

Optimisation of treatment of HIV and HIV-TB co- infections



EDCTP Stakeholder meeting

Lisbon – Portugal

19 May 2009

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By: Emilia Valadas, Meeting Chairperson

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1. Introduction

The European and Developing Countries Clinical Trials Partnership (EDCTP) funds clinical trials for the development of interventions to fight the human immunodeficiency virus (HIV), tuberculosis (TB) and malaria. On 19 May 2009 EDCTP organised a stakeholders' meeting on optimisation of HIV treatment and HIV-TB co-infection to guide the Partnership on a strategy for funding new integrated projects in HIV treatment and related major co-infections, especially TB.

The aim of this meeting, which was hosted by Portugal and took place in Lisbon, was to identify and prioritise potential products in the pipeline; recommend the funding procedure, whether through an open call or brokering; or indeed whether to fund this a call at all.

The meeting was chaired by Prof. Emilia Valadas, a senior scientist of University of Portugal at the University Clinic for Infectious Diseases in Lisbon.

Dr Ligia Amancio, the Vice President of Portugal's Ministry of Science, Technology, and Higher Education (Fundação para a Ciência e a Tecnologia or FCT), welcomed participants. The opening address was followed by brief remarks from Prof. Charles Mgone, the Executive Director of EDCTP. He explained that EDCTP had reserved 5 million euros for funding trials on this subject and matching funds were expected from European Member States and further funding from third parties. The agenda for the meeting is attached as **Annex 3**.

2. Science and products

The state of the art presentation was made by Dr Nick Paton of the Medical Research Council of the United Kingdom. His talk covered the following areas:

Products in the pipeline

For purposes of EDCTP funded trials products will come from those pharmaceutical developers that have tested them in the USA and Europe for the HIV market. Pipeline for EDCTP funded trials may be anything from phase II and III through to early licensed products that may be new to Africa (e.g. raltegravir). The trials may need different considerations for other diseases e.g. TB

Why do we need new HIV drugs

- 1) Drugs are not completely free from long-term toxicity. These side effects include lipodystrophy, lactic acidosis, neuropathy and renal impairment among others
- 2) Cross-resistance within classes of drugs is common
- 3) Cost of multi-drug therapy is a major consideration in both resource-rich and resource-limited settings

New HIV drugs

- 1) Integrase inhibitors
 - a) Raltegravir is licensed
 - b) Elvitegravir is in phase III trials
- 2) Entry inhibitors
 - a) Maraviroc is licensed
- 3) New non-nucleoside reverse transcriptase inhibitors (NNRTIs)
 - a) Etravirine is licensed

In trials Raltegravir has lesser side effects than efavirenz although the major concern is that its effect on the brain is still unknown.

Advantages of integrase inhibitors are that they are a novel antiretroviral class, with no known cross-resistance with other antiretroviral classes. They are synergistic in combination with approved antiretroviral agents and they target third essential enzymes for HIV replication (i.e. reverse transcriptase, protease and integrase) and can be taken orally. Their disadvantages are due their long-term adverse effects that are not yet fully defined and viral resistance with failure likely from the relatively low genetic barrier to resistance.

HIV-1 entry inhibitors are a novel antiretroviral class that are effective against viruses resistant to nucleoside reverse transcriptase inhibitors (NRT), NNRTI, Protease Inhibitors (PI), and Enfuvirtide (ENF). In the trials they are well tolerated in oral administration and produced better CD4 count benefits. However they are limited to protection against R5 virus only. Viruses like X4 and DM are not covered. Their long-term safety and resistance is not well defined and the cost and availability of tropism assay is not determined at this time.

Etravirine is a new NNRTI. It has activity against Efavirenz and niverapine resistant virus. But it is compromised when more than three resistance mutations (common in patients failing NNRTI-based regimen in absence of viral load monitoring) occurs.

New TB drugs

The ongoing trials e.g. REMoxTB and Rifaquin use moxifloxacin. The aim is to substitute moxifloxacin for isoniazid (INH) or Ethambutol to shorten treatment duration. Rifaquin trial is also using high-dose rifapentine besides moxifloxacin.

Current research priorities for optimisation of HIV treatment

- 1) New treatment combinations
 - a) NRTI or NNRTI-sparing?
- 2) Treatment simplification
 - a) PI monotherapy?
- 3) When to start ART?

