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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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).

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.

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. 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.

- Around 37 million people are infected with HIV worldwide. Only 15.8 million, a 42.7% of them, have access to antiretroviral treatment.
- There are approximately 2 million new HIV infections every year.
- AIDS has killed 34 million people since the onset of the epidemic. An estimated 1 million people lose their lives due to AIDS every year.
- The most affected region in the world is sub-Saharan Africa, with 26 million people infected with HIV and 70% of new infections.
- It is estimated that a mere 54% of people with HIV globally know they are infected.
NEWLY NOTIFIED HIV INFECTIONS

IN SPAIN AND CATALONIA
(2014 DATA)

<table>
<thead>
<tr>
<th></th>
<th>ESPANYA</th>
<th>CATALUNYA</th>
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<tbody>
<tr>
<td>NOVES INFECCIONS DE VIH NOTIFICADES</td>
<td>3,366</td>
<td>734</td>
</tr>
<tr>
<td>HIV PERCENTAGES BY GENDER</td>
<td>84,7% men – 15,3% women</td>
<td>88% homes – 12% women</td>
</tr>
<tr>
<td>HIV TRANSMITTED THROUGH</td>
<td>53,9%</td>
<td>51%</td>
</tr>
<tr>
<td>SEXUAL ACTIVITY AMONG MSM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV TRANSMITTED THROUGH</td>
<td>26%</td>
<td>Men (10%), women (7,5%)</td>
</tr>
<tr>
<td>SEXUAL ACTIVITY AMONG HETEROSEXUALS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV TRANSMITTED AMONG INJECTED DRUG USERS</td>
<td>3,4%</td>
<td>2%</td>
</tr>
<tr>
<td>PEOPLE WITH HIV FROM OTHER COUNTRIES</td>
<td>32,1%</td>
<td>40%</td>
</tr>
<tr>
<td>LATE DIAGNOSIS OF HIV</td>
<td>46,2%</td>
<td>42%</td>
</tr>
<tr>
<td>AIDS CASES</td>
<td>557</td>
<td>115</td>
</tr>
<tr>
<td>AIDS PERCENTAGES BY GENDER</td>
<td>79,3% men</td>
<td>83% women</td>
</tr>
</tbody>
</table>

- The rate of notification of HIV diagnosis in Catalonia and Spain has remained stable, being higher than the European average.
- Sexual transmission is the principal route of new diagnoses and the majority are MSM.
- Elevated levels of new HIV diagnoses among immigrants have been maintained.
- In the last 10 years, the proportion of people with a late diagnosis has been decreasing, although it is still an elevated percentage.
- The number of AIDS cases continues to fall, reflecting good accessibility to antiretroviral treatment by those affected.

SOURCES:
- CEEISCAT reports, Center for Surveillance of HIV infection and AIDS in Catalonia.
- UNAIDS (epidemiological reports)
MISSION: HEALTHCARE – RESEARCH – KNOWLEDGE TRANSFER

▶ To offer the best human and health care to people with HIV: since the Foundation was created, multidisciplinary experts (physicians, psychologists, dieticians, nurses and social workers, among others) have joined the HIV Unit to offer comprehensive, high quality clinical care to HIV sufferers.
▶ To conduct independent and competitive research in the field of HIV infection. Thanks to the proximity and communication between patients, caregivers and researchers, research is constantly adapting to the challenges posed daily by HIV. This model also allows rapid incorporation into clinical practice of the scientific advances.
▶ To transfer the knowledge acquired to society and professionals.
  - Participation in the development of clinical guidelines and action policies on HIV globally.
  - Application of knowledge generated in HIV research in other fields of medicine such as hepatitis C and cancer.
  - Training of experts in HIV/AIDS.
  - Professional advice on research projects in Africa.

UNAIDS HAS DEVELOPED THE 90-90-90 STRATEGY IN ORDER TO TACKLE HIV AND FIGHT THE PANDEMIC AT A GLOBAL LEVEL. THIS STRATEGY HAS A THREEFOLD GOAL FOR 2020:

_ for 90% of people infected with HIV to be aware they have it and to be diagnosed.
_ Among these people, for 90% to receive treatment;
_ and among this group, for 90% to have an undetectable viral load

Obtaining these figures for 2020, it is estimated that the world would be free of AIDS by 2030.

Not just the scientific community but humanity as a whole has undertaken a commitment to stop AIDS over the next few years. The work of the Fight AIDS Foundation is geared towards reaching this target, taking part in all fronts of this battle.
ERADICATE AIDS

The Foundation has aligned itself with this strategy with the global aim to eradicate AIDS, and its activity extends to all 90-90-90 targets: diagnosis, treatment and viral suppression. This list is completed by two additional aspects necessary for a complete overview on the fight against HIV: prevention and eradication.

PREVENTION

- Pre-exposition Prophylaxis (PREP): administration of pharmaceuticals to prevent HIV infection in especially vulnerable groups.
- Preventative Vaccine: to stop new infections.
- Education y public outreach: conferences mainly directed at youngsters and various campaigns to raise awareness in the general public. general.

DIAGNOSIS

- Detection of HIV and other sexually transmitted diseases, and rapid derivation to specialist HIV treatment units to begin treatment as soon as possible (in collaboration with community centers).
- Campaigns to raise awareness: -about the necessity to do HIV tests and early diagnosis. -against discrimination and stigma.

TREATMENT

- Side-effects associated with HIV and antiretroviral drugs:
  - Cardiovascular risk
  - Kidney and bone toxicity
  - Premature aging
  - Neurocognitive alterations
- New pharmaceuticals and combinations with other antiretrovirals, and more efficient treatment strategies with better adherence: monotherapy and other simplifications.
- HIV Coinfections with other viruses like Hepatitis or Human Papillomavirus
- Quality of life: Psychological aspects, Psychiatry, Nutrition, etc.
- Study of the Microbiome: the imbalances in the composition and function of the intestinal flora (microbiome) influence the immune system and health in general. The study of this relationship could be the key to combating HIV more effectively.
When a person is in treatment and remains undetectable, the infection is not transmitted. If the treatment is followed correctly and begins as soon as possible, the life expectancy of HIV carriers is practically the same as the rest of the population.

**ERADICATE AIDS**

**VIRAL SUPRESSION**
- Study and evaluation of the implications of HIV resistance to antiretrovirals: epidemiology, mechanisms and medical consequences for public health, with special attention placed on Africa and countries with fewer infra-structures.
- Collaboration with the World Health Organization with clinical guidelines and public health policies related to resistance.

**ERADICATION**
- OBJECTIVE: to find a functional cure for HIV.
  - Create our own therapeutic vaccine: the first clinical trials in humans will begin in 2017.
  - Other eradication strategies based on antibody neutralization, modified immunoglobulin and latent HIV reactivation.
WHAT WE DO?

