

REPORT OF RESEARCH INVOLVING THE HUMAN PERSON (RIPH) OPEN FOR INCLUSION IN 2025 AT GUSTAVE ROUSSY



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EXECUTIVE SUMMARY

In 2025, 7,505 patients at Gustave Roussy participated in research involving human subjects. This represents a 141.0% increase compared with 2019. The rise in inclusions in 2025 can largely be attributed to the molecular screening program, which correspond to two GR-sponsored studies (STING and MAPPYACTS2) that together enrolled 3,173 patients.

In 2025, 18,525 patients were hospitalized at least once for cancer at Gustave Roussy (including day-care and radiotherapy units). Among them, 23.4% were included in a clinical trial and 17.1% in a molecular screening study conducted at GR, totaling 40.5% of treated patients participating in research.

A total of 618 studies were open to recruitment in 2025, representing a +48.2% increase between 2016 and 2025 and +5.5% compared with 2024. Furthermore, 215 news studies were initiated during the year. Of these studies, 57% were sponsored by industry, 12% by Gustave Roussy, and 31% by other academic sponsors. Overall, 420 studies (68%) were international multicenter trials. Among the 516 clinical trials, 36% were phase I, 31% phase II, 31% phase III, and 1% phase IV.

The 73 GR-sponsored studies enrolled 4,889 patients in 2025, including 3,173 within the GR molecular screening program. The 40 GR-sponsored clinical trials covered all phases: 18% were phase I, 43% phase II, and 40% phase III clinical trials.

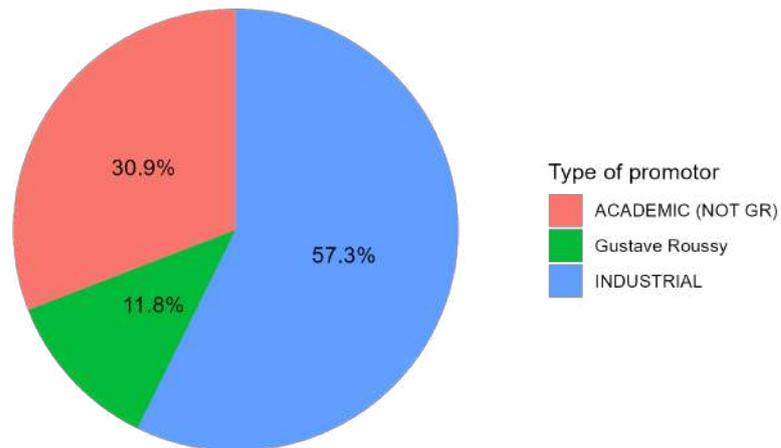
In 2025, 1,108 patients were enrolled in 354 industry-sponsored studies. Compared with 2024, this corresponds to 14 additional studies (with a marked rise in phase I trials and stabilization of phase II and III trials in 2025), but 23 fewer patients (-2.0%). Most of the industry-sponsored trials open at GR in 2025 were phase I (51%), followed by phase III (26%) and phase II trials (22%).

I. Description of studies open for inclusions at Gustave Roussy

In 2025, a total of 618 studies were open for inclusion at Gustave Roussy, including 354 studies (57.3%) with an industrial sponsor, 191 studies (30.9%) with an academic sponsor outside Gustave Roussy, and 73 studies (11.8%) sponsored by Gustave Roussy.

Figure 1 presents the distribution of the number of studies, by sponsor type. Regardless of sponsor, the number of studies open for inclusion in GR increased between 2024 and 2025 (+5.5%) and between 2016 and 2025 (+48.2%).

Figure 1: Repartition of the number of studies open for inclusion 2025, by type of sponsor



At the end of 2025, most studies were in inclusion (55.2%) or in follow-up after inclusion completion (17.5%). In addition, 80 studies (12.9%) were in the setup phase, 55 studies (8.9%) were closed, and 34 studies (5.5%) had been discontinued or cancelled. **Table 1** shows the distribution of these studies' status at the end of 2025.

Table 1: Repartition of the status of the studies at the end of 2025

Status of the research	N (%)
Cancelled	3 (0.5%)
Closed	55 (8.9%)
Discontinued	31 (5.0%)
Inclusion finished. Follow-up ongoing	108 (17.5%)
Setting up	80 (12.9%)
Still in inclusion	341 (55.2%)
Total	618 (100.0%)

Clinical Trials

Among the 516 studies that are clinical trials (*i.e.* phase I to IV, which represents 479 of the 482 studies evaluating a drug and 5 of the 16 studies evaluating a medical device), 36.2% are phase I, 31.4% phase II, 31.0% phase III and 1.4% phase IV. As shown in **Table 2**, industry sponsors accounted for the majority of phase I, while all sponsor types conducted phase II and III trials.

