The Power of Partnerships

SLIPTA e-Tool to streamline data collection and analysis

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ASLM 2016, Cape Town, December 4, 2016

Global Scientific Solutions for Health

Mission: Turn policy into practice

Focus: clinical laboratory services & clinical research.

GSSHealth takes a progressive, quality focused approach to laboratory strengthening

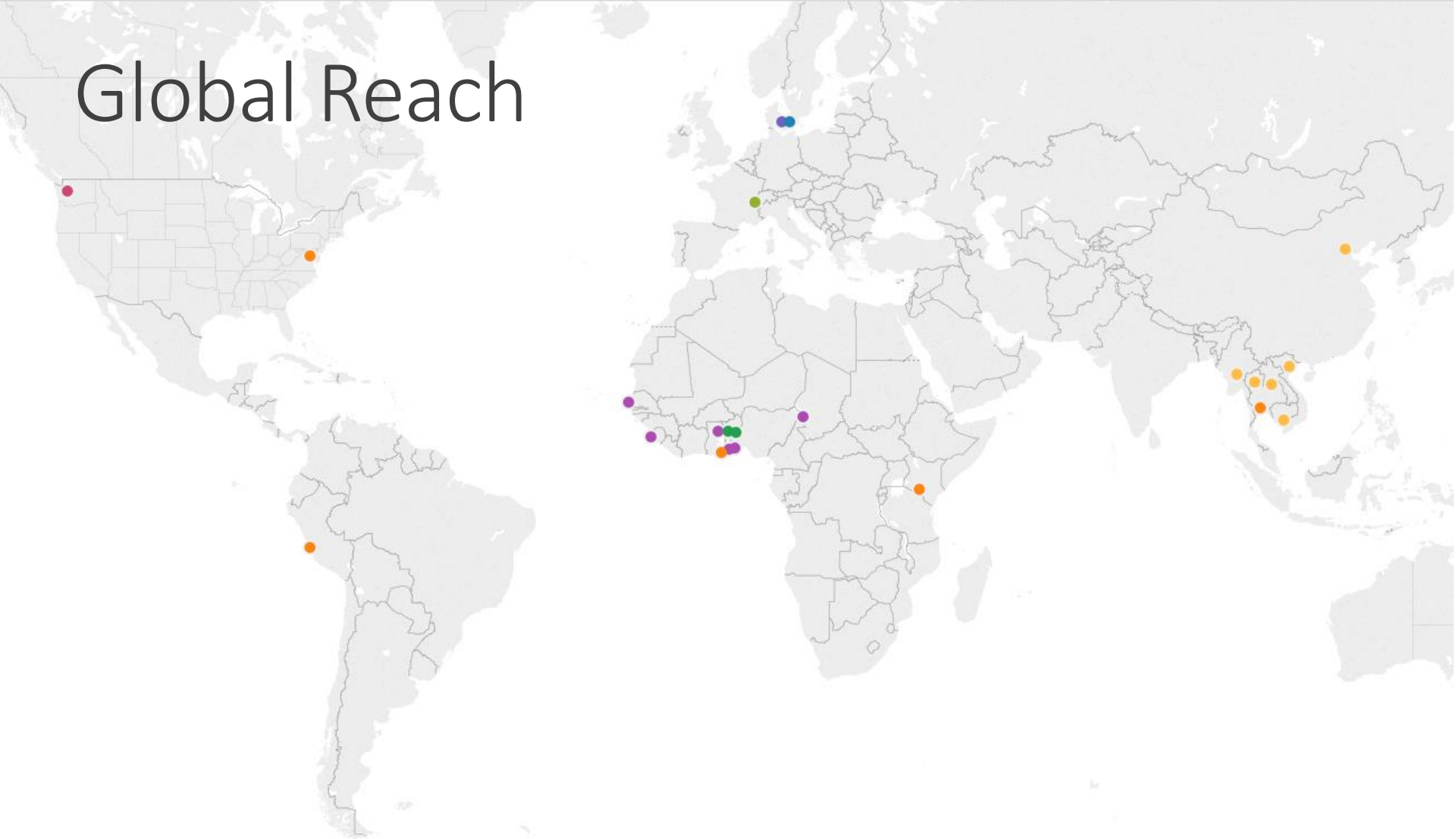
Sustain

Strengthen

Plan

Audit

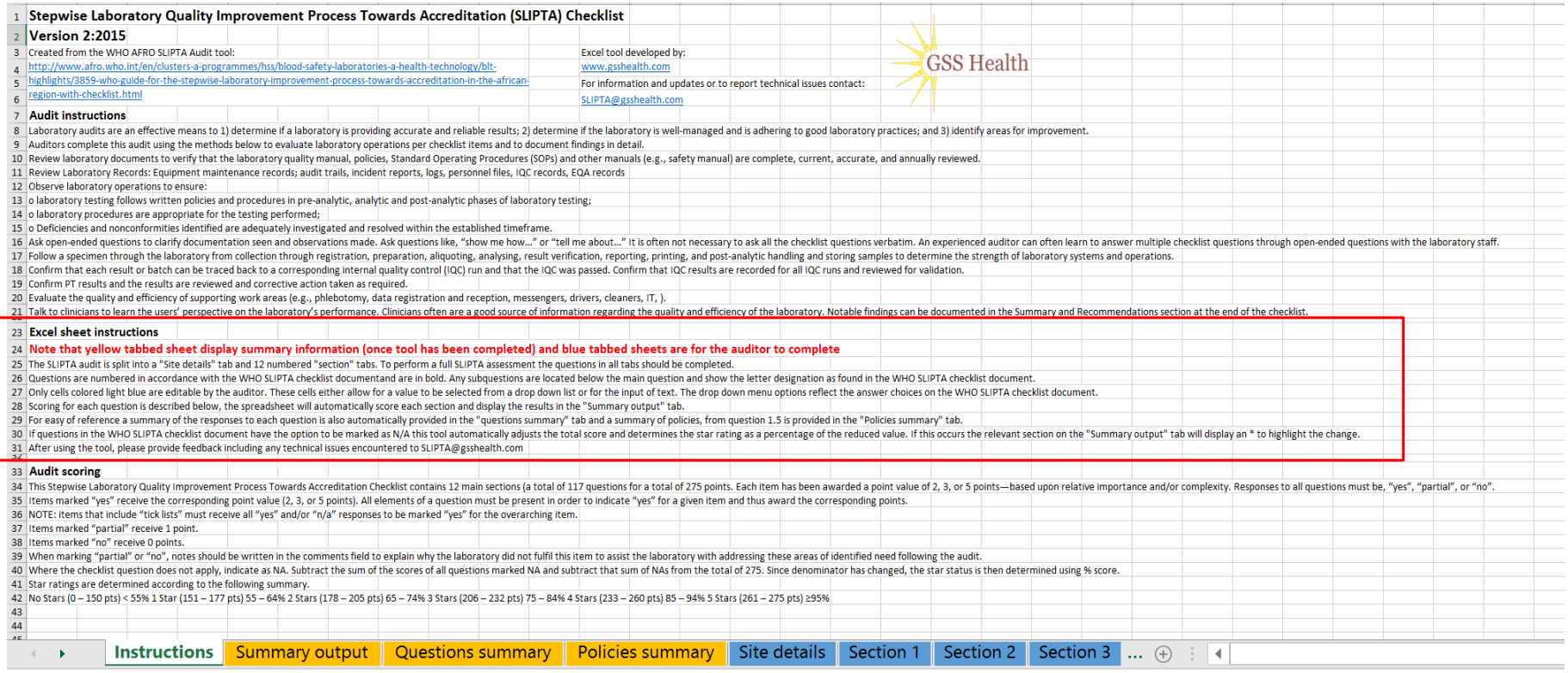
Global Reach



Challenges of audits

- Huge variety of checklist depending upon project goals
- Usually paper based (SLIPTA is 44 pages for just the questions)
- Manual calculation of scores
- Scanned data not always accessible
- Transcription errors
- Language

Accessible Audit Tool



Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Checklist

Version 2:2015

Created from the WHO AFRO SLIPTA Audit tool:
http://www.afro.who.int/en/clusters-a-programmes/hss/blood-safety-laboratories-a-health-technology/blt-highlights/3859-who-guide-for-the-stepwise-laboratory-improvement-process-towards-accreditation-in-the-african-region-with-checklist.html

Excel tool developed by:
www.gsshealth.com

For information and updates or to report technical issues contact:
SLIPTA@gsshealth.com

GSS Health

Audit instructions

Laboratory audits are an effective means to 1) determine if a laboratory is providing accurate and reliable results; 2) determine if the laboratory is well-managed and is adhering to good laboratory practices; and 3) identify areas for improvement.
Auditors complete this audit using the methods below to evaluate laboratory operations per checklist items and to document findings in detail.
Review laboratory documents to verify that the laboratory quality manual, policies, Standard Operating Procedures (SOPs) and other manuals (e.g., safety manual) are complete, current, accurate, and annually reviewed.
