

Note from the EDCTP Africa Office



Michael Makanga, Capacity Development Manager

The world is moved not only by the mighty shoves of the heroes but also by the aggregate of tiny pushes of each honest worker – Helen Keller

As we enter the last quarter of 2008, I am delighted to introduce the October issue of the EDCTP newsletter. The third quarter of 2008 has been a period of considerable scaling up of EDCTP activities in Africa. It also marks an important milestone of EDCTP celebrating its fifth anniversary on 15 September 2008. We launched calls for proposals on malaria treatment, malaria vaccines, Senior Fellowships and strengthening of Ethics Review Committees in Africa, and continued with the Joint Programme Activities call. A tuberculosis diagnostics stakeholder meeting was also successfully held with very valuable recommendations. Additionally, EDCTP funded a number of new projects that develop African scientific leadership and strengthen the ethics and regulatory framework in Africa.

EDCTP has continued its site visit activities to EDCTP funded projects. During the third quarter, EDCTP representatives visited institutions in Mali, Senegal, South Africa and the African Union in Ethiopia. The current issue of the newsletter also contains the call for new members to join both the PB and DCCC constituencies as well as an update on hosting agreements.

With the aggregate of tiny pushes of all EDCTP Secretariat staff, constituency members and stakeholders, together we contribute to a reduction of the challenges of the world's major poverty related diseases.

Events

EDCTP's fifth anniversary: Five years of HIV/AIDS, TB and malaria research integration

On Monday 15 September, EDCTP celebrated its fifth anniversary. Over 100 stakeholders and relations attended this informal event which was conducted simultaneously at the EDCTP Secretariat offices in The Hague and Cape Town. The event offered the opportunity to inform stakeholders on the ongoing activities and future strategies. EDCTP thanks all those who graced the events or sent words of congratulations and encouragement.



On the occasion of EDCTP's fifth anniversary a movie on the past, present and future of the partnership was produced. The movie, which is around 10 minutes, guides through EDCTP's inception, its goals, its achievements and future outlooks. Interested parties are invited to watch the movie at the EDCTP website: www.edctp.org and click on 'Movies' in the Newsroom.

Contents

Note from the Africa Office

Events

- EDCTP's Fifth Anniversary
- Fifth EDCTP Forum: One World, One Partnership

News about EDCTP Governance

- Vacancies: PB and DCCC members
- NWO extends hosting agreement to September 2010

News about Calls and Grants

- Calls open for application
 - Malaria Treatment
 - Malaria Vaccines
 - Ethics Review Committees
 - Senior Fellowships
 - Joint Programme Activities
 - Call for Experts
- Small Grants programme discontinued
- Funded projects
- TB Diagnosis stakeholder meeting

Focus on EDCTP grantees

- AMANET launches fourth web-based training

Meetings and visits

- High Representative visits African Union
- EDCTP site visit to Mali
- EDCTP site visit to Senegal
- EDCTP site visit to South Africa



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).



Events

Fifth EDCTP Forum (12-14 October 2009): One World, One Partnership

First announcement

The Fifth EDCTP Forum will take place in Arusha, Tanzania from 12 to 14 October 2009. The theme of the Forum is *Fighting HIV/AIDS, Tuberculosis and Malaria: One World, One Partnership*, and it will focus on the outcome and progress of EDCTP funding efforts in research and capacity strengthening activities in sub-Saharan Africa. It will be an important platform for everyone involved in research on the main three poverty related diseases (HIV/AIDS, tuberculosis and malaria) to establish or reinforce cooperation and synergy.

The programme

The forum programme will involve speakers from both the scientific and the political realm and focus on advances and agenda setting for clinical research on HIV/AIDS, tuberculosis and malaria. The programme will contain a mix of the following:

- Keynote addresses by invited speakers
- Plenary and parallel sessions
- Roundtable discussions
- Oral presentations of EDCTP funded projects on HIV/AIDS, tuberculosis and malaria in Africa
- Electronic posters sessions.

