EDCTP
European and Developing Countries Clinical Trials Partnership

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Executive Director's note

Dear readers,

As we say goodbye to 2010 and welcome 2011, it goes beyond simply ushering a new year, but also the beginning of a new era. Following the positive evaluation and impact assessment of the EDCTP programme, which included a public consultation, EDCTP-EEIG member states and the European Commission (EC) met and unanimously agreed to continue with the Partnership. At the Member State Consensus Meeting that was held on 27-28 September 2010 in Brussels, the participating member states, Latvia (observer member state), Poland, African representatives and the EC agreed to continue with EDCTP. It was agreed that the EDCTP-II programme, building on the current one should be bigger and more ambitious covering a period of up to twelve years divided into three terms. This includes (while still focusing on the current scope of HIV/AIDS, tuberculosis and malaria phase II and III clinical trials) to gradually expand to involve all clinical trials phases (I-IV), health service/optimisation research, other neglected tropical diseases, increased membership in Europe and collaborating with other developing countries besides sub-Saharan Africa. Thus in preparation for the EDCTP renewal, the participating member states through the Belgium presidency of the European Union have on 26 November 2010 presented to the EU Competitiveness Council our intension to continue with EDCTP. The plan is to launch EDCTP-II in 2012. This is indeed welcome news.

I wish all our partners and stakeholders a prosperous 2011 and the greater things to follow.

Professor Charles Mgone
EDCTP Executive Director

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Sixth EDCTP Forum: opening of registration and call for abstracts

EDCTP is pleased to announce that the Sixth EDCTP Forum registration is open through the forum website (www.edctpforum.org) and welcomes submission of abstracts. The theme of the forum is Strengthening Research Partnerships for Better Health and Sustainable Development, taking into account the past, present and future of EDCTP. The forum will be held from 9 to 12 October 2011 at the International Conference Centre in Addis Ababa, Ethiopia.

Abstract submission
Abstracts can be submitted in the following categories:
1. HIV/AIDS
2. Tuberculosis
3. Malaria
4. Cross-cutting issues (including Capacity Development, Networking, Ethics and Regulatory Affairs).

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The EDCTP Newsletter is available in three languages namely English, French and Portuguese. It is available in electronic format on our website (www.edctp.org) and in print in English for distribution mainly in sub-Saharan Africa.

Persons who wish to receive the print format should subscribe on the website (www.edctp.org, click on Newsroom).

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Events (continued from page 1)

Scientists involved in EDCTP-funded projects are required to share new developments and results from their projects. Selected abstracts will be published in the Sixth EDCTP Forum book and in a peer reviewed international journal.

Abstracts can be submitted through the online registration form available on the forum website at www.edctpforum.org by **30 June 2011.**

Scholarships
A limited number of individuals from sub-Saharan African countries will be sponsored by EDCTP to attend the Sixth Forum. Selection is based on individual's ability to present good-quality research in the development of new or improved drugs, vaccines, microbicides and diagnostics against HIV/AIDS, tuberculosis and malaria; or in other cross-cutting issues related to clinical trials in Africa such as ethics, regulatory affairs, capacity development and networking.

Scholarships can be submitted through the online registration form available on the forum website at www.edctpforum.org by **30 June 2011.**

The programme at a glance is now available online at www.edctpforum.org. It gives an overview of the whole week's thematic areas that will be addressed during the plenary and parallel sessions. In addition to the main programme, the satellite meeting "Clinical trials in practice: how to achieve the best protection of the study subjects?" will take place on Tuesday 11 October 2011 from 12:30 to 14:00 at the forum's venue. Organised by the "Switching the Poles" Clinical Research Network, this satellite meeting focuses on the challenge of achieving appropriate protection of patients participating in clinical trials carried out in resource-constrained settings.

For more information about the Sixth EDCTP Forum, please visit www.edctpforum.org.

EDCTP Awards to Outstanding African Scientists open for nomination

EDCTP is accepting nominations for the 2011 EDCTP awards to outstanding African scientists. These awards are open to anyone working in HIV/AIDS, tuberculosis and malaria within the scope of EDCTP programme of clinical trials, capacity development and networking, and are aimed at fostering the research activities of the winners.