Review Laboratory Records: Equipment maintenance records; audit trails, incident reports, logs, personnel files, IQC records, EQA records
Observe laboratory operations to ensure:
o laboratory testing follows written policies and procedures in pre-analytic, analytic and post-analytic phases of laboratory testing;
o laboratory procedures are appropriate for the testing performed;
o Deficiencies and nonconformities identified are adequately investigated and resolved within the established timeframe.
Ask open-ended questions to clarify documentation seen and observations made. Ask questions like, "show me how…" or "tell me about…" It is often not necessary to ask all the checklist questions verbatim. An experienced auditor can often learn to answer multiple checklist questions through open-ended questions with the laboratory staff.
Follow a specimen through the laboratory from collection through registration, preparation, aliquoting, analysing, result verification, reporting, printing, and post-analytic handling and storing samples to determine the strength of laboratory systems and operations.
Confirm that each result or batch can be traced back to a corresponding internal quality control (IQC) run and that the IQC was passed. Confirm that IQC results are recorded for all IQC runs and reviewed for validation.
Confirm PT results and the results are reviewed and corrective action taken as required.
Evaluate the quality and efficiency of supporting work areas (e.g., phlebotomy, data registration and reception, messengers, drivers, cleaners, IT,).
Talk to clinicians to learn the users' perspective on the laboratory's performance. Clinicians often are a good source of information regarding the quality and efficiency of the laboratory. Notable findings can be documented in the Summary and Recommendations section at the end of the checklist.

