The Italian health research in partnership with Africa:

a survey on the ongoing projects

The *RicercaItaliaAfrica* Initiative of the Istituto Superiore di Sanità

The Italian health research in partnership with Africa:

a survey on the ongoing projects

The *RicercaItaliaAfrica* Initiative of the Istituto Superiore di Sanità

Rome (Italy), 2021

Istituto Superiore di Sanità

The Italian health research in partnership with Africa: a survey on the ongoing projects.

Edited by The Working Group *RicercaItaliaAfrica* Initiative of the Istituto Superiore di Sanità. 2021, 52 p.

In 2020 the *RicercaItaliaAfrica* Initiative of the Istituto Superiore di Sanità (Italian National Institute of Health ISS), launched a survey consulting about a hundred Italian researchers with records of collaborations with African partners to obtain a first map of Italy-Africa collaborative health research. The survey collected information on 39 ongoing project involving basic/preclinical, clinical and operational research, mainly on infectious diseases and to a lesser extent on health systems and non-communicable diseases, in many cases focused on child and maternal health. The project participants, working in different types of Italian public, no profit and private organizations, established partnerships with over 70 African institutions in Northern and Sub-Saharan Africa in projects where they act as coordinators, partners or third parties. Total budget available to the 39 projects is approximately €50 M, of which about €30 M directly supporting activities of Italian beneficiaries. This budget is largely provided by Privates, Foundations and Product Development Partnerships (PDPs). The European Commission is the largest public funder, contributing 15% of the total budget, and the Italian public agencies contribute altogether for 4% of the total budget of the national collaborative health research. The survey does not cover all Italy-Africa collaborative health research. A few projects are not recorded in this publication, funded by The Europe & Developing Countries Clinical Trial Partnership (EDCTP) or by the 5% Global Fund Initiative of the Italian Agency of Cooperation for Development (AICS). Some research activities are also conducted under academic high education collaborative schemes or within projects run by Italian civil society organisations. The missing information, however, does not significantly, quantitatively or qualitatively, modify the survey conclusions. This analysis reveals a very different landscape of the Italian collaborative research with Africa, in terms of the nature of the involved organizations and institutions as well as in the type and size of research activities. Motives of concern are that these activities are poorly, if at all, interconnected and that the marginal and erratic support by national public funding schemes prevents continuity and long term planning of the projects. On the other hand, the survey indicates that the scientific know-how spans several fields of basic, clinical and operational health research at a level which is clearly competitive and able to engage successful partnerships with laboratories and institutions of excellence throughout the African continent. This survey, the first updated source of information on Italy-Africa collaborations in health research, aims to prompt mutual communication and networking among researchers in Italy, Africa and worldwide. The *RicercaItaliaAfrica* Initiative of the ISS aims to further expand and use these results towards increasing the national public support of Italy-Africa collaborative health research.

Kew words: global health research; Africa-Italy partnership; *RicercaItaliaAfrica* Initiative

La recherche italienne en santé en partenariat avec l'Afrique: un aperçu des projets en cours.

Édité par l'Equipe *RicercaItaliaAfrica* Initiative of the Istituto Superiore di Sanità. 2021, 52 p.

L'Initiative *RicercaItaliaAfrica* de l'Istituto Superiore di Sanità, Rome, Italie, a lancé en 2020 une enquête auprès d'une centaine de chercheurs italiens ayant des rapports de collaborations avec des partenaires africains en vue d'obtenir une première carte de la collaboration Italie-Afrique dans le domaine de la recherche en santé. L'enquête a permis de recueillir des informations sur 39 projets en cours, impliquant la recherche fondamentale/préclinique, clinique et opérationnelle, principalement sur les maladies infectieuses et dans une moindre mesure sur les systèmes de santé et sur les maladies non transmissibles, dans de nombreux cas axés sur la santé infantile et maternelle. Les participants au projet, affiliés à divers types d'organisations italiennes (publiques, à but non lucratif et privées) ont établi des partenariats avec plus de 70 institutions en Afrique du Nord et en Afrique subsaharienne dans le cadre de projets où ils agissent en tant que coordinateurs, partenaires ou «third parties». Le budget total disponible pour les 39 projets est d'environ 50 M€, dont 30 M€ soutenant directement les activités des bénéficiaires italiens. Ce budget est largement fourni par des entreprises privées, des fondations et des "Product Development Partnership"(PDP); la Commission Européenne est le principal bailleur de fonds public, contribuant à 15% du budget total; les agences publiques italiennes contribuent au total à hauteur de 4% du budget total de la recherche en santé entre l'Italie et l'Afrique. L'enquête ne couvre pas toutes les collaborations de recherche en santé Italie-Afrique. Quelques projets, financés par EDCTP ou par l'Initiative «5% Global Fund» de l'Agence Italienne de Coopération pour le Développement (AICS) ne sont pas enregistrés ici. Certaines activités de recherche sont également menées dans le cadre de programmes de collaborations universitaires ou dans le cadre de projets gérés par des organisations de la société civile italienne. Cependant, ces informations ne modifient pas de manière significative, quantitative ou qualitative, les conclusions de l'enquête. Cette analyse révèle un paysage très diversifié de la collaboration dans le domaine de la recherche entre l'Italie et l'Afrique, en termes de la nature des organisations et institutions impliquées ainsi que du type et de la taille des activités de recherche. Les motifs de préoccupation sont que ces activités sont faiblement, voire pas du tout, interconnectées et que le soutien limité des régimes nationaux de financement public empêche la continuité et la planification à long terme des projets. D'autre part, l'enquête indique que le savoir-faire scientifique couvre plusieurs domaines de la recherche fondamentale, clinique et opérationnelle en santé à un niveau clairement compétitif et capable d'engager des partenariats fructueux avec des laboratoires et des institutions d'excellence sur tout le continent africain. Cette enquête, première source d'informations actualisées sur les collaborations Italie-Afrique dans la recherche en santé, vise à favoriser une communication mutuelle et un réseautage entre les chercheurs en Italie, en Afrique et dans le monde. L'Initiative *RicercaItaliaAfrica* de l'Istituto Superiore di Sanità vise à étendre davantage et à utiliser ces résultats pour accroître le soutien public national à la collaboration Italie-Afrique dans le domaine de la recherche en santé.

Mots clés: recherche en santé globale; partenariat Afrique-Italie; Initiative *RicercaItaliaAfrica*

A investigação italiana em saúde em parceria com a África: um inquérito dos projetos em andamento.
Editado pelo Equipe de Trabalho *RicercaItaliaAfrica* Initiative of the Istituto Superiore di Sanità. 2021, 52 p.

A Iniciativa *RicercaItaliaAfrica* do Istituto Superiore di Sanità, Roma, Italia, lançou em 2020 uma pesquisa que consultou cerca de cem pesquisadores italianos com registros de colaborações com parceiros africanos para obter um primeiro mapa de investigação colaborativa em saúde Itália-Africa. O inquérito recolheu informações sobre 39 projectos em curso envolvendo investigação básica/pré-clínica, clínica e operacional, principalmente sobre doenças infecciosas e, em menor medida, sobre sistemas de saúde e doenças não transmissíveis, em muitos casos focados na saúde infantil e materna. Os participantes do projecto, afiliados a diversos tipos de organizações italianas (públicas, sem fins lucrativos e privadas) estabeleceram parcerias com mais de 70 instituições africanas na Africa do Norte e na África Subsaariana, em projetos onde atuam como coordenadores, parceiros ou terceiros. O orçamento total disponível para os 39 projetos é de aproximadamente 50 M€, dos quais 30 M€ apoiam directamente as atividades dos beneficiários italianos. Este orçamento é amplamente fornecido por empresas privadas, fundações e "Product Development Partnership" (PDPs); a Comissão Europeia é o maior financiador público, contribuindo com 15% do orçamento total; os órgãos públicos italianos contribuem com 4% do orçamento total da investigação colaborativa em saúde Italia-Africa. A pesquisa não abrange todas as investigações colaborativas em saúde Itália-África. Alguns projetos não estão registrados aqui, financiados pela EDCTP ou pela "5% Global Fund Initiative" da Agência Italiana de Cooperação para o Desenvolvimento (AICS). Algumas atividades de investigaçãosão também realizadas no âmbito de esquemas de colaboração de ensino superior académico ou em projectos executados por organizações da sociedade civil italiana. Essas informações, entretanto, não modificam de forma significativa, quantitativa ou qualitativa, as conclusões da investigação. Esta análise revela uma paisagem muito diversa da pesquisa colaborativa italiana com África, em termos da natureza das organizações e instituições envolvidas, bem como no tipo e tamanho das atividades de investigação. Motivos de preocupação são que essas atividades estão mal, ou nada interconectadas e que o apoio marginal dos esquemas de financiamento público nacional impede a continuidade e o planeamento a longo prazo dos projetos. Por outro lado, o inquérito indica que o know-how científico abrange vários campos da investigação básica, clínica e operacional em saúde, a um nível claramente competitivo e capaz de estabelecer parcerias de sucesso com laboratórios e instituições de excelência em todo o continente africano. Esta pesquisa, a primeira fonte atualizada de informações sobre as colaborações Itália-África na investigação em saúde, tem como objetivo estimular a comunicação mútua e o trabalho em rede entre investigadores na Itália, em África e no restodo mundo. A Iniciativa *RicercaItaliaAfrica* do Istituto Superiore di Sanità visa expandir e usar esses resultados para aumentar o apoio público nacional à investigação colaborativa em saúde Itália-África.
Palavras-chave: investigação em saúde global; parceria África-Itália; Iniciativa *RicercaItaliaAfrica*

Correspondence to: ricercaitaliaafrica@iss.it

Acknowledgments
The *RicercaItaliaAfrica* Initiative is supported by the Istituto Superiore di Sanità.The Initiative is an Italy Independent Activity in the scope of EDCTP2 recorded as Participant State Initiated Activity - PSIA2020-2557. The *RicercaItaliaAfrica* Initiative gratefully acknowledges Marco Mirra, Luca Fucili, Massimiliano Di Gregorio and Stefano Lucattini, Istituto Superiore di Sanità, for the establishment and maintenance of the *RicercaItaliaAfrica* web survey database.

Graphic design and editing:
Giovanna Morini (Scientific Communication Service/Servizio Comunicazione Scientifica)

Cover:
Massimo Delle Femmine (Scientific Communication Service/Servizio Comunicazione Scientifica)

THE ITALIAN HEALTH RESEARCH IN PARTNERSHIP WITH AFRICA: A SURVEY ON THE ONGOING PROJECTS

Working Group The *RicercaItaliaAfrica* Initiative of the Istituto Superiore di Sanità*

Correspondence to: ricercaitaliaafrica@iss.it

Introduction

The interministerial Conference Italia-Africa on October 2018 in Rome and the Europe-Africa Forum on December 2018 in Wien highlighted how a partnership with Africa, based on equity and aiming to fuel a sustainable development in both continents, is a priority at the national and European level, respectively. Scientific research, particularly the one promoting global health, is a key element of such a partnership, inscribed in the Italian commitment to achieve the United Nations 2030 Sustainable Development Goals.

In the fight against infectious diseases, in 2019 the Italian commitment has been confirmed at the G7 meeting with the 15% increase in 2020-2022 of Italy's contribution to the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria, reaching a total of €161 M and confirming Italy's role as the 9th largest Global Fund donor in the world. Of particular relevance the Technical Support Spending initiative, for which 5% of the Italian contribution to the Global Fund is used to finance projects with a specific component on research in line with the Fund's activities, carried out by Italian research centres and institutions and civil society organisations.

In Africa, millions of people die prematurely for inadequate access to health care and for preventable/treatable diseases due to intolerable global inequalities, with nutritional deficiencies and communicable diseases being major causes of this disease burden. Importantly, climate changes, the increasing global movement of people and goods and the changing patterns of infectious diseases in Europe (e.g. the spread of multidrug resistant tuberculosis or the outbreaks of new/re-emerging vector borne diseases) indicate that an Italy-Africa partnership in global health research is needed to address societal needs and knowledge gaps on both sides of the Mediterranean.

A preliminary survey conducted in 2018 by the Istituto Superiore di Sanità (Italian National Institute of Health, ISS) showed that research in global health in collaboration with African partners is an important activity in Italian academic institutions, public health research centres, foundations and some non-governmental organizations. The 2018 survey mapped over 30 ongoing projects, funded by a variety of international and national, public and private agencies, involving 18 African countries and including preclinical, clinical and operational research across several fields of investigation, from infectious diseases to paediatrics and nutrition. The survey, however, highlighted a severe lack of coordination among the Italian funding agencies, leading to a fragmented and discontinuous support of the Italy-Africa collaborative research and a poor alignment of the national activities with the international and, importantly, the African efforts in this field.

(*) Working Group The *RicercaItaliaAfrica* Initiative of the Istituto Superiore di Sanità: Pietro Alano (Dipartimento di Malattie Infettive), Raffaella Bucciardini, Marco Simonelli (Centro Nazionale Salute Globale), Luisa Minghetti (Servizio Tecnico-Scientifico Coordinamento e Supporto alla Ricerca), Luca Rosi (Servizio Relazioni Esterne e Centro Rapporti Internazionali), coordination with the President of Istituto Superiore di Sanità: Luigi Bertinato (Segreteria Scientifica, Presidenza).

Aiming to contribute at the national level to address these gaps, ISS launched the *RicercaItaliaAfrica* Initiative. The ISS role as a coordinating hub for Italy-Africa collaborative health research has been recently identified at a dedicated interministerial Table held at ISS on October 2018 and it was previously recognized when in 2004 and in 2014 ISS was appointed by the Ministry of Education, University and Research to officially represent Italy in the Europe & Developing Countries Clinical Trial Partnership (EDCTP) Association, the EU initiative to support collaborative clinical research in infectious diseases in Sub-Saharan Africa.

At present, an updated source of information on Italian health research activities with Africa is missing. Inspection of interactive websites dedicated to mapping research and development activities related to developing countries (1) retrieves partial or outdated information. In Italy, the website dedicated by the Ministry of University and Research and the Ministry of Foreign Affairs and International Cooperation to map Italian researchers abroad (2) contains, for the African continent, accessible information only for Egypt and South Africa.

The present document reports the results of the 2020 *RicercaItaliaAfrica* survey on the ongoing Italy-Africa collaborative health research. The information presented here was collected to be eventually organized and made accessible at a dedicated *RicercaItaliaAfrica* webpage in the ISS official website (3). This will be an interactive database of the ongoing projects with the objectives to promote national and international research networking, to provide updated information to public agencies, and to disseminate the progress of Italian collaborative health research in partnership with Africa.

