



Workstream Update: GLP Site Accreditation

Friday 23rd June, I2I Convening, Hotel Kempinski, Geneva

Graham Small (IVCC) and Alex Wright (Consultant to I2I)

Presentation Objectives

1. Recap on the progress and key achievements of the workstream over the last 12 months
2. Present the workstream's view of WHO's new product evaluation system
3. Outline the future priorities of the workstream

GLP Workstream Members



Industry Focal Point



Graham Small
IVCC



Dominic Schuler
WHO PQ



Anna Drexler
WHO NTD



John Lucas
Sumitomo Chemical



Dave Malone
IVCC



Emmanuel Temu
WHO GMP



Rajpal Yadav
WHO NTD

GLP Workstream Objectives

From the Terms of Reference:

- *The purpose of the GLP Workstream is to enable manufacturers to generate data at GLP certified facilities to be used in dossier reviews by WHO PQ*

- *This will be achieved by the development of:*
 - *Site-specific plans for obtaining GLP certification*
 - *Best Practice Standard Operating Procedures (SOPs) for the testing of Vector Control products*

GLP Workstream Outputs



From the GLP Workplan:

i2i Good Laboratory Practice Workplan 2017



Objective	Activity	2017			
		Q1	Q2	Q3	Q4
GLP Workstream					
Development of site-specific plans for reaching GLP compliance	Agreement of bespoke site development plans and budgets	█			
	Facility Capacity and Development Matrix Developed and Shared				
	Facility Capacity and Development Matrix updated quarterly		█	█	█
	Develop plan on how to forecast to site capacity need annually by manufacturers	█			
	Develop plan on how to support sites to achieve sustainability once GLP compliance is achieved	█			
	Begin to implement sustainability support plans			█	█
Development of Best Practice SOPs for the testing of VCproducts	Publish Moshi site SOPs	█			
	Collation of other existing SOPs				
	Identify Best Practice and Duplication	█	█		
	Expert review				
	Stakeholder consultation and finalisation			█	

1. 16 individual site plans to obtain GLP certification
2. These sites to be GLP certified by end of 2018
3. Site matrix developed and updated regularly on I2I website, conveying features of sites and progress in development
4. Develop Best Practice SOPs for testing Vector Control products
5. Sustainability Plan to support sites post-compliance
6. Forecasting tool to monitor site capacity

GLP Site Development



*Status Key	1. Site development
	2. Quality manual approved
	3. Pre-inspection complete
	4. Conducting pilot GLP trials
	5. Full inspection complete
	6. GLP Compliant

Facilities in Africa	Status*	Site Capabilities	Compliance Target
Kilimanjaro Christian Medical University College, Moshi, Tanzania	6. GLP Compliant	IRS P1-3; LLIN P1-3; Larv P1-3	N/A
Institut de Recherche en Sciences de la Sante (IRSS), Centre Muraz Bobo-Dioulasso, Burkina Faso	1. Site Development	IRS P1-3; LLIN P1-3	2018 Q2
LSHTM-CREC (Centre de Recherches Entomologiques de Cotonou), Benin	1. Site Development	IRS P1-3; LLIN P1-3; Larv P1	2017 Q4

GLP Site Development



Facilities in Africa (continued)	Status	Site Capabilities	Compliance Target
Centre Suisse de Recherches Scientifiques en Côte D'Ivoire (CSRS), Abidjan, Côte D'Ivoire	1. Site Development	IRS P1-3; LLIN P1-3; Larv P1-3	2017 Q4
Institut Pierre Richet (IPR), Institut National de Sante Publique, Cote D'Ivoire	1. Site Development	IRS P1-3; LLIN P1-3; Larv P1-3	2018 Q2
Ifakara Health Institute, Tanzania (Bagamoyo and Ifakara sites)	1. Site Development	IRS P2-3; LLIN P2-3	2017 Q4
Amani Research Centre-NIMR (National Institute of Medical Research), Muheza, Tanzania	1. Site Development	IRS P3; LLIN P1-3; Larv P1-3	2018 Q2