Excel sheet instructions

Note that yellow tabbed sheet display summary information (once tool has been completed) and blue tabbed sheets are for the auditor to complete

The SLIPTA audit is split into a "Site details" tab and 12 numbered "section" tabs. To perform a full SLIPTA assessment the questions in all tabs should be completed.
Questions are numbered in accordance with the WHO SLIPTA checklist documentand are in bold. Any subquestions are located below the main question and show the letter designation as found in the WHO SLIPTA checklist document.
Only cells colored light blue are editable by the auditor. These cells either allow for a value to be selected from a drop down list or for the input of text. The drop down menu options reflect the answer choices on the WHO SLIPTA checklist document.
Scoring for each question is described below, the spreadsheet will automatically score each section and display the results in the "Summary output" tab.
For easy of reference a summary of the responses to each question is also automatically provided in the "questions summary" tab and a summary of policies, from question 1.5 is provided in the "Policies summary" tab.
If questions in the WHO SLIPTA checklist document have the option to be marked as N/A this tool automatically adjusts the total score and determines the star rating as a percentage of the reduced value. If this occurs the relevant section on the "Summary output" tab will display an * to highlight the change.
After using the tool, please provide feedback including any technical issues encountered to SLIPTA@gsshealth.com

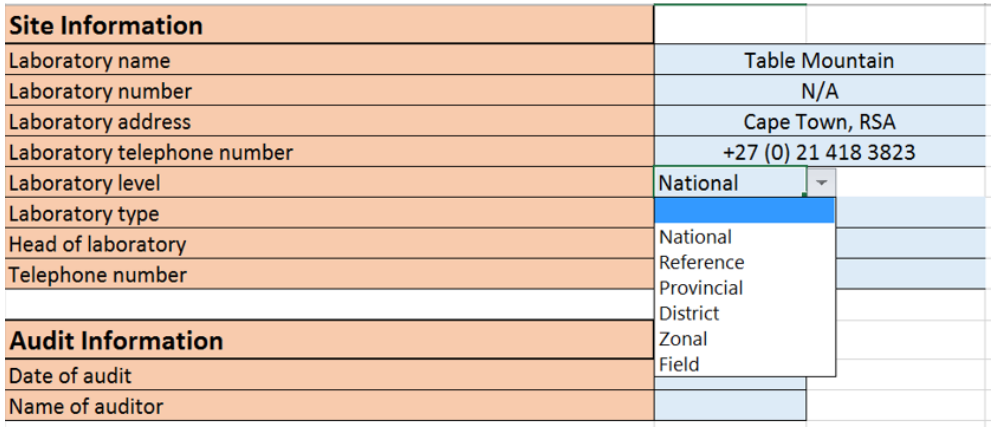
Audit scoring

This Stepwise Laboratory Quality Improvement Process Towards Accreditation Checklist contains 12 main sections (a total of 117 questions for a total of 275 points. Each item has been awarded a point value of 2, 3, or 5 points—based upon relative importance and/or complexity. Responses to all questions must be, "yes", "partial", or "no".
Items marked "yes" receive the corresponding point value (2, 3, or 5 points). All elements of a question must be present in order to indicate "yes" for a given item and thus award the corresponding points.
NOTE: items that include "tick lists" must receive all "yes" and/or "n/a" responses to be marked "yes" for the overarching item.
Items marked "partial" receive 1 point.
Items marked "no" receive 0 points.
When marking "partial" or "no", notes should be written in the comments field to explain why the laboratory did not fulfil this item to assist the laboratory with addressing these areas of identified need following the audit.
Where the checklist question does not apply, indicate as NA. Subtract the sum of the scores of all questions marked NA and subtract that sum of NAs from the total of 275. Since denominator has changed, the star status is then determined using % score.
Star ratings are determined according to the following summary.
No Stars (0 – 150 pts) < 55% 1 Star (151 – 177 pts) 55 – 64% 2 Stars (178 – 205 pts) 65 – 74% 3 Stars (206 – 232 pts) 75 – 84% 4 Stars (233 – 260 pts) 85 – 94% 5 Stars (261 – 275 pts) ≥95%

Instructions | Summary output | Questions summary | Policies summary | Site details | Section 1 | Section 2 | Section 3 | …

Site information

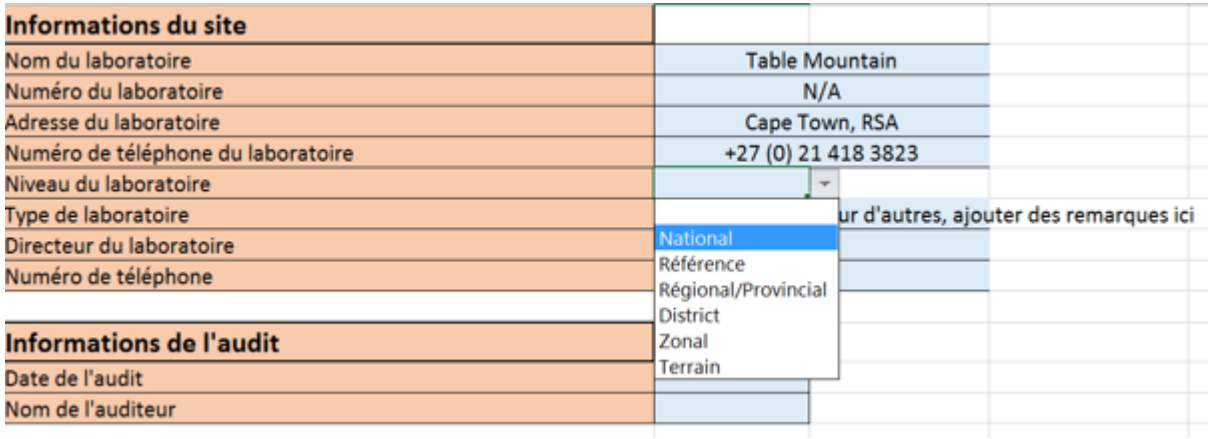
English version



Site Information	
Laboratory name	Table Mountain
Laboratory number	N/A
Laboratory address	Cape Town, RSA
Laboratory telephone number	+27 (0) 21 418 3823
Laboratory level	National
Laboratory type	
Head of laboratory	
Telephone number	
Audit Information	
Date of audit	
Name of auditor	

