RESEARCH

ANNUAL REPORT 22

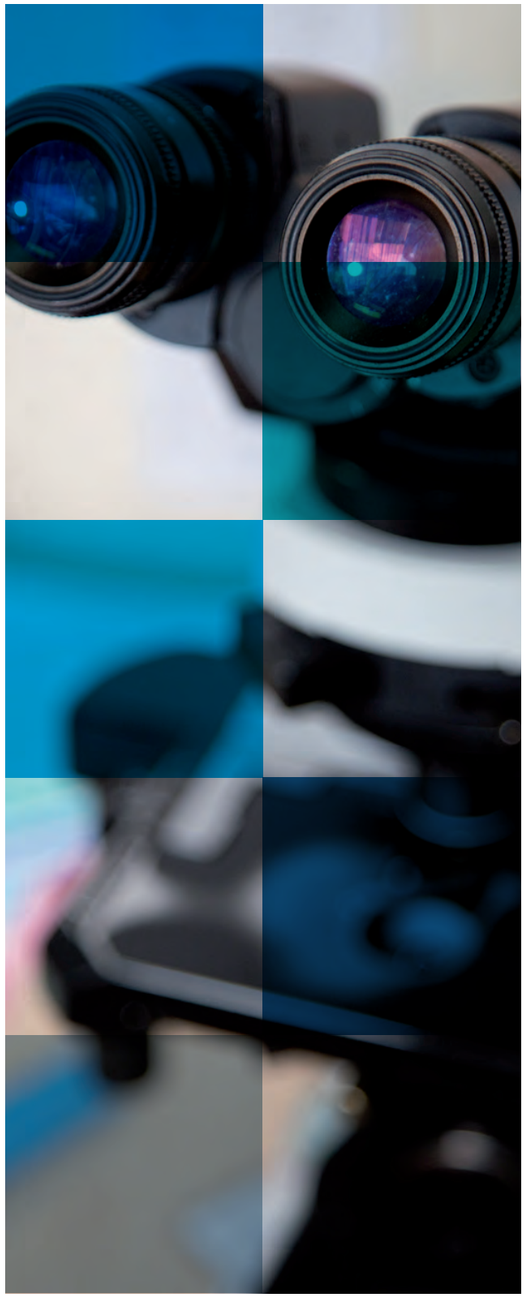
unicancer RESEARCH

Research is at the heart of Unicancer's action. In recent years, cancer research has proven to be a formidable field of therapeutic, technological and organisational innovation.

Pr. Jean-Yves BLAY, PRESIDENT

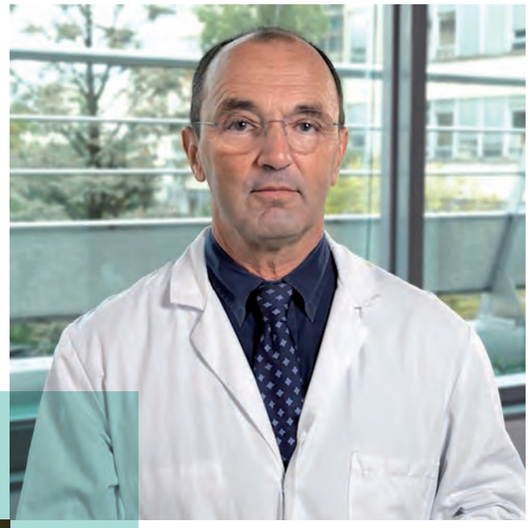
Innovative by nature, the Centres in our network have always been at the forefront of the fight against cancer to improve patient care by ensuring rapid access to innovations in care and research.

Sophie BEAUPÈRE, GENERAL DIRECTOR



About us

Leading academic clinical trial sponsor in France, Unicancer is a major stakeholder in cancer research in France and in Europe.
Its mission, to move research and treatments forward in a translational approach using health data; Its ambition, to work to serve public health and benefit all patients, with a special focus on rare cancer and cancer with poor prognosis and on specific populations, especially paediatric and geriatric.



Sophie BEAUPÈRE
General Director

Pr. Jean-Yves BLAY
President

L'Histoire de la prise en charge des cancers en France est ancienne, avec certains de nos centres existant depuis près de 100 ans. En 1945, par ordonnance du Général De Gaulle, les Centres de lutte contre le cancer (CLCC) ont été officiellement créés en tant qu'établissements de santé exclusivement dédiés à la cancérologie. Cette cancérologie, qui a profondément évolué, et qui n'est plus, en 2022 ou 2023, la même que la cancérologie des années 80, 90 et même de 2010. Avec la connaissance, de plus en plus fine mais encore imparfaite, des mécanismes intimes de l'oncogenèse, notre discipline et la prise en charge du cancer sont entrées dans une période formidable, avec des progrès majeurs enregistrés, en matière de survie mais aussi de techniques et de qualité de vie des patients.
Les progrès des traitements locaux, l'avènement de la biologie moléculaire, les promesses de l'intelligence artificielle : nous avons désormais à notre disposition des outils qui nous permettent de mieux diagnostiquer à l'aide notamment des biomarqueurs, de comprendre l'oncogenèse et le comportement de la tumeur vis-à-vis du système immunitaire et surtout de mieux classifier, décrire la maladie et de guider le traitement.
La conséquence immédiate est une fragmentation de la pathologie cancéreuse en une série de maladies rares, spécifiques, qui sous-tend le développement des thérapies ciblées dans une approche de médecine personnalisée.
L'autre conséquence est qu'on ne peut plus toujours conduire des essais cliniques selon les méthodes traditionnelles. Unicancer promeut l'adoption de nouveaux modèles d'essais cliniques et surtout souhaite lever les freins pour renfoncer l'activité et la compétitivité de la France pour les essais cliniques et faciliter l'accès à l'innovation pour les patients.

Le modèle Unicancer mise sur l'agilité et l'excellence. Parmi les chercheurs les plus cités en médecine clinique, toutes disciplines confondues, la moitié sont des cancérologues membres du réseau Unicancer, ce qui témoigne encore une fois de la dynamique de progrès que vit notre discipline et de l'engagement et de l'excellence des médecins et chercheurs de nos centres.
Avec un objectif qui nous réunit tous : faire avancer les connaissances et les pratiques cliniques au bénéfice de tous les patients, de la prévention au suivi post-cancer en passant par les traitements les plus pointus et ciblés. Avec de nombreux succès et plus de 100 essais en cours, l'année 2022 a été une nouvelle incarnation de la lutte sans relâche que nous menons contre le cancer.

EDITORIAL

The history of cancer management in France goes back a long way, with some of our centres dating back almost 100 years. In 1945, by decree of General De Gaulle, the Centres de lutte contre le cancer (CLCC) were officially created as health institutions exclusively dedicated to cancer research.
This cancer research, which has undergone profound changes, is not the same, in 2022 or 2023, as the cancer research of the 80s, 90s and even 2010. With our increasingly detailed but still imperfect knowledge of the intimate mechanisms of oncogenesis, our discipline and the management of cancer have entered a formidable period, with major progress being made not only in terms of survival, but also of techniques and quality of life for patients.
Advances in local treatments, the advent of molecular biology, the promise of artificial intelligence: we now have tools at our disposal that enable us to make better diagnoses using biomarkers in particular, to understand oncogenesis and the behaviour of the tumour in relation to the immune system, and above all to better classify and describe the disease and guide treatment.
The immediate result of this is the fragmentation of cancer pathology into a series of rare, specific diseases, underpinning the development of targeted therapies in a personalised medicine approach.
The other consequence is that clinical trials can no longer always be conducted using traditional methods. Unicancer is promoting the adoption of new clinical trial models and, above all, removing the obstacles to boosting France's clinical trial activity and competitiveness, and facilitating access to innovation for patients.

The Unicancer model focuses on agility and excellence. Half of the most frequently cited researchers in clinical medicine, across all disciplines, are cancer specialists who are members of the Unicancer network, once again demonstrating the dynamic progress being made in our field and the commitment and excellence of our doctors and researchers in our centres.

Our common objective is to advance knowledge and clinical practice for the benefit of all patients, from prevention to post-cancer follow-up, and including the most advanced, targeted treatments.
With many successes and more than 100 tests under way, 2022 was a new incarnation of our relentless fight against cancer.

EDITORIAL

Dr Muriel DAHAN
Director of Research and Development

From improved diagnosis to treatment, the progress made in recent years has revolutionised cancer care. Earlier and more accurate diagnoses, increasingly effective drugs and medical devices, molecular targeting, digital technology, artificial intelligence, real-life monitoring: precision medicine has become a reality, and we now have a panoply of research techniques that enable us to diversify sources of knowledge and implement this knowledge to advance cancer treatments.

The development of this "evidence-based medicine" (EBM) is profoundly changing the way clinical research is conducted, which until now has been anchored on the totem pole of double-blind randomised clinical trials. Adaptive, pragmatic, platform, outpatient, digital or AI arm trials are now improving the way studies are conducted and, beyond that, our understanding of the disease and treatments.

Without replacing the double-blind randomised trial, which remains the gold standard whenever possible, they enrich EBM with new robust methodologies whose levels of evidence can be quantified for situations where it is not possible to implement them.

Faced with these paradigm shifts, major challenges lie ahead. Unicancer is and must be a pioneer in the implementation of these new trials, which are as close as possible to the patient's reality, which also involve community medicine, which use real-life health data and which must free themselves in part from certain cumbersome regulations. With the aim of improving prevention and screening, speeding up innovation, saving time and increasing agility - and therefore attractiveness - these developments will help limit diagnostic and therapeutic errors, adverse reactions and avoidable loss of opportunity, and consequently unjustified expenditure, making better use of human and financial resources. The length of time that each trial usually takes, currently around ten years, is sometimes a source of lost opportunity for the patient, especially when treatment standards for a disease evolve in the meantime, which is often the case nowadays with the acceleration of discoveries and the increasing personalisation of treatments.

Unicancer's strength lies in the fact that it is a specialist network of excellence: with over 730 trials conducted throughout the CLCC network, 109 of which are sponsored by Unicancer R&D, thanks to the 150 or so professionals in my department, organised around "organ groups" and "cross-disciplinary groups", a network of specialist centres and the best cancer experts, we have everything we need to pursue an ambitious R&D strategy that will advance knowledge and change practices.

As the new Director of Research and Development, 2022 seems to me to be an excellent example of this proliferation of projects, with 9 new projects being implemented (2023 is also shaping up to be very dynamic). The MyPeBS programme, which is nearing the end of its inclusion period, a strong emphasis on therapeutic de-escalation studies, an increase in translational research and numerous ancillary research projects to exploit the samples and data from the trials are all illustrations of Unicancer's strength.

Structuring and making the most of this accumulated wealth is one of the challenges for 2023, which is included in the roadmap we are currently finalising, alongside maintaining excellence, strengthening relations with our industrial and academic partners and improving the visibility of our research activities as close as possible to centres and patients.

De l'amélioration du diagnostic à la conduite des traitements, les progrès des dernières années ont bouleversé la prise en charge en cancérologie. Des diagnostics de plus en plus précoces et précis, des médicaments et dispositifs médicaux de plus en plus performants, le ciblage moléculaire, le numérique, l'intelligence artificielle, le suivi en vie réelle : la médecine de précision est devenue une réalité et nous disposons désormais d'une panoplie de techniques de recherche qui permettent de diversifier les sources de connaissances et d'implémenter ces connaissances pour faire avancer les traitements contre le cancer. L'évolution de cette « evidence-based medicine » (EBM) bouleverse profondément les modalités de la recherche clinique, jusqu'ici ancrée sur le totem des essais cliniques randomisés en double aveugle. Désormais les essais adaptatifs, pragmatiques, plateforme, en ambulatoire, avec bras numérique ou bras IA améliorent la conduite des études et au-delà, notre compréhension de la maladie et des traitements.

Sans remplacer l'essai randomisé double aveugle qui reste le gold standard quand il est possible, ils enrichissent l'EBM de nouvelles méthodologies robustes dont les niveaux de preuve peuvent être quantifiés pour les situations où il n'est pas possible de le mettre en œuvre.

Face à ces changements de paradigme, des enjeux majeurs sont devant nous. Unicancer est et doit être pionnier dans la mise en œuvre de ces nouveaux essais qui vont au plus près de la réalité du patient, qui impliquent aussi la médecine de ville, qui utilisent les données de santé en vie réelle et qui doivent s'affranchir en partie de certaines lourdeurs règlementaires.

Avec en ligne de mire la volonté d'améliorer la prévention et le dépistage, d'accélérer l'innovation, de gagner en temps et en agilité, donc en attractivité, ces évolutions permettront de limiter les errances diagnostiques et thérapeutiques, les effets indésirables et les pertes de chances évitables, et par conséquent les dépenses injustifiées, donc de mieux utiliser les ressources humaines et financières. Le temps long usuel d'une dizaine d'années que dure actuellement chaque essai est parfois source de perte de chance pour le patient, surtout lorsque les standards de traitement d'une pathologie évoluent dans l'intervalle, ce qui est souvent le cas actuellement avec l'accélération des découvertes et la personnalisation croissante des traitements.

La force d'Unicancer est d'être un réseau d'excellence spécialisé : avec plus de 730 essais conduits dans l'ensemble du réseau des CLCC, dont 109 sont promus en propre par Unicancer R&D, grâce aux quelque 150 professionnels que compte ma direction, organisée autour de « groupes organes » et de « groupes transverses », un réseau de centres spécialisés et les meilleurs experts cancérologues, nous avons tous les atouts pour mener une stratégie de R&D ambitieuse, qui fait avancer les connaissances et changer les pratiques.

En tant que nouvelle directrice de la recherche et du développement, 2022 me parait être un excellent exemple de ce foisonnement de projets avec notamment 9 nouveaux projets mis en œuvre (2023 s'annonçant également très dynamique). Le programme MyPeBS qui arrive en fin d'inclusion, un accent fort mis sur les études de désescalade thérapeutique, une montée en charge de la recherche translationnelle et de nombreux projets de recherche ancillaire pour exploiter les échantillons et données issus des essais, sont autant d'illustrations de la force de frappe d'Unicancer. Structurer et valoriser cette richesse accumulée est un des enjeux de 2023, qui figure sur la feuille de route que sommes en train de finaliser, avec le maintien de l'excellence, du renforcement des relations avec nos partenaires industriels et académiques et de l'amélioration de la visibilité de nos activités de recherche au plus près des centres et des patients.

EDITORIAL

The Data & Partnerships Department was created in 2020 to meet the current challenges of health data research. In 2022, it continued to develop its missions by launching a project to pool infrastructures and tools, which should lead to the development of a network of CLCC (centre de lutte contre le cancer - cancer research centre) warehouses, along with collaboration with other health institutions that treat cancer, with the aim of accelerating innovation. Research into healthcare data should make it possible to respond to the challenges of personalised care, from diagnosis to post-cancer support (cancer modelling, development of artificial intelligence algorithms and medical decision support tools), while providing objective elements for assessing the efficacy of treatments, therapeutic strategies and care pathways with a view to informing public decision-making. This research should also contribute to the development of new methodologies that will enable innovation in clinical research and provide evidence of the efficacy of treatments, particularly in the field of rare cancers. It is intended to provide a foundation for knowledge and to support all aspects of innovation for the benefit of patients.

Access to this huge pool of information is now within our grasp, but we need to develop and pool our know-how and tools, build data warehouses and work on data interoperability and quality. The OncoDS (Onco Data Share) federated warehouse project, winner of the call for tenders for hospital health data warehouses led by DGOS (direction générale de l'offre de soins - directorate general for healthcare) and the BPI (bibliothèque publique d'information - public information library) under the aegis of HDH (health data hub), which already brings together 12 CLCCs, will be the key to our ability to federate the cancer ecosystem to develop these innovations.
Pioneering programmes such as the UNIBASE programme, operated in partnership with HDH, and the CONSORE tool developed several years ago, fit in perfectly with this vision of structuring a network of local warehouses.

Anne-laure MARTIN
Director of Health Datas and Partnerships

Moreover, following the success of the ESME programme, the first centralised health data warehouse (HDW) implemented by Unicancer, 2022 will also see the deployment of a second centralised warehouse: ODH (Onco Data Hub), launched in 2021, which has obtained authorisation from CNIL (Commission nationale de l'informatique et des libertés - French data protection authority) and began exporting data in 2022. This ambitious and innovative programme is based on an automated data collection approach, which should enable real-life data to be made available very quickly and therefore used. With 30 partner institutions due to join by the end of 2022, this warehouse is intended to be a "drug observatory" serving the medical community and public and private partners.

