

Australian
**Genomic
Cancer
Medicine**



Precision Oncology:
The Australian Genomic Cancer Medicine Centre

AGCMC's platform enables Precision Oncology

- AGCMC offers a molecular signal-seeking “live” drug development platform
- Master protocol of novel “basket” clinical trial design
- Identification of new targets and populations via high-throughput live matching of patients to cognate drugs
- Accelerated protocol development and trial completion
- World-class biospecimen-rich correlative science

Drug development Trials

- Molecular Screening
- Basket Trial Protocol Design
- Pre Phase 2 Trials
- Registrational Trials

Data Collection

Germline Trial and Data
Real world evidence
Correlative science

Government Policy Innovation

Pan Cancer Trial Design
Trial completion
Patient Advocacy

Medical education

Immersion in Precision
Oncology Program
Fellowships

AGCMC is a risk sharing collaboration between industry, cancer research and government

Australian Genomic Cancer Medicine



- Patient centred national eco-system supported by state and federal governments
- 8 Academic Centres of Excellence & 3 medical research centres across Australia
- Focus is rare, less common, early-onset and poor outcomes cancers

Academia



Canberra Hospital



**Royal Adelaide
Hospital**

**Royal Darwin
Hospital**

**Royal Hobart
Hospital**

Princess Alexandra Hospital

Government and Societies



Australian Government

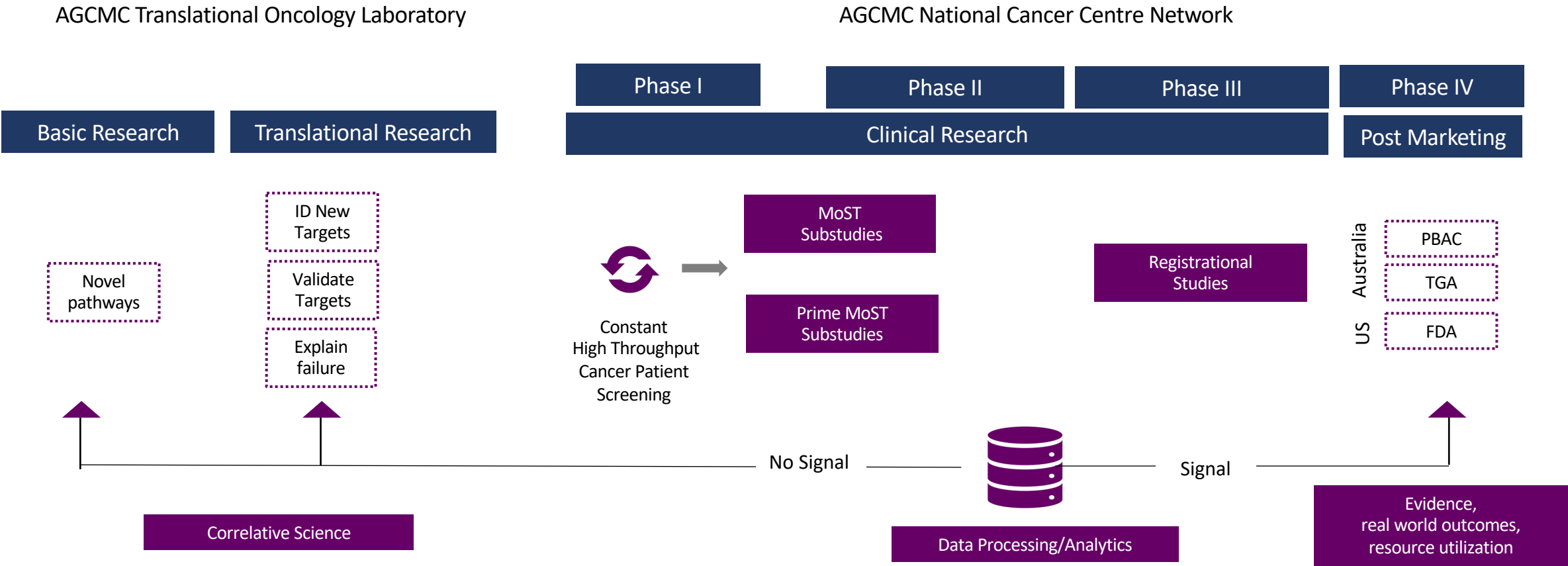


80 Organizations across Australia

AGCMC is a “one stop shop” platform that collaborates with all stakeholders in precision oncology from research to patients

Value proposition for each Cancer Stakeholder	Government	<ol style="list-style-type: none"> 1. Screen and treat Australians with rare cancer 2. Support policy in screening & treatment of cancer
	Industry	<ol style="list-style-type: none"> 1. Rapid molecular signal seeking drug dev platform 2. Rich correlative science to inform pipeline planning
	Precision Oncology Cos	<ol style="list-style-type: none"> 1. Consolidated access to experts, capabilities, data & patients 2. End to end beta platform in precision oncology
	Patient Advocacy	<ol style="list-style-type: none"> 1. Access to screening & treatment for Australians 2. Informing policy to improve cancer care
	Corporate Sponsors	National program that addresses a significant unmet need for Australians with rare cancer

