

REPORT OF RESEARCH INVOLVING THE HUMAN PERSON (RIPH) OPEN FOR INCLUSION IN 2024 AT GUSTAVE ROUSSY



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EXECUTIVE SUMMARY

In 2024, 6,115 patients at Gustave Roussy participated in research involving human subjects (RIPH). This number of inclusions has increased with 96.2% from 2019. The increase in the number of inclusions in 2024 can largely be explained by the molecular screening program (corresponding to the 5 studies: STING, MAPPYACT2, MO43989, EORTC 1553 / SPECTA Rare, and MICCHADO, representing 2757 patients) and the inclusions in industrial-sponsored trials. Considering that 17,167 patients were hospitalized at least one time for cancer at Gustave Roussy in 2024 (including in day care unit or radiotherapy), respectively 19.6% and 16.1% of patients treated at Gustave Roussy were included in a clinical study or in a molecular screening study at GR in 2024, representing 35.7% in total.

In 2024, 586 studies were open to recruitment (+54.2% between 2015 and 2024, +4.1% from 2023 to 2024): 58% were sponsored by industry, 12% by Gustave Roussy and 30% by another academic sponsor. 390 (67%) of these studies were multicentric international studies. Among the 487 clinical trials, 33% are phase I, 36% are phase II, 30% are phase III trials and 1% are phase IV.

The 71 GR-sponsored studies enrolled 3823 patients in 2024, of which 2757 in the molecular screening GR-program. The 38 GR-sponsored trials cover all phases of clinical trials as 24% are phase I, 40% are phase II, and 36% are phase III trials.

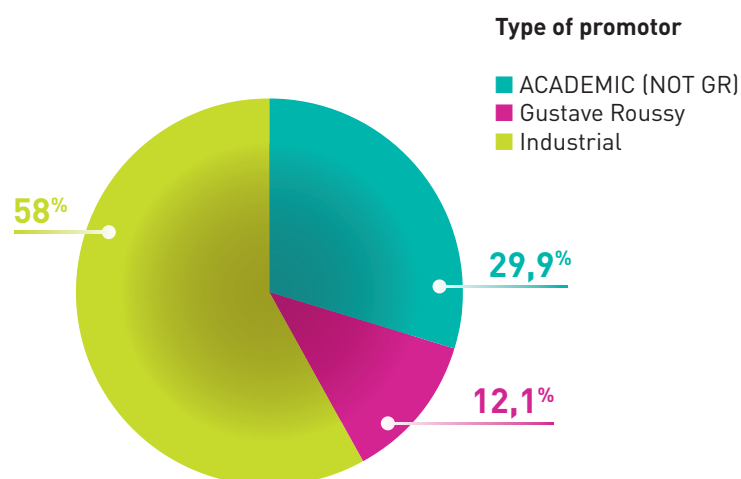
A total of 1131 patients were included in 340 industry-sponsored studies in 2024, including 27 patients in molecular screening studies. As compared to 2023, it represented 91 additional patients (+22.9%) and 12 additional studies. The majority of the 326 industry-sponsored trials opened at GR in 2024 were phase I trials (45%), followed by phase II and III (27% and 26% respectively) trials.

I. DESCRIPTION OF STUDIES OPEN FOR INCLUSIONS AT GUSTAVE ROUSSY

In 2024, there were 586 studies open for inclusions at Gustave Roussy, corresponding to 340 (58.0%) studies with an industrial sponsor, 175 (29.9%) studies with an academic sponsor outside Gustave Roussy and 71 (12.1%) studies sponsored by Gustave Roussy.

Figure 1 presents the distribution of the number of studies, by type of sponsor. Whatever the sponsor, there is an increase in the number of studies open for inclusion in GR between 2023 and 2024 (+4.1%) and between 2015 and 2024 (+54.2%).