In parallel with these warehouse programmes, and because we want to be able to integrate all the dimensions linked to the patient in personalising treatments and care pathways, 10 years after its creation the CANTO cohort has been transformed into a genuine data acquisition infrastructure. This will serve to activate other cohorts in other organs and indications, so as to offer the research community high-quality real-life data enriched by SHS, quality of life, neurocognition and biology components, in line with the arrival of innovation across the whole field of cancer research. Finally, the WeShare programme, initiated in 2021, has launched its first module offerings on quality of life and human and social sciences, which will enable us to better integrate global monitoring and patient vision.

Our strength clearly lies in the fact that we look at health data in terms of different uses, different information scopes and different time scales, with projects that are both unifying and highly structuring for institutions in terms of implementing their local warehouse strategy, and mobilising for the community of public and private researchers, because our objective is clear: to improve patient care and put patients at the heart of our thinking.

In particular, 2023 will be a decisive year for the creation of an ethics, professional conduct and patients' rights committee that will apply across all our programmes and those of the CLCCs, and in which representatives of patients' and users' associations will be heavily involved.

Créée en 2020 en vue de répondre aux enjeux actuels de la recherche sur les données de santé, la Direction Data & Partenariats a poursuivi en 2022 le développement de ses missions en lançant le chantier de la mutualisation d'infrastructures et d'outils devant conduire au développement d'un réseau d'entrepôts des CLCC, ainsi que la collaboration avec d'autres établissements de santé prenant en charge le cancer avec l'ambition d'accélérer l'innovation.
La recherche sur les données de santé, doit en effet permettre de répondre aux enjeux de la personnalisation de la prise en charge, du diagnostic à l'accompagnement de l'après cancer (modélisation du cancer, développement d'algorithmes d'intelligence artificielle ou d'outils d'aide à la décision médicale), tout en apportant des éléments objectifs de l'évaluation de l'efficacité des traitements, des stratégies thérapeutiques et des parcours de soin en vue d'éclairer la décision publique.
Cette recherche doit également contribuer au développement de nouvelles méthodologies permettant d'innover en matière de recherche clinique et en vue d'apporter des preuves d'efficacité des traitements notamment dans le champ des cancers rares. Elle doit permettre d'asseoir les connaissances et d'accompagner l'innovation, au bénéfice des patients, dans toutes ses composantes.
Accéder à ce formidable vivier d'informations est désormais à notre portée mais nécessite de développer et de mutualiser les savoir-faire et les outils, de disposer d'entrepôts de données, de travailler sur l'interopérabilité et la qualité des données. Le projet d'entrepôt fédéré OncoDS (Onco Data Share), lauréat de l'appel d'offre entrepôts de données de santé hospitaliers piloté par la DGOS et la BPI sous l'égide du HDH, qui réunit d'ores et déjà 12 CLCC, sera la clé de notre capacité à fédérer l'écosystème de la cancérologie pour développer ces innovations. Des programmes pionniers tels que le programme UNIBASE conduit en partenariat avec le HDH, et l'outil CONSORE développé depuis plusieurs années s'intègrent parfaitement dans cette vision de structuration d'un réseau d'entrepôts locaux.

Par ailleurs, après le succès du programme ESME, premier entrepôt de données de santé (EDS) centralisé mis en œuvre par Unicancer, l'année 2022 a également été marquée par déploiement d'un second entrepôt centralisé : ODH (Onco Data Hub), lancé en 2021, et qui a obtenu l'autorisation de la CNIL et opéré ses premiers exports de données en 2022. Ce programme ambitieux et novateur est basé sur une approche de collecte automatisée des données, ce qui doit permettre une mise à disposition très rapide des données de vie réelle et donc leur utilisation. Intégrant 30 établissements partenaires fin 2022, cet entrepôt se conçoit comme un "observatoire du médicament" au service de la communauté médicale et des partenaires publics et privés.

En parallèle de ces programmes d'entrepôts, et parce que nous souhaitons pouvoir intégrer toutes les dimensions liées au patient dans la personnalisation des traitements et des parcours de soin, 10 ans après sa création la cohorte CANTO a été transformée en véritable infrastructure d'acquisition de données, ce qui permettra d'activer d'autres cohortes dans d'autres organes et indications afin d'offrir à la communauté des chercheurs des données de vie réelle de qualité enrichies par des composante SHS, qualité de vie, neurocognition et biologie, collant à l'arrivée de l'innovation sur tout le champ de la cancérologie. Enfin le programme WeShare initié en 2021 a lancé ses premières offres de modules sur la qualité de vie et les sciences humaines et sociales ce qui va nous permettre de mieux intégrer le suivi global et la vision des patients. Notre force réside clairement dans le fait d'envisager la donnée de santé sous différents cas d'usage, différents périmètres informatifs, différents temps de mise à disposition, avec des projets à la fois fédérateurs et hautement structurants pour les établissements en termes de mise en œuvre de leur stratégie locale d'entrepôt, que mobilisateurs pour la communauté de chercheurs publics et privés car l'objectif est clair pour nous : améliorer la prise en charge des patients et les placer au cœur de notre réflexion. 2023 sera notamment une année décisive pour la constitution d'un comité d'éthique, de déontologie et de droits des patients transverse à l'ensemble de nos programmes et de ceux des CLCC où les représentants des associations de patients et usagers seront fortement impliqués.

UNICANCER RESEARCH PRIORITIES AND CHALLENGES

Over 2021-2022, this commitment is seen in three strategic priorities answering to the main challenges of oncology in the 21st Century:

1: UNDERSTAND AND ERADICATE CANCER

Faced with a polymorphic, progressive and sometimes so-called chronic disease, Unicancer uses an integrated and comprehensive approach. From research into risk factors through the development and evaluation of new therapies, to post-cancer mental health and welfare care, and investing especially in:

- The development of early phase trials to fast track access to innovation, especially for cancer with poor prognosis,
- Study of the benefit-risk ratio of new treatments,
- Evaluation and optimisation of treatment strategies and sequences,
- Personalisation of treatments according to the genetic and molecular profile of patients and tumours,
- Prevention and early detection of cancer especially through large cohort studies,
- Improvement of quality of life of patients by treatment de-escalation and long-term follow-up.

2: BE AT THE FOREFRONT OF KNOWLEDGE AND TECHNOLOGIES

Positioning ourselves at the front of oncology innovations requires combining scientific excellence, new paradigms and disruptive technology. Spearhead of innovation in oncology, as much in research as in care, Unicancer has taken a firm stance on:

- Circulating DNA detection techniques for improving early diagnosis, predicting treatment response, refining the prognosis and adapting supportive care,
- Collection and exploitation of health data, by launching or integrating large-scale database programmes and working on their interoperability,
- Artificial intelligence especially to support pathology.

3: MEET UNMET MEDICAL NEEDS AND MAJOR HEALTH ISSUES

Go where no one has gone before, to areas little covered by the pharmaceutical industry, looking at specific populations, especially the elderly, targeting rare cancers and cancer with poor prognosis: Unicancer dedicates a large part of its activity to rare diseases, because the medical and human challenges are significant in that area.
Beyond that, by investing in translational research and cross-analysis of data from clinical trials and real-life health data, Unicancer has been rolling out an innovative and to the purpose R&D strategy.
As a bonus, major publications hailed by the international community and changes in practices to benefit patients. Improving patient treatment and quality-of-life and answering to major health issues remains Unicancer's ambition in the years to come.

UNICANCER STRENGTHS & ASSETS

A network of 18 French Comprehensive Cancer Centers and 2 afiliates members, exclusive expertise in cancer, a culture of collaboration, integrated approach to the fight against cancer, Unicancer Research's strengths and assets can be covered in 3 points:

1: EXPERTISE AND INTEGRATION

- French network of dedicated cancer centres working on the three missions that are care, research and training.
- A philosophy and organisation true to the spirit of Comprehensive Cancer Centers, leading to integrated and multidimensional management and a cross-sectoral research approach, from fundamental research to real-life data, through clinical research, with a new Data Department especially.
- Researchers with groups per therapeutic area and cross-disciplinary groups for reinforced, but shared and collegial expertise.

2: AGILITY, LEADING-EDGE TECHNOLOGIES, PRAGMATISM

- Unicancer, an expert, human-sized network with tried-and-tested and efficient networking.
- A combination of agility and pragmatism so as not to spread resources thin and to use all sources and opportunities for innovation.
- Leading-edge technical hubs for conducting innovative and ambitious projects.
- ISO 9001-certified clinical research activity.
- A biological resource centre in Lyon, a data centre in Montpellier.
- Certified and centralised biobanks and data platforms.

3: NETWORK, PARTNERSHIP AND COLLABORATION

- The coming together of site research and a network within cancer centres and research through major programmes coordinated by Unicancer R&D Departments.
- A tradition within cancer centres raised to the rank of philosophy and strongly anchored in how Unicancer operates.
- A historic leaning which is seen in terms of multidisciplinarity, but also internationally and with all types of bodies, especially public-private (pharmaceutical companies and start-ups).
- Two concrete examples:
  - MATWIN (Maturation & accelerating translation with industry): innovation development centre in oncology and example of Unicancer's ambitious partner-based and translational dynamic.
  - EORTC (European Organization for Research and Treatment of Cancer) liaison office: a central role and recognition of Unicancer's excellence in cancer research.

PATIENT'S ROLE

THE PATIENT, KEY STAKEHOLDER IN UNICANCER RESEARCH

For some years now, 4, 5 or 6P medicine has placed the patient at the heart of healthcare strategies. Patients also are staking a claim to a place in the field of research little by little, whereby the concept of "patient expert" takes on its full meaning. A patient that is also a carer, trainer, resource who has gained knowledge of their disease and the related stakes. Initially a figure of rare or chronic diseases, the patient-expert is now a key stakeholder in the fight against cancer, and at Unicancer has a central place in the vision the institution is developing in the management of patients and cancerous diseases. From prevention to reinsertion through care and clinical research. Stakeholder in their disease and treatment, the patient is asked to get involved in reviewing research protocols and results in liaison with Unicancer research departments. Because their viewpoint is relevant and their position and perception bring up additional issues. **In 2022, several tangible initiatives and actions on the role of the patient in research were launched or continued. They embody the drive of Unicancer researchers to work with and for patients and are among the strategic objectives for 2023.**

Setting up patient committees

Even if working with patients' associations is commonplace, they are often rigid and intimidating to patients.
Unicancer would therefore like to go further and set up patient committees which would become involved in research priorities and projects. Far beyond the idea of simple consent, the aim is to involve patients in research choices, in creating trial synopses but also in building networks of patients and former patients. The objective here is also to maintain a link and to measure the impact of the chronic burden of disease and to fuel discussions on human and social sciences and health data and health data platforms.

Sharing all research results

All results from Unicancer research projects, both positive and negative, are published in peer-reviewed papers and/or presented at congresses. However these data are little accessible to the public. In 2022, the Unicancer Clinical and Translational Research Department therefore took the initiative to write summary, popularised reports on the results of clinical trials in a language and format easy to read and understand for patients.
This initiative will be continued and escalated in 2023.

EXPERT GROUPS

Unicancer provides structural support to 10 internationally recognised and multidisciplinary expert groups dedicated to designing and steering innovative clinical studies.
Their goals are to offer patients access to innovative treatments, to optimise therapeutic strategies and to contribute to scientific education and dissemination in their field, notably by developing collaborative networks.

TUMOR GROUPS

FRENCH BREAST CANCER INTERGROUP (UCBG)

President : Thomas Bachelot, Centre Léon Bérard, Lyon

Strategic priorities

Subtypes with poor prognosis, biology-driven strategies of therapeutic de-escalation, survivorship.

GASTRO-INTESTINAL GROUP (UCGI)

President : Christelle de la Fouchardière, Centre Léon Bérard, Lyon

Strategic priorities

Innovative phase II studies, new diagnostic approaches towards personalized treatment, translational research, large randomised phase II/III studies, rare cancers.

GENITOURINARY GROUP (GETUG)

President : Karim Fizazi, Gustave Roussy, Villejuif

Strategic priorities

Therapeutic strategy studies, research programmes in rare tumours, development of biological research programmes in connection with clinical projects.

HEAD & NECK GROUP

President : Caroline Even, Gustave Roussy, Villejuif

Strategic priorities

Early-phase studies, rare cancers, biology-driven medicine.

SARCOMA / RARE CANCERS GROUP

President : Nathalie Gaspard, Gustave Roussy, Villejuif (paediatrics) ; Jean-Yves Blay, Centre Léon Bérard, Lyon (adults)

Strategic priorities

Improvement of early management of sarcomas and other rare connective tissue tumours, translational research, biobankings.

CROSS-PATHOLOGY GROUPS

IMMUNO-ONCOLOGY GROUP (IOG)

President : Jean-Pierre DELORD, Vice-president, IUCT-Oncopole, Toulouse

Strategic priorities

Cancer immunotherapy research, translational research, identification of predictors and biomarkers of extreme response or poor tolerance to immunotherapy.

ONCOLOGY GERIATRICS (GERICO)

President : Capucine Baldini, Gustave Roussy, Villejuif

Strategic priorities

Innovative clinical research in oncogeriatry, methodological adaptation of the evaluation criteria to the geriatric population, diagnostic and therapeutic rationalisation. Expertise in the evaluation and description of geriatric populations, promote the use of G-CODE developed in the framework of DIALOG (Oncogeriatric intergroup associating SOFOG), specific questions for elderly subjects, innovative methodology & adaptive phase II, Evaluation of strategies in elderly patients.

PERSONALISED MEDICINE GROUP (MED PERSO)

President : Fabrice André, Gustave Roussy, Villejuif

Strategic priorities

Personalized biology-drivenmedicine, proof of concept studies, identification of predictors or biomarkers of treatment efficacy or resistance.

SUPPORTIVE CARE INTERGROUP (SDS AFSOS)

President : Didier Mayeur, Centre Georges François Leclerc, Dijon

Strategic priorities

High standard clinical programmes for the evaluation of supportive cares, quality of life, cost-efficiency, humanities and social sciences.
4 strategic axes have been identified: The organization of the care pathway, Symptom management, Health Behaviour, Develop and strengthen patient trials.

TRANSLATIONAL RESEARCH AND DEVELOPMENT IN ONCOLOGY RADIATION (UNITRAD)

President : Sophia Rivera, Gustave Roussy, Villejuif

Strategic priorities

Changing practice clinical studies integrating translational research, Artificial Intelligence radiomic/Imaging, radiobiology (immunoradiotherapy /radiosensitivity/ radiopotentialisation), radiotherapy quality assurance, PROMs and real-world data, new technologies and physics innovation.

MATWIN
MATURATION & ACCELERATING TRANSLATION WITH INDUSTRY

MATWIN

Maturation and Accelerating Translation With INdustry

MATWIN is a French open-innovation platform, fully-owned subsidiary of Unicancer, dedicated to supporting innovation in oncology. For more than ten years, its goal has been to help scientists and entrepreneurs evaluate and optimize opportunities to transform their research into product, for the benefit of the patient.

MATWIN main objectives are to select R&D innovative oncology projects with high technology transfer potential, drive asset identification and support the most promising ones in accelerating development and optimizing collaboration opportunities.
The process is based on a continuing partnership with major international companies working in oncology (Amgen, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Gilead, GlaxoSmithKline, MSD, Nanostring Technologies, Novartis, Pfizer, Pierre Fabre, Roche, Sanofi) willing to benefit from the attractiveness of French research in oncology.

The MATWIN's accelerator programme is open to European academic teams and startups looking forward accessing high value-added expertise and network of stakeholders to foster partnership opportunities.

In addition to this program, MATWIN has also co-organised the annual European Oncology Partnering Convention MEET2WIN since 2015. This event has proved increasingly successful and is becoming a reference meeting point to boost collaborative opportunities in the oncology field in Europe gathering each year around 300 attendees (international companies, SMEs, startups, investors, researchers,…).