Platform capability extends beyond research to inform discovery, expedite drug development & support approvals



MoST study is a “live” Precision Medicine Platform for biomarker driven signal seeking clinical studies

Study Rationale

Expedite testing of novel therapeutics with platform that is constantly screening patients

Progress to date in POC

- N= 1200+ Screened
- 509/806 recommended treatment
- 8 Studies
- 9 Compounds studies

Details

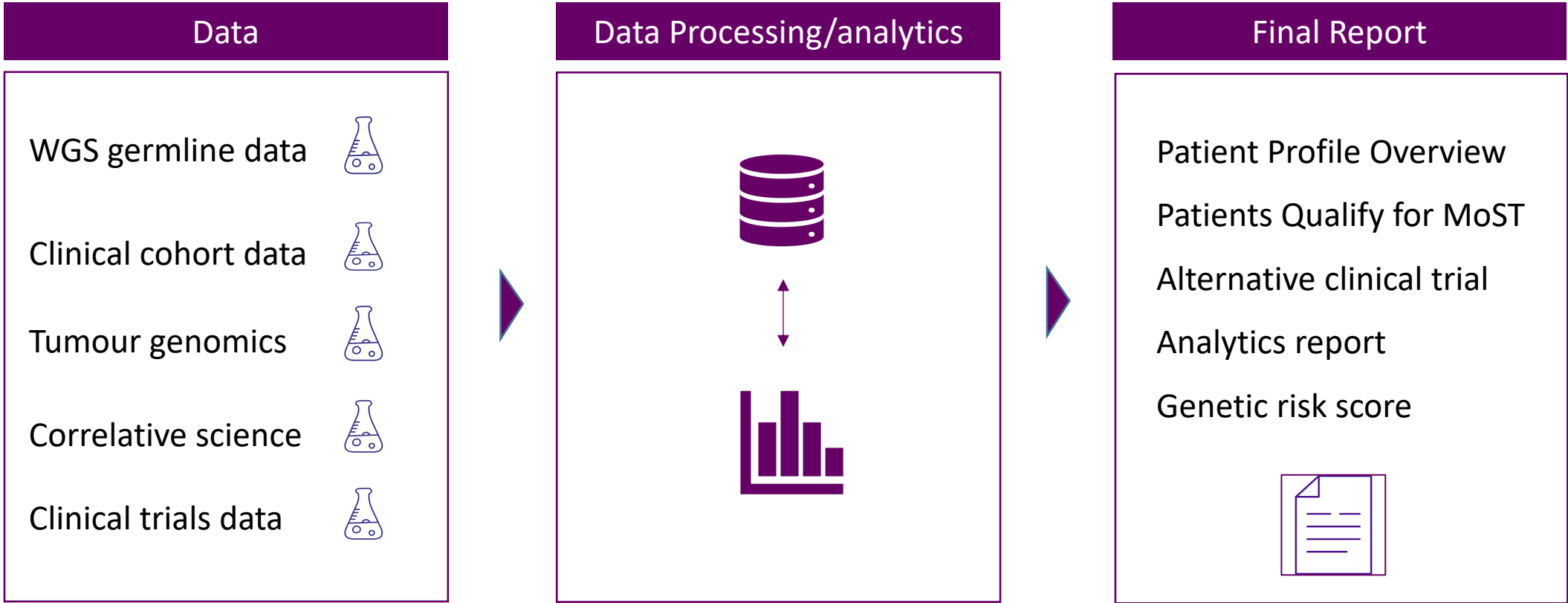
- 80% Rare Cancers
- Includes common cancers
- Leverages Master Protocol
- Multiple studies running on platform
- Combination studies

