

REPORT OF RESEARCH INVOLVING THE HUMAN PERSON (RIPH) OPEN FOR INCLUSION IN 2022 AT GUSTAVE ROUSSY



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Tuesday March 3, 2023

EXECUTIVE SUMMARY

In 2022, 5,746 patients at Gustave Roussy participated to research involving humans (RIPH). This number of inclusions has increased since 2019 by 84.4%. The increase in the number of inclusions in 2022 can largely be explained by the molecular screening program (including the STING, PIONEER and MAPPYACT studies, representing 2175 patients), whereas the number of inclusions in others studies (excluding screening program) increased by 14.6% since 2019. Considering that 14,332 patients were hospitalized at least one time for cancer at Gustave Roussy in 2022, respectively 24.9% and 15.2% of patients seen at Gustave Roussy were included in a clinical study or in a molecular screening study at GR in 2022.

584 studies were open in 2022 (+5.9% compared to 2021, +15.9% compared to 2019): 59% were sponsored by an industrial, 11% by Gustave Roussy and 30% by another academic sponsor. 68% of these studies were international studies. Among the 506 clinical trials, 32% are phase I, 37% are phase II, 30% are phase III trials and 2% are phase IV.

The 64 GR-sponsor studies enrolled 3413 patients in 2022, including 2175 in molecular screening program. The 38 GR-sponsored trials cover all phases of clinical trials as 21% are phase I, 55% are phase II and 21% are phase III trials.

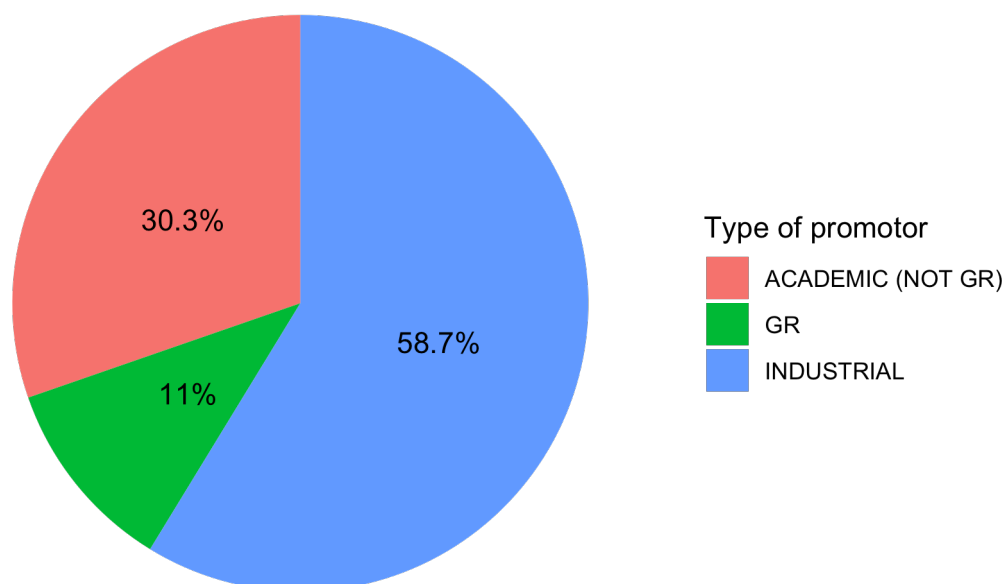
829 patients were included in 343 industry-sponsored studies in 2022. As compared to 2021, it represented 30 additional patients (+3.6%) and 27 additional studies (+7.8%). The majority of the 328 industrial-sponsor trials conducted at GR in 2022 were early-stage trials (44% of phase I), followed by phase II and III (26% each) trials.

I. Description of studies open for inclusions at Gustave Roussy

In 2022, there were 584 studies open for inclusions at Gustave Roussy, corresponding to 343 (58.7%) studies with an industrial sponsor, 177 (30.3%) studies with an academic sponsor outside Gustave Roussy and 64 (11.0%) 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 2012 and 2022 (+5.9% from 2021 to 2022), and 15.9% compared to 2019.

