資料 1.　NIH Clinical Protocol に登録されている組換えワクチン臨床プロトコール

1　　Evaluating the Infectivity, Safety, and Immunogenicity of a Recombinant Live-Attenuated Respiratory Syncytial Virus Vaccine in RSV-Seronegative Infants and Children 6 to 24 Months of Age

Respiratory Syncytial Virus Infections

"The purpose of this study is to evaluate the safety, infectivity, and immunogenicity of a single dose of a recombinant live-attenuated respiratory syncytial virus (RSV) vaccine in RSV-seronegative infants 6 to 24 months of age.（**組換え技術を用いて弱毒化した** RSV **ワクチン**）

This study is a companion study to IMPAACT 2011.

Phase ; Respiratory Syncytial Virus Infections,　Biological: RSV LID ΔM2-2 1030s vaccine,　Biological: Placebo

Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)

Primary Purpose: Prevention

Official Title: Phase I Placebo-Controlled Study of the Infectivity, Safety and Immunogenicity of a Single Dose of a Recombinant Live-attenuated Respiratory Syncytial Virus Vaccine, LID ΔM2-2 1030s, Lot RSV#010A, Delivered as Nose Drops to RSV-Seronegative Infants and Children 6 to 24 Months of Age

2　　Infectivity, Safety and Immunogenicity of a Recombinant Live-Attenuated Respiratory Syncytial Virus Vaccine (RSV LID cp ΔM2-2) in RSV-Seronegative Infants and Children 6 to 24 Months of Age

Condition:　　Respiratory Syncytial Virus Infections

Interventions:　Biological: RSV LID cp ΔM2-2 Vaccine;　Biological: Placebo

"The purpose of this study is to evaluate the safety, infectivity, and immunogenicity of a single dose of a recombinant live-attenuated respiratory syncytial virus (RSV) vaccine in RSV-seronegative infants and children 6 to 24 months of age.

Study Design: Allocation: Randomized

Intervention Model: Parallel Assignment

Masking: Participant, Care Provider, Investigator, Outcomes Assessor

Primary Purpose: Official Title: Phase I Placebo-Controlled Study of the Infectivity, Safety and Immunogenicity of a Single Dose of a Recombinant Live-attenuated Respiratory Syncytial Virus Vaccine, LID cp ΔM2-2, Lot RSV#009B, Delivered as Nose Drops to RSV-Seronegative Infants and Children 6 to 24 Months of Age

3 Evaluating the Infectivity, Safety and Immunogenicity of a Recombinant Live-Attenuated Respiratory Syncytial Virus Vaccine in RSV-Seronegative Infants 6 to 24 Months of Age

Condition: Respiratory Syncytial Virus Infections

Interventions: Biological: RSV LID ΔM2-2 1030s vaccine; Biological: Placebo

"Purpose

The purpose of this study is to evaluate the safety, infectivity, and immunogenicity of a single dose of a recombinant live-attenuated respiratory syncytial virus (RSV) vaccine in RSV-seronegative infants 6 to 24 months of age.

This study is a companion study to CIR 311

Phase

Respiratory Syncytial Virus Infections

Biological: RSV LID ΔM2-2 1030s vaccine

Biological: Placebo

4 Evaluating the Infectivity, Safety and Immunogenicity of a Recombinant Live-Attenuated Respiratory Syncytial Virus Vaccine (RSV LID cp ΔM2-2) in RSV-Seronegative Infants 6 to 24 Months of Age

Condition: Respiratory Syncytial Virus Infections

Interventions: Biological: RSV LID cp ΔM2-2 Vaccine; Biological: Placebo

5 Safety of and Immune Response to Recombinant Live-Attenuated Parainfluenza Type 1 Virus Vaccine

Conditions: Parainfluenza; Virus Diseases

Interventions: Biological: rHPIV1 84/del170/942A, Lot PIV1 #104A vaccine; Biological: Placebo

" Recombinant Live attenuated parainfluenza virus（組換え技術を利用して弱毒化）

Human Parainfluenza Virus Type 1 (HPIV1) is a leading cause of viral respiratory infections in children, the elderly, and those with compromised immune systems. HPIV1 is also the leading cause of viral croup in children under 6 years old. The purpose of this study is to determine the safety of and immune response to a HPIV1 vaccine, rHPIVI1 84/del170/942A, in 2 groups of adults and then in children who have been previously exposed to HPIV1. Once the safety of this vaccine has been established in these groups, an additional 2 groups of infants and children who have not been previously exposed to HPIV1 will be vaccinated. Naïve infants and children are the most vulnerable to naturally circulating HPIV1 and are the target population of this vaccine.

6 Safety and Immunogenicity of the Dengue Virus Vaccine TV005 (TetraVax-DV TV005) in Healthy Adults, Adolescents, and Children in Dhaka, BangladeshCondition:Dengue
Interventions:Biological: TV005 vaccine; Biological: Placebo
"The purpose of this study is to evaluate the safety and immunogenicity of the recombinant live attenuated tetravalent dengue virus vaccine admixture TV005 (TetraVax-DV T005) in healthy adults, adolescents, and children in Dhaka, Bangladesh.
Dengue （組換え技術を用いた弱毒化 4 価デングワクチン）
Biological: TV005 vaccine Biological: Placebo
Study Type: Interventional
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Prevention
Official Title: Phase II, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Immunogenicity of the Recombinant Live Attenuated Tetravalent Dengue Virus Vaccine Admixture TV005 (TetraVax-DV TV005) in Healthy Adults, Adolescents, and Children in Dhaka, Bangladesh "

7 Safety and Immune Response to Recombinant Live-Attenuated Influenza H2N2 Virus Vaccine
Conditions: Influenza; Virus Diseases
Intervention: Biological: H2N2 1960 AA ca recombinant vaccine
"Purpose ; In the 20th century, influenza pandemics occurred in 1918, 1957, and 1968, and were associated with significant morbidity and mortality. It is estimated that, in the United States alone, the next influenza pandemic could cause approximately 200,000 deaths and 750,000 hospitalizations. Thus, the development of a vaccine against potential influenza strains has become a priority. The purpose of this study is to determine the safety and immune response to an H2N2 influenza vaccine candidate.
Phase ; Influenza Virus Diseases
Biological: H2N2 1960 AA ca recombinant vaccine

8 Safety of and Immune Response to Recombinant Live-Attenuated Influenza H6N1 Virus Vaccine Vaccine
Conditions: Influenza; Virus Diseases

Intervention: Biological: H6N1 Teal HK 97/AA ca recombinant vaccine
"Purpose ; In the 20th century, influenza pandemics occurred in 1918, 1957, and 1968, and were associated with significant morbidity and mortality. It is estimated that, in the United States alone, the next influenza pandemic could cause approximately 200,000 deaths and 750,000 hospitalizations. Thus, the development of a vaccine against potential influenza strains has become a priority. The purpose of this study is to determine the safety and immune response to an H6N1 influenza vaccine candidate.
Phase ; Influenza Virus Diseases
Biological: H6N1 Teal HK 97/AA ca recombinant vaccine
Study Design: Allocation: Non-Randomized
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Prevention

9 Safety of and Immune Response to Recombinant Live Attenuated Parainfluenza Type 3 Virus Vaccine in Healthy Infants and Children
Conditions: Paramyxoviridae Infections; Virus Diseases
Interventions: Drug: rHPIV3cp45; Drug: rHPIV3cp45 placebo
" Purpose; Human parainfluenza viruses (HPIVs) are a major health concern in infants and young children under 5 years of age, causing serious respiratory tract disease. The primary purpose of this study is to test the safety of and immune response to a new HPIV vaccine in healthy infants and children.
Phase ; Paramyxoviridae Infections Virus Diseases
Drug: rHPIV3cp45
Drug: rHPIV3cp45 placebo
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator)
Primary Purpose: Prevention
Official Title: Phase I Study to Determine the Safety, Infectivity, and Tolerability of 2 Doses of Live Attenuated Recombinant Cold-Passaged (cp) 45 Human Parainfluenza Type 3 Virus Vaccine, rHPIV3cp45, Lot PIV3#102A, Delivered as Nose Drops to HPIV3-Seronegative Infants and Children 6 to 36 Months of Age, at a 6 Month Interval

10 Evaluation of the Safety and Immune Response of Five Admixtures of a Tetravalent Dengue Virus Vaccine

Condition: Dengue

Interventions:

Biological: TetraVax-DV Vaccine-Admixture 1; Biological: TetraVax-DV Vaccine-Admixture 2; Biological: TetraVax-DV Vaccine-Admixture 3; Biological: TetraVax-DV Vaccine-Admixture 4; Biological: Placebo; Biological: TetraVax-DV Vaccine-Admixture 5

"Purpose; Dengue viruses can cause dengue fever and other serious health conditions, primarily affecting people living in tropical regions of the world. This study will evaluate the safety and immune responses of five formulations of a tetravalent dengue virus vaccine in healthy adults.

Dengue; Biological: TetraVax-DV Vaccine-Admixture 1, Biological: TetraVax-DV Vaccine-Admixture 2, Biological: TetraVax-DV Vaccine-Admixture 3, Biological: TetraVax-DV Vaccine-Admixture 4

Biological: Placebo

Biological: TetraVax-DV Vaccine-Admixture 5

11 Evaluating the Safety and Immune Response to Two Admixtures of a Tetravalent Dengue Virus Vaccine

Condition: Dengue

Interventions:

Biological: TetraVax-DV Vaccine - Admixture TV003; Biological: TetraVax-DV Vaccine - Admixture TV005; Biological: Placebo

Purpose ; Dengue viruses can cause dengue fever and other serious health conditions, primarily affecting people living in tropical regions of the world. This study will evaluate the safety and immune responses to two formulations of a tetravalent dengue virus vaccine in healthy adults.

