EDCTP

The power of sharing science

EDCTP Strategic Research Agenda

Version 2 – October 2017

Supported by the European Union

Introduction

The EDCTP Executive Secretariat (SEC) with scientific and strategic advice from the Scientific Advisory Committee (SAC) prepares a Strategic Research Agenda (SRA). This document is updated annually and provides the basis for the SEC to propose the annual work programme of the following year to the General Assembly for approval. The SRA outlines the key research and capacity gaps for diseases within the EDCTP scope and ranks them in terms of priorities. It aims to help researchers and other partners better understand current EDCTP research priorities, in light of EDCTP's overall mission to enhance research capacity and accelerate the development of new or improved medical interventions against poverty-related neglected diseases. The priority rankings consider the current importance of a topic and whether EDCTP, Participating States, or other partners are already funding projects addressing it. An asterix is added to a ranking if the topic is considered important but it is not within EDCTP's remit. The priority rankings are:

- **A** Areas of research or research capacity development of utmost importance for the short term
- **B** Areas of research or research capacity for the medium term
- **C** Areas of research for the long term
- **D** Areas of research that do not have to be addressed by EDCTP
- **A** **B** **C** **D** Areas of research that are deemed as priority topics in the field but are not a primary priority for EDCTP

The SRA also indicates how those priorities are being addressed, either through calls for proposals that are centrally managed by EDCTP or through Participating States Initiated Activities. (PSIAs).

Funding arrangements

EDCTP receives funds from the European Union through the Horizon 2020 programme. Participating States also make contributions (cash or in-kind) to activities aligned with EDCTP's goals. Third parties, including industry, product development partnerships, development organisations and research institutions, also make cash or in-kind contributions to EDCTP calls.

The table below indicates the type(s) of Horizon 2020 actions that could be used to address a priority.

Participating States-Initiated Activities

The EDCTP2 portfolio also includes activities that, although they are implemented or funded by one or more Participating States, fall within the scope of EDCTP2. These Participating States-Initiated Activities (PSIAs) are included in EDCTP2 annual work plans to promote coordination and, where appropriate, integration of national programmes and activities.

In the table, the PSIAs are indicated to the right of the column on EDCTP-funded studies. The table presents EDCTP priorities for research on the following poverty-related diseases: human immunodeficiency virus (HIV), tuberculosis (TB), malaria, neglected infectious diseases (NID), emerging and re-emerging infectious diseases with epidemic potential, diarrhoeal diseases, lower respiratory tract infections, and ethics/regulatory issues.

HIV

In light of changing demographics in Africa that will mean increasing numbers of young people at risk of HIV exposure, along with ongoing challenges with antiretroviral (ARV) drug resistance and gaps in progress toward the 90-90-90 targets (90% of people living with HIV knowing their status, 90% of HIV-positive people on antiretroviral treatment [ART], and 90% of people on ART virally supressed), the 2018 strategic research agenda for HIV focuses on trials of innovative biomedical HIV prevention tools, strategies to reduce ARV resistance, and product-focused implementation research. Understanding biological susceptibility and pathogenesis remains paramount. Following on the September 2017 Stakeholder meeting on co-morbidities and co-infections, the 2018 strategic research agenda for HIV includes co-infections with human papilloma virus (HPV), malaria, and schistosomiasis, as well as research investigating the impact of the vaginal microbiome on product efficacy. Other priorities include treatment optimisation for adults, children, adolescents, and pregnant women; improved diagnostics; and strategies to address the sexual and reproductive health needs of women living with and at risk of HIV. Priority topics that are already being addressed by EDCTP or other partners have been given lower ratings and/or an asterix.

Topic	Description	Priority	EDCTP grant type	EDCTP2-funded studies (grant code, acronym)	PSIA code, EDCTP Participating State[1]
Pathogen traits	Multi-clade virus	D	-		
Disease profile			-		
Epidemiology	HIV/HPV co-infections, particularly in women	A	TMA	TMA2015CDF-1032 (TEHSA)	
	HIV and malaria co-infection in malaria endemic areas in all age groups	A	RIA, CSA, TMA		
	Description of causes of death associated with HIV	D	-		PSIA-2014-747 (PLATO II) United Kingdom
					PSIA-2014-747 United Kingdom
					PSIA-2014-753 United Kingdom
	Other co-infections and co-morbidities in HIV-infected patients				**PSIA-2016-384** Italy
Pathogenesis/host response / immune response	Improving our understanding of HIV pathogenesis and host immune responses for prevention and treatment.	A	RIA	TMA2016CDF-1582 (MIDAS)	PSIA-2014-747 United Kingdom
				TMA2016CDF-1598 (Kenya CVHIV)	PSIA-2014-747 United Kingdom
				TMA2016CDF-1597 (EDIIMark2)	
	HIV susceptibility, the vaginal microbiome (inflammatory cytokines, prevotella bivia, gardnerella), and vaginal tissue tenofovir levels	A	RIA, CSA, TMA		
Diagnosis and tracking	Tracking HIV drug resistance to prevent and limit spread of antiretroviral resistance	A	RIA, TMA		

