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FRANÇAISE

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Égalité
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MALADIES INFECTIEUSES
ÉMERGENTES **Inserm**

ACTIVITY REPORT

2022

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EDITORIAL

4

As in the previous year, 2022 was severely marked by the COVID-19 pandemic with, at the beginning of the year, the Omicron wave, the continued state of emergency up to 31 July, and the need to provide therapeutic solutions for individuals suffering from long COVID. It is important to acknowledge efforts by research teams to advance knowledge about SARS-CoV-2, COVID-19 prevention, vaccination, treatments, and the impact of this pandemic on populations. We are working with researchers to support their work in order to face existing and future epidemics.

While continuing to strongly support research on HIV/AIDS, viral hepatitis, sexually transmitted infections and tuberculosis, with ambitious objectives and a significant portion of the dedicated budget, we unfortunately had to deal with the emergence of other pathogens and other epidemics, including the mpox epidemic, over the year. The rate of emergence and re-emergence of pathogens is probably, in fact, being accelerated by climate change and adjustments in human activities. A key part of the vision shared by ANRS | Emerging Infectious Diseases is to create a world in which emerging infectious diseases would no longer be a threat: we are thus working to promptly implement actions that will allow us more effectively to prepare for and anticipate the emergence of new pathogens and health crises. In 2022, at the same time, initiatives focused on emerging infectious diseases, and significant funding commitments were made.

For example, throughout the year, the agency worked on defining the priority research programme and equipment strategy on the prevention and control of emerging infectious diseases (PEPR MIE), which is part of the "Emerging Infectious Diseases and Nuclear, Radiological, Biological and Chemical Threats" (MIE-MN) national acceleration strategy supported as part of the France 2030 framework. This was achieved by the launch of the first call for projects at the beginning of 2023.

The agency has also set up a research system to better respond to health crises. As of May 2022, this device had been tested in the context of the outbreak of mpox infections. Declared an "inter-

national public health emergency" by the World Health Organization (WHO) last July, this epidemic led to more than 80,000 cases worldwide in 2022. In order to offer a coordinated and effective response, ANRS | Emerging Infectious Diseases responded very early on by attending an international meeting organised by WHO in June bringing together a group of over 500 experts to review the scope of scientific knowledge and define research priorities. In addition to scientific monitoring shared with public authorities and researchers, a call for projects was launched in mid-June to fund 10 research projects totalling almost three million euros. In addition, through the implementation of large-scale mpox projects (MOSAIC and UNITY studies, described in detail in this report), the agency played a leading role coordinating on an international scale.

In 2022, ANRS | Emerging Infectious Diseases continued its construction and structural development. We continued scientific coordination for HIV and hepatitis, defining research priorities more precisely, and building a community focusing on tuberculosis, notably by bringing together both fundamental research and clinical research. The same work is under way on STIs. We continued to fund research within our scope, with the implementation of eight calls for projects in 2022, compared to four in 2021 and two previously.

Major projects started in 2022 include the agency's strategic orientations for the period 2023-2027. This work made considerable progress last year, thanks to the support of the internationally renowned researcher, Kevin De Cock.

We have undertaken a series of meetings and interviews with the scientific community, partner institutions and representatives of patient associations. This work will be finalised in 2023.

From an organisational point of view, the agency located to PariSanté Campus, in the 15th arrondissement of Paris, in February 2022, as a base for its 110 employees. This site brings together five public operators (Inserm, Université PSL, Inria, Health Data Hub, French Digital Health Agency) and private research and innovation partners, based on a common goal: to bring together their skills and expertise to create a world-class digital health centre.

We are convinced that the agency has a key contribution to make in improving coordination between research stakeholders, in France and in Europe, particularly with regard to regulatory aspects. We recognise that excessive regulatory constraints can hinder the effective and rapid implementation of research. Some flexibility can be achieved while maintaining a high level of patient and data protection. We need to join in a collective effort in order to work with national and European decision-makers in an advisory capacity.

Therefore, as described herein, ANRS | Emerging Infectious Diseases teams are constantly mobilised to continue to build an agency as close as possible to the needs and expectations of researchers and, ultimately, society to meet the challenges of infectious diseases.

Isabelle Richard,
Chair of the Advisory Board
Yazdan Yazdanpanah,
Director

2022 KEY FIGURES

BUDGET



73

million EUR budget
(expenditure), with

81%

of funds executed allocated
to direct research funding

HUMAN RESOURCES



110

FTEs end 2022

CALLS FOR PROJECTS



8

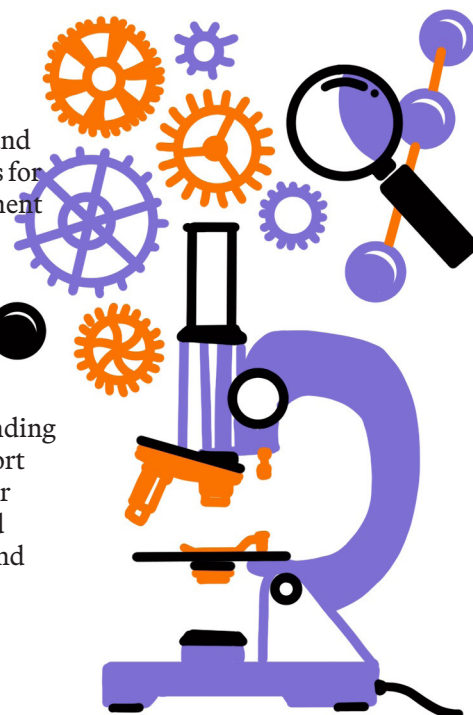
in 2022, including 2 generic
calls for projects (HIV/
AIDS, viral hepatitis, STI
and tuberculosis) and 6 calls
for projects on emerging
infectious diseases

162

new research projects, research grants and
initiation contracts were funded by calls for
projects, representing a direct commitment
to scientific research of

34

EUR
million under the new 2022 financial
commitments, supplemented by the funding
of scientific leadership, structural support
for clinical research – including posts for
clinical or biological study monitors and
the biobank – together with symposia and
publications



CLINICAL AND PUBLIC HEALTH STUDIES



80

studies sponsored by the agency in the follow-up or enrolment phase, including

35

in low- and middle-income countries

A centralised biobank holding

1,700,000

samples

8

methodology and management centres: 6 on a multiannual grant basis and 2 benefiting from other funding arrangements with the agency (including 1 binational French-Côte d'Ivoire study, MEREVA)

90

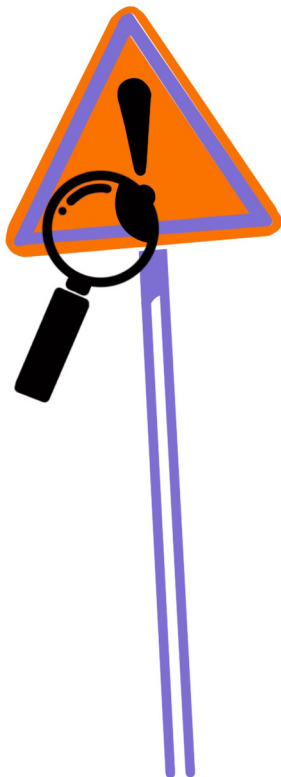
FTE clinical trial monitors (CTM) and biological study monitors (BTM) funded by the agency to support clinical investigation

A network of

300

hospital departments, 40 of which account for 70% of activity

PHARMACOVIGILANCE



145

studies monitored by the pharmacovigilance department in 2022:

59

sponsored by the agency

84

sponsored by Inserm

2

sponsored by European consortia

3,236

serious adverse events assessed in 2022

96

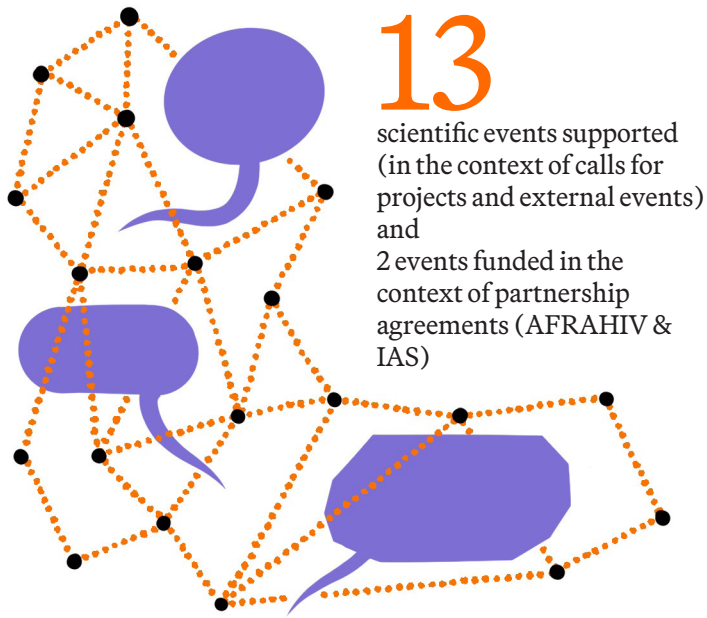
reports in 2022 to the authorities (ANSM or those of the countries involved) and the European Medicines Agency

COHORTS

10

received financial support from the agency at the end of 2022

SCIENTIFIC LEADERSHIP



13

scientific events supported (in the context of calls for projects and external events) and 2 events funded in the context of partnership agreements (AFRAHIV & IAS)

A central event: the agency's Scientific Day Seminars on 15 and 16 March 2022.

38

invited experts

380

participants on site

180

connected

50

tweets

580 likes and

90,000 impressions

22

working groups, task forces, and coordination theme-based groups

300

mailshots sent to the research community and agency staff

7

interviews conducted

INTERNATIONAL NETWORK



8

partner sites (Brazil, Burkina Faso, Cambodia, Cameroon, Côte d'Ivoire, Egypt, Senegal, and Vietnam)

2

international global health research platforms (PRISME): the first created in May 2022, in Guinea, and the second in preparation in the Democratic Republic of the Congo



2

ad hoc partnerships in Mali and the Democratic Republic of the Congo

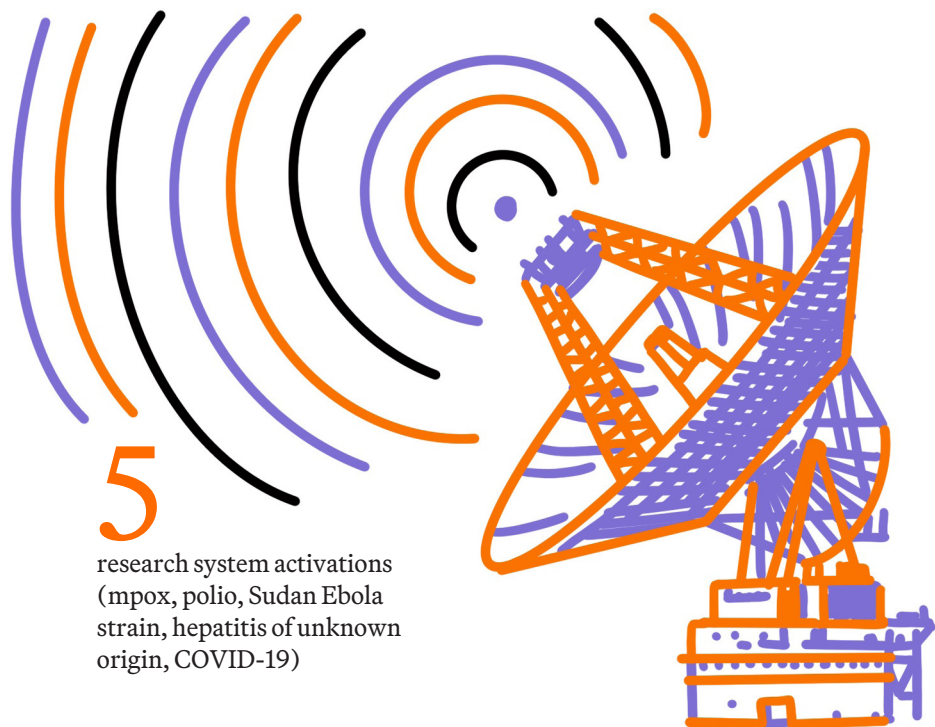
5

international technical experts in 2022 (in Burkina Faso, Cambodia, Cameroon, Senegal, and Vietnam)



8

RESPONSE TO EMERGING DISEASES



5

research system activations
(mpox, polio, Sudan Ebola
strain, hepatitis of unknown
origin, COVID-19)

5

scientific reviews were drafted, distributed
and updated weekly, consulted by

480

readers per week on average

2

consumer articles published
in *The Conversation France*

COMMUNICATION

13

press updates followed by
22 journalists on average

22

press releases and a press kit
sent to the media

141

press
requests sent to the
Communication Department
or to experts related to the
agency

499

media benefits (written
press, web, radio, and
TV) identified as a result
of the actions carried out
by the Communication
Department

4,051

followers on Twitter
(+ 1,051 vs. 2021)

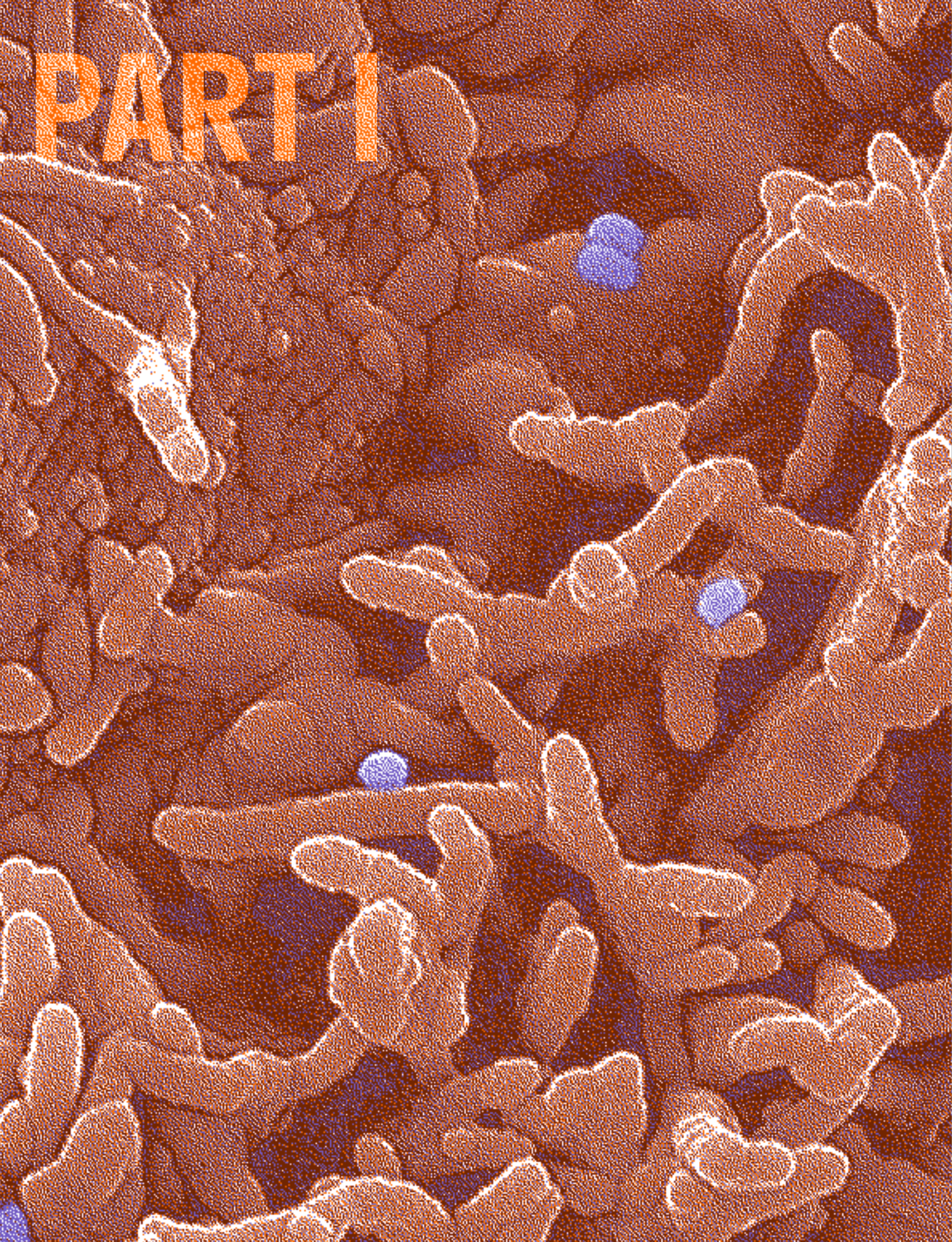
4,822

followers on LinkedIn
(+ 2,822 vs. 2021)

7,809

newsletter subscribers
(+ 609 vs. 2021)

PART I





Strengths of the agency's scientific activity

HIV/AIDS

REMISSION

The **ANRS RHIVIERA** consortium (for *Remission of HIV Infection ERA*) aims to understand the mechanisms governing the establishment of the viral reservoir in order to develop new therapeutic strategies for sustained remission of HIV infection. Coordinated by Asier Sáez-Cirión (Institut Pasteur) and Christine Rouzioux (Université Paris Cité), it brings together multidisciplinary teams around collaborative research, from fundamental to clinical aspects, in order to offer patients innovative therapeutic tools aimed for remission, thus allowing them to stop their antiretroviral treatment in the long term, without the risk of viral rebound.

Six publications related to this consortium were published in 2022:

→ **Expansion of Immature Neutrophils During SIV Infection Is Associated With Their Capacity to Modulate T-Cell Function**, Lemaitre J. et al. *Front Immunol*, 2022 Feb 3

→ **Reprogramming dysfunctional CD8+ T cells to promote properties associated with natural HIV control**. Perdomo-Celis F. et al. *J Clin Invest* 2022



HIV controllers are rare patients who are able to control HIV naturally, without treatment. In these individuals, CD8+ T immune cells play a central role in durably maintaining viral load at the lowest level, despite the absence of antiretroviral therapy. By deciphering the control mechanisms in these patients, the researchers were able to reprogram CD8+ T cells from non-controllers by giving them the controller type properties. Cell reprogramming was performed in vitro via transient exposure to a molecule that targets signalling pathways identified as active within controller cells.

These results provide proof of concept of effective cell therapy to achieve remission of HIV infection.

→ **Transient viral exposure drives functionally-coordinated humoral immune responses in HIV-1 post-treatment controllers**, Molinos-Albert LM. et al. *Nature Communications* 13, 1944 (2022).



Other individuals with HIV-1, called "post-treatment controllers" or PTC, are able to control the infection after discontinuation of antiretroviral therapy. This study showed that the humoral immune response of PTCs was both effective and robust, which could contribute to the control of infection in the absence of treatment.

