The Fundació Lluita contra la Sida (Fight AIDS Foundation) is in the HIV Unit at the Germans Trias i Pujol University Hospital, a public hospital managed by the Institut Català de la Salut (Catalan Health Institute). Part of the activities described in this report should be seen as a result of the work done together with the hospital’s staff. Similarly, the Foundation works closely with the Institute for AIDS Research IrsiCaixa, where more than 50 scientists focus on basic research to understand the mechanisms of HIV infection and to find new therapies and vaccines. This collaborative work facilitates the transfer of knowledge between health professionals and clinical and basic researchers, making us a unique benchmark worldwide.
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Bonaventura Clotet
PRESIDENT

MESSAGE OF THE PRESIDENT

It has been a long wait and many lives have been lost, but finally thirty years after its appearance, we have started talking about a firm date for a cure for HIV/AIDS: 2020. In five or six years we hope to have a treatment to stop this pandemic that has killed more than 39 million people all over the world, whilst 35 million more are living with it today.

The precise objective followed by our team is to cure the HIV infection. We have developed an innovative therapeutic vaccine that will be applied in clinical trials on humans in 2016. Additionally, we have a very promising design based on immunoglobulin (antibodies) that might block the entry of HIV into healthy cells. Our intention is to combine both approaches of eradication in 2018. However, until we find a cure for AIDS, we will work every day in the Fight AIDS Foundation to offer the best quality of life for people with HIV.

Currently, we are paying special attention to the study of the relationship that exists between the Human Microbiome (the community of microbes that live in our body) and the status of the immunological system in people with HIV. This relationship could provide a key element to increase the level of defenses in the fight against the infection. Additionally, healthy microbiota could assure aging with less frailty. AIDS causes an accelerated model of aging and the study about the role of the microbiome in this process might have far-ranging applications that could benefit society in general.

We also develop clinical trials concerning the adverse effects that may be caused by antiretroviral drugs and by the HIV infection itself. The results obtained allow us to develop new treatment strategies to prevent or minimize these adverse effects.

The investigation in the field of Hepatitis C experienced a revolution in 2014, with drugs that cure the infection in nearly 100% of patients. This spectacular advance has been possible, in large part, due to the knowledge generated in the field of treatments for HIV. Undoubtedly, the coinfection of HIV with the Hepatitis virus and with the Human Papillomavirus generates great interest for the study of the impact caused on the quality of life of patients.

From the Fight AIDS Foundation, we work in a network with prestigious international centers, making daily efforts to adapt our research to the needs of our patients. We try to offer them complete assistance with the maximum quality possible. However, in order to continue with our tasks, we need all the institutional, corporate and social support we can obtain. The horizon is optimistic, as long as we do not let down our guard and we keep working hard. Between all of us, we can finally achieve an end to AIDS.
Thanks to the positive effect of antiretroviral therapy and scientific advances, HIV has evolved from a deadly to a chronic disease, and new needs have emerged. The Foundation has taken on the mission of finding answers to these needs by tracking coinfection by hepatitis and human papillomaviruses, controlling cardiovascular problems, detecting cognitive impairment and diagnosing and treating complications related to general aging.
MISSION

-To offer the best human and health care to people with HIV.
-To conduct independent and competitive research in the field of HIV infection.
-To transfer the knowledge acquired to society and to healthcare professionals.

QUALITY POLICY

The Fight Aids Foundation renewed its ISO 9001:2008 certification in November 2014. It was achieved for the first time in 2006 as a result of the Foundation’s commitment to quality and continuous improvement of all its activities.
BEING INFECTED WITH HIV IS NOT THE SAME AS HAVING AIDS

HIV is the acronym for the “Human Immunodeficiency Virus”. This virus affects immune cells by destroying them or altering their functioning, which implies the progressive impairment of the immune system (the one that protects us against external diseases). Generally, a person with HIV may not show symptoms for a long time, but can transmit the virus.

AIDS is the acronym for “Acquired Immune Deficiency Syndrome”. When the HIV infection is in its most advanced stage, after having caused a severe impairment of the immune system, opportunistic infections appear. These are a diverse group of non frequent diseases that are often associated with AIDS. The use of antiretroviral therapy can control the HIV replication and strengthen the immune system. The consequence, therefore, is that infection becomes chronic and does not result in AIDS.

Contrary to popular belief nowadays, HIV does not only affect certain collectives. HIV can affect anybody. Although in our context, new infections are produced mainly between men who have sex with men.

ROUTES OF HIV TRANSMISSION:

There are three mechanisms of transmission:

1. SEXUAL ROUTE
HIV can be transmitted through unprotected sexual intercourse (vaginal, anal or oral) with a person with detectable viral levels in blood. In people following an antiretroviral treatment and with an undetectable viral load, the risk is nearly inexistent.

2. BLOOD ROUTE
Transmission of HIV can occur through transfusions with contaminated blood or after sharing injection material or other cutting objects.

3. VERTICAL ROUTE (MOTHER TO CHILD)
Mothers may transmit the HIV infection to children during pregnancy, delivery or breast-feeding. Nowadays, vertical transmission is totally controlled in developed countries, especially in those cases where the mother knows that she is infected with HIV.
HOW TO PREVENT NEW INFECTIONS

- Use condoms in all sexual intercourse to avoid the transmission of HIV and other sexually transmitted diseases.

- Do not share any type of syringe or needle and take extreme precautions if there are injuries, hemorrhages or any type of cut that might be bleeding.

- Women infected with HIV that are contemplating pregnancy must consider the risks and start antiretroviral treatment, if they are not taking it already.

- PEP and Prep: Post-Exposition Prophylaxis (PEP) means taking antiretroviral medication as soon as possible after having been exposed to HIV (in a maximum of 72 hours), so that this exposure does not end in an unwanted infection. These drugs are only available with a medical prescription. The pre-Exposition Prophylaxis (Prep) consists of taking antiretroviral medication before possible contact with HIV to reduce the risk of infection and is only available in some countries. This prophylaxis treatment should be specified in high risk populations. These include: men who have sex with men, people with an HIV-infected partner who is not currently taking antiretroviral treatment, people who inject drugs or sex workers.

In order to avoid new infections, it is crucial to establish an early diagnosis and follow up with the prescribed antiretroviral therapy. With adequate treatment, HIV can become undetectable in blood, the immune system can recover and the possibility of transmission decreases.
HIV AND AIDS

VIH/SIDA

HIV: EPIDEMIOLOGIC DATA

- It is estimated that HIV affects more than 35 million people all over the world.
- Every 10 seconds, there is a new infection, meaning nearly 9,000 people every day. 1,000 of them are children.
- Every year, more than 2 million new diagnoses are made. 50% are women.
- In our country, it is estimated that 30% of people that have HIV do not even know it.
- Only 37% of them are receiving antiretroviral treatment.

AIDS

- Since the beginning of the pandemic, 39 million people have died because of AIDS all over the world.
- 17.8 million children have lost one or both parents because of AIDS.
- The number of AIDS cases is reduced every year in those countries with good access to antiretroviral treatment.

THE TREATMENT

Nowadays, there is still no preventive vaccine to avoid new infections or a treatment to cure HIV/AIDS. However, existing antiretroviral treatments impede the multiplication of the virus in the body. They do not kill HIV, but they do help to avoid the weakening of the immune system.

The therapy is individualized and must be prescribed, reviewed and modified, if necessary, by specialists that follow the patient’s evolution. If the treatment is followed correctly and is started as early as possible, the life expectancy of people with HIV is practically the same as the rest of the population. However, if the therapy is not followed properly, the virus can become resistant to the drugs being used, therefore reducing the efficacy of the treatment.

- The variability and capacity of mutation of the HIV virus means that people can be infected with a virus that is especially aggressive and resistant to treatment.
- Drugs may have adverse effects.
WHAT WE DO?