Site Development



Facilities in Asia	Status	Site Capabilities	Compliance Target
National Institute of Malaria Research, Delhi, India	1. Site Development	IRS P1-3; LLIN P1-3; Larv P1-3	2018 Q2
Vector Control Research Centre (VCRC), Puducherry, India	1. Site Development	IRS P1-3; LLIN P1-3; Larv P1-3	2018 Q2
Vector Control Research Unit (VCRU), Penang, Malaysia	1. Site Development	SS P1-3; Larv P1-3	2018 Q2
Institute for Medical Research (IMR), Kuala Lumpur, Malaysia	1. Site Development	SS P1-3; Larv P1-3	2018 Q2
National Institute for Communicable Disease Control and Prevention (ICDC), China	1. Site Development	IRS P1-3; LLIN P1-3; Larv P1-3; SS P1-3	2018 Q2

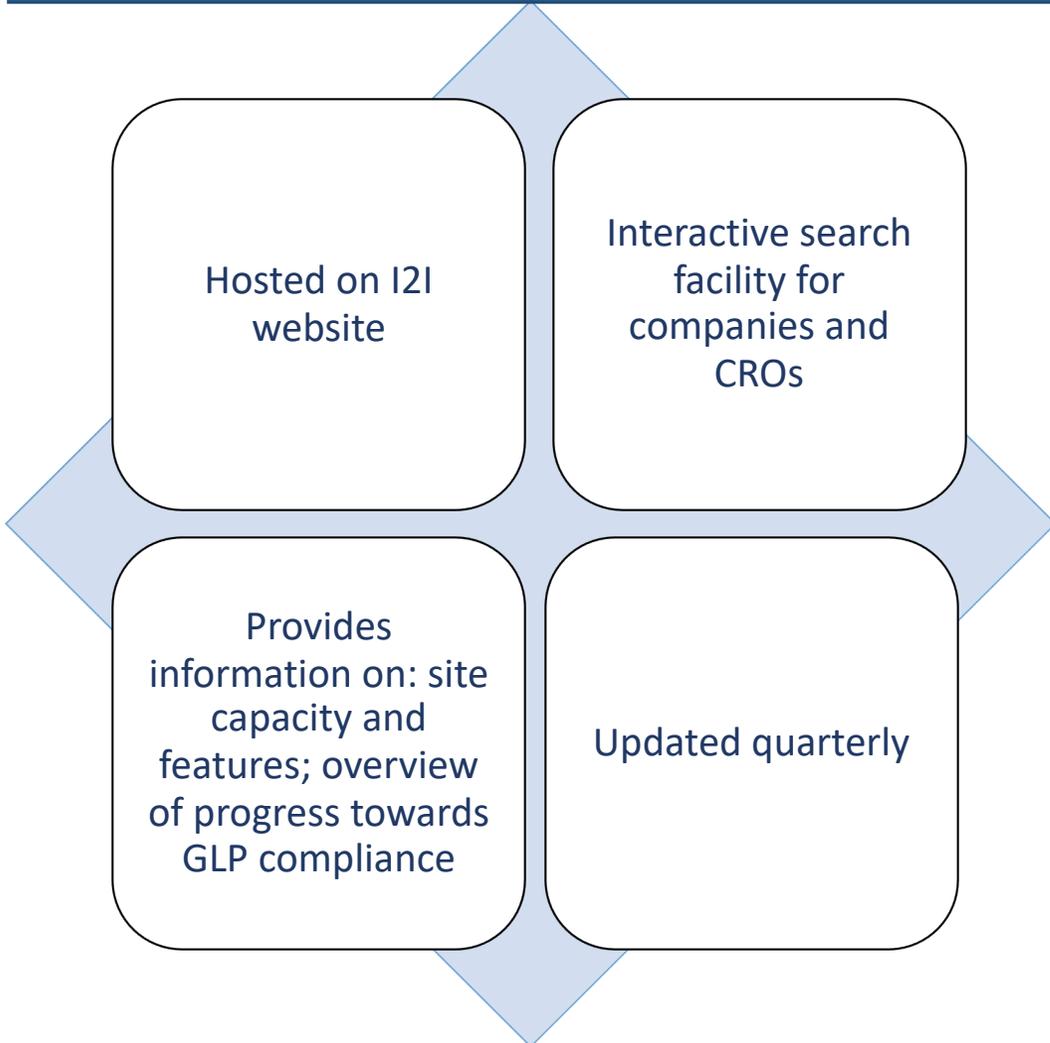
GLP Site Development



Facilities in the Americas	Status	Site Capabilities	Compliance Target
Centro de Investigaciones de Plagas e Insecticidas (CIPEIN), Buenos Aires, Argentina	1. Site Development	To be determined	To be determined
Fundação Oswaldo Cruz FIOCRUZ, Rio de Janeiro, Brazil	1. Site Development	To be determined	To be determined
Centro Regional de Investigación en Salud Pública, Instituto Nacional des Salud Pública, Tapachula, Mexico	1. Site Development	To be determined	To be determined
Universidad Autonoma de Yucatan, Mexico	1. Site Development	To be determined	To be determined

Facilities in Europe	Status	Site Capabilities	Compliance Target
IRD, Montpellier, France	1. Site Development	IRS P1; LLIN P1; Larv P1; SS P1	To be determined

GLP Site Matrix



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Search facility

Region

West Africa

Product Testing

<input type="checkbox"/> Lab Trials (Phase I)	IRS	<input type="checkbox"/> Small-scale Trials (Phase II) <input type="checkbox"/> Large-scale Trials (Phase III)
<input type="checkbox"/> Lab Trials (Phase I)	LLINS	<input type="checkbox"/> Small-scale Trials (Phase II) <input type="checkbox"/> Large-scale Trials (Phase III)