MATWIN is also in charge of the coordination of OncoSTART, a French consortium which brings together 13 key national organisations dedicated to oncology research and innovation, pooling their specific expertise, know-how and networks to boost entrepreneurship in the fight against cancer.

onco START

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https://matwin.fr/en/meet2win-2022/

AMGEN
AstraZeneca
Boehringer Ingelheim
Bristol Myers Squibb
GILEAD
GSK
MSD
nanoString
NOVARTIS
Pfizer
Pierre Fabre
sanofi
Roche
unicancer

MEET2WIN
Oncology Partnering Convention

Each year, MEET2WIN is combining conferences, workshops, projects elevator pitches and thousands of face to face meetings. A large time is dedicated to networking, and a showcase is offered for startups looking forward to fundraising via a dedicated session called OUI (Oncology Upward Investment). This specific session allows selected companies to pitch their innovative solutions in front of a review panel of 15 major European investors able to support their growth, thus offering new opportunities of development support to leverage cutting edge innovation in oncology.

A few figures from MATWIN's review (2009-2022):

- **+260** applicant projects
- **105** projects interviewed by the MATWIN International Board
- **+45** startups created post MATWIN support (PDC*line, Syndivia, Apmonia Therapeutics, H Immune, Gliocure, ROCA Therapeutics, Celeos, ORAKL,…)
- **+40** collaborations with biotechs or pharmas

2022 KEY FIGURES

22 734

PATIENTS
included in Unicancer R&D sponsored-clinical trials of which 20 572 in MyPeBS

109

ONGOING CLINICAL TRIALS
for the Unicancer R&D department, including 50 recruiting trials

60

PUBLICATIONS
in scientific journals

83 000

PATIENTS
registered in the ESME database

208

INVESTIGATIONAL SITES INVOLVED*
(public hospitals, private clinics, comprehensive cancer centres), including 40 Abroad

9

NEWLY INITIATED CLINICAL TRIALS

Unicancer is ISO 9001 certified for its clinical research activity

** The French general practitioners, gynaecologists and radiologists who contributed to the MyPeBS recruitment in 2019 are not included in this number.*

INTERNATIONAL COLLABORATIONS

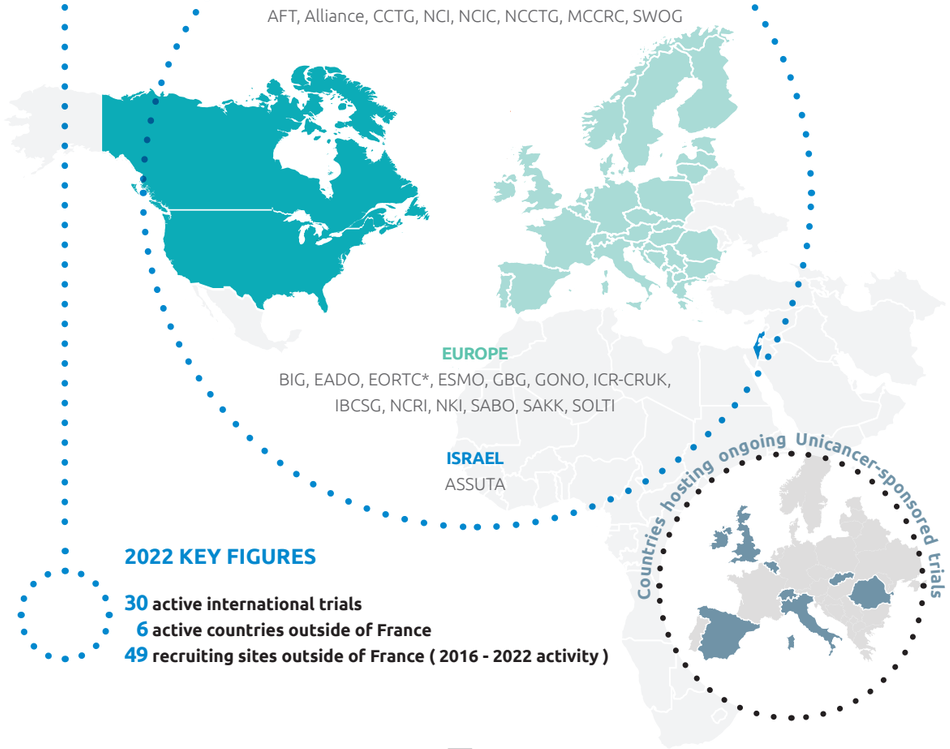
Several major trials sponsored by Unicancer are conducted at an international level, thanks to key partnerships with other academic cancer research groups, or through an extended network of collaborating university hospitals and research teams, mainly in Europe but also overseas. Unicancer, as a major European academic sponsor in oncology, seeks to gain worldwide visibility, with the ultimate goal of developing high-quality practice-changing clinical research and accelerating patients' access to innovation.

Glossary of cancer research groups and networks

AFT: Alliance Foundation Trials in oncology
BIG: Breast International Group
CCTG: Canadian Cancer Trials Group
CRUK: Cancer Research UK
EADO: European Association of Dermato Oncology
EORTC: European Organisation for Research and Treatment of Cancer
FAGE: Federación Argentina de Gastroenterología
GBG: German Breast Group
ICR-CRUK: Institute of Cancer Research - Cancer Research UK centre
IBCSG: International Breast Cancer Study Group
GONO: Gruppo Oncologico del Nord Ovest
MCCRC: Multiprofessional Critical Care Review Course
NCCTG: North Central Cancer Treatment Group
NCI: National Cancer Institute - USA
NCIC: National Cancer Institute of Canada
NCRI: National Cancer Research Institute - UK
NKI: Netherlands Cancer Institute
SABO: Swedish Association of Breast Oncologists
SAKK: Groupe Suisse de Recherche

Unicancer's international partners

NORTH AMERICA
AFT, Alliance, CCTG, NCI, NCIC, NCCTG, MCCRC, SWOG



EUROPE
BIG, EADO, EORTC*, ESMO, GBG, GONO, ICR-CRUK, IBCSG, NCRI, NKI, SABO, SAKK, SOLTI

ISRAEL
ASSUTA

2022 KEY FIGURES

30 active international trials
6 active countries outside of France
49 recruiting sites outside of France (2016 - 2022 activity)

Clinical Research

Better prevention, better screening, better treatment: these are the objectives of the projects led by Unicancer's R&D teams. MyPeBS (My Personal Breast Cancer Screening) is a clinical study designed to improve and personalise breast cancer screening strategies.

Clinical Trials

https://recherche.unicancer.fr/fr/fr/la-recherche-clinique/les-essais-cliniques-unicancer/

Currently at the end of its inclusion phase, this study paves the way for deployment to other cancers, particularly colorectal cancers, for which screening strategies are currently unsatisfactory.
Combined with improved screening and prevention, personalised medicine now offers the hope of understanding and targeting the right treatment for the right patient. This is the challenge of the many projects currently under way or in the pipeline, and the abundance of ideas that enable our teams to build solid scientific projects, to advance knowledge and gain ground every day in the fight against cancer, for all patients.

MAIN CLINICAL RESEARCH PROJECTS

Study of chronic toxicities related to the treatment of non-metastatic cancer

CANTO is a prospective cohort dedicated to research questions regarding survival after breast cancer. The objective is to identify medium and long-term toxicities of anticancer treatments, evaluate their impact on patients and society, and predict them using molecular markers.
The cohort included 12 012 patients between 2012 and 2018. In addition to regular medical follow-up, specific CANTO follow-up includes the response to 40 questionnaires for each patient. It also involves the collection of 8 blood samples as well as fecal samples. It allows for the collection of primary tumor and data on radiotherapy, brain MRI, and HE/HES slide scanning, which aided in the cancer diagnosis. Since the end of 2020, the inclusions have allowed for the inclusion of patients under 45 years old at the initial diagnosis. 1250 young patients are expected to be included by the end of 2024. 792 patients have been included so far (including 414 in 2022).
This will enrich the cohort with young patients who have the highest prevalence of several post-treatment toxicities and deterioration of quality of life (QoL).
To expand the cohort, it is also planned to include 3000 patients treated with innovative therapies to assess their impact on QoL. **Since January 2022, 358 patients have been included in this context (including 311 in 2022); in 2023, recruitment will be expanded by opening a new cohort for lung cancers (1500 patients).** The objective is to subsequently complete the program by focusing on other organs, and other cohorts will be considered (ovarian, digestive, head, and neck).

In 2022, discussions around the 7 strategic axes (1 fatigue, physical activity, and weight; 2 medical-economics and return to work; 3 cognition and psycho-oncology; 4 impact of systemic treatment; 5 treatment adherence; 6 genetic risk and adverse effects; 7 radiotherapy) identified for the valorization of the cohort have intensified. Currently, 72 research projects, led by consortium members and/or in collaboration with other research teams, are underway. The research results in 2022 led to 14 publications (total of 34) and 7 new presentations (total of 50) at national and international conferences (ESMO, ESTRO, CWE, CCTF, EPH).

The challenges for CANTO in 2023 will be to:

- Maintain the existing cohort. Data collection will continue to have data with a follow-up period of up to 10 years post-diagnosis.
- Continue recruiting patients under 45 years old (CANTO Young) to acquire more power for conducting analyses, particularly regarding the impact of the disease and its management on return to work.
- Continue recruiting patients likely to be treated with innovative therapies (CANTO Innov) (olaparib, TDM1, pembrolizumab), including initiating a cohort for a different indication than breast cancer (lung cancer).
- Create a new core dataset to expand the quantity of available data for researchers, especially for the 7 CANTO research axes.
- Complete the infrastructure transformation and develop data management procedures in a continuous quality development approach.
- Initiate the first data matching with the SNDS (French National Health Data System) for a research project via the INCA cancer data platform (CANTO work project validated by CESREES and CNIL).
- Maintain our business plan to become self-financed by 2025.
- Enrich the database with biological data and specifically develop omics analyses from the collected samples (genomics, proteomics, metabolomics, etc.).
- Open a cohort focused on therapeutic innovation in lung cancer and continue considering the possibility of opening cohorts for other indications (ovarian, digestive, head, and neck).

Cumulative inclusion of participants by country in the MyPeBS study as of December 31, 2022

17 310 Italy

9 283 France

8 701 Israel

4 721 Great Britain

1 736 Belgium

1 705 Spain

MyPeBS
Personalising
Breast Screening

The MyPeBS (**My Pe**rsonal **B**reast **S**creening) project is a large-scale clinical trial to evaluate a new approach to breast cancer screening.
The study is being conducted in several European countries, randomized and multicentre with the purpose of evaluating the **effectiveness of a personalised breast cancer screening.** MyPeBS seeks to develop a new fundamental approach to breast cancer screening that takes into account a given woman's individual risk factor for developing the disease compared to a standard screening.

Overall, we hope to recruit **56 435 women volunteers** (approximately 12 500 in France), living in Italy, France, the UK, Israel, Belgium, or Spain; aged between 40 and 70, and with no history of breast cancer. The personal experience of these women is crucial in this new procedure that this study is undertaking, as well as the associated psychosocial aspects that will be analyzed in MyPeBS and compared to the standard arm.

The ultimate goal of MyPeBS is to provide a more effective (better benefit/risk ratio) breast cancer screening in Europe, while demonstrating the acceptability, practical feasibility, and economic viability of such an approach. MyPeBS is a groundbreaking initiative that has the potential to transform breast cancer screenings and improve outcomes for women.

This 8 year project is coordinated by Dr Suzette Delaloge (Gustave Roussy, Villejuif) and managed by Unicancer. It involves 27 partners in 8 countries and is funded by the EU (H2020 - grant agreement number 755394) and the French NCI in France (PHRC 2017 research programs).

Sponsored by Unicancer, the MyPeBS clinical trial started in July 2019 and has included **43 456 participants as of December 31, 2022**, distributed as shown in the figure, while a total of 22 883 participants were recruited in 2022.

www.mypebs.eu

INCLUSIONS BY EXPERT GROUPS

Number of patients included in 2022 per Group and per institution type

-	UCBG	UNITRAD	MED PERSO	UCGI	GETUG	IOG		SARCOMA	SDS	GERICO	UCH&N	UNICANCER SPECIFIC PROJECTS	TOTAL	%
Public hospitals of Paris (AP-HP)	599	19	0	104	119	6		40	27	11	24	0	949	4,2 %
Other public hospitals (excl AP-HP)	18578	0	0	51	30	0		0	0	0	0	0	18659	82,1 %
FCCCs	1062	90	12	103	254	27		43	25	76	43	0	1735	7,6 %
Other private non-profit hospitals	16	1	0	21	33	1		3	0	2	8	0	85	0,4 %
Private clinics	249	36	0	34	80	7		0	0	0	0	0	406	1,8 %
City medical practice	11	5	0	22	14	3		0	12	0	0	0	67	0,3 %
Foreign institutions	833	0	0	0	0	0		0	0	0	0	0	833	3,7 %
TOTAL	21348	151	12	335	530	44		86	64	89	75	0	22734	
POURCENTAGE	93,9 %	0,7 %	0,1 %	1,5 %	2,3 %	0,2 %		0,4 %	0,3 %	0,4 %	0,3 %	0,0 %		

INCLUSIONS BY EXPERT GROUPS

Focus on the Unicancer network of French Comprehensive Cancer Centres (FCCCs)

-	UCBG	UNITRAD	MED PERSO	UCGI	GETUG	IOG	SARCOMA	SDS	GERICO	UCH&N	UNICANCER SPECIFIC PROJECTS	TOTAL	%
Léon Bérard center	129	3	0	11	5	0	11	0	11	5	0	176	10,2 %
Jean Perrin center	24	1	1	0	9	1	0	0	10	0	0	45	2,6 %
Curie Institute	72	7	2	0	10	0	10	0	7	0	0	106	6,1 %
Gustave Roussy	342	14	0	6	33	0	6	0	4	7	0	406	23,4 %
Oscar Lambret center	44	6	1	5	20	1	7	0	11	3	0	100	5,8 %
Francois Baclesse center	37	1	1	9	7	0	0	9	8	1	0	75	4,3 %
Institute of Cancer research in Western France	110	11	1	11	44	3	0	3	0	0	0	178	10,3 %
Bergonie Institute	45	3	0	3	31	0	3	0	0	0	0	86	5,0 %
Claudius Regaud Institute	34	5	2	1	20	6	4	0	20	14	0	102	5,9 %
Lorraine Institute of Oncology	16	2	2	0	2	0	0	0	2	0	0	22	1,3 %
Jean Godinot Institute	53	6	0	15	0	0	0	1	2	0	0	79	4,6 %
Paoli calmettes Institute	13	1	0	3	14	4	0	0	0	0	0	35	2,0 %
Montpellier Cancer Institute - Val d'Aurelle	4	6	0	5	4	0	1	0	0	0	0	28	1,6 %
Antoine Lacassagne center	6	9	2	10	10	2	0	0	0	8	0	57	3,3 %
Georges-François Leclerc center	53	4	0	5	19	2	0	0	0	1	0	80	4,6 %
Paul Strauss center	3	5	0	7	19	2	0	0	0	1	0	35	2,0 %
Henri Becquerel center	44	6	0	0	0	0	0	0	1	0	0	50	2,9 %
Eugène Marquis center	21	9	0	2	3	1	1	13	0	0	0	35	2,0 %
Sainte-Catherine Institute	12	4	0	8	4	5	0	0	0	3	0	38	2,2 %
TOTAL	1062	103	12	101	254	27	43	26	76	43	0	1733	
POURCENTAGE	61,3 %	4,4%	0,7 %	5,8 %	14,7 %	1,6 %	2,5 %	1,1%	4,4 %	2,5 %	0,0%		

INCLUSIONS BY TUMOUR LOCALISATION

Number of patients included in 2022 by tumour localisation and institution type

-	BREAST	BREAST_OF WHICH MYPEBS	BREAST_OF WHICH TUMOSPEC	DIGESTIVE	GENITO-URINARY	SARCOMA		LUNG	GYNEACOLOGICAL	HEAD & NECK	MULTIPLE LOCALISATIONS	TOTAL	%
Public hospitals of Paris (AP-HP)	60	559	141	104	119	42		4	0	24	37	949	4,2 %
Other public hospitals (excl AP-HP)	17	18561	404	51	30	0		0	0	0	0	18659	82,1 %
FCCCs	782	381	826	103	254	66		34	0	43	72	1735	7,6 %
Other private non-profit hospitals	5	12	0	21	33	5		0	0	8	1	85	0,4 %
Private clinics	52	222	58	34	80	0		4	0	0	14	406	1,8 %
City medical practice	7	4	0	22	14	0		5	0	0	15	67	0,3 %
Foreign institutions	0	833	0	0	0	0		0	0	0	0	833	3,7 %
TOTAL	923	20572	1429	335	530	113		47	0	75	139	22734	
POURCENTAGE	4,1 %	90,5 %	7,1%	1,5 %	2,3 %	0,5 %		0,2 %	0,0 %	0,3 %	0,6 %		

PARAMEDICAL RESEARCH

A strong axis of the Unicancer strategic plan

At the forefront of research, Unicancer's agile model allows and encourages the implementation of paramedical research on priority themes.
Paramedical research is a decisive factor in improving treatment and organisation and is a genuine mission of the Cancer Centres (CLCC).
Thus, all the medical assistants in the CLCCs have the possibility of investing in research, benefiting from favourable conditions: adapted time, allocated means, inter-institutional synergies. The Unicancer network supports emerging professions in healthcare research (IPA , IDEC , IDES, etc.)
The emulation and inspiration generated by such projects enhance the value of staff, build team loyalty and strengthen the attractiveness of our centres of excellence, by offering them stimulating and dynamic career prospects.
To date, more than 50 paramedical research projects have been carried out or initiated. This figure illustrates the commitment of the teams, for whom constantly improving patient care is an absolute priority.