12 Safety and Immune Response to a Live-Attenuated Respiratory Syncytial Virus (RSV) Vaccine in RSV-Seronegative Infants and Children

Condition: Respiratory Syncytial Virus Infections

Interventions: Biological: RSV LID ΔM2-2 Vaccine; Biological: Placebo Vaccine

"Purpose; Respiratory syncytial virus (RSV) is a common cause of illness in infants and children around the world. This study will evaluate the safety and immune response to an RSV vaccine in RSV-seronegative infants and children.

This study is a companion study to IMPAACT 2000.

Phase ; Respiratory Syncytial Virus Infections, Biological: RSV LID ΔM2-2 Vaccine,

Biological: Placebo Vaccine

13 Safety and Immune Response to a Live-Attenuated Respiratory Syncytial Virus (RSV) Vaccine in RSV-Seronegative Infants and Children
Condition: Respiratory Syncytial Virus Infections
Interventions: Biological: RSV LID ΔM2-2 Vaccine; Biological: Placebo Vaccine
"Purpose ; Respiratory syncytial virus (RSV) is a common cause of illness in infants and children around the world. This study will evaluate the safety and immune response to an 組換え live RSV vaccine in RSV-seronegative infants and children.
This study is a companion study to CIR 291.

14 Evaluating the Safety and Immune Response to Two Admixtures of a Tetravalent Dengue Virus Vaccine
Condition: Dengue
Interventions:
Biological: TetraVax-DV Vaccine - Admixture TV003; Biological: TetraVax-DV Vaccine - Admixture TV005; Biological: Placebo

15 Evaluating the Safety and Immune Response to a Single Dose of a Respiratory Syncytial Virus (RSV) Vaccine in RSV-Seronegative Infants and Children
Condition: Respiratory Syncytial Virus Infections
Interventions: Biological: RSV cps2 Vaccine; Biological: Placebo Vaccine

16 Evaluating the Safety and Immune Response to a Single Dose of a Respiratory Syncytial Virus (RSV) Vaccine in RSV-Seronegative Infants and Children
Condition: Respiratory Syncytial Virus Infections
Interventions: Biological: RSV cps2 Vaccine; Biological: Placebo Vaccine

17 Evaluation of the Safety and Immunogenicity of a Live Attenuated Human Metapneumovirus Vaccine
Condition: Metapneumovirus
Interventions:
Biological: 10^6 PFU rHMPV-Pa vaccine; Biological: 10^5 PFU rHMPV-Pa vaccine; Biological: Placebo Vaccine
"Purpose ； People who are infected with human metapneumovirus (HMPV) may develop upper and lower respiratory illnesses. Children are particularly sensitive to

HMPV infection. This study will evaluate the safety and immune response of an HMPV vaccine in healthy adults, HMPV-seropositive children, and HMPV-seronegative infants and children.
Phase ； Metapneumovirus, Biological: 10^6 PFU rHMPV-Pa vaccine, Biological: 10^5 PFU rHMPV-Pa vaccine
Biological: Placebo Vaccine

18 Safety of a Live Attenuated Human Parainfluenza Virus Type 2 (HPIV2) Vaccine for Adults, Children, and Infants
Condition: Human Parainfluenza Virus 2
Interventions:Biological: Standard Dose HPIV2 Vaccine; Biological: Low dose HPIV2 vaccine; Other: Placebo
"Purpose ； Human parainfluenza virus type 2 (HPIV2) can result in severe respiratory illness in infants and young children. This study will test the safety of and immune response to an HPIV2 vaccine aimed at infants and children.
Phase ； Human Parainfluenza Virus 2、 Biological: Standard Dose HPIV2 Vaccine, Biological: Low dose HPIV2 vaccine
Other: Placebo, Phase 1
Study Design: Allocation: Randomized

19 Evaluating the Safety and Immune Response to a Single Dose of a Respiratory Syncytial Virus (RSV) Vaccine in Infants and Children
Condition: Respiratory Syncytial Virus Infections
Interventions:Biological: RSV ΔNS2 Δ1313 I1314L Vaccine; Biological: Placebo (1x Le ibovitz L-15

20 Evaluating the Safety and Immune Response to a Respiratory Syncytial Virus (RSV) Vaccine in Adults, RSV-Seropositive Children, and RSV-Seronegative Infants and Children
Condition: Respiratory Syncytial Virus Infections
Interventions: Biological: RSV MEDI ΔM2-2 vaccine; Biological: Placebo vaccine

21 Safety, Tolerability, and Immunogenicity of an Investigational Vaccine With Recombinant Human Albumin (rHA) in Children 12 to 18 Months of Age (V205C-009)(COMPLETED)
Conditions: Measles; Mumps; Rubella; Varicella

Interventions: Biological: measles, mumps, and rubella virus vaccine live; Biological: Comparator: Measles, Mumps, and Rubella Virus Vaccine Live
"Purpose; The purpose of this trial is to study the safety and immune response to measles, mumps, and rubella in children who were vaccinated with an investigational measles-mumps-rubella live vaccine made with artificially made human protein.
Measles, Mumps, Rubella, Varicella, Biological: measles, mumps, and rubella virus vaccine live
Biological: Comparator: Measles, Mumps, and Rubella Virus Vaccine Live
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Prevention

21 Evaluating the Safety and Protective Efficacy of a Single Dose of a Trivalent Live Attenuated Dengue Vaccine to Protect Against Infection With DENV-2
Condition: Dengue
Interventions: Biological: Recombinant live attenuated trivalent dengue vaccine; Biological: Placebo; Biological: rDEN2Δ30-7169 vaccine

22 Comparison of a Live Herpes Zoster Vaccine and a Recombinant Vaccine in 50-59 and 70-85 Year Olds
Conditions: Shingles; Herpes Zoster
Interventions:Biological: Zostavax; Biological: HZ/su vaccine; Biological: Placebo
" Purpose; This study will compare the two vaccines that have been developed to prevent and/or lessen the effects of shingles. One vaccine is live (Zostavax, licensed by FDA) and the other, herpes zoster subunit (HZ/su), contains a piece of the shingles virus (not live) and an ingredient that may enhance the body's immune response to the vaccine, and is currently investigational. The vaccines are being compared to assess their ability to stimulated protection against shingles. The study will provide an opportunity to determine the safety profile of each vaccine in a single trial. The study will also look at the effect of age on the immune response to the two vaccines and on the persistence of these responses.

23 Evaluating the Safety and Immunogenicity of a H7N9 Vaccine for the Prevention of Influenza H7N9 Disease in Adults 50 to 70 Years Old
Condition: Influenza A Virus, H7N9 Subtype

Interventions:Biological: H7N9 Anhui 2013/AA ca; Biological: Inactivated subvirion H7N9 vaccine

"Purpose ; H7N9 viruses have caused an outbreak of severe respiratory disease in 2013-2014 in China that affected many older adults. This study will evaluate the safety of and immune response to a live attenuated H7N9 vaccine in adults 50 to 70 years old.

Phase; Influenza A Virus, H7N9 Subtype, Biological: H7N9 Anhui 2013/AA ca, Biological: Inactivated subvirion H7N9 vaccine

Study Design: Intervention Model: Single Group Assignment

Masking: No masking

24 Dose-Escalation Study on Safety and Immunogenicity of VPM1002 in Comparison to BCG in Healthy Volunteers in South Africa

Condition: Tuberculosis

Interventions: Biological: VPM1002 live vaccine; Biological: commercially available live vaccine BCG

"Purpose ; Goal of VPM is the development of a recombinant urease C-deficient listeriolysin expressing BCG vaccine strain (VPM1002) as a safe, well tolerated and efficacious vaccine against tuberculosis (TB) for residents in endemic areas and persons at risk in non-endemic areas. The new vaccine should be at least as potent as the current strain and should be safer than BCG (Kaufmann, 2007a; Grode et al., 2005). The vaccine is formulated as live lyophilised bacteria to be re-suspended before intradermal injection. The preceding clinical trial in 80 volunteers in Germany indicated immunogenicity and safety being sufficient for proceeding with the clinical development. Hence, the current study is commenced in South Africa, a country highly endemic for tuberculosis.

24 volunteers were randomly allocated to 4 groups each with 6 adult healthy volunteers.