FIGURE 1: Repartition of the number of studies open for inclusion 2024, by type of sponsor



At the end of 2024, the large majority of the studies were in inclusion (52.6%) or in follow-up after inclusion had been completed (25.1%), and 77 studies were set up (13.1%). There were 34 (5.8%) studies closed and 20 (3.4%) were discontinued. **Table 1** shows the distribution of the status of these studies at the end of 2024.

TABLE 1: Repartition of the status of the studies at the end of 2024

STATUS OF THE RESEARCH	N (%)
Closed	34 (5.8%)
Discontinued	20 (3.4%)
Inclusion finished. Follow-up ongoing	147 (25.1%)
Setting up	77 (13.1%)
Still in inclusion	308 (52.6%)
TOTAL	586 (100.0%)

If we focus on the 487 studies that are clinical trials (i.e. phase I to phase IV), 33.3% of the trials are phase I, 35.5% are phase II and 29.8% 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)	Gustave Roussy	Industrial	
I	5 (4.1%)	9 (23.7%)	148 (45.4%)	162 (33.3%)
II	69 (56.1%)	15 (39.5%)	89 (27.3%)	173 (35.5%)
III	48 (39.0%)	14 (36.8%)	83 (25.5%)	145 (29.8%)
IV	1 (0.8%)	0 (0%)	6 (1.8%)	7 (1.4%)
TOTAL	123 (25.3%)	38 (7.8%)	326 (66.9%)	487 (100.0%)

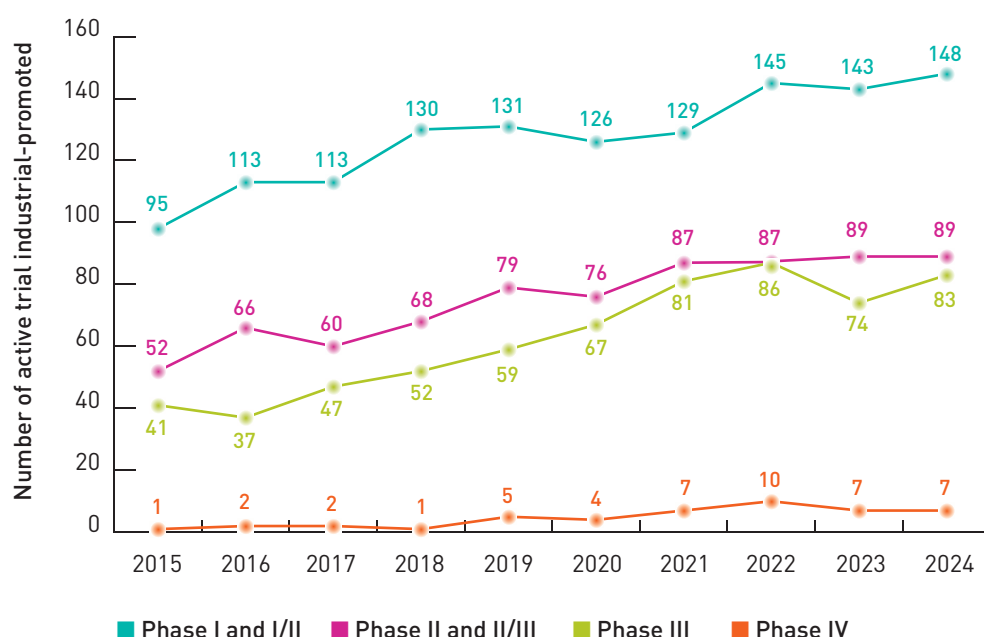
Regarding the Loi Jardé classification, 534 studies are classified as Type 1 or 2, mostly in industrial-sponsored studies, as presented in **Table 3**:

TABLE 3: Repartition of the number of studies according Loi Jardé classification, by type of sponsor

CLASSIFICATION JARDÉ	TYPE OF SPONSOR			TOTAL
	Academic (not GR)	Gustave Roussy	Industrial	
Type 1/2	155 (88.5%)	50 (70.4%)	329 (96.8%)	534 (91.1%)
Type 3	20 (11.5%)	21 (29.6%)	11 (3.2%)	52 (8.8%)
TOTAL	175 (100.0%)	71 (100.0%)	340 (100.0%)	586 (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 whatever the phase, with an increase of phase I trials and stabilization of the number of phase II and III trials in 2024 (**Figure 2**).