National
Reference
Provincial
District
Zonal
Field

French version



Informations du site	
Nom du laboratoire	Table Mountain
Numéro du laboratoire	N/A
Adresse du laboratoire	Cape Town, RSA
Numéro de téléphone du laboratoire	+27 (0) 21 418 3823
Niveau du laboratoire	
Type de laboratoire	
Directeur du laboratoire	
Numéro de téléphone	
Informations de l'audit	
Date de l'audit	
Nom de l'auditeur	

ur d'autres, ajouter des remarques ici

National
Référence
Régional/Provincial
District
Zonal
Terrain

Sample questions

Section 7 - Purchasing & Inventory						
Question no.	Question	Avaliable Score	**Answer**	**Score**	Comments	Standard
7.6	**Does management review/approve the finalized supply requests?**	2	**Yes**	**2**	Management must sign off on each request	ISO15189:2012 Clause 5.3.2.3; 5.3.2.7 Note: Due to the fact that labs have different purchasing approval systems, there should be a system in place that the lab reviews final approval of their original request.
7.7	**Laboratory Inventory System**	2	**Partial**	**1**	Paper based system	ISO15189:2012 Clause 5.3.2 Note: The laboratory inventory system should reliably inform staff of the minimum amount of stock to be kept in order to avoid interruption of service due to stock-outs and the maximum amount to be kept by the laboratory to prevent expiry of reagents.
	a) Are inventory records complete and accurate, with minimum and maximum stock levels denoted and monitored?		**Partial**		No min and max levels set	
	b) Is the consumption rate of all reagents and consumables monitored?		**No**		Just in time procurement used	
	c) Are stock counts routinely performed?		**Yes**		Counts performed by lab manager	
7.8	**Are storage areas set up and monitored appropriately?**	2	**0**	**0**		ISO15189:2012 Clause 5.3.2.2 Note: Storage of supplies and consumables must be as per the manufacturer's specifications.
	a) Is the storage area well-organized and free of clutter?					
	b) Are there designated places labeled for all inventory items?					
	c) Is adequate cold storage available?					
	d) Are storage areas monitored as per prescribed storage conditions?					

Yes
No
Partial

Sample questions – N/A

Section 8 - Process Control						
Question no.	Question	Avaliable Score	Answer	Score	Comments	Standard
8.11	**Does the laboratory compare results of the same test performed with different procedures and equipment?**	0	**N/A**	**0**	Laboratory does not have multiple pieces of identical equipment/multiple instruments for each test	ISO15189:2012 Clause 5.6.4 Note: The lab should document and implement a system to ensure there is comparability of results, this could be done by the use of EQA performance; using blinded samples, parallel testing.
If not applicable select N/A for all sub questions	a) Where there is more than one procedure for the same measure, does the laboratory compare results from the different procedures, equipment or methods?		**N/A**			
	b) Does the lab discuss, document and act upon (including notifying users) problems or deficiencies from these comparison studies?		**N/A**			
8.12	**Are environmental conditions checked and reviewed accurately?**	2	**All N/A**	**0**		ISO15189:2012 Clause 5.4.1 Note: The laboratory shall monitor, control and record environmental conditions, as required by relevant specifications or where they may influence the quality of the results and/or the health of staff.
Are the following environmental conditions checked daily?	a) Room temperature		**N/A**			
	b) Freezer		**N/A**			
	c) Refrigerator		**N/A**			
	d) Incubator		**N/A**			
	e) Water bath		**N/A**			

8.12	**Are environmental conditions checked and reviewed accurately?**	2	**Yes**	**2**	Only room temp is monitored as the lab lacks other equipment types
Are the following environmental conditions checked daily?	a) Room temperature		**Yes**		
	b) Freezer		**N/A**		Equipment not present
	c) Refrigerator		**N/A**		Equipment not present
	d) Incubator		**N/A**		Equipment not present
	e) Water bath		**N/A**		Equipment not present

Summary Output

GSS Health

eTool based on WHO Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Checklist Version 2:2015

				Current Audit		Select a previous audit for comparison	Previous Audit	
							N/A	
				Audit date:	25-Dec-16		Audit Date:	None
Category	Published maximum score	Current audit maximum score		Audit score	Current Percentage		Previous audit score	Previous audit percentage
1: Documents and Records	28	28		20	71%		Select	0%
2: Management Reviews	14	14		12	86%		comparison	0%
3: Organization and Personnel	22	22		20	91%		audit	0%
4: Client Management and Customer Service	10	10		1	10%		from	0%
5: Equipment	35	35		28	80%		dropdown	0%
6: Evaluation and Audits	15	15		13	87%		list	0%
7: Purchasing and Inventory	24	24		19	79%		in	0%
8: Process Control and Internal and External Quality Assessment	32	30	*	29	97%		blue	0%
9: Information Management	21	21		10	48%		cell	0%
10: Corrective Action	19	19		10	53%		above	0%
11: Occurrence Management and Process Improvement	12	12		5	42%			0%
12: Facilities and Safety	43	43		25	58%			0%
Total	275	273	*	**192**	**70%**			0%

* shown if any audit category is outside of standard maximum score due to answers being marked N/A