→ **Novel role of UHRF1 in the epigenetic repression of the latent HIV-1**. Verdikt V. et al. *eBioMedicine*, vol. 79, 2022

→ **Isotopic Radiolabeling of the Antiretroviral Drug [18F]Dolutegravir for Pharmacokinetic PET Imaging**. Tisseraud M. et al. *Pharmaceuticals (Basel)* 2022 May

→ **Prolonged Antiretroviral Treatment Induces Adipose Tissue Remodelling Associated with Mild Inflammation in SIV-Infected Macaques**. Mausoléo A. et al. *Cells* 2022

Two clinical studies, ANRS 175 RHIVIERA 01 and ANRS 176 RHIVIERA 02 obtained regulatory authorisations in 2021 and 2022. The ANRS 175 RHIVIERA 01 trial will focus on people whose treatment was initiated early and who have a specific genotype profile associated with remission - profile studied in the **ANRS iVISCANTI** study. The ANRS 176 RHIVIERA 02 trial, conducted in collaboration with Rockefeller University in New York, will test the impact on HIV-1 control, after interruption of treatment, of two broad-spectrum neutralising antibodies, in combination with antiretroviral treatment in individuals screened during the primary infection phase.

In addition, in 2022, the RHIVIERA consortium launched a series of bimonthly webinars

12

discussing the results and prospects of the projects. RHIVIERA also created a dedicated website (rhiviera.com) and a Twitter account ([@ANRS_Rhiviera](https://twitter.com/ANRS_Rhiviera)) in April.

Another study sponsored and funded by the agency, **SYNACTHIV**, is looking at optimising the "shock" phase of the "shock and kill" strategy. The goal is to make HIV-infected dormant cells visible to the immune system by reactivating them to promote their elimination. By reducing the viral reservoir to a sufficiently low level, effective infection control after treatment interruption may be possible. The ANRS SYNACTHIV open-label phase I clinical trial is assessing the safety and tolerability of a combination of two HIV-1 inducers (decitabine and romidepsin) in HIV-1 (subtype B) infected patients treated with a combination of antiretroviral drugs with undetectable plasma HIV RNA. This is the first time these two inducers have been given together in patients living with HIV. The new administration procedures of the two HIV-1 inducers tested in different sequences will be assessed clinically and by blood samples after each procedure. The trial, which takes place in France and Belgium, enrolled its first patient in December 2022. A total of 15 patients are expected.

TREATMENTS

Among the avenues explored to improve the safety of antiretroviral treatments in people living with HIV and to reduce costs, the **ANRS QUAT-UOR** project showed the non-inferiority of taking the treatment four days a week compared to daily intake, as a maintenance regimen after 48 weeks of follow-up in 636 patients. This is the first randomised study to assess this strategy. The first article on this study was published in February 2022 in *The Lancet HIV*.

PREVENTION AND VULNERABLE POPULATIONS

The **ANRS PREVENIR** study, conducted in partnership with charities and which lasted three years, published its results in June in *The Lancet HIV*: they confirm that oral pre-exposure prophylaxis (PrEP) with tenofovir disoproxil and emtricitabine on demand is as effective and safe as daily PrEP in HIV prevention. Among the 3,056 study volunteers, all at high risk of infection, the incidence of HIV with PrEP was low (1.1 cases per 1,000 person-years of follow-up) and did not differ between the daily and on-demand PrEP groups.

Based on the perception of PrEP, the **OMaPrEP** research project focused on missed opportunities for PrEP use among 168 individuals recently infected with HIV (less than six months ago) who were eligible for PrEP. Of these, only 26% received information on PrEP in the previous year, and 5% used it. The two most common reasons mentioned by participants who were familiar with PrEP but did not want to use it were fear of side effects and low perception of the risk of HIV infection. The analysis of participants' responses shows that there are two failings in the PrEP access pathway: insufficient provision of information on PrEP by healthcare professionals (mainly general practitioners) and poor acceptability of PrEP by informed and eligible patients. These results were published in *HIV Medicine* in August.

Regarding people born abroad and living in Île-de-France, two studies have provided new data:

📌 In 2022, the [ANRS MAKASI study](#) ended. This is an interventional research that aims to strengthen the potential for sexual health action among immigrants from sub-Saharan Africa living in Île-de-France, with two charities, namely Africa Avenir and ARCAT. A truck visited busy areas frequented by the sub-Saharan African community and offered HIV and hepatitis testing. At the same time as the routine screening offered, a personalised motivational interview was offered to immigrants identified as precarious and exposed to sexual risks, with a health mediator who helped participants prioritise their needs, followed by active referral to organisations suited to the needs expressed by the participants. A total of 849 individuals benefited from this action. Articles are expected to be published in scientific journals, together with a book on this project in 2023, as part of the ANRS Social Sciences and AIDS collection | Emerging Infectious Diseases.

📌 The preliminary results of the [ANRS GAN-YMEDE](#) study were presented at the conference of the French Society for the Prevention and Treatment of AIDS in November. This study focuses on the acquisition of HIV and the lifestyles of men who have sex with men (MSM) born abroad and followed up in Île-de-France. A questionnaire was completed by 840 participants for this purpose. The results showed that 35% had left their country for reasons related to sexual orientation, and 54% felt forced to leave their country of birth. A total of 48% per cent of participants acquired HIV after migration. Among the main findings, the survey found that 21% of participants were forced to perform sexual acts, 15% never talked about their HIV infection, and 18% gave up medical care that was considered important. The remainder of the study will involve estimating the proportions of post-migration HIV acquisition and linking them to identified vulnerability factors.

On an international scale, the [ANRS CohMSM-PrEP](#) study [published its results in *AIDS and Be-*](#)

[havior in April](#), focusing on factors possibly limiting the efficacy of PrEP among 520 men who have sex with men in West Africa (Burkina Faso, Côte d'Ivoire, Mali, and Togo). The barriers identified by the researchers include financial difficulties, difficulty using PrEP, concealing sexual orientation, high alcohol consumption, and also not being part of a community association or having a stable male partner. These results should be taken into account in order to effectively incorporate PrEP into national HIV prevention programmes in West Africa.

The DRIVE-COVID survey, published at the end of January in [Harm Reduction Journal](#) and in December in the [International Journal of Drug Policy](#), the quantitative component of which was presented at CROI2022, demonstrates the impact of the first wave of COVID-19 on the daily life of injecting drug users (PWIDs) in Haiphong, a city in Vietnam where there is a high prevalence of drug use and HIV in this population. Researchers observed that risky injection practices, already uncommon, continued to decrease in PWIDs in Haiphong thanks to a high level of awareness of the risks of HIV and HCV infection associated with injection and also due to the prescription of methadone treatment. The research team noted that care services for PWIDs were maintained during the COVID-19 crisis. No increase in the number of cases of HIV or HCV infection was observed. Social distancing measures taken to curb the pandemic – including the various lockdowns – nonetheless contributed to exacerbating the social situation of the most vulnerable, including PWIDs and female sex workers. Indeed, these women report having been compelled by their precarious financial situation to have more unsafe sex during these periods of restrictions, increasing their risk of contracting HIV and HCV.

In the psychiatric component, disorders are very common among people who inject drugs and are associated with delayed access to care, less efficiency in terms of patient management, and an increased risk of practices at risk for HIV and HCV. Two studies were set up in Haiphong. The first, DRIVE MIND I, initiated in March 2019, aimed

to demonstrate the feasibility of setting up a community psychiatric intervention with PWIDs suffering from psychiatric disorders (depression, psychotic syndrome, suicidal risk). The DRIVE MIND II study, for which inclusions began in March, is extending follow-up for DRIVE MIND I participants by a year, and will include 200 patients receiving psychiatric intervention and 400 PWIDs without psychiatric disorders (half of whom live with HIV). The objective is to show that management can reduce the risk of infection (HIV and HCV) in subjects with psychiatric disorders to the same degree as those without psychiatric disorders. It also involves demonstrating the feasibility of leading a long-term community support-based psychiatric intervention in this population, together with the medium- and long-term future of patients with psychiatric disorders induced by methamphetamines.

VACCINE RESEARCH

The Vaccine Research Institute (VRI), the laboratory of excellence supported by ANRS | Emerging Infectious Diseases and Université Paris-Est Créteil (UPEC), and the agency are currently involved in two phase I HIV/AIDS vaccine trials:

⚡ ANRS VRI06: in this trial, the vaccine candidate, CD40.HIVRI.Env, is a protein vaccine (HIV envelope protein) that is coupled with an antibody that allows the vaccine to target key immune system cells, dendritic cells. This new platform has been developed by the VRI over several years. This vaccine candidate is administered alone or in combination with another vaccine in development (but has already been used in many volunteers), DNA-HIV-PT123 (a DNA vaccine). Enrolment of the 72 healthy volunteers required for the trial in France, and Switzerland ended in October 2022. Initial results show that the vaccine is safe and induces an early, strong, and durable immune response, and an initial presentation of these results was made at CROI 2023.

⚡ EHVA P01/ANRS VRI08 trial: this trial is conducted as part of the European HIV Vaccine Alliance (EHVA) consortium, a project funded by the European Union (Horizon 2020 programme) and the Swiss government, and is sponsored by ANRS | Emerging Infectious Diseases. It relies on the use of a vaccine candidate based on another technology, such as DNA vaccine using the DREP platform. The vaccine, known as "DREP-HIV-PT1", allows the expression of the HIV Gp140 envelope protein, and is liable to trigger strong and lasting immune responses against this protein. The first part of Phase I, which began in August in the UK, assesses the safety of the vaccine: the vaccine candidate was injected into 10 healthy volunteers aged 18 to 55 years, at a dose of 0.2 mg or 1 mg. As the vaccine was well tolerated (as the initial results seem to show), the second part began in 2023. It is taking place in France and Switzerland and measures the immune response induced by the vaccine and its duration, while comparing them with those induced by DNA-HIV-PT123. Both vaccines will be combined with another protein vaccine that is also being assessed in other clinical trials, namely CN54-gp140. Sixty volunteers will be enrolled to participate in this second part.

VIRAL HEPATITIS

FUNDAMENTAL RESEARCH

Published in [Nature in May](#), a study characterised a crucial protein in liver cells. The "NTCP" protein is the entry door for bile salts, but also for certain hepatitis viruses. These results reveal the 3D structure of NTCP and that of the two forms it can adopt: the first where the protein opens a wide entry path for bile salts, to which hepatitis B (HBV) and hepatitis D (HDV) viruses can bind, and a second which is "closed", folded back onto itself, thereby blocking targeting by viruses. The first "open" conformation is original because no other known molecular transporter forms this type of "wide open" pore. The second could guide research into molecules that block HBV and HDV infection. This study was partly supported by the agency.

PREVENTION

The Pacific-West and South-East Asia regions are high endemic areas for chronic hepatitis B. One of the drivers of the epidemic is the mother-to-child transmission (MTCT). In Cambodia, the TA-PROHM project studied an alternative strategy, without immunoglobulins, based on the tools available in the country (rapid testing, antiviral prophylaxis with tenofovir, and vaccination) to prevent this transmission through a prospective phase IV interventional trial with a multicentre open-label arm in five hospitals across the country. [The study published its results in May in *The Lancet Infectious Diseases*](#). In the absence of immunoglobulins, the study reports that, in women with a high viral load of HBV DNA, it is possible to eliminate HBV transmission if tenofovir is initiated at least one month before birth and in combination with vaccination of the child at birth. The study also shows that women treated for less than one month still have a high rate of HBV transmission (8%). The rate of HBV transmission for those not eligible for tenofovir is 1%. Among eligible women, 94% were able to start tenofovir treatment, and early vaccination of children in the birth room within the first two and 24 hours of life was possible for 85% and 95% of them, respectively. Given the good results in terms of screening and antenatal care already obtained in the country for HIV and syphilis, the implementation of the TA-PROHM strategy across the country could enable Cambodia to achieve triple elimination of HIV, syphilis, and HBV by 2030.

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TREATMENTS

In February 2022, a first patient was enrolled in the ANRS HB07 IP-cure-B clinical trial, supported by the agency, as part of the IP-cure-B project. This is a phase II clinical trial in non-cirrhotic patients with negative HBeAg and virologically controlled chronic hepatitis B. The trial aims to propose a change in treatment paradigm with the development of new therapeutic combinations for chronic hepatitis B. It serves to assess whether stopping treatment with nucleoside or nucleotide analogues (NUC) or stopping NUC therapy after administration of selgantolimod (SLGN) may increase the rate of HBsAg reduction relative to standard of care treatment for chronic hepatitis B. Additional exploratory analyses will help to identify whether changes in the liver immune environment are responsible for HBsAg reduction. More broadly, the IP-Cure-B project, funded by the European Union, aims to develop new curative concepts for chronic hepatitis B.

With regard to hepatitis delta (HDV), the ANRS HD EP 01 BuleDelta project, which assesses the efficacy of bulevirtide treatment in HBV/HDV co-infected patients, evolved over the course of the year: the decision was made in 2022 to expand the cohort to all treatments for hepatitis D and to include untreated patients. This will result in an increase in the dedicated budget, and the number of subjects included will go from 400 to 800. This project resulted in four papers and two posters at different conferences in 2022 (AFEF, JFHOD, AASLD, EASL, APASL and Delta Cure).

INTERVENTION

Inspired by the various DRIVE studies conducted in Vietnam, the ICONÉ project, carried out in Montpellier, demonstrated the effectiveness of a community intervention in screening for and treating hepatitis C in people far removed from the care system, drug users. This project has shown that the *Respondent-Driven Sampling* (RDS)-type enrolment technique is very effective and can be used in France. A majority of users not receiving care were able to be treated and cured thanks to the strong involvement of the peers enlisted. Hence, enlisting peers for the enrolment and healthcare support of users is an effective measure. This could be considered a proof of concept study in order to be implemented on a larger scale in France. This project ended in 2022 and led to [an article being published in *Open Forum Infectious Diseases* in April 2022](#). This project will be followed up in five other French cities.

CROSS-SECTIONAL RESEARCH HIV/AIDS, VIRAL HEPATITIS AND STIS

TUBERCULOSIS

TREATMENTS

18

The Minister of Solidarity and Health has tasked the French National AIDS Council (CNS) and ANRS | Emerging Infectious Diseases with revising the French recommendations for the management of HIV, viral hepatitis, and STIs.

Pierre Delobel (Head of the Infectious and Tropical Diseases Department at Toulouse University Hospital) is responsible for supervising the expert report, and coordinating the recommendations for the management of HIV infection, assisted by Françoise Roudot-Thoraval (Hepatology Department, Hôpital Henri-Mondor, AH-HP, Créteil) with a view to coordinating the recommendations for the management of viral hepatitis, and by Sébastien Fouéré (Genital Disorders and STI Centre, Hôpital Saint-Louis, AP-HP, Paris) with a view to coordinating the recommendations for management of STIs.

These recommendations are conducted under the auspices of the CNS and ANRS | Emerging Infectious Diseases, together with the HAS (French HTA Agency) for the chapters relating to anti-infective, curative and preventive therapeutic aspects. The setting-up of the expert groups was finalised in 2022.

Funded by the EDCTP (European & Developing Countries Clinical Trials Partnership) and sponsored by ANRS | Emerging Infectious Diseases, the ANRS INTENSE-TBM project aims to improve the management of patients with tuberculosis meningitis. Started in 2019, it is expected to end in 2023. The teams included the 100th patient in January 2022. The randomised, multicentre clinical trial is investigating a new therapeutic strategy: the efficacy of an intensified anti-tuberculosis treatment compared with the WHO standard of care and the efficacy of adding aspirin to anti-tuberculosis treatment relative to the absence of aspirin (placebo). It was set up in four countries in sub-Saharan Africa: South Africa, Côte d'Ivoire, Uganda, and Madagascar. The research protocol and [results were published in *Trials* in November 2022.](#)

As tuberculosis is the leading cause of death in people living with HIV, the ANRS DATURA project, co-financed by ANRS | Emerging Infectious Diseases and EDCTP, is an international phase III clinical trial assessing the efficacy and safety of an intensified anti-tuberculosis treatment (with higher doses of rifampicin and isoniazid relative to WHO standard of care and the addition of systemic corticosteroids during the initial phase of treatment) relative to tuberculosis mortality in immunocompromised individuals (inpatient adults and adolescents), and HIV-infected individuals. It is being implemented in six countries in sub-Saharan Africa and South-East Asia: Cambodia, Cameroon, Guinea, Uganda, Vietnam, and Zambia. Patient enrolment began in April 2022, in Guinea.

COVID-19

19

PREVENTION

The ANRS 0166s PRECOVIM prospective cohort study showed, in an [article published in October 2022 in The Journal of Infection](#), the effect of pre-prophylactic administration in severely immunocompromised patients with the combination of tixagevimab/cilgavimab (Evusheld®) on different SARS-CoV-2 variants. The serum neutralising activity of immunocompromised patients one month after administration of Evusheld® 300 mg (150 and 150 mg) indicates very low activity against the BA.1 and BA.5 variant, partially recovered against BA.2, and a complete absence of neutralisation on BQ.1.1 after administration of Evusheld® 600 mg (300 and 300 mg).

[article published in April in The Journal of Infection](#), the research team showed that sotrovimab effectively protects patients infected with a mild to moderate form of Omicron BA.1 against progression to a severe form. However, sotrovimab does not appear to protect patients who have been infected with BA.2.

VACCINES

The ANRS 0001s COV-POPART cohort was launched in March 2021 to assess the immune response induced by COVID-19 vaccines in various groups of subjects followed up for a disease of interest (solid cancer, solid organ transplant, allogeneic haematopoietic stem cell transplant, obesity, diabetes, multiple sclerosis, hypogammaglobulinaemia, chronic kidney disease, HIV, autoimmune diseases, chronic inflammatory rheumatism), relative to healthy subjects ("control" groups).

Some results showed that a booster dose before six months in participants having received two doses initially increases the humoral response to vaccination in almost all subpopulations, but that the effect of the booster in participants who received three doses in their initial vaccine regimen is more mixed.

In addition, in a poster presented at the international CROI 2022 conference, the team of researchers showed that people living with HIV have a high response rate to COVID-19 vaccination, although slightly lower than the control group and dependent on the stage of the disease. Lastly, a paediatric component for children and adolescents aged 5 to 17 years was initiated in February 2022.

Another study, the COVIBOOST trial, conducted within the COVIREIVAC platform, aims to measure and compare the immune response induced by two recombinant protein vaccine candidates developed by Sanofi and GSK, and that of a third dose of the Pfizer-BioNTech mRNA vaccine (Comirnaty®) in participants previous-

TREATMENTS

The multi-institutional pre-clinical study group (GEPC) has assessed more than 30 molecules *in vitro* or *in vivo* since 2020 with a view to treating or preventing COVID-19. During 2022, GEPC expanded its scope to emerging pathogens other than SARS-CoV-2.

This group is associated with several scientific articles, including the following:

✚ The research on hydroxychloroquine and azithromycin, [published in January in Antiviral Research](#), confirms that these two molecules, alone or in combination, do not block *ex vivo* replication of SARS-CoV-2 in human bronchial airway epithelium and do not show antiviral activity in a Syrian hamster model.

✚ Another study published [in August 2022 in Nature Communications](#) assessed the effects of the drug favipiravir on the Zika virus and the SARS-CoV-2 virus in cynomolgus monkeys, which is the reference animal model. The researchers showed that the molecule has antiviral activity against Zika virus. On the other hand, it has no effect on SARS-CoV-2 in this model and could even exacerbate the disease.