HEALTHCARE
2015 DATA | 3.259 PATIENTS | 18.200 VISITS

PHYSICIANS: 13.179 (248 first visits, 12.931 follow-up visits)
PSYCHOLOGY: 2.279 (339 first visits, 1.940 follow-up visits)
NUTRITION: 1.375 (65 first visits, 1.310 follow-up visits)
PSYCHIATRY: 556 (49 first visits, 507 follow-up visits)
GYNECOLOGY: 435 (15 first visits, 420 follow-up visits)
SOCIAL CARE: 376 (97 first visits, 279 follow-up visits)
NURSING: 13.599 (trials, treatments, analytics, etc.)
FIBROSCAN: 476 hepatic elastographies.
PROCTOLOGY: 1.733 (1.021 cytologies, 368 anuscopies, 186 post chirurgic controls, 158 treatments with infrared).

ASSESSMENT OF THE SERVICE

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.

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<th>5</th>
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<tbody>
<tr>
<td>General evaluation</td>
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<td></td>
<td></td>
<td></td>
<td>4,49</td>
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<tr>
<td>Information received</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4,62</td>
</tr>
<tr>
<td>Visit time</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4,69</td>
</tr>
<tr>
<td>Waiting time</td>
<td></td>
<td></td>
<td></td>
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<td>4,76</td>
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QUALITY POLICY

The Fight Aids Foundation renewed its ISO 9001:2008 certification in November 2015. 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.

SERVICES OFFERED

- **Medicine**: HIV infection and associated disorders diagnosis and follow-up, advice and counseling 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 counseling, 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 and treatment of gynecologic aspects on women with HIV.
- **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.

In 2015, 55 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.

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

* MORE INFORMATION ABOUT STUDIES AND PUBLICATIONS IN THE CORRESPONDING ATTACHMENT.
CLINICAL VIROLOGY AND THE MICROBIOTA GENOME
Or how human pathogens and their balance with the organism cause disease.

The line of clinical virology and the microbiota genome has three main areas of investigation:

1. The study of HIV-1 resistance to antiretroviral drugs: This area covers Epidemiology, the mechanisms, and the medical and public health consequences of developing resistance to antiretroviral drugs.
   2. The development of new therapeutic strategies that permit antiretroviral treatment simplification and avoid the development of resistance to antiretrovirals.
   3. The study of the Human Microbiome in the development of HIV infection, chronic inflammation, reaction to vaccines and premature aging in people infected with HIV-1.

These objectives are conducted through our own clinical studies and in collaboration with the IrsiCaixa AIDS Research Institute, as well as with national and international groups.

WHAT DOES IT MEAN?

VIROLOGY?
Virology is the study of viruses: their structure, classification and evolution, the way they infect and take advantage of target cells to reproduce themselves, their interaction with guests, their immunity, the disease they cause, 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 lead the infected person to become sick.

RESISTANCES TO ANTIRETROVIRAL DRUGS
Resistance to medication refers to the capacity for a virus to continue multiplying itself despite the presence of drugs designed to combat it. In the case of HIV, resistance is caused by changes (mutations) in the genetic structure: these mutations are very common in HIV principally due to its capacity to multiply so quickly. Consequently, the act of not taking the medication adequately (in the quantities and frequency prescribed by the doctor) can favor the appearance of resistance. This means the viral load (the quantity of HIV in blood) begins to rise, and to combat this viral rebound, it is necessary to modify the treatment. Viral resistance progressively leaves the patient without treatment options.
MICROBIOME

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. 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.

DURING 2015

Regarding resistance and therapeutic options:

- In a study done in collaboration with the Irsicaixa Institute for AIDS Research, Emory University and the Harvard Medical School, it was shown that up to 70% of treatment failures with Tenofovir in South Africa developed resistance to this drug. This limits the treatment options for these people.
- In collaboration with IS Global, the determining factors in the failure of the first line of treatment in Mozambique have been analyzed. Of the 334 adults in treatment for more than 3 years, a quarter were failing, and of these, 90% had high-level resistance. The most important factors involved in these failures were: Young age, start of treatment at an advanced stage of infection and low adherence. This data allows us to identify in which areas efforts should be concentrated to assure the benefits of antiretroviral treatment.
- Various studies have been published about monotherapy, the simplification of antiretroviral treatment, the specific effects of some pharmaceuticals and the consequences of changing medication due to the appearance of failure or resistance. Raltegravir, Maraviroc, Tenofovir and Dolutegravir were some of the medications studied.

Participation in clinical guidelines and public health policies:

The Clinical virology line has continued to participate actively in the updating of the guide to resistance from IAS-USA (International Antiviral Society-USA), which is the most consulted worldwide. They also continued their collaboration with the World Health Organization’s resistance working group to evaluate the implications of resistance in developing countries. In fact, in 2015 Dr. Roger Paredes was invited to participate in the steering group created by the WHO to develop a worldwide plan of policies to combat the rise of resistance to antiretrovirals, especially in African countries.
Regarding microbiome:

Various transverse studies had already indicated that HIV infection was associated with alterations in the intestinal microbiome, but what about sexual practices? Do they have any influence over the microbiome? To answer this question, investigators composed 2 cohorts with 156 men in Barcelona (129 HIV-positive, 27 HIV-negative) and 84 in Stockholm (77 HIV-positive, 7 HIV-negative).

The results obtained suggest that sexual practice could have a substantial impact on the intestinal microbiome and should be taken into account when evaluating alterations associated with the disease. However, given that the study had relatively few participants without HIV and that those with HIV had the disease well under control, it would be necessary to conduct more studies in this area to establish definitive conclusions and practices. The study has shown though that independently of other factors, HIV infection reduced the richness of the intestinal microbiome, especially in patients with bad recovery of CD4+. The line of investigation is performing studies to better understand the implications of this phenomenon and find ways to improve the immune system's response to treatment through the modification of the microbiome.
AGING AND COMPLICATIONS ASSOCIATED WITH HIV AND ANTIRETROVIRALS

Or identifying, preventing and avoiding premature aging and adverse effects that can be caused by antiretrovirals and HIV itself.

The aging and complications associated with HIV and antiretrovirals 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. With the objective of preventing them, treating them early if present and to improve quality of life, a specific multidisciplinary health circuit has been created to be able to attend patients over 60 years of age. Two studies in this field are about to begin:

- One of them, to evaluate the utility of an APP to prevent comorbidity, improve clinical control and quality of life in patients over 60 years of age.

- The other, to compare the prevalence of comorbidity and complications associated with patients over 55 years of age with HIV and others uninfected, paired by age and sex, using complementary tests (ECG, densitometry, thorax and lumbar radiographies), questionnaires and a whole battery of functional tests, neuropsychology about social themes, etc., similar to a study of immune activation, inflammation and immunosenescence.

WHAT DOES IT MEAN?

SYSTEMIC INFLAMMATION

The immune system of people with HIV is permanently activated in order to combat the effects of the virus: this involves systemic and 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 inflammatory effects, aggravating or accelerating the process.

