

The TRT-5 group:

lessons learned over fifteen years of representing PLWHA in research

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The TRT-5 Group: why?

In 1992, for the AIDS fight associations which are confronted with the climax of the epidemic crisis, the only hope lies in the discovery of the effective treatments. The expectations of the managers of these associations are focused on researchers, pharmaceutical laboratories and clinicians. Pragmatically, these representatives responded to many associations' requests through collective gatherings. New meeting areas were subsequently created where association representatives objectively recognized themselves in the same side. Trying, to take the best advantage of this opportunity, they decided to meet again, join forces, discuss and set out common fronts. Progressively, the repetition of these meetings became a habit. Finally, in order to identify this new inter associative group, a suitable name had to confirm this union. The name was «TRT-5 » Traitement et Recherche Therapeutique (Therapeutic Research Treatment), the number 5 refers to the number of the associations that are involved: Actions Traitements, Act Up-Paris, Aides, Arcat-sida et Vaincre le Sida).

The TRT-5 Group: how?

Then, some rules had to be established. The start of this sharing won't be so simple: It was crucial to make a fresh start with new bases, forgetting the rivalry that has divided, at one time or another, these associations that are different and complementary. To establish these rules, it was decided that the TRT-5 will be an informal work group dealing with only medical issues, where decisions are taken under consensus mode. Later on, this scientific link will turn out to be one of the few sound bridges in the associative world of the AIDS. It's the conflicts that will make the group united. As soon as it is formed, the TRT-5 faces pharmaceutical industry for an early access on molecules, during the development of medications. When making strong contacts with laboratories through regularly meetings, the TRT-5 supports the compassionate access to many new molecules that are set out during scientific markets in the early 90s: d4T, 3TC, later on the protease inhibitors. At every time, it was a success. France seems to benefit from this receiving medications, first and foremost, in comparison with other European countries.

The TRT-5 Group: partners

In the same time, the TRT-5 becomes a reckoned partner with different authorities: National Agency for research against AIDS and viral hepatitis (ANRS), French Medecines Regulatory Agency (AFSSaPS) as well as the EMEA (European Medicines Agency), le Conseil National du Sida (National AIDS Council), le Ministère de la Santé (French Ministry of Health), and ethical Committees for biomedical research. The discovery and the coming of the protease inhibitors, in 1997, will be at the peak of this expert and pressure work to attain the antiretrovirals. With time, new spokespersons appeared: la Haute Autorité en Santé (The High Commission for Health) and l'Assurance Maladie (National Health Insurance).

TRT-5 facing institutional partners



The TRT-5 Group: 15 years

During all these years, the TRT-5 will always care about the patients' points of view, which we represent to the public authorities, the agencies and the industry. Each voice, each moan, each hope is being expressed through us. It's the role of intermediary that allowed the TRT-5 and the associations to fight against AIDS, trying to improve the situation of the patient towards science. Today, the TRT-5 gathers eight associations. Others were added to the founders: Dessine Moi Un Mouton, Nova Dona, Sida Info Service and SolEnSi. It's a united group where internal crisis are solved in order to create an unquestionable feeling of friendship.

Our Values: Yesterday and Today

- To represent the voice of patients
- Supremacy of the interest of people over the interest of science (Declaration of Helsinki, World Medical Association)
- Global view of the VIH/AIDS care
- No judgement, no discrimination
- Confidentiality
- Evidence-based medicine
- Enhancement of benefit / risk balance
- Real access to solutions

Patients facing science: ethical goals

Two objectives:

- * to promote the needs of PLHAs and advocate on their behalf in the areas of clinical research, standard of care, governmental institutions and the pharmaceutical industry.
- * to facilitate the dissemination amongst PLHAs of accurate and up to date information on treatments and clinical research results through its network and the organisation of a yearly symposium that focuses on a single high priority issue.