The prospective ANRS COCOPREV cohort includes adult patients infected with SARS-CoV-2 at high risk of progression to a severe form, receiving treatment as part of a cohort ATU. [In an](#)

ly vaccinated with two doses of Comirnaty®. The initial results in terms of reactogenicity and immune response induced by the three different vaccines 15 days and 28 days after their injection were analysed and were the subject of [a letter published in the New England Journal of Medicine in June](#). The three booster vaccines amplify the immune response. However, a stronger response is produced by the Sanofi/GSK vaccine candidate based on beta variant, the original strain of the virus, and the various variants of SARS-CoV-2 tested, including the Omicron BA.1 variant. The safety profiles were similar for all three vaccines. Persistence of immune response induced by the three booster vaccines will be assessed at 3, 6, and 12 months.

The development of the nasally administered protein vaccine candidate, led by the BioMAP research team at the "Infectious Diseases and Public Health" Joint Research Unit (Inrae/Université de Tours), supported by the Ministry of Higher Education for Research and supported by the agency, led to the creation of a French start-up, LoValTech, in January, awarded the Deeptech label by BPI France, holding the exclusive worldwide license for use of the vaccine patent. Its objective is to manage the project from the development phases of vaccine formulation to clinical trials in humans, which will be sponsored by ANRS | Emerging Infectious Diseases and Tours University Hospital. The pre-clinical results obtained with the delta variant in winter 2021 demonstrated the robustness of the concept of this vaccine blocking the contagiousness with SARS-CoV-2.

A social science project entitled "Impact of COVID-19 on vaccination in France" (ICOVAC France) was supported as part of CAPNET (see page 49). It aims to monitor and document, in the coming years, vaccination challenges surrounding COVID-19, and to study the impact of this crisis on attitudes and behaviours towards vaccination in general and other existing or future vaccines. This research is structured around four themes:

- 1 vaccine challenges in the general population (using specific surveys, longitudinal interviews, experience of perceived side effects of COVID-19 vaccines, analysis of adverse event reports collected by the ANSM);
- 2 uptake and public debates on vaccination (with ethnography in terms of uptake and analysis of discussions on Twitter and in general media);
- 3 focus on healthcare professionals (with interviews with general practitioners, community and hospital nurses, paediatricians, etc.);
- 4 the organisation, leadership, and value-creation associated with research in the field of human and social sciences on vaccine challenges.

GENOMIC MONITORING

The EMERGEN consortium, coordinated by ANRS | Emerging Infectious Diseases and Santé publique France, has set up active surveillance of the emergence and circulation of SARS-CoV-2 variants in France, accompanied by research programmes. The work of this consortium gave rise to several publications in 2022:

✚ The beneficial effects of a so-called "reactive" vaccination strategy, in which vaccination is proposed to the infected person's family circle, could have beneficial effects, reducing the number of COVID-19 cases in certain epidemic situations. [These results were published in Nature Communications in March.](#)

✚ The SEVARVIR project investigated the clinical and virological characteristics associated with the severity of Omicron infection in patients hospitalised in critical care or intensive care departments, compared to infection with the delta variant, the results of which were [published in the journal Nature Communications in October 2022](#). They showed that the clinical phenotype of COVID-19 patients hospitalised in critical care or intensive care differed according to the variant: patients infected with the Omicron variant had a higher tendency to be vaccinated but more immunocompromised than those infected with the delta variant. 28-day mortality was not different between the two groups.

ARBOVIRUSES

Arbo-France is a French arbovirus study network designed to facilitate the preparation and response to epidemics of human and animal arboviruses in mainland France and overseas territories. This network is under the aegis of the agency. The network has developed a strategy with five main objectives:

- ✚ provide an alert function to ANRS | Emerging Infectious Diseases with a view to preparing, engaging, and mobilising arbovirology research in the event of an epidemic;
- ✚ contribute to scientific excellence by expanding the interactions between the research teams and encouraging participation in calls for projects;
- ✚ strengthen the integration and structuring of arbovirology projects, particularly in overseas territories;
- ✚ contribute to the preparation of a response plan for French research in arbovirology;
- ✚ actively integrate human and social sciences into research projects.

ZIKA

A GEPC study, [published in August 2022 in Nature Communications](#), demonstrated a potential benefit of favipiravir against Zika virus in cynomolgus monkeys (see page 9).

MPOX

TREATMENTS

Simian smallpox, an endemic disease in West and Central Africa, was the subject of human-to-human transmission in numerous countries around the world, including in France at the beginning of May. Following the appearance of these first cases, ANRS | Emerging Infectious Diseases, in conjunction with the Ministry of Higher Education and Research and the Ministry of Health and Prevention, set up an emergency research programme. Two major international studies have been deployed in this context:

🏢 ANRS MOSAIC, an international cohort of people infected with mpox, in collaboration with the Oxford University, Geneva University Hospitals, and ANRS | Emerging Infectious Diseases for Europe, was elected to the European MPX-RESPONSE funding. This is being conducted in several European countries (Belgium, Spain, France, Italy, the Netherlands, United Kingdom, and Switzerland). This project aims to shed light on the disease and assess the impact of the management of patients infected with the mpox virus. The first patients were included in France on 13 July 2022 and a total of 129 patients were able to be enrolled prospectively in three countries (UK, Switzerland and France). However, the study could not reach the desired size due to a rapid drop in cases between the peak in June and September, and also due to administrative difficulties and regulatory deadlines. [A publication, accepted at the end of 2022 in Virology](#), is already learning from this trial, showing that innovative multi-country governance for clinical research taking place in an international public health emergency remains a challenge, requiring international regulatory harmonisation and simplification of administrative and legal requirements, together with an improvement in the clinical trial approval process. The MOSAIC study will be amended in 2023 to accept retrospective inclusions.

A sub-study of this cohort was accepted for the call for projects on mpox launched in June: the MOVIDA project, the aim of which is to obtain additional information on the induced immunological response.

🏢 The UNITY international clinical trial is a multi-country adaptive phase III trial assessing

the safety and efficacy of tecovirimat in the treatment of mpox disease, coordinated by ANRS | Emerging Infectious Diseases on an international scale. Geneva University Hospitals and Fiocruz, Brazil, are jointly sponsoring the trial. The study will be expanded in 2023 to other countries reporting cases of mpox, notably in Latin America. Shortly after an epidemic was declared by WHO, ANRS | Emerging Infectious Diseases, the National Institute for Biomedical Research (INRB) in the Democratic Republic of the Congo, and US NIAID/NIH, in collaboration with WHO R&D Blueprint for epidemics, organised two consultations in the summer of 2022, bringing together more than 500 experts to develop a common protocol. This "CORE" protocol allows the development of a trial that facilitates the participation, under joint governance, of any country or regional network that wishes to contribute to generating missing data and reducing uncertainties surrounding treatments for mpox. The UNITY trial, together with the European EPOXI study, led by ECRAID, and the African MOSA study, led by the Panther network, are based on an adaptation of this protocol. The three trials are working together very closely, and have a joint DSMB to consider joint analyses. This allows for close international collaboration between three studies covering diverse geographical regions, to accelerate the collection of robust data on the efficacy of tecovirimat that may be administered to patients. These three clinical trials are working together as part of the MPX-RESPONSE project (funded by the European Union Horizon Europe research and innovation programme under grant agreement 101115188), led by Inserm and ANRS | Emerging Infectious Diseases.

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VACCINATION

Following the first cases of mpox in France in May, it was recommended that the vaccine be used as a protective measure as from July for men who have sex with men (MSM) with multiple partners. The ANRS DOXYVAC study, designed to assess interventions to prevent sexually transmitted infections among MSM taking PrEP, was expanded to explore the vaccine impact of the Modified Vaccinia Ankara vaccine (MVA-BN) on the incidence of the mpox virus. Results showing the high level of vaccine protection were presented at CROI 2023. Among the study volunteers, the incidence of infection with the mpox virus was 67.4 per 1,000 person-months between 9 May and 10 July. This fell to 24.4 per 1,000 person-months between 11 July (when the vaccine became available) and 20 September. The research team observed that vaccination alone against the mpox virus in 2022 was associated with a reduction in the risk of developing the disease with 99% efficacy, and the impact of behavioural change was limited in this highly vaccinated population (87%).

The agency also supported the implementation of a cohort of contact persons at risk of mpox infection (MONKEYVAX), sponsored by AP-HP, which aimed to study the efficacy of post-exposure vaccination (MVA-BN vaccine). The first patients were included in France in July 2022. The three MOSAIC, UNITY, and MONKEYVAX studies will shed more light on the natural history of the disease, treatment, and prevention of the mpox virus.

PUBLIC HEALTH AND HSS

Other projects were funded as a result of the call for projects in the field of mpox in June, some of which assessed transmission and public health interventions, modelling of the epidemic or perception of risks, health measures and vaccination, for example. Hence, when the call for projects was launched, the majority of cases in France involved men who have sex with men, with multiple partners in the majority of cases.

Uncertainties remained regarding the modes of transmission of the mpox virus, transmissibility, symptoms, scale, the presence or absence of serious forms in France, and vaccination strategies. In this context, the general objective of the "Monkeypox-HSS: perception of risks, health measures, and vaccination" (MPX - HSS) project is to document, in the real-world context, the health, social and political challenges of the mpox epidemic in France, using social science methods (interviews, observations, and flash questionnaire), at various levels: patient experiences, experiences of healthcare professionals, perspectives of LGBT and AIDS associations, health authority responses and communication strategies, investigating how the risk of mpox is experienced, debated, appropriated and/or challenged. Analyses are currently in progress. A poster will be presented at the AIDS Impact Conference in June 2023, and a Community Forum on the results of the research is scheduled for September 2023, and will allow public health recommendations to be drawn up.

VIRAL HAEMORRHAGIC FEVER

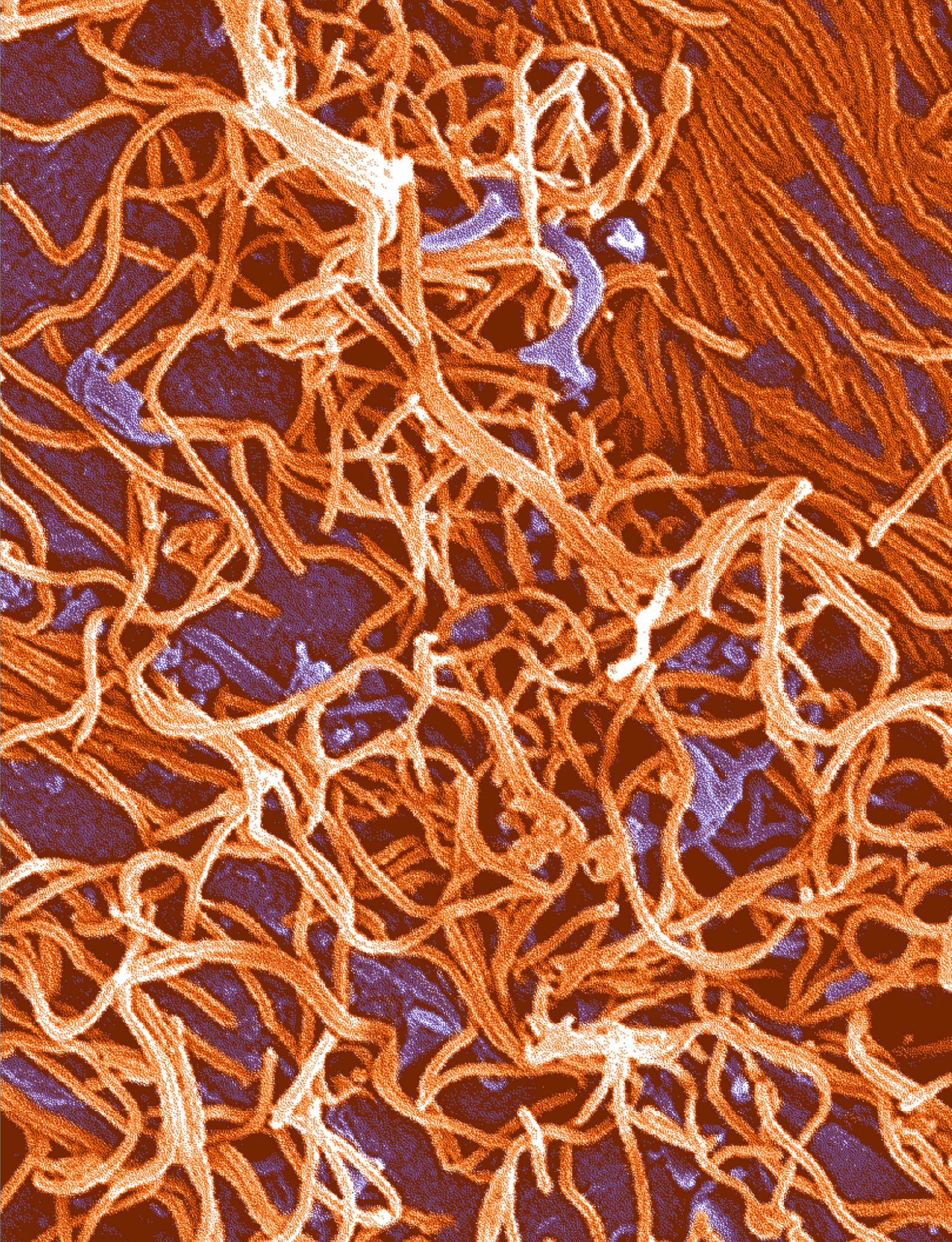
EBOLA

The PREVAC international consortium, bringing together Inserm, the London School of Hygiene & Tropical Medicine, the NIH, health authorities and scientists from Guinea, Liberia, Mali and Sierra Leone, the Alima NGO and pharmaceutical companies Merck, Johnson & Johnson and Bavarian Nordic Companies, was set up in March 2017. The agency funds this consortium and manages the clinical trial work package. The consortium published the results of a large randomised clinical trial [in December in the New England Journal of Medicine](#). These results confirm the safety of three different vaccine regimens, together with the maintenance of the induced immune response at 12 months. The first vaccine regimen tested consisted in injecting a dose of the ZEBOV vaccine followed 56 days later by a dose of MVA-BN-Filo, the second regimen consisted in injecting a dose of rVSVvG-ZEBOV-GP; and, lastly, the third regimen started with a dose of rVSVΔG-ZEBOV-GP with a booster of same vaccine administered 56 days later. These three vaccine regimens led to a rapid increase in the level of antibodies to the virus after 14 days, peaking between one and three months after the first vaccination. While it is not possible to assert that this immune response prevents infection, the scientific literature suggests that there is a strong correlation between these antibody levels and protection against the virus. These antibody levels remain detectable for up to 12 months after the first injection. It is also interesting to note that this vaccine-induced immune response is higher in children than in adults. These data will make it possible to refine the vaccination recommendations during the Ebola epidemic in Zaire, but also between epidemics, in at-risk populations.

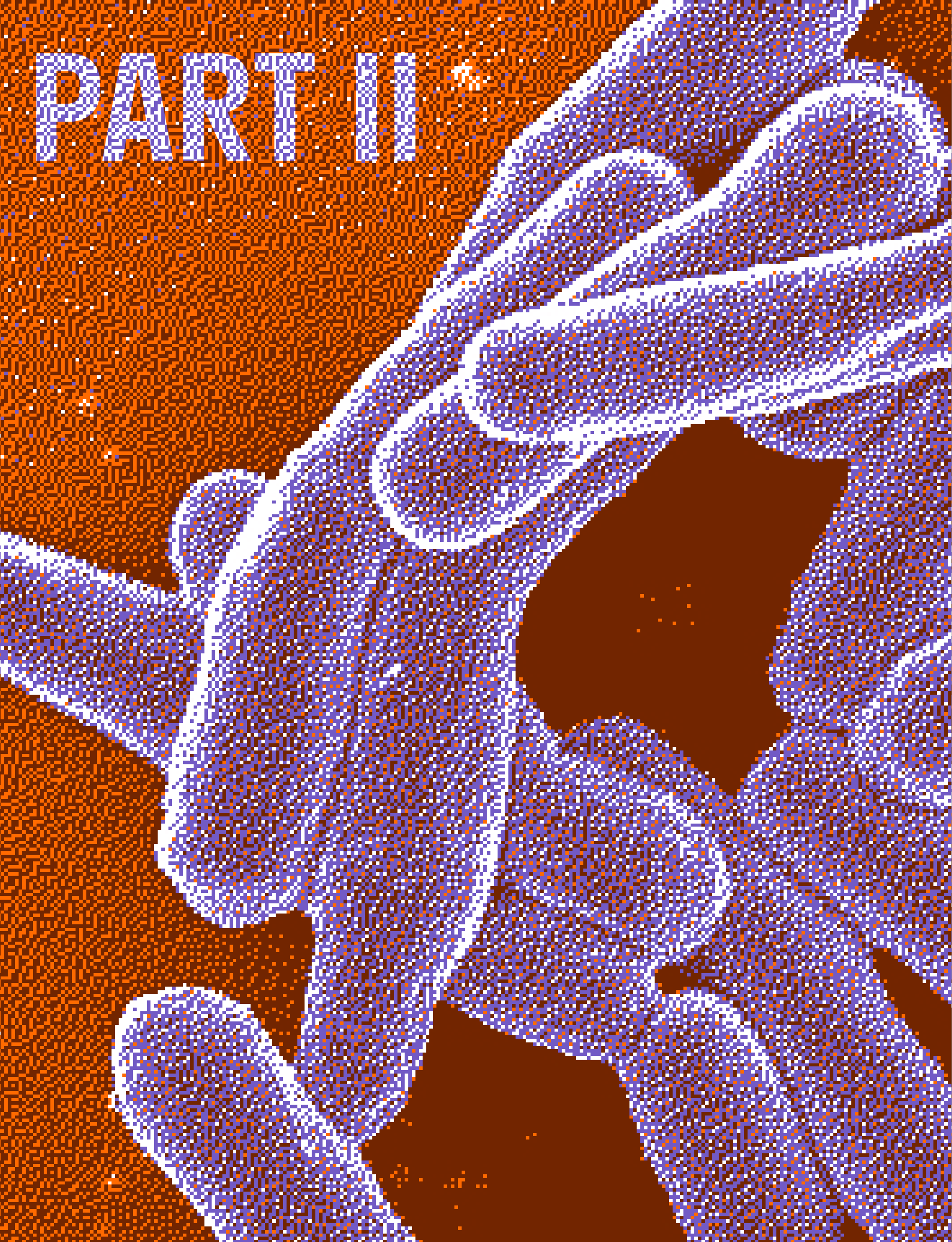
LASSA FEVER

The LASCOPE study, sponsored by the NGO Alima, is the first prospective cohort describing the characteristics, management, prognosis and factors associated with the mortality of patients hospitalised for Lassa fever. It has been taking place in Nigeria since 2018. The objective of the cohort is to reduce morbidity and mortality associated with Lassa fever in the state of Ondo and deepen knowledge of this disease in order to prepare future clinical trials. Approximately 1,000 patients with confirmed Lassa fever were included in the cohort. The LASCOPE programme led to the creation of a P3 class laboratory at the Owo site by the NGO ALIMA to allow patients with Lassa fever to benefit from appropriate laboratory monitoring under safe conditions. In January, the agency continued funding the study with a view to examining more specific scientific questions (cases affecting children, pregnant women, improvement in the management of serious cases, etc.). In addition, a project within LASCOPE, subject to the Emerging Diseases LMIC 2022 call for projects, was selected. It will assess the safety, tolerability, and pharmacokinetics of a new antiviral agent, namely RNA-75039, for the treatment of Lassa fever in West African countries. In addition, LASCOPE is the foundation for other therapeutic trials (SAFARI and INTEGRATE - see page 33) which aim to identify new therapeutic strategies for this pathogen.