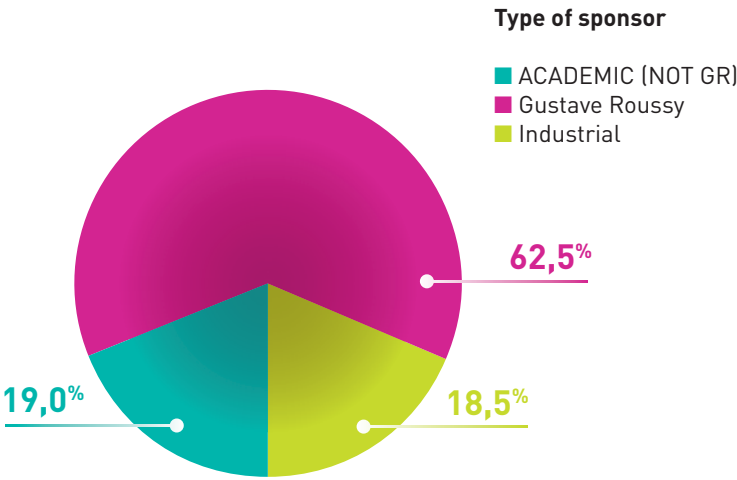
FIGURE 2: Evolution of the number of industrial-sponsored trials, by phase



II. DESCRIPTION OF THE NUMBER OF INCLUSIONS

In 2024, 6115 patients were included in research involving humans open for inclusion at GR. Among these 6115 patients, 62.5% were included in GR-sponsor research, 19.0% in non-GR academic-sponsor research and 18.5% in industrial-sponsor studies (Figure 3).

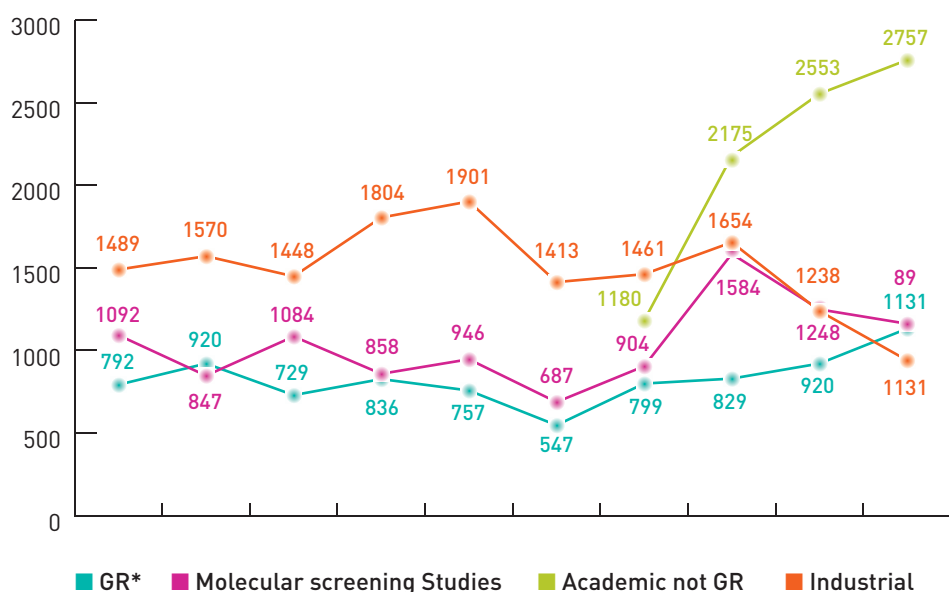
FIGURE 3: Repartition of the patient inclusions in 2024, by type of sponsor



SPONSOR TYPE	N (%)
Academic (Not GR)	1161 (19.0%)
Gustave Roussy	3823 (62.5%)
Industrial	1131 (18.5%)
TOTAL	6115 (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 2757 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-sponsor studies (STING and MAPPYACT2) and 3 molecular studies sponsored by other sponsors (MO43989 (Roche), EORTC 1553 / SPECTA Rare (EORTC), and MICCHADO (Curie).