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

Phase	Type of sponsor			Total
	Academic (not GR)	Gustave Roussy	Industrial	
I	8 (5.9%)	7 (17.5%)	172 (50.6%)	187 (36.2%)
II	70 (51.5%)	17 (42.5%)	75 (22.1%)	162 (31.4%)
III	56 (41.2%)	16 (40.0%)	88 (25.9%)	160 (31.0%)
IV	2 (1.5%)	0 (0%)	5 (1.5%)	7 (1.4%)
Total	136 (26.4%)	40 (7.8%)	340 (65.9%)	516 (100.0%)

Regulatory classification

Studies were classified according to the applicable European regulatory framework (for medicinal drugs and medical devices) and, for studies involving neither drugs nor devices, according to the French Jardé Law.

Clinical trials of medicinal products conducted under the EU Clinical Trials Regulation accounted for 482 studies. Research involving medical devices comprised 16 studies (15 device-only studies and 1 combined drug–device study). For research not involving drugs or devices, conducted under the Jardé Law, 27 studies were classified as RIPH1 (interventional studies involving more than minimal risk), 38 as RIPH2 (interventional studies involving minimal risk and constraints), and 55 as RIPH3 (non-interventional studies), as shown in **Table 3**:

Table 3: Repartition of the number of studies by regulatory classification and type of sponsor

Classification	Type of sponsor			Total
	Academic (not GR)	Gustave Roussy	Industrial	
Medicinal products	109 (57.0%)	35 (47.9%)	338 (95.4%)	482 (78.0%)
Medical device	8 (4.2%)	1 (1.3%)	7 (2.0%)	16 (2.6%)
IVDR	0	0	0	0
RIPH1 (excluding drugs and devices)	21 (11.0%)	6 (8.2%)	0	27 (4.4%)
RIPH2	28 (14.6%)	10 (13.7%)	0	38 (6.1%)
RIPH3	25 (13.1%)	21 (28.8%)	9 (2.6%)	55 (8.9%)
Total	191 (100.0%)	73 (100.0%)	354 (100.0%)	618 (100.0%)

IVDR = In Vitro Diagnostic Medical Devices. For non-drug and non-device research, RIPH1 refers to study refers to interventional studies with more than minimal risk, RIPH2 for interventional but minimal risk and constraints, and RIPH3 for non-interventional.

Trials sponsored by industry and academic sponsors

Over time, the number of industry-sponsored trials increased across all phases, with a marked rise in phase I trials and stabilization of phase II and III trials in 2025 (Figure 2). The number of academic trials remained stable, with phase II and phase III trials accounting for the majority.