Phase ; Tuberculosis, Biological: VPM1002 live vaccine, Biological: commercially available live vaccine BCG

25 Safety and Efficacy Study of Vaccine Schedule With Ad26.Mos.HIV and MVA-Mosaic in Human Immunodeficiency Virus (HIV)-Infected Adults

Condition: Human Immunodeficiency Virus (HIV)

Interventions: Biological: Ad26.Mos.HIV; Biological: MVA-Mosaic; Drug: Placebo

"Purpose ; The purpose of the study is to assess: 1 safety and tolerability of adenovirus serotype 26 (Ad26) prime and Modified Vaccinia Ankara (MVA) boost versus placebo in participants on suppressive antiretroviral therapy (ART) that was initiated during

acute Human Immunodeficiency Virus (HIV) infection; 2) Measure the frequency and duration of sustained viremic control after receiving Ad26 prime/MVA boost or placebo, defined as greater than 24 weeks with plasma HIV ribonucleic acid (RNA) lesser than (<)50 copies/ml after antiretroviral (ARV) analytical treatment interruption (ATI).
Phase ; Human Immunodeficiency Virus (HIV), Biological: Ad26.Mos.HIV, Biological: MVA-Mosaic
Drug: Placebo
Phase 1 & Phase 2
Study Design: Allocation: Randomized

26 Dose-Escalation Study on Safety and Immunogenicity of VPM1002 in Comparison With BCG in Healthy Male Volunteers
Conditions: Tuberculosis; Healthy
Interventions: Biological: VPM1002; Biological: BCG
" Purpose; Goal of VPM is the development of a recombinant urease C-deficient listeriolysin expressing BCG vaccine strain (VPM1002) as a safe, well tolerated and efficacious vaccine against TB for residents in endemic areas and persons at risk in non-endemic areas. The new live vaccine VPM1002 should be at least as potent as the currently used BCG vaccine and should cause fewer side effects (Kaufmann, 2007; Grode et al., 2005). It is formulated as lyophilised bacteria to be resuspended before intradermal injection. First application of VPM1002 in human male volunteers will evaluate its safety, local and systemic tolerability as well as its immunogenicity. The study has a dose-escalating sequential design with comparison to commercially available BCG. 80 volunteers in Germany will randomly be allocated to 4 groups each with 20 volunteers stratified for their history of BCG-vaccination.
Phase ; Tuberculosis Healthy, Biological: VPM1002, Biological: BCG
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Open Label

27 Study to Evaluate the Safety and Immunogenicity of VPM1002 in Comparison With BCG in HIV-exposed/-Unexposed Newborn Infants in South Africa
Condition: Tuberculosis
Interventions:Biological: VPM1002; Biological: BCG; Biological: VPM1002(Hyg+)
"Purpose ; Goal of Serum Institute of India Limited (SIIL) is the development of a recombinant urease C-deficient listeriolysin expressing BCG vaccine strain (VPM1002)

as a safe, well tolerated and efficacious vaccine against tuberculosis (TB) for residents in endemic areas and persons at risk in non-endemic areas. The new vaccine should be at least as potent as the current strain and should be safer than BCG.

The preceding phase-IIa trial was the first investigation of VPM1002 in newborn infants in a high burden setting in South Africa. The vaccination of HIV-unexposed infants with VPM1002 indicated again safety, tolerability and immunogenicity sufficient to proceed in HIV-exposed infants.

The current study is a multiple site trial in South Africa to evaluate safety and immunogenicity in HIV-unexposed and -exposed newborn infants.

Tuberculosis, Biological: VPM1002, Biological: BCG, Biological: VPM1002(Hyg+)

Phase 2

Study Design: Allocation: Randomized

28 Single Group Study of the Safety of and Immune Response to a Bird Flu Vaccine (H7N3) in Healthy Adults

Conditions: Influenza; Virus Diseases

Intervention: Biological: Live Influenza A Vaccine H7N3 (6-2) AA ca Recombinant (A/chicken/British Columbia/CN-6/2004 x A/Ann Arbor/6/60 ca)

"Purpose; Over the past decade, avian influenza (AI) has become a major health concern. The development of safe and effective vaccines against avian strains infecting people is important. The purpose of this study is to determine the safety of and immune response to a new AI vaccine in healthy adults against the H7N3 strain of avian influenza.

Condition Influenza Virus Diseases, Biological: Live Influenza A Vaccine H7N3 (6-2) AA ca Recombinant (A/chicken/British Columbia/CN-6/2004 x A/Ann Arbor/6/60 ca)

Study Design: Allocation: Non-Randomized

Intervention Model: Single Group Assignment

Masking: Open Label

Primary Purpose: Prevention

29 Group Study of the Safety of and Immune Response to a Single Dose of Bird Flu Vaccine (H7N3) in Healthy Adults

Conditions: Influenza; Virus Diseases

Intervention: Biological: Live Influenza A Vaccine H7N3 (6-2) AA ca Recombinant (A/chicken/British Columbia/CN-6/2004 x A/Ann Arbor/6/60 ca)

30 Evaluating the Safety, Tolerability, and Immunogenicity of a Tetravalent

Dengue Vaccine (V180) in Healthy Adults Who Previously Received a Live-Attenuated Tetravalent Vaccine (TV003 or TV005)

Condition: Dengue

Interventions: Biological: V180; Biological: Alhydrogel™; Biological: Placebo

Purpose ; Dengue viruses are mosquito-borne flaviviruses. Each year, dengue viruses infect millions of people throughout the tropics and subtropics. This study will evaluate the safety, tolerability, and immunogenicity of a tetravalent recombinant subunit dengue vaccine (V180) in healthy adults who previously received a live-attenuated tetravalent dengue vaccine (TV003 or TV005).

31 Evaluating the Safety and Immunogenicity of a Live Attenuated West Nile Virus Vaccine for West Nile Encephalitis in Adults 50 to 65 Years of Age

Condition: West Nile Virus

Interventions: Biological: WN/DEN4Δ30 Vaccine; Biological: Placebo

"Purpose; West Nile virus (WNV) is considered an emerging virus in the United States, and infection can lead to severe illness in older adults. This study will evaluate the safety of and immune response to a live West Nile virus vaccine (WN/DEN4Δ30) for the prevention of West Nile encephalitis in adults 50 to 65 years old.

Phase; West Nile Virus, Biological: WN/DEN4Δ30 Vaccine, Biological: Placebo

Phase 1 Study Design: Allocation: Randomized

Intervention Model: Parallel Assignment

Masking: Participant, Care Provider, Investigator, Outcomes Assessor

31 Safety of and Immune Response to a Bird Flu Virus Vaccine (H5N1) in Healthy Adults

Conditions: Influenza; Virus Diseases

Intervention: Biological: H5N1 (6-2) AA ca Recombinant (A/VietNam/1203/2004 x A/AnnArbor/6/60/ca)

"Purpose ; Avian influenza (AI), or bird flu, has recently become a major health concern in Asia and other parts of the world. The need for a vaccine to prevent the spread of AI among livestock and to humans is sorely needed. The purpose of this study is to test the safety of and immune response to a new AI vaccine in healthy adults.

Phase ; Influenza Virus Diseases, Biological: H5N1 (6-2) AA ca Recombinant (A/VietNam/1203/2004 x A/AnnArbor/6/60/ca)

Phase 1 Study Design: Allocation: Randomized

Intervention Model: Parallel Assignment

Masking: Open Label

32 A Phase I Safety and Immunogenicity Trial of Live Recombinant Canarypox ALVAC-HIV (vCP205) and HIV-1 SF-2 rgp120 in HIV-1 Uninfected Volunteers to Evaluate Accelerated Vaccine Schedules

Condition: HIV Infections

Interventions:

Biological: ALVAC-HIV MN120TMG (vCP205); Biological: ALVAC-RG Rabie s Glycoprotein (vCP65); Biological: rgp120/HIV-1 SF-2

"Purpose ; To evaluate the safety and immunogenicity of an accelerated schedule of recombinant canarypox vaccine ALVAC-HIV MN120TMG (vCP205) versus control followed by boost with rgp120/HIV-1 SF2 vaccine in HIV-negative volunteers. Frequent injections of ALVAC-HIV vCP205 may result in more rapid induction of cytotoxic T-lymphocytes. This trial will evaluate whether an accelerated vaccination schedule can produce immunological responses comparable to those obtained in other trials of ALVAC-HIV vCP205.

Phase ; HIV Infections, Biological: ALVAC-HIV MN120TMG (vCP205), Biological: ALVAC-RG Rabies Glycoprotein (vCP65)

33 Immunogenicity and Safety of Live Attenuated Influenza Vaccine (Flumist) Administered by Nasal and Sublingual Route

Has Results Condition: Healthy

Intervention: Biological: Influenza vaccine

"Purpose; Background: It is well established that live attenuated organisms can be highly effective vaccines, immune responses elicited can often be of greater magnitude and of longer duration than those produced by non-living antigens and are often able to confer protection after a single dose. Unlike killed influenza vaccine preparations injected by the parenteral route, live influenza vaccines are able to induce potent secretory (mainly IgA) antibody responses in the airway mucosae and can also evoke cell mediated responses. T cell proliferation, cytokine production, cytotoxic T cell responses and antibody-dependent cell cytotoxicity have all been elicited by live attenuated vaccines.

34 Safety and Immunogenicity of Live Influenza A Vaccine for Avian Influenza H7N7

Condition: Influenza A

Intervention: Biological: Influenza A H7N7 vaccine
"Purpose ; Every year the human population suffers from seasonal outbreaks of influenza resulting in both illness and death. However, the rates of illness and death from seasonal outbreaks are significantly lower than those suffered during times of influenza pandemic, such as those experienced in 1918, 1957, and 1968. The reason for this difference lies in presence of immunity within a population. With seasonal outbreaks of influenza most people have some immunity to the circulating strain and usually only those with weakened immune systems experience serious complications. Influenza pandemics, in contrast, are the result of a completely new viral subtype to which nobody possesses an immunity, leaving everyone vulnerable to the most serious of complications.

