

# PROJECT DATA SHEET

A = Add  
C = Change  
D = Delete

Amendment Number

DOCUMENT CODE

3

2. COUNTRY/ENTITY: World Bank

3. PROJECT NUMBER: 930-0907

4. BUREAU/OFFICE: Office of Health

5. PROJECT TITLE (maximum 40 characters): Malaria Field Trials

6. PROJECT ASSISTANCE COMPLETION DATE (PACD):  
MM DD YY  
06 30 93

7. ESTIMATED DATE OF OBLIGATION (Under "B" below, enter 1, 2, 3, or 4)  
A. Initial FY 87 B. Quarter 4 C. Final FY 93

## 3. COSTS (\$000 OR EQUIVALENT \$1 =

A. FUNDING SOURCE	FIRST FY <u>87</u>			LIFE OF PROJECT		
	B. FX	C. L/C	D. Total	E. FX	F. L/C	G. Total
AID Appropriated Total	2,000		2,000	8,000		8,000
(Grant)	( 2,000 )	( )	( 2,000 )	( 8,000 )	( )	( 8,000 )
(Loan)	( )	( )	( )	( )	( )	( )
Other U.S.	1.					
	2.					
Host Country						
Other Donor(s)						
<b>TOTALS</b>	<b>2,000</b>		<b>2,000</b>	<b>8,000</b>		<b>8,000</b>

## 9. SCHEDULE OF AID FUNDING (\$000)

A. APPROPRIATION	B. PRIMARY PURPOSE CODE	C. PRIMARY TECH CODE		D. OBLIGATIONS TO DATE		E. AMOUNT APPROVED THIS ACTION		F. LIFE OF PROJECT	
		1. Grant	2. Loan	1. Grant	2. Loan	1. Grant	2. Loan	1. Grant	2. Loan
(1) HE	520	550				8,000		8,000	
(2)									
(3)									
(4)									
<b>TOTALS</b>						<b>8,000</b>		<b>8,000</b>	

10. SECONDARY TECHNICAL CODES (maximum 5 codes of 3 positions each)

11. SECONDARY PURPOSE CODE

12. SPECIAL CONCERNS CODES (maximum 7 codes of 4 positions each)

13. PROJECT PURPOSE (maximum 480 characters)

The project will develop, conduct and evaluate human field trials of genetically-engineered candidate malaria vaccines in Papua New Guinea. Appropriate experiments on candidate vaccines will be conducted to determine their effectiveness and safety in order to license the vaccines in the U.S. for production and distribution.

14. SCHEDULED EVALUATIONS

Interim: MM YY MM YY Final: MM YY

15. SOURCE/ORIGIN OF GOODS AND SERVICES

16. APPROVED SIGNATURE OF AGENCIES PROPOSED (This is page 1 of a \_\_\_\_\_ page PF Amendment)

17. APPROVED

Signature: Kenneth L. Hill  
Title: Agency Director for Health  
Date Signed: MM DD YY

18. DATE DOCUMENT RECEIVED IN AID/W, OR FOR AID/W DOCUMENTS, DATE OF DISTRIBUTION

MM DD YY

PROJECT AUTHORIZATION

Country: Papua New Guinea  
Project Title: Malaria Field Trials  
Project No. 936-5967

1. Pursuant to Section 104(c) of the Foreign Assistance Act of 1961, as amended, I hereby authorize the first phase of the centrally-funded project, **Malaria Field Trials**, involving planned obligations not to exceed **\$8,000,000** in grant funds over a five-year period from the date of authorization, subject to the availability of funds in accordance with the A.I.D. OYB/allotment process.

2. These funds will finance the project to develop, conduct, and evaluate human field trials of candidate malaria vaccines in Papua New Guinea. Appropriate trials of candidate vaccines will be conducted to determine their effectiveness and safety in the U. S. first and then in field settings. It is expected that the vaccines will eventually become commercially available as a public health tool in the control of malaria.

3. The agreement(s) which may be negotiated and executed by the officer(s) to whom such authority is delegated in accordance with A.I.D. regulations and Delegations of Authority shall be subject to the following terms and conditions, together with such other terms and conditions as A.I.D. may deem appropriate.

