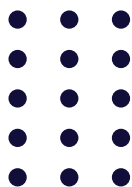


REPORT OF RESEARCH INVOLVING THE HUMAN PERSON (RIPH) OPEN FOR INCLUSION IN 2023 AT GUSTAVE ROUSSY



METRICS team:

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April, 1st, 2024

EXECUTIVE SUMMARY

In 2023, 5,661 patients at Gustave Roussy participated in research involving human subjects (RIPH). This number of inclusions has increased with 81.6% from 2019. The increase in the number of inclusions in 2023 can largely be explained by the molecular screening program (corresponding to the 6 studies STING, MAPPYACT2, MO43989, EORTC 1553 / SPECTA Rare, RNASARC and MICCHADO, representing 2553 patients), whereas the number of inclusions in other studies (excluding screening program) remains stable since 2019. Considering that 15 274 patients were hospitalized at least one time for cancer at Gustave Roussy in 2023, respectively 20.3% and 16.7% of patients seen at Gustave Roussy were included in a clinical study or in a molecular screening study at GR in 2023.

In 2023, 563 studies were open to recruitment (+52.5% between 2014 and 2023, -3.5% from 2022 to 2023): 58% were sponsored by industry, 11% by Gustave Roussy and 30% by another academic sponsor. 375 (66%) of these studies were multicentric international studies. Among the 474 clinical trials, 33% are phase I, 36% are phase II, 29% are phase III trials and 2% are phase IV.

The 63 GR-sponsored studies enrolled 3290 patients in 2023, of which 2353 in the molecular screening GR-program. The 33 GR-sponsored trials cover all phases of clinical trials as 24% are phase I, 49% are phase II, 24% are phase III trials and 3% and phase IV.

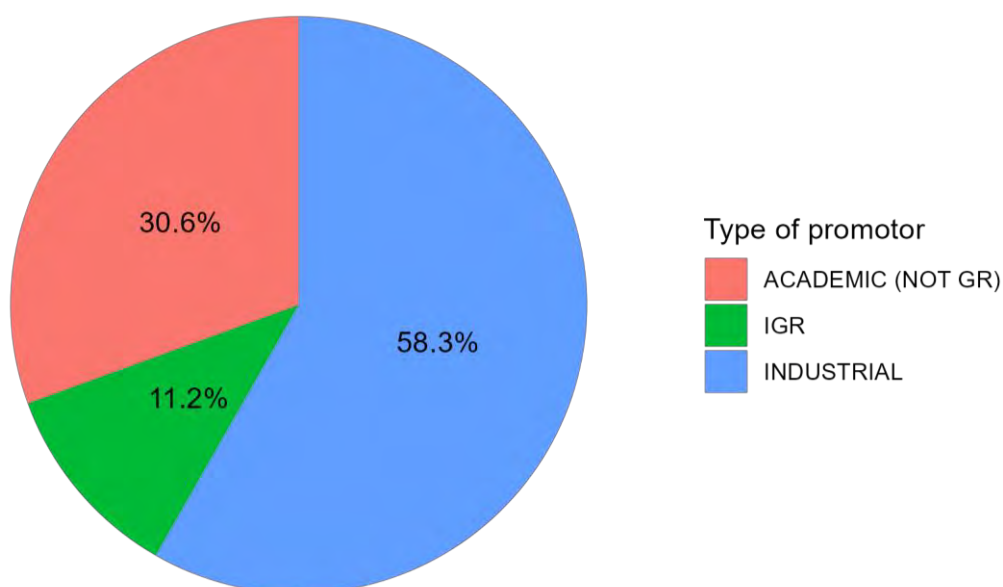
939 patients were included in 328 industry-sponsored studies in 2023, including 19 patients in molecular screening studies. As compared to 2022, it represented 110 additional patients (+13.2%) even if there were 15 studies less (-4.3%). The majority of the 313 industry-sponsored trials opened at GR in 2023 were phase I trials (46%), followed by phase II and III (28% and 24% respectively) trials.

I. Description of studies open for inclusions at Gustave Roussy

In 2023, there were 563 studies open for inclusions at Gustave Roussy, corresponding to 328 (58.3%) studies with an industrial sponsor, 172 (30.6%) studies with an academic sponsor outside Gustave Roussy and 63 (11.2%) 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 open for inclusion in GR between 2014 and 2023 (+52.5%) but a slight decrease compared to 2022 (-3.5% from 2022 to 2023).

