REPORT OF RESEARCH INVOLVING THE HUMAN PERSON (RIPH) OPEN FOR INCLUSION

in 2021 at gustave roussy

GUSTAVE ROUSSY
CANCER CAMPUS
GRAND PARIS

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EXECUTIVE SUMMARY

In 2021, 4,555 patients at Gustave Roussy participated to research involving humans (RIPH). This number of inclusions has increased since 2019. The increase in the number of inclusions in 2021 can largely be explained by the molecular screening program STING (1180 patients included), whereas the number of inclusions in treatment-related academic or industrial-sponsor studies remain stable. Considering that 15,269 patients were hospitalized at least one time for cancer at Gustave Roussy in 2021, respectively 22.0% and 7.7% of patients seen at Gustave Roussy were included in a clinical study or in a molecular screening study at GR in 2021.

551 studies were open for inclusion in 2021 (+5.1% compared to 2020): 57% were sponsored by an industrial, 11% by Gustave Roussy and 32% by an academic sponsor. 68% of these studies were international studies. Among the 483 clinical trials, 30% of the trials are phase I or I/II, 37% are phase II and 32% are phase III trials.

The 60 GR-sponsor studies enrolled 2852 patients in 2021 (+48% compared to 2020), GR-sponsored trials cover all phases of clinical trials as 25% of trials are phase I or I/II, 44% are phase II and 28% are phase III.

799 patients were included in 316 industry-sponsored studies in 2021, back on track as before the pandemic. The majority of industrial-sponsor studies conducted at GR in 2021 were early-stage trials (42% phase I or I/II), followed by phase III (28%) and phase II (26%) trials.

THE DEPARTEMENT OF CLINICAL RESEARCH IN 2021

In 2021, Gustave Roussy clinical research has been reorganized to support the ambitions of the Institute Strategic Plan in terms of clinical research:

- to be readable by all partners,
- to facilitate projects implementation, execution and valuation,
- to meet high international quality standards.

Clinical research organization has been regrouped in five distinct offices:

- **The Projects and Sponsorship Office**, which includes all clinical research activities for studies promoted by Gustave Roussy, set-up activities for studies conducted at Gustave Roussy as investigator site and all finance and contract aspects. It centralizes the trial proposals into a "single point of contact" for a rapid study set-up and manages all clinical trials contracts, budget and invoices.
- **The Biostatistics and Epidemiology Office**, which ensures statistical analysis of clinical trials, associated translational studies, and of real world data, data management and handling of clinical trials sponsored by Gustave Roussy, from protocol to publication, clinical trials methodology, meta-analysis, cancer epidemiology, health economics and metrics production to analyze clinical research activity of Gustave Roussy
- **The Clinical Operations Office** labelled Clinical Research Center by the Ministry of Health, ensures clinical research activities for all clinical trials and studies conducted at Gustave Roussy as an investigator site. This service is provided regardless of the sponsor category (pharma industries, biotech, scientific associations, academic institutions), at all development phases (from early to advanced phase) including strategic areas such as Molecular Medicine, Antitumor Immunology, DNA repair and rare Cancers.
- **The Quality Office,** which ensures a regulatory watch on GCPs, and inform departments/offices concerned of any regulatory changes, processes harmonization and rules / procedures dissemination, organization of the GCPs training for the clinical research team and for health care professionals, audits / inspections preparation, coordination and reporting, to be the quality representative of the clinical research division for the Quality division, the organization of the ISO9001 certification within the clinical research division The Quality Office includes the Functional Pharmacovigilance Unit, which performs real-time assessment of the safety of the investigational medicinal products used in all clinical trials sponsored by Gustave Roussy or by other academic sponsors, in particular, from the Ile-de-France region (within the framework of GIRCI*). and which develops a research program in pharmacovigilance.
- **The Valorization Office**, which optimizes the clinical and biological data use and dissemination and promotes the synergy with the translational research.

