

APPENDIXES

APPENDIX A: Status of Vaccine Research and Development, 2012

Target Agent	Vaccine	Basic R&D	Preclinical	Phase I	Phase II	Phase III
<i>Ancylostoma duodenale</i>	Recombinant protein	+	+	+		
<i>Bacillus anthracis</i>	Recombinant protein (eg rPA, rPA + other anthrax proteins)	+	+	+	+	
	Viral vectored	+	+			
	Bacterial vectored	+	+			
	Conjugate (eg PGA-PA)	+	+	+		
	Spore vectored	+				
	DNA	+	+	+		
<i>Bordetella pertussis</i>	AVA + CpG	+	+	+		
	<i>B. pertussis</i> surface protein expressed by vector (e.g., <i>Salmonella</i> and <i>Vibrio cholerae</i>)	+	+			
	PT peptides-CRM conjugates	+	+			
	Purified adenylate cyclase	+	+			
<i>Blastomyces dermatitidis</i>	Purified yeast cell proteins (e.g., WI-1)	+	+			
	Recombinant proteins (e.g., WI-1)	+				
	WI-1 DWA	+	+			
	Live attenuated strain	+	+			
<i>Borrelia burgdorferi</i>	Recombinant Osp A	+	+	+	+	+
	Osp A-based DNA vaccine	+	+			
	BCG-expressed Osp A	+	+			
	Purified Osp B, Osp C	+	+	+		
	Osp C (polyvalent)	+	+	+	+	
	DpbA	+				
	DpbB	+				
	AcGal	+				

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Target Agent	Vaccine	Basic R&D	Preclinical	Phase I	Phase II	Phase III
	RevA	+				
	BBK32, BB0323	+				
<i>Brugia malayi</i>	Purified parasite antigens (paramyosin, etc.)	+	+			
<i>Campylobacter jejuni</i>	Whole cell (intact)	+	+	+	+	
	<i>E. coli</i> recombinant flagellin, intranasal delivery	+	+	+		
	Protein subunit vaccine	+	+	+	+	
	Whole cell	+	+	+		
	Polysaccharide capsules	+	+			
	Flagella secreted protein A1 (FspA1)	+				
	ACE393 recombinant protein, systemic delivery with alum	+	+	+	+	
	Monovalent capsule conjugate (CRM197)	+	+			
<i>Candida albicans</i>	Cell surface oligomannosyl epitope	+	+			
	Recombinant Als1p surface protein	+	+			
	Recombinant Als3p surface protein	+	+			
<i>Chikungunya virus</i>	Live attenuated (conventional)	+	+	+	+	
	Adenovirus-vectorized (various)	+				
	Adeno-associated virus-vectorized	+				
	Newcastle disease virus-vectorized	+				
	Alphavirus-based chimeras	+				
	Virus-like particle vaccine	+				
	Cationic-liposome-DNA complex	+				
<i>Chlamydia pneumoniae</i>	Purified, major outer membrane protein, heat shock protein	+				
	Outer membrane protein-based DWA vaccine	+				
<i>Chlamydia trachomatis</i>	Major outer membrane protein (MOMP)	+	+			

Target Agent	Vaccine	Basic R&D	Preclinical	Phase I	Phase II	Phase III
	Polymorphic membrane protein D	+				
	Chlamydia-secreted protease factor (CPAF)	+				
<i>Clostridium botulinum</i>	Toxoids	+	+	+	+	
	Recombinant AB vaccine	+	+	+	+	
	Recombinant heavy chain	+	+			
	Recombinant light chain LHN	+				
	Viral vectored	+				
	Replicon based	+				
	DNA	+				
	Nonneurotoxic peptides	+				
<i>Clostridium difficile</i>	Toxin mutants	+	+	+	+	
	Toxin mutants expressed in a bacterial system (endotoxin-free <i>Bacillus megaterium</i>)	+				
	Surface layer protein	+				
<i>Clostridium tetani</i>	Recombinant toxin	+	+			
	<i>Salmonella</i> vector	+	+	+		
	Microencapsulation	+	+			
	Transcutaneous immunization	+	+			
<i>Coccidioides immitis</i>	Formalin-killed spherules	+	+	+	+	+
	Recombinant protein for Ag2, rAg2 (PRAg2)	+	+			
	Spherule homogenate (27kxg)	+	+			
	C-ASWS (Ag2)	+	+			
	Urease (recombinant and cDNA) (rURE)	+	+			
	Spherule outer wall glycoprotein (SOWgp)	+	+			
	PMP-1	+	+			
<i>Corynebacterium diphtheriae</i>	Recombinant toxin	+	+			

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<i>Coxiella burnetii</i>	<i>Salmonella</i> vector	+	+	+		
	Transcutaneous immunization	+	+			
<i>Cryptococcus neoformans</i>	Formalin inactivated	+	+	+	+	
	Antigen immunization	+				
	DNA vaccine	+				
<i>Cytomegalovirus (CMV)</i>	Partially purified capsular polysaccharide	+	+			
	Glycoconjugate of capsular polysaccharide with tetanus toxoid	+	+	+		
<i>Dengue virus</i>	Live attenuated strains (conventional)	+	+	+	+	
	Live attenuated strains (engineered)	+	+	+		
	Glycoprotein subunit vaccine	+	+	+	+	
	Multiprotein subunit vaccine	+				
	Nucleic acid (DNA) vaccines	+	+	+	+	+
	Canarypox vectored	+	+	+		
	VEE-vectored	+	+	+	+	+
	Peptide	+				
	DNA prime + inactivated boost	+				
<i>Leishmania</i>	Replication-defective	+				
	Purified rDNA-expressed viral proteins	+	+			
	Yellow fever/dengue chimeric virus	+	+	+	+	
	Inactivated whole virus particle	+	+	+		
	VEE replicon vector	+	+			
	Naked DNA	+	+			
	Vaccinia vector (live)	+	+			
	Vaccinia subunit	+	+			
<i>Plasmodium falciparum</i>	Synthetic peptide	+	+			

