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NOVEMBER 5
2025

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STRENGTHENING COLLABORATION WITH FRENCH COHORTS FOR HEALTH INNOVATION

COHORT INNOVATION DAY


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3. The 2024 EU Industrial R&D Investment Scoreboard
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PROGRAM

8H45 – 9H00 : **Opening Remarks**	**Didier SAMUEL,** Président Directeur Général, Inserm **Marc BONNEVILLE,** President, Ariis **Christian DELEUZE,** Président, Medicen Paris Region
9H00– 9H25 : **Presentation and overview of Cohorts structuration in France**	**Benoit LABARTHE,** Responsible Recherche et Transfert de Technologie, Agence de l'Innovation en Santé **Gregoire REY,** Directeur de l'Infrastructure nationale France Cohortes, Inserm
9H25 – 10H15: **Round Table "Cohorts as Drivers of Innovation for Businesses – Roundtable and Testimonials"**	**Linda Aidouni,** RWE Partnership & Innovation, Medical Evidence Generation Pfizer Global **Fabrice CARRAT,** Coordinateur de la Cohorte HEPATER **Mireille CARALP,** Health Data Business Development Director, Inserm Transfert **Christophe HEZODE,** Directeur Médical Liver Disease, Gilead **Alexandre MEBAZAA,** Coordinateur de la Cohorte FROG-ICU
10H15 – 11H00: **Overview cohort**	**FRENCHIE –** Gabriel Philippe STEG **SFDT1 –** Laura SABLONE **French Gut –** Pr. Robert BENAMOUZIG
11H00– 11H15 :	**BREAK**

11H15 – 12H05 : **Round table "AI for Cohorts: What Does the Future Hold?"**	**Sofiane KAB,** Coordinateur Cohort CONSTANCES, Inserm **Anne-Laure MARTIN,** Directrice, direction des Datas et des Partenariats, UNICANCER **Emmanuel PHAM,** SVP Science & Customer Experience Europe, Nova In Silico **Mati LOPEZ GRANCHA,** Development Real World Evidence Lead, Sanofi **Raphael PORCHER,** Professeur de biostatistique, Inserm, AP-HP, Université Paris Cité
12H05 – 12H35 : **Overview Cohort**	**CDK-Rein –** Natalia ALENCAR DE PINHO **IMMINENT –** David Launay
12H35 – 12H50 : **Keynote Industrial testimony**	**Jacques VOLCKMANN,** Global head External innovation, Translational medicine unit Research & development, Sanofi
12H50 – 13H20 : **Keynote EU & Cohort**	**Daria JULKOWSKA,** Scientific Coordinator, ERDERA **Stefanie HAEBERLE,** Clinical research coordinator, ERDERA **Marco ROOS,** Group leader Leiden Biosemantics group, ERDERA
13H20 – 14H00 :	**LUNCH BREAK**
14H00 – 18H00 :	**B2B SESSIONS**

SOMMAIRE


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CARDIOVASCULAR AND METABOLIC DISEASES

Cohort SURVI

AP-HP

STUDIES STATUS :
Follow-up

NUMBER OF PARTICIPANTS / PATIENTS :
1 000 participants/ patients targeted
1 145 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
NCT04746534 and NCT03518099

Acute mesenteric ischemia (AMI) is one of the most severe of vascular and digestive emergencies, leading to an early and high mortality that has remained unchanged for decades. (Eslami et al. Vascular 2016; Reintam et al.

Crit Care 2024) AMI may involve a large group of patients, with an incidence increasing from 25 to 217/100,000 person- years after 70 and 85 years-old. Developed on the model of “stroke units”, a first-of-its-kind intensive care unit dedicated to the 24/7 care of AMI has been implemented in France at Beaujon Hospital, APHP, in 2016 (SURVI unit).

In the recent international cohort AMESI involving 32 centers, Reintam et al. reported in-hospital mortality of 8% in the French SURVI unit vs. 58% in the 31 other non-specialized centers. Indeed, after 7 years and 1000+ patients admitted, our results have shown survival > 70%, without intestinal resection in >50% of patients. (Corcos et al. Clin Gastroenterol Hepatol 2013) This represents not only a therapeutic progress, but also a major diagnostic hope.

SURVI has significantly propelled patient recruitment, a crucial step for advancements in AMI research that nurtures hope for the future discovery of new diagnostic tools for an early diagnosis, the clinical application of which could bring major changes in the recognition, epidemiology, treatment, and prognosis of the disease. With funding from the MSD-Avenir sponsorship (1.9M€), SURVI (Intestinal Stroke Center) has been able to initiate collaborations and conduct unique clinical and molecular studies. Our preliminary achievements have thus enabled: the creation, implementation and monitoring of SURVIBASE, an ongoing prospective cohort of > 1000 patients with mesenteric ischemia or digestive vascular diseases (NCT04746534) with an already operational governance. SURVIBASE has contributed to:

1) > 20 impactful publications, such as criteria for early suspicion of AMI in the emergency rooms, CT protocols enhancing diagnostic performance and interobserver variability, development of the non-invasive “SURVI-score” for intestinal necrosis (now included in several international guidelines, WSES 2017-2022, British Society of Coloproctology 2021, ESPEN 2018, VALDIG 2024), and of an anatomical classification proposal for the superior mesenteric artery (SMA) to standardize clinical and research reporting;

2) the SURVIBIO biobank (NCT03518099) containing biological samples (blood, urine) from 400+ AMI patients and non-ischemic abdominal pain controls ;

3) the identification of diagnostic biomarker candidates that have already led to the filing of an international patent ;

4) the identification of candidate academic centers for a future national multicentric extension of the SURVIBASE and a multicentric care/research network. This unique prospective observational cohort and associated biobank is now nationally and internationally recognized and drives transformative research projects.

Website

https://www.survi.fr/en

Paris Prospective Study III (PPS3)

INSERM

STUDIES STATUS :
Follow-up

NUMBER OF PARTICIPANTS / PATIENTS :
10 157 participants/ patients targeted
10 157 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
NCT00741728 + EudraCT 2007-A01386-47

This is an ongoing French prospective cohort study aiming to address novel determinants of incident cardiovascular disease events in 10,157 healthy males and females. This is an INSERM promoted cohort. PPS3 is unique for 3 main reasons:

1. A deep phenotyping of vascular ageing since all the study participants underwent a carotid echotracking permitting to measure structural and functional vascular aging biomarkers together with an evaluation of baroreflex sensitivity; we are further currently performing radiomics analysis on raw data;

2. A huge biobank with 20 aliquoted tubes per participants representing a total of 200,000 samples stored at -80° in a dedicated platform; in addition to standard assessments (lipids, renal function, blood counts ...), we have assessed biomarkers from several disease-pathways such as hs-CRP, IL-6 and IL-1 bêta (immuno inflammatory bms), NT-proBNP (mycardial stress) and ultra-sensitive troponin I (myocardial damage) for the whole cohort.

3. A follow-up over 12 years with 83% retention rate, 800 incident and clinically validated CVD events. In addition to the event follow-up, participants are contacted every two years to update their health status by questionnaire. These follow-up questionnaires address health status sleep health (duration, chronotype, sleep apnea, excessive daytime sleepiness) depression, medications, life style risk factors and cancer onset. A second re-examination is about to start mid May 25 (all ethical agreements obtained) permitting to have in particular 2 assessments of vascular aging evaluation 14 years a part.

The cohort has obtained several high competing grants including 3 consecutive ANR (French National Agency for Research), one Horizon grant (partner), and several grants from Foundations. Besides, the cohort received additional support from INSERM in the framework of its International Research Project.

Since 2015, more than 40 scientific papers of high quality have been published. They have in particular validated the measurements and scientific value of vascular aging biomarkers, and of the biobank. We can cite a series of papers showing the association of vascular aging biomarkers with incident depression and several clinical outcomes. We have also recently showing for the first time the associations of ultra-sensitive troponin I and incident CVD events.

We believe that the extremely well-annotated and deeply phenotyped of the cohort, its 12 years follow-up with very low drop out and its recognized scientific value make PPS3 a very important tool in the field of cardiovascular disease. We are clearly opened for collaboration with industrial partners.

Website

https://epp3.org/fr

French registry of Sudden Unexpected Death Ininfancy (SUDI)

NANTES UNIVERSITY HOSPITAL

STUDIES STATUS :
Recruitement
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
10 000 participants/ patients targeted
2 197 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
not specified

Sudden unexpected death in infancy (SUDI) is defined as "a death occurring suddenly in a child under 1 year of age, when nothing in the known history could have predicted it"; following all the investigations recommended by the French National Authority for Health (HAS), including analysis of the history and a certain number of recommended additional examinations (biology, imaging, autopsy, etc.), either the cause of death is explained (infection, cardiac or metabolic disease, accidental or inflicted trauma, asphyxia, etc.), or it remains unexplained. In such cases, either the cause of death is explained (infection, cardiac or metabolic disease, accidental or inflicted trauma, asphyxia, etc.), or it remains unexplained and is referred to as Sudden Infant Death Syndrome (SIDS).

In France, the HAS has set 2 years as the upper age limit for SUDI. In 2007, the HAS published recommendations on the management of SUDI for SUDI referal centers (CRMIN), describing the diagnostic procedures to be implemented. There is very little research into this pathology, even though it still affects 250 to 350 infants a year, 50 to 70% of whom die of unexplained causes.

It is thus the leading cause of death between 1 month and 1 year in France. In May 2015, the National Association of Reference Centers for MIN (ANCReMIN) in collaboration with the Nantes University Hospital set up a French registry of sudden unexpected death in infancy (OMIN registry) to collect nationwide standardised data concerning biological, clinical, environmental and social characteristics of SUDI in children aged 1–2 years. A biobank has existed since July 2020 to store biological samples for each case.

