

03. Pre-approval of access to new TB drugs:  
what, where and howTHE 46<sup>TH</sup> UNION  
WORLD CONFERENCE  
ON LUNG HEALTHCAPE TOWN, SOUTH AFRICA  
2-6 DECEMBER 2015

Friday, 04 December 2015, 10:30 - 12:00

Room Roof Terrace

Type of session	Symposium
Track	Drug-resistant TB care and treatment, including trials
Description	Access to MDR-TB and XDR-TB treatment is severely lacking in many high-burden MDR-TB countries. New TB drugs such as bedaquiline and delamanid are still difficult to access and compassionate use and expanded access are insufficient to meet the demand of the estimated 480,000 new cases of MDR-TB in 2013. This symposium will describe needs, challenges and experiences in pre-approved access to new TB drugs.
Target audience	<ol style="list-style-type: none"> <li>1. Clinical and academic researchers</li> <li>2. MDR-TB care providers</li> <li>3. Civil society and community stakeholders</li> </ol>
Objectives	<ol style="list-style-type: none"> <li>1. Share experiences of compassionate use from the field</li> <li>2. Present the experience of a pre-approval access program</li> <li>3. Provide the community perspective of access to new TB drugs</li> <li>4. Highlight challenges confronting those who attempt to gain pre-approval access to drugs</li> <li>5. Describe the industry viewpoint of compassionate use and expanded access</li> </ol>
Keywords	Drug access; drug-resistant tuberculosis; compassionate use
Coordinator(s)	Carly Rodriguez (USA), Erica Lessem (USA)
Chair(s)	Jennifer Furin (USA), Robert Horsburgh (USA)
Presentations	<p><b>10:30 - 10:40</b> From the field: experience of compassionate use Francis Varaine (France)</p> <p><b>10:45 - 10:55</b> From pilot to rollout: South Africa's bedaquiline clinical access program Francesca Conradie (South Africa)</p> <p><b>11:00 - 11:10</b> Why pre-approval access matters, and how to move forward Marcus Low (South Africa)</p> <p><b>11:15 - 11:25</b> Pre-approval access from the industry perspective: Janssen Chrispin Kambili (USA)</p> <p><b>11:45 - 12:00</b> Discussion</p>