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FROM DIAGNOSIS TO TREATMENT

The Role of Xpert Ultra & XDR Across the TB Care Continuum

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The Question Every Clinician Asks

You have the result. Can you trust it enough to act?

Diagnosis is not the endpoint. Treatment selection is.

Not what the test detects what it means for the patient in front of you. That's what this session answers.

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Two Lenses. One Confident Decision.

You've heard what the result is. Here's what it means.

ANALYTICAL INTERPRETATION

Already covered — MedSci

- Reflex mechanics why, when, sample requirements
- What each result category is (detected, trace, resistant, invalid)
- Limit of detection and assay sensitivity

CLINICAL INTERPRETATION

This session

- What each result means for the patient in front of you
- The decision and action each result drives
- Why the design serves the patient not a gap
- How the pathway plays out in practice, and what it delivers across the continuum

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The Moment Ultra Decides Treatment

One result. Three clear paths. Zero guesswork.

MTB Detected
RIF Susceptible

- **Start treatment today, first-line[1]**
- Counsel, ensure adherence[2]
- Follow up per guidelines[2]

RIF Resistant/ Indeterminate

- **Stop do NOT start first-line[1]**
- Reflex to Xpert MTB/XDR, same specimen[3]
- Start RR-TB regimen, notify DR-TB program[4]

MTB Not Detected

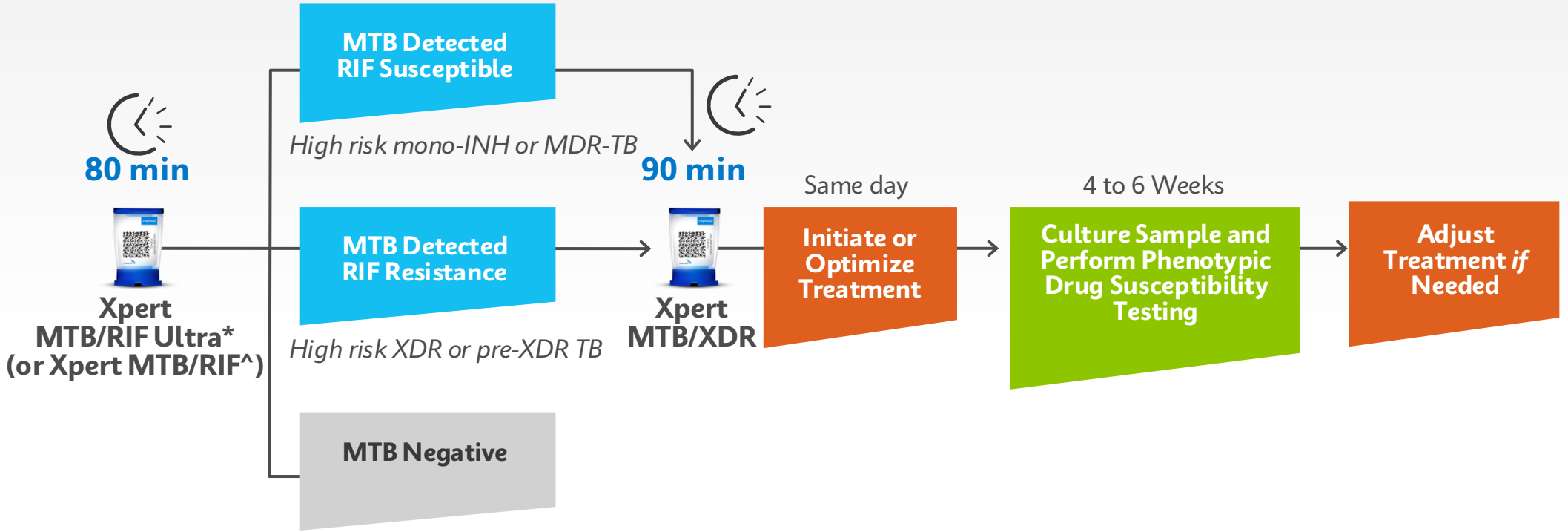
- **Don't close the door**
- High suspicion? Repeat, culture, LPA/TST-IGRA[1,2]
- Manage alternative diagnoses in parallel[2]

WHO Consolidated Guidelines on Tuberculosis: Module 3, Diagnosis; South African National Tuberculosis Management Guidelines; WHO Operational Handbook on Tuberculosis: Module 3, Diagnosis; and South African Management of Drug-Resistant Tuberculosis Guidelines.

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Xpert® MTB/XDR*

Diagnostic Pathway for Accurate Results



Fast molecular DST will shorten the time for appropriate treatment initiation while waiting for the culture result

CE-IVD. In Vitro Diagnostic Medical Device. May not be available in all countries. Not available in the United States. CE-IVD. In Vitro Diagnostic Medical Device. May not be available in all countries.

