



Rob Jones

Chief Investigator

Early Phase Lead in Wales

Speciality Lead for Cancer in Wales

Reader and Consultant in Medical Oncology

Lesley Radley

Public Partner

FAKTION; A phase 1b/randomised placebo controlled phase II trial of Fulvestrant +/- (AKT inhibition) in patients with incurable breast cancer



NIHR/CRUK Combinations Alliance National Portfolio Investigator Led Trial

Cardiff University and Velindre Chief Investigator; Rob Jones
Coordinated by **Cardiff University Centre for Trials Research**
PPI Lesley Radley

Sponsored by Velindre NHS Trust, Cardiff

Circulating tumour DNA translational research being carried out on by Cardiff University Clinical Research Fellow in All Wales Genetics Laboratory

Data from this Trial accepted as an Oral presentation at ASCO June 2019 and being submitted to The Lancet Oncology for publication



FAKTION

SCOTLAND

NORTHERN
IRELAND

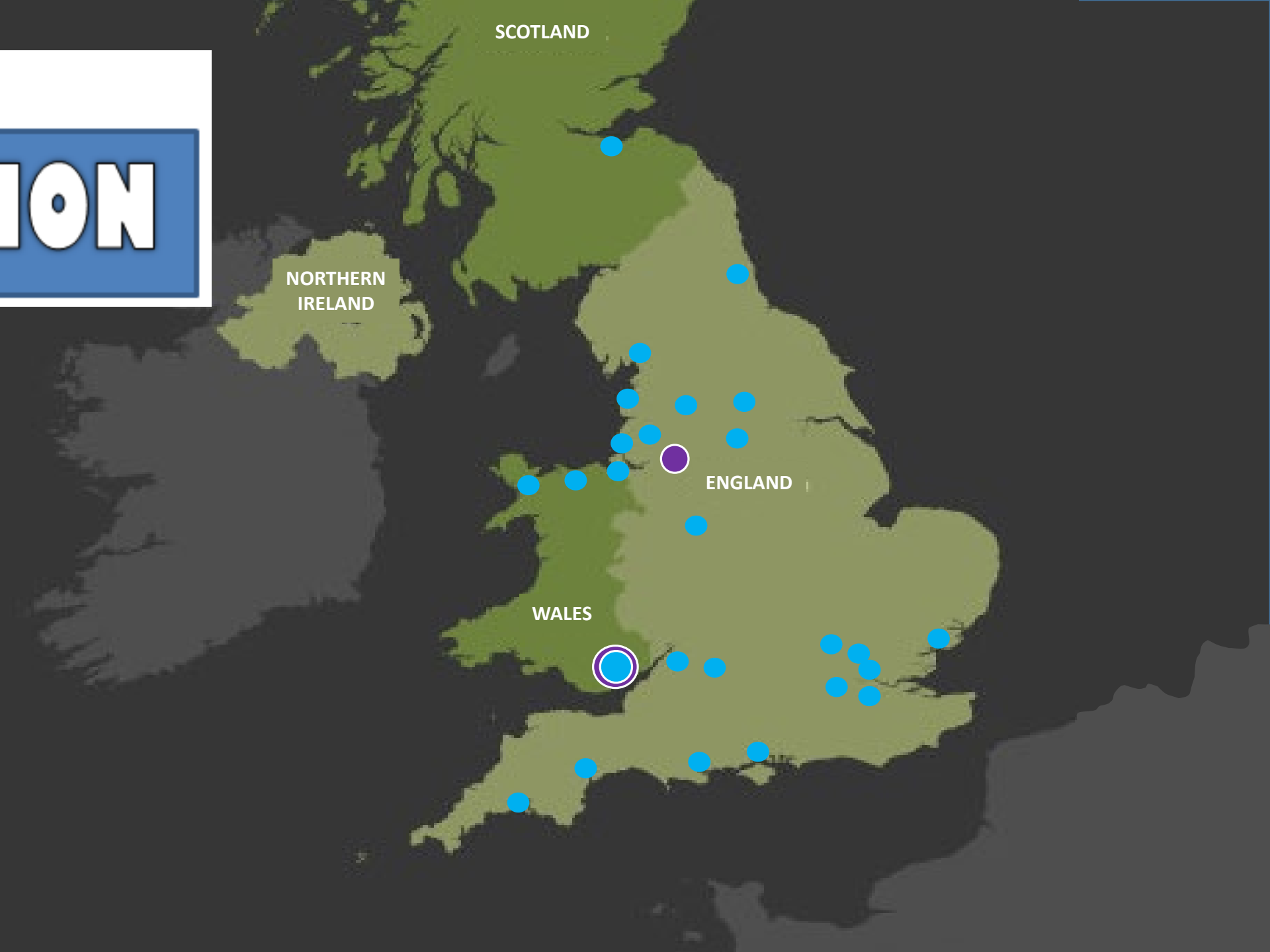
ENGLAND

WALES





FAKTION



SCOTLAND