Survey methodology

The *RicercaItaliaAfrica* Initiative compiled a mailing list of approximately 95 Italian researchers, mainly based in public research institutions, with records of past or present activities in collaborative health research or training activities with African partners. On June, 5 2020 researchers were asked to register at a dedicated ISS website (4) and were given one month to submit information on health research projects conducted in collaboration with African institutions. *RicercaItaliaAfrica* also informed of the survey a variety of institutions and associations such as the Research Divisions and Internationalization Offices of the Ministries of University and Research, of Health, of Foreign Affairs and International Cooperation, of the Conference of Regions and Autonomous Provinces, of the Conference of University Rectorates, and of the Italian Agency of Cooperation for Development.

The survey was specifically dedicated to map projects including one or more types of research activities, indicated as basic/preclinical, clinical and operational, which could possibly, but not necessarily, include training and educational activities. The survey was not designed to collect information on collaborative projects in which training, education, capacity building or cooperation activities were not linked to research activities. Also, the survey was not designed to collect information on Italian research projects with obvious implications for health in Africa, but conducted without official collaborations with African institutions.

The survey website was structured to collect information in editable fields for each submitted project. The keywords to describe the research areas were adapted from the terminology hierarchy used for the Global Burden of Disease (5). The non-mutually exclusive choices for the first hierarchical level were: Infectious diseases, Non-communicable diseases, Health and environment, Health systems, with each term leading to select more specific terms. Researchers were asked to describe the project, the challenge addressed and its objectives, to provide information on the role of participants, to indicate the project coordinating institution, the participating institutions in Africa and elsewhere, the total budget and the fraction dedicated to the Italian participants with information on the main funding agency and the publications derived from and acknowledging the specific project.

Fortyfive researchers registered at the survey webpage, consented to publish their names and contact details, and submitted information on 53 projects. To finalize the present document, the project submitters were asked to control and update information and to confirm that projects were active in 2020, resulting in the 41 project sheets in the present document.

RicercaItaliaAfrica limited the editing of the information sheets to checking consistency of names of institutions and agencies. In two cases, in which teams with different roles submitted information on the same project, all submitted information was maintained (*see pages 12, 13 and 17, 51*).

As *RicercaItaliaAfrica* was not in the position to control the data presented, the researchers are entirely responsible for the accuracy of the reported details on objectives, partnerships, affiliations and budget details of the submitted project information.

Results

The *RicercaItaliaAfrica* 2020 survey

The *RicercaItaliaAfrica* 2020 survey collected 41 information sheets corresponding to a total of 39 ongoing projects. The main information is presented in Table 1 and participants and project details are presented from page 12 to page 52.

The projects are carried on following one or more types of research approaches: 12 include basic/preclinical research, 21 clinical research, and 16 operational research. Out of 39 projects, 26 include education and training.

The field of research of the majority of projects is defined by the keyword "Infectious diseases", with 30 projects further indicating one or sometimes more of the following terms: "HIV/AIDS and sexually transmitted infections", "Respiratory infections and tuberculosis", "Neglected tropical diseases and malaria", "Enteric infections" and "Other infectious diseases". Five projects indicate both keywords "Infectious diseases" and "Health systems", one indicates both "Infectious diseases" and "Health and environment", three indicate "Non-communicable diseases", further indicating "Cardiovascular diseases", "Maternal and neonatal disorders" and "Mental disorders". Despite the diversity in approaches and the wide range of themes, Italian health research with Africa appears to dedicate a particular attention to studies aiming to prevent or cure infectious and non-communicable diseases with a high impact on children and maternal health.

The project participants work for different types of institutions/organizations, grouped as follows.

Fourteen participants belong to legal entities grouped under the definition "Private sector/Foundation/Onlus": specifically, GSK Vaccines Institute for Global Health, Penta, Fondazione San Raffaele, Sclavo Vaccines Association. Of these, 9 participants act as the coordinator, 4 as a partner and one as a third party in the respective projects.

Twentyfour participants belong to public structures administered by the Ministry of Health, i.e. Istituti di Ricovero e Cura a Carattere Scientifico and Istituto Superiore di Sanità, grouped under the definition "IRCCS/ISS", specifically Ospedale San Raffaele, Policlinico San Donato, Istituto Superiore di Sanità. Of these, 8 participants act as the coordinator, 14 as a partner and 2 as third party in the respective projects.

Finally, 3 participants belong to 2 Universities, Milan and Pisa, in both cases with the role of project partners in the respective projects.

The projects involve collaborations with the following 39 African countries: Algeria, Angola, Benin, Botswana, Burkina Faso, Cameroon, Cape Verde, Cote Ivoire, Democratic Republic of the Congo, Egypt, Eritrea, Ethiopia, Gambia, Ghana, Gibuti, Guinea, Guinea-Bissau, Kenya, Liberia, Libya, Malawi, Mali, Marocco, Mauritania, Mozambique, Niger, Nigeria, Senegal, Sierra Leone, Somalia, South Africa, South Sudan, Swaziland, Tanzania, Togo, Tunisia, Uganda, Zambia, Zimbabwe. Approximately, half of the projects have the collaborating partner(s) in a single African country and half in two or more countries. Altogether, the projects rely on partnerships with over 70 African institutions.

The total budget available to the 39 projects is approximately €50,6 M. The largest fraction (84%) is for beneficiaries in "Private sector/Foundation/Onlus", whereas 15% supports activities in "IRCCS/ISS" and 1% in "Universities". It should be noticed that approximately half of the €42,5 M of the "Private sector/Foundation/ONLUS" budget, namely the budgets of the projects EPIICAL, SMILE and ODYSSEY are not destined for the support of activities of Italian beneficiaries but of institutions based in Africa and in other continents.

The source of the above budget is largely provided by funds from Privates, Foundations and Product Development Partnerships (PDPs), accounting for 77% of the total (€39,1 M). The European Commission contributes 15% of the total budget, with public foreign agencies providing an additional 3%. Italian public agencies contribute altogether for 4% (€2,1 M) of the total budget of collaborative health research.

Other data on Italy-Africa collaborative health research

We are aware that the above results capture only in part the ongoing Italy-Africa collaborations, as the initial mailing list is likely to be incomplete and not all researchers replied. Additional information from other sources is here presented to provide a more accurate scenario.

The Europe & Developing Countries Clinical Trial Partnership (EDCTP)

The second EDCTP programme, EDCTP2, is the Horizon 2020 initiative supporting clinical research on infectious diseases in Sub-Saharan Africa (6). In the period 2015-2020, EDCTP2 has supported 12 projects in which 5 Italian institutions participated as coordinators (in 2 projects) or partners, receiving altogether a total funding of € 4,461,332.

Ten out of these projects are presently ongoing and the Italian participating institutions/organisations are: Università degli Studi di Verona, Emergency, Istituto Nazionale per le Malattie Infettive (INMI) Lazzaro Spallanzani, Università degli Studi di Torino, Ospedale San Raffaele Milano, Fondazione Penta Onlus, Istituto Superiore di Sanità, Azienda Ospedaliero-Universitaria di Modena.

In addition, 4 projects with Italian beneficiaries have been selected in recent EDCTP2 calls and are now in negotiation or pre-activation. A conservative estimate, including the latter 4 projects, is that Italian beneficiaries altogether have received/are receiving approximately €6,6 M, which represents 1% of the €635 M invested by EDCTP2 in 2015-2020 in a total of 123 projects.

Eight out of the above 14 projects are described in this document (*see pages 16, 24, 27, 31, 39, 41, 42, 44*). A database of the EDCTP2 projects is accessible at the EDCTP website (7).

Italy is a member of the EDCTP Association, the legal entity governing the EDCTP2 initiative, a status requiring that the country supports with public funds Italy-Africa research projects in the scope of EDCTP2. Presently, 5 activities are ongoing: 3 are presented here (see *pages 28, 37, 43*), the fourth is the *RicercaItaliaAfrica* Initiative.

The 5% Global Fund Initiative of the Italian Agency of Cooperation for Development (AICS) (8)

Italy contributes to the Global Fund to fight HIV/AIDS, Tubercolosis and Malaria (9), with the agreement to dedicate 5% of the national contribution to projects carried on by Italian civil society organisations and by public research institutions in synergy with the Global Fund offices in selected countries. This scheme started in 2017 and has funded so far 17 projects, all based in Africa, with a total budget of €6,5 M. Although the 5% Global Fund Initiative is not specifically dedicated to fund research*, some projects include research activities. Five projects are here described (*see pages 29, 43, 46, 49, 50*), which may suggest that this survey may have missed additional Italy-Africa research activities in the projects supported by this scheme.

Finally, additional Italy-Africa initiatives conducted by a variety of Italian organisations and institutions deserve attention as they do, or may, include health research activities.

Italian academic institutions have a long tradition in establishing links with several universities in Africa and they presently coordinate these activities in initiatives such as the "Coordinamento Universitario per la Cooperazione allo Sviluppo (CUCS)" (10), the Commissione Internazionale Cooperazione per lo Sviluppo (CICOPS) (11) and the Commissione Internazionalizzazione of the Conferenza dei Rettori delle Università Italiane (CRUI) (12). The main scope of these activities is promoting exchanges in high level education programmes and supporting the establishment and improvement of African academic institutions. A preliminary survey conducted by *RicercaItaliaAfrica* in 2018 mapped activities and projects on health in collaboration with several African countries carried out by the Univer-

(*) Main objective of the initiative is to finance innovative projects that are synergistic and complementary with Global Fund investments and in particular with the Strategic Objectives 2017-2022: 1. "Maximize impact against HIV, TB and malaria", 2. "Build Resilient and Sustainable Systems for Health" and 3. "Promote and Protect Human Rights and Gender Equality".

sities Tor Vergata and Sapienza (Rome), the Universities of Brescia, Modena-Reggio Emilia, Milan, Turin, Padua, Ferrara, Camerino, Genoa, Pavia, Siena, and Pisa. Some of these collaborations included research activities; noticeably, one led to establish *The Journal of Public Health in Africa* (13), dedicated to publish contributions on research and practice for global health in the continent.

Italy and Africa are historically linked by the activities of a multitude of no-profit and non-governmental organizations and foundations, many of which dedicated to capacity building and cooperation projects for health improvement. These activities only rarely include a component of health research. Nevertheless, the preliminary 2018 *RicercaItaliaAfrica* survey identified projects including research activities.

CUAMM-Medici con l'Africa (Doctors with Africa), active in 8 Sub-Saharan African countries (Angola, Central African Republic, Ethiopia, Mozambique, Sierra Leone, South Sudan, Tanzania, Uganda), dedicates a section of its website to report the results of operational research conducted under the CUAMM supported projects (14). The Fondazione Ivo De Carneri (15) runs in Pemba (Tanzania) the Public Health Laboratory, where operational research activities are carried on (16). Also, activities in Senegal by the organization StopTB Italia (17) included projects to develop sustainable approaches in the fight against tubercolosis.

Finally, the massive international mobilisation of resources to globally face the COVID-19 emergency, detailed below, also supported research. Some funding schemes have been dedicated to North-South collaborations, including collaborative partnerships with Africa. In Italy, two major public calls for COVID-19 related research proposals have been launched, namely by the Ministry of Health in April 2020, with a €7 M budget, and by the Ministry of University and Research in May 2020, with a budget of €21,9 M. Out of the 10 projects financed under the former scheme, to the best of our knowledge, none included activities with African partners (18), whereas the list of projects selected under the latter scheme is not yet available.

Discussion

The objective of the 2020 survey conducted by *RicercaItaliaAfrica* was to map the collaborative health research activities between Italy and Africa. Africa is a vast and diverse continent and Italian research is a complex and fragmented reality, making it difficult for this analysis to escape from inaccuracies and approximations. Nevertheless, from this first effort to systematically map these activities nationwide it is possible to outline both the potential and the critical issues of the state of Italy-Africa collaborative health research.

At an international level, Italian public funding provides significant support to several initiatives to promote and safeguard public health globally, including Africa. The most relevant are the €1,1 billion contribution to the Global Fund since 2001, of which the €161 M contribution for the 2020-2022 triennium (19), the over €1.1 billion in support to the Global Alliance for Vaccines and Immunization (GAVI), and its innovative mechanisms, since 2005, of which €498 M in the period 2016-2020 (20), the €125 M used, only in 2019, by the Italian Agency of Cooperation for Development in over 92 health related projects worldwide (21), and the contribution to the health-related European Union Framework Programmes.

In 2020, Italy has been well aware that the global crisis generated by the COVID-19 pandemic is hindering progress towards achieving the Sustainable Development Goals, globally and specifically in critical areas where progress has been limited (22). Although in Africa the COVID-19 pandemic has been less deadly than elsewhere, the region is, and will be, heavily affected by the economic consequences of the pandemic, aggravating the structural inequalities in most African economies.

Italy has actively supported the multilateral approach to the COVID-19 pandemic at the March 2020 extraordinary G20 Summit which launched the Accelerator ACT-Access to Covid-19 Tools - the partnership launched by the World Health Organization (WHO) to support the fastest, most coordinated and successful global effort to develop tools to fight COVID-19 (23, 24). In addition, Italy contributed to promote the President of the European Commission Coronavirus Global Response Pledging Conference and the June 2020 Global Vaccine Summit, which refinanced the Global Alliance for Vaccines and Immunization (GAVI) and launched the COVAX Facility (25). Besides ensuring by 2025 the immunisation of 300 million people against 18 in-

fectious diseases, GAVI will guarantee the equitable distribution of the available COVID-19 vaccine through establishment of the GAVI Advance Market Commitment (AMC)/ Covax Facility. In 2020, Italy announced for the 2021-2025 period a €120 M funding to GAVI, with €20 M dedicated to the GAVI AMC, €137,5 M funding to the International Finance Facility for Immunization (IFFIM), and an additional $79,4 M funding to the GAVI AMC-Covax Facility, which makes Italy one of the main donors for equitable access to the Covax-19 vaccine in developing countries and the 6th largest donor to the GAVI Alliance.

Finally, in 2020 Italy announced a €10 M contribution to the Coalition for Epidemic Preparedness Innovations (CEPI), joining the Coalition's Investors Council.

Besides COVID-19, and specifically to Africa, the continent attracts significant public and private investments from Italy. The United Nations World Investment Records 2020 ranks our country as the seventh top investor in the continent in 2018 after France, The Netherlands, United Kingdom, USA, China and South Africa (26).

The above figures are altogether indicative of the significant Italian public and private commitments towards global health and towards Africa's economy and development, well before the advent of the pandemic. In sharp contrast, it is remarkable that the Italian public support to collaborative health research with Africa, as it emerges from the present survey, is negligible. Although possibly calculated in defect, the survey indicates that Italian public agencies are currently spending slightly over €2 M in Italy-Africa collaborative health research projects, providing less than 5% of the total budget today available to Italian beneficiary institutions/ organizations running this type of research.

