P1.17.57 : Estimates of clinical endpoints in matched patients between the French Cancer Cohort (FCC) and durvalumab stage III NSCLC EAP

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INTRODUCTION

Early Access Programs are an opportunity to document first use of innovative treatments in real-world settings. Since 2021, French HTA body has recommended a linkage of EAP with NHDS, the French health claims database.

→ **OBJECTIVE**: to investigate if FCC, an NHDS extract of patients with cancer, can substitute a follow-up EAP study to estimate OS and treatment duration; and to evaluate if time to first subsequent therapy or death (TFST) can be used as a PFS proxy.

METHODS

Indirect deterministic linkage was performed between :

- French EAP follow up study of locally advanced unresectable NSCLC patients who initiated durvalumab between Oct.1 2017 and Dec. 31 2018, and treated up to 12 months (n=342)
- Patients from FCC who received durvalumab at time of EAP (n=666)

In FCC, clinical outcomes such as disease progression can only be approximated by reported healthcare consumptions. Systemic cancer treatments were considered for TFST.

All endpoints were calculated from first durvalumab administration date and up to last point contact for EAP, Nov.30 2020 for FCC. First and last administration dates were reported in EAP vs each injection in FCC.

RESULTS

Linkage

- 278 matched patients were included in analyses (linkage rate=81.4%).
- Discordances were limited in first and last durvalumab administration dates between EAP and FCC: in 51 patients (18.3%) for first date and in 35 patients (12.6%) for last date (median difference FCC-EAP: 47 [28;83] days and -1 [-28;14] day respectively).

Follow-up

- Median [IQR] EAP follow up was 747.5 [550;822] days vs. 812.5 [545;895] days in FCC.

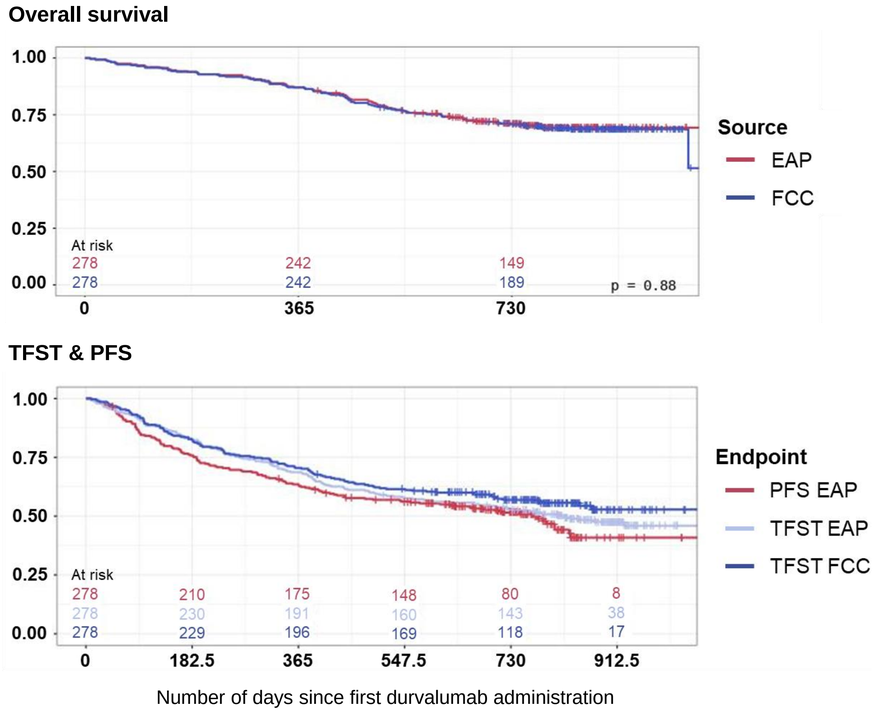
Table 1

	OS		PFS	TFST	
	EAP	FCC	EAP	EAP	FCC
N° events / N° patients	82 / 278	87* / 278	140 / 278	122 / 278	143 / 278
Rate 1 year (%) [95% CI] $	**87.1** [85.0-89.1]	**87.1** [85.0-89.1]	**63.2** [60.3-66.1]	**70.5** [67.8-73.2]	**68.7** [65.9-71.5]
Rate 2 years (%) [95% CI] $	**71.0** [68.3-73.8]	**70.8** [68.0-73.5]	**51.5** [48.4-54.6]	**56.9** [53.9-59.9]	**52.8** [49.8-55.8]

** : 5 additional deaths in FCC due to longer follow up*
$: +/- survival standard error

- **OS**: 81/82 deaths in EAP were reported in FCC with death date equal +/- 1 day in 75 (91.5%). OS 1-year (87.1% in both sources) and 2-years (71% and 70.8%) rates in EAP and FCC fully overlap (Table 1, Figure 1).
- **Treatment duration** was longer in EAP (median 328.5 [274;346] days vs 295 [242;323] days in FCC).
- **TFST & PFS**: Although TFST in FCC is close to PFS in EAP at 2 years (Table 1, Figure 1), TFST rates are not consistent between the 2 sources (+21 events in FCC).

Figure 1: Estimation of follow-up's endpoints and comparison between sources (EAP and FCC) in the 278 matched patients



DISCUSSION AND CONCLUSION

- **Estimates of OS are aligned** between the 2 sources and confirm the interest to use NHDS to document OS in a real-world setting.
- EAP **treatment duration** can be underestimated in FCC since free-of-charge treatment like compassionate use are not recorded.
- No evidence was found to use **TFST** in NHDS as a **PFS proxy**. Studies with longer follow up will be needed for this evaluation.

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