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Example of Clinical Pathway for MTB Testing

Who to be tested: Presumptive TB or high-risk — PLHIV, prior TB, close contact, MDR exposure

Molecular Testing (NAAT): Sputum preferred

MTB RIF detected: Collect 2nd specimen → Reflex XDR (INH/FQ/2nd-line) → Culture + DST → Start MDR-TB regimen.

MTB detected, RIF not detected: Start first-line treatment. **Reflex to XDR if:** prior TB, treatment failure, DR-TB contact, high-burden setting.

TRACE: Review history & signs. Treat now if high suspicion. Repeat NAAT if uncertain.

MTB not detected: Low suspicion → consider alternatives. High suspicion → repeat NAAT, alt specimen.

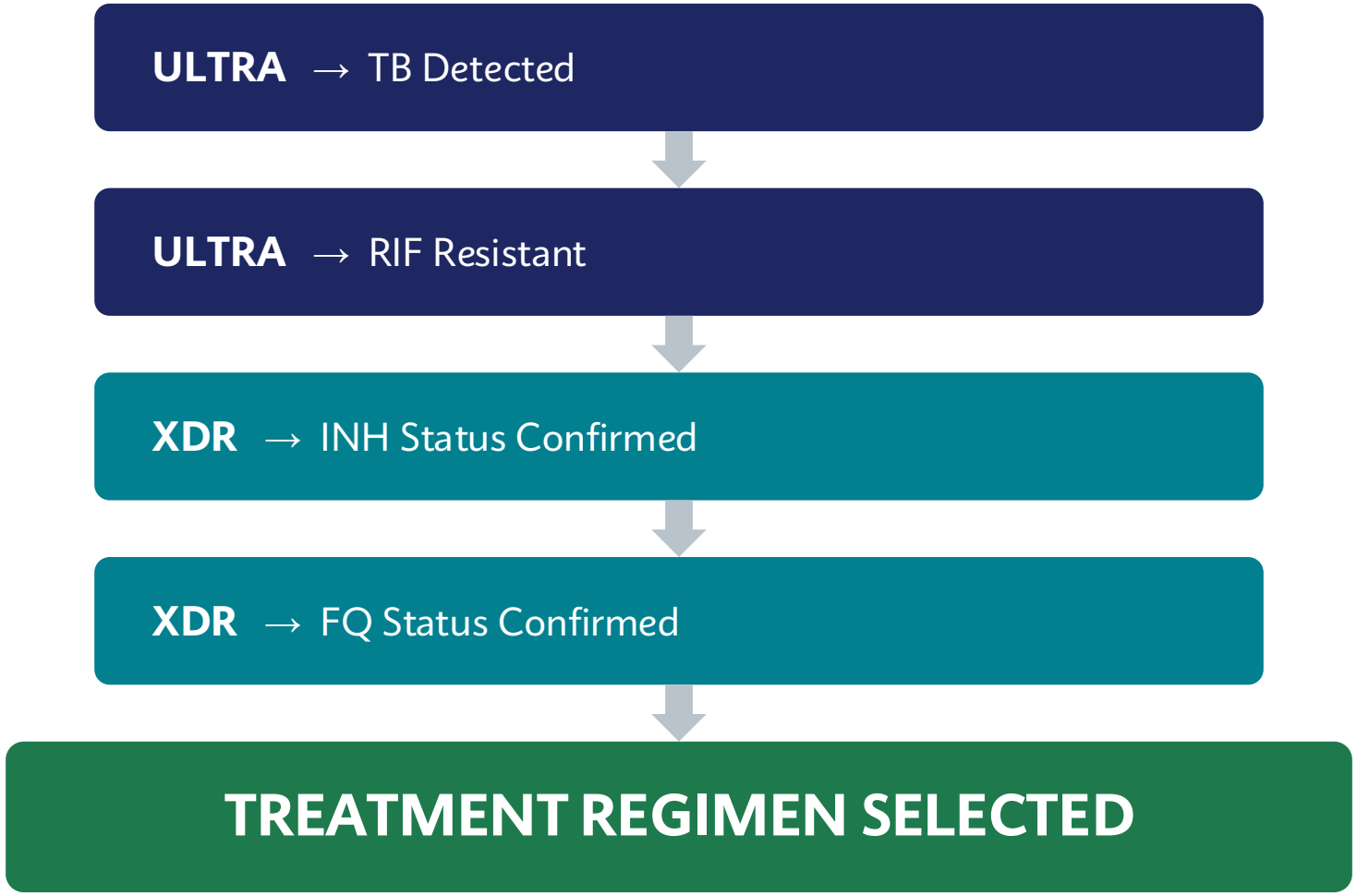
MTB = *Mycobacterium tuberculosis*; RIF = *Rifampicin*; MDR = *Multidrug-resistant*; XDR = *Extensively drug-resistant*; INH = *Isoniazid*; FQ = *Fluoroquinolone*; TB = *Tuberculosis; Rx= treatment; EPTB= Extrapulmonary Tuberculosis; PLHIV= People living with HIV; Stat= immediately*.

