GUSTAVE ROUSSY

CANCER CAMPUS
GRAND PARIS

CLINICAL RESEARCH DIVISION

PHARMACOVIGILANCE UNIT

SINCE ITS CREATION IN 1926, GUSTAVE ROUSSY, THE PREMIER EUROPEAN CANCER CENTRE, HAS BUILT ITS REPUTATION ON ITS FULLY INTEGRATED APPROACH TO PATIENT CARE, RESEARCH AND TEACHING.

The Clinical Research Division (DRC), under the responsibility of Professor Benjamin Besse, is dedicated to carrying out **the clinical research** strategy of Gustave Roussy, ensuring constant **therapeutic innovation** that places it at the forefront in a number of different domains.

In 2005, **the Pharmacovigilance Unit (UFPV)** was set up to strengthen the DRC team and to meet the stringent requirements of the **European Directive** on the conduct of clinical trials on medicines for human use.

The UFPV monitors, in real time, **the safety** of the investigational medicinal products used in nearly 90 clinical trials sponsored by Gustave Roussy or by other academic sponsors in the Ile-de-France region, in accordance with current French (Jardé law) and European (Directive 2001/20/EC and Regulation (EU) No 536/2014) regulatory requirements.

The UFPV actively contributes to the development of clinical research in France through its participation in the activities of the Coordination of Institutional Sponsors (CPI) and those of the Pharmacovigilance working group (REVISE) of the Delegations for Clinical Research and Innovation (DRCI).

OUR REASON FOR BEING

To ensure the safety of patients included in national and international, phase-I to phase-III studies.

Both in adults and children.

VIGILANCE IN CLINICAL TRIALS INVOLVING CHEMOTHERAPY, IMMUNOTHERAPY, RADIATION THERAPY, MEDICAL DEVICES, GENE THERAPY OR CELL THERAPY AS WELL AS STUDIES ON THERAPEUTIC, DIAGNOSTIC, SURGICAL AND/OR RESUSCITATION STRATEGIES

OUR MISSIONS

Receipt and recording of cases, assessment of causal relationship and expectedness, data entry and MedDRA coding of SAEs

Reporting of new safety-related information

Submission of SUSARs to the regulatory authorities and ethics committees concerned, as well as to Eudravigilance.

- Preparation/validation of safety section of clinical study protocol and CRF
- Preparation of Pharmacovigilance Plan and of Risk Minimisation Plan
- Preparation/validation of safety Data Exchange Agreements (SDEAs)
- Preparation of Development Safety Update Reports (DSURs) and the safety section of clinical study reports
- Preparation of reports for Independent Data Monitoring Committee (IDMC)

- Training and assistance to investigators and clinical research associates on handling and reporting of serious adverse events (SAEs)

- Information of investigators (newsletters, Dear Investigator letters...)

Budget Projection | Signal Detection | Regulatory Intelligence

Reconciliation of clinical and pharmacovigilance databases

Implementation and handling of unblinding procedures 24 hours a day, 7 days a week

HUMAN RESOURCES

The UFPV is composed of physicians and pharmacists who have several years of experience in vigilance activities in clinical research

5

Full-time equivalent employees

2

part-time employees on professional training contracts

All of the members of the UFPV team have received training on vigilance, the regulations related to clinical trials, Eudravigilance, XEVMPD and MedDRA coding.

MATERIAL RESOURCES

1

Pharmacovigilance database (eVeReport),
completely E2B R3-compliant and interfaced with EudraVigilance, the pharmacovigilance database of the European Medicines Agency (EMA). Data are saved to two dedicated servers on a daily basis.

1

Web portal
for on-line reporting of SAEs (my e-clinical) via internet, smart phone or tablet computer

THE

MedDRA
coding dictionary

RESEARCH ACTIVITIES

- 1 - PREMIS

Interventional study whose main objective is to identify non-invasive predictive biomarkers of immune-related adverse events (irAE) in patients treated with immune checkpoint inhibitors.

The results of this study will allow to propose appropriate strategies for the prevention and management of irAEs and to make the use of immune checkpoint inhibitors safer.

- 2 - REISAMIC

Nation-wide project involving the Registry of Severe Adverse Reactions to Immunomodulatory Monoclonal Antibodies used in Oncology

The study concerns adverse reactions (ARs) at CTCAE grade 3 or higher and immune-mediated ARs at grade 2 or higher related to new drugs in immuno-oncology, whether prescribed in the context of a Marketing Authorisation (MA), a Temporary Authorisation for Use (TAU) or a clinical trial, regardless of the indication.

- 3 - SACHA

Observational study that collects prospective toxicity and efficacy data of innovative therapies administered off-label or in a context of a temporary authorization of use, in children, adolescents and young adults (under 25 years of age) with cancer who have failed to respond to therapeutic treatment or who have relapsed and who are not eligible for a clinical trial.

Supported by **the French Society for Childhood and Adolescent Cancer and Leukemia (SFCE)** and financed by **the LEEM Foundation** and **the associations "Imagine for Margo"** and **"Hubert Gouin- Enfance & Cancer"**.

The study is conducted in collaboration with the network of inter-regional hospital organizations for pediatric oncology (OIR) which organize Pediatric Inter-regional Multidisciplinary Consultation Meetings (RCPPI) bringing together the 31 SFCE centers which participate in the collection of data for the national cohort.

THE UFPV IN FIVE KEY FIGURES

≃ 90

clinical studies currently on-going

≃ 3800

patients participating in studies

≃ 1200

serious adverse events reported per year

≃ 30

SUSAR reports submitted per year

≃ 65

development safety update reports submitted per year

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PHARMACOVIGILANCE UNIT (UFPV)

114, rue Edouard Vaillant

94805 Villejuif cedex-France

TEL : +33 (0)1 42 11 61 00 **- FAX :** +33 (0)1 42 11 61 50

EMAIL : CTpharmacovigilance@gustaveroussy.fr

Read about our latest projects and news
at the UFPV internet pages

afaq ISO 9001 Qualité AFNOR CERTIFICATION

The UFPV has been certified
ISO 9001 since 2007