RATIONAL:
The development of new, more effective TB vaccines have been recognized in the Stop TB Strategy and the Global Plan to Stop TB as essential to achieving the target of eliminating TB by 2050. Much progress has been made in the field of TB vaccine research over the past decade, with 9 candidates currently in clinical trials and several more in preclinical development and discovery phases. The TB community must continue to build the TB vaccine pipeline and accelerate TB vaccine development, but we must also look to the future and lay the groundwork over the next decade for the licensure and distribution of new TB vaccines.

Substantial resources and global support will be required to move these candidates and those that will follow through clinical trials to licensure. To ensure that there is minimal delay between licensure and distribution, it will also be essential to work closely with the WHO on prequalification processes and policy recommendations via the Strategic Advisory Group of Experts (SAGE).

SUMMARY:
The TB vaccine community convened in Tallinn, Estonia from 21-24 September to review progress in the field and determine what will be required over the next decade to reach the goal of developing new, more effective TB vaccines. Input from this successful Forum will provide a foundation for a TB Vaccine Blueprint to be developed over the next year, which will serve as a TB vaccine guidance document defining the critical challenges for basic research, product development, manufacturing and clinical development, and will lay the groundwork for rapid uptake and adoption of a new TB vaccine when licensed. Expanding the funding base and ensuring the support and engagement of high burden countries have also been identified as critical issues. These priority areas are in alignment with and will expand upon the objectives and activities outlined in the revised Global Plan to Stop TB 2011-2015.

In order to accelerate distribution and delivery of new TB vaccines when licensed, the TB vaccine research community is initiating discussions with the WHO Strategic Advisory Group of Experts (SAGE) regarding prequalification processes, at the Spring 2011 meeting.

DECISIONS REQUESTED (FROM STOP TB COORDINATING BOARD):

- Commit to supporting an environment that will promote and accelerate the development of new TB vaccines
- Endorse priority issues for TB vaccine development as outlined in early discussions of the TB Vaccine Blueprint and identification of Coordinating Board member(s) to participate in the development of the TB Vaccine Blueprint
- Support for the designation of TB vaccines as a priority global disease strategy by the Strategic Advisory Group of Experts to facilitate WHO vaccine policy processes and SAGE deliberations on global TB immunization programs.
**IMPLICATIONS (POLITICAL / FINANCIAL / STAFFING, ETC):**

**Next Steps**

**ACTION REQUIRED:**
- Identify Coordinating Board members interested in working with the TB vaccine research community on the development of a *TB Vaccine Blueprint*.
- Provide a statement supporting the designation of TB and TV vaccine products for the prevention of TB, to be included in the TB vaccine discussions at the spring 2011 SAGE meeting.
- Call upon the donor community to expand the financial basis for development and delivery of new TB vaccines.

**FOCAL POINT:** U. Fruth, J. Woolley

**TIMEFRAME:** October 2010 – October 2011