PREMATURE AGING

Aging is a structural and functional deterioration of the body. This deterioration, that occurs at a cellular level in the organs and tissues, makes the person more vulnerable and there is a higher risk of various illnesses and death. Health professionals agree on special handling of the elderly. People who live with HIV present more comorbidity (coexisting illnesses) and could be aging more prematurely than uninfected people. Les persones que viuen amb VIH presenten més comorbiditats (malalties coexistents) i podrien estar envellint d’una manera més precoç que aquelles no infectades pel virus.
MOST FREQUENT COMORBIDITIES AMONG HIV-PATIENTS:

CARDIOVASCULAR RISK

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.

RENAI DISORDERS

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 co-existing pathologies or treatments that are also toxic to this organ.

BONE TOXICITY

Patients with HIV infections have lower bone mineral density and higher risk of fractures due to Osteoporosis. Some antiretrovirals are associated with these side effects. Routine screenings are conducted to detect Osteoporosis in people who visit the HIV Unit, and if diagnosed, the effects of different strategies are being studied to try to recover the lost bone density.

DURING 2015

- A study was conducted to evaluate the long term safety of polyacrylamide hydrogel (Aquamid), injecting it to treat facial lipodystrophy. Information was gathered in the HIV unit from all of the patients who were treated with this substance 10 years ago, concluding that grave complications were low and the patient satisfaction with the cosmetic result was high. However, facial infections could appear in the long term. Therefore, HIV patients who received synthetic substances for cosmetic purposes to treat lipoatrophy should receive periodic check-ups.
- A study evaluated endothelial toxicity (endothelium is a tissue that forms the walls of our intestines) of two families of antiretrovirals: protease inhibitors and reverse-transcriptase non-nucleoside inhibitors. It was done by cultivating human endothelial cells with different doses of these antiretrovirals (“in vitro” study). The study is awaiting analysis and publication of the results.
- Els pacients amb VIH que reben teràpia antiretroviral poden tenir tendència a tenir alts nivells de triglicèrids o alteracions al colesterol, factors associats a un major risc cardiovascular. Es va publicar un estudi en que es valorava que algunes persones amb VIH poden estar genèticament predisposades a aquests problemes amb el seu perfil lipídic, con-cloent que hi ha variacions genètiques que protegeixen i d'altres predisposen a desenvolupar dislipèmia aterogènica, una situació d’especial risc cardiovascular en què la persona presenta nivells molt alts de triglicèrids i molt baixos d’HDL (l’anomenat “colesterol bo”).
- Patients with HIV who receive antiretroviral therapy can have a tendency to have high triglyceride levels or alterations in cholesterol, factors associated with higher cardiovascular
risk. A study was published in which it was pondered whether some people with HIV can be genetically predisposed to these problems because of their lipid profile. It concluded that there are genetic variations that protect and others that predispose development of Atherogenic dyslipidemia, of special cardiovascular risk, where people have high levels of triglycerides and very low HDL (the so-called “good cholesterol”)

- Although some clinical studies had studied the impact of antiretroviral treatments on bone mineral density, they lacked information on the impact of monotherapy with protease inhibitors. For this reason, a study was done to evaluate changes in bone density after 1, 2 and 3 years of treatment with this family of pharmaceuticals, using the DEXA technique (very low intensity x-rays)

- Another clinical trial concluded that the change from tenofovir to abacavir appeared to produce a positive effect on bone tissue and managed to reduce the bone turnover markers. Moreover, the levels of sclerostin circulating rose (a value associated with an improvement in improved bone properties).

- The results of a study were published in which changes in bone density comparing two different strategies with a drug called zoledronato, administered in a single dose or two doses over two years. The results obtained were similar with both strategies.

- In collaboration with the Nephrology service and the Biochemistry laboratory of the Germans Trias i Pujol Hospital, renal check-up measures have been implemented, taking into account the peculiarity of people with HIV, adapting to the new needs and latest recommendations in clinical guidelines.

- Currently, the presence of different proteins in blood and urine are being studied and can vary according to the renal disease the subject presents. In patients where a renal biopsy is appropriate for a better diagnosis, we will try to establish links between the study of the proteins and the biopsy
**CLINICAL PHARMACOLOGY**

Or assess the relationship between drug levels in the blood and their therapeutic effects in groups of people and specific individuals.

Clinical Pharmacology assesses the effects of drugs and their concentrations, both in the general population and in specific patients or patient groups. It focuses on the relationship between the levels of the drugs in the blood and their therapeutic effects.

This line investigates how the antiretrovirals 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 2015**

- Collaboration continues in international studies to evaluate the safety of antiretroviral drugs and possible changes in the concentration of these drugs in the blood of 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.
- The pharmacokinetics of some drugs were evaluated in special patient populations, such as those receiving treatment with hemodialysis for chronic renal insufficiency (2016). Specifically, during 2015, we evaluated the pharmacokinetics of Dolutegravir in terminal renal insufficiency.
- 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 chemotherapy for cancer 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 Erlotinib and Gefitinib.
- During 2015, collaboration began between the lines of immunology and vaccines to optimize the treatment with some medications which could be used to eradicate HIV from the body. This project has received public financing from the FIS fund.
COINFECTION WITH HEPATITIS AND COHORTS

Or to consider how to help people who must fight both infections at the same time, tracking different cohorts (groups of people with HIV).

HIV coinfection with Hepatitis B and C is frequent. The fact of having a longer life and aging with HIV thanks to the efficacy of antiretrovirals against the virus, the importance of Hepatitis infections has emerged. In fact, viral Hepatitis is considered one of the principal causes of death in HIV-positive people (It is estimated that around 30% are coinfected with HCV).

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 2015

- With the appearance of the new drugs for Hepatitis C (that do not use Interferon as their base), a whole new line of therapy has been opened for those infected. Since the HIV Unit created a multidisciplinary committee in March 2015, which meets weekly to determine which patients are opportune to receive this new medication, they have been prioritizing the gravest cases according to two principal factors: the genotype of the virus and the degree of Hepatic fibrosis. This selection has been done gradually, based on the budget available for this treatment. Although the price has fallen over time, it still represents a high cost for public healthcare.

  Between 2014 and 2016 (the moment of writing this report), 222 patients have been treated with the new drugs available. The efficacy of the treatment is higher than 90%.

- Publication of the results of a clinical study called STARTVerso4, which showed the efficacy of the treatment with the Protease inhibitor Faldaprevir added to pegylated Interferon and Ribavirina to cure Genotype 1 Hepatitis C in nearly three quarters of the people coinfected with HIV. This equals the results obtained with the same drug combination in people only infected with Hepatitis C.

- Participation in a study to compare the results obtained from hepatic biopsies with those hepatic biopsies obtained calculated with the Fib4 index, a non-invasive test, to determine the
state of the liver and liver functioning. The results put in doubt the convenience of using hepatic biopsies to predict the mortality or risk of complications in patients coinfected with HIV and Hepatitis C, as is done currently, after discovering that the non-invasive Fib4 index test can be more effective to discover the long term prognosis.