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PART II





**Bringing together and
leading communities**

ADAPTATION OF THE LEADERSHIP PROGRAMME TO THE NEW SCOPE OF THE AGENCY IN PROGRESS

Work started in 2021 with the consultation of researchers; the review of scientific leadership bodies continued in 2022, and will continue in 2023. Hence, several new coordination groups (AC) and theme-based working groups were created while others were redesigned.

AC41-AC42 "CURE" CROSS-SECTIONAL GROUP

In July, the HIV and hepatitis B "cure" scientific communities met with the objective of pooling certain technologies, tools or methods to shed light on the reservoir and viral persistence of these two viruses.

AC44

The coordination group dedicated to HIV clinical research was restructured with a strengthening of the North/South partnership and the creation of the AC44/41 cross-sectional groups.

STI COORDINATION GROUP

Discussions were held in 2022 to prepare for the creation of this future coordination group.

TUBERCULOSIS COORDINATION GROUP

Redesigned in 2022, the purpose of this coordination group is to strengthen existing collaborations and networks, particularly with countries in Africa and Asia, which remain the most affected by the disease. Bringing together the fundamental, translational and clinical research communities, it provides a forum for discussion and reflection on the research challenges of tuberculosis infection, and allows for the development of collaborative research projects. It is chaired by Olivier Neyrolles (IPBS, CNRS, Toulouse) and François-Xavier Blanc (Nantes University Hospital), and consists of three cross-sectional working groups covering the physiopathology of the disease (pathogen biology, host immune response, host-pathogen interactions), prevention, diagnosis, treatment, and public health:

- **WG1: Tuberculosis in the mother-child relationship**, coordinated by Olivier Marcy (IRD) and Philippe Van de Perre (Montpellier University Hospital)

- **WG2: Tuberculosis and immunosuppression**, coordinated by François-Xavier Blanc (Nantes University Hospital) and Nathalie De Castro (AP-HP)

- **WG3: New therapeutic and vaccine strategies**, coordinated by Alain Baulard (Institut Pasteur, Lille) and Maryline Bonnet (IRD, Epicentre)

The opening symposium for the TB coordination group, initially scheduled for November 2022, was postponed to January 2023.

"RESPIRATORY VIRAL DISEASE" COORDINATION GROUP

2022 marked the implementation and structuring of this coordination group in order to follow on from the various working groups launched by REACTing and then by ANRS | Emerging Infectious Diseases on COVID-19. Chaired by Karine Lacombe (AP-HP, Sorbonne Université) and Edouard Lhomme (Bordeaux University Hospital, University of Bordeaux), this coordination group provides a scientific leadership and supporting role for innovative clinical research projects in the field of respiratory viral diseases. An initial plenary meeting was held in March.

LONG COVID COORDINATION GROUP

Regular meetings took place during 2022. Chaired by Olivier Robineau (Lille University Hospital), Marc Bardou (Dijon University Hospital) and Henri Partouche (Université Paris Cité), the coordination group started the year with a review of the projects accepted by the first call for projects on long COVID issued by the ANRS | Emerging Infectious Diseases at the end of 2021 and the identification of missing themes to prepare for the 2022 call for projects. The regular meetings provided an opportunity to review the epidemiological, physiopathological, clinical, therapeutic, and management aspects related to long COVID. They led to the development of research projects, several of which were accepted for funding by the agency during the second call for projects. At the end of 2022, a working group focusing on the physiopathology of post-COVID-19 syndrome was created; its purpose was to conduct an analysis of the literature, and draw up a scientific publication in 2023, at the request of the agency.

"HUMAN-TO-HUMAN TRANSMISSION OF RESPIRATORY VIRUSES" COORDINATION GROUP

Chaired by Arnaud Fontanet (Institut Pasteur), this coordination group was redeveloped following the multidisciplinary seminar on the "Transmission of respiratory viral diseases and non-pharmaceutical barrier measures" coordination group held in September 2022. The new coordination group consists of about seventy members and is organised around two working groups:

- WG1: Physiopathology of transmission, coordinated by Arnaud Fontanet and Caroline Goujon (Institut de recherche en infectiologie, Montpellier)
- WG2: Respiratory virus control strategies and interventions, coordinated by Arnaud Fontanet and Jocelyn Raude (EHESP)

The first meetings began in February 2023.

MODELLING COORDINATION GROUP

This coordination group, stepped up in 2022, covers a wide range of themes focusing on the modelling of infectious diseases (population models, epidemic emergence and dynamics, quantitative epidemiology, intra-host modelling, evolutionary processes & phylodynamics, consideration of behaviours and health economics). It is chaired by Vittoria Colizza (Inserm) and Simon Cauchemez (Institut Pasteur), and has five working groups:

- Mesoscopic models of epidemic dynamics, coordinated by Eugenio Valdano (Inserm) and Elisabeta Vergu¹ (Inria)
- Modelling of intra-host dynamics, coordinated by Jérémie Guedj (Inserm) and Mélanie Prague (Inria)
- Behaviour taken into account in epidemic dynamics models, coordinated by Benjamin Roche (IRD)
- Models for epidemiological intelligence and surveillance, coordinated by Pascal Crépey (EHESP) and Harold Noël (Santé publique France)
- COVID-19 and respiratory diseases (closed in 2022)

Over 70 modelling specialists met at the second annual coordination group meeting in Bordeaux in November 2022.

AVATHER GROUP

The agency, in consultation with the coordinators of the working groups on "monoclonal antibodies for the treatment of COVID-19" (MabTher) and "Prioritisation of treatments", merged these two groups to form a single entity with the aim of working on antivirals in clinical development (monoclonal or other type of agent) and in more extensive context of respiratory viral disorders than COVID-19. This new working group, called "AvATher" (for "therapeutic monoclonal antibodies and antiviral agents"), is coordinated by Lionel Piroth (Dijon University Hospital) and Laurence Weiss (AP-HP). It will provide evidence-based recommendations or opinions regarding antiviral agents in the final phase of pre-clinical development targeting respiratory viral diseases.

VACCINE-RESPIRATORY VIRAL DISEASES GROUP

Taking into account the recommendations of the Advisory Board for the Vaccine Strategy and the Vaccine Committee, the agency set up a working group coordinated by Brigitte Autran (Sorbonne Université, Covars) and Odile Launay (AP-HP) bringing together experts from different disciplines, aiming to consider research questions on immune response induced by SARS-CoV-2 vaccination, particularly in the changing context of different viral variants. The group thus met on several occasions, and defined the priority lines of research in order to obtain data to inform the authorities in decision-making involving the changes in the vaccination rules in autumn 2022. These lines of research were as follows:

- study of humoral cross-reactivity following a vaccine booster against sub-variants of the Omicron class;
- assessment of protective correlations from confirmed post-vaccination Omicron infections;
- assessment of cellular response;
- in-depth study of memory B response and the diversity of the antigen repertoire recognised by memory B cells faced with Omicron.

¹ Elisabeta Vergu passed away in May 2023; ANRS | Emerging Infectious Diseases would like to honour this researcher, her work and her contribution to the modelling coordination group that allowed several communities to meet. The agency conveys its sympathy to her family, loved ones, and colleagues.

STRENGTHENING INTERNATIONAL PARTNERSHIPS AND LEADERSHIP OF THE AGENCY'S INTERNATIONAL NETWORK

Due to the dynamics of the pandemic and the occurrence of other respiratory virus epidemics (RSV, influenza, etc.), the agency redirected the focus of this group towards a long-term leadership structure. Discussions on the implementation of the vaccination (respiratory viruses) coordination group are ongoing.

🏢 "INTERVENTIONAL VACCINE RESEARCH" WORKING GROUP

Set in place in September 2021, this working group was created at the end of the expert consultation meeting with the following title: "Structuring of vaccine research in France on infectious diseases with epidemic potential". Its objective is to determine the types of essential and effective actions to improve immunisation coverage and restore vaccine confidence. It is chaired by Elisabeth Botelho-Nevers (Saint-Étienne University Hospital) and Pierre Verger (ORS PACA). The group met twice in 2022. One of the group's priorities was to carry out a global diagnosis, and to provide feedback on the situation in France foregrounding the construction of an interventional research strategy in France. The objectives of this feedback, aiming to define structural lines of research, are as follows:

- creation of a literature and documentation-based summary on the current state of knowledge;
- creating an inventory of research work;
- individual interviews with experts.

A NEW CONCEPT OF INTERNATIONAL COLLABORATION

In 2022, ANRS | Emerging Infectious Diseases designed an innovative partnership model with its French and international partners: global health research platforms (PRISME). This new collaborative model, inclusive and adaptable according to each partnership, finds its strength in the federation of various French and local institutions around a joint scientific, technical, and academic cooperation project that fully includes the scope of emerging infectious diseases.

The creation of these international research platforms in global health is among the main objectives of the international action of ANRS | Emerging Infectious Diseases:

🏢 promote the integration of scientific research into global health priorities by actively engaging in European and international strategic networks, and strengthening the international dimension of the agency's governance mechanisms;

🏢 reinforce the coordination role of ANRS | Emerging Infectious Diseases in the field of infectious diseases in order to improve collaboration between the various stakeholders, and increase the visibility of French institutions internationally;

🏢 contribute to strengthening infrastructures, capacities, and research networks of partner countries.

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This model aims to face a number of current challenges while respecting the ethical and historical principles of ANRS | Emerging Infectious Diseases. It aims to unite all existing research partners and initiatives in response to global health challenges within the same virtual platform, led by a national structure, in order to provide:

- a framework for multi-stakeholder and international reflection and consultation;
- a space for sharing action and resources with the various parties;
- a research continuum ranging from the identification of research priorities to value creation.

The first PRISME platform was created on 19 May in **Guinea**, by the Guinean Ministries of Public Health, Higher Education, Scientific Research and Innovation, Guinean Centre for Research and Training in Infectious Diseases (CERFIG), Gamal Abdel Nacer University in Conakry, ANRS | Emerging Infectious Diseases, Inserm, and IRD. It is led by Abdoulaye Touré (CERFIG). The French contact person for the platform is Eric Delaporte (TransVIHMI, University of Montpellier/Inserm/IRD). It serves to consolidate strong historical international and inter-institutional cooperation, particularly by IRD and ANRS | Emerging Infectious Diseases with the Guinean Centre for Research and Training in Infectious Diseases (CERFIG).

The creation of a new international global health research platform with the **Democratic Republic of Congo** was also in preparation in 2022, and other platforms will be created in the future.

STRENGTHENING COOPERATION WITH WHO ON HIV, HEPATITIS, AND STIS

In order to establish strategic cross-sectional reflection, WHO (HHS HIV, Hepatitis and STI Department) and ANRS | Emerging Infectious Diseases signed a memorandum of agreement on 27 June. This aims to strengthen scientific and technical cooperation between the two institutions, both by identifying common research priorities and by ensuring the transfer of knowledge, on a global level, within the framework of the creation of WHO recommendations and in the partner countries of ANRS | Emerging Infectious Diseases, particularly in **West and Central Africa**.

Through this protocol, the two institutions have undertaken to facilitate the dialogue between research conducted in LMIC and public health stakeholders, on pre-identified priority themes.

This first memorandum of understanding between the WHO/HHS and ANRS | Emerging Infectious Diseases is part of the general framework of cooperation between France and WHO, signed on 31 December 2019, on the building of a strengthened partnership for the period 2020-2025.

BRINGING TOGETHER THE INTERNATIONAL COMMUNITY

The first day seminars organised by the International Network of the agency, held on 27 and 28 June, on the PariSanté Campus, brought together researchers from France and partner countries, institutional representatives, and associations, with the aim of presenting an overview of research conducted in partnership with low- and middle-income countries (LMIC), and to identify joint work priorities for all of its themes.

In 2022, two partner sites of ANRS | Emerging Infectious Diseases organised their science day seminars to discuss central research topics, including HIV/AIDS and emerging diseases, and the One Health approach.

🏠 The 7th science day seminars of the partner site of ANRS | Emerging Infectious Diseases in **Cameroon** took place on 28 February and 1 March, in Yaoundé and online. The last event was held in 2016. These day seminars were an opportunity to present the vast array of ongoing or finalised projects led by the partner site and its network, such as MEDIACAM (project on trust and suspicion with regard to social media in order to refine public health responses to COVID-19 in Cameroon), NAMSAL (assessing dolutegravir vs. efavirenz, both combined with tenofovir disoproxil fumarate and lamivudine for the initial management of HIV-infected adults in resource-limited settings) or ARIACOV (research-action project to support the African response to the COVID-19 epidemic).

🏠 The 11th science day seminars of the partner site of ANRS | Emerging Infectious Diseases in **Burkina Faso** took place on 21 and 22 November, in Ouagadougou and online. Organised for the first time since 2018, these two-day seminars were used to present the projects by the partner site and its network, and to discuss key research topics: HIV/AIDS, cervical cancer prevention, viral hepatitis, *One Health*, and emerging diseases, including three emblematic projects: ORHEB (characterisation of a hepatitis E epidemic in a humanitarian emergency context in Burkina Faso according to a *One Health* approach), TRI-MOM (integrated strategy for preventing mother-to-child transmission of HIV, syphilis and HBV in Burkina Faso and Gambia), and AFROSCREEN (integrating genomic surveillance of SARS-CoV-2 into an existing national system).

One of the agency's missions was also organised in **Brazil** in October, bringing together the leaders of the Arbo-France network. It aims to explore the avenues for collaboration between ANRS | Emerging Infectious Diseases and Brazil in the area of arboviruses, and opened the scope of this collaboration to new stakeholders, in particular the Research Support Fund of the State of São Paulo with which an agreement was signed in 2023.

A workshop on research ethics in the South was also held in **Cameroon** in October. This was led by Brigitte Bazin, an ethics consultant, and took place in the presence of around twenty people, together with the two joint site coordinators, Anne-Cécile Bissek (Head of the Operational Health Research Division, Cameroon Ministry of Health) and Éric Delaporte (TransVIHMI, University of Montpellier/Inserm/IRD), based on two themes: the role of the community and associations within research and the collection of biological specimens derived from research.

CENTRALISED PHARMACOVIGILANCE AND TRANSFER OF SKILLS

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The agency's Clinical Research Vigilance Department implemented a centralised pharmacovigilance system in two multinational European consortia: Connect4Children or C4C (one of the largest consortia funded by the European Commission on Paediatric Clinical Research) for paediatric research and EU-Response for COVID-19 platform trials in the European Union. In this type of clinical trial comprising various European countries, centralised pharmacovigilance involves harmonising complex safety processes, creating a network of local safety officers (LSOs) and centralising all safety-related activities. In 2022, the teams from the agency's Clinical Research Vigilance Department wrote a scientific article, [published in February 2023 in the British Journal of Clinical Pharmacology](#), which draws lessons from their experience in centralised pharmacovigilance relating to four clinical trials from these two consortia. It appears that this system is effective and responsive, even during a pandemic. Overall, there were 1,312 serious adverse events (SAEs) in EU-Response and 83 SAEs in C4C during the four clinical trials. Processing of SAEs in a single database guaranteed full control of safety data, and continuous assessment of the risk/benefit ratio. The LSO network has been involved in effective regulatory compliance in several countries, particularly in the event of changes in safety legislation. This approach strengthens pharmacovigilance capabilities, and can be used by multiple university sponsors.

Knowledge transfer is a strong dimension of these two consortia. The Clinical Research Vigilance Department coordinates the courses in the paediatric pharmacovigilance module as part of the C4C Academy training courses. A training section for LSO is also provided by the department in the EU-SolidAct trial.

The transfer of skills in terms of sponsorship is one of the central points in the projects and infrastructure in preparation for epidemic crises. For example, ANRS | Emerging Infectious Diseases are joint sponsors with the Irrua Specialist Teaching Hospital (ISTH) in Nigeria of the INTEGRATE phase II/III adaptive platform trial submitted as part of the EDCTP programme, assessing the efficacy, tolerability, and safety of

new or repositioned treatments for Lassa fever in West Africa. The objective is to strengthen the capacities of ISTH in terms of sponsorship and pharmacovigilance. With 200 patients envisaged for each of the treatments assessed, the trial will begin in Nigeria at the beginning of 2024, before being extended to Liberia, Guinea, and Benin.

ACTIONS IN CIVIL SOCIETY AND PATIENT ASSOCIATIONS

As is the case each year, the agency organises regular meetings with the TRT-5 CHV, the inter-association collective in the field of HIV/AIDS and hepatitis, which celebrated its 30th anniversary in 2022. Six meetings took place this year.

In addition, during the TRT-5 CHV scientific day seminar on 27 September, which brought together associations, researchers, doctors, and companies on the theme of health innovation, Ventzislava Petrov-Sanchez, head of the agency's Clinical Research Department, was invited to give a talk on the theme "How is a research project created? What is relevant research?".

SCIENTIFIC EVENTS & MEETINGS

EVENTS ORGANISED BY THE AGENCY'S SCIENTIFIC COMMUNITY

JANUARY ●

AC41 WORKSHOP/ ANRS CO-5 HIV-2 COHORT

AC41 brought together researchers and clinicians for a joint workshop to continue the translational studies within the ANRS CO-5 HIV-2 cohort. The community agreed to focus on HIV-2 integration sites and viral reservoirs (measurement/integration and reactivation sites) and on the immuno-genetic profiles and innate immune responses.

MARCH ●

1ST PLENARY MEETING OF THE "RESPIRATORY VIRAL DISEASE" COORDINATION GROUP

15 & 16 MARCH ○

ANRS | EMERGING INFECTIOUS DISEASES SCIENCE DAY SEMINARS

This first edition was an opportunity to present the agency's actions to the national and international scientific community. It brought together 38 invited experts and over 380 participants on site, with 180 online attendees. The presence of leading scientific names in the field, together with representatives from the agency's supervisory bodies (Frédérique Vidal, Minister of Higher Education, Research and Innovation, Olivier Véran, Minister of Solidarity and Health, and Gilles Bloch, Inserm Chairman and Chief Executive Officer), created a unique opportunity for bringing together different research stakeholders at this event.

● JUNE

2ND PLENARY MEETING OF THE "RESPIRATORY VIRAL DISEASE" COORDINATION GROUP

○ 7 & 8 JUNE

AC42 ANNUAL MEETING – 2022 NATIONAL HEPATITIS NETWORK

This event brought together between 150 and 2002 participants for its first edition, exclusively with on-site attendance. The objective was to discuss the latest French advances in fundamental and translational research in viral hepatitis.

