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## **Challenge TB - Core Bedaquiline Coordination Year 2**

### **Quarterly Monitoring Report January-March 2016**

**Submission date: April 29, 2016**

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*Cover photo:* Consultation session of attending health care workers and (XDR-TB) patient to discuss treatment progress of treatment, MDR-TB DOTS polyclinic, Hassan Sadikin Hospital, Bandung, Indonesia. Treatment regimen for the XDR-TB was started in September 2015 and included bedaquiline. The patient is now in the continuation phase of the XDR-TB treatment, and has been culture-negative since October 2015.

Credit: Assistant medical officer, Hassan Sadikin Hospital, Bandung, Indonesia.

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### **Disclaimer**

The authors' views expressed in this publication do not necessarily reflect the views of the United States Agency for International Development or the United States Government.

## 1. Quarterly Overview

Core	Bedaquiline Coordination project
Lead Partner	KNCV Tuberculosis Foundation
Other partners	
Workplan timeframe	October 2015 – September 2016
Reporting period	January-March 2016

### Summary progress report:

The work plan was approved in November 2015. Dr Fraser Wares started working for KNCV from 14 March 2016 and took over as coordinator of this project from 1 April 2016.

The core project team consists of:

- Fraser Wares, project coordinator (since 1/4/16)
- Susan van den Hof, leading the operational research and pharmacovigilance
- Antonia Kwiecien (MSH/SIAPS), leading the PSCM aspects
- Agnes Gebhard, regional/country level overview and training (since 1/4/16)
- Gunta Dravniece, clinical management
- Ieva Leimane, training and capacity building
- Edine Tiemersma, PV and operational research

### Activities under the project:

A "Challenge TB Bedaquiline (Bdq) core project workshop" took place of the CTB coalition partners in The Hague, The Netherlands, from March 31st to April 1st 2016. The aim of the workshop was to ensure a coordinated, efficient and effective approach towards the rapid introduction of Bdq in CTB project countries, making best use of resources and the joint experiences of the coalition partners and benefiting from the upcoming CTB APA3 planning cycle and adjustments to APA2 Quarter 3 and 4 country workplans. Next steps for the coming months were developed from the workshop. The workshop summary report is attached as Annex 1. One of the first deliverables from the workshop was a summary of the "Status of essential critical steps, with CTB planning and timelines for the introduction of Bdq in 8 priority countries" which is attached as Annex 2. A series of follow up discussions will be held as soon as possible with each respective country team and coalition partner to discuss modified APA 2 workplans and APA 3 workplans.

The Bdq core project team participates in and contributes to the DR STAT core group meetings (with discussions focused on Mozambique, the Russian Federation and Ukraine in Feb – March 2016, and a discussion planned on the availability of delamanid via GDF in April 2016).

A final draft implementation protocol for "Evaluation of the feasibility, effectiveness and safety of the MDR/XDR-TB Patient Triage Approach" has been developed. The underlying CTB approach is the early triage of TB patients: using rapid (preferably molecular) methods. The quick triaging of patients ("the right diagnosis") will allow for fast and appropriate treatment initiation ("the right treatment") with 1<sup>st</sup> line drugs, a shorter regimen for uncomplicated MDR-TB and regimens containing new drugs e.g. Bdq, for those patients with additional resistance to fluoroquinolones (FQ) and/or 2<sup>nd</sup> line injectables (SLI), or with other indications (such as intolerance to other SL drugs, etc.). The generic triage algorithm will require to be adjusted to fit the local epidemiological and technological situations.

The majority of the data/indicators proposed to be collected under the protocol are "basic" ones which are needed for quality implementation of PMDT, including aDSM, in accordance with WHO guidelines for the introduction of the new drugs. This equates to intensified monitoring and evaluation in order to ensure "quality improvement in the wider context of the PMDT environment in the countries". Any additional data collection as determined by the respective country, such as that required for cost-effectiveness studies etc., need to be separated in the protocol from those elements which should be considered "basic" or "routine" data that are required for the provision of quality PMDT, including aDSM. The protocol will be finalized with input from partners in April/May 2016.

The team has compiled an inventory of available training and supportive materials, which will be completed in Q3 of APA 2 (April – June 2016), and with subsequent user friendly access to the documents provided via the most relevant website.

