ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2 Exhibit)

February 2003

BUDGET ACTIVITY
5 - System Development and Demonstration

PE NUMBER AND TITLE
0604807A - Medical Materiel/Medical Biological Defense Equipm

COST (In Thousands)		FY 2002 Actual	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	Cost to Complete	Total Cost
Total Program Element (PE) Cost		17070	18790	12202	11715	12403	14338	15589	15629	Continuing	Continuing
812	MIL HIV VAC&DRUG DEV	0	0	3245	3756	4207	4505	4511	4508	0	24879
832	COMBAT MEDICAL MATL ED	13037	9385	3726	3464	3844	3758	5270	5296	Continuing	Continuing
834	SOLDIER SYS PROT-ED	851	782	1412	1064	882	3005	1818	1766	Continuing	Continuing
849	INFEC DIS DRUG/VACC ED	3182	3270	3819	3431	3470	3070	3990	4059	Continuing	Continuing
A10	RAMAN CHEMICAL BIOTHREAT DETECTION PROGRAM	0	5353	0	0	0	0	0	0	0	5353

A. Mission Description and Budget Item Justification: This program element (PE) funds advanced development of medical materiel within system demonstration and low rate initial production portions of the acquisition life cycle. The PE supports products that successfully transitioned through the Systems Development and Demonstration In-Process Review (IPR). This principally includes Phase 3 human clinical trials as well as related stability and production manufacturing testing for medical pharmaceuticals, biologics, and devices. Further operational testing (IOT&E) for military unique requirements is evaluated and fulfilled.

Infectious disease vaccines and preventive drugs that will reduce the risk of service members contracting debilitating or fatal diseases, especially within a battlefield of growing potentials as urban warfare risks increase. Disease and non-battle injury (DNBI) rates are the largest contributor to medical footprint, and reduction in ill patients could have a significant reduction in echelon 3 facilities. Equally important, the reduction of patient evacuation within Objective Force (OF) units will act as a force multiplier because timely replacement of these uniquely skilled soldiers will be nearly impossible.

Combat Casualty Care devices and biologics that have two major focuses: enhance forward care at the first responder level and reduce footprint of medical organizations for greater mobility and easier sustainment. The OF concept will place soldiers into a more austere environment with lengthened evacuation times (both arrival and transit). This requires greater capability in the hands of medics and first responders to save lives and extend stabilization. Reduction in weight, cube, and sustainment will allow medical units to increase mobility and maintain contact with its supported maneuver units.

Soldier Performance Enhancers in the form of drugs or diagnostics that will allow commanders to increase soldiers' cognitive awareness and stamina. This has direct relationship to increased soldier capabilities and a potential to reduce casualties.

This program is managed by the U.S. Army Medical Research and Materiel Command.

This PE includes congressionally directed research on the Cartilage Infuser.

Project 812, Military HIV Vaccine and Development funds militarily relevant human immunodeficiency virus (HIV) research.

This program supports the OF transition path of the Transformation Campaign Plan (TCP).

$8.2M of Defense Emergency Response Funds was provided to this program element in support of the Hemostatic Dressing program (project 832).

B. Program Change Summary	FY 2002	FY 2003	FY 2004	FY 2005
Previous President's Budget (FY 2003)	9153	12625	8799	8720
Current Budget (FY 2004/2005 PB)	17070	18790	12202	11715
Total Adjustments	7917	6165	3403	2995
Congressional program reductions				
Congressional rescissions		-315		
Congressional increases		7100		
Reprogrammings	8151	-108		
SBIR/STTR Transfer	-234	-512		
Adjustments to Budget Years			3403	2995

Change Summary Explanation: Funding – FY 2002: Funds reprogrammed into project 832 to accelerate the Hemostatic Dressing program (+8155). FY 2004/2005: Funding increase due to the reinstatement of the Military HIV Vaccine and Drug Development program.