The European Commission (EC), contributing 15% of the total budget of the 39 projects mapped here, is the single public body providing the largest support to Italy-Africa collaborative research. Yet, Italian research only minimally benefits of EC resources. In the case of EDCTP2, the main EU instrument to fund collaborative clinical research on infectious diseases in Sub-Saharan Africa, Italian beneficiaries have obtained only 1% of the €635 M budget disbursed by EDCTP2 from 2015 to now. Along the same line, Italy "in kind" public contributions to EDCTP2 accounted for less than 0.5% of the total budget committed to this aim by the 14 European EDCTP partners (27).

Somehow mirroring the source of investments, also the distribution of the current budget is uneven comparing public and non public beneficiary institutions/organizations. The survey indicates that the 13 participants from the Private/ Foundation/Onlus sector are funded with a total of €42,5 M, in 8 cases receiving budgets over €1 M, whereas the 26 participants from public organizations (health research centres and universities) share altogether a total budget of €8,1 M, in only two cases receiving budgets over €1 M.

The first conclusion from the 2020 *RicercaItaliaAfrica* survey is that, despite the fact that investment in scientific research is a reliable indicator of modern and sustainable economies and that Italian governments have often emphasized the priority of establishing a durable partnership with Africa, Italian public agencies have not yet developed a common vision and implemented mechanisms to support Italian collaborative health research with Africa.

The second conclusion is that the landscape of Italian collaborative research with Africa is very diverse. Institutions and organisations from the public, private and no-profit sectors coordinate or participate in highly diverse research activities with Africa, ranging from the complex management of international clinical trial networks to the individual project supervision of African Ph.D. students. A concerning feature of this landscape is that these activities, concentrated in the Centre and North of Italy, are minimally, if at all, interconnected.

Nevertheless, the survey provides a clear indication that Italian scientific know-how in health research is competitive and proved to be appropriate to meet the need of African partners, as Italian researchers have been able to establish collaborations with over 70 institutions/organisations in 38 African countries on a variety of health research themes.

As much as it would be important that this potential is captured and valorised by Italian institutional stakeholders and public agencies, an analysis of recent strategic documents could not find adequate indications in this direction.

The National Plan of Research 2021-2027 (28) of the Italian Ministry of University and Research, for instance, does not foresee specific activities and frameworks for Italy-Africa scientific collaborations, despite the fact that establishing transcontinental schemes in high level education and promoting a new and collaborative scientific leadership in Italy and in Africa would be of strategic importance.

Another example is the document *Partnership with Africa* (Il Partenariato con l'Africa) (29), presented in December 2020 by the Italian Ministry of Foreign Affairs and International Cooperation to set the strategic basis for Italy's future activities with Africa. The section dedicated to science and research reports that bilateral agreements in science and technology cooperation exist so far only with Egypt, Algeria and South Africa and that the Italian scientific diplomacy in Africa counts on dedicated attachés only at the Embassies of Pretoria, South Africa and Cairo, Egypt, although two additional positions are announced at Dakar, Senegal and Nairobi, Kenya. Health research is not highlighted in this section, where the only concrete action indicated is Italy's support to the UNESCO ICTP-East Africa Institute of Fundamental Research in the field of physics and cosmology (30).

In the past years, a rare positive example worth being mentioned here was the establishment of a bilateral Italy-South Africa Research Programme (ISARP) initiative that included support to one health research project through a collaboration, in Italy, between the Ministry of Foreign Affairs and International Cooperation and the Ministry of Health (*see page 37*).

In conclusion, the present survey is a first step towards establishing a platform of interactive and updated information from/to Italian researchers and from/to national public funding agencies on Italy-Africa collaborations in health research. This resource aims to contribute to develop mechanisms of mutual communication, networking, planning and support of Italy-Africa collaborative health research as an essential part of the establishment of a Italy-Africa long term partnership.

Conflict of interest statement

The authors declare that there are no conflicts of interest.

Website list

1. https://gfinderdata.policycuresresearch.org/
2. https://innovitalia.esteri.it/
3. www.iss.it
4. https://globapp.iss.it/
5. http://ghdx.healthdata.org/gbd-2017/data-input-sources
6. https://www.edctp.org/
7. https://www.edctp.org/edctp2-project-portal/
8. https://www.aics.gov.it/news/2020/62260
9. https://www.theglobalfund.org/en/
10. https://www.unibs.it/ricerca/ricerca-internazionale-e-cooperazione/cucs-coordinamento-universitario-la-cooperazione-allo-sviluppo
11. http://cicops.unipv.it/
12. https://www.crui.it/crui-english.html
13. https://www.publichealthinafrica.org/index.php/jphia
14. https://www.mediciconlafrica.org/ricercaoperativa/; https://pubmed.ncbi.nlm.nih.gov/?term=CUAMM&sort=date)
15. http://www.fondazionedecarneri.it/en/
16. http://phlidc.org/research/
17. https://stoptb.it/
18. http://www.salute.gov.it/imgs/C_17_bandi_216_3_file.pdf
19. https://data-service.theglobalfund.org/file_download/pledges_contributions_report/excel
20. https://www.gavi.org/investing-gavi/funding/donor-profiles/italy
21. https://openaid.aics.gov.it/
22. https://unstats.un.org/sdgs/report/2020/The-Sustainable-Development-Goals-Report-2020.pdf
23. https://www.who.int/initiatives/act-accelerator
24. https://www.who.int/docs/default-source/coronaviruse/act-accelerator/20210212---act-a-commitment-tracker_vf.xlsx?sfvrsn=2b30c983_1&download=true
25. https://ec.europa.eu/international-partnerships/topics/eu-global-response-covid-19_it
26. https://unctad.org/system/files/official-document/wir2020_en.pdf
27. https://www.edctp.org/publication/edctp-annual-report-2019/
28. https://www.mur.gov.it/sites/default/files/2021-01/Pnr2021-27.pdf
29. https://www.esteri.it/mae/it/politica_estera/aree_geografiche/africa/il-partenariato-con-l-africa.html
30. https://eaifr.ictp.it/

Table. A glance at the project information submitted at the *RicercaItaliaAfrica* survey website
(full details from page 12 to 52)

Project title	Type of Italian beneficiary	Italian participant	Project Coordinator	African Country(ies) involved	Main funding agency	Budget to Italian participant	Project info at page
Advancing a GMMA-based vaccine against invasive non-typhoidal salmonellosis through Phase 1 trial in Europe and Sub-Saharan Africa	Foundation/Private/ Onlus	GSK Vaccines Institute for Global Health	Sclavo Vaccines Association, Italy	Burkina Faso, Kenya, Ghana, Malawi	European Commission	€ 1,576,515	12
Advancing a GMMA-based vaccine against invasive non-typhoidal salmonellosis through Phase 1 trial in Europe and Sub-Saharan Africa	Foundation/Private/ Onlus	Sclavo Vaccines Association	Sclavo Vaccines Association, Italy	Burkina Faso, Kenya, Ghana, Malawi	European Commission	€ 3,069,844	13
Applying a Standardised Approach to Strengthen Performances of GeneXpert Networks (ASAP-GxNet)	Foundation/Private/ Onlus	Fondazione Centro San Raffaele	Fondazione Centro San Raffaele, Italy	Burkina Faso	STOP TB Partnership-TB REACH	€ 118,720	14
Assess the variation in lipopolysaccharide structure in circulating African invasive *Salmonella Typhimurium* isolates to predict vaccine coverage	Foundation/Private/ Onlus	GSK Vaccines Institute for Global Health	Institute of Tropical Medicine Antwerp, Belgium	Democratic Republic of the Congo, South Africa	Bactivac MRC	€ 4,000	15
EMPIRICAL	Foundation/Private/ Onlus	Penta	Madrid Health Service (SERMAS), Spain	Uganda, Mozambique, Zimbabwe, Cote Ivoire, Zambia	EU-EDCTP2	€ 571,421	16
EPIICAL	Foundation/Private/ Onlus	Penta	Penta, Italy	South Africa, Mozambique	ViiV Healthcare UK	€ 8,502,750	17
GMMA-based 4-component Shigella vaccine early clinical development	Foundation/Private/ Onlus	GSK Vaccines Institute for Global Health	GlaxoSmithKline Vaccines, Rixensart, Belgium	Kenya	GlaxoSmithKline	€ 2,893,520	18
GMMA-based multicomponent Shigella vaccine for endemic countries	Foundation/Private/ Onlus	GSK Vaccines Institute for Global Health	GlaxoSmithKline Vaccines, Rixensart, Belgium	Kenya	GlaxoSmithKline	€ 7,401,541	19
GMMA-based Shigella vaccine serology and schedule finding trial	Foundation/Private/ Onlus	GSK Vaccines Institute for Global Health	GlaxoSmithKline Vaccines, Rixensart, Belgium	Kenya	GlaxoSmithKline	€ 944,110	20
Letter of Agreement with World Health Organization HQ	Foundation/Private/ Onlus	Fondazione Centro San Raffaele	Fondazione Centro San Raffaele, Italy	Burkina Faso, Cote Ivoire, Eritrea, Ethiopia, Djibouti, Mauritania, Mozambique, Nigeria, South Africa, Swaziland	WHO-HQ	€ 1,506,514	21
NeoAMR Observational Study (NeoOBS)	Foundation/Private/ Onlus	Penta	Penta, Italy	Uganda, Kenya, South Africa	Global Antibiotic Research and Development Partnership	€ 2,497,461	22

continued

continued

Project title	Type of Italian beneficiary	Italian participant	Project Coordinator	African Country(ies) involved	Main funding agency	Budget to Italian participant	Project info at page
ODYSSEY	Foundation/Private/ Onlus	Penta	Penta, Italy	Uganda, Zimbabwe, South Africa	ViiV Healthcare UK	€ 11,590,153	23
PediCAP Trial	Foundation/Private/ Onlus	Penta	Penta, Italy	South Africa, Zimbabwe, Zambia, Uganda	EU-EDCTP2	€ 792,756	24
SMILE	Foundation/Private/ Onlus	Penta	Penta, Italy	Uganda, South Africa	ViiV Healthcare UK	€ 2,644,961	25
A client-centred model of Antiretroviral Therapy Delivery in southern Tigray. A Piloty study - CASA 3	IRCCS/ISS	Istituto Superiore di Sanità	Istituto Superiore di Sanità, Italy	Ethiopia	Agenzia Italiana per la Cooperazione allo Sviluppo	€ 203,909	26
A randomized control trial to evaluate a scalable active case-finding intervention for tuberculosis using a point-of-care molecular tool (Xpert Omni)	IRCCS/ISS	Ospedale San Raffaele	The University of Cape Town Lung Institute (Pty) Ltd, South Africa	South Africa, Mozambique, Zimbabwe	EU-EDCTP2	€ 166,547	27
Training and operational research to improve retention in care of HIV people in Tigray, Ethiopia - CASA 2	IRCCS/ISS	Istituto Superiore di Sanità	Istituto Superiore di Sanità, Italy	Ethiopia	Agenzia Italiana per la Cooperazione allo Sviluppo	€ 768,240	28
Be free! Community and health system integration to promote young people free from HIV and stigma	IRCCS/ISS	Istituto Superiore di Sanità	Servizio Volontario Internazionale, Italy	Kenya	Agenzia Italiana per la Cooperazione allo Sviluppo (Iniziativa 5% Global Fund)	€ 33,000	29
Children's heart for Africa	IRCCS/ISS	IRCCS Policlinico San Donato	IRCCS Policlinico San Donato, Italy	Egypt, Ethiopia, Tunisia, Marocco, Nigeria, Botswana, Cameroon, Senegal	Bambini Cardiopatici nel Mondo IRCCS Policlicico San Donato	€ 2,500,000	30
Close the gap, increase Access, Provide adequate Therapy (TB-CAPT)	IRCCS/ISS	Ospedale San Raffaele	Foundation for Innovative New Diagnostics FIND, Switzerland	Ethiopia, Mozambique, Tanzania, South Africa	EU-EDCTP2	€ 417,418	31
Extended follow-up of the Tat vaccine phase II trial (ISS T-003)	IRCCS/ISS	Istituto Superiore di Sanità	Istituto Superiore di Sanità, Italy	South Africa	Ministero della Salute	€ 35,000	32
ISS/DMI-ENI/NAOC Cooperative proposal for the implementation of a malaria diagnostic quality control project and a drug resistance surveillance activity in Nigeria	IRCCS/ISS	Istituto Superiore di Sanità	Istituto Superiore di Sanità, Italy	Nigeria	Ente Nazionale Idrocarburi	€ 51,000	33
Ex vivo activity of antimalarial compounds on *Plasmodium falciparum* gametocytes and their mosquito transmission efficiency	IRCCS/ISS	Istituto Superiore di Sanità	National Centre for Malaria Research and Training (CNRFP), Burkina Faso	Burkina Faso	National Centre for Malaria Research and Training (CNRFP), Burkina Faso	€ 10,000	34

continued

continued

Project title	Type of Italian beneficiary	Italian participant	Project Coordinator	African Country(ies) involved	Main funding agency	Budget to Italian participant	Project info at page
MediLabSecure (MLS)	IRCCS/ISS	Istituto Superiore di Sanità	Institut Pasteur, Paris, France	Algeria, Burkina Faso, Egypt, Libya, Mali, Mauritania, Marocco, Niger, Senegal, Tunisia	European Commission	€ 1,221,323	35
Network of European and African Researchers on Antimicrobial Resistance (NEAR-AMR)	IRCCS/ISS	Istituto Superiore di Sanità	Liverpool School of Tropical Medicine, United Kingdom	Egypt, Ghana, Kenya, Liberia, Malawi, South Sudan, Tanzania, Uganda	Joint Programming Initiative on Antimicrobial Resistance (JPIAMR)	No budget	36
New generation drugs against *Plasmodium falciparum* transmission for malaria eradication	IRCCS/ISS	Istituto Superiore di Sanità	Istituto Superiore di Sanità, Italy	South Africa	Ministero della Salute	€ 223,000	37
Origin and development of maturing gametocytes of *Plasmodium falciparum* in deep tissues and peripheral circulation	IRCCS/ISS	Istituto Superiore di Sanità	University of Health and Allied Sciences, Ho, Ghana	Ghana	The Royal Society UK - Future Leaders - African Independent Research	€ 15,000	38
PedMAb: Phase I/II study to determine Safety and Pharmacokinetics of subcutaneous administration of potent and broad anti HIV-1 neutralizing monoclonal antibodies (bNAbs), given to HIV-1 exposed neonates and infants	IRCCS/ISS	Ospedale San Raffaele	Ospedale San Raffaele, Italy	South Africa	EU-EDCTP2	€ 918,538	39
Pilot ultrasoundsurvey of human cystic echinococcosis in livestock-keeping communities of Northern Tanzania	IRCCS/ISS	Istituto Superiore di Sanità	University of Glasgow, United Kingdom	Tanzania	European Society of Clinical Microbiology and Infectious Diseases (ESCMID)	No budget	40
POR TB consortium; Phase 2 trial to determine efficacy of the multistage vaccine H56: IC31 for Prevention of Recurrent TB disease	IRCCS/ISS	Ospedale San Raffaele	Statens Serum Institut, Denmark	Tanzania, South Africa	EU-EDCTP2	€ 260,000	41
Prevention of invasive Group B Streptococcus diseases in young infants: a pathway for the evaluation and licensure of an investigational maternal GBS vaccine (PREPARE)	IRCCS/ISS	Istituto Superiore di Sanità	St. George's Hospital Medical School, London, United Kingdom	Uganda, South Africa, Malawi	EU-EDCTP2	€ 32,000	42
Prevention of mother-to-child transmission of HIV: an analysis of maternal retention and of infants health in the first year after delivery	IRCCS/ISS	Istituto Superiore di Sanità	Istituto Superiore di Sanità, Italy	South Africa	Agenzia Italiana per la Cooperazione allo Sviluppo (Iniziativa 5% Global Fund)	€ 250,000	43