35 Safety and Immunogenicity of a Live Attenuated H7N9 Influenza Virus Vaccine in Healthy Adults
Condition: Influenza A Virus, H7N9 Subtype
Interventions: Biological: Live attenuated H7N9 A/Anhui/13 ca influenza virus vaccine; Biological: Inactivated subvirion H7N9 influenza vaccine
"Purpose ; H7N9 avian influenza (AI) viruses have caused a recent outbreak of severe respiratory disease in humans in China. The purpose of this study is to evaluate the safety and immunogenicity of a live attenuated H7N9 A/Anhui/13 ca influenza virus vaccine in healthy adults. A single dose of inactivated subvirion H7N9 influenza vaccine will be administered 3 months later.
Phase : Influenza A Virus, H7N9 Subtype, Biological: Live attenuated H7N9 A/Anhui/13 ca influenza virus vaccine
Biological: Inactivated subvirion H7N9 influenza vaccine

36 Evaluating the Safety and Immune Response to a Live H7N9 Influenza Virus Vaccine Followed by an Inactivated H7N9 Influenza Virus Vaccine, Given at Varying Intervals
Condition: Influenza A Virus, H7N9 Subtype
Interventions: Biological: H7N9 A/Anhui/13 ca influenza virus vaccine; Biological: Inactivated subvirion H7N9 vaccine

37 Evaluating the Safety and Immunogenicity of a Live Attenuated Virus Vaccine to Prevent Influenza H3N2v Disease
Condition: Influenza

Interventions: Biological: H3N2v MN 2010/AA ca live attenuated influenza vaccine (LAIV); Biological: H3N2v inactivated subvirion influenza vaccine; Biological: Placebo

"Purpose; This study will evaluate the safety and immunogenicity of the H3N2v MN 2010/AA ca live attenuated influenza vaccine (H3N2v LAIV) in healthy children and adults, 6 to 26 years old.

Phase; Influenza, Biological: H3N2v MN 2010/AA ca live attenuated influenza vaccine (LAIV), Biological: H3N2v inactivated subvirion influenza vaccine, Biological: Placebo

Study Design: Allocation: Randomized

Intervention Model: Parallel Assignment

Masking: Open Label

38 Safety, Tolerability, and Immunogenicity Study of Homologous Ad26 Mosaic Vector Vaccine Regimens or Heterologous Ad26 Mosaic and MVA Mosaic Vector Vaccine Regimens With Glycoprotein 140 (gp140) for Human Immunodeficiency Virus (HIV)

Interventions:

Biological: Ad26.Mos.HIV; Biological: MVA-Mosaic; Biological: gp140 DP Low-dose; Biological: gp140 DP High-dose; Drug: Placebo

"Purpose ; The purpose of this study is to assess the safety and tolerability of various regimens containing adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV), Modified Vaccinia Ankara (MVA)-Mosaic, and/or HIV type 1 Clade C glycoprotein 140 drug product (gp140 DP) components and to compare envelope binding antibody responses between the different vaccine regimens.

Phase; Healthy, Biological: Ad26.Mos.HIV, Biological: MVA-Mosaic, Biological: gp140 DP Low-dose, Biological: gp140 DP High-dose, Drug: Placebo

Phase 2 Study Design: Allocation: Randomized

39 Safety and Immunogenicity Study of the Recombinant Human Bovine Reassortant Rotavirus Vaccine in Healthy Indian Infants

Condition: Rotavirus Infections

Interventions: Biological: Live Attenuated Tetravalent (G1-G4) Bovine-Human Reassortant Rotavirus Vaccine [BRV-TV]; Other: Placebo

"Purpose; A randomized, double-blind, placebo-controlled, staged dosage escalation study to evaluate the safety, tolerability, and immunogenicity of a 3-dose series of Live Attenuated Tetravalent (G1-G4) Bovine-Human Reassortant Rotavirus Vaccine

[BRV-TV] administered to healthy Indian infants concurrently with other standard EPI vaccines would be undertaken to evaluate the study hypothesis that a 3-dose series of BRV-TV (containing the VP7 serotypes G1, G2, G3, and G4) administered orally to healthy Indian infants at 6-8, 10-12, and 14-16 weeks of age concurrently with other standard EPI vaccines would be generally well tolerated and immunogenic.
Phase; Rotavirus Infections, Biological: Live Attenuated Tetravalent (G1-G4) Bovine-Human Reassortant Rotavirus Vaccine [BRV-TV], Other: Placebo

40 Evaluation of the Safety and Immunogenicity of a Live Attenuated Virus Vaccine for the Prevention of H2N3 Influenza
Condition: Influenza A Virus Infection
Intervention: Biological: H2N3 MO 2003/AA ca Vaccine

41 Single Group Study of the Safety of and Immune Response to a Bird Flu Virus Vaccine (H5N1) in Healthy Adults
Conditions: Influenza; Virus Diseases
Intervention: Biological: H5N1 (6-2) AA ca Recombinant (A/Hong Kong/213/2003 x A/AnnArbor/6/60 ca)

42 A Randomized Phase I Safety and Immunogenicity Trial of Live Recombinant Canarypox ALVAC-HIV vCP205 Delivered by Alternate Mucosal Routes in HIV-1 Uninfected Adult Volunteers
Condition: HIV Infections
Interventions:

Biological: MN rgp120/HIV-1 and GNE8 rgp120/HIV-1; Biological: ALVAC-H IV MN120TMG (vCP205); Biological: ALVAC-RG Rabies Glycoprotein (vCP65)
"Purpose ; To compare the safety of ALVAC-HIV vCP205 to that of ALVAC-RG vCP65 rabies glycoprotein, delivered by a variety of mucosal routes. To evaluate the antibody, humoral, and cellular immune responses resulting from ALVAC-HIV vCP205. [AS PER AMENDMENT 8/3/98: To obtain safety data on AIDSVAX B/B boosting administered by the intramuscular and intranasal routes in the context of previous immunization via alternate mucosal routes or intramuscularly with a canarypox vector expressing HIV-1 antigens (vCP205). To obtain immunogenicity data on AIDSVAX B/B boosting.] One of the earliest observations in the HIV epidemic was the demonstration of HIV infection at mucosal surfaces of cells in the genital tract. These data suggest that priming of immune defenses of viral infected cells may be an important component in the strategy

of developing an effective HIV vaccine. Direct immunization of relevant mucosal surfaces with a vectored vaccine may stimulate mucosal immunity. The ALVAC-HIV vCP205 immunogen is constructed from a live recombinant canarypox vector that has a good safety profile in volunteers and should allow mucosal induction of immunity.

43 Evaluating the Safety and Protective Efficacy of a Single Dose of the Live Attenuated Tetravalent Dengue Vaccine TV005 to Protect Against Infection With rDEN3Δ30

Condition: Dengue

Interventions:

Biological: TetraVax-DV-TV005; Biological: rDEN3Δ30; Biological: Placebo

"Dengue infection ranging from mild illness to life-threatening disease is widespread in most tropical and subtropical regions of the world. Infection with any of the four serotypes of dengue virus (DENV-1, DENV-2, DENV-3, and DENV-4) can cause dengue illness. TetraVax-DV-TV005 (referred to as TV005) is a live attenuated recombinant tetravalent dengue virus vaccine developed to protect against all four dengue virus serotypes. This study will evaluate the ability of a single dose of TV005 to protect against infection with rDEN3Δ30, a naturally attenuated DENV-3, given 6 months following vaccination with TV005.

44 Recombinant Attenuated Salmonella Typhi Vaccine Vectors Producing Streptococcus Pneumoniae PspA

Condition: Pneumonia

Intervention: Biological: Salmonella Typhi-vectored pneumonia vaccine

"Detailed Description:

The use of attenuated Salmonella strains that are unable to cause clinical disease but trigger a self-limiting infection leading to stimulation of protective immunity presents an attractive alternative to killed and subunit vaccines. Live, attenuated Salmonella strains have been shown to be excellent carriers, or vectors, for prokaryotic or eukaryotic antigens, being able to stimulate strong systemic and local immune responses against the expressed antigens. Three Salmonella Typhi strains have been engineered to express a gene encoding the alpha-helical domain of the Streptococcus pneumoniae surface protein, PspA, and will serve as live biological vaccine vectors in the proposed clinical trial to evaluate maximum safe and tolerable single dose levels after their oral administration to subjects. In this Phase I study, healthy young adults 18-40 years of age will participate in a dose escalating, dose sequential study divided

into four Arms to receive doses of 10^7, 10^8, 10^9 and 10^10 CFU. Each Arm (1-4) will consist of 3 groups of 5 subjects per group to receive a single oral dose of one of three recombinant attenuated S. Typhi vaccine vectors producing the pneumococcal antigen PspA. Each group per Arm will receive the same dose of one of the three vaccines for a total of 60 subjects (15 subjects per dose-escalating Arm, 3 groups per Arm, 5 subjects per group). Subject participation lasts 6 months after receiving the oral vaccine dosage with approximately the first 12-15 days (study Days 0-14) in confinement. Release criteria include 2 negative blood cultures in a row through study Day 7 (inpatient monitoring for 8 days) and 2 negative stool cultures in a row through study Day 5. The objectives of the study are 1) to evaluate maximum safe tolerable single dose levels of the three recombinant attenuated S. Typhi vaccine vectors using dose-escalation, dose-sequential studies in healthy adult subjects, and 2) to evaluate immunogenicity of the three recombinant attenuated S. Typhi vaccine vectors with regard to their abilities to induce mucosal and systemic antibody responses to the S. pneumoniae PspA and S. Typhi antigens. The vaccines are not anticipated to prevent disease. Although the immune responses generated by the vaccine vectors may confer some degree of protection against future infection with S. pneumoniae and S. Typhi, such protection is incidental. It is not the goal of this study to develop or test either a pneumonia or typhoid vaccine, but to select the S. Typhi vector that provides optimal delivery of the PspA antigen in a safe and immunogenic manner."

45 A Phase I Safety and Immunogenicity Trial of Live Recombinant Canarypox-gp160 MN (ALVAC vCP125, HIV-1 gp160 MN) in HIV-1 Uninfected Adult Volunteers

Condition: HIV Infections

Interventions:

Biological: ALVAC-HIV gp160MN (vCP125); Biological: ALVAC-RG Rabies G lycoprotein (vCP65); Biological: rgp120/HIV-1 SF-2

"Purpose ; Part A: To evaluate the safety and immunogenicity of ALVAC vCP125 HIV-1 gp160 MN live canarypox recombinant vaccine (ALVAC gp160 MN) versus a recombinant canarypox expressing the rabies glycoprotein (ALVAC rabies glycoprotein) as a control in healthy, HIV-1 uninfected adult volunteers.

