

# Overview of patients inclusions and outcomes into modern phase 1 trials at Gustave Roussy over the last 5 years, OVATION Study

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## BACKGROUND

- Phase 1 trials historically involve heavily pretreated patients (pts) with no more effective therapeutic options available and generally with poor expected outcomes.
- Phase 1 trials evolved over the past years and are now widely considered.
- However, there is scarce data regarding phase 1 cancer centers activity and outcomes of pts enrolled into modern phase 1 trials.

## OBJECTIVE

We sought to provide an overview of pts inclusions and outcomes into early phase trials at Gustave Roussy (GR) over the last 5 years.

## PATIENTS AND METHODS

- All pts who were consecutively treated from January 2017 to December 2021 in early phase trials for advanced cancer or hematological malignancies at the Drug Development Department of GR were retrospectively reviewed.
- Data regarding pts demographics, tumor types, investigational treatments, toxicity, efficacy and survival outcomes were collected.
- The cutoff date for the present analysis was the 31st March 2022. All pts who were alive at the time of last follow-up were censored.

## RESULTS

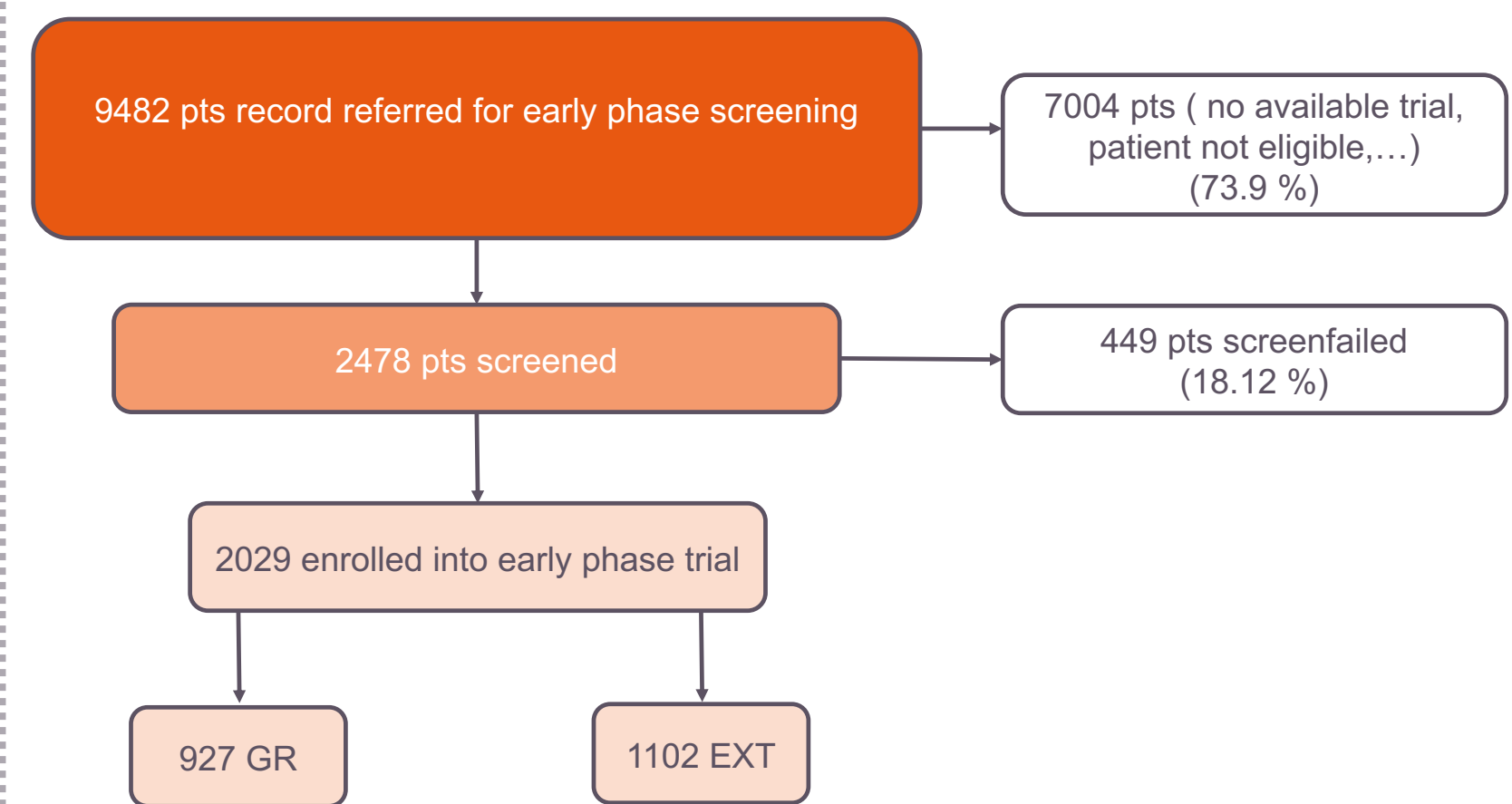


Fig. 1: Flow chart : Pts inclusions into early phase trials between 2017 and 2021

- In total, 9482 pts with advanced solid tumors or hematological malignancies were oriented towards early phase trials.
- 2478 pts were screened, among which 449 (18.1%) failed screening. Reasons of screen failure were medical event (44%), biological abnormalities (21%), administrative issue (9%), technical issue (9%), other (13%) or unknown (4%).
- 2029 pts finally received at least one treatment dose. 169 (8.33%) pts were enrolled in at least two early phase trials.