Website

https://www.omin.fr/

EPICARD

AP-HP

STUDIES STATUS :
Study Completed

NUMBER OF PARTICIPANTS / PATIENTS :
2 348 participants/ patients targeted
2 348 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
not specified

Epidemiology of Congenital Heart Defects: A population-based prospective cohort study (EPICARD). EPICARD was a population-based, prospective cohort study with long-term follow-up of all children with a CHD born to women in the Greater Paris area (Paris and its surrounding suburbs).

All cases (live births, terminations of pregnancy for fetal anomaly (TOPFA), fetal deaths) diagnosed in the prenatal period or up to 1 year of age in the birth cohorts between 1 May 2005 and 30 April 2008 born to women residing in Greater Paris were eligible for inclusion. Diagnoses were confirmed in specialised paediatric cardiology departments and for the majority of TOPFA and fetal deaths by a standardised pathology examination. When a pathology exam could not be done the diagnoses were confirmed by a paediatric cardiologist and a specialist in echocardiography in the EPICARD Study group, using the results of prenatal echocardiography examination.

Multiple sources of data including all maternity units, paediatric cardiology and cardiac surgery centres, fetal and neonatal pathology departments, neonatal and paediatric intensive units, infant units and outpatient clinics in Greater Paris and a neighbouring tertiary care centre were regularly consulted to attain completeness of case registrations. Informed consent was obtained from study participants. The last cases included in the study were those in the 2008 birth cohort who were diagnosed in 2009.
Follow-up of children in the EPICARD cohort is now completed and included assessment of children's health and neurodevelopmental outcomes until 8 years of age. Details of coding and classification of cases for the EPICARD Study have been published. Briefly, two paediatric cardiologists in the EPICARD Study group attributed by consensus to each case, one, or in less than 20% of cases, two or up to six, six-digit code(s) of the long list of the International Paediatric and Congenital Cardiac Code.

Several papers have been published based on the data from the EPICARD study a few of which are mentioned below. Others are planned and include studies of growth using multi-level models and predictive models of the long-term outcomes of the newborns with CHD using Machine Learning methods.

Website

not specified

PreciLITH

CHU AMIENS PICARDIE

STUDIES STATUS :
Recruitment
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
2 000 participants/ patients targeted
760 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
NCT0537063

Nephrolithiasis (NL) is the most frequent renal disease, affecting ~ 10% individuals. NL is commonly recurrent with up to 30%, and 50% of individuals experiencing a second episode within 3, or 5 years of their initial presentation, respectively. After each episode of renal colic the risk of recurrence increases and the time lapse between two recurrences decreases. Unfortunately, urological treatment for recurrent NL has been linked to a decline in renal function.

This high incidence rate and the risk of chronic kidney disease associated with recurrent nephrolithiasis are advocating for the development of a strong preventive strategy. However, despite many decades of research, the pathophysiological mechanism underlying NL are still largely unknown. As a consequence, prediction of recurrence remains a challenge and no specific and effective treatment to prevent kidney stone recurrence has emerged. The only effective treatment remains the increase in water intake to keep the urinary output >2L/day and dietary counseling to reduce salt and protein intake.

These goals is very difficult to achieve in many patients with a very poor compliance and therefore limited efficacy. Thus, the dissection of pathophysiological mechanisms causing NL remains a medical priority as it is the first step required to develop a precision medicine approach to treat this frequent human disease. Therefore, we are recruiting a cohort of 2000 patients affected by NL in which we collect an extensive biobanking including blood DNA, PBMCs, Urine cells, plasma, urine and urinary extracellular vesicles. Patients are followed for 5 years with repeated sampling at 1, 3 and 5 years. These trajectory of the disease is also recorded.

Therefore, our cohort will be suitable to perform multiplication analyses to identify prognostic biomarkers and scores and to identify pathophysiological pathways that can be targeted.

Website

not specified

Cohorte Obésité Bichat Louis Mourier (COBILOM)

AP-HP

STUDIES STATUS :
Recruitment
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
420 participants/patients targeted
340 participants/patients already included

CLINICAL.TRIAL.GOV ID :
NCT03538210

The pathophysiological mechanisms of the development of obesity and its comorbidities are still imperfectly understood and the observations made in mouse models are not always transposable to humans. It is therefore necessary to set up cohorts in humans in order to better specify these mechanisms, with collection of both clinical data and biological samples.

Notably, gut, adipose tissue and liver are implicated in metabolic disturbances associated with obesity and interact altogether in the development of inflammation and insulin resistance, but are not easily accessible. We have therefore established a Cohort of adult patients, candidates for bariatric surgery, and primo-operated or re-operated with or without residual obesity (in the event of weight loss failure or digestive complications) within the AP-HP University Hospital groups of Université Paris Cité. The main objective was to systematize the intraoperative collection and storage of biological samples (blood and both frozen and fixed samples of visceral and subcutaneous adipose tissue, stomach, intestine, liver) from well-phenotyped patients (including anthropometric and metabolic anonymized data) and to make it available to institutional or private research teams.

The project planned to include 420 patients from 2018 to 2026 and, to date, 340 subjects have been included. Both clinical data, blood and tissular samples are available for each patient, which makes it a unique cohort.

Several research projects with institutional teams have been initiated, based on the cohort, concerning the study of the renewal and reprogramming of gastric and intestinal stem cells in obesity and after bariatric surgery, phenotypic and functional characterization of gastric and intestinal T lymphocytes and dialogue with the microbiota, role of MAIT cells or hepatic macrophages in metabolic disorders associated with obesity, characterization of subcutaneous and mesenteric TA before and after bariatric surgery, role of peripheral adipose and hepatic clock and identification of biological factors predictive of success or failure of bariatric surgery.

The presentation during the cohort innovative day will make it possible to develop collaborations with other institutional teams or industrial partners in order to implement the projects based on the cohort

by recruiting thanks to diversified expertise. This will allow to improve our knowledge on the development of obesity and its comorbidities and on the mechanisms explaining the beneficial effects of bariatric surgery, in terms of weight loss and improvement of metabolic disorders, which could lead to new therapies.

Website

www.cinfo.fr

FRENCHIE

AP-HP

STUDIES STATUS :
Recruitment
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
30 000 participants/ patients targeted
19 681 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
NCT04050956

FRENCHIE is a multicenter nationwide active cohorte of patients admitted for Acute Myocardial Infarction. Currently, close to 20,000 patients have already been enrolled. Patients are well phenotyped during the index admission.
Follow up is accrued by linkage to the SNDS. Enrolment started in March 2019 and is ongoing. Nested observational studies and randomized trials have been performed within the FRENCHIE cohort.

More information is available in Gautier A, Danchin N, Ducrocq G, Rousseau A, Cottin Y, Cayla G, Prunier F, Durand-Zaleski I, Ravaud P, Angoulvant D, Coste P, Lemesle G, Bouleti C, Popovic B, Ferrari E, Silvain J, Dubreuil O, Lhermusier T, Goube P, Schiele F, Vanzetto G, Aboyans V, Gallet R, Eltchaninoff H, Thuaire C, Dillinger JG, Paganelli F, Gourmelen J, Steg PG, Simon T; FRENCHIE investigators. Rationale and design of the FRENch CoHort of myocardial Infarction Evaluation (FRENCHIE) study. Arch Cardiovasc Dis. 2024 Jun-Jul;117(6-7):417-426. doi: 10.1016/j.acvd.2024.04.004. Epub 2024 May 22. PMID: 38821761.

Website

not specified

HAMA

PAU HOSPITAL

STUDIES STATUS :
Recruitment
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
2 000 participants/ patients targeted
620 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
NCT03755726

Malignant hypertension (MHT) is a critical condition marked by acute hypertensive microangiopathy affecting all organ vascular beds. This rare but severe form of hypertension is rapidly fatal if untreated. Despite its increasing incidence, particularly among young adults aged from 35 to 55 years, scientific research remains limited. The diagnostic criteria and treatment recommendations have not or barely been updated since 1929, highlighting an urgent need for evidence-based update to improve patient management and prognosis.

Beyond clear clinical need, this unique situation presents an exceptional opportunity to understand microvascular resilience and susceptibility to hypertensive damages.
While severe hypertension is common (up to 13% of admitted patients in emergency department), only a small percentage of patients transition to MHT, suggesting the presence of vulnerability and protective factors. Familial occurrences support the idea of a genetic predisposition.

Deciphering the determinant of the transition from severe to MHT and the multiomic signature associated with target organ damage offers unique opportunities to improve the management of these patients. This includes identifying MHT crisis risk biomarkers supporting precision medecine, developing diagnostic tools to differentiate between benign severe hypertension and MHT in emergency settings, and discovering new therapeutic targets focused on microvascular protection rather than just lowering blood pressure.

To adress these ambitious objectives, we launched in 2019 the HAMA (Hypertension Artérielle MAligne) program, based on the HAMA Cohort (NCT03755726). This prospective, multicenter, european, consecutive cohort involves 45 multidisciplinary centers across France and Poland, and will include more european countries in the near future. It currently enrolles 115 patients annually, providing a comprehensive representation of the clinical spectrum of the disease. This cohort aims to serve as a platform for numerous substudies, including randomized controlled trials if needed.

IVAMA (NCT04991077), the completed pilot pathophysiological study, and HAMA-Bank (NCT06629363) are such substudies. HAMA-Bank is a key substudy aiming at investigate the pathophysiology of malignant hypertension.

It seeks to characterize the determinants of the transition from severe to malignant hypertension and the mechanisms -including inflammatory- driving target organ damage. HAMA patients willing to participate will provide biological samples, including DNA, RNA, serum, plasma, whole blood, and urine. These samples will be collected during the acute crisis and three months after resolution, to better highlight the mechanisms involved during acute crisis.