- Realització d’un estudi conjuntament amb IrsiCaixa sobre l’impacte a curt termini de l’interferó alfa sobre la persistència del VIH i els seus efectes sobre l’activació del sistema immunològic unit a la teràpia antiretroviral.
- Completion of a joint study with IrsiCaixa about the short term impact of Interferon Alfa on HIV persistence and its effects on the activation of the immune system when combined with antiretroviral therapy.
In people with HIV, with a weakened immune system, opportunistic infections can emerge. These are diseases related to the progression and 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 2015**

- The line published a case in “AIDS” of the first patient with HIV suffering from an aggressive form of nasosinusal inverted papillomavirus, who after HPV vaccination, has not relapsed. Nasosinusal inverted papillomavirus causes injuries around the nose. The patient was visited and treated for the lesions in 2009 and 2012. In hindsight, the patient was diagnosed and vaccinated against the human papillomavirus, and the possibility of the relationship between the inverted papillomavirus and HPV infection was confirmed in later observations, the last being in January 2015, when no new lesions were found.

- The Check-early study was initiated, focusing on the early detection of STIs (sexually transmitted infections): BCN Checkpoint, the community center for HIV and ITS detection is run by the Noms-Hispanosida Project and put Check-early in motion in collaboration with the Fight AIDS Foundation and IrsiCaixa AIDS Research Institute. It concerns a new study about the incidence of and prevalence of STIs in men who have sex with men (MSM) and transsexual women. It involves a free confidential program of early detection of these infections. For a year, the participants permit health checks for the principal STIs which include detection tests for HIV, Syphilis, Chlamydia, Gonorrhea and Hepatitis A, B and C.

The project also proposes to show that the collaboration between a community center like
BCN Checkpoint and a leading hospital in HIV can be very efficient and effective at reducing the time to a minimum from when someone is infected until their viral load becomes undetectable. This permits infected people to maintain normal CD4 levels or help them to recover, have less reservoirs of HIV, reduce the anxiety with risk of transmission and, definitively, have a better quality of life.

- The CHECK-EAR study, initiated in 2009, has continued and is the predecessor to CHECK-EARLY. BCN Checkpoint collaborates with the Clinic Foundation, Irsicaixa and the Fight AIDS Foundation. In this study, data is collected regarding the prevalence of human papillomavirus and other STIs, in which 268 MSM and transsexual women have participated. Almost 15% of the participants in the Check-Ear have been diagnosed with an STI although many did not show any symptoms. Despite the asymptomatic nature at times, if these infections are not detected and treated early, they can have adverse effects on health and continue being transmitted. In addition, the presence of other STIs significantly increases the risk of HIV infection, especially in the case of those STIs that provoke lesions or ulcers, which can facilitate the entry of the virus.
IMMUNOLOGY AND VACCINES

Or to work with the aim of eradicating HIV with the help of drugs that act on the immune system and designing therapeutic or preventative 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). These lines 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 an unprecedented public-private consortium in Spain, placing our country at the forefront of international research conducted in this area. It consists of the IrsiCaixa AIDS Research Institute and the AIDS and Infectious Diseases Service of the Clinic Hospital in 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. The HIVACAT program is an internationally renowned entity: in 2013, it was the organizer of the AIDS vaccine 2013 congress, the largest and most prestigious focused exclusively on HIV vaccine investigation.

The investigative objectives of the Immunology and Vaccines line are focused on three large areas:

- Design and development of preventative and therapeutic vaccines.
- Creation and maintenance of Cohorts of patients for studies of factors related to the natural control of HIV infection and phenomena associated with early antiretroviral treatment start.
- Studies of the eradication of the virus through the use of immunomodulators or reactivating medication or purges of the viral reservoir.
WHAT DOES IT MEAN?

PREVENTATIVE versus THERAPEUTIC VACCINE

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 preventative vaccines. The ones used to help control the virus in people who are already infected are called therapeutic vaccines.

RESERVOIR

Viral reservoirs are cells infected with HIV which remain latent despite the antiretroviral therapy.

DURING 2015

Cohorts follow-up

- **Early_cART (PI-14-072):** Cohort started in 2014 to monitor individuals with acute/recent and documented HIV-1 infection, and early treatment start. The objective is to have a clinical platform of candidates to participate in clinical trials of therapeutic vaccine and eradication strategies and, in turn, to have biological samples collected prospectively from the start of antiretroviral therapy to study the immune response, and to establish the viral reservoir and changes in the intestinal microbiome. No clinical intervention is performed beyond taking additional biological samples and stool collection for microbiome studies. For the creation of the cohort, we are working closely with BCN Checkpoint and other community centers for the detection of HIV and other sexually transmitted diseases. Currently this cohort performs a prospective follow-up of more than 150 people.

- **Controllers (EO-09-042):** study of cohorts began in 2009 in collaboration with Vall d’Hebron Hospital and some prisons in the city of Barcelona to prospectively follow people with HIV with an undetectable or low viral load in absence of antiretroviral treatment, those known as elite or viremic controllers. The objective of the cohort is to study the virological and immunological mechanisms that work to spontaneously control the HIV virus that could help us to develop new therapeutic vaccines for HIV. No clinical intervention is done other than to extract additional biological samples. The Late Progressors or Losers project, studies the factors that cause the patients, who have been controllers of the virus, to lose this. It comprises the active follow-up of more than 60 people with different HIV-infection-controlling phenotypes.
Clinical trials of therapeutic vaccines:

- Promising results have been obtained in the HTI therapeutic vaccine, designed by IrsiCaixa investigators. The HTI model starts from a unique focus: it is the first that bases itself on the immune response of people who are able to control the HIV infection in absence of antiretrovirals. HTI has the potential to become the first immunotherapy able to efficiently cure the HIV infection. Human trials will begin in 2017.

- During October 2015, the BCN01 clinical trial finished, initiated in 2013. It is a trial with candidates for a therapeutic vaccine called ChAdV63.HIVconsv y MVA.HIVconsv, developed by investigators from Oxford University. These vaccines try to combat the viral diversity through the stimulation of the immune response in the more preserved zones of the virus. 48 people were included with documented acute/recent infection by HIV-1 and had started early antiretroviral treatment. The vaccines were administered using two viral vectors: a chimpanzee adenovirus (Chad) and vaccinia virus (MVA). It also included 24 people treated early but without receiving the vaccine. The objectives of the trial included a study of the security of the vaccine administration, the immune response to the two vaccine strategies, as well as the evaluation of the reduction of the viral reservoir in the context of the start of early treatment and therapeutic vaccination. The patients did not interrupt the antiretroviral treatment over the course of the study. Results were presented in various congresses in 2015 and further results await publication.

- The BCN02-Romi (NCT02616874) clinical trial is an eradication study that evaluates the efficacy of a ‘Kick & Kill’ strategy using therapeutic vaccines that have proven more immunogenic up until now (HIVconsv) in combination with the most powerful latent viral reactivator medication available at the moment (RMD, Romidepsina). HIV-positive people who have been treated early and who were previously vaccinated in the BCN01 clinical trial represent an ideal group to demonstrate the efficacy of this combined strategy in the reduction of the viral reservoir and the control of viral rebound after treatment is withdrawn. The study is financed by the competitive meeting of AES (FIS modality) in 2015 (PI15 / 01188). Dr. J Moltó and Dr. B. Mothe are the principal investigators and count on the participation of the Clinic Hospital, BCN-Checkpoint community center, Oxford University and the Celgene pharmaceutical company. During 2015, they have worked on the fine-tuning and regulatory approval for the study.