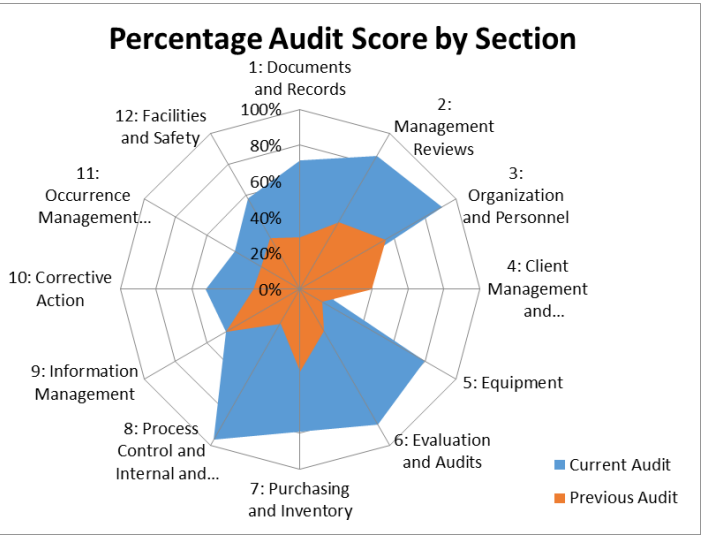
Laboratory name	**Table Mountain**
Laboratory level	**National**
Laboratory type	**Public**
Audit carried out by	**GSSHealth**
Audit date	**25-Dec-16**
Comments word count	**27**

Current Audit		Previous Audit
70%	**Percentage Score**	N/A
2 star	**Star Rating**	**N/A**

Immediate comparisons

			Current Audit		Select a previous audit for comparison	Previous Audit	
						Baseline Audit	
			Audit date:	25-Dec-16		Audit Date:	1-Jan-15
Published maximum score	Current audit maximum score		Audit score	Current Percentage	Change	Previous audit score	Previous audit percentage
28	28		20	71%	42%	8	29%
14	14		12	86%	43%	6	43%
22	22		20	91%	36%	12	55%
10	10		1	10%	-30%	4	40%
35	35		28	80%	66%	5	14%
15	15		13	87%	60%	4	27%
24	24		19	79%	33%	11	46%
32	30	*	29	97%	75%	7	22%
21	21		10	48%	0%	10	48%
19	19		10	53%	27%	5	26%
12	12		5	42%	17%	3	25%
43	43		25	58%	25%	14	33%
275	273	*	**192**	**70%**		89	32%

* shown if any audit category is outside of standard maximum score due to answers being marked N/A



Current Audit		Previous Audit
70%	**Percentage Score**	**32%**
2 star	**Star Rating**	**0 star**

Questions summary

Question number	Question	Answer	Score	Comments
Occurrence Management and Process Improvement				
11.1	Are graphical tools (charts and graphs) used to communicate quality findings and identify trends?	No	0	No communication of quality data to lab team/clients
11.2	Does the laboratory identify and undertake continual quality improvement projects?	Partial	1	Not systematically but small scale projects have recently begun
11.3	Does the laboratory communicate with upper management regularly regarding needs for continual improvement?	Yes	2	Yes, via monthly head of dept meetings
11.4	Are quality indicators (TAT, rejected specimens, stock-outs, etc.) selected, tracked and reviewed?	Partial	1	TAT is tracked but this is the only consistent quality indicator
11.5	Is the outcome of the review of quality indicators used to improve lab performance?	Partial	1	To a limited extent, not well documented
11.6	Are the actions taken checked and monitored to determine the effectiveness of improved quality of lab performance?	No	0	No systematic follow up of actions/deadlines

Can be printed as a 5 page summary including SLIPTA questions with comments, answers and awarded score.