NORTHERN
IRELAND

ENGLAND

WALES



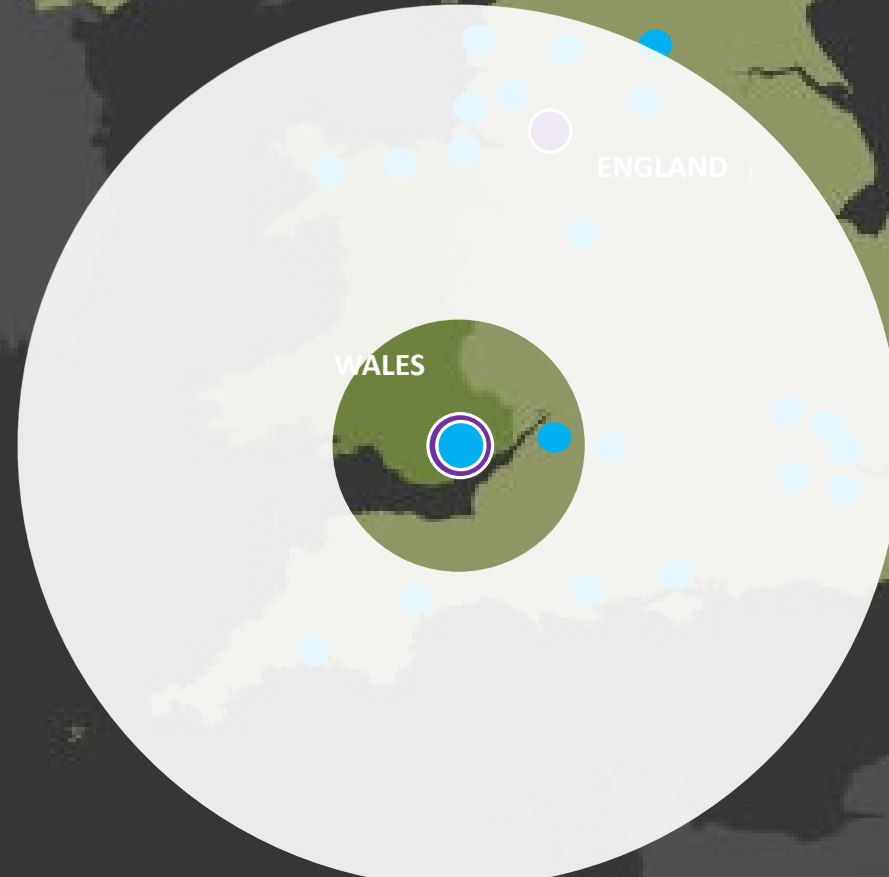
FAKTION

SCOTLAND

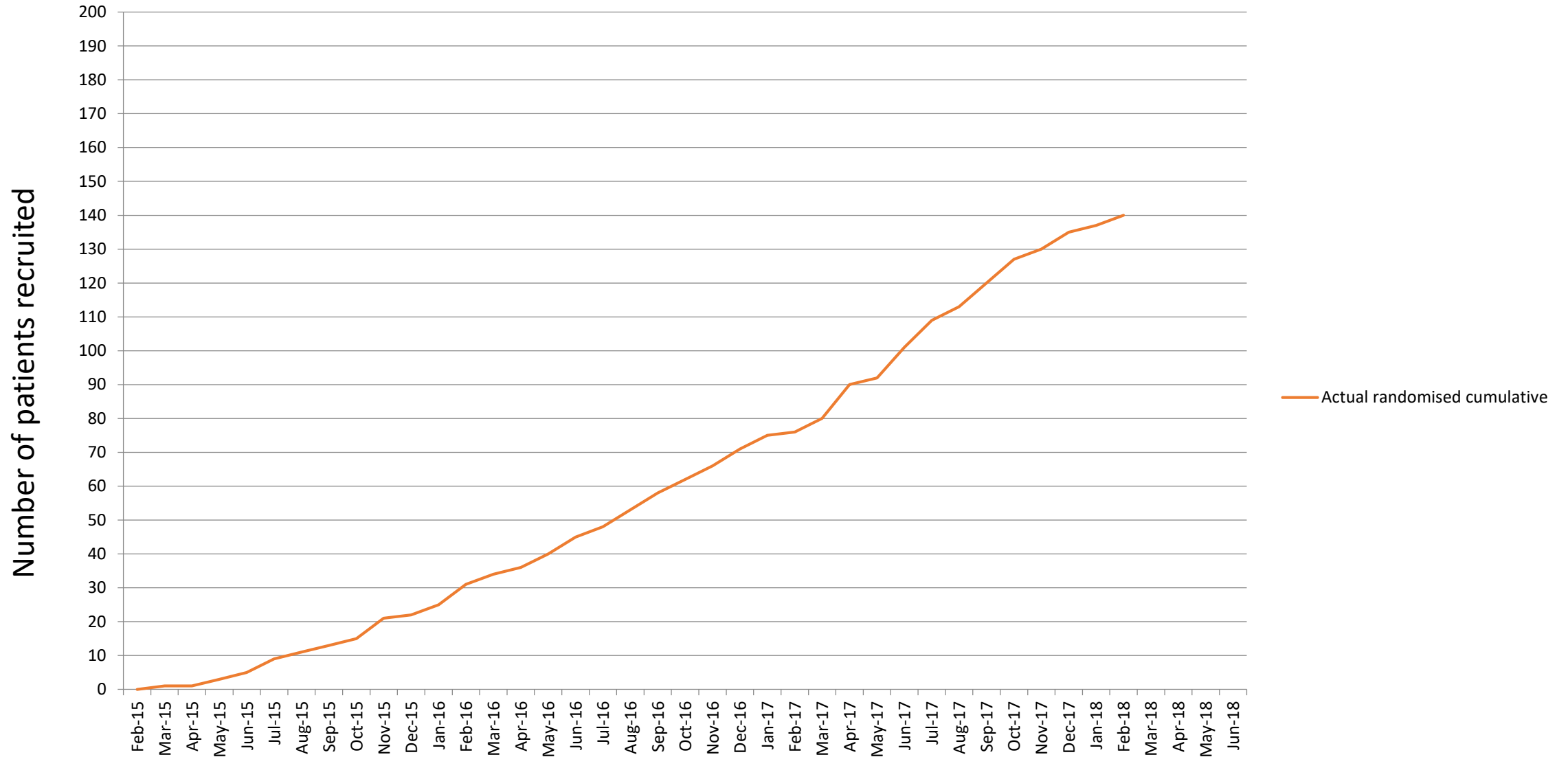
NORTHERN
IRELAND

ENGLAND

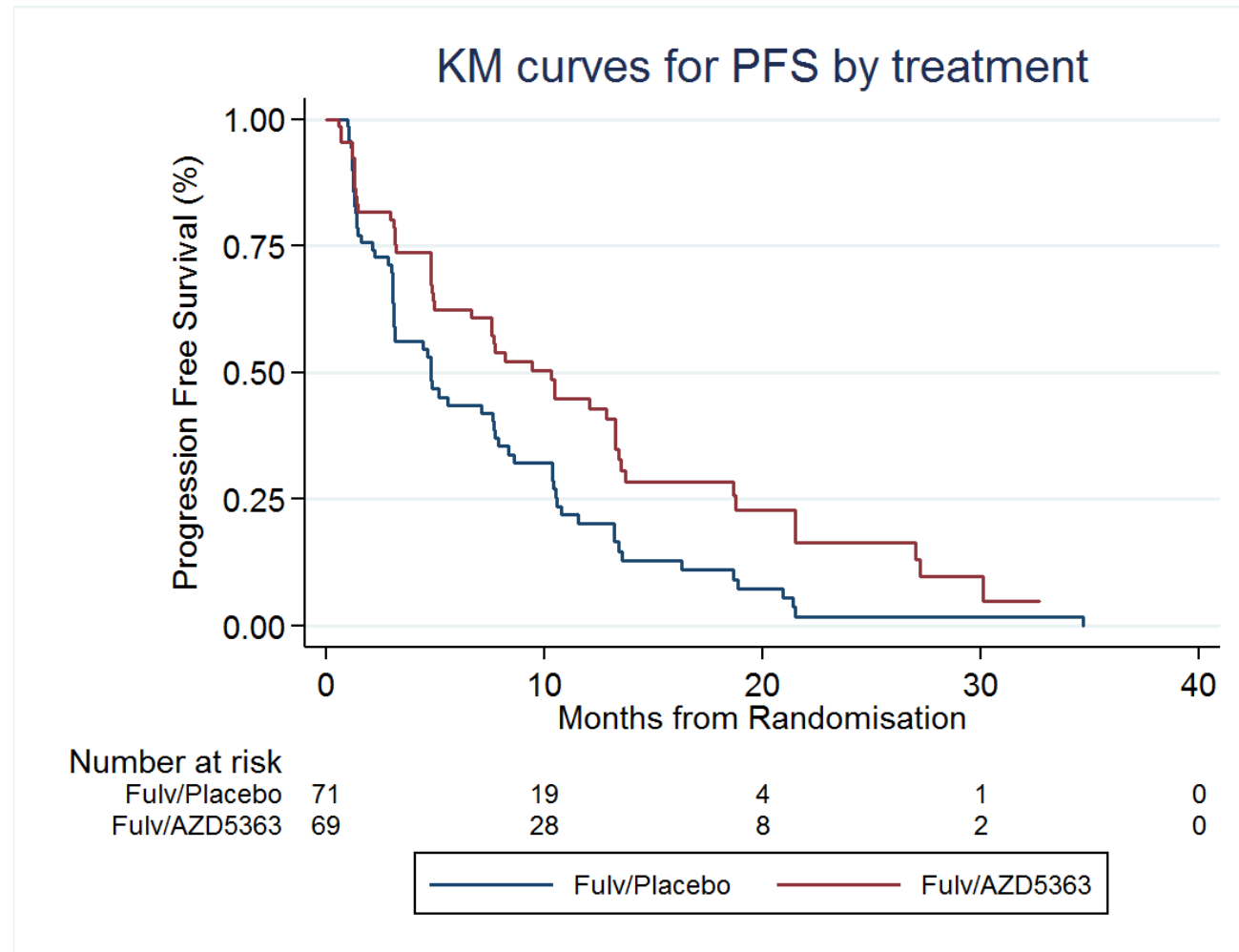
WALES



Recruitment into the Phase 2 part of FAKTION Trial took place for over 3 years (Phase 1b approximately 12 months)