The EDCTP awards consist of certificates of recognition together with a cash prize of 10,000 Euros for one junior scientist (less than 30 years old) and 20,000 Euros for one senior scientist. The funds could be used on activities such as support for short study periods at other institutions, collection of data for baseline studies or facilitation of travel for attendance of pertinent conferences.

Awards are granted in recognition of the scientist's achievements within their field whose fundamental discoveries, new theories, or breakthroughs have significantly impacted on their own discipline in theory and practise; and who are expected to continue developing in their field in the future. The prizes will be awarded at the Sixth EDCTP Forum in Addis Ababa, Ethiopia on 12 October 2011.

Please visit www.edctpforum.org for more information about the nominations criteria and procedure, and to download the nominations form. The completed nomination form should be sent to the EDCTP Secretariat before **Thursday 30 June 2011** through award@edctp.org.

News about EDCTP Governance

EDCTP announces African representation at the General Assembly

The European and Developing Countries Clinical Trials Partnership (EDCTP) promotes African commitment, leadership and co-ownership of the Partnership. In order to further strengthen African commitment and active involvement in EDCTP, the European Economic Interest Group (EEIG) General Assembly (GA) now has included African representatives as associate members. The current African representation includes members from the African Union (AU) Commission of Social Affairs, the East African Community (EAC), the Economic Community of Central African States (ECCAS) and the African Regional Committee of Health Ministers.

"I feel Africa has great potential to contribute to solving the many health problems especially those health problems associated with poverty. My role will be to advocate for improvement on the health systems. Advancement in medicines alone cannot solve the health problems", says Dr Alasford Ngwengwe, Zambian representative for the African Regional Committee of Health Ministers.

Dr Marlyse Peyou Ndi, from the Organisation for the Coordination of the Struggle Against Epidemics in Central Africa (OCEAC), the health arm of ECCAS, adds "I believe the role of African Representatives could be very strategic in increasing African participation, co-funding and ownership. This could be done more easily if they where GA members. All contributions of African institutions in terms of human resources and other contributions should be evaluated financially. A discussion should also be held with Regional Economic Blocks to encourage and empower them to advocate for budget lines for EDCTP activities at regional and country levels".

News about EDCTP governance (continued)

The current African representation at the GA comprises of:

The African Union (AU) Commission of Social Affairs
- Advocate Bience Gawanas, Commissioner Social Affairs of AU
- Dr Olawale Maiyegun, Director for Social Affairs of AU (Alternate representative for Advocate Gawanas)

The East African Community (EAC)
- Ambassador Juma Mwapachu, Secretary General of EAC
- Dr Stanley Sonoiya, Principal Health Officer of EAC (Alternate representative for Ambassador Mwapachu)

Dr Stanley Sonoiya, Professor John Gyapong, Professor Hannah Akuffo (GA chair) and Dr Olawale Maiyegun at the GA meeting on 19 November 2010

The Economic Community of Central African States (ECCAS) and the Organisation for the Coordination of the Struggle Against Epidemics in Central Africa (OCEAC)
- Dr Jean Jacques Moka, the Secretary General of OCEAC
- Dr Marlyse Peyou Ndi, Head of Studies, Planning and Training Department of OCEAC (Alternate representative for Dr Moka)

The African Regional Committee of Health Ministers
- Professor John Gyapong, Director Health Research Division Ghana
- Dr Alasford M. Ngwengwe, Chairperson of the Zambian National Health Research Advisory Committee (Alternate representative for Professor Gyapong)

Representation from the Regional Economic Communities (RECs) and the Regional Committee of Health Ministers is a two year membership on rotational basis. This is aimed at involving all RECs (officially recognised by AU) and African Ministries of Health.

The profiles of the African representatives are available on the EDCTP website at www.edctp.org

PB elects new Chair and welcomes a new member

Professor Shabbar Jaffar

The members of the EDCTP Partnership Board (PB) have elected Professor Shabbar Jaffar as their new Chair. Shabbar Jaffar is Professor of Epidemiology and Head of the MRC Tropical Epidemiology Group at London School of Hygiene and Tropical Medicine (LSHTM) where he has been based for almost 20 years. His main research areas are HIV, HIV/TB and health services/optimisation research. He has lived and worked in The Gambia, Uganda and South Africa and is currently involved in a number of public health research trials in partnership with health programme managers and other colleagues in Uganda, Tanzania and Zambia. He is a joint editor of the Tropical Medicine and International Health journal.