The venue

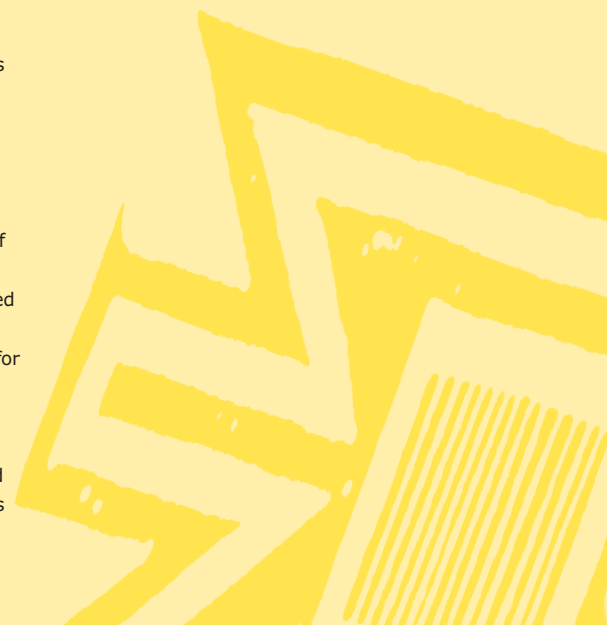
Ngurdoto Mountain Lodge, located in Arusha, Tanzania. Forum participants can stay at the hotel. Additionally, a list of alternative accommodation will be made available.

Participating in the Fifth EDCTP Forum

EDCTP will invite prominent keynote speakers for the plenary and parallel sessions. In addition, abstracts will be invited for oral and electronic poster presentations, preferably on EDCTP funded projects. EDCTP will publish a call for abstracts on its website soon and will circulate the information through a number of channels. A limited number of persons from sub-Saharan African working on EDCTP funded projects will be awarded bursaries. Details on how to submit an abstract and how to apply for a bursary will be published together with the call for abstracts.

In the coming months, EDCTP will launch and maintain the Fifth EDCTP Forum website. This website will give regular updates on the programme and on opportunities to join the

Forum. EDCTP will use various channels to announce the launch of this website and other updates on the Fifth EDCTP Forum, but for now please check the EDCTP website (www.edctp.org) regularly for any updates.



News about EDCTP Governance

Vacancies: PB and DCCC members (closing date 30 November)

EDCTP is seeking two new members for its Partnership Board (PB) and three members for its Developing Countries Coordinating Committee (DCCC).

Partnership Board (PB) members

The PB develops the strategic framework for the research programme of EDCTP and advises the General Assembly on technical and scientific matters relating to the EDCTP programme. The composition of the PB, comprising members from both the North and from disease-endemic countries, is a core element of the South-North partnership approach, which is at the basis of the EDCTP initiative.

EDCTP is looking for two senior scientific experts and health professionals with experience in one of the following areas:

- Industry/Regulatory Affairs
- Tuberculosis

Members shall be appointed for an initial term of up to two years, followed by conditional renewable terms of one year each for a

maximum period of five years. Two positions will become available from 1 January 2009. Applications will be accepted until 30 November 2008. We invite you to read the vacancy text for PB members (on www.edctp.org) for more details on the membership and how to apply.

Developing Countries Coordination Committee (DCCC) members

The DCCC ensures commitment, ownership and leadership of the EDCTP programme by the participating sub-Saharan Africa countries. The DCCC comprises 15 experts from sub-Saharan Africa who are involved in research, capacity strengthening related to disease management, and clinical trials on HIV/AIDS, tuberculosis and malaria.

EDCTP is looking for three senior scientific experts and health professionals from sub-Saharan Africa with experience in one or more of the following areas:

- HIV/AIDS (1 position for West African Region, 1 position for East African Region)
- Malaria (1 position for Central African Region)

Members shall be appointed for an initial term of up to two years, followed by conditional renewable terms of one year each for a maximum period of five years. Three positions will become available from 1 January 2009. Applications will be accepted until 30 November 2008. We invite you to read the vacancy text for DCCC members (on www.edctp.org) for more details on the membership and how to apply.

NWO extends hosting agreement to 15 September 2010

The Netherlands Organisation for Scientific Research (NWO) has extended its hosting agreement with EDCTP to 15 September 2010. This follows the extension of the South Africa's Medical Research Council's (MRC SA) hosting agreement to the same date for EDCTP's Africa Office earlier this year. Both NWO and MRC SA have confirmed that they will tender to host EDCTP secretariats after September 2010.