Study Summary

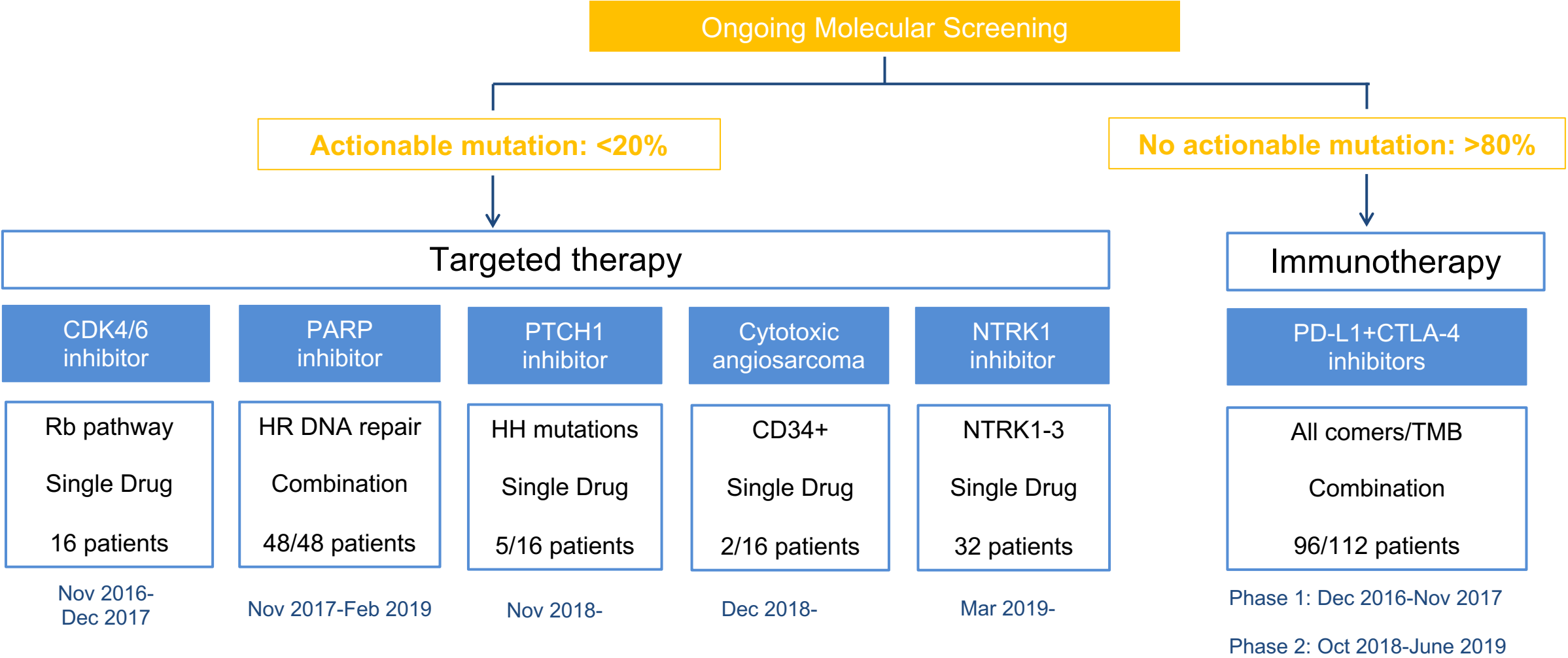
- Objective: Identify potential signals of activity for novel therapeutics
- Population is patients with confirmed advanced or metastatic solid cancer, failed other therapies
- Screening for molecular features
- Various panels tested
- Tests broad range of therapeutics to increase number of patients treated
- Target N= 3000 + screened

AGCMC Data enables basic research and translational research

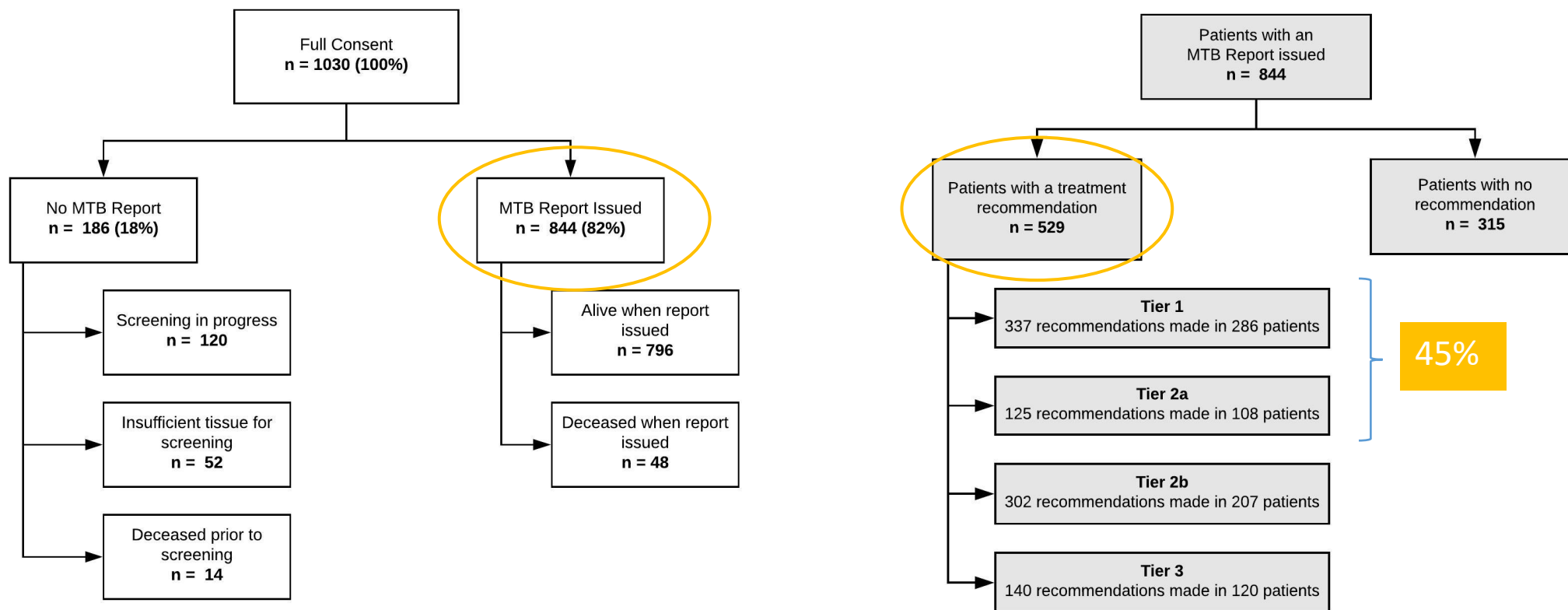
- Biospecimen-rich correlative science driving drug development
- National capacity for ‘real world’ registries to support regulatory approval