● 5 JULY

9TH ANRS HBV CURE WORKSHOP

SEPTEMBER

○ 23 & 24 SEPTEMBER

SEMINAR ON THE "TRANSMISSION OF RESPIRATORY VIRAL DISEASES AND NON- PHARMACEUTICAL BARRIER MEASURES" COORDINATION GROUP

○ 26 SEPTEMBER ○

AC41-AC44 MOTHER-CHILD GROUP PLENARY MEETING

● 13 & 14 OCTOBER ●

ANNUAL SYMPOSIUM OF THE ARBO-FRANCE NETWORK

NOVEMBER

14 & 15 NOVEMBER ○
AC41 INTERNATIONAL SYMPOSIUM

21 & 22 NOVEMBER ○
"MODELLING" COORDINATION GROUP PLENARY
MEETING

DECEMBER ●

3RD AC41 PLENARY MEETING

15 DECEMBER ○

SCIENCE DAY SEMINAR

"YELLOW FEVER EPIDEMIC IN THE WEST INDIES: STATUS REPORT AND RECOMMENDATIONS"

This day seminar, jointly organised by Arbo-France, Martinique Regional Health Agency, Martinique Territorial Collectivity and Institut Pasteur, aimed to assess shortcomings and needs in terms of research, diagnosis, patient management, vaccination and vector control.

PART II

BRINGING TOGETHER AND
LEADING COMMUNITIES

AGENCY PARTICIPATION IN MAJOR SCIENTIFIC MEETINGS

Researchers, whose work has been supported by the agency, are encouraged to submit them to national and international conferences in order to promote French research. For example, at CROI 2022, two papers and 16 posters from research funded and/or sponsored by the agency were selected, and one paper, and 20 posters were selected at AIDS 2022.

The agency also helped fund 13 symposia, such as the 2022 I4ID conference, which took place on [23 and 24 November](#) and which promotes interactions between the pharmaceutical industries, research laboratories, service providers, technology developers, and clinicians, and thus contributes to the development of innovative strategies against infectious diseases in a multidisciplinary approach.

Another example is the 36th International HBV Meeting, which took place in Paris from [18 to 22 September](#). Coordinated by the Hepatitis B Foundation and ICE-HBV, this symposium was co-organised by David Durantel (Inserm and member of the host/virus interactions AC41) and Hélène Strick-Marchand (Institut Pasteur and member of the hepatitis virus AC42), with the financial support of the agency. It welcomed numerous high-level French and international specialists.

Three symposia were organised by the agency at international conferences:

🏛️ APRIL

The 11th edition of the international conference of AFRAHIV was held in Marseille. On this occasion, ANRS | Emerging Infectious Diseases presented a symposium on equal access to COVID-19 vaccination.

🏛️ JULY

At the International AIDS conference on HIV/AIDS, organised by the International AIDS Society, the agency organised a symposium on community research with the following title "*Comm-*

nity based participatory research: Good Science for Appropriate Response". This symposium led to the drafting of a press kit on community research and a press update before the event.

🏛️ OCTOBER

The ANRS | Emerging Infectious Diseases at the AFEF in Dijon was dedicated to hepatitis delta.

In addition, the agency hosted two major events at ParisSanté Campus:

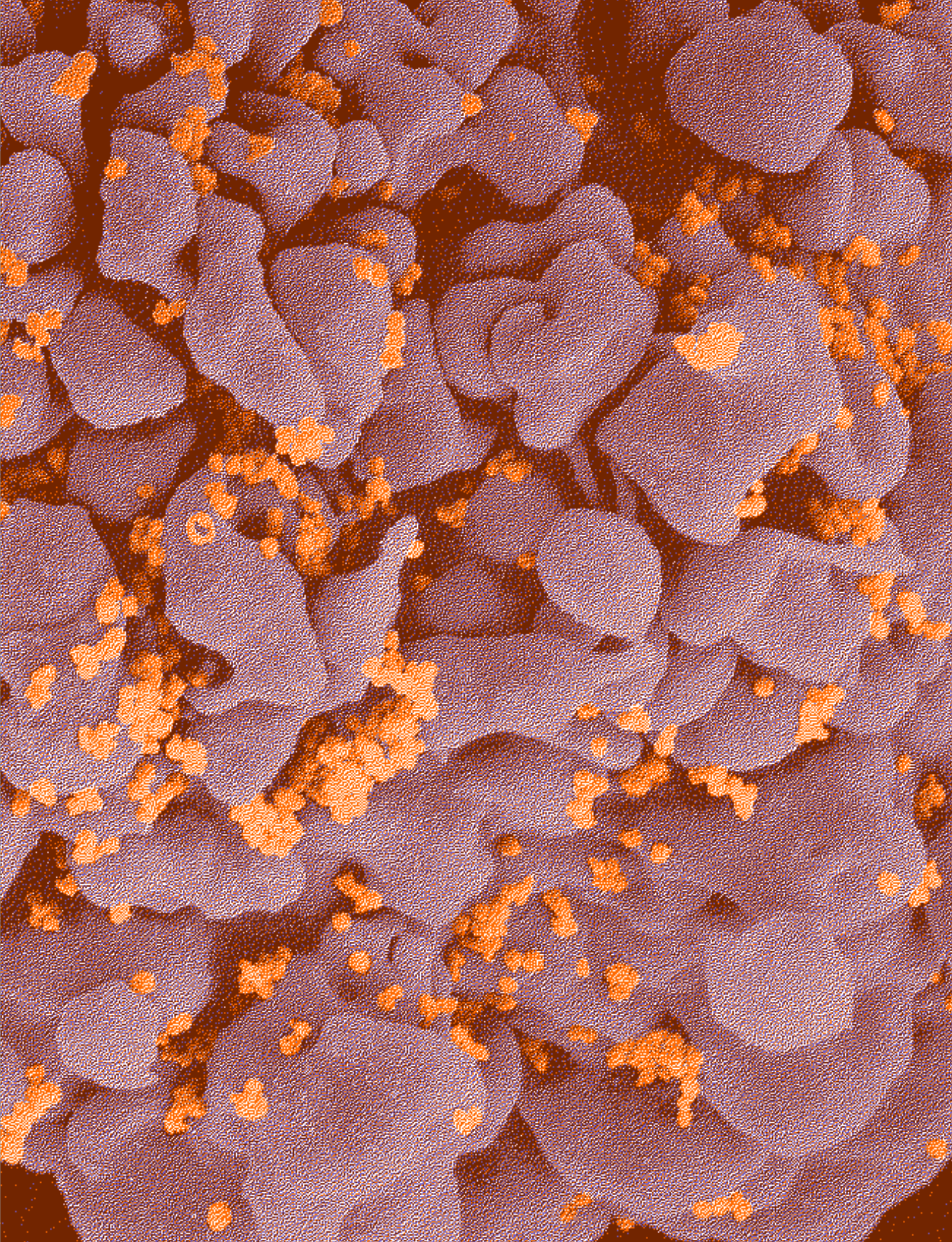
🏛️ MAY

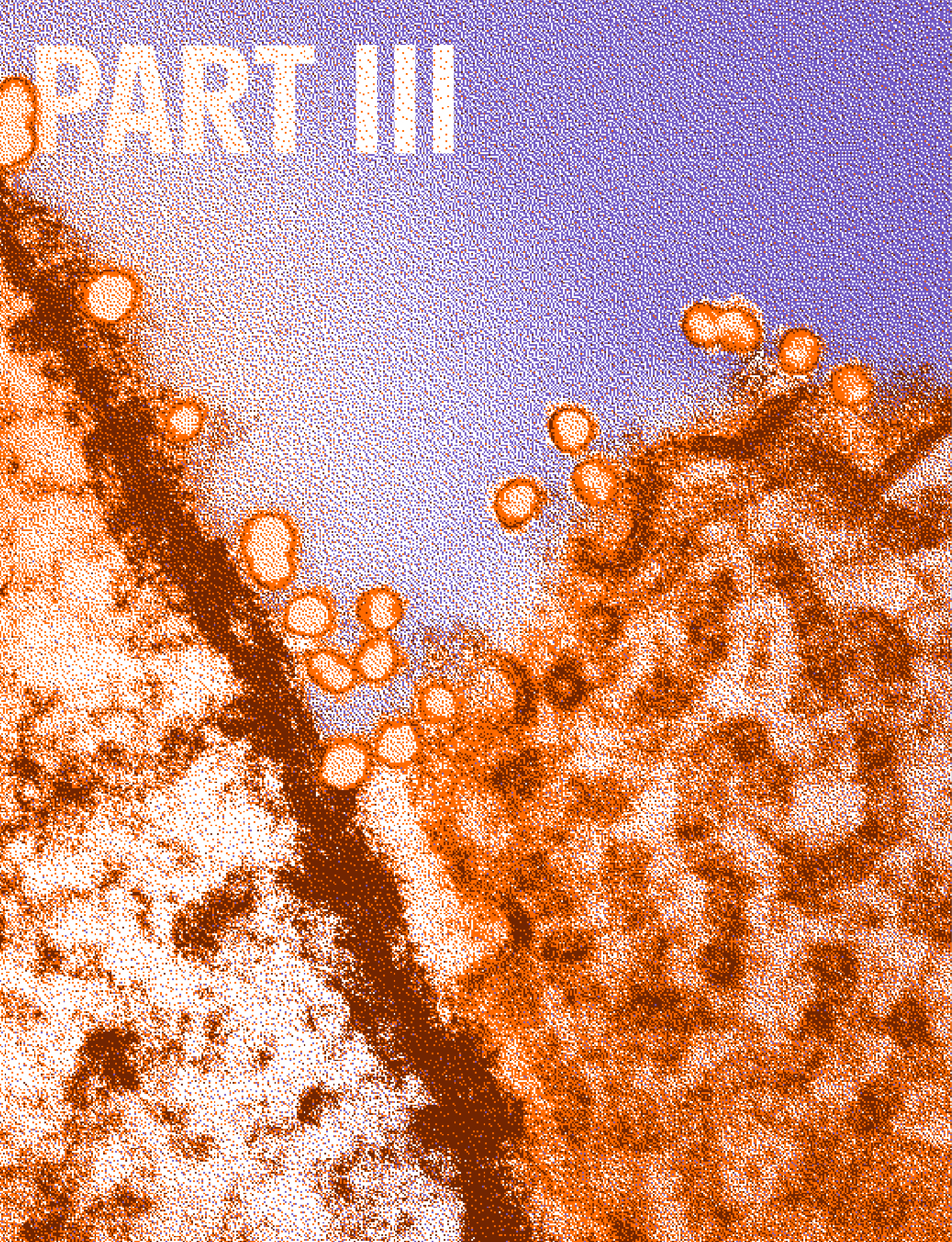
Launch of the third programme of the European and Developing Countries Clinical Trials Partnership (EDCTP) to strengthen collaboration between the European Union and Africa on global health research.

🏛️ JUNE

The representatives of ten European COVID-19 Scientific Councils met at the initiative of the French COVID-19 Scientific Advisory Board. They discussed lessons to be learned from their experiences as scientific advisers, in particular on relations with national health agencies, political authorities, the media, but also with citizens. They issued recommendations for building a European vision for response to health crises.

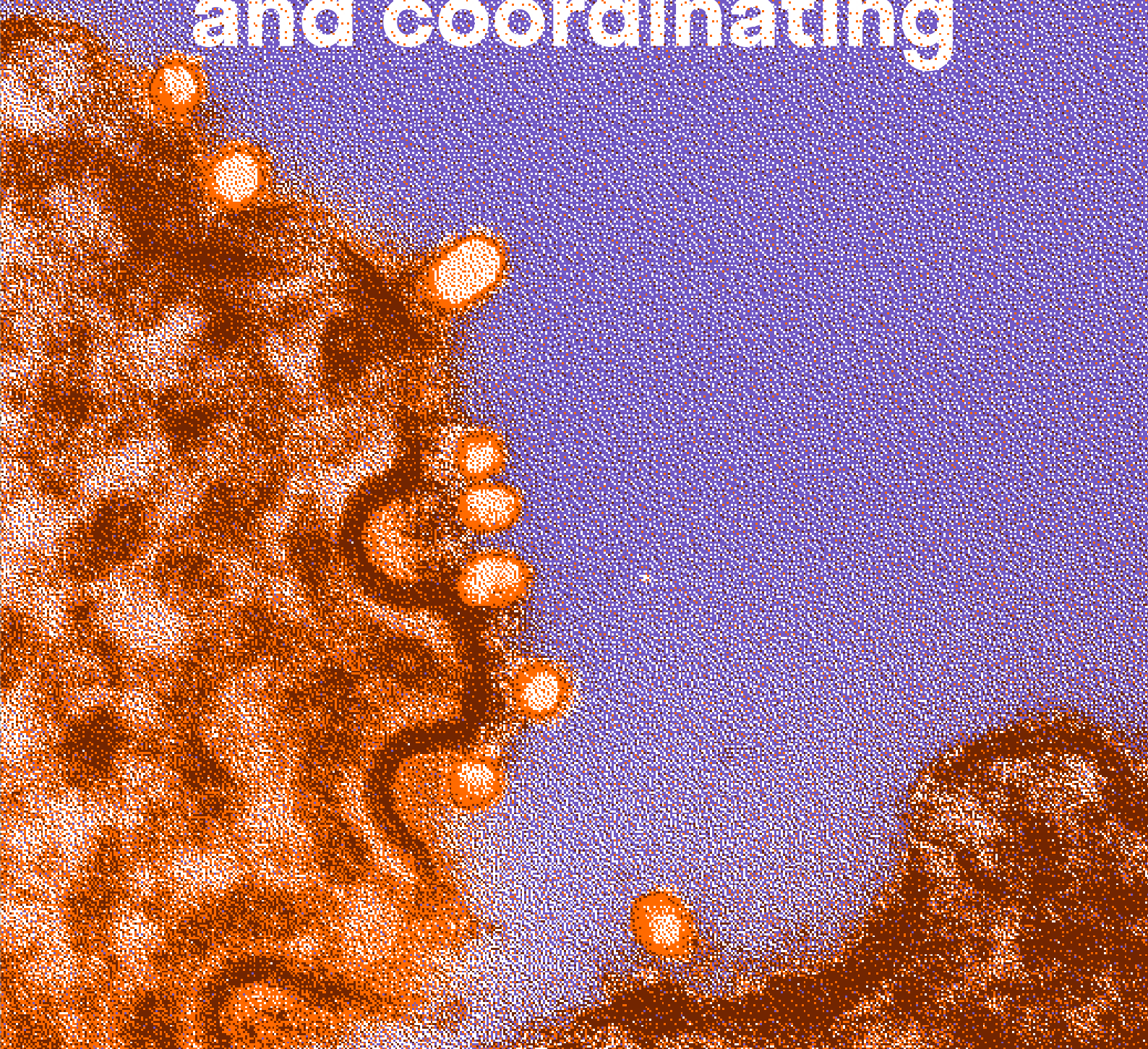
The Director of the Agency, for his part, represented the agency within the French delegation of the seventy-fifth World Health Assembly from 22 to 28 May in Geneva, with Yves Souteyrand, scientific adviser of the Strategy & Partnerships Department. Yazdan Yazdanpanah was also invited to the international meeting "Paediatric HIV & TB: Rome Action Plan", which took place in Vatican from 5 to 7 December. He took part in the session "*Solutions and actions on research and development related to medicines for pregnant and breastfeeding women (HIV and TB)*".





PART III

Structuring, financing, and coordinating



STRUCTURING AND FINANCING THE AGENCY'S ACTIVITIES

REVISION OF MOASF

The document containing the agency's administrative, scientific, and financial organisational methods (MOASF), defining the internal regulations of the ANRS | Emerging Infectious Diseases, was revised during the year in order to adapt it to the characteristics of the new agency. It was submitted to the agency's steering committee for an opinion, and approved by Inserm board of directors in December. The main developments include a reference to a document explaining the methods for managing health crises, the introduction of the concept of establishing an emergency fund for agency subsidies, increased information of the steering committee for the initiation of research projects and structuring actions, and strengthening the role of the scientific advisory board.

DEVELOPMENT OF THE 2023-2027 STRATEGIC GUIDANCE DOCUMENT

In view of the significant expansion of its mandate and the increase in its human and financial resources, the agency decided to initiate a strategic planning exercise, taking advantage of the gradual exit from the COVID-19 pandemic, which had been heavily mobilised until then. This exercise, initiated at the beginning of 2022, was conducted in collaboration with Kevin De Cock, a high-level international expert. It aimed to redefine the agency's vision and mission and establish the strategic objectives associated with this mission, in the context of new epidemiological, geopolitical and environmental realities and within an institution with a significantly expanded mandate and human and financial resources. The 2023-2027 strategic guidance document, resulting from this work, to be published in 2023, was drawn up on the basis of numerous interviews with researchers, the agency's governance bodies and civil society, and was designed in close liaison with the scientific advisory board.

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CREATION OF THE PARTNER COUNCIL

In 2022, a new body was created: the partner council. This brings together representatives from various institutions (listed on pages 52-53): hospital and university stakeholders, corporate health stakeholders, scientific and health authorities, associations and civil society, stakeholders from associations of young doctors, pharmacists, scientists and from learned societies consistent with topics covered by the agency.

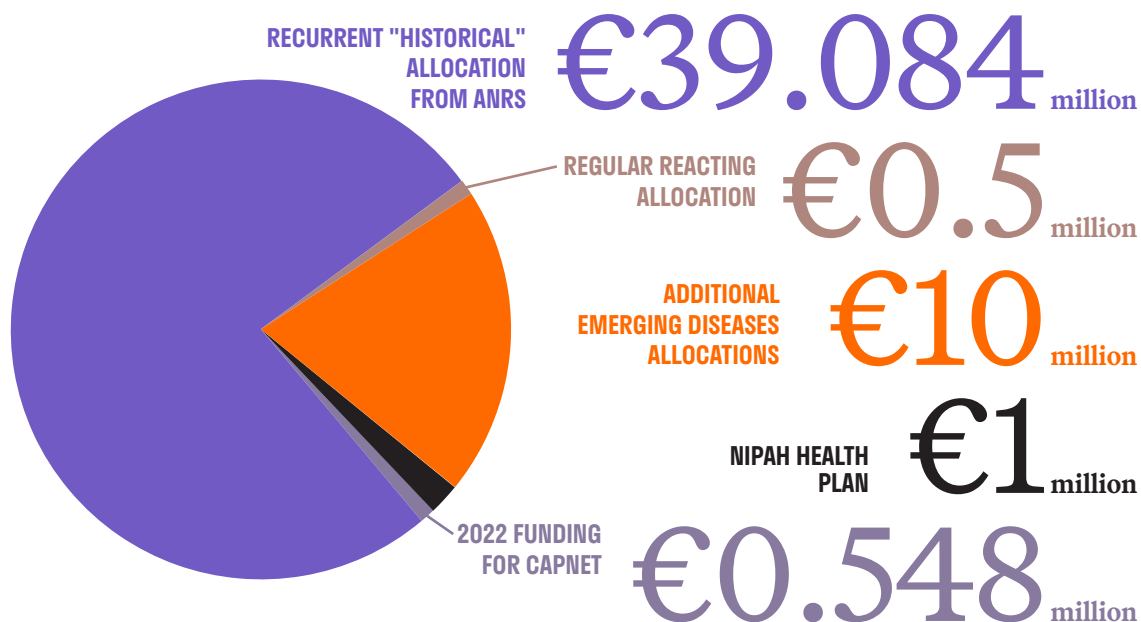
Meeting twice a year, this board is a place for institutional, strategic, and scientific exchanges. Its missions include sharing information on the agency's activity, current issues and research challenges within its remit, insight or opinion on the content and implementation of the agency's strategy, the contribution to the coordination of joint efforts in preparing and responding to crises related to emerging diseases and, lastly, the contribution to the identification of mobilisable resources.