1. Categorisation based on PSIA reporting

	The evaluation of novel diagnostic devices used in resource-limited settings	A	RIA		PSIA-2016-397 United Kingdom
	HIV-associated co-morbidities in adults and children	B	RIA, TMA	DRIA2014-314 (DREAMM)	
	ARV drug resistance in children	A	RIA, TMA	TMA2015SF-1037 (HIVDR)	
	Improve HIV diagnosis in infants born to HIV-positive mothers	A	RIA, TMA		PSIA-2015-730 Burkina Faso
	Early detection of HIV infection in pregnancy through point of care (POC) repeat testing at antenatal care (ANC) to reduce MTCT and improve maternal health	A	RIA, TMA	RIA2016MC-1615 (LIFE study)	
	Evaluation of combo tests for syphilis and HIV both in pregnant women at ANC and non-pregnant adults	B	RIA		
Treatments	Evaluation of new simple and tolerable paediatric ARV formulations as well as dose optimisation studies (based on pharmacokinetics, pharmacodynamics, pharmacogenetics [PK/PD/PG]) in infants and children	A	RIA	TRIA2015-1078 (CHAPAS-4)	
	Treatment optimisation based on PK/PD/PG of ART using existing drugs for the general adult population by sex, age, body weight, presence of co-infections, risk of drug interactions, etc. and for specific sub-populations such as pregnant and breastfeeding women, PWID (people who inject drugs), MSM (men who have sex with men), transgender people (interactions with hormone therapy), and elderly individuals with co-morbidities, etc.	A	RIA	TMA2016SF-1508 (PRACE) TMA2015CDF-1027 (READY-Study) TMA2016CDF-1566 (SPATOMA)	PSIA-2016-397 United Kingdom PSIA-2016-767 Zambia PSIA-2014-639 Italy PSIA-2014-753 United Kingdom
	Treatment of HIV- schistosomiasis coinfection in girls and women (female genital schistosomiasis) in endemic settings	A	RIA		
	Investigating novel therapeutics and novel use of existing therapeutics (ex: long-lasting formulations) to maximise adherence and prevent the evolution and impact of resistance	C	RIA, CSA, TMA		PSIA-2015-748 United Kingdom PSIA-2014-690 Ireland PSIA-2015-776 South Africa
	Reducing short- and long-term ART-associated complications and toxicities, and their impact on adherence and ARV resistance.	A	RIA, CSA, TMA	TMA2015CDF-1002 (TREND study)	PSIA-2014-751 United Kingdom PSIA-2014-747 United Kingdom PSIA-2014-747 United Kingdom

	Treatment of opportunistic infections and co-morbidities	A	RIA, CSA, TMA	TRIA2015-1092 (AMBITION-cm)	PSIA-2015-748 United Kingdom
					PSIA-2014-749 United Kingdom
					PSIA-2014-749 United Kingdom
					PSIA-2014-751 United Kingdom
					PSIA2016-397 United Kingdom
	ARVs and anti-tuberculosis drugs and dose optimisation studies to improve HIV-TB co- treatment	B	RIA, TMA	TMA2016CDF-1580 (SAEFRIF)	
	ARVs and anti-malarial drugs and dose optimisation studies to improve HIV-malaria co- treatment	A	RIA		
	ARV and other medications during pregnancy and breastfeeding	A	RIA, TMA		
	ARVs and anti-cancer drugs dose optimization studies to improve treatment of HIV-associated malignancies	B	RIA, TMA		
Prevention	HIV pre-exposure prophylaxis using long acting ARVs formulated as injectables, implants, and vaginal rings for prevention of HIV	B	RIA, CSA, TMA	SRIA2015-1061 CAPRISA 018	PSIA-2015-788 CAPRISA 008 South Africa
				RIA2016MC-1616 (CHAPS)	
	Examining new prevention technologies including combination biomedical prevention and multipurpose prevention technologies to prevent both pregnancy and HIV	B	RIA, TMA		PSIA-2014-620 Sweden
	Large-scale trials of HIV vaccines that have demonstrated suitable level of immunogenicity in early phase trials	B	CSA	SRIA2015-1066 (GREAT)	PSIA-2014-747 United Kingdom
				RIA2016V-1644 (PrEPVacc)	PSIA-2014-747 United Kingdom
					PSIA-2014-747 United Kingdom
	Studies of passive immunity strategies of antibody-mediated prevention (AMP) using promising broadly neutralizing antibodies as infusions or injections.	A	RIA, CSA, TMA		
	Effectiveness evaluation of option B+: adherence and impact	A	RIA, CSA, TMA		

	Prevention strategies for sexually transmitted infections, including vaccine-preventable infections such as HPV infection, in HIV-infected women	A	RIA		PSIA-2015-748 (PH01/14-39) United Kingdom PSIA-2014-747 United Kingdom
Product-focused implementation research	Examining models of service delivery that can increase acceptability to counselling and HIV testing in an equitable, sustainable, and ethical way to reach the first 90 of the 90-90-90 targets, i.e. 90% of people living with HIV knowing their HIV status. (e.g.: multi-centre cluster randomized trials to evaluate community-oriented approaches (home-based and outreach) employing community health care workers or lay counsellors)	B	RIA, CSA	EDCTP-CSA-2014-279 (TRIP)	PSIA-2016-397 United Kingdom PSIA-2015-379 Italy PSIA-2014-790 Uganda
	Optimising the integration of HIV/PMTCT and TB services, HIV/sexual and reproductive health/family planning and PMTCT programmes to identify HIV-positive women in late pregnancy or while breastfeeding, and to support long-term adherence to lifelong ART for the mothers and timely diagnosis of infection in infants and children	B	CSA, TMA	EDCTP-CSA-2014-279 (WISH)	PSIA-2015-752 United Kingdom PSIA-2014-608 Sweden PSIA-2014-645 Italy
				TMA2015CDF-1036 (sTEPWIse)	
				RIA2016MC-1617 (PROMISE-EPI)	
	Implementation research for HIV prevention, treatment, care and support for adolescents and youth	A	CSA, TMA	TMA2016CDF-1574 (FERDAR)	PSIA-2016-403 United Kingdom
	Supporting implementation science research to stimulate and sustain declines in population level HIV incidence, including through combination prevention trials that combine behavioural, structural, and biomedical interventions	C	RIA, CSA, TMA		PSIA-2014-751 United Kingdom
	Optimising effective linkage to care and adherence to treatment	A	RIA, CSA, TMA	TMA2015CDF-972 (REMIND)	PSIA-2014-789 Uganda
				TMA2016CDF-1602 (ABOUT)	PSIA-2014-798 Senegal
				TMA2016CDF-1548 (ARA)	
Critical infrastructure & human development needs	How best to expanding HIV treatment services to address the need for integrated sexual and reproductive health services for women living with HIV (including family planning and cervical cancer screening and treatment)	A	CSA,TMA		PSIA-2015-748 United Kingdom PSIA-2016-414 Sweden PSIA-2014-753 United Kingdom PSIA-2014-753 United Kingdom

Tuberculosis

Tuberculosis (TB) remains one of the main causes of death in sub-Saharan countries and in 2016, 40% of all deaths among people living with HIV were due to TB. There is still a poor understanding of the disease profile, especially the quiescent sub-clinical phase that could benefit from targeted interventions for early diagnosis, treatment, or prevention. TB diagnosis is sputum-based, which excludes young children and patients with extra-pulmonary or disseminated forms of disease. There is still no real point-of-care (POC) diagnostic test for TB. Efforts to shorten duration of treatment of both drug-susceptible and drug-resistant-tuberculosis should be continued and adjuvant host-directed therapies to improve response and prevent complications should be further evaluated. Potential drug-drug interactions with HIV treatment should be taken into account, given the high levels of HIV-TB co-infection. HIV infection is one of the main risk factors for tuberculosis in Africa. Research on both pathogen and host biomarkers for diagnosis, treatment, and prognosis of tuberculosis remain key priorities.

