INCREASING NATIONAL IMPACT AND UPTAKE OF GOOD PARTICIPATORY PRACTICE GUIDELINES FOR BIOMEDICAL HIV **PREVENTION (GPP): THREE COUNTRY CASE STUDIES**

Hannah S¹, Ecuru J², Likitwonnawut U³, Slack C⁴, Yola N⁵ ¹ AVAC, ² Uganda National Council for Science and Technology, ³ Thai NGO Coalition on AIDS, ⁴ HIV/AIDS Vaccine Ethics Group, ⁵ Networking HIV/AIDS Community of South Africa

BACKGROUND

The Good Participatory Practice Guidelines for *Biomedical HIV Prevention Trials* (GPP) provide a systematic framework for stakeholder engagement. GPP has been applied at site, network and sponsor levels to enhance trial-specific and general site operations. GPP contains recommendations, not

requirements and no entity is established to ensure implementers' compliance. There is increasing interest in incorporating GPP into national trial oversight processes as a way to strengthen positive impact on research conduct and for concerned stakeholders We review case studies from South Africa, Thailand and Uganda. Each country is key to biomedical HIV prevention research and has implemented strong engagement and GPP programs.

NATIONAL MODELS UGANDA

UNCST² oversees ethical and regulatory approval of research nationally guidelines for research involving humans to reflect contemporary best

- GPP programs have been implemented at trial site level since 2010. GP Partners PrEP⁷, two key trials conducted in the country.
- Research organizations engaged UNCST in GPP efforts. Consequently, L guidelines revision, setting GPP as standard practice for research.

SOUTH AFRICA

A national GPP framework was formulated out of consultations with exp included trial implementers, CABs⁸, civil society representatives, local/r representatives.

A GPP role for REC members has been explored within biomedical HIV p were reviewed, identifying outstanding needs, especially training on cor REC member-specific training component is being developed as part of

Recently published regulations for health research with human participation the participating community or other relevant stakeholders—strengthe South African health research.

THAILAND

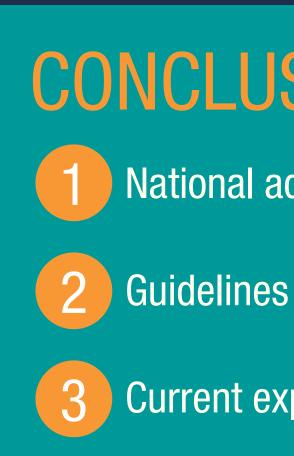
By 2012, HIV prevention research centers throughout the country recognition engagement and systematically implemented engagement efforts accord

Building out of this work, in 2013, TNCA³ led the establishment of a NCA research institutions and one MSM¹² research-focused CAB. The NCAB their research competency and ability to provide independent input to he

In 2014, NCAB members have begun to influence national level research for the research agenda and GPP implementation. The National Sub-Cor asked NCAB members to develop a national GPP plan.

ACRONYMS AND REFERENCES

- Ndase P, et al, 1 Jun 2014
- ⁸ Community Advisory Board
- ⁹ Research Ethics Committee
- ⁶ Mack N, et al, 25 Oct 2013 ¹⁰ National Strategic [HIV] Plan
 - ¹¹ National Community Advisory Board
 - ¹² Men who have Sex with Men
 - AVAC lobal Advocacy for HIV Preventio
- ed at HIVR4P Cape Town, South Africa



ENGAGING STAKEHOLDERS IN EFFECTIVE PARTNERSHIPS FOR DESIGN AND IMPLEMENTATION OF HIV PREVENTION RESEARCH **IS VITAL TO ETHICALLY ROBUST, LOCALLY APPROPRIATE CLINICAL TRIALS.**

RESULTS AND NEXT STEPS NATIONAL GPP IMPLEMENTATION EFFORTS HAVE ACHIEVED INTERIM **RESULTS IN EACH COUNTRY.** NEXT STEPS ARE PLANNED TO **MOVE TOWARD GREATER** IMPACT.

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Initial steps to incorporate GPP into national mechanisms and ethico-legal CONCLUSIONS Initial steps to incorporate GPP into national incorpo

National adoption can enhance sustainability of engagement beyond individual trials.