RESOURCES AND USE OF RESOURCES

REVENUE

A total of EUR 51.132 million of state grants (MESRI) were collected in 2022. This sum can be broken down as follows:

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In addition to state grants (SG), revenues are partly made up of own resources (OR) of EUR 5.126 million. These mainly include EUR 3.667 million of contractual resources related to research contracts such as COVICOMPARE Africa, and AFROSCREEN. Day-to-day management revenues were multiplied by around 3.7 during execution, with a collected sum of EUR 1.46 million relative to predictions of EUR 0.4 million. The amount of securities issued in this section (EUR 0.935 million) is higher than predicted, reflecting the significant effort to recover the balance of completed projects. The allocated donations and legacies have a higher execution rate than expected, up to +39%, due to the collection of the ANRS RHIVIERA project balance, for the MSD Avenir sponsorship, i.e. EUR 2.3 million.

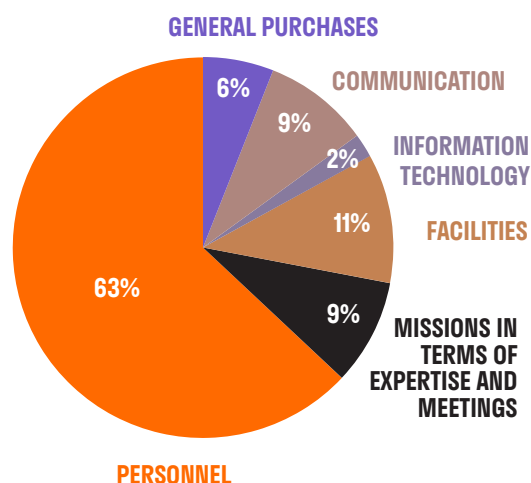
In total, revenues for 2022 amounted to EUR 56.258 million (all sources combined, SG and OR).

EXPENSES

At the end of the second amending budget, the amount of funds open for expenditure was set at EUR 72.934 million. These funds were executed at a rate above 90%, indicating a marked improvement over 2021.

State grant expenditure accounts for the vast majority of expenditures: EUR 60.3 million committed to SG compared to EUR 7.1 million in own resources.

Overall agency operating expenditure reached EUR 8.3 million, consisting of EUR 5.2 million in payroll (excluding provision) and EUR 3.1 million in current expenditure. This is broken down as follows:



DISTRIBUTION OF AGENCY OPERATING EXPENSES BY TYPE OF EXPENDITURE

In 2022, the total amount spent on research funding was EUR 51.953 million, representing 86% of the total funding available for state grants.

RESEARCH FUNDING: DIVERSIFICATION OF CALLS FOR PROJECTS

In 2022, as in previous years, the two generic calls for projects, a legacy of the historical ANRS, funding research on HIV, viral hepatitis, STIs, tuberculosis, and their co-infections were opened from January to March and from June to September. A total of 107 projects were selected for funding.

With the scope of the agency expanding to emerging and re-emerging infectious diseases, and faced with the impact of these diseases on health, but also on economies and societies, ANRS | Emerging Infectious Diseases, in conjunction with its regulatory authorities, has deployed new support mechanisms for research into emerging and re-emerging infectious diseases, particularly for research funding, in France and internationally.

As a result, new calls for recurrent projects have been put in place since 2022, in conjunction with existing national and international funding mechanisms, particularly in Europe.

📌 **THE RECH-MIE CALL FOR PROJECTS** is a new mechanism within the framework of healthcare research programmes and the provision of care funded by the Ministry of Health and Prevention, with EUR 10 million per year and led by the agency. This annual call targets clinical research projects in emerging and re-emerging infectious diseases led by French healthcare institutions. An initial accelerated call was launched in 2022, with a selected project, followed by a second standard two-stage call (letters of intent followed by the complete dossier) launched in September 2022. The final results of the latter will be known in 2023.

📌 **THE EMERGING DISEASES CALL FOR PROJECTS IN LMIC** is an annual call for projects for the financing of collaborative research projects between French teams and low- and middle-income countries on emerging and re-emerging infectious diseases. In particular, it targets large-scale, multi-disciplinary projects involving several countries and enabling the structuring of research in the countries involved. The call was launched in September, and four projects were selected for funding.

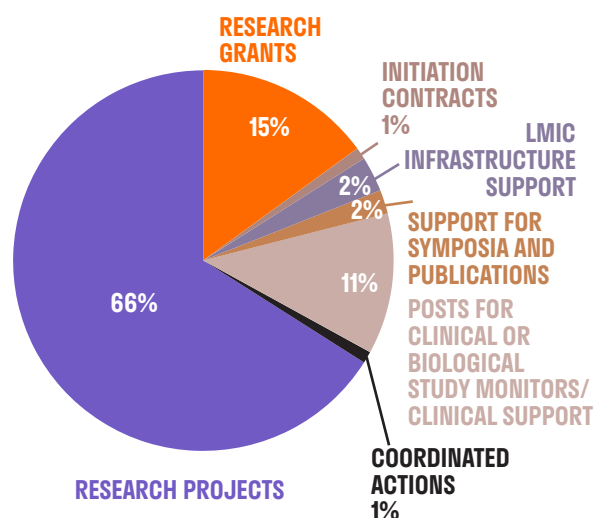
🏗️ **ARBO-FRANCE PH.D. GRANTS – ANRS | EMERGING INFECTIOUS DISEASES** is an annual call for applications organised as part of the Arbo-France network's actions, enabling the financing of doctoral grants on priority themes on arboviruses. Two prize-winners were selected.

Lastly, flash calls were deployed within short time frames in response to epidemics:

🏗️ **THE 2022 CALL FOR PROJECTS ON LONG COVID** (second session), focusing on the medium- and long-term effects and consequences of SARS-CoV-2 infection, in France and internationally, according to defined scientific priorities. After an initial session in 2021 that helped finance 10 projects, the second session of the call for projects on "Long COVID" was launched in February 2022 by ANRS | Emerging Infectious Diseases, in collaboration with the Foundation for Medical Research (FRM), and with the support of the Ministries of Higher Education, Research and Innovation and Solidarity and Health *via* CAPNET. 18 projects and five research grants were selected.

🏗️ **CALL FOR PROJECTS ON MPOX**: after an initial case of monkeypox reported in the United Kingdom on 7 May 2022, in mid-June, ANRS | Emerging Infectious Diseases launched, as an emergency, the pan-European research infrastructure on highly pathogenic microorganisms, a call for projects to finance research that provides short-term knowledge on monkeypox, with the support of the ERINHA team. Out of 17 projects submitted, 10 were selected for funding, thanks to support from the Ministry of Higher Education and Research, reaching a total of almost three million euros.

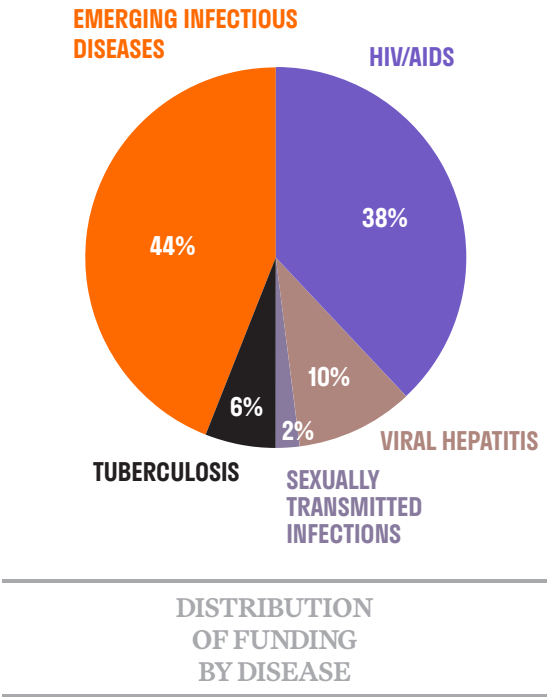
In total, eight calls for projects were therefore organised by the agency. The mobilisation of the research community in France and in partner countries has been strong, with numerous quality projects submitted. The creation of new scientific evaluation committees, sometimes as an emergency, has also demonstrated the benefit and commitment of experts in supporting the development of the agency and its funding offer.



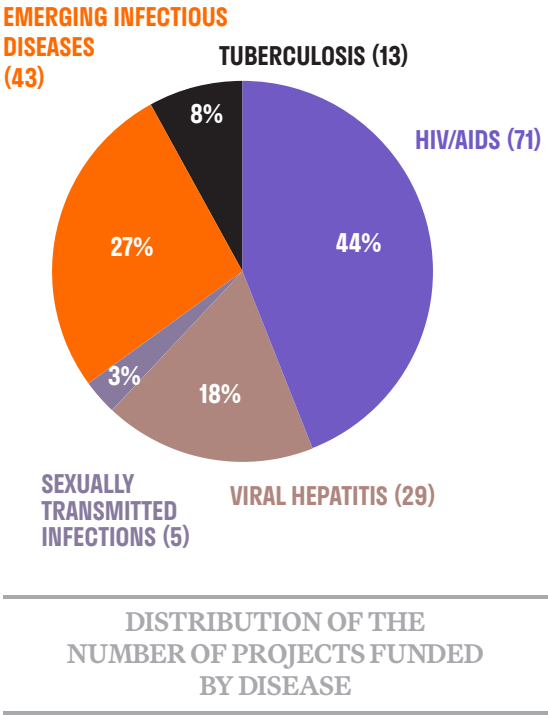
BREAKDOWN OF SUMS ALLOCATED BY TYPE OF PROJECT

In 2022, the agency continued to promote and fund significant research projects in the historical fields of HIV and hepatitis (representing EUR 16 million, i.e. more than 6 out of 10 projects). In addition, the agency devoted a significant portion of its resources (EUR 15 million, i.e. around 3 out of 10 projects) to funding research on emerging and re-emerging infectious diseases (such as COVID-19, mpox, Lassa fever, Nipah virus, plague).

The distribution of direct research funding, by disease is broken down as follows:

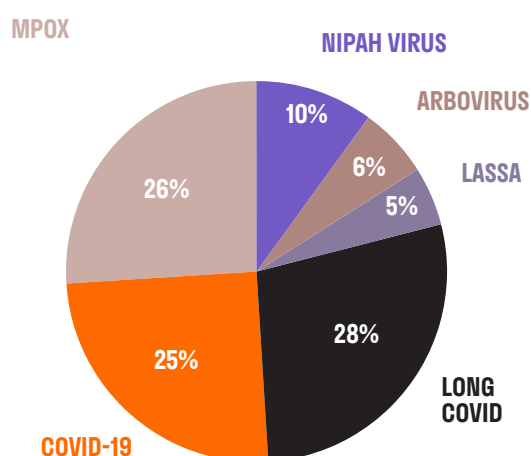


This differs when looking at the number of projects funded by disease (as a % of the 162 projects):



With regard to HIV, the agency continued its focus on host/virus interactions (EUR 3.6 million) and the pathogenesis of the disease (EUR 1.2 million). In 2022, funding for research into viral hepatitis focused on HBV (EUR 1.2 million), HCV (EUR 1 million), HEV (EUR 700,000), and HDV (EUR 600,000). Regarding tuberculosis, the agency focused its investments on a series of projects shedding light on host/pathogen interactions and pathogenesis (EUR 500,000) together with screening, treatment, vaccination, and diagnosis (EUR 1.7 million). Regarding sexually transmitted infections, the agency focused its funding on HPV.

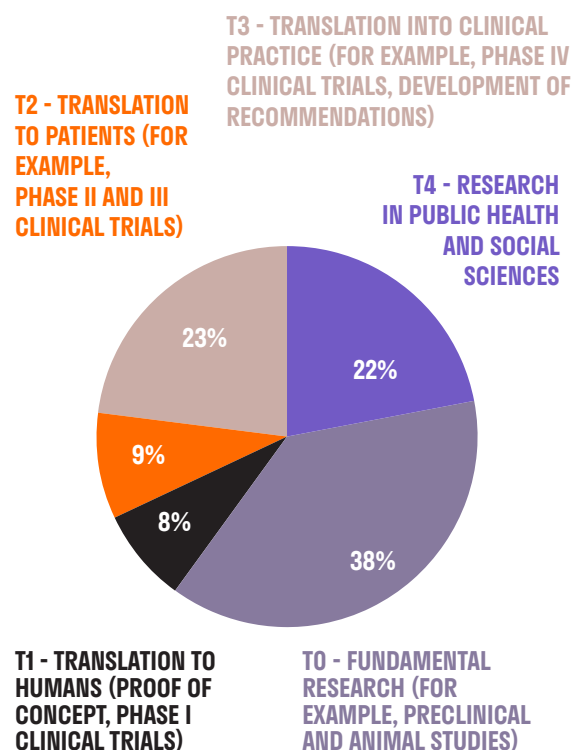
The funding of emerging infectious diseases projects is broken down as follows:



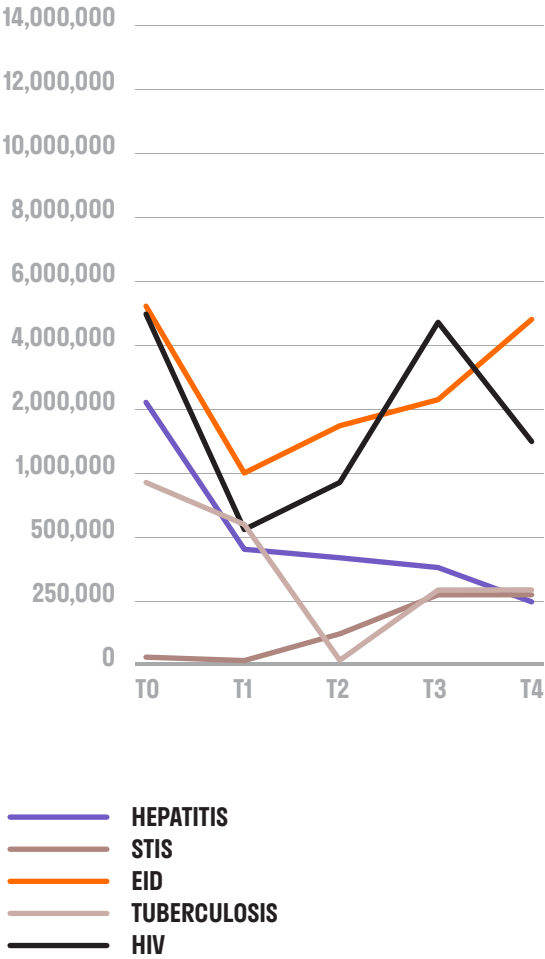
BREAKDOWN OF
PROJECTS FUNDED IN EMERGING
INFECTIOUS DISEASES

This graph does not take into account clinical trials resulting from the ReCH-MIE call for projects, led by the agency but funded by the DGOS.

The distribution of 2022 funding for all pathogens combined by type of research shows that the agency dedicated a significant share of its resources to the financing of fundamental research, with 14.7 million euros (more than 5 in 10 projects), clinical and translational research (11 million euros), and public health and social sciences research (8.4 million euros). The graph below illustrates the distribution of funding by positioning projects in the research continuum:



DISTRIBUTION OF
FUNDING ACCORDING TO
RESEARCH CONTINUUM



FOCUS ON 2022 COHORTS

The agency devoted

EUR **4.4** million

to supporting and setting up cohorts
(including a new mpox cohort).

FOCUS ON RESEARCH GRANTS

Encouraging young researchers by providing
training is an integral part of the agency's
missions.

Hence, in 2022,

it spent EUR **5.9** million

on research grants, including 3.5 million
for doctoral grants and 2.4 million for post-
doctoral grants. The majority of new 2022
grants involve fundamental research (primarily
HIV and hepatitis).

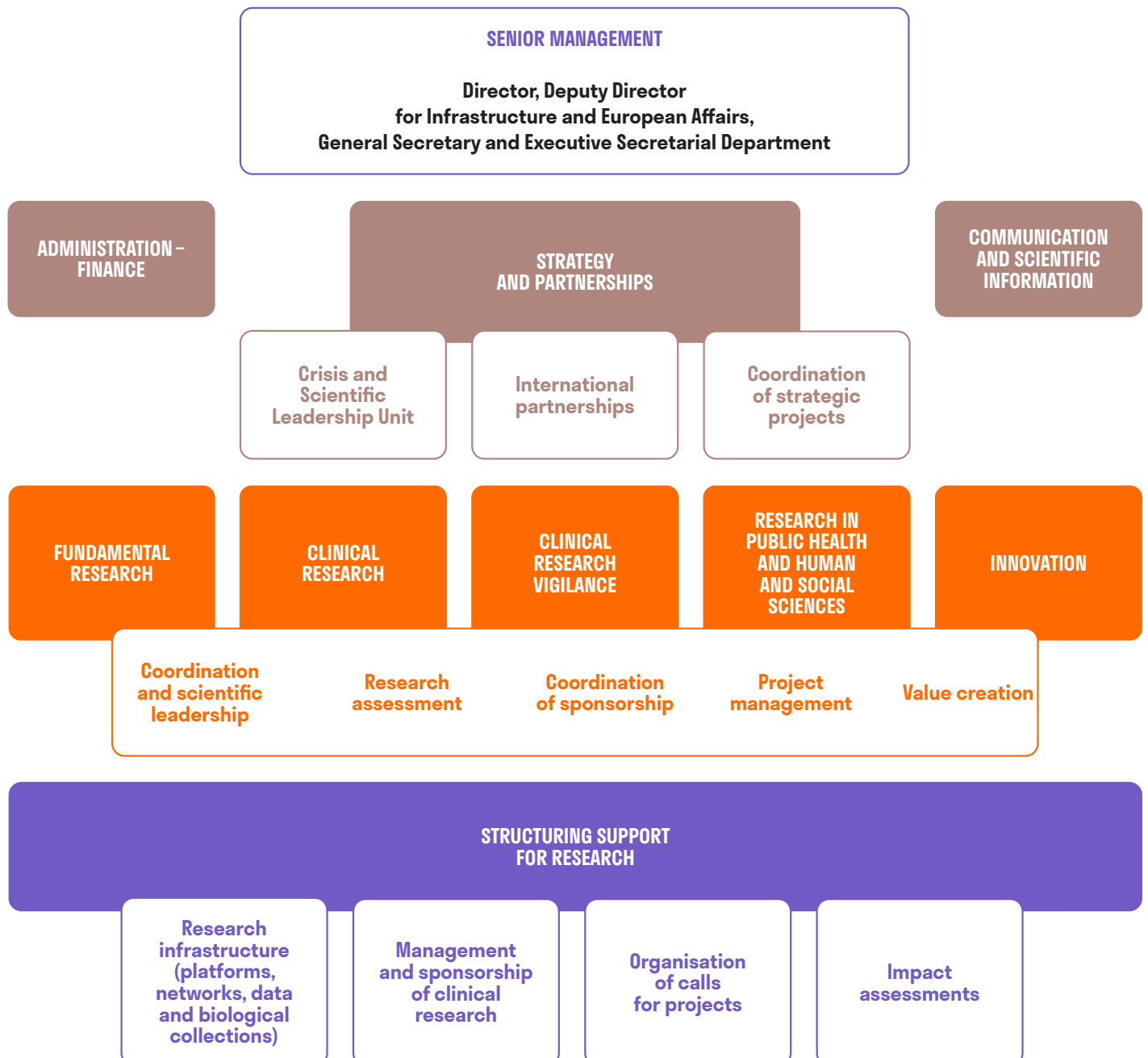
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DISTRIBUTION OF FUNDING, BY
PATHOLOGY AND POSITIONING IN THE
CONTINUUM (EUR)

HUMAN RESOURCES

At the end of 2022, the agency had 110 employees, with a target of 115 FTEs in total.