Target Agent	Vaccine	Basic R&D	Preclinical	Phase I	Phase II	Phase III
Eastern equine encephalitis virus	Yeast subunit	+	+			
	Drosophila-expressed recombinant subunit	+	+		+	
	Baculovirus-expressed recombinant subunit	+	+			
	Live attenuated dengue virus (monovalent)	+	+	+		+
	Live attenuated dengue virus (combined quadrivalent)	+	+	+		+
	Adenovirus vector	+	+			
Ebola virus	Inactivated whole virus particles	+	+	+		+
	VEE virus replicon particle	+	+			
	DNA vaccine	+				
	Alphavirus-based chimeras	+				
	Cationic-liposome-DNA complex	+				
	Recombinant protein subunit (various virus and eucaryotic expression and delivery systems)	+	+			
Hantavirus	VEE virus replicon particle	+	+			
	Kunjin virus replicon particle	+				
	Plasmid DNA prime/adenovirus-expressed protein boost	+	+			
	Plasmid DNA	+	+			
	Virus-like particle (VLP)	+				
	Various adenovirus-vectored	+	+			
	rVSV-vectored	+	+			
	Paramyxovirus-vectored	+				
	CMV-vectored	+				
	Combination DNA/VLP	+				
	Multi-agent DNA	+				

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	rVSV-vectorized multi-agent vaccine (Lassa, Ebola, Marburg)	+				
	Prophylactic monoclonal antibodies	+				
Endotoxin (Gram-negative sepsis)	Detoxified lipopolysaccharide from <i>E. coli</i> O111:B4, Rc (J5)	+	+			
<i>Entamoeba histolytica</i>	Yeast subunit	+	+			
	Recombinant galactose-binding protein	+	+			
	Galactose-binding proteins expressed in <i>Salmonella</i>	+	+			
Epstein-Barr virus (EBV)	Glycoprotein subunit (gp350)	+	+	+	+	
	Vaccinia recombinant virus expressing gp350	+	+	+		
	Peptide induction of CTL	+	+	+		
Enterohemorrhagic <i>Escherichia coli</i> (EHEC) [Shiga toxin-producing <i>E. coli</i> (STEC)]	Nontoxic mutant toxins	+	+			
	Intimin	+	+			
	LPS conjugates	+	+			
	Intimin expression in plants	+	+			
	Stx-1 beta-subunit in <i>Vibrio cholerae</i> vector	+	+			
	Attenuated EHEC vector based vaccine (attaching/effacing determinants attenuated)	+	+			
Enterotoxigenic <i>E. coli</i> (ETEC)	Killed cells and beta-subunit of cholera toxin	+	+	+	+	
	Nontoxigenic ETEC derivative, live attenuated	+	+	+	+	
	Formalin killed outer expressed colonization factors CFAI, CS2, CS4, CS5 and CS6	+	+	+		
	Killed whole cells vaccine containing CTB	+	+	+	+	+
	ACE527 polyvalent live attenuated vaccine	+	+	+	+	

Target Agent	Vaccine	Basic R&D	Preclinical	Phase I	Phase II	Phase III
<i>Escherichia coli</i> (urinary tract)	Anti-CFAI and CfaE bovine IgG (passive immunization)	+	+	+	+	
	Peru-15 (pCTB plus ETEC)	+	+	+	+	
	Double mutant heat labile enterotoxin	+	+	+		
	Heat labile enterotoxin transcutaneous delivery (patch) for traveler's diarrhea (lomai)	+	+	+	+	+
	Attenuated EHEC vector based vaccine for delivery ETEC adhesin and toxin targets (CFAI & LT)	+		+		
	Adhesin-toxoid chimera CFAI/CfaE-CTA2 candidate	+		+		
	Heat labile and heat stable toxin A (LT-STa)-chimera toxoid	+				
	Conjugated (BSA) heat stable toxin	+				
	Molecular targets on <i>E. coli</i> surface, early stages of discovery	+				
	<i>E. coli</i> veriome including all major pathotypes (diarrheal and extraintestinal)	+				
<i>Francisella tularensis</i>	Attenuated ETEC strains PTL002 and PTL003 expressing CFA/II	+	+	+	+ PTL003	
	Shigella strains expressing ETEC adhesions antigens (CVD1208, 1233, 1252)	+	+	+		
	<i>S. flexneri</i> 2a (SC602) expressing CfaB and LTB	+	+			
	Anti-FimH adhesin	+	+			
	Live attenuated	+	+	+	+	

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	Isolated outer membrane proteins	+				
Group A streptococcus	Glycoconjugate group A polysaccharide with tetanus toxoid	+	+			
	M protein, multivalent type-specific epitopes	+	+	+		
	M protein conserved epitope expressed in a commensal vector (<i>S. gordonii</i>)	+	+			
	M protein conserved epitope in combination with M serotype epitopes	+	+			
	Cysteine protease	+	+			
	C5a peptidase	+	+			
	Fibronectin-binding protein Sfb1	+	+			
	Streptococcal pyrogenic exotoxins	+	+			
	Surface protein(s)	+	+			
Group B streptococcus	Glycoconjugate vaccines of type Ia, Ib, II, III, and V polysaccharides linked to carrier proteins	+	+	+	+	+
	Surface protein(s)	+	+			
<i>Haemophilus ducreyi</i>	Outer membrane proteins	+	+			
	Hemolysin/cytotoxin	+	+			
	Hemoglobin receptor	+	+			
<i>Haemophilus influenzae</i> (nontypeable)	Recombinant protein subunit containing either P1, P2, or P6 proteins to serve as carriers in conjugate vaccine preparations	+	+			
	Recombinant protein subunit containing P4 and P6	+	+			
	P4 and P6	+	+			
	Subunit Hi nontypeable 47 OMP (adjuvanted)	+	+			
	Subunit lipoprotein D (nonacylated)	+	+	+		