HEALTHCARE

2014 DATA

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<th></th>
<th>2.797 patients</th>
<th>15.888 visits</th>
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<tr>
<td>PHYSICIENS:</td>
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<tr>
<td>(737 first visits,</td>
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<tr>
<td>10.518 follow-up visits)</td>
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<tr>
<td>PSYCHOLOGY:</td>
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<tr>
<td>(263 first visits,</td>
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<tr>
<td>1.416 follow-up visits)</td>
<td></td>
<td></td>
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<tr>
<td>NUTRITION:</td>
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</tr>
<tr>
<td>(86 first visits, 1.553</td>
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<td></td>
</tr>
<tr>
<td>follow-up visits)</td>
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<td>PSYCHIATRY:</td>
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<tr>
<td>(87 first visits, 413</td>
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</tr>
<tr>
<td>follow-up visits)</td>
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<tr>
<td>GYNECOLOGY:</td>
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<tr>
<td>(28 first visits, 412</td>
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<td>follow-up visits)</td>
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<td>SOCIAL CARE:</td>
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<td>follow-up visits)</td>
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<td>NURSING:</td>
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<td>(trials, treatments,</td>
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<td>FIBROSCAN:</td>
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<td>PROCTOLOGY:</td>
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<td>(1.032 cytologies, 480</td>
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<tr>
<td>anuscopies, 106 post chirurgic controls, 108 treatments with infrared).</td>
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OVERALL ASSESSMENT OF THE SERVICE 2014

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<td>Waiting time</td>
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<td>Visit time</td>
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The Foundation continuously assesses quality of care by means of satisfaction surveys that are administered to users. These surveys assess different professionals in particular and the Unit in general.
People with HIV come to the HIV Unit at Germans Trias i Pujol Hospital either on their own initiative or by referral from another hospital service, primary health centre or community centre.

Once in the Unit, and thanks to the Fight AIDS Foundation, the person can access the services of experts in various disciplines who act together to provide the best possible care. All staff members are constantly in touch to determine what actions each person requires specifically in the area of healthcare, treatment, or to propose participation in a clinical study. Services offered are diverse, ensuring personalized attention and quality:

- **MEDICINE**: HIV infection and associated disorders diagnosis and follow-up, advice and counselling in cases of accidental exposure to HIV, monitoring and supervision of clinical trials.
- **NURSING**: blood tests, outpatient treatment, training for self-administration of drugs, advice and counselling, monitoring and supervision of clinical trials.
- **PSYCHOLOGY**: emotional support for patients and those close to them, psychological treatment, support in adherence to treatment, neuropsychological assessment.
- **NUTRITION**: nutritional assessment and intervention.
- **SOCIAL WORK**: information, advice and finding resources for the HIV patient.
- **GYNECOLOGY**: control i tractament dels aspectes ginecològics en dones amb VIH.
- **PSYCHIATRY**: diagnosis and treatment of psychiatric problems related to HIV infection.
- **PROCTOLOGY**: control and treatment of anal diseases related to HIV, in particular those caused by the human papillomavirus.

Since 2005, the Foundation has provided screening, diagnosis, monitoring and treatment of lesions caused by the human papillomavirus in HIV-positive men and women. Germans Trias i Pujol University Hospital is one of the first hospitals in Europe to offer regular proctology care for people with HIV and treat pre-cancerous lesions detected by infrared rays, a technique that eliminates the lesion on an outpatient basis without hospitalization or surgery.
• CONDUCTING VARIOUS TESTS to help establishing a diagnosis: assessment of the state of the liver (hepatic elastography with FibroScan), tests to assess cardiovascular risk (measured by pulse wave velocity or VOP) and to determine bone density and body composition (DEXA technique), etc.

Since 2007, the Foundation has used FibroScan to perform hepatic elastographies in patients co-infected with HIV and hepatitis C. These tests, similar to an ultrasound, can assess the different degrees of liver fibrosis avoiding biopsies, which are more invasive and aggressive.

• COORDINATED CARE with other hospital services such as the plastic surgery department (treatment of lipodystrophy-related problems), ophthalmology specialists and the pain clinic.
Research at the Foundation is organized into separate lines that allow greater specialization of professionals and better use of resources. This diversification makes it possible to face the different challenges posed by HIV.

Researchers from each of the lines are also healthcare professionals and they simultaneously engage in contact with people with HIV every day. Research is carried out by them and is tailored to the needs of people with HIV.

We work with the world’s most prestigious research centers and the publications by our researchers are among those with greatest international impact.

In 2014, 86 clinical studies were conducted by the HIV Unit and the Fight AIDS Foundation. We seek to answer unresolved questions and these include all phases of clinical trials, observational studies and cohort studies. More information in the corresponding attachment.
CLINICAL VIROLOGY

Virology is the study of viruses: their structure, classification and evolution, their interaction with guests, their immunity, the disease they cause, the way they infect and take advantage of target cells to reproduce themselves, techniques to isolate and cultivate them and their therapeutic use.

The Clinical Virology line at the Foundation studies the characteristics and functioning of HIV that causes the infected person to become ill.

HIV is a retrovirus: it contains genetic information in RNA and requires the DNA of a host cell for its reproduction. When the virus penetrates the body, it begins to replicate itself and adheres to T-Cells from the immune system (mainly CD4 cells). The virus also infects other cells, such as Dendritic cells and those of the central nervous system.

HIV changes very quickly once inside the body of the infected individual and this sudden change, called mutation, affects the ability of the immune system to recognize the virus. Indeed, the fascinating ability of HIV to mutate is one of the aspects that makes it particularly difficult to find an effective vaccine for it. Similarly, these mutations can cause the virus to become resistant to antiretroviral drugs and when resistance appears, the viral load (amount of HIV in the blood) begins to rise. In order to cope with the increasing quantity of the virus, the therapy should be modified. However, the development of resistance gradually leaves patients without treatment options.
“The Guide” app: every year the Foundation publishes “The HIV & Hepatitis Drug Resistance and PK Guide”, which is a guide written in English drawn up by international experts. It provides comprehensive and updated information on HIV mutations, Hepatitis and resistance treatment. It is an extremely useful tool for clinical management. In December 2012, an application for mobile devices was launched and it offers the ability to access this information instantly and simply. It is available for free at the Apple Store (The HIV & Hepatitis Drug Resistance and PK Guide) and the Android Market (The HIV & Hepatitis Guide). More information is available at: www.florida.org/theguide.
During 2014

• Several studies have been published on monotherapy with protease inhibitors (one of the components of HIV that the virus needs to complete its replication process). In the last decade there has been great progress in the simplification of antiretroviral treatment: reductions in the number of daily doses and pills to be taken, the once-daily dosages (monotherapy) and the reduction of the toxic effects of drugs among other improvements have radically facilitated adherence to treatment.

• It has been demonstrated that the new mass sequencing techniques for the virus may help doctors to predict which treatment will work best for each patient. This allows us the possibility of more accurately analyzing the characteristics of the type of HIV that affects each person (especially those affected by minority variations or a multi-resistant virus). This is an important step to improve medical care and makes it possible to provide more effective, safer and personalized medicine.

• The line of clinical virology has remained active in updating the IAS-USA (International Antiviral Society) resistance guideline, which is the most accessed in the world, and the Spanish tropism guides that are useful for clinical management of patients. Collaboration with the WHO (World Health Organization) Group of Resistances has also continued to assess the implications of resistance in developing countries.
More than 99% of “our” genetic information actually comes from information from the millions of microbes that inhabit our bodies, our microbiota. It seems increasingly likely that this “second genome”, as it is sometimes called, exerts a greater influence on our health than perhaps even the genes we inherit from our parents. Inherited genes are more or less fixed, unchanging; however, it seems that the second genome carried by microbiota can be remodeled, and even regenerated.

