2 doses * 18-60 year olds ** > 60 year olds
23	sanofi pasteur (USA)	H5N1 (A/Vietnam/1203 /2004)	Inactivated Split virus	Egg	None	7.5 / 15 / 45 / 90	Ph I&II* Adult**	Start: Apr 2005 End: Feb 2006	2 doses * Trial conducted by NIAID ** 18-64 year olds
24	sanofi pasteur (USA)	H5N1 (A/Vietnam/1203 /2004)	Inactivated Split virus	Egg	None	45 / 90 (Study 1)	Ph I&II* Elderly**	Start: Oct 2005	* Trial conducted by NIAID ** > 65 year olds
					Alum	3.75 / 7.5 / 15 / 45 (Study 2)		Start: Mar 2006	
25	sanofi pasteur (USA)	H5N1 (A/Vietnam/1203 /2004)	Inactivated Split virus	Egg	None	45	Ph I&II* Child**	Start: Jan 2006 End: Feb 2007	* Trial conducted by NIAID ** 2-9 year olds
26	sanofi pasteur (USA)	H5N1 (A/Vietnam/1203 /2004)	Inactivated Split virus	Egg	Alum	7.5 / 15 / 45	Ph I* Adult	2006	* Trial conducted by NIAID
27	sanofi pasteur (USA)	H5N1 (A/Vietnam/1203 /2004)	Inactivated Split virus	Egg	None	3 / 9*	Ph I*** Adult	2005	2 doses * Intramuscular ** Intradermal *** Trial conducted by NIAID
						15 / 45**			
28	sanofi pasteur (USA)	H7N7	Inactivated Split virus	Egg	Alum		Ph I* Adult	Start: 2007	* Trial conducted by NIAID

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29	sanofi pasteur (France)*	H7N1	Inactivated Split virus	Cell**	Alum	12 / 24	Ph I Adult***	Start: Sep 2006	2 doses * with EU Flupan Project <a href="http://www.nibsc.ac.uk/spotlight/fluplan/">http://www.nibsc.ac.uk/spotlight/fluplan/</a> ** PER.C6(R) cell-Crucell *** 20-40 year olds
30	Solvay Pharmaceuticals (Netherlands)	H5N1	Inactivated Surface antigen	Egg	Alum	To be determined	Ph I Adult*	Start: 2007	* 18-49 year olds
31	Solvay Pharmaceuticals (Netherlands)	H5N1 (NIBRG-14)	Inactivated Surface antigen	Cell MDCK	Alum & *	To be determined	Ph I Adult**	Start: 2007	* Novel adjuvant ** 18-49 year olds

### About the Pandemic R&D table:

The table lists all the prototype avian / pandemic influenza vaccines under development by IFPMA Influenza Vaccine Supply International Task Force member companies. As such, it covers the vast majority of R&D projects being undertaken in this field. The number of projects and the commitment of these companies to undertake the necessary clinical trials underline the innovative vaccine industry's commitment to help minimize the global health impact of avian and pandemic influenza.

The number of industry avian/pandemic vaccine projects continues to grow, with 31 on-going and 5 completed, conducted by 15 manufacturers, located in Australia, Austria, Canada, Czech Republic, France, Germany, Italy, Japan, the Netherlands, Switzerland, UK and USA. Altogether, 12 Phase II clinical trials and one Phase III are on-going or planned. Two prototype vaccine "Mock Up" dossiers have been submitted for approval by the EU regulatory authority (EMA).

The majority of projects target specific strains of influenza virus (H2N2, wild type H5N1, H5N1, H5N3, H7N1, H7N7, H9N2), but one focuses on development of a universal influenza vaccine, using an M-2 peptide conjugate protein. A variety of vaccine types are employed, including inactivated (whole virion, split virus and surface antigen), live attenuated and virosome.

Delivery systems include both subcutaneous and intramuscular injection, while one company uses a nasal spray. To reduce the amount of antigen required, many companies use an adjuvant to stimulate the immune response. Adjuvants used included the well-established aluminum salt, aluminum phosphate, MF59 and other novel adjuvants, while the virosome approach provides a combined carrier/adjuvant system. Most projects use the traditional egg culture technology currently used to manufacture seasonal influenza vaccines, but six use cell culture systems which offer the potential to reduce production time.

**About the IFPMA ([www.ifpma.org](http://www.ifpma.org)):**

The International Federation of Pharmaceutical Manufacturers & Associations is the global non-profit NGO directly representing twenty-six research-based pharmaceutical, biotech and vaccine companies and sixty national industry associations in developed and developing countries. The industry's R&D pipeline contains hundreds of new medicines and vaccines being developed to address global disease threats, including cancer, heart disease, HIV/AIDS and malaria. The IFPMA Clinical Trials Portal ([www.ifpma.org/clinicaltrials](http://www.ifpma.org/clinicaltrials)) and the IFPMA Health Partnerships Survey help make the industry's activities more transparent. The IFPMA strengthens patient safety by improving risk assessment of medicines and combating their counterfeiting. It also provides the secretariat for the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

**About the IFPMA Influenza Vaccine Supply International Task Force:**

The IFPMA Influenza Vaccine Supply Interventional Task Force (IVS ITF), established in February 2002, brings together research-based influenza vaccine manufacturers from around the world, which are conducting the R&D necessary to develop safe, effective, high-quality vaccines against avian and pandemic influenza threats. The IVS ITF works within the constraints of anti-trust law to address the advocacy, communication, policymaking, regulatory, scientific and technical issues related to interpandemic and pandemic influenza vaccines. IVS ITF members are committed to make their unique expertise in R&D, logistics, manufacturing, safety and regulatory issues available to help governmental and intergovernmental bodies in pandemic planning and decision-making.

For more information, see: [www.ifpma.org/influenza](http://www.ifpma.org/influenza)

As of October 2006, IFPMA IVS ITF members are: Baxter, Berna Biotech (a Crucell Company), Biken, CSL Limited, Crucell, Denka Seiken, GlaxoSmithKline Biologicals (including former ID Biomedical), Kaketsuken, Kitasato Institute, MedImmune, Nobilon International BV, Novartis Vaccines and Diagnostics (former Chiron Vaccines), sanofi pasteur, Sanofi Pasteur MSD and Solvay Pharmaceuticals.

**For further information, please contact:**

Ryoko Krause

Director, Biologicals and Vaccines, IFPMA

e-mail: [r.krause@ifpma.org](mailto:r.krause@ifpma.org)

Tel: +41-22-338 32 00