News about calls and grants

Calls open for application

Malaria Treatment: support of clinical trials, capacity building and networking

The main objectives of this call are:

- To conduct clinical trials using registered drugs on special groups including children and individuals co-infected with HIV. These studies may also include pharmacokinetics and interactions of anti-retroviral drugs
- To conduct phase II studies on new GMP antimalarials involving either artemisinin based combinations or non artemisinin based combinations.

Total available funds: € 6 million*

Open for application: 30 July 2008

Closed for application: 30 November 2008

* We expect the EDCTP contribution of to be matched by at least an equivalent amount of cofunding from the EDCTP-EEIG Member States and possibly from other organisations (third parties).

Malaria Vaccines: support of clinical trials, capacity building and networking

The main objective of this call is to conduct Phase I/II trials of malaria vaccines in African countries, including age de-escalating clinical trials. These may include safety, immunogenicity and efficacy trials in target populations which might be infants or children depending on transmission intensity and prior exposure.

Total available funds: € 6.5 million*

Open for application: 30 July 2008

Closed for application: 20 November 2008

* We expect the EDCTP contribution of to be matched by at least an equivalent amount of cofunding from the EDCTP-EEIG Member States and possibly from other organisations (third parties).

Ethics Review Committees

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 to ensure sustainability beyond the EDCTP funding. Strengthening of NECs and IRBs aims at making them operational and support their ongoing functions. Networking and training is encouraged and supported. Additional support in the form of online literature access, documents, access to websites on ethics and GCP will be facilitated.

Available funds: € 500,000

Open to application: 30 July 2008

Deadline for application: 30 November 2008

Senior Fellowships

Through this call, 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 (re-entry grant).

Available funds: € 1,200,000

Open to application: 30 July 2008

Deadline of application: 30 November 2008

Joint Programme Activities

The grant aims to fund projects that will identify and strengthen Joint Programme Activities (JPAs) and contribute to the integration of the national programmes of EDCTP Member States on HIV/AIDS, tuberculosis and malaria clinical trials within EDCTP scope in sub-Saharan Africa. It aims to enhance the activities of researchers investigating the same topic or disease, reduce duplication of effort and improve collaborations within or between African institutions.

Available funds: € 5 million

Open to application: 26 March 2008

Deadline of application: 5 December 2008

Call for Experts

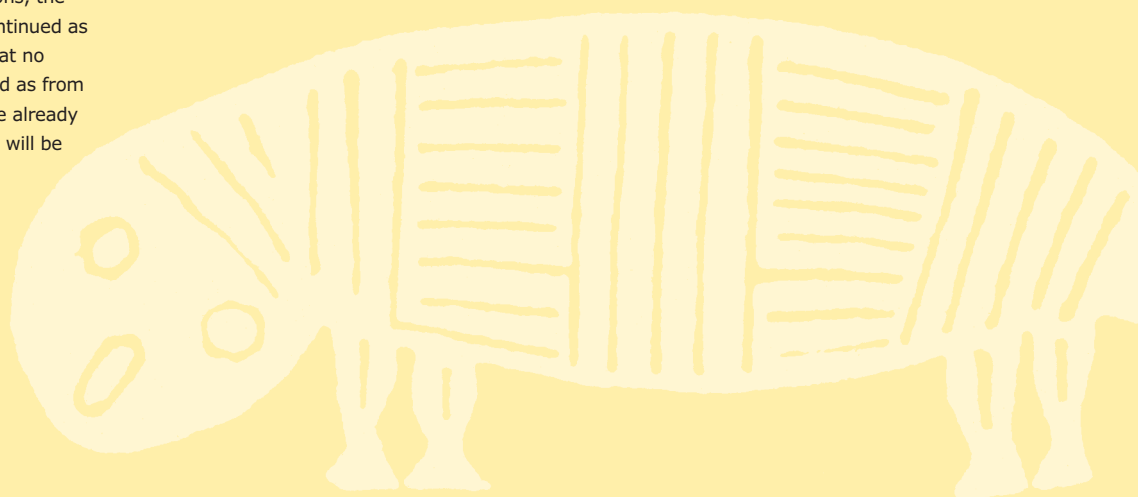
EDCTP invites applications from individuals wishing to serve on the EDCTP Scientific Review Committee (SRC) or as External Reviewers (ER) on the following subjects:

- Clinical trials for the diseases HIV/AIDS, tuberculosis and malaria
- Postgraduate training awards
- Capacity building grants including ethics and establishment of networks of excellence.