The Fight AIDS Foundation and IrsiCaixa have started a new line of research to analyze how the imbalances in the composition and function of intestinal flora (Microbiome) affect both the chronic inflammatory condition of people with HIV and the fragility of people in general. In the case of people with compromised immune systems, such as people with HIV, the study of the influence of the Microbiome on the immune system may provide a key to improving quality of life and increasing defenses to fight the infection. Similarly, healthy microbiota could ensure better quality of life and less fragile aging. The goal of researchers is to obtain relevant data to help prevent disease and improve health through nutritional intervention and changes in diet.
TOXICITY AND NEW TREATMENT STRATEGIES

The Toxicity and New Treatment Strategies line focuses on identifying the adverse side effects of antiretroviral treatment and other complications associated with the virus itself and with the systemic inflammation caused by HIV in the body. Recently, its research has focused on the aging population as patients become older thanks to improved survival. This trend implies an increase in comorbidities.

The immune system of people with HIV is permanently activated in order to combat the effects of the virus: this involves chronic inflammation that can cause harmful effects to the body, such as cardiovascular, bone or renal problems. In addition, there is aging and its associated effects of inflammation, aggravating or accelerating these processes.

During 2014

Compared to the general population, people with HIV suffer from more cardiovascular disease. Each antiretroviral drug has a different impact on metabolic alterations and therefore it is better to use those that affect them less, especially in patients with additional risk factors. It is also important to understand each person’s genetic predisposition to suffer from such complications. In this regard, two articles have been published recently on genetic predisposition of the patient to undergo more alterations in lipid parameters and the impact of genetic variants in the evolution of an HIV infection.

- A study performed at the Foundation with 467 people with HIV shows that there are different genetic variations that predispose either to protect from or to develop Atherogenic Dyslipidemia. This causes a situation of particular cardiovascular risk in which the person has very high levels of triglycerides and very low HDL (the “good cholesterol”). It has also been observed that some of these genetic variants involved in the development of Atherogenic Dyslipidemia can also influence the balance of the immune status of people with HIV. The results of this research project were published in 2014 (Antiviral Res. 2014 Dec 8; 114C: 48–52. Doi: 10.1016 / j.antiviral.2014.12.002. [Epub ahead of print].
• The results of a study conducted to determine the role of arterial stiffness in cardiovascular risk have been published. When comparing the results in people with HIV to the general population, no differences were observed in arterial elasticity. None of the variables related to HIV (CD4 cell count, viral load, etc.) was related to arterial stiffness, probably due to the good immunological and virological status of participants. However, high levels of triglycerides and high diastolic pressure when determining pulse wave velocity were indeed considered risk factors.

Pulse wave velocity (PWV) is a technique to assess cardiovascular risk that allows the detection of incipient alterations. PWV is calculated from the time it takes the pulse wave to propagate throughout the arterial system, from the carotid to the femur, with greater speed indicating higher stiffness.

• A study that aims to evaluate endothelial toxicity (the endothelium is the tissue that forms the wall of our intestine) of two families of antiretroviral drugs has been conducted: protease inhibitors and reverse transcriptase inhibitors not analogous to nucleosides. This kind of toxicity has been evaluated by cultivating human endothelial cells with different doses of these antiretroviral drugs (“in vitro”). Analyses and publication of results pending.

• A new treatment strategy has allowed the improvement of the levels of cholesterol and triglycerides in patients who introduced the drug called Maraviroc in their therapy.

Renal disorders are becoming more and more common in people with HIV. This is related mainly to the increase in life expectancy and the corresponding aging of the population with HIV, but also with the rise in diseases such as hypertension or diabetes mellitus. Moreover, some antiretroviral drugs can worsen kidney functioning, especially when there are other coexisting pathologies or treatments that are also toxic to this organ.

- In collaboration with the Nephrology and Biochemistry Laboratory at Germans Trias i Pujol Hospital, renal control measures are being implemented considering the particularities of people with HIV. They are adapting them to the new needs and the latest recommendations in clinical guidelines.

- Once again in collaboration with the nephrology service, a study to assess the frequency and characteristics of renal disorders in nearly 1,000 patients seen in the HIV Unit was conducted. In our cohort of patients, advanced renal disease is rare (less than 1%), but in contrast, almost 50% of subjects showed some renal disorder even without suffering from a fully established renal disease. In this study, factors associated with an increased risk of suffering such abnormalities were the presence of hypertension and aging. On the other hand, higher CD4 counts were a protective factor. This study was published by AIDS Patients Care and STDs (2014 Oct; 28 (10): 524-9. Doi: 10.1089 / apc.2014.0172. Epub 2014 Sep 19.)

- Currently, the presence of different proteins in blood and urine is being studied and may vary depending on the type of kidney disease that the subject presents. In patients whose renal biopsy is indicated to show better diagnosis, researchers will try to establish relationships between the study of these proteins and their biopsy results.
BONE TOXICITY

• Regular checks are performed on people who attend the HIV Unit to obtain information on their bone mineral density by using the DEXA technique to detect problems such as osteoporosis. This is performed with a device that emits very low doses of x-rays.

• The effects of different strategies to try to recover the loss of bone mineral density are being studied; such as the administration of drugs for osteoporosis (Zoledronate) or the replacement of some antiretroviral drugs by others that are less involved in bone loss (changes from protease inhibitors to integrase inhibitors, such as Dolutegravir, for example).

• The results of a study evaluating changes in bone density and markers of bone remodeling after two years of receiving Zoledronate or after replacement of Tenofovir by Abacavir have been published recently.

• A collaboration with the ICFO (Institute of Photonic Sciences) has been launched. Currently, different characteristics of the bone are being evaluated through spectroscopy (light-based technique).
Clinical Pharmacology is a medical specialization that assesses the effects of drugs on patients, both in the general population and in specific patients or patient groups. It focuses on the relationship between drug levels in the blood and their therapeutic effects. It is necessary to know what the appropriate levels are to obtain the desired effects.

This line mainly investigates how antiretroviral drugs behave in the body, and also how they interact with each other (antiretroviral therapy combines different drugs) and with other medications commonly used in HIV-positive patients.

Antiretroviral drugs are classified into several families according to how they inhibit the HIV replication cycle. In antiretroviral therapy, combinations of drugs belonging to different families hinder the development of drug resistant mutations and maintain the suppression of the viral load.
During 2014

- Researchers have worked on optimizing the doses of antiretroviral drugs, evaluating the efficacy and safety of dose reduction strategies of a protease inhibitor. These strategies, in which a lower quantity of a drug is administered, aim to optimize the efficiency (cost/benefit) of treatment and maximize the use of available resources. Accordingly, the DRV600 trial was finished and its aim was to evaluate the efficacy of two antiretroviral drugs (Darunavir in combination with Ritonavir) in lower doses than those approved. The results show that lower doses of Darunavir are equally effective for maintaining control of viral replication in those patients without prior treatment failure, previously suppressed with treatment and taking medication correctly.

- Collaboration is continuing in international studies to evaluate the safety of antiretroviral drugs and possible changes in the concentration of these drugs in the blood in pregnant women. The study of the pharmacokinetics in this population in particular is essential, because a reduction in the concentration of drugs during pregnancy could increase the risk of treatment failure, and consequent HIV transmission to the baby. In 2014, results were reported concerning Raltegravir, Atazanavir, Darunavir and Abacavir.

- Pharmacokinetics of some drugs in special populations has been evaluated in collaboration with other national groups. Specifically, the pharmacokinetics of Raltegravir in patients with advanced liver cirrhosis has been in the spotlight during 2014.

- Work continues on a new area of research involving the use of various computer programs to simulate the possible drug interactions in patient populations that are difficult to study in the clinical setting. These include people with HIV who are receiving cancer chemotherapy and antiretroviral therapy simultaneously. Initial results have been reported regarding the interaction between Ritonavir and Erlotinib (used for lung cancer treatment) and the initial study has been expanded to observe interactions between Ritonavir, Efavirenz and Etravirine with Eroltinib and Gefitinib.
Thanks to the availability and great extent of antiretroviral treatments, opportunistic disease rates have fallen gradually and people with HIV have been increasing their quality of life and life expectancy.