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

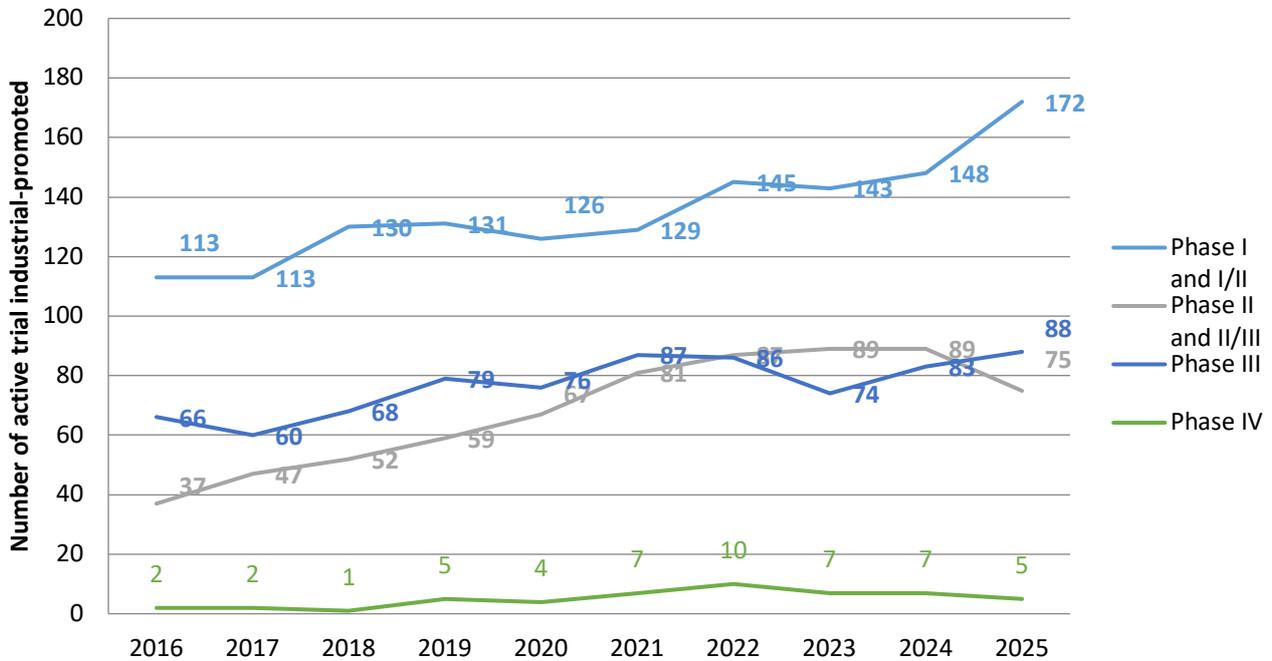
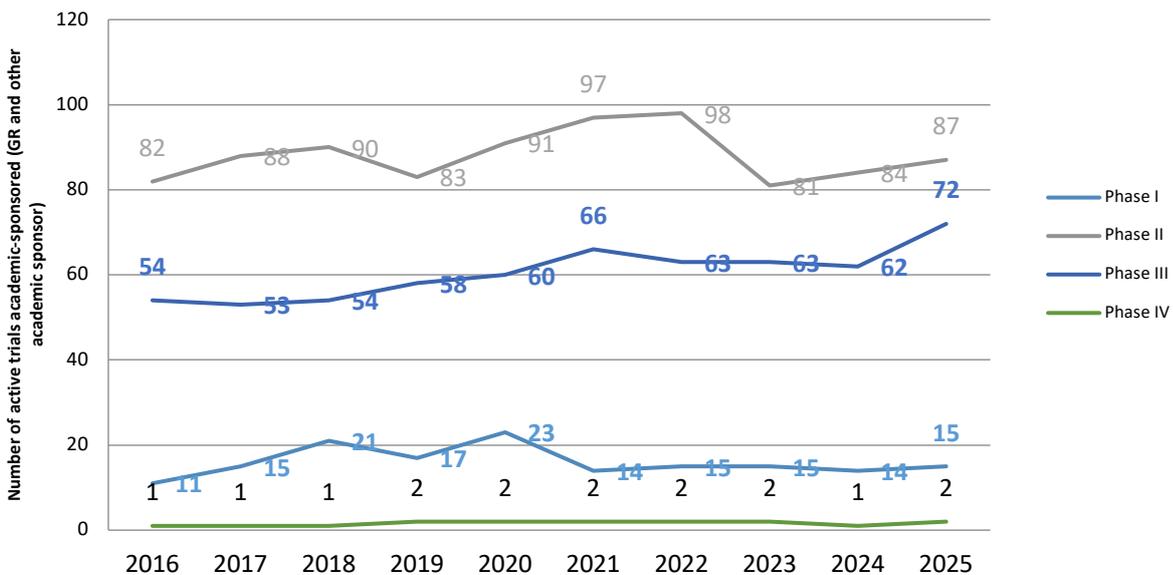


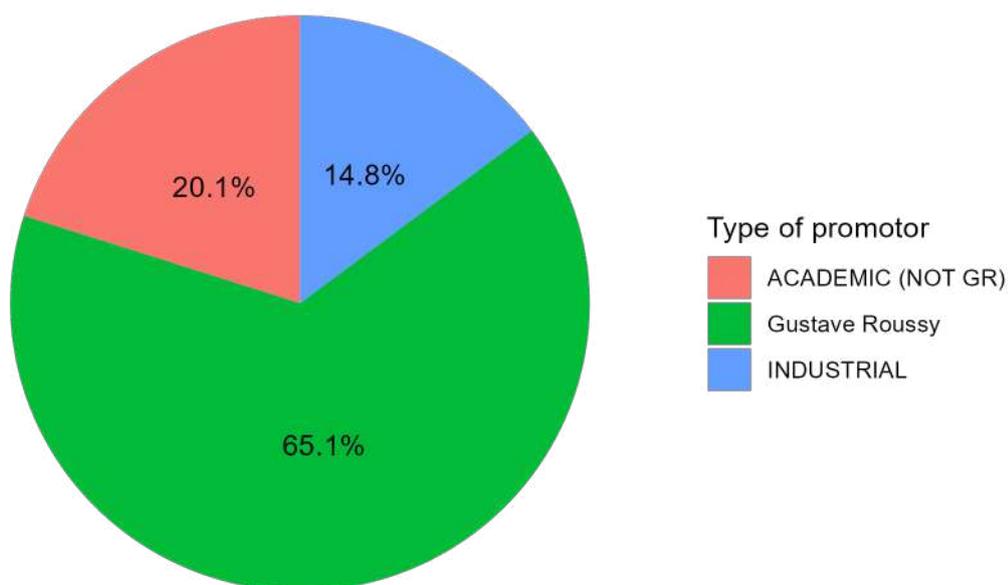
Figure 3: Evolution of the number of academic sponsored trials (GR and others), by phase