Agency organisational chart:



NEW ORGANISATION OF THE ADMINISTRATION AND FINANCE DEPARTMENT

This department established a new organisation in 2022, dividing its activity into three divisions:

RESEARCH CONTRACT AND FUNDING UNIT,

responsible for the operational implementation of funding for agency calls for projects and, more generally, all research funding actions. It ensures the administrative and financial follow-up of the projects throughout their duration and until their closure, and assists project managers with administrative and financial aspects.

BUDGET, REVENUE, AND MANAGEMENT CONTROL UNIT,

responsible for preparing the agency's overall budget, implementing it in SAFIr, and controlling its implementation. It monitors revenue from public contracts (ANR, European Union) and private contracts (companies, charities, etc.), including contracts and financial reporting. It also monitors the agency's workforce and their allocated budget, together with implementation of the budget for the two expenditure divisions, and carries out internal control and auditing actions.

PURCHASING AND LOGISTICS DIVISION,

which ensures the day-to-day management of operating expenses of agency departments, which contributes to the organisation of general and logistical resources, and which acts as platform coordinators (particularly for the management of user access rights). This unit is also responsible for monitoring contract execution, and liaises with the Inserm central purchasing department.

AGENCY COMM

OPEN SCIENCE

Communication, dissemination, and openness of data and results is one of the agency's top ten strategic objectives. The legal and regulatory corpus also defines obligations for researchers and public institutions in the field of open science, in addition to the recommendations of the second National Plan for Open Science, launched by MESRI in July 2021. As a signatory of the San Francisco Declaration on Research Assessment (DORA) in January 2020, together with the joint declaration of French funding agencies for open science (in June 2020), highlighting the six points of the intention of ANR, Anses, INCa, Ademe, and ANRS to develop a concerted approach to promote the dissemination and sharing of knowledge, the agency has made a strong commitment to open science.

It thus participates in several working groups:

- the working group of the French research funding agencies network, which shared its feedback during the "Open science in the South" symposium in Cotonou, October 2022;

- the network of data administrators within the MESRI, which brings together representatives from universities, Inserm, ANR, CNRS, INRAE, INRIA and CEA, who discuss data policy, algorithms and source codes as part of the "2021-2024 Roadmap". Among the notable achievements in 2022 discussed within the network, the creation of Recherche Data Gouv, a national multidisciplinary and federated research data platform, accompanied by a network of supporting offers;

- the Dora working group, set up by MESRI, to draft the Paris Research Assessment Call, presented at the "Open Science European Conference", organised in Paris in February and which supports reform of the current research assessment system taking into account all research outputs, in all their diversity, by assessing them on the basis of their intrinsic merits and impacts.

Two new agreements were signed in 2022:

- agreement to reform the assessment of research, commitment and participation in the Coalition on Advancing Research Assessment (CoARA) in October 2022. The agency is a member of the constituent assembly of the coalition, which brings together 440 organisations in more than 40 countries. CoARA is intended to provide a forum for exchange on good assessment practices and a platform for managing and trialling new methods and tools for a fairer and more qualitative evaluation of research;

- the White House call for open access to publications and data on mpox infection in August 2022.

In 2022, ANRS | Emerging Infectious Diseases carried out three main actions confirming its commitment to open science:

- the introduction of open science requirements in the regulation relating to calls for projects: funded project leaders are encouraged to submit scientific publications resulting from their projects (full text) in an open archive, either directly in HAL or through a local institutional archive. They are also advised to favour publications in original open-access journals or books and to commit to providing a data management plan (recommendation for use of the DMP tool "DMP OPIDoR");

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the addition to the MOASF of a new article focusing on open science, specifying the legal and regulatory framework, the measures put in place at the agency and indicated in the regulation relating to calls for projects;

the development and implementation of a cycle of five webinars to raise awareness on open science among agency staff, organised as part of the network of funding agencies with the support of the Open Science Committee, which is continued in 2023.

This work will continue in the coming years with, in view of the immediate availability of open access publications, showing eligibility for funding of publication fees in calls for projects, and the input of information into the open platform for French public data, data.gouv.fr, etc.

As a result of its activities to promote clinical trials, ANRS | Emerging Infectious Diseases is also engaged in reflection on the sharing of research data. Several working meetings were organised to deal with the sharing of research data, with the European consortium ReCoDID and Inserm in order to harmonise and open data from four COVID-19 cohorts (French Covid, Sapis, COCO-PREV, PRECOVIM), with the methodology and management centres within the agency network, with the ADLIN science start-up, and GLOPID-R, ISARIC, IDDO and HDH.

In addition, the agency and its pharmacovigilance and clinical research departments initiated a project to publish end-of-study results in the dedicated registries (EudraCT and Clinicaltrials).

SIMPLIFICATION MEASURES - RESEARCH PROGRAMMING LAW

The appelsprojetsrecherche.fr website is a portal intended for research stakeholders. Falling within the scope of the Research Programming Law, it is currently supported by six partners: Ademe, ANR, Inserm/ANRS | Emerging Infectious Diseases, ANSES, and INCa. It thus offers unified access to future and ongoing calls for proposals or applications, for greater visibility of the research funding offer. Launched in September 2021, it has gradually taken on new features, and been joined by new partners in order to expand the funding offer accessible from the portal, and further simplify procedures to be followed by researchers.

Presenting the diversity and richness of the project-based research funding offer is the key primary objective of this portal. Extending the visibility of project-based research funding offers helps to increase equity among research communities.

In 2022, the agency actively contributed to the development of this portal, thus ensuring that the specific characteristics of its research areas were taken into account. An interface with the Apogée project submission platform was created in order to facilitate and streamline the display of the calls for proposals issued by the agency via the portal. Lastly, harmonisation work was initiated to simplify the compilation of dossiers to be submitted by researchers in response to calls for projects.

INITIATIVES FOR YOUNG RESEARCHERS

Several new or existing initiatives helped to promote networking among young researchers, and highlight their work with the scientific community.

☞ The network of young researchers within AC41, known as "AMYB" for "ANRS Young Basic Research Community Network" was launched in September. It has a board made up of four young researchers, Philippe Rascle, Sophie Aicher, Viviana Scoca, and Rémi Denise. A [LinkedIn page](#), linked to the agency's page, was created to disseminate information of interest to members of the network and beyond. It has 91 subscribers.

☞ Six Ph.D. awards were given to young researchers in fundamental science over the year, in partnership with the French Society of Virology. The prize-winners were as follows:

- Marie Armani-Tourret and Jérémy Dufloo for their work on HIV (Dominique Dormont award);
- Marion Delphin and Virgil Rat for their work on viral hepatitis;
- Benoît Arragain and Paul Bastard for their work on emerging viruses.

Everyone was given a prize of EUR1,000, and had the opportunity to present their Ph.D. work at an event bringing together experts from each field. Their profiles were also posted on the agency's website.

☞ In order to support research on arboviruses and as part of the actions carried out by the Arbo-France network, ANRS | Emerging Infectious Diseases launched a call for applications to fund two Ph.D. grants at the end of 2022, on the following themes:

- innovative vector control strategies (not based on the use of chemical insecticides);
- innovative vaccination strategies (excluding inactivated vaccines and evaluation of commercial vaccines).

Scholarships were selected at the beginning of January 2023.

☞ Internationally, ANRS | Emerging Infectious Diseases offers two types of grants for master's degrees:

- scholarships contributing to the emergence of researchers in the agency's partner sites: in 2022, three master's fellowships were awarded to a Senegalese socio-anthropologist and a physician from Burkina Faso to study for the master's degree in "global health in the South" at ISPED/University of Bordeaux, and to a Senegalese doctor to study for the specialised master's degree in "public health" from Institut Pasteur/Cnam;
- the "Françoise Barré-Sinoussi" annual scholarship for excellence, established in 2012 to allow a candidate from sub-Saharan Africa or South-East Asia to study for the master's degree in "global health in the South" (ISPED/University of Bordeaux). In 2022, this scholarship was awarded to a candidate, a clinical study doctor from Côte d'Ivoire, already involved in the activities of the PAC-CI programme, partner site of ANRS | Emerging Infectious Diseases in Côte d'Ivoire.

☞ The coordination group on modelling financially supported young researchers to participate in its annual day seminars in Bordeaux and allowed them to present their work (papers or posters).

ANRS | Emerging Infectious Diseases was created during the COVID-19 pandemic in order to equip France with an agency able to strengthen, through research, the French response to epidemic crises. It has established the ways in which research is organised to strengthen preparedness mechanisms for future epidemics, and to make research one of the foundations of crisis response.

In terms of preparation, ANRS | Infectious diseases mainly relies on the priority research programme and equipment strategy on the prevention and control of emerging infectious diseases (PEPR MIE), which it oversees (see next page)

In terms of crisis response, it is through the experience of its commitment to recent epidemics on diverse scales (COVID-19, mpox, hepatitis of unknown aetiology, Sudan Ebola strain, vaccine-derived poliomyelitis, bronchiolitis, etc.) that ANRS | Infectious diseases developed a crisis response system in synergy with the national acceleration strategy "Emerging infectious diseases and nuclear, radiological, biological and chemical threats".

COVID-19 - CAPNET AND STANDBY STATUS

With the end of the state of health emergency since 1 August, CAPNET (*ad hoc* steering committee for therapeutic trials and other research on COVID-19), set up to organise French COVID-19 research, was placed on standby.

This scheme was based on:

- the creation of a COVID-19 scientific advisory board (CS) from REACTing, then ANRS | Emerging Infectious Diseases from 1 January 2021, in charge of defining evolving research priorities and the scientific and methodological evaluation of projects requesting a "national research priority" label;

- the establishment of an *ad hoc* steering committee for therapeutic trials and other research on COVID-19 (CAPNET committee), a consultative body consisting of various stakeholders involved in human research (HR), aiming to regulate vaccine studies, clinical studies (type 1, 2 and 3 human research, and non-human research) and pre-clinical studies on COVID-19 in order to accelerate those falling within the scope of national priorities and are the most promising. The agency provided secretarial resources for CAPNET;

- the creation of a "National Research Priority" (PNR) label awarded by the CAPNET committee to projects submitted on the basis of the scientific and methodological evaluation of the agency's Scientific Advisory Board on COVID-19. This label allowed exclusive access to an accelerated procedure for evaluating the regulatory authorisation dossier (CPP (IEC/IRB), ANSM), specific value creation relating to inclusions carried out via the research and clinical trial information and management system (SIGREC), together with any funding.

Since 2020, over 250 projects have been reviewed by the Agency's Scientific Advisory Board on COVID-19 and CAPNET, enabling the PNR label to be awarded to 106 studies amounting to EUR 52 million in funding.

OTHER EMERGING DISEASES - DEVELOPMENT OF AN "EMERGING DISEASES SYSTEM"

In addition to COVID-19, 2022 was marked by several crises due to the emergence or re-emergence of a pathogen: hepatitis of unknown origin, mpox, poliomyelitis derived from a vaccine strain, Ebola (Sudan strain). This is the context in which the agency developed a research response system in the event of emerging diseases. This system, currently being finalised, includes three response levels:

COORDINATION OF RESEARCH DURING THE EPIDEMIC PERIOD

🏠 LEVEL 1

Implementation of enhanced scientific monitoring in the event of an epidemic crisis, definition of preventive research priorities (preparedness for crises) in collaboration with scientific communities, expert groups, and associations, information production for public decision-makers (level applied in response to the emergence of hepatitis of unknown origin, poliomyelitis derived from a vaccine strain and Sudan Ebola strain);

🏠 LEVEL 2

Releasing emergency funding in order to implement research actions within the framework of research priorities established at level 1 and coordination with European and international responses (level applied in response to the mpox crisis);

🏠 LEVEL 3

In the event of a crisis requiring enhanced coordination at the national level, implementation of specific response mechanisms coordinated with all stakeholders involved in French research.

In 2022, the agency continued to step up its French research coordination efforts to prepare for future health crises caused by emerging or re-emerging infectious diseases. It was therefore possible to propose and build new methods based on the agency's experience in historical diseases (HIV, viral hepatitis, STIs, and tuberculosis) together with the experience acquired during the COVID-19 epidemic, and in close connection with national and international reflections and actions, to support French research over the coming years.

NATIONAL LEVEL: PRIORITY RESEARCH PROGRAMME AND EQUIPMENT STRATEGY ON THE PREVENTION AND CONTROL OF EMERGING INFECTIOUS DISEASES (PEPR MIE)

In order to prepare France to face a new major health crisis, in 2021 the government launched a "Emerging Infectious Diseases and Nuclear, Radiological, Biological and Chemical Threats" (MIE-MN) national acceleration strategy, which is part of the 2030 Health Innovation component of France 2030. ANRS | Emerging Infectious Diseases plays a major role for Inserm in this acceleration strategy: central intervention within the framework of research measures, participation in the management and monitoring of other measures, particularly for the innovation component, the organisational component of crisis prevention, preparedness, and management, and the training component.

The implementation of ambitious research projects is essential in order to better understand, prevent, and control the emergence of infectious diseases, but also to develop countermeasures to diagnose, protect or treat individuals. Hence, a global integrated response can be put in place to limit their impacts.

The scientific foundation of acceleration strategies is made up of priority research programmes and equipment strategies (PEPR), new mechanisms put in place by the government to build or consolidate French leadership in priority scientific fields at national or European level and liable to lead to large-scale transformation. As part of the MIE-MN acceleration strategy, two complementary PEPR strategies are being implemented in close collaboration over five years:

PEPR MIE

which aims to effectively prevent and control emerging and re-emerging infectious diseases at individual and collective level and to enable better preparedness for the risk of an epidemic and/or health crisis;

PEPR PREZODE

which focuses on the prevention of emerging zoonoses (viruses, bacteria or parasites transmitted to humans by animals or insects).

ANRS | Emerging Infectious Diseases has been appointed, for Inserm, as the scientific manager and operator of the priority research programme and equipment strategy on the prevention and control of emerging infectious diseases (PEPR MIE), with EUR 80 million. The agency worked in conjunction with all of its French academic partners to launch this priority research programme and equipment strategy (PEPR) in 2022, with the official validation of the proposed programme in August 2022, followed by the preparation of the first call for projects of the priority research programme and equipment strategy on the prevention and control of emerging infectious diseases (PEPR MIE) launched in February 2023.

Priority research programme and equipment strategy on the prevention and control of emerging infectious diseases (PEPR MIE) to fund, coordinate, and lead research:

UNDERSTAND

ACQUIRE FUNDAMENTAL KNOWLEDGE ON EMERGING INFECTIOUS DISEASES...

Work package #1

- Prevent and limit the mechanisms for emergence
- Understand the molecular mechanisms related to infections and contributing to the developing of counter-measures for the prevention and treatment of these infectious diseases

PREPARE

...PROMOTE INNOVATION IN DIAGNOSIS, VACCINES AND TREATMENTS...

Work package #2

- Treatment sector
- Vaccine sector
- Diagnosis sector

...AND ALLOW PUBLIC POLICIES AND SOCIETY TO DEAL WITH EPIDEMIC CRISES

Work package #3

- Clarify the public decision-making process
- Assess the impact of possible scenarios
- Allow diverse populations to be informed and involved
- Promote free adoption of the proposed measures
- Offset the negative impacts of these measures

COORDINATION AND SCIENTIFIC LEADERSHIP

Work package #4

THE PEPR MIE SHOULD ALLOW:

- better preparation for the pandemic risk,
- faster and more effective response capability (detection, prevention, treatment);
- a significant increase in cohesion and reactivity among the French scientific community in the next pandemic, notably through its capacity for rapid transfer and industrial scale-up of results and resources born out of academic research and/or public/private partnerships.

It is presented based on three types of actions for supporting research:

- **Three successive calls for projects (CFP)** with a view to supporting ambitious structuring fundamental research projects, in public health and human and social sciences, and R&D (TRL between 1 and 3).
This series of CFP in 2023, 2024 and 2025 will notably offer support for projects at different stages of development over time, and thus allow the research continuum to move forward so as to then benefit from support by MIE-MN acceleration strategy measures at a later stage in the process.
Each CFP will cover the three branches of the PEPR MIE. Priority research topics will be identified for each branch, and will be re-assessed for each subsequent call for projects.
- **Three successive calls for expressions of interest (CEI)** for funding research equipment and infrastructure, planned in 2023, 2024 and 2025.
- **A call for applicants for chairs** planned in 2024.

In particular, the agency monitors the link with measures supporting the pre-development and development phases, with the objective of accelerating the application of research project results, notably supported by the priority research programme and equipment strategy on the prevention and control of emerging infectious diseases (PEPR MIE), to promote the development of innovative countermeasures able to be applied on an industrial scale, together with the measure targeting national platforms enabling the demonstration or validation of countermeasures in accordance with national and international standards, between crises and with the capacity to increase in strength to assess countermeasures in the event of a crisis.

Hence, in 2022, as part of the "Emerging Infectious Diseases and Nuclear, Radiological, Biological and Chemical Threats" (MIE-MN) acceleration strategy, ANRS | Emerging Infectious Diseases:

☒ contributed to the construction of the CA-TRIEM consortium, a collective of 24 members of the French innovation ecosystem led by Inserm Transfert and SATT PULSALYS, prize-winner of the "development/pre-development" call for projects of the "Emerging Infectious Diseases and

Nuclear, Radiological, Biological and Chemical Threats" (MIE-MN) acceleration strategy in February 2023;

☒ created links with BPI France, an operator of calls for partnership research projects for ambitious development projects;

☒ coordinated reflections and proposals for funding by mutual agreement aimed at continuing the deployment and extension to all emerging infectious diseases of the national platforms set up as part of the COVID-19 crisis, particularly for platforms led by Inserm and the agency (Discovery, Covireivac, EMERGEN);

☒ participated in the initial work, including feedback, carried out by the government to equip the R&D&I ecosystem with a rapid and organised mobilisation capacity for healthcare services, research and innovation (including evaluation or certification), together with industrial capacity to produce and renew stocks quickly and efficiently, in order to respond, owing to organisational mechanisms and adapted or exceptional regulatory procedures and able to be mobilised from the first alerts, as effectively as possible in the event of a new health crisis.

