Table S2. Overview of the studies included in the meta-analysis

eTrack number / NCT number	Abbreviated title	Country	Study duration	N	Inclusion criteria[a]	Exclusion criteria[a]
263855/002 / NCT01267058	Tdap-002	Australia	11/9/1997–26/2/1998	38	Healthy men or women aged ≥18 years at the time of vaccination.	• Major congenital defects or serious chronic illness. • History of progressive neurological disease. • Any suspected or confirmed immune disorder (including HIV infection). • Immunosuppressive therapy (except topical corticosteroids). • Immunoglobulin therapy or administration of any blood products within the previous 3 months or during the study.
106316 / NCT00346073	Tdap0.3-007	US	13/7/2006–17/4/2007	51	Men or women aged 19–64 years at the time of vaccination; healthy as established by medical history and history-directed physical examination	• Any confirmed or suspected immunosuppressive or immunodeficient condition based on medical history and physical examination (no laboratory testing required). • History of encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) within 7 days of administration of a previous dose of pertussis vaccine that was not

before entering the study.	attributable to another identifiable cause. • Progressive neurological disorder, uncontrolled epilepsy or progressive encephalopathy: pertussis vaccine was not to be administered to individuals with these conditions until a treatment regimen had been established and the condition had stabilized. • Acute disease at the time of vaccination, defined as the presence of a moderate or severe illness with or without fever. Vaccines could be administered to persons with a minor illness such as diarrhea or mild upper respiratory infection without fever, i.e., oral/axillary temperature <99.5°F (37.5°C). • Chronic administration (defined as more than 14 days) of immunosuppressants or other immune-modifying drugs within 6 months prior to study vaccine administration. For corticosteroids, this meant prednisone, or equivalent, ≥0.5 mg/kg/day. Inhaled and topical steroids were allowed.

						• Administration of immunoglobulins and/or any blood products within the 3 months preceding the administration of study vaccine or planned administration during the active phase of the study.
106323 / NCT00385255	Tdap0.3-008	US	23/10/2006–28/2/2007	25	Healthy men or women aged 19–64 years (for the primary cohort) or ≥65 years (for the exploratory cohort) at the time of vaccination.	• Any confirmed or suspected immunosuppressive or immunodeficient condition based on medical history and physical examination (no laboratory testing required). • History of serious allergic reaction (e.g., anaphylaxis) following any other tetanus toxoid-, diphtheria toxoid- or pertussis-containing vaccine, influenza vaccine or any component of the study vaccines, including egg or chicken proteins or latex. • History of encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) within 7 days of administration of a previous dose of pertussis vaccine that was not attributable to another identifiable cause.

• Progressive neurological disorder, uncontrolled epilepsy or progressive encephalopathy: pertussis vaccine was not to be administered to individuals with these conditions until a treatment regimen had been established and the condition had stabilized.

• Acute disease at the time of vaccination, defined as the presence of a moderate or severe illness with or without fever. Vaccines could be administered to persons with a minor illness such as diarrhea or mild upper respiratory infection without fever, i.e., oral/axillary temperature <99.5°F (37.5°C).

• Chronic administration (defined as more than 14 days) of immunosuppressants or other immune-modifying drugs within 6 months prior to vaccination or planned administration during the study. For corticosteroids, this meant prednisone, or equivalent, ≥0.5 mg/kg/day for more than 14 days. Inhaled and topical steroids were allowed.

						• Administration of immunoglobulins and/or any blood products within the 3 months preceding vaccination or planned administration during the study.
111413 / NCT00835237	Tdap0.3-011	US	Active phase: 17/2/2009–23/7/2009 Extended safety follow-up: until 15/10/2009	64	Men or women aged ≥65 years at the time of study entry; free of an acute aggravation of the health status as established by medical history and clinical examination before entering the study.	• Progressive neurologic disorder, uncontrolled epilepsy or progressive encephalopathy: pertussis vaccine was not to be administered to individuals with these conditions until a treatment regimen was established and the condition had stabilized. • Acute (active) clinically significant pulmonary, cardiovascular, hepatic or renal functional abnormality, as determined by clinical evaluation (medical history and medical history-directed physical examination) or pre-existing laboratory screening tests. • Any confirmed or suspected immunosuppressive or immunodeficient condition based on medical history and physical examination (no laboratory testing required).

						• Chronic administration (defined as more than 14 days) of immunosuppressants or other immune-modifying drugs within 6 months prior to vaccination or planned administration during the study. For corticosteroids, this meant prednisone, or equivalent, ≥0.5 mg/kg/day for more than 14 days. Inhaled and topical steroids were allowed. • Administration of immunoglobulins and/or any blood products within the 3 months preceding vaccination or planned administration during the study.
116887 / NCT02052596	Zoster-042	US	7/2/2014–21/4/2016	44	Men or women aged ≥50 years at the time of first vaccination.	• Any condition which, in the opinion of the investigator, prevented the person from participating in the study. • Any condition that, in the judgement of the investigator, would make intramuscular injection unsafe. • Encephalopathy (e.g., coma, decreased consciousness, prolonged seizures) not attributable to an identifiable cause within 7 days of

administration of a previous pertussis antigen-containing vaccine.

• Progressive or unstable neurological disorder.

• Any confirmed or suspected immunosuppressive or immunodeficient condition resulting from disease (e.g., malignancy, HIV infection) or immunosuppressive/cytotoxic therapy (e.g., medications used during cancer chemotherapy, organ transplantation or to treat autoimmune disorders).

• Chronic administration (defined as more than 14 consecutive days) of immunosuppressants or other immune-modifying drugs within 6 months prior to the first vaccine dose. For corticosteroids, this meant prednisone ≥20 mg/day, or equivalent; a prednisone dose of <20 mg/day was allowed. Inhaled, topical and intra-articular corticosteroids were allowed.

• Administration of long-acting immune-modifying drugs (e.g., infliximab) within 6 months prior to

		the first vaccine dose or expected administration at any time during the study. • Administration of immunoglobulins and/or any blood products within the 3 months preceding the first dose of study vaccine or planned administration during the study.

Tdap, GSK's reduced-antigen tetanus, diphtheria and acellular pertussis vaccine; N, number of participants in the meta-analysis (total vaccinated cohort); HIV, human immunodeficiency virus; US, United States.

[a]Only criteria relevant for the current meta-analysis are shown.