In African settings the questions of new combinations for first-line regimen, simplification strategies and when to start should also be done with considerations to decreasing early morbidity/mortality after starting ART, new strategies of when to switch treatment and how to treat HIV and TB co-infection. High cost and lack of fixed-dose combinations are limitations with these new ideas. New patent-free pool of products may solve this problem. However, the situation in Africa is further complicated by shifting national guidelines (some countries have moved to 250 CD4 count for all adults and less than 350 for pregnant women to initiate lifelong ART). International acceptability of fixed standards in these settings is uncertain. The causes of earlier mortality in the African region are also complex. Co-infections like TB, bacterial infections, fungal infections and parasites play a role but conditions like immune reconstitution inflammatory syndrome (IRIS) and malnutrition are also major factors.

HIV and TB co-infection research

The research areas include:

- 1) How soon to start ART in TB co-infected patients
- 2) TB prophylaxis trials
- 3) Managing TB in patients requiring PIs

Isoniazid prophylaxis for 6-12 months to prevent TB has been well-studied as has been the 3 month regimen of rifampicin plus pyrazinamide. The role for more prophylaxis studies maybe best integrated with ART studies. Combination of TB and HIV drugs raise toxicity

and efficacy concerns. Rifampicin decreases levels of efavirenz and niverapine, PI and Raltegravir. Efavirenz is safer to use with TB drugs and its doses can be increased within safety levels but increased PI levels are contraindicated. Rifabutin has fewer interactions with all HIV drugs, but may still has a problem with PIs although the data is very limited. Availability of Rifabutin was previously limited due to cost, but is has recently been added to World Health Organisation (WHO) essential drugs list although it still needs more pharmacokinetics work.

3. Overview participating organisations

3.1 European public organisations

3.1.1 Medical Research Council (MRC) – United Kingdom

The Medical Research Council (MRC) is a publicly-funded organisation dedicated to improving human health. It supports research across the entire spectrum of medical sciences, in universities and hospitals, in its own units and institutes in the UK, and its units in Africa. MRC was represented by Dr Nick Paton who also presented the state of the art paper. The presentation is attached as **Annex 5.2**.

3.1.2 University of Lisbon

University of Lisbon is a public University which is active in TB and HIV clinical research. Apart from the Chairperson of this meeting the university was represented by several scientists. **See Annex 4** for a full list of the participants.

3.1.3 KNCV Tuberculosis Foundation

The Dutch Royal Tuberculosis Foundation (KNCV) is a publicly funded organisation in The Hague. The organisation supports policy development, technical assistance, advisory services, training programs, capacity building, as well as epidemiological and operational research. Dr Frank Cobelens represented KNCV.

3.1.4 Centre for Poverty-related Communicable Diseases (CPCD) and INTERACT project

CPCD is an academic centre affiliated to the University of Amsterdam. It aims to link science and implementation in the fight against TB, HIV and malaria. Dr Frank Cobelens and Professor Joep Lange represented CPCD. The presentation on INTERACT given by Dr Cobelens is attached as **Annex 5.6**.

3.1.5 The Institute of Tropical Medicine (ITM)

The Institute of Tropical Medicine in Antwerp, Belgium (ITM) is one of the world's leading institutes for training, research and services delivery in tropical medicine and health care in developing countries. Dr Bob Colebunders represented ITM. The presentation made by Dr Colebunders on drug resistant TB and HIV is attached as **Annex 5.12**.

3.1.6 Agence Nationale de Recherches sur le SIDA et les Hepatites Virales (ARNS)

The ANRS is a French research agency fighting against HIV/AIDS and viral hepatitis. It was represented in the meeting by Dr Brigitte Bazin. The presentation made by Dr Bazin is attached as **Annex 5.5**.

3.1.6 Karolinska Institutet

Karolinska Institutet is a university for medical education in Stockholm (Sweden). A research group at the Department for Clinical Research and Education (South Hospital)at

the institute is involved in various research activities that include improving TB diagnosis, new TB drugs, nasal vaccine delivery methods and operational research for TB-HIV co-infection. Dr Stefan Svenson represented the research group and his presentation is attached as **Annex 5.11**.

