

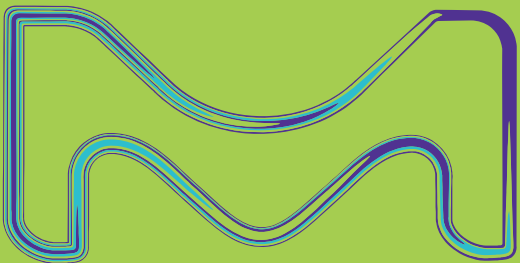


MERCK case study

Shaping Evolving Clinical Data into Fast Patient Access and Changing Standard of Care in Australia

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MERCK

Precision Medicine: Public and Private Partnerships?

<https://www.omico.com.au/about-us/our-network-partners/>

Together, cancer meets its match

Omico is a government-backed national network of leading researchers, clinicians and industry partners that's using precision medicine to unlock new potential in Australian research and turn the tide on cancer. With fast-tracked molecular screening, biomarker-led trial set up and patient enrolment from the entire nation we're accelerating access to next-generation treatments and preventive strategies, improving outcomes for all Australians affected by cancer.



Precision Medicine: Affording the success of science Omico CEO Prof David Thomas

<https://www.nature.com/articles/s41698-022-00343-y>

ASPIRATION

An observational and interventional cohort study to assess the clinical impact of comprehensive genomic profiling (CGP) in patients with non-squamous advanced/metastatic NSCLC

A collaboration between:



With support from:



8th Australian Lung Cancer Conference
Melbourne Convention and Exhibition Centre
19 - 21 February 2020