Topic	Description	Priority	EDCTP grant type	EDCTP2-funded studies (grant code, acronym)	PSIA code, EDCTP Participating State1
Pathogen traits	Evaluation of Mycobacterium tuberculosis strains' genomic differences in the species/lineages of the nine species of M. tuberculosis complex (MTBC) and their effect on the efficacy of distinct control tools in certain geographical areas.	C	CSA, TMA or PSIAs		
Disease profile	Evaluation of the sub-clinical TB stage in order to identify potential specific interventions (diagnosis; treatment; prevention	A	CSA, TMA or PSIAs	TMA2016CDF-1604 (TDRIFT)	
Epidemiology	Evaluation of drug-resistant TB in adults and children with and without concomitant HIV infection, focusing on a diagnostic or treatment product/regimen..	A	CSA, TMA or PSIAs	TMA2016CDF-1583 HCWs in HIV Clinics)	PSIA-2015-746 Mozambique
Pathogenesis/host response / immune response	Evaluation of specific host response and host signatures (notably immune response and signatures) as predictors of susceptibility, protection, prognosis, and response to treatment.	B	CSA, TMA or PSIAs	TMA2015SF-1043 (DTB)	PSIA-2015-748 United Kingdom
				TMA2015CDF-1012 (TB-Lung FACT)	PSIA-2014-747 United Kingdom
				TMA2016CDF-1546 (MyTB)	PSIA-2014-747 United Kingdom
				TMA2016SF-1535 (CaTCH-22)	PSIA-2014-747 United Kingdom
					PSIA-2014-753 United Kingdom
					PSIA-2014-753 United Kingdom

1. Categorisation based on PSIA reporting

Diagnosis and tracking	Evaluation of point-of-care diagnostic and prognostic products that are sensitive, specific, cheap, easy to use, yield a rapid result, and are applicable for the diagnosis of both drug-sensitive and drug-resistant TB. This will include existing and new diagnostics and prognostics in HIV-negative and HIV-positive adults and children.	A	RIA	DRIA2014-309 (Stop TB/HIV at One)	PSIA-2014-751 United Kingdom
				DRIA2014-326 (DIAMA)	PSIA-2015-752 United Kingdom
				TMA2015SF-1041 (OPTIMAL DIAGNOSIS)	
				RIA2016MC-1623 (RaPaed TB)	PSIA-2014-600 Norway PSIA-2015-779 South Africa PSIA-2014-791 Uganda PSIA-2015-760 Zambia PSIA-2015-806 and PSIA-2016-809 Mali and Germany PSIA-2016-734 Ghana
	Evaluation of diagnostic and prognostic pathogen and host biomarkers for the accurate identification of and differentiation between latent TB infection, sub-clinical disease, and active clinical TB disease (pulmonary TB and extrapulmonary TB), as well as prognostic biomarkers for the accurate prediction of TB risk in individuals with latent TB infection (LTBI) for prophylactic drug treatment.	B	RIA	DRIA2014-311 (ScreenTB)	PSIA-2014-753 United Kingdom
Treatment	Evaluating novel interventions using new TB drugs or formulations with new combination regimens.	A	RIA	RIA2016S-1632 (TREATS)	PSIA-2014-751 United Kingdom
				TRIA2015-1102 (PanACEA)	PSIA-2016-401 United Kingdom
				TMA2015CDF-1018 (Linezolid for DR-TB in South Africa)	PSIA-2015-808 Mali

Evaluate treatment regimens using a range of adjunct 'host-directed therapies' to shorten duration of therapy.	A	RIA		PSIA-2016-413 Spain PSIA-2016-771 Zambia PSIA-2016-782 and PSIA-2016-803 South Africa and Uganda PSIA-2016-413 Spain PSIA-2016-814 Congo
Improve treatment outcomes, and prevent long-term pulmonary and extra-pulmonary complications and other co-morbidity in adults and children with drug-sensitive and drug-resistant TB.	B	RIA	SRIA2015-1065 (Predict TB)	PSIA-2015-741 Niger
			TMA2015CDF-1052 (BTR-TB)	PSIA-2016-733 Ghana
			TMA2016CDF-1576 (Evaluate 4mTB)	
Pharmacokinetic drug interaction studies to determine optimal drug dosing and safety (especially in pregnancy, among children, and in the context of HIV coinfection).	A	RIA	RIA2016MC-1606 (VirTUAL)	
Identify optimal combination of medicines and treatment regimen-design for TB patients (adults and children) with isoniazid-resistant, rifampicin-resistant, multidrug-resistant (MDR-TB), and extensively drug-resistant (XDR-TB).	A	RIA		PSIA-2014-749 (STREAM) United Kingdom PSIA-2015-752 United Kingdom PSIA-2015-772 Gabon

Prevention	Evaluation of new vaccines and chemoprophylactic TB drug regimens.	A	RIA	RIA2016S-1638 (POI-TB)	PSIA-2016-385 and PSIA-2014-388 Norway/Denmark
				RIA2016V-1645 (priMe)	PSIA-2014-751 United Kingdom
				RIA2016V-1631 (POR TB consortium)	
				RIA2016V-1637 (MTBVAC – Newborns)	
Product-focused implementation research	Delivery methods and research on the use of diagnostics and drugs after they have been tested successfully and in a cost-effective manner.	B	CSA, TMA or PSIAs	EDCTP-CSA-2014-283 (TWENDE)	PSIA-2016-397 United Kingdom
				CSA2016S-1627 (PAVIA)	
	Scale up and integration of HIV/TB prevention, treatment, and services; and innovative use of existing and new strategies to prevent, diagnose, and manage TB, MDR-TB and TB/HIV co-infections.	B	PSIAs	TMA2016CDF-1570 (ECIP)	PSIA-2016-397 United Kingdom PSIA-2016-398 United Kingdom PSIA-2016-403 United Kingdom PSIA-2016-400 United Kingdom
				CSA2016S-1608 (EXIT-TB)	PSIA-2016-397 United Kingdom PSIA-2016-397 United Kingdom PSIA-2016-397 United Kingdom

