

NGS Strategy Development Tool

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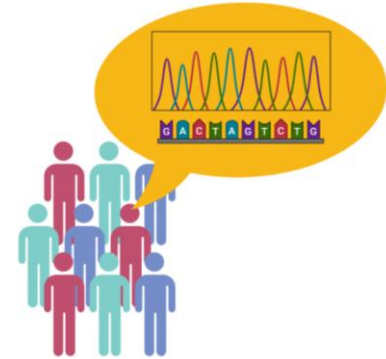
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Background & Rational

- ❖ 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



World Health Organization
REGIONAL OFFICE FOR Europe

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:
	I. Basic questions [put description here]
	II. Stakeholders [put description here]
	III. Funding [put description here]
	IV. Diagnostics purpose [put description here]
	V. Surveillance purpose [put description here]
	VI. Necessities of Infrastructure [put description here]
	VII. HR capacity [put description here]
	VIII. Technical capacities [put description here]
	IX. Sequencer and IT capacities [put description here]
	X. QMS [put description here]



Overview of the tool

I. Basic questions				II. Stakeholders				III. Funding availability and potential funding sources (and long term)				IV. Diagnostic as main purpose				V. Molecular surveillance purpose			
Question	Answer	Answer Options	Answer	Question	Answer	Answer Options	Answer	Question	Answer	Answer Options	Answer	Question	Answer	Answer Options	Answer	Question	Answer	Answer Options	Answer
Scope of sequencing				Disease crosscutting				a. Funding for sequencing platform				a. National regulations				a. National regulations			
1 Will you use NGS for infectious, non-infectious diseases or both?	Yes/No	Infectious diseases (e.g. TB, HIV, Hepatitis, Tuberculosis, COVID-19, Malaria, etc.) Non-infectious diseases (e.g. Cancer, etc.) Other: _____	1	1 Is a technical working group for sequencing established?	Yes/No	1	1	1 Is a sequencing platform already purchased?	Yes/No	1	1	1 Is sequencing included in your national guidelines as diagnostic method?	Yes/No	1	1	1 Is sequencing included in your national guidelines as surveillance method?	Yes/No	1	1
2 Which are the pathogen(s)/disease(s) of interest?	Free text		2	2 Which entities would collect sample?	Free text	2	2	2 Through which funding source?	Free text	2	2	2 If yes, which sequencing method is included in your national guidelines?	Free text	2	2	2 Will the method be implemented officially authorized to report results to the Ministry of Health and/or Public Health entity?	Yes/No	2	2
3 Are you interested in implementing NGS for detection of drug-resistance in samples from Tuberculosis diagnosis?	Yes/No		3	3 Which entity would be doing NGS analysis?	Free text	3	3	3 How much funding is available for a sequencer?	Free text	3	3	3 Is the laboratory where NGS will be implemented officially authorized to report results back to the Ministry of Health and/or Healthcare facilities?	Yes/No	3	3	3	3	3	3
4 What is the purpose of pathogen sequencing?	Free text		4	4 Which entity would be doing the analysis?	Free text	4	4	4 Through which funding source?	Free text	4	4	4	4	4	4	4	4	4	4
5	Free text		5	5 Which entity would be doing the reporting?	Free text	5	5	5 How much funding is available for a sequencer?	Free text	5	5	5	5	5	5	5	5	5	5
6	Free text		6	6 To which entities reports need to be sent?	Free text	6	6	6 Through which funding source?	Free text	6	6	6	6	6	6	6	6	6	6
7	Free text		7	7 Do different entities need different funding?	Yes/No	7	7	7	7	7	7	7	7	7	7	7	7	7	7
8	Free text		8	8 Who is the main funding entity for NGS?	Free text	8	8	8	8	8	8	8	8	8	8	8	8	8	8
9	Free text		9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
10	Free text		10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
11	Free text		11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11