Finaly, by leveraging the knowledges obtained from this caricatural, severe and acute model, we aim to better understand the microvascular injuries associated with more common situation such as chronic hypertension, diabetes, obesity, and aging.

Website

https://www.ch-pau.fr/professionnel-de-sante/la-recherche-clinique/cohorte-hama/

ICONIC

INSERM

STUDIES STATUS :
Recruitment
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
2 400 participants/ patients targeted
0 participant/patient already included

CLINICAL.TRIAL.GOV ID :
not specified

A strategic opportunity: advanced population imaging of the heart and liver in France. This project, born from the meeting of two national research infrastructures, the IHU ICAN and CONSTANCES cohort, will create a large database of labeled medical images in connection with the CONSTANCES cohort non-imaging data.
These unique non-invasive magnetic resonance (MRI) and ultrasound imaging data, from the IHU ICAN platform, will be analyzed to establish state-of-the-art structural and functional measurements of the heart, large vessels and liver in a large.

Website

https://ihuican.org/le-projet-iconic-creation-du-1er-atlas-dimagerie-cardiaque-ethepatique-en-population-generale-incluant-des-personnes-de-moins-de-40-ans/

EpOS-LT

ICAN

STUDIES STATUS :
Recruitment
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
3 400 participants/ patients targeted
2 400 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
not specified

Metabolic-Associated Fatty Liver Disease (MAFLD) is considered the liver manifestation of metabolic syndrome, and is now one of the most common causes of chronic liver disease. Steatosis on ultrasound is found in about 30% of individuals in the general population and transaminases are elevated in about 8%. The histological spectrum of MAFLD covers

(a) Metabolic-Associated fatty liver (MAFL),
(b) steatohepatitis (MASH), which combines lesions of lobular inflammation and hepatocyte ballooning,
(c) fibrosis, and (d) cirrhosis. Liver-related mortality is determined primarily by the occurrence of cirrhosis, which is responsible for episodes of decompensation, sepsis, and hepatocellular carcinoma.

Hepatocellular carcinoma (HCC) is the sixth most common cancer in the world by incidence and the fourth most common by mortality. It occurs in patients with chronic liver disease, most often in the cirrhosis stage. The steady increase in the prevalence of obesity and diabetes explains why the incidence of metabolic HCC has increased by 9% annually in the U.S. and has thus become the liver transplant indication with the largest increase.
European data collected in the North of England during the decade 2000-2010 showed that metabolic risk factors are found in 35% of patients newly diagnosed with HCC, but there are no effective screening policies and is becoming a major medical issue.

The obesity epidemic is closely associated with the increasing prevalence and severity of MAFLD. Finally, several single-center trials have shown liver improvement following surgery. However, not all patients are responders to bariatric surgery, and some with insulin resistance have achieved modest metabolic and liver benefit. However, there are uncertainties regarding the natural history and prognosis of MAFLD.
In particular, the stratification of patients in whom there is significant inter-individual variability (in particular the severity and speed of disease progression, cases of regression), the prognosis of progression, the progression to cancer, the role of comorbidities or complications, the impact of a therapeutic intervention (drug or surgery) on the course of the disease.

These major themes will be addressed through the identification and validation of non-invasive markers capable of identifying candidates for treatment but also of tracing the evolution of the disease (progression or regression), within a cohort of well-characterized patients covering the entire spectrum of MAFLD severity.
The analyses will include artificial intelligence tools best suited to integrate heterogeneous complex data (including imaging and OMICS), as well as to improve the reading of biopsies currently dependent not only on sampling and inter-observer variability but also on a purely qualitative or semi-quantitative evaluation of the lesions of interest (inflammation, fibrosis).

Website

https://ihuican.org/wp-content/uploads/2023/06/EPOS-LT_Information-patient-27062023.pdf

Liver Biobank Network

INSERM

STUDIES STATUS :
Recruitment
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
0 participant/patient targeted
4736 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
not specified

These major themes will be addressed through the identification and validation of non-invasive markers capable of identifying candidates for treatment but also of tracing the evolution of the disease (progression or regression), within a cohort of well-characterized patients covering the entire spectrum of MAFLD severity.

The analyses will include artificial intelligence tools best suited to integrate heterogeneous complex data (including imaging and OMICS), as well as to improve the reading of biopsies currently dependent not only on sampling and inter-observer variability but also on a purely qualitative or semi-quantitative evaluation of the lesions of interest (inflammation, fibrosis).

Website

https://host.credim.u-bordeaux.fr/CRBFOIE-P/

Chronic Kidney Disease-Renal Epidemiology and Information Network (CKD-REIN)

INSERM

STUDIES STATUS :
Follow-up

NUMBER OF PARTICIPANTS / PATIENTS :
3 033 participants/ patients targeted
3 033 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
NCT03381950

The CKD-REIN cohort study aims to improve the understanding of determinants and biomarkers of chronic kidney disease (CKD) progression and complications, to identify practices associated with better outcomes, and to bring to light what matters in CKD from the patient's perspective. Coordinated with the international CKD Outcomes and Practice Pattern Study (CKDopps), CKD-REIN enrolled 3033 adult patients with moderate or severe CKD from a representative national sample of 40 nephrology clinics between 2013 and 2016.

Clinical research associates followed CKD-REIN participants for 5 years. An extensive amount of data was collected, at baseline and annually, in relation with CKD and its treatments, patients' social characteristics, and perceived health, through medical records, patient interviews, and patient self-administered questionnaires. Additionally, information about clinical practices and nephrology service organization was collected.

Blood and urine samples were collected at baseline, 2 years, and 5 years. The initial phase of follow-up by clinical research associates ended in December 2020, transitioning to the second phase of follow-up, including a self-administered questionnaire to participants in 2022 and cohort linkage with the National Health Data System (SNDS) and the national REIN registry for dialysis and kidney transplantation, covering the entire study followup (since 2013), and planned until the end of 2026.

Website

https://francecohortes.org/cohortes/annuaire-des-cohortes/CKD-REIN

Constances

INSERM

STUDIES STATUS :
Follow-up

NUMBER OF PARTICIPANTS / PATIENTS :
220 000 participants/ patients targeted
220 000 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
not specified

La cohorte CONSTANCES est une méga cohorte en population générale visant à la représentativité de la population française. Infrastructure Nationale de Recherche ouverte à la communauté scientifique française et internationale, Constances est également une source de données pour les autorités de santé publique.

A l'inclusion les volontaires tirés au sort ont bénéficié d'un examen médical dans un des 21 Centres d'examens de santé (CES) de la Sécurité Sociale et ont signé un consentement au suivi et à la réutilisation de leurs données sous couvert d'une information et de la possibilité d'exercer leur droit d'opposition.

Le socle du suivi consiste en un auto-questionnaire annuel, un retour au CES tous les 4 ans et l'appariement aux bases de données nationale de santé (SNDS) et socio-professionnelles (Assurance vieillesse). Les données recueillies concernent la santé et des paramètres physiologiques et biologiques, les comportements, le recours aux soins, la qualité de vie, les caractéristiques sociodémographiques, les conditions de vie, de travail et d'environnement social, professionnel et résidentiel. Une biobanque contient des échantillons de sang et d'urine de près de 58 000 participants.
Les inclusions des volontaires se sont déroulées entre 2012 et 2021, avec 219 144 volontaires âgés de 18 à 69 ans à l'inclusion. Afin de contrôler les effets de sélection une cohorte de référence de 450 000 individus suivis dans les bases administratives a également été mise en place et permet de pondérer la cohorte pour des estimations non biaisées. https://www.constances.fr.

Pour une gestion optimale de ce patrimoine de données de santé unique en France, l'équipe a mis en place une gouvernance de données permettant de définir un ensemble de processus, rôles, règles, et normes pour assurer en continu une utilisation efficace et efficiente des données pour atteindre ses objectifs, tout en garantissant accessibilité, fiabilité, qualité, conformité et sécurité.

Le partage des données est au coeur du fonctionnement de l'infrastructure. Les règles et procédures d'accès à la cohorte sont définies dans une Charte validée par le Comité des tutelles.

A date et depuis 2014, 274 demandes d'accès ont été évaluées, 244 acceptées dont 6 avec des demandes d'accès aux échantillons de la bio banque. Les domaines scientifiques des recherches sont très diversifiés : recherche biomédicale , génétique, comportements de santé, économie de la santé, COVID19, cardiovasculaire, neurocognitif, pollution, santé respiratoire etc.. Toutes les évaluations de Constances ont souligné l'excellence du projet.

Constances accompagnée d'Inserm Transfert a mis en place des contrats type pour les partenariats privés. https://www.constances.fr/la-cohorte/les-partenaires/partenaires-prives

Website

https://www.constances.fr/

FROG-ICU

AP-HP

STUDIES STATUS :
Study Completed

NUMBER OF PARTICIPANTS / PATIENTS :
2 087 participants/ patients targeted
2 087 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
NCT 01367093

Rationale: In France, intensive care units admit several thousand patients with one or more organ failures every day. Mortality in intensive care is high, between 15% and 20% in France.

The study of the determinants of mortality in intensive care has given rise to numerous scores such as the IGS II which are used to predict the risk of death in intensive care. The aim of FROG ICU (French and EuRopean Outcome reGistry in Intensive Care Unit) is to identify patients who are at high risk of death within the year following a stay, for serious illness, in an intensive care unit. Type of study: FROG ICU (French and EuRopean Outcome reGistry in Intensive Care Unit) is an epidemiological, non-interventional, prospective, multicenter study of a cohort with descriptive, prognostic and evaluative aims.