*Progress in countries since the project approval:*

- Ukraine: All critical steps for the introduction of Bdq have been completed, with expected enrolment of first patients on Bdq containing regimens in August 2016. Bdq will be ordered by the NTP and supplied to the country via humanitarian mechanism, registration of drug in country pending.
- Tajikistan: Optimized diagnostic algorithms and clinical protocols for the treatment of non-complicated MDR-TB cases and pre-XDR-TB and XDR-TB patients with new drugs and shorter regimens developed, awaiting finalization and subsequent endorsement by NTP.
- Vietnam: started treatment of patients on Bdq as from Dec 2015, expected to have 80 patients on treatment by end of September 2016.
- Kyrgyzstan: All critical steps for the introduction of Bdq have been completed, with expected enrolment of first patients on Bdq containing regimens in August 2016. Bdq was ordered by NTP/UNDP and will be supplied to the country via a waiver mechanism, pending registration of the drug in country.
- Indonesia: started treatment of patients on Bdq as from Oct 2015 (with 26 patients on treatment to date), and is expected to have 75 patients on treatment by the end of September 2016.
- India: Guidelines for introduction of Bdq under the NTP were published in Feb 2016. The initial 6 sites are being supported via CTB. First patients are expected to be enrolled on treatment in May 2016 (initial 600 patient courses of Bdq donated by Janssen directly to Government of India).

*Support to programmatic introduction of Bedaquiline in Kazakhstan*

Following discussions in Cape Town, South Africa in December 2015, further in-country discussions have been held between the regional USAID mission (Arman Toktabayanov), the regional KNCV office (Svetlana Pak and Maria Idrissova) and the NTP in relation to possible CTB (core project) support to the introduction of Bdq in Kazakhstan. It has been agreed that any possible support will be limited to TA only and to those sites not covered under the endTB project. A workplan for the period April to September 2016 has been developed to provide TA to both the national and regional levels of NTP in three main activities:

1. Programmatic preparations for implementation of new drugs;
2. Build programmatic capacity for initial scale-up of Bdq treatment, including aDSM in East-Kazakhstan, and national roll-out; and
3. Systematic M&E for implementation of Bdq.

Approval of USAID for the workplan is currently being sought. Further discussions will be required with the NTP to clarify who will provide the other required components for ensuring quality PMDT services are available in East Kazakhstan into which Bdq can be introduced.

**Technical/administrative challenges and actions to overcome them:**

The preliminary analyses of the status of introduction of Bdq and other new drugs conducted during the recent "Challenge TB Bedaquiline core project workshop", highlighted the wide differences between the respective CTB countries in their stage of implementation. Challenges were seen at all stages of the introduction of the new drugs and were highly country specific.

In order to accelerate the introduction of new drugs, a thorough review of each country's APA2 workplan with the lead technical partners is required, with reprogramming of funds to Q3-4 activities where appropriate. Discussions which feed into the APA3 planning cycle are also required, to obtain CTB country buy-in, prioritization of this work area in discussions with NTP, and inclusion of essential steps into the APA3 work plans. To facilitate this, the core project team has reached out to all CTB coalition partners in order to organize a series of discussions with the respective lead technical partners and country teams in the coming weeks e.g. for Tanzania on 4 May and India on 6 May 2016, on this area of work. Others will follow in May.

To meet the identified need of HR capacity building on the introduction of new drugs within the CTB coalition partners and their country office teams, a training for the CTB country teams is planned in June 2016 prior to the Country Directors' week in The Hague, The Netherlands. Preparations for the training are on-going.

For most of the essential steps/components for introduction of new drugs, tools, training materials, etc., are available. However they may need editing and to be made readily accessible

in a user friendly site to enable their adaptation and use by the respective countries and/or partners. The available tools, training materials, etc., will be collected together for providing user friendly access to the documents via the relevant website within the coming quarter.

Gaps in the supportive materials have been identified, especially regarding capacity building for the implementation of aDSM. Discussions are ongoing between KNCV and MSH for the development of materials to support countries to implement aDSM, including on signal detection and causality assessment. MSF Geneva is included in this area of work in their role as member of WHO's Task Force on implementation of aDSM. A draft training package should be available in the coming quarter.

The protocol for "Evaluation of the feasibility, effectiveness and safety of the MDR/XDR-TB Patient Triaging Approach" will be finalized with input from partners in April/May 2016, and discussions for implementation in appropriate countries conducted.