Having a longer life and aging with HIV involve a series of new complications. One of these is to fight coinfection with other viruses such as hepatitis. In fact, viral hepatitis is considered one of the leading causes of death among people with HIV. The main complications of chronic infection by hepatitis C are cirrhosis and liver cancer.

Many people with HIV have to fight both infections at the same time. It is essential to advance in the understanding of the factors that lead a person to present hepatic complications in order to be able to prevent, diagnose and treat them.

Regarding cohorts (groups of patients), the Foundation mainly focuses its activity on participating in multicenter studies from a national and international perspective, such as the PISCIS cohort study (Catalan), CoRIS cohort (Spanish) and Eurosida cohort (European).
During 2014

- The impact of the severity of liver fibrosis on the evolution of infections with hepatitis C is being assessed. The evaluation of fibrosis by three non-invasive methods is studied: liver elastography (using a machine called Fibroscan), ARFI (Acoustic Radiation Force Impulse) and analytical methods (biochemical).
- The association between HIV and hepatitis C coinfection and intra-abdominal fat accumulation is also being studied.

Clinical studies on drugs

- MK5172-061 Study: Phase III study to assess the efficacy and safety of the combination of MK-5172 / MK8742 drugs in patients coinfected with HCV and HIV, HCV treatment naïve (genotypes 1, 4, 5 and 6).
- Phase III opened study to assess the efficacy and safety of treatment with Boceprevir in patients coinfected with HIV and HCV (Genotype 1) who have failed in therapy with Ribavirin and peglNF.
- Effect of interferon alfa-2a on the reservoir of HIV-1 in peripheral blood CD4 lymphocytes in patients coinfected with HCV.
- Active participation in international multicenter clinical trials in which new drugs (HCV protease inhibitors) that increase the therapeutic effectiveness up to 75% in curing HCV are tested.

Cohort follow-up:

The PISCIS cohort: this cohort provides information on patients with HIV/AIDS visited since January 1, 1998 in different hospitals in Catalonia and the Balearic Islands. Results of monitoring of this cohort have shown increased mortality in patients with HIV infection due to cancers, and cardiovascular and liver diseases not related to HIV.
In people with HIV, with a weakened immune system, opportunistic infections can emerge. These are diseases related to the progression and the development of AIDS as a result of lower defenses.

Infection by the Human Papillomavirus (HPV) is the most common sexually-transmitted infection: 75% of the general population will acquire it during their lifetime. In general, the body eliminates HPV naturally without causing any injury. However, in people with weakened immune systems, the virus can cause the development of cancer precursor lesions that in the worst case scenario could evolve into cancers (mainly in the cervix and anus).

Results obtained in these 10 years of preventive medicine and research show a high percentage of people with HIV co-infected with HPV. Figures show the need to implement routine tests for the detection of Human Papillomavirus in men and women with HIV, regardless of their sexual practices.
During 2014

- An article about the natural history of oral infection with HPV in a cohort of HIV-positive men (538 men who have sex with men -MSM- and 195 heterosexual) was published. HPV prevalence was 16%. Genotype 16 was the most prevalent (in 3.7% of MSM and 7.8% of heterosexuals); the overall incidence was similar in both groups (11%) but genotype 16 was higher in heterosexuals. The conclusion is that not only MSM are at risk of HPV infection, but also heterosexuals.

- In a review article, the incidence and clinical management of oral HPV infection in men is described. The description is written in the form of a series of short messages, understandable for the professional who cares for patients with this clinical condition.

- In an editorial in the journal “Medicina Clínica”, anal intraepithelial neoplasia is described as the precursor of anal cancer. The article talks about cytology screening, identification of premalignant lesions by high-resolution anoscopy and treatment.

- The CHECK-EAR study has been continuing, collecting data on the prevalence of the Papillomavirus and other STDs among men who have sex with men who are HIV negative. The study is being conducted under HIVACAT, the program for the research and development of an HIV vaccine in Catalonia. The study is being carried out with the support of the Fight AIDS Foundation, BCN Checkpoint (a community center run by the Projecte dels Noms–Hispanosida Association), the Clinic Foundation and the IrsiCaixa Institute for AIDS Research.
**IMMUNOLOGY AND VACCINES**

The Immunology and Vaccines research line tracks patients participating in studies with immunomodulators (the kind of drugs that stimulate the growth and production of the body’s defenses). They also coordinate the clinical application of HIVACAT projects, the program for the research and development of an HIV vaccine in Catalonia.

HIVACAT is carried out through a public-private consortium unprecedented in Spain placing our country at the forefront of international research conducted in this area. It consists of the IrsiCaixa Institute for AIDS Research and the AIDS and Infectious Diseases Service of the Clinic Hospital of Barcelona. HIVACAT investigates the development of a new HIV vaccine in coordination with Esteve and with the support of “la Caixa”, the Departments of Health and Innovation and Universities and Enterprise of the Government of Catalonia, and the Clinic Foundation.

An effective vaccine provides the immune system with tools to fight against a particular microorganism and prevent it from causing disease. Although there is currently no vaccine to prevent or treat HIV, researchers are preparing and testing experimental vaccines against this virus. HIV vaccines that are used to prevent the infection are called preventive vaccines. The ones used to help control the virus in people who are already infected are called therapeutic vaccines.

**During 2014**

**Clinical trials of therapeutic vaccines:**
- The generation of HTI therapeutic vaccine candidates were completed. Unlike previous candidates, HTI vaccines are the first designed according to the response detected in people with HIV who better control the infection in the absence of antiretroviral treatment, known as "elite controllers". These people represent an excellent model of functional care. Phase I and II trials will begin thanks to the good results achieved in tests with mice and monkeys, previously presented at the Vaccine World Congress 2013 and recently published (Mothe B. et al, 2015 JTM Hancock G et al will begin , Plos Path 2015). Simultaneously, HTI design has been optimized in order to be effective against highly mutated virus that may be more resistant to previous immunizations. The first human trials are planned for 2016.
- Two teams from the Clinic Hospital and the IrsiCaixa Institute for AIDS Research are working on the development of preventive vaccines based on the induction of specific antibodies against HIV. These designs are at an earlier stage of development (experiments in mice).
• BCN01 clinical trial was completed. It tested the safety and immune response of two new therapeutic vaccine candidates developed by researchers at Oxford. These vaccines are unique for two main reasons: Firstly, one of the candidates uses a virus derived from the common cold of chimpanzees as its vehicle. The difference between the animal virus and the human one could provide a key to ensure antibodies do not block the vaccine, thus achieving a greater response. Secondly, these vaccines try to stimulate the immune system to attack the parts of the virus that suffer fewer mutations.

• Researchers at the Fight AIDS Foundation and IrsiCaixa are involved in a new European project to find a therapeutic vaccine for HIV called iHIVARNA. This project is directed by Felipe Garcia PhD, from the Clinic Hospital of Barcelona. Its goal is to test the effectiveness of a new candidate, an innovative concept of vaccine that aims to stimulate dendritic cells in the body. The project has just received approval from the Spanish Agency of Medicines and the first clinical trial to test the safety of the strategy will be started during the second half of 2015. The Fight Against AIDS Foundation will recruit and include patients in the second phase of the study, in conjunction with five more centers. More information at www.ihivarna.org.

• Thanks to the platform created by HIVACAT to test vaccines, the Foundation has participated in studies promoted by external developers such as TH-HIV11 or Vacc-4x in which the effects of vaccine candidates that allow the control of the virus in the absence of treatment are evaluated.

**Cohorts**

• Throughout 2014, the Early_cART study for the creation of a cohort of 150 to 200 individuals with demonstrated recent HIV infection and initiating antiretroviral therapy in the first 6 months after the transmission has started. The main reason why antiretroviral treatment fails to eradicate the virus from the body is the existence of viral reservoirs, which lie dormant in cells and wake up when treatment is stopped. The initiation of antiretroviral therapy during the first weeks of infection (period known as “acute or recent infection”) offers an opportunity to reduce these viral reservoirs, restricting the ability of the virus to mutate and provides a better immune recovery that could lead to obtaining a favorable response to therapeutic vaccines. For the creation of the cohort, the Fight Against AIDS Foundation works closely with BCN Checkpoint and other community centers that work on prevention of HIV and other sexually transmitted diseases.