This study initially includes an exhaustive recording of cases hospitalized in intensive care and then from the patients recorded the constitution of a longitudinal cohort of patients including a one-year follow-up.

The main objective of FROG ICU is to identify the incidence and risk factors for death in the year following a stay in intensive care. The factors included will include the «classic» clinico-biological factors, usually included in the severity scores of intensive care as well as the biomarkers mentioned above. Secondary objectives:

1)Evaluate the quality of life in the year following a stay in intensive care;
2)Identify the main determinants of cardiovascular morbidity and mortality in the year following a stay in intensive care;
3)Study the performance of plasma biomarkers usually measured in intensive care: Procalcitonin (PCT), C-reactive protein (CRP), natriuretic peptides, troponins and uric acid, in terms of reclassification of the risk of death in intensive care and at 1 year;

4) To constitute a biological collection of plasma and urine, for the study of new plasma biomarkers in the evaluation of prognosis in the year following a stay in intensive care Inclusion criteria: adult patients hospitalized in medical, surgical or multipurpose intensive care with 8 beds or more, in France, having been intubated and ventilated and/or having received a positive inotropic agent for more than 24 hours, and non-opposition of the patient or the relative/parent/trusted person during the stay in intensive care.

Total duration of the study: 24 months
Duration of patient participation: 12 months
Duration of inclusions: 12 months

Data collection: The study's clinical research technicians collect data on the history of the patients included, the sociodemographic, clinical, biological and therapeutic characteristics on arrival at the hospital, during the stay and on discharge. Biological samples will be taken when patients are admitted to intensive care and, in survivors, when they leave intensive care. Data on care, hospitalizations and survival are collected during the 12 months following discharge from intensive care.

Website

not specified

HARMONIC-RT

Inserm, AUH, UK Essen

STUDIES STATUS :
Recruitment
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
10 000 participants/ patients targeted
2 400 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
4746729

«Current evidence regarding the long-term clinical benefits and harms of particle therapy and contemporary photon-beam techniques is insufficient, especially in pediatric patients. Relevant indications for particle therapy are also still debating.

The "HARMONIC-Radiotherapy" study (NCT 04746729) aims to evaluate long-term clinical outcomes of advanced techniques of external beam radiotherapy (EBRT) in children, adolescents, and young adults.

HARMONIC-Radiotherapy is a non-interventional registry complemented by a biobank and substudies exploring specific patient subsets undergoing interventional procedures. The registry includes patients treated with EBRT (photons, particle) for a first neoplasm from 2000 onwards before the age of 22 years. It is currently active in five centres in Belgium, Denmark, France, and Germany. The registry study is open to enrolling retrospectively or prospectively patients for ten years (2021–2031) and collecting follow-up information for 10–20 years (2021–2041).

The collected data includes demographics, socioeconomics, general health information, risk factors, routine biological tests, treatments (radiation, surgeries, and systemic therapy), cancer events, and relevant chronic, or fatal health conditions. DICOM-RT files are centrally stored and evaluated allowing whole-body dosimetry calculation from therapeutic and imaging exposures. The substudies investigate early-/intermediate-term endpoints measured on MRIs or blood/saliva samples, and parent-/patient-reported outcomes. Linkage with population-based cancer registries and national health insurance databases is planned for long-term follow-up.

HARMONIC-Radiotherapy is the first multi-centric registration system of paediatric patients treated with contemporary EBRT techniques (photons, particle) in Europe. It complements large cohorts of young individuals treated with older EBRT techniques, and registries on contemporary EBRT currently running outside Europe.

Adhering to FAIR principles, HARMONIC-RT aims to support future international studies on the late effects of technical advancements in paediatric EBRT. While enrolment and follow-up are continuing in the participating centres, we aim to open the registry to other centres. We projected that 10,000 patients could be included by 2031 in a large European study – enabling the evaluation of various clinical indications and long-term outcomes.»

Website

https://harmonicproject.eu/

BNDMR

not specified

STUDIES STATUS :
Follow-up

NUMBER OF PARTICIPANTS / PATIENTS :
3 000 000 participants/patients targeted
1 600 000 participants/patients already included

CLINICAL.TRIAL.GOV ID :
ot specified

The BNDMR, a French National Rare Disease Data Registry, is a project that was funded by the French Ministry of Health during the 2nd French National Rare Disease Plan.

The General Directorate for Healthcare Supply (DGOS) has therefore commissioned the Assistance Publique - Hôpitaux de Paris (AP-HP) to ensure the project management of the BNDMR, through the development and deployment of the BaMaRa application made available free of charge to each Rare Disease Reference and Competence Center (CRMR/CCMR).
Once deployed, BaMaRa offers healthcare professionals the ability to collect and leverage a minimum national data set (MDS).

The data collected or transmitted to BaMaRa is then transferred each month to the BNDMR Registry after a pseudonymization process (removal of directly identifying data).

A section of the MDS of the BaMaRa application already provides information on whether a patient is participating in a clinical trial by indicating for which drug treatment specific to the rare disease.
This national database aims to provide France with a homogeneous collection of data based on the SDM to document the care and health status of patients with rare diseases in French expert centers, and to better evaluate the effect of national plans.

In the BaMaRa application, complementary collections to the MDS have also been developed, for care purposes, as part of specific actions of the 3rd French National Rare Disease Plan (e.g. reducing diagnostic wandering and dead-ends (action 1.7), monitoring patients eligible for treatments subject to early access programs requiring the collection of efficacy and safety data on the treatment).

The MDS-G (Genomics) was a first project of complementary collections to the MDS which made it possible to add new fields available in the BaMaRa application to collect more complete genetic and genomic data.

A project currently being deployed also provides for the implementation of interoperability with the sequencing platforms with the Molecular Biology Laboratories (LBM) of the PFMG 2020-2025 SeqOIA and AURAGEN.

To date, the BNDMR project includes:

- More than 1.6 millions patients
- More than 130 healthcare facilities
- More than 2260 centers

Website

https://www.bndmr.fr/

Therapeutic area : Cardiovascular and metabolic diseases Inflammatory and immune diseases Neurodegenerative diseases Digest. / Gastroint. disorders Cancer & Oncology Antibiotic Resistance

FRENCH GUT

INRAE

STUDIES STATUS :
Recruitment
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
100 000 participants/ patients targeted
24 000 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
NCT05758961

The French Gut project is a large-scale citizen science initiative aimed at mapping the gut microbiome of the French population.
Launched as part of the Million Microbiome of Humans Project (MMHP), it seeks to analyze 100,000 stool samples to better understand the relationship between gut microbiota, diet, lifestyle, and health. This ambitious study is led by INRAE in collaboration with INSERM, APHP, CEA, AgroParisTech, Pasteur Institute, and about 10 private partners.

The gut microbiome, a complex ecosystem of trillions of microorganisms, plays a crucial role in digestion, immunity, and metabolic health. Disruptions in its composition have been linked to numerous diseases, including obesity, diabetes, inflammatory bowel disease, and neurological disorders. By collecting and sequencing a large number of microbiota samples, the French Gut project aims to establish a reference database that will serve as a foundation for future research and personalized medicine approaches.
Participants voluntarily contribute stool samples and dietary/ lifestyle data via questionnaires. The data are pseudo-anonymized and analyzed using WGS metagenomics, allowing researchers to identify bacterial strains, their functions, and their links to health conditions. One key goal is to define a «healthy» French microbiome by capturing the diversity influenced by regional diets, genetics, and environmental factors.

Ultimately, French Gut aims to empower individuals by raising awareness of the impact of gut microbiota on well-being and to provide insights for developing personalized nutrition strategies and microbiome-based therapies. By integrating microbiome science into public health strategies, this project paves the way for preventive medicine and innovative treatments.

The success of French Gut will contribute to global microbiome research, helping to unravel the complex interactions between microbes and human health and leading to novel approaches for disease prevention and management.

Website

https://lefrenchgut.fr/

Therapeutic area : Cardiovascular and metabolic diseases Neurodegenerative diseases Thromboembolic diseases Cancer, psoriasis, macular degeneration, asthma, cholecystectomy, depression, migraine

E3N-GENERATIONS

INRAE

STUDIES STATUS :
Recruitment
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
200 000 participants/ patients targeted
139 000 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
NCT03285230

The E3N-Generations cohort (www.e3n-generations.fr) is an epidemiological cohort that currently includes 139,000 participants from around 20,000 families and is the largest prospective cohort with a family design in France and one of the few of this kind in the world. E3N-Generations was established as a development of the existing E3N female cohort, most of which is the French component of the European Investigation into Cancer and Nutrition (EPIC, https://epic.iarc.fr/ and https://epic.iarc.fr/centres/france/).

Through the participation in EPIC, coordinated by the International Agency for Research on Cancer (IARC, World Health Organisation, Lyon) and involving 500,000 men and women from 10 countries, the cohort contributes or leads several projects on cancer, cardiometabolic diseases, Parkinson's disease and other chronic diseases associated with ageing.

The E3N is a prospective cohort of almost 100,000 women aged 40-65 years at the time of recruitment in 1990 who were members of the health insurance scheme of the national education system (Mutuelle Générale de l'Éducation Nationale, MGEN). Active follow-up of the cohort is still performed after more than 30 years with self-administered questionnaires every 2-3 years completed on average by more than 80% of the eligible cohort participants (Clavel-Chapelon et al. Int J Epidemiol 2015). The questionnaires focus on medical history, perceived health, used of medications and supplements, and on a large variety of factors related to personal characteristics (e.g. anthropometry), lifestyle (e.g. physical activity and diet) and environmental factors.
The baseline questionnaire was completed in 1990 by 98,995 women while the 13th questionnaire was completed in 2021-2022 by 55,478 women (more than 85% of eligible participants). Passive follow-up is ensured through linkage to death records and to the MGEN drug claim database. The link with MGEN ensures long-term monitoring of participants and reduces the risk of losing information: changes of address or marital status, deaths and medico-administrative data are regularly transmitted by MGEN, with the agreement of the Commission Nationale de l'Informatique et des Libertés (CNIL).

