

### 03. Introduction of bedaquiline into the National TB programme of South Africa: a story of successful private public partnership

**THE 46<sup>TH</sup> UNION  
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Friday, 04 December 2015, 07:30 - 08:45

Room BR West-Westin

Type of session	Sponsored Satellite Symposium
Track	Drug-resistant TB care and treatment, including trials
Organised by	Right to Care and Janssen Pharmaceutical companies
Description	<p>There is an urgent need to improve the outcomes of M/XDR TB treatment. For the first time in decades, there are a number of new and repurposed drugs now available that have the potential to improve the outcomes. These include bedaquiline and linezolid. Randomized Controlled Clinical Trial data is eagerly awaited as to how to incorporate these drugs into effective regimens. However, there is a need to provide access to these more urgently to patients with few treatment options remaining. Adequate measures need to be taken to assess both safety and efficacy. In addition, injudicious use of the new drugs without an optimized background regimen may result in resistance. With a background HIV prevalence of at least 10% in most provinces in South Africa, the new drugs would need to be combined with antiretrovirals in many patients. This session describes the how bedaquiline was introduced into the National programme in South Africa following a successful clinical access programme. With careful attention paid to the regulatory framework and ethical consideration, the National Department decided to embark on an access programme. In a collaboration led by the National Department of Health of South Africa, Janssen Pharmaceutica and other partners including Right to Care and Médecins Sans Frontiers, access was provided to bedaquiline to over 200 patients prior to registration. Following registration in October 2014, a bold decision was made to provide access as broadly as possible within South Africa. Input from experts in South Africa was used to decide on a framework for introduction of new drug and new drug regimens for the treatment of Drug Resistant TB in South Africa. We also describe the mechanism adopted to ensure the ongoing protection of the drug and monitoring for resistance.</p>
Target audience	<ol style="list-style-type: none"> <li>1. Clinicians involved in care of RR TB</li> <li>2. TB programme managers at all levels of care, including National</li> <li>3. Microbiologists, and advocacy groups.</li> </ol>
Objectives	<ol style="list-style-type: none"> <li>1. To describe the Bedaquiline Clinical Access programme and the subsequent roll out of the drug by the National TB Programme of South Africa</li> <li>2. To launch the Policy Framework for the "Introduction of the new drugs and new drug regimens for the treatment of Drug Resistant TB in South Africa"</li> <li>3. To describe the monitoring of resistant for bedaquiline</li> </ol>
Keywords	Bedaquiline; South Africa
Coordinator(s)	Suann Bruce (South Africa), Abeda Williams (South Africa)
Chair(s)	Graeme Ayton Meintjes (South Africa), Rodolfo Romero Leyet (South Africa)
Presentations	<p><b>07:30 - 07:35</b> Opening remarks Norbert Ndjeka (South Africa)</p> <p><b>07:35 - 07:55</b> Early outcomes of the patients on the Bedaquiline clinical and lessons learnt Iqbal Master (South Africa)</p> <p><b>07:55 - 08:15</b> Launch of the framework for the Yogapragasen Pillay (South Africa)</p> <p><b>08:15 - 08:30</b> Focus on patient selection for bedaquiline and other new drugs Francesca Conradie (South Africa)</p> <p><b>08:30 - 08:45</b> Bedaquiline resistance monitoring Nazir Ismail (South Africa)</p>