Memorandum of Understanding

Between

The European & Developing Countries Clinical Trials Partnership (EDCTP), a European Economic Interest Group having its registered office in The Netherlands, at Laan van Nieuw Oost Indië 334, Den Haag, NL-2593 CE – registered with the Trade Register of 's Gravenhage on 26 June 2003 (end duration: 31 December 2025)

and

The European Federation of Pharmaceutical Industries and Associations (EFPIA), an international organisation with a permanent office in Brussels located Rue du Trône 108, Boîte 1, Brussels, B-1050 – registered under N° BE0418762559

for Clinical Research Fellowships with the collaboration of European-based pharmaceutical companies

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WHEREAS,
The European & Developing Countries Clinical Trials Partnership (EDCTP), created in 2003 as a European response to the global health crisis caused by the three main poverty-related diseases (PRDs) of HIV/AIDS, tuberculosis and malaria is currently a partnership between 16 European Countries, European Union and sub-Saharan African countries. The aim of the programme is to accelerate the development of new or improved drugs, vaccines, microbicides, and diagnostics against HIV/AIDS, tuberculosis and malaria through a partnership of European national research programmes on PRDs with their African counterparts in collaboration with the pharmaceutical industry and like-minded organisations.

WHEREAS,
The European Federation of Pharmaceutical Industries and Associations (EFPIA), created in 1978, which has no profit-making purpose, aims to promoting pharmaceutical discovery and development in Europe and to bring to the market medicinal products in order to improve human health worldwide. It operates as the representative organisation of the pharmaceutical industry in Europe. It pursues a mainly scientific aim, ensuring and promoting the technological and economic development of the pharmaceutical industry in Europe. The activities of the Association shall extend to all matters of common interest to its members. In particular, it aims to foster an environment that encourages pharmaceutical research and development, manufacture in compliance with high quality standards, intellectual property protection and the introduction of regulatory requirements to allow patients rapid access to medicinal products.

European & Developing Countries Clinical Trials Partnership
Laan van Nieuw Oost Indië 334, 2593 CE, The Hague, The Netherlands
Tel +31 (0)70-3440880
Fax +31 (0)70-3440899
Email info@edctp.org
Web www.edctp.org

Fédération Européenne d'Associations et d'Industries Pharmaceutiques
Leopold Plaza Building Rue du Trône 108 Boîte 1 B-1050 Bruxelles
T +32 2 626 25 55
www.efpia.eu

PARTIES HEREBY AGREE AS FOLLOWS:
EDCTP and EFPIA jointly agree to establish a Fellowship scheme for Clinical Researchers in European-based pharmaceutical companies' research centres.

1. Purpose of the EDCTP-EFPIA Fellowship scheme

1.1. The objective of this fellowship scheme is to support EDCTP capacity-building efforts by hosting clinical researchers from sub-Saharan Africa within European operations of EFPIA corporate members, in order for them to acquire specific skills related to the design, conduct or analysis of clinical trials and to offer training opportunities in the broader field of clinical research, beyond what can be gained from academic study or usual employment.

1.2. The fellowship should enable researchers to increase their competences as clinical research scientists and learning state-of-the-art methods in the conduction of trials.

2. Rationale for the EDCTP-EFPIA Fellowship scheme

2.1. The research-based pharmaceutical industry has developed skills related to clinical trials that cannot be acquired through academic training or medical/scientific practice. These skills encompass a broad range of topics, including clinical research and study design, biostatistics, data management, project management, study monitoring, report writing, pharmaceutical sciences, regulatory submissions, audits, etc. Within European-based pharmaceutical companies, these activities are performed to a very high standard. The intention is to offer sub-Saharan African scientists who are actively involved in clinical research projects the opportunity to gain hands-on experience in a pharmaceutical research setting. This exposure is expected to benefit these researchers and their home-institutions.

3. Expected benefits of the cooperation

3.1. Sub-Saharan African scientists are expected to acquire state-of-the-art skills related to clinical research that are directly relevant to their own professional goals. These will contribute to capacity-building in their home institutions and countries.

3.2. EDCTP is expected to benefit from this scheme in terms of its contribution to fulfilling the EDCTP capacity-building objectives.

3.3. Pharmaceutical research is expected to benefit from interactions with scientists from diverse backgrounds, including Sub-Saharan perspectives and experiences that will optimise knowledge exchange that is beneficial to the development of new or improved treatments in PRDs.

4. Framework

4.1. Researchers (both clinical and non-clinical staff) from an institution based or operating in sub-Saharan Africa with the adequate skills and experience (on a case-by-case basis and adapted

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to the available fellowship positions) are eligible to apply for an EDCTP-EFPIA Fellowship for training in a European-based pharmaceutical company[1].

4.2. The Fellowships will be awarded through open calls for proposals published by EDCTP, in coordination with pharmaceutical companies. EDCTP will be responsible for the pre-selection of candidates and the final selection of Fellows will be decided together with the pharmaceutical companies.

4.3. The Fellows will be placed in a selected pharmaceutical company for a period of 6 to 24 months, and their training will be tailored to meet objectives including the acquisition of specific skills agreed upon prior to the start of the scheme.

