Vaccintrials bij de GGD Rotterdam-Rijnmond (2004-2013)

- A double-blind, randomized, controlled study to evaluate the immunogenicity and safety of GlaxoSmithKline Biologicals' **herpes simplex candidate vaccine** (gD2-AS04) in healthy HSV seropositive female subjects aged 10 - 17 years: GlaxoSmithKline (GSK) (2004-2007).

- A phase III, double-blind, randomized study to assess the consistency of the immunogenicity of three consecutive production lots of GlaxoSmithKline Biologicals' HPV-16/18 VPL/AS04 vaccine administered intramuscularly according to a 0, 1, 6-month schedule in healthy female subjects aged 10-25 years and to demonstrate the non-inferiority of the Hi5 formulation of the **candidate HPV vaccine** versus the Hi5/SF9 vaccine formulation: GlaxoSmithKline (GSK) (2004-2005).

- A phase III, observer blind, randomised study to evaluate the safety and immunogenicity of one and two administrations of pandemic **monovalent (H5N1) influenza vaccine** (split virus formulation containing 15 ug HA and adjuvanted with AS03) in adults aged 18 years and older (2006-2007).

- A phase II, single-blind, randomized, controlled, multicentre vaccination study to evaluate the safety and immune response of the GSK Biologicals' **Zoster vaccine**, gE/AS01$_B$, and to compare 3 doses of gE with AS01B adjuvant in healthy elderly subjects, aged 60 to 69 and 70 years and above (2007-2009).

- A phase II, observer-blind, multicountry, multicentre, randomized study to evaluate the immunogenicity, safety and reactogenicity of the GlaxoSmithKline Biologicals' **influenza vaccine** adjuvanted with various doses of the oil in water emulsion and MPL, administered in adults aged 65 years and older, and compared to Fluarix (2007-2008).

- A phase III, observer-blind, multicountry, multicentre study to evaluate the safety, reactogenicity and immunogenicity of GlaxoSmithKline Biologicals' GSK 2186877A **influenza vaccine** administered to adults aged 65 years and older compared to Fluarix^{TM} administered to adults aged 18-41 years and 65 years and older, who previously participated in the 110874 study (2008-2009).

- A phase III, observer-blind, multicountry, multicentre study to evaluate the safety, reactogenicity and immunogenicity of GlaxoSmithKline Biologicals' GSK 2186877A **influenza vaccine** administered to adults aged 66 years and older compared to Fluarix^{TM} administered to adults aged 19-43 years and 66 years and older, who previously participated in the 11737 study (2009-2010).

- Randomized, observer-blind, active-controlled phase III study to demonstrate the superior efficacy of GlaxoSmithKline Biologicals' **adjuvanted influenza candidate vaccine** [GSK2186877A], administered intramuscularly in elderly aged 65 years or above, as compared to Fluarix^{TM} (2008-2011).

- A phase IIIb, open, controlled study to evaluate the immunogenicity and safety of GlaxoSmithKline Biologicals' **HPV-16/18 L1 VLP AS04** vaccine (Cervarix^{TM}) co-administrated with GlaxoSmithKline Biologicals' Hepatitis B vaccine (Engerix^{TM}) in healthy female subjects aged 9-15 years (2008-2009).

- A phase IV, open label, randomized, multicountry,study to evaluate immunogenicity and safety of GlaxoSmithKline Biologicals' seasonal (201-2011) **influenza vaccine** Fluarix^{TM} in children previously vaccinated with GSK Biologicals'H1N1 vaccine (Pandemrix ^{TM}) (2010-2011).

- An open, phase II long term extension study to evaluate the immune responses to and safety of GSK Biolocigals'candidate **herpes zoster vaccine,** (gE/AS01$_B$), at months 48, 60 and 72 post-vaccination in healthy subjects aged 60 years of age and older (2011-2013).