continued

continued

Project title	Type of Italian beneficiary	Italian participant	Project Coordinator	African Country(ies) involved	Main funding agency	Budget to Italian participant	Project info at page
Safety and efficacy of Dolutegravir and EFV400 for pregnant and breast feeding women: a randomized non-inferiority clinical trial (PREGART)	IRCCS/ISS	Istituto Superiore di Sanità	Hawassa University, Ethiopia	Ethiopia, Uganda	EU-EDCTP2	€ 245,000	44
SeqMDRTB_NET	IRCCS/ISS	Ospedale San Raffaele	Research Center Borstel, Germany	Eswatini, Mozambique, Namibia	Federal Ministry of Health, Germany	€ 30,000	45
Stop TB and HIV in Angola: Improving access to TB and HIV treatment by enhancing the diagnostic quality and patient management in the Province of Luanda	IRCCS/ISS	Istituto Superiore di Sanità	Medici con l'Africa Cuamm, Italy	Angola	Agenzia Italiana per la Cooperazione allo Sviluppo (Iniziativa 5% Global Fund)	ISS study missions covered by the Project coordination	46
TB-Lab	IRCCS/ISS	Ospedale San Raffaele	Supranational TB Reference Laboratory, Benin	Benin, Burkina Faso, Cape Verde, Cote Ivoire, Gambia, Ghana, Guinea, Guinea-Bissau, Liberia, Mali, Mauritania, Niger, Nigeria, Senegal, Sierra Leone, Togo	The Global Fund	€ 95,095	47
The UMBRELLA trial: an open-label phase 1/2 trial evaluating the safety and pharmacokinetics of VRC07-523-LS, a potent long acting broadly neutralizing monoclonal antibody, in HIV-1 exposed infants in South Africa	IRCCS/ISS	Ospedale San Raffaele	INSERM - Montpellier, France	South Africa	National Agency of Research, France	€ 64,460	48
THUPIME TANZANIA! Tuberculosis & HIV Undermining through Prevention, Investigation, Management & Education	IRCCS/ISS	Ospedale San Raffaele	Cooperazione Paesi Emergenti (COPE), Italy	Tanzania	Agenzia Italiana per la Cooperazione allo Sviluppo (Iniziativa 5% Global Fund)	€ 63,339	49
Enhancement of malaria response in South Sudan through the improvement in access, utilization and quality of preventive/ diagnostic/curative services and their integration to the three levels of care of the health system of Amadi state	University	Università degli Studi di Pisa	Medici con l'Africa Cuamm, Italy	South Sudan	Agenzia Italiana per la Cooperazione allo Sviluppo (Iniziativa 5% Global Fund)	€ 450,000	50
New generation drugs against *Plasmodium falciparum* transmission for malaria eradication	University	Università degli Studi di Milano	Istituto Superiore di Sanità, Italy	South Africa	Ministero della Salute	€ 64,000	51
Somaliland going forward: support to social-health excellences in pediatrics and mental health	University	Università degli Studi di Milano	Gruppo per le Relazioni Transculturali (GRT), Italy	Somalia	Agenzia Italiana per la Cooperazione allo Sviluppo	No budget	52

Advancing a GMMA-based vaccine against invasive non-typhoidal salmonellosis through Phase 1 trial in Europe and Sub-Saharan Africa

Description

Development of a vaccine against invasive non-typhoidal Salmonellosis, a neglected infectious disease causing a very significant health and socio-economic impact in Sub-Saharan Africa. Vacc-iNTS.

https://vacc-ints.eu/

Challenge

Invasive non-typhoidal Salmonellosis (iNTS) is an important neglected infectious disease of Sub-Saharan Africa, where it ranks among the leading causes of bacteremia. Very young children aged 9-24 months, HIV-infected and fragile individuals are the most affected. There is no licensed vaccine against iNTS and the emergence of antimicrobial resistant strains is compromising efficacy of current therapies. High case-fatality rates, difficult diagnosis, and the increasing antibiotic resistance strongly advocate for rapid development of an effective vaccine for the poorest area of the world.

Objectives

- iNTS-GMMA vaccine and placebo lots GMP manufacture;
- two-staged Phase I study to demonstrate vaccine safety and immunogenicity in healthy European and African adults;
- immunological and molecular signatures analyses;
- sero-epidemiology studies in high-burden African site;
- development of 2 disease burden models and literature search;
- planning and evaluation of effective deployment and uptake of the iNTS-GMMA vaccine;
- training of physicians and laboratory staff from iNTS endemic countries;
- strengthen a multidisciplinary collaborative network of iNTS expert institutions.

Project participant

GSK Vaccines Institute for Global Health, Rocio Canals Alvarez - rocio.x.canalsalvarez@gsk.com

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Enteric infections	Partner	Sclavo Vaccines Association, Italy	**Burkina Faso** • University of Ouagadougou **Kenya** • Kenya Medical Research Institute **Ghana** • Kwame Nkrumah University of Science and Technology Kumasi **Malawi** • University of Malawi	**Italy** • GSK Vaccines Institute for Global Health • Fondazione Achille Sclavo Onlus • Università degli Studi di Siena **United Kingdom** • University of Oxford • University of Cambridge • University of Liverpool **Belgium** • Institute of Tropical Medicine **New Zealand** • University of Otago **Switzerland** • MMGH Consulting GMBH

Project period	Main funding agency	Total budget	Budget Italian institution
2019-2024	European Commission	€ 6,871,189	€ 1,576,515

Advancing a GMMA-based vaccine against invasive non-typhoidal salmonellosis through Phase 1 trial in Europe and Sub-Saharan Africa

Description

Development of a vaccine against invasive non-typhoidal Salmonellosis, a neglected infectious disease causing a very significant health and socioeconomic impact in Sub-Saharan Africa. Vacc-iNTS.

https://vacc-ints.eu/

Challenge

Invasive non-typhoidal Salmonellosis (iNTS) is an important neglected infectious disease of Sub-Saharan Africa, where it ranks among the leading causes of bacteremia. Very young children aged 9-24 months, HIV-infected and fragile individuals are the most affected. There is no licensed vaccine against iNTS and the emergence of antimicrobial resistant strains is compromising efficacy of current therapies. High case-fatality rates, difficult diagnosis, and the increasing antibiotic resistance strongly advocate for rapid development of an effective vaccine for the poorest area of the world.

Objectives

- iNTS-GMMA vaccine and placebo lots GMP manufacture;
- two-staged Phase I study to demonstrate vaccine safety and immunogenicity in healthy European and African adults;
- immunological and molecular signatures analyses;
- sero-epidemiology studies in high-burden African site;
- development of 2 disease burden models and literature search;
- planning and evaluation of effective deployment and uptake of the iNTS-GMMA vaccine;
- training of physicians and laboratory staff from iNTS endemic countries;
- strengthen a multidisciplinary collaborative network of iNTS expert institutions.

Project participant

Sclavo Vaccines Association, Rino Rappuoli - president@sclavo.org

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Enteric infections	Coordinator	Sclavo Vaccines Association, Italy	**Burkina Faso** • University of Ouagadougou **Kenya** • Kenya Medical Research Institute **Ghana** • Kwame Nkrumah University of Science and Technology, Kumasi **Malawi** • University of Malawi	**Italy** • GSK Vaccines Institute for Global Health • Fondazione Achille Sclavo Onlus • Università degli Studi di Siena **United Kingdom** • University of Oxford • University of Cambridge • University of Liverpool **Belgium** • Institute of Tropical Medicine **New Zealand** • University of Otago **Switzerland** • MMGH Consulting GMBH

Project period	Main funding agency	Total budget	Budget Italian institution
2019-2024	European Commission	€ 6,871,189	€ 3,069,844

Applying a Standardised Approach to Strengthen Performances of GeneXpert Networks (ASAP-GxNet)

Description

To strengthen local managerial skills and conduct a standardized impact assessment of national GeneXpert network.

https://twitter.com/asapgxnet

Challenge

The roll-out had also demonstrated that the efficient and impactful introduction of Xpert MTB/RIF should not be merely limited to aligning local policies with international diagnostic guidelines, but it is also conditioned by national capacities to ensure the delivery of high-quality of diagnostic services. In this context, high managerial skills and appropriate allocation of resources through evidence-based decision-making are essential to achieve the expected outcomes.

Objectives

To develop a standardised phase-to-phase approach for strengthening national management skills, identifying gaps through standardised impact assessments and continuously improving quality of the national GeneXpert networks.

Project participant

Fondazione Centro San Raffaele, Riccardo Alagna - alagna.riccardo@hsr.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Respiratory infections and tuberculosis	Third Party	Fondazione Centro San Raffaele, Italy	**Burkina Faso** • National TB Program	

Project period	Main funding agency	Total budget	Budget Italian institution
2018-2020	STOP TB Partnership-TB REACH	€ 118,720	€ 118,720

Assess the variation in lipopolysaccharide structure in circulating African invasive *Salmonella Typhimurium* isolates to predict vaccine coverage

Description

Analyse the genomic and structural variation of O-antigen of *Salmonella Typhimurium* isolates from the Democratic Republic of the Congo.

Challenge

Invasive non-typhoidal Salmonella (iNTS) is an important neglected bacterial infectious disease of Sub-Saharan Africa, where it ranks among the leading causes of bacteremia. There is no licensed vaccine against iNTS, and the emergence of antimicrobial resistant strains is compromising efficacy of current therapies. Different O-antigen based vaccines are about to enter phase 1 clinical trials. The results from this project will give insights on the O-antigen variability in African iNTS isolates and guide the design of improved O-antigen based vaccines.

Objectives

- Identification of strain with structural variations (looking in particular to O-acetylation pattern) and their genetic mechanism; strain selection for further analyses;
- proven causality of new genetic mechanisms 3;
- determination of physical-chemical O-antigen structure.

Project participant

GSK Vaccines Institute for Global Health, Francesca Micoli - francesca.x.micoli@gsk.com

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Enteric infections	Partner	Institute of Tropical Medicine Antwerp, Belgium	**Democratic Republic of the Congo** • National Institute for Biomedical Research (INRB) **South Africa** • University of Capetown	**Italy** • Università degli Studi di Trieste **Belgium** • Institute of Tropical Medicine Antwerp

Project period	Main funding agency	Total budget	Budget Italian institution
2019-2020	Bactivac MRC	€ 48,848	€ 4,000

EMPIRICAL

Description

A clinical trial investigating the treatment of cytomegalovirus and tuberculosis in HIV-positive infants with severe pneumonia.

https://empiricaledctp.eu/

Challenge

Around 30% of HIV-infected children admitted to a hospital die up to 3 months after admission, with pneumonia being a major cause of death. The project will search for new therapeutic approaches for the treatment of severe pneumonia in HIV-infected infants and thereby reduce hospitalisations and deaths of HIV positive children.

Objectives

Evaluate whether empirical treatment against cytomegalovirus and tuberculosis improves the survival of HIV-infected infants with severe pneumonia.

Project participant

Penta, Carlo Giaquinto - info@penta-id.org

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • HIV/AIDS and sexually transmitted infections	Partner	Madrid Health Service (SERMAS), Spain	**Uganda** • Makerere University (MU) **Mozambique** • Eduardo Mondlane University/Maputo Central Hospital (UEM/HCM) • Manhiça Foundation/ Manhiça Research Center **Zimbabwe** • University of Zimbabwe Clinical Research Centre (UZCHS-CTRC) **Cote Ivoire** • Programme PAC-CI **Zambia** • HerpeZ Limited (HerpeZ)	**France** • University of Bordeaux (UBx) **Netherlands** • Stichting Catholic University **Spain** • Barcelona Institute for Global Health (ISGlobal) **United Kingdom** • University of Lincoln (UoL)

Project period	Main funding agency	Total budget	Budget Italian institution
2019-2024	EU-EDCTP2	€ 7,680,619	€ 571,421

EPIICAL

Description
Investigate novel strategies to obtain long-term viral remission in early treated HIV-infected children.

https://www.epiical.org/

Challenge
HIV infection still requires lifelong therapy, but lifelong therapy leads to side effects which affect vital human organs, such as heart, kidneys and bones. Side effects are also one of the key reasons why HIV sufferers do not continue their therapy. The EPIICAL project is working to solve this by obtaining the remission of HIV infection in patients without the need for continuous treatment.

Objectives
Establish new, early scientific efforts leading to treatments aimed at HIV remission in children.
In phase 1, EPIICAL designed and conducted studies on children living with HIV, by establishing well-characterized cohorts in Europe and Africa.
In this new phase EPIICAL will:
- follow-up the already established cohorts of early treated HIV infected children and recruit into new cohorts;
- analyse and understand the adherence issues with children and adolescents on antiretrovirals;
- innovate current methodological approaches to HIV research by adding cutting-edge technologies.

Medline link to publications
https://pubmed.ncbi.nlm.nih.gov/32678875/
https://pubmed.ncbi.nlm.nih.gov/32386722/
https://pubmed.ncbi.nlm.nih.gov/32046642/

Project participant
Penta, Carlo Giaquinto - info@penta-id.org

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • HIV/AIDS and sexually transmitted infections	Coordinator	Penta, Italy	**South Africa** • Stellenbosch University • University of Kwazulu-Natal Africa Cente • University of the Witwatersrand • Umkhuseli Innovation and research management **Mozambique** • The Elizabeth Glaser Pediatric AIDS Foundation • The Manhiça Health Research Centre	**United Kingdom** • University College London **Spain** • Hospital 12 De Octubre **Thailand** • Faculty of Medicine, Chulalongkorn University **France** • Association for Research in Virology and Dermatology

Project period	Main funding agency	Total budget	Budget Italian institution
2020-2024	ViiV Healthcare UK	€ 8,502,750	€ 8,502,750

GMMA-based 4-component Shigella vaccine early clinical development

Description

This project aims to conduct clinical testing of altSonflex1-2-3 in healthy European and Kenyan populations from adult to older infants.