Success: Internal Audits in Togo

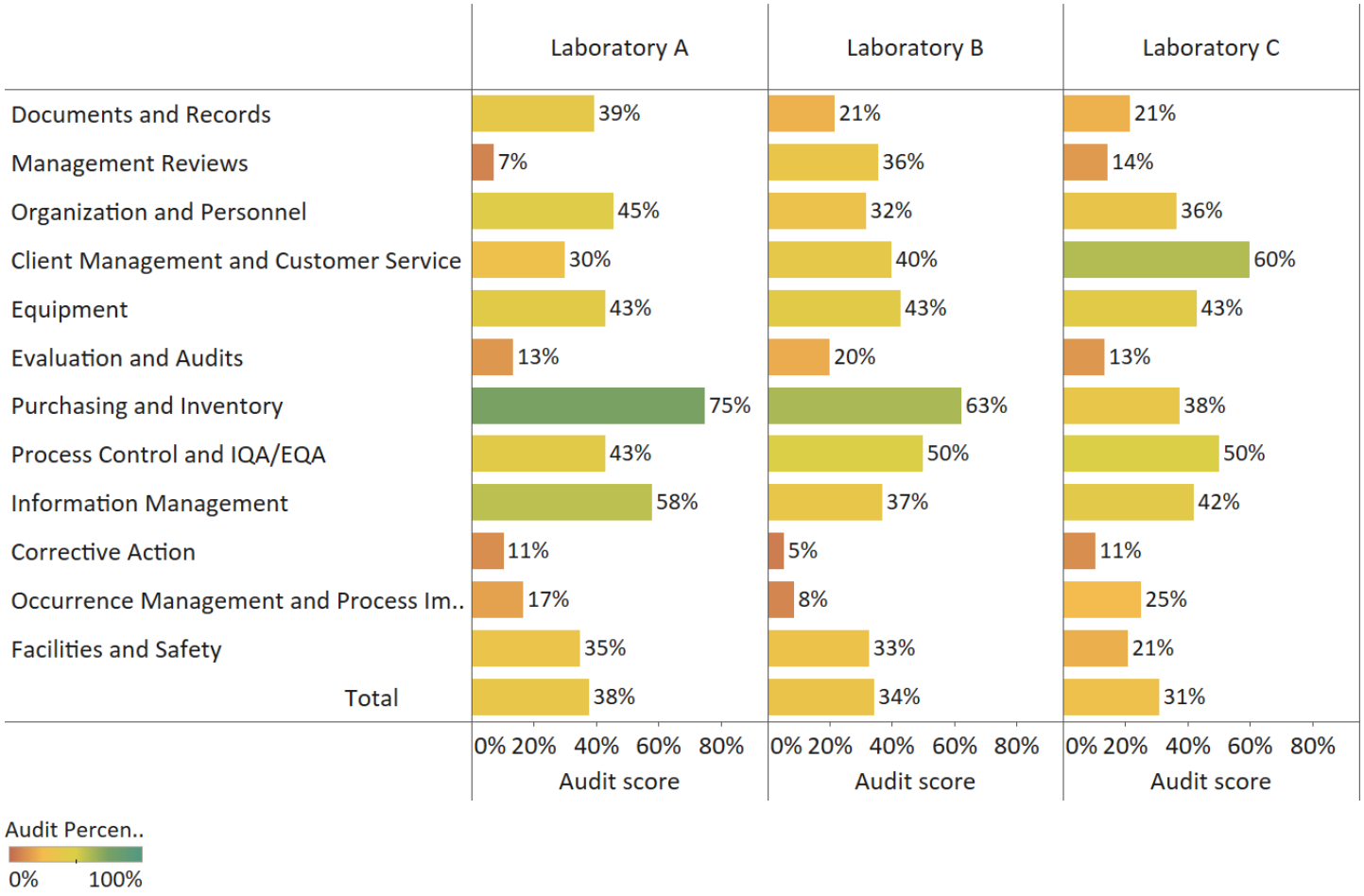
- 31 participants from MOH & MOD trained in the use of the tool
- Pilot audits completed March 2016
- Feedback & updates on the audit tool

Togolese MOH has expanded assessment & completed audits at over 80 laboratories

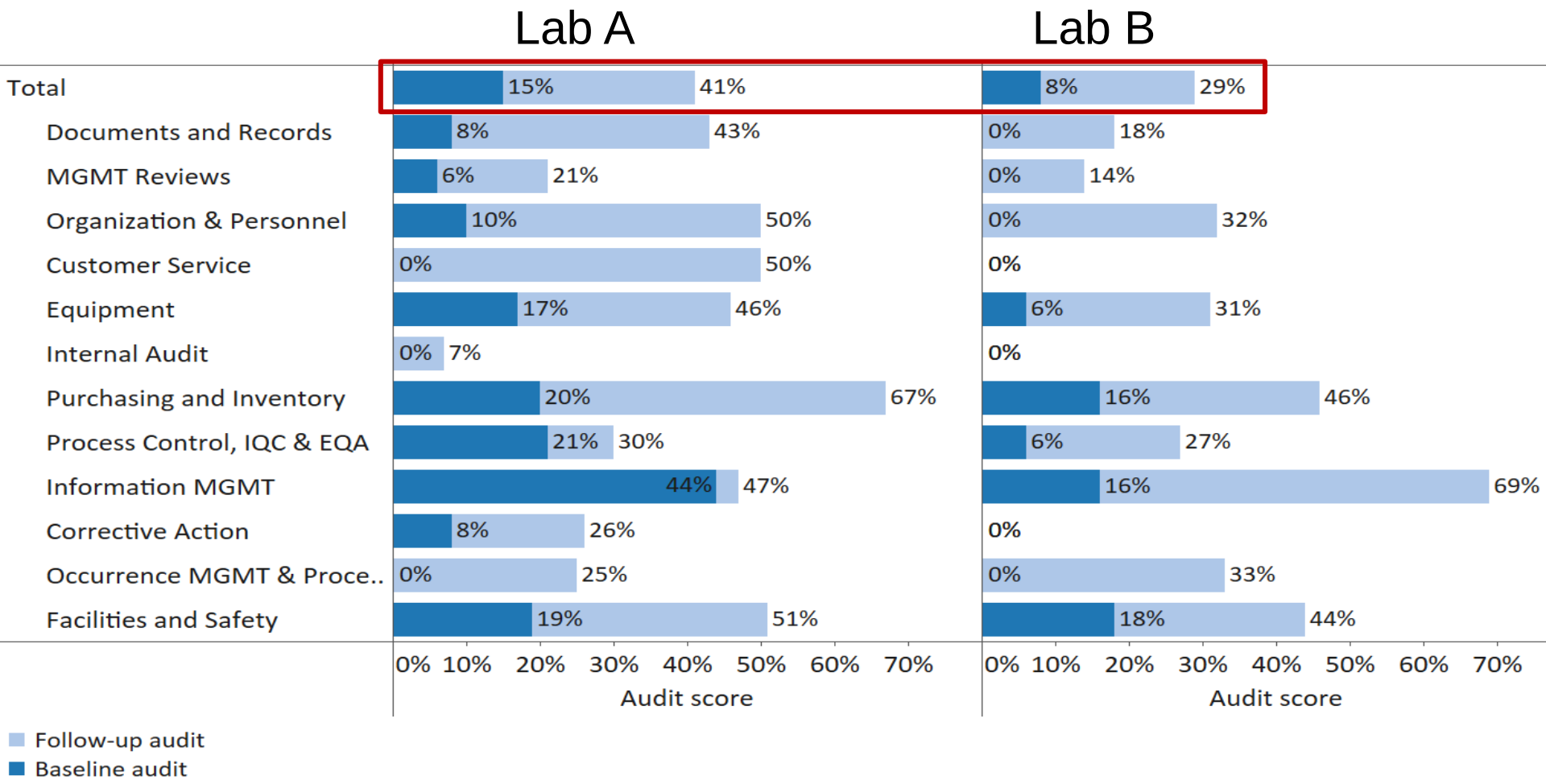
Tool has been shared with over 20 countries and organisations

