Delivering Integrated Diagnostics

Partnership Approach

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Agenda

1. Guidelines and recommendations: what does integration mean?
2. Benefits: why integrate?
3. Barriers: what are these and how can they be addressed?
4. Country Examples and Testimonials
5. Annex: how we partner to support integration
    a. Roche Healthcare Consulting
    b. Technical Capabilities
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Guidelines and recommendations

What does integration mean?

Achieving elimination through integration

Programmes, donors and implementing partners are **prioritizing diagnostics integration** to strengthen, and optimise health systems.

Opportunities to integrate occur throughout the diagnostics continuum (for HIV, MTB, HPV and other diseases): at the **program and network level, and within the laboratory**.

As a partner for integration, Roche can support with the **capabilities, technologies and tools** to enable integrations across the diagnostics pathway.

WHO recommends integration across ALL areas of diagnostics

"Several technologies already exist that can test for many different diseases and analytes and/or be used for various monitoring approaches; therefore, **WHO strongly supports and encourages diagnostic integration** across diseases and programmes."

Molecular Diagnostics Integration Global Meeting Report 2019 [WHO/ ASLM][1]

Molecular Diagnostics integration

- HIV
- TB
- HPV
- HCV / HBV

Program Integration

- Financing
- Supply Chain & Procurement
- Training & HR
- Sample Collection & Transport
- Data Management
- Quality Assurance

Sources:
1 - Molecular diagnostics integration global meeting report, 10-12 July 2019, Geneva Switzerland

Benefits

Why integrate?

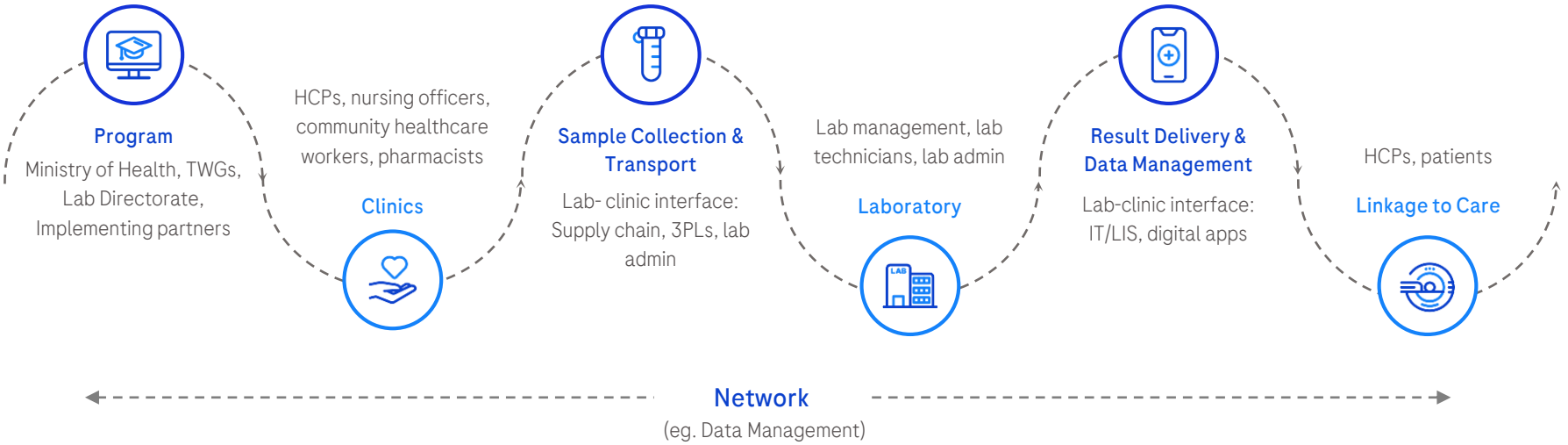
Donors, Policy Makers & Implementing Partners see the benefit of integration*

- Provides diagnosis in a **one-stop shop**
- Enables programs to respond to the **global co-infection crises, prepare for pandemics** and respond to outbreaks
- Improves **test efficiency turnaround time**
- Lowers costs on instruments by improving utilisation of **existing platforms**
- Lowers **testing costs** through leveraging existing infrastructure