Critical infrastructure & human development needs	Development and expansion of TB clinical trials sites.	A	PSIAs	PSIA-2015-780 South Africa PSIA-2016-783 South Africa PSIA-2016-732 Ghana

Malaria

Sub-Saharan Africa continues to be plagued by malaria, despite some success in reducing infection rates in countries. WHO estimates that malaria accounts for 25–35% of all outpatient visits, 20–45% of hospital admissions, and 15–35% of hospital deaths in endemic African countries each year. However, accurate estimates of the current clinical and cost burden of malaria are difficult to make due to variation in the methods used to diagnose malaria and lack of adequate data. To solve this, methodologies for identifying, estimating, and tracking the malaria burden, as well as new strategies to measure transmission, are indispensable. According to WHO, over the last 15 years malaria incidence fell by 37% globally and death rates fell by 60%. However, serious bottlenecks remain in providing full access to malaria prevention, diagnostic testing, and treatment.

Almost 70% of the global total of new HIV infections annually occurs in SSA. The majority of these, which includes 3 million children and nearly 13 million women of reproductive age living with HIV, are people residing in malaria endemic areas. Negative interactions between HIV and malaria in the context of co-infection have been described but the full extent of this requires further investigation. With new policies such as offering antiretroviral treatment (ART) immediately to all people diagnosed as HIV-positive, including pregnant women to prevent vertical transmission, many people receiving ART in Africa will also be exposed to drugs to prevent or treat malaria infections. Documenting the safety, efficacy, and drug interactions of antiretroviral and antimalarial drugs is a priority.

In the era of malaria elimination, radical cure of both P falciparum and P vivax asymptomatic infections in the entire population is the cornerstone. This includes vulnerable population groups such as children, pregnant women, individuals living with HIV, and those with genetic haemoglobinopathies. These individuals require antimalarial drugs that are not only highly efficacious but also have adequate safety profiles. Although a number of antimalarial drugs have been developed under the EDCTP1 umbrella over the last 10 years, the potential for development of resistance requires further research efforts to find new antimalarial drugs with modes of action that are different to those in current use. Given the added challenge being posed to the success of malaria control and elimination by the rise in insecticide resistance, research on new insecticides and ways to delay the onset of resistance is an urgent priority. Although there has been important progress in developing the first malaria vaccine, which is now entering pilot implementation trials, this vaccine product's efficacy is modest and relatively short-lasting. There is a continuing need to support the development and evaluation of more effective malaria vaccines. These are likely to be key to malaria elimination. There is a need to build on the EDCTP1 investments that supported two major phase II clinical trials of candidate malaria vaccines and enhanced capacity to conduct such trials by participating now in the evaluation of the current most promising vaccine candidates - sporozoite and combination vaccines.

Topic	Description	Priority	EDCTP grant type	EDCTP2-funded studies (grant code, acronym)	PSIA code, EDCTP Participating State
Pathogen traits	Evaluation of parasite determinants for severe disease especially in children and pregnant women.	D	-		
Disease profile	Evaluation of the contribution of asymptomatic malaria for disease transmission.	B	RIA, TMA		
Epidemiology	Evaluation of simple methodologies of identifying malaria transmission hotspots and the impact of focal control strategies on transmission, especially in relation to elimination strategies.	A	CSA, TMA	TMA2016SF-1514 (MEPIE study)	PSIA-2015-748 United Kingdom PSIA-2015-762 Zambia PSIA-2014-747 United Kingdom PSIA-2014-753 United Kingdom PSIA-2014-753 United Kingdom

1. Categorisation based on PSIA reporting

					PSIA-2015-770 United Kingdom PSIA-2015-773 Gabon
	Evaluation of simple ways of monitoring of drug and insecticide resistance and assessing the impact of such resistance on disease burden and transmission.	B	RIA, CSA, TMA	TMA2015CDF-973 (IPTp-SP resistance in Nigeria)	PSIA-2015-770 United Kingdom
	Defining indicators for surveillance: detecting infections and measuring transmission compared to measuring morbidity and mortality to malaria.	C	RIA, CSA, TMA		
Pathogenesis/host response / immune response	Determinants of host-parasite interaction and natural acquisition of immunity and its loss. Evaluation of biomarkers of protection for malaria.	C	CSA, TMA	TMA2015SF-1001 (SMART)	PSIA-2014-660 The Netherlands
				TMA2016CDF-1559 (EcoHeMa-Imuno)	PSIA-2014-753 United Kingdom
				TMA2016SF-1513 (CoNAIPS)	PSIA-2015-752 United Kingdom
					PSIA-2015-770 United Kingdom
					PSIA-2016-398 United Kingdom
					PSIA-2015-818 Senegal
Diagnosis and tracking	Evaluation of novel point of care diagnostic tests, including those for detection of P. vivax hypnozoites, and G6PD deficiency	A	RIA, CSA, TMA	TMA2016CDF-1605 (PSOP24-377)	PSIA-2014-747 United Kingdom
					PSIA-2016-785 South Africa
					PSIA-2015-770 United Kingdom
	Innovative use of new or existing technologies for malaria control and elimination efforts.	A	RIA, CSA, TMA		PSIA-2015-742 Niger
Treatments	Safety and efficacy testing of new drugs and optimisation of existing drugs, including evaluation of drug-drug interactions between antimalarials and other drugs such as ARVs (especially amongst children and pregnant women) and anti-TB drugs.	A	RIA,	TMA2016CDF-1555 (ESSLDPQ P4502D6)	PSIA-2015-761 Zambia PSIA-2014-616 Sweden

	Evaluation of malaria control approaches using drugs and vaccines including Mass Drug Administration (MDA) for malaria elimination.	A	RIA, CSA, TMA		PSIA-2014-751 United Kingdom
					PSIA-2014-747 United Kingdom
					PSIA-2014-751 United Kingdom
					PSIA-2014-792 Uganda
					PSIA-2014-756 Zambia
					PSIA-2014-619 Sweden
					PSIA-2014-617 Sweden
					PSIA-2016-768 Zambia
Prevention	Evaluation of novel drugs for prevention targeting different populations such as infants and pregnant women.	A	RIA	TRIA2015-1076 (IMPROVE study)	PSIA-2014-601 Norway
				TRIA2015-1076 b (IMPROVE-2 study)	PSIA-2014-751 United Kingdom
				RIA2016MC-1613 (MAMAH study)	PSIA-2014-751 United Kingdom
				TMA2016CDF-1584 (ETRAM)	PSIA-2014-751 United Kingdom
					PSIA-2014-753 United Kingdom
					PSIA-2014-757 Zambia
					PSIA-2014-745 Mozambique
					PSIA-2016-769 Zambia