Regarding the 487 trials (i.e. phase I to phase 4), there were 1366 patients included in 2024. The **Table 4** presented the number of patients included by phase and by sponsor.

TABLE 4: Number of patients included, by phase and by sponsor type

PHASE	TYPE OF SPONSOR			TOTAL N=487 trials
	Academic (not GR) N=123 trials	Gustave Roussy N=38 trials	Industrial N=326 trials	
I	6	42	391	439
II	173	69	204	446
III	162	100	145	407
IV	9	0	65	74
TOTAL	350	211	805	1366

The DITEP department (early-phase trial department) included 3080 patients in 2024, including 2684 patients in the STING study and 396 patients in other non-molecular screening clinical studies.

Regarding the number of inclusions in trials still open for inclusion or whose inclusion finished in 2024, the mean (median) number of patients included per phase and type of sponsor is presented in **Table 5**. The mean number of patients included is higher for GR-sponsored trials, regardless of the phase.

TABLE 5: Mean and median number of patients included in studies opened to inclusion, per phase and per sponsor type

PHASE	TYPE OF SPONSOR		
	Academic (not GR) N=175 trials	Gustave Roussy N=71 trials	Industrial N=340 trials
I	N=5 trials 1.2 (1.0) [0-3]	N=9 trials 4.7 (3) [0-15]	N=148 trials 2.6 (1) [0-19]
II	N=69 trials 2.5 (4) [0-12]	N=15 trials 4.6 (3) [0-14]	N=89 trials 2.3 (1) [0-21]
III	N=48 trials 3.4 (1) [0-25]	N=14 trials 7.1 (7) [0-19]	N=83 trials 1.7 (0) [0-30]
IV	N=1 trial 9 (NA)	N=0	N=6 trials 13.0 (0) [0-58]
Other studies (not trial)	N=52 studies 15.6 (2.5) [0-165]	N=33 studies 112.7 (11) [0-2684]	N=14 studies 24.5 (3.5) [0-215]
TOTAL	N=175 STUDIES 6.3 (1) [0-134]	N=71 STUDIES 53.8 (6) [0-2681]	N=340 STUDIES 3.3 (1) [0-215]

Results are presented as n, means (median) [range] for the studies still in inclusion

Regarding the Loi Jardé classification, 4,820 patients were included in Type 1 or 2, mostly in GR sponsored studies, as presented in **Table 6**:

TABLE 6: Repartition of the number of inclusions according Loi Jardé classification, by type of sponsor

CLASSIFICATION JARDÉ	TYPE OF SPONSOR			TOTAL
	Academic (not GR)	Gustave Roussy	Industrial	
Type 1/2	741 (63.8%)	3212 (84.0%)	867 (76.7%)	4820 (78.8%)
Type 3	420 (36.1%)	611 (16.0%)	264 (23.3%)	1295 (21.2%)
TOTAL	1161 (100.0%)	3823 (100.0%)	1131 (100.0%)	6115 (100.0%)

In 2024, 646 patients were pre-screened, 6536 patients were screened, and 6115 patients were included in a study at Gustave Roussy, corresponding to a ratio of included/screened of 93.6%. The repartition of the number of patients screened and included, and the corresponding ratio included/screened by study type and sponsor type are given in **Table 7**.

TABLE 7: 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	6536	6115	93.6%
In clinical trials			
Gustave Roussy	255	211	82.7%
Academic not GR	423	350	82.7%
Industrial	1059	805	76.0%
TOTAL	1737	1366	78.6%
In other studies			
Gustave Roussy	3632	3612	99.4%
Academic not GR	831	811	97.6%
Industrial	336	326	97.0%
TOTAL	4799	4749	98.9%

