	TB CHAMP PK Lead-in Palatability and Acceptability											Page 1 of 2 V2.1 14 Feb 2017							
	Child PID:						Visit Date					D	D	M	M	M	Y	Y	Y
Visit	<input type="checkbox"/> Baseline					<input type="checkbox"/> PK					<input type="checkbox"/> Unscheduled								

A. For the study clinician






Note: Observe the child taking the levofloxacin dose and indicate the option that most closely describes how the child took the dose

1	Everything swallowed: no liquid residuals found during oral inspection
2	Small runlet: liquid rinse or flowing out of the mouth
3	Spat out: no observed swallowing and the child disgorged the syrup directly
4	Choked on: some of the liquid was inhaled or a cough was caused during swallowing
5	Refused to take: all actions preventing the placing the dosing instrument into the mouth, or intentionally closing the lips

B. Questions to the parent or caregiver

Note: At Baseline visit, questions are asked regarding the first levofloxacin dose, given at the study site. At the PK visit, questions are regarding the levofloxacin doses given at home.






1. In your assessment, how did the child appear to feel about the taste of the dose? (caregiver)

1 Dislike very much 	2 Dislike 	3 Neutral 	4 Like 	5 Like very much 
--	--	--	---	---






2. In your assessment, how did the child appear to feel about the amount (volume) of the dose? (caregiver)

1	Amount/volume was okay
2	Amount/volume was too large






3. Overall, how do you feel about the preparation of the doses? (caregiver)

1 Very difficult 	2 Difficult 	3 Neutral 	4 Easy 	5 Very easy 
---	--	--	---	--

4. Overall, how do you feel about how easily the tablet dissolved in water? (caregiver)

1 Very difficult 	2 Difficult 	3 Neutral 	4 Easy 	5 Very easy 
---	--	--	---	--

5. Overall, how do you feel about the administration of the doses? (caregiver)

1 Very difficult 	2 Difficult 	3 Neutral 	4 Easy 	5 Very easy 
---	--	--	---	--

6. How did you feel about the size of the tablet? (caregiver)

1	Size was okay
2	Size was too large

NB! Section 7 should be omitted at the baseline visit

7. At the PK visit only When giving the levofloxacin at home, in what form did you give the tablet to the child? Multiple options can apply					
7.1.a. <input type="checkbox"/> Whole tablet with water		<input type="checkbox"/> Broken in half with water		<input type="checkbox"/> Crushed (If yes, go to question 7.1.b)	
<input type="checkbox"/> Dissolved the tablet in solution (If yes, go to question 7.1.c)					
7.1.b. If crushed, indicate how the drug was given below:					
<input type="checkbox"/> With liquid		<input type="checkbox"/> With food		<input type="checkbox"/> Other	
7.1.c If dissolved, please select the solution below:					
<input type="checkbox"/> Water		<input type="checkbox"/> Juice		<input type="checkbox"/> Milk	
				<input type="checkbox"/> Yoghurt	
<input type="checkbox"/> Other					
7.1.d If other selected, please specify:					
8. Did you have to give food or liquid like yoghurt, milk, etc. AFTER the tablet was given, to help the child take the medication?					
<input type="checkbox"/> Yes			<input type="checkbox"/> No		
If yes, describe what you gave after the tablet was taken					
<input type="checkbox"/> Water		<input type="checkbox"/> Juice		<input type="checkbox"/> Milk	
				<input type="checkbox"/> Yoghurt	
<input type="checkbox"/> Other					
If other selected, please specify:					
9. Prior to this study, was your child taking medications for preventing MDR-TB?					
<input type="checkbox"/> Yes <i>(If yes continue)</i>			<input type="checkbox"/> No <i>(If no skip to end)</i>		
1. How did the preparation of the study medication dose compare to the preparation of the previous MDR-TB medications?					
<input type="checkbox"/> Unsure		<input type="checkbox"/> Much worse		<input type="checkbox"/> Worse	
				<input type="checkbox"/> No different	
				<input type="checkbox"/> Better	
				<input type="checkbox"/> Much better	
2. How did the taste of the study medication dose compare to the taste of the previous MDR-TB medications?					
<input type="checkbox"/> Unsure		<input type="checkbox"/> Much worse		<input type="checkbox"/> Worse	
				<input type="checkbox"/> No different	
				<input type="checkbox"/> Better	
				<input type="checkbox"/> Much better	

Completed By: Name	Signature									Date													
										D	D	M	M	M	Y	Y	Y	Y					
Quality Checked By: Name	Signature									Date													
										D	D	M	M	M	Y	Y	Y	Y					
Date of Database Entry 1:										D	D	M	M	M	Y	Y	Y	Y	RA code of data entry officer:				
Date of Database Entry 2:										D	D	M	M	M	Y	Y	Y	Y	RA code of data entry officer:				