Sources:
1 - https://www.theglobalfund.org/media/11612/strategy_globalfund2023-2028_narrative_en.pdf
2- https://aslm.org/wp-content/uploads/2021/03/1616528283-Integration-overview_May-2019-1.pdf?x89467
3 - https://www.state.gov/wp-content/uploads/2023/02/PEPFAR-2023-Country-and-Regional-Operational-Plan.pdf

*implementation partner sinclude CHAI, DREAM, IPAC and JHPIEGO

Collaborating with partners at every level to achieve integration



Roche acknowledges the the need to coordinate and collaborate with stakeholders and experts to enable integration across the continuum at the **program, network** and **laboratory level**.

Roche's experience in integration across the spectrum

Program

Impact:

Collaboration at the program level **accelerated response** to utilising cobas systems in response to COVID pandemic.

COVID/ HIV: 7 countries

Côte d'Ivoire, Eswatini, Kenya, Nigeria, Rwanda, Uganda & Zambia

- Worked with Lab Directorate to identify systems with capacity
- Leveraged existing HIV sample transportation network
- Roche Consultants/ Application teams supported discussions to optimise workflow to ensure TAT met for both tests

Network

Impact:

Engagement - across all countries - ensures **networks will be optimised** enabling access to TB diagnostics at medium and high-throughput settings

HIV / MTB: 5 countries (IN PROGRESS)

Nigeria, Kenya, Zambia, Côte d'Ivoire, Mozambique

- Engaging with TWGs to explore options for integration of TB and HIV referral networks and laboratories
- Supporting the introduction of high volume MTB / RIF/ INH testing into existing TB programs

Laboratory

Impact:

Workflow for **cobas** systems that retain spare capacity - placed primarily for HIV testing - **leveraged to test patients for HCV and HPV**

Hepatitis/ HIV: 4 countries

Côte d'Ivoire, Niger, Nigeria & Senegal

- Collaborated with the MoH to verify and validate new assays

HPV/HIV: 6 countries (IN PROGRESS)

Nigeria, Zambia, Burkina Faso, Uganda, Rwanda & Mozambique

- Leveraging the existing HIV instruments and sample transportation networks

Collaborating to address barriers to integration

Barriers	Roche capabilities (to address barriers)
 **Allocation of Budget and Resource** Programs operate in Silos with separate budgets and resources	**Program/ Network Level** • Workshop facilitation & roadmap development • Demonstration project to build data/evidence
 **Sample Referral, Collection & Transport** Fragmented, inefficient system	**Network Level** • Support program and laboratories to pilot integrated sample transport systems through consulting; activities can include Visioning Workshops to identify the ‘’future state’’; mapping out labs; and iii) sample referral and sample transport networks
 **Sample Preparation and Integrated testing on Instruments** Change of laboratory processes	**Network/ Laboratory Level** • Support partners to conduct trainings on laboratory systems strengthening (e.g. LARC and CLICQ!) • Assist with development of forecast (to inform workflow) • Co-create lab design, optimise workflow and identify task shifting opportunities
 **Results Delivery & Data Management** New system introduced with existing Data Management System	**Network/ Laboratory Level** • Design solutions integrated into LIS, workflow assessment to optimize instrument performance, inventory management, and results delivery improvements

Country Examples and Testimonials

Integrated Testing in Nigeria

HIV and SARS-COV 2

Benefits

- **Instrument able to manage *24hr utilisation uninterrupted***
- **Automated system *increased efficiency* and accelerated decision to run assays on separate runs**
- ***Reduction in errors* and efficient workflow: single process ensures operator masters process**

Key Considerations

- **Sample Transportation & Testing Allocation** - coordinated at network level
- **Scenario Planning** - developed with lab managers
- **Resources** - organised into shifts based on experience and skilled
- **Sample Preparation** - Additional biosafety cabinets installed
- **Storage** - provision made or additional consumables and spare parts

Nigeria Institute of Medical Research, Lagos

Assay	Daily Throughput	Annual Throughput
HIV	2200	**151,366**
COVID	960	**36,500**