• The cohort of elite controllers (individuals who are able to keep HIV under control without continued antiretroviral therapy) was kept in collaboration with Vall d’Hebron Hospital in Barcelona and some of the city’s prisons. In addition, the Late Progressors or Losers project is examining the factors that cause patients who have controllers of the virus to lose this privileged condition.
WHAT WE DO?

RESEARCH

RESEARCH LINES

PSYCHOLOGY

People with HIV, as well as those living with other chronic diseases, require comprehensive care that includes psychological assistance. The Foundation provides and promotes the psychotherapeutic approach for the emotional difficulties that must be faced by people with HIV and the people around them. The Foundation also conducts studies focused on improving the quality of life of those affected.

Research in the Psychology line focuses on the study of disorders in people with HIV that can be caused by problems related to chronic infection and aging, on the early detection of cognitive and psychomotor impairment, and on the effects of psychological stress on immune function.

During 2014

• During 2014, the studies called HIV-SEX MALE and Resil-HIV began. The first one is intended to describe sexual activity among HIV-1 infected men and to assess the presence and degree of erectile dysfunction, and the frequency and associated factors concerning unprotected sex. The Resil-HIV study evaluates the effect of resilience in coping with aging and chronicity among patients infected by HIV-1. The results of the two studies are expected to be reported during 2015.

*Mindfulness*, is the ability to be consciously connected with the present. Many times, our mind tends to operate in a mode that could be called “autopilot” without paying much attention to our experiences. With a practical discipline similar to meditation, we can switch to a “full consciousness” mode. Therefore, we can learn to accept emotions, thoughts and feelings that arise from our experience without judging them, allowing ourselves to be more compassionate with others and especially with ourselves.
• The conference “A multidisciplinary approach in the treatment and quality of life of patients with HIV” was held in Madrid in June, organized by SEISIDA. The presentation, “Efficacy of mindfulness-based cognitive therapy in improving the quality of life, emotional state and CD4 cell counts in people aging with HIV Infection” won the award for best oral communication of the conference.

• The benefits of implementing mindfulness programs in people infected with HIV were also presented in a panel discussion at the First International Congress on Mindfulness, which was held in Zaragoza in June.

• Dr. Carmina R. Fumaz expanded her training in mindfulness interventions carrying out the “Program on mindfulness and self-compassion,” based on the Mindful Self-Compassion Program by Kristin Neff and Christopher Germer. This training is a complement to support emotional interventions provided to patients at the Fight Against AIDS Foundation.

With the development of antiretroviral therapies and the increased life expectancy of people with HIV, there have been important advances in understanding the effects that the virus itself and the medication may have on the central nervous system. From the first weeks of infection, HIV can cause alterations at a motor and cognitive level, with a large negative impact on the quality of life and daily functioning of those affected.

• New results for the screening of cognitive impairment in patients with HIV were released in the 7th International Symposium on Neuropsychiatry (Barcelona, Spain) with two oral communications.

• At the 2014 Conference on Retroviruses and Opportunistic Infections (Boston) new results from the instrument NEU*, first presented in 2013, were released. This time, the findings focused exclusively on virological control and, therefore, had been proven in a smaller population group from the one used in the validation study of this method. The findings were similar to those of the original study, verifying that the NEU’s instrument accuracy is quite suitable for using it in people with HIV.

• Also associated with this line of accessible and reliable methods for cognitive impairment screening, a study was published in the journal PLoS ONE where risk factors were identified by the presence of neurocognitive impairment through predictive models based on demographic and clinical variables. This work can be valuable for the medical community and other professionals dedicated to the care of people with HIV, regardless of the performance of neuropsychological examinations. It could also help them learn about the cognitive status and Central nervous system conditions of their patients.

* The NEU instrument is a tool to detect cognitive impairment in patients with HIV. The NEU requires less than 10 minutes to be applied when usually neuropsychological evaluation methods require two or three hours. Following the footsteps of some tests on paper, the patient is requested to develop certain tasks to measure the speed in processing information, executive functioning and verbal fluency.
NUTRITION

Diet has been shown to be a vitally important factor from the early stages of HIV infection. Even though a good diet does not play a role in the prevention of HIV and will not cure AIDS, it can contribute to a patient’s treatment and improve their quality of life. A balanced diet reinforces the immune system and helps the body combat the possible effects of the disease.

During 2014

- Diet and nutritional assessment of patients has been ongoing, offering specific dietary advice for each situation.
- The Foundation participates in numerous clinical trials conducting dietary, nutritional and anthropometrical evaluations (diet control, assessment of the benefits that nutrients have for the body, and measurement of different parts of the body such as the waist, hips or arms). For example:
  1. TULIP Study
  2. Alicia-FLS Protocol, to evaluate the effect of associating educational workshops about cooking, when implementing dietary advice.
  3. MetaHIV-Pheno, in which information concerning the usual diet of the participants was collected, in order to describe it carefully.
- Measurement of bone mineral density: using the DEXA technique, a device that emits very low-level X rays. This is useful for detecting conditions such as osteoporosis or to measure body fat.
- Presentations and educational lectures on Nutrition and HIV have been held.

The study of body composition is an important aspect in the assessment of nutritional status because it allows the quantification of the body’s reserves. Therefore, allowing detection and correction of nutritional problems and situations of overweight, obesity or, alternatively, malnutrition. The measurement of body composition by densitometry (DEXA) can provide assessment going beyond weight and the traditional body mass index (BMI) to determine body fat distribution.
RESEARCH SUPPORT

Study monitors are qualified professionals with specific training in the management of clinical trials: they monitor the progress of the trial from its inception to the presentation of the results ensuring that they are carried out according to good clinical practices.

Their job consists of:
- Supporting the drafting of the protocol and the documentation for each specific project.
- Obtaining the necessary legally-required approvals according to the study and prevailing legislation.
- Preparing and maintaining the sponsor and investigator files.
- Making start, monitoring (protocol follow-up) and closure visits to participating centres.

Although originally only trials related with HIV were conducted, the expertise of the team enabled it to manage studies in other therapeutic areas led by external investigators or promoters (neurology, cardiology, hepatitis B, hemodynamics, pharmacology etc.). Since 2008, we have operated with a more generic name, FLS-Research Support.
STATISTICS

The statistics team contributes to the research projects at the Foundation by applying the necessary statistical techniques and methods at each stage of a project. It participates in the design of the studies, monitors data collection, and lastly analyses the results and presents conclusions.

During this year special attention has been paid to exploring and applying pharmacoeconomic tolos in the evaluation of different therapeutic strategies.

Through an educational cooperation agreement with the Universitat Politècnica de Catalunya (UPC), students at the university are encouraged to complete their training at the Foundation. Additionally, the relationship with the UPC means the Foundation has the opportunity to work with the most modern techniques and the latest advances.

RESEARCH GRANTS AND FINANCIAL HELP

TRIANT-TE Study: A prospective randomized controlled study to compare the efficacy and safety of two different pharmacological strategies on neurocognitive disorder in HIV infection.

- CAIBER grant (Consortium for Biomedical Networking Research Support)
- Project funded by the Ministry of Health and Social Policy of Spain in the 2010 call for funding to promote independent clinical research.
- Researcher: José A. Muñoz- Moreno.

Clinical trial to evaluate the efficacy, safety and economic impact of reduced doses of darunavir in HIV-infected patients treated with darunavir/ritonavir once daily.