II. Description of the number of inclusions

In 2025, 7505 patients were included in research involving humans open for inclusion at Gustave Roussy. Among them, 65.1% were included in GR-sponsored studies, 20.1% in non-GR academic-sponsor research and 14.8% in industry-sponsored studies (**Figure 4**).

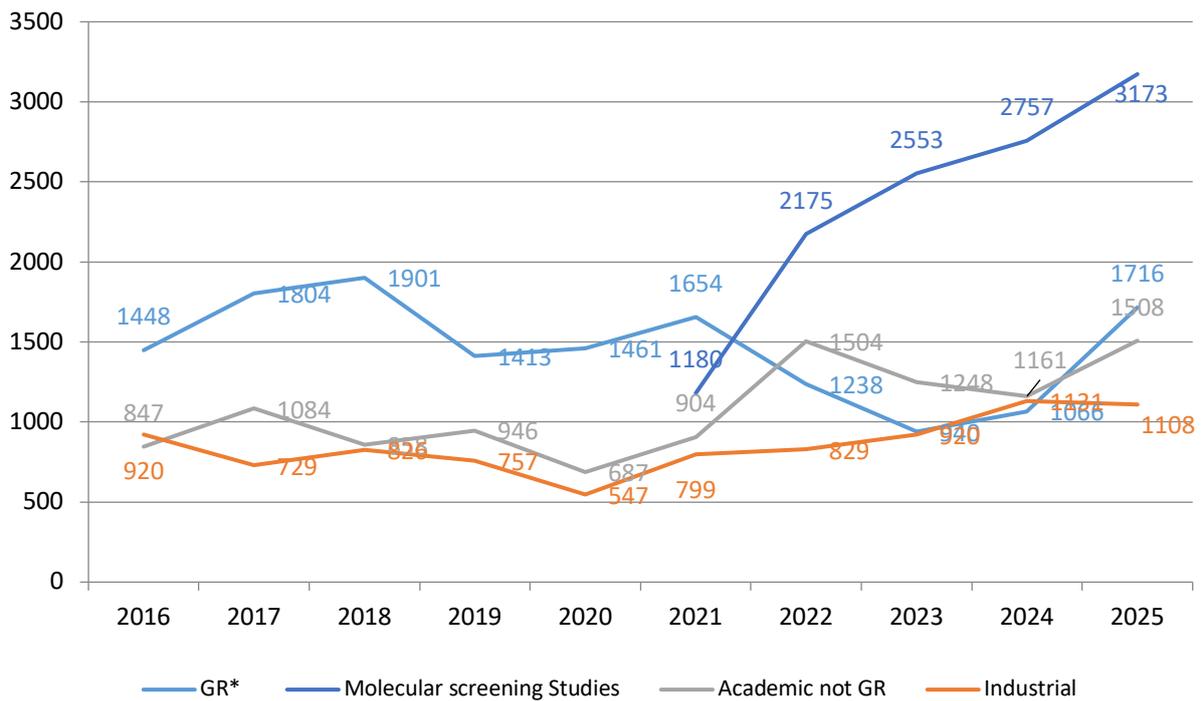
Figure 4: Repartition of the patient inclusions in 2025, by type of sponsor



Sponsor type	N (%)
Academic (Not GR)	1508 (20.1%)
Gustave Roussy	4889 (65.1%)
Industrial	1108 (14.8%)
Total	7505 (100.0%)

The evolution of the number of patient inclusions by sponsor type over time is shown in **Figure 5**. Notably, the molecular screening program included 3173 pts.