Figure 1: Repartition of the number of studies open for inclusion 2022, by type of sponsor



At the end of 2022, the large majority of these studies were in inclusion (56.0%) or in follow-up after inclusion has been completed (27.1%). In 2022, 19 (3.3%) studies were closed, 4 (0.7%) studies were abandoned, and 13 (2.2%) were discontinued. **Table 1** shows the distribution of the status of these studies at the end of 2022.

Table 1: Repartition of the status of the studies at the end of 2022

Status of the research	N (%)
Abandoned	4 (0.7%)
Closed	19 (3.3%)
Discontinued	13 (2.2%)
Inclusion finished. Follow-up ongoing	158 (27.1%)
Setting up	63 (10.8%)
Still in inclusion	327 (56.0%)
Total	584 (100.0%)

If we focus on the 506 studies that are clinical trials (i.e. phase I to phase IV), 31.6% of the trials are phase I, 36.6% are phase II and 29.4% are phase III trials. As shown in **Table 2**, sponsors are mostly

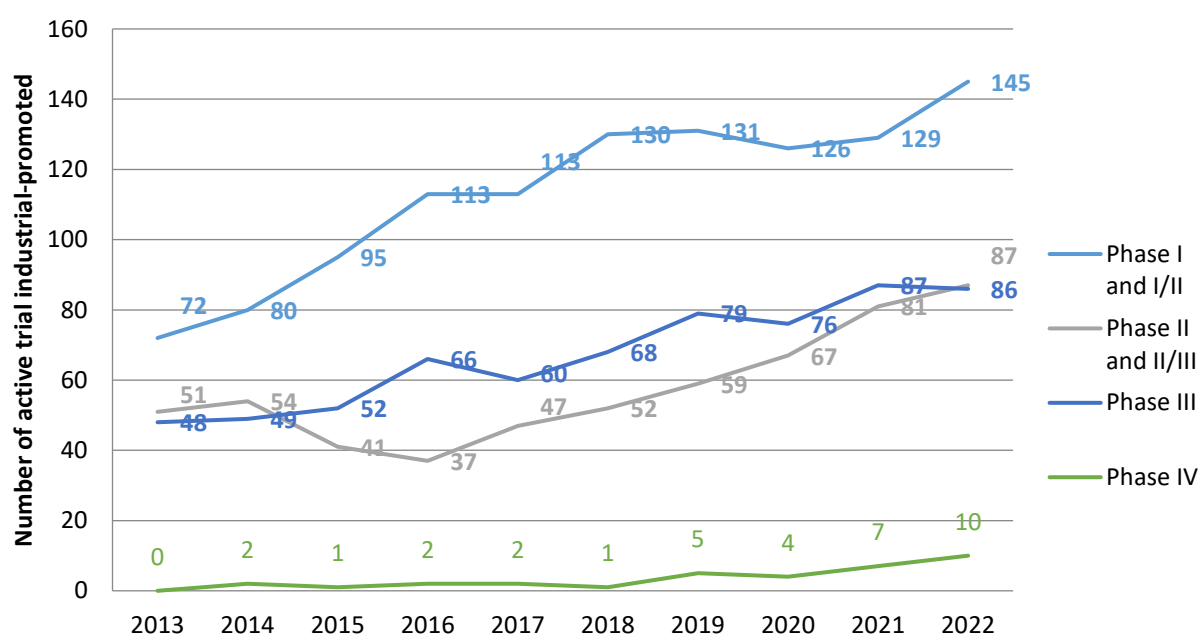
industrial for phase I, while phase II trials have a majority of non-GR academic or industrial sponsors. All sponsors are involved in phase III trials.

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

Phase	Type of sponsor			Total
	Academic (not GR)	GR	Industrial	
I	7 (5.0%)	8 (21.1%)	145 (44.2%)	160 (31.6%)
II	77 (55.0%)	21 (55.3%)	87 (26.5%)	185 (36.6%)
III	55 (39.3%)	8 (21.1%)	86 (26.2%)	149 (29.4%)
IV	1 (0.7%)	1 (2.6%)	10 (3.0%)	12 (2.4%)
Total	140 (27.7%)	38 (7.5%)	328 (64.8%)	506 (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, and this concerns all phases of clinical trials (**Figure 2**).