Prof. Jaffar succeeds Dr Sodimon Sirima as the PB Chair. EDCTP wishes to thank Dr Sirima for his dedication and invaluable contributions to the Partnership during the years of his term.

Additionally, Dr Salim Abdulla joined the PB as a new malaria expert. Dr Salim Abdulla is the Chief Executive Director of Ifakara Health Institute. He trained in medicine (MD) and epidemiology (MSc, PhD), and is currently involved in the evaluation of malaria vaccines and new malaria treatments for regulatory licensure. Previously he has managed large scale evaluations of insecticide treated bed nets and artemisinin based combinations therapy for national policy formulation. Dr Abdulla has published extensively on malaria intervention strategies and has interest in the translation of research results into policy and capacity development issues. He has received international awards including the Centenary Medal of the Royal Society of Tropical Medicine and Hygiene in the United Kingdom.

EDCTP welcomes new staff members

Sophie Mathewson
Networking Officer

Miss Sophie Mathewson is from London, United Kingdom. She has an undergraduate degree in Modern History and Modern Languages (Italian) from Wadham College, Oxford and an MSc in Public Health from the London School of Hygiene and Tropical Medicine. She has previously worked in areas ranging from journalism to public health, and has a particular interest in medical journalism. She also has experience in the UK Department of Health and completed a traineeship in the Health Research Unit of the DG-Research in the European Commission.

Nuraan Fakier
Project Officer

Miss Nuraan Fakier was born in Cape Town, South Africa. She has a background in psychology, with a Masters degree in Psychological Research from the University of Cape Town. Miss Fakier is currently completing a post-graduate diploma in International Research Ethics (University of Cape Town). Prior to her joining EDCTP, she worked as a researcher in stress and anxiety disorders and the substance abuse field. She now joins the EDCTP team as a Project Officer.

Jean Marie Vianney Habarugira
Project Officer

Mr Jean Marie was born and raised in Burundi. In 2000, he moved to Russia where he received his Master of Science in Pharmacy at the Volgograd State Medical University in 2006. He later moved to The Netherlands, continuing his academic education in a Drug Innovation program at the Utrecht University. He has been conducting research at the Royal Netherlands Tuberculosis Association (KNCV Tuberculosis Foundation), the Dutch Medicines Evaluation Board and conducted a six months research project at EDCTP as an intern.

News about calls and grants

Announcement of calls

The following calls for proposals will be launched in February 2011:

Call: Senior Fellowships
Call: Senior Fellowships linked to regional networks of excellence (NoE)

Purpose of the grants
Through these calls, EDCTP intends to identify and support senior researchers capable of building and leading research groups at sub-Saharan African institutions that will be internationally competitive and capable of winning grants from international funding bodies. This grant is both available for researchers already working in Africa as well as those looking to return to the continent. Regarding the Senior Fellowship NoE call, EDCTP specifically targets to contribute towards building of sustainable capacity through training and networking with links to the EDCTP supported regional networks of excellence in sub-Saharan Africa.

Call: Establishment and strengthening of African National Ethics Committees (NECs) and Institutional Review Boards (IRBs)

Purpose of the grant
EDCTP wishes to promote the establishment and strengthening of National Ethics Committees (NEC) and Institutional Review Boards (IRB) that are competent and independent. The NECs and the IRBs are encouraged to establish themselves administratively and financially so as to ensure sustained and independent function beyond the EDCTP funding. Strengthening of NEC or IRB aims at making them operational and gives support to their ongoing functions. Networking and training is encouraged and supported. Additional support in the form of online literature access, documentation, access to websites on ethics and GCP will be facilitated.

Funded projects

EDCTP is pleased to announce funding of the following projects:

Call: TB vaccines

Phase II double-blind, randomised, placebo-controlled study to evaluate the safety and immunogenicity of H1, an adjuvanted TB subunit vaccine in HIV-infected, BCG-vaccinated adults with CD4+ lymphocyte counts greater than 350 cells/mm3
Project Coordinator: Gavin J. Churchyard
Budget: € 2,389,273 (€1,112,275 EDCTP)
Duration of project: 30 September 2010-4 October 2012
African countries involved: South Africa and Tanzania.