4. **Source and Origin of Commodities, Nationality of Services**

a. Commodities financed by A.I.D. under the project shall have their source and origin in the Cooperating Country or in the United States except as A.I.D. may otherwise agree in writing. Except for ocean shipping, the suppliers of commodities or services shall have the Cooperating Country of the United States as their place of nationality, except as A.I.D. may otherwise agree in writing.

b. Ocean shipping financed by A.I.D. under the project shall, except as A.I.D. may otherwise agree in writing, be financed only on flag vessels of the United States.

5. Waivers

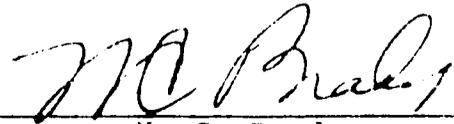
Based on the justification set forth in the attached Action Memorandum, I hereby

a. determine that special circumstances exist to waive, and I do hereby waive, the requirements of Section 636(i) of the Foreign Assistance Act of 1961, as amended, with respect to motor vehicles and approve a procurement source waiver from A.I.D. Code 000 to A.I.D. Code 935;

b. approve a procurement source waiver from A.I.D. Code 000 to A.I.D. Code 935 for the commodities and services described in the attached Action Memorandum;

c. certify that, with respect to the procurement of commodities, the exclusion of procurement from Free World countries other than the cooperating country and countries included in Code 941 would seriously impede attainment of U.S. foreign policy objectives and objectives of the foreign assistance program; and

d. certify that, with respect to the procurement of services, the interests of the United States are best served by permitting the procurement of services from Free World countries other than the cooperating country and countries included in Code 941.



N. C. Brady

Senior Assistant Administrator  
Science and Technology

9/11/87

Date

Clearances:

S&T/H:GPettigrew (draft)	Date	8/21/87
ST/H:AVandusen (draft)	Date	8/21/87
ST/PO:GGower <i>Rm</i>	Date	9/10/87
DAA/S&T:DBrennan <i>183</i>	Date	9/11/87
DAA, S&T: [signature]	Date	9/11/87
GC/CP:Triedler (draft)	Date	9/8/87
DAA/ANE:JNorris <i>Ja</i>	Date	17 SEP 1987

Drafted: S&T/H:GPettigrew:gp:8/21/87:5253a

1)

AGENCY FOR INTERNATIONAL DEVELOPMENT  
WASHINGTON, D.C. 20523

SEP 17 1987

ACTION MEMORANDUM FOR THE ACTING ASSISTANT ADMINISTRATOR,  
BUREAU FOR ASIA AND NEAR EAST

FROM: ANE/PD, Ronald F. Venezia *R. Venezia*

SUBJECT: S&T Bureau Project for Malaria Vaccine Trials in  
Papua New Guinea

Action: We request your clearance for SAA/S&T authorization of  
Malaria Vaccine trials in Papua New Guinea.

Discussion: After discussion with ANE staff and Regional  
Director Paupe of the Suva Mission, S&T proposes to authorize  
an eight million dollar (\$8,000,000) five-year malaria vaccine  
trial activity in Papua New Guinea.

Separately SAA/S&T has given preliminary (PID-level) approval  
of a 23 million dollar (\$23,000,000) five-year (from FY 1988)  
worldwide vaccine trial project for Papua New Guinea and three  
other sites (possibly Thailand, Africa and LAC). Two Million  
dollars of FY 1987 funds are available for the Papua New Guinea  
activity, and 23 million were given preliminary approval  
starting with five million in FY 1988. S&T will provide all  
funding for vaccine trials, and will also continue funding (\$10  
million annually) for vaccine development.

We and RDO Suva endorse the technical merits of the Papua New  
Guinea trials and the high priority S&T assigns malaria vaccine.

ANE staff had two concerns about this proposal:

1. Budget for high-cost, high-inflation Papua New Guinea  
may be underestimated. S&T has flexibility in FY 1988 and  
following years to revise cost estimates with experience,  
and we expect delay in starting other country trials which  
will offset cost increases in Papua New Guinea.
2. Staffing of the Suva Mission to support this activity  
will be strained, particularly during the initial two years.  
This is when construction of expatriate housing and test  
facilities and when staff and equipment arrive in country.  
In staff discussions, S&T/H indicated their intent to util-  
ize an "observer" personal services contractor (PSC) posi-  
tion to provide administrative support for these initial  
activities. S&T/H will work out details with the Suva

We are satisfied that our concerns will be met during implementation of the activity.