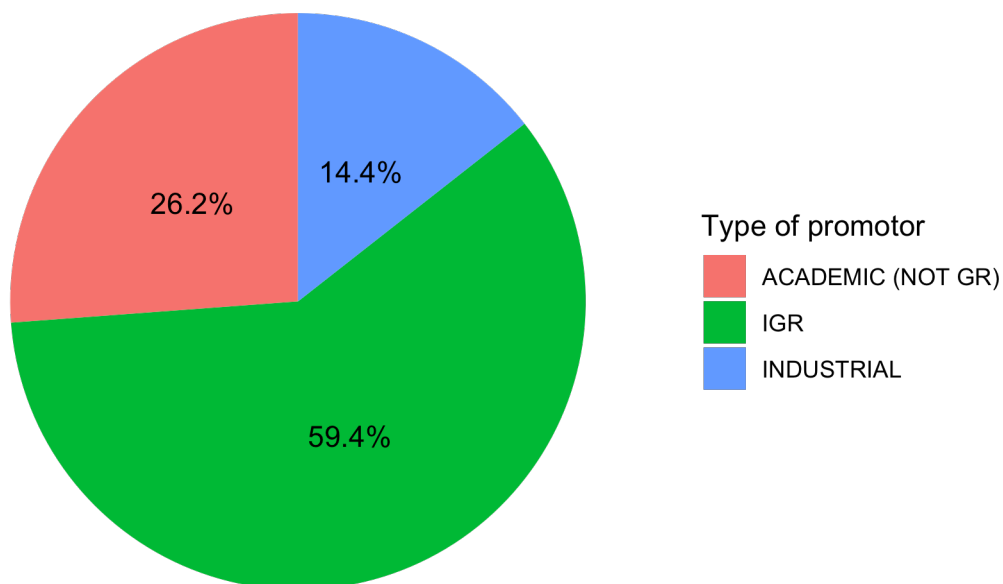
Figure 2: Evolution of the number of industrial-sponsored trials, by phase



II. Description of the number of inclusions

In 2022, 5,746 patients were included in research involving humans open for inclusion at GR. Among these 5,746 patients, 59.4% were included in GR-sponsor research, 26.2% in non-GR academic-sponsor research and 14.4% in industrial-sponsor studies (**Figure 3**).

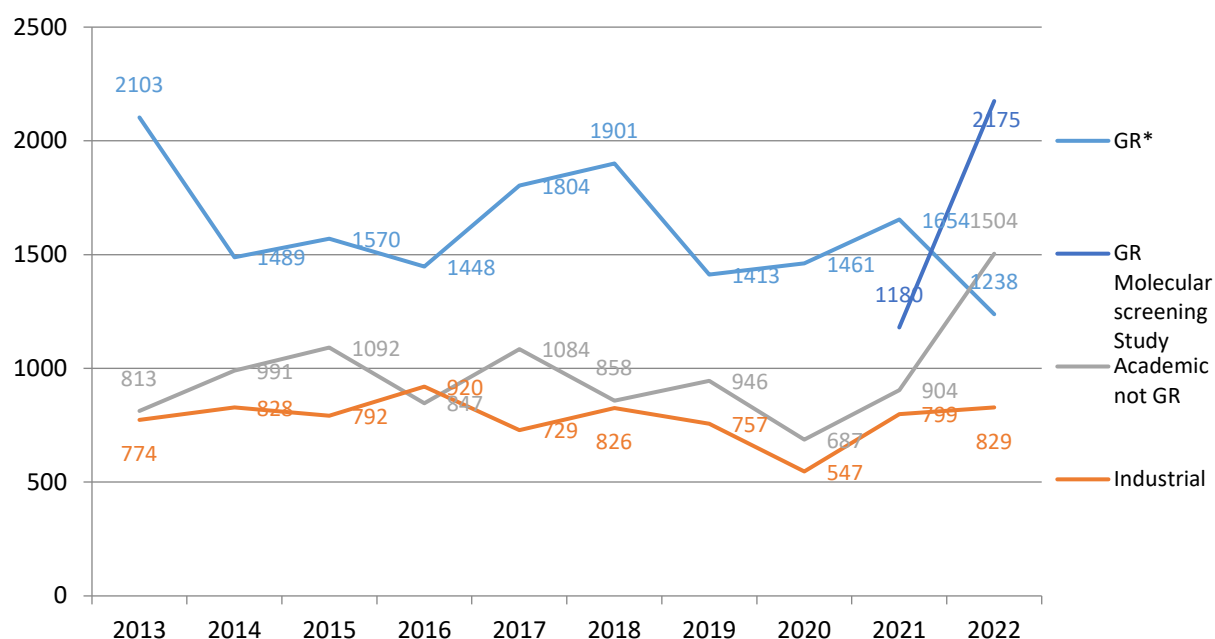
Figure 3: Repartition of the patient inclusions in 2022, by type of sponsor