Target Agent	Vaccine	Basic R&D	Preclinical	Phase I	Phase II	Phase III
<i>Haemophilus influenzae</i> type b (Hib)	Subunit detoxified lipooligosaccharide conjugate to tetanus toxoid	+	+			
	Subunit detoxified lipooligosaccharide conjugated to HMW protein from <i>H. influenzae</i> (nontypeable)	+	+			
	OMP HiN47	+	+	+	+	
	Pili (HifE)	+	+			
	Glycoconjugate of Hib PRP with CRM197	+	+	+	+	+
Hantaan virus	Glycoconjugate of Hib PRP with diphtheria toxoid	+	+	+	+	+
	Glycoconjugate of Hib PRP with tetanus toxoid	+	+	+	+	+
	Hib-IPV-HBV	+	+	+	+	+
	Glycoconjugate of Hib PRP with meningococcal type B outer membrane protein	+	+	+	+	+
	Glycoconjugate Hib with meningococcal type A and/or C	+	+	+		
<i>Helicobacter pylori</i>	Recombinant subunit	+	+			
	Nonreplicating adenovirus vector	+	+			
	Naked DNA	+	+	+		
	VSV vector	+				
	Recombinant <i>H. pylori</i> urease and cholera toxin-oral vaccine	+	+	+		
	Recombinant <i>H. pylori</i> vacuolating cytotoxin A (VacA), cytotoxin associated antigen A (CagA) neutrophil activating protein (NAP) with aluminum hydroxide	+	+			
	Whole cell vaccine with mutant <i>E. coli</i> heat-labile toxin (LT) adjuvant	+	+	+	+	
	<i>H. pylori</i> antigens and mutant CT or LT	+	+	+		
	Killed whole cells	+	+			
	<i>Salmonella</i> vectored <i>H. pylori</i> antigens	+	+			

Target Agent	Vaccine	Basic R&D	Preclinical	Phase I	Phase II	Phase III
	Multi-epitope DNA vaccine	+				
Hepatitis A virus (HAV)	Inactivated HAV particles	+	+	+	+	+
	Live attenuated HAV	+	+	+	+	+
	Virosome-formulated inactivated HAV	+	+	+	+	+
	Viral proteins expressed by vectors (baculovirus or vaccinia virus)	+	+			
Hepatitis B virus (HBV)	HBV core protein and woodchuck antigens expressed by rDNA	+	+			
	HBV proteins expressed in yeast cells by rDNA	+	+	+	+	+
	<i>Salmonella</i> and <i>Listeria monocytogenes</i> vectors	+	+			
	Variants	+	+			
	Generation of cytotoxic T lymphocytes	+	+	+	+	
	DNA vaccines	+	+			
	rDNA, plants	+	+	+		
	Intranasal vaccines	+	+			
	HBV recombinant vaccine with MPL adjuvant (Fendrix)	+	+	+		+
	HBV vaccine with novel adjuvants—chitosan, oil emulsions, hydrogels delivering GM-CSF, AS02v, etc.	+	+	+		
Combined HAV/HBV vaccine	Combined inactivated components	+	+	+	+	+
Hepatitis C virus (HCV)	Recombinant pro-apoptotic BCG (rpaBCG) vaccines that express HCV antigens	+				
	MVA-based rVac w/3 NS protein genes	+	+			
	Recombinant viruses carrying HCV non structural genes: adenovirus	+	+			
	Bacterial recombinants with HCV proteins: <i>Listeria monocytogenes</i>	+				

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Hepatitis C virus (HCV)	Cell-based vaccines; yeast	+				
	Plants systems for HCV protein expression	+				
	Human dendritic cells (matured <i>in vitro</i> with HCV peptides), for autologous transfer	+				
Hepatitis D virus (HDV)	Synthetic peptides	+	+			
	Recombinant pro-apoptotic BCG (rpaBCG) vaccines that express HCV antigens	+				
	Lentivirus derived HCV-like particles	+				
Hepatitis E virus (HEV)	Expressed proteins	+	+	+	+	
	Recombinant protein (<i>E. coli</i> expressed)	+	+	+	+	+
Herpes simplex virus types 1 and 2	gD2 recombinant protein	+	+	+	+	+
	Inactivated virus	+	+	+		
<i>Histoplasma capsulatum</i>	Purified yeast cell proteins (e.g., His-62)	+	+			
	Recombinant proteins (e.g., His 62, H antigen, hsp-70)	+	+			
Human immunodeficiency virus (HIV)	See DAIDS appendix					
Human papillomavirus (HPV)	Bivalent VLP L1 (HPV-11, HPV-16)	+	+	+	+	+
	Quadrivalent recombinant VLP L1 (from HPV-6, HPV-11, HPV-16, and HPV-18)	+	+	+	+	+
Influenza virus	Inactivated (interpandemic)	+	+	+	+	+
	Inactivated (pandemic)	+	+	+	+	+
	Live attenuated (interpandemic)	+	+	+	+	+
	Live attenuated (pandemic)	+	+	+	+	+
	Liposome containing viral HA	+	+	+	+	+
	Recombinant viral proteins	+	+	+	+	+
	Inactivated with novel adjuvants	+	+	+	+	+

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	Cell culture derived influenza vaccine	+	+	+	+	+
	M2e vaccines	+	+	+	+	
	Recombinant viral vector vaccines	+	+	+	+	
	Plant-based NECVLP vaccine	+	+	+	+	
	DNA vaccines	+	+	+		
	Peptide vaccines	+	+	+		
Japanese encephalitis virus	Whole, inactivated virus particles (JE-VAX, mouse brain-derived)	+	+	+	+	+
	Whole, inactivated virus particles, (IXIARO, Vero cell culture-derived, licensed in the United States in 2009)	+	+	+	+	+
	Infectious clone	+	+			
	Purified DNA expressed protein	+	+			
	Live attenuated virus (SA-14-14-2)	+	+	+	+	+
	Vaccinia vector (live)	+	+	+		
	Live attenuated YF17D-vectored JE chimera (ChimeriVax-JE)	+	+	+		+
	Fusion loop peptide	+				
Junin virus (Argentine hemorrhagic fever)	Live attenuated (Candid #1)	+	+	+	+	
	Live attenuated YF17D-vectored multi-valent chimera (YF, Junin and other arenaviruses)	+				
Lassa virus	Chimeric live reassortant Mopeia/Lassa virus	+				
	DNA vaccine	+				
	Viral-like particles	+				
	Live attenuated YF17D-vectored bivalent chimera (YF, Lassa)	+				
	rVSV-vectored multi-agent vaccine (Lassa, Ebola, Marburg)	+				