Audit QC & feedback session, Lomé, Togo

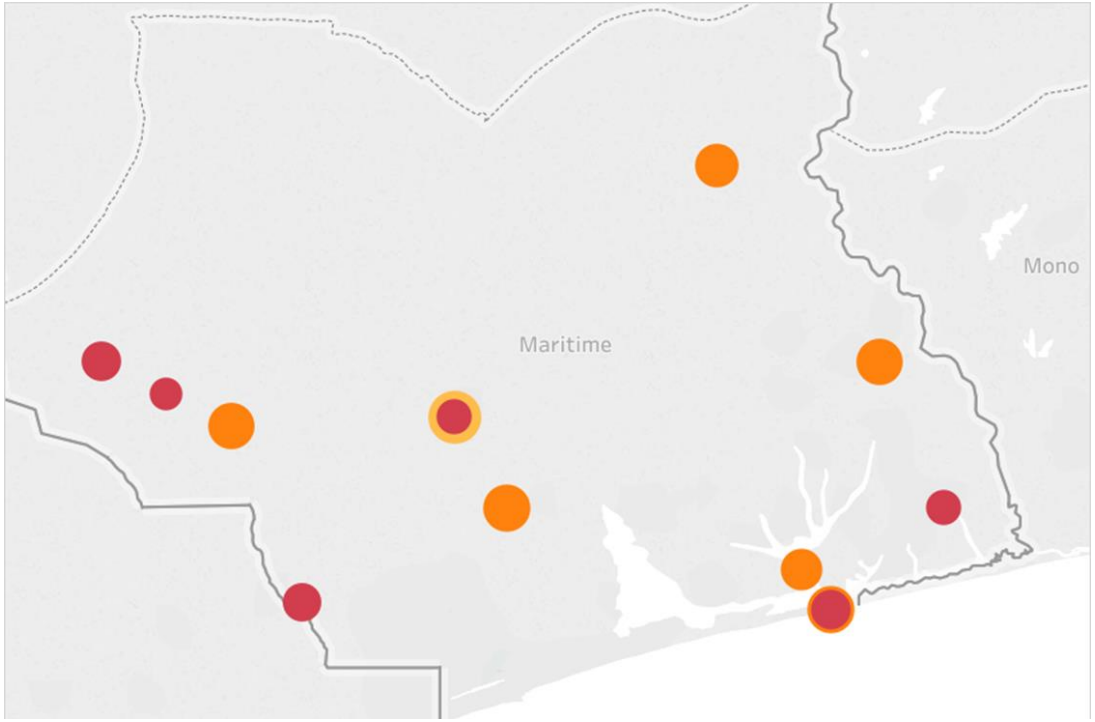
Comparative Analysis



Results


Lab A
Lab B
Total
Documents and Records
MGMT Reviews
Organization & Personnel
Customer Service
Equipment
Internal Audit
Purchasing and Inventory
Process Control, IQC & EQA
Information MGMT
Corrective Action
Occurrence MGMT & Proce..
Facilities and Safety
15% 41%
8% 43%
6% 21%
10% 50%
0% 50%
17% 46%
0% 7%
20% 67%
21% 30%
44% 47%
8% 26%
0% 25%
19% 51%
8% 29%
0% 18%
0% 14%
0% 32%
0%
6% 31%
0%
16% 46%
6% 27%
16% 69%
0%
0% 33%
18% 44%
0% 10% 20% 30% 40% 50% 60% 70%
Audit score
0% 10% 20% 30% 40% 50% 60% 70%
Audit score
Follow-up audit
Baseline audit

