NGS Strategy Development Tool

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World Health Organization Europe

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Background & Rational

World Health Organization

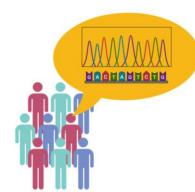
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- Country asking for sequencing TA
- Sequencer already ordered and delivered
- Request of technical assistance
- What is the vision?
- What is the goal?
- What are the capacities in place?
- What are the missing capacities?
- What are the needs?
 - → thorough needs assessment
 - → thorough capacity assessment













Expected outputs



Sequencing Strategy Development Tool

From a Robust Strategy to Integrated & Sustainable Implementation

- In-depth analysis of the goals, existing as well as necessary capacities including infrastructure, supply chains, and other critical components with integration and sustainability in focus.
- The tool will help countries to identify their current needs and available resources
- Facilitate customized assistance throughout the sequencing implementation process.











Overview of the tool





European Laboratory Initiative (ELI) 2024

NGS Strategy Development Tool

From a Robust Needs and Capacity Assessment to Integrated and Sustainable NGS Implementation

Based on TB as an example

Implementation of genome sequencing requires a robust strategy based on thorough and solid needs and capacity assessment data including the infrastructure basis, supply chains and many other critical components. This tool aims to map the needs and available capacities, as well as to point out the competencies that have to be developed in order to implement the suitable NGS technology to meet the countries goals, visions and needs. Altogether the information that can be collected using this comprehensive tool will allow a tailored support for the NGS implementation process.

Quick Links

Assessment Sections:

IX. Sequencer and IT capacities

X. QMS











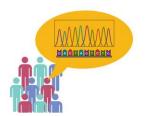
Overview of the tool



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Rasic questions	II. Otababababa		IV. Diagnostic as main purpose	V 10-1-			
Answer	II. Stakeholders	III. Funding availability and potential funding se	Question An		r surveillance purpose		
Question Answer Options Answ	Question	and long term)	National regulations Is sequencing included in your national guidelines as diagnostic method?	Question	100	Answer	Answer Options Answer
Scope of sequencing 1 Villyou use NGS for infectious, non-infectious Infectious	Disease crosscutting	Question	2 If yes, which sequencing method is included in your national guidelines?	a. National regi			Yes/No
diseases or both? 2 Which is fare the pathogen(s) (disease(s) of interest? Tuberculosis C If selec		a. Funding for sequencing platform 1 Is a sequencer already purchased?	3 Is the laboratory where tNGS will be implemented officially authorized to report results back to the Ministry of Health and/or Healthcare facilities?	1 Is seque	our national guidelines as surveillance method? Thod is included in your national guidelines?		tNGS/WGS/tNGS and WGS
OMD-					rill be implemented officially authorized to report	results	Yes/No/ No but will
Others 3 Are you interested in implementing NGS for detection Yes/No	Which entities would collect sample: Which entity would be doing tNGS an 2	Through utilish funding course?			nd/or Public Health entity?		be authorized
of drug-resistance in samples from Tuberculosis 5. What is the purpose of pathogen sequencing?	4 Which entity would be doing the acc 2	Is funding for a sequencer available?	4 Is the diagnostic sequencing lab meant to perform				soon (i.e. <1 year)/
diagnostics Please	5 Which entity would be doing the rend 4	Through which funding source?	b. Sample size and charact				No, but will be
surveil_ import	6 To which entities reports need to be	How much funding is available for a sequencer?	1 Will only prescreened				authorized in the
surveillance Please— surveil	7 Do different entities need different f 1	Funding for consumables (plasticware/reagents) is available?					long-term (within the next 2 years)
research Please		? Through which funding source?			stics		ure next 2 years)
surveil	8 Who is the main funding entity for tN 3	How much funding for consumables is available			sucs specific characteristic be sequenced? E	i.a.	Free text
6 What is the framework of establishing the sequencing capacity?	9 4	For how long do you have funding for			specific drug-resistance by other metho		
Research project YesfNo National long-term strategy YesfNo	10 Is a crosscutting sequencing hub/dep 6	Through which fur			d (e.g. sputum, BAL, saliva, blood, CSi		Free text
7 Is the sequencing lab meant to offer sequencing as a service at national level? Yes/No	11 Is any approval needed for clinical us 7	Howm					
service at national level? 8 Is the sequencing to offer sequencing as Yes/No					ly established in the designated sequ	encing	Yes/No
a service at international level? 8 Is sequencing capacity already available in your YesfNo If Yes, ple	lease use the next question to describe each lo		4 Is the diagnostic sequencing lab mean to posture 1 Vill ollow processed Eq. 9 posture Cq. 9		is used, please specify?		Free text
country? (e.g. SARS-CoV-2 sequencing) (Institute and the S	e), also the man purpose of the anni Sequencer device used:				s used, please specify?		Free text
8.1 If yes, which entity is already doing sequencing? Free test 9 Other purpose of esisting sequencing? Free test e.g. to sty	20de				lance per year?		Number of samples
					number of samples respective to	each of	
							Number of samples
					f samples for each of the		
					for surveillance?	$\overline{}$	Number of samples "The object
VI. Necessities of Infrastructu			INS COVE Spice Ct and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and Logical and		for surveillance?	oing ingland	- Number of samples "The objection laboratory choice
Question					ctenal genome sequen	iong implementa	accontractory choice
Is a laboratory assigned to perform sequence							
2 Is a specific space designated for sequencing						4ti	Account Constrain
What is the current lab bench space you have a							
place a sequencer? The required space depend					1. Organization		
type of sequencer.				res/No	4 A formal quality assequent against that resource consistent presenters. The management to an and quality will are remedite in fundring a suffice or selected on quality material in the laboratory assemble 4 the nations for complex modification.	The library a Statistic from all the	us Yeeg offer in Hilliam have quality the Laboratory quality staff who sid If should be sornified in the assure
type of sequencer. 4 Did you assign dedicated lab space to store con:					supported by againm for anguing quality modification.	laboratory/institutional trust:	slaff was braised with reports to be
for NGS? Including -20 °C and 8 °C storages?				Yes/No	_	——	ubralle hall training was prefere
5 Do you have a dedicated area/lab for PCR proces			perly?	TeS/NO Yes/No		Quality officer	le nour some fields are noured by l prosserural, arabed alse age, equi absold be a prosedure deleration of
PCR and Post-PCR areas)?			quake after set-up and QC run approval?	Yes/No			and how the laborator quantum in also
6 Do you have dedicated equipment for pre-PCR ar					크	Safely office	alberilies.
PCR areas?			2 Has your organization centralized storage capacity?	Yes/No Yes/No	=	Equipmed officer Personnel officer	
7 Is it possible to maintain a lab temperature of 1			3 is it planned to be implemented in the next 12 months?	Yes/No	_]	Procure and officer/Slarage	
30°C (22.5°C ±7.5°C)? During sequencing operation	5	wides acks or microtube racks	4 How many Terabytes of hard drive space for data storage are available?		1	Are there quality denominate at	The name as in the number of all instit
allow the ambient temperature to vary more tha		otubes)	oj Uninterruptible power supply apparatus (UPS) (e.g. BR1500Gi APC Power:	saving		the takeraling freet available?	descurels, but laboratory descure
8 Is there an Ethernet local network connection clu	6	www.electrophoresis apparatus	o High-speed internet connection (at least 10 Mbps upload speed for intern network uploads)	nai 📙	Pressure	Recthere campby reasonal to	
place of installation of the sequencer?	7 10	1 Mini-cooler (4°C) for microtubes	7 Office computer for data upload and analysis in the cloud (internet require	ed)	Skilled and qualified a laft are the greatest asset for takeratory quality underst. Teatring, undirekting, and requirement are armital suspensed on the quality accordance of the quality accordance of the graph of	prefera Irala asserding to the rationaled workland Jenisting	[
Does this connection also provide internet acce:	"	~ ~ ~ ~ ~ 2 Magnetic stand for 96-well plates	8 Computer for local data analysis (e.g. WGS), similar or better to:		1 braining processors required to be descoveded within it	Irela plan argarening[2	The head-up pressure I should note
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abrupt interruption on power supply?	p. mred and trained (h	5 PCR workstation (UV Cabinet)	Linux Ubuntu >18			Are pressured fractional from these Agree ago [decourseled	1
Langer areas appropriate for power suppriy:	1 Technician molecular biology/NG	S 6 Microcentrifuge for PCR workstation (e.g. Eppendor			1		
i	2 Bioinformatician	MiniSpin) 7 Centrifuge for conical tubes including aerosol-	memory; CUDA Compute Capability >6.1) 32GB 2X16GB DDR4			la prafisirang traling praerdare in plane [danament]?	
i	3 Molecular lab Research associate	e containment cups (BSL3/2+)	SSD BODT + OPTIONAL SSD1TB		1	la competence accessed	
•		8 Spectrophotometer (e.g. NanoDrop 2000/Denovix D		 		presedere in place (decembel)?	
		 Fluorometer (e.g. Qubit 3/4/Flex, Denovix DS-11FX) Automated DNA fragment analysis device (e.g. 	ZTB 5400RPM SATA 2.5" HDD RAID 1 FOR SATA HDD		Equipment All takes dang equipment must be maintained for easier aprealing. Additionally, take about		A manifer find that montains all equip
		in Indication of the Hagilieric already to device (e.g.	The state of the s		manilar equipment installation, supplier massers, salibration processors, and replaneared 4 subrelates to researe the highest quality alandards.	la librer an equipment manter tint	laboratory with dates of rearest and prediction etc.

Envisioned Workflow For Tool Utilization

Request for Implementation and Support of NGS















Next steps

World Health Organization

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- Incorporation of all feedbacks received
 - -
- Finalization of the first pilot project
- Draft the user manual and manuscript
- ❖ Publish the tool











References



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- Global Fund Project Kazakhstan
- NRL head and staff KAZ
- Inna Friesen, Borstel Research Center

WHO EURO JID

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Thank you for your attention

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