Call: HIV treatment

Nutritional support for Africans starting antiretroviral therapy (NUSTART)
Project Coordinator: Suzanne Filteau
Budget: € 3,684,959 (€ 789,935 EDCTP)
Duration of project: 15 November 2010-15 November 2013
African countries involved: Ethiopia, Tanzania and Zambia.

Prevention of early mortality by presumptive tuberculosis treatment in HIV infected patients initiating antiretroviral therapy
Project Coordinator: Joseph Marie Albert Lange
Budget: € 4,066,409 (€ 2,434,484 EDCTP)
Duration of project: 17 September 2010-1 July 2013
African countries involved: Gabon, Mozambique, South Africa and Uganda.

Focus on EDCTP selected projects

The impact of rapid molecular diagnosis of tuberculosis on tuberculosis services and patient care – a cluster randomised trial (Professor Mark Nicol)

Improving diagnosis of tuberculosis (TB) is among the studies that EDCTP funds. An important recent advance has been the development of rapid nucleic acid amplification assays for detection of tuberculosis. One of the tests is the GeneXpert MTB/Rif that includes an integrated specimen processing real time PCR amplification systems designed for use at or close to the point of care. Through a Senior Fellowship grant by EDCTP, Professor Mark Nicol of the University of Cape Town has conducted a study on the impact of GeneXpert at clinic and patient level. In other studies GeneXpert has shown high sensitivity of diagnosis of TB in both smear-positive as well as smear-negative, culture-positive individuals including detection of the presence of rifampicin resistance. This is a cluster randomised study aiming to determine the impact of rapid testing with GeneXpert MTB/RIF when compared to the routine diagnostic algorithm. The primary impact outcomes to be assessed include time between first patient presentation to clinic with symptoms and appropriate treatment for TB and the proportion of patients in each arm with undiagnosed TB two months after the first TB test.

The study has established working relationships with the Foundation for Innovative New Diagnostics (FIND) and the grantee and his team are consortium members of the TB Clinical Diagnostics Research Consortium led from Johns Hopkins University of USA. The team is also part of the EDCTP sponsored TB-NEAT consortium led by Associate Professor Keertan Dheda.

The findings in the study to date show a potential great impact of Xpert testing in improving the diagnosis of tuberculosis in settings of high HIV prevalence. The study is still underway and final results are expected in 2011. However, the preliminary results formed a substantial component of a report submitted to the WHO Strategic and Technical Advisory Group (STAG) for Tuberculosis that endorsed the use GeneXpert to diagnose tuberculosis. Additionally, the National Health Laboratory Service of South Africa is evaluating the possible roll out of GeneXpert testing for routine services. The data from this study will be central to informing any policy decisions.

Focus on EDCTP selected projects

Capacity building for TB vaccine trials in Kenya (Dr Anja van't Hoog)

Currently, there is no vaccine that can reliably prevent pulmonary tuberculosis (TB) in adults. *Mycobacterium tuberculosis*, the primary causative agent of TB, is reportedly responsible for eight million new cases of the disease and two million deaths each year, making it one of the world's most lethal infectious agents and one that causes more adult deaths than any other pathogen. Additionally, strains of *M tuberculosis* resistant to the antibiotics used to treat TB are rapidly emerging worldwide. Dr Anja van't Hoog from the Kenya Medical Research Institute (KEMRI), in collaboration with Aeras Global TB Vaccine Foundation (USA), Centre for Disease Control and Prevention (CDC), KNCV Tuberculosis Foundation (Netherlands), Ministry of Health (Kenya), San Raffaelle del Monte Tabor Foundation (Italy), University of Cape Town (South Africa) and the Vienna School of Clinical Research (Austria), and with an EDCTP grant, coordinates a project to strengthen the KEMRI research site to build the capacity for future phase II and III TB vaccine trials according to International Conference on Harmonisation (ICH)/Good Clinical Practice (GCP) standards in Western Kenya.

This project led by Dr van't Hoog aims to develop the capacity of the KREMRI/CDC site to carry out phase II and III vaccine trials through the execution of two epidemiological studies to form, track and retain a neonatal and an adolescent cohort, develop capacity to vaccinate infants (delivered at home) within 96 hours, measure the incidence of TB disease in neonates, the prevalence and incidence of *Mycobacterium tuberculosis* infection and TB disease in adolescents, develop active surveillance for tuberculosis in neonates and adolescents, develop staff capacity to conduct clinical trials, and improve clinical research and TB laboratory infrastructure.