Figure 1: Repartition of the number of studies open for inclusion 2023, by type of sponsor



At the end of 2023, the large majority of the studies were in inclusion (49.2%) or in follow-up after inclusion has been completed (28.8%), and 60 studies were set up (10.7%). There were 42 (7.5%) studies closed and 22 (3.9%) were abandoned. **Table 1** shows the distribution of the status of these studies at the end of 2023.

Table 1: Repartition of the status of the studies at the end of 2023

Status of the research	N (%)
Closed	42 (7.5%)
Discontinued	22 (3.9%)
Inclusion finished. Follow-up ongoing	162 (28.8%)
Setting up	60 (10.7%)
Still in inclusion	277 (49.2%)
Total	563 (100.0%)

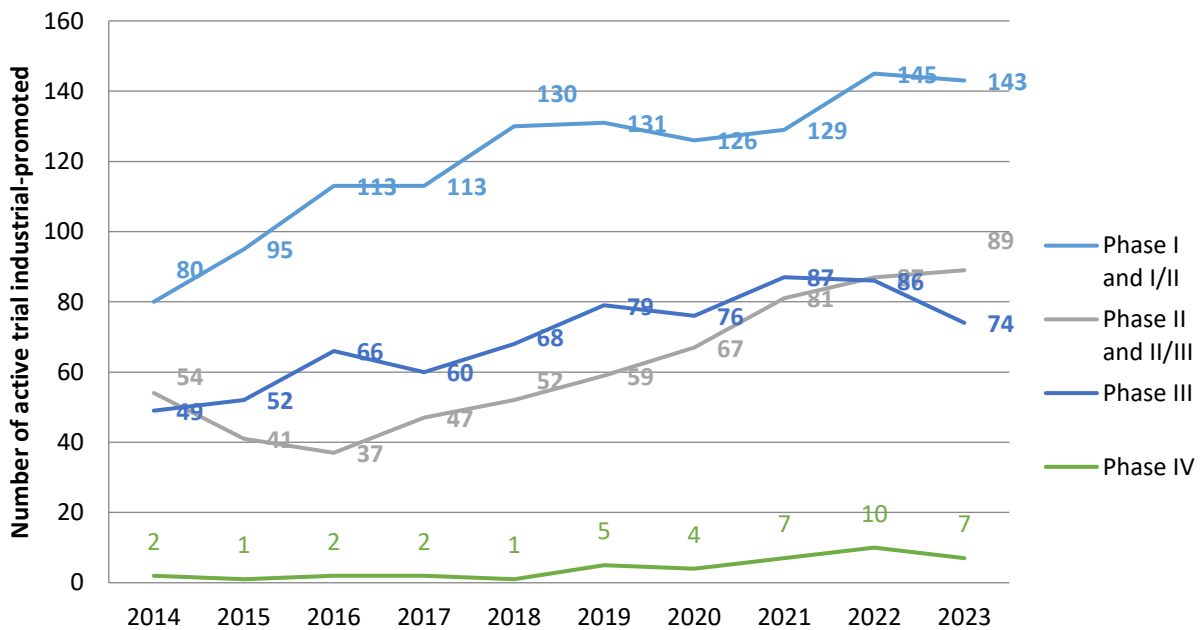
If we focus on the 474 studies that are clinical trials (*i.e.* phase I to phase IV), 33.3% of the trials are phase I, 35.9% are phase II and 28.9% are phase III trials. As shown in **Table 2**, sponsors are mostly industrial for phase I, while phase II trials have a majority of academic (GR and non-GR) sponsors. All three types sponsors have 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	7 (5.5%)	8 (24.2%)	143 (45.7%)	158 (33.3%)
II	65 (50.8%)	16 (48.5%)	89 (28.4%)	170 (35.9%)
III	55 (43.0%)	8 (24.2%)	74 (23.6%)	137 (28.9%)
IV	1 (0.8%)	1 (3.0%)	7 (2.2%)	9 (1.9%)
Total	128 (27.0%)	33 (7.0%)	313 (66.0%)	474 (100.0%)

When focusing on the evolution of the number of the industrial trials over time, we observe an increase in the number of trials until 2022 whatever the phase, followed by a decrease in the number of phase III in 2023 (Figure 2).