Part B: To evaluate the schedule of two immunizations with ALVAC gp160 MN for optimal immunogenicity.

46 A Multicenter, Randomized, Placebo-Controlled, Double-Blinded, Phase I Trial

to Evaluate the Safety and Immunogenicity of Live Recombinant Canarypox ALVAC-HIV vCP205 Combined With GM-CSF in Healthy, HIV-1 Uninfected Volunteers

Condition: HIV Infections
Interventions:
Biological: APL 400-047; Biological: ALVAC-HIV MN120TMG (vCP205); D rug: Sargramostim
Purpose ; To evaluate the safety and immunogenicity of live recombinant canarypox ALVAC-HIV vCP205 in combination with recombinant human granulocyte-macrophage colony-stimulating factor (GM-CSF) at 80 microg and 250 microg. [AS PER AMENDMENT 4/30/99: To study the safety of following 4 ALVAC immunizations with a nucleic acid gag/pol HIV-1 immunogen (APL-400-047, Wyeth-Lederle). To assess the ability of this sequence of immunization to boost the LTL, T-helper cell, and antibody response.] ALVAC-HIV candidate vaccines have induced HIV-specific CTL responses in more than half of recipients in some protocols. Depending on the HIV-1 gene products expressed by the particular ALVAC-HIV candidate vaccine, volunteers have generated anti-Envelope (vCP125, vCP205, and vCP300), anti-Gag (vCP205 and vCP300), and anti-Nef (vCP300) CTL activity. Although 3 to 4 immunizations with the different ALVAC-HIV experimental vaccines induce anti-HIV-1 neutralizing antibodies in a portion, often the majority, of volunteers, the geometric mean titers of these antibodies are modest, usually less than 50. This study will determine whether there is an increase in the anti-HIV antibody titers when GM-CSF is used as an adjuvant with ALVAC-HIV vCP205 and will also examine the kinetics and magnitude of the HIV-specific CTL response.

47 A Phase 1/2A Study to Evaluate the Safety, Immunogenicity, and Shedding of MEDI-560 in Infants 1 to < 12 Months of Age
Has Results Condition: Healthy
Interventions: Biological: MEDI-560; Biological: Placebo
"Purpose ; The primary objective of this study is to describe the safety and tolerability of 3 doses of MEDI-560 at 10^5 TCID50 when administered to children 6 to < 12 months of age who are HPIV3 (human parainfluenza virus type 3) seronegative at baseline and to infants 1 to < 3 months of age regardless of baseline serostatus.
Healthy ; Biological: MEDI-560, Biological: Placebo, Phase 1 & Phase 2
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Official Title: An Expanded Phase1/2a Randomized, Double-blind, Placebo-controlled

Study to Evaluate the Safety, Tolerability, Immunogenicity, and Viral Shedding of MEDI-560, A Live, Attenuated Recombinant Parainfluenza Virus Type 3 (PIV3) Vaccine, Administered Intranasally to Healthy Infants 1 to <12 Mos. of Age
Secondary Outcome Measures: •Number of Participants Shedding Vaccine-like Virus at Any Time During Study Participation [Time Frame: Days 7, 12, and 28 after each dose and during visits for pre-specified illness symptoms occurring Day 0 through 180 days post final dose.]

48 A Phase I, Multicenter, Randomized Trial to Evaluate the Safety and Immunogenicity of Vaccinia-Derived MN HIV-1 Recombinant Envelope Glycoprotein (rgp160) of Human Immunodeficiency Virus at Two Different Vaccination Schedules
Conditions: HIV Infections; HIV Seronegativity
Intervention: Biological: gp160 Vaccine (Immuno-AG)
"Purpose ; AMENDED 8/94: To expand the safety and immunogenicity profile of MN rgp160 vaccine (Immuno-AG) by administering a higher dose (800 mcg) at 0, 1, 6, and 12 months and 0, 2, 8 and 14 months (these two schedules were compared in VEU 013A using a dose of 200 mcg). To obtain plasma following the fourth immunization. To evaluate skin test reactivity.
ORIGINAL (replaced): To determine in healthy volunteers the safety and immunogenicity of two immunizations of MN rgp160 vaccine (Immuno-AG) in combination with a live recombinant vaccinia virus LAV HIV-1 gp160 vaccine (HIVAC-1e) versus DryVax (the standard smallpox vaccine that was used for many years) control in combination with placebo.

49 A Phase II Safety and Immunogenicity Trial of Live Recombinant Canarypox ALVAC-HIV vCP205 With or Without HIV-1 SF-2 RGP120 in HIV-1 Uninfected Adult Volunteers
Condition: HIV Infections
Interventions:
Biological: MN rgp120/HIV-1 and GNE8 rgp120/HIV-1; Biological: MN rgp120/HIV-1 and A244 rgp120/HIV-1; Biological: ALVAC-HIV MN120TMG (vCP205); Biological: rgp120/HIV-1 SF-2
"Purpose ; To expand the available data regarding the safety and immunogenicity of 2 HIV-1 vaccine strategies: canarypox vector vCP205, or vCP205 with SF-2 rgp120. [AS PER AMENDMENT 7/2/98: To obtain immunogenicity and safety data on gp120 subunits that may induce enhanced neutralizing antibody response to primary isolates

of HIV-1 in the context of previous immunization with a canarypox vector expressing HIV antigens (vCP205). To evaluate cytotoxic T lymphocyte responses at 1 and 2 years after initial vaccination with vCP205 plus rgp120 SF-2 or vCP205 alone.] In previous ALVAC vCP205/SF-2 rgp 120 studies, patients have developed antibodies that neutralize homologous laboratory strains; over 50% of patients have developed CD8+ cytotoxic T-lymphocyte responses to HIV env and gag epitopes at some point in the study. This Phase II study seeks to confirm these results among persons at lower or higher risk for HIV infection with a new lot of ALVAC vCP205, at a dose that is suitable for potential large-scale trials. [AS PER AMENDMENT 7/2/98: Addition of AIDSVAX B/B or AIDSVAX B/E boosts starting at least 12 months after receiving rgp120 or ALVAC vaccines may induce enhanced neutralizing antibody response as deemed from prior studies and thus is planned as ""follow-up"" therapy.]
Official Title: A Phase II Safety and Immunogenicity Trial of Live Recombinant Canarypox ALVAC-HIV vCP205 With or Without HIV-1 SF-2 RGP120 in HIV-1 Uninfected Adult Volunteers "

50 A Multicenter, Randomized, Placebo-Controlled, Double-Blind Trial to Evaluate the Safety and Immunogenicity of a Recombinant Vaccinia-HIV-1 IIIB Env/Gag/Pol Vaccine (TBC-3B)
Condition: HIV Infections
Interventions: Biological: TBC-3B Vaccine; Biological: Smallpox Vaccine
" Purpose ; To evaluate, in healthy HIV-1 seronegative vaccinia-immune and vaccinia-naive volunteers, the safety and immunogenicity of an HIV-1 candidate vaccine (TBC-3B) consisting of a live recombinant vaccinia virus expressing the env, gag, and pol genes of HIV-1 IIIB strain. To evaluate the potential of boosting with one of a variety of HIV-1 recombinant subunit, peptide, or pseudovirion vaccines, if available, to augment the immune responses of the vaccinees.

51 Evaluating the Safety and Immunogenicity of a Human Parainfluenza Type 3 (HPIV3) Virus Vaccine in Infants and Children
Condition: Parainfluenza Virus 3, Human
Interventions: Biological: rHPIV3cp45 Vaccine; Biological: Placebo Vaccine
"Purpose; Human parainfluenza virus type 3 (HPIV3) is a major cause of pneumonia and other respiratory diseases in infants and children. This study will evaluate the safety and immune response of an HPIV3 vaccine in infants and young children. Parainfluenza Virus 3, Human, Biological: rHPIV3cp45 Vaccine, Biological: Placebo

Vaccine, Phase 1

52 A Phase I Safety and Immunogenicity Trial of Live Recombinant Canarypox ALVAC-HIV (vCP205) in HIV-1 Uninfected Adult Volunteers
Condition: HIV Infections
Interventions:
Biological: ALVAC-HIV MN120TMG (vCP205); Biological: ALVAC-RG Rabies Glycoprotein (vCP65); Biological: rgp120/HIV-1 SF-2

53 Immunogenicity of Recombinant Vesicular Stomatitis Vaccine for Ebola-Zaire (rVSV[Delta]G-ZEBOV-GP) for Pre-Exposure Prophylaxis (PREP) in People at Potential Occupational Risk for Ebola Virus Exposure
Condition: Healthy Volunteers
Intervention: Drug: rVSVdeltaG-ZEBOV GP (2X 107 pfu/mL)
"Background: The Ebola virus causes a severe disease. It can be fatal. The usual incubation period after being exposed is 2 to 21 days. There is no approved treatment for Ebola infection. There is also no vaccine to prevent infection either before or after exposure. Researchers want to test an Ebola vaccine. They want to give it to people before they are exposed to the virus in order to prevent the disease.
Objectives: to see how long-lasting and effective the vaccine rVSV[delta]G ZEBOV-GP (V920) is at preventing Ebola.

54 Safety of and Immune Response to a Human Parainfluenza Virus Vaccine (rHPIV3cp45) in Healthy Infants
Conditions: Paramyxoviridae Infections; Virus Diseases
Interventions: Biological: rHPIV3cp45; Biological: Placebo
"Human parainfluenza viruses (HPIVs) are a major health concern in infants and young children under 5 years of age, causing serious respiratory tract disease. The purpose of this study is to test the safety of and immune response to a new HPIV vaccine in healthy infants and children.