The study which began in June 2007 is conducted in Karemo division of the Siaya district in Kenya.

The project combines an observational cohort study with no experimental interventions of neonates and of 14-18 year old adolescents. The neonatal study aims to build capacity to estimate the one year incidence of TB disease as diagnosed by two sputum smears positive for AFB and/or a positive *Mycobacterial* culture. The adolescent study aims to estimate the optimal way to access an adolescent population in vaccine trials.

By May 2010, the adolescent cohort study had concluded its full enrolment with data analysis completed by September 2010. The infant cohort

From the left: Dr Kayla Laserson, the Research Unit Director, Dr Anja van't Hoog (middle) and Dr Videlis Nduba (right), the site investigators.

study completed enrolment of 2900 newborns in June 2010 and follow up will continue until mid 2011. All project staff have been trained in good clinical practice as well as some 25 staff members participating in an Ethical Aspects in Clinical Research course organised by the Vienna School of Clinical Research. Three staff members are working on PhD's, and four on Master's degrees. A state of the art TB laboratory is operational since early 2010 and a clinical facility to enhance the diagnosis of paediatric TB has been established in Siaya District Hospital.

KEMRI/CDC site investigators are among the founding members of the TB-VACSIN network. This network aims at strengthening African capacity for multi-site TB vaccine trials through sharing experiences and the development of diagnostic and quality standards, and has enhanced South-South networking within the project. The South-North collaboration has promoted training and technical assistance from European and American collaborating partners in the areas of clinical research, laboratory practice, TB diagnosis and PhD degree programs.

This project has facilitated readiness of the KEMRI/CDC site and the first TB vaccine trial has started at the site in 2010. A phase IIB clinical trial has started in 2010 in infants, utilising the capacity that has been built through the epidemiological studies. The epidemiological studies will be completed in 2010 and 2011. It is expected that more trials will follow as more suitable vaccine candidates move through the pipeline.

EDCTP-funded clinical trial of SQ109 receives international support

Sequella, Inc. has signed an agreement with the Ludwig-Maximilians-University (LMU) to coordinate with the European and Developing Countries Clinical Trials Partnership (EDCTP) a grant for phase II clinical trials of SQ109 in adult pulmonary tuberculosis (TB) in seven sites in Africa.

The studies, which will support international regulatory submissions, will be performed by the Pan African Consortium for Evaluation of Antituberculosis Antibiotics (PanACEA).
The studies will be funded by a € 12 million grant by EDCTP and a € 3 million commitment by Sequella for in-kind and corporate funding. The multi-year clinical program will be directed by Professor Michael Hoelscher, Department of Infectious Diseases and Tropical Medicine, University Hospital of LMU, in conjunction with Sequella.

PanACEA is the EDCTP-funded network that aims at simplifying and shortening tuberculosis treatment. Its members include TB experts from six European research institutions, twelve sub-Saharan Africa clinical trial sites and two pharmaceutical companies. The trials will be conducted in clinical sites located in South Africa, Tanzania, Gabon, and Zambia.

Read the full press release on the EDCTP website at www.edctp.org.

Focus on EDCTP grantees

AMANET launches a Phase 2 clinical trial of candidate malaria vaccine GMZ2

In an EDCTP-funded project, the African Malaria Network Trust (AMANET) has launched a multi-site phase IIb clinical trial of the candidate malaria vaccine GMZ2 to assess its efficacy and safety among young children with a high risk of getting malaria in Burkina Faso, Gabon, Ghana and Uganda.

GMZ2 works by targeting the malaria parasite in the blood stage (merozoite), stimulating the body's immune system to produce agents (antibodies) that target GLURP and MSP3 receptors on the malaria parasite. GLURP and anti-MSP3 antibodies have been demonstrated to be able to completely inhibit malaria parasite growth in animal experiments. Earlier studies of the GMZ2 candidate malaria vaccine confirmed that GMZ2 is safe for use in humans. It has been further confirmed that GMZ2 is able to induce the production of specific antibodies and memory B-cells targeting the plasmodial proteins GLURP and MSP3 at high levels.