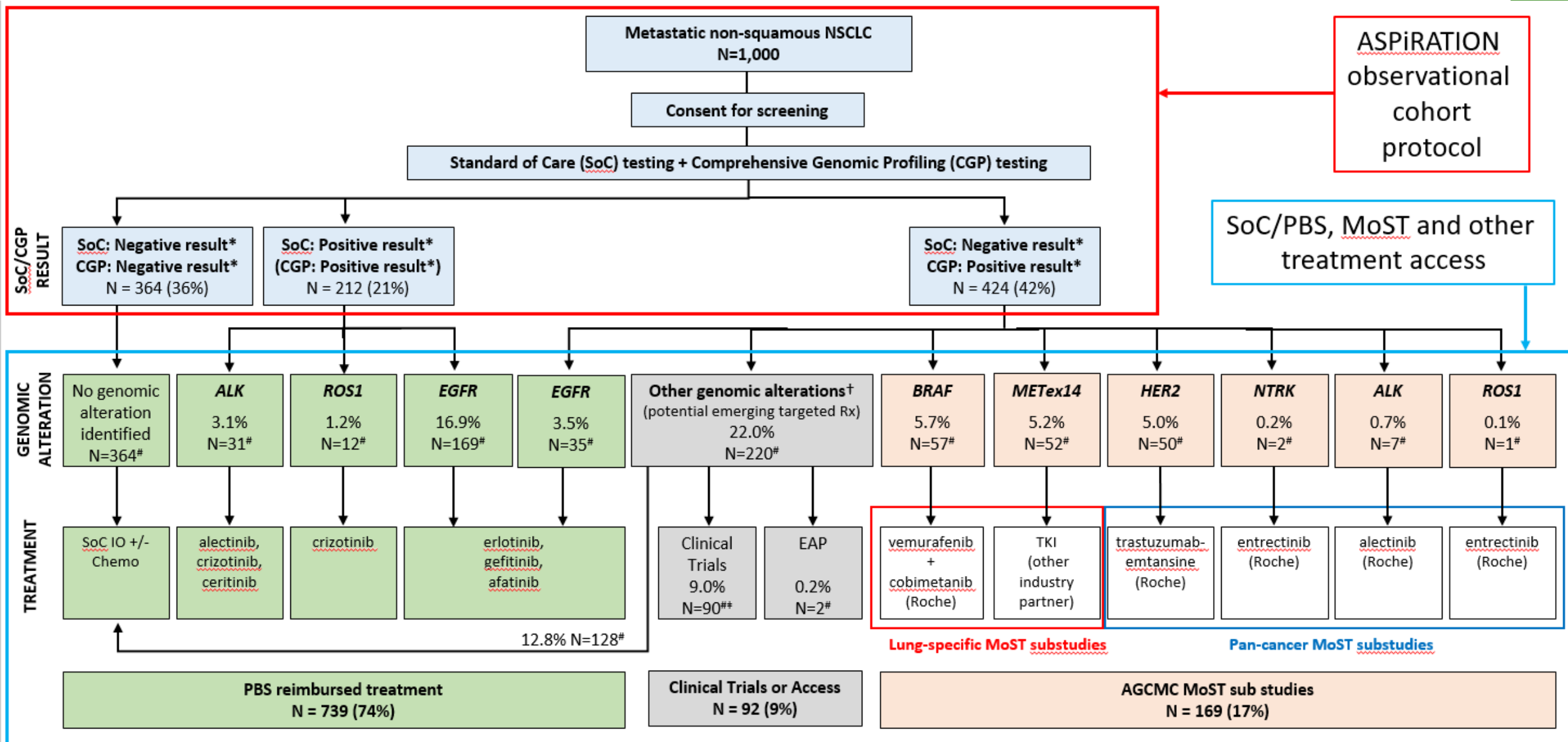


In collaboration with:



A time of *hope* in lung cancer





Abbreviations: EAP=Expanded Access Program; IO=immunotherapy (pembrolizumab, nivolumab, atezolizumab); N=number of patients; TKI=Tyrosine Kinase Inhibitor

References: Alteration rates and patient estimates based on Lin 2019, Schrock 2016, Singal 2019, Solomon 2019, Kris 2014 (See Attachment for full reference list and calculations). Clinical trial participation rates CINSW 2018 (<https://www.cancer.nsw.gov.au/>). EAP patient estimate is uncertain and reliant on availability of such programs from other sponsors.

Notes: * Positive result: actionable genomic alteration identified, Negative result: no actionable genomic alteration identified; # Estimated;

† Other genomic alterations with potential emerging targeted treatments, e.g. RET, KRAS; ‡ Patients eligible for PBS reimbursed treatment may participate in a clinical trial

ASPiRATION Trial

AN OBSERVATIONAL COHORT STUDY TO ASSESS THE CLINICAL IMPACT OF COMPREHENSIVE GENOMIC PROFILING IN METASTATIC LUNG CANCER PATIENTS

THE ASPIRATION PROGRAM IS A PIONEERING PARTNERSHIP BETWEEN GOVERNMENT, INDUSTRY AND ACADEMIA.



THE ASPIRATION STUDY IS THE FIRST OF ITS KIND IN AUSTRALIA TO GENERATE HIGH-QUALITY, REAL-WORLD DATA ABOUT THE IMPACT AND VALUE OF COMPREHENSIVE GENOMIC PROFILING IN DELIVERING PRECISION MEDICINE & PERSONALISED HEALTHCARE. IDENTIFYING ACTIONABLE MOLECULAR TARGETS THROUGH CGP PROVIDES PATIENTS WITH OPPORTUNITIES TO RECEIVE NOVEL TARGETED TREATMENTS VIA THERAPEUTIC SUBSTUDIES

AS OF APRIL 2023
898/1000
PATIENTS HAVE BEEN
RECRUITED



8 / 16 PATIENTS HAVE
BEEN RECRUITED INTO
THE TEPOTINIB
SUBGROUP



Stephanie Gasking
MSL Oncology
Merck Healthcare ANZ

<https://ctc.usyd.edu.au/our-research/research-areas/cancer/cancer-divisions/thoracic-cancers/open-trials/aspiration/>