- The RisVac 03 (NCT01571466) clinical trial is a MVA-B candidate for a therapeutic vaccine conducted in collaboration with Clinic Hospital, Barcelona and Gregorio Marañón, Madrid. 30 people with correctly suppressed HIV-1 participated. 10 participants received a placebo and 20 the vaccine. The first results were presented at AIDS vaccine 2013 and published in JAC 2015 (Mothe et al), indicating that although stimulation of the immune response was observed, the vaccine did not show sufficient efficacy to control the viral rebound once the patients stopped antiretroviral treatment. Currently, the factors that can influence the delay of the viral rebound once the vaccination is administered are being evaluated. The project is financed by a grant from AMFAR.

- The iHIVARNA-01 (NCT02413645) clinical trial began in June 2015 with the iHIVARNA therapeutic vaccine candidate. It includes 21 patients with chronic HIV-1 infection correctly suppressed, distributed consecutively to receive increasing doses of the iHIVARNA vaccine containing the HTI immunogen and the Trimix adjuvant. The objectives of the clinical trial
include studying the safety of the vaccine administration, the immunological response produced and the efficacy of the viral reactivation. The first trial began in June 2015, directed and coordinated from Clinic Hospital, Barcelona. The Fight AIDS Foundation will recruit and include patients in the 2nd phase of the study (iHIVARNA-02), with another five international centers. More information at ihivarna.org.
PSYCHOLOGY
Or to intervene in improving the emotional state of patients with HIV, determining issues such as cognitive impairment or the consequences of stress.

Like people with other chronic illnesses, people who are HIV-positive require integrated care which must include psychological support. The Foundation not only provides that support but also promotes psychotherapeutic intervention to help with the emotional difficulties that arise in patients with HIV and those around them and has conducted a number of different studies focusing 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, the early detection of cognitive and central nervous system impairment, and the effects of psychological stress on immune function.

WHAT DOES IT MEAN?

RESILIENCE
Psychological resilience is the capacity a person has to resist and overcome continued attacks. It is related to self-esteem. It is demonstrated that resilience is greater when a person can count on at least one loving relationship with someone. When a person behaves resiliently, they can recover from a traumatic experience and even come out of it stronger.

DURING 2015

▶ At the beginning of 2015, the TRIANT-TE study finished, which was a clinical trial to compare the efficacy and safety of two pharmacological strategies concerning Neurocognitive alterations in HIV-infection. At the time of writing this report, the results are being analyzed and the report is being written for publication.
▶ In October, the ARBRE study began, which is a project that tries to comprehensively understand the benefits of starting antiretroviral therapy on cerebral functioning. Similarly in people beginning early antiretroviral treatment and those starting later or those uninfected by
HIV, cerebral functioning is evaluated using cognitive functioning: daily functioning, quality of life and emotional status; and recently, anatomical and functional cerebral markers using the latest generation functional magnetic resonance.

- At the end of the year, a proposal was presented to investigate the impact of an HIV eradication strategy on the central nervous system, in an international project call for entries (amfAR - Call 2015 for HIVCure). This proposal was not accepted, but despite that, the project will be run throughout 2016. Precisely, developed as a sub-study of the BCN02-ROMI Project.

- Regarding Education: 2015 was the second year the Psychology line has collaborated with the Open University of Catalonia (UOC) in the development context of a Masters in General Health Psychology, through the coordination of Jose A. Muñoz- Moreno as the expert in Health Psychology.

- In December 2015, results of the “Resilis HIV” study were published in the AIDS Care journal, and evaluated the effects of resilience on confronting illness chronicity, like aging in people infected with HIV. This study took a sample of 151 patients with at least ten years since diagnosis. As principal inclusions, we should highlight that elevated resilience is related to two factors of perception (good cognitive self-concept and good subjective social relationships), the use of positive reinforcement as a confronting strategy and a better emotional status. Almost half of the participants showed elevated levels of resilience. Our study shows that positive aging is possible in HIV-infected people. The main author of this work, Carmina R. Fumaz, was also co-author of an article published in AIDS & Behavior, in which the psychometric properties of Screenphiv (an instrument for measuring psychological variables related to HIV) were presented. Screenphiv has proven to be a valid and reliable instrument that can be used in research and clinical contexts in Spain.

- Finally, during 2015, we began following the cohort of patients receiving oral treatments for their coinfection with HCV. The objective of the study is to evaluate the effect of these new treatment strategies on the quality of life and emotional status of these patients.
DIETETICS
Or to study how diet and nutritional habits can help improve the immunological status of people with HIV.

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.

The study of body composition is an important aspect in the assessment of nutritional status because it permits the quantification of the body’s reserves. Therefore, allowing us to detect and correct nutritional problems like being overweight or obesity, or, to the contrary, malnutrition. The measurement of body composition using densitometry (DEXA) can provide assessment going beyond weight and the traditional body mass index (BMI) to determine body fat distribution.

DURING 2015

- The ALICIA study results were published, in which the positive effects of educational workshops with people with HIV on food intake and lipid profile are shown.
- The Dietetics Line collaborates in projects with the other research lines of the Foundation:  
  - It works closely with the toxicities line associated with HIV and antiretrovirals in areas such as facial lipoatrophy, bone mineral density and cholesterol levels.  
  - In relation to the study of microbial genetics, it collaborates with the description of the diet of people with HIV linking it to the different composition of microbiome profiles.
- Regarding Education: in November 2015 a class was given about nutrition and AIDS to Nutrition Grad students from Vic University - Central University of Catalonia (UVic-UCC), within the framework of the university chair of AIDS and associated diseases, of this university.
- In 2015, the line began updating the dietary educational material relative to people with HIV.
RESEARCH SUPPORT

MONITORING OF CLINICAL STUDIES

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 following good clinical practices.

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

Although originally only trials related to 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 under a more generic name, FLS-Research Support.

STATISTICS

The statistics team contributes to the research projects at the Fight AIDS 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.

Through an educational cooperation agreement with the Polytechnic University of 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 latest advances.

RESEARCH GRANTS AND FINANCIAL HELP

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
  -> Investigator: José Moltó
Efficacy and safety of the VIHconsv with Romidepsina vaccine in the reduction of the viral reservoir and control after the interruption of cART. PK / PD Population Analysis and study of predictors.
   --> Investigators: Bea Mothe and José Moltó.

Elimination of Dolutegravir for hemodialysis in patients infected with VIH with renal disease in a terminal stage.
   - ViiV Healthcare, pharmaceutical company
   --> Investigator: José Moltó

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 2010 call for funding to promote independent clinical research.
   --> Investigator: José A. Muñoz- Moreno.