4.4. Fellows should have a guaranteed position at their home institution and will be expected to return to their home institution for a minimum of two years post-fellowship.

5. Design of the call, review procedure and evaluation process

5.1. EDCTP and EFPIA will design a Call for Fellowships, outlining the training areas to be covered, the duration of the Fellowships, planned schedule for the scheme etc. Calls may be launched either in general terms or to support specific training activities.

5.2. EDCTP will carry out the first evaluation of candidates based on predefined set of criteria agreed by both parties, and will inform the participating pharmaceutical companies of eligible applications received for the Fellowship scheme. Through a transparent and mutually agreed process, EDCTP and the companies that have expressed interest in specific candidates will jointly decide on the selected Fellows.

5.3. Candidates will have the opportunity to express a preference as to the pharmaceutical company they wish to be placed.

5.4. In order to monitor developments and outcome of the fellowships, Fellows and their company supervisors will be required to submit to EDCTP and copied to their home institutions, mid-term, final reports as well as a report one year after the end of the fellowships. A template of the reports will be available from the start of the fellowship to ensure that the aims of the scheme are closely followed by both the Fellow and the pharmaceutical supervisor. The reports will be completed by both the Fellow and the pharmaceutical supervisor, who will provide a report on the Fellow including identification of core skills, achievements during the course of the fellowship and potential areas of improvement and future development.

5.5. At the end of the Fellowships the pharmaceutical companies will not be allowed to retain the Fellows for a 2-year period following the Fellowship.

5.6. The Fellow will be required to submit a report and respond to a questionnaire 1 year after the end of the Fellowship.

6. Training scheme contents

6.1. The scheme should offer training in clinical trials that is focused on specific skills that the Fellow wishes to acquire and improve within the scope of an existing or potential EDCTP project.

[1] A European-based pharmaceutical company is a company whose headquarters are based in Europe, or which has an subsidiary in Europe, actively involded in fields relevant for the followship scheme.

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6.2. The Call for EDCTP-EFPIA Fellowships should be focused on clinical research activities that will develop Fellow's competences with relevance to each company's areas of activity. If relevant, the scheme may include working within different departments of the company, and in compliance with local laws and regulations, as well as EFPIA's applicable Codes, and with sub-contractors or other partners involved in relevant fields.

6.3. In agreement with the Fellow, each pharmaceutical company will design a customised scheme related to its on-going activities and in reference to the individual trainee's field of interest and expertise. This will include clearly defined ethics and compliance rules, outcomes and short- and long-term goals.

7. Administrative and financial terms

7.1. A contract drafted by EDCTP will be signed by the Fellow, his/her home institution and pharmaceutical sponsor.

7.2. An internal agreement or contract between the Fellow and the pharmaceutical sponsor will address specific conditions including confidentiality and professional conduct.

7.3. EDCTP will be responsible for costs as defined in the call relating to:

- Travel between home and host countries including visa procurement
- Living expenses except where companies pay salaries to visiting Fellows as usual practice
- Health and work insurance (as required and as applicable in the country(ies) where the fellowship is being executed)
- Funds to support a home visit when required for a training period of more than one year, for personal reasons and to support the link with the home institution.

7.4. The principal contribution of the pharmaceutical company will be in the form of in-kind funding, including time spent by the industry tutors, companies' materials and through fellow's access to internal training opportunities, etc, and be submitted to the EFPIA Codes. On a case-by-case basis, support for specific costs (e.g. health costs, salaries or stipends, housing, travel funds) may be provided by individual pharmaceutical companies and this will be reported to EDCTP so that the grant amount will be adjusted accordingly. Where appropriate, the pharmaceutical company would also support business-related expenses of up to €5000 (five thousand euroes) to attend relevant conferences and to support visits to other clinical trial centres where relevant.

7.5. EDCTP will be responsible for publication and dissemination of the calls and management of financial and administrative aspects.

8. Further secondment opportunities for industry personnel

8.1. In addition to the proposed fellowship scheme, EDCTP and EFPIA recognise the need and demand for opportunities to send or second European researchers from pharmaceutical companies to train for brief periods with African researchers in African research institutions and other relevant settings. This would also provide an opportunity to strengthen links between the research communities in the North and South as well as building capacity and delivering training on site. EDCTP could eventually play a role in facilitating such exchanges, but the initial focus would be on developing the fellowship scheme, which could then act as a platform for future initiatives and partnerships with Industry.

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8.2. EDCTP will also tap into the expertise available within European industry to assist in audits and reviews of on-going projects and applications. This may include using the expertise of retired industry employees who are willing to offer such expertise including in peer review.

9. Period of the agreement

9.1. This agreement becomes effective on the date of the last signature and continues for the duration of the second EDCTP programme. It may be modified by mutual written consent of both parties. The agreement may be terminated by any party upon a 60 day advance written notice to the other party.

Prof. Charles S. Mgone Date EDCTP Executive Director	Mr Andrew Witty Date EFPIA President
Prof. Hannah Akuffo Date EDCTP GA Chair Administration	Mr Richard Bergström Date EFPIA Director General

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