Challenge

Shigellosis is a major global health problem, especially in children under the age of 5 years in low- and middle-income countries. The disease symptoms range from mild diarrhea to severe dysentery with fever. Shigellosis is also associated with morbidity and long-term consequences, including stunting and growth retardation. Antibiotic resistance of Shigella is increasing and most of the affordable antibiotics are no longer effective. Currently, no vaccines are widely available.

Objectives

- First in human trial conducted in European adults;
- an age descending evaluation of the vaccine from adults to infants in Kenya, where shigellosis is a significant disease burden.

Project participant

GSK Vaccines Institute for Global Health, Francesca Micoli - francesca.x.micoli@gsk.com

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Enteric infections	Coordinator	GlaxoSmithKline Vaccines, Rixensart, Belgium	**Kenya** • Kenya Medical Research Institute (KEMRI) • Wellcome Trust Research Directorate (USAMRD) • Kericho Field Station	**USA** • Walter Reed Army Institute of Research/ Henry Jackson Foundation **Belgium** • Centre for Vaccinology, Ghent

Project period	Main funding agency	Total budget	Budget Italian institution
2021-2024	GlaxoSmithKline	€ 4,992,331	€ 2,893,520

GMMA-based multicomponent Shigella vaccine for endemic countries

Description

The project goal is the development of a GMMA-based multivalent Shigella vaccine through to Phase 2 Proof of Concept (PoC) in infants of countries where shigellosis is a significant disease burden.

Challenge

Shigellosis is a major global health problem, especially in children under the age of 5 years in low- and middle-income countries. The disease symptoms range from mild diarrhea to severe dysentery with fever. Shigellosis is also associated with morbidity and long-term consequences, including stunting and growth retardation. Antibiotic resistance of Shigella is increasing and most of the affordable antibiotics are no longer effective. Currently, no vaccines are widely available.

Objectives

- Preclinical development and generation of 3 *S. flexneri* GMMA drug substances and 4-component Shigella drug product including *S. sonnei* GMMA;
- evaluation of *S. sonnei* GMMA in a CHIM study;
- generation of an alternative *S. sonnei* GMMA construct and its incorporation into a 4-component Shigella vaccine;
- manufacture and release of the 4-component Shigella vaccine;
- GLP toxicology study of 4-component Shigella vaccine to support clinical trial application preparation and submission.

Project participant

GSK Vaccines Institute for Global Health, Francesca Micoli - francesca.x.micoli@gsk.com

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Enteric infections	Coordinator	GlaxoSmithKline Vaccines, Rixensart, Belgium	**Kenya** • Kenya Medical Research Institute (KEMRI) • Wellcome Trust Research Directorate (USAMRD) • Kericho Field Station	**Belgium** • Centre for Vaccinology, Ghent **USA** • Cincinnati Children's Hospital Medical Center • Walter Reed Army Institute of Research

Project period	Main funding agency	Total budget	Budget Italian institution
2015-2021	GlaxoSmithKline	€ 10,779,189	€ 7,401,541

GMMA-based Shigella vaccine serology and schedule finding trial

Description

This project aims to impact human health through accelerating the clinical development of a novel 4-component GMMA Shigella vaccine in the target population, young children in LMICs.

Challenge

Shigellosis is a major global health problem, especially in children under the age of 5 years in low- and middle-income countries. The disease symptoms range from mild diarrhea to severe dysentery with fever. Shigellosis is also associated with morbidity and long-term consequences, including stunting and growth retardation. Antibiotic resistance of Shigella is increasing and most of the affordable antibiotics are no longer effective. Currently, no vaccines are widely available.

Objectives

- Additional serologic evaluation of human samples collected in a prior trial evaluating 4-component GMMA Shigella vaccine in EU and African volunteers;
- a schedule finding study in African infants of 4-component GMMA Shigella vaccine.

Project participant

GSK Vaccines Institute for Global Health, Francesca Micoli - francesca.x.micoli@gsk.com

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Enteric infections	Coordinator	GlaxoSmithKline Vaccines, Rixensart, Belgium	**Kenya** • Kenya Medical Research Institute (KEMRI) • Wellcome Trust Research Directorate (USAMRD) • Kericho Field Station	**Belgium** • Centre for Vaccinology, Ghent **USA** • Walter Reed Army Institute of Research/ Henry Jackson Foundation of Research

Project period	Main funding agency	Total budget	Budget Italian institution
2021-2024	GlaxoSmithKline	€ 1,876,388	€ 944,110

Letter of Agreement with World Health Organization HQ

Description
Strengthen TB laboratory system.

http://whocctblab.fondazionesanraffaele.it/tb-supranational-reference-laboratory.html

Challenge
Close TB diagnostic gap in high TB burden countries.

Objectives
Strengthen TB laboratory system of high TB burden countries and perform whole genome sequencing (WGS). Provide assistance and technical support.

Medline link to publications
https://pubmed.ncbi.nlm.nih.gov/29574065/
https://pubmed.ncbi.nlm.nih.gov/29247181/
https://pubmed.ncbi.nlm.nih.gov/33384044/

Project participant
Fondazione Centro San Raffaele, Daniela Maria Cirillo - cirillo.daniela@hsr.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Respiratory infections and tuberculosis	Coordinator	Fondazione Centro San Raffaele, Italy	**Burkina Faso** **Cote Ivoire** **Eritrea** **Ethiopia** **Djibouti** **Mauritania** **Mozambique** **Nigeria** **South Africa** **Swaziland** • National TB Programmes	

Project period	Main funding agency	Total budget	Budget Italian institution
2014-2020	WHO-HQ	€ 1,506,514	€ 1,506,514

NeoAMR Observational Study (NeoOBS)

Description

The Global Neonatal Sepsis Observational Study is collecting data to inform the design of clinical trials and assessing the efficacy of novel antibiotic regimens in areas with high endemic antimicrobial resistance (AMR) rates.

https://penta-id.org/severe-infections-and-antimicrobial-resistance/neovanc-2/

Challenge

An increasing number of infections which occur in babies in hospitals are resistant to antibiotics. This means that in the future these antibiotics may not work as well.

Objectives

The aim of the study is to find out more about antibiotic-resistant infections and how to treat them best. The study is collecting information on hospitalised babies who are being treated for an infection with intravenous antibiotics. The collected information includes basic information about babies, their treatment and the infections.

Project participant

Penta, Carlo Giaquinto - info@penta-id.org

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Non communicable diseases • Antimicrobial resistance	Partner	Penta, Italy	**Uganda** • Kampala Charlotte Maxeke Academic Hospital **Kenya** • Kenya Medical Research Institute (KEMRI) • Kilifi County Hospital Mulago Hospital **South Africa** • Johannesburg Tygerberg Children's Hospital • Cape Town Chris Hani Baragwanath Academic Hospital	**Bangladesh** • Dhaka Shishu Hospital • Dhaka FCM da Santa Casa de Sao Paulo Shenzhen Children's Hospital **China** • Shenzhen Beijing Children's Guangdong Woman and Children's Hospital • Guangdong Hippokration Hospital **India** • Thessaloniki JPIMER, Puducherry • Tamil Nadu Sadfarjung Hospital, Delhi KEM **Thailand** • Chiangrai Prachanukroh Hospital • Queen Sirikit National Institute of Child Health **Vietnam** • National Hospital of Pediatrics **Italy** • Ospedale Pediatrico Bambino Gesù

Project period	Main funding agency	Budget Italian institution
2017-2020	Global Antibiotic Research and Development Partnership (GARDP)	€ 2,497,461

ODYSSEY

Description

ODYSSEY is a study of dolutegravir-based antiretroviral treatments *versus* the standard of care of HIV-positive children starting first-line or switching to second-line antiretroviral treatment.

https://odysseytrial.org/

Challenge

The lack of appropriate medication, such as dolutegravir, for HIV positive children, means that children, who need treatment for life, do not get access to these treatments early in life.

Objectives

ODYSSEY is a pragmatic strategy trial evaluating the efficacy and safety of dolutegravir-based antiretroviral therapy compared with standard of care in children starting first- or second-line antiretroviral therapy in resource-limited and well-resourced settings.

Medline link to publications

https://pubmed.ncbi.nlm.nih.gov/32763217/

Project participant

Penta, Carlo Giaquinto - info@penta-id.org

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • HIV/AIDS and sexually transmitted infections	Coordinator	Penta, Italy	**Uganda** • Makerere University-Johns Hopkins University • Joint Clinical Research Centre **Zimbabwe** • University of Zimbabwe Clinical Research Centre **South Africa** • Perinatal HIV Research Unit • Africa Health Research Institute • Family Centre for Research with Ubuntu (FAMCRU)	**Thailand** • Chiangrai Prachanukroh Hospital • Nakornping Hospital • Khon Kaen Hospital • Mahasarakam Hospital • The HIV Netherlands Australia Thailand Research Collaboration (HIV-NAT) • Prapokklao Hospital • Phayao Hospital

Project period	Main funding agency	Total budget	Budget Italian institution
2016-2021	ViiV Healthcare UK	€ 11,590,153	€ 11,590,153

PediCAP Trial

Description
Childhood Community Acquired Pneumonia. A research project focused on antibiotic treatment of severe and very severe childhood community-acquired pneumonia.

https://projectpedicap.org/

Challenge
Injectable regiments are effective but lead to longer hospital stays and increase the risk of nosocomial infections and acquisition of multidrug-resistant colonising bacteria. The project will fill the gap for oral antibiotics, which would shorten hospital stay. Providing oral treatment for paediatric pneumonia could reduce mortality and minimise the length of hospitalisation of children in lower and middle-income countries.

Objectives
- Improve antibiotic treatment for childhood pneumonia in low middle-income countries through an innovative duration-response trial design;
- understand if intravenous medications are better at curing children than oral treatments;
- understand which treatment options are most effective in treating, reducing hospital stay and antimicrobial resistance.

Medline link to publications
https://pubmed.ncbi.nlm.nih.gov/31123008/

Project participant
Penta, Carlo Giaquinto - info@penta-id.org

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Respiratory infections and tuberculosis	Coordinator	Penta, Italy	**South Africa** • University of Cape Town • KwaZulu-Natal Research Institute for TB-HIV • Wits Health Consortium **Zimbabwe** • University of Zimbabwe College of Health Sciences **Zambia** • University of Zambia/ School of Medicine **Uganda** • Makerere University	**Switzerland** • GARDP Foundation • Swiss Tropical and Public Health Institute **Belgium** • University of Antwerp **United Kingdom** • St. George's Hospital Medical School

Project period	Main funding agency	Total budget	Budget Italian institution
2019-2024	EU-EDCTP2	€ 6,997,077	€ 792,756

SMILE

Description
A study evaluating safety and antiviral effect of current standard antiretroviral therapy (ART) compared to once daily integrase inhibitor administered with DRV/r in HIV-1 infected, virologically suppressed children.

https://penta-id.org

Challenge
Nucleoside/Nucleotide Reverse Transcriptase Inhibitors (NRTIs) are a potent source of adverse effects, which contribute to the discontinuation of treatment of HIV positive adolescents.

Objectives
Assess the outcomes following a switch from a fully suppressive 3 drug regimen including 2 NRTIs to DRV/r plus a once-daily INSTI compared with continuing standard of care therapy.

Project participant
Penta, Carlo Giaquinto - info@penta-id.org

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • HIV/AIDS and sexually transmitted infections	Coordinator	Penta, Italy	**Uganda** • Joint Clinical Research Centre • Baylor College of Medicine Children's Foundation-Uganda **South Africa** • Faculty of Health Sciences, Stellenbosch University • KID-CRU/Ward J8 Children's (FAMCRU) • Perinatal HIV Research Unit (PHRU)	**United Kingdom** • MRC CTU **France** • INSERM PHTP

Project period	Main funding agency	Total budget	Budget Italian institution
2016-2020	ViiV Healthcare UK	€ 2,644,961	€ 2,644,961

A client-centred model of Antiretroviral Therapy Delivery in Southern Tigray. A Piloty study - CASA 3

Description

The CASA project intends to contribute to the long-term therapeutic success by improving the retention in care and in antiretroviral therapy (ART) through a full community-based model of ART delivery.

https://casaproject.info/

Challenge

In Ethiopia, despite a proven record of universal access to HIV care and treatment, long term ART retention still represents one of the major health challenges. It is our assumption that a full community-based model of care may represent the next decentralization step of service delivery in the Ethiopian heath system. This new model designed for stable individuals, run by health extension workers with the support of trained adherence supporters, may reduce congestion of health facilities, which could then allow the shifting of resources to clients with more advanced HIV infection and complex clinical problems.

Objectives

General objective

Contribute to the goal of reaching the Joint United Nations Programme on HIV/AIDS (UNAIDS) 90-90-90 target.

Specific objective

Contribute to improving the retention in ART and adherence to therapy of people living with HIV in Tigray/ Ethiopia.

Medline link to publications

https://www.ajol.info/index.php/ajsw/article/view/192187
https://emjema.org/index.php/EMJ/article/view/1064/pdf_253
https://europepmc.org/article/med/29082011
https://europepmc.org/article/med/26340271
https://www.researchgate.net/publication/258959996_Progetto_CASA

Project participant

Istituto Superiore di Sanità, Raffaella Bucciardini - raffaella.bucciardini@iss.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases **Health systems**	Coordinator	Istituto Superiore di Sanità, Italy	**Ethiopia** • Tigray Health Bureau • Mekelle University	

Project period	Main funding agency	Total budget	Budget Istituto Superiore di Sanità
2021-2022	Agenzia Italiana per la Cooperazione allo Sviluppo	€ 503,888	€ 203,909

A randomized control trial to evaluate a scalable active case-finding intervention for tuberculosis using a point-of-care molecular tool (Xpert Omni)

Description
A randomized controlled trial to evaluate the feasibility and impact of Xpert performed at point of care (POC) (using the Omni platform) compared to the Xpert performed in a centralized laboratory (XACT III).

Challenge
The lack of suitable diagnostic tools has been a major hurdle in finding the 'missing cases' in the community.

Objectives
A randomized controlled trial to evaluate the feasibility and impact of Xpert performed at POC (using the Omni platform) compared to the Xpert performed in a centralized laboratory (XACT III).