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<i>Legionella pneumophila</i>	Attenuated mutant	+	+			
	Purified bacterial surface protein	+	+			
<i>Leishmania major</i>	Attenuated or killed whole parasites	+	+	+	+	+
	Deletion mutagenized, attenuated parasite	+	+			
	Recombinant trivalent polypeptide	+	+	+	+	
<i>Leishmania amazonensis</i>	Killed whole parasites	+	+	+	+	
Multiple Leishmania spp.	Leishmanial surface antigens (gp63, 46 kD, and lipophosphoglycan)	+	+			
<i>Listeria monocytogenes</i>	cytoLLO/cytoPFO vaccine strains	+				
	Epicutaneous strategies with cholera toxin adjuvant		+			
Marburg virus	DNA	+	+	+		
	DNA/adenovirus boost	+	+	+		
	VEE virus replicon particle	+				
	Various adenovirus-vectored vaccines	+	+			
	Virus-like particle (VLP)	+				
	rVSV-vectored multi-agent vaccine (Lassa, Ebola, Marburg)	+				
	Prophylactic monoclonal antibodies	+				
Measles virus	rDNA HA and fusion proteins	+	+	+		
	Live attenuated	+	+	+	+	+
	High-titer live (multiple strains)	+	+	+	+	+
	VEE virus replicon particle	+	+			
	Dry powder	+	+			
	DNA + Vaxfectin	+	+			
<i>Moraxella catarrhalis</i>	High molecular weight, outer membrane proteins CD, E, B1, and LBP for use in conjugate vaccines	+	+			

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	Detoxified LOS conjugated to either tetanus toxoid or high MW proteins from nontypeable <i>H. influenzae</i>	+	+			
	Subunit derived from type IV pilin protein	+				
<i>Mycobacterium leprae</i>	<i>Mycobacterium bovis</i> BCG (Bacillus Calmette Guérin)	+	+	+	+	+
	<i>Mycobacterium indicus pranii</i> (MIP)	+	+	+	+	+
	BCG + killed <i>Mycobacterium leprae</i>	+	+	+	+	+
	ICRC bacilli, heat killed (Indian Cancer Research Center strain)	+	+	+	+	+
	<i>Mycobacterium w</i> (<i>M. welchii</i>), live and killed	+	+			
	BCG-70M (secreting a fusion protein of BCG Hsp70 and <i>M. leprae</i> major membrane protein II)	+				
	BCG-SM (secreting <i>M. leprae</i> major membrane protein II)	+				
	Adjuvanted <i>Mycobacterium leprae</i> antigen ML0276	+				
	BCG homologous and heterologous boosting	+	+	+	+	+
	BCG delivered orally	+	+	+		
	<i>Mycobacterium vaccae</i> , heat killed	+	+	+	+	+
	Recombinant BCG with endosome escape, overexpressing several key antigens	+	+			
	Recombinant BCG with endosome escape (rBCG Ure:CHly+)	+	+	+		
	Superoxide dismutase (SOD) diminished BCG	+	+			
<i>Mycobacterium tuberculosis</i>	Live attenuated <i>Mycobacterium tuberculosis</i> strains	+	+			
	Modified vaccinia virus expressing <i>Mycobacterium tuberculosis</i> Ag85A (MVA-85A)	+	+	+		
	Ag85B + ESAT6 (Hybrid-1) subunit vaccine in IC3 adjuvant	+	+	+		

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<i>Mycobacterium tuberculosis</i>	Ag85B + TB10.4 (HyVac4) subunit vaccine in IC3 adjuvant	+	+	+		
	M72f (Mtb39 + Mtb32) subunit vaccine in adjuvant AS01 adjuvant	+	+	+	+	
	Hsp65 DNA vaccine	+	+			
	AERAS-402/Crucell Ad35 (replication deficient Adenovirus 35 expressing Mtb antigens, Ag85 A, Ag85 and B, and TB10.4	+	+	+	+	
	Double stranded RNA capsids encoding <i>Mycobacterium tuberculosis</i> antigens	+	+			
	Various adjuvanted protein antigens of <i>Mycobacterium tuberculosis</i>	+				
<i>Mycoplasma pneumoniae</i>	Various Mycobacterium tuberculosis antigens as DNA vaccines	+				
	Recombinant membrane-associated proteins	+	+			
	Purified outer membrane protein	+	+			
	Inactivated (heat-killed) oral vaccine	+	+	+		
<i>Neisseria gonorrhoeae</i>	Por (protein I)	+	+			
	Recombinant Por protein	+	+			
	Iron-binding protein (BPs)	+				
	LPS anti-idiotype	+				
<i>Neisseria meningitidis</i> (Group A)	Glycoconjugate with tetanus toxoid	+	+			
	Group A LOS	+				
<i>Neisseria meningitidis</i> (Group B)	Native outer membrane vesicle (NOMV)-intranasal route	+	+	+		
	OMP-dLPS liposome	+	+			
	Recombinant PorA outer membrane protein in liposomes	+	+			
	Recombinant factor H binding protein	+	+			
	Membrane vesicle-based vaccine (containing over-expressed proteins normally expressed in low amounts)	+				

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	Polysaccharide derivative	+				
	Outer membrane vesicles (OMV), high MW proteins, and C polysaccharide	+	+	+	+	+
	Hexavalent PorA outer membrane vesicle vaccine	+	+	+	+	
	Outer membrane vesicles (deoxycholate extracted)	+	+	+	+	+
	Recombinant transferrin binding protein (TBP1 and TBP2)	+	+			
	Recombinant low MW (NspA) outer membrane protein	+	+			
	Glycoconjugate modified polysaccharide with recombinant PorB protein	+	+			
	LOS micelle-based vaccine	+				
	Genome-derived <i>Neisseria</i> antigen (Universal)	+				
	De-N-acetyl sialic acid polysaccharide derivative-TT	+	+			
	Recombinant Protein B (TspB)	+				
<i>Neisseria meningitidis</i> (Group C)	Glycoconjugate with tetanus toxoid	+	+	+	+	+
<i>Neisseria meningitidis</i> A and C	Glycoconjugate A and C with CRM197	+	+	+	+	
	Glycoconjugate A and C with DT	+	+	+		
<i>Neisseria meningitidis</i> A, B, and C	Combination glycoconjugate with recombinant PorB	+	+			
<i>Neisseria meningitidis</i> A, B, C, and W-135	Glycoconjugate with DT	+	+	+		
Nipah virus	Poxvirus vectors expressing G glycoproteins	+	+			
	Soluble G glycoproteins	+	+			
Norwalk virus (Human Noroviruses including Norwalk (GI.1))	Norwalk VLPs (GI.1)	+	+	+		