For details on the calls, the various advertisements and how to apply, please consult the relevant call texts and advertisements at the EDCTP website: www.edctp.org.

Small grants programme discontinued

Due to strategic and operational reasons, the small grants programme will be discontinued as from 15 October 2008. This means that no more new applications will be accepted as from this date. Those applications that have already been submitted on or before this date will be treated accordingly.



EDCTP TB Diagnosis stakeholder meeting, Paris 7 October 2008

EDCTP has a strategy for its calls and grants that focuses on a product-based approach. In order to realise this strategy EDCTP holds regular stakeholder meetings, which are used to recommend priorities to EDCTP in terms of products in the pipeline and suitable sites in sub-Saharan Africa to conduct the trials. On 7 October 2008, a stakeholder meeting on TB Diagnosis was held in Paris, at the Institut Pasteur. EDCTP has budgeted 8 million Euros to support clinical trials in TB diagnosis with expected matching funds from European member states. The studies will be funded from 2009 to 2011.

EDCTP realises that a more effective TB diagnostic tool is an essential component for both clinical research and treatment. In the light of this, the Partnership Board has recommended that EDCTP should launch a call that will lead to development of simpler, cheaper and more accurate TB diagnostic tools.

Sixty people participated in the meeting, including 35 scientific experts, 2 EDCTP General Assembly members, 7 Partnership Board members, 6 European Networking Officers, 3 DCCC members and 7 EDCTP Secretariat staff members. It was agreed at the meeting that EDCTP should seek application through an open call. The focus will be clinical trials of existing products near delivery at the point of care. Additionally, the trials would be part and parcel of ongoing TB trials in established clinical trial sites without the need to open new trial sites. The other areas to be included in the call will be those of improving TB diagnosis in children and establishment of a local repository of samples if feasible. EDCTP will launch this call in the first quarter of 2009 with the aim to start funding successful projects by end of that year.

Funded projects

EDCTP is pleased to announce funding of the following projects:

Senior Fellowships

- **Mark Nicol:** The impact of rapid genotypic detection of multi-drug resistant tuberculosis on treatment outcome in a semi-rural region of South Africa
- **Harr Freeya Njai:** Characterisation of neutralizing antibody responses in Chronic Clades A and D Human immunodeficiency virus type 1 (HIV-1) infections and the relationship with established markers of disease progression – A longitudinal study in Rural Uganda
- **Nicaise Ndembu:** Frequency and determinants of dual infection with different strains of HIV-1 in low and high risk populations in Uganda
- **Keertan Dheda:** Human lung innate immune pathways regulating the stasis and killing of *M. tuberculosis* in a high burden setting
- **Daniel Dodoo:** Assessment of functionality of antibodies that associate with protection from clinical malaria using the in vitro *p. falciparum* growth inhibition assay.

Establishment and the strengthening of African National Ethics Committees (NECs) or Institutional Review Boards (IRBs)

- **Ministry of Health Rwanda:** Strengthening of the Rwanda National Ethics Committee

- **Tanzania Health Research Forum:** Strengthening ethical standards and practices in the protection of participants in health research in Tanzania
- **Uganda National Council for Science and Technology:** Strengthening the National Scientific and Ethical Review System and Process in Uganda
- **National Institute for Medical Research:** Establishment of a local Institutional Review Board (IRB) in Mwanza, Tanzania and strengthen collaboration between the local and national IRBs
- **Ethiopian Bioethics Initiative:** Strengthening the Ethics of Health Research in Ethiopia
- **University of Ibadan:** Strengthening the National Health Research Ethics Committee of Nigeria (NHREC)
- **Biomedical Research & Training Institute:** Establishing an Ethics Research Unit.