- Ministry of Health and Social Policy of Spain: funding to encourage the uptake of the therapeutic application of orphan medicines for human and advanced therapies.
- Project funded by the Ministry of Health and Social Policy of Spain in the 2011 call for funding to promote independent clinical research.
- Researcher: José Moltó.
Study of HIV pathogenesis and the effect of antiretroviral therapy in gut-associated lymphoid tissue.
  • FIS Grant. Ministry of Economy and Competitiveness.
  • Researcher: José Moltó

Open multicenter randomized study on the efficacy and safety of removing inactive nucleoside and nucleotide analogues or intermediate resistance in subjects with HIV-1 treated with multiple drugs and with viral suppression.
  • Ministry of Health and Social Policy of Spain.
  • Project funded by the Ministry of Health and Social Policy of Spain in the 2011 call for funding to promote clinical independent research.
  • Researcher: Josep M. Llibre

OSTEODOLU: Multicenter study to assess changes in bone mineral density change produced by changing protease inhibitors to dolutegravir in HIV-1-infected subjects with low bone mineral density.
  • ViiV Healthcare, pharmaceutical company specialized in HIV.
  • Researcher: Eugènia Negredo

Project: Evaluation of safety 10 years after receiving facial injections with polyacrylamide gel (Aquamid®) in patients with HIV infection and facial lipoatrophy.
  • Contura, Aquamid® gel manufacturer.
  • Researcher: Eugènia Negredo

Project: Circulating MicroRNAs as potential biomarkers of liver disease in HIV-infected patients.
  • FIS Grant. Ministry of Economy and Competitiveness.
  • Researcher: Cristina Tural

PROTEST: Utility of genotypic tropism of HIV-1 from proviral DNA to guide treatment with CCR5 antagonists in subjects with undetectable HIV-1 viral load.
  • ViiV Healthcare, pharmaceutical company specialized in HIV.
  • Researcher: Roger Paredes
INI-VAIN: Incidence, prevalence and clinical consequences of virological failure in first generation integrase inhibitors (INI) in Spain.
  • ViiV Healthcare, pharmaceutical company specialized in HIV.
  • Researcher: Bonaventura Clotet

TULIP: Prospective, randomized, crossover, double-blind, placebo-controlled clinical trial to evaluate the effect of co-formulation of tenofovir/emtricitabine vs. placebo on reducing lipids in patients infected with HIV-1 with dyslipidemia and sustained virologic suppression receiving monotherapy with protease inhibitors boosted with ritonavir.
  • Gilead Sciences
  • Researcher: Bonaventura Clotet

Project: Coevolution of gut Microbiome and inflammatory response after acute infection of HIV-1.
  • Project funded by the Ministry of Economy and Competitiveness through the Carlos III Institute and the Foundation Feder.
  • Researcher: Roger Paredes

Project: The Frail Elder Microbiome.
  • Catalunya-La Pedrera Foundation – SARquavitae Foundation
  • Researcher: Roger Paredes

  • Philanthropy.
  • Researcher: Roger Paredes

Project: Prevalence of virological failure, immune deterioration, antiretroviral drug resistance and sub-optimal antiretroviral levels in HIV-1 infected subjects receiving antiretroviral treatment in Manhiça (PREVIR–2012).
  • Gilead Sciences, pharmaceutical company.
  • Researcher: Roger Paredes
In the area of education, the Foundation focuses especially on training specialists in HIV and facilitating knowledge transfer between health professionals and researchers. Dissemination of knowledge among the general public is also one of our goals.

Training of pre-doctoral and post-doctoral students and researchers:

- Several university students have done their internships at the HIV Unit in 2013 in areas such as medicine, dietetics, statistics and monitoring of clinical studies.

During 2014, the following theses were presented:

  - Universitat Politècnica de Catalunya, Doctoral Program: Department of Statistics and Operative Research.
  - Supervisors: Guadalupe Gómez and Roger Paredes.
- José Ramon Santos. Simplification strategies and impact of mutations in antiretroviral therapy in patients infected with HIV-1.
  - Supervisor: Bonaventura Clotet.
  - Tutor: Jordi Tor

Currently, the following theses are in progress:

- Patricia Echeverría. Comparative study of the changes induced in the liver and lipid profile of HIV patients treated with protease inhibitors (PIs) and their relationship to cardiovascular risk.
  - Supervisors: Eugènia Negredo and Bonaventura Clotet.
ORIENTATION AND PARTICIPATION IN SYMPOSIA, CONFERENCES AND SEMINARS FOR SCIENTIFIC AND CLINICAL UPDATE

- **Post-CROI**: The Foundation organizes this annual event, which is a summary of the highlights of the CROI (Conference on Retroviruses and Opportunistic Infections), one of the most important conferences on HIV/AIDS worldwide. This meeting is one of the most relevant in Spain, known for its quality and high attendance. It is held with the support of Gilead, and the presentations of the speakers are available at www.flsida.org/post-croi-2014.

- **Workshop on eradication, vaccines and immunological recovery in HIV**: sixth meeting with Dr. Mario Stevenson, from the University of Massachusetts, and other experts in this field. Sponsored by MSD.

- **Teleconferences on resistances**: these have been held regularly since 2004 and are telephone sessions during which clinical cases involving resistance to antiretroviral treatment are discussed. The procedure is highly practical: the participating hospitals send a clinical case and decisions have to be made on the most suitable treatment according to the patient’s profile, their medical history, etc. Three experts assess these cases prior to the teleconference: Dr. Jonathan Schapiro (Stanford University), Dr. Santiago Moreno (Ramón y Cajal Hospital) and Dr. Bonaventura Clotet (Germans Trias i Pujol Hospital). During the teleconference, all the participants discuss the case and reach a conclusion. This is a particularly useful resource for centers with few HIV specialists and an important teaching tool for resident and student doctors. Gilead and Janssen support them.

- **Treatment of viral hepatitis in people coinfected with HIV. A new paradigm for clinical and pharmaceutical administration**: Treatment of viral hepatitis is experiencing a turning point that may suggest the beginning of a much more widespread healing. Clinicians treating patients coinfected with HIV must assess the indication and efficiency of treatments with as much information as possible, knowing which resources are available.
The Foundation regularly organizes events and campaigns in order to increase public awareness and sensitivity towards HIV/AIDS and the stigma that surrounds it. Some of these activities also aim to raise funds to finance research projects.

1st NIGHT FOR RESEARCH IN CENTRAL CATALONIA

On June 12th, 2014, at the place for celebrations “El Serrat del Figaro” in Taradell, the 1st Night for Research in Central Catalonia took place and was promoted by the Fight AIDS Foundation, the University of Vic, Central University of Catalonia and the IrsiCaixa Institute for AIDS Research. 225 people attended the event and 49,300 Euros were collected, fully intended for the study of the Microbiome and the aging process related to HIV infection developed within the Chair of AIDS and Related Diseases in the UVic-UCC.

The dinner show, served by chef Nandu Jubany, was attended by many personalities from the world of politics, business, culture and entertainment. The event was hosted and presented by the journalist Helena Garcia Melero and the actress Aina Clotet. It was enlivened with performances by Lucrecia, Jordi LP, Leslie from the Sirex and Dr. Estivill among others, under the artistic direction of the musician Pep Sala.

Given the success achieved in this 1st Night for Research, Dr. Ventura Clotet announced that the following year, the second edition would be held in La Garrotxa or in El Bages.
TOYZ BY FLS

Swab Barcelona, International Fair of Contemporary Art, launched a new edition of “Swab Toyz by FLS”: the proposal is to deliver blank Toys (8 “Qee Bunnys) to various designers and artists for each to create their personal version.

Thanks to the collaboration of Sotheby’s, a live auction of 20 Toys was held on June 19th in El Palauet (Pg. De Gracia 113, Barcelona). The rest of the pieces were auctioned online in the days following.

FUNDRAISING INITIATIVE BY THE BOIA*NIT, IN CADAQUÉS

During the summer of 2014, the Boia*Nit cocktails bar launched a fundraising campaign to support the fight against HIV/AIDS. This legendary venue in Cadaqués allocated part of the proceeds from their cocktail named LIFE to research projects to find a cure for AIDS, conducted by the IrsiCaixa Institute for AIDS Research and the Fight Against AIDS Foundation. The cocktail, which has become part of the Boia*Nit’s menu, contains Cava L’Hereu 2011 Raventós i Blanc, the juice of red fruits, vanilla essence and lime.
BARCELONA STANDS UP FOR AIDS

Each year in November and December, the Fight Against AIDS Foundation holds an awareness campaign.