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<i>Calicivirus</i>	Norwalk VLPs in transgenic potatoes	+	+	+		
	Norwalk VLPs in transgenic tomatoes (lyophilized)	+	+			
	Intranasally-delivered Norwalk VLPs w/MPL and Chitosan	+	+	+		
	Intranasal Norwalk VLPs: challenged with characterized Norwalk virus pool	+	+	+		
	Intramuscular Norwalk VLPs and Norovirus (GII.4) VLPs plus MPL, Chitosan	+	+	+		
<i>Onchocerca volvulus</i>	Recombinant proteins	+	+			
<i>Paracoccidioides brasiliensis</i>	Purified yeast cell proteins	+	+			
	Recombinant proteins	+	+			
	Synthetic peptide or multi peptide construction (P10, MAP-10)	+	+			
	DNA plasmid with gp43 gene	+	+			
Parainfluenza virus	Cold-adapted PIV3 attenuated virus	+	+	+	+	
	Purified HN and F protein subunit vaccine	+	+			
	Bovine attenuated PIV3 vaccine	+	+	+	+	
<i>Plasmodium falciparum</i>	Circumsporozoite antigen-based peptide or recombinant protein	+	+			
	Circumsporozoite antigen fused to hepatitis B surface antigen viral-like particle (RTS, S)	+	+	+	+	+
	Circumsporozoite antigen epitopes in viral-like particles	+	+	+		
	Circumsporozoite antigen expressed in various vectors	+	+	+	+	
	Circumsporozoite antigen-based DNA vaccine	+				
	Noncircumsporozoite, pre-erythrocytic antigen-based constructs	+	+	+		
	VAR2CSA, pregnancy associated antigens	+	+			

Target Agent	Vaccine	Basic R&D	Preclinical	Phase I	Phase II	Phase III
<i>Plasmodium falciparum</i>	Merozoite surface protein-1 (MSP-1) based recombinant protein	+	+	+		
	Non-MSP-1 asexual blood stage antigens	+	+	+	+	
	25-kD gametocyte antigen recombinant protein (TBV25H)	+	+	+		
	Other sexual stage antigens	+	+			
	Multivalent viral vector-based combination vaccines incorporating different stage-specific antigens (e.g., NYVAC Pf7)	+	+	+	+	
	DNA-based combination vaccines incorporating different stage-specific antigens	+	+	+		
	Combination vaccines incorporating different stage-specific antigens (e.g., SPf 66)	+	+	+	+	
	Purified irradiated sporozoites	+	+	+		
	Genetically attenuated sporozoite	+	+			
<i>Plasmodium vivax</i>	Circumsporozoite antigen-based peptide or recombinant protein	+	+	+		
	Asexual erythrocytic antigens	+	+			
Poliovirus	Codon-deoptimized poliovirus for new IPV seed stock	+				
	miRNA target inserted poliovirus in high fidelity polymerase mutant backbone for a new IPV stock and OPV	+	+			
	Chimeric vaccines such as wild type capsid protein expressing from Sabin strain backbone or type 3 capsid in type 1 backbone	+	+			
	Mutant poliovirus carrying mutations in 5'non-coding region for a new IPV seed stock		+			
<i>Pseudomonas aeruginosa</i>	Purified bacterial proteins, including flagellar Ag, LPS-O, porins, several inactivated bacterial toxins, and high MW polysaccharide antigen and glycoconjugate	+	+	+		
	Inactivated whole bacteria-oral preparation	+	+	+		
	Synthetic peptides	+	+	+		
	Live attenuated <i>Pseudomonas</i> vaccine (aroA mutant)	+	+			

Target Agent	Vaccine	Basic R&D	Preclinical	Phase I	Phase II	Phase III
<i>Pseudomonas (Burkholderia) cepacia</i>	Purified bacterial proteins, LPS	+				
<i>Pythium insidiosum</i>	Sonicated hyphal antigens	+	+			
	Culture filtrate antigens	+	+			
	Purified proteins (e.g., 28, 30, 32 kD)	+	+			
Rabies virus	rDNA vaccinia virus recombinant for use in sylvatic rabies (veterinary vaccine)	+	+	+	+	+
	Inactivated mammalian brain	+	+	+	+	+
	Inactivated cell culture	+	+	+	+	+
	Replication-defective adenovirus vector	+	+			
	Live attenuated	+	+			
Respiratory syncytial virus (RSV)	Purified F protein subunit vaccine	+	+	+	+	
	RSV live attenuated strains	+	+	+	+	
	Nanoparticle vaccine carrying G polypeptide against CXC3 motif of RSV G protein	+	+			
	Recombinant Sendai virus expressing RSV F protein	+	+	+		
	Recombinant attenuated parainfluenza virus type 3 expressing RSV F protein	+	+	+		
	Recombinant Newcastle Disease virus expressing RSV F protein	+	+			
	Recombinant RSV virus F protein particle vaccine (VLP)	+	+	+		
Ricin toxin	Recombinant inactivated toxin	+	+	+		
	Ricin A (RiVax) plus adjuvant vaccine—formulation optimization	+	+			
	Vaccine formulation and lyophilization for intradermal/intranasal delivery	+	+			
<i>Rickettsia rickettsii</i>	Subunit vaccine containing major surface proteins (155 and 120 kD)	+	+			

NOTE This list outlines publicly available information concerning the status of vaccines in the research and development pipeline and should not be considered inclusive of all ongoing vaccine research and development.