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

February 2003

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
5 - System Development and Demonstration	**0604807A - Medical Materiel/Medical Biological Defense Equipm**	**812**

COST (In Thousands)		FY 2002 Actual	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	Cost to Complete	Total Cost
812	MIL HIV VAC&DRUG DEV	0	0	3245	3756	4207	4505	4511	4508	0	24879

A. Mission Description and Budget Item Justification: This project funds Congressionally mandated, militarily relevant human immunodeficiency virus (HIV) medical countermeasures. These funds provides for engineering and manufacturing development of sufficient candidate vaccines and drugs to permit large-scale field testing and education/training materials. Development efforts are focused on militarily unique needs affecting manning, mobilization, and deployment. The major contractor is Henry M. Jackson Foundation for the Advancement of Military Medicine, Rockville, MD. This program supports the Legacy to Objective transition path of the Transformation Campaign Plan (TCP).

Accomplishments/Planned Program	FY 2002	FY 2003	FY 2004	FY 2005
FY03 - Program transferred to National Institutes of Health (NIH), and funding was provided to Medical Research and Materiel Command (MRMC) to continue efforts on this vaccine. FY04 – Program returned to the Army. Begin multi-year phase 3 clinical trial to determine effectiveness of prime-boost HIV vaccine against the clade E virus strain. FY05 - Continue multi-year phase 3 clinical trial to determine effectiveness of prime boost HIV vaccine against the clade E virus strain.	0	0	3245	3756
Totals	0	0	3245	3756

B. Other Program Funding Summary: Not applicable for this item.

C. Acquisition Strategy: Test and evaluate commercially developed vaccine candidates in government-managed trials.

ARMY RDT&E COST ANALYSIS(R-3)

February 2003

BUDGET ACTIVITY
5 - System Development and Demonstration

PE NUMBER AND TITLE
0604807A - Medical Materiel/Medical Biological Defense Equipm

PROJECT
812

I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . Product Development	Cooperative Agreement	Henry M. Jackson Foundation, Rockville, MD	2200	0		2693		3117		0	8010	0
Subtotal:			2200	0		2693		3117		0	8010	0

II. Support Cost	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than $1M individually			201	0		146		169		0	516	0
Subtotal:			201	0		146		169		0	516	0

ARMY RDT&E COST ANALYSIS(R-3)

February 2003

BUDGET ACTIVITY
5 - System Development and Demonstration

PE NUMBER AND TITLE
0604807A - Medical Materiel/Medical Biological Defense Equipm

PROJECT
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III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . Test and Evaluation	Government Laboratory	Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD	0	0		357		413		0	770	0
Subtotal:			0	0		357		413		0	770	0

IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than $1M individually			105	0		49		57		0	211	0
Subtotal:			105	0		49		57		0	211	0

Project Total Cost:			2506	0		3245		3756		0	9507	0

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

February 2003

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
5 - System Development and Demonstration	**0604807A - Medical Materiel/Medical Biological Defense Equipm**	**832**

COST (In Thousands)	FY 2002 Actual	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	Cost to Complete	Total Cost
832 COMBAT MEDICAL MATL ED	13037	9385	3726	3464	3844	3758	5270	5296	Continuing	Continuing

A. Mission Description and Budget Item Justification: This project funds technical development of candidate medical products for the advancement of combat casualty care; especially far forward on the battlefield with first responders, combat life savers, and field medics. This primarily funds Phase 3 human clinical trials or mechanical engineering evaluations for efficacy of devices or biologics unique to military operational requirements. This work is frequently completed through a joint laboratory and contractor team with the contractor assuming ultimate Food and Drug Administration (FDA) licensure. These products (enhanced location and diagnostic devices of patients; more potent resuscitative biologics) will decrease mortality rates, thereby increasing soldier morale and willingness to place themselves in danger. Additionally, several products (DEFTOS, Oxygen Generator, Blood Processor) will reduce medical organizational sustainment footprint through smaller weight and cube or equipment independence from supporting materiels. Priority is given to those products that provide the greatest clinical benefit balanced with the technical and financial risks. These products positively support both the Army Transformation Campaign Plan (TCP) and Objective Force (OF) doctrine/organizational structure.

Major contractors/intragovernmental agencies include: Cambridge Consultants Corporation, IGR Enterprises, Army Medical Department Board Test Center, and the American National Red Cross.