Project participant
Ospedale San Raffaele, Daniela Maria Cirillo - cirillo.daniela@hsr.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Respiratory infections and tuberculosis	Partner	The University of Cape Town Lung Institute (Pty) Ltd, South Africa	**South Africa** • University of Cape Town Lung Institute (Pty) • University of Cape Town **Mozambique** • National Institute of Health **Zimbabwe** • Biomedical Research and Training Institute	**Netherlands** • Radboud University Medical Center

Project period	Main funding agency	Total budget	Budget Italian institution
2020-2024	EU-EDCTP2	€ 2,662,342	€ 166,547

Training and operational research to improve retention in care of HIV people in Tigray, Ethiopia - CASA 2

Description

The CASA project intends to contribute to the long-term therapeutic success by improving the retention in care through training and research (cohort study of HIV patients on ART).

https://casaproject.info/

Challenge

In the third decade of the pandemic, despite the success of free ART services, Ethiopia is facing two major challenges: the increase of ART coverage and the need for better management of patients on ART. A substantial barrier to program effectiveness is represented by suboptimal adherence and ART retention. Maintaining a high level of patient retention in care is indeed a key factor for personal and public health benefits. Identification of determinants of attrition is therefore needed to design appropriate interventions.

Objectives

General objective

Contribute to the goal of reaching the Joint United Nations Programme on HIV/AIDS (UNAIDS) 90-90-90 target.

Specific objective

Contribute to improve the retention in care of people living with HIV in Tigray/Ethiopia.

Medline link to publications

https://www.ajol.info/index.php/ajsw/article/view/192187
https://emjema.org/index.php/EMJ/article/view/1064/pdf_253
https://europepmc.org/article/med/29082011
https://europepmc.org/article/med/26340271
https://www.researchgate.net/publication/258959996_Progetto_CASA

Project participant

Istituto Superiore di Sanità, Raffaella Bucciardini - raffaella.bucciardini@iss.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious disease **Health systems**	Coordinator	Istituto Superiore di Sanità, Italy	**Ethiopia** • Tigray Health Bureau • Mekelle University	

Project period	Main funding agency	Total budget	Budget Istituto Superiore di Sanità
2021-2022	Agenzia Italiana per la Cooperazione allo Sviluppo	€ 1,766,501	€ 768,240

Be free! Community and health system integration to promote young people free from HIV and stigma

Description

Reduction of new HIV infections, AIDS-related mortality, stigma and HIV discrimination among adolescents and young people, particularly women, key population (KP) and internal displaced people (IDPs).

Challenge

Kenya is home to the third of the world's worst HIV and AIDS epidemics, with 1,6 million of people affected by HIV and 53% of them unaware of their HIV status. The prevalence rate is 4.7%. The country did significant progress in fighting HIV. Nevertheless, there is a very high number of new infections among KP. The Nairobi City Council (NCC) is one of the main geographical areas that contribute to the HIV burden in Kenya. The urban density and high mobility of Nairobi have a strong relevance in the diffusion of HIV, mainly within people who live in slums.

Objectives

The overall objective aims at contributing to the national and international strategy of fighting and ending HIV in Kenya within 2030. The specific objective is to strengthen the integration between communities and the health system, in order to reduce new HIV infections, the mortality rate related to AIDS, the stigma and discrimination caused by HIV among adolescents and young people, particularly in women, KP, IDPs in the informal settlement of Nairobi.

Project participant

Istituto Superiore di Sanità, Marco Simonelli - marco.simonelli@iss.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • HIV AIDS and sexually transmitted infections	Partner	Servizio Volontario Internazionale, Italy	**Kenya** • Women Fighting AIDS in Kenya (WOFAK) • Girl Child Network (GCN)	• Medicus Mundi Italia

Project period	Main funding agency	Total budget	Budget Italian institution
2020-2022	Agenzia Italiana per la Cooperazione allo Sviluppo (Iniziativa 5% Global Fund)	€ 502,470	€ 33,000

CHILDREN'S HEART FOR AFRICA

Description

The Children's Heart for Africa is a project designed to create specialized centers dedicated to congenital heart disease and to promote training and clinical programs in developing African countries.

https://www.bambinicardiopatici.it/

Challenge

Congenital heart diseases remain the first cause of death among the congenital malformations and definitely the third one in infants younger than 1 year of age. Africa is the continent with the major lack of cardiac surgery centers for congenital heart disease. We hope to set up Cardiac Surgery Centers able to autonomously take care of patients with congenital cardiac disease from diagnosis to cardiac surgery treatment. This aspect has an important impact on reducing infant mortality rate.

Objectives

The principal objectives of this project are to:

- promote the progress in the treatment of congenital heart diseases in selected reference centers of developing African countries;
- sustain the building completion and organization of the centers;
- develop advanced training and educational programs with professional figures.

Medline link to publications

https://pubmed.ncbi.nlm.nih.gov/30018948/
https://pubmed.ncbi.nlm.nih.gov/28154662/
https://pubmed.ncbi.nlm.nih.gov/28533720/
https://pubmed.ncbi.nlm.nih.gov/22121420/

Project participant

IRCCS Policlinico San Donato, Alessandro Frigiola - alessandro.frigiola@grupposandonato.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Non communicable diseases • Cardiovascular diseases	Coordinator	IRCCS Policlinico San Donato, Italy	**Egypt** • Cairo University, Children's Hospital Abou El Reesh **Tunisia** • La Rabta University Hospital, Tunis **Marocco** • Casablanca University • Fez University **Nigeria** • University of Ibadan **Botswana** • Ministry of Health and Wellness **Cameroon** • Tertiary Sisters of Saint Francis, Capuchin Friars **Ethiopia** • Black Lion Hospital **Senegal** • University Hospital Fann	**Italy** • Associazione Cuore Fratello Onlus • Capuchin Friars **France** • European Heart for Children

Project period	Main funding agency	Total budget	Budget Italian institution
2015-2021	• Bambini Cardiopatici nel Mondo • IRCCS Policlinico San Donato	€ 2,800,000	€ 2,500,000

Close the gap, increase Access, Provide adequate Therapy (TB-CAPT)

Description

The project aims at generating evidence to inform the impactful implementation of tuberculosis (TB) and TB/HIV co-infection diagnostic strategies including drug-susceptibility testing (DST) at the point of care (POC).

https://www.era-learn.eu/network-information/networks/edctp-ii/strategic-actions-supporting-large-scale-clinical-trials-1/cap-tb-close-the-gap-increase-access-provide-adequate-therapy

Challenge

Need to optimize implementation strategies for novel tests and improved linkage to treatment.

Objectives

Generate evidence to inform the impactful implementation of tuberculosis (TB) and TB/HIV co-infection diagnostic strategies including drug-susceptibility testing (DST) at the POC, through a series of trials that will take place in intended settings of use in Tanzania, Mozambique and South Africa.

Project participant

Ospedale San Raffaele, Daniela Maria Cirillo - cirillo.daniela@hsr.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Respiratory infections and tuberculosis	Partner	Foundation for Innovative New Diagnostics FIND, Switzerland	**Ethiopia** • African Society for Laboratory Medicine **Mozambique** • Manhiça Health Research Center • National Institute of Health **Tanzania** • Ifakara Health Institute Trust • National Institute for Medical Research **South Africa** • Tanzania University of Cape Town • Wits Health Consortium (Pty) Ltd	**Switzerland** • Foundation for Innovative New Diagnostics • Swiss Tropical and Public Health Institute **Spain** • Barcelona Institute for Global Health **Germany** • Ludwig-Maximilians University, München

Project period	Main funding agency	Total budget	Budget Italian institution
2019-2022	EU-EDCTP2	€ 5,975,984	€ 417,418

Extended follow-up of the Tat vaccine phase II trial (ISS T-003)

Description

Volunteers previously enrolled in a phase II vaccine trial completed in 2016 in South Africa will be re-enrolled in an extended follow-up study to evaluate long-term outcomes.

Challenge

- Assure continuity to the clinical-laboratory platform previously built by ISS-CNAIDS in South Africa;
- build upon previous achievements while providing the Clinical Research Unit (Mecru) at the Sefako Makgatho University new with new resources for new tasks;
- verify Mecru capacity of long-term retention of volunteers referring to several public health clinics in a vast catchment area.

Objectives

Complete the extended follow-up study follow-up of the Tat vaccine phase II trial (ISS T-003) to continue evaluating vaccine safety and immunogenicity (primary outcomes) and efficacy proxy-biomarkers (secondary aim).

Medline link to publications

https://pubmed.ncbi.nlm.nih.gov/27277839/

Project participant

Istituto Superiore di sanità, Barbara Ensoli - barbara.ensoli@iss.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • HIV/AIDS and sexually transmitted infections **Health systems** • Clinical trial design assessment	Coordinator	Istituto Superiore di Sanità, Italy	**South Africa** • Mecru Clinical Research Unit (MeCRU) • Sefako Makgatho Health Sciences University (SMU)	

Project period	Main funding agency	Total budget	Budget Italian institution
2020-2022	Ministero della Salute	€ 35,000	€ 35,000

ISS/DMI-ENI/NAOC Cooperative proposal for the implementation of a malaria diagnostic quality control project and a drug resistance surveillance activity in Nigeria

Description

The project activities include: refresher courses on the malaria diagnostic (on site); molecular epidemiology investigation on drug resistance in Nigeria; training on job and external quality assessment (EQA).

Challenge

To carry out the molecular diagnosis of human plasmodium infections, including mixed infections, and to assess the prevalence of *Plasmodium falciparum* sub-microscopic infections in isolates from patients attending the NAOC clinic in Central (Abuja) and Southern Nigeria (Delta Niger area). To analyze the polymorphisms in the marker genes for resistance to antimalarials (pfcrt, pfmdr1 and pfK13) in samples collected in Nigerian endemic areas and diagnosed positives to *P. falciparum* mono-infections by the real time PCR. Particular attention will be devoted to artemisinin derivatives based drugs.

Objectives

General objective

To carry out a molecular epidemiology investigation on drug resistance in Nigeria.

Specific objectives

- Molecular diagnosis of malaria cases and prevalence of *P. falciparum* sub-microscopic infections in Central and Southern Nigeria (Delta Niger area);
- monitoring antimalarials resistance in Nigeria;
- external quality assessment (EQA) for malaria laboratory diagnosis *via* submission of blind sampfrom ISS to NAOC laboratory staff in order to verify percentage of accuracy in malaria slides diagnosis.

Project participant

Istituto Superiore di Sanità, Carlo Severini - carlo.severini@iss.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Neglected tropical infectious diseases and malaria	Coordinator	Istituto Superiore di Sanità, Italy	**Nigeria** • Nigerian Agip Oil Company (NAOC)	

Project period	Main funding agency	Total budget	Budget Italian institution
2020-2021	Ente Nazionale Idrocarburi	€ 51,000	€ 51,000

Ex vivo activity of antimalarial compounds on *Plasmodium falciparum* gametocytes and their mosquito transmission efficiency

Description

The project studies the effect of drugs specific for the male and female gametocytes of *Plasmodium falciparum* in blocking parasite transmission from naturally infected individuals to laboratory mosquitoes.

Challenge

The need to block malaria parasite transmission prompted research to develop drugs blocking *P. falciparum* transmission from humans to Anopheles mosquitoes. It is critical to evaluate efficacy of such anti-transmission drugs on gametocytes (the Plasmodium transmission stages) from natural infections. The project aims to develop a *P. falciparum* gametocyte assay with male and female gametocyte specific mRNAs and to use it in an *ex-vivo* protocol where gametocytes from infected individuals are drug treated and tested for ability to infect mosquitoes in Anopheles experimental infections.

Objectives

The project objectives are to:

- develop a qRT-PCR assay on *P. falciparum* male and female gametocyte transcripts and validate the assay with *in vitro* treated-gametocytes;
- transfer *in vitro* gametocyte cultivation protocol and qRT-PCR assay to the CNRFP laboratory in Ouagadougou;
- use the qRT-PCR assay in the *ex-vivo* analysis of gametocyte trasmissibility after treatment with drugs and compounds with sex specific activity;
- measure impact of gametocyte sex ratio on parasite transmission efficiency.

Medline link to publications

https://www.ncbi.nlm.nih.gov/pubmed/30866941

Project participant

Istituto Superiore di Sanità, Pietro Alano - pietro.alano@iss.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Neglected tropical infectious diseases and malaria	Partner	National Centre for Malaria Research and Training (CNRFP), Burkina Faso	**Burkina Faso** • National Centre for Malaria Research and Training (CNRFP)	**Netherlands** • TROPIQ, Nijmegen

Project period	Main funding agency	Total budget	Budget Italian institution
2019-2021	National Centre for Malaria Research and Training (CNRFP)	€ 47,000	€ 10,000

MediLabSecure (MLS)

Description

Preventing biological risks increased by environmental and climate change in the Mediterranean, Black Sea and Sahel regions by strengthening institutional capacities in the context of One Health (MediLabSecure, MLS).

https://www.medilabsecure.com/

Challenge

Considering that the majority of emerging threats are zoonotic, and many include vector(s) in their transmission cycle, a country's capacity to effectively respond is dependent on the coordinated involvement of multiple actors from a variety of sectors and at different levels of implementation. Only early detection of these viruses can prevent possible relevant epidemics. In particular, the incidence of diseases caused by arboviruses in humans and in a wide range of domestic and wild animals has conquered new geographical areas, posing a threat due to their epidemic and zoonotic potential.

Objectives

Create a framework to improve surveillance and monitoring of emerging vector-borne zoonotic diseases of viral origin with a One Health approach. Provide training for public health experts and improve national laboratories capacities to increase the communicable disease control in the Mediterranean, Black Sea and Sahel regions. Enhance intersectoral and cross-border collaboration. Strengthen integrated surveillance (animal health, human health, entomological and environmental data).