	Evaluation of vaccines for prevention targeting different populations such as infants and pregnant women.			RIA2016V-1649 (MMVC)	PSIA-2014-718 Spain PSIA-2014-747 United Kingdom PSIA-2014-747 United Kingdom PSIA-2014-753 United Kingdom PSIA-2014-718 Spain PSIA-2014-786 Senegal PSIA-2014-846 Tanzania PSIA-2015-850 and PSIA-2016-810 Tanzania and Mali
Product-focused implementation research	Evaluation of novel implementation approaches for new and existing interventions.	B	RIA, CSA, TMA	EDCTP-CSA-2014-276 (IMPP-ACT)	PSIA-2016-398 United Kingdom PSIA-2016-401 United Kingdom PSIA-2015-842 The Gambia PSIA-2015-843 The Gambia
	Improved strategies for scale-up of access to drugs, vaccines, and diagnostics and for monitoring and evaluation of coverage.	A	RIA, CSA, TMA	EDCTP-CSA-2014-282 IMPACT	PSIA-2014-751 United Kingdom PSIA-2015-836 Cameroon PSIA-2016-853 The Gambia
	Evaluation of the feasibility and cost-effectiveness of improved information systems for optimising malaria treatment strategies and prevention of drug stock-outs.	A	RIA, CSA, TMA		PSIA-2014-751 United Kingdom

Critical infrastructure & human development needs	Development of infrastructure for conduct of Phase I to Phase IV trials of malaria interventions.	B	CSA	TMA2015SF-998 (MaReCa)	PSIA-2014-724 Austria PSIA-2016-734 Congo
	Development of infrastructure to support epidemiological studies and assessment of transmission reduction potential of new malaria interventions including diagnostics, drugs and vaccines.	D	-		PSIA-2015-752 United Kingdom PSIA-2016-415 Sweden

Neglected Infectious Diseases (NIDs)

The 17 NIDs cover a broad range of different diseases. Even within groups, such as 'helminthic diseases', the challenges to achieving control and elimination are very different for individual diseases. One sixth of the world population is suffering from one or more NIDs with 50% of the affected population living in sub-Saharan Africa. Many of these diseases are avoidable or treatable. More precise tools for diagnosis, better treatment regimens, novel drugs, and enhanced awareness are needed to make progress in the control and elimination of these diseases. A prominent area of neglect is in the understanding of the consequences of NID infections in the context of malaria, TB, or HIV infection but in the presence of non-communicable diseases (NCDs). Development of drugs, diagnostics, and vaccines are a priority, if poorly covered by other programs, along with improved understanding of the consequences of co-infection and co-morbidity. Finally, because many NID exist due to fragile local health systems, programmes to strengthen them by building better infrastructure for good clinical and regulatory practice are required.

Topic	Description	Priority	EDCTP grant type	EDCTP2-funded studies (grant code, acronym)	PSIA code, EDCTP Participating State
Pathogen traits	NIDs include 17 different viral, bacterial, fungal, protozoal and helminth infections with diverse manifestations, life cycles and methods of transmission. They include: buruli ulcer, dengue/severe dengue, dracunculiasis (guinea-worm disease), echinococcosis, foodborne trematodiases, human African trypanosomiasis (sleeping sickness), leishmaniases, leprosy (Hansen disease), leptospirosis, lymphatic filariasis, mycetoma, onchocerciasis (river blindness), rabies, schistosomiasis, soil-transmitted helminthiases, taeniasis/cysticercosis, trachoma, and yaws	No priority needed as all diseases are part of NIDs	-		
Disease profile		D	RIA		
Epidemiology		D	CSA		PSIA-2014-747 United Kingdom
					PSIA-2014-753 United Kingdom
Pathogenesis/host response / immune response	Diverse mechanisms of pathogenesis and immunity. Potential for vaccines for buruli ulcer, dengue, hookworm, leishmaniasis, rabies, schistosomiasis. Provide focus for clinical studies.	B	RIA, TMA	TMA2016CDF-1571 (Maquisard)	PSIA-2015-748 United Kingdom
				TMA2016CDF-1561 (SecBILE)	PSIA-2015-748 United Kingdom
					PSIA2016-397 United Kingdom
					PSIA-2015-748 United Kingdom
					PSIA-2015-748 United Kingdom

1. Categorisation based on PSIA reporting

Diagnosis and tracking	Evaluation of diagnostic / biomarkers including response products to be used in population surveillance & monitoring for control, elimination, or eradication programmes.	A	RIA	DRIA2014-308 (SOLID)	PSIA-2015-680 Finland PSIA-2015-762 Zambia
				DRIA2014-306 (DiTECT-HAT)	PSIA-2015-748 United Kingdom
				TMA2015CDF-979 (BU-RPA)	PSIA-2016-766 Zambia
				TMA2015CDF-995 (UCE)	
				TMA2016SF-1437 (EvaLAMP & db-NALFIA)	
				RIA2016MC-1626 (FREEBILY)	
Treatments	The evaluation of novel drugs, drug combinations, immuno-chemotherapy, and formulations for treatment (in particular for buruli ulcer, dengue, human African trypanosomiasis, mycetoma, schistosomiasis, the filariases, and the leishmaniases).	A	RIA	RIA2016S-1635 (Afri-KA-DIA)	PSIA-2014-602 (OXA002) Norway
				RIA2016S-1641 (PZQ4PSAC)	PSIA-2014-602 Norway
				TMA2016SF-1509 (BuruliNox)	PSIA-2014-751 United Kingdom
					PSIA-2015-752 United Kingdom
					PSIA-2015-748 United Kingdom
					PSIA-2014-747 United Kingdom
					PSIA-2015-752 United Kingdom
Prevention	Evaluation of safety and efficacy of candidate vaccines (e.g. buruli ulcer, dengue, leishmaniasis, leprosy, rabies, schistosomiasis, and soil-transmitted helminths (STH)).	A	RIA	RIA2016V-1640 (PREV_PKDL)	
	Strengthen preventive chemotherapy and transmission control, used in MDA (mass drug administration) and MSAT (mass screen and treatment), of STHs, filariases, and trachoma through evaluation of drug combinations, formulations, and treatment regimens.	B	CSA		