55 Safety and Immunogenicity of the RSV D46cpΔM2-2 Vaccine in RSV-Seropositive Children and RSV-Seronegative Infants and Children
Condition: Respiratory Syncytial Virus Infections
Interventions: Biological: D46cpΔM2-2 vaccine; Biological: Placebo
Purpose ; The purpose of this study is to evaluate the safety and immunogenicity of the

RSV D46cpΔM2-2 vaccine in RSV-seropositive children and RSV-seronegative infants and A Phase I Study of the Safety and Immunogenicity of a Single Dose of the Live Recombinant RSV D46cpΔM2-2 Vero Grown Virus Vaccine (Lot RSV #008A), Delivered as Nose Drops to RSV-Seropositive Children 12 to 59 Months of Age and RSV-Seronegative Infants and Children 6 to 24 Months of Ag

56 A Phase I Safety and Immunogenicity Trial of Live Recombinant Canarypox ALVAC-HIV vCP300 and HIV-1 SF-2 rgp120 in HIV-1 Uninfected Adult Volunteers
HIV MN120TMGNP (vCP300); Biological: ALVAC-RG Rabies Glycoprotein (vCP65); Biological: rgp120/HIV-1 SF-2
"Purpose; To evaluate, in HIV-negative volunteers, the safety and immunogenicity of ALVAC-HIV MN120TMGNP (vCP300) followed by or combined with boosting using rgp120/HIV-1SF2. To compare ALVAC-HIV vCP300 with ALVAC-RG rabies glycoprotein (vCP65) as a control. To evaluate an accelerated immunization schedule at 0, 1, 3, and 6 months versus 0, 1, 6, and 9 months.
The combination of a live recombinant primer followed by a subunit boost has the potential to induce not only cytotoxic T lymphocytes but also neutralizing antibody.
A Phase I Safety and Immunogenicity Trial of Live Recombinant Canarypox ALVAC-HIV vCP300 and HIV-1 SF-2 rgp120 in HIV-1 Uninfected Adult Volunteers"

57 Safety and Immunogenicity of a Vaccine for Cutaneous Leishmaniasis Using Recombinant Human Interleukin-12 and Aluminum Hydroxide Gel as Adjuvants
Condition: Cutaneous Leishmaniasis
Intervention: Biological: Combination of autoclaved leishmania antigen with recombinant human interleukin-12 (rhIL-12) and aluminum hydroxide gel as adjuvants

58 A Phase I Safety and Immunogenicity Trial of Live Recombinant Canarypox ALVAC-HIV (vCP205) and HIV-1 SF-2 rgp120 in HIV-1 Uninfected Adult Volunteers
Condition: HIV Infections
Interventions:
Biological: ALVAC-HIV MN120TMG (vCP205); Biological: ALVAC-RG Rabies Glycoprotein (vCP65); Biological: rgp120/HIV-1 SF-2

59 Safety of and Immune Response to a Dengue Virus Vaccine (rDEN3delta30/31‐7164) in Healthy Adults
Condition: Dengue Fever

Intervention: Biological: rDEN3delta30/31 - 7164
"Purpose ; Dengue fever, which is caused by dengue viruses, is a major health problem in tropical and subtropical regions of the world. The purpose of this study is to test the safety of and immune response to a new dengue virus vaccine in healthy adults.
Experimental: Group 1 ; Group 1 will consist of healthy participants receiving an immunization of 10^3 PFU rDEN3delta30/31 - 7164, Biological: rDEN3delta30/31 - 7164 ; A live attenuated, recombinant DEN3 candidate vaccine virus

60 Safety and Immune Response Study of High-Dose Canarypox ALVAC-HIV Vaccine in Healthy, HIV Uninfected Adults
Conditions: HIV Infections; HIV Seronegativity
Intervention: Biological: ALVAC(2)120(B,MN)GNP (vCP1452)
"Purpose ; The purpose of this study is to see if the experimental vaccine, ALVAC-HIV (vCP1452) is safe and to study how the immune system responds to the vaccine. This trial is designed to determine whether a higher vaccine dose (6 times the usual dose) will elicit a higher immune response.

61 Completed A Study to See Whether Two HIV Vaccines Are Safe and Can Prevent HIV Infection
Conditions: HIV Infections; HIV Seronegativity
Interventions:
Biological: gp160 MN/LAI-2; Biological: ALVAC-HIV MN120TMG (vCP205)

62 Completed Safety and Effectiveness of Anti-HIV Vaccines in HIV-Negative Adults
Condition: HIV Infections
Interventions:Biological: ALVAC(2)120(B,MN)GNP (vCP1452); Biological: gp160 MN/LAI-2; Biological: ALVAC(1)120(B,MN)GNP (vCP1433); Biological: ALVAC-HIV MN120TMG (vCP205); Biological: ALVAC-RG Rabies Glycoprotein (vCP65)
"Purpose ; The purpose of this study is to find out whether three different anti-HIV vaccines are safe and whether they help prevent HIV infection. These vaccines are called vCP205, vCP1433, and vCP1452. Some patients also receive another anti-HIV vaccine, gp160. The vaccines are made up of small pieces of HIV, which help the body learn to recognize and destroy HIV. You cannot get HIV from these vaccines.

63 Completed Safety and Immunogenicity Study to Assess TDV, a Live

Attenuated Tetravalent Vaccine for Prevention of Dengue Fever
Has Results Condition: Dengue Fever
Interventions:Biological: TDV - Low Dose; Biological: TDV - High Dose; Biological: Placebo
"Purpose ; The purpose of this study is to assess the safety of Takeda's Tetravalent Dengue Vaccine Candidate (TDV) (previously DENVax) in healthy adults when given as either a subcutaneous (SC) or intradermal (ID) injection at two dose levels (low and high). The vaccine will be given as two doses 90 days apart. Safety assessments include injection site evaluation and adverse events. The immune response generated after vaccination will be assessed up to 9 months after the first vaccination

64 Study of CYD Dengue Vaccine in Healthy Children and Adolescents in South America
Has Results Conditions: Dengue; Dengue Hemorrhagic Fever
Interventions: Biological: Live, attenuated, recombinant dengue serotype 1 , 2, 3 , and 4 virus; Biological: NaCl 0.9%; Biological: Tetanus toxoid, reduced diphtheria toxoid, acellular pertussis vaccine adsorbed; Biological: Meningococcal A+C vaccine
"Purpose ; The purpose of this study is to generate immunogenicity and safety data in preparation for efficacy studies in Latin America.

65 Study of a Tetravalent Dengue Vaccine in Healthy Children Aged 2 to 11 Years in Malaysia
Conditions: Dengue Fever; Dengue Hemorrhagic Fever
Interventions: Biological: Live, attenuated, recombinant dengue serotypes 1, 2, 3, and 4 virus; Biological: Placebo: NaCl 0.9%

66 Study of a Tetravalent Dengue Vaccine in Healthy Adult Subjects Aged 18 to 45 Years in India
Has Results Conditions:Dengue; Dengue Fever; Dengue Hemorrhagic Fever
Interventions: Biological: Live, attenuated, recombinant dengue serotype 1, 2, 3, 4 virus; Biological: Placebo: NaCl 0.9% solution

67 Safety and Effectiveness of the Vaccine ALVAC-HIV vCP205 in HIV-Negative Adult Volunteers in Uganda
Condition: HIV Infections
Interventions:

Biological: ALVAC-HIV MN120TMG (vCP205); Biological: ALVAC-RG Rabie s Glycoprotein (vCP65)

69 Reactogenicity, Safety and Immunogenicity of a TB/FLU-04L Tuberculosis Vaccine

Condition: Tuberculosis

Interventions: Biological: tuberculosis vaccine; Biological: Placebo

"Purpose ; The study is a single centre, phase I, double-blind, randomized, placebo-controlled trial that explored the safety and immunogenicity of 2 doses (Day 1 and Day 21) TB/FLU-04L tuberculosis vaccine versus matched placebo in BCG-vaccinated healthy adult subjects aged 18-50 years.

Biological: tuberculosis vaccine , Live recombinant influenza vectored tuberculosis vaccine

Other Name: TB/FLU-04L

Sponsor: Research Institute for Biological Safety Problems

Collaborators: National Center for Tuberculosis Problems, Kazakhstan Research Institute of Influenza, Russia"

70 Surgery and Vaccine Therapy in Treating Patients With Early Cervical CancerCondition: Cervical Cancer

Interventions: Biological: human papillomavirus 16 E7 peptide; Biological: synthetic human papillomavirus 16 E6

peptide; Procedure: adjuvant therapy; Procedure: surgical procedure; Radiation: radiation therapy

"Purpose; RATIONALE: Vaccines made from human papillomavirus may make the body build an immune response to and kill cervical cancer cells. Combining vaccine therapy with surgery may be a more effective treatment for cervical cancer.

PURPOSE: This phase II trial is studying how well giving vaccine therapy together with surgery works in treating patients with early cervical cancer.

71 Safety of and Immune Response to a Modified Vaccinia Ankara (MVA) HIV Vaccine in HIV Uninfected Adults

Condition: HIV Infections

Interventions: Biological: MVA-CMDR; Biological: Placebo

"Purpose ; The purpose of this study is to determine the safety and the immune responses to the HIV vaccine candidate, MVA-CMDR. This vaccine was designed to

induce immune responses to three HIV ""passenger"" genes encoded with the viral vector, MVA.