<input type="checkbox"/> Lab Trials (Phase I)	SS	<input type="checkbox"/> Small-scale Trials (Phase II) <input type="checkbox"/> Large-scale Trials (Phase III)
<input type="checkbox"/> Lab Trials (Phase I)	LARVICIDES	<input type="checkbox"/> Small-scale Trials (Phase II) <input type="checkbox"/> Large-scale Trials (Phase III)

Hut Testing Available

<input type="checkbox"/> January	<input type="checkbox"/> February	<input type="checkbox"/> March
<input type="checkbox"/> April	<input type="checkbox"/> May	<input type="checkbox"/> June
<input type="checkbox"/> July	<input type="checkbox"/> August	<input type="checkbox"/> September
<input type="checkbox"/> October	<input type="checkbox"/> November	<input type="checkbox"/> December
<input type="checkbox"/> TBC		

Village Scale Trials Possible

FACILITIES FOUND

4

View available facilities

WEST AFRICA

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WEST AFRICA

Institut de Recherche en Sciences de

GLP workstream: Best Practice SOPs (1/2)

Objective:

- *To produce a comprehensive list of GLP Best Practice SOPs for the laboratory testing of vector control products focusing on SOPs for the testing of LLINs, IRS, space sprays and larvicides*



GLP workstream: Best Practice SOPs (2/2)



Milestone	By When	Status	Comment
Lead consultant hired	Jan		Complete
Existing SOPs collated where possible from testing sites	Mar		Complete
Expert Panels convened for IRS, LLINs, SS and Larvicides	Apr		Complete
IRS and LLIN SOPs sifted and duplicates removed	Apr		Complete
SS and Larvicide SOPs sifted and duplicates removed	Apr		Lack of SOPs available
Composite Best Practice identified	May		Complete
SOPs for IRS and LLINs reviewed by panels	May		In progress
Conflicting panel guidance resolved by workstream	Jul		If necessary
IRS and LLIN SOPs finalised and shared	Aug		On track
SS and Larvicide SOPs finalised and shared	Aug		Requires action

Due to lack of SOPs available, change to project scope required in order to write comprehensive SOPs for larvicides and space sprays, rather than build on existing ones.