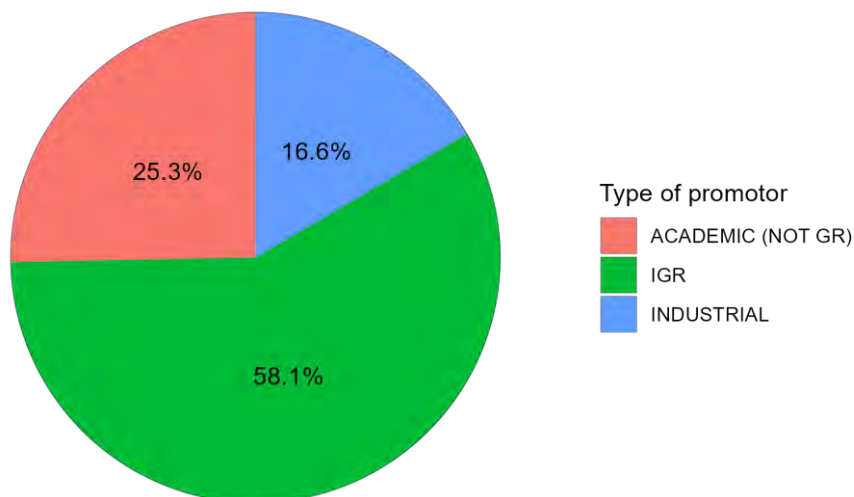
Figure 2: Evolution of the number of industrial-sponsored trials, by phase



II. Description of the number of inclusions

In 2023, 5,661 patients were included in research involving humans open for inclusion at GR. Among these 5,661 patients, 58.1% were included in GR-sponsor research, 25.3% in non-GR academic-sponsor research and 16.6% in industrial-sponsor studies (**Figure 3**).

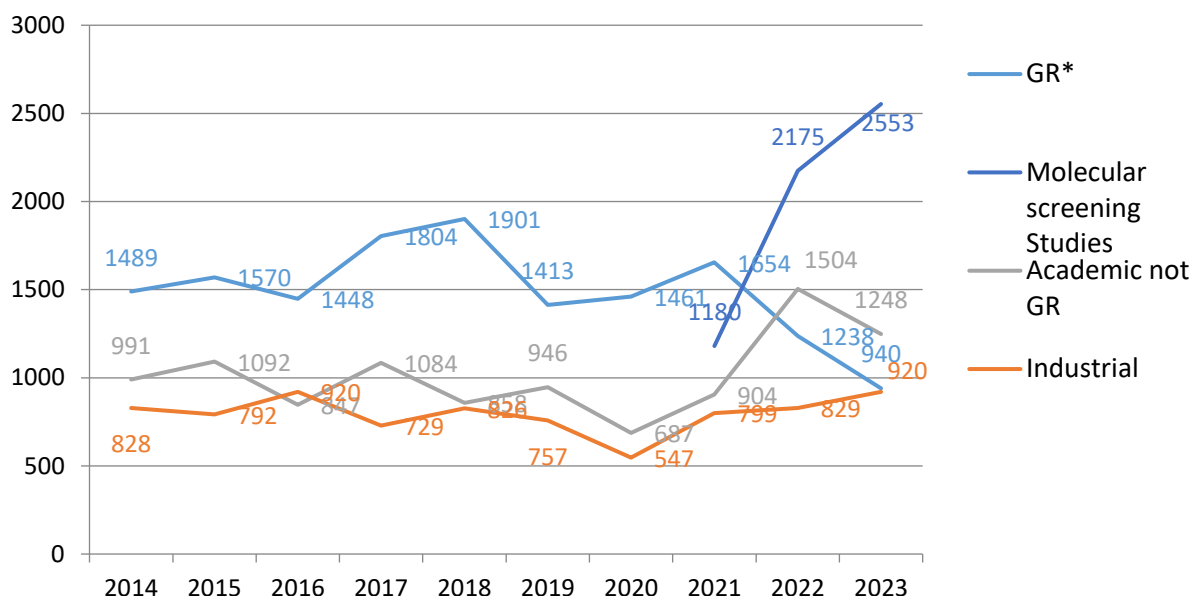
Figure 3: Repartition of the patient inclusions in 2023, by type of sponsor



Sponsor type	N (%)
ACADEMIC (NOT GR)	1432 (25.3%)
IGR	3290 (58.1%)
INDUSTRIAL	939 (16.6%)
Total	5661 (100.0%)

The evolution of the number of patients included in a study, by sponsor type, over time is as follows (**Figure 4**). Of note the molecular screening studies included 2553 pts.

