

H1N1 Clinical Studies

Source: BARDA (September 10, 2009)

Manufacturer	Brief Description	Sample Size	Estimated Start
Sanofi Pasteur	Adult/Elderly safety/immunogenicity (US)	850	08/06/09
	Pediatric safety/immunogenicity (US)	450	08/06/09
	Adult/Elderly with and without adjuvant	650	09/15/09
GSK	Adult with and without adjuvant (UK) (HPLC)	128	08/11/09
	Adult with and without adjuvant (UK) (SRID)	128	09/08/09
	Adult/Elderly Adjuvant (US/Canada)	1260	10/13/09
	Adult/Elderly with and without adjuvant (US/Canada)	4000	10/13/09
	Pediatric with and without adjuvant (US/Canada)	800	10/06/09
	Seasonal/H1N1 Interference with and without adjuvant (US/Canada)	600	10/09/09
Novartis (NVD) <i>Fluvirin</i>	Safety/immunogenicity with and without adjuvant (Costa Rica)	392	08/17/09
	Safety/immunogenicity with and without adjuvant (peds) (Costa Rica)	392	08/17/09
	Adult safety/immunogenicity with and without adjuvant (US/Mexico)	2380	09/11/09
	Pediatric safety/immunogenicity with and without adjuvant (US/Mexico)	1190	09/11/09
	6-35 month old safety/immunogenicity with and without adjuvant	TBD	09/30/09
<i>Flu Cell Cult</i>	Adult safety/immunogenicity (UK)	175	07/24/09
	Adult safety/immunogenicity with and without adjuvant (EU)	600	08/08/09
	Pediatric safety/immunogenicity with and without adjuvant (EU)	720	08/19/09
<i>Focetria (EU)</i>	Adult safety/immunogenicity with and without adjuvant (EU)	600	08/25/09
	Pediatric safety/immunogenicity with and without adjuvant (EU)	720	09/09/09
CSL	Adult/Elderly safety/immunogenicity (Australia)	240	07/22/09
	Pediatric safety/immunogenicity (Australia)	400	08/03/09
	Adult/Elderly safety/immunogenicity (US)	1300	08/24/09
	Pediatric safety/immunogenicity (US)	450	08/24/09
MedImmune	Adult safety and immunogenicity 18-49 years old	300	08/17/09
	Pediatric safety and immunogenicity 2-17 years old	300	08/17/09
NIH	Adult/Elderly safety/immunogenicity	400	08/07/09
	Pediatric safety/immunogenicity	600	08/19/09
	Adult/Elderly safety/immunogenicity	400	08/07/09
	Adult seasonal/H1N1 (3 doses)	800	08/07/09
	Peds Seasonal/H1N1 (3 doses)	600	08/20/09
	Adult safety/immunogenicity with and without adjuvant	TBD	09/15/09
	Adult safety/immunogenicity with and without adjuvant	TBD	11/01/09
	Pregnant women HIV+	130	TBD
	Asthmatics 12 years and older	350	TBD
	H1N1 pregnancy	120	09/09/09
	Baxter	Adult/Elderly safety/immunogenicity (cell based in EU)	600

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