Accomplishments/Planned Program	FY 2002	FY 2003	FY 2004	FY 2005
Hemostatic Dressing (HD): In FY02, conducted animal trials required by FDA and prepared Investigational New Drug Application. In FY03, continue testing and prepare for a Milestone B In-Process-Review (IPR). In FY04, conduct elective surgery trials (human clinical trials) using informed consent, and conduct the MS B IPR. In FY05, continue elective surgery trials (human clinical trials) using informed consent, and prepare Biologics License Application for submission to the FDA.	10441	7950	2321	1816

Accomplishments/Planned Program (continued)	FY 2002	FY 2003	FY 2004	FY 2005
Conduct testing and milestone IPRs for field medical treatment and treatment aid devices. (1) Dental Field Treatment and Operating System (DEFTOS): In FY02, conducted a MS A/Program Initiation IPR and worldwide user evaluation. In FY03/FY04, redesign to reflect test results and conduct limited testing, and conduct a MS C IPR. (2) Thawed Blood Processing System (TBPS): In FY02, conducted in vitro tests, validated software, and prepared Investigational Device Exemption. In FY03, fabricate disposables, conduct in vitro tests, and submit IDE to FDA. In FY04, conduct clinical trails and submit premarket notification for FDA approval. In FY05, conduct user evaluations, procure Low Rate Initial Production (LRIP), and conduct a MS C IPR. (3) Ceramic Oxygen Generator System (COGS): In FY02, scaled up oxygen generator cells from test sizes to full size, approximately a 10-fold increase in area, and proved the performance and durability of the ceramic compounds and fabrication methods. In FY03, integrate oxygen generator cells into a portable oxygen generator and fabricate prototype oxygen generators for a user evaluation. In FY04, develop techniques for reliable and repeatable large-scale production of oxygen generators and conduct a MS B IPR. In FY05, prepare MS C package. (4) Cartilage Infuser: In FY02, initiated plans for the development of the Cartilage Infuser; a variable rate blood warming and infusion system.	2596	1435	1405	1648
Totals	13037	9385	3726	3464

B. Other Program Funding Summary: Not applicable for this item.

C. Acquisition Strategy: Evaluate commercially developed materiel in government-managed trials.

ARMY RDT&E COST ANALYSIS(R-3)

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BUDGET ACTIVITY
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PROJECT
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I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . Hemostatic Dressing		American National Red Cross, Charlotte, NC	12150	7768		2348		1850		Continue	Continue	0
b . Thawed Blood Processing System		Mission Medical Inc. , Freemont, CA	1625	1617		1378		1614		Continue	Continue	0
Subtotal:			13775	9385		3726		3464		Continue	Continue	0

II. Support Cost	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . Not Applicable			0	0		0		0		0	0	0
Subtotal:			0	0		0		0		0	0	0

ARMY RDT&E COST ANALYSIS(R-3)

February 2003

BUDGET ACTIVITY
5 - System Development and Demonstration

PE NUMBER AND TITLE
0604807A - Medical Materiel/Medical Biological Defense Equipm

PROJECT
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III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . Not Applicable			0	0		0		0		0	0	0
Subtotal:			0	0		0		0		0	0	0

IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than $1M individually			7609	0		0		0		Continue	7609	0
Subtotal:			7609	0		0		0		Continue	7609	0

Project Total Cost:			21384	9385		3726		3464		Continue	Continue	0

Schedule Profile Detail (R-4a Exhibit)

February 2003

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
5 - System Development and Demonstration	**0604807A - Medical Materiel/Medical Biological Defense Equipm**	**832**

Schedule Detail	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Hemostatic Dressing (MS B); (MS C)			2Q		3Q			
Oxygen Generator Systems (MS B); (MS C)			2Q		4Q			
Thawed Blood Processing System (MS C)				2Q				
Dental Field Treatment and Operating System (MS C)		4Q						

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

February 2003

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
5 - System Development and Demonstration	**0604807A - Medical Materiel/Medical Biological Defense Equipm**	**834**

COST (In Thousands)	FY 2002 Actual	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	Cost to Complete	Total Cost
834 SOLDIER SYS PROT-ED	851	782	1412	1064	882	3005	1818	1766	Continuing	Continuing

A. Mission Description and Budget Item Justification: This project supports system development and demonstration of preventive medicine materiel, including devices, pharmacologicals, and other tools to provide protection, sustainment, and enhancement of the physiological and psychological capabilities of soldiers in the face of combat operations under all environmental conditions. Focus is on reduction in the incidence of personnel losses due to preventable disease and nonbattle injuries through development of environmental and physiological performance monitors and other preventive medicine countermeasures. A major contractor is Allermed Laboratories, Inc., San Diego, CA. This program supports the Objective Force transition path of the Transformation Campaign Plan (TCP).