UCBG

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FRENCH BREAST CANCER INTERGROUP

Group overview

The UCBG is a French Breast Cancer Intergroup, accredited by INCa (French national cancer institute) since 2013. It is the preferred contact for the pharmaceutical and biotechnology industries and academic partners at the national and international levels for the development of breast cancer studies in France. It brings together a network of researchers and centres dedicated to clinical and translational research in all areas of breast cancer (prevention, screening, diagnosis, surgery, medical treatments, radiotherapy, survivorship, support care). **Focusing on a multidisciplinary approach, UCBG has been a pioneer in personalised medicine, through the SAFIR programmes, and is also heavily involved in studies of therapeutic de-escalation and approaches to long-term survival and sequelae.** In terms of figures, the UCBG Group has more than 100 investigation centres throughout France and has enrolled more than 45 000 patients in 40 studies over the last 20 years.

2022 achievements
Major results and an innovative approach

Aster 70s, PADA-1, SAFIR-02 Breast, TRAK-ER, UNIRAD: 2022 was rich in results from major breast cancer studies, with prestigious communications and publications at ASCO, in The Lancet Oncology, Nature and JCO.

In elderly patients, the **Aster 70s** phase 3 clinical trial sponsored by Unicancer and led by Dr Etienne Brain from Institut Curie, looked at the issue of optimising and de-escalating treatment, personalising treatments and access to innovation for this elderly population. The highly anticipated final results of the study were presented in an oral session at ASCO.

The **PADA-1** prospective phase III study (1 017 women treated in the first line with an aromatase inhibitor combined with palbociclib, who provided blood samples for ESR1 mutation screening) demonstrated the clinical usefulness of monitoring ESR1 mutations in blood.

The results were published in The Lancet Oncology. The **TRAK-ER** study, which began in September, is a continuation of this therapeutic strategy in the adjuvant setting in collaboration with the Royal Marsden Hospital (London). The results were published in The Lancet Oncology.

Published in the journal Nature, the **SAFIR02-Breast** study showed that genomically targeted therapies improved progression-free survival (PFS) in patients with metastatic breast cancer presenting with genomic alterations classified as level I/II according to the ESCAT scale.

Published in the Journal of Clinical Oncology, the results of the international **UNIRAD** study, sponsored by UNICANCER, showed no benefit from everolimus administered in addition to standard hormone therapy in 1 278 patients with localised luminal cancer at high risk of relapse, followed for three years.

Thomas BACHELOT
President

> The publications and communications from 2022 prove that our research initiatives are innovative, well thought-out and address unmet clinical needs. It is thanks to our entire network of study Investigators that we can continue to address highly relevant issues, including new approaches to personalised medicine, the challenges of survival, molecular markers of recurrent disease and breast cancer prevention.

Outlook for 2023

Prevention, precision medicine and therapeutic de-escalation

In line with the guidelines of the ten-year cancer plan, the Intergroup's strategic priorities target three key areas: the development of prevention studies, precision medicine, particularly in the context of immunological selection or circulating DNA and pre-operative settings, rational therapeutic de escalation and studies of long-term survival and sequelae.

GASTROINTESTINAL GROUP (UCGI)

Group overview

One of the first Unicancer research groups, set up in 1991 and dedicated to digestive cancers. There are four levers for action: large-scale studies aimed at changing practices; phase II trials, with a particular focus on rare cancers, to provide access to innovative therapies; and translational research programmes to improve our understanding of these tumours, propose new diagnostic approaches and personalise treatments.

Christelle DE LA FOUCHARDIÈRE
President

2022 has been a landmark year, with the UCGI Group producing numerous results, particularly with respect to the pancreas, with numerous publications and presentations at conferences.
The Group's strong dynamism is illustrated this year by the creation of the UCGI Academy and the continuation of our training initiatives. While the multi-disciplinary nature of our office contributes to a wealth of interaction and visibility for our industrial and academic partners in France and internationally, the involvement of the centres, which we will continue to visit in 2023, remains essential to the Group's activity and the development of innovative studies.

2022 achievements
Advances in pancreatic cancer and creation of the UCGI Academy

Three new trials initiated, almost 400 patients included in 7 trials in total, 3 oral presentations and 3 posters at conferences and 4 publications in scientific journals: 2022 was an intense and rich year for the UCGI Group. Looking beyond the figures, the Group made a particularly strong showing in 2022 in pancreatic cancer, with the results of three studies presented at ESMO in Paris:

- the study **PRODIGE65-UCGI36-GEMPAX** comparing gemcitabine with or without paclitaxel in 2nd line metastatic pancreatic cancer,
- the **PRODIGE29-ACCORD26-NEOPAN** study comparing FOLFIRINOX to gemcitabine in locally advanced patients, and
- A study evaluating a sensitivity signature to gemcitabine based on the use of the PRODIGE24-ACCORD24 biological collection, which previously established FOLFIRINOX as the standard treatment in the adjuvant setting.

In addition to these significant advances in improving the therapeutic management of these difficult cancers, the Group has stepped up its involvement in training with the creation of the UCGI Academy, a forum for exchanges to support young investigators within the Group and in setting up new studies within the UCGI Group and the French PRODIGE intergroup.

Outlook for 2023
Major trials and training

2023 promises to be just as rich a year, with a number of highlights including the presentation of study results awaited by the international community, the launch of projects and cohorts, and the intensification of training and information initiatives for young oncologists.
Following on from the numerous communications in 2022, the 5-year results of the **PRODIGE 23** study and those of the PANIRINOX study, which is based on an innovative selection of patients using liquid biopsies, will be unveiled during 2023. While pancreatic cancer has been the focus of much attention over the past year, other digestive system cancers will be in the spotlight in 2023, with the launch of trials and projects focusing on innovative compounds or techniques, notably through the **TACE-3, HESTIA and ALICE trials in liver cancer and LOGICAN and TIRAGA in oesogastric cancers.**
With regard to colorectal cancers, and in particular BRAF-mutated metastatic forms, a major national clinical-biological cohort is to be launched. In pancreatic and colon cancer, research projects based on the biological collections gathered during the trials will be launched in 2023. The specific treatment of certain categories of patients is also at the heart of the Group's concerns, with the launch of projects dedicated to patients with DPD deficiency for whom fluoropyrimidines, the cornerstone of digestive oncology treatments, cannot be used.
In terms of education and communication, 2023 will see an increase in training and information initiatives: targeted workshops and webinars will be organised for young oncologists who are members of the UCGI Academy and Clinical Research Associates. The ABCD Days, a major annual event bringing together clinical practitioners and researchers, was held again this year, with more than 200 people taking part in face-to-face sessions.
The continuation of the Grand Tour de France of centres is also on the agenda for 2023. All these initiatives help to raise the profile of the UCGI Group and promote the major trials conducted by Unicancer.

GETUG

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GENITOURINARY GROUP

Group overview

The GETUG Group is a multi-disciplinary group with a focus on genitourinary cancers. Since its creation in 1994, it has developed a number of partnerships with hospitals, CLCCs and other organisations in France and abroad, as well as with the French Urology Association. **Objective: to develop research projects and phase II and III therapeutic trials, both nationally and internationally.**

Karim FIZAZI
President

Three landmark trials in prostate and bladder cancer have marked 2022, opening up new therapeutic perspectives. The promising results of the PEACE 1 trial in metastatic prostate cancer, the exploration of new options for vulnerable patients in the Peace 6 Vulnerable trial, and the focus on bladder cancer at high risk of recurrence in the Alban trial demonstrate our commitment to offering hope to patients. In 2023, GETUG will continue its active research, focusing on competitive trials and innovative local treatments, integrating medical imaging and DNA repair.

2022 achievements
Three flagship trials in prostate and bladder cancers

The PEACE 1, Alban and Peace 6 Vulnerable trials, conducted in partnership with pharmaceutical companies, were the main events of 2022.

Starting with a major publication in The Lancet of the highly promising results of the **PEACE 1** trial (Prostate Cancer Consortium in Europe). This prospective randomised phase III trial evaluated the combination of several treatment options (androgen deprivation with docetaxel, with or without radiotherapy, with or without abiraterone and prednisone) in metastatic hormone-related prostate cancer. 1 173 men were included at 100 European sites between 2013 and 2018 as part of this European trial funded as part of a PHRC (Hospital Clinical Research Programme) and by Janssen Pharmaceutical NV, Ipsen and Sanofi.

Also in prostate cancer, but in patients with vulnerable "de novo" metastatic prostate cancer with reduced functional capacity who are ineligible for docetaxel or agents targeting androgen receptors, the **Peace 6** Vulnerable trial is a randomised, double-blind study evaluating the efficacy of ADT ± darolutamide.

This Phase III trial is funded by Bayer and is being conducted in some ten countries.

In non-muscle-invasive bladder cancer with a high risk of recurrence, the **Alban** trial, financed by Roche, has continued its recruitment, with a target of 516 patients to be included in this randomised, open-label phase III trial evaluating the combination of immunotherapy and BCG. This phase III trial is financed by Bayer and is being conducted in some ten countries. A monoclonal antibody (atezolizumab) is administered concomitantly with bladder instillations of BCG (Bacille Calmette-Guérin) for 1 year, compared with BCG alone in the control group, in patients not previously treated with BCG.

Outlook for 2023
New therapeutic strategies and competitive trials

Backed by proven expertise in clinical trials and a long series of partnerships, GETUG is deploying an aggressive research strategy. Three major areas have been defined for 2023: prioritising highly competitive trials that have the potential to change practices, enhancing the value of previous clinical trials and defining new therapeutic strategies. On this last point, in 2023 GETUG will focus in particular on non-irradiating local treatments, the integration of imaging into research projects and subjects linked to DNA repair.

UCH&N

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HEAD & NECK GROUP

Group overview

One of the first groups to be created, then reactivated in 2009, **the Head and Neck Organ Cancers group mainly carries out phase I/II studies to develop new treatments or optimise existing ones, and conducts studies on biological collections to gain a better understanding of diseases and responses to treatment.**
Rare ENT cancers, therapeutic de-escalation and oncogeriatrics, and adapting treatments for HPV-induced cancers are currently among the Group's key topics. The ambition is to meet the major challenges in ENT oncology through multi-disciplinarity within the group and a network of academic collaborations in France, in particular via the cooperative intergroup accredited by INCA and GORTEC, and abroad. Strong emphasis has also been placed on training and informing professionals, patients and the general public about ENT diseases.

2022 achievements
Recruitment, ESMO and public awareness

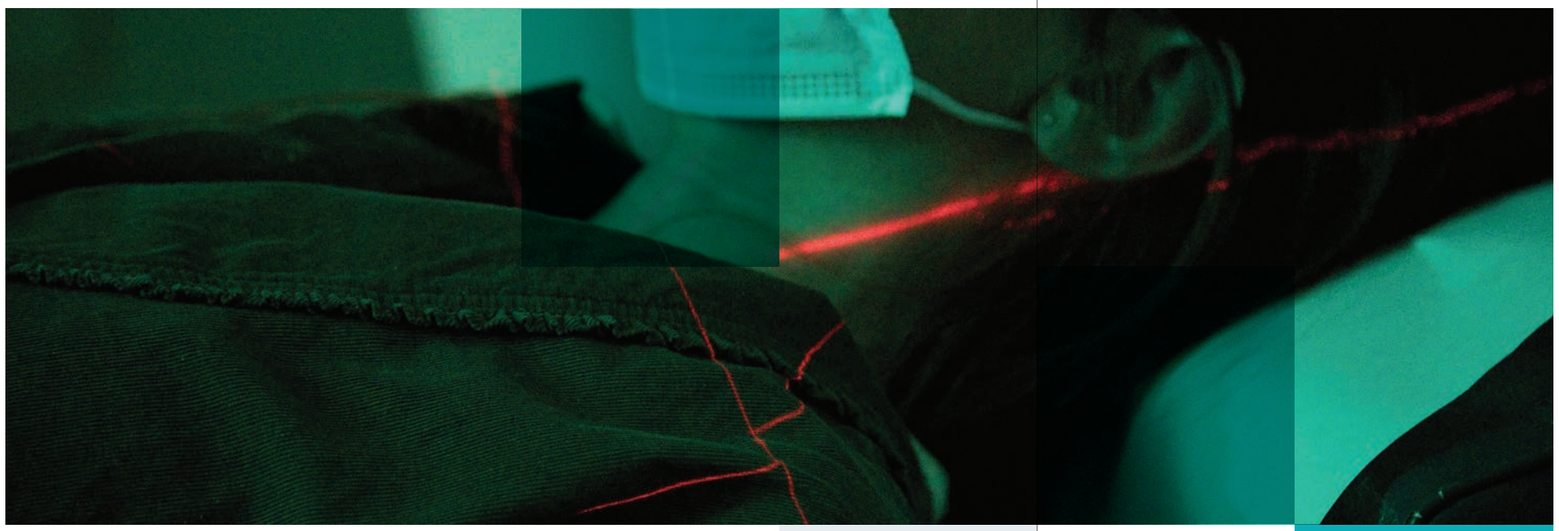
Seventy-five patients included in 3 trials and presentations of results at leading conferences including ESMO: 2022 has led to significant scientific advances.
The initial results of the **IMMUNEBOOST-HPV** trial, which is investigating neoadjuvant immunotherapy in HPV-induced cancer patients at high risk of relapse, were presented at ESMO, along with those of two ancillary projects from the **TOPNIVO** trial, including the galectin project, which was published in Oncoimmunology in December 2022. We are also continuing to recruit patients for the international **PATHOS** trial, which is investigating therapeutic de-escalation in patients with HPV-induced cancer.
The Group is working actively with the Groupement des Entreprises Françaises dans la Lutte contre le Cancer (French Business Group for the Fight against Cancer) to raise awareness of ENT cancers, filming videos and organising in-company information sessions.

> In 2022, the UCHN group had a major presence on the international stage with various publications and presentations at ESMO. But 2022 was also a year of change internally, with a change of chairmanship. Our ambition is threefold: to stimulate the emergence of new research projects, to maintain strong and close collaboration with GORTEC and the ENT Intergroup, and to extend our international links to respond to large-scale calls for projects. With the aim of conducting trials to advance practices in the management of squamous cell carcinomas or rare tumours.

Caroline EVEN
President

Outlook for 2023
Calls for proposals, new trials and the role of the patient

While 2022 was marked by a change of presidency at the head of the group, 2023 will see a renewed dynamic with new research projects and a strengthening of partnerships in the pipeline (GORTEC, ENT Intergroup and internationally) with the ambition of responding to large-scale calls for proposals targeting squamous cell carcinomas and rare tumours in particular. In terms of projects, 2023 will see the launch of a number of ambitious projects. **SURVEILLE-HPV** is an ambitious, first-of-its-kind project funded as part of a PHRC (hospital clinical research programme) grant awarded in 2022. It focuses on the use of circulating DNA to optimise and simplify the monitoring of patients with HPV-induced ENT cancer. In connection with the **IMMUNEBOOST-HPV** study, which took pride of place in 2022, a major ancillary project will be launched in 2023 based on the biological collection resulting from the study. To support both academic and translational studies, the group also wishes to build up a large clinical and biological database to answer theoretical questions about therapeutic strategies, for example, but also to develop approaches right down to the patient's bedside. This translational approach is also embodied in the setting up of new therapeutic trials based on innovative compounds in partnership with start-ups and biotech companies, in addition to collaborations with major established groups.
Therapeutic de-escalation and the reduction of sequelae are a major focus of the Group's development.
This focus on the patient's experience is also at the heart of the partnership that the Group initiated this year with the patient association CORASSO.
In 2023, the research training mission will also include this aspect of the patient experience through patient presentations and webinars for CRAs. Prevention initiatives in collaboration with the Onco-Addiction group will also be put in place as part of major public awareness campaigns.