Website

https://www.e3n-generations.fr/

E-COHORTE SFDT1

Francophone Foundation for Diabetes Research (FFRD)

STUDIES STATUS :
Recruitment
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
10 000 participants/ patients targeted
4 700 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
NCT04657783

Cardiovascular diseases are the most frequent type 1 diabetes (T1D) complications1. A recent epidemiological study showed that patients with T1D have a two-fold cardiovascular (CV) mortality risk, even in case of good glycemic control2. In addition, it has been shown that patients with T1D with no traditional CV risk factors had about a 80% higher risk of cardiovascular event compared to non-diabetic individuals3. This indicates that further modifiable and not risk factors in relation to CV mortality remain to be explored.

One of the candidates that could help to disentangle the factors associated with the increased CV mortality in T1D patients is glycemic variability. Brownlee and Hirsch4 previously postulated that glycemic variables other than glycated haemoglobin (Hb1Ac) may contribute to diabetes complications. Indeed, severe hypoglycaemia, one of the most severe consequence of glycaemic instability, are associated with a higher mortality in patients with type 1 and type 2 diabetes5.
One explanation is that severe hypoglycemia are associated with QTc interval prolongation in patients with T1D6, which could lead to fatal arrhythmia7. Furthermore, HbA1c variability, intra-day and day to day glycaemic variability, could explain morbid-mortality in T1D8,9.

Hence, in order to evaluate the relation between glycemic variability and CV risk as well as some other questions related to health determinants of T1D, we plan to build up a large observational, prospective, multi-centric cohort study of patients gathering 10,000 patients with T1D, age above 6 years old, to perform the following:
-Collecting clinical information (electronic case report form (e-CRF))
-Evaluating Glycemic variability (assessed by the coefficient of variation of glucose (CV) calculated from downloaded continuous glucose monitoring data (CGM) through the FreeStyle Libre device which is reimbursed in all patients with T1D in France)
-Biobanking including plasma, DNA, urine, saliva and hair.
-Collecting patients' reported outcomes through auto-questionnaires (online questionnaires).

-Doing an active follow-up for a period of 10 years with an intermediate visit every 3 years and a passive follow-up for 30 years using the French medico-administrative information thanks to a linkage with the SNDS (Système National des Données de Santé) with a determinist pairing.

Website

https://sfdt1.fr/

THROMBOEMBOLIC DISEASES

BIOMARKERS ALGORITHM FOR STROKE DIAGNOSIS AND TREATMENT RESISTANCE PREDICTION – BOOST

AP-HP

STUDIES STATUS :
Recruitment
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
4 000 participants/ patients targeted
3 856 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
CT04726839 + IDRCB no. 2020-A00258-31

Triage of acute ischemic stroke (AIS) patients is critical, to decrease time to treatment, and improve functional outcome. The therapeutic standard of care for AIS consecutive to large vessel occlusion (LVO) is the association of intravenous (IV) alteplase administration and mechanical thrombectomy (MT).

However, there are limited places where MT can be performed. Therefore, there is a need for innovative tools to identify, in the ambulance, patients with LVO that require MT. Sending the patients at the right, avoiding futile stops (i.e. in places where MT is not available), is definitively a strategy that saves time.

There is currently no biomarker nor Point Of Care (POC) Lab Testing to solve this issue and clinical scoring methods such as the NIHSS have a low accuracy rate to detect LVO. The relevance of blood biomarkers for LVO diagnosis and therapeutic decisions needs to be confirmed for effective triage in the setting of AIS with LVO, which represent 30% of all AIS.

Website

https://rhubooster.for.paris/la-recherche/#etclin

CONSTITUTION OF A CLINICO-RADIOLOGICAL DATABASE AND A BIOBANK FOR PATIENTS WITH LACUNAR INFARCTS DHU-LAC COHORT

AP-HP

STUDIES STATUS :
Recruitment
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
500 participants/patients targeted
323 participants/patients already included

CLINICAL.TRIAL.GOV ID :
CT03552926 + ID-RCB : 2015-A01107-42

This bi-centric cohort study aims at determining in patients with recent lacunar strokes (<15 days), the main clinical, radiological, or genetic predictive markers of recurrent stroke, cognitive impairment, dementia, depression gait disturbances and disability.

Website

not specified

COHORT FRANCE-PAD

FRANCE-PAD

STUDIES STATUS :
Recruitment
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
10 000 participants/ patients targeted 0 participant/patient already included

CLINICAL.TRIAL.GOV ID :
None

FRANCE-PAD is a clinical investigation network gathering 6 French healthcare institutions, with high surgical activity volumes of peripheral arterial diseases (PAD).

FRANCE-PAD is mainly dedicated to the evaluation of implantable medical devices through retrospective or prospective studies. The network, recently created, will implement AI-based solution to accelerate data-collection directly from medical report, and to improve data-quality of eCRF.

From this initial activity, FRANCE-PAD has the ambition to set-up a national prospective cohort of clinical data, and provide reports and studies linking clinical data with the national SNDS database.

Website

not specified

ENDOVASCULAR TREATMENT IN ISCHEMIC STROKE FOLLOW-UP EVALUATION (ETIS)

ASSOCIATION HOSPITAL FOCH

STUDIES STATUS :
Recruitment
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
10 000 participants/35 000 participants/patients targeted
27 908 participants/patients already included

CLINICAL.TRIAL.GOV ID :
NCT03776877

Stroke is a leading cause of death and disability in France, with approximately 150,000 new cases annually—equating to one stroke every four minutes—and resulting in around 30,000 deaths each year. Among these, acute ischemic stroke (AIS) accounts for approximately 80% of cases and is caused by the occlusion of a cerebral artery by a thrombus, making it a major neurological emergency.

Mechanical thrombectomy and intravenous thrombolysis are the standard interventions for AIS; however, their efficacy is highly dependent on rapid intervention and precise patient selection. Despite advancements in stroke care, access to these treatments remains unevenly distributed across France due to regional disparities in healthcare infrastructure. These delays have a direct impact on patient outcomes—every minute without treatment results in the loss of approximately 2 million neurons, significantly increasing the risk of death or severe disability.

To address these challenges, the ETIS registry is a multicentric, prospective cohort study designed to evaluate clinical, imaging, and plasma biomarkers in patients treated for AIS via endovascular therapy or medical management. By leveraging real-world clinical and imaging data, ETIS aims to refine patient stratification, optimize treatment pathways, and improve long-term functional outcomes.

This study collects structured real-world data (RWD) from 40 participating centers across France, with 12 additional sites, including overseas territories, set to join. The ETIS registry integrates detailed clinical variables, imaging datasets (ETIS Images), and procedural information to assess treatment efficacy and safety. All data are securely stored within a regulated environment, ensuring compliance with stringent ethical and data protection standards (MR-001).

The cohort includes both minor and adult patients with AIS eligible for thrombolysis, thrombectomy, or medical therapy, with systematic follow-up at three months post-intervention.

Website

not specified

INFLAMMATORY AND IMMUNE DISEASES

EFRAIM 3

GROUPE DE RECHERCHE RESPIRATOIRE EN REANIMATION ONCOHEMATOLOGIQUE

STUDIES STATUS :
Follow-up

NUMBER OF PARTICIPANTS / PATIENTS :
9 855 participants/ patients targeted
9 855 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
not specified

Among the 300 000 patients admitted each year to intensive care units (ICUs) in France, one third are immunocompromised. Acute respiratory failure (ARF, shortness of breath, new pulmonary infiltrates, and need for oxygen or mechanical ventilation) is their primary reason for ICU admission.

The proportion of patients who die is overall 50%, but varies from 35% in highly experienced centers (>50 such patients per year) to 70% in centers with limited experience. Besides the large experience of high-volume centers and the dialogue between ICU and primary specialists, protocolized diagnostic workups and availability of a comprehensive technical equipment certainly overcomes important barriers to identify the ARF etiology faced in hospitals with lower case volume.

Indeed, a major determinant of death in immunocompromised patients with ARF is the inability to identify the ARF cause which is associated with a twofold to threefold mortality in several studies. This finding raises concerns about the optimal diagnostic workup for each patient, and calls for an individualized approach to pathogen identification and treatment in this setting. In addition, as the number of immunocompromised patients increases steadily over time, transferring all patients to high volume ICUs would not only overwhelm the capacities of those ICUs, but also exacerbate the case-volume effect. Instead, transferring knowledge and empowering physicians from low-volume centers to manage respiratory complications appears a much more appropriate approach.

The GRRR-OH is a group of French specialists of intensive care and investigators. It is endorsed by the National Institute of Cancer (INCA). Acute respiratory failure is the main research area in the GRRR-OH. Over the last two years we have constituted a cohort of immunocompromised patients admitted for ARF in 100 ICUs from 26 countries. We have three major objectives:

1. update prognostic factors for mortality and identify new targets for improving outcomes.

2. develop an algorithm to identify the ARF etiology using a customized diagnostic workup. This clinical decision-making system – once validated - will be available on an app and disseminated to corresponding specialists through medical schools, universities, teaching societies, specialized institutes and health or research agencies.

3. identify patient's phenotypes and endotypes (biomarkers) that would benefit from a more personalized approach to ARF etiology identification.

The Efraim 3 cohort is a unique international collaborative effort for severe and vulnerable patients.