GLP workstream: SOP Compilation Exercise

Team

Fred Yeomans (I2I)
Graham Small (IVCC)
Alex Wright (LSHTM/Consultant to I2I)

Timeline

Start Date: January 2017
Proposed End Date: September 2017

Aim

To compile a set of best practice insecticide-testing SOPs for Phase I and II IRS, LLIN, Space Spray, and Larviciding

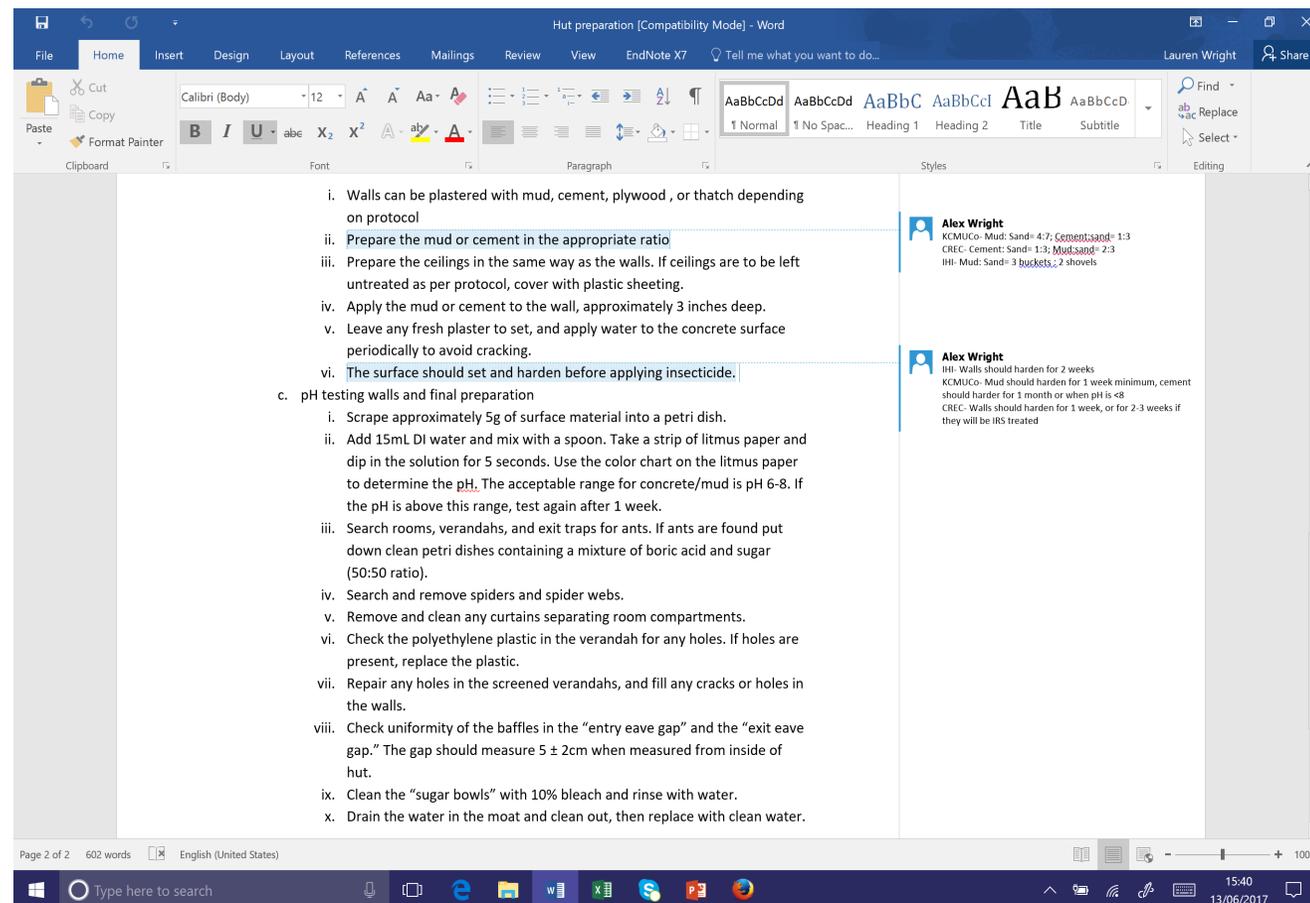
GLP workstream: SOP Compilation Exercise

- **Step 1-** Contact multiple institutions to gather SOPs for insecticide testing
- **Step 2-** Gather SOPs from all institutions and started grouping them into categories (LLIN or IRS, Phase I or Phase II)