MoST launched in 2016 as a POC at one academic centre then scaled to a national Australian Precision Oncology Platform

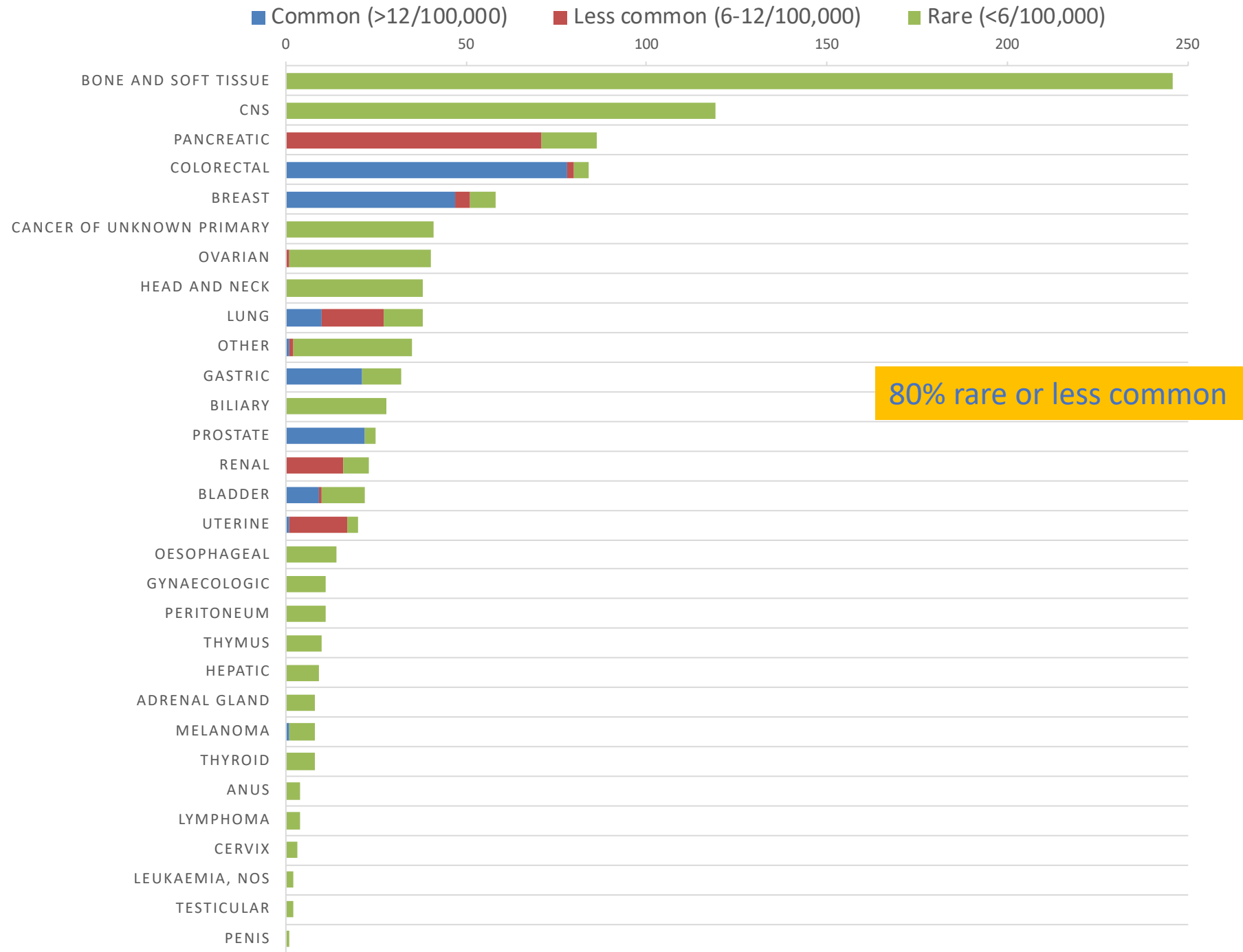


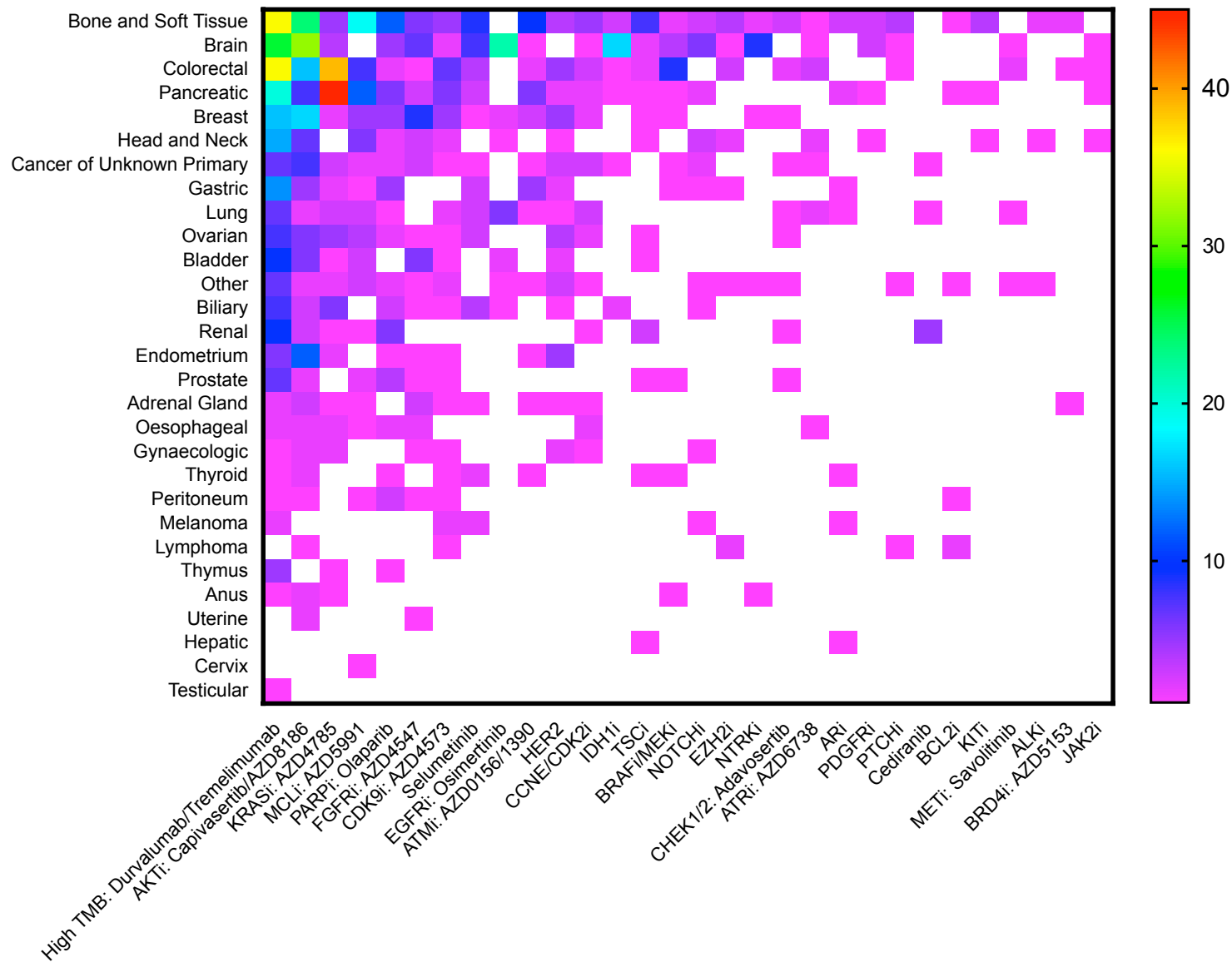
MoST progress in first 2 years



FFPE-based panel systems under evaluation:

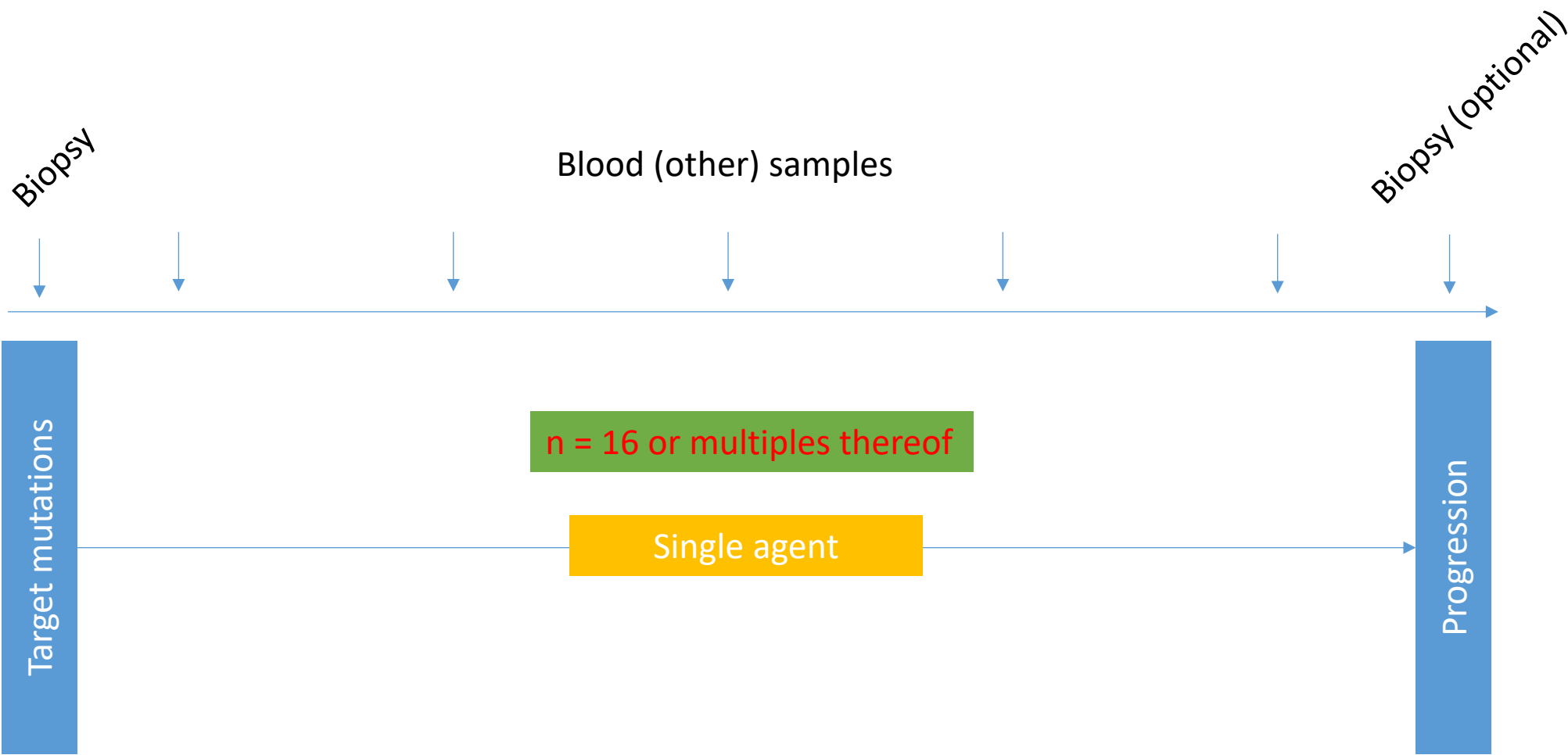
- In-house
- TST170
- Oncomine



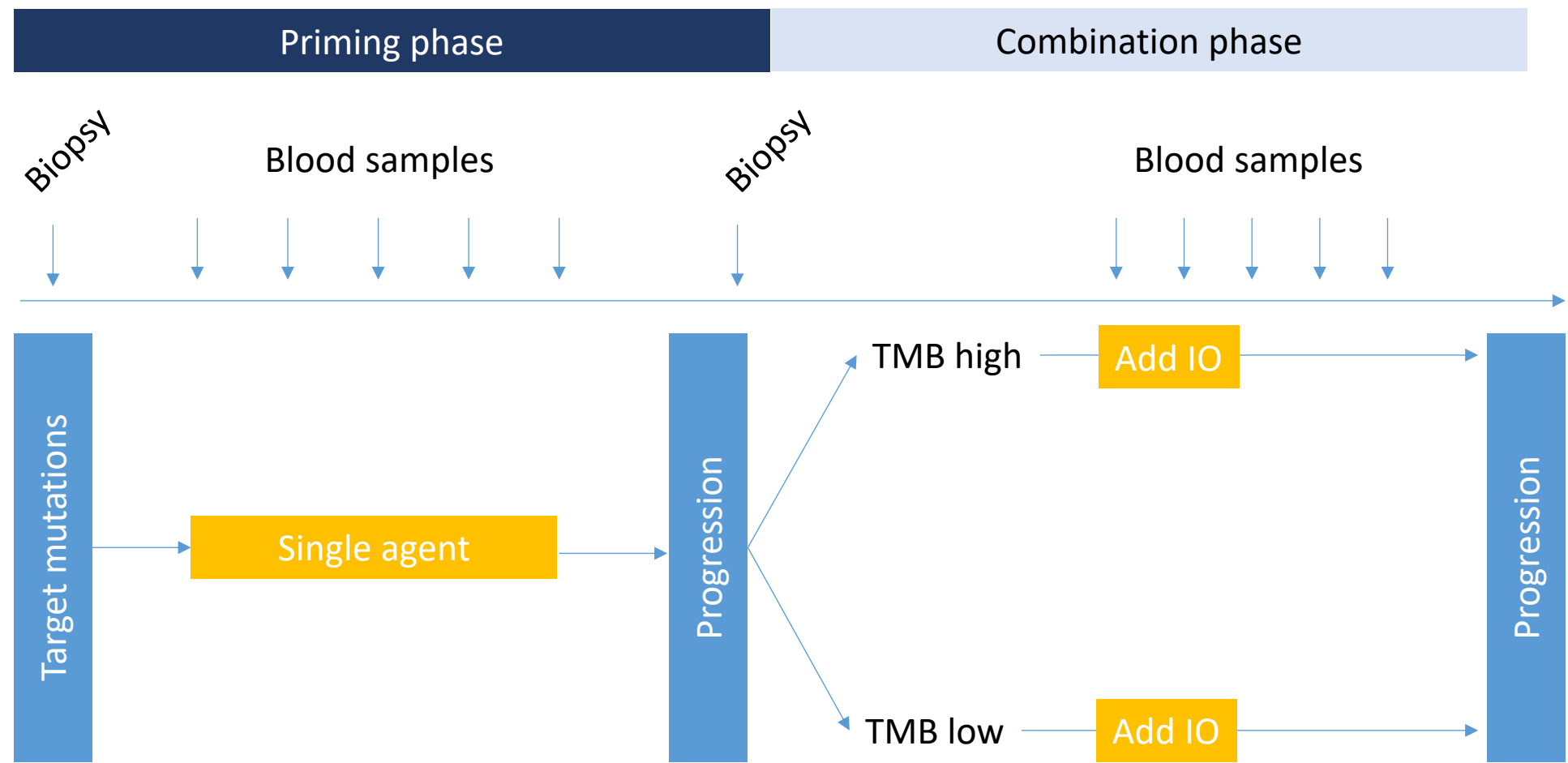




MoST design



Prime-MoST is a novel trial design for combination drug development and will launch via the platform in 2020



TRANSLATIONAL ONCOLOGY LAB

- Biospecimen processing and handling
- Genomics
 - DNA/RNAseq
 - TCR/BCR clonotyping
 - Long-read capacity
 - Bioinformatics
 - Microbiomics
- Proteomics
 - PCT-SWATH mass spectroscopy
- Cell-based assays

Summary of services provided leveraging national ecosystem of cancer research centres, clinics and labs

Services	End Users
Clinical Trials Ph 1 & 2 <i>(Protocol Design & Dev, Monitoring, Safety)</i>	<ul style="list-style-type: none"> • Industry • Government • Medical Community (Referrals) • Patient Organizations (Referrals)
Registrational Trials	<ul style="list-style-type: none"> • Industry • Medical Community (Referrals) • Patient Organizations (Referrals)
Translational Research	<ul style="list-style-type: none"> • Industry
Basic Research	<ul style="list-style-type: none"> • Industry
Real World Data	<ul style="list-style-type: none"> • Industry • Government
Data Processing/Analytics	<ul style="list-style-type: none"> • 3rd Party Precision Onc Co • Industry
Policy Support	<ul style="list-style-type: none"> • Industry • Government • Patient Organization
Education/Thought Leadership	<ul style="list-style-type: none"> • Industry • Medical Community

AGCMC expansion includes adding more molecules, registrational trials, and policy support

Objective	Signal Seeking	Registration Trials	PBAC/Managed Access
Key Activity	<ul style="list-style-type: none"> Repurposed drugs New compounds New combinations 	<ul style="list-style-type: none"> Pan Cancer Registrational Trials 	<ul style="list-style-type: none"> Build use case Support with data/analytics KOL support/Pt Advocacy
Target Outcomes	<ul style="list-style-type: none"> New Targets Novel trial designs Correlative Science 	<ul style="list-style-type: none"> Novel Therapeutic Indications 	<ul style="list-style-type: none"> Expedited approval process Contextual Data Package Confirmed for Rapid Access
3-5 Year Horizon	Scale Platform to Asia: <ul style="list-style-type: none"> China Korea Singapore 	<ul style="list-style-type: none"> FDA Registration 	Upgrade data package: <ul style="list-style-type: none"> China Support reimbursement US