3.2 African partners

3.2.1 Representatives of EDCTP funded Networks of Excellence

Two HIV experts (for Eastern Africa and Western Africa respectively) and one TB expert (for Central Africa) attended the meeting. These also belong to DCCC of EDCTP. See section 3.4.1 and **Annex 4** for details. The presentation made by DCCC member, Dr Abraham Alabi, on strengths and gaps in Africa is attached as **Annex 5.3**.

3.2.3 Joint clinical research centre, Uganda

JCRC is Uganda's centre of excellence for AIDS care, treatment, research and training that was founded at the height of the AIDS crisis in Uganda by the government as a strategic partnership between the Ministry of Health, Ministry of Education and the Ministry of Defence. JCRC is an autonomous non-profit limited liability company without share capital, governed by a Board of Trustees. Dr Francis Ssali represented JCRC.

3.2.4 Infectious Disease Institute, Uganda

The Infectious Diseases Institute (IDI) is a Uganda-registered NGO, owned by Makerere University. IDI conducts care, training and research for HIV and related infectious diseases. Dr Yukari Manabe represented IDI in the meeting.

3.2.5 Mutti Clinic, Zambia

The clinic was represented by Dr Dorothy Kasonda from Zambia. She has experience in management of HIV/AIDS patients in an African setting.

3.3 Private Sector and collaborative projects

3.3.1 United Nations Industrial Development Organisation (UNIDO) project (Heidleberg)

The UNIDO Pharmaceutical Production Partnership Platform (U4P) is a project that is designed as a platform promoting partnerships between producers from both industrialised and developing countries to produce medicines against HIV/AIDS, malaria, TB and neglected tropical diseases as well as World Health Organisation Essential Drugs. Dr Fredrich von Massow represented this project. Dr von Massow's presentation is attached as **Annex 5.9**.

3.3.2 Global HIV Vaccine Research Cryorepository project

This is a collaborative project between Institut Biomedizineche Technik (Germany), Universitat des Saarlandes and an FP7 funded project (UCONET). The project aims to establish a new quality in cryo-preservation, improve processing and distribution of clinical specimens, implement technology transfer and teaching and produce/distribution HIVpp for nAb assays. Dr Andreas Meyerhans represented the project. A presentation made by Dr Meyerhans is attached as **Annex 5.7**.

3.3.3 Viro Pharmaceuticals and Hannover Medical School project

The Division of Immunology and Rheumatology of Hannover Medical School is a partner of Viro Pharmaceuticals in preclinical evaluation of VIR-576, a novel antiretroviral peptide for

the therapy of HIV infection. The project was represented by Professor Wol-Georg Forssmann. A presentation by Prof. Forssmann is attached as **Annex 5.8**.

3.3.4 EuResist project

EuResist is a FP6 funded project that aims at optimization of HIV treatment by helping medical caregivers across Europe in accessing expert help in managing patients with different patterns of HIV resistant strains. The EuResist engine is offered to assist treatment switch in clinical trials as well. The project has three data sources and biomedical sites (University of Siena in Italy, University of Koeln in Germany and Karolinska in Sweden). The other partners Max-Planck Institute for Bioinformatics in Germany, IBM Machine Learning Group in Israel, RMKI in Hungary, Informa srl in Italy and Kingston University in London. Dr Maurizio Zazzi represented the project. Dr Zazzi's presentation is attached as **Annex 5.10**.

3.3.5 Tibotec

Tibotec is a pharmaceutical company that invest in research and development of drugs against infectious diseases like HIV and hepatitis C virus. Mr Karel De Beule represented the company in the meeting.

3.3.6 Emergent Biosolutions Inc

Emergent BioSolutions Inc. is a biopharmaceutical company focused on the development, manufacture and commercialization of vaccines and therapeutics that assist the body's immune system to prevent or treat disease. Emergent's development pipeline includes programs focused on anthrax, botulism, tuberculosis, typhoid, hepatitis B and Chlamydia. Dr Robert McLeod represented the company in the meeting.

3.4 Other participants

3.4.1 Host country officials

Other participants from Portugal included the former Portuguese President Mr Sampiao and National Programme Coordinator for HIV, Dr Henrique de Barros.

3.4.2 European and Developing Countries Clinical Trial Partnership (EDCTP)

EDCTP was represented by four members of the Partnership Board (PB), five member of the Developing Countries Coordinating Committee (DCCC) and six staff members of the Secretariat.