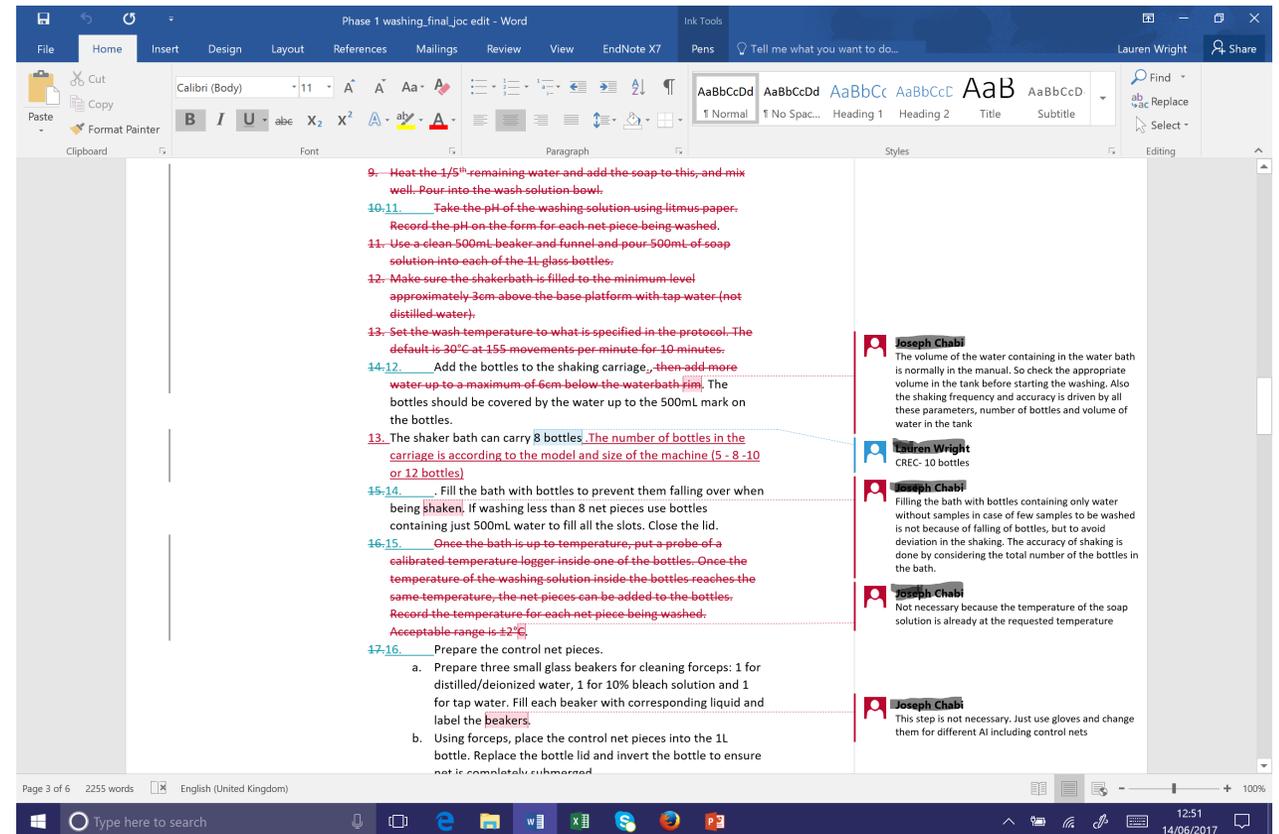
GLP workstream: SOP Compilation Exercise

- **Step 3-** Compare SOPs of each technique from each institution and compile into 1 SOP, taking into account WHOPES Guidelines
- **Step 4-** Send final compiled SOP out to Expert Panel members for comment



GLP workstream: SOP Compilation Exercise

- **Step 5-** Compile comments back from Expert Panel members and revise into final version of SOP (*current stage*)
- **Step 6-** Expert panel areas of difference will be resolved after GLP Workstream discussion (*July/August 2017*)



Phase 1 washing_final_joc edit - Word

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9. ~~Heat the 1/5th remaining water and add the soap to this, and mix well. Pour into the wash solution bowl.~~

10-11. ~~Take the pH of the washing solution using litmus paper. Record the pH on the form for each net piece being washed.~~

11. ~~Use a clean 500mL beaker and funnel and pour 500mL of soap solution into each of the 1L glass bottles.~~