72 Intranasal AD4-H5-VTN as an Adenovirus Vaccine
Condition: Healthy Volunteer
Intervention: Biological: Ad4-H5-Vtn Sponsor:National Institute of Allergy and Infectious Diseases (NIAID)
"Detailed Description: This is a Phase 1 single center, dose-escalation study designed to evaluate the safety and immunogenicity of live, replication competent recombinant Adenovirus type 4-H5N1 Influenza Vietnam 1194 Hemagglutinin (HA) (Ad4-H5-Vtn). Determining the optimal route and dose for this recombinant platform will greatly accelerate investigations of this vector as an influenza vaccine and an HIV vaccine platform.

73 HIV Candidate Vaccine, ALVAC-HIV-1, Administration in HIV-Negative AdultsConditions: HIV Infections; HIV Seronegativity
Intervention: Biological: ALVAC-HIV MN120TMG (vCP205)

74 A Study to Evaluate the Safety and Effectiveness of HIV-1 LAI gp120 (an HIV Vaccine) Given With or Without HIV-1 MN rgp120 (Another HIV Vaccine) to HIV-Negative Volunteers
Conditions: HIV Infections; HIV Seronegativity
Interventions: Biological: Salmonella typhi CVD 908-HIV-1 LAI gp 120 (VVG 203); Biological: Aluminum hydroxide; Biological: MF59; Biological: rgp120/HIV-1MN

75 HIV Vaccine Trial in Thai Adults
Condition: HIV Infection
Interventions:
Biological: ALVAC-HIV vCP1521 + AIDSVAX; Biological: ALVAC Placebo + A IDSVAX Placebo

76 Evaluating the Safety and Effectiveness of a Dengue Virus Vaccine in Healthy Adults
Condition: Dengue
Interventions:

Biological: TetraVax-DV-TV003; Biological: rDEN2Δ30-7169; Biological: Pl acebo

"Dengue viruses can cause dengue illness ranging from a mild illness to life-threatening disease. The purpose of this study is to evaluate the protective effectiveness of a dengue virus vaccine in healthy adults.

77 Study of Boosting Strategies After Vaccination With ALVAC-HIV and AIDSVAX® B/E

Condition: HIV Infections

Interventions:

Biological: ALVAC-HIV; Biological: AIDSVAX B/E; Biological: ALVAC-HIV Placebo; Biological: AIDSVAX B/E Placebo

"The primary purpose of the study is to better define the relative contributions of AIDSVAX® B/E alone, ALVAC-HIV alone, or ALVAC-HIV plus AIDSVAX® B/E combination to the observed immune profile in the weeks and months after receiving the original prime and boost vaccine regimen from study protocol RV 144, and their booster effects in both the systemic and mucosal compartments. In addition, this study will provide more intensive and comprehensive characterization of the innate, cell-mediated and humoral immune responses than possible within the RV 144 study.

78 A Study of Dengue Vaccine in Healthy Toddlers Aged 12 to 15 Months in the Philippines

Conditions: Dengue Fever; Dengue Hemorrhagic Fever

Interventions: Biological: Live, attenuated, recombinant dengue serotypes 1, 2, 3 and 4 virus; Biological: OKAVAX®:Attenuated live varicella-zoster virus and AVAXIM® 80U: Hepatitis A virus Vaccines; Biological: Live, attenuated, recombinant dengue serotypes 1, 2, 3 and 4 virus and Childhood vaccines; Biological: Live, attenuated, recombinant dengue serotypes 1, 2, 3 and 4 virus and NaCl (Placebo)

Sponsor: Sanofi

79 Completed Evaluation of the Safety and Efficacy of a Single Dose of a Dengue Vaccine (TV005) in Healthy Adults

Condition: Dengue

Interventions:

Biological: TV005; Biological: Placebo; Biological: rDEN2Δ30-7169"Biologi cal: TV005

TV005 is a live attenuated recombinant tetravalent dengue virus vaccine. It will be administered as a 0.5 mL dose containing 10^3 plaque forming units (PFUs) of each component (10^3.3 PFUs/mL of rDEN1Δ30, 10^4.3 PFU/mL of rDEN2/4Δ30(ME), 10^3.3 PFU/mL of rDEN3Δ30/31-7164 and 10^3.3 PFU/mL of rDEN4Δ30). It will be delivered by subcutaneous injection in the deltoid region of the upper arm.
Biological: rDEN2Δ30-7169

80 Immune Response to Different Schedules of a Tetravalent Dengue Vaccine Given With or Without Yellow Fever Vaccine
Conditions:Dengue; Dengue Fever; Dengue Hemorrhagic Fever; Yellow Fever
Interventions: Biological: Live, attenuated, recombinant dengue serotypes 1, 2, 3, and 4 virus; Biological: Yellow Fever
"Purpose The aim of this study is to evaluate the administration of CYD dengue vaccine following a compressed schedule in different populations.
Primary Objectives:
·To describe the humoral immune response to each of the 4 parental dengue virus serotypes at baseline and 28 days after CYD dengue vaccine Dose 3 in defined study groups.

81 Active, not recruiting Experimental AD4-H5-VTN Vaccine in Healthy Volunteers
Condition: H5N1 Influenza
Interventions: Biological: Ad4-H5-VTN vaccination-tonsillar route; Biological: Ad4-H5-vaccination-oral route
" Purpose This is a Phase 1 randomized, single center, dose-escalation study designed to evaluate the safety and immunogenicity of live, replication competent recombinant Adenovirus type 4-H5N1Influenza Vietnam 1194 Hemagglutinin (HA) (Ad4-H5-Vtn). Determining the optimal route and dose for this recombinant platform will greatly accelerate investigations of this vector as an influenza vaccine and an HIV vaccine platform.

82 Tetravalent Chimeric Dengue Vaccine Trial
Condition: Dengue
Interventions: Drug: Placebo (SC); Drug: Placebo (ID); Biological: Modified Live Tetravalent Chimeric Dengue Vaccine (SC); Biological: Modified Live Tetravalent Chimeric Dengue Vaccine (ID)

"Drug: Placebo (ID)

83 Study of Late Boost Strategies for HIV-uninfected Participants From Protocol RV 144

Condition: HIV Infections

Interventions:

Biological: ALVAC-HIV; Biological: AIDSVAX B/E; Biological: ALVAC-HIV Placebo; Biological: AIDSVAX B/E Placebo

"Randomized, Double Blind Evaluation of Late Boost Strategies for HIV-uninfected Participants in the HIV Vaccine Efficacy Trial RV 144: ""Aventis Pasteur Live Recombinant ALVAC-HIV (vCP1521) Priming With VaxGen gp120 B/E (AIDSVAX B/E) Boosting in HIV-uninfected Thai Adults""

Sponsor: U.S. Army Medical Research and Materiel Command

Collaborator: National Institutes of Health (NIH)

ALVAC-CEA vaccine is a cancer vaccine containing a canary pox virus (ALVAC) combined with the carcinoembryonic antigen (CEA) human gene. A phase I trial in 118 patients showed safety in humans(**別製品の情報から、**HIV **抗原を発現するカナリア** POX **ワクチ**) "

84 Study of a Tetravalent Dengue Vaccine in Healthy Adults in Australia

Conditions: Dengue Fever; Dengue Hemorrhagic Fever

Interventions: Biological: Live, attenuated, recombinant dengue serotypes 1, 2, 3, & 4 virus; Biological: Placebo: NaCl 0.9%

"Biological: Live, attenuated, recombinant dengue serotypes 1, 2, 3, & 4 virus
Biological: Placebo: NaCl 0.9%

Sponsor: Sanofi Pasteur, a Sanofi Company "

85 Partnership for Research on Ebola Vaccines in Liberia (PREVAIL)

Condition: Ebola Virus

Interventions:

Biological: VSVG-ZEBOV; Biological: ChAd3-EBO Z; Drug: Placebo

"Experimental: 2

ChAd3-EBO Z Biological: ChAd3-EBO Z

The ChAd3-EBO Z vaccine is comprised of a ChAd3 vector with a DNA fragment insert that encodes the Ebola virus glycoprotein, which is expressed on the virion surface and is critical for attachment to host cells and catalysis of membrane fusion.

Experimental: 3

86 African-Canadian Study of HIV-Infected Adults and a Vaccine for Ebola - ACHIV-Ebola
Condition: Ebola
Interventions: Biological: V920 (rVSVΔG-ZEBOV-GP) Ebola Virus Vaccine; Other: Saline

87 Phase 1b Study PVSRIPO for Recurrent Malignant Glioma in Children
Conditions:Malignant Glioma; Anaplastic Astrocytoma; Anaplastic Oligoastrocyto ma; Anaplastic Oligodendroglioma; Glioblastoma; Gliosarcoma
Intervention: Biological: Polio/Rhinovirus Recombinant (PVSRIPO)

88 Safety and Immunogenicity of Replication-Competent Adenovirus 4-vectored Vaccine for Avian Influenza H5N1
Conditions: Bird Flu; Influenza
Interventions: Other: Placebo; Biological: Ad4-H5-Vtn; Biological: Sanofi Pasteur Influenza Virus Vaccine, H5N1
"Experimental: Cohort 1
three vaccinations of 10^7vp Ad4-H5-Vtn or placebo Other: Placebo
enteric coated capsule containing no vaccine virus
Other Name: Placebo for Ad4-H5-Vtn
Biological: Ad4-H5-Vtn