Sarcoma Group

unicancer

SARCOMA / RARE CANCERS GROUP

Group overview

With 13 studies and over 2 000 patients included since it was set up in 1999, the Unicancer Sarcoma Group is a key player in the fight against rare sarcomas and cancers, particularly in children. The group works closely with the INTERSARC cooperative intergroup and the Groupe Sarcome Français et Groupe d'Etude des Tumeurs Osseuses (GSF-GETO) and the Société Française de lutte contre les Cancers et les Leucémies de l'Enfant et de l'adolescent (SFCE). **Understanding pathophysiological mechanisms, defining new predictive or prognostic biomarkers and discovering new therapeutic targets are at the core of the Sarcoma Group's translational research activities.**

Nathalie GASPARD
President (paediatrics)

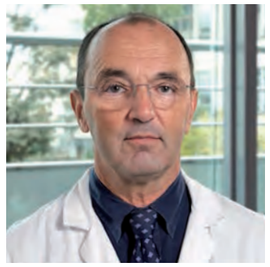
2022 achievements
Database and success stories on calls for proposals

In 2022, the Sarcoma group strengthened its involvement and collaboration in data sharing, a major issue in rare diseases such as sarcoma. The Group is thus involved in setting up a consortium, which will become official in 2022: this national pooling of clinical and biological data on osteosarcomas within the **BoostDatas database** is evidence of a real collective drive to accelerate the sharing of knowledge. More broadly, a dozen translational research projects are under way thanks to the sharing of data and samples collected. Finally, 2022 was marked by the Group's success in calls for proposals, with two PHRCs awarded.

Outlook for 2023
Launch of two flagship studies

2023 will see the completion and launch of the two major flagship studies, L-UTECIN and Inter-Ewing, funded as part of Hospital Clinical Research Programmes (PHRC). The **L-UTECIN** study will assess the value of adjuvant chemotherapy in women with operated leiomyosarcoma at high risk of relapse - a risk established using the CINSARC genomic signature - the aim being to avoid or delay recurrence of this aggressive form of cancer. Coordinated by the University of Birmingham, the **Inter-Ewing** study aims to improve the survival of patients newly diagnosed with Ewing sarcoma.
This international study involves twelve countries and almost 900 patients, including 225 in France, are expected to take part. The study is doubly complex, due to the number of countries involved, the variety of treatment pathway options and the predominantly paediatric population concerned.
The programme will compare several treatment modalities, including innovative molecules for induction treatment, maintenance chemotherapy and radiotherapy in modalities yet to be evaluated. The Sarcoma group, with its organisation and experience of this type of project, is one of the pillars of this major and eagerly-awaited study.

> Undeniably, 2022 was a good year for the Sarcoma group, which won 2 PHRC contracts to set up the L-UTECIN and Inter-Ewing international programmes from 2023. It was also a good year in terms of translational research, with more than a dozen research projects under way using our databases and biobanks, some with particularly promising preliminary results.



Jean-Yves BLAY
President (adults)

Immuno-Oncology Group

unicancer

IMMUNO-ONCOLOGY GROUP

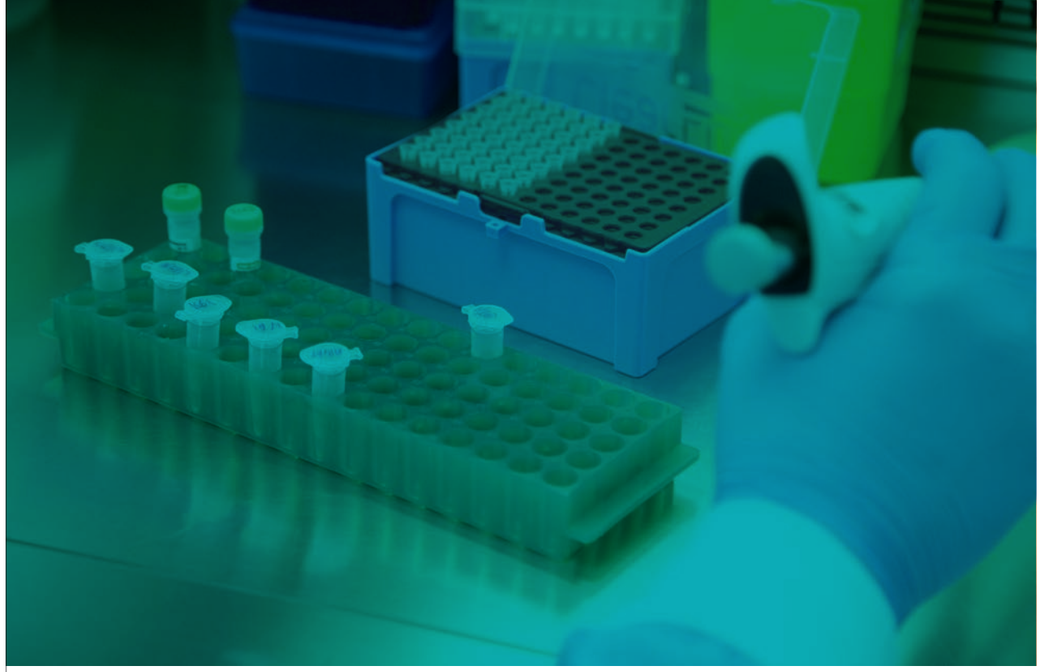
Group overview

In re cent years, immuno-oncology has been the focus of many hopes, but also challenges, in terms of cancer treatment.
The Immuno-Oncology group, one of the most recent to be created within Unicancer, embodies this revolution and these major advances. Cross-disciplinary, multi-disciplinary and pan-tumour, the Immuno-Oncology group (GIO), created in 2016, proposes an ambitious oncology immunotherapy research programme around the following 5 strategic areas:

- **the search for predictors of response to immunotherapies to adapt treatments to the patient's profile,**
- **the understanding of the mechanisms of primary resistance to immunotherapies, via a translational approach,**
- **the identification of the factors of occurrence of toxicities related to immunotherapies using large prospective cohorts,**
- **the development and evaluation of therapeutic strategies including immunotherapies,**
- **the development of research programmes promoting patient access to innovation.**

2022 achievements
Clinical trials and ancillary research: inclusions and initial results

The Group's dense and positive 2022 business review focuses on several flagship projects, including the **AcSé immunotherapy programme**. The two trials in this programme, **AcSé Nivolumab and AcSé pembrolizumab**, raise questions about access to immune checkpoint inhibitors (anti-PD-1) in rare cancers: 269 and 334 patients were enrolled respectively.
The first results of the POLE and Skin (basal cell carcinoma) cohorts in the **AcSé Nivolumab** trial were published in 2022.
The ancillary research of this programme, **AcSé Cible**, proposes a multi-parameter analysis of the clinical, biological and radiological characteristics of patients treated with anti-PD-1 in the two trials, with the ultimate aim of identifying biomarkers with a good negative predictive value of cancer immunotherapy efficacy which could help clinicians to select for patients with real expected benefits from immunotherapy. The first results of the transcriptomic/genomic and radiomic analyses from this translational programme are expected in 2024.
During the year, the GIO also developed new projects and new academic and industrial collaborations: **MOIO** is a non-inferiority randomised phase III trial comparing the standard scheduling of a variety of immunotherapy (IO) regimens versus 3-monthly scheduling in adult patients with metastatic or locally advanced cancer in partial or complete response after 6 months of approved standard IO (except melanoma in complete response). Should the hypothesis of non-inferiority with an IO reduced dose intensity be validated, alternate scheduling could preserve efficacy while being cost-effective and allowing a reduction of the toxicity, with an increase in patient's quality of life. The first patient was included in March 2022 (646 patients expected over 3 years). MOIO study progress was presented at ASCO and ESMO in 2022.
In collaboration with AstraZeneca, **DurvaLung** is a randomised, multi-centre, open-label, phase II trial in limited disease small cell lung cancer evaluating the efficacy of durvalumab maintenance therapy versus surveillance in frail patients with a disease control post standard concomitant or sequential thoracic chemo-radiotherapy. The trial received regulatory approval in September 2022 and is currently open for enrolment (110 randomised patients planned).



Outlook for 2023
New projects and new ambitions

In line with the progress made on the projects in 2022, a number of publications are expected in 2023, including the results of the Skin (trichoblastic carcinoma)/Sarcoma/Penis cohorts from the **AcSé Immunotherapy** programme and a methodological article on the **MOIO** trial in BMC. In 2023, the Group will also launch the Pan-MSI-ACSE project of INCa's new AcSé programme, part of the 2021-2023 ten-year cancer control strategy. This new multi-arm, multi-target, multi-drug programme will help to answer the current clinical research questions posed by the latest approved targeted therapies and provide a larger number of patients with innovative treatments in an optimised and secure environment. **Pan-MSI-ACSE** is an open-label, randomised, multi-centre, comparative phase II trial evaluating the activity of an anti-PD1, dostarlimab, as a first-line treatment for unresectable metastatic or locally advanced non-colorectal and non-endometrial dMMR/MSI cancers, compared to standard chemotherapy.
In 2023, the GIO aims to continue its momentum with a focus on 5 areas:

- **developing new clinical and translational projects, strengthening collaborations with new partners (learned societies, cooperative research groups, industrial companies, start-ups, etc.) to pool skills and set up innovative and strategic projects dedicated to immunotherapy,**
- **improving its national and international visibility,**
- **developing activities of its biological task force (valorisation of existing biological collections, harmonisation of collection practices, emergence of a network of centres of excellence for specific analyses to serve the community).**

> The initial idea of building this cross-disciplinary Immuno-Oncology group is supported by the 2022 activity report. Unicancer has a group of experts capable of asking major clinical questions and proposing high-quality translational research. We are very proud and happy about this and would like to thank the whole team.

Jean-Pierre DELORD
Vice-President

GERICO

unicancer

ONCOLOGY GERIATRICS

Group overview

Dedicated to clinical research in oncogeriatrics, a fast-growing speciality as the population ages, the GERICO group was set up in 2002. **A multi-disciplinary cooperative group, GERICO has been a stakeholder since 2014 in the DIALOG intergroup dedicated to clinical research in oncogeriatrics, labelled by InCa, along with SoFOG** (Société Française d'Onco-Gériatrie - French oncogeriatrics society) **and more recently PACAN** (Personnes Agées CANcer - Cancer and the elderly) platform.

Capucine BALDINI
President

> In 2022, GERICO made remarkable advances in geriatric research, thanks in particular to methodological studies and the ground-breaking ASTER 70 trial. It is vital to develop clinical research tailored to the needs of the elderly, taking into account their quality of life. GERICO's priorities for 2023 focus on the development of geriatric databases, the promotion of innovation and access to new therapies, along with the integration of translational approaches in clinical trials and active patient participation.

2022 achievements
Methodological issues and the ASTER 70 study

2022 was a year of consolidation for GERICO, with a great deal of progress made in the various areas of the action plan developed by the Group. Faced with a specific population, the GERICO group is conducting a number of methodological projects, including the evaluation and assessment of the geriatric population and specific strategies for the elderly, and the definition of a minimum set of geriatric data for clinical research, which has led to the introduction and promotion of the use of **G-CODE (Geriatric Core Data sEt)**. In elderly patients, specific questions relating to inclusion criteria and stratification according to degree of frailty or therapeutic de-escalation are particularly important.
The Group has also strengthened its partnerships with cooperative groups and industry.
The latest news and the flagship project for 2022 concern the **Aster 70s** study, the results of which were unveiled at ASCO: this ground-breaking clinical trial involved almost 2,000 patients over the age of 70 with hormone-dependent breast cancer, and showed that there was only marginal benefit for some patients in combining chemotherapy with hormone therapy. This study, led by Dr Etienne Brain, who was awarded the ASCO BJ Kennedy Geriatric Oncology Award 2022, highlights the need for specific clinical research in the elderly in order to take better account of the notion of quality of life in therapeutic strategies.

Outlook for 2023
Four priorities, four levers for action

Four priorities will be pursued in 2023, with a strong emphasis on developing a geriatric section of the databases, but also on access to innovation and new compounds, the translational approach within trials, and patient involvement at all stages of research. Faced with these major challenges, **the GERICO group will continue with intra-and trans-tumour trials and the development of methodological tools recognised at the national and international levels, as well as working more closely on real-life data and deploying an organ- or theme-based approach.** Because the leverage of major calls for proposals is unavoidable, the Group will develop a watch on relevant calls for proposals to strengthen its presence in these major consortia and projects.

Personalized Medicine Group

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PERSONALISED MEDICINE GROUP

Group overview

A new medical grail, personalised medicine first made its mark in oncology, and as early as 2013 Unicancer was one of the pioneers in developing a dedicated strategic axis, defined by ESMO as "an approach to care whose primary objective is to identify the most beneficial procedures for the right patients, in relation to the characteristics of the individual and their disease". (Yates, Ann Oncol, 2018). Over the last ten years, the Personalised Medicine group has conducted approximately ten clinical trials leading to high-impact publications.

The key differentiating factor is the ability to carry out cutting-edge, original and complex projects, using innovative technologies or medicines and incorporating a strong transfer research component, dedicated to understanding mechanisms of action and discovering biomarkers.

> In 2022, the question of the usefulness of precision medicine in breast cancer will be positively answered, and the baton will be passed to the era of dynamic cancer monitoring using circulating tumour DNA analysis. This approach, which is both simple for patients and based on high-precision technologies, is in itself a genuine revolution, opening up a new and exciting field of exploration for the Group. This year, our Group has also demonstrated its expertise in leading cutting-edge and disruptive projects, in collaborating to develop high-level translational research, and in its ability to produce results with a strong medical and scientific impact.

Fabrice ANDRÉ
President

2022 achievements
Publication in Nature and presentation at ESMO in support of advances in breast cancer treatment

2022 provides a concrete demonstration of the usefulness of precision medicine, with major results obtained in breast cancer that were the subject of a paper in the Nature journal and at ESMO.

The **SAFIR02-Breast** study thus showed a survival benefit for patients with metastatic breast cancer when tumour genetic abnormalities are identified and treatments with therapeutic impact can be selected using benchmarks such as the ESMO Scale for Clinical Actionability of molecular Targets (ESCAT). These results, which demonstrate the value of genomics in the choice of treatments, were published in October in Nature.

Also in metastatic breast cancer, the clinical results of the **DAISY** study were presented at ESMO Breast in the spring and at ESMO in Paris in the autumn.

There are two major points to note: this study provided early access to an innovative conjugated antibody (trastuzumab-deruxtecan), and the collection of a large number of samples enabled progress to be made in patient stratification (individualisation of HER2low patients) and in understanding the mechanisms of action and resistance, which are still poorly understood. Proposing innovative compounds, refining their therapeutic positioning and exploring pathophysiology and pharmacology together, using the latest knowledge and technologies, are at the core of the Group's approach.