Website

https://www.grrroh.fr/

IMMINENT COHORT

LILLE UNIVERSITY HOSPITAL

STUDIES STATUS :
Recruitment Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
4 000 participants/ patients targeted
1 403 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
CT04334031 + EudraCT 2019-A01309-48

Chronic immune and inflammatory diseases (CIID) most often affect young individuals, imposing significant personal, professional, economic, and social burdens. These diseases considerably impair patients' quality of life and can lead to major functional disabilities. Additionally, they are associated with increased premature mortality. A critical contemporary challenge is managing complex CIID, particularly those that are treatment-resistant or associated with complications arising from treatment or disease progression.

Beyond their individual impacts, CIIDs share many commonalities, such as underlying mechanisms and therapeutic strategies referred to as «targeted therapies.» These medications have recently improved patient management and enhanced quality of life; nevertheless, substantial research remains necessary across clinical, therapeutic, and fundamental domains. To address these multifaceted challenges, the FHU PRECISE (Precision Health in Inflammatory Diseases; https://www.fhu-precise.fr/) project has been officially endorsed following international expert evaluation. FHU PRECISE is led by the Lille University Hospital and is funded by this hospital, the University of Lille and INSERM.

The project's cornerstone is the establishment of a multicenter clinical-biological database, known as the IMMINENT cohort (Immune Mediated Inflammatory Diseases AND Targeted therapies), associated with a biobank (CPP 2019-A01309-48; NCT04334031). This large, prospective, national, and multidisciplinary cohort (Internal Medicine, Immunology, Neurology, Rheumatology, Dermatology, Pulmonology, Gastroenterology, etc.) of patients with CIID leverages the transdisciplinary framework of the FHU for pathophysiological, clinical, and therapeutic studies. The main objectives of this ongoing database and biobank, which currently includes 24 centers in France with 1,400 enrolled patients, are to identify novel prognostic and therapeutic biomarkers, discover new therapeutic targets, and determine prognostic factors and determinants influencing disease activity, severity, and patient quality of life.

Website

ttps://www.fhu-precise.fr/la-cohorte-fhu

REVIGORE40

AP-HP

STUDIES STATUS :
Recruitment
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
250 participants/ patients targeted
56 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
NCT06669000

Gout is characterized by episodes of acute arthritis of the lower limbs due to intermittent activation of innate immunity in the joints where urate crystals have formed. These crystals occur when serum urate (SUA) levels have been above 70 mg/L for many years. They can be dissolved by lowering SUA levels to at least 60 mg/L (treat-to-target - T2T - strategy).

Once the crystals are dissolved, patients are no longer symptomatic and are considered to be in remission (treat-to-dissolve - T2D - strategy).
The presence of crystals and their dissolution during treatment can be monitored by repeated ultrasound (US) scans of the feet and knees.

The time required for complete dissolution varies from patient to patient. ReViGore40 is a cohort designed to i) determine the time to complete dissolution of urate deposits in joints when SUA levels are maintained below 40 mg/L, ii) determine the factors (clinical, biological, genetic) associated with the time required for complete dissolution of urate deposits within joints.

Website

Not specified

CUB TRAJECTORY IDENTIFICATION MULTICENTRIQUE DE BIOMARQUEURS DES PATHOLOGIES RESPIRATOIRES CHRONIQUES PAR INTELLIGENCE ARTIFICIELLE

ASSOCIATION HÔPITAL FOCH

STUDIES STATUS :
Recruitment
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
40 000 participants/ patients targeted
20 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
Not specified

Chronic airway diseases (CADs), including asthma, chronic obstructive pulmonary disease (COPD), and bronchiectasis, represent a significant global health burden due to their progressive nature, exacerbations, and heterogeneous clinical manifestations. Current classifications rely on broad nosological categories that do not fully capture the complexity of disease trajectories and treatment responses.

The CUB Trajectory project aims to leverage artificial intelligence (AI) to identify shared biomarkers across CADs, thereby enabling improved disease stratification, personalized treatments, and predictive modeling of disease progression.

This multicentric, ambispective cohort study will collect and structure real-world data (RWD) from electronic medical records across multiple healthcare institutions. Lifen DataLab, an AI-powered platform, will be utilized to process medical reports, extract structured variables, and ensure compliance with stringent regulatory and security standards (MR004). By applying AI-driven data structuring and pseudonymization techniques, CUB Trajectory will facilitate the identification of clinically relevant subgroups, optimize patient selection for targeted therapies, and improve real-time disease monitoring.

The study will include adult patients diagnosed with CADs, with at least one year of follow-up and documented airflow obstruction based on lung function measurements. Eligible patients will be identified via automated screening algorithms applied to hospital data warehouses, with additional validation steps to ensure accuracy. A total of 20 centers will participate, targeting an inclusion of 40,000 patients.

Primary objectives include developing predictive models to assess treatment responses and disease trajectories. Secondary objectives involve constructing a high-quality RWD dataset to refine CAD phenotyping, integrating clinical and biological data models, and demonstrating the feasibility of rapid data integration across multiple sites.

By bridging the gap between real-world clinical practice and precision medicine, CUB Trajectory seeks to enhance patient management, facilitate interdisciplinary collaboration, and contribute to the advancement of AI-driven respiratory research. This initiative will provide a scalable model for data-driven innovation in chronic disease management, fostering improved healthcare outcomes through AI-powered biomarker discovery.

Website

Not specified

CAPYCH
CALCIUM PYROPSHOPHATE CRYSTAL DEPOSITION COHORT

GROUPE HOSPITALIER DE L'INSTITUT CATHOLIQUE DE LILLE

STUDIES STATUS :
Recruitment
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
500 participants/patients targeted
0 participant/patient already included

CLINICAL.TRIAL.GOV ID :
Not available yet

Calcium pyrophosphate (CPP) deposition disease is a common but little-known disease occurring mainly among people over 60 years old. It is probably the most common cause of inflammatory arthritis in this age group. CPP crystals trigger an inflammatory reaction causing various joint manifestations. Acute CPP crystal arthritis (pseudogout) often occurs during hospitalization, either as a single episode or recurrence. It was recently associated with a higher risk of cardiovascular events, particularly during the first two years after the episode. Chronic forms can present as recurrent acute arthritis and/or persistent polyarthritis.
Chondrocalcinosis, which refers to calcium deposits visible on the imaging (conventional radiography, ultrasound (increasingly used), CT, including dual-energy CT), is common (>30% of subjects over 80 years old). The factors causing this asymptomatic chondrocalcinosis are very little known, as are the factors explaining the transition from asymptomatic chondrocalcinosis to symptomatic CPP crystal deposition disease. More generally, there is very little knowledge about the course of the disease with and without treatment.

Treatments are currently limited to those aimed at controlling inflammation, as none have proven capable of dissolving the CPP crystal deposits. Conventional treatments mainly include colchicine and systemic or intra-articular corticosteroids, methotrexate, and more rarely non-steroidal anti-inflammatory drugs. Targeted biologic and synthetic treatments are increasingly considered in refractory cases. Interleukin-1 blocking agents appear to be particularly useful in acute forms, while interleukin-6 receptor blockers are promising in chronic forms and a placebo-controlled clinical trial has recently started. A clinical trial of a JAK inhibitor (baricitinib) is also underway.

There are many unanswered questions concerning CPPD, about its pathophysiology, the factors (including genetic factors) causing crystal deposits and explaining the development of symptoms, how deposits and symptoms evolve with and without treatment, response to treatments in routine practice, and associated comorbidities.
With this in mind, we wish to set up a prospective national observatory with longitudinal follow-up to attempt to answer all of these questions.

Website

Not specified

TRANSIMMUNOM

AP-HP

STUDIES STATUS :
Study Completed

NUMBER OF PARTICIPANTS / PATIENTS :
535 participants/ patients targeted
535 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
NCT02466217

Autoimmune and autoinflammatory diseases (AIDs) represent a socioeconomic burden as the second cause of chronic illness in Western countries. In this context, the TRANSIMMUNOM clinical protocol is designed to revisit the nosology of AIDs by combining basic, clinical and information sciences. Based on classical and systems biology analyses, it aims to uncover important phenotypes that cut across diagnostic groups so as to discover biomarkers and identify novel therapeutic targets. Methods and analysis: TRANSIMMUNOM is an observational clinical protocol that aims to cross-phenotype a set of 19 AIDs, six related control diseases and healthy volunteers.

We assembled a multidisciplinary cohort management team tasked with (1) selecting informative biological (routine and omics type) and clinical parameters to be captured, (2) standardising the sample collection and shipment circuit, (3) selecting omics technologies and benchmarking omics data providers, (4) designing and implementing a multidisease electronic case report form and an omics database and (5) implementing supervised and unsupervised data analyses.

Ethics and dissemination: The study was approved by the institutional review board of Pitié-Salpêtrière Hospital (ethics committee Ile-De-France 48-15) and done in accordance with the Declaration of Helsinki and good clinical practice. Written informed consent is obtained from all participants before enrolment in the study. TRANSIMMUNOM's project website provides information about the protocol (https://www.transimmunom.fr/en/) including experimental set-up and tool developments. Results will be disseminated during annual scientific committees appraising the project progresses and at national and international scientific conferences. Discussion: Systems biology approaches are increasingly implemented in human pathophysiology research. The TRANSIMMUNOM study applies such approach to the pathophysiology of AIDs. We believe that this translational systems immunology approach has the potential to provide breakthrough discoveries for better understanding and treatment of AIDs.