FAKTION Trial; Progression Free Survival by Treatment



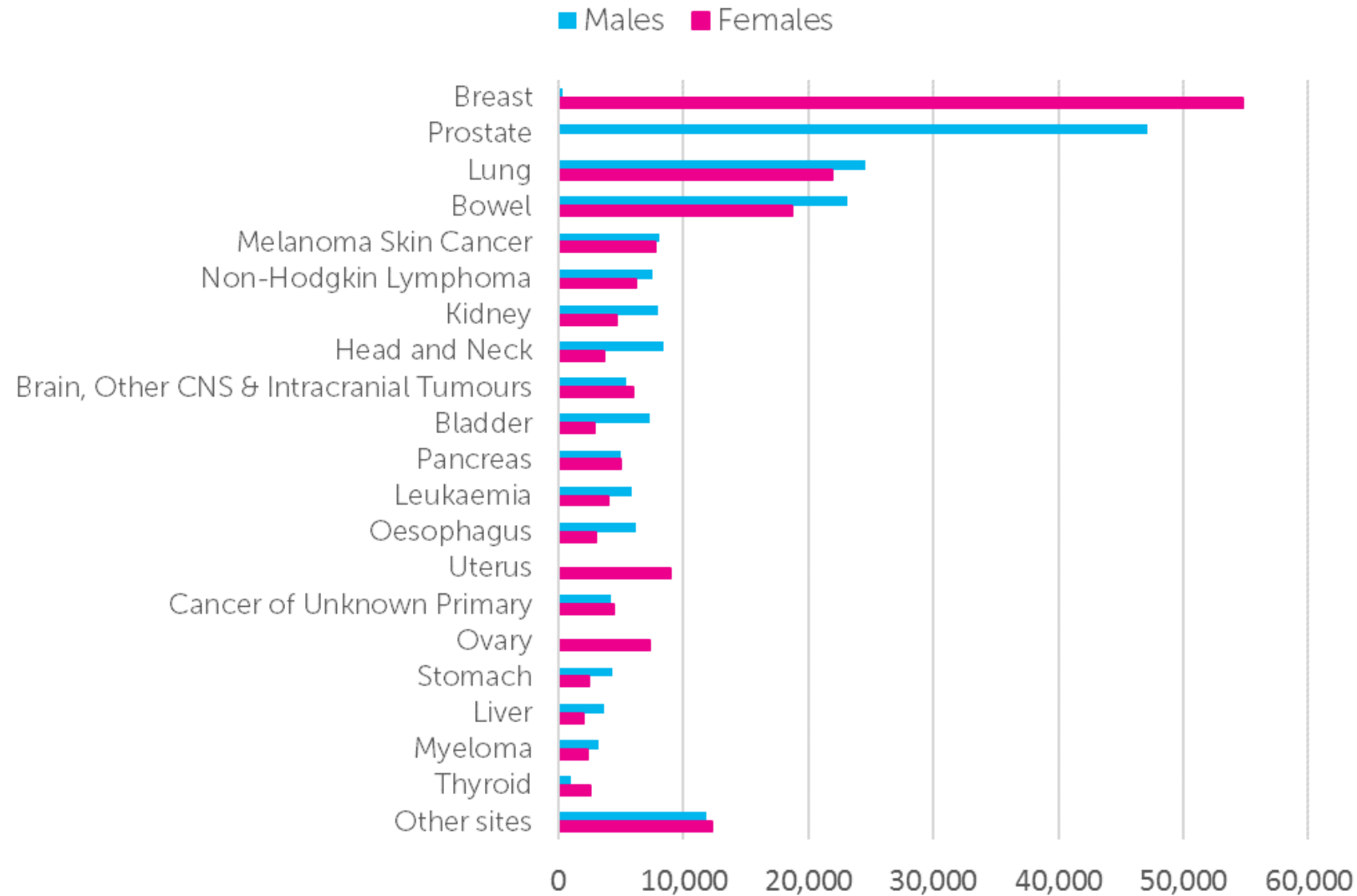
FAKTION outcome data

	Fulvestrant with Placebo	Fulvestrant with Capavasetrib
Response Rate % of patients who had a significant Shrinkage in their Cancer	12%	41%
Progression Free Survival Average time patients cancer was controlled on treatment	4.8 months	10.3 months
Overall Survival How long patients lived for	20 months	26 months

Comparison of PALOMA and FAKTION Trial data

	PALOMA (leading to Pablociclib becoming SOC)	FAKTION
Progression Free Survival advantage in Treatment group	Hazard Ratio 0.58 (24.8 vs 14.5)	Hazard Ratio 0.57 (10.32 vs 4.8)
Overall Survival advantage in Treatment group	6.9 months (34.9 VS 28)	6.02 months (26.02 vs 20)

Incidence of different Cancer types



FAKTION Summary

- FAKTION is a UK wide National Portfolio trial led from Cardiff
- The results are high impact (Oral Presentation ASCO 2019 and manuscript in being submitted to The Lancet Oncology)
- One of first trials to have significant PPI involvement
- Protocol currently in development with AZ to confirm findings of Phase 2 with an international Phase 3
- Could lead to a change in the SOC for tens of millions of Breast Cancer patients