GOALS:
1. Showing solidarity with people living with HIV.
2. Fighting for no new infections. 2 million are produced every year.
3. Calling for scientific research to find a definitive solution to HIV/AIDS.

Since 2010, this initiative has had the support of Barcelona City Council and has three main actions:
4. 1GALA SIDA BARCELONA
5. DECEMBER 1, BARCELONA LIGHTS UP IN RED
6. ONLINE ACTION: WE ARE FIGHTERS AGAINST AIDS
GALA SIDA BARCELONA 2014

The Gala Sida Barcelona has become one of the most important charity events in Spain.

5th Gala Sida Barcelona:

- More than 700 attendees.
- €717,808 collected.
- Media Impact valued at 3 million euros.

Miguel Bosé, Ambassador of the Foundation, has been the director of the Gala since its inception. The fifth edition was held in the Oval Room of the MNAC, the National Art Museum of Catalonia, and included Martina Klein as an ambassador and an amazing show by the flamenco dancer Sara Baras.

Representatives from the business, social and political world, and personalities from show business, annually attend the Gala.

Thanks to attendees and sponsors (including MAC Aids Fund, Damm Foundation, Repsol, Telefonica and Volkswagen at the top) the collection again exceeded that of the previous galas, with more than €700,000.
DECEMBER 1, WORLD AIDS DAY: BARCELONA lights up in red

Between 6 and 12pm on December 1st, Barcelona colored red its most important buildings and landmarks, once again becoming the city of the world where most buildings are light up in red for this good cause. In all, there were 32 places participating, including: Agbar Tower, Sagrada Familia, MACBA, Casa Batlló, El Palauet, Palau de la Música Catalana, National Theater, Gran Via 2 Mall, Pedralbes Centre, L’Auditori, Majestic Hotel, W Hotel, Claris Hotel, Room Mate Hotel, Les Glòries Mall, Les Arenes Mall, CosmoCaixa, CaixaForum, El Molino, Poble Espanyol, Lliure Theater, El Palauet, Suñol Foundation, Barcelona City Council, Gran Via with Passeig de Gracia Fountain, Montjuic Magic Fountain, the Arc de Triomf, Virreina Palace, Parc Güell Three Crosses, Macaya Palace, Sant Pau modernist building and the old Estrella Damm factory.

ONLINE ACTION: “WE ARE FIGHTERS AGAINST AIDS”

The campaign “Barcelona stands up to AIDS” also includes public awareness action in social networks. In 2014, the slogan was “We are fighters against AIDS”.

“We are fighters against AIDS” aimed to give visibility to HIV/AIDS and inspire others to keep fighting. Anyone could explain their personal fight against the disease on the Facebook page of the Foundation.

Other events and parallel actions for awareness and fundraising completed during the 2014 campaign:

• Celebration of the party “Que trabaje Rita” to benefit research projects of the Foundation, on November 23.
• “I Love Dance Solidarity 2014”, Charity dance marathon held at Europolis Holmes Place, on November 29.
• L’Oreal campaign “Hairdressers against AIDS”, on December 1.
**BOARD**
Its function is to ensure the fulfillment of the core aims of the Foundation, to assess the work carried out, to oversee management actions, and to appoint executive positions. Its members are representatives of different areas of society who, with their different sensitivities and needs, initiate new challenges for the organization.

**Chairman**
Bonaventura Clotet

**Secretary and treasurer**
Guillem Sirera

**Members**
Leopoldo Biete, Maria Llatjós, Caterina Mieras, Lola Mitjans, Roger Paredes, Montserrat Pinyol, Gemma Recoder, Joan Romeu, Mònica Segarra, Ricard Vaccaro, Elvira Vázquez i Anna Veiga
CARMEN ALCALDE
Nurse.
Coinfection by HPV and Opportunistic Infections Line.

ANGELS ANDREU
Collaborator: Pharmacist.

AINTZANE AYESTARÁN
Statistics Trainee.
Student from the Master in Statistics and Operations Research (Universitat Politècnica de Catalunya).

ANNA BONJOCH
Physician and Researcher.
Toxicity and New Treatment Strategies Line.

ISABEL BRAVO
Nurse.
Clinical Virology Line.

ANNA CHAMORRO
Nurse.
Coinfection by HPV and Opportunistic Infections Line.

SÒNIA CLEMARES
Clerical Worker.

BONAVENTURA CLOTET
Physician and Researcher.
President.

PATRICIA COBARSI
Nurse.
Coinfection by HPV and Opportunistic Infections and Immunology and Vaccines Lines.

PEP COLL
Médico e investigador.
Coinfection by HPV and Opportunistic Infections Line.

CRISANTO DÍEZ
Collaborator: Head of the Psychiatry Department.

PATRICIA ECHEVERRÍA
Physician and Researcher.
Toxicity and New Treatment Strategies Line.

ROSER ESCRIG
Clinical Trial Monitor.

CARLA ESTANY
Dietician.
Head of the Dietetics Line.

MERCÈ FERRÀNDIZ
Clerical Worker in Clinical Trial Monitoring.

Mª JOSÉ FERRER
Psychologist.
Head of the Psychology Line.

SANDRA FLORES
Clerical Worker.

MIRIAM GARCÍA
Clinical Trial Monitor Trainee.

FRANCESC GARCIA-CUYÀS
Collaborator: Gastrointestinal Surgeon.

SÍLVIA GEL
Clinical Trial Monitor.
Internal Clinical Trials Coordinator.
Quality Manager.

GUADalupe GóMEZ
Professor of Statistics at the UPC.

GEMMA GUILLÉN
Head of Communication and Fundraising.

Cristina Herrero
Clinical Trial Monitor.

CARMEN HIGUERAS
Collaborator: Head of the Plastic Surgeon Department.

ANTONI JOU
Physician and Researcher.
Coinfection by Hepatotropic Viruses Line. Cohorts.

BEGOÑA LEMOS
Social Worker.

JOSEP MARIA LLIBRE
Physician and Researcher.
Clinical Virology Line.

INGRID MARTÍNEZ
Clerical Worker.

MANUEL MEDINA
Collaborator: Plastic Surgeon.

CRISTINA MIRANDA
Nurse.
Clinical Pharmacology Line.

JOSÉ MOLTÓ
Physician and Researcher.
Head of Clinical Pharmacology Line.
BEATRIZ MOTHE
Physician and Researcher.
Immunology and Vaccines Line.

JOSÉ A. MUÑOZ-MORENO
Psychologist.
Psychology Line.

MARIA NAVARRO
Accountant.

EUGÉNIA NEGREDO
Physician and Researcher.
Head of Toxicity and New Treatment Strategies Line.

ARELLY ORNELAS
Statistics.

MAITE ORODEA
Clerical Worker.

ROGER PAREDES
Physician and Researcher.
Head of the Clinical Virology Line.

DEBORAH PARÍS
Clerical Worker.

NÚRIA PÉREZ
Statistics.

MARTA PIÑOL
Collaborator: Gastrointestinal Surgeon.

RAMON PLANAS
Collaborator: Head of the Gastroenterology Department.

JORDI PUIG
Nurse.
Toxicity and New Treatment Strategies Line.
External Clinical Trials Coordinator.

BORIS REVOLLO
Physician and Researcher.
Coinfection by Hepatotropic Viruses Line. Cohorts.

CARMINA R. FUMAZ
Psychologist.
Psychology Line.

JOAN ROMEU
Physician and Researcher.
Head of the Immunology and Vaccines Line.

SUSANA RUIZ
Collaborator: Ophthalmologist.

ANNA SALAS
Nurse.
Coinfection by Hepatotropic Viruses Line. Cohorts

JOSÉ RAMÓN SANTOS
Physician and Researcher.
Clinical Virology Lines.