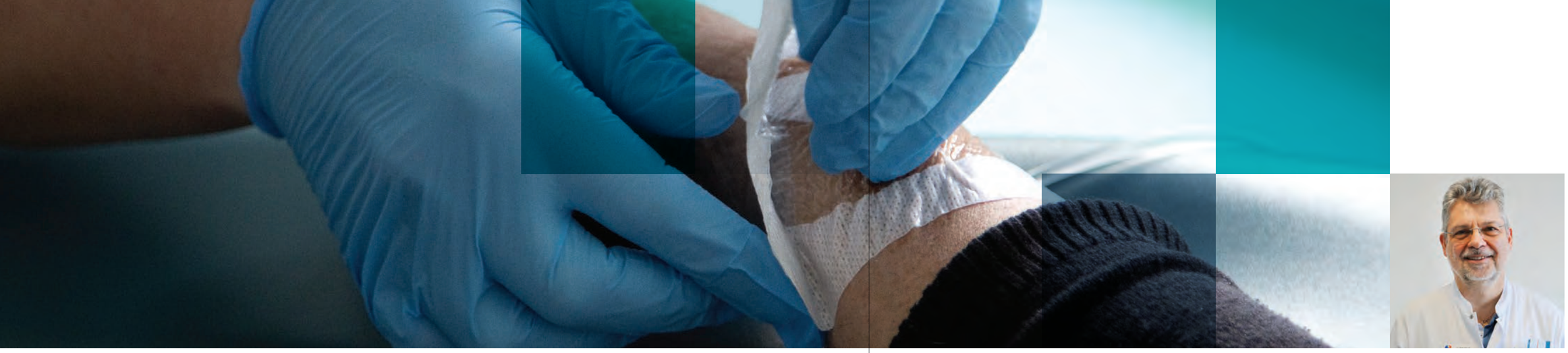
Outlook for 2023
Disruptive projects and circulating tumour DNA

By analysing circulating tumour DNA, an approach that is both simple for patients and highly precise and ground-breaking in terms of the dynamic monitoring of cancers, the Group is firmly positioned to usher in a new era of research. The ramp-up of clinical projects based on ctDNA is therefore the priority objective for 2023, with three projects under way.

The aim of the new **TRACK-ER** project is to detect and treat breast cancer relapse in advance by means of regular ctDNA analysis at a distance from adjuvant treatment.

The **SAFIR03** programme on metastatic breast cancer treated with anti-CDK4/6 uses ctDNA to detect disease resistant to this treatment at an early stage, so as to adjust the treatment as early as possible and prevent progression.

In bile duct cancer, the **SAFIR-ABC10** project relies on ctDNA to detect molecular abnormalities that can be used to personalise treatment with an appropriate targeted therapy. Used from diagnosis and as a complement to tumour biopsy when the latter is inconclusive or not possible, ctDNA analysis gives as many people as possible access to innovation. The use of circulating tumour DNA opens up a new and exciting field of exploration, which is fully in line with the Group's ambitions to pursue disruptive projects with a high medical and scientific impact.



Supportive Care Group

unicancer

SUPPORTIVE CARE INTERGROUP

Group overview

Created in 2013 at the suggestion of the Association Francophone pour les Soins Oncologiques de Support (French-speaking association for supportive cancer care) and as part of an agreement with Unicancer, the SDS AFSOS group is a multi-disciplinary group (oncologists, psychologists, economists, methodologists) whose mission is to promote clinical trials in the field of supportive care.
In line with InCa's objectives, and by integrating its expertise and a medical-economic component, **the group is working on three nationally-defined priorities: better management of symptoms linked to the disease and treatments, better access to supportive care in institutions and at home, and improving quality of life to provide better care for patients and their families within the services.**

Didier MAYEUR
President

"The achievements of 2022 laid the foundations for an in-depth understanding of the socio-economic impact of cancer, revealing the challenges faced by patients and care systems. Building on these advances, in 2023 we are committed to strengthening our actions in our four strategic areas, by promoting a multi-disciplinary approach, multi-centre projects and high-impact publications.
Our aim is to transform this research into beneficial practice for patients, by improving the organisation of care, symptom management, analysis of health behaviours along with the active participation of patients in all phases of research."

2022 achievements
A project on the socio-economic impact of cancer

As a cross-disciplinary group, in 2021 the AFSOS SDS group initiated collaboration with the "Organ" groups: these actions were strengthened in 2022 with the identification of "supportive care" referents. Actions aimed at increasing multi-disciplinarity, national and international collaborations and developing the Onco-addiction theme have also been carried out.
In terms of projects, the flagship 2022 project focused on assessing the socio-economic impact of cancer.
A 41-question questionnaire was sent to 2,507 patients undergoing treatment, or treated in the previous two years, in 14 European countries, involving 15 healthcare structures and 14 patient associations, with Unicancer participating for France. The SEC-Trial project was the subject of a paper presented at the MASCC conference in Toronto in June 2022.

Outlook for 2023
Building momentum around four strategic priorities

The group's objectives for the coming years include multi-centre projects of European or international scope, methodologies adapted to complex interventions, a multi-disciplinary and cross-disciplinary approach, promotion through high-impact publications and a real contribution to changes in practices for patients.
The focus for 2023 will be on the four strategic areas of research, which concern:
- the organisation of the care pathway (the benefits of joint management including support care, identifying needs and vulnerabilities, best practices, active patient participation, post-cancer management, etc.);
- symptom management (drug treatments and non-drug approaches, optimising treatments, tolerance management, etc.); - the analysis of health behaviours (nutrition, physical activity, health promotion, etc.) and
- development of patient trials and patient involvement, from study design to scientific exploitation in palliative care on the occasion of an unscheduled hospitalization in emergency service.

UNITRAD

unicancer

TRANSLATIONAL RESEARCH AND DEVELOPMENT IN ONCOLOGY RADIATION

Group overview

Created in 2014, Unicancer Translational Research and Development Group in Oncological Radiotherapy (UNITRAD) aims to facilitate clinical research in radiotherapy, thereby accelerating progress in this field to bring benefit to as many cancer patients as possible.

Including professionals from different disciplines and a patient representative, and working transversally with the other Unicancer groups, UNITRAD organises its activity around five working groups:

- **WG1: Artificial Intelligence, Radiomics/Imaging**
- **WG2: Radiobiology Immunoradiotherapy Radiosensitivity / Radiopotentialisation**
- **WG3: New Technologies and Physics Development**
- **WG4: Radiotherapy Quality Assurance / Safety**
- **WG5: PROMs/ Real-world data**

These five areas of research are fuelling the implementation of therapeutic trials and innovative clinical studies with a strong translational component, with the aim of standardising practices and facilitating access to innovation.

Since its creation, UNITRAD has been developing its portfolio of clinical and translational studies, with currently eight active clinical projects involving more than 1 600 patients, 65% of whom are in phase III. The Group is also involved in major real-life and cohort projects such as CANTO-RT, and is developing collaborative networks in France and abroad for the development of innovative radiotherapy research programmes.

2022 achievements
Launch of the European H2021 - PRE-ACT project

The UNITRAD working groups are very active, implementing various programmes and initiatives of their own while developing inter-working group collaborations to optimise the quality of trials and the use of available data and materials. In 2022, various programmes will be launched: a project on the automatic and interoperable extraction of **DICOM images** for trials and real-life projects for WG1, the implementation of ancillary biological studies for WG2, and a series of webinars on the interoperability of data from radiotherapy care in order to accelerate research programmes for WG5.

However, the flagship project for 2022 is European and is part of UNITRAD's drive to develop its international collaborations: the **PRE-ACT** project, funded as part of the Horizon Europe 2021 programme, was launched, for 5 years, in October 2022 (https://preact-horizoneurope.eu/). The PRE-ACT consortium, of which UNITRAD is a member, is made up of researchers from the UK, Greece, the Netherlands, France (UNITRAD), Italy and Switzerland, with combined expertise in computer science, AI, radiation oncology, medical physics, genetics, psychology and health economics.

The PRE-ACT project focuses on the use of explainable artificial intelligence (AI) to predict the side effects of radiotherapy in breast cancer patients, and to test how clinicians and patients react to knowledge of the prediction of the risk of toxicity in choosing a radiotherapy regimen. Explainable AI is a set of processes and methods that enable users to understand and trust the results and information generated by AI machine learning algorithms. This project will integrate data from three multi-centre patient cohorts/trials (REQUITE - University of Leicester, CANTO -Unicancer, HypoG-01 - Unicancer/UNITRAD) to build an AI tool that predicts the risk of arm lymphedema after locoregional irradiation for node-positive breast cancer. The clinical impact of this tool will be studied in an international prospective randomised controlled phase III clinical trial, PRE-ACT01, sponsored by Unicancer and coordinated by UNITRAD. This trial will evaluate whether the use of the predictive model modifies the rate of lymphoedema in the arm and has an impact on treatment decisions and patients' quality of life.

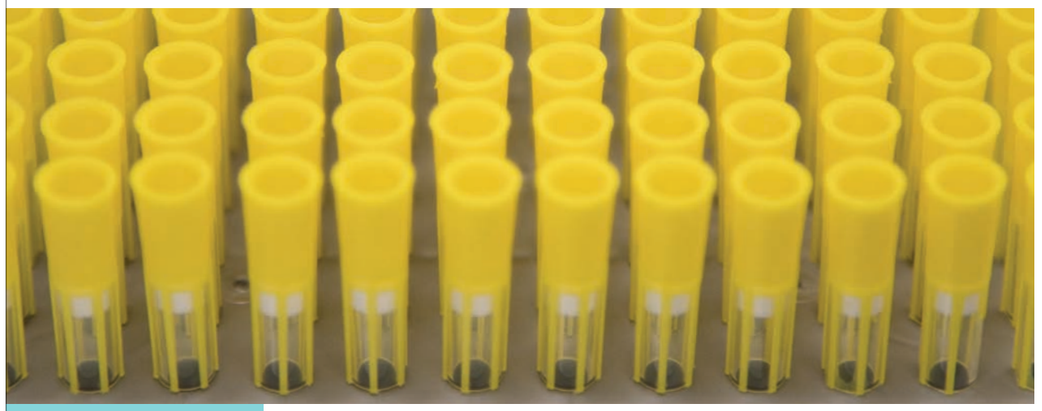
Other trials, coordinated by UNITRAD, are currently ongoing: **STEREO-OS, NIRVANA-LUNG, ROMANCE, PRIMALUNG, BEPCOME-MB and HYPOG-01.**

Outlook for 2023
Conferences, visibility and major projects

While 2022 was a year of maturation, 2023 will be a year of communication! Starting with the oral presentation to the ESTRO plenary session of the first results of the HYPOG-01 phase III trial, comparing normofractionated radiotherapy versus moderate hypofractionated radiotherapy in 1 265 patients. This could lead to real changes in radiotherapy practice.

More generally, UNITRAD's objectives for 2023 are as follows:

- **to develop new clinical and translational trials with a high clinical impact and international scope;**
- **to enhance the value of clinical studies through biology/radiomics/IA/dosimetry/quality assurance;**
- **to strengthen collaborations (learned societies/ research cooperative groups/industrial companies / start-ups, etc.) in order to pool skills and set up innovative and strategic projects dedicated to radiotherapy**
- **to raise UNITRAD's national and international profile through congresses, publications and training courses**



Sophia RIVERA
President

In 2022, a number of international collaborations were launched (H2021 consortium, Canadian Cancer Trials Group, etc.), strengthening the Group's global position. Several of UNITRAD's flagship projects have reached maturity and their main endpoint, heralding a year 2023 rich in communications and publications.

EORTC
European Organisation for Research and Treatment of Cancer

The future of cancer therapy

EORTC

EORTC trials portfolio and recruitment status in France in 2022

Unicancer has been the local representative of EORTC in France since 2009. This collaboration aims to facilitate the activation of EORTC-sponsored trials in France and to stimulate the participation of the French investigational centres.

The Unicancer EORTC liaison officer ensures all regulatory and operational tasks required for site initiation and monitoring in France and is the preferred contact person of all French participating sites for all regulatory and operational questions.

In 2022, we had 2 new EORTC-sponsored trials activated and 19 studies open for recruitment in France.

https://recherche.unicancer.fr/en/unicancer-research/eortc/

List of EORTC studies approved in France in 2022

EORTC RESEARCH GROUP(S)	STUDY	TITLE	STUDY APPROVAL DATE IN FRANCE	NATIONAL COORDINATOR IN FRANCE	NUMBER OF EXPECTED PATIENTS (FRANCE/ALL COUNTRIES)
LCG	1920 (BIORADON)	Molecular characterization of NSCLC patients and exposure to indoor randon in Europe	31/01/2022	Pr Benjamin BESSE (Institut Gustave Roussy, Villejuif)	ND/975
BTG	1926 (RIGOLETTO)	Romiplostim for thrombocytopenia induced by lomustine at first progression of MGMT promoter-methuylated glioblastoma: a randomized phase II open label multicenter study	28/07/2022	Dr François DUCRAY (Hôpital Neurologique Pierre Wertheimer, Lyon)	20/100

List of EORTC studies active in France in 2022

EORTC RESEARCH GROUP(S)	STUDY	TITLE	STUDY APPROVAL DATE IN FRANCE	NUMBER OF INCLUDED PATIENTS AS OF DEC 31, 2022 (FRANCE/ ALL COUNTRIES)
BTG	1419 (ETERNITY)	Molecular genetic, host-derived and clinical determinants of long-term survival in glioblastoma	05/07/2015	157/599
CLTF	1754 (REACH)	Study to determine the aetiology of chlormetine gel induced-skin drug reaction in early stage mycosis fungoides cutaleous T cell lymphoma (MF-CTCL)	28/10/2021	1/1
CLTF	1820 (MOGAT)	Open-Label, phase II, Multi-Center, study of Anti-CCR4 Monoclonal Antibody (mogamulizumab) Plus Total Skin Electron Beam therapy (TSEB) in patients with stage IB-IIB Cutaneous T-Cell Lymphoma	22/07/2021	0/43
GUCG-ROG	1414 (Pegasus)	Phase IIIb randomized trial comparing irradiation plus long-term adjuvant androgen deprivation with GnRH antagonist versus GnRH agonist plus flare protection in patients with very high risk localized or locally advanced prostate cancer. A joint study of the EORTC ROG and GUCG- Pegasus	09/08/2017	86/365
HNCG-ROG	1420 (Best Of)	Phase III study assessing the "best of" radiotherapy compared to the "best of" surgery (trans-oral surgery (TOS)) in patients with T1-T2, N0 oropharyngeal carcinoma	18/09/2017	1/70
HNCG	1559 (UPSTREAM)	A pilot study of personalized biomarker-based treatment strategy or immunotherapy in patients with recurrent/metastatic squamous cell carcinoma of the head and neck "UPSTREAM"	24/11/2017	138/241
GITCG	1707 (VESTIGE)	Adjuvant immunotherapy in patients with resected gastric cancer following preoperative chemotherapy and high risk for recurrence (N+ and/or R1)- an open label randomized controlled phase 2 study	14/06/2019	27/197
LCG	1525 (NivoThym)	Single-arm, multicenter, phase II study of nivolumab in patients with type B3 thynoma and thymic carcinoma previously treated with chemotherapy	03/06/2019	44/107
LCG-ROG	1702 (HALT)	Targeted therapy with or without dose intensified radiotherapy for oligo-progressive disease in oncogene-addicted lung tumors	07/01/2019	1/2
LCG	1825 (ALKALINE)	Activity of Lorlatinib based on ALK resistance mutations on blood in ALK positive NSCLC patients previously treated with 2nd generation ALK inhibitor	17/01/2021	9/49
MG	1612 (EBIN)	Combination of targeted therapy (Encorrafebib and Binimetinib) followed by combination of immunotherapy (Ipilumab and Nivolumb) vs immediate combination of immunotherapy in patinets with unresectable or metastatic melanoma with BRAF V600 mutation: an EORTC phase II randomized study	04/07/2018	196/271
STBSG	1809 (STRASS 2)	A randomized phase III study of neoadjuvant chemotherapy followed by surgery alone for patients with High Risk RetroPeritoneal Sarcoma	22/09/2020	4/47
QLG-BCG-ROG	1617	Follow-up in Early and Locally Advanced Breast Cancer Patients	01/07/2021	4/833
All groups	1811 (E^2-RADIATE)	EORTC-ESTRO RADiotherapy InfrAstrucTure for Europe	11/06/2019	1/1704
All groups	1945 (OligoRARE)	Stereotactic body radiotherapy in addition to standard of care treatment in patients with rare oligometastic cancers (OligoRARE): a randomized, phase 3, open-label trial	05/03/2021	7/53
All groups	1553 (SPECTA*), RP-1759 (AYA/TYA)	Screening Cancer Patients for Efficient Clinical Trial Access Investigations on adolescent and young adults cohort within 1553-SPECTA	30/03/2017	16/114
All groups	1553 (SPECTA*), RP-1828 (IMMUcan)	Screening Cancer Patients for Efficient Clinical Trial Access Integrated IMMUnoprofiling of large adaptive CANcer patients cohorts	30/03/2017	265/787