Pilot study to evaluate the health impact of a mobile device application (APP) on the clinical results and satisfaction of HIV-infected elderly patients, as a new instrument for healthcare, education and prevention.
   - Gilead Fellowship
   --> Investigator: Eugènia Negredo

RALATOR: Study the effect of Atorvastatina to reduce the inflammation related to the aging of HIV-infected patients over 60 receiving a protease inhibitor based regimen when compared to a Raltegravir one.
   - MSD, pharmaceutical company
   --> Investigator: Eugènia Negredo

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

Project: Safety evaluation 10 years after receiving facial injections with polyacrylamide gel (Aquamid®) in patients with HIV infection and facial lipoatrophy.
   - Contura, Aquamid® gel manufacturer.
   --> Investigator: Eugènia Negredo
Project: Circulating MicroRNAs as potential biomarkers of liver disease in HIV-infected patients.
   - FIS Grant. Ministry of Economy and Competitiveness.
   --> Investigator: 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.
   --> Investigator: Roger Paredes

Project: Co-evolution 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 Feder Foundation.
   --> Investigator: Roger Paredes

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

   - Philanthropy.
   --> Investigator: Roger Paredes

Project: Prevalence of virological failure, immune deterioration, antiretroviral drug resistance and suboptimal antiretroviral levels in HIV-1 infected subjects receiving antiretroviral treatment in Manhiça (PREVIR-2012).
   - Gilead Sciences, pharmaceutical company.
   --> Investigator: 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 2015 in areas such as medicine, dietetics, statistics and monitoring of clinical studies.
- During 2015, the following thesis was presented:
  - 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.

**ORGANIZATION 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.

**2nd Conference on Hepatitis C treatment with HIV-coinfection:** This conference aims to be a space for interaction between clinicians, administration and pharmaceutical companies. Hepatitis C treatment is experiencing a paradigm shift with a cure as the clear objective. The clinics that treat those HIV-coinfected should evaluate the best method to treat each case based on available treatments and resources. Conference coordinated by doctors Bonaventura Clotet and Josep M. Gatell with the support of Abbvie, MSD, Bristol-Myers Squibb and Gilead.
Prospects for HIV cure and post treatment remission: EACS (15th European AIDS Conference) satellite symposium organized by the Fight AIDS Foundation (FLSIDA) with the support of MSD, where various experts speak about immunological recovery, vaccines and advances in the eradication of HIV.

More information about the program and speakers’ presentations at the conference can be found in “Courses and Seminars” at www.flsida.org.

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 of 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.
SOCIAL COMMITMENT

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.

EPIDEMIA THE GAME

2015 is the year of a new fundraising initiative: the videogame called EPIDEMIA THE GAME. It is an APP for cell phones and tablets available for iOS and Android, and also Facebook, with a cost of 0.99€. It is an arcade style game where the player controls the movements of the character (“Pitu” in Google Play and “Tupi” in Apple Store) who combats waves of virus shooting at them with pills and protecting itself from attack.

Epidemia the Game was created with two objectives: as a fundraising tool for accelerating research in HIV eradication, and by using the playful virtual game world as an excuse to promote the use of condoms as the primary method to avoid HIV transmission and the concept of antiretroviral treatment as prevention.
SOCIAL COMMITMENT

Jesús Vázquez is the patron of the initiative which also has the support of Mediaset and its online and offline communications network. The game also has other patrons, such as the ex-footballer Carles Puyol, the Tricicle actor Carles Sans and the producer of Reset TV and founder of Gestmusic-Endemol Toni Cruz. Epidemia the Game is currently translated into 18 languages and has received worldwide support via social media from many celebrities including Sharon Stone, Rafa Nadal, Malú, Alejandro Sanz, Gerard Piqué, Jorge Lorenzo, Laura Pausini, Pau Gasol, Jordi Évole, Andrés Iniesta, Abraham Mateo and David Bisbal.

For the launch of the game, the Fight AIDS Foundation (FLSIDA) organized a party with 150 personalities from the world of culture, sport and society in the “Palauet” (113 Passeig de Gracia) in Barcelona on the 4th of May.

SOLIDARITY SMS TO 28099

A new form of collaboration with the Foundation: send an SMS with the word epidemia to 28099. For each SMS, the Foundation receives 1.20 € thanks to the collaboration of Orange, Telefonica, Vodafone and the Amplexus Foundation.

Jesús Vázquez continues to be the spokesman for the campaign, gaining huge audiences in all of his TV appearances (for example, a special appearance on the Pasapalabra TV program on December 24th).

This campaign will remain active without establishing an end date.
SOCIAL COMMITMENT

2ND NIGHT FOR INVESTIGATION

The 2nd Night For Investigation in Central Catalonia was held the night of Friday May 29th in Món Sant Benet (Sant Fruitós del Bages) with the organization done by the Catalunya-La Pedrera Foundation and a menu designed by the kitchen staff of Món Sant Benet and the Alicia Foundation.

The funds obtained are destined to finance the study of the human microbiome and its relationship with premature aging being conducted by the head of AIDS and associated diseases at UVic-UCC.

The act was presented by the actress Aina Clotet and Lari the Magician. There were performances by Pep Sala, from Lari the Magician himself, Salva Racero (Singer of Lax’n’Busto) and Llibert Fortuny.
1ST COSTA BRAVA SOLIDARITY NIGHT

It was held on August 9th in Palamos in the Romanic Cloister of Mas del Vent. The organizers were Focus Engelhorn, the Lluís Coromina Foundation and the BonArt magazine in favor of the Fight AIDS Foundation.

Presented by Lari the Magician, the gala meal was created by Michelin star chefs from Baix Emporda and Pla de l’Estany with special collaboration from the Celler de Can Roca. There were acts from Lari the Magician himself, the Cobosmika contemporary dance company and the musical duo of Isabel Vinardell and Isabelle Laudenbach.

Although the majority of the act was celebrated in Mas del Vent (Palamos), the event began at 6pm with the inauguration of an AIDS exposition at the Palamos Fishing Museum.

A part of the funds obtained from the 1st Costa Brava Solidarity Night was given to the Palamos Christmas Fair, which destines profits to organizations that work with disabled people in Baix Empordà.
BARCELONA AIDS COUNTDOWN

“BCN AIDS Countdown” (www.bcncountdown.com) is a campaign created so that everyone can take part towards an AIDS cure. Diverse activities were proposed for this final sprint.

The final destiny for these funds will be the Fight AIDS Foundation investigation projects concentrating on eradicating HIV and finding a cure, in collaboration with the IrsiCaixa AIDS Institute, and study of the relationship between the microbiome health, the immune system and premature aging, and the improvement in the quality of life of people with HIV.