In addition, the agency oversees the integration of this programme into the national research ecosystem, by ensuring complementarity with other existing or reflection mechanisms to provide a global coordinated response to the challenges of research in emerging infectious diseases. In particular, a link is being put in place with the priority research programme and equipment strategy (PEPR) for the "digital health" and "Biotherapies and bioproduction of innovative therapies" acceleration strategies, with calls for projects supported by other organisations, foundations or funding agencies, notably the ANR, with work carried out by partner agencies or with emergency mechanisms to support research in times of crisis.

While 2022 has been a year of reflection and construction with partners, the upcoming period should allow the agency to consolidate its role in coordinating research on emerging infectious diseases, in preparation for future emerging diseases or re-emerging diseases, but also in response to crises. ANRS | Emerging Infectious Diseases will thus be able to fully support the structuring of the French research landscape on this theme, to ensure optimal use of available resources, improve responsiveness, support scientific excellence, and an ability to innovate to allow a better response to future crises while confirming France's leadership in this field.

ON A EUROPEAN LEVEL: THE BE READY CONSORTIUM

Given its international commitment to preparedness and response to pandemics, the European Commission entrusted the agency with coordinating the Be Ready CSA (*Building a European Strategic Research and innovation Area in Direct Synergy with other EU and International Initiatives for Pandemic Preparedness*), since 1 June 2022 and for a period of three years. The BE READY project aims to set in place the foundations of the future European partnership for pandemic preparedness. Its objective is to contribute to the creation of a European Research and Innovation

Area, which will enable better coordination and support of research and innovation in pandemic preparedness, thereby improving the European Union's ability to predict and respond to emerging infectious threats. As part of this initiative, ANRS | Emerging Infectious Diseases is specifically responsible for defining the strategic research and innovation agenda, coordinating a consortium made up of 24 public organisations and institutions from 15 different countries that play a key role in the preparation and response activities in their respective countries.

ON AN INTERNATIONAL LEVEL

ANRS | Emerging Infectious Diseases is part of several international networks.

GLOPID-R

The agency is a member of the Global Health Security Initiative and Global Research Collaboration for Infectious Disease Preparedness (GloPID-R), a network of research funding agencies related to preparedness and response to emerging infectious diseases. GloPID-R stimulates better coordination of responses to epidemics by analysing the current state of knowledge, identifying scientific gaps to be funded as a priority, creating a framework for data sharing, and improving the rapid allocation of research funds. Founded in 2013, the project is funded by the Horizon Europe research and innovation programme.

Yazdan Yazdanpanah has been one of the Vice Presidents of the GloPID-R alliance since 2018. The agency is also represented in three GloPID-R working groups, the Data Sharing Working Group, the Clinical Trials Network Working Group, and the Low- and Middle-Income Working Group.

The agency and the GloPID-R alliance also pool their resources for the implementation of major initiatives aimed at improving international research funding, like the development of regional research funding hubs in Asia, Southern Africa and South America, or calls for coordinated and

multi-country projects on infectious diseases.

ISARIC

The agency is a member of the International Severe Acute Respiratory and emerging Infection Consortium (ISARIC), a federation of clinical research networks created in 2011, and bringing together more than 50 members worldwide. The aim of this federation is to coordinate its member network to produce and disseminate clinical research data on infectious diseases with epidemic potential, and thus promote better global preparedness for emerging diseases. In response to the COVID-19 epidemic, it developed a standardised, open-access clinical data collection platform in January 2020. The agency joined the ISARIC network in November 2021. The agency takes part in coordination and information meetings with other members of the network, and in discussions on the evolution of the COVID-19 platform.

ONE SUSTAINABLE HEALTH FORUM

The OSH Forum is an initiative supported by the foundation Une Santé Durable pour Tous (USDT) in partnership with the World Health Summit (WHS) launched in October 2020, the goal of which is to provide a set of operational recommendations in the form of the "OSH Declaration" aimed at guiding international public health stakeholders in the development of sustainable and holistic policies and initiatives. The agency has been a member of the strategic partners committee of the initiative since joining the initiative in May 2021. As such, it takes part in exploratory meetings and discussions on the recommendations to be produced.

EDCTP

ANRS | Emerging Infectious Diseases also continues to be an active member of the European and Developing Countries Clinical Trials Partnership (EDCTP). It is strongly involved in defining the directions of the partnership, and in operational aspects. It takes part in the EDCTP general meeting alongside the Ministry of Higher Education and Research, and thus acts as a liaison for all French research institutions.

- Éric D'Ortenzio, Head of the Strategy & Partnerships Department of ANRS | Emerging Infectious Diseases has represented France within the EDCTP Executive Committee since May 2022 (taking over from Yazdan Yazdanpanah, 2019 to 2022). Two technical advisers from the agency also take part in the EDCTP general meeting;
- ANRS | Emerging Infectious Diseases, in conjunction with ITMO I3M and the Ministry of Higher Education and Research, leads an EDCTP mirror group as part of Aviesan Sud in order to share information and stimulate cooperation between French institutions;
- lastly, the agency is responsible for centralising French *in-kind contributions*, and acts as an *interface between French research institutions and the administrative teams within the EDCTP programme*.

Lastly, the agency's participation in research coordination efforts at national, European or global level also involves providing expertise, notably corresponding to participation of its staff in working groups, scientific advisory boards, network management, projects, etc. This representation takes place, for example, within initiatives such as EU-Response, ECRAID, ERINHA, ICE-HBV.

STRUCTURING: RESEARCH NETWORKS AND INFRASTRUCTURES

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ANRS | Emerging Infectious Diseases supports the strengthening of national and global research capacity by setting in place or supporting infrastructure and networks. This was one of the historic strengths of the ANRS, and the mobilisation in response to the COVID-19 crisis was decisive in the agency's ability and speed in implementing research projects from the start of the epidemic. Hence, gradually opening up existing infrastructure to emerging infectious diseases and creating or maintaining infrastructure dedicated to emerging infectious diseases were among the agency's priorities in 2022, and will continue to be pursued in the coming years.

These infrastructures include:

ANRS | EMERGING INFECTIOUS DISEASES NETWORK OF CLINICAL RESEARCH HOSPITALS

In France and in low- and middle-income countries (LMIC): a key network of partners for the implementation of clinical studies and supported by the agency, notably through the funding of a network of clinical and biological study monitors in France, including overseas territories, and supporting research activities in clinical departments and hospital laboratories as part of the agency's projects.

INTERNATIONAL NETWORK OF VIROLOGY AND MEDICAL PHARMACOLOGY

Formerly known as CA43, this extremely active network is recognised both in France and internationally. It is involved in national, European, and global recommendations, bringing together dozens of laboratories across the country, including overseas departments, as well as internationally, with partner laboratories in LMIC. From the beginning of the COVID-19 pandemic, this network has been able to offer its expertise and tools to crisis response teams. Organisational changes took place in 2022, and since 2023, the network has been formally part of the agency's research infrastructures and has been identified and equipped as such. Its roles have not been modified, and correspond to the interface between scientific coordination, monitoring

and project building. Its organisation and coordination have been reviewed to integrate emerging diseases, starting with respiratory viral diseases, and working on increasing the strength of its international dimension. An annual plenary meeting was held in 2022.

NETWORK OF METHODOLOGY AND MANAGEMENT CENTRES (MMC) IN FRANCE AND IN LMIC

These structures carry out some of the tasks associated with the sponsor of clinical studies on behalf of the agency, particularly involving the technical and regulatory management of the study, methodology, and data management. In order to promptly mobilise experienced clinical research professionals for studies supported by the agency, multi annual allocation, and access to regulatory tools and information are granted for the most active MMCs. To date, seven MMCs in France and a binational France/ Côte d'Ivoire MMC (MEREVA) have received cross-sectional support from the agency, constituting the core network, with other peripheral structures working with the agency in the context of specific projects. In 2022, a new collaborative process was put in place, with the first joint accreditation of a MMC with AP-HP, which brings together the skills of the teams to ensure the rapid and coordinated launch of studies on infectious diseases in France and internationally.

CLINICAL RESEARCH PLATFORMS

- With the COVID-19 crisis, Inserm and the agency have been working hard to support the implementation of national and European clinical trial platforms, but also in Africa, to provide a structure for the rapid implementation of studies. Particularly of note are the Covireivac vaccine trial platform, which allows academic or industrial COVID-19 studies in France and Africa to be implemented, together with the Discovery/SolidAct therapeutic trial platforms as part of EU-RESPONSE for COVID-19 or MPX-RESPONSE for monkeypox infection, with European structuring and support for a global trial coordinated by the agency, the INTEGRATE platform for research on Lassa fever in Nigeria, and the ANTICOV plat-

form trial for the identification of treatments for moderate forms of COVID-19, bringing together 14 countries in Africa and South America.

- In 2022, the agency continued to support structuring cohorts on HIV and viral hepatitis. A number of organisational changes were scheduled in keeping with the results of the evaluation of the 12 ANRS | Emerging Infectious Diseases cohorts carried out at the end of 2021 by the cohort evaluation committee. New cohorts have also been proposed for implementation from 2023, subject to favourable specific scientific evaluation. These cohorts are valuable due to the quantity and quality of the data and samples collected and able to be made available to new research projects. Cohorts are also structures enabling the implementation of ancillary studies targeting specific scientific questions or responding to an urgent need for knowledge acquisition during an epidemic period. As part of its scientific strategy, and in keeping with the recommendations of the cohort evaluation committee, ANRS | Emerging Infectious Diseases plans to develop scientific leadership around the cohorts, improve their visibility, and facilitate the reuse of data and biological collections from studies by the scientific community.

GENOMIC SURVEILLANCE AND RESEARCH NETWORKS

In response to the COVID-19 crisis, two structuring projects were set up in 2021, EMERGEN coordinated by ANRS | Emerging Infectious Diseases and Santé publique France in France and in overseas territories, and AFROSCREEN, funded by AFD as part of the Santé en Commun initiative, coordinated and implemented by ANRS | Emerging Infectious Diseases, IRD and Institut Pasteur, and cooperation with 13 African countries.

- In 2022, EMERGEN made it possible to continue strengthening sequencing capacities, with more than 700,000 sequences produced since January 2021, with nearly 600,000 available internationally via GISAID, placing France in 5th place in the global ranking for sequence sharing. A number of bioinformatics platforms have been developed by the IFB (French Institute of Bioinformatics) to collect, manage, analyse, and allow access to data and metadata produced in the context of the project, and moreover by Inserm with a HDH (Health Data Host Certification) platform for access to personal data, also allowing matching with other necessary health data due to dedicated secure spaces for the projects. To date, access to data for research purposes remains limited by regulatory and organisational constraints. In terms of public health, regular analyses of SARS-CoV-2 sequences by Santé publique France and the CNR of respiratory viruses have enabled the rapid detection of new variants of concern since 2021, and contributed to the better interpretation of pandemic dynamics and adjustment of control measures by the Ministry of Health. All results have been widely disseminated (on a weekly basis) to health authorities at national and regional level, microbiologists, infectious disease specialists and other scientists, along with the media, using various channels. The research component of the project allowed it to be implemented in 2022, and following a rigorous and transparent scientific evaluation, 15 research projects with high potential for impact and an infrastructure project on SARS-CoV-2 variants for a total sum of EUR 9.3 million, according to four predefined areas:

- anticipation and analysis of the importance of variants based on an "experimental research and models" component;
- identification, characterisation and analysis of the changes in new variants in cohorts;
- modelling the changes and impact of these variants;
- and lastly, evaluating the use of wastewater as an instrument for monitoring variants.

The rapid implementation of research projects and the strong link between research teams from different disciplines have made it possible to rapidly obtain results which helped guide decision-makers in crisis management, and led to numerous high-impact scientific communications.

The end of the state of emergency and the changes in the reimbursement system for sequencing in 2022 accelerated the reorganisation of the consortium to ensure business continuity during the post-crisis period, but also to design development proposals to transpose the experience acquired by the consortium to any emerging or re-emerging infectious pathogens, starting with other respiratory viruses. The ultimate objective will be to have an existing and functional infrastructure during the periods between crises, and to allow for extra capacity during health crises, with all activities taking place between crises aiming to prepare for a crisis. EMERGEN will continue to include a *One Health* dimension. Regulatory (personal data) and open science issues (charter on access and value creation) may be anticipated so as to avoid the pitfalls of emergency implementation.

- AFROSCREEN is a multi-institutional project that aims to strengthen genomic sequencing and surveillance capabilities in sub-Saharan Africa, thus meeting the need for equitable access to genomics for global health. Funded by AFD and coordinated by the agency, the project is being led by a consortium of three institutes: ANRS | Emerging Infectious Diseases, Institut Pasteur and IRD, and 25 partners in 13 African countries: Benin, Burkina Faso, Cameroon, Central African Republic, Democratic Republic of the Congo, Ghana, Madagascar, Mali, Niger, Republic of Côte d'Ivoire, Republic of Guinea, Senegal, and Togo. It is being conducted in coordination with Africa CDC/PGI and WHO-AFRO, with the aim of creating a synergy of activities aiming for a common goal. AFROSCREEN provides training, materials, and reagents to strengthen the capacity of partners to identify virus mutations. In 2022, with support from AFROSCREEN, 20 laboratories were able to perform 7,200 PCR screening tests for SARS-CoV-2 mutations, and 11 laboratories submitted 8,000 SARS-CoV-2 sequences on the GISAID open source platform. The project also adapted to epidemiological developments, and has begun to provide reagents for the diagnosis and characterisation of priority viruses in the various countries (Ebola, mpox, measles, dengue fever, etc.). In addition, AFROSCREEN contributed to the creation and strengthening of 75 SARS-CoV-2 sentinel monitoring sites in 11 countries. Two webinars were organised as part

of the project, and can be viewed on the project website. AFROSCREEN facilitates the development of genomic detection, characterisation, and surveillance of pathogens for the preparation of future epidemics in African countries. The consolidated platforms will also enable research projects that will support scientific capacity while addressing the challenges of "*One Health - Global Health*".

✚ The agency biobank is a national infrastructure that manages and stores most samples from agency-supported studies (more than 1.7 million tubes), aimed at improving the quality of management and storage of biological samples, in order to ensure the availability of biological collections for research teams, while ensuring compliance with regulations and ethics. The biobank has proven its robustness by being able to absorb the increase in activity due to the introduction of emerging diseases within the agency's remit, particularly during the COVID-19 crisis. In 2022, the volume of activities did not decrease, particularly in connection with the large number of ongoing COVID-19 studies. Discussions on the agency's strategic priorities around biological specimens and the positioning of this biobank in conjunction with other national and international initiatives have led to the development of areas of work for the coming period in order to increase the visibility of existing collections and data, and facilitate their reuse; define a strategy for the development of future collections; to strengthen the biobank and, in particular, its emergency response capacity; and to maintain and strengthen the agency's support for the constitution and management of biological collections in LMIC, taking into account local regulations, constraints, and ethical concerns.

VARIOUS BODIES WITHIN THE AGENCY: COMPOSITION IN 2022

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- **Roger Le Grand**, representative from the CEA
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- **Christian Rabaud**, qualified person
- **Yazdan Yazdanpanah**, Director of ANRS | Emerging Infectious Diseases
- **Jean-François Sicard**, Secretary-General of ANRS | Emerging Infectious Diseases
- **Thierry Menvielle**, Head of Financial Affairs at ANRS | Emerging Infectious Diseases

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- **Jean-François Sicard**, Secretary-General of ANRS | Emerging Infectious Diseases
- **Thierry Menvielle**, Head of Financial Affairs at ANRS | Emerging Infectious Diseases

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- Conference of university hospital managing directors
- National health conference
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SECTOR-BASED SCIENTIFIC COMMITTEES

- CSS11 - Basic research on HIV/AIDS, tuberculosis and STIs: from virus to host
Chair:
Nicolas Chomont, University of Montreal, Canada
- CSS12 - Basic research on viral hepatitis
Chair:
Massimo Levrero, Lyon Cancer Research Centre (CRCL), Lyon
- CSS13 - Clinical research
Chairs:
Alexandra Calmy, University Hospitals of Geneva, Switzerland, and **Marc Bourlière**, Hôpital Saint-Joseph, Marseille
- CSS14 - Research in public health and human and social sciences
Chairs:
Marie Préau, Inserm and Université Lyon 2, and **Joseph Larmarange**, Population and Development Centre (Ceped), IRD, *Paris*

SCIENTIFIC LEADERSHIP GROUPS

AC41 – Host/virus interactions

Michaela Müller-Truwin (Institut Pasteur)

AC42 – Hepatitis virus

François-Loïc Cosset (CIRI)

AC43 – Medical virology

Vincent Calvez (AP-HP), **Stéphane Chevaliez**

(AH-HP), **Avelin Aghokeng** (IRD)

AC44 – HIV clinical research **Olivier Lambotte**

(AP-HP) and **Serge Eholié** (Treichville

University Hospital, Abidjan)

AC45 – Hepatitis clinical research

Victor de Ledinghen (Bordeaux University

Hospital)

AC46 – Research in public health

and human science

Didier Ekouevi (Inserm) and **Bruno Spire**

(Inserm)

AC47 – Dynamics and control

of HIV and viral hepatitis

Dominique Costagliola (Inserm)

Tuberculosis coordination group

Olivier Neyrolles (IPBS, CNRS, Toulouse)

and **François-Xavier Blanc** (Nantes University

Hospital)

Coordination group on "Human-to-human

transmission of respiratory viruses"

Arnaud Fontanet (Institut Pasteur)

Coordination group on Respiratory viral

diseases

Karine Lacombe (AP-HP, University of

Bordeaux) and **Edouard Lhomme**

(Bordeaux University Hospital, University of

Bordeaux)

Coordination group on long COVID

Olivier Robineau (Lille University Hospital),

Marc Bardou (Dijon University Hospital)

and **Henri Partouche** (Université Paris Cité)

Coordination group on modelling

Vittoria Colizza (Inserm)

and **Simon Cauchemez** (Institut Pasteur)

Coordination group on HPV

Joseph Monsonego (Eurogyn)

and **Christine Katlama** (AP-HP)

RHIVIERA task force

Asier Sáez-Cirión (Institut Pasteur),

Christine Rouzioux (Université Paris Cité)

HBV Cure task force

Fabien Zoulim (Hospices Civils de Lyon,

University of Lyon, Inserm)

Arbo-France

Xavier de Lamballerie (Aix Marseille

Université) and **Anne-Bella Failloux**

(Institut Pasteur)

Viral haemorrhagic fever WG

Sylvain Baize (Institut Pasteur)

and **Marie Jaspard** (Alima)

AvATher WG

Lionel Piroth (Dijon University Hospital)

and **Laurence Weiss** (AP-HP)

Vaccine-respiratory viral diseases WG -

Brigitte Autran (Sorbonne Université, Covars)

and **Odile Launay** (AP-HP)

Working group on "Vaccine-based

interventional research" **Elisabeth Botelho-**

Nevers (Saint-Etienne University Hospital)

and **Pierre Verger** (ORS PACA)

WG – Mother to child between AC41-44

Albert Faye (AP-HP), **Pierre Frange** (AP-HP),

Valériane Leroy (Inserm)

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