CRISTINA SEGUNDO
Nurse.
Coinfection by Hepatotropic Viruses and Opportunistic Infections and Coinfection by HPV Lines.

GUILLEM SIRERA
Physician and Researcher.
Head of Opportunistic Infections and Coinfection by HPV Line.

ESTHER SOLER
Nurse.
Coinfection by Hepatotropic Viruses Line. Cohorts.

ANTONI TARRATS
Collaborator: Gynecologist.

JÉSSICA TORO
Clinical Trial Monitor.

ALBERT TULDRÀ
Manager.

CRISTINA TURAL
Physician and Researcher.
Head of the Coinfection by Hepatotropic Viruses Line. Cohorts.

SEBASTIÀ VIDEJA
Collaborator: Clinical pharmacologist.
FINANCIAL AND ECONOMIC DATA

TOTAL OUTGOINGS
€ 2,599,774.10

- 9% Healthcare
- 53% Research
- 14% Education
- 24% Administrative and Fundraising Expenses

TOTAL INCOME
€ 2,361,785

- 34% Services
- 59% Members and Donations
- 7% Grants and Others
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As an individual: you can make a contribution, become a member and participate in the charity activities organized by the Foundation.

As a company: you can collaborate permanently with the Foundation by sponsoring a research Project or a specific event.

You will find these and other options at [www.flsida.org](http://www.flsida.org)

Want more information? Write to: [comunicacio@flsida.org](mailto:comunicacio@flsida.org)
1. PUBLICATIONS


Moltó, J; Valle, M; Ferrer, E; Domínguez, P; Curran, A; Santos, JR; Mateo, MG; Di Yacovo, S; Miranda, C; Podzamczer, D; Clotet, B. Reduced Darunavir Dose Is as Effective in Maintaining HIV Suppression as the Standard Dose in Virologically Suppressed HIV-Infected Patients. A Randomised Clinical Trial. Journal of Antimicrobial Chemotherapy. 2014 Dec 18. pii: dku516. IF: 5,439


and Infection. In press. (*joint senior authorship). IF: 5.197


2. COMMUNICATIONS AT CONFERENCES


Badia R, Pauls E, Ruiz A, Riveira E, Permanyer M, Clotet B, Keppler OT, Este JA. Inhibitors of CDK2 and CDK6 Block HIV-1 RT Through the Control of SAMHD1 Activity. Conference on Retroviruses and Opportunistic Infections (CROI 2014), Boston, March 2014


Carrillo J, Molinos–Albert L-M, Rodriguez de la Concepción ML, Marfil S, García E, Clotet B, Blanco J. Gp120/CD4 blocking antibodies are frequently elicited in ART-naive chronically HIV infected individuals. HIVR4P Capetown, 2014


Franco S, Aparicio E, Parera P, Clotet B, Tural C and Martinez MA. IFNL4 ss469415590 Variant Is a Better Predictor than ILF3 (IL28B) rs12979860 of PegIFN-α/RBV Therapy Failure in HCV/HIV-1 Coinfected Patients. CROI 2014, Boston USA.


Llibre JM, Bravo I, Santos JR, Ornelas A, Chamorro A, Puig J, Pérez-Álvarez N, Martin-Iguacel R, Clotet B. Virological failure to a switch to nevirapine, TDF and FTC (or 3TC) in patients with suppression. Abstract P_68. 12th European


Muñoz-Moreno JA. When and How to Screen for Neurocognitive Impairment in HIV Individuals. 7th International Symposium on Neuropsychiatry. 13-14 June 2014, Barcelona, Spain (Plenary Session).


Nevot M, Franco S, Revollo B, Clotet B, Tural Cy Martinez MA. Detección de un virus de la hepatitis C resistente a un inhibidor de la proteasa, Ns3/4a perteneciente a una red epidemiológica de transmisión entre hombres que tienen sexo con hombres y coinfectados con el virus de la inmunodeficiencia humana de tipo 1. VI Congreso Nacional Gesida 2014, Malaga.


3. INTERNAL STUDIES

The Foundation develops its research participating in studies conducted by external promoters but also conducting its own clinical trials to answer unresolved questions.

In 2014, the Foundation has conducted the following studies:

Clinical Trials:

**OSTEO Dolu: 2013-000547-85, NCT01966822**
Multicentre study to assess changes in bone mineral density of the switch from protease inhibitors to dolutegravir in HIV-1-infected subjects with low bone mineral density.

**NUKE-OUT: 2012-000198-21**
A multicenter randomised opened study to assess the efficacy and safety of the withdrawal of nucleos/tide analogues with complete or intermediate resistance in multitrated HIV-1-infected subjects with virological suppression.

**MARAVIPREX: 2012-003119-73, NCT01719627**
First study to evaluate the capacity of Maraviroc drug to protect against HIV infection in samples of rectal mucosa from healthy volunteers.

**TRIANT-TE: 2010-024510-57, NCT01348282**
Randomized, prospective, controlled study, to compare the efficacy and safety of two different pharmacological strategies on neurocognitive disorder in HIV infection.

**TULIP: 2011-002853-77, NCT01458977**
Clinical trial to evaluate the effect of co-formulation of tenofovir / emtricitabine on lipid lowering in patients infected with HIV-1 (cholesterol and triglycerides). The study was performed with subjects with dyslipidemia and sustained virologic suppression, and receiving monotherapy with boosted protease inhibitors with ritonavir.

**PROTEST: 2011-000799-32, NCT01378910**
Utility of genotypic tropism of HIV-1 from the proviral DNA to guide treatment with CCR5 antagonists in subjects with undetectable HIV-1 viral load.

Observational Studies:

**HIV-SEX-MALE**
Cross-sectional study to describe the sexual activity of HIV-1 infected men.

**ARFI**
Pilot study to evaluate the concordance between two non-invasive techniques (transient elastometry and acoustic radiation force impulse) and the Shasta index for the prediction of liver fibrosis in patients coinfected with HIV/HCV.

**RESIL-HIV**
Transversal study to evaluate the effect of resilience in coping with chronicity and aging in HIV-1 infected patients.

**IP and ENDOTHEL/FLS-IPS-2012-01**
Endothelial dysfunction in patients with HIV infection in treatment with protease inhibitors.

**TENOFOVIRIARANO-PROS/FLS-TEN-2012-01**
Prospective/retrospective observational study to evaluate the evolution of the kidney after stopping tenofovir in patients with renal impairment.

**HPV WOMEN COHORT: FLS-VPH-2007-02**
Prospective cohort study (HIV-positive and negative women) about the coexistence of human papillomavirus (HPV) infection in cervix, anus and oral cavity and cytological and histological lesions precursors of cancer.

**HPV MEN COHORT: FLS-VPH-2007-01**
Prospective study on the prevalence of infection with human papillomavirus (HPV) in oral cavity, anus and penis and the incidence of anal cancer in HIV-positive men.

**CHECK-EAR**
Study on the prevalence and incidence of sexually transmitted infections and diseases related to human papiloma virus in HIV-negative men who have sex with men (MSM).

**CONTROLLERS**
A cohort study: HIV-positive patients elite controllers and non-progressors are tracked prospectively.

**LATE PROGRESSORS**
Caracterització dels factors immunològics, genètics i virals que determinen la pèrdua del control de la infecció pel VIH en la població de progressors lents (LTNP).

**SPECTROBONE**
Observational, comparative, case-control and proof of concept study specifical-
ly designed to assess bone physiological parameters in patients infected by HIV.

**AGI-FIBROSI**
Association between the accumulation of intra-abdominal fat and the stage of liver fibrosis in patients coinfected by the Human Immunodeficiency Virus (HIV) and the Hepatitis C virus (HCV).

**EARLY-CART**
Cohort of individuals with acute/recent infection of HIV-1 starting antiretroviral therapy.

**EPIMAP**
Epitope mapping of T cell response against HIV and analysis of HLA restriction.