Target Agent	Vaccine	Basic R&D	Preclinical	Phase I	Phase II	Phase III
Rift Valley fever virus	Inactivated	+	+	+	+	
	Live attenuated virus (MP-12)	+	+	+	+	
	VEE virus replicon particle	+				
	Sindbis virus replicon particle	+				
	Virus-like particle (VLP)	+				
	Live attenuated recombinant virus	+				
Rotavirus	Attenuated human rotavirus strain 89-12 P1A[8] ,G1	+	+	+	+	+
	Salmonella expressing VP4, VP7, or both	+	+			
	Attenuated bovine/human virus reassortants (G1-WC3; G2-WC3; G3-WC3; G4-WC3; P1A[8]-WC3)	+	+	+	+	+
	Human nursery strains—116E (India)	+	+	+	+	+
	Human nursery strains—RV3 (Australia)					
	Purified rotavirus proteins rDNA-derived virus-like particles (VLPs)	+	+			
	Vaccinia virus recombinant expressing		+			
	VP4, VP7, or both	+				
	DNA vaccines	+	+			
	VP6 vaccines with maltose binding protein (MBP)	+	+			
Rubella virus	Inactivated rotavirus vaccine (G1p[8]) with Alum	+	+			
	Intranasal attenuated rotavirus vaccine or IN rotavirus VLPs	+	+			
Salmonella typhi	Live attenuated	+	+	+	+	+
	Vi carbohydrate	+	+	+	+	+
	Live attenuated Ty21a vaccine	+	+	+	+	+
	Live attenuated auxotrophic mutants	+	+	+	+	
	Vi conjugate vaccine	+	+	+	+	+

Target Agent	Vaccine	Basic R&D	Preclinical	Phase I	Phase II	Phase III
<i>Schistosoma mansoni</i>	Purified larval antigens	+	+			
	Recombinant antigens	+	+			
	Multiple antigen peptides (MAP)	+	+			
	DNA vaccines	+				
<i>Schistosoma haematobium</i>	Recombinant Sh28 GST (<i>S. haematobium</i> glutathione-S-transferase)	+	+	+		
<i>Schistosoma japonicum</i>	Recombinant larval antigens	+	+			
	DNA vaccine	+	+			
Sendai virus	Recombinant Sendai virus	+	+	+		
	Sendai virus for gene therapy and vaccination	+	+			
Severe acute respiratory syndrome (SARS Co-V)	DNA plasmid expressing S protein	+	+	+		
	Inactivated viral vaccines	+	+	+		
	Baculovirus expressed S protein	+	+			
	CHO cell expressed S protein	+	+			
	Baculovirus expressed S protein with novel adjuvant, intranasally delivered	+	+			
	Alphavirus replicon vaccine	+	+			
	Virus-like particle vaccine	+				
	Rhabdovirus (rabies) expressing S protein	+	+			
	Modified vaccinia Ankara (MVA) expressing S protein	+	+			
	Adenovirus vector expresssing S1 or N	+	+			
<i>Shigella dysenteriae</i>	B- and T-epitope peptide-based vaccine	+				
	Live auxotrophic, attenuated mutants	+	+	+		
	Polysaccharide-protein conjugate	+	+	+	+	
<i>Shigella flexneri</i>	<i>E. coli</i> hybrids	+	+	+	+	
	Polysaccharide-protein conjugate	+	+	+	+	

NOTE This list outlines publicly available information concerning the status of vaccines in the research and development pipeline and should not be considered inclusive of all ongoing vaccine research and development.

Target Agent	Vaccine	Basic R&D	Preclinical	Phase I	Phase II	Phase III
<i>Shigella sonnei</i>	Live attenuated oral vaccines	+	+	+	+	
	LPS proteosome (intranasal)	+	+			
	LPS-invasin proteins (IpaB/C) complex	+	+	+	+	
<i>Shigella flexneri/sonnei</i>	Live attenuated (WRSS1) oral vaccine	+	+	+	+	
	LPS proteosome (intranasal)	+	+			
	Polysaccharide-protein conjugate	+	+	+	+	
	Nucleoprotein	+	+			
<i>Staphylococcus aureus</i>	Polysaccharide-protein conjugate	+	+	+	+	+
<i>Staphylococcus aureus</i>	Clumping factor B	+				
	rAls3p-N	+				
	Polymeric N-acetylglucosamine	+	+	+		
	<i>S. aureus</i> protein/polypeptide antigen expressed in yeast					
	Surface proteins lsdA, lsdB, sdrD, sdrE	+				
	Pentavalent vaccine candidate	+	+	+		
<i>Staphylococcal enterotoxin B</i>	Tetraivalent bioconjugate vaccine CP5-EPA/CP8-EPA and clumping factor A (ClfA) and-alpha toxoid	+				
	Recombinant toxin	+	+			
<i>Streptococcus pneumoniae</i>	Glycoconjugate vaccine (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) conjugated to CRM197	+	+	+	+	+
	23-valent licensed vaccine with novel adjuvants (Quil A, QS21, MPL)	+	+	+		
	Glycoconjugate multivalent vaccine with novel adjuvants (e.g., MPL)	+	+	+		
	PspA	+	+	+		
	PsaA	+	+			

Target Agent	Vaccine	Basic R&D	Preclinical	Phase I	Phase II	Phase III
	Pneumolysin	+	+			
	Autolysin	+	+			
	Neuraminidase	+	+			
	Glycoconjugate vaccine (1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, 23F) linked to either tetanus or diphtheria toxoid carrier	+	+	+	+	+
	Phospholcholine	+	+			
	Synthetic peptide epitopes and capsular polysaccharide combined	+	+			
	Genetic fusions (PspA-IL2 and PspA-GM-CSF)	+	+			
	CpG motifs cross-linked with 7-valent pneumococcal vaccine	+	+			
	PGCvax (a fusion protein)	+	+	+		
Tick-borne encephalitis virus	DNA vaccine	+	+			
	Inactivated, alum adjuvant	+	+	+	+	
	Drosophila-expressed recombinant subunit vaccine	+				
	Live attenuated dengue/TBE chimera	+				
	Recombinant vaccinia virus	+				
<i>Toxoplasma gondii</i>	Recombinant parasite surface protein (p30)	+	+			
	Live attenuated parasites	+	+			
	Parasite surface protein expressed in viral vector	+	+			
	Polyepitope DNA	+				
<i>Treponema pallidum</i>	Membrane proteins	+				
<i>Trypanosoma cruzi</i>	Recombinant peptide	+	+			
Varicella zoster virus	Live attenuated vaccine	+	+	+	+	+
	Subunit, glycoproteins	+				
	Vaccinia-vectored glycoprotein	+				

NOTE This list outlines publicly available information concerning the status of vaccines in the research and development pipeline and should not be considered inclusive of all ongoing vaccine research and development.

