

### **A Risk-Assessment Tool**

PATH, an international nonprofit organization that studies vaccines for infectious diseases in developing countries, developed a simple risk-assessment tool to determine the expected level of communications risk for each of its vaccine trials. The tool does not evaluate the technical or scientific risk that may be involved with a trial; instead it looks at the potential for controversy, the risks to PATH's reputation, and expected communication challenges that could affect the trial. A similar approach can easily be adopted for other types of research and clinical trials.

All PATH vaccine trials are checked against the indicators below. Each indicator is given the appropriate number of "flags" (0, 1, or 2) depending on the risk. The tally of flags for that particular trial determines the trial's overall "communications risk factor" (see below), which in turn indicates the level of communications effort and financial resources required.

Determining the risk factor is an internal process at PATH—the results of the assessment are not shared with partners or other external groups. In principle, this tool should provide more consistent judgments and planning for communication related to clinical trials.

Below is the chart filled out for an imaginary Phase III trial in India evaluating the safety and efficacy of an experimental pediatric vaccine (as tested by a "challenge") against pneumonia.

Indicators		One flag	Two flags	Total flags per
Type of trial	Phase	Phase I	Phase III	□□
	Challenge/non-challenge and inpatient/outpatient	Challenge or inpatient	Challenge and inpatient	□
Location	Geographic location	Resource poor setting	Possible social or political issues of concern; high background mortality rate	□
	PATH presence	No PATH office/staff		
Population	Age (*Descending age trials get two flags)	Children/toddlers	Infants	□
	Health	At-risk (includes pregnancy)		
Product	Route of administration	Nose spray, patch, or injection in the arm	Subcutaneous/intramuscular	□
	Suspected safety issue(s) (e.g., Reiter's syndrome, intussusception)	Any suspected safety issue(s) with this or similar products		
	Type of vaccine	Live attenuated and/or adjuvant not yet licensed		
	Disease target	Deadly/high mortality rate (e.g., meningitis, HIV)		□
Communications capacity	Staff and experience		No communications contact(s) or experience	
<b>Total Flags</b>				<b>7</b>


**Total Flags**  
 0-3 = Low risk  
 4-6 = Moderate risk  
 7+ = High risk

**This trial is at relatively high risk for controversy**