This reorganization has been done stepwise by firstly analyzing the way clinical research was operating, then by identifying and including new functions, by merging teams which were distinct in the former organization by creating and harmonizing processes and by recruiting resources.

In 2021 :

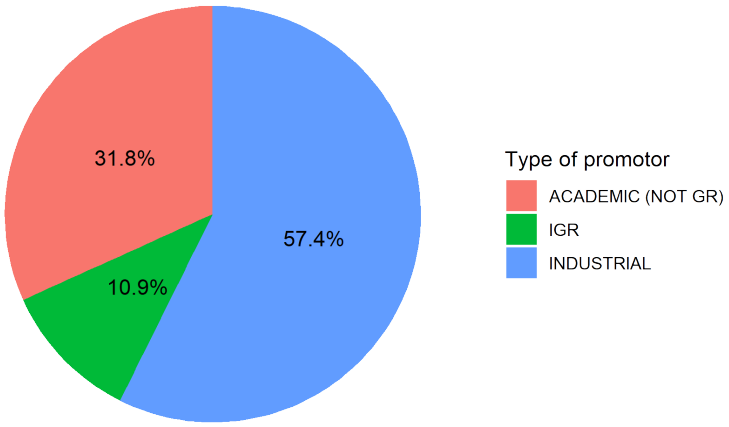
- 137 clinical studies managed as GR sponsor institution, including 119 RIPH type 1&2, 8 studies initiated this year and 3300 patients including 1180* patients in the STING study.
- Pharmacovigilance activities performed on all GR sponsored studies and on 13 additional clinical studies performed by another academic sponsor
- 13 audits, 1 inspection by the French Health Authority and 1 FDA pre inspection managed and process improvements implemented for the main findings
- Statistical activities performed for 150 active studies including 102 clinical trials, 91 active databases managed, and 99 publications in peer-reviewed journals including 14 in journals of high impact factor.

*: source = COMETH report

I. Description of studies open for inclusions at Gustave Roussy

In 2021, there were 551 studies open for inclusion at Gustave Roussy, including 316 (57.4%) studies with an industrial sponsor, 175 (31.8%) studies with an academic sponsor outside GR and 60 (10.9%) studies sponsored by Gustave Roussy.
Figure 1 presents the distribution of the number of studies, by type of sponsor. There is an increase in the number of studies opened for inclusion in GR between 2011 and 2021 (+5.1% from 2020 to 2021).

Figure 1: Repartition of the number of studies open for inclusion 2021, by type of sponsor



In 2021, the large majority of these studies (58.8%) were in inclusion or in follow-up after inclusion has been completed (23.6%). In 2021, 12 (2.2%) studies were closed, 6 (1.1%) studies were abandoned, and 6 (1.1%) were discontinued. **Table 1** shows the distribution of the status of these studies in 2021.

Table 1: Repartition of the status of the studies in 2021

Status of the research	N (%)
Abandoned	6 (1.1%)
Closed	12 (2.2%)
Discontinued	6 (1.1%)
Inclusion finished. Follow-up ongoing	130 (23.6%)
Setting up	73 (13.2%)
Still in inclusion	324 (58.8%)
Total	551 (100.0%)