Medline link to publications

https://pubmed.ncbi.nlm.nih.gov/29534445/
http://www.iss.it/documents/20126/45616/18_20_web.pdf
https://pubmed.ncbi.nlm.nih.gov/30724030/
https://pubmed.ncbi.nlm.nih.gov/31936412/
https://pubmed.ncbi.nlm.nih.gov/32382554/

Project participant

Istituto Superiore di Sanità, Silvia Declich, Maria Grazia Dente - silvia.declich@iss.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Vector-borne zoonotic diseases of viral origin with a One Health approach **Health and environment** • Animal health • Human health • Entomological and environmental data • Human related veterinary health • Environmental health	Partner	Institut Pasteur Paris, France	**Algeria** **Burkina Faso** **Egypt** **Libya** **Mali** **Mauritania,** **Marocco** **Niger** **Senegal** **Tunisia**	**France** • Institut Pasteur, Paris • The French National Research Institute for Sustainable Development **Spain** • The National Research Institute for Agricultural and Food Research and Technology (INIA) **Italy** • Istituto Superiore di Sanità • Istituto Zooprofilattico Sperimentale Lazio e Toscana **Belgium** • Avia-GIS, Zoersel In addition, collaborative sub-contracting party **12 Balkans, Middle East and Black Sea countries**

Project period	Main funding agency	Total budget	Budget Italian institution
2014-2022	European Commission	€ 9,181,665	€ 1,221,323

Network of European and African Researchers on Antimicrobial Resistance (NEAR-AMR)

Description

The NEAR-AMR represents a group of experts in antimicrobial resistance from leading institutions, located throughout Europe and Africa, encompassing a One Health approach to antimicrobial resistance (AMR).

https://www.lstmed.ac.uk/near-amr

Challenge

Develop a Strategic Action Plan on Training to identify opportunities for capacity building and strengthen capability, with a focus on young investigators. Develop a plan for a Global Platform for data sharing (e.g. clinical samples/ data, scientific information and infrastructures including libraries or catalogues).

Objectives

- To find the most effective strategies for maximizing training opportunities for young researchers whilst building capacity and strengthening capability in African nations;
- to develop a "preferred platform profile" for a global data sharing tool, which will link (and complement) existing platforms (e.g. from the ECDC);
- to disseminate the findings from the project between other surveillance networks related to AMR (i.e. other JPIAMR networks, ESCMID working group, etc.);
- to incorporate the findings of other networks into a consensus and disseminate it as widely as possible.

Medline link to publications

https://www.lstmed.ac.uk/near-amr

Project participant

Istituto Superiore di Sanità, Patrizia Spigaglia - patrizia.spigaglia@iss.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Respiratory infections and tuberculosis • Enteric infections • AMR bacterial infections	Partner	Liverpool School of Tropical Medicine, United Kingdom	**Egypt** **Ghana** **Kenya** **Liberia** **Malawi** **South Sudan** **Tanzania** **Uganda**	

Project period	Main funding agency	Total budget	Budget Italian institution
2019-2020	Joint Programming Initiative on Antimicrobial Resistance (JPIAMR)	€ 50,000	no budget

New generation drugs against *Plasmodium falciparum* transmission for malaria eradication

Description

The project aims to develop innovative cell based assays to test libraries of chemical compounds on the *Plasmodium falciparum* stages responsible for the human-to-mosquito transmission of the malaria parasites.

Challenge

Malaria parasites infect annually 220 million individuals and kill over 450,000. It is now clear that elimination of the disease must, in addition to curing the disease, also block Plasmodium parasite transmission from humans to the Anopheles vector and viceversa. As *P. falciparum* gametocytes, responsible for the human-to-mosquito trasmission, are not susceptible to the same drugs used to kill the pathogenic asexual parasites, the project aims to develop cell-based assays and use them to screen chemical libraries for novel anti-gametocyte compounds.

Objectives

Teams at the Istituto Superiore di Sanità, Universities of Pretoria and Milan and the Council for Scientific and Industrial Research, Pretoria, join their forces with the objectives to:

- produce *P. falciparum* transgenic parasite lines expressing luciferases in male and female gametocytes to develop innovative cell-based anti-gametocyte assays;
- screen compound libraries to identify anti-gametocyte hits;
- use independent assays to validate activity of the hits and to measure selectivity of the compounds *vs* the asexual pathogenic parasites and *vs* human cells to assess their cytotoxicity.

Medline link to publications

https://www.ncbi.nlm.nih.gov/pubmed/30866941
https://www.ncbi.nlm.nih.gov/pubmed/32256458
https://pubmed.ncbi.nlm.nih.gov/32425505

Project participant

Istituto Superiore di Sanità, Pietro Alano - pietro.alano@iss.it·

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Neglected tropical infectious diseases and malaria	Coordinator	Istituto Superiore di Sanità, Italy	**South Africa** • University of Pretoria • Council for Scientific and Industrial Research, Pretoria	**Italy** • Università degli Studi di Milano

Project period	Main funding agency	Total budget	Budget Italian institution
2018-2021	Ministero della Salute	€ 287,000	€ 223,000

Origin and development of maturing gametocytes of *Plasmodium falciparum* in deep tissues and peripheral circulation

Description

The project aims to study the host/parasite cellular-molecular interplay of the *Plasmodium falciparum* transmission stages in their maturation in the human bone marrow of asymptomatic infected individuals.

Challenge

Malaria parasite transmission from humans to mosquitoes is ensured by the Plasmodium gametocytes. In *P. falciparum* gametocytes mature for 10-12 days in the bone marrow, where they are able to reach the marrow stroma. As direct analysis of gametocyte maturation in bone marrow in natural infections is ethically unacceptable, the project had ethical approval from the Ghana and the ISS Ethics Committee to study this process with advanced microscopy and molecular markers analysing waste specimens from orthopedic surgeries on malaria asymptomatic individuals carrying gametocytes.

Objectives

The project aims to establish a protocol to fix and react specimens of bone marrow biopsies from waste orthopedic surgery with *P. falciparum* gametocyte-specific antibodies from asymptomatic individuals in the Ghana Volta Region. Specimens will be used in conventional and two photon confocal microscopy to obtain 3D reconstructions of gametocyte infected bone marrow vascular and extravascular compartments. Host/parasite RNASeq and immune cell typing from these specimens will contribute to identify the gametocyte cell interactions with bone marrow cell types.

Project participant

Istituto Superiore di Sanità, Pietro Alano - pietro.alano@iss.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Neglected tropical infectious diseases and malaria	Partner	University of Health and Allied Sciences, Ho, Ghana	**Ghana** • University of Health and Allied Sciences, Ho	**Italy** • Istituto Italiano di Tecnologia, Sapienza Università, Roma **United Kingdom** • Liverpool School of Tropical Medicine **Sweden** • Umea University

Project period	Main funding agency	Total budget	Budget Italian institution
2020-2022	The Royal Society UK - Future Leaders - African Independent Research	€ 330,000	€ 15,000

PedMAb: Phase I/II study to determine Safety and Pharmacokinetics of subcutaneous administration of potent and broad anti HIV-1 neutralizing monoclonal antibodies (bNAbs), given to HIV-1 exposed neonates and infants

Description

Phase I/II study to determine Safety and Pharmacokinetics of subcutaneous administration of potent and broad anti HIV-1 neutralizing monoclonal antibodies in HIV-1 exposed neonates and infants.

Challenge

In 2018 approximately 160,000 new HIV-infections were in children <9 years; half of these occurred during breastfeeding. Given the challenges of maternal and child access and adherence to antiretroviral therapy in high HIV prevalence settings (46%), innovative biomedical solutions, including long-acting, injectable formulations, offer a paradigm shift in the pediatric HIV/AIDS epidemic. Modified HIV-1 broadly neutralizing antibodies are highly potent and long-acting, and therefore have indisputable potential for protection from HIV-1 peri- and postnatal transmission.

Objectives

PedMAb will define the optimal dose(s), timing, and the ideal combination(s) of bNAbs to prevent HIV breast-milk transmission.
First objective is a multi-step approach phase I (dose finding) study followed by a phase II study to test the safety, tolerability and pharmacokinetic profile of two long-acting bNAbs administered subcutaneously alone or in combinations to breastfeeding, HIV-exposed, uninfected neonates alongside standard-of-care ARVs, and repeated once (at 4 or 6 months) in infants.
Second objective is to support capacity building, knowledge, and technology transfer.

Project participant

Ospedale San Raffaele, Gabriella Scarlatti - scarlatti.gabriella@hsr.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • HIV/AIDS and sexually transmitted infections **Health systems** • Clinical trial design assessment	Coordinator	Ospedale San Raffaele, Italy	**South Africa** • South African Medical Research Council • University of the Witwatersrand	**France** • Immunology, Inflammation, Infectiology, and Microbiology (I3M) **Norway** • University of Bergen

Project period	Main funding agency	Total budget	Budget Italian institution
2020-2024	EU-EDCTP2	€ 3,965,161	€ 918,538

Pilot ultrasound survey of human cystic echinococcosis in livestock-keeping communities of Northern Tanzania

Description

Cross-sectional ultrasound-based prevalence study of human cystic echinococcosis in Maasai communities of Northern Tanzania.

Challenge

Recent research carried out by Glasgow University and Kilimanjaro Clinical Research Institute has identified in Maasai communities of Northern Tanzania a devastating increase in cerebral coenurosis in small ruminants, caused by *Taenia multiceps*. Given the overlapping life cycle between *Echinococcus granulosus* (agent of cystic echinococcosis - CE) and *T. multiceps*, it is likely that factors underlying the emergence of coenurosis may also be increasing the risk of CE in people, constituting a potential for a hidden public health threat which may become apparent in the next future.

Objectives

Given the overlapping life cycle between the agent of ovine coenurosis and human and livestock cystic echinococcosis, the aim of the study is to investigate the epidemiological situation of CE in two Maasai communities, by means of ultrasound screening in communities and abattoir inspection and genotyping analyses of parasitic cysts in livestock. This will provide health authorities with baseline data to inform public health strategies.

Project participant

Istituto Superiore di Sanità, Francesca Tamarozzi - francesca.tamarozzi@glasgow.ac.uk

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Neglected tropical infectious diseases and malaria	Partner	University of Glasgow, United Kingdom	**Tanzania** • Kilimanjaro Clinical Research Institute, Kilimanjaro Christian Medical Centre, Moshi	**Italy** • Istituto Superiore di Sanità **United Kingdom** • Institute of Biodiversity, Animal Health & Comparative Medicine College of Medical, Veterinary and Life Sciences, University of Glasgow

Project period	Main funding agency	Total budget	Budget Italian institution
2019-2021	European Society of Clinical Microbiology and Infectious Diseases (ESCMID)	€ 20,000,00	No budget

POR TB consortium; Phase 2 trial to determine efficacy of the multistage vaccine H56: IC31 for Prevention of Recurrent TB disease

Description

The primary objective of this proposal is to unite six African and two European research institutions to conduct an innovative and cost-effective TB vaccine Phase 2b efficacy trial.

https://www.porconsortium.org/

Challenge

The current tools for controlling TB are clearly insufficient and without new efficacious TB vaccines.

Objectives

Test efficacy of the multistage vaccine H56:IC31.

Project participant

Ospedale San Raffaele, Daniela Maria Cirillo - cirillo.daniela@hsr.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Respiratory infections and tuberculosis	Partner	Statens Serum Institut, Denmark	**Tanzania** • National Institute for Medical Research **South Africa** • Tanzania TASK Foundation NPC • The Aurum Institute NPC • University of Cape Town • University of Cape Town Lung Institute (Pty) • Ltd Aeras Global Tuberculosis Foundation NPC	

Project period	Main funding agency	Total budget	Budget Italian institution
2017-2022	EU-EDCTP2	€ 13,788,161	€ 260,000

Prevention of invasive Group B Streptococcus diseases in young infants: a pathway for the evaluation and licensure of an investigational maternal GBS vaccine (PREPARE)

Description

Network of African (Uganda, Malawi, South Africa) and European sites (UK, Italy, France, Netherlands) to advance the understanding of the immunogenicity and efficacy of Group B streptococcus (GBS) candidate vaccines.

https://gbsprepare.org

Challenge

GBS is the leading cause of sepsis and meningitis in the first three months of life in both developing and developed countries. It is globally responsible for 410,000 cases of invasive neonatal infections, 147,000 stillbirths/infant deaths and 33,000 severe infections in pregnant or post-partum women, each year. It counts for 13% of all cases is in Africa. The development of GBS vaccines for maternal immunization has been identified as a priority for the WHO Initiative for Vaccine Research. Several vaccine candidates are currently in development.

Objectives

- To develop a clinical vaccine trial site in a Sub-Saharan setting capable of undertaking phase II-IV trials;
- to determine the pregnancy outcome rates in this population in preparation for trials of vaccines in pregnant women;
- to define the burden of neonatal, infant and maternal GBS disease in a Sub-Saharan African population;
- to estimate the serocorrelates of protection against the major GBS types causing disease in European and African setting;
- to conduct two trials of candidate GBS vaccines.

Medline link to publications

https://pubmed.ncbi.nlm.nih.gov/33115542/

Project participant

Istituto Superiore di Sanità, Roberta Creti - roberta.creti@iss.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Invasive infections by Group B streptococci in newborns and infants **Health systems** • Vaccine trial design	Third Party	St. George's Hospital Medical School, London, United Kingdom	**Uganda** • Makerere U. Johns Hopkins U (MU-JHU) Research Collaboration **South Africa** • Wits Health Consortium (PTY) LTD **Malawi** • Malawi Liverpool-Wellcome (MLW) Trust Clinical Research Program	**France** • AP-HP Hospitals, Paris **Netherlands** • Amsterdam University Medical Center **Italy** • Azienda Ospedaliero-Universitaria Policlinico di Modena **United Kingdom** • University College London (UCL) • London School of Hygiene and Tropical Medicine (LSHTM) **Denmark** • Minervax ApS **United States** • Pfizer Inc.

Project period	Main funding agency	Total budget	Budget Italian institution
2019-2024	EU-EDCTP2	€ 9,995,744	€ 32,000

Prevention of mother-to-child transmission of HIV: an analysis of maternal retention and of infants health in the first year after delivery

Description

Observational study enrolling one cohort of HIV-infected mothers and their children and a contemporary cohort of HIV-negative mothers with their HIV-unexposed children in Malawi (GF-ISS study).

Challenge

The administration of antiretroviral therapy to HIV-infected women during pregnancy and breastfeeding has led to a strong reduction of vertical transmission of HIV. However, improvements in the preventive programs are needed to optimize strategies. Maternal retention and early infant HIV diagnosis (EID) are critical steps that may limit efficiency of the programs. Also, it is well known that HIV-exposed infants have a greater morbidity and mortality compared to HIV-unexposed infants. Although the reasons for this have not been clearly elucidated, a dysfunctional immunological response may be involved.

Objectives

To assess the factors that determine retention in care of mother-infant pairs and investigate the impact of maternal HIV infection and ART on health and immunological response of HIV-exposed infants under the current preventive program in Malawi. Specifically, rate and causes of maternal loss to follow-up and rate and determinants of early infant diagnosis of HIV will be evaluated. Also, morbidity and mortality will be compared between HIV-exposed and HIV-unexposed infants up to 1 year of age. Antibody responses to vaccines against Hepatitis B, Pneumococcus and Rotavirus will be measured at 6 and 12 months of age in HIV-exposed and -unexposed infants.