## 2. Year 2 activity progress

Sub-objective 3. Patient-centered care and treatment								
Planned Key Activities for the Current Year	Activity #	Planned Milestones				Milestone status	Milestone met? (Met, partially, not met)	Remarks (reason for not meeting milestone, actions to address challenges, etc.)
		Oct-Dec 2015	Jan-Mar 2016	Apr-Jun 2016	Year end	Oct 2015 -March 2016		
Development of detailed strategy per CTB country	<b>1</b>	2 countries	4 countries (planned to include Tajikistan, Nigeria)	6 countries (planned to include Kazakhstan, Botswana, DRC)	8 countries (planned to include Ethiopia, Burma)	4 countries have strategies developed (Indonesia, Kyrgyzstan, Ukraine and Vietnam). Indonesia and Vietnam are enrolling patients on Bdq containing regimens	<b>Met</b>	CTB TA funded though CTB country budgets – ongoing discussions on reprogramming APA2 funds and inclusion in APA3 workplans
Development of generic training modules, to be used in all countries	<b>2</b>	Drafts ready: based on inventory and CTB/SIAPS developed modules	Full set ready: development of additionally required modules	Dissemination of training modules to CTB partners. Use of training modules in countries ready to start using new drugs and regimens (Kyrgyzstan, Ukraine, Tajikistan)	Use of training modules in other countries ready to start using new drugs and regimens (to be determined)	An inventory of training modules made	<b>Partially met</b>	Inventory in final stage of development
Development of generic materials and protocols, to be adjusted per country	<b>3</b>	Draft ready: Development draft generic protocol	Full set ready: Share generic protocol and materials with partners for	Capacity building rGLCs and others	Continued updating generic materials base	The development of several of the documents is ongoing led by KNCV (essential steps overview, generic and country-specific implementation M&E	<b>Partially met</b>	Overview documents e.g. essential steps, M&E protocol etc., to be finalized in coming quarter. Approved country

			<p>comments and finalize</p> <p>Development country-specific protocols and materials (Kyrgyzstan, Ukraine, Tajikistan)</p> <p>Orientation/capacity building CTB partners</p>		Capacity building rGLCs and others	protocol, SOPs) and SIAPS (electronic PV recording system, PViMS), with many documents nearly finalized.		specific guidelines already available in some countries (e.g. India), awaiting approval in others (eg Ukraine). Country specific TA to be continued to facilitate further development and approval of country specific documents.
Coordination with USAID/SIAPS/CTB partners and support data collection for evidence related to ND&R introduction	<b>4</b>	CTB partners appointed focal points for BDQ TA Core Project	<p>- all CTB FP's have up to date information on the project</p> <p>- identify needs for capacity building on ND&amp;R introduction among CTB partners</p> <p>- partners familiar with project M&amp;E</p> <p>Integration of qualitative M&amp;E on ND&amp;R implementation into the CTB management system</p>	Data collection	Data collection	7 of the 9 coalition partners attended the Bdq workshop 31 March to 1 April 2016. All updated on current information and policies. Integration of qualitative M&E with dashboard mechanism for monitoring progress in implementation. Enrolment and outcome indicators to be reported separately	<b>Partially met</b>	<p>Ongoing discussions with all coalition partners and their respective country teams to prioritize the area of work, preferably through reprogramming of APA2 funding and inclusion in draft APA3 workplans.</p> <p>Capacity building training planned in June 2016 for PMDT Focal Points in country office and HQ teams.</p> <p>Finalisation of the "Evaluation of the feasibility, effectiveness and safety of the MDR/XDR-TB Patient Triaging Approach"</p>

								protocol in the coming quarter and discussions held with appropriate countries for implementation.
Additional support visits from HQ to Challenge TB countries when needed	<b>5</b>	1 country	3 countries	4 countries	5 countries	Missions to 22 countries as detailed in section 3 were conducted, but all funded from country project funds, not with core project funding as indicated in this table.	<b>Met</b>	In addition, KNCV HQ and RO staff developed a modified APA2 workplan for support to Bdq introduction in East Kazakhstan with the NTP, and in collaboration with the USAID regional mission