"NIMR as a frontline responder to the (COVID) pandemic screened people for free. We also subsidized the cost of HBV viral load and tested over 100,000 individuals using the platform we already had" - ***Disu (Laboratory Scientific Officer)***

Integrated Testing in Nigeria

HIV and HPV: All Turnaround Times met (or exceeded) for HIV & HPV after integration

Benefits

- **System runs 16 hrs per day (lab has a backup system but was not required)**
- **HIV and HPV placed on the same runs to maximise throughput**
- **One person required to manage system with walk away time of 4 hours (comfortable managing both systems)**

Key Considerations

- **Sample Preparation** - Resource allocated to sample prep and barcoding implemented
- **Training** - Lab readiness and training across all functions
- **Hypercare** - Focused on-site support
- **Loading** - cobas x800 Systems Instrument Buffer retains 235 samples, with up to 3 assays being allocated per run (based on instrument specification and sample profile)

Lagos State University Teaching Hospital

Assay	Daily Throughput	Annual Throughput
HIV	500	**228,000**
HPV	24-96*	**3,400**

* Depends on sample flow

"Being able to perform different assays on the same platform raises our profile as a laboratory and increases our revenue"
- Nnamani (Lab Supervisor)

Integrated Testing in Germany

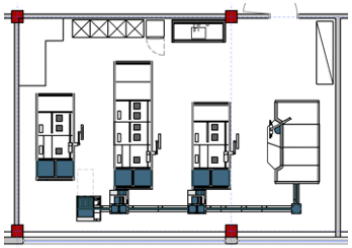
Full automation for HIV, HPV, HCV and many more

Benefits

- **Reduced manual hands-on time and human error**
- **Increases overnight capacity and improved TAT**
- **Prepared for the next pandemic**
- **Built in capacity to expand testing to CT/NG, Influenza, CMV, BKV and EBV**

Key Considerations

- Coverage of Covid testing for >6.000 samples / day
- Use full automation for other parameters as well



Western Germany

Assay	Daily Throughput	Annual Throughput
HPV	280	**70,000**
HBV	130	**32,500**
Noro	125	**31,250**
HLA-B27	100	**25,000**
HCV	90	**22,500**
HIV	25	**6,250**

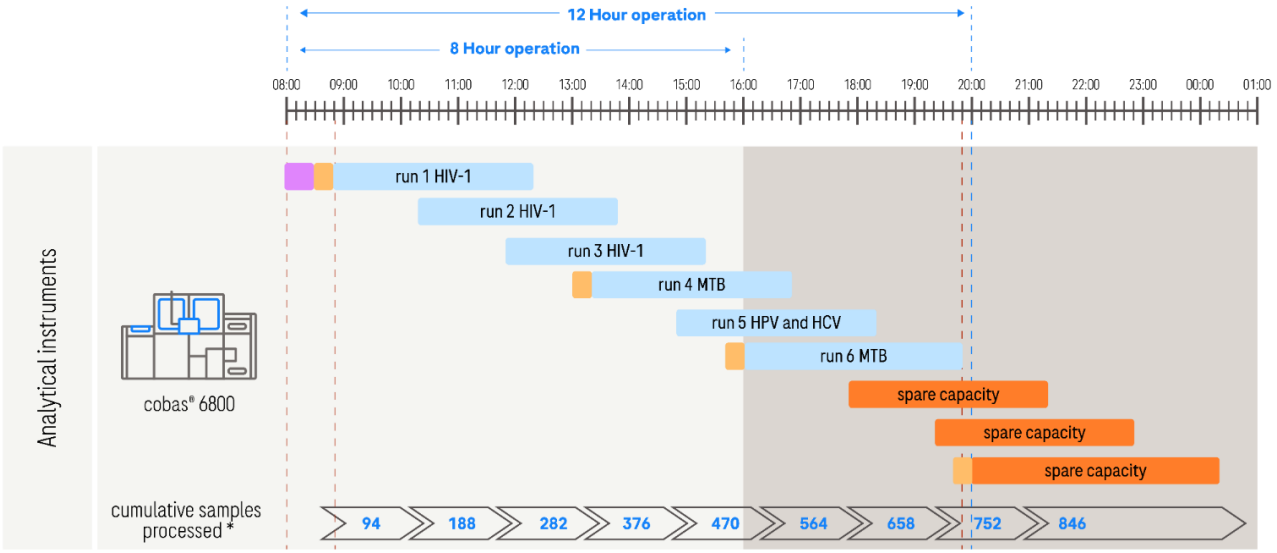
Workflow for integrating multiple assays on a cobas 6800 System