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



For Figure 4, the molecular screening program consisted in 2 GR-promotor studies (STING and MAPPYACT2) and 4 molecular studies sponsored by other promotors (MO43989 (Roche), EORTC 1553 / SPECTA Rare (EORTC), RNASARC (Leon Berard) and MICCHADO (Curie)).

Regarding the 474 trials (i.e. phase I to phase 4), there were 1610 patients included in 2023. The **Table 3** presented the number of patients included by phase and by sponsor.

Table 3: Number of patients included, by phase and by sponsor type

Phase	Type of sponsor			TOTAL N=474 trials
	Academic (not GR) N=128 trials	GR N=33 trials	Industrial N=313 trials	
I	6	20	397	423
II	203	96	166	465
III	426	66	154	646
IV	3	0	73	76
TOTAL	638	182	790	1610

The DITEP department (early-phase trial department) included 2644 patients in 2023, including 2328 patients in the STING study and 316 patients in other non-molecular screening clinical studies.

Regarding the number of inclusions in trials still open for inclusion or whose inclusion finished in 2023, the mean number of patients included per phase and type of sponsor is presented in **Table 4**. The mean number of patients included is higher for GR-sponsored trials, whatever the phase.

Table 4: Mean number of patients included in trials opened to inclusion, per phase and per sponsor type

Phase	Type of sponsor		
	Academic (not GR)	GR	Industrial
	N=128 trials	N=33 trials	N=313 trials
I	N=5	N=6	N=105
	1.2 (1.1)	3.2 (2.7)	2.8 (3.9)
	[0-3]	[0-7]	[0-24]
II	N=56	N=13	N=68
	3.6 (4.7)	6.5 (5.0)	2.3 (2.5)
	[0-20]	[0-15]	[0-10]
III	N=47	N=7	N=64
	9.0 (30.8)	9.4 (7.1)	2.3 (3.5)
	[0-213]	[3-20]	[0-24]
IV	N=1	N=1	N=5
	3 (NA)	0 (NA)	14.6 (31.5)
			[0-71]
Total	5.8 (20.6)	6.3 (5.6)	2.8 (5.6)
	[1-5]	[0-20]	[0-71]

Results are presented as n, means (std) [range] for the trials still inclusion or whose inclusion finished in 2023

Regarding the Loi Jardé classification, 4,885 patients were included in Type 1 or 2, mostly in GR sponsored studies, as presented in **Table 5**:

Table 5: Repartition of the number of inclusions according Loi Jardé classification, by type of sponsor

Classification Jardé	Type of sponsor			Total
	Academic (not GR)	GR	Industrial	
Type 1/2	1053 (73.5%)	2976 (90.5%)	856 (91.2%)	4885 (86.2%)
Type 3	379 (26.5%)	314 (9.5%)	83 (8.8%)	776 (13.7%)
Total	1432 (100.0%)	3413 (100.0%)	939 (100.0%)	5661 (100.0%)

In 2023, 6144 patients were screened and 5661 patients were included in a study at Gustave Roussy, corresponding to a ratio included/screened of 92.1%. The repartition of the number of patients screened and included, and the ratio included/screened by study type and sponsor type are given in **Table 6**.

Table 6: Repartition of the number of screenings and inclusions, by type of sponsor and study

Sponsor type	N screened	N included (%)	Ratio included/screened
All studies	6144	5661	92.1%
In clinical trials			
GR	219	182	83.1%
ACADEMIC NOT GR	760	638	83.9%
INDUSTRIAL	1070	790	73.8%
Total	2049	1610	78.6%
In other studies			
GR	3075	3108	101.0 %*
ACADEMIC NOT GR	830	794	95.6%
INDUSTRIAL	190	149	78.4%
Total	4095	4051	98.9%

*As some screening of patients included in January 2023 occurred in December 2022.

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