The campaign has four focuses:
- Solidarity Nights
- AIDS Gala Barcelona
- Initiatives against AIDS
- AIDS World Cycling
SOCIAL COMMITMENT

- The Solidarity Nights commenced November 20th. Various venues held events to obtain funds to fight against AIDS and sensitize the general public towards the disease. These venues participated: Luz de Gas, Sala B, Razzmatazz, Sala Bikini, Sala Metro, and the bars of Hotel W, Majestic and Mandarin.
- The AIDS Gala Barcelona was held November 30th in the MNAC (Museo Nacional de Arte de Cataluña), under Miguel Bosé’s direction and Belén Rueda as ambassador. Tricicle performed. The 2nd edition of Barcelona AIDS Awards were given by Dr. Mario Stevenson, head of the Division of Infectious Diseases and Director of the HIV/AIDS Institute at the Miller School of Medicine from Miami University and M • A • C Aids Fund.

- In the Initiatives against AIDS section, the activities organized by people or organizations outside the Foundation, to make money or sensitize the public to the fight against AIDS, are detailed:
  - Sale of surgical Robin Hats
  - Room to Help Campaign by Room Mate Hotels
  - Fashion against AIDS, exposition in Bilbao
  - Sale of We Party CD online
  - “Despéinate contra el sida” (Undo your hairdo), Hairdressing project – L’Oréal
  - Zumbathon, master class of Zumba in Malgrat de Mar
  - Selfie, sensitizing project by XXSS
  - Illuminating iconic Barcelona buildings in red

- Lastly, AIDS World Cycling will be a 12 hour indoor cycling marathon in teams to be held in 2016.
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 awareness 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, Mónica Segarra, Elvira Vázquez and Anna Veiga

* Clinical research associates  ** Registered nurses
Carmen Alcalde
Nurse.
Coinfection by HPV and Opportunistic Infections Line.

Àngels Andreu
Collaborator: Pharmacist of Hospital Germans Trias

Anna Bonjoch
Physician and Researcher. 
Aging and complications associated with HIV and antiretrovirals line.

Isabel Bravo
Nurse. 
Clinical virology and microbiome genome line.

Pere Carbonell
Statistician in work practice. 
University masters student in Statistics and Operative Investigation (Polytechnic University of Catalonia).

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
Physician and Researcher. 
Coinfection by HPV and Opportunistic Infections Line.

Crisanto Díez
Collaborator: Head of the Psychiatry Department of Germans Trias Hospital.

Laura Duran
Public Relations and communication.

Patricia Echeverría
Physician and Researcher. 
Aging and complications associated with HIV and antiretrovirals 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
Trainee Clinical Trial Monitor.

Francesc García-Cuyàs
Collaborator: Gastrointestinal Surgeon of Germans Trias Hospital.

Sílvia Gel
Clinical Trial Monitor. 
Internal Clinical Trials Coordinator. 
Quality Manager.

Guadalupe Gómez
Collaborator: 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 of Germans Trias Hospital.

Antoni Jou
Physician and Researcher. 
Coinfection by Hepatotropic Viruses Line. Cohorts.

Begoña Lemos
Social Worker.

Josep Maria Llibre
Physician and Researcher. 
Clinical virology and microbiome genome line.

Ingrid Martínez
Clerical Worker.

Manuel Medina
Collaborator: Plastic Surgeon at Germans Trias Hospital.
STAFF

Cristina Miranda

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.

Eugènia Negredo
Physician and Researcher. Head of the Aging and complications associated with HIV and antiretrovirals line.

Aroa Nieto
Nurse Coinfection by HPV and Opportunistic Infections Line, and Immunology and Vaccines Line.

Arelly Ornelas
Statistician.

Maite Orodea
Clerical Worker.

Roger Paredes

Deborah París
Clerical Worker.

Núria Pérez
Statistician.

Marta Piñol
Collaborator: Gastrointestinal Surgeon of Germans Trias Hospital.

Ramon Planas
Collaborator: Head of the Gastroenterology Department of Germans Trias Hospital.

Jordi Puig
Nurse. Aging and complications associated with HIV and antiretrovirals line. External Clinical Trials Coordinator.

Boris Revollo
Physician and Researcher. Coinfection by Hepatitis and human papillomavirus line.

Carmina R. Fumaz
Psychologist. Psychology Line.

Joan Romeu
Physician and Researcher. Head of the Immunology and Vaccines Line.

Susana Ruiz
Collaborator: Ophthalmologist at Germans Trias Hospital.

Anna Salas

José Ramón Santos
Physician and Researcher.

Clinical virology and microbiome genome line.

Cristina Segundo
Nurse Coinfection by Hepatotropic Viruses and Opportunistic Infections.

Guillem Sirera
Physician and Researcher. Head of Opportunistic Infections and Coinfection by HPV Line.

Esther Soler

Antoni Tarrats
Collaborator: Gynecologist at Germans Trias Hospital.

Jéssica Toro
Clinical Trial Monitor.

Miryam Solé
Clinical Trial Monitor.

Albert Tuldrà
Manager.

Cristina Tural

Sebastià Videla
Collaborator: Clinical pharmacologist.
FINANCIAL AND ECONOMIC DATA

TOTAL INCOME
2.567.847 €
- Grants 7%
- Members and donations 59%
- Services 34%

TOTAL DESPESES
2.563.673 €
- Healthcare 7%
- Research 59%
- Education 7%
- Administrative and fundraising expenses 27%
As an individual:
you can make a contribution, become a member and partici-
pate 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.

WANT MORE INFORMATION?
WRITE TO COMUNICACIO@FLSIDA.ORG

YOU WILL FIND THESE AND OTHER OPTIONS AT
WWW.FLSIDA.ORG

COLLABORATING COMPANIES AND INSTITUTIONS 2015

- ABADAL
- ABBVIE
- ACTIVA
- AJUNTAMENT DE BARCELONA
- ALBERTO CERDÁN
- ARA
- ARAYMOND
- AUSA
- AUTOLICA
- AVINENT IMPLANT SYSTEMS
- BANCO SANTANDER
- BCN CHECKPOINT – PROJECTE DELS NOMS
- BODEGAS LA HORRA CORIMBO
- BOIA NIT
- BOTTEGA VENETTA
- BRISTOL MYERS SQUIBB
- BRUGAROL
- BUSQUET ECONOMISTES
- BVLGARI
- CAIXA BANK
- CAROLINA HERRERA NEW YORK
- CASA BATLLÓ
- CC LES ARENES
- CLH
- CLÍNICA BARCELONETA
- COCA-COLA
- COCA-COLA IBERIAN PARTNERS
- CONFIDE
- CONSULTORI BAYÉS
- COMMON SENSE
- CONSORCI HOSPITALARI DE VIC
- COTS I CLARET
- DIPUTACIÓ DE BARCELONA
- DIPUTACIÓ DE GIRONA
- DOGA GESTIÓ · GRUP EMPRESARIAL
- DOLCE GABANNA
- ECUADOR AMA LA VIDA
- EL MOLINO
- EL MUNDO
- EL PALAUET
- EL PERIÓDICO
- EL POBLE ESPANYOL
- EL PUNT AVUI
- ESTEVE
- ESTRATEGIS ADVISORS
- EUROFIRMS
- EXPANSIÓN
- FOCUS
- FOCUS ENGELHORN
- FUNDACIÓN ALÍCIA
- FUNDACIÓN AMPANS
- FUNDACIÓN AMPLEXUS
- FUNDACIÓN ARTAIDS
- FUNDACIÓN CATALUNYA – LA PEDRERA
- FUNDACIÓN DAMM
- FUNDACIÓN DKV
- FUNDACIÓN LLUÍS COROMINA
- FUNDACIÓN SAGRADA FAMÍLIA
- FUNDACIÓN SOCIOSANITÀRIA DE MANRESA
- FUNDACIÓN SUÑOL
- FUNDACIÓN UNIVERSITÀRIA BALMES
- FUNDACIÓN UNIVERSITÀRIA DEL BAGES
- FUNDACIÓN VILA CASAS
- GARAJE ANDREU
- GAS NATURAL FENOSA
- GENERALITAT DE CATALUNYA
- GILEAD
- GIORGIO ARMANI
- GRAMONA
- GRAN TEATRE DEL LICEU
- GRUP VILÀ VILA
- GRUP VILAR-RIBA
- GRUPO JULIÁ
COLLABORATING COMPANIES AND INSTITUTIONS 2015