List of EORTC studies active in France in 2022

EORTC RESEARCH GROUP(S)	STUDY	TITLE	STUDY APPROVAL DATE IN FRANCE	NUMBER OF INCLUDED PATIENTS AS OF DEC 31, 2022 (FRANCE/ALL COUNTRIES)
All groups	1553 (SPECTA*), RP-1843 (Arcagen)	Screening Cancer Patients for Efficient Clinical Trial Access Molecular characterization of rare cancer	30/03/2017	435/983
All groups	1553 (SPECTA*), RP-1920 (BioRadon)	Molecular characterization of NSCLC patients and exposure to indoor randon in Europe	31/01/2022	31/01/2022

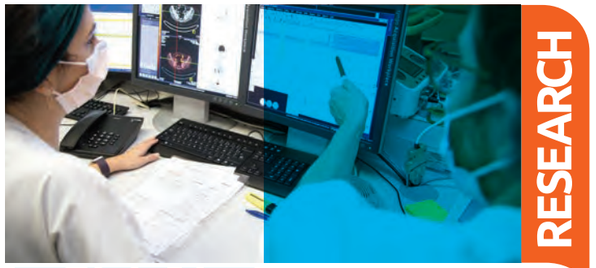
**SPECTA is a collaborative European platform that helps deliver high quality, molecular and pathological screening across tumor types to aid patient selection into clinical trials.*

SPECTA program web site: https://spectaplatform.org

Glossary

BTG: BRAIN TUMOR GROUP (EORTC BTG)
CLTF: CUTANEOUS LYMPHOMA TASK FORCE (EORTC CLTF)
GITCG: GASTROINTESTINAL TRACT CANCER GROUP (EORTC GITCG)
GUCG:GENITOURINARY CANCER GROUP (EORTC GUCG)
HNCG:HEAD&NECK CANCER GROUP (EORTC HNCG)
LCG: LUNG CANCER GROUP (EORTC LCG)
MG: Melanoma Group (EORTC MG)
QLG: QUALITY OF LIFE GROUP (EORTC QLQ)
ROG: RADIATION ONCOLOGY GROUP (EORTC ROG)
STBSG: SOFT TISSUE AND BONE SARCOMA GROUP (EORTC STBSG)

Translational Research



Appearing in the twentyfirst century, the concept of translational research perfectly embodies what Unicancer research is.
Collaborative, multidisciplinary research which, from “bench to bedside” according to the accepted expression, has a direct and rapid impact for patients. Studying the microbiota, defining the molecular signature of tumours, developing tests to detect relapse based on circulating DNA are some of the areas currently being explored in these ambitious translational research programmes.

TRANSLATIONAL RESEARCH

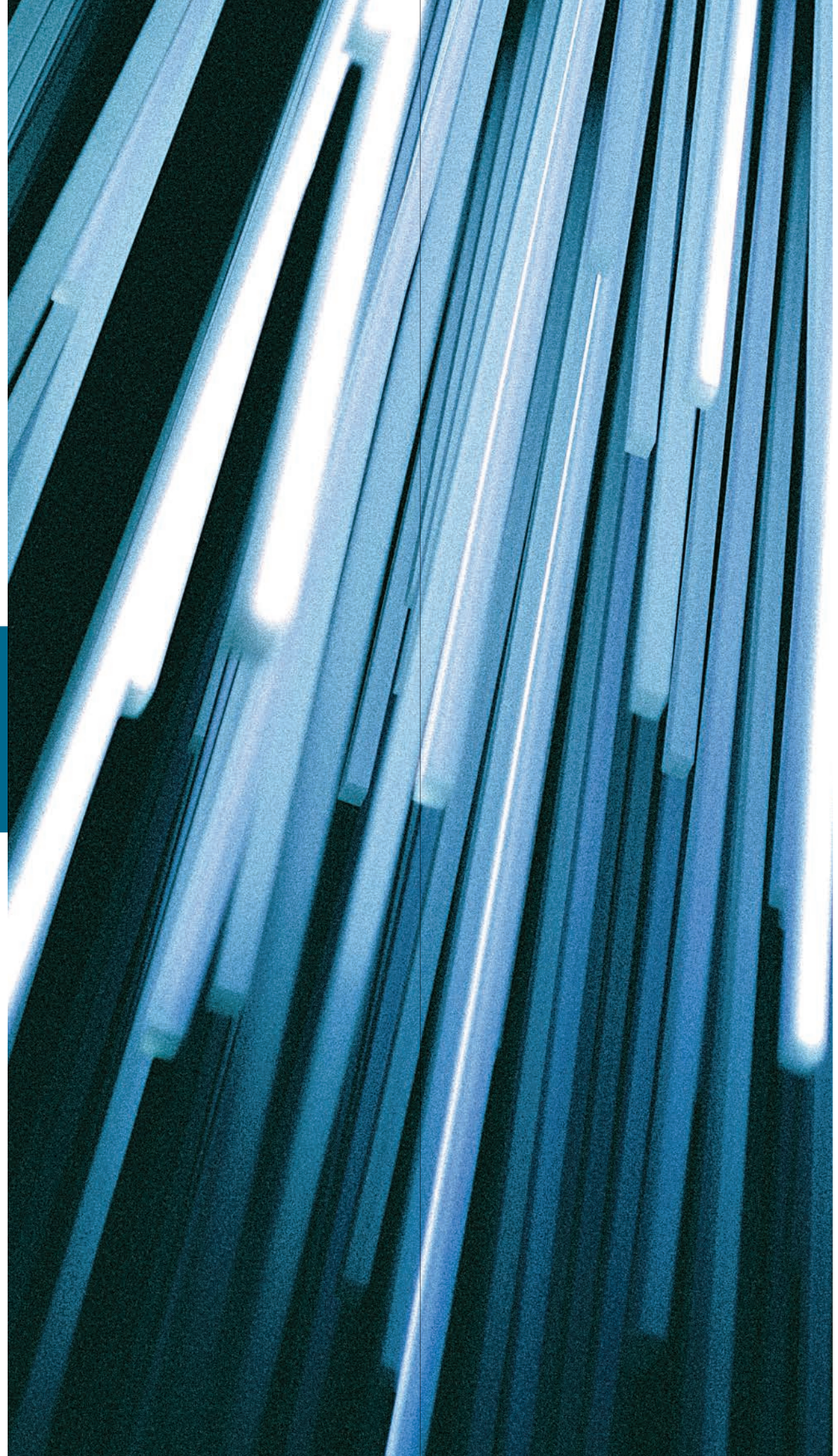
From research to care: that is the mission of Unicancer, and the translational research, also known as transfer research, conducted within the group embodies this constantly reaffirmed position.

This position is reflected in the increasing emphasis on translational research.

Oncobiome, a European program studying the microbiome and its impact on neoplasia, and MyProbe, which aims to predict the risk of relapse in breast cancer, are two flagship programs currently underway.

Like other translational research projects, they rely on the collections of biological samples established within the framework of various clinical trials promoted by Unicancer Research.

This wealth needs to be structured and exploited to advance knowledge and develop tests and medications for the direct benefit of patients.



AcSé

AcSé Cible the translational phase of the AcSé immunotherapy programme

The ancillary programme **AcSé Cible** which is part of the **AcSé immunotherapy** programme, proposes to take a more pragmatic approach on the question of biomarkers for immunotherapy. This programme focus on factors that may contraindicate treatment with PD-1 antagonists, allowing clinicians to identify patients for whom treatment may have an absence of effect or even a deleterious effect (e.g. toxicity without efficacy, paradoxical hyper-progression, …).

A multi-parametric analysis of the clinical, biological, and radiological characteristics of the AcSé patients treated by anti-PD-1 (nivolumab or pembrolizumab) is performed in order to identify combination of factors which strongly correlate with early failure of nivolumab or pembrolizumab therapy, as follows:

- **Leverage the baseline tumour genomics & transcriptomics to identify mutations, pathways, or molecules associated to early treatments failure (WES + RNAseq on tumour samples at baseline).**

- **Determine the on-treatment disease kinetics for early preemptive treatment stratification upon anti-PD-1 Failure (ctDNA analysis).**

- **Identify features of the baseline immune tumour environment or circulating biomarkers (including anti-microbiota serum reactions) associated to an absence of clinical benefit to anti-PD1 therapy.**

Two hundred patients from the two AcSé studies have been pooled and are being analysed together (“discovery cohort”), regardless of the tumour type, in order to develop a signature or a combination of markers predictive of treatment failure.

The reliability of the signature in predicting clinical outcome will be tested in the 300 additional patients in the AcSé programme on top of the first 200 patients (“validation set”).

This ancillary project will provide practical clinical tools to select the prescription of these expensive treatments to patients with expected benefits while preventing patients without any hope of immunotherapy efficacy to be exposed to immune related adverse events.

Moreover, the results of this collaborative work will highlight new biological pathways responsible for primary resistance to anti-PD1 and identify potential novel therapeutic targets for cancer immunotherapy.

BIOLOGICAL RESOURCE CENTRE

The Unicancer biobank was set up in 2012 to meet the research strategy requirements by creating a collection of samples from the clinical research program. This collection was made available to all research teams to promote biological research and advances in cancer treatment.

The whole collection includes **85 106 samples,** centralised at the Unicancer Biological Resource Center (BRC) located at Centre Léon Bérard, Lyon. Samples were collected from **18 871 patients** enrolled in a total of **71 studies.** Historical collections are mostly focused on breast cancer. **10 242 new samples entered the collection in 2022.**

The BRC Steering Committee pursued the reflection initiated at the end of 2020 on a new global strategy to enhance the value of the existing collections and to rationalise the constitution of future collections.
In 2022, 5 323 samples were unarchived to feed 10 translational research projects, mainly based on advanced technics of molecular biology and deep learning medical imaging. Although our samples collections are available for all types of institutions, they have been mainly released for academic research teams in the CLCCs. Samples can also be made available to industrial companies involved in research partnerships. Access to the collections is granted upon submission of a valid research project and subject to approval by the Unicancer's translational steering committee.
In order to increase the number of research projects received and to inform a broader community of research teams (universities other than CLCCs, industries, etc.), Unicancer has decided to improve its communication about the collections available. To this end, a new web portal will be made available through Unicancer website allowing the entire scientific community to access biological collection information (including the innate characteristics of the sample, the clinical parameters of the patient, and the genomic analyses already performed).

Through the **mesdonnees.unicancer.fr** website, patients treated within the network or people who have participated in a clinical trial can be informed about the re-use of their data and samples.
This dynamic website meets the requirements of the General Data Protection Regulation (GDPR).

https://mesdonnees.unicancer.fr/en

85 106
samples stored

in total, representing approximately
205 000
aliquots*

10 242
new entries in 2022

5 323
outputs in 2022 used in 10 research projects

** Samples represent collection timepoints: several individual biological samples (called aliquots) can be collected at one given collection timepoint (e.g.baseline or Day 1 post treatment), therefore 1 sample actually represents 1 or more aliquots.*

SAMPLE DISTRIBUTION BY TUMOUR LOCALISATION

- Breast **70 793**
- Basket trial **14 857**
- Prostate **5 226**
- Lung **4 649**
- Head & Neck **3 646**
- Pancreas **1 689**
- Bone **1 090**
- Colorectal **1 019**
- Kidney **936**
- Stomach **518**
- Stem cells **16**
- Solid tumours **12**

NUMBER OF SAMPLES BY SUBTYPE

- Plasma **30 751**
- FFPE block **15 309**
- Slide **14 159**
- Whole blood **11 128**
- Serum **9 853**
- DNA **6 988**
- Frozen tumor **5 679**
- Peripheral Blood Mononuclear Cells **3 701**
- Tissue fragment **3 001**
- RNA **1 826**
- Buffy coat **771**
- Powder **731**
- Platelet-rich plasma **343**
- Dried blood spot **245**
- Protein **217**
- Urine **59**
- Dry tube sediment **29**
- Stool **22**
- Saliva **7**

Health Data Research

While the Onco DataHub (ODH) programme automates data collection and can rapidly deliver information in the spirit of an observatory on therapeutic use, ESME (Épidémio-Stratégie Médico-Economique - medical-economic epidemiology and strategy) enables the collection of in-depth longitudinal information on a disease and its treatment, thanks to a more traditional collection method based on patient records.

The CANTO cohort provides enriched real-life data on the patient and biological dimensions. These three types of programme are designed to address different use cases. The launch of CANTO Innov, a cohort initially targeting localised breast cancer, now makes it possible to activate new cohorts in other indications, depending on research needs. Three different but complementary approaches and entry points for the data collected, combined with the strength of a network of interoperable institutional repositories, will make it possible to cover all the needs of cancer research and forge strong international alliances. The strength of the Data projects initiated within Unicancer is a reflection of the structure: agile and innovative, adaptable and adaptable.

ESMÉ

2022 KEY FIGURES

Metastatic Breast Cancer

31 673
CASES SELECTED
Metastatic breast cancer database

Advanced & Metastatic Lung Cancer

41 429
CASES SELECTED
Lung cancer database

Ovarian Cancer

13 331
CASES SELECTED
Ovarian cancer database

143
PROJECTS
since the start of the ESMÉ research programme

27
COMMUNICATIONS AND PUBLICATIONS
in 2022

afaq ISO 9001 Qualité AFNOR CERTIFICATION

Unicancer is ISO 9001 certified for its clinical research activity

ESMÉ

The ESME research program is a French platform of longitudinal retros - pective real world data on cancer management in oncology.
It is a unique platform centralizing data from patient medical files describing the therapeutic decisions and care management in routine practice.

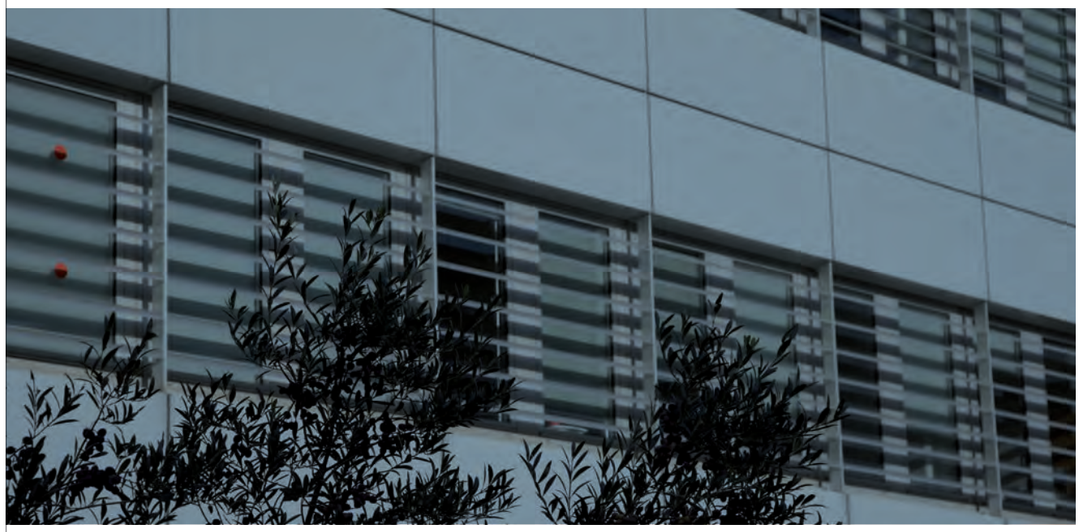
4 objectives :

- **Describe cancer management in France, and its evolution over time**
- **Provide data on innovative drug use in medical institutions**
- **Describe therapeutic trend**
- **Provide data to support the Health Economic Models and requirements of the Health Technology Assessment bodies**

The prospects for 2023 are promising. In addition to the referencing of the three ESME databases (metastatic breast cancer, lung and bronchus cancer, ovarian cancer) by the French National Authority for Health (HAS), preparations are underway for the implementation of an inter-connection with the French National Health Data System (SNDS) and the capacity to host a derived database from the SNDS.

As part of the development of Unicancer data warehouses, major programs such as ESME, CANTO, and ODH will gradually become interoperable through the use of a single data format and harmonized data governance. This approach will allow medium-term projects, including those based on artificial intelligence, to be conducted by leveraging data from various programs and connecting them with the SNDS.

After eight years of existence, the ESME program now aims to expand internationally by working collaboratively with other European or American databases.



OncoDataHub:
The oncology drug observatory

The French RWD oncology drug centralized observatory to describe patient care in routine practice open to all actors accross the health system.