4. EDCTP procedures

4.1 Overview of EDCTP procedures

4.1.1 Call / Brokering

EDCTP calls can either be an open call or brokered procedure. Both procedures were explained to the participants.

4.1.2 Timelines for initiating funding procedure

The timelines will be determined when this report is endorsed by the meeting chairperson and approved by both the Partnership Board and the General Assembly of EDCTP. Tentatively the planned date for launching the call is August 2009.

5. Summary discussion

The discussion was opened by Prof. Emilia Valadas, the chairperson of the stakeholders' meeting.

The following comments were captured from the discussion:

- 1) Large efficacy trials are expensive and the EDCTP funds available for this call may not be sufficient. The challenge for the meeting was to decide what kind of trials they could do with the amount of resources and within the timelines that were announced by the EDCTP Executive Director in his opening remarks
- 2) Emphasis on new HIV drugs needed to be approached with caution since their central nervous system concentrations and effects on inducing dementia were not yet known. In addition genetic barriers of resistance to such drugs on the virus were yet to be explored. Although there is need to have new drugs in the HIV field prevention programmes were still the key to curbing the epidemic. New drugs are extensively evaluated in developed countries and whether further efficacy trials are needed in the African setting was less clear. New regimens are also expensive and unaffordable by the majority of African programmes and so their evaluation in the African setting needs to be done with caution.
- 3) The question of when to start anti-retroviral treatment (ART) in HIV infected and HIV-TB co-infected patients was very crucial. While there was overwhelming evidence that ART should be started earlier than current levels, exactly when it should be started, and the costs and benefits of this were unclear. Costs would need to be taken into account both from the health service and the patient perspective. There would be a major benefit in reduction in early mortality but the effects on adherence and subsequent treatment failure are unknown. A further major attraction of early initiation is the potential that this strategy might impact on the incidence of new infections in the community.
- 4) Because of the differences in pathology between Africa and developed countries, it would be important to evaluate a strategy of very early initiation of ART against early (so for example, at above 350 vs above 500 CD4 count per microlitre or higher. Such a trial would be large, expensive.
- 5) Another challenge was to single out which antiretroviral therapies might be efficacious enough as mono-therapies among the new or emerging drugs
- 6) Coupled with research on when to start ART are studies that address factors associated with early mortality among HIV patients like malnutrition, micro and macro-nutrient deficiency, IRIS and opportunistic infections
- 7) Although earlier initiation of ART would prevent early mortality, many HIV-infected subjects in Africa will continue to present for treatment with advanced HIV disease and evaluation of interventions to reduce early mortality (for example use of prophylaxis or nutrition-based therapies) needs evaluation
- 8) For TB the major research questions surround simplification of treatment and safe combinations with ART. Apart for improving diagnosis (which is a call EDCTP already launched in 2009) prophylaxis to prevent TB disease in those infected with *Mycobacterium tuberculosis* is another important research area
- 9) Whatever research questions were to be selected in the stakeholders' meeting it was important to consider studies that will produce results within 5 to 10 years. Also of critical importance was to keep trials simple – one trial should not address all of the questions above.
- 10) Capacity building was an essential component of the research activities to be proposed
- 11) There is need for investment in HIV drug resistance surveillance and treatment options research. However this is relevant in programmes that provide second and third

generation ART alternatives. This area of research may not be a priority in Africa since individualised drug regimens are not part of the current HIV treatment programmes

- 12) Former President of Portugal, President Dr Jorge Sampaio, who is the United Nations Special Envoy for TB offered his support to mobilise resources to combat the dual infections among populations. His support could come in form of stimulating political commitment to scale up treatment programmes of effective interventions.

The meeting concluded that:

- 1) The decision of whether it would be an open call or not would depend on the type of research questions that would be agreed upon at the end of the discussion. An open call was generally favoured
- 2) Important issues included CD4 cut off points for starting ART i.e. when to start (above 350 vs above 500 CD4 count); reduction of early mortality and morbidity. There was a backing for these approaches not only from research point of view but also from that of Public Health
- 3) HIV fuels TB epidemic and in general studies on controlling the effects of HIV should also consider TB
- 4) Clinical health intervention trials with INH prophylaxis could be worth considering. These could be piggy-backed on the already funded EDCTP HIV and TB projects
- 5) Prevention of infections other than TB and conditions like malnutrition needed attention in the call but the danger of making the required trials too complex must be avoided
- 6) Coupled with trials (like those of starting ART early) should be the cost-effective analyses
- 7) The question of improving treatment of HIV should include research that leads to understanding the differences between different HIV subtypes. This can be enhanced by adding genotyping components to the trials
- 8) Whatever trials will be chosen, all other areas of EDCTP 's focus namely capacity building and networking should be included
- 9) The study sites should not be limited to specific group or research networks like the EDCTP Networks of Excellence. Such groupings can only be encouraged or advised to apply
- 10) The strategy to mobilize more money into the call was needed. The use of already existing initiatives like those presented by several speakers during the meeting should be encouraged
- 11) Although the call on TB diagnostics is relevant to the call to be designed through this meeting it was late to link the two calls.

6. Recommendations to EDCTP

The meeting recommended that:

- 1) EDCTP should launch a call that focuses on both optimization of HIV treatment in TB patients and when to start the treatment in order to reduce the high early mortality. Research could include either a focus on the control and management TB co-infection, on when to initiate ART in HIV-infection or on alternative interventions (for example macro or nutrient therapies) in either HIV or HIV/TB co-infected subjects.
- 2) An open call should be launched.

Annex 1: Member state and third party contribution to the stakeholder meeting

Estimate of all costs covered by hosting country	
Item	Amount (Euro)
Travel	0
Hotel	0
Catering	1849,34
Administration support	320,00
Venue	1000
Other	0
Sum	3169,34

Signed by organising Member State: Portugal
Name: Ana Faisca
Date: 29 June 2009

Annex 2: EDCTP Guidelines for Stakeholder meetings

Please see the guidelines on www.edctp.org

Annex 3: Agenda

EDCTP Stakeholder Meeting

Optimisation of treatment of HIV and HIV-TB co-infections

Tuesday 19 May 2009. 9:00hrs - 16:00hrs

Centro Cientifico e Cultural de Macau

Rua da Junqueira, nº5 e nº30 .1300-343 Lisbon, Portugal

Aim of the meeting:

- Identify and prioritise potential products in the pipeline
- Recommend if the funding procedure of EDCTP will be an open call, brokering or whether EDCTP should fund this topic at all
- Recommend EDCTP 's timeline concerning the initiation of funding for this topic

Agenda items	By	Timelines
Coffee/Tea		9:00 – 9:15
1.0 Welcome	Prof Charles Mgone (Executive Director EDCTP) Prof Ligia Amancio (Vice President FCT (Host)) Prof Emilia Valadas (Chairperson)	09:15 - 09:30
2.0 Approval of the agenda	All	09:30 - 09:40
3.0 EDCTP procedures	Prof Charles Mgone	09:40 - 10:00
4.0 Scientific overview of the field including products in the pipeline	Dr Nick Paton	10:00 - 10:30
5.0 Discussion on science and products	All	10:30 - 11:00
Coffee / Tea		11:00 - 11:15
6.0 Strength and gaps in the field of HIV and TB co-infection in Africa	Dr Abraham Alabi Dr Mecky Matee	11:15 - 11:30
7.0 Discussion on strength and gaps in the field in Africa	All	11:30 - 12:00
8.0 Member states programmes and commitment - Portugal	Prof Henrique de Barros	12:00 – 12:30
9.0 Address by special guest from host country	Dr Jorge Sampaio (Former President of Portugal)	12:30 – 12:45
Lunch		12:45 – 13:45

10.0 Member states programmes and commitment - Netherlands - France - Germany	Fransciscus Cobelens Brigitte Bazin Andreas Meyerhans	13:45 – 13:55 13:55 – 14:05 13:05 – 14:15
11.0 Profile of products by product development partners - Viro Pharma - UNIDO / Heidelberg Pharma - EuResist Network	W. Forssmann F. von Massow M. Zazzi	14:15 – 14:25 14:25 – 14:35 14:35 – 14:45
12.0 Recommendations to EDCTP	All	14:45 - 15:45
13.0 Summary of recommendations	Chairperson	15:45 - 16:00
14.0 Closing Remarks	Chairperson	16:00 – 16:10
Thank you and appreciation	Waley Salami	16:10 – 16:15
Coffee / Tea		16:15 – 16:30