12. ~~Make sure the shaker bath is filled to the minimum level approximately 3cm above the base platform with tap water (not distilled water).~~

13. ~~Set the wash temperature to what is specified in the protocol. The default is 30°C at 155 movements per minute for 10 minutes.~~

14-12. ~~Add the bottles to the shaking carriage, then add more water up to a maximum of 6cm below the water bath rim. The bottles should be covered by the water up to the 500mL mark on the bottles.~~

13. The shaker bath can carry 8 bottles. The number of bottles in the carriage is according to the model and size of the machine (5 - 8 - 10 or 12 bottles)

15-14. Fill the bath with bottles to prevent them falling over when being shaken. If washing less than 8 net pieces use bottles containing just 500mL water to fill all the slots. Close the lid.

16-15. Once the bath is up to temperature, put a probe of a calibrated temperature logger inside one of the bottles. Once the temperature of the washing solution inside the bottles reaches the same temperature, the net pieces can be added to the bottles. Record the temperature for each net piece being washed. Acceptable range is 42°C

17-16. Prepare the control net pieces.

a. Prepare three small glass beakers for cleaning forceps: 1 for distilled/deionized water, 1 for 10% bleach solution and 1 for tap water. Fill each beaker with corresponding liquid and label the beakers.

b. Using forceps, place the control net pieces into the 1L bottle. Replace the bottle lid and invert the bottle to ensure net is completely submerged.

Joseph Chabi
The volume of the water containing in the water bath is normally in the manual. So check the appropriate volume in the tank before starting the washing. Also the shaking frequency and accuracy is driven by all these parameters, number of bottles and volume of water in the tank.

Lauren Wright
CREC- 10 bottles

Joseph Chabi
Filling the bath with bottles containing only water without samples in case of few samples to be washed is not because of falling of bottles, but to avoid deviation in the shaking. The accuracy of shaking is done by considering the total number of the bottles in the bath.

Joseph Chabi
Not necessary because the temperature of the soap solution is already at the requested temperature

Joseph Chabi
This step is not necessary. Just use gloves and change them for different AI including control nets

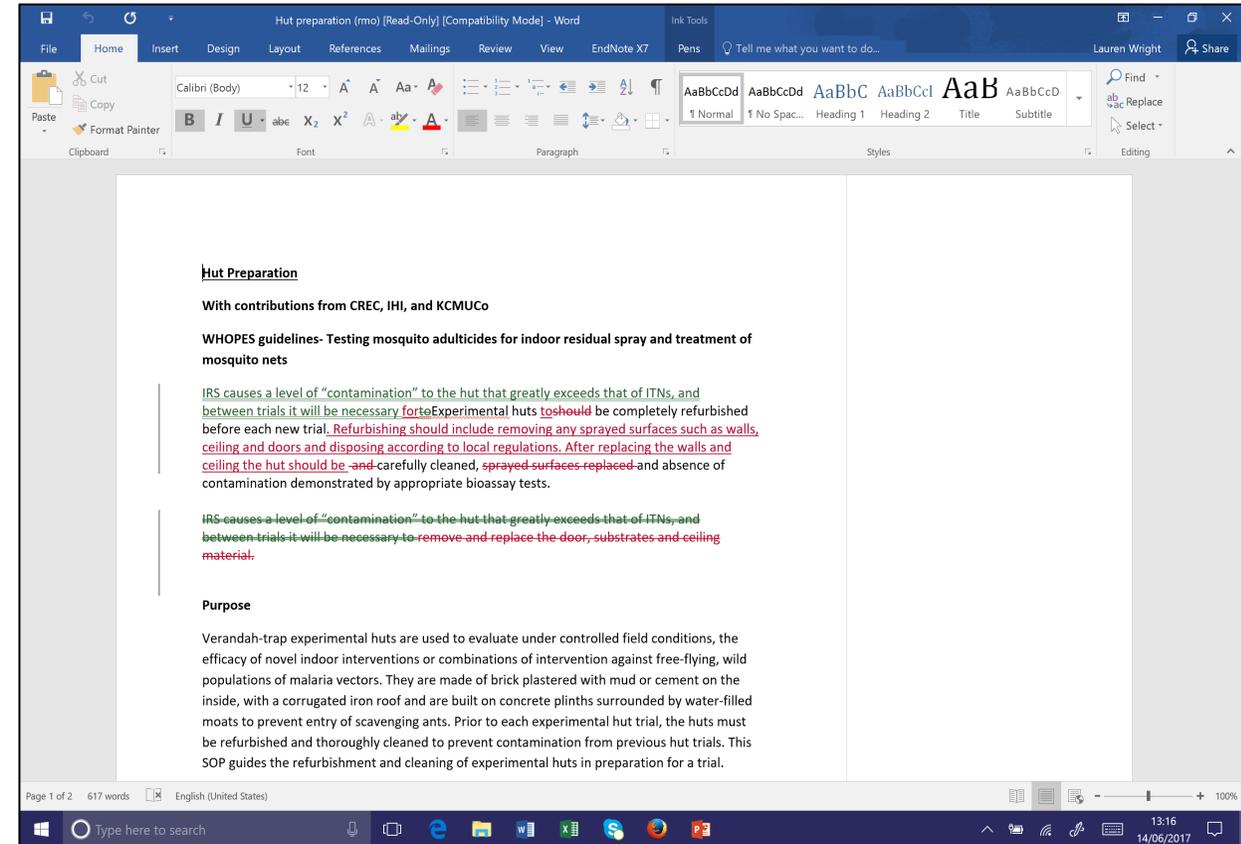
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GLP workstream: SOP Compilation Exercise