Recommendation: That you concur in the attached SAA/S&T authorization of the Papua New Guinea malaria vaccine trial activity.

Attachment:  
action memo and authorization

AGENCY FOR INTERNATIONAL DEVELOPMENT  
WASHINGTON, D.C. 20523

AUG 28 1987

ACTION MEMORANDUM FOR THE SENIOR ASSISTANT ADMINISTRATOR FOR  
SCIENCE AND TECHNOLOGY

FROM: S&T/H, Kenneth J. Bart, M. D. *A. J. Tucker for*

SUBJECT: Approval of Malaria Field Trials Activities in Papua  
New Guinea (936-5967)

Problem: Your approval is required to authorize Malaria Field Trials activities in Papua New Guinea. This funding will be used to develop, conduct and evaluate human field trials of candidate malaria vaccines. Appropriate trials of candidate vaccines are being conducted in the U. S. to determine their effectiveness and safety in accordance with FDA regulations concerning the licensing of vaccines in the U.S. for production and distribution. Although FDA clearance is not required for the trials to take place, protocols for the trials have been reviewed by the appropriate ethical review committees in NIH. In addition, A.I.D. will follow the ethical standards of Papua New Guinea. After an extensive selection process, Papua New Guinea was chosen as one of two countries in Asia where field trials should begin. Once U. S. trials are completed, field trials will commence in Papua New Guinea under this activity.

This activity is expected to cost \$8,000,000 in grant funds over a five year period. The initial funding in FY 1987 will be \$2,000,000. The project assistance completion date for this activity will be June 30, 1993.

Discussion: Malaria continues to be a major cause of morbidity and mortality in Less Developed Countries (LDCs). It is estimated that more than two billion people are at risk from malaria infection, and on the African subcontinent alone, it is estimated that one million children die of malaria infection annually. A.I.D. has taken the lead and was in the forefront of activities to initiate research programs to develop supplementary and alternative methods of controlling the disease. During the past 20 years, the S&T Bureau selected a series of leading laboratories in the U. S. and developed a network of scientists working on a series of research projects leading toward the development of malaria vaccines.

In the last 3 years this support has led to the development of potential, candidate vaccines. Recent technical breakthroughs in malaria vaccine development, such as those at New York University, Scripps Institute, the Universities of Missouri and Hawaii, by A.I.D.-funded researchers and others around the world has been remarkable, prompting accelerated planning for clinical and field trials of several prototype malaria vaccines in malaria endemic and non-endemic areas of the world. As a result of these concentrated efforts, today several prototype malaria vaccine candidates are available for clinical trials.

Preliminary site visits to approximately 10 countries in Asia resulted in recommendations of two countries where initial field trials should begin; they are Papua New Guinea and Thailand. The field trials for the first series of candidate antigens will begin in Papua New Guinea and will take 2 - 3 years to complete. A Project Agreement will be signed in September 1987 with the Institute of Medical Research (IMR) in the Ministry of Health of the Government of Papua New Guinea. A.I.D. will have direct involvement in monitoring the activity and will provide technical coordination through a Personal Services Contract arrangement. Dr. Michael Alpers, Director of IMR, has indicated his desire to have the A.I.D. technical coordinator on site and will provide office space.

The field trials will take at least three years to complete for the first series of candidate antigens and will address questions of vaccine safety, efficacy, and public health impact. It is expected that the test sites will investigate a series of potential malaria vaccine candidates over the life of the project. Clinical Phase I and Phase II trials will take place in Port Moresby under strict clinical and ethical conditions by a medical officer. The Phase III field trials will take place near Maprik, East Sepik in an endemic area. The late Phase III trials will include high risk population groups such as pregnant women and infants in malaria endemic areas.

The Office of Health has reviewed all the ethical and environmental considerations related to use of the vaccine in field trials and find that the planned procedures meet the standards approved by the National Institutes of Health. The conduct of the trials will comply with all special considerations concerning human clinical trials.

The initiation of the malaria field trials in Papua New Guinea represent an innovative and far reaching approach to transferring new medical discoveries made possible by biotechnology from the laboratories to the field. It is expected that the vaccines will eventually become a major field available as a public health tool for the control of malaria.