Strengthening of regulatory environment in Africa

- **WHO-EDCTP Collaborative Project:** Programme to strengthen regulatory systems in African countries.

Focus on EDCTP grantees

AMANET launches fourth web-based training: Advanced Health Research Ethics Course

In September, the African Malaria Network Trust (AMANET) launched its fourth web-based course on Advanced Course on Health Research Ethics. This EDCTP-funded course provides a basic understanding of ethical issues and equips trainees (members of ethics committees, health researchers, scientists and other key personnel in health research) with the necessary tools and knowledge required to safeguard the safety

and welfare of human research participants. Other ongoing AMANET web-based courses are Basic Health Research Ethics (English version), Basic Health Research Ethics (French version) and Basic Good Clinical Practice. All courses are freely available at <http://webcourses.amanet-trust.org>.

Source: AMANET website (<http://www.amanet-trust.org>)

Meetings and Visits

High Representative visits African Union

Dr Pascoal Mocumbi, the EDCTP High Representative, visited the African Union (AU) Commission in Addis Ababa (Ethiopia) on 26 September 2008. He held talks with several officials including Professor Jean-Pierre Ezin, the Commissioner for Human Resources and Science and Technology. Dr Mocumbi updated AU officials on the work EDCTP is currently conducting and its future plans. In discussing EDCTP's future Dr Mocumbi requested political support in negotiations between the European Union (EU) and AU Commissions to consider allocation of development funds to clinical trials including strengthening and harmonisation of national regulatory and ethics environment at regional economic community levels in sub-Saharan Africa. The commission is anticipated to raise these issues at their next AU/EU Commissioners' meeting in Brussels.

EDCTP site visit to Mali

From 14 to 18 July 2008, EDCTP visited the University of Bamako and various patient recruitment sites in Bancoumana and Kolle in Mali. The EDCTP team consisted of Dr Pascoal Mocumbi (High Representative), Mr Simon Belcher (Director of Finance and Administration) and Dr Michael Makanga (Capacity Development Manager). The team had meetings with the scientists and management of the Malaria Research Training Centre (MRTC) of the University of Bamako, as well as Malian Government Ministers and other senior officials.

The Malaria Research Training Centre (MRTC), University of Bamako, which is involved in the following EDCTP supported projects:

- Assessment of the public health benefit of artemisinin based combination therapies for uncomplicated malaria treatment in Mali. This is a Senior Fellowship project for Dr Abdoulaye Djimde.
- Capacity building to prepare West African sites for clinical trials on HIV, TB and Malaria. This is part of the West African Network of Excellence project coordinated by Prof. Souleymane Mboup with Prof. Ogobara Doumbo as the Malian collaborator.
- Phase IIIb randomised comparative, open, multicentre study of efficacy, safety and impact on malaria incidence of repetitive treatment with 4 ACTs: pyronaridine-artesunate (PYR-AS), dihydroartemesinin-piperazine, amodiaquine-artesunate

EDCTP site visit to Senegal

From 18 to 22, August 2008, EDCTP made a visit to some of research institutions in Senegal. The EDCTP team consisted of Dr Pascoal Mocumbi (High Representative), Mr. Simon Belcher (Director of Finance and Administration), Dr Michael Makanga (Capacity Development Manager) and Prof. Alioune Dieye (DCCC member from Senegal). The team had meetings with the scientists and management of the following institutions with EDCTP supported projects:

Laboratory of Bacteriology and Virology of Le Dantec Hospital in Dakar (Laboratoire de Bactériologie-Virologie Le Dantec: LBVD)

- Capacity building to prepare West African sites for clinical trials on HIV, TB and Malaria. Prof. Souleymane Mboup is coordinator for this project.



- A proof-of-concept Phase IIb clinical trial to evaluate the protective efficacy of a booster MVA85A vaccination administered to healthy, HIV-infected adults in South Africa, Senegal and The Gambia: Prof. Souleymane Mboup is collaborating investigator in Senegal for this project.

University Cheikh Anta Diop of Dakar

- Randomized trial of the acceptability and efficacy of four drug regimens for seasonal intermittent preventive treatment for malaria. This is a Senior Fellowship project for Dr Badara Cisse.
- Capacity building to prepare West African sites for clinical trials on HIV, TB and Malaria. Prof. Souleymane Mboup is coordinator for this project.



