

Request for Applications

Field Evaluation of Rapid Diagnostics for Sexually Transmitted Infections (STIs)

RFA: RFA-SDI-2001-02

Diagnostics Research and Development/Sexually Transmitted Diseases Diagnostic Initiative

Release Date: July 28, 2001

The Sexually Transmitted Diseases Diagnostics Initiative (SDI) is inviting applications from investigators interested in working with SDI on the evaluation of rapid tests for STIs.

The SDI is an initiative within the UNDP/World Bank/World Health Organization Special Programme for Research and Training in Tropical Diseases (TDR). Its mission is to promote the development, evaluation and application of STI diagnostic tests appropriate for use in primary health care settings in developing countries. In consultation with STI experts from developing countries, SDI has identified the following priorities for rapid diagnostics:

Disease	Indication	Sample Study location
Chlamydia & Gonorrhoea	Screening of high/moderate risk populations	STD clinics; non-clinic based settings
	Support syndromic management in high and low disease prevalence settings	Primary health care and family planning clinics
Syphilis	Screening	Prenatal clinic, STD clinics

A number of rapid tests for these diseases are now commercially available, but it is not known whether these tests meet disease control needs. SDI will be conducting a 2-stage evaluation of these rapid tests. Tests will be evaluated first in the laboratory for test performance, reproducibility, stability and ease of use. A limited number of the most promising tests from these laboratory-based evaluations will be selected for evaluation of test performance and utility in field settings. With this RFA, SDI is seeking to establish a network of field sites in diverse geographic areas suitable for the evaluation of one or more of the indications described above. Sites will be selected on the basis of:

- 1) Site director with proven track record of field trials and commitment to the project
- 2) Access to any of the patient populations indicated above
- 3) Provision of good standard of care including availability of treatment
- 4) Strong links to a laboratory site with capacity and proven proficiency at performing current gold standard tests: RPR and TPHA for syphilis, nucleic acid amplification tests for chlamydia, and culture for gonorrhoea
- 5) Availability of local mechanism of institutional review and ethics approval
- 6) Strong government and community support for its activities
- 7) Ability to perform evaluations in a timely manner

How to Apply

Please complete the appended questionnaire and return it, by email or fax, with the applicant's curriculum vitae to Dr. Rosanna Peeling, WHO/TDR/SDI, 20 Avenue Appia, Geneva, Switzerland, Fax: 41 22 791 4854, Email: peelingr@who.int.

Questionnaire: Evaluation of Rapid STI Diagnostics

Applications for SDI Field Sites

Part 1. Administrative information

1.1. Name of applicant and institutional affiliation
(please enclose applicant's curriculum vitae)

Title:

Surname:

First name(s):

1.2. Full name of institution:

1.3. Full postal address of applicant:

1.4. Telephone:

1.5. Fax:

1.6. Email:

Part 2: Field Site Information

2. General information:

2.1. Type of clinic:

Primary health care _____ referral _____

Public _____ private _____

Other (specify) _____

2.2. STI patient population: (please include any information that may be relevant to the indications for which the rapid STI tests are being evaluated, e.g. high or low risk populations as stated in the RFA)

2.3. STI services offered at the site:

Symptomatic patients:

Are patients managed using a syndromic approach? yes ___ no ___

If yes, please provide details of guidelines/algorithm used (attach if applicable)

STI syndrome	Number of symptomatic patients/yr.	Treatment
Urethral discharge		
Vaginal discharge		
Genital ulcer		

Asymptomatic patients:

Is STI screening done on site? Yes ___ no ___

If yes, please provide details of testing:

for diagnostic tests

STI	Tests (brand name & manufacturer, if applicable)	No. of tests/yr	% positive	
			Men	Women
Syphilis				
<i>Chlamydia trachomatis</i>				
<i>Neisseria gonorrhoeae</i>				
chancroid				
HSV-2				
HIV				

2.4. Site capacity, facility and management:

Number of clinical staff and qualifications

Professional: _____

Clerical: _____

Are clinic records computerized? yes ___ no ___

If yes, please give details of computer software package currently used

3.3. Brief description of other research activities:

3.4. Is a mechanism for ethical review of research involving human subjects available locally? If yes, approximately how long does the process take once the protocol is submitted?

3.5. If your site were selected to be a SDI field site for the evaluation of rapid STI diagnostics, could the clinic be ready to participate in field site preparations (e.g. hiring of trial co-ordinator, protocol development, workshops on Good Clinical Practice and data management) by late 2001 or early