Annex 4: List of participants

No.	First Name	Family Name	Role/ affiliation	E-mail
1	Abraham	Alabi	DCCC HIV focal person West Africa	aalabi@hivresearch.org
2	Omu	Anzala	DCCC HIV focal person East Africa	oanzala@kaviuon.org
3	Nkandu	Luo	DCCC HIV focal person Southern Africa	nluo22@yahoo.co.uk
4	Veronique	Penlap	DCCC TB focal person Central Africa	ypenlap@yahoo.co.uk
5	Hulda	Swai	DCCC TB focal person Southern Africa	hswai@csir.co.za
6	Carolyn	Petersen	PB Member	cpetersenconsulting@gmail.com
7	Christian	Burri	PB Member	christian.burri@unibas.ch
8	Shabber	Jaffar	PB Member	Shabbar.Jaffar@lshtm.ac.uk
9	Peter	Kremsner	PB Member	peter.kremsner@uni-tuebingen.de
10	Francis	Ssali	Clinical Research Director, Joint Clinical Research Centre, Uganda	franssali@jcrc.co.ug
11	Roxana	Rustomjee	EDCTP NoE Grantee - NoE Coordinator, Southern Africa	
12	Nick	Paton	State of the Art Speaker, MRC UK	
13	Emilia	Valadas	Chairperson - University of Lisbon	evaladas@fm.ul.pt
14	Wolf-Georg	Forssmann	Industry Representative (Viro Pharma)(HIV)	wg.forssmann@pharis.de / Immunologie@mh-hannover.de / H.Mainitz@Pharis.de
15	Friedrich	Von Massow	UNIDO / Heidelberg Pharma(TB+HIV)	massow.i-LSE@t-online.de
16	Mr. Karel	De Beule	Industry Representative (Tibotec)(TB)	kdbeule@its.inj.com
17	Dorothy	Kasonde	Mutti Clinic	muttimc@iconnect.zm
18	Robert	McLeod	Emergent BioSolutions Inc.	mcleodr@ebsi.com
19	Yukari	Manabe	Head of Research - Infectious Diseases Institute - Associate Professor of Medicine - Johns Hopkins School of Medicine - Associate Clinical Lab Director - MU-JHU Infectious Diseases Institute	ymanabe@mu-jhu.idi.co.ug
20	Maurizio	Zazzi	EuResist Network	zazzi@unisi.it
21	Bob	Colebunders	Institute of Tropical Medicine, Antwerp.	
22	Charles	Mgone	EDCTP Secretariat	mgone@edctp.org
23	Waley	Salami	EDCTP Secretariat	salami@edctp.org
24	David	Coles	EDCTP Secretariat	coles@edctp.org
25	Anabela	Atanasio	EDCTP Secretariat	atanasio@edctp.org
26	Tom	Nyirenda	EDCTP Secretariat	nyirenda@edctp.org
27	Peter	Murphy	EDCTP Secretariat	
28	Ligia	Amâncio	Host Country Representative - FCT Vice President	
29	Henrique	de Barros	Host Country Representative - National programme Coordinator	
30	Thomas	Hanscheid	Host Country Representative	
31	Maria dos Anjos	Machado	Host Country Representative	
32	Ana	Faísca	Host Country Representative	
33	Catarina	Resende	Host Country Representative	

34	Stefan	Svenson	Sweden - Scientific Advisor	Stefan.svenson@vmm.slu.se
35	Gunilla	Källenius	Sweden - Scientific Advisor	gunilla.kallenius@smi.se
36	Franciscus	Cobelens	Netherlands - Scientific Advisor	c.baank@amc-cpcd.org ; f.cobelens@amc-cpcd.org
37	Joseph	Lange	Netherlands - Scientific Advisor no 2	c.baank@amc-cpcd.org ; f.cobelens@amc-cpcd.org
38	Brigitte	Bazin	France - Scientific Advisor	brigitte.bazin@anrs.fr
39	Andreas	Meyerhans	Germany - Scientific Advisor	andreas.meyerhans@uniklinik-saarland.de
40	Jorge	President Sampiao	Former President of Portugal – Guest Speaker	

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Annex 5.2: Optimisation of the treatment of HIV and HIV-TB coinfections (Nick Paton)

Annex 5.3: Strengths and gaps in the areas of TB-HIV coinfection in Africa (Abraham Alabi and Mecky Matee)

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