INH resistance can occur without rifampicin resistance; molecular detection supports early regimen optimisation and improved treatment outcomes.

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1.WHO TB guidelines (2021, 2024) and SA National TB Diagnostic Algorithm (NICD/NHLS & NDoH).

The Decision Ladder: Result to Regimen



Adapted from SA National TB Diagnostic & Treatment Guidelines (NDoH; NICD/NHLS) and WHO consolidated TB guidance.

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The Moment XDR Decides the Regimen

Run after MTB is detected turning a resistance profile into a treatment plan

XDR Detected (Pre-XDR / XDR)

- **Individualize now BPaL/M or per guidelines**
- Refer to DR-TB specialist center
- Monitor closely, support adherence

Not XDR

- **Use appropriate RR-TB regimen (FQ-based)**
- Ensure adherence and monitoring
- Follow up per guidelines

Invalid / Error

- **Repeat with a new cartridge**
- Check sample quality and handling
- Escalate if it happens again

Adapted from the WHO Consolidated Guidelines on Tuberculosis: Module 4, Treatment - Drug-Resistant Tuberculosis; WHO Operational Handbook on Tuberculosis: Module 4, Treatment; and the South African Drug-Resistant Tuberculosis Management Guidelines

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Programmatic use of sequential testing

Same specimen, same sequential test the clinical decision point differs by program

Sequential: Monitor, Then Escalate

- Run Ultra, get the result, treat
- Monitor patient response to first-line treatment
- If not responding, escalate to XDR

Full Reflex, Up Front

- Run Ultra on the specimen
- Positive result reflexed straight to XDR same specimen
- Full resistance profile known before treatment starts

Neither is "correct" it's where each program sits on the pathway today. Same platform, same confidence either way.

Adapted from WHO tuberculosis diagnosis and DR-TB treatment guidance.

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Built for the Patient You Can't Afford to Miss

Two questions clinicians ask answered the way confidence is earned

1

"Why isn't INH on first line?"

Because **catching the TB comes first**[1]. Sequencing the pathway this way **protects patients from false negatives**[1] at the step that matters most then **resistance typing follows**[2], informing treatment. That's not a shortcut. That's discipline.

2

"What does a trace result mean for my patient?"

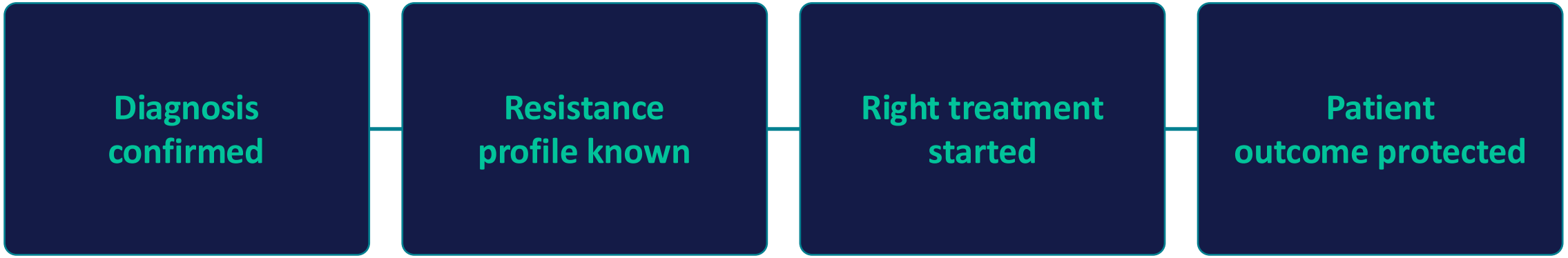
It flags exactly the patients most **at risk of being missed**[1,3] **early disease,** HIV co-infection, paucibacillary presentation, ACF/community-screened patients. These are the cases a clinical pathway can't afford to call negative.

[1] WHO Consolidated Guidelines on Tuberculosis: Module 3, Diagnosis. [2] WHO Operational Handbook on Tuberculosis: Module 3, Diagnosis. [3] South African National Tuberculosis Management Guidelines.

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Diagnosis to Treatment, Across the Continuum

A fast answer is not useful if it doesn't change management.



The test is not the endpoint. The patient outcome is.

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The Pathway You Can Stand Behind

Analytical interpretation tells you **what the result is**.

Clinical interpretation tells you what it means for the person in front of you.

Put together, that's a pathway built to be trusted not just used.

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Thank you for your time.

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