Figure 5: Evolution of the number of patients included over time, by sponsor type



*For Figure 5, the molecular screening program consists of two GR-sponsor studies (STING and MAPPYACT2).

Inclusions in clinical trials

Among the 516 trials (phase I to 4, which represent 479 of the 482 studies evaluating a drug and 5 of the 16 studies evaluating a medical device), 1506 patients were enrolled in 2025. **Table 4** presents 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=516 trials
	Academic (not GR) N=136 trials	Gustave Roussy N=40 trials	Industrial N=340 trials	
I	8	49	466	523
II	185	78	128	391
III	175	203	192	570
IV	5	0	17	22
TOTAL	373	330	803	1506

Mean and median number of inclusions per study

Table 5 presents the mean and median number of patients included per study, by phase and type of sponsor. Overall, GR-sponsored trials enrolled more patients on average, regardless of the phase.

Table 5: Mean and median number of patients included, per phase and per sponsor type

Phase	Type of sponsor		
	Academic (not GR) N=191 studies	Gustave Roussy N=73 studies	Industrial N= 354 studies
I	N=3 trials	N=7 trials	N=109 trials
	1.7 (2)	7.0 (4)	3.7 (2)
	[0-3]	[1-18]	[0-35]
II	N=60 trials	N=11 trials	N=51 trials
	3.0 (2)	7.1 (4)	2.3 (1)
	[0-17]	[0-24]	[0-17]
III	N=45 trials	N=15 trials	N=64 trials
	3.9 (3)	13.5 (8)	2.7 (2)
	[0-16]	[0-99]	[0-15]
IV	N=1 trial	N=0	N=3 trials
	5 (5)		0.7 (0)
			[0-2]
Other studies (not trial)	N=55 studies	N=33 studies	N=14 studies
	23.1 (0)	147.0 (29)	21.8 (4)
	[0-462]	[0-3134]	[0-213]
Total	N=191 studies	N=73 studies	N=354 studies
	7.9 (2)	67.0 (8)	3.1 (1)
	[0-462]	[0-3134]	[0-213]

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

Inclusions by regulatory classification

According to the French and EU regulatory framework, 1298 patients were included in a clinical trial evaluating a drug, 76 in medical device studies and 3 in combined drug–device studies.

For non-drug and non-device research, 3244 patients were included in RIPH1 studies (interventional, more than minimal risk), 1115 in RIPH2 studies (interventional, minimal risk and constraints), and 1772 in RIPH3 (non-interventional) studies, as presented in **Table 6**:

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

Classification	Type of sponsor				Total
	Academic (not GR)	Gustave Roussy All studies	Gustave Roussy All studies except the molecular screening	Industrial	
Medicinal products (drug)	300 (19.9%)	215 (4.4%)	215 (12.5%)	783 (70.7%)	1298 (17.3%)
Medical device	19 (1.3%)	4 (0.1%)	4 (0.2%)	50 (4.5%)	73 (1.0%)
Combined drug and device	3 (0.2%)	0	0	0	3 (<0.1%)
RIPH1 (excluding drugs and devices)	47 (3.1%)	3197 (65.3%)	24 (1.4%)	0	3244 (43.2%)
RIPH2	631 (41.8%)	484 (9.9%)	484 (28.2%)	0	1115 (14.9%)
RIPH3	508 (33.7%)	989 (20.2%)	989 (57.6%)	275 (24.8%)	1772 (23.6%)
Total	1508 (100.0%)	4889 (100.0%)	1716 (100.0%)	1108 (100.0%)	7505 (100.0%)

For non-drug and non-device research, Category 1 refers to study refers to interventional studies with more than minimal risk, Category 2 for interventional but minimal risk and constraints, and Category 3 for non-interventional.

Screening and inclusion rates

In 2025, 568 patients were pre-screened, 8167 patients were screened, and 7505 patients were included in a study at Gustave Roussy, corresponding to a ratio of included/screened of 91.9%, and a ratio of 86.8% when excluding the studies of molecular screening.

The **Table 7** presents the number of patients screened and included, and the corresponding ratio included/screened by study and sponsor type

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	8167	7505	91.9%
All studies except the studies of molecular screening	4993	4332	86.8%
In clinical trials			
Gustave Roussy	392	330	84.1%
Academic not GR	573	373	65.1%
Industrial	1154	803	69.6%
Total	2119	1506	71.1%
In other studies			
Gustave Roussy	1147	1135	98.9%
Academic not GR	4592	4559	99.3%
Industrial	309	305	98.7%
Total	6048	5999	99.2%

