STA00011 Expanded Access Program

Inclusion/Exclusion Criteria (Protocol Amendment 3, dated 28 March 2017)

Subject ID: _____ Date: _____

Check box for **Yes** or **No**

(Place completed form in patients chart)

An individual must fulfill **all of the following criteria** (all must be YES) in order to be eligible for participation in this EAP:

YES	NO	Inclusion Criteria
		Persons in the United States who are at high risk for YF, including researchers, laboratory workers, vaccine production staff, and those who are traveling within 30 days to a YF-endemic region or to a country requiring proof of YF vaccination under IHRs.
		≥9 months of age on the day of vaccination
		An ICF, indicating that Stamaril vaccine (non-US-licensed) is being administered in place of YF-VAX, has been signed and dated by persons ≥ 18 years of age.
		An assent form has been signed and dated by persons 7 years to < 18 years of age, and ICF has been signed and dated by parent(s) or guardian(s) for persons ≥ 9 months to < 18 years of age.

An individual fulfilling any of the following criteria (all must be NO) is to be **excluded** from participation in this EAP:

YES	NO	Exclusion Criteria
		Age < 9 months
		Breastfeeding, if the nursing cannot be discontinued for at least 14 days following vaccination. **Note**: Yellow Fever vaccine virus may be transmissible via breast milk by nursing mothers who are vaccinated during the final 2 weeks of pregnancy or post-partum. Following transmission, infants may develop encephalitis. The minimum time of discontinuation of breastfeeding for 14 days after vaccination is based on the expected clearance of live-attenuated vaccine virus.
		Immunosuppression, whether congenital or idiopathic, including for example, leukemia, lymphoma, other malignancies, and patients who are receiving immunosuppressant medications (e.g., systemic corticosteroids [greater than the standard dose of topical or inhaled steroids], alkylating drugs, antimetabolites, or other cytotoxic or immunomodulatory drugs) or radiation therapy, or organ transplantation.
		Symptomatic HIV infection
		Known hypersensitivity to the active substance or to any of the excipients of Stamaril vaccine or to eggs or chicken proteins
		Asymptomatic HIV infection when accompanied by evidence severe immune suppression. **Note**: Evidence of severe immune suppression includes CD4+ T-cell counts < 200/mm3 (or < 15% total lymphocytes in children aged < 6 years), or as

		determined by the HCP.
		History of thymus dysfunction (including myasthenia gravis, thymoma, thymectomy).
		Moderate or severe febrile illness or acute illness **Note**: Participation in the EAP can be reassessed when moderate or severe febrile illness or acute illness has resolved.

An individual fulfilling any of the following criteria may participate in this EAP, if travel cannot be avoided, and if in the judgment of the HCP, the benefits of vaccination outweigh potential risks:

Check box if applicable	Precautions
	Pregnancy Note: Live attenuated virus vaccines given to pregnant women might be capable of crossing the placenta and infecting the fetus. No animal reproductive or development studies have been conducted with Stamaril vaccine and the potential for risk to the fetus is unknown. Stamaril vaccine should not be used in pregnant woman, unless when clearly needed and following an assessment of the risks and benefits. Vaccination during pregnancy must be reported to Sanofi Pasteur. Report to sanofi on the Pharmacovigilance Reporting Form
	Age ≥ 60 years Note: Some serious and potentially fatal ARs including systemic and neurological reactions persisting more than 48 hours (YF vaccine-Associated Viscerotropic Disease and YF vaccine-Associated Neurotropic Disease) appear to occur at higher frequencies among individuals ≥ 60 years.
	Asymptomatic HIV infection with moderate immune suppression or no evidence of immune suppression. Note: Persons with asymptomatic HIV infection with moderate immune suppression or no evidence of immune suppression, as determined by the HCP, may participate in the EAP. The rate of seroconversion following vaccination is reduced and appears to depend on HIV viral load and CD4+ T-cell count. Evidence of moderate immune suppression includes CD4+ T-cell counts 200–499/mm^3 (or 15%–24% of total lymphocytes in children aged < 6 years), or as determined by the HCP. No evidence of immune suppression includes CD4+ T-cell counts ≥ 500/mm^3 or ≥ 25% of total lymphocytes for children aged < 6 years, or as determined by the HCP.

Signed_____ Date_____