Accomplishments/Planned Program	FY 2002	FY 2003	FY 2004	FY 2005
In FY02, resolved the technical issues raised by the U.S. Food and Drug Administration (FDA) on the manufacture of the skin test for Leishmania mexicana, which causes leishmaniasis in the Americas and conducted a Phase 1 safety trial; established good manufacturing practices (GMP) manufacturing line for the skin test for L. tropica, which causes leishmaniasis in Southwest Asia. In FY03, produce the FDA-required three-lot consistency lots of the L. tropica skin test and begin a Phase 1 safety trial. In FY04, conduct stability studies on the three lots of L. tropica skin tests and manufacture the skin tests for the Phase 3 pivotal studies to be conducted in Turkey. In FY05, continue the stability testing of the original three lots, start stability testing on the skin tests made for Phase 3 study, and begin a Phase 2 field trial with L. tropica skin test.	851	782	1412	1064
Totals	851	782	1412	1064

B. Other Program Funding Summary: Not applicable for this item.

C. Acquisition Strategy: Test and evaluate in-house and commercially developed vaccine candidates in government-managed trials to meet FDA requirements.

Schedule Profile Detail (R-4a Exhibit)

February 2003

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
5 - System Development and Demonstration	**0604807A - Medical Materiel/Medical Biological Defense Equipm**	**834**

Schedule Detail	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Leishmania skin test (MS B); (MS C)		1Q		4Q				

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

February 2003

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
5 - System Development and Demonstration	**0604807A - Medical Materiel/Medical Biological Defense Equipm**	**849**

COST (In Thousands)		FY 2002 Actual	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	Cost to Complete	Total Cost
849	INFEC DIS DRUG/VACC ED	3182	3270	3819	3431	3470	3070	3990	4059	Continuing	Continuing

A. Mission Description and Budget Item Justification: This project funds technical development of candidate medical countermeasures to infectious diseases that occur within militarily relevant areas of the world. These products fall within three major areas: vaccines, drugs, and diagnostic kits. The funds support Phase 3 human clinical trials for large-scale efficacy testing, long-term animal studies, and related manufacturing tests. This work, which is jointly performed by military laboratories and civilian contracted pharmaceutical firms, is directed toward the prevention of disease, early diagnosis if contracted, and speeding recovery once diagnosed. These trials are required to meet U.S. Food and Drug Administration (FDA) regulatory approval guidance, a mandatory obligation for all military products placed into the hands of medical providers or service members. Priority is based upon four major factors: the extent of the disease within the Combatant Commands theater of operations, the clinical severity of the disease, the technical maturity of the proposed solution, and the affordability of the solution (development and production). Consequently, malaria, dysentery, hepatitis, and dengue diseases (which are found in CENTCOM, EUCOM, SOUTHCOM, and PACOM areas) come to the top of the requirement. The reduction in risk to contract infectious diseases within the force supports the Army Transformation Campaign Plan (TCP) and directly enables the Objective Force (OF) concept through reduction of evacuations of uniquely qualified soldiers and decrease in medical footprint to sustain the evacuees.