• Observations/Conclusion

- Larviciding and Space Spray SOPs difficult to compile
- Panel members sometimes commenting on WHOPES guidelines as well as SOP techniques
- Techniques can vary widely between sites
- In the first instance, areas that still need clarity will be taken to the GLP Workstream for consideration in July/August 2017



GLP workstream: Site Sustainability (1/2)

Objectives:

- 1. Identify the key barriers to sustainability faced by the GLP testing sites, both shared and individual*
- 2. Identify ways in which these barriers may be addressed so that the sites can be supported to plan and adapt their business operations to maintain sustainability in the market after achieving GLP compliance.*

GLP workstream: Site Sustainability (2/2)



Milestone	By When	Status	Comments
Hire consultant	May	●	Complete
Consultation to agree action plan	Jun	●	In progress
Prepare survey	Jun	●	On track
Review survey	Jun	●	On track
Consult with industry reps	Jul	●	On track
Sensitise sites	Jul	●	In progress
Final review survey	Jul	●	On track
Submit survey	Jul	●	On track
Review, collate completed surveys	Aug	●	On track
Review survey results	Aug	●	On track
Key informant interviews with sites	Sep	●	On track
Review interviews	Sep	●	On track
Final written report	Oct	●	On track

GLP workstream: Capacity Forecasting Tool (1/



Objectives:

- 1. Develop a tool which allows GLP testing sites to provide a snapshot of their capacity, projected over an annual period*
- 2. Use an aggregate picture to identify bottlenecks and slack across the sites*

GLP workstream: Capacity Forecasting Tool (2/



Milestone	By When	Status	Comments
Review getting data from WHO	May	●	Method not feasible
Review getting data from industry	May	●	Method not feasible
Review getting data from sites	May	●	Method most accessible
Workstream to review	Jun	●	Delayed
Discuss with testing sites	Jul	●	On track
Develop tool	Aug	●	On track
Pilot tool	Sep	●	On track
Amend and launch tool	Oct	●	On track
Quarterly updates begin	Q1 '18	●	On track