Product-focused implementation research	Evaluating different approaches to interventions, ranging from novel treatments, MDA, vaccines, and diagnostics for both (i) improved treatment and (ii) disease elimination / control at population level.	A	RIA	TMA2015CDF-976 (Twice yearly treatment for the control of LF)	
	Optimisation and integration of the management of co-endemic NIDs (e.g. co-endemicity of lymphatic filariasis and onchocerciasis with loiasis); evaluation of the different disease burdens (regional versus localised); and effect of MDA including drug delivery, uptake, compliance and adherence, and strategies for accessing treatment especially during the endgame phase for PRDs targeted for elimination.	B	RIA		PSIA-2015-752 United Kingdom
Critical infrastructure & human development needs	MDA in populations across sub-Saharan Africa for helminth and trachoma infections that will require development/strengthening of surveillance and monitoring infrastructure, along with training of staff for pharmacovigilance and recognition of changing patterns of drug susceptibility.		CSA	CSA2016S-1618 (PROFORMA)	PSIA-2014-602 Norway

Emerging and re-emerging infectious diseases with epidemic potential

The outbreak of Ebola Virus Disease (EVD) in Guinea, Liberia, and Sierra Leone in 2014 had a devastating effect in those countries, causing over 10,000 deaths from EVD and many more than this through the disruption of the health systems for several years. Desperate attempts were made to develop and evaluate vaccines, treatments, and diagnostics for EVD during the epidemic, but these were largely unsuccessful because systems and capacity were not in place to carry out these activities on a very rapid timescale. It is vital that capacity is developed for the rapid evaluation of interventions in clinical trials should future outbreaks occur of emerging or re-emerging diseases. In parallel, strengthening surveillance systems to detect such outbreaks at an early stage and of laboratory systems to rapidly confirm diagnoses are of high priority. There is also a need to assemble background data on diseases, such as Lassa Fever, that are currently prevalent and have epidemic potential, which will aid in the planning of intervention trials of new interventions, such as vaccines and treatments, as these are developed.

Topic	Description	Priority	EDCTP grant type	EDCTP2-funded studies (grant code, acronym)	PSIA code, EDCTP Participating State
Pathogen traits	Pathogens with epidemic potential in sub-Saharan Africa. Obtaining baseline data on emerging and re-emerging pathogens, including antimicrobial resistance (incidence, prevalence and trends with time) Creating national and regional databases in existing local surveillance systems for emerging and re-emerging pathogens	A	CSA, TMA or PSIAs		
Disease profile	No defined priorities. Priorities will be developed when a major outbreak occurs	-	Fast track RIA1		
Epidemiology	Epidemiological studies of Lassa fever to identify risk factors for infection and areas of high infection incidence/prevalence which might be suitable for Phase 3 vaccine trials	A	Fast track RIA, CSA, TMA or PSIAs		PSIA-2014-747 United Kingdom
	Epidemiological studies of other priority pathogens on the WHO list needing urgent R&D attention (not all of which have been identified in sub-Saharan Africa): Arenaviral haemorrhagic fevers (including Lassa Fever); Crimean Congo Haemorrhagic Fever; Filoviral diseases (including Ebola and Marburg), Middle East Respiratory Syndrome Coronavirus (MERS-CoV), other highly pathogenic coronaviral diseases (such as Severe Acute Respiratory Syndrome (SARS)), Nipah, and related henipaviral diseases; Rift Valley Fever, Severe Fever with Thrombocytopenia Syndrome; and affordable. Collecting surveillance data on disease burden of these pathogens, where applicable, as a foundation for conducting future trials.	B	Fast track RIA, CSA, TMA or PSIAs		PSIA-2016-397 United Kingdom
					PSIA-2016-397 United Kingdom

1. Categorisation based on PSIA reporting

Pathogenesis/host response / immune response	No defined priorities. Priorities will be developed when a major outbreak occurs		Fast track RIA		PSIA-2016-397 United Kingdom
Diagnosis and tracking	Developing, evaluating, and deploying novel diagnostics and strengthening laboratory systems at country and regional levels, especially at the point-of-care and point-of-need sites for WHO priority pathogens (see above). This is to enable accurate and timely collection and analysis of information, along with laboratory systems capable of safely and accurately detecting all major dangerous pathogens with minimal bio risk.	A	CSA, TMA and/ or PSIAs	TMA2016CDF-1545 (EBOV-RDT-ROC)	
Treatments	No priorities currently. Several treatments are under development for a range of pathogens. These will require evaluation in the future when outbreaks occur	C	Fast track RIA		
	Development of capacity to conduct treatment trials when an outbreak occurs	B	CSA		
Prevention	Vaccines: Lassa Fever, Avian Influenza, Ebola Virus Disease	B	RIA	RIA2016V-1633 (NIFTY)	PSIA-2016-715 Germany PSIA-2016-907 Norway PSIA-2015-752 United Kingdom PSIA2016-907 Norway
Product-focused implementation research	No priorities currently.	-	-		
Critical infrastructure & human development needs	Promotion and development of national, regional, and pan-African capacities and monitoring systems that can identify emerging and re-emerging infectious disease threats through early warning and pro-active surveillance, enabling rapid response to emerging infectious diseases threats.	A	RIA, CSA	CSA-Ebola-2015-360 (ID-Clinical Capacity) CSA-Ebola-2015-353 (Capa-CT) CSA-Ebola-2015-337 (ENDORSE) EDCTP-CSA-Ebola-355 (RECAP-SL) EDCTP-CSA-Ebola-363 (SECC)	

			CSA-Ebola-2015-334 (SELeCT)
			TMA2016SF-1463 (REMODEL-TZ)
			TMA2016CDF-1563 (VxMedSSurv)
Development of regional clinical trial capacity for the rapid conduct of GCP-compliant Phase 1, 2 and 3 trials of new vaccines and other interventions against emerging pathogens	A	CSA and EDCTP NoE	RIA2016E-1612 (ALERRT)
			RIA2016E-1609 (PANDORA-ID-NET)
Mobile laboratories	A	PSIAs	

Diarrhoeal diseases

Following the Stakeholder meeting held in Amsterdam in July 2016 that reviewed the status of development of vaccines against diarrheal diseases, three major issues emerged that support the orientations proposed by the EDCTP SAC.