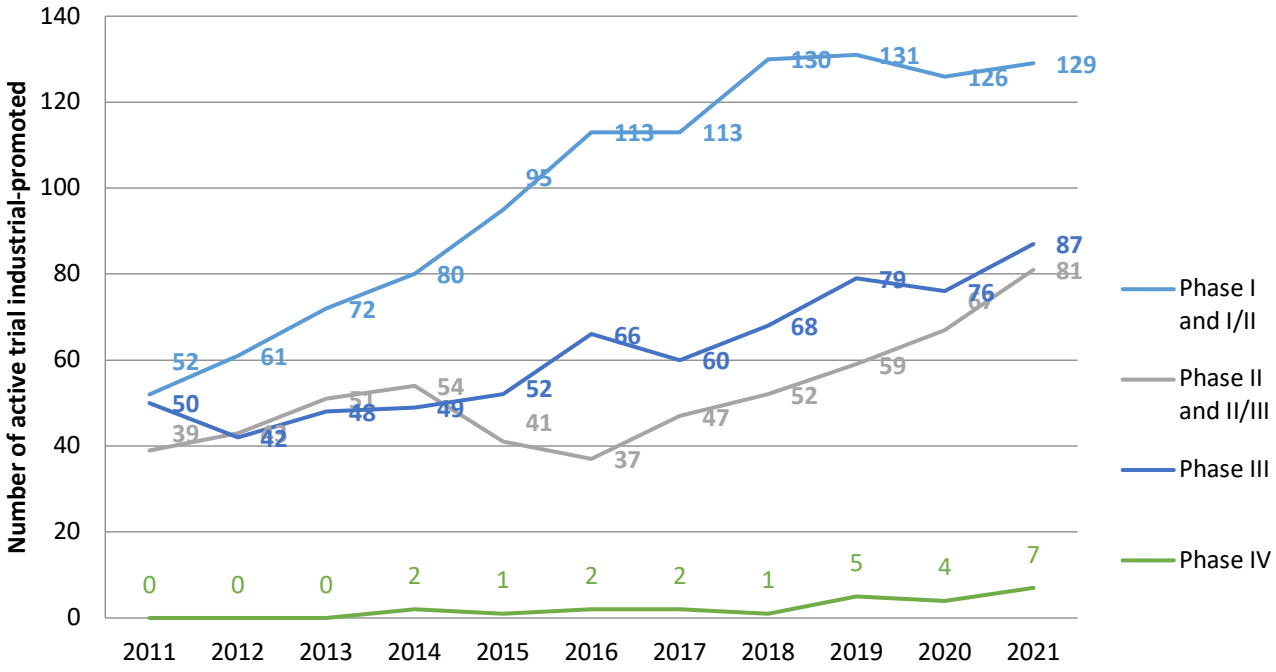
If we focus on the studies that are clinical trials, among the 483 trials opened for inclusion in GR in 2021, 29.6% of the trials are phase I or I/II, 36.9% are phase II and 31.7% are phase III trials. As shown in **Table *2***, sponsors are mostly industrial for phase I or I/II trials, while phase II trials have a majority of non-GR academic sponsors. All sponsors are involved in phase III trials.

Table 2: Repartition of trials, by phase and by sponsor type

Phase	Type of sponsor			Total
	Academic (not GR)	GR	Industrial	
I or I/II	5 (3.5%)	9 (25.0%)	129 (42.4%)	143 (29.6%)
II	81 (56.6%)	16 (44.4%)	81 (26.6%)	178 (36.9%)
III	56 (39.2%)	10 (27.8%)	87 (28.6%)	153 (31.7%)
IV	1 (0.7%)	1 (2.8%)	7 (2.3%)	9 (1.9%)
Total	143 (29.6%)	36 (7.5%)	304 (62.9%)	483 (100.0%)

When focusing on the evolution of the number of industrial trials over time, we observe an increase in the number of trials until 2021, and this concerns all phases of clinical trials (**Figure *2***).

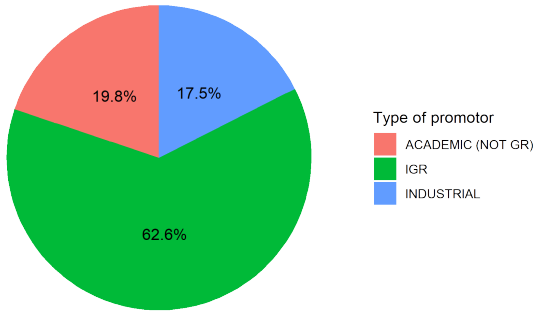
Figure 2: Evolution of the number of industrial-sponsored trials, by phase



II. Description of the number of inclusions

In 2021, 4555 patients were included in research involving humans open for inclusion at GR. Among these 4555 patients, 62.6% were included in GR-sponsor research, 19.8% in non-GR academic-sponsor research and 17.5% in industrial-sponsor studies (**Figure *3***).