A total of 1870 children aged between one and five years will be taking part of this trial from four participating sites in Banfora (Burkina Faso), Iganga (Uganda), Lambaréné (Gabon) and Navrongo (Ghana). In the trial, half the number of the participating children will receive three doses each of 100 µg of GMZ2 test vaccine while the other half (comparator group) will receive rabies vaccine. In three months, each child will have received three doses of either the test or comparator vaccine. All children will be observed for a period of two years. During this time, safety, immune response and clinical information will be collected and assessed to answer the question of whether this candidate malaria vaccine protects against malaria.

The trials are conducted by the GMZ2 Consortium, which is funded by EDCTP and has several work packages fostering research capacity strengthening, networking and project management coordinated by AMANET. Other partners for the consortium are the Centre National de Recherche et de Formation sur le Paludisme (CNRFP) in Burkina Faso, Statens Serum Institut (SSI) in Denmark, the Medical Research Unit at Albert Schweitzer Hospital (MRU-ASH) in Gabon, the Medical Research Council (MRC) Laboratories in The Gambia, University of Tübingen in Germany, Makerere University in Uganda and the London School of Hygiene and Tropical Medicine (LSHTM) in the UK.

Read the full press release on the EDCTP website at www.edctp.org.

Trials begin on potential vaccine to prevent mother-to-child transmission

In an EDCTP-funded project the Medical Research Council, UK (MRC, UK) in collaboration with researchers from Kenya, The Gambia, United States of America, Sweden, and Spain has started enrolment in two infant HIV-1 vaccine trials, known collectively as PedVacc. These trials examine the safety of a novel HIV-1 vaccine, MVA.HIVA, in infants. The trials are taking place in The Gambia and Kenya and will recruit in total 120 healthy, HIV-negative infants born to healthy, either HIV-positive or HIV-negative mothers.

The ultimate aim of this vaccine strategy in infants is to prevent mother-to-child transmission of HIV after birth. Over 60% of the global HIV-infected population lives in Africa and about half of the infected adults are women of childbearing age. Approximately half of mother-to-child transmission is due to breast-feeding, but formula feeding is not an option for many HIV-1 infected mothers. One of the best hopes for protecting newborns and infants in developing countries against mother-to-child transmission of HIV is through a safe, effective, accessible prophylactic vaccine, which would both reduce the adult burden of infection and/or protect neonates against acquiring HIV from their infected mothers during pregnancy or while breastfeeding.

The MVA.HIVA vaccine has been previously tested in 13 studies in the UK and Africa, involving a total of 375 adult volunteers. There have been no serious reactions related to this vaccine and it is confirmed to be safe and well tolerated. Furthermore, the MVA component was administered to more than 120,000 vaccines as part of the smallpox eradication programme, with no reported reactions, despite the deliberate vaccination of high-risk groups. More recently, a similar MVA-based vaccine for tuberculosis has been shown to be safe in infants in The Gambia.

The trials are being co-lead by investigators at the University of Nairobi, Kenya; MRC Unit Gambia; the University of Washington, USA; and the Karolinska Institute, Sweden. PedVacc also encompasses additional HIV vaccine development, which is headed by investigators at Hospital Clinic Barcelona, Spain.

Read the full press release on the EDCTP website at www.edctp.org.

Associate Professor Keertan Dheda receives Union Scientific Award for outstanding scientific achievements

The International Union Against Tuberculosis and Lung Disease (IUATLD) has awarded Associate Professor Keertan Dheda the 2010 Union Scientific Award at the 2010 IUATLD meeting in Berlin for his expertise on the fields of diagnostics and drug-resistant tuberculosis. The prestigious award is made annually to a researcher under the age of 45 who has made an outstanding contribution to the filed of tuberculosis and/or lung disease. Associate Professor Dheda, Director of the Lung Infection and Immunity Unit in the Department of Medicine at the University of Cape Town, is an EDCTP Senior Fellow and internationally recognised for his work in TB drug, TB immunology and drug-resistant TB. In addition, his work has influenced decisions and recommendations made by leading international TB health organisations.

Associate Professor Keertan Dheda (right) is congratulated on his IUATLD award by Dr Michael Kimerling of the Bill and Melinda Gates Foundation's Global ealth Programme for Infectious Disease

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