1 – The aetiology of severe diarrheal diseases in children below five in low income countries (LICs) corresponds to a limited set of pathogenic microorganisms encompassing rotavirus, Shigella, ST-producing enterotoxic E. coli (ETEC), and cryptosporidiosis; Campylobacter, and V. cholerae to a lesser extent.

2 – Growing implementation of the oral rotavirus vaccine shows spectacular decrease in incidence of diarrheal diseases in LICs, particularly in sub-saharan Africa.

3 – Shigella, ETEC and cryptosporidium hence have now reached a status of priority target for vaccine development with two particular orientations: Shigella and ETEC should should be considered in the form of a combined vaccine. The remote expectation for a candidate vaccine against cryposporidiosis calls for accelerated development or repurposing of efficient drugs. Because several oral and parenteral vaccine candidates against Shigella and ETEC have successfully passed the stage of phase 1 studies in the North, priority should be given to perform phase 2 studies in endemic zones, thus also calling for expert centres benefiting of a good epidemiological coverage of the relevant diseases.

Topic	Description	Priority	EDCTP grant type	EDCTP2-funded studies (grant code, acronym)	PSIA code, EDCTP Participating State
Pathogen traits	Rotavirus, Shigella, ETEC (ST and/or LT), Cryptosporidium, and Norovirus.	n/a	-		PSIA-2015-752 United Kingdom
Intestinal ecology	Microbiome, pathogens, and malnutrition	n/a	-		
Epidemiology	Collecting surveillance data on burden of diarrhoeal diseases and pathogens as a foundation for conducting future vaccine trials (In areas where clinical studies will be conducted)	A	CSA		
Pathogenesis/host response / immune response	Understanding oral vaccine effectiveness by examining mechanisms of host susceptibility to vaccine strains: histo/ blood group antigens, gut microbiome, effect of chronic/ repeated diarrhoeal episodes, and paediatric environmental enteropathy.	B	RIA, CSA, TMA	TMA2016CDF-1550 (ChoVaxim)	
	Improving immunogenicity of parenteral vaccines in infants and improving the development of good mucosal responses upon parenteral immunisation, Improving /combining routes and modes of immunization and defining/optimizing immunomonitoring assays and correlates of protection (i.e. B cell memory).	B	RIA, CSA, TMA		
Diagnosis and tracking	Developing point-of-care, multiplexed diagnostic tools allowing quick and reliable detection and diagnostic methods to be used in clinical trials and transferring this knowledge to laboratories in sub-Saharan Africa.	C	RIA, CSA, TMA		
Treatments	Testing of candidate molecules against Cryptosporidiosis, including drug repurposing, as cases occurring in non-immunocompromised patients are on average refractory to current treatments.	A	RIA		

1. Categorisation based on PSIA reporting

Prevention	Testing available vaccine candidates (phase 1 – validated) against the most prevalent diarrhoeal pathogens (i.e. Shigella, ETEC, and against Vibrio cholerae).	A	RIA	
	Improving effectiveness of existing rotavirus vaccines.	A	CSA, TMA	
Product-focused implementation research	Global implementation of current rotavirus vaccines.	D	-	TMA2016SF-1511 (ROVAS-2)
	Evaluating the immunogenicity of current Shigella, and ETEC vaccines in endemic zones.	A	RIA	
Critical infrastructure & human development needs	Community programs to reduce child morbidity and mortality through integrated community case management programs where diarrhoeal diseases are treated with zinc.	D	-	
	Selection and capacity strengthening of sites with epidemiological competence and experience in clinical trials.	A	CSA, TMA	
	Improved sentinel/ surveillance networks for diarrhoeal disease surveillance within and across regions.	D	-	

Lower Respiratory Tract Infections

Lower respiratory tract infections (LRTIs) caused by a range of pathogens in community or hospital settings are among the top four causes of mortality in children and adults globally. Further documentation of emerging threats from antibiotic-resistant bacteria in community-acquired or nosocomial LRTI in sub-Saharan African is urgently needed. Key research priorities are the improvement of diagnosis of LRTI through evaluation of optimised clinical algorithms; development of rapid multiplex platforms for diagnosis of bacteria, fungi, and viruses; and design of innovative imaging methods that are suitable to the conditions of health facilities of LMIC. Trials on shorter duration of antibiotic treatment for community-acquired LRTI among adults and children (living with HIV and HIV-negative) remain top priority, along with evaluation of adjunct 'host-directed therapies' to improve treatment outcomes. Development of new vaccines, evaluation of the impact of latest vaccines on the aetiology and severity of LRTI, and research on implementation models and on the scale-up of existing vaccines are also part of priorities.

Topic	Description	Priority	EDCTP grant type	EDCTP2-funded studies (grant code, acronym)	PSIA code, EDCTP Participating State[1]
Pathogen traits	To explore the traits of the following pathogens: Neonates and children: Group B Streptococcus; Respiratory Syncytial Virus; pneumococcus; cytomegalovirus; Bordetella pertussis for neonates Adults: pneumococcus, Haemophilus influenza, Klebsiella pneumoniae In HIV-infected patients: Pneumocystis jirovecii, fungal infections (e.g. Aspergillus fumigatus). Pregnant women: influenza and para influenza virus.	D	-		
	To document the emerging threats from antibiotic-resistant bacteria (extended spectrum beta-lactamase (ESBL)-producing K. pneumoniae and methicillin-resistant S. aureus (MRSA).	A	CSA, TMA or PSIAs		
Disease profile	To define the severity and outcome of LRTIs in: Adults with and without HIV infection Children with and without HIV infection Neonates Pregnant women Elderly persons Patients with other comorbidities.	B	CSA, TMA or PSIAs		