Sponsor type	N (%)
ACADEMIC (NOT GR)	1504 (26.2%)
GR	3413 (59.4%)
INDUSTRIAL	829 (14.4%)
Total	5746 (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 study STING included 2149 pts. Regarding the academic not GR sponsored studies, the increase may be explained by the increase of inclusion in ACABi PRONOBIL (+546 pts, observational type III study) and MyPeBS (+65 pts, with 228 pts in 2022 *versus* 163 pts in 2021).

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



For Figure 4 : GR* studies included all GR-sponsor studies, except STING, PIONEER and MAPPYACT2, the 3 molecular screening studies).

Regarding the number of inclusions in trials still open for inclusion or whose inclusion finished in 2022, the mean number of patients included per phase and per type of sponsor is presented in **Table 3**. The mean number of patients included is higher for GR-sponsored trials, except for phase III trials.

Table 3: 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=120 trials	N=29 trials	N=272 trials
I	N=4	N=6	N=120
	2.5 (2.4)	4.5 (4.6)	2.2 (2.7)
	[0-5]	[0-13]	[0-14]
II	N=67	N=15	N=73
	2.5 (2.7)	7.6 (8.5)	2.4 (3.6)
	[0-13]	[0-24]	[0-15]
III	N=48	N=7	N=70
	9.2 (32.6)	6.4 (3.4)	2.8 (4.1)
	[0-228]	[3-10]	[0-20]
IV	N=1	N=1	N=9
	1.0 (NA)	9.0 (NA)	1.4 (2.4)
	[1-1]	[9-9]	[0-6]
Total	5.2 (20.9)	6.7 (6.6)	2.4 (3.4)

Phase	Type of sponsor		
	Academic (not GR)	GR	Industrial
	N=120 trials	N=29 trials	N=272 trials
	[0-228]	[0-24]	[0-20]

Results are presented as n, means (std) [range] for the trials still inclusion or whose inclusion finished in 2022

Regarding the Loi Jardé classification, 4,816 patients were included in Type 1 or 2, mostly in GR sponsored studies, as presented in **Table 4**:

Table 4: Repartition of the number of inclusions according Loi Jardé classification, by type of sponsor

Phase	Type of sponsor			Total
	Academic (not GR)	GR	Industrial	
Type 1/2	834 (55.5%)	3198 (93.7%)	784 (94.6%)	4816 (83.8%)
Type 3	670 (44.5%)	215 (6.3%)	45 (5.4%)	930 (16.2%)
Total	1504 (100.0%)	3413 (100.0%)	829 (100.0%)	5746 (100.0%)

In 2022, 6651 patients were screened and 5746 patients were included in a study at Gustave Roussy, corresponding to a ratio included/screened is 87.7%. The repartition of the number of patients screened and included, and the ratio included/screened by study type and sponsor type is given in **Table 5**. Of note, 378 patients were included in trial by the Drug Development Department (DITEP) in clinical trials.

Table 5: 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	6551	5746	87.7%
In clinical trials			
GR	250	211	84.4%
ACADEMIC NOT GR	764	639	83.6%
INDUSTRIAL	1254	750	59.8%
Total	2268	1600	70.5%
In other studies			
GR	3307	3202	96.8%
ACADEMIC NOT GR	891	865	97.0%
INDUSTRIAL	85	79	92.9%
Total	4283	4146	96.8%