Target Agent	Vaccine	Basic R&D	Preclinical	Phase I	Phase II	Phase III
Variola	DNA subunit	+	+			
	Non-replicating attenuated strain	+	+	+	+	
	Replicating attenuated strain	+	+			
	Recombinant subunit	+	+			
Venezuelan equine encephalitis	Inactivated, whole virus particles	+	+	+	+	
	Live attenuated virus strain (TC-83)	+	+	+	+	
	Live attenuated mutagenized virus (V3526)	+	+	+		
	Inactivated V3526	+				
	Infectious clones	+	+			
	VEE virus replicon particle	+	+			
	DNA	+				
	Adenovirus-vectorized	+				
	Multi-epitope peptide	+				
	Cationic liposome-DNA complex	+				
<i>Vibrio cholerae</i>	Alphavirus-based chimeras	+				
	Prophylactic monoclonal antibodies	+				
	Killed bacteria plus toxin B subunit	+	+	+	+	+
	Live recombinant O1	+	+	+	+	+
	Live recombinant O139	+	+	+	+	
	Conjugate lipopolysaccharide (LPS)	+	+			
	Killed bivalent (O1/O139)	+	+	+	+	+
Yellow fever virus	Live attenuated oral O1	+	+	+	+	
	Live attenuated (YF17D, Licensed in the United States)	+	+	+	+	+
	Infectious clone	+	+			
	Inactivated whole virus particles	+				
	Recombinant, bivalent YF17D/Lassa	+				

Target Agent	Vaccine	Basic R&D	Preclinical	Phase I	Phase II	Phase III
	Fusion loop peptide	+				
	Prophylactic monoclonal antibodies	+				
Western equine encephalitis virus	Inactivated, whole virus particles	+	+	+	+	
	VEE virus replicon particle	+	+			
	DNA	+				
	Baculovirus-expressed subunit protein	+				
	Cationic-liposome-DNA complex	+				
	Alphavirus-based chimeras	+				
West Nile virus	YF17D/ WNV chimera	+	+	+	+	
	Dengue4/WNV chimeras	+	+	+	+	
	DNA plasmid vaccines	+	+	+	+	
	Drosophila-expressed recombinant subunit vaccine (HBV-002)	+	+	+	+	
	Engineered, attenuated, single-cycle virus vaccine	+				
	Mutated, live attenuated vaccine	+				
	Kunjin-based WNV DNA vaccine	+				
	Fusion loop peptide	+				
<i>Yersinia pestis</i>	F1-V fusion protein	+	+	+	+	
	F1 + V protein	+	+	+	+	
	Nanodelivered F1-V	+	+	+	+	
	Bacterial vectored	+				
	Viral vectored	+				
	LcrV subunit	+				
	rV10 subunit	+	+			
	Flagellin adjuvanted F1-V	+	+			
	MVA-V combination	+				

NOTE This list outlines publicly available information concerning the status of vaccines in the research and development pipeline and should not be considered inclusive of all ongoing vaccine research and development.

Target Agent	Vaccine	Basic R&D	Preclinical	Phase I	Phase II	Phase III
	T-4 display		+			
	Outer membrane proteins		+			
	PNAG conjugated vaccine		+			
	Oral bacterial vectored		+			

APPENDIX B: NIAID-Supported HIV Vaccine Candidates in Preclinical Development, July 2011

Vaccine*	HIV Subtype	Preclinical Partners**	Manufacture
Multi-gene DNA (+ GM-CSF) + MVA	B	NIAID (Moss lab), GeoVax (Robinson)	VGXI/BioReliance
Multi-gene DNAs + cytokines DNA + Electroporation devices	A, B, C	U. Penn (D. Weiner), Inovio	Althea and VGXI/Inovio
VEE replicons	C	Alphavax	Alphavax
Novel serotype Adenoviral Vectors (Ad25, Ad35) + protein	A, mosaics	Harvard (Barouch)	Crucell
Multi-gene DNAs + cytokines DNA + Electroporation devices + VSV Gag	B	Profectus/Ichor	Boeringer Ingelheim/DSM Biologics/Henogen/Ichor
AAV-based vectors	A	Children's Hospital of Philadelphia	Targeted Genetics
Mosaic DNA + NYVAC HIV Env	mosaics	CHAVI (Haynes), Sanofi, EuroVacc	Althea/IDT and Sanofi
NYVAC + Env protein + adjuvant (Poly IC/LC)	C	FHCRC (J. McElrath), Oncovir, Sanofi	Sanofi/TBD
Multigene DNA + NYVAC	C	IPPOX, Eurovacc	Vical/IDT and Sanofi
Replication Competent Adenovirus, Type 4	mosaics	NIAID (Connors), NCI (Guroff)	PaxVax
Envelope Proteins	A,C	Novartis	TBD
Chimp-serotype based Adenovirus vectors	B	Wistar (Ertl)	TBD
Multi-clade DNA and proteins	A, B, C, D, E	U. Mass (Lu)	TBD

APPENDIX C: Ongoing Clinical Trials of HIV Vaccine Candidates in HIV-Uninfected Adults, July 2011