1. Categorisation based on PSIA reporting

Epidemiology	To identify the risk factors of LRTI in: Adults with and without HIV infection Children with and without HIV infection Neonates Pregnant women Patients with co-morbid diseases, e.g. diabetes mellitus, chronic obstructive pulmonary disease (COPD), and chronic renal and liver failure, who are likely to be infected with Gram-negative organisms such as Pseudomonas aeruginosa, K. pneumoniae and Escherichia coli.	D	CSA, TMA and/ or PSIA		
	To assess the incidence of community-acquired atypical pneumonia (there is uncertainty about the true incidence of so-called 'atypical infections' in patients with pneumonia in Africa. Infections with organisms such as C. pneumoniae and M. pneumoniae are cyclical).	D	-		
	To develop adequate surveillance programs to better clarify the epidemiology, aetiology, antimicrobial susceptibility patterns, and the effectiveness of preventive and curative strategies in place against paediatric LRTIs.	B	CSA, TMA and/ or PSIAs	TMA2015CDF-1033 (ALRTI)	
	Treatment: To assess the impact of early ART initiation on the occurrence of LRTI in patients living with HIV.	B	RIA CSA, TMA and/ or PSIAs		
	Vaccines: To assess the impact of latest vaccines for prevention of LRTIs (type b Haemophilus influenzae, Bordetella pertussis, Streptococcus pneumoniae, RSV, and Influenza) especially in children, pregnant women, and immunosuppressed patients).	C	RIA, CSA, TMA, PSIAs		
Pathogenesis/host response / immune response	To study peripheral blood and lung immune responses in LRTI affecting adults, children (both living with HIV and HIV-negative).	C	CSA, TMA and/ or PSIAs		PSIA-2016-397 United Kingdom

Diagnosis and tracking	To develop and evaluate more accurate clinical diagnostic and management algorithms for LRTIs according to age groups, comorbidities, and severity	B	RIA		
	To evaluate the latest multiplex diagnostic platforms for rapid diagnosis of bacterial, viral, and fungal causes of LRTIs.	A	RIA		
	To develop and evaluate innovative specimen collection methods that are easy to perform at lower level health facilities and well-tolerated to improve the aetiologic diagnosis of LRTI in neonates, children, and adults.	A	CSA, TMA and/ or PSIAs		
	To evaluate/optimise chest X-ray and new imaging technologies for diagnosis of LRTI (digitalized mobile X-ray, thermal imaging, computerized readers, portable ultrasound).	A	CSA, TMA and/ or PSIAs		
	To evaluate new or existing host-biomarkers (clinical and laboratory), clinical algorithms and currently available diagnostic tests for determining: 1) severity of illness and prognosis, 2) need for hospitalisation, 3) decision to prescribe antibiotics, and 4) how to improve treatment outcomes.	B	CSA, TMA and/ or PSIAs		
Treatments	To evaluate the efficacy of shorter duration antibiotic treatment regimens for community acquired LRTI, in children and adults (including those immunocompromised)	A	RIA		
	To evaluate simplified tools for management of hypoxemia for children with severe LRTI in resource limited settings.	A	RIA, CSA, TMA	RIA2016S-1636 (COAST-Nutrition)	PSIA-2015-748 United Kingdom
	To evaluate adjunct 'host-directed therapies' to improve treatment outcomes for LRTIs in HIV-infected adults and children, and to prevent long term pulmonary functional disability.	B	RIA		

Prevention	Chemoprophylactic prevention of LRTI in adults and children	A	RIA	PSIA-2014-747 United Kingdom
	To assess the impact of RSV vaccination of pregnant women on the rates, outcomes, and aetiologies of LRTIs in pregnant women and in their offspring	A	RIA, CSA, TMA	
	To evaluate novel non-capsular antigen vaccines for pneumococcus.	A	RIA, CSA, TMA	
	To evaluate the impact of conjugated pneumococcal vaccines in adults.	A	CSA, PSIAs	PSIA-2015-752 United Kingdom
	To evaluate the impact of group B streptococcus targeted vaccines in pregnant women on neonatal mortality and morbidity	B	RIA	
Product-focused implementation research	To optimize delivery and scaling-up of new vaccines (e.g. RSV) for LRTIs in partnership with other funders.	A	RIA, CSA, TMA	
	To support epidemiological and operational research to optimise cost-effective delivery and scaling-up of new diagnostics, drugs, and vaccines for LRTI after they have been tested successfully. This will also include scale-up and integration within acute medical services.	B	CSA or PSIAs	
	To assess the integration of LRTI management with HIV/TB/ malaria/diarrhoea treatments and services.	B	PSIAs	
Critical infrastructure & human development needs	To support training of local laboratory scientists/staff identified as a critical need, as well as good laboratory collection of baseline data for LRTIs.	B	PSIA and TMA	

Ethics and Regulatory

Critical infrastructure and human development needs	EDCTP2-funded studies (grant code, title of study, acronym)
	CSA2015ERC-880, Renforcement de l'Ethique des Essais Cliniques en Afrique de l'Ouest (REECAO)
	CSA2015ERC-873, Improving ethical review process in Sudan through capacity building of National Regulatory Authorities (Enhancing Ethics in Sudan)
	CSA2015ERC-863, Consortium for clinical research regulation and ethics capacity development in Uganda (CREDU)
	CSA2015ERC-876, East Africa pharmacovigilance initiative (EAPI)
	CSA2015ERC-872, Coast to coast: Transcontinental ethics partnership (C2C-TEP)
	CSA2015ERC-868, Developing LMHRA capacity to effectively exercise its regulatory mandate in clinical trials and health research in Liberia (Lib-Regul-Trials)
	CSA2016ERC-1422, AFRica Ethics Excellence NETwork (AFREENET)
	CSA2016ERC-1420, Improved Governance and Research Capacities in Diagnostics for Infectious Diseases of the Liberian Medicines and Health Products Regulatory Authority (IGORCADIA)
	CSA2016ERC-1418, HATUA - Enabling Compliance And Building Capacity And Community For Clinical Research In Kenya (HATUA – KENYA)
	CSA2016ERC-1423, Strengthening Bioethics Committees in Lusophone African Region (LusoAfro-BioEthics)
	CSA2016ERC-1416, Deepening Research Ethics in Nigeria Project (DREIN)
	CSA2016ERC-1432 Streamlining Ethics review process and Regulatory framework in Tanzania (SMERT)
	CSA2016ERC-1417, Strengthening the Capacity of the National Research and Ethics Review Committee and the National Regulatory Authority for Clinical Trials in Ethiopia (SteRN)
	CSA2016ERC-1414, Biomedical Ethics and Regulatory Capacity Building Partnership for Portuguese-Speaking African Countries (BERC-Luso)