IMMUNO-ONCOLOGY SERVICES

• PK • Immunogenicity • PD • Biomarkers

AGILEX BIOLABS

Why Agilex Biolabs?

Unparalleled Experience
>150 years of combined experience in early phase research.

Data Integrity and Quality Assurance
Our FDA-inspected facilities have OECD GLP recognition and ISO 17025 Accreditation with NATA. Highest quality data acceptable to all regulatory agencies.

Timeliness and Speed
Fast turnaround for Single Ascending Dose (SAD) and Multiple Ascending Dose (MAD) studies.

43.5% R&D Tax Incentive
Eligible biotechs can receive a 43.5% cash refund of Australian R&D expenses.

What is Immuno-Oncology?

Immuno-Oncology (IO) is the study and development of novel treatments which harness the power of the immune system to fight cancer. The tumour microenvironment in cancers comprises a complex cellular network, consisting of an array of malignant, stromal and immune cells.

With an unprecedented rise in the number of new investigational agents and companies in the immuno-oncology field, the demand for specialised pharmacokinetic (PK), highly sensitive and drug tolerant immunogenicity (ADA) assays and targeted pharmacodynamic assays to identify target engagement and mode of action has increased exponentially in recent years.

Over the past year alone, there has been a global increase in T-cell targeted immunomodulator and cancer cell therapies (as shown in figures below). Developing such therapies requires highly specialised assays and a bioanalytical partner with a depth of expertise, experience and leading-edge equipment.

What Agilex Biolabs offers?

- extensive experience in PD-1, PD-L1, CTLA4, IL-17 monotherapies for oncology and immuno-oncology applications, including T-cell targeted immunomodulator therapies.
- PD1-CD47, PD1-VEGF or other bispecific antibody therapies and biosimilars.

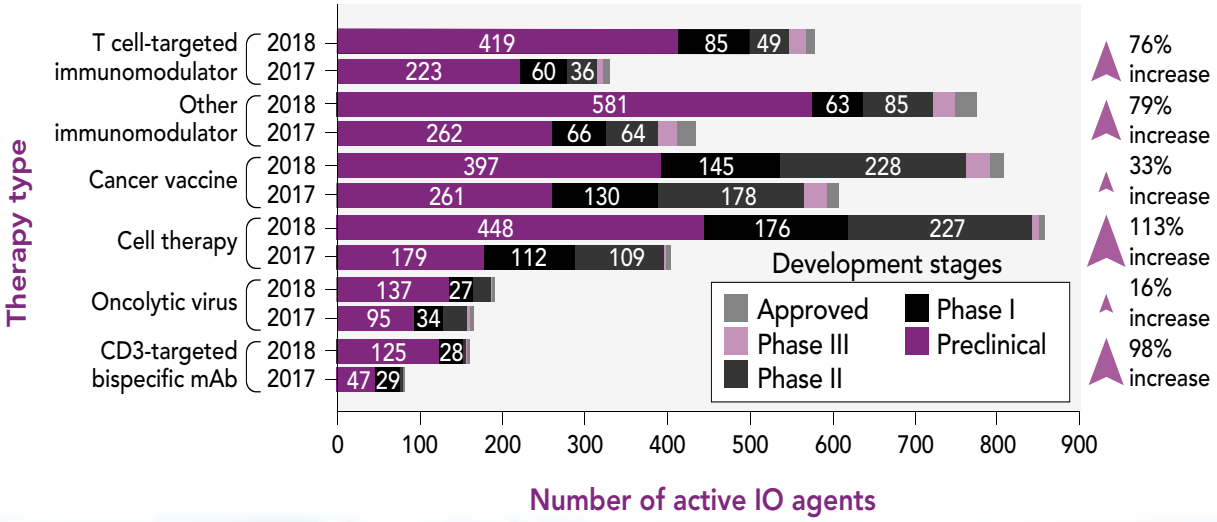

Figure 1 | **Trends in the global IO pipeline.** 3,394 agents were identified in six main classes in September 2018, an increase of 67% since the previous survey. IO, immuno-oncology; mAb, monoclonal antibody. Source Tang, J., et al (2018): Trends in Immuno-oncology.

IMMUNO-ONCOLOGY SERVICES

• PK • Immunogenicity • PD • Biomarkers

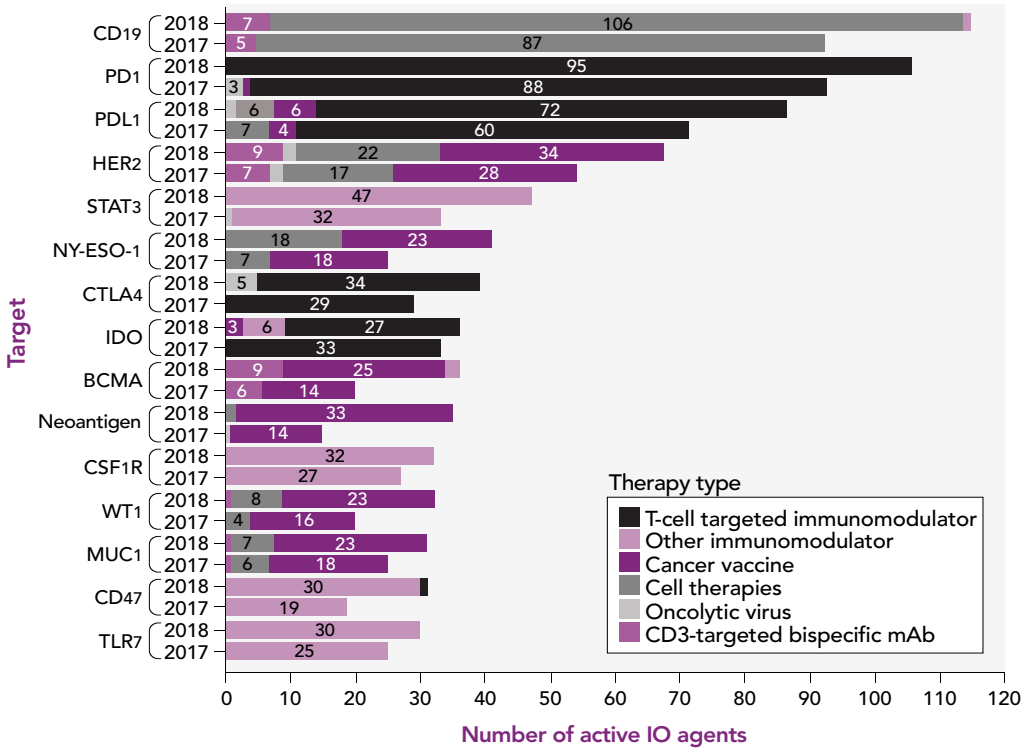

Figure 2 | **Trends in IO targets.** The top 15 of a total of 417 immuno-oncology targets in the current pipeline, a 50% increase since the previous survey. IO, immuno-oncology; mAb, monoclonal antibody.

Services

Our experienced team can develop and validate a wide array of assays to the latest FDA/EMA bioanalytical guidance, utilising the very latest technology and equipment. Examples include:

Pharmacokinetics (PK)
Immunoassay ligand-binding (ELISA, MSD, Gyrolab) and LC-MS-MS bioanalytical services

Immunogenicity
Anti-drug antibody assays (homogenous with acid dissociation, SPEAD, PandA) and neutralising antibody assays (nAb)

Pharmacodynamics
Receptor occupancy by flow cytometry
Immunophenotyping by flow cytometry
Mode of action (Cell-based assays)
Cytokine release assays (PBMC or whole blood)
Cell-based assays (nAb)
Tissue extraction and analysis of intracellular signaling

Biomarkers
MSD or Luminex single or multiplex