Potential scenario includes HIV, MTB, HPV and HCV and achieving 24 hours TAT

	Workload calculations - cobas® 6800											
	Samples per year	Samples per week	Samples per day	Days per week operation	Controls per run	Equivalent runs per day	Assumed TAT	Suggested run frequency	Total instrument running time	Final operator interventio n	Additional sample capacity in an 8hr operation	Additional sample capacity in an 12hr operation	Necessary runs per day
HIV - 1	50,000	962	192	5	3	2,10	24 hrs	3 runs per day	11 HOURS	16:00	179	461	6
MTB	40,000	769	154	5	2	1,64	24 hrs	2 runs per day					
HPV	5,000	96	19	5	2	0,22	24 hrs	1 run per day					
HCV	5,000	96	19	5	3	0,23	24 hrs	1 run per day					

Workflow for integrating multiple assays on a cobas 6800 System

Overview of workflow



Weekly Maintenance (no daily maintenance)

Load Reagents and Consumables, Empty Waste

*Assuming a full plate of a single quantitative test, requiring two controls per batch

This scenario considers a **cobas 6800** system running approx. a total of 100K tests per annum, with daily 12 hour shift.

System is able to consolidate HIV, MTB, HPV and HCV and meet TATs - with an additional spare capacity.

Summary of the Roche Integrated Testing Support

Co-creation
Supporting integration across all levels of the health system - program, network, and laboratory

Optimisation
Capabilities to design and implement integration that achieve the benefits of efficiency and cost savings

Holistic
Considering the many barriers to integration across the diagnostics continuum

Solutions
Leveraging instruments and technology designed for efficient testing to support integration at the lab level

Experience
Drawing from projects completed to successfully integrate testing across multiple settings

Partnering
Driving collaboration to help programs realize the benefits of integrated testing

Annex

Roche Healthcare Consulting Capabilities

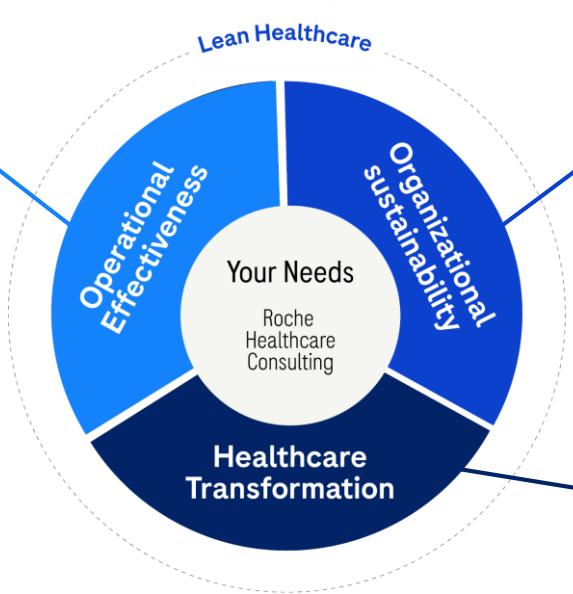
Roche Healthcare Consultants: experienced group worldwide

300 consultants:

- Certified Lean Consultants
- Certified Lean Six Sigma Consultants
- Change management experts
- **Cross-functional expertise:** lab management, pathology, engineering, administration, pharmacy, biomedicine, medicine
- Data analysis and interpretation experts

Consulting offerings to drive effectiveness, sustainability & transformation through lean healthcare

Customised for each project's needs



1. Technical consultancy (lab design, simulations)
2. SystemScan (Capacity analysis)
3. Sub-process Scan
4. LabScan
5. Rapid Improvement Event (RIE)
6. Training Continuous Improvement (Lean)