### Source and Origin of Commodities, Nationality of Services

Commodities and vehicles financed by A.I.D. under the project shall have their source and origin in the United States and the Cooperating Country except as A.I.D. may otherwise agree in writing. Suppliers of commodities or services shall have the United States or the Cooperating Country as their place of nationality except as A.I.D. may otherwise agree in writing. Based on the following justification, authority is requested to procure certain goods and services and vehicles from Geographic Code 935 countries.

### Justification

Circumstances critical to the achievement and success of this project's objectives necessitate procurement of certain commodities, vehicles, and services from Geographic Code 935 countries. Exclusion of procurement from free world countries, other than the cooperating country or countries included in Code 941, would seriously impede the attainment of U.S. foreign policy objectives and the objectives of the foreign assistance program. Also the interests of the United States are best served by permitting the procurement of services from Free World countries other than the cooperating country and countries included in Code 941.

### Commodities

The project will require electrical equipment such as electrical generators, refrigerators, laboratory and office equipment which must be compatible with the electrical system in PNG and other equipment such as field equipment and tools which must be compatible with equipment currently used in PNG and for which repairs, service and spare parts are available. The project will also require certain categories of equipment which are not manufactured in the United States such as video cassette recorders and players. Most commodities in the foregoing categories are of Australian or Japanese source and origin and suitable U.S. - made commodities are not available. The total value of such commodities to be procured is estimated to be approximately \$ 750,000.

### Vehicles

The use of U.S.-made vehicles in PNG is precluded since there are no sources of spare parts for and no maintenance and repair facilities capable of handling U.S. - made vehicles located in PNG. Unlike U.S.-made vehicles, the vehicles used in PNG are equipped with right-hand drive, and the metric system is used in their construction. Thus, there is no compatibility between locally available vehicles and U.S. vehicles. The site of the malaria field trials is a rugged environment where access to spare parts and trained mechanics will be critical. Most vehicles in PNG are of Australian or Japanese manufacture. The total value of such motor vehicles to be procured is approximately \$ 120,000.

Technical Assistance

The Papua New Guinea Institute of Medical Research (IMR) will conduct the field trials and Papua New Guineans will be involved at all levels of the project. However, expatriate scientific expertise will be needed by and involved in this project since the PNG staff may not have the full panoply of scientific experience, medical knowledge, or technical training needed. It is imperative that non-PNG scientists also have a knowledge of the culture and environment of these field trials since there is no time to train scientists in the understanding of sociological or environmental conditions affecting the field sites. Finding an American with the combination of technical skills and cultural/environmental sensitivity will be extremely difficult. In the interest of expeditiously implementing this project and using human resources efficiently, non-U. S. and non-PNG staff and consultants will be needed. A malaria field epidemiologist from Australia is likely to have both the unique technical skills and knowledge of the culture and physical environment necessary to provide appropriate technical assistance. Prior to contracting third country expatriate services or firms, the IMR will be required to first determine that the needed services or firms cannot be provided for by the Host Country or the United States. The total value of such services is estimated to be approximately \$ 750,000.

Attached is a Concept Paper for \$23 million for your separate approval for a worldwide field trials program of which our efforts in Papua New Guinea is just a part. A Project Paper will be developed in early FY 1988 to authorize the entire field trials program. The Papua New Guinea activity is being accelerated in order to take advantage of opportunities in FY 1987.

An Advice of Program Change to Congress has been processed and expires September 22, 1987.

Recommendation: That you approve this malaria field trials activity, including use of Code 935 countries, by signing the attached project authorization.

Attachments: a/s

Clearances:

S&T/H:GPettigrew (draft)	Date	8/21/87
S&T/H:AVandusen (draft)	Date	8/21/87
ST/PO:GGower <i>KG</i>	Date	9/10/87
DAA/S&T:DBrennan <i>AB</i>	Date	9/11/87
S&T/H:RLoggia <i>BL</i>	Date	9/11/87
S&T/H:RMiller (draft)	Date	9/8/87
DAA/ANE:JNorris <i>JN</i>	Date	9/17/87
M/S&R/OP:TMcMahon <i>JM</i>	Date	

Drafted: S&T/H:GPettigrew:gp:8/20/87:5253u  
Revised: 9/2/87

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