Over 200 questions covering sub questions covering 10 key subject areas

VI. Necessities of Infrastructure				VII. Laboratory equipment and consumables				VIII. Personnel				IX. Quality assurance			
Question	Answer	Answer Options	Answer	Question	Answer	Answer Options	Answer	Question	Answer	Answer Options	Answer	Question	Answer	Answer Options	Answer
1 Is a laboratory assigned to perform sequencing?	Yes/No		1	1 Mini-cooler (4°C) for microtubes	Yes/No	1	1	1 Do you have enough personnel to perform the sequencing?	Yes/No	1	1	1 Do you have a quality control system for sequencing?	Yes/No	1	1
2 Is a specific space designated for sequencing?	Yes/No		2	2 Magnetic stand for 96-well plates	Yes/No	2	2	2 Do you have a quality control system for sequencing?	Yes/No	2	2	2 Do you have a quality control system for sequencing?	Yes/No	2	2
3 What is the current lab bench space you have a place a sequencer? The required space depends on type of sequencer.	Free text		3	3 Magnetic stand for microtubes	Yes/No	3	3	3 Do you have a quality control system for sequencing?	Yes/No	3	3	3 Do you have a quality control system for sequencing?	Yes/No	3	3
4 Did you assign dedicated lab space to store consumables for NGS? Including -20 °C and 8 °C storage?	Yes/No		4	4 96-well thermal cycler	Yes/No	4	4	4 Do you have a quality control system for sequencing?	Yes/No	4	4	4 Do you have a quality control system for sequencing?	Yes/No	4	4
5 Do you have a dedicated area/lab for PCR processes (PCR and Post-PCR areas)?	Yes/No		5	5 PCR workstation (UV Cabinet)	Yes/No	5	5	5 Do you have a quality control system for sequencing?	Yes/No	5	5	5 Do you have a quality control system for sequencing?	Yes/No	5	5
6 Do you have dedicated equipment for pre-PCR and PCR areas?	Yes/No		6	6 Microcentrifuge for PCR workstation (e.g. Eppendorf MiniSpin)	Yes/No	6	6	6 Do you have a quality control system for sequencing?	Yes/No	6	6	6 Do you have a quality control system for sequencing?	Yes/No	6	6
7 Is it possible to maintain a lab temperature of 10-30°C (22.5°C ± 7.5°C)? During sequencing operation allow the ambient temperature to vary more than 5°C (9°F) (e.g. for microtubes)?	Yes/No		7	7 Centrifuge for conical tubes including aerosol-containment cups (BSL3/2+)	Yes/No	7	7	7 Do you have a quality control system for sequencing?	Yes/No	7	7	7 Do you have a quality control system for sequencing?	Yes/No	7	7
8 Is there an Ethernet local network connection at place of installation of the sequencer?	Yes/No		8	8 Spectrophotometer (e.g. NanoDrop 2000/GenoFlex DS-11)	Yes/No	8	8	8 Do you have a quality control system for sequencing?	Yes/No	8	8	8 Do you have a quality control system for sequencing?	Yes/No	8	8
9 Does this connection also provide internet access?	Yes/No		9	9 Fluorometer (e.g. Qubit 3.0/4.0, Denovix DS-11FX)	Yes/No	9	9	9 Do you have a quality control system for sequencing?	Yes/No	9	9	9 Do you have a quality control system for sequencing?	Yes/No	9	9
10 Does your lab have an electricity generator in case of abrupt interruption on power supply?	Yes/No		10	10 Automated DNA fragment analysis device (e.g. Illumina MiSeq)	Yes/No	10	10	10 Do you have a quality control system for sequencing?	Yes/No	10	10	10 Do you have a quality control system for sequencing?	Yes/No	10	10

Envisioned Workflow For Tool Utilization



① Request for Implementation and Support of NGS



Next steps



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

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- NRL head and staff KAZ
- Inna Friesen, Borstel Research Center

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Thank you for your attention

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