Internal SLIPTA Audits

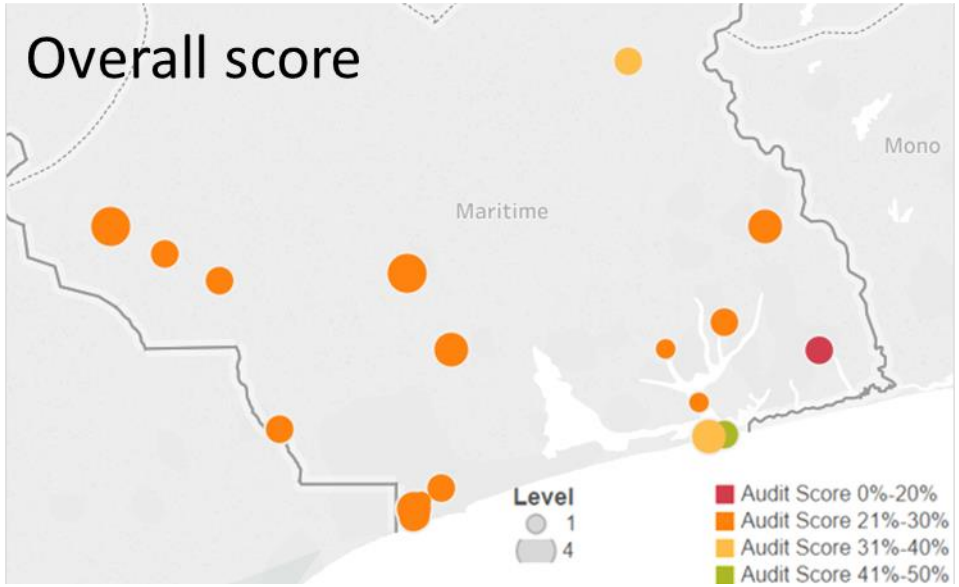


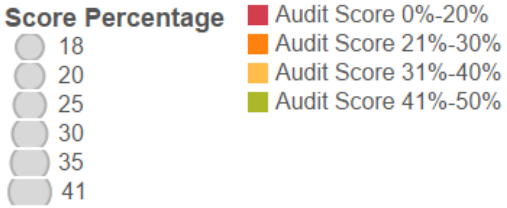
Percent Score

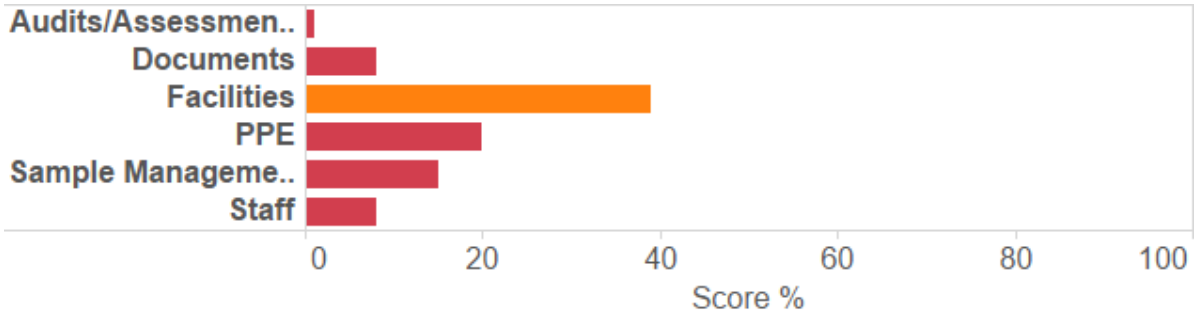
- 12%
- 15%
- 20%
- 25%
- 30%
- 34%

- Audit Score 0%-20%
- Audit Score 21%-30%
- Audit Score 31%-40%

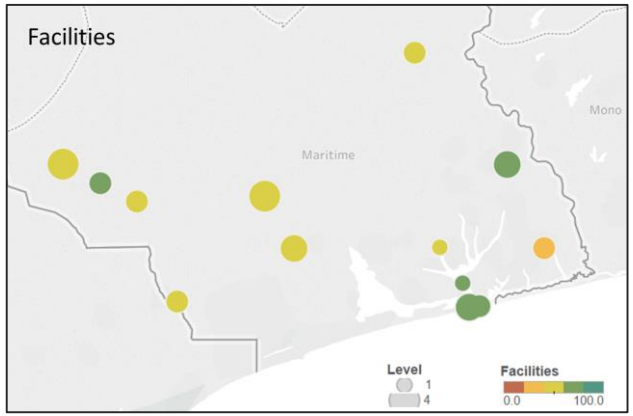
BS&S Audits in Togo

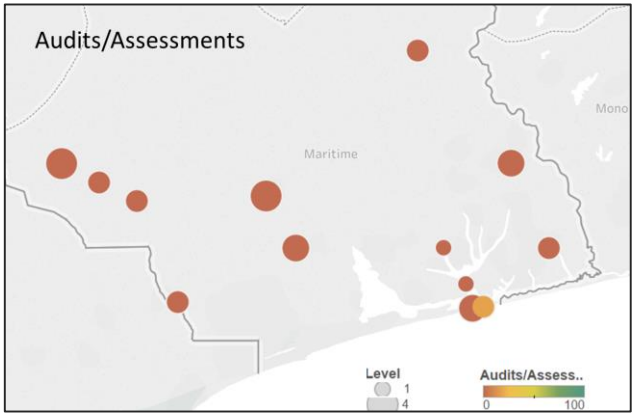


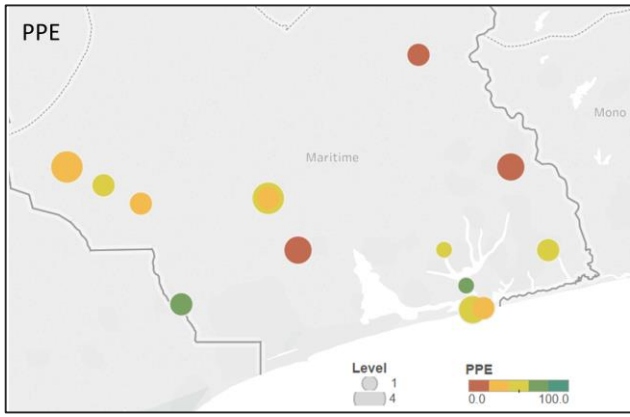




Success: Data Mapping







Where next?

- Wider distribution
- Continued user feedback and evolution of the tool
- Support for additional languages beyond English and French
- Toggleable language function to further simplify sharing data
- Updates as new SLIPTA versions are released
- Increased data analysis
- Additional questions/detail e.g. Biosafety and Biosecurity (BS&S)
  - Tailored to project needs
  - Must be based on solid source material e.g. WHO and CDC Biosafety manuals

Questions?

To obtain the tool find me or my GSSHealth colleagues around the conference or email

SLIPTA@gsshealth.com

Thank you for your attention