Website

Not specified

CRYOSTEM

CRYOSTEM ASSOCIATION

STUDIES STATUS :
Study Completed

NUMBER OF PARTICIPANTS / PATIENTS :
4 312 participants/ patients targeted
5 787 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
N/A

Hematopoietic stem cell transplantation (HSCT) is the only treatment for many hematological diseases. Graft-versus-Host Disease (GvHD) is one of the major complications. If GvHD is the leading cause of transplant-related mortality, its pathophysiology and the associated long-term complications remain poorly understood. In this context, Prof. Peffault de Latour and Dr. Calmels initiated the CRYOSTEM project in 2010, with the support of SFGM-TC (Société Francophone de Greffe de Moelle et de Thérapie Cellulaire). Initially focused on GvHD, CRYOSTEM enlarged its interests in 2016 to all HSCT complications.

The CRYOSTEM project was accepted and selected by the French National Research Agency (ANR) in relation to the "Cohorts" call for projects funded under the French government's "National Investment Programme" ("Investissements d'avenir") in June 2010.
CRYOSTEM has succeeded to set up a collaborative network of 33 transplant units, adult and pediatric, and 23 Biological Resource Centers (BRCs) to implement the CRYOSTEM cohort and the associated biological resources collection. The network governance is ISO 9001 certified since 2015.
The CRYOSTEM collection has reached more than 200,000 samples from nearly 6,000 patients and 2,400 donors. ISO 9001 certification of CRYOSTEM governance has largely contributed to the cohort quality, currently recognized internationally.
As part of the access to the CRYOSTEM collection, more than 13,000 samples have been provided to 26 international and French research projects between 2015 and 2024. At the end of 2024, 9 scientific publications have emerged in high-ranking journals, based on the experimental results obtained from CRYOSTEM biological resources.

Moreover, since 2018, the CRYOSTEM network has been recognized as a European pioneer in network biobanking in the field of HSCT and has expanded its expertise to 11 collaborative projects, dedicated to rare diseases or innovative therapeutic approaches, in order to implement harmonized multicentric biocollections.

As part of its final evaluation in 2024 requested by the ANR, international experts have considered the CRYOSTEM cohort as an incredible and very important initiative with excellent progress. As proof, the Ministry of Higher Education and Research has decided to sustain the CRYOSTEM cohort in 2024 via the Projet de Loi de Finances (PLF) 2025.

Website

https://www.cryostem.org/en/

HLH-GENE

AP-HP

STUDIES STATUS :
Study Completed

NUMBER OF PARTICIPANTS / PATIENTS :
250 participants/ patients targeted
250 participants/patients already included

CLINICAL.TRIAL.GOV ID :
NCT05063110

Between 2012 and 2019, we developed a clinical research clinical projet called “HLH genes cohort” (PHRC 2010) aimed to study the physiopathology and the potential genetic contribution of “HLH related genes” to the onset and severity of the syndrome. This project has been developed thanks to the “HLH French study group,”.

This « French Network » is involved in the questions of diagnosis, physiopathology and treatment of adult form of HLH, which and has emerged during this last five years. Members are mostly physician acting as expert on these questions, each in their French Medical area. The team gathers :

- Prof. E. Lazaro (CHU BORDEAUX Internal Medicine)
- Prof. T. Martin (CHU Strasbourg, Internal Medecine)
- Prof. D. Launay (CHU Lille, Internal Medecine)
- Prof. O. Hermine (CHU Necker/Imagine Institut)
- Dr. G. Urbansky (CHU Angers)
- Prof. M. Michel (CHU Henri Mondor, APHP)
- Prof. O. Lambotte (CHU, Bicêtre)

They have largely contributed to the biocollection and the building database of the « HLH genes project » over the past ten years. Indeed, they are all experts in the field of HLH and they are in the corner stone of treatment decisions for each new patient in their geographic region. Thus, their advices are logically required for new patients. Their contribution has facilitated the development of HLH gene project network with at least more than 65 French medical centers that have included patients in the cohort.

The HLHa inclusion criteria for adult patients were adapted from the HLH-2004 diagnostic criteria37. Informed consent was obtained from all study participants in accordance with the Declaration of Helsinki. The regional Ethics Committee of Paris (n° ID-RCB: 2009-AO00301-56) approved the study. The data collected included clinical and biological features of HLH, associated diseases, infectious trigger events, treatment and outcome (refractoriness, intensive care unit (ICU) transfer and death) at HLH onset and during a one-year follow-up. Selected associated diseases included neoplastic diseases (haematologic malignancies, solid tumours) or autoimmune/inflammatory-associated diseases (AIDs).

The patients were classified as idiopathic if they did not have a history of neoplasia and/or AID including during the one-year follow-up. Bacterial, viral, parasitic or miscellaneous infectious events were collected. Treatment of HLH was collected particularly the use of corticosteroids and etoposide, which is used in severe forms of HLH39.
HLHs was classified as severe when patients required at least one additional intervention, such as transfer to the ICU, had refractory disease or died and was classified as not severe when patients had no events as defined above. During 5 years, almost 50 patients having HLH were recruited per years in almost 65 five inclusion centers.
This project included 250 patients, 250 DNA, 150 cells (PBMC) and serum samples and a clinical data base with a follow up of one year after inclusion.

Website

Not specified

ENCEPHALITICA

AP-HP

STUDIES STATUS :
Study Completed

NUMBER OF PARTICIPANTS / PATIENTS :
350 participants/ patients targeted
350 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
NCT02906631

Background
Factors influencing outcomes in patients with severe encephalitis remain poorly characterized. We aimed to describe the incidence of disability or death at 3 months and to analyse recovery trajectories up to one year after severe encephalitis.

Methods
We conducted a prospective multicentre cohort study across 31 French centres from October 2017 to April 2021, involving adults with probable or confirmed encephalitis admitted to the ICU. The primary endpoint was unfavourable outcome at three months, defined by a modified Rankin scale (mRS) score of 3 to 6, indicating moderate-to-severe disability or death.

Findings
Among the 310 patients included, 123 (40%) were diagnosed with infectious encephalitis, 42 (14%) with autoimmune encephalitis, 37 (12%) with other causes, and 108 (35%) had encephalitis of unknown origin. Overall, 161 patients (52%, 95%CI 46.2–57.6) had an unfavourable outcome at 3 months, including 84 (27%) deaths. Independent factors associated with unfavourable outcome included age (Odds ratio (OR) per 5-year increment 1.28, 95%CI 1.16–1.41) and immunocompromised status (OR 3.12, 95%CI 1.57–6.40), while intravenous acyclovir on the day of ICU admission was associated with favourable outcome (OR 0.38, 95%CI 0.20–0.72). The proportion of patients achieving functional independence remained stable from three months to one year (absolute difference (AD): 1.1%, 95%CI: -7% to 9%). Analyses based on aetiological groups revealed that patients with autoimmune encephalitis showed significant improvement (AD 10%, 95%CI: 2% to 18%), whereas no significant changes were seen in patients with infectious causes (AD 1%, 95%CI: -0.7% to 9%), other causes (AD 1%, 95%CI: -7%to 9%), or unknown origin (AD 2%, 95% CI: -1% to 9%).

Interpretation
We observed a severe prognosis in half of adult patients with severe encephalitis, with significant variability in recovery trajectories at one year depending on aetiological categories. Patients with autoimmune encephalitis experienced more favourable outcomes, as compared to other aetiological groups.

Website

Not specified

CANCERS

ONCODATAHUB

UNICANCER

STUDIES STATUS :
Recruitment
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
150 000 participants/ patients targeted
70 000 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
Not specified

OncoDataHub (ODH) is a centralized pan-cancer repository. This repository project is an Observatory of Drugs and Therapeutic Innovation in Oncology, for patients exposed to at least one parenteral therapy as of January 1, 2020. ODH is focused on breast and lung cancers before extension to other organs. It aims to provide healthcare stakeholders with a set of high-quality, longitudinal data representative of the care of cancer patients in France. A data set of 60 variables including patient characteristics, disease at diagnosis, biomarkers, treatments... has been defined by the scientific experts. The objectives of this Platform are:

- Enabling a better understanding of oncology care, and better identifying unmet medical needs
- Serving as an observatory for medication and therapeutic innovation in oncology.

ODH automatically collects patient data from electronic medical records. Automated data extraction is performed once a year and more frequently if necessary. The identified data sources are:

- Healthcare facility pharmacy dispensing software
- Electronic patient records (EPR) including laboratory analysis reports, pathology reports, surgical reports, and medical imaging reports
- Medical information systems program (PMSI)
- Multidisciplinary consultation meeting (RCP) reports
- Patient administrative management software
- Healthcare facility internal health data warehouse

About 50 representative public/private hospitals and comprehensive cancer centers across the country contribute to ODH.
ODH strategy is defined by a steering committee and each project is reviewed by an independent scientific and ethics committee.
Pairing with SNDS in 2025.

Website

https://www.unicancer.fr/fr/programmes/odh/

UROCCR

BORDEAUX UNIVERSITY HOSPITAL

STUDIES STATUS :
Recruitment
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
20 269 participants/ patients targeted
20 269participants/ patients already included

CLINICAL.TRIAL.GOV ID :
NCT03293563

Kidney cancer is the 14th most common cancer worldwide, with its incidence steadily rising. For localized and locally advanced stages, surgery remains the standard of care. However, recurrence after surgery remains a major concern, depending on the tumor stage.
The rising incidence of kidney cancer coupled with its risk of high recurrence, underscore the urgent need to improve current diagnostic, prognostic, and interventional strategies. Additionally, optimizing the collection, management, and analysis of patient data is essential for gaining a deeper understanding of this pathology.