**Summary milestone data as of March 2016**

Total # of milestones expected by Q2 (cumulative for Oct 15 - Mar 16)	Milestones <b>met</b> by Q2 (Oct 15-Mar 16)		Milestones <b>partially met</b> by Q2 (Oct 15-Mar 16)		Milestones <b>not met</b> by Q2 (Oct 15-Mar 16)	
	#	%	#	%	#	%
N						
5	2	40	3	60	0	0

### 3. Challenge TB-supported international visits (technical and management-related trips to this project)

#	Partner	Name of consultant	Planned quarter				Specific mission objectives	Status (cancelled, pending, completed)	Dates completed	Duration of visit (# of days)	Additional Remarks (Optional)
			Q 1	Q 2	Q 3	Q 4					
1	KNCV	Susan van den Hof, Gunta Dravniece	x				<b>Kyrgyzstan</b> Facilitation of WS on development of national guidance for the introduction of new drugs and short regimens	Complete	28/09/-03/10/15	5	Reported in country QMR
2	KNCV/PATH	Gunta Dravniece	x				<b>Ukraine</b> Assessment of the M/XDR-TB situation, preparedness of the NTP for implementation of shortened regimens and new drugs	Complete	19/-22/10/15	4	Reported in country QMR
3	KNCV	Gunta Dravniece	x				<b>Nigeria</b> Facilitation of introductory WS on new drugs and short regimens	Complete	23/-27/11/15	5	Reported in country QMR
4	KNCV/PATH	Gunta Dravniece	x				<b>Ukraine</b> Development of OR protocol for short regimens and new drugs	Complete	30/11/-04/12/15	5	Reported in country QMR
5	KNCV/WHO	Svetlana Pak	x				<b>Kyrgyzstan</b> Co-facilitation the workshop on aDSM	Complete	08/ - 11/12/15	4	The workshop was organized by WHO and funded by USAID country mission. KNCV was invited to co-facilitate the workshop.

6	KNCV	Svetlana Pak	x				<b>Tajikistan</b> Co facilitation of aDSM workshop	Complete	13/ - 18/12/15	5	Reported country QMR
7	KNCV	Suzanne Verver	x				<b>Tajikistan</b> Co facilitation of aDSM workshop	Complete	13/ - 18/12/15	5	Reported in country QMR
8	KNCV	Agnes Gebhard	x				<b>Vietnam</b> Monitoring mission on Bdq	Complete	12/ - 19/12/15	7	GFATM funded
9	KNCV	Edine Tiemersma	x				<b>Indonesia</b> Monitoring mission for PV	Complete	02/ - 13/11/15	12	Reported in country QMR
10	KNCV / PATH	Sandra Kik, Maria Idrissova, Gunta Dravniece		x			<b>Ukraine</b> Development of the OR protocol for introduction of shortened MDR-TB treatment regimens and new drugs in Ukraine	Complete	24/ - 27/01/16	4	Reported in country QMR
11	KNCV	Valentina Anisimova, Svetlana Pak		x			<b>Tajikistan</b> Optimization of diagnostic algorithm for implementation of new drugs and shortened regimens	Complete	24/ - 30/01/16	6	Reported in country QMR
12	KNCV	Gunta Dravniece		x			<b>Botswana</b> Analysis of MDR-TB situation and readiness of NTP for implementation of new drugs and short MDR-TB treatment regimens	Complete	08/-18/01/16	10	Reported in country QMR
13	KNCV	Susan van den Hof, Gunta Dravniece		x			<b>Kyrgyzstan</b> Development of operational research protocol for the introduction of new drugs and shortened MDR-TB treatment regimens	Complete	28/02/ - 04/03/16	5	Reported in country QMR
14	KNCV	Maria Idrissova, Gunta Dravniece		x			<b>Tajikistan</b> Development of Clinical protocols for treatment of non-complicated	Complete	09/ -18/03/16	10	Reported in country QMR