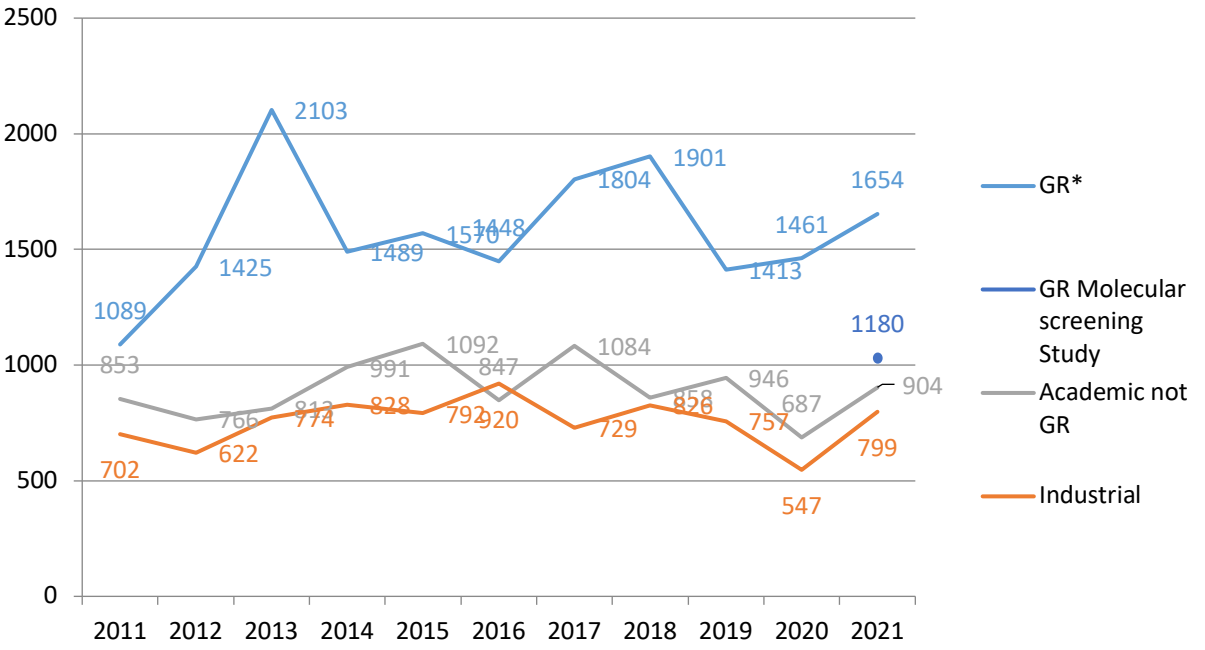
Figure 3: Repartition of the patient inclusions in 2021, by type of sponsor



Sponsor type	N (%)
GR	2852 (62.6%)
ACADEMIC (NOT GR)	904 (19.8%)
INDUSTRIAL	799 (17.5%)
Total	4555 (100.0%)

The evolution of the number of patients included in a study, by sponsor type, over time is as follows (**Figure 4**):

Figure 4: Evolution of the number of patients included over time, by sponsor type



*GR studies included all GR-sponsor studies, except ONCOVID (n=18 patients)

When focusing on clinical trials, in 2021, 1635 patients were included in a clinical trial at Gustave Roussy. The repartition of the number of patients included, by sponsor type is given in **Table 3**.

Table 3: Repartition of the number of inclusions in a clinical trial, by type of sponsor

Sponsor type	N (%)
GR	287 (17.5%)
ACADEMIC NOT GR	640 (39.1%)
INDUSTRIAL	708 (43.3%)
Total	1635 (100.0%)

By focusing by type of cancer location, the number of patients included in 2021 by each committee is presented in **Figure 5**.

Figure 5: Number of patients included by each cancer commitee