Main missions:

- * Access to new treatment strategies for people whose treatment is failing
- * Recognition and acknowledgement of specific care needs related to short/ long term adverse events/toxicities
- * Analysis and ethical monitoring of public or industry promoted clinical research protocols
- * Participation in the drafting of new French guidelines on HIV standard of care

French guidelines on HIV standard of care

Prise en charge médicale

des personnes

par le VIH

A constantly ethical vigilance

The needs of treatments/the needs of testing

- The needs of research that are not enough covered
 - Co-infections (quality of life, social science)
- The needs of populations: women, migrants
- New strategies

The testing profiles (opportunity, objectives, inclusion, procedure, treatment access: Switch and « after test ».

The rights: Agreement, security, information returning (issues

The work of TRT-5

- the representation in the National Agency for research against AIDS and viral hepatitis (ANRS)
- * Scientific Council
- * Working groups to promote new studies ("Actions coordonnées") on cohorts (AC7), clinical trials on HIV infection (AC5), viral hepatitis (AC24), HIV-viral hepatitis coinfections, clinical trials in the developing countries (AC26, CSS6), vaccine research (AC28)
- * Data safety monitoring boards (DSMB) of the ANRS promoted trials
- * Working group on the quality of information documents and consent forms in the trials

• the representation of TRT-5 in the Health system

Participation in the drafting of new French guidelines on HIV standard of care, every two years since 1992

In the Ministry of Health, input on setting up of new regional coordination frameworks (COREVIH, Regional Coordination Centres promoting the fight against HIV infection, replacing the former CISIH)

Cooperation with the Ministry of Health and the National Health Insurance (CNAM-TS) on standard of care delivery for the long term sick and disabled in the context of health care provision reform

cooperation with Afssaps (French medecines regulatory agency) on a project about side effects reported by patients, with a view to promote a better understanding of licensed drugs' risk-benefit balance,

• the representation of TRT-5 in Sidaction, a private fundraiser

Participating to the medical and scientific Committee, which selects the projects to be grant

• TRT-5 working with the pharmaceutical industry

Participating some scientific committees and some Data safety monitoring boards of their clinical trials



TRT-5 facing pharmaceutical industry

Fulfilled work

The group also gained recognition that permitted it to take respected public positions on essential therapeutic questions, research issues, and the development of French legislation on biomedical research and to be part of the French experts group for recommendations on HIV infection.

The stands taken on these issues contributed to the evolution of research in France. The success of our work helped PLWHA, either as a result of the decisions produced by our group's actions, or as a result of the intervention of member organizations.

Challenges

To know how to keep the position of the representative of PVVIH, it's to know the right place towards the spokespersons between the patients'expert and the scientific one.

To face the evolution of the epidemic context in France: Complexification of the research and knowledge, mobilisation of fewer and fewer active members. Worldwide spread of research: Protection of the patients versus competitiveness of the French research

Perspectives

Turn our victories into lasting solutions; strengthening the rights for all people, for the future and for the active strength. To share our experience with others:

Related to the research in the developing countries from the ANRS, to develop a partnership and mutual exchanges To be a model for other working groups of French organizations To gain and to provide perspective on a mode of collaborative work between medical professionals and patients.

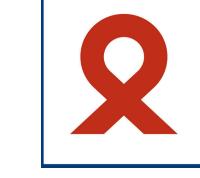
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TRT-5 (Traitements & Recherche Thérapeutique 5) is a coalition of eight French HIV/AIDS organisations, both community-based and services, working on access to best standard of care and on HIV & Aids clinical researcth: Act Up-Paris, Actions Traitements, AIDES, Arcat, Dessine Moi un Mouton, Nova Dona, Sida Info Service and Sol en Si. TRT-5 was founded in 1992 by five HIV/AIDS organisations in the context of a medical and treatment emergency situation for people with HIV and AIDS. Its objectives are to promote the needs of PLHAs and advocate on their behalf in the areas of clinical research, standard of care, governmental institutions and the pharmaceutical industry, and to facilitate the dissemination amongst PLHAs of accurate and up to date information on treatments and clinical research results through its network and the organisation of a yearly symposium that focuses on a single high



