- The ALK Project -

A real-world national database and network

Fabio Gomes[1], K Yip[2], N Tokaca[3], A Greystoke[4], C Escriu[5], J Conibear[6], S Ghosh[7], G J Doherty[8], IG Funingana[8], T Ahmad[9], S Ahmed[10], A Cox[11], T Newsom-Davis[12], H Mills[12], R Shah[13], N Dorey[14], A Harle[15], G Dancey[16], S Baijal[17], T Geldart[18], Q Ghafoor[19], K Tarver[20], T Talbot[21], M Forster[22], L Cove-Smith1[1,23], R Califano[1,23], F Blackhall[1], S Popat[3] & Y Summers[1,23]

1- The Christie NHS FT; 2- Ipswich Hospital NHS FT; 3- The Royal Marsden NHS FT; 4 - Newcastle upon Tyne NHS FT; 5- Clatterbridge Cancer Centre NHS FT; 6- East and North Hertfordshire NHS FT; 7- Guy's and St Thomas' NHS FT; 8- Cambridge University Hospitals NHS FT; 9- Royal Free London NHS FT; 10- University Hospitals of Leicester NHS FT; 11- Royal United Hospitals Bath NHS FT; 12- Chelsea and Westminster Hospital NHS FT; 13- Maidstone and Tunbridge Wells NHS FT; 14- Royal Devon and Exeter NHS FT; 15- Dorset County Hospital NHS FT; 16- Southend University Hospital NHS FT; 17- Heart of England NHS FT; 18- Royal Bournemouth and Christchurch Hospitals NHS FT; 19- University Hospitals Birmingham NHS FT; 20- Barking, Havering and Redbridge University Hospitals NHS FT; 21- Royal Cornwall Hospitals NHS FT; 22- University College London Hospital NHS FT; 23- University Hospitals South Manchester NHS FT.

fabio.gomes@christie.nhs.uk

Introduction

- ALK+ NSCLC accounts for ~1,600 cases per year in England.
- The treatment landscape and prognosis of ALK+ patients has been revolutionised in recent years.
- The **ALK project** is establishing a national collaborative ALK network and database. Its aims are to analyse treatment patterns/outcomes, promote research and establish a collaborative network.

Methods and Materials

- As part of this active project and expanding network, we conducted a multicentre retrospective analysis across **23 active NHS trusts**.
- The **ALK+ UK Patient Group** has been supporting the expansion of this network.
- **Eligibility criteria:** ALK+ patients who were offered treatment until Sept/2018 with any of the 2nd and 3rd generation ALK inhibitors (ceritinib, alectinib, brigatinib and lorlatinib).
- Primary aim: overall survival (OS) from diagnosis of advanced/metastatic disease.
- Secondary aims: analyse treatment patterns, exposure times to each ALK inhibitor (surrogate of clinical benefit), objective response rate (ORR) and toxicity.

Results

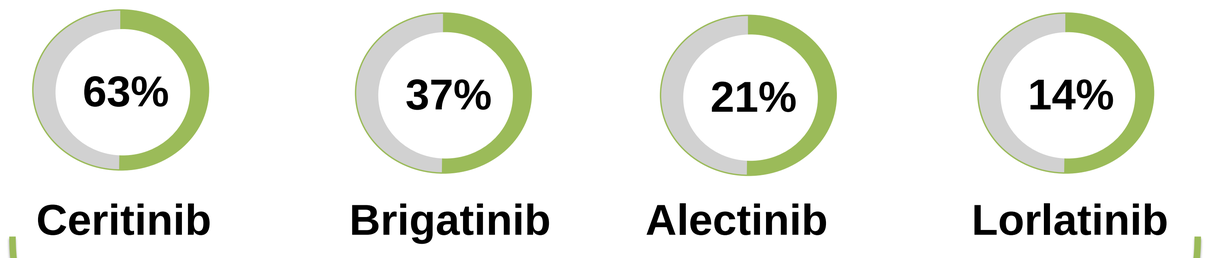
Demographics	n= 132
Age (median)	53y
Female	54%
Never smoker	69%
ECOG-PS 0-1 (at diagnosis)	89%
Advanced/metastatic disease (at diagnosis)	87%
Brain metastasis (at any point)	52%