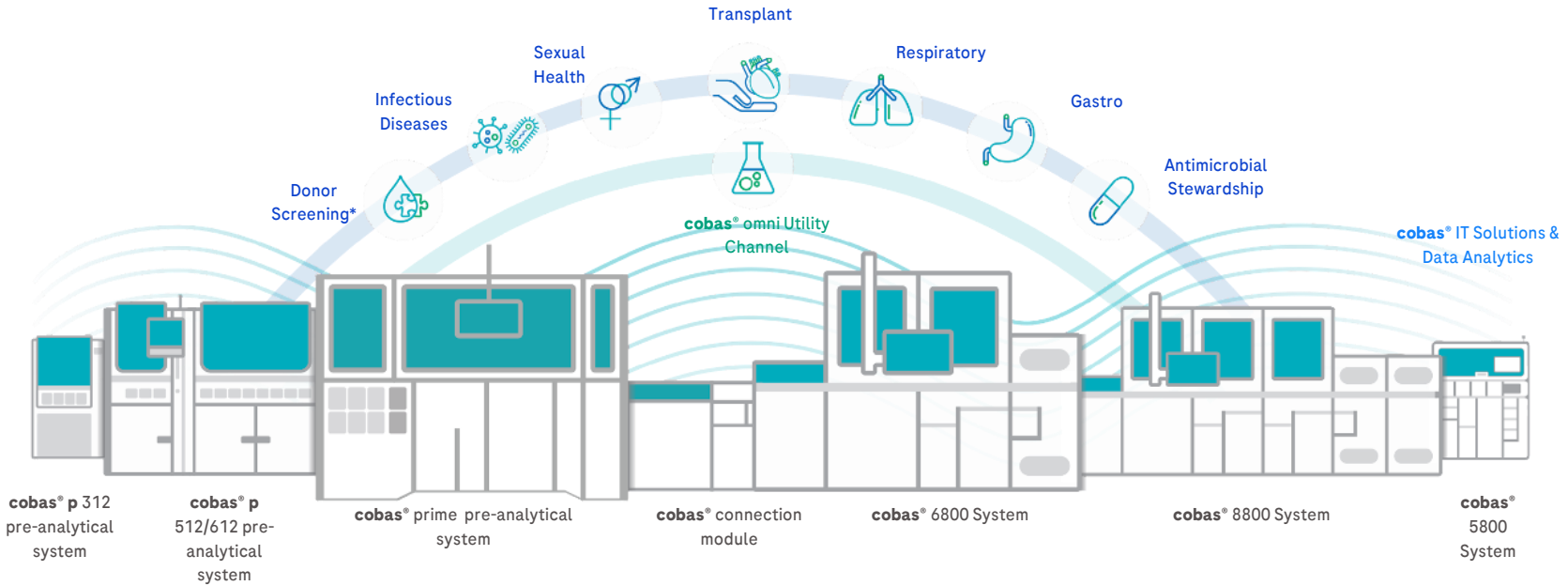
1. Vision & Strategy deployment
2. Value Stream Analysis to enhance Lab collaboration/ integration

1. Training Change Mgmt

Annex

Technical capabilities of the Roche Molecular Work Area

An agile solution that can grow as your lab grows



| *When consolidated with infectious disease testing on the same cobas® 6800/8800 System

cobas® 5800/ 6800/ 8800 Systems offer fully automated analytical processes for simplified and efficient testing

Features enabling integration

- **Broad assay menu**, with ample **onboard capacity** of up to 15 reagent cassettes enabling consolidation
- Perform up to **6 different assays per run**, on different sample types in the same run
- Software ensures the most **efficient testing scheduling** - samples and assays can be prioritized as required
- The onboard reagent capacity - **15 assays** – stored in a temperature-controlled compartment, with an **onboard stability of up to 36 days**
- **cobas®** omni Utility Channel, allows running laboratory developed tests on the same system, simultaneously with IVD assays

Features enabling further optimisation

- **Universal sample preparation** methodology
- Fully **automated work-away** system and **sample pipetting**
- Amplification and detection using real-time PCR
- **System surveillance** of liquid handling, temperatures, disposables, reagent status, waste, and maintenance schedule
- **Intuitive** user interface
- Ensures **efficient wastage** reducing impact on environment and exposure to hazardous waste

Doing now what patients need next

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