Prof Nick Pavlakis, Royal North Shore Hospital, Sydney

Prof Ben Solomon, Peter MacCallum Cancer Centre, Melbourne



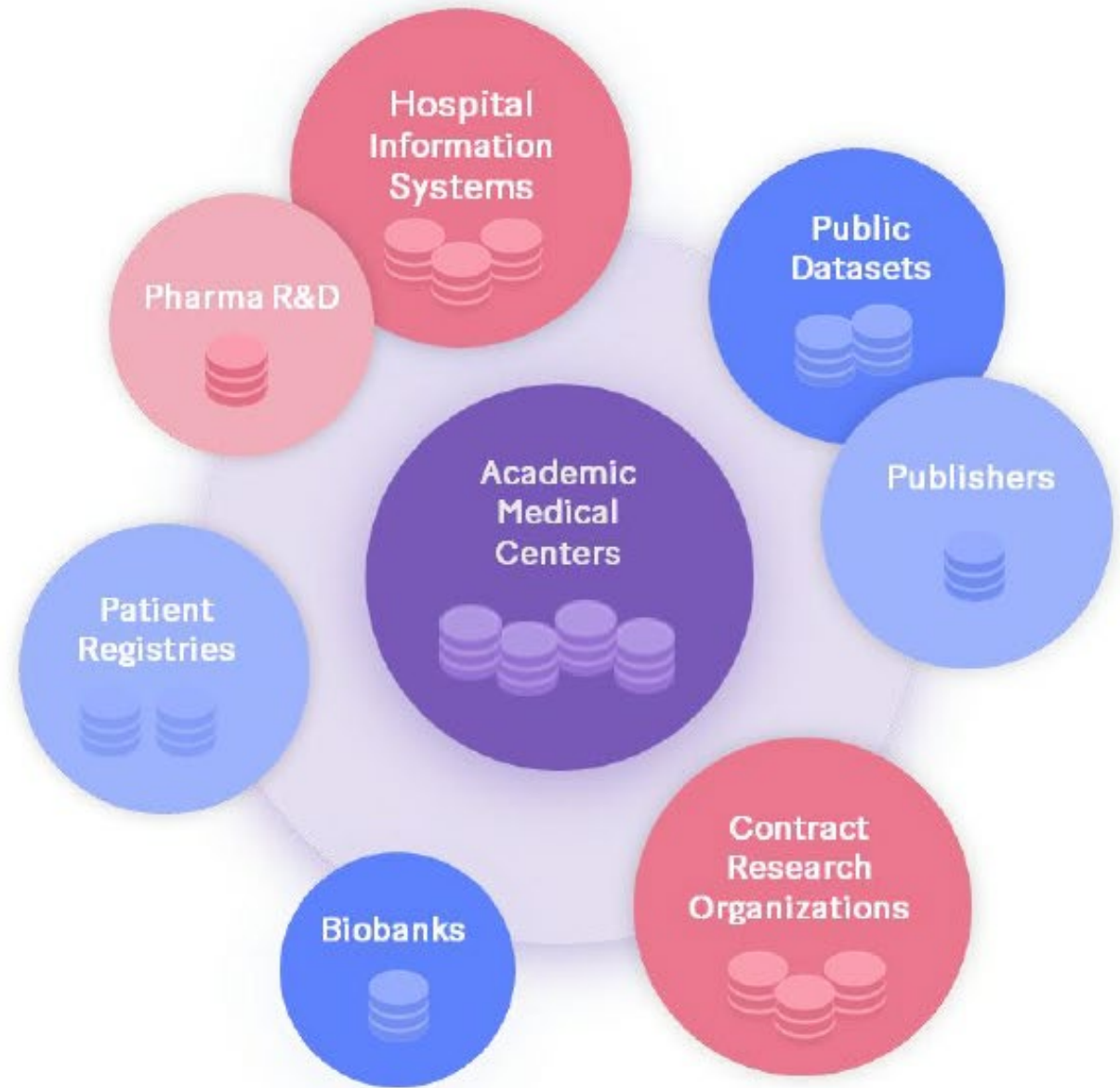
Precision Medicine: Tepmetko® (tepotinib)

How did Merck optimize fast patient access in Australia?

- NSCLC with MET alterations: Rare Disease with ODD status, oral once daily therapy
- Considered expedited evaluation via Project Orbis pathways
- FDA, Health Canada, Swissmedic and TGA reviewed phase II submission data n=152
- Each regulator made independent evaluation decisions
- KTL, PAG, HCP professional bodies engagement, Commercial Eyes as consultants
- Speed with sequential & parallel evaluation: 91 days, fastest approval in 2022 of ANY non covid medicine
- TGA Regulatory: Line agnostic label
- MSAC Diagnostic: Agnostic NGS platform
- AMNOG equivalent ie PBAC public reimbursement: First time approval Oct 2022
- Full registration is next...



Biomedical data is siloed across the healthcare ecosystem



Enterprise Data: The way forward?

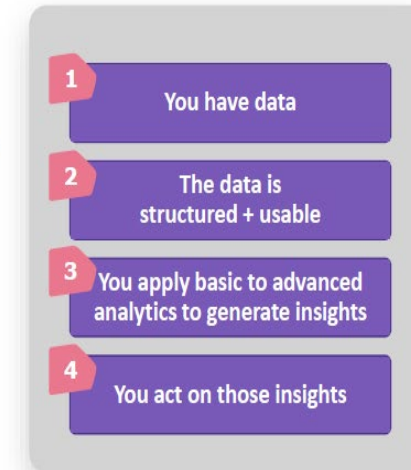
<https://syntropy.com/> A Merck Palantir Joint Venture

WHY HEALTHCARE DATA IS DIFFICULT



 Unlocking the value from your data

The boring part ←



→ The exciting part

Turning Data into Knowledge Faster

<https://www.darmstaedterheinerfest.de/>
29 Juni – 3 Juli



<https://blog.palantir.com/four-ways-healthcare-startups-use-palantir-foundry-180b5f3ef943>

<https://www.merckgroup.com/de/research/science-space/envisioning-tomorrow/future-of-scientific-work/bigdata.html>

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