Accomplishments/Planned Program	FY 2002	FY 2003	FY 2004	FY 2005
Clinical trials, developmental testing, and appropriate reviews of malarial/antimalarial vaccines, drugs, and diagnostics: In FY02, analyzed data from one Phase 3 clinical trial to evaluate the effectiveness of tafenoquine, an antimalarial prophylatic drug, and determined it to be efficacious against malaria, but identified several technical problems; in support of reinitiating the tafenoquine Investigational New Drug (IND), met with three expert panels to address resolution of technical problems; successfully completed developmental testing of a prototype Malaria Rapid Diagnostic Device (MRDD), which is being commercialized by a contractor for rapid, dependable and inexpensive diagnosis of malaria. In FY03, conduct a Milestone (MS) B In Process Review (IPR) for MRDD; prepare and submit a Pre-Market Approval application to the FDA for MRDD; conduct a MS C IPR for MRDD; conduct a Phase 1 safety study and begin a multi-site multiyear Phase 3 study to evaluate the safety and effectiveness of tafenoquine. In FY04, continue multi-site multiyear Phase 3 studies to evaluate effectiveness of tafenoquine. In FY05, complete multi-site multiyear Phase 3 study to evaluate effectiveness of tafenoquine.	764	2125	2024	961
Studies, trials, and reviews of diarrheal vaccines: In FY02, completed a Phase 3 pivotal study of the Enterotoxigenic Escherichia-coli (ETEC) vaccine; completed a Phase 2 efficacy trial in Egyptian infants of ETEC vaccine; conducted a Phase 2 challenge trial for new adjuvant lot of Campylobacter diarrheal vaccine. In FY03, conduct a MS C IPR for ETEC vaccine for the prevention of traveler's diarrhea; conduct a Phase 2 trial for new adjuvant lot of Campylobacter vaccine. In FY04, conduct an expanded Phase 2 trial of the Campylobacter vaccine. In FY05, begin a Phase 3 Shigella flexneri vaccine trial.	1559	818	955	480

Accomplishments/Planned Program (continued)	FY 2002	FY 2003	FY 2004	FY 2005
Clinical studies and trials, and appropriate reviews of grouped vaccines, drugs, and diagnostics (Leishmaniasis, Paromomycin, Tick-borne Encephalitis Vaccine (TBEV), and Hepatitis E): In FY02, conducted the first part of a 2-year Phase 3 clinical trial to determine the effectiveness of paromomycin/gentamicin topical antileishmanial cream; conducted a Phase 1 safety trial of Leishmania mexicana skin test kits; completed acceptance testing on each of the five colors for both visual and near infrared signature profile and finalized input to new military specification for performance of camouflage face paint. In FY03, work with the manufacturer of TBEV to conduct lot consistency and safety studies; continue 2-year Phase 3 clinical trial to determine the effectiveness of paromomycin/gentamicin topical antileishmanial; conduct Phase 2 clinical study to determine the safety, sensitivity, and specificity of new L. mexicana skin test components; complete Phase 1 safety trial with L. tropica skin test kits; submit new IND application for good manufacturing practices (GMP) L. tropica skin test kits and prepare for Phase 2 safety trials with industry partner's Leishmania skin test kits. In FY04, complete Phase 1 safety trial with L.tropica skin test kits. In FY05, begin Phase 2 field trial in Turkey to evaluate safety and efficacy of the L. tropica skin test kits.	859	327	382	343
In FY04, begin field site preparations for a Phase 3 dengue vaccine efficacy trial. In FY05, continue field site preparation and initiate a dengue vaccine Phase 3 efficacy trial.	0	0	458	1647
Totals	3182	3270	3819	3431

B. Other Program Funding Summary: Not applicable for this item.

C. Acquisition Strategy: Test and evaluate in-house and commercially developed products in government-managed trials to meet FDA requirements and Environmental Protection Agency registration.

Schedule Profile Detail (R-4a Exhibit)

February 2003

BUDGET ACTIVITY
5 - System Development and Demonstration

PE NUMBER AND TITLE
0604807A - Medical Materiel/Medical Biological Defense Equipm

PROJECT
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Schedule Detail	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
ETEC vaccine (MS C)		2Q						
Tafenoquine antimalarial drug (MS C)				3Q				
Malaria Rapid Diagnostic Device (MS B/C)		4Q						
Leishmania skin test (MS B); (MS C)				4Q				
Shigella flexneri (MS B)			2Q					
Paromomycin/Gentamicin (MS B/C)			4Q					
RTS,S malaria vaccine (MS B)		4Q						
Dengue tetravalent vaccine (MS B)			1Q					