60 variables automated data flow – from Electronic Medical Records in institutions

Breast and lung cancers prior enlargement to other indications

Goal : 60 representative French hospitals by 2024 both non-profite and private

Objectives :

• Describe cancer management in France, and its evolution over the time (multi-annual updates).

• Provide data on innovative drug use (pre-MA and real-life setting) in medical institutions.

• Describe therapeutic trends (e.g. sequence of treatment strategies).

• Provide data to support the Health Economic Models of the Health Technology Assessment (HTA) bodiess.

GO FURTHER :

- New cancers
- Broaden the data-set

2023-2024 : GROWTH AND OPENNESS

- LINKAGE WITH OTHER DATABASES
- NEW HOSPITALS
- NEW INVESTORS AND PARTNERS

2022 : 25 hospitals, 30 000 patients with processed and reliable data

2021 Launch

Web-based Exploitation of Social and Human sciences to Advance cancer REsearch

Unicancer, in association with a multidisciplinary consortium, is creating a new digital infrastructure: WeShare.
Coordinated scientifically by Dr Ines Vaz Luis from Gustave Roussy, it will enable the acceleration of a research in Human and Social Sciences and Quality of Life in cancer and post-cancer. Three main axes are identified and described in Fig 1 below :

- **Implementation of a decentralized research via digital tools (ePROs, eCosnent, Randomization, Biosensors ...).**

- **Creation of a Health Data Warehouse that will allow the conduct of large-scale ancillary or secondary studies (using FAIR standards).**

- **Creation of active communities of researchers (transformative cancer research) and patients, users and citizens (patient-centred research).**

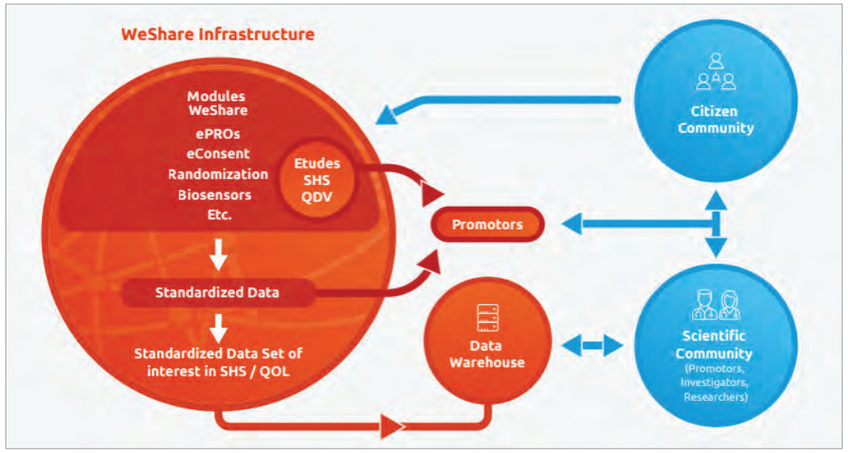
The ultimate objective of the WeShare platform is to identify new levers to act on the impact of cancer and its treatment on patients' quality of life.
WeShare (ANR-21-ESRE-0017) has been selected for the 2020 Equipex call for projects by the ANR (French National Research Agency) under the "Investissements d'avenir" programme and has been awarded €11M in funding.

WeShare will last 8 years. In 2022, the second year of the implementation phase, the project has progressed primarily in the following areas:

- Contractual : consortium agreement signed and drafting of the Platform User Agreement template;
- Regulatory : drafting of the Impact Analysis Plan for transmission to the CNIL in 2023 with the intention of creating a Health Data Warehouse;
- Technical developments : Unicancer is in charge of developing the platform. The modules implemented in 2022 are the Core (Administration) and ePROs modules in accordance with the needs of the pilot studies planned for 2022-23. The API module (connexion) has been implemented and will be validated as soon as the 1st pilot study will be launched. Requirements for the eConsent, Randomization and Biosensors modules has started with the objective of deploying them in 2023;
- Communication and dissemination; Communication tools have been developed, social networks relating to the launch of the program has begun and WeShare has been mentioned at 4 conferences ;
- Partnership: a partnership has been set up with the VHIO team in Spain in the framework of the PRAGMATIL study.

This partnership will contribute to the dissemination of WeShare as well as to the internationalization of the platform.

Perspectives : In 2023, the WeShare program will be officially launched with the use of the ePros, eConsent, API, Randomization and Biosensors modules by the first pilots studies at the national and international levels. The WeShare Website will be deployed in French and English. Work on the creation of 2 communities (researchers and citizens) will begin.



CONSORE
continuum soins recherche
unicancer

Unicancer is a player in oncology research and innovation in the field of real-world data. Cancer centers have been at the forefront in this field with the development of Consore since 2012. **The objective of Consore is to enable the creation of databases with the ability to provide structured data from 9 different sources derived from routine care.**

In 2022, Consore was enhanced with new structured data using natural language processing techniques to meet the objectives of multicenter projects (see UNIBASE). Consore was chosen to enable the centers participating in the Paris Saclay Cancer Cluster (PSCC) project to provide quality data to accelerate real-world data research. New financial resources will be allocated to improve the tool and strengthen the coordination team.

In 2022, it was decided to ensure the interoperability of Consore by transforming the data into the OSIRIS RWD model.

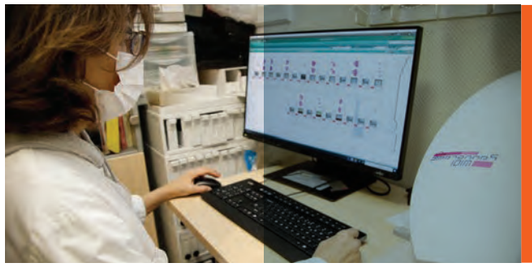
Beyond Consore, an entire software suite will be made available to Cancer Centers. Thus, Consore will be a central element of the hospital data repositories in the centers.

The objective is to meet the FAIR acronym: data that are Findable, Accessible, Interoperable, and Reusable.

UNIBASE

The UNIBASE program, initiated in 2021, aims to conduct multicenter studies using real-world data to address major scientific questions. **The goal is to accelerate research using real-world data in the field of cancer and make an impact on patient care.**
In 2022, 10 projects were submitted to a jury, and three projects were selected. The **DASTO** project aims to predict the risk of venous thromboembolism in cancer patients. The project involves 4 centers with the objective of creating a cohort of nearly 100,000 patients to answer this question.
The **REALIGIST** project will establish a cohort of patients with gastrointestinal stromal tumors (GIST) in partnership with 6 Comprehensive Cancer Centers (CLCC) to better understand why some patients do not respond to targeted therapies.
The **ISIS** project studies the risk of infertility after breast cancer in young women and the potential consequences of anti-cancer therapies on pregnancy, childbirth, and the child.
In 2023, the UNIBASE program continues with a Call for Expression of Interest open to all hospitals producing cancer data, in addition to the Cancer Centers. It will be possible to fund 5 new innovative scientific projects in oncology with the financial support of the National League Against Cancer.
The partnership between the Health Data Hub and Unicancer is multi-year. Including the first project (Precision Predict) funded in the first call for projects, a total of 8 projects will be conducted in 2023 under this program, with probably 4 additional projects the following year. Thus, gradually, a reference database catalog in oncology is being built to enable collaborative research.
The databases thus established, some of which will be linked with data from the national health data system and associated with images, will allow for multiple research studies using artificial intelligence techniques.

Research in the FCCCs



Unicancer groups together 18 French Comprehensive Cancer Centres (FCCCs) spread across 20 hospital sites throughout France and one affiliate member.

They are private, non-profit health establishments dedicated to cancer care, research and education.

Most of the research platforms accredited by the French National Cancer Institute (INCa) are hosted in our FCCCs, thus demonstrating the excellence and innovativeness of our research in the field of precision medicine.

2022 KEY FIGURES

16%
OF THE PATIENTS
treated in the FCCCs are included in a clinical trial versus 8.5% of cancer patients in average in France

739
ACTIVE CLINICAL TRIALS
sponsored by the Unicancer network

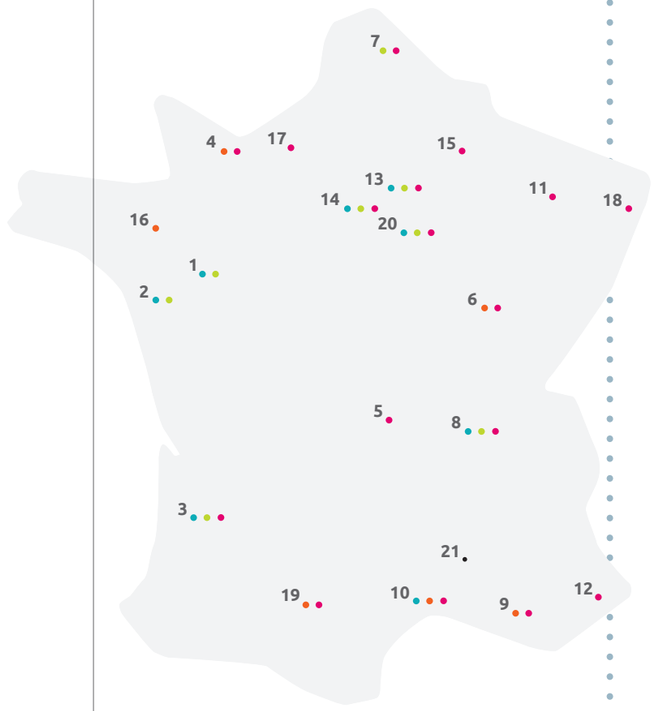
104
NEW TRIALS
sponsored by the Unicancer network

afaq ISO 9001 Qualité — Unicancer is ISO 9001 certified for its clinical research activity

SIRIC HOSTED IN A FCCC OR INTEGRATING A FCCC:

BRIO / Bordeaux Recherche Intégrée Oncologie (Institut Bergonié, Bordeaux)
LYriCAN / Manipulating cell plasticity for innovative cancer treatment (Centre Léon Bérard, Lyon)
SIRIC ILIAD / Imaging and Longitudinal Investigations to Ameliorate Decision Making (Institut de cancérologie de l'Ouest, Angers/Nantes)
SOCRATE 2.0 / Stratified Oncology Cell DNA Repair and Tumor Elimination 2.0 (Gustave Roussy, Villejuif)
SIRIC Montpellier Cancer (Institut du Cancer de Montpellier, Montpellier)
SIRIC Curie (Institut Curie, Paris)

UNICANCER, A UNIQUE NETWORK OF EXPERT CENTRES IN FRANCE



- *SIRIC*
- *CLIP² - adult*
- *CLIP² - adult and paediatric*
- *Molecular genetics platform*

INSTITUT DE CANCÉROLOGIE DE L'OUEST •• **1 - 2**
Unicancer Pays de la Loire

INSTITUT BERGONIÉ ••• **3**
Unicancer Nouvelle-Aquitaine

CENTRE JEAN PERRIN • **4**
Unicancer Clermont Auvergne Métropole

CENTRE FRANÇOIS BACLESSE •• **5**
Unicancer Normandie-Caen

CENTRE GEORGES-FRANÇOIS LECLERC •• **6**
Unicancer Bourgogne Franche-Comté

CENTRE OSCAR LAMBRET •• **7**
Unicancer Hauts-de-France

CENTRE LÉON BÉRARD ••• **8**
Unicancer Lyon, Auvergne-Rhône-Alpes

INSTITUT PAOLI-CALMETTES •• **9**
Unicancer Marseille

INSTITUT DU CANCER DE MONTPELLIER ••• **10**
Montpellier

INSTITUT DE CANCÉROLOGIE DE LORRAINE • **11**

CENTRE ANTOINE LACASSAGNE • **12**
Unicancer Nice

INSTITUT CURIE ••• **13 - 14**
Unicancer Paris – Saint-Cloud – Orsay

INSTITUT GODINOT • **15**
Unicancer Reims en Champagne

CENTRE EUGÈNE MARQUIS • **16**

CENTRE HENRI BECQUEREL • **17**
Unicancer Normandie-Rouen

ICANS • **18**
Unicancer Strasbourg

IUCT ONCOPOLE – INSTITUT CLAUDIUS REGAUD •• **19**

GUSTAVE ROUSSY ••• **20**

ICAP - Sainte Catherine • **21**
Avignon-Provence

CLINICAL TRIALS INCLUSIONS IN THE FCCCs

FRENCH COMPREHENSITE CANCER CENTRE (FCCCS)	CITY	ACTIVE PATIENT FILE	PATIENTS INCLUDED IN A CLINICAL TRIAL	TOTAL ACTIVE TRIALS	AVERAGE NUMBER OF PATIENTS INCLUDED PER CLINICAL TRIAL	% OF PATIENTS SIGNING AN INFORMED CONSENT *	% OF THE ACTIVE PATIENT FILE INCLUDED IN A CLINICAL TRIAL	ACADEMIC SPONSOR			INDUSTRIAL SPONSOR	
								NUMBER OF PATIENTS INCLUDED	NUMBER OF ACTIVE TRIALS	% OF PATIENTS INCLUDED IN AN INSTITUTIONAL CLINICAL TRIAL	NUMBER OF PATIENTS INCLUDED	NUMBER OF ACTIVE TRIALS
Bergonie Institute	Bordeaux	8 516	2 140	350	6,1	39 %	25 %	1847	169	86 %	293	181
Francois Baclesse Centre	Caen	7 957	611	162	3,8	8 %	8 %	534	110	87 %	77	52
Jean Perrin Centre	Clermont	6 269	415	122	3,4	28 %	7 %	346	81	83 %	69	41
Georges-François Leclerc centre	Dijon	5 236	823	282	2,9	16 %	16 %	656	149	80 %	167	133
Oscar Lambret Centre	Lille	7 057	1 235	166	7,4	20 %	18 %	1021	116	83 %	214	50
Léon Bérard Centre	Lyon	11 131	1 711	408	4,2	18 %	15 %	1177	220	69 %	534	188
Paoli calmettes Institute	Marseille	10 268	958	249	3,8	11 %	9 %	785	156	82 %	173	93
Montpellier Cancer Institute - Val d'Aurelle	Montpellier	7 410	1 521	194	7,8	24 %	21 %	1409	120	93 %	112	74
Lorraine Institute of Oncology	Nancy	5 843	664	110	6,0	11 %	11 %	616	75	93 %	48	35
Institute of Cancer research in Western France	Nantes / Angers	12 859	1 053	250	4,2	12 %	8 %	818	154	78 %	235	96
Antoine Lacassagne Centre	Nice	5 506	411	173	2,4	8 %	7 %	302	115	73 %	109	58
Curie Institute	Paris Saint Cloud	15 043	2 051	219	9,4	14 %	14 %	1728	122	84 %	323	97
Jean Godinot Institute	Reims	3 908	369	77	4,8	10 %	9 %	306	62	83 %	63	15
Eugène Marquis centre	Rennes	5 098	717	110	6,5	15 %	14 %	600	72	84 %	117	38
Henri Becquerel centre	Rouen	6 291	286	145	2,0	5 %	5 %	230	104	80 %	56	41
Paul Strauss Centre	Strasbourg	6 736	676	232	2,9	11 %	10 %	534	148	79 %	142	84
Claudius Regaud Institute	Toulouse	7 856	1 073	223	4,8	14 %	14 %	750	105	70 %	323	118
Gustave Roussy	Villejuif	12 861	4 761	495	9,6	40 %	37 %	4065	162	85 %	696	333
Total		145 845	21 475			18 %	15 %	17 724		83 %	3 751	
Mean		8 103	1 193	220	5	17 %	14 %	985	124	82 %	208	96
+/- SD		3109	1052	109	2	10 %	8 %	902	40	7 %	175	77
median		7 234	891	207	5	14 %	12 %	703	118	83 %	155	79
min		3 908	286	77	2	5 %	5 %	230	62	69 %	48	15
max		15 043	4 761	495	10	40 %	37 %	4 065	220	93 %	696	333

** With the development of personalised medicine, an increasing number of clinical trials include a molecular screening as eligibility criteria. Patients who have accepted and signed an informed consent can be denied in a second step due to the negative result of the molecular screening (on average, 67% of patients are not included in the trial after the molecular screening). Such trials represent an average 40% of industrially sponsered trials and 13% of the academically sponsored trials proposed in our centres.*

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Excellence and Innovation
in patients care

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