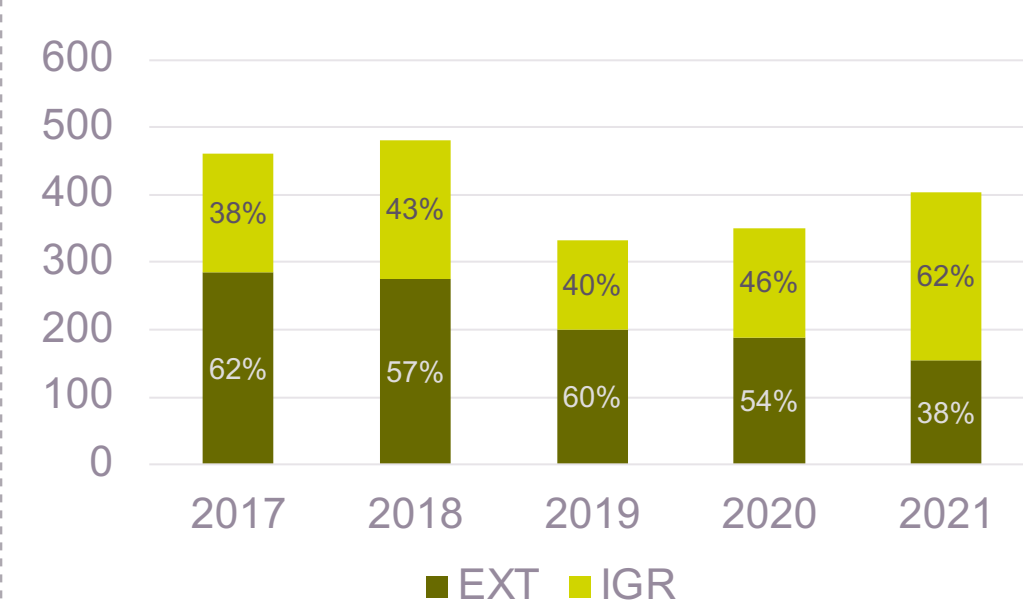


Fig. 2: Number of pts included per year into early phase trials at GR

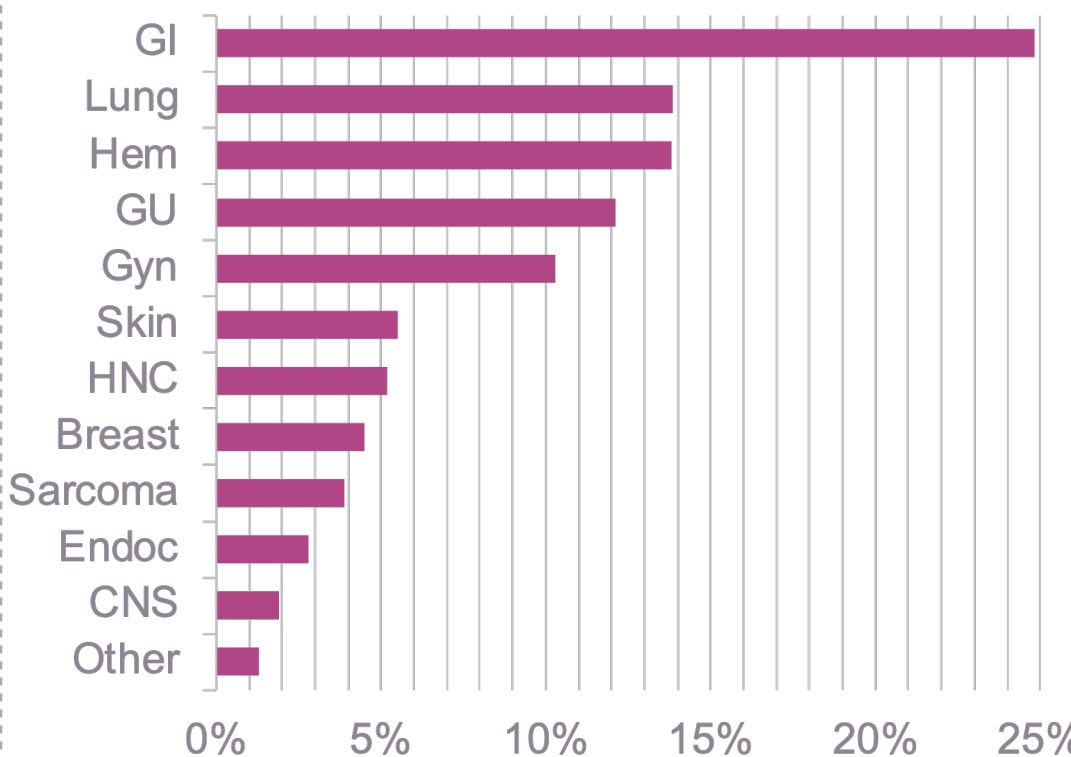


Fig. 3: Cancer type distribution among pts included into early phase trials

- Median age was 59 years old (18-91).
- Tumor types were gastro intestinal (25%), lung (14%), genitourinary (12%), hematological (12%) and other types (37%).
- There were 214 ongoing trials overall.
- Amongst all pts treated and evaluable for response (1953 pts), overall response rate (ORR) was 15.9% and disease response rate (DCR) was 46.7%.

Best response	Number (%)
Complete response	55 (2.8%)
Partial response	256 (13.1%)
Stable disease	602 (30.8%)
Progressive disease	1040 (53.3%)
Non evaluable	76

Table 1: Best overall response for pts included in early phase trials

- Median progression free survival (mPFS) and median overall survival (mOS) were respectively of 2.7 mo (95%CI, 2.5-2.8) and 12.6 mo (95%CI, 11.9-13.7).

- For all pts, mOS after end of treatment (EOT) was 7.6 mo (95%CI, 7.2-8.4).