Data Collection/Correlative Science →

Publications →

CapTCR seq for hybrid capture TCR repertoire profiling

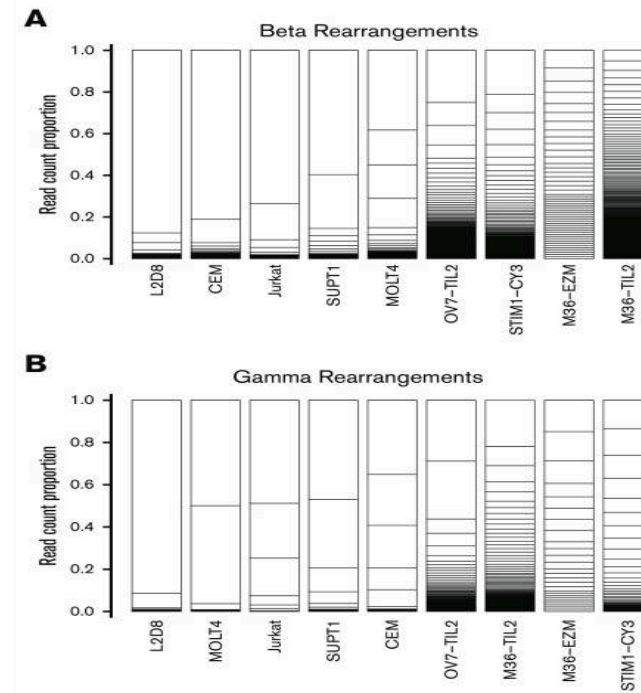
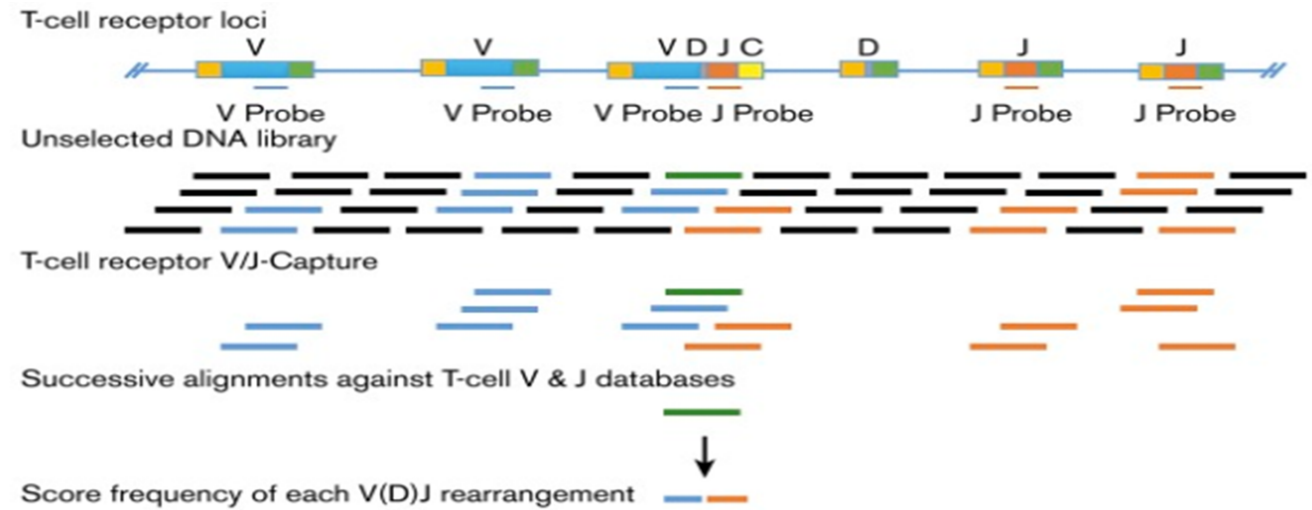
Identification of clonal population of T-cells that possess common rearrangements T-cell receptor

Method developed by Prof Trevor Pugh, Blood Advances 2018, Dec 11: 2(23) 3506

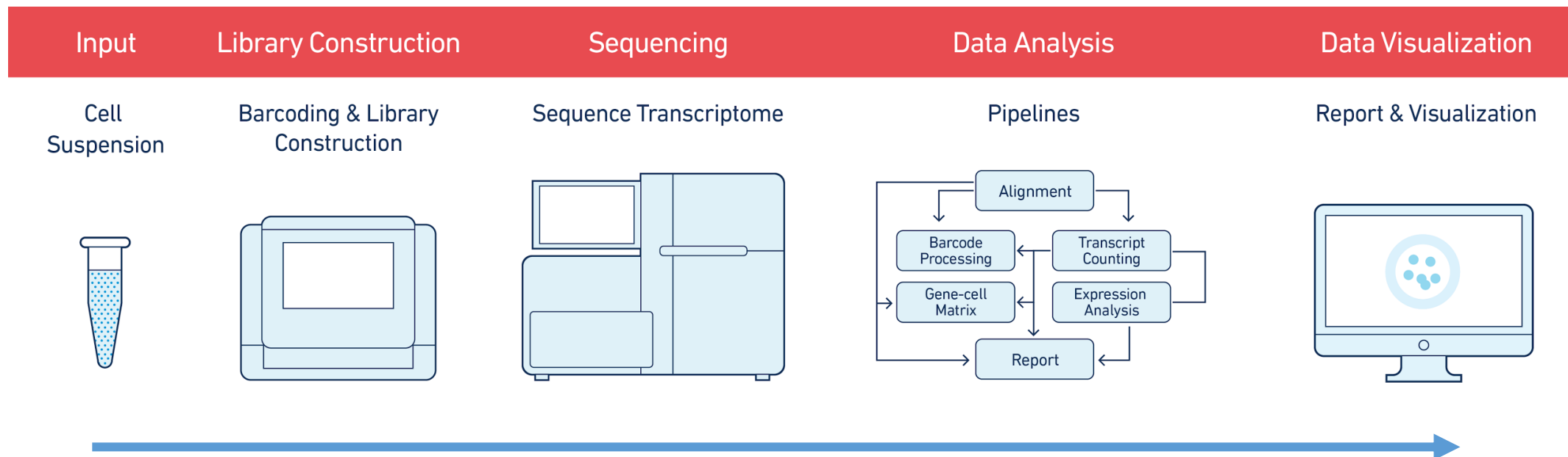
Investigate baseline PBMCs, baseline tumor and 4 week post Tx PBMCs

A recent study shows that peripheral blood TCR repertoire may facilitate patient stratification for ICB in melanoma, Hogan, SA et al Cancer Immunology Res, 2018.

Sequencing has been done, analysis underway



Established process for generating single cell sequence data



We have currently sequence on average 150,000 cells per week

We have capacity to generate data for 50 patient samples per week, although this can be easily increased with additional staffing