						MDR-TB cases with shortened (9-month) regimens and pre-XDR-TB and XDR-TB patients				
15	KNCV / PATH	Gunta Dravniece		x		<b>Ukraine</b> Development of National TB program for 2017-2021	Complete	30/03/ - 01/04 /16	3	Reported in country QMR
16	UNION	Sarabjit Chadha		x		<b>India</b> Finalisation of the BDQ CAP guidelines and training of trainers	Complete	05/ - 08/01/16	4	Reported in country QMR
17	UNION	Sarabjit Chadha		x		<b>India</b> Constitution of the DSM Committee for the BDQ CAP	Complete	08/02/16	0.5	Reported in country QMR
18	KNCV	Petra de Haas Moses Joloba		X		<b>Nigeria</b> Support to a USAID-led assessment of the TB laboratory network	Complete	12/ - 25/03/16	13	Reported in country QMR
19	KNCV	Marleen Heus		X		<b>Tanzania</b> Support to the decentralization of PMDT care - piloting of training materials for ambulatory care	Complete	16/ - 25/01/16	9	Reported in country QMR
20	KNCV	Jerod Scholten		X		<b>Tanzania</b> Supervision and monitoring, including to the Kibong'oto Infectious Diseases Hospital (the only current PMDT service site in the country)	Complete	22/2/ - 2/03/16	8	Reported in country QMR
21	KNCV	Kathleen England		X		<b>Cambodia</b> Support for 2 <sup>nd</sup> line DST capacity	Complete	6/03/2016 - 2/4/2016	27	Reported in country QMR
22	KNCV, UNION, WHO	Jerod Scholten Nico Kalisvaart Matteo Zignol Wilfred Nkhoma Ronald Ncube Kelvin Charambira		X		<b>Zimbabwe</b> Mid-term review of TB drug resistance survey	Complete	7/ -11/03/16	5	Reported in country QMR

Total number of visits conducted (cumulative for fiscal year)	22 (reported in the country QMR's, and all supported from country project funding)
Total number of visits conducted from core project funding	0
<i>Total number of visits planned in approved core project funding / country work plan funding</i>	5
<i>Percent of planned international consultant visits conducted from core project funding / country workplan funding</i>	0 (instead country project funding was used)

## 4. Financial overview

### Challenge TB Quarterly financial report

Country	Bedaquiline coordination
Lead partner	KNCV

Period: Jan 2016 - March 2016

	Total
Total obligation	500,000
Total budgeted	305,766
Funds to be programmed	194,234
Total expenditures	64,424
Pipeline	241,342

	Total expenditures excl. ACF
Exp Jan-March 2016	40,107
Exp Oct-Dec 15	9,984
Exp July-Sept 15	
Exp April-June 15	
Average burn rate	25,046

#### Year 2

Partner	Approved budget	Previously reported expenditures	Reported expenditures this quarter	Accruals this quarter	Total expenditures	Remaining funds	% level of spending
KNCV	282,833	9,984	40,107	-	50,091	232,742	18%
ACF	22,932	5,733	8,600	-	14,333	8,600	62%
<b>TOTAL</b>	<b>305,766</b>	<b>15,717</b>	<b>48,707</b>	<b>-</b>	<b>64,424</b>	<b>241,342</b>	<b>21%</b>

Budget category	Approved budget	Previously reported	Reported this quarter	Accruals this quarter	Total expenditures	Remaining funds	% level of spending
Salary and wages	158,631	5,923	23,766		29,690	128,941	19%
Travel and transportation	14,945	-	-		-	14,945	0%
Other Direct Costs	500	-	-		-	500	0%
Indirect costs	108,757	4,061	16,341		20,402	88,356	19%
ACF	22,932	5,733	8,600		14,333	8,600	62%
<b>TOTAL</b>	<b>305,766</b>	<b>15,717</b>	<b>48,707</b>	<b>-</b>	<b>64,424</b>	<b>241,342</b>	<b>21%</b>

Budget category	Approved budget	Previously reported	Reported this quarter	Accruals this quarter	Total expenditures	Remaining funds	% level of spending
Staffing and operations	282,833	9,984	40,107		50,091	232,742	18%
ACF	22,932	5,733	8,600		14,333	8,600	62%
<b>TOTAL</b>	<b>3,699,767</b>	<b>135,528</b>	<b>529,992</b>	<b>-</b>	<b>665,520</b>	<b>3,034,247</b>	<b>18%</b>

Budget category	Approved budget	Previously reported	Reported this quarter	Accruals this quarter	Total expenditures	Remaining funds	% level of spending
HQ costs	305,766	15,717	48,707	-	64,424	241,342	21%
<b>TOTAL</b>	<b>305,766</b>	<b>15,717</b>	<b>48,707</b>	<b>-</b>	<b>64,424</b>	<b>241,342</b>	<b>21%</b>