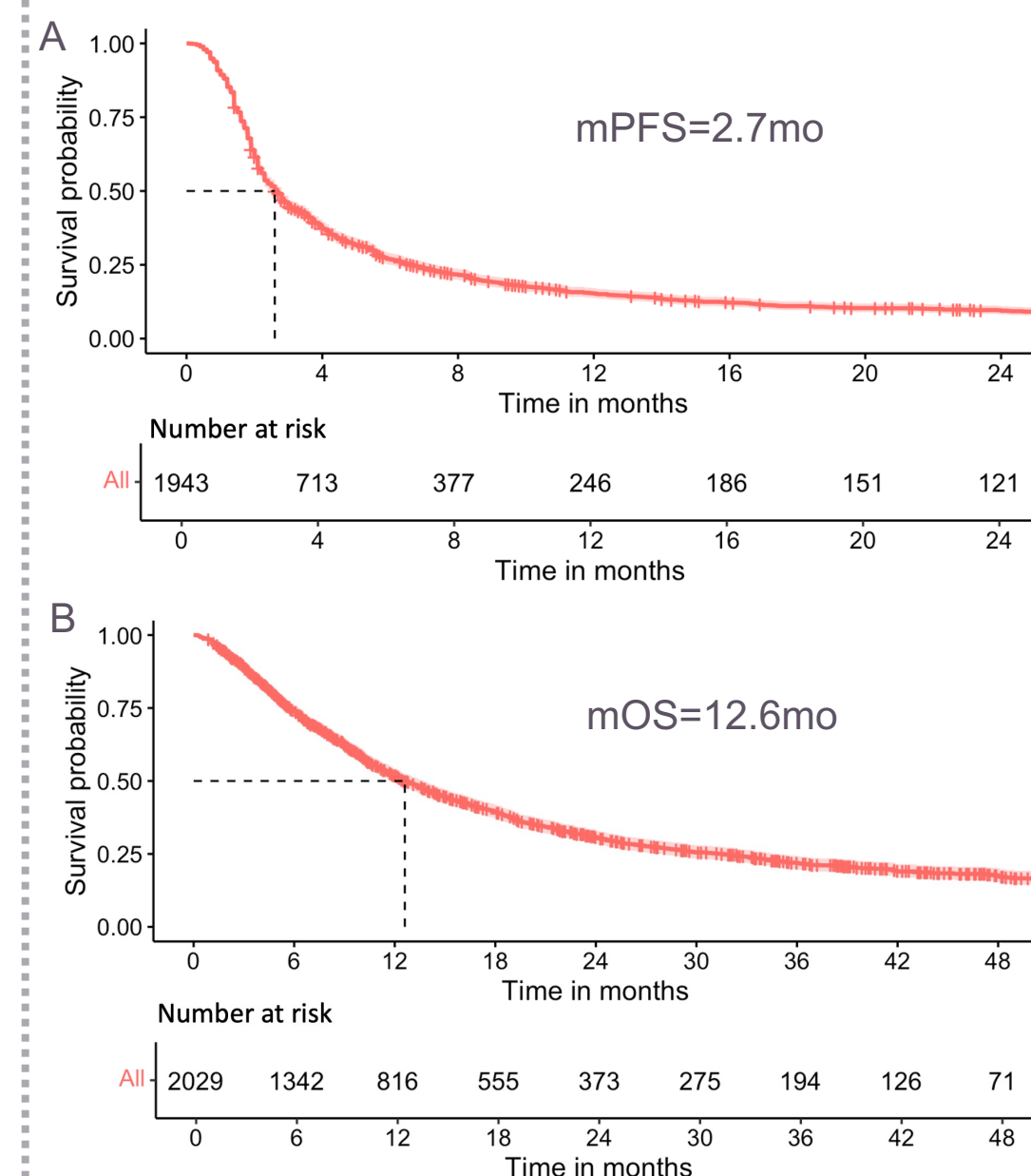


Fig 4: Kaplan Meier Progression-free (A) and Overall survival curves (B)

- EOT and death due to toxicity occurred in 74 (3.65%) and in 7 (0.34%) pts, respectively.

## CONCLUSION

As compared to historical data, our study shows that outcomes of patients included into modern phase 1 oncology trials have improved and that these trials constitute nowadays a valid and safe therapeutic option. These updated data provide facts for adapting the methodology, role and place of phase 1 trials over the next years.

## REFERENCES

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