89 Pneumococcal Vaccine and Routine Pediatric Immunizations in HIV-Infected Children Receiving Anti-HIV Drugs
Conditions:HIV Infections; Hepatitis B; Measles; Pneumococcal Infections; Per tussis
Interventions: Biological: Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed; Biological: Measles-Mumps-Rubella Vaccine (Live); Biological: Pneumococcal Vaccine, Polyvalent (23-valent); Biological: Pneumococcal Conjugate Vaccine, Heptavalent; Biological: Hepatitis B Vaccine (Recombinant)

90 Study of a Booster Injection of Pentaxim™ Vaccine Administered With Dengue Vaccine in Healthy Toddlers
Conditions: Dengue; Dengue Hemorrhagic Fever

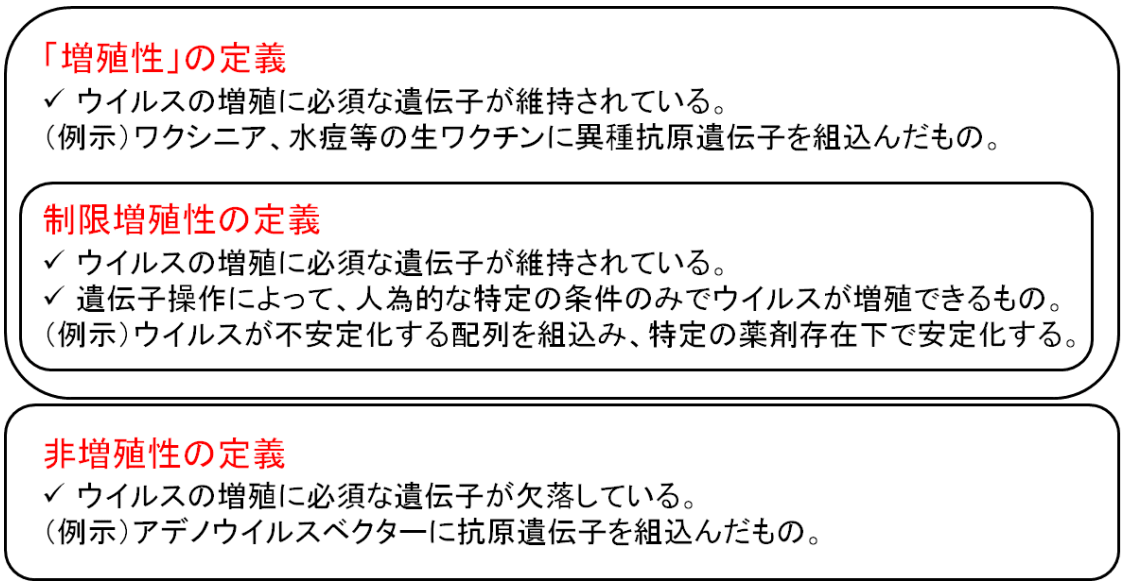

図 1. 遺伝子組換えワクチンの増殖性に関する分類

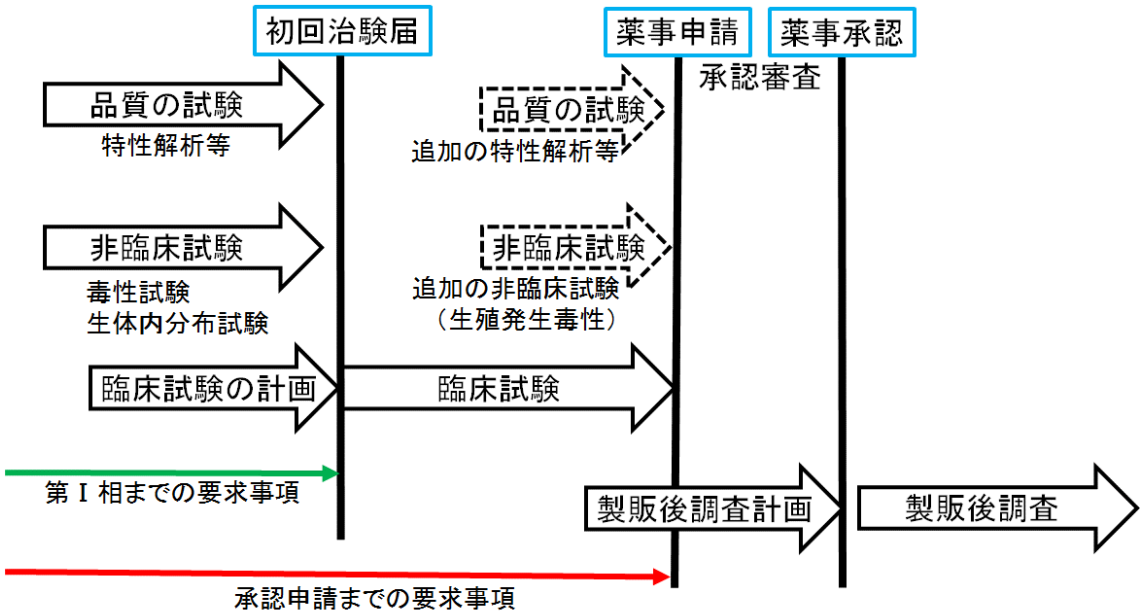

図 2. 遺伝子組換えワクチンの治験から薬事承認のスキーム

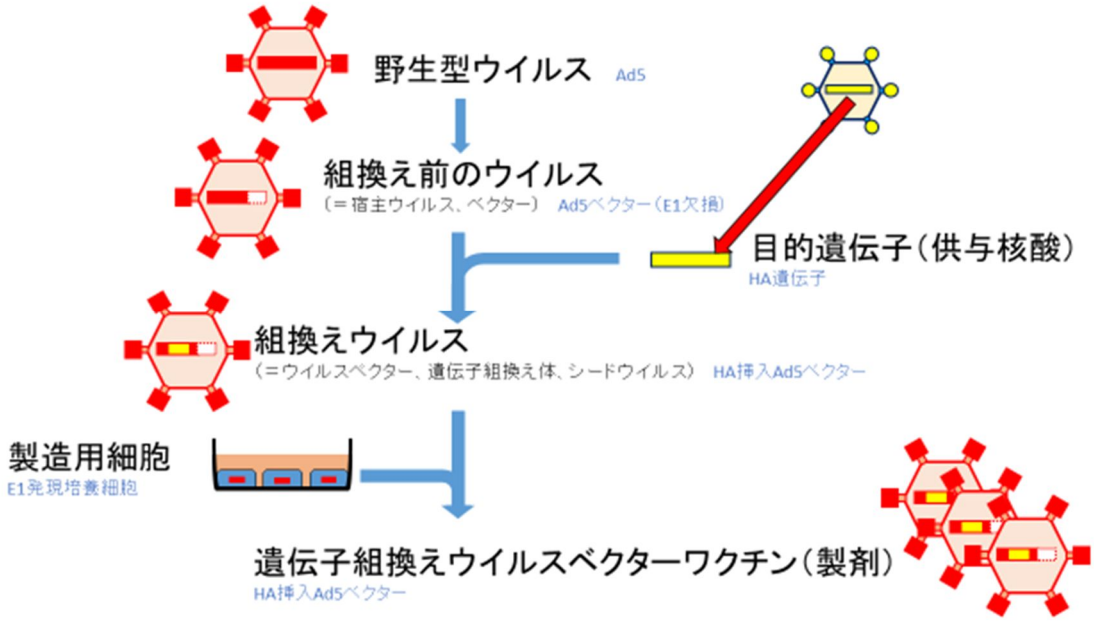

図 3．遺伝子組換えワクチンの製造

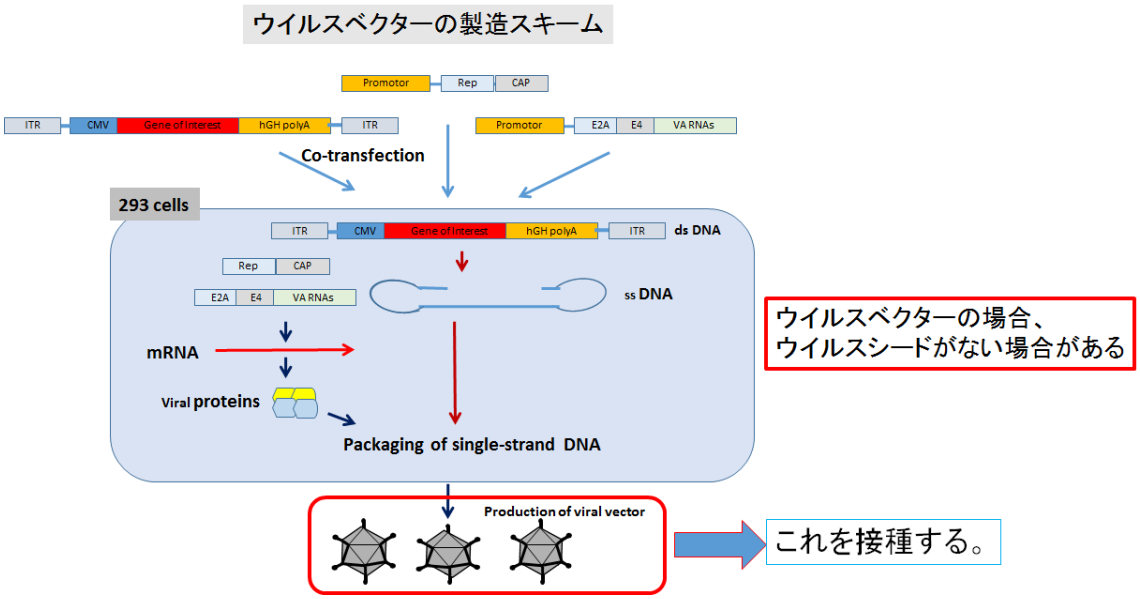

図 4．ウイルスベクターの基本的な製造スキーム