In response to these needs, we established in 2011 the first French multidisciplinary medico-scientific network, dedicated to kidney cancer: UroCCR. This national network, including to date 58 centers, is focused on the therapeutic management and applied research of renal tumors.
It facilitates the prospective collection and centralized exploitation of real-world data from all newly diagnosed patients in participating centers. The collected data spans demographic, clinical, and experimental parameters, as well as biological samples, patient-reported experience measures (PREMs) and outcome measures (PROMs), thereby creating a rich shared database. The creation of this national network represents a major asset for the realization of collaborative research projects

Website

www.uroccr.fr

HARMONIE

UNICANCER

STUDIES STATUS :
Recruitment
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
2 878 027 participants/patients targeted
2 878 027 participants/patients already included

CLINICAL.TRIAL.GOV ID :
not specified

L'entrepôt HARMONIE (Health dAta to fosteR Meaningfull ONcologIc Evaluations) doit se déployer en 2025 et permettre d'enrichir les données des trois programmes phares d'Unicancer avec les données de la base principale du SNDS. Son objectif est de favoriser la réalisation d'études permettant de mieux comprendre la prise en charge globale des patients, leurs parcours de soin et l'impact global de la maladie et des traitements.
Les bases de données incluses dans l'entrepôts sont :

-Le programme Épidémio-Stratégie Médico-Economique (« ESMÉ ») a été lancé en 2014 afin de centraliser les données de vie réelle de patients traités pour un cancer en France. Il a débuté en 2014 par un volet sur la prise en charge du cancer du sein métastatique et s'est poursuivi en 2017 sur la prise en charge du cancer de l'ovaire et du cancer broncho-pulmonaire. Le programme permet de répondre à des questions de recherche dans le domaine de la cancérologie, qu'il s'agisse de décrire des populations d'intérêt ou des stratégies thérapeutiques, de mesurer l'efficience des stratégies, de construire des bras contrôle externes à des fins d'études comparatives ou de conduire des évaluations médico-économiques. Le programme ESME représente la plus grande base de données de vie réelle avec un suivi un longitudinal profond de patients traités pour un cancer en France.

L'OncoDataHub (ODH) est un observatoire du médicament et de l'innovation thérapeutique en cancérologie. Il a été lancé en 2022 afin de mettre à la disposition des acteurs de l'écosystème de la santé (médecins, acteurs académiques, laboratoires, institutions, etc.) un ensemble centralisé de données structurées automatiquement à partir des systèmes d'information hospitaliers. Plus de 50 établissements de santé publics et privés y contribuent assurant ainsi la représentativité d'ODH. ODH s'inscrit dans la dynamique nationale et européenne de déploiement d'entrepôts de données de santé. Il couvre dans un premier temps les indications du cancer du sein et du cancer du poumon.

L'étude CANTO (CANcer - TOxicité) est une étude de cohorte prospective dédiée aux questions de recherche relatives à l'après cancer. Son objectif principal est d'identifier les toxicités à moyen et long terme des traitements anticancéreux, d'évaluer leur impact sur les patients et la société et de les prédire grâce à des marqueurs multimodaux. Initiée en 2011 avec les premières inclusions de patientes porteuses de cancer du sein localisé, élargie en 2023 aux patients atteints de cancer broncho-pulmonaire localisé avant ouverture à d'autres indications en 2025, la cohorte CANTO inclus des données de suivi, de questionnaires patients, de prélèvements (sanguins, fèces, tumoraux) et d'imagerie.

Website

not specified

NEURODEGENERATIVE DISEASES

CIRCAME

AP-HP

STUDIES STATUS :
Recruitment
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
1 499 participants/ patients targeted
400 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
NCT05977712

The diagnosis of Alzheimer's disease (AD) and related disorders (vascular dementia, Lewy body dementia, frontotemporal dementia, etc.) is made on the basis of a wide range of clinical, behavioural, neurological and biological tests, such as magnetic resonance imaging or cerebrospinal fluid (CSF) biomarkers.

These measurements are mainly carried out in specialist centres, and it is likely that some people with AD or a related disorder who are not oriented to these centres are not diagnosed and therefore do not receive appropriate care and support. With the ageing of the population, the number of people with AD and related disorders is on the rise, highlighting the urgent need to identify scalable, inexpensive and valid tools for screening for these diseases in primary care, in order to be able to offer appropriate care to people suffering from these conditions. Furthermore, the factors associated with the progression of AD and related diseases remain poorly understood, limiting the scope for intervention to improve the quality of life of patients and their careers, and to slow the progression of the disease.

In this context, the CIRCAME cohort, based on 1500 patients from two memory clinics in Paris, was set up to test the effectiveness of innovative biomarkers for screening adults in primary care before they are referred to specialist care.
The choice of markers in this project is guided by the conditions described above: they must not be invasive, they must be cost-effective, they must be usable on a large scale to reduce inequalities in care and they must have preventive potential. This will make it possible to offer appropriate care, targeted interventions and secondary prevention. The markers of interest include a cognitive test app, plasma biomarkers, retinal biomarkers, circadian rhythm markers, and a hearing test. The major advantages of these markers are that their measurement is non-invasive, relatively inexpensive and can be extended to the whole population.

Website

https://circame.fr/index.php/en/study-presentation/

BIOCOGBANK

AP-HP

Prospective bicentric cohort including patient with cognitive decline (ALzheimer's disease, Lewy BOdy dementia, Fronto temporal dementia, vascular dementia).

The data bank include clinical information with brain MRI
The biological bank include CSF, DNA, plasma

STUDIES STATUS :
Recruitment
Ongoing

NUMBER OF PARTICIPANTS / PATIENTS :
1 300 participants/ patients targeted
300 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
Not specified

Website

not specified

AUTRES AIRES THÉRAPEUTIQUES

REALYSA

HOSPICES CIVILS DE LYON – WITH FULL DELEGATION TO LYSARC

STUDIES STATUS :
Follow-up

NUMBER OF PARTICIPANTS / PATIENTS :
6 000 participants/ patients targeted
6 000 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
NCT03869619

Background: Age-adjusted lymphoma incidence rates continue to rise in France since the early 80's, although rates have slowed since 2010 and vary across subtypes. Recent improvements in patient survival in major lymphoma subtypes at population level raise new questions about patient outcomes (i.e. quality of life, long-term sequelae). Epidemiologicalstudies have investigated factors related to lymphoma risk, but few have addressed the extent to which socioeconomic status, social institutional context (i.e. healthcare system), socialrelationships, environmental context (exposures), individual behaviours (lifestyle) or genetic determinants influence lymphoma outcomes, especially in the general population. Moreover, the knowledge of the disease behaviour mainly obtained from clinical trials data is partly biased because of patient selection.

Methods: The REALYSA ("REal world dAta in LYmphoma and Survival in Adults") study is a real-life multicentric cohort set up in French areas covered by population-based cancer registries to study the prognostic value of epidemiological, clinical and biological factors with a prospective 9-year follow-up. We have included 6000 patients over 5years. Adult patients without lymphoma history and newly diagnosed with one of the following7 lymphoma subtypes (diffuse large B-cell, follicular, marginal zone, mantle cell, Burkitt, Hodgkin, mature T-cell) were invited to participate during a medical consultation with their hematologist. Exclusion criteria are: having already received anti-lymphoma treatment (except pre-phase) and having a documented HIV infection.

Patients are treated according to the standard practice in their center. Clinical data, including treatment received, are extracted from patients' medical records. Patients' risk factors exposures and other epidemiological data are obtained at baseline by filling out a questionnaire during an interview led by a clinical research assistant. Biological samples are collected at baseline and during treatment. A virtual tumor biobank is constituted for baseline tumor samples. Follow-up data, both clinical and epidemiological, are collected every 6 months in the first 3 years and every year thereafter.

Discussion: This cohort constitutes an innovative platform for clinical, biological, epidemiological and socio¬economic research projects and provides an opportunity to improve knowledge on factors associated to outcome of lymphoma patients in real life.
Trial registration: 2018-A01332–53, ClinicalTrials.gov identifier: NCT03869619.

Website

https://experts-recherche-lymphome.org/lysa/parcourir-les-etudes-cliniques-en-cours/realysa/

TRAUMABASE

AP-HP

STUDIES STATUS :
Severe trauma

NUMBER OF PARTICIPANTS / PATIENTS :
100 000 participants/ patients targeted
56 000 participants/ patients already included

CLINICAL.TRIAL.GOV ID :
Not specified

Trauma is a major public health issue in France, particularly affecting young and active individuals. It is the leading cause of death among patients aged 16-50 years and ranks third in disability-adjusted life years lost nationwide.

Beyond its devastating health consequences, trauma also leads to long-term disability and social exclusion. However, severe trauma is not an inevitability, and healthcare professionals are committed to continuously improving the quality of trauma care. Despite its profound societal impact, the investment in trauma research and healthcare infrastructure remains below what its burden would warrant. Established in 2012, the Traumabase cohort is a national trauma registry in France, currently evolving into a Health Data Warehouse in compliance with CNIL guidelines.

The database collects comprehensive clinical, biological, and imaging data from the scene of injury through hospital admission and up to the 30th day post-trauma. This dataset enables the continuous evaluation of trauma epidemiology, injuries severity, triage processes, treatment strategies and patient outcomes. Currently, 32 level I trauma center units across France contribute to this registry, with over 56,000 trauma patients from 16 years old included to date. The collection of data following pediatric trauma is planned in the coming months. The aim of the Traumabase is to optimize severe trauma patient management strategies, enhance predictive models, and improve trauma care network in France.

The ultimate goal is to refine care pathways and drive the development of personalized therapeutic approaches based on large-scale data analysis.

Traumabase fosters multidisciplinary national and international collaborations, including partnerships to develop artificial intelligence (AI)-based decision-support tools. With 56 original research publications in peer-reviewed journals and numerous presentations at national and international conferences, Traumabase provides high-quality, real-world data for trauma research and healthcare innovation.

Website

ttps://www.traumabase.eu/fr_FR

NOVARTIS

Ensemble, imaginons la médecine de demain

FA-11300789 - Octobre 2024

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