Protocol	Type of Vaccine – Prime – Boost	Vaccines – Prime – Boost	HIV Antigens [Clade] – expressed by Prime – expressed by Boost	Adjuvants – with Prime – with Boost	Developer/ Manufacturer – Prime – Boost	Phase	Location of Clinical Sites
<i>DNA (alone)</i>							
HVTN 080	DNA plasmids	PENN VAX(TM)-B [PV-B] via INOVIO® Electroporation Device	Gag [B], Pol [B], Env [B]	IL-12 DNA plasmid	U Penn. School of Medicine	1	USA
<i>DNA plus Live Vector: Adenovirus 5 (Ad5)</i>							
HVTN 505	DNA plasmids Live Vector	VRC-HIVDNA016-00-VP VRC-HIVADV014-00-VP	Gag [B]; Pol [B]; Nef [B]; Env [A]; Env [B]; Env [C] Gag-Pol [B]; Env [A]; Env [B]; Env [C]	— —	VRC VRC	2	USA
HVTN 077	DNA plasmids Live Vector	VRC-HIVDNA044-00-VP VRC-HIVADV038-00-VP	Env [A] Env [A]	— —	VRC VRC	1-B	USA
HVTN 082	DNA plasmids Live Vector	VRC-HIVDNA016-00-VP VRC-HIVADV014-00-VP	Gag [B]; Pol [B]; Nef [B]; Env [A]; Env [B]; Env [C] Gag-Pol [B]; Env [A]; Env [B]; Env [C].	— —	VRC VRC	1-B	USA
<i>DNA plus Live Vector: Adenovirus 35 (Ad35)</i>							
HVTN 077	DNA plasmids Live Vector	VRC-HIVDNA044-00-VP VRC-HIVADV027-00-VP	Env [A] Env [A]	— —	VRC	1-B	USA
<i>Live Vector: Adenovirus 5 (Ad5)</i>							
Merck 018/ HVTN 050	Live Vector	MRKAd5 HIV-1 gag [homologous boost]	Gag [B]	—	Merck	1	USA, Puerto Rico, Peru, Haiti, S. Africa, Malawi
HVTN 071	Live Vector	MRKAd5 HIV-1 gag/pol/ nef [homologous boost]	Gag [B]; Pol [B]; Nef [B]	—	Merck	1-B	USA
HVTN 083	Live Vector	VRC-HIVADV038-00-VP [homologous boost]	Env [A]	—	VRC	1	USA
HVTN 083	Live Vector Live Vector	VRC-HIVADV038-00-VP VRC-HIVADV052-00-VP	Env [A] Env [B]	— —	VRC VRC	1	USA
HVTN 503 'Phambili'	Live Vector	MRKAd5 HIV-1 gag/pol/ nef [homologous boost]	Gag [B]; Pol [B]; Nef [B]	—	Merck	2-B	South Africa
VRC 015	Live Vector	VRC-HIVADV014-00-VP [given by Biojector versus needle]	Gag-Pol [B]; Env [A]; Env [B]; Env [C]	—	VRC	1	USA

Protocol	Type of Vaccine – Prime – Boost	Vaccines – Prime – Boost	HIV Antigens [Clade] – expressed by Prime – expressed by Boost	Adjuvants – with Prime – with Boost	Developer/ Manufacturer – Prime – Boost	Phase	Location of Clinical Sites
<i>Live Vector: Adenovirus 35 (Ad35)</i>							
VRC 012 Part A	Live Vector	VRC-HIVADV027-00 <i>[dose escalation for Part B]</i>	Env [A]	—	VRC	1	USA
HVTN 083	Live Vector	VRC-HIVADV027-00	Env [A]	—	VRC	1	USA
<i>Live Vectors: Adenovirus 5 (Ad5) and Adenovirus 35 (Ad35) or Ad35 and Ad5</i>							
VRC 012 Part B	Live Vector Live Vector	VRC-HIVADV027-00-VP VRC-HIVADV038-00-VP	Env [A] Env [A]	— —	VRC VRC	1	USA
HVTN 077	Live Vector Live Vector	VRC-HIVADV027-00-VP VRC-HIVADV038-00-VP	Env [A] Env [A]	— —	VRC VRC	1-B	USA
HVTN 083	Live Vector Live Vector	VRC-HIVADV027-00-VP VRC-HIVADV052-00-VP	Env [A] Env [B]	— —	VRC VRC	1	USA
HVTN 083	Live Vector Live Vector	VRC-HIVADV027-00-VP VRC-HIVADV038-00-VP	Env [A] Env [A]	— —	VRC	1	USA
<i>DNA plus Live Vector: Modified Vaccinia Ankara (MVA)</i>							
HVTN 205	DNA Plasmid Live Vector	pGA2/J57 DNA [GeoVax] MVA/HIV62	Gag-PR-RT- Env-Tat-Rev-Vpu [B] (as single transcript) Gag-Pol-Env [B] (same gene sequences as in DNA)	— —	GeoVax GeoVax	2-A	USA, Peru
HVTN 073/ SAAVI 102	DNA Plasmid Live Vector	SAAVI DNA-C2 <i>(multigene)</i> SAAVI MVA-C <i>(multigene)</i>	Gag-RT-Tat-Nef [C]; and gp150 [C] Gag-RT-Tat-Nef [C];	— —	SAAVI SAAVI	1	South Africa
RV 262	DNA Plasmids Live Vector	PENNVA-G DNA <i>(env & gag)</i> MVA-CMDR	Gag [multisubtype consensus]; Env [A]; Env [C]; Env [D] HIV-1 CM235 Env gp150 [E] plus CM240 Gag/Pol [A]	— —	U Penn. School of Medicine WRAIR & NIAID/LVD	1	USA, Kenya, Uganda, Tanzania, Thailand
<i>Live Vectors: Adenovirus 26 (Ad26)</i>							
IPCAVD 001	Live Vector	Ad26.ENVA.01 <i>[homologous boost]</i>	Env [A]	—	D Barouch/ Crucell	1	USA
IPCAVD 003	Live Vector	Ad26.ENVA.01 <i>[homologous boost]</i> [Innate & Mucosal immunity]	Env [A]	—	D Barouch/ Crucell	1	USA
<i>Live Vectors: Adenovirus 26 (Ad26) combined with Adenovirus 48 Highly Variable Region (HVR48)</i>							
IPCAVD 002	Live Vector	Ad5HVR48.ENVA.01 <i>[homologous boost]</i>	Env [A]	—	D Barouch/ Crucell	1	USA, Kenya, Rwanda, S. Africa
<i>Live Vectors: Adenovirus 5 (Ad5) and NYVAC or NYVAC and Ad5</i>							
HVTN 078	Live Vector Live Vector	VRC-HIVADV014-00-VP NYVAC-HIV-B	Gag-Pol [B]; Env [A]; Env [B]; Env [C] Gag-Pol-Nef [B] and gp120 [B]	— —	VRC EuroVacc	1	Switzerland



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