Treatment patterns	
Chemotherapy (prior to ALK inh)	45%
Immunotherapy (at any point)	6%
ALK genomic re-testing (at any point)	10%
Average number of treatment lines	3

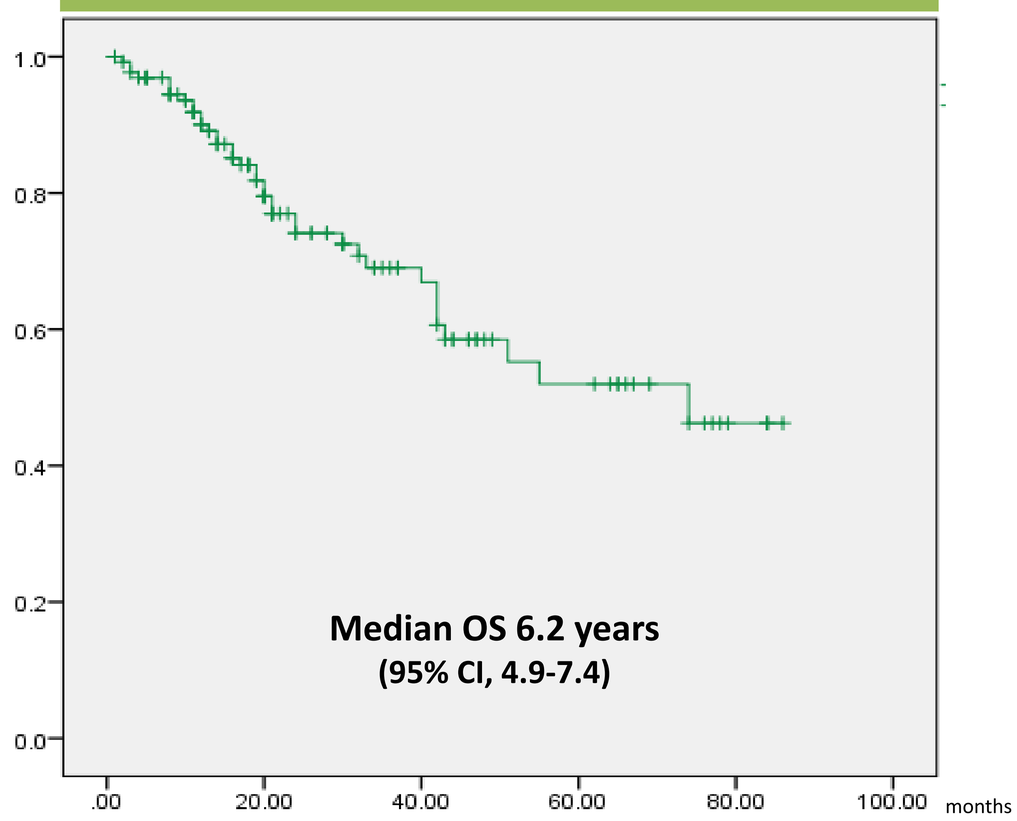
ALK inhibitors use per line, efficacy and toxicity

	1st line	2nd line	3rd line	≥4th line	Exposure months (95%CI)	ORR	Grade 3-4 tox
Ceritinib (%)	13	27	49	11	9 (5.1-12.9)	69	37
Brigatinib (%)	14	29	24	33	9 (3.1-14.9)	61	16
Alectinib (%)	43	25	7	25	NR	77	14
Lorlatinib (%)	11	0	6	83	NR	60	6

NR = not reached



Survival analysis (OS)



Conclusions

- **A nationwide collaboration is possible and should be promoted, particularly with rare cancer subtypes.**
- **The involvement of patient groups helps shaping projects' aims and identify further unmet needs.**
- **The remarkable survival of ALK+ patients mirrors the revolution in the treatment landscape.**
- **All efforts should be done to exclude ALK rearrangement, particularly in never smokers due to the significant prognostic implications.**