

WORKSTREAM BULLETIN



Notes from: GLP Workstream Call

Date: 25th January 2018

Key Discussion Points:

- Site Sustainability Report
 - Bob Taylor's report on site sustainability was discussed
 - IVCC/i2i are planning on address issues raised with a business management workshop and follow-up
- Best Practice SOP's
 - IRS/LLINS SOPs– developed and awaiting final input
 - Larvicides and space sprays SOPs – experts identified to work with Alex Wright and the timescale estimated at 6 months
- Strategic Issues
 - Clarification still required as to which product types would require WHO PQ evaluation data to be generated
 - Clarification needed on whether there will be GLP/GCP requirements for Phase 3 epi trials
 - Update on progress of sites towards GLP certification
 - Africa
 - KCMUCo (Tanzania) – attained
 - CREC (Benin) – application submitted
 - IHI (Tanzania) / CSRS (Cote de Ivoire) / IRSS Burkina Faso) – applications to be submitted in 2018
 - NIMR (Tanzania) / IPR (Cote de Ivoire) – applications to be submitted 2019
 - Asia
 - VCRC (India) / NIMR (India) / IMR (Malaysia) / VCRU (Malaysia) – applications to be submitted late 2018
 - ICDC (China) – Discussions on-going to identify a GLP monitoring authority that can grant certification
 - Singapore – product testing - will be certified by end 2018
 - Data Ownership and Publishing
 - Some model language for contracts has been provided by MMV demonstrating how data ownership by the sponsor is compatible with academic institutions publishing

Next Steps:

- IVCC/i2i plan for addressing site sustainability issues to be shared with workstream
- Guidance note on data ownership to be drafted by the workstream with the aim of circulating to trial sites, academic institutions and manufacturers.