EDCTP representatives and WHO Representative for Mali, Dr Diallo Fatoumata Binta (left) visit patient recruitment site in Bancoumana

- (AQ-AS) and artemether-lumefranine (AL) for uncomplicated malaria in children. This is a new integrated project with Dr Abdoulaye Djimde as PI.
- Host immunogenetic factors involved in the susceptibility and/or protection to malaria in patients with different malaria infection histories and in sympatric ethnic groups (Dogon and Fulani) in Mali: potential role of dendritic cells in protection against malaria. This is a PhD project for Dr Arama Charles.

Meetings with Government Minister and other senior officials

The EDCTP team had separate meetings with the Prime Minister of Republic of Mali,

Honourable Modibo Sidibé; the Minister of Secondary Education, High Education and Scientific Research, Honourable Amadou Touré; Minister of Health, Honourable Oumar Ibrahima Touré; Counsellor for Public Health; Dr Oumou Maiga; The WHO Representative for Mali, Dr Diallo Fatoumata Binta; the vice-Chancellor of the University of Mali, Prof. Amadou Diallo; the President of the Faculty of Medicine, Pharmacy and Odontostomatology (FMPOS) Ethics Review Committee, Prof. Mamadou Marouf Keita; the vice-Dean of FMPOS, Prof. Drissa Diallo; and the Director of Pharmacy and Medicines Board (DPM) Bamako, Prof. Ousmane Doumbia among others.



Regional Research and Training Centre of Fann (Centre Regional de Recherche et de Formation de Fann: CRCF)

- A proof-of-concept Phase IIb clinical trial to evaluate the protective efficacy of a booster MVA85A vaccination administered to healthy, HIV-infected adults in South Africa, Senegal and The Gambia: Prof. Souleymane Mboup is collaborating investigator in Senegal for this project.

Meetings with Minister of Health and other Senior Officials

The EDCTP team had separate meetings with the following persons among others: Honourable Dr Safiatou Thiam, Minister of Health and Prevention of Republic of Senegal;

EDCTP representatives meet with Honourable Dr Safiatou Thiam, Minister of Health and Prevention of Republic of Senegal (fourth from left)

Prof. Oumar Fei, Director Medical Services; Prof. Abdou Salam Sall, Vice Chancellor of the University Cheikh Anta Diop of Dakar (CAD); Prof. Cheikh Saad Bouh Boye, Dean Faculty of Medicine, Pharmacy and Odonto-Stomatology, CAD; Prof. Oumar Gaye, Head of department of Parasitology, CAD; Prof. Papa Salif Sow, Director of CRCF and Prof. Bernard Diop, Deputy Director CRCF.

Site visit to South Africa

From 29 September to 3 October 2008, EDCTP visited some of the EDCTP supported institutions in South Africa. The EDCTP team consisted of Mr Simon Belcher (Director of Finance and Administration), Dr Michael Makanga (Capacity Development Manager) and Dr Hulda Swai (the DCCC member based in South Africa). The team had meetings with the scientists and management of the following institutions that are involved in EDCTP-supported projects:

AURUM Institute for Health Research

- A controlled clinical trial to evaluate high dose rifampentine and moxifloxacin in the treatment of pulmonary tuberculosis: Dr Amina Jindani is Principal investigator and Professor Gavin Churchyard as co-investigator.
- Feasibility of and capacity building for adolescent HIV vaccine trials in South

Africa: Prof. Linda Bekker is coordinating investigator and Professor Gavin Churchyard as co-investigator.

Africa Centre for Health and Population Studies, University of Kwazulu-Natal

- A multicentre clinical trial investigating the impact of highly active antiretroviral therapy (HAART) during pregnancy and breastfeeding on MTCT and mother's health: The Kesho Bora Study: Prof. Marie Louise Newell.
- Feasibility of and capacity building for adolescent HIV vaccine trials in South Africa: Prof. Linda Bekker is coordinating investigator and Prof Marie Louise Newell as co-investigator.

EDCTP site visit to the Africa Centre for Health and Population Studies



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