Project participant

Istituto Superiore di Sanità, Marina Giuliano - marina.giuliano@iss.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious Diseases • HIV/AIDS and sexually transmitted infections	Coordinator	Istituto Superiore di Sanità, Italy	**South Africa** • DREAM Program, Community of S. Egidio, Malawi	**Italy** • Programma DREAM, Comunità di S. Egidio

Project period	Main funding agency	Total budget	Budget Italian institution
2018-2021	Agenzia Italiana per la Cooperazione allo Sviluppo (Iniziativa 5% Global Fund)	€ 276,000	€ 250,000

Safety and efficacy of Dolutegravir and EFV400 for pregnant and breast feeding women: a randomized non-inferiority clinical trial (PREGART)

Description

To provide evidence-based recommendations for safe and effective first line antiretroviral therapy (ART) regimens for PMTCT and treatment of HIV-infected pregnant and breastfeeding women living in resource limited settings.

https://www.pregart.eu/

Challenge

Safe and effective antiretroviral drugs during pregnancy and breastfeeding is key. Dolutegravir (DTG), a second-generation integrase strand transfer inhibitor-based ART regimen demonstrated minimum drug interaction, lower risk of treatment discontinuation and superior virological suppression against other first-line agents, including efavirenz and boosted protease inhibitors. DTG and low dose EFV 400mg/day (EFV400) are recommended by WHO as an alternative first line regimen for adults and are promising alternatives for pregnant/breastfeeding women.

Objectives

General objective

To provide evidence based recommendations for safe and effective first line ART regimens for PMTCT and treatment of HIV-infected pregnant and breastfeeding women living in resource limited settings. The study will contribute towards optimization of existing WHO and regional guidelines of ART for HIV-infected pregnant and breastfeeding women.

Specific objectives

To identify safer and more effective ART regimen for pregnant and breastfeeding women by comparing three alternative first line ART regimens for their safety and efficacy using randomized clinical trial.

Project participant

Istituto Superiore di Sanità, Marco Simonelli - marco.simonelli@iss.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • HIV/AIDS and sexually transmitted infections	Partner	Hawassa University, Ethiopia	**Ethiopia** • Hawassa University **Uganda** • Makerere University	**Sweden** • Karolinska Institute

Project period	Main funding agency	Total budget	Budget Italian institution
2019-2024	EU-EDCTP2	€ 3,902,468	€ 245,000

SeqMDRTB_NET

Description
Network for the application of sequencing technologies for the fight against resistant tuberculosis in high incidence settings.

https://ghpp.de/en/projects/seqmdrtb-net

Challenge
Successful control of M/XDR-TB requires efficient drug susceptibility testing (DST) as basis for designing effective therapy regimens. However, e.g. due to inadequate infrastructure, DST is often missing or delayed in countries with medium or high TB incidence, leading to empirical treatment regimens with low cure rates.

Objectives
This project will support countries with a high TB incidence such as Moldova in Eastern Europe and Kyrgyzstan in Central Asia and three countries in Southern Africa, Eswatini, Namibia and Mozambique, in establishing sequencing technologies as diagnostic tools for the rapid prediction of drug resistance.

Project participant
Ospedale San Raffaele, Daniela Maria Cirillo - cirillo.daniela@hsr.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Respiratory infections and tuberculosis	Partner	Research Center Borstel, Germany	**Eswatini** • Eswatini Ministry of Health, Mbabane **Mozambique** • National Institute of Health **Namibia** • University of Namibia, School of Medicine, Windhoek	**Kyrgyzstan** • National Tuberculosis Center of the Kyrgyz Republic, Bishkek **Moldova** • Institute of Phthisiopneumology, "Chiril Draganiuc", Chisinau

Project period	Main funding agency	Total budget	Budget Italian institution
2020-2021	Federal Ministry of Health, Germany	€ 300,000	€ 30,000

Stop TB and HIV in Angola: Improving access to TB and HIV treatment by enhancing the diagnostic quality and patient management in the Province of Luanda

Description

To support health authorities in improving the quality of diagnosis and management services for patients affected by TB and TB/HIV co-infection and strengthening the data collection system.

Challenge

The epidemiological situation in Angola is characterized by the triple burden of TB and multidrug resistant TB, HIV, and persistent rates of TB/HIV co-infection. Luanda is among the first Provinces for the incidence of TB (326/100,000) and as regards HIV, 10% of the tests carried out in the Province in 2013 were HIV-positive while the national average was 4.7%. Thirty percent of the country's HIV-positive population is concentrated in this Province. As for the multidrug resistant TB, the Province is confirmed as one of the most affected in the country. The situation is aggravated by the fragility of the Angolan health system and by the inadequacy of the health information and data management system.

Objectives

The aim is to improve the quality of diagnostic and management services for patients suffering from TB and TB/HIV co-infection at the anti-tuberculosis Dispensary and the Sanatório Hospital in Luanda. The intervention strategy includes the strengthening of data collection system, in order to improve the planning of TB services and quality of care provided. ISS is involved in the assessment to identify needs and gaps in the information system; digitization of the health registers; training of health personnel in charge of data collection at target health facilities.

Project participant

Istituto Superiore di Sanità, Marco Simonelli - marco.simonelli@iss.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • HIV/AIDS and sexually transmitted infections, • Respiratory infections and tuberculosis **Health systems** • Public health structure organization	Partner	Medici con l'Africa Cuamm, Italy	**Angola** • Luanda Provincial 4 Directorate of Health (DPSL) **Guinea-Bissau** • ADPP	

Project period	Main funding agency	Total budget	Budget Italian institution
2018-2020	Agenzia Italiana per la Cooperazione allo Sviluppo (Iniziativa 5% Global Fund)	€ 588,235	ISS study missions covered by the Project coordination

TB-Lab

Description
Strengthen TB laboratory system in West Central African Countries.

https://srlcotonou.org/tb-lab/

Challenge
Quality of TB laboratory system is a challenge in many low resource countries.

Objectives
Strenghten TB laboratory system of high TB burden countries and perform whole genome sequencing (WGS).

Project participant
Ospedale San Raffaele, Daniela Maria Cirillo - cirillo.daniela@hsr.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Respiratory infections and tuberculosis	Third Party	Supranational TB Reference Laboratory, Benin	**Benin** **Burkina Faso** **Cape Verde** **Cote Ivoire** **Gambia** **Ghana** **Guinea** **Guinea-Bissau** **Liberia** **Mali** **Mauritania** **Niger** **Nigeria** **Senegal** **Sierra Leone** **Togo** • National TB programmes	**Belgium** • TB Reference Laboratory

Project period	Main funding agency	Total budget	Budget Italian institution
2019-2021	The Global Fund	€ 5,314,488	€ 95,095

The UMBRELLA trial: an open-label phase 1/2 trial evaluating the safety and pharmacokinetics of VRC07-523-LS, a potent long acting broadly neutralizing monclonal antibody, in HIV-1 exposed infants in South Africa

Description

An open-label phase 1/2 trial to evaluate the safety and prophylactic properties of long-acting potent monoclonal antibodies in breastfed HIV-exposed infants, in Pretoria.

Challenge

Passive immunoprophylaxis by means of human monoclonal antibodies with broadly neutralizing (bNAb) properties is an appealing new strategy to eliminate residual transmission of HIV by breastfeeding. VRC07-523-LS is one of such bNAb that is targeting the CD4 binding site of the >96% of viruses including clade C. The Umbrella trial is an open-label phase 1/2 trial evaluating the safety and pharmacokinetics (protective antibody titre) of VRC07-523-LS in HIV-1 exposed neonates and infants in a large academic Hospital in Pretoria, South Africa.

Objectives

Primary objectives are to evaluate the 6 months safety and pharmacokinetics of a single perinatal subcutaneous (SC) injection of VRC07-523-LS, administered within 72 hours of birth in HIV-1 exposed uninfected infants in South Africa. Secondary objectives are to evaluate the 12 months safety and pharmacokinetics of a second SC injection of VRC07-523-LS administered at 4 months in the participants who are still breastfed and exposed to HIV.

Project participant

Ospedale San Raffaele, Gabriella Scarlatti - scarlatti.gabriella@hsr.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • HIV/AIDS and sexually transmitted **Health systems** • Clinical trial design assessment	Partner	INSERM - Montpellier, France	**South Africa** • Ameena Goga, South African Medical Research Council	**Norway** • University of Bergen **France** • Pathogenesis and Control of Chronic Infection, INSERM, Montpellier NIH-Vaccine Research Center as supplier of the medical product

Project period	Main funding agency	Total budget	Budget Italian institution
2020-2023	National Agency of Research, France	€ 649,515	€ 64,460

THUPIME TANZANIA!
Tuberculosis & HIV Undermining through Prevention, Investigation, Management & Education

Description
Support the government of Tanzania in control and prevent HIV and TB.

http://openaid.aics.gov.it/en/iati-activity/XM-DAC-6-4-011587-07-4

Challenge
Accessibility to diagnostic services is challenging in low-resource settings.

Objectives
Support the government of Tanzania in control and prevent HIV and TB trough the implementation of a multidisciplinary approach based on strengthening public health service and the awareness of the population. Improve early diagnosis and quality of integrated treatment services for HIV and TB, in Iringa Region, and increase resilience/capacity of target communities to fight the spread of HIV and TB.

Project participant
Ospedale San Raffaele, Daniela Maria Cirillo - cirillo.daniela@hsr.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Respiratory infections and tuberculosis	Partner	Cooperazione Paesi Emergenti (COPE), Italy	**Tanzania** • Kituo Cha Afya (KCA) Rural Health Centre, Nyololo • Mufindi District, Medical Officer (DMO) • University of Dodoma (DMO), Department of Medicine	

Project period	Main funding agency	Total budget	Budget Italian institution
2019-2021	Agenzia Italiana per la Cooperazione allo Sviluppo (Iniziativa 5% Global Fund)	€ 404,989	€ 63,339

Enhancement of malaria response in South Sudan through the improvement in access, utilization and quality of preventive/diagnostic/curative services and their integration to the three levels of care of the health system of Amadi state

Description

Intervention in support to South Sudan health system in the fight against communicable diseases, funded in the framework of the Technical Support Spending to Global Fund for HIV/AIDS, TB and Malaria.

Challenge

Malaria is endemic in South Sudan, and represents the leading cause of morbidity and mortality in the country. Implementation of preventive, diagnostic and therapeutic measures and definition of a comprehensive, evidence-based malaria response plan are hampered by supplies stock out, limited knowledge of health staff, lack of resources and coordination, limited surveillance capacities.

Objectives

The project aims at improving the malaria response at community and health system level for host and displaced population and most vulnerable groups in (former) Amadi State. The main objective of operative research is to fill current gaps in malaria epidemiology knowledge (prevalence of infection, Plasmodium species, HRP deletion and antimalarial drug resistance in *Plasmodium falciparum*) and in diagnosis skills (rapid diagnostic test, microscopy) through large-scale molecular investigations and capacity building at three peripheral health centers.

Project participant

Università degli Studi di Pisa, Valentina Mangano - valentina.mangano@unipi.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Neglected tropical diseases and malaria **Health Systems** • Public health structure organization	Coordinator Partner Third Party	Medici con l'Africa Cuamm, Italy	**South Sudan**	

Project period	Main funding agency	Total budget	Budget Italian institution
2020-2021	Agenzia Italiana per la Cooperazione allo Sviluppo (Iniziativa 5% Global Fund)	€ 537,579	€ 450,000

New generation drugs against *Plasmodium falciparum* transmission for malaria eradication

Description

The aims of the project are to identify new classes of drugs to block the transmission of the malaria parasite *P. falciparum* from humans to mosquitos, killing the sexual gametocyte stage.

Challenge

Identify new classes of drugs to block the transmission of the malaria parasite *P. falciparum* from humans to mosquito. These drugs, directed against the sexual, non-proliferating, gametocyte stage, address the need to accelerate the eradication of malaria worldwide, by eliminating *P. falciparum* transmission from asymptomatic individuals, the major parasite reservoir in a future when further reduction of malaria morbidity will occur.

Objectives

For the UNIMI partner:

- to conduct *in vitro* studies on novel transmission blocking drugs to determine antiparasitic activity and to define the host/parasite selectivity index of selected hits;
- to investigate the biological/biochemical parasite pathways to address the mechanism of action and target identification of the most promising gametocyte-selective hits;
- to conduct preliminary investigation on potential use of new hits with known anti-asexual drugs to identify synergistic or antagonistic drug-drug interactions.

Medline link to publications

https://pubmed.ncbi.nlm.nih.gov/32425505/

Project participant

Università degli Studi di Milano, Donatella Taramelli - donatella.taramelli@unimi.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Infectious diseases • Neglected tropical infectious diseases and malaria	Partner	Istituto Superiore di Sanità, Italy	**South Africa** • University of Pretoria • Council for Scientific and Industrial Research	**Italy** • Istituto Superiore di Sanità

Project period	Main funding agency	Total budget	Budget Italian institution
2018-2021	Ministero della Salute	€ 287,000	€ 64,000

Somaliland going forward: support to social-health excellences in pediatrics and mental health

Description

Improving the access and the quality of the mental health services and providing specialized and sustainable high quality pediatric care according to the policy of Somaliland Ministry of Health.

https://www.grtitalia.org/en/project/-/somalia

Challenge

Improve the access and the quality of the mental health services and provide specialized and sustainable high quality pediatric care according to the policy of Somaliland Ministry of Health. Training of medical staff (psychiatrists, psychologists, nurses, social workers).

Objectives

- Integration of modern medicine and traditional practices in mental health;
- modernization and humanization of the National Psychiatric Hospital;
- development of the psychosocial therapy in the community;
- training for appropriate use of drugs.

Project participant

Università degli Studi di Milano, Paolo Inghilleri - paolo.inghilleri@unimi.it

Area of research	Role in the Project	Project coordination	African Countries & Partners	Non-African Countries & Partners
Non communicable diseases • Maternal and neonatal disorders • Mental disorders	Coordinator	Gruppo per le Relazioni Transculturali (GRT), Italy	**Somalia** • General Assistance and Volunteers Organization (GAVO)	**Italy** • Terre Solidali Onlus

Project period	Main funding agency	Total budget	Budget Italian institution
2017-2020	Agenzia Italiana per la Cooperazione allo Sviluppo	€ 1,527,362	No budget

Annex to *Notiziario dell'Istituto Superiore di Sanità 2021;34(3)*
ISSN 0394-9303 (print) - ISSN 1827-6296 (online)

Legal representative and President of the Istituto Superiore di Sanità: Silvio Brusaferro
Responsible Director: Paola De Castro
Press Register - Court of Rome
no. 475 of 16 September 1988 (print)
and no. 117 of 16 May 2014 (online)

In-house printed, April 2021

Istituto Superiore di Sanità

Viale Regina Elena, 299 - 00161 Roma
www.iss.it