

TEST-OF-CONCEPT VERSUS PHASE III: A COMPARISON*

TEST-OF-CONCEPT STUDY	PHASE III
Designed to guide later development	Designed to license product
May use surrogate endpoint	Endpoint must be acceptable for registration
May use prototype product	Use final formulation and manufacturing process
Study population may be limited and focused	Study population must represent intended use
Smaller, faster	Larger, longer

*Source: Mark Feinberg, MD, PhD, Merck HIV Vaccine Division, HVTN Conference May 2, 2007