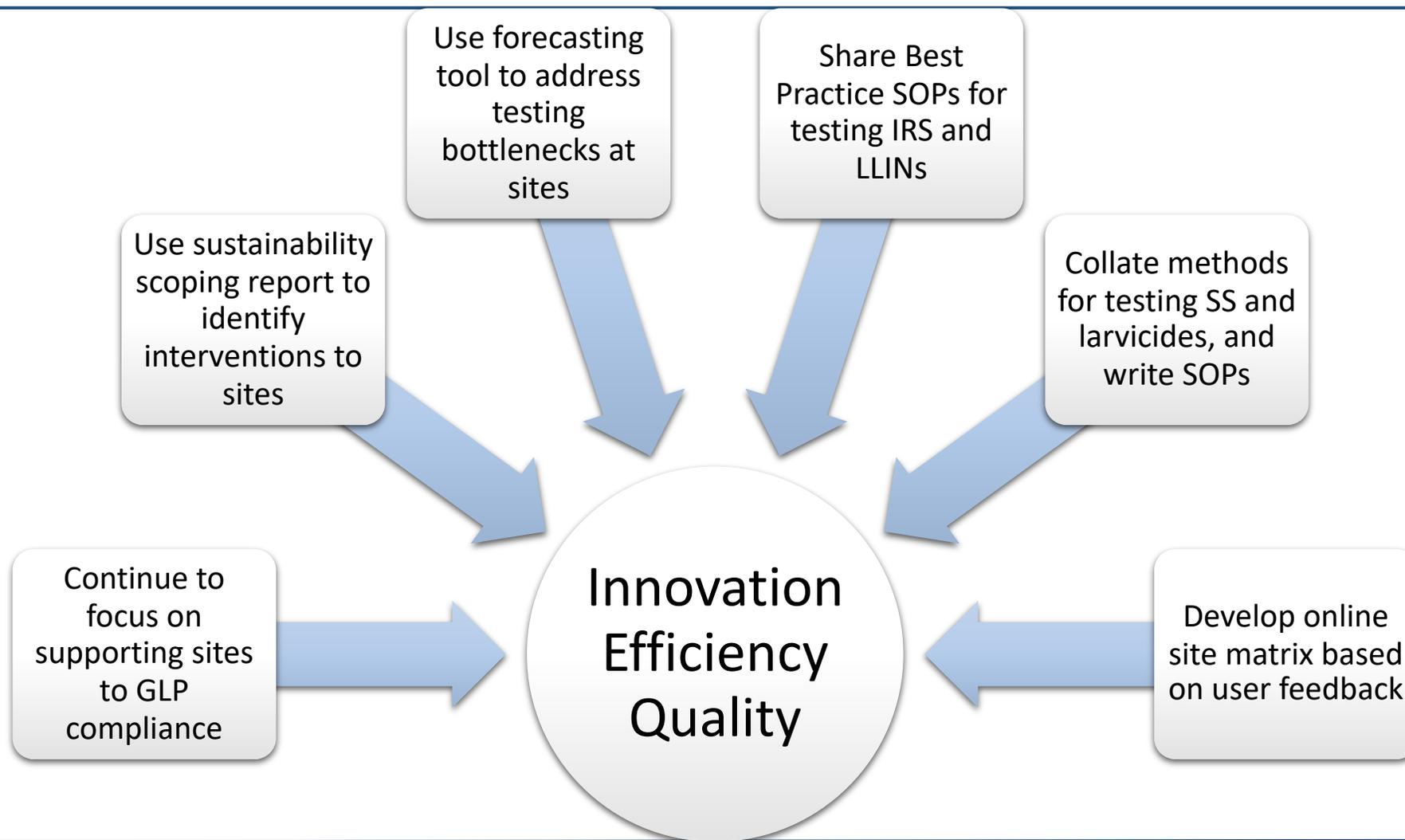
GLP Workstream View on New WHO System



- *To be finalised on afternoon of convening Day One in workstream breakouts, but suggested topics are:*



GLP workstream: Future Priorities



GLP workstream: Future Priorities

Questions to consider in workstream breakout group (afternoon of convening Day 1):

- Do you envisage additional areas of focus?
- Have some issues become obsolete?
- Do you have the right membership to reach these goals?
- Are there areas where input from other stakeholders is required?
- Do you see the need to a new/more focused group to address a particular issue?



GLP workstream: Other Questions to Consider in Breakout Session



- What is cost of GLP vs old system (actual cost vs cost/benefit)?
- Are data ownership issues resolved by conducting trials to GLP...what is current experience in PQ?
- Are conflict of interest issues resolved (real/perceived)... what is current experience in PQ?
- Analytical capacity ... (Gembloux can be a rate limiting step) ... there are plenty of GLP labs out therecan we use them now, do these need to be on a pre-approved list or is this decided at dossier submission stage (etc)?
- When will SOPs on Phase III studies be developed?