- GUCCI
- HAN NEFKENS
- HOTEL ARTS
- HERET VYNOLES
- HOTEL MAJESTIC
- HOTEL MANDARIN
- HOTEL W
- IBERIA
- IMPREMTA MAROT
- JANSSEN
- JUBANY
- KAY PRODUCCIONS
- L’AUDITORI
- L’ORÉAL PROFESSIONNEL (PELUQUEROS CONTRA EL SIDA)
- LA RAZÓN
- LA VANGUARDIA
- LAS CINCO
- LUZ DE GAS
- MACBA
- MAF (MAC AIDS FUND)
- MAHALA COMUNICACIÓN
- MEDIAPRO
- MEDIASET
- MERCÈS
- MEROIL
- MIQUEL Y COSTAS
- MNAC (MUSEU NACIONAL D'ART DE CATALUNYA)
- MÓN SANT BENET
- MSD
- NOEL ALIMENTARIA
- OBRA SOCIAL "LA CAIXA"
- OLIVA TORRAS GRUP
- PALAU DE LA MÚSICA CATALANA
- PATRONAT DE TURISME COSTA BRAVA
- PAZO DE SEÑORANS
- PEDRALBES CENTRE
- PFIZER
- PROVETS
- QÜESTIONS
- RENFE
- REPSOL
- ROOM MATE HOTELS
- ROQUETA
- ROYAL
- RQP ARQUITECTURA
- SALA METRO
- SANSIBAR – AMICS DE LA FOSCA
- SANT PAU, RECINTE MODERNISTA
- SANTASUSANA
- SELBA
- SIEMENS
- TEATRE LLIURE
- TNC
- TORRE AGBAR
- TOTÉ VIGNAU
- TOUS
- TRANSVERSA
- UNIDOS EN RED
- UNIVERSITAT DE VIC – UNIVERSITAT CENTRAL DE CATALUNYA
- VALENTINO
- VIIV HEALTHCARE
ATTACHMENTS: PUBLICATIONS

PUBLICATIONS 2015


Llibre JM, Bravo I, Ornelas A, Santos JR, Puig J, Martin-Iguacel R, Paredes R, Clotet B. Effectiveness
of a treatment switch to nevirapine plus tenofovir and emtricitabine (or lamivudine) in adults with HIV-1 suppressed viremia. PLoS One. 2015 Jun 24;10(6):e0128131. (IF: 3.23)


Sirera G, Videla S, Vergés J, Chamorro A, Cañadas M, Clotet B. Aggressive human papillomavirus...


Badía R, Ballana E, Riveira-Muñoz E, Clotet B, Esté JA. Inhibition of herpes simplex virus type 1 (HSV-1) by the CDK6 inhibitor PD-0332991 (palbociclib) through the control of SAMHD1. *ICAR*, 2015, Roma, Italy.


Clotet B. Utilidad de los inhibidores de la Integrasa. 1 August 2015, Montevideo, Uruguay.


Muñoz-Moreno JA. An Alternative Approach to Screen for HAND Using Clinical and Demographic Information.
COMMUNICATIONS AT CONFERENCES

8th International Symposium on Neuropsychiatry and HIV. 12-13 June 2015, Barcelona, Spain (Oral Communication).

Muñoz-Moreno JA. Screening for HAND: Update to June 2015. 8th International Symposium on Neuropsychiatry and HIV. 12-13 June 2015, Barcelona, Spain (Oral Communication).

Negredo E, Tarr P. Meet the expert: bone. 15th EACS. 21-24 October 2015.


COMMUNICATIONS AT CONFERENCES


Ruiz A, Jiménez E, Peña R, Goulder P, Clotet B, Prado J. CD8 sensing relies on nanomolar levels of antigen presented upon HIV-reactivation. 7th International Workshop on HIV Persistence during Therapy. 8-11 December 2015, Miami USA.


Salgado M, Gálvez C, Dalmau J, Carrillo J, Urrea V, Clotet B, Blanco J, Martinez-Picado J. Low Viral Reservoir Treated patients (LoViReT): clinical predictors of low HIV-1 DNA. 7th International Workshop on HIV Persistence during Therapy. 8-11 December 2015, Miami, USA.
STUDIES

Internal studies 2015

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

In 2015, the Foundation has conducted the following studies:

Clinical Trials

OSTEODOLU: 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.

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

DTG_HD: 2015-000856-16, NCT02487706
Exploratory study to evaluate the withdrawal of Dolutegravir for hemodialysis in HIV-infected patients with terminal chronic renal insufficiency.

RALATOR: 2015-002682-30, NCT02577042
Study of the effect of Atorvastatina to reduce inflammation related to aging in HIV-infected patients over 60 receiving treatment with protease inhibitors, in comparison with one based on Raltegravir.

DOLAM: 2015-000274-35
Open clinical trial, randomized and controlled, to evaluate the safety, tolerability and efficacy of two simplified strategies with Dolutegravir in HIV-infected patients with sustained viral suppression.

Observational Studies

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

COHORT VPH HOMES: 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.

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

LATE PROGRESSORS
Characterization of immunological, genetic and viral factors that determine loss of control of the viral in the slow-progressor population (LTNP).

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.

ARBRE: FLS-ANT-2015-01
Prospective observational exploratory study to evaluate the impact of the latest antiretroviral therapy on cerebral functioning.
OVER-60
Aging of the HIV-infected population. Cohort study of HIV-infected patients over 60.

INSTINCT: FLS-INI-2014-01
Use and efficacy of Integrasa inhibitors in Spain (INSTINCT)

Monitored Studies by FLS with an external promoter:
The CRO of FLS has monitored 12 studies in other areas. For example, neurology, cardiology, hepatopathy... (Unspecified due to confidentiality).

External studies:
In 2015, the HIV Unit and the Foundation have participated in 40 external studies with external promoters (unspecified due to confidentiality).
These studies include all phases of clinical trials, observational and cohort studies.