2 Guidelines and policies at national level will only be realized when put into practice.

3 Current experiences provide models for other countries.

Cross-CAB Forum using GPP for

- rporated into national ethics guidelines, to be with RECs
- included in REC training, with possible tion into review
- ite level implementation achieved
- endation framework for national GPP ntation developed
- hieved from national research council, / council, Department of Health
- ovincial, and/or national researcherer engagement forums to be held
- tion to be made on criteria for high-impact ent plans in protocols
- endations to be rolled out in 5 provinces

bacity built on research concepts and national adenda

- ns to issue PrEP position statement and other actions
- embers to institutionalize GPP in national committees and HIV prevention policy and

mulated positions on PrEP research and rollout

Ongoing

GPP rolled out with International AIDS Vaccine Initiative partner research centers in South Africa and Uganda July

UNAIDS/AVAC publish GPP 2nd edition

April/May

Thai Treatment Action Group publishes Stakeholder **Recommendations in HIV Biomedical Prevention Trials**

October

Critical Path to TB Drug Regimens releases GPP Guidelines for TB Drug Trials

May

TNCA establishes NCAB in Thailand

May

NCAB conducts GPP seminar, involving Thai research institutions

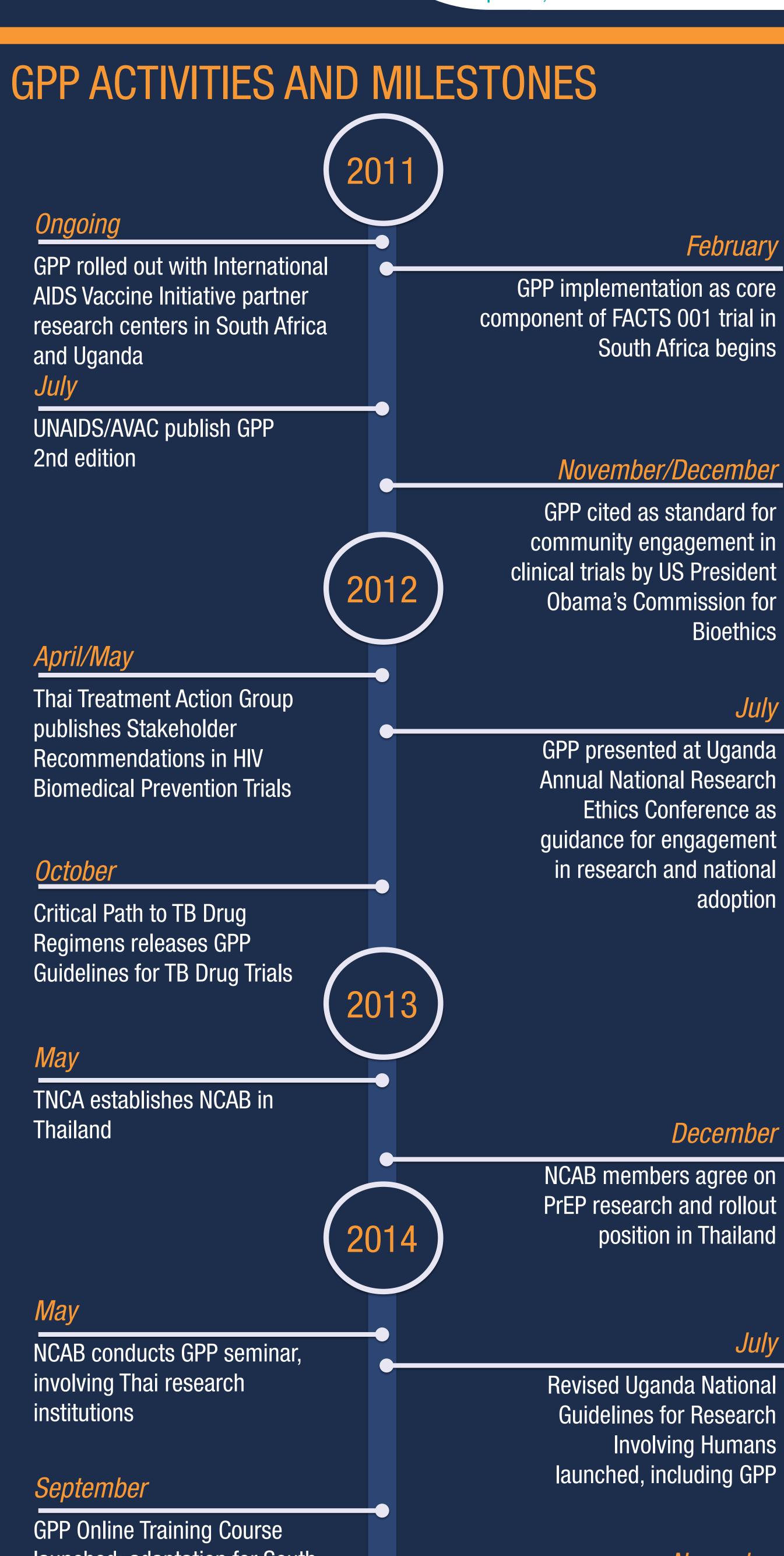
September

GPP Online Training Course launched; adaptation for South Africa REC members begins





Cape Town, South Africa 28-31 October 2014



November

July

July

GPP themed Cross-CAB Forum held in Uganda