



## Biomarker Discovery & Validation

*Discovery, verification & analytical validation crucial to biomarker development*



*Proteomics International (PI) entered Export Hall of Fame at the Western Australian Industry & Export Awards 2019*

*Three-time winner of the Health & Biotechnology Award 2015, 2016 & 2018*

### Facility and Portfolio Expansion

PI expanded infrastructure by bringing in new advanced instrumentation and highly skilled staff

- Orbitrap mass spectrometer
- Triple Quadrupole mass spectrometer

*Plethora of high resolution and sensitive instruments along with years of expertise gives PI the leverage to engage in specialised projects and expand the services portfolio to cater to the ever-growing realm of biomarker discovery & development*

- ✓ ISO 17025 accreditation
- ✓ State-of-the-art facilities
- ✓ Validated tests and methods
- ✓ Advanced platforms and instrumentation
- ✓ Widely accepted techniques for biomarker discovery & development
- ✓ Experience with wide range of disease cohorts
- ✓ Stringent QC & QA checks
- ✓ Comprehensive and tailored experimental designs
- ✓ Successful submissions to regulatory agencies
- ✓ Satisfied international blue-chip clientele



Data underpins all further biomarker development activities and is therefore rigorously tested.

### Quality accredited proteomics laboratory

All work is in accordance with the laboratory standards of ISO/IEC 17025:2005 (Chemical Testing, and Research and Development). ISO 17025 is recognised worldwide as the main ISO standard used by testing and calibration laboratories, and ensures technically valid results each time



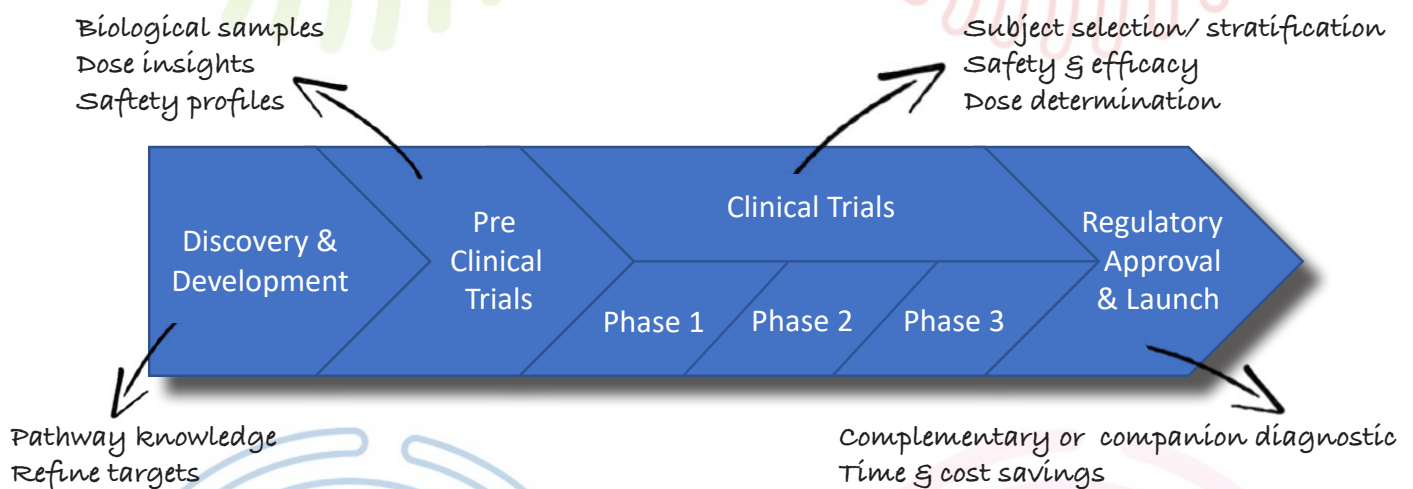
## What are Biomarkers?

- Biomarkers are biological indicators, including proteins, measured and evaluated as identifiers of abnormal biological processes, pathogenic processes, or pharmacological responses to a therapeutic intervention.
- The levels of particular protein biomarkers in a person, crop, or sample can be indicative of a wide range of disease states. An assay measuring these specific proteins unlocks information that can both prognose and diagnose future disease, well before symptoms are present.



## Protein Biomarkers in Clinical Trials

Biomarkers play an important role in clinical trials to examine patient biology and therapeutic intervention. The availability of specific biomarkers that are tied uniquely to a pharmaceutical drug will help immensely in identifying direct treatment benefits contributing to future regulatory success.



Protein biomarkers can be diagnostic and/or prognostic and can provide pharmacodynamic insights into patient biology. They can:

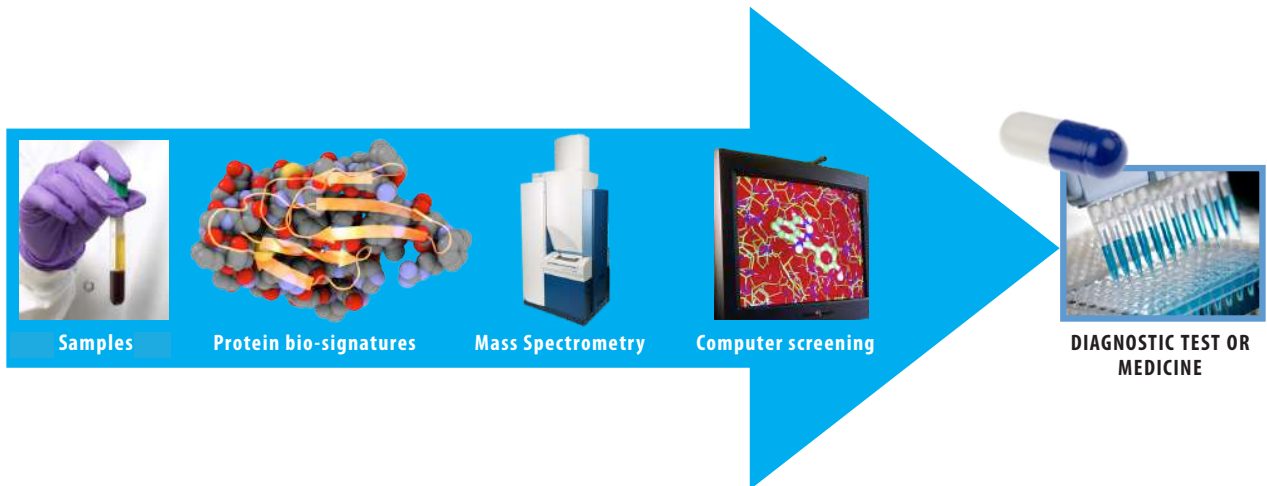
- Help address patient stratification and/or guide patient selection.
- Lead to better patient outcomes through earlier risk detection and safer future dosing.
- Enhance clinical trial success for efficacy measurement and account for individual subject responses.

The development and qualification of biomarkers can commence in discovery or pre-clinical stages and can still be effectively accomplished in the clinical testing phase alongside pharmacokinetic testing.

# Promarker™ Platform for Biomarker Development

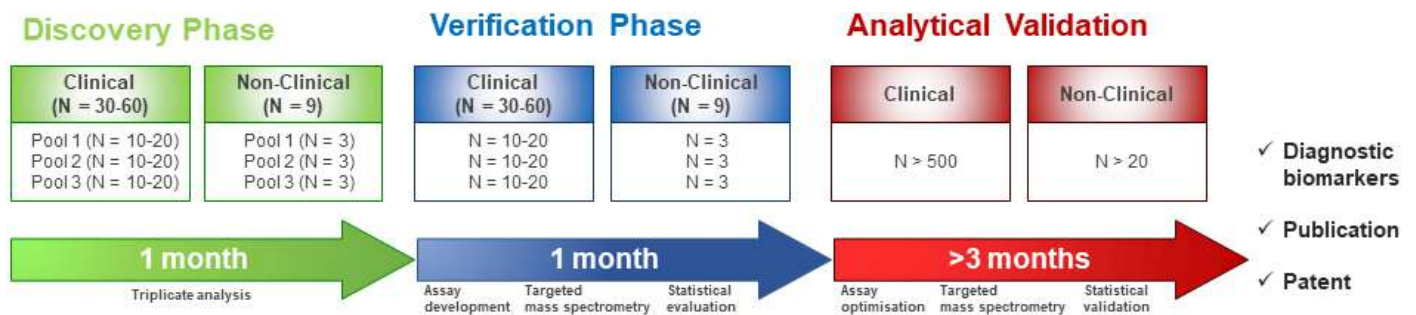
Proteomics International has developed a proprietary mass spectrometry based technology platform for discovery, verification and analytical validation of protein biomarkers. Promarker™ is a ground-breaking platform technology that takes advantage of the ubiquity of proteins in the human body. Proteins are responsible for carrying out various functions in the body, with many diseases causing different proteins to be secreted into the blood, in varying concentrations.

The Promarker™ platform uses mass spectrometry-based technology to identify these proteins that can be used as biological markers of a particular disease and/or other conditions.



*Biomarker discovery, verification and analytical validation is available as a fee for service model or through a collaborative partnership with Proteomics International.*

## Experimental Timeline



Biomarker projects require candidate biomarker discovery, verification and subsequent validation to identify the most robust biomarkers. Validated biomarkers can then be used in patents, publications and/or serve as possible drug targets.

The Promarker™ platform technology continues to be used by Proteomics International to address the following areas of unmet need:

- Endometriosis
- Crop disease
- Biofuel



## A Success in Biomarker Development

The Promarker™ platform was used by Proteomics International to discover, verify and validate a panel of protein biomarkers for diabetic kidney disease. The result is PromarkerD, a diagnostic and prognostic test that gives diabetics a window into their future kidney health.

PromarkerD is a blood test that can diagnose and predict whether a patient will develop diabetic kidney disease. PromarkerD can predict the onset of diabetic kidney disease before clinical symptoms appear. PromarkerD accurately predicted 86% of previously disease-free patients who went on to develop diabetic kidney disease within four years.

Patents for the PromarkerD test have been secured in the USA, Europe, Japan, Australia, Russia, Singapore, Indonesia and China (covering a potential market size of 214 million diabetics).

Learn more at [promarkerd.com](http://promarkerd.com)

# PromarkerD

**CHANGING LIVES**

*A new blood test for predicting diabetic kidney disease*



## About the Company

Founded in 2001, Proteomics International is a medical technology company focused on industrial scale studies of the structure and function of proteins

World's first ISO 17025 laboratory accreditation for quality proteomics services

Leading mass spectrometry technology (LC-MS/MS) for high sensitivity and throughput

Automated sample preparation for rapid turnaround times and reliable outcomes

State-of